URGENT – Medical Device Correction
Extended Brilliance Workstation - NM

MUGA study ejection fraction result may be incorrect

Dear Customer,

A problem has been detected in the Philips Multiple Gated Radionuclide Angiocardiography (MUGA) application on the Extended Brilliance Workstation – NM that if it were to re-occur, could pose a risk for patients. This Field Safety Notice 88200413 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
- 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.

For customers in North America if you need any further information or support concerning this issue, please contact our Customer Care Solutions Center at 1-800-722-9377. Select option 5 for "All Imaging Systems". Enter your site ID # (If you do not have a site ID #, simply pause for a moment.). Select option 5 for "Nuclear Medicine" and finally select option 1 for "SPECT" support. In all other countries the local Philips Healthcare office should be contacted.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

[redacted]
Director, Quality and Regulatory
Philips Healthcare – Computed Tomography and Nuclear Medicine

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AFFECTED PRODUCTS	EBW-NM all software versions (1.0P, 1.1.1A, 1.5H, 1.5.1A and 2.0Q – Field Test period)
PROBLEM DESCRIPTION	Philips has become aware of an issue that may be encountered when completing the workflow described in this paragraph which may result in the system providing inaccurate ejection fraction information. Workflow: 1. When processing a MUGA, the user sets the left ventricular bounding ellipse required for both available automatic edge detection methods (MugaC and GBP). 2. After detecting the left ventricular regions, an automatic or manual background region is created. 3. The user then moves forward from the Define Regions workstep to the Review Results workstep and checks the respective results. 4. The user may then wish to go back to the Define Regions workstep in order to reposition the left ventricular bounding ellipse or modify the left ventricular regions defined. In this case, the user will almost always leave the background region alone, as they had previously defined it in an appropriate location before proceeding the first time. 5. After resetting the contour and re-running the auto edge detection or editing the regions, the user proceeds back to the Review Results page. This workflow may result in an ejection fraction that is substantially higher (10 to 50%) than the initial ejection fraction reported during the first execution of the application.
HAZARD INVOLVED	If this were to occur, a false-negative misinterpretation due to a falsely elevated ejection fraction could lead to a patient receiving additional chemotherapy, which can harm the oncology patient. Furthermore, related to a false negative, chemotherapy could be started on a patient that in fact has a heart condition where chemotherapy utilization would be contraindicated (Ejection Fraction < 30%). A second scenario could be a false positive misinterpretation due to a falsely low ejection fraction for oncology patients. An example of this would be where chemotherapy may be withheld (or stopped) from a patient due to the contraindications (Ejection Fraction < 30%).
HOW TO IDENTIFY AFFECTED PRODUCTS	To identify the affected units click on "Help" on the main EBW - NM user interface and read the version number. The following software versions are subject to this Field Safety Notice: 1.0P, 1.1.1A, 1.5H, and 1.5.1A. In addition, you are also affected if you have version 2.0Q, which are systems under Field Test Agreements.

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ACTION TO BE TAKEN BY CUSTOMER / USER	Philips has a temporary workaround that you must follow to avoid risk to patients. Specifically, when making any adjustments to the left ventricular regions of interest in step 4 above, you must re-draw or reposition the background region of interest immediately before proceeding to the results workstep. Users should review any data that may have been affected to confirm reading accuracy. This letter should be placed in your Instructions for Use until otherwise notified. Philips service will contact you to arrange a time for Philips to conduct the appropriate field safety correction.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is voluntarily initiating a corrective action consisting of: • Distribution of this Field Safety Notice (FSN) and • Conducting a field safety correction to fix the issue. The field safety correction will involve installation of EBW NM V2.0AB. (The installation must be performed by a Philips Service Engineer.) The completion of the installation of EBW NM V2. 0AB will be 6 (six) months.
FURTHER INFORMATION AND SUPPORT	For customers in North America if you need any further information or support concerning this issue, please contact our Customer Care Solutions Center at 1-800-722-9377. Select option 5 for "All Imaging Systems". Enter your site ID # (If you do not have a site ID #, simply pause for a moment.). Select option 5 for "Nuclear Medicine" and finally select option 1 for "SPECT" support. In all other countries the local Philips Healthcare office should be contacted.