

URGENT Field Safety Notice

CombiDiagnost R90 and ProxiDiagnost N90

Component damage due to short circuit & table stop due to broken tabletop cable

February 2023

Dear Distributor,

Philips is initiating a Field Safety Corrective Action due to a problem identified in the Philips CombiDiagnost R90 and ProxiDiagnost N90 systems that could pose a risk for patients, users and bystanders.

It is imperative that all customers with affected products receive the attached URGENT Field Safety Notice that informs about:

- The problem and under what circumstances it can occur
- The actions that the customer/user should take to prevent risk for patients/users/bystanders
- The actions planned by Philips to correct the problem

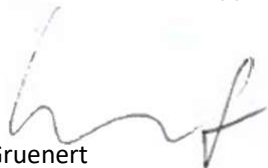
Philips is requesting customers to return a Response Form to acknowledge receipt and understanding of the URGENT Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected product.

Together with this letter we are providing a list of affected products that Philips has sold to your organization. As distributor of the affected products, we kindly request that you:

- Submit this Field Safety Corrective Action to the Regulatory Agency. In case of any inquiries from the Regulatory Agency, contact Philips.
- Add in the Response Form attached your contact information.
- Send the attached Field Safety Notice to each customer to whom you have distributed any affected product as soon as possible and no later than 30 days, together with the Response Form.
- Perform a good faith effort to get the Response Form (3 notification attempts) and inform Philips about the responses received.
- Implement the Technical solution established by Philips as soon as available within the timeframe communicated by Philips and confirm Philips the implementation in all affected products. In case a product is not corrected, inform Philips on the reason why the technical solution cannot be implemented.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your Philips representative.

Sincerely,



Karmen Gruenert
Head of Diagnostic X-Ray (DXR) Quality and Regulatory