

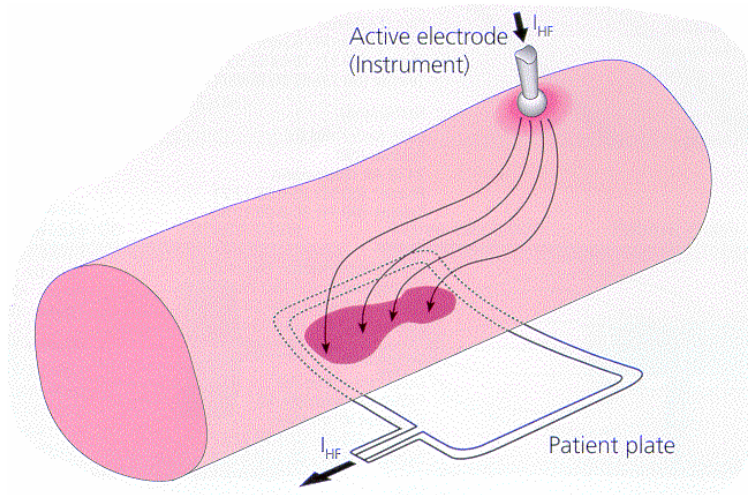
Reducing Grounding Pad Burns During High Current Electrosurgical Procedures

The recent introduction of electrosurgical devices and surgical techniques that apply high levels of current to the patient for extended periods of time **increase the risk** of patient burns at the grounding pad site **above** the risk presented in "traditional" electrosurgical procedures. Safety measures that have proven effective using traditional electrosurgical procedures may not be sufficient to prevent grounding pad burns when used in procedures that require **any combination** of **high current**, **long activation times** and the **use of conductive fluids** (e.g., saline) for irrigation or distention. The problem is that some of new electrosurgical devices and surgical techniques can produce higher current levels than an AAMI HF-18 compliant grounding pad can safely withstand, significantly increasing the risk of a burn at the grounding pad site.

This technical bulletin will explain the factors that increase the risk of a burn at the grounding pad site and will conclude with recommendations to minimize that risk.

Basics of Electrosurgery

Traditional electrosurgery uses radiofrequency (RF) electrosurgical current to cut and coagulate tissue. The electrosurgical current is conducted through a circuit consisting of the following: (1) an electrosurgical unit (ESU) or an RF generator that produces electrosurgical current; (2) insulated cables that connect the active electrode to the generator; (3) an active electrode that delivers the electrosurgical current to the target tissue; (4) the patient; and (5) a grounding pad or patient plate with its own cord or cable.



The grounding pad—adhered to the patient's skin away from the surgical site—is intended to safely return the electrical current from the patient back to the generator through a cord or cable. Because the conductive surface area of the grounding pad is much larger than the active electrode (where cutting, coagulation, or ablation occur), the current is dispersed over a wide area, minimizing the heating of the tissue under the grounding pad. The risk of a patient burn is increased when there is poor contact quality

between the grounding pad and the patient because the current is concentrated at the contact points rather than dispersed over the entire grounding pad.

Increased Risk of Grounding Pad Site Burns

Surgical techniques using very high current and/or current applied continuously for very long times have increased over the years. In traditional electrosurgery, the surgeon activates the generator for only a few seconds at a time to gradually excise tissue (as opposed to activating the generator and cutting continuously until the procedure is done). This intermittent activation allowed the removal of heat by the body, typically through the perfusion of blood through the tissue under the grounding pad. However, in certain ablation procedures performed today, very high current levels can be applied for continuous periods of 5 to 20 minutes. For comparison purposes, activation of current during traditional electrosurgical procedures is usually one minute or less. The level of current delivered to the grounding pad in these high-current, long-activation-time procedures can overwhelm the grounding pad and substantially increase the risk of a patient burn. The use of conductive fluids for irrigation or distention aggravates this problem.

