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STATEMENT

OF

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ON BEHALF OF

THE MEDICAL IMAGING & TECHNOLOGY ALLIANCE (MITA)

REGARDING A HEARING ON

“Examining Improvements to the Regulation of Medical Technologies”

**BEFORE THE
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH**

Tuesday, May 2, 2017

SUMMARY OF TESTIMONY

- MITA fully supports H.R. 2009, the Fostering Innovation in Medical Imaging Act of 2017 and H.R. 2118, the Medical Device Servicing and Accountability Act and urges their inclusion in the MDUFA IV legislation.
- H.R. 2009 will help manufacturers of medical imaging devices clear unnecessary regulatory hurdles and improve access to advancements in medical imaging that help physicians detect disease earlier when it's more treatable. It will also permit, but not require, medical imaging contrast agent manufacturers to conform the indications to the new device indication by adding the new device indication through a NDA supplement. Removing impediments to technological advancements in medical imaging will encourage innovation and allow physicians to better diagnose and treat patients in the United States in a manner that is consistent with medical practice internationally.
- H.R. 2118 will help to ensure patient safety and medical device performance by requiring that medical device servicing organizations register with the FDA, maintain an internal complaint handling system, and file adverse event reports. This legislation seeks to protect patients and ensure effective device performance through increased visibility and accountability for medical device servicers.

Chairman Burgess, Ranking Member Green, and distinguished members of the Subcommittee. Thank you for the opportunity to appear before you today to discuss improvements to the regulation of medical technologies. I am Joe Robinson, Senior Vice President of Health Systems Solutions for Philips North America and chair of the MITA Board of Directors. I'm here today to testify on behalf of the Medical Imaging and Technology Alliance (MITA).

MITA is pleased to submit the following testimony on H.R. 2009, the Fostering Innovation in Medical Imaging Act of 2017 and H.R. 2118, the Medical Device Servicing and Accountability Act. These very important pieces of legislation will help patients get the care they need safely and effectively.

MITA also supports H.R. 1736, also the subject of this hearing, to make improvements to the FDA's inspections process.

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H.R. 2009 – THE FOSTERING INNOVATION IN MEDICAL IMAGING ACT OF 2017

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information

systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.

The Council on Radionuclides and Radiopharmaceuticals (CORAR) is an association comprised of companies who manufacture and distribute radiopharmaceuticals, radionuclides, and contrast agents primarily used in medicine and life science research. CORAR advocates for regulations and legislation that facilitate innovation in diagnosis and therapy to advance health care for patients and providers. Specifically, CORAR focuses on manufacturing, transportation, safety, security, government reimbursement, and regulatory issues that can impact the radiopharmaceutical, radionuclide, sealed source, and contrast agent industries. CORAR pursues a proactive agenda which includes education of the Congress and regulatory bodies on the benefits of radiopharmaceuticals, radionuclides, and contrast agents to medical and life sciences.

FDA CLEARANCE OF IMAGING DEVICES AND THE USE OF CONTRAST IMAGING AGENTS

Contrast agents and radiopharmaceuticals may be prescribed by physicians for use with diagnostic imaging equipment for a number of clinical applications to enhance images allowing for improved visualization and characterization of organs and tissues for diagnostic purposes. For contrast agents, these uses include pediatric diagnosis, MRI for adults, MRA of the brain, CT and many other imaging uses as stipulated in the contrast agents' indications for use. The use of contrast agents has become a central part of modern clinical practice including ultrasound scans,

x-ray exams, computed tomography scans and magnetic resonance imaging. Although some imaging procedures may be performed without contrast agents, the administration of contrast agents improves the clarity of the images obtained. Radiopharmaceuticals are integral to nuclear medicine and positron emission tomography (PET) procedures, as there is no image generated without the use of the radiopharmaceutical.

Contrast agents and radiopharmaceuticals are administered in different ways. Some are administered orally; others are injected or delivered through an intravenous line. After the imaging procedure, most are naturally excreted by the body.

The United States Food and Drug Administration (FDA) is currently not willing to approve or clear imaging devices, or imaging device enhancements, for use with currently approved contrast agents if the contrast agents are not also labeled for that use. Since a contrast agent manufacturer often has no need or incentive to revise the labeling, updates to contrast agent labeling are not keeping pace with the technological advancements of medical imaging devices, and such advancements are not being approved or cleared by FDA. FDA believes that their regulations prevent them from approving or clearing a device for use with an approved contrast agent where the use is not also specified in the contrast agent labeling. The purpose of this bill is to authorize FDA, under narrowly specified conditions, to approve or clear an imaging device or an imaging device enhancement (called an “applicable medical imaging device” in the bill) for use with a contrast agent in a new indication that is not among the approved indications of the contrast agent.

MITA, CORAR, and their respective members have been working collaboratively with the FDA for nearly 20 years to find a reasonable solution to this issue. In fact, the topic was addressed as part of the MDUFA II agreement in 2007. Ten years later, the problem has yet to be

resolved by the Agency. Therefore, we are asking Congress to pass H.R. 2009, the *Fostering Innovation in Medical Imaging Act of 2017* to provide clarification to the Agency on an appropriate clearance and approval pathway for imaging devices used with contrast agents.

WHY THIS MATTERS TO PATIENTS AND PHYSICIANS

Diagnostic imaging that utilizes contrast agents to enhance the image is a safe and invaluable tool for clinicians and the standard of care in many cases. Neither physicians nor patients benefit from the current situation as new imaging innovations are being held up at the Agency or are being omitted from equipment in order to obtain approval or clearance, while being widely available in other parts of the world. Without the benefit of new imaging innovations, physicians know less about a patient's condition and must make a less informed decision about the required course of treatment.

This legislation would allow patients to have more rapid access to new imaging technologies that involve the use of contrast agents. We believe this would allow for a broader and more equitable adoption of the latest innovation in the use of medical imaging. Currently, there can be a disparity between research centers of excellence and the community hospitals that serve most patients across the country. Research centers have the capability and resources to conduct the research necessary to use imaging technology in an expanded way. Through this research, they develop advanced imaging techniques. Generally, device manufacturers are then able to use the research and seek clearance or approval for expanded indications. For indications that include the use of contrast agents, the regulatory pathway for expanded indications is confusing and cumbersome, and manufacturers have been unable to obtain clearance or approval. Therefore, information about the new indications is not reaching outside of the research centers, meaning many American patients do not have access to the latest innovation. In some cases, new

indications for contrast agents and medical imaging devices are widely available in other countries years before they are available to American patients.

MITA urges Congress to pass H.R. 2009, the *Fostering Innovation in Medical Imaging Act of 2017* to ensure that patients and physicians, regardless of the type of institution, have access to innovative diagnostic imaging capabilities.

FDA TREATMENT OF NEW CONTRAST INDICATIONS FOR DEVICES

In December 2009, FDA released a guidance document entitled: “Guidance for Industry: New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.” This Guidance was part of an agreement under the Medical Device User Fee Amendments of 2007 (MDUFA). Specifically, FDA agreed to develop a guidance document for medical imaging devices used with “contrast agents or radiopharmaceuticals” to help both FDA reviewers and industry to understand the appropriate pathway for approval or clearance of these products.

Imaging device manufacturers requested this guidance from FDA because for years they had struggled to find a consistent pathway through the FDA regulatory process and anticipated the guidance providing stability and transparency. Unfortunately, the 2009 guidance did not provide the clarity manufacturers’ were seeking. In many ways it is so restrictive that it has made the process more confusing and cumbersome than before, essentially restricting the regulatory process for innovative imaging devices that may be used with contrast agents, where the device indication is not described in the labeling of the contrast.

Over the course of 2010, as the guidance was implemented, the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) struggled to interpret the guidance with regard to the circumstances in which the use of contrast

agent may be acceptable. As a result, imaging devices that had been cleared by FDA even a year or two before guidance was issued, that included features involving the use of approved contrast agents were no longer being cleared or approved by the Agency. This left manufacturers with few options for FDA clearance short of stripping new devices of contrast imaging functionalities — in effect “defeaturing” devices — turning back the clock on technology and running counter to the practice of medicine. Further, these basic features are not new or novel.

In 2011, the FDA met with key stakeholders, including MITA and the American College of Radiology (ACR) to discuss the potential public health consequences of continued implementation of the guidance. The FDA agreed to a non-enforcement policy for a period of two years while they considered a more efficient method for approving medical imaging equipment that may be used with contrast agents with non-conforming labels. The two-year period has long since expired, and the guidance is still in place on the FDA website, which could lead to further confusion in the marketplace and the Agency. MITA and CORAR have met with FDA throughout the intervening years to discuss the issue, but no resolution has been forthcoming.

H.R. 2009, FOSTERING INNOVATION IN MEDICAL IMAGING ACT OF 2017

The current situation for contrast agent and medical imaging device approval and clearance hinders the Agency’s goals of fostering medical device innovation, enhancing regulatory predictability, improving patient safety and promoting public health. The Fostering Innovation in Medical Imaging Act of 2017 makes clear that CDRH has the authority to consider and approve or clear, under certain specified conditions, a premarket application or notification for a medical imaging device for use with a contrast agent even if the labeled indications do not match. The bill also specifies that contrast agent manufacturers are permitted, but not required, to

update their labels to add the new device contrast indication through an NDA supplement. MITA and CORAR support the passage of this legislation.

Specifically, CDRH may clear or approve a medical imaging device for a new indication involving the use of an approved contrast agent where the contrast agent is not approved for that indication, as long as the contrast agent is not used:

- in a concentration, rate of administration, or route of administration that is different from those described in the approved labeling of the contrast agent;
- in a region, organ, or system of the body that is different from those described in the approved labeling of the contrast agent, unless the Secretary determines, based on information contained in the device application or 510(k) notification, that the difference does not affect the safety of the contrast agent when used with the device;
- in a patient population different from the patient population described in the approved labeling for such contrast agent, unless the Secretary determines that there is no increased risk; or
- in an imaging modality, such as ultrasonic, ionizing radiation, or magnetic resonance, that is different from those described in the approved labeling of the contrast agent.

By clarifying the process for imaging equipment manufacturers to gain approval or clearance for new technologies that utilize formerly approved contrast agents, this bill will spur even more innovation. This is an opportunity to ensure patient access to new imaging technology and give their physicians even more specific information when considering treatment options. This bipartisan bill provides medical imaging device and contrast agent manufacturers a clear regulatory pathway to ensure all patients have timely access to innovative advanced

medical imaging technologies. Many of these new medical imaging technologies are indicated with previously approved contrast agents. In many instances, medical imaging technology advancements have outpaced the approved contrast agent labels.

