Perfusor® Space

and Accessories

Rx only

Instructions for Use

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

US Valid for software 588U

B BRAUN

*The availability of the listed features depends on the configuration of the pump's biomed file.
**Technical Safety Check.

PERFUSOR® SPACE OVERVIEW

Follow on screen prompts using arrow keys to navigate menus, select parameters, change values and respond to on screen prompts.

Press to clear values in programming screens or to go back one screen.

Drive head with claw mechanism to hold the syringe plunger plate.

Protective Cap
Note:
Emergency release button on outside of drive head is located below protective cap. Replace protective cap after pressing.

Press to initiate bolus.

Press to turn pump on/off and initiate standby mode.

Yellow LED: Pre-alarm or reminder alarm

Green or Red LED: or
Green LED: Infusing
Red LED: Operating or Device Alarm

Blue LED: Initiating connection to wireless battery or SpaceStation

OK

Press to select and/or confirm values/settings/ alarms/messages.

Press to initiate autoprogramming orders when prompted.

Start Stop

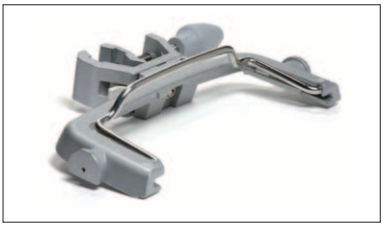
Press to Start/Stop the infusion.

The syringe holder locks the syringe in position. To remove the syringe, pull and turn to the right. The drive head automatically retracts.

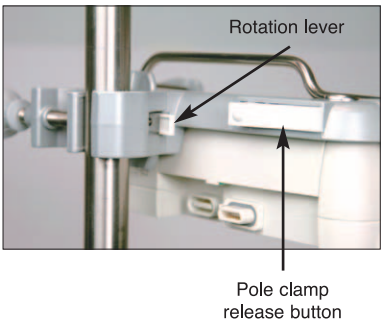
Cover of Battery Compartment

Port P3 for future options

Port P2 for power supply, SpaceStation, combi lead and additional accessory leads (staff call, service plug)



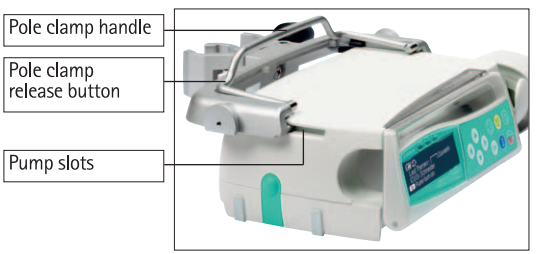
Pole Clamp SP (model 8713130)



Attaching Pole Clamp to IV Pole
Position the opening of the Pole Clamp on pole and turn the grey locking knob clockwise until pole clamp is secured to IV pole. Turn grey knob counter clockwise to release from IV pole. For vertical positioning of Pole Clamp, push rotation lever down and rotate pump either way until lever clicks into notch. Push lever for rotation.

⚠ Caution: Do not lean on pump when attached to pole.

A maximum of three B. Braun Space pumps can be stacked together when used with the PoleClamp SP. Rotating position while infusing may result in temporary increase in flow rate or bolus.



Attaching Pump to Pole Clamp
Line up slots on top sides of pump with grooves of Pole Clamp and slide pump into Pole Clamp until locking mechanism clicks. To remove, simultaneously press release button on frame and push handle down while pulling pump out from pole clamp.

Locking Devices Together

A maximum of three pumps (Infusomat® Space or Perfusor® Space) may be interlocked on a single pole clamp.

In Transport (ex: road, rotary and fixed-wing ambulances) a maximum of one Space pump may be used per Space pole clamp.

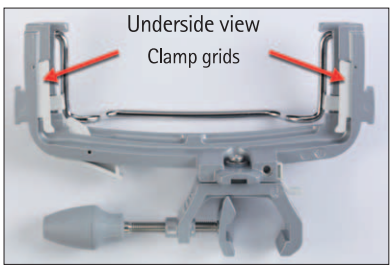
⚠ Caution: Avoid external mechanical action.

Line up the grooves of the lower pump with the slots of the upper pump and slide the lower pump in until the lock clicks and the green buttons are aligned with each other.

To disconnect, push green locking button of upper pump and slide lower pump out.

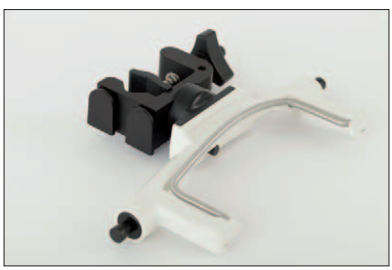
The pump is now securely attached to Pole Clamp.

⚠ Caution: Do not position the pump unit over the patient.



⚠ Cautions:

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



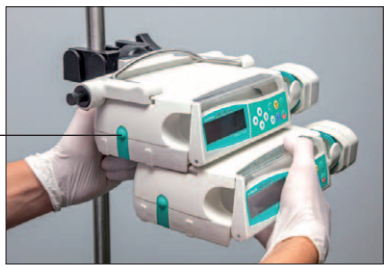
Space Pole Clamp (speed clamp) (model 8713131)

Attaching Pole Clamp to IV Pole
Position the opening of the Pole Clamp on pole and turn black knob clockwise until pole clamp is secured to IV pole. Turn black knob counter clockwise to release from IV pole.

Attaching Pump to Pole Clamp
Line up slots on top sides of pump with grooves of Pole Clamp and slide pump into Pole Clamp until locking mechanism clicks.

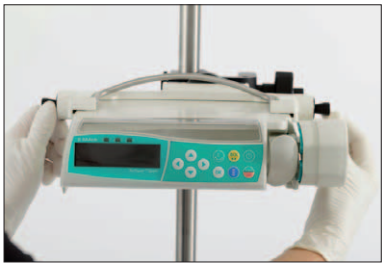
The pump is now securely attached to the pole clamp.

⚠ Caution: Do not position the pump unit over the patient.

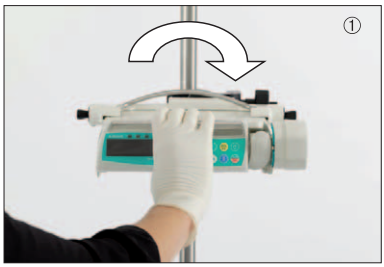


Locking Devices Together
Line up the grooves of the lower pump with the slots of the upper pump and slide the lower pump until the lock clicks and the green buttons are aligned with each other. To disconnect, push green locking button of the upper pump and slide lower pump out.
A maximum of three pumps (Infusomat® Space or Perfusor® Space) may be interlocked on a single pole clamp.
In Transport (ex: road, rotary and fixed-wing ambulances) a maximum of one Space pump may be used per Space pole clamp.

⚠ Caution: Avoid external mechanical action.

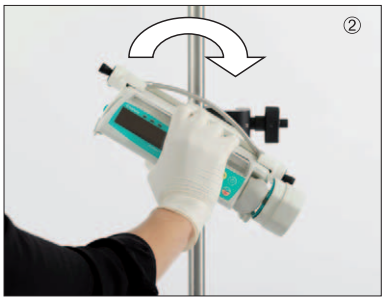


Removing Pump from Pole Clamp
Pull both end tabs simultaneously to gently eject/release the pump from pole clamp. Slide pump out by hand to remove fully from pole clamp.



Vertical Positioning
Simply turn the pump either way until it clicks into notch at 90 degree/vertical position.

⚠ Caution: Rotating position while infusing may result in temporary increase in flow rate bolus.



⚠ Caution: Do not lean on pump when attached to pole!
A maximum of three B. Braun Space pumps can be stacked together when used with the Space Pole Clamp (speed clamp). In Transport (ex: road, rotary and fixed-wing ambulances) a maximum of one Space pump may be used per Space pole clamp. Avoid external mechanical influence.

Power supply holder
The Space Pole Clamp (speed clamp) can hold up to 2 Space Power Supplies (8713112D) on the rear of the pole clamp.

⚠ Caution: DO NOT use any Pole Clamp that shows signs of damage.

SYMBOLS ON PRODUCT

IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance			
Symbol	**Title**	**Reference-number**	**Explanatory text or meaning**
	Follow Instructions for Use.	D.2-10	Mandatory action: See Instructions for Use.
	General warning sign	D.2-2	To signify a general warning
	Defibrillation-proof type CF applied part	D.1-27	To identify a defibrillation-proof type CF applied part.
	Class II equipment	D.1-9	To identify equipment meeting the safety requirements specified for Class II equipment.
	Direct current	D.1-4	To indicate on the rating plate that the equipment is suitable for direct current only.

ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements			
Symbol	**Title**	**Reference-number**	**Explanatory text or meaning**
	Temperature limit	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation	5.3.8	Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Manufacturer	5.1.1	Indicates the medical device manufacturer.
	Date of manufacture	5.1.3	Indicates the date when the medical device was manufactured.

ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements			
Symbol	**Title**	**Reference-number**	**Explanatory text or meaning**
	Batch code	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog number	5.1.6	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Serial number	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Consult Instructions for Use	5.4.3	Indicates the need for the user to consult the Instructions for Use.
	Caution	5.4.4	Indicates the need for the user to consult the Instructions for Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

IEC TR 60878: Technical Report Graphical symbols for electrical equipment in medical practice			
Symbol	**Title**	**Reference-number**	**Explanatory text or meaning**
	Non-ionizing electro-magnetic radiation	5140	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	MR Unsafe	62570-7.3.3	To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	MR Conditional	62570-7.3.2	To identify an item which poses no unacceptable risks within defined conditions to the patient, medical staff or other persons within the MR environment. *see Warning statement regarding MR information in Patient Safety section for further information.

List of abbreviations

KVO = Keep Vein Open
LED = Light-Emitting Diode (indicator lamps)
EHR = Electronic Health Record
VTBI = Volume To Be Infused
MR = Magnetic Resonance Imaging
BSA = Body Surface Area
Li-Ion = Lithium Ion

PATIENT SAFETY

Read Instructions for Use prior to operation. The infusion device should only be used by trained healthcare professionals.

Indications for Use

The Perfusor® Space Syringe Infusion Pump System is intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral fluids, enteral fluids, medications, blood and blood products through clinically accepted routes of administration. These routes include intravenous, intra-arterial, subcutaneous, epidural and enteral.

The Perfusor® Space Syringe Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities and for medical ground and/or air transport situations.

Dedicated Syringes

The Perfusor® Space Infusion Pump is intended to be used with only dedicated syringes labeled for the different routes of administration.

Warnings

- The initial training of the Perfusor® Space is to be performed by B. Braun sales and/or clinical personnel or other authorized persons. After each software update, the user must refer to the Instructions for Use to review changes to the device and software.
- Prior to administration, visibly inspect the pump for damage, missing parts or contamination and check audible and visible alarms during self-test.
- Ensure syringe sizes and models are compatible with the Perfusor® Space (refer to Chapter 7). Use of incompatible syringes can cause improper pump operation resulting in inaccurate fluid delivery, insufficient occlusion (blockage) sensing, and other potential problems.
- Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates (e.g., less than 5 mL per hr, and especially flow rates less than 0.5 mL per hr). Using a larger syringe when infusing at low rates can lead to inadequate syringe pump performance including delivery inaccuracies, delay of therapy and delayed generation of occlusion alarms. This is due to the increased friction and compliance of the syringe plunger tip with larger syringes.
- Electronically prime the syringe pump system before starting an infusion or after replacing a syringe with a replacement syringe.
  - Verify the fluid flow to the patient is OFF, and if enabled, use the prime function on the syringe pump to remove any mechanical slack in the system.
  - Using the syringe pump's prime feature engages the mechanical components of the pump and decreases the syringe's friction and compliance (i.e. stiffness) to minimize startup delays and delivery inaccuracies, especially at low infusion rates.

  - Failure to use the prime feature on the syringe pump after every syringe change and/or tubing change can significantly delay the infusion delivery startup time and lead to delivery inaccuracies.
- During priming and bolusing the pressure limits are set to the maximum level.
- Only connect to patient once the syringe has been correctly inserted and the line completely primed (See Chapter 1.1). Disconnect from patient during syringe change to prevent unintended delivery.
- During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen matches the syringe size and model loaded onto the syringe pump.
- Use syringes approved for Perfusor Space and only use luer lock fittings to connect IV line to syringe. During administration of epidural or enteral solutions only use syringes and tubing approved for epidural or enteral administration (See Chapter 7).
- Ideally, the syringe pump should be level with the distal tip of the catheter (e.g. the site of fluid delivery; if accessing a central line the syringe pump should be at the level of the patient's heart). If the pump height is raised relative to the distal tip of the catheter (e.g. during patient transport), the increase in height of the syringe pump can result in a temporary increase in fluid delivery or bolus until the flow rate stabilizes. Alternatively, if the pump is lowered relative to the distal tip of the catheter, the decrease in height of the syringe pump may result in a decrease in delivery or under-infusion until the flow rate stabilizes. Rotating the pump between the horizontal and vertical position while infusing may also result in temporary increase in fluid delivery or bolus.
- To minimize the amount of time it takes the pump to recognize an occlusion (blockage) and generate an alarm while infusing at low rates (e.g., less than 5 mL per hr, and especially flow rates less than 0.5 mL per hr):
  - Consider the plunger force or occlusion pressure threshold setting and adjust it, as necessary. The lower the plunger force setting or occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (e.g., lipids) the plunger force or occlusion pressure threshold setting may need to be adjusted to reduce false alarms. See Chapter 2.2.1 for further detail.
  - Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance (i.e., stiffness) of the syringe plunger tip. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery and faster occlusion detection than larger syringes.
  - Use the prime feature on the pump when inserting a new syringe and changing a syringe and/or tubing.

