



URGENT FIELD SAFETY NOTICE

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

31 March 2015

GEHC Ref# 12226

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

RE: **Improper installation by GE Healthcare or its agents of certain ceiling suspended radiation shields and surgical lamps.**

GE Healthcare performed an inspection through FMI 12209 of the Kenex ceiling suspension with radiation shield and/or surgical lamps installed at your facility. The affected products are limited to devices that did not meet the inspection criteria of FMI 12209. **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 an improper installation of a ceiling suspended pendent supporting a radiation shield and/or surgical lamp. The pendent system was not installed per specified installation requirements. There has been a reported incident of a radiation shield falling from the ceiling causing a minor injury.

Safety Instructions

If you observe any abnormal movement of the ceiling mount, immediately stop using the suspended system and contact your local GE Healthcare Service Representative. Please ensure those responsible for the service and maintenance of relevant Kenex products refer to the procedures detailed in the current versions of the appropriate Kenex manuals.

Affected Product Details

Kenex ceiling-suspended radiation shields and surgical lamps
E03971AA, E03981AA, E30421AA, E30431AA, E30591CA, E30591HD, E30591HL, E30591EB, E30511P, E30591AB, E30591B, E30591C, E30591A, E30591RR, E30591CB, E30591E, E33591PA, E33591PC.
See attached Appendix for a list of system.

Product Correction

GE Healthcare will work with you to correct all affected systems. 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 GE Healthcare 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,

James W. Dennison
Vice President Devices
GE Healthcare

Werner Van den Eynde, M.D.
Acting Chief Medical Officer
GE Healthcare

APPENDIX: AFFECTED PRODUCT SYSTEM ID'S

00055VAS01	083016002000488	083016200615113	083016600027812	083016802101749	083016860044513	916734XR	A5214942
00060VAS03	083016002001498	083016201000713	083016600031813	083016802102518	083016860048012	A147111802	A5219606
00095VAS08	08301600206936	083016201003810	083016600043813	083016802200044	083016861001510	A4185526	A5220710
00109VAS03	083016002100785	083016201004212	083016600046713	083016804632212	083016862100377	A4199383	A5286803
00115VAS01	083016002100969	083016201013312	083016600047612	083016804911211	083016862100448	A4213138	A5306808
00115VAS02	083016002101569	083016201018413	083016600057180	08301680520687	08301686210076	A4498248	A5306813
00132VAS01	083016002101581	083016201108211	083016601019313	083016807519408	083016862101259	A4498251	A5330714
00133VAS02	083016002101599	083016201112111	083016601019510	083016808517010	083016862101268	A5102671	A5333035
00171VAS02	083016002101753	083016201122313	083016601021610	083016808780010	083016862101407	A5105732	A5333036
00175VAS01	083016002102098	083016202100349	083016601103211	083016809878812	083016862101656	A5108239	A5333037
00192VAS04	083016002102378	083016202101917	083016602000612	083016820010512	083016862101916	A5108714	A5359404
00192VAS05	083016005000139	083016202705313	083016602003112	083016820050413	08301699537802	A5109212	A5360405
00197VAS01	083016006937510	08301621006236	083016602100229	083016821001413	0843160006	A5110156	A5360408
00265VAS03	083016007351458	08301622006008	083016602101617	083016821012310	0843160016	A5111034	A5360421
00272VAS01	083016007393112	083016240005912	083016602101807	083016821017310	0853060152	A5113511	A5365407
00282VAS02	083016020004212	083016240006012	083016602200077	083016821020410	0853060184	A5115143	A5367508
00285VAS02	083016020038813	083016240046711	083016602200254	083016821022010	0853060202	A51152101	A5379601
00285VAS03	083016022101218	083016241009210	083016602200304	083016821188412	0853060204	A5119428	A5379605
00358VAS01	08301603024062	083016241106811	083016603066811	083016821946912	0856060009	A5120519	A5381110
00371VAS01	08301603078802	083016241121412	083016603067111	083016822000444	0856160001	A5123529	A5400910
00379VAS02	08301603125002	083016242100481	083016604001512	083016822100478	0856160004	A5125119	A5401314
00440VAS02	083016040016512	083016242100879	083016606751111	083016822100515	0856160006	A5125125	A5401383
00440VAS04	083016041019813	083016242100936	083016607134210	083016822100563	0856160010	A5127281	A5401389
00440VAS06	083016060019313	083016242101355	083016607685310	083016822100808	0856160012	A5128612	A5401513
00490VAS04	083016060032211	083016243938114	083016608157389	083016822101107	0920169006	A5129811	A5605732
00860VAS01	083016060032411	083016280021513	083016608167379	083016822101187	10086VAS04	A5129951	A5605743
00929VAS01	083016060034111	083016280032711	083016608278289	083016822101587	10086VAS05	A5129953	A5618322
01278VAS01	083016060155411	083016281008510	083016608404049	083016822101709	10100VAS04	A5129954	A5624127
05217VAS03	083016062000898	083016281019910	083016608404110	083016823585112	10100VAS05	A5130609	A5624129
082406060001	083016062101579	083016281022711	083016608558510	083016826936710	126292XR01	A5131858	A5630803
082416040002	08301606216203	083016281107211	083016800004811	083016840020110	20001VAS02	A5140730	A5632421
082416200006	083016066772811	083016282100259	083016800019513	083016840035912	600002VA01	A5154412	A56364110
083006202101017	083016066828777	083016282101457	083016800036112	083016840570312	600010VA01	A5155141	A56364120
083006590088383	083016100009212	083016282101759	083016800036512	083016841003410	600034VA01	A5156832	A5687002
083006590208491	083016102002169	08301628448937	083016800047012	083016841016210	600042VA02	A5162256	A5697709
083006590208529	083016102100795	083016590002700	083016802100337	083016841626612	600050VA01	A5163317	A5730901
083006592815007	083016200018312	083016590020020	083016802100484	083016842101033	600050VA02	A5164510	A5764002
083006592830240	083016200019810	083016590670229	083016802100516	083016842101519	600151VA01	A5178024	A5805519
083016000006813	083016200023513	083016592416686	083016802100809	083016842101946	617340LC	A5180419	A58080104
083016000030812	083016200023813	083016600005112	083016802100854	083016842102488	714229INNOVA	A5183634	A5812244
083016000200047	083016200024913	083016600007012	083016802100866	083016860019010	77451VAS01	A5189713	A5812258
083016001011312	083016200026710	083016600011313	083016802101197	083016860033211	77451VAS02	A5196328	A9190167
083016001016610	083016200035913	083016600013213	083016802101285	083016860036012	788000XR02	A5203209	AZ1003VA01

