

URGENT – Field Safety Notice Philips Efficia DFM100 Defibrillator/Monitor

Dear Customer,

Philips has identified an issue that could impact the safety and/or performance of Efficia DFM100 defibrillator/monitors. This issue is further detailed in the attached Field Safety Notice.

Please see the following pages, which 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.

This Field Safety Notice is intended to inform you about:

- what the issue is and under what conditions it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients
- 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 need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instructions for Use.

The issue identified is that the DFM100 device may display dashed lines in place of the ECG waveform only for the Pads ECG waveform under the following conditions:

1. Paddles are set in the paddle tray and the paddle connector is not connected to the device.
2. Pads are on the patient and the Handsfree Connector is connected to the device.

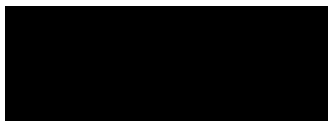
As a result, the user will not be able to view pads ECG waveform to determine whether defibrillation or treatment is needed. In AED mode, the DFM100 is unable to analyze the rhythm with a dashed line on the waveform.

Philips is initiating a software upgrade that will be provided to customers free of charge. Your local Philips dealer/distributor or Authorized Service Provider will contact you to arrange for installation of the software upgrade. We appreciate your patience as we work to schedule your upgrade.

This voluntary correction has been reported to the appropriate regulatory agencies.

Philips sincerely apologizes for any inconvenience this may cause you. 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,



John Pardo
Director QA/RA, Emergency Care and Resuscitation

URGENT – Field Safety Notice Philips Efficia DFM100 Defibrillator/Monitor

<p>AFFECTED PRODUCTS</p>	<p>Product: Philips Efficia DFM100 Defibrillator/Monitors</p> <p>Model: 866199</p> <p>Units Affected: DFM100 units with a serial number within the following ranges:</p> <p>CN32601159, CN32601168~CN32601170; CN32601182~CN32601199; CN32601201~CN32601585; CN32601589~CN32601598; CN32600066~CN32600369; CN32600372~CN32600947; CN32600973~CN32601158, CN32601160; CN32601162, CN32601171~CN32601173; CN32601176, CN32601182~ CN32601199; CN32601201~ CN32601393; CN32601398~ CN32601404; CN32601409~ CN32601924; CN32601929~ CN32601930; CN32601933~ CN32601941; CN32601979~ CN32602234; CN32602235~ CN32602303; CN32602305, CN32602306,CN32602307; CN32602308~ CN32602311; CN32602318~ CN32602352; CN32602312~ CN32602317; CN32602334~ CN32602343; CN32602360, CN32602358; CN32602355,CN32602357</p>
<p>PROBLEM DESCRIPTION</p>	<p>The device will display dashed lines in place of the ECG waveform only for the Pads ECG waveform under the following conditions:</p> <ol style="list-style-type: none"> 1. Paddles are set in the paddle tray and the paddle connector is not connected to the device. 2. Pads are on the patient and the Handsfree Connector is connected to the device.
<p>HAZARD INVOLVED</p>	<p>User is not able to view pads ECG waveform to determine whether defibrillation or treatment is needed. In AED mode, the DFM100 is unable to analyze the rhythm with a dashed line on the waveform.</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>Philips Efficia DFM100 Defibrillator/Monitors identified above are affected this issue.</p> <p>The model and serial numbers of the Efficia DFM100 Defibrillator/Monitor are printed on the primary label on the bottom of the DFM100.</p>

URGENT – Field Safety Notice **Philips Efficia DFM100 Defibrillator/Monitor**

ACTION TO BE TAKEN BY CUSTOMER / USER	<p>You can continue to use your DFM100 prior to receiving the software upgrade, provided that you follow the guidance provided:</p> <p style="text-align: center;">If using pads, remove the paddles from the paddle holder pockets.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips is initiating a correction to affected devices. A software upgrade will be provided free of charge for all units affected by this issue. A Philips dealer/distributor or Authorized Service Provider will contact customers with affected devices to arrange for installation of the upgrade.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country></p>