HEALTH DEVICES
December 2001, Volume 30, Number 12

Guidance Article

The Safe Use of Equipment in the Magnetic Resonance Environment

Also in This Issue

ECRI
A NONPROFIT AGENCY

Health Devices Editorial and Scientific Policy

CHARTER AND GENERAL POLICY

ECRI. ECRI (formerly known as the Emergency Care Research Institute) is a nonprofit health services research agency established in 1955.

Peer review. The extensive technical studies reported in *Health Devices* are conducted by ECRI's staff. All our articles are intensively reviewed by engineering and clinical professionals, both within and outside ECRI, before publication.

Impartiality. ECRI respects and is impartial toward all ethical medical device companies and practices. Neither ECRI nor any of its staff members has a direct or indirect financial interest in promoting the sale of any medical device. ECRI employees do not undertake private consulting work for the medical device industry or own stock in medical device companies. We accept no royalties, gifts, finder's fees, or commissions, nor does *Health Devices* accept advertising. ECRI prohibits manufacturers from using or referring to our product ratings or reports, in whole or in part, in advertising or promotional materials.

COMPARATIVE EVALUATIONS

Scope. Device Evaluations, unless otherwise noted, cover only the specific models discussed. We caution readers against applying the ratings to models that we did not evaluate. If we do not include a currently marketed device in an Evaluation, this does not necessarily mean that it is no longer available or imply anything about its value, safety, or performance.

Ratings. Our ratings system is explained in each Evaluation. We urge readers to review it closely and to read Evaluations in their entirety before making medical device related decisions.

ECRI accountability. Neither ECRI nor the Health Devices System implies any warranty, including a warranty of merchantability or fitness for a particular purpose, or assumes liability for the safety, performance, or effectiveness of the evaluated products. We invite manufacturers to discuss their products and to review test data before publication. However, ECRI assumes responsibility for the final Evaluation of a device.

Restrictions on the use of *Health Devices* content. As an impartial evaluator of biomedical technology, ECRI does not endorse any specific brand or model of device. Reproducing excerpts from our product Evaluations in promotional materials implies endorsement, contravenes ECRI policy, and may violate copyright law. Please report any instances of improper use of ECRI's published materials directly to: Legal Department, ECRI.

ECRI PROBLEM REPORTING SYSTEM

Purpose. We encourage readers, healthcare providers, patients, and device suppliers to report all medical device related incidents and deficiencies to us so that we can determine whether a report reflects a random failure or one that is likely to recur and cause harm. (Please refer to the ECRI Problem Reporting System section in each issue of *Health Devices* for complete information.)

Hazard Reports and User Experience Network™ (UEN™) articles. A hazard is a possible source of peril, danger, or difficulty. We publish generic or unit-specific Hazard Reports when we have identified a fault or design feature that *might,* under certain circumstances, place patients or users at risk. In contrast, UEN articles describe problems that we believe are unlikely to pose a significant hazard. Most UEN articles describe common or nuisance problems that can be corrected with an available modification or revised operating or maintenance procedures.

Submitting a medical device problem report. Concerned parties can submit problem reports to us by letter, by using a copy of the Problem Reporting Form included in the *Health Devices* binder (additional copies are available on request), or by completing the online form accessible through ECRI's home page (www.ecri.org). We also accept reports submitted by facsimile transmission, as well as by telephone.

Postmaster

Send address change to *Health Devices,* 5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA ▪ Periodical postage paid at Plymouth Meeting, PA, and at additional mailing offices.

A NONPROFIT AGENCY

Web site www.ecri.org ▪ E-mail healthdevices@ecri.org

United States. ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA ▪ Telephone +1 (610) 825-6000 ▪ Fax +1 (610) 834-1275

Europe. ECRI, Weltech Centre, Ridgeway, Welwyn Garden City, Herts AL7 2AA, UK ▪ Telephone +44 (1707) 871 511 ▪ Fax +44 (1707) 393 138

Southeast Asia. ECRI Berhad (Company No. 448950 P), 9-2-7, Jalan 3/109F, Danau Business Centre, Taman Danau Desa, 58100 Kuala Lumpur, Malaysia ▪ Telephone +60 3 7982 5792 ▪ Fax +60 3 7982 5839

Middle East. ECRI-IMD, City Tower 2, Suite 510, Sheikh Zayed Road, PO Box 71059, Dubai, United Arab Emirates ▪ Telephone +971 4 3322682, +971 4 3321490 ▪ Fax +971 4 3321476

PUBLISHING STAFF

Robert W. Schluth, BA, Editorial Director, Health Devices Group
Garrett J. Hayner, BA, Editor
Alison L. Stone, BA, Assistant Editor

Production

Etta M. Berry, Production Manager
Courtney Bowman, AAS
Suzanne R. Gehris
Marlene P. Hartzell
Soon-Ae Jo, BA

Copyediting

Jill Greshes, MA, MEd, Copyediting Coordinator
Robin A. Henry, BA
Katy Mancini, BA
Coreen Tossona, BA

Library. Evelyn H. Kuserk, MLS, Supervisor

Communications. Laurie D. Menyo, BA, Manager

Circulation. Rita Stout, Manager

SUBSCRIPTION INFORMATION

Health Devices (ISSN 0046-7022) is published monthly by ECRI. Subscriptions to *Health Devices* are available only through membership in the Health Devices System or SELECTplus. Single copies of *Health Devices* are available: standard issue price — $275 ($75 for members); double issue price — $335 ($95 for members); prices may vary for Special Issues.

Membership benefits. Annual membership includes *Health Devices, Health Devices Alerts,* and other benefits. Contact ECRI's Communications Department — +1 (610) 825-6000, ext. 5888 — for more information.

Health Devices System (2001). $3,495 (special rates available for shared services). Additional subscriptions to *Health Devices,* with membership, for use within the same institution and location and mailed with the original subscription: $685 per volume.

SELECTplus. Contact ECRI for pricing information.

476205
424-001

HEALTH DEVICES

December 2001
Volume 30, Number 12

Executive Summary

Featured in This Issue . . .

Making the MR Environment Safer

The use of equipment and devices in the magnetic resonance (MR) environment can be hazardous — occasionally even deadly. This fact was tragically illustrated last July when a young patient at a New York–area hospital was struck and killed by a metal oxygen canister that was pulled into the bore of the MR system where the patient was lying.

That accident was an instance of the "projectile effect," which is the most spectacular and publicly recognized hazard of the MR environment. But there are others. For example, implanted or embedded magnetic objects (even tiny ones) can cause harm or death if they torque or twist inside the patient's body, and conductive objects can heat and cause patient burns. And many medical devices unsuited for the MR environment can malfunction, possibly injuring the patient, or can impair the ability of the MR scanner to image accurately.

These hazards will become even more significant as increasing amounts of equipment and instrumentation are brought into MR scan rooms. Add to this the increasing popularity of high-field-strength MR systems — which are more liable to be involved in adverse incidents than other types — and you have an environment whose risks are only likely to increase.

How can hospitals address these steepening odds? In the Guidance Article on page 421, we discuss the issues and methods involved in increasing the safety of device use in the MR environment. Following a rundown of basic MR technology (including a description of the different types of magnetic fields), we outline the hazards presented by various elements of the MR environment and provide ECRI's recommendations for using equipment safely in this environment. We also present a starter list of equipment and devices that are marketed by their suppliers as MR compatible.

Understanding ASPs

Increasingly, hospitals are turning to application service providers (ASPs) to provide and support software applications. Using an ASP provides quick access to applications without the need for new equipment or staff. But it also raises some uncertainties. For one thing, the boom in ASP companies means that many of them are young and difficult to assess. Also, these companies can differ widely, both in the services they offer and in how they define themselves. And no one company is likely to be able to provide all the services you need, meaning that you could have to use multiple ASPs for multiple software applications.

On page 445, we answer some fundamental ASP questions. What sorts of healthcare applications are available from ASPs? What pricing models are available for ASP services? How do you decide between using an ASP or managing the software in-house? And if you do choose the ASP route, how do you select the company or companies that will meet your needs?

Also in This Issue

Thanks! Over the past year, generous folks donated their time to scrutinize our major articles in draft form. By offering their invaluable comments, these clinical reviewers have helped us maintain the accuracy and reliability of *Health Devices.* We thank them on page 453.

Problem reports. This issue's Problem Reporting section (page 454) includes Hazard Reports on the Baxter Ipump and Zoll Medical M Series defibrillator paddles.

We Have a Winner!

Congratulations to Ann Barkowitz — Biomed Tech at Clement J. Zablocki Veterans Affairs Medical Center in Milwaukee, Wisconsin — whose completed 2001 Health Devices System Member questionnaire was drawn from all completed surveys to win the Palm m105™ handheld organizer. Thank you to Ann and everyone else who took the time to complete the questionnaire. ◆

476113
424-001

The Safe Use of Equipment in the Magnetic Resonance Environment

UMDNS information. Scanning Systems, Magnetic Resonance Imaging [16-260]

Summary. The clinical literature and problem reporting databases include numerous reports of injuries — and a few deaths — in magnetic resonance (MR) centers. Many of these incidents occurred because ferromagnetic materials (that is, materials that can become strongly magnetized) were mistakenly brought into the MR environment. The most spectacular outcome of such an error is the projectile effect, in which an object becomes airborne and literally flies through the air, crashing into the magnet. (A patient death from an airborne oxygen canister was widely reported last July.) Other incidents can be attributed to the use of devices within the MR environment in a manner not in accordance with their restrictions or limitations.

Such incidents continue to occur despite the widely known risks of the MR environment. As the amount of equipment used in this environment increases, and as more powerful MR systems grow in popularity, staff awareness of MR hazards becomes ever more vital. In this Guidance Article, we discuss the basic technology of MR systems (including a description of the different types of magnetic field), outline the hazards presented by various elements of the MR environment, provide ECRI's recommendations for using equipment safely in this environment, and present a starter list of equipment and devices that are marketed by their suppliers as MR compatible.

476099
424-001

Safety Concerns in the MR Environment

Unique Environment, Unique Risks

A metal oxygen canister that had been brought into the area of a magnetic resonance (MR) system became a deadly projectile when it was pulled into the bore of the MR system's magnet. The six-year-old patient lying inside the system suffered a fatal head injury.*

A 71-year-old patient undergoing a magnetic resonance imaging (MRI) procedure received a burn on the finger where a pulse oximeter probe had been placed. The patient had been under anesthesia during the procedure, and the burn was severe enough to warrant amputation to the second knuckle.**

Incidents such as these are caused by interactions between an MR system's electromagnetic fields and other equipment stationed in or brought into the MR environment — an area that encompasses not only the MR system, but also a three-dimensional magnetic field that surrounds the system. Often, the incidents result in harm to patients or staff or costly damage to equipment.

The clinical literature and problem reporting databases include numerous reports of injuries in MR centers and a few reports of deaths. Most of these incidents can be attributed to the presence of ferromagnetic devices and equipment, including implants, in the MR environment. (Ferromagnetic objects are permanent magnets or other materials that can become strongly magnetized in the presence of an external magnetic field.) Other incidents can be attributed to the use of devices in a manner that is not in accordance with their restrictions or limitations.

Fortunately, considering the large number of MRI examinations performed each year, the number of reported incidents is actually quite low. The primary reason for this is that MR personnel typically adhere to strict safety protocols. The MR environment is a controlled-access environment; as a result, only carefully screened patients and knowledgeable staff — and sometimes carefully screened family members or other accompanying personnel — are allowed in this environment.

* ECRI discussed this incident, which was reported in the *New York Times* on July 31, 2001, in the August 2001 *Health Devices;* see the Hazard Report "Patient Death Illustrates the Importance of Adhering to Safety Precautions in Magnetic Resonance Environments" on pages 311 to 314 of that issue.

** This incident was described in the U.S. Food and Drug Administration's (FDA) Medical Device Reporting (MDR) database: Access Nos. M291515 (1992 Jun 24) and M297255 (1992 Jun 26).

Definition

The **MR environment** is commonly defined as the volume where the magnetic field strength of the MR system is greater than 5 gauss (G), or 0.0005 tesla (T). (1 T = 10,000 G.) We use this definition in this article. ◆

Another contributing factor is that very few types of equipment have traditionally been needed in the MR suite for standard diagnostic procedures. With current practice, though, an increasing amount of equipment and instrumentation is being used in MR scan rooms — for example, to conduct surgeries under MR guidance. As the amount of equipment used in the MR environment increases, so too does the risk of adverse incidents — especially considering the increasing popularity of high-field-strength MR systems. (As we discuss later in this article, high-field-strength systems may be more likely to be involved in adverse incidents than other types of MR systems.)

Thus, it's more important than ever that healthcare facilities pay careful attention to MR safety protocols. Furthermore, with surgical staff and other non-MR personnel present in the MR environment more frequently, the range of individuals who need to be educated about both the hazards that exist in the MR environment and the precautions that must be followed will need to be expanded beyond MR personnel.

Although some risks may always be involved in the use of MR systems, adverse incidents can typically be prevented — provided that the individuals who enter the MR environment have a clear understanding of the uniqueness of that environment.

Introduction to Magnetic Resonance Imaging

MRI is a noninvasive imaging modality that can be used to image anatomy in multiple planes, or slices. In this sense, it is like computed tomography (CT) and ultrasound. Unlike CT, however, MRI constructs images using

electromagnetic fields, not x-rays (i.e., ionizing radiation). Thus, MRI is viewed as a biologically safer procedure. And unlike ultrasound, which also doesn't use ionizing radiation, MRI scans are not obstructed by bone; in addition, MRI can be used to image structures that contain air.

To complete an MRI scan, the part of the body to be imaged is maneuvered into the bore (the physical opening) of the MR system, where it is exposed to a set of magnetic fields. The MR system then constructs images of the underlying anatomy by interpreting tissue reactions to the applied magnetic fields. (See Principles of Operation, below, for a more detailed discussion.)

APPLICATIONS

MRI as a diagnostic tool. The first MRI whole-body scan was demonstrated in 1977. Since that time, MR systems have become practical clinical tools for investigating anatomic structures — thanks in large part to their excellent ability to image soft tissue. MR technology is extremely useful for investigating the brain, spinal cord, and vertebrae, as well as surrounding tissues. MRI is also the best noninvasive way to view abnormalities in cartilage, tendons, and ligaments, making it useful for investigating joints. In addition, MRI can be used to image the eyes and sinuses, to identify tumors throughout the body and ascertain their stage of development, and to evaluate large blood vessels.

Although a useful diagnostic tool, MRI is not without disadvantages. For example: In some MR systems, the patient must remain still within the small confines of the magnet bore for relatively long periods of time. Completing a single image can take anywhere from parts of a second to several minutes, and completing all imaging sequences in an exam can take up to 45 minutes. The requirement to remain stationary and in an enclosed area is especially difficult for pediatric patients, who may have a hard time keeping still, and for patients with claustrophobia. (Some newer MR systems incorporate mechanisms for addressing the issues of motion artifact and claustrophobia; see Beyond Diagnosis, below.)

Also, in high-field-strength MR systems (i.e., those systems with the strongest static magnetic fields; see The Role of the Magnetic Fields, below), the process used to generate images creates acoustic noise in the form of loud thumping sounds. This noise can create stress for the

Ferromagnetic versus Ferrous Materials

The terms *ferromagnetic* and *ferrous* are often used interchangeably in the literature, but the terms are not synonymous:

- **Ferromagnetic** materials are materials that are or that can become strongly magnetized in relatively weak magnetic fields. Such materials may be permanent magnets — examples include high carbon steel alloys, alnico, barium ferrite, magnetite, and hematite. Or they may be materials that become magnetized in the presence of an external magnetic field and that subsequently maintain their field once the external field has been removed — examples include pure iron, permalloy, superpermalloy, nickel, and cobalt.

  All ferromagnetic materials can be problematic in the MR environment, since all such materials are susceptible to static-magnetic-field-induced forces. Thus, equipment that includes such materials either should be prohibited from the MR environment or should be maintained a safe distance from the MR system. (Some devices that include some amount of ferromagnetic materials are designated as being MR safe or MR compatible with gauss-line restrictions. This means that the devices can be used in the MR environment as long as they are kept a specified distance from the MR system. See the supplementary article on page 432 for additional discussion.)
- **Ferrous** materials are simply materials that are composed of or that contain the element iron. Some of these will also be ferromagnetic, but some will not. Thus, not all ferrous materials will be affected by static-magnetic-field-induced forces.

MR safety programs typically focus on ferromagnetic materials because of their ability to become projectiles or to torque in the MR environment. However, facilities also need to recognize that other materials, such as other magnetic materials and conductive materials (some of which may be ferrous, though not ferromagnetic), can likewise be problematic in the MR environment for reasons discussed in the main text. ◆

patient and can interfere with communications between the patient and staff.

