PHILIPS

Customer Information Letter
Philips Efficia DFM100 Monitor/Defibrillator

Efficia DFM100 Monitor/Defibrillator
False Low Battery Indication

Dear Valued Efficia DFM100 Customer,

Philips determined that the 866199 Efficia DFM100 Defibrillator/Monitor may give a false low battery indication, caused by a voltage inrush, when the battery is inserted or removed. If operators believe that the DFM100 has insufficient battery power, this false indication could cause a delay in therapy or therapy not to be delivered. A device with this failure will also be unable to recharge its battery.

Philips requests that customers check and verify that the battery fuel gauge, and battery status indication on the screen, correctly depict a full battery upon insertion. Customers should also verify that the Ready For Use Indicator indicates that a discharged battery is recharging whenever a battery is inserted. Any device repairs required will be addressed with retrofit on failure FCO86100228.

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 to correct the identified devices

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

The following pages provide information on how to identify affected devices and instructions on actions to take. 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,

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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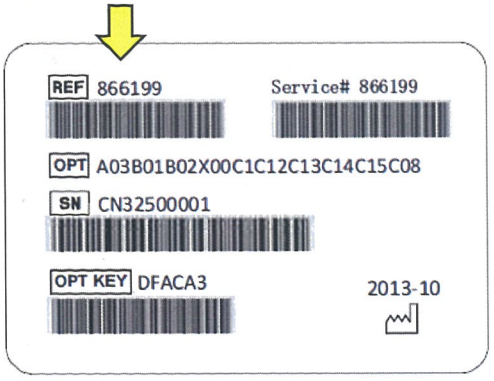
AFFECTED PRODUCTS	**Product:** All Philips Efficia Defibrillator/Monitor (Model number 866199) manufactured prior to March-30th-2020. **Affected Countries:** Worldwide, excluding US and Canada
PROBLEM DESCRIPTION	Philips determined that the 866199 Efficia DFM100 Defibrillator/Monitor may give a false low battery indication, caused by a voltage inrush, when the battery is inserted or removed.
HAZARD INVOLVED	This false indication could cause a delay in therapy, or therapy not to be delivered, if operators believe that the DFM100 has insufficient battery power. A device with this failure will also be unable to recharge its battery.
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 

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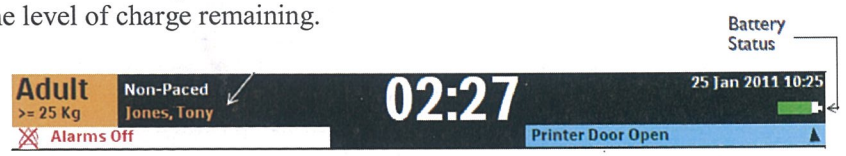
ACTION TO BE TAKEN BY CUSTOMER / USER	Philips requests that customers check and verify that the battery fuel gauge, and battery status indication on the screen, correctly depict a full battery upon insertion. As instructed in the IFU, please follow the instructions below on how to check the following values. **Step 1: Check the Battery Fuel Gauge** To check the power remaining in your Lithium Ion battery when it is not installed in the Efficia DFM100, press the Battery Power Gauge located on the end of the battery opposite the battery tab. Each solid blue light indicates approximately 20 percent charge. A flashing blue light farthest to the button indicates the battery is too weak to enable the device to deliver a shock and must be recharged before use.  **Step 2: Check the Battery Status** The Power Indicators are located in the upper right corner of the Efficia DFM100's front panel. If a battery is installed, the battery icon indicates the level of charge remaining.  Battery Charge Level:  Customers should also verify that the Ready For Use Indicator does not show a blinking red X accompanied by a periodic audible chirp. **Step 3: Check the Ready For Use Indicator** The Ready For Use (RFU) Indicator is located in the upper right section on the front of the device. It indicates the status of the therapy delivery functions using the following conventions:

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ACTION TO BE TAKEN BY CUSTOMER / USER (Continued)

Blinking Hourglass		Indicates the shock, pacing and ECG functions of the device are ready for use. Sufficient battery power is available for device operation.
Blinking red "X" with periodic audio chirp		Indicates either: • A low battery condition exists and the battery is not charging. • There is no battery installed and the device is running on AC power only.
Blinking red "X" without periodic audio chirp		Indicates a low battery power condition but the battery is currently charging. The device can be used but its battery-only operation time is limited.
Solid red "X" with periodic audio chirp		Indicates a critical failure has been detected that may prevent the delivery of defibrillation therapy, pacing or ECG acquisition.
Solid red "X" without periodic audio chirp		Indicates no power available or the device cannot power on. If, after power is returned, the indicator reverts to the blinking black hourglass symbol, the device is ready for use.

The device is safe to use and can remain in service if the above indications are correct.

If you identify a device for which the indications are incorrect, please remove the device from service and contact Philips to request service. Any device repairs required will be addressed with retrofit on failure FCO86100228 at no charge.

To acknowledge receipt of this notification, please complete and fax the Customer Reply Form to: <Philips representative contact details to be completed by the KM / country>

ACTIONS PLANNED BY PHILIPS

Any device repairs required will be addressed with retrofit on failure FCO86100228 at no charge.

FURTHER INFORMATION AND SUPPORT

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

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Customer Reply for CIL86100225A

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

CUSTOMER ACKNOWLEDGEMENT

I certify the Customer Information Letter CIL86100225A 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 <Philips representative contact details to be completed by the KM / country>.

2. Fax completed and signed form to <Philips representative contact details to be completed by the KM / country>.