



URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref# 10912

To: Hospital Administrators/Risk Managers
Managers of Radiology/Cardiology
Radiologists/Cardiologists

RE: **Potential fall of XR 6000 Systems horizontal tube arm by detaching from the system.**

GE Healthcare has recently become aware of a potential safety issue with the horizontal tube arm of the system used on XR 6000 systems. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

**Safety
Issue**

There has been a reported incident of a horizontal tube arm falling from the system. A fall of a tube arm suspending the collimator and tube apparatus could result in a serious injury or death to a patient or operator. A minor injury has been reported as a result of this issue. Our investigation of this issue is continuing.

**Safety
Instructions**

GE Healthcare recommends that your site cease use of your XR 6000 System until GE can correct your system.

**Affected
Product
Details**

XR6000 Systems. See attached Appendix Sheet 1 and Sheet 2 for a list of serial numbers.

**Product
Correction**

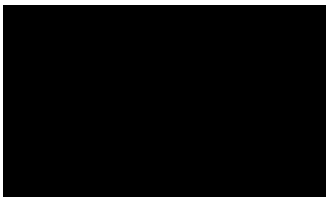
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to evaluate your affected unit(s) for necessary corrective actions.

**Contact
Information**

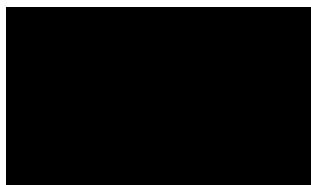
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



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



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

APPENDIX

Affected serials:

Sheet 1:

00000071942HL7	00000082543HL0	00000096885HL9	00000121741HL3	00000129450HL3
00000071954HL2	00000083179HL2	00000097053HL3	00000121744HL7	00000129613HL6
00000072075HL5	00000083704HL7	00000098265HL2	00000121797HL5	00000130051HL6
00000072078HL9	00000083882HL1	00000098537HL4	00000121800HL7	00000130206HL6
00000072225HL6	00000084243HL5	00000099622HL3	00000121803HL1	00000130306HL4
00000072228HL0	00000084548HL7	00000099625HL6	00000122513HL5	00000130721HL4
00000074502HL6	00000084669HL1	00000099960HL7	00000122847HL7	00000130948HL3
00000074833HL5	00000084962HL0	00000100400HL1	00000123803HL9	00000131242HL0
00000074975HL4	00000085239HL2	00000100754HL1	00000123806HL2	00000131247HL9
00000075131HL3	00000085395HL2	00000101331HL7	00000123809HL6	00000131952HL4
00000075134HL7	00000085958HL7	00000101926HL4	00000123812HL0	00000132744HL4
00000075137HL0	00000086248HL2	00000101929HL8	00000123815HL3	00000133105HL7
00000075536HL3	00000086497HL5	00000102271HL4	00000123818HL7	00000133884HL7
00000076199HL9	00000087457HL8	00000102274HL8	00000124758HL4	00000133980HL3
00000076979HL4	00000087725HL8	00000102773HL9	00000125403HL6	00000134097HL5
00000076982HL8	00000088124HL3	00000104438HL7	00000125406HL9	00000134485HL2
00000077431HL5	00000088402HL3	00000104674HL7	00000125409HL3	00000135257HL4
00000077434HL9	00000088961HL8	00000105306HL5	00000125412HL7	00000135262HL4
00000077580HL9	00000089131HL7	00000105309HL9	00000125492HL9	00000135749HL0
00000077583HL3	00000089532HL6	00000105312HL3	00000125710HL4	00000137736HL5
00000077886HL0	00000089535HL9	00000105673HL8	00000125866HL4	00000137992HL4
00000077889HL4	00000089621HL7	00000107122HL4	00000126167HL6	00000138040HL1
00000079432HL1	00000090008HL4	00000108795HL6	00000126438HL1	00000138298HL5
00000079435HL4	00000090011HL8	00000110022HL1	00000126526HL3	00000138501HL2
00000079755HL5	00000090587HL7	00000110025HL4	00000127428HL1	00000138902HL2
00000080562HL2	00000090590HL1	00000110476HL9	00000127447HL1	00000139265HL3
00000080565HL5	00000091677HL5	00000111670HL6	00000127851HL4	00000139477HL4
00000080967HL3	00000092167HL6	00000112873HL5	00000128192HL2	00000139582HL1
00000081529HL0	00000092763HL2	00000116564HL6	00000128218HL5	00000139642HL3
00000081664HL5	00000093033HL9	00000116950HL7	00000128346HL4	00000140166HL0
00000081667HL8	00000093064HL4	00000116953HL1	00000128421HL5	00000140584HL4
00000081670HL2	00000094047HL8	00000119540HL3	00000128770HL5	00000140877HL2
00000081673HL6	00000094134HL4	00000119745HL8	00000128856HL2	00000140940HL8
00000081676HL9	00000094411HL6	00000121008HL7	00000129067HL5	00000140945HL7
00000082405HL2	00000095036HL0	00000121117HL6	00000129070HL9	00000141389HL7
00000082408HL6	00000096244HL9	00000121696HL9	00000129204HL4	
00000082540HL6	00000096247HL2	00000121700HL9	00000129222HL6	

