

Cost justification for using FDA Cleared MR Conditional Disposable EEG Electrodes for cEEG when 24/7 Neurodiagnostic Technologist Staff Coverage is not available

Abstract:

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Objective:

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Compare costs and patient benefit of using EEG Electrodes that are FDA Cleared and can remain on a patient while in an MRI environment versus using traditional EEG electrodes that must be removed and reapplied before and after each MRI is performed.

Keywords: EEG, cEEG (Continuous EEG), FDA, MRI, (ASTM) American Society for Testing and Materials, MRI, Healthcare Acquired Infections (HAIs), disposable single patient electrodes; reusable electrodes, Neurodiagnostic Technologist, ICU, ER.

Supplemental data at
www.rhythmlink.com

Introduction:

Continuous EEG (cEEG) is increasingly becoming more common in assessing critically ill patients and with the rise of outcome studies and statistics to support the use of cEEG in intensive care units (ICU) the momentum as a standard of care is building at a rapid pace. Additionally, there have been increased conversations revolving around the patient benefit of monitoring brain function upon entrance to the facility (i.e. Emergency Room) and new innovations are emerging to meet these pioneering levels of care. But, despite major technological advancements one problem continued to exist until earlier in 2013: no FDA Cleared EEG Electrode was available to the market for use in an MRI environment. This void in availability was a major road block as electrodes must be applied to the patient to record cEEG and the subsequent development of a staffing model to cover 24/7 for electrode removal and re-applicable when needed is nearly impossible for many facilities due to cost and lack of staff availability. But, in June 2013, three EEG Electrodes were cleared by the FDA and in October 2013 the first of three approved products became available to the market (for more information on MR Conditional EEG Cup Electrodes, MR Conditional EEG Webb Electrodes, and MR Conditional EEG PressOn™ Electrodes see www.rhythmlink.com). This product clearance and availability is instrumental to the success of brain function monitoring for ICUs or other emergent care areas. This paper analyzes the costs and patient benefits of recording cEEG using FDA Cleared Rhythmlink MR Conditional EEG Electrodes versus using reusable non-MR Cleared electrodes which must be removed and reapplied for each MR scan.

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Current challenge: EEG Electrodes that can remain applied during patient's imaging isn't the only area where challenges exist to achieve success to recording cEEG. Other challenges include who is qualified and available to apply the electrodes for the onset of cEEG recording, what equipment is best suited for cEEG data review, who is qualified and available when needed to interpret the data, and lastly how to maintain the electrodes once the cEEG recording begins to maximize efficiency, minimize patient skin injury due to reapplication, and ensure safety.

This paper concentrates on the following: Comparing management options and costs to enable cEEG recording, as needed, with patients that require MR imaging.

What is an MRI? MRI is short for Magnetic Resonance Imaging. Before one can appreciate the importance of MR conditional electrodes, it is critical to understand the technology and terminology of the MR environment. An MRI is a procedure used to scan patients to create detailed images of the body and determine the severity of certain injuries. Unlike other images such as CT, the MR device uses strong magnetic fields to create these detailed images. In addition to creating detailed images the strong magnetic fields also can induce a potentially harmful displacement force and torque (i.e. a patient with metal in/on/around their body can be injured due to the strength of the magnetic field attracting the metal), produce potentially harmful radio frequency heating (i.e. a patient can experience a severe burn) and create image artifacts rendering the image useless. Because of these potential risks only certain medical devices can be used in an MRI environment.

What is involved with testing and submitting a medical device product for MR Clearance from the FDA?

With the growth of the use of MR technology, the FDA recognized the need for a consensus on standards of practice and the FDA sought out the American Society for Testing and Materials International (ASTM) to achieve them. ASTM is a globally recognized leader in the development and delivery of international voluntary consensus standards. Today, some 12,000 ASTM standards are used around the world to improve product quality, enhance safety, facilitate market access and trade, and build consumer confidence. Working with key stakeholders, ASTM developed standard F2503, the Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Along with internal guidelines the FDA references ASTM standard F2503 to guide their clearance process for medical devices used in an MRI environment to ensure that the product in question is proven to be both safe and effective in specific MRI environments. Medical device companies must submit rigorous testing and validation data to the FDA to back up the manufacturer's claims of what the product's intended use is before the manufacturer is allowed to market the device.