H.R. 2009, the Fostering Innovation in Medical Imaging Act of 2017 will help manufacturers of medical imaging devices clear unnecessary regulatory hurdles and improve access to advancements in medical imaging that help physicians detect disease earlier when it's more treatable. It will also permit, but not require, contrast agent manufacturers to conform the indications to the new device indication by adding the new device indication through a NDA supplement. Removing impediments to technological advancements in imaging will encourage innovation and allow physicians to better diagnose and treat patients in the United States in a manner that is consistent with medical practice internationally. This bill builds on the 2017 user fee agreements and will ultimately allow patients in all communities to access the cutting edge innovation in diagnostic imaging by labeling products with new indications for use.

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H.R. 2118 - THE MEDICAL DEVICE SERVICING AND ACCOUNTABILITY ACT

Currently, only servicing activities performed by medical device manufacturers are held to any quality, safety, or regulatory requirements by the FDA. Non-manufacturer entities have no FDA oversight and do not have to follow FDA regulations. This is an important problem because performance of servicing activities within a quality system by properly trained personnel using

qualified properly sourced parts reduces the risk of harm to the patient, healthcare provider, or device operator and reduces risk of poor performance of the device.

The medical device servicing industry has changed significantly since the issue of device servicing was last seriously considered by the FDA in 1997-98. The number of unregulated and unregistered organizations and persons servicing medical devices has increased over the last twenty years without any comparable adjustment in the regulatory framework governing these activities. Unregulated and unregistered service providers are a growing and significant portion of the industry about which the FDA, healthcare providers, patients, and manufacturers know very little due to the lack of regulatory oversight, registration, or reporting.

Our goal is to ensure that performance of these activities always results in the safe and effective operation of medical devices. H.R. 2118, the Medical Device Servicing and Accountability Act takes an important first step toward this goal by requiring that all medical device servicers register with the Food and Drug Administration (FDA), maintain an internal complaint handling system, and report adverse events to the FDA.

MITA member companies are responsible for the innovation, original design, manufacture, packaging, labeling, assembling and upgrading of medical devices. Original equipment manufacturers also often provide servicing activities for installed devices both their own and those originally manufactured by other companies.

Whether or not the manufacturer is also the entity which services a device, it has a stake in all service activities. Improper servicing presents significant concerns to the manufacturer, including creating challenges such as:

- Difficulties in future manufacturer-provided servicing operations and the potential for significant periods of downtime if poorly performed previous repairs must be remedied;
- Difficulties in providing future field upgrades or field corrections to the device if improper parts have been used or if the device has otherwise been altered;
- Lack of required regulatory reporting and incomplete device history does not allow for tracking of significant events, root cause investigation, or prevention of adverse events;
- Voided existing device certifications (e.g. UL certifications);
- Diminished brand value due to unsafe and ineffective operation of the device; and
- Liability concerns for the manufacturer if the device injures directly or indirectly a patient or operator.

Due to the fact that our member companies and their service departments regularly encounter these and other challenges, we have raised this issue with the FDA several times over the past few years. In raising this issue, our goal is to ensure the performance of servicing activities always results in the safe and effective operation of medical devices.

More specifically, our interest in this issue is driven by patient safety. It is because of patient need that medical imaging devices exist. Medical imaging is essential for the screening, diagnosis, staging, therapy guidance, therapy monitoring, risk stratification, and surveillance of a multitude of medical conditions. For this reason, the patient is the most important stakeholder in medical device servicing. Patients and their healthcare providers count on the safe, effective, and reliable operation of medical devices. If medical devices do not perform properly or do not perform at all due to improper servicing, patients may not be able to receive the care they need and healthcare professionals are unable to do their job effectively.

The nature of the risk to the patient is discussed in greater detail below, but, in general, there are two main categories of patient harm:

- 1) Direct bodily harm resulting from improper functioning of the device due to mechanical, maintenance, or calibration issues¹ or healthcare-associated infections²
- 2) Indirect harm resulting from delayed diagnosis or misdiagnosis due to poor image quality³

Generally there is a risk of delivering non-conforming devices if servicing activities are not properly performed as defined by the original equipment manufacturer. A non-conforming device means that the device does not fulfill its specifications and poses a risk in regards to the safety and effectiveness of the device, and thus potentially also to the health and safety of patients and users.

Although this is not a comprehensive list, there are a number of specific risks depending on the kind of device in question:

- **Electrical shock**—All medical imaging devices require electricity to function. If the device has not been properly wired, has incorrect parts, etc..., then there is the risk that a living being interacting with the device could receive an electrical shock.
- **Over exposure to radiation**—Some imaging devices, including X-Ray and CT scanners, emit radiation, resulting in potential over-exposure if not properly calibrated or maintained, leading to bodily harm.

¹ E.g. excessive radiation from incorrectly calibrated equipment or physical injury from mechanical failure

² E.g. infections resulting from improperly sealed ultrasound transducers

³ E.g. blurry images due to miscalibration, resulting in obfuscation of malady

- **Poor image quality**—If improper servicing leads to a device being improperly calibrated, the images the device produces could be of poor diagnostic quality due to artifacts or other issues. This could lead to misdiagnosis including both false positives and false negatives. It could also require re-imaging due to poor image quality.
- **Mechanical failure**—If the device in question experiences mechanical failure due to improper servicing, bodily harm to the patient ranging from pinching to crushing could result.
- **Air embolism**—In the case of injection devices, if the device has not been properly serviced, the patient could experience an air embolism and die.
- **Infection**—In the case of ultrasound and other devices, if the device has not been properly sealed as part of servicing activities, patient infection could result.
- **Explosion**—If the magnet in an MRI machine is not properly vented, pressure can build up inside the magnet resulting in eventual explosion.
- **Burns**— Incorrect replacement materials or parts in an MRI machine may disrupt the path of radiofrequency energy, causing excessive heating and resulting in patient burns.
- **Interference with other equipment**—If a device’s electromagnetic shielding has been improperly serviced, operation of the device could be potentially detrimental to other equipment in surrounding area.
- **Asphyxiation**—If the magnet in an MRI is improperly vented, then helium gas could displace air in the room, resulting in asphyxiation.

The patient has the most at stake if the device fails to perform in a safe and effective manner due to improper servicing. Patients should be able to assume an equivalent level of safety and efficacy regardless of the service provider. Performance of these activities within a quality system by properly trained personnel using qualified, properly sourced parts greatly reduces the risk of harm to the patient.

Unfortunately, it is not currently possible to know the full scope of problems that have occurred when there has been no prior scrutiny or any regulatory oversight of non-manufacturer service providers and other third parties which would require reporting of problems. The only way to determine the magnitude of the problems associated with improper performance of these activities would be through regulation of all entities which perform these activities, including registration and reporting.

Although further steps will be necessary to ensure consistent safety and quality, the Medical Device Servicing and Accountability Act will take a crucial first step in addressing this issue by requiring that non-manufacturer 3rd party servicing organizations step out of the dark and make themselves known to the FDA and the American public, maintain an internal complaint handling system, and report adverse events to the FDA.

Often, a manufacturer does not learn of an issue with its device unless the owner or operator of the device or a third party service entity reports an issue to the manufacturer. This does not happen in all cases. Further, the manufacturer often is not notified of an issue with the device until the device has failed or encountered some other problem which the servicer has been unable to resolve. Although the manufacturer may be made aware of the issue at this juncture, the manufacturer is not necessarily informed of the issues which led to this event. In many cases, there will have been a series of problems with the device for which assistance from a non-

manufacturer entity was sought. These activities performed by the non-manufacturer entity are not required to be reported to the FDA or to any other organization which would be compiling and trending a comprehensive database of problems.

Further complicating the situation is the fact that it is often difficult for manufacturers to determine the source of observed problems because third parties generally do not place any labeling on the device to indicate it has passed through their hands. Awareness of device problems will decrease as equipment becomes less traceable due to turnovers in service providers and equipment ownership.

Manufacturers regularly encounter examples of improper servicing. Although they are in no way comprehensive or inclusive, the examples below serve as a sample of the issues that are regularly encountered. In some cases, we have photographic documentation of the issue. However, not all situations easily lend themselves to visual representation.

IMPROPER SERVICING OF AN MRI SYSTEM

The following photos were obtained in January 2017 from an MRI system being used to scanning patients. The manufacturer was contacted to service the system due to poor image quality that the third party was unable to correct. The system was found to be in significant disrepair with several components damaged, poorly repaired or missing. After a detailed evaluation the manufacturer recommended a significant amount of repair that was similar to deinstalling and reinstalling the system to replace the necessary components and recalibrate the system.

Receive Channels Disconnected

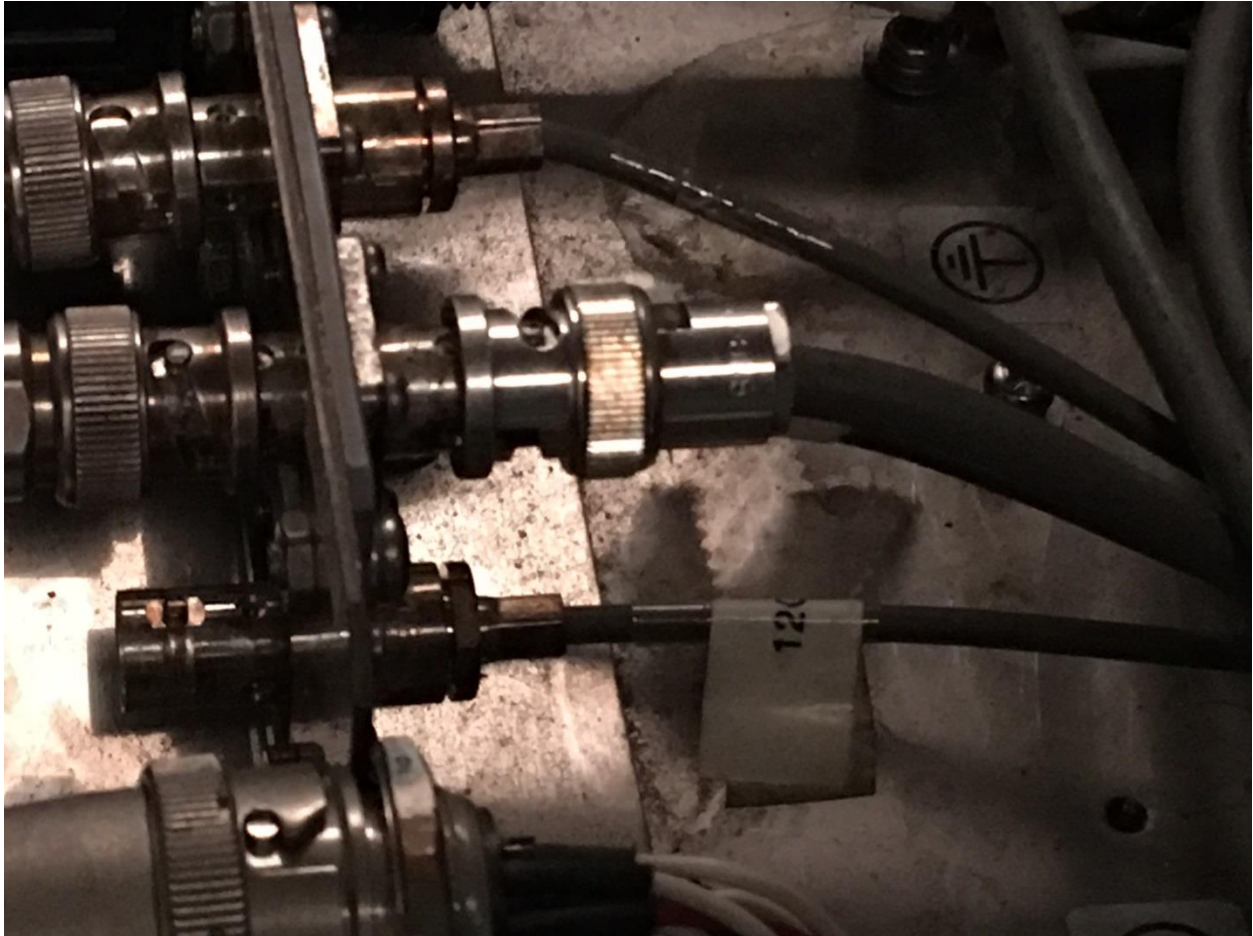
This MRI system includes four receive channels from the coils used to scan different portions of the anatomy. As shown in this photo, three of the four channels were disconnected because they were nonfunctional. Troubleshooting showed all three other were open and the fourth connected line was also compromised with readings that were outside of specification.