  - Use accessory devices, which have the smallest internal volume or deadspace (e.g., microbore tubing when infusing at low rates, shorter length of tubing, etc.). See Chapter 9, page 74 for further detail.
- When addressing or clearing an occlusion:
  - Ensure the fluid flow to the patient is OFF to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing, or relieve the excess pressure through a stopcock, if present. The healthcare professional should weigh the relative risks of disconnection with the risks of unintended bolus of drug.
  - Be aware that using larger size syringes on a high plunger force setting may produce a larger post occlusion bolus due to excessive syringe plunger tip compliance.
- Not to be used adjacent to and/or stacked with other equipment except B. Braun Space devices.
- Compare the displayed value on the pump with the entered value prior to starting infusion.
- Compare medication order to programming parameters including drug name, concentration and dose prior to starting infusion.
- Check default values pre-populated from drug library with physician order prior to starting infusion.
- The default values and limits of the drug library provide a safety net for programming and are not intended to be used to define treatment.
- Consider additional monitoring which may be required when using high risk medications.
- Consider plausibility of calculated flow rate for infusions programmed with BSA to assist in determining accuracy of BSA value.
- If the pump is dropped or is exposed to force, it must be checked by the service department.
- Do not apply force or hold the pump by the drive head while infusing or during transport.
- Do not allow liquids to enter into or come into contact with any openings or electrical connections on the pump or power supply. Fluid exposure in these areas may result in the risk of short circuit, corrosion or breakdown of sensitive electrical components, and/or electrical shock. If fluid exposure occurs, the device should be exchanged with another device in a manner that presents minimal interruption to patient care. The device should remain unplugged until it can be inspected by a trained technician for any evidence of damage and/or residual moisture which may impair the function of the device.

- If staff call is used, check the equipment once after connecting the pump to ensure staff call is working.

Cautions

- Use compatible components which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (e.g. less than 5 mL per hr, and especially flow rates less than 0.5 mL per hr). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times. For example:
  - Tubing internal diameter: Small bore or microbore tubing is recommended when infusing at low rates
  - Tubing length: Tubing length should be minimized, when possible
  - Filters: Internal volume (deadspace) of in-line filters should be minimized
  - Connection sites: The number of connection sites such as stopcocks and Y-sites should be limited, and high risk or life-sustaining solutions should be connected as close to the intravenous access site as possible.
- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (e.g. 50-200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (e.g. less than 5 mL per hr, and especially flow rates less than 0.5 mL per hr)
- Manually prime the syringe and tubing to remove all air, before connecting to the pump unless using the priming feature on the pump to remove air from the tubing (See Chapter 1.1)
- If using multiple syringe pumps and it is not clinically feasible to have all pumps level with the distal tip of the catheter (or the site of fluid delivery), place the high risk or life-sustaining medications as close to level with the distal tip of the catheter as possible. When infusing multiple high risk or life sustaining medications, consider placing the ones infusing at the lowest rates as close to the level with the distal tip of the catheter as possible.
- Minimize the height difference between the pump and the patient and avoid changes in the height of the pump (e.g., during transport of critically ill patients) to prevent unintended fluctuations in the flow rate
- Ensure the unit is properly positioned and secured (See Perfusor® Space Overview). Do not position pump above patient or in a position where a patient could be harmed if the pump should fall.
- Ensure the infusion line is free of kinks.
- Do not operate in the presence of flammable anesthetics or in a hyperbaric oxygen chamber.

- The Perfusor Space or the Space System and its accessories should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Perfusor Space or the Space System and its accessories should be observed to verify normal operation in the configuration in which it will be used.
- Sporadic device alarms may occur when the pump is exposed to strong RF electromagnetic fields in the 860 – 960 MHz range. Pump stoppage associated with an "alarm of high priority" is consistent with the safety concept of the device, and is remedied in this case by the user resuming the current operation or by restarting the pump.

Safety Standards

Perfusor® Space satisfies all safety standards for medical electrical devices in compliance with IEC 60601-1:2005 and IEC 60601-2-24: 2012.

- The EMC-limits (electro-magnetic compatibility) according to IEC 60601-1-2:2007 and IEC 60601-2-24: 2012 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.), this equipment may be disturbed. Maintain the protective distances recommended by the manufacturers of these devices.
- During transport of patients the Perfusor® Space needs to be fixed on a suitable restraint system by means of SpaceStation, Pole Clamp SP or Space Pole Clamp (speed clamp).
- When stored under temperature conditions beyond the defined operating temperature limits the Perfusor® Space needs to remain under room temperature at least one hour before usage.

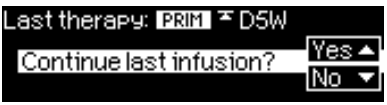
The Perfusor® Space Infusion Pump is unsafe when used as a standalone device in proximity to magnetic resonance imaging (MRI) equipment. The pumps, when within the SpaceStation MRI, can be used conditionally in the MR environment when complying to the SpaceStation MRI Instructions for Use. Do not remove the pump from the SpaceStation MRI in proximity to MRI equipment.

MENU STRUCTURE / NAVIGATION

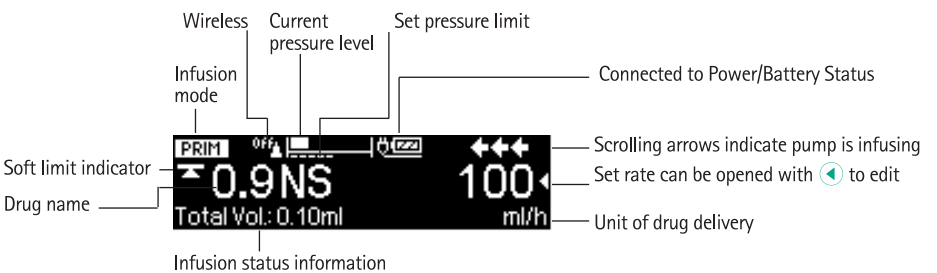
Overview of Keys and Displays

- On/Off key
- Start/Stop key
- Bolus key
- Clear and/or back key
- OK key
- Keypad with arrows
- Initiation of Auto-programming order

All display screen shots are examples and may be different depending on pump configuration and infusion settings.

Display	Meaning
	At the top of the screen the last infusion is indicated. "Continue last infusion" question can be answered with Yes/No by pressing ▲ for yes or ▼ for no. Pressing yes recalls all parameters of the last infusion prior to power off. The question appears if configured in the service tool.
	Parameters can be changed (e.g. rate in mL/h) by opening the editor screen with ◀ or OK. When editing parameters, use the ◀ or ▶ to move to the digit to be programmed. The white background indicates current digit. Use ▲ or ▼ to change current setting or C key to clear the values. Text on the top of the screen indicates infusion mode and soft limit symbol.

Typical display during infusion:



Display	Meaning
	All status information is available in the bottom line of the display. The desired information can be selected by using ▼ or ▲ and will be displayed (e. g. Care Unit, drug long name, time/ VTBI remaining, drug concentration, total volume, infused totals) until changed by user.
	This prompt appears if a user tries to edit or change a parameter by pressing ◀ when that parameter is unable to be changed.
	Set pressure level with ◀ or ▶ and confirm by pressing OK. Cancel to edit pressure by using C.
	Pre-alarms are indicated by a message on the display (e.g. "VTBI near end"), an audible tone and a flashing yellow LED. To confirm a pre-alarm press OK. Operating alarms stop the infusion, an audible tone sounds and the red LED flashes. Confirm alarm by pressing OK. Confirming does not provide 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. The syringe must be removed to power the pump off. Pump will go into stand-by if the syringe is not removed.

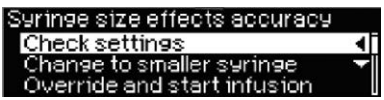
OPTIMIZING PERFORMANCE: START UP TIME, FLOW ACCURACY AND TIME TO OCCLUSION

Optimization of the Perfusor Space syringe pump performance is dependent on following several recommendations outlined below.

First, always use syringes approved for use with the Perfusor® Space (See Chapter 7) and select the smallest syringe size for the volume and flow rate of fluid being administered. Syringe size impacts start up time and time to occlusion as well as flow variability at low rates. Post occlusion bolus volume may also be increased when a large syringe is used at a low flow rate with a high occlusion limit setting.

Each syringe size has a recommended minimal flow rate (See Chapter 7.1 for table with flow rates).

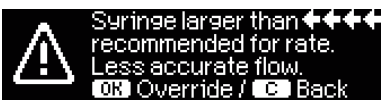
When a programmed rate falls below the recommendation for the inserted syringe, an alert will be generated.



The alert allows for 3 possible actions:

- check settings for possible re-programming
- change to smaller syringe size
- override and start infusion

When titrating a running infusion, a similar alert will occur when the rate is below that recommended for the syringe size.



The alert allows for 2 possible actions,

- override the alert and initiate the new flow rate
- go back to rate/dose editor and re-program

Second, insure proper syringe insertion and confirmation. Start up times are affected by the compliance and friction of the syringe, each syringe brand and size has unique values. Larger syringes have higher friction and compliance and therefore longer start up times. It is important to properly insert the syringe (See Chapter 1.1 to insert and

prime the syringe) and then confirm both the correct brand and size when inserting the syringe as the pump software adjusts for the characteristics of each syringe. Additionally, using the prime feature on the pump may enhance start up time.

Third, use small diameter tubing for low flow rates and minimize the length as well as the number of additional components such as stop cocks and filters.

- Use compatible components (See Chapter 7.1) which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates. This reduces the amount of time it takes the fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times. For example:
  - Tubing internal diameter: Small bore or microbore tubing is recommended when infusing at low rates
  - Tubing length: Tubing length should be minimized, when possible
  - Filters: Internal volume (deadspace) of in-line filters should be minimized
  - Connection sites: the number of connection sites such as stopcocks and Y-sites should be limited, and high risk or life-sustaining solutions should be connected as close to the intravenous access site as possible
  - Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (e.g. 50-200 mmHg) to open and allow fluid flow and may result in a sudden bolus.

Fourth, set the occlusion limit (See Chapter 2.2.1 to set downstream pressure limit), at the lowest setting for the infusion taking into consideration syringe size (smaller syringes require higher infusion pressures), patient line type, flow rate, fluid viscosity, and tubing characteristics (diameter, filters, length, etc.). Setting to the lowest occlusion limit that does not produce nuisance alarms shortens time to occlusion alarm and minimizes post occlusion bolus volumes (See Chapter 7.2 for time to occlusion and post occlusion bolus volumes per syringe size, rate and pressure setting). Post occlusion bolus occurs, in particular with larger syringes, when fluid volume builds up or gets "stored" in the system and is infused when the occlusion is removed. The Perfusor Space has software that minimizes post occlusion bolus by pulling back on the syringe plunger to minimize the amount of the bolus. This does not totally eliminate the bolus. For the maximum post occlusion bolus volume please refer to Chapter 7.

Consider the plunger force or occlusion pressure threshold setting and adjust it, as necessary. The lower the occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (e.g. lipids) the occlusion pressure threshold setting may need to be adjusted to a higher setting to reduce false alarms.

Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance (i.e. stiffness) of the syringe plunger tip. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes and faster occlusion detection.

- Use the prime feature on the pump when inserting a new syringe, changing a syringe and/or tubing

- Use accessory devices which have the smallest internal volume or deadspace (e.g. microbore tubing when infusing at low rates, shorter length of tubing, etc.)
- When addressing or clearing an occlusion:
  - Ensure the fluid flow to the patient is OFF to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing, or relieve the excess pressure through a stopcock, if present. The healthcare professional should weigh the relative risks of disconnection with the risks of unintended bolus of drug.
  - Be aware that using larger size syringes on a high plunger force setting may produce a larger post occlusion bolus due to excessive syringe plunger tip compliance.

Fifth, consider height and location of syringe pump system.

If the pump height is raised relative to the distal tip of the catheter (e.g. during patient transport), the increase in height of the syringe pump can result in a temporary increase in fluid delivery or bolus until the flow rate stabilizes. Alternatively, if the pump is lowered relative to the distal tip of the catheter, the decrease in height of the syringe pump may result in a decrease in delivery or under-infusion until the flow rate stabilizes.

ENTERING VALUES

In order to enter and/or edit an infusion parameter, the pump displays the name of the value being edited (rate, doserate, etc), format and unit of measure (dosing unit, volume, time, etc).

In the screen below, a Doserate value is to be entered, which in this case is specified as mcg/kg/h. The underbars indicate the places which can be entered both to the left and right side of the decimal point.

The value to be entered must be selected by using ▲ and ▼ to move the cursor so the desired numerical value to be changed is highlighted. Use ◀ and ▶ to move the cursor and the Up and Down arrows keys to increase or decrease the number.

Entering a new value:

For example, a value of 9.5 can be entered by pressing ▲ in the "ones" place 9 times and then press ▶ once to move the cursor to the "tenths" decimal place and pressing ▲ 5 times.

Press OK to confirm the value, as indicated in the title bar of the display.

Titrate an existing value:

Select the value to be changed by using ▶ and ◀ keys to highlight desired number, in this case the "ones" place.

To Titrate to another value, e.g. 11.5 press ▼ eight times to get 1.5

Then press ◀ to move the cursor to the "tens" place and press ▲ once .

Arithmetic logic:

An alternative method for entering and titrating values uses arithmetic logic:

Pressing ▲ one time in the "ones" place increases the value to 10.5

Pressing ▼ from the "ones" place decreases the value to 9.5

Pressing ▲ from the "ones" place 2 times increases the value to 11.5

Hard Limits:

The editor function keeps the displayed values between the minimum and maximum hard limits for the selected infusion parameter. This can be either general pump limits or drug specific limits defined in the drug library. In cases where an increase in value would exceed a hard limit, the pump will display the highest acceptable value presuming the user wanted a maximum value.

Example: Assume the selected drug has a hard limit set at 15 mcg/kg/h.

Trying to titrate from 9.5 to 19.5, press ◀ to move the cursor to the "tens" place.

Press ▲ in order to increment to 19.5. As 19.5 is above the limit, the value displayed is 15, as the hard limit is the highest acceptable value.

