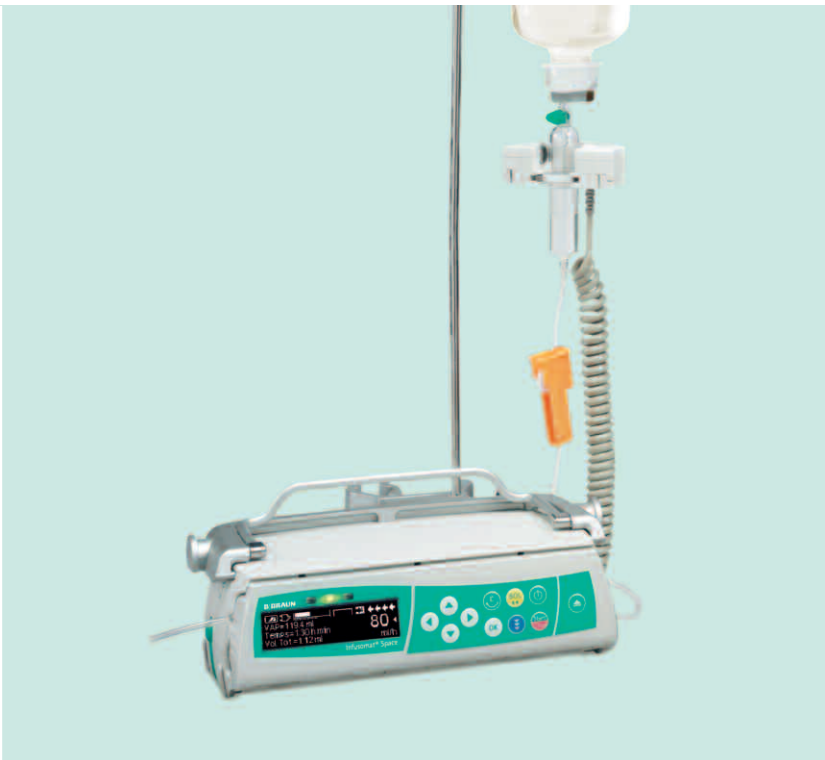
Infusomat® Space

and Accessories



Instructions for Use

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

CE 0123

GB Valid for software 686N

B BRAUN

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*The availability of the listed features is depending on the configuration of the pump.
**Technical Safety Check.

INFUSOMAT® SPACE OVERVIEW

Arrow up and –down
Scroll through menus, change setting of numbers from 0–9, answer Yes/No questions.
Arrow left and –right
Select data from a scale and switch between digits when numbers are entered. Open a function while pump is running or stopped with the left arrow key.

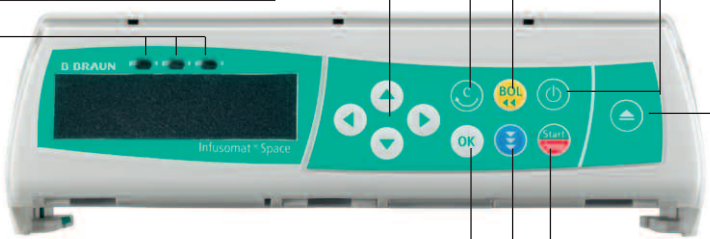
Press to reset single values to zero and switch back to the previous screen/menu level.

Press to open the pump door.

Yellow LED: Pre-alarm, reminder alarm
Green LED: Infusing
Red LED: Operating or device alarm
Blue LED: Initiating connection to wireless battery or Space Station

Press to initiate bolus.

Press to turn pump on/off.

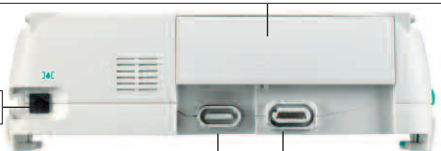


OK
Open certain functions and press to confirm values/settings/alarms.

Press to initiate auto-programming orders when prompted.

Start Stop
Press to Start/Stop infusion.

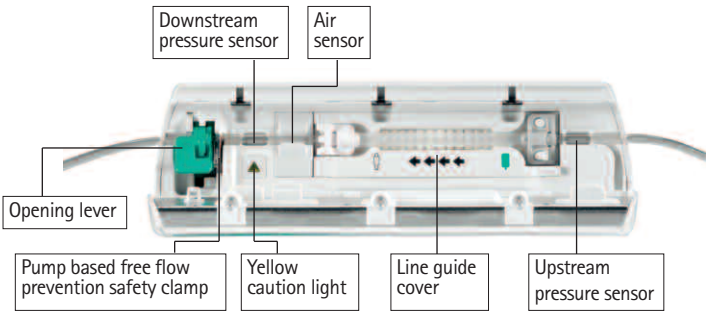
Cover of Battery Compartment
Before changing the battery, always disconnect the pump from the patient and switch off the device.
To remove the battery cover push the button below the battery compartment with a pointed pen and pull the cover away from device. Slide green locking mechanism on back of battery up and take out battery pack for exchange.
A crank in order to open the pump door in case of emergency is attached to the inside of the battery compartment cover (for closer information see 1.4).



Port for drop sensor

Port P3 for future options

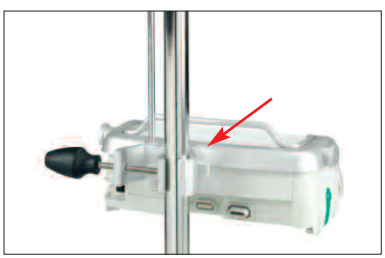
Port P2 for power supply, SpaceStation, connection lead (12V), combi lead and further accessory leads (staff call, service)



Fixaton of PoleClamp (Universal Clamp)
Line up bar of pump with bar of PoleClamp and slide PoleClamp forward until locking mechanism clicks.
To remove, press release button on frame, push handle down and pull PoleClamp backwards.

Transport
A maximum of three pumps (Infusomat® Space or Perfusor® Space) plus one SpaceControl may be stacked together (in ambulance cars and helicopters only one pump). Avoid external mechanical influence.

Locking Devices Together
Line up the bar of the lower pump with the bar of the pump above and slide the lower pump backwards until the lock clicks and the green buttons are above each other.
To disconnect, push green locking buttons of top pump device and slide bottom pump forward.
Caution: Avoid external mechanical action.



Pole Fixation
Push the opening of PoleClamp against the vertical pole and lock the screw tightly. Unscrew to release. For vertical position push lever down and rotate either way until lever clicks into notch. Push lever for rotation.
Caution: A maximum of three B. Braun Space pumps can be stacked together only in horizontal pump position when used with the PoleClamp SP.

SYMBOLS ON PRODUCT

Symbol	Explanation
	Mandatory action: see instruction for use.
	See accompanying documents.
	Type CF unit with defibrillation protection
	Protection class II device
	Symbol indicating separate collection for electrical and electronic equipment (2002/96/EC) only for valid for Europe, not applicable for US
CE 0123	CE mark compliant to Directive 93/42/EEC
	Temperature Limit
	Moisture Limit
	Limitation of the atmospheric pressure
	Non-ionizing electromagnetic radiation
	General warning sign (e.g. Caution)
	Unsafe symbol (Do not use in MRI environment)
LOT	Batch number
SN	Serial number
REF	Catalogue number
	Manufacturer
	Date of manufacture

PATIENT SAFETY

Read Instructions for Use prior to use. The infusion device should only be used by specially trained staff.

Intended use

The Infusomat® Space Volumetric Infusion Pump System includes an external transportable electronic volumetric infusion pump, dedicated administration sets, and pump accessories. The system is intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted routes of administration. These routes include, but are not limited to intravenous, irrigation/epidural, and enteral. The system is used for the delivery of medications indicated for infusion therapy including but not limited to colloids and cristalloids, blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat® Space Volumetric Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.

Using TCI the scope of patients is:

	Minimum	Maximum
Weight [kg]	30	200
Height [cm]	130	220
Age [Yrs]	16	100

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.

Using TCI the scope of procedures is:

- Propofol: Anaesthesia and Conscious Sedation
- Remifentanil: Anaesthesia

Qualified medical staff should decide how the device should be used based on its features and specifications. For more details, please read the Instructions for Use.

Operation

- The initial training of the Infusomat® Space is to be performed by B. Braun sales personnel or other authorized persons. After each software update, the user is required to inform himself about the changes to the device and accessories in the instructions for use.

⚠ Caution: Ensure the unit is properly positioned and secured. Do not position pump unit above patient or in a position where a patient could come to harm, should the pump fall.

- Prior to administration, visibly inspect the pump for damage, missing parts or contamination and check audible and visible alarms during selftest.

- Not be used adjacent and stacked with other equipment except B. Braun Space devices.
- Only connect to patient once the line has been correctly inserted and completley primed. Interrupt connection during line change to prevent incorrect dose delivery.
- During priming and bolusing the pressure limits are set to the maximum level.
- Select infusion line/catheter suitable for use with the intended medical application.

⚠ Caution: Position the infusion line free of kinks.

- Recommended change of disposable every 96 h (or as per national hygiene regulations).
- Installation in medically used rooms must comply with the appropriate regulations (e.g. VDE 0100, VDE 0107 or IEC-publications). Observe national specifications and deviations.

⚠ Caution: Operate the pump at least 25 cm from flammable anaesthetics to prevent explosion.

- Compare the displayed value with the entered value prior to starting infusion.
- If staff call is used we recommend checking the equipment once after connecting the pump.
- Protect the device and the power supply against moisture.
- If the pump falls down or is exposed to force, it must be checked by the service department.
- The displayed data must always be checked by the user prior to making further medical decisions.
- During mobile use (homecare, patient transport inside and outside the hospital): Make sure the device is securely fixed and positioned. Positioning changes and severe shock can lead to minor changes in the delivery accuracy and/or unintentional bolus administration.
- A supplemental patient monitoring must be carried out if life-saving medication is performed.
- The air detector cannot detect air diffusing in the following components: three-way stopcocks, infusion adapters and further lines placed between pump and patient.
- In case high potent drugs are given be sure to have a second infusion pump for that drug at hand. The therapy documentation should be suitable to continue the therapy at the second infusion pump.
- Independant of the soft limits the selected values have to be the medically correct ones for the given patient.

- In case values relevant for the dose rate calculation are changing always the flow rate will be updated and the dose rate will be fix.
- Consider startup characteristics before using low infusion rates (0.1ml/h) with critical drugs.

Enteral Nutrition

The Infusomat® Space may be used for enteral nutrition. Do not use enteral fluids for intravenous infusion as this may harm your patient. For this reason only use disposables dedicated and labeled for enteral nutrition.

Transfusion

The Infusomat® Space may be used for blood transfusion, too. For this therapy only use disposables dedicated and labelled for transfusion.

Other components

- Use only pressure-proof and compatible disposable items (min. 2 bar/ 1500 mm Hg) to avoid influencing performance data - which would result in impairing patient safety.
- Where several infusion lines are connected on one single vascular access, the possibility of the lines exerting a mutual influence over each other cannot be excluded.
- Refer to respective manufacturer's information for possible incompatibilities of equipment with respect to drugs.
- Use only compatible combinations of equipment, accessories, working parts and disposables with luer lock connectors.
- Connected electrical equipment must comply with the relevant IEC/EN-specifications (e.g. IEC/EN 60950 for data-processing equipment). The user/operator is responsible for the system configuration if additional equipment is connected. The international standard IEC/EN 60601-1-1 has to be taken into account.

Safety Standards

Infusomat® Space satisfies all safety standards for medical electrical devices in compliance with IEC/EN 60601-1 and IEC/EN 60601-2-24.

- The EMC-limits (electro-magnetic compatibility) according to IEC 60601-1-2:2007 and IEC 60601-2-24: 2012 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.) may be disturbed. Maintain the protective distances recommended by the manufacturers of these devices.
- The Infusomat® Space fulfils the applicable requirements of EN 13718 to be used in the air, on the water and in difficult terrain. During transport the Infusomat® Space needs to be fixed on a suitable restraint system by means

of SpaceStation or Pole Clamp SP. When stored under temperature conditions beyond the defined operating conditions the Infusomat® Space needs to remain under room temperature at least one hour before usage.

- As there is no dedicated norm existing for enteral feeding pumps the safety features of Infusomat Space are also for enteral nutrition according to the a.m. norms.

Safety instructions for using PCA

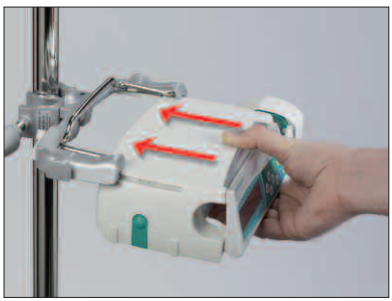
- In case the demand button is used with SpaceStation the PCA pump has to be placed in the lowest slot of the lowest SpaceStation.
- Access to the pump settings can be prohibited by DataLock 3. The code for DataLock level 3 should differ from the one for levels 1 and 2 in case the pump is only allowed to be used by pain management professionals.
- When ending PCA and starting it again the therapy data are set to default values.
- Using the demand button also the patient is a permitted user. With the demand button only a PCA-bolus can be requested. This is limited to pre-defined doses by drug list and pump settings.

Safety instructions for using TCI

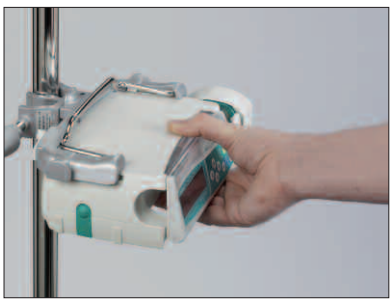
- TCI should only be performed by experienced anaesthetists being familiar with the principles of TCI and properly trained in using the present device.
- The use of TCI with B. Braun Space does not limit the responsibility of the anaesthetist for administration of drugs. They need to be fully aware of 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 have to be taken into account 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.
- B. Braun has verified the accuracy of the mathematical model implementation, the usability as well as pump delivery accuracy.
- While using TCI an appropriate patient monitoring is mandatory.
- Take care of using the right dilution/concentration of the drug and make sure the right dilution is selected at the pump.

- Never administer Propofol or Remifentanil by a second infusion as long as you use TCI.
- It is possible to completely switch off the TCI mode to avoid the use of TCI accidentally.
- By using Infusomat® Space a change of drug concentration will not be possible within the same therapy.

Safety Instructions for using Pole Clamp



1. Line pump up with the Pole Clamp guide rails.
2. Slide pump fully into place onto the guide rails.
3. An audible "Click" should heard.
4. Test the pump is secure.



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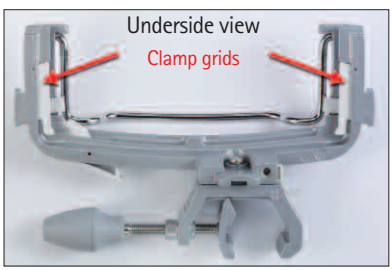
The pump ist now securely attached to Pole Clamp.

