El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una alerta asociada a:

NOMBRE DEL DISPOSITIVO MÉDICO	Desfibrilador HEARTSTAR
NO. IDENTIFICACIÓN RISARH	A1402-97
REFERENCIAS DEL DISPOSITIVO MEDICO	M3535A, M3536A y M4735A
REGISTRO SANITARIO	2009EBC-0005096
INDICACIONES Y USO ESTABLECIDOS	Indicado para reanimación cardiaca y monitorización del paciente
NOMBRE DEL FABRICANTE	Philips Medical Systems
DESCRIPCION DEL PROBLEMA	Tabla Anexa
FUENTE	Anexos
FECHA DE NOTIFICACION	28 de Febrero 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

Tabla Anexa

MODELO	FALLA	SERIE
M3535A/ M3536A	Al utilizar los medidores de Q-CPR y al encontrarse el desfibrilador en modo automático (DEA), puede aparecer el mensaje "*no tocar al paciente*" en el momento inadecuado provocando la confusión del personal médico para realizar correctamente el procedimiento de RCP.	US00100253 hasta US00571587
M3535A	Se presenta el desgaste acelerado del cable de electrodos o paletas, lo que puede conllevar a que el equipo no reconozca el accesorio, una posible entrega de energía de desfibrilación al paciente o al usuario y por consiguiente una RCP fallida.	US00100104 hasta US00572207
M3536A	Se presenta el desgaste acelerado del cable de electrodos o paletas, lo que puede conllevar a que el equipo no reconozca el accesorio, una posible entrega de energía de desfibrilación al paciente o al usuario y por consiguiente una RCP fallida.	US00100902 hasta US00543688
M3535A	Se afirma que los procesadores de la tarjeta principal pueden ser susceptibles a daños por descargas electrostáticas, lo cual desencadena ruido en la señal de ECG y de SpO_2 y esto a su vez inconvenientes para la desfibrilación en modo automático (DEA).	US00100100 hasta US00541372
M3536A	Se afirma que los procesadores de la tarjeta principal pueden ser susceptibles a daños por descargas electrostáticas, lo cual desencadena ruido en la señal de ECG y de SpO_2 y esto a su vez inconvenientes para la desfibrilación en modo automático (DEA).	US00100902 hasta US00541375
M3535A/ M3536A	Se presenta el desgaste acelerado del cable troncal de ECG, lo que puede conllevar a que el equipo no reconozca el accesorio, ausencia de desfibrilación en modo automático e incapacidad para cardioversión sincrónica.	US00100100 hasta US00550668
M3535A/ M3536A	Se afirma que un componente en la tarjeta de tratamiento puede funcionar de forma inadecuada provocando que no se entregue la energía adecuada al paciente o simplemente que no se pueda administrar descarga.	US00100204 hasta US00570921
M4735A	Se afirma que un componente en la tarjeta de poder puede funcionar de forma inadecuada provocando que no se entregue la energía adecuada al paciente o simplemente que no se pueda administrar descarga.	US00101665 hasta US00608704**

** Unidades fabricadas entre mayo y noviembre de 2013

A21864 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: March 7, 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
- Nursing
- OR/Surgery

Geographic Regions:
- Worldwide

Philips—HeartStart MRx Monitor/Defibrillators: Processor Board May Be Damaged by Electrostatic Discharge

Product Identifier:

HeartStart MRx Monitor/Defibrillators:	Serial Nos.:
M3535A	US00100100 through US00541372
M3536A	US00100902 through US00541375
M3536J	US00209838 through US00332675
M3536MC	US00500001 through US00500020

[Capital Equipment]

Manufacturer:
- Philips Healthcare North America3000 Minuteman Rd, Andover, MA 01810-1099,

Problem: In a February 2014 Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, Philips states that a component in the processor board of the above monitor/defibrillators may be susceptible to damage from electrostatic discharge (ESD), potentially disrupting electrocardiogram (ECG) and pulse oximetry (SpO2) functionality. This problem may prevent the device from performing demand mode pacing, 12-lead ECG acquisition and analysis, ECG monitoring with leads, and SpO2. If this problem occurs, the "Ready for Use" (RFU) indicator will display a solid red "X" and a periodic audio chirp will occur. Philips states that defibrillation, fixed mode pacing, ECG monitoring with pads/paddles, and other monitoring functions are not affected by this problem.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the February 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. Philips states that you can continue to use the affected device. If the monitor/defibrillator displays a red "X" in the RFU indicator and the "ECG Equip Malfunction" INOP, a failure has been detected that may disable ECG and SpO2 functionality. If this occurs during patient care, treat the patient according to existing protocols, but be aware of the following:
- ECG monitoring with leads and 12-lead acquisition analysis may not be available. If ECG monitoring is needed, connect the pads or paddles cable and press the lead select button until the pads or paddles ECG waveform is displayed.
- Demand mode pacing may not be available. If pacing is needed, change the pacing mode to "fixed" in the "Pacer Mode" menu.
- Sp02 functionality may not be available.

