Infusomat® 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 586U

B|BRAUN

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

INFUSOMAT® 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.

Press to open the pump door.

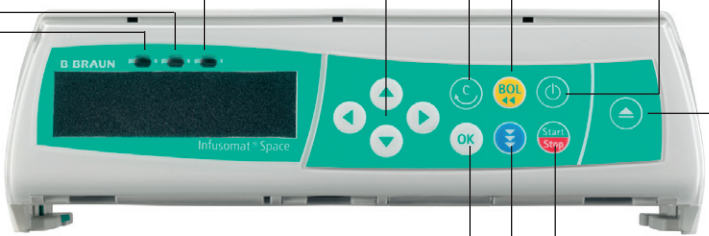
Yellow LED: Pre-alarm, reminder alarm

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

Blue LED: Initiating connection to wireless battery or SpaceStation

Press to initiate bolus.

Press to turn pump on/off and initiate stand by mode.



OK

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

Press to initiate auto-programming orders when prompted.

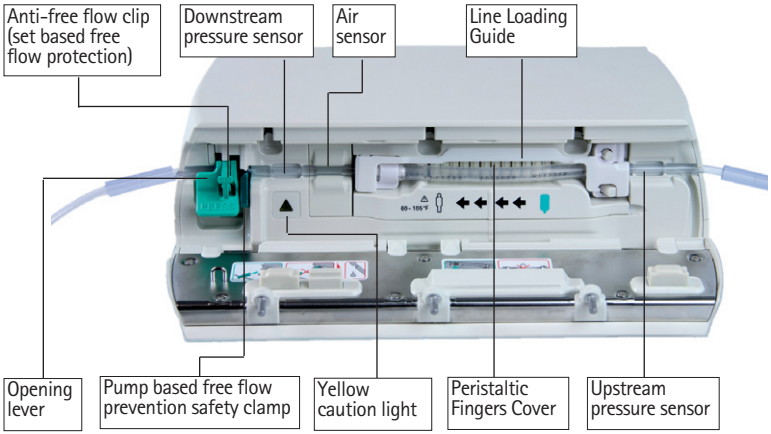
Start Stop

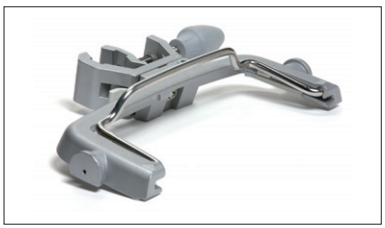
Press to Start/Stop infusion.

Cover of Battery Compartment
Before changing the battery, always disconnect the pump from the patient and switch the device off.
To remove the battery cover, push the button below the battery compartment with the point of a pen and pull the cover away from the device. Slide the green locking mechanism on the back of the battery up and take out the battery pack for replacement.
A crank key used to open the pump door, which is stuck closed, is attached to the inside of the battery compartment cover (for more information see subchapter 1.12).

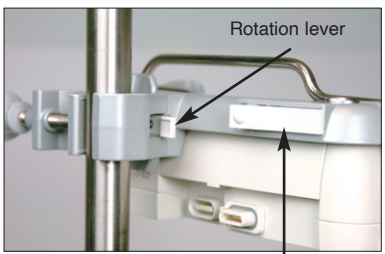
Port P3, removed from more recently-produced devices

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





Pole Clamp SP (model 8713130)



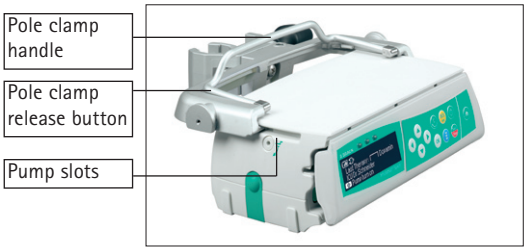
Attaching Pole Clamp to IV Pole

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.

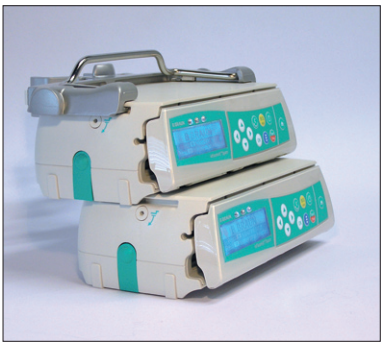
For vertical positioning of Pole Clamp push rotation lever down and rotate pump either way until lever clicks into notch. Push lever for rotation.

Caution: Do not lean on pump when attached to pole!

Caution: A maximum of three B. Braun Space® pumps can be stacked together when used with the Pole Clamp SP.



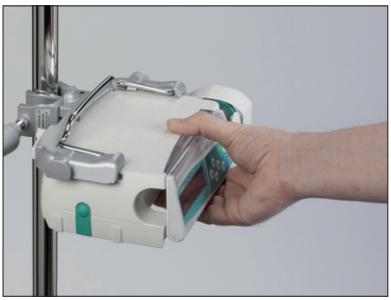
Attaching Pump to Pole Clamp
Line up slots on top sides of pump with grooves of Pole Clamp and slide pump into Pole Clamp until locking mechanism clicks. To remove, simultaneously press release button on frame and push handle down while pulling pump out from pole clamp.



Locking Devices Together
A maximum of three pumps (Infusomat® Space® or Perfusor® Space®) may be inter-locked on a single pole clamp.

⚠ Caution: Avoid external mechanical action.

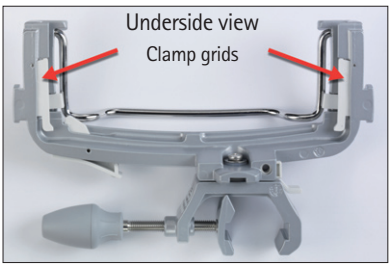
Line up the grooves of the lower pump with the slots of the upper pump and slide the lower pump in until the lock clicks and the green buttons are aligned with each other. To disconnect, push green locking button of upper pump and slide lower pump out.



⚠

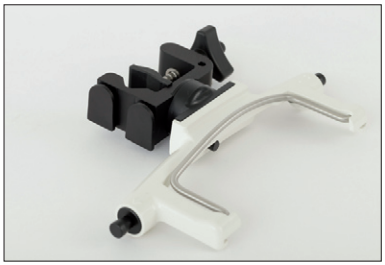
The pump is now securely attached to Pole Clamp.

- Do not position the pump unit over the patient.



⚠

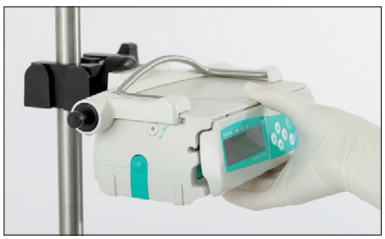
- DO NOT use any Pole Clamp that shows signs of damage.
- DO NOT use Pole Clamp with missing clamp grids.



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.

- 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.

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.

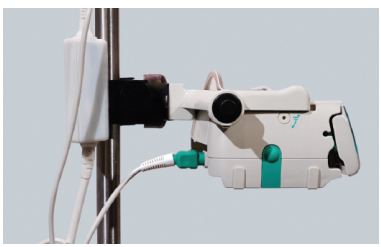
Vertical Positioning
Simply turn the pump either way until it clicks into notch at 90 degree/vertical position.

Caution: Do not lean on pump when attached to pole!

Caution: A maximum of three B. Braun Space® pumps can be stacked together when used with the Space Pole Clamp (speed clamp).

Power supply holder
The Space Pole Clamp (speed clamp) can hold up to 2 Space Power Supplies (8713127 or 8713112D) on the rear of the Pole Clamp.

