BD Alaris™ MRI Capsule Model: 80300MRI01-33

en Directions For Use

CE 0086

BD

Contents

Introduction

MRI Scanners use strong magnetic fields that can cause partial or permanent damage to Infusion Pumps. The BD Alaris™ MRI Capsule (hereinafter referred to as *MRI Capsule*) has been designed to allow the hospital staff to use the Alaris™ Infusion Pumps in the MRI environment. There is no need for complicated and expensive non-magnetic Infusion Pumps specially designed for the MRI use.
The MRI Capsule will be used to provide mounting, power and Pump Alarm Location Beacon display of Infusion Pumps within the operating environment range specified in this Directions For Use (DFU).

Intended Use

The MRI Capsule is designed for use in a Professional Healthcare Facility Environment and to be used in Magnetic Resonances Systems environment with controlled access. The MRI Capsule is intended to be used to protect the MRI images from RF wave interference and also prevent the MRI Scanner from attracting infusion pumps to the magnet. The MRI Capsule is designed to not directly impact or prevent the infusion delivery process.
Only BD authorized pumps can be used with the MRI Capsule.
The MRI Capsule is designed to accommodate the following Pumps which will communicate with the Pump Alarm Location Beacon for High, Medium and Low priority alarms where applicable. For further alarm information, refer to Pump DFU.

Compatible Alaris™ Infusion Pumps for MRI Capsule

Pump Model	**Model Code**	**Minimum Supported Firmware Version**
Alaris™ CC Syringe Pump (All variants)	80033UN01 80033UN01-G 8003MED01 8003MED01-G 8003TIG01 8003TIG01-G 8003TIG03 8003TIG03-G	All
Alaris™ GH Syringe Pump (All variants)	80023UN01 80023UN01-G 8002MED01 8002MED01-G 8002TIG01 8002TIG01-G 8002TIG03 8002TIG03-G	All
Alaris™ PK Syringe Pump (All variants)	80053UN01 8005PK201 8005TIG03	All
Alaris™ VP Plus Guardrails™ Volumetric Pump (All variants)	9003MED01-G 9003TIG01-G 9003TIG03-G	v1.4.9

If a compatible Pump is visibly damaged, there is the possibility that RF interference could cause artefact to the scan image, and a replacement Pump may be required. Prior to commencing the scan it is advised that the image be checked for any interference.

Prior to using an AlarisTM VP Plus Guardrails Volumetric Pump with the MRI Capsule, check the firmware version of the Pump. If it is below v1.4.9, do not use with the MRI Capsule, as it would require the use of a Model 180 flow sensor. The Model 180 flow sensor is not compatible with the MRI Capsule. Arrange with your local BD representative for the Pump firmware to be upgraded to v1.4.9 or greater.

The AeroScout tags, all models, are compatible with the BD Alaris™ MRI Capsule.

Intended Positioning of the MRI Capsule

The MRI Capsule incorporates a Magnetic Indicator that is used to safely position the MRI Capsule in relation to the MRI Scanner. The MRI Capsule should be positioned as near to the patient as possible, ensuring the Magnetic Indicator is illuminated Green which indicates a magnetic field density equal to or less than 20mT (millitesla).

Intended user population

The MRI Capsule and its compatible Pumps can only be used by trained and qualified medical staff within the MRI environment.

Intended patient population

The MRI Capsule can only be used on one patient at a time, and it serves the same population of patients as the compatible Alaris™ Infusion Pumps.

Contraindications

The MRI Capsule is not designed to be used in Home Care environments. Please refer to the 'Product Specifications' section for more information.

Incompatible Alaris™ Infusion Pumps and Accessories for MRI Capsule

Pump Model	**Model Code**
Alaris™ GW Volumetric Pump	All variants
Alaris™ GW 800 Volumetric Pump	All variants
Alaris™ GP Volumetric Pump (all variants)	All variants
Flow Sensor	180 180A

About This Manual

The user must be thoroughly familiar with the BD Alaris™ MRI Capsule described in this manual prior to use.
Please refer to the relevant *Directions For Use (DFU)* for correct operation of the Pumps.
All illustrations used in this manual show typical settings and values which may be used in setting up the functions of the MRI Capsule. These settings and values are for illustrative use only. The complete range of settings and values are shown in the Specifications section.
The illustrations in this DFU show example configurations and equipment that might not be available to all markets and regions. Please contact the local BD office or distributor for further information.

	**Keep this Manual for future reference during the MRI Capsule's operational life.** **It is important to ensure that you only refer to the most recent version of the Directions for Use and Technical Service Manual for your BD products. These documents are referenced on bd.com. Paper copies of the Directions For Use can be obtained free of charge by contacting your local BD representative. An estimated delivery time will be provided when the order is placed.**

Conventions Used in this Manual

Bold	Used for Display names, software commands, controls and indicators referenced in this manual, for example, **Battery Indicator**, **ON/OFF** button.
'Single quotes'	Used to indicate cross-references made to another section of this manual. For example, see 'Battery Supply'.
Italics	Used to refer to other documents or manuals. For example, "refer to *Pump DFU*." Also used to define special terms e.g. *MRI Capsule*.
Note	Notes contain supplementary information or emphasize a point or procedure.
	Warning symbol. A warning is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the MRI Capsule.
	Caution symbol. A caution is a statement that alerts the user to the possibility of a problem with the MRI Capsule associated with its use or misuse. Such problems may include MRI Capsule or Pump malfunction, failure or damage, or damage to other property. The caution statement includes the precaution(s) that should be taken to avoid the hazard.

User	Person interacting with the MRI capsule and infusion devices connected to the patient while delivering treatment and monitors their use.
Qualified Service Personnel	Service and repair the product.
Control Room	This room is immediately adjacent to MRI room. It contains all the equipment required to control the MRI Scanner.
MRI Room	Magnetic Resonance Imaging rooms have strong magnetic fields. Equipment should be kept as near as possible to the patient with a limitation of 20 mT from the strongest magnetic point to avoid harm.
Tesla	Tesla is a unit of magnetic flux density.
Magnetic Field	Magnetic field is a region around magnetic material or changing electric field within which magnetic field is observable.
MRI	Magnetic Resonance Imaging is a diagnostic technique that produces detailed images of organs and tissues within the body using strong magnetic fields.

Controls and Indicators

Controls

Symbol	Description
	ON/OFF Button - Press once to switch the MRI Capsule on. Press and hold for two seconds to switch the MRI Capsule off. In the event that the system needs to be reset, press and hold for at least four seconds, then press again to switch the MRI Capsule on.

Indicators

Symbol	Description
	Battery Indicator - When illuminated the MRI Capsule is operating from internal battery; when flashing the battery power is low and auto power down is imminent.
	AC Power Indicator - When illuminated the MRI Capsule is connected to the AC Power supply and the battery is being charged.
A **B**	**A Status Indicator** - Provides a visual indication of the internal software activity. **B Status Indicator** - Provides a visual indication of communication activity of the network within the MRI Capsule.
	ON Status Indicator - When illuminated the MRI Capsule is powered on.
	System Fault Indicator - The MRI Capsule will illuminate this indicator when an internal fault is present and detected or will momentarily illuminate when the MRI Capsule is operating from internal battery.

Magnetic Indicator

The Magnetic Indicator is an integrated system to continuously measure the magnetic field strength in the MRI environment. The Magnetic Indicator is equipped with both visual and audio alarms. If the MRI Capsule is placed too close to the magnet bore, the Magnetic Indicator will alarm and data will be logged. The Magnetic Indicator is used to advise the user if the MRI Capsule is in a safe distance from the magnet bore.

Indicator	Positioning	Risk	Magnetic Indicator LED Colour	Audio Signal	Action
	Magnetic field density <20mT	Low	Green LED flashes	No	The MRI Capsule is in position for safe operation.
	Magnetic field density 20 - 40mT	Medium	Yellow LED flashes	Yes	Move the MRI Capsule until the Magnetic Indicator green LED flashes.
	Magnetic field density >40mT	High	Red LED flashes	Yes	Move the MRI Capsule until the Magnetic Indicator green LED flashes.

Note: If the MRI Capsule is moved into an area where the Magnetic Indicator is flashing red and the Pump(s) do not alarm, they should be checked by Qualified Service Personnel at the earliest opportunity.

If the magnetic indicator flashes red or orange, and a simultaneous alarm is generated on the Pump(s), the Pump(s) must be replaced, and checked by a qualified service person before being used again.