If the problem persists, remove the device from use and contact Philips. A Philips service engineer will contact your facility to install a hardware upgrade.

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

References:

- United States. Food and Drug Administration. Center for Devices and

Radiological Health. Medical device recalls: Class 2 recall—HeartStart MRx monitor/defribillator [online]. 2014 Feb 25 [cited 2014 Mar 7]. Available from Internet: 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 Feb 24. Member Hospital. FSN86100131
- 2014 Feb 25. Manufacturer. Manufacturer confirmed source documents
- 2014 Mar 7. FDA CDRH Database. Class II. Z-1090-2014

A21908 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: February 27, 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
- Nursing
- OR/Surgery
- Information Technology

Geographic Regions:
- Worldwide

Philips—Q-CPR Meters Used with HeartStart MRx Monitor/Defibrillators: May Provide Incorrect CPR Instructions

Product Identifier:
Option B08 Q-CPR Meters used with the following HeartStart MRx Monitor/Defibrillators: (1) Model 3535A, (2) Model M3536A *[Capital Equipment]*
Serial Nos.: US00100253 through US00571587

Manufacturer:
- Philips Healthcare North America3000 Minuteman Rd, Andover, MA 01810-1099, United States

Problem: In a February 2014 Urgent Medical Device Correction letter, Philips states that when the above Q-CPR meters are used with the above monitor/defibrillators they may provide incorrect cardiopulmonary resuscitation (CPR) instructions. Philips states that when the monitor/defibrillator is in automated external defibrillator (AED) mode, the meter should display the "Do Not Touch the Patient" icon during the shock advisory analysis period. If the user continues to deliver chest compressions when the shock advisory analysis begins, the icon may incorrectly remain on the screen after analysis or shock delivery is complete. In AED mode the device continues to reanalyze for the shock advisory every 2 min. When the monitor/defibrillator is in manual mode, the meter is designed to display the "Do Not Touch the Patient" icon when the device is charging to the selected energy. If the user continues to provide chest compressions while the device is charging, the icon may incorrectly remain on the screen after shock delivery is complete. If users follow the "Do Not Touch the Patient" command on the meter and do not resume chest compressions in a timely manner and delay CPR, patient outcome could be affected. Philips states that the shock advisory decision and shock delivery continue to be executed correctly in all modes and that with the exception of the meter feedback, voice prompt feedback, including "resume CPR" and "Pause, Analyzing," operates as intended.
Action Needed: Identify any affected product in your inventory. If you have affected product, verify that you have received the February 2014 Urgent Medical Device Correction letter from Philips. To identify affected units, locate the B08 text printed in the OPT field on the primary label on the back of the unit in battery bay B, Part No 861444 is printed in the REF field on the upgrade primary label on the back of battery bay A. Philips states that you can continue to use the device without the meter attached. If you continue to use the device with the meter and observe the "Do Not Touch the Patient" icon at an unexpected time, follow the instructions for use (IFU), remove the meter from the patient, and continue CPR according to your organization's protocol. A Philips service engineer will contact your facility to implement a softwarei upgrade on affected systems at no charge.
For Further Information:
Philips local representative
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 Feb 26. Manufacturer Letter. FSN86100128
- 2014 Feb 27. Manufacturer. Manufacturer confirmed source documents

A21872 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: February 27, 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
- Nursing
- OR/Surgery

Geographic Regions:
- Worldwide

Philips—HeartStart MRx Monitor/Defibrillators: May Exhibit Accelerated Wear

Product Identifier:

HeartStart MRx Monitor/Defibrillators:	Serial Nos.:
M3535A	US00100104 through US00572207
M3536A	US00100902 through US00543688
M3536J	US00209838 through US00332675
M3536M	US00500002 through US00500009
M3536MC	US00500002 through US00500028

[Capital Equipment]

