

## 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:

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Desfibrilador ZOLL
<b>NO. IDENTIFICACIÓN RISARH</b>	I1411-457
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	SERIE M y SERIE R
<b>REGISTRO SANITARIO</b>	2009EBC-0003880
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Este producto combina un desfibrilador con capacidades avanzadas de monitores ECG y ritmo transcutáneo no invasivo (NTP) con capacidades de comunicación, impresión de datos y grabación, diseñado como apoyo para reanimación cardiopulmonar.
<b>NOMBRE DEL FABRICANTE</b>	Zoll Medical Corporation
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante informa que la lengüeta de los electrodos CPR stat-padz y CPR-D-padz puede ser insertada de forma incorrecta en la carcasa del conector del cable multifunción provocando un mensaje de error "Attach Pads", lo cual si no es corregido podría evitar la descarga del equipo, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
<b>FUENTE</b>	ANEXO 1
<b>FECHA DE NOTIFICACION</b>	07 de Noviembre de 2014

### 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](mailto:tecnovigilancia@invima.gov.co)

**ANEXO 1**

www.ecri.org • Printed from *Health Devices Alerts* on Friday, November 07, 2014 Page 1

**H0239 - Normal Priority Medical Device Alert**

**Medical Device  
Hazard Report**

Updated: November 5, 2014

**UMDNS Terms:**

- Defibrillators, External, Automated/Manual [29579]
- Electrodes, Cardiac, External Defibrillator [15033]

**Suggested Distribution:**

- Cardiology/Cardiac Catheterization Laboratory
- Clinical/Biomedical Engineering
- Critical Care
- Emergency/Outpatient Services
- EMS/Transport
- Risk Management/Continuous Quality Improvement

**Geographic Regions:**

- Worldwide

**Zoll—CPR Stat-padz and CPR-D-padz Electrodes: Can Be Misinserted into Defibrillator Multifunction Cables**

**Product Identifier:**

Defibrillator Electrodes: (1) CPR Stat-padz, (2) CPR-D-padz [Consumable]  
Used with the following Zoll Defibrillators: E Series, M Series, R Series

**Manufacturer:**

- ZOLL Medical Corp 269 Mill Rd, Chelmsford, MA 01824-4105, United States

**Problem:**

A tab on the connector of the Zoll CPR Stat-padz and CPR-D-padz electrodes can be incorrectly inserted into the Multifunction cable connector housing on the E Series, M Series, and R Series defibrillators, interfering with proper connection of the electrode to the defibrillator (see Figure 1). The resulting misinsertion can cause an error message (e.g., "Attach Pads") and, if not corrected, will prevent the defibrillator from delivering a lifesaving shock.



*Figure 1. A. Correct connection with tab outside connector; B. Incorrect connection with tab inside connector.*

**Background**

An ECR Institute member facility reported that the possible misinsertion of the CPR Stat-padz with the Multifunction cable was discovered during incoming inspection. The Multifunction cable is a component of the E Series, M Series, and R Series defibrillators that can be connected to the defibrillator paddles or a variety of electrodes for defibrillation, cardioversion, and pacing. The facility did not report any adverse events related to this problem. ECR Institute found that misinsertion can also occur with the CPR-D-padz, which have the same connector as the CPR Stat-padz.

The Zoll CPR Stat-padz and CPR-D-padz electrodes are primarily intended for use with the AED Pro or AED Plus, but are also compatible with the Multifunction cable on the E Series, M Series, or R Series defibrillators. This allows therapy to be started with an AED, and, when users trained in Advanced Life Support (ALS) arrive, the electrodes can be switched to the manual defibrillator without removing the electrodes from the patient.

This misinsertion problem applies only to the CPR Stat-padz and CPR-D-padz when used with the E Series, M Series, and R Series defibrillators; it does not apply to Zoll's AEDs or other electrodes.

**Discussion**

When the CPR Stat-padz and CPR-D-padz are connected directly (without the optional CPR adapter) to the Multifunction cable, a tab on the electrodes' connector is intended to latch onto the top of the Multifunction cable and prevent inadvertent disconnection. However, the tab can slide inside the Multifunction cable connector housing if the user inadvertently presses on the tab, inserts the connectors at an angle, or wiggles the connectors during insertion. Although a warning may be displayed on the defibrillator screen, users may be confused and not know how to respond, especially because the CPR Stat-padz and CPR-D-padz are typically connected to the Multifunction cable at the time of use, when a hurried user may not notice the misinsertion. This can result in a delay of therapy while users attempt to troubleshoot or find a replacement defibrillator or electrodes.

**Supplier's Perspectives**

Zoll indicates that users should be informed of this issue, and should be alert for potential misinsertion. If an error message such as "Attach pads" appears, users should verify that the connection is correct.

Zoll also offers CPR adapters for use with the CPR Stat-padz and CPR-D-padz and the E Series, M Series, and R Series defibrillators that would minimize the risk of a misinsertion. The adapters are intended for use with Real CPR Help (a feature that offers real-time feedback on CPR compressions, which some ALS-trained users may not want). The adapters accept the connectors on the CPR Stat-padz and CPR-D-padz in only one way, eliminating this misinsertion problem. However, ECRI Institute notes that adapters can be lost or misplaced, adding to user confusion and possible delays in therapy.

**ECRI Institute Recommendations:**

ECRI Institute recommends the following for facilities using the Zoll CPR Stat-padz or CPR-D-padz with the Zoll E Series, M Series, or R Series defibrillators without a CPR adapter:

- (1) Inform users that the tab on the CPR Stat-padz and CPR-D-padz connectors can be inserted into the Multifunction cable connector housing and interfere with proper connection of the electrode to the defibrillator. When the connection is correct, users should see that the green tab is latched on the outside of the red Multifunction cable.
- (2) If an "Attach Pads" error message appears, verify that the connection between the electrodes and the defibrillator is correct.
- (3) Alternative electrode options are available from Zoll that will eliminate this problem. However, a change in the products used should be made only after careful consideration of the advantages and disadvantages, consideration of how the new products fit in with procedures (and possible need to revise procedures), and consultation with appropriate clinical personnel.
- (4) Consider using the CPR adapter that is appropriate for each defibrillator with the CPR Stat-padz or CPR-D-padz when used with the E Series, M Series, or R Series defibrillators. However, note that using these electrodes with the CPR adapter will enable Real CPR Help, which some ALS users may not want. In addition, if the adapter is misplaced or lost, confusion may contribute to a delay in therapy.
- (5) Consider using alternative electrodes that are compatible only with E Series, M Series, and/or R Series defibrillators (such as the OneStep series or the Pro-padz series of electrodes) if your facility does not use the AED Plus or AED Pro. Note that these electrodes may offer different capabilities and may vary in price.
- (6) Contact Zoll Medical Corporation by telephone at (978) 421-9655 (direct) or (800) 348-9011 (toll free) for further information.

**Comment:**

- 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 Nov 3. ECRI Institute researched member report.