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)
= Total Parenteral Nutrition
VTBI = Volume To Be Infused
MRI = Magnetic Resonance Imaging
BSA = Body Surface Area

Code of Federal Regulations Title 21 Food and Drugs			
Symbol	**Title**	**Reference-number**	**Explanatory text or meaning**
Rx only	Rx Only	21 CFR 801.109	Caution: Federal law restricts this device to sale by or on the order of a physician.

IEC 60529: Degrees of protection provided by enclosures (IP Code)			
Symbol	**Title**	**Reference-number**	**Explanatory text or meaning**
IPXX	Degree of protection	N/A	A coding system to indicate the degrees of protection provided by an enclosure against access to hazardous parts, ingress of solid foreign objects, ingress of water and to give additional information in connection with such protection.

UL Solutions			
Symbol	**Title**	**Reference-number**	**Explanatory text or meaning**
c UL us	UL Recognized Component Mark	N/A	UL Solutions Recognized Component. Used on component parts that are part of a larger product or system. The C-UL-US Component Recognition Mark indicates compliance with both Canadian and U.S. requirements.

IEC TR 60878: Technical Report Graphical symbols for electrical equipment in medical practice			
Symbol	**Title**	**Reference-number**	**Explanatory text or meaning**
	Keep away from rain	0626	To indicate that the transport package shall be kept away from rain and in dry conditions.
	For indoor use only	5957	To identify electrical equipment designed primarily for indoor use.

PATIENT SAFETY

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

Indications for Use

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

Infusomat® Space® Volumetric Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities.

Dedicated Disposables

The Infusomat® Space® is intended to be used with only dedicated disposables labeled for the different routes of administration.

Warnings and Cautions

- Qualified medical staff should decide how the device should be used based on its features and specifications. For more details, please read the Instructions for Use.
- Despite careful packaging, the risk of damage during transport cannot be entirely prevented. Upon delivery, please check that all items are present. Do not use a damaged device. Contact the service department. Testing the proper function of the device should be performed before initial use.
- The initial training of the Infusomat® 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.
- Any serious incident that has occurred in relation to this product should be reported to B. Braun and the competent authority (or equivalent country specific authority) of the country in which the product is operated.

Caution: Ensure the unit is properly positioned and secured (see ch. Infusomat® Space® Overview). Do not position pump above patient or in a position where a patient could be harmed, should the pump fall.

- Prior to administration, visibly inspect the pump for damage, missing parts or contamination and check audible and visible alarms during self-test.
- Only connect to patient once the line has been correctly inserted and completely primed (chapter 1.1). Disconnect from patient during line change to prevent unintended delivery.

Note: Epidural administration should be limited to drugs that are approved for epidural use as drugs not approved for administration by the epidural route could result in serious patient harm.


Caution: Ensure the infusion line is free of kinks.


Caution: Do not operate in the presence of flammable anesthetics or in a hyperbaric oxygen chamber.

- Not be used adjacent and stacked with other equipment except B. Braun Space® devices.


Warning: The Infusomat® 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.

- Compare the displayed value with the entered value prior to starting infusion.
- Compare physician order to programming parameters including drug name, patient profile and dosing prior to starting infusion.
- Check default values pre-populated from drug library with physician order prior to starting infusion.
- Consider additional monitoring which may be required when infusing high risk medications.
- Consider plausibility of calculated flow rate for infusions programmed with BSA to assist in determining accuracy of patient height and weight values.
- If staff call is used, it is recommended to check the equipment once after connecting the pump to ensure staff call is working.
- If the pump is dropped or is exposed to force, it must be checked by the service department.
- The default values and limits of the Drug Library provide a safety net and are not intended to be used to define treatment.
- Changes in position of pump height in relation to patient during infusion may lead to minor changes in flow accuracy.
- Do not allow liquids to enter into or come into contact with any openings or electrical connections on the pump or power supply. Fluid exposure in these areas may result in the risk of short circuit, corrosion or breakdown of sensitive electrical components, and/or electrical shock. If fluid exposure occurs, the device should be swapped out with another device in a manner that presents minimal interruption to patient care. The device should remain

unplugged until it can be inspected by a trained technician for any evidence of damage and/or residual moisture which may impair the function of the device.

- Any serious incident that has occurred in relation to this product should be reported to B. Braun and the competent authority of the country in which the product is operated.

Safety Standards

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

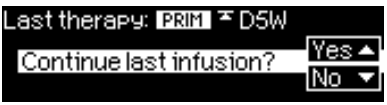
- The EMC-limits (electro-magnetic compatibility) according to IEC 60601-1-2:2007 and IEC 60601-2-24: 2012 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.) may be disturbed. Maintain the protective distances recommended by the manufacturers of these devices.
- During transport of patients within the facility the Infusomat® 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 conditions the Infusomat® Space® needs to remain under room temperature at least one hour before usage.

MENU STRUCTURE / NAVIGATION

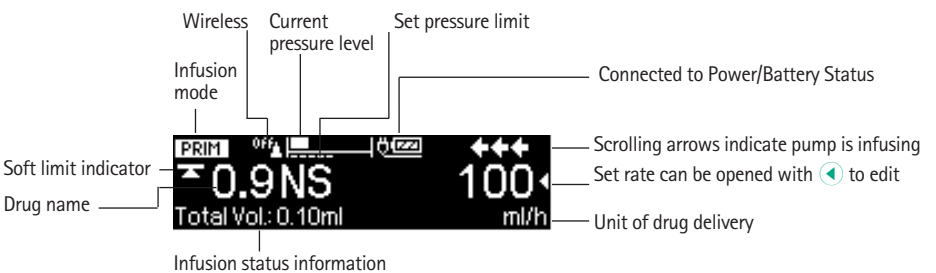
Overview of Keys and Displays

- On/Off key
- Door open 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 question by pressing ▲ for yes or ▼ for no. Pressing yes recalls all parameters of the last infusion prior to power off, both the last primary and secondary therapies are retained.
	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 bottom or top of the screen indicates infusion mode, 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 ▼ ▲ and will be displayed (e. g. care area, drug long name, time/ VTBI remaining drug concentration, total volume, infused totals for PRIMary and SECondary) 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 IV line must be removed to power the pump off. Pump will go into stand-by if the IV line is not removed.

ENTERING VALUES

For an infusion parameter to be entered and/or edited, 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 the arrow buttons to move the cursor so the desired numerical value to be changed is highlighted. Use the Left and Right arrows buttons 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 the Up arrow button ▲ in the "ones" place 9 times and then press the Right arrow button ▶ once to move the cursor to the "tenths" decimal place and pressing the Up arrow button ▲ 5 times.

Press the OK button 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 the right ▶ and left arrow ◀ keys to highlight desired number, in this case the "ones" place.

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

Then press the Left arrow button ◀ to move the cursor to the "tens" place and press the Up arrow button ▲ once .

Arithmetic logic:

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

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

Pressing the Down arrow button ▼ from the "ones" place decreases the value to 9.5

Pressing the Up arrow button ▲ 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 case an increase of a value would exceed a hard limit, the pump displays 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 the Left button ◀ to move the cursor to the "tens" place.

Press the Up button ▲ 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 the down arrow is pressed on the above screen, the pump displays the previous value i.e. 9.5.

If the up arrow 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 the OK button, the pump prefills the programming editor field with the last value programmed and confirmed prior to the value that created the alert.

While in the editor function the arrow buttons and the OK button are used to define and confirm a value, the C (clear) button can be used to reset the value to 0.

