El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una Alerta asociada a:

NOMBRE DEL DISPOSITIVO MÉDICO	PET/CT PHILIPS - Equipos Combinados de Tomografía Por Emisión de Positrones y Tomografía Computarizada de Rayos X
NO. IDENTIFICACIÓN RISARH	A1402-66
REFERENCIAS DEL DISPOSITIVO MEDICO	GEMINI TF 16 PET/CT y GEMINI TF 64 PET/CT
REGISTRO SANITARIO	INVIMA 2008EBC-0001538
INDICACIONES Y USO ESTABLECIDOS	La tecnología de tomografía por emisión de positrones y la tomografía computarizada de rayos x.
NOMBRE DEL FABRICANTE	PHILIPS Medical Systems (Cleveland) Inc.
DESCRIPCION DEL PROBLEMA	Se informa que el servidor de reconstrucción PET (PRS) puede bloquearse después de la adquisición de CT en bajas dosis y puede no permitir la adquisición de PET lo que resultaría en estudios incompletos, por ende potenciales diagnósticos erróneos y eventos adversos sobre el paciente.
FUENTE	Anexo
FECHA DE NOTIFICACION	14 de Febrero de 2014

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

A21544 01 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: February 11, 2014

UMDNS Terms:
- Scanning Systems, Computed Tomography/Positron Emission Tomography [20161]
- Scanning Systems, Positron Emission Tomography [16375]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Diagnostic Imaging
- Information Technology

Geographic Regions:
- (Impact in specific regions has not been identified or ruled out at the time of this posting)
- Worldwide

*Philips—Gemini Positron Emission Tomography/Computed Tomography Systems: PRS Database May Lock Up, Potentially Resulting in Additional Radiation Exposure [Update]

Product Identifier:
[February 7, 2014] Section 1

Gemini TF Positron Emission Tomography (PET)/Computed Tomography (CT) Systems:	Model Nos.:	Serial Nos.:
16-Slice	882470	7003, 7004, 7005, 7006, 7008, 7009, 7010, 7011, 7014, 7015, 7017, 7019, 7020, 7021, 7022, 7024, 7025, 7026, 7031, 7034, 7035, 7036, 7039, 7043, 7045, 7049, 7050, 7052, 7053, 7054, 7058, 7060, 7062, 7064, 7066, 7068, 7069, 7074, 7075, 7077, 7080, 7081, 7084, 7085, 7086, 7087, 7089, 7093, 7094, 7095, 7096, 7097, 7098, 7099, 7108, 7112, 7114, 7115, 7118, 7120, 7121, 7122, 7123, 7124, 7125, 7128, 7129, 7131, 7135, 7137, 7138, 7139, 7140, 7142, 7143, 7145, 7147, 7148, 7156, 7159, 7161, 7163, 7166, 7168, 7173, 7174, 7176, 7177, 7181, 7183, 7184, 7185, 7186, 7187, 7193, 7194, 7195, 7196, 7197, 7198, 7199, 7200, 7207, 7208, 7210, 7211, 7215, 7216, 7223, 7224, 7226, 7228, 7230, 7233, 7235, 7239, 7240, 7242, 7501, 7503, 7507, 7508, 7511, 7514, 7517, 7518, 7520, 7521, 7523, 7527, 7528, 7529, 7530, 7531, 7532, 7533, 7536, 7538, 7540, 7545, 7546, 7554, 7559, 7564, 7566, 7568, 7570, 7573, 7581, 7583, 7584, 7586, 7590, 7591, 7104M, 7106M, 7170M, 7582M

64-Slice	882471	7007, 7012, 7013, 7016, 7027, 7028, 7029, 7030, 7032, 7037, 7042, 7044, 7048, 7055, 7057, 7059, 7061, 7063, 7065, 7071, 7072, 7076, 7078, 7079, 7082, 7083, 7088, 7091, 7092, 7102, 7103, 7105, 7116, 7117, 7119, 7126, 7132, 7136, 7141, 7144, 7146, 7149, 7152, 7153, 7154, 7158, 7160, 7164, 7167, 7169, 7171, 7172, 7175, 7178, 7179, 7180, 7182, 7188, 7189, 7190, 7192, 7201, 7202, 7203, 7204, 7205, 7206, 7209, 7212, 7213, 7214, 7217, 7218, 7219, 7221, 7227, 7229, 7231, 7234, 7236, 7238, 7241, 7245, 7251, 7252, 7253, 7254, 7255, 7256, 7257, 7258, 7504, 7506, 7509, 7510, 7512, 7515, 7516, 7519, 7524, 7525, 7535, 7537, 7539, 7542, 7543, 7544, 7548, 7549, 7550, 7552, 7553, 7555, 7556, 7557, 7558, 7560, 7561, 7562, 7563, 7567, 7569, 7572, 7574, 7575, 7577, 7578, 7579, 7585, 7587, 7589, 7592

