

# Perfusor® Space

and Accessory

## Instructions for Use



Valid for Software 688D

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The Perfusor® Space is according to IEC/EN 60601-1 resp. IEC/EN 60601-2-24 a transportable infusion syringe pump for administering fluids in nutritional therapy and infusion technique as well as for home care applications. 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.

# 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.

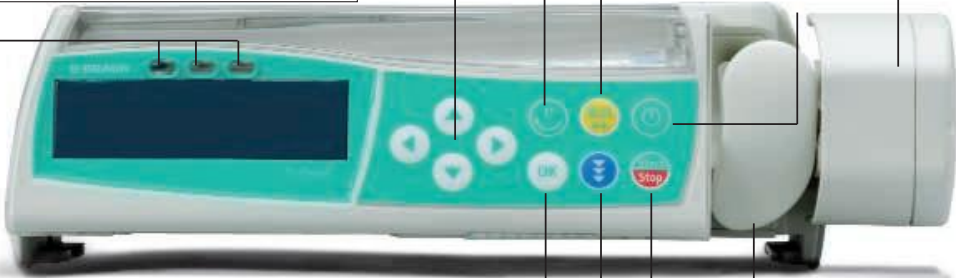
Press to reset single values to zero and switch back to the previous screen/menu level.

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

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

Press to initiate bolus.

Press to turn pump on/off.



OK

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

Down arrow icon

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

Start/Stop icon

Press to Start/Stop infusion.

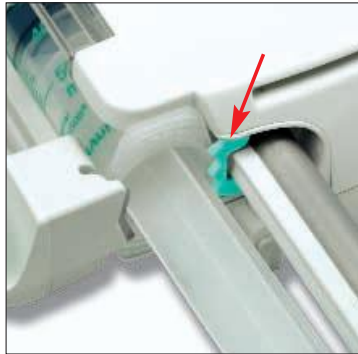
Syringe holder locks syringe in position. To remove syringe: Pull and move to the right. Answer question using arrow up key. The drive will automatically move back.

**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 SpaceControl

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 to the left of the axial fixation before closing syringe holder. Make sure that syringe is properly inserted.

**Caution:** Don't touch piston brake when moving forward.



#### Fixation of PoleClamp (Universal Clamp)

Line up bar of pump with bar of PoleClamp and slide PoleClamp forward until locking mechanism clicks.

To remove, 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. Avoid external mechanical influence.

#### Locking Devices Together

Line up the bar of lower pump with bar of pump above and slide 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 opening of PoleClamp against vertical pole and lock screw tight. 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!

## PATIENT SAFETY



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

### 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 requested to inform himself about the changes of the device and accessories in the Instructions for Use.
- Ensure the unit is properly positioned and secured. Do not position pump unit above patient.
- Prior to administration, visibly inspect the pump and especially the axial fixation for damage, missing parts or contamination and check audible and visible alarms during selftest.
- Connect to patient only after correct syringe insertion and 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.

- A supplemental patient monitoring must be carried out if life-saving medication is performed.
- Avoid applying external force on the drive mechanism during administration.

#### 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 respective manufacturer's information for possible incompatibilities of equipment with respect to drugs.
- Use only compatible combinations of equipment, accessories, working parts and disposables with luer lock connectors.
- 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.

