



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref#12207

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

RE: **Innova 2100^{IQ}, Innova 2121^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 3131^{IQ}, Innova 4100, Innova 4100^{IQ}, Innova IGS 620, Innova IGS 630 Cardiovascular X-ray imaging systems - Potential boot up issue, or loss of imaging on systems equipped with CE marked PDB (Power Distribution Box).**

GE Healthcare has become aware of a potential safety issue with the system boot up. **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. No injuries have been reported due to this issue.

Safety Instructions

Before each use, please ensure the Innova system emits X-rays and is in working condition. Perform a quick system functional check by creating a test patient on the system console and verify that fluoroscopy/record acquisitions are available. 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 1 & 2 on the following pages for a list of system ID's.

Product Correction

GE Healthcare will correct all affected systems at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

Contact Information

If you have any questions or concerns regarding this notification, please call the following phone numbers:

Saudi Arabia Toll Free number: 8001243002.

Saudi Arabia Service Center: SaudiArabiaServiceCenter@ge.com

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 Dennison
Vice President QARA
GE Healthcare Systems

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

GEHC Ref#12207 APPENDIX 1: Innova 2100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 4100, Innova 4100^{IQ}, Cardiovascular X-ray imaging systems installed with CE marked PDB

00052VAS03	58010VAS01	BY4015VA02	KW1018VA02	RU1295VA01	RU2741VA03
00052VAS04	600098VA01	CS1006VA04	KW1018VA03	RU1295VA02	RU2747VA01
00052VAS05	600123VA02	DZ1027VA02	KW1018VA04	RU1295VA03	RU2886VA01
00060VAS02	600130VA01	DZ1060VA01	KW1018VA05	RU1295VA04	RU2969VA01
00060VAS03	600152VA01	DZ1104VA01	KW1055VA01	RU1295VA05	RU2992VA01
00084VAS02	622223XR01	DZ1292VA01	LB1039VA01	RU1318VA01	RU3053VA01
00100VAS01	63012VAS01	G4191713	LB1160VA01	RU1326VA01	RU3092VA01
00109VAS01	64002VAS01	GE1004VA01	LT4000VA04	RU1346VA01	RU3105VA01
00109VAS02	71004VAS01	GE1005VA01	LT4001VA02	RU1354VA01	RU3137VA01
00109VAS03	77137VAS01	GE1009VA01	LV4000VA02	RU1449VA01	RU3138VA02
00109VAS04	77451VAS01	H1420VAS23	LV4000VA03	RU1457VA01	RU3191VA01
00175VAS01	80002VAS01	H1823VAS11	LV4001VA02	RU1464VA01	RU3213VA01
00192VAS04	A5105151	HC1819XR08	LV4012VA01	RU1475VA01	RU3230VA01
00192VAS05	A5111034	HC2001XR02	M2569317	RU1481VA01	RU3230VA02
00197VAS01	A5119437	HC4348XR01	MA1004VA02	RU1482VA02	RU3253VA01
00203VAS01	A5127281	HC4348XR02	MC1010VA01	RU1550VA01	RU3285VA01
00860VAS01	A51273120	HC4480XR05	MC1024VA01	RU1550VA02	RU3290VA01
01224VAS04	A5129025	HR4106VA01	NO1005VA05	RU1581VA01	RU3293VA01
01243VAS03	A5178024	HR4107VA01	NO1064VA03	RU1632VA01	RU3301VA01
01367VAS02	A5190949	HU1039VA02	NO1064VA04	RU1646VA01	RU3305VA01
828160007	A5286803	HU1042VA01	PL1082VA01	RU1670VA01	RU3317VA01
828160008	A5333035	HU1094VA01	PL1508VA02	RU1692VA01	RU3328VA01
828160012	A5333036	HU1116VA01	PL1553VA01	RU1757VA02	RU3331VA01
834160003	A5333037	HU1173VA02	PL1622VA01	RU1820VA01	RU3412VA01
834160007	A5364462	HU1173VA03	PL1688VA01	RU1830VA01	RU3430VA01
835160018	A56364110	IE1100VA01	RO1180VA01	RU1857VA01	RU6261VA01
835160021	A5697709	IE1100VA02	RS4024VA01	RU1899VA01	RU6340VA01
835160023	A5718004	IQ1083VA01	RU1000VA01	RU1971VA01	SD1038VA01
835160024	A5807919	IQ1083VA02	RU1013VA02	RU1999VA01	SD1063VA01
835160025	A58080104	IQ1126VA01	RU1018VA03	RU2011VA01	SI4069VA01
835160027	AL4009VA01	IQ1165VA01	RU1047VA02	RU2031VA01	SK1064VA01
843160005	AL4009VA02	IQ1309VA01	RU1050VA03	RU2036VA01	SY1001VA02
847160004	AO1001VA01	IR1026VA02	RU1063VA01	RU2076VA02	SY2005VA01
10086VAS04	B5129910	IR1748VA01	RU1100VA01	RU2442VA01	TN1016VA01
10507VAS01	BA4020VA01	IS1001VA01	RU1102VA02	RU2457VA01	TN1366VA01
17005VAS01	BA4073VA01	J5274803	RU1136VA01	RU2526VA01	UA4230VA01
21007VAS01	BA4080VA01	KW1001VA03	RU1140VA02	RU2558VA01	UK1015VA01
34268VAS01	BG4033VA01	KW1001VA04	RU1142VA01	RU2581VA01	X1347902
34280VAS01	BG4042VA01	KW1011VA01	RU1156VA01	RU2714VA01	
35049VAS01	BG4549VA02	KW1013VA01	RU1254VA01	RU2741VA01	
553003XR01	BY4001VA03	KW1018VA01	RU1283VA01	RU2741VA02	