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

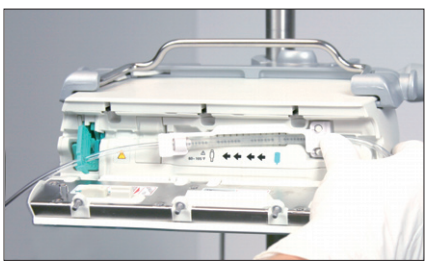
OPERATION

1.1 Inserting IV Line and Priming in Pump

- Ensure that the pump is properly installed (see Infusomat® Space® Overview above). Check the equipment for completeness and damages.
- Spike infusion bag and fill drip chamber to 2/3 full.
- 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 followed by the set limit for the accumulated air volume and the max. size of air bubbles.
- Observe B. Braun landing page and press OK to enter infusion parameters followed IV line insertion, or press ⏏ and then press ▲ to open the pump door and insert the line.

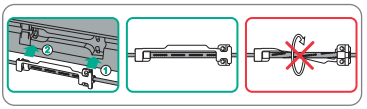
Note: Observe message indicating the roller clamp should be closed during set change.

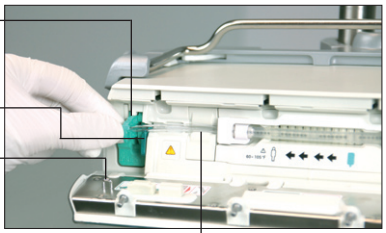
Caution: Close the roller clamp before inserting the IV line and do not connect to patient until properly loaded and primed.



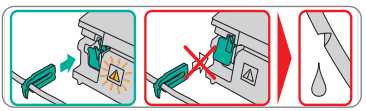
Insert the IV line from right to the left starting with the 2 hole clip.

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





Insert the green anti-freeflow clip in the green slot, in the direction indicated by the arrow, until the opening lever snaps out, yellow light goes out and pump based free flow protection safety clamp occludes the lines.



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

Caution: Pump door will not close if the anti free-flow clip is not properly inserted. Do not force door closed - if door is too difficult to close, check IV line and anti free-flow clip (green) for proper loading.

Caution: Before opening door, close roller clamp. If the door hook appears damaged or broken remove the pump from service.

- If priming is activated, press ▲ to select yes to prime IV line and note prompt to disconnect IV line 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.

Note: During priming, all air in line alarms are inactive.

- Connect IV 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.

1.2 Drug Library

The Infusomat® 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 sub-divided into 30 categories. These drugs can be assigned to 50 care units and 16 Patient Profiles.

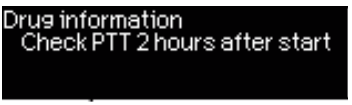
Note: The maximum number of drug names in each Drug Library File may be limited based on the number of care units, concentrations, and patient profiles that are utilized when building the drug library.

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, 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 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.

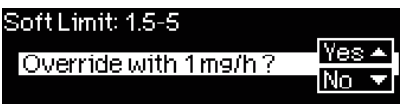
- Weight or BSA may be changed by scrolling to weight or BSA on home screen and editing weight or BSA.
- Drugs may have a clinical advisory set up in the drug library which must be confirmed by pressing ◀ or OK before proceeding.



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 value 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 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:

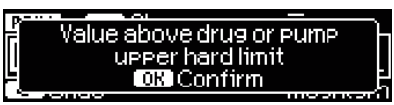
The infusion is within the range of the lower and upper soft limits	=	⧗
The infusion is below the upper soft limit	=	▼
The infusion is above the lower soft limit	=	▼
The infusion is above the upper soft limit	=	▲
The infusion is below the lower soft limit	=	▼
No soft or hard limits are set	=	⚠

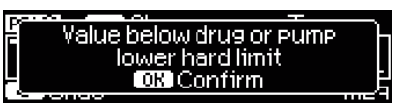
Drugs may be marked for PRIMary only, SECondary only or both in the drug library. When selecting drugs, in the library drug names will only appear if marked for that mode in the drug library file. In addition a drug may be marked to deactivate SECondary mode.

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 of 1200 mL/hr 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.

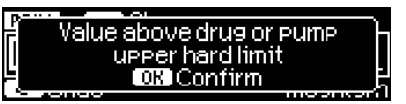
Below are 3 examples of values entered that exceed the hard limit of the drug library or the pump:

Example 1:
Drug with a 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 the ▲ is pressed again the hard limit message is displayed and remains until confirmed by pressing OK.



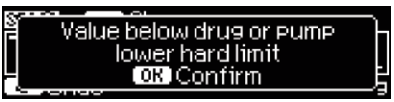
Upon pressing the OK button, the pump editor field reverts to the last confirmed value programmed prior to the value that created the alert.

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

Current value is 0.3 g

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

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



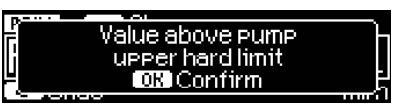
Upon pressing OK the pump editor reverts to the last confirmed value programmed prior to the value that created the alert.

Example 3:
Pump maximum rate is 1200 mL/hr

Current value 1100 mL/hr

Pressing the ▲ once with the cursor in the hundreds column displays value of 1200 mL/hr which is at but not above the hard limit.

When the ▲ 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 physician order.

1.3 Programming a PRIMary Infusion in Drug Library

When the IV line has been loaded and 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 IV line by pressing (OK) from this screen.

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

Note: A basic infusion may be selected from this list. Basic infusions are addressed in Section 1.11.

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 arrow keys and confirm with (◀) arrow or (OK). If no profile is set in the drug library, this step will be skipped.

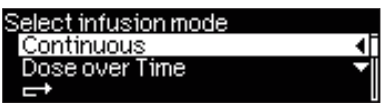
- Select the drug category using arrow keys and confirming with ◀ arrow or OK. "All drugs" may be selected or search by specific category. If no categories have been set in the drug library this step will be skipped.

- All drugs are listed alphabetically. Navigate through the list with ▲ and ▼ arrows or use ◀ and ▶ arrows to quickly skip through the alphabet in groups of 3 (i.e. ABC-DEF). Press ◀ arrow or OK 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 Section 1.9 for instructions on changing the Care Unit while infusing.

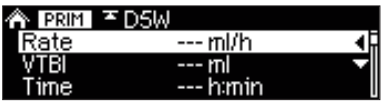
- Choose drug concentration using ▲ and ▼ arrows, press ◀ arrow or OK to select.

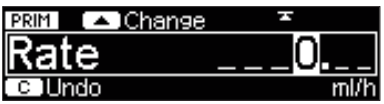
Note: Some drugs may be set up for more than one infusion type, such as Continuous and Dose over Time, choose the mode using ▲ and ▼ arrows. Select with ◀ or OK key. Refer to Section 1.5 for instructions on Dose over Time therapy.



- 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 ◀ arrow 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 key 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: Home symbol is displayed in upper left of home screen. Home screen may be accessed from run screen by pressing (C) key.

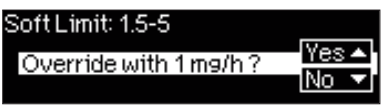
Note: Default values may be present when set in drug library, in this case the editor screens do not appear, confirm values and press (Start/Stop) to begin the infusion or press (◄) arrow to edit default values. Observe green LED and arrows moving right to left in upper right of display indicating infusion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

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

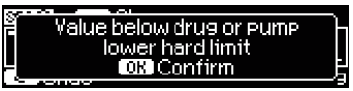
Note: While programming, the soft limit symbol appears above the value, indicating where the value is in relation to the soft limits.

- 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 over-ride soft limit.

Note: Change in soft limit symbol when over-ridden.