IMPORTANT: If a value increase or decrease is not possible due to a hard limit (as 19.5 could be expected in this case), the value of the hard limit is displayed as the highest acceptable value.

If ▼ is pressed on the above screen, the pump displays the previous value i.e. 9.5.

If ▲ is pressed on the above screen, the pump displays a clear message that the value entered exceeds the hard limit.

After the user confirms the message by pressing OK, the pump pre-fills the programming editor field with the last value programmed and confirmed prior to the value that created the alert.

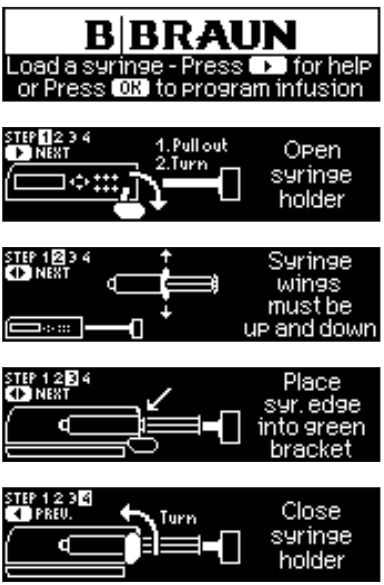
While in the editor function, ⚙ and OK are used to define and confirm a value, the C can be used to reset the value to 0.

To exit the editor function, press C again. The value of the infusion parameter reverts to the last confirmed value.

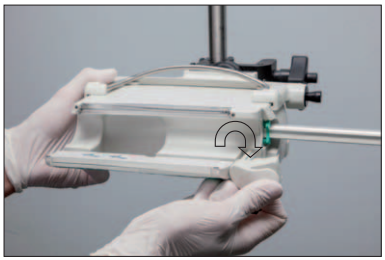
OPERATION

1.1 Inserting Syringe and Priming Line in Pump

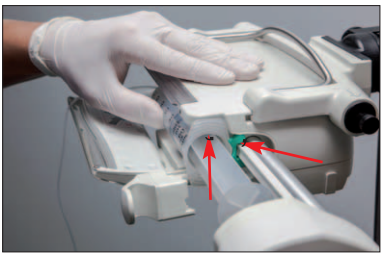
- Ensure that the pump is properly installed (see Perfusor® Space Overview). Check the equipment for completeness and damages.
- Press ⏻ to power on. The message "Self-test active" and the software version are displayed, two audible tones sound and all three LEDs (yellow, green/red and blue) flash once. The power supply indicator and the set pressure level are displayed.
- Observe B. Braun landing page and press OK to enter infusion parameters followed by syringe insertion, or press ▶ for steps required to load syringe. Use ▶ to advance through animated syringe loading steps. After step 4, open the pump door by pulling down.



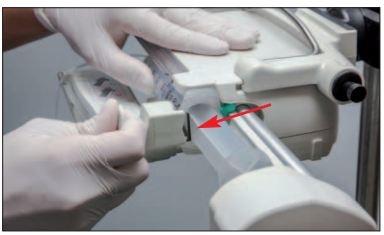
⚠ Caution: Close patient connection during syringe change.



Pull the syringe holder, which is to the immediate right of the pump door, straight out and turn completely to the right.

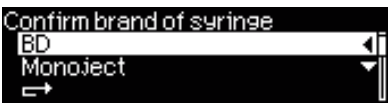


Insert the syringe with wings/flange in the vertical position so that the flange fits between the pump housing and the green syringe guide. Graduations on syringe should be facing forward and easily visible.

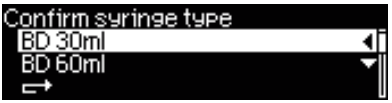


Close syringe holder by turning back to left. Note that piston brake engages to hold plunger in place until drive head closes.

Confirm syringe brand by using ▲ or ▼ to select brand and OK to confirm selection.



Confirm syringe size by using ▲ or ▼ to select size and ◀ or OK to confirm selection. Drive head engages and moves to secure syringe once brand and size are confirmed. Piston brake is released once drive head has secured syringe.



- ⚠ Caution: Manually prime the syringe and tubing to remove all air before connecting to the pump unless using the priming feature on the pump to remove air from the tubing.

  If priming is activated, press ▲ to select yes to prime syringe and note prompt to disconnect syringe from patient before priming. Press OK to confirm and begin priming. Respond to "priming stopped" message by confirming with OK. Respond to "repeat priming" prompt with ▲ for yes if line is not fully primed or ▼ for no if fully primed. Please refer to the priming volume on each disposable label.

- Connect line to the patient and observe B. Braun landing page. Press OK to program infusion.

Note: Pump automatically powers up in the drug library for all new infusions.

Note: Last infusion, if any, will be displayed with prompt "Continue last infusion?". Press ▲ for yes or ▼ for no. If yes, confirm each infusion parameter by scrolling with ⊙ and pressing OK to confirm values. If no, press OK on B. Braun landing page to program new infusion. The question appears if configured in the service tool.

1.2 Drug Library

The Perfusor® Space powers up in the drug library, providing a safety net for clinicians during programming.

The drug library allows for up to 1200 drug names in up to 10 concentrations per drug to be subdivided into 30 categories. These drugs can be assigned to 50 Care Units and 16 Patient Profiles. Drug categories allow the drug names to be subdivided, such as by drug type. Patient profiles allow one drug to have different settings such as dose limits, concentration, clinical advisories, pressure limits, loading dose and bolus settings, and

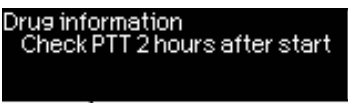
infusion type based on patient type or condition. Care Units allow drugs to have different settings based on location or classes of patients.

The maximum number of drug names in each drug library file may be limited based on the number of Care Units, concentrations, and Patient Profiles that are utilized when building the drug library.

- The pump will prompt user to enter weight for weight based dosing and BSA for m^2 dosing.

Note: Changing the weight during a weight based infusion or BSA during a m^2 infusion will result in a change in the infusion rate to deliver the programmed dose at the new weight or BSA.

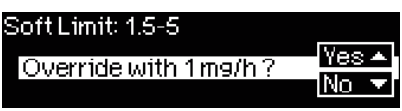
- Weight or BSA may be changed by scrolling to weight or BSA on home screen and editing weight or BSA.
- Drugs may have a clinical advisory set up in the drug library which must be confirmed by pressing ◀ or OK before proceeding.



Note: It is possible to view the clinical advisory at any time by accessing the Status menu from the home screen and scrolling to Drug Info, see Chapter 2.3 for details on the Status Menu.

The drug library provides the ability to set limits for continuous infusions around rate or doserate, intermittent infusions with limits on dose and time, loading dose and programmed bolus doses with dose and rate. In addition, default values may be entered in the drug library and will be populated in the infusion parameters on the pump, these values may be edited.

The drug library allows both soft and hard limits to be set. Soft limits may be overridden or values re-programmed per your institutional policy. Hard limits may not be over-ridden. The soft limit symbol appears to the left of the run screen, as seen in the figure below, to indicate when infusion is within, below or above limits.



Soft Limits:

The following symbols describe the display status with regard to the limits:

The infusion is within the range of the lower and upper soft limits	=	
The infusion is within the upper soft limit	=	
The infusion is within the lower soft limit	=	
The infusion is above the upper soft limit	=	
The infusion is below the lower soft limit	=	
No soft or hard limits are set	=	⚠

Hard Limits:

Two types of hard limits are possible. Hard limits may be set in the drug library for rate/doserate, and amount or time of administration for each drug. If the set rate/doserate (continuous, bolus or loading) or amount (dose or volume) is outside the values set in the drug library as a hard limit, it is not possible to exceed the hard limit.

In addition, the pump has hard limits, the maximum rate for the syringe size cannot be exceeded. Additionally, the pump may be set in the configuration file to have maximum limits for both continuous and bolus rates which cannot be exceeded. These also produce hard limit alerts when attempting to program values which exceed the set limit.

The hard limit message stays on the screen until confirmed by the user and the editor reverts to the last value that was confirmed.

Below are 3 examples of values entered that exceed the hard limit of the drug library or the pump:

Example 1:
Drug with an upper hard limit set at 15 mcg/kg/h

Current value is 10 mcg/kg/h

Pressing the ▲ once with the cursor in the tens column would produce a value of 20 mcg/kg/h which is above the hard limit of 15 mcg/kg/h. The pump displays 15 mcg/kg/hr, the hard limit value.

When ▲ is pressed again, the hard limit message is displayed and remains until confirmed by pressing OK.

Upon pressing OK, the pump editor field reverts to the last confirmed value programmed prior to the value that created the alert.

Example 2:
Drug with a lower hard limit of 0.2 g

Current value is 0.3 g

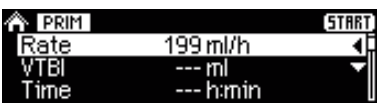
Pressing ▼ once with the cursor in the tenths column, displays value of 0.2 g which is at but not below the hard limit.

When ▼ is pressed once again with the cursor in the tenths column the hard limit message is displayed and remains until confirmed by pressing OK.

Upon pressing OK, the pump editor reverts to the last confirmed value programmed prior to the value that created the alert.

Example 3:
Pump maximum rate depends on syringe size, see syringe rate table in Chapter 7. For this example the inserted syringe is 5 mL with a max rate of 200 mL/hr.

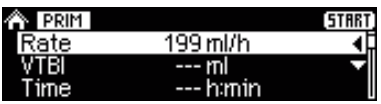
Current value 199 mL/hr



Pressing ▲ once with the cursor in the hundreds column displays value of 200 mL/hr which is at but not above the hard limit.

When ▲ is pressed, once again with the cursor in the hundreds column, the hard limit message is displayed and remains until confirmed by pressing OK.

Upon pressing OK, the pump editor field reverts to the last confirmed value programmed prior to the value that created the alert.



Note: It is important to carefully check default values to be certain they match the physician order.

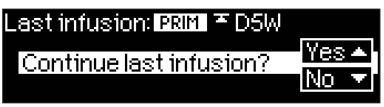
1.3 Programming a PRIMary Infusion in the Drug Library

When the syringe has been loaded and the infusion line primed, the B. Braun landing page appears.

- Press OK to program an infusion.

Note: Programming of infusion parameters may be done prior to loading the syringe by pressing OK from this screen.

Note: When a previous infusion has been programmed on the pump, prompt "Continue last infusion?" will be displayed with previous infusion information.



- Select the Care Unit using ▲ and ▼ to scroll through the list and press ◀ or OK to make selection.

Note: A basic infusion may be selected from this list. Basic infusions are addressed in Chapter 1.10.

Note: Scroll bar appears on all screens when additional information is available, use arrow keys to scroll. In all menus the screen always loops back to the top when bottom of list is reached.

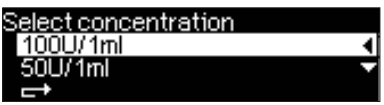
- Select Patient Profile using and confirm with or . If no profile is set in the drug library, this step will be skipped.

- Select the drug category using and confirm with or . "All drugs" may be selected or search by specific category. If no categories have been set in the drug library, this step will be skipped.

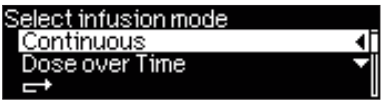
- All drugs are listed alphabetically. Navigate through the list with and or use and to quickly skip through the alphabet in groups of 3 (i.e. ABC-DEF) . Press or to select drug.

Note: Care Unit may be changed on any of the above navigation screens. This will require re-programming the therapy when a Care Unit change is done prior to beginning the infusion. See Chapter 1.8 for instructions on changing the Care Unit while infusing.

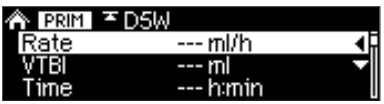
- Choose drug concentration using and , press or to select.

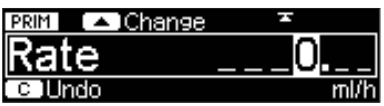


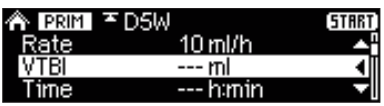
Note: Some drugs may be set up for more than one infusion type, such as Continuous and Dose over Time. Choose the mode using and . Select with or . Refer to Chapter 1.4 for instructions on Dose over Time therapy.



- After drug and concentration selection, the home screen will be displayed with rate, doserate or total dose highlighted in white depending on the infusion type and drug library settings. To program rate or doserate, press ◄ or OK to open the editor screen. The total dose editor will be displayed for Dose over Time infusions.
- When editing parameters, use the ► and ◄ arrow keys to move to the digit to be programmed. The white background indicates current digit. The C may be used to clear existing values. Use ▲ or ▼ to program new values. Text on the bottom of the screen indicates the parameter that changes based on programmed value in the editor, as an example, if rate is being edited, the time will appear on bottom of screen and will change based on rate change (this requires VTBI to have been entered). The top of the screen indicates infusion mode, confirm value with OK, and soft limit symbol.







Note: If flow rate is too high for inserted syringe, prompt indicates value not possible with current syringe. Upon confirming prompt with OK the display returns to editor for re-programming.

Note: Home symbol is displayed in upper left of home screen. Home screen may be accessed from run screen by pressing C.

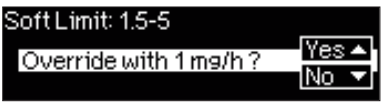
Note: Default values may be present when set in drug library. In this case the editor screens do not appear. Confirm values and press Start/Stop to begin the infusion or press ◄ to edit default values. Observe green LED and arrows moving right to left in upper right of display indicating infusion is running.

Note: It is necessary to confirm that default values match physician order.

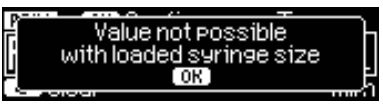
Note: While programming, the soft limit symbol appears above the value, indicating where the value is in relation to the soft limits.

