

# Infusomat<sup>®</sup> Space

## and Accessories



Instructions for Use

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

**CE** 0123

**GB** Valid for software 686J

**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 / Red LED: Infusion occurring / device alarm, operating alarm  
 Blue LED: Currently connected to SpaceControl

Press to initiate bolus.

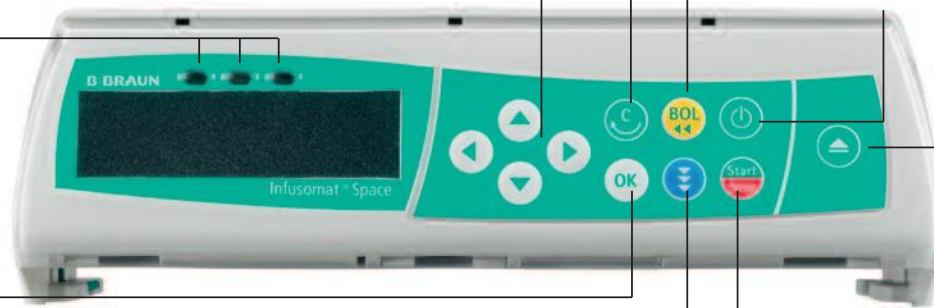
Press to turn pump on/off.

OK

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

Press to link the pump to SpaceControl and to assign a barcode after scanning.

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.

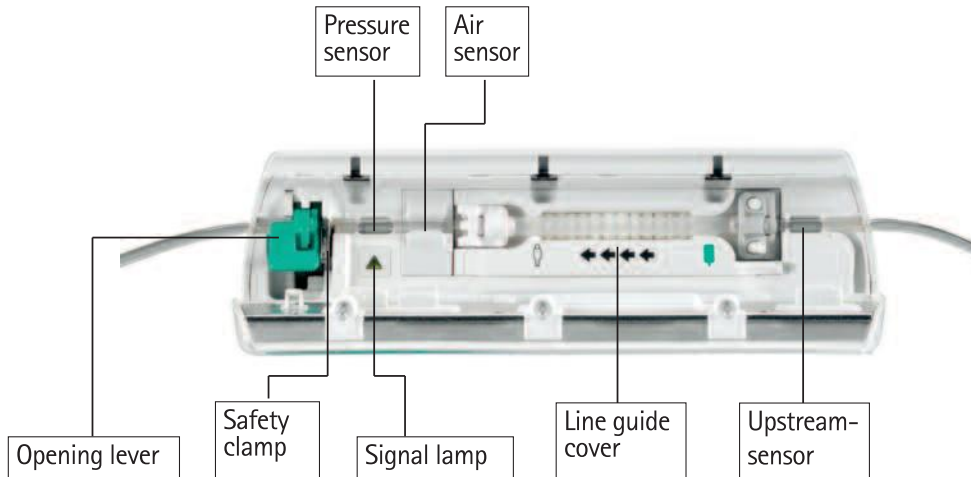
A crank in order to open the pump door in case of emergency is attached to the inside of the battery compartment cover (for closer information see 1.4).

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)



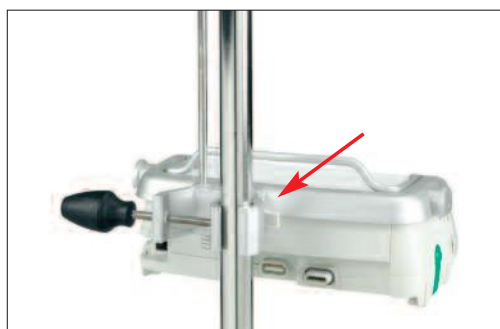


**Fixation of PoleClamp (Universal Clamp)**  
 Line up bar of pump with bar of PoleClamp and slide PoleClamp forward until locking mechanism clicks.  
 To remove, press release button on frame, push handle down and pull PoleClamp backwards.








**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.



**Pole Fixation**  
 Push the opening of the PoleClamp against the vertical pole and lock the screw tightly. Unscrew to release.  
 For vertical fixation of PoleClamp push lever down and rotate either way until lever clicks into notch. Push lever for rotation.  
**Caution:** Do not lean on pump when attached to pole!

## SYMBOLS ON PRODUCT

Symbol	Explanation
	Caution, general warning symbol Caution, see documentation supplied with the product
	Type CF unit with defibrillation protection
	Protection class II device
	Labeling of electric and electronic devices according to directive 2002/96/EC (WEEE)
	CE mark compliant to Directive 93/42/EEC

## 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/ablation, and enteral. The system is used for the delivery of medications indicated for infusion therapy including but not limited to colloids and crystalloids, 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
- Remifentanyl: 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.
- Ensure the unit is properly positioned and secured. The pump must be positioned on a level surface if used in combination with the short stand. Do not position the pump above the patient.
- Prior to administration, visibly inspect the pump for damage, missing parts or contamination and check audible and visible alarms during selftest.

- Only connect to patient once the line has been correctly inserted and completely primed. Interrupt connection during line change to prevent incorrect dose delivery.
- Select infusion line/catheter suitable for use with the intended medical application.
- 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.
- Do not operate the pump in the presence of flammable anaesthetics to prevent explosion.
- Compare the displayed value with the entered value. Only start the infusion if the values showing are the same.
- 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.
- 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.
- Independent 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.

### Enteral Nutrition

The Infusomat Space may be used for enteral nutrition, too. Do not use enteral fluids for intravenous infusion as this may harm your patient. For this reason only use disposables dedicated and labelled 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/EN 60601-1-2 and IEC/EN 60601-2-24 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.) maintain the recommended protective distances from 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.

