

## 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>	Sistemas de Rayos X Móviles en C
<b>NO. IDENTIFICACIÓN RISARH</b>	I1410-415
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	OEC 9800, OEC UroView 2800, FlexiView 8800, OEC MiniView 6800, seriales específicos
<b>REGISTRO SANITARIO</b>	2009EBC-0003260
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Los sistemas de rayos X o "arcos móviles en C" son equipos de diagnóstico de propósito general, con movilidad alrededor de la mesa de operación o examen, basados en tecnología de rayos X que permiten: la obtención y/o registro de imágenes fijas (radiografía convencional y digital) de estructuras internas del cuerpo mediante la exposición de una parte del cuerpo a una pequeña dosis de radiación de rayos x; la obtención y/o registro de imágenes en movimiento en tiempo real (fluoroscopia continua, por pulsos o instantánea) y la toma de video de estructuras internas del paciente como soporte durante procedimientos de diagnóstico, quirúrgicos y procedimientos de intervención. Estos equipos están diseñados para visualizar estructuras anatómicas convirtiendo un patrón de radiación X en una imagen visible a través de amplificación electrónica. Las aplicaciones clínicas incluyen, sin limitarse, a las siguientes: colangiografía, endoscopia, urología, ortopedia, neurología vascular y cardiaca incluida la implantación de dispositivos de gestión del ritmo cardiaco, localización de cálculo, cirugía de tórax, investigaciones del tracto gastrointestinal, angiografía de los vasos de piernas, corazón y cerebro, y puede ser utilizado para otras aplicaciones de imagenología a discreción del médico
<b>NOMBRE DEL FABRICANTE</b>	GE Medical Systems Gmbh GE Hualun Medical Systems Co., Ltd GE Oec Medical Systems Inc
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante afirma que ha detectado que diversos componentes de los sistemas anteriores pueden haber sido reemplazados con versiones anteriores, ocasionando riesgos de seguridad y conllevando a que se presenten posibles eventos adversos sobre los pacientes o usuarios..
<b>FUENTE</b>	ANEXO 1
<b>FECHA DE NOTIFICACION</b>	17 de Octubre de 2014

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

**ANEXO 1**

www.ecri.org • Printed from Health Devices Alerts on Friday, October 17, 2014 Page 1

**A23154 - High Priority Medical Device Alert**

**Medical Device  
Ongoing Action**

Updated: October 16, 2014

**UMDMS Terms:**

- Radiographic/Fluoroscopic Systems, Urologic [16212]
- Radiographic/Fluoroscopic Units, Mobile [11758]

**Suggested Distribution:**

- Clinical/Biomedical Engineering
- Diagnostic Imaging
- Information Technology
- Urology

**Geographic Regions:**

- Worldwide

**GE OEC—Various Radiographic/Fluoroscopic Systems: Various Components May Have Been Replaced with Earlier Versions, Potentially Causing Safety Risks**

**Product Identifier:**

Radiographic/Fluoroscopic Systems: (1) FlexiView 8800, (2) OEC 9800, (3) OEC MiniView 6800, (4) OEC UroView 2800 [Capital Equipment]

**Manufacturer:**

- GE Healthcare Surgery384 Wright Brothers Dr, Salt Lake City, UT 84116, United States

**Problem:**

In an October 3, 2014, Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, GE states that the above systems may be affected by the following problems:

**Problem 1:**

Affected System:	Affected Serial Nos.:
Model 9800	82-0190, 82-0357, 82-0528, 82-0597, 82-0707, 82-0818, 82-0855, 82-0946, 82-1040, 82-1052, 82-1106, 82-1199, 82-1324, 82-1348, 82-1411, 82-1526, 82-1608, 82-1709, 82-1773, 82-2017, 82-2165, 82-2169, 82-2454, 82-2459, 82-2535, 82-2909, 82-2945, 82-3226, 82-3241, 82-3319, 82-3395, 82-3837, 82-7048-MH, 89-0028, 89-0037, 89-0184, 89-0316, 89-0388, 89-0427, 89-0586, 89-0600, 89-0623, 89-0643, 89-0825, 89-0827, 89-0840, 89-0846, 89-0881, 89-0894, 89-0947, 89-0995, 89-1145, 89-1157, 89-1204, 89-1375, 89-1408, 89-1751, 89-1984, 89-2682, 89-2777, 89-3311, 89-3419, 8S-0014-C, 8S-0059, 8S-0070, 8S-0113, 8S-0224, 8S-0511, 8S-0605, 8S-0997, 8S-1000, 8S-1165, 8S-1427, 8S-1585, 8S-1897, 8S-2232, 8S-2385, 8S-2491, 8S-2550

The workstation front cover may have been replaced with an earlier revision that can be removed without the use of a tool. If the workstation front cover is removed, the user could be exposed to high voltage, resulting in an electric shock.

**Problem 2:**

Affected Systems:	Affected Serial Nos.:
Model 2800	P4-0490-R, P6-0705-L
Model FlexiView 8800	5640PU8, 6052PU5, FIB0064
Model 9800	82-2751, 82-7066-MH, 85-0232, 85-2530, 85-3272-H

The surge suppressor board may have been replaced with an earlier revision. If the surge suppressor board is subjected to high-voltage surges, damage to surge suppressor board components may occur and prevent the system from booting.

**Problem 3:**

Affected System:	Affected Serial Nos.:
Model 9800	82-7103-MH, 89-1209, 89-1544, 89-2170, 89-2550, 89-2623, 89-3124-N, 85-0755, 85-0766, 85-0933-C, 85-3162-H, 85-3289-H

The solid state drive may have been replaced with a magnetic hard disk drive. The magnetic hard disk drive is more susceptible to data corruption that may prevent your system from booting.

