



Philips Healthcare

- 1/3 -

FSN86000260A

August 2019

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

<Hospital/Clinic Name>

cc: Chairman Medical Board and relevant Head of Departments

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**

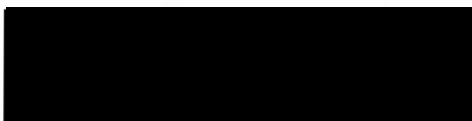
Please review the following information with all members of your staff who should be aware of the contents of this communication.

Please retain a copy with the equipment Instructions for Use.

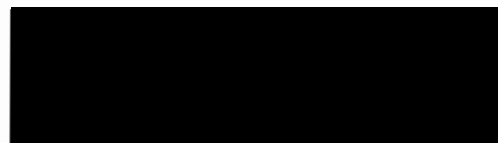
Follow the “ACTION TO BE TAKEN BY CUSTOMER / USER” section of the notice.

If you have questions regarding this notification or need any further information or support, please contact your local Philips representative. <Philips representative contact details to be completed by the KM / country>.

Sincerely,

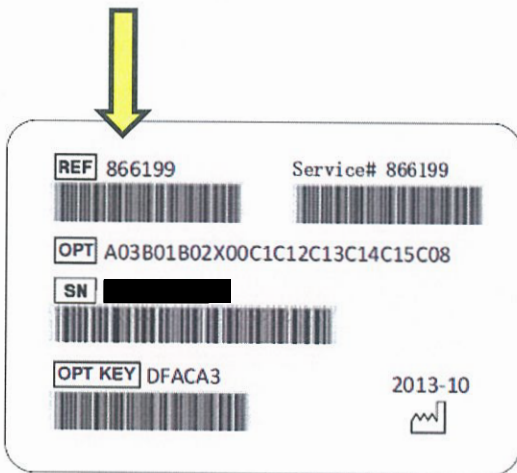


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MA & TC Q&R PQMS

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<b>AFFECTED PRODUCTS</b>	All Philips Efficia Defibrillator/Monitor (Model number 866199)
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<p>The model number of the Philips Efficia DFM100 is printed on the primary label on the bottom of the device</p> 
<b>BEHAVIOR DESCRIPTION</b>	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.
<b>HAZARD INVOLVED</b>	<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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- 3/3 -

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<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	<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>
<b>ACTIONS PLANNED BY PHILIPS</b>	<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>
<b>FURTHER INFORMATION AND SUPPORT</b>	<p>If you need further information or support concerning this notification, please contact your local Philips representative 1800-744-5477 or (Overseas Number).</p>