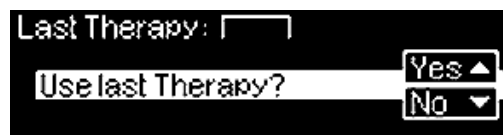
## MENU STRUCTURE / NAVIGATION

### Cutline



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

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










### Display



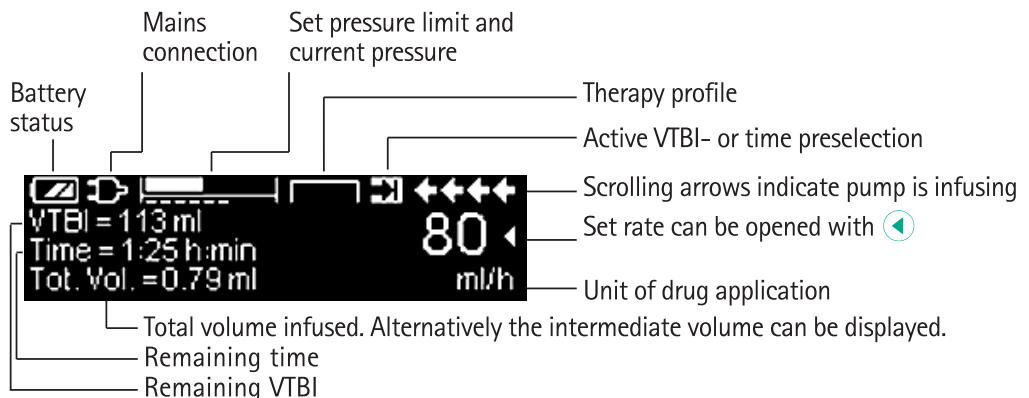
### Meaning

At the top of the screen the last therapy is indicated. Yes/No question can be answered by pressing  for yes or  for no.

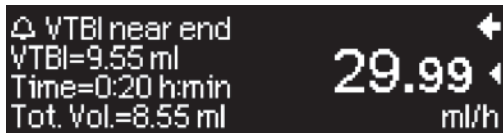


Parameters which can be changed (e.g. rate in ml/h) are opened with  or . When editing parameters, switch digits/levels using  . White background indicates current digit/level. Use  or  to change current setting. Help text on the bottom/top of the screen indicates options how to proceed (e.g. confirm rate with , start infusion with  or clear rate by pressing ).

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, etc.).

has been pressed while the pump is infusing. Start manual bolus at 1200 ml/h by pressing (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 . Cancel to edit pressure by using .


Pre-alarms are indicated by a message on the display (e.g. "VTBI near end"), an audible tone and a flashing yellow LED. To confirm a pre-alarm press .






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 . 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.

## 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.
- Fill the infusion line from bottom to top, then close the roller clamp.
- 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 . Then the desired language must be selected with  and confirmed with . Answer the following question with  in order to activate the selected language.

- Press  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:** 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.

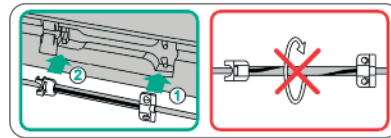
**Caution:** Inserting different lines into the pump is identical. Please see instructions and packaging of the different lines (standard, transfusion, opaque, enterel nutrition etc.) to receive information about preparation and usage of these lines.



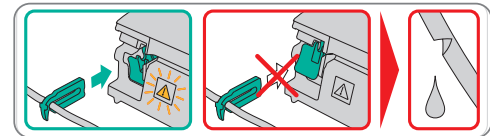
Insert the infusion line from right to the left. Make sure that the line is routed straight. At first, route the line through the upstream sensor. Then, insert the two-hole clip.





In the next step, attach the white clip without twisting the line. Properly insert the line into the air-sensor.






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).








- Make sure the line is properly inserted into the sensors (especially the air-sensor needs an accurately inserted line).
- Close the pump door. Then select the inserted line with  and confirm it with . Open the roller clamp.

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

- Press  if the prime function is enabled to prime the infusion line with the rate displayed. Cancel priming with . 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. If you select  with no drop sensor connected, you must first enter a VTBI which is smaller than the container filling and confirm it with .

**Note:** At rates smaller 1 ml/h the detection of a closed roller clamp cannot always be ensured due to physical reasons. Therefore it is recommended especially at small rates to use a drop sensor.

#### Adjusting the delivery rate:

- In the Main Menu, open the rate with  and set it with .
- Press  to start the infusion. 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 . 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.

## 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 Main 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 .
- Select time with  and open with .
- Enter time with  and confirm with .

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

There are three ways to administer a bolus:

- 1.) Manual Bolus: Press . Then press  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 . Then press  and set bolus dose limit by using . Press  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 . Then press  and set bolus dose by using . Press  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  to confirm and start bolus.


After pressing the button , the bolus unit can be selected by using . The selected unit will be stored and offered as default later on. By this also in dose mode it is possible to administer a bolus in ml.



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 , 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 .

Answer the following question by pressing  in order to start the purge process. Cancel by pressing  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 . 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  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:** If for an unknown reason the pump door cannot be opened anymore, you need to take a crank from the inside of the battery compartment cover. Use this crank to remove the emergency aperture cover of the pump. Place the crank in the aperture and turn it clockwise until the pump door opens.

- Close the pump door, confirm the inserted line with  and open the roller clamp.
- If required, prime the pump with . Then press  to proceed.
- Establish the patient connection and check the parameters with .
- Start the infusion by pressing .

**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  (repeatedly) and follow the instructions as described.

## 1.5 End of Infusion






- Press  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.

## 1.6 Standby Mode





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

- Press  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. Change of remaining time by pressing .
- Exit standby by pressing .






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 .