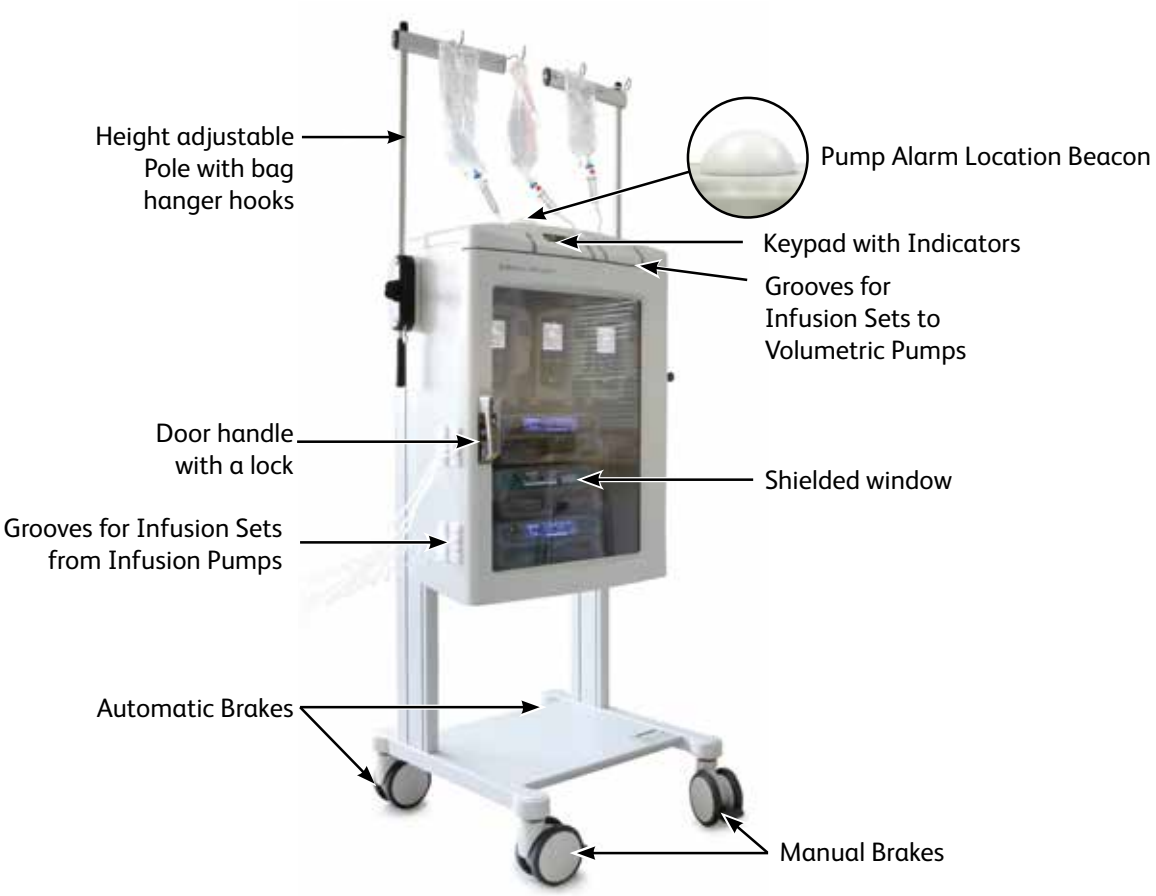
Indicator	Description	Audio Signal
	Battery Indicator - When flashing the battery power is low and auto power down is imminent. Contact Qualified Service Personnel to replace the battery.	Yes, single sound only
	Error Indicator - The Magnetic Indicator will illuminate when an internal fault is present and detected.	Yes

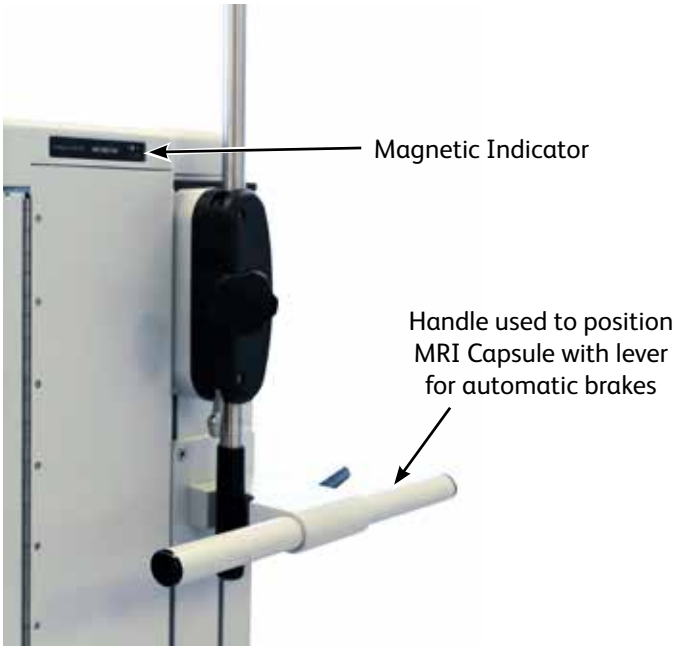
Symbol Definitions

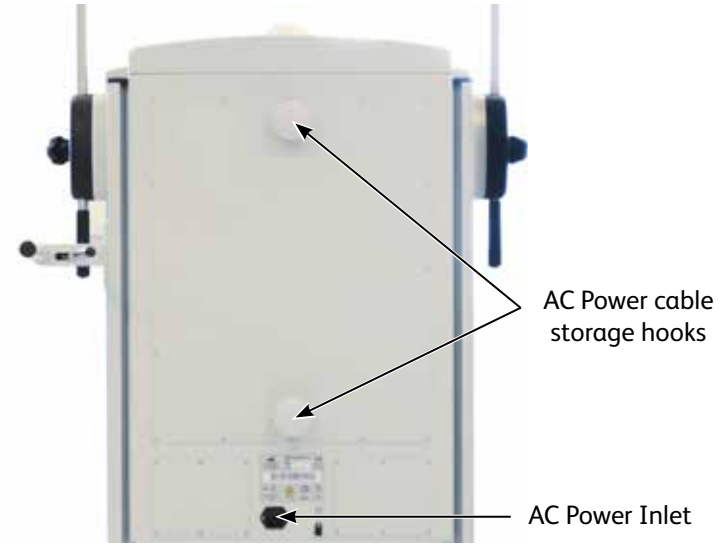
Labelling Symbols

Symbol	Description
	AC Power Inlet
	Fuse Rating
	Consult accompanying documents
	Potential Equalisation (PE) Connector
	Alternating Current
CE 0086	MRI Capsule complies with the requirements of Council Directive 93/42/EEC as amended by 2007/47/EC.
IPX2	Protected against water droplets deflected up to 15° from vertical.
	Date of Manufacture
	Manufacturer
	Not for Municipal Waste
M	Mass including its safe working load in kg
	Warning electrical shock hazard do not tamper.
	Electrostatic discharge (ESD) precautions
	MR conditional - The device does not cause any hazard in a specified MR Environment
SN	Product serial number
REF	Product reference / part number

Features of the MRI Capsule







Trolley

When the MRI Capsule is not being transported or is positioned in place, the manual brakes should be engaged.

Automatic Brakes

The automatic brake lever is located with the MRI Capsule handle. Squeeze and hold the brake lever to release the brakes and locate the MRI Capsule in the desired position. To engage the automatic brakes, release the brake lever.

Manual Brakes

To operate the manual Trolley brakes:

1. Locate brake mechanism at the end of the wheels.

2. Press down to engage the brakes.

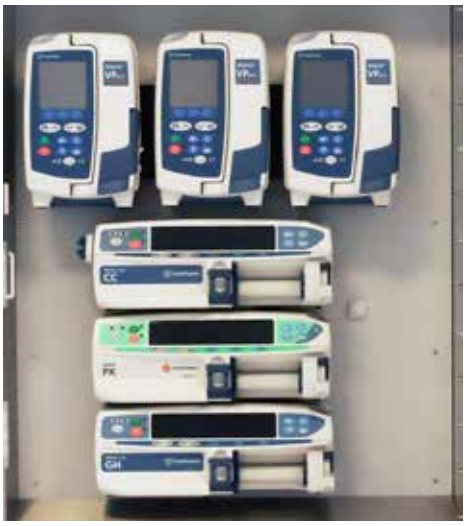
3. Pull up to disengage the brakes.

All wheels should be set to the same engaged or disengaged state.

Prior to moving the MRI Capsule all brakes should be disengaged.

