

URGENT - Medical Device Correction
Precedence and SKYLIGHT SPECT Systems

A Collision and/or Excessive Force Exerted on the Detector Lower Arm May Cause the Arm and Detector to Fall

Dear Customer,

We have received reports regarding a problem involving the detector arm of certain Philips Precedence and SKYLIGHT SPECT Systems. We have conducted an investigation and have determined that a collision and/or excessive force exerted on the detector lower arm may cause the arm to fail and the detector and detector arm to fall, posing a risk for patients or users. This Medical Device Correction is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instructions for Use.

If you need any further information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,


Senior Director
Quality & Regulatory, CT/NM



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AFFECTED PRODUCTS	<p>Precedence: 16 Slice 3/8", 16 Slice 5/8", 6 Slice 3/8", and 6 Slice 5/8". The affected Precedence system serial numbers are listed in attachment A.</p> <p>SKYLIGHT: 8FT-3/8" SPECT, 9FT-3/8" SPECT, 8FT-5/8" SPECT, 9FT-5/8" SPECT, AZ 8FT 3/8", AZ 8FT 5/8", AZ 9FT 3/8", and AZ 9FT 5/8". The affected SKYLIGHT system serial numbers are listed in attachment B.</p>
PROBLEM DESCRIPTION	<p>Philips has recently become aware of collisions and excessive force exerted on the lower portion of the detector arms of Precedence and SKYLIGHT SPECT Systems which may have resulted in the detector arms breaking. A collision or excessive force may lead to a crack or fracture in the upper portion of the arm, which may cause the detector arms to break and the arm and detector to fall.</p>
HAZARD INVOLVED	<p>A collision of the detector arms with a static object (such as the patient table or the floor) or excessive force applied to the detector arm (for example, during a collimator exchange) could lead to a crack in the detector arm which may cause the detector to fall, swing, or pivot and possibly strike a patient or user in its path.</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Precedence: To identify the affected units, look at the serial number label located on the cover of the medicine cabinet which is on the bottom left hand side of the Precedence.</p> <p>SKYLIGHT: To identify the affected units, look at the serial number label located on the lower left corner of the back wall of the SKYLIGHT.</p>



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<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>1. You should immediately stop using this system and contact a Philips service representative for an immediate inspection if any one of the following apply:</p> <ul style="list-style-type: none"> - You have reason to believe any of the system's arms have experienced a collision with any static object, such as the patient table, floor, etc.; - You have reason to believe any of the system's arms experienced excessive force during a collimator exchange or otherwise; or - You have noticed any abnormal or unexpected vibration or shaking of any of the system's arms. <p>2. To avoid a collision or force on the detector that may result in the detector arm cracking or falling, be sure to follow the instructions in the system's Instructions For Use, including those below:</p> <ul style="list-style-type: none"> - If any part of the system looks like it is going to collide with the patient, use an Emergency Stop button to halt all system motion. - If the system does not function properly or fails to respond to the commands, stop the study and remove the patient from the area. Immediately contact Philips and report the incident. Do not use the equipment if any intermittent problems occur with any mechanical control device (handcontroller, Emergency Stop switches, collision sensors, etc.). - If you perform a preprogrammed motion with the patient on the imaging table, monitor the equipment motions closely to avoid contact with the patient or objects. - Watch the patient closely while performing PPMs, and press STOP or EMERGENCY STOP if it looks as though the camera may contact the patient or equipment. Never leave the room while performing PPMs. - Observe the following precautions to help prevent collisions that could injure your patient or damage the equipment: <ul style="list-style-type: none"> • Make sure that a qualified operator is always present during use to prevent collisions with the patient. • Vigilantly watch the patient to ensure that equipment and/or patient motion does not result in patient harm or equipment damage. • The red Emergency Stop switches activate quickly to stop system motions. • Make sure that you are familiar with the location of the Emergency Stop Switches, and do not hesitate to use them. • If you use PPMs when a patient is on the imaging table, to avoid patient injury, make sure that no part of the patient extends into the range of detector motions. • To avoid injury, stay clear of all moving parts, and stay out of the area that is within three feet of the gantry. • Watch the patient closely while performing PPMs, and press STOP or EMERGENCY STOP if it looks as though the camera may contact the patient or equipment. Never leave the room while performing PPMs. <p>Philips service will contact you to arrange a time for Philips to:</p> <ul style="list-style-type: none"> - Conduct an inspection of the system - Conduct the appropriate field safety correction <p>This letter should be placed in your Instructions for Use until otherwise notified.</p>
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<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips Healthcare is voluntarily initiating a corrective action consisting of:</p> <ul style="list-style-type: none"> • Distribution of this Field Safety Notice (FSN) • Conducting an inspection of the system • Conducting the appropriate field safety correction <p>Patient and product safety continues to be our primary focus. As a valued customer of Philips Healthcare, we want to ensure that your Philips equipment can be used safely.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative. In the United States and Canada, please contact the Philips Healthcare Customer Care Solutions Center at 1-800-722-9377 and follow the recorded menu options to reach a Customer Solutions Engineer; in all other countries please dial your local Philips Healthcare office.</p>



