

Infusomat® Space

and Accessory

Instructions for Use



Valid for Software 686C

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The Infusomat® Space is according to IEC/EN 60601-1 resp. IEC/EN 60601-2-24 a volumetric infusion pump for infusion of small and large volumes at highest accuracy and is suitable for intravenous applications, for blood transfusion and for enteral nutrition. The medical specialist has to decide on the suitability of the application. The decision has to be made on the basis of the warranted properties and technical data. For further details please refer to the Instructions for Use.

INFUSOMAT® SPACE OVERVIEW

Arrow up and -down

Scroll through menus, change setting of numbers from 0-9, answer Yes/No questions.

Arrow left and -right

Select data from a scale and switch between digits when numbers are entered. Open a function while pump is running or stopped with the left arrow key.



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

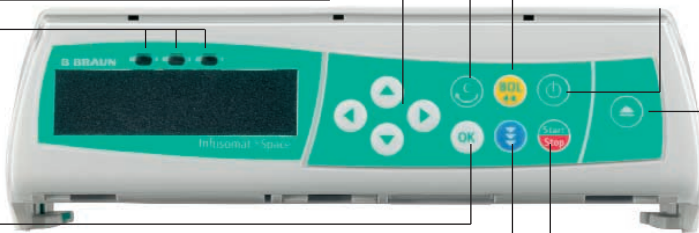
Press to reset single values to zero and switch back to the previous screen/menu level.

Press to open the pump door.



Press to initiate bolus.

Press to turn pump on/off.



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

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

Press to Start/Stop infusion.

Cover of Battery Compartment

Before changing the battery, always disconnect the pump from the patient and switch off the device.

To remove the battery cover push the button below the battery compartment with a pointed pen and pull the cover away from device. Slide green locking mechanism on back of battery up and take out battery pack for exchange.

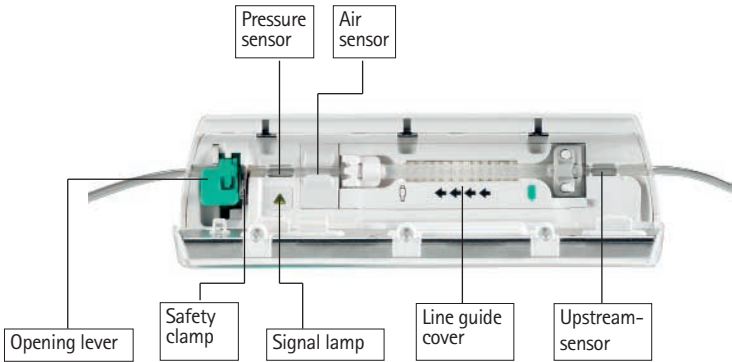
A crank in order to open the pump door in case of emergency is attached to the inside of the battery compartment cover (for closer information see 1.4).



Port for drop sensor

Port P3 for SpaceControl

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



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



Transport
 A maximum of three pumps (Infusomat® Space or Perfusor® Space) plus one SpaceControl may be stacked together. Avoid external mechanical influence.

Locking Devices Together
 Line up the bar of lower pump with bar of pump above and slide lower pump backwards until the lock clicks and the green buttons are above each other.
 To disconnect, push green locking buttons of top pump device and slide bottom pump forward.



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

PATIENT SAFETY



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

Operation

- The initial training of the Infusomat® Space is to be performed by B. Braun sales personnel or other authorized persons. After each software update, the user is requested to inform himself about the changes of the device and accessories in the Instructions for Use.
- Ensure the unit is properly positioned and secured. The pump must be positioned on a level surface if used in combination with the short stand. Do not position the pump above the patient.
- Prior to administration, visibly inspect the pump for damage, missing parts or contamination and check audible and visible alarms during selftest.
- Connect to patient only after the line was correctly inserted and completely primed. Interrupt connection during line change to prevent incorrect dose delivery.
- Select infusion line/catheter suitable for use with the intended medical application.
- Position the infusion line free of kinks.
- Recommended change of disposable each 24 h (or as per national hygiene regulations).
- Installation in medically used rooms must comply with the appropriate regulations (e.g. VDE 0100, VDE 0107 or IEC-publications). Observe national specifications and deviations.
- Do not operate the pump in the presence of flammable anaesthetics to prevent explosion.
- Compare the displayed value with the entered value. Start infusion only if the values are corresponding.
- If staff call is used we recommend checking the equipment once after connecting the pump.
- Protect the device and the power supply against moisture.
- If the pump falls down or is exposed to force, it must be checked by the service department.
- The displayed data must always be checked by the user prior to making further medical decisions.
- During mobile use (homecare, patient transport inside and outside the hospital): Make sure the device is securely fixed and positioned. Positioning changes and severe shock can lead to minor changes in the delivery accuracy.

