



## URGENT FIELD SAFETY NOTICE

GE Healthcare

Surgery

384 Wright Brothers Drive  
Salt Lake City, UT 84116  
USA

24 October 2014

GEHC Ref# 15126

**TO:** Facility Administrator  
Director/Manager of Radiology and Radiologists  
Radiology Department

**RE: Part Replacement on OEC 9800, OEC UroView 2800, OEC MiniView 6800, FlexiView 8800**

GE Healthcare has recently become aware of potential safety issues due to part replacement associated with certain components of your OEC 9800, FlexiView 8800, OEC MiniView 6800 or OEC UroView 2800 system.

**Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

**Safety Issue #1**      **RE: Workstation front cover may have been replaced with an earlier revision that can be removed without the use of a tool.**

The workstation cover may be able to 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.

### **Safety Instructions**

You may continue to use your system with the current front cover. Take precautions to prevent unauthorized access to components inside of the workstation front cover.

**Safety Issue #2**      **RE: 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.

### **Safety Instructions**

You may continue to use your system with the current surge suppressor board. If your system fails to initialize, follow the error recovery steps as described in the Operators Guide.

**Safety Issue #3**      **RE: 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.

### **Safety Instructions**

You may continue to use your system with the magnetic hard disk drive. If your system fails to initialize, follow the error recovery steps as described in the Operators Guide.

**Safety Issue #4**      **RE: 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 potential connection failure, and prevent the system from booting.

### **Safety Instructions**

You may continue to use your system with the current power cable. If your system fails to initialize, follow the error recovery steps as described in the Operators Guide.

**Affected Product  
Details**

Refer to the Appendix for a list of affected products.

**Product Correction**

Your local GE Healthcare Field Engineer will contact you to coordinate an inspection of the affected part/s, replacement of the affected part/s if necessary, and will ensure that your system meets specifications. These activities will be performed at no cost to you.

**Contact Information**

If you have any questions or concerns regarding this notification, please contact your local GE Healthcare Service Representative:

**Fredrik Brorson**

Vascular & Surgery Modality Leader  
+44 7979 293186  
GE Healthcare  
Pollards Wood  
Nightingales Lane  
Chalfont St Giles, HP8 4SP  
United Kingdom

You can also contact:

**Paul Mardle**

Regulatory Affairs Manager  
+44 1707 289520  
GE Healthcare  
Pollards Wood  
Nightingales Lane  
Chalfont St Giles, HP8 4SP  
United Kingdom

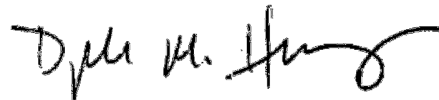
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,



Dan Eagar  
Executive, QARA  
GE Healthcare Surgery



Douglas M. Hansell, M.D., MPH  
Chief Medical Officer  
GE Healthcare

### Appendix: Affected Product Details

Issue	Description	Affected Products Details																																																																																
<p><b>Safety Issue #1</b></p>	<p>Workstation front cover may have been replaced with an earlier revision that can be removed without the use of a tool.</p>	<p>OEC 9800 systems with the following serial numbers:</p> <table border="1" data-bbox="699 338 1321 963"> <tr><td>82-0190</td><td>82-1608</td><td>82-7048-MH</td><td>89-0894</td><td>8S-0070</td></tr> <tr><td>82-0357</td><td>82-1709</td><td>89-0028</td><td>89-0947</td><td>8S-0113</td></tr> <tr><td>82-0528</td><td>82-1773</td><td>89-0037</td><td>89-0995</td><td>8S-0224</td></tr> <tr><td>82-0597</td><td>82-2017</td><td>89-0184</td><td>89-1145</td><td>8S-0511</td></tr> <tr><td>82-0707</td><td>82-2165</td><td>89-0316</td><td>89-1157</td><td>8S-0605</td></tr> <tr><td>82-0818</td><td>82-2169</td><td>89-0388</td><td>89-1204</td><td>8S-0997</td></tr> <tr><td>82-0855</td><td>82-2454</td><td>89-0427</td><td>89-1375</td><td>8S-1000</td></tr> <tr><td>82-0946</td><td>82-2459</td><td>89-0586</td><td>89-1408</td><td>8S-1165</td></tr> <tr><td>82-1040</td><td>82-2535</td><td>89-0600</td><td>89-1751</td><td>8S-1427</td></tr> <tr><td>82-1052</td><td>82-2909</td><td>89-0623</td><td>89-1984</td><td>8S-1585</td></tr> <tr><td>82-1106</td><td>82-2945</td><td>89-0643</td><td>89-2682</td><td>8S-1897</td></tr> <tr><td>82-1199</td><td>82-3226</td><td>89-0825</td><td>89-2777</td><td>8S-2232</td></tr> <tr><td>82-1324</td><td>82-3241</td><td>89-0827</td><td>89-3311</td><td>8S-2385</td></tr> <tr><td>82-1348</td><td>82-3319</td><td>89-0840</td><td>89-3419</td><td>8S-2491</td></tr> <tr><td>82-1411</td><td>82-3395</td><td>89-0846</td><td>8S-0014-C</td><td>8S-2550</td></tr> <tr><td>82-1526</td><td>82-3837</td><td>89-0881</td><td>8S-0059</td><td></td></tr> </table>	82-0190	82-1608	82-7048-MH	89-0894	8S-0070	82-0357	82-1709	89-0028	89-0947	8S-0113	82-0528	82-1773	89-0037	89-0995	8S-0224	82-0597	82-2017	89-0184	89-1145	8S-0511	82-0707	82-2165	89-0316	89-1157	8S-0605	82-0818	82-2169	89-0388	89-1204	8S-0997	82-0855	82-2454	89-0427	89-1375	8S-1000	82-0946	82-2459	89-0586	89-1408	8S-1165	82-1040	82-2535	89-0600	89-1751	8S-1427	82-1052	82-2909	89-0623	89-1984	8S-1585	82-1106	82-2945	89-0643	89-2682	8S-1897	82-1199	82-3226	89-0825	89-2777	8S-2232	82-1324	82-3241	89-0827	89-3311	8S-2385	82-1348	82-3319	89-0840	89-3419	8S-2491	82-1411	82-3395	89-0846	8S-0014-C	8S-2550	82-1526	82-3837	89-0881	8S-0059	
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**Safety Issue  
#4 (con't)**

