

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 Oxigenador - QUADROX-I, Reservatorio – VHK y Filtro - QUART
NO. IDENTIFICACIÓN RISARH	I1503-135
REFERENCIAS DEL DISPOSITIVO MEDICO	QUADROX-I, concerniente al Set avanzado HLS, Membrana de difusión adulto, Membrana de difusión adulto pequeña y Set PLS.
REGISTRO SANITARIO	2013DM-0010086
INDICACIONES Y USO ESTABLECIDOS	Sistema indicado para ser usado durante la derivación cardiopulmonar en intervenciones cardioquirurgicas con circulación extracorpórea en donde el sistema permite oxigenar y eliminar el dióxido de carbono de la sangre y ajustar la temperatura sanguínea, que junto con el reservorio recolectar, almacenar y filtrar la sangre..
NOMBRE DEL FABRICANTE	Maquet Cardiopulmonary A. G. Maquet Cardipulmonary- Medikal T
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado una fuga de sangre en el puerto de salida (área de la parte más baja del oxigenador), conllevando a que se presenten potencialmente eventos adversos sobre los pacientes o usuarios por exposición a sangre.
FUENTE	https://www.ecri.org/Components/Alerts/Pages/TrackingUser/AlertDisplay.aspx?GL=Y&AId=1621839&entryID=2&Page=AlertDisplay
FECHA DE NOTIFICACION	ANEXO 1

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] - A24059 : MAQUET—QUADROX iD Diffusion Membrane , HLS Set Advanced, and PLS Set Oxygenators: Gas Outlet Port May Leak Medical Device Ongoing Action

Published: Thursday, March 19, 2015
Last Updated: Friday, March 20, 2015

UMDNS Terms:

- Oxygenators, Regional Perfusion [13319]

Product Identifier:

Oxygenators: (1) HLS Set Advanced, (2) QUADROX iD Diffusion Membrane Adult, (3) QUADROX iD Diffusion Membrane Small Adult (4) PLS Set [Consumable]

Geographic Regions: Argentina, Australia, Brazil, Canada, Chile, Colombia, Europe, Israel, Japan, Mexico, Saudi Arabia, Singapore, South Korea, Taiwan, Thailand, Uruguay

Manufacturer(s): MAQUET Cardiopulmonary AG A Getinge Group CoHechinger Strasse 38, Hirrlingen, D-72145, Germany

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, OR/Surgery, Pulmonology/Respiratory Therapy, Materials Management

Problem:

In a December 11, 2014, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and the German Federal Institute for Drugs and Medical Devices (BfArM), MAQUET states that the above oxygenators may leak blood from the gas outlet port (the area at the lowest part of the oxygenator). MAQUET also states that in previous incidences, the leakage was a slow drip and often identified during priming. When identified during patient use, the leakage stopped without medical personnel or was such a small amount that the procedure could continue. MAQUET also states that users should be aware of the following hazards as a result of blood leakage from the gas outlet port:

- (1) Possible reduction in gas transfer efficiency.
- (2) Medical staff exposure to blood that has dripped from affected product.
- (3) Significant blood loss in patient that requires transfusion.
- (4) Blood dripping backward into affected product that may activate a clotting cascade.

MAQUET has received no reports of reduced gas efficiency, medical staff exposure to leaked blood, or significant blood loss in patients. MAQUET has received reports that the dripping blood stopped after a period of time, indicating that some clotting did occur.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the December 11, 2014, Urgent Field Safety Notice letter from MAQUET. Complete the Response Form, and return it to MAQUET using the instructions on the form. Inspect affected product and connection for leaks before patient use, as described in the QUADROX oxygenator instructions for use (IFU). If leaks are evident, do not use affected product. The IFU also recommends that a second product or replacement set be available if problems occur during patient use. If blood leakage is evident during patient use, MAQUET recommends the following:

- (1) Reinspect all connections to confirm that they are tight and are not the cause of the leakage.
 - (2) Take necessary precautions to protect yourself and others from potential exposure to draining blood.
 - (3) Monitor the blood leakage, and prepare a second oxygenator or set for exchange (priming and removal of air from the system).
- MAQUET also recommends that users consider the patient's condition, amount of blood loss or leakage, and estimated length of time to complete the procedure when determining whether to exchange the oxygenator or set. If an exchange is necessary, follow your facility's standard procedures. MAQUET recommends that you consider the additional priming volume and determine the need for additional transfusions to prevent or reduce the risk of hemodilution because of the exchange. MAQUET is developing a corrective action for this problem and will notify affected customers when it is available. Inform all relevant personnel of the information in the Urgent Field Safety Notice letter, and forward a copy of the letter to any facility to which you have further distributed affected product.

For Further Information:

MAQUET local representative

Website: [Click here](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Maquet Cardiopulmonary. Infusion & transfusion, heart lung circuits. Oxygenator membrane, Quadrox-iD adult/small adult [online]. London: Department of Health; 2014 Dec 29 [cited 2015 Mar 10]. (Field safety notice; reference no. 2014/012/023/081/003). Available from Internet: [Click here](#).
- Germany. Federal Institute for Drugs and Medical Devices. Urgent Safety Notice for the products Quadrox-iD adult/small adult, HLS Set Advanced and PLS Set, Maquet Cardiopulmonary AG [online]. 2015 Jan 30 [cited 2015 Mar 10]. Available from Internet: [Click here](#).

Comments:

- For information regarding this problem specific to the U.S., see [Alert Accession No. A23992](#).
- 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 Mar 18. BfArM (Germany). 8417/14 [Download](#)
- 2015 Mar 18. BfArM (Germany). MAQUET letter posted by BfArM [Download](#)
- 2015 Mar 18. MHRA FSN. 2014/012/023/081/003 [Download](#)
- 2015 Mar 18. MHRA FSN. MAQUET letter posted by MHRA [Download](#)

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