#### 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".

## SPECIAL FUNCTIONS

### 3.1 Dosing Units and Dose Rate Calculation (Overview)

The following table shows the dosing units of the gram and unit family and their conversion used in the pump:

Gram family	10 <sup>6</sup> ng	10 <sup>3</sup> µg	1 mg	10 <sup>-3</sup> g
Unit family	10 <sup>3</sup> mIU	1 IU	10 <sup>-3</sup> kIU	10 <sup>-6</sup> MIU

In addition to these dosing units the user can choose:

- Feeding: kcal, mEq, mmol
- kg
- Surface related amount units: m<sup>2</sup>

The pump is calculating the body surface area with the "Dubois" formula (DuBois D, DuBois EF. A formula. Arch Intern Med 1916; 17: 863):  

$$BSA(m^2) = 0.007184 \times \text{weight}(kg)^{0.425} \times \text{height}(cm)^{0.725}$$









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.











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

#### 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 in kg or lbs or m<sup>2</sup> or grams.
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 .
- If the patient's weight does not need to be entered press . Press  to choose "weight" or "surface" and confirm with .

- Set the patient weight with  and confirm with .
- Select the dose prescription with  and confirm it with .
- Set the dose with  and confirm with . 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 .
- Check the parameters with  on plausibility before starting with .

Concentration and 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 Areas 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 Area and creation date (see headline) should be checked in the pump.

**Note:** Barcode search is possible in Drug libraries with one Care Area and one patient only.

There are different ways of embedding the drug library into the therapy. 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 Area with . If you have already set the Care Area once on your pump this step will be skipped for the next time.
- Change the Care Area by navigating through the list until "Change Care Area" will be displayed. Press  to change the Care Area.
- 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 .
- Check if the drug short name in the Main Menu is the same as the selected drug. Check the parameter in the Main Menu with  and start infusion with .

**Note:** Care Area 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 .

**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 representative 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 directly 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  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-authorized access to the settings can be anticipated.

The code is entered with  and confirmed with .

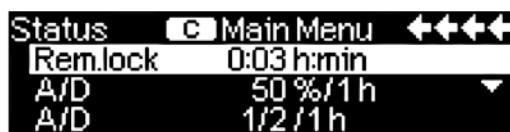


The pump display now may look like this.


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.

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: .

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

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

\*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.



**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).

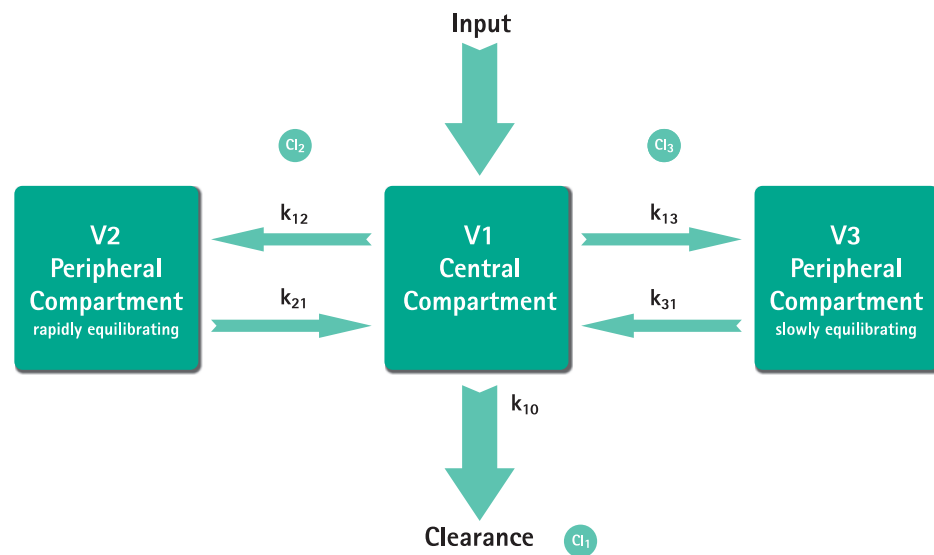
### 3.5 Target Controlled Infusion (TCI)

#### 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.

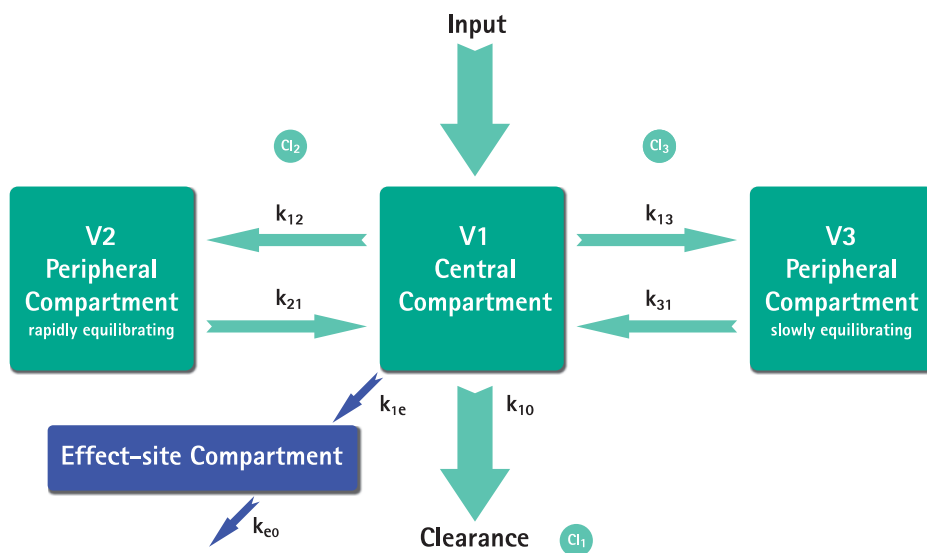
A PK model can be parameterized to use it for different drugs as long as it is suitable for that said drug. The pharmacokinetic model and its parameters are schematically depicted by the following illustration:



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 on the next page.



