

MEGA 2000® Patient Return Electrode System

Frequently Asked Questions

[Do any of MEGADYNE's products contain latex?](#)

Is the system FDA approved?

How is the MEGA 2000 Patient Return Electrode system different from the adherent/adhesive backed gel pad grounding system?

How much contact does the patient have to have with the MEGA 2000 pad?

What happens if not enough patient is on the MEGA 2000 pad?

Do any of MEGADYNE's products contain latex?

No. None of MEGADYNE's products contain latex.

Is the system FDA approved?

Yes, the MEGA 2000 family has gone through the FDA's 510(k) process and has been found substantially equivalent to devices marketed prior to 1976 and may be marketed. The 510(k) number for the MEGA 2000 is k982826. The 510(k) number for the MEGA 2000 Soft is k021077 and for the MEGA 2000 Soft Dual Cord is k031285.

How is the MEGA 2000 Patient Return Electrode system different from the adherent/adhesive backed gel pad grounding system?

Both systems are intended to safely exit electrosurgical current from the patient and return it back to the generator. The principles on which they provide safety are different and are best explained by the [Theory of Operations](#) document.

How much contact does the patient have to have with the MEGA 2000 pad?

This will vary from patient to patient. It depends primarily on the amount of insulating materials between the patient and the MEGA 2000 system and the amount of weight bearing "contact" the patient has with the pad. Do not place excessive linens or other materials between the patient and the MEGA 2000 Reusable Patient Return Electrode system and maximize the "contact" between the patient and pad. Excessive materials between the patient and MEGA 2000 system, or too little "contact" between the patient and pad may diminish the surgical effect at the active electrode at equivalent power settings. In certain situations, the individuals at these institutions will need to evaluate when effective electrosurgery is no longer being performed.

What happens if not enough patient is on the MEGA 2000 pad?

The surgeon may experience a diminished effect at the active electrode at comparable power settings. Improper installation may increase the risk of alternate current pathways. Power settings should not be turned up until the installation of the MEGA 2000 and all cable connections have been checked.

What are the patient weight limits (high and low) for this system?

The MEGA 2000 family of electrodes may be used on patients greater than 25 pounds (11.3 kg).

How do I safely ground a large patient (>300 pounds)?

Follow the instructions for use. There are no special considerations for larger patients.

How do I safely ground patients that I cannot get enough surface area on the MEGA 2000 pad?

If there is insufficient "contact" with the MEGA 2000 system the surgeon may see a diminished effect at the active electrode. Safety is still provided due to the bulk resistivity technology of the pad. If the surgeon does not receive the desired effect at the active electrode you may need to reposition the patient to have more "contact" with the pad, decrease the materials between the patient and pad, or as a last resort use a disposable gel pad. Additional detail on the technology of the pad can be found in the [Theory of Operations](#).

How do I safely ground patients that are less than 25 pounds?

At this point in time you must use a disposable gel pad indicated for patients in the desired weight range.

Are there any patient positions that do not work with this grounding system?

We are not aware of patient positions that do not work with the MEGA 2000 at this time. Please refer to the patient positioning reference chart for positioning suggestions.

Can I use a heating/cooling blanket with this product?

Yes, placing the MEGA 2000 on top of the blanket will insure the best electrosurgical performance, but may diminish the thermal effects of the heating/cooling blanket (consult with your blanket manufacturer). If placed beneath the heating/cooling blanket the surgeon may see a diminished effect at the active electrode. Another approach is to stagger the blanket and MEGA 2000 system.

When using the MEGA 2000 Soft or MEGA 2000 Soft Dual Cord place the pad on top of the heating pad 30 minutes before the procedure. Set the heating pad to the desired temperature and the MEGA 2000 Soft will warm up to approximately the temperature of the heating pad.

Can you use a pressure relief gel-pad with a MEGA 2000 pad?

MEGADYNE recommends the use of the MEGA 2000 Soft to obtain the benefits of the MEGA 2000 technology and pressure reduction.

When using the standard MEGA 2000 the best electrosurgical performance is obtained with the MEGA 2000 assembly on top of the gel pad, however it is possible, albeit less desirable, to place the MEGA 2000 below these devices. Additional suggestions to maximize the performance of both products are:

- Place the MEGA 2000 and the gel pad adjacent to one another so that there are no added materials between the patient and either pad while maintaining adequate contact with each device.
- Stagger the pads to minimize the overlap and dampening effect that each pad has on the other and in a manner that maintains adequate contact with the MEGA 2000.
- Place the MEGA 2000 below the gel pad, maximizing patient contact area. Low power output or failure of the electrosurgical equipment to function correctly at normal settings may indicate excessive materials between the patient and MEGA 2000 assembly. Customers should not increase power output before checking for obvious defects or misapplication. Misapplication of the dispersive electrode increases the risk for alternate current pathways.