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Incorrect Cable Replacement

At the foot of the patient table one of the 4 receive cables (the only remaining functional) was replaced with the incorrect cable. The incorrect cable is the larger diameter cable the center of the photo.



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Shoulder Coil Serviced With Tape

The shoulder coil was found damaged with several attempted repairs using a white tape. The use of tape would prevent proper cleaning of the coil. The coil failed to meet specification when tested.



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Head Coil Latch Damaged and Non Functional

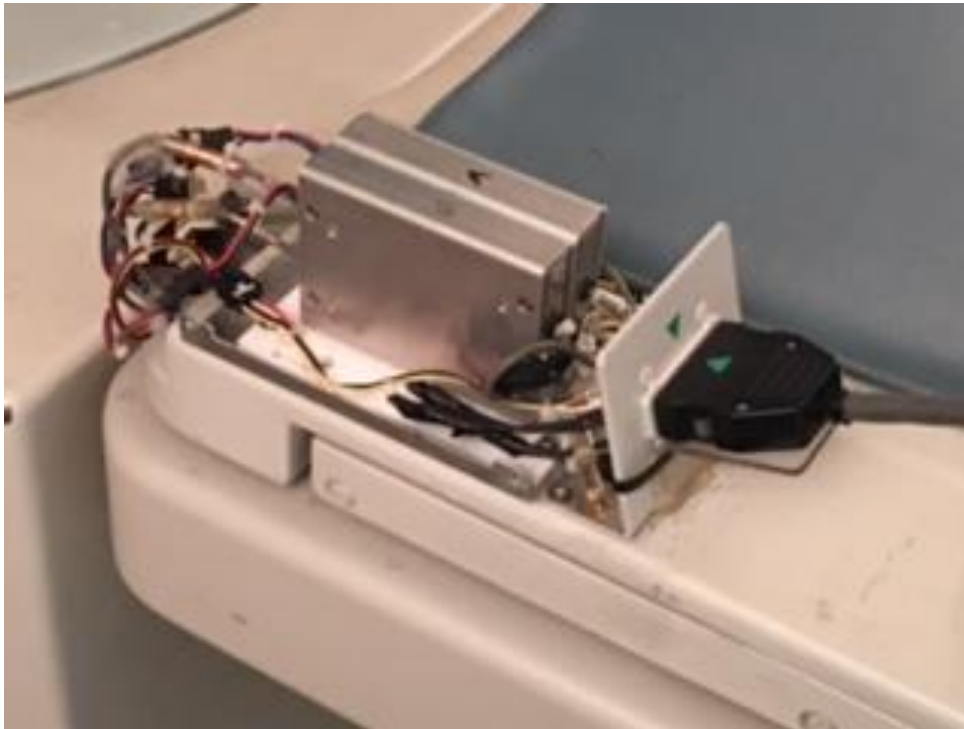
The screw holes on both sides of the coil latch were stripped out. Repairs were attempted with incorrectly sized screws and tape. The top portion of the coil could not be properly secured to assure a good connection of the receive lines in the top portion of the coil.



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Missing Signal Amplifiers

The patient table is equipped with 4 pre-amps. The manufacturer found two of the pre-amps were missing from the system and had not been replaced.



Incorrect Computer Replacement

The manufacturer found the commercial grade SUN workstation normally used to operate the system replaced with a consumer grade system. The possible impact on system performance is not clear and would require extensive testing to validate and verify proper operation when combined with the entire MRI system. No photo available. Additionally the system indicated it was upgraded but the proper software upgrade was not loaded. This would indicate an incorrect software reload was performed.

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Aluminum Foil Used for Shielding

The manufacturer found aluminum foil used to shield some of the cables in the scan room. It is believed this was an effort to shield the receive cables to correct poor signal and artifacts in the images. This can present safety and electrical issues when used within the MRI filter panel that contains high voltage.



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Patient Table Pads Damaged

The patient table pads were damaged and should be replaced to allow for proper cleaning.



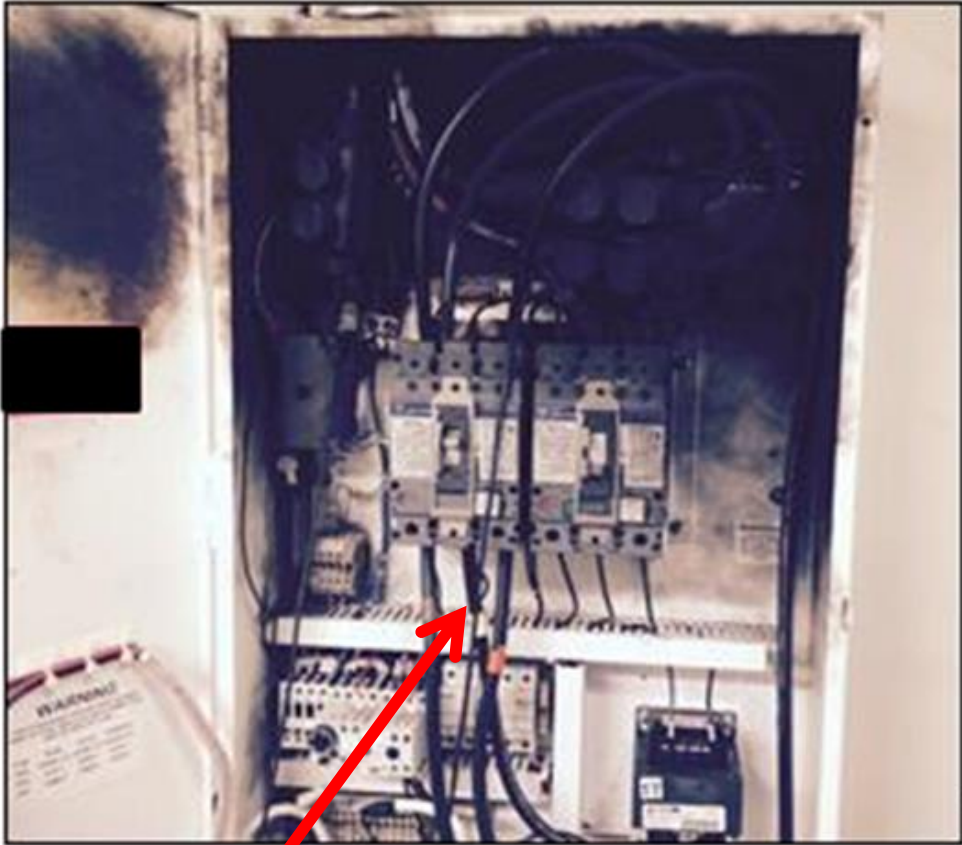
IMPROPER SERVICING OF AN MRI SYSTEM

A third party service sub-contractor hired by an onsite contractor was working at a customer site troubleshooting an MRI system. The servicer was working in the service panel with the power on when an arc flash occurred resulting in burns to the contractor. The blast knocked him back and onto the floor. Other people working in the area said the event sounded like an explosion. The event also resulted in approximately half of the hospital losing power.

It is not known with total certainty what the servicer was doing at the time of the event or what caused the event to occur. He was going to be hooking up a power monitor to the system, but at what stage of that process he was at is unknown. He could have been checking the voltages prior to connecting the monitor or performing some other troubleshooting activity.

It is known, however, that he did not have on his Arc Flash Personal Protection Equipment (PPE) at the time of the event. The PPE itself would not have prevented the incident from occurring, but it would have prevented or lessened the severity of the injuries that occurred. This is potentially an example of inadequate training and non-compliance which resulted in bodily harm, equipment damage, and loss of power to the hospital.

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Panel where arc flash occurred

IMPROPER PART IN AN ANGIOGRAPHIC POWER INJECTOR SYSTEM

During a recent service call for an angiographic power injector, it was observed that a third-party service vendor inappropriately substituted an original equipment manufacturer's steel pin with a simple sheet metal screw to hold a syringe turret in place.

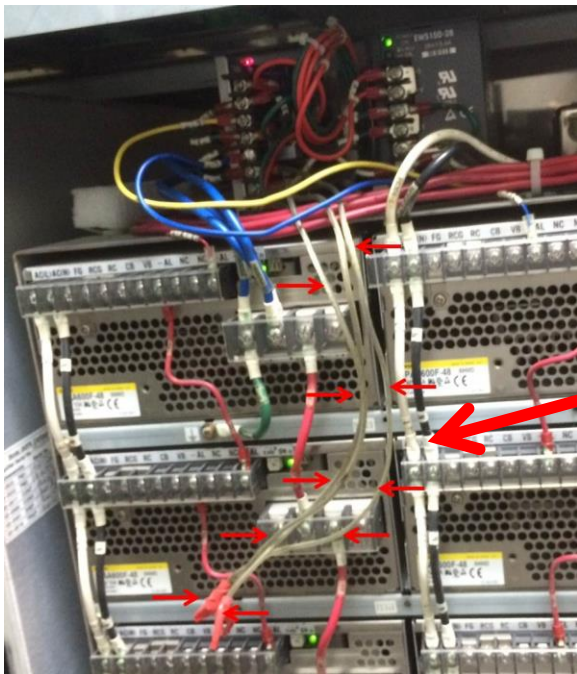
Angiographic power injectors of this class can inject fluid at pressures of up to 1200 psi. If this substituted sheet metal screw were to break or otherwise fail during a procedure, the turret could break free, potentially causing the turret and connected syringe to act as dangerous projectiles. Additionally, this improper part could cause vibrations during the injection, thereby leading to ancillary issues such as delay of procedure and eventual diagnosis due to unexpected equipment behavior.



