

URGENT FIELD SAFETY NOTICE



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

**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.

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,



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



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
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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
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E9-2201	E9-2500	E9-2899	ES-2413	ES-2855	ES-3071	ES-7337-CMH	ESXXX04394
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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
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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

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80162453
80183950
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80163547
80171532
80156410
80176650

P/N 5485304

10557644
118687327

P/N 5761613

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105114645