It is illegal to market a product as MR Conditional if a medical device manufacturer has not received clearance to do so from the FDA.



What do FDA Clearance terms mean and why are they important?

As noted above, the clearance process is a complicated, multi-layered and can be extremely expensive and time consuming. But, medical facilities, radiology and risk management departments understand substantial benefits are gained by the use of a FDA cleared product versus non FDA cleared products for a variety of reasons. The FDA clears products for MR environments according to different levels of safety and other factors. The FDA and terms such as “MR friendly” and “MR compatible” are not recognized by the FDA or ASTM. The following terms and symbols are what the FDA and ASTM recognize:

(It is critical to understand these terms as you evaluate product)



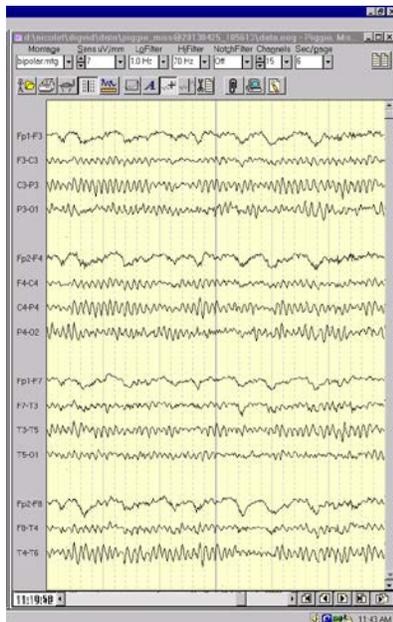
MR Safe — used for items that are nonconducting, nonmetallic and nonmagnetic, such as a plastic Petri dish, and pose no known hazards in all MR environments.



MR Conditional — used for an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Conditions that define the MR environment include static magnetic field strength, radio frequency fields, specific absorption rate and other factors. For MR conditional items, the item labeling includes results of testing sufficient to characterize the behavior of the item in the MR environment.



MR Unsafe — defines an item that is known to pose hazards in all MRI environments, such as a pair of ferromagnetic scissors.



Disposable versus Reusable EEG Electrodes – Does it matter?

Only within the past 5 years has EEG Electrode technology really transitioned from reusable products to disposable single patient devices. This topic is discussed in more detail in other various other papers but regardless of the facility or services it may be employing it would difficult to recommend the continued use of reusable products within any area of critical care due to the unique challenges that an ICU environment presents over traditional clinical EEG labs. ICU environments are challenging because there is more potential for exposure to bodily fluids due to significant physical defects to the skull which can lead to increased contamination the electrode cup and the lead wire. This exposure to bodily fluids can lead to lengthy

decontamination processes and ultimately to increased HAIs. Disposable EEG Electrodes are easily accessible, affordable/cost justifiable, reduce risk of cross contaminations/HAIs, and provide high quality data results (see RhythmLink Disposable EEG Cup Electrode Product # DADG102600 data sample to the left).

The FDA's criteria and process for market clearance for reusable and disposable EEG cup electrodes is substantially similar. Likewise, the FDA's criterion for determining MR Conditionality for reusable and disposable EEG cup electrodes is substantially similar. Because most reusable cup electrodes are metal based this could explain why no reusable or disposable metal EEG cup electrodes have been cleared for use in an MRI environment.

Cost Analysis – What options are available to record cEEG in an ICU when needed? What will cEEG require for staff and what will they cost?

As stated in the introduction, various areas must be considered but this section will concentrate solely on the technical aspect of applying the electrodes and maintaining the electrodes when a patient requires an MRI.

So, what are the options? We will first review the traditional strategy of staffing EEG Technologists to accomplish 24/7 coverage. Without much debate, most would agree this is the preferred choice as it employs the best technical team to apply and maintain the electrodes but negatives exist with this model:

OPTION #1 – 24/7 Technologist Coverage:

- 1) 24/7 coverage can be nearly impossible to achieve (unless you are one of the fortunate large institutions or academic centers) with today's availability of R.EEGT or CLTMs. There simply are not enough technologists available for all facilities for 24/7 coverage.
- 2) If you are one of the 24/7 coverage facilities, this model fulfills the staffing requirements but still will not fulfill the patient care concerns (which include the increasing concern regarding skin breakdown and increased risk of infection) of removing and reapplying electrodes for each MRI unless the electrodes are FDA Cleared as MR Conditional and can remain on during the imaging session.
- 3) Lastly, but certainly not least, employing 24/7 staff models is expensive. Refer to the analysis below to see average costs.