Most importantly, however, interactions between the electromagnetic fields required for MRI and other equipment present in the MR environment can lead to a variety of hazards that are unique to this environment. These interactions can result in patient or personnel injury — for example, by turning nearby objects into dangerous projectiles drawn toward the MR system's magnet. They can damage medical devices or other equipment, including the MR system itself. They can interfere with the system's ability to image anatomy properly. And they can prevent the proper functioning of equipment. We discuss the hazards present in the MR environment in detail in this article.

Beyond diagnosis. Technological advances in MR systems have expanded their functionality beyond purely diagnostic applications.

> Today, MRI can be used for investigating virtually every part of the body.

The development of systems that offer faster imaging times, thereby reducing motion artifacts, has allowed MRI to be used for a host of new applications. These include abdominal and cardiac imaging, functional studies of the brain (called functional MRI, or fMRI), and the dynamic evaluation of joints. Today, in fact, MRI can be used for investigating virtually every part of the body.

In addition, the development of systems with an open configuration — that is, with a larger or more open bore — has not only made MRI more tolerable for patients who experience claustrophobia, but has also expanded the range of applications for which MRI can be used by allowing greater access to the patient. As a result, MRI can now be used to help plan, guide, and monitor both open surgeries (e.g., cardiac surgery, brain surgery) and less invasive procedures and therapies (e.g., percutaneous biopsies, cyst drainage, catheter insertions, sinus endoscopy, thermal ablations and cryoablations of tumors). The use of MR technology in this manner allows the physician to see beyond the exposed area, to visualize anatomic changes that can occur during tissue manipulation, and to view the position of instruments to guide the procedure or surgery.

This MRI application is still in its infancy. However, because MR guidance can potentially reduce the invasiveness of surgery, decrease the length of hospitalization, increase the safety of procedures, and reduce morbidity, the number of procedures performed under MR guidance is expected to increase rapidly. As a result, it will become increasingly important for surgeons and other healthcare practitioners to understand the uniqueness of the MR environment and the hazards that exist when medical devices and other equipment are used in this environment.

PRINCIPLES OF OPERATION

MR system components. MR systems consist of the following components:

- A magnet — The magnet creates the static magnetic field — the first of three fields necessary for MRI. Current MR systems use one of three magnet types — permanent, resistive, or superconductive — with the different types associated with different field strengths, as discussed below.
- Radio-frequency (RF) coils — RF coils create the second field necessary for MRI, the RF electromagnetic field. These coils are typically resistive windings that can be integral to the MR system (the coils are located under the thin plastic covering in the bore of the magnet) or can be separate devices that are physically placed around the body part of interest (e.g., a head coil, a knee coil). The RF coils are used to transmit RF signals to and receive RF signals from the tissues being imaged. As such, the RF coils and their associated equipment are among the most important components affecting the quality of MR images.
- Gradient coils — These coils, which are sets of coils or resistive windings located inside the walls of the MR system, set up a pulsed, or switched, gradient magnetic field — the third field necessary for MRI.
- A patient table — The table transports the patient (specifically, the part of the patient to be imaged) into the bore of the magnet.
- A computer system and an operator console.

The role of the magnetic fields. The magnetic fields established by the magnet, the RF coils, and the gradient coils — that is, the static field, the RF field, and the gradient field, respectively — each play a role in constructing an image of the underlying anatomy.

The static magnetic field. This field, which is commonly referred to as B_0, is fundamental to producing a net magnetization of the protons in the patient's tissue such that the net magnetization of the protons will be aligned in the direction of B_0. Individuals are subjected to this field

when they are in the vicinity of the MR system, when they approach or lie on the patient table, or when they are positioned inside the bore of the MR system for scanning.

The strength of the static magnetic field is usually in the range of 0.064 to 3.0 T, as measured at the center of the bore.* (Systems with field strengths up to 3.0 T have been approved by the U.S. Food and Drug Administration [FDA], but systems with field strengths as high as 8.0 T exist for research applications.) MR systems with magnetic field strengths greater than or equal to 1.0 T are loosely classified as "high-field-strength" systems, although systems with field strengths of 0.5 T or higher are sometimes included in this classification. "Mid-field-strength" systems typically have field-strength values ranging anywhere from 0.2 T to 1.0 T, and "low-field-strength" systems generally have field-strength values below 0.3 T.

Field strength is determined by the type of magnet used. High-field-strength systems generally use superconductive magnets, while mid- and low-field-strength systems typically use either permanent or resistive magnets.

> The 5 G line can extend outside the MR scan room, even to the floors directly above and below the MR system.

The RF magnetic field. When electromagnetic pulses are applied from the RF transmitter (an RF coil that transmits RF signals), an oscillating RF magnetic field is created that alters the static magnetic field. When this happens, the net magnetization of the protons in the patient's tissues that were aligned in the direction of the static magnetic field moves out of alignment with that field. After the RF pulse stops, the net proton magnetization relaxes back to its original position and, in doing so, emits an RF signal that is picked up by the RF receivers (RF coils that receive RF signals). The MR system then uses extremely sophisticated computer-analysis techniques to convert the signals into images that provide information about the anatomy. Different tissues can be distinguished from one another by the rates at which the proton magnetization realigns itself in the static magnetic field after the RF pulse stops. These rates are referred to as the tissue's relaxation times. Different tissues have different relaxation times, and it is the differences in relaxation times that can be used to differentiate between normal and abnormal tissue.

The gradient magnetic field. This field is established when the gradient coils located inside the walls of the MR system are rapidly switched on and off. When pulsed on and off in between and during RF pulses, the coils spatially encode information contained in the RF pulse to localize the signal and create an image. In simpler terms, the gradients determine the following: the section location of the MR image, the size of the field of view, and whether a thick or thin slice (i.e., cross section) of the area being imaged will result. Stronger gradients, for instance, provide smaller fields of view and thinner slices than do weaker gradients.

Characterizing the static magnetic field: The spatial gradient. The static magnetic field set up by the magnet does not end at the edge of the MR system. Rather, it extends beyond the MR system in all directions, with the strength of the field decreasing as the distance from the magnet increases. The decrease in magnetic field strength over distance establishes what is called the static-magnetic-field spatial gradient, or simply the spatial gradient (not to be confused with the gradient field). The quicker the field strength of an MR system drops off, the higher the spatial gradient is. Systems that incorporate some form of magnetic field shielding (e.g., to minimize the volume over which the static magnetic field extends) have higher spatial gradients than unshielded systems. For instance, close to the bore of a shielded MR system, it is not uncommon for the magnetic field strength to drop from 1.5 T to 0.2 T over a distance of only a few inches.

Defining the safety boundaries: The 5 G line. The distance from the MR system at which the static magnetic field has diminished sufficiently to pose no physical threat to the general public is defined as the 5 G line ("G" stands for "gauss"). (See the figure on page 426.) The 5 G line defines the boundary between areas where the MR system's magnetic field strength is either greater than or less than 5 G (or 0.0005 T). Within the 5 G line, some objects could be pulled into the magnet, and many devices will not operate properly. For this reason, FDA and International Electrotechnical Commission (IEC) safety guidelines require warning signs in any area where the magnetic field strength exceeds 5 G. (It should be noted that the 5 G line can extend outside the MR scan room and can even extend to the floors directly above and below the MR system. It should also be noted that some sensitive equipment — for example, computer CRT screens — can be affected by much smaller field strengths, even those below 1 G.)

* For comparison, the earth's magnetic field measures approximately 0.00006 T.

In addition to posting warning signs acknowledging the 5 G line, healthcare facilities should exercise administrative control at this point. For example, to minimize the risk of adverse incidents, only knowledgeable staff and carefully screened patients (or similarly screened accompanying individuals) should be permitted past the 5 G line. The general public should not be permitted in this area, nor should people with cardiac pacemakers.

The distance to the 5 G line from the MR system will differ depending on the type of MR system, the strength of the magnet, and the presence, amount, and configuration of MR system magnetic field shielding. Generally, the distance to the 5 G line will be greater for unshielded, higher-field-strength MR systems. For instance, the 5 G line is typically 13 m (43 ft) for an unshielded 1.5 T system and 9 m (30 ft) for an unshielded 0.5 T system (AAPM 1987). However, with magnet shielding (which is more common today), the distance to the 5 G line can be less than 4 m (13 ft) for a 1.5 T system and less than 3 m (10 ft) for a 0.5 T system. Specified 5 G distances generally have orientation along the main axis of the MR system.

Hazards in the MR Environment

Interactions between an MR system's electromagnetic fields and other devices can lead to a variety of adverse incidents that can result in injury (or death), misdiagnosis, or equipment damage. Most often, hazards in the MR environment can be attributed to one of the following phenomena:

- Static-magnetic-field-induced forces
- RF heating
- Image artifacts
- Device malfunctions

We discuss each of these below. Incident reports referenced in this discussion have been drawn from a variety of sources, including FDA's MDR, PRP, and MAUDE databases; ECRI's problem reporting system; and peer-reviewed literature. In the section that starts on page 431, we provide recommendations for reducing or eliminating the risks of the types of problems discussed here.

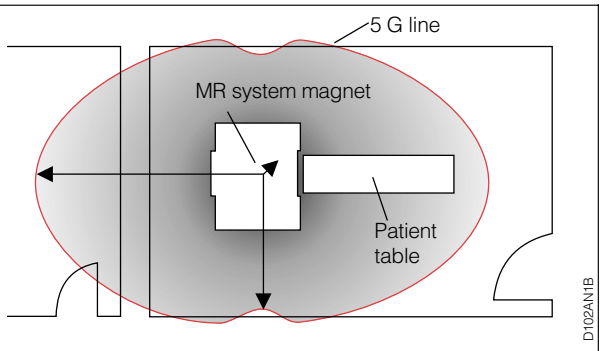

Figure. Simplified illustration of an MR scan room showing the location of the 5 G line for one type of MR system. The 5 G line delineates the boundary between areas where the MR system's static magnetic field strength is either greater than 5 G (the field strength increases dramatically as the distance to the magnet decreases) or less than 5 G. Within the 5 G line, some objects could be pulled into the magnet, and many devices will not operate properly. (Note that the static magnetic field extends in all directions around the magnet, including above and below the system.)

STATIC-MAGNETIC-FIELD-INDUCED FORCES

Because of the existence of the MR system's static magnetic field, ferromagnetic and other magnetic materials — located either inside or outside the bore of the magnet — are subject to two separate forces in the MR environment:

- Torque — This is a rotational force that causes an object to align parallel to the static magnetic field. The amount of torque experienced by an object depends on the object's size, shape, and magnetic properties (the force is greater for ferromagnetic materials), as well as the magnitude of the MR system's static magnetic field and its spatial gradient at the point where the object is located.

  Torque is greatest at the geometric center of the MR system's magnet, where the magnetic field strength is greatest. However, torque still exists outside the magnet bore, where the magnetic field strength is less.
- Translational force — This is a linear force that tends to attract an object into the bore of the magnet. The amount of translational force experienced by an object depends on the object's size and composition (the force is greater for ferromagnetic materials), as well as the magnitude of the MR system's spatial gradient and its static magnetic field at the point where the object is located.

  As a rule, the closer a magnetic object gets to the MR system's magnet, the higher the spatial gradient that exists and the greater the translational force that the object will experience — and thus the greater the likelihood that the object will be drawn toward the MR system's magnet. Depending on the magnetic properties of the object, the greatest translational force will occur

either where the magnitude of the spatial gradient is maximum or where the product of the magnitudes of the spatial gradient and magnetic field strength is maximum. (Note that these locations will differ for shielded and unshielded magnets.) Because high-field-strength systems generally have higher spatial gradients, such systems are more likely to attract an object than lower-field-strength systems.

Torque and translational forces tend to act simultaneously on both fixed and unrestrained magnetic devices and equipment. And both types of forces can cause injuries and other types of problems in the MR environment. For example: Static-magnetic-field-induced forces can cause implanted magnetic objects (e.g., aneurysm clips) to shift, possibly damaging internal structures. They can turn unrestrained magnetic objects into projectiles that could strike anyone or anything located between the object and the center of the MR system's magnet. And they can cause magnetic components of a fixed object or device to break free from their foundation, which can lead to device failure or injury to individuals nearby.

Paper clips and hairpins pulled into a magnet can reach speeds up to 40 mph.

Effects on implanted objects. For magnetic implants, static-magnetic-field-induced forces (primarily torque) can result in the compression or twisting of the tissue surrounding the implant, which can lead to the rupture of blood vessels. Several incidents have been reported in which static-magnetic-field-induced forces have caused a ferromagnetic implanted device to shift. Reports have involved intracranial or cerebral aneurysm clips, cochlear implants, and orbital implants. One of these cases caused fatal hemorrhaging, even though the patient had never reached the bore of the magnet. For these reasons, most ferromagnetic implants contraindicate MRI, and unscreened patients are not permitted past the 5 G line.

Furthermore, static-magnetic-field-induced forces can cause magnetic particles that have found their way into the patient to shift. For example, people who have had careers working with sheet metal or who have worked for a substantial length of time in other situations that involve the grinding of metal may have tiny magnetic particles embedded around their eyes. The shifting of these particles can injure blood vessels or nerves and can cause blindness. MR centers generally require x-ray screening (i.e., plain-film radiography) for metal workers who have sustained an eye injury and who are not certain whether all metal particles associated with the injury have been removed (Seidenwurm et al. 2000). Particles too small to be seen by x-ray generally do not pose a hazard to the patient, although they may cause image artifacts (we discuss artifacts below).

The projectile effect. Perhaps the most sensational hazard associated with MR systems is a phenomenon commonly referred to as the projectile effect, or missile effect. The projectile effect describes instances in which static-magnetic-field-induced forces (primarily translational forces) cause unrestrained ferromagnetic or other magnetic objects to become airborne and literally fly through the air and crash into the magnet. The projectile effect can be quite hazardous, since the force on objects can be significant. Even very small objects can cause injury to patients or personnel. For instance, paper clips and hairpins pulled into a 1.5 T magnet can reach speeds up to 40 mph (Kaut-Roth 1996).

The list of devices and objects that have crashed into MR systems is extensive. It includes chairs, floor buffers, forklift parts, hair barrettes, IV poles, ladders, laundry carts, oscilloscopes, oxygen cylinders, pens, pulse oximeters, scissors, stethoscopes, syringe infusion pumps, and tools. In a recent incident, a young patient suffered a fatal blow to the head from a metal oxygen canister that flew into the MR system where the patient was lying.

Even devices that might appear safe have become projectiles in the MR environment. One incident involved a sandbag placed on a patient to cover an entrance site from a catheterization procedure. The sandbag was pulled from its position on the patient's groin into the magnet. Although sandbags are often assumed to contain only sand, some also contain ferromagnetic pellets to add weight to the bag without increasing its size. These pellets can be attracted by the static magnetic field.* In another incident, a hospital pillow was attracted to an MR system. Although most people would assume pillows to be filled with only padding materials, some contain ferromagnetic springs, which can be attracted by MR systems. The springs allow fresh air to circulate (keeping the pillow dry and at a constant temperature) and enhance the resilience of the pillow.

* For more information, see "Ferromagnetic Sandbags Are Hazardous in Magnetic Resonance Imaging (MRI) Environments," published in the July 1998 *Health Devices* (pages 266-267).

Some of these projectile incidents have resulted in serious injuries to patients — for example, from objects flying into the bore of the magnet where the patient was lying. And some incidents have resulted in serious injuries to personnel — for example, from personnel trying to restrain the object. In addition, the force of the impact frequently causes damage to the devices or objects or to the magnet itself.

Another potential consequence of a projectile incident is that it can cause or require a quench of a superconductive magnet. A quench occurs when a superconductive magnet loses superconductivity. During a quench, the cryogen used in MR systems as a coolant rapidly evaporates. (Liquid helium is used as a cryogen in newer MR systems, while older systems use liquid helium and liquid nitrogen.) If the scan room's ventilation system fails to ventilate the room quickly enough, the evaporation of cryogen can displace the oxygen in the air in the room, possibly asphyxiating patients and personnel.

> The static magnetic field is always present, even if the system is sitting idly.

Finally, many of these incidents are associated with downtime (which can amount to several days) while objects are retrieved from the MR system. These objects must be removed from the magnet, since imaging would otherwise be impaired. Resistive-magnet and superconductive-magnet systems can be turned off to free trapped patients and objects from the magnet's grip. However, this takes time. In addition, for superconductive-magnet systems, the process of turning off the magnet must be done by service personnel and can be very costly. A permanent magnet, on the other hand, cannot be turned off. This means that removing an object from its grip requires physically applying enough force to the object to pull it away. For larger objects especially, this can be a formidable task. For instance, it has been estimated that the force required to remove a 5 lb ferromagnetic sandbag (dimensions: $6 \times 6 \times 2$ in) from the grip of a 1.5 T magnet is greater than 500 lb (Chu and Sangster 1986).

