Less risk, ease of use, and reducing budgets:

Making a case for single-patient disposable electrodes for polysomnography and electroencephalography

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Abstract:

Study Objective: To evaluate the benefits of single-patient disposable electrodes (SPDE) with intended use in polysomnography (PSG), electroencephalograph (EEG), long term epilepsy monitoring (LTEM), and other peripheral inpatient and outpatient testing procedures which use surface electrodes within its application. We evaluate and compare ease of use and the hospital acquired infection (HAI) risk between reusable electrodes and single patient disposable electrodes (SPDE) and analyze the benefits of SPDE within intended use. Considerations for cost and benefit will also be analyzed.

Methods:
Cleaning and disinfecting protocols required for any reusable electrode (RE) are included to provide a comparison of effort required for use in contrast to disposable electrodes.

Keywords: abrade, abrasion, abrasive agent, semi-critical item, non-critical item, critical item, electroencephalograph, polysomnography, long term epilepsy monitoring, single patient disposable electrode, reusable electrode, Healthcare Acquired Infection

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Glossary

Hospital-acquired infection = an infection which is a result of treatment in a hospital or healthcare service unit, but secondary to the patient's original condition
Abrade; abrasion = to scrape or rub off; wear away by scraping or rubbing
Semi-critical item = an item which has contact with mucous membranes or nonintact skin
Non-critical item = an item which has contact with intact skin
Critical item = an item which enters or penetrates sterile tissue, cavity or bloodstream
Spaulding classification = a classification system used by the Center for Disease Control (CDC) which divides instruments and items for patient care into three categories : critical, semi-critical or non-critical items.

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Introduction: The use of electroencephalographic (EEG) electrodes has been an acceptable standard for over 50 years. Until recent years, medical specialties that utilized such electrodes had no alternative to the reusable products. The utilization of reusable supplies within healthcare facilities has been transformed with the introduction of disposable products and aggressive technological advances that have produced disposables which outperform their reusable predecessors. In addition to the technological trends, price of disposables have lowered throughout the past 2-3 decades. The price point alone was not enough to bring the disposable transition to the forefront. Ease of use and reduced risk of cross contamination/hospital acquired infection rates have also contributed to the transfer to disposable technology. PSG, EEG, and other similar testing environments have resisted transition from reusable products to SPDE but the transformation is imminent.

Materials and Procedure: To collect EEG data electrodes must be connected to the patient. Nearly all facilities and services apply surface EEG electrodes in a similar way and the widely accepted application technique incorporates the use of a cotton tip applicator (such as a Q-Tip®) and commercially available abrasive products (such as NuPrep™) to **lightly abrade** or "prep" the patient skin to achieve optimal impedance readings. Proper impedance is critical to achieve acceptable data quality for diagnostic interpretation. The quality of contact between patient's skin and electrode directly affects the recording system's ability to distinguish patient data from environmental artifact. Using a mild abrasive agent on the patient's skin (i.e. prepping the skin) in the location where the electrode will be placed significantly increases the recording systems ability to produce acceptable data enhancing the patient's diagnostic and prognostic process. By performing this "prepping" action, the surface electrode, becomes a **semi-critical item** which mandates a specific process for cleaning and disinfecting the reusable electrode after each use. The definition of a semi-critical item is part of the **Spaulding classification** system, which is used by the CDC and was developed by Earle Spaulding in 1968. Spaulding's classification categorizes medical devices into three categories which can assist the clinician in determining which devices should be cleaned, disinfected and or sterilized prior to use in patient care. The three category classifications are (1) critical (2) semi-critical and (3) non-critical. The Spaulding system encompasses all types of supplies and equipment. Below is an example of the type of products and equipment that fall into these categories: According to Am. J. END Technology 40:73-97,2000 ASET, Iowa

Fig 1: Spaulding Classification table

Category	Level Required	Example of items
Critical	Requires sterilization before/after each use	Subdermal Needle Electrodes, EMG Needles, Sphenoidal Electrodes, Indwelling Electrodes….
Semi-critical	Requires intermediate to high level disinfecting after each use	**Surface Electrodes used with abrasive skin prep/agent or blunt tip syringe**, ERG Electrodes, Nasopharyngeal, Nasal/Oral Thermocouples, cPAP,/BiPAP masks and tubing, any electrode exposed to nonintact skin, blood, or body fluids…
Non-critical	Requires cleaning and/or low level of disinfecting after each use	Tape measures, calipers, oximeter probe, marking pencils, etc….

