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	Acelerador Lineal PRECISE
NO. IDENTIFICACIÓN RISARH	I1410-409
REFERENCIAS DEL DISPOSITIVO MEDICO	Mesa de Tratamiento PRECISE, seriales específicos
REGISTRO SANITARIO	2009EBC-0005074
INDICACIONES Y USO ESTABLECIDOS	Este sistema integrado está diseñado 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 las mesas de los equipos anteriores pueden presentar un error de posición si los sensores de posición no se instalan correctamente durante el mantenimiento correctivo, el sistema tiene un chequeo por software para encontrar grandes errores de posición, pero la mesa puede ser colocada con un margen de error > 5 mm sin mostrar ninguna alerta, lo que puede conllevar a posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	14 de Octubre 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

A22943 01 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: October 8, 2014
UMDNS Terms:
- Tables, Radiotherapy [16751]

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

Geographic Regions:
- Worldwide

Elekta—Precise Treatment Tables: Positional Error May Occur

Product Identifier:
Precise Treatment Tables *[Capital Equipment]*
Serial Nos.: 124001 through 125803, 125807 through 125880, 125883 through 125899, 125902 through 125917, 125920 through 125949, 125952 through 125963, 125967 through 125153, 126158 through 126170, 126174 through 126208, 126212 through 126230, 126232 through 126261, 126269 through 126281, 126293 through 126309, 126318 through 126330, 126338 through 126373, 126375 through 126397, 126400 through 133999, 213000 and above

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

Summary: This Alert provides additional information based on manufacturer correspondence regarding Alert Accession No. A22943. Additional information is provided in the Geographic Regions field (see bolded region).

Problem:
[September 26, 2014]
In an Urgent Important Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Elekta states that the above tables may exhibit a positional error if the positional sensors are not correctly installed during corrective maintenance, potentially resulting in clinical mistreatment for a patient in an incorrect position. The system has a software check to find large positional errors, but the table may be positioned with errors >5 mm without displaying any inhibits.

Action Needed:
Identify any affected product in your inventory. If you have any affected product, verify that you have received the Urgent Important Field Safety Notice letter and Important Field Safety Notice Acknowledgment Form from Elekta. Complete the Acknowledgment Form, and return it to Elekta using the instructions on the form. Insert a copy of the Urgent Important Field Safety Notice letter in the user manual for the above tables. Refer to the Precise Treatment Table instructions for use (IFU; 1502625_02 and later) for the procedure to check for the error. Elekta recommends that you verify the accuracy of the treatment table position as shown by the treatment room monitor (TRM) during daily machine checks. The following procedure is an example of how to do this:
When you perform this check, record measurements to the accuracy of 1 mm. A test object, such as a cube or steel ruler, can be used.
(1) Rotate the gantry to 0°.
(2) Put the test object at isocenter, and align it to the room lasers at the central axis. Note the treatment table longitudinal (X) TRM as d_1.
(3) Use the user interface module to move the treatment table 20 mm in a longitudinal direction.
(4) Ensure that the distance moved, as measured by the test object, is the same as the change in the TRM. If the error is >1 mm, contact your Elekta local service representative. Record the value as d_2.
(5) Use the user interface module to move the test object its initial position (isocenter), and align it to the room lasers at the central axis. Record the value in the TRM as d_3.
(6) Calculate the difference between d_3 and d_1. This is the positional error. If the error is >1 mm, contact your local service representative.
(7) Repeat steps 1 through 6 for treatment table movements in the lateral (Y) and height (Z) directions.
Elekta will supply your local field service engineer with an improved method of installation for positional sensors to use when the part is replaced.

For Further Information:
Elekta
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Elekta. Radiotherapy treatment couch. Precise treatment table [online]. London: Department of Health; 2014 Aug 26 [cited 2014 Sep 26]. (Field safety notice; reference no. 2014/008/019/081/001). 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 Oct 6. MHRA FSN.
- 2014/008/019/081/001
- 2014 Oct 6. MHRA FSN.
- Field Change Order (FCO) Reference No. 200 01 204 011; Field Corrective Action (FCA) No. FCA-EL-0001 (includes reply form)
- 2014 Oct 6. Manufacturer. Manufacturer confirmed information contained in source material