Configurations

3 Volumetric and 3 Syringe Pumps



4 Volumetric Pumps

4 Syringe Pumps

Compatible Infusion Sets

The following list of Compatible infusion and extension sets are recommended for use in the MRI Capsule with the Alaris™ Infusion pumps:

MRI Capsule Compatible product	**Product Reference**	**Description**
Alaris™ CC Syringe Pump	G30402M	Alaris™ CC Extension Set. 200cm. Pressure sensor disc. PVC.
	G30453V	Alaris™ CC Extension Set. Low Sorbing. Light Resistant (Amber). 200cm. Pressure sensor disc. PE lined PVC.
	G30302M	Alaris™ CC Extension Set. Low Sorbing. 206cm. 1 Pinch clamp. Pressure sensor disc. PE lined PVC.
	MFX2213	Alaris™ CC Extension Set. 200cm. Low Sorbing. Pressure sensor disc. PVC.
	MFX2211	Alaris™ CC TPN Extension Set. Light Resistant (Amber). 200cm. 1.2 µm filter. Pinch clamp. 1 Pinch clamp. Pressure sensor disc.
	MFX2299E	Alaris™ CC Extension Set. Low Sorbing. SmartSite NeedleFree connector. 205cm. Pinch clamp. Pressure sensor disc. PE lined PVC.
	G30653V	Alaris™ CC Extenstion Set. Light Resistant (Amber). 200cm. Pressure sensor disc. PVC.
	MFX2294	Alaris™ CC Extension Set. Light Resistant (Amber). 205cm. Pinch clamp. Pressure sensor disc. PE lined PVC.
	MFX2210	Alaris™ CC Extension Set. 200cm. Pressure sensor disc. 0.2 µm filter. Polyurethane.
	MFX2206E	Alaris™ CC TPN System. Light Resistant (Amber). SmartSite Needle Free Valve. Auxilary set 205cm. 1 spiked drip chamber. Hydrophobic air inlet filter. 20 drops per ml. 2 pinch clamps. Pressure sensor disc. 15 µm Drip Chamber Filter.
Alaris™ GH Syringe Pump Alaris™ PK Syringe Pump	G40720	Extension Set. Low Sorbing. 206cm. Pinch clamp.
	G40015	Extension set. 150cm. PVC.
	G40020B	Extension set. 200cm. PVC.
	G40615K	Extension set. 150cm. Polyethylene. Low sorbing.
	G40620K	Extension set. 200cm. Polyethylene. Low Sorbing.
	30852	Y' Extension Set. 183cm. 2 way Y Connector. 2 pinch clamps. 1 back-check valve. 1 female luer anti-siphon valve. PVC.
	30832	Y Extension Set. 178 cm. 2 Way Y Connector. 1 Female Luer Y Site. 2 Pinch Clamps. 1 Back-Check Valve. Rotating Male Luer. PVC
	MFX1952	Spiral tubing extension set. 200cm. Low sorbing. Polyethylene. 1 Slide clamp.
	MFX1953	Spiral tubing extension set. 300cm. Low sorbing. Polyethylene. 1 Slide clamp.
	MFX1954	Spiral tubing extension set. 400cm. Low sorbing. Polyethylene. 1 Slide clamp.
	G40015	Extension Set. 150cm. PVC.
	04100010162	Extension set. 105cm.
Alaris™ VP Plus Guardrails™ Volumetric Pump	70593	Alaris™ VP Infusion set. 300cm. 15 µm filter. Pressure sensor disc. 1 Roller Clamp. PVC. 1 Roller Clamp. 1 Pinch Clamp. PVC.
	70693E	Alaris™ VP infusion set. 265cm. 15 µm filter. Pressure sensor disc. 1 SmartSite valve Y port.
	70643	Alaris™ VP infusion set. 300cm. 15 µm filter. Pressure sensor disc. Light Resistant (Amber). 1 Roller Clamp. 1 Pinch Clamp. PVC.
	70895	Alaris™ VP Transfusion Set. 300cm. 200 µm filter. Pressure sensor disc. 1 Roller Clamp. 1 Pinch Clamp. PVC.

Precautions while managing Infusion and Extension Sets from Alaris™ Infusion Pumps:

- Ensure the sets are securely located in the grooves, when closing the MRI Capsule door and when installing the pumps.
- After installing a pump, ensure its related set is correctly placed within the grooves of its associated outlet.

All these sets and accessories have been tested for compatibility in a MRI environment.

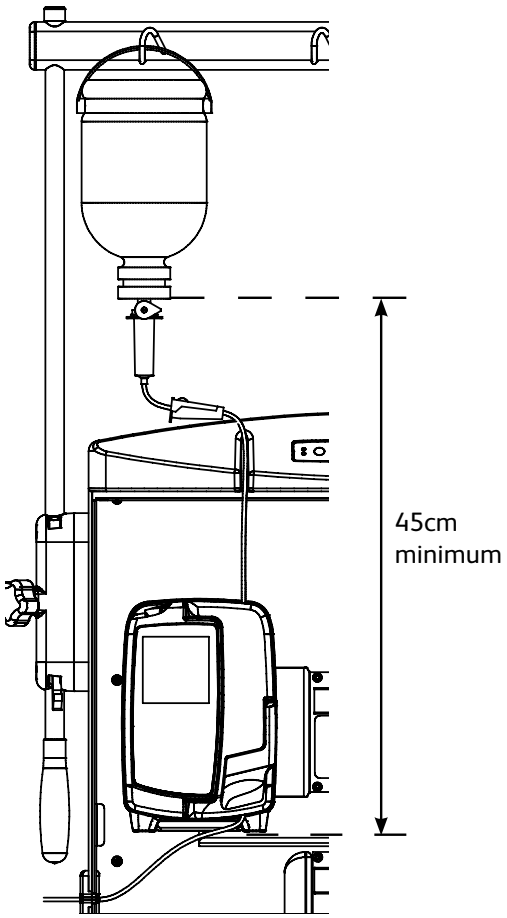
It is recommended that sets are changed according to the Directions for Use. Carefully read the Directions for Use supplied with the set prior to use.

Height Adjustable Poles

The height adjustable poles have been designed as a convenient means of securing the fluid bags onto the MRI Capsule. The height adjustable poles support a maximum load of 4 kg (i.e. 2 kg per height adjustable pole). The height adjustable poles are held securely by a clamp and a slip catch. This gives additional flexibility when selecting the required height of the fluid bags.

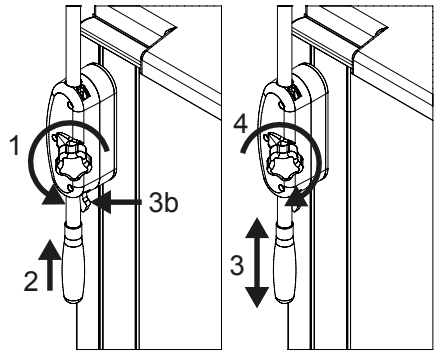
Recommended Height For The Fluids For The Alaris™ VP Plus Guardrails™ Volumetric Pump

Hang the fluid container at a minimum height of 45 cm from the bottom of the Pump to the bottom of the fluid container. Raise the fluid container higher than the minimum height where possible, to minimise loops and kinks in the infusion set tubing.



To operate the clamp:

1. Grip the handle at the lower end of the pole and carefully loosen the hand wheel.
2. Apply an upward pressure to the pole handle, this will release the locking lever and allow the pole to move freely.
3. Changing the bag hanger height:
   a) To increase the bag hanger height: Continue pushing the pole upward to the required height. Once set, release the pressure on the pole, re-engaging the locking lever.
   b) To reduce the bag hanger height: Hold the locking lever in the released position and adjust the pole downward to the required height. Release the locking lever and release the pressure on the pole, re-engaging the locking lever.
4. Tighten the hand wheel to securely lock the pole into position.



Power Input

The MRI Capsule is powered from the AC Power Supply through a standard IEC AC Power connector (i.e. C13, C14). When connected to the AC Power Supply the AC Power indicator is illuminated. Both the Live and Neutral lines of the main supply are protected using fuses carried in a double fuse holder located on the AC Power Supply inlet connector.

When connected to the AC Power Supply, a three wire (Live, Neutral, Earth) supply must be used. If the integrity of the external protective conductor in the installation or its arrangement is in doubt, then the MRI Capsule must not be used.

To isolate the MRI Capsule from the AC Power Supply remove the AC Power cord from the source socket. The MRI Capsule should be positioned to allow access for disconnecting the AC Power cord.

Battery Supply

There are two batteries in the MRI Capsule:

MRI Capsule Internal Battery

The MRI Capsule should normally be operated from the AC Power supply. However, in the event of temporary loss of AC Power, an internal power supply will provide approximately 60 minutes of backup power. AC Power to the Pumps will be discontinued.

AC Power should be re-applied as soon as possible as there will be no AC Power supplied to the Pumps while the MRI Capsule is running on the battery.

Note: When the AC Power is disconnected, the Pumps on the MRI Capsule Medical Device Interface (MDI) tiles (herein after referred to as tiles) that generate an alarm will be replicated on the Pump Alarm Location Beacon.

