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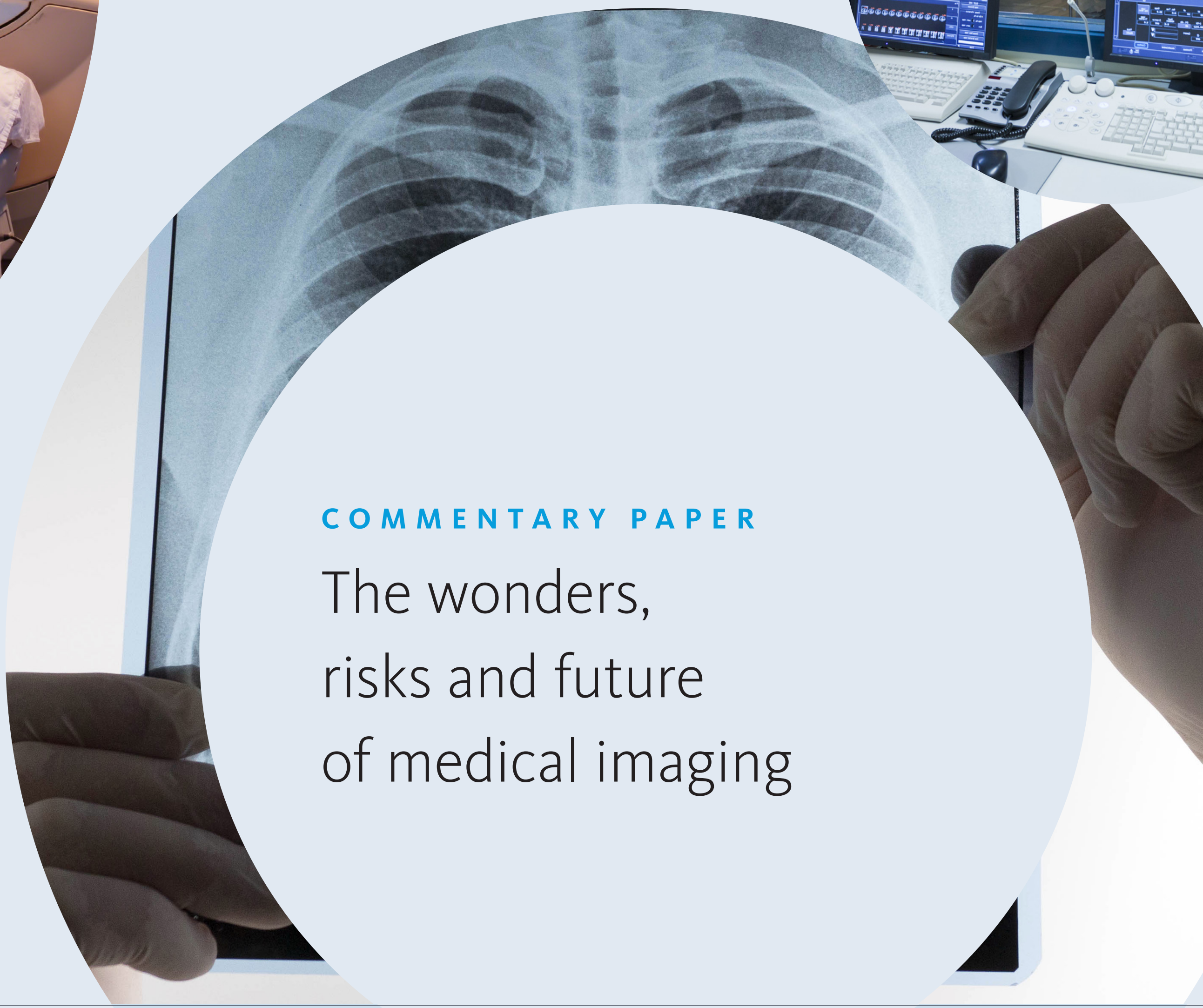