Any lab or service can certainly elect to continue to use reusable electrodes but obviously, cleaning and disinfecting takes valuable time and resources to manage and coordinate. However, SPDE products provide ease of use advantage over reusables by eliminating the time, effort and resources required to properly ensure electrodes are disinfected and maintained after each use.

A Case Study For Disposable EEG Cup Electrodes

A study was performed by **Caroline Finnegan ,** The Walton Centre for Neurology and Neurosurgery,Department of Neurophysiology, Liverpool, UK;
The findings that were revealed clearly demonstrated the benefits of disposable electrodes. Excerpts from the article :
Author **Caroline Finnegan ,** The Walton Centre for Neurology and Neurosurgery,Department of Neurophysiology, Liverpool, UK; A Case Study For Disposable EEG Cup electrodes By Finnegan,

Risks associated with reusable EEG electrodes

1.If skin debri is left on the electrode cup it can lead to cross infection (i.e. MRSA and Varicella Zoster)
2. Using electrodes in both in and out patients increases the risk of cross infection between these groups
3. Decontamination of reuseable electrodes cannot eliminate CJD prions.

Audit of surgical site surveillance/ Infection rate
in depth and grid EEG telemetry patients (The Walton Centre)

2004 - 2005	***18%***	***Pre-use of disposable electrodes***
2005 - 2006	***0%***	***After 12 months of using disposable electrodes***

Detection of Occult Blood on EEG Surface Electrodes.

Other studies have been done to examine the reusable surface electrode, such as the article published in the Am. J. END Technol. 37:251-257, 1997 **Steve Bild, R.EEGT/EPT**, Rush Comprehensive Epilepsy Center Department of Neurological Sciences, Rush-Presbyterian Medical Center in Chicago, Illinois.
This article used a forensic test, designed to detect blood at crime scenes on EEG surface Electrodes after routine EEG recordings. Results revealed (excerpts from the article)

7 out of 574 electrodes were positive for the presence of blood
0 of the positive electrodes had visible blood on the electrode or at the electrode site
3 of the positive electrodes were from sites at which both abrasive skin prep and a blunt needle were used to lower impedance
3 of the positive electrodes were from sites at which only abrasive skin prep was used to lower impedance
1 of the positive electrodes the method of impedance reduction was not documented

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Flavobacterium Indologenes Bacteremia Linked To Contaminated Electroencephalograph Electrodes

AJIC American Journal of Infection Control: Volume 26(2)April 1998p 158
Abstracts for The Apic 25Th Annual Educational Conference And International Meeting, San Diego, California, May 10-14, 1998: Oral Presentations: Tuesday, May 12, 1998: Devices]
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(excerpt) Flavobacterium indologenes is an unusual gram-negative organism found in soil and water. When F. indologenes was isolated from the blood culture of a patient hospitalized on the 28-bed neurology unit at Yale-New Haven Hospital (YNHH), an investigation was undertaken. Five days after the patient was admitted for continuous electroencephalography (EEG) monitoring, she was noted to have a temperature of 104[degree sign]F and blood cultures were obtained. The patient repeatedly pulled off the EEG leads and on exam there were denuded and abraded areas on her scalp, otherwise the rest of the exam was unrevealing for a portal of entry. F. indologenes was not isolated from any other patients.

***On review of the procedures used for applying and processing the reusable gold EEG electrodes, it was recognized that there was a break in aseptic technique after the initial high level disinfection used for this semi-critical item*.**

There are methods available to manage the risk such as changes in the standard application technique. The article below addresses one such strategy by suggesting the deletion of the abrasive prep "step" of the process. By eliminating the abrasive prep of the patient's skin, the surface electrode can become a non-critical item, which as we have seen previously, requires significantly less time and maintenance after each use.

