HOSPITAL MENONITA GUAYAMA
Sirviendo con Amor Cristiano

Br. 1
52-30883-01
03036506

October 4, 2019

Shawn W. Seeley, Health Physicist
USNRC
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Subject: Notification of License No. 52-30883-0 (Hospital Menonita Guayama)

We are notifying you through this letter of the temporary closure of all services provided to our patients in the area of nuclear medicine. We have received urgent information from Philips company in which they have detected a problem in some Philips Forte Camera Range. This situation forces us not to offer the service to patients until the Philips company solves the problem.

Please view the attachment received by Philips.

If additional information is needed call to my office, phone number (787) 864-4300 ext. 1901 or Mr. Carmelo Pérez (RSO) (787) 432-9320.

Thanks in advance for your cooperation on this matter.

Sincerely,

Rogelio Díaz García, MHSA
Administrator
Hospital Menonita Guayama

Attachments:

1. Field Safety Notice

P.O. Box 10018 Ave. Pedro Albizu Campos Urb. La Hacienda Guayama, P.R. 00785
Tel. (787) 864-4300 ext. 1901 Fax (787) 864 –4466

PHILIPS

Field Safety Notice

Advanced Molecular Imaging FSN 88200523 Revision: 01 2019 SEP 19

URGENT - Field Safety Notice

Medical Device Correction

Forte, Forte JETStream, Forte JETStream AZ, Forte JETStream AZ upgrade, Forte JETStream upgrade, Diamond Select Forte, Diamond Select Forte JETStream

Forte Detector Unimpeded Motion

Discontinue system use until further notice

Dear Customer,

A problem has been detected in the Philips Forte product line that, if it were to re-occur, could pose a risk for patients or users. This Field Safety Notice 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 or users
- 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.

If you need any further information or support concerning this issue, please contact your local Philips representative: For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377).

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

Holly Wright Lee

Holly Wright Lee

Sr. Manager, Post Market Surveillance

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AFFECTED PRODUCTS	882020 Forte, 882290 Forte JETStream, 882291 Forte JETStream upgrade, 882320 Forte JETStream AZ, 882321 Forte JETStream AZ upgrade, 889456 Diamond Select Forte, 889471 Diamond Select Forte JETStream
PROBLEM DESCRIPTION	As a result of a customer reported problem during detector radius movement, Philips identified an issue affecting the Forte family of gamma cameras that could result in either detector 1 or detector 2 falling unimpeded vertically to the end stops of its travel limit.
HAZARD INVOLVED	There is a possibility that a detector may fall unimpeded vertically to the end stops of its travel limit, due to a mechanical failure, possibly making contact with a patient that could result in entrapment, serious injury, or death.
HOW TO IDENTIFY AFFECTED PRODUCTS	This issue applies to all Forte gamma cameras: Forte, Forte JETStream, Forte JETStream upgrade, Forte JETStream AZ, Forte JETStream AZ upgrade, Diamond Select Forte, Diamond Select Forte JETStream The product type can be determined by finding the name of the system of the product label. Refer to the representative photos below.

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	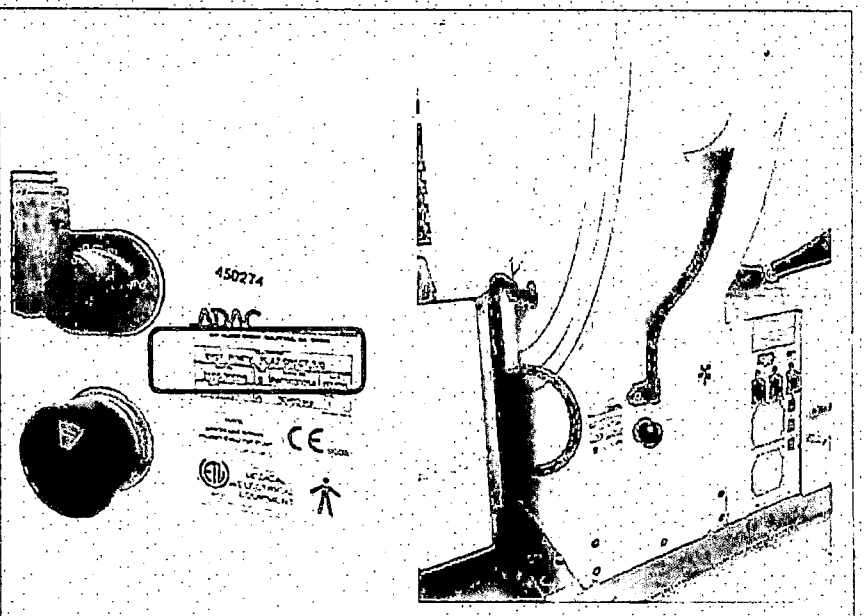
ACTION TO BE TAKEN BY CUSTOMER / USER	➢ **Discontinue use of the system until further notice.** ➢ Inform those who need to be aware within your organization or any organization where the potentially affected devices have been transferred (If appropriate). ➢ Maintain this notice with your system Instructions for Use (IFU) until the correction is made to the system.

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ACTIONS PLANNED BY PHILIPS	Philips Healthcare is distributing this FSN to all affected customers/users and will deploy a solution addressing the issue upon completion of the investigation.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: For SUPPORT in North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377, follow the prompts).

PHILIPS

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Customer Response Form

INSTRUCTIONS: Please complete this form with the customer upon delivery of the Field Safety Notice and return to the BIU. ***Please email completed form to CTNM.QARA@Philips.com.***

Customer Name:	System Code	System Serial No.
Address:		

Our records indicate that your firm has received affected systems. By signing this form, you acknowledge having received, read, and understood the content of this letter and have taken appropriate actions.

Signature: _____ **Date:** _____

Print Name: _____ **Email:** _____

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Hospital Menonita Guayama
Attn: Carmelo Perez
Radiation Safety Officer
P.O. 10011
Guayama, Puerto Rico 00785-4011

Date
10/25/2019

License Number(s)
52-30883-01

Mail Control Number(s)
Notification 616803

Licensing and/or Technical Reviewer or Branch
Medical Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 10/04/2019

The initial processing, which included an administrative review, has been performed.

☐ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link:** http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5513 or (610) 337-5239