El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Equipo De Tomografía Computarizada
NO. IDENTIFICACIÓN RISARH	I1407-279
REFERENCIAS DEL DISPOSITIVO MEDICO	Brillance CT Big Bore, referencias 728243 y 728244 con seriales específicos
REGISTRO SANITARIO	2008EBC-0001540
INDICACIONES Y USO ESTABLECIDOS	Adquisición de imágenes diagnosticas radiológicas empleando la tomografía computarizada de rayos x para ayudar a los médicos en el diagnostico y tratamiento de enfermedades proporcionando imágenes.
NOMBRE DEL FABRICANTE	Philips Medical System Technologies Ltd. Dunlee División Of Philips Medical Systems (Cleveland) Inc Philips Medical Systems (Cleveland) Inc. Philips And Neusoft Medical System
DESCRIPCION DEL PROBLEMA	El fabricante informa que los equipos mencionados anteriormente pueden estar por fuera de la tolerancia correspondiente a las emisiones de radiofrecuencia, específicamente en la frecuencia de 48 MHz, donde las pruebas arrojan como resultado 3.5dB uV/m por encima de lo permitido en la norma aplicable (IEC 60601-1-2), conllevando a que se presenten posibles variaciones en los resultados de los exámenes e interferencia electromagnética circundante en otros equipos.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	07 de Julio 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

A22575 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: June 30, 2014
UMDNS Terms:
- Scanning Systems, Computed Tomography, Axial, Full-Body [15956]
- Scanning Systems, Computed Tomography, Axial, Head [15955]
- Scanning Systems, Computed Tomography, Electron Beam [16899]
- Scanning Systems, Computed Tomography, Spiral [18443]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Diagnostic Imaging
- Radiation Oncology/Medical Physics

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

Philips—Brilliance Big Bore Computed Tomography Systems: May Be Out of Tolerance for Radio Frequency Emissions

Product Identifier:

Brilliance Big Bore Computed Tomography (CT) Systems:	Model Nos.:	Serial Nos.:
Oncology	728243	7185, 7187 through 7189, 7191 through 7199, 7201 through 7243, 7245 through 7251, 7253 through 7267, 7269, 7270, 7272 through 7297, 7299, 7300, 7302, 7304 through 7317, 7319 through 7374, 7376 through 7379, 7381, 7382, 7385, 7387 through 7389, 7391 through 7393, 7395, 7397 through 7401, 7403 through 7406, 7409 through 7429, 7431 through 7433, 7435 through 7438, 7440 through 7451, 7454 through 7457, 7459, 7462 through 7485, 7487 through 7509, 7511 through 7513, 7515 through 7519, 7521 through 7524, 7526 through 7528, 7530 through 7532, 7534 through 7537, 7539 through 7542, 7544, 7545, 7547, 7549 through 7556, 7558 through 7562, 7564 through 7566, 7568, 7569, 7573, 7574, 7577 through 7582, 7584, 7585, 7588 through 7593, 7596 through 7599, 7601 through 7603, 7605, 7608, 7609, 7611 through 7613, 7615 through 7618, 7620, 7622 through 7624, 7626 through 7630, 7634, 7635, 7637 through 7648, 75000

Radiology	728244	7190, 7200, 7244, 7252, 7268, 7271, 7301, 7318, 7375, 7380, 7383, 7384, 7386, 7390, 7396, 7402, 7407, 7408, 7427, 7430, 7439, 7452, 7453, 7458, 7486, 7510, 7514, 7520, 7525, 7529, 7533, 7538, 7543, 7546, 7557, 7570 through 7572, 7575, 7576, 7583, 7586, 7587, 7595, 7600, 7604, 7607, 7610, 7614, 7619, 7621, 7625, 7631 through 7633, 7636

[Capital Equipment]
454 units distributed

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

Problem: FDA's Center for Devices and Radiological Health (CDRH) states that the above systems may be out of tolerance for radio frequency emissions. Specifically, at the 48MHz frequency, the testing indicated the systems were 3.5dB uV/meter higher than the applicable IEC 60601-1-2 standard specification. FDA's CDRH also states that the manufacturer initiated a correction by Urgent Medical Device Correction letter dated December 10, 2013. The manufacturer has not confirmed the information provided in the source material.
Action Needed: Identify any affected product in your inventory. If you have affected product, verify that you have received the December 10, 2013, Urgent Medical Device Correction letter from Philips. A Philips field service engineer will visit your facility to perform an electro-magnetic interference (EMI) noise reduction update on affected systems.
For Further Information:
Philips
Tel.: (800) 722-9377
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 2 device recall Philips Brilliance CT Big Bore Oncology and Philips Brilliance CT Big Bore Radiology [online]. 2014 Jun 22 [cited 2014 Jun 25]. 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 Jun 25. FDA CDRH Database. Class II. Z-1745-2014