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URGENT Field Safety Notice

Efficia DFM100 Defibrillator/Monitor (866199)
Boot-Up Failure with SW 2.00.33

02-DEC-2025

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 this letter for your records.

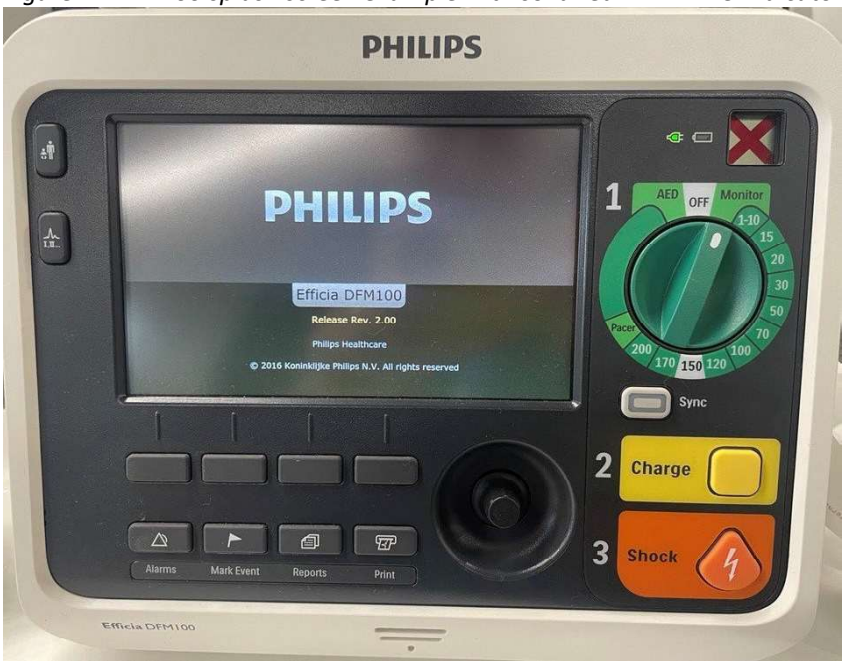
Dear Valued Customer/Distributor,

Philips issued this Field Safety Notice due to a potential safety issue with the Efficia DFM100 Defibrillator/Monitor where the device may fail to complete its boot-up sequence. This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

The Efficia DFM100 Defibrillator/Monitor, with software revision 2.00.33 installed, may fail to complete its boot-up sequence. This could occur either 1) during manual boot-up if the knob is turned to AED/Manual/Pacer or 2) as part of a self-test if the device is turned off and connected to any power source. Instead of completing the boot-up sequence, the device may repeatedly display the splash screen (see Figure 1 below) and will not be available for clinical use. This will be indicated to the user by displaying a solid red "X" in the Ready For Use (RFU) indicator.

Figure 1: DFM100 splash screen example with solid red "X" in RFU indicator



This issue was identified via customer complaints. Philips has not received any reports of patient harm related to this issue.

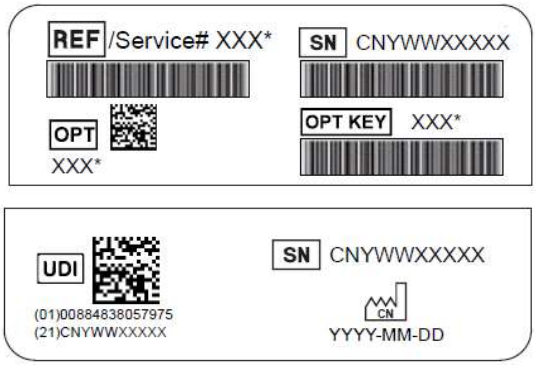
2. Hazard/harm associated with the issue

If the device fails to boot, defibrillation or pacing therapy may be delayed in an emergency, potentially contributing to a failure to resuscitate. In many cases, automated tests detected the issue when the device was turned off and connected to a power source, alerting the user with a solid red "X" in the RFU indicator. However, the issue may go unnoticed before clinical use or may arise during manual startup, potentially causing a delay in therapy.

3. Affected products and how to identify them

This Field Safety Notice applies to Efficia DFM100 devices with software revision 2.00.33 installed.
See Appendix A for instructions to determine if software revision 2.00.33 is installed. The model number of the Efficia DFM100, 866199, is printed on the primary label next to REF/Service# (see Figure 2 below).

