Chapter 1 — Safety

The Oasis MRI System provides high-quality imaging and comprehensive clinical applications using a superconductive magnet design and advanced technology. Properly used, the Oasis MRI System can provide substantial benefit to many patients. Misused, it can cause serious injury or death to patients, clinical users, and ancillary personnel. Misuse could also result in significant damage to the equipment. The clinical user must be vigilant to the potential for injury or equipment damage in day-to-day operations of the Oasis MRI System.

The guidelines in this chapter strongly emphasize the need for rigorous control of personnel and equipment while in the environment of the Oasis MRI System.

Contraindications, Warnings, Cautions, Precautions

When operating the Oasis MRI System, you must be fully cognizant of procedures for the safe and effective use of the equipment, including MRI contraindications, warnings, cautions, and precautions.

Indications for Use

The Oasis MRI System is an imaging device intended to provide the physician with physiological and clinical information, obtained noninvasively and without the use of ionizing radiation. The Oasis MRI System produces transverse, coronal, sagittal, or oblique cross-sectional images that display the internal structure of the head, body, or extremities.

⚠️ Caution

Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
The images produced by the Oasis MRI System reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The nuclear magnetic resonance properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis.

A brief summary of the Oasis MRI System capabilities is provided below:

**Anatomical Region:**
- Head
- Body
- Spine
- Extremities

**Nucleus Excited:**
- Proton

**Diagnostic Uses:**
- 2D, 3D, T1 / T2 Weighted Imaging
- MRI Angiography
- Image Processing
- Echo Planar Imaging
- Diffusion-Weighted Imaging

**Contraindications**
Use of the Oasis MRI System is contraindicated for patients who have electrically, magnetically, or mechanically activated implants (such as cardiac pacemakers), because the magnetic and electromagnetic fields produced by the Oasis MRI System may interfere with the operation of these devices.

Use of the Oasis MRI System also is contraindicated for patients who have intracranial aneurysm clips, unless the physician is certain that the clips are not magnetically active.

Use of the Oasis MRI System is also contraindicated for patients who have undergone permanent eyelining as a cosmetic surgical procedure (essentially eyelid tattooing), unless the physician is certain the product used in this procedure is not ferromagnetically active.

**Caution**
The Oasis MRI System is limited by United States Federal Law to investigational use for any indications not listed in the Food and Drug Administration’s (FDA) 510(k) Indications for Use statement.
**Caution**
Hitachi has provided recommended protocols that have been tested and proven to deliver good image quality. If the user deviates from these recommended protocols, Hitachi cannot guarantee image quality.

**Warning**
Do not allow persons with cardiac pacemakers or other implanted devices to enter the Controlled Access Area (within the 5-gauss field). The strong magnetic field could cause such devices to malfunction and pose a risk of serious injury or death to the person.

**General Safety Concerns**

Magnetic resonance imaging systems pose general safety concerns for anyone who is near the magnet. For the Oasis MRI System, these concerns are primarily due to the static magnetic field.

As stated previously, the discussions in this section apply to anyone who is near the system, including users; patients; and maintenance, emergency, or other personnel. All personnel who will work in or around the Oasis MRI System should be aware of these concerns.

**Static Magnetic Field**
The Oasis MRI System magnet produces a static magnetic field of 1.2 tesla, or 12,000 gauss. For comparison purposes, the earth’s magnetic field is 0.5 gauss and a refrigerator magnet’s is approximately 100 to 350 gauss.

Hitachi’s Oasis MRI System employs a magnet that exhibits a vertical magnetic field. Like all magnetic fields, the force spreads in all directions and is most concentrated at the magnet isocenter. Consequently, the attractive force of the magnet is also greatest in this area.

The attractive force of the magnet only affects ferromagnetic materials (such as steel), and is based on the mass of the object and the distance from the magnet isocenter. Larger objects are more forcefully attracted, and the attractive force increases exponentially as the distance to the magnet decreases. Numerous studies have been performed to determine the biological effects of exposure to magnetic fields on humans. To date, there is no conclusive evidence that static magnetic fields up to 4 tesla can cause lasting harmful biological effects. In 1996, the FDA established that static magnetic field levels below 4 tesla are considered a nonsignificant risk.
The FDA has established specific requirements related to establishing a Controlled Access Area surrounding MRI systems to ensure their safe use and the safety of those in the area. The FDA requires that the magnetic field outside of the controlled area not exceed 5 gauss. The necessity of a Controlled Access Area is due primarily to the potential risk from the attraction of objects containing iron or other magnetically active materials, or from torque on metallic materials. For more information, refer to the “Safety Precautions Within the Controlled Access Area” section in this chapter.

**Missile Effect**

Because the attractive force is so great, ferromagnetic objects can move toward the magnet with considerable force. If it is close enough, an object will become airborne and fly toward the magnet, an occurrence commonly referred to as the “missile effect.” Anyone or anything in the object’s direct path may be struck as the object moves toward the magnet.

**Warning**

Do not permit ferromagnetic objects, such as oxygen tanks, scissors, tools, or floor cleaning equipment, to come into close proximity to the magnet. Such objects are strongly attracted to the magnet and could become projectiles. Larger objects are more strongly attracted. Persons in the path of these objects could be seriously injured.

Caution should be taken before introducing an object into the scan room. Objects such as gurneys or tools should be tested with a hand-held magnet to determine whether they are ferromagnetic. If they are, they cannot be used inside the scan room.

All personnel working in the vicinity of the Oasis MRI System must be aware of the strong magnetic force and the possible dangers that they may face.

**Caution**

Do not allow small ferromagnetic materials inside the scan room (within the 5-gauss field). Magnetic objects (such as hairpins, safety pins, zippers, or bra fasteners/underwires) will affect the homogeneity of the magnetic field, and may adversely affect the resulting MR image quality.
Interference with Implants and Other Devices

The static magnetic field can affect ferromagnetic materials that are inside a person’s body. This effect is a particular concern for people with certain implanted medical devices (such as intracranial aneurysm clips, cardiac pacemakers, or infusion pumps), because the devices may be dislodged by magnetic fields exceeding a certain level. Follow all MRI Safety criteria for implants made from electronically conductive materials.

⚠️ Warning

Do not allow patients to be scanned unless they have been carefully screened for the following risks:

- Implanted pacemakers, surgical clips, aneurysm clips, prostheses, or other ferromagnetic materials
- Accidentally implanted ferromagnetic materials
- Embedded metal fragments from military activities

Failure to carefully screen the patient for risks could result in discomfort, skin irritation, or burns.

The magnetic field may disodge or move these materials, and embedded metal objects may heat up. The eye is one of the areas of the anatomy most vulnerable to this effect.

Electronic equipment not specifically made for use in an MRI environment may not work properly in the presence of the magnetic field. This equipment also could be attracted to the magnet.

⚠️ Caution

Do not allow sensitive instruments or magnetic media inside the scan room (within the 5-gauss field). The magnetic field can damage sensitive instruments such as watches or cameras, and can erase bank and credit cards, magnetic tapes, disks, and other magnetic recording media.

⚠️ Danger

Do not allow patients with implanted arterial brain clips to be scanned or to enter the controlled access area, EXCEPT when assured that the clip is made of a nonmagnetic material. If the clip is made of a magnetic material, the strong magnetic field may move or dislodge the clip, or the high-frequency RF field may cause a burn.
Safety Responsibilities

Imaging Facility Owner/Manager Responsibilities

The persons with overall responsibility for the Oasis MRI System and the surrounding environment are responsible for ensuring the following:

- All federal, state, county, and local regulations and requirements are met. In some countries, legislation may exist covering the exposure of employees to noise and static magnetic fields.
- A Controlled Access Area is defined and maintained. Any local statutory requirements that restrict access to the Controlled Access Area must be followed.
- Appropriate warning and safety labels are visibly posted and maintained.
- The Oasis MRI System is only operated by qualified personnel who have been adequately trained in the use of magnetic resonance diagnostic equipment and in the safe and effective use of the Oasis MRI System.
- A procedure is in place for patient screening.
- Adequate measures are taken to limit access to the MRI scan room and equipment during scanning and to prevent access to the MRI scan room and equipment by unauthorized personnel.
- All persons with incidental exposure to the Oasis MRI System (such as community emergency personnel, local fire and police departments, and housekeeping/maintenance personnel) are properly informed of special precautions and procedures associated with entering the magnet area in an MRI facility.
- Appropriate emergency procedures are established.
- The use of auxiliary equipment is controlled.
- Manufacturer-recommended maintenance schedules are followed.
Clinical User/Operator Responsibilities

The persons who operate the Oasis MRI System are responsible for ensuring the following:

- All safety recommendations outlined in this chapter and in all other chapters of the Oasis MRI System Reference Manual are followed.
- Any supplemental safety procedures instituted by the imaging facility owner/manager are followed.
- The system is never left unattended while a patient is being scanned.
- The Controlled Access Area rules are understood and maintained.
- Routine monitoring of the patient by verbal, visual, and auditory contact is maintained during the scan.
- Physiological monitoring of an anesthetized patient is maintained during the scan.
- The use of auxiliary equipment is controlled.
- The location and function of all emergency controls are known.
- Swift and responsible action in the event of an emergency situation will be taken.
- The magnet scan room door is securely closed during all patient or phantom imaging.
- Daily quality assurance checks are performed.
- Daily helium checks are performed.

Caution

Do not touch the contact pins on the coil connectors. These sensitive electronic parts could be damaged by static electricity if not handled properly.
Occupational Exposure

MRI workers, such as system operators, nurses, or other authorized personnel, that must enter the controlled access area are exposed to the static magnetic field and electromagnetic fields (EMF) emitted by the equipment. In order to ensure MRI workers’ safety, MRI workers must be trained so that they can perform all their tasks in a way that minimizes or avoids exposure to the fields generated by the equipment.

**Warning**
Screen all MRI workers for contraindicated implants, etc. before they can be qualified to operate the equipment. Failure to screen could result in serious injury.

Because the fields in question are strongest as you approach the magnet isocenter, if the MRI worker must be present in the exam room, they should stay beyond the laser locator position to minimize exposure.

The following are the risk factors associated with the possible EMF exposure levels for MRI workers and the ways to mitigate these risk factors:

1. The possible physiological effect of exposure to RF radiation is heating. Exposure to RF radiation can be minimized by keeping away from the transmit RF coil or by reducing the time of exposure during scanning.

2. The possible physiological effect of exposure to the gradient output is peripheral nerve stimulation which can be painful. Exposure to gradient output can be minimized by keeping sufficient distance away from the gradient coils during scanning.

3. The possible physiological effects of exposure to static magnetic field are dizziness, vertigo, and a metallic taste in the mouth. Exposure to the static magnetic field can be minimized by staying away from the magnet at all times and by avoiding rapid movements of the head while in the static magnetic field. MRI workers with implants cannot go beyond the 5 gauss line.

**Caution**
Hearing protection is required for patients undergoing an Oasis MRI system exam. Acoustic noise may annoy, cause discomfort, or affect the hearing of patients with certain auditory conditions.

It is generally accepted that there is no published evidence supporting the occurrence of cumulative and/or long-term effects after exposure to EMF emitted by the MRI equipment.
Extra precaution is advisable for pregnant MRI workers to minimize exposure to MRI fields although there is no currently available epidemiological evidence for any negative health effects of such exposure. As a precaution, MRI workers should not remain within the exam room during the actual operation of the scanner.

It may be required in some countries that the ‘member of the public’ limit be applied to the fetus, which implies that the pregnant MRI worker is not allowed to be present in the exam room during scanning. Careful attention should be paid to applicable local regulations.

