

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	Angiógrafo GENERAL ELECTRIC
NO. IDENTIFICACIÓN RISARH	I1612-570
REFERENCIAS DEL DISPOSITIVO MEDICO	INNOVA 2000
REGISTRO SANITARIO	2009EBC-0003319
INDICACIONES Y USO ESTABLECIDOS	Estos equipos están diseñados para visualizar estructuras anatómicas internas del paciente convirtiendo el patrón de la radiación de rayos x en una imagen visible a través de la amplificación electrónica y la visualización radiológica del corazón, vasos sanguíneos o sistema linfático durante o después de una inyección de medio de contraste. Están indicados para su uso en procedimientos como diagnóstico e intervencionismo de angiografía vascular para la generación de imágenes fluoroscópicas de la anatomía humana, exploración en rotación, cardiología y otros.
NOMBRE DEL FABRICANTE	Xpro Sistemas Ltda Ge Medical Systems Scs (Gems Scs) Ge Hualun Medical Systems Co., Ltd
DESCRIPCION DEL PROBLEMA	El fabricante fabricante afirma que los monitores anteriores pueden caer de la suspensión del monitor a causa del envejecimiento del mismo, conllevando a que se presenten posibles eventos adversos serios sobre el paciente u operador.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	13 de Diciembre de 2016

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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 1

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[High Priority] - A27655 : GE—CRT Monitors Used with Various Fluoroscopic X-Ray Systems: May Fall off Monitor Suspension Medical Device Ongoing Action

Published: Wednesday, November 30, 2016
Last Updated: Monday, December 5, 2016

UMDNS Terms:

- Monitors, Video [16603]
- Radiographic/Fluoroscopic Systems [18436]
- Facility Booms [22612]

Product Identifier:

CRT Monitors used with the following Fluoroscopic X-Ray Systems: (1) ADVANTX, (2) Innova 2000, (3) Legacy, (4) Precision 500D, (5) Prestige 2, (6) Prestige SI, (7) Prestige VH, (8) Prestilix, (9) RFX/SFX [Capital Equipment] System ID Nos.: 00658FLU01, 05074FLU02, 053086LEG, 082408040013, 082408040013, 082408100085, 0850080428, 0850080430, 0850080467, 0853080151, 0853080151, 0853080154, 0853080154, 0859080008, 0910062022, 0910062022, 0910796005, 1025, 1301, 1443, 1711, 201754LEG, 201754PRES, 201754RF6, 201754RF8, 201858RM3, 2025761X40, 2025761X46, 203246RF3, 203797LEG1, 204623RF1, 205345RF2, 205345RF3, 205387LRF, 205534RMD, 205554VAL, 205592MLC, 205592MLC, 205655LRF, 205783LRF2, 205793FLEG, 205793FR1, 205801KRF4, 205877LRF2, 205930LRF, 206244RMD, 206385RM1, 207255RF2, 207262SRF3, 207262SRF3, 207373RF1, 209221TCX, 209225LEG3, 209384MMRF, 209386ATWRF, 209577LEG, 209578AVTX, 209992CPI, 210428VCATH2, 210575CRF1, 210575CRF2, 210614NRF1, 210614NW1, 210614RF1, 210614SRF1, 210704SRP1, 210705SRMC4, 212463LEGACY, 212844RM3, 213266SFX, 214320RF1, 214345PRF, 214376VARF2, 214820RF1, 214827RF, 214947RF4, 215221CL1, 215576LC2, 215576RF18, 215707LEGACY, 215776LRF3, 215831SP, 215881RF1, 217337CXF2, 217383CRF1, 217544JRMF, 217544RMI, 217788LEG2, 218726SMRF2, 219284RMDN, 219284RMSN, 219416ADV, 219416PRE, 219886NLP, 225222LEG, 225635RF1, 225769RF1, 228314RF, 228575XCR1, 228575XCR2, 228575XCR3, 228809SR2, 229312DRS, 229353TR2, 231547ADV, 231845RMB, 239369RM3, 239931RMD, 248551RMI2, 248937LEG, 252641HRLEG, 256235ORF1, 256235ORF2, 256386LD1, 256386LD2, 256517EF2, 256534RMI, 260425SJRFF6, 260425SJRFF6, 262321RF1, 262687RF112, 281218HSLXXX, 281338CL5, 281599LEG, 281618LEG, 301279RF2, 301681RF, 301762RF1, 301891RM1, 301896RF, 301896RF1, 301981RF5, 303320CL2, 303398RF, 303440BCHRM4, 303450RMD, 303695RF1, 303695ROOM3, 303695ROOM4, 303695RF2, 303778RM3A, 303788RM9, 304235WVX1B, 304256RX1A, 304256RX1A, 304348MX3, 304348SX2, 304424RF1, 304462LEG, 304647GX1, 305227PRESTIGE1, 305227PRESTIGE2, 305668RF1, 306778RF1, 307332RF, 307332RF, 309343CRF4, 309347RF1, 309655FNCRF1, 309655FNCRF1, 310289LEGACY2, 310665PREST, 312567PR6, 312792GEMNET, 312792RINOVR2, 312CCHGECATH, 312CCHGECATH, 313295LEG, 313493ADV, 313576RMI663, 313576RMI661, 313576RMB622, 313576RMB645, 313593LEG1, 313593LEG2, 313574SRF4, 314525APR, 314577TUSHRF1, 314625SJR2, 315393RF1, 315764MRF1, 316672PDI, 316759LEGACY, 317338SVP, 317621LEGACY, 317662RM3, 317662RM4, 317662RM5, 318227SRM5, 318253LEG, 318255GRM1, 318327RM7, 318327RM8, 318327RM9, 318327SFCH2, 318329GRM6, 318335RF2, 318336LEG, 318377RM3, 318388RF3, 318435RF1, 318448COP1, 318478RF2, 318531FRM4, 318539LEG, 318675LR8, 318728RF1, 318783ARF, 318798HR3, 318798HRM4, 318948DRS, 319352WR2, 319652ADVRF, 321752WLG1, 323669ADV, 326582XF1, 330332R18, 330385FL6, 330665RM1, 330837R4, 330837R4, 330841R5, 334293JLD3, 336719NR151, 336835HCR1, 352344RFELEG, 352351RMD, 352394LGI, 352689RF, 352861RF1, 361552LEG01, 361985RF2, 36811857XRAND, 38828380XNROR, 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Geographic Regions: Worldwide