Common sheet metal screw substituted for steel pin

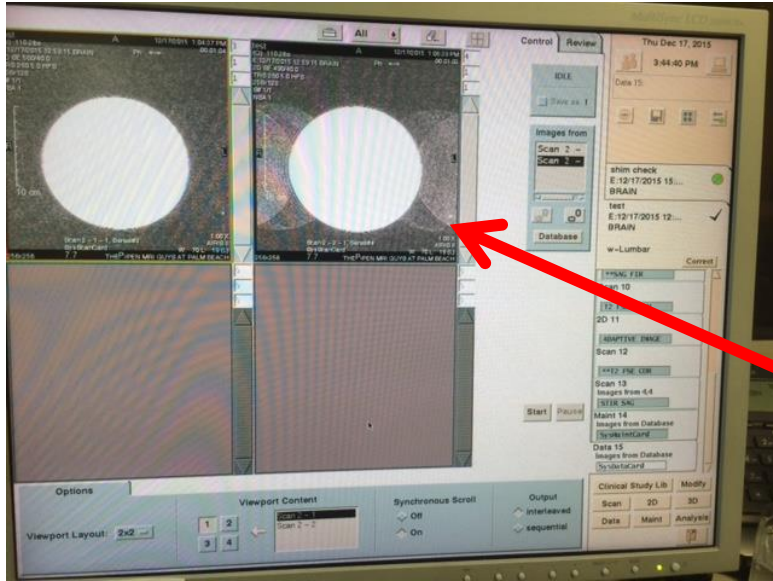
IMPROPER SERVICING OF AN MRI SYSTEM

In this example a customer called the manufacturer and requested service on a 0.3T permanent magnet MRI due to ghosting on multiple images. The customer had been experiencing machine downtime due to the inability to properly scan patients. It is unknown for how long this problem existed. The manufacturer determined that the device had been improperly serviced, noting that additional wiring had been added to the electronics cabinet with no markings and terminations using hand-secured wire nuts. Further, the primary power supply cables lacked strain relief and protection from abrasions.

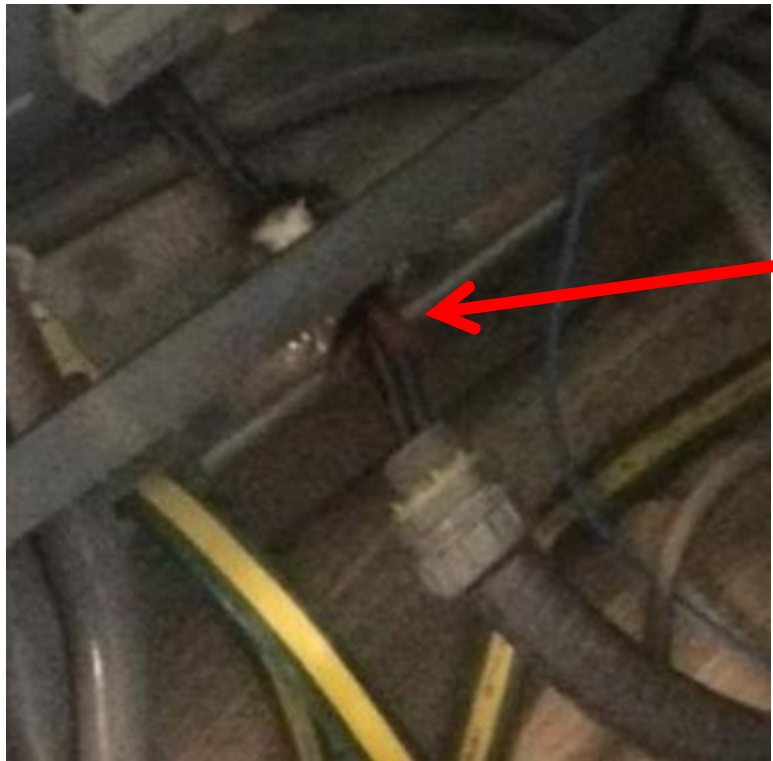


Speaker wire connecting power supply to unknown points and terminated with wire nuts

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Example of ghosting on medical images



The primary power supply cables lacked strain relief and protection from abrasion

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This posed a risk of patient harm for a number of reasons:

- Ghosting which may require additional patient scans, delaying care or causing a misdiagnosis;
- Noise bands which may require additional patient scans, delaying care or causing a misdiagnosis;
- Additional wiring which may void any NRTL listing of the system (i.e. UL or ETL certification) and may not meet electrical codes;
- The primary power supply cables entering the electronics cabinet did not have the proper strain relief and were not properly protected from abrasion where they entered the cabinet, potentially causing an electrical short, fire, or electrocution; and
- These issues may have resulted in the device no longer meeting electrical codes.

This improper servicing caused decreased equipment performance due to the resulting poor image quality as well as the electrical issues which may have caused an electrical short, fire, or electrocution.

The customer was advised to discontinue use of the system and was provided with a proposal to perform a full system installation review for repair and calibration.

IMPROPER SERVICING OF A CT SCANNER

In a CT scanner it was discovered that the computer cooling ducts, image control system, and image reconstruction cabinet had clogged filters and ducts. Further, it was noted that:

- The image evaluation system software back-up was out of date;
- The image evaluation system CD drive did not work;
- The image reconstruction system computer CD drive did not work, requiring computer replacement;
- The gantry water temperature was showing as “Out of Tolerance”;
- The gantry water pressure was too low and out of specification;
- The gantry left front cover safety switch required replacement;
- The CT control box buttons were worn out;
- The table vertical drive was emanating scraping noises; and
- The network node (creation/deletion) problem had existed for approximately one year.

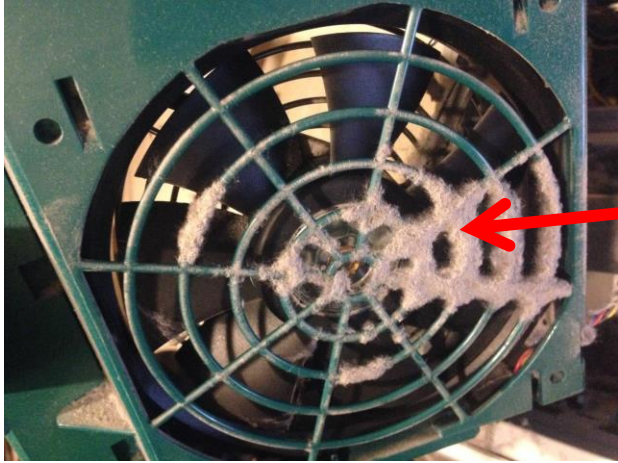
This resulted in the reliability of the image control system being compromised. The database could not be rebuilt, causing slow system performance. Further, the image reconstruction system was compromised, causing slow image reconstruction. The CT scanner was offline for several days while the issue was remedied.

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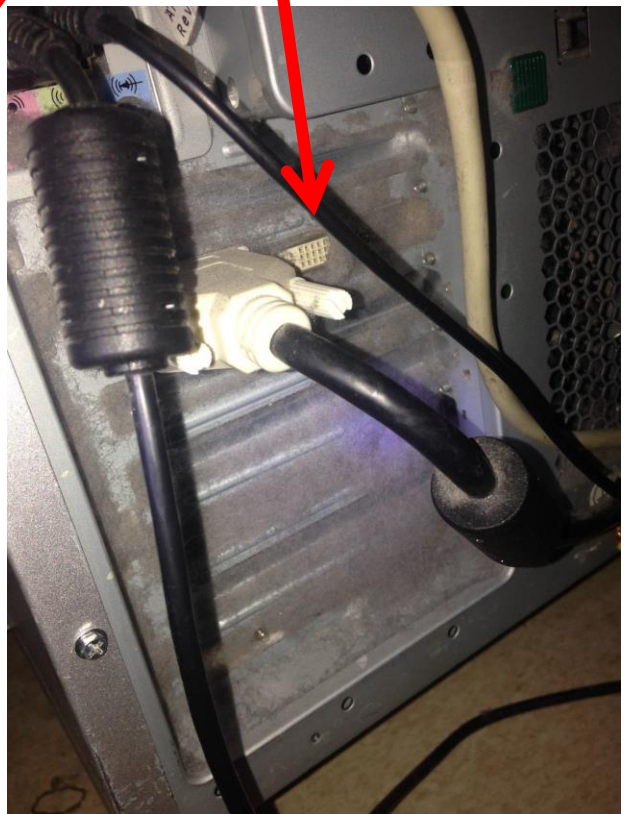
Clogs resulting from improper servicing



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Clogs resulting from improper servicing



IMPROPER SERVICING OF A NUCLEAR MEDICINE CAMERA

A manufacturer was contacted by a dealer who was dealing with a customer complaint about their nuclear medicine camera. The customer had been using a third party servicer which improperly serviced their device and was now refusing to return and correct the issue.

The device had numerous masked adjacent pixels in the detector image which could also mask any heart defects in the image. Further, the cooling unit was improperly connected to external power, bypassing the system's isolated power and grounding system potentially compromising patient safety and device performance.

When adjacent pixels are removed, a portion of the imaging detector is lost, so portions of the heart would not be imaged, meaning a heart defect could go undetected by the reviewing physician. When one pixel fails, the system uses data from adjacent pixels surrounding the failed pixel to extrapolate. If two adjacent pixels are bad, then the system does not have a complete sampling of data surrounding the pixels to get a good image. The resulting image would have a blurred spot, resulting in lower diagnostic quality.

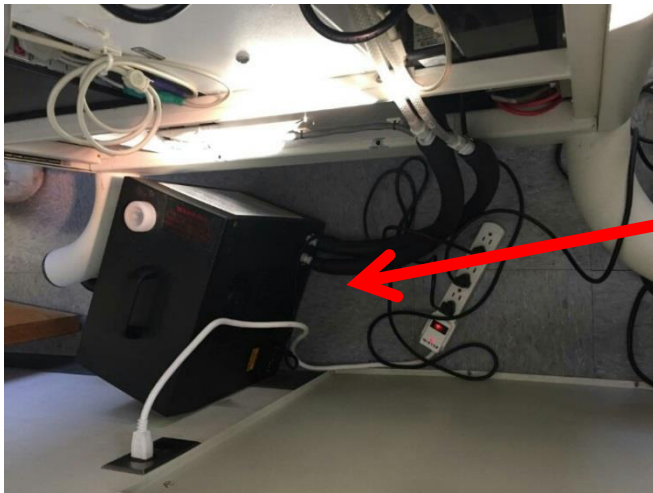
With respect to the improper power connection of the cooling system, the way in which the system was connected violates the manufacturer's power and grounding isolation scheme, potentially compromising patient safety and device performance. Further, this issue could have led to the detector overheating and pixels failing. These modifications violate the Nationally Recognized Test Lab (NRTL) (e.g. UL/EL) listing of the device.