- A supplemental patient monitoring must be carried out if life-saving medication is performed
- The air detector cannot detect air diffusing in the following components: three-way stopcocks, infusion adapters and further lines placed between pump and patient.

Other components

- Use only pressure-proof and compatible disposable items (min. 2 bar/ 1500 mm Hg) to avoid that performance data are influenced – which would result in impairing patient safety.
- Where several infusion lines are connected on one single vascular access, the possibility of the lines exerting a mutual influence over each other cannot be excluded.
- Refer to respective manufacturer's information for possible incompatibilities of equipment with respect to drugs.
- Use only compatible combinations of equipment, accessories, working parts and disposables with luer lock connectors.
- Connected electrical equipment must comply with the relevant IEC/EN-specifications (e.g. IEC/EN 60950 for data-processing equipment). The user/operator is responsible for the system configuration if additional equipment is connected. The international standard IEC/EN 60601-1-1 has to be taken into account.









Safety Standards

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

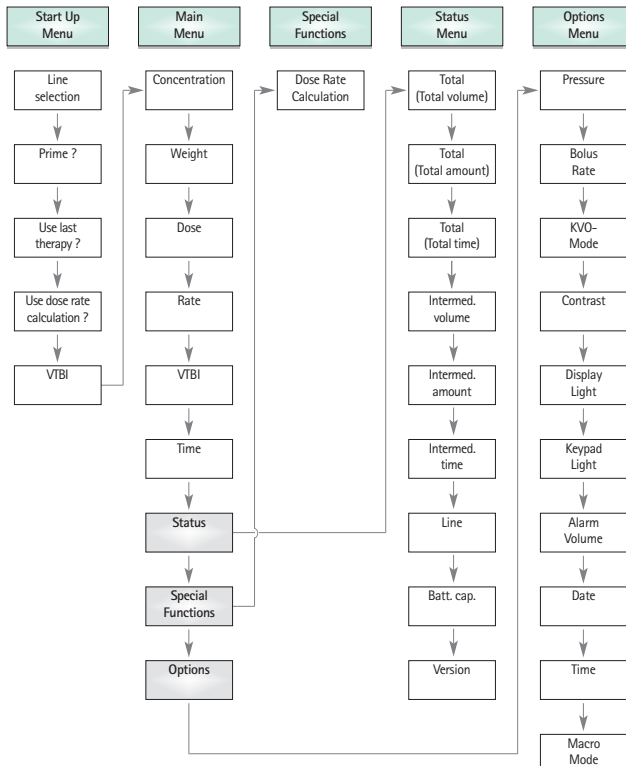
- The EMC-limits (electro-magnetic compatibility) according to IEC/EN 60601-1-2 and IEC/EN 60601-2-24 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones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

MENU STRUCTURE / OVERVIEW

Cutline

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

Menu Structure



The pump can be customized by (de-)activating the menu items of the Start Up (except VTBI) and Options Menu as well as the bolus function via the service program. 7

MENU STRUCTURE / NAVIGATION

Display



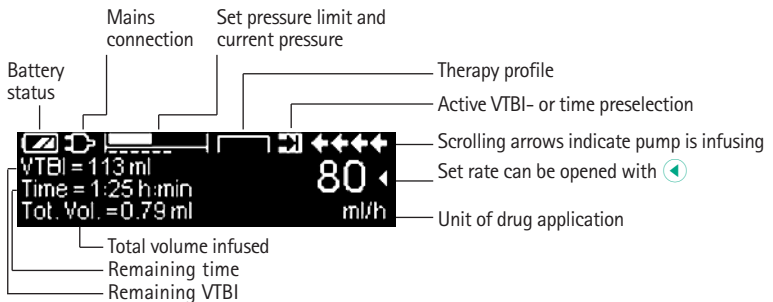
Meaning

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



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

Typical display during infusion:



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



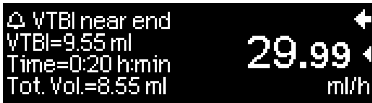
This hint pops up if a user tries to edit or change a parameter by pressing when that parameter is unable to be changed.