Projectile incidents have occurred both during the workday and during off-hours. The danger with MR systems is that it is impossible to tell simply by looking at them whether their static magnetic field is present. Unless an MR system has been shut down to remove an object that has become attached to the system, the static magnetic field of all types of MR systems is always present, even if the system is sitting idly and there is no noise coming from the system, if there is no operator at the console, or if the workday has ended.

RF HEATING

An MR system's RF electromagnetic field can induce currents in electrically conductive materials (e.g., medical device cables) present within the bore of the MR system. The induced current, in turn, can cause heating of the conductor, which can lead to a patient burn if the conductor is in contact with the patient's body.*

The exact circumstances that lead to heating severe enough to cause a burn are not always clear. However, several factors appear to increase the likelihood of a burn: First, the potential for heating in a conductor increases with increasing RF power. Since higher-field-strength MR systems require higher RF transmitted power, thermal injuries are more likely to occur in higher-field-strength systems. Also, the amount of power dissipated into the conductor depends on the distance of the conductor from the RF transmitter coil. Thus, the closer the conductor to the RF transmitter coil, the greater the chance of thermal injury. Finally, the magnitude of the current induced in conductors depends on the conductor's resistance and its geometry. Currents may be induced in looped conductors; thus, the looping of conductors may increase the risk of burns. Larger loops will induce more current than smaller loops.

Reported incidents of patient burns or localized heating implicate a wide variety of electrically conductive materials. For example:

- Patients have received burns from contact with conductive medical equipment cables (e.g., ECG leads, pulse oximeter cables) and MR accessory cables (e.g., RF coil leads) during scanning. Reportedly, burns have occurred both with cables that were in use and those that were not in use, and they have occurred both with cables that had been looped (or coiled) and those that had not been looped.
- Burns have been reported at the site of pulse oximeter sensors.

* Although the gradient field can induce currents in conductors as well, the currents induced from the gradient field are 1,000 times smaller than those induced by the RF field. As such, these currents do not pose much of a concern for thermal injury.

- Burns have been reported at the site of ECG electrodes (even when the electrode was not connected to lead wires).
- Medical devices that incorporate conductive loops (e.g., halo devices, cervical traction devices or immobilizers) have been associated with reports of heating or burning sensations at their contact point(s) with the patient.
- Patients have received burns at the point where their thumb or hand touched the same-side thigh or at the point where their thighs touched or their arms crossed. (In such cases, it's suspected that parts of the patient's body formed a conductive loop.)
- Burns or burning sensations have been reported at or near the sites of implantable infusion pumps, nitroglycerin patches, metal-containing tissue expanders, and pacing electrodes.
- Patients have been burned after contacting the RF coils or the magnet bore wall.
- Rare reports have suggested that patients with tattoos have experienced minor burns from localized heating. (Tattoos may contain iron oxide or other ferromagnetic substances that are conductive.)

Most thermal injuries that have been reported are first-degree burns, but second- and third-degree burns have also occurred. The more serious burns often occur while patients are under sedation and unable to respond to discomfort. Some of these burns have required skin grafts and, in a few cases, amputation of a toe or portion of a finger.

IMAGE ARTIFACTS

Anything in an MR image that does not accurately represent the imaged object or area is called an image artifact. Because they affect image quality, image artifacts also affect diagnostic value. Artifacts often appear as geometric distortions, unwanted signals or patterns, or areas of signal loss, called signal voids, in an image. Image artifacts can be produced in numerous ways; in this article, we discuss only those artifacts caused by the use of devices and equipment in the MR environment.

Artifacts resulting from field disturbances. The presence of ferromagnetic materials — and even some nonferromagnetic materials — near the anatomy being imaged can disturb the homogeneity (uniformity) of the MR system's static magnetic field. This is because these materials can have their own associated magnetic field when they are placed in an external magnetic field. Because the MR system's static magnetic field must be homogeneous for accurate image reconstruction, significant disturbances in the homogeneity of the static magnetic field can result in MR image artifacts. Breast expanders with magnetic injection ports, stereotactic headframes with ferromagnetic pins, and stainless steel internal fixation hip implants have all reportedly caused MR image artifacts.

In addition, RF pulses and/or gradient switching can set up eddy currents in conductive material present in the scanning region. This creates a weak magnetic field that can cause distortion as well. The mass and shape of the material will affect the type of distortion observed.

Signal voids caused by conductive materials. Image artifacts can also be caused by the presence of metal or other conductive devices or materials inside the bore near the imaging site. The presence of these materials often produces signal voids that can black out a substantial part of the imaging area around the conductive material. Examples include implants, metallic biopsy needles, zipper pulls, bra hooks, and even mascara. The size of the signal void typically depends on the composition and size of the object and the field strength of the MR system. One of the biggest problems with signal voids is that they can be misinterpreted and misdiagnosed as pathologies if the radiologist is unaware of the seemingly insignificant metal or conductor in or on the patient's body.

Artifacts caused by RF noise. An MR system's RF receiver can pick up RF signals emitted from other equipment if those signals are close to the same frequency as the signals emitted by the protons in the patient's tissue (e.g., 21.3 MHz for 0.5 T systems, 64 MHz for 1.5 T systems). The result is RF noise that can affect image quality by introducing noise lines (stripes across the image) or by decreasing the contrast in the image.

Although standards exist to define acceptable levels of RF emissions from devices, none of the standards address issues of MR compatibility. If not properly RF shielded, devices within the MR environment that contain display screens (e.g., LCDs, CRTs), microprocessors, or LEDs can all emit frequencies that can be picked up by the MR system's RF receiver. As a result, they all could create artifacts that affect image quality. (RF signals from equipment located outside the MR scan room would not cause a problem since the scan room is usually RF shielded.)

DEVICE MALFUNCTIONS

An MR system's static magnetic field and its RF and gradient magnetic fields can seriously affect the operation,

reliability, and accuracy of medical devices that have not been properly designed for the MR environment.

Effects of the static magnetic field. Anesthesia units, infusion pumps, ventilators, and contrast injectors often have components — such as analog gauges or electric motors (which contain magnets and coils) — that can be affected by an MR system's static magnetic field. Also, some devices include electronic circuits made up of components such as transformers, relays, and switches that are also affected by the static magnetic field. The magnetic field's effect on these components can cause the components to malfunction or to cease functioning altogether. This, in turn, can affect the performance or accuracy of the medical device, possibly jeopardizing patient safety.

In one example of a patient-controlled analgesic (PCA) infusion pump malfunction, the static magnetic field caused the PCA pump's motor to operate in reverse, despite relatively normal displays presented to the user. If not for a fail-safe one-way valve in the IV delivery line, blood could have been withdrawn from the patient into the reservoir. A similar incident was reported for an insulin infusion pump. And in at least one report involving the use of a ventilator (which was not approved for MR use), the ventilator delivered inadequate inspiratory pressure when operated in the MR environment.

The static magnetic field can also create problems for devices that depend on magnetization to attach to the patient. These devices, such as some dental devices and otologic implants, can become demagnetized in the static magnetic field. Similarly, some implanted devices that are magnetically, electrically, or mechanically activated are contraindicated for MRI because their functionality can be affected by the magnetic field. Examples include some cochlear implants, drug infusion pumps, neurostimulators, ocular prostheses, and cardiac pacemakers.

Finally, electric measurements can be especially complicated in the MR environment, particularly if they are performed close to the MR system. As an example, the static magnetic field of high-field-strength MR systems has been known to distort the ECG waveform of patients within the field, often increasing the T-wave or ST-segment amplitude. Because an increase in the T-wave can indicate true physiologic problems (e.g., hyperkalemia), caregivers need to be aware of the potential for such an interaction. For high-risk patients, caregivers may want to obtain a baseline ECG before and then immediately after the patient is subjected to the MR environment.

Effects of the RF magnetic field. Medical device leads can act as antennas for RF energy, which can lead to device malfunctions and possible injury to the patient. For instance, RF energy from the MR system's transmitter coils can couple into the electrically conductive sensor leads of an ECG monitor or pulse oximeter if those leads are situated near the imaging site. This coupling can result in temporary loss of the parameter being measured or can damage the device. (However, suppliers can often design an ECG monitor or pulse oximeter in a manner that controls the amount of RF energy that can be coupled by the device's leads.)

As another example, pacemaker leads can act as antennas for RF energy. The result is that RF energy from the MR system can interact with the pacemaker's output circuit, causing, for example, rapid pacing. Furthermore, currents induced in pacemaker leads from the MR system's RF transmitter coil can cause pacemakers to pace at the wrong point in the cardiac cycle, potentially causing arrhythmias and increasing the risk of fibrillation.

Effects of the gradient magnetic field. The gradient magnetic field of many new MR systems can mimic physiologic signals in their frequency content and, therefore, can interfere with ECG signals. This interference can easily cause ECG signals to be misinterpreted (e.g., missed ECG complexes). Manufacturers of monitoring equipment can often effectively eliminate this artifact through design — using filtering and digital signal-processing techniques.

Recommendations

Ensuring the Safe Use of Equipment in the MR Environment

The following recommendations will help ensure the safe use of equipment in the MR environment.

General Recommendations

- Appoint a safety officer responsible for ensuring that procedures are in effect and enforced to ensure safety in the MR environment.
- Establish and routinely review MR policies and procedures, and assess the level of compliance by staff.
- Identify zones in the MR suite and surrounding rooms (including adjacent floors) where the magnetic field strength exceeds 5 G. Define this area as the MR environment, and restrict access to this area.

  At the time of site planning for the MR suite, the MR system supplier should have provided a layout plan to the site with at least the 5 G line clearly marked. Every effort should be made during site planning to restrict the 5 G line to areas that are not used or are not generally accessible. Note that although the 5 G line is a safety mark for the general public, some equipment (e.g., computer CRT screens) located outside the 5 G line may still be affected by the static magnetic field.
- Provide formal training on safety considerations in the MR environment to all MR staff and to other personnel who would have an opportunity to enter the MR environment. This might include surgical, transport, security, housekeeping, and maintenance personnel, as well as emergency response personnel (e.g., firefighters).
- Carefully screen all people entering the MR environment for magnetic or conductive objects
  - — in their bodies (e.g., implants, bullets, shrapnel),
  - — on their bodies (e.g., hairpins, brassieres, buttons, zippers, jewelry, mascara), or
  - — attached to their bodies (e.g., body piercings).*

  Magnetic or conductive objects on or attached to the bodies of patients, staff members, or family members (or other individuals accompanying the patient) should be removed if feasible. (Dental fillings are an example of a nonremovable item that is generally allowed in the MR environment.)

  Patients with ferromagnetic materials in their bodies may not be candidates for MR imaging, unless the physician has reviewed the case and approved scanning. The presence of conductive, nonmagnetic materials in a patient's body does not necessarily rule out MRI, although these materials can potentially lead to heating or image artifacts (depending on their location).
- Check the patient's medical records carefully for implants and other suspected foreign objects.

Do not alter MR-safe or MR-compatible equipment.

- Have patients wear hospital gowns — those without metallic fasteners — for MR procedures if possible. Patients' regular clothing can contain magnetic or conductive objects (e.g., fasteners, hooks, zippers).
- Don't allow equipment and devices containing magnetic (especially ferromagnetic) components past the 5 G line, unless they have been tested by the device manufacturer and have been labeled MR safe or MR compatible *for your specific MR environment.* Also, adhere to any restrictions provided by suppliers regarding the use of MR-safe and MR-compatible devices and equipment in your MR environment. (See the supplementary article on page 432 for a discussion of the terms *MR safe* and *MR compatible*.)
- Maintain a list of MR-safe and MR-compatible equipment, including restrictions for use. This list should be kept in every MR center by the MR safety officer. It is critical that the safety officer know which equipment has been determined to be safe or compatible for which

* A pre-MRI screening form can be found in: Sawyer-Glover AM, Shellock FG. Pre-MRI procedure screening: recommendations and safety considerations for biomedical implants and devices [review]. *J Magn Reson Imaging* 2000 Jul;12(1):92-106.

particular MR environments. Further, if MR systems are upgraded or new MR systems are purchased, the safety officer must determine whether the equipment is still MR safe or MR compatible with the new or upgraded system.

- Do not alter MR-safe or MR-compatible equipment. As a case in point, ECRI recently found, while on a hospital visit, that the hospital had used a ferromagnetic wire to attach a plastic sign to an MR-compatible oxygen regulator, thereby making the device incompatible.
- Be extremely careful if you must use equipment containing ferromagnetic components in the MR environment. (As discussed in the supplementary article on this page, some devices can be considered MR safe or MR compatible *with gauss-line restrictions.* This means that the devices can be used in some parts of the MR environment [e.g., locations where field strengths do not exceed 150 G], but not others.)

  — To prevent such equipment from being moved too close to the MR system, the equipment should be

Defining "MR Safe" and "MR Compatible"

To help medical device suppliers communicate whether their products can be safely used in the magnetic resonance (MR) environment, the U.S. Food and Drug Administration (FDA) has defined* two terms describing devices and equipment that have been shown to be safe for use in this environment: "MR safe" and "MR compatible." These definitions are also being adopted by the U.K. Medical Devices Agency (MDA).

- **MR safe.** A label of MR safe specifies that "the device, when used in the MR environment, has been demonstrated to present no additional risk to the patient, but may affect the quality of the diagnostic information."
- **MR compatible.** A label of MR compatible specifies that "the device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device."

While suppliers can use these terms to describe their devices — provided that they can support their claims — FDA stresses that these terms alone are insufficient to describe a device. For the reasons discussed below, neither FDA nor ECRI advocates the use of these labels without reference to the particular MR environment for which the label applies.

KNOW THE TEST CONDITIONS

Before labeling a device as being either MR safe or MR compatible, the device supplier typically performs testing that, ideally, represents the most severe imaging sequences and the longest scanning times to which the device would be exposed in a certain MR environment. However, a device that is safe or compatible under one set of conditions may not be safe or compatible under more extreme conditions. For example, a device that is tested with a 1.5 T system and found to be compatible — and thus is labeled MR compatible — may actually be incompatible for use with a 3.0 T system. Without additional information, a facility that uses a 3.0 T system might mistakenly believe that this device would be safe for use with its system.

For this reason, both FDA and ECRI recommend that, along with the MR-safe or MR-compatible label, suppliers specify the MR conditions in which the device was tested. That is, descriptions of MR safety or compatibility should also specify information such as the magnetic field strength in which the device was tested (which should be the maximum strength of the magnet), the magnitude and location of the maximum spatial gradient, the specific absorption rate (SAR) of radio-frequency (RF) energy, and the time rate of change of the gradient field (dB/dt level). FDA suggests that suppliers affix this information to the device and that they include detailed information about the testing conditions and the test results in device-related literature, such as an operator's manual.*

* Center for Devices and Radiological Health (CDRH) Magnetic Resonance Working Group. A primer on medical device interactions with magnetic resonance imaging systems [draft online]. 1997 Feb 7 [cited 1999 Apr 26]. Available from Internet: www.fda.gov/cdrh/ode/primerf6.html.

properly labeled and should be physically secured a safe distance (as defined by the equipment supplier) from the MR system through nonmagnetic means — for example, through the use of nonmagnetic bolts, ropes, plastic chains, or weighted base assembles. It is important that the method used to secure the equipment be adequately tested before it is used.

— Any small, ferromagnetic components of a device, such as caps and covers, should be firmly attached to the device (by nonmagnetic means), since ferromagnetic components can work loose over time.

— Be aware that the introduction of ferromagnetic objects can disturb the homogeneity of the static magnetic field. As a result, the presence of such objects could require that the homogeneity of the magnet be restored (re-shimmed).

- If possible, use fiberoptic (ideally), carbon fiber, graphite, or high-impedance leads instead of conductive leads

Thus, more useful than a label specifying only that a device is MR compatible would be a label that states that the device is, for example, "MR compatible in a 1.5 T MR system environment with maximum spatial gradient of 500 G/cm, with SAR of 1.0 W/kg, and with dB/dt of 20 T/sec."

UNDERSTAND APPLICABLE RESTRICTIONS

It's critically important that staff recognize that even though a device is labeled MR safe or MR compatible for a particular environment, the device may not be safe to use at all points within that MR environment. Many MR-compatible devices, such as some physiologic monitors and ventilators (but generally excluding implants), have either gauss-line or RF pulse sequence restrictions. Gauss-line restrictions mean that the device can't be placed in any area where the strength of the static magnetic field exceeds a specified level (expressed in gauss, or G). RF pulse sequence restrictions — which are related to the SAR — mean that the device may become incompatible when certain MR pulse sequences are used.