**Problem 4:**

Affected Systems:	Affected Serial Nos.: Serial Nos.:
Model MiniView 6800	86-0039, 86-0135, 86-0191, 86-0318, 86-0334, 86-0587, 86-0611, 86-0619, 86-0758, 86-0782, 86-0931, 86-0935-R.C, 86-1129, 86-1220, 86-1241, 86-1376, 86-1432, 86-1503, 86-1551, 86-1614, 86-1678, 86-1702, 86-1736, 86-1959
Model 8800	3120PU3, 4851PU2
Model 9800	82-0013, 82-0045, 82-0061, 82-0071, 82-0085, 82-0122, 82-0133, 82-0246,

<p>82-0533, 82-0626, 82-0699, 82-0702, 82-0718, 82-0805, 82-0818, 82-0854, 82-0855, 82-1052, 82-1062, 82-1133, 82-1199, 82-1292, 82-1453, 82-1460, 82-1542, 82-1651, 82-1658, 82-1679, 82-1709, 82-1731, 82-1773, 82-1822, 82-1867, 82-1882, 82-1905, 82-1914, 82-1979, 82-2018, 82-2024, 82-2030, 82-2036, 82-2049, 82-2165, 82-2206, 82-2225, 82-2241, 82-2279, 82-2356, 82-2388, 82-2398, 82-2454, 82-2455, 82-2474, 82-2565, 82-2603, 82-2650, 82-2655, 82-2735, 82-2761, 82-2767, 82-2783, 82-2851, 82-2855, 82-2930, 82-2975, 82-3003, 82-3094, 82-3096, 82-3169, 82-3210, 82-3232, 82-3241, 82-3319, 82-3325, 82-3377, 82-3389, 82-3406, 82-3424, 82-3430, 82-3456, 82-3459, 82-3500, 82-3523, 82-3534, 82-3539, 82-3569, 82-3571, 82-3629, 82-3713, 82-3748, 82-3774, 82-3826, 82-3851, 82-3895, 82-7066-MH, 89-0028, 89-0034, 89-0072, 89-0105, 89-0113, 89-0135-RC, 89-0192, 89-0308, 89-0311, 89-0318, 89-0388, 89-0396, 89-0517, 89-0623, 89-0624, 89-0642, 89-0643, 89-0743, 89-0843, 89-0866, 89-0930, 89-1023, 89-1157, 89-1202, 89-1260, 89-1308, 89-1327, 89-1392, 89-1411, 89-1652, 89-1671, 89-1698, 89-1804, 89-1849, 89-1868, 89-1956, 89-1964, 89-1986, 89-2031, 89-2050, 89-2083, 89-2085, 89-2094, 89-2118, 89-2142, 89-2199, 89-2244, 89-2250, 89-2336, 89-2354, 89-2459, 89-2555, 89-2598, 89-2674, 89-2682, 89-2690, 89-2695, 89-2767, 89-2850, 89-2862, 89-2900, 89-3031, 89-3032, 89-3165, 89-3171, 89-3222, 89-3252, 89-3254, 89-3318, 89-3346, 89-3359, 89-3367, 89-3368, 89-3438, 89-3531, 8S-0026, 8S-0029, 8S-0058, 8S-0070, 8S-0162, 8S-0389, 8S-0467, 8S-0511, 8S-0529, 8S-0531, 8S-0549, 8S-0782, 8S-0858, 8S-0876, 8S-1015, 8S-1147, 8S-1165, 8S-1166, 8S-1192, 8S-1447, 8S-1509-C, 8S-1565, 8S-1907, 8S-2008-N, 8S-2053, 8S-2062, 8S-2092, 8S-2103, 8S-2107, 8S-2234, 8S-2268, 8S-2310, 8S-2385, 8S-2408, 8S-2432, 8S-2445, 8S-2471-C, 8S-2491, 8S-2543, 8S-2554, 8S-2564, 8S-2618, 8S-2650, 8S-2651, 8S-2671, 8S-2675, 8S-2695, 8S-2701, 8S-2734, 8S-2746, 8S-2770, 8S-2792, 8S-2798, 8S-2819, 8S-2835, 8S-2861, 8S-2862, 8S-2914, 8S-2922, 8S-2984, 8S-3004, 8S-3048, 8S-3055, 8S-3088, 8S-3143, 8S-3219, 8S-7102-MH</p>
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The workstation power cable may have been replaced with an earlier revision. The earlier revision of the workstation power cable contains an unnecessary connection that could be subject to a connection failure and prevent the system from booting.

**Action Needed:**

Identify any affected product in your inventory. If you have affected product, verify that you have received the October 3, 2014, Urgent Medical Device Correction letter and list of affected product from GE. GE recommends that you perform the following actions:

**(Problem 1):** You may continue to use your system with the current front cover. Take precautions to prevent unauthorized access to components inside of the workstation cover.

**(Problem 2):** You may continue to use your system with the current surge suppressor board. If your system fails to initialize, follow the error recovery steps described in the operators guide.

**(Problem 3):** You may continue to use your system with the magnetic hard disk drive. If your system fails to initialize, follow the error recovery steps described in the operators guide.

**(Problem 4):** You may continue to use your system with the current power cable. If your system fails to initialize, follow the error recovery steps described in the operators guide.

A GE Healthcare field engineer will contact your facility to arrange to inspect affected systems and make replacements if necessary and ensure that systems meet specifications, at no cost.

**For Further Information:**

GE Healthcare service team  
Tel.: (800) 874-7378 (select option 8)  
Website: [Click here](#)

**Comment:**

- 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):**

- 2014 Oct 9. Member Hospital. GE letter submitted by ECRI Institute member hospital; Reference No. 15126
- 2014 Oct 15. Manufacturer. Manufacturer confirmed the information provided in the source material.