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Economic Justification for the FERRALERT™ Ferromagnetic Detection System for MRI

Abstract

OBJECTIVE To analyze the potential financial implications of the acquisition of the FERRALERT™ ferromagnetic detection system in terms of capital outlay compared with the expected accrual of potential operational savings through the device's use.

SUMMARY CONCLUSION Using data derived from independently published reports, the savings in terms of reduction of annual risk-weighted liability, more efficient patient management, and reduction of scanner downtime can definitely offset the initial acquisition cost in a relatively short period of time. Improved safety for staff and patients can enhance the bottom line. In the baseline case, the payback period is less than one year.

Introduction

FERRALERT™ DESCRIPTION

FERRALERT™ is passive sensing device which detects only those objects that are attracted to a magnet. The product's purpose and goal is to reduce the risk of missile effect accidents occurring in the MR environment. The website, www.koppdevelopment.com contains further product information. FERRALERT™ ENTRY provides an audible and visual final alert in the event of larger ferrous materials approaching the magnet room door. Objects made of non-ferrous materials pass unnoticed.

In order to prescreen patients and other personnel for small objects such as hairpins and paper clips, an especially common scheduled throughput reducer, an additional product has been developed. This product, called FERRALERT™ PRESCREEN, requires only the earth's magnetic field to detect small ferrous objects. It is a free standing unit that can be positioned in a convenient location away from the magnet room door wherever patient prescreening is usually performed.

FERROMAGNETIC PROJECTILE RISKS ASSOCIATED WITH MRI

As stated by FDA in its Primer¹:

“Current state-of-the-art technology is pushing this upper limit to 4 or 5 tesla in research MRI systems. This is up to 100,000 times the magnetic field strength of the earth. This strong magnetic field strength drops off rapidly with distance away from the magnet, producing a large spatial gradient. As a result of this large gradient, magnetizable objects introduced into the field are accelerated and can quickly become dangerous projectiles. Imagine a pair of sharp scissors flying through the air pulled into the magnet bore.”

(See MDRs² listed in reference section).



THE RISKS ARE INCREASING

A number of factors are contributing to the ferromagnetic projectile risk and its increase. The VA National Center for Patient Safety MR Alert³ provides an excellent summary:

“What Makes These Hazards Tricky?”

- 1.) *Large invisible magnetic fields that extend in 3 dimensions*
- 2.) *It is impossible to tell by looking at an MR system whether it is “ON” or not*
- 3.) *Many objects that don’t appear to contain iron (or ferromagnetic / hazardous material)
For example, sandbags – some contain ferrous materials even though one would not think so.*
- 4.) *Labeling on devices or in documentation can be confusing
“MR safe” and “MR compatible” are specific to a particular MR environment. The terms are not intended to be used without further specifying the particular MR environment where the devices have been tested and found safe and compatible for “MR safe” and “MR compatible” may not be with more powerful MRIs.*
- 5.) *Combination of complacency, work-arounds for speed, and diffuse responsibility*
- 6.) *If you need to emergently shut off the MRI, there are hazards and \$20,000-\$500,000 cost*
- 7.) *Equipment and consumables that are “safe” 99% of the time become “unsafe” near MRI*
- 8.) *People and equipment that are “new” to MRI suite (more interventions and surgeries)*
- 9.) *It is difficult and inaccurate to make “simple” lists of unsafe materials
In general, magnetic materials can become projectiles or twist in the bore (e.g., high carbon steel alloys, pure iron); and all metals conduct so they all can become hot or interfere with imaging in the bore. However, to be complete, you run more risks by compiling simple lists than diligently identifying and labeling items appropriate to enter the MR room and the bore.”*

In addition, with the increased use of higher strength field magnets and self shielded magnets, the maximum force of attraction increases dramatically. Increasing static magnetic field strength from 1.5T to 3.0T can cause the maximum force applied to an object to increase over 300%⁴

Analysis

DISCUSSION A number of referenced, authoritative sources were used as a basis of analysis. The data will vary with specific sites and types of sites. Mobile sites, for example, are at higher risk than the general population. The mobile scanner expects to get infrastructure support from the host hospital, including staff, which may not be familiar with the requisite safety procedures.

Large objects Please refer to Worksheet I which follows. A primary basis for the frequency and incident cost data for large object projectile incidents is a survey performed by Dr. Chaljub and colleagues⁵ in 1999. The survey was sent out to 250 imaging facilities across the US asking about the occurrence of MRI-related accidents. Among the responses, 52% mentioned airborne objects: a defibrillator, a wheelchair, a respirator, ankle weights, an IV pole, a toolbox, sandbags containing metal pellets, a vacuum cleaner, and mop buckets.