For example, ECRI is aware of an infusion pump that is marketed for use in a 1.5 T MR environment, but that can't be used in magnetic field strengths that exceed 150 G. Product literature states that the following could occur if the pump is positioned or used in an area where the field strength exceeds 150 G: The pump may pose a projectile hazard, its operation could be affected by the magnetic fields, or the presence of the pump could affect the quality of the MR images. Furthermore, the product literature states that the pump should not be used if unconventional or nonstandard MR system RF pulse sequences (i.e., those other than the standard spin echo, fast spin echo, and gradient echo pulse sequences) are to be used. As long as users adhere to the pump's restrictions in the MR environment, the pump is MR compatible in that environment. However, if not used according to its restrictions, the pump could pose a safety hazard.

Restrictions such as those described in the above example may apply to a wide range of devices that might be used in the MR environment. Because the consequences of using a device in a way that makes it incompatible are so serious, it's essential that MR centers (1) question suppliers about restrictions associated with the use of MR-compatible devices in their particular MR environment, (2) read any pertinent product literature about those restrictions, and (3) abide by the specified restrictions and limitations.

IN CONCLUSION . . .

The composition of the materials used in a device has the greatest effect on whether the device will be safe to use in the MR environment. As we discuss in the main text, magnetic (especially ferromagnetic) and electrically conductive materials are the most problematic in MR environments. Even with this knowledge, however, it's generally not possible to tell simply by looking at a device whether it's MR safe or MR compatible. Thus, we recommend that MR personnel err on the side of caution and assume that materials are neither MR safe nor MR compatible unless proven to be so for their particular MR environment.

Furthermore, because statements of a device's MR safety or compatibility apply only to the specific conditions under which the device was tested, healthcare facilities will need to reexamine each device's compatibility status whenever changes are made to the MR environment, such as when switching to a new MR system or upgrading an existing system. ◆

to limit RF-induced currents. Also, use low-impedance, large-surface-area ECG electrodes, if possible, to maintain as low a current density as possible on the skin/electrode surface. Be sure to follow the suppliers' recommendations for electrode site preparation.

Any leads or electrodes that will be used must be approved for use in the MR environment and must be appropriate for use with the device to which they will be connected.

- Remove all unused or unnecessary electrically conductive material (e.g., electrodes, sensors, cables, RF coils) from the patient and from the bore. If electrically conductive material must remain in the bore, be sure to prevent this material from contacting the patient.
- Provide the patient with an MR-safe or MR-compatible alarm device to alert the staff in case of emergency.

Don't assume that objects such as sandbags and hospital pillows are MR safe.

- At minimum, MR scan rooms should be equipped with a low-oxygen monitor/alarm to alert MR personnel to magnet quenches. Ideally, the monitor/alarm would be configured to automatically activate scan-room ventilation.

Additional, Hazard-Specific Recommendations

In addition to following the general recommendations listed above, facilities should follow the precautions detailed below to prevent the specific hazards described.

To prevent injuries or damage from static-magnetic-field-induced forces

- Always assume that the MR system's static magnetic field is present, and treat the system accordingly.
- Bring nonambulatory patients into the MR environment using a nonmagnetic wheelchair or wheeled stretcher. Ensure that no oxygen bottles, sandbags, or other magnetic objects are concealed under blankets or stowed away on the transport equipment.
- Ensure that IV poles accompanying the patient for the MRI procedure are not magnetic.
- Don't make assumptions about equipment (e.g., sandbags, hospital pillows) being MR safe. Err on the side of caution: Unless a device or piece of equipment has been proven to be MR safe, do not bring it into the MR environment.

On occasion when uncertainty exists, facilities use a powerful handheld magnet to determine whether a piece of equipment or device will likely be attracted by the MR system. While this test may be useful for detecting sizable magnetic objects (for instance, it can distinguish a magnetic oxygen cylinder from a nonmagnetic one), it will not catch all magnetic materials. (For example, it probably won't detect ferromagnetic pellets in a sandbag or ferromagnetic springs in a pillow.)

- Consider installing piped medical gas systems in the individual MR scan rooms if patients will require sedation and/or anesthesia. (The presence of piped medical gas systems can help reduce the likelihood that some problematic equipment, such as oxygen cylinders, would be brought into the MR environment.)
- If uncertainty or confusion exists regarding metallic foreign bodies in a patient's body, x-rays can be used to confirm the presence of metal objects that could pose a problem.
- Determine whether implanted objects and other foreign bodies are MR safe. (Resources that can help healthcare facilities make such determinations are listed in the section that follows these recommendations.) When a facility is uncertain whether an implanted object is MR safe, and the safety of the object in the MR environment cannot be tested, the determination for or against scanning will usually be made by considering the risk-benefit ratio.

To prevent burns caused by RF heating

- As a general rule, do not loop conductive cables or leads or allow cables to cross one another.
- Position all conductive cables and leads so that they do not touch the wall of the magnet bore and, if possible, so that they do not touch the patient (other than at the intended point of patient contact). Thermal and electrical insulation should be placed between the patient and any wires or cables.
- Do not let the patient touch the wall of the magnet bore. Foam padding can be used for insulation.
- Route cables down the center of the magnet — that is, as far away from the bore wall and RF coils as possible — and have them exit the bore as close as possible

to the center of the table. If a cable must be placed close to the bore wall, use insulation (e.g., foam pads, a blanket) to prevent accidental movement of the cable closer to the bore wall.

- Do not cause the patient's body to become a conductive path by making loops with any parts of the patient's body (for example, by allowing the patient's thumb or hand to touch the same-side thigh). Skin-to-skin contact can be reduced by placing foam pads or other nonconductive material under the patient's hands or between the patient's legs, if necessary.
- Place sensors as far as possible from the RF coils.
- Regularly check all sensors, cables, and MRI accessories (e.g., RF coils and cables) for any breaks in insulation. Do not use them if any breaks in insulation are found.
- Install an intercom system between the MR scan room and the control room, and check its operation regularly. Instruct conscious patients to alert staff if they experience warming anywhere, especially at the sites of sensor application.
- During scans on unconscious patients, periodically check the sites of sensor locations for any evidence of heating.
- If heating is a concern for patients with tattoos (including tattooed eyeliner), a cold compress can be used to dissipate heat on such areas of a patient's body.

To prevent problems associated with image artifacts

- Note the locations of magnetic and conductive implants so that any image artifacts caused by such objects are not subsequently misinterpreted on the image, possibly

Metal Detectors in the MR Center?

Why ECRI Says No

In the months since a child was killed by a metal oxygen canister that had been inappropriately brought into the magnetic resonance (MR) scan room of a New York hospital, ECRI has received numerous inquiries from MR centers questioning whether metal detectors should be placed outside MR scan rooms to prevent this type of projectile incident. While the use of metal detectors may seem like a good idea, ECRI recommends against this approach for addressing safety concerns in the MR environment.

Proponents of using metal detectors in MR centers argue that an automatic safety intervention, such as the use of a metal detector, works better than nonautomatic approaches, such as training a large number of employees in the proper safety measures and relying on that training to prevent incidents. This point has some degree of validity — a metal detector would indeed have detected the oxygen cylinder in the New York case. However, metal detectors have some significant limitations for this application, as we learned from our conversations with MR experts. For example:

- Most metal detectors do not differentiate between ferromagnetic materials (i.e., those that can become projectiles and/or are susceptible to torque) and nonferromagnetic materials (i.e., those not affected by static-magnetic-field-induced forces). Because of this, a detector could be set off quite often — even by MR-safe and MR-compatible equipment — leading to frequent false alarms that would likely result in decreased vigilance.
- Metal detectors often provide a false sense of security. Most significantly, they can't detect all materials that could lead to injury in the MR environment. For example, they can't detect very small ferromagnetic fragments, like the one that caused blindness in an incident that occurred in the early 1980s. Furthermore, they have varied, and variable, sensitivity settings, and the skills of metal detector operators can likewise vary. Thus, facilities may not be getting the foolproof protection they think they're getting.

In short, we believe that the presence of a metal detector (1) provides inadequate MR safety and (2) is likely to cause facilities to decrease vigilance in the MR environment — a combination that increases, rather than diminishes, risk. For these reasons, we do not recommend the use of metal detectors for preventing the projectile effect. Instead, we believe that comprehensive MR safety policies (e.g., screening anyone entering the environment, restricting access to the environment) and ongoing training are much more reliable approaches. ◆

leading to a misdiagnosis. (Even though some magnetic and conductive implants may not experience significant static-magnetic-field-induced forces, such objects can still cause image artifacts.)

- Use only MR-compatible audio and video equipment (generally that which uses fiberoptic connections or infrared transmissions) if needed for patient relaxation in the scan room.

To prevent device malfunctions

- Do not subject a patient to an MRI scan if the patient has an implanted device whose function could be altered by the magnetic field. MRI is generally contraindicated unless the implanted device in question has been shown to be unaffected by the MR environment (i.e., it is MR compatible).
- Immediately remove from the patient and from the MR environment any external, non-life-support equipment that does not appear to be functioning properly, even if the device is supposed to be MR compatible. Afterward, be sure to determine the reason for the malfunction (e.g., if the device was not used in accordance with supplier-specified limitations), tag the device appropriately, and verify that no permanent damage has occurred.

Resources

Sources of MR Safety and Device Compatibility Information

Many of the hazards in the MR environment can be eliminated through staff education and through the use of MR-safe or MR-compatible devices. In this section, we list resources that readers can refer to both when researching MR safety issues and when locating MR-safe or MR-compatible equipment, and we provide a starter list of devices and equipment marketed as MR compatible.

Resource List

We confirmed any Web addresses shown below shortly before press time. However, the information on any Web site — and even the site itself — can be transitory. Readers should be sure that a Web resource is reputable (as we believe the ones below to be) before acting on the information provided.*

- FDA has a Web site on MR safety that provides links to documents on safety in the MR environment and that lists standards related to MR safety and MR compatibility. See: www.fda.gov/cdrh/safety/mrisafety.html.
- A Web site created and maintained by Dr. Emanuel Kanal — The Magnetic Resonance Safety Site — exists to rapidly disseminate information about MR safety to the MR community. The site is targeted to the specific needs and questions of the MR community. See: www.radiology.upmc.edu/MRsafety.

  Also note that Dr. Kanal fields MR safety questions directly by e-mail at ekanal@pitt.edu. Since August 1995, more than 6,600 MR safety questions have been answered.
- A Web site created and maintained by Dr. Frank Shellock provides information on MR safety, bioeffects, and patient management to radiologists, technologists, healthcare workers, and patients. It includes the following: a searchable database of more than 900 implants, devices, and materials tested for MR safety; peer-reviewed articles on MR safety; and a downloadable screening form for MR procedures. See: www. MRIsafety.com.

  Also note that Dr. Shellock answers MR safety questions directly by e-mail at frank.shellock@gte.net.
- A list of implants and devices tested for MR safety and MR compatibility is provided in: Shellock FG, ed. *Magnetic resonance procedures: health effects and safety*. Boca Raton (FL): CRC Press; 2001. See Chapter 15 (pages 327-391).

  This text also provides information on health effects, safety issues, and patient management within the MR environment.
- A list of more than 900 implants, materials, devices, and objects that have been tested for MR safety and MR compatibility is provided in: Shellock FG. *Pocket guide to MR procedures and metallic objects: update 2001*. Philadelphia: Lippincott Williams & Wilkins; 2001. See pages 162-287.

  The book also contains MR safety information, including the latest guidelines and recommendations.
- GE offers a Web site that includes an extensive list of MR-compatible products and their suppliers. See: www.gemedicalsystems.com/rad/mri/products/spi/vendors2.html.
- A list of suppliers of MR-compatible instruments and devices can be found in: Jolesz FA, Morrison PR, Koran SJ, et al. Compatible instrumentation for intraoperative MRI: expanding resources [review]. *J Magn Reson Imaging* 1998 Jan-Feb;8(1):8-11. See page 10.
- A list of MR-compatible physiologic monitors is available in: Shellock FG, Lipczak H, Kanal E. Monitoring patients during MR procedures: a review. *Appl Radiol* 1995 Feb;24(2):11-7. See page 13. Also available from Internet: www.invivocorp.com/topics/vital_signs/review.html.
- Another list of MR-compatible monitoring devices can be found in: Elster AD. *Questions and answers in magnetic resonance imaging*. St. Louis: Mosby-Year Book; 1994. See page 252.
- A list of metallic objects, their dimensions, and their category of magnetism is available in: Planert J, Modler H,

* For a discussion of this topic, refer to the Talk to the Specialist article "How Reliable Is Internet Information?" in the January-February 2001 *Health Devices*.

Vosshenrich R. Measurements of magnetism-related forces and torque moments affecting medical instruments, implants, and foreign objects during magnetic resonance imaging at all degrees of freedom. *Med Phys* 1996 Jun;23(6):851-6. See pages 853-854.

Devices and Equipment Marketed as MR Compatible

Many of the hazards in the MR environment can be eliminated through use of MR-safe or MR-compatible devices or equipment. However, such products can be difficult to find. To help healthcare facilities locate products that can be safely used in the MR environment, we have compiled a list of specific device models that have been characterized by their suppliers as being MR compatible. This list is presented on pages 440 through 442.

ABOUT THE LIST

As its name implies, the Starter List of Devices and Equipment Marketed as MR Compatible is not meant to be comprehensive. Rather, it provides a starting point for organizations interested in locating MR-compatible products. When using this information, healthcare facilities should keep the following points in mind:

- The information listed was provided to us by the suppliers themselves. ECRI has not independently verified claims of MR compatibility. Thus, ECRI makes no guarantees of any sort regarding the MR compatibility of the products listed.
- It's imperative that healthcare facilities check with the supplier to determine whether a product can be safely used in their specific MR environment. For example, many of the products listed here have been tested by the supplier for compatibility with 1.5 T MR systems. However, they may not be compatible with 3.0 T systems, which produce greater static-magnetic-field-induced forces. At least one supplier will provide compatibility certificates for its equipment. These certificates list the MR systems that are compatible with the supplier's devices.
- The MR compatibility of many of the products may be restricted, meaning that the products can be used safely only at specific locations within the MR environment or with certain RF pulse sequences. Thus, it's crucial that healthcare facilities identify whether a product has any associated restrictions for use and that they adhere to such restrictions at all times.

SUPPLIER CONTACT INFORMATION

The following suppliers market the devices and equipment listed on pages 440 through 442 as MR compatible. Note that additional suppliers may also market products as being safe for the MR environment.

Allied Healthcare Products Inc. [105171]
St. Louis, MO (USA)
+1 (800) 444-3954, +1 (314) 771-2400
Fax: +1 (314) 771-1806
www.alliedhpi.com

Ambu Inc. [104479]
Linthicum, MD (USA)
+1 (800) 262-8462, +1 (410) 636-1144
Fax: +1 (410) 636-9969
www.ambuusa.com

Avotec Inc. [185713]
Stuart, FL (USA)
+1 (800) 272-2238, +1 (561) 692-0750
Fax: +1 (561) 692-0788
www.avotec.org

Bio-Med Devices [104004]
Guilford, CT (USA)
+1 (800) 224-6633, +1 (203) 458-0202
Fax: +1 (203) 458-0440
www.biomeddevices.com

Blease Medical Equipment Ltd. [150950]
Chesham, Buckinghamshire (UK)
+44 (1494) 784422
Fax: +44 (1494) 791497
www.blease.com

Datascope Corp., Patient Monitoring Division [101670]
Mahwah, NJ (USA)
+1 (800) 288-2121, +1 (201) 995-8000
Fax: +1 (201) 995-8659
www.datascope.com

Datex-Ohmeda (Anesthesia Products), An Instrumentarium Co. [347595]
Madison, WI (USA)
+1 (800) 345-2700, +1 (608) 221-1551
Fax: +1 (608) 222-9147
www.datex-ohmeda.com

Dräger Medical Inc. [371341]
Telford, PA (USA)
+1 (800) 437-2437, +1 (215) 721-5400
Fax: +1 (215) 723-5935
www.draegermedical.com

Dräger Medizintechnik GmbH [374044]
Lübeck (Germany)
+49 451 882 0
Fax: +49 451 882 2080
www.draeger.com

Invivo Research Inc. [103961]
Orlando, FL (USA)
+1 (800) 331-3220, +1 (407) 275-3220
Fax: +1 (407) 249-2022
www.invivoresearch.com

Luxtron Corp. [104768]
Santa Clara, CA (USA)
+1 (800) 627-1666, +1 (408) 727-1600
Fax: +1 (408) 727-1677
www.luxtron.com

Magmedix [401031]
Gardner, MA (USA)
+1 (866) 646-3349, +1 (978) 630-5580
Fax: +1 (978) 630-5583
www.magmedix.com

Mammendorfer Institut für Physik und Medizin (MIPM) GmbH [303199]
München (Germany)
+49 8145 92090
Fax: +49 8145 920933
www.mipm.com

Medex Medical [101538]
Dublin, OH (USA)
+1 (800) 848-1757, +1 (614) 889-2220
Fax: +1 (614) 889-2651
www.medexmedical.cc

Medrad Inc. [105381]
Indianola, PA (USA)
+1 (800) 633-7231, +1 (412) 767-2400
Fax: +1 (412) 767-4128
www.medrad.com

Nonin Medical Inc. [106455]
Plymouth, MN (USA)
+1 (800) 356-8874, +1 (612) 553-9968
Fax: +1 (612) 553-7807
www.nonin.com

Penlon Ltd. [139281]
Abingdon, Oxfordshire (UK)
+44 (1235) 547001
Fax: +44 (1235) 547021
www.penlon.com

PneuPAC Ltd. [150970]
Luton, Bedfordshire (UK)
+44 (1582) 430000
Fax: +44 (1582) 430001

Schiller Medical S.A. [391125]
Wissembourg (France)
+33 (3) 8863 3600
Fax: +33 (3) 8894 1282
www.schiller-medical.com

Siare Hospital Supplies Srl [152520]
Crespellano, BO (Italy)
+39 051 969802
Fax: +39 051 969366
www.siare.it

Ulco Engineering Pty. Ltd. [157051]
Marrickville (Australia)
+61 (2) 9519 5881
Fax: +61 (2) 9550 2841
www.ulco.com.au

Vortran Medical Technology [156127]
Sacramento, CA (USA)
+1 (800) 434-4034, +1 (916) 648-8460
Fax: +1 (916) 648-9751
www.vortran.com

Starter List of Devices and Equipment Marketed as MR Compatible (Page 1 of 3)

Warning: ECRI makes no guarantees of any sort regarding the MR compatibility of the products listed here. Although these products have been described by their suppliers as being MR compatible, the products may not be compatible in all MR environments, or they may not be safe to use at all points within a specific MR environment (e.g., many products need to stay a specified minimum distance from the MR system's magnet). Before using any product in the MR environment, healthcare facilities should ensure that the product is safe for use in their particular MR environment, and they should identify and adhere to any restrictions for use.

