

Safety Communication

رسالة سلامة

Therapy Selector Switch may fail in HeartStart MRx Monitor/Defibrillator

Device/ Product Description:	HeartStart MRx Monitor/Defibrillator
Brand:	Philips
Affected product:	HeartStart MRx Monitor/Defibrillators with model numbers: 861288:M3535, 861483:M3536M4, 861289:M3536A, 881484:M3536M5, 881464:M3536M, 861491:M3536M6, 861465:M3536M0, 860396:M3536M7, 861481:M3536M2, 860397:M3536M8, 861482:M3536M3, 860398:M3536M9
Manufacturer:	Philips Healthcare
Problem:	<p>The Therapy Selector Switch, controlled by the therapy knob, is used to turn the HeartStart MRx on in the desired mode of operation and selects the energy setting. The therapy switch may fail, resulting in the device exhibiting the following behaviors:</p> <ul style="list-style-type: none"> • The device may not perform the selected function. • The therapy knob may not change to the energy setting selected. • The device may deliver a shock with an energy level different from the setting selected by the user.
Recommendation /Actions:	<p>Philips advice customers to perform the Shift and Operational Checks as described in the FSN. If the MRx Therapy Switch fails, Philips will arrange for the replacement of the switch at no charge to the customer</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center</p>

<p>Devices/Products photo:</p>	 <p>FRU: Item: Material Number: 453563345221 Description: Optical Switch Kit</p> <p>Picture:</p> <p>Base Part: NOT REPAIRABLE Use Up Allowed: Part Status: SUPPORTED Replaced By:</p>
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<p>Authorized Representative Details</p>	<p>AR name:</p>	<p>Philips Healthcare Saudi Arabia Ltd.</p>
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