

MEGA SOFT™ Return Electrode

Monopolar Electrosurgery

Monopolar surgery is ubiquitous in hospitals, ambulatory surgery centers, and surgical procedures throughout the world. It has been used as far back as 1926, and while many of the fundamental concepts are the same, improvements have been made to improve patient safety¹. One significant improvement is the MEGADYNE™ MEGA SOFT™ Reusable Patient Return Electrode, a capacitive return electrode.

A fundamental principle of electricity is that a circuit must be complete. This means current (flow of electrons) that leaves the power source (generator) must return to that generator. In electrosurgery, the current flows to an active electrode (e.g. monopolar blade), into the patient, and then back via a return electrode.

The current near the monopolar blade is concentrated in a small area, resulting in a high current density. This high current density locally increases the temperature, providing the desired clinical effect of cut or coagulation. Conversely, the current near the return electrode is spread over a much larger area with a low current density, resulting in little to no change in temperature (Figure 1).

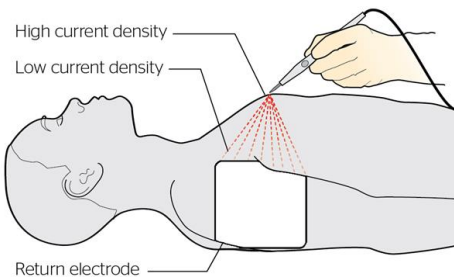


Figure 1. Current Density at the Active and Return Electrodes

Monopolar electrosurgery uses alternating current (AC). This means the flow of current changes direction many thousands of times per second. Thus, current both enters and leaves the patient through the monopolar blade and the return electrode. The implications of AC are discussed in the Theory of Operation section at the end of this document.

Adhesive Return Electrodes

One method of completing the surgical circuit, providing a pathway for the current to flow from the generator, through the monopolar blade and patient, and back to the generator is to use an adhesive return electrode placed on the patient's skin (as shown in Figure 2). An adhesive return electrode acts like a resistor through which current physically flows. The adhesive material helps maintain a strong physical connection to the patient's skin. This physical connection across a large area is essential to complete the circuit while maintaining low current density.

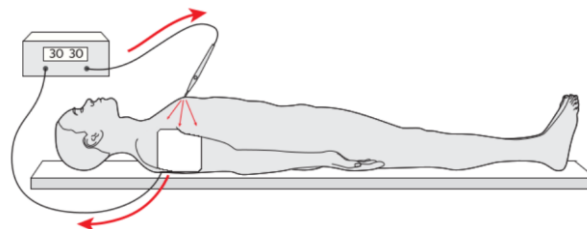


Figure 2. Circuit with Adhesive Return Electrode

Capacitive Return Electrodes

The MEGA SOFT™ Patient Return Electrode uses a different approach than resistance to complete the circuit. It uses capacitance. A capacitor is created when two conductive plates are separated by an insulator. Current does not flow directly between the two plates due to the layer of insulation (Figure 3A). Instead, current from the active electrode causes a charge to gather on the first conductive plate. This causes an equal but opposite charge to form on the second conductive plate (Figure 3B). The charge on the second plate produces current that returns to the generator and completes the circuit. The “communication” between the two plates occurs through an electromagnetic field. Charge can therefore flow “through” a capacitor even though no individual electron passes from one side to the other. Because the generator provides an alternating current, the accumulated charge switches rapidly between the first and second plates. This maintains a current without fully charging the capacitor.

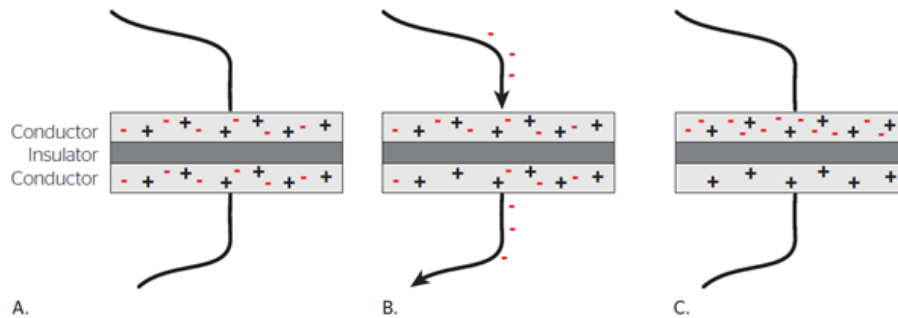


Figure 3. A. Prior to the application of a current the charge on both conductive plates is the same. B. As current is applied to the top plate (electrons), its electromagnetic field causes a different electron on the bottom plate to flow back to the generator. C. After a period of time, the top plate becomes predominantly negatively charged and the bottom plate, with few electrons, is predominantly positively charged. As the current changes direction, the charges accumulate on the opposite plates, changing thousands of times per second.

