PHILIPS

URGENT - Medical Device Correction

Philips Sterilizable Defibrillator Paddles

Addendum to IFU to Add Insulation Resistance Test to Paddle Checks for Sterilizable Switched Internal Defibrillator Paddles (M4741A, M4742A, M4743A, M4744A)

Dear Valued Philips Internal Paddles Customer,

Philips determined that the periodic Paddle Checks recommended in the Instructions for Use for Sterilizable Defibrillator Paddles may not detect one failure mode for the Switched Internal Defibrillator Paddles **(Models M4741A, M4742A, M4743A, and M4744A).** Philips has created an addendum to the IFU, that includes a test for the switched paddles only, which will detect this failure mode. Because Philips uses a common IFU for all models of Sterilizable Defibrillator Paddles and many customers have purchased both switched and switchless Philips sterilizable paddles, all copies of the IFU should be updated. Consequently, Philips is sending this notice to purchasers of both switched and switchless internal paddles, even though the failure mode and test in the addendum, apply only to the switched paddles.

The purpose of this notification is to:

- describe actions that you should take to mitigate risk to patients
- remind you to follow the Instructions for Use and the attached Addendum
- describe Philips' plan to address the problem

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.

Please retain a copy with the equipment Instructions for Use.

The following pages 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.

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

Sincerely,

Tanya DeSchmidt
Director, Quality, Emergency Care and Resuscitation

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AFFECTED PRODUCTS	**Product:** Philips Sterilizable Internal Defibrillator Paddles • Switched M4741A, M4742A, M4743A, M4744A Switchless M1741A, M1742A, M1743A, M1744A (Instructions for use only) All units manufactured and distributed January 2015 to August 2020.
PROBLEM DESCRIPTION	Philips determined that the insulation between conductors in the affected ***Switched*** Internal Paddles may break down over multiple use cycles. This is a failure mode that may not be detected by the existing tests identified in the Paddle Checks section of the Instructions for Use (IFU). Early signs of insulation breakdown can be detected by adding an insulation resistance test to the existing paddle checks for the Switched Internal Paddles only. Philips uses a common IFU with all models of sterilizable internal paddles (switched and switchless) and many users have both types of paddles. Consequently, Philips determined that all recipients of the common IFU should be notified and update their copies, even though the added test is recommended only for the switched internal paddles. All Internal Paddles wear out over time and may no longer perform as intended. By following the directions in the IFU to perform routine operational checks, users can ensure that their Internal Paddles are ready for use. These Paddle Check activities include Mechanical Check, Visual Inspection, Functional Check, Continuity Check, and Insulation Resistance Check. If one or more of these Paddle Checks fail, the IFU directs that the paddles should be removed from service and replaced.
HAZARD INVOLVED	A damaged Internal Switched Paddle may not be able to deliver a shock with the intended energy to the patient.

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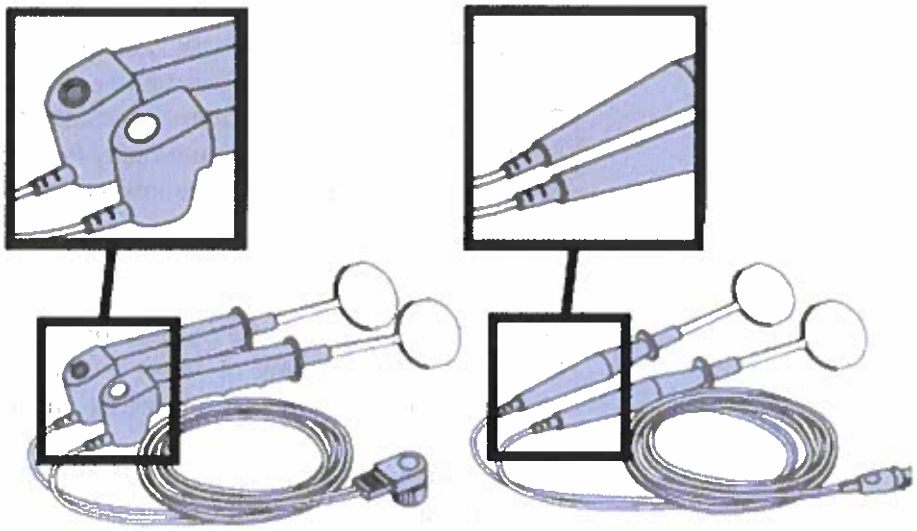
HOW TO IDENTIFY AFFECTED PRODUCTS	The model number of the Philips Switched and Switchless Internal Paddles with the product numbers identified above are affected by this notification.  Switched (left) and Switchless (right) Internal Paddles

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ACTION TO BE TAKEN BY CUSTOMER / USER	Insert a copy of the attached Instructions for Use Addendum: *Sterilizable Defibrillator Paddles: Insulation Resistance Check for Switched Internal Paddles* to the Sterilizable Defibrillator Paddles IFU. Follow the Instructions for Use, *Paddles Checks* section. The Paddle Checks activities include: Mechanical Check, Visual Inspection, Functional Check, Continuity Check, and Insulation Resistance Check. Perform these activities to confirm the paddles are safe and ready for use. The Insulation Resistance Test is to be applied only to Switched Internal Paddles (M4741A, M4742A, M4743A, and M4744A). Continue to perform the Paddles Checks activities as recommended in the IFU, before use as this reduces the risk of a failure as the paddles age. If your Internal Paddles fail any of these Paddle Checks, the IFU directs that the paddles should be removed from service and replaced. **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	Philips is providing this Medical Device Correction Notification and IFU Addendum to customers who have received the Instructions for Use for Sterilizable Defibrillator Paddles.
FURTHER INFORMATION AND SUPPORT	If you need further information or support concerning this notification, please contact your local Philips representative or call us at <Philips representative contact details to be completed by the KM / country>.

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Customer Reply for FSN86100222A

Please complete, sign, and return this form at your earliest convenience.

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

CUSTOMER ACKNOWLEDGEMENT

I certify the Field Safety Notification FSN86100222A and IFU Addendum was received, read, and understood by staff who may use the Switched Internal Paddles and that a copy has been placed with the Sterilizable Internal Paddles Instructions for Use.

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>.