The Battery indicator illuminates whenever the MRI Capsule is running from the internal battery. When illuminated the MRI Capsule is operating from internal battery; when flashing the battery power is low and auto power down is imminent. The battery is automatically charged whenever the MRI Capsule is connected to the AC Power Supply. As the MRI Capsule is designed to operate from the AC Power supply it will only power up when connected to the AC Power Supply.

If transfer of the MRI Capsule is required, then prior to disconnecting from AC Power supply the User must ensure there is sufficient battery power on each of the Pumps.

In the event of a power loss, the MRI Capsule will provide a visual indicator and emit an audible tone every 30 seconds for the first 14 minutes to alert operators. This audible tone and visual indicator will escalate to every 15 seconds after 14 minutes until the battery is fully depleted. These tones and indications should not be confused with the continuous alarm and LED notification that is initiated if the MRI Capsule exhibits a fault condition.

Magnetic Indicator Battery

The Magnetic Indicator has an independent Primary Alkaline Battery. It is a non-rechargeable battery to provide power to the Magnetic Indicator. The function of the battery is to operate the Magnetic Indicator independently from the AC Power supply or the MRI Capsule internal battery. The battery indicator of the Magnetic Indicator will be flashing when the battery power is low and BD recommends replacing the battery every two years. Please contact Qualified Service Personnel to replace the battery.

Note: The Magnetic Indicator will always be on.

AC Power Output to Infusion Pumps

The MRI Capsule has its own power distribution circuit to supply AC Power to the attached Pumps. Each MRI Capsule tile IEC connector will have AC Power present on the connector, without the Pump attached to the MRI Capsule, and the tile green LED will be illuminated. When a Pump is fully attached to the MRI Capsule tile the AC Power indicator on the Pump will illuminate to indicate the Pump is powered and charging.

The MRI Capsule tile AC Power outlet connection is intended only for connection to the aforementioned Pumps. Please refer to the compatibility matrix in the 'Intended Use' section of this guide. Never attach any other equipment to the outlet connector.

System Notifications

The MRI Capsule is equipped with both audio and visual notifications to promote user awareness. System Notifications have been segregated into three different categories: Status Notifications, System Fault Indications and Pump Alarms, based on their required response and method of user awareness. All System Notifications generated by the MRI Capsule are considered Information Signals. They are not used to indicate an Alarm State but maybe used to replicate an Alarm Signal present on the attached Pumps. The Primary and Secondary Speakers are used to generate the auditory notifications. The purpose of the Primary speaker is to relay the MRI Capsule status. Whereas the Secondary speaker indicates a failure within the system. The table below summarizes the behaviour of the auditory speakers.

Audio Generator	**Approximate Sound Pressure Level at 1 metre**	**Notification Type**
Primary Speaker	≤ 45 dB(A)	Informational
Secondary Speaker	≥ 45 dB(A)	Informational

In some user environments the Sound Pressure Level of the Primary and Secondary Speakers could be less than the ambient noise.

A high level summary of the System notifications can be found in the table below. Status Notifications are represented by small LEDs and are the only System Notifications that use the primary speaker. System Fault Indications are represented by the System Fault Indicator and use the secondary speaker. The Pump Alarm Location Beacon is used to replicate the Pump Alarm Condition.

Trigger	**Visual Indicator**	**Audio Indicator**	**Category**	**Description**
MRI Capsule AC Power Disconnect	Battery Indicator and System Fault Indicator flash momentarily	Momentary audible tone on Secondary Speaker	Status	See ‘Battery Supply’
Pump Alarm	Pump Alarm Location Beacon	N/A	Pump Alarm	See ‘Pump Alarm Location Beacon’
Power on	On Status Indicator	Both Speakers	Status	See ‘Operation of MRI Capsule’
SFI	System Fault Indicator	Secondary Speaker	Fault	See ‘System Fault Indication’
MRI Capsule in area for safe operation	Magnetic Indicator green LED flashing	N/A	Status	See 'Magnetic Indicator'
MRI Capsule in area unsafe for operation	Magnetic Indicator yellow LED flashing	Magnetic Indicator Speaker	Status	See 'Magnetic Indicator'
MRI Capsule in area unsafe for operation too close to the magnet bore	Magnetic Indicator red LED flashing	Magnetic Indicator Speaker	Status	See 'Magnetic Indicator'

It is recommended that all Pumps in a single care area be configured with the same alarm tones, where applicable, to avoid User confusion. The Hospital/Facility is responsible for selecting and configuring the desired alarm scheme.

Refer to each individual Pump’s Directions for Use for further details on the alarm schemes. The User should always refer to the alarm on the Pump for the correct priority.

System Fault Indication

Continuous monitoring of the power distribution and communications system integrity is performed by the MRI Capsule. In the event that a system fault occurs whilst in use, the System Fault Indicator will be illuminated accompanied by an audible tone. To avoid any possible interruption to the infusion, AC Power to the Pumps will be maintained on the MRI Capsule tile should a system fault be detected.
In addition to scenarios described above the MRI Capsule also briefly illuminates the System Fault Indicator and activates the audible tone each time the MRI Capsule is switched on.

Trigger	**Visual Indicator**	**Audio Indicator**	**Description**
Communication Failure	System Fault Indicator	Secondary Speaker	Communication failure of the internal components of the MRI Capsule.
POST failure	System Fault Indicator	Secondary Speaker	Failure of any of the step defined in the 'Operation of MRI Capsule' Section

If the System Fault Indicator fails to illuminate when the MRI Capsule is switched on, remove the MRI Capsule from service and contact Qualified Service Personnel.

Should a System Fault occur during use, remove the MRI Capsule from service as soon as possible and contact Qualified Service Personnel.

The MRI Capsule auditory SFI signal is a continuous tone.

Pump Alarm Location Beacon

The Pump Alarm Location Beacon is mounted at the top of the MRI Capsule to assist with identifying the presence of any alarms generated by the Pumps. When lit, the Pump Alarm Location Beacon colour matches that of the visual status indicator on the Pumps. Alarms of high priority, such as when an infusion is terminated are reflected as flashing Red. Alarms of medium priority, such as Battery Low, are reflected as flashing or solid Yellow. Alarms of low priority, such as AC Power Disconnection, are reflected as solid Yellow. The Pump Alarm Location Beacon will indicate the highest priority of alarm if there are multiple Pumps in an alarm state. The Pump Alarm Location Beacon flashes automatically whenever any Pump located on an MRI Capsule Tile enters the alarm condition, and stops when the condition is cleared on the Pump. The Pump Alarm Location Beacon automatically illuminates Red then Yellow each time the MRI Capsule is switched on.

The Pump Alarm Location Beacon alerts the user to a Pump being in an alarm condition whilst it is connected to the MRI Capsule, it does not replace the alarm on the Pump which remains the principle indicator that the attention of a clinician is required.

A summary of the Pump Alarm Priority Level Indicators can be found below.

Pump Alarm Priority	**Colour**	**Frequency**
HIGH Priority	Red	Flashing faster than Medium Priority
MEDIUM Priority	Yellow	Flashing or solid
LOW Priority	Yellow	Solid

Note: In the occurrence of a Pump alarm being transmitted to the alarm location beacon, the clinician must decide on the urgency of alarm by referring to the Pump's DFU to determine whether it needs to be rectified. If the clinician decides they need to rectify the alarm condition, they must follow the local hospital policy for entering the scan room. To clear the Pump Alarm Location Beacon state on the MRI Capsule, the clinician has to clear the alarm state on the Pump first.

If the Pump Alarm Location Beacon fails to illuminate when the MRI Capsule is switched on, suspect a fault. Remove the MRI Capsule from service and contact Qualified Service Personnel.

There may be a delay, of approximately six seconds, between the Pump going into alarm and the Pump Alarm Location Beacon activating via the MRI Capsule.

In the event of a communication fault between the MRI Capsule and the Pump, the MRI Capsule Pump Alarm Location Beacon and Pump Alarm Beacon may not be synchronised. In this case, refer to the Pump's Alarm status. Communication faults could result from hardware failures or incorrect configuration of the Pump communication parameters

Note: See the 'Introduction' section for lists of the Pump Alarm Location Beacon compatibility between the Pumps and MRI Capsule.

Note: Refer to the individual Pump DFU for alarm priority information.