Unlike an adhesive return electrode, no direct contact to the skin is required. The MEGA SOFT™ Return Electrode is a large capacitive pad, much larger than an adhesive return electrode, that is placed below the patient as shown in Figure 4. An electrical charge accumulates at the patient, and an opposite charge accumulates just like a capacitor in the MEGA SOFT™ Return Electrode pad. The alternating current provided by the generator provides a continuous current by switching the charge.

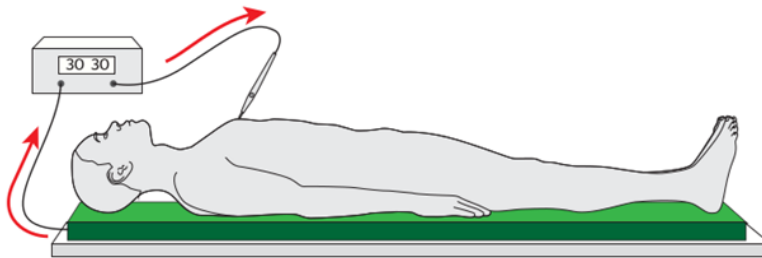


Figure 4. MEGA SOFT™ Return Electrode and the patient form a capacitor. The patient acts as the top plate of the capacitor. There is a dielectric material in the MEGA SOFT™ Return Electrode pad separating a conductive plate and the patient, forming the capacitor.

The nature of capacitance leads to some considerations for clinical use.

- No direct contact is required between the pad and the skin. A sheet and draw sheet may be placed over the pad, but the separation distance between pad and patient should be kept to a minimum. As with any capacitor, it is easier to induce a charge across the two plates when the distance between those plates is minimized. As the plates are moved farther apart, the current decreases, resulting in a diminished electrosurgical effect.
- The area of overlap between the patient and the pad should be as great as possible. With any capacitor, it is easier to induce a charge across the two plates when the plates are aligned. As the plates are moved away from each other, the current decreases, resulting in a diminished electrosurgical effect.

Monopolar Electrosurgery Risks

There are risks inherent with electrosurgery. Even with advances made over almost 100 years, certain risks exist with monopolar electrosurgery.

Pad Site Burns

With an adhesive return electrode, there is risk of a pad site burn. Burns may occur when a reduced surface area (area of contact between the patient and the electrode) results in higher current densities and subsequently higher temperatures (Figure 5). The surface area can be reduced in several ways, such as the pad partially detaching from the patient or the pad crimping/folding on itself.

Because of this risk, manufacturers have implemented Contact Quality Monitoring (CQM). CQM is a generic term for technologies such as REM™ (Return Electrode Monitoring, used by Medtronic) and other trademarked systems from individual generator manufacturers. There are several different CQM approaches, but the concept is fundamentally the same. The generator actively monitors the quality of the pad contact with the patient’s skin. Should the quality of contact decrease past a threshold, the generator stops the current preventing a pad site burn. In general, this approach has a decent safety record. But as with any active design there is always a potential for device failure or misuse that can result in a pad site burn.

Additionally, if a higher power setting is required for a procedure, the temperature at the return electrode may increase to the point where adapters are required to allow more than one return electrode to be used simultaneously to increase the surface area. This approach requires prior knowledge that the procedure will require these higher power levels, which may not always be known.

With capacitive return electrodes like the MEGA SOFT™ Return Electrode, there is no risk of a pad site burn when used according to the instructions for use and under reasonably foreseeable misuse. As the surface area (area of overlap) decreases or the distance between the pad and patient increases, the charge on both the active electrode and return pad decreases, resulting in a decreased capacitance while maintaining a constant temperature (Figure 5). There are no active design components controlling this relationship, it is fundamental in the design of the MEGA SOFT™ Return Electrode.

