Case report

“MR conditional” respiratory ventilator system incident in a 3-T MRI environment

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Received 10 April 2011; revised 7 July 2011; accepted 7 July 2011

Abstract

The misunderstanding of the labeling for an “MR conditional” respiratory ventilator system resulted in the placement of this device, which had substantial ferromagnetic components, too close to a 3-T magnetic resonance (MR) system, causing a projectile incident. Magnetic resonance imaging health care professionals should be aware of the potentially dangerous consequences when such medical devices that have Food and Drug Administration-approved MR conditional labeling are brought into the MR system room. Recommendations to prevent future incidents are provided herein.

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Keywords: Magnetic resonance imaging, MRI; MRI safety; Accidents

1. Case report

Two respiratory therapists with 2.5 and 2 years of experience, respectively, accompanied a patient to a 3-T (Magnetom Verio, Siemens Medical Solutions, Malvern, PA, USA) magnetic resonance imaging (MRI) facility to set up an MR conditional, respiratory ventilator system (SERVO-i, Maquet Inc., Wayne, NJ, USA) for an intubated patient referred for an MRI procedure. The ventilator and associated accessories (i.e., the ventilator system includes the ventilator, mobile cart and battery packs) weigh approximately 20 kg and are powered by at least two and up to six exchangeable/rechargeable batteries, housed in the ventilator’s main body (Fig. 1A and B). Each battery pack measures 15 cm×9 cm×2 cm (Fig. 2).

The senior respiratory therapist brought the ventilator into the 3-T MR system room and placed it, without locking the wheels on the cart, in a position that was clearly beyond the demarcated 200-gauss line. Moments later, the MRI technologist who was present heard a loud noise and promptly entered the room to find a portion of the ventilator system detached from the cart and affixed to the front of the 3-T scanner. Notably, this ventilator component was raised several inches off the floor by the strong attractive force of the MR system’s magnet (unfortunately, a picture showing the device “stuck” on the MR system is unavailable).

Brute strength alone was insufficient to remove the attached device from the MR system. The MRI technologist decided to lock the door to the room and to contact the MR system manufacturer’s (i.e., Siemens Medical Solutions) in-house service representative. Over the next 6 h, the service engineer, assisted by the MRI technologist, dismantled the respiratory ventilator system to facilitate removal from the MR system. In the process of this activity, the battery packs used with this apparatus were noted to be highly ferromagnetic (i.e., there was apparent strong attraction to the 3-T static magnetic field).

After removing the battery packs, it was possible to detach the main portion of the ventilator from the MR system. The 3-T scanner sustained no substantial damage; however, the total downtime for the MRI facility was approximately 8 h, and the respiratory ventilator system was completely disassembled, rendering it inoperable.
2. Discussion

In 2007, the Food and Drug Administration classified the ventilator system involved in this incident (i.e., SERVO-i) as being MR conditional [1], which is defined as an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use [2–4]. According to the manufacturer, “The SERVO-i is intended for treatment and monitoring of all patients, neonatal, pediatric and adult who require mechanical ventilation. The new SERVO-i MR environment option is capable of providing critically ill patients with advanced ventilatory care using the same machine wherever they are in the hospital — in the ICU, in the MR examination room and during transport to and from the MR room.”

Notably, this respiratory ventilator system has information stating that it is classified for use in MRI environments, if the conditions in the “MR Environment Declaration for SERVO-i” are met (Personal Communication, Maquet: Declaration SERVO-i MR Environment, November 2010). These conditions include the following:

- Allowed field strength of scanner: 1.0, 1.5 and 3 T
- Always keep the SERVO-i outside of the safety line in the MR room
- Strongest spatial gradient: 80 mT/m
- Fastest temporal gradient: 200 mT/m/ms
- Strongest RF transmitter: 25 kW

Note: Both brakes must always be on before letting go of the SERVO-i in the MR environment.
[Commentary regarding the manufacturer’s labeling: We find it unusual that, for a medical device intended to be used outside of the bore of the MR system, the manufacturer states information for the time-varying and RF fields insofar as there would be no impact of these electromagnetic fields on an item that would not be inside of the MR system during scanning. Furthermore, the value listed for the RF field is in a nonstandard format, instead of being indicated in watts/kilogram.]

While the respiratory and MRI technologists were aware of above indicated labeling information, they apparently did not know that the respiratory ventilator system contained extremely ferromagnetic components (i.e., the battery packs). This emphasizes the fact that even items labeled as “MR conditional” may incorporate ferromagnetic parts that can pose serious hazards if the labeling information is not understood and followed. Following this event, a report was filed with the Food and Drug Administration (i.e., using the Manufacturer and User Facility Device Experience) [5], the manufacturer of the respiratory ventilator system was contacted and in-service training of the relevant personnel was repeated.

The number of MR systems in existence combined with the amount of patient support devices (e.g., ventilators, monitoring equipment, suction equipment, infusion pumps, etc.) available for use in the MRI environment is quite extensive and continues to grow as the need to manage high-risk patients referred for MRI examinations increases [4]. The medical personnel involved in the MRI setting tend to have a varying degree of MRI experience and may or may not have undergone safety training. Therefore, to prevent accidents and incidents, it is vital for all health care professionals working in the MRI environment to have an understanding of the issues related to the use of potentially dangerous equipment, particularly if ferromagnetic objects are unknowingly brought into the MR system room.