Manufacturer(s): GE Healthcare3000 N. Grandview Blvd. - W440, Waukesha, WI 53188, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Diagnostic Imaging

Problem:

In a November 21, 2016, Urgent Medical Device Correction letter submitted by ECRI Institute member hospitals, GE states that the above monitors may fall off the monitor suspension because of product aging, potentially resulting in serious injury to users and patients. GE also states that CRT monitors, CRT monitor feet, and CRT suspensions systems that have exceeded their nominal life are obsolete.

Action Needed:

Identify any affected monitors in your inventory. If you have affected monitors, verify that you have received the November 21, 2016, Urgent Medical Device Correction letter from GE. Adhere to the following precautions until the monitor feet on the systems are replaced:

- Inspect the CRT monitor and suspension, and use them with caution. Ensure that the monitors are secured properly to the tray before each use. Immediately stop using the system if there is any looseness of the monitor, and contact your GE service representative.
- Do not position the monitor above the patient.
- Position the monitor by grasping the handle at the side or front of the tray and gently move to the position as recommended in the User Manual 45-296411.
- Before non-GE service personnel attempt to perform service or preventive maintenance of the monitor on a GE system, GE recommends that you obtain an updated copy of the service and preventive maintenance procedures from a GE Healthcare representative or download them from the GE On-Line Documentation [website](#). These may be found under the product name.

A GE representative will contact your facility to arrange for product correction. Notify all relevant personnel at your facility of the information in the Urgent Medical Device Correction letter.

For Further Information:

GE service department
Tel.: (800) 437-1171
Website: [Click here](#)

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):

- 2016 Nov 21. Member Hospital. GE Reference No. FMI 10913 [Download](#)
- 2016 Nov 30. Manufacturer. The manufacturer confirmed the information provided in the source material.
- 2016 Dec 5. BfArM (Germany). 10465/16 [Download](#)
- 2016 Dec 5. BfArM (Germany). GE Reference No. FMI 10913 [Download](#)

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