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	Aceleradores de Alta y Baja Energía
NO. IDENTIFICACIÓN RISARH	I1407-272
REFERENCIAS DEL DISPOSITIVO MEDICO	CLINAC 21 EX, CLINAC 23 EX,CLINAC 2100 C/D, CLINAC 2300 C/D, CLINAC CX, CLINAC iX, CLINAC DX, NOVALIS Tx, TRILOGY y TRILOGY Tx
REGISTRO SANITARIO	2009EBC-0004716
INDICACIONES Y USO ESTABLECIDOS	Los aceleradores lineales de alta y baja energía marca VARIAN modelo CLINAC proporcionan un sistema de radioterapia convencional o radiocirugía estereotactica para el manejo de lesiones, tumores en cualquier parte del cuerpo cuando se indique un tratamiento por radiación, no diagnostica ninguna enfermedad sino que proporciona un tratamiento para el cáncer.
NOMBRE DEL FABRICANTE	Varian Medical Systems Beijing Co., Ltd
DESCRIPCION DEL PROBLEMA	El fabricante informa que se ha presentado una disminución inesperada en la salida del haz para el modo de tratamiento de fotones de 6MV (6SRS, 6FFF Y 6X) debido a perdida de electrones primarios y por ende reducción de fotones en el objetivo, conllevando a que se presenten deficiencias de los tratamientos efectuados sobre los pacientes.
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

ANEXO 1

A22589 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: June 25, 2014
UMDNS Terms:
- Radiotherapy Systems, Linear Accelerator [12364]

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

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

Varian—C-Series High Energy Linear Accelerators: May Exhibit Unexpected 6MV Beam Output Variations

Product Identifier:
C-Series High Energy Linear Accelerators with 6MV Configurations: (1) Clinac 21 EX, (2) Clinac 23 EX, (3) Clinac 2100 C/D, (4) Clinac 2300C/D, (5) Clinac CX, (6) Clinac iX, (7) Clinac DX, (8) Novalis Tx, (9) Trilogy, (10) Trilogy Tx [Capital Equipment]

Manufacturer:
- Varian Medical Systems Inc3100 Hansen Way, Palo Alto, CA 94304-1038, United States

Problem:
In a June 17, 2014, Urgent Medical Device Correction Urgent Field Safety Notice letter submitted by an ECRI Institute member hospital, Varian states that it has received reports of unexpected decrease in beam output in the above linear accelerators for 6MV photon treatment mode. Varian also states that it has determined that the cause of the unexpected variations in beam output is degradation of the 6MV target. Varian further states that the effects of modern, highly modulated treatment modes can create high levels and frequency of stress cycles in the targets, particularly if the beam spot size is small, potentially leading to deterioration of the targets and failure at an accelerated rate, resulting in a rapid change in the beam output and symmetry. Varian states that, specifically:
(1) The photon generation, or bremsstrahlung yield, decreases as fewer electrons are converted to photons in the target, and;
(2) Because of a resulting escape of primary electrons, the output of photons, as measured by the ion chamber, may appear to be constant, but the actual photon output is decreasing.
Varian also states that this failure mode in the target affects only the 6MV photon treatment modes (6SRS, 6FFF, and 6X) and that no other energies are affected by this problem. 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 June 17, 2014, Urgent Medical Device Correction Urgent Field Safety Notice letter and Recall Return Response form from Varian. Varian recommends that your facility implement daily output constancy checks of photon beams as recommended by the AAPM, specifically those provided by the following:
(1) *AAPM, Task Group 142 Report: Quality Assurance of Medical Accelerators*, Medical Physics publication 36 (9), September 2009.
(2) *AAPM Report No. 46, Comprehensive QA for Radiation Oncology*, Report of Task Group No. 40 Radiation Therapy Committee, April 1994.
Varian states that it is particularly important that these daily output constancy checks include all 6MV beams (6SRS, 6FFF, and 6X) and that your facility should particularly check for any sudden decreases in dose output 3% per day, or 6% per week. Measurements should be made with buildup (5 cm water equivalent) that is beyond the electron range to avoid electron contamination of measurements. If any sudden decrease in dose output is observed, stop using all 6MV beams and immediately contact Varian using the information below. A Varian service representative will then visit your facility to investigate whether the target is degrading or has failed. Varian recommends that a service call be requested in the even system faults are generated for target cooling to investigate and determine whether a cooling circulation problem exists. For additional information regarding Dosimetry System Calibration and system reliability, see CTB-GE-228, which is available here.

Complete the Recall Return Response form, and return it to Varian by e-mail at returnresponse@varian.com. Retain a copy of the Urgent Medical Device Correction urgent Field Safety Notice letter with your most current product labeling and notify all relevant personnel at your facility of the information in the letter.

For Further Information:
Varian local representative or Varian Oncology Help Desk
U.S. and Canada:
Tel.: (888) 827-4265
E-mail: support-americas@varian.com
Asia and China
E-mail: support-china@varian.com
Australia and New Zealand
E-mail: support-anz@varian.com
Europe
Tel.: 41 (41) 7498844
E-mail: support-emea@varian.com
Japan
Email: support-japan@varian.com
Latin America
E-mail: soporte.al@varian.com
Southeast Asia
E-mail: support-sea@varian.com
Website: 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 24. Member Hospital. Varian letter submitted by an ECRI Institute member hospital