

<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 Philips DigitalDiagnost C50 System due to FCO 71200191. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: <serial number>

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:

DXR Suzhou

FSN MA-FCO 71200191

11-DEC-2018

URGENT — Medical Device Correction DigitalDiagnost C50 Missing Label

Dear Customer,

As part of Philips' focus on reliability and safety, we continuously monitor the performance of our products. During recent evaluations of the Philips DigitalDiagnost C50 system, we identified a missing label. This letter is intended to provide you with information regarding:

- what the issue is, and relevant affected product.
- the actions you required to be taken
- the actions planned by Philips to correct the issue

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.

If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Customer Service: 1-800-722-9377.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Li, Xin
Q&R Director, IS China

DXR Suzhou

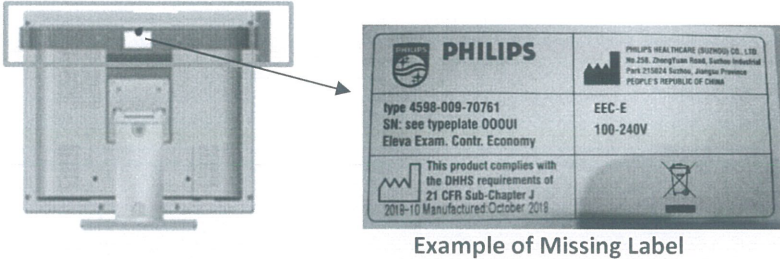
FSN MA-FCO 71200191

11-DEC-2018

URGENT — Medical Device Correction
DigitalDiagnost C50
Missing Label

Important

Electronic Product Radiation Warning

AFFECTED PRODUCTS	DigitalDiagnost C50 systems Product Number: 712201						
PROBLEM DESCRIPTION	A label is missing on the Eleva Examination Control of DigitalDiagnost C50 in Puerto Rico.  <p style="text-align: center;">Example of Missing Label</p>						
HAZARD INVOLVED	There is no impact on clinical use and no hazard involved due to a missing label for identification only.						
HOW TO IDENTIFY AFFECTED PRODUCTS	Following DigitalDiagnost C50 system serial numbers (SN) are affected, which you could find on the system label pasted on the tube assembly cover. <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Product Number</th> <th>System Serial Number</th> </tr> </thead> <tbody> <tr> <td>712201</td> <td></td> </tr> <tr> <td>712201</td> <td></td> </tr> </tbody> </table>	Product Number	System Serial Number	712201		712201	
Product Number	System Serial Number						
712201							
712201							
ACTION TO BE TAKEN BY CUSTOMER / USER	No action is required to be taken by Customer/User. The devices continues to meet functionality and performance requirements. The missing label does not affect clinical use.						
ACTIONS PLANNED BY PHILIPS	Philips will implement field action FCO71200191 as to address this issue, free of charge. A Philips Service Engineer will contact you when the Field Action Kit is available to be implemented.						
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. Please reference FCO71200191 when contacting your local Philips representative.						

The manufacture will, without charge, remedy the defect or bring the product into compliance with each applicable Federal standard in accordance with a plan to be approved by the Secretary of Health and Human Services, the details of which will be included in a subsequent communication to you.