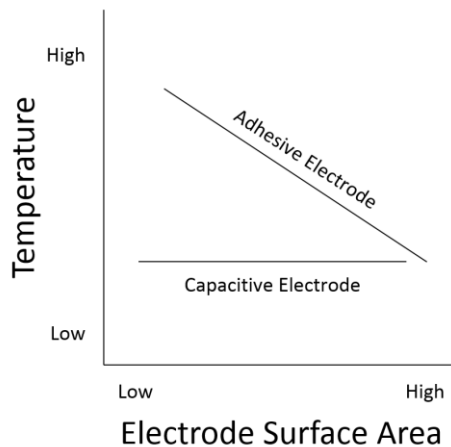


Figure 5. Relationship between surface area and temperature for capacitive and adhesive electrodes.

Burns due to Conductive Materials

When an adhesive electrode is used, if a conductive material (jewelry, tattoo, piercing, implant) contacts the electrode the current can be concentrated at that point. This can result in increased temperature and a greater potential for a burn injury.

The MEGA SOFT™ Return Electrode has no direct conductive contact with the patient. Any conductive material on the patient will simply become part of the top conductive plate and will not create an area with high current density. This means that removing conductive materials is not required to minimize patient injury with the MEGA SOFT™ Return Electrode.

Note that the MEGA SOFT™ Return Electrode and an adhesive return electrode have the same risk for burns from caustic fluids and materials. As with any medical device, avoid pooling of chemicals or fluids that may contribute to patient skin breakdown or pressure ulcer formation.

Alternate Site Injuries

Most modern generators are isolated from ground. Ground isolation means that a conductive pathway like a saline drip cannot close the circuit. However, no generator is completely isolated from ground. There is always a residual current called leakage current. If an alternate pathway to ground contacts the patient, the leakage current may take this pathway and a burn may occur at the site of contact. This is possible regardless of the type of return electrode used.

Additionally, should the power be increased for either electrode to have a greater surgical effect, the risk for alternate site injuries increases. This is because a higher power setting results in a higher voltage and therefore greater potential for current to find an alternate pathway to ground. This risk is present for both adhesive and capacitive return electrodes if they are not used according to their instructions for use (IFU).

Benefits/Considerations When Using the MEGA SOFT™ Return Electrode

There are several clinical benefits of using the MEGA SOFT™ Return Electrode.

No Adhesive Related Injuries

The MEGA SOFT™ Return Electrode does not include any adhesive material. For patients with a sensitivity to adhesives (for example pediatric, geriatric, and patients with significant burns) there is no risk of secondary injury to the dermis from an adhesive.

Simple to Set Up and Use

AORN published recommended practices for electrosurgery to provide guidance to clinical teams on safe and effective use of electrosurgery². A capacitive return electrode, such as the MEGA SOFT™ Return Electrode, has a simpler preparation and intra-procedural operation per the AORN guidance. Below is a summary of these guidelines also including additional material from the MEGA SOFT™ Return Electrode instructions for use³. Of particular importance, the MEGA SOFT™ Return Electrode requires only a compatible isolated generator and does not require CQM for safe operation. Additionally, during patient repositioning in the operating room, vigilance is required to ensure the adhesive return electrode is properly adhered to the patient. This level of vigilance is not needed with a capacitive return electrode.

The steps and considerations required peri-operatively for the MEGA SOFT™ Return Electrode are considerably less than those needed for an adhesive return electrode.

Adhesive Return Electrode Preparation, Placement, and Removal – Summary of AORN guidelines

1. Assess the condition of the patient's skin.
2. Remove hair if it interferes with electrode-skin contact.
3. Place the return electrode on the patient after final patient positioning. Moving the patient may disrupt the electrode-skin contact.
4. Place the return electrode on clean, dry skin over a large, well-perfused muscle mass and as close as possible to the surgical site.
5. Do not place the return electrode over bony prominences, scar tissue, hair, weight-bearing surfaces, potential pressure points, areas distal to tourniquets, implanted metal prostheses, or tattoos.
6. Place the return electrode away from any warming device.
7. Avoid contact between the patient and metal devices which could offer a potential alternate return path for electrical current.
8. Keep the electrode dry and protected from fluids seeping or pooling.
9. Remove the patient's metal jewelry, including body piercings.
10. Place monitoring electrodes as far away from the surgical site as possible. Avoid using needle electrodes.
11. Verify uniform electrode-skin contact with no tenting, gaping, or moisture interfering with adhesion.
12. If any tension is applied to the return electrode cord, check the electrode for damage, electrode-skin contact, and connection to the generator.
13. If the patient is repositioned, check the electrode-skin contact.
14. Do not reuse or reposition the return electrode. It may not adhere properly to the skin.
15. Remove the return electrode, holding the skin in place and peeling back the electrode slowly.
16. Assess the condition of the patient's skin.