This resulted in such great degradation to the detector head that the customer could not use the device.

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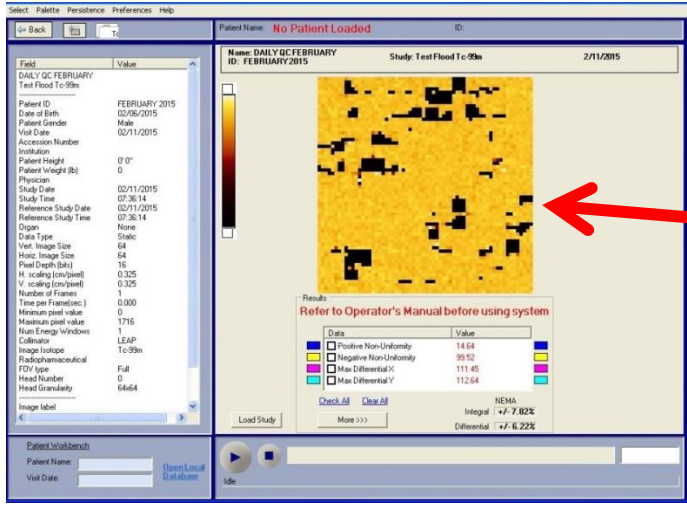


Remote chiller installed outside the unit on the floor with the cover of the unit off, exposing the camera internals

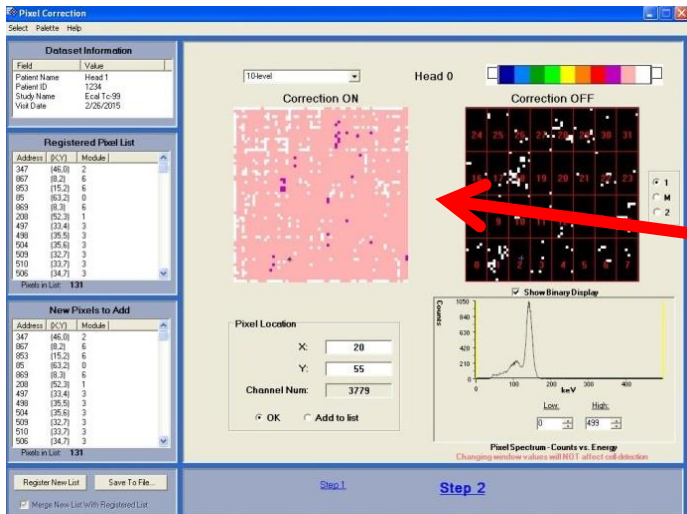


Remote chiller installed outside the unit on the floor with the cover of the unit off, exposing the camera internals

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Masked pixels



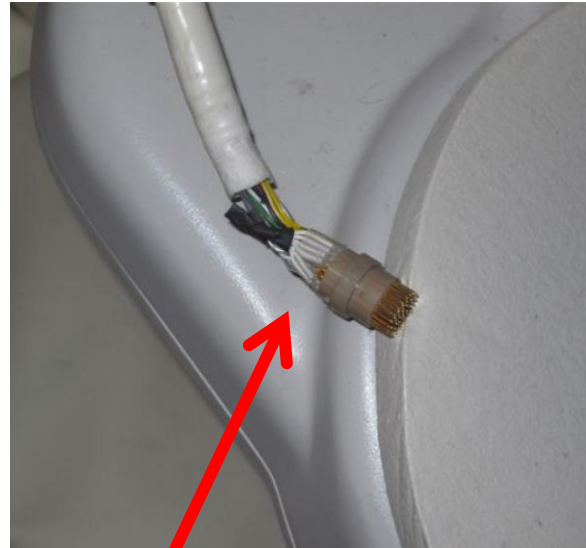
Masked pixels

IMPROPER REPAIR OF AN MRI COIL

In a 0.3T permanent magnet MRI RF coil the signal cable had been pulled out of a connector housing and was repaired with zip ties and plastic tubing. It is unknown for how long the hazard was present.



Coil with plastic tubing and zip ties used to cover damaged cable



Example of failed coil that was hidden using zip ties and plastic tubing

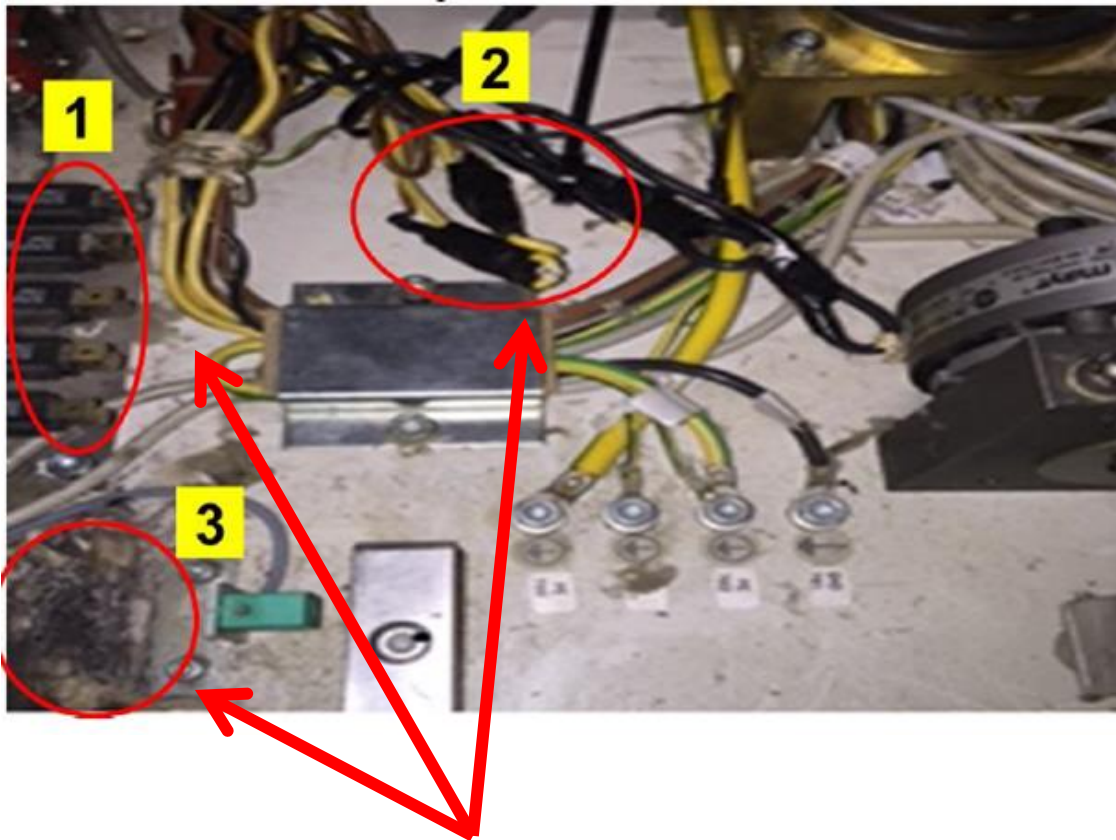
This posed a risk of patient harm for a number of reasons:

- Cable failure may result in:
 - Lost signal or image artifacts causing misdiagnosis or requiring additional scans
 - Electrical arcing causing electrocution or burns
- Zip tie edges are not smooth and may catch on patient skin or clothing;
- Zip ties and plastic tubing did not appear to be material tested and approved for patient contact;
- Zip ties and tubing did not provide proper strain relief for the cable and may have allowed further cable failure; and
- Plastic tubing may have further hidden additional cable failure

This improperly repaired coil did not meet manufacturer quality specifications and was removed from service and repaired.

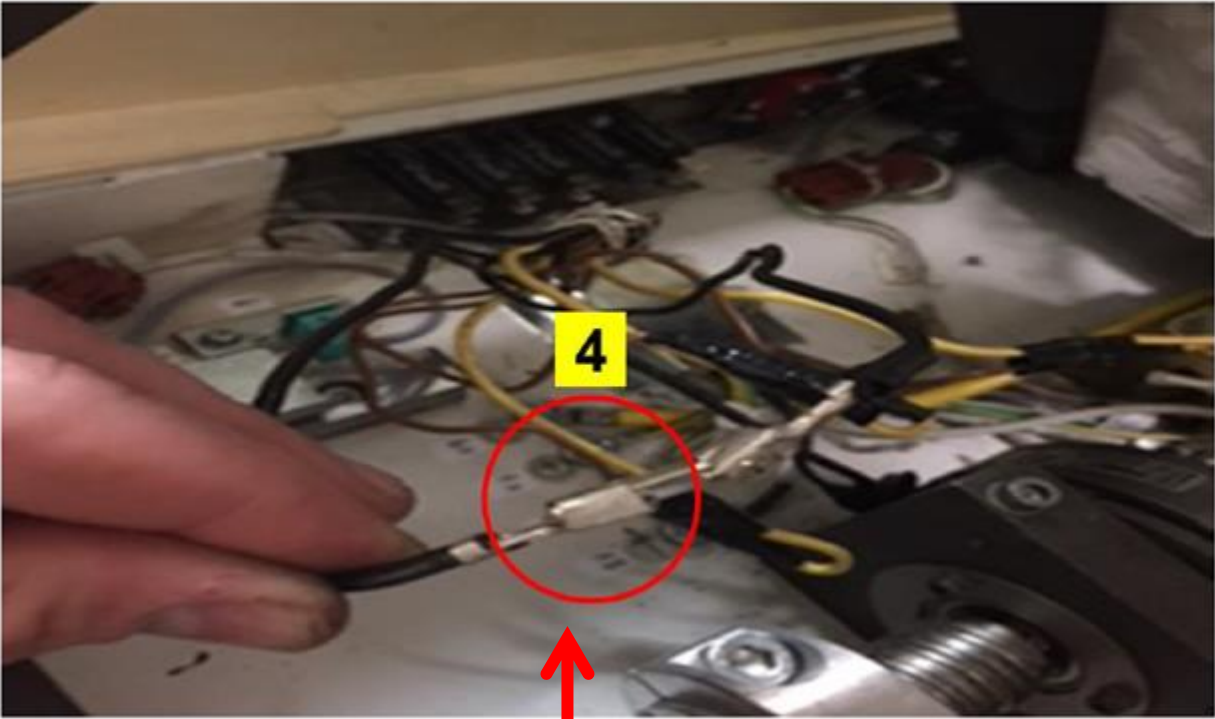
IMPROPER SERVICING OF A CT SCANNER

A facility reported to the manufacturer that it had been having issues with a CT table, workstation, and tube for approximately six months. The manufacturer's service engineer identified table cabling connections that were modified to be non-standard, exposed wiring, non-manufacturer fuses installed, improperly exposed and non-manufacturer soldering connections, cable connections routed and repaired using electrical tape, bent table bolt, and defective transmit cable.