In some countries legislation may exist covering occupational limits for exposure to EMF. Careful attention should be paid to applicable local regulations.
Safety Precautions Within the Controlled Access Area

⚠️ Warning

Do not allow entry into the Controlled Access Area until proper screening occurs. Do not allow maintenance or housekeeping staff in the area without screening and supervision. Failure to properly screen and supervise maintenance or housekeeping staff before allowing entry to the Controlled Access Area could result in serious injury.

The Controlled Access Area is the physical area immediately surrounding the Oasis MRI System magnet that is controlled for safety reasons. The Controlled Access Area represents the area bordered by the 5-gauss line. Outside the area, the static magnetic field measures less than 5 gauss. Regulations must be enforced within the MR imaging facility to restrict access to the Controlled Access Area for the following reasons:

- To control the potential risk to persons with medical implants who may inadvertently enter the area and be affected by the possible malfunction of their implants.
- To control the potential risk to persons within the Controlled Access Area from the attraction or torque exerted upon ferromagnetic objects inadvertently introduced into the Controlled Access Area.

Strong magnetic fields greater than 5 gauss present a risk to persons with cardiac pacemakers or other implanted electronic devices.

⚠️ Warning

Do not allow persons with cardiac pacemakers or other implanted devices to enter the Controlled Access Area (within the 5-gauss field). The strong magnetic field could cause such devices to malfunction and pose a risk of serious injury or death.

The inadvertent introduction of ferromagnetic materials such as tools, scissors, gurneys, or floor cleaning equipment into the Oasis magnetic field presents a risk to patients and other persons. The magnetic field is strong enough to forcibly attract ferromagnetic materials and may cause such objects to become projectiles, striking patients and/or other personnel in their path. A Controlled Access Area must be established to minimize such hazards.
Warning

Do not permit ferromagnetic objects, such as scissors, tools, or floor cleaning equipment, to come into close proximity to the magnet. Such objects are strongly attracted to the magnet and could become projectiles. Larger objects are more strongly attracted. Persons caught in the path of these objects could be seriously injured.

Personnel who need to enter the Controlled Access Area in the course of their normal duties must possess the following qualifications:

• Be fully instructed in the safety aspects of the MRI equipment, including the following:
  • Electrical equipment
  • Time-varying magnetic field gradient equipment
  • Static magnetic fields
• Be fully instructed in emergency procedures for persons within the Controlled Access Area.
• Be fully instructed on the screening of all patients, visitors, and other ancillary personnel prior to granting them permission to enter the Controlled Access Area.
• Be fully conversant with local regulations, if any, concerning the MRI equipment and its location.
• Be fully instructed regarding the potential hazards of static magnetic fields and the significance of the Controlled Access Area, including the following:
  • The effect of magnetic fields upon implanted objects in the patient, including cardiac pacemakers, ferromagnetic implants, and aneurysm clips.
  • The effect of magnetic fields upon personal effects (such as watches or credit cards).
• The strong forces that can be exerted upon ferromagnetic objects (such as keys, scissors, tools, gurneys, fire extinguishers, or floor sweepers) when they are introduced into the magnetic field, causing them to become projectiles or missiles and inflicting serious injury or damage.
Outside the Controlled Access Area, the magnetic field is less than 5 gauss. Typical 5-gauss isocontours are shown on the following pages. Actual isocontours may vary from these typical isocontours as a result of specific site and environmental factors.

When installed according to Hitachi site planning guidelines, the Hitachi Oasis magnet scan room complies with the FDA guidelines for the physical indication of the Controlled Access Area, as defined by the outside walls, ceiling, floor, and door(s) of the scan room. This area is indicated by appropriate signs and warnings.

Auxiliary equipment (such as patient physiological monitoring and sensing devices, life support devices, or emergency care equipment) that is not specified or recommended for use in the Controlled Access Area may be adversely affected by the RF field and the high magnetic field. In addition, this auxiliary equipment may adversely affect the image quality and functioning of the Oasis MRI System.

Any tools and equipment used in close proximity to the Oasis MRI System magnet should be nonferromagnetic.

**Definition:**
RF refers to radio frequency.
Magnetic Field Isocontours

Description

Outside the Controlled Access Area, the magnetic field is less than 5 gauss. Typical magnetic field isocontours are provided in the following figures. Actual isocontours may vary from these typical isocontours as a result of specific site and environmental factors.

Figures 1-1 and 1-2 illustrate the magnetic field contours at which the Oasis MRI System magnet may affect a variety of objects and at which the Oasis MRI System may be affected by objects around the MRI magnet.

![Magnetic field contour diagram]

Figure 1-1. Magnetic field contour, overhead view.
Figure 1-2. Magnetic field contour, side view.
Magnet Proximity Limit Table

The table below illustrates general guidelines for minimum safe distances from objects that may either be affected by the MRI magnetic field or may affect the magnet field and have an impact on image quality.

Devices affected by the Oasis MRI System should be located outside of the following limits:

<table>
<thead>
<tr>
<th>Limits</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 gauss (2 mT)</td>
<td>• Motors</td>
</tr>
<tr>
<td></td>
<td>• Cameras</td>
</tr>
<tr>
<td>15 gauss (1.5 mT)</td>
<td>• Black/White Monitor</td>
</tr>
<tr>
<td>10 gauss (1.0 mT)</td>
<td>• Watches</td>
</tr>
<tr>
<td></td>
<td>• Credit Cards</td>
</tr>
<tr>
<td></td>
<td>• Magnetic Tapes</td>
</tr>
<tr>
<td></td>
<td>• Computer Magnetic Disk Drives</td>
</tr>
<tr>
<td>5 gauss (0.5 mT)</td>
<td>• Pacemakers (per FDA regulations)</td>
</tr>
<tr>
<td></td>
<td>• CT Scanner</td>
</tr>
<tr>
<td>3 gauss (0.3 mT)</td>
<td>• Ultrasound</td>
</tr>
<tr>
<td></td>
<td>• Color Monitor</td>
</tr>
<tr>
<td></td>
<td>• Imager Intensifier</td>
</tr>
<tr>
<td></td>
<td>• Microscope</td>
</tr>
<tr>
<td></td>
<td>• Linac</td>
</tr>
<tr>
<td></td>
<td>• Scintillation Camera</td>
</tr>
<tr>
<td></td>
<td>• CT Scanner with Image Intensifier</td>
</tr>
<tr>
<td>0.5 gauss (0.05 mT)</td>
<td>• Emission CT</td>
</tr>
</tbody>
</table>

Devices affecting the Oasis MRI System should be located outside of the following limits:

<table>
<thead>
<tr>
<th>Limits</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 ft</td>
<td>• Fixed Steel Structure</td>
</tr>
<tr>
<td>20 ft</td>
<td>• HVAC Air Handler or Condenser</td>
</tr>
<tr>
<td>35 ft</td>
<td>• Automobiles</td>
</tr>
<tr>
<td>40 ft</td>
<td>• Trucks</td>
</tr>
<tr>
<td></td>
<td>• Elevators</td>
</tr>
<tr>
<td></td>
<td>• Large Power Transformers</td>
</tr>
</tbody>
</table>
Spatial Gradient of the Main Magnetic Field

Refer to the section titled System Specifications in Chapter 3, System Overview, for complete spatial gradient details.

Patient Screening, Handling, and Supervision

Patient Screening

Your imaging facility must establish a procedure for screening patients prior to imaging. Technologists or other appropriately qualified personnel should perform this screening.

The screening procedure identifies those patients who could be placed at risk because of one or more of the following factors:

• Professional activity
• Past medical history
• Present medical state
• Physical environment of the MRI equipment

⚠️ Warning

Do not allow patients to be scanned unless carefully screened for the following risks:

• Implanted pacemakers, surgical clips, aneurysm clips, prostheses, or other ferromagnetic materials.
• Accidental implantation of ferromagnetic materials through occupation, especially in or near the eyes.
• Imbedded metal fragments from military activities.

Failure to carefully screen the patient for risks could result in discomfort, skin irritation, or burns.

⚠️ Warning

Do not scan infants, neonates, or pregnant patients. Failure to comply could result in excessive warming, discomfort, or other adverse effects.

⚠️ Warning

The practice of requiring all patients to change into an MRI-approved examination gown prior to scanning is recommended. This helps ensure that metallic yarns (Lurex) woven into patient clothing is kept out of the magnet. Failure to comply could result in RF heating and potential skin burns.
**Warning**

Do not allow patients to be scanned unless they are carefully screened for:

- Impaired ability to perspire.
- Decompensated cardiac and febrile conditions.
- Compromised thermoregulatory systems (such as neonates, low-birth weight infants, or certain cancer patients).
- Loss of feeling in any body part (e.g., paralysis of arms or legs).

Failure to carefully monitor the patient for risks could result in excessive warming or discomfort.

---

**Caution**

Take care when imaging patients with permanent (tattoo) eyeliner or facial makeup. Skin irritation can occur in some instances.

A small percentage of patients with tattooed eyeliner have experienced transient skin irritation in association with MRI. The patient must decide if this slight risk warrants undergoing the examination and may want to discuss this matter with his or her referring physician.

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**Caution**

Take care when imaging patients with tattoos other than permanent eyeliner or facial makeup. Some tattoo inks may contain metallic salts or powders that could cause skin irritation in some instances.

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**Caution**

Caution must be exercised when imaging patients who are likely to develop seizures or sustain claustrophobic reactions. Failure to properly prepare these patients could result in injury.

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**Caution**

Follow all MRI safety criteria for implants made from electrically conductive materials. Failure to comply could result in patient injury.

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**Caution**

Carefully screen patients for pre-existing auditory conditions. Gradient acoustic noise may negatively affect these patients, causing pain or discomfort. Ensure that properly fitting hearing protection is used in all cases.
**Caution**

Remove all metallic materials from the patient before entering the MRI scanner room, including but not limited to cosmetics, tinted contact lenses, manicure paraphernalia, and fashion products. Some eye makeup may contain metallic particles that may cause eye and skin irritation.

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**Caution**

Do not perform an MRI examination on a patient with an adhesive skin patch that contains conductive metal or metallic powder since RF heating can occur and potentially cause skin burns.

The screening procedure must be sufficiently detailed to identify patients at risk and also provide recommendations to adequately safeguard them from injury. The procedure must screen for patients for whom MRI examinations are contraindicated, and for patients who have a higher-than-normal likelihood of requiring emergency medical treatment independent of the physical environment of the MRI equipment.

Your procedures must include a process for informing the referring physician of any contraindications discovered during the screening process.

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**Sample Screening Form**

The MRI screening form shown on the following pages has been downloaded from www.MRISafety.com and is provided as a template for your facility to use in developing your own patient screening procedure. This sample screening form is intended solely for reference because the practice of medicine and MR imaging continuously evolves. You are encouraged to visit the website for the most current screening sheets available.

Consult with your own medical and legal advisors concerning the development of your facility’s patient screening procedure. Neither Hitachi Medical Corporation, Hitachi Medical Systems America, Inc., nor any of their respective representatives may give medical or legal advice.