OPTION #2 – Day Shift Coverage with afterhours/weekend call service:

- 1) Arguably the most common strategy used by hospitals today is day shift coverage with after-hours and weekend call service. This strategy maintains coverage for diagnostic and urgent-care situations daily for typically 8-12 hours and covers urgent patient issues after hours and weekends.
- 2) This can be cost effective for the facility. Refer to the cost analysis below.
- 3) But, when it comes to applying electrodes to record cEEG while coordinating MRI requirements, this model falls short of what the facilities and patients need. A technologist can easily be called in for an emergent application for cEEG but that means a few things must be realized:
 - i. Timing of the call-in typically works around the MRI schedule because it would be useless to call a technologist in to apply electrodes only to remove them shortly after application for the MRI. This means the cEEG recording may not happen as quickly as needed for the patient.
 - ii. Additionally, after the initial EEG electrode application is completed and cEEG begins future MRIs require the technologist to come in again to reapply the electrodes which again would require coordination with the MRI and on-call technologist availability. Unexpected MRIs can cause costs to increase substantially for a service that needs even infrequent MRIs after hours as on-call pay is higher. Refer to the analysis below to see average costs.

OPTION #3 – No after-hours on-call service available due to complexity and cost; cEEG is not performed if MRIs are anticipated:

- 1) Alas, this is the option for many facilities as staff is not available 24/7 or on an on-call basis to reapply electrodes and/or costs are simply too high to develop cEEG monitoring as a standard of care.
- 2) For readers who may not believe that a substantial number of facilities do not have any coverage, refer to the survey conducted by ASET in 2011 where survey respondents were asked about their on-call services and only 60% responded that they have an on-call service. The remaining 40% of facilities either incorporate 24/7 coverage or do not have any on call service after hours. My experience is only large centers can afford 24/7 coverage leaving the majority of this remaining 40% simply without any on call option for cEEG

COST ANALYSIS:

The section below is not intended to be all inclusive of costs but is to simply show a general example of costs.

Facilities that employ 24/7 staffing models using R.EEGT, LTEM or similar credentialed staff are not part of the analysis below. But, staff coverage for a 24/7 service can be assumed to employ an average of at least seven (7) technologists with an estimated staff cost of nearly \$500,000 per year.

Data Collected using the ASET 2011 Salary Survey:

- The average salary of a Neurodiagnostic Technologist is \$65,226 per year but this number does not include any additional benefits or overhead for the employee. Using data from September 2013 Bureau of Labor Statistics 30% is an average additional cost for employee benefits. With 30% added the average salary of a Neurodiagnostic Technologist is \$84,973 per year.
- The average yearly salary with benefits calculates into hourly wage of \$40.77.

Assumptions:

- The calculations below assume the facility utilizes an afterhours call-in service as described in Option #2 in the previous section and not 24/7 coverage.
- The facility is utilizing an hourly Technologist rate of \$40.77 per hour.
- After the initial hook-up using MR Conditional Electrodes would NOT require a call-in for disconnection or reconnection as other available staff such a CCRN would perform simple disconnect and reconnect step as needed.
- cEEG Model #3 uses the newly released Disposable EEG PressOn™ Electrodes with FDA Clearance for MR Conditional Use.

