Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الادارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Unable to return to a ready for use state which result in delay of therapy

Device/ Product Description:	+ Defibrillator/Monitor		
Brand:	HeartStart XL		
Lot/Serial Number:	All for Model number 861290		
Manufacturer:	Philips Healthcare		
Problem:	The affected devices may fail to turn on or unexpectedly attempt to restart, rendering it unable to return to a ready for use state. Additionally, this issue may occur when the device is in standby mode, when attempting to power on to run a self-test. If this occurs, the device will indicate that it is not ready for use. These device behaviors could result in a delay of therapy being delivered to a patient if the defibrillator/monitor is needed for immediate use.		
Recommendation/Actions:	 Identify a device that exhibit these behaviors and remove the device from service Contact Philips authorized representative to perform the planned action. For more information you may click here		
Devices/Products photo:			

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		Charge 2 PHILLIPS
Authorized Representative Details	AR name:	Philips Healthcare
	Assigned Contact Person:	Mohammad Alsamhan
	Mobile/Phone:	0503879145
	Email:	sfda.sa.met@philips.com

SFDA

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