# INFORME DE SEGURIDAD

## DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

**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** | Desfibrilador SCHILLER |
| **NO. IDENTIFICACIÓN RISARH** | I1704-136 |
| **REFERENCIAS DEL DISPOSITIVO MEDICO** | FRED EASYPORT, concerniente a las baterías referencia 4-07-0001, lotes HYB 16-0056, HYB 16-0057, HYB 16-0058, HYB 16-0059. |
| **REGISTRO SANITARIO** | 2009EBC-0003126 |
| **INDICACIONES Y USO ESTABLECIDOS** | Este equipo diagnostica y trata los paros cardiorespiratorios por fibrilación ventricular o taquicardia ventricular sin pulso, restableciendo un ritmo cardiaco efectivo eléctrica y mecánicamente al emitir un pulso de corriente continua al corazón. |
| **NOMBRE DEL FABRICANTE** | Schiller Ag |
| **DESCRIPCION DEL PROBLEMA** | El fabricante informa que las baterías referenciadas pueden ocasionar un mensaje de error "Batería Descargada" cuando son utilizadas en los DEA, también establece que las baterías con este defecto no se pueden ser utilizadas y que el fallo es detectado automáticamente por el desfibrilador cuando la batería es instalada, conllevando a que se presenten eventos adversos sobre los pacientes en caso de no detectar el mensaje de error. |
| **FUENTE** | ANEXO 1 |
| **FECHA DE NOTIFICACION** | 12 de Abril de 2017 |

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**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

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## DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

**ANEXO 1**



### [High Priority ] - A28324 : SCHILLER—FRED easy Defibrillator Batteries: May Fail When Inserted into Defibrillator

Medical Device Ongoing Action

**Published:** Monday, April 3, 2017

**UMDNS Terms:**

- Defibrillators, External, Automated [17116]
- Batteries [16640]

**Product Identifier:**
Batteries for use with FRED easy Automated External Defibrillators (AEDs) *[Consumable, Capital Equipment]*
Battery Reference No. 4-07-0001; Battery Lot Nos.: HYB 16-0056, HYB 16-0057, HYB 16-0058, HYB 16-0059
Batteries sold between October 1, 2016, and January 15, 2017

**Geographic Regions:** Asia, Europe, Latin America

**Manufacturer(s):** SCHILLER AG Altgasse 68, CH-6341, Baar, Switzerland

**Suggested Distribution:** Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, Home Care, EMS/Transport, Materials Management

**Problem:**
In a January 17, 2017, Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), SCHILLER states that the above batteries may cause a "BATTERY EMPTY" failure when inserted into the above AEDs. SCHILLER also states that batteries with this fault cannot be used and that the fault is detected automatically by the defibrillator when the battery is inserted into the device.

**Action Needed:**
Identify any affected product in your inventory. For an image of the location of the reference number and lot number on the battery packaging, see the image in the Affected Devices section of the letter . If you have affected product, verify that you have received the January 17, 2017, Field Safety Notice letter from SCHILLER. Test affected batteries by inserting them into your AED (for instructions on how to do this, see section 3.1 "Inserting the battery" in the FRED easy user manual). The unit will perform its self-test. At the end of the self-test, the unit will shut down. If the green LED flashes, the battery is free from defects and can be used without limitation. For an image of the green LED, see the letter . If, after the self-test, the green LED remains off and the display reads "EMPTY BATTERY>REPLACE BATTERY" (for an image of this display, see the letter ), the battery is defective. Contact SCHILLER to arrange for defective battery replacement.

**For Further Information:**
SCHILLER
Website: Click here

**References:**

- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for defibrillator battery FRED easy, Schiller Medical SAS [online]. 2017 Mar 28 [cited 2017 Mar 29]. Available from Internet: Click here .

**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):**

- 2017 Mar 29. BfArM (Germany). 01529/17 Download
- 2017 Mar 29. BfArM (Germany). Download
- 2017 Apr 3. Manufacturer. SCHILLER confirmed the information provided in the source material.