- Do not lean on the pump when attached to the Pole Clamp.
- Do not position the pump unit above the patient.



⚠

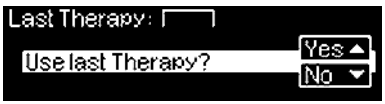
- DO NOT use any Pole Clamp that shows signs of damage.
- DO NOT use Pole Clamp with missing clamp grids.

MENU STRUCTURE / NAVIGATION

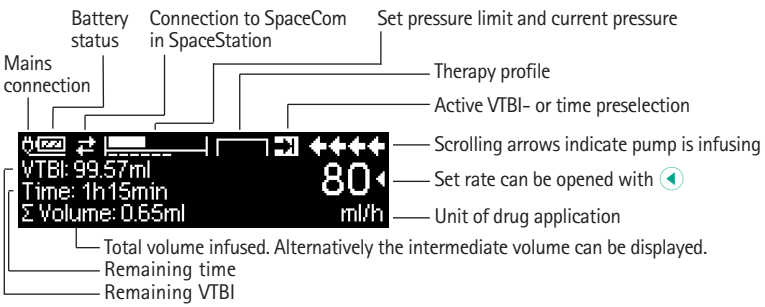
Cutline

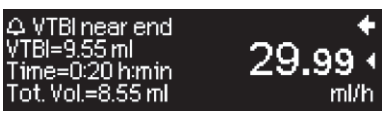
- On/Off button
- Door open button
- Start/Stop button
- Bolus button
- Clear button
- OK button
- Keypad with arrow up, -down, -left, -right button
- Connection button

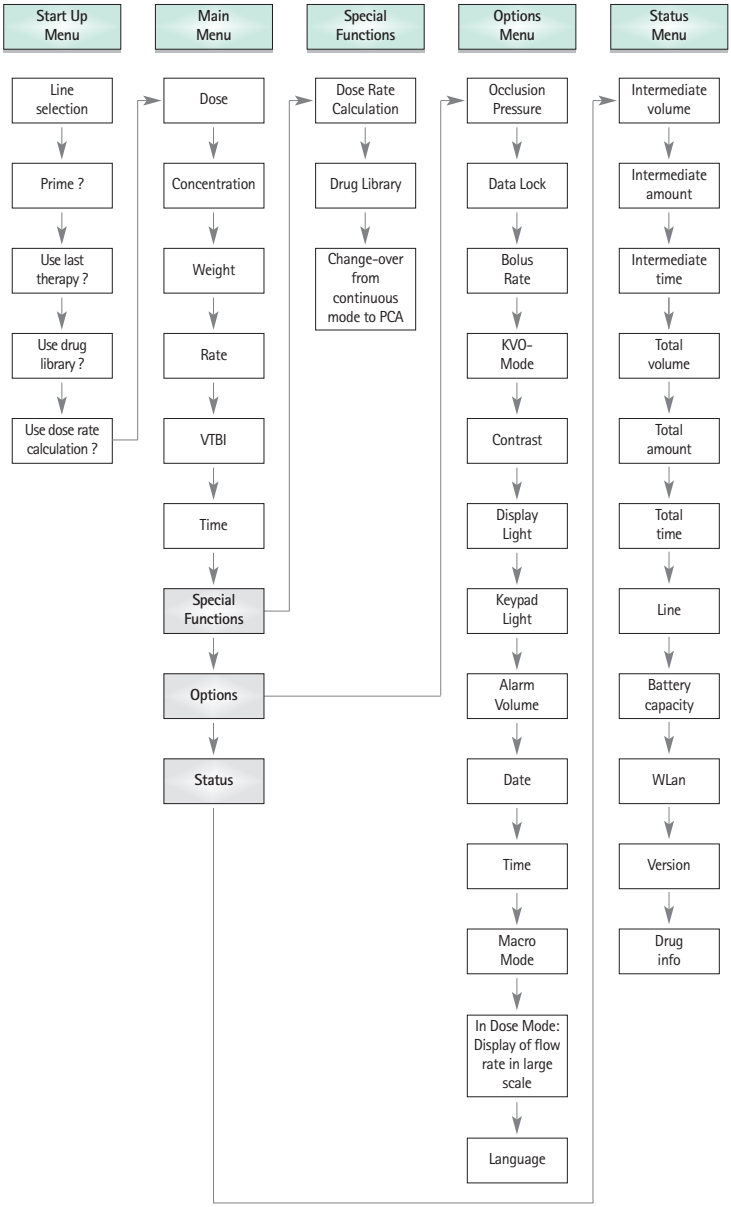
All display screen shots are examples and may be different when related to an individual patient and individualized therapy.

Display	Meaning
	At the top of the screen the last therapy is indicated. Yes/No question can be answered by pressing ▲ for yes or ▼ for no.
	Parameters which can be changed (e.g. rate in ml/h) are opened with ◀ or OK. When editing parameters, switch digits/levels using ◀ ▶. White background indicates current digit/level. Use ▲ or ▼ to change current setting. Help text on the bottom/top of the screen indicates options how to proceed (e.g. confirm rate with OK, start infusion with Start/Stop or clear rate by pressing C).

Typical display during infusion:



Display	Meaning
	All status information is available in the bottom line of the display. The desired information can be selected by using ▼ ▲ and will be displayed permanently thereafter (e. g. drug long name, current system pressure etc.).
	BOL has been pressed while the pump is infusing. Start manual bolus at 1200 ml/h by pressing OK (see top of display) or proceed to set bolus limit with ◀ (see bottom of display).
	This hint pops up if a user tries to edit or change a parameter by pressing ◀ when that parameter is unable to be changed.
	Set pressure level with ◀ or ▶ and confirm by pressing OK. Cancel to edit pressure by using C.
	Pre-alarms are indicated by a message on the display (e.g. "VTBI near end"), an audible tone and the yellow LED is constantly on. To confirm a pre-alarm press OK.
	In case of an operating alarm (e.g. "VTBI infused") the infusion stops, an audible tone sounds and the red LED flashes. Confirm alarm by using OK. Confirming does not activate an acoustic feedback.
	Press and hold ⏻ for 3 sec to turn pump off. A white bar stretches from left to right and counts down the 3 sec. As long there is an infusion line inserted the pump will not turn off but will use standby.


Start Up Menu
Line selection
Prime ?
Use last therapy ?
Use drug library ?
Use dose rate calculation ?
Main Menu
Dose
Concentration
Weight
Rate
VTBI
Time
Special Functions
Options
Status
Special Functions
Dose Rate Calculation
Drug Library
Change-over from continuous mode to PCA
Options Menu
Occlusion Pressure
Data Lock
Bolus Rate
KVO-Mode
Contrast
Display Light
Keypad Light
Alarm Volume
Date
Time
Macro Mode
In Dose Mode: Display of flow rate in large scale
Language
Status Menu
Intermediate volume
Intermediate amount
Intermediate time
Total volume
Total amount
Total time
Line
Battery capacity
WLan
Version
Drug info

OPERATION

1.1 Start of Infusion

- Ensure that the pump is properly installed. Check the equipment for completeness and damages. Do not attach the infusion bottle below the pump level.
- Put the spike vertically into the infusion bottle. Fill the bottom part of the drop chamber by max. 2/3.

⚠ Caution: Close the roller clamp before inserting the IV line and do not connect to patient until properly loaded and primed.

- If the device is connected to the mains, the display indicates the battery status, the mains connection symbol and the last therapy.
- Press ⏻ to switch on the device. Observe the automatic self-test: The message "Self-test active" and the software version are displayed, two audible tones sound and all three LEDs (yellow, green/red and blue) flash once. Information about the power supply (mains or battery operation) and the set pressure level are indicated. In addition, the line type appears at first (provided that the line is already inserted). Then, the accumulated air volume and the max. size of air bubbles is indicated which is triggering the air alarm of the device.

The pump offers the possibility to load up to four languages into the pump (depending on the number of the language specific characters), among which the user can choose during the operation of the pump. During the first ever start-up of the device, the user is requested to select the languages and to mark them with ◀. After that, the selection has to be confirmed by choosing the last menu item at the bottom of the list and pressing OK. Then the desired language must be selected with ▲▼ and confirmed with OK. Answer the following question with ▼ in order to activate the selected language.

- Press C to start the direct entry of therapy parameters, or press ⏏ and ▲ to open the pump door in order to continue with inserting the line.

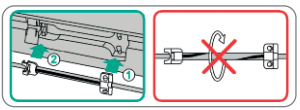
⚠ Caution: Close the roller clamp before inserting the IV line and do not connect to patient until properly loaded and primed.

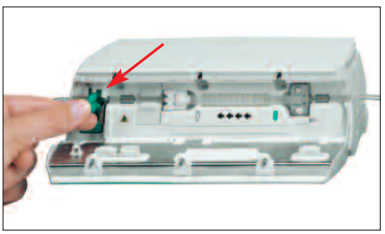
Caution: You may only insert the line while the device is switched on and the line guide element is inserted. Otherwise, there is the danger of freeflow. Pay attention to keep the roller clamp closed before inserting the infusion line especially at a temperature scale of 10 - 15 °C. Never leave the pump unattended when inserting the tube.

Caution: Inserting different lines into the pump is identical. Please see instructions and packaging of the different lines (standard, transfusion, opaque, enterel nutrition etc.) to receive information about preparation and usage of these lines.

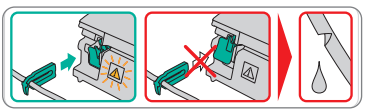
Insert the infusion line from right to the left. Make sure that the line is routed straight. At first, route the line through the upstream sensor. Then, insert the two-hole clip.

Next attach the white clip.
Insure silicone segment is not stretched or twisted, stars on tubing must be in straight line and should not be twisted.





Insert the freeflow clamp (see red arrow) in the opened aperture, in the direction indicated by the arrow, until the opening lever locks in and the safety clamp squeezes the lines (flashing signal lamp goes out).



- Firmly press tubing into the air sensor guide to make sure the line is properly inserted into the sensors. Thread the tubing through the notches on the right and left side of the pump.
- Close the pump door by firmly placing pressure with both hands on each side of the pump door, continue to press firmly until you hear and feel the motorized door latch pull the door shut. Do not open roller clamp until the pump directs you to do so when self test is completed. Then select the inserted line with and confirm it with . Open the roller clamp.

Caution: Do not force door closed – If door is difficult to close, please check IV set and anti free-flow slide clamp (green) for proper installation.

Caution: Before opening door, please close roller clamp and ensure door does not fall open. If door opens to the horizontal position, please check that the slide clamp (green) is properly occluding the IV set and the door extension hook is not broken. If the door hook is found damaged or broken remove the pump from service.

Caution: If a wrong line is selected the time until the pump goes into a pressure alarm may be prolonged. Also a wrong delivery rate is possible.

- Press ▲ if the prime function is enabled to prime the infusion line with the rate displayed. Cancel priming with OK. Repeat the procedure until the line is completely primed. Then press ▼ to proceed.

Note: During priming, all air and drop alarms are switched off.

- Establish the patient connection.
- Answer the question whether the old therapy is to be used either with ▲ or ▼ (the question can be deactivated via the service manual). If you select ▲, the pump jumps to the Main Menu.

Note: At rates smaller 10 ml/h the detection of a closed roller clamp cannot always be ensured due to physical reasons. A drop sensor may be used to avoid this risk.

Adjusting the delivey rate:

- In the Main Menu, open the rate with ◀ and set it with  .
- Press Start/Stop to start the infusion. VTBI is required to start the infusion. Time will be calculated when rate is entered. When time is entered, rate/doserate will be calculated. Running arrows on the display and the green LED indicate that the pump is infusing.

Note: The running infusion can be cancelled at any time by pressing Start/Stop. The pump can be turned off at any time by pressing ⏻ for 3 sec (Exception: Data lock level 2) and as long a disposable is inserted.

Handling with Infusomat® Space Line SafeSet

Note: If Infusomat® Space Line SafeSet is used, VTBI is not required.

A unique airtight filter membrane acts as a barrier, protecting against air-in-line situation. As the fluid level reaches the membrane, the upstream alarm will occur and the pump stops delivery whereas no air will pass the AirStop filter.

For this reason a fast switch over to next container requires no aditionally workload for priming.

In case of a "Check upstream" alarm, the upstream sensor detects an underpressure situation in the IV set between the pump and the drip chamber.

Therefore check always if the roller clamp is open, if the line is kinked or if the bag and/or drip chamber is empty.

Please do not start the pump again by not fixing the "Check upstream" alarm situation.

If too many times, the pump is started without fixing the situation, the upstream sensor calibrates on the current existing underpressure in the line and air might pass the AirStop membrane. In this case please ensure that the the drip chamber is refilled and then open the door for recalibration of the upstream sensor.

1.2 Entry With Different Combinations of Rate, VTBI (= Volume To Be Infused) and Time

The Infusomat® Space offers the possibility to enter a volume- and time limit in addition to an infusion rate. When two of these parameters are entered, the third is calculated by the pump. If a volume and/or time is preselected, an arrow symbol is placed in front of one of these parameters in the Main Menu. It is called the "target". During the infusion of the pump, this target symbol is displayed next to the moving arrows in the run display (this symbol is not visible in case TCI is used). This indicates that the pump has been programmed, either with a volume- or time limit. The assignment of the target symbol, apparent in the Main Menu, shows the established parameter for the application (VTBI or time). When the rate is changed, the so-called target parameter is principally not adjusted to the new rate but to the parameter which does not have the target symbol in front. After the infusion has started, the remaining VTBI and time are displayed in the status menu and the run display (values are counting down).

1.) Enter VTBI and time: The infusion rate will be calculated and displayed on the bottom of the display.
Target: Volume

- Select VTBI with and open with .
- Enter VTBI with and confirm with OK.
- Select time with and open with .
- Enter time with and confirm with OK.

Check calculated rate on plausibility.

Proceed in the same way to calculate 2.) and 3.).

2.) Infusion with volume limit
Enter rate and VTBI: The infusion time will be calculated and displayed on the bottom of the display.
Target: VTBI

3.) Infusion with time limit
Enter rate and time: The infusion volume will be calculated and displayed on the bottom of the display.
Target: Time

Changing already entered values of VTBI and time (rate, VTBI and time already exist at the point of change):

a) Target symbol is placed in front of VTBI:
- Change of VTBI => Adjustment of time. Old and new target: VTBI
- Change of time => Adjustment of rate. Old and new target: VTBI

b) Target symbol is placed in front of time:
- Change of time => Adjustment of VTBI. Old and new target: Time
- Change of VTBI => Adjustment of time. New target: VTBI

1.3 Bolus Application

After pressing the button BOL, the bolus unit can be selected by using ▼.

Note: The selected unit will not be stored. It is possible to administer a bolus in ml.

There are three ways to administer a bolus:

1.) Manual Bolus: Press BOL. Then press OK and hold button. Fluid is administered for as long as the button is held down.. The infused bolus volume is displayed.
The max. bolus time is limited to 10 sec.
Reaching this limit is indicated by an acoustic signal.