Incident cost data was derived primarily from Dr. Chaljub⁵ and the JMRI paper by Dr. Colletti⁶. Facility operating cost data was derived from the “Outpatient Imaging Venture Analysis” by AGI Healthcare Group⁷.

Small Objects Please refer to Worksheet II which follows. The source for data indicating the type and likelihood of ferromagnetic objects missed by current screening procedures is from the ASNR paper by Dr. Thomas and Dr. Kanal delivered May 25, 2005 “Ferromagnetic Detector to Screen Patients for Metallic Foreign Bodies Prior to MR Imaging”⁸. The test population consisted of 228 non-selected, ambulatory outpatients and inpatients who were asked to remove all loose metallic objects and after completing a comprehensive screening process. The data showed that 44% of the patients still were confirmed to have ferromagnetic objects on their person.

Not every object needed to be or could be removed. Surgical prosthesis was the cause for the alarm in 8 of the cases. “In 92 patients, the ferromagnetic foreign body was identified, removed and the patients were subsequently re-screened with Ferralert™ with negative results and uneventful imaging examinations.”⁸

From the above, 92 of the 228 or 44% of patients screened had ferromagnetic foreign bodies removed that could have compromised the MR image or patient safety. Not all ferromagnetic foreign objects represent an imaging event. If the objects are small, well attached, and not in proximity to the imaging area, for example rivets in blue jeans on patient undergoing a head exam, the objects may be uneventful. The assumption was made that 50% of the confirmed patients with foreign ferromagnetic objects, or 22%, could have had an MRI uneventfully.

The lost scan time cost estimates appearing on Worksheet II result from the interruption in patient flow at the scheduled scan time. The ferromagnetic detection system is used away from the magnet, before the patient is scheduled for imaging. As a result, scanner time is not lost in detecting, identifying, removing, and storing foreign ferromagnetic objects. Similarly, if an object is found that cannot be removed or is a contraindication to an MRI, time is available before the scheduled scan to adjust the schedule and as such reduce or eliminate wasted scanner time.

Potential cost impact of litigation from events involving small objects has not been considered in the Worksheet II document. There is, however, considerable data from the FDA MDRs² and elsewhere documenting incidents involving objects such as guns discharging in the magnet, as well as scissors and knife projectiles. In addition, at the CMRS Annual Meeting⁹, Dr. Kanal reported in his presentation, a hairpin requiring surgical removal from a patient’s nose and a missed finger nail clipper destroying a patient’s eye.

Results

MAJOR PROJECTILE ACCIDENTS Referring to Worksheet I, the range of costs for an incident can vary widely depending upon the amount of damage to the magnet, to the cost from damage to the equipment “sucked in”, the amount of time the magnet is not available for imaging, the number of hours per year of imaging, the number of scans per year performed, the current cost and availability of service as well as other variables. With this variability in mind, the cost per incident can vary from about \$40,000 to \$500,000. A base cost of \$183,000 was chosen as it seems to represent a typical case involving a quench.

Litigation

If litigation is involved, the range of cost can vary greatly. Some data was derived from Dr. Chaljub and colleagues⁵ but in most settlements, details of the settlement and the associated costs are generally not available. Litigation can be the largest cost item of the accident.

Dr. Chaljub and Colleagues⁵ reported that in their institutions there a total of 30 operating years for their 4 magnets. Since there were reported 5 incidents involving projectile cylinder accidents over this period, a projectile missile occurred on average every 6 years. The occurrence rate may be low as Dr. Chaljub⁵ points out:

“Our experience suggests that, despite MR safety education, projectile cylinder accidents and incidents may be on the increase. More sick patients are undergoing scanning while on life support equipment, as evidenced by four of the five accidents occurring within the past 3 years at our institutions.”

Nonetheless the conservative number of one incident every 6 years was used for our calculations in Worksheet I. It is important to note that only projectile cylinder incidents and accidents were considered here. The occurrence rate of projectile missile incidents and accidents will be higher when other objects in addition to cylinders are considered. Florida, for example, with its high elderly population will likely have increased occurrences missile effect projectile accidents from canes, wheelchairs and walkers.

Of the missile effect projectile events report by Dr. Chaljub⁵, 40% involved litigation. This translates to one lawsuit approximately every 15 years.

A facility would reasonably accrue the necessary financial resources to pay for an incident when it is likely to occur. For this reason, one sixth of the accumulated base cost of an accident is used to calculate the risk-weighted annual liability totaling \$31,206. Similarly, one fifteenth of the additional costs resulting from litigation is used to calculate the risk-weighted annual liability from litigation of \$27,090. This results in a total Risk-Weighted Annual Liability for a Major Projectile Accident of \$58,296.

