

# URGENT MEDICAL DEVICE CORRECTION



GE OEC Medical Systems, Inc.  
384 Wright Brothers Drive  
Salt Lake City, UT, 84116, USA

Date of Letter Deployment

GE HealthCare Ref. #15146

To: Director/Manager of Radiology  
Hospital Administrator  
Head of Radiology Department  
PACS Administrator  
Director of IT Department  
Head, Biomedical Engineering

RE: **Flexiview 8800, OEC 9800, OEC 9900 and OEC Elite systems with 9-inch Image Intensifier**

## Safety Issue

GE HealthCare has become aware that the 9-inch Image Intensifier for OEC Flexiview 8800, OEC 9800, OEC 9900 and OEC Elite systems can become detached if the systems encounter a large impact force when moved. No instances of this issue have occurred in clinical use. GE HealthCare became aware of one instance of image intensifier detachment during shipment.

If these systems are transported in an incorrect orientation (for example, over scan position) and the system impacts a large threshold or other impact force, the image intensifier could become detached at the time of impact and fall. This could lead to injury (such as fracture(s), hematoma, contusion, bruise, pain, etc.).

There have been no injuries reported as a result of this potential issue.

## Actions to be taken by Customer /User

You can continue to use your device. When transporting the device, ensure it is always in the Anterior Posterior (AP) position (see Figure 1 below), as instructed in the systems' Operator Manual.

Use caution when moving system to avoid a large impact force.



Figure 1 – C-Arm in AP Position

Please complete the attached Medical Device Notification Acknowledgement Response form and send to [fielddactionssurgery@ge.com](mailto:fielddactionssurgery@ge.com)

**Affected Product Details**

OEC Flexiview 8800 systems with 9-inch Image Intensifier  
OEC 9800 systems with 9-inch Image Intensifier  
OEC 9900 systems with 9-inch Image Intensifier  
OEC Elite systems with 9-inch Image Intensifier

Field Upgrade Kits:

P/N 5451208 RIU, 9 INCH, TOSHIBA  
P/N 5485304 SERVICE PART, IMAGE INTENSIFIER, 9 INCH, TOSHIBA  
P/N 5761613 SERVICE PART, IMAGE INTENSIFIER, 9 INCH

See attached Appendix for a list of affected serial numbers.

**Intended Use**

To provide fluoroscopic and digital spot images of the patient anatomy, interventional tools/devices, and contrast agents during diagnostic, interventional, and surgical procedures.

**Product Correction**

GE HealthCare will correct all affected products at no cost to you. A GE HealthCare representative will contact you to plan execution for the correction.

**Contact Information**

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

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,



Laila Gurney  
Chief Quality & Regulatory Officer  
GE HealthCare



Scott Kelley  
Chief Medical & Safety Officer  
GE HealthCare

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT  
RESPONSE REQUIRED**

**Please complete this form and return it to GE Healthcare promptly upon receipt of this letter and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.**

\*Customer/Consignee  
Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/ZIP/Country: \_\_\_\_\_

\*Customer Email Address: \_\_\_\_\_

\*Customer Phone Number: \_\_\_\_\_

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

**Please provide the name of the individual with responsibility who completed this form.**

Signature: \_\_\_\_\_

\*Printed Name: \_\_\_\_\_

\*Title: \_\_\_\_\_

\*Date (DD/MM/YYYY): \_\_\_\_\_

\*Indicates Mandatory Fields

**Please return completed form by scanning or taking a photo of the completed form and email to: [fielddactionssurgery@ge.com](mailto:fielddactionssurgery@ge.com)**