2.) Bolus with volume preselection: Press BOL. Then press ◀ and set bolus dose limit by using ⚙. Press BOL to confirm and start bolus. Depending on the service tool settings an acoustic signal will sound after finishing the bolus volume.

3.) Bolus with rate calculation: Press BOL. Then press ◀ and set bolus dose by using ⚙. Press OK to confirm bolus dose. Set time with ⚙ in which a bolus is to be delivered. Calculated bolus rate is shown on top of the display. Press BOL to confirm and start bolus.

You can use the service program to enter a default and a maximum bolus rate. Once a new therapy is started the device always returns to the default rate - even if the bolus rate was manually changed beforehand.

Note: If the bolus limit is not entered after pressing BOL, the pump switches back into the run display automatically.

Note: The infused volume during bolus with volume preselection counts up.

In order to purge the line at any time while the pump is stopped press BOL.

Answer the following question by pressing ▲ in order to start the purge process. Cancel by pressing OK or any other key.

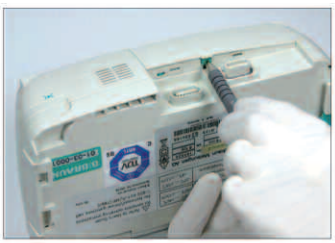
Caution: Take care not to overdose! Given a bolus rate of 1200 ml/h, 1 ml will be administered in just 3 sec. To cancel bolus infusion at any time press OK. At low bolus volumes, under dosages due to the start up characteristic of the pump and the tolerances in the infusion system cannot be excluded. Disconnect patient while purging.

1.4 Infusion Line Change and New Therapy Start

Note: Always interrupt the patient connection before changing a line to avoid dosing errors. Never let the pump run unattended when changing the line. Check and clean the safety clamp regularly.

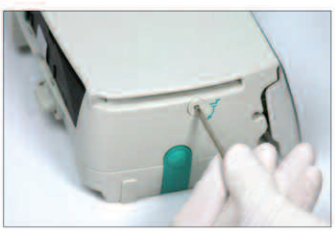
- Press Start Stop to stop the delivery. The green LED goes out. Close the roller clamp and interrupt the patient connection.
- Press ⏏ and open the pump door with ▲. Press down the green opening lever completely until it locks in place, remove the line and insert a new line.

Note: In the unlikely event the pump door cannot be opened remove the allen key from the inside of the battery compartment cover. Use this key to remove the emergency aperture cover of the pump. Place the crank in the aperture and turn it clockwise until the pump door opens.



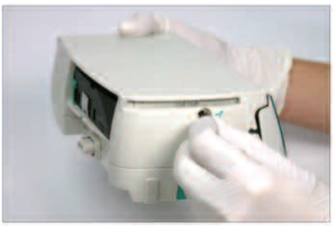
Push cover opening with pen.

Remove crank from inside of battery cover.



Turn crank to remove emergency aperture cover.

Remove emergency aperture cover.



Turn crank inside aperture to open the door.

- Close the pump door, confirm the inserted line with OK and open the roller clamp.
- If required, prime the pump with ▲. Then press ▼ to proceed when priming is complete.
- Establish the patient connection and check the parameters with .
- Start the infusion by pressing Start/Stop.

Note: A new therapy can be started at any time during a stopped infusion. If the pump is in the Main, Status or Options Menu, press C (repeatedly) and follow the instructions as described.

1.5 End of Infusion

- Press Start/Stop to stop the infusion. The green LED goes out. Close the roller clamp and interrupt the patient connection.
- Press ⏏. Answer the question whether the pump door is to be opened with ▲.
- Press down the green opening lever completely until it locks in place. Remove the line and close the pump door.
- Press ⏻ for 3 sec to switch off the pump.

Note: The settings will be permanently saved by the switched off device.

Note: Pump cannot be powered off with IV line inserted.

1.6 Standby Mode

In the case of extended interruption, the user has the option to maintain the set values.

- Press Start Stop to stop the infusion. Then press ⏻ for less than 3 sec.
- Confirm that the pump is supposed to switch to standby by pressing ▲.
- The pump is now in Standby.

While the pump is in the standby mode, it's display shows the drug and the remaining time for this mode, standby may be set from 1 min to 24 hours. Change of remaining time by pressing ◀. Exit standby by pressing ⏻ . The pump will alarm when the standby time expires.

As long as a disposable is inserted in the pump will use standby also in case ⏻ is pressed for at least or more than 3 sec.

ADVANCED OPERATIONS

2.1 Status Request of Pump when Infusion is Running

Press to switch between run display and Main Menu while the device is infusing. Navigate through the menu using to check parameters. In order to check the menu parameters in the Status-/Options Menu, select "Status" respectively "Options" in the Main Menu, open menu with and scroll through menu with .

2.2 Rate, VTBI and Time Change Without Infusion Interruption and Reset Of Status Menu Data

- Press when the pump is in the run display in order to switch to the Main Menu. Select rate/VTBI/time with and press in order to open the parameter.
- Enter new value with and confirm with OK.

Reset Status Menu Data:

The parameters intermediate volume and -time can be reset when the pump is infusing or when the pump has stopped.

- Select "Status" in Main Menu with and press .
- Highlight intermediate volume (in ml) or intermediate time (in h:min) with and open parameter with .
- Reset values by pressing .

Both parameter total volume and -time, are displayed in the pump as "Total" with the according unit and can be reset by starting a new therapy. A second way to reset the parameters when the pump is in the Main Menu: Press , answer the question whether the last therapy is to be used with and reset the values with .

The type of the inserted line is displayed in menu item „Line" and cannot be changed once it has been confirmed at the beginning of the infusion. The drug info states the drug name, the name of the drug list and its date of origin. If the change from the secondary to the primary infusion will be performed manually or automatically will be displayed in line "PGY change". The current battery capacity in hours and minutes is displayed in the menu item "Battery Cap." and the current software version in menu item "Version". In-line pressure can also be read in the Status menu in mmHg or Bar depending on the service settings.

SPECIAL FUNCTIONS

3.1 Dosing Units and Dose Rate Calculation (Overview)

The following list shows the units used in the pump:

Gram family:	ng, mcg, mg, g
Unit family:	mIU, IU, kIU, MIU
Equivalents family:	mEq
Mole family:	mmol
Kilocalorie family:	kcal
Millitliter family:	ml, ml/kg

In addition to these dosing units the user can choose:

- Feeding: kcal, mEq, mmol
- Surface related amount units: m^2

$$\text{Infusion rate [ml/h]} = \frac{\text{Dose}}{\text{Concentration}} \times \left[\text{Patient weight (optional)}\right]$$

The pump is calculating the body surface area with the "Dubois" formula (DuBois D, DuBois EF. A formula. Arch Intern Med 1916; 17: 863): BSA(m2) = 0.007184 x weight(kg)0.425 x height(cm)0.725.

Check plausibility of calculated body surface area value and resulting delivery rate before starting the infusion, also, if body surface area related dose rate is set by Barcode. The dose rate calculation enables a calculation of the rate in ml/h based on the entered dose parameters.

Setting parameters:

1. Concentration as the amount of the active ingredient per volume.
   - Amount of the active ingredient
   - Volume in ml
2. Where necessary: Patient weight or Patient height
   Note:
   - Patient weight can be entered in kg, lbs or grams.
   - Patient hight is entered in m (is used to calculate BSA)
3. Dose prescription:
   - time related as the amount of the active ingredient per min, h or 24h.
   - time and patient weight related as the amount of the active ingredient per kg per min, h or 24h or BSA.
4. Where necessary: VTBI in ml.

3.2 Dose Rate Calculation (Operation)

- Select dose rate calculation with ◀.
- Select the unit of the active ingredient with ⚙ and confirm it with ◀.

- Enter the concentration by entering the amount of the active ingredient and the volume. In order to do so set the values with and confirm with (OK).
- If the patient's weight does not need to be entered press (◀). Press to choose "weight" or "surface" and confirm with (OK).
- Set the patient weight with and confirm with (OK).
- Select the dose prescription with and confirm it with (◀).
- Set the dose with and confirm with (OK). The rate will be automatically calculated and displayed at the bottom of the display.
- Check the calculated rate and if necessary the adapted parameters with on plausibility before starting the infusion with (Start/Stop).
- Check the parameters with on plausibility before starting with (Start/Stop).

Dose can belatedly be changed in the Main Menu in the same way as the rate, VTBI and time (compare 2.2). The effect of dose modifications on other parameters is shown at the bottom of the display.

Additionally the total and intermediate amount of the infused drug can be taken from the Status Menu. These can be checked and reset in the same way as the other total and intermediate values.

A deactivation of the dose rate calculation is only possible when the pump is stopped. Press from Main Menu and then press (▼).

Caution: A change of the patient weight or height will alter the flow rate.

3.3 Drug Library

Up to 1200 drug names including therapy data, information and up to 10 concentrations per drug can be stored in 30 categories. These drugs can be subdivided in 50 care units and 16 Patient Profiles. The loading process into the pump can be performed via a separate PC program (Space Upload Manager & HiBaSeD).

Note: The drug library can be started over the Start Up and Special Functions Menu. The user has to make sure prior to the therapy start that the drug library in the pump complies with the patient target group. The name of the care unit and creation date (see headline) should be checked in the pump.

There are different ways assigning a drug to an infusion. This can be done while the infusion is running or when the pump is stopped.

On the one hand, a drug name including the according therapy data can be taken from the drug library. On the other hand, if a rate, VTBI and/or time were already defined in the Main Menu, the drug name and the adjusted values of the data set will be loaded. If a dose rate calculation has already been started a belated assignment of the drug name nevertheless is possible.

Loading a drug (including the according parameters) from the Main Menu:

- Go to Special Functions Menu and press ◀.
- Open the drug library by pressing ◀.
- Navigate through the list with ↕ and select the care unit with ◀. If you have already set the care unit once on your pump this step will be skipped for the next time.
- Change the care unit by navigating through the list until "Change Care Area" will be displayed. Press OK to change the care unit.
- Navigate through the list with ↕ and select the patient profile with ◀. If no profile is set, this step will be skipped.
- Navigate through the list with ↕ and select in alphabetical order (all drugs) or within a category with ◀.
- If different therapies are related to a drug, choose therapy type with ↕ and confirm with ◀.
- Confirm the displayed drug information with ◀.

- Decide if the safety limits for the drug are to be applied ▲ or if only the drug name should be used ▼.
- Check if the drug short name in the Run Menu is the same as the selected drug. Check the parameter in the Main Menu with ↕ and start infusion with Start/Stop.

Note: If a drug name has been assigned without safety limits, the following hint is provided in the RUN screen:

Note: Care unit and Patient Profile can not be changed within a therapy (incl. Piggyback mode).

Initial Bolus:

Initial Bolus has to be configured in the Drug List Manager.

- Use the drug library according to the instructions for use.
- Select the desired drug with ↕ and press ◀. Before the initial bolus begins, the bolus menu is displayed to allow editing the bolus with ⚙.
- Check the parameter and start infusion with Start/Stop.

Hard Limits:

If the set rate/dose/bolus volume and bolus rate exceed the values stored in the drug library (hard limits), the drug will be rejected, a hint will be displayed and the pump will fall back into the drug selection. If this occurs while the pump is infusing the pump will continue to administrate.

Soft Limits:

For the same parameters so called soft limits can be preset via the Drug List Editor. These can be exceeded without any constraint. The following symbols that describe the status with regard to the soft limits are being displayed:

The infusion is within the range of the minimum and maximum soft limits	=	
The infusion is within the range of the maximum soft limit	=	
The infusion is within the range of the minimum soft limit	=	
Violation of the upper soft limit	=	
Violation of the lower soft limit	=	
No soft limit is defined	=	⚠
Only a drug name is available (It is possible to select a drug name only from the drug library)	=	⚠

The limits of the drug library have to comply with the limits of the pump and the disposable.

Note: An adequate monitoring when infusing highly potent drugs is recommended.

Note: In case a drug from the drug library is selected and the pump is running under dose rate calculation the initial values will be overwritten by the drug library values if selected.

Remote Drug Library update from Upload Manager (Space Online Suite)
The file icon blinks every 2 s. An update is available.

The Drug Library Upload starts as soon as the pump is in Passive mode.

Note: You can cancel the upload by pressing .

Please contact your local sales represantative in case you like to use Remote Drug Library update.

3.4 Patient Controlled Analgesia (PCA)

For PCA a drug list with at least one drug activating the profile PCA is necessary. By this the conditions for an effective and safe therapy are defined.

Switch on pump with ⏻ and wait until self-check is finished. Depending on the settings the choice of a drug is offered direcly or the pump is in "Main Menu".

Select "Special Functions" with ↕ from "Main Menu" and confirm with ◀.

Select drug list, category and desired drug by using ✣.

After the selection the pump offers additional drug related Information which are confirmed by ◀.

Select profile PCA by using and confirm with ↕ .The therapy settings stored in the drug list are displayed *.

The therapy can be started now with Start/Stop in case all values are defined.

Depending on the pre-defined settings the therapy is started with an initial bolus and a basal rate or not.

Before leaving the patient the pump should be put into DataLock level 3 with ✣ in Menu "Options". This is necessary especially in case non-authorised access to the settings can be anticipated.

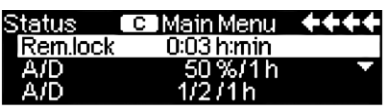
The code is entered with ✣ and confirmed with OK.

The pump display now may look like this.

In this state the patient is allowed to demand boli. Depending on the status of the therapy these are either administered or denied. Changing the disposable is also possible by using the code for level 1 or level 2. Altering the settings for PCA or other therapies however is only possible with the code for level 3.

The status of the therapy can be checked in the menu „Status" .

Enter the „Main Menu" with ↺ and select the "Status" with ✣.



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

*Bolus volume is the volume of a single bolus the patient may demand. Max. Limit is the amount of drug or volume a patient may demand within a certain time in total. Lockout is the time in between two boli.

An acoustic confirmation of demanded boli can be activated and modulated by in Data Lock 3.

Is a demand button connected, the therapy symbol looks like this: PCA

In case there is no demand button connected the therapy symbol looks like this: PCA .

The demand button is connected to the interface P2 at the rear side of the pump.

Hint: It is possible to start a therapy in continuous mode and switch over to PCA later on (in case the drug is dedicated for use with continuous and PCA application).

SpacePCA-Chart

If ▶ is pressed on the RUN screen, the SpacePCA-Chart is displayed:

The bar represents a time axis, with the points above the axis representing the number of boli administered and the points below the axis representing the number of boli refused.

The chart has a 15 minute resolution and shows max of 5 points per 15 minutes. Should more then 5 boli be given or refused in this time, the last point will be turn bold.

Changes to the PCA parameters are displayed as arrowheads at the bottom of the chart.

