Perfusor® Space

and Accessories

Instructions for Use

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

CE 0123

GB Valid for software 688L

B BRAUN

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

PERFUSOR® 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.

Drive head with claws to hold the syringe plunger plate and emergency release button.

Press to initiate bolus.

Press to turn pump on/off.

Yellow LED:	Pre-alarm, reminder alarm
Green / Red LED:	Infusion occuring / device alarm, operating alarm
Blue LED:	Currently connected to SpaceControl

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.

Start
Stop

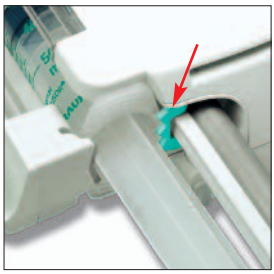
Press to Start/Stop infusion.

Syringe holder locks syringe in position. The drive will automatically move back.

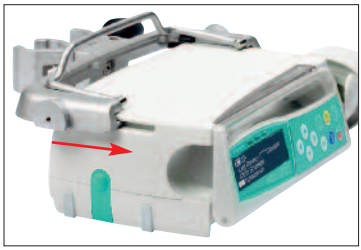
Cover of Battery Compartment
Before changing the battery, always disconnect the pump from the patient and switch off the device.
To remove the battery cover push the button below the battery compartment with a pointed pen and pull the cover away from device. Slide green locking mechanism on back of battery up and take out battery pack for exchange.

Port P3 for future options

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



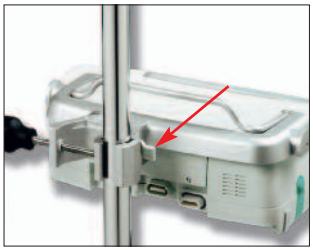
Syringe Fixation
Pull and turn the syringe holder to the right to open the green axial fixation (see red arrow). Syringe must be fixed with wings upright in the slot (found to the left hand side of the axial fixation) before closing syringe holder. Make sure that syringe is properly inserted.
Caution: Don't touch piston brake when moving forward.



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

Transport
A maximum of three pumps (Perfusor® Space or Infusomat® Space) plus one SpaceControl may be stacked together (in ambulance cars or 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 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, 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 0123	CE mark compliant to Directive 93/42/EEC
	Temperature Limit
	Moisture Limit
	Limitation of the atmospheric pressure

PATIENT SAFETY

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

Intended use

The Perfusor® Space Infusion Syringe Pump System includes an external transportable electronic infusion syringe pump 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, intra-arterial, subcutaneous, epidural, and enteral. The system is used for the delivery of medications indicated for infusion therapy including but not limited to drugs like anesthetics, sedatives, analgesics, catecholamines, anticoagulants etc.; blood and blood components; Total Parenteral Nutrition (TPN); lipids, and enteral fluids. The Perfusor® Space Infusion Syringe Pump System is intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.

Using TCI the scope of patients is:

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

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

Using TCI the scope of procedures is:

- Propofol: Anaesthesia and Conscious Sedation
- Remifentanil: Anaesthesia

The medical specialist must decide on suitability for application on the basis of the warranted properties and the technical data.

For further details please refer to the Instructions for Use.

Operation

- The initial training of the Perfusor® 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 of the changes to the device and accessories by referring to the Instructions for Use.
- Ensure the unit is properly positioned and secured. Do not position pump unit above patient or in a position where a patient could come to harm, should the pump fall.
- Prior to administration, visibly inspect the pump and the accessories (especially the axial fixation) for damage, missing parts or contamination and check audible and visible alarms during selftest.

- Only connect to patient once the syringe has been inserted correctly and there is proper fixation of the syringe pressure plate by the claws of the drive head. Interrupt connection during syringe change to prevent incorrect dose delivery.
- Select syringe/catheter suitable for use with the intended medical application.
- Position the infusion line free of kinks.
- Recommended change of disposable each 24 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. Start infusion only if the values are corresponding.
- If staff call is used we recommend checking the equipment once after connecting the pump.
- Protect the device and the power supply against moisture.
- Do not carry the pump device by it's drive mechanism during transportation.
- If the pump device falls or is exposed to force it needs to be examined by the service department.
- The displayed data must always be checked by the user prior to making further medical decisions.
- During mobile use (homecare, patient transport inside and outside the hospital): Make sure the device is securely fixed and positioned. Positioning changes and severe shock can lead to minor changes in the delivery accuracy and/or unintentional bolus administration.
- A supplemental patient monitoring must be carried out if life-saving medication is performed.
- Avoid applying external force on the drive mechanism during administration.
- In case high potent drugs are given be sure to have a second infusion pump for that drug at hand. The therapy documentation should be suitable to continue the therapy at the second infusion pump.
- Independant of the soft limits the selected values have to be the medically correct ones for the given patient.
- In case values relevant for the dose rate calculation (e.g. body weight) are changing always the flow rate will be updated and the dose rate will be fix.
- Consider startup characteristics before using low infusion rates (0.1ml/h) with critical drugs.

Enteral Nutrition

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

Other components

- Only use pressure resistant tubes (min. 2 bar/1500 mmHg).
- 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 the according 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.
- The use of incompatible disposables may influence the technical specifications of the device.
- 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

Perfusor® 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 Perfusor® Space fulfils the applicable requirements of EN 13718 to be used in the air, on the water and in difficult terrain. During transport the Perfusor® 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 Perfusor® Space needs to remain under room temperature at least one hour before usage.

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.

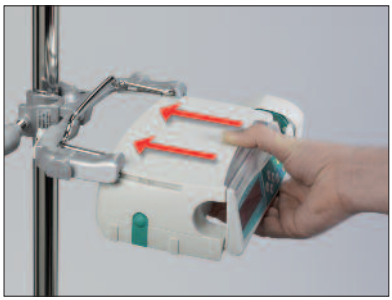
- Access to the pump settings can be prohibited by DataLock 3. The code for DataLock level 3 should differ from the one for levels 1 and 2 in case the pump is only allowed to be used by pain management professionals.
- For additional safety the removal of the syringe can be prevented by the use of the Syringe Anti Removal Cap (see accessories) and the locking of the syringe holder. The Syringe Anti Removal Cap is usable for the following syringes: B. Braun Original Perfusor Syringe 50 ml, B. Braun Omnifix 50 ml, BD Plastipak 50/60 ml and Tyco Monoject 50 ml. The locking of the syringe holder is under the pump and is locked by a clockwise turn of 90°. Make sure the syringe holder is safely locked. Opening of the syringe holder may not be possible after locking.
- In case opioids are administered and the Syringe Anti Removal Cap is not in use and the syringe holder is not locked the therapy only should be performed under surveillance of medical staff. This especially is necessary in case non-authorised access to the drug can be anticipated.
- 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.
- Consider startup characteristics before using low infusion rates (0.1ml/h) with critical drugs.

Safety instructions for using TCI

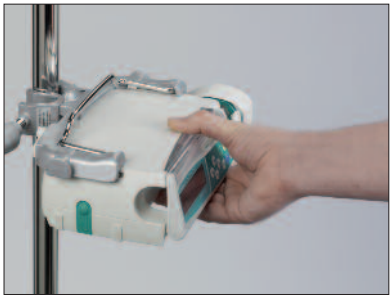
- TCI should only be performed by experienced anaesthetists being familiar with the principles of TCI and properly trained in using the present device.
- The use of TCI with B. Braun Space does not limit the responsibility of the anaesthetist for administration of drugs. They need to be fully aware of 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.

Safety Instructions for using Pole Clamp



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



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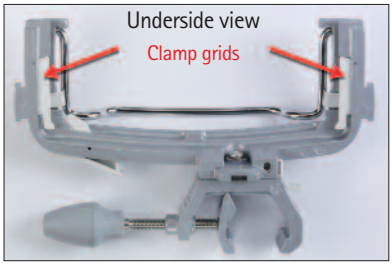
The pump ist now securely attached to Pole Clamp.

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



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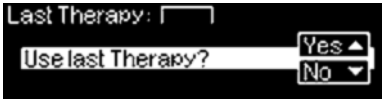
- DO NOT use any Pole Clamp that shows signs of damage.
- DO NOT use Pole Clamp with missing clamp grids.