Existing standards for grounding pads do not address these extreme conditions. According to the AAMI HF-18 standard, an adult grounding pad should be designed to safely carry a current load of 500 milliamperes (mA) for a continuous period of 60 seconds. In order to pass the AAMI HF-18 performance test, an adult grounding pad must safely carry twice this amount of power, i.e., 700 mA for a continuous period of 60 seconds.¹ However, some of the newer radiofrequency devices can deliver current levels of 1000 to 2000 mA for a few minutes or up to 20 minutes or longer. Under these conditions, an AAMI HF-18 compliant grounding pad may not safely and effectively disperse the current, resulting in a patient burn at the site of the grounding pad.

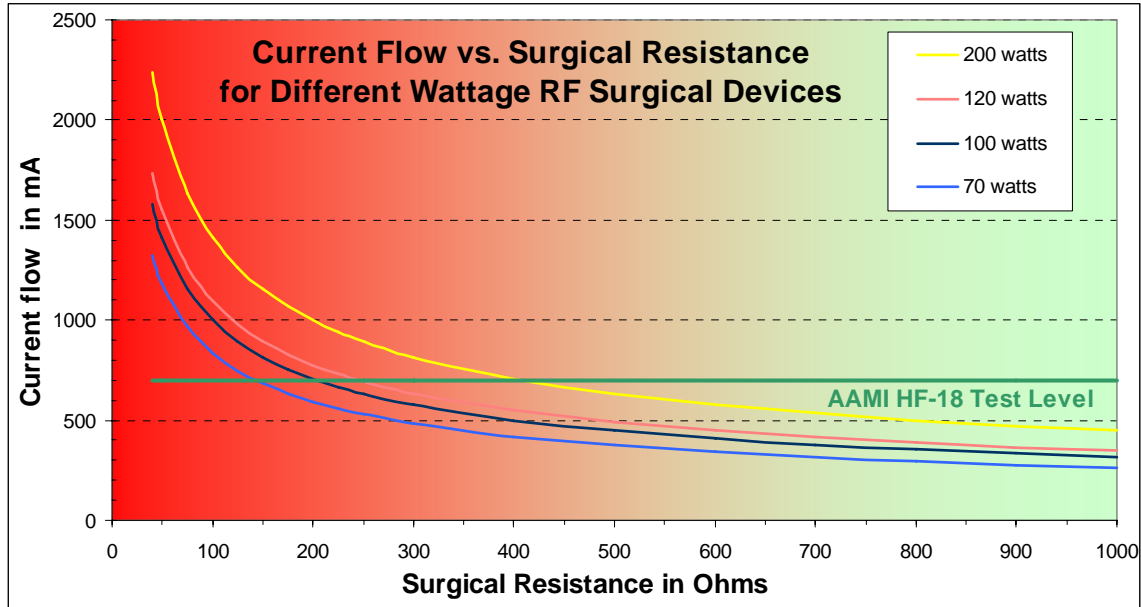
The use of a conductive solution, such as saline, as an irrigation or distention medium, can be an additional factor contributing to the delivery of high current levels. A distention medium is typically used in endoscopic procedures (e.g., arthroscopy, laparoscopy, etc.). The electrosurgical effect is rendered less effective because the conductive solutions disperse current away from the intended surgical site. This effect occurs most notably when the active accessory, such as a roller ablation electrode, has a significant portion of its surface area in contact with the conductive medium. The conductive nature of the surrounding medium disperses the current and causes a dramatic reduction of surgical effect. This may cause the operator to increase the output power settings on the generator. In addition, the conductive solution lowers the electrical impedance of the active electrode accessory, which in turn elevates the current level. Low impedance combined with a higher power setting can significantly increase the amount of current conducted through the grounding pad, possibly overwhelming what an AAMI HF-18 compliant grounding pad can withstand.

Please note that electrosurgical generators equipped with contact quality monitoring systems such as REM™, ARM™, NESSY™, etc., measure **only** whether sufficient contact is made by the pad with the patient's skin. Although this technology works well in traditional electrosurgical procedures, it simply does not address those situations where current can be delivered that exceeds what an AAMI HF-18 compliant grounding pad can handle. These systems **will not** alert hospital personnel if the current delivered exceeds the dispersive capacity of a properly placed grounding pad.