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Attachment A
Affected Precedence System Serial Numbers

3000002	3000003	3000006	3000027	3000028	3000029
3000030	3000031	3000031	3000032	3000032	3000033
3000033	3000034	3000034	3000035	3000035	3000036
3000036	3000037	3000037	3000038	3000038	3000039
3000039	3000040	3000040	3000041	3000041	3000042
3000042	3000043	3000043	3000044	3000044	3000045
3000045	3000046	3000047	3000048	3000049	3000050
3000051	3000052	3000053	3000054	3000055	3000056
3000057	3000058	3000059	3000060	3000061	3000062
3000063	3000064	3000065	3000066	3000067	3000068
3000069	3000070	3000071	3000072	3000073	3000074
3000075	3000076	3000077	3000078	3000079	3000080
3000081	3000082	3000083	3000084	3000085	3000708005
30006120020	30007010017	30007020002	30007020021	30007020023	30007030020
30007030021	30007030025	30007040024	30007040026	30007050022	30007050023
30007060024	30007060027	30007060028	30007060029	30007070025	30007070030
K06020011	K06110017	KP05040006	KP05070002	KP05080007	KP05090003
KP05100002	KP0510008	KP05110003	KP05110004	KP06010005	KP06020006
KP06040012	KP06050013	KP06060014	KP06070007	KP06070015	KP06080001
KP06080010	KP06090002	KP06090012	KP06100005	KP06100013	KP06100016
KP06110015	KP06110018	KP06110019			



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Attachment B
Affected SKYLIGHT System Serial Numbers