Figure 2: Efficia DFM100 label example



Efficia DFM100 Defibrillator/Monitor Intended Use
The Efficia DFM100 is intended for use in a hospital or EMS setting by users trained in the operation of the device and qualified by training in BLS and ALS. The Efficia DFM100 is intended for use for emergency resuscitation as follows: in AED mode, the Efficia DFM100 is intended to detect a shockable rhythm and deliver a shock; in Manual mode, the Efficia DFM100 is intended to deliver asynchronous and synchronous defibrillation; in Pacing mode, the Efficia DFM100 is intended to deliver external cardiac pacing; and in Monitor mode, the Efficia DFM100 is intended to measure heart rate and heart rhythm via ECG, measure blood oxygen saturation via SpO2, measure exhaled CO2 via EtCO2, and measure systolic, diastolic, and mean blood pressure via NBP.

4. Actions that should be taken by the customer / user to prevent risks for patients or users

- Provide power to the device when it is off so automated tests can run, as part of routine maintenance. Continue to observe the Ready for Use (RFU) Indicator to confirm the device's readiness. See "Maintenance" in the Efficia DFM100 Instructions for Use (IFU).
- You may continue to use your Efficia DFM100 if your device does not exhibit the issue described in this notice. If you identify a device that exhibits this behavior, please remove the device from service and contact your local representative.
- Customers should back up device data (patient event records and device logs) prior to the software upgrade as device data will be erased during the upgrade — see "Data Management

Mode" in the DFM100 IFU for patient event record export and "Export Device Info" in the Service Manual for device logs export.
- Place this Urgent Field Safety Notice with the documentation of the system.
- Complete and return the Urgent Field Safety Notification Response Form included with this letter within 30 days of receipt.

Share this notice with all relevant personnel within your organization and with any organization where affected devices have been transferred.

5. Actions that should be taken by distributors

- If you are a distributor with DFM100 devices in stock, please quarantine the devices to conduct FCO86100240 and contact your local representative.
- Modify the Urgent Field Safety Notice Response Form to substitute your firm's email and fax information.
- Send a copy of this Urgent Field Safety Notice (with a modified response form) to each customer to whom you distributed the affected product as soon as possible and no later than 30 days from receipt of this notice.
- Complete and return the Urgent Field Safety Notice Response Form included with this letter within 30 days of receipt of this notice.

Please ensure customers receive the letters that you send to customers with affected product(s). This notice must be shared with all relevant personnel within your organization and with any organization where the affected devices have been transferred.

6. Actions planned by Philips Emergency Care (CN-MF-000003921) to correct the problem

Philips is providing this Urgent Field Safety Notice to inform affected customers. The software solution has been released (SW 2.00.46 or higher), and Philips will correct devices that have SW 2.00.33 installed via FCO86100240.

If you need any further information or support concerning this issue, please contact your local representative: *<Representative contact details to be completed by the Market>*

This notice has been reported to the appropriate Regulatory Agencies. Philips regrets any inconvenience caused by this problem.

Sincerely,

Tanya Deschmidt
Director of Quality

Tony She
Senior QMS Manager

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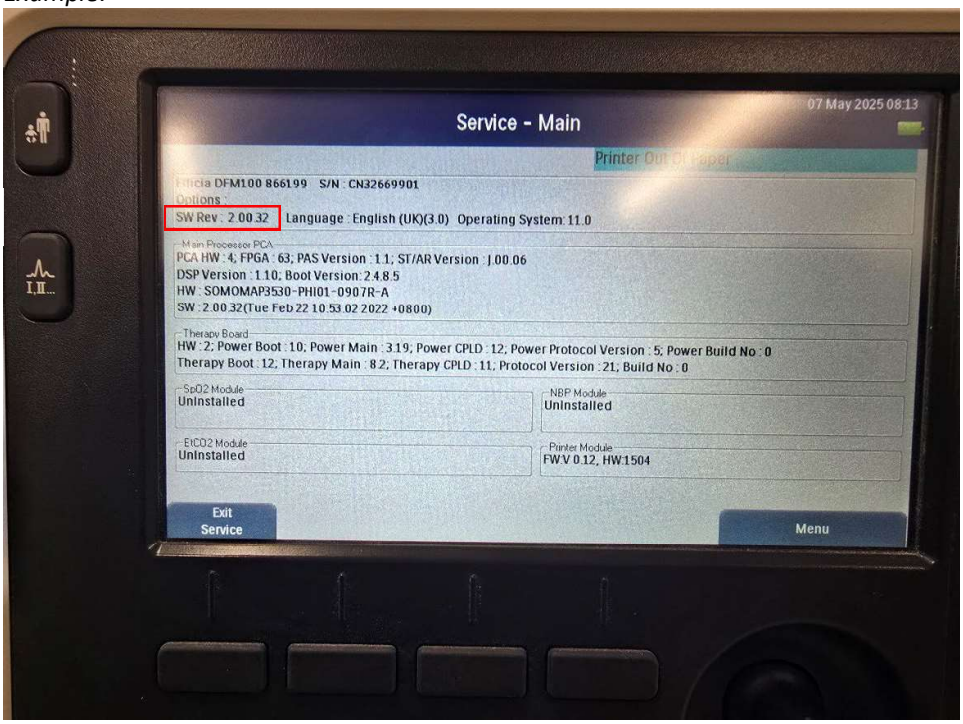
Appendix A