¹ 700 mA is double the power of 500 mA according to the equation $POWER = CURRENT^2 \times SURGICAL RESISTANCE$

Illustration of the Problem

The graph below shows the electrical relationship between the delivered wattage of a radiofrequency medical device and the amount of current the device will pass through the grounding pad during use depending upon the level of surgical resistance.²



Each curve represents the delivered wattage (or power) of different radiofrequency medical devices and demonstrates the relationship between surgical resistance and the amount of current passing through the grounding pad. The left side of the graph illustrates that, as surgical resistance decreases (as happens when using conductive fluids), the amount of current that will pass through the grounding pad increases exponentially. The AAMI HF-18 performance threshold of 700 mA appears as a straight green line on the graph. The portion of each curve above this line represents a level of current flow that will pass through the grounding pad in excess of the AAMI HF-18 standard. Although grounding pad burns may happen at anytime due to poor placement or improper use, this situation presents an **increased risk for patient burns even when properly applied.**

The new radio frequency devices and active accessories that pose a risk to patient safety have a number of factors in common. They are intended to deliver **high levels of current**, often requiring application of multiple grounding pads. (The use of 2 to 4 is common) They are intended for use with **very long, continuous activation times** and they are designed to deliver current into **very low surgical resistance**. Although several factors contribute to surgical resistance, the most significant factor is the resistance between the electrosurgical pencil (or other active accessory) and the patient's tissue at the surgical site. Surgical resistance in "traditional" electrosurgical procedures is generally between 300 and 1000 ohms. However, some of these devices are designed to deliver the maximum power (or wattage) into a surgical resistance as low as 50 ohms, resulting in a current flow far in excess of the AAMI HF-18 grounding pad performance test. This means that even a 70-watt generator can deliver current above 700mA.

Circumstances that Pose the Greatest Risk

² The curves on the graph were calculated by the use of the formula: (Power in Watts) = (Current in Amperes)² X (Surgical Resistance in Ohms).

To prevent patient injuries, hospital personnel need to recognize the types of equipment and procedures that are most likely to result in the delivery of high current levels that can overwhelm an AAMI HF-18 compliant grounding pad. The following factors pose the greatest risk as they may result in delivery of high current levels, have long activation times and/or low surgical impedance:

- **Ablation or other procedures**
 - ▶ Tumor ablation
 - ▶ Cardiac ablation
 - ▶ Liver ablation or resection
 - ▶ Endoscopic ablation (e.g., shoulder arthroscopy)
 - ▶ Bulk tissue ablation such as transurethral resection of prostate or uterus
- **Application of high current to the patient's tissue**
 - ▶ Use of a high-current or specialty generator intended for large-volume tissue ablation
 - ▶ Use of active electrodes such as a roller ablation electrode
 - ▶ Required use of multiple (2 to 4) grounding pads at the same time.
 - ▶ Required use of multiple active electrodes
- **Application of current for an extended period of time to the patient's tissue**
 - ▶ Use of a general purpose electrosurgical generator with either long-activation periods or little time between activations.
 - ▶ Use of a specialty purpose electrosurgical generator with long-activation periods
- **Use of conductive solutions such as saline that lower surgical impedance**
 - ▶ Use of an active accessory that is designed to be used with or dispense saline or has a significant portion of its surface area in contact with a conductive medium such as saline
 - ▶ Use of an active accessory that is fully immersed in flowing blood for extended periods of time (e.g., cardiac ablation)

Reducing the Risk

Hospital personnel may not recognize the risk associated with high-current, long-activation-time electrosurgical procedures or procedures that involve the use of conductive fluids (e.g., saline) for irrigation or distention. To minimize the risk of a burn at the grounding pad site during such procedures, 3M recommends the following:

1. **Recognize** that the ESUs, RF devices and accessories in your facility are capable of producing current levels that can exceed what an AAMI HF-18 compliant grounding pad can withstand in procedures involving any combination of **high current, long-activation times** and/or the **use of conductive fluids** for irrigation or distention.
2. **Identify** the electrosurgical procedures performed in the facility that may require the use of high current, long-activation times and/or the use of conductive fluids for irrigation or distention.
3. **Educate** operating room clinicians, doctors, and risk managers on the increased risk of burns associated with high-current, long-activation electrosurgical procedures or procedures that involve the use of conductive fluids for irrigation or distention.
4. **Train** operating room clinicians about how burns occur, how to recognize when there is an increased risk of electrosurgical burns and what to do to minimize the risk.
5. **Require** operating room clinicians to be familiar with the instructions for use and warnings of each piece of equipment – ESU or RF generator, active electrodes and grounding pads.
6. **Make sure** that the grounding pad is in full contact with the patient and verify the pad manufacturer's instructions were followed regarding pad application.

