

## **URGENT - Medical Device Correction Philips Efficia DFM100 Monitor/Defibrillator**

### **Efficia DFM100 Monitor/Defibrillator Missing Therapy Connector Stabilization Collar**

Dear Valued Efficia DFM100 Customer,

Philips has identified that certain Efficia DFM100 Defibrillator/Monitors (Model number 866199) may not have the therapy connector stabilization collar fitted. This could result in intermittent therapy connector contact causing a delay or inability to deliver therapy.

Philips is requesting that customers check the stabilization collar on potentially affected devices and notify Philips if the stabilization collar or screws are missing. Any repairs required will be addressed with retrofit on failure FCO86100226.

The purpose of this notification is to:

- Describe the problem and actions that you should take to mitigate risk to patients.
- Describe the actions planned by Philips to correct the problem.

#### **This document contains important information for the correction of the identified devices**

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

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.

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.

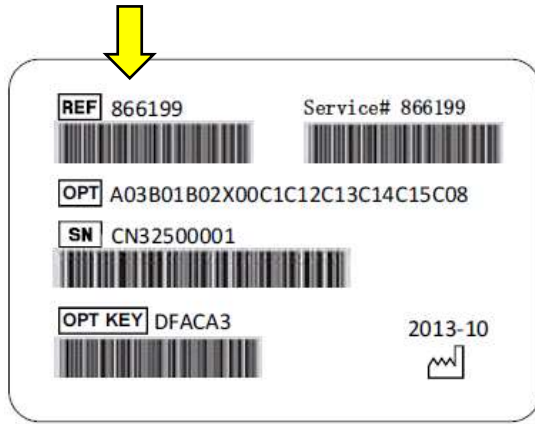
Sincerely,

Tanya DeSchmidt  
Director, Quality  
Emergency Care and Resuscitation

Li Ping  
Senior Quality & Regulatory Manager  
Monitoring and Analytics  
& Emergency Care and Resuscitation



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<b>AFFECTED PRODUCTS</b>	<p><b>Product:</b> Efficia Defibrillator/Monitor (Model number 866199)</p> <p><b>Affected Countries:</b> Belgium, Brazil, China, Czech Republic, France, Germany, India, Indonesia, Ireland, Italy, Japan, Kenya, Malaysia, Mexico, Morocco, Philippines, Poland, Romania, Russian Federation, Saudi Arabia, South Africa, Spain, Sweden, Turkey, United Arab Emirates, United Kingdom</p>
<b>PROBLEM DESCRIPTION</b>	Philips has identified that certain Efficia DFM100 Defibrillator/Monitors (Model number 866199) may not have the therapy connector stabilization collar fitted.
<b>HAZARD INVOLVED</b>	Efficia DFM100 Defibrillator/Monitors (Model number 866199) may not have the therapy connector stabilization collar fitted. This could result in intermittent therapy connector contact causing a delay or inability to deliver therapy.
<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>ADVICE ON ACTIONS 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> <p>To acknowledge receipt of this notification, please complete and fax the Customer Reply Form to: <a href="mailto:safetynoticeuki@philips.com">safetynoticeuki@philips.com</a></p>

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<b>ACTIONS PLANNED BY PHILIPS</b>	<p>Philips is requesting that customers check the stabilization collar on potentially affected devices and notify Philips if the stabilization collar or screws are missing.</p> <p>Correct assembly fitting is as shown below</p>  <p>Incorrect assembly is shown below (note the absence of the collar and three associated screws)</p> 
<b>FURTHER INFORMATION AND SUPPORT</b>	<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>

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### **Customer Reply for FSN86100224A**

Customer ID:	
Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address	
City, State, Postal Code:	
Country:	

### **CUSTOMER ACKNOWLEDGEMENT**

I certify the Field Safety Notification FSN86100224A was received, read, and understood by staff who may use the Efficia DFM100.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Please return your completed form at your earliest convenience by either method below.

1. Email completed and signed form to [safetynoticeuki@philips.com](mailto:safetynoticeuki@philips.com)