Manufacturer:
- Philips Healthcare North America3000 Minuteman Rd, Andover, MA 01810-1099, United States

Problem: In a February 2014 Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, Philips states that when the above monitor/defibrillators are used in hospital transport, the connection between the pads/paddles therapy cable (including the CPR therapy cable, external paddles cable, and internal paddles cable/adapter) and the therapy connection port could exhibit high levels of stress, potentially causing accelerated wear. Wear of the connection could prevent the device from sensing that the pads/paddles therapy cable is connected and may cause the device to inappropriately identify the pads therapy cables, external paddles, or internal paddles. If the pads/paddles therapy cable and therapy connection port become worn, delay of therapy, delivery of incorrect energy, spontaneous or unintended discharge therapy energy, shock to the person delivering therapy, and/or interrupted pacing with lost capture and an inability to recapture may occur.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the February 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. Philips states that you can continue to use the affected device, but users should:

- Inspect ongoing therapy connections on all devices to detect wear. Consult the instructions for use (IFU) (numbers 453564396411 Ed 1, 453564307761 Ed 2, or 453564174011), and a previously circulated "Therapy Connection Maintenance and Inspection When Used in Transport" Addendum, Edition 6, to identify wear.
- If wear is detected, remove affected devices and contact Philips to arrange for service.

Philips states that the service life of therapy cables/external paddles is up to 3 years. To maintain reliable performance and reduce the possibility of failure during patient use, replace cables and paddles every 3 years from the time they were initially placed into service or if they fail the inspection criteria in the IFU. A Philips representative will contact your facility to arrange for service at no charge to inspect therapy connection and install a stabilizing collar if one is not present. If wear is detected,

therapy components (including therapy pads/cables, CPR therapy cable, external paddles cable, and internal paddles cable/adapter) within their service life will be replaced. After inspection and hardware upgrade, Philips states that you should continue to perform ongoing therapy connection in accordance with the IFU to detect wear in the future. hilips states that the service life of therapy cables/external paddles is up to 3 years. To maintain reliable performance and reduce the possibility of failure during patient use, replace cables and paddles every 3 years from the time they were initially placed into service or if they fail the inspection criteria in the IFU. A Philips representative will contact your facility to arrange for service at no charge to inspect therapy connection and install a stabilizing collar if one is not present. If wear is detected, therapy components (including therapy pads/cables, CPR therapy cable, external paddles cable, and internal paddles cable/adapter) within their service life will be replaced. After inspection and hardware upgrade, Philips states that you should continue to perform ongoing therapy connection inspections in accordance with the IFU to detect wear in the future.

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

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 2 recall—Philips HeartStart MRx monitor/defibrillator [online]. 2014 Feb 26 [cited 2014 Feb 27]. Available from Internet: 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 Feb 24. Member Hospital. FSN86100132
- 2014 Feb 27. FDA CDRH Database. Class II. Z-1110-2014
- 2014 Feb 27. Manufacturer. Manufacturer confirmed source documents

A21860 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: March 4, 2014
UMDNS Terms:
- Defibrillator/Pacemakers, External [17882]
- Defibrillators, External, Manual [11134]

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

Geographic Regions:
- Worldwide

Philips—HeartStart MRx Monitor/Defibrillators: Leads ECG Cable Connection May Experience Accelerated Wear

Product Identifier:
HeartStart MRx Monitor/Defibrillators: (1) M3535A, (2) M3536A, (3) M3536J, (4) M3536M, (5) M3536M5, (6) M3536MC *[Capital Equipment]*
Serial Nos.: US00100100 through US00550668

Manufacturer:
- Philips Healthcare North America3000 Minuteman Rd, Andover, MA 01810-1099, United States

Problem: In a February 2014 Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, Philips states that the ECG trunk cable and connector block of the above monitor/defibrillators may be susceptible to accelerated wear, potentially resulting in an interrupted ECG signal. This may lead to loss of demand mode pacing, inability to perform synchronized cardioversion with paddles, and the delay of appropriate treatment from disruption of leads. Philips states that defibrillation, fixed mode pacing, ECG monitoring by paddles/pads, and other monitoring functions are not affected by this problem. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the February 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. Philips states that not every serial number within the listed range is affected and to contact Philips if you have question about whether your device is affected by this problem. Philips states that you can continue to use the device. If any of the above problems occur refer to the instructions for use (IFU) for troubleshooting assistance. Philips states the following actions can be taken:
- If demand mode pacing is not available, fixed mode pacing can be used by changing the pacing mode to "fixed" in the pacer mode menu
- If synchronized cardioversion with paddles is not available, switch to sync cardioversion with pads.
- If lead ECG monitoring is not available, ECG monitoring with pads/paddles is available. Connect the pads or paddles cable and press the lead select button until the pads or paddles ECG waveform is displayed.
- Connect a spare ECG trunk cable if one is available.

