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	Acelerador Lineal Elekta
NO. IDENTIFICACIÓN RISARH	A1409-382
REFERENCIAS DEL DISPOSITIVO MEDICO	Todos los aceleradores digitales
REGISTRO SANITARIO	2009EBC-0005074 y 2009EBC-0005037
INDICACIONES Y USO ESTABLECIDOS	Sistema integrado para garantizar que se logren fácilmente los parámetros requeridos para una amplia gama de técnicas de radioterapia y aplicaciones avanzadas.
NOMBRE DEL FABRICANTE	Elekta Instrument Ab
DESCRIPCION DEL PROBLEMA	El fabricante afirma que los usuarios pueden restablecer los valores fuera de los ajustes de fábrica recomendados, un cambio a los valores de auto-tracking puede comprometer el cumplimiento de las normas de seguridad, potencialmente resultando en un aumento de la dosis de radiación no deseada para el paciente, lo que puede conllevar a potenciales eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	19 de Septiembre 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

A22001 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: September 17, 2014
UMDNS Terms:
- Radiotherapy Systems, Linear Accelerator [12364]

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

Geographic Regions:
- Worldwide

Elekta—Various Medical Linear Accelerators: Default Values May Be Reset Outside Recommended Factory Settings

Product Identifier:
All Digital Accelerators with: (1) Electrons and Beam Modulator, (2) MLCi, (3) MLCi2, (4) Agility, or (5) Asymmetric Heads *[Capital Equipment]*

Manufacturer:
- Elekta Ltd (UK) Linac House, Fleming Way, Crawley, RH10 9RR, England

Problem: FDA's Center for Devices and Radiological Health (CDRH) states that customers may be resetting the default values outside the recommended factory settings for the above linear accelerators. A change to auto-tracking values may compromise compliance with safety standards, potentially resulting in an unwanted increased radiation dose to the patient. FDA's CDRH also states that the manufacturer initiated a product correction by Important Field Safety Notice letter on May 28, 2013. Elekta states that the firm informed all affected customers of the problem in July 2013.

Action Needed:
Identify any affected product in your inventory. If you have any affected product, verify that you have received the Important Field Safety Notice letter from Elekta. Follow the instructions and advice in the manuals and system dialogs. Refer to the tables in the Important Field Safety Notice letter for information about the settings, and check all machines against the default settings. If the actual settings are greater than the default settings, Elekta recommends that you reapply the default settings and perform all relevant physics checks (e.g. beam uniformity, output factor); however, if auto-tracking values are increased beyond the factory-set defaults, then measure electron applicator radiation leakage to ensure the IEC safety compliance of the system. Elekta will provide a mandatory upgrade to Integrity 1.2 for all users of Desktop Pro and Integrity 1.1 software. The upgrade path to Integrity 1.2 differs depending on system configurations; Elekta has released 3 separate Important Field Safety Modifications.

For Further Information:
Elekta local representative
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall medical linear accelerator [online]. 2014 Mar 14 [cited 2014 Sep 8]. 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 Sep 15. FDA CDRH Database. Class II. Z-1064-2014
- 2014 Sep 16. Manufacturer Letter.