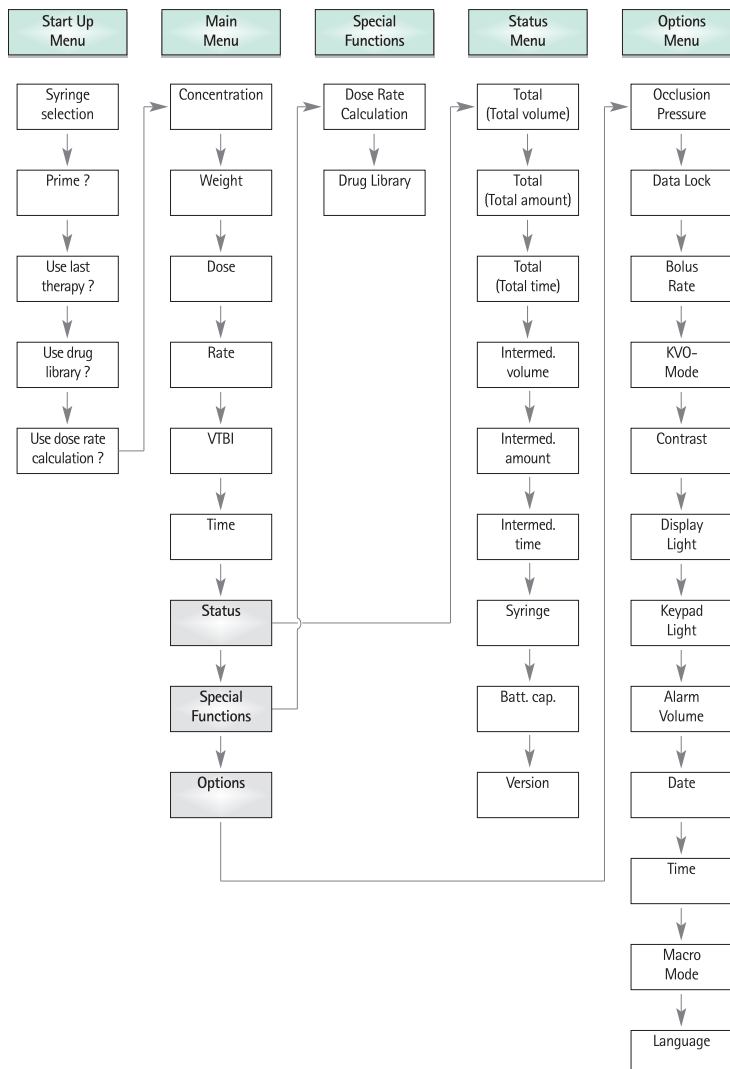
- The EMC-limits (electro-magnetic compatibility) according to IEC/EN 60601-1-2 and IEC/EN 60601-2-24 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.) maintain the recommended protective distances from these devices.

## MENU STRUCTURE / OVERVIEW

### Cutline

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

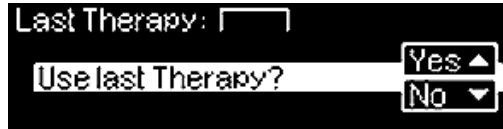
### Menu Structure



The pump can be customized by (de-)activating the menu items of the Start Up- and Options Menu as well as the bolus function via the service program.

## MENU STRUCTURE / NAVIGATION

### Display



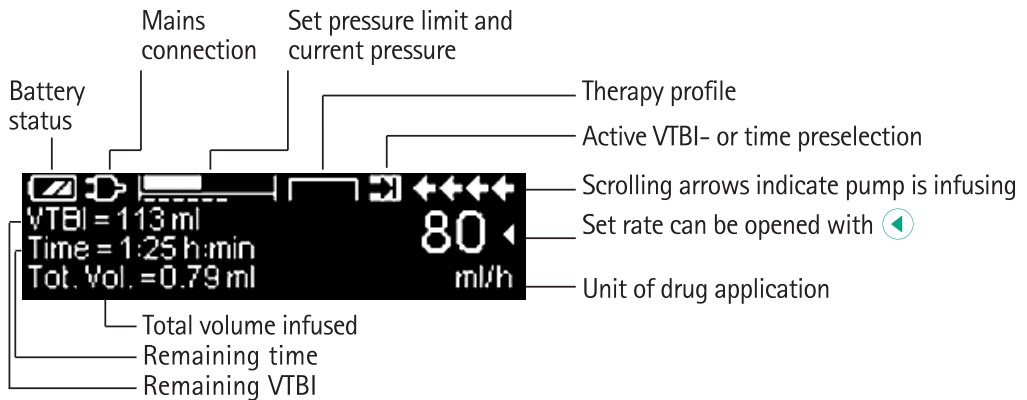
### Meaning

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



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

Typical display during infusion:



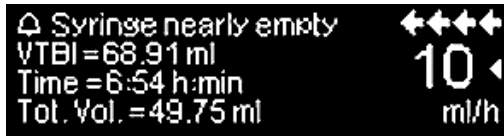
has been pressed while the pump is infusing. Start manual bolus at 1200 ml/h by pressing (see top of display) or proceed to set bolus limit with (see bottom of display).



