SpaceStation MRI

MRI System Rack for Space® Infusion Pumps

Rx only

Instructions for Use

US/CA

B. BRAUN

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PATIENT SAFETY

Important information concerning the safety of the patient.

⚠ Caution: It is vital to read the accompanying documents on the SpaceStation MRI and the Space® pumps.

- Read Instructions for Use prior to use.
- The MR technician must check functional safety of the SpaceStation MRI.
- The user must check functional safety of the SpaceStation MRI.
- Check the functions of the SpaceStation MRI before starting operation.
- Functional inspection and technical safety checks have to be carried out separately for the Space® infusion pumps.
- Check the connection to the AC power and connect the unit.
- Check the AC voltage details on the type (rating) plate.

⚠ Caution: Use of the Space® System only by qualified staff.

- Use Space® System only after you have received training.
- This Instruction for Use and the B. Braun Perfusor® Space and Infusomat® Space Instruction for Use are necessary for proper use of the system.
- The Instructions for Use should be available to the user.

Proper Use

⚠ Caution: The SpaceStation MRI must be anchored by the tether before using in the MRI room.

The MR technician is responsible for proper positioning and securement of the SpaceStation MRI. The MR technician secures the device using the tether.

- The SpaceStation MRI is designed for the operation of up to four Space® infusion pumps in the MRI unit.
- The SpaceStation MRI is designed for one patient at a time.
- The system is used in stationary operation. It must be used by properly trained medical personnel.
- Check if the current software and hardware version of the components of the Space® System are the same as this Instructions for Use refers to.
- Prevent the SpaceStation MRI from rolling by using the wheel locks.
- Only connect the power cable once the system has been set up.
- The SpaceStation MRI can be operated with a single power cable.

⚠ Caution: The device is not designed to be used outdoors, in homecare, ambulances, helicopters, aircraft, submarines, boats, hyperbaric chambers, explosive or flammable environments.

- Use only compatible combinations of equipment, accessories, working parts and disposables.
- Do not simultaneously touch the monitor, monitor parts and a patient.

STOP WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Do not position the equipment to make it difficult to operate the disconnection device from power supply via unplugging the appliance coupler or AC power plug.

STOP WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SpaceStation MRI, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

To avoid the risk of electric shock, the SpaceStation MRI must only be connected to an AC power supply with ground. If the integrity of the ground or system is in doubt the internal electrical power source (battery) is to be used.

- Use only original spare parts. Functional safety is only guaranteed by the manufacturer when recommended compatible disposables are used.
- Carefully read the Instructions for Use of the infusion pumps and infusion syringe pumps used.
- The user must make sure the pumps and other components of the system are secured correctly.
- The connecting leads must be laid so that people do not stumble over them and work with the Space® System is not hampered.
- Use routing on device intended for proper positioning of IV tubing.
- Make sure the pumps are inserted and removed correctly.
- Be especially careful positioning the device when a patient is connected to prevent tension on IV lines.

Only for the use of

- Infusomat® Space
- Perfusor® Space

STOP Warning: Only use combined with approved devices/accessories by the manufacturer, otherwise this may lead to higher emission or reduced immunity.

- The Space® System should only be operated in areas which are well protected against vibration, corrosive dust and explosive gases, extreme temperatures and humidity. Do not cover the ventilation slots. The equipment must be free of condensate during operation.
- In case of central alarm on the cover it is necessary to check which infusion pump caused the alarm.

Direct contact of the connectors of the SpaceStation MRI during operation can lead to malfunction due to electrostatic discharge.

International safety standards

The Space® System meets

- IEC/EN 60601-1,
- IEC/EN 60601-1-2 and
- IEC/EN 60601-2-24

The device is designed for professional healthcare facility environments according to Figure 3 of IEC 60601-1-2:2014. For some test cases the higher test levels of home healthcare environment were selected.

The SpaceStation MRI needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Transport damage

Inspection on delivery. Despite careful packaging, the risk of transport damage cannot be entirely prevented. Upon delivery, please check that nothing is missing. Do not use a damaged device. Contact the service department.

Packaging

Packages are designed in a way that: electrostatic charges are prevented and batteries on printed boards cannot be discharged.

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

Intended Use of SpaceStation MRI

The SpaceStation MRI is a MRI (Magnetic Resonance Imaging) System Rack for operation of Space® Infusion Pumps during MRI examinations (MRI procedures) of adult, pediatric or neonatal patients.

The product is intended to be used by qualified healthcare professionals.

Prescription: In the USA, federal law restricts this device to sale by or on the order of a physician.

Contraindication:
The SpaceStation MRI is not designed to be used outdoors, in homecare, ambulances, helicopters, air craft, submarines, boats, hyperbaric chambers, explosive or flammable environments.

DEFINITION OF TERMS AND DESCRIPTION OF SYMBOLS

Definition of Terms

MR Scanner / MRI Scanner / MR Imaging System / MRI Unit / MR Equipment:
Medical electrical equipment for examination of patients by Magnetic Resonance Imaging (MRI).

MR Examination:
Process of acquiring data by Magnetic Resonance (MR) from a patient with a MR Scanner.

Magnet Room / MRI Room / MRI Scanner Room / MRI Procedure Room / MR Environment:
Room shielded from high frequencies, in which the MR Scanner is situated. The MR Environment is the dimensional volume of space surrounding the MR magnet (MR Scanner) that contains both the Faraday shielded volume and the 0.50mT field contour (5 gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR Equipment (MR Scanner) and accessories.

MR Control room:
The room immediately adjacent to the magnet room, from where the user (MR technician) controls the examination.

MR Safe:
A device that poses no known hazards resulting from exposure to any MR Environment.