Operating Precautions

Operating Environment

- Users of the MRI Capsule should read all instructions in this manual before using this medical device.
- The MRI Capsule is suitable for various establishments, including those directly connected to the public low-voltage power supply network.
- When setting up the MRI Capsule, an assessment of any potential hazards associated with the routing of electrical leads and infusion lines should be made. Where appropriate, mitigations should be identified and implemented.
- The MRI Capsule should only be used with compatible BD products and accessories.
- While being used for patient therapy, each MRI Capsule should be dedicated to the care of a single patient.
- This MRI Capsule is not intended to be used in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

Electromagnetic Compatibility and Interference

- This MRI Capsule is protected against the effects of external interference, including high energy radio frequency emissions, magnetic fields and electrostatic discharge (for example, as generated by electrosurgical and cauterising equipment, large motors, portable radios, cellular telephones etc.) and has been tested to relevant standards for electromagnetic and radio frequency interference. Where variations of the standards exist, additional testing to meet these requirements have been completed.
- If the door of the MRI Capsule is open, and the Pumps are infusing, portable communication devices should be used no closer than 30cm from the MRI Capsule. Otherwise degradation of the performance of the Pumps could result.
- The MRI Capsule is a Class IIb device. When Alaris™ Infusion Pumps are attached and operational, the system becomes a Class IIb system.
- This MRI Capsule is a Class IIb device . Therefore, its RF emissions are very low and are not likely to cause any interference with the nearby electronic equipment. However, this MRI Capsule emits a certain level of electromagnetic radiation which is within the levels specified by IEC/EN60601-2-24 and IEC/EN60601-1-2 (where applicable). If however the MRI Capsule interacts with other equipment, measures should be taken to minimise the effects, for instance by repositioning or relocation.
- The emissions characteristics of the MRI Capsule make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) the MRI Capsule might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as re-locating or re-orientating the MRI Capsule.
- **Therapeutic Radiation Equipment**: Do not use the MRI Capsule in the vicinity of any Therapeutic Radiation Equipment. Levels of radiation generated by the radiation therapy equipment such as a Linear Accelerator, may severely affect functioning of the MRI Capsule. Please consult manufacturer's recommendations for safe distance and other precautionary requirements. For further information, please contact your local BD representative.
- **Magnetic Resonance Imaging (MRI)**: The Pumps contain ferromagnetic materials which are susceptible to interference with magnetic field generated by the MRI devices. Therefore, the MRI Capsule should be used within the specified safe distance only. This safe distance should be established in accordance with the manufacturers' recommendations regarding electromagnetic interference (EMI). Alternatively, contact your local BD representative for further guidance.

- Do not use any non-recommended accessory with the MRI Capsule. The MRI Capsule is tested and compliant with the relevant EMC claims only when used with the recommended accessories. Use of any accessory, transducer or cable other than those specified by BD may result in increased emissions or decreased MRI Capsule immunity.
- In some circumstances the MRI Capsule may be affected by an electrostatic discharge through air at levels above 15kV; or by radio frequency radiation above 10V/m. If the MRI Capsule is affected by this external interference, it will remain in a safe mode and alerts the user by generating a combination of visual indicators and audible tones. Should any encountered alarm condition persist, even after user intervention, remove the MRI Capsule from service for inspection by Qualified Service Personnel.
- Portable and mobile RF communications equipment can affect other, nearby medical electrical equipment.

Hazards

- The MRI Capsule is heavy and poses a potential handling hazard. Use caution when unpacking and installing the MRI Capsule.
- All Pumps mounted within the MRI Capsule (and in a single care area) should be configured with the same alarm tones to avoid user confusion. Please refer to the individual Pump DFU for more information on alarm tone settings.
- Data logged by the Magnetic Indicator is stored such that older data will be overwritten by new data when the storage capacity has been reached.

- An explosion hazard exists if the MRI Capsule is used in the presence of flammable anaesthetics. Exercise care to locate the MRI Capsule away from any such hazardous sources.

- **Dangerous Voltage:** An electrical shock hazard exists if the MRI Capsule's casing is opened or removed. Refer all servicing to qualified service personnel.
- When connected to an external power source, a three-wire (Live, Neutral, Earth) supply must be used. If the integrity of the external protective conductor in the installation or its arrangement is in doubt, the MRI Capsule should not be used.
- If any of the following conditions occur with the MRI Capsule remove it from service for inspection by Qualified Service Personnel:
  - Dropped
  - Excessive moisture
  - Fluid spillage
  - High humidity
  - High temperature
  - Suspicion of damage
- When transporting or storing the MRI Capsule, use original packaging where possible, and adhere to temperature, humidity and pressure ranges stated in the Specifications section.

- 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.

- 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 MRI Capsule, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

- The MRI Capsule should not be modified or altered in any way, except where explicitly directed or authorised by BD. Any use of the MRI Capsule which has been altered or modified otherwise than in strict application of directions provided by BD, is at your sole risk, and BD does not provide any warranty for or endorsement on any MRI Capsule that has been so modified or altered. BD product warranty shall not apply in the event the MRI Capsule has suffered damage or premature wear, or malfunctions or otherwise operates incorrectly, as a result of unauthorised modification or alteration of the MRI Capsule.

- If the MRI Capsule is moved to an area where the Magnetic Indicator is flashing red, and the Pumps do not alarm, the user must move the MRI Capsule back to a position where the Magnetic Indicator flashes green. The infusions can continue without interruption. The Pumps must be checked by qualified service personnel when the infusions are complete.
- If the MRI Capsule is moved in to an area where the Magnetic Indicator is flashing red momentarily, and Pumps do not alarm, user must move the MRI Capsule back into an area where the Magnetic Indicator is flashing green and continue infusions without interruption.

Operation of the MRI Capsule

Switching On

Note: Magnetic Indicator is permanently on and is not affected by switching on/off the MRI Capsule.

1. Connect the AC Power cord from the AC Power Supply to the AC Power inlet socket at the back of the MRI Capsule.
2. Verify the AC Power indicator is illuminated.
3. Press the ⏻ key once to switch the MRI Capsule on.
   Note: When powered on the MRI Capsule will illuminate the alarm location beacon, red then amber, and generate an audible tone.
4. After initially switching on the MRI Capsule, it may take up to 90 seconds to become fully operational.

⚠ **Do not switch off the MRI Capsule during this initial 90 second period.**

⚠ **If any of the verification checks fail when the MRI Capsule is switched on, suspect a fault. Remove the MRI Capsule from service and contact Qualified Service Personnel.**

Switching Off

Press the ⏻ key and hold for two seconds to switch the MRI Capsule off.

Resetting the MRI Capsule

In the unlikely event that the MRI Capsule needs to be reset, press and hold the ⏻ key for at least four seconds until the **ON Status** Indicator is extinguished, release the key then press again to switch the MRI Capsule back on.

⚠ **If the MRI Capsule still fails to operate correctly after resetting, remove the MRI Capsule from service and contact Qualified Service Personnel.**

⚠ **Resetting the MRI Capsule is also required to clear any System Fault Indicator.**

The MRI Capsule in the MRI Environment

Control Room

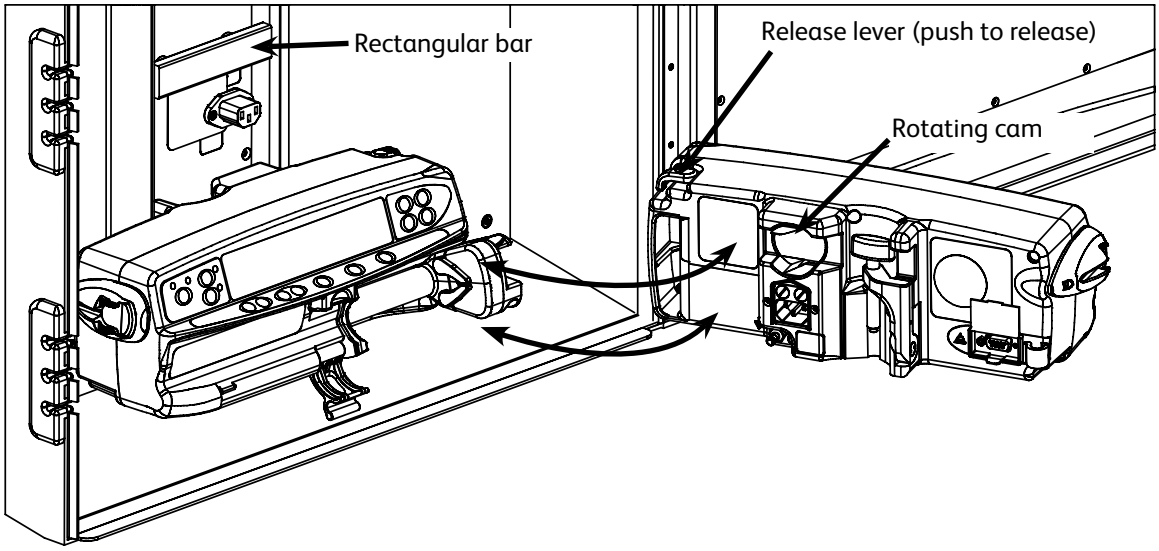
Only dock the compatible Pumps into the MRI Capsule, see 'Compatible Alaris™ Infusion Pumps for MRI Capsule' section.

