

URGENT Field Safety Notice

Efficia Pads Adapter Cable (989803197111)

Could unexpectedly fail, preventing cardiac ECG monitoring, defibrillation, synchronized cardioversion, or transcutaneous pacing

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 Valued Philips Distributor,

The Efficia Pads Adapter Cable, when used with either the Efficia DFM100 or HeartStart Intrepid Monitor/Defibrillator, has a problem 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

Efficia DFM100 and HeartStart Intrepid Monitor/Defibrillators are at risk of failed ECG monitoring, defibrillation, synchronized cardioversion, or transcutaneous pacing when using the affected Efficia Pads Adapter Cables. There are no reliable indications that predict when such an episode may occur.

This issue was identified as a result of a customer complaint. Philips received one report of a patient death; however, it is unclear whether this issue affected patient outcome or not.

The Efficia Pads Adapter Cable is compatible with both Efficia DFM100 and HeartStart Intrepid defibrillator/monitor devices. It connects the defibrillator device to the multifunctional electrode pads.

2. Describe the hazard/harm associated with the issue

Due to wear and tear from flexing of the Pads Adapter Cable, Efficia Pads Adapter Cables may unexpectedly fail causing Efficia DFM100 and HeartStart Intrepid Monitor/defibrillator devices to be unable to perform ECG monitoring, defibrillation, synchronized cardioversion, or transcutaneous pacing.

However, the risk associated with this issue could be reduced if the Pads Adapter Cable is discarded after its recommended service life, as stated in the Instructions for Use.

3. Affected products and how to identify them

The affected products can be identified by dates of manufacture between September 2018 (9/18) and November 2020 (11/20).

Philips has provided an example below in Figure 1 that shows how the date of manufacture can be identified on each Pads Adapter Cable. The arrow points to the month, while the numbers inside the circle indicate the year; the example below shows a date of manufacture of May 2022 (8/22):

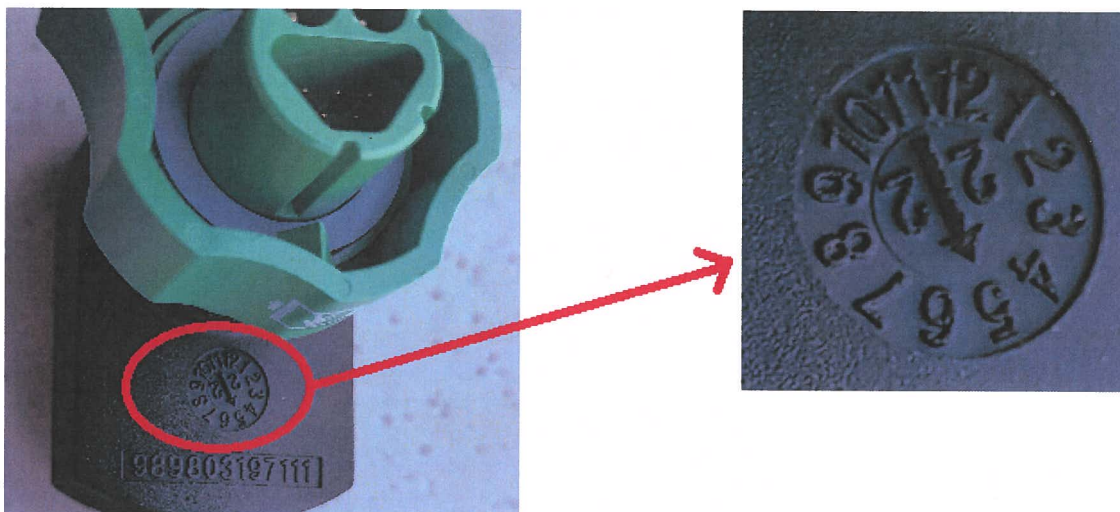


Figure 1: Example of a date of manufacture of May 2022 (5/22)

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

- Please check whether your Pads Adapter Cable(s) are affected by this action. Affected products have a date of manufacture between September 2018 (9/18) and November 2020 (11/20).
- If you have affected Pads Adapter Cable(s), Philips recommends replacing affected cables with spare cables manufactured after November 2020 (11/20), if available to you, until you receive replacement cable(s).
- If you do not have any spare Pads Adapter Cables manufactured after November 2020, you may continue to use the affected Pads Adapter Cable(s).
- Please complete and return the Urgent Field Safety Notice Response Form included in this correspondence.

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

This notice needs to be provided to all those who need to be aware within your organization, or to any organization where the potentially affected Pads Adapter Cables have been transferred.

5. Describe the actions that should be taken by the Distributors

- If you have any Efficia Pads Adapter Cables with affected dates of manufacture that have not been distributed, quarantine them in a secure, non-clinical location. Do not distribute them.
- Please modify the URGENT FIELD SAFETY NOTICE RESPONSE FORM found on the last page of the URGENT Field Safety Notice letter (Document Identification: FSN-2022-CC-EC-010) to substitute your firm's own email and fax information (an electronic copy will be provided.)
- Please send a copy of the URGENT Field Safety Notice letter (Document Identification: FSN-2022-CC-EC-010) with the modified response form to each customer with Efficia Pads Adapter Cables with affected dates of manufacture as soon as practical and not more than 30 days from receipt of this letter.
- Please complete and send to Philips the URGENT FIELD SAFETY NOTICE RESPONSE FORM found on the last page of this letter (Document Identification: DISTRIBUTOR-FSN-2022-CC-EC-010) no later than 30 days from receipt.

After the letters have been sent to customers with affected dates of manufacture, please take steps to ensure that customers have received the letters.

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).

Please transfer this notice to other organizations on which this action has an impact.

6. 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 Pads Adapter Cables 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* >

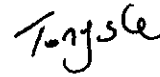
This notice has been reported to the appropriate Regulatory Agencies. Be sure to report any occurrence of this issue to Philips, your Philips representative, or to your local Regulatory authority.

Philips regrets any inconvenience caused by this problem.

Sincerely,



Tanya Deschmidt
Director of Quality



Tony She
PQMS Quality & Compliance

DISTRIBUTOR URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: Efficia Pads Adapter Cable (989803197111) Could unexpectedly fail cardiac ECG monitoring, defibrillation, synchronized cardioversion, or transcutaneous pacing

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, understanding of the issue, and required actions to be taken.

Customer / Consignee / Facility Name: _____

Street Address: _____

City / State / Zip / Country: _____

Distributor Actions:

- If you have any Efficia Pads Adapter Cables with affected dates of manufacture that have not been distributed, quarantine them in a secure, non-clinical location. Do not distribute them.
- Please modify the URGENT FIELD SAFETY NOTICE RESPONSE FORM found on the last page of the URGENT Field Safety Notice letter (Document Identification: FSN-2022-CC-EC-010) to substitute your firm’s own email and fax information (an electronic copy will be provided.)
- Please send a copy of the URGENT Field Safety Notice letter (Document Identification: FSN-2022-CC-EC-010) with the modified response form to each customer with Efficia Pads Adapter Cables with affected dates of manufacture as soon as practical and not more than 30 days from receipt of this letter.
- Please complete and send to Philips the URGENT FIELD SAFETY NOTICE RESPONSE FORM found on the last page of this letter (Document Identification: DISTRIBUTOR-FSN-2022-CC-EC-010) no later than 30 days from receipt.

I acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Notice has been properly passed to those who need to be aware.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD-MMM-YYYY): _____

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