Scalp electrode impedance, infection risk, and EEG data quality

Thomas C. Ferree, Phan Luu, Gerald S. Russell, Don M. Tucker,
Abstract (excerpt)

Objectives: Breaking the skin when applying scalp electroencephalographic (EEG) electrodes creates the risk of infection from bloodborn pathogens such as HIV, Hepatitis-C, and Creutzfeldt-Jacob Disease. Modern engineering principles suggest that excellent EEG signals can be collected with high scalp impedance (<40 kV) without scalp abrasion. The present study was designed to evaluate the effect of electrode-scalp impedance on EEG data quality.

Methods: The first section of the paper reviews electrophysiological recording with modern high input-impedance differential amplifiers and subject isolation, and explains how scalp-electrode impedance influences EEG signal amplitude and power line noise. The second section of the paper presents an experimental study of EEG data quality as a function of scalp-electrode impedance for the standard frequency bands in EEG and event-related potential (ERP) recordings and for 60 Hz noise.

Results: There was no significant amplitude change in any EEG frequency bands as scalp-electrode impedance increased from less than 10 kV (abraded skin) to 40 kV (intact skin). 60 Hz was nearly independent of impedance mismatch, suggesting that capacitively coupled noise appearing differentially across mismatched electrode impedances did not contribute substantially to the observed 60 Hz noise levels.

Costs analysis: Price of product and overall budgetary investment

The cost is not simply the price of the product but instead the overall investment. Use the template below to research the overall costs for your department/service.

Just like any analysis you will need to gather pieces of information that will help you begin the investigational process. Below is an example of the information an EEG clinic should gather to review the cost/benefit analysis of disposable versus reusable electrodes.

Fig 2: Cost analysis table:

General Information	EEG	LTM	PSG	ICU
Application being evaluated			x	
EEG Leads used per procedure (amt to create a "set" for one patient)			10	
Number of procedures per year			1,000	
Number of procedures per month			84	

Section #1 - Per Procedure Costs (Electrodes)	Reusable	Disposable
Price per pouch/box (10 per package)	$110.00	$6.00
Price per unit (electrode)	$11.10	$0.60
Cost of a "set" of electrode Assumption: 12 electrodes per patient	$133.20	$7.20
Average life of product	6 months	Single patient
Number of patients tested per "set" before replacing electrodes	504	1
Average per procedure cost	**$0.26**	**$7.20**
Average per procedure cost x annual # of pts	**$260.00**	**$7,200.00**

Section #2 - Per Procedure Costs (Chemicals)	Reusable	Disposable
Chemical #1 required for cleaning/disinfecting	Brand X	Not required
Cost of chemical#1 required for cleaning/disinfecting	$85 Six 32oz bottles	$0.00
Life of product (how long does it last)	60 days	Not required
Average cost of chemical #1 per patient	$0.93	$0.00
Chemical #2 required for cleaning/disinfecting	Brand Y	Not required
Cost of chemical #2 required for cleaning/disinfecting	$3.85 160 cleaning cloths	$0.00
Life of product (how long does it last)	3.5 months	Single Patient
Average cost of chemical #2 per patient	$0.02	$0.00
Cost of cleaning and disinfecting per procedure	**$.95**	**$0.00**
Cost of cleaning/disinfecting x annual # of pts	**$950.00**	**$0.00**

Section #3 - Per Procedure Costs (Staff Time)	Reusable	Disposable
Amount of time required to clean/disinfect	20 minutes	0 minutes
Staff hourly rate with benefits	$30.00	$30.00
Cost of staff per procedure to clean/disinfect (salary/time)	$10.00	$0.00
Staff time x annual # of patients	**$10,000.00**	**$0.00**

Section #4 - Overhead Inventory: (i.e. Product waiting to be used) Assumption: reorder every 6 months	Reusable	Disposable
# of unopened pouches held in inventory	10 pouches (100 electrodes)	10 pouches (100 electrodes)
Cost of unopened pouches	$1,100.00	$60.00
# of opened "spare" electrodes kept in the lab	2 pouches (20 electrodes)	2 pouches (20 electrodes)
Cost of opened spare electrodes	$220.00	$12.00
Cost of inventory per 6 months (opened + unopened)	$1,320.00	$82.00
Annual Inventory Investment (6 mos x 2)	**$2,640.00**	**$164.00**

SUMMARY: _____ Hospital Cost/Benefit Analysis		
	Reusable Electrodes	Disposable Electrodes
Section #1 Total	$ 260.00	$ 7,200.00
Section #2 Total	$ 950.00	$ -
Section #3 Total	$ 10,000.00	$ -
Section #4 Total	$ 2,640.00	$ 164.00
Total Costs/ Year	**$ 13,850**	**$ 7,364**

The above analysis shows a very common result of cost comparison between the two types of electrodes. When adding the increased risk of hospital acquired infection with the use of reusable electrodes the justification strengthens the argument for the use of SPDE.