# APPENDIX

## OEC 8800 SERIAL NUMBERS

3228PU4

6936PU9

## OEC 9800 SERIAL NUMBERS

89-0223	89-1854	8S-0124	8S-2046-C
89-0282	89-1920	8S-0175	8S-2426
89-0296	89-2101	8S-0200	8S-2580
89-0317	89-2167	8S-0233-C	8S-2836
89-0461	89-2340	8S-0394	8S-2988
89-0554	89-2459	8S-0410	8S-3039
89-0609-RC	89-2913	8S-0509	8S-3278
89-0979	89-3028	8S-0748	8SXXX03626
89-1155	89-3102	8S-1029	8SXXX03679
89-1278	89-3132	8S-1109	8SXXX03680
89-1308	89-3245	8S-1167	8SXXX03681
89-1579-N	89-3451	8S-1293	8SXXX03682
89-1590	89-3809	8S-1574	8SXXX03683
89-1623	89-3810	8S-1894	
89-1713	8S-0108	8S-1926	

## OEC 9900 SERIAL NUMBERS

E9-0056	E9-2401	E9-2660	E9XXX03481	ES-2786	ES-2986	ES-3342	ESXXXL00102
E9-0231	E9-2402	E9-2661	E9XXX03484	ES-2787	ES-2987	ES-3343	ESXXXL00103
E9-0259	E9-2403	E9-2662	E9XXX03485	ES-2788	ES-2988	ES-3344	ESXXXL00104
E9-0409	E9-2404	E9-2663	E9XXX03486	ES-2789	ES-2990	ES-3401	ESXXXL00105
E9-0731	E9-2405	E9-2664	E9XXX03487	ES-2790	ES-2991	ES-3450	ESXXXL00106
E9-0935	E9-2406	E9-2665	E9XXX03488	ES-2807	ES-2992	ES-3538	ESXXXL00137
E9-0950	E9-2407	E9-2666	E9XXX03490	ES-2808	ES-2993	ES-3598	ESXXX03863
E9-0975	E9-2408	E9-2667	E9XXX03491	ES-2809	ES-2994	ES-3642	ESXXX03911
E9-1266	E9-2409	E9-2678	E9XXX03492	ES-2810	ES-2995	ES-3745	ESXXX04049
E9-1519	E9-2410	E9-2679	E9XXX03493	ES-2823	ES-2996	ES-7168-CMH	ESXXX04061
E9-1695	E9-2411	E9-2747	E9XXX03494	ES-2824	ES-2997	ES-7227-CMH	ESXXX04338
E9-1716	E9-2451	E9-2748	E9XXX03495	ES-2825	ES-2998	ES-7307-CMH	ESXXX04365
E9-1719	E9-2452	E9-2778	E9XXX03496	ES-2834	ES-2999	ES-7316-CMH	ESXXX04366
E9-2182	E9-2453	E9-2831	ES-0080	ES-2835	ES-3038	ES-7317-CMH	ESXXX04367
E9-2183	E9-2488	E9-2832	ES-0306	ES-2836	ES-3040	ES-7322-CMH	ESXXX04368
E9-2184	E9-2490	E9-2833	ES-0613	ES-2837	ES-3056	ES-7323-CMH	ESXXX04369
E9-2185	E9-2491	E9-2834	ES-0662	ES-2846	ES-3058	ES-7324-CMH	ESXXX04370
E9-2186	E9-2492	E9-2835	ES-1052	ES-2847	ES-3062	ES-7325-CMH	ESXXX04376
E9-2187	E9-2493	E9-2836	ES-1067	ES-2848	ES-3063	ES-7326-CMH	ESXXX04377
E9-2189	E9-2494	E9-2837	ES-1548	ES-2849	ES-3064	ES-7328-CMH	ESXXX04378
E9-2190	E9-2495	E9-2838	ES-1598	ES-2850	ES-3065	ES-7330-CMH	ESXXX04379
E9-2195	E9-2496	E9-2839	ES-1631	ES-2851	ES-3066	ES-7331-CMH	ESXXX04380
E9-2196	E9-2497	E9-2841	ES-1717-CH	ES-2852	ES-3068	ES-7332-CMH	ESXXX04391
E9-2197	E9-2498	E9-2842	ES-1782	ES-2853	ES-3069	ES-7335-CMH	ESXXX04392
E9-2200	E9-2499	E9-2889	ES-2346	ES-2854	ES-3070	ES-7336-CMH	ESXXX04393
E9-2201	E9-2500	E9-2899	ES-2413	ES-2855	ES-3071	ES-7337-CMH	ESXXX04394
E9-2202	E9-2501	E9XXX03001	ES-2472	ES-2856	ES-3072-CH	ES-7346-CMH	ESXXX04402