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**Caution**

Check all patient information on the screening form prior to the MRI examination. Failure to comply could result in patient injury.
MAGNETIC RESONANCE (MR) PROCEDURE SCREENING FORM FOR PATIENTS

<table>
<thead>
<tr>
<th>Date __ / __ / __</th>
<th>Patient Number ____________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name ____________________________</td>
<td>Age __________</td>
</tr>
<tr>
<td>Last name</td>
<td>First name</td>
</tr>
<tr>
<td>Date of Birth __ / __ / __</td>
<td>Male □ Female □</td>
</tr>
<tr>
<td>Address ____________________________</td>
<td>Telephone (home) (____) - - - - - - - - - - -</td>
</tr>
<tr>
<td>City ____________________________</td>
<td>Telephone (work) (____) - - - - - - - - - - -</td>
</tr>
<tr>
<td>State</td>
<td>Zip Code ____________________________</td>
</tr>
</tbody>
</table>

Reason for MRI and/or Symptoms ____________________________________________

Referring Physician ____________________________ | Telephone (____) - - - - - - - - - - - |

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? □ No □ Yes
   If yes, please indicate the date and type of surgery:
   Date __ / __ / __ | Type of surgery __________ |
   Date __ / __ / __ | Type of surgery __________ |

2. Have you had a prior diagnostic imaging study or examination (MRI, CT, Ultrasound, X-ray, etc.)? □ No □ Yes
   If yes, please list:
   MRI __ / __ / __ | Body part __________ | Date __ / __ / __ | Facility __________ |
   CT/CAT Scan __ / __ / __ | __________ | __________ |
   X-Ray __ / __ / __ | __________ | __________ |
   Ultrasound __ / __ / __ | __________ | __________ |
   Nuclear Medicine __ / __ / __ | __________ | __________ |
   Other __________ | __________ | __________ |

3. Have you experienced any problem related to a previous MRI examination or MR procedure? □ No □ Yes
   If yes, please describe: ____________________________

4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)? □ No □ Yes
   If yes, please describe: ____________________________

5. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? □ No □ Yes
   If yes, please describe: ____________________________

6. Are you currently taking or have you recently taken any medication or drug? □ No □ Yes
   If yes, please list: ____________________________________________

7. Are you allergic to any medication? □ No □ Yes
   If yes, please list: ____________________________________________

8. Do you have a history of asthma, allergic reaction, respiratory disease, or reaction to a contrast medium or dye used for an MRI, CT, or X-ray examination? □ No □ Yes

9. Do you have anemia or any disease(s) that affects your blood, a history of renal (kidney) disease, renal (kidney) failure, renal (kidney) transplant, high blood pressure (hypertension), liver (hepatic) disease or seizures? □ No □ Yes
   If yes, please describe: ____________________________________________

For female patients:

10. Date of last menstrual period:____ / ____ / ____ | Post menopausal? □ No □ Yes |

11. Are you pregnant or experiencing a late menstrual period? □ No □ Yes

12. Are you taking oral contraceptives or receiving hormonal treatment? □ No □ Yes

13. Are you taking any type of fertility medication or having fertility treatments? □ No □ Yes
   If yes, please describe: ____________________________________________

14. Are you currently breastfeeding? □ No □ Yes
WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the MRI Technologist or Radiologist BEFORE entering the MR system room. The MR system magnet is ALWAYS on.

Please indicate if you have any of the following:

☐ Yes ☐ No  
Aneurysm clip(s)

☐ Yes ☐ No  
Cardiac pacemaker

☐ Yes ☐ No  
Implanted cardioverter defibrillator (ICD)

☐ Yes ☐ No  
Electronic implant or device

☐ Yes ☐ No  
Magnetically-activated implant or device

☐ Yes ☐ No  
Neurostimulation system

☐ Yes ☐ No  
Spinal cord stimulator

☐ Yes ☐ No  
Internal electrodes or wires

☐ Yes ☐ No  
Bone growth/bone fusion stimulator

☐ Yes ☐ No  
Cochlear, otologic, or other ear implant

☐ Yes ☐ No  
Insulin or other infusion pump

☐ Yes ☐ No  
Implanted drug infusion device

☐ Yes ☐ No  
Any type of prosthesis (eye, penile, etc.)

☐ Yes ☐ No  
Heart valve prosthesis

☐ Yes ☐ No  
Eyelid spring or wire

☐ Yes ☐ No  
Artificial or prosthetic limb

☐ Yes ☐ No  
Metallic stent, filter, or coil

☐ Yes ☐ No  
Shunt (spinal or intraventricular)

☐ Yes ☐ No  
Vascular access port and/or catheter

☐ Yes ☐ No  
Radiation seeds or implants

☐ Yes ☐ No  
Swan-Ganz or thermodilution catheter

☐ Yes ☐ No  
Medication patch (Nicotine, Nitroglycerine)

☐ Yes ☐ No  
Any metallic fragment or foreign body

☐ Yes ☐ No  
Wire mesh implant

☐ Yes ☐ No  
Tissue expander (e.g., breast)

☐ Yes ☐ No  
Surgical staples, clips, or metallic sutures

☐ Yes ☐ No  
Joint replacement (hip, knee, etc.)

☐ Yes ☐ No  
Bone/joint pin, screw, nail, wire, plate, etc.

☐ Yes ☐ No  
IUD, diaphragm, or pessary

☐ Yes ☐ No  
Dentures or partial plates

☐ Yes ☐ No  
Tattoo or permanent makeup

☐ Yes ☐ No  
Body piercing jewelry

☐ Yes ☐ No  
Hearing aid

(Remove before entering MR system room)

☐ Yes ☐ No  
Other implant

☐ Yes ☐ No  
Breathing problem or motion disorder

☐ Yes ☐ No  
Claustrophobia

IMPORTANT INSTRUCTIONS

Before entering the MR environment or MR system room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room.

NOTE: You may be advised or required to wear earplugs or other hearing protection during the MR procedure to prevent possible problems or hazards related to acoustic noise.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

Signature of Person Completing Form: ________________________________  Signature ________________________________  Date ____________/________/________

Form Completed By: ☐ Patient  ☐ Relative  ☐ Nurse ________________________________  Print name ________________________________  Relationship to patient ________________________________

Form Information Reviewed By: ________________________________  Print name ________________________________  Signature ________________________________

☐ MRI Technologist  ☐ Nurse  ☐ Radiologist  ☐ Other ________________________________  Print name ________________________________  Signature ________________________________

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Patient Handling
A suitably trained person should describe to the patient and any companions the patient screening procedure and the MRI examination, including the possible length of the examination and the sights, sounds, and experiences to be anticipated.

⚠️ Caution
Caution must be exercised when moving the patient table. Check continuously for patient safety and avoid pinch hazards. If a patient has long hair, secure it away from moving parts. Failure to comply may result in injury. Also take care not to step on the patient table body cover when moving the patient table.

Patient Supervision
At all times during the scanning, the patient should be able to make contact with the operator and to notify him or her of any discomforts or concerns. Maintain visual and auditory contact with the patient. If you are working with an anesthetized patient, maintain physiological monitoring during the scan. For patients with special medical conditions or needs, supervision by qualified medical professionals should be provided.

⚠️ Caution
To prevent the patient from falling or movement during an exam, always use the immobilizing belts. Failure to comply could result in patient injury.

Emergency Evacuation
The patient table can be moved manually (figure 1-3) for an emergency evacuation in case of a power failure, or in case the MRI on/off button on the control unit is pressed and turns the MRI system off.

The emergency evacuation bar is found at the foot end of the patient table. Press and hold the bar to manually remove the table from inside the gantry. You must press the RELEASE button (found on the gantry) to end this emergency evacuation state, which also ends the manual moving of the patient table.

In an emergency, press the table release bar in the direction of the arrow to move the patient table out of the gantry.

Table release bar

Figure 1-3. Patient table manual operation.
Caution
To prevent unnecessary wear to the emergency evacuation components of the patient table, use the emergency evacuation mode only during true emergencies.

Lasers for Patient Alignment

The Oasis MRI System uses four Class II visible-red lasers for patient alignment. Two laser lamps are located in the top front of the gantry, and a laser lamp is located in each of the two support columns.

Lasers are rated based on risks of pinpoint exposure. Class II lasers pose a risk of eye damage only when the laser is aimed directly at the eye. Even with pinpoint exposure, the normal blink reflex to high light levels should protect the eye from this class of laser. The Oasis MRI System lasers are diffused into a series of lines and therefore are less of a vision hazard.

The laser sources are identified with the following label, which is repeated on the left and right edges of the gantry.

Caution
Avoid staring into the laser beams; eye injury could result. Instruct patients to close their eyes when the lasers are turned on.

Caution
Use the lasers for patient alignment only. Any other use could result in eye injury.

Turning Off the Patient Alignment Lasers

Press LASER to turn off the lasers. The lasers also can be turned off by pressing and holding SET to advance the patient into the magnet. The lasers will turn off once the region to be imaged reaches the magnet isocenter. The lasers automatically turn off after 60 seconds if no action is taken by the operator.
Patient Safety

In addition to the topics covered in the “General Safety Concerns” section of this chapter, additional safety precautions must be taken for MRI patients.

**Gradient Magnetic Fields, RF Energy, and Acoustic Noise**

The international voluntary safety standard IEC-60601-2-33, Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis, establishes requirements for the safety of MRI equipment in order to provide protection for the patient, the operator, ancillary personnel, and the general public. This standard defines operating modes for the MRI equipment that are based upon certain action levels of time-varying magnetic fields (dB/dt), radio frequency magnetic fields, specific absorption rate (SAR), and acoustic noise.

**Operating Modes**

The IEC 60601-2-33 standard specifies three operating modes: Normal, First Level Controlled, and Second Level Controlled. These operating parameters define the permissible limit values for dB/dt, SAR, and acoustic noise. The action levels for these limits are based on current scientific literature related to patient safety. The Oasis MRI System recognizes dB/dt and SAR levels corresponding to these three IEC operating modes.

In the Normal Operating Mode, all operating parameters of the MRI system are below the level that may cause physiological stress to patients, as shown in figure 1-4. Only routine monitoring (visual and auditory contact and communication with the patient, as appropriate) is required, and no specific indications or measures need to be displayed.

![Figure 1-4. Normal level controlled operation mode indicator.](image-url)
If operating in the First Level Controlled Mode, physiological stress may occur. In addition to monitoring, medical supervision is required to assess the risk versus benefit of the particular scan.

The warning window, shown in figure 1-5, provides the following options:

**YES** — Confirms the user would like to proceed with the scan.

**NO** — Cancels the scan start. The user must adjust the scan parameters to reduce the SAR or dB/dt and restart the scan task.

Operating in the Second Level Controlled Mode may produce significant risk to patients; it is not permitted for normal clinical use. This mode is used for approved human studies only. Security measures (software password) prevent unauthorized operation in this mode.

---

**Figure 1-5. First level controlled operation mode indicator.**

---
Time-Varying Magnetic Fields (dB/dt)

Time-varying gradient magnetic fields may stimulate nerves and muscles by inducing electric currents. These fields are described by a measurement called dB/dt.

Caution

The time-varying gradient magnetic fields (dB/dt) for the Oasis MRI System can exceed the limit for the Normal Operating Mode. When values are higher than this limit, the patient may experience peripheral nerve stimulation.

If the dB/dt value exceeds the Normal Operating Mode, peripheral nerve stimulation (PNS) can occur, causing a tingling or spasmodic sensation of the epidermis. The location and characteristics of PNS differ from patient to patient. The practical thresholds for the first and second operating levels are:

1. Tolerable PNS (first level threshold)
2. Painful PNS (second level threshold)

If the scan sequence that is selected can cause the level to exceed the Normal Operating Mode limit, a warning will appear on the operating window. In order to proceed with the scan, this warning must be acknowledged. The patient must be closely monitored for any potential discomfort caused by the rapidly changing gradients.

Follow the procedure below to prevent patient discomfort from PNS:

• Explain to patients that PNS can occur.
• Instruct patients not to grasp their hands together, as this can cause a conductive loop and increase the possibility of stimulus to occur.
• If stimulus is observed or reported, terminate the scan.
Radio Frequency Magnetic Fields SAR Limits

Some of the radio frequency power produced by the Oasis MRI System during a scan is deposited within the body tissues. The amount absorbed is described by a measurement called specific absorption rate (SAR).

The Oasis MRI System recognizes SAR levels corresponding to the three IEC 60601-2-33 (2002) operating modes listed in the table below.

The SAR limit values below are based on environmental conditions of a magnet scan room temperature below 24°C and a relative humidity below 60%.