Display



Meaning

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



Pre-alarms are indicated by 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**.




In case of an operating alarm (e.g. "VTBI infused") the infusion stops, an audible tone sounds and the red LED flashes. Confirm alarm by using **OK**.









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

OPERATION

1.1 Start of Infusion

- Ensure that the pump is properly installed. Check the equipment for completeness and damages. Do not attach the infusion bottle below the pump level.
- Put the spike vertically into the infusion bottle. Fill the bottom part of the drop chamber by max. 2/3.
- Fill the infusion line from below to the top, then close the roller clamp.
- If the device is connected to the mains, the display indicates the battery status, the mains connection symbol and the last therapy.
- Press  to switch on the device. Observe the automatic self-test: The message "Self-test active" and the software version are displayed, two audible tones sound and all three LEDs (yellow, green/red and blue) flash once. Information about the power supply (mains or battery operation) and the set pressure level are indicated. In addition, the line type appears at first (provided that the line is already inserted). Then, the accumulated air volume and the max. size of air bubbles is indicated which is triggering the air alarm of the device.

During the first ever start-up of the device, the user is requested to select the language with  and confirm with . Answer the following question with  in order to take over language.

- Press  to start the direct entry of therapy parameters, or press  and  to open the pump door in order to continue with inserting the line.

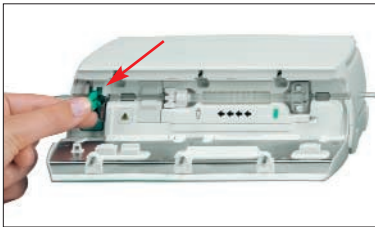
Caution: You may only insert the line while the device is switched on and the line guide element is inserted. Otherwise, there is the danger of freeflow. Pay attention to keep the roller clamp closed before inserting the infusion line especially at a temperature scale of 10 - 15 °C. Never leave the pump unattended when inserting the tube.





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






In the next step, attach the white clip without twisting the line.








Insert the freeflow clamp (see red arrow) in the opened aperture, in the direction indicated by the arrow, until the opening lever locks in and the safety clamp squeezes the lines (flashing signal lamp goes out).

- Close the pump door. Then select the inserted line with  and confirm it with . Open the roller clamp.

Caution: If a wrong line is selected, errors may occur during VTBI delivery and the alarm limits are shifted.




- Press  if the prime function is enabled to prime the infusion line with the rate displayed. Cancel priming with . Repeat the procedure until the line is completely primed. Then press  to proceed.



Note: During priming, all air and drop alarms are switched off.

- Establish the patient connection.
- Answer the question whether the old therapy is to be used either with  or  (the question can be deactivated via the service manual). If you select , the pump jumps to the Main Menu. If you select  with no drop sensor connected, you must first enter a VTBI which is smaller than the container filling and confirm it with .

Note: Due to safety reasons, it is recommended to use the drop sensor – particularly in connection with delivery rates ≤ 10 ml/h.

Adjusting the delivery rate:

- In the Main Menu, open the rate with  and set it with .
- Press  to start the infusion. Running arrows on the display and the green LED indicate that the pump is infusing.









Note: The running infusion can be cancelled at any time by pressing . The pump can be switched off at any time by pressing  for 3 sec.

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

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

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

Target: Volume

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

Check calculated rate on plausibility.

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

2.) Infusion with volume limit

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

Target: VTBI

3.) Infusion with time limit

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

Target: Time

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

a) Target symbol is placed in front of VTBI:













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

b) Target symbol is placed in front of time:

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


1.3 Bolus Application


There are three ways to administer a bolus:

- 1.) Manual Bolus: Press . Then press  and hold button. Fluid is administered as long as button is held down. The infused bolus volume is displayed. The max. bolus volume is limited to 10 sec.
- 2.) Bolus with volume preselection: Press . Then press  and set bolus limit by using . Press  to confirm and start bolus.
- 3.) Bolus with rate calculation: Press . Then press  and set bolus limit by using . Press  to confirm bolus limit. Set time with  in which a bolus is to be delivered. Calculated bolus rate is shown on top of the display. Press  to confirm and start bolus.

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




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

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




Caution: Take care not to overdose! Given a bolus rate of 1200 ml/h, 1 ml will be administered in just 3 sec. To cancel bolus infusion at any time press .