APPENDIX: AFFECTED PRODUCT SYSTEM ID's

AZ1003VA02	D5810523	IE1100VA02	PL1075VA02	RU2275VA02	XF0160	YV0066	YV0468	YV0685	YV1906	YX1450
AZ4001VA01	DE188442	IE1513VA01	PL1082VA01	RU2714VA01	XF0200	YV0067	YV0469	YV0690	YV1907	YX1453
AZ4013VA01	DE203229	IL1043VA01	PL1101VA02	RU2751VA01	XF0250	YV0068	YV0470	YV0700	YV1908	YX1454
B1650215	DE641223	IL1098OE02	PL1101VA03	RU2969VA01	YE626911	YV0070	YV0471	YV0707	YV1909	YX1458
B5112507	DPN88402	J5274803	PL1107VA03	RU3138VA02	YE645824	YV0071	YV0472	YV0717	YV1910	YX1465
B51142117	EG1003VA01	M1327508	PL1465VA01	RU3213VA01	YP170A12	YV0073	YV0473	YV0870	YV1911	YX1466
B5114289	EG1102VA01	M1524103	PL1494VA01	RU3285VA01	YV0001	YV0074	YV0474	YV0873	YV1950	YX1470
B5167319	EG1235VA01	M199701601	PL1508VA02	RU3564VA01	YV0003	YV0075	YV0476	YV0874	YX0921	YX1476
B5332001	EG1741VA01	M2030707	PL1553VA01	RU4765VA01	YV0005	YV0076	YV0477	YV0875	YX0950	YX1483
B5381808	FE416040	M2812105	PL1622VA01	RU7189VA01	YV0006	YV0077	YV0478	YV0876	YX0955	YX1486
B5418905	FE421134	M2844529	PL1640VA01	RU8412VA01	YV0007	YV0078	YV0480	YV0888	YX0959	YX1488
B5603933	FEB52037	M40330122	PL1650VA02	SA160056	YV0009	YV0079	YV0481	YV1000	YX0978	YX1491
B5801711	FEE08424	M4040085	PL1672VA01	SA1005VA05	YV0010	YV0080	YV0500	YV1001	YX0982	YX1492
B5811426	FEE12418	M4152252	PL1677VA01	SA1005VA06	YV0011	YV0081	YV0501	YV1002	YX1001	YX1500
BG4009VA01	FI1015VA01	M4161021	PL1688VA01	SA1011VA01	YV0012	YV0082	YV0510	YV1005	YX1007	YX1501
BG4549VA01	FI1017VA02	M4163030	PL1768VA01	SA1039VA01	YV0013	YV0083	YV0520	YV1010	YX1013	YX1504
BG4604VA01	FI1017VA03	M4169342	PL1786VA01	SA1054VA02	YV0014	YV0085	YV0555	YV1011	YX1014	YX1512
BG4621VA01	FI1023VA03	M4176111	PL1804VA01	SA1060VA01	YV0025	YV0086	YV0562	YV1022	YX1046	YX1515
BG4639RX01	FI1025VA01	M4183841	PL1807VA01	SA1231VA01	YV0026	YV0090	YV0563	YV1201	YX1047	YX1520
BY4001VA03	FI1064VA01	M4196634	PL1808VA01	SA1237VA01	YV0027	YV0100	YV0564	YV1203	YX1062	YX1525
BY4002VA03	FI1126VA02	M4198062	PL2631VA01	SA1340RX01	YV0028	YV0162	YV0565	YV1204	YX1066	YX1543