**GEHC Ref#12208 APPENDIX 2: Innova 2121^{IQ}, Innova 3131^{IQ}, Innova IGS 620, Innova IGS 630
Cardiovascular X-ray imaging systems installed with CE marked PDB**

834160004	34006VAS02	LY1086VA01	YV0472
834160005	542120XR02	M4152252	YV0475
834160006	A5102694	M4166990	YV0476
835160028	A5320145	M4198064	YV0477
847160005	A5360408	M4212443	YV0478
847160006	A5379605	MEX68922	YV0480
850060739	A5632421	N4192939	YV0500
850060744	AE1225VA01	PER18124	YV0510
850060749	AZ1003VA02	PL1804VA01	YV0520
853060198	AZ4001VA01	RO1095VA01	YV0555
853060200	B51142125	RU1086VA04	YV1800
853060201	B5114298	RU1156VA02	YV1801
853060202	BG4009VA01	RU2741VA04	YV1803
853060209	BH1000VA01	RU3427VA01	YV1804
853060211	BY4020VA02	RU3847VA01	YV1805
853060212	BY4033VA01	RU3883VA01	YV1818
856160010	CS1006VA05	SA1060VA01	YV1900
856160012	CS1340VA01	SA2236VA01	YV1901
910162015	EG1000VA01	SA2253VA01	YV1902
82416040046	HC1819XR10	SA2308VA01	YV1903
82416070010	HC5284XR38	YE1002VA01	YV1904
82416150007	HC5284XR39	YV0166	YV1905
82416210022	HU1167VA01	YV0362	YV1906
83016862100448	IE1100VA03	YV0364	YV1909
00026VAS01	INNOVA12CC20022	YV0367	YV1910
00095VAS08	IQ1165VA02	YV0370	YV1950
00234VAS02	IQ1364VA01	YV0388	ZA2239VA01
00243VAS02	KA2752VA01	YV0464	
00440VAS04	KW1011VA02	YV0466	
05448VAS01	KW1098VA01	YV0467	
10086VAS07	KW1098VA02	YV0468	
10307VAS01	LB1331VA01	YV0469	