The SAR limit values are reduced for elevated temperature and humidity, as these environmental conditions impact the body’s thermoregulatory system and could change the operating mode for a given value of SAR. The reduction of SAR limits for environmental temperature starts at the derating temperature, which is 25°C, with a relative humidity of less than 60%. For each 10% increase in relative humidity above 60%, the derating temperature is reduced by 0.25°C (for example, at 100% relative humidity, the derating temperature would be 24°C). For each degree of environmental temperature that exceeds the SAR-derating temperature, the Whole Body SAR limit will be reduced by 0.25 W/kg, until the SAR is 2 W/kg for First Level Controlled Mode or 0 for Normal Operating Mode.

<table>
<thead>
<tr>
<th>Averaging Time</th>
<th>6 Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole body SAR</td>
</tr>
<tr>
<td>Body Region</td>
<td></td>
</tr>
<tr>
<td>Whole body</td>
<td>(W/kg)</td>
</tr>
<tr>
<td>Exposed body</td>
<td>(W/kg)</td>
</tr>
<tr>
<td>part</td>
<td>(W/kg)</td>
</tr>
<tr>
<td>Head</td>
<td>(W/kg)</td>
</tr>
<tr>
<td>Trunk</td>
<td>(W/kg)</td>
</tr>
<tr>
<td>Extremities</td>
<td>(W/kg)</td>
</tr>
<tr>
<td>Operating Mode</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>2</td>
</tr>
<tr>
<td>First Level</td>
<td>4</td>
</tr>
<tr>
<td>Controlled</td>
<td>&gt;4</td>
</tr>
<tr>
<td>Second Level</td>
<td></td>
</tr>
<tr>
<td>Controlled</td>
<td></td>
</tr>
<tr>
<td>Short term</td>
<td></td>
</tr>
<tr>
<td>SAR</td>
<td></td>
</tr>
</tbody>
</table>

^ The limit scales dynamically with the ratio “exposed patient mass / patient mass”

**Normal Operating Mode:**
Partial body SAR = 10 W/kg - (8 W/kg x exposed patient mass / patient mass)

**First Level Controlled Operating Mode:**
Partial body SAR = 10 W/kg - (6 W/kg x exposed patient mass / patient mass)

^ In cases where the orbit is in the field of a small local RF transmit coil, care should be taken to ensure that the temperature rise is limited to 1 degree C.
Caution
SAR values for the Oasis MRI System can exceed the limit for the Normal Operating Mode. If SAR values are higher than this limit, the patient may experience tissue heating.

Caution
High scan room temperature or humidity may compromise patient safety. Carefully monitor the patient during the scan if the scan room temperature exceeds 24°C or if the humidity is above 60%, noncondensing. These conditions can limit the patient’s ability to dissipate heat and could result in an injury.

Local RF Heating
The Cautions below apply to local RF heating.

Caution
The following risk factors may increase the potential for local excessive RF heating resulting from the RF magnetic fields in the MRI equipment. In the event that any of the following situations occur, stop the Oasis MRI system immediately, and remove the patient from the system.
- The presence of conductive (metallic) objects or implants.
- Clothing containing metallic thread or any metallic objects such as a watch or coins.
- The use of medicinal products in transdermal patches which may cause burns to the underlying skin area.
- The presence of damp clothing.
- Placement of the body or extremities against the RF transmit coil surface (magnet bore). Use pads, sheets, or blankets as shown in figure 1-6 to prevent the patient’s body or extremities from contacting the magnet bore (0.25” min).

Figure 1-6. Using pads, sheets, or blankets to prevent magnet bore contact.
Note:
Any reference to “cable” applies to all types of cables that come in contact with the patient.

- Contact between the patient and the RF receiver coil cable. Use towels or pads as shown in figure 1-7 to prevent direct contact between the patient and the RF receiver coil cable.

![Figure 1-7. Using towels or pads to prevent direct coil cable contact.](image)

- Routing of the RF coil cable in close proximity to the RF transmit coil.
- Formation of loops with the RF receiver coil cable and photonic MRI microcoil (PMM) leads.
- The use of incompatible PMM electrodes and leads.
- The presence of unconnected receiver coils that remain in the RF transmit coil during scan acquisition.
- The patient forming a closed loop with his or her body, such as with inner thigh-to-inner thigh, calf-to-calf, hand-to-hand, hand-to-body, or ankle-to-ankle contact. Use pads as shown in figure 1-8 to prevent body parts from forming closed RF loops.

![Figure 1-8. Using pads to prevent body parts from forming closed RF loops.](image)

**Caution**

Caution must be exercised when scanning patients who may not be able to alert the operator in case of excessive heating and associated discomfort or pain. Check the patient’s condition frequently. Failure to comply may result in injury.
MRI Patient Warming Prevention Plan

The following four pages can be extracted and used at your site as a guide for preventing patient warming during the MRI process. Alternatively, a copy of this prevention plan in pdf format can be downloaded from: http://www.hitachimed.com/CustomerSite/supportingdocs/MR_Patient_Warming_Prevention_Plan.pdf

Phase 1: Screen Patient and Companion

Patient and companion screening is the most effective way to avoid potential safety hazards to persons entering the scan room. Careful questioning and education can produce a controlled MRI environment. This is achieved by utilizing a comprehensive screening process which includes:

- Using a printed form to document the screening procedure
- Reviewing the information on the screening form
- Conducting a verbal interview to verify the information on the form

⚠️ Warning

Never allow a patient or companion to have a ferrous or electronic device, implant or prosthesis that is a contraindication for MRI to enter the scan room.

⚠️ Warning

All metallic objects that could produce heat and cause burns must be removed from the patient or companion prior to scanning.

⚠️ Warning

All patients should remove shoes and change to a dressing gown prior to scanning.

⚠️ Warning

All patients should wash off removable cosmetics prior to scanning.

⚠️ Warning

Patients with permanent eyeliner or tattoos should be informed of possible skin irritation. Patients that experience this event should be instructed to seek prompt medical attention.
Phase 2: Limit RF Exposure

Radio Frequency (RF) can heat a patient’s tissue if delivered faster than the patient’s tissue can dissipate the generated heat. The heating depends on the patient’s weight, type of pulse sequence, timing factors, number of slices, and the operation of imaging options such as saturation.

Therefore, the absorption of RF energy or Specific Absorption Rate (SAR) should be monitored to minimize the possibility of occurrence. The patient’s weight and the selected pulse sequence parameters are important factors when monitoring SAR (figure 1-9).

⚠️ Warning
Always enter the patient’s correct weight to set the SAR values and operating limits and prevent excessive RF exposure.

⚠️ Warning
Carefully monitor patients with reduced thermoregulatory capacity at all times. Patients with reduced thermoregulatory capacity include those with cardiac impairment and reduced circulatory function, hypertension, diabetes, old age, obesity, fever, or an impaired ability to perspire.

Important
Maintain a temperature within the scan room of 70 degrees Fahrenheit or below and 60 percent relative humidity.

Phase 3: Eliminate Contact Points

Inadequate padding has been reported as the cause in 73 percent of all reported thermal injury events. Therefore, use the Hitachi approved pads to prevent the patient’s skin from coming into direct contact with the magnet bore and surface coil, and to prevent the patient’s body from creating loops, e.g., between patient’s thighs, knees, and hands. A minimum thickness of 0.25 inches of nonconductive padding is recommended.

Figure 1-10 illustrates how to place pads between the patient and the magnet bore.
Figure 1-10. Using pads to prevent patient-to-bore contact.

Figure 1-11 illustrates how to place pads to prevent skin-to-skin contact and RF cable-to-skin contact.

Figure 1-11. Using pads to prevent skin-to-skin and RF cable-to-skin contact.

Figure 1-12 illustrates how to place a pad under the patient’s arm to eliminate direct contact with the transmitter cover.

Figure 1-12. Using pads to prevent direct contact with transmitter cover.

Figure 1-13 illustrates how to use towels or blankets to eliminate direct contact with the magnet (0.25” min.). The thicker the cover, the better the insulation.

Figure 1-13. Using blankets to prevent direct contact with the magnet bore.
Warning
Failure to follow these preventative actions could result in an RF burn.

Warning
Never allow the patient to directly contact the magnet bore or any surface coil.

Warning
Always instruct the patient to use the patient alert switch if they are getting too warm. However, RF injury can happen quickly so do not rely totally on this method to warn of excessive warming or discomfort.

Phase 4: Safeguard Ancillary Device
Never use ancillary devices that are damaged and/or not functioning properly. All monitoring equipment must be MRI safe and approved for use with Hitachi MRI systems.

Route cables down the center of the magnet bore to prevent loops or crossing. Cables placed at the side of the magnet bore are at risk for heating due to induced currents. Use padding to prevent direct contact between the cables and the patient.

Warning
Do not use ECG patches that are beyond their expiration date or appear to be damaged.

Warning
Do not allow gating cables to contact a surface coil or surface coil cable.

Warning
Verify that only the peripheral gating sensor touches the patient and that the cables do not come in direct contact with the patient.
Acoustic Noise

The gradients used to decode the spatial position of the MRI signal create acoustic noise while operating. Hearing protection is required for the safety of the patient if the maximum A-weighted rms sound pressure level can exceed 99 decibels audible (dBA) (Normal Operating Mode limit). This hearing protection must be sufficient to reduce the A-weighted rms sound pressure level to below 99 dBA.

The Oasis MRI System maximum A-weighted rms sound pressure level will exceed 99 dBA without hearing protection. Contact Hitachi if you require further acoustic level specifications.

Caution

Hearing protection is required for patients undergoing an Oasis MRI System exam. Acoustic noise may annoy, cause discomfort, or affect the hearing of patients with certain auditory conditions.

Warning

If hearing protection is not worn during the MRI examination, the patient can suffer from temporary or permanent auditory disorder.

The MRI system operator should be trained in, and give special attention to, the proper positioning of hearing protection (figure 1-13a).

Figure 1-13a. Earplug fitting is easier if the ear canal is straightened and enlarged by pulling the ear outward and upward during insertion.

Anesthetized patients may have less than normal protection against high sound pressure, so ear protection for these patients should be used, even at moderate sound levels.
Use of Auxiliary Equipment

General Information
Auxiliary equipment may include any of the following:

- Physiological (ECG, Respiratory, Peripheral Pulse) gating units
- Patient monitoring equipment
- RF coils
- Life support devices
- Other emergency care equipment

Some of this equipment may not be specifically designed for safe and effective use within the MRI environment and therefore should not be brought into the Controlled Access Area.

Warning
Do not use any equipment or accessories with the Oasis MRI system other than those approved by Hitachi. Using the Oasis MRI system together with any unapproved equipment or devices can potentially cause fatal or severe injury to the patient.

The use of auxiliary equipment, such as physiological monitoring, gating equipment or radio frequency coils, that has not been specifically tested and approved for use in the Oasis MRI environment, may result in injuries to the patient. The responsibility for qualifying accessory equipment to be used for the patient as MRI safe belongs to the user facility.

Caution
Auxiliary equipment (such as physiological monitoring equipment) that is not MRI-compatible should not be used with the MRI system. This auxiliary equipment may adversely affect the operation of the Oasis MRI System, may be adversely affected by the Oasis MRI system, and may result in erroneous readings.

Auxiliary equipment labeled as compatible for use with magnetic resonance imagers may still be capable of causing burns and other injuries to the patient if instructions from the manufacturer of the device (especially with respect to electrically conducting lead positioning) are not followed.

Caution
Do not place auxiliary equipment near the receiver coils. This auxiliary equipment may adversely affect the operation of the Oasis MRI system, may be adversely affected by the Oasis MRI system, and may result in erroneous readings.
Cautions

The following cautions should be observed when using auxiliary equipment, physiological (ECG, Respiratory, Peripheral Pulse) gating units, patient call devices, or RF coils, as provided by Hitachi and intended for use with the Oasis MRI System. Hitachi has not evaluated other third-party-provided auxiliary devices for safe or effective use with the Oasis MRI System. The use of such auxiliary devices is at the discretion and responsibility of the imaging facility owner/manager.

