



## Electrosurgical generators and accessories... are they electrically compatible? New labeling information

Electrosurgical device innovations and new radiofrequency (RF) procedures have been introduced into the operating room and specialty departments over the past few years. Some of these devices and procedures are very different from traditional electrosurgical instruments and procedures that perioperative staff has been familiar with in the past. New accessories may interface with existing electrosurgical units (ESU) or RF generators, but it is not always clear whether an instrument or cable from one manufacturer is electrically compatible with another manufacturer's hardware. For instance, is a laparoscopic electrode capable of withstanding the same power and voltage settings as an electrosurgical pencil? Are there any settings restrictions when using an instrument cable from one manufacturer with another manufacturer's ESU?

In order to ensure generator and accessory compatibility while keeping patient and staff safety a priority, the safety standard covering electrosurgical devices<sup>1</sup> now requires manufacturers of accessories and hardware to phase in additional user information to the product labeling. This Clinical Hotline newsletter will review these changes and explain how the labeling may be utilized to advance safe use of electrosurgical accessories.

Electrosurgical cables and accessories are designed to deliver the intended RF output energy to the active portion of the instrument while shielding or insulating the remainder of the instrument and cable to prevent unintentional injury to the patient or user. The manufacturer verifies that the insulation materials used within and on the surface of the accessory or cable

will withstand the required output voltages of each generator mode.

Typically the user has the ability to adjust or control the output power of a generator. This output power is usually measured in **watts**. In order to create the output power, the generator controls the output **voltage** (measured in volts) and **current** (measured in amps). Power (or watts) is the product of the voltage times the current. Depending on the output mode, the voltage can be very different. For instance, 15 watts of monopolar coag uses a high output voltage and low current while 15 watts of bipolar uses a low output voltage and moderate current. Thus the insulation needed in each case is different for monopolar and bipolar instruments and cables.

Accordingly, it is the RF output **voltage** that determines the electrical compatibility between an accessory and the generator output. Using an output voltage that exceeds what the accessory is designed for could result in insulation failure and possibly contribute to an injury or fire.

Updated instructions for use (IFU) will soon include the required labeling and accompany the RF accessory in the shipping carton. The new information will state the **maximum voltage** the accessory can withstand. This new information may be communicated in various ways using similar terminology such as:

- Intended for use with a maximum voltage of XXX volts
- Rated accessory voltage XXX volts
- Do not use with RF voltages greater than XXX volts
- Maximum peak voltage XXX volts

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**NOTE:** The voltage listed refers to the peak voltage. You may or may not actually see the word “peak.” The voltage will be represented numerically followed by the term volts or the abbreviation V.

The ESU user manual will also be undergoing changes. In the technical specifications section, manufacturers will be listing the maximum peak voltage for each output mode. In addition, this section will also have a graph of the output voltage versus the front panel output setting (usually in watts) for each mode. This will allow for comparing the rated accessory voltage to the output of the ESU.

So how does this work? Below are several examples of how users can determine if the electrosurgical accessory maximum voltage is compatible with the ESUs output modes.

**EXAMPLE 1:**

The electrosurgical pencil has the following information in its IFU:

Intended for use with a maximum voltage of **9500** volts

The hospital has standardized on a single type of electrosurgical generator with the following information in the user manual:

- PURE CUT mode maximum voltage 2300 volts peak
- BLEND mode maximum voltage 1650 volts peak
- FULGURATE COAG mode maximum voltage 4250 volts peak
- SPRAY COAG mode maximum voltage 4500 volts peak
- BIPOLAR mode maximum voltage 150 volts peak

Since the above generator output voltages are less than the maximum accessory voltage of 9500 volts, the pencil may be used with all modes and all powers available on the generator.

**NOTE:** The generator’s *maximum output voltage* is measured at the *maximum power setting* for any given mode.

**NOTE:** If the generator has not been recently purchased, the user manual may list the output voltages for each mode as volts peak-to-peak, peak-to-peak voltage or volts P-P, which is roughly twice the peak voltage. In this case, divide the P-P voltage in half to obtain the peak voltage.