Importantly, if a device with ferromagnetic components is improperly positioned relative to the MR system and/or not secured, it can become a projectile and pose danger to individuals and/or damage to the MR system [4–8]. To prevent potential problems, medical equipment intended for use in the MRI environment (i.e., patient support devices as opposed to biomedical implants) must undergo rigorous testing to characterize MRI issues including, but not limited to, magnetic field interactions and functional disturbances caused by the MR system on the device and vice versa. After testing, the product is placed into one of three categories: MR safe, MR conditional or MR unsafe [2–4]. For patient support equipment, an MR safe item is safe in all MRI environments, regardless of how it is used. An example would be plastic intravenous tubing that is nonconducting, nonmetallic and nonmagnetic. An MR unsafe item is unsafe in all MRI environments, such as a scalpel made from ferromagnetic stainless steel. An MR conditional item, such as the respiratory ventilator system in this case, poses no known hazards in a specified environment when specified conditions of use are met [2–4]. These specified MRI-related and product-related conditions, unique to each device, should be detailed in the manufacturer’s Instructions for Use or other appropriate labeling. In this situation, the manufacturer’s conditions included the statement “Both brakes must always be on before letting go of the SERVO-i” (Personal Communication, Maquet: Declaration SERVO-i MR Environment, November 2010). What was not clearly mentioned in the basic instructions for this respiratory ventilator system is the potentially unsafe situation caused by the ferromagnetic batteries (although there is a statement indicating “…SERVO-i batteries must be exchanged outside of the MR environment.”) In this incident, only four of the six possible batteries were installed on the respiratory ventilator system. If more batteries had been in place and/or if an individual (e.g., the respiratory therapist or MRI technologist) had been standing in between the equipment and the 3-T scanner, there could have been a more disastrous outcome.

3. Recommendations to prevent similar incidents with MR conditional patient support equipment

The following recommendations are proposed to prevent potentially hazardous situations involving the use of patient support equipment in the MRI environment:

3.1. Recommendations for the manufacturer of the device

3.1.1. MR conditional labeling

Critical parameters that affect the safe and appropriate use of a medical device in the MRI setting must be clearly stated by the manufacturer in the Instructions for Use or other appropriate manual and document. Furthermore, this information should be readily available to health care professionals including the MRI technologists and others responsible for the use of the device in the MRI environment.

3.1.2. Markings and warnings

The device must be prominently marked with an external label using the appropriate icon for “MR Safe,” “MR Unsafe” or “MR Conditional” [2–4]. If the device is MR conditional, brief statements should be included in the external labeling regarding the acceptable conditions of use. For example, the label may state, “Do not position closer than 200-gauss from the MR system” or “Warning: This device contains ferromagnetic components.” Furthermore, the label should advise careful review of specific MR conditional information prior to use of the device.

3.1.3. Training

The manufacturer should assist in the training of the device for proper use in the MRI environment. During this training activity, all pertinent details that will ensure safe and acceptable utilization of the device should be presented.

3.1.4. Device positioning

If the device may present hazards or other issues related to a positioning in the MR system room and, thus, must be
maintained at a designated gauss level (e.g., 200 gauss), a suitable means to accomplish this must be provided (see below).

3.2. Recommendations for the MRI facility

3.2.1. Training

Health care professionals, including MRI technologists, must be educated regarding MRI safety, particularly with respect to the terminology (i.e., MR safe, MR unsafe and MR conditional) used to mark and label patient support devices and the importance of adhering to the specific information. This training should be performed for all new personnel working in the MRI environment and repeated on an annual basis.

3.2.2. Device positioning

If a device must be maintained at a designated gauss level relative to the MR system, this area should be clearly demarcated on the floor of the MR system room, and all health care personnel must be educated regarding the importance of maintaining the device at or behind this marked area.

One way to ensure this would be to attach a tether or restraint strap to the MR conditional equipment that provides a mechanism that could “catch” in order to prevent encroachment of the device to an unsafe area. The tether system should only be used to prevent disaster and not relied on as the primary restraint mechanism.

Alternatively, the device called the GaussAlert (Kopp Development Inc., Jensen Beach, FL, USA) can be utilized to maintain MR conditional equipment outside of a particular MRI exclusion zone [9]. This magnetic field strength alarm system was specifically designed for this task and produces an audio alert when a preset magnetic field strength is exceeded. The GaussAlert easily attaches to any piece of equipment and has been used on a variety of MR conditional devices intended for use in the MR system room including infusion pumps, contrast injectors, patient monitors, anesthesia machines and others (Fig. 3).

4. Conclusions

In conclusion, this case report demonstrates that there may be an incomplete understanding or appreciation of MR conditional equipment both by device manufacturers and by health care professionals. The safe operation of patient support devices relies on clear and in-depth instructions from the manufacturer and quality personnel training. By following recommendations, improving the labeling and designing products in a safer manner, incidents or accidents related to the use of such equipment may be prevented.

References


Fig. 3. The magnetic field strength alarm system (GaussAlert (Kopp Development Inc., Jensen Beach, FL) designed to help keep MR Conditional equipment outside of the MRI exclusion zone, shown attached to a pole mount used for a physiologic monitor.


