

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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	Bomba de Infusión SAPPHIRE
NO. IDENTIFICACIÓN RISARH	I1708-350
REFERENCIAS DEL DISPOSITIVO MEDICO	Concerniente a las CAJAS DE SEGURIDAD / LOCKBOXES
REGISTRO SANITARIO	2014EBC-0011258
INDICACIONES Y USO ESTABLECIDOS	Entrega controlada a través de rutas intravascular, subcutánea, intraarterial y epidural. La bomba está diseñada para entregar sueros salinos, nutrición parenteral total (TPN), lípidos, medicamento iv, medicamento epidural, sangre y productos sanguíneos. La bomba SAPPHIRE incluye los siguientes modos de infusión para todos los usos previstos: continuo, intermitente, TPN, PCA, multi-paso y epidural. La bomba está indicada para ser usada tanto por profesionales de la salud en un ambiente clínico como por usuarios domésticos en un ambiente ambulatorio. La bomba SAPPHIRE está diseñada para seguir al paciente a través de las diversas áreas de cuidado y es adecuada para usarse en diferentes configuraciones.
NOMBRE DEL FABRICANTE	Q Core Medical Ltd
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos pueden ser abiertas con artículos disponibles en una unidad de cuidados intensivos, los pacientes u otras personas no autorizadas, pueden manipular la caja fuerte sin romperla y tener acceso a la medicación, dicha posibilidad de acceder al medicamento representa un riesgo para que sean hurtados o manipulados, conllevando a que se presenten potenciales eventos adversos sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	18 de Agosto de 2017

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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

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ANEXO

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[High Priority] - H0394 : ICU Medical/Q Core Medical—Sapphire Lockboxes: Can Be Defeated, Providing Medication Access to Unauthorized Persons [ECRI Exclusive Hazard Report]

Medical Device Hazard Report

Published: Tuesday, August 15, 2017

UMDNS Terms:

- Infusion Pumps, Analgesic, Patient-Controlled [16924]

Product Identifier:

Sapphire Lockboxes [Capital Equipment]

Geographic Regions: Worldwide

Distributor(s): • ICU Medical Inc951 Calle Amanecer, San Clemente, CA 92673, United States

Manufacturer(s): Q Core Medical Ltd29 Yad Haruzim Street, Netanya IL-42505, Israel

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, Nursing, Risk Management/Continuous Quality Improvement, Pharmacy, IV Therapy

Problem:

1. ICU Medical/Q Core Medical Sapphire lockboxes may be defeated with items available in a care unit.
2. Patients or other unauthorized persons (e.g., family members) may tamper with the lockbox without breaking it and gain access to medication.
 - The ability to gain access to the medication presents a risk of unauthorized persons tampering with and/or stealing the medication.
3. Interruption and/or delay in pain therapy may occur as a result of this problem.
4. The pump does not recognize or alarm if the lockbox is tampered with, even if an infusion is ongoing.

ECRI Institute Recommendations:

1. Notify clinician staff about the potential for unauthorized persons to gain access to medication when an ICU Medical/Q Core Medical lockbox is used.
2. Clinicians should conduct a physical and visual check at a specific interval (e.g., every shift change) to ensure that the lockbox is appropriately secured.
3. If unauthorized access to medication is suspected, report the incident per your facility's policy.

Manufacturer's Perspectives or Comments:

1. The ICU Medical/Q Core Medical operational manual states:
 - "PCA Lockboxes are designed to secure the IV bag, primarily for treatments involving narcotics or opioids, without interrupting the treatment workflow."
2. There are no known cases of medication diversion when locked in the Sapphire lockbox.

Background:

- ECRI Institute has received reports from member facilities about patients gaining access to patient-controlled analgesia (PCA) pump lockboxes.
 - Reports pertain to a different manufacturer's PCA pump lockbox than what is discussed in this report.
- ECRI Institute identified the ability to gain access to the ICU Medical/Q Core Medical lockbox without a key in our laboratory testing.
- ECRI Institute is currently not aware of any alternative methods to secure the medication, beyond the lockbox, with this particular pump model.
- In the past, ECRI Institute has mainly received reports and investigated incidents regarding medication diversion by hospital staff. Recent reports of patients gaining access to their medications suggest a growing trend. Considering the ongoing opioid epidemic in the U.S., we want to ensure that facilities are aware of these shortcomings and provide them with recommendations to act accordingly.

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

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source documents, to the original alert. For additional information regarding the format of this alert, refer to our [HDA Format Guide](#) .

Source(s):

- 2017 Aug 1. ECRI Institute researched member report