1.4 Infusion Line Change and New Therapy Start


Note: Always interrupt the patient connection before changing a line to avoid dosing errors. Never let the pump run unattended when changing the line. Check and clean the safety clamp regularly.

- Press  to stop the delivery. The green LED goes out. Close the roller clamp and interrupt the patient connection.
- Press  and open the pump door with . Press down the green opening lever completely until it locks in place, remove the line and insert a new line.





Note: If for an unknown reason the pump door cannot be opened anymore, you need to take a crank from the inside of the battery compartment cover. Use this crank to remove the emergency aperture cover of the pump. Place the crank in the aperture and turn it clockwise until the pump door opens.

- Close the pump door, confirm the inserted line with  and open the roller clamp.
- If required, prime the pump with . Then press  to proceed.

- Establish the patient connection and check the parameters with .
- Start the infusion by pressing .

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








1.5 End of Infusion

- Press  to stop the infusion. The green LED goes out. Close the roller clamp and interrupt the patient connection.
- Press . Answer the question whether the pump door is to be opened with .
- Press down the green opening lever completely until it locks in place. Remove the line and close the pump door.
- Press  for 3 sec to switch off the pump.

Note: The settings will be permanently saved by the switched off device.





1.6 Standby Mode

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






- Press  to stop the infusion. Then press  for less than 3 sec.
 - Confirm the pump is supposed to switch into standby by pressing .
 - The default time for standby is displayed. Accept the default time with  or change it with  (0-24 hours) and then confirm it by pressing .
- => While the pump is in the standby mode, it's display shows the remaining time for this mode. Exit standby by pressing .

ADVANCED OPERATIONS

2.1 Status Request of Pump when Infusion is Running






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




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

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

Reset Status Menu Data:

The parameters intermediate volume and -time can be resetted when the pump is infusing or when the pump is stopped.

- Select "Status" in Main Menu with  and press .
- Highlight intermediate volume (in ml) or intermediate time (in h:min) with  and open parameter with .
- Reset values by pressing .

Both parameter total volume and -time, are being displayed in the pump as "Total" with the according unit and can be reset by starting a new therapy. A second way to reset the parameters when the pump is in the Main Menu: Press , answer question if the last therapy is to be used with  and reset the values with .

The type of the inserted line is displayed in menu item „Line“ and cannot be changed once it has been confirmed at the beginning of the infusion. The current battery capacity in hours and minutes is displayed in the menu item "Battery Cap." and the current software version in menu item "Version".

SPECIAL FUNCTIONS


















3.1 Dose Rate Calculation (Overview)

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

Setting parameters:



1. Concentration as the amount of the active ingredient per volume.
 - Amount of the active ingredient in μg , mg, mmol, IU or mEq.
 - Volume in ml.
2. Where necessary: Patient weight in kg.
3. Dose prescription:
 - time related as the amount of the active ingredient per min, h or 24h.
 - time and patient weight related as the amount of the active ingredient per kg per min, h or 24h.
4. Where necessary: VTBI in ml.

3.2 Dose Rate Calculation (Operation)



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

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

Additionally the total and intermediate amount of the infused drug can be taken from the Status Menu. These can be checked and resetted in the same way as the other total and intermediate values.





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

OPTIONS

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

4.1 Occlusion Pressure

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

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



4.2 Bolus Rate

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

Note: Set bolus rate according to therapy requirements. Take care not to overdose! Given a bolus rate of 1200 ml/h, e.g. 0.33 ml are reached within just one second.


4.3 KVO-Mode

The pump can continue the infusion with a preset KVO-rate after a preselected VTBI/time has passed (see "Technical Data"). The duration of the KVO delivery is defined in the service program.

- Open the KVO-mode in the Options Menu with .
- Answer the Yes/No question with  to enable the KVO-mode.





4.4 Contrast / Display Light / Keypad Light

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




- Open contrast/display light/keypad light in Options Menu by pressing .
- Choose between 9 contrast- and display light levels with  or  and confirm with .

4.5 Alarm Volume

Chose between 9 different alarm volume levels.



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


4.6 Date / Time

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

4.7 Macro Mode





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

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

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


ALARM

The Infusomat® Space is equipped with a audible and optical alarm signal.

