INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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	Laser de Oftalmología CARL ZEISS
NO. IDENTIFICACIÓN RISARH	I1706-255
REFERENCIAS DEL DISPOSITIVO MEDICO	VISUMAX, concerniente a las fuentes de poder con seriales 963599 hasta 1157772.
REGISTRO SANITARIO	2011EBC-0007348
INDICACIONES Y USO ESTABLECIDOS	Indicado en cirugía refractiva, indicado en tratamiento sin hemorragia de las enfermedades intraoculares, permite la corrección de ametropías, seguimiento ocular de alto rendimiento y terapia de la retina.
NOMBRE DEL FABRICANTE	Carl Zeiss Meditec Ag
DESCRIPCION DEL PROBLEMA	El fabricante establece que los componentes del circuito de prueba de la batería de los dispositivos referenciados pueden fallar, conduciendo a la combustión de los componentes electrónicos; intoxicación por humo y olor a quemado, conllevando a que se presenten posibles eventos adversos sobre pacientes y usuarios.
FUENTE	ANEXO
FECHA DE NOTIFICACION	27 de Junio de 2017

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

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ANEXO

[High Priority] - A28365 : Carl Zeiss—Uninterruptible Power Supply Used with VisuMax Systems: Battery Test Circuit Components May Combust

Medical Device Ongoing Action

Published: Monday, June 12, 2017
Last Updated: Tuesday, June 27, 2017

UMDNS Terms:

- Lasers, Yb:YAG [31525]
- Power Supplies [18557]

Product Identifier:
Uninterruptible Power Supplies (UPSs) used with VisuMax Systems *[Capital Equipment]*
Serial Nos.: 963599 through 1157772 (not including those with a previously replaced UPS)

Geographic Regions: Worldwide

Manufacturer(s): Carl Zeiss Meditec AGGoeschwitzer Strasse 51-52, D-07745 Jena, Germany

Suggested Distribution: Clinical/Biomedical Engineering, OR/Surgery, Ophthalmology

Problem:
In a January 23, 2017, Field Corrective Action letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and a March 17, 2017, Field Corrective Action letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Carl Zeiss states that the battery test circuit components of the above systems may fail, potentially leading to combustion of device components. Carl Zeiss also states that the probability of a serious injury occurring in association with this problem is extremely unlikely because of a fire enclosure and other risk control measures; however, smoke intoxication may occur as a result of the components generating smoke and a burning smell during combustion. Additionally, Carl Zeiss states that newly manufactured UPS modules do not pose this risk because they have an updated design preventing the problem.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received either the January 23, 2017, and/or the March 17, 2017, Field Corrective Action letter(s) and feedback sheet from Carl Zeiss. Complete the feedback sheet, and return it to Carl Zeiss by email at: fca-jen.med.de@zeiss.com . Carl Zeiss refractive support team will contact your facility with additional information regarding the handling of this Field Corrective Action.
For Further Information:
Carl Zeiss
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. VisuMax with treatment-pack and accessories [online]. London: Department of Health; 2017 May 2 [cited 2017 Jun 7]. (Field safety notice; reference no. 2017/004/025/299/027). Available from Internet: here .
- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for VisuMax, Carl Zeiss Meditec AG [online]. 2017 Apr 4 [cited 2017 Jun 7]. Available from Internet: Click here .

Comments:

- 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):

- 2017 Jun 7. MHRA FSN. 2017/004/025/299/027 Download
- 2017 Jun 7. MHRA FSN. Carl Zeiss reference no. 3485 Download
- 2017 Jun 7. BfArM (Germany). 00737/17 Download
- 2017 Jun 7. BfArM (Germany). Carl Zeiss reference no. 3485 Download
- 2017 Jun 27. Manufacturer. The manufacturer confirmed the information in the source material.