UNDETECTED SMALL FERROMAGNETIC OBJECTS. Referring to Worksheet II, although the cost associated with any single undetected small ferromagnetic object is not substantial, taken together these small costs add up to a very large number indeed. This data was generated at a facility which has excellent staff training and comprehensive screening procedures. Even in this facility, the total annual recoverable losses are \$110,663

Conclusion

If a ferromagnetic detection system is used to control entry to the magnet, the annual risk weighted liability of \$58,296 is considerably greater than the cost of the ferromagnetic detection system such as FERRALERT™ ENTRY. Even if the cost of litigation is ignored and the detection accuracy is 75% the installed cost of FERRALERT™ ENTRY is offset in less than 1 year.

If an individual screening ferromagnetic detection system such as FERRALERT™ PRESCREEN is used to reduce the total annual recoverable losses from small ferromagnetic objects by \$110,633. The installed cost of FERRALERT™ PRESCREEN is similarly offset in less than 1 year.

Worksheet I - Major Projectile Accident-Emergency Incident Cost Analysis

System Data & Assumptions

1. Refill of Liquid Helium	
Quantity in Liters.....	600 Liters
Cost/Liter.....	\$17
Refill of Liquid Helium⁶ – Cost Total	\$10,000
2. Emergency After-Hours Service	
Rate / Hour	\$1,600
Hours Charged.....	60 Hrs
Emergency After-Hours Service⁶ – Cost Total	\$96,000
3. Normal Scheduled Service	
Rate / Hour ¹⁰	\$376
Hours Charged ⁶	60 Hrs
Normal Scheduled Service^{10,6} – Cost Total	\$22,560
4. Equipment Damage^{5,6}	
a. Low End Estimate.....	\$8,000
b. Upper End Estimate.....	\$50,000
5. Cost of Lost Scans with Emergency After Hours Service^{6,7}	
Minutes / Scan Average	45 Minutes
Weighted Average Scan Technical Reimbursement Rate	\$655
Cost / Hour Lost	\$873
Hours Down Time	34 Hrs
Cost of Lost Scans with Emergency After Hours Service –Cost Total	\$29,693
6. Cost of Lost Scans with Normal Scheduled Service	
Cost / Hour Lost ⁷	\$873
Hours Down Time ⁵	72 Hrs
Cost of Lost Scans with Normal Scheduled Service –Cost Total	\$62,880
7. Installed Cost of FERRALERT™ ENTRY	\$18,500

Accumulated Cost of an Accident with NO Injuries or Litigation

• Low cost - (# 3 + # 4a + 12Hrs lost scanning time).....	\$41,040
• Base cost - (# 1 + # 2 + # 4b + # 5 above).....	\$185,693
• High cost - (VA National Center for Patient Safety Data) ³	\$500,000

Additional Costs Resulting from Litigation

Litigation & Negative Publicity Costs	
Internal review, preparation	\$10,000
Legal Fees	\$75,000
Settlement ⁵	\$100,000
Fines ⁴	\$22,000
Loss of business resulting from negative publicity (10%)	\$180,000
Additional Cost Resulting from Litigation –Cost Total	\$387,000

Risk Weighted Annual Liability

Risk-Weighted Annual Liability from Accidents (Base cost X 17% likelihood of an accident – one Accident occurring every 6 years).....	\$31,568
Risk-Weighted Annual Liability from Litigation (Additional cost resulting from litigation x 7% likelihood of litigation - 1 suit every 15 yrs.).....	\$27,090
RISK-WEIGHTED ANNUAL LIABILITY TOTAL	\$58,658

Payback Period

RETURN ON INVESTMENT PAYBACK PERIOD	0.32 YRs
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Worksheet II -- Undetected Small Ferromagnetic Object Cost Analysis

System Operation Data

1. Operating Weeks/Year	52 Wks/Yr
2. Operating Days/Week.....	5.5 Days/Wk
3. Operating Hours/Day.....	12.0 Hrs/Day
4. Average Minutes/Scan.....	45 Minutes
5. Number of scans per day.....	16 Scans/Day
6. Number of scans per year	4576.00
7. Reimbursement rate / scan ⁷	\$655.00
8. Per Minute Value of Scanner Time	\$14.56

Ferrous Object Detected Data

9. Percentage of Scans for which FERRALERT™ Prescreen found Undetected Ferromagnetic Objects on patients and visitors after oral screening procedure ⁸	44.0%
a. Assumption that only 1/2 of the % found in 9 above require further attention	22.0%
b. Assumption that 90% of objects found in 9a. above will be found before scan.....	20.0%
c. Assumption that ALL of remaining % is discovered in the scanner bore.	2.0%