MENU STRUCTURE / NAVIGATION

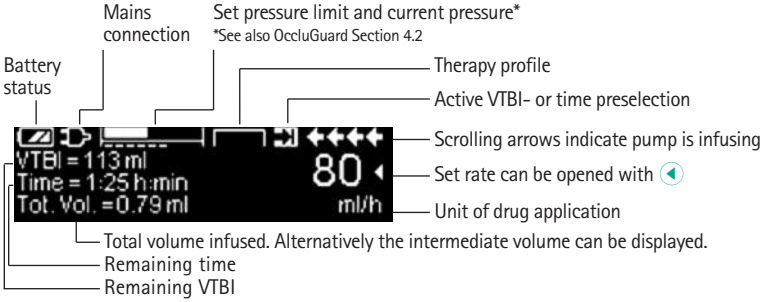
Cutline

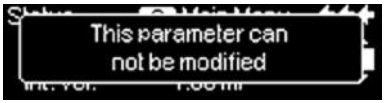
- On/Off button
- Start/Stop button
- Bolus button
- Clear button
- OK button
- Keypad with arrow up, -down, -left, -right button
- Connection button

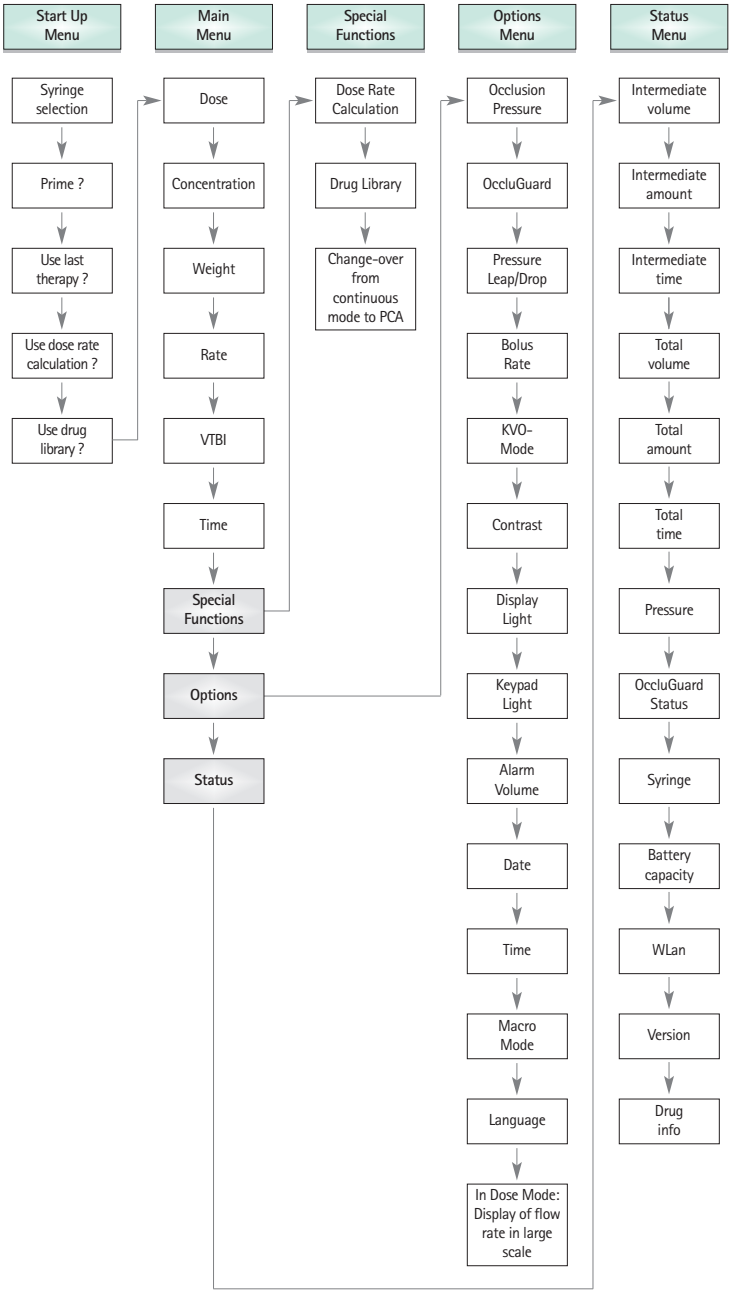
All display screen shots are examples and may be different when related to an individual patient and individualized therapy.

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

Typical display during infusion:



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


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

OPERATION

1.1 Start of Infusion

- Ensure correct installation of the pump device. If the pump is connected to mains, the display states information such as the battery status, the mains connection symbol and the last therapy.
- Press ⏻ to switch on unit. Note the automatic selfcheck: "Selftest active" and the software version are displayed, two audible tones sound and all three LEDs (yellow, green/red and blue) flash once. Information on power supply (battery or mains connection), the set pressure level and the syringe (if syringe already inserted) are displayed. Hence the drive moves backwards.

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

- Press C to start with direct entry of therapy parameters or open pump cover and syringe holder to start with syringe insertion.
- Insert syringe with wings of the syringe upright in the slot to the right of the housing. Close syringe holder and pump door. Piston brake moves forward.

Caution: Never leave the pump unattended during syringe loading.

- Confirm syringe type with OK. Type of syringe indicated must coincide with syringe inserted.
- Drive will advance and grip pressure plate of syringe.

Caution: Keep your hands away from advancing device.

Note: Make sure that the piston brake moves back into the syringe holder.

- If the prime function is activated, press ▲ to prime infusion set at 1200 ml/h (pressing key once = 1 ml). Interrupt prime function with OK. Repeat procedure until infusion line is fully primed. Then press ▼ to proceed.
- Connect with patient.
- Respectively answer questions in Start Up Menu with ▲ and ▼, until the rate is displayed in the Main Menu.

Enter infusion rate:

- Press ◀ and set rate using ⚙.

- Press Start/Stop to commence infusion. Running arrows on display and green LED above display indicate pump is infusing.

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

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

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

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

- Select VTBI with ↕ and open with ◀.
- Enter VTBI with ⁘ and confirm with OK.
- Select time with ↕ and open with ◀.
- Enter time with ⁘ and confirm with OK.

Check calculated rate on plausibility.

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

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

3.) Infusion with time limit
Enter rate and time: The infusion volume will be calculated and displayed at 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

Note: Changing VTBI/time is only possible while the pump has been stopped.

1.3 Bolus Application

There are three ways to administer a bolus:

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

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

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

After pressing the button BOL 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 BOL, the pump switches back into the run display automatically.

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

In order to purge the line at any time while the pump is stopped press BOL. Answer the following question by pressing ▲ in order to start the purge process. Cancel by pressing ▲ or any other key.

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

1.4 Syringe Change and New Therapy Start

Note: To avoid incorrect dosing, always disconnect the pump from the patient when changing the syringe. Never leave the pump device unattended during syringe change. Before inserting a new syringe check if the axial fixation is properly working.

- Press Start/Stop to stop the infusion. The green LED will disappear. Disconnect the pump from the patient.
- Open syringe holder. Drive mechanism moves backwards into starting position. If the syringe holder is being opened more than 30 sec after the pump was stopped the question if a syringe change should be performed must first be answered with ▲ before the drive moves backwards (regardless of the time this always applies in case of a syringe holder alarm). If a syringe holder is pulled just shortly (less than one second) the displayed question must first be answered by pressing ▲ to initiate the release of the syringe plunger.
- Open pump door, remove syringe and insert new syringe.

Note: In case the plunger head of the syringe is not released anymore by the claws when performing a syringe change, the emergency release button needs to be pressed to release the claws of the drive head. The emergency release button is placed on the outside of the drive head. It can be released with a pointed pen. Then manually open the claws and take out the syringe.

- Close the syringe holder (Note: Piston brake must move forward!) and the pump door and confirm the inserted syringe type with OK. Drive advances and grips pressure plate of syringe.

Note: Do not block advancing drive unit with any objects. Piston brake must move backwards into the syringe holder.

