



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 17104

<Date>

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

RE: **Potential for FlashPad™ Wireless Digital Detector to fall due to out-of-specification nylon detector support hooks on the Discovery XR656 wall stand systems.**

GE Healthcare has become aware of a potential safety issue involving the nylon hooks which support the FlashPad™ detector on the Discovery XR656 wall stand systems. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

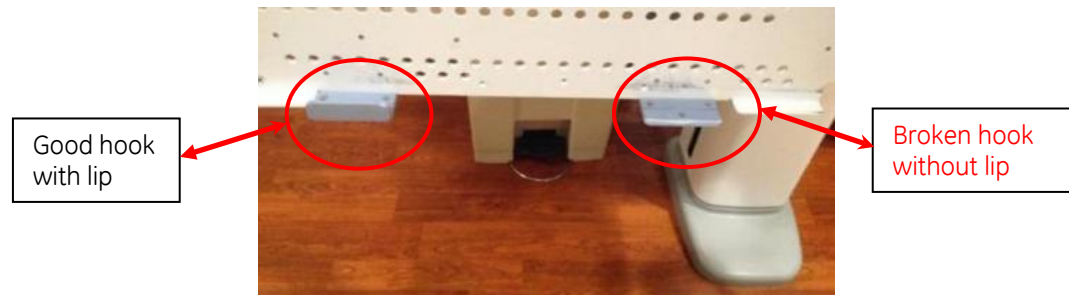
Safety Issue

GE Healthcare has recently become aware of two FlashPad™ detector falls due to a broken nylon support hook. A detector fall could result in an injury to a patient or operator. There have been reported incidents of detector falls, but no injuries have been reported.

Safety Instructions

As demonstrated in the example on the **right** in the picture below, if you observe either one of the nylon support hooks as broken or loose on the Discovery XR656 wall stand system, immediately stop use and contact your local GE Healthcare service representative. If the hooks are as shown in the example on the **left** below and not broken, you may continue to use the wall stand system.

Discovery XR656 wall stand system:



Affected Product Details

Discovery XR656 wall stand system having part numbers 5374989/5397837 manufactured from January 2013 to July 2014. See appendix for serial details.

Product Correction

GE Healthcare will correct all affected systems by replacing the nylon hooks 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 regarding this Field Safety Notice or the identification of affected items please contact your local sales/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.

Sincerely,

A handwritten signature in black ink, appearing to read "James".

James Dennison
Vice President QARA
GE Healthcare Systems

A handwritten signature in black ink, appearing to read "Douglas M. Hansell".

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

Appendix

Affected serial number listing part number: 5374989:

0000098015HL1	00000101258HL2	00000105502HL9	00000108129HL8
0000098016HL9	00000101259HL0	00000105503HL7	00000108130HL6
0000098927HL7	00000101260HL8	00000105504HL5	00000108131HL4
0000099007HL7	00000101261HL6	00000105505HL2	00000108132HL2
0000099010HL1	00000101881HL1	00000105506HL0	00000108133HL0
0000099011HL9	00000101882HL9	00000105507HL8	00000108134HL8
0000099012HL7	00000101883HL7	00000105980HL7	00000108135HL5
0000099013HL5	00000102301HL9	00000105981HL5	00000108136HL3
0000099014HL3	00000102302HL7	00000106114HL2	00000108137HL1
0000099015HL0	00000102303HL5	00000106115HL9	00000108138HL9
0000099016HL8	00000102304HL3	00000106116HL7	00000108405HL2
0000099437HL6	00000102305HL0	00000106117HL5	00000108406HL0
0000099438HL4	00000102306HL8	00000106118HL3	00000108407HL8
0000099439HL2	00000102307HL6	00000106119HL1	00000108408HL6
0000099440HL0	00000102575HL8	00000106120HL9	00000108409HL4
0000099441HL8	00000102576HL6	00000106121HL7	00000108410HL2
0000099442HL6	00000102577HL4	00000106122HL5	00000108411HL0
0000099443HL4	00000102578HL2	00000106123HL3	00000108412HL8
0000099444HL2	00000102851HL3	00000106124HL1	00000108701HL4
0000099445HL9	00000102852HL1	00000106672HL9	00000108702HL2
0000099446HL7	00000102853HL9	00000106673HL7	00000108703HL0
0000099447HL5	00000103438HL8	00000106674HL5	00000108704HL8
0000099448HL3	00000103439HL6	00000106675HL2	00000108705HL5
0000099845HL0	00000103440HL4	00000106676HL0	00000108706HL3
0000099846HL8	00000103441HL2	00000106677HL8	00000108707HL1
0000099847HL6	00000103669HL8	00000106678HL6	00000108708HL9
0000099848HL4	00000103670HL6	00000106968HL1	00000108709HL7
0000099849HL2	00000103671HL4	00000106969HL9	00000108710HL5
0000099850HL0	00000103672HL2	00000106970HL7	00000108711HL3
0000099851HL8	00000103673HL0	00000106971HL5	00000108712HL1
00000100227HL8	00000103674HL8	00000106972HL3	00000108714HL7
00000100228HL6	00000103675HL5	00000106973HL1	00000108715HL4
00000100229HL4	00000103959HL3	00000106974HL9	00000108716HL2
00000100230HL2	00000103960HL1	00000106975HL6	00000108717HL0
00000100231HL0	00000103961HL9	00000106976HL4	00000108718HL8
00000100232HL8	00000104239HL9	00000107176HL0	00000108719HL6
00000100233HL6	00000104240HL7	00000107177HL8	00000108720HL4
00000100364HL9	00000104241HL5	00000107178HL6	00000108721HL2
00000100365HL6	00000104242HL3	00000107179HL4	00000108722HL0
00000100366HL4	00000104243HL1	00000107180HL2	00000108723HL8
00000100367HL2	00000104244HL9	00000107181HL0	00000108724HL6
00000100368HL0	00000104673HL9	00000107182HL8	00000108725HL3
00000100369HL8	00000104709HL1	00000107380HL8	00000109154HL5
00000100653HL5	00000104710HL9	00000107381HL6	00000109561HL1
00000100654HL3	00000104711HL7	00000107382HL4	00000109562HL9
00000100655HL0	00000104712HL5	00000107383HL2	00000109563HL7
00000100656HL8	00000104713HL3	00000107384HL0	00000109564HL5
00000100657HL6	00000104714HL1	00000107385HL7	00000109565HL2
00000100658HL4	00000104715HL8	00000107386HL5	00000109566HL0
00000100659HL2	00000104716HL6	00000107387HL3	00000109567HL8
00000101139HL4	00000104717HL4	00000107388HL1	00000109568HL6