- Soft Limit Warning: a soft limit warning will be generated upon confirming a value that is outside the soft limit set in the drug library. A prompt will appear asking to override with programmed value. Press ▼ for No to reprogram, editor will appear with previously confirmed value. Press ▲ for yes to override soft limit.

Note: Change in soft limit symbol when overridden.

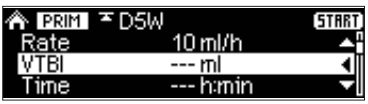


- Hard Limit Warning: when a hard limit value is exceeded, a message is displayed indicating the value exceeds drug or pump limits. Press OK to confirm alert, pump returns to the editor screen to re-program.



Note: The Perfusor® Space delivery rates are determined by the syringe size. When a rate is set that exceeds the possible rate for the inserted syringe, the display will indicate programming is not compatible with the syringe. It is possible in the service program to set lower rate limits for continuous and bolus infusions. When these limits are set in the pump configuration file, a hard limit alert is generated when programming exceeds set pump limits.

- Scroll down to enter and/or review VTBI and Time. VTBI is not required, pump will continue to deliver until syringe end alarm unless VTBI or time are entered which are less than syringe volume or time to completion at current rate. Time will be calculated when VTBI is entered. When time is entered, VTBI is calculated if rate/doserate has been programmed.
- When all parameters have been entered and confirmed with OK, "Start" appears in upper right of display.



- Press Start/Stop to begin infusion.

Note: PRIM will appear in upper left of screen to indicate PRIMary is running. When pump is stopped, PRIM appears next to home symbol.

Titration: The doserate/rate may be titrated while the pump is running.

- Press ◀ to open editor.
- Program desired value, press OK to confirm. The new doserate/rate is not active until confirmed.

Failure to confirm the new value results in a reminder alarm in 30 seconds. The pump continues to infuse at the old rate until confirmed.

Note: Respond to soft and hard limit dose alerts that occur during titration as described above.

1.4 Programming an Intermittent Dose Over Time Infusion

Dose over Time is used to administer a specific dose of a medication in a specific time. Dose over Time can only be used within the drug library. Limits can be set around both total dose and total time in the drug library. The rate and VTBI are calculated based on the drug concentration, dose and time. The rate may not be edited.

Note: Changing the VTBI will result in a change to the dose and the rate.

The symbol appears next to the mode symbol on the pump display when a medication is set up as Dose over Time.

To Program a Dose over Time infusion:

- Selected drug must be set for dose over time in the drug library.
- Choose drug per steps in Chapter 1.3.
- Enter weight or BSA, as prompted, based on dose settings in drug library.
- Enter total dose and press (OK) to confirm.

- Enter Total time and press (OK) to confirm.

Note: When default values have been set in the drug library there will not be a prompt to enter values. Values may be edited by scrolling to the parameter and pressing the (◀).

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

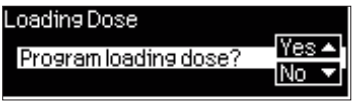
1.5 Programming a Loading Dose in the Drug Library

The Perfusor® Space allows for the delivery of a loading dose for medications that have been set up in the drug library for loading dose. Loading doses may have soft and hard limits set in the drug library. The pump will prompt and allow the user to proceed with a loading dose or go right to the continuous infusion. Once "No" has been selected to "Program Loading Dose?" it is not possible to recall it on the pump without

exiting and clearing the infusion by pressing the C and re-programming the drug from the beginning.

To Program a loading dose:

- Press ▲ to answer yes to loading dose prompt.



- Enter loading dose amount using ⁘, confirm with OK.

- Enter loading dose time using ⁘, confirm with OK.

Note: Soft and Hard limit alerts will be generated based on drug library settings.

- Press ◀ to access doserate/rate editor to set continuous infusion.
- Enter doserate or rate for continuous infusion and confirm with OK.

- VTBI or Time may be entered but are not required.

Note: "LD dos and Start" alternate in upper right corner of screen.

- Press Start/Stop to begin infusion.

Note: The word LOAD is super-imposed on the run arrows.

Note: The loading dose may be stopped at any time by pressing the Start/Stop. Press Start/Stop to deliver remaining loading dose. There will be nothing infusing until Load Dose is resumed or canceled and continuous infusion started.

- When pump is stopped intentionally or by an alarm state, the pump will display the amount that has been delivered of the total amount programmed. Press OK to confirm.

- Upon pressing Start/Stop, the pump will prompt to deliver remaining loading dose. Press ▲ for yes, ▼ for no.

Note: Once "No" is selected, it is no longer possible to recall the loading dose.

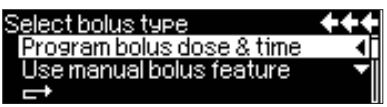
1.6 Programming a Bolus with Dose and Time in the Drug Library

The Perfusor® Space allows for delivery of a programmed bolus for drugs which have been set up in the drug library for bolus dosing.

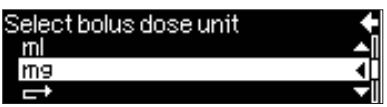
- Press BOLUS.
- Select Program bolus dose and time.

Note: Drugs which do not have manual bolus enabled will skip this step.

Note: Bolus rate and volume is limited by syringe size. See Chapter 7.1



- Select dosing unit and confirm with OK.



Note: Pump defaults to bolus units set in the drug library. If the bolus ordered is in different units, press ▲ or ▼ to change units. The pump will perform all necessary calculations and apply dosing limits set in the drug library.

- Enter Bolus amount and confirm with (OK).

- Enter Bolus time and confirm with (OK).

- Review and confirm bolus parameters and press (BOL) to begin bolus.

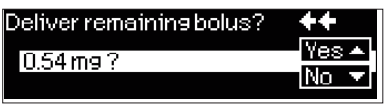
Note: The word Bolus superimposed over the run arrows is displayed on the screen.

Note: Failure to press BOL to start bolus will result in reminder alarm.

- The pump will automatically convert back to the continuous infusion when the bolus is complete.

Note: The bolus may be stopped at any time by pressing the (C), the continuous infusion will then run. Press (BOL) to deliver remaining bolus.

- Press (Start/Stop) to stop the infusion entirely.
- When bolus is stopped intentionally by pressing (C), or pump is stopped by an alarm state, the pump will display the amount that has been delivered of the total amount programmed. Press (OK) to confirm.



- If pump was not running, as after an operating alarm, press Start/Stop to begin the infusion and respond to prompt to deliver remaining bolus as previously described in this chapter.

  The last bolus dose is recorded in the status menu, refer to Chapter 2.3.

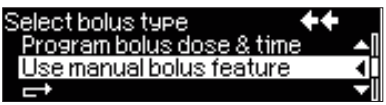
1.7 Manual Bolus

The Perfusor® Space allows for the delivery of a manual bolus when the drug is set up in the drug library for a manual bolus. A manual bolus requires the user to continually hold the bolus button to deliver the bolus.

Note: Drug library limits do not apply to manual boluses.

To deliver a manual bolus:

- While an infusion is running, press BOL.
- Select "Use manual bolus feature".



- Press and hold BOL.
- Bolus amount will count up on pump display.

Manual bolus is limited to 10 seconds.

The pump may be set in the configuration data to emit an audible tone every 1 mL of solution delivered.

Bolus amount will be displayed when 10 seconds is complete or BOL is released.

The pump converts to the continuous infusion when the BOL is released or 10 seconds is completed.

1.8 Changing Care Unit

The Perfusor® Space allows the Care Unit to be changed when patients are transferred. All drug library limits for the new Care Unit are immediately applied and a limit alert appears if soft limits are exceeded in the new Care Unit. If a hard limit is exceeded the pump reverts back to the previous Care Unit. The pump does not allow a Care Unit change in the following circumstances: if the drug or concentration are not available in the new Care Unit, if bolus settings do not match, or if hard limit is exceeded.

To change a Care Unit:

- While infusion is running press the to get to home screen.
- Scroll to "Change Care Unit", select with or .

- Scroll to desired Care Unit and select with or .
- Pump will display confirmation of new Care Unit.

The doserate, dose or time editor will appear and require confirmation if parameter exceeds the soft limit in the new Care Unit. The soft limit warning will be shown requiring an override or new programming to proceed as in Chapter 1.2. Pump will display message if Care Unit was not changed because drug or drug concentration is not available in new Care Unit or hard limits are exceeded.

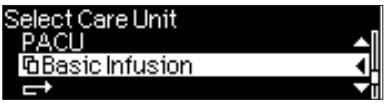
1.9 Changing Display While Pump is Running

- While pump is running, press to choose preferred value to display on bottom left corner of display.

Values displayed will vary with type of therapy and may include drug long name, concentration, volume totals, remaining time, Care Unit, etc. Displayed value will remain until changed by user.

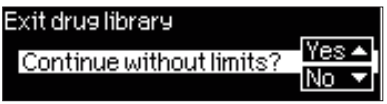
1.10 Basic Infusion (programming the pump outside of the drug library)

The Perfusor® Space allows programming outside the drug library, referred to as a Basic infusion. To program a Basic infusion, select "Basic Infusion" from the Care Unit, Patient Profile, Drug Category or Drug selection screens.



- The pump provides a prompt that programming outside the drug library has no safety limits, press OK.

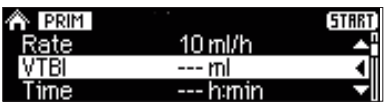
- A second prompt requires responding yes with ▲ to "Continue without limits?".



- Respond "yes" or "no" to "Use dose rate calc?" (if configured). See Chapter 2.2.3

Note: While under Basic Infusion, the pump is not using any drug library safety limits.

- The pump requires user to enter rate, or VTBI and time which results in calculation of rate. The pump will determine, but not display, the VTBI by sensing the syringe plunger location and infuse until the syringe end alarm or VTBI may be programmed to a value less than the syringe volume.



Programmed bolus and manual bolus are also available in Basic mode, see Chapter 1.4, 1.6, and 1.7. The target symbol →| appears next to the programmed value, other than rate, that was first set by the user. When a rate titration is made, the value with the →| is not changed, rather the 3rd calculated value is adjusted for the new rate. As an example, if a rate of 10 mL/hr and time of 20 hrs is programmed, the VTBI is calculated. When rate is titrated, the VTBI is changed, not the time. If the rate and VTBI are initially programmed, the time would change with a change in rate. The parameter with the target symbol does not change during titration of either of the other 2 parameters.

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

- 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 .

Rate titration will result in adjustment of time. Alternatively:

2.) Enter rate and VTBI: The infusion time will be calculated and displayed on the bottom of the display.
Rate titration will result in re-calculation of time.

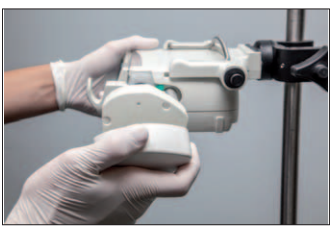
3.) Enter rate and time: The infusion volume will be calculated and displayed on the bottom of the display.
Rate titration will result in re-calculation of VTBI.

1.11 Syringe Change and New Therapy Start

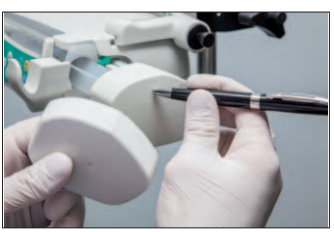
Note: Always clamp and/or disconnect the line from the patient before changing syringe to avoid inadvertent flow.

- Press to stop the delivery. The green LED goes out. Clamp and disconnect line from the patient.
- Open the syringe holder and respond to prompt that IV-line is clamped, syringe driver will open. Lower pump door and remove syringe.

Note: In the unlikely event the plunger plate is not released by the claws, remove cover from the drive head and press the emergency release button to unlock the claws on the drive head. The emergency release button is located on the exterior of the drive head. It can be released by being pressed by a pointed object (e.g. pen). The claws can then be opened manually and the syringe removed. The device should then be sent to service for repair.



Remove drive head cover.



Insert pointed object (e.g. pen) into hole on end of drive head to release claws.

- Insert new syringe per Chapter 1.1. Open the roller clamp.
- If prompted, prime the pump with ▲. Then press ▼ to proceed when priming is complete.
- Connect infusion line to patient and check the parameters with ⚙.
- Start the infusion by pressing Start/Stop.

Note: A new infusion can be started at any time during a stopped infusion. Press C and respond yes to prompt "Exit and clear infusion".

1.12 End of Infusion

- Press Start/Stop to stop the infusion. The green LED goes out. Close the roller clamp and disconnect the line from the patient.
- Remove syringe per Chapter 1.11.
- Close door and press ⏻ for 3 sec to power off the pump.

Note: When pump is powered up, user will be prompted to continue last infusion, answering No returns to B. Braun landing page.

Note: Pump cannot be powered off with syringe inserted.

1.13 Standby Mode

The pump may be placed in standby rather than powering off so that re-starting an infusion is quicker.

- Press Start/Stop to stop the infusion, leave syringe inserted in pump. Then press and hold ⏻ for 3 sec.
- The pump is now in Standby.

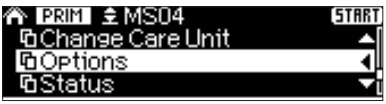
While the pump is in the standby mode, the display shows infusion mode, drug name and the remaining time for standby mode. Change remaining time by pressing ◀, standby may be set from 1 min to 24 hours. Exit standby by pressing C. The pump will alarm when the standby time expires.

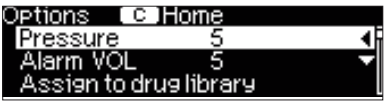
- Press C to cancel standby.

PUMP MENUS

Menus are accessed from the Home screen using . Press while pump is running to access home menu. All menus may be accessed while the pump is running. Features displayed in the menus are determined by your facility and set in the service program. All features listed below may not be available.

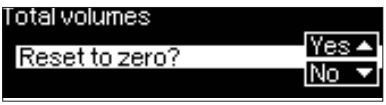
- To edit a menu item, select the desired menu item in the Home screen and press . Then select desired function with and follow the directional arrow prompts.