- Prime pump if necessary with ▲ then press ▼ to continue.
- Connect the patient to the pump and check set parameters using .
- Press Start/Stop to start infusion.

To start a new therapy after a syringe change:

- Press C when pump is in the Main Menu.
- Press ▼ and continue to set new therapy parameters with .
- Press Start/Stop to start infusion.

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

1.5 End of Infusion

- Press Start/Stop to stop the infusion. The green LED disappears. Disconnect the pump from the patient.
- Open the syringe holder. Answer the question whether a syringe change should be performed with ▲. The drive moves backwards into the starting position.
- Open pump cover. Remove the syringe, move the syringe holder into an upright position and close the front door.
- Press ⏻ for 3 sec. to switch the pump off. The drive moves into parking position.

Note: The settings will be permanently saved by the switched off device.
As long as a disposable is inserted the pump will use standby.

1.6 Standby Mode

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

- Press Start/Stop to stop the infusion. Then press ⏻ for less than 3 sec.
- Confirm that the pump is supposed to switch into 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 OK.

Reset Status Menu Data:

The parameters intermediate volume and -time can be reset when the pump is infusing or when the pump is 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 question if the last therapy is to be used with and reset the values with .

The type of the inserted syringe is displayed in menu item „Syringe" 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. The current battery capacity in hours and minutes is displayed in the menu item "Battery Cap." and the current software version in menu item "Version". In-line pressure can also be read in the Status menu in mmHg or Bar depending on the service settings.

SPECIAL FUNCTIONS

3.1 Dosing Units and Dose Rate Calculation (Overview)

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

Gram family	10^6 ng	10^3 µg	1 mg	10^{-3} g
Unit family	10^3 mIU	1 IU	10^{-3} kIU	10^{-6} MIU

In addition to these dosing units the user can choose:

- Feeding: kcal, mEq, mmol
- kg
- Surface related amount units: m^2
  The pump is calculating the body surface area with the "Dubois" formula (DuBois D, DuBois EF. A formula. Arch Intern Med 1916; 17: 863):
  $BSA(m^2) = 0.007184 \times weight(kg)^{0.425} \times height(cm)^{0.725}$

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.

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

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^2 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 OK.
- If the patient weight shall not be entered press ▼.
  Press ⚙ to choose "weight" or "surface" and confirm with OK.

- Set the patient weight with and confirm with OK.
- Select the dose prescription with and confirm it with ◀.
- Set the dose with and confirm with OK. The rate will automatically be calculated and displayed at the bottom of the display.
- Check the calculated rate and if necessary the adapted parameters with on plausibility before starting the infusion with Start/Stop.

Concentration and dose can later 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 resetted in the same way as the other total and intermediate values.

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

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

3.3 Drug Library

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

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

Note: Barcode search is possible in Drug libraries with one care unit 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 unit with . If you have already set the care unit once on your pump this step will be skipped for the next time.
- Change the care unit by navigating through the list until "Change care unit" will be displayed. Press OK to change the care unit.
- Navigate through the list with and select the patient profile with . If no profile is set, this step will be skipped.
- Navigate through the list with and select in alphabetical order (all drugs) or within a category with .
- If different therapies are related to a drug, choose therapy type with and confirm with .
- Confirm the displayed drug information with .
- Check if the drug short name in the Run Menu is the same as the selected drug. Check the parameter in the Main Menu with and start infusion with Start Stop.

Note: Care unit and Patient Profile can not be changed within a therapy.

Initial Bolus:

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

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

Hard Limits:

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

Soft Limits:

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

The infusion is within the range of the minimum and maximum soft limits	=	
The infusion is within the range of the maximum soft limit	=	
The infusion is within the range of the minimum soft limit	=	
Violation of the upper soft limit	=	

Violation of the lower soft limit = 

No soft limit is defined = 

Only a drug name is available = 
(It is possible to select a drug name only from the drug library)

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

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

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

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

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

Note: You can cancel the upload by pressing  .

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

3.4 Patient Controlled Analgesia (PCA)

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

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

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

Select drug list, category and desired drug by using  .

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

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

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

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

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

The code is entered with and confirmed with OK.

The pump display now may look like this.

In this state the patient is allowed to demand boli. Depending on the status of the therapy these are either administered or denied. Changing the syringe 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: PCA

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

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

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

*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.

SpacePCA-Chart

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

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

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

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

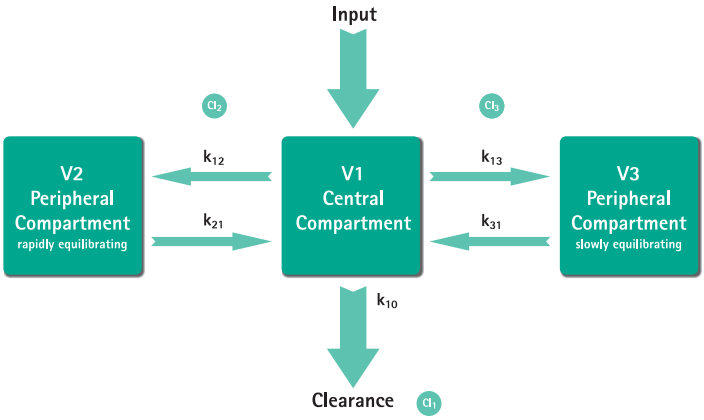
3.5 Target Controlled Infusion (TCI)

Introduction

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

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

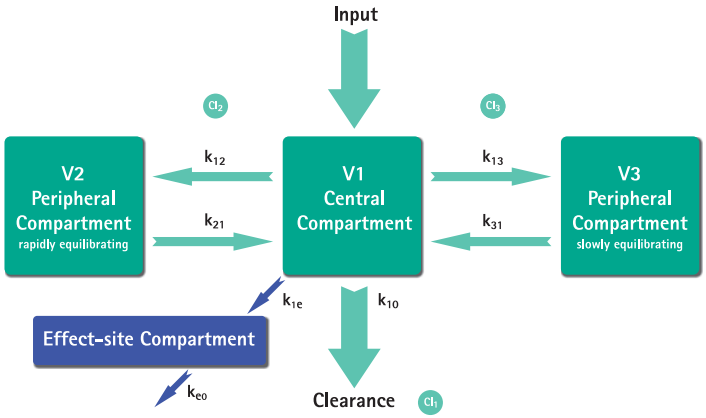
A PK model can be parameterized to use it for different drugs as long as it is suitable for that said drug. The pharmacokinetic model and its parameters are schematically depicted by the following illustration:



B. Braun Space is offering two modes for TCI:

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

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



TCI with B. Braun Space is possible with two drugs: Propofol and Remifentanil. For Propofol the user can choose between two parameter sets. The parameter sets used for these drugs are (Not all parameter sets allow effect-site targeting):

Drug / Parameter	Propofol		Remifentanil
V_1 [Litre]	0,228 * Weight	4,27	5,1 - 0,0201 * (Age - 40) + 0,072 * (LBM - 55)
k_{10} [min-1]	0,119	0,443 + 0,0107 * (Weight - 77) - 0,0159 * (LBM - 59) + 0,0062 * (Height - 177)	[2,6 - 0,0162 * (Age - 40) + 0,0191 * (LBM - 55)] / [5.1 - 0.0201 * (Age - 40) + 0.072 * (LBM - 55)]
k_{12} [min-1]	0,112	0,302 - 0,0056 * (Age - 53)	[2,05 - 0,0301 * (Age - 40)] / [5.1 - 0.0201 * (Age - 40) + 0.072 * (LBM - 55)]
k_{13} [min-1]	0,0419	0,196	[0,076 - 0,00113 * (Age - 40)] / [5.1 - 0.0201 * (Age - 40) + 0.072 * (LBM - 55)]
k_{21} [min-1]	0,055	[1,29 - 0,024 * (Age - 53)] / [18,9 - 0,391 * (Age - 53)	[2,05 - 0,0301 * (Age - 40)] / [9,82 - 0,0811 * (Age - 40) + 0,108 * (LBM - 55)]
k_{31} [min-1]	0,0033	0,0035	0.01402 - 0,0002085 * (Age -40)
k_{e0} [min-1]	0,26	0,456	0,595 - 0,007 * (Age - 40)
Reference	Marsh et al., Br. J. Anaesthesia, Vol. 67, 1991, 41-48	Schnider et al., Anesthesiology, Vol. 88, 1998, 1170-1182 Schnider et al., Anesthesiology, Vol. 90, 1999, 1502-1516	Minto et al., Anesthesiology, Vol. 86, 1997, 10-33
Effect-site targeting	No	Yes	Yes

Drug List

The pre-installed drug list offers the following values:

	Propofol	Remifentanil
Available Concentrations	5 mg/ml 10 mg/ml 20 mg/ml	20 µg/ml 50 µg/ml
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

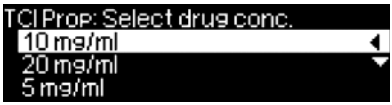
For TCI a drug list with at least one drug activating the profile TCI is necessary. The drug list in this version is pre-defined. By this the conditions for an effective and safe therapy are defined.

