URGENT Field Safety Notice

Efficia External Paddles (989803196431)
Not adequately identified when connected to a Philips Efficia DFM100 or HeartStart Intrepid Monitor/Defibrillator

10-NOV-2022

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 Instruction for Use.

Dear Customer,

A problem has been identified in the Philips Efficia External Paddles that could pose a risk for patients. 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 External Paddles are intended to be used with the Efficia DFM100 and HeartStart Intrepid Monitor/Defibrillators – by applying the external paddles to the patient's chest to deliver cardioversion and defibrillation therapy. The external paddles may also be used to obtain an ECG as a quick assessment; however, are not for continuous monitoring.

The Efficia External Paddles may not be properly identified by an Efficia DFM100 or HeartStart Intrepid Monitor/Defibrillator when connected to the device. The device may display an error message reading "Pads/Paddle Type Unknown" as shown in Figure 1. When this occurs, it is accompanied by a menu prompting the user to select a therapy cable type, also shown in Figure 1 below. The message cannot be cleared until the user either selects the cable type, disconnects and reconnects the cable, or restarts the device.

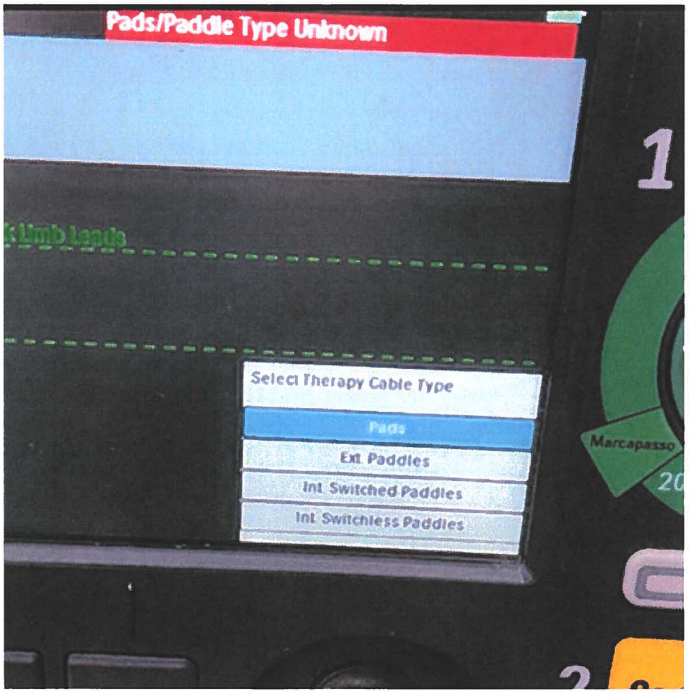

Figure 1: Screen display from DFM100 experiencing paddles misidentification issue.

2. Describe the hazard/harm associated with the issue

If an Efficia DFM100 or HeartStart Intrepid Monitor/Defibrillator is needed for clinical use and experiences these device behaviors, then that could result in a delay of therapy being delivered to a patient.

Three adverse events have been reported to Philips, which are related or may be related to this issue.

3. Affected products and how to identify them

All Efficia External Paddles with a date of manufacture prior to August 2022 (8/22), irrespective of the monitor/defibrillator they are used with, are affected by this action.

Philips has provided an example below (in Figure 2) that shows how the date of manufacture can be identified on each Efficia External Paddles set. The arrow points to the month, while the numbers inside the circle indicate the year; this example shows a date of manufacture of August 2020 (8/20):