This hint pops up if a user tries to edit or change a parameter by pressing when that parameter is unable to be changed.



Display



Meaning

Set pressure level with ◀ or ▶ and confirm by pressing **OK**.  
Cancel to edit pressure by using **ESC**.


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**.


Press and hold **STOP** for 3 sec to turn pump off. A white bar stretches from left to right and counts down the 3 sec.

## 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.

During the first ever startup of the device, the user is requested to select the language with  and confirm with . Answer the following question with  in order to take over language before the drive moves backwards.






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



**Caution:** Keep hands away from advancing drive.

**Note:** Make sure that 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 . 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  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 . The pump can be turned off at any time by pressing  for 3 sec (Exception: Data lock level 2).

## 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 will be 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 indicates that the pump has been programmed, either with a volume- or time limit. The assignment of the target symbol, apparent in the Main Menu, shows the established parameter for the application (VTBI or time). When the rate is changed, the so-called target parameter is principally not adjusted to the new rate but to the parameter which does not have the target symbol in front. After the infusion has started, the remaining VTBI and time are displayed in the Main Menu and the run display (values are counting down).

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

Target: Volume

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

Check calculated rate on plausibility.

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

2.) Infusion with volume limit

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

Target: VTBI

3.) Infusion with time limit

Enter rate and time: The infusion volume will be calculated and displayed on the bottom of the display.

Target: Time

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

a) Target symbol is placed in front of VTBI:

- Change of VTBI => Adjustment of time. Old and new target: VTBI
- Change of time => Adjustment of rate. Old and new target: VTBI













b) Target symbol is placed in front of time:

- Change of time => Adjustment of VTBI. Old and new target: Time
- Change of VTBI => Adjustment of time. New target: VTBI

**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 . Then press  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.
- 2.) Bolus with volume preselection: Press . Then press  and set bolus limit by using . Press  to confirm and start bolus.
- 3.) Bolus with rate calculation: Press . Then press  and set bolus limit by using . Press  to confirm bolus limit. Set time with  in which a bolus is to be delivered. Calculated bolus rate is shown on top of the display. Press  to confirm and start bolus.

The unit of the bolus always depends on the selected dose. If the dose is for example selected as mg/kg/h, then the bolus will be given in mg/kg. If a dose is administered without a relation to the patient's weight (mg/h), then the bolus will be given in mg.



You can use the service program to enter a default and a maximum bolus rate. After a new therapy start, however, the device always returns to the default rate - even if the bolus rate was manually changed beforehand.

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

**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 .

## 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  to stop the infusion. The green LED will disappear.  
Disconnect the pump from the patient.
- Open syringe holder. Answer question if syringe change should be performed with . Drive unit moves backwards into starting position.
- 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 syringe holder (**Note:** Piston brake must move forward!) and pump door


and confirm inserted syringe type with . 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  to start infusion.

To start a new therapy after a syringe change:

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

**Note:** It can be started with a new therapy at any time while the infusion is stopped. Press  (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  to stop the infusion. The green LED disappears. Disconnect the pump from the patient.
- Open the syringe holder. Answer question if 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.

## 1.6 Standby Mode





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

- Press  to stop the infusion. Then press  for less than 3 sec.
- Confirm the pump is supposed to switch into standby by pressing .
- The default time for standby is displayed. Accept the default time with  or change it with  (0-24 hours) and then confirm it by pressing .






=> While the pump is in the standby mode, it's display shows the remaining time for this mode. Exit standby by pressing .

