

URGENT - Field Safety Notice ProxiDiagnost N90

System software update (improved dose rate control and improved Lock-in functionality)

Dear Customer,

As part of Philips's continuous focus on reliability and safety, we continuously monitor the performance of our products. During recent evaluations of Philips ProxiDiagnost N90, we have identified a potential issue that, may affect the performance of the equipment under certain conditions:

- what the issue is, and under what circumstances it can occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Philips to correct the issue.

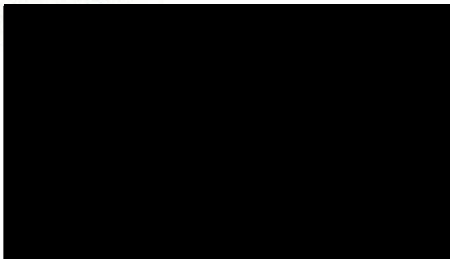
This document contains important information for the continued safe and proper use of your equipment

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:

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.



URGENT - Field Safety Notice






















ProxiDiagnost N90

System software update (improved dose rate control and improved Lock-in functionality)

AFFECTED PRODUCTS	ProxiDiagnost N90 systems with software version 1.0.4 and 1.0.5																																	
PROBLEM DESCRIPTION	<p>Issue A: Under the specific use conditions described below, a malfunction of the automatic dose rate control (automatic exposure control – AEC) may cause the system to stabilize at a higher dose rate than necessary. Under no condition will the stabilized dose rate exceed the design limit of 88 mGy/min (10 R/min). The following settings are affected:</p> <ul style="list-style-type: none">During continuous fluoroscopy, the malfunction occurs at 20x20 cm (8x8 inch) and at 15x15 cm (6x6 inch) image format in combination with the large center AEC field.During grid-controlled fluoroscopy (GCF) with a frame rate of 30 fps, the malfunction occurs at 20x20 cm (8x8 inch) and at 15x15 cm (6x6 inch) image format in combination with the large center AEC field.During grid controlled fluoroscopy (GCF) with a frame rate of 20 fps(*), the malfunction occurs at 30x30 cm (12x12 inch), 20x20 cm (8x8 inch) and at 15x15 cm (6x6 inch) in combination with different AEC field selections. <p>Overview of affected settings:</p> <table><tr><th>Fluoroscopy mode</th><th>Frame rate</th><th colspan="2">Image format</th><th>AEC field</th></tr><tr><td rowspan="2">Continuous fluoroscopy</td><td rowspan="2"></td><td>15x15 cm</td><td>6x6 inch</td><td>Large center</td></tr><tr><td>20x20 cm</td><td>8x8 inch</td><td>Large center</td></tr><tr><td rowspan="7">Grid controlled fluoroscopy (GCF)</td><td rowspan="2">30 fps</td><td>15x15 cm</td><td>6x6 inch</td><td>Large center</td></tr><tr><td>20x20 cm</td><td>8x8 inch</td><td>Large center</td></tr><tr><td rowspan="5">20 fps(*)</td><td>15x15 cm</td><td>6x6 inch</td><td>Large center</td></tr><tr><td>20x20 cm</td><td>8x8 inch</td><td>Large center</td></tr><tr><td rowspan="3">30x30 cm</td><td rowspan="3">12x12 inch</td><td>Large center</td></tr><tr><td>Side all</td></tr><tr><td>All measuring fields</td></tr></table> <p>(*)20 fps is not a default setting.</p> <p>All other combinations are not affected and work as described in the instructions for use.</p> <p>Issue B: After the user selects the Lock-in command, the kV and mA values are not locked immediately and can change if the collimator shutter position is changed directly after the Lock-in command. This will lead to a change of technique factors. If the user stops and restarts fluoroscopy then the Lock-in works as specified and collimation can be changed to the needs of the examination.</p>	Fluoroscopy mode	Frame rate	Image format		AEC field	Continuous fluoroscopy		15x15 cm	6x6 inch	Large center	20x20 cm	8x8 inch	Large center	Grid controlled fluoroscopy (GCF)	30 fps	15x15 cm	6x6 inch	Large center	20x20 cm	8x8 inch	Large center	20 fps(*)	15x15 cm	6x6 inch	Large center	20x20 cm	8x8 inch	Large center	30x30 cm	12x12 inch	Large center	Side all	All measuring fields
Fluoroscopy mode	Frame rate	Image format		AEC field																														
Continuous fluoroscopy		15x15 cm	6x6 inch	Large center																														
		20x20 cm	8x8 inch	Large center																														
Grid controlled fluoroscopy (GCF)	30 fps	15x15 cm	6x6 inch	Large center																														
		20x20 cm	8x8 inch	Large center																														
	20 fps(*)	15x15 cm	6x6 inch	Large center																														
		20x20 cm	8x8 inch	Large center																														
		30x30 cm	12x12 inch	Large center																														
				Side all																														
				All measuring fields																														
HAZARD INVOLVED	<p>Issue A: Additional radiation dose to the patient</p> <p>Issue B: Additional radiation dose to the patient</p>																																	
HOW TO IDENTIFY AFFECTED PRODUCTS	ProxiDiagnost N90 systems with software version 1.0.4 and 1.0.5																																	