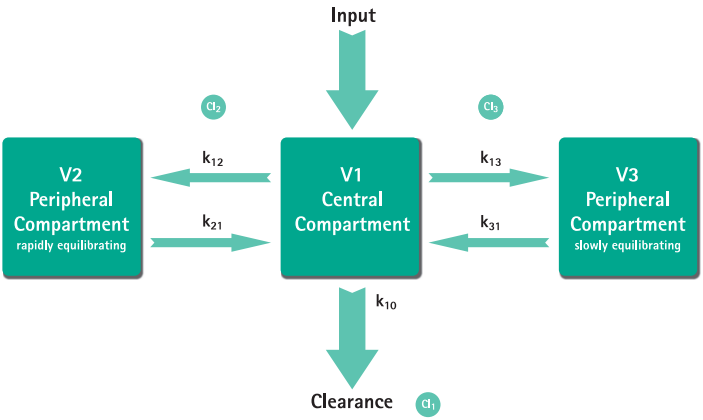
3.5 Target Controlled Infusion (TCI)

Introduction

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 said concentration are calculated by the pump using an algorithm based on a three-compartment pharmacokinetic model.

A pharmacokinetic model (PK model) is a mathematic model to predict the concentration of a drug in the human body (e.g. plasma level) after a bolus or a continuous infusion of different duration. A PK model is developed by measurement of plasma level values of a population of patients or volunteers and the respective statistical analysis. A PK model mostly is a 2- or 3-compartment model indicating the volumes of the compartments, indicating rates for the exchange amongst the compartments and indicating rates for elimination / metabolism of the drug.

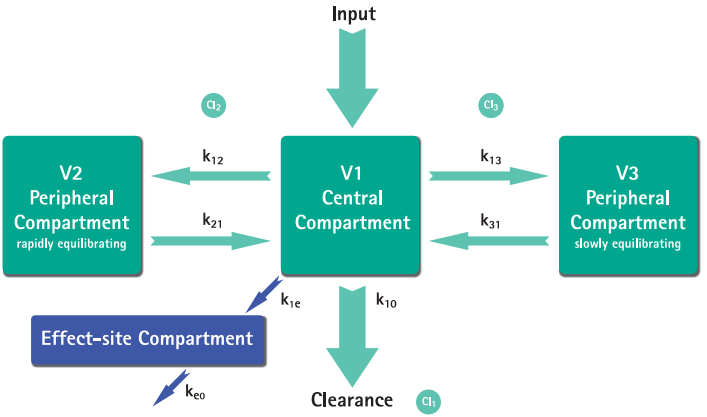
A PK model can be parameterized to use it for different drugs as long as it is suitable for that said drug. The pharmacokinetic model and its parameters are schematically depicted by the following illustration:



B. Braun Space is offering two modes for TCI:

- TCI by targeting the plasma concentration
  In this mode the user selects the desired concentration of a drug in the blood plasma and the PK model is used to calculate the infusion rates required to achieve that concentration as quick as possible (unless there is no restriction defined by the user).
- TCI by targeting the effect-site concentration
  In this mode the user selects the desired concentration of a drug at the site of action and the PK model is used to calculate the infusion rates required to achieve that concentration as quick as possible (unless there is no restriction defined by the user). A certain overshoot of the concentration in the plasma is resulting from this mode.

For effect-site targeting there is a link between pharmacokinetics and pharmacodynamics necessary. As the effect-site compartment is considered to have no volume and the rate constant k_{1e} can be ignored the rate constant k_{e0} is the parameter necessary to perform effect-site TCI. A pharmacokinetic model modified in such way is schematically depicted by the illustration.



TCI with B. Braun Space is possible with the following drugs: Propofol and Remifentanil.

For Propofol the user can choose between two parameter sets. The parameter sets used for these drugs are (Not all parameter sets allow effect-site targeting):

Drug / Parameter	Propofol Marsh	Propofol Schnider	Remifentanil
$V_c = V_1$ [ml]	-	-	-
V_1 [Litre]	0,228 * Weight	4,27	5,1 - 0,0201 * (Age - 40) + 0,072 * (LBM - 55)
k_{10} [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)]
k_{12} [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)]
k_{13} [min-1]	0,0419	0,196	[0,076 - 0,00113 * (Age - 40)] / [5.1 - 0.0201 * (Age - 40) + 0.072 * (LBM - 55)]
k_{21} [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)]
k_{31} [min-1]	0,0033	0,0035	0.01402 - 0,0002085 * (Age -40)
k_{e0} [min-1]	0,26	0,456	0,595 - 0,007 * (Age - 40)
Reference	Marsh et al., Br. J. Anaesthesia, Vol. 67, 1991, 41-48	Schnider et al., Anesthesiology, Vol. 88, 1998, 1170-1182 Schnider et al., Anesthesiology, Vol. 90, 1999, 1502-1516	Minto et al., Anesthesiology, Vol. 86, 1997, 10-33
Effect-site targeting	No	Yes	Yes

Drug List

The pre-installed drug list offers the following values:

	Propofol	Remifentanil
Available Concentrations	5 mg/ml 10 mg/ml 20 mg/ml	20 µg/ml 50 µg/ml
Default Max. Rate	1.200 ml/h	1.200 ml/h
Hard Limit Rate	Max of pump	Max of pump
Plasma Limit Default	400 %	400 %
Plasma Limit Hard Low	100 %	100 %
Plasma Limit Soft Max	450 %	450 %
Default Target	0.0 µg/ml	0.0 ng/ml
Target Soft Max	8.0 µg/ml	8.0 ng/ml
Target Hard Max	15.0 µg/ml	20.0 ng/ml
Decrement Concentration Default	1.0 µg/ml	1.0 ng/ml
Default Parameter Set	Marsh	Minto

Important note: Before installing an additional drug list please contact your local B. Braun representative!

Setting up the pump

For TCI a drug list with at least one drug activating the profile TCI is necessary. The drug list in this version is pre-defined. By this the conditions for an effective and safe therapy are defined.

Switch on pump with and wait until self-check is finished. Insert disposable and use the drug lib according to Instructions for Use.

Selecting a drug

Select drug list, category (the TCI drugs need to be selected from the category "TCI") and desired drug by using .

In this example: Propofol.

As a next step select the correct dilution (concentration) of the drug to be administered as well as the parameter set (model) and the Mode (Effect-Site Targeting or Plasma Targeting)

These steps are only necessary in case there are different options for that drug.

Input of patient data

Depending on the parameter set one or more of the following data are necessary:

- Weight
- Height
- Gender
- Age

Use for editing the patient data. Example.

The editor window appears with the initial setting "0" to make sure editing a value takes place (exemption: initial setting for gender is "male").

Important notes:

- Be sure to enter the data corresponding to the respective patient.
- Once the TCI is started patient data can not be altered!

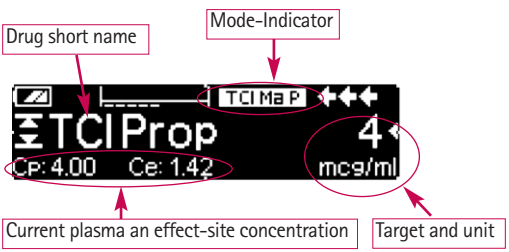
Editing a target and starting TCI

The editor window for setting the target comes up with the default value from the drug list.

Editing this parameter is guided by the dose error reduction system "DoseGuard™" according to the limits defined in the drug list.

Confirm target with OK. TCI can be started now with Start/Stop.

After TCI is started the screen looks the following:



In the top line there is an icon indicating the parameter set and the mode (Mode Indicator) with following meaning:

- "TCI Ma P": TCI Marsh plasma targeting
- "TCI Sc P": TCI Schnider plasma targeting
- "TCI Sc E": TCI Schnider effect-site targeting
- "TCI Mi P": TCI Minto plasma targeting
- "TCI Mi E": TCI Minto effect-site targeting

v

In the bottom line the status parameters like flow rate, Cp/Ce, infused volume etc. can be displayed. The desired parameter can be selected by using . It is recommended to select Cp/Ce.

In case it is necessary to change the target press to edit the value.

Useful information while pump is running

By pressing additional information can be requested.

Pressing a second time is offering a graphical overview.

The line describes the course of Cp over the time and the area describes the course of Ce over the time. The time window is 20 min (15 min past, 5 min future).

Additional information is left with .

Finishing TCI

There are two possibilities to finish the TCI Therapy (reversion of anaesthesia or sedation):

- Set Target= 0
- Stop pump

It is recommended to simply stop the pump by pressing .

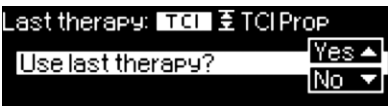
Pressing the pump offers additional information – in this case the information is modified the following way:

Pressing again shows up the graph.

After the therapy is ended there are two possibilities:

a) The pump may be used for TCI with the same drug again but with a new patient. In this case, cancel old therapy and use new disposables.
b) The pump may go with the patient but in continuous mode (without TCI).

In both cases the "old" TCI needs to be ended by and selecting "Yes" in this screen by pressing .



In case a) press in the menu - in case b) press .

3.6 Barcoding

The barcoding functionality is included but initially not activated. Please contact your local sales representative in case you like to use barcoding.

3.7 Piggyback Function

The piggyback-mode offers the possibility to interrupt the current (primary) infusion temporarily in order to administer a piggyback (secondary) infusion. Above the pump the piggyback-infusion line is connected with a Y-connector to the administration set. The secondary infusion is supposed to be located approx. 20 cm higher than the primary infusion. All infusion lines need to be completely primed. A back check valve has to be placed according to the drawing (see next page).

A precondition to start the piggyback function is that the pump is stopped.

Note: Please mind to set a VTBI of the primary and secondary infusion that corresponds to the size of the container. The piggyback infusion can be delivered in continuous mode or dose over time mode only.

- Enter the rate manually or load into the pump via the dose rate calculation or the drug library. It is not possible to begin with the secondary infusion if the data for the primary infusion (rate and VTBI) is not set. To enhance comfort list of drugs can be adjusted to secondary mode by DrugLib.
- Select „Piggyback" from the Special Functions Menu and confirm with .
- The change from the secondary to the primary infusion ("PIGY" to "PRIM") can be done manually or automatically. Correspondingly, if an automatic change is to be made automatically or manually is to be answered with or .

- The rate and VTBI of the secondary infusion can be loaded via the dose rate calculation, the drug library or are to be entered manually with .
- Start secondary infusion by pressing . Device delivers the piggyback volume with the set piggyback rate.

Symbols in the headline of the run display ("PRIM" or "PIGY") will indicate if the primary or secondary infusion is currently running.

When the piggyback volume is infused the pump automatically changes to the primary infusion if this was selected. If the VTBI of primary infusion is infused the pump will continue with the KVO-rate respectively after the KVO-operation the pump stops and activates an alarm. If a manual change from secondary infusion to primary infusion was selected, the pump will stop or continue with KVO after the secondary infusion is completed and the user manually has to change via the menu item "Change to PRIM" in the Main Menu to the primary infusion and start with .

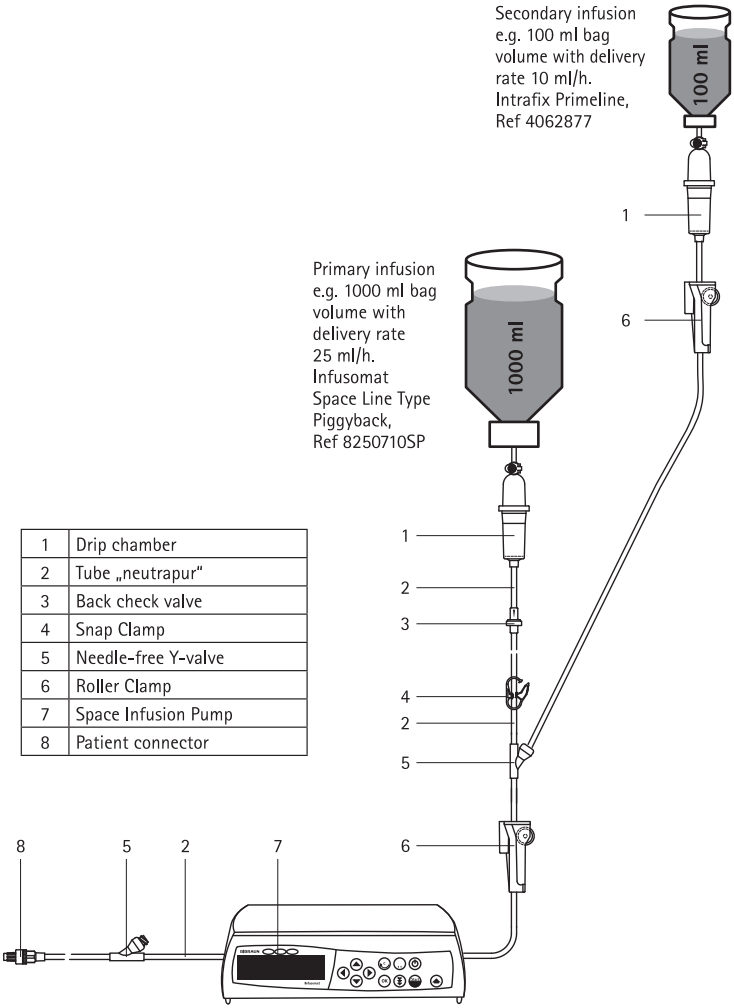
Note: Infusion bag must contain residual volume for KVO after infused VTBI.

Note: Switching manually between primary and secondary infusion in the Main Menu is possible at any time while the pump is stopped. It is recommended to keep the roller clamp of the non-active infusion closed.

The piggyback therapy can be repeated many times by changing the piggyback medicament or by reset of the piggyback medicament.

- Go to „Set new Piggyback" in the Special Functions Menu and confirm with .

Note: The Piggyback infusion can be deleted by starting a new Piggyback and by pressing cancel and answering the question „Use last therapy" with „no". Resetting the data of the last secondary will also reset VTBI.



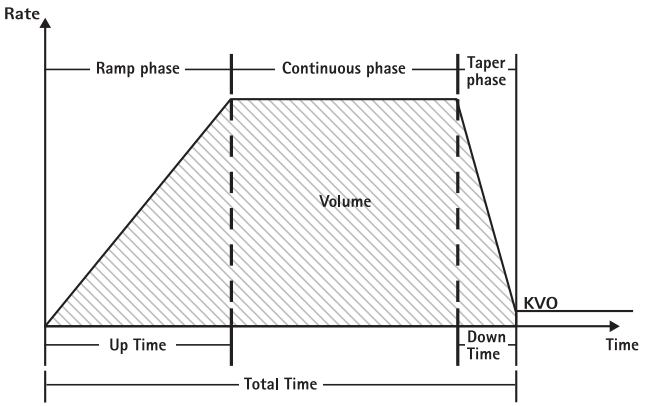
1	Drip chamber
2	Tube „neutrapur"
3	Back check valve
4	Snap Clamp
5	Needle-free Y-valve
6	Roller Clamp
7	Space Infusion Pump
8	Patient connector

3.8 Ramp and Taper Mode

The Ramp and Taper Mode is designed to deliver infusions with gradual ramp up and taper down rates. The pump automatically calculates the rate increase and decrease required to match the total volume, time and ramp up/ramp down time parameters. It consists of 3 phases.