## ADVANCED OPERATIONS

### 2.1 Status Request of Pump when Infusion is Running






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




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

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

#### Reset Status Menu Data:

The parameters intermediate volume and -time can be resetted 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 being 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 current battery capacity in hours and minutes is displayed in the menu item "Battery Cap." and the current software version in menu item "Version".

## SPECIAL FUNCTIONS
















### 3.1 Dose Rate Calculation (Overview)

The dose rate calculation enables a calculation of the rate in ml/h.

#### Setting parameters:



1. Concentration as the amount of the active ingredient per volume.
  - Amount of the active ingredient in  $\mu\text{g}$ , mg, mmol, IU or mEq.
  - Volume in ml.
2. Where necessary: Patient weight in kg.
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.

### 3.2 Dose Rate Calculation (Operation)

- Select dose rate calculation with .
- Select the unit of the active ingredient with  and confirm it with .
- Enter the concentration by entering the amount of the active ingredient and the volume. In order to do so set the values with  and confirm with .
- If the patient weight shall not be entered press .  
Press  for a time and weight related calculation, set the patient weight with  and confirm it with .
- Select the dose prescription with  and confirm it with .
- Set the dose with  and confirm with . The rate will be automatically calculated and displayed on the bottom of the display.
- Check the parameters with  on plausibility before starting with .

Concentration and dose can belatedly be changed in the Main Menu in the same way as the rate, VTBI and time (compare 2.2). The effect of weight and dose modifications on other parameter are being shown on 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 .

### 3.3 Drug Library







300 drug names including therapy data and information can be stored in 15 categories. The loading process into the pump can be performed via a separate PC program („Drug List Editor Space“).

**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 drug library (see headline) will be displayed on the pump.

There are different ways of embedding the drug library into the therapy. This can be done while the infusion is running or 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 was already started a belated assignment of the drug name is not possible anymore.

In the following the loading of a drug including the according parameters will be described:



- Open the drug library by pressing .
- Navigate through list with  and select the drug from category in alphabetical order (all drugs) or within a category with .
- Respectively confirm the displayed drug information with .
- Check if the drug short name in the Main Menu is the same as the selected drug. Check the parameter in the Main Menu with  and start infusion with .

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

**Note:** An adequate monitoring of highly potent drug administration is required by law.







## OPTIONS

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

### 4.1 Occlusion Pressure

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

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

### 4.2 Data Lock

The data lock function protects the device against unauthorized access. A four digit code (default setting "9119"), which can be changed via the service program activates this function. There are two 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. 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 are only possible after the code was entered.

#### Activation of the function:

- Open data lock in Options Menu with .
- Select between level 1/2 with  and  and confirm with .
- Enter code with  and press  in order to activate data lock.

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

value was reached while data lock is active a new start of the pump is only possible after entering the code.

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



### 4.3 Bolus Rate

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

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





### 4.4 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.





### 4.5 Contrast / Display Light / Keypad Light

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

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

### 4.6 Alarm Volume

Chose between 9 different alarm volume levels.



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

## 4.7 Date / Time

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

## 4.8 Macro Mode




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

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

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





## 4.9 Language

This function enables a change of the pump language.

- Open language in the Options Menu with .
- Select language with t, then press .
- Confirm Yes/No question with .


## ALARM

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 hold  until the pump switches off after a few seconds.
Operating-Alarm	yes	flashes	off	see alarm description	yes	Press  to acknowledge the audible alarm, alarm text and staff call. The red LED remains on until the infusion is restarted.
Pre-Alarm	yes	off	flashes	see alarm description	(de-)activate via service program	Press  to mute alarm and turn off staff call. Visible alarm remains until end.
Reminder Alarm	yes	off	flashes	see alarm description	yes	Press  to mute alarm, turn off staff call and delete the alarm text.
Alarm Hint	yes	off	off	see alarm description	no	Hint disappears without confirmation.

### 5.1 Pre-Alarms and Operating Alarms

#### Pre-alarms:

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


Display message	Pre-alarm reason
"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 active"	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.

