RECALL

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 Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Doppler Vascular y Ginecológico VIASYS NEUROCARE
NO. IDENTIFICACIÓN RISARH	R1707-277
REFERENCIAS DEL DISPOSITIVO MEDICO	Concerniente a las sondas referencia, NW20, N200, N300, N500.
REGISTRO SANITARIO	2008EBC-0002443
INDICACIONES Y USO ESTABLECIDOS	Diagnóstico y monitoreo del sistema vascular y obstétrico.
NOMBRE DEL FABRICANTE	Natus Neurology Incorporated
DESCRIPCION DEL PROBLEMA	El fabricante ha identificado que las sondas referenciadas pueden presentar ruido de fondo excesivo que puede enmascarar los resultados del examen y disminuir la capacidad del usuario para escuchar claramente la frecuencia cardíaca o del flujo sanguíneo, conllevando a que se presenten posibles eventos adversos sobre el paciente o prolongación del tiempo del examen.
FUENTE	ANEXO
FECHA DE NOTIFICACION	13 de Julio 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

[Normal Priority] - A28819 : Natus—Elite 2 and 3 MHz Obstetric Probes and 5 MHz Vascular Probes: May Exhibit Excessive Background Noise
Medical Device Ongoing Action

Published: Friday, June 23, 2017
Last Updated: Monday, July 10, 2017

UMDNS Terms:

- Probes, Ultrasonic [16272]

Product Identifier:

Probes:	Part Nos.:	Catalog Nos.:
2 MHz OB	X1L007	NW20
2 MHz OB Waterproof	X1L008	N200
3 MHz OB	X1L001	N300
5 MHz Vascular	X1L004	N500

[Consumable]
For affected serial numbers and shipment dates, see the letter sent to your facility.

Geographic Regions: Australia, Canada, Chile, Colombia, Germany, India, Japan, Jordan, Kuwait, Latvia, The Netherlands, Papua New Guinea, Philippines, Qatar, Saudi Arabia, Singapore, Sweden, Switzerland, Thailand, U.K., U.S.

Manufacturer(s): Natus Medical Inc6701 Koll Center Pkwy Suite 120, Pleasanton, CA 94070, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Obstetrics/Gynecology/Labor and Delivery, OR/Surgery, Diagnostic Imaging, Vascular Laboratory, Materials Management

Summary:
This Alert is updated with additional information from the manufacturer, which can be found in the following section:

- Geographic Distribution

Problem:
In a June 20, 2017, Urgent Recall Notification Field Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), and submitted by an ECRI Institute member hospital, Natus states that the above probes may exhibit excessive background noise that may mask the user's ability to clearly hear heart rate and/or blood flow.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the June 20, 2017, Urgent Recall Notification/Field Notice letter and verification form from Natus. For an illustration of where to find product name and serial number, see the photographs in the letter . Complete the verification form, and return to Natus using the instructions on the form. To obtain a UPS return authorization number and arrange for product return, contact Janessa Boone, Natus, by telephone at (608) 829-8603, by fax at (608) 829-8771, or by e-mail at Janessa.boone@natus.com . Return only affected probes that are in functioning order; upon receipt of functional affected probes, Natus will provide your facility with replacement probes at no cost. If required by local country regulations, report this field action to your competent authority or regulatory agency and inform Natus if you do so.
For Further Information:
Natus
Website: Click here
References:

Health Canada. Imex Elite 100 and 200 Doppler (2017-06-12) [online]. 2017 Jul 6 [cited 2017 Jul 10]. Available from Internet: Click here .

Great Britain. Medicines and Healthcare Products Regulatory Agency. Natus: Nicolet® Elite® Probes [online]. London: Department of Health; 2017 Jun 26 [cited 2017 Jun 26]. (Field safety notice; reference no. 2017/006/015/701/007). 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):

- 2017 Jun 23. Member Hospital. Natus letter submitted by an ECRI Institute member hospital Download
- 2017 Jun 26. MHRA FSN. 2017/006/015/701/007 Download
- 2017 Jun 26. MHRA FSN. (includes reply form) Download
- 2017 Jul 10. Health Canada Recall Listings. Type II. Health Canada Reference No. RA-63844 Download