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 HEARTSTAR
NO. IDENTIFICACIÓN RISARH	I1412-499
REFERENCIAS DEL DISPOSITIVO MEDICO	M3535A y M3536A
REGISTRO SANITARIO	2009EBC-0005096
INDICACIONES Y USO ESTABLECIDOS	Indicado para reanimación cardiaca y monitorización del paciente
NOMBRE DEL FABRICANTE	Philips Medical System
DESCRIPCION DEL PROBLEMA	El fabricante afirma que el equipo puede ejecutar pruebas automáticas semanales provocando su desgaste prematuro y el de sus componentes electrónicos de descarga, además existe la posibilidad de que el indicador de batería no refleje el estado real de carga, todo esto obedeciendo a una configuración interna del software incorrecta, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	04 de Diciembre 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

A23362 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: November 26, 2014

UMDNS Terms:
- Defibrillator/Pacemakers, External [17882]
- Defibrillators, External, Manual [11134]

Suggested Distribution:
- Cardiology/Cardiac Catheterization Laboratory
- Clinical/Biomedical Engineering
- Critical Care
- Emergency/Outpatient Services
- EMS/Transport
- Information Technology
- Nursing
- OR/Surgery

Geographic Regions:
- Worldwide

Philips—HeartStart MRx Monitor/Defibrillators: Internal Software Settings May Be Incorrect

Product Identifier:
HeartStart MRx Monitor/Defibrillators: (1) M3535A, (2) M3536A *[Capital Equipment]*
Serial Nos.: US00101159, US00322848, US00326834, US00328432, US00328439, US00328442, US00328443, US00328446, US00328450, US00328461, US00328464, US00328465, US00328468, US00328473, US00328478, US00330393, US00533518, US00533521 through US00535118, US00539526, US00540124, US00543102, US00543104, US00543138, US00543158, US00543161, US00543166, US00543167, US00543187, US00543204, US00543223, US00543239, US00546804

Manufacturer:
- Philips Medical Systems Cardiac & Monitoring Systems Div3000 Minuteman Rd Mailstop 101, Andover, MA 01810, Unites States

Problem:
In a November 2014 Urgent Medical Device Correction letter, Philips states that the internal software settings on the above monitor/defibrillators may be incorrect, potentially resulting in the following problems:
(1) The device may perform the weekly automated tests hourly, which could cause the therapy capacitors to degrade sooner than intended. There is no hazard if the device performs the weekly automated tests hourly, but the device could indicate that service is required sooner than intended because of degradation of the therapy capacitor.
(2) While connected to AC or DC power and with either no battery installed or with the battery at charge level of less than 10%, the Ready for Use (RFU) indicator may not provide the expected low battery indication (flashing red X with audible chirp). Instead, the RFU will show a flashing black hourglass, indicating that sufficient battery power is available for device operation. There is the potential for delay in therapy because of insufficient battery power, since the user may not be alerted by the RFU indicator that no battery is installed or that a low battery condition exists before disconnecting from AC or DC power. Philips states that once the device is disconnected from AC or DC power, the RFU indicator will provide the appropriate low battery indications. All other battery charge indicators will continue to operate normally, including the on-screen battery fuel gauges, low battery messages, and low battery alarms. The LED charge level indicators on the batteries themselves will also operate normally.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the November 2014 Urgent Medical Device Correction letter from Philips. To identify affected units, locate the model and serial number on the primary label on the back of the unit in battery bay B. A Philips service provider will service the device and ensure that it is operating within specification. Philips states that you can continue to use your device provided that the following steps are followed to prevent further accelerated degradation of the therapy capacitor and to eliminate the above described behavior for no/low battery conditions. To correct the problem, set the configuration of the device to "factory defaults" in configuration mode by performing the following steps:
(1) Turn the therapy knob to the On/Monitor position.
(2) Press the Menu Select button to activate the Main Menu.
(3) Use the Navigation buttons to select Other, then select Configuration. Press the Menu Select button again to Acknowledge.
(4) Press the Change Configuration soft key. Use the Navigation buttons to enter the Configuration Password when prompted (387466), select Done, and press the Menu Select button. Press the Factory Defaults soft key, and finally the Save Changes soft key.
(5) If you use custom configurations, make any desired changes to the default configuration choices consistent with your protocols and press Save Changes again, then press the Exit Config soft key.
(6) For correcting multiple devices: Once you have reset one unit to the factory defaults and confirmed your desired configuration settings, you can then copy the configuration to a data card for import into your other devices. Importing this good

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configuration into an affected device will correct the problem. Philips states that configuration settings can be printed before resetting to factory defaults. This will provide a record of any customized configuration parameters for reference. Print instructions are available in the "Printing Configuration Settings" in the instructions for use (IFU).
Perform either of the following to confirm that each device's configuration settings has been corrected:

- If an AC or DC power source is available, connect the power source and remove the batteries from the back of the device. If the RFU indicator flashes a red "X" and chirps, then the problem has been corrected.
- If an AC or DC power source is not available, view the Auto Test Summary by going to: Main menu, Other, Op Check, Auto Test Summary. If the first listed test is "Hourly," then the problem has been corrected. It will typically take up to an hour with the device turned off and a battery installed for an hourly test result to be posted to the Auto Test Summary.

If the therapy capacitor degrades to a level where service may be required, the RFU indicator will show a solid red "X" with a periodic chirp. Philips states that the RFU indicator may show this status for reasons other than the above problem. If this occurs, follow these instructions in the IFU to troubleshoot:

- Turn the Therapy Knob to Monitor. An inop message describing the failure is displayed. See Troubleshooting, for the corrective action. If needed, run an Operational Check for further information. If the condition persists, take the device out of use and call for service.

A Philips representative will contact your facility to arrange to replace the therapy capacitor and reset internal software settings at no charge.

For Further Information:
Philips
Tel: (800) 722-9377
Website: Click here

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 17. Manufacturer Letter. FSN86100162A
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- 2014 Nov 20. Manufacturer. Manufacturer confirmed source documents

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