Perform the following steps in the control room before taking the patient and the MRI Capsule to the MRI Room.

1. Connect the MRI Capsule to AC Power, and turn on the MRI Capsule. Ensure the LED on each tile is lit, to indicate the tile is receiving power

   Note: The MRI Capsule needs to be connected to AC Power before the MRI Capsule can be turned on
2. Determine whether the pump can or cannot be used in the MRI Capsule. Please refer to the 'Compatible Alaris™ Infusion Pumps for MRI Capsule' section, and also see the label on the MRI Capsule tile.
3. If using the Alaris™ VP Plus Guardrails™ Volumetric Pump, hang the fluid bags on the height adjustable poles, and secure the infusion sets in the grooves in the top of the MRI Capsule.

   Note: When docking an Alaris™ VP Plus Guardrails™ Volumetric Pump to the top left MRI Tile follow the best practice specified on the next page.
4. Align the rotating cam on the rear of the Pump with the rectangular bar on the MRI Capsule tile.
5. Hold the pump horizontally, push the pump firmly onto the horizontal bar.
6. The pump should click into position when fitted to the bar. Verify that the AC Power indicator on the Pump is illuminated when the MRI Capsule is connected to AC Power.
7. Verify Pump is secure by gently pulling the Pump away from the MRI Capsule tile without using the release lever. When the Pump is securely attached, it should not come away from the MRI Capsule tile.
8. Check all the sets are connected to the patient and securely placed in the grooves on the left side of the MRI Capsule.
9. Close and lock the door and secure the door latch.



When using Volumetric Pumps with the MRI Capsule, it is recommended that, where possible infusion bags are located on a height adjustable pole directly above the Pump with which they are being used. This minimises the potential for confusion of sets when multiple Volumetric Pumps are used.

If a Pump is removed and replaced while the MRI Capsule is operational, it may take up to 10 seconds for the Pump to establish AC Power once correctly located on the MRI Capsule tile.

Pump may fall off the MRI Capsule tile if not properly mounted which could result in user and/or patient harm.

Adjusting the Pump's height relative to the patient's heart level can lead to temporary increases or decreases in fluid delivery. Please refer to the appropriate Pump DFU for further details.

If the magnetic indicator flashes red or orange and a simultaneous alarm is generated on the Pump(s), the Pump(s) must be replaced and checked by Qualified Service Personnel.

Removing a Pump

1. Unlock and open the MRI Capsule door.
2. Holding the Pump with both hands, push the release lever on the right hand side of the Pump backwards.
3. Keeping the lever pushed back, pull the Pump horizontally towards you.
4. Slide the Infusion Sets away from the grooves
5. Check that the green LED indicator on the MRI Capsule tile is not extinguished after removal of the Pump with AC Power present on the MRI Capsule.

   Note: When removing an Alaris™ VP Plus Guardrails™ Volumetric Pump from the top left MRI Tile follow the best practice specified below.

If the indicator in the MRI Capsule tile is *not* illuminated when no infusion Pump is attached to the MRI Capsule tile, (with AC Power present) suspect a fault with the MRI Capsule tile. Remove the MRI Capsule from service and contact Qualified Service Personnel.

Best practice for docking and undocking Alaris™ VP Plus Guardrails™ Volumetric Pumps

Hand positioning for docking Pump on top left MRI Tile

Hand positioning for undocking Pump on top left MRI Tile

Positioning of hand, as shown opposite, when handling the Pump in the MRI Capsule could result in user harm.

Getting Started in the MRI Room

Before entering the MRI Room, ensure that the MRI Capsule is switched on. Disconnect the MRI Capsule from AC Power before entering the MRI Room.

Before entering the MRI Room, ensure that the MRI Capsule door is closed and securely locked.

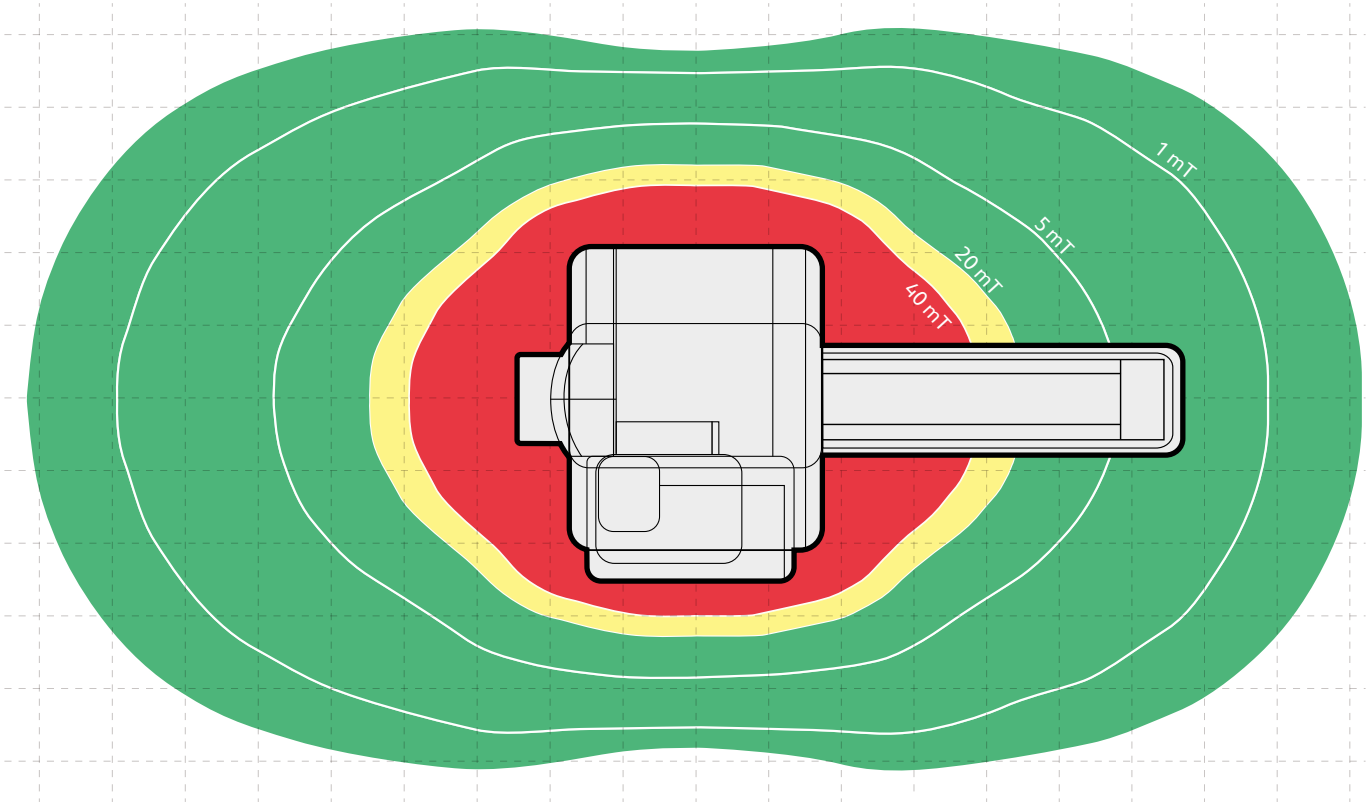
1. Release the automatic brake lever and manual brakes and move the MRI Capsule carefully in the MRI Room and position it whilst constantly checking the Magnetic Indicator to ensure the green LED is flashing
2. If the Magnetic Indicator changes from green to yellow, move the MRI Capsule back to an area where the Magnetic Indicator changes back to green. When the MRI Capsule is in a safe working area with the Magnetic Indicator flashing green, release the automatic brake lever, and apply the manual brakes.

After placing the MRI Capsule in position, you must ensure that all the braking systems are activated and working correctly. Inadvertent movement of the MRI Capsule could result if the brakes are not correctly engaged.

3. Lock the MRI Capsule in position with the MRI Capsule window facing the control room window. Ensure the two automatic brakes are engaged, and the manual brakes are secured
4. Make sure the MRI Capsule door is securely locked, to prevent RF waves from the pumps distorting the MRI images and/or the magnetic field damaging the pumps.
5. Connect the AC Power cord from the MRI Capsule to the AC Power supply. Ensure the MRI Capsule is receiving AC Power by observing the LED on the keypad, and the audio alarm is not present.

The MRI Capsule may be operated at a maximum magnetic field strength of 20mT / 200 gauss. Depending on the different MRI Scanners this could be a distance of approximately 1.2m to the opening of the bore (based on actively shielded 1.5T MRI Scanner).