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

5.1 Pre-Alarms and Operating Alarms

Pre-alarms:


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

Display message	Pre-alarm reason
"VTBI near end"	The preselected volume is nearly infused.
"Time near end"	The preselected time is almost over.
"Battery nearly empty"	The battery is almost discharged.
"KVO active"	VTBI/time are reached and the pump continues the infusion at the KVO-rate.

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

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

Operating alarms:

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



Display message	Alarm reason
"VTBI infused "	The preselected volume was infused. Continue therapy or select new therapy.
"Time expired"	The preselected time has ended. Continue therapy or select new therapy.
"Battery empty"	The battery pack is discharged. Connect device with mains and/or exchange battery pack. The battery alarm will be on for 3 min. Then the pump will automatically turn off.
"Pressure high"	An occlusion occurred in the system. The set pressure level was exceeded. A bolus reduction is automatically initiated by the pump. Check if tubing contains kinks or is damaged as well as IV- and filter patency. Increase occlusion pressure if necessary.
"KVO finished"	The KVO-time has ended. Continue therapy or set new therapy.
"Battery cover removed"	The battery cover is not properly engaged on the battery compartment. When pushing on the battery cover listen for "click".
"Standby time expired"	The set standby time has ended. Set new time or continue with previously set therapy.
"No battery inserted"	It is not possible do use the pump without a battery pack. Turn off pump and insert battery pack according to description "Overview Infusomat® Space".
"Drive blocked"	Stepper motor does not deliver due to excess pressure in the system. Interrupt patient connection and reinsert the line.
"Calibrate device"	Pump calibration data have changed (e.g. after an update). Recalibrate device via the service program.

"Drop sensor connection"	Contact to the drop sensor is interrupted while the pump is delivering. Check whether the drop sensor is correctly placed on the drop chamber. If necessary, replace the drop sensor or preselect VTBI/time and proceed with therapy.
"Check upstream"	The upstream sensor triggers an alarm. Check if roller clamp is closed or infusion line is kinked.
"Air bubble "/"Accumulated air"	Air inside the system. Check the line for small air bubbles and disconnect from patient to repeat priming, if necessary.
"No drops"	The drop sensor does not detect any drops. The infusion container is empty, the roller clamp is closed, the drop sensor is not put on, check the line for obstructions, condensation on drop chamber (remove by shaking it).
"Too few drops"	The number of fallen drops is lower than the preset rate. A negative pressure in a glass infusion container can be eliminated by opening the vent flap on the drop chamber. Check whether the infusion bottle is empty, the roller clamp is completely opened and whether there are any kinks in the line.
"Too many drops"	The number of fallen drops is higher than the preset rate. Check the line for damage and make sure that the line is correctly inserted.
"Flow"	Drop chamber is completely filled or leak in the system. Examine the line for damage and check the drop chamber.
"Data were reset"	Therapy and pump settings could not be restored. Enter therapy and pump settings anew.
"Therapy data were reset"	Therapy data could not be restored. Enter therapy anew.

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

5.2 Reminder Alarms

Reminder alarms only occur in two cases:

1. A line is inserted, the pump does not deliver, no value is edited and the device is not operated for two minutes.
An acoustic tone sounds, the yellow LED blinks and a staff call is activated.
 - a) The display states "Reminder alarm!"
 - b) The display states "Config. not finished!"Confirm alarm with  and continue to set therapy/Start Up configuration.
2. A value edition was started but not finished and confirmed. This is also possible with a missing disposable.
An acoustic tone sounds, the display states "Value not accepted", the yellow LED blinks and a staff call is activated.
Confirm alarm with  and continue to set therapy.

5.3 Alarm Hints

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

BATTERY OPERATION AND MAINTENANCE

The Infusomat® Space is equipped with the latest NiMH-battery. It has an operating lifetime of 4 hours at 100 ml/h when new. For optimal treatment of the battery, the device is equipped with protection against overcharge and deep depletion. The battery pack is charged by the pump during connection to mains. When disconnected from mains or in case of power failure, the pump automatically switches to battery power.

Note: Before changing the battery, always disconnect the pump from the patient and switch off the device.

The battery status indicator is a trend display (low, medium, high). For more detailed information on the current battery capacity (operating time in hours and minutes) please refer to menu item "Batt. Cap." in the Status Menu of the Infusomat® Space.