DEVICE TYPE	SUPPLIER	MODEL	MARKET
MANUFACTURERS*			
Anesthesia systems**	Blease Medical Equipment Ltd.	Frontline Genius NRI	Worldwide
	Datex-Ohmeda (Anesthesia Products), An Instrumentarium Co.	Aestiva/5 MRI	Worldwide
	Dräger Medical Inc.	Narkomed MRI-2	Asia, North America, South America
	Dräger Medizintechnik GmbH	Titus NMR	Worldwide, except North America
	Penlon Ltd.	Prima SP (all basic models)	Worldwide
	PneuPAC Ltd.	PneuPAC 880 (available with optional ventilator)	Worldwide, except Japan and the United States
	Siare Hospital Supplies Srl	PERSEO MRI Workstation	Worldwide, except Canada and the United States
	Ulco Engineering Pty. Ltd.	Compact (does not include a ventilator)***	Australia and Southeast Asia
	Ulco Engineering Pty. Ltd.	Elite 615 (this model will be replaced by the Signet 615 in 2002)***	Australia and Southeast Asia
Anesthesia ventilators and accessories	Penlon Ltd.	IDP Alarm (self-contained battery-powered alarm for use during ventilation)	Worldwide
	Penlon Ltd.	Nuffield 200	Worldwide
ECG electrodes	Invivo Research Inc.	Quadtrode MRI-Compatible ECG Electrode	Worldwide
Extrication collars and immobilizers	Ambu Inc.	Mini Perfit ACE Extrication Collar (infant, pediatric; adjustable)	Worldwide
	Ambu Inc.	NAJO Head Wedge Immobilizer	Worldwide
	Ambu Inc.	Perfit ACE Extrication Collar (adult; adjustable)	Worldwide
	Ambu Inc.	Perfit Extrication Collar (fixed size)	Worldwide
Infusion pumps	Mammendorfer Institut für Physik und Medizin (MIPM) GmbH	MRI-Caddy	Asia, Europe, and India
	Medex Medical	Medfusion 3010a	Worldwide
	Medex Medical	Protégé 3010	Worldwide
Laryngoscopes	Penlon Ltd.	Mac 3.5 (adult)	Worldwide
	Penlon Ltd.	Miller 1 (infant)	Worldwide
Patient comfort systems	Medrad Inc.	Musicbox Sound System	Worldwide
Physiologic monitors	Datascope Corp., Patient Monitoring Division	MR Monitor†	The Middle East, North America, and South America
	Datex-Ohmeda (Anesthesia Products), An Instrumentarium Co.	S/5 MRI-Compatible Monitor	Worldwide, except Canada and the United States

* This list is not comprehensive. Devices and equipment marketed as MR compatible may be available from other manufacturers and distributors.
** Unless otherwise noted, these systems include an anesthesia ventilator.
*** The device is manufactured to be MR compatible on order; thus, purchasers should specify MR compatible when contacting the manufacturer.
† The Datascope MR Monitor is the same monitor as the Schiller Medical Maglife C. System. Datascope markets the product in the Middle East, North America, and South America.

Starter List of Devices and Equipment Marketed as MR Compatible (Page 2 of 3)

Warning: ECRI makes no guarantees of any sort regarding the MR compatibility of the products listed here. Although these products have been described by their suppliers as being MR compatible, the products may not be compatible in all MR environments, or they may not be safe to use at all points within a specific MR environment (e.g., many products need to stay a specified minimum distance from the MR system's magnet). Before using any product in the MR environment, healthcare facilities should ensure that the product is safe for use in their particular MR environment, and they should identify and adhere to any restrictions for use.

DEVICE TYPE	SUPPLIER	MODEL	MARKET
MANUFACTURERS* (continued)			
Physiologic monitors (continued)	Dräger Medizintechnik GmbH	PM 8050 MRI Patient Monitor	Worldwide, except North America
	Invivo Research Inc.	3100 MRI Vital Signs Monitoring System	Worldwide
	Invivo Research Inc.	3150 MRI Vital Signs Monitoring System	Worldwide
	Invivo Research Inc.	Magnitude MRI Vital Signs Monitoring System	Worldwide
	Invivo Research Inc.	MRI Non-Invasive Blood Pressure Monitor (3103-1)	Worldwide
	Mammendorfer Institut für Physik und Medizin (MIPM) GmbH	Tesla^{plus} (four different models)	Europe
	Medrad Inc.	Model 9500 Multigas Patient Monitor	Worldwide, except Japan
	Schiller Medical S.A.	Maglife C. System	Worldwide**
Pulse oximeters	Invivo Research Inc.	MRI Pulse Oximeter (3109-1)	Worldwide
	Invivo Research Inc.	MRI Pulse Oximeter with Battery (3109-3)	Worldwide
	Mammendorfer Institut für Physik und Medizin (MIPM) GmbH	Tesla^{junior}	Europe
	Nonin Medical Inc.	8600FO (fiberoptic)***	Worldwide
	Nonin Medical Inc.	8600FOM (8600FO with memory)***	Worldwide
Resuscitators			
Automatic, disposable	Vortran Medical Technology	VAR-RC (allows for delivery of FiO_2 at 50% or 100%)	Worldwide
	Vortran Medical Technology	VAR-RT (allows for delivery of FiO_2 at 100%)	Worldwide
Manual	Ambu Inc.	Baby (baby; reusable)	Worldwide
	Ambu Inc.	Mark III (adult; reusable)	Worldwide
	Ambu Inc.	MediBag (adult, infant; disposable)	Worldwide
	Ambu Inc.	Silicone (adult, infant, neonate; reusable)	Worldwide
	Ambu Inc.	SPUR Disposable (adult, infant)	Worldwide
Temperature monitors	Luxtron Corp.	Model 3100	Worldwide
Ventilators and accessories	Allied Healthcare Products Inc.	Omni-Vent Series D MRI-Compatible Ventilator (adult, pediatric, neonatal; transport)	Worldwide
	Allied Healthcare Products Inc.	Omni-Vent Series D/TAU MRI-Compatible Ventilator (adult, pediatric, neonatal; transport)	Worldwide
	Bio-Med Devices	IC-2A MRI-Compatible Ventilator (pediatric, adult; transport)	Worldwide

* This list is not comprehensive. Devices and equipment marketed as MR compatible may be available from other manufacturers and distributors.
** The Datascope MR Monitor is the same monitor as the Schiller Medical Maglife C. System. Datascope markets the product in the Middle East, North America, and South America.
*** These pulse oximeters must be used with Nonin Medical's fiberoptic sensors: 8000FC20 (adult and ped, 20-foot-long lead), 8000FC30 (adult and ped, 30-foot-long lead), 8000FI20 (infant and ped, 20-foot-long lead), and 8000FI30 (infant and ped, 30-foot-long lead).

Starter List of Devices and Equipment Marketed as MR Compatible (Page 3 of 3)

Warning: ECRI makes no guarantees of any sort regarding the MR compatibility of the products listed here. Although these products have been described by their suppliers as being MR compatible, the products may not be compatible in all MR environments, or they may not be safe to use at all points within a specific MR environment (e.g., many products need to stay a specified minimum distance from the MR system's magnet). Before using any product in the MR environment, healthcare facilities should ensure that the product is safe for use in their particular MR environment, and they should identify and adhere to any restrictions for use.

DEVICE TYPE	SUPPLIER	MODEL	MARKET
MANUFACTURERS* (continued)			
Ventilators and accessories (continued)	Bio-Med Devices	MVP-10 MRI-Compatible Ventilator (neonatal, pediatric; transport)	Worldwide
	Bio-Med Devices	Various MRI-compatible accessories (e.g., oxygen blenders, cylinders, and regulators)	Worldwide
	PneuPAC Ltd.	babyPAC/MRI	Worldwide
	PneuPAC Ltd.	paraPAC/MRI	Worldwide
	PneuPAC Ltd.	transPAC/MRI	Worldwide
	PneuPAC Ltd.	ventiPAC/MRI	Worldwide
Visual and auditory stimulation	Avotec Inc.	Silent Scan audio system**	Worldwide
	Avotec Inc.	Silent Vision video system**	Worldwide
DISTRIBUTOR*			
Miscellaneous equipment and accessories	Magmedix	Supplier distributes a wide variety of MR-compatible equipment, including: ▪ Patient comfort systems ▪ Patient transport equipment (e.g., wheelchairs, stretchers) ▪ Physiologic monitoring equipment (e.g., physiologic monitoring systems, pulse oximeters, stethoscopes, laryngoscopes) ▪ Respiratory equipment (e.g., ventilators, tracheal suction, oxygen and gas cylinders, regulators, flowmeters, blenders) ▪ Nonmagnetic general equipment (e.g., carts, fire extinguishers, IV poles, stands, stools, tables, tools, tweezers, warning signs) ▪ Measuring, testing, and shielding equipment (e.g., handheld metal detectors, monitor enclosures, gaussmeters, phantoms)	Worldwide

* This list is not comprehensive. Devices and equipment marketed as MR compatible may be available from other manufacturers and distributors.
** Models are available for both clinical and fMRI applications.

Bibliography

American Association of Physicists in Medicine (AAPM). Site planning for magnetic resonance systems. New York: American Institute of Physics Inc.; 1987. Report No. 20.

Black PM, Moriarty T, Alexander E 3rd, et al. The development and implementation of intraoperative MRI and its neurosurgical applications [online]. [cited 1999 Apr 23]. Available from Internet: http://splweb.bwh.harvard.edu:8000/pages/papers/intra/intra.html.

Center for Devices and Radiological Health (CDRH) Magnetic Resonance Working Group:

A primer on medical device interactions with magnetic resonance imaging systems [draft online]. 1997 Feb 7 [cited 1999 Apr 26]. Available from Internet: www.fda.gov/cdrh/ode/primerf6.html.

Guidance for testing MR interaction with aneurysm clips [draft online]. 1996 May 22 [cited 1999 Sep 23]. Available from Internet: www.fda.gov/cdrh/ode/odeclip.pdf.

Chaljub G, Kramer LA, Johnson RF, et al. Projectile cylinder accidents resulting from the presence of ferromagnetic nitrous oxide or oxygen tanks in the MR suite. *AJR Am J Roentgenol* 2001 Jul;177(1):27-30.

Chen DW. Boy, 6, dies of skull injury during M.R.I. *N Y Times* 2001 Jul 31;Sect. B:1, 5.

Chu WK, Sangster W. Potential impacts of MRI accidents. *Radiol Technol* 1986 Nov-Dec;58(2):139-41.

Condon B, Hadley DM, Hodgson R. The ferromagnetic pillow: a potential MR hazard not detectable by a hand-held magnet. *Br J Radiol* 2001 Sep;74(885):847-51.

Dempsey MF, Condon B, Hadley DM. Investigation of the factors responsible for burns during MRI. *J Magn Reson Imaging* 2001 Apr; 13(4):627-31.

Diagnostic Assurance Professionals. Magnetic resonance imaging (MRI) [online]. [cited 1999 Mar 30]. Available from Internet: www.wellweb.com/diagnost/arnief/mri.htm.

Duffy FJ, May JW. Tissue expanders and magnetic resonance imaging: the "hot" breast implant. *Ann Plast Surg* 1995 Dec;35(6):647-9.

Ebraheim NA, Savolaine ER, Zeiss J, et al. Titanium hip implants for improved magnetic resonance and computed tomography examinations. *Clin Orthop* 1992 Feb;(275):194-8.

ECRI:

Avoiding thermal injuries during MRI studies. *Healthc Risk Control* 1996 Jan;4:Radiology 5.3:1-2.

Ferromagnetic sandbags are hazardous in magnetic resonance imaging (MRI) environments [hazard report]. *Health Devices* 1998 Jul; 27(7):266-7.

Magnetic resonance imaging (MRI) units. *Healthc Prod Compar Syst* 1999 May:1-16.

MRI safety considerations. *Healthc Risk Control* 1996 Jan;4:Radiology 5:1-6.

Patient death illustrates the importance of adhering to safety precautions in magnetic resonance environments. *Health Devices* 2001 Aug; 30(8):311-4.

Patient safety during MRI. *Healthc Risk Control* 1996 Jan;4:Radiology 5.2:1-5.

Thermal injuries and patient monitoring during MRI studies [hazard report]. *Health Devices* 1991 Sep;20(9):362-3.

Eisenkraft JB, Leibowitz AB. Ventilators in the operating room. *Int Anesthesiol Clin* 1997 Winter;35(1):87-108.

Elster AD. *Questions and answers in magnetic resonance imaging.* St. Louis: Mosby-Year Book; 1994:252.

Feldman DR, Conway WF, Spicer KM, et al. Ferromagnetic artifact from a tissue expander used for breast reconstruction [letter]. *Plast Reconstr Surg* 1995 Feb;95(2):426-7.

Fontaine JM, Mohamed FB, Gottlieb C, et al. Rapid ventricular pacing in a pacemaker patient undergoing magnetic resonance imaging. *Pacing Clin Electrophysiol* 1998 Jun;21(6):1336-9.

Gangarosa RE, Minnis JE, Nobbe J, et al. Operational safety issues in MRI. *Magn Reson Imaging* 1987;5(4):287-92.

GE Magnetic Resonance. Listing of MR compatible equipment vendors [online]. 1998 [cited 1999 May 12]. Available from Internet: www.gemedicalsystems.com/rad/mri/products/spi/vendors2.html.

Gould SW, Darzi A. The interventional magnetic resonance unit — the minimal access operating theatre of the future? *Br J Radiol* 1997 Nov;70:S89-97.

Hatfield M, Eschbach J. Metallic foreign bodies and MR imaging [letter]. *AJR Am J Roentgenol* 1996 Dec;167(6):1597-8.

Heiken JP, Brown JJ, eds. *Manual of clinical magnetic resonance imaging*. 2nd ed. New York: Raven Press; 1991.

Jolesz FA:

Image-guided procedures and the operating room of the future [online]. [cited 1999 Apr 26]. Available from Internet: http://splweb.bwh.harvard.edu:8000/pages/papers/horizon/horizon.html.

Interventional and intraoperative MRI: a general overview of the field [review]. *J Magn Reson Imaging* 1998 Jan-Feb;8(1):3-7.

Jolesz FA, Morrison PR, Koran SJ, et al. Compatible instrumentation for intraoperative MRI: expanding resources [review]. *J Magn Reson Imaging* 1998 Jan-Feb;8(1):8-11.

Kanal E:

Magnetic resonance safe practice guidelines of the University of Pittsburgh Medical Center. In: Kanal E, ed. Special cross-specialty categorical course in diagnostic radiology: practical MR safety considerations for physicians, physicists, and technologists [RSNA 2001 syllabus]. Radiological Society of North America; 2001:155-63.

Magnetic Resonance Safety Web Site. [cited 1999 Mar 30]. Pittsburgh (PA): University of Pittsburgh Medical Center. Available from Internet: www.radiology.upmc.edu/MRsafety.