For exact positioning of the MRI Capsule please use the integrated Magnetic Indicator.



Fringe Field of MRI Scanner	Typical values of approximate distances to opening of magnet bore		Allowed position in MRI Environment
	Static Magnetic field of MRI Scanner: 3.0 tesla	Static Magnetic field of MRI Scanner: 1.5 tesla	
200mT / 2000 gauss	0.6m	0.5m	No
70mT / 700 gauss	0.9m	0.8m	No
40mT / 400 gauss	1.1m	1.0m	No
30mT / 300 gauss	1.2m	1.1m	No
20mT / 200 gauss	1.4m	1.2m	Yes
10mT / 100 gauss	1.7m	1.5m	Yes
5mT / 50 gauss	2.1m	1.8m	Yes

Do not place the MRI Capsule any closer than 1.2m of magnet bore for 1.5 tesla MRI Scanner.
Do not place the MRI Capsule any closer than 1.4m of magnet bore for 3.0 tesla MRI Scanner.

Prolonged exposure to a magnetic field in an area where the Magnetic Indicator is flashing red can cause functional damage to the Pumps.

Product Specifications

Electrical

Protection Against Electrical Shock:
Class I
Supply Voltage:
115–230V, ~50–60Hz
Rating:
460VA (Maximum)
Fuses:
2 × 4A/H Time-Lag T
Consult Qualified Service Personnel for replacement of fuses.
AC Power Outlets:
MRI Capsule Tile: 115–230V, ~50–60Hz, 60VA
Protection against fluid ingress:
IPX2 – Protection against water droplets deflected up to 15° from vertical.

Battery

MRI Capsule Battery

Type:
Nickel Metal Hydride
Charge time:
With no Pumps attached: Up to 8 hours to 95% charge time based on battery life cycle.
With Pumps attached: Up to 16 hours to 95% charge time based on battery life cycle and a 6 Pump load.
Operating time:
60 minutes

Magnetic Indicator Battery

Type:
Primary Alkaline Battery (Zn/MnO_2)
Operating time:
Approximately 2 years, under normal conditions

Environmental

	Operating	**Transport and Storage**
Temperature:	+5°C to +40°C	–20°C to +50°C
Humidity:	20% to 90%	20% to 90%
Atmospheric Pressure:	70 to 106kPa	50 to 106kPa

Mode of Operation

Continuous Operation

Regulatory Compliance

Complies with IEC/EN60601-1, IEC/EN60601-1-2.

Potential Equalisation Conductor

The function of the Potential Equalisation Connector (Conductor) is to provide a direct connection between the MRI Capsule and the potential equalisation busbar of the electrical installation. To use the Potential Equalisation Connector, connect the Potential Equalisation Connector on the MRI Capsule to the potential equalisation busbar of the electrical installation.

Physical

Dimensions:
780 mm (w) × 1780 mm (h) × 635 mm (d).
Weight:
60 kg (excluding Pumps and Infusion Bags).
Maximum Weight:
80 kg including Pumps, Infusion Bags and accessories

Maintenance

Routine Maintenance Procedures

To ensure that this MRI Capsule remains in good operating condition, it is important to keep it clean and carry out the routine maintenance procedures described below. All servicing should be performed by Qualified Service Personnel with reference to the Technical Service Manual.
Circuit diagrams, components parts lists and all other servicing information which will assist the Qualified Service Personnel in performing repair of the parts designated as repairable, are available upon request from BD.

If the MRI Capsule is dropped, damaged, remains in an area where the Magnetic Indicator is flashing red for prolonged period, subjected to excessive moisture or high temperature, immediately take it out of service for examination by Qualified Service Personnel.

All preventative and corrective maintenance and all such activities shall be performed at a compliant work place in accordance with the information supplied. BD will not be held responsible should any of these actions be performed outside the instructions or information supplied by BD. For Preventative and Corrective Maintenance instructions please refer to the Technical Service Manual (TSM).

All preventative and corrective maintenance and all such activities should be performed by Qualified Service Personnel only, with reference to the TSM.

Interval	**Routine Maintenance Procedure**
When loading Pumps	Check that each Pump is properly located on the MRI Capsule tile and is securely locked into position.
When removing Pumps	Check that the MRI Capsule tile green LED stays on when the Pump is removed but AC Power is still connected to the MRI Capsule. If the LED turns off, the MRI Capsule should be serviced by Qualified Service Personnel.
As per Hospital Policy	Thoroughly clean external surfaces of the equipment before and after prolonged periods of storage.
At least once per year (Refer to TSM for identification of parts)	• Inspect AC Power outlets, and the AC Power inlet for damage. • Perform electrical safety checks. The complete unit leakage current must be measured. If more than 500µA the equipment should not be used, but should be serviced by Qualified Service Personnel.

Battery

It is recommended that only Qualified Service Personnel replace the batteries, using only BD recommended batteries. For further information regarding the replacement of batteries refer to the Technical Service Manual.
The battery pack used in this MRI Capsule is manufactured by BD and includes a proprietary PCB (printed circuit board) designed specifically for the MRI Capsule. Furthermore, the Magnetic Indicator has its own non-rechargeable battery pack and BD recommends replacing the Magnetic Indicator battery every two years. Any use of battery packs that are not manufactured by BD in the MRI Capsule is at your sole risk, and BD does not provide any warranty for or endorsement on any battery packs that are not manufactured by BD. BD product warranty shall not apply in the event the MRI Capsule has suffered damage or premature wear, or malfunctions or otherwise operates incorrectly, as a result of use with a battery pack that is not manufactured by BD.

Replacing the AC Power Fuses

If the AC Power indicator does not illuminate when the MRI Capsule is connected to the AC Power supply, either the power supply fuse in the AC Power plug or, the AC Power fuses of the MRI Capsule have blown.
First check the power supply fuse in the AC Power plug, if the **AC Power** indicator does not illuminate proceed to check the MRI Capsule AC Power fuses. Switch the power off and disconnect the MRI Capsule from the AC Power supply.
It is recommended that only Qualified Service Personnel replace the AC Power fuses. For further information regarding the replacement of internal AC Power fuses refer to the Technical Service Manual.

If the fuses continue to blow, suspect an electrical fault and have the Capsule and power supply checked by Qualified Service Personnel.

Recommended Cleaning

MRI Capsule Tile Cleaning

This section refers to the compatible cleaning agents for the MRI Capsule Tiles.
Before the transfer of the MRI Capsule to a new patient it is advisable to clean and disinfect the MRI Capsule Tiles by wiping over with a lint-free cloth lightly dampened with warm water and a standard disinfectant / detergent solution.
Recommended cleaners are:

- Hibiscrub 20% (v/v)
- Virkon 1% (w/v)

Do not use the following disinfectant types:

- Disinfectants which are known to be corrosive to metals must not be used. These include:
  - Cationic Surfactants > 1% (such as benzalkonium chloride)
  - Aldehydes (such as Cidex)
  - Hypochlorites (such as Chlorasol)
  - NaDcc (such as Presept)
- Use of Iodine (such as Betadine) will cause surface discoloration.
- Concentrated isopropyl alcohol based cleaners will degrade plastic parts.

The following products were tested and are acceptable for use on the MRI Capsule Tile if used in accordance with the specified manufacturer's guidelines.

- Warm soapy water
- Mild detergent in water (e.g. Young's Hospec)
- 40% isopropyl alcohol in water
- Chlor-Clean
- TriGene Advance
- Tristel Fuse sachets
- Tristel Trio wipes system
- Tuffie 5 wipe

MRI Capsule Exterior, Interior Sides and Door Cleaning

This Cleaning section refers to the compatible cleaning agents for:

- The MRI Capsule exterior
- The MRI Capsule plastic interior sides and the door

The following products were tested and are acceptable for use on the MRI Capsule if used in accordance with the specified manufacturer's guidelines.
Only use recommended products for the glass window, to avoid clouding.
Recommended cleaners are:

Brand	Name	Form	Recommended Application
Pharmacy generic	Isopropyl	Liquid	Surface
Antiseptica	Descogen Liquid	Liquid	Surface and Acrylic Glass
Diversey Inc	Oxivir TB	Tissues	Surface
Hartmann / Bode	Microbac Tissues	Tissues	Surface
Hartmann	Bacillol AF	Liquid, Tissues, Foam	Surface
Hartmann	Bacillol Plus	Surface	Surface
Hartmann	Dismozon plus	Granules	Surface
Schülke & Mayr	mikrozid – sensitive	Liquid , Spray, Tissues	Surface and Acrylic Glass
Walter & Schmidt	AHK Spiritus	Liquid	Surface

- **Before cleaning the MRI Capsule always switch it off and disconnect it from the AC Power supply.**
- **Never allow liquid to enter the casing and avoid excess fluid buildup on the MRI Capsule.**
- **Do not use aggressive cleaning agents as these may damage the exterior surface of the MRI Capsule.**
- **Do not steam autoclave, ethylene oxide sterilise or immerse this MRI Capsule in any fluid.**

If the MRI Capsule has visible cracks or damage to the case do not clean and immediately take out of service for examination by Qualified Service Personnel.