Can I bend/fold this product over positioning devices (bean bags, wedges, etc.)?

The compliant nature of the MEGA 2000 pad allows it to be placed over the above mentioned positioning devices. Avoid placing the MEGA 2000 assembly directly onto a metal surface.

Can I fold the pad without damaging it?

The MEGA 2000 can be folded without damaging the product. The compliant nature of the MEGA 2000 family allows it to be placed over various positioning devices.

Folding the MEGA 2000 Soft for storage and transport is not recommended. For these situations the MEGA 2000 Soft should be rolled.

Can two MEGA 2000 pads be used on the same table?

If two pads are required we recommend the MEGA 2000 Soft Dual Cord Patient Return Electrode which can be connected to two separate generators.

If using two MEGA 2000 pads we recommend that you minimize the overlap of the pads when possible. The surgeon may see a diminished effect at the active electrode for the pad furthest from the patient, if there is insufficient weight-bearing "contact" area or an excessive amount of material between the patient and the pad. Insufficient "contact" may increase the risk of alternate current pathways.

Can I use this product on the carbon fiber endovascular table? Where do I place the pad on the table?

Place the pad assembly on the operating room table pad in a location to maximize patient "contact" (e.g. at the head, or foot of the bed).

Can you use the laser with this product?

Yes.

Can you use the Argon Beam Coagulator with this product?

Yes, the M2K-06 cable is required to adapt the pad to the Argon Beam coagulator.

Why can't the MEGA 2000 be placed on top of the patient (over legs for example)?

The weight bearing portion of the patient enhances coupling and efficacy at the surgical tip. The surgeon may experience a diminished effect at the active electrode without any of the patient's weight over the pad.

What do I do if I am using two ESUs or two pencils?

Two pencils from one ESU does not require any change. The use of two ESUs requires the use of two patient return electrodes or we recommend that you use the MEGA 2000 Soft Dual Cord Patient Return Electrode. If not using the MEGA 2000 Soft Dual Cord pad you may use two MEGA 2000s, two sticky, gel pads, or one MEGA 2000 and one sticky, gel pad.

Can I use the MEGA 2000 with a ground referenced ESU?

The MEGA 2000 should be used with isolated generators only. If used with ground referenced ESUs a ground fault alarm may be triggered which would delay the surgical case.

Why doesn't current travel to another ground (ECG electrode, metal table part)?

The MEGA 2000 family of electrodes is indicated for use with isolated generators only. This means that essentially all of the current output by the generator must be returned back to the generator via the return electrode, not through an alternate path (i.e. earth, ground). ECG electrodes and metal table parts are not part of the isolated circuit.

What happens if prep solutions pool on the MEGA 2000 pad, or between the pad and the patient?

From an electrosurgical standpoint, the pooling of fluids will not adversely affect the safe exiting of current from the patient. However, it is always best to follow AORN's Recommended Practices and minimize the pooling of fluids. Pooling of fluids may irritate tissue, or cause chemical burns.

Can I use alcohol or an alcohol-based prep without damaging the pad?

No, alcohol, or an alcohol based prep is not recommended for cleaning the pads. In addition, AORN recommends that the ESU not be used in the presence of flammable agents (e.g. alcohol, tincture-based fluids).

What do I do if blood, or other bodily fluids get on the pad?

Follow the guidelines established by your institution for cleaning blood and bodily fluids from other reusable, non-sterile devices (e.g. O.R. table pad). A list of agents compatible with the pad are listed in the instructions for use.

Why replace the pad on its labeled expiration date? (Can the pad last indefinitely?)

We have conducted extensive safety and efficacy testing to support a product life of 24 months (18 for the standard MEGA 2000). We have no data to support the use of the pad beyond this time. At the time of expiration, the product indemnity against claims by patients does expire.

The FDA requires medical device manufacturers to have a means for identifying a reusable product's end-of-life. Based on the product design and our safety and efficacy testing we have chosen to place an expiration date on the pad to identify its end-of-life. The FDA reviewed our 510(k) submission with this information and has allowed us to market the product.

