


## Safety Communication

### Higher rate of failure than expected for HeartStart MRx Monitor/Defibrillator.

|                                     |   |
|-------------------------------------|---|
| <b>Device/ Product Description:</b> | HeartStart MRx  |
| <b>Brand Name:</b>                  | Philips   |
| <b>Lot numbers/Serials:</b>         | <p><b>Product:</b> HeartStart MRx Monitor/Defibrillators with model numbers M3535A, M3536A, M3536M, M3536MC, M3536M2, M3536M3, M3536M4, M3536M5, M3536M6, M3536M7, M3536M8, and M3536M9.</p> <p>Devices with these model numbers are only affected if they are configured with a <b>M3539A AC</b> Power Module for AC operation or charging batteries.</p>  |
| <b>Manufacturer:</b>                | Philips Medical Systems   |
| <b>Problem:</b>                     | <p>Philips has determined that the M3539A AC Power Module for the HeartStart MRx Monitor/Defibrillator may fail at a higher than expected rate. These failures were due to either an internal component failure, excess solder used at the time of manufacture, physical damage in the field, or the AC Power Module reaching the end of its useful life.</p> <p>Philips has received approximately 100 complaints per year since September 2004.</p> |
| <b>Recommendation/ Actions:</b>     | <ul style="list-style-type: none"> <li>• Read the manufacturer's <a href="#">Field Safety Notice (FSN)</a> carefully.</li> <li>• Determine if your device is one of the affected model numbers, and if affected follow instructions in the "Action to be Taken by Customer/User Section" of the FSN.</li> <li>• In the event a failed AC power module is identified contact Philips immediately to arrange for a replacement.</li> </ul>              |

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|--|--|---------------------------------------|
| <p><b>Devices/Products</b><br/><b>photo:</b></p> |  |                                       |
| <p><b>Authorized Representative Details</b></p>  | <p><b>Company name:</b></p>  | <p><b>Philips Medical Systems</b></p> |
|  | <p><b>Contact Person:</b></p>  | <p><b>Mohammed AlSamhan</b></p>       |
|  | <p><b>Phone:</b></p>   | <p><b>+966 11 4628060</b></p>         |
|  | <p><b>Email:</b></p>   | <p><b>SFDA_SA_MET@philips.com</b></p> |

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

**[National Center for Medical Devices Reporting.](#)**

Medical Devices Sector  
Saudi Food and Drug Authority  
Postal Address: Saudi Arabia - Saudi Food and Drug Authority  
4904 northern ring branch rd - Hitteen Dist.  
RIYADH 13513 - 7148  
Tel: +966 (11) 2038222 Ext: 2995, 2952  
Fax: +966 (11) 2757245

Or

**[Saudi Vigilance](#)**

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Sincerely,  
NCMDR Team