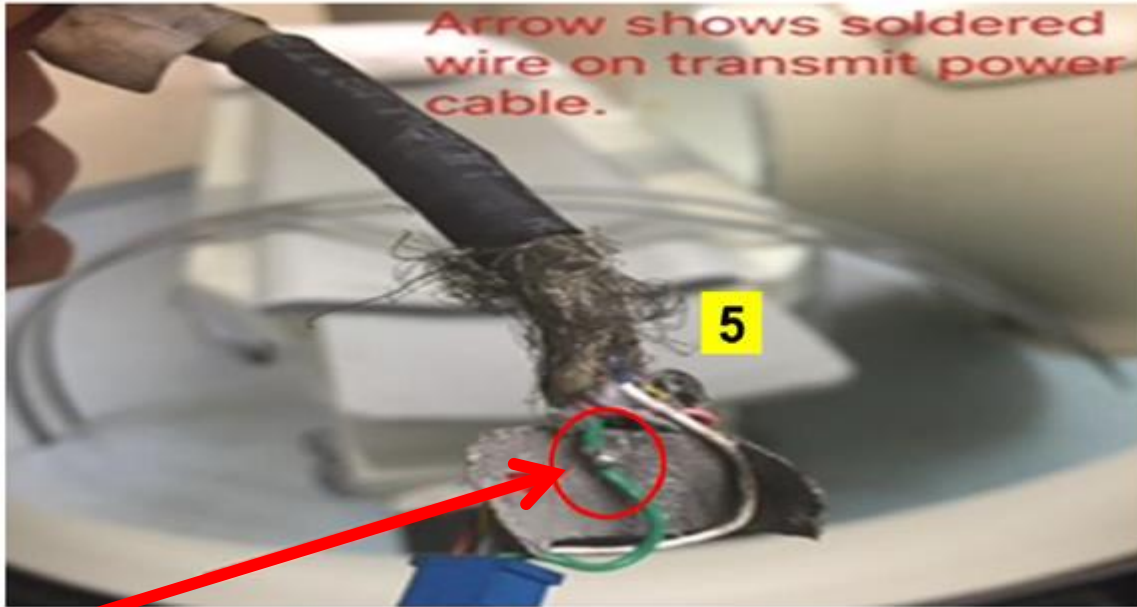


1. The bank of black fuses is not connected to cables, per original equipment manufacturer design and manufacturing specifications
2. Cables have been field repaired with fuses taped to the cable
3. Grease identified in cabling area

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4. Non-qualified fuse, with field repair to reform connector to fit around non-qualified fuse



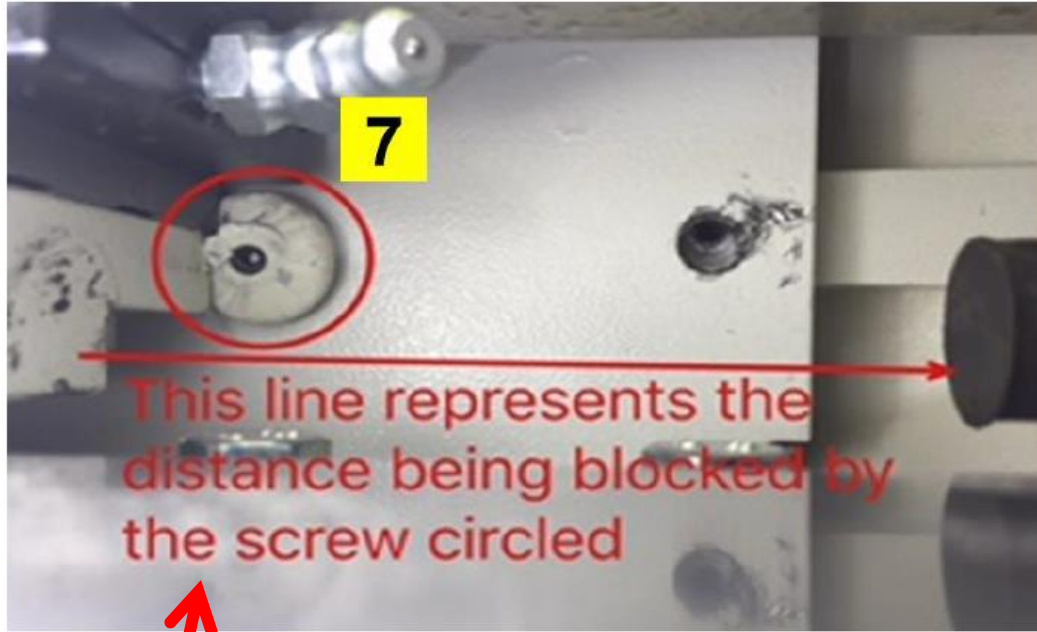
5. Transmit wire connection repaired previously and taped and visible and exposed at joint of green wire

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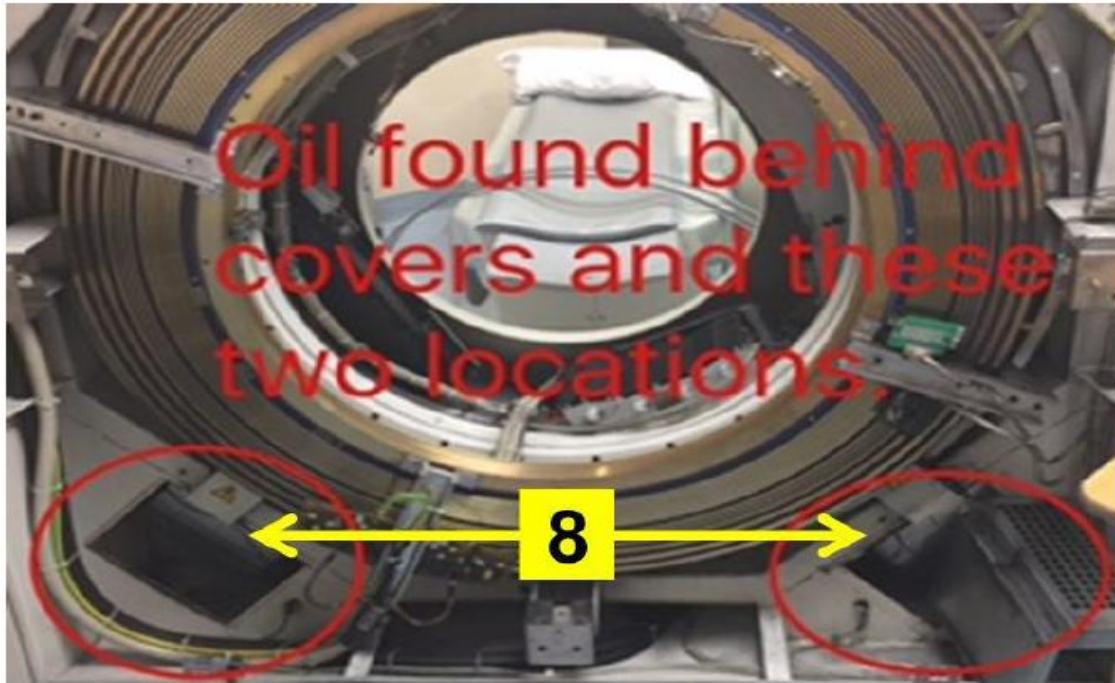
6. Bent screw found, preventing table from full range of horizontal motion

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7. Manufacturer's service engineer identified horizontal travel distance blocked by bent screw

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8. Excessive oil identified

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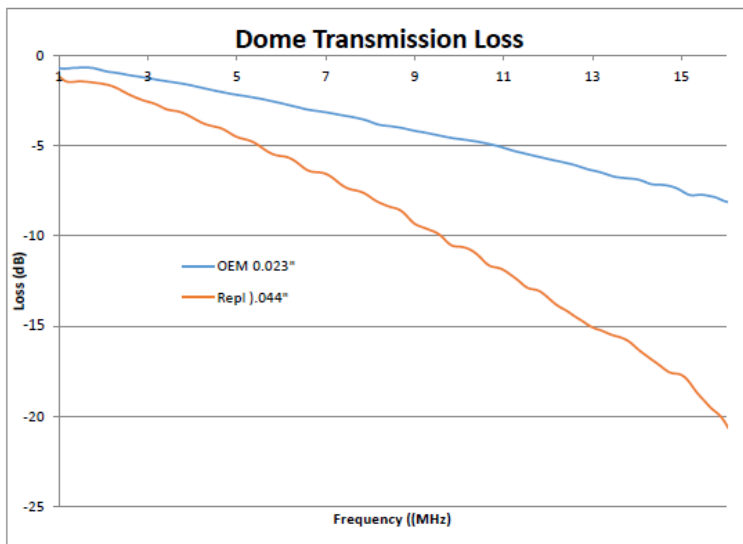


9. Oil and debris identified in back corners of gantry

Improper Repair of an Ultrasound System

An ultrasound endocavitary probe was received for testing from a US hospital. The dome had been replaced as part of a repair done by a third party. The dome material and thickness were different than that of the original device. The result was significantly more attenuation of the acoustic signal as shown below. The clinical user was complaining of lack of depth of penetration in the B-Mode image of the “repaired” probe.

Improper ultrasound probe dome



This improper repair could have resulted in delayed diagnosis or misdiagnosis as well as health conditions associated with a non-biocompatible material.

Improper Parts in an MRI System

In a 0.3T permanent magnet MRI the system CPU and monitor were replaced with unknown aftermarket units that were not tested and validated to operate with the manufacturer's software. It is unknown for how long the hazard was present.



Aftermarket monitor installed on the MRI system



Aftermarket CPU installed on the MRI system

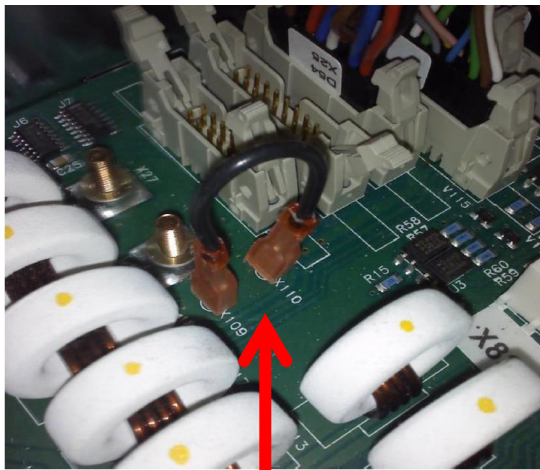
This posed a risk of patient harm for a number of reasons:

- Potential for improper operation or failure of the MRI software due to unknown or untested drivers for the computer components and monitor, and
- Since the monitor was not properly sourced, there is the potential for incorrect calibration or inadequate function for displaying patient images.