MR Conditional:
A device with demonstrated safety in the MR Environment within defined conditions (The SpaceStation MRI is MR Conditional)

MR Unsafe:
A device which poses unacceptable risks to the patient, medical staff or other persons within the MR Environment

mT (MilliTesla):
Unit of magnetic flux density.

System / Space® System:
SpaceStation MRI (including IV stand) and Space® pumps.

SpaceStation MRI:
MRI rack system (including IV stand) for maximum of four Space® Infusion Pumps.

Space® Pumps:
B. Braun Space® volumetric and syringe pumps.

TeslaSpy:
Integrated, independent monitoring of the magnetic field for optimum placement of the SpaceStation MRI in the magnet room. An optical and audible indicator is triggered if the permitted flux density is exceeded.

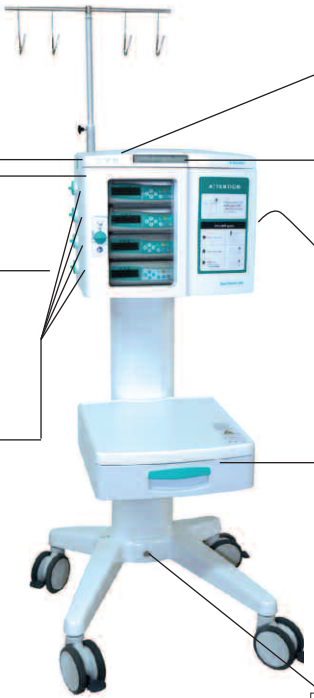
Description of Symbols

Symbol	Title of the Symbol	Reference Number	Explanatory text or meaning	
REF	Catalog number	5.1.6	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1
SN	Serial number	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1
LOT	Batch code	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1
	Date of manufacture	5.1.3	Indicates the date when the medical device was manufactured.	ISO 15223-1
	Manufacturer	5.1.1	Indicates the medical device manufacturer.	ISO 15223-1
CE	CE conformity marking	Annex XII	Indicates conformity with the provisions of the applicable Directive.	Directive 93/42/EEC (MDD)
IP22	Ingress protection rating	D.3.2	Protected against solid foreign objects of 12.5 mm and greater. Protection against vertically falling water drops when Enclosure tilted up to 15 degrees.	IEC 60601-1
	Consult Instructions for Use	5.4.3	Indicates the need for the user to consult the Instructions for Use.	ISO 15223-1
	Follow Instructions for Use.	D.2-10	Mandatory action: See Instructions for Use.	IEC 60601-1
	Defibrillation-proof type CF applied part	D.1-27	To identify a defibrillation-proof type CF applied part.	IEC 60601-1
	WEEE symbol	Annex IX	Symbol indicating separate collection for electrical and electronic equipment in Europe.	2012/19/EU (WEEE)

Description of Symbols

Symbol	Title of the Symbol	Reference Number	Explanatory text or meaning	
	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.	IEC TR 60878
	Temperature Limit	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1
	Humidity limitation	5.3.8	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1
	Atmospheric pressure limitation	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1
	Fuse	60417-5016	To identify the fuse boxes or their location.	IEC TR 60878
	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.	ISO 15223-1
	Medical device	5.7.7	Indicates the item is a medical device	ISO 15223-1

SPACESTATION MRI IN DETAIL



COMBINATION OF PUMPS WITHIN A SPACESTATION MRI

The following pumps can be combined within a SpaceStation MRI:

- Maximum 4 pumps; Infusomat® Space or Perfusor® Space

⚠ Caution: The SpaceStation MRI is not designed for pumps other than Infusomat® Space or Perfusor® Space. See Chapter: ordering information on page 39.

Recommendation: When using Infusomat® Space and Perfusor® Space together, position the Infusomat® Space in the upper slots for better handling of the infusion lines into the infusion line guide and place the Perfusor® Space in the lower slots.

INSERTING AND REMOVING INDIVIDUAL PUMPS IN SPACESTATION MRI

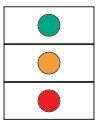
⚠ Caution: Before inserting a pump please ensure the side rotary knob is in the vertical position.

The guide rails of the SpaceStation MRI must engage in the guide grooves of the pump. The pump is then gently pushed into the SpaceStation MRI. The pump is automatically locked in the system with an audible click and haptic feedback as well as the side rotary knob moving to the horizontal position. When using Infusomat® pumps load pumps from the bottom to the top of the SpaceStation MRI and remove from top down to optimize tubing management.

To release, turn the knob clockwise to the vertical position and remove the pump. After release the pump is held in the SpaceStation MRI by the guide rails, but can drop due to bumping or during movement of the SpaceStation MRI.

COVER OF SPACESTATION MRI

All the necessary operating and display components are integrated in the cover of the SpaceStation MRI. The cover is equipped on the front with a pump status and alarm display and the *TeslaSpy*. All the status and alarm conditions of the pumps within the system, as well as of the pumps themselves are displayed. The following conditions can be indicated:



Green -> OK, at least one pump is in operation.

Yellow -> Prealarm in a pump within the system.

Red -> Alarm of a pump in the system

Details of the individual prealarms and alarms are to be found in the Instructions for Use of the pumps.