A stopwatch on the display counts down the remaining time (depending on the service program, between 3-30 min). After that, the pump changes to the operating alarm.

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

#### Operating alarms:

Operating alarms lead to an interruption of the infusion. An audible tone sounds, the red LED flashes and a staff call is activated. The display states "Alarm" and the reason for the operating alarm. The signal tone and the staff call are turned off with . Corrections are to be made according to the alarm reason.

Display message	Alarm reason
"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 occurred 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.

	Insertt syringe according to description 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 the plunger plate sensor of 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 do 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"	It was tried to stop or switch the pump off without entering the code. Enter the correct code in order to continue the therapy respectively turning the pump off.


The red LED doesn't extinguish until the administration is started again respectively the pump is turned off.


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

## 5.2 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  and continue to set therapy/Start Up configuration.

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

## 5.3 Alarm Hints

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

## BATTERY OPERATION AND MAINTENANCE

The 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 only can be realized if the pump operates continuously with a fully charged battery at room temperature. The display of the battery operating time on the pump is an approximate value based on the current delivery rate. If the battery is aged it may differ from the actual achievable operating time.



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

**Battery maintenance:**

To accurately balance the battery capacity a cyclical battery maintenance is necessary. The pump asks the user to perform a battery maintenance every 30 days. The battery maintenance mode detects a possible capacity loss (e.g. through ageing of the battery pack) and then the capacity/running time will be calculated anew. After a longer storage time or a longer operation without battery maintenance it can happen that the battery pre-alarm time can no longer be maintained. In this case it is necessary to perform a battery maintenance.

To initiate the discharge process the writing „Battery maintenance“ and the -key will be displayed after switching the pump off. By pressing  and  the discharge process will start. The process is interrupted by switching the pump on again. If the battery maintenance shall 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 the possibly reduced battery operating time when the battery maintenance isn't completed yet.

## 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.<sup>1)</sup>) to ensure specific syringe brand compatibility.

The Time to Occlusion<sup>2)</sup> alarm has been measured at 5ml/h. The measured data are typical average values which can vary because of possible syringe tolerances.

**Manufacturer:**  
**B. Braun**

Syringe Type B. Braun	Omnifix 2 ml	Omnifix 5 ml	Omnifix 10 ml	Omnifix 20 ml	Omnifix 30 ml	Omnifix 50 ml
Mat. No. <sup>1)</sup>	461 7029	461 7053	461 7100	461 7207	461 7304	461 7509
Time to Occl. <sup>2)</sup>	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:39	0:58	0:47	1:04	1:13	1:16
P 9 [mm:ss]	1:05	1:32	2:08	3:26	6:07	13:46

**Manufacturer:**  
**B. Braun**

Syringe Type B. Braun	OPS 20 ml	OPS 50 ml
Mat. No. <sup>1)</sup>	872 8615	872 8810
Time to Occl. <sup>2)</sup>	typ.	typ.
P 1 [mm:ss]	1:08	1:34
P 9 [mm:ss]	4:35	15:27

**Manufacturer:**  
**Fresenius**

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

**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. <sup>1)</sup>	1100- 603495	1100- 606159	1100- 612173	1100- 620036	1100- 635430	1100- 650090
Time to Occl. <sup>2)</sup>	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

Chapter 7

**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. <sup>1)</sup>	8881- 513934 8881- 713005	8881- 516937 8881- 716008	8881- 512878 8881- 712023	8881- 520657	8881- 535762	8881- 560125 8881- 760089
Time to Occl. <sup>2)</sup>	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**

