

# Product Bulletin

## For Distribution To:

- International Distributors
- International Management
- U.S. Field Sales & Clinical Specialists
- U.S. Technical & Field Service

Date: January 16, 2013

## RE: Use of a Hospital Grade Isolation Transformer in Conjunction with AER Installations

Some healthcare organizations are classifying AERs as “patient connected equipment” and are requiring that this equipment meet the leakage current requirements for this class of equipment.

The International Electrotechnical Commission (IEC) standard 60601 describes “patient connected” medical equipment as electrical equipment that has an applied part, or transfers energy, to or from a patient, and is intended for use in the diagnosis, treatment or monitoring of a patient. There is a broad range of patient connected medical equipment, and the allowable leakage current to the patient varies based on the device/equipment and its application. Examples of such devices would include items such as IV lines, heart monitors, dialysis equipment, among many other diagnostic or therapeutic devices.

Using the above description of patient connected equipment, it can be stated that endoscope reprocessors would not fall into the “patient connected” classification. All Medivators reprocessors are ETL (electrical safety testing) listed, and conform to UL Standard 61010-1 and EN Standard 61010-1, and are classified as “laboratory equipment” under these standards.

The leakage current standard for “patient connected” equipment has a limit 1/10th that of the standard for laboratory equipment. Should facilities decide that AERs must comply with the standards for patient connected equipment, the use of an isolation transformer will allow laboratory equipment to meet the related leakage current requirements. Should an isolation transformer be required, Medivators now offers the TRIPP LITE Hospital Grade Isolation Transformer, model number IS1800HG, as an option with the purchase of endoscope reprocessors. The part number for this item is: 36530-006. The description and specifications for the transformer are as follows:

“Hospital Grade Isolation Transformer: Power Rating 1800 VA, Voltage 120, Voltage Output 120, Output Current 15 Amps. Dimensions 7.75in (H) x 12.25in (D) x 8.25in (W). Includes 6 ft power cord and 6 outlets. Noise Attenuation is 35-65 dB. UL60601-1 Listed.”

By December 1, 2010 all Medivators reprocessors will also have new labeling on the devices themselves, as well as on the shipping carton, to indicate the laboratory equipment designation.

Any questions or requests for additional information should be directed to MEDIVATORS Technical Support at 1-800-444-4729.



MEDIVATORS Inc. Headquarters  
14605 28th Avenue North  
Minneapolis, MN  
55447-4822 USA  
Tel: +1.800.444.4729  
Fax: +763.553.3387

MEDIVATORS BV  
Sourthweg 11  
6422PC Heerlen  
The Netherlands  
Tel: +31.45.5.471.471  
Fax: +31.45.5.429.695

MEDIVATORS Asia/Pacific Pte Ltd  
1 A International Business Park  
#05-01 Singapore 609933  
Tel: +65.6227.9698  
Fax: +65.6225.6848

MEDIVATORS Beijing Representative Office  
Room 708, 7th Floor Kaiheng Center, Block B  
No. 2 Chaoyangmennei Street  
Dongcheng District, Beijing China 100010  
Tel: +8610.6567.8446  
Fax: +8610.6567.8445

[www.medivators.com](http://www.medivators.com)