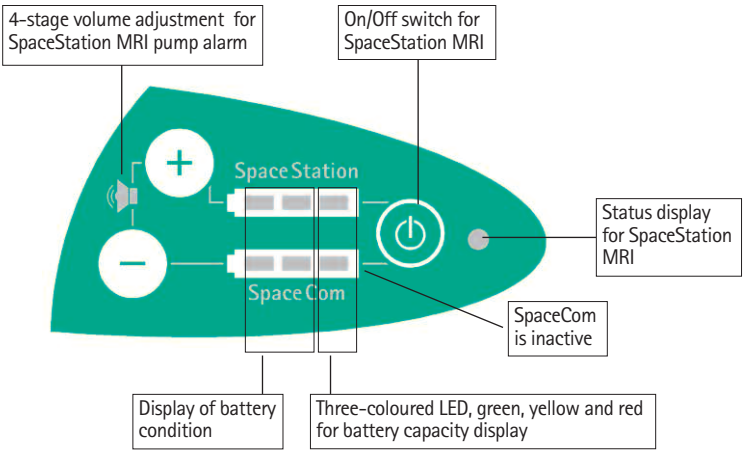
A rechargeable battery is used in the SpaceStation MRI. This rechargeable battery ensures complete system functionality when the voltage supply is interrupted.
A speaker is integrated in the unit to sound the alarms from the pumps. The volume can be adjusted in four steps using the controls on the side.

⚠ Caution: The environmental noise within the MRI unit is much louder during the examination than the alarm sounds made by either the Space® pumps or the SpaceStation MRI.

⚠ Caution: The magnet room is soundproof, so any acoustic alarms will be inaudible. Observe for any visual alarms on the SpaceStation MRI cover and through the door.

We recommend that the SpaceStation MRI is always positioned in such a way that the alarm displays on the front can be seen at all times.

4.1 Operating Elements and Status Display on the SpaceCover



4.1.1 Display of SpaceStation MRI cover Battery Condition

The display elements indicate the condition of the rechargeable battery in the SpaceStation MRI cover (this does not indicate status of *TeslaSpy*). The following conditions are indicated.

Battery condition	LED left	LED middle	LED right
> 75% capacity	●	●	●
> 50% capacity	○	●	●
> 25% capacity	○	○	●
< 25% capacity	○	○	●
< 30 min operating time	○	○	flashing
< 3 min operating time	○	○	flashing
Maintenance required	●	●	●
Maintenance active (capacity > 75%)	●	●	flashing
Maintenance active (capacity > 50%)	○	●	flashing
Maintenance active (capacity > 25%)	○	○	flashing
Maintenance active (capacity < 25%)	○	○	flashing

Battery pre alarms and end alarms can be acknowledged with the "**+**" and "**–**" volume control buttons. When the audible alarm is silenced, the visual alarm is still displayed.

Battery alarms are cancelled automatically when the system is reconnected to the AC power.

4.1.2 Switching On/Off

Ensure system is on when a pump is infusing. The on/off switch only functions when the system is in battery mode.

When the system is connected to AC power the device is always on and the pumps are supplied with AC power.

⚠ Caution: If the system is not needed and is also not connected to the AC power it should be switched off.

The on/off switch must be pressed for three seconds to switch off.
The status diode will flash for approximately 5 seconds and will then go out.

4.1.3 Volume control

The volume of the speaker can be controlled with the buttons "+" and "-".
The setting is made in 4 steps and after every new step an auditory signal is sounded at the new volume. When the maximum or minimum volume is reached, a deep tone is heard. The last volume setting is saved when the system is switched off.

4.1.4 Brightness Sensor

Every SpaceStation MRI is equipped with a brightness sensor that adapts the brightness of the alarm display in the cover to the environment. The brightness cannot be adjusted manually.

4.1.5 Battery Maintenance Program

To guarantee maximum battery capacity and at the same time a long service life, a battery maintenance program is integrated in the system. The battery maintenance is displayed automatically depending on the operation of the unit. The battery maintenance program can only be initiated when the system is connected to the AC power.

The maintenance program is started by pressing the On/Off button and "+" button at the same time. The battery will be recharged when the maintenance program has been completed.

4.1.6 Status display

		The system is operating with AC power voltage
		The system is operating on battery
	flashing	Wrong configuration, check the system setup
		Unrecoverable error, contact service technician to exchange cover

4.1.7 Self check during Start Up

During the start up of the SpaceStation MRI a self check is started automatically. The three LEDs at the front will be tested in the sequence: red, yellow, green and after this the status indicators of SpaceStation MRI are tested.

If an alarm LED on the front is defective, the yellow alarm LED is constantly on (if light is functional) and the status display on the side will be illuminated (red). In this case, determine the need to proceed with the MR scan and insure pump status can be assessed by viewing pumps through the door.

STEP BY STEP INSTRUCTION FOR SAFE USE OF INFUSION PUMPS IN THE MR ENVIRONMENT

Read the Instruction for Use and be aware of the conditions for use of the SpaceStation MRI including its accessories in the MR environment.

Symbol	Description
	MR Scanner: 1.5T; 3.0T MR Conditional (according to ASTM F 2503) Not intended for use in the Magnet Bore of MR Scanner Distance to MR Scanner: ≥ 1.5m Magnetic Field in MR Environment: ≤ 20 mT / 200 Gauss
≤ 20 mT / 200 Gauss **≥ 1.5 m (based on a 3 T)** Do not exceed 200 Gauss or 20 mT Projectile hazard Equipment operation may be impacted Use with MRI Tether Engage wheel locks when not in motion	
 **Magnet Indicator**	Caution! Observe the Magnet Indicator *Tesla*^{Spy}. Important for the user to consult the Instructions for Use for important warnings and precautions.
	Lock the brakes of the four castors.

The SpaceStation MRI may be operated safely up to a maximum magnetic field of 20mT / 200G as measured by the *Tesla*^{Spy} indicator. **DO NOT EXCEED 20 mT or 200 G.**
Depending on the different MR Scanners this means a distance of approximately 1.5m / 5ft to the opening of the bore (based on actively shielded 3T scanner).
Consult the Technical Description from the Manufacturer of the MR Scanner for details regarding the spatial distribution of surrounding field and safe working distance. It is recommended to mark the critical magnetic field on the floor.

