El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una alerta asociada a:

NOMBRE DEL DISPOSITIVO MÉDICO	Ventilador Controlado
NO. IDENTIFICACIÓN RISARH	A1405-206
REFERENCIAS DEL DISPOSITIVO MEDICO	HAMILTON-G5 Y HAMILTON-S1
REGISTRO SANITARIO	2008EBC-0001977
INDICACIONES Y USO ESTABLECIDOS	Se utiliza en obstrucción de las vías respiratorias, insuficiencia respiratoria, dificultades para respirar y todos los traumas, lesiones o enfermedades que pueden interferir en la respiración
NOMBRE DEL FABRICANTE	Hamilton Medical AG
DESCRIPCION DEL PROBLEMA	El fabricante informa que han detectado que los equipos mencionados pueden suprimir la asistencia ventilatoria después de realizar maniobras de aspiración iniciadas al pulsar el “flush” de enriquecimiento de O_2 por parte del usuario, lo que puede conllevar a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	20 de Mayo 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

A22273 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: May 15, 2014
UMDNS Terms:
- Ventilators, Intensive Care [17429]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Critical Care
- NICU
- Nursing
- Pediatrics
- Pulmonology/Respiratory Therapy

Geographic Regions:
- Worldwide

HAMILTON—HAMILTON-G5 and HAMILTON-S1 Ventilators: May Be Unintentionally Suppressed after Activation of Suctioning Maneuver

Product Identifier:
Ventilators (1) HAMILTON-G5, (2) HAMILTON-S1 *[Capital Equipment]*
Software Versions: V2.00 through V2.31

Manufacturer:
- HAMILTON MEDICAL AGvia Crusch 8, Bonaduz, CH-7402, Switzerland

Problem:
In an April 11, 2014, Medical Device Safety Corrective Action letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), HAMILTON states that the above ventilators may become unintentionally supressed after the user activates a suctioning maneuver and that this problem may occur regardless of the selected patient group. HAMILTON states that the vulnerability of the ventilator exists within an interference-prone time window of 50 milliseconds after the ventilator detects a disconnection during a suctioning maneuver that has been initiated by the operator pressing the O_2-enrichment key on the ventilator. This vulnerability exists under either of the following conditions:

- When the user presses the O_2-enrichment key a second time within 50 milliseconds after the disconnection is detected, or
- When disconnection is detected immediately before the O_2-enrichment period ends

The detection of disconnection and termination of O_2-enrichment occur within 50 milliseconds of each other. HAMILTON states that when either of these conditions is met, the interference results in the termination of mechanical ventilation and suppression of alarms, with the exception of the medium-priority alarm "loss of PEEP" when PEEP is set > 4 mbar. HAMILTON also states that ambient exhalation valves of the ventilator are opened so that a spontaneously breathing patient can breathe room air unassisted by the ventilator. If the error is not detected by the operator after the suctioning maneuver at the patient and PEEP is set to 4 mbar, a hypoxia of the patient may occur.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the April 11, 2014, Medical Device Safety Corrective Action letter from HAMILTON. After a suctioning maneuver is finished, verify that the ventilation continues. If ventilation does not continue, HAMILTON states that one of the following options can be used to re-establish ventilation:

- Press the "Manual Breath" key on the front side of the ventilator
- Change the ventilation mode
- Switch to the "Standby Mode" and return to the previously used ventilation mode

File the Medical Device Safety Corrective Action letter with the operator's manual. Hamilton states that it is providing the software key for inactivation of the suctioning maneuver functionality to all distributors and that the firm will update the operator's manual for affected product.

For Further Information:
HAMILTON MEDICAL AG technical support
Tel.: 41 (81) 6606010
E-mail: techsupport@hamilton-medical.ch
Website: Click here

References:
- Great Britain. Medicines and Healthcare Products Regulatory Agency. Hamilton Medical. Lung ventilators. HAMILTON-G5 / S1 [online]. London: Department of Health; 2014 May 6 [cited 2014 May 9]. 1 p. (Field safety notice; reference no. 2014/004/025/081/007). 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 May 9. MHRA FSN. 2014/004/025/081/007
- 2014 May 9. MHRA FSN.
- 2014 May 15. Manufacturer. Manufacturer confirmed information