COMMENTARY PAPER

The wonders, risks and future of medical imaging

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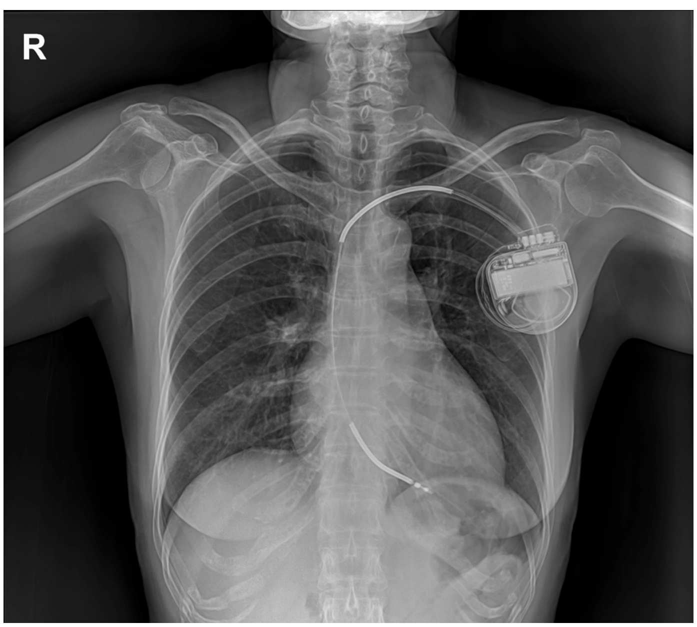
The wonders, risks and future of medical imaging

The imaging sector is growing rapidly, as are the risks of malfunction and catastrophic failure. Imaging equipment manufacturers are the primary service providers for equipment repairs. However, there can be a wide range of warranty exclusions that leave high-repair costs or replacement decisions in the hands of the equipment's owner. To mitigate risk and ensure swift recovery following a loss event requires an understanding of the equipment, potential challenges and future considerations.

The basics: Imaging terminology and equipment

Modern medical imaging equipment dates to the 1950s. Up until then, the traditional radiography, better known as the X-ray, was the only way to acquire skeletal and foreign object images within the human body. The 1970s and 80s brought innovation that greatly expanded the modalities and tools that became available to diagnostic radiologists. Radioactive tracers, ultrasound scanning, thermography, computerized axial tomography (CAT), nuclear magnetic resonance (NMR) imaging or magnetic resonance imaging (MRI) and digital radiography.



Conventional X-ray

Similar to visible light, X-rays are a form of electromagnetic radiation. Unlike light, they comprise of higher energy that can pass through most objects. X-rays that travel through the body and a detector on the other side, form an image that represents the shadows of bones or objects inside the body. While all X-ray technologies depend on at least some level of radiation exposure, they have become more sophisticated and less harmful over the years. Today, X-ray radiology is used to not only detect bone fractures, but certain tumors and abnormal masses, pneumonia, calcification (buildup of calcium in the body) and dental problems.

Computerized axial tomography (CAT) or computerized tomography (CT) X-ray

A CAT scanner is a device that combines X-ray technology with computer processing. It is used to capture successive exposures of body parts by moving the X-ray source in an arc or through a full circle around the patient. Stationary sensors record the measurements, which are combined to generate a series of cross-sectional images (slices), that ultimately form a three-dimensional image. CAT scans help diagnose muscle and bone disorders, pinpoint the location of a tumor, infection or blood clot, detect and monitor cancer, heart disease, lung nodules and liver masses, as well as detect internal injuries and bleeding.

Nuclear magnetic resonance (NMR) or magnetic resonance imaging (MRI)

As it relates to medical imaging, a common misconception for the word "nuclear" is that it means radiation or nuclear power. In this case, the word refers to the nucleus or center of an atom. In fact, nuclear magnetic resonance (NMR) imaging was renamed magnetic resonance imaging (MRI) to avoid the undesirable connotations of the word nuclear among the lay public.

Unlike CAT scans, MRI's do not use X-rays, but rather radio waves and a large magnet to create high-resolution three-dimensional images of soft tissue structures. An MRI provides a clearer picture of muscle ligaments and tendons, the brain, spinal cord and nerves as well as bones and joints. Because of the strong magnet, an MRI cannot be used to scan people with implanted pacemakers, certain prosthetic devices, iron-based metal implants, and internal metallic objects such as shrapnel, screws, metal sutures or a wire mesh.

When a doctor recommends an MRI or a CAT scan, most of us do not fully appreciate why a certain modality was chosen over the other. As it relates to cost, CAT scans are almost half the price of MRIs. The average CAT scan costs approximately $1,200 while an MRI is about $2,000. So, what's the difference between both scanning options? Both CAT scans and MRIs can view internal structures. However, a CAT scan is faster and can provide pictures of tissues, organs, skeletal structure and may be recommended if a patient cannot have an MRI because of implanted devices. An MRI is highly adept at capturing images that highlight abnormal tissues; the images are more detailed, without involving any radiation to obtain them.