- 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 Infusomat® Space® may deliver rates to 1200 mL/hr. 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 required to start the infusion. 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 ◀ arrow key 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 a SECondary Infusion in the Drug Library

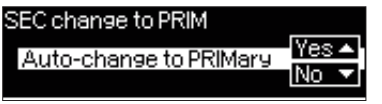
The Infusomat® Space® allows SECondary (piggyback) infusions to be programmed. Spike bag and prime SECondary tubing manually, close roller clamp and connect to primary tubing at needleless port above the pump.

Note: SECondary infusion should not be used for critical infusions.

- Stop PRIMary infusion by pressing Start/Stop key.
- Scroll to SECondary menu by pressing ▼ arrow.
- Select SECondary by pressing ◀ arrow or OK key.

Four sub-menu items will be displayed: New SECondary, Use a Previous SEC infusion, Back to PRIM and Basic Infusion.

"Back to PRIM" allows the pump to be set to require a manual switch back to PRIMary in which case the pump stops and alarms when the SECondary is complete, or autochange whereby the pump converts to the PRIMary setting when the SECondary dose/VTBI has been infused.



Note: The method of switching back to PRIMary remains for all SECondary infusions until changed.

- Select "New SECondary"
- Select the drug category and scroll to the desired drug name.

The Care Area and Patient Profile are retained from the PRIMary infusion. Select infusion mode and concentration as done above when programming a PRIMary infusion.

Note: Medications may be set up in the drug library for SECondary only and will only appear in the drug list when in the SECondary menu.

Note: PRIMary medications may be set in drug library to prohibit SECondary infusions. A message will appear indicating SECondary has been disabled for the drug.

SECondary meds, which are administered intermittently, will most frequently be set up for Dose over Time. SECondary meds set up as continuous are programmed as above for PRIMary programming.

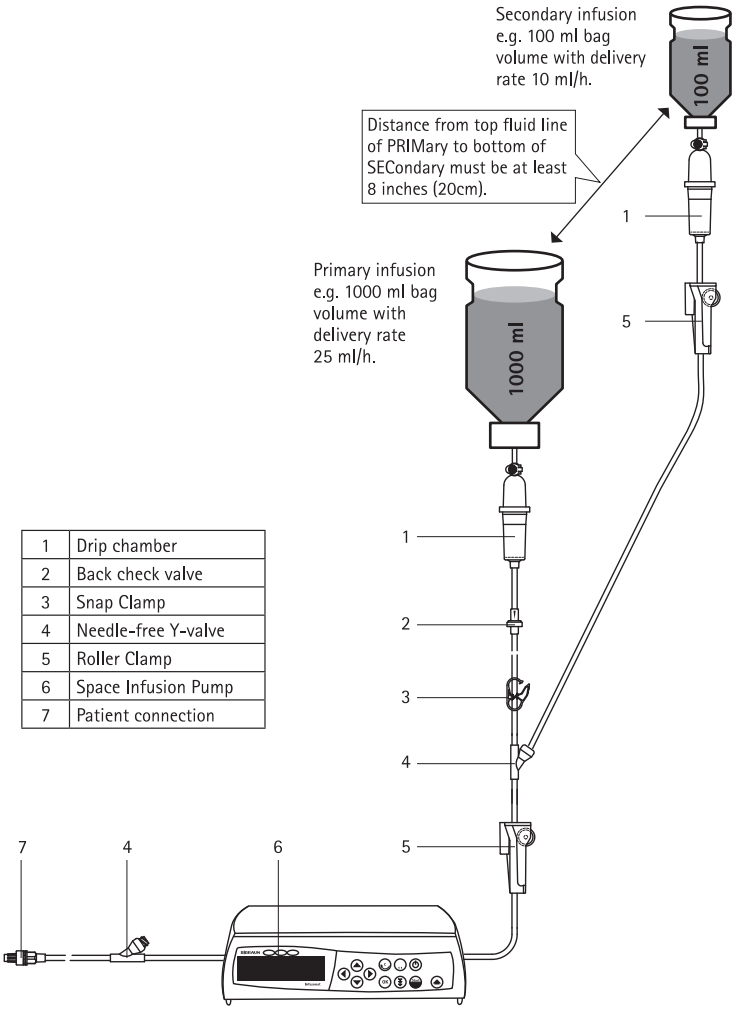
- Enter total dose and confirm with OK.

- Enter total time and confirm with OK.

Note: The pump calculates the rate and VTBI.

- Press Start/Stop key, note message reminder to check bag height and unclamp secondary.
- Press Start/Stop again to confirm message and start SECondary.

Note: The SECondary bag must be hung at least 8 inches above the PRIMary. The 8 inch interval is measured from the bottom of the SECondary bag to the top of fluid level in the PRIMary.



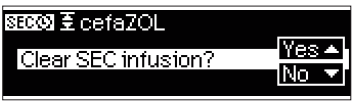
1	Drip chamber
2	Back check valve
3	Snap Clamp
4	Needle-free Y-valve
5	Roller Clamp
6	Space Infusion Pump
7	Patient connection

Note: When running a SECondary infusion at rates greater than 300 mL/hr clamp off the PRIMary infusion to prevent concurrent flow.

Dose over Time run screen will indicate drug name and count down remaining time.

Note: During SECondary administration, the PRIMary may be resumed at any time by pressing the key to stop the SECondary infusion, scrolling to and selecting "resume PRIMary", selecting it with ◀ or OK switches back to the primary infusion. Pressing leads to an acknowledging prompt to clamp or remove SECondary, then pressing key to infuse PRIM. To resume SECondary, stop PRIM and scroll to and select "resume SECondary". The menu item "resume SECondary" will not appear if the SECondary dose/volume was completed.

- To stop and clear a current SECondary infusion prior to completion of dose/volume, press key, then press key, then press ▲ arrow to answer yes to "Clear SECinfusion". SECondary drug will remain in the list of previous SECondary infusions.

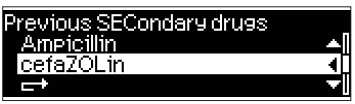


The Infusomat® Space® stores up to 5 of the previously administered SECondary medications for easier programming of repetitive SECondary medications. The previous SECondary medications are cleared when the Care Unit changes, the pump is powered off or answering "yes" to New Patient when bar coding.

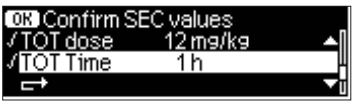
Note: When a SECondary medication with the same name but different concentration or dose is programmed, the prior medication with that name is deleted from the list. SECondary infusions which are cleared prior to completion will remain in the list of previous SECondary medications.

- Stop PRIMary by pressing key.
- Scroll to SECondary menu and select by pressing ◀ arrow or OK key.
- Select "Use a Previous SECondary" by pressing ◀ arrow or OK key.

- Scroll to desired drug, press ◀ arrow or OK to select.



- Confirm previous values by scrolling to each parameter. When all are checked press OK to confirm and then press Start/Stop to begin infusion.



Note: Reminder to check bag height and unclamp SECondary will appear, press Start/Stop again to begin SECondary infusion.

1.5 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 in either the PRIMary or SECondary mode. 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 above in Section 1.3.
- Enter weight or weight and height 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 ◀ arrow key.

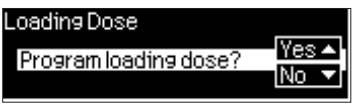
Note: The KVO and Bolus functions are disabled during Dose Over Time.

1.6 Programming a Loading Dose in Drug Library

The Infusomat® 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 ☎ key and re-programming the drug from the beginning.