TCl with B. Braun Space is possible with two drugs: Propofol and Remifentanyl. 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		Remifentanyl
$V_1$ [Litre]	$0,228 * \text{Weight}$	4,27	$5,1 - 0,0201 * (\text{Age} - 40) + 0,072 * (\text{LBM} - 55)$
$k_{10}$ [min <sup>-1</sup> ]	0,119	$0,443 + 0,0107 * (\text{Weight} - 77) - 0,0159 * (\text{LBM} - 59) + 0,0062 * (\text{Height} - 177)$	$[2,6 - 0,0162 * (\text{Age} - 40) + 0,0191 * (\text{LBM} - 55)] / [5.1 - 0.0201 * (\text{Age} - 40) + 0.072 * (\text{LBM} - 55)]$
$k_{12}$ [min <sup>-1</sup> ]	0,112	$0,302 - 0,0056 * (\text{Age} - 53)$	$[2,05 - 0,0301 * (\text{Age} - 40)] / [5.1 - 0.0201 * (\text{Age} - 40) + 0.072 * (\text{LBM} - 55)]$
$k_{13}$ [min <sup>-1</sup> ]	0,0419	0,196	$[0,076 - 0,00113 * (\text{Age} - 40)] / [5.1 - 0.0201 * (\text{Age} - 40) + 0.072 * (\text{LBM} - 55)]$
$k_{21}$ [min <sup>-1</sup> ]	0,055	$[1,29 - 0,024 * (\text{Age} - 53)] / [18,9 - 0,391 * (\text{Age} - 53)]$	$[2,05 - 0,0301 * (\text{Age} - 40)] / [9,82 - 0,0811 * (\text{Age} - 40) + 0,108 * (\text{LBM} - 55)]$
$k_{31}$ [min <sup>-1</sup> ]	0,0033	0,0035	$0,01402 - 0,0002085 * (\text{Age} - 40)$
$k_{e0}$ [min <sup>-1</sup> ]	0,26	0,456	$0,595 - 0,007 * (\text{Age} - 40)$
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
Short name	TCIProp	TCIRemi
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!

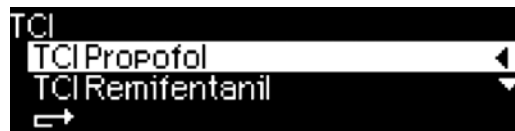
## Setting up the pump

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.

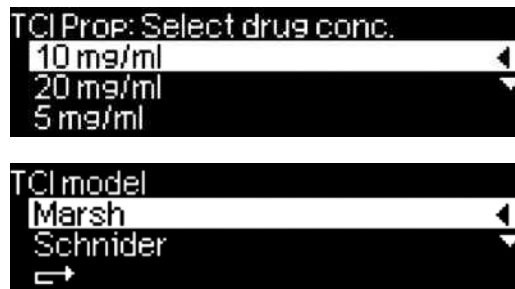
Switch on pump with  and wait until self-check is finished. Insert disposable and use the drug lib according to Instructions for Use.

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

Using effect-site targeting the weight may be limited due to the constraints of the LBM calculation.

### 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

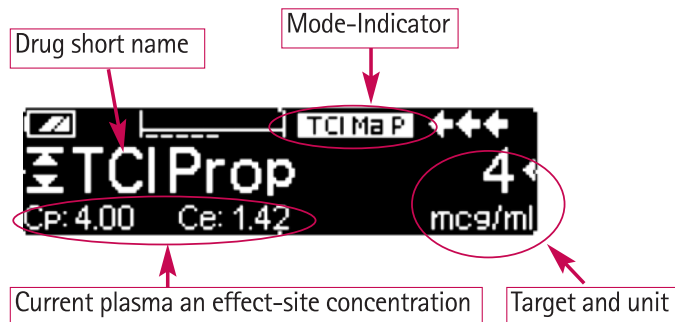
The editor window for setting the target comes up with the default value from the drug list.



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


Confirm target with . TCI can be started now with .

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

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:



```
TCI info  [C] Main Menu
DecConc.  1 mcg/ml
Decrem.   0:08 h:min
CP: 3.86  Ce: 2.46 mcg/ml
```

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 - use new disposables !
- b) The pump may go with the patient but in continuous mode (without TCI).

```
Therapy:  TCI  TCI Prop
Quit TCI  Yes ▲
          No  ▼
```

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

```
Last therapy: TCI  TCI Prop
Use last therapy?  Yes ▲
                  No  ▼
```

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

## 3.6 Barcoding






Software version J has the barcoding functionality 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:** VTBI must consider volume for KVO.

