

Safety Communication

Increased Battery Power Consumption and Absence of Low Battery Alarms.

Device/ Product Description:	IntelliVue MX40
Brand Name:	Philips
Lot numbers/Serials:	All Philips IntelliVue MX40 Patient Worn Monitors.
Manufacturer:	Philips Medical Systems
Problem:	The MX40 may experience increased power consumption and may have a lack of visual and/or audible notifications while in a "Low Battery State". The patient and nearby caregivers may not realize that monitoring has been lost and the battery should be replaced, which may result in a delay in recognition of the need for therapy and/or therapy delivery.
Recommendation/ Actions:	<p>ACTION TO BE TAKEN BY CUSTOMER / USER : Until you have upgraded the software on your MX40, replace your batteries every 8 hours, unless you are using Monitor Mode and SpO2 measurement (Manual, Continuous or Auto modes) with AA batteries, in which case replacement should be done every 2 hours.</p> <p>ACTIONS PLANNED BY PHILIPS: Philips Healthcare has released a software upgrade (MX40 rev B.06.59), which will correct these problems. Philips will contact you to arrange for software correction.</p>

Devices/Products photo:									
	Authorized Representative Details	<table border="1"> <tr> <td>Company name:</td> <td>Philips Medical Systems</td> </tr> <tr> <td>Contact Person:</td> <td>Mohammed AlSamhan</td> </tr> <tr> <td>Phone:</td> <td>+966 11 4628060</td> </tr> <tr> <td>Email:</td> <td>SFDA_SA_MET@philips.com</td> </tr> </table>	Company name:	Philips Medical Systems	Contact Person:	Mohammed AlSamhan	Phone:	+966 11 4628060	Email:
Company name:	Philips Medical Systems								
Contact Person:	Mohammed AlSamhan								
Phone:	+966 11 4628060								
Email:	SFDA_SA_MET@philips.com								

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](#)

For latest published FSCAs, please visit ([NCMDR Website](#))

Sincerely,
NCMDR Team