Positron emission transaxial tomography (PETT) or positron emission tomography (PET)

While CAT scans use X-rays and MRIs use magnets and radio waves, both produce still images of organs and body structures. PET scans use a radioactive tracer to show how an organ is functioning in real time. Radioactive tracer is a chemical that is injected into the blood stream but has no side effects. The tracer is radiolabeled, meaning it emits energy that can be detected by the scanner.

PET scan images can detect cellular changes in organs and tissues earlier than CT and MRI scans. In some cases, a PET scan and a CT scan are performed at the same time (PET-CT), which produces three dimensional (3D) images that allow for a more accurate diagnosis. Today, some hospitals use a hybrid PET/MRI scan. This new technology creates extremely high-contrast images and is primarily used for diagnosing and monitoring cancers of the soft tissues (brain, liver and pelvis).

Ultrasound

An ultrasound is a safe, noninvasive imaging test that uses sound waves to produce pictures of the inside of the body without the use of radiation. The images produced during this examination are called sonograms. When high frequency sound waves are projected forward, they continue moving until they collide with an object, at which point a certain amount of sound bounces back. In fact, this is the same technology that serves as the eyes and ears for submarines. Ultrasound scans help diagnose the causes of pain, swelling and infection in the body's internal organs and to examine the fetus in pregnant women. In infants, doctors commonly use ultrasound to evaluate the brain, hips and spine. It also helps guide biopsies, diagnose heart conditions, and assess damage after a heart attack.

Equipment risks

Virtually all U.S. hospitals and imaging centers have service contracts with at least one original equipment manufacturer (OEM) for post-warranty service of their diagnostic imaging equipment. This includes everything from break-and-fix to uptime guarantees, cyber security and remote diagnostics —no different than other critical systems, imaging equipment malfunctions, and at times, catastrophically.

According to the European Society of Radiology (ESR):

- Radiological equipment has a finite life cycle span – resulting in unavoidable breakdown and decrease or loss of image quality which renders equipment useless after a certain time period.
- Equipment older than 10 years is no longer state-of-the-art equipment and replacement may be essential. Operating costs of older equipment will be high when compared to new equipment, and sometimes maintenance will be impossible if spare parts are not readily available.
- Older equipment has a high risk of failure and breakdown – causing delays in diagnosis and treatment and safety problems both for the patient and the medical staff.

Despite the low occurrence of hospital fires, MRI suites pose significant fire protection and life safety risks. As each new generation of MRI machines increases in performance, they use more powerful magnets and consume more power, which in turn increases the risk to people and the equipment.

MRI explosion

On March 6, 2015, an MRI exploded at Oradell Animal Hospital while three MRI technicians were dismantling the leased unit. No fire resulted from the explosion, but the fire department discovered a small liquid helium leak from the device. MRIs incorporate magnets thousands of times stronger than the ones on your kitchen fridge that are kept operational by liquid helium cooled to about -452˚F (-270˚C). If that helium escapes its casing, evaporates and mixes with oxygen, pressure from the rapidly escaping gas can cause an explosion. While imaging equipment fires and other hazardous incidents do not happen often, when they do happen, it is usually during installation, removal or servicing of the MRI hardware.

MRI quench

Imaging equipment provider, Block Imaging, describes an MRI quench as follows: Superconductive, high-field MRI systems are basically giant electromagnets. The majority of them operate at 1.5 Tesla (T), a unit of measure for magnetic field density, which is about 30,000 times stronger than the earth's magnetic field. This is enough magnetic power to lift a car. The element that makes these magnets so powerful is liquid helium, which takes the resistance in the coil windings around the magnet, down to zero. This allows the electricity to flow continuously as long as the liquid helium is maintained at a steady negative 452.2˚F.

There are a couple of ways to power off an MRI. The slower, more machine-friendly and economical way, is to have a technician remove the electrical current by utilizing a magnet power supply. The power supply will ramp the magnetic field down to zero, a process called ramp down. When the power supply adds current to start the machine, the process is called ramp up.

The more exciting way to power off an MRI is by pressing the large, red emergency quench button. A quench occurs when there is a rise in the magnets temperature, resulting in a loss of superconductivity and causing a chain reaction. Increasing resistance causes more and more heat, which then causes the liquid helium to boil into gas, which causes pressure to build up until there is a sudden, dramatic and expensive release of helium gas. All MRIs are equipped with a helium quench pipe, which vents the gas safely out of the building.

While there are planned quenches during system decommissioning, quenches that are not triggered by a technician or a radiographer happen as well. MRIs may quench on their own as a result of a leak, ice in the magnet, a failure in the magnets cooling system, or even critically-low helium levels.