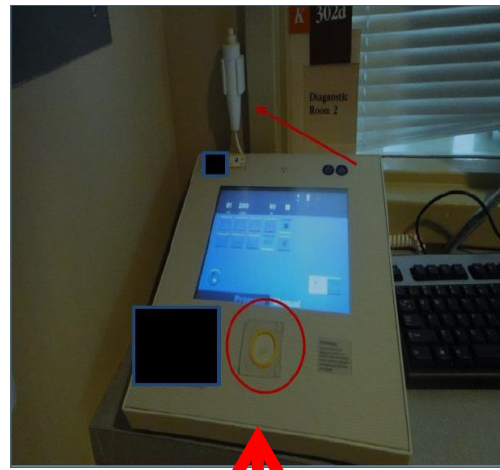
These improper parts were removed and replaced with qualified parts.

Improper Servicing of a Fluoroscopy/Radiography System

In this example, the detector on a fluoroscopy/radiography system had been replaced with a third party detector system which included the third party's user-console and radiation release button. Further, the third party had installed a jumper cable on circuitry to allow grid movement and sensing to be bypassed. This also allowed for multiple exposures to be taking on a single cassette without reseating/resetting the bucky. This, in effect, removed the manufacturer's double-exposure safety feature.



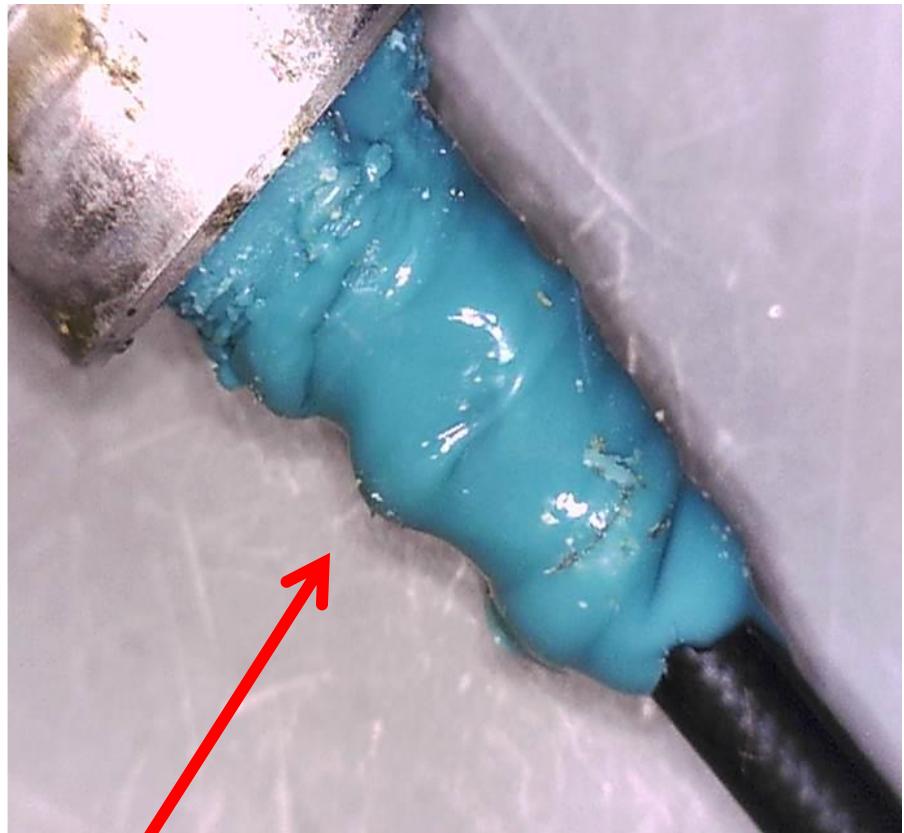
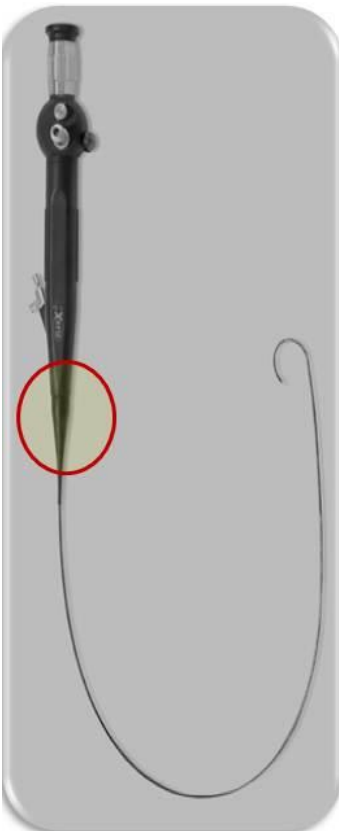
Third party installed a jumper cable on manufacturer circuitry to allow grid movement and sensing to be bypassed



Manufacturer detector replaced with non-qualified detector system which included their user-console and radiation release button (manufacturer exposure button covered over w/Plexiglas plate to

Improper Materials Used to Seal an Endoscope

In this example, a porous unidentified material has been used by a non-manufacturer to seal the shaft from the handle of an endoscope. Being porous, there is a chance for bioburden to infiltrate the device and potentially cause cross contamination. Further, it is unclear whether this material will hold up to sterilization parameters. The scope could fail during use if the shaft were to disconnect from the handle.



Unidentified porous material used to seal the shaft of an endoscope.

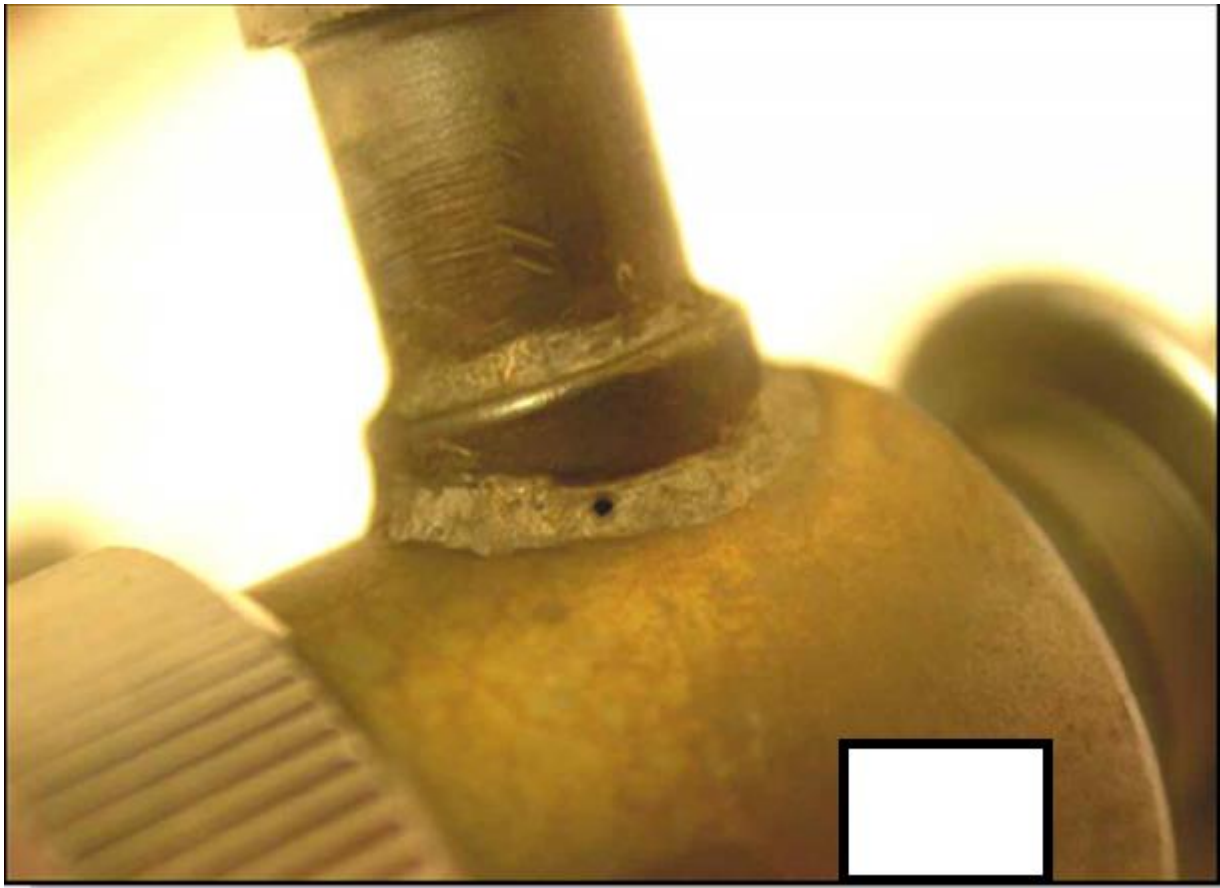
Improper Materials Used to Seal a Laparoscope

In this example, the light post of a laparoscope has been improperly sealed using non-manufacturer epoxy. The epoxy is failing and bubbling. This improper material will not hold up to sterilization parameters. Further, epoxy can harbor bioburden. Charring is also visible in this picture due to pyrogenic reaction. This could cause the light post to overheat and potentially ignite.



Improper Sealing on an Optical Forcep

In this example, non-manufacturer epoxy has been used on the flushing end of an optical forcep. This material would not hold up to reprocessing and sterilization. The material is pitting and the pitted areas can harbor bioburden. Further, a hole has formed in the material. The integrity of this material could fail and the port could break off during a surgical procedure.



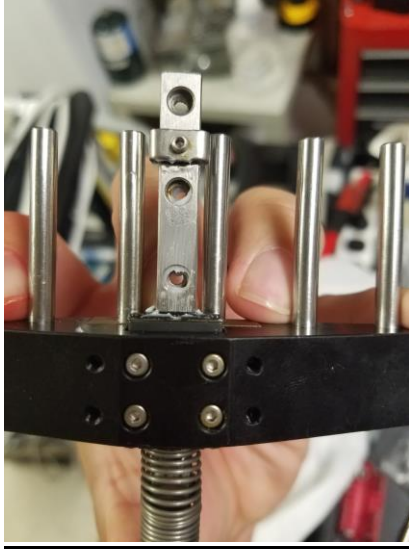
Improperly Serviced Hemostasis Management System

In this example, the field service technician was asked to service a Hemostasis Management System due to motor stalls. The unit was previously serviced by a 3rd- Party provider on June 17th, 2016. Upon inspection of the unit, the field service technician found the x – motor slide assembly completely inoperable, due to dried grease on the gear. While repairing the unit, the field service technician found multiple other errors, such as a bad ADU board, xy interface board, spring sensor, stripped out hardware, resulting in a \$13,000 repair of the unit.

This is a time-sensitive multi-functional testing system that is used to help preserve patient’s clotting factors, assist in the prevention of thrombus formation, and monitor multiple aspects of clot formation. The benefits of the system include fewer complications associated with excess blood loss, preservation of the coagulation system, resulting in fewer transfusions, and fewer surgical reoperations.