2.1 Infusion Totals

- Infusion totals may be cleared by scrolling to "Infusion Totals" while in Home screen. Select with . Total volume is displayed. Press to clear and respond to prompt to zero the value.



Pumps with U15 software: The infusion totals are cleared when cleared by user, on power cycle and when previous infusion is not continued if prompted on power up.

Pumps with U 11 and U12 software: The infusion totals are cleared when cleared by user and when previous infusion is not continued if prompted on power up. Totals are NOT cleared on power cycle when no prompt to continue last infusion is configured.

To determine SW version go the Status menu on the home screen and scroll to version

2.2 Options

2.2.1 Downstream Occlusion Pressure

The downstream occlusion pressure setting is the threshold at which the plunger force or occlusion pressure threshold will result in an occlusion alarm. The lower the plunger force setting or occlusion pressure threshold setting, the shorter the occlusion detection time. The higher the pressure level is set, the higher the pressure level must rise before triggering an occlusion pressure alarm.

⚠ Caution: Consider the plunger force or occlusion pressure threshold setting and adjust it, as necessary. The lower plunger force setting or occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (e.g. lipids) the plunger force or occlusion pressure threshold setting may need to be adjusted to reduce false alarms.

- Enter "Pressure" in Options Menu by pressing ◀ to set downstream pressure limit.
- Choose between nine pressure levels (1=lowest level; 9=highest level) by pressing ◀ or ▶ and confirm entry with OK. Pressure levels and equivalent mmHg are displayed when left arrow is pressed while in pressure menu.

Note: The pressure will remain at set level until changed by user unless the drug selected had a pressure level set in the drug library. When infusion is cleared by pressing the C key or pump is powered off, pressure level returns to default value set in service program unless drug selected has a different pressure level set in the drug library.

2.2.2 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.

Note: Alarm volume remains at set level, even during power cycle, until changed by user.

2.2.3 Dose Rate Calculator

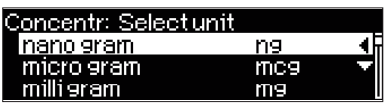
The Dose Rate Calculator may be used to calculate a doserate for a medication that is not in the drug library. While the pump will calculate the rate, it is important to realize there are no dose limits.

- To access the Dose Rate Calculator go to the Home screen and scroll to Options.

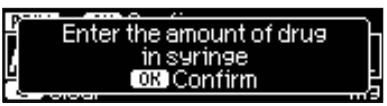
Note: Pump may be set up in service program to prompt "Use Dose Rate Calculator?" when a basic infusion is selected.

- Press OK to prompt to select concentration units.

- Scroll to and select units for concentration (units of drug in syringe) using , confirm with OK.



- Press OK to prompt for entering amount of drug in syringe.

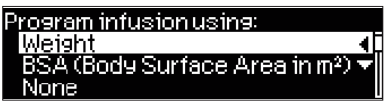


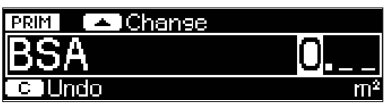
- Enter the amount of drug using and confirm with OK.

- Press OK to prompt for entering the volume of the syringe.

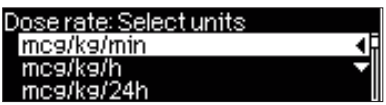
- Enter the volume of the syringe using and confirm with .

- Select patient parameter, if any, for dosing calculation. Choices are weight, BSA, or none.





- Select the doserate units.



- Enter doserate using and confirm with .
  Confirm and start infusion.
- Enter VTBI or Time if desired.
- To exit Dose Rate Calculation, the pump must be stopped. Press the from Home screen and answer "yes" to "Exit and clear infusion?"

Assigning a basic or doserate calculation infusion to drug library:

An infusion started without using the drug library, either a basic or doserate calculation, may be assigned to the drug library without stopping the infusion.

- Access the Home screen by pressing the .
- Scroll to and select "Options".
- Scroll to and select "Assign to drug library".

- Program for the drug library following the same steps covered in Chapter 1.3 to program within the drug library, beginning with selecting the Care Unit.

2.2.4 Data Lock

The pump offers 2 levels of security to prevent unauthorized access which may be set in this menu. A third level may be set in the drug library by drug. A four digit code (default setting "9119") must be entered within 20 seconds to prevent a data lock alarm. The code can be changed via the service program for Level 1 and Level 2.

Level 1:
All keys except Start/Stop are locked and require entry of data lock code. The syringe may be changed.

Level 2:
Functions the same as level 1 and in addition requires code to start infusion.

Note: Once code has been entered, changes may be made for 20 seconds until the pump locks again and requires re-entry of the code.

Level 3:
Functions the same as level 2 but has a custom code set in the drug library. In addition, the pump display may have a custom message.

Event	Level 1	Level 2	Level 3
Syringe Change	□	×	× with code for level 2/3
Start infusion	□	×	□
Change parameters	×	×	×
Stop infusion	□	□ %	□
Powering off pump / Standby	□	×	× %
Displays customized message when running	NA	NA	□

□ = possible | × = requires code | %= followed by data lock alarm

Activation of the function:

- Open data lock in Options Menu with ◀.

- Select between level 1 or 2 with ◀ and ▶ and confirm with OK.
- Enter code with and press OK in order to activate data lock.

Note: Upon activation of data lock, the symbol appears on the run screen to the right of the rate/dose indicating changes are only possible after entering the code. If the wrong code is entered four times the pump will go into an audible alarm, the yellow LED will light, and the pump display indicates invalid code.

- To deactivate data lock, select "Off" in the data lock menu, press OK.

2.2.5 KVO-Mode

The pump can continue the infusion with a preset KVO rate after an infusion time or VTBI has ended and syringe is not empty. The rate and duration of the KVO delivery is set in the service program. When KVO feature is activated in the service program, the pump will automatically go into KVO unless it has been turned off in the Options menu.

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

Note: KVO function is disabled in Dose over Time.

2.2.6 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.

2.2.7 Bolus Rate

The pump has a default bolus rate which is set in the service program. This rate is used for manual bolusing. For a programmed bolus, this rate will be converted to a time in the time editor screen if no default bolus rate has been set in the drug library and may be changed by adjusting the time.

Note: Bolus rates and volume may be limited by syringe size, see Chapter 7.1.

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

2.2.8 Date / Time

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

2.2.9 Macro Mode

The infusion rate appears much larger and the drug name much smaller 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.

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

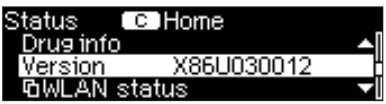
2.2.10 Wireless Activation

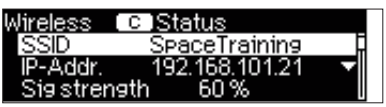
Allows wireless to be set for active or inactive.

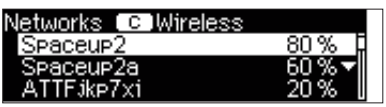
2.3 Status Menu

The status menu is accessed from the Home screen. In the status menu it is possible to review the following:

- Battery time remaining at current infusion rate
- Last bolus amount, date and time
- Drug info which includes Care Unit, drug file creation date, current drug selection, Patient Profile and clinical advisory (if any).
- Pump software version
- Wireless status
- Syringe selection







ALARMS

The Perfusor® Space is equipped with an audible and optical alarm signal.

Alarm-type	Audible signal	Optical signal			Staff call	User confirmation
		Red LED	Yellow LED	Text		
Device Alarm	yes	flashes	off	device alarm and alarm code	yes	Follow the instruction on the display to press OK.
Operating Alarm	yes	flashes	off	alarm type	yes	Press OK to acknowledge and cancel alarm
Pre-Alarm	yes	off	constant on	alarm type	(de)activate via service program	Press OK to acknowledge and cancel alarm
Reminder Alarm	yes	off	constant on	alarm type	yes	Press OK to acknowledge and cancel alarm
Alarm Hint	no	off	off	alarm type	no	Message disappears without confirmation.

3.1 Device Alarms

When a device alarm occurs, the infusion is immediately stopped and display indicates "device alarm" with a code. The audible alarm is permanent. Press ⏻ for 3 seconds to switch off the device. Then switch the device on again by pressing ⏻. In the case of a repeated device alarm the pump must be sent for service.

3.2 Pre-Alarms and Operating Alarms

Pre-alarms:
Pre-alarms are set in the service program. Pre-alarms occur a few minutes (specific time set in service settings) prior to operating alarms. During pre-alarms an audible tone sounds, the yellow LED is constantly on and a staff call is activated (optional). The display message varies depending on the reason for the alarm. The signal tone and the staff call are turned off with OK. Display and LED stay in pre-alarm until condition causing the pre-alarm results in an operating alarm. Pre-alarms do not stop the infusion.

Display message	Pre-alarm reason
"VTBI near end"	The programmed volume is almost infused.
"Time near end"	The programmed time is almost over.
"Syringe near end"	Syringe volume is almost infused.
"Battery near end"	The battery is almost discharged.

"KVO mode"	VTBI or time are complete and the pump converted to the KVO rate.

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

Operating alarms:
Operating alarms immediately stop the infusion. An audible tone sounds, the red LED flashes and a staff call is activated (optional). The display states "Alarm" and the reason for the operating alarm. The alarm tone and message as well as the staff call are turned off with OK. Correcting the alarm state depends on the cause of the alarm.

Display message	Alarm reason
"Syringe end"	Replace with new syringe. Due to different syringe tolerances some syringes may not empty completely. See Chapter 7.1 for more information.
"VTBI infused"	The programmed volume was infused. Insert new syringe and/or reset VTBI.
"Time expired"	The programmed time has ended. Insert new syringe and/or reset time.
"Battery empty"	The battery is discharged. The battery alarm will be on for 3 min. Then the pump will automatically turn off. Plug pump in immediately to re-charge battery.
"Downstream occlusion"	The set downstream pressure level was exceeded. Post occlusion bolus reduction is automatically initiated by the pump. Check tubing for kinks , closed stopcocks, filter patency, and IV site. Increase occlusion pressure if necessary per your institutional policy. ⚠ Warning: Ensure the fluid flow to the patient is OFF to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing, or relieve the excess pressure through a stopcock, if present.

Display message	Alarm reason
"KVO time finished"	The KVO time has ended. Program new settings.
"Syringe holder"	Syringe holder opened during an infusion.
"Battery cover removed"	The battery cover is not properly engaged on the battery compartment. Reposition cover, listening for click when battery cover is locked in place.
"Standby time expired"	The set standby time has ended. Set new standby time or initiate infusion.
"No battery inserted"	It is not possible to use the pump without a battery. Send pump to biomed.
"Drive blocked"	Drive is blocked from moving due to external interference. Check syringe drive, if alarm persists send to service.
"Calibrate device"	Return to service for calibration.
"Claw Malfunction"	Emergency release (See Chapter 1.11) was pressed. Remove syringe and send for service.
"Pump set back to default settings"	Pump settings could not be restored. Enter infusion parameters again.
"Infusion values were cleared"	Infusion data could not be restored. Enter infusion parameters again.
"Data lock"	An attempt was made to access the pump without entering the code. Enter the correct code.
"Syringe plunger plate not locked"	The syringe's plunger plate is not in contact with the plunger plate sensor. Check syringe placement.

The red LED extinguishes and audible alarm ceases with the acknowledgment of the operating alarm.

3.3 Reminder Alarms

Reminder alarms occur in 2 different scenarios.

1. A syringe is inserted, the pump is not infusing, programming is incomplete, and there has been no interaction with the pump for two minutes. An acoustic tone sounds, the yellow LED is constantly on and a staff call is activated (optional).

a) The display states "Reminder alarm" and reason for alarm.

b) The display states "Programming not done"

Confirm alarm with OK and continue to program.

2. An editor screen was open for programming but no values were confirmed or values were entered but no syringe is inserted in pump. An acoustic tone sounds in 20 seconds, the display states "Value not confirmed", the yellow LED is constantly on and a staff call is activated (optional).
   Confirm alarm with OK and continue to program infusion.

Sample reminder alarms include:

Display message	Alarm reason
"Bolus NOT running"	BOL was not pressed after programming bolus dose and time.
"Order still pending"	Autoprogramming order was sent to pump but not confirmed.

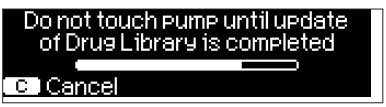
3.4 Alarm Prompts

A prompt provides direction to assist in properly operating the pump. (e.g. "Bolus function disabled", "Download failed", or "The parameter cannot be modified"). Prompts do not have to be confirmed and will disappear within a few seconds.

WIRELESS DRUG LIBRARY UPLOAD

The pump has the ability to accept new drug library files wirelessly. A file symbol will flash alternately with the wireless antenna symbol on the top of the pump display when a new file is available. The wireless antenna symbol is seen on run screen, standby screen and when pump is powered off and plugged in.

- Press Start/Stop to stop infusion when patient condition allows.
- Clamp and disconnect line from patient, remove syringe per Chapter 1.11 and 1.12.
- Power pump off.
- Wait 10 seconds, progress bar appears on pump. Do not power pump back on until Drug Upload is complete as indicated by progress bar.



- Display will indicate drug library update is successful when complete. On power up, display indicates new drug library is activated on pump.

Note: Canceling the drug library update will remove all drug library files from the pump. A small drug library may load very quickly and not be able to be canceled.

- Press ⏻ to re-start pump, respond to 2 prompts that all values are cleared and new drug library has been loaded.

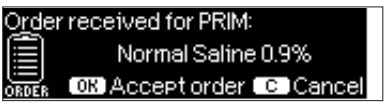
- Confirm prompt that previous programming values have been cleared. New drug library has been activated on pump.