OPERATING EXPENSES	cEEG Model #1	cEEG Model #2	cEEG Model #3*
Description	Using Traditional Disposable EEG Cup Electrodes	Using Disposable EEG Cup Electrodes with FDA Clearance for MR Conditional Use	Using Disposable EEG PressOn™ Electrodes with FDA Clearance for MR Conditional Use
			
Technical Staff Requirements [assuming standard staff models as detailed in Option #2 in the previous section]	R.EEGT, CLTM, or other similar credentialed staff for initial electrode application and subsequent disconnect/reconnect requirement when an MRI is required	R.EEGT, CLTM, or other similar credentialed staff for initial electrode application	Designed to be used by any appropriate medical staff such as critical care nursing staff or similar professionals
Type of Electrode	Disposable EEG Cup Electrode Cannot be used with imaging	Disposable EEG Cup Electrode FDA Cleared MR/CT Conditional Can stay on for imaging	Disposable EEG PressOn™ FDA Cleared MR/CT Conditional Can stay on for imaging
Cost of 22 Electrodes	\$13.20	\$120.00	\$286.00
Cost of initial tech call-in to hook-up	\$163.08	\$163.08	\$0.00
Time of initial electrode hook-up (time waiting for data to begin post patient presentation)	90 mins	90 mins	10 mins
Cost for tech call-in when initial MRI is required	\$122.31	\$0.00	\$0.00
Cost for add'l tech call-in when subsequent MRI is required	\$122.31	\$0.00	\$0.00
Total Costs for cEEG [includes initial hookup and 2 MRIs] Cost savings will continue to increase with each MRI imaging session where a technologist is not needed to be called-in for electrode reconnection	\$420.90	\$283.08	\$286.00

As you can see, even using conservative salary and overhead assumptions, the use of Disposable MR Conditional EEG Electrodes are more cost effective than using Non MR Conditional EEG Electrodes and call-in staff for reapplication (and for initial application if using the PressOn)

**What is the PressOn™ EEG Electrode?*

A disposable electrode specifically designed to collect continuous EEG (cEEG) without skin prep, adhesives, or chemicals. It was designed to address the one of the biggest challenges of monitoring cEEG in ICU and critical care environments which is not having Neurodiagnostic Technologists available immediately when the situation arises to apply electrodes. The PressOn electrode can be applied by Neurodiagnostic Technologists but it's specifically designed for application by other medical professionals already present in the unit such as Critical Care Nursing Staff saving staff call-in costs but even more importantly saving valuable time waiting for brain monitor to begin. As noted in the table above the electrode is FDA Cleared as MR Conditional and an entire 22 electrode array can be applied in 5-7 minutes. www.rhythmink.com

Conclusion:

The FDA cleared three Disposable EEG Electrode products in 2013 as MR Conditional (www.rhythmink.com) and this clearance provides radiology, neurology, risk management, and other areas the confidence these products are safe and effective for patient use as marketed. This opens new avenues for patient care for all facilities to pursue cEEG recordings as a standard of care and particularly for services that employ call-in services or 24/7 services where technologists are not guaranteed to be immediately available as needed. In addition to the clear budget savings, the tangible patient benefit by reducing skin injury due to repeat application processes adds value not even included in the above analysis making the justification for use even more impactful. The introduction of the first FDA Cleared Disposable MR Conditional EEG Electrodes open new pathways to providing cEEG in the ICU and ER by reducing the challenges that have historically halted the realistic achievement of recording true cEEG where MRIs are needed as part of the patient care plan

Conflict of Interest Disclaimer: All authors are employees of Rhythmink International, LLC.

Rhythmink is a medical device manufacturer and distributor of both reusable and disposable EEG electrodes.

ADDITIONAL REFERENCES

Suzette LaRoche, Associate Professor of Neurology, Emory University School of Medicine. 2013. *Handbook of ICU EEG Monitoring*. Demos Medical Publishing, New York, NY.

Bruce J. Fisch, Professor of Neurology, University of New Mexico. 2010. *Epilepsy and Intensive Care Monitoring*. Demos Medical Publishing, New York, NY.

ASET, The Neurodiagnostic Society. 2011. *Neurodiagnostic Professional Salary and Benefits Report*. ASET, Kansas City, MO.

Leah L. Hanson, Shawn Regan, Stacey Askelson, *Less risk, ease of use, and reducing budgets: Making a case for single-patient disposable electrodes for polysomnography and electroencephalography*, Rhythmlink International LLC, 2011

ASET, The Neurodiagnostic Society. 2008. *Acute EEG/cEEG ICU Monitoring*. ASET, Kansas City, MO.

Mark Scheuer, Department of Neurology, University of Pittsburgh. 2002. *Continuous EEG in the Intensive Care Unit*. Blackwell Publishing