Hotline News

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Extreme Energy Demands and the Traditional Patient Return Electrode:

Updates to Patient Return Electrode Instructions for Use

The Covidien Energy-based Devices Clinical HOTLINE has received an increasing number of calls related to new radiofrequency (RF) technologies and the use of Valleylab™ patient return electrodes (PREs) with these technologies. Many of these new devices have a patient return electrode port design, which conveniently allows currently available patient return electrodes to interface. But, similarity of product design is not always an indication of complete compatibility and safety.

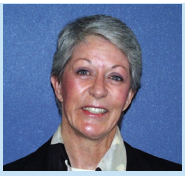
The safety measures and adoption of standards that have proven effective in **traditional** electrosurgery, virtually eliminating pad site injuries for over two decades, is being challenged by unconventional radiofrequency technologies and techniques. The ECRI Institute reports "the use of newer electrosurgical devices and techniques that apply higher currents to the patient for longer periods of time has created a new set of burn risks."[1]

Prior to the development of contact quality monitoring, patient return electrode (PRE) burns accounted for 70% of the injuries reported during the use of electrosurgery.[2] During **traditional** monopolar electrosurgery, the electrosurgical unit (ESU) or generator produces the current that travels through the active electrode and into the target tissue to produce a therapeutic (cut, coag, vaporization) tissue effect. The current then passes through the patient's body to the PRE where it is collected and carried back to the generator, completing the patient/generator circuit. The patient return electrode is a critical component in the monopolar electrosurgical circuit and a potential source of patient injury.[3] Improper application or poor conductivity of a return electrode can result in a pad site burn.[4]

The challenge in the early 1980s was to mitigate the number of reported pad site injuries by designing a PRE that minimized the heat produced in and under the return electrode while maximizing current distribution to improve patient outcomes. In 1983 the Valleylab **PolyHesive™ hydrogel** PRE (single section and dual section) was developed to enhance electrode conductivity, lower skin resistance and decrease thermal concentration by maximizing current distribution.

Valleylab™ also introduced the first return electrode contact quality monitoring (RECQM) system in 1981. This technology actively monitors the patient/pad interface throughout the surgical procedure. If the system detects a poor quality pad-to-patient interface, the ESU is disabled and the surgical staff is notified by an audible and visual alarm. The surgical procedure cannot continue until the alarm condition is corrected. The RECQM system is composed of **two** key elements: the Valleylab REM™ dual section patient return electrode (PolyHesive™II) and the Valleylab REM™ equipped electrosurgical generator. A single section or standard PRE connected to an ESU with RECQM circuitry negates the contact quality monitor safety feature.[5] The use of the RECQM system has significantly reduced patient injury due to burns at the PRE site, and RECQM has been considered the standard of care.[6]

More recently, newer types of electrosurgical devices and RF procedures involve the continuous delivery of high current, four to five times that of traditional electrosurgery, for periods ranging from a few minutes to 20 minutes or even longer. Such procedures include tumor ablation, cardiac ablation, joint ablation and tissue ablation using a conductive distention medium. "If high power



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settings are used for an extended period of time in a conductive solution, the surface area of the PRE may be too small to disperse the current safely. Concentration of any current creates heat. Should the heat exceed 45°C (112°F), varying degrees of tissue injury will occur."[7] In contrast, traditional electrosurgery recommends the use of the lowest power setting that will achieve the desired tissue effect, short activation times (duty cycles) of 10 seconds on and 30 seconds off and non-conductive distention solutions.

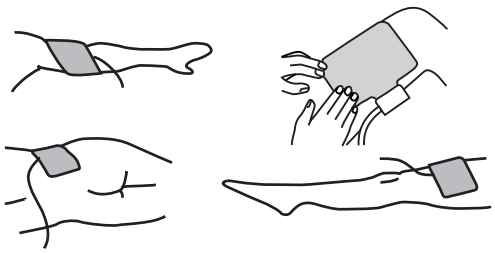
The extreme energy-demand conditions encountered during high-current, long-activation time electrosurgical treatments can produce thermal stress effects on the dispersive return electrode.[8] This can in effect overwhelm the conventional patient return electrode, increasing the risk of patient burns at the site of that electrode.[9] Existing RECQM technology works well for **traditional** electrosurgery. However, currently available RECQM designs do not ensure there is adequate area of contact to safely disperse the high currents encountered during use of these newer technologies and techniques (i.e., when the current exceeds the dispersive capacity of a properly placed PRE).[10] Such techniques and devices were not envisioned during the development of standards for high-frequency electrosurgical devices, namely ANSI/AAMI HF18* or IEC 60601-2-2.† **Consequently, conventional return electrodes are not designed to handle these types of conditions.**[11]

As a result of these new concerns and potential risks, Covidien Energy-based Devices (EbD) has made important changes to the PRE instructions for use (IFU). These changes reflect a concerted effort to keep perioperative professionals informed about these new risks and current practices to help reduce those risks.

CHANGES TO THE VALLEYLAB™ PATIENT RETURN ELECTRODE INSTRUCTIONS FOR USE

Statements Regarding Intended Use:

- All Valleylab™ patient return electrodes are designed for use in **traditional** monopolar electrosurgical procedures with duty cycles of 25% or less (for example, 10 seconds on followed by 30 seconds off).
- During a surgical procedure, the amount of current delivered in a given time determines the amount of heat that occurs under the patient return electrode. It is not possible to foresee what combination of current and duty cycle may be safely used in every situation.
- When using a Valleylab™ patient return electrode, the user should consult the generator and accessory manufacturers' recommendations and technical specifications regarding recommended maximum duty cycles.