Patient % Calculations

10. Breakdown of 9c above, Ferrous Objects discovered in the Scanner bore;	
a. % of patients that can be rescanned after the object is removed,	1.5%
b. % of patients that have not easily removed metal; Scan Cancelled	0.4%
c. % of patients that cause ferrous object to be “stuck” to the magnet.	0.1%

Lost Scan Time Calculations

11. Lost Scan Time:	
a. To Identify nature of the object and walk patient / visitor back to locker to secure missed item	5 Minutes
b. To Remove patient from scanner to identify and remove object causing an artifact during the pre-scan	15 Minutes
c. Because of not easily removed ferromagnetic objects (for example hair extensions).....	45 Minutes
d. To Remove object stuck in the magnet	180 Minutes

Annual Recoverable Cost Calculations

12. Annual Cost of #11a. above (lost minutes of # 11a X # 8 cost/minute X # 6 scans/yr X % in # 9b)	\$66,673
13. Annual Cost of #11b. above (lost minutes of # 11b X # 8 cost/minute X # 6 scans/yr X % in #10a).....	\$19,782
14. Annual Cost of #11c. above (lost minutes of # 11c X # 8 cost/minute X # 6 scans/yr X % in #10b).....	\$11,989
15. Annual Cost of #11d. above (lost minutes of # 11d X # 8 cost/minute X # 6 scans/yr X % in #10c)	\$11,989
TOTAL ANNUAL RECOVERABLE LOSSES WITH FERRALERT™ PRESCREEN	\$110,433

Payback Period

INSTALLED COST OF FERRALERT™ PRESCREEN	\$18,750
RETURN ON INVESTMENT PAYBACK PERIOD.....	0.17 YRs



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2. Medical Device Reporting (MDR) database. (The reports are accessible through FDA's Web site [<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM>]. We have provided a brief description of each report.)
 - M531154. An AC power transformer for a pulse oximeter was attracted to the magnet
 - M526280. A vendor carried a helium cylinder into the magnet room, and the cylinder was attracted to the magnet
 - M376631. An IV pole was pulled off a cot and drawn to the magnet
 - M362867. A stainless steel mop bucket was attracted to the magnet
 - M345725. A ferrous (i.e., composed of or containing iron) laundry cart was attracted to the magnet
 - M308257. A chair was attracted to the magnet
 - M305054. The ferrous braces of an aluminum ladder were attracted to the magnet
 - M271989. An oxygen bottle was attracted to the magnet
 - M247320. A floor buffer was attracted to the magnet
 - M232626. A weight bag was attracted to the magnet
 - M231855. Ferrous BBs from a sandbag that had sprung a leak were attracted to the magnet
 - M179495. A light fixture in a mobile scan room fell from the ceiling and was attracted to the magnet
 - M178048. A ferrous part from a patient lift was attracted to the magnet
 - M143702. A magnetic tool brought into the room by a workman was attracted to the magnet
 - M405200. A pair of scissors was pulled out of a nurse's hand as she entered the magnet room. The scissors hit a patient causing a cut on the patient's head
 - M547886. An IV pole was attracted to the magnet and struck a patient, cutting his arm. The patient required stapling of the cut
 - M234698. A patient was struck by an oxygen bottle while being placed in the magnet bore. The patient received injuries requiring sutures
3. John Gosbee and Joe DeRosier MR Hazard Summary – AUGUST 2001 UPDATE, VA National Center for Patient Safety <http://www.va.gov/ncps/alerts/MRI.doc>
4. Baker K, Nyenhuis J, et al. Neurostimulation Systems: Assessment of Magnetic Field Interactions Associated with 1.5- and 3-Tesla MR systems. JMRI 2005;21:72-77
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8. Thomas S, Kanal E. Ferromagnetic Detector to Screen Patients for Metallic Foreign Bodies Prior to MR Imaging. Presentation Number 278 ASNR Annual Meeting May 25, 2005
9. Kanal E, MR Safety Update Presented at the 2004 CMRS Annual Society Meeting June 24, 2004
10. GENISYS databank of USCS Equipment Technology Solutions. MRI/CT Maintenance Labor Rates Show Biggest Increase August 11, 2003 <http://www.auntminnie.com/index.asp?Sec=sup&Sub=imc&pag=dis&ItemId=58713>
11. State of New York, Dept. of Health. Health Department Fines Westchester Medical Center \$22,000 for its failure to Ensure Patient Safety During MRI Procedures September 28, 2001 <http://www.health.state.ny.us/press/releases/2001/wmcmri.htm>