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 Distributor,

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.

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.

It is imperative that all end-users with affected devices as identified in the "AFFECTED PRODUCTS" section of the Customer Information Letter, receive this Device Correction Notice. Because Philips sells these products through distributors, including your organization, we may not have the information to contact all users. Therefore, send a copy of the attached package to any customer to whom you have distributed the Sterilizable Defibrillator Paddles. Be sure to include the Customer Information Letter.

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Note: Philips has sent this notification to all customers to whom Philips shipped directly (i.e. customers in the "Ship To" field on the original invoice).

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 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,

Tanya DeSchmidt
Director, Quality, Emergency Care and Resuscitation

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Distributor 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:	

DISTRIBUTOR ACKNOWLEDGEMENT

☐ I acknowledge that I have reviewed and understand this Field Safety Notice.
I confirm that all customers are notified with the Switched Internal Paddles with model numbers listed above. I certify that the information in the Field Safety Notice is sent to all customers.

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>.