AUTOPROGRAMMING

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

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

- Using the hand held device or laptop, review the order and follow your hospital protocol for scanning the syringe, patient, pump and nurse (optional).
- For initial order ensure pump is on B. Braun landing page (press C to return to landing page).
- Once order is confirmed on the hand held or laptop, prompt EHR to send order directly to pump. The order will arrive and appear on the pump within 10 seconds.
- New Order message will appear with drug name and mode.



- Press OK to accept or C to cancel order and respond to prompt.
- Select Care Unit and Patient Profile as in drug library programming in Chapter 1.
- Pump will search for drug library match.

Note: If no drug library match, which may be due to no matching name, concentration or dosing units, pump displays reason for no match and depending on your hospitals configuration either allows programming outside the drug library per Chapter 1.10 or rejects order completely. An order that is confirmed outside the drug library will have a triangle with an exclamation point on display to indicate there are no drug library settings.

- Scroll to each value to confirm using .

Note: Order may be canceled prior to confirming order.

- Once all values are confirmed, the Home screen is displayed.

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

- Press Start/Stop to start infusion.

Updates to Current Primary Infusion

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

New Primary Infusion:

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

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

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

BATTERY OPERATION AND MAINTENANCE

The battery module of Space guarantees operation independent of AC power when transporting patients. The wireless battery module contains a wireless transceiver module to allow data transmission during these transports or when connected to AC power.

6.1 General

The Perfusor® Space is equipped with a NiMH or Li-Ion battery. The device is equipped with protection against overcharge and deep depletion. The battery pack is charged by the pump when connected to AC power. When disconnected from power or in case of power failure, the pump automatically switches to battery power.

Note: Prior to a prolonged storage of the pump (> 5 months), the battery pack must be completely charged and then removed from the pump.

If the battery symbol on the display is blinking while connected to AC power, the battery is either discharged or has a reduced capacity and pump must remain plugged in while in 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 lifetime 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 approximately 500 times before its lifetime decreases.
- When the pump is not connected to AC 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 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.

The wireless is only available when using a battery module with a wireless transceiver and the wireless function is activated via the service program (HiBaSeD) or within the Options menu of the pump.

The wireless battery module contains a wireless transceiver module to allow data transmission during transports or when connected to AC power.

The wireless operation mode supports 802.11 a/b/g/n with static IP-address setting or DHCP in ad-hoc mode or within an infrastructure.

⚠ Caution: Exposure considerations require that a 20 cm (8 inch) separation distance between users and the installed antenna location shall be maintained at all times when the module is energized. OEM (Original Equipment Manufacturer) installers must consider suitable module and antenna installation locations in order to assure there is 20 cm (8 inch) separation, and end users should also be advised of the requirement.

6.2 Safety Instructions

Safety Instruction for B. Braun Battery Pack SP (Li-Ion)
Battery pack is suitable only for use with B. Braun Space Infusion devices. Please follow local ordinance and/or regulations for disposal. Fire or chemical burn hazard may occur if battery is mishandled. To avoid possible injury:

- Do not open or expose to heat above 80°C (176°F).
- Do not use damaged Battery Packs.
- Do not attempt to disable.
- Do not short circuit.
- Do not expose it to water or rain.

⚠ Caution: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

This device/firmware contains components that are licensed under the GNU General Public License version 2 (see Chapter 9).

To receive the source code of these components as required by that license, please get in contact with your local distributor.

⚠ Caution: The recommendations of IEC 80001 should be observed.

Note: In case of electrostatic discharge, pump may need to be plugged into wall outlet to re-start the battery.

The battery is charged by the pump during connection to AC power. When disconnected from AC or in case of power failure, the pump automatically switches to battery power.

Connection to AC power is displayed by the symbol in the main menu of the pump. Recharging of WiFi battery while connected to AC power and active WiFi is ensured as long as environmental temperature outside Infusion pump is ≤ 35 °C (95°F).

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

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

The status of the wireless connection is displayed on the run screen. When the wireless transmitter is switched off, wireless symbol will show "off".

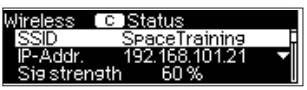
If the wireless is activated, the status of the connection is shown.

Wireless operation mode is switched on but no connection to the network.

Note: An "X" through the wireless antenna indicates wireless connection has been lost, contact your bio-medical engineering or IT department to determine cause.

Wireless operation mode is switched on and connection to the network is established.

Additional information regarding the status of the wireless connection can be viewed in the Status menu.

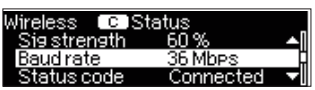


SSID: The Service Set Identifier, or SSID, is a name that identifies a particular 802.11 wireless LAN. The SSID can be up to 32 characters long and can only be set with the service tool HiBaSeD.

IP-Address shows the assigned IP address of the infusion pump.

Signal strength: The signal strength shows the quality of the connection.

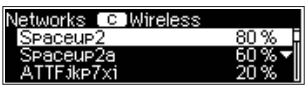
Baud rate is the maximum communication speed in mega bits per second (Mbps). The maximum baud rate strongly depends on the wireless standard (802.11 a/b/g/n).



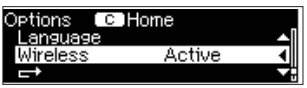
Status code displays the current status of the wireless connection. If there is a problem with the wireless connection an error code is displayed. Error codes can be:

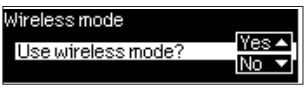
10 to 12: internal malfunction
13: wireless interface does not find any network
14: wireless interface is trying to connect to a network
15: the interface is being configured
16: the interface is waiting for authentication
17: DHCP request is sent out
19: internal failure

Available Networks opens a sub menu showing the available wireless networks (SSID) and their signal strength. It is not possible to change to another network.
The Space pump always connects to the network with the highest signal strength.



Within the Options menu the wireless mode can be switched on or off.





6.3 Battery Maintenance

To accurately balance the battery capacity, a cyclical battery maintenance is necessary. The pump asks the user to perform battery maintenance every 30 days when the feature is enabled in the service program. The battery maintenance mode detects a possible capacity loss (e.g. through aging of the battery pack) and then the capacity/running time will be recalculated. After a longer storage time or a longer operation without battery maintenance, the battery pre-alarm time may no longer be maintained. In this case it is necessary to perform 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 approximately twelve hours.

⚠ Caution: When the battery maintenance has not been completed, there is a possibility of a reduced battery operating time.

SYRINGES FOR USE WITH PERFUSOR® SPACE

The syringes listed in the following tables may be used with the Perfusor® Space, however, this may not be a complete list of those syringes qualified for use on the Perfusor® Space Infusion Pump. Please reference the Perfusor® Space SWU Compatible Syringes document for additional syringes which may be qualified for use with the Perfusor® Space Pump. Contact your local Sales/Marketing representative for a copy of the Perfusor® Space SWU Compatible Syringes document.

Syringes listed include both those manufactured by B. Braun and other suppliers. Because B. Braun does not control the quality of syringes from other manufacturers it is possible that quality inconsistencies can lead to changes in technical properties of the syringe performance in the pump. B. Braun is not liable for deviations caused by use of a syringe from manufacturers other than B. Braun approved syringes.

7.1 Syringe Flow Rates and Infusion Volumes

The table below lists all syringes validated for use with parenteral, enteral or epidural infusions with Perfusor® Space and includes information on flow rates and infusion volumes. Only syringes validated for epidural use may be used for epidural infusions and are indicated in the table. Neomed syringes are only for enteral use and require use of compatible tubing.

Manufacturer/ item #	Size	Minimum rate	Minimum recommended rate [1]	Maximum rate	Minimum bolus rate	Maximum bolus rate	Max. Remaining volume at syringe end alarm	Epidural admin
	mL	mL/h	mL/h	mL/h	mL/h	mL/h	mL	
B. Braun Omnifix								
4610303-02	3	0.01	0.1	100	1	150	0.1	no
4617053V-02	5	0.01	0.1	200	1	300	0.1	no
4617100V-02	10	0.01	0.1	300	1	500	0.2	no
4617207V-02	20	0.01	0.2	500	1	800	0.2	no
4617304F-02	30	0.01	0.2	700	1	1200	0.4	yes
US4617509F-02	50	0.01	0.5	999.9	1	1800	0.6	yes
Becton Dickinson								
309657	3	0.01	0.1	100	1	150	0.2	no
309646	5	0.01	0.1	200	1	300	0.1	no
302995	10	0.01	0.1	300	1	500	0.4	no
302830	20	0.01	0.2	500	1	800	0.2	no
302832	30	0.01	0.2	700	1	1200	0.2	yes
309653	50	0.01	0.5	999.9	1	1800	0.6	yes
Monoject								
1180300777	3	0.01	0.1	100	1	150	0.1	no
1180600777	6	0.01	0.1	200	1	300	0.1	no
1181200777	12	0.01	0.1	300	1	500	0.5	no
1182000777	20	0.01	0.2	500	1	800	0.2	no
1183500777	35	0.01	0.2	700	1	1200	0.6	yes
1186000777T	60	0.01	0.5	999.9	1	1800	0.1	yes
Neomed (Enteral only)								
NM-S6NC / PNM-S6NC	6	0.01	0.1	200	1	300	0.2	no
NM-S12NC / PNM-S12NC	12	0.01	0.1	300	1	500	0.4	no
NM-S20NC / PNM-S20NC	20	0.01	0.2	500	1	800	0.1	no
NM-S35NC / PNM-S35NC	35	0.01	0.2	700	1	1200	0.5	no
NM-S60NC / PNM-S60NC	60	0.01	0.5	999.9	1	1800	0.2	no

[1] Accuracy for rates below minimum recommended rate is +/-20%

7.2 Time to Occlusion

The table below lists time to occlusion for each syringe at pressure settings 1 (75 mmHg), 5 (487 mmHg) and 9 (900 mmHg) and flow rates 0.01, 1 and 5 mL/hr as well as post occlusion bolus volumes.

Manufacturer/ item #	Syringe size	Pressure Level	Max. Time to occlusion at 0.01 mL/h	Max. Time to occlusion at 1 mL/h	Max. Time to occlusion at 5 mL/h	Maximum Post occlusion bolus volume
			hr:min:sec	hr:min:sec	hr:min:sec	mL
B Braun Omnifix						
	3 mL	P1	> 3 h	---	00:00:45	< 0.1
4610303-02		P5	> 3 h	---	00:01:30	< 0.1
		P9	> 3 h	---	00:02:30	< 0.1
4617053V-02	5 mL	P1	> 3 h	---	00:00:45	< 0.1
		P5	> 3 h	---	00:02:00	0.1
		P9	> 3 h	---	00:03:00	0.1
4617100V-02	10 mL	P1	> 3 h	---	00:01:30	< 0.1
		P5	> 3 h	---	00:02:30	0.1
		P9	> 3 h	---	00:03:40	0.1
4617207V-02	20 mL	P1	> 3 h	---	00:01:00	< 0.1
		P5	> 3 h	---	00:04:00	0.1
		P9	> 3 h	---	00:06:00	0.1
4617304F-02	30 mL	P1	> 3 h	---	00:01:00	< 0.1
		P5	> 3 h	---	00:06:00	0.1
		P9	> 3 h	---	00:09:00	0.2
US4617509F-02	50 mL	P1	> 3 h	00:12:50	00:02:30	0.2
		P5	> 3 h	01:02:40	00:09:30	0.2
		P9	> 3 h	01:30:30	00:16:00	0.2
Becton Dickinson						
309657	3 mL	P1	> 3 h	00:04:15	00:01:00	< 0.1
		P5	> 3 h	00:10:45	00:02:10	0.1
		P9	> 3 h	00:17:00	00:03:00	0.2
309646	5 mL	P1	> 3 h	00:07:30	00:01:10	< 0.1
		P5	> 3 h	00:12:30	00:02:15	0.1
		P9	> 3 h	00:18:00	00:03:15	0.2
302995	10 mL	P1	> 3 h	---	00:01:00	0.1
		P5	> 3 h	---	00:03:20	0.2
		P9	> 3 h	---	00:04:15	0.2
302830	20 mL	P1	> 3 h	00:13:00	00:02:30	0.2
		P5	> 3 h	00:25:00	00:04:45	0.2
		P9	> 3 h	00:36:00	00:07:15	0.2
302832	30 mL	P1	> 3 h	00:17:00	00:02:45	0.2
		P5	> 3 h	00:41:00	00:07:45	0.25
		P9	> 3 h	00:56:00	00:10:00	0.25
309653	50 mL	P1	> 3 h	00:10:00	00:03:45	0.2
		P5	> 3 h	01:05:00	00:14:00	0.25
		P9	> 3 h	01:35:00	00:18:00	0.25

Manufacturer/ item #	Syringe size	Pressure Level	Max. Time to occlusion at 0.01 mL/h	Max. Time to occlusion at 1 mL/h	Max. Time to occlusion at 5 mL/h	Maximum Post occlusion bolus volume
			hr:min:sec	hr:min:sec	hr:min:sec	mL
Monoject						
1180300777	3 mL	P1	> 3 h	---	00:00:40	< 0.1
		P5	> 3 h	---	00:01:15	0.1
		P9	> 3 h	---	00:02:00	0.1
1180600777	6 mL	P1	> 3 h	---	00:00:30	< 0.1
		P5	> 3 h	---	00:01:00	< 0.1
		P9	> 3 h	---	00:01:45	< 0.1
1181200777	12 mL	P1	> 3 h	---	00:00:45	< 0.1
		P5	> 3 h	---	00:01:30	< 0.1
		P9	> 3 h	---	00:02:45	< 0.1
1182000777	20 mL	P1	> 3 h	---	00:01:40	0.1
		P5	> 3 h	---	00:04:30	0.1
		P9	> 3 h	---	00:07:00	0.1
1183500777	35 mL	P1	> 3 h	---	00:01:00	< 0.1
		P5	> 3 h	---	00:08:00	0.1
		P9	> 3 h	---	00:14:00	0.2
1186000777T	60 mL	P1	> 3 h	---	00:01:15	0.1
		P5	> 3 h	---	00:08:30	0.2
		P9	> 3 h	---	00:14:30	0.2
Neomed						
NM-S6NC / PNM-S6NC	6 mL	P1	> 3 h	---	00:04:00	0.3
		P5	> 3 h	---	00:07:30	0.4
		P9	> 3 h	---	00:10:40	0.6
NM-S12NC / PNM-S12NC	12 mL	P1	> 3 h	---	00:03:50	0.3
		P5	> 3 h	---	00:07:50	0.6
		P9	> 3 h	---	00:12:10	0.7
NM-S20NC / PNM-S20NC	20 mL	P1	> 3 h	---	00:06:30	0.4
		P5	> 3 h	---	00:10:40	0.6
		P9	> 3 h	---	00:15:50	0.7
NM-S35NC / PNM-S35NC	35 mL	P1	> 3 h	---	00:08:10	0.4
		P5	> 3 h	---	00:16:00	0.7
		P9	> 3 h	---	00:23:00	0.8
NM-S60NC / PNM-S60NC	60 mL	P1	> 3 h	---	00:08:30	0.4
		P5	> 3 h	---	00:16:30	0.4
		P9	> 3 h	---	00:24:00	0.6

Note: Values for "Max. time to occlusion at 1 mL/h" are given for representative syringe types only.