- Read and follow all procedures outlined in the Oasis MRI System Reference Manual.
- Connect cable(s) only to the appropriate connector(s).
- Do not use any cables with abraded insulation or with exposed metal surfaces that can come in contact with the patient. Have all damaged cables repaired or replaced promptly.
- Remove RF coils, cables, lead wires, physiological gating devices, or any ancillary equipment from the magnet when they are not in use.
- Minimize the length of the RF coil cable within the magnet bore. Do not allow the coil cable, patient call device, ECG, respiratory, or peripheral-pulse cables to form loops.
- Minimize the length of the ECG leadwires and ECG cable within the magnet bore. Do not allow the leadwires and cable to form loops.
- Prevent the RF coil cable from coming in contact with the patient’s skin. Use padding or other materials to separate the cable from the patient.
- Prevent the ECG leadwires and ECG cable from coming in contact with the patient’s skin. Use padding or other materials to separate the ECG leadwires and the ECG cable from the patient.
- Minimize the area of the loop formed by the ECG leadwires. The amount of RF current induced into the leadwires is directly proportional to the loop area. Larger induced currents can cause burns if the electrodes or leadwires come in contact with the patient’s skin.
- Prevent the RF coil cable, the ECG leadwires, and the ECG cable from touching the sides of the magnet bore.
- Use only the graphite-fiber ECG leadwires and radio-transparent ECG electrodes that have been provided.
- Radio-transparent ECG electrodes are disposable and are intended for single application only. Because the graphite-fiber ECG leadwires have a limited lifetime, verify the reliable operation of the leadwires for each patient requiring ECG-gated scanning.
RF coils and physiological gating units contain sensitive electronics. Do not drop the devices, apply mechanical shocks or undue tension, or allow crimping, pinching, or bending of the cables and leadwires. Do not apply undue force to the connectors.

Observe the ECG waveform before starting a scan and make sure the ECG is functioning properly.

Position all cables to prevent “crosspoints.” A crosspoint is the point where a cable crosses another cable, where a cable loops across itself, or where a cable touches either the patient or sides of the magnet bore more than once.

Position all cables and wires so that they exit as close as possible to the center of the MRI table.

Do not position conductive leads, cables, or wires across the area of an external metallic prosthesis or other similar device that is in contact with the patient.

Any auxiliary devices or equipment that do not appear to be operating properly should be immediately removed from patient contact.

If the patient reports feeling warm or hot in association with the use of coils or monitoring equipment, discontinue the MRI procedure immediately and thoroughly assess the equipment to determine proper functioning.

With the electrodes, lead cords and relay cords connected, do not perform a scan in any mode other than the ECG gated mode.

If a scan time exceeds 15 minutes, or scans are performed successively in the ECG gated mode, check with the patient to make sure the temperature of the electrodes are not uncomfortably high.

Use the electrodes, lead cords, relay cords, and transmitters only in the shielded room.

Search the patient for any previously-used electrodes and cables that may have been inadvertently left behind, either in clothing, in the sheets, or on the patient. Remove any electrodes or cables that are not being actively used for monitoring.

After the MRI exam is complete, patients (especially those who cannot verbalize) should be checked for possible burns or reddening of the skin under the electrodes.

**Caution**

Do not scan if the coil or coils are not plugged into the table connector completely, as this may damage the coil electronics or cause patient injury.

**Caution**

If a patient receives a burn, make sure the patient gets the appropriate treatment. Also quarantine any equipment involved. Failure to comply could result in further injury.
Safety Information for Police, Fire, Emergency Service, and Cleaning/Maintenance Personnel

This section is formatted to facilitate easy photocopying.

Magnetic Resonance Imaging (MRI) equipment operates using a large magnet. MRI magnets are very powerful and pose a serious danger for police, firefighters, and EMS personnel, as well as cleaning and maintenance personnel.

⚠️ Warning
Obey the warning signs posted at the entry of the magnet scan room to avoid potential injury.

MRI systems pose a serious danger for personnel carrying metallic objects into the scan room. These objects can be uncontrollably attracted to the magnetic field. The force will be stronger the closer the object is to the magnet. The magnetic force will also be stronger for larger objects than for smaller objects.

⚠️ Warning
Do not enter the scan room with metallic objects. Such objects could become dangerous projectiles that could cause serious injury.

Firefighters’ equipment containing iron, such as axes, tools, oxygen bottles, fire extinguishers, ladders, and even smaller objects, will be forcefully pulled into the magnet if they get too close.

Likewise, police firearms, handcuffs, and other metallic equipment could become dangerous projectiles because of the attractive force of the MRI magnet.

Large equipment, such as floor sweepers, waxers, vacuum cleaners, and pails will be drawn toward and into the magnet with such force that they cannot be held back nor removed from the magnet. Standard tools containing iron, such as hammers, pipe, screwdrivers, knives, pliers, nails, screws, and staples, will similarly be drawn into the magnet.

Electronic equipment not specifically made for use in a MRI environment, including pacemakers or other implanted devices, may not work properly if brought close to the magnet.
**Warning**

Do not enter the magnet room if you have a pacemaker or other implanted device. The implanted device may fail and cause a serious injury.

This facility has an MRI system that uses a superconductive magnet containing liquid helium. Because it is superconductive, the magnet is difficult to turn off. In some cases, the liquid helium can escape the magnet. The helium turns to gas that can cause severe burns to skin on contact.

**Warning**

Do not enter the scan room if alarms are activated. Escaping helium can displace the air in the room, creating an asphyxiation hazard.

As an emergency or service person, you must become acquainted with the safety precautions and procedures associated with this equipment. See the facility administrator for more information.
Daily and Weekly Checks

To ensure that the Oasis MRI System operates safely and optimally, perform the following daily and weekly checks at the recommended intervals. Detailed steps are included in this manual.

Using Caution in Maintenance and Inspection

⚠️ Caution
- Exercise caution when accessing the equipment cabinets. The driving mechanisms may cause injury.
- Do not allow excess water or other liquid to enter the equipment when cleaning the equipment and installation room.

⚠️ Warning
Never bring ferromagnetic tools, measuring instruments, electronic equipment, cleaning apparatus or patient transporting equipment into the scan room due to the high magnetic field. Failure to comply could result in serious injury.

Daily Checks
Perform the following checks daily:
- Check to ensure that the helium refrigerator and compressor are running.
- Check for the presence of ice on the MRI unit.
- Check and record the helium level.

Weekly Checks
Perform the following check weekly:
- Check the Emergency Rundown Unit (ERDU) to ensure that the clear plastic cover is intact and the seal is not broken.
# Daily Inspection

## Inspection Before Starting Daily Work

<table>
<thead>
<tr>
<th>Inspect the Alarm Box</th>
<th>Inspection items: Check for the Helium level, Megstop, Pressure, Battery Low or Corms Fouls Alarm indicators.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution:</td>
<td>Should any abnormality be found, contact Hitachi or our authorized service representative for troubleshooting.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inspect the Operating Panel</th>
<th>Inspection items: Verify push buttons and indicators operate normally.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution:</td>
<td>Should any abnormality be found, contact Hitachi or our authorized service representative for troubleshooting.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inspect the Technologist Alert System</th>
<th>Inspection items: Press the Operation Switch and verify the chime rings. Press the Talk Button and verify the chime stops ringing.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution:</td>
<td>Should any abnormality be found, contact Hitachi or our authorized service representative for troubleshooting.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inspect the Equipment Operating Space</th>
<th>Inspection items: Verify that there is no equipment obstructing the operating space of the patient table.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution:</td>
<td>Remove the equipment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inspect Cable Connections</th>
<th>Inspection items: Verify the integrity and connection of all cables.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution:</td>
<td>Should any abnormality be found, contact Hitachi or our authorized service representative for troubleshooting.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Verify Room Temperature and Humidity</th>
<th>Inspection items: Verify the scan room is between 68-75 degrees F (20-24 degrees C) and 45-60 percent humidity. Verify the control and equipment rooms are between 64-79 degrees F (18-26 degrees C) and 20-60 percent humidity.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution:</td>
<td>Adjust the thermostat.</td>
</tr>
</tbody>
</table>
## Inspection After Finishing Daily Work

### Inspect the Operating Panel

<table>
<thead>
<tr>
<th>Inspection items:</th>
<th>Verify push buttons and indicators operate normally.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution:</td>
<td>Should any abnormality be found, contact Hitachi or our authorized service representative for troubleshooting.</td>
</tr>
<tr>
<td></td>
<td>If any contamination is found, clean it following the procedures listed in the <em>Cleaning / Disinfecting Recommendations</em> section of this chapter.</td>
</tr>
</tbody>
</table>

### Inspect the Technologist Alert System

<table>
<thead>
<tr>
<th>Inspection items:</th>
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<tr>
<td>Solution:</td>
<td>Should any abnormality be found, contact Hitachi or our authorized service representative for troubleshooting.</td>
</tr>
</tbody>
</table>

### Inspect the Gantry Unit and Patient Table

<table>
<thead>
<tr>
<th>Inspection items:</th>
<th>Look for damage, dents, or contamination.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution:</td>
<td>Should any abnormality be found, contact Hitachi or our authorized service representative for troubleshooting.</td>
</tr>
</tbody>
</table>
Daily Image Checks

Signal-to-Noise Ratio (SNR) Check

The SNR should be checked daily using a phantom (figure 1-14). The SNR accuracy greatly depends on the temperature of the phantom. It is desirable to maintain the temperature of the phantom at nearly the same temperature as the scan room. If the phantom's temperature greatly differs from the temperature in the scan room, it is recommended that you store the phantom in the scan room. It will take several hours until the temperature of the phantom reaches the temperature in the scan room, so monitor the phantom's temperature before the SNR check is carried out. It is also recommended that the temperature in the scan room be kept at a constant value (temperature fluctuation within ±1°C).

Figure 1-14. Using a phantom to check SNR.
Follow these procedures to perform the daily SNR check:

1. Use the **Patient Registration** window to register the phantom as a “new patient.”

2. Set the No. 13 phantom in the RAPID head coil (figure 1-15).

3. Connect the RF connector to the patient table.

4. Press the LASER button on the control panel of the gantry and position the axial laser so that it crosses the center of the phantom.

5. Press the SET button to set the RAPID head coil at the center of the magnetic field.

![Figure 1-15. Setting the phantom in the RAPID head coil.](image-url)
6. Acquire a scan using the Daily QA protocol established by your Hitachi field service engineer (figure 1-16). Do not change or reset the parameter values in the Daily QA protocol.

Figure 1-16. Select and load the Daily QA protocol.
7. After scanning, click the Image SNR Image Analysis task in the Protocol area. The Image Analysis Setting area will open on the right side of the Exam window.

8. In the Series area, drag the SNR reconstructed image into the viewport, as shown in figure 1-17.

9. Select HMC S/N Check from the Analyze list, as shown in figure 1-17.

10. Set an ROI at the center of the phantom. Click START. The SNR will be displayed in the Result area.

11. Click SAVE at the bottom of the Image Analysis Setting area to save this SNR entry so that it will be shown in the HMC S/N Log Display window. For more information about the HMC Log Display window, refer to the Maintenance Service Tool & Diagnostic Window section of Chapter 9, Additional Launcher Functions.

Definition:
SNR is an acronym for signal-to-noise ratio.
ROI is an acronym for region of interest.

Figure 1-17. The SNR reconstructed image.
12. Keep a record of the measured SNR in your patient log book. If a pattern of change is noticed, contact your Hitachi field service engineer.

**Background Noise Check**

After recording the SNR, change the WW/WL (window width/window level) of the acquired image to check for background noise artifacts (such as streak noise or broadband noise).