How to determine if your Efficia DFM100 has SW revision 2.00.33

If the service mode password is available:

- Power up the device to monitor mode
- Press smart selection knob to show the “Main Menu”
- Select “Other” by rotating the knob and press the knob to enter
- Select “Service” under “Other” and press the knob
- Confirm to exit Clinical Mode by selecting “Yes” and press knob
- Enter Service mode password in the “Service-Password Entry” Page, select OK and press the knob
- “Service-Main” page will be displayed, and user can see the SW version from “SW Rev: 2.00.XX”

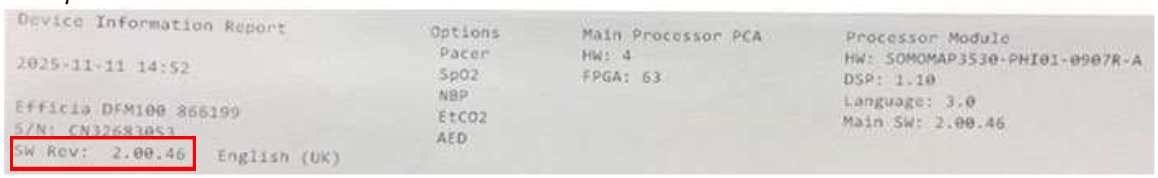
Example:



If the service mode password is not available:

- Power up the device to monitor mode
- Press smart selection knob to show the “Main Menu”
- Select “Other” by rotating the knob and press the knob to enter
- Select “Service” under “Other” and press the knob
- Confirm to exit Clinical Mode by selecting “Yes” and press knob
- Press “Print Device Info” at the middle bottom, device will print device information report
- Check the printed report, user can see the SW version from “SW Rev: 2.00.XX in the report

Example:



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URGENT Field Safety Notice Response Form

Reference: FSN-2025-CC-EC-018 – Efficia DFM100 Boot-Up Failure with SW 2.00.33
Instructions: Please complete and return this form promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice and understanding of the issue and required actions to be taken.
Customer/Consignee/Facility Name: _____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:

- Provide power to the device when it is off so automated tests can run, as part of routine maintenance. Continue to observe the Ready for Use (RFU) Indicator to confirm the device's readiness. See "Maintenance" in the Efficia DFM100 Instructions for Use (IFU).
- You may continue to use your Efficia DFM100 if your device does not exhibit the issue described in this notice. If you identify a device that exhibits this behavior, please remove the device from service and contact your local representative.
- Customers should back up device data (patient event records and device logs) prior to the software upgrade as device data will be erased during the upgrade — see "Data Management Mode" in the DFM100 IFU for patient event record export and "Export Device Info" in the Service Manual for device logs export.

Distributor Actions:

- If you are a distributor with DFM100 devices in stock, please quarantine the devices to conduct FCO86100240 and contact your local representative.
- Modify the Urgent Field Safety Notice Response Form to substitute your firm's email and fax information.
- Send a copy of this Urgent Field Safety Notice (with a modified response form) to each customer to whom you distributed the affected product as soon as possible and no later than 30 days from receipt of this notice.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the Efficia DFM100 Defibrillator/Monitor.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date (DD/MM/YYYY):_____

Please return this form by email or fax: ***<Reply information to be completed by Market or Distributor>***