Kanal E, Shellock FG, Talagala L. Safety considerations in MR imaging. *Radiology* 1990 Sep;176(3):593-606.

Kaut-Roth C. MRI safety [online]. 1996 Nov [cited 1999 Mar 30]. Available from Internet: www.t2star.com/safety_1/safety1.html.

Keeler EK, Casey FX, Engels H, et al. Accessory equipment considerations with respect to MRI compatibility [review]. *J Magn Reson Imaging* 1998 Jan-Feb;8(1):12-8.

Leeson-Payne CG, Towell T, Englishby VL. Magnetic mayhem [letter and reply]. *Anaesthesia* 1996 Nov;51(11):1081-2.

Liu CY, Farahani K, Lu DS, et al. Safety of MRI-guided endovascular guidewire applications. *J Magn Reson Imaging* 2000 Jul;12(1):75-8.

Liu H, Hall WA, Martin AJ, et al. Biopsy needle tip artifact in MR-guided neurosurgery. *J Magn Reson Imaging* 2001 Jan;13(1):16-22.

McJury M, Shellock FG. Auditory noise associated with MR procedures: a review. *J Magn Reson Imaging* 2000 Jul;12(1):37-45.

Medical Devices Agency (MDA), U.K. MRI static magnetic field safety considerations — the projectile effect caused by the influence of the static magnetic field of magnetic resonance imaging systems [device bulletin]. London: MDA; 1998 Apr. MDA/DB/9803.

Medical Devices Directorate. Guidelines for magnetic resonance diagnostic equipment in clinical use with particular reference to safety. Norwich (UK): Her Majesty's Stationary Office (HMSO); 1993 Feb.

National Health and Medical Research Council. Safety guidelines for magnetic resonance diagnostic facilities. Canberra (Australia): Australian Government Publishing Service; 1991. Radiation Health Series No. 34.

NessAiver M. *All you really need to know about MRI physics.* Baltimore: Simply Physics; 1997.

Planert J, Modler H, Vosshenrich R. Measurements of magnetism-related forces and torque moments affecting medical instruments, implants, and foreign objects during magnetic resonance imaging at all degrees of freedom. *Med Phys* 1996 Jun;23(6):851-6.

Power W, Collum LM. Magnetic resonance imaging and magnetic eye implants [letter]. *Lancet* 1988 Jul 23;2(8604):227.

Sawyer-Glover AM, Shellock FG. Pre-MRI procedure screening: recommendations and safety considerations for biomedical implants and devices [review]. *J Magn Reson Imaging* 2000 Jul;12(1):92-106.

Schenck JF:

MR safety at high magnetic fields. *Magn Reson Imaging Clin N Am* 1998 Nov; 6(4):715-30.

Safety of strong, static magnetic fields [review]. *J Magn Reson Imaging* 2000 Jul;12(1):2-19.

The role of magnetic susceptibility in magnetic resonance imaging: MRI magnetic compatibility of the first and second kinds. *Med Phys* 1996 Jun;23(6):815-50.

Seidenwurm DJ, McDonnell CH 3rd, Raghavan N, et al. Cost utility analysis of radiographic screening for an orbital foreign body before MR imaging. *AJNR Am J Neuroradiol* 2000 Feb;21(2):426-33.

Shellock FG:

International Safety Information Resource Web Site. 2000 [cited 2000 Aug 29]. Available from Internet: www.MRIsafety.com.

MR imaging and cervical fixation devices: evaluation of ferromagnetism, heating, and artifacts at 1.5 tesla [technical work]. *Magn Reson Imaging* 1996;14(9):1093-8.

Pocket guide to MR procedures and metallic objects: update 2001. Philadelphia: Lippincott Williams & Wilkins; 2001.

Shellock FG, ed. *Magnetic resonance procedures: health effects and safety.* Boca Raton (FL): CRC Press; 2001.

Shellock FG, Kanal E:

Burns associated with use of monitoring equipment during MR procedures [letter]. *J Magn Reson Imaging* 1996 Jan-Feb;6(1):271-2.

Magnetic resonance bioeffects, safety, and patient management. 2nd ed. New York: Raven Press; 1996.

Shellock FG, Lipczak H, Kanal E. Monitoring patients during MR procedures: a review. *Appl Radiol* 1995 Feb;24(2):11-7. Also available from Internet: www.invivocorp.com/topics/vital_signs/review.html.

Shellock FG, Morisoli S, Kanal E. MR procedures and biomedical implants, materials, and devices: 1993 update. *Radiology* 1993 Nov; 189(2):587-99.

Silverman SG, Jolesz FA, Newman RW, et al. Design and implementation of an interventional MR imaging suite. *AJR Am J Roentgenol* 1997 Jun;168(6):1465-71.

Sobol WT. Artifacts in magnetic resonance imaging. *Appl Radiol* 1994 Aug;23(8):11-6.

Westchester Medical Center:

WCJCC incident review [online]. 2001 [cited 2001 Sep 25]. Available from Internet; select the Investigation Report link located at: www.wcmc.com/news/ba_8.22.01.html.

Westchester Medical Center releases internal MRI investigation report [news release online]. 2001 Aug 21 [cited 2001 Sep 25]. Available from Internet: www.wcmc.com/news/ba_8.22.01.html. ◆

The ABCs of ASPs

What Healthcare Facilities Need to Know when Choosing an Application Service Provider

Summary. Two of the most important questions to consider when selecting a new software application are (1) does the application include the features and functionality desired? And (2) should the application be implemented and supported by in-house personnel or by an outside organization — namely, an application service provider, or ASP? Answering the first question is usually a straightforward process. Answering the second question, however, can be more difficult — especially considering the recent proliferation of ASPs and the wide variety of healthcare services now being offered by these organizations.

In this article, we discuss the advantages and disadvantages of contracting with an ASP and offer guidance to help healthcare facilities determine whether an ASP would be an appropriate choice for their situation. We also provide guidance to help those facilities that choose to contract with an ASP select an appropriate provider and pricing model.

475950
424-001

The Basics
About Application Service Providers

ASPs: An Alternative to In-House Installations

When selecting a new software application, healthcare facilities must consider not only whether the application includes the desired features and functionality, but also whether the application should be implemented and supported by in-house personnel or by an application service provider (ASP). ASPs are organizations that provide clients with access to and use of software applications through a network in exchange for payments made on an ongoing basis (e.g., pay-per-use, fixed monthly fees).

For many facilities, the ASP model of software acquisition, implementation, and management is an attractive alternative because it provides access to desired applications without requiring a large initial capital outlay or dedicated, in-house staff of information technology (IT) personnel to install and maintain the system. With the ASP model, the ASP owns, hosts, and manages the software application and the corresponding hardware and network from its location remote from the healthcare facility. The ASP also hosts and manages the data entered into or generated by the software application, and in some cases it retains ownership of this data. Typically, the client — that is, the healthcare facility — provides its own workstations and a means to connect to the ASP's network. (The ASP may operate using either the Internet or dedicated lines.)

Decisions about whether to use an ASP, and which ASP to use, are complicated by a variety of factors. Although the ASP concept is not new (ASPs have existed for years under different names, such as "shared services"), many of the ASP services are. The tremendous growth in the number of ASPs in recent years means that many of the companies offering these services are still young; thus, information about an ASP's long-term performance or its future stability may not be available. Another complicating factor is that ASPs can differ greatly from one another, both in the services offered and in how they define themselves. This can make direct comparisons of ASP alternatives difficult. Finally, it's unlikely that a facility will be able to identify a single ASP that meets all its outsourcing needs. As a result, the facility could end up dealing with multiple vendors for different software applications.

When considering a new software application, some healthcare facilities will look specifically for an ASP solution — often because the facility wishes to minimize staffing requirements or capital expenditures. Other facilities will specifically avoid the ASP approach — perhaps because they wish to maintain greater control over the application. Many others, however, will investigate both ASPs and traditional in-house-supported software options to find the solution that best meets their clinical, operational, and financial needs.

Available Healthcare Applications and Pricing Models

HEALTHCARE APPLICATIONS

ASPs currently offer a variety of software applications for healthcare facilities, and the number of healthcare applications available through ASPs is expected to increase. Current healthcare ASPs focus on a few general areas: clinical ordering, clinical data and reference management, and financial and benefit services. We briefly describe each of these areas below. An application may be limited to one of these functions, or it may provide a comprehensive service that combines several areas.*

Clinical ordering. The use of an ASP's clinical ordering application can, for example, allow physicians to order laboratory tests, allow clinicians to retrieve those orders to obtain samples, and allow clinical laboratory personnel to view the orders and run the necessary tests. Similarly, with medication order-entry services, which are offered by some ASPs, clinicians can order prescriptions for patients, pharmacy staff can retrieve and fill those orders, and nurses can document administration of the medications. In addition, some pharmacy order-entry ASPs will even flag hazardous drug interactions in a manner similar to in-house developed or supported order-entry applications.

Scheduling services may also be offered as part of a clinical ordering application. In one example of such a service, a physician would schedule a patient for an exam, and administrative staff and technicians would subsequently review the schedules and modify them as necessary. In addition, a few ASPs offer dictation services that allow a clinician to dictate reports using a speech-recognition application.

* Computerized provider order-entry (CPOE) systems are one example of a comprehensive service available through an ASP arrangement. For more information about CPOE systems, refer to ECRI's Evaluation in the September-October 2001 *Health Devices.*

Clinical data and reference management. Data storage and retrieval is another common ASP service. For example, the ASP may store clinical laboratory data and allow clinicians to retrieve that data, or it may offer image archiving and retrieval services for use by the facility's picture archiving and communication system (PACS) or cardiology information system. In the latter example, the arrangement might work as follows: The facility's PACS or cardiology information system would transmit studies to the ASP for storage. The radiologist or cardiologist would then access the ASP to review the desired studies, along with any relevant prior studies. Any changes made by the radiologist or cardiologist would be saved to the ASP system, possibly along with reports created by the radiologist or cardiologist. Finally, referring physicians would be able to access the reports and related images when needed.

A capability offered by some ASPs is a computer-based patient record system (CPRS). This system would replace traditional paper-based records or an in-house CPRS. In conjunction with these systems, some ASPs also offer data-analysis capabilities that facilitate the collection and analysis of data from numerous patients at a facility. These functions can be used, for example, to determine the best practices and outcomes for patients.

Additionally, some ASPs offer clinical reference applications. These include medical dictionaries, medical databases, and drug and health information that can be referenced by clinicians as needed.

Financial and benefit services. ASPs offer a variety of services in this area, such as applications for claims submissions and claims status monitoring, coding, patient billing and account inquiry, and referral processing. ASPs also offer physician directories, benefits comparisons, patient enrollment information, authorization information, and other information related to health plan benefits. In addition, some ASPs offer enterprise resource planning services, which allow healthcare organizations to plan resource allocation to improve efficiency and reduce costs.

PRICING MODELS

One of the most significant advantages of using an ASP is that the service provides the facility with financial flexibility. Rather than making a large initial capital investment to acquire and install the software, a facility can obtain the application on more of a "pay-as-you-go" basis. (As discussed under Cost Issues on page 448, the use of an ASP shifts costs from the capital budget to the operating budget.) In addition, although individual ASPs may offer only one or two pricing options, different ASPs offer different pricing models, so facilities can look for a model that will best fit their needs. We discuss some of the most commonly offered models below.

Pay-per-use. This is perhaps the most common pricing method for ASPs. Under the pay-per-use model, a facility is charged a fixed fee (e.g., $1 to $15) for each ASP use. This model can be applied in a variety of ways; for example:

- An ASP that offers a scheduling application might charge a fee for each patient visit that the healthcare facility schedules.
- An ASP that offers PACS image archiving capabilities might charge a fee for each image or study that the facility stores, or it might offer storage for free but charge a fee each time the facility accesses an image or study for review.
- An ASP that offers an application for handling billing services and insurance enrollment determinations might charge one fee for each billing transaction and another fee for each enrollment lookup.

These examples illustrate how pay-per-use options can vary depending on the ASP service provided. Facilities considering this option will need to investigate which per-use pricing model will best meet their needs. (See the Money Matters feature on page 449 for advice on making this choice.)

Pay-per-user. ASPs may offer one of two pay-per-user options:

- In one option, a healthcare facility simply pays a fee for each user who will access the software application (e.g., $250 to $1,000 per user per month).
- In the other option, multiple user levels are established, and pricing varies for each of these levels. Returning to the PACS archiving example, for instance, a higher fee would be charged for radiologists than for referring physicians since a radiologist will use the service considerably more than the referring physician. In exchange for the higher fee, users may be given additional benefits, such as increased access time each month or access to additional functionality and features.

Percentage-of-revenue. Under this pricing method, a facility is charged a fee relative to the amount of revenue it generates. For instance, a laboratory information system ASP may charge a fee based on the monthly revenue generated by the facility's clinical laboratory.

Fixed-fee. Under fixed-fee pricing, healthcare facilities pay the ASP a fixed fee each month, similar to a rental

fee. In some cases, the ASP may offer a "rent-to-own" option that allows the facility to apply monthly fees toward payment for software or hardware.

ASP or In-House Installation?

10 Factors to Consider

Facilities will need to weigh a variety of advantages and disadvantages when deciding whether to acquire an application as an ASP or as an in-house installation. We discuss 10 of the most important considerations below. Note that, in some cases, a factor may be an advantage for one facility and a disadvantage for another.

1. Cost Issues

Acquiring an application as an ASP shifts costs from the capital budget to the operating budget. For many healthcare organizations with limited budgets, this is a key advantage of the ASP approach and a primary reason for acquiring an application as an ASP. Facilities with limited budgets might not otherwise be able to afford the high acquisition costs of new software applications, the costs of future upgrades to an application (upgrades are typically included in an ASP agreement), or the costs of new servers, archives, or other hardware needed to host the increasingly complex and data-intensive applications used in healthcare.

By selecting an ASP, such healthcare organizations can access new applications and avoid technology obsolescence without significant capital costs. Also, because the facility pays only for what it uses, an ASP may result in cost savings over time for a facility with relatively low demand for the application.

For larger healthcare organizations with greater resources, however, an in-house facility-owned application may be a more financially advantageous approach. Many larger healthcare organizations can afford the software acquisition costs, the costs of routinely implementing new software and hardware, and the costs of hiring, training, and retaining IT personnel to implement and support the application. Furthermore, because larger institutions will have a greater number of users or will use an application more times than a smaller facility, they are likely to incur much higher ASP fees.

2. Information Technology Expertise

Healthcare organizations often find that they cannot attract qualified IT personnel or cannot afford to pay the high salaries required to hire and retain such personnel. As a result, facilities often lack the staff required to meet their IT needs. Using an ASP means that it is the ASP — and not the healthcare organization — that supports the software and, in some cases, the hardware and network. Therefore, healthcare facilities may be able to operate with fewer IT employees, which may help reduce costs and reduce the need for more qualified personnel.

3. Speed of Implementation

Installing new software and its related hardware can be time-consuming, as well as costly. However, when an ASP is used, the application is ready — at least in theory — at the time of subscription to the ASP, allowing almost instantaneous implementation of new software. In reality, some delays will likely be encountered — such as if a suitable infrastructure does not exist, if interfacing to existing systems or hardware is difficult, or if data conversion or migration from an existing system is problematic or difficult. However, even with delays such as these, an ASP implementation will usually be much faster than an in-house installation.

4. Scalability

As a healthcare organization grows, it will eventually exceed the capabilities and capacities of its existing technologies. Expanding in-house applications to meet the facility's growing demands can be expensive (e.g., additional software licenses and new hardware may need to be purchased) and can take a considerable amount of time. Expansion may even result in system downtime — for example, while data is migrated from an old archive to a new, larger archive. However, with an ASP, expansion can be achieved relatively painlessly. New users can be added at any time, and the facility does not have to worry about purchasing additional hardware to support its increasing IT needs as it grows. Instead, the ASP upgrades its hardware to improve its own capabilities. Often, this is done without affecting users.

5. Disaster Recovery

Many healthcare organizations require that data be stored off-site as part of their disaster recovery or contingency plans. Because most ASPs back up their data remotely, the use of an ASP eliminates the need to rent additional space to house data off-site.

6. The Use of Software on a Trial Basis

Because the cost of purchasing and installing new software is high, healthcare facilities typically can't risk investing in an application that isn't critical to the facility's operations or that may prove to be of only limited value. By using an ASP, however, a healthcare organization can more readily try new software applications on a trial basis to gauge their usefulness. For a small cost, the organization can give a limited number of users access to new software. Input from these individuals can then be used to determine whether the application should be implemented on a larger scale. (Note, however, that data conversion or interface issues may make limited trials problematic in some instances.)