**EXAMPLE 2:**

An extended monopolar electrode has the following information in its IFU:

- Do not use with an output power greater than **40** watts
- Do not use with voltages greater than **4500** volts peak

The generator has the same information in the user manual as shown in Example 1.

Since all the generator output voltages do not exceed the maximum voltage for the accessory, you may use the extended electrode with any monopolar mode as long as you follow the listed recommendation of 40 watts as the maximum output power.

**EXAMPLE 3:**

A laparoscopic electrode has the following information in its IFU:

- Do not use with an output power greater than **40** watts
- Do not use with voltages greater than **2600** volts peak

The generator has the same information in the user manual as shown in Example 1.

Since the generator coag modes have maximum voltages greater than the accessory maximum voltage of 2600 volts, you will need to refer to the graphs in the technical specifications section of the generator user manual. The accessory IFU also limits the output power to 40 watts or less. Locate the technical specifications section of the generator user manual and refer to the graphs showing the coag modes output voltages versus output power. If the highest coag output voltage at 40 watts is equal to or less than 2600 volts then you may use the laparoscopic electrode as long as the 40 watt limit is not exceeded. If the generator has an output voltage greater than 2600 volts at 40 watts, you should limit the output power (watts) to that value where you will not exceed 2600 volts.

**EXAMPLE 4:**

An extended monopolar electrode has the following information in its IFU:

- Do not use with output powers greater than **40** watts
- Do not use with voltages greater than **3250** volts peak

Some generators have the following information in their user manual (group A):

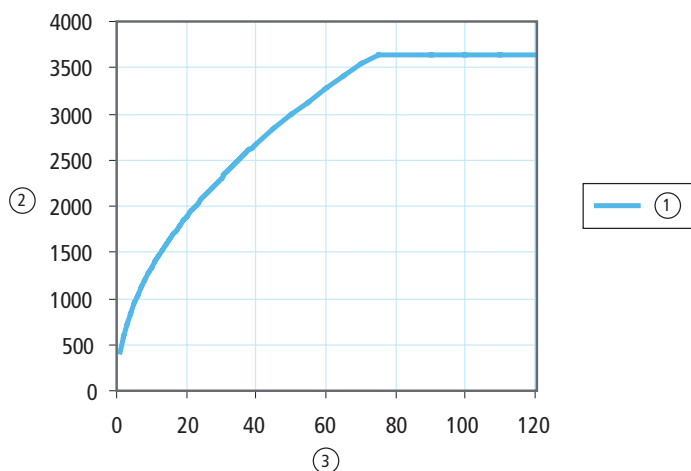
- PURE CUT mode maximum voltage 2300 volts peak
- BLEND mode maximum voltage 1650 volts peak
- FULGURATE COAG mode maximum voltage 2550 volts peak
- SPRAY COAG mode maximum voltage 3000 volts peak
- BIPOLAR mode maximum voltage 150 volts peak

Other generators have the following information in their user manual (group B):

- PURE CUT mode maximum voltage 2300 volts peak
- BLEND mode maximum voltage 1650 volts peak
- FULGURATE COAG mode maximum voltage 3000 volts peak
- SPRAY COAG mode maximum voltage **3700** volts peak
- BIPOLAR mode maximum voltage 150 volts peak

The generators in Group A have output voltages that are less than the accessory maximum voltage, therefore the extended electrode may be used with any monopolar mode while following the listed recommendation on maximum output power of 40 watts.

The generators in Group B have output voltages in the spray coag mode that exceed the accessory maximum voltage. However, when referring to the graph showing the spray coag mode output



- ① Open Circuit Spray Peak Voltage vs. Power Setting
- ② Peak Voltage
- ③ Power Setting

Figure 1: Peak voltage versus power setting for spray coag mode

voltage versus output power (see Figure 1) it shows the highest coag output voltage at 40 watts is equal to or less than the 3250 volt limit for the extended electrode.

