

## Safety Communication

## رسالة سلامة

### Helium Indicator Inaccuracy and Unexpected Shutdown

<b>Device/ Product Description:</b>	Cardiosave IABP
<b>Affected product:</b>	Product Code/Part: 0998-XX-0800-XX All Lot Numbers Distribution Dates: Since March 6, 2012
<b>Manufacturer:</b>	Getinge
<b>Problem:</b>	Issue 1: Helium Indicator Inaccuracy in the Presence of Continuous EMC Disturbances.  Issue 2: Shutdown Upon Battery Removal.
<b>Recommendation /Actions:</b>	<p><b>For Issue 1:</b></p> <p><b>Cardiosave Hybrid</b> Follow the recommended separation distances between communications equipment and the Cardiosave equipment as specified in the Cardiosave Operating instructions manual.</p> <p><b>Cardiosave Rescue</b> Prior to any use, ensure the internal helium reservoir is full. If the on-screen helium indicator is not showing full, fill the internal helium reservoir via the hospital cart or Helium Refilling Station. Please review the Cardiosave IABP Operation – Transport Quick Reference Guide (0002-08-9772) for details on using the Cardiosave Rescue in transport.</p> <p><b>For Issue 2:</b></p> <p>To ensure that the Cardiosave Hybrid is not susceptible to the shutdown during the removal of a battery, users should not eject a battery when:</p>

	<ul style="list-style-type: none"> <li>• There is a singular battery in either battery charging bay and unused battery bay is empty.</li> <li>• The battery is charging on AC power (indicated by a flashing LED on the battery pack).</li> </ul> <p>Additionally, the user can prevent the issue by ensuring that a battery is inserted into each of the two battery bays. Should a charging battery be ejected inadvertently, the unit will automatically switch over to the second battery, thus preventing system shutdown.</p> <p>For more information, please click <a href="#">here</a>.</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:  <a href="#">NCMDR</a>  <a href="#">Vigilance system</a>          (19999 )unified call center</p>	
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