For safe use of infusion pumps in the MR Environment within the SpaceStation MRI complete the following tasks sequentially and obey the warnings and cautions.

5.1 Preparation outside the MRI room

⚠ Caution: MR technician must ensure station is in working order.

1) 

Turn the rotary knob into the door open position and open the door of the SpaceStation MRI.

2) The release button for each empty infusion pump slot must be in vertical position.

   ⚠ Caution: Before inserting an infusion pump, please ensure the vertical position of the side rotary knob.

3) If you are using the Infusomat® Space pump, select the upper slots in the SpaceStation MRI. If you are using the Perfusor® Space, select the lower slots in the SpaceStation MRI. Insert infusion pumps from bottom slot up.

4) Insert each individual infusion pump into the integrated rack of the SpaceStation MRI. Refer to the detailed description in Chapter 3.

5) Check for acoustic and haptic feedback when inserting the infusion pump. The rotary knob must turn automatically into horizontal position.

6) For volumetric infusion, hang the fluid containers on the infusion pole. Make sure to have sufficient volume of infusion liquid in the fluid containers or syringes to avoid disposable changes during MR examination.

7) 

For volumetric infusion, insert the Infusomat® Lines from the fluid containers into the door inlet guide on the left side and tubing guide inside above the first pump slot on the SpaceStation MRI from left to right.

8) Loop the patient side tubing back to the left and through the individual pump door outlet guide hole.

9) 

Push the door to close and turn the rotary knob into the horizontal door lock position. Check for acoustic and haptic feedback to ensure that the door is closed.

⚠ Caution: Do not squeeze or obstruct the infusion lines or any other objects which are preventing a proper closing of the SpaceStation MRI door.

10) Check the remaining battery capacity of the SpaceStation MRI and the infusion pumps in case there is no AC power supply available in the MRI room.

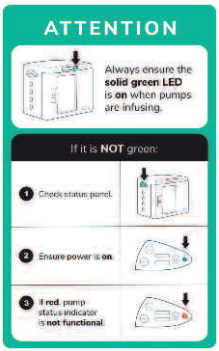
A battery charge level of greater than 50% is recommended to avoid low battery during MR examination. Refer to the detailed description in Chapter 4.1.1 and to the Instructions for Use of B. Braun Perfusor® Space and Infusomat® Space.

Recommendation: Keep the SpaceStation MRI continuously connected to AC power supply and disconnect it only when moving it.

⚠ Caution: Always connect the AC power supply cable first to the SpaceStation MRI and then to the wall socket. Connect the AC power cable in a straight line and ensure that no loops arise. Do not roll up the AC power cable.

⚠ Caution: The AC power cable must neither be subject to tension nor be lying on the floor in a position where it can be tripped over. The connecting leads must be laid so that people do not stumble over them and work with the Space® System is not hampered.

11)



Ensure that green light on pump status indicator is working when a pump is infusing. If not follow directions on front of door: check status on side, ensure power is on as indicated by green light if plugged in and yellow light if running on battery. Red light indicates pump status system is not functional.

5.2 Placement inside the MRI room prior to initiation of MR Scan

1) Disconnect the SpaceStation MRI from AC power supply and unlock the brakes of the four castors/wheels prior to moving the SpaceStation MRI inside the MRI room.

2) Push the station/IV pole carefully and look out for any possible obstacles on the floor.

⚠ Caution: Always keep the drawer and the door closed while moving the SpaceStation MRI.

⚠ Caution: Always lock the brakes of the four castors/wheels before releasing the SpaceStation MRI to avoid unintentional movement especially on inclined surfaces. Check for acoustic and haptic feedback of brake locks on the four castors/wheels.

3)

Inside the MRI room the MR technician should attach the safety tether's snap link to the closest wall mounted hook.

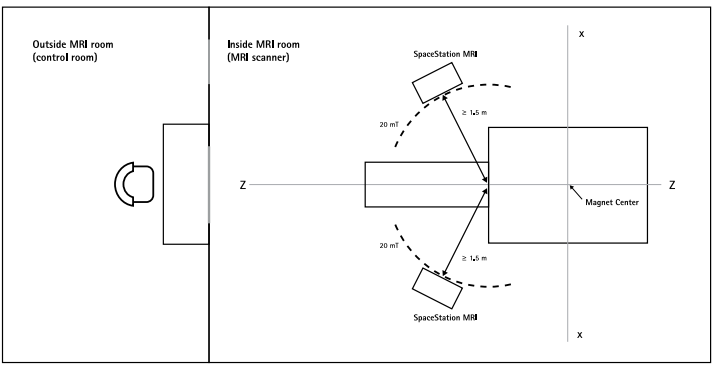
⚠ Caution: **THE SPACESTATION MRI MUST BE ANCHORED BY THE TETHER BEFORE USING IN THE MRI ROOM.** The tether makes sure that the SpaceStation MRI stays in the intended range of 20 mT / 200 Gauss.

⚠ Caution: Be careful not to trip over the tether.

4) Once the SpaceStation MRI tether hook has been attached to mounted wall hook, hold the station firmly to avoid unintentional movement and release the brakes of the four castors/wheels if locked.

5) Slowly move the SpaceStation MRI towards the MR scanner while observing the magnetic field strength visually and acoustically from the *TeslaSpy* indicator. Refer to the detailed description of the *TeslaSpy* indication in Chapter 6 and follow the related instructions.

