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 Ventilación Invasivo y No Invasivo
NO. IDENTIFICACIÓN RISARH	I1408-343
REFERENCIAS DEL DISPOSITIVO MEDICO	Stellar 100 y Stellar 150
REGISTRO SANITARIO	2011DM-0007955
INDICACIONES Y USO ESTABLECIDOS	El sistema de ventilación STELLAR está diseñado para proporcionar ventilación a pacientes adultos y pediátricos no dependientes (de 13 kg/30 lb o más), que respiran espontáneamente y que padecen insuficiencia respiratoria parcial o total, con o sin apnea obstructiva del sueño. El dispositivo es para uso no invasivo, o para uso invasivo con un tubo de traqueotomía sin manguito o con manguito. Para uso en el hospital o en casa.
NOMBRE DEL FABRICANTE	Resmed Paris Resmed West Coast Warehouse Resmed Germany Inc Resmed Ltd Resmed-Duncan Distribution Center Resmed Asia Operations Pty Ltd Resmed Corp
DESCRIPCION DEL PROBLEMA	El fabricante informa que el procedimiento descrito en las instrucciones de la guía de usuario referentes a la forma de configurar el circuito respiratorio para medición de impedancia y puesta a punto del ventilador antes del uso pueden ser mal interpretadas por el usuario, resultando que la presión entregada por el equipo pueda ser incorrecta o la presión visualizada no corresponda a la presión ejercida por el equipo, lo que puede conllevar a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	25 de Agosto 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

A22849 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: August 14, 2014
UMDNS Terms:
- Ventilators, Portable/Home Care [17423]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Critical Care
- Anesthesia
- Home Care
- Nursing
- OR/Surgery
- Pulmonology/Respiratory Therapy
- Risk Management/Continuous Quality Improvement

Geographic Regions:
- Worldwide

ResMed—Stellar 100 and 150 Ventilators: "Learn Circuit" Instructions in User Guide May Be Misinterpreted

Product Identifier:
Stellar Ventilators: (1) 100, (2) 150 [Capital Equipment]

Manufacturer:
- ResMed Germany IncFraunhoferstraße 16, 82152 Martinsried, Germany

Summary:
On August 14, 2014, the manufacturer confirmed the information provided in the source material.

Problem:
In an August 1, 2014, letter submitted by an ECRI Institute member hospital, ResMed states that post-market surveillance of the above ventilators suggests that the "Learn Circuit" instructions in the user guide may be misinterpreted. The firm has received one report of an occurrence of an over pressure event which was largely the result of misinterpretation of the "Learn Circuit" instructions. ResMed also states that if the "Learn Circuit" procedures are not performed or if they are performed with an incorrect circuit set-up, the delivered pressure(s) may be incorrect, the device may deliver a pressure spike in the event of a sudden circuit reconnection (potentially briefly reaching 60 cm H_2O), and/or the reported pressure may not accurately reflect the delivered pressures. ResMed further states that it has reviewed the risk associated with misinterpretation of the "Learn Circuit" instructions and determined that the likelihood of this problem occurring is remote and that, if it does occur, it is not likely to lead to serious injury.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the August 1, 2014, letter and a copy of the "Learn Circuit" Clinical Bulletin (CB#008). Review the Clinical Bulletin, including the revised "Learn Circuit" instructions (see the Clinical Bulletin enclosed with the letter), and follow these instructions when using affected product. Notify all relevant personnel at your facility of the information in the letter and the Clinical Bulletin, and forward a copy of the letter and bulletin to any facility to which you have further distributed affected product.

For Further Information:
ResMed local representative or David Baerveldt, ResMed associate product manager, respiratory care
Tel.: (858) 836-6387
E-mail: david.baerveldt@resmed.com
Website: 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 Aug 11. Member Hospital. ResMed letter submitted by an ECRI Institute member hospital
- 2014 Aug 14. Manufacturer. ResMed confirmed the information provided in the source material.