OEC 9800 systems with the following serial numbers:

82-0013	82-2356	82-7066-MH	89-2244	8S-1192
82-0045	82-2388	89-0028	89-2250	8S-1447
82-0061	82-2398	89-0034	89-2336	8S-1509-C
82-0071	82-2454	89-0072	89-2354	8S-1565
82-0085	82-2455	89-0105	89-2459	8S-1907
82-0122	82-2474	89-0113	89-2555	8S-2008-N
82-0133	82-2565	89-0135-RC	89-2598	8S-2053
82-0246	82-2603	89-0192	89-2674	8S-2062
82-0533	82-2650	89-0308	89-2682	8S-2092
82-0626	82-2655	89-0311	89-2690	8S-2103
82-0699	82-2735	89-0318	89-2695	8S-2107
82-0702	82-2761	89-0388	89-2767	8S-2234
82-0718	82-2767	89-0396	89-2850	8S-2268
82-0805	82-2783	89-0517	89-2862	8S-2310
82-0818	82-2851	89-0623	89-2900	8S-2385
82-0854	82-2855	89-0624	89-3031	8S-2408
82-0855	82-2930	89-0642	89-3032	8S-2432
82-1052	82-2975	89-0643	89-3165	8S-2445
82-1062	82-3003	89-0743	89-3171	8S-2471-C
82-1133	82-3094	89-0843	89-3222	8S-2491
82-1199	82-3096	89-0866	89-3252	8S-2543
82-1292	82-3169	89-0930	89-3254	8S-2554
82-1453	82-3210	89-1023	89-3318	8S-2564
82-1460	82-3232	89-1157	89-3346	8S-2618
82-1542	82-3241	89-1202	89-3359	8S-2650
82-1651	82-3319	89-1260	89-3367	8S-2651
82-1658	82-3325	89-1308	89-3368	8S-2671
82-1679	82-3377	89-1327	89-3438	8S-2675
82-1709	82-3389	89-1392	89-3531	8S-2695
82-1731	82-3406	89-1411	8S-0026	8S-2701
82-1773	82-3424	89-1652	8S-0029	8S-2734
82-1822	82-3430	89-1671	8S-0058	8S-2746
82-1867	82-3456	89-1698	8S-0070	8S-2770
82-1882	82-3459	89-1804	8S-0162	8S-2792
82-1905	82-3500	89-1849	8S-0389	8S-2798
82-1914	82-3523	89-1868	8S-0467	8S-2819
82-1979	82-3534	89-1956	8S-0511	8S-2835
82-2018	82-3539	89-1964	8S-0529	8S-2861
82-2024	82-3569	89-1986	8S-0531	8S-2862
82-2030	82-3571	89-2031	8S-0549	8S-2914
82-2036	82-3629	89-2050	8S-0782	8S-2922
82-2049	82-3713	89-2083	8S-0858	8S-2984
82-2165	82-3748	89-2085	8S-0876	8S-3004
82-2206	82-3774	89-2094	8S-1015	8S-3048

OEC 9800 systems with the following serial numbers:

82-2225	82-3826	89-2118	8S-1147	8S-3055
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<b>Safety Issue #4 (con't)</b>		82-2241	82-3851	89-2142	8S-1165	8S-3088
		82-2279	82-3895	89-2199	8S-1166	8S-3143
						8S-3219
						8S-7102-MH

# Customer Reply Form

PLEASE COMPLETE and FAX to GE Healthcare

## CUSTOMER CONTACT INFORMATION

Note: please list all site locations and names if you are responsible for more than one site or if your site is known by other names. Thank you.

Site Name		Site Contact		
Other site				
Street Address		City		
State		Postal Code	Country	
Phone		Email		

By signing below, I acknowledge receipt of the letter and I accept to follow and to apply the safety instructions. Please record below the date on which your facility received this information.

<u>Name and Title</u>	<u>Date</u>
<u>Signature</u>	

**Please FAX back to:**

**+44 (0) 1 75 341 7098**

**Or Email to:**  
[SafetyNotice@ge.com](mailto:SafetyNotice@ge.com)

Attention:  
**GE Healthcare**  
 EMEA Customer Safety letters Specialist  
 283, rue de la Minière  
 78530 Buc - France