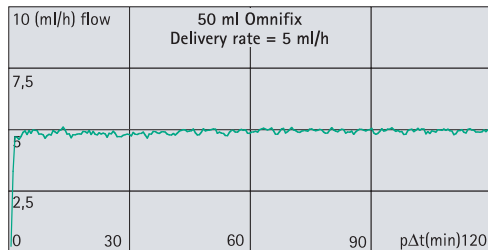
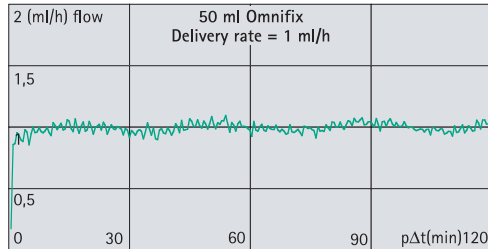
Syringe Type B-D EU/USA	Plastipak 3 ml	Plastipak 5 ml	Plastipak 10 ml	Plastipak 20 ml	Plastipak 30 ml	Plastipak 50/60 ml
Mat. No. <sup>1)</sup>	309585 300910	309603 300911	309604 300912	309661 300913 300134 300629	309662 300863	309663 300865 300869
Time to Occl. <sup>2)</sup>	typ.	typ.	typ.	typ.	typ.	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:**  
**TERUMO**

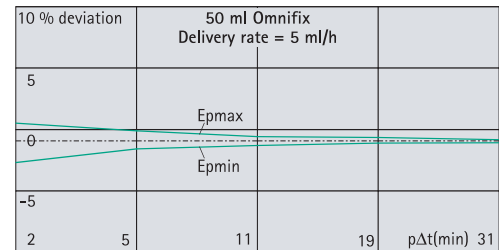
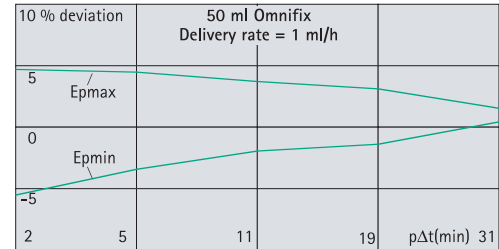
Syringe Type TERUMO EU/USA/JAP	3 ml	5 ml	10 ml	20 ml	30 ml	50 ml	60 ml
Mat. No. <sup>1)</sup>	3SS*03L	3SS*05L 1SS*05LZ1	3SS*10L 1SS*10LZ1	3SS*20L SS*20ES	1SS*30LZ1	2BS-50LG	3SS*60L
Time to Occl. <sup>2)</sup>	typ.	typ.	typ.	typ.	typ.	typ.	typ.
P 1 [mm:ss]	0:43	0:35	0:55	2:12	2:25	3:01	3:34
P 9 [mm:ss]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

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. If other syringes (disposables) than those stated in the order data are used, deviations from the technical data of the pump cannot be excluded.

Trumpet Curves

Measured values for second hour in each case.

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

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

Start-up Curves

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

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

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

## TECHNICAL DATA

Type of unit	Infusion Syringe Pump
Classification (acc. to IEC/EN 60601-1)	<input checked="" type="checkbox"/> Defibrillator-proof; CF equipment <input type="checkbox"/> Protective Class II; Protective Class I in combination with SpaceStation
Class (acc. to Directive 93/42 EEC)	IIb
Moisture protection	IP 22 (drip protected for horizontal usage)
External power supply:	
• Rated voltage	Via B. Braun SpaceStation or optional mains adaptor (rated voltage 100 ... 240 V AC~, 50/60 Hz) for stand alone operation
• External low voltage	11 ... 16 V DC === via external power supply 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	30 % ... 90 % (without condensation)
• Temperature	-20 ... +55 °C
• Atmospheric pressure	500 ... 1060 mbar
Type of battery pack (rechargeable)	NiMH
Operating time of rechargeable battery	Approx. 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 from 0.1 - 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] 50/60	[ml/h] 0.01 - 200 optional 0.01 - 999.9	[ml/h] 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.  $\pm$  2 %

Max. bolus after bolus reduction

$\leq$  0.2 ml

KVO-rate

rate  $\geq$  10 ml/h: KVO-rate 3 ml/h  
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

## WARRANTY / TSC\* / SERVICE / CLEANING / DISPOSAL

### Responsibility of the Manufacturer

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

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

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

B. Braun  
Melsungen AG

### Warranty

B. Braun provides 24 months warranty, as from the date of delivery, for every 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.