7. **Use** the lowest possible power settings and shortest activation times to achieve the desired surgical effect. If long activation times are necessary, allow sufficient time off between activations to allow the tissue to cool under patient plate. The amount of time off required will vary depending upon the amount of current used, the length of activation time and the individual characteristics of the patient. This may require equal time off as activation time.
8. **Confirm** the use of the appropriate irrigation/distention medium with the surgeon before any electrosurgical procedure. Use a non-conductive solution as the distention/irrigation medium unless specific medical reasons indicate otherwise or the manufacturer of the generator or accessory recommends otherwise. Numerous non-conductive fluids are available. Common ones include 1.5% glycine, 3% sorbitol, 5% mannitol, and sterile water. **Note:** Not all non-conductive media are appropriate for all procedures. Selection must be based on the surgical procedure. For example, long procedures involving large volumes of media require that the patient's fluid balance be carefully monitored to avoid fluid overload which can lead to serious complications such as pulmonary edema, congestive heart failure, cerebral edema, hypotension, and electrolyte imbalance.
9. **Avoid** use of a roller ablation electrode with a conductive fluid, unless otherwise indicated by the electrode manufacturer, because a significant portion of its surface area will be in contact with the conductive medium, causing a loss of surgical effect. Increasing the power settings will increase the amount of current delivered to the grounding pad. If high power is used for too long, the current may overwhelm the grounding pad, resulting in a patient burn.
10. **Verify** that the correct distention/irrigation medium has been selected if there is no surgical effect or less than a desired surgical effect. **Inspect** the grounding pad to ensure that it is applied according to the manufacturer's instructions and in full contact with the patient before increasing the power setting on the generator.
11. **Use** two identical grounding pads placed symmetrically and equidistant from the surgical site where there is a concern that the use of high current, extended activation times, and/or the use of a conduction irrigation/distention fluid may pose an increased risk of an electrosurgical burn at the grounding pad site. Such placement will divide the current flow between the two pads and reduce the risk of a burn. Suitable placement sites include: 1) the left and right anterior thigh; 2) the left and right buttock; or 3) the left and right bicep.

Avoid placing multiple grounding pads in the following configurations because they will increase the risk of a burn:

- a. **Placement of one grounding pad below another grounding pad on a single limb.** With this placement, nearly all of the current will be collected by the grounding pad closer to the surgical site, increasing the risk for a burn at the pad located nearest to the surgical site.
 - b. **Asymmetrical placement of grounding pads on two limbs, such as the right thigh and left calf.** With this placement, the current flow to the right thigh will be substantially more than the left calf.
 - c. **Placement of two grounding pads directly next to each other.** With this placement, the current will be more heavily concentrated at the edges of the grounding pad closest to the surgical site, increasing the risk for a burn at this location.
 - d. **Placement of two grounding pads on one limb, particularly if this placement causes the encirclement of an entire limb by grounding pads.** If more than one grounding pad is used on any limb and the current flow is very high, it is possible that the high level of current flow through the limb will increase the temperature of the entire limb.
12. **Follow** the pad manufacturer's instructions for grounding pad placement if the instructions for use for a radiofrequency medical device or active accessory call for the use of more than two grounding pads. If the instructions for use do not include grounding pad placement for two or more grounding

pads, contact the manufacturer and request written instructions for multiple grounding pad placement.

Summary

New electrosurgical devices and surgical techniques that employ any combination of high current, long activation times and/or the use of conductive fluids for irrigation or distention **increase the risk** of patient burns at the grounding pad site risk **above** that of “traditional” electrosurgical procedures. The resulting current levels can be greater than what an AAMI HF-18 compliant grounding pad can safely withstand. Health care personnel at all levels must recognize these situations and take appropriate steps to minimize this risk.



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