⚠ Caution: Do not place the SpaceStation MRI any closer than 20mT / 200G (1.5m / 5ft) to the MR Scanner.



6) Position the SpaceStation MRI in such a way that the alarm display for the infusion pumps can be easily observed.

7)  Lock the brakes of the four castors/wheels when a safe working distance is indicated by the *TeslaSpy*.

⚠ Caution: Never place the SpaceStation MRI immediately next to the magnet bore of the MR Scanner.

8) Connect the SpaceStation MRI to AC power supply and check the status display for correct operation. For details refer to Chapter 4.1.6.

STOP WARNING: Do not insert or remove individual infusion pumps from the SpaceStation MRI while inside the MRI room. Infusion pumps must be inserted or removed only outside the MRI room.

⚠ Caution: Observe the infusion lines when moving the patient on or off of the examination table and into or out of the MR Scanner to avoid dislodging the IV line.

5.3 Precautions during MR Examination / MR Scan

1) The environmental noise of the MR Scanner during MR examination may prevent hearing the acoustic alarms of the infusion pumps or the SpaceStation MRI.
2) During patient infusion therapy use the following precautions:
   - Observe the acoustic and visual alarm signals from the alarm display for the infusion pumps. For a detailed description refer to Chapter 4.

   ⚠ Caution: Acoustic alarm signals may not be recognized during MR examinations. Observe the visual alarm signalization.

   - Identify an infusion pump alarm visually through the door window and read the related infusion pump display. For detailed description refer to the instructions for use of B. Braun Perfusor® Space and Infusomat® Space.
3) Keep the door of the SpaceStation MRI closed during MR examination to avoid artifacts on MR Images and open the door only between the MR scan sequences if necessary. In urgent situations or to address alarms the door may be opened at any time.

   ⚠ Caution: An open door of the SpaceStation MRI during MR scan may lead to artifacts on the MR images.

   STOP WARNING: Do not insert or remove individual infusion pumps from the SpaceStation MRI while inside the MRI room. Infusion pumps must be inserted or removed only outside the MRI room.
4) Store only nonmagnetic components in the drawer of the station/IV pole. Parts of the infusion pumps and the SpaceStation MRI consist of ferromagnetic materials.

   STOP WARNING: An infusion pump must not be placed on the examination table of the MR Scanner as this could lead to a projectile hazard through magnetic attraction.

5.4 After MR Examination / Remove from the MRI room

1) Prepare to move SpaceStation MRI out of MRI room. Hold the station/IV pole firmly to avoid unintentional movement while releasing the brakes of the four castors/wheels.
2) Detach the safety tether's snap link from the wall mounted hook.
3) Disconnect the AC power cable from wall socket. Refer for detailed description to Chapter 4.1.2.

4) Move the SpaceStation MRI outside the MRI room.

5) Turn the rotary knob into the door open position and open the door of the SpaceStation MRI to remove the infusion pumps.

6) Choose the infusion line to pull out of the door outlet guide hole. For volumetric infusions remove the Infusomat® Line from the tubing guide and door inlet guide hole in the opposite order they were inserted. Remove the fluid container from the infusion pole.

   ⚠ Caution: Too much force pulling the infusion line may cause damage to the line.

7) Turn the pump release button at the SpaceStation MRI to release the inserted infusion pump while pulling it out of the slot.

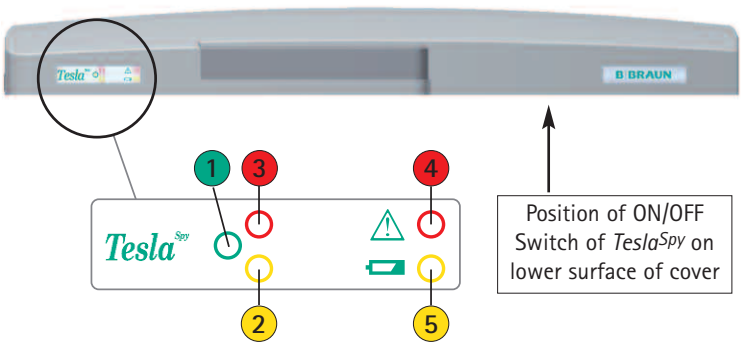
   ⚠ Caution: Hold the infusion pump firmly while releasing pumps to avoid dropping the device.

8) Push the door to close and turn the rotary knob into door lock position. Check for acoustic and haptic feedback.

9) For storage: Make sure that the brakes of the four castors/wheels are locked and the SpaceStation MRI is connected to AC power supply.

MAGNET INDICATOR TESLA^{SPY}

- The Magnet Indicator *Tesla^{Spy}* is an integrated instrument for measuring the magnetic flux density.
- The display unit (LED's) is located on the device itself, at the top left, to the right of the label (see below).
- The *Tesla^{Spy}* is an aid that allows the SpaceStation MRI to be operated as close as possible to the MR Scanner (while still being safe).
- The ON/OFF switch of *Tesla^{Spy}* has to be pushed (activated) once before first use. Do no switch it off after use. The *Tesla^{Spy}* is power supplied by a rechargeable battery. In case of an empty battery the device automatically turns off. After connecting to the AC Power supply the *Tesla^{Spy}* will re-start again automatically (Not necessary to press ON/OFF switch).
- Signals of *Tesla^{Spy}*:



A flashing green LED indicates that the *Tesla^{Spy}* is operational.

#	Positioning / Indication	Priority	Color	Display	Instruction
1	Normal operation; Magnetic field < 20 mT	Low	1	Green LED flashes each 2 seconds.	The SpaceStation MRI is located outside the critical magnetic field. Safe operation is ensured
2	⚠ Caution: Magnetic field 20 – 40 mT	Medium	2	Yellow LED flashes each 1.5 seconds and speaker sounds an auditory signal.	The critical magnetic field is reached. The SpaceStation MRI has to be moved back to within green area and not moved closer to the MR Scanner.