- Ramp phase: the pump rate is linearly increased until it reaches a predefined rate (plateau rate) in a predefined time (Up-Time)
- Continuous phase: the plateau rate is used as a continuous infusion
- Taper phase: the pump rate is decreased linearly after the continuous phase until the KVO rate is reached or pump is stopped in a predefined time (Down-Time)

Example:



Ramp and Taper should only be performed by an experienced user that is familiar with the principles of the Ramp and Taper function and properly trained in using the present device.

Note: The active Ramp and Taper function is always symbolised with an characteristical symbol in the Display (/ /).

Note: Bolus function is disabled for Ramp and Taper Mode.

Set Profile Parameters: The therapy can be started directly via the drug library or via the Main Menu/Special functions.

Starting Ramp and Taper via Drug Library:

Note: Ramp and Taper settings have been configured in the Drug List Manager before and have been uploaded into the pump.

- Switch on pump with and wait until self-check is finished.

- Insert disposable and use the drug library according to the Instructions for Use.
- Select the desired drug with ⇕ and press ◀.

The pump now lists the possible therapy profiles.

- Select "Ramp and Taper Mode" with ⇕ and press ◀.
  The therapy settings for "Ramp and Taper Mode" are shown on the display.
- To change the values, press ◀ to change and OK to confirm.

The pump can be started now by pressing Start/Stop.

Starting Ramp and Taper via Special Function Menu:

- Switch on pump with ⏻ and wait until self-check is finished.
- Insert disposable.
- Go to Special Functions Menu and select Ramp and Taper.
- Press ◀ to enter parameters and OK to confirm.
- After entering all desired parameters the pump can be started by pressing Start/Stop.

The status of the therapy is shown in the upper part of the display of the pump by the icon for "Ramp and Taper Mode".

The screen shows the following:

Ramp phase

The pump now linearly increases the rate in the predefined time until it reaches the plateau rate and then automatically switches to continuous phase.

Continuous phase

The pump continuously infuses the same rate for a predefined time and then automatically switches to taper phase.

Taper phase

The pump linearly decreases the rate in the predefined time until it reaches the KVO rate

Note: After starting infusion it is only possible to change rates, time and VTBI in the continuous phase.

By editing (increasing/decreasing) the plateau rate, the therapy is recalculated. With the increase/decrease of the plateau rate the volumes in the ramp phase, the continuous phase and the taper phase are increased/decreased. The continuous phase is shortened/prolonged to infuse the VTBI still completely with the end of the taper phase.

By editing the Ramp/Taper-Time, the therapy is recalculated. The Continuous Phase is extended/shortened to infuse the VTBI still completely until the end of the Taper phase.

By increasing/decreasing the VTBI, the continuous phase is prolonged/shortened to infuse the new entered VTBI completely with the end of the taper phase.

Note: The delivery of drugs can be stopped and started again in Ramp and Taper Mode at any time by pressig Start Stop. Ramp and Taper is stopped immediately without Taper phase and started without a new Ramp phase.

Immediate Taper Down

By chosing the Immediate Taper Down Function the therapy can be ended with a taper phase before the originally defined VTBI is completely infused.

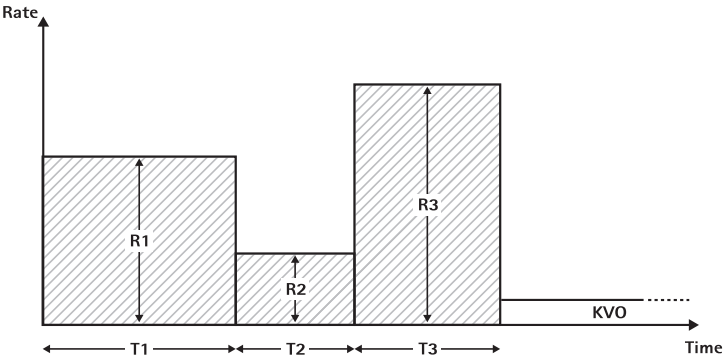
- Press C during continuous phase.
- Use ▲▼ to select Special Functions and press ◀.
- Select Immediate Taper Down Function and confirm with ◀.
- Edit taper time by using ▲▼ and press OK to confirm.
  The pump automatically changes to Taper phase and linearly decreases the rate.

3.9 Program Mode

Program Mode is for infusion requiring a non-standard delivery pattern. The user defines a series of intervals (max. 12 intervals) by certain parameters (rate, time, volume) for each cycle.

The pump automatically gives each programmed period, one after the other.

Example:



Program Mode should only be performed by an experienced user being familiar with the principles of the Program Mode function and properly trained in using the present device.

Note: The active Program Mode function always displays this icon in the Display ( ).

Note: Bolus function is disabled for Program Mode.

Set Profile Parameters: The therapy can be started directly via the drug library or via the Main Menu/Special functions.

Starting Program Mode via Drug Library:

Note: Program Mode settings have been configured in the Drug List Manager before and have been uploaded into the pump.

- Switch on pump with ⏻ and wait until self-check is finished.
- Insert disposable and use the drug library according to Instructions for Use.
- Select the desired drug with and press ◀.
- Select Program Mode with ◀.

In the following screen the user has to confirm the number of steps for the therapy with OK.

The settings for the steps of the infusion are shown on the display. These settings, configured in the Drug List Editor, need to be confirmed with ▶.

- To change the values, press ◀ to change and OK to confirm.

- Adjust VTBI with .

The pump can be started now by pressing .

Starting Program Mode via Special Function Menu:

- Switch on pump with and wait until self-check is finished.
- Insert disposable.
- Go to Special Functions Menu and select Program Mode.
- Press to enter parameters and OK to confirm.
- Adjust VTBI with .

After entering all desired parameters the pump can be started by pressing .

In the upper part of the display the icon for "Program Mode" appears.
The screen shows the following:

The pump infuses the predefined rate in the predefined time for the current step.

Only the VTBI may be changed during an infusion that is running.

- Press to check upcoming Program Mode intervals in Main Menu.

It is possible to cancel one step of the running therapy. All following steps in the programmed sequence persist.

- Go to Main Menu by pressing .
- Use to navigate through the Main Menu and select Current with .
- For checking upcoming intervals press .
- Select "Program Parameters" with .
- Go through all interval steps with .

Note: The delivery of drugs can be stopped and started again in the Program Mode at any time by pressing .

Number of cycles is defined by VTBI. Take care to set the VTBI in the correct relation to the volume of one Cycle. VTBI may needs to be adjusted after Changing the intervals.

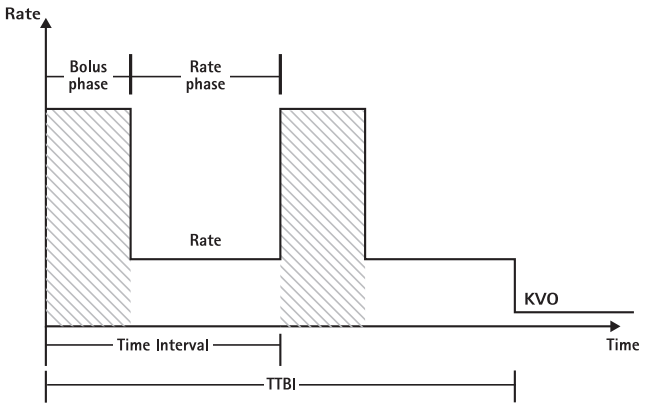
The Main menu informs about the current interval. The configured parameters can be checked by Program Parameter Menu in Main.

3.10 Intermittent Mode

The Intermittent Mode consists of 2 phases. This phases will be repeated.

- Bolus phase: the configured bolus is active
- Rate phase: time during the therapy in which the entered rate is active

Example:



Intermittent Mode should only be performed by an experienced user being familiar with the principles of the Intermittent Mode and properly trained in using the present device.

Note: The active Multi Dose Mode function always displays this icon in the Display (⎍⎍⎍).

Note: Regular Bolus function is disabled for Intermittent Mode.

In Intemittent Bolus the bolus service settings are active. The pressure level is automatically set to max value.

Set Profile Parameters: The therapy can be started directly via the drug library or via the Main Menu/Special functions.

Starting Intermittent Mode via Drug Library:

Note: Intermittent Mode settings have been configured in the Drug List Manager before and have been uploaded into the pump.

- Switch on pump with ⏻ and wait until self-check is finished.
- Insert disposable and use the drug library according to Instructions for Use.
- Select the desired drug with ▲▼ and press ◀.

The pump now offers the possible therapy profiles.

- Select "Intermittent Mode" with ▲▼ and press ◀. The therapy settings for "Intermittent Mode" are shown on the display.
- For changing the parameters, press ◀ to change and OK to confirm.

Note: Bolus rate is calculated by editable parameters. These parameters have to be checked by the user before starting the infusion.

The pump can be started now by pressing Start/Stop.

Starting Intermittent Mode via Special Function Menu:

- Switch on pump with Start/Stop and wait until self-check is finished.
- Insert disposable.
- Go to Special Functions Menu and select Intermittent Mode.
- Press ◀ to enter parameters and OK to confirm.

After entering all desired parameters the pump can be started by pressing Start/Stop.

In the upper part of the display the icon for "Intermittent Mode" appears.

In bolus phase the screen shows the following:

The pump now delivers the predefined bolus.

After the bolus phase the pump switches to rate phase and the screen shows the following:

The pump now delivers the predefined rate.

Note: To cancel bolus infusion in the Intermittet Bolus therapy at any time it is only possible with Start/Stop.

Note: The delivery of drugs can be stopped and started again in the Intermittent Mode at any time by pressing Start/Stop.

During infusion it is possible to change the bolus volume, amount, VTBI as well as the time interval.

- Press C.
- Use ▲▼ to navigate through the parameter list and select the parameter to be changed with ◀.
- Enter the new value and press OK.
  The pump continues infusion.

Changing the bolus after start:

If the user edits the bolus the therapy progression changes.

- Press C.

- Use ⇕ to select Bolus and press ◀.
- Change Bolus by using ⇕ and press OK to confirm.
  The pump automatically recalculates all other settings of the therapy.

Changing the time interval after start:

If the user edits the time interval the therapy progression changes.

- Press C.
- Use ⇕ to select Interval and press ◀.
- Change Interval by using ⇕ and press OK to confirm.
  The pump automatically recalculates all other settings of the therapy.

3.11 Dose Over Time

Dose Over Time is used to administer a specific dose of antibiotics in a specific time. Dose Over Time is an own therapy and cannot be used in combination with another therapy except Piggyback. It can only be activated via the Drug List Manager. It can be used for standard infusion and/or piggyback.

The active Dose Over time function is always symbolised with a characteristical symbol in the Display ( ). If besides DOT the piggyback therapy is active, a combined symbol for both therapies will be displayed ( ).

Note: Dose Over Time should only be performed by experienced users being familiar with the principles of the Dose Over Time function and properly trained in using the present device.

The infusion rate in Dose Over Time can not be changed. This parameter is a result of the total dose and the infusion time setting. Directly, after the Drug selection, the infusion time and the total dose intended to be infused have to be set. If the drug library contains default values for these parameters, the default values are used as preset values.

If changes are necessary during infusion, the delivery can be controlled by changing the time. The pump calculates the new rate by using the remaining total dose and the remaining time. In the Main Menu total dose, time and VTBI can be changed, also during RUN-Mode. Other parameters (dose rate, basal rate, concentration, patient weight and patient height) cannot be changed.

Note: The KVO function and Bolus function are disabled during Dose Over Time.

Note: The feature Dose Over Time always requires the usage of dosing units (i.e., mg or mg/kg patient weight).

Before using Dose Over Time contact your local B. Braun representative!
Starting Dose Over Time via Drug Library:

Note: Dose Over Time settings have been configured in the Drug List Manager

before and have been uploaded into the pump.

- Switch on pump with ⏻ and wait until self-check is finished.
- Insert disposable and use the drug library according to the Instructions for Use.
- Select a drug by using ⇕ and press ◀.

The pump now offers the possible therapy profiles. Select "Dose over Time" with ⇕ and press ◀.

The editor for Total Dose is shown if a drug with therapy Dose over Time is selected from drug library and no default value for Total Dose was entered in library. The editor is also shown if the Total Dose is edited in the Main menu.

Enter the total dose, if necessary, and confirm with OK.

The editor for Time is shown if a drug with therapy Dose over Time is selected from drug library and no default value for Time was entered in library. The editor is also shown if the Time is edited in Main Menu.

Enter the time, if necessary, and confirm with OK.

The VTBI is calculated automatically and the following screen is displayed:

Check calculated rate by using ⇕ for plausibility

Start Dose Over Time by pressing Start/Stop.

Run Menu: The time is used to control the therapy. For this reason the remaining time is shown big digits in menu Run. The parameter in the lower left corner can be scrolled. Set to Rate when leaving the pump.

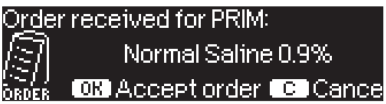
Note: It is always possible to press the key C in the Run Menu and edit or check values in the Main Menu while the pump is delivering.

AUTOPROGRAMMING

Note: All normal pump functions remain in place when orders are received via autoprogramming.

The pump can accept drug orders wirelessly from the EHR system or from SpaceStation with SpaceCom. The workflow to accept an order wirelessly will vary depending on your EHR vendor.

- Using the hand held device or lap top, review the order and follow your hospital protocol for scanning the bag/syringe, pump, patient and nurse (optional).
- Once order is confirmed on the hand held or laptop, prompt EHR to send order directly to pump. The order will arrive and appear on the pump within 10 seconds.
- Ensure pump is in the Main Menu, passive mode or Standby.
- New Order message will appear with drug name and mode.



- Press OK to accept or C key to cancel order and respond to prompt.
- Select Care Unit and Patient Profile as in Drug Library programming.
- Pump will search for Drug Library match.

Note: If no drug library match, which may be due to no matching name, concentration or dosing units, pump displays reason for no match and depending on your hospitals configuration either allows manual programming outside the drug library or rejects order completely. An order that is confirmed outside the drug library will have a triangle with an exclamation point on display to indicate there are no drug library settings.

- Scroll to each value to confirm using arrow keys.

Note: Order may be cancelled prior to confirming order.

- Once all values are confirmed, the Main Menu is displayed.

Note: Soft Limit alert will be issued if value exceeds any soft limits set in drug library, soft limit may be overridden or value re-programmed per institutional policy. Order will be rejected if hard limit is exceeded. (except in circumstance where pump service program is not set to perform drug library match for auto-programming).