11131	556653	1000165	2000004	2000005	2000072
2000073	2000074	2000075	2000076	2000077	2000078
2000079	2000146	2000147	2000148	2000149	2000150
2000151	2000152	2000153	2000154	2000155	2000156
2000157	2000158	2000159	2000160	2000161	2000162
2000163	2000164	2000165	2000166	2000167	2000168
2000169	2000170	2000171	2000172	2000173	2000174
2000175	2000176	2000177	2000178	2000179	2000180
2000181	2000182	2000183	2000184	2000185	2000186
2000187	2000188	2000189	2000190	2000191	35836765
20002080145	20006120062	20006120064	20006120112	20006120113	20006120114
20007010065	20007010115	20007010116	20007020117	20007020118	20007020119
20007020120	20007020120	20007020121	20007020122	20007030066	20007030123
20007030125	20007040067	20007040068	20007040126	20007040128	20007050129
20007050130	20007050131	20007050132	20007050133	20007060069	20007060134
20007060135	20007060136	20007070137	20007070138	20007070139	20007070140
20007080071	20007080141	20007080142	20007080143	20007080144	K02120001
K03020002	K03020003	K03020021	K03030140	K03050033	K03050120
K03070004	K03080053	K03080054	K03080136	K03090055	K03090056
K03090057	K03090058	K03090059	K03090060	K03090137	K03090138
K03100061	K03100062	K03100063	K03100064	K03100065	K03100139
K03100140	K03100141	K03100142	K03110066	K03110143	K03110144
K03110145	K03110146	K03110147	K03120067	K03120148	K04010068
K04010069	K04010070	K04010074	K04010149	K04010150	K04010152
K04010153	K04020072	K04020073	K04020074	K04020154	k04030076
K04030077	K04030077	K04030078	K04030079	K04030080	K04030155
K04030156	K04030157	K04030158	K04040003	K04040081	K04040082
K04040083	K04040084	K04040159	K04040160	K04050005	K04050085
K04050086	K04050087	K04050088	K04050161	K04050162	K04050163
K04060089	K04060090	K04060091	K04060093	K04060094	K04060095
K04060164	K04060165	K04060166	K04060167	K04070095	K04070096
K04070097	K04070098	K04070099	K04070168	K04070169	K04070170
K04070171	K04080100	K04080101	K04080102	K04080172	K04080174
K04080175	K04080176	K04090006	K04090103	K04090104	K04090105
K04090106	K04090107	K04090108	K04090109	K04090177	K04090178
K04090179	K04090180	K04090300	K04100110	K04100111	K04100112
K04100183	K04100184	K04100186	K04100187	K04100188	K04110001
K04110002	K04110003	K04110113	K04110114	K04110115	K04110116



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Attachment B Continued
Affected SKYLIGHT System Serial Numbers

K04110117	K04110118	K04110119	K04120002	K04120120	K04120121
K04120122	K04120123	K04120124	K04120125	K04120126	K04120127
K05010003	K05010004	K05010004-1	K05010005	K05010005	K05010006
K05010007	K05010025	K05010128	K05010129	K05010130	K05010131
K05010189	K05010190	K05020006	K05020008	K05020009	K05020132
K05020191	K05030007	K05030009	K05030010	K05030011	K05040010
K05040011	K05040012	K05040012-1	K05040013	K05040013	K05040014
K05040015	K05040016	K05040017	K05050014	K05050015	K05050016
K05050017	K05050018	K05050019	K05050020	K05050021	K05050366
K05060018	K05060019	K05060020	K05060022	K05060023	K05060024
K05060025	K05060026	K05060027	K05070021	K05070022	K05070023
K05070028	K05070029	K05070030	K05070031	K05070032	K05080033
K05080034	K05080035	K05080036	K05080037	K05080038	K05080039
K05090040	K05090041	K05090042	K05090043	K05090044	K05090045
K05100001	K05100024	K05100026	K05100027	K05100046	K05100047
K05100048	K05110028	K05110029	K05110049	K05110050	K05110051
K05110052	K05110053	K05120030	K05120055	K06010031	K06010032
K06010056	K06010057	K06010058	K06010059	K06010060	K06010061
K06020002	K06020033	K06020034	K06020062	K06020063	K06020064
K06020065	K06030003	K06030035	K06030036	K06030066	K06030067
K06030068	K06030069	K06040037	K06040038	K06040039	K06040040
K06040071	K06040072	K06040073	K06040074	K06040075	K06040076
K06040077	K06050078	K06050079	K06060041	K06060042	K06060043
K06060044	K06060045	K06060046	K06060080	K06060081	K06060082
K06070047	K06070048	K06070049	K06070083	K06070084	K06070085
K06070086	K06080050	K06080051	K06080051	K06080052	K06080087
K06080088	K06080089	K06080090	K06080091	K06080093	K06080094
K06080095	K06080095	K06080096	K06080097	K06090053	K06090054
K06090099	K06090100	K06090101	K06090103	K06090486	K06100001
K06100055	K06100056	K06100057	K06100058	K06100104	K06100105
K06100106	K06100107	K06100108	K06100109	K06110059	K06110060
K06110061	K06110110	K06110111			