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Improperly Serviced Hemostasis Management System

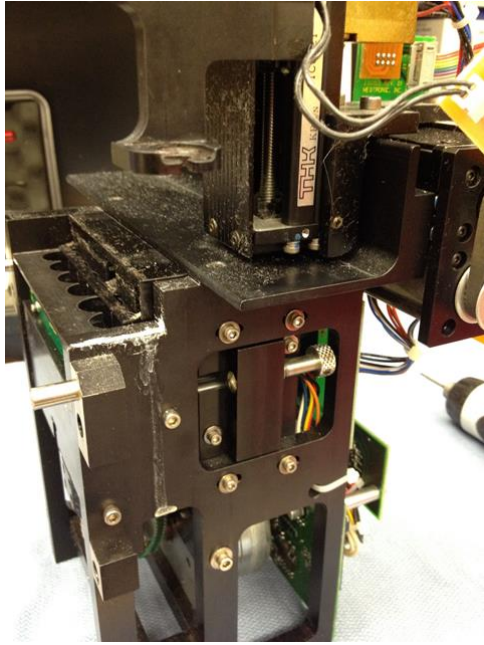
In this example, the field service technician was asked to service a hemostasis management system due to motor stalls. Upon arrive the field service technician noted that the unit has a PM sticker from a 3rd party service provider indicating a preventive maintenance (PM) was completed a few weeks prior on the unit.

Per procedures, the unit is required to be disassembled, cleaned, lubricated, and verification of calibrations. The attached images indicate that the unit was never opened to complete the requirements of a PM.

Improper lubrication of the unit, as in this case, could cause inaccurate dispensing volumes and inaccurate test results.

Improper cleaning may cause the EQC to give false error codes or actual test cartridges not to function properly, enhance possible false or erroneous results to the patient.

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Improperly Serviced Blood Transfusion System

In this example, the field service technician was contacted by the hospital to service their autologous blood transfusion system due to noise coming from the centrifuge bowl. The unit was serviced by a 3rd party provider. Based on the field service technician's assessment he determined that:

- The roller assembly was never removed for cleaning
- The roller assembly significant issues of rust and corrosion
- The centrifuge holder was not in proper position and was pushing the centrifuge assembly to one side of the unit.

This would cause improper function of the roller head for processing blood, additional wear and tear to the disposable tubing, improper volume calculations, and potential motor stalls to the point of not being usable during a case.



Improperly Serviced Cardiopulmonary Bypass Unit

In this example, the field service technician was at the facility to complete service on a cardiopulmonary bypass unit. The technician noted autologous blood transfusion system unit with a calibration tag dating back to January of 2015. The technician informed the hospital biomedical engineer that the unit was overdue for service. The hospital biomedical engineer informed the field service technician that the unit was recently serviced by a third-party provider.

The field service technician showed the attached image to the hospital biomedical engineer and informed her that the autologous transfusion system contains internal filters, and if these filters become obstructed, such as in this case can lead to equipment malfunctions of improper operation inadequate vacuum and overheating.



Improperly Serviced Cardiopulmonary Bypass Unit

In this example, the field service technician noticed an issue with a cardiopulmonary bypass procedures. As a good faith gesture, the field service technician powered on the equipment to confirm the unit was functioning. The field service technician noticed a third-party service card that indicated the unit was just serviced.

The unit failed to power-on due to depleted batteries which are a critical safety feature of the device. Concerned for the increased risk to the patient and operator, had the operator tried using this unit in the battery mode, the operator would have to change to the hand crank operation to maintain proper flow for the patient until AC power was available, the field service technician, notified the customer of the issue. The hospital submitted a P.O. to service the equipment resulting in additional charges to the hospital over what the hospital paid the third-party service provider.

The image is the manufacturer's 'tamper' sticker that remained intact after the unit was serviced by the third-party. Verifying that the unit's cover was not removed by the third-party service provider to conduct proper servicing, which is also necessary to test or replace the unit's batteries.



Improperly Serviced Speed Controller System

In this example, the field service technician was called to service a Speed Controller System. The unit was just serviced by a 3rd- party provider, however, when they turned the unit to battery (back- up for power failure or unavailability of power), the unit stopped functioning. If the battery fails during patient support, the perfusionist must operate in manual mode and hand crank the blood through the system until an alternate power source can be identified.

Based on the state of the equipment, the field service technician determined that the unit was not removed from the base of the heart lung machine. The unit contains two external filters. One filter was obstructed (over-heating, improper performance) and the other was completely missing, allowing dirt and contaminants to get into the electro-mechanical parts.

Along with debris getting inside the unit with the potential to over-heat the equipment, if the operator needed to use this unit in the battery mode, it would increase patient and operator risk. The operator would have to change to the hand crank operations to maintain proper flow for the patient until AC power was available.



An informal survey of the manufacturer community also revealed several other frequently encountered issues with improper servicing:

- Conversion of analog X-ray systems to digital, which include interfacing and modification of circuits. Modifications of this nature have been performed by multiple third party entities. These modifications resulted in rewiring, the blockage of safety features, and changing, at least in part, the intended use of the device. These modifications are being done without coordinating with the manufacturer to ensure that safety, efficacy, and other product requirements are maintained.
- Angiographic X-ray systems:
 - Breaking the video circuit for various purposes (video capture for storage and manipulation). In many cases, the exposure circuit was also broken to trigger the video. In these events, rarely is the equipment isolated or properly grounded. This leads to noise injected into the video and can create a safety issue in which equipment could be touched by the patient while a wire is in him or her.
 - Installation of various wire guidance devices or ultrasound systems physically attached to system. Power and data are typically run on the outside of the system and usually are taped or Velcroed to the imaging system. The improper parts may actually be physically attached to the device, creating grounding loops.
- Mobile Conversions to MR and CT Systems: In general the manufacturer has learned of instances in which third parties have been installing fixed site equipment into uncertified mobile trailers. These installations do not meet planning guide requirements that certified trailer manufacturer's must adhere to. The manufacturer's mobile conversion kits were

not installed and the manufacturer's mobile planning guide not followed. It is important to note that the device was not ordered from the factory as a mobile device and the manufacturer's 510(k)s are not filed for certain MR and CT systems to be used as mobile equipment.

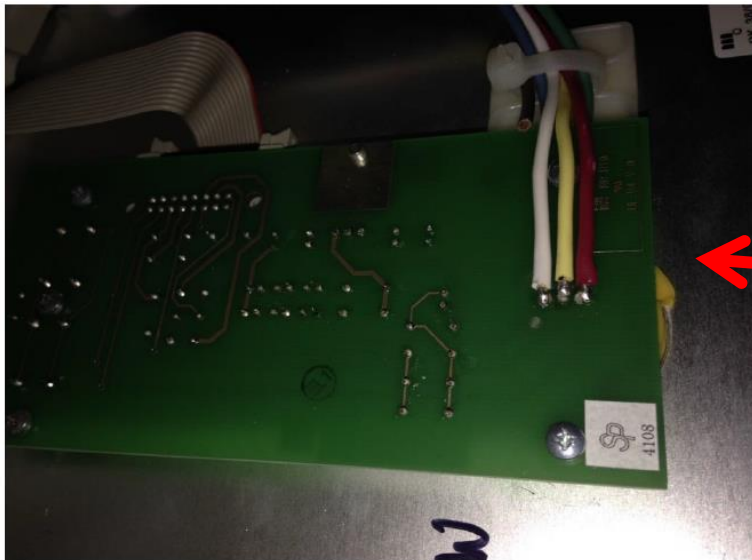
- Converting a fixed site MRI system into an uncertified trailer without using mobile specific components creates an unsafe, unserviceable system. The system did not have proper magnet venting and magnetic shielding. The system's cabling had been modified, compromising access to electronics. The magnetic shielding did not contain magnetic field, posing significant risks. The quench vent had not been validated. The magnet venting had not been rated for high altitude. The serial number was not recognized as a mobile system by factory. Safety updates specific to mobile equipment will not be issued.
- Host computer swap on a mobile MR system:
 - In general this creates an issue as any software updates issued will not be compatible with the host installed as updates are serial number-specific. This also results in software licenses that were purchased for a particular serial number being used on a completely different piece of equipment.
- In a case involving maintenance by a third-party company, an overhead counterpoise support system arm (accessory to a powered contrast injector system) separated and fell, striking a radiology technologist due to a support arm separation. That company, which had the maintenance contract for this equipment, also did not maintain adequate service history records for the system. When the manufacturer was called to address the incident, it was unclear if the equipment had been regularly inspected and maintained appropriately. Regular preventive maintenance is important in ensuring that the device

continues to meet its performance specifications. Thus, the cause of this failure may have been identified and prevented from occurring if routine preventive maintenance had been conducted.

- A case was recently logged detailing a third-party service vendor that had improperly removed a printed circuit board from a powered contrast injector during servicing.

During the manufacturer's investigation, it was determined that the service vendor had applied excessive force to the connector, pulling it away from the Servo/CPU board. This instance resulted in several damaged components that had to be replaced in order to restore the equipment to normal operation.

- Improper third party parts installed as depicted in pictures below:

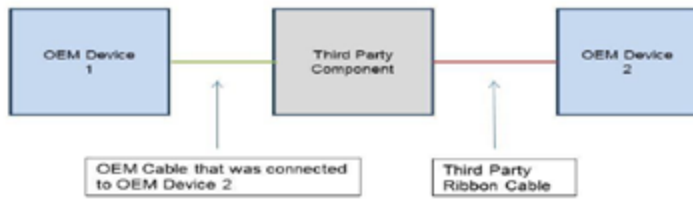


Wires soldered to exposure switch circuit board by third party vendor (it is unknown what these wires do)



Third party vendor power supply and other cables inside control box





A third party component and cable were inserted on the cable that was connecting Device 1 to Device 2 as seen in the diagram and picture

The above examples in no way are a fully comprehensive or inclusive list of the problems or kinds of problems which have been caused by improper servicing. A true statistical analysis and a complete understanding of the extent of the problems caused by improper servicing cannot be achieved unless all service providers are held to the same regulatory, registration, and reporting requirements.

CONCLUSION

All entities engaged in servicing of medical devices should be required to have an appropriately scaled quality system adequate to the activity being performed, meet minimum quality, safety, and regulatory requirements. Although further steps will be required to address all of these concerns, the Medical Device Servicing and Accountability Act takes an important first step in requiring that all servicers register with the FDA and maintain a complaint handling system to address device safety and performance issues caused by poor servicing.

* * * *

MITA urges Congress to include both H.R. 2009 and H.R. 2118 in the MDUFA IV reauthorization. We believe that passage of both of these bills will protect the safety of patients and ensure patients have timely access to the most innovative devices and diagnostics necessary. Thank you for the opportunity to present our views.