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!

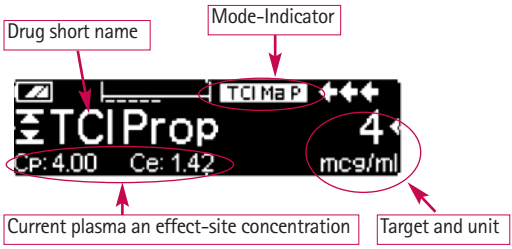
Editing a target and starting TCI

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

After TCI is started the screen looks the following:



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

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

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 C.

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 Start/Stop.

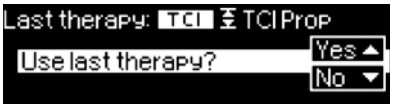
Pressing ▶ the pump offers additional information – in this case the information is modified the following way:

Pressing ▶ again shows up the graph.

After the therapy is ended there are two possibilities:

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

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



In case a) press ▲ in the menu – in case b) press ▼.

3.6 Barcoding

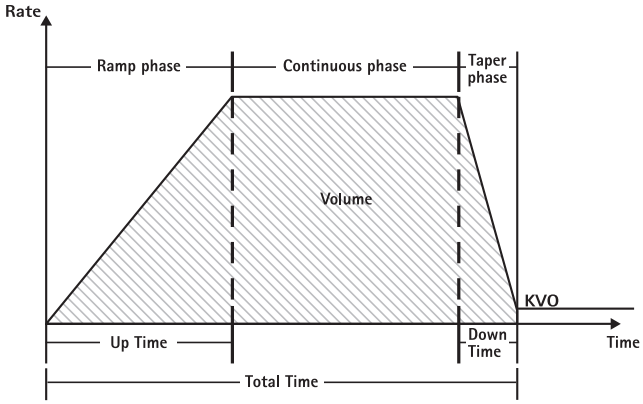
Software version L has the barcoding functionality included but initially not activated. Please contact your local sales representative in case you like to use barcoding.

3.7 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 ist stopped in a predefined time (Down-Time)

Example:



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

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

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

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

Starting Ramp and Taper via Drug Library:

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

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

The pump now lits the possible therapy profiles.

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

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

Starting Ramp and Taper via Special Function Menu:

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

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

The screen shows the following:

Ramp phase

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

Continuous phase

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

Taper phase

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

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

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

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

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

Note: The delivery of drugs can be stopped and started again in Ramp and Taper Mode at any time by pressing Start/Stop. Ramp and Taper is stopped immediately without Taper phase and started without a new Ramp phase. This will not have any effect on the settings of the therapy.

Immediate Taper Down

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

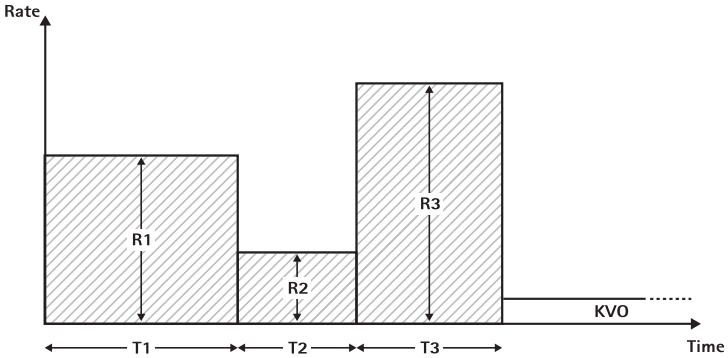
- Press C during continuous phase.
- Use ↕ to select Special Functions and press ◀.
- Select Immediate Taper Down Function and confirm with ◀.
- Edit taper time by using ↕ and press OK to confirm.
  The pump automatically changes to Taper phase and linearly decreases the rate.

3.8 Program Mode

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

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

Example:



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

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

Note: Bolus function is disabled for Program Mode.

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

Starting Program Mode via Drug Library:

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

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

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

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

- To change the values, press ◀ to change and OK to confirm.
- Adjust VTBI with ⁘.

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

Starting Program Mode via Special Function Menu:

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

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

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 Start/Stop. This will not have any effect on the settings of the therapy.

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

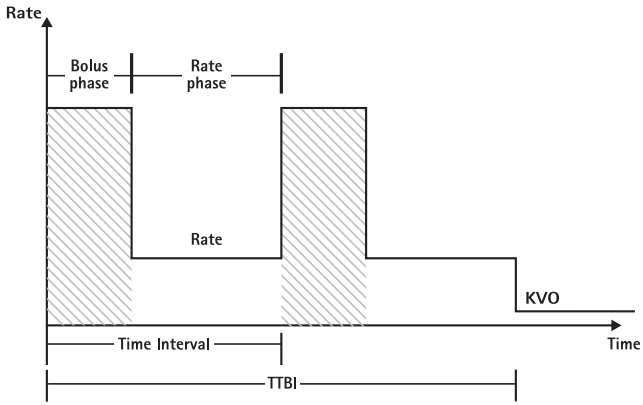
The Main menu informs about the current interval. The configured parameters can be checked by Program Parameter Menu in Main.

3.9 Intermittent Mode

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

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

Example:



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

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

Note: Regular Bolus function is disabled for Intermittent Mode.

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

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

Starting Intermittent Mode via Drug Library:

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

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

The pump now offers the possible therapy profiles.

- Select "Intermittent Mode" with and press . The therapy settings for "Intermittent Mode" are shown on the display.
- For changing the parameters, press to change and 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 C.
- Use ▲▼ to navigate through the parameter list and select the parameter to be changed with ◀.
- Enter the new value and press OK.
  The pump continues infusion.

Changing the bolus after start:

If the user edits the bolus the therapy progression changes.

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

Changing the time interval after start:

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

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

3.10 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. It can only be activated via the Drug List Manager. It can be used for standard infusion.

The active Dose Over time function is always symbolised with a characteristical symbol in the Display ( ).

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

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

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

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

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

Before using Dose Over Time contact your local B. Braun representative!

Starting Dose Over Time via Drug Library:

Note: Dose Over Time settings have been configured in the Drug List Manager before and have been uploaded into the pump.

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

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

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

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

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

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

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

Check calculated rate by using ⇕ for plausibility

Start Dose Over Time by pressing Start/Stop.

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

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

3.11 Take Over Mode (TOM)

Take Over Mode is a feature to support the user during syringe changes by automatically starting a second Perfusor® Space pump when the first has run empty. The second pump automatically takes over the infusion rate from the first pump.

Activation:

- Start an infusion of the desired medication from the drug library on a Perfusor® Space pump (see Section 3.3).

- Place a second a Perfusor® Space pump in an adjacent slot of the SpaceStation (either above or below).
  Note: Make sure that the pumps are correctly inserted in the SpaceStation.
- Navigate to the Drug Library on the second pump (Note: The drug library can be started over the Start Up or Special Functions Menu).
- Navigate through the list with and select the Care Unit with . The Care Unit of the second pump must be the same as the first.
  Note: If you have already set the Care Unit once on your pump this step will be skipped for the next time.
- Navigate through the list with and select the patient profile with . The patient profile of the second pump must be the same as the first.
  Note: 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 . The drug selected in the second pump must be the same as the first.
- Navigate through the list with and select a concentration with . The concentration in the second pump must be the same as the first.
- Confirm 'Use Take Over Mode' with .
- Check IV line of TOM 2 is connected to the patient and that stopcocks are open.