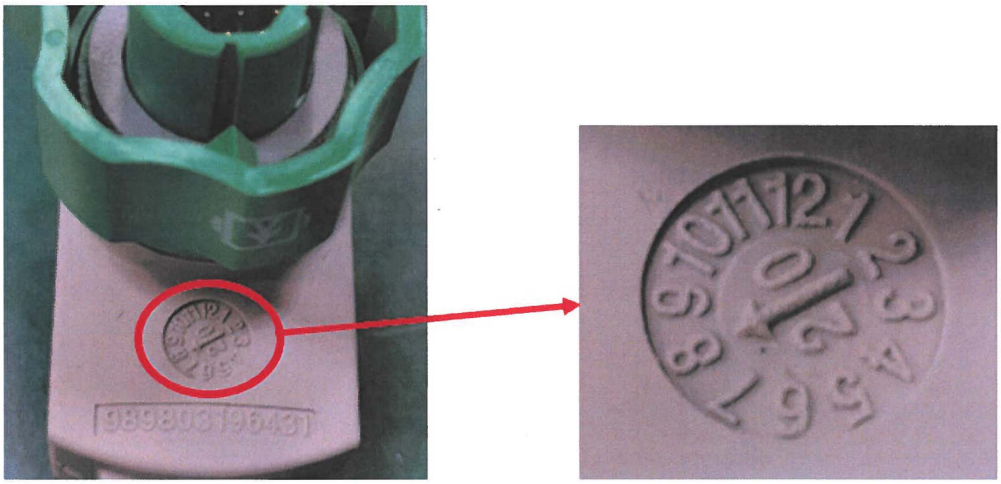

Figure 2: Example of a date of manufacture of August 2020 (8/20)

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

You can continue to use your Efficia External Paddles if you take the following precautions:

- If the device displays an error message reading, "Pads/Paddle Type Unknown," accompanied by a menu prompting the user to select a therapy cable type, select the therapy cable type you are using. You can also remove the prompt from the display by disconnecting and reconnecting the cable or restarting the device.
- Follow the monitor/defibrillator Instructions for Use (IFU) and ensure that Operational Checks are performed to the monitor/defibrillator with the Efficia External Paddles connected. These Operational Checks will alert the user immediately upon misidentification and should be done before the device is needed for therapy.
- Continue with the recommended daily and weekly Automated Tests described in the device IFU.
- Complete and return the Urgent Field Safety Notice Response Form included at the end of this letter.

As a reminder to customers, per the HeartStart Intrepid and Efficia DFM100 Instructions for Use, Philips recommends replacing the Efficia External Paddles every three years from the time they were initially placed into service or if they fail inspection.

Please pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

5. Describe the actions planned by Philips Emergency Care (CN-MF-000003921) to correct the problem

Your Philips representative will contact you to arrange for replacement Efficia External Paddles to be provided, as applicable, at no cost to you.

If you need any further information or support concerning this issue, please contact your local Philips representative: *< Key Markets insert contact information here >*

This notice has been reported to the appropriate Regulatory Agencies, and a response form is needed by Philips from your organization upon your receipt of this notification.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Tanya DeSchmidt
Director of Quality

Tony She
PQMS Quality & Compliance

URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: Efficia External Paddles (989803196431) not adequately identified when connected to a Philips Efficia DFM100 or HeartStart Intrepid Monitor/Defibrillator

Instructions: Please complete and return this form to Philips promptly upon receipt 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 the required actions to be taken.

Customer / Consignee / Facility Name: _____

Street Address: _____

City / State / Zip / Country: _____

Customer Actions:

- If the device displays an error message reading, "Pads/Paddle Type Unknown," accompanied by a menu prompting the user to select a therapy cable type, select the therapy cable type you are using. You can also remove the prompt from the display by disconnecting and reconnecting the cable or restarting the device.
- Follow the monitor/defibrillator Instructions for Use (IFU) and ensure that Operational Checks are performed to the monitor/defibrillator with the Efficia External Paddles connected. These Operational Checks will alert the user immediately upon misidentification and should be done before the device is needed for therapy.
- Continue with the recommended daily and weekly Automated Tests described in the device IFU.
- Complete and return the Urgent Field Safety Notice Response Form included at the end of this letter.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Notification has been properly distributed to all users that handle the Efficia External Paddles (989803196431).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD-MM-YYYY): _____

Please return this form to Philips by email or fax *< Key Market to add email and fax information here >*