URGENT - Medical Device Correction

Efficia Combined Cable/3-Leadset Grabber, AAMI
Efficia Combined Cable/3-Leadset Grabber, IEC
Efficia Combined Cable/3-Leadset Snap, AAMI
Efficia Combined Cable/3-Leadset Snap, IEC
Efficia Combined Cable/5-Leadset Grabber, AAMI
Efficia Combined Cable/5-Leadset Grabber, IEC
Efficia Combined Cable/5-Leadset Snap, AAMI
Efficia Combined Cable/5-Leadset Snap, IEC

Possible Reduction of Defibrillation Energy Delivered or Failure to Deliver Defibrillation Energy and Possible Electric Shock Hazard

Dear Customer,

A problem has been detected in the Philips Efficia Combined Cable/3 or 5 Leadsets ("Efficia Combined Cable/Leadsets") that, if it were to re-occur, could pose a risk for patients and users. This Field Safety Notice is intended to inform you about:

- What the problem is and under what circumstances it can occur.
- The actions that should be taken by the customer / user in order to prevent risks for patients and users.
- The actions planned by Philips to correct 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 Instructions for Use.

During use of Efficia Combined Cable/Leadsets, if the patient required electrical energy for defibrillation or cardioversion, it is possible for some of the energy to be diverted away from the patient's thoracic cavity through the ECG cable. This could result in reduction of defibrillation energy delivered to the patient, or failure to deliver defibrillation energy to the patient. During defibrillation, there is also a possibility of an unintentional electrical shock hazard to the patient and/or clinician. For the patient, this hazard may be present if the Efficia Combined Cable/Leadset remains connected to the electrodes on the patient during the delivery of therapy. For the clinician, this hazard may be present if the clinician is touching the cable during defibrillation. The issue is present due to manufacturing variability during assembly of the cables.

Our records indicate that you may have an affected Efficia Combined Cable/Leadsets. The following page provides additional instructions and actions to be taken. If you need any further information or support concerning this problem, 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 Agency. Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Christine Trefethen
Head of Quality & Regulatory, Medical Consumables and Sensors

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AFFECTED PRODUCTS

Part Number	Part Description
989803160731	Efficia Combined Cable/3-Leadset Grabber, AAMI
989803160741	Efficia Combined Cable/3-Leadset Grabber, IEC
989803160751	Efficia Combined Cable/3-Leadset Snap, AAMI
989803160761	Efficia Combined Cable/3-Leadset Snap, IEC
989803160771	Efficia Combined Cable/5-Leadset Grabber, AAMI
989803160781	Efficia Combined Cable/5-Leadset Grabber, IEC
989803160791	Efficia Combined Cable/5-Leadset Snap, AAMI
989803160801	Efficia Combined Cable/5-Leadset Snap, IEC

All cables currently in distribution are affected. The Efficia Combined Cable/Leadsets are for use with G30E, G40E, DFM 100 and Efficia CM series monitors.

PROBLEM DESCRIPTION

During use of Efficia Combined Cable/Leadsets, if the patient required electrical energy for defibrillation or cardioversion, it is possible for some of the energy to be diverted away from the patient's thoracic cavity through the ECG cable. This could result in reduction of defibrillation energy delivered to the patient, or failure to deliver defibrillation energy to the patient. During defibrillation, there is also a possibility of an unintentional electrical shock hazard to the patient and/or clinician. For the patient, this hazard may be present if the Efficia Combined Cable/Leadset remains connected to the electrodes on the patient during the delivery of therapy. For the clinician, this hazard may be present if the clinician is touching the cable during defibrillation. The issue is present due to manufacturing variability during assembly of the cables.

HAZARD INVOLVED

Reduction of defibrillation energy delivered to the patient, or failure to deliver defibrillation energy to the patient. Potential unintentional electrical shock to the clinician or patient during defibrillation. The hazard may be present for the clinician only if the clinician is touching the cable during defibrillation.

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HOW TO IDENTIFY AFFECTED PRODUCTS	Locate all Efficia Combined Cable/Leadsets (part numbers 989803160731, 989803160741, 989803160751, 989803160761, 989803160771, 989803160781, 989803160791, 989803160801) in your facility. The picture to the right depicts the location of the part number on each product. 
ACTION TO BE TAKEN BY CUSTOMER / USER	Affected cables can continue to be used for monitoring until replacement cables are received. Should a patient require defibrillation or synchronized cardioversion, disconnect the Efficia Combined Cable/Leadset from the electrodes on the patient prior to the delivery of therapy. 1. Identify all affected Efficia Combined Cable/Leadsets in your facility using the instructions provided in the **HOW TO IDENTIFY AFFECTED PRODUCTS** section above. 2. Fill out the reply form provided on the last page of this letter. 3. Sign the reply form provided on the last page of this letter. 4. Send the completed and signed reply form to Philips via the contact information located on the form. 5. Dispose of all affected Efficia Combined Cable/Leadsets in your inventory in accordance with your local regulations once replacement cables are received. Please do not return any affected product to Philips.
ACTIONS PLANNED BY PHILIPS	Philips will replace all affected Efficia Combined Cable/Leadsets free of charge. Upon receipt of the completed and signed reply form, an order for replacement product will be entered and shipped to the address provided on the reply form.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this problem, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>.

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Reply Form

Upon receipt of the completed and signed reply form, an order for replacement product will be entered and shipped to the address provided below.

Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address City, State/Country Zip or Postal Code:	

Please check one option below:

☐ **Our facility does not have any affected inventory of these products.** *(Please sign below.)*

☐ **Our facility has affected inventory of these products.** *(Please complete the table and sign below.)*

	Total number of cables in inventory/scrapped/needing replacement
989803160731 (Efficia Combined Cable/3-Leadset Grabber, AAMI)	
989803160741 (Efficia Combined Cable/3-Leadset Grabber, IEC)	
989803160751 (Efficia Combined Cable/3-Leadset Snap, AAMI)	
989803160761 (Efficia Combined Cable/3-Leadset Snap, IEC)	
989803160771 (Efficia Combined Cable/5-Leadset Grabber, AAMI)	
989803160781 (Efficia Combined Cable/5-Leadset Grabber, IEC)	
989803160791 (Efficia Combined Cable/5-Leadset Snap, AAMI)	
989803160801 (Efficia Combined Cable/5-Leadset Snap, IEC)	

I certify that our facility did not have any affected inventory of the Efficia Combined Cable/Leadsets. *–or–* I certify that users have been notified that affected Efficia Combined Cable/Leadsets should be disconnected from the electrodes on the patient prior to the delivery of therapy. I certify that our facility will dispose of all affected Efficia Combined Cable/Leadsets in our inventory once replacement cables are received.

Signature: _____ Date: _____

Please return the completed and signed reply form to: <Reply form return details to be completed by the KM / country>.