Capacitive Return Electrode Preparation, Placement, and Removal – Summary of AORN guidelines

1. Check the pad and cables for tears or breaks in the surface material before use.
2. Ensure adequate contact with the patient. Minimize the materials placed between the patient and the return electrode.
3. Avoid contact between the patient and metal devices which could offer a potential alternate return path for electrical current.
4. Keep the electrode dry and protected from fluids seeping or pooling.
5. Remove the patient's jewelry, such as rings, which may cause swelling at the site during surgery or recovery.
6. Place monitoring electrodes as far away from the surgical site as possible. Avoid using needle electrodes.
7. After use, clean the pad with an appropriate cleaning solution.

Can Be Used with Warming Devices

The MEGA SOFT™ Return Electrode can be used with warming pads. The electrode needs to be placed on top of the warming pad to minimize the separation between the patient and the electrode. The MEGA SOFT™ Return Electrode can be prewarmed in a blanket warming cabinet to reduce the time it takes for the warming pad to heat the electrode.

The time it takes for the MEGA SOFT™ Return Electrode to warm is dependent on the wattage of the warming pad, the target temperature, and the operating room temperature. For each example below, the targeted warming temperature is 110°F (43°C), a maximum temperature for one style electric blanket controller and well below ECRI guidance of 130°F (54°C)^{4,5}. Changing the targeted temperature will decrease the time for lower temperatures and conversely increase the time for warmer temperatures.

For the MEGA SOFT™ Universal Return Electrode, figure 6A shows the time it takes to warm the electrode to 110°F (43°C) based on the peak wattage of the warming pad in an operating room with a temperature of 68°F (20°C). The peak pad wattage is the power used initially by the controller. Some warming controllers can range in power from 580 watts to as high as 850 watts³. A relatively low peak power wattage can take approximately 6 to 7 minutes to warm the electrode while higher wattages can achieve the targeted temperature in less than 5 minutes. Figure 6B shows the time it takes for the electrode to come to a temperature of 110°F (43°C) assuming a peak 580 watts in different operating room temperatures, 64°F to 82°F (18°C to 28°C). As shown, the temperature of the operating room can influence warming time by as much as ten minutes over the evaluated range.

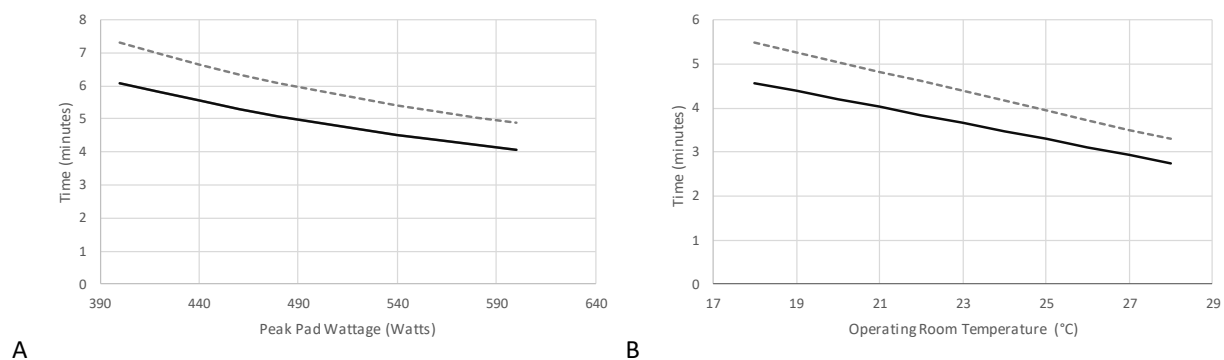


Figure 6. A. The time it takes for the electrode to warm based on the peak pad wattage, assuming an operating room temperature of 68°F (20°C) and targeted temperature of 110°F (43°C). Dashed line represents a 20% margin of error. B. The time it takes for the electrode to warm based on the operating room temperature, assuming a peak blanket wattage of 580 watts. Dashed line represents a 20% margin of error.