Summary: Current practice is transitioning from use of reusable EEG Electrodes to the use of SPDE for all clinical applications, critical care, and testing within intraoperative environments. The stand against disposables as too costly has waned since reusable maintenance is expensive and will continue to rise in accordance with salary. Critical infection and contamination risk is lessened with the use of disposable products and the trends throughout our specialties and patient care settings.

EXPANDED GLOSSARY

Antimicrobial agent: any agent that kills or suppresses the growth of microorganisms.

Antiseptic: substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them. The term is used especially for preparations applied topically to living tissue.

Asepsis: prevention of contact with microorganisms.

Autoclave: device that sterilizes instruments or other objects using steam under pressure. The length of time required for sterilization depends on temperature, vacuum, and pressure.

Bacterial count: method of estimating the number of bacteria per unit sample. The term also refers to the estimated number of bacteria per unit sample, usually expressed as number of colony-forming units.

Bactericide: agent that kills bacteria.

Contact time: time a disinfectant is in direct contact with the surface or item to be disinfected For surface disinfection, this period is framed by the application to the surface until complete drying has occurred.

Contaminated: state of having actual or potential contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that could produce disease or infection

Cleaning: removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

Decontamination: according to OSHA, "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal" [29 CFR 1910.1030]. In health-care facilities, the term generally refers to all pathogenic organisms.

Decontamination area: area of a health-care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

Detergent: cleaning agent that makes no antimicrobial claims on the label. They comprise a hydrophilic component and a lipohilic component and can be divided into four types: anionic, cationic, amphoteric, and non-ionic detergents.

Disinfectant: usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects. EPA groups disinfectants by product label claims of "limited," "general," or "hospital" disinfection.

Disinfection: thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

Exposure time: period in a sterilization process during which items are exposed to the sterilant at the specified sterilization parameters. For example, in a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

Flash sterilization: process designed for the steam sterilization of unwrapped patient-care items for immediate use (or placed in a specially designed, covered, rigid container to allow for rapid penetration of steam).

Fungicide: agent that destroys fungi (including yeasts) and/or fungal spores pathogenic to humans or other animals in the inanimate environment.

General disinfectant: EPA-registered disinfectant labeled for use against both gram-negative and gram-positive bacteria. Efficacy is demonstrated against both *Salmonella choleraesuis* and *Staphylococcus aureus*. Also called *broad-spectrum disinfectant*.

Germicide: agent that destroys microorganisms, especially pathogenic organisms.
High-level disinfectant: agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions. It therefore is expected to kill all other microorganisms.
Hospital disinfectant: disinfectant registered for use in hospitals, clinics, dental offices, and any other medical-related facility. Efficacy is demonstrated against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa.* EPA has registered approximately 1,200 hospital disinfectants
Intermediate-level disinfectant: agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores.
Low-level disinfectant: agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores
One-step disinfection process: simultaneous cleaning and disinfection of a noncritical surface or item.
Pasteurization: process developed by Louis Pasteur of heating milk, wine, or other liquids to 65–77oC (or the equivalent) for approximately 30 minutes to kill or markedly reduce the number of pathogenic and spoilage organisms other than bacterial spores.
Sanitizer: agent that reduces the number of bacterial contaminants to safe levels as judged by public health requirements. Commonly used with substances applied to inanimate objects. According to the protocol for the official sanitizer test, a sanitizer is a chemical that kills 99.999% of the specific test bacteria in 30 seconds under the conditions of the test.
Steam sterilization: sterilization process that uses saturated steam under pressure for a specified exposure time and at a specified temperature, as the sterilizing agent
Sterilization: validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

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

Rhythmlink is an electrode accessory manufacturer and distributor of both reusable and disposable EEG electrodes.

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