To Program a loading dose:

- Press ▲ arrow to answer yes to loading dose prompt.



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

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

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

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

- Enter VTBI or Time.

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

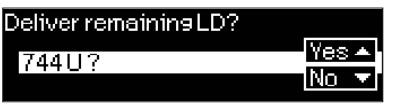
- Press Start/Stop to begin infusion.

Note: The word LOAD is superimposed on the run arrows.

Note: The loading dose may be stopped at any time by pressing the Start/Stop key. Press Start/Stop key to deliver remaining loading dose. There will be nothing infusing until Load Dose is resumed or cancelled 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 ▲ arrow for yes, ▼ arrow for no.



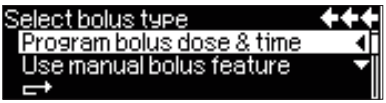
Note: Once "No" is selected it is no longer possible to recall the loading dose.

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

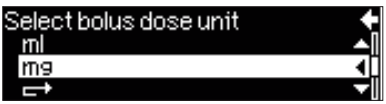
The Infusomat® Space® allows for delivery of a programmed bolus for drugs which have been set up in the drug library for bolus dosing.

- Press yellow BOL key.
- Select Program bolus dose and time.

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



- Select dosing unit and confirm with OK key.



Note: Pump defaults to bolus units set in the drug library. If the bolus ordered is in different units, press the ▲ or ▼ arrow key 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.

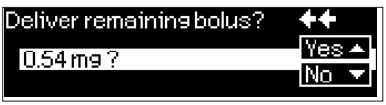
Note: The word Bolus superimposed over the run arrows is displayed on the screen.

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 key, the continuous will then run. Press key to deliver remaining bolus.

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



- If pump was not running, as after an operating alarm, press to begin the infusion and respond to prompt to deliver remaining bolus per above.

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

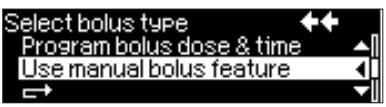
1.8 Manual Bolus

The Infusomat® 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 key.
- Select "Use Manual Bolus feature".



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

Manual bolus is limited to 10 seconds.

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

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

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

1.9 Changing Care Unit

The Infusomat® 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: during SECondary infusions, if the drug or concentration are not available in the new Care Unit and if hard limit is exceeded.

To change a Care Unit:

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

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

The doserate, dose or time editor will appear and required confirmation if parameter exceeds the soft limit in the new Care Unit. The soft limit warning will be shown requiring an over ride or new programming to proceed as in Section 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.

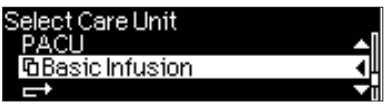
1.10 Changing display while pump is running

- While pump is running, press ▼ arrow 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 area, etc. Displayed value will remain until changed by user.

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

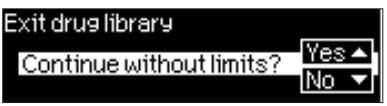
The Infusomat® Space® allows programming outside the drug library, referred to as a Basic infusion. To program a Basic infusion, select "Basic Infusion" from the Care Unit, Patient Profile, Drug Category or Drug selection screens.



Note: Basic infusion may be selected in the SECondary menu.

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

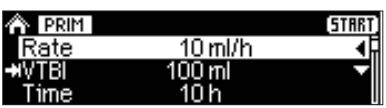
- A second prompt requires responding yes with ▲ to "Continue without limits".



- Respond "yes" or "no" to "Use dose rate calc?" (if configured). See Section 2.2.4.

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

- The pump requires user to enter 2 out of 3 of the following parameters: rate, VTBI or time. When 2 are entered, the pump calculates the 3rd parameter.



SECondary, programmed bolus and manual bolus are also available in Basic mode if enabled in the configuration. See Section 1.4, 1.7, 1.8. 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 20hrs 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 OK.

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.

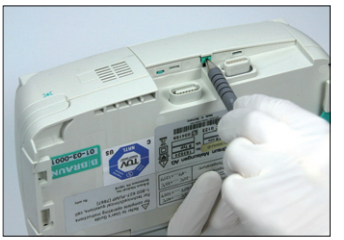
3.) Enter rate and time: The infusion volume will be calculated and displayed on the bottom of the display.
Rate titration will result in re-calculation of VTBI.

1.12 IV Line Change and New Therapy Start

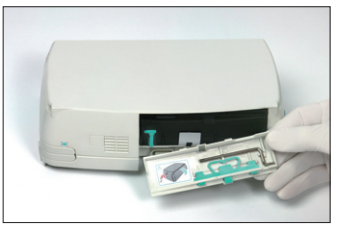
Note: Always close roller clamp and disconnect the line from the patient before changing a line to avoid inadvertent free flow.

- Press Start/Stop to stop the delivery. The green LED goes out. Close the roller clamp and disconnect line from the patient.
- Press and open the pump door with . Once door finishes opening automatically, pull down on door to fully open. Expect some resistance. Press down the green opening lever completely until it locks in place, releasing the pump based safety free flow clamp, and yellow light flashes, then remove the IV line from right to left and insert a new IV line, note that green anti-free flow clip occludes the IV line when removed.

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

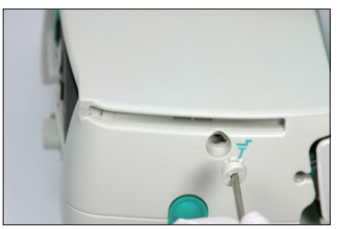


Push cover opening with pen.

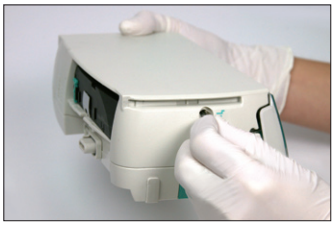


Remove crank from inside of battery cover.

Turn crank to remove emergency aperture cover.



Remove emergency aperture cover.



Turn crank inside aperture to open the door.

- Insert new IV line per Chapter 1.1. Close the pump door and open the roller clamp.
- If prompted, prime the pump with ▲. Then press ▼ to proceed when priming is complete.
- Connect IV 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 ↺ and respond yes to prompt "Exit and clear infusion". Note prompt will indicate if PRIM, SEC or both will be cleared depending on current pump mode and infusion status. B. Braun landing page will be displayed.

1.13 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.
- Press ⏏ and open the pump door with ▲ and remove IV line per above in Section 1.12.
- Close door and press ⏻ for 3 sec. to power off the pump.

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

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

1.14 Standby Mode

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

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

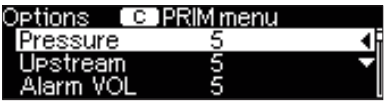
While the pump is in the standby mode, the display shows infusion mode, drug name and the remaining time for standby mode. Change remaining time by pressing ◀, standby may be set from 1 min. to 24 hours. Exit standby by pressing C.
The pump will alarm when the standby time expires.

- Press C to cancel standby.

PUMP MENUS

Menus are accessed from the Home screen using the arrow keys. Press key while pump is running to access home menu. All menus may be accessed while the pump is running except the SECondary menu. 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 . Primary, Secondary and Total of both are displayed. Scroll and select desired value, respond to prompt to zero the value.

Note: Pumps with U6, U10, U12, U15 and higher versions software the infusion totals are cleared when cleared by user, on power cycle and when previous infusion is not ued if prompted on power up.

Pumps with U11 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 to the Status menu on the home screen and scroll to version.

2.2 Options

2.2.1 Downstream Occlusion Pressure

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

- 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 Upstream Occlusion Pressure

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

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

2.2.3 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.