URGENT - Field Safety Notice ProxiDiagnost N90

System software update (improved dose rate control and improved Lock-in functionality)

ACTION TO BE TAKEN BY CUSTOMER / USER	<p>User should discontinue the use of fluoroscopy on the affected systems. Radiography can continue to be used.</p> <p>If discontinuing the use of fluoroscopy is not an option, the system can be used safely under the following conditions to avoid the issue during fluoroscopy: (Print out this guidance and place next to the ProxiDiagnost N90 user interface)</p> <p>Issue A:</p> <ol style="list-style-type: none"> 1) Use pulsed fluoroscopy at 15 fps or lower. Always select the lowest appropriate frame speed for fluoroscopy. 2) Do not use the 20x20 cm (8x8 inch) or the 15x15 cm (6x6 inch) format during continuous fluoroscopy in combination with the large center AEC field. Instead, use small center AEC field as described below. 3) Do not use the 20x20 cm (8x8 inch) or the 15x15 cm (6x6 inch) format during grid controlled fluoroscopy (GCF) at 30 fps or 20 fps in combination with the large center AEC field. Instead, use small center AEC field as described below. 4) For dynamic swallow studies use small center AEC field as described below. <p><u>How to use small center AEC field:</u> The small center AEC field will be selected automatically by the system as soon as the user collimates laterally, or it can be selected explicitly by selecting it via the clinical user interface. Small center AEC field can also be stored in the EPX database. Afterwards, this AEC field will automatically be selected with the examination, and the automatic dose rate control will perform as specified. Further information about AEC field selection can be found in the IfU.</p> <table border="1" data-bbox="1061 857 1458 1603"> <thead> <tr> <th>Symbol</th><th>Meaning</th></tr> </thead> <tbody> <tr> <td></td><td>Small centre field</td></tr> <tr> <td></td><td>Large centre field</td></tr> <tr> <td></td><td>Upper side fields</td></tr> <tr> <td></td><td>Upper side and centre fields</td></tr> <tr> <td></td><td>Middle vertical fields</td></tr> <tr> <td></td><td>Upper and lower side fields</td></tr> <tr> <td></td><td>All measuring fields</td></tr> </tbody> </table> <p>Source from IfU</p> <p>Issue B:</p> <ol style="list-style-type: none"> 1) Stop fluoroscopy after Lock-in selection before changing collimation. Collimation can also be changed on the Last Image Hold (LIH) image. 2) Following Lock-in selection, monitor kV and mA. If values change, then unlock and lock kV-mA again. 	Symbol	Meaning		Small centre field		Large centre field		Upper side fields		Upper side and centre fields		Middle vertical fields		Upper and lower side fields		All measuring fields
Symbol	Meaning																
	Small centre field																
	Large centre field																
	Upper side fields																
	Upper side and centre fields																
	Middle vertical fields																
	Upper and lower side fields																
	All measuring fields																
ACTIONS PLANNED BY PHILIPS	<p>Philips will release Field Change Order (FCO) FCO70600104, which includes updated system software that resolves the discussed issues. Should you need to communicate with Philips regarding this update, please reference Field Change Order 70600104.</p>																

DXR

Quality Management System DXR

DXR Field Safety Notice

FSN MA-FCO-70600104

2020-December-08

URGENT - Field Safety Notice ProxiDiagnost N90

System software update (improved dose rate control and improved Lock-in functionality)

FURTHER INFORMATION AND SUPPORT

If you need any further information or support concerning this issue, please contact your local Philips representative.

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 will be included in a subsequent communication to you.