Symbols:

TOM 1 first Perfusor® Space pump

TOM 2 second Perfusor® Space pump

Deactivation:

- Press the button on the TOM 2 pump.

Take Over Phase:

When the TOM1 syringe is nearly empty, a pre-alarm will sound on the TOM1 pump.

When the TOM1 syringe is empty, the TOM2 pump will automatically start infusing at the correct rate.

Note: Start-up behaviour is not influenced by TOM. See Chapter 8 for information on Start Up Curves.

TOM Requirements:

TOM will only be offered if the following requirements are met:

- Same drug selected on both pumps.
- Same drug concentration selected on both pumps.
- First Perfusor® Space pump must have a running infusion with a drug from drug library.

TOM Hints:

The following TOM hints are to be observed:

TOM Hint	Recommendation
Take Over Mode not possible, Other pump not in Run menu	Ensure first Perfusor® Space pump is infusing
Take Over Mode not possible, Other pump in wrong therapy	Ensure first Perfusor® Space pump must be running in 'continuous mode' (i.e. ml/h or a dose rate; not KVO, PCA etc.)
Take Over Mode not possible, DataLock active in other pump	Deactivate Data Lock
Take Over Mode not possible, Data connection lost	Data connection must be active between pumps – check the positioning of pumps in the SpaceStation
Take Over Mode not possible, Different syringe sizes	Ensure both pumps must have a syringe of the same size
Take Over Mode not possible, Different care units selected	Ensure both pumps have the same Care Unit selected
Take Over Mode not possible, Different patient profiles	Ensure same patient profile selected on both pumps
Take Over Mode not possible, Software update required	Both pumps must have the same software version – contact your service department
Take Over Mode not possible, Mod.data update required	Both pumps must have the same modification data – contact your service department
Take Over Mode not possible, Invalid config. 'Stop at syr. end'	Both pumps must have the same 'Stop at syr. end' settings – contact your service department
Take Over Mode not possible, TOM not enabled in other pump	Both pumps must have TOM activated – contact your service department

More information regarding alarm hints may be found in chapter 5.

Changes in TOM system:

Change	Reaction
Rate changed in TOM1 pump	No user interaction necessary, TOM2 will start infusion at new rate when TOM1 syringe is empty.
TOM1 pump is stopped	TOM2 pump shows "connection lost – TOM aborted" alarm. TOM may be reactivated by pressing OK and then ▲ when prompted "Return to Take Over M."
TOM1 pump is put in standby	
VTBI ended in TOM1	

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 OK.

4.2 OccluGuard & Pressure Leap/Drop detection

OccluGuard

OccluGuard speeds up time to alarm when an occlusion is present. Occlusions can be caused by problems in IV access (e.g. a blocked catheter), problems in the infusion setup (e.g. closed stopcocks) or 'syringe occlusions' i.e. Due to varying syringe tolerances of syringes from other manufacturers, an OccluGuard alarm may occur because of high syringe friction forces. OccluGuard can be used with all syringe sizes and drugs, but is ideally suited to infusions at low rates and/or with drugs of short half life (e.g. Catecholamines).

OccluGuard activation / deactivation from the Main Menu

- Go to Options Menu and press ◀.
- Navigate through the list with ⊙ and select OccluGuard.
- OccluGuard can be activated with ▲ and deactivated with ▼.

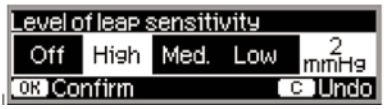
Pressure Leap/Drop detection

The pressure leap/drop software detects sudden increases and decreases in infusion pressure respectively which can be caused by problems in IV access, or changes in pump position in the SpaceStation.

Pressure Leap/Drop detection activation / deactivation from the Main Menu

- Go to Options Menu and press ◀.
- Navigate through the list with ⊙ and select "Pr. leap/drop".
- Navigate to Off with ◀ ▶ and press OK to deactivate pressure leap/drop.

- Navigate to high (2mmHg), medium (8mmHg) or low (20mmHg) with ◀ ▶ and press OK to activate pressure leap/drop.



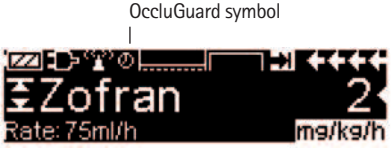
Note: after a restart of the pump, these settings remain at the levels set before the restart.

Area of application

OccluGuard and pressure leap/drop are active below the following infusion rates. Should the rates increase, the OccluGuard Inactive symbol (⊠) is shown in run screen.

Syringe Size	Maximum Rate (typical)
50 ml	30 ml/h
20 ml	14 ml/h
10 ml	9.8 ml/h

Symbols



OccluGuard Symbol	Meaning	Recommendation
	OccluGuard is active. Infusion is running stably	n/a
	Pending – OccluGuard has not enough data	n/a
	OccluGuard Inactive	OccluGuard will automatically reactivate as soon as infusion rate drops below threshold levels – see above.
 Pressure rise detect	Occlusion has been detected	Confirm alarm and check IV access, IV setup and syringe for cause of occlusion. Should the cause of the alarm be removed, the alarm will stop automatically.
(no symbol)	OccluGuard is deactivated	Activate OccluGuard – see below

Pressure leap/drop Symbol	Meaning	Recommendation
 Pressure leap detect.	Sudden pressure leap detected	Check IV access and IV setup
 Pressure drop detect.	Sudden pressure drop detected	Check IV access and IV setup

Note:

- The OccluGuard status can be checked in the status menu
- Perfusor® Space continues to infuse during OccluGuard and Pressure leap/drop alarms.

- The existing occlusion alarm pressure levels are unaffected by OccluGuard.

When a change is made to the infusion system (e.g. addition or removal of a pump to a SpaceStation, a change of infusion rate, a bolus application) the OccluGuard and pressure leap/drop are temporarily set to 'pending' ( ) to allow the system to reach a hydrostatic balance, and so prevent false alarms.

4.3 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 syringe, however, is possible by using the code defined for the other levels. An overview about the differences between the levels 1, 2 and 3 is given by the following table.

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

•= possible | · = not possible | 🔔= followed by standby-alarm

Activation of the function:

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

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

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

4.4 Bolus Rate

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

Note: Set bolus rate according to therapy requirements. Take care not to overdose! Given a bolus rate of 1800 ml/h, e.g. 0,5 ml are reached within just one second.

4.5 KVO-Mode

After reaching a preselected VTBI/time, the pump can continue the infusion with a predefined KVO-rate (see "Technical Data"). The duration of the KVO-infusion is set via the service program.

- Open KVO-Mode in Options Menu with ◀.
- Answer Yes/No question with ▲, to activate KVO.

4.6 Contrast / Display Light / Keypad Light

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

- Open contrast/display light/keypad light in Options Menu by pressing ◀.
- Choose between 9 contrast- and display light levels with ◀ or ▶ and confirm with OK. For use with light sensitive drugs the keypad- respectively syringe light can be completely turned off.

4.7 Alarm Volume

Chose between 9 different alarm volume levels.

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

4.8 Date / Time

- Open date/time in Options Menu with ◀.
- Change date/time with ⚙ and confirm with OK.

4.9 Macro Mode

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

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

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

4.10 Language

This function enables a change of the pump language.