Important information for battery self-check:

If the battery symbol is blinking during mains operation, the battery is either discharged or has a reduced capacity. In this case, the pump should not be disconnected from mains. If it is necessary to disconnect the pump from mains power for urgent reasons, the user should check to ensure if the battery capacity is sufficient for the proposed use. When the battery symbol blinks permanently (>1h), the battery must be checked by a technician and replaced if necessary.

Directions for optimal battery use:

The actual battery life may vary due to




- ambient temperature
- varying load (e.g. frequent boluses).

The life of a battery can be prolonged if the battery is regularly charged and discharged. For this the pump must be used in the battery mode until the battery alarm sounds. Subsequently, the pump should be connected to mains for at least 6 h. This process is recommended to be done once per month. Furthermore:

- If possible, only charge the battery if it has been completely discharged.
- If a battery, which is not completely discharged, is charged several times, its capacity can be reduced. Its original capacity can be reached again if the battery is completely discharged and then recharged.
- Under normal temperature conditions a battery can be charged and discharged approx. 500 times before its lifetime decreases.
- When the pump is not connected to mains power the battery discharges itself slowly. This can occur even when the pump is not operating. The original capacity will only be reached after several cycles of charging and discharging.
- The battery operating time only can be realized if the pump operates continuously with a fully charged battery at room temperature. The display of the battery operating time on the pump is an approximate value based on the current delivery rate. If the battery is aged it may differ from the actual achievable operating time.

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

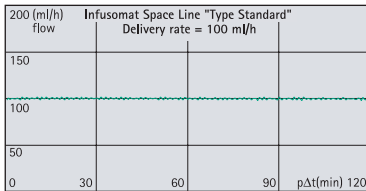
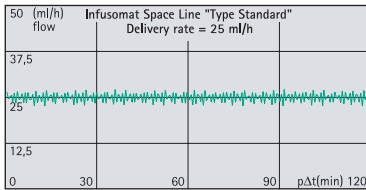
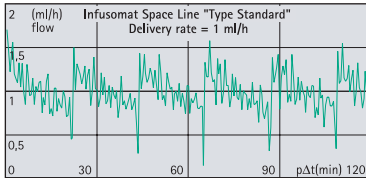
Battery maintenance:

If the pump has been connected to mains for 30 days, a complete discharge of the battery is necessary in order to prolong the lifetime of the battery. To initiate the discharge process the writing „Battery maintenance“ and the -key will be displayed after switching the pump off. By pressing  and  the discharge process will start. The process is interrupted by switching the pump on again. If the battery maintenance shall be continued a new activation is necessary. After completely discharging the battery it will be completely charged again. The total duration of the battery maintenance process takes approx. twelve hours.

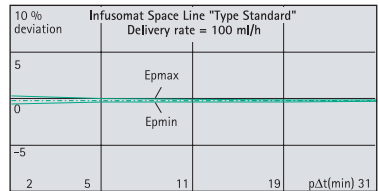
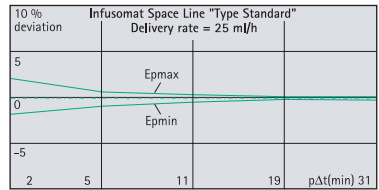
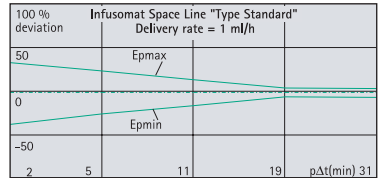
Caution: Please take into account the possibly reduced battery operating time when the battery maintenance isn't completed yet.

START UP GRAPHS AND TRUMPET CURVES

Start Up Graphs



Trumpet Curves



The graphs show the accuracy/uniformity of flow in relation to time. They allow for the following:

The delivery behaviour or delivery precision is essentially influenced by the type of the disposable used. If other lines (disposables) than those stated in the order data are used, deviations from the technical data of the pump cannot be excluded.

Trumpet Curves

Measured values for second hour in each case.