**Warning**

The sealed phantom (figure 1-18) contains a carcinogenic nickel solution. Do not inhale or drink the solution and avoid eye and skin contact. Failure to comply could result in skin and eye irritations, allergic skin reactions or death. Dispose of the solution properly in accordance with all government regulations.
Oxygen Monitor

Note: Oxygen monitors and sensors are not installed by Hitachi. Therefore not all sites will have them.

The oxygen monitor, when present, is typically located in the control room. It is connected to an oxygen sensor, which is located in the scan room, usually in the ceiling above the magnet. An ambient oxygen concentration of less than 17- to 19-percent is not sufficient for human respiration.

Verify that the display reads 20.9 percent. If the concentration is less than this value, contact the manufacturer, since this is considered to be an alarm state. (Hitachi does not service these units.)

Emergency Rundown Unit (ERDU)

The ERDU (figures 1-19 and 1-20) is used only in emergency situations where the magnetic field must be removed quickly.

Activating the ERDU initiates a magnet quench, which will deplete the liquid helium inside the magnet. Service is required to restore normal operation.

A clear, hard-plastic shield covers the red STOP button to prevent accidental quenching of the Oasis magnet.

Caution

Pressing the red STOP button will quench the magnet.

Figure 1-19. ERDU1 located in scan room.
**Caution**
Pressing the red STOP button will quench the magnet.

Press ACKNOWLEDGE to silence the audible warning alarm

![Alarm Box Image](image)

Figure 1-20. ERDU2 / alarm box located in operator room.

When an error is detected in one of the systems that is routinely monitored by the magnet supervisory unit, the ERDU2 / alarm box located in the operator room will sound an alarm and an LED on the face of the ERDU2 / alarm box will illuminate, indicating the system where the error was detected. To disable the alarm and reset the LED indicators, press the ACKNOWLEDGE button (figure 1-20).

**Cryogens**

The Oasis MRI System uses a superconducting magnet and is equipped with a cryogenic cooling system. The type of cryogen used for the Oasis MRI System magnet is liquid helium. For helium to remain in a liquid state, it must be kept at a temperature of −269°C (4.17°K). Because of the very low temperatures at which the helium is kept, hazardous situations are possible. The installers or other maintenance personnel must take special precautions to prevent injury, and these are noted in the “Handling Cryogens Safely” section of this chapter.

**Warning**
Do not handle or expose yourself to cryogens. Cryogen exposure can cause burns, eye damage, asphyxiation, permanent injury, or death.

The MRI personnel should never handle the cryogen materials. This task should be left to the expertise of the installers or other maintenance personnel. MRI personnel should be aware of cryogen exposure hazards and should know
and follow proper evacuation plans in the event of helium exposure. The two situations in which a person might be exposed to helium are during a quench or during a routine cryogen fill. For the recommended procedure in the event of a magnet quench, refer to the Magnet Quench section of this chapter. In either case, the technologist and other personnel should know the properties of cryogens and the proper evacuation procedures.

If skin is exposed to liquid helium, burns similar to heat-induced burns may result. Permanent damage to the eye can occur if it is contacted by liquid helium. Cryogens can create an oxygen-deficient atmosphere and suffocate the occupants of the area. The rapid rate at which liquid helium changes to gas (the gas/liquid ratio for helium is approximately 750/1) can cause such a pressure change that the ear’s tympanic membrane may rupture. If proper evacuation does not take place immediately, dizziness, nausea, blackout, and possibly death could occur.

**Handling Cryogens Safely**

Only your Hitachi field service engineer or contracted cryogen service provider should handle and refill cryogens for your Oasis MRI System. Proper protective clothing, as listed below, is essential for all work done with cryogens:

- Safety gloves
- Work gloves
- Face shield
- Laboratory coat/overalls (cotton/linen)
- Nonmagnetic safety shoes

Periodically refill the cryogen to keep the liquid helium above the safety level and to prevent a magnet quench. Even during refilling, excessive boil-off of the cryogenic gas occurs, which could create the same conditions as a magnet quench. During a normal refilling, about 10- to 30-percent of the liquid helium will boil off and be converted to gas.

The following additional precautions must be taken.

---

**Caution**

Use only nonmagnetic 250-liter dewars for cryogen refilling. Other containers, such as compressed gas cylinders, can be forcibly attracted to the magnet and become dangerous projectiles. Failure to comply could result in injury or equipment damage.
**Warning**

Do not use ferromagnetic tools during cryogen refilling. Such tools can be forcibly attracted to the magnet and become dangerous projectiles. Failure to comply could result in death or serious injury.

---

**Caution**

Do not try to refill the magnet with cryogens; only properly trained authorized personnel can do so. Failure to comply could cause injury or equipment damage.

---

**Warning**

Do not allow flammable or combustible materials near the cryogen dewars, refrigeration system, or the magnet. During a magnet quench, escaping helium can condense oxygen in the air, creating a fire hazard. Failure to comply could result in death or serious injury.

---

**Warning**

Do not touch the liquid cryogen. Contact can result in cold injuries, which damage the skin and tissue much like a burn. Eyes are particularly vulnerable. Failure to comply could result in serious injury.

---

**Warning**

Do not enter the scan room during a magnet quench. The air in the room might be displaced by helium, making it difficult, if not impossible, to breathe. Failure to comply could result in death or serious injury.

---

**Caution**

Do not touch frosted pipes, valves, or surfaces. During a magnet quench, escaping helium can freeze these surfaces. Failure to comply could result in injury.

---

**Gas Monitoring**

The Oasis MRI System measures and displays the liquid helium level and pressure within the superconducting magnet. The level and pressure are automatically measured once a day, when the power is turned on. The measurements can also be performed manually, although cryogen consumption
increases slightly. For more information, refer to the Equipment Electrical Requirements, Maintenance, and Service section of this chapter.

Additionally, the scan room has a sensor that continuously measures the concentration of oxygen in the room. If the oxygen concentration falls below safe levels, an alarm will sound.

**Magnet Quench**

A magnet quench is a rapid collapse of the main magnet field caused by excessive heating of the magnet’s wires immersed in the liquid helium. A quench is either controlled (by pressing the emergency STOP button on the ERDU) or uncontrolled (as a result of too low a level of cryogen or other reasons).

If a magnet quench occurs, perform the following steps:

1. Immediately remove the patient from the magnet and from the scan room.
2. Close the scan room door.
3. Contact your Hitachi field service engineer.

---

**Warning**

Evacuate the scan room immediately in the event of a magnet quench. Escaping cryogens could displace the oxygen in the room. If a vent system failure occurs, overpressurization could prevent the scan room door from opening. Failure to comply could result in death or serious injury.

---

**Warning**

When a quench occurs, the magnetic field strength in the controlled access area becomes one-and-a-half times higher than normal for a few seconds. For people with cardiac pacemakers or other implanted electronic devices, the stronger magnetic field could cause the devices to malfunction and pose a risk of serious injury or death.

In a controlled magnet quench, the ERDU is used to force the magnet to quench. This procedure may be necessary if a ferromagnetic object becomes stuck to the magnet and is causing an immediate safety problem.

In an uncontrolled magnet quench, there is insufficient cryogen to cool and maintain the superconducting state of the magnet coil windings. The magnet coil windings become normally conductive, with internal resistance, and the flowing current generates heat.

In either a controlled or uncontrolled quench, the internally generated heat will result in excessive boil-off of the cryogen.
**Caution**

Avoid vibrations or impact shock caused by heavy objects, such as cryogen tanks. Such incidents can cause loss of magnetic field distribution or increase the potential for a magnet quench. Failure to comply could affect image quality or damage equipment.

At ambient temperature (20°C), one liter of liquid helium will produce approximately 750 liters of helium gas. During normal operation, the superconducting magnet boils off several hundred liters of helium gas daily. During a magnet quench, approximately 100,000 liters of gas at atmospheric pressure can be boiled off in several minutes.

Cryogens present unique hazards, such as cold injuries, danger of suffocation, and the possibility of oxygen depletion.

## Helium Refrigerator Unit

The cryocooler system (helium refrigerator unit) cools the thermoshields of the cryostat. The system consists of a helium compressor, a cold head (expander), interconnecting gas lines, and electrical cabling. Helium gas is the refrigerant. Although helium is also contained in the helium vessel, it does not mix with the refrigerant.

Follow the procedures below to ensure that the helium refrigerator unit is functioning properly:

- Verify that the refrigerator operates continuously.
- Listen to the compressor. You should hear rhythmic fluctuations, free of metallic noises.

**Caution**

Do not allow the refrigeration unit to stop running. If it stops, the helium boil-off rate could become excessive, and could lead to a magnet quench. Failure to comply could result in equipment damage or extended downtime.

**Caution**

Inspect the refrigeration unit after a power failure. The unit will resume normal operation within 30 minutes after power is restored. Failure of the unit could result in equipment damage or extended downtime.
**Warning**

All rooms where cryogens are stored or used must be adequately ventilated to prevent degradation of air quality, and must be fitted with oxygen monitoring equipment.

---

**Warning**

Containers of cryogenic liquids must not be completely closed as this would result in a large build up of pressure and could present an explosion hazard.

---

**Superconducting Magnet Turret**

The superconducting magnet turret, or cold head, is part of the refrigerator unit. Follow the procedures below to ensure that the turret is functioning properly.

- Listen to the cold head for sounds other than rhythmic fluctuations (such as slower or irregular fluctuations, or metallic noises).

- Check for frost or condensation on the upper part of the service turret and the helium exhaust pipes. Substantial frost or condensation indicates increased helium evaporation and consumption. Contact your Hitachi field service engineer if these conditions exist.

- Listen to the compressor. You should hear rhythmic fluctuations, free of metallic noises.
Liquid Helium Level (Superconducting Magnet)

The Helium Level Display depicts the system’s helium level measurement. Helium levels are displayed as a measurement or as a log display, as shown in figures 1-21 and 1-22.
Checking the Helium Level

Check and record the helium level by performing the following steps:

1. Click the Maintenance Launcher button to access the Service Tool & Diagnostic window.

2. Click the System Check arrow and click System Status Measurement And Log Display from the menu that appears, as shown in figure 1-23.

3. The System Status Measurement & Log Display window opens, as shown in figure 1-24. This window allows you to display the helium level measurement of the system’s superconducting magnet.

Perform daily checks of the helium level as follows:

- Click the Measurement tab.
- Click the down arrow button on the list box. Click Helium Level from the list, as shown in figure 1-24.
- Click the Start button.
- The helium measurement is displayed as a percentage under the Helium Level (Measure) [%] column. Record the helium measurement in your site’s Patient Log book or ACR Phantom Log sheet.
Note:
For more information about the maintenance functions, refer to Chapter 9, "Additional Launcher Functions."

4. To close the System Status Measurement & Log Display window, click the X button in the upper right corner of the window.
The **System Status Measurement & Log Display** window also gives you the option to display the helium level graphically over a period of time. Click the **Log Display** tab to display the helium level in a graph, as shown in figure 1-25. The helium level is updated automatically upon system startup and is displayed with the date and time under the graph.

---

**Caution**

Do not allow the magnet’s helium level to fall below 40 percent. At percentages below this level, the magnet could quench, resulting in the loss of the superconducting state and remaining cryogens. Failure to comply with this limit could result in equipment damage or extended downtime.

---

*Figure 1-25. Helium level displayed graphically.*
Equipment Electrical Requirements, Maintenance, and Service

The Oasis MRI System is designed and manufactured with major consideration given to the safety of the patient, the safety of the operator and ancillary personnel, and the reliability of the equipment. Electrical equipment may be hazardous if misused. Follow the guidelines and precautions below for personnel and equipment safety.

