

<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN

CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Change Order pertaining to the Efficia 3/5 ECG Trunk Cable, AAMI/IEC due to FCO 86400024. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: Not applicable

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date:

URGENT - Medical Device Correction Efficia 3/5 ECG Trunk Cable, AAMI/IEC

Possible Reduction of Defibrillation Energy Delivered or Failure to Deliver Defibrillation Energy

Dear Customer,

A problem has been detected in the Philips Efficia 3/5 ECG Trunk Cable, AAMI/IEC ("Efficia ECG Trunk Cable") that, if it were to re-occur, could pose a risk for patients. 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
- 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 Instruction for Use.

During use of certain Efficia ECG Trunk Cables, 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 a reduction in defibrillation energy delivered to the patient. In addition, it is possible for the patient to not receive defibrillation therapy as expected.

Our records indicate that you may have an affected Efficia ECG Trunk Cable. 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,






Rusty Kelly
Head of Quality & Regulatory
Medical Consumables and Sensors

URGENT - Medical Device Correction
Efficia 3/5 ECG Trunk Cable, AAMI/IEC**Possible Reduction of Defibrillation Energy Delivered or Failure to Deliver
Defibrillation Energy**

AFFECTED PRODUCTS	Part Number: 989803160641 Part Description: Efficia 3/5 ECG Trunk Cable, AAMI/IEC Affected cables were produced from February 2014 through September 2018
PROBLEM DESCRIPTION	During use of certain Efficia ECG Trunk Cables, 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 a reduction in defibrillation energy delivered to the patient. In addition, it is possible for the patient to not receive defibrillation therapy as expected.
HAZARD INVOLVED	Reduction of defibrillation energy delivered to the patient, or failure to deliver defibrillation energy to the patient. There is no risk of external electrical exposure to the caregiver.

URGENT - Medical Device Correction
Efficia 3/5 ECG Trunk Cable, AAMI/IEC

Possible Reduction of Defibrillation Energy Delivered or Failure to Deliver Defibrillation Energy

HOW TO IDENTIFY AFFECTED PRODUCTS	Step	Action	Supporting Picture
	1	Locate all Efficia ECG Trunk Cables (part number 989803160641) in your facility. The picture to the right depicts the location of the part number on the product.	
	2	Review the lot number dial of each cable. The picture to the right depicts the location of lot number dial on the cable. The twelve numbers around the outside of the dial represent the twelve months of the year. The number located in the middle of the dial represents the last two digits of the year. The dial's arrow points to the month in which the cable was produced. The lot number of the cable in the picture to the right is 0118 (January 2018). Cables produced from February 2014 through September 2018 are potentially affected. Lot numbers outside of this range are NOT affected.	
	3	For Efficia ECG Trunk Cables in your facility produced from February 2014 through September 2018, look for the presence of an "HP" label applied to the cable. Cables bearing the "HP" label are NOT affected (see picture to the right). Cables not bearing the "HP" label that were produced from February 2014 through September 2018 ARE affected.	

URGENT - Medical Device Correction

Efficia 3/5 ECG Trunk Cable, AAMI/IEC

Possible Reduction of Defibrillation Energy Delivered or Failure to Deliver Defibrillation Energy

ACTION TO BE TAKEN BY CUSTOMER / USER	<ol style="list-style-type: none"> 1. Identify all affected Efficia ECG Trunk Cables in your facility using the instructions provided in the HOW TO IDENTIFY AFFECTED PRODUCTS section above. 2. Discontinue use of all affected Efficia ECG Trunk Cables. 3. Fill out and 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 ECG Trunk Cables in your inventory in accordance with your local regulations. Please do not return any affected product to Philips. <p><i>Please return the reply form, even if you do not have any inventory of the affected Efficia ECG Trunk Cables.</i></p>
ACTIONS PLANNED BY PHILIPS	<p>Philips will replace all affected Efficia ECG Trunk Cables 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.</p>
FURTHER INFORMATION AND SUPPORT	<p>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>.</p>

**URGENT - Medical Device Correction
Efficia 3/5 ECG Trunk Cable, AAMI/IEC**

**Possible Reduction of Defibrillation Energy Delivered or Failure to Deliver
Defibrillation Energy**

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 Zip:	

Please check one option below:

- Our facility does not have any affected inventory of this product. *(Please sign below.)*
- Our facility has affected inventory of this product. *(Please complete the table and sign below.)*

	989803160641 (Efficia 3/5 ECG Trunk Cable, AAMI/IEC) Produced in February 2014 through September 2018 No "HP" label
Total number of cables in inventory/scrapped/needng replacement	

I certify that our facility did not have any affected inventory of the 989803160641 (Efficia 3/5 ECG Trunk Cable, AAMI/IEC) –or– that our facility has disposed of all affected 989803160641 (Efficia 3/5 ECG Trunk Cable, AAMI/IEC) in our inventory.

Signature: _____ Date: _____

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

If you experience difficulty in carrying out the instructions contained in this communication, contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>.