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

ALARMS

The Perfusor® 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.
Opera-tingA-larm	yes	flashes	off	see alarm de-scription	yes	Press OK to acknowledge the audible alarm, alarm text and staff call. The red LED goes off.
Pre-Alarm	yes	off	flashes	see alarm de-scription	(de-)activate via service program	Press OK to mute alarm and turn off staff call. Visible alarm remains until end.
Reminder Alarm	yes	off	flashes	see alarm de-scription	yes	Press OK to mute alarm, turn off staff call and delete the alarm text.
Alarm Hint	no	off	off	see alarm de-scription	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 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, excluding OccluGuard and pressure leap/drop pre-alarms) 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 OK. 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
"Syringe nearly empty"	Very little fluid is left in syringe.
"VTBI near end"	The preselected volume is nearly infused.
"Time near end"	The preselected time is almost over.
"Battery nearly empty"	The battery is almost discharged.
"KVO mode"	Volume/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.
"Pressure rise detect."	OccluGuard has detected an occlusion. Check IV access, IV setup and syringe for cause of occlusion. Should the cause of the alarm be removed, the alarm will stop automatically. Due to varying syringe tolerances of syringes from other manufacturers, a pressure alarm may occur because of high syringe friction forces.
"Pressure leap detect."	A sudden pressure leap has been detected – check IV access.
"Pressure drop detect."	A sudden pressure drop has been detected – check IV access.
"TOM pending"	Very little fluid is left in syringe, infusion will be handed over to second Perfusor® Space pump when syringe is empty (Take Over Mode only).
TOM aborted"	Take Over Mode has been aborted (Take Over Mode only)

Except OccluGuard and pressure leap/drop pre-alarms, 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 (OK). Corrections should be made in accordance with the alarm reason.

Display message	Alarm reason
"Syringe empty"	There is no fluid left in the syringe. Due to varying syringe tolerances of syringes from other manufacturers, some fluid may be left inside the syringe. Restarting the infusion leads to a complete depletion of the syringe and shut-off via the pressure sensor. Perform syringe change as described in 1.4.
"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.
"KVO finished"	KVO is reached. Continue with old or set new therapy.
"Pressure high"	An occlusion occured in the system. The set pressure level was exceeded. A bolus reduction is automatically initiated by the pump. Check if syringe is empty, kinks are in tubing and tubing isn't damaged, IV patency and filter patency. Increase occlusion pressure if necessary. Due to varying syringe tolerances of syringes from other manufacturers, a pressure alarm may occur because of high syringe friction forces.
"Syringe not correctly inserted"	The wings of the syringe are not properly inserted. Insert syringe according to describtion in "Overview Perfusor® Space" as well as 1.1.
"Syringe holder"	The syringe holder was opened during a running infusion. Close syringe holder.
"Battery cover removed"	The battery cover is not properly engaged on the battery compartment. When pushing on the battery cover listen for "click".
"Drive blocked"	An external interference kept the drive unit from advancing. Basically prevent all external interferences. Consider "Patient Safety".
"Calibrate device"	Pump calibration data have changed (e.g. after an update). Recalibrate device via the service program.

"Claw malfunction"	The emergency release button was pressed and the claws manually opened. Take out syringe and contact technical service department.
"Plunger plate not prop. fixed"	The syringe plunger plate does not attach to the plunger plate sensor on the pump. Check system for negative pressure and eliminate cause. Consider "Patient Safety".
"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 describtion "Overview Perfusor® Space".
"Data were reset"	Therapy and pump settings could not be restored. Enter therapy and pump settings anew.
"Therapy data were reset"	Therapy data could not be restored. Enter therapy anew.
"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 or in order to turn the pump off.
"Connection lost – TOM aborted"	Data connection between TOM pumps in the SpaceStation has been lost and TOM has been aborted (Take Over Mode only). TOM may be reactivated by pressing OK and then ▲ when prompted "Return to Take Over M."
"Infusion taken over by other pump"	Infusion been handed over to second Perfusor® Space pump (Take Over Mode only)

The red LED extinguishes with the acknowledgement of the alarm.

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

5.3 Reminder Alarms

Reminder alarms only occur in two cases:

1. A syringe is inserted, the pump doesn't administrate, no value is being 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 OK and continue to set therapy/Start Up configuration.

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

5.4 Alarm Hints

If inproper entries are made the display states corresponding hints (e.g. "Bol.rate out of range"; "Download failed"; "The parameter can not be modified"). These hints disappear after a few seconds and don't need to be confirmed.

BATTERY OPERATION AND MAINTENANCE

The Perfusor® Space is equipped with the latest NiMH-battery. It has an operating lifetime of 8 hours at 25 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 Perfusor® 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 can only 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 OK-key will be displayed after switching the pump off. By pressing OK and ▲ the discharge process will start. The process is interrupted by switching the pump on again. If the battery maintenance is to be continued a new activation is necessary. After completely discharging the battery it will be completely charged again. The total duration of the battery maintenance process takes approx. twelve hours.

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

COMPATIBLE SYRINGES

The syringe types listed in the following tables can be used with the Perfusor® Space.

Please refer to the listed material number (Mat. No.[1)]) to ensure specific syringe brand compatibility.

The Time to Occlusion[2)] alarm has been measured at 5 ml/h. The measured data are typical values which may vary because of possible syringe tolerances.

Manufacturer:
B. Braun

Syringe Type B. Braun	Omnifix 2 ml	Omnifix 5 ml	Omnifix 20 ml	Omnifix 30 ml	Omnifix 50 ml
Mat. No.[1)]	461 7029V	461 7053V	461 7207V	461 7304F	461 7509F
Time to Occl.[2)]	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:39	0:58	1:04	1:13	1:16
P 9 [mm:ss]	1:05	1:32	3:26	6:07	13:46

Manufacturer:
B. Braun

Syringe Type B. Braun	OPS 20 ml	OPS 50 ml
Mat. No.[1)]	872 8615	872 8810F
Time to Occl.[2)]	typ.	typ.
P 1 [mm:ss]	00:50	1:34
P 9 [mm:ss]	05:50	15:27

Manufacturer:
B. Braun

Syringe Type B. Braun	Omnifix 3ml[3)]	Omnifix 10ml LL
Mat. No.[1)]	4617022V A/P 4617022V-03 US 4610303V-02	4617100V A/P 4617100V-03 US 4617100V-02
Time to Occl.[2)]	typ.	typ.
P 1 [mm:ss]	0:25	0:53
P 9 [mm:ss]	1:43	3:50

Manufacturer:
TYCO EU

Syringe Type TYCO EU	Monoject 3 ml	Monoject 6 ml	Monoject 12 ml	Monoject 20 ml	Monoject 35 ml	Monoject 50/60 ml
Mat. No.[1)]	1100-603495	1100-606159	1100-612173	1100-620036	1100-635430	1100-650090
Time to Occl.[2)]	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:51	0:56	1:04	1:19	1:32	2:23
P 9 [mm:ss]	1:16	1:41	3:27	5:27	12:05	15:58

Manufacturer: TYCO USA

Syringe Type TYCO USA	Monoject 3 ml	Monoject 6 ml	Monoject 12 ml	Monoject 20 ml	Monoject 35 ml	Monoject 50/60 ml
Mat. No.[1]	8881-513934 8881-713005	8881-516937 8881-716008	8881-512878 8881-712023	8881-520657	8881-535762	8881-560125 8881-760089
Time to Occl.[2]	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:41	0:50	1:07	1:13	1:27	1:35
P 9 [mm:ss]	1:17	2:07	3:45	4:49	11:50	15:46

Manufacturer: Becton Dickinson

Syringe Type B-D EU/USA	Plastipak 3 ml	Plastipak 5 ml	Plastipak 10 ml	Plastipak 20 ml	Plastipak 30 ml	Plastipak 50/60 ml
Mat. No.[1]	309585 300910	309603 300911	309604 300912	309661 300913 300134 300629	309662 300863	309663 300865 300869
Time to Occl.[2]	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:53	0:55	1:15	2:05	2:14	2:53
P 9 [mm:ss]	1:15	1:34	3:27	6:30	6:36	15:34

Manufacturer: Becton Dickinson

Syringe Type B-D EU/USA	Plastipak BD 30 ml	BD Luer Lock 3 ml A/P[3]	BD Luer Lock 5 ml A/P[3]	BD Luer Lock 10 ml A/P[3]	BD Luer Lock 20 ml A/P[3]	BD Luer Lock 50 ml A/P[3]
Mat. No.[1]	301229	302113	302135	300149	300141	300144
Time to Occl.[2]						
P 1 [mm:ss]	1:25	0:24	0:28	0:50	1:11	3:17
P 9 [mm:ss]	8:50	1:04	1:22	2:36	5:03	16:36