Do not clean the AC Power connector and socket. Please contact local BD Qualified Service Personnel for further guidance.

Disposal

Disposal of Waste Electrical & Electronic Equipment

This ⌧ symbol on the product and/or accompanying documents means that used electrical and electronic products should not be mixed with household waste.
If you wish to discard electrical and electronic equipment, please contact your BD affiliate office or distributor for further information.
Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

Disposal in Countries outside the European Union

This ⌧ symbol is only valid in the European Union. The product should be disposed of taking environmental factors into consideration. To ensure no risk or hazard, remove the internal rechargeable battery and dispose of as outlined by the local country regulations. All other components can be safely disposed of as per local regulations.

Spare Parts

Spare Parts

A comprehensive list of spare parts for this MRI Capsule is included within the Technical Service Manual.
The Technical Service Manual is now available in electronic format on the World Wide Web at:
bd.com/int-Alaris-technical
A username and password are required to access our manuals. Please contact a local customer services representative to obtain login details.

Contact Us

For full contact information please refer to bd.com.

Customer Service Information

Country	Telephone	email
Australia	Freephone: 1 800 656 100	AUS_customerservice@bd.com
België	+32(0)53 720 556	info.benelux@bd.com
Canada	+1 800 387 8309	CanadaCapital@carefusion.com.
Danmark	+45 43 43 45 66	bddenmark@bd.com
Deutschland	+49 622 1305 558	GMB-DE-CustService-Alaris@bd.com
España	+34 902 555 660	info.spain@carefusion.com
France	+33 (0) 1 30 02 81 41	mms_infusion@bd.com
Italia	+39 02 48 24 01	customer.service-italy@bd.com
Magyarország	(36) 1 488 0233	info.cfn.export@bd.com
Nederland	+31(0)20 582 94 20	info.benelux@bd.com
New Zealand	Freephone: 0800 572 468	NZ_customerservice@bd.com
Norge	+47 64 00 99 00	bdnorge@bd.com
Polska	(48) 22 545 05 80	dok@medicart.eu
Portugal	+351 219 152 593	dl-pt-geral@carefusion.com
South Africa	Freephone: 0860 597 572 +27 11 603 2620	bdsa_customer_centre@bd.com
Suomi	+358-9-8870 780	bdsuomi@bd.com
Sverige	+46 8-7755160	bdsweden@bd.com
Switzerland	+41 61 485 22 66	Customer_Care_Switzerland@bd.com
United Kingdom	Freephone: 0800 917 8776	BDUK_CustomerService@bd.com
United States of America	Freephone: 800 482 4822	CustCareInfusion@carefusion.com
中国	400 878 8885	serviceclientbdf@bd.com

Document History

Issue	Date	Description
1	March 2018	Initial release
2	October 2018	Final release version
3	November 2018	Additional electromagnetic immunity data
4	March 2019	Added minimum supported firmware version to Compatibility table, and updated Recommended Cleaning

Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The MRI Capsule is intended for use in the electromagnetic environment specified below.
The customer or the user of the MRI Capsule should assure that it is used in such an environment.

Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
CISPR 11 RF Emissions	Group 1	The MRI Capsule uses RF energy only for its internal function in the normal product offering. Therefore, its RF emissions are very low and are not likely to cause any interface in nearby electronic equipment.
CISPR 11 RF Emissions	Class A system when used in conjunction with pumps Class B in stand alone operation	The MRI Capsule is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
EN 61000-3-2 Harmonic Emissions	Class A	
EN 61000-3-3 Voltage Fluctuations, Flicker Emissions	Complies	

Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The MRI Capsule is intended for use in the electromagnetic environment specified below.
The customer or the user of MRI Capsule should assure that it is used in such an environment.

Immunity Test	**EN 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
EN 61000-4-2 Electro-Static Discharge (ESD)	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
EN 61000-4-4 Electrical Fast Transient, Burst (EFT) (Note 2)	± 2 kV at 100 kHz repetition frequency for Input a.c. power ports ± 2 kV at 100 kHz repetition frequency for Input d.c. power ports ± 1 kV at 100 kHz repetition frequency for Signal input/ output ports	± 2 kV at 100 kHz repetition frequency for Input a.c. power ports ± 2 kV at 100 kHz repetition frequency for Input d.c. power ports ± 1 kV at 100 kHz repetition frequency for Signal input/ output ports	AC power quality should be that of a typical commercial or hospital environment.
EN 61000-4-5 Power Line Surge (Note 2)	± 0.5 kV, ± 1 kV Line-to-line for Input Power Ports ± 0.5 kV, ± 1 kV, ± 2 kV Line-to-Ground for Input Power Ports ± 2 kV Line-to-ground for Signal input/ output	± 0.5 kV, ± 1 kV Line-to-line for Input Power Ports ± 0.5 kV, ± 1 kV, ± 2 kV Line-to-Ground for Input Power Ports ± 2 kV Line-to-ground for Signal input/ output	AC power quality should be that of a typical commercial or hospital environment.
EN 61000-4-8 Power Frequency Magnetic Field (50/60 Hz)	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
EN 61000-4-11 Voltage Dips, Short Interruptions (Note 2)	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	AC power quality should be that of a typical commercial or hospital environment. If the user of the MRI Capsule requires continued operation during AC Power interruptions, it is recommended that the MRI Capsule be powered from an uninterruptible power supply or a battery. The MRI Capsule does employ an internal short duration battery.
	0 % UT; 1 cycle Single phase: at 0°	0 % UT; 1 cycle Single phase: at 0°	
	70 % UT; 25/30 cycles Single phase: at 0°	70 % UT; 25/30 cycles Single phase: at 0°	
	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	

Note 1 – *U*T is the AC Power voltage prior to application of the test level.
Note 2 – Performed at the Minimum and Maximum Rated Input Voltage.
Note 3 – BD recommends using signal cables of less than 3 metres in length and this requirement is applicable only if signal cables are 3 metres or more in length. (EN 60601-1-2:2002, Clause 36.202.4)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity – Life Support Equipment

The MRI Capsule is intended for use in the electromagnetic environment specified below.
The customer or the user of the MRI Capsule should ensure that it is used in such an environment.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment – Guidance
EN 61000-4-6 Conducted disturbances induced by RF fields	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the MRI Capsule, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ $d = \left[\frac{12}{V2}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{12}{E1}\right]\sqrt{P}$ 80 MHz to 2.5 GHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$ 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 metres (m).[a] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, b should be less than the compliance level in each frequency range.[c] Interference may occur in the vicinity of equipment marked with the following symbol: 
EN 61000-4-3 Radiated RF EM fields	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	

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.

The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
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 MRI Capsule is used exceeds the applicable RF compliance level above, the MRI Capsule should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MRI Capsule.
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended Separation Distances

Recommended Separation Distances for Life Support Equipment between portable and mobile RF communications equipment and the MRI Capsule

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

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter** m			
	150 kHz to 80 MHz Outside ISM bands 3.5 d = [------] $\sqrt{P}$ V1	150 kHz to 80 MHz In ISM bands 12 d = [------] $\sqrt{P}$ V2	80 MHz to 800 MHz 12 d = [------] $\sqrt{P}$ E1	800 MHz to 2.5 GHz 23 d = [------] $\sqrt{P}$ E1
0.01	0.03	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.20	1.20	2.30
10	1.11	3.80	3.80	7.28
100	3.50	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 1 – At 80 MHz and 800 MHz, the separation distance for the higher frequency range apply.
Note 2 – The ISM (Industrial, Scientific, and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
Note 3 – An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 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 4 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Recommended Separation Distances for between portable and mobile RF communications equipment and the MRI Capsule

The MRI Capsule is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. 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 MRI Capsule, including cables specified by the manufacturer. Otherwise, degradation of the performance of the MRI Capsule could result.
The MRI Capsule should not be used next to other equipment. If adjacent use is necessary, the MRI Capsule should be observed to verify normal operation in the configuration in which it will be used.
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment in accordance to IEC 60601-1-2:2014:

Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380 - 390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	Pulse Modulation 18 Hz	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9

BD Switzerland Sàrl, Route de Crassier 17, Business Park Terre-Bonne,
Batiment A4, 1262 Eysins, Switzerland

bd.com