**Warning**

Do not operate the MRI equipment without covers. The MRI equipment must not be operated with covers, shrouds, panels, or doors removed or opened on any of its components, because of the potential for electrical shock hazards. Such protective devices may be removed only by factory-qualified service personnel. Failure to comply may cause serious or fatal injury to the patient, user, or ancillary personnel.

- The Oasis MRI System must be grounded in accordance with Hitachi Site Planning Standard Details specifications.
- Internal electrical components of the equipment contain line voltage and high voltage. Do not attempt any repairs or service procedures other than those described in the Hitachi-provided manuals. Opening and removing covers may expose personnel to dangerous voltage points or other hazards. Refer all servicing to qualified service personnel.
- Do not make modifications or replacements other than those described in the Hitachi-provided manuals.
- Never attempt to continue operating the equipment in a fault or warning condition. Remove power to the equipment and contact Hitachi Customer Service. Be prepared to describe in detail the fault condition and sequence of events leading up to it.
- Slots and openings in the sides, back, bottom, and top of the cabinet are provided for ventilation. To ensure reliable operation of the product and to protect from overheating, these openings must not be blocked or covered.
- Never push objects of any kind into the equipment through cabinet slots: they may touch dangerous voltage points or short out parts, causing an electrical shock or fire.
- Do not allow objects to rest on the power cords or electrical cables. Following equipment installation, cords and cables should be routed so that personnel will not walk on them.
Do not use cords or cables which become frayed or otherwise damaged. Contact Hitachi Customer Service for repair.

Never force a connector into a port. Check that the connector matches the port and is correctly aligned and positioned in relation to the port.

Always disconnect cables and cords by pulling on the connector, not the cord.

Do not place equipment components on unstable surfaces, chairs, or tables. The equipment may fall, causing equipment damage or personnel injury.

Never spill liquid of any kind on the image processor, keyboard, mouse, or other components. If you do, turn off the equipment or component before cleaning up the spill. Depending on what was spilled and how much, it may be necessary to contact Hitachi Customer Service, as in the following situations:

- If clear, thin liquid is spilled on the keyboard, discontinue operation, turn the keyboard upside down to let the liquid drain, and let it dry for 24 hours at room temperature. If, after taking these steps, the keyboard is still not operational, contact Hitachi Customer Service.

- If the liquid is sticky, sweet, or greasy, discontinue operation and contact Hitachi Customer Service.

- Do not attach electronic equipment with direct line cord power to the patient.

- Follow all manufacturer-recommended preventive maintenance and service intervals, including those performed by qualified service personnel.

- All ancillary equipment that you intend to use with the Oasis MRI System should be evaluated by a qualified Hitachi representative or by other personnel appropriately qualified with respect to MRI principles and safety.

---

**Note:**
The multi-tap unit is a powerstrip located under the console not meant for routine use. Do not use for anything other than Hitachi use. For more information, contact Hitachi service.

---

**Caution**
Do not connect electrical equipment that is not specified as part of the Oasis MRI system to the multi-tap unit. It may cause abnormal system operation.

---

**Caution**
The maximum permitted load for the multi-tap unit is 100V, total output is 700VA.

---

**Caution**
The multi-tap unit is only to be used for the Oasis MRI system. Do not use it for any other equipment.
**Caution**

Do not place the multi-tap unit on the floor.

**Caution**

The power for the LCD monitor at the workstation shall be supplied as a part of the system from the multi-tap unit. Do not connect the LCD monitor directly to a wall outlet. Abnormal operation may occur.

- Avoid installing the equipment where the following environmental conditions exist:
  - Ambient temperature may be lower than 18°C or higher than 26°C.
  - Atmospheric pressure may be lower than 700 hPa or higher than 1060 hPa.
  - The equipment may be exposed to harmful or corrosive gases.
  - The humidity may be excessively high.
  - The equipment may be exposed to steam.
  - The equipment may be splashed with water.
  - The equipment may be exposed to direct sunlight.
  - Excessive dust is present.
  - Excessively dense oil vapor is present.
  - The equipment is exposed to salt air.
  - Explosive gas or dust concentrations are present.
  - The equipment is subjected to excessive vibration or shock.
  - The equipment is inclined more than 10°.
  - The line voltage fluctuates abnormally, or rises or drops abnormally while the equipment is under a load.
  - A strong magnetic field is present near the equipment.
  - Ferromagnetic material is present near the equipment.
Required Markings and Identification

Indication of Origin
Hitachi Medical Corporation
Medical Systems Group, Kashiwa
2-1, Shintoygofuta, Kashiwa-shi
Chiba, 277-0804
Japan

Model or Type Reference: Oasis

Classification
Class I—Equipment in which protection against electric shock does not rely on basic insulation only, but includes an additional safety precaution that provides for the connection of the equipment to a protective earth conductor. The fixed wiring of the installation is grounded in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

Degree of Protection Against Electric Shock
Type B Applied Part(s)—Respiratory, Peripheral Pulse Sensors
Applied part complying with the specified requirements of IEC-60601-1 Standard to provide protection against electrical shock, particularly regarding allowable leakage current, and marked with the symbol Type B Equipment/Type B Applied Part.

Type BF Applied Part(s)—ECG Sensor
Applied part complying with the specified requirements of IEC-60601-1 Standard to provide a higher degree of protection against electrical shock than that provided by Type B Applied Part(s), and marked with the symbol Type BF Equipment/Type BF Applied Part.

Degree of Protection Against Ingress of Water
IPX0: Not protected against ingress of water.

Degree of Safety in the Presence of a Flammable Mixture with Air
Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Mode of Operation
Continuous operation.
Warning Sign and Symbol Definitions

Warning signs must be posted in the environment of the Oasis MRI System facility and are required to delineate the Controlled Access Area. These warning signs make use of warning and prohibitive symbols, which are defined in the table below.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Symbol]</td>
<td>Strong magnetic field</td>
<td>Warning</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>High frequency RF field</td>
<td>Warning</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Pinch hazard</td>
<td>Warning</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>No pacemakers</td>
<td>Prohibitive</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>No ferromagnetic metallic implants</td>
<td>Prohibitive</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>No ferromagnetic containers</td>
<td>Prohibitive</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>No ferromagnetic carriers, wagons, or hand carts</td>
<td>Prohibitive</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>No iron wheelchairs No ferromagnetic medical supplies</td>
<td>Prohibitive</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>No loose ferromagnetic objects</td>
<td>Prohibitive</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>No ferromagnetic tools or cleaning equipment</td>
<td>Prohibitive</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>No metallic objects worn on the body</td>
<td>Prohibitive</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>No precision electronic instruments</td>
<td>Prohibitive</td>
</tr>
<tr>
<td>Symbol</td>
<td>Definition</td>
<td>Type</td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>No magnetic memory media</td>
<td>Prohibitive</td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>Alternating current</td>
<td>Electric Current</td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>Protective earth (Ground)</td>
<td>Earth</td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>Earth (Ground)</td>
<td>Earth</td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>Attention, consult <em>Accompanying Documents</em></td>
<td></td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>Off (Power: disconnection from the mains)</td>
<td></td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>On (Power: connection to the mains)</td>
<td></td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>Off (only for part of Equipment)</td>
<td></td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>On (only for part of Equipment)</td>
<td></td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>Type B <em>Equipment / Type B Applied Part</em></td>
<td>Medical Equipment</td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>Type BF <em>Equipment / Type BF Applied Part</em></td>
<td>Medical Equipment</td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>Dangerous voltage</td>
<td>Safety</td>
</tr>
<tr>
<td><img src="#" alt="Symbol" /></td>
<td>STOP</td>
<td>Stop</td>
</tr>
</tbody>
</table>
A warning sign similar to the one depicted below must be posted on the entrance of the Oasis magnet room.

![Warning sign for entering the MRI room](image-url)
Labels Attached to MRI System Components

The following labels are attached to the Oasis MRI System and must be heeded.

**Gantry**

![CAUTION]

**Laser Radiation**

DO NOT STARE INTO BEAM
CLASS 2 LASER PRODUCT
CW, 600-700nm
Max. 1mW
Classified to IEC60825-1: 2007-03

This equipment complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007

**Patient Table**

![NOTICE]

DON'T STEP ON THE COVER.

![NOTICE]

In case of emergency, push the switch in the direction of arrow, and pull it back.

![CAUTION]

Pinch hazard
Can cause injury of finger or hand.

Keep your hands off the gap.
**System Serial Number Information**

This plaque is located on the back lower section of the magnet.

![MR IMAGING SYSTEM](attachment:MRIMAGINGSYSTEM.png)

**Console**

<table>
<thead>
<tr>
<th>WARNING</th>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>This MRI imaging system may be dangerous to patient and operator unless operating instructions are observed.</td>
<td>U.S. federal law restricts this device to sale or use by or on the order of a physician or licensed practitioner.</td>
</tr>
</tbody>
</table>

**注意**

- 本装置のラインは常時接続しています。保守、点検時には必ず、UPS 電源及び MRI ユニット内のブレーカーを切って AC POWER ユニットのブレーカーを切ってから作業を行ってください。

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power line to this unit is continuously energized. Shut off the power switch of UPS and MAINS breaker in MRI unit or AC POWER unit at the time of maintenance</td>
</tr>
</tbody>
</table>

**お願い**

- 本装置は MRI 装置専用です。他の機器に接続しないで下さい。

<table>
<thead>
<tr>
<th>NOTICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>This Multi Tap is only used for this MRI equipment. Do not use this Multi Tap for other equipment.</td>
</tr>
</tbody>
</table>
Uninterruptible Power Supply (to CPU)

⚠️ 注意 ⚠️ CAUTION

MR 1 装置を使用中は Do not turn off this UPS
本装置の電源を切らないで下さい, when this MRI equipment
is used.

⚠️ 注意

本装置はMR I 装置専用です
他の機器に接続しないで下さい。

⚠️ CAUTION

This UPS is only used
for this MRI equipment.
Do not use this UPS
for other equipment.

Power Supply Cabinet

⚠️ WARNING

To reduce the risk of
electric shock, do not remove
cover. Refer servicing to qualified
service personnel.

RF and Gradient Coils (GC) Cabinets

⚠️ WARNING

To reduce the risk of
electric shock, do not remove
cover. Refer servicing to qualified
service personnel.
Cleaning/Disinfection Recommendations

Each imaging facility’s Infection Control Practitioner should develop specific cleaning and disinfection procedures for the facility in accordance with current infection control practices.

This cleaning and disinfection section reflects the Occupational Safety and Health Act (OSHA) Blood-Borne Pathogens Standard and is intended only as a supplement to the Exposure Control Plan of the imaging facility. The Exposure Control Plan is required by the OSHA Standard for employees who have occupational exposure to blood or other potentially infectious materials. These general cleaning and disinfection guidelines are based upon the concept of “Universal Precautions,” in which all human blood and certain human body fluids are treated as if known to be infectious for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other blood-borne pathogens.

Before any patient is imaged, the imaging facility should clean and disinfect the Oasis MRI System and any other patient contact items following exposure to a source individual. The Oasis MRI System should always be cleaned and disinfected following any contact with blood or body fluids.

General Rules for Cleaning or Cleaning/Disinfection

Follow these general rules when cleaning or disinfecting the Oasis MRI System:

- Always make sure that the power to the control console is off and the Oasis MRI System and patient table are turned off before starting any cleaning or cleaning/disinfection procedures.
- Do not use aerosol-can-based cleaning or cleaning/disinfection products. Aerosol cans usually are not MRI-compatible and, when near the magnet, may become projectiles, which could present a hazard to patients and other persons.
- Do not use aerosol sprays, solvents, or abrasives. These products may damage the finish of the equipment. In addition, aerosol or atomizer cleaning or cleaning/disinfection delivery systems create a mist that may be drawn into the equipment by air current convection. This mist may condense on sensitive electronics and present an electrical hazard or corrode the circuits.
- Do not use cleaning or cleaning/disinfection products that may evaporate to form potentially explosive atmospheres. Always provide adequate ventilation and allow adequate time for any vapors to disperse before using the equipment.
- Do not apply cleaning or cleaning/disinfection products at full strength or at high concentrations because these solutions may decrease the usable life of the plastics and other external surface materials.
• Clean the equipment exteriors with a damp (not wet) lint-free cloth, using a mild detergent solution. Do not allow liquids to enter any equipment openings, as this may cause an electrical hazard.