Manufacturer: TERUMO

Syringe Type TERUMO EU/USA/JAP	3 ml	5 ml	10 ml	20 ml	30 ml	50 ml	60 ml
Mat. No.[1]	3SS*03L	3SS*05L 1SS*05LZ1	3SS*10L 1SS*10LZ1	3SS*20L SS*20ES	1SS*30LZ1	2BS-50LG	3SS*60L
Time to Occl.[2]	typ.	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:43	0:35	0:55	2:12	2:25	3:01	3:34
P 9 [mm:ss]	1:17	1:16	4:48	7:53	8:18	16:55	17:03

Manufacturer: Codan

Syringe Type Codan	Codan 2 ml[3]	Codan 5 ml[3]	Codan 10 ml[3]	Codan 20 ml[3]	Codan 30/35 ml[3]	Codan 50/60 ml[3]
Mat. No.[1]	62.2637	62.4717	62.6706	62.7704	62.9555	62.8426
Time to Occl.[2]						
P 1 [mm:ss]	0:07	0:09	0:19	0:36	0:45	1:48
P 9 [mm:ss]	0:58	1:18	2:23	4:14	4:22	11:41

Manufacturer: Fresenius

Syringe Type Fresenius	Injectomat 50 ml
Mat. No.[1]	9000701
Time to Occl.[2]	typ.
P 1 [mm:ss]	4:37
P 9 [mm:ss]	21:09

Manufacturer: Becton-Dickinson

Syringe Type B-D Precise	BD Precise 50 ml A/P	BD Precise 20 ml A/P
Mat. No.[1)]	300144	300141
Time to Occl.[2)]		
P 1 [mm:ss]	03:17	01:11
P 9 [mm:ss]	16:36	05:03

Manufacturer: Polfa

Syringe Type	Polfa 50 ml
Mat. No.[1)]	n/a
Time to Occl.[2)]	
P 1 [mm:ss]	01:54
P 9 [mm:ss]	16:58

Manufacturer: Hwajin Medical

Syringe Type	Sofjec 10 ml	Sofjec 20 ml	Sofjec 40 ml	Sofjec 50 ml
Mat. No.[1)]	n/a	n/a	n/a	n/a
Time to Occl.[2)]				
P 1 [mm:ss]	00:13	03:18	04:09	07:18
P 9 [mm:ss]	03:10	08:14	12:45	24:47

Syringes not specified in IEC/EN 60601-2-24

Nutrition pumps, in contrast to infusion pumps, are not classified as Class IIa according to the infusion pump norm IEC/EN 60601-2-24. There are therefore no direct guidelines concerning the technical characteristics (accuracy of infusion rate, alarm parameters etc) of the relevant disposables.

The syringes types listed in the following tables can be used with the Perfusor® Space. However, due to the relatively high tolerances allowed in the disposables, the accuracy of infusion rate and the alarm parameters are not comparable with infusion syringes.

Precautions must be taken as follows:

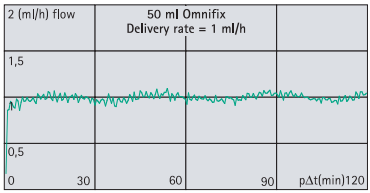
- Consider the risks involved in the use of a non LuerLock connection prior to the therapy
- Permanently observe the connection between the syringe and the infusion set, in order to detect any break in the connection
- If syringe and tubing line are not fixed, a disconnection can occur possibly leading to air infusion, reverse infusion, under- /over delivery and/or nonsterility.

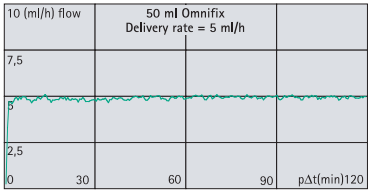
Manufacturer	Sizes (ml)
Baxa	60, 20, 10, 5, 3
NeoMed	60, 35, 20, 12, 6, 3

Complete list available on request.

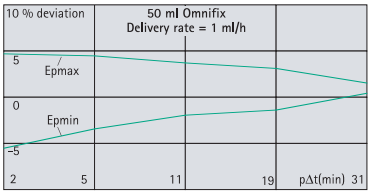
START UP GRAPHS AND TRUMPET CURVES

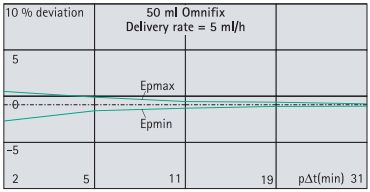
Start Up Curves





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 (disposable syringe) used. Deviations from the technical data of the pump cannot be excluded if syringes (disposables) other than those stated in the order data are used.

Trumpet Curves

Measured values for second hour in each case.

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

Start Up Graphs

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

TECHNICAL DATA

Type of unit	Infusion Syringe Pump
Classification (acc. to IEC/EN 60601-1)	Defibrillator–proof; CF equipment Protective Class II; Protective Class I in combination with SpaceStation
Class (acc. to Directive 93/42 EEC)	IIb
Moisture protection	IP 22 (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	+5 ... +40 °C
■ Atmospheric pressure	500 ... 1060 mbar
Storage conditions:	
■ Relative humidity	20 % ... 90 % (without condensation)
■ Temperature	-20 ... +55 °C
■ Atmospheric pressure	500 ... 1060 mbar
Type of battery pack (rechargeable)	NiMH
Operating time of rechargeable battery	Approx. 8 hours at 25 ml/h
Recharging time	Approx. 6 hours
Weight	Approx. 1.4 kg
Dimensions (W x H x D)	249 x 68 x 152 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	± 2 % according to IEC/EN 60601-2-24
Occlusion alarm pressure	9 levels up to 1.2 bar
Alarm in the case of incorrect dose	For incorrect dosages of 0.1 ml due to malfunctions of the device the pump will automatically shut off.
Technical inspection (safety check)	Every 2 years

Selectable delivery rates

Continuous infusion rate range / bolus rates in dependence on syringe sizes:

Syringe sizes	Cont. rates*	Bolus rates
[ml]	[ml/h]	[ml/h]
50/60	0.01 - 200 optional 0.01 - 999.9	1 - 1800
30/35	0.01 -100	1 - 1200
20	0.01 -100	1 - 800
10/12	0.01 -50	1- 500
5/6	0.01 -50	1 - 300
2/3	0.01 -25	1 - 150

Rate increments	0.01* - 99.99 ml/h in increments of 0.01 ml/h 100.0 - 999.9 ml/h in increments of 0.1 ml/h
Accuracy of bolus infusion	typ. ± 2 %
Max. bolus after bolus reduction	≤ 0.2 ml
KVO-rate	Delivery rate > 10 ml/h: KVO-rate 3 ml/h Delivery rate < 10 ml/h: KVO-rate 1 ml/h Delivery rate < 1 ml/h: KVO-rate = set rate (default setting 0.1 ml/h)
Computer connection	USB connection in combination with B. Braun interface lead CAN SP (8713230) including electrical insulation. Please pay attention to safety notices.
History protocol	1000 last history entries. 100 events for system diagnose. Refer to separate documents of the History Viewer for closer information.

*as default, infusion rates starting from 0.1 ml/h can be set

Guidance and manufacturer´s declararion on electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emission		
The Space System is intended for use in the electromagnetic environment specified below. The customer or the user of the Space System or any component should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Space System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Space System or any component is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	only for SpaceStation applicable Class A	
Voltage fluctu-ations / flicker emissions IEC 61000-3-3	Complies	
Note: Maximum emissions are measured with a complete system (SpaceStation and components).		

