

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	Medidor Jaundice Meter DRAEGER
NO. IDENTIFICACIÓN RISARH	I1703-106
REFERENCIAS DEL DISPOSITIVO MEDICO	JM-105, lotes B2001001 hasta B2001085, B3001011 hasta B3001471, B3101001 hasta B3101125, B3201001 hasta B3201101, B3301001 hasta B3301020, B3401001 hasta B3401020 (Incluido el escáner de código de barras); B2501001 hasta B2501150, B3501017 hasta B3501288, B3601001 hasta B3601090, B3701001 hasta B3701090, B3801001 hasta B3801020, B3901001 hasta B3901020 (Incluido el escáner de código de barras), fabricados entre octubre de 2013 y febrero de 2015.
REGISTRO SANITARIO	2008DM-0002757
INDICACIONES Y USO ESTABLECIDOS	Usado para la medición de la bilirrubina transcutánea (BTC) para diagnóstico de ictericia.
NOMBRE DEL FABRICANTE	Draeger Medical Systems, Inc. Konica Minolta Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos médicos referenciados después de 1 a 2 años de uso pueden quedarse sin batería después de tomar algunas mediciones, a pesar de tener la batería totalmente cargada, además recalca que con el uso normal, el medidor debe ser capaz de tomar 200 a 250 mediciones, este problema es causado por el deterioro de la batería a causa de una corriente de carga limitada, lo cual podría conllevar a que se presenten retrasos en la atención de los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	21 de Marzo de 2017

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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 1

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[High Priority] - A28107 : Draeger—Jaundice Meters: Battery May Prematurely Deteriorate Medical Device Ongoing Action

Published: Wednesday, March 1, 2017
Last Updated: Thursday, March 2, 2017

UMDNS Terms:

- Bilirubinometers, Cutaneous [16166]

Product Identifier:

Jaundice Meters [Capital Equipment]
Model No. JM-105; Serial Nos.: B2001001 through B2001085, B3001011 through B3001471, B3101001 through B3101125, B3201001 through B3201101, B3301001 through B3301020, B3401001 through B3401020 (Without Barcode Scanner); B2501001 through B2501150, B3501017 through B3501288, B3601001 through B3601090, B3701001 through B3701090, B3801001 through B3801020, B3901001 through B3901020 (With Barcode Scanner)

Units manufactured between October 2013 and February 2015

Geographic Regions: Worldwide

Manufacturer(s): Draegerwerk AG & Co KGaAMoislinger Allee 53-55, 23558 Luebeck, Germany

Suggested Distribution: Clinical/Biomedical Engineering, Nursery, Nursing, Obstetrics/Gynecology/Labor and Delivery, Pediatrics, Home Care, NICU

Problem:

In a January 9, 2017, letter submitted by an ECRI Institute member hospital, Draeger states that continuous post market surveillance has shown that if the above meters are fully charged, after 1 to 2 years of usage they may run out of battery after taking a few measurements. Draeger further states that with average use, the meter should be able to take 200 to 250 measurements, if the device is fully charged. An investigation has found that this problem is caused by battery deterioration because of a limited charging current; therefore, the charging circuit board has been modified in order to improve the battery life.

Action Needed:

Identify any affected product in your inventory and your meter runs out of battery after taking a few measurements, contact Draeger service department to upgrade affected meters, at no charge, during the next maintenance cycle for minimal disturbance of your hospital operation. Devices should be sent to Draeger's repair center.

For Further Information:

Draeger service support department

U.S.

Tel.: (800) 437-2437

Canada

Tel.: (866) 343-2273

E-mail: canadaservicesupport@draeger.com

Outside U.S. and Canada, contact your local Draeger representative

Website: [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 Feb 17. Member Hospital. Draeger letter submitted by an ECRI Institute member hospital [Download](#)
- 2017 Mar 1. Manufacturer. Manufacturer confirmed source documents