Managing Surgical Effect

If the area of overlap between the electrode and patient decreases or the separation distance between the patient and electrode increases, a reduced surgical effect may be observed. This is due to the nature of capacitance. It is easier to induce a charge across the capacitor plates when they are closely aligned.

For optimal surgical effect, the patient should be placed over as much of the MEGA SOFT™ Return Electrode as possible. Additionally, the separation distance between the patient and the MEGA SOFT™ Return Electrode should be as small as possible. Ideally, only a sheet and draw sheet are placed over the electrode.

Should the procedure require reduced area of overlap or greater separation distance, an increase in generator power may be required to have the same surgical effect. It is important to recognize that increasing the generator power does not increase the power seen at the surgical site.

Theory of Operation

This section provides greater detail on the operation of adhesive return electrodes and the MEGA SOFT™ Return Electrode. When an adhesive pad is used in the electrosurgical circuit the current flows from the generator as shown in Figure 7A. The direction of the flow of current reverses as the voltage from the generator alternates between plus (+) voltage and minus (-) voltage values.

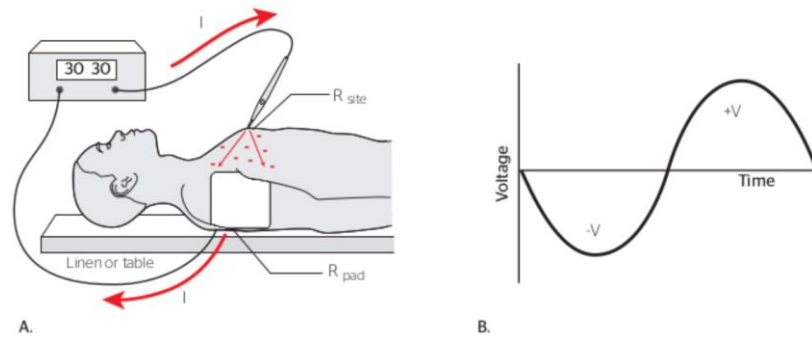


Figure 7. Adhesive pad with a -V has the current flowing as shown. For +V the current flow reverses, starting from the generator, into the pad, then the surgical instrument, and back to the generator.

The MEGA SOFT™ family of reusable patient return electrodes functions on the principle of a parallel plate capacitor. Parallel plate capacitors consist of two conductive plates separated by an insulator (non-conductive) material⁸. Charge builds as current flows into one plate of a capacitor. This charge induces an equal but opposite charge to build up across the gap on the opposite conductive plate. The buildup of charge on the opposite plate causes current to flow from that plate. This induced charge balance continues to occur as the voltage alternates between plus (+) voltage and minus (-) voltage values on each conductive plate. In this manner the flow of current is induced across a capacitor without ever actually having current flow across the gap (Figure 3).

The energy required to induce a charge across the gap is stored in the capacitor, not lost or dissipated, but is not available for use in other areas of the electrical circuit⁹. How easy it is to induce a charge across the two conductive plates in a capacitor (capacitive coupling) is controlled by the size of plates, the separation distance between the plates, and the distinctive electrical properties (dielectric) of the material between the plates⁹. The flow of current through an electrical circuit is restricted by the presence of a capacitor, like that of a resistor. This “resistance” is due to the capacitive impedance that occurs with capacitive coupling. Placing a capacitor in an electrical circuit results in a 90° phase shift between the current and voltage for the capacitive component^{8,9}. Note that capacitors are a common component in all electrosurgical generators. The IEC 60601-2-2 international standard for medical equipment requires that capacitors be included in the patient circuit of each electrosurgical generator as one means of patient protection (neuromuscular stimulation)¹⁰.

When using a return electrode from the MEGA SOFT™ family, the patient becomes one of the conductive plates of a capacitor and the conductive mesh built in the electrode becomes the other conductive plate (Figure 8)⁶. The gel and urethane above the conductive mesh and any additional materials placed between the electrode and patient make up the dielectric of the material between the two “plates” and results in the separation distance between the two conductive plates (Figure 8). When the electrosurgical pencil is in contact with the patient and activated, the current flows from the generator and the patient is charged to a minus (-) voltage. This induces an equal but opposite charge on the conductive mesh in the electrode. The patient is capacitively coupled to the conductive mesh in the MEGA SOFT™ Return Electrode, the flow of current is induced across the electrode (there is NO direct current pathway) and allowed to safely complete the circuit back to the generator⁶.