7. Security and Privacy Measures

Regardless of whether an in-house or ASP application is used, measures must be taken to ensure data security. Some healthcare facilities will prefer to leave security issues to an ASP, which may offer better security than is provided by current practice at the facility. Other facilities, however, may be uncomfortable with transmitting data outside the facility over the Internet or other external networks, entrusting this data to an outside organization, or

Money Matters

Considerations for Selecting an ASP Pricing Model

As described in the main text, ASPs offer a variety of pricing models: some are based on usage or revenue, while others involve fixed fees. Facilities that are considering ASPs will need to compare the options offered by each supplier to identify the model that provides the most affordable solution.

When evaluating pricing models, be sure to consider the following:

- **Basic pricing structure.** In addition to choosing from among the different pricing models — such as pay-per-use, pay-per-user, percentage-of-revenue, and fixed-fee pricing — you may need to choose from among the different implementations of a specific option. For example, a facility interested in a pay-per-use pricing model for a PACS-study-archiving ASP might need to choose between an implementation that charges a fee for each study that is stored and one that charges a fee each time a study is viewed. If referring physicians as well as radiologists typically view studies, then a pay-per-study-stored option may be less expensive than a pay-per-view option. On the other hand, if only radiologists view studies and if the number of prior studies viewed for each patient is minimal, then the pay-per-view option may be more cost-effective.
- **Additional service fees.** ASPs often charge fees for other services. For example:
  - — An ASP may charge for system setup. As part of this service, the ASP would visit the healthcare facility, set up the connection to the ASP, interface the ASP to existing systems, and possibly provide user training.
  - — An ASP may charge monthly maintenance and service fees. These fees are typically fixed, regardless of the pricing model offered by the ASP, and are used to cover hardware and software maintenance and upgrades. As part of these fees, healthcare facilities are typically entitled to service calls and/or e-mail support. As service coverage increases (e.g., from 9-to-5 daily coverage to 24-hour coverage), the service fee increases.
- **The costs of change.** A facility should find out how much the ASP will charge for adding users. It also should determine whether the price structure will change as usage changes. For example, the ASP may offer a discounted price-per-use if the number of uses reaches a certain volume.
- **Penalties.** The ASP should be made to specify any penalties it pays for failing to meet its uptime guarantees. Additionally, the facility should determine any penalties that it would owe for escaping a contract early, for switching to another ASP, or for moving data to another system or ASP.

Once a facility has a clear picture of the costs it can expect with its preferred ASP alternative, it can perform a life-cycle cost analysis to determine whether the ASP will prove to be more cost-effective than an in-house application. ◆

having security measures lie outside the facility's control. These organizations will prefer an in-house application with data security under their own control.

Note that even when an ASP model is used, the healthcare facility will still be responsible for some aspects of protecting privacy, such as providing training and enforcing personnel data use practices. In addition, the healthcare facility will be responsible for ensuring that data security and privacy are maintained during data transmission to the ASP. (Data transmitted over the Internet or other networks may be exposed to additional risk of interception that may jeopardize the data's integrity and privacy.) And the facility will need to verify that the ASP has good data security and privacy practices.

8. Consistency of Performance

ASPs rely on the Internet or other networks as the means for transmitting information from a healthcare facility to the ASP, and vice versa. Unfortunately, fast, reliable connections to the Internet or outside networks are still not always available. If, for example, a facility's Internet connection fails or if transmission speeds are slowed, then an application or data within that application may not be available to the facility when it is needed.

While improvements to networking technology are continually being made, the use of an internal network will generally be more reliable than remote data transmission. However, if the ASP service is delivered through a dedicated line from a high-quality data carrier, reliability may be as good as, or better than, an internal network.

9. Level of Customization

Because ASPs need to develop applications that are generic enough to apply to a broad range of facilities, ASP applications typically cannot be customized to the same degree as in-house installations (if they can be customized at all). As a result, an ASP application may not be able to meet a specific facility's preferences or requirements, or it may not be able to offer all the features or functionality that users expect. While ASPs continually enhance their applications, enhancements will usually be made to appeal to a broad range of healthcare facilities. Thus, specific requests that come from only a few facilities may never be implemented.

10. Market Uncertainty and Organizational Stability

Many ASPs are small organizations that have only limited experience in healthcare. Thus, the risk that an ASP will cease operation in the future is very real. Even in cases where larger organizations offer ASP services, the services themselves are relatively new and still unproven. As a result, these organizations could decide to terminate the services if they are not profitable. ECRI expects to see continuing changes in the market, with some ASPs ceasing operations, while other organizations introduce new ASP services. In addition, the costs of ASP services will likely change as the ASP marketplace continues to develop.

Weighing Each Option

The ASP approach theoretically offers several advantages, especially for small and midsized facilities that (1) cannot afford large capital expenditures or (2) cannot afford to hire, train, and retain substantial IT staff. However, the ASP approach does have associated disadvantages that must be considered. In some cases, these limitations will steer a facility toward an in-house installation. In particular, facilities with greater financial and IT department resources may find an in-house installation to be the more appealing option. (Refer to the table on page 451 for a brief summary of the pros and cons of using an ASP.)

Any facility considering the use of an ASP should carefully investigate the ASP options currently available. Before signing a contract with an ASP, the facility needs to be sure that it is fully comfortable with both the ASP and its services.

Selecting an ASP

ECRI recommends that healthcare facilities investigate both traditional in-house software options and ASPs when planning to acquire a new application. For those facilities that decide that an ASP implementation will best meet their clinical, operational, and financial needs, the next step will be to begin the ASP selection process — a process that can be very time-consuming.

Because of the vast number of ASP offerings currently available and the relative newness and inexperience of many ASPs, it is imperative that facilities invest the time required to carefully investigate alternatives. If a facility chooses an ASP that later ceases operation or that does not provide the type of services expected, the facility may find it difficult — or maybe even impossible — to recover its data and transfer it to another system or ASP. In addition, switching ASPs can result in substantial additional

expense, as well as significant inconvenience for users, who would be required to learn a new application that might not have all the features or functionality of the previous application.

Selection Considerations

ASP CHARACTERISTICS

When assessing potential suppliers, we recommend that facilities consider — in addition to the functional and other differences in ASPs' systems — the following characteristics:

- The length of time the ASP has been in business. ASPs that have existed for several years may offer additional comfort for an organization worried about the experience of the ASP and whether the ASP will continue to exist in the future.
- The software and hardware used and supported by the ASP. An assessment of the age of ASP hardware and software may illustrate the capability of the system, and it may indicate how often the ASP updates its infrastructure. Also, a healthcare facility may be aware of specific problems with or limitations of certain hardware or software, which could provide clues about the stability of the ASP infrastructure.
- The security and privacy guarantees offered and methods used by the ASP. Because security and privacy are in the hands of the ASP, healthcare facilities should be assured that their data will be well protected. Characteristics of a complete security program include whether the ASP does the following: assigns security officers, performs regular security audits, provides details of security audits to users, and details the specific security methods used.
- The ASP's data transfer method. Dedicated lines are used for many data transfers to the ASP, but differences in data security and transmission speeds can still exist; this issue may be of particular concern if the Internet is used.
- The number of users currently supported by the ASP. This information will provide some indication of the ASP's experience. However, the facility should determine whether an ASP's use of shared servers and archives could diminish service performance if too many users share limited resources.
- The ASP's technical and business partners. If the ASP uses unreliable hardware providers, for example, the ASP may not receive upgrades in a timely manner, or it may experience considerable downtime.
- The ASP's support capabilities and costs. If an installation will be complex (such as one that would require interfaces to existing systems) or if data conversion will be difficult, the facility will need to consider whether the ASP can provide adequate support to handle installation and conversion in a timely manner. In addition, the facility should investigate installation and support costs, which in some cases can be significant and which may not be included as part of the standard (e.g., pay-per-use, pay-per-user) contract.
- The training offered by the ASP. As with any application, the odds that users will avoid using the system or will use the system incorrectly increase if the level of training is insufficient.
- The uptime guarantees offered by the ASP. Even a small period of downtime for a critical application may be unacceptable.
- The pricing options offered by the ASP. Different ASPs offer different pricing options, and not all options will make economic sense for all facilities. (Refer to the discussion of Pricing Models on page 447, as well as the Money Matters feature on page 449.)

Summary of ASP Pros and Cons

Pros	Cons
▪ Costs shift from capital budget to operating budget (which some facilities may prefer)	▪ Reliance on outside organization for data security/privacy
▪ Reduced personnel needs	▪ Inconsistent performance may be likely unless dedicated lines are used
▪ Rapid implementation	▪ Limited customization
▪ Simple scalability	▪ Market uncertainty
▪ Off-site data storage for disaster recovery	
▪ Ability to use software on a trial basis (without incurring significant expense)	

USER EXPERIENCE

One of the most critical parts of the ASP selection process is to contact other users of the ASP. Ideally, at least some of the users should be located in the same geographic region as the facility. This will allow the facility to gauge whether the distance between the facility and the ASP servers and archives will play any role in quality of service.

We recommend that facilities ask for a substantial number of references when considering a particular ASP. The more references you contact, the more confidence you'll have in your selection decision. An ASP that can't or won't supply more than a few references may not support many users,

or it may be attempting to limit your contacts to only facilities that will likely provide a favorable review.

When contacting other users, be sure to address the following questions:

- Has the ASP met its uptime guarantees?
- Has the service met all the users' needs and expectations?
- Can new users be easily added to the service?
- Have service costs changed over time?
- Does the ASP provide sufficient training and support?

You'll need to speak with both IT staff and system users, since these groups may have different perspectives on the ASP.

Contract Considerations

Once an ASP has been selected, the facility should ensure that the contract explicitly defines its needs. Details that should be specified in the contract include the following:

- Agreed-upon uptime and performance (e.g., speed of access to clinical data) guarantees.
- Clear definitions of who owns and supports each component of the service (e.g., software, hardware, data) and how upgrades to those components will be conducted. Facilities should ensure that they retain ownership of their data.
- Time requirements for implementing the service, as well as time requirements for adding new users.
- Descriptions of the privacy, security, and disaster recovery measures that the ASP will provide, as well as the penalties that will be imposed if these measures are not followed or if security is violated.
- The length of time that the contract will remain in force and assurances that the ASP will help transfer and convert data if the facility chooses to switch to another ASP or system. A penalty-free escape clause should also be included.

  One reason it is important to choose an ASP carefully is that switching from one ASP to another can be both difficult and expensive. In addition to penalties that an ASP may charge for canceling a service, the ASP may charge migration fees to move data to another ASP or to a facility's archive. Furthermore, if the data isn't in a standard format, an expensive data conversion process may be required. Thus, we recommend that facilities gain assurances in the contract that the ASP will help transfer and convert data.
- Specific details on pricing and payments. Regardless of the type of pricing offered by the ASP, the ASP should clearly define in its contract any additional fees that it will charge. (See the Money Matters feature for additional discussion.)

Bibliography

Cross MA. Out with the old, in with the new [case study]. *Health Data Manag* 1999 Dec;7(12):68-71.

Kiel JM. Buy software or "pay-per-view": the ASP option. *MD Comput* 2000 Jul-Aug;17(4):27-8.

Mancilla R. ASP infrastructure: beyond copper wire and fiber optics. *Decis Imaging Econ* 2000 Nov-Dec;13(7 Suppl):4-5, 19.

Nussbaum GM. Bitten by the ASP: application service providers [session 7]. In: Healthcare Information and Management Systems Society (HIMSS). *2001 HIMSS proceedings: volume 1*. 2001 Feb 4-8; New Orleans (LA). Chicago (IL): HIMSS; 2001:1-9.

Porter C. ASPs in healthcare industry report: providers and payers [poster session 21]. In: Healthcare Information and Management Systems Society (HIMSS). *2001 HIMSS proceedings: posters.* 2001 Feb 4-8; New Orleans (LA). Chicago (IL): HIMSS; 2001:1-14.

Turisco F. Evaluating ASP pricing models and contract terms. *Healthc Financ Manage* 2000 Aug;54(8):80-1. ◆

Thank You

To All Our Clinical Reviewers

We deeply appreciate the contributions made by the following professionals, who gave their time and expertise as reviewers of the Evaluations and major Guidance Articles published in *Health Devices* during the past year. We also would like to thank the countless others — too numerous to mention here — who have helped us inform the healthcare community about medical device related problems through our Problem Reporting System.

Terri Hart Andrews
Joan S. Ash, PhD, MLS, MBA
Peter Axelson, MS
Mike Baca
Robin Bailey
Stephen Baker, PhD
James R. Barba, MA, RT(R)
Michael Barretti
David W. Bates, MD
Dan Benson, MSBME
Bruce H. Berg, MD, MBA
Jennifer Bourguignon, MS, RNC
Eric Bower
Charles A. Broutman, MSBME
Bob F. Bury, FRCS, FRCR
Francis Casey
Deniese Chaney, MPH
David Clunie, MB
Dave Cobb
Mike Cohen, MS, FASHP
Barbara Corso
Mike Crader
Jay Crowley, ME
Richard Cummins, MD, MPH, MSc
Dennis Kingsbury Curry
David Daly
Dan Emig
Steve Erban, MD
Tracey Erickson
Roland Fischer
Lynn Giglione, RN, CRNI
Mark Gonzales
John Gosbee, MD, MS
Dr. Mohd Halim bin Abu Bakar
David Hambrick, CGRN
Mary Fran Hazinski, RN, MSN
Maynard High, PhD
Debbie Jackson
Emanuel Kanal, MD, FACR
Andrew Karellas, PhD
Tamara Kear, RN, MSN, CNN
Elaine K. Keeler, PhD
Andre Kliczak
G. Guy Knickerbocker, PhD, PE, CCE
Mark Kotfila
Suzanne LaMountain, RN, MBA
Jim Lawrence
John W. Leeger
John Leroux
Susie Q. Lew, MD, FACP
Joe Lewandowski, CCE
Dale Lillie
Elizabeth J. Lindley, PhD, MIPEM
Karen McKeon, RN
Michael McPeck, RRT
Alicia S. Miller, MS, RPh
Neil Morgan
Linda Morrell
Dorrie Napoleone
Lily Ng, RN, MSN, MPH
Jerry O'Connor, MBA
Joseph Ornato, MD
Roxanne Perucca
Ronald R. Price, PhD
Margaret M. Quinn, MD, FACP
Mark Raymond
Sheryl Riley
Roberto J. Rodrigues, MD
Kelli Rosenthal, MS, RNC, CRNI, CANP
Dr. Llera Armando Samuels
Bruce Saylor
John A. Schaefer, MFS, CIH
Dr. Roderick F. Schmitz
Bernard Segal, PhD, MEng
Frank G. Shellock, PhD
Elliot B. Sloane, PhD, CSP
Jack Slover, MHA, RT(R)
Aline Stant
Don Stanze
Lisa C. Stegall, RN, CPN
Wanchun Tang, MD
Mary-Jane Thommen, RT(R)
Margarita Torres, MD
Wil Van der Putten, PhD
Betty Walker
Mary Walsh, RN
Mary Weick-Brady, RN, MSN
Jed Weissberg, MD
Roger White, MD
Peggy Wollnik
Terry O. Woods, PhD
Julie Zelno

475754
424-001

Problem Reports

ECRI Problem Reporting System

Policy statement. ECRI encourages members, healthcare providers, patients, and suppliers to report all medical device related incidents and deficiencies to us so that we can determine whether a report reflects a random failure or one that is likely to recur and cause harm. Reports can be generic or model specific. We add all reports to our internal confidential databases to track trends of device failure or lot-specific defects. Although many reports do not result in a published article, we inform the reporting party of our findings or opinions when appropriate. As soon as we become aware of device hazards and problems, we inform the suppliers and invite them to respond constructively.

If our investigations yield information that should be communicated to the healthcare community, we publish the information in *Health Devices* as either a Hazard Report or a User Experience Network™ (UEN™) article, depending on the level of risk associated with the problem. Member hospitals may reproduce these reports for internal distribution only. This policy does not apply to other articles in *Health Devices,* unless otherwise noted.

Submitting a report. Please report problems to us by mailing or faxing one of the problem reporting forms in your *Health Devices* binder, by sending us a letter, by completing the online form accessible through the product listing on ECRI's home page (www.ecri.org), or by calling +1 (610) 825-6000. The identity of the reporting individual or institution is never revealed without permission.

Hazard Report

Restarting Baxter Ipump Using PREVIOUS RX? *Function Reverts Settings to Original Prescription*

PROBLEM

A member hospital reports that when a Baxter Ipump patient-controlled analgesic (PCA) infusion pump was powered off and then restarted on the same patient, the pump reverted to the patient's original prescription rather than to the settings that had been adjusted during therapy. The patient had undergone a magnetic resonance imaging (MRI) procedure, during which the PCA pump had to be turned off. This problem has occurred on several occasions and has led to the overmedication of patients.