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

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

Start Up Graphs

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

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

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

TECHNICAL DATA

Type of unit	Volumetric infusion pump
Classification (acc. to IEC/EN 60601-1)	<input checked="" type="checkbox"/> defibrillator-proof; CF equipment <input type="checkbox"/> Protective Class II; Protective Class I in combination with SpaceStation
Class (acc. to Directive 93/42 EEC)	IIb
Moisture protection	IP 22 (drip protected for horizontal usage)
External power supply:	
• Rated voltage	Via B. Braun SpaceStation or optional mains adaptor (rated voltage 100 ... 240 V AC~, 50/60 Hz) for stand alone operation
• External low voltage	11 ... 16 V DC --- via external power supply 12 V or via SpaceStation
Staff call	Max. 24 V / 0,5 A / 24 VA (VDE 0834)
EMC	IEC/EN 60601-1-2 / 60601-2-24
Time of operation	100 % (continuous operation)
Operating conditions:	
• Relative humidity	30 % ... 90 % (without condensation)
• Temperature	+10 ... +40 °C
• Atmospheric pressure	500 ... 1060 mbar
Storage conditions:	
• Relative humidity	30 % ... 90 % (without condensation)
• Temperature	-20 ... +55 °C
• Atmospheric pressure	500 ... 1060 mbar
Type of battery pack (rechargeable)	NiMH
Operating time of rechargeable battery	Approx. 4 hours at 100 ml/h
Recharging time	Approx. 6 hours
Weight	Approx. 1.4 kg
Dimensions (W x H x D)	214 x 68 x 124 mm
Volume preselection	0.1 - 99.99 ml in increments of 0.01 ml 100.0 - 999.0 ml in increments 0.1 ml 1000 - 9999 ml in increments 1 ml
Time preselection	00:01 - 99:59 h
Accuracy of set delivery rate	± 5 % according to IEC/EN 60601-2-24
Alarm in the case of incorrect dose	For incorrect dosages of 1,4 ml due to malfunctions of the device the pump will automatically shut off
Technical inspection (safety check)	Every 2 years

Rate increments	0.1 - 99.99 ml/h in increments of 0.01 ml/h 100.0 - 999.9 ml/h in increments of 0.1 ml/h 1000.0 - 1200 ml/h in increments of 1 ml/h
Accuracy of bolus infusion	typ. \pm 5 %
KVO-rate	Delivery rate \geq 10 ml/h: KVO-rate 3 ml/h Delivery rate < 10 ml/h: KVO-rate 1 ml/h Delivery rate < 1 ml/h: KVO-rate = set rate
Computer connection	USB connection in combination with B. Braun interface lead CAN SP (8713230) including electrical insulation. Please pay attention to safety notices.
Air detector	Technical sensitivity: Detection of air bubbles \geq 0.01 ml Alarm triggering: At an air bubble size of typ. 0.02 - 0.3 ml* respectively 1.5 ml/h** (cumulated value over 1 h from air bubbles size 0.01ml).
Occlusion alarm pressures	9 levels from 0.1 - 1.2 bar

	Occlusion pressure				Time to occlusion alarm [min] at rate	Max. bolus [ml]
	[bar]	[1 ml/h]	[25 ml/h]	[100 ml/h]		
Level 1	typ. 0.3	09:07	00:33	00:07	0.0347	
Level 5	typ. 0.7	25:53	01:14	00:15	0.0987	
Level 9	typ. 1.2	46:50	02:06	00:24	0.1787	

Mechanical occlusion pressure limit under fault conditions

Occlusion alarm pressure max. 2.1 bar (210 kPa).
Max. bolus volume 2 ml.

History protocol

1000 last history entries.
100 events for system diagnose.
Refer to separate documents of the History Viewer for closer information.

* to be set via the service program in increments of 0.01ml

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

Note: The technical data stated in this Instructions for Use manual were determined with the Infusomat® Space lines as of "Type Standard" (870 0036 SP).

WARRANTY / TSC* / SERVICE / CLEANING / DISPOSAL

Responsibility of the Manufacturer

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

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

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

B. Braun
Melsungen AG

Warranty

B. Braun provides 24 months warranty, as from the date of delivery, for every Infusomat® Space (12 months for every Battery-Pack SP). This covers repair or replacement of parts damaged as a result of design/manufacturing errors or material defects. Modifications or repairs to the unit undertaken by the user/operator or by third parties invalidate the warranty.

The warranty does not cover the following:

Elimination of faults attributable to incorrect/unauthorized handling, or to normal wear and tear.

Technical Safety Check*) / Service

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

Check regularly

Check for cleanliness, completeness and damage. Use only according to Instructions for Use. Check the following items each time the pump is switched on: self-check, audible alarm, process- and alarm control indication.

Cleaning

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

Disposal

The pumps as well as battery packs can be returned to B. Braun for further disposal. When taking care of disposing of disposables as well as infusion solutions, please consider the applicable hygiene and disposal regulations.