Metallic objects in an MRI suite

Metallic objects in the presence of a strong magnetic field become magnetized because ferromagnetic materials (materials that have a high susceptibility to magnetization) and easily accept an induced magnetic field.

When a patient enters an active MRI suite wearing a pair of earrings, the earrings will instantly become magnetized and will try to align/orient themselves with the powerful MRI magnet.

Strict measures are put in place to ensure that there are no metallic objects in the vicinity of the machine when it is powered on. Because the liquid helium has to stay cold, MRIs are always powered on. In other words, don't be surprised if you're asked to remove your earrings or wedding ring before entering an MRI suite.

While a picture of a floor polisher that was drawn into the MRI is shown below, a myriad of other metal items have caused physical impact damage to MRIs. Also known as the "missile effect", metal objects become projectiles because of the considerable force that is exerted on them. Oxygen tanks, scissors, keys, hammers, wheelchairs and even complete patient beds.

A floor polisher was attracted by an MRI. The polisher could only be removed by ramping down the magnetic field. Creative Commons Attribution-Share Alike 4.0 International, author: Xksev

In the event that a patient does gets pinned inside an MRI, the radiographer would push the emergency quench button, effectively demagnetizing the magnet. Once quenched, bringing the MRI back up to field, or ramping it up is an expensive process and not always successful the first time around.

Natural and man-made disasters

The 2018 edition of the Facility Guidelines Institute's (FGI's) Guidelines for Design and Construction of Hospitals and Outpatient Facilities, offers some insight regarding where imaging equipment is supposed to be housed within a medical facility. Table 2.2-2 within the guide titled "Imaging services" describes the following for a class 1 imaging room.:

- Use: Diagnostic radiography, fluoroscopy, mammography, computed tomography, ultrasound, magnetic resonance imaging, and other imaging modalities.
- Room type: Unrestricted area.
- Location: Access from an unrestricted area.

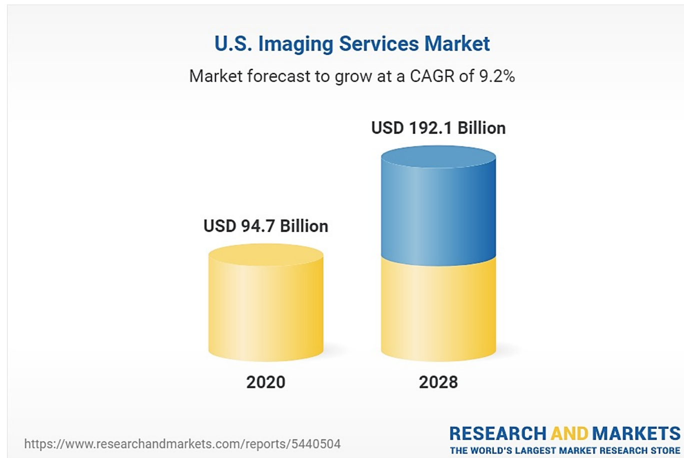
The medical industry's most widely recognized guidelines basically revolve around planning, design, construction, space, built-in furnishing, building system requirements and infection prevention. Imaging equipment can be placed just about anywhere, as long as there is access from an unrestricted area. Getting your nails done at a strip mall salon, followed by a scan at the suite next door, will become more and more commonplace. Unfortunately, hospitals and imaging centers are just as susceptible to damage from natural and man-made disasters, as any other facility.

As previously noted, virtually all U.S. hospitals and imaging centers have service contracts with at least one OEM for post-warranty service of their diagnostic imaging equipment. Manufacturers and service vendors are quick to point out that an "acts of God" exclusion exists in just about every service contract. Here is an example from a Siemens Medical Solutions proposal: "This Agreement specifically excludes labor, parts and expenses necessary to repair equipment damaged by fire, accident, misuse, abuse, negligence, improper application or alteration or by a force majeure occurrence as described in Section 17 hereof, or by the customer's failure to operate the equipment in accordance with the manufacturer's instructions or to maintain the recommended operating environment and line conditions".

Experienced loss consultants are all too familiar with this exclusion, and work with OEMs, as well as third party service providers, to ensure that equipment is restored to a pre-loss condition, while assuring warranties and service contracts remain intact.

A glimpse into the future of medical imaging

The medical imaging service sector is growing at a rapid pace. Technology will transform the business model, such that far more people in developing countries will have access to equipment and services that some individuals in the western world take for granted.