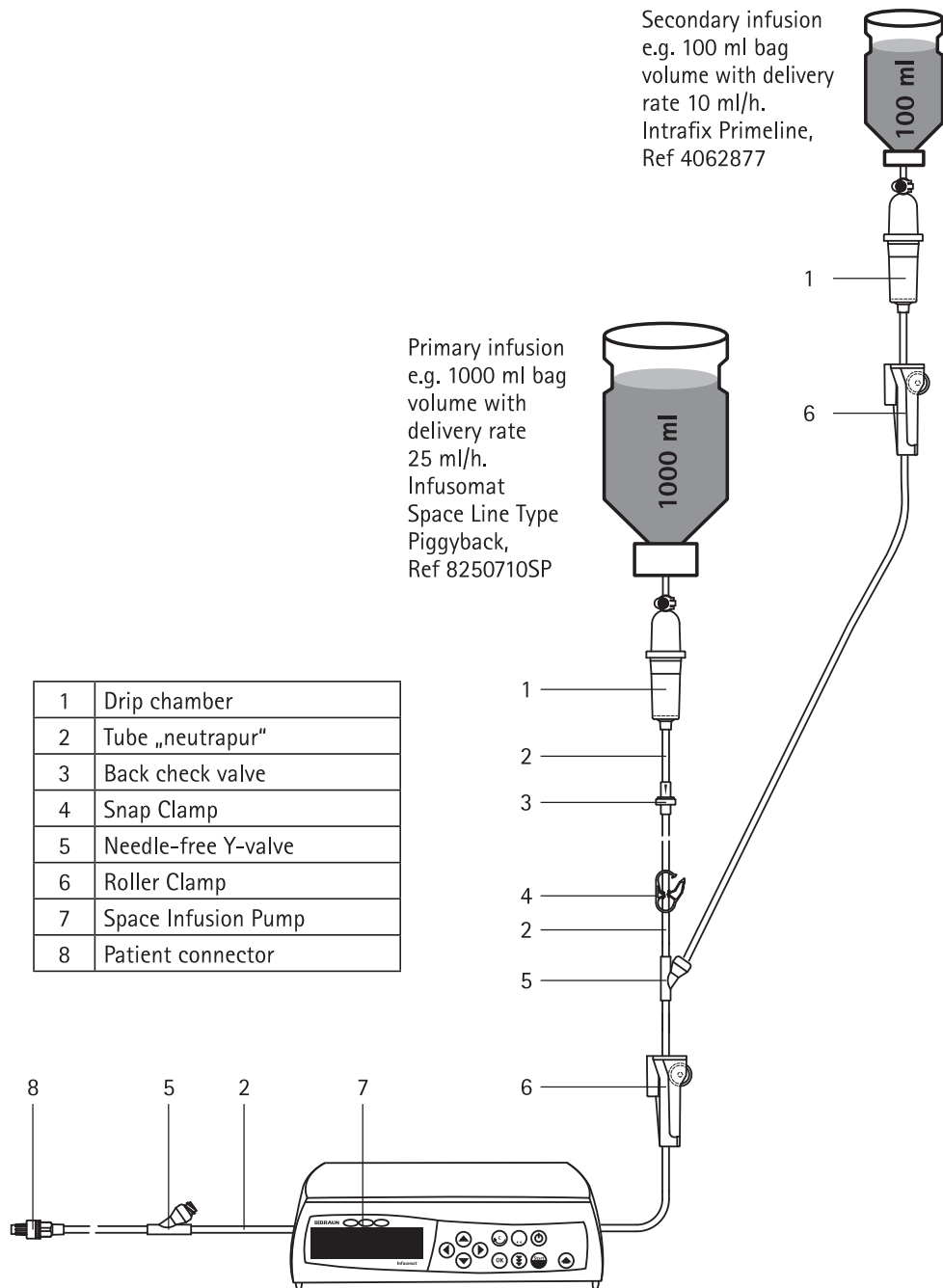
**Note:** Switching manually between primary and secondary infusion in the Main Menu is possible at any time while the pump is stopped. It is recommended to keep the roller clamp of the non-active infusion closed.

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:** Resetting the data of the last secondary will also reset VTBI

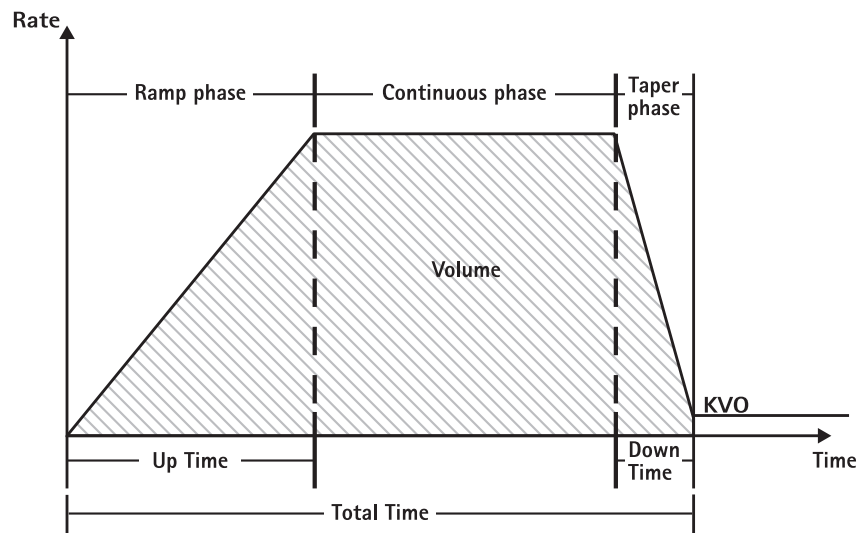


### 3.8 Ramp and Taper Mode

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 a characteristic 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  to confirm.

The pump can be started now by pressing .

**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  to confirm.
- After entering all desired parameters the pump can be started by pressing .

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 pressing . Ramp and Taper is stopped immediately without Taper phase and started without a new Ramp phase.

### Immediate Taper Down

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

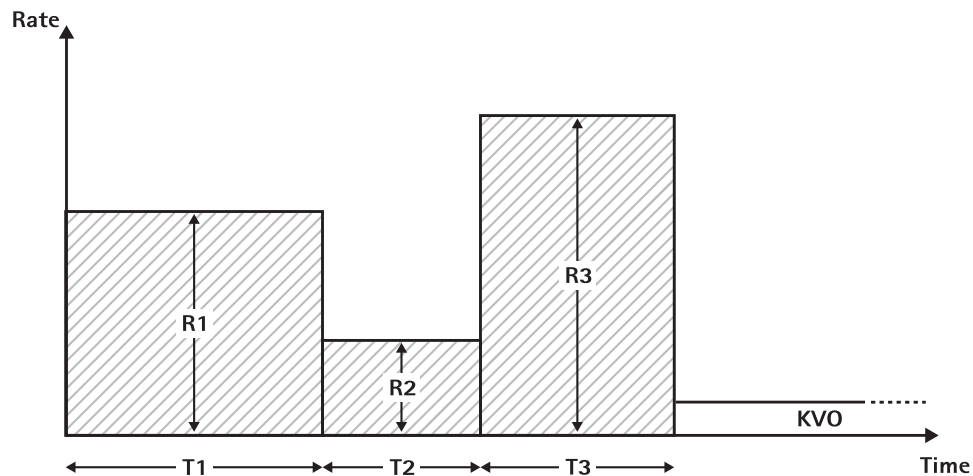
- Press  during continuous phase.
- Use  to select Special Functions and press .
- Select Immediate Taper Down Function and confirm with .
- Edit taper time by using  and press  to confirm.  
The pump automatically changes to Taper phase and linearly decreases the rate.