00000101140HL2	00000104718HL2	00000107815HL3	00000109569HL4
00000101251HL7	00000104719HL0	00000107816HL1	00000109570HL2
00000101252HL5	00000105160HL6	00000107817HL9	00000109571HL0
00000101253HL3	00000105161HL4	00000107818HL7	00000109572HL8
00000101254HL1	00000105162HL2	00000107819HL5	00000109986HL0
00000101255HL8	00000105163HL0	00000107820HL3	00000109987HL8
00000101256HL6	00000105164HL8	00000107821HL1	00000109988HL6
00000101257HL4	00000105165HL5	00000107822HL9	00000109990HL2
00000109991HL0	00000110172HL4	00000110432HL2	00000111362HL0
00000109992HL8	00000110173HL2	00000110869HL5	00000111363HL8
00000109993HL6	00000110174HL0	00000110870HL3	00000111371HL1
00000110166HL6	00000110175HL7	00000110873HL7	00000111381HL0
00000110167HL4	00000110427HL2	00000110876HL0	00000112379HL3
00000110168HL2	00000110428HL0	00000110877HL8	00000113283HL6
00000110169HL0	00000110429HL8	00000110878HL6	
00000110170HL8	00000110430HL6	00000110879HL4	
00000110171HL6	00000110431HL4	00000111359HL6	

Affected serial number listing part number: 5397837:

00000099003HL6	00000103955HL1	00000106125HL8	00000110164HL1
00000099005HL1	00000103956HL9	00000106126HL6	00000110165HL8
00000099459HL0	00000103957HL7	00000107374HL1	00000110425HL6
00000099460HL8	00000103958HL5	00000107375HL8	00000110866HL1
00000099843HL5	00000104238HL1	00000107376HL6	00000111353HL9
00000099844HL3	00000104668HL9	00000107377HL4	00000111354HL7
00000100362HL3	00000104669HL7	00000107378HL2	00000111355HL4
00000100363HL1	00000104704HL2	00000107812HL0	00000111356HL2
00000101250HL9	00000104705HL9	00000107813HL8	00000111369HL5
00000101884HL5	00000104706HL7	00000107814HL6	00000111401HL6
00000102579HL0	00000104707HL5	00000108139HL7	00000112358HL7
00000102580HL8	00000104708HL3	00000108413HL6	
00000103435HL4	00000105156HL4	00000108693HL3	
00000103436HL2	00000105157HL2	00000108694HL1	
00000103666HL4	00000105158HL0	00000108695HL8	
00000103667HL2	00000105159HL8	00000108696HL6	
00000103668HL0	00000105500HL3	00000108697HL4	
00000103954HL4	00000105501HL1	00000108700HL6	