#	Positioning / Indication	Priority	Color	Display	Instruction
3	STOP Warning: Magnetic field > 40 mT	High	3	Red LED flashes each 500 ms and speaker sounds an auditory signal.	Maximum magnetic field exceeded. Move the SpaceStation MRI away from the MR Scanner immediately! (The event is stored in the internal memory and can be read out by authorized technical service.) Before using SpaceStation MRI and pumps again a Technical Safety Check should be performed.
4	Error of *Tesla^Spy*	High	4	Red LED flashes each 500 ms and speaker sounds an auditory signal.	Error of *Tesla^Spy* (e.g. Watchdog failure, Sensor failure etc.). Function has to be checked by authorized technical service.
5	Battery Low *Tesla^Spy*	Low	5	Yellow LED is constantly on and speaker sounds an auditory signal once.	Connect the SpaceStation MRI to AC power supply to recharge battery.
6	Battery empty or *Tesla^Spy* is switched off	–	No light	No light	Connect the SpaceStation MRI to AC power supply immediately to recharge battery. If the *Tesla^Spy* does not automatically restart again, check that the device is switched on.

- All signals of *Tesla^Spy* are non-latching.
- Fix the position of the SpaceStation MRI by locking the brakes of castors (to avoid any accidental movement of the station).
- It is recommended to mark the critical magnetic field on the floor.

INSTALLING TETHER

7.1 Overview

The SpaceStation MRI tether is a required safety feature for application in the MR environment. It protects the SpaceStation MRI from being drawn towards the MRI scanner.

The SpaceStation MRI tether is attached to two anchors. One anchor is attached to the station IV stand and the other one is installed on the wall or appropriate position in the MRI room.

7.2 Components

The SpaceStation MRI comes with an already installed safety ring to attached one end of the tether. It is located at the bottom of the station/IV pole on the front side center.

The SpaceStation MRI tether set (Tether & Power Cord US, Part No 8713136) comprises the following components:

Quantity	Description	Picture
1	Tether (5 m / 196 inch) with snap link (D-ring clip)	
1	Screw-pin shackle	
1	Wall hook	
1	Warning sticker	≤ 20 mT / 200 Gauss ≥ 1.5 m (based on a 3 T) Do not exceed 200 Gauss or 20 mT Projectile hazard Equipment operation may be impacted Use with MRI Tether Engage whell locks when not in motion

Quantity	Description	Picture
1	QRG sticker	
1	Power Cord US	
1	Refer to Instructions for Use for complete operating instructions and the Symbols Glossary	Refer to Instructions for Use for complete operating instructions and the Symbols Glossary Distributed by: **B. Braun Medical Inc.** 824 12th Avenue, Bethlehem, PA 18018-3524 USA Technical questions call 1-800-627-PUMP (7867) Technical questions call 1-800-854-6851

7.3 Installation and Set Up

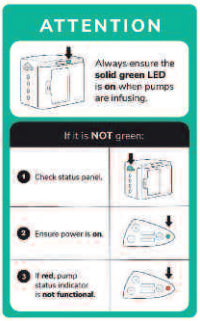
Add additional sticker for MRI Warning on drawer above the existing label.

≤ 20 mT / 200 Gauss
≥ 1.5 m (based on a 3 T)
Do not exceed 200 Gauss
or 20 mT
Projectile hazard
Equipment operation
may be impacted
Use with MRI Tether
Engage whell locks
when not in motion

Add Refer to Instruction for Use at the back of the SpaceStation MRI box

Refer to Instructions for Use for complete operating instructions and the Symbols Glossary
Distributed by:
B. Braun Medical Inc.
824 12th Avenue, Bethlehem, PA
18018-3524 USA
Technical questions call
1-800-627-PUMP (7867)
Technical questions call
1-800-854-6851

Add QRG sticker on door to the right door window.



Refer to diagram in Chapter 5, page 20, for proper positioning of the SpaceStation MRI in the MRI room at a safe distance to the MRI scanner.

Installing the wall hook in the MRI room

⚠ Caution: When installing the safety anchor in the MRI room follow all local laws, regulations and safety procedures applicable for working in an MR environment. Install the wall hook on a wall in the MRI room or use an appropriate available wall hook / anchor. Be aware of the maximum tether length (see chapter 7.2).

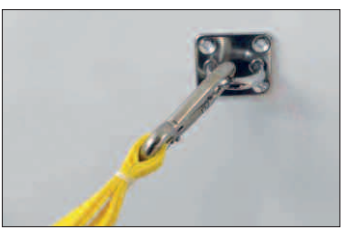
When installing the wall hook make sure that it can support a minimum of 51 kg / 112.4 lbs.

Assembling the SpaceStation MRI tether

1. Attach the snap link at one end of the tether to the wall mounted hook / anchor.

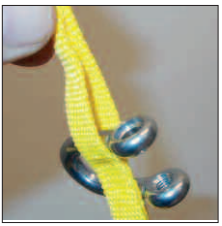
   ⚠ Caution: THE SPACESTATION MRI MUST BE ANCHORED BY THE TETHER BEFORE USING IN THE MRI ROOM.

   The tether makes sure that the SpaceStation MRI stays in the intended range of 20 mT = 200 Gauss.



