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URGENT – Field Safety Notice

CombiDiagnost R90/ProxiDiagnost N90
Missing Warning Labels

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.

October 2021

Dear Customer,

Philips has identified an issue with the Philips CombiDiagnost R90 and ProxiDiagnost N90 systems. This Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

X-ray warning label(s) are missing from the Eleva Examination Console on CombiDiagnost C90 and ProxiDiagnost N90 systems. Regulations require that these labels be affixed to the system. The location and content of where the labels should be affixed are shown in Figure 1 and Table 1.

Figure 1. Label Locations

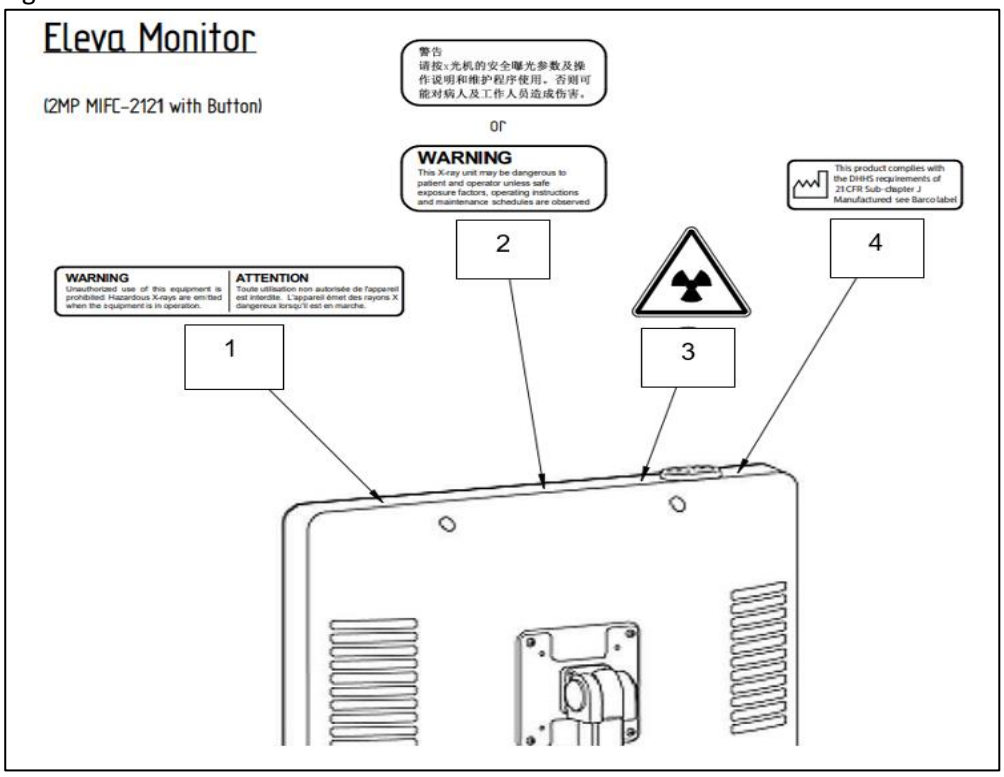

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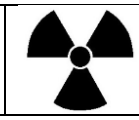
Table 1. Detailed label content and associated Regulation

Label #	Label Description	Regulation
Label 1	Warning Label Canada: WARNING Unauthorized use of this equipment is prohibited. Hazardous X-rays are emitted when the equipment is in operation. ATTENTION *I<Identical warning in french language>*	Canada: C.R.C., c. 1370, part 12
Label 2	Radiation warning label (U.S.A): WARNING This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.	FDA 21CFR 1020.30 (j)
Label 3	X-Ray Label 	Canada: C.R.C., c. 1370, part 12
Label 4	DHHS Label: This product complies with the DHHS requirements of 21 CFR Sub-chapter J	FDA 21CFR 1002 requires labeling of certifiable items

2. Describe the hazard/harm associated with the issue

There is no safety risk to patients or users associated with this issue. There have been no complaints or adverse events reported to Philips as of September 2021.

3. Affected products and how to identify them

If you are receiving this letter, your CombiDiagnost R90 or Proxidiagnost N90 systems may have monitors that are missing labels. Potentially impacted models are listed Table 2 and Figure 2 shows how to identify your model number.

Figure 2. System Label Example

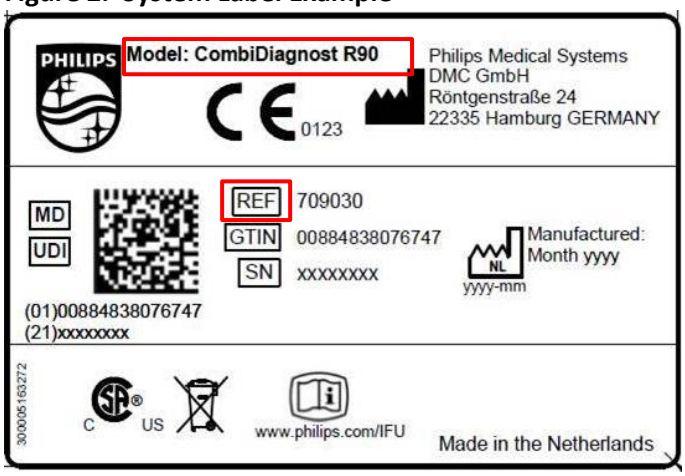


Table 2. Affected Systems

Model	Model Number
CombiDiagnost R90	709030
CombiDiagnost R90	709031
ProxiDiagnost N90	706100

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4. **Describe the actions that should be taken by the customer / user in order to prevent risks for patients or users**

   There is no safety risk to patients or users associated with this issue. You may continue to use the device according to its intended use.

   Please complete and return the attached acknowledgment form to Philips DXR promptly upon receipt and no later than 30 days from receipt via email to: DIFCO@philips.com.

5. **Describe the actions planned by Philips DXR to correct the problem**

   A Philips Field Service Engineer (FSE) will visit your site to check for the required labels and if they are missing, will resolve the issue by applying the required labels on your CombiDiagnost R90 and ProxiDiagnost N90 system(s).

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, or by fax.

The manufacturer 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 are communicated in this letter.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this issue, please contact your local Customer Care Solutions Center and reference FCO-70900056 (CombiDiagnost R90 or FCO-70600107 (ProxiDiagnost N90.

Sincerely,

David H 06oct2021

David Hanly
Quality Leader

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Field Safety Notice Response Form

Reference: System label update, CombiDiagnost R90, FCO-70900056 or ProxiDiagnost N90, FCO-70600107

Instructions: Please complete and return this form to Philips promptly upon receipt and no later than 30 days from receipt. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:
There is no safety risk to patients or users associated with this issue. You may continue to use the system according to its intended use.

We acknowledge receipt and understanding of the accompanying Electronic Product Radiation Correction letter and confirm that the information from this notification has been properly distributed to all CombiDiagnost R90 and ProxiDiagnost N90 users.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please complete and return the attached acknowledgment form to Philips DXR via email to: DIFCO@philips.com.