### 3.9 Program Mode

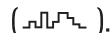
Program Mode is for infusion requiring a non-standard delivery pattern. The user defines a series of intervals (max. 12 intervals) by certain parameters (rate, time, volume) for each cycle.

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 .







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  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  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 need to be adjusted after Changing the intervals.

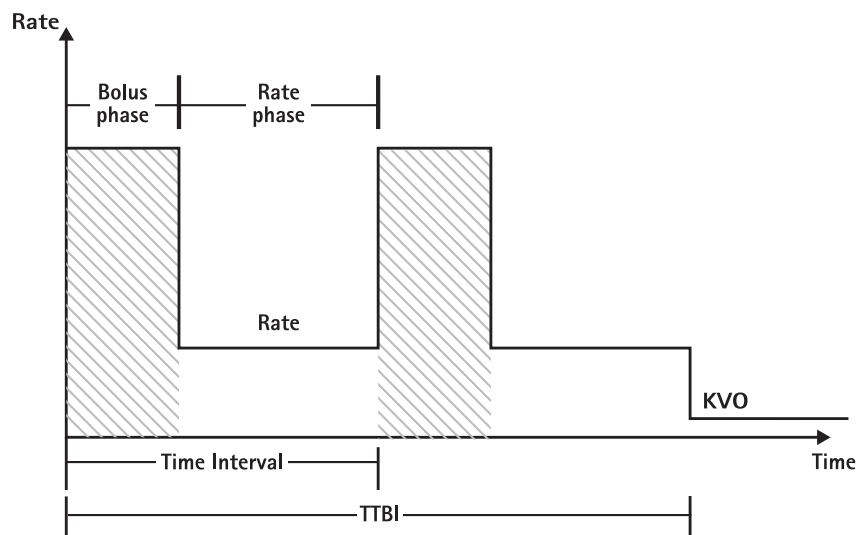
The Main menu informs about the current interval. The configured parameters can be checked by Program Parameter Menu in Main.

### 3.10 Intermittent Mode


The Intermittent Mode consists of 2 phases. These 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 Intermittent 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  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 .

**Starting Intermittent 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 Intermittent Mode.
- Press  to enter parameters and  to confirm.

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

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 .

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








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

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






#### Changing the bolus after start:

If the user edits the bolus the therapy progression changes.

- Press .
- Use  to select Bolus and press .
- Change Bolus by using  and press  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 .
- Use  to select Interval and press .
- Change Interval by using  and press  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 characteristic 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 .


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 .

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




Check calculated rate by using  for plausibility



Start Dose Over Time by pressing .



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  in the Run Menu and edit or check values in the Main Menu while the pump is delivering.

## 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.

### 4.1 Occlusion Pressure

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

- 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 .

### 4.2 Data Lock

The data lock function protects the device against unauthorized access. A four digit code (default setting "9119"), which can be changed via the service program activates this function in level 1 or level 2. 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 .
- Enter code with and press 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 , enter the code and press again.



## 4.3 Bolus Rate

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

**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.





## 4.4 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.





## 4.5 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 .

## 4.6 Alarm Volume

Chose between 9 different alarm volume levels.



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

## 4.7 Date / Time

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

## 4.8 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.





## 4.9 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 .





## 4.10 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 .

## 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	flashes	device alarm and alarm code (see service program)	yes	Press  and follow the instruction on the display.
Operating Alarm	yes	flashes	off	see alarm description	yes	Press  to acknowledge the audible alarm, alarm text and staff call. The red LED remains on until the infusion is restarted.
Pre-Alarm	yes	off	flashes	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	flashes	see alarm description	yes	Press  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.

### 5.1 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.

### 5.2 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 blinks 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 active"	VTBI/time are reached and the pump continues the infusion at the KVO-rate.
"Communication error"	The pump is located in a system in which at least one device is incompatible or defective. The use of this device in a system is not permitted. The system is to be checked by a service technician.

A stopwatch on the display counts down the remaining time (depending on the service program, between 3-30 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" and the reason for the operating alarm. The signal tone and the staff call are turned off with . 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 occurred 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 doesn't extinguish until the administration is started again respectively the pump is turned off.

**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.

### 5.3 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 blinks and a staff call is activated.
  - a) The display states "Reminder alarm!"
  - b) The display states "Config. not finished!"
 Confirm alarm with  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 blinks and a staff call is activated.  
Confirm alarm with  and continue to set therapy.

## 5.4 Alarm Hints

If improper entries are made the display states corresponding hints (e.g. "Attention! Rate is out of range"; "The parameter can not be modified") and an audible tone sounds. These hints disappear after a few seconds and don't need to be confirmed.

## BATTERY OPERATION AND MAINTENANCE

The Infusomat® Space is equipped with the latest NiMH-battery. It 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 (> 0,5 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.

### Important information for battery self-check:

If the battery symbol is blinking during mains operation, the battery is either discharged or has a reduced 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 possible, only charge the battery if it has been completely discharged.
- If a battery, which is not completely discharged, is charged several times, its capacity can be reduced. Its original capacity can be reached again if the battery is completely discharged and then recharged.
- 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 original capacity will only be reached after several cycles of charging and discharging.
- The battery operating time only can be realized if the pump operates continuously with a fully charged battery at room temperature. The display of the battery operating time on the pump is an approximate value based on the current delivery rate. If the battery is aged it may differ from the actual achievable operating time.

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

#### Battery maintenance:

To accurately balance the battery capacity a cyclical battery maintenance is necessary. The pump asks the user to perform a battery maintenance every 30 days. 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.