Affected serials**Sheet2:**

S4S10001	S4S12004	S4S13007	S4S15001	S6S15009
S4S10002	S4S12005	S4S13008	S4S15002	S4S15031
S4S10003	S4S12006	S4S13009	S4S15003	S6S15010
S4S10004	S4S12007	S4S13010	S4S15004	S4S15032
S4S10005	S4S12008	S4S13011	S4S15005	S6S15011
S4S10006	S4S12010	S4S13012	S4S15006	S6S15012
S4S11001	S4S12011	S4S13013	S4S15007	S6S15013
S4S11002	S4S12012	S4S13014	S4S15008	S6S15014
S4S11003	S4S12013	S4S13015	S4S15009	S6S15015
S4S11004	S4S12014	S4S13016	S4S15010	S6S15016
S4S11006	S4S12015	S4S13017	S4S15011	S4S15033
S4S11005	S4S12016	S4S13018	S4S15012	S6S15017
S4S11008	S4S12017	S4S13019	S4S15013	S6S16001
S4S11007	S4S12018	S4S13020	S4S15014	S6S16002
S4S11009	S4S12019	S4S13021	S4S15015	S6S16003
S4S11010	S4S12020	S4S13023	S4S15017	S6S16004
S4S11011	S4S12021	S4S13024	S4S15018	S6S16005
S4S11012	S4S12022	S4S13025	S4S15019	S6S16006
S4S11013	S4S12023	S4S13027	S4S15020	S6S16007
S4S11014	S4S12024	S4S13026	S4S15021	S6S16008
S4S11015	S4S12025	S4S13028	S4S15022	S4S16001
S4S11016	S4S12026	S4S13029	S4S15016	S6S16009
S4S11017	S4S12028	S4S14001	S6S15002	S6S1600010
S4S11018	S4S12029	S4S14003	S4S15023	S6S1600011
S4S11019	S4S12031	S4S14004	S4S15024	S6S1600012
S4S11020	S4S12030	S4S14002	S4S15025	S6S1600013
S4S11021	S4S12032	S4S14006	S6S15003	S6S1600014
S4S11027	S4S12034	S4S14007	S6S15004	S6S1600015
S4S11022	S4S12033	S4S14005	S4S15027	S6S1600016
S4S11023	S4S12035	S4S14008	S6S15005	S6S1600017
S4S11024	S4S12036	S4S13030	S4S15026	S6S1600018
S4S11025	S4S13001	S4S14010	S6S15006	S6S1600019
S4S11028	S4S13002	S6S14001	S4S15028	S6S1600020
S4S11026	S4S13003	S4S14011	S4S15029	S6S1600021
S4S12001	S4S13004	S4S14012	S4S15030	S6S1600022
S4S12002	S4S13005	S6S14002	S6S15007	
S4S12003	S4S13006	S6S15001	S6S15008	