Referring to the graphs showing the coag modes output voltages versus output power enables the user to determine that the extended electrode may be used with the generators in Group A or B as long as the listed recommendation on maximum power is followed.

**EXAMPLE 5:**

A recently purchased neurosurgical bipolar forceps has the following information in its IFU:

Maximum voltage = 250 volts peak

The disposable bipolar cord that will connect the bipolar forceps to the ESU has the following information in its IFU:

Maximum voltage = 500 V peak

The generator dedicated to the neurosurgery suite has the following information in its user manual:

Precise (Low) bipolar mode maximum voltage 450 V P-P (divided by 2 equals 225 V peak)

Standard (Medium) bipolar mode maximum voltage 320 V P-P (divided by 2 equals 160 V peak)

The generator output voltages in the precise and standard bipolar modes are less than the bipolar forceps maximum voltage rating and the bipolar cord maximum voltage rating. As a result the bipolar forceps and the bipolar cord may be used without voltage or watts restrictions when used with the generator dedicated to the neurosurgery suite.

**SUMMARY:**

Although this information may seem complicated or overwhelming, there is some good news. Most manufacturers of electrosurgical technology design their products to be fully compatible with all of the output modes and voltages of their own generators. Many manufacturers take it a step further and design products to function with the voltages found in all generators on the market. If the compatibility of an accessory is unknown, it will be important to have access to the generator user manual and the IFU supplied with the accessory in order to make this determination. The Covidien Energy-based Devices (EbD) Clinical Hotline for Valleylab™ products frequently receives calls from customers requesting information that is provided in the accessory IFU or the generator user manual, but the caller does not have immediate access to the information. The 2009 AORN Perioperative Standards and Recommended Practices on page 332 states:

**The ESU and accessories should be used according to manufacturers’ written instructions.**

*Instructions for ESU use, warranties, and a manual for maintenance and inspections should be obtained from the manufacturer and be readily available to users. Each type of ESU has specific manufacturers’ written operating instructions to be followed for safe operation of the unit. A brief set of clearly readable operating instructions should be readily accessible with each system. These instructions should be placed on or attached to each ESU for reference.*

*Accessories should be used, handled, cleaned, and processed according to manufacturers’ instructions.*

Because of these new compatibility labeling changes it will be essential for ESU manuals to be kept with each generator and accessory IFUs to be accessible online or in hard copy for easy reference. For questions, concerns or verification of compatibility it is recommended that the appropriate accessory manufacturer be contacted for assistance.

Covidien EbD is committed to rolling out these new labeling requirements in a timely manner. Until that time we would like to provide the following information:

- All Valleylab™ monopolar accessories (pencils, electrodes, electrode extenders, suction coagulators and active cords) are completely compatible with the monopolar output modes and voltages of current and past Valleylab™ generators as long as any output power limitation listed in the accessory IFU is followed.
- All Valleylab™ bipolar accessories (forceps and cords) are completely compatible with the bipolar output modes and voltages of current and past Valleylab™ generators as long as any power limitations listed in the IFU are followed.
- All LigaSure™ instruments are completely compatible with the vessel sealing and tissue fusion output modes and voltages of the LigaSure™ and ForceTriad™ generators.

The Covidien EbD Clinical Hotline for Valleylab™ products is dedicated to patient and staff safety. If you need assistance with the safe use of Valleylab™ products, please call 800-255-8522, and select option 1.

1. ANSI/AAMI/IEC 60601-2-2 Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

ANSI – American National Standards Institute  
AAMI – Association for the Advancement of Medical Instrumentation  
IEC – International Electrotechnical Commission

We would like to thank Jeffrey L. Eggleston, P.E., Director of Standards Compliance at Covidien Energy-based Devices for being a primary contributor to this newsletter.



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R0009628 Rev. 2009/08

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