DISCUSSION

PCA pumps deliver narcotics to patients for pain management. Often, the nurse or clinician programs the pump with an initial prescription and then adjusts the settings depending on how a particular patient responds to the therapy. It is not unusual for a PCA pump to be reprogrammed several times during a patient's therapy.

A PCA pump is not commonly powered off during therapy. When such an event occurs (as in the reported case), the convention of most pumps is that therapy is resumed

475996
424-001

at the last programmed dose, not the original prescription. However, when the Ipump is powered off and then restarted using the PREVIOUS RX? function, the pump reverts to the original prescription entered. (Users have two options when restarting the Ipump: They can clear the pump and reprogram it, or they can use the PREVIOUS RX? function.) Baxter states that the PREVIOUS RX? capabilities were designed for facilities that use a standard therapy for all patients. Thus, when the pump is turned off following one patient's therapy, the pump reverts to the standard therapy for the next patient.

The Ipump does require that the user review all pump settings before restarting therapy, but the user merely has to press ENTER to accept each setting. It is possible for a user to press ENTER quickly each time and miss the fact that the pump reverted to the original settings. As a result, the patient may receive too high or too low a dosage, which may lead to overmedication or undermedication.

RECOMMENDATIONS

We believe that this problem poses a potential risk to patients. Hospitals should follow these recommendations:

1. Alert all staff who program the Baxter Ipump to this problem and to our report. Explain how the PREVIOUS RX? function works.
2. Instruct staff to clearly document all current pump settings before the Ipump is powered off during therapy. When the pump is turned back on, staff should reprogram it with those settings and confirm each setting before restarting therapy.

ECRI's Hazard Reports

A Hazard Report describes a possible source of peril, danger, or difficulty. We publish reports about those units in which we have identified a fault or design feature that *might,* under certain circumstances, place patients or users at risk. These reports describe the problem and ECRI's recommendations on how to correct or avoid it. Publication of a report on a specific brand name and model of device in no way implies that competitive devices lack hazardous characteristics.

When deciding whether to discontinue using a device that ECRI believes poses a risk, staff should balance the needs of individual patients, the clinical priorities, and the availability of safer or superior products against the information we provide. Clinical judgment is more significant than an administrative, engineering, or liability decision. Users can often take precautions to reduce the possibility of injury while waiting for equipment to be modified or replaced.

UMDNS information. Infusion Pumps, Patient-Controlled Analgesic [16-924]

Supplier information. Baxter Healthcare Corp., IV Therapy [393248], Round Lake, Illinois (USA); +1 (888) 229-0001, +1 (847) 546-6311; www.baxter.com

The Baxter Ipump is sold in Canada, Europe, New Zealand, Singapore, and the United States. ◆

Hazard Report

Zoll Medical M Series Paddles May Become Disconnected from Defibrillator

PROBLEM

A member hospital reports that on three of its Zoll M Series defibrillators, the cable that connects the external paddles to the defibrillator pulled out of the paddles without the release button being pressed.

The incidents, which occurred during resuscitation attempts, prevented the defibrillator from monitoring or shocking the patient. No patients were injured; however, this problem could delay resuscitation efforts, which can result in death.

DISCUSSION

The paddles are connected to the Zoll M Series defibrillator by a cable. This cable is screwed into the defibrillator and has a connector on the other end that plugs into one of the paddles (see the figure on the next page). The paddle connector engages with a latching mechanism inside the paddle. (The paddles are connected to each other by another cable.) To disconnect the cable from the paddle, the user presses a release button on the paddle. In addition, Zoll has designed the M Series so that the cable-to-paddle interface disconnects if the pull force is greater than 15 lb.

This design was meant to prevent cables from breaking. However, it's likely that the disconnections reported to ECRI happened at pull forces lower than 15 lb.

If the cable becomes disconnected, the defibrillator will not be able to read the patient's heart rhythm or shock the patient because there won't be a connection between the defibrillator and the paddles. Improper attachment or disconnection of the cable produces audible and visual messages of "CHECK PADS" and "POOR PAD CONTACT." However, users may interpret these as meaning that the paddles are making poor contact with the patient rather than that the cable has become disconnected. This may delay the diagnosis and correction of the problem.

SUPPLIER'S CORRECTIVE ACTION

The supplier is aware of the problem and has had similar reports from several other hospitals. Zoll has identified the two major causes of the problem. First, the size of the connector entry on the paddle may be larger than it should be because the paddle top cover is separating from the paddle body; second, the latch mechanism may be damaged because the defibrillator or the paddle was dropped or hit against a hard surface. Zoll states that it has addressed the first issue by increasing the size of the tabs that hold the top cover and paddle body together. This change was implemented on paddles manufactured after September 1999, starting with serial number U991. Since that time, there have been fewer paddle disconnections reported to Zoll. (The paddles involved in the report received by ECRI were manufactured before September 1999.)

RECOMMENDATIONS

ECRI recommends that healthcare facilities educate their staff on the proper use of the Zoll M Series defibrillator and paddles and that they monitor staff performance to ensure that the device is not abused or misused. Also, we recommend that healthcare facilities inspect the connectors by lightly pulling on the cable while the connector is inserted into the paddle to see if it disconnects. If it does disconnect, contact Zoll's technical department at +1 (800) 348-9011.

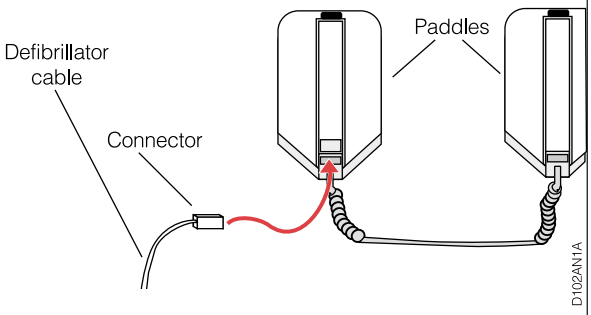

Figure. The Zoll M Series paddles are connected to the defibrillator by a cable. This cable is screwed into the defibrillator and has a connector on the other end that plugs into one of the paddles. To disconnect the paddles from the defibrillator, the user is supposed to press a release button on one of the paddles. However, the cable may pull out without the release button being pressed.

UMDNS information. Defibrillator/Pacemakers, External [17-882]

Supplier information. Zoll Medical Corp. [150032], Burlington, Massachusetts (USA); +1 (800) 348-9011, +1 (781) 229-0020; www.zoll.com

The Zoll M Series defibrillator and paddles are marketed worldwide. ◆

Hazard Report

Exposed Connections in Pulse Oximeter Sensors Can Cause Electrochemical Burns

PROBLEM

An attending nurse at a member hospital noticed that a patient had a dry, blackened skin lesion at a site that is common for pulse oximeter sensor placement. The nurse suspected the cause of the injury to be a disposable (single-patient-use) SpO_2 sensor that had subsequently been moved to a different site on the patient. When the nurse removed the sensor, the skin underneath was reddened; however,

there was no evidence of a lesion. A large section of the insulation that is normally present over the LED portion of the sensor was missing (it had been torn or ripped). As a result, a few of the sensor's electrical connections were exposed, which had allowed contact with the patient's skin.

DISCUSSION

ECRI's investigation of this incident revealed that the patient had indeed received a burn from the disposable SpO_2 sensor. However, the burn was not thermal, as one might suspect; it was an electrochemical burn caused by low-voltage, direct-current (DC) tissue electrolysis that occurred at the site of the exposed electrical connections.

The process of tissue electrolysis caused by application of a medical device, though rare, is well known and well documented (Grossi et al. 1993; Leeming et al. 1970; Orpin 1982). Electrolysis of saline in the skin produces sodium hydroxide and hydrogen gas at the cathode (the negative electrode). This breaks down the skin, resulting in a whitish lesion underneath and surrounding the cathode. At the anode (the positive electrode), hydrochloric acid (HCl) is produced, along with chlorine gas and/or oxygen. These combinations cause a dark discoloration of the skin under and around the anode.

CONCLUSIONS

Electrochemical burns from SpO_2 sensors can be prevented by not allowing a damaged sensor's exposed electrical connections to come in contact with a patient. Therefore, it is important for clinicians to inspect a sensor before placing it on a patient or when moving it to another location. Damaged sensors should not be placed on a patient.

ECRI believes this type of incident may occur with any supplier's SpO_2 monitoring equipment (pulse oximeter or physiologic monitor) when uninsulated electrical connections of a sensor are exposed to a patient's skin.

RECOMMENDATIONS

1. Alert hospital staff to this problem and to our report.
2. Ensure that clinical protocols include a check of the integrity of all SpO_2 sensors (disposable and reusable) before they are placed on a patient and when they are moved to a new location. Specifically, the sensor and sensor cable should be inspected for cracks or breaks in the insulation, for exposed electrical connections or wires, and for any other damage. (Note: Disposable sensors should be reused on the same patient only per the sensor supplier's directions for use.)
3. Instruct staff to follow the supplier's directions when assessing skin integrity at the sensor site and when changing sensor locations. Doing so will help ensure that any injuries, should they occur, are treated promptly.
4. Warn staff not to use a damaged sensor or sensor cable. The sensor or cable should be clearly labeled as damaged and sent to biomedical engineering staff for evaluation and to allow occurrences of such problems to be tracked. Notify ECRI if problems are repeatedly encountered.

UMDNS information. Probes, Oximeter [17-594] ■ Oximeters, Pulse [17-148] ■ Physiologic Monitoring Systems, Acute Care [12-647] ■ Physiologic Monitoring Systems, Neonatal [15-791]

Supplier information. These devices are available from a variety of suppliers; consult ECRI's *Health Devices Sourcebook* for a list of companies.

References

ECRI. Lesions and shocks during iontophoresis [hazard]. *Health Devices* 1997 Mar;26(3):123-5.

Grossi EA, Parish MA, Kralik MR, et al. Direct-current injury from external pacemaker results in tissue electrolysis [case report]. *Ann Thorac Surg* 1993 Jul;56(1): 156-7.

Leeming MN, Ray C Jr, Howland WS. Low-voltage, direct-current burns. *JAMA* 1970 Nov 30;214(9):1681-4.

Orpin JA. Unexpected burns under skin electrodes. *CMA J* 1982 Dec 1;127:1106. ◆

User Experience Network

Drug Dose Rate Calculator Resolution on Alaris MedSystem III Is Limited

HOSPITAL

While using the drug dose rate calculator on an Alaris MedSystem III infusion pump, we found that the lowest dose that can be programmed into the calculator in the most commonly used unit — mcg — is 0.1 mcg/kg/min; however, some of the drugs we use (e.g., fenoldopam, isoproterenol, norepinephrine) have dose ranges below 0.1 mcg/kg/min. The dose rate calculator does have an option to program in ng/kg/min, but all our drug package inserts, published drug references, and standards for practice use mcg/kg/min. Using ng/kg/min requires manual conversion from mcg/kg/min, which increases the potential for calculation error and defeats the purpose of a dose rate calculator. The dose can be adjusted below 0.1 mcg/kg/min by lowering the rate of titration (the pump allows titration by rate in 0.1 mL/hr increments); however, the pump merely

Talk to the Specialist

FDA Medical Device Classes

Question. Can you please explain the three FDA device classes?

Answer. The U.S. Food and Drug Administration (FDA) has established medical device classifications for each of its approximately 1,700 different generic types of devices. Devices are designated as Class I, II, or III based on the risk that each one poses to users and patients. For each class, there is a particular level of control necessary to ensure the safety and effectiveness of the device. Most devices — 93% of them — fall into Class I or II. In brief, the three classes are as follows:

- **Class I.** These devices — which include elastic bandages, examination gloves, and handheld surgical instruments — present minimal potential for harm to the user or the patient. They are usually simpler in design than Class II or Class III devices and are subject to the least regulatory control. In fact, many Class I devices may be marketed without specific permission from FDA.
- **Class II.** These devices — such as powered wheelchairs, infusion pumps, and surgical drapes — require additional controls to ensure safety and effectiveness (assuming methods are available). The additional controls include special labeling requirements, mandatory performance standards, and postmarket surveillance.
- **Class III.** Class III is the most stringent regulatory category. It includes devices such as fetal pulse oximeters, implantable pacemakers, and vascular grafts. According to FDA, Class III devices are those which "support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury." The safety and effectiveness of Class III devices cannot be ensured solely through the controls established for Class I and II devices.

For more information on the subject of acquiring medical device marketing approval from FDA, please refer to the Talk to the Specialist article "FDA 'Approval' of Medical Devices" on page 235 of our May-June 1999 issue. FDA's Web site (www.fda.gov/cdrh) is also an excellent source of information on this subject. ◆

Talk to the Specialist

In this column, we provide answers to questions frequently asked of ECRI's specialists. Members of either the Health Devices System or the SELECTplus™ Program are encouraged to contact ECRI's experts to pose questions such as these or to seek assistance on healthcare technology issues. This type of direct, personal assistance is a membership benefit available to all individuals at subscribing healthcare facilities.

displays the dose as <0.1 mcg/kg/min. Thus, the operator would not be sure of the actual dose being infused. For doses that require a range below 0.1 mcg/kg/min, we use a different calculator.

ECRI

Drug dose rate calculators automatically calculate an appropriate delivery rate for a particular drug after a clinician enters necessary information, including the patient's weight, the drug concentration, and the dose. Provided that the information is entered correctly, these devices can help to prevent errors that can be made when rates are manually calculated. Such errors may cause overdelivery or underdelivery of medication.

Staff generally rely on the pump for calculations; as a result, they may not remember how to calculate manually. And if a medication requires a smaller dose than is available on the calculator, as in the reported case, staff may have to perform manual calculations.

Alaris is aware of the design limitations of the MedSystem III calculator but has no plans to change the calculator's resolution, due to the device's age (the pump was designed in the 1980s) and the fact that only a very small number of infusions require this resolution (most very dilute drug solutions are not typically given as weight-based infusions).

RECOMMENDATIONS

For most infusions, the drug dose rate calculator on the Alaris MedSystem III has sufficient resolution; however, for doses below 0.1 mcg/kg/min, the calculator should not be used. In these cases, the clinician should use another calculator with sufficient resolution and then enter the correct rate into the pump. If such calculations are commonly made, be sure that an appropriate backup calculator is readily available. In addition, whenever a user must make manual calculations, another staff member should confirm them before the pump is programmed.

UMDNS information. Infusion Pumps, General-Purpose [13-215]

Supplier information. Alaris Medical Systems Inc. [308442], San Diego, California (USA); +1 (800) 854-7128, +1 (858) 458-7000; www.alarismed.com

The MedSystem III is marketed in Canada, France, Germany, the United Kingdom, and the United States. ◆

New Procedure for Patient Lifts Now on IPM Web Page

An ECRI procedure for patient lifts has recently been posted on the *Health Devices Inspection and Preventive Maintenance (IPM) System* page on ECRI's Web site (www.ecri.org). The procedure provides inspection tasks required to ensure the safe use of this equipment.

This procedure is one of dozens included in Version 4 of the *IPM System,* which was released earlier this year. The *IPM System* is a Windows®-compatible program that provides hassle-free compliance with JCAHO, ISO 9001, and other quality system requirements for clinical equipment and support system IPM activities. A database of ready-to-use inspection procedures and forms will meet your IPM needs for commonly inspected devices and systems. Templates are also included to allow you to quickly create procedures for additional device types and models. *IPM System* users can register for access to the IPM page of ECRI's Web site to post and download user-customized and new, ECRI-developed procedures.

The *IPM System* currently contains 72 procedures for more than 150 devices. These procedures have been developed, tested, and updated to comply with quality standards and to take into account safety standards. The system's procedures are based on clinically significant considerations, not just manufacturers' recommendations, enabling you to maximize efficiency while maintaining a high standard of equipment maintenance. Additionally, the *IPM System* offers seamless integration with ECRI's HECS™ 4.7 maintenance management system.

In addition to the database of procedures and forms, the system includes IPM Topics — a collection of articles that offer guidance on operating, monitoring, and optimizing an IPM program. This material serves as an in-depth resource for complying with regulations, standards, and workplace safety requirements. Conversion tables and an extensive list of test equipment sources are also provided.

For more information about the *Health Devices IPM System,* contact Tim Ritter at +1 (610) 825-6000, ext. 5168, or at ipm@ecri.org. ◆

A Publication of the
HEALTH DEVICES SYSTEM

Health Devices System
Objectives

To improve the effectiveness, safety, and economy of health services by:

1. Providing independent, objective judgment for selecting, purchasing, managing, and using medical devices, equipment, and systems.
2. Functioning as an information clearinghouse for hazards and deficiencies in medical devices.
3. Encouraging the improvement of medical devices through an informed marketplace.

ECRI
A NONPROFIT AGENCY

www.ecri.org
5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA
Telephone +1 (610) 825-6000 ▪ Fax +1 (610) 834-1275 ▪ E-mail healthdevices@ecri.org