For PRIMary Orders (Either 'Continuous' oder 'Dose over Time'):

Note: The first order sent send as 'Continuous' is always considered as the PRIMary infusion, subsequent orders will be considered PIGGYback.

Note: Order sent as 'Dose over Time' is always considered the PRIMary infusion, no subsequent order can be received. Additional, no updates can be received for 'Dose over Time'.

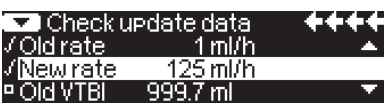
- Press Start/Stop key to start infusion.

Updates to Current Primary Infusion

Updates may be received for PRIMary infusions while pump is running or stopped and while in PRIMary or PIGGYback.

While in PRIMary:

- Update icon will appear on display, follow on screen prompts to accept or cancel the order. Confirmation screen will indicate both OLD and NEW value for parameter(s) that changed.



While in PIGGYback:

- Message will appear on top of display indicating update is available for PRIMary.
- Press key to view order.
- Follow prompt, pressing to accept order or key to cancel and hold order for later.

New Primary Infusion:

- To accept a new PRIMary order, stop infusion and clear current PRIMary infusion by pressing key and responding "yes" to clear current infusion.

PIGGYback **Orders:**

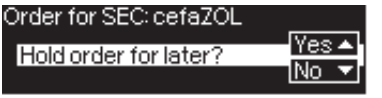
Orders received after PRIMary has been set will be for PIGGYback infusions, follow prompts on screen to stop the PRIMary to accept the PIGGYback order.

- Confirm order values as above for PRIMary orders.
- Respond to prompts to check bag height and clamps prior to startingPIGGYback.

New PIGGYback order while PIGGYback is Infusing:

- Follow display prompts to stop current infusion.

Note: A PIGGYback order may be held for later by pressing key to cancel order and answering yes to "hold for later".



Note: Changing values on any incoming order may only be done after confirming all values. Once all values are confirmed you may scroll to any value and open editor with ◀ to change value. Alternately, order may be cancelled and request made for revised order to be sent.

Note: If pump is placed in standby while order is pending new order will flash on top of stand by display, press ⏬ key to accept order (pump will come out of standby).

OPTIONS

The options functions may be selected and changed while the pump is infusing or stopped. To edit a menu item, select "Options" in the Main Menu and press ◀.
Then select desired function with ▲▼ and follow the Instructions for Use as described.

5.1 Occlusion Pressure

The higher the pressure level is set at, the higher the pressure level must rise before triggering an occlusion pressure alarm.

Using the occlusion pressure, the alarm sounding period can be kept short in the event of system occlusions. It generally applies that the set pressure should always be set higher than the system pressure. If pressure alarms occur in a pressure level without a system occlusion, the pressure level must be adjusted upward. In order to be able to ensure short alarm times, a low pressure level should be started with and the pressure level increased until the infusion starts up.

Depending on the different influences, such as the tube length, tube diameter, viscosity of the liquid and the filter used in the system set-up, adjustments may need to be made to the pressure level..

- Enter pressure in Options Menu by pressing ◀.
- Choose between nine pressure levels (1=lowest level; 9=highest level) by pressing ◀ or ▶ and confirm entry with OK.

Note: The pressure will remain at set level until changed by user unless the drug selected had a pressure level set in the drug library. When pump is powered off pressure level returns to default value set in service program when powered back on unless drug selected has a different pressure level set in the drug library.

The top line is the current infusion pressure. The buttom dashed line shows the pressure alarm setting, currently 5 out of 9 which is represented by 5 dashed. The picture shows a current presure of ~ 30 % of the pressure level 5.

If occlussion pressure levels lower than the level 1 are needed, it can be activated via the service tool.

Please contact your local sales representative for further data if you use pressure levels below lever 1.

The editor is extended by maximal 3 dashes.

Confirm new pressure level with (OK) and go back to Options Menu.

In the Run Menu the top line shows the current infusion pressure. The bottom line and the 3 dashes before the symbol shows the pressure alarm settings.

5.2 Upstream Occlusion Pressure

The device is equipped with an upstream pressure sensor that detects an occlusion (e.g. closed roller clamp, kinked line) between the container and the pump. The higher the pressure level is set at, the lower the pressure level must drop before triggering an upstream occlusion pressure alarm.

- Access upstream pressure in Options Menu by pressing (◀).
- Choose between nine pressure levels (1=lowest level; 9=highest level) by pressing (◀) or (▶) and confirm entry with (OK).

5.3 Data Lock

The data lock function protects the device against unauthorized access. It is recommended to adapt the four digit code for level 1 and 2 from the default setting (9119), using the service program. There are three security levels.

Level 1:
A modification of values as well as a bolus application are not possible but a change of the disposable can be conducted. It is possible to navigate through all menus and status data can be checked. Starting, interrupting and switching the pump off is possible.

Level 2:
This level has the same performance characteristic as described under level 1 and additional will not allow the change of disposable. In order to prevent a data lock alarm the correct code must be entered within 20 sec after the pump was stopped. Changing the disposable and switching the pump off is only possible after the code was entered.

Level 3:
This level will allow starting and stopping the pump as well as switching off. The code for this level may be different for each drug and is defined in the drug list. A change of the disposable, however, is possible by using the code defined for the other levels. An overview about the differences between the levels 1, 2 and 3 is given by the following table.

Event	Level 1	Level 2	Level 3
Change of disposable	✓	×	✓ with code for level 1/2
Start of infusion	✓	×	✓
Change of parameters	×	×	×
Stop of infusion	✓	✓ 🔔	✓
Switching off pump / Standby	✓	×	×
PCA bolus with pump-based bolus button	×	×	✓
Customisable screen	×	×	✓
Acoustic feedback of demanded boli	×	×	✓
Indicates denied PCA boli	✓	✓	×

✓= possible | × = not possible | 🔔 = followed by standby-alarm

Activation of the function:

- Open data lock in Options Menu with ◀.
- Select between level 1, 2 or 3 (if activated) with ◀ and ▶ and confirm with OK.
- Enter code with and press OK in order to activate data lock.

Changes to the protected values and the bolus function which are marked with are only possible after entering the code. After 20 sec in the Main Menu, Status Menu, Special Functions Menu and Options Menu the lock will be activated again. If the wrong code is entered twice the pump will switch into the last menu. If the wrong code is entered twice again the pump will go into an audible alarm, a nurse call will go off and the yellow LED blinks. If a target value was reached while data lock is active a new start of the pump is only possible after entering the code.

In order to deactivate the function, select "Off" in the data lock, press OK, enter the code and press OK again.

5.4 Bolus Rate

- Open bolus rate in Options Menu with ◀.
- Change bolus rate with ⚙ and confirm setting with OK.

Note: Set bolus rate according to therapy requirements. Take care not to overdose! Given a bolus rate of 1200 ml/h, e.g. 0.33 ml are reached within just one second.

5.5 KVO-Mode

The pump can continue the infusion with a preset KVO-rate after a preselected VTBI/time has passed (see "Technical Data"). The duration of the KVO delivery is selected in the service program.

- Open the KVO-mode in the Options Menu with ◀.
- Answer the Yes/No question with ▲ to enable the KVO-mode.

5.6 Contrast / Display Light / Keypad Light

Contrast as well as display- and keypad light can be adjusted individually according to the lighting conditions.

- Open contrast/display light/keypad light in Options Menu by pressing ◀.
- Choose between 9 contrast- and display light levels with ◀ or ▶ and confirm with OK.

5.7 Alarm Volume

Chose between 9 different alarm volume levels.

- Open alarm volume in Options Menu with ◀.
- Set volume with ◀ or ▶ and confirm entry with OK.

5.8 Date / Time

- Open date/time in the Options Menu with ◀.
- Modify date and time with ⚙ and confirm the setting with OK.

5.9 Macro Mode

The infusion rate appears larger on the display when the macro mode is activated and the pump is infusing.

- Open macro mode in Options Menu with ◀.
- Answer Yes/No question by pressing ▲ to activate the macro mode.

For quick activation of macro mode: Press and hold ▶ while the pump is infusing until the font size changes.

5.10 Language

This function enables a change of the pump language.

- Open language in the Options Menu with ◀.
- Select language with ▲▼ then press ◀.
- Confirm Yes/No question with ▲.

ALARMS

The Infusomat® Space is equipped with a audible and optical alarm signal.

Alarm-type	Audible signal	Optical signal			Staff call	User confirmation
		Red LED	Yellow LED	Text		
Device Alarm	yes	flashes	off	device alarm and alarm code (see service program)	yes	Press ⏻ and follow the instruction on the display.
OperatingAlarm	yes	flashes	off	see alarm description	yes	Press OK to acknowledge the audible alarm, alarm text and staff call. Press 🔕 to mute the alarm for 2 minutes.
Pre-Alarm	yes	off	constant on	see alarm description	(de-)activate via service program	Press 🔕 to mute alarm and turn off staff call. Visible alarm remains until end.
Reminder Alarm	yes	off	constant on	see alarm description	yes	Press OK to mute alarm, turn off staff call and delete the alarm text.
Alarm Hint	no	off	off	see alarm description	no	Hint disappears without confirmation.

6.1 Device Alarms

When a device alarm occurs the infusion is immediately stopped. Press ⏻ to switch off the device. Then switch the device on again. In case of a repeated device alarm you must close the rollerclamp, disconnect from the patient, open the front door of the pump and take out the disposable. The device needs to be handed to the service department.

6.2 Pre-Alarms and Operating Alarms

Pre-alarms:
Pre-alarms occur a few minutes (dependable on service settings) prior to operating alarms. During pre-alarms an audible tone sounds, the yellow LED is constantly on and a staff call is activated (optional). The display message varies depending on the alarm reason. The signal tone and the staff call are turned off with 🔕 . Display and LED stay in pre-alarm until the operating alarm goes off. Pre-alarms don't lead to an interruption of the infusion.

Display message	Pre-alarm reason
"VTBI near end"	The preselected volume is nearly infused.
"Time near end"	The preselected time is almost over.
"Battery nearly empty"	The battery is almost discharged.
"KVO mode"	VTBI/time are reached and the pump continues the infusion at the KVO-rate.

A stopwatch on the display counts down the remaining time (depending on the service program, between 0-30 min). After that, the pump changes to the operating alarm.

The pre-alarms "VTBI near end" (volume preselection) and "Time near end" (time preselection) can be deactivated via the service program.

Operating alarms:
Operating alarms lead to an interruption of the infusion. An audible tone sounds, the red LED flashes and a staff call is activated.
The display states "Alarm", the reason for the operating alarm and gives the option to either confirm the alarm by pressing OK or mute the alarm by pressing . If the alarm is muted, the alarm message will remain on the screen until it is confirmed by pressing OK. After 2 minutes, if the alarm has not been confirmed by pressing OK, the audible tone will sound again. The alarm tone, the alarm message, and the staff call (optional) are all cleared by pressing OK. Corrections are to be made according to the alarm reason.

Display message	Alarm reason
"VTBI infused "	The preselected volume was infused. Continue therapy or select new therapy.
"Time expired"	The preselected time has ended. Continue therapy or select new therapy.
"Battery empty"	The battery pack is discharged. Connect device with mains and/or exchange battery pack. The battery alarm will be on for 3 min. Then the pump will automatically turn off.
"Pressure high"	An occlusion occured in the system. The set pressure level was exceeded. A bolus reduction is automatically initiated by the pump. Check if tubing contains kinks or is damaged as well as IV- and filter patency. Increase occlusion pressure if necessary.
"KVO finished"	The KVO-time has ended. Continue therapy or set new therapy.

Battery cover removed"	The battery cover is not properly engaged on the battery compartment. When pushing on the battery cover listen for "click".
"Standby time expired"	The set standby time has ended. Set new time or continue with previously set therapy.
"No battery inserted"	It is not possible to use the pump without a battery pack. Turn off pump and insert battery pack according to description "Overview Infusomat® Space".
"Drive blocked"	Stepper motor does not deliver due to excess pressure in the system. Interrupt patient connection and reinsert the line.
"Calibrate device"	Pump calibration data have changed (e.g. after an update). Recalibrate device via the service program.
"Drop sensor connection"	Contact to the drop sensor is interrupted while the pump is delivering. Check whether the drop sensor is correctly placed on the drop chamber. If necessary, replace the drop sensor or preselect VTBI/time and proceed with therapy.
"Check upstream"	The upstream sensor triggers an alarm. Check if roller clamp is closed or infusion line is kinked. If a drop sensor is connected the upstream alarm is deactivated.
"Air bubble "/"Accumulated air"	Air inside the system. Check the line for small air bubbles and disconnect from patient to repeat priming, if necessary.
"No drops"	The drop sensor does not detect any drops. The infusion container is empty, the roller clamp is closed, the drop sensor is not put on, check the line for obstructions, condensation on drop chamber (remove by shaking it).
"Too few drops"	The number of fallen drops is lower than the preset rate. A negative pressure in a glass infusion container can be eliminated by opening the vent flap on the drop chamber. Check whether the infusion bottle is empty, the roller clamp is completely opened and whether there are any kinks in the line.
"Too many drops"	The number of fallen drops is higher than the preset rate.

	Check the line for damage and make sure that the line is correctly inserted.
"Flow"	Drop chamber is completely filled or leak in the system. Examine the line for damage and check the drop chamber.
"Data were reset"	Therapy and pump settings could not be restored. Enter therapy again.
"Therapy data were reset"	Therapy data could not be restored. Enter therapy again.
"Data Lock"	An attempt was made to stop or switch the pump off without entering the code. Enter the correct code in order to continue the therapy respectively turning the pump off.

The red LED extinguishes with the acknowledgement of the alarm.

Caution: If a wrench ( ) is displayed and/or a yellow, red and blue LED blink then the pump is in the service mode and is not permitted to be used on a patient. The pump must then be checked by a service technician.

Caution: If the OFF is constantly displayed in the headline, the audible alarm for the pre- and operating alarm is silenced for a predefined time via service tool. Only the visual alarm is still displayed at the pump. After the predefined time is elapsed the pump provides the audible alarm.

6.3 Reminder Alarms

Reminder alarms only occur in two cases:

1. A line is inserted, the pump does not deliver, no value is edited and the device is not operated for two minutes.
   An acoustic tone sounds, the yellow LED is constantly on and a staff call is activated.
   a) The display states "Reminder alarm!"
   b) The display states "Config. not finished!"
   Confirm alarm with OK and continue to set therapy/Start Up configuration.

2. A value edition was started but not finished and confirmed. This is also possible with a missing disposable.
   An acoustic tone sounds, the display states "Value not accepted", the yellow LED is constantly on and a staff call is activated.
   Confirm alarm with OK and continue to set therapy.

6.4 Alarm Hints

If inproper entries are made the display states corresponding hints (e.g. "Bol.rate out of range"; "Download failed"; "The parameter can not be modified").

