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 Anestesia FLOW - i / MAQUET
NO. IDENTIFICACIÓN RISARH	I1503-113
REFERENCIAS DEL DISPOSITIVO MEDICO	FLOW-i, seriales específicos
REGISTRO SANITARIO	2011EBC-0008130
INDICACIONES Y USO ESTABLECIDOS	Destinado para la administración de anestesia al tiempo que se controla la ventilación completa de pacientes sin capacidad de respirar, así como en el apoyo de pacientes con capacidad de respirar limitada.
NOMBRE DEL FABRICANTE	Maquet Critical Care Ab
DESCRIPCION DEL PROBLEMA	El fabricante establece que los módulos de O_2 y de succión de los equipos referenciados, no pueden ser activados o controlados por el *switch* "*on/off*" de la unidad de succión, lo cual podría dar lugar a una disminución o pérdida de la capacidad de aspiración, haciendo difícil mantener despejada la vía aérea del paciente, conllevando a que se presenten potencialmente eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	13 de Marzo 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

[Normal Priority] - A23991 : MAQUET— FLOW-i Anesthesia System Auxiliary O2 and Suction Modules: On/Off Switch May Not Activate Suctioning Function

Medical Device Ongoing Action

Published: Thursday, March 12, 2015
Last Updated: Friday, March 13, 2015

UMDNS Terms:

- Anesthesia Units [10134]

Product Identifier: FLOW-i Anesthesia System Auxiliary O2 and Suction Modules *[Capital Equipment]*
Part No. 66 79 847; Serial Nos.: 4, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 26, 27, 28, 29, 31, 37, 40, 56, 138, 199, 205, 367, 369, 370, 371, 372, 391, 394, 395, 416, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 517, 519, 525, 567, 568, 570, 582, 583, 606, 613, 619, 627, 629, 630, 631, 633, 635, 636, 637, 638, 639, 640, 641, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665
Units distributed between March 12, 2013, and December 31, 2014

Geographic Regions: Worldwide

Manufacturer(s): MAQUET Critical Care ABRontgenvagen 2, Solna, SE-171 95, Sweden

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, OR/Surgery, EMS/Transport

Problem: In a March 2, 2015, Urgent Medical Device Field Action Removal and Replacement letter submitted by an ECRI Institute member hospital, MAQUET states that the auxiliary O2 and suction modules for the above anesthesia systems may not be activated or controlled by the suction unit's "on/off" switch, potentially leading to a decrease or loss of suctioning capability. This decrease or loss of suctioning may make it difficult to keep a patient's airway free, or to extract bodily fluids from the stomach. The module's ability to deliver O2 to the patient is not affected. MAQUET also states that it has received no reports of patient injury related to this problem.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the March 2, 2015, Urgent Medical Device Field Action Removal and Replacement letter and Device Removal Response Form from MAQUET. Complete the Response Form, and return it to MAQUET using the instructions on the form. After the suction module has been tested during system checks, keep the module turned on and regulate the suction pressure as needed, with the knob on the far right for vacuum setting (as pictured in the letter). This will minimize potential for the suction unit's "on/off" switch to malfunction. Ensure that the back-up gas cylinders are closed after checkout to minimize gas consumption from the back-up cylinders. Inform all relevant personnel of the information in the Urgent Medical Device Field Action Removal and Replacement letter, and provide a copy of the letter to any facility to which you have distributed affected product. A MAQUET service representative will contact your facility to arrange for removal and replacement of affected product.
For Further Information:
MAQUET technical support department or local MAQUET representative
U.S.
Tel.: (888) 627-8383 (option 3, option 1, then option 1 again) 8:00 a.m. to 5:00 p.m. Eastern time, Monday through Friday
Website: Click here
Outside U.S.
Local MAQUET representative

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 Mar 10. Member Hospital. MAQUET letter submitted by member hospital (includes reply form) Download
- 2015 Mar 12. Manufacturer. Manufacturer confirmed information.