

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	Humidificador – FISHER & PAYKEL
NO. IDENTIFICACIÓN RISARH	I1506-239
REFERENCIAS DEL DISPOSITIVO MEDICO	AIRVO 2
REGISTRO SANITARIO	2014DM-0011418
INDICACIONES Y USO ESTABLECIDOS	El MY AIRVO 2 está destinado al tratamiento de pacientes que respiran espontáneamente y que se beneficiarían de la administración de gases respiratorios calentados y humidificados de alto flujo. Los pacientes que hayan sido intervenidos para recibir un bypass en las vías respiratorias superiores también quedarían encuadrados dentro de este grupo. El flujo puede estar entre 2 - 60 l/min según la interfaz del paciente. El MY AIRVO 2 debe utilizarse en pacientes en el domicilio a en centros de atención a largo plazo. El AIRVO 2 está destinado al tratamiento de pacientes que respiran espontáneamente y que se beneficiarían de la administración de gases respiratorios calentados y humidificados con flujo alto. Los pacientes que hayan sido intervenidos para recibir un bypass en las vías respiratorias superiores también quedarían encuadrados dentro de este grupo. El flujo puede estar entre 2 - 60 l/min según la interfaz del paciente. El AIRVO 2 debe utilizarse en pacientes hospitalizados o en centros de atención a largo plazo.
NOMBRE DEL FABRICANTE	Fisher & Paykel Healthcare Limited.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que los dispositivos referenciados pueden ser incapaces de entregar flujos de aire u oxígeno al paciente cuando la línea eléctrica se interrumpe, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	05 de Junio de 2015

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

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[High Priority] - H0257 : Fisher & Paykel—AIRVO 2 Humidifiers: Will Not Deliver Flows of Air or O2 to Patient When Line Power is Lost [Hazard Report] Medical Device Hazard Report

Published: Friday, May 29, 2015

UMDNS Terms:

- Humidifiers, Artificial Airway, Heated [12050]

Product Identifier:

AIRVO 2 Humidifiers [Capital Equipment]

Geographic Regions: Worldwide

Manufacturer(s): Fisher & Paykel Healthcare Inc15365 Barranca Pkwy, Irvine, CA 92618, United States

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Nursing, Pulmonology/Respiratory Therapy, Staff Education, NICU

Problem:

1. The AIRVO 2 humidifier stops delivering flows of air and supplemental oxygen when disconnected from line power. The patient can continue to spontaneously breathe room air.
2. The alarm that sounds with the loss of line power may not be sufficiently loud or long enough to alert clinicians to the loss of supplemental oxygen.
3. For patients requiring supplemental oxygen, the loss of oxygen could lead to low oxygen saturation and its attendant sequelae (e.g., shortness of breath, potential cardiac arrhythmia and/or arrest).

ECRI Institute Recommendations:

1. Inform users that loss of line power disrupts air and supplemental oxygen flow from the AIRVO 2 during which the patient can breathe room air only.
2. Inform users that loss of line power may go undetected because the loss of line power alarm duration is short (2 min), the alarm is not loud, and oxygen flow meters of auxiliary sources continue to register their set flow, giving a false appearance that oxygen is flowing to the patient.
3. Per the [user manual](#), use continuous SpO₂ monitoring for patients requiring supplemental oxygen via the AIRVO 2.
4. Position the AIRVO 2 so that its display can be easily observed and its alarms heard.
5. Check the display on the AIRVO 2 to determine if oxygen is flowing to the patient. Do not depend on the flowmeter on the oxygen source to indicate if oxygen is flowing to the patient.
6. Plug the AIRVO 2 power cord directly into a wall outlet, never into a power strip.

Background:

- The AIRVO 2 is a heated humidifier with an internal flow generator for use with spontaneously breathing patients. Supplemental oxygen can be supplied to a patient by connecting a low-flow oxygen source (e.g., flowmeter connected to wall outlet) to the inlet on the device, and the delivered oxygen fraction is controlled indirectly by adjusting the flow of oxygen at the flowmeter (there is an oxygen sensor and delivered FiO₂ is displayed on the screen). It can deliver room air or a blend of room air and oxygen at a rate of 2-60 L/min and is used with a variety of patient interfaces (e.g., nasal cannula, mask, tracheostomy connection). Total flow rate and temperature are controlled directly on the device.
- When the AIRVO 2 loses power, the internal flow generator stops delivering air and thereby any supplemental oxygen. When this occurs, the patient can still spontaneously breathe room air. When the device loses power, an alarm sounds for 2 min.
- A member hospital reports two incidents in which patients were found with low oxygen saturation despite being connected to supplemental oxygen through the AIRVO 2. Clinicians report that no power loss alarm was heard. In both instances, oxygen was flowing from the oxygen source at the set rate, as indicated by the flowmeter on the oxygen source, causing the clinicians to believe that the patient was receiving supplemental oxygen.
- The facility's investigation determined that, in each case, the AIRVO 2 inadvertently became disconnected from line power and was not operating.
- The facility has removed the AIRVO 2 from the acute care setting because they consider its response to a loss of power inadequate for patients that require high levels of oxygen.

Manufacturer's Perspectives:

- Fisher & Paykel (FPK) has not received any reports in the U.S. of patient injury resulting from the interruption of air and oxygen flow when the AIRVO 2 is disconnected from line power.

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- According to the [AIRVO 2 user manual](#), “The unit is not intended for life support” and “...is for the treatment of spontaneously breathing patients.”
- The AIRVO 2 user manual instructs users to “Use continuous oxygen monitoring on patients who would desaturate significantly in the event of disruption to their oxygen supply.” In addition, the warning “Monitor patient O₂ saturations” scrolls on the “O₂ setting” screen.

FPH will release a mounting kit in the U.S. in May 2015 to allow a medical-grade Tripp-Lite SMART700HG uninterruptible power supply (UPS) to be fitted to the mobile pole stand. The UPS is intended to provide backup power during intra-hospital transport.

Discussion:

- According to the user manual, the alarm volume is 45 dB at 1 meter and is not configurable. FPH set the alarm at this level to not compete with more critical alarms (e.g., alarm volumes for ICU ventilators are typically in the range of 50-85 dB). Because the AIRVO 2 alarm is not as loud as some other alarms, the 2 min duration may not be long enough to be noticed in many acute care environments.
- As stated above, FPH will be releasing an optional mounting kit from FPH that will allow the use of a UPS with the AIRVO 2. This is intended to allow the use of the AIRVO 2 during transport, not as a backup battery. With respect to the behavior described in this report, if the AIRVO 2 is plugged into the UPS and the UPS becomes inadvertently unplugged from the wall, the UPS will power the AIRVO 2 for at least 18 min (compared to immediately ceasing operation without the UPS), and the UPS will alarm the entire time (compared to the 2 min power loss alarm on the AIRVO 2). However, this is only if the disconnection occurs between the UPS and the wall; if the AIRVO 2 becomes unplugged from the UPS it will act as described above.

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):

- 2015 May 29. ECRI Institute researched member report.

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