

URGENT – Medical Device Correction
Philips Efficia DFM100 may fail to turn on or may unexpectedly attempt to restart

Dear Customer,

Philips has identified that the Efficia DFM100 Defibrillator/Monitor (Model number 866199) may fail to turn on or unexpectedly attempt to restart, rendering it unable to return to a ready for use state. This could result in a delay of therapy being delivered to a patient if the defibrillator/monitor is needed for immediate use. This device behavior may be caused in some cases by a defect in the DFM100 memory management software and in other cases by a malfunction of the System On Module (SOM) installed on the Processor printed circuit assembly (PCA). As a remedy, Philips is releasing replacement hardware and a software upgrade to correct these issues.

The purpose of this notification is to:

- Describe actions that you should take to mitigate risk to patients
- Recommend that unit be removed from service if they exhibit these symptoms
- Describe the corrective action planned by Philips to address the issue

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who should be aware of the contents of this communication.

Please retain a copy with the equipment Instructions for Use.

Follow the “ACTION TO BE TAKEN BY CUSTOMER / USER” section of the notice.

If you have questions regarding this notification or need any further information or support, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.


Sincerely,



Tom Fallon
Senior Director QA/RA,
Emergency Care and Resuscitation

Li Ping
Senior Q&R Manager
MA & TC Q&R PQMS

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<p>AFFECTED PRODUCTS</p>	<p>All Philips Efficia Defibrillator/Monitor (Model number 866199)</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>The model number of the Philips Efficia DFM100 is printed on the primary label on the bottom of the device</p> 
<p>BEHAVIOR DESCRIPTION</p>	<p>The Philips Efficia Defibrillator/Monitor 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.</p>
<p>HAZARD INVOLVED</p>	<p>These device behaviors could result in a delay of therapy being delivered to a patient if the defibrillator/monitor is needed for immediate use.</p> <p>Philips has not received any reports of patient deaths potentially associated with this failure of an Efficia DFM100 Monitor/Defibrillator.</p>

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ACTION TO BE TAKEN BY CUSTOMER / USER	<p>The device is safe to use and can remain in service if it does not exhibit any of these behaviors described in this notice.</p> <p>If you identify a device that exhibit these behaviors, please remove the device from service and contact Philips to request service.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips will contact you to arrange for repair of your unit. Philips will install a replacement SOM module and perform a software upgrade for the affected devices at no charge to the customer.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need further information or support concerning this notification, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.</p>