Inspection on Delivery

Despite careful packaging, the risk of damage during transport cannot be entirely prevented. Upon delivery, please check that all items are present. Do not use a damaged device. Contact the service department.

Included in Delivery

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

INSTRUCTIONS FOR USE ACCESSORY

SpaceStation (8713140)

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

SpaceCover Standard (871 3147)

SpaceCover Comfort (871 3145)

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

PoleClamp SP (8713130)

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

Power Supply SP (8713110-8713114)

The Power Supply SP is adequate to supply power for a single pump and one SpaceControl.

- 1.) Connect plug of Power Supply SP with socket P2 on back of pump (ensure that plug "clicks").
- 2.) Push power plug into wall outlet.

Note: For disconnection from pump, press lever on plug down.

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

Technical Data: 100 – 240V AC~, 50/60 Hz

Combi Lead SP 12 V (8713133)

The Combi Lead SP can connect up to three pumps. All pumps can then be operated via the Connection Lead SP (12 V).

- 1.) Connect plug of the Combi Lead SP 12 V with the socket P2 on the back of the pump.
- 2.) Connect plug of Connection Lead SP with Combi Lead SP.
- 3.) Push plug of Connection Lead SP into 12 V connector.

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

Drop Sensor SP (8713180)

The drop sensor provides an additional safety function and is therefore particularly recommended in connection with low delivery rates.

The connection of the Drop Sensor SP on the pump is located at the rear of the device, in the lower left corner. At the time of delivery the port of the drop sensor is protected by a cover. Use a screw driver to break off the cover for further disposal.

Use holder on PoleClamp, in order to park the drop sensor.

Short Stand SP (8713135)

Use the Short Stand SP to attach an infusion container to the pump.

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

- 1.) Push the PoleClamp on the pump.
- 2.) Plug the short stand into the aperture on the PoleClamp; make sure that it audibly locks in.
- 3.) To remove the short stand: Press the white button at the lower end of the PoleClamp and remove the short stand.

Battery-Pack SP (8713180)

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

Interface Lead CAN SP (8713230)

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

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

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

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

Connection Lead SP (12 V) (8713231)

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

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

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

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

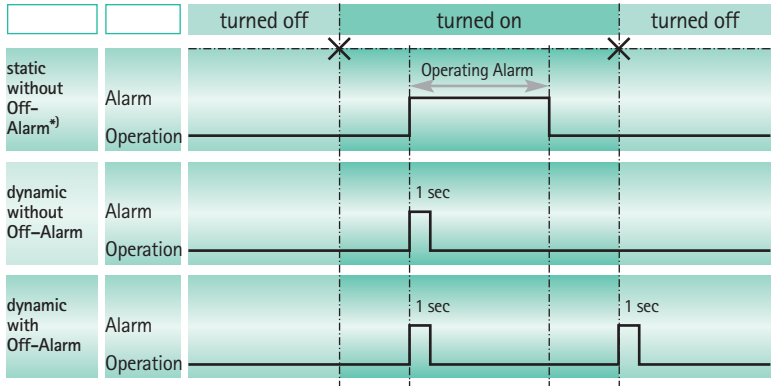
Note: A maximum of three plugs can be stacked upon each other in socket P2.


Connection Lead for Staff Call SP (8713232)

To connect the Infusomat® Space to staff call, use the Connection Lead for Staff Call SP. The staff call needs to comply with the requirements of VDE 0834 (consider country specific regulations).

Note: Test staff call signalling before every use.

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



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

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

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

Technical Data

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

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

	Art. No.
B. Braun Infusomat® Space (100 – 240 V)	871 3050

Recommended accessories for the B. Braun Infusomat® Space:

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

Infusomat® Space Lines

Type Standard; length 250 cm	870 0036 SP
Type Standard; length 300 cm	827 0350 SP
Type Injection; with injection port.....	870 0087 SP
Type Transfusion; with 200 µm blood filter.....	827 0066 SP
Type Opaque; UV-protected.....	870 0125 SP
Type Siliconized; with siliconized spike.....	870 0230 SP
Type Neutrapur® PVC-free; PVC-free set for the administration of cytotoxic agents.....	825 0731 SP
Type Neutrapur® PVC-free; PVC-free set for the administration of cytotoxic agents incl. 0.2 µm filter.....	870 0095 SP
Type Y-Piece*	875 1668 SP

*only available in selected A/P countries



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