2.2.4 Dose Rate Calculator

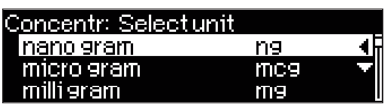
The Dose Rate Calculator may be used to calculate a doserate for a medication that is not in the drug library. While the pump will calculate the rate, it is important to realize there are no dose limits.

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

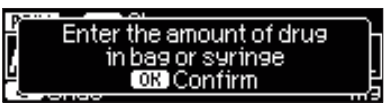
Note: Pump may be set up in service program to prompt "Use Dose Rate Calculator?" when a basic infusion is selected.

- Press (OK) to prompt to select concentration units.

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



- Press (OK) to prompt for entering amount of drug in bag.

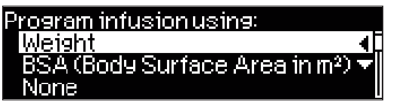


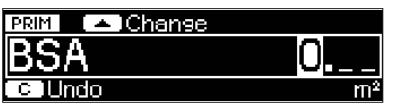
- Enter the amount of drug using arrow keys and confirm with (OK).

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

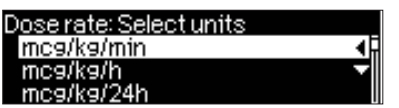
- Enter the volume of the bag using arrow keys and confirm with OK.

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





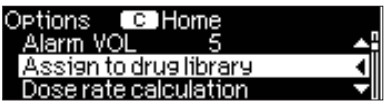
- Select the doserate units.



- Enter doserate using arrow keys and confirm with OK.
  Confirm and start infusion.
- *Enter VTBI or Time.
- To exit Dose Rate Calculation: the pump must be stopped. Press the C Key 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 key.
- 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.

2.2.5 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 door open and are locked and require entry of data lock code. The IV line may be changed.

Level 2:
Functions the same as level 1 and in addition does not allow the door to be opened and 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
Change IV line	✓	×	× 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 that 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.

2.2.6 KVO-Mode

The pump can continue the infusion with a preset KVO rate after an infusion time or VTBI has ended. 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.

2.2.7 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.

2.2.8 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.

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

2.2.9 Date / Time

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

2.2.10 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.

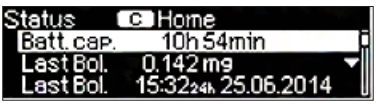
2.2.11 Wireless Activation

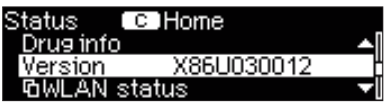
Allows wireless to set for active or inactive.

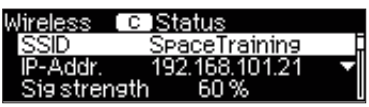
2.3 Status Menu

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
- IV line







ALARMS

The Infusomat® 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 unique. Press ⏻ to switch off the device. Then switch the device on again. 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.
"Battery nearly empty"	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
"VTBI infused "	The programmed volume was infused. Hang new bag and/or reset VTBI
"Time expired"	The programmed time has ended. Hang new bag 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.
"KVO time finished"	The KVO time has ended. Program new settings.
"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. Turn off pump and insert battery according to directions in "Overview Infusomat® Space®".
"Drive blocked"	Excess pressure in system or motor failure. Remove tubing and reinsert, if persists pump must be sent for service.
"Calibrate device"	Return to service for calibration.

Display message	Alarm reason
"Upstream occlusion - above pump"	The upstream pressure between the bag and the pump is high. Check if roller clamp is closed, or infusion line is kinked.
"Air bubble alarm"/ "Accumulated air exceeds limit"	Air detector limits are set in the service program. The air bubble size can be set between 0.02 - 0.3 mL in increments of 0.01. The accumulated air value may be set between 0.5 - 3.8 mL/hr in increments of 0.1 mL. The display will indicate air bubble or accumulated air as the cause of the alarm. When an air alarm is cleared (disconnect line from patient and follow display prompts to prime the air bubble out or follow hospital protocol) the system resets to zero.
"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.
Danger of FreeFlow - Clamp IV line	Anti-free flow clip not properly inserted. Close roller clamp, open door and re-insert IV line.

The red LED extinguishes with the acknowledgment of the operating alarm.

3.3 Reminder Alarms

Reminder alarms occur in 2 different scenarios.

1. A line 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 line 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.

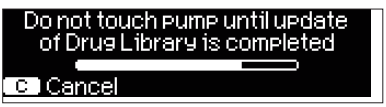
3.4 Alarm Prompts

A prompt provides direction to assist in properly operating the pump. (e.g. "Bolus function disabled", "Download failed", or "The parameter can not be modified").

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 key to stop infusion when patient condition allows.
- Close roller clamp, disconnect IV line from patient, press and remove IV line from right to left per Section 1.12 and 1.13.
- 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 DL 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 power key to restart 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.

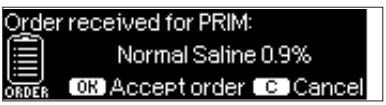
  New drug library has been activated on pump.

AUTOPROGRAMMING

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

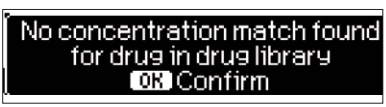
The pump can accept drug orders wirelessly from the EHR system. The workflow to accept an order wirelessly will vary depending on your EHR vendor.

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

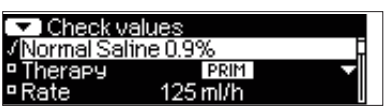


- Press OK to accept or C key to cancel order and respond to prompt.
- Select Care Unit and Patient Profile as in Drug Library programming in Chapter 1.
- Pump will search for Drug Library match.

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 manual programming outside the drug library per Chapter 1 Section 1.11 or rejects order completely. An order that is confirmed outside the drug library will have a triangle with an exclamation point on display to indicate there are no drug library settings.



- Scroll to each value to confirm using arrow keys.



Note: Order may be 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 autoprogramming).

For PRIMary Orders:

Note: The first order sent is always considered the PRIMary infusion, subsequent orders will be considered SECondary.

- Press Start/Stop key to start infusion.

Updates to Current Primary Infusion

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

While in PRIMary:

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

While in SECondary:

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

New Primary Infusion:

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

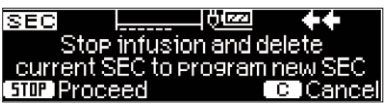
SECondary Orders:

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

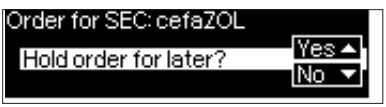
- Confirm order values as above for PRIMary orders.
- Respond to prompts to check bag height and clamps prior to starting SECondary.

New SECondary order while SECondary is Infusing:

- Follow display prompts to stop current infusion.

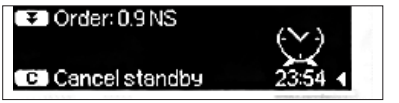


Note: A SECondary order may be held for later by pressing key to cancel order and answering yes to "hold for later".



Note: Changing values on any incoming order may only be done after confirming all values. Once all values are confirmed you may scroll to any value and open editor with to change value. Alternately, order may be 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 key to accept order (pump will come out of standby).



BATTERY OPERATION AND MAINTENANCE

Intended Use

The battery module of Space® guaranties operation independent of AC power when transporting patients within the facility. 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 Infusomat® 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 (article code 8713182U) and the wireless function is activated via the service program (HiBaSeD) or within the Options menu of the pump.
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 installers must consider suitable module and antenna installation locations in order to assure this in 20 cm (8 inch) separation, and end users be 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 if battery is mishandled. To avoid possible injury.

