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	Electromiógrafo NEUROMAX, XCALIBUR.
NO. IDENTIFICACIÓN RISARH	I1501-43
REFERENCIAS DEL DISPOSITIVO MEDICO	Protektor
REGISTRO SANITARIO	2009DM-0004064
INDICACIONES Y USO ESTABLECIDOS	Los electromiógrafo digitales con potenciales evocados se usan para adquirir, visualizar, guardar y archivar señales neurofisiológicas, las cuales permiten al especialista diagnosticar de forma precisa a los pacientes.
NOMBRE DEL FABRICANTE	Natus Medical Incorporated (Incorporated Dba Excel Tech Limited) Alpine Biomed Aps
DESCRIPCION DEL PROBLEMA	El fabricante establece que cuando el software PROTEKTOR IOM para monitorización remota es utilizado con el sistema local de adquisición y configurado para bloquear los cambios de adquisición remotos, en estas condiciones, si el usuario remoto intenta detener el grupo de forma de onda de funcionamiento libre, el sistema puede mostrar un mensaje de que este tiene privilegios suficientes para realizar dicha acción y la forma de onda en el sistema remoto ya no actualizará los datos fisiológicos, pero se actualizará el sello de tiempo en la etiqueta, estas condiciones podrían estar presentes en versiones EPWorks anteriores a la 6.0, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	23 de Enero de 2015

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

[High Priority] - A23655 01 : Natus—Protektor IOM Systems and Remote Review Software: Free-Run Waveform on Remote System No Longer Updates Physiological Data under Certain Conditions

Medical Device Ongoing Action

UMDNS Terms:

- Software, Physiologic Recording, Evoked Potential [26745]
- Recorders, Graphic, Evoked Potential [11614]

Product Identifier:
Intraoperative Monitoring (IOM) Systems with EPWorks Software: (1) Protektor, (2) Protektor32 *[Capital Equipment]*
EPWorks Software Versions below 6.0

Geographic Regions: Argentina, Australia, Bulgaria, Canada, Chile, China, Colombia, Croatia, Cyprus, Denmark, France, Germany, Hong Kong, India, Indonesia, Iraq, Israel, Italy, Korea, Malaysia, Mexico, Morocco, The Netherlands, Oman, Pakistan, Poland, Portugal, Puerto Rico, Romania, Russia, Saudi Arabia, Spain, Thailand, Turkey, U.K., U.S.

Manufacturer(s): Natus Medical Inc. DBA Excel-Tech Ltd (Xltek)2568 Bristol Circle, Oakville, ON L6H 5S1, Canada

Suggested Distribution: Clinical/Biomedical Engineering, OR/Surgery, Information Technology, Neurology

Summary:
This Alert provides additional information based on manufacturer correspondence regarding Alert Accession No. A23655 . Additional information is bolded in the Geographic Regions field.

Problem:
[January 14, 2015]
In a December 23, 2014, Urgent Medical Device Correction Notification letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Natus states that when the above software for remote monitoring is used with the local acquisition system configured to block remote acquisition changes, if the remote user tries to stop the free-run waveform group, the system may display a message that the user does not have sufficient privilege to perform this action. After this point, the free-run waveform on the remote system will no longer update the physiological data, but will update the time stamp in the label. Natus states that all the conditions causing this error were present in EPWorks versions before version 6.0. All other indications of the software (local monitoring and acquisition) are not affected by this problem. Natus also states that the following errors may occur in the above software when it is used with the Protektor32 system:
(1) When the Protektor 32 stimulates in biphasic mode the firmware limits the number of stims to 2, as it should be; however when switching back to monophasic mode, the software may not reset the number of stims from 2 to whatever is specified.
(2) Using the single-shot low-voltage biphasic stimulator may block further use of the electrical stimulator until reset.

Action Needed:
The following actions are those listed in Alert Accession No. A23655 . Identify any affected product in your inventory. If you have affected product, verify that you have received the December 23, 2014, Urgent Medical Device Correction Notification letter, software installation instructions, and Previous Version Removed from Use Confirmation Form from Natus. Follow the instructions provided with the letter to update the EPWorks software for your Protektor32 or Protektor system. After the update is installed, complete the Previous Version Removed from Use Confirmation Form and return it to Natus using the information on the form.

For Further Information:
Natus technical service department
Tel.: (800) 387-7516
E-mail: Oakville_Technical_Service@xltek.com or ots@natus.com
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Natus. Stimulators diagnostic, nerve stimulator. 002978, 002979, 002980, 005030, Protektor systems /Xltek [online]. London: Department of Health; 2015 Jan 5 [cited 2015 Jan 9]. (Field safety notice; reference no. 2014/012/030/081/007). 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):

- 2015 Jan 19. MHRA FSN. 2014/012/030/081/007 Download
- 2015 Jan 19. MHRA FSN. Download
- 2015 Jan 19. Manufacturer. Manufacturer confirmed information