

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Generador de Electrocirugía FORCE TRIAD
NO. IDENTIFICACIÓN RISARH	I1501-14
REFERENCIAS DEL DISPOSITIVO MEDICO	FORCE TRIAD
REGISTRO SANITARIO	2007EBC-0000505
INDICACIONES Y USO ESTABLECIDOS	Proporciona energía de radiofrecuencia para aplicaciones quirúrgicas monopolares, bipolares así como fusión de tejidos LIGASURE.
NOMBRE DEL FABRICANTE	Bovie Medical Corporation Covidien New Deantronics Taiwan Ltd Bernstein Ag Kirwan Surgical Products, Llc Buffalo Filter, Llc Deroyal Industries, Inc. Cea Medical Manufacturing Sutter Medizintechnik Gmbh Covidien Medical Products (Shanghai) Manufacturing Llc Covidien Llc Linemaster Switch Corp
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado un fallo eléctrico potencial, referente al cableado del generador que suministra energía de bajo voltaje a los componentes, tales como pantallas y los escáneres de códigos de barras, ocasionando pérdida de conectividad de los componentes mencionados o el código de error "E275", así como, la conmutación del equipo a <i>modo seguro a prueba de fallos</i> , previniendo el suministro de energía no deseado al paciente, lo que puede conllevar a que se presenten potencialmente interrupción de los procedimientos quirúrgicos.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	09 de Enero de 2015

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

ANEXO 1

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[Normal Priority] - S0266 : ECRI Institute User Experience Network—Covidien—ForceTriad Energy Platforms: Low-Voltage Power Cable and Connector May Fail Medical Device Special Report

UMDNS Terms:

- Electrosurgical Units [11490]
- Electrosurgical Units, Monopolar/Bipolar [18231]

Product Identifier: ForceTriad Energy Platforms [Capital Equipment]

Geographic Regions: Worldwide

Manufacturer(s): Covidien Surgical Solutions Group 5920 Longbow Dr, Boulder, CO 80301-3299, United States

Suggested Distribution: Clinical/Biomedical Engineering, Nursing, Obstetrics/Gynecology/Labor and Delivery, OR/Surgery

Problem:

The ForceTriad ElectroSurgical Generator may not power on or operate properly because of a failure of an internal low-voltage power supply cable connection.

Discussion

A member facility found that 7 out of their 33 ForceTriad units (which had all been in service for greater than 24 months) manifested one or more of the following issues over a 3 year period:

- Unit not powering on
- Error Code 275 upon startup (an indication of self-test failure)
- Intermittent screen operation
- A deviation of the 5V power supply output (a potential precursor to the above three issues; however, a deviation may exist without there being a connector failure)
- A discolored internal connector, indicating that heating occurred at the connector (Figure 1).



Figure 1. Front view of rear panel within the ForceTriad chassis. The low voltage power cable is indicated with a red arrow. Note that the white connector appears discolored due to heat exposure at its top.

The cable attached to this discolored connector is a low-voltage power supply cable (one of two) that powers items such as the displays and barcode scanners. The facility was instructed by Covidien to measure the voltage at the 5V power supply cable test points; units with readings below 4.8 volts may have a flickering screen or display other erratic behavior.

After servicing by Covidien, the hospital found that the connector had been removed and replaced with soldered connections.

Supplier Response/Perspective

Covidien reports the incidence rate of this issue as less than 2% over 5-7 years and has been unable to discover why the reporter has experienced such a high failure rate. The manufacturer states that this failure has only occurred at startup due to the high current load the cable and connector experience during the generator's self-test. The issue does not seem to be unique to any particular lot, production period, or configuration of the ForceTriad.

Covidien is treating this as an as-needed service issue. Replacement is performed free-of-charge on units with discoloration of the cable connector or if the voltage at the 5V power supply cable test points is less than 4.8 V. Covidien will provide an information sheet regarding this issue upon inquiry (it has been [attached to this Alert](#) for the reader's convenience). Covidien is continuing to explore this issue and will provide updated preventive maintenance and troubleshooting instructions as appropriate.

Covidien recommends the following:

- (1) Per the Periodic Safety Check instructions, perform visual inspection of the internal components of the generator at least once every 12 months. This is a means to identify connector discoloration in advance of other symptoms.
- (2) If your generator is displaying any of the symptoms enumerated in the "Discussion," perform a Digital Voltmeter (DVM) test of the low-voltage power supply cable test points TP81 and TP82. If the DVM test falls below 4.8 volts, contact Covidien for diagnostic evaluation and service. If diagnosis is confirmed, service will be covered under complimentary extended warranty coverage.

ECRI Institute Recommendations:

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ECRI Institute recommends the following:

(1) If your ForceTriad unit shows signs of the failures described in this report, remove the unit from use and have it serviced. Note that symptoms that will prompt free servicing from Covidien, even if your unit is out-of-warranty, include:

- Low-voltage power supply cable connector with any signs of heat deformation or discoloration due to heat exposure.
- A low measurement on the DVM test of point TP81 using TP82 for ground (below 4.8 V).

(2) Consider having a backup electrosurgical unit available in ForceTriad procedures to minimize any possible delay of patient care should your generator fail to power on.

(3) Contact Covidien Customer Service by telephone at (800) 255-8522 if your facility has a ForceTriad that has a deformed connector independent of or in conjunction with displaying error codes, not functioning as intended, or failing the low-voltage power supply cable test.

Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our [HDA Format Guide](#).

Source(s):

- 2014 Dec 30. ECRI Institute researched member report.
- 2014 Dec 30. Manufacturer Letter. Covidien information sheet. [Download](#)