- Do not open or expose to heat above 60 °C (140 °F).
- Do not use damaged Battery-Packs.
- Do not attempt to disable it.
- Do not short circuit it.
- 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 the IEC 80001 should be observed.

6.3 Battery with WiFi

Handling the Battery Pack SP with WiFi:

The Battery Pack SP can be exchanged by any user.
No special qualification is required. Replace Battery Pack SP model 8713182U with corresponding models only. Replace battery pack for Space® with battery packs released by B. Braun. Other batteries may cause injury, fire or explosion.

Caution: The pump must be switched off before opening the battery compartment.

Open the cover of the battery compartment (see ch. 1.12), unlock the battery by sliding the green hook and pull out the battery using the metal handle. Replace the Battery Pack SP in the battery compartment, lock it with the green hook and test the proper placement by pulling the metal handle. Close the battery compartment again.

Note: In case of ESD, Pump may need to be plugged into wall outlet to restart the battery.

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

Connection to A/C power is displayed by the symbol in the main menu of the pump. Recharging of WiFi battery while connected to A/C 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 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 in the run screen. When the wireless transmitter is switched off, no symbol is shown in the status of the run screen.

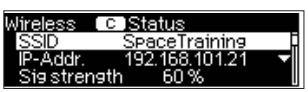
If the wireless is activated, the status of the connection is shown.

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

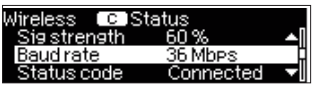
Note: An "X" through the wireless antenna indicates wireless connection has been lost, contact your bio-medical engineering or IT department to determine cause.

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

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



SSID: The Service Set Identifier 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.

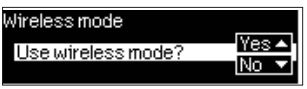
Baud rate is the maximum communication speed in mega bits per second (Mbps). The maximum baud rate strongly depends on the wireless standard (802.11 a/b/g/n).

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.



6.4 Battery maintenance

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

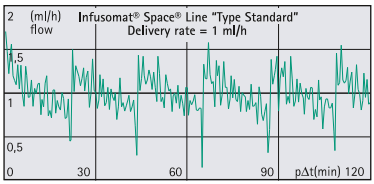
battery pre-alarm time may no longer be maintained. In this case it is necessary to perform a battery maintenance.

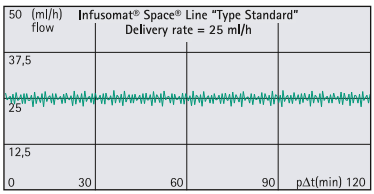
To initiate the discharge process the message "Battery maintenance" and the OK key will be displayed after switching the pump off. By pressing OK and ▲ the discharge process will start. The process is interrupted by switching the pump on again. If the battery maintenance is to be continued a new activation is necessary. After completely discharging the battery it will be completely charged again. The total duration of the battery maintenance process takes approximately twelve hours.

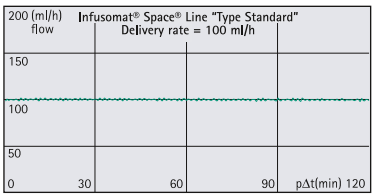
Caution: When the battery maintenance has not been completed there is a possibility of a reduced battery operating time.

START UP GRAPHS AND TRUMPET CURVES

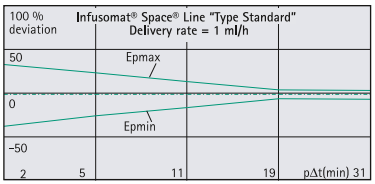
Start Up Graphs

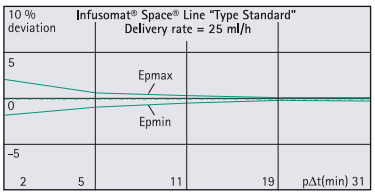


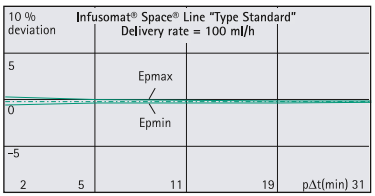




Trumpet Curves







The graphs show the accuracy/uniformity of flow in relation to time.
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)

TECHNICAL DATA

Type of unit	Volumetric infusion pump
Classification (acc. to IEC/EN 60601-1)	♥ defibrillator-proof; CF equipment ☐ Protective Class II; Protective Class I in combination with SpaceStation
Class (acc. to Directive 93/42 EEC)	IIb
Classification acc. to 21 CFR 880.5725	Class II (Product code FRN and FPA)
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 Lead SP	11 – 16 V DC, 8 VA ⎓ via Connection 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 ■ Temperature ■ Atmospheric pressure	 30 % – 90 % (without condensation) +60 – + 105 °F (+15 °C to 40 °C) 500 – 1060 mbar
Storage conditions: ■ Relative humidity ■ Temperature ■ Atmospheric pressure	 20 % – 90 % (without condensation) -4 – +131 °F (-20 °C to +55 °C) 500 – 1060 mbar
Type of battery pack (rechargeable)	Li-Ion NiMH
Operating time of rechargeable battery Li-Ion	 wireless active Infusomat® at 100 mL/h 4.0 hours wireless active Infusomat® at 1200 mL/h 2.5 hours wireless inactive Infusomat® at 100 mL/h 12.0 hours wireless inactive Infusomat® at 1200 mL/h 5.0 hours
NiMH	at 100 mL/h 13 hours at 1200 mL/h 5 hours
Recharging time	Approximately 6 hours
Weight	Approximately 1.4 kg
sions (W x H x D)	214 x 68 x 124 mm = 8.4 x 2.6 x 4.8 inches

Volume increments	0.1 - 99.99 mL in increments of 0.01 mL 100.0 – 999.9 mL in increments 0.1 mL 1000 – 9999 mL in increments 1 mL
Time selection	00:01 – 99:59 h
Accuracy of set delivery rate	± 5 % according to IEC/EN 60601-2-24
Administration Set Change Interval	Pumping accuracy is maintained for a minimum of 96 hours.
Max. Volume in case of single fault condition	For incorrect dosages of 1.4 mL due to malfunctions of the device the pump will automatically shut off
Technical inspection (safety check)	Every 2 years
Rate increments	0.1 - 99.99 mL/h in increments of 0.01 mL/h 100.0 - 999.9 mL/h in increments of 0.1 mL/h 1000.0 - 1200 mL/h in increments of 1 mL/h
Multiple lines connected to one patient port	Connecting multiple infusion lines with different flow rates may affect the rate for all infusions past the point of connection.
Accuracy of bolus infusion	typically ± 5 % 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.
Computer connection for Service Program	USB connection in combination with B. Braun interface lead CAN SP (8713230) including electrical insulation. Please pay attention to safety notices.
Air detector	The Infusomat® Space® Volumetric Infusion pump includes an ultrasonic air detection sensor that is used to detect air in the disposable set. Per the requirements of the IEC 60601-2-24 (2nd Ed. 51.104 and 3rd Ed. 201.12.4.4.107) the software uses this sensor to detect the accumulation of air not to exceed 1 mL/15 minutes of any air bubbles greater than or equal to 0.01 mL (10 uL). The air accumulating value may be set between