E9-2203	E9-2502	E9XXX03005	ES-2602	ES-2858	ES-3073	ES-7348-CMH	ESXXX04403
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E9-2205	E9-2506	E9XXX03024	ES-2629	ES-2865	ES-3075	ESCHXX90026	ESXXX04405
E9-2206	E9-2507	E9XXX03025	ES-2630	ES-2866	ES-3076	ESCHXX90027	ESXXX04406
E9-2207	E9-2508	E9XXX03163	ES-2633	ES-2867	ES-3077	ESCHXX90028	ESXXX04407
E9-2208	E9-2509	E9XXX03336	ES-2634	ES-2868	ES-3078	ESCHXX90029	ESXXX04417
E9-2209	E9-2510	E9XXX03347	ES-2635	ES-2869	ES-3079	ESCHXX90030	ESXXX04418
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E9-2211	E9-2512	E9XXX03349	ES-2637	ES-2873	ES-3081	ESCHXX90033	ESXXX04420
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E9-2246	E9-2515	E9XXX03351	ES-2640	ES-2889	ES-3083	ESCHXX90035	ESXXX04422
E9-2252	E9-2516	E9XXX03352	ES-2641	ES-2890	ES-3084	ESCHXX90036	ESXXX04423
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E9-2345	E9-2641	E9XXXX03460	ES-2756	ES-2970	ES-3214	ESXXXL00086	ESXXXX04480
E9-2346	E9-2642	E9XXXX03466	ES-2761	ES-2971	ES-3215	ESXXXL00087	ESXXXX04481
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E9-2390	E9-2646	E9XXXX03470	ES-2765	ES-2975	ES-3240	ESXXXL00091	ESXXXX04485
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E9-2392	E9-2650	E9XXXX03472	ES-2768	ES-2977-CH	ES-3285	ESXXXL00093	ESXXXX04487
E9-2393	E9-2651	E9XXXX03473	ES-2769	ES-2978	ES-3290	ESXXXL00094	ESXXXX04488
E9-2394	E9-2652	E9XXXX03474	ES-2770	ES-2979	ES-3296	ESXXXL00095	ESXXXX04489
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E9-2398	E9-2656	E9XXXX03478	ES-2774	ES-2983	ES-3300	ESXXXL00099	ESXXXX04493
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E9-2400	E9-2659	E9XXXX03480	ES-2776	ES-2985	ES-3341	ESXXXL00101	ESXXXX04495
ESXXX04496	ESXXX04497	ESXXX04498	ESXXX04499	ESXXX04500	ESXXX04501	ESXXX04502	ESXXX04503
ESXXX04504	ESXXX04505	ESXXX04506	ESXXX04507	ESXXX04508	ESXXX04509	ESXXX04511	ESXXX04512
ESXXX04513	ESXXX04514	ESXXX04515	ESXXX04516	ESXXX04517	ESXXX04518	ESXXX04519	ESXXX04520
ESXXX04521	ESXXX04522	ESXXX04523	ESXXX04524	ESXXX04525	ESXXX04526	ESXXX04527	ESXXX04528
ESXXX04529	ESXXX04530	ESXXX04531					

**OEC ELITE SERIAL NUMBER RANGE**

F9XXTX00001 THROUGH F9XXTX00259

F9XXXX00001 THROUGH F9XXXX00070

FSXXTX00003 THROUGH FSXXTX00442

FSXXXX00001 THROUGH FSXXXX00068

**FIELD UPGRADE KITS WITH SALES ORDER NUMBER**

**P/N 5451208**

80165102  
80171955  
80173514  
80162453  
80183950  
80151733  
80163547  
80171532  
80156410  
80176650

**P/N 5485304**

10557644  
118687327

**P/N 5761613**

10283014  
10152211  
105108003  
105114645