### Technical Safety Check\*) / Service

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

### Check regularly

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

## Cleaning

Clean external surface of pump using mild soap suds. Do not use spray disinfectants at the mains power connection. Recommended: disinfectant for wiping available from B. Braun (e.g. Meliseptol®). 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.

## 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.

## 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 (871 3147)

### SpaceCover Comfort (871 3145)

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

### PoleClamp SP (8713130)

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

### Power Supply SP (8713110-8713114)

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 (8713180)

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

## Interface Lead CAN SP (8713230)

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

- 1.) Push plug into socket F3 on the SpaceStation or P2 on the pump and connect with the CAN/USB converter.
- 2.) Connect CAN/USB converter to computer outlet as described in the Instructions for Use manual.

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

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

## Connection Lead SP (12 V) (8713231)

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

- 1.) Connect plug to socket P2 on back of pump or F3 on SpaceStation respectively.
- 2.) Put the connection lead into the car socket.
- 3.) If necessary, remove red adaptor of motor vehicle connector by slightly turning and simultaneously pulling.

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

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

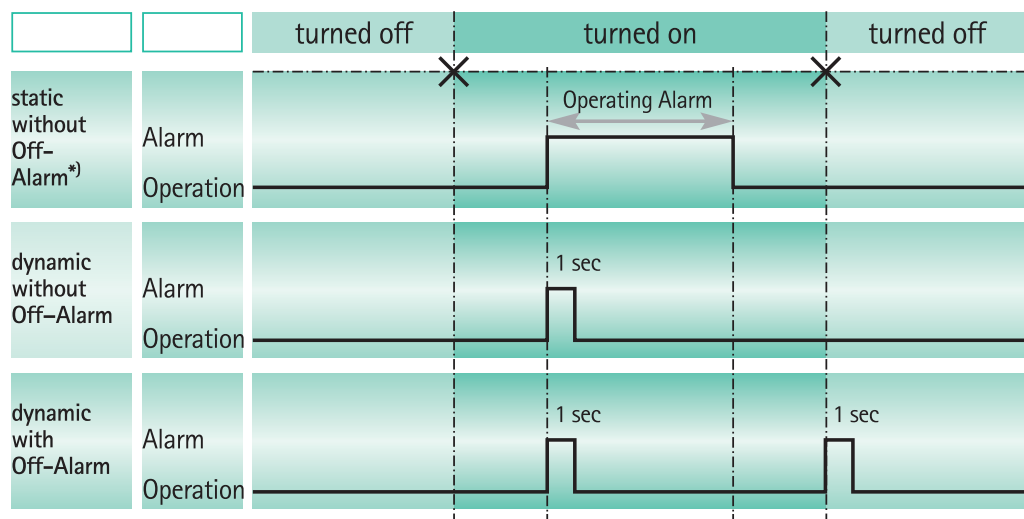
**Note:** A maximum of three plugs can be stacked upon each other in socket P2.


## Connection Lead for Staff Call SP (8713232)

To connect the 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 suppressed with 

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

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

### Technical Data

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

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

	Art. No.
<b>B. Braun Perfusor® Space (100 – 240 V)</b> .....	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 3110
Power Supply SP (UK Plug) .....	871 3111
Power Supply SP (US Plug) .....	871 3112
Power Supply SP (Australian Plug) .....	871 3113
Power Supply SP (Universal Plug) .....	871 3114
Combi Lead SP 12 V .....	871 3133
Battery-Pack SP (NiMH) .....	871 3180
Interface Lead CAN SP .....	871 3230
Connection Lead SP (12 V) .....	871 3231
Connection Lead for Staff Call SP .....	871 3232

**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® 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



**Manufactured by**  
B. Braun Melsungen AG  
Postfach 1120  
D-34209 Melsungen  
Tel (0 56 61) 71-0

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