

## **URGENT - Medical Device Correction**

### **Efficia 3/5 ECG Trunk Cable, AAMI/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 3/5 ECG Trunk Cable, AAMI/IEC ("Efficia ECG Trunk Cable") 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 Instruction for Use.

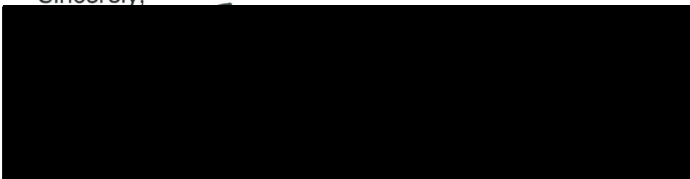
During use of certain Efficia ECG Trunk Cables, if the patient required electrical energy for defibrillation or cardioversion, it is possible for some of the energy to be diverted away from the patient's thoracic cavity through the ECG cable. This could result in reduction of defibrillation energy delivered to the patient, or failure to deliver defibrillation energy to the patient. There is also a possibility of an unintentional electrical shock hazard to the clinician and/or patient during defibrillation.

*NOTE: Philips had previously issued FSN86400024A to address one issue with the product (possible reduction of defibrillation energy delivered to the patient, or failure to deliver defibrillation energy to the patient). A second issue in the product has since been identified (possible electrical shock hazard). The result is this action (FSN86400029A), which supersedes FSN86400024A.*

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,



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### Efficia 3/5 ECG Trunk Cable, AAMI/IEC

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

<b>AFFECTED PRODUCTS</b>	Part Number: 989803160641 Part Description: Efficia 3/5 ECG Trunk Cable, AAMI/IEC All cables produced in the years 2014 through 2018											
<b>PROBLEM DESCRIPTION</b>	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 reduction of defibrillation energy delivered to the patient, or failure to deliver defibrillation energy to the patient. There is also a possibility of an unintentional electrical shock hazard to the clinician and/or patient during defibrillation.											
<b>HAZARD INVOLVED</b>	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.											
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<table><tr><th>Step</th><th>Action</th><th>Supporting Picture</th></tr><tr><td>1</td><td>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.</td><td><p>PN 989803160641</p></td></tr><tr><td>2</td><td>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). All cables produced in the years 2014 through 2018 are affected.</td><td><p>LOT: 0118</p></td></tr></table>			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.	 <p>PN 989803160641</p>	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). All cables produced in the years 2014 through 2018 are affected.	  <p>LOT: 0118</p>
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Defibrillation Energy and Possible Electric Shock Hazard**

<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	<ol style="list-style-type: none"><li>1. Identify all affected Efficia ECG Trunk Cables in your facility using the instructions provided in the <b>HOW TO IDENTIFY AFFECTED PRODUCTS</b> section above.</li><li>2. Discontinue use of all affected Efficia ECG Trunk Cables.</li><li>3. Fill out and sign the reply form provided on the last page of this letter.</li><li>4. Send the completed and signed reply form to Philips via the contact information located on the form.</li><li>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.</li></ol> <p><b>NOTE:</b> <i>If you responded to the previous action taken by Philips related to this product (FSN86400024A), please re-review your cable inventory and determine if you have any additional cables affected by this action. Please return the reply form for this action (FSN86400029A), even if you do not have any additional inventory of the affected Efficia ECG Trunk Cables.</i></p>
<b>ACTIONS PLANNED BY PHILIPS</b>	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.
<b>FURTHER INFORMATION AND SUPPORT</b>	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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**Efficia 3/5 ECG Trunk Cable, AAMI/IEC****Possible Reduction of Defibrillation Energy Delivered or Failure to Deliver  
Defibrillation Energy and Possible Electric Shock Hazard****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.)*

	<b>Part Number 989803160641</b> <b>Efficia 3/5 ECG Trunk Cable, AAMI/IEC</b> <b>Produced in the years 2014 through 2018</b>
Total number of cables in inventory/scrapped/needing 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>.