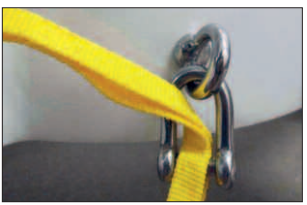
2. Position the SpaceStation MRI correctly in the MRI room (Observe the *Tesla*^{Spy} indicator lights. See section 3.1 and 3.2).
3. Pull the tether tight so that it reaches the previously determined position to the SpaceStation MRI.
   Be careful not to trip over the tether.

4. On the tether select the loop closest to the SpaceStation MRI when the tether is tight and insert the screw-pin shackle into the loop.



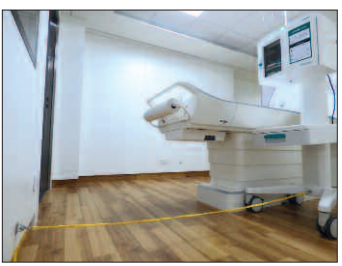
5. Place the shackle over the safety ring on the SpaceStation MRI IV stand and insert the locking screw.

6. Tighten the screw using a screwdriver. The tether is now attached to the station/IV stand.



7. Cut off any excess tether.

Once the tether is attached and in place cut off the excess line. In order to maintain the integrity and full strength of the tether it is important to leave at least 4 cm / 1.5 inch at the end of the line. Lock the brakes of the four castors/wheels when a safe working distance is indicated by the *Tesla*^{Spy}.



The SpaceStation MRI is now in safe and proper position in the MRI room.

Chapter 8

SERVICE

The SpaceStation MRI must have a technical safety check with registration in the service manual every 24 months.

The Technical Safety Checks may only be performed by technicians trained by B. Braun or technical personnel of B. Braun Medical Inc..

MAINTENANCE/ CLEANING AND DISINFECTING

9.1 Maintenance

Operate the system only in accordance with the Instructions for Use.

Check, clean and disinfect the SpaceSystem MRI at regular intervals.

Check for cleanliness, completeness and damage.

Only use original spare parts and accessories.

9.2 Cleaning and Disinfecting

Disconnect from AC power. Clean all external surfaces using a clean, soft, lint-free cloth dampened with a mild cleaning solution of soapy water. Make sure to remove any visible residue from all surfaces prior to disinfecting. Use EPA registered hospital disinfectants containing isopropyl alcohol, ethanol, dodecyl dimenthyl ammonium chloride, diisobutylphenoxyethyl dimethyl benzyl ammonium chloride, or sodium hypochlorite. Follow directions provided with disinfectant, if there is notable degradation to the label after cleaning then contact the service department.

Let the unit dry for at least 1 minute before starting operation again. Do not spray in system openings (openings for necessary cooling, power supply input, interfaces etc). Heed the disposal and hygienic instructions!

⚠ 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 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.

9.3 Disposal

Dispose of the system according to the local regulations.
Old units are taken back and removed by the manufacturer on request.
Regularly check the rear of the AC power connection for signs of contamination (e.g. spilled fluid) and clean it if necessary. For safety reasons, the SpaceStation MRI must be disconnected from the AC power while it is being cleaned.

9.4 Rechargeable Batteries

The following applies for the battery in the SpaceStation MRI:

Charge the battery before initial start-up.

The mean service life of the batteries is approximately 36 months.

Recharging period: typically, six hours.

In case of a power failure, the system will automatically switch over to the rechargeable battery.

If the SpaceStation MRI is kept in storage for a long time, it is recommended that it be charged at least every six months.

The service life of the batteries can be prolonged if they are regularly completely discharged and recharged.

Rechargeable batteries must be recycled (special waste).

TECHNICAL DATA ON THE SPACESTATION MRI

Type of unit	MRI rack system (MR Conditional) for connection of up to 4 Space® infusion pumps (Syringe and/or Volumetric Pumps)
Conditions of use in MR Environment of SpaceStation MRI with inserted Space® Infusion Pumps	MR Scanner: 1.5T; 3.0T MR Conditional (according to ASTM F 2503)* Not intended for use in the Magnet Bore of MR Scanner Distance to MR Scanner: ≥ 1.5m Magnetic Field in MR Environment: ≤ 20 mT / 200 Gauss * The SpaceStation MRI is MR Conditional and not intended to be used in the Magnet Bore of the MR Scanner. Non-clinical testing has demonstrated the SpaceStation MRI is MR Conditional. It can be scanned safely under the following conditions: • static magnetic field of MR Scanner max. 3 Tesla • spatial gradient field / fringe field of MR Scanner max. 20mT / 200 Gauss • maximum whole body averaged specific absorption rate (SAR) of 4W/kg for 30 minutes of scanning. The scan produced a temperature rise of less than 1°C on SpaceStation MRI.
Device type	MR-compatible unit for up to four Space® infusion pumps
Classification (in accordance with IEC/EN 60601-1)	Defibrillation-protected; type CF protective class I
Protection category	IP 22 (protection against water drops)
AC power supply	Voltage: 100–240 VAC Frequency: 50/60Hz Power Consumption: max. 80VA (with 4 infusion pumps) AC power fuse: 2x T2A/H 250V (slow blow, type H) Continuous (Duty cycle: 100 %)
AC Power Supply input	IEC socket for standard cable
Radio interference suppression in accordance with	IEC EN 60601-1-2 and IEC EN 60601-2-24
EMC in accordance with	IEC EN 60601-1-2 and IEC EN 60601-2-24