Note: Values for "maximum post occlusion bolus volume" are given for small bore and microbore tubing only. For standard bore tubing the values can be up to 0.4 mL in addition, depending on the pressure settings.

7.3 Administration Sets for Use with Perfusor® Space

B. Braun Microbore Sets	
Material #	Description
V6220	Microbore Extension Set with Female Luer Lock Connector, Spin-Lock® Connector, and PE Fluid Path Tubing, 36 in., ID 0.020 in., priming volume 0.3 mL
V6203	Microbore Extension Set with Female Luer Lock Connector, Spin-Lock® Connector, and PE Fluid Path Tubing, 36 in., ID 0.030 in., priming volume 0.6 mL
V6222	Microbore Extension Set with Female Luer Lock Connector, Spin-Lock® Connector, and PE Fluid Path Tubing, 60 in., ID 0.020 in., priming volume 0.5 mL
V6223	Microbore Extension Set with Female Luer Lock Connector, Spin-Lock® Connector, and PE Fluid Path Tubing, 60 in., ID 0.030 in., priming volume 0.8 mL
V6215	Microbore Extension Set with Female Luer Lock Connector, Supor® Membrane 0.2 µm Air Eliminating Filter, Spin-Lock® Connector, and PE Fluid Path Tubing, 60 in., ID 0.030 in., priming volume 1.3 mL
V5424	Microbore Extension Set with Female and Male Luer Lock Connectors, 19 in., ID 0.050 in., priming volume 0.6 mL
V5450	Microbore Extension Set with two Male Luer Lock Connectors. Proximal and distal male luer locks., 0.04 in. ID., slide clamp. Priming volume: 0.6 mL, Length: 31 in. (79 cm)

B. Braun Standard Bore Sets	
Material #	Description
V5402	Extension Set with Injection Site and Female Luer Lock and Spin-Lock® Connector, 8 in., ID 0.108 in., priming volume 1.2 mL
V5406	Extension Set with Female Luer Lock Connector and Spin-Lock® Connector, 21 in., ID 0.108 in., priming volume 3 mL
V5409	Extension Set with Female Luer Lock Connector, two Injection Sites, and Spin-Lock® Connector, 34 in., ID 0.108 in., priming volume 5 mL
V5484	Extension Set with Female Luer Lock Connector and Spin-Lock® Connector, 31 in., ID 0.108 in., priming volume 4.3 mL
473012	Extension Set with Female Luer Lock Connector and Spin-Lock® Connector, 30 in., ID 0.110 in., priming volume 4.3 mL

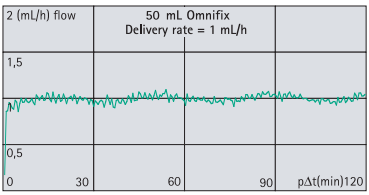
B. Braun Small Bore Sets	
Material #	**Description**
473105	Smallbore Extension Set with Female Luer Lock Connector and Spin-Lock® Connector, 13 in., ID 0.050 in., priming volume 0.4 mL
471973	Smallbore Extension Set with Female Luer Lock and Spin-Lock® Connectors, 61 in., ID 0.050 in., priming volume 2 mL
473022	Smallbore T-Port Extension Set with Female Luer Lock Connector, Injection Site on Male Luer Slip T-Port, and removable Slide Clamp, 38 in., ID 0.050 in., priming volume 1.2 mL

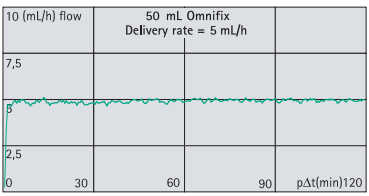
Note: For enteral administration use enteral administration sets with ENFit connector.

Contact your local B. Braun sales representative for the most up to date list of B. Braun extension sets validated for use with the Perfusor®.

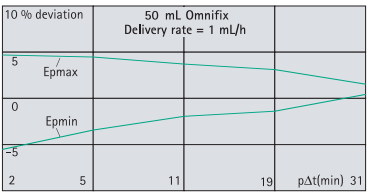
START UP GRAPHS AND TRUMPET CURVES

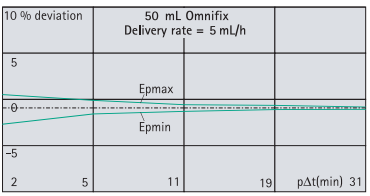
Start Up Graphs





Trumpet Curves





The graphs show the accuracy/uniformity of flow in relation to time. The delivery behavior or delivery precision is influenced by the type of the disposable used. Deviations from the technical data of the pump cannot be excluded if lines (disposables) other than B. Braun approved sets 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)

Note: The start up of fluid delivery by a syringe pump follows a startup curve as described in this chapter. The material in the piston of syringes creates friction forces such that fluid flow from the syringe may not be immediate upon pressing start with a newly inserted syringe. To reduce the time to overcome the friction force of the syringe and shorten start up times, a mechanism to improve the start-up behavior is incorporated in the syringe pump. This feature reduces the time for fluid to exit the syringe by applying additional motor steps, to a maximum of 50 mcl of volume at the start of the infusion. This feature is only engaged after insertion of a syringe. When restarting an infusion, e.g. after an occlusion alarm, the feature is inactive.

TECHNICAL DATA

Type of unit		Syringe infusion pump
Classification (acc. to IEC/EN 60601-1)		defibrillator-proof; CF equipment Protective Class II; Protective Class I in combination with SpaceStation
Moisture protection		IP 22 (drip protected for horizontal usage)
External power supply:		
■ Rated voltage		Via B. Braun SpaceStation or optional AC adaptor (rated voltage 100 - 240 V AC~, 50-60 Hz) for stand alone operation
■ External low voltage		11 – 16 V DC ⎓ 8 VA typically, via Connection Lead SP 12 V or via SpaceStation
Staff call		Max. 24 V / 0.5 A / 24 VA
EMC		IEC/EN 60601-1-2 / 60601-2-24
Time of operation		100 % (continuous operation)
Operating conditions:		
■ Relative humidity		30 % – 90 % (without condensation)
■ Temperature		+41° F – +105° F (+5° C - +40° C)
■ Atmospheric pressure		500 – 1060 mbar
Storage conditions:		
■ Relative humidity		20 % – 90 % (without condensation)
■ Temperature		-4° F – +131° F (-20° C - +55° C)
■ Atmospheric pressure		500 – 1060 mbar
Type of battery pack (rechargeable)		Li-Ion, NiMH
Operating time:	Li-Ion	wireless active Perfusor® at 5 mL/hr typically 4 hours at 25 mL/hr typically 2.5 hours wireless inactive Perfusor® at 5 mL/hr typically 15 hours at 25 mL/hr typically 10 hours
	NiMH	at 5 mL/hr typically 19 hours at 25 mL/hr typically 10 hours
Recharging time		Approximately 6 hours
Weight		Approximately 3.1 lbs (1.4 kg)
Dimensions (W x H x D)		9.8 x 2.6 x 5.9 inches (249 x 68 x 152 mm)
Volume increments		0.01 - 99.99 mL in increments of 0.01 mL 100.0 – 999.0 mL in increments 0.1 mL 1,000 – 9,999 mL in increments 1 mL
Time selection		00:01 – 99:59 h

Accuracy of set delivery rate	± 2 % according to IEC/EN 60601-2-24
Administration Set Change Interval	Please refer to instructions for use of administration set
Max. Volume in case of single fault condition	For incorrect dosages of 0.1 mL due to malfunctions of the device, the pump will alarm and automatically shut off
Technical inspection (safety check)	Every 2 years
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
Multiple lines connected to one patient port	Connecting multiple infusion lines with different flow rates will temporarily affect the rate for all infusions past the point of connection when the flow rate for one is changed.
Accuracy of bolus infusion	typically ± 2 % for a bolus volume > 1 mL
KVO rate	KVO rates are set in configuration data for rates < 1 mL/hr, < 10 mL/hr and > 10 mL/hr. Pump will not infuse KVO rate above current infusion flow rate.
Occlusion alarm pressures (downstream pressure)	9 levels from 75 mmHg to 900 mmHg
Alarm volume	9 levels (>50dBa to >65dBa)
Pump log	Logs are accessed via the service program. Pump logs include history log of 1000 past entries, alarm log, key stroke and notes log. Refer to HiBaSed IFU for more information.

⚠ Caution: If a wrench is displayed and/or the yellow, red and blue LEDs blink, then the pump is in the service mode and cannot be used on a patient. The pump must then be checked by a service technician.

Note: The technical data stated in this Instructions for Use Manual were determined with the B. Braun Omnifix® 50 mL syringe and Original Perfusor® Line (150 cm) at 22° C. This technical data can change when using different set configurations.

- Use only infusion lines that tolerate a minimum pressure of 2 bar or 1500 mmHg to avoid influencing performance data.
- Use only compatible combinations of equipment, accessories, working parts and disposables.

- The Perfusor® Space System is unsafe to use in proximity to magnetic resonance imaging (MR) equipment.
- Only use Perfusor® Space System combined with approved devices/ accessories by the manufacturer, otherwise this may lead to higher emission or reduced immunity.

Essential Performance for Infusion pumps

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

Dosing families

Drug and rate units and the abbreviation for each as they appear on the pump are the following:

gram	=	g
milli gram	=	mg
micro gram	=	mcg
nano gram	=	ng
unit	=	U
milli unit	=	mU
kilo unit	=	kU
million unit	=	MU
milli equivalent	=	mEq
milli mole	=	mmol
kilo calorie	=	kcal
milli liter	=	mL
kilo gram	=	kg
meters squared	=	m^2
body surface area	=	BSA
minutes	=	min
hour	=	h
seconds	=	sec

The following table shows the drug/rate units and options available for administration of medications using dosing/rate units in combination with patient metrics and time units. Dosing units are derived by selecting any one unit from each column in any combination. The dosing units may be pre-set in the drug library (refer to Chapter 1.2) or selected when using the Dose Rate Calculator (refer to Chapter 2.2.3).

Drug Units	Patient Units	Time Units
ng	(none)	min
mcg	kg	h
mg	m^2	24h
g		sec (bolus only)
meq		
mmol		
mU		
U		
kU*		
MU*		
kcal**		
Rate Units		
mL	(none)	h
mL	kg	h
* no m^2 or per minute dosing		
** no m^2, per minute, or per hour dosing		

The table below shows the conversion for the dosing units of the gram and units families:

Gram family	10^6 ng	10^3 mcg	1 mg	10^{-3} g
Unit family	10^3 mU	1 U	10^{-3} kU	10^{-6} MU

The following formula is used to calculate flow rate:

Infusion rate (mL/h) = Dose/concentration x (patient weight or BSA)

Perfusor® Space 2nd Generation – Default Settings

Note: The following settings are the factory default settings contained in the pump. Most of these settings can be customized based on facility preference by using the B. Braun HiBaSeD Service Software. Please contact your B. Braun Representative for more information on how to customize these settings.

Rates

Menu Item	Default Value
Basal	
Basal rate minimum	0.1 mL/h
Basal rate maximum	999.9 mL/h
Bolus	
Bolus rate minimum	1 mL/h
Bolus rate maximum	1800 mL/h
Bolus Default Rates (by Syringe Size)	
for 50/60 mL syringe	1800 mL/h
for 30/35 mL syringe	1200 mL/h
for 20 mL syringe	800 mL/h
for 10/12 mL syringe	500 mL/h
for 5 mL syringe	300 mL/h
for 3 mL syringe	150 mL/h
Bolus volume	
Bolus volume minimum	0.1 mL
Bolus volume maximum	60 mL
Priming of the Line	
Priming Menu	enabled
Priming Volume	0.3 mL
Priming Rate	1800 mL/h

KVO

Menu Item	Default Value
KVO Function	disabled
Rate	
Rate < 1 mL/h	0.1 mL/h
1 mL/h ≤ Rate < 10 mL/h	1 mL/h
(Rate ≥ 10 mL/h)	3 mL/h
KVO Time Limit	0 Min.
KVO Pre-alarm	0 Min.

