

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 para Hemodiálisis de Alta Permeabilidad - PRISMAFLEX.
NO. IDENTIFICACIÓN RISARH	I1502-58
REFERENCIAS DEL DISPOSITIVO MEDICO	PRISMAFLEX
REGISTRO SANITARIO	2010EBC-0006651
INDICACIONES Y USO ESTABLECIDOS	La unidad de control PRISMAFLEX está indicada para: terapia de reemplazo renal continua (CRRT, por sus siglas en inglés) para pacientes con insuficiencia renal aguda y/o sobrecarga de fluido. Terapia de intercambio terapéutico de plasma (TPE, por sus siglas en inglés) para pacientes con trastornos en los cuales se indica el retiro de los componentes del plasma
NOMBRE DEL FABRICANTE	Gambro Lundia AB
DESCRIPCION DEL PROBLEMA	El fabricante afirma que después de realizar la actualización del software a la versión 7.11 de los equipos referenciados, las alarmas auditivas pueden ser difíciles de reconocer por los cambios en su presentación (volumen y tono), resultando posiblemente en que el personal médico no se encuentre familiarizado con las condiciones de la alarma, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	09 de Febrero 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] - H0244 : Gambro—PrismaFlex CRRT Systems: Audible Alarms May Not Be Adequate after Software Update 7.11 Medical Device Hazard Report

UMDNS Terms:

- Hemodialysis Units, Renal, Continuous Replacement Therapy [23426]

Product Identifier:

PrismaFlex CRRT (Continuous Renal Replacement Therapy) Systems [Capital Equipment]
Software Version 7.11

Geographic Regions: Worldwide

Manufacturer(s): Gambro Americas 14143 Denver W Pkwy, Lakewood, CO 80401, United States

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Nursing, NICU

Problem:

1. After the software of PrismaFlex CRRT units is updated to version 7.11, auditory alarms may be hard to recognize because of changes in alarm presentation, possibly resulting in clinicians not being alerted to alarm conditions.
2. Missed alarms can result in serious patient injury or death.

ECRI Institute Recommendations:

ECRI Institute recommends that users of the PrismaFlex with software version 7.11 (or following upgrade to 7.11) do the following:

Clinicians

1. Assess whether Prismaflex alarms will reliably be heard and recognized in the appropriate areas and under the appropriate conditions.
2. Report any difficulty in hearing Prismaflex alarms to Clinical Engineering.

Clinical Engineering Staff

1. Assess whether Prismaflex alarms will reliably be heard and will alert clinicians to alarm conditions in each area where the system is used, taking into account environmental factors (e.g., range of ambient noise, closed doors) that may exist in each location.
2. If the audible alarm is inadequate, verify that the unit's volume and sound pattern/melody are still set at default settings of High (the maximum level). If the alarm is still inadequate, consider an ancillary alarm notification system.

Background

1. An ECRI Institute member reports that clinicians reported difficulty hearing alarms on Prismaflex systems following a software update to version 7.11, even when the units were configured to the maximum settings for volume and sound pattern.
2. In particular, staff have problems hearing the alarms when the Prismaflex is being used in areas with sound barriers, such as isolation rooms.

Supplier Perspectives

1. Gambro states that the volume level of the alarms did not change with the introduction of software version 7.11. Rather, the sound patterns or "melodies" were changed or expanded to comply with industry standards. Previously, there was one sound pattern. In version 7.11, the peak volume is the same as before but the sound patterns vary depending on the nature of the alarm, with the sounds, number of sound pulses, and frequency varying depending on the potential criticality of the alarm.
2. Gambro states that if clinicians believe that they are having difficulties clearly perceiving the alarms, then clinical engineering staff can adjust both the sound and pattern. Three settings are available: Low, Moderate or High, which are accessed in the service mode. The default setting is "High" for both volume and sound pattern settings.
3. The Prismaflex control unit can also be interfaced to a remote alarm device.
4. Instructions for accessing the service menu and interfacing the unit are in the PrismaFlex Operator's Manual.

Source(s):

- 2015 Jan 30. ECRI Institute researched member report.

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