	0.5 – 3.8 mL/hr in increments of 0.1 mL/hr during configuration. In addition, the pump also has a configurable single bubble alarm that can be set between 0.02 – 0.3 mL in increments of 0.01 mL. The pump display indicates if the alarm is a Single bubble alarm or an Accumulated Air alarm and stops the infusion thus requiring intervention from the user to address the alarm.
"Upstream sensor"	9 levels from -90 mmHg to -160 mmHg (pressure reduction)
Occlusion alarm pressures (downstream pressure)	9 levels from 225mmHg to 900 mmHg

Occlusion pressure		Time to occlusion alarm [h:min:sec] at rate				Max bolus
	[mmHg]	[0.1 mL/hr]	[1 mL/hr]	[25 mL/hr]	[100 mL/hr]	[mL]
Level 1	typ. 226	08:40:00	00:09:07	00:00:33	00:00:07	0.0347
Level 5	typ. 563	> 10 h	00:25:53	00:01:14	00:00:15	0.0987
Level 9	typ. 900	> 10 h	00:46:50	00:02:06	00:00:24	0.1787

Alarm volume	9 levels (>50dBa to >65dBa)
Mechanical occlusion pressure limit under fault conditions	Occlusion alarm pressure max. 1575 mmHg (210 kPa). Maximum posts occlusion bolus volume 2 mL.
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 Infusomat® Space® line (870 0036 SP). These technical data can change when using different set configurations.

- Use only pressure proof and compatible disposable items (min. 2 bar/ 1500 mm Hg) to avoid influencing performance data - which would result in impairing patient safety.

- Use only compatible combinations of equipment, accessories, working parts and disposables with luer lock connectors.
- MR Conditional when used within the SpaceStation MRI.
- Only use 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 from air-infusion
- Protection against unintended bolus volumes and occlusion (added by IEC 60601-2-24)
- Alarm signal of high priority (added by IEC 60601-2-24)

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 (except where noted otherwise). The dosing units may be pre-set in the Drub Library (refer to Chapter 1.2) or selected when using the Dose Rate Calculator (refer to Chapter 2.2.4).

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/hr) = Dose/concentration x (patient weight or BSA)

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 (8713185) is used RF energy is transmitted by the Space® System. Refer to technical data of Battery-Pack SP with Wifi IFU and/or SpaceStation and SpaceCom for details.
RF emissions CISPR 11	Class B (Note 2)	The Space® System or any component is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	applicable only for SpaceStation Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
Note 1: Maximum emissions are measured with a complete system (SpaceStation and components). Note 2: If Class A equipment is attached to the Space® System, the Space® System will become Class A too. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting 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: ± 6 kV IEC 60601-2-24: ± 8 kV air IEC 60601-1-2: ± 8 kV IEC 60601-2-24: ± 15 kV	± 6 kV no disturbances ± 8 kV stop with alarm possible ± 8 kV no disturbances ± 15 kV 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	± 2 kV ± 1 kV	A/C power quality should be that of a typical commercial or hospital environment.
Surge according IEC 61000-4-5	differential mode ± 1 kV common mode ± 2 kV	± 1 kV ± 2 kV	A/C power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines according IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec. < 5 % UT for 5 sec. (> 95 % dip)	complies by use of internal battery	A/C power quality should be that of a typical commercial or hospital environment. If the user of the Space® System requires continued operation during long time A/C power interruptions, it is recommended that the Space® System or component be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field according IEC 61000-4-8	3 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: Different test values of IEC 60601-2-24 are marked in the table. At the test values no ...us 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. **Recommended separation distance**
radiated electromagnetic RF fields according IEC 61000-4-6	IEC 60601-1-2: 3 Veff normal and 10 Veff in ISM frequency band		d = 1.2 √P Field strengths should be less then 10 V/m
	IEC 60601-2-24: 10 Veff 150 kHz to 80 MHz	10 Veff 150 kHz to 80 MHz	d = 1.2 √P 80 MHz to 800 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 = 2.3 √P 800 MHz to 2.5GHz where p is the maximum output power rating of the transmitter in watts (W) according to the 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 Space® System 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 reorienting or relocating the Space® System.

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

rated power of the ratio transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz 1.2 √P	**80 MHz to 800 MHz** 1.2 √P	**800 MHz to 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, readjustments, 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 version X86U. Please ask your local representative for further details.

Technical Safety Check* (TSC) / 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.

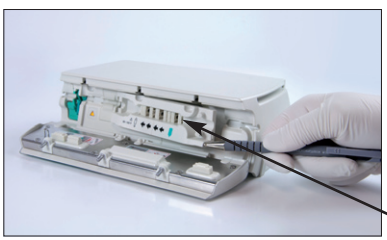
Clean all external surfaces (includes inside the pump door) using a clean, soft, low lint cloth dampened with product or commercial wipes containing an approved agent. Make sure to remove any visible residue from all surfaces prior to disinfecting. Disinfect the housing of Infusomat® Space® and surface 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.

Cleaning for Peristaltic Fingers

- To clean and disinfect the peristaltic fingers and membrane, the peristaltic fingers cover can be removed using a pointed object (ballpoint pen) inserted in the lower right corner.

Caution: Do not touch peristaltic fingers cover or peristaltic pumping area of pump with sharp object.

Caution: Do not touch the peristaltic fingers and membrane area of pump with sharp object.



- Do not use chloride disinfectant products (bleach) on the peristaltic fingers and membrane area of the pump.
- Clean cover, peristaltic fingers and membrane using a clean, soft, low lint cloth dampened with product containing an approved agent EXCLUDING sodium hypochlorite.

- The peristaltic fingers cover may be cleaned under running water after it is removed from the pump.
- Disinfect peristaltic fingers cover, peristaltic fingers and membrane following the same procedure as stated above. Caution: Do not touch the peristaltic fingers and membrane area of pump with sharp object.
- When reinserting the peristaltic fingers cover, make sure that it is not damaged and that it audibly locks in place.

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 manufacturers' 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.

Disposal

The pumps as well as battery packs can be returned to B. Braun for disposal. Separate disposal is required for electrical and electronic equipment.

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 service.
The device should be tested for proper functioning before initial use.

Included in Delivery

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

OPTIONAL SPACE® ACCESSORIES

SpaceStation (8713140U)

Station that can hold for 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 Infusomat® Space®" and "Patient Safety."

Space Power Supply – US (8713127) / Power Supply SP (8713112D)

The Power Supply can supply power for a single pump.

1.) Connect P2 plug of Power Supply 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 (8713112D) or 0.5-0.2A (8713127).

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.

Interface Lead CAN SP (8713230)

Interface Lead CAN SP is needed in order to set up a connection between the SpaceStation and /or pump and the computer to use the service program (HiBaSed).

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

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

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

SpaceStation MRI (8713152)

The SpaceStation MRI allows to use up to four pumps within the MRI Environment up to 20mT / 200 Gauss line. Refer to SpaceStation MRI Instruction for Use.

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

	Art. No.
B. Braun Infusomat® Space® (100 – 240 V) + Battery-Pack SP with Wifi (Li-Ion)	8713051U
B. Braun Infusomat® Space® (100 – 240 V) + Battery-Pack SP without Wifi (NiMH)	8713052U

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

SpaceStation	8713140U
SpaceStation with SpaceCom	8713142U
SpaceCover Comfort	8713145U
Space Pole Clamp (speed clamp)	8713131
Space Power Supply – US	8713127
Power Supply SP (US Plug)	8713112D
Combi Lead SP 12 V	8713133
Interface Lead CAN SP	8713230
Interface Lead RS232 SP	8713234
SpaceStation MRI	8713152

Infusomat® Space® Lines/Sets – Product families:

- 15 Drop Set
- 60 Drop Set
- Blood Set
- Epidural Set
- Filtered Set

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,
- 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.

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