

<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 Corrective Order pertaining to the <product name> due to FCO XXXXXXXX . Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: XXXXXX, XXXXXX, XXXXXXXX, XXXXXX

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 – Recall Notice
Philips Network Firewall (Cisco ASA 5506)**

Firewall installed with Philips IntelliVue Information Center iX or Information Center Classic may have a defective component, which may result in loss of connection to the Information Center iX

Dear Customer,

A problem has been detected with the Cisco Adaptive Security Appliance (ASA) 5506 firewall that is installed with the Philips IntelliVue Information Center iX and the Information Center Classic. Philips markets the Cisco ASA 5506 as the 867098 Philips Network Firewall. 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 or 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.

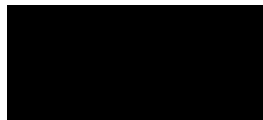
The defect involves the clock signal component within the firewall. This component has a high probability of failing in appliances that have been running for greater than 18 months. If the clock signal component were to fail, the firewall will stop functioning, will not boot, and is not recoverable.

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>.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

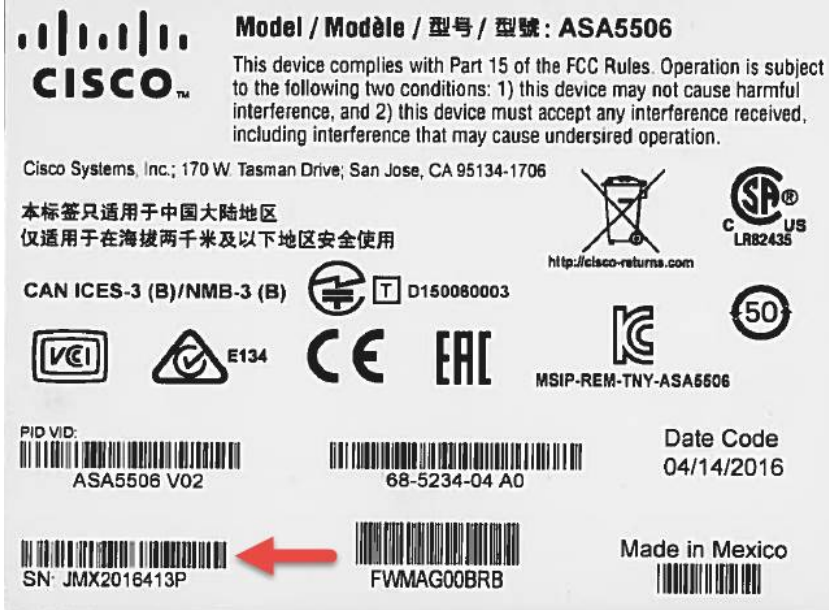












Sincerely,



Kristen Phillips
Head of Quality and Regulatory

Patient Monitoring Andover

AFFECTED PRODUCTS	Philips Network Firewall 867098 (Cisco ASA 5506 Firewall) used with the Philips IntelliVue Information Center iX or Classic Information Center.
PROBLEM DESCRIPTION	The defect involves the clock signal component within the firewall. This component has a high probability of failing in appliances that have been running for greater than 18 months. If the clock signal component were to fail, the firewall will stop functioning, will not boot, and is unable to recover from the component failure. This failure will result in a loss of communication between devices that are separated by the firewall, which may cause the Information Center to reboot.
HAZARD INVOLVED	If a patient experiences an event requiring intervention while the Information Center application is restarting, there is a potential for a delay in responding to the patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>In order to verify if your Cisco Adaptive Security Appliance (ASA) is affected by this issue, examine the serial number for the Cisco firewall</p> <p>Any appliance with a serial number less than JMX2050000 are affected.</p> <p>There are two ways to obtain the serial number: the command line interface (CLI) and visual examination of the chassis.</p> <p>Using Command Line Interface</p> <p>Enter the show inventory command in order to obtain the Serial Number of the appliance (show in bold below):</p> <pre>asa> show inventory</pre> <p>Name: "Chassis", DESCR: "ASA 5508-X with FirePOWER services, 8GE, AC, DES"</p> <p>PID: ASA5506 , VID: V01 , SN: JMX1234ABCD</p>

<p>HOW TO IDENTIFY AFFECTED PRODUCTS (cont)</p>	<p>Visual Inspection of the ASA Security Appliance</p> <p>The serial number label is located on the bottom surface of the appliance as highlighted in the image below.</p>  <p>Model / Modèle / 型号 / 型號 : ASA5506</p> <p>This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesired operation.</p> <p>Cisco Systems, Inc.; 170 W. Tasman Drive; San Jose, CA 95134-1706</p> <p>本标签只适用于中国大陆地区 仅适用于在海拔两千米及以下地区安全使用</p> <p>CAN ICES-3 (B)/NMB-3 (B)  T D150080003</p> <p>      MSIP-REM-TNY-ASA5506</p> <p>PID VID:  ASA5506 V02  68-5234-04 A0 Date Code 04/14/2016</p> <p> SN: JMX2016413P  FWMAG00BRB  Made in Mexico</p>
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>No customer action is required.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips representatives will contact affected customers to arrange for replacement of all affected units supplied by Philips.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>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>.</p>