PHILIPS

URGENT – Medical Device Correction
Efficia DFM100 (Model number 866199)
Corrected version

Dear Distributor,

Philips has identified that the Efficia DFM100 Defibrillator/Monitor (Model number 866199) rotary therapy selector switch may fail, resulting in unpredictable device behaviour. These behaviours include:

- The device may not turn on
- The device may not perform the selected function
- The device may deliver a shock with an energy level different than the setting selected by the user

Should one of these behaviours occur, appropriate therapy delivery may be delayed. To date, Philips has not received any reports of deaths resulting from this switch failure.

As a remedy, Philips will install a replacement switch in affected devices at no charge to the customer.

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.

The following pages provide information on how to identify affected devices and instructions on actions to be taken. Follow the “ACTION TO BE TAKEN BY CUSTOMER / USER” section of the notice. It is imperative that all end-users with affected devices as identified in the “AFFECTED PRODUCTS” section of the Field Safety Notice, receive this Device Recall Notice. Because Philips sells these products through distributors, including your organization, we may not have the information to contact all users.

Therefore, send a copy of the attached package to any customer to whom you have distributed the Efficia DFM100 Defibrillator/Monitor. Be sure to include the Field Safety Notice. Note: Philips has sent this notification to all customers to whom Philips shipped directly (i.e. customers in the “Ship To” field on the original invoice).

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If you have questions regarding this notification or need any further information or support, please contact your local Philips representative:

0800 80 3000

Sincerely,

Gregory M Ayers, MD, PhD
Head of Post Market Surveillance
Associate Chief Medical Officer
Monitoring & Analytics and Therapeutic Care

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

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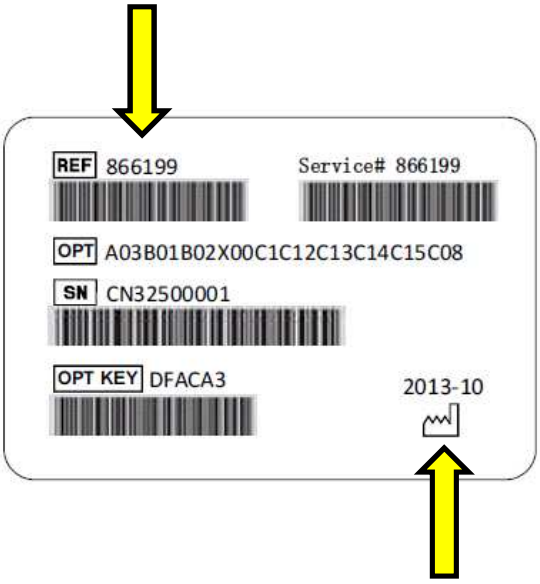
AFFECTED PRODUCTS	All Philips Efficia DFM100 Defibrillator/Monitor manufactured (Model number 866199) prior to 1 May 2017
HOW TO IDENTIFY AFFECTED PRODUCTS	The model number of the Philips Efficia DFM100 is printed on the primary label on the bottom of the device  The date of manufacture of the Philips Efficia DFM100 is printed on the primary label on the bottom of the device

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BEHAVIOUR DESCRIPTION	The Philips Efficia DFM100 Defibrillator/Monitor rotary therapy selector switch may fail, resulting in unexpected device behaviour. These behaviours include: • The device may not turn on • The device may not perform the selected function • The device may deliver a shock with an energy level different from the setting selected by the user

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HAZARD INVOLVED	These device behaviours could result in a delay in therapy or failure to deliver the intended therapy. Philips has not received any reports of patient deaths associated with this failure of an Efficia DFM100 Monitor/Defibrillator.
ACTION TO BE TAKEN BY CUSTOMER / USER	*The device can continue to be used if it does not exhibit any of these behaviors described in this Notice.* *Continue to perform Shift Checks and Operational checks as recommended in the Instructions for Use (IFU) as this reduces the risk of a failure during use.* *If you have a defibrillator other than the target device, you could consider using it as a backup. Each customer must determine the best approach for their institution.* *If you identify a device that exhibit any of these behaviors, please remove it from service and contact Philips to request service.*
ACTIONS PLANNED BY PHILIPS	Philips will contact you to arrange for repair of your unit. Philips will install a replacement switch in affected devices at no charge to the customer.
FURTHER INFORMATION AND SUPPORT	If you need further information or support concerning this notification, please contact your local Philips representative: **0800 80 3000**