• A nonabrasive automotive polish may be used to preserve the finish of the equipment.

• Thoroughly clean before performing any disinfection procedures because germicides and hypochlorite solutions are substantially deactivated in the presence of blood and other organic fluids.

• Certain components of the Oasis MRI System, such as the patient mattresses and RF coil covers, may be difficult to disinfect due to their semiporous or porous nature. Take a preventive approach to minimize the contamination of these items by blood or body fluids.

Hitachi recommends the use of trauma pads or procedure pads to protect the patient mattresses and recommends the use of equipment or surgical drapes to protect the RF coils. These pads and drapes are readily available from a variety of laboratory suppliers.

**Cleaning/Disinfection Agents**

The cleaning/disinfection agents listed below have been evaluated by Hitachi. When used according to the dilutions recommended by the Centers for Disease Control (CDC), the U.S. Department of Public Health, and OSHA, or according to the manufacturer’s recommended dilution, they were found to have no harmful effects on the plastics and other external surface materials used in the Oasis MRI System.

This list is not intended to be all-inclusive, nor should it be considered as a product recommendation or endorsement by Hitachi.

Hitachi does not currently supply these decontamination agents because they are readily available from a variety of laboratory suppliers.

<table>
<thead>
<tr>
<th>Common/Trade Name</th>
<th>Chemistry</th>
<th>Cleaning Usage</th>
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</table>
| Chlorine          | Hypochlorite | • Daily  
|                   |           | • Weekly  
|                   |           | • Disinfectant |
| Ethyl alcohol     | Alcohol   | • Daily  
|                   |           | • Weekly  
|                   |           | • Disinfectant |
| Isopropyl alcohol | Hydrogen Peroxide | • Daily  
|                   |           | • Weekly  
|                   |           | • Disinfectant |
| Hydrogen Peroxide | Hydrogen Peroxide | • Daily  
|                   |           | • Weekly  
|                   |           | • Disinfectant |
| Lysol® Brand I.C.™ Quaternary Disinfectant Cleaner | Quaternary Ammonium | • Daily  
|                   |           | • Weekly  
|                   |           | • Disinfectant |
| Professional AMPHYL® Disinfectant Cleaner | Phenolic | • Disinfectant |
The manufacturer of the Lysol® I.C.™ decontamination agents may be contacted directly at the following address:

Reckitt Benekiser Professional
399 Interpace Pkwy.
P.O. Box 225
Parsippany, NJ 07054-0225
800-677-9218

Lysol® is a registered trademark of Reckitt Benekiser.
I.C.™ is a trademark of Reckitt Benekiser.

- Solutions of chlorine (household bleach) in recommended concentrations achieve an intermediate-level disinfection and are recommended by the CDC, U.S. Department of Public Health, and OSHA for the disinfection of areas contaminated with blood or body fluids. Hypochlorite solutions are corrosive to metals, bleach fabrics, rapidly evolve into toxic chlorine gas when mixed with acid, break down in the presence of light, and are substantially deactivated in the presence of blood and other organic fluids.

- In recommended concentrations, ethyl and isopropyl alcohols achieve an intermediate-level disinfection because they are ineffective against bacterial spores. Isopropyl alcohol is ineffective against hydrophilic viruses (echovirus, coxsackie virus, poliovirus).

- Alcohols swell, harden, and bleach rubber and some plastics after prolonged and repeated use. Alcohols are flammable and must be stored in a cool, well-ventilated area; their rapid evaporation makes extended contact times difficult without immersion.

- In recommended concentrations, hydrogen peroxide achieves a high-level disinfection but is corrosive to copper, brass, and zinc.

- In manufacturer-recommended concentrations, quaternary ammonium chloride-based cleaners achieve a low-level disinfection and are commonly used for ordinary environmental sanitation. The quaternary-based cleaner should not be used for the disinfection of areas contaminated with blood or body fluids.

- Phenolic-based cleaners, in manufacturer-recommended concentrations, achieve an intermediate-level disinfection and are used for environmental, laboratory surface, and noncritical medical and surgical decontamination.

- Thorough cleaning must precede all disinfection procedures because germicides and hypochlorite solutions are substantially deactivated in the presence of blood and other organic fluids.
**General Cleaning**

The Infection Control Practitioner for each imaging facility should develop general cleaning and disinfection procedures for the facility in accordance with current infection control practices. These procedures usually include the following steps.

**Daily Cleaning**

1. Dress in appropriate personal protective equipment, including gloves, gown or laboratory coat, and face and eye protection.
2. Clean the patient table, auxiliary tabletop, and headrests in accordance with industry-accepted hygienic practices.
3. Disinfect the patient table, auxiliary tabletop, and headrests.
4. Clean the patient mattresses, VELCRO® straps, and RF coil covers in accordance with industry-accepted hygienic practices.
5. Disinfect the VELCRO straps.
6. Remove the RF coil covers from the RF coils and disinfect them by immersion soaking.
7. While the RF coil covers are removed, clean and disinfect the plastic housings of the RF coils. Do not immersion-soak the RF coils.
8. Following disinfection, thoroughly rinse the RF coil covers to remove any residual disinfectant.
9. Allow the RF coil covers to completely dry, then carefully reassemble the covers onto the RF coils.

VELCRO is a registered trademark of Velcro Industries B.U.
Weekly Cleaning

Follow all daily cleaning instructions, as well as the following instructions for weekly cleaning:

1. Dress in appropriate personal protective equipment, including gloves, gown or laboratory coat, and face and eye protection.

2. Clean the equipment exteriors with a damp (not wet) lint-free cloth, using a mild detergent solution. Do not allow liquids to enter any equipment openings.

3. The monitor has a nonglare and anti-electrostatic treatment on the surface of the screen. Use water or alcoholic solvent with a soft cloth-like gauze to clean the surface of the screen. Never use abrasive glass cleaners containing highly concentrated ammonia and strong base chemicals; they damage the surface treatment. Clean the monitor screen and the operator’s console display and control panels with a damp (not wet) lint-free cloth, using isopropyl alcohol or other products intended to clean high-resolution graphics displays. Do not spray the cleaner directly on the screens because the liquid might drip into the monitor, keyboard, or Operator’s Console. Prepackaged screen wipes are available from many computer stores and other supply sources.

4. Clean the magnet gantry covers in accordance with general hygiene requirements.

5. Disinfect the magnet gantry covers.

6. Verify that patient accessories (such as patient VELCRO restraints and RF coil covers) are not damaged. Promptly replace all damaged items.
Disinfection

The Infection Control Practitioner of each imaging facility should develop general cleaning and disinfection procedures for the facility in accordance with current infection control practices. These procedures usually include the following steps:

1. Dress in appropriate personal protective equipment, including gloves, gown or laboratory coat, and face and eye protection.

2. Restrict the access of other personnel to minimize or prevent contact with the area(s) or item(s) contaminated with blood or body fluids.

3. Thoroughly clean before conducting all disinfection procedures because germicides and hypochlorite solutions are substantially deactivated in the presence of blood and other organic fluids.

4. Absorb the excess blood or body fluid with an absorbent material. This material must be carefully transferred to a red bag or appropriate regulated waste container and handled as regulated waste.

5. Use an Environmental Protection Agency (EPA)-registered tuberculocidal disinfectant, using the appropriate strength and contact time as indicated in the directions for using the disinfectant. If no EPA-registered disinfectant is available, sodium hypochlorite or hydrogen peroxide in recommended concentrations may be used. Follow recommended contact times for effective disinfection.

6. After thoroughly disinfecting the affected area, wash and remove any further staining using appropriate personal protective measures.

7. Handle all absorbent material, cleaning materials, and used personal protective equipment as regulated waste, to be appropriately labeled and disposed of in accordance with U.S. federal, state, county, and local regulations.

Training and Education

MRI is a sophisticated, multifaceted, rapidly changing imaging technique requiring specialized knowledge and training. It is essential that all personnel associated with the Oasis MRI System receive adequate training and education at an appropriate level for their normal duties and in the event of an emergency.
Physician Training

Hitachi recommends that physicians attend at least two professional meetings or MRI education courses annually. Examples of such meetings include the following:

- Radiological Society of North America (RSNA)
- International Society of Magnetic Resonance in Medicine (ISMRM)
- National MR Symposium
- American Society of Neuroradiology (ASNR)

Technologist Training

Training requirements vary from state to state. Various educational opportunities are available for MRI technologists to take advantage of. Examples of such opportunities include:

- MR Technologists Conference
- Hitachi online training courses
- Webinars

Operator training is essential and is provided by Hitachi, including free admission to the Hitachi Institute for Technologists (HITS) training classes and on-site training. The application specialist provides comprehensive information on the following topics during onsite training following installation of the Oasis MRI System.

- Oasis MRI System components
- Personnel safety
- System operation
- Patient safety, preparation, and positioning
- Protocol selection
- Image acquisition
- Image analysis and evaluation
- Quality assurance

Caution

Operation of the MRI equipment by a person who is not sufficiently trained in MRI may cause severe bodily injury or misdiagnosis.
Environmental Protection

During the operating life of the magnet no harmful waste products or residues are produced. Before magnet disposal, all cryogenic liquids are to be vented safely to atmosphere. The cryostat vacuum must be released using the Hitachi approved method by trained personnel only. All stainless steel, aluminum, copper and brass used in the magnet construction are recyclable. All other materials must be disposed of in accordance with local law regulations.

If the magnet is to be disposed, do it according to the instructions from Hitachi or our authorized representative. Decommissioning must only be carried out by trained personnel.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Only for EU countries</td>
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<tr>
<td>Do not dispose of medical devices together with household waste!</td>
<td></td>
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<tr>
<td>In observance of the European Directive 2002/96/EC on waste electrical and electronic equipment and its implementation in accordance with national law, medical devices that have reached the end of their product life must be collected separately and returned to an environmentally compatible recycling facility.</td>
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</tr>
<tr>
<td>Please contact your local Hitachi distributor for information about qualified recycling facilities.</td>
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</tbody>
</table>

⚠️ **Caution**

Do not attempt magnet decommissioning without consulting the Hitachi service department. Improper decommissioning procedures can create a potential for accidental release of cryogens into the atmosphere.
Electrostatic Discharge (ESD)

Electrostatic discharge (ESD) is generally known as static electric shock, and is part of natural phenomena. ESD typically occurs in a low-humidity environment. In a low-humidity environment, static charge is naturally accumulated in a human body and tends to cause static electric shock. When a human body highly charged with static electrical energy touches a metallic object or another human body, ESD may be triggered. The Oasis MRI system is sensitive to ESD and might be damaged with such discharge.

To suppress the influence of ESD on the Oasis MRI system, contact pins of an electrical connector such as a RF receive coil, having the ESD alert symbol illustrated below, must not be touched. Notify all users and other staff concerning this precaution.

Magnet Decommissioning

Danger
Do not decommission the Oasis MRI system without consulting Hitachi or our authorized distributor. There is a risk of explosion if decommissioning is not carried out correctly.

To decommission a magnet safely, the magnetic field and all cryogens must be removed, any cold vessels raised to room temperature and the vacuum released. This is highly specialized work and must not be attempted by anyone who does not have the appropriate experience and training. All magnet services including the quench line must be intact and operational before starting decommissioning.

Decommissioning will take approximately 10 days to complete depending on the type of magnet. Always contact the Hitachi service department for advice before commencing a decommissioning.
References