Other
(adjustable settings at start-up of device/bolus features/pressure defaults)

Menu Item	Default Value
General	
Bolus Function	enabled
Manual Bolus Function	enabled
Start-up	
Continue last infusion	disabled
Use dose rate calculation (Dose rate calculator)	disabled
Default settings	
Pressure sensor downstream	5

Menu: Home
(Enabled menus will appear on the "Home" screen of the pump)

Menu Item	Default Value
Change Care Unit	enabled
Options	enabled
Status	enabled
Infused Totals	enabled
Infused Totals Sub-Menu	
Total	enabled

Menu – Status
(Enabled information will be shown in the "Status" Menu of the pump)

Menu Item	Default Value
Battery Capacity	enabled
Wireless Status	enabled
Software Version	enabled
Drug Information	enabled
Syringe	enabled
Last bolus dose	enabled
Last bolus time and date	enabled

Menu - Options

(Enabled functions will be shown and are adjustable in the "Options" Menu of the pump)

Menu Item	Default Value
Downstream pressure	enabled
Alarm volume	enabled
Assign to drug library	enabled
Dose rate calculator	enabled
Data lock	enabled
Data Lock Pin	9119
KVO mode	disabled
Display contrast	enabled
Display lighting	enabled
Keypad lighting	enabled
Bolus rate	disabled
Date / Time	disabled
Macro Mode	disabled
Wireless	enabled

Time and Date Options

Menu Item	Default Value
Default settings	
Standby time	1440 minutes (24h 00min)
Date format	
dd.mm.yyyy	disabled
yyyy.mm.dd	disabled
Mm/dd/yyyy	enabled

Alarms

Menu Item	Default Value
Pre-Alarms	
Syringe end (min)	3 minutes
VTBI (min	10 minutes
Time (min)	10 minutes
Repeating acoustical signal	enabled
Battery Empty	30 minutes
Bolus acoustic tone	
Every ... mL	1 mL
Syringe Alarms	
STOP at syringe end	enabled
Low Flow Rate Alert	enabled
Staff call options (Off alarms)	
Static	enabled
Dynamic 1 second	disabled
Dynamic 1 second with alarm off	disabled
Acoustic Alarm in SpaceStation (Alarm Status when pump is mounted in Space Station) Note: only 1 is possible. Only applicable if pump is placed in a SpaceStation	
Only SpaceStation alarms	enabled
SpaceStation and pump both alarm	disabled
Default Settings	
Alarm volume	5

Display

Menu Item	Default Value
Minimal lighting Pump is turned on and using Battery Power (not connected to A/C power)	
Display	Level 1
Keypad	Level 0
Passive Pump is turned off, but it is connected to A/C power.	
Display	Level 0
Default Settings	
Display lighting	8
Display contrast	5
Keypad lighting	5
Macro mode	disabled

Service

Menu Item	Default Value
Battery Maintenance Mode	
Days	256 Days
Active	disabled

Default Disposables

Disposable Brand and Size	Factory Default Setting
B. Braun Omnifix	
50 mL	ON
30 mL	ON
20 mL	ON
10 mL	ON
5 mL	ON
3 mL	ON
Becton Dickinson	
50 mL	ON
30 mL	ON
20 mL	ON
10 mL	ON
5 mL	ON
3 mL	ON
Cardinal Monoject	
60 mL	ON
35 mL	ON
20 mL	ON
12 mL	ON
6 mL	ON
3 mL	ON
Neomed (Enteral only)	
60 mL	ON
35 mL	ON
20 mL	ON
12 mL	ON
6 mL	ON

Guidance and manufacturer's declaration on electromagnetic compatibility

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The Space System is intended for use in the electromagnetic environment specified below. The customer or the user of the Space System or any component should assure that it is used in such an environment.			
Immunity test	**test level IEC 60601-1-2 IEC 60601-2-24**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) according IEC 60601-4-2	contact IEC 60601-1-2: ±6KV IEC 60601-2-24: ±8KV air IEC 60601-1-2: ±8KV IEC 60601-2-24: ±15KV	±6KV no disturbances ±8KV stop with alarm possible ±8KV no disturbances ±15KV stop with alarm possible	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst according IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	±2KV ±1KV	AC power quality should be that of a typical commercial or hospital environment.
Surge according IEC 61000-4-5	differential mode ±1KV common mode ±2KV	±1KV ±2KV	AC power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines according IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec <5% UT for 5 s (>95% dip)	complies by use of internal battery	AC 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 AC power interruptions, it is recommended that the Space System or component be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field according IEC 61000-4-8	3 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: Different test values of IEC 60601-2-24 are marked in the table. At the test values no dangerous disturbances occurred at the lower test values of IEC 60601-1-2.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Space System is intended for use in the electromagnetic environment specified below. The customer or the user of the Space System or any component should assure that it is used in such an environment.			
Immunity test	**test level IEC 60601-1-2 IEC 60601-2-24**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Space System or it's components, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
radiated electromagnetic RF fields according IEC 61000-4-6	IEC 60601-1-2: 3 Veff normal and 10 Veff in ISM frequency band IEC 60601-2-24: 10 Veff 150 KHz to 80 MHz	10Veff 150 KHz to 80 MHz	Recommended separation distance d = 1.2 √P 150 KHz to 80 MHz
radiated electromagnetic RF fields according IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 3 GHz	d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

NOTE 3: See next page.

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

Band (MHz)	Service	max P_{ERP} (W)	IMMUNITY TEST LEVEL (V/m)	compliance level E (V/m)
380-390	TETRA 400	1.8	27	100
430-470	GMRS460, FRS 460	2	28	40
704-787	LTE Band 13, 17	2	9	100
800-960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	2	28	50
1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	2	28	60
2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	2	28	100
5100-5800	WLAN 802.11 a/n	0.2	9	100

For all noted services, a minimum separation distance of 0.3 m is recommended. In case the separation distance is underrun or higher levels of field strength are present, device alarms may occur.

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 maximum 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√P	80 MHz bis 800 MHz 1.2√P	800 MHz bis 2.5 GHz 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.27
100	12	12	23

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

TRAINING / TSC* / SERVICE / DISINFECTING / DISPOSAL

B. Braun is the legal 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. IEC 60364 "Electrical installations of buildings 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.

Training

B. Braun offers a training for software version 588U. 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 by B. Braun trained personnel.

Cleaning and Disinfecting

⚠ Caution: Before cleaning and disinfecting the pump, always disconnect the pump from the patient, switch off the device and disconnect pump from AC power outlet and other devices. The pump may be cleaned and disinfected with EPA registered products containing the following agents:

- 1-propanol
- isopropyl alcohol
- ethanol
- didecyl dimethyl ammonium chloride
- diisobutylphenoxyethyl dimethyl benzyl ammonium chloride
- sodium hypochlorite

Follow manufacturers' instructions for proper use of disinfecting products. Clean all external surfaces (includes inside the pump door) using a clean, soft, low lint cloth dampened with product or commercial wipes containing an approved agent. Make

sure to remove any visible residue from all surfaces prior to disinfecting. Disinfect the housing of Perfusor® Space and surface areas inside the door with product containing an approved agent. Do not spray disinfectants directly on the pump, use a soft, low lint cloth dampened but not saturated with product or commercial wipes containing an approved agent. After cleaning and disinfecting, confirm the instrument is thoroughly dry before use.

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

Do not allow moisture or disinfectants to come into contact with the electrical connections of the device (P2 or P3 connectors) or any device openings. To reduce the likelihood of moisture ingress into the electrical connectors, the P2 connector of a power supply or combi lead cable may be used to cover the connections during cleaning and disinfecting. Ensure that any connectors used to cover are not connected to a wall outlet or other electrical source. Once the cleaning has been completed, remove the connector and inspect all connectors for residual moisture and evidence of damage or breakdown to the plating on the connectors. Allow any residual moisture to evaporate before plugging the device into a wall outlet. Replace any connectors which exhibit damage or evidence of plating breakdown prior to returning the device to service. Utilize electrical contact cleaner that does not react with plastics to remove any deposits of material which may be present inside the electrical connectors as required.

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

Pump accessory cords and cables:
Clean all surfaces using a clean, soft, low lint cloth dampened with product or commercial wipes containing an approved agent. Make sure to remove any visible residue from all surfaces prior to disinfecting. Disinfect with product containing an approved agent. Do not spray disinfectants directly on the product, use a soft, low lint cloth dampened but not saturated with product or commercial wipes containing an approved agent. Follow manufacturers' instructions for proper use of disinfecting products. After cleaning and disinfecting, confirm the instrument is thoroughly dry before use.

Pole clamp:
Clean and disinfect all surfaces using a clean, soft, low lint cloth dampened but not saturated with a mild solution. Make sure to remove any visible residue from all surfaces. Do not spray solution directly on the product. Follow manu-

facturers' instructions for proper use of disinfecting products. After cleaning and disinfecting, confirm the clamp is thoroughly dry before use.

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

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 B. Braun customer service or your local representative. The device should be tested for proper functioning before initial use.

Included in Delivery

Perfusor® Space, Battery-Pack SP (with or without Wifi).

OPTIONAL SPACE ACCESSORIES

SpaceStation (8713140U)

Station that can hold up to four B. Braun Space pumps. Refer to SpaceStation user manual for operating instructions. For further information contact your B. Braun Representative or call B. Braun Customer Service at 1-800-627-7867.

SpaceStation with SpaceCom (8713142U)

SpaceStation with data communication capabilities. Refer to SpaceStation user manual for operating instructions.

SpaceCover Comfort (8713145U)

The SpaceCover Comfort, which attaches to the top of the SpaceStation, includes a handle, central alarm management and alarm LEDs.

Space Pole Clamp (speed clamp) (8713131)

Incorporates "speed clamp" for faster attaching/removing from IV Pole.
A maximum of three B. Braun Space pumps can be stacked together when used with the Space Pole Clamp. For detailed instructions please refer to the "Overview Perfusor® Space" and "Patient Safety."

Power Supply SP (8713112D)

The Power Supply SP can supply power for a single pump.

1.) Connect P2 plug of Power Supply SP with P2 socket on back of pump (ensure that plug “clicks”).

2.) Push power plug into wall outlet.

Note: To disconnect plug from pump, firmly grasp the connector and pull straight out. Do not twist or bend the cord or connector.

⚠ Caution: Do not pull on cord to remove connector.

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

Technical Data: 100 – 240V AC~, 50/60 Hz, 0.4-0.2A

Combi Lead SP 12 V (8713133)

The Combi Lead SP can connect up to three pumps. All pumps can then be operated by one Power Supply SP.

1.) Connect P2 plug of the Combi Lead SP 12 V with the P2 socket on the back of the pump.
2.) Connect P2 plug of Power Supply SP with Combi Lead SP.
3.) Push plug of Power Supply SP into the wall outlet.

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

Connection Lead SP (12 V) (8713231)

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

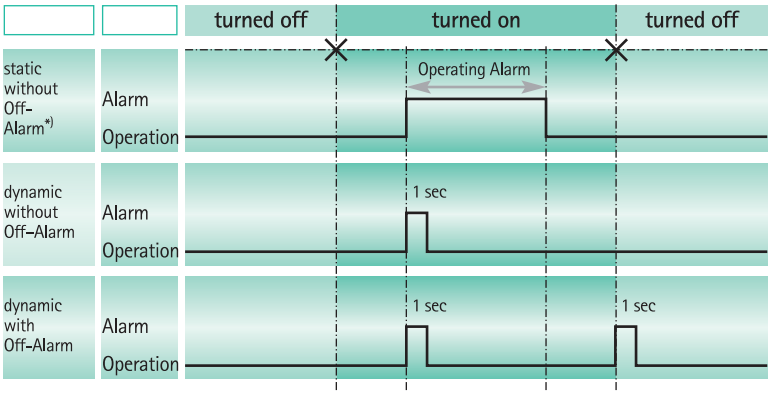
1.) Connect plug to socket P2 on back of pump or F3 on SpaceStation.
2.) Put the connection lead into the vehicle socket.
3.) If necessary, remove red adaptor of motor vehicle connector by slightly turning and simultaneously pulling.

The green LED of the electronic box shows the operating voltage.

⚠ Caution: Plug into vehicle charger and connect to pump. Do not connect pump to patient if vehicle battery/generator is powering on.

SpaceStation MRI (8713152)

The SpaceStation MRI allows use of up to 4 Space pumps in MR Suite positioned as close as 20mT/200 Gauss line. Refer to SpaceStation MRI Instructions for Use.



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

⚠ Caution: The user should respond to the local pump alarms as well.

Technical Data

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

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

Recommended accessories for the B. Braun Perfusor® Space:

SpaceStation	8713140U
SpaceStation with SpaceCom	8713142U
SpaceCover Comfort	8713145U
Space Pole Clamp (speed clamp)	8713131
Power Supply SP (US Plug)	8713112D
Combi Lead SP 12 V	8713133
Connection Lead SP (12 V)	8713231

Technical Support

If the pump fails to respond to the operating or troubleshooting procedures listed in this manual and the cause cannot be determined, discontinue use and forward it to an authorized B. Braun Service Center.

Should it be necessary to return the pump for repair, contact Technical Support at B. Braun Customer Service at (800) 627-PUMP. A Returned Materials Authorization number will be provided. Carefully pack the pump (preferably in the original packing), and ship it prepaid to the address below. B. Braun cannot assume any responsibility for loss or damage to returned instruments while they are in transit.

Service and product performance information, operation training, service training, and service manuals may be obtained from the manufacturer by contacting:

B. Braun Medical Inc.
1601 Wallace Drive, Suite 150
Carrollton, TX 75006
Attn: Service Manager
or call (800) 627-PUMP

Product complaints may be sent to the Quality Assurance Manager at the above address.
With each complaint, please include:

- the pump's serial number and software revision,
- a description of the difficulty experienced,
- the pressure limit setting,
- the rate/dose setting,
- the initial volume(s) to be infused (VTBI),
- the type of fluid(s),
- the amount of time between the start of the infusion and the time the difficulty was noticed,
- the message displayed at the time the difficulty occurred,
- brand and size of syringe in use,
- the catalog and lot number of the set(s) in use,
- the diagnostic code (if applicable), and
- any other information which might aid in the investigation of the complaint.

Authorization to return products must be received from B. Braun prior to shipment. Please contact Customer Service at the above phone number for a Returned Materials Authorization Number.

Clinical Support

The customer may speak with a Registered Nurse for clarification of operating instructions or clinical applications for the Space pump, etc.
A (Clinical Support Specialist) Nurse Consultant may be reached at (800) 854-6851.

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