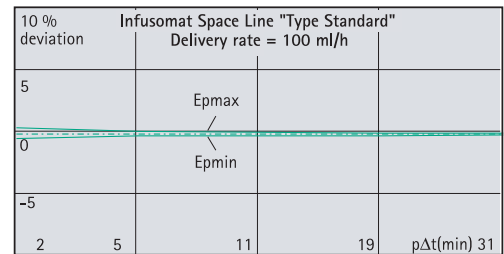
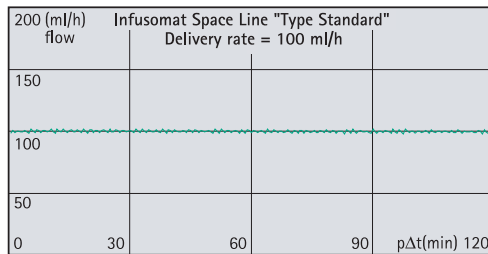
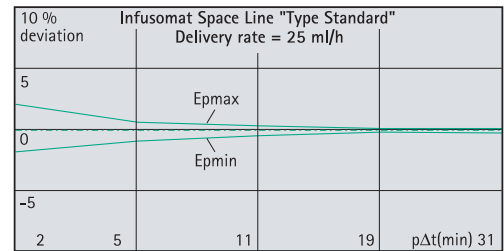
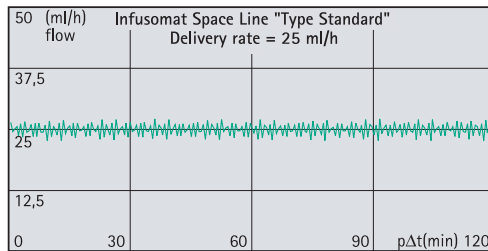
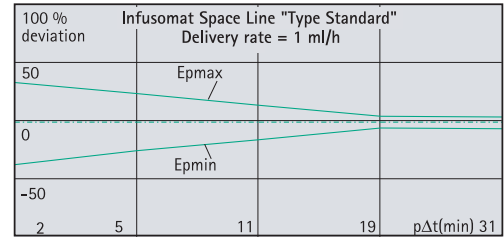
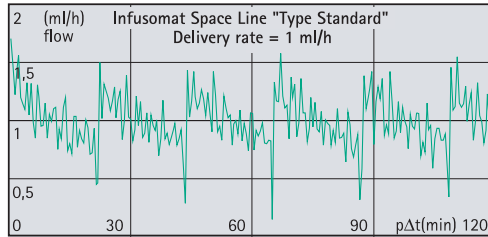
To initiate the discharge process the message „Battery maintenance" and the -key will be displayed after switching the pump off. By pressing  and  the discharge process will start. The process is interrupted by switching the pump on again. If the battery maintenance is to be continued a new activation 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.

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 excluded if lines (disposables) other than those stated in the order data are used.

Trumpet Curves

Measured values for second hour in each case.

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

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

Start Up Graphs

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

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

Flow  $Q_i \text{ (ml/h)}$

## TECHNICAL DATA

Type of unit	Volumetric infusion pump
Classification (acc. to IEC/EN 60601-1)	<input checked="" type="checkbox"/> defibrillator-proof; CF equipment <input type="checkbox"/> Protective Class II; Protective Class I in combination with SpaceStation
Class (acc. to Directive 93/42 EEC)	IIb
Moisture protection	IP 22 (drip 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	30 % ... 90 % (without condensation)
■ Temperature	-20 ... +55 °C
■ Atmospheric pressure	500 ... 1060 mbar
Type of battery pack (rechargeable)	NiMH
Operating time of rechargeable battery	Approx. 4 hours at 100 ml/h
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 - 9999 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
Alarm in the case of incorrect dose	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



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. $\pm$ 5 % as of a bolus volume > 1 ml
KVO-rate	Delivery rate $\geq$ 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: At an air bubble size of typ. 0.02 - 0.3 ml* respectively 1.5 ml/h** (cumulated value over 1 h from air bubbles size 0.01ml).
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			Max. bolus [ml]
	[bar]	[1 ml/h]	[25 ml/h]	[100 ml/h]	
Level 1	typ. 0.3	09:07	00:33	00:07	0.0347
Level 5	typ. 0.7	25:53	01:14	00:15	0.0987
Level 9	typ. 1.2	46:50	02:06	00:24	0.1787

Mechanical occlusion pressure limit under fault conditions	Occlusion alarm pressure max. 2.1 bar (210 kPa). Max. bolus volume 2 ml.
--	---

History protocol	1000 last history entries. 100 events for system diagnose. Refer to separate documents of the History Viewer for closer information.
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\* to be set via the service program in increments of 0.01ml

\*\* to be set via the service program from 0.5-3.8 ml/h in increments of 0.1ml

**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.

## WARRANTY / TRAINING / TSC\* / SERVICE / CLEANING / 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 14<sup>th</sup> June 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.

Separate collection for electrical and electronic equipment (currently applicable to EU community only).



### Training

B. Braun offers a training for version J. 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 B. Braun 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.

## Cleaning

Clean external surface of pump using mild soap suds. Do not use spray disinfectants at the mains power connection. Recommended: disinfectant for wiping available from B. Braun (e.g. Meliseptol® Foam pure, Melsitt 10% and Melsept SF 10%). After cleaning, allow the device to vent for at least 1 min prior to use. Do not spray into openings in the device. Be sure to observe the instructions provided concerning waste disposal and hygiene for batteries and disposables. The line guide element can be loosened with the help of a pointed object (e.g. ballpoint pen) which is inserted in the lower right hand corner. The cover can then be cleaned under running water. Spray disinfectant on the peristalsis and wipe it with a soft cloth (**Caution:** Do not touch peristalsis with sharp object!). When reinserting the line guide element, make sure that it is not damaged and that it audibly locks in. Prime the next infusion line in order to ensure the proper position of each finger. Do not use Hexaquart® or an other alkylamine containing disinfectants.

