URGENT –Medical Device Recall
Philips Switched Reusable Internal Defibrillation Paddles (Product Numbers M4741A, M4742A, M4743A and M4744A)

Paddle shock switch may fail to actuate and delay or prevent delivery of defibrillation therapy

Dear Customer,

A problem has been detected in Philips Switched Reusable Internal Paddles (Product numbers M4741A, M4742A, M4743A and M4744A) manufactured from September 1, 2008 to December 30, 2008 that, if it were to occur, could delay or prevent the delivery of defibrillation energy, thereby posing a risk for patients requiring direct cardiac defibrillation, e.g., during or after open-chest procedures or in trauma resuscitation. This Field Safety Notice is intended to inform you about:

- What the problem is and under what circumstances it can occur
- Actions that should be taken by the customer/user in order to mitigate risks for patients/caregivers
- Actions planned by Philips 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. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

The discharge switch on the handle in affected devices may stick or fail to actuate and prevent the user from delivering defibrillation therapy. This was caused by a manufacturing defect in the paddle switch assembly. The affected devices were manufactured only between September 1, 2008 and December 30, 2008. The defect has been addressed and does not affect paddles produced outside of this date range. To eliminate the possibility of this issue impacting patient care, Philips will replace units within the date range free of charge.

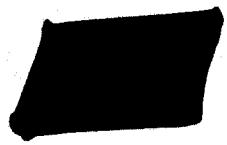
Please see the attached Field Safety Notice that provides information on how to identify affected devices and instructions on actions to be taken. Please follow the “ACTION TO BE TAKEN BY CUSTOMER / USER” section of the notice.

Should you have any questions or concerns about the Device Correction, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem. Ensuring that you have the highest quality medical devices, accessories and supporting documentation is our top priority. Your satisfaction with Philips products as well as with our response to this problem is very important to us.

