



## Urgent Field Safety Notice

GE Healthcare

3000 N. Grandview Blvd. - W440  
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref#12254

To: Director of Biomedical Engineering  
Director of Radiology  
Chief of Cardiology

RE: **Innova 2100<sup>IQ</sup>, Innova 3100, Innova 3100<sup>IQ</sup>, Innova 4100, Innova 4100<sup>IQ</sup>, Cardiovascular X-ray imaging systems - Potential boot up issue, or loss of imaging on systems equipped with a GE Power Distribution Box (PDB).**

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

### Safety Issue

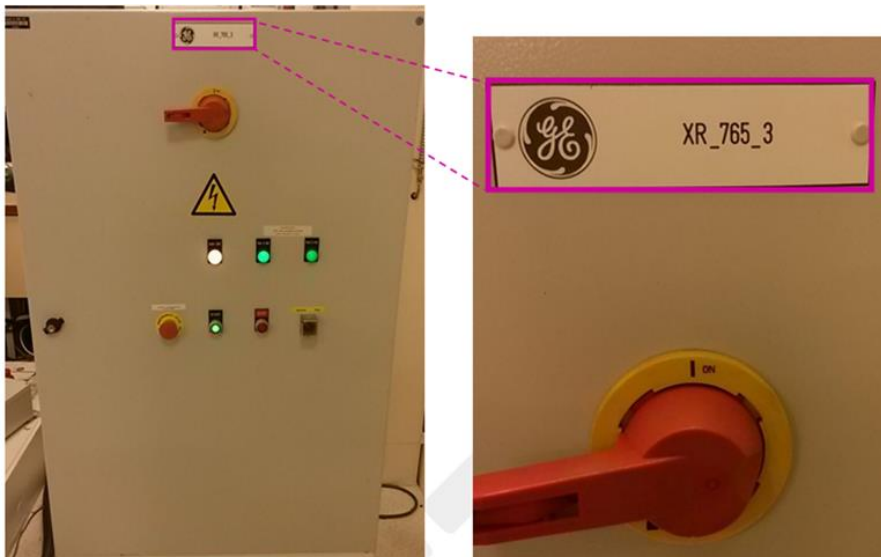
The Innova system may not boot up properly after a power-on or after a system reset. Additionally, it may shut down unexpectedly during an exam which may result in the total loss of real-time interventional imaging capability. This can cause a delay before or during the procedure until power can be restored to the system. No injuries have been reported due to this issue.

### Safety Instructions

Before each use, please ensure the Innova system is fully functional as indicated in the GE product labeling. Perform a quick system functional check by creating a test patient on the system console and verify that fluoroscopy/record acquisitions are available. Follow your established procedures before and during each use to manage the patient in the case of a complete loss of fluoroscopic viewing capability. If your system does not boot up, then reset the system. If the problem persists, contact your local GE Healthcare Service Representative.

### Affected Product Details

See attached Appendix for list of affected system ID's. **This issue is applicable only to customers who have a GE PDB** (refer to the below label image to determine if you have a GE PDB installed along with the Innova system. This GE label would be located on the front door of the GE PDB). You will be contacted by a GE Service Representative to have you verify the presence of a GE PDB on your system.



Front Door of GE PDB

**Product  
Correction**

GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange 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.

You can also contact:

**Fredrik Brorson**

Vascular & Surgery Modality Leader

+44 7979 293186

GE Healthcare

Pollards Wood

Nightingales Lane

Chalfont St Giles, HP8 4SP

United Kingdom

**Paul Mardle**

Regulatory Affairs Manager

+44 1707 263570

GE Healthcare

71 Great North Road

Hatfield Herts AL9 5EN

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,



James W. Dennison  
Vice President - Quality & Regulatory  
GE Healthcare



Jeff Hersh, M.D.  
Chief Medical Officer  
GE Healthcare

## APPENDIX

### Affected System ID List:

00065VAS01	A004RX01	B5483438	FPG93008	M40480151
00137VAS01	A020RX13	B5603933	G4191715	M40480167
00234VAS01	A147111802	B5811426	GF1002VA02	M4163030
00282VAS02	A4166952	BG4604VA01	GP179808	M4176519
00371VAS01	A5105732	BRD0411	GPQ13903	M4198062
00440VAS02	A5123529	BY4066VA01	H1039VAS22	M4198195
00463VAS06	A5125119	BY4067VA02	H1420VAS04	M4200108
00888VAS02	A5125125	BY4069VA01	H1420VAS16	M4484974
00929VAS01	A5131858	C5123625	H17654VAS8	M4496941
010120RX44	A5152993	C5123626	H17654VAS9	M4505274
01012VAS01	A5155141	C5294640	H2077VAS27	M5480755
01065VAS01	A5162256	C5323515	HC0220XR07	MA1013VA03
05208VAS02	A5163317	C5346705	HC0222XR35	MA1251VA01
05217VAS02	A5164510	C5603903	HC1536XR04	ME612436
06014VAS01	A5189718	CEE15663	HC1819XR09	MPX82206
06052VAS01	A5203215	CS1054VA01	HC1995XR03	NG1043VA01
10086VAS06	A5219606	D5345903	HC1998XR06	NG1049VA01
110019RX13	A5220710	D5810520	HC3884XR02	NO1037VA01
110028RX15	A5330714	D5810523	HL0090XR11	NPV15952
110028RX16	A5361319	DE188442	HU1099VA04	PC0016XR01
21007VAS02	A5381121	DE641223	HU1205VA01	PER00218
34009VAS06	A5400910	DK1066VA03	IE1077VA01	PER08306
34316VAS01	A5605732	DPM32143	IL1043VA01	PK1301VA01
407953XR01	A5605743	DPN88402	IR1460VA01	PL1008VA02
41018VAS01	A5624112	DZ1050VA01	IR1819VA01	PL1101VA03
468668XR01	A5624127	EG1029VA01	JO1000VA01	PL1196VA02
487692XR01	A5624129	EG1729VA01	LB1003VA01	PL1640VA01
507902XR01	A5630803	EG1741VA01	LB1042VA01	PL1677VA01
526354XR13	A5764002	EG1794VA01	LB1148VA01	R4211476
58002VAS01	A5800506	FEB52055	LT4000VA05	SA1005VA06
583694XR01	A5805519	FEG35027	LT4026RX01	SA1010VA02
600002VA01	A5812244	FI1015VA01	LV4000VA04	SK1083VA01
600010VA01	A5812258	FI1017VA02	M1230007	SK1110VA01
60001VAS01	A9190149	FI1017VA03	M1504003	SK1110VA02
600042VA02	B1650215	FI1025VA01	M181374801	SK1110VA03
600042VA03	B4192944	FI1064VA01	M2002624	TN1027VA02
600050VA01	B4192946	FPA99414	M2030711	UC1129XR33
600050VA02	B5112507	FPE43A05	M2208715	UPW21603
600151VA01	B5120723	FPG30528	M4016034	Z001RX07
606427XR01	B5332001	FPG86403	M4016565	ZA2239RX01

# 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