Built-in electronics with the following functions	
Fuses for the pump slots	The slots are only supplied with current once the pump has been inserted Electronic fusing 12V/1.8A
Protection of Cover	Release of power outlet only if cover is mounted Electronic fuse 12V/1.5A
Interfaces	
AC power voltage input	Inlet connector for non-heating apparatus
Pump slots	4 pump slots (F2A..F2D) for connection to Infusomat® Space or Perfusor® Space
Potential Equalization Conductor	1 terminal for connection of a Potential Equalization Conductor
Service Interface *Tesla*^{Spy} (only for authorized Technical Service)	USB socket
Operating conditions	
Relative humidity	30% ... 90%, without condensation
Temperature	5°C (41°F) ... 40°C (104°F)
Atmospheric pressure	500mbar ... 1060mbar
Storage conditions	
Relative humidity	20% ... 90%, without condensation
Temperature	-20°C (-4°F) ... 55°C (131°F)
Atmospheric pressure	500mbar ... 1060mbar
Altitude	max. 3000m (9842.52 feet)
Weight, including MR suitable IV stand	
without Space® pumps	50 kg / 110lbs
with Space® pumps incl. IV bags	approximately 62 kg / 136lbs, depending on fluid volumes
Mass including its safe working load (SpaceStation MRI incl. stand and IV Pole and four volumetric pumps and IV fluids	75 kg / 165 lbs
Max. load on drawer	10 kg / 22 lbs
Max. load in drawer	3 kg / 6.6 lbs
Max. load on IV Pole (IV bags)	4.5 kg / 9.9 lbs
Dimensions, W x D x L (with stand incl. IV-Pole)	60 x 62 x 195 cm / 23.6 x 24.4 x 76.8 inch
Dimensions Width x Depth x Height (SpaceStation MRI incl. stand)	60 x 62 x 142 cm / 23.6 x 24.4 x 55.9 inch
Speaker	For SpaceStation MRI central acoustic alarms
Speaker Magnet Indicator (*Tesla*^{Spy})	Auditory signals of Magnet Indicator *Tesla*^{Spy}
Luminous LED fields	For central optical status display of the SpaceStation MRI

	5 LED's for Indication of visual signals - Magnetic Field (green, yellow, red) - Error (red) - Battery Low (yellow)
Display and operating unit (Cover) (Operating elements and status display on Cover)	Display of battery status Display of battery/AC power operating modes Switching the SpaceStation MRI on and off in battery operation Error indicator Trigger battery maintenance
Type of battery pack	2x NiMH battery pack
Operating time of battery (SpaceStation MRI	appr. 10h
Operating Time of battery *Tesla*^{Spy}	appr. 28 days
Charging time	approx. 6 h
Tesla^{Spy}	Independent, patented magnetic field monitoring system independent of the SpaceStation MRI with separate status indicator and warning device. Vectorial recognition of the magnetic field components in three axes. Events are stored in real time when the critical limits are exceeded.
Addressing of pumps (Rack)	Dynamic addressing related to the position of the pump within the SpaceStation MRI

The SpaceStation MRI has no Essential Performance.

EMC (ELECTROMAGNETIC COMPATIBILITY)

Guidance and manufacturer's declaration on electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emission		
The SpaceStation MRI is intended for use in the electromagnetic environment specified below. The customer or the user of the SpaceStation MRI or any component should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment guidance*** *in accordance to IEC 60601-1-2:2007
RF emissions CISPR 11	Group 1	The SpaceStation MRI uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B (Note 2)	The SpaceStation MRI 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
Note 1: Maximum emissions are measured with a complete system (SpaceStation MRI and components).		
Note 2: If Class A equipment is attached to the SpaceStation MRI, the SpaceStation MRI 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 SpaceStation MRI 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 to IEC 61000-4-2	contact ± 8 kV air ± 15 kV	± 6 kV no disturbances ± 8 kV stop with alarm allowed ±8 kV no disturbances ±15 kV stop with alarm allowed	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 to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV ± 1 kV	AC power quality should be that of a typical commercial or hospital environment.
Surge according to IEC 61000-4-5	differential mode ± 1 kV common mode ± 2 kV	± 1 kV ± 2 kV	AC power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec <5 % U_T for 5 s (>95% dip in U_T)	complies by use of internal battery	AC power quality should be that of a typical commercial or hospital environment. If the user of the SpaceStation MRI requires continued operation during long time AC power interruptions, it is recommended that the SpaceStation MRI or component be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	3 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: Different test values of IEC 60601-2-24 are marked in the table. At the test values no dangerous disturbances occurred at the lower test values of IEC 60601-1-2.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The SpaceStation MRI is intended for use in the electromagnetic environment specified below. The customer or the user of the SpaceStation MRI 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 SpaceStation MRI or its components, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
conducted electromagnetic RF fields according to IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 10 Vrms in ISM-band	 10 Vrms in all bands	**Recommended separation distance** d = 1.2 √P
radiated electromagnetic RF fields according to IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 3 GHz	Field strengths should be less then 10 V/m d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

NOTE 3: Different test values of IEC 60601-2-24 are marked in the table. At 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 SpaceStation MRI is used exceeds the applicable RF compliance level above, the SpaceStation MRI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SpaceStation MRI.

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

rated power of the ratio transmitter W	**Separation distance according to frequency of transmitter *** m		
	150 kHz 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	7.3
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.

* in accordance to IEC 60601-1-2:2007

Compatible products:

SpaceStation MRI.....8713152

Perfusor® Space.....8713030U

B. Braun Perfusor® Space (100 - 240 V) +
Battery-Pack SP with Wifi (Li-Ion).....8713031U

B. Braun Perfusor® Space (100 - 240 V) +
Battery-Pack SP without Wifi (NiMH).....8713032U

Perfusor® Space (Canada).....8713030C

Infusomat® Space.....8713050U

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

Infusomat® Space (Canada).....8713050C

Perfusor® Space PCA.....8713080U

Tether and Power Cord US.....8713136

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