What should I check if the ESU pencil does not work?

For no electrosurgical effect, check pencil and pad cable connections, and generator settings.

Confirm that the generator is not alarming due to lack of return electrode. If alarm is sounding/illuminated check connections and replace return electrode with an alternate MEGA 2000, or disposable gel pad on the patient. If problem is unrelated to return electrode, replace the pencil.

For a diminished effect check the installation of the MEGA 2000. If excessive materials are between the patient and pad, the surgeon may see a diminished effect at the active electrode at equivalent power settings. If the desired result is still unsatisfactory, increase the weight-bearing contact area and/or lessen the amount of material between the patient and MEGA 2000, or place a disposable gel pad on the patient.

What is the difference between direct current and radio frequency current?

Direct current is commonly used by battery powered devices. With radio frequency, the current alternates (AC) from one pole to another. This is similar to the AC current in your house.

Household AC current oscillates at 60 Hertz (cycles per second). Radio frequency current oscillates between 200,000 and 4,000,000 Hertz. Radio frequency current is used in electrosurgery to avoid neuromuscular stimulation.

Do the return electrode monitoring features of the ESU still work with this system?

No, the MEGA 2000 family of electrodes relies on different technology ("bulk resistivity" explained in the **Theory of Operations**) to provide an equivalent level of safety.

Does Valleylab/USSC support this technology?

To date Valleylab has sent several disparaging letters to potential and existing customers of the MEGA 2000 family of electrodes. MEGA 2000 is a competitive product to those produced by Valleylab/USSC. ECRI (an independent, non-profit, health services research agency) has published an evaluation of the MEGA 2000. A copy of this report from is available from your MEGADYNE sales representative free of charge.

You may also obtain a copy of the report from ECRI. ECRI can be reached by writing to the following:

ECRI
5200 Butler Pike
Plymouth Meeting, PA 19462-1298, USA
Phone: 610-825-6000
Fax: 610-834-1275

Can the MEGA 2000 pad interact with a gel pad circuit when the MEGA 2000 pad is not plugged into any ESU?

No, the pad is a passive device which will not interact with the electrosurgical circuit when it is not plugged into an ESU.

How can current arc from the pencil without activating alarms?

As long as the circuit is complete (i.e. pencil plugged in generator, pad attached to generator and patient) the pencil can arc without being in contact with tissue regardless of the return electrode used. Radio frequency current can capacitively couple to the patient and return current back to the generator via the return electrode even when the pencil is not in contact with the patient. An analogy to help in understanding this is to consider a radio. The pencil acts as a transmitter and the patient/return electrode a very large antenna. When a patient, who is conductive, is connected to a return electrode (sticky gel pad, or MEGA 2000) the return pad essentially assumes the size of the patient, and becomes a very large antenna. The antenna, or patient, receives the signal transmitted by the pencil and thus activates without sounding any ESU alarms.

What happens if the ESU pencil is activated prior to contact with the patient or an instrument?

The pencil will activate and current will look for the path of least resistance to complete the circuit and return back to the generator. Activating a pencil at a distance from the target tissue will cause current to arc in a less controlled manner than if the pencil is activated in very close proximity, or in contact with the target tissue.

How do I assess skin integrity after electrosurgery with this system? What should I look for?

Assess skin integrity in the same manner you do now. Assess the area of the patient that is in "contact" with the pad.

Are the pads radio-opaque? Can you C-arm through them without affecting the image?

The MEGA 2000 pad is radio-lucent so you may x-ray/C-arm through them.

Can you use the MEGA 2000 without the plastic sheath? Can you substitute something else for the MEGADYNE sheath?

The sheath is an important safety feature of the standard MEGA 2000 system should any unnoticed nicks, holes, or tears be present in the pad. A substitute can not be used for the MEGA 2000 sheath because it has particular specifications associated with it and must be used for the "hold harmless" section of the Warranty to be valid.

The MEGA 2000 Soft does not require a sheath due to the unique characteristics of the Akton® Polymer.

Is there a wattage limit with the use of this pad?

No.

What if the pad becomes damaged?

Replace the standard MEGA 2000 pad if there are any signs of damage. Please refer to the MEGA 2000 Warranty for product failure due to normal wear and tear.

If the surface of the MEGA 2000 Soft (or MEGA 2000 Soft Dual Cord) is damaged it may be repaired by using the MEGADYNE patch kit.

What are my resources if I have questions?

You may contact Megadyne's technical support staff at 1-800-747-6110.