Guidance and manufacturer's declaration – electromagnetic immunity			
The Space System is intended for use in the electromagnetic environment specified below. The customer or the user of the Space System or any component should assure that it is used in such an environment.			
Immunity test	**test level IEC 60601-1-2 IEC 60601-2-24**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) according IEC 60601-4-2	contact IEC 60601-1-2: ±6KV IEC 60601-2-24: ±8KV air IEC 60601-1-2: ±8KV IEC 60601-2-24: ±15KV	±6KV no disturbances ±8KV stop with alarm possible ±8KV no disturbances ±15KV stop with alarm possible	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst according IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	±2KV ±1KV	Mains power quality should be that of a typical commercial or hospital environment.
Surge according IEC 61000-4-5	Gegentaktspannung ±1KV Gleichtaktspannung ±2KV	±1KV ±2KV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines according IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec <5% UT for 5 s (>95% dip)	complies by using of internal battery	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Space System requires continued operation during long time power mains interruptions, it is recom-mended that the Space System or component be powered from an uninter-ruptible power sup-ply or a battery.
Power frequency (50/60 Hz) magnetic field according IEC 61000-4-8	IEC 60601-2-24: 400 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical com-mer-cial or hospital envi-ronment.
Note: Different test values of IEC 60601-2-24 are marked in the table. At this test values none dangerous disturbances are allowed while at the lower test values of IEC 60601-1-2 no disturbances are allowed.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Space System is intended for use in the electromagnetic environment specified below. The customer or the user of the Space System or any component should assure that it is used in such an environment.			
Immunity test	**test level IEC 60601-1-2 IEC 60601-2-24**	**Compliance level**	**Electromagnetic environment - guidance**
radiated electromagnetic HF fields according IEC 61000-4-6	IEC 60601-1-2: 3 Veff normal and 10Veff in ISM frequency band IEC 60601-2-24: 10 Veff 150KHz to 80MHz	10Veff 150KHz to 80MHz	Portable and mobile RF communi-cations equipment should be used no closer to any part of the Space System or it's components, includ-ing cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1,2 √P Field strengths should be less then 10V/m d = 1,2 √P 80 MHz to 800 MHz
radiated electromagnetic HF fields according IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m 80 MHz to 3 GHz	d = 2,3 √P 800 MHz to 2,5GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmit-ter manufacturer and d is the rec-ommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3: Different test values of IEC 60601-2-24 are marked in the table. At this test values none dangerous disturbances are allowed while at the lower test values of IEC 60601-1-2 no disturbances are allowed.

Recommended separation distances between portable and mobile RF communications equipment and the Space System

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

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

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

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

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

WARRANTY / TSC* / SERVICE / TRAINING / 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 14th June 1993.

B. Braun Melsungen AG

Warranty

B. Braun provides 24 months warranty, as from the date of delivery, for every Perfusor® 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 L. 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: 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. Wipe magnifying- and displayglas on front of pump door only with a soft cloth. Do not use Hexaquart® or 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 funciton of the device should be performed before initial use. This is even ruled by law in several countries. A respective form can be obtained from B. Braun.

Included in Delivery

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

INSTRUCTIONS FOR USE ACCESSORY

SpaceStation (8713140)

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

SpaceCover Standard (8713147)
SpaceCover Comfort (8713145)

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

PoleClamp SP (8713130)

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

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.

Interface Lead RS232 SP (8713234)

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

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

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

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

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

Connection Lead SP (12 V) (8713231)

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

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

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

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

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

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

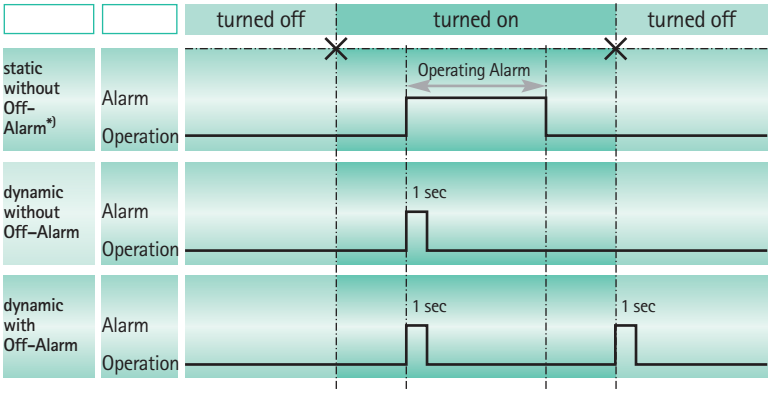
Note: A maximum of three plugs can be stacked upon each other in socket P2.

Connection Lead for Staff Call SP (8713232)

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



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

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

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

Technical Data

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

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

PCA-Accessories

- Space PCA-Kit (REF 8713554) consisting of: :

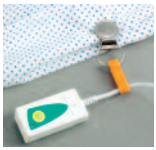
  - Demand button
  - Hook and loop tape
    for fixation of the demand button at the patient s arm
  - Line fixation
    connection between hook and loop tape and demand button
  - Metal clip
    alternatively for fixation at the bed sheet
  - Cable strap
    for wrapping the cable of the demand button
  - PCA-Key
    for locking the syringe holder or the Syringe Anti Removal Cap

- Syringe Anti Removal Cap PSP (REF 8713556)

Fixation of the demand button:

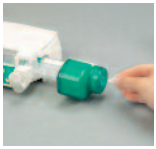
at the wrist:

or at the bed sheet:



Usage of the cable strap:

Usage of the Syringe Anti Removal Cap PSP:



The Syringe Anti Removal Cap PSP is slided over the drive head from the front and is fixed with the PCA-key (270° clockwise rotation). Mind the markings – make sure it is securely locked. Dismantling: counter clockwise rotation of 270°. Push to the left and disengage.

Caution: When Syringe Anti Removal Cap is used always change the syringe as soon the „syringe empty" alarm appears.

	Art. No.
B. Braun Perfusor® Space (100 – 240 V)	871 3030

Recommended accessories for the B. Braun Perfusor® 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 (RSA Plug)	871 3115A
Combi Lead SP 12 V	871 3133
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
Interface Lead RS232 SP	871 3234
Space PCA Kit	871 2554
Syringe Anti Removal Cap PSP	871 3556

Original Perfusor® Syringes:

Original Perfusor® Syringe 50 ml without needle	872 8844F
Original Perfusor® Syringe 50 ml with aspiration needle	872 8810F
Original Perfusor® Syringe 50 ml with aspiration needle and particle filter	872 8852F
Original Perfusor® Syringe 50 ml black with aspiration needle and particle filter	872 8828F
Original Perfusor® Syringe 20 ml without needle	872 8615
Original Perfusor® Syringe 20 ml with aspiration needle	872 8623
Omnifix® 50/60 ml Luer Lock	461 7509F
Omnifix® 30 ml Luer Lock	461 7304F
Omnifix® 20 ml Luer Lock	461 7207V
Omnifix® 10 ml Luer Lock	461 7100V
Omnifix® 5 ml Luer Lock	461 7053V
Omnifix® 3 ml Luer Lock	461 7022V

Omnifix® 2 ml Luer Lock 461 7029V

Original Perfusor® Lines:

Original Perfusor® Line, made of PVC; 50 cm 825 5172

Original Perfusor® Line, made of PVC; 150 cm 872 2960

Original Perfusor® Line, made of PVC; 200 cm 872 2862

Original Perfusor® Line, made of PVC; 250 cm 825 5490

Original Perfusor® Line, made of PVC; 300 cm 825 5253

Original Perfusor® Line, made of PE; 50 cm 825 5059

Original Perfusor® Line, made of PE; 100 cm 825 5067

Original Perfusor® Line, made of PE; 150 cm 872 2935

Original Perfusor® Line, made of PE; 200 cm 872 3060

Original Perfusor® Line, made of PE; 250 cm 827 2565

Original Perfusor® Line, type Safesite, made of PVC,
with Safesite safety connector; 150 cm 872 2820

Original Perfusor® Line, type Filter, made of PVC,
with injection filter 0.22 µm; 200 cm 872 3001

Original Perfusor® Line, type PCA, made of PVC
with back check valve; 168 cm 872 6019

Original Perfusor® Line, type MR, made of PVC,
with swivel nut; 75 cm 872 2870

Original Perfusor® Line, type MR, made of PVC,
with swivel nut; 150 cm 825 5504

Original Perfusor® Line, made of PE, black; 150 cm 872 3010

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