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	Sistema de Presión Positiva Continua – CPAP
NO. IDENTIFICACIÓN RISARH	I1407-303
REFERENCIAS DEL DISPOSITIVO MEDICO	DV51D-HH, DV53D-HH, DV53D-HH-S, DV54D-HH, DV54D-HH-S, DV55D-HH, DV55D-HH-S, DV55D-S y DV57D-HH.
REGISTRO SANITARIO	2013DM-0010871
INDICACIONES Y USO ESTABLECIDOS	Tratamiento de la apnea obstructiva nocturna en adultos mediante la presión positiva continúa en la vía aérea (CPAP): envía aire con una presión continúa a las vías aéreas superiores para mantenerlas abiertas.
NOMBRE DEL FABRICANTE	Devilbiss Healthcare Llc
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos médicos pueden haber sido fabricados y distribuidos sin el número de serie programado en la unidad, causando que en la pantalla en lugar del dato correcto se visualice el mensaje “RUN TEST”, lo que puede conllevar a confusiones en el inventario de las unidades dentro de las instituciones.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	18 de Julio 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

ANEXO 1

A22642 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: July 15, 2014
UMDNS Terms:
- Positive Airway Pressure Units, Continuous [11001]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Nursing
- Pulmonology/Respiratory Therapy
- Home Care

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- Colombia
- Honduras
- Iran
- Thailand
- Uruguay
- U.S.

DeVilbiss—DV5x Series Continuous Positive Airway Pressure Units: Serial Number May Not Be Programmed into Unit

Product Identifier:
DV5x Series Continuous Positive Airway Pressure (CPAP) Units *[Capital Equipment]*
Model Nos.: DV51D-HH, DV53D-HH, DV53D-HH-S, DV54D-HH, DV54D-HH-S, DV55D-HH, DV55D-HH-S, DV55D-S, DV57D-HH
For a list of affected serial numbers, see the distribution list sent to your facility
1,809 units distributed

Manufacturer:
- DeVilbiss Healthcare Inc100 DeVilbiss Dr, Somerset, PA, 15501-2125, United States

Problem:
FDA's Center for Devices and Radiological Health (CDRH) states that the above CPAP units may have been manufactured and shipped without the serial number programmed into the unit, potentially causing the unit serial number on the LCD display to appear as "RUN-TEST" instead of the correct serial number. FDA's CDRH also states that the manufacturer initiated a correction by Urgent Medical Device Correction letter dated May 13, 2014. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify and isolate any affected product in your inventory. If you have affected product, verify that you have received the May 13, 2014, Urgent Medical Device Correction letter and serial number distribution list from DeVilbiss. Identify and isolate any affected product in your inventory. To arrange to have the serial number programmed into affected product, contact the DeVilbiss customer service department using the information below. Notify all relevant personnel at your facility of the information in the Urgent Medical Device Correction letter, and forward a copy of the letter to any facility to which you have further distributed affected product.

For Further Information:
DeVilbiss customer service department
Tel.: (800) 338-1988, 8 a.m. to 5 p.m. Easter time
Website: Click here

References:
- United States. Center for Devices and Radiological Health. Class 3 device recall DeVilbiss [online]. 2014 Jul 1 [cited 2014 Jul 7]. 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 Jul 7. FDA CDRH Database. Class III. Z-1949-2014