Example 1

NEW WARNING

Valleylab™ Adult Patient Return Electrodes:
(E7506, E7507, E7507-DB, E7508, E7509, E7509B)
For use on patients >13.6 kg or > 30 lb

- Non-traditional procedures that utilize high current, long duty cycles or both (for example, tissue lesioning, tissue ablation, tissue vaporization and procedures in which conductive fluids such as saline or lactated Ringer's solution are introduced into the surgical site for distention or to conduct the RF current) increase the risk of excessive heating under a fully applied return electrode to the point of injuring the patient. Use of more than one patient return electrode ***may*** help mitigate the increased risk.

Valleylab™ Infant Patient Return Electrode
(E7510-25, E7510-25DB)
For use on patients 2.7 kg – 13.6 kg (6 lb – 30 lb)

Valleylab™ Neonatal Patient Return Electrode (E7512)
For use on patients 0.45 kg – 2.7 kg (1 lb – 6 lb)

- **Do not** use the infant (E7510 series) or neonatal (E7512) patient return electrode in high-current and/or long-duty cycle procedures (for example, tissue lesioning, tissue ablation, tissue vaporization and procedures in which conductive fluids such as saline or lactated Ringer's solution are introduced into the surgical site for distention or to conduct the RF current). These conditions increase the risk of excessive heating under a fully applied return electrode to the point of seriously injuring the patient.

NEW CAUTION

When applying the return electrode(s), do not allow adjoining edges to touch or overlap.

- This caution applies to situations where the best application site is an extremity and/or when multiple PREs are used. Placing the PRE on the bias or slightly angled prevents overlapping and reduces the chance of a tourniquet effect.
- In general, when a PRE is placed on an extremity it should be oriented so the longest edge is facing the surgical site. Placing the longest edge perpendicular to the extremity accommodates the PRE more readily. However, the unique properties of PolyHesive™ hydrogel as well as pad design allow Valleylab's return electrode to be safely placed at any angle.[12] *(See Example 1)*
- If multiple PREs are used, they should be placed equidistant from the surgical site.

Ultimately, technological solutions will need to be developed and standards will need to be revised to significantly address the concerns presented by the new high-current technologies and techniques. Until such time it is imperative that perioperative professionals are made aware of the technologies and techniques that can put the patient at risk, in addition to precautions and interventions that can help minimize that risk. Some general recommendations are listed below, but as new technologies and techniques emerge, facilities will have to consider policies and procedures focusing on their own unique situation.

General recommendations include, but are not limited to:

1. Review the surgical procedures performed in the facility and identify those that may require the use of high-current and long-activation time RF ablation and electrosurgical techniques.[13]
2. Provide clinicians with training, which includes understanding how burns occur, recognizing when problems may occur and knowing the preventive measures to take.[14]
3. Review the facility's current inventory of RF generators, newly purchased generators and generators being evaluated to determine if they are used for high-current, long-activation time RF ablation procedures.
   - Is the technology a "complete system" with accompanying accessories? Does it require the use of another manufacturer's accessories and if so, what tests have been done to ensure function, compatibility and safety? Is the data available? *(Please note: Valleylab™ only tests its patient return electrodes and accessories with Valleylab generators).*
   - Review the operator's manual for each generator and the IFU for each accessory to ensure familiarity with all devices.
   - Be familiar with any literature (positive, negative or indifferent) related to the technology, operative technique and outcomes.
4. Verify the dispersive electrode(s) is properly applied to the patient according to manufacturer's instructions. Ensure complete pad-to-patient interface and secure connection of the PRE(s) to the RF generator before starting the procedure. If the patient is repositioned, check all connections.[15]
5. Suspend the use of any RF generator when a surgical effect is not evident or less than expected for the surgical circumstances. Verify correct distention/irrigation medium selection and check all PRE connections before gradually increasing normal power settings.
6. Use the lowest possible power setting and shortest activation times that achieve the desired tissue effect.
7. Use non-conductive distention solution or irrigation medium unless specific medical reasons indicate otherwise. Confirm the selection of the appropriate medium with the surgeon before the use of any RF technology.[16]
8. In situations where high-current, long-activation times may pose a risk of a PRE site burn and no specific instructions are provided by the device manufacturer, consider the use of two or more dispersive electrodes (may require a special adapter) or a larger surface conductive electrode. Be advised this is an incomplete solution! The RECQM (if available) or other protective features of the generator will not ensure that two dispersive electrodes are used or that a larger electrode is used, and will not ensure adequate total contact area with the patient. In essence, existing RECQMs cannot effectively monitor such configurations.[17]

The ECRI Institute states that until the needed technological solutions are incorporated into RF generators, a greater burden is placed on clinicians to recognize the level of patient protection to which they are accustomed may no longer be present during certain electrosurgical procedures. Clinicians need to know what electrosurgical techniques place their patients at risk, and to implement appropriate precautions to reduce the risks of burns.

As a medical manufacturer, Covidien EbD has taken a proactive approach by recognizing the risks associated with certain electrosurgical techniques and technologies and updating our PRE instructions for use to reflect that concern. Although the IFU is packaged in the case with all products, the instructions are frequently tossed out once the items are removed and stocked according to hospital policy. It is the intent of this newsletter to make this information more readily available for review. All updates made to the patient return electrode IFUs are not presented in this newsletter, but copies are available upon request to the Clinical HOTLINE.

* *ANSI/AAMI HF18-2001. Electrosurgical Devices. Arlington, Va: Association for the Advancement of Medical Instrumentation (AAMI).*

† *IEC 60601-2-2. Medical Electrical Equipment: Part 2-2; Particular requirements for the safety of high frequency surgical equipment. Geneva: International Electrotechnical Commission.*

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