

# 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:**

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Equipo de Rayos X SEDECAL
<b>NO. IDENTIFICACIÓN RISARH</b>	I1707-306
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	Concerniente a los carros radiográficos.
<b>REGISTRO SANITARIO</b>	2011EBC-0008353 2008EBC-0002368 2008EBC-0002158
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Sistema de radiología general, para aplicaciones generales de trauma, tórax, urología, abdomen urgencias, permitiendo realizar proyecciones tanto AP como laterales con o sin mesa rodante y oblicua.
<b>NOMBRE DEL FABRICANTE</b>	Sedecal S.A. (Sociedad Española de Electromedicina y Calidad S.A.)
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante ha identificado que la placa de montaje de las ruedas en los carros radiográficos móviles podría presentar una fractura por fatiga, conduciendo potencialmente a un fallo catastrófico de las ruedas delanteras, en caso de presentarse dicha novedad la unidad deber ser puesta fuera de servicio para evitar su bloqueo total, igualmente informa que estos carros pueden estar siendo utilizados por otros fabricantes de equipos de rayos X móviles, conllevando a que se presenten potenciales eventos adversos sobre los pacientes o usuarios.
<b>FUENTE</b>	ANEXO
<b>FECHA DE NOTIFICACION</b>	21 de Julio de 2017

### 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

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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](mailto:tecnovigilancia@invima.gov.co)

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### ANEXO

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#### [Normal Priority ] - S0323 : Sedecal—Mobile Radiography Carts Supplied by Agfa, Canon, Philips, and Samsung: Fatigue Fractures May Cause Caster Mount Failure [ECRI Exclusive User Experience Network]

##### Medical Device Special Report

Published: Thursday, July 20, 2017

##### UMDNS Terms:

- Radiographic Units, Mobile [13272]

##### Product Identifier:

Sedecal Mobile Radiography Carts supplied with Mobile Radiographic Units from various suppliers, including the following: (1) Agfa, (2) Canon, (3) Philips, (4) Samsung, (5) Sedecal [Capital Equipment]

Geographic Regions: Worldwide

Manufacturer(s): SEDECAL Poligono Industrial Rio de Janeiro, E-28110 Algete (Madrid), Spain

Suggested Distribution: Clinical/Biomedical Engineering, Emergency/Outpatient Services, OR/Surgery, Orthopedics, Diagnostic Imaging

##### Problem:

1. The caster mounting plate on the above mobile radiography carts is subject to fatigue fracture, potentially leading to catastrophic failure of the front casters.
2. When one caster falls off, the device will remain balanced and drivable. This is not considered an immediate safety risk; however, if this occurs, ECRI Institute recommends that the unit be taken out of service, which may adversely affect patient diagnosis and care.
3. After one caster falls off, the remaining caster will be subject to excessive forces that increase the likelihood of failure of the remaining caster. If the second caster fails, the x-ray unit will no longer be drivable.

##### Manufacturer's Corrective Action/Recommendations:

1. Do not drive the cart over a threshold exceeding 25 mm (1 inch).

##### ECRI Institute Recommendations:

1. To prevent or reduce the risk of this problem occurring:
  1. Drive the cart slowly when crossing any uneven thresholds.
  2. Perform a monthly inspection of the caster mounts, look for fractures or cracks around the caster collar. The front chassis cover does not need to be taken off. To view the underside of the front caster mounts on the cart, use a mirror and flashlight.
  3. Purchase an extended warranty from the manufacturer to cover the repair or replacement of mobile radiographic carts.
2. If a crack is detected:
  1. Continue to use the cart if the cracks are smaller than 1 inch, but avoid driving over rough and uneven surfaces and thresholds. Consider storing the carts near the areas of regular use to minimize travel distance.
  2. Record and monitor the cracks. Stop using the cart if the cracks get larger.
3. If a caster falls off:
  1. Do not use the device.
  2. Contact the manufacturer for guidance and to schedule repair.
  3. Report any cases of caster mount cracking and subsequent failures to ECRI Institute.

##### Background:

- ECRI institute has investigated 2 mobile x-ray units whose cart's base steel plate was affected by fatigue fracture during routine use within reasonable clinical settings. The front caster fell off of one of these units.
- There are several medical device suppliers that use Sedecal carts for their mobile radiographic x-ray units, including Agfa, Canon, Philips, Samsung, and Sedecal.
- The Sedecal carts have 2 small casters mounted at the front and 2 large driving wheels mounted at the back.
- The casters are mounted on a 6 mm thick steel plate that is integral with the steel frame of the cart's main chassis assembly.
- Fatigue fractures may form in the mounting plate when the cart is subject to repeated stress or significant vibration when, for example, driving over uneven or rough surfaces, small steps, door or elevator thresholds, and outdoor pavements.

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- The mounting plate may fail and the caster may fall off because of fatigue failures that occur over time.
- Failure of a caster during use is unlikely to cause the cart to tip over because of its low center of gravity.
- Because the rear wheels are the weightbearing components, the unit is still drivable when 1 caster falls off.

#### 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):

- 2017 Jul 12. ECRI Institute researched member report