A Philips service engineer will contact your facility to implement a hardware upgrade on affected systems at no charge.

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

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 2 recall—Philips HeartStart MRx Monitor/Defribillator [online]. 2014 Feb 26 [cited 2014 Mar 4]. Available from Internet: 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 Feb 21. Member Hospital. FSN86100135

A21851 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: February 25, 2014
UMDNS Terms:
- Defibrillator/Pacemakers, External [17882]
- Defibrillators, External, Manual [11134]

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

Geographic Regions:
- Worldwide

Philips—HeartStart MRx Monitor/Defibrillators: May Fail to Charge, Defibrillate or Externally Pace

Product Identifier:
HeartStart MRx Monitor/Defibrillators: (1) 861288, (2) 861289, (3) 861464, (4) 861483, (5) 861491, (6) M3535A, (7) M3536A, (8) M3536M, (9) M3536M4, (10) M3536M6 *[Capital Equipment]*
Serial Nos.: US00100204 through US00570921

Manufacturer:
- Philips Healthcare North America3000 Minuteman Rd, Andover, MA 01810-1099, United States

Problem: Philips states that an internal component on the above monitor/defibrillators' therapy board may malfunction and cause the device to be unable to charge, defibrillate, or externally pace at the selected output current, potentially causing a delay in therapy. In addition, when the monitor/defibrillators are used for external pacing, this problem may result in a loss of capture during pacing. Philips states that the device may display a red "X" in the ready for use (RFU) indicator during automated tests, informing the user that a failure has been detected that may prevent the delivery of a shock and pacing.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the February 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. Philips states that you can continue to use the device, but if users observe the red "X" in the RFU indicator during automated tests, a failure has been detected that may prevent the delivery of a shock or pacing. If this problem occurs, turn the therapy knob to "monitor." An INOP message describing the failure will display. If needed, run an operational check for further information. If the problem persists, remove the device from use and call Philips for service. Philips recommends that a backup defibrillator be made available. A Philips service engineer will contact your facility to implement a hardware upgrade on affected systems at no charge.

For Further Information:
Philips local representative
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 Feb 20. Manufacturer Letter.
- FSN861000127
- 2014 Feb 25. Manufacturer. Manufacturer confirmed source documents

A21907 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: March 4, 2014
UMDNS Terms:
- Defibrillator/Pacemakers, External [17882]
- Defibrillators, External, Manual [11134]

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

Geographic Regions:
- Worldwide

Philips—Model M4735A HeartStart XL Monitor/Defibrillators: May Fail to Defibrillate or Externally Pace at Selected Output Current

Product Identifier:
Model M4735A HeartStart XL Monitor/Defibrillators *[Capital Equipment]*
Serial Nos.: US00101665 through US00608704
Units manufactured between May and November 2013
Not every serial number within the listed range is affected. If you have questions about whether or not your device is affected, contact Philips at the number below.

Manufacturer:
- Philips Healthcare North America3000 Minuteman Rd, Andover, MA 01810-1099, United States

Problem: In a February 2014 Urgent Medical Device Correction letter, Philips states that an internal component on the above monitor/defibrillators' power board may malfunction, potentially preventing the device from charging and delivering a shock. Philips states that this malfunction may also result in loss of capture when the device is used for external pacing.
Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the February 2014 Urgent Medical Device Correction letter from Philips. To identify affected units, locate the model and serial number on the primary label on the bottom of the device. Philips states that you can continue to use the affected device. Ensure that a backup defibrillator is available to use if the above monitor/defibrillators fail to delivery therapy. A Philips representative will contact your facility to arrange to replace your power board at no charge.
For Further Information:
Philips
Tel: (800) 722-9377
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 2 recall—Philips Hearstart XL [online]. 2014 Feb 26[cited 2014 Mar 4]. Available from Internet: 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 Feb 25. Manufacturer Letter.
-
- FSN86100136
- 2014 Mar 3. Manufacturer. Manufacturer confirmed source documents
- 2014 Mar 4. FDA CDRH Database. Class II. Z-1109-2014