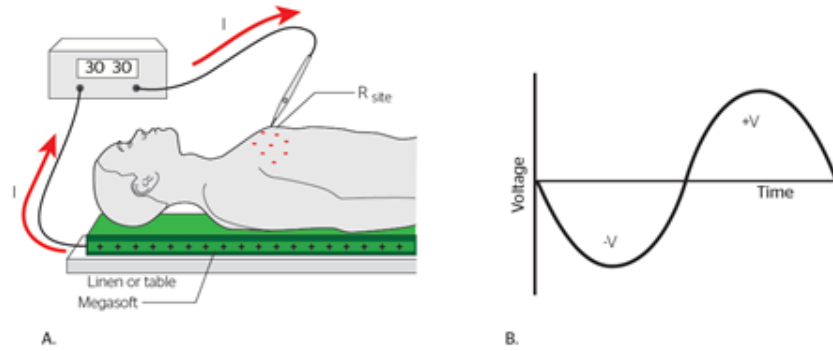


Figure 8. Capacitive pad with a -V accumulates a negative charge at the surgical site and a positive charge at the on the MEGA SOFT™ Return Electrode. The current is not flowing through the patient. The positive charge on the MEGA SOFT™ Return Electrode is called an induced charge.

As briefly discussed above, an electrosurgical circuit can be divided into the following sub-groups:

- Generator
- Active electrode, pencil and cable
- Surgical site
- Patient
- Return electrode and cable

These items combine to form a closed circuit that allows current to flow during electrosurgery⁶. In this circuit, there are several components that contribute resistance to the flow of current. The total resistance in the electrosurgical circuit contributes to the surgical effect available to the surgeon. To compare the function of the MEGA SOFT™ Return Electrode to that of an adhesive pad only the resistance from the surgical site and the resistance between the patient and return electrode need to be considered. The resistance in the rest of the electrosurgical circuit (i.e. Generator, Pencil, Cable and Patient) is equivalent and negligible when comparing the two types of return electrodes.

While the true nature of the physics involved are complex, a few simplifications can be made regarding the function of return electrodes. It is assumed, for the purpose of this discussion, that an adhesive pad adds a “resistive” type of impedance to the flow of current^{6,7}. To simplify the discussion in this document the term “current” (and label “I”) is used to describe the actual flow of electrons in the electrosurgical circuit, where the normal convention is understood to show the flow of current in the opposite direction as the flow of electrons.

How much energy it takes to induce the flow of current between the patient and the MEGA SOFT™ Return Electrode is controlled by how large the patient contact area is with the electrode and the separation distance (number of sheets, other materials, positioning aids, etc.) between the patient and conductive mesh in the MEGA SOFT™ Return Electrode. More patient contact area with the MEGA SOFT™ Return Electrode and/or reduced separation distance provides better capacitive coupling and lower impedance to the flow of current. This results in the desired surgical effect at the active electrode. Increasing the number of layers of material and separation distance between the patient and MEGA SOFT™ Return Electrode and/or reducing the patient contact area causes a decrease in capacitive coupling. This leads to higher impedance to the flow of current and could result in diminished surgical effect at the surgical site. To understand the impedance, we need to talk about the resistance inherent in the circuit.

A resistor is a device that allows a current to flow through it that is proportional to the voltage drop (eq. 1). An adhesive pad typically adds 5 to 30 ohms of resistance to the electrosurgical circuit, which is similar to the effect of adding a resistor to an electrical circuit^{6,7}. The resistance of the surgical site and sticky pad are both “resistive” in nature and therefore add directly together when calculating how the flow of current is affected (eq. 2)⁷.

$$\text{Eq. 1 } R = \frac{V}{I}, \text{ Resistance as a function of voltage and current}$$

$$\text{Eq. 2 } R_{\text{Total}} = R_{\text{SurgicalSite}} + R_{\text{AdhesivePd}}, \text{ Resistance of the adhesive return electrode circuit}$$

The resistance of a capacitor is not the same as that of a traditional resistor. A capacitor's resistance is a function of the frequency and the capacitance, with the symbol X used to denote the resistance of the capacitor (eq. 3). A capacitor has a phase shift of 90°, so cannot be directly added to the surgical site resistance. The resistance of each must be treated as a vector, with the surgical site resistance at 0° and the capacitive pad site resistance at 90° (eq. 4). As this is a simple 90° phase shift, the overall resistance can be calculated using Pythagorean's theorem (eq. 5). This is also shown graphically in Figure 9, where the two resistance vectors are shown having a 90° angle to each other and the total resistance is the hypotenuse.