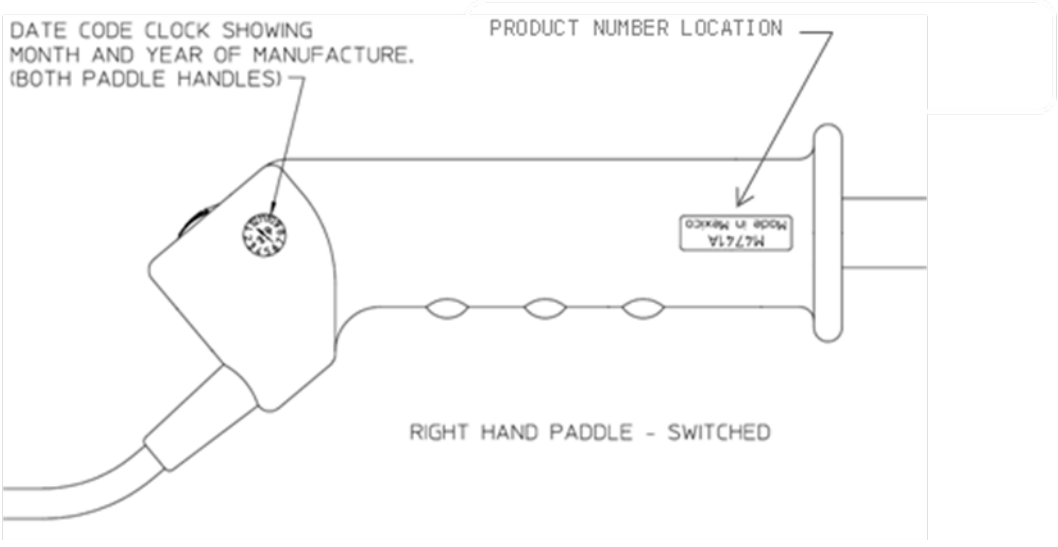
Sincerely,



[redacted]
General Manager, Emergency Care Solutions
Cardiac Care

Attachments

Field Safety Notice

AFFECTED PRODUCTS	**Product:** Philips Switched Reusable Internal Paddles, (Product Numbers M4741A, M4742A, M4743A, M4744A) **Units Affected:** Units manufactured by Philips between September 1, 2008 and December 30, 2008. **Manufactured by:** Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.
PROBLEM DESCRIPTION	The discharge switch on the handle in affected devices may stick or fail to actuate and prevent the user from delivering defibrillation therapy. This was caused by a manufacturing defect in the paddle switch assembly.
HAZARD INVOLVED	During open heart surgical procedures or during trauma resuscitation, the internal switched paddles are used to manually deliver shocks directly to the myocardium. If the paddle switch actuator sticks or fails to reset, defibrillation therapy may be prevented or delayed, particularly if a back-up paddle set is not readily available.
HOW TO IDENTIFY AFFECTED PRODUCTS	Units with date codes (mmyy) of 0908, 1008, 1108, 1208 (Units manufactured between September 1, 2008 and December 30, 2008) To identify an affected product, locate the date code clock at the wire end of the handle on either paddle. The year 2008 is represented as: **0↑8** and the arrow points to the month of manufacture 09, 10, 11 or 12.  September 2008  October 2008  November 2008  December 2008 

ACTION TO BE TAKEN BY CUSTOMER / USER	Immediately check all Switched Reusable Internal Paddle Sets for affected date codes and remove the affected products from service. Units manufactured outside of this date range (i.e. before September 1, 2008 AND after December 30, 2008) are not affected and can continue to stay in service. **Please complete and retain the following Customer Switched Internal Paddles Record Form** which will be used by you to communicate information regarding the switched internal paddles you have in the Affected Product section above. **Do not discard affected paddles**. A Philips Healthcare representative will contact you to confirm the quantity, product number type, date code (recorded on your record form) and schedule replacement of your affected paddles. Instructions for use recommend checking paddles to ensure that they are safe and ready for use. Please insure that the following occur: - Mechanical Check Before each use - Operational Check Before each use - Continuity Check Every 3 months
ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a removal of all affected internal paddles and will replace them free of charge. Philips will contact customers to retrieve information from the record form and to schedule shipment of replacement paddles to customers and provide customers with instructions on where and how to return affected paddles to Philips.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative <Philips representative contact details to be completed by the KM / country>.

Customer Switched Internal Paddles Record Form

Please complete and retain

This form is provided to allow your institution to make a record of affected paddles to inform Philips Healthcare of the amount, model, and date code of Switched Internal Paddles covered by Field Safety Notice (FSN86100088A). This Field Safety Notice recalls only certain switched internal paddles manufactured from 9/1/2008 to 12/30/2008 with defective switches. Please refer to the instructions outlined in the notice, indicate below the number of affected switched internal paddles in your inventory. If you do not have any affected switched internal paddles (i.e. those models indicated in the FSN manufactured between 9/1/2008 and 12/30/2008), please indicate in the space provided below. A Philips Healthcare representative will contact you to confirm the quantity, type, date code, and schedule replacement of your affected paddles.

☐ We have inspected our products as instructed in the Field Safety Notice and we **have** the following affected Internal Switched Paddles

Product Number	Diameter	Number of Affected Internal Switched Paddles taken out of service requiring replacement
M4741A	7.5cm (3.0”) Adult	9/08 _____ 10/08 _____ 11/08 _____ 12/08 _____
M4742A	6.0cm (2.4”) Adult	9/08 _____ 10/08 _____ 11/08 _____ 12/08 _____
M4743A	4.5cm (1.8”) Pediatric	9/08 _____ 10/08 _____ 11/08 _____ 12/08 _____
M4744A	2.8cm (1.1”) Infant	9/08 _____ 10/08 _____ 11/08 _____ 12/08 _____

☐ We have inspected our products as instructed in the Field Safety Notice and we **do not have** any affected Internal Switched Paddles

Note: Philips Healthcare will process 1-for-1 new replacement paddles with corrected switches for only affected product. Upon receipt of replacement switched internal paddles, the affected internal switched paddles will be destroyed by a Philips Healthcare representative.