## 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 function 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 (871 3147)

### SpaceCover Comfort (871 3145)

Cover to be placed on upper SpaceStation incl. built-in handle. The SpaceCover Comfort additionally 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 (8713110A - 8713114A)

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.

**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.

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.

**Caution:** Only position the pump on a level surface if the pump is used in combination with the short stand.

- 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.

## Battery-Pack SP (NiMH) (8713180)

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

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

## 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.

## 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 simultaneously 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!

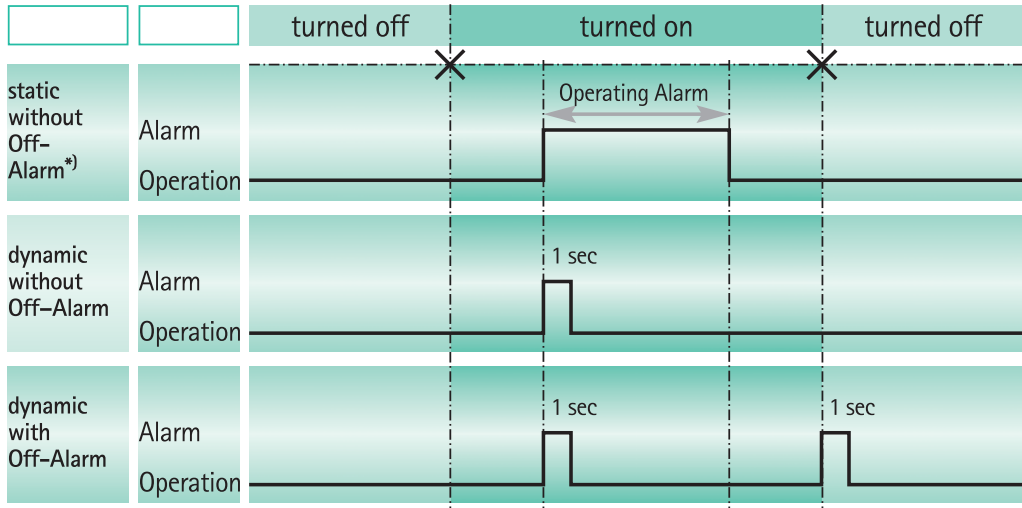
**Note:** A maximum of three plugs can be stacked upon each other in socket P2.

## 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 suppressed with

**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>B. Braun Infusomat® Space (100 - 240 V)</b> .....	871 3050

**Recommended accessories for the B. Braun Infusomat® Space:**

SpaceStation.....	871 3140
SpaceCover Standard.....	871 3147
SpaceCover Comfort.....	871 3145
PoleClamp SP .....	871 3130
Power Supply SP (Euro Plug) .....	871 3110A
Power Supply SP (UK Plug) .....	871 3111A
Power Supply SP (US Plug) .....	871 3112A
Power Supply SP (Australian Plug) .....	871 3113A
Power Supply SP (Universal Plug) .....	871 3114A
Power Supply SP (RSA Plug) .....	871 3115A
Combi Lead SP 12 V.....	871 3133
Drop Sensor SP .....	871 3175
Short Stand SP.....	871 3135
Battery-Pack SP (NiMH) .....	871 3180
Battery-Pack SP (NiMH) incl. Pin .....	871 3180A
Interface Lead CAN SP .....	871 3230
Connection Lead SP (12 V) .....	871 3231
Connection Lead for Staff Call SP .....	871 3232
Space PCA Kit .....	871 2554

**Infusomat® Space Lines:**

**IV-Standard**

Single packed .....	870 0036 SP
Single packed - Extra long (3M) .....	827 0350 SP
Neutrapur® .....	825 0731 SP
with Eurofix injection port for needle access .....	870 0087 SP
Neutrapur® - with Safeflow needle-free Y-port .....	870 0110 SP
Neutrapur® - with Y-port for needle access .....	825 0383 SP

**UV-protected**

Opaque - light protected, black tubing.....	870 0125 SP
Opaque - light protected, with orange injection port for needle access.....	825 0430 SP

Transfusion with 200 µm blood filter.....	827 0066 SP
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**Enteral Nutrition**

with 1000 ml Nutrifix® bag .....	825 0839 SP
Neutrapur® - with multi connector.....	825 0857 SP

## Neonate

Dosifix® - 150 ml burette, Neutrapur® with needle free Safeflow Y-Port.....	825 0245 SP
Dosifix® - 150 ml burette, DEHP-Free tubing with Y-Port for needle access.....	825 0294 SP

## Oncology

Neutrapur® - with inline 0.2 µm Sterifix® Filter.....	870 0095 SP
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## Piggyback

with needle-based port + 200 µm filter.....	825 0715 SP
secondary line, needle-based .....	A 2581 NF
with needle free Safeflow injection port and integrated BCV.....	825 0710 SP
secondary line with integrated BCV.....	406 2877

## CytoSets:

## Secondary Lines (Preparation)

Cyto-Set Mix, Neutrapur® with 1 Safesite valve and integrated BCV.....	A 2902 N
Cyto-Set Mix, Neutrapur® with 1 Safesite valve and 0,2 Sterifix particle filter .....	A 92023 N
Cyto-Set Line, Neutrapur® with integrated BCV.....	A 25811 NF
Cyto-Set Line Neutrapur® .....	A 25812 NF

## Application Infusomat Space® Lines

Cyto Set Neutrapur®, with 3 Safesite valves.....	825 0910 SP
Cyto Set Neutrapur®, with 5 Safesite valves .....	825 0812 SP
Cyto Set Neutrapur®, with 5 Safesite valves and 0.2µm Sterifix® .....	825 0413 SP







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