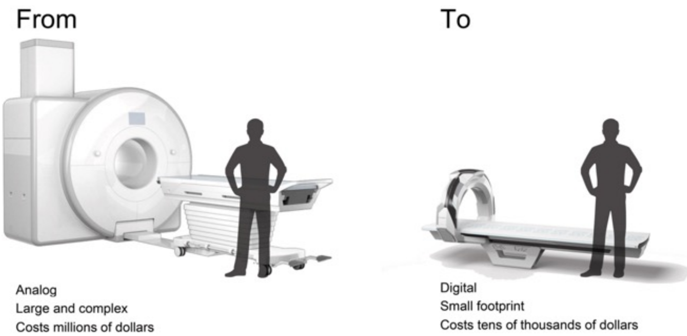
Radiology-as-a-Service (RaaS)

Traditionally, hospitals purchased imaging equipment and maintained it utilizing in-house biomedical personnel, or through paid maintenance service contracts with OEMs. In the "as-a-service" model, care providers are not required to purchase equipment outright. Instead, they partner with imaging vendors who provide the necessary equipment and related services, with payments made either on a pay-per-use/scan or a periodic basis. Under this arrangement, the upfront capital costs are drastically reduced, thereby easing the burden on the budgets of care providers.

In February 2022, the Food and Drug Administration (FDA) cleared the world's first portable, low cost MRI, which is now used for imaging of the brain and head in patient of all ages. The MRI costs $50,000, which is 20 times cheaper than traditional systems, operates on 35 times less power and weighs 10 times less than a normal 1.5T unit.

Traditional X-ray procedures have not changed much since Wilhelm Conrad Röntgen reported the discovery in 1895. These days we have sophisticated X-ray devises, better known as CT scanners, described above. CT scanners are bulky for several reasons. A large amount of electronics is required to generate and detect the X-rays. The X-ray source must be able to quickly circle around the patient to create proper 3D images. Large cooling components are required as X-ray generation also generates a significant amount of heat.

When considering the Radiology-as-a-Service sales platform, manufacturers have far more incentive to develop high-resolution, low-cost equipment, versus high-resolution, high-cost modalities. In the image below, the smaller (154lb) Star-trek looking digital CT scanner costs around $10,000, while the larger (4409lb) analog scanner usually costs anywhere from $1 million to $3 million.



Additionally, we are cognizant that the average CT scan costs approximately $1,200. Scans on the star-trek looking version costs around $40. The dramatic cost-per-scan difference, with minimal capital expenditure upfront, makes this and similar technologies attractive for healthcare facilities globally.

As it relates to property losses, not every imaging modality will immediately experience a significant cost reduction, as noted by the portable MRI and low profile CT scanner above. Some equipment will cost millions for years to come. Understanding what should be restored post loss, how it should be restored, and which items make no economic sense to restore, are important steps that should be considered immediately, to mitigate equipment deterioration and minimize business income loss.

Key takeaways

- Utilization of medical imaging is growing at a rapid pace.
- Imaging equipment routinely fails from normal wear and tear. As a result, virtually all U.S. hospitals and imaging centers have service contracts with at least one OEM for post-warranty service.
- Hospitals and imaging centers are just as susceptible to damage from natural and man-made disasters, as any other facility.
- Imaging equipment can be housed anywhere, as long as there is access from an unrestricted area.
- Manufacturers and service vendors are quick to point out that an "acts of God" exclusion exists in just about every service contract.
- Following a loss, experienced loss consultants work with OEMs, as well as third party service providers, to ensure that equipment is restored to a pre-loss condition, while assuring warranties and service contracts remain intact.
- The imaging equipment sector is being transformed by incredible innovation. $50,000 portable MRI units are now available and $10,000 CT scanners will be available in the near future. Other imaging modalities could still cost millions for years to come.
- Qualifying what should be restored post loss, how it should be restored, and which items make no economic sence to restore, is an important part of managing liability and minimizing business interruption.
- Partnering with independent technical loss consultants who understand the restoration process and consider OEM warranties, is key to maintaining patient medical services, as well as minimizing business income loss and high-capital costs of replacing equipment that may otherwise be restored.

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Get in touch with an expert

Curtis Anderson

Curtis Anderson has over seven years of mechanical engineering experience, including approximately three years in mechanical forensics and four years in the heavy-duty truck manufacturing industry, and has been a registered professional engineer since 2018. He has completed investigations of residential/commercial plumbing failures, fires, and product failures in both the field and the lab. His lab analysis has included examination of evidence using X-ray, computerized tomography (CT), FT-IR, scanning electron microscopy with energy dispersion X-ray spectroscopy, and optical microscopy.

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