Big Bore	882476	9004, 9005, 9006, 9008, 9009, 9010, 9011, 9012, 9013, 9014, 9015, 9016, 9017, 9018, 9019, 9020, 9021, 9022, 9023, 9201, 9202, 9203, 9204, 9205, 9206, 9207, 9208, 9209, 9210, 9211, 9213, 9214, 9215, 9216, 9217, 9218, 9219, 9220, 9221, 9222, 9223, 9224, 9225, 9226, 9228, 9229, 9231
LXL	882412	14701, 14702, 14704, 14705, 14706, 14707, 14708, 14709, 14710, 14711
Ready	882473	7040, 7048, 7070, 7095, 7111, 7113, 7127, 7130, 7134, 7150, 7151, 7155, 7157, 7162, 7237, 7249

TruFlight Select	882438	17002, 17003, 17004, 17005, 17006, 17007, 17008, 17009, 17010, 17011, 17012, 17013, 17014, 17015, 17017, 17018, 17019, 17021, 17022, 17023, 17024, 17025, 17026, 17028

[Capital Equipment]

[January 2, 2014] Section 2

Gemini TF Positron Emission Tomography (PET)/Computed Tomography (CT) Systems:	Software Versions:
(1) 16-Slice	(1 and 2) 3.5.1, 3.5.1.1, 3.5.2, 3.5.2.1
(2) 64-Slice	
(3) Big Bore	(3) 3.6, 3.6.1, 3.6.2
(4) LXL	(4 and 5) 3.5.2
(5) Ready	
(6) TruFlight Select	(6) V3.5.3

[Capital Equipment]

Manufacturer:

- Philips Healthcare North America3000 Minuteman Rd, Andover, MA 01810-1099, United States

Summary: This Alert provides additional information based on FDA's Center for Devices and Radiological Health (CDRH) source material regarding Alert Accession Number A21544. FDA's CDRH states that the manufacturer initiated a recall by Field Safety Notice letter dated December 4, 2013. Additional information is provided in the following field:

- Product Identifier (see Section 1)

Problem:
[December 31, 2013]
In a December 4, 2013, Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital and posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Philips states that the PET reconstruction server (PRS) database in the above systems may lock up after the low-dose CT acquisition is complete and may not allow the PET acquisition to begin, resulting in an incomplete study. Philips states that if this problem occurs, users cannot fix it and a service interaction is required before the system will become operational. Delay of a patient's study may necessitate a rescan and/or patient reinjection if a short half-life isotope or radiopharmaceutical is used, exposing the patient to additional radiation. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
The following actions are those listed in Alert Accession Number A21544. Identify any affected product in your inventory by clicking the help button and "Product Info" tab to display the software version. If you have affected product, verify that you have received the December 4, 2013, Urgent Medical Device Correction letter from Philips. A Philips service engineer will contact your facility to arrange to install a software update on affected systems.
For Further Information:
North America
Philips customer care solutions center
Tel.: (800) 722-9377 (select option 5)
Europe
Philips UK Customer Care Service Centre
Tel.: (0870) 5329741
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Philips Medical Systems. Nuclear medicine, PET-CT PET-CT system. GEMINI TF 16, GEMINI TF 64, GEMINI TF Big Bore, TruFlight Select, GEMINI TF Ready and GEMINI LXL PET/CT systems [online]. London: Department of Health; 2013 Dec 20 [cited 2013 Dec 31]. (Field safety notice; reference no. 2013/012/017/291/009). Available from Internet: Click here.
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 2 recall—Gemini LXL Gemini TF PET/CT16 Gemini TF PET/CT 64 [online]. 2014 Feb 4 [cited 2014 Feb 7]. Available from Internet: Click here.

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide.

Source(s):

- 2014 Feb 7. FDA CDRH Database. Class II. Z-0932-2014
- 2014 Feb 7. Member Hospital. FSN 88200465-471
- 2014 Feb 7. MHRA FSN. 2013/012/017/291/009