BATTERY OPERATION AND MAINTENANCE

The battery has an operating lifetime of 4 hours at 100 ml/h when new. For optimal treatment of the battery, the device is equipped with protection against overcharge and deep depletion. The battery pack is charged by the pump during connection to mains. When disconnected from mains or in case of power failure, the pump automatically switches to battery power.

Note: Prior to a longer storage of the pump (> 5 months) the battery pack must be completely charged and then removed from the pump. Before changing the battery, always disconnect the pump from the patient and switch off the device.

The battery status indicator is a trend display (low, medium, high). For more detailed information on the current battery capacity (operating time in hours and minutes) please refer to menu item "Batt. Cap." in the Status Menu of the Infusomat® Space.

Caution: The display of the battery operating time on the pump is an approximate value based on the current delivery rate. Changes in the delivery rate may affect the battery operating time.

Disposable change procedures require a high power consumption. A sudden break down of the battery operating time can be possible with an aged battery. In this case the battery has to be replaced by a new one.

If highly potent drugs are to be given over an extended time without mains power, it is recommended to have a fully charged reserve pump at hand.

Note: In case of ESD, Pump may need plugged into wall outlet to re-start the battery.

Attention: If the battery module is stored for long periods of time outside the pump, it is recommended to fully charge the battery and store it at room temperature.

Caution: Batteries may explode or leak if they are opened or incinerated. Consider disposal directions!

Important information for battery self-check:

If the battery symbol is blinking during mains operation, the battery has less then 30 minutes remaining capacity.

In this case, the pump should not be disconnected from mains. If it is necessary to disconnect the pump from mains power for urgent reasons, the user should check to ensure if the battery capacity is sufficient for the proposed use. When the battery symbol blinks permanently (>1h), the battery must be checked by a technician and replaced if necessary.

Directions for optimal battery use:

The actual battery life may vary due to

- ambient temperature
- varying load (e.g. frequent boluses).

The optimal life time of a battery pack will only be reached if it's completely discharged from time to time. A maintenance mode which conducts this battery maintenance is built in. This function should be activated once a month. Furthermore:

- If a battery, which is not completely discharged, is charged several times, its capacity can be reduced.
- Under normal temperature conditions a battery can be charged and discharged approx. 500 times before its lifetime decreases.
- When the pump is not connected to mains power the battery discharges itself slowly. This can occur even when the pump is not operating.
- The battery operating time can only be realized if the pump operates continuously with a fully charged battery at room temperature.

Battery maintenance:

To accurately balance the battery capacity a cyclical battery maintenance is necessary. The frequency of battery maintenance may be set in the service tool. The battery maintenance mode detects a possible capacity loss (e.g. through ageing of the battery pack) and then the capacity/running time will be calculated anew. After a longer storage time or a longer operation without battery maintenance it can happen that the battery pre-alarm time can no longer be maintained. In this case it is necessary to perform a battery maintenance.
To initiate the discharge process the message „Battery maintenance" and the OK-key will be displayed after switching the pump off. By pressing OK and ▲ the discharge process will start. The process is interrupted by switching the pump on again. If the battery maintenance is to be continued a new activation is necessary. After completely discharging the battery it will be completely charged again. The total duration of the battery maintenance process takes approx. twelve hours.

Caution: Please take into account that, if the battery maintenance has not been completed there is a possibility of a reduced battery operating time.

Replacing batteries:

The Battery Pack SP can be exchanged by any user. No special qualification is required.

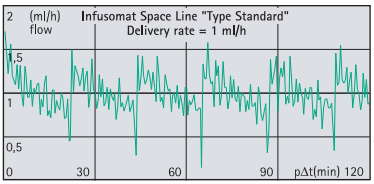
All rechargeable batteries exhibit a reduction in capacity as they age. This aging is dependant on several factors including charging cycles, temperature and battery usage.

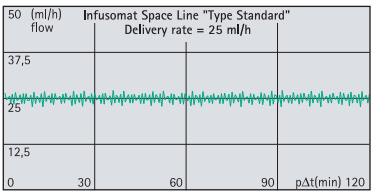
It is recommended to periodically check the function of the battery. A battery should no longer be used if a change of disposable leads to a "Battery nearly empty" or a "Battery empty" alarm when it is fully charged.

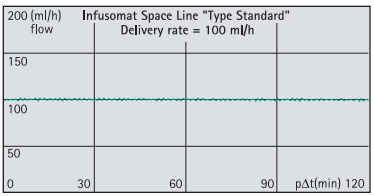
Caution: Batteries may explode or leak if they are opened or incinerated. Consider disposal directions!

START UP GRAPHS AND TRUMPET CURVES

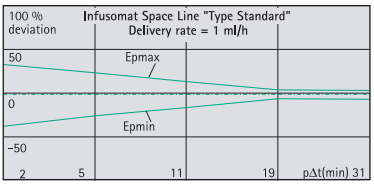
Start Up Graphs

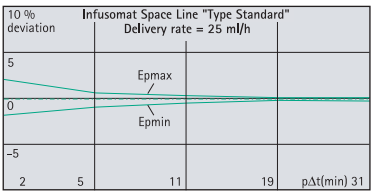


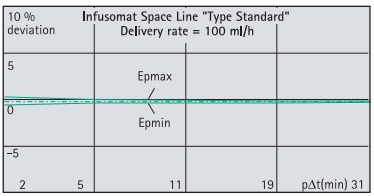




Trumpet Curves







The graphs show the accuracy/uniformity of flow in relation to time. They allow for the following:
The delivery behaviour or delivery precision is essentially influenced by the type of the disposable used. Deviations from the technical data of the pump cannot be guaranteed as the manufacturer may change IV-set specification significant to system accuracy without prior notification.

System accuracy is +/- 5% typical by volume as measured using the trumpet curve test method defined in IEC 60601-2-24 at rates of 1ml/h (23°C) and when the pump is used with recommended sets.

Trumpet Curves
Measured values for second hour in each case.

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

Start Up Graphs

Measurement interval	$\Delta t = 0.5$ min
Measurement duration	$T = 120$ min
Flow Q_i	(ml/h)

TECHNICAL DATA

Type of unit	Volumetric infusion pump
Classification (acc. to IEC/EN 60601-1)	♥ defibrillator-proof; CF equipment ☐ Protective Class II; Protective Class I in combination with SpaceStation
Class (acc. to Directive 93/42 EEC)	IIb
Moisture protection	IP 22 (fluid protected for horizontal usage)
External power supply:	
■ Rated voltage	Via B. Braun SpaceStation or optional mains adaptor (rated voltage 100 ... 240 V AC~, 50/60 Hz) for stand alone operation
■ External low voltage	11 ... 16 V DC ⎓ via Connection Lead SP 12 V or via SpaceStation
Staff call	Max. 24 V / 0,5 A / 24 VA (VDE 0834)
EMC	IEC/EN 60601-1-2 / 60601-2-24
Time of operation	100 % (continuous operation)
Operating conditions:	
■ Relative humidity	30 % ... 90 % (without condensation)
■ Temperature	+10 ... +40 °C
■ Atmospheric pressure	500 ... 1060 mbar
Storage conditions:	
■ Relative humidity	20 % ... 90 % (without condensation)
■ Temperature	-20 ... +55 °C
■ Atmospheric pressure	500 ... 1060 mbar
Type of battery pack (rechargeable)	Li-Ion NiMH
Operating time of rechargeable battery	Li-Ion Wireless active Infusomat® at 100 ml/h typ. 4 hours Wireless active Infusomat® at 1200 ml/h typ. 2.5 hours Wireless active Infusomat® at 25 ml/h typ. 4 hours Wireless inactive Infusomat® at 100 ml/h typ. 12 hours Wireless inactive Infusomat® at 1200 ml/h 5 hours Wireless inactive Infusomat® at 25 ml/h 15 hours NiMH at 100 ml/h typ. 13 hours at 1200 ml/h typ. 5 hours at 25 ml/h typ. 16 hours

Recharging time	Approx. 6 hours
Weight	Approx. 1.4 kg
Dimensions (W x H x D)	214 x 68 x 124 mm
Volume preselection	0.1 - 99.99 ml in increments of 0.01 ml 100.0 – 999.0 ml in increments 0.1 ml 1000 – 99999 ml in increments 1 ml
Time preselection	00:01 – 99:59 h
Accuracy of set delivery rate	± 5 % according to IEC/EN 60601-2-24
Max. Volume in case of single fault condition	For incorrect dosages of 1,4 ml due to malfunctions of the device the pump will automatically shut off
Technical inspection (safety check)	Every 2 years
Administration Set Change Interval	Pumping accuracy is maintained for a minimum of 96 hours.
Multiple lines connected to one patient port	Connecting multiple infusion lines with different flow rates may affect the rate for all infusions past the point of connection.
Rate increments	0.1 - 99.99 ml/h in increments of 0.01 ml/h 100.0 - 999.9 ml/h in increments of 0.1 ml/h 1000.0 - 1200 ml/h in increments of 1 ml/H
Accuracy of bolus infusion	typ. ± 5 % as of a bolus volume > 1 ml
KVO-rate	Delivery rate ≥ 10 ml/h: KVO-rate 3 ml/h Delivery rate < 10 ml/h: KVO-rate 1 ml/h Delivery rate < 1 ml/h: KVO-rate = set rate (default setting 0.1 ml/h)
Computer connection	USB connection in combination with B. Braun interface lead CAN SP (8713230) including electrical insulation. Please pay attention to safety notices.
Air detector	Technical sensitivity: Detection of air bubbles ≥ 0.01 ml Alarm triggering: Single bubble alarm: 0.02 – 0.3 ml

	(default 0.3 ml) Cumulative air alarm: 0.5 – 3.8 ml/h (default 1.5 ml/h) Resolution: 0.01 ml
Sensitivity upstream sensor	9 levels from -0.12 bar to -0.21 bar (pressure reduction)
Occlusion alarm pressures	9 levels up to 1.2 bar

Occlusion pressure		Time to occlusion alarm [min] at rate		
	[bar]	[1 ml/h]	[25 ml/h]	[100 ml/h]
Level 1	typ. 0.3	09:07	00:33	00:07
Level 5	typ. 0.7	25:53	01:14	00:15
Level 9	typ. 1.2	46:50	02:06	00:24

Note: At a rate of 0,01ml/h, the time of occlusion alarm is > 3 hours.

Max. bolus after bolus reduction	≤ 0.2 ml
Alarm volume	9 levels from 1 (59dBA) to 9 (74dBA)
Mechanical occlusion pressure limit under fault conditions	Occlusion alarm pressure max. 2.1 bar (210 kPa). Maximum posts occlusion bolus volume 2ml.
History protocol	> 3000 last history entries 100 events for system diagnose. Refer to separate documents of the History Viewer for closer information.

- Use only pressure proof and compatible disposable items (min. 2 bar/1500 mm Hg) to avoid influencing performance data - which would result in impairing patient safety.
- Only use combined with approved devices/accessories by the manufacturer, otherwise this may lead to higher emission or reduced immunity.
- Use only compatible combinations of equipment, accessories, working parts and disposables with luer lock connectors.

Essential Performance for Infusion pumps:

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

Note: The technical data stated in this Instructions for Use manual were determined with the Infusomat® Space lines as of "Type Standard" (870 0036 SP). These technical data can change when using set configurations.

EMC (ELECTROMAGNETIC COMPATIBILITY)

Guidance and manufacturer's declaration on electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emission		
The Space System is intended for use in the electromagnetic environment specified below. The customer or the user of the Space System or any component should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment guidance**
RF emissions CISPR 11	Group 1	The Space System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. If WLAN-Module is installed within Battery module (8713182A) or WLAN USB Stick for SpaceCom (8713185) is used RF energy is transmitted by the Space System. Refer to technical data of Battery-Pack SP with Wifi IFU and/or SpaceStation and SpaceCom for details.
RF emissions CISPR 11	Class B (Note 2)	The Space System or any component is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	applicable only for SpaceStation Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
Note 1: Maximum emissions are measured with a complete system (SpaceStation and components). Note 2: If Class A equipment is attached to the Space System, the Space System will become Class A too. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Space System or shielding the location.		

Guidance and manufacturer's declaration – electromagnetic immunity			
The Space System is intended for use in the electromagnetic environment specified below. The customer or the user of the Space System or any component should assure that it is used in such an environment.			
Immunity test	**test level IEC 60601-1-2 IEC 60601-2-24**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) according IEC 60601-4-2	contact IEC 60601-1-2: ±6KV IEC 60601-2-24: ±8KV air IEC 60601-1-2: ±8KV IEC 60601-2-24: ±15KV	±6KV no disturbances ±8KV stop with alarm possible ±8KV no disturbances ±15KV stop with alarm possible	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst according IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	±2KV ±1KV	A/C power quality should be that of a typical commercial or hospital environment.
Surge according IEC 61000-4-5	differential mode ±1KV common mode ±2KV	±1KV ±2KV	A/C power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines according IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec <5% UT for 5 s (>95% dip)	complies by use of internal battery	A/C power quality should be that of a typical commercial or hospital environment. If the user of the Space System requires continued operation during long time A/C power interruptions, it is recommended that the Space System or component be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field according IEC 61000-4-8	3 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.
Note: Different test values of IEC 60601-2-24 are marked in the table. At the test values no dangerous disturbances occurred at the lower test values of IEC 60601-1-2.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Space System is intended for use in the electromagnetic environment specified below. The customer or the user of the Space System or any component should assure that it is used in such an environment.			
Immunity test	**test level IEC 60601-1-2 IEC 60601-2-24**	**Compliance level**	**Electromagnetic environment - guidance**
radiated electromagnetic RF fields according IEC 61000-4-6	IEC 60601-1-2: 3 Veff normal and 10Veff in ISM frequency band IEC 60601-2-24: 10 Veff 150KHz to 80MHz	10Veff 150KHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Space System or it's components, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1,2 √P Field strengths should be less then 10V/m d = 1,2 √P 80 MHz to 800 MHz
conducted electromagnetic RF fields according IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m 80 MHz to 3 GHz	d = 2,3 √P 800 MHz to 2,5GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmit-ter manufacturer and d is the rec-ommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 3: See next page.			

NOTE 3: Different test values of IEC 60601-2-24 are marked in the table. At these test values no dangerous disturbances are allowed while at the lower test values of IEC 60601-1-2. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electro-magnetic site survey should be considered. If the measured field strength in the location in which the SpaceSystem is used exceeds the applicable RF compliance level above, the Space System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Space System.

The Space System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Space System or component can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Space System as recommended below, according to the maxi-mum output power of the communications equipment

rated power of the ratio transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz bis 80 MHz $1,2\sqrt{P}$	**80 MHz bis 800 MHz** $1,2\sqrt{P}$	**800 MHz bis 2,5 GHz** $2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,27
100	12	12	23

NOTE 1: For transmitters rated at a maximum power output not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequen-cy of the transmitter, where (P) is the maximum output power rating of the transmit-ter in watts (W) according to the transmitter manufacturer.