$$\text{Eq. 3 } X_{\text{CapacitivPad}} = \frac{1}{2\pi f C}, \text{ Capacitor resistance as a function of frequency (f) and capacitance (C)}$$

$$\text{Eq. 4 } R_{\text{Total}} = \left[\frac{R_{\text{SurgicalSite}}}{\angle 0^\circ} \right] + \left[\frac{X_{\text{CapacitivPad}}}{\angle 90^\circ} \right], \text{ Resistance of the capacitive return electrode circuit}$$

$$\text{Eq. 5 } R_{\text{Total}} = \sqrt{(R_{\text{SurgicalSite}})^2 + (X_{\text{CapacitivPad}})^2}, \text{ Resistance of the capacitive return electrode circuit}$$

Typical surgical site resistance values range between 900 ohms and 4,000 ohms with a small number of surgeries (e.g. prostate and liver) taking place at sites with surgical site resistance values below 900 ohms^{7,11}. With surgical site resistance values at or above 900 ohms the total resistance in the system is essentially identical when using an adhesive pad and a capacitive electrode (eqs. 2 and 5), this translates into essentially identical surgical effect for the surgeon.

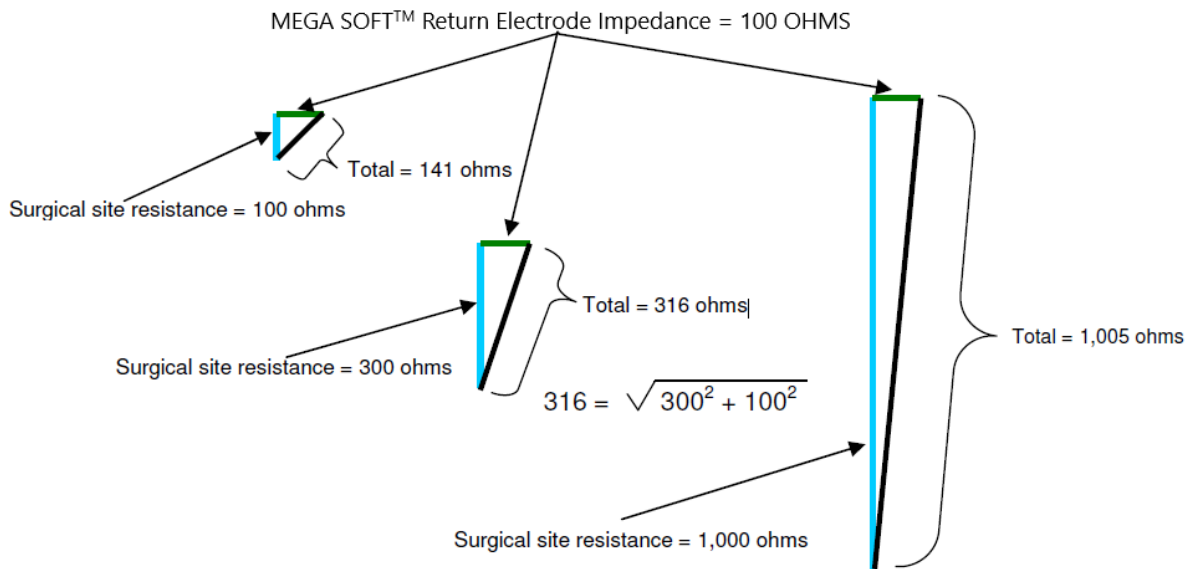


Figure 9. Graphical representation of vector summation of the two resistance vectors, surgical site resistance and the MEGA SOFT™ Return Electrode Impedance

At a surgical site resistance much below 900 ohms the effect of the additional capacitive impedance from a MEGA SOFT™ Return Electrode might be noticed, on rare occasions (such as in pediatric cases), by the surgeon as diminished surgical effect. This can be seen in Figure 9. This can occur because some of the energy usually available at the surgical site with a sticky pad is now used/stored in the function of the capacitive return electrode. By increasing the power “setting” on the generator (as an example, 30 watts to 33 watts) the surgeon can achieve the exact same current available at the surgical site to produce the same surgical effect.

For complete indications, contraindications, precautions, warnings, and adverse reactions, please reference full package insert.
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