BY4020VA02	FI1314VA02	M4202928	PL2958VA01	SA2122VA01	YV0030	YV0164	YV0600	YV1205	YX1070	YX1675
BY4026VA01	FPA99414	M4212443	PL2961VA01	SA2191VA01	YV0031	YV0165	YV0654	YV1206	YX1100	YX1681
BY4033VA01	FPG08002	M4496941	R4211476	SA2236VA01	YV0033	YV0167	YV0662	YV1207	YX1120	
BY4069VA01	FPG30528	M5484994	RU1001VA02	SA2253VA01	YV0035	YV0169	YV0663	YV1208	YX1136	
C5123609	GF1002VA02	M86323601	RU1011VA01	SA2308VA01	YV0037	YV0170	YV0664	YV1216	YX1140	
C5123625	HC0220XR10	M9162723	RU1016VA02	SI4069VA01	YV0038	YV0171	YV0665	YV1400	YX1183	
C5123626	HC3260XR04	MP473910	RU1100VA01	TN1003VA01	YV0039	YV0176	YV0666	YV1401	YX1186	
C5294640	HC5533XR08	NE185034	RU1136VA01	TN1012VA01	YV0040	YV0180	YV0667	YV1402	YX1200	
C5323515	HC5687XR09	NG1089VA01	RU1295VA01	X1347901	YV0042	YV0362	YV0668	YV1403	YX1243	
C5343110	HU1094VA01	NO1009VA03	RU1295VA03	X1347902	YV0045	YV0363	YV0669	YV1800	YX1245	
C5603903	HU1173VA02	NO1015VA03	RU1295VA05	X76305707	YV0046	YV0364	YV0670	YV1801	YX1308	
C5803121	HU1173VA03	NO1015VA04	RU1295VA06	XF0015	YV0047	YV0365	YV0671	YV1802	YX1344	
C5822413	HU1205VA01	NO1017VA03	RU1326VA01	XF0149	YV0048	YV0366	YV0672	YV1803	YX1348	
CE557044	IE1004VA03	NO1037VA01	RU1457VA01	XF0150	YV0049	YV0367	YV0673	YV1804	YX1353	
CEE15649	IE1004VA04	NO1064VA03	RU1464VA01	XF0151	YV0051	YV0370	YV0674	YV1805	YX1355	
CEE15663	IE1016VA01	OM1013VA01	RU1464VA02	XF0152	YV0054	YV0388	YV0675	YV1818	YX1393	
CS1006VA04	IE1016VA02	PC3006XR03	RU1475VA01	XF0153	YV0058	YV0400	YV0676	YV1900	YX1394	
CS1006VA05	IE1029VA01	PC6834XR03	RU1482VA02	XF0154	YV0060	YV0462	YV0677	YV1901	YX1395	
CS1019VA01	IE1031VA03	PL1008VA01	RU1646VA01	XF0155	YV0061	YV0463	YV0678	YV1902	YX1397	
CS1021RX02	IE1031VA04	PL1008VA02	RU1717VA02	XF0156	YV0063	YV0464	YV0680	YV1903	YX1437	
CS1081RX02	IE1077VA01	PL1029VA01	RU1899VA01	XF0157	YV0064	YV0466	YV0682	YV1904	YX1440	
D5810520	IE1100VA01	PL1042VA03	RU1999VA01	XF0158	YV0065	YV0467	YV0683	YV1905	YX1443	