NOTE 2: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the frequency range 0.15 MHz to 2.5 GHz to decrease the likelihood that mobile/ portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARRANTY / TRAINING / TSC* / SERVICE / DISINFECTING / DISPOSAL

Responsibility of the Manufacturer

The manufacturer, assembler, installer or importer is responsible for the effects on safety, reliability and performance of the equipment only if:

- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by authorized personnel,
- the electrical installation of the relevant room complies with the appropriate requirements (e.g. VDE 0100, 0107 and/or the IEC-publications resp. national requirements),
- the equipment is used in accordance with the Instructions for Use and
- the Technical Safety Checks are carried out regularly.

The CE mark confirms that this medical product complies with the "Council Directive on Medical Devices 93/42/EEC" dated 14th Junde 1993.

B. Braun Melsungen AG

Warranty

B. Braun provides 24 months warranty, as from the date of delivery, for every Infusomat® Space (12 months for every Battery-Pack SP). This covers repair or replacement of parts damaged as a result of design/manufacturing errors or material defects. Modifications or repairs to the unit undertaken by the user/operator or by third parties invalidate the warranty.

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

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

WARNING: Do not modify this equipment without authorization of the manufacturer.

Labeling of electric and electronic devices according to directive 2012/19/EU (WEEE).

Training

B. Braun offers a training. Please ask your local representative for further details.

Technical Safety Check* / Service

The Technical Safety Check is recommended to be carried out every 2 years and should be documented. Servicing work must be carried out exclusively by trained personnel.

Check regularly

Check for cleanliness, completeness and damage. Use only according to Instructions for Use. During an exchange interval of the disposable the pump has to perform a self-test. Check the following items each time the pump is switched on: self-check, audible alarm, process- and alarm control indication.

Disinfecting

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

Clean all exposed surfaces using a clean, soft, lint-free cloth dampened with a mild cleaning solution of warm, soapy water. Make sure to remove any visible residue from all surfaces prior to disinfecting. Do not spray disinfectants directly on the pump, use a soft, low lint cloth dampened but not saturated with product. After cleaning allow device to dry for at least 20 minutes prior to use. The line guide element can be removed using a pointed object (ballpoint pen) inserted in the lower right corner. The cover can then be immersed, to be cleaned, wipe "fingers" with a soft cloth. Wipe magnifying- and displayglas on front of pump door only with a soft cloth.



Note: Keep instrument upright and do not allow any part of instrument to become saturated with or submersed in fluid during cleaning operation.

Do not allow moisture or detergents to come into contact with the electrical connections of the device (P2 or P3 connectors) or any device openings. To reduce the likelihood of moisture ingress into the electrical connectors, the P2 connector of a power supply or combi cable may be used to cover the connections during cleaning operations. Ensure that any connectors used to cover are not connected to a wall outlet or other electrical source. Once the cleaning has been completed, remove the connector and inspect all connectors

for residual moisture and evidence of damage or breakdown to the plating on the connectors. Allow any residual moisture to evaporate before plugging the device into a wall outlet. Replace any connectors which exhibit damage or evidence of plating breakdown prior to returning the device to service.
Utilize electrical contact cleaner that does not react with plastics to remove any deposits of material which may be present inside the electrical connectors as required.

Caution: Do not allow liquids to enter into or come into contact with any openings or electrical connections on the pump or power supply. Fluid exposure in these areas may result in the risk of short circuit, corrosion or breakdown of sensitive electrical components, and/or electrical shock. If fluid exposure occurs, the device should be swapped out with another device in a manner that presents minimal interruption to patient care. The device should remain unplugged until it can be inspected by a trained technician for any evidence of damage and/or residual moisture which may impair the function of the device.

Caution: Do not touch line guide element or peristalitic pumping area of pump with sharp object.

When reinserting the line guide element, make sure that it is not damaged and that it audibly locks in place.

Substances of the listed groups are approved for cleaning and regular disinfection routines of surfaces according to recommendation of disinfectant manufacturer.

Group	Active Substance
Quaternary ammonium compounds	DDAC (Didecyldimethylammoniumchlorid)
	BAC (Benzalkoniumchlorid)
Aldehydes	Glutaral
	Glyoxal
Peroxides	Hydrogen Peroxide
Active chlorine	Sodium Hypochlorite
Acid	Citric Acid

Note: Do not use Hexaquart® or other alkylamine containing disinfectants. Recommended: disinfectant for wiping available from B. Braun: Meliseptol® Foam pure, Melsitt 10% and Melsept SF 10%.

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

Disposal

The pumps as well as battery packs can be returned to B. Braun for further disposal. When taking care of disposing of disposables as well as infusion solutions, please consider the applicable hygiene and disposal regulations.

Inspection on Delivery

Despite careful packaging, the risk of damage during transport cannot be entirely prevented. Upon delivery, please check that all items are present. Do not use a damaged device. Contact the service department.
Testing the proper funciton of the device should be performed before initial use. This is even ruled by law in several countries. A respective form can be obtained from B. Braun.

Included in Delivery

Infusomat® Space, Battery-Pack SP, Instructions for Use-Set.

INSTRUCTIONS FOR USE ACCESSORY

SpaceStation (8713140)

Station for up to four pumps. For further information see Instructions for Use of SpaceStation.

SpaceCover Standard (8713147)
SpaceCover Comfort (8713145)

Cover to be placed on upper SpaceStation incl. built-in handle. The SpaceCover Comfort additionaly includes a central alarm management and alarm LEDs.

PoleClamp SP (8713130)

A maximum of three B. Braun Space pumps and one SpaceControl can be stacked together when used with the PoleClamp SP. For detailed instructions on secure fixation of the PoleClamp SP please refer to "Overview Infusomat® Space" and "Patient Safety".

Power Supply SP (8713110D - 8713123D)

The Power Supply SP is adequate to supply power for a single pump and one SpaceControl.

1.) Connect plug of Power Supply SP with socket P2 on back of pump (ensure that plug "clicks").
2.) Push power plug into wall outlet.

Note: For disconnection from pump, press lever on plug down.
A maximum of three plugs can be stacked upon each other in socket P2.

Prior to use, visibly inspect the power supply and if reject if damaged.

Technical Data: 100 – 240V AC~, 50/60 Hz

Combi Lead SP 12 V (8713133)

The Combi Lead SP can connect up to three pumps. All pumps can then be operated via the Connection Lead SP (12 V).

1.) Connect plug of the Combi Lead SP 12 V with the socket P2 on the back of the pump.
2.) Connect plug of Connection Lead SP with Combi Lead SP.
3.) Push plug of Connection Lead SP into 12 V connector.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Drop Sensor SP (8713175)

The drop sensor provides an additional safety function and is therefore particularly recommended in connection with low delivery rates (10 ml/h).

The connection of the Drop Sensor SP on the pump is located at the rear of the device, in the lower left corner. At the time of delivery the port of the drop sensor is protected by a cover. Use a screw driver to break off the cover for further disposal.

Use holder on PoleClamp, in order to park the drop sensor.

Short Stand SP (8713135)

Use the Short Stand SP to attach an infusion container to the pump.

1.) Push the PoleClamp on the pump.

2.) Plug the short stand into the aperture on the PoleClamp; make sure that it audibly locks in.

3.) To remove the short stand: Press the white button at the lower end of the PoleClamp and remove the short stand.

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

Note: Insure pump is properly secured before attaching fluid bag to short stand and connecting to patient to assure pump cannot fall and harm patient.

Battery-Pack SP (NiMH) (8713180)
Battery-Pack SP (NiMH) incl. Pin (8713180A)

For further information on the Battery-Pack SP (NiMH) see “Battery Operation”.

Battery-Pack SP (LiIon) incl. Pin and WiFi (8713182A)

For further information see Instructions for Use of "Battery Pack SP with WiFi".

Interface Lead CAN SP (8713230)

Interface Lead CAN SP is needed in order to set up a connection between the SpaceStation/pump and the computer outlet (for service requirements).

1.) Push plug into socket F3 on the SpaceStation or P2 on the pump and connect with the CAN/USB converter.

2.) Connect CAN/USB converter to computer outlet as described in the Instructions for Use manual.

Caution: The Interface Lead CAN SP is only to be used by the service department; never use while patient is connected.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Interface Lead RS232 SP (8713234)

Interface Lead RS232 SP is needed in order to set up a connection between the Space pump and the computer outlet (for service requirements).

1.) Push plug into socket P2 on the pump and connect with the Interface Lead RS232 SP.

2.) Connect Interface Lead RS232 SP to computer outlet as described in the Instructions for Use manual.

Caution: The Interface Lead RS232 SP is only to be used by the service department; never use while patient is connected.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Connection Lead SP (12 V) (8713231)

Install the Connection Lead SP (12 V) in the following way:

1.) Connect plug to socket P2 on back of pump or F3 on SpaceStation respectively.

2.) Put the connection lead into the car socket.

3.) If necessary, remove red adaptor of motor vehicle connector by slightly turning and simultanously pulling.

The green LED of the electronic box shows the operating voltage. The mains connector can easily be replaced by another plug if required.

Caution: Do not connect the pump to a patient during external car battery charging!

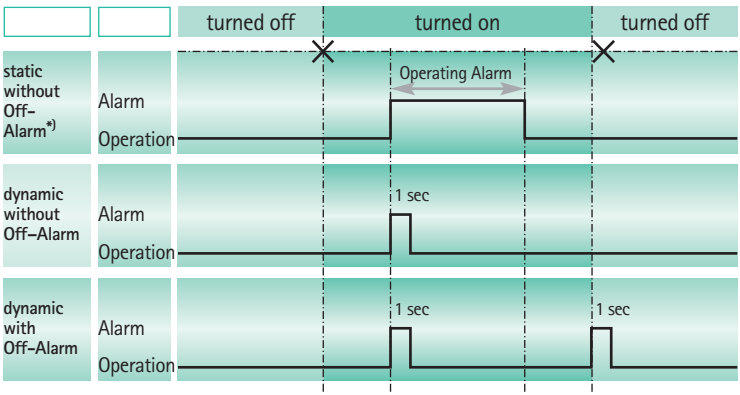
Note: A maximum of three plugs can be stacked upon each other in socket P2.

Connection Lead for Staff Call SP (8713232)

To connect the Infusomat® Space to staff call, use the Connection Lead for Staff Call SP. The staff call needs to comply with the requirements of VDE 0834 (consider country specific regulations).

Note: Test staff call signalling before every use.

The Infusomat® Space offers three different staff call operating modes. They are displayed in the signalling scheme. Consider the staff call of the hospital when choosing an operating mode. Choose the operating mode via the service program.



*) in the mode static without Off-Alarm, the staff call can be surpressed with OK

Caution: The user should always closely observe the local pump alarms as well.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Technical Data

	Connecting Wire	
	white and green	white and brown
Alarm	disconnected	connected
Operation	connected	disconnected

Polarity of connexion is arbitrary:
max. 24 V / 0.5 A / 12 VA

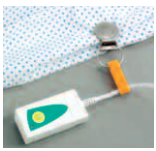
PCA-ACCESSORIES

- Space PCA-Kit (REF 8713554) consisting of: :
  - Demand button
  - Hook and loop tape
    for fixation of the demand button at the patient s arm
  - Line fixation
    connection between hook and loop tape and demand button
  - Metal clip
    alternatively for fixation at the bed sheet
  - Cable strap
    for wrapping the cable of the demand button

Fixation of the demand button:

at the wrist:

or at the bed sheet:



Usage of the cable strap:

	Art. No.
B. Braun Infusomat® Space (100 – 240 V)	8713050

Recommended accessories for the B. Braun Infusomat® Space:

SpaceStation	8713140
SpaceCover Standard	8713147
SpaceCover Comfort	8713145
PoleClamp SP	8713130
Power Supply SP EU III	8713110D
Power Supply SP EU III 3.0m	8713123D
Power Supply SP GB III	871111D
Power Supply SP US III	8713112D
Power Supply SP AU III	8713113D
Power Supply SP-RSA plug	871115D
Power Supply SP CN III	8713117D
Power Supply SP DK III	8713118D
Power Supply SP BR III	8713119D
Power Supply SP KR III	8713120D
Combi Lead SP 12 V	8713133
Drop Sensor SP	8713175
Short Stand SP.	8713135
Battery-Pack SP (NiMH)	8713180
Battery-Pack SP (NiMH) incl. Pin	8713180A
Battery-Pack SP (LiIon) incl. Pin and WiFi	8713182A
Interface Lead CAN SP	8713230
Interface Lead RS232 SP	8713234
Connection Lead SP (12 V)	8713231
Connection Lead for Staff Call SP	8713232
Space PCA Kit	87 3554

Infusomat® Space Lines:

IV - Standard

Single packed	8700036 SP
Secondary packaging (10x10)	8700435 SP
Single packed extra long (300cm)	8270350 SP
Neutrapur	8250731 SP
with Eurofix injection port por needle access	8700087 SP
Neutrapur - with Safeflow needle free Y-port	8700110 SP
Neutrapur - with Y-Port for needle access	8250383 SP

SafeSet IV – Standard:

Single packed ..... 8701148 SP
Single packed extra long (300cm) ..... 8270358 SP
Neutrapur ..... 8701149 SP
Neutrapur - with Safeflow needle free Y-port ..... 8700118 SP

UV light protected:

Amber - light protected, orange tubing ..... 8700127 SP
SafeSet, amber - light protected, orange tubing ..... 8700128 SP
Amber - light protected, needle free Y-Port, orange tubing ..... 8250437 SP
SafeSet, amber - light protected, needle free Y-Port, orange tubing ..... 8250438 SP
Opaque - light protected, black tubing ..... 8700125 SP

Transfusion:

with 200 µm blood filter ..... 8270066 SP
with 200µm blood filter, needle free Y-port ..... 8270074 SP

Enteral Nutrition:

with 1000 ml Nutrifix bag, Y-port Luer Lock ..... 8250839 SP
with 1000 ml Nutrifix bag, inverse Safety Y-Port, EN Lock pat. connector ..... 8250836 SP
Neutrapur - with multi bottle connector ..... 8250857 SP
Neutrapur - with multi bottle connector inverse Safety Y-Port, EN Lock pat. connector ..... 8250856 SP

Neonate:

Dosifix® - 150 ml burette, Neutrapur® with needle free Safeflow Y-Port ..... 8250245 SP
Dosifix® - 150 ml burette, DEHP-Free tubing with Y-Port for needle access ..... 8250294 SP

Oncology

Neutrapur® - with inline 0.2 m Sterifix® Filter	8700095 SP
SafeSet Neutrapur® - with inline 0.2 m Sterifix® Filter	8700098 SP

Piggyback

with needle free Safeflow injection port and integrated BCV	8250710 SP
SafeSet with needle free Safeflow injection port and integrated BCV	8250718 SP
secondary line with integrated BCV	4062877
SafeSet secondary line with integrated BCV	4062878

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