

Field Safety Notice

Ceiling Suspension Motorized (CSM) – Difficult Vertical Movement

September 30, 2025

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 this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue which could occur with the ceiling suspension of Philips Diagnostic X-Ray (DXR) systems identified in Section 3 of this notice. This Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

Philips has identified that some ceiling suspension telescopic carriages manufactured from July 2024 through June 2025 may be difficult to move vertically (i.e. additional force/physical exertion required for manual movement) due to potential manufacturing issues.

As of September 2025, Philips has received 43 complaints associated with this issue. There has been one (1) report where two users experienced minor shoulder injury as a result of this issue.

2. Hazard/harm associated with the issue.

Repeatedly applying excessive force (>80N) over time to manually move the ceiling suspension telescopic carriage vertically could result in physical injury including pain, hematoma, damage to ligaments, and peripheral nervous injury.

3. Affected products and how to identify them.

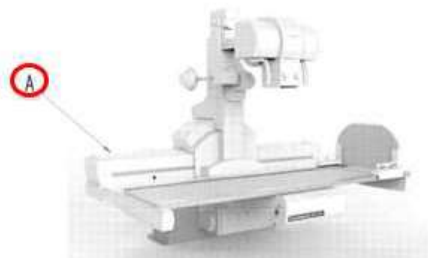
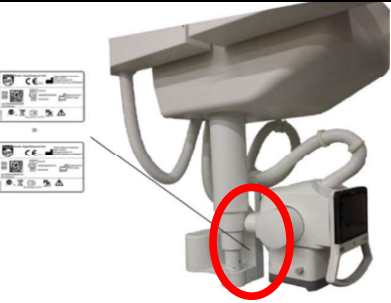
Identification of Impacted Systems:

The impacted systems can be identified by the product name (model), product number (REF), and system serial number (SN). The product name (model), product number (REF), and system serial number (SN) can be found on the system label, as indicated by Figures 1 and 2. Refer to Appendix A for the list of impacted serial numbers (SN).

Table 1. Impacted systems

Figure 1. Label Example	Product Name (model)	Product Number (REF)
	ProxiDiagnost N90	706110
	CombiDiagnost R90	709031
	DigitalDiagnost 4 High Performance	712031
	DigitalDiagnost 4 Flex/Value	712032
	DigitalDiagnost C90 High Performance	712034
	DigitalDiagnost C90 Flex/Value/Chest/ER	712035
	Radiography 7300 C	712037

Table 2. Label locations

Figure 2. Label Location	Model	REF number
	ProxiDiagnost N90	706110
	CombiDiagnost R90	709031
	DigitalDiagnost 4	712031, 712032
	DigitalDiagnost C90	712034, 712035
	Radiography 7300 C	712037

Intended Use:

ProxiDiagnost N90 and CombiDiagnost R90 are multi-functional general R/F systems. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.

The DigitalDiagnost 4 and DigitalDiagnost C90 consist of several components that can be combined in various configurations to form X-ray systems. It is intended to acquire, process, store, display and export digital radiographic images. The DigitalDiagnost systems are suitable for all routine radiography examinations, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography, and mammography.

Radiography 7300 C system is suitable for all routine radiographic examinations, including specialist areas such as intensive care, trauma, or pediatric work. Also advanced applications such as Bone Suppression shall be performed with the system.

All of these systems consist of several components that can be combined to create a variety of different X-ray configurations. One of the components is the Ceiling Suspension. The Ceiling Suspension can be freely moved longitudinally and transversely. The telescoping column allows the tube assembly, collimator and control grip to move vertically up and down.

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users.

- A. You may continue to use your system(s) in accordance with the intended use.
- Until a Field Service Engineer (FSE) visits your site to inspect the ceiling suspension and implement a hardware correction (if required), Philips recommends using the motorized movement option.

- If the force for movement exceeds 110N, the system may experience motor drive errors which restrict the motorized movement. If the motorized movement does not function, please contact your local Philips service representative.
- B. Circulate this notice to all users of this device so that they are aware of the issue and associated hazard/harm.
- C. Please retain this Field Safety Notice with your system(s) until the solution is installed; ensure the notice is in a place likely to be seen/viewed.
- D. Please complete and return the attached response form to Philips DXR promptly and no later than 30 days from receipt of this letter via email to: **<Market to insert local contact information>**. Completing this form confirms receipt of the Field Safety Notice, understanding of the issues, and required actions to be taken.

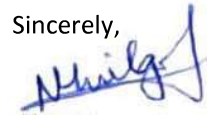
5. Actions planned by Philips to correct the problem.

A Philips representative will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site to inspect the ceiling suspension and implement a follow-up hardware correction, if required (reference 2025-PD-DXR-008).

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 Agencies.

Sincerely,



Naveen Huilgol
Head of Quality - DXR

Field Safety Notice Response Form

Reference: Ceiling Suspension Motorized (CSM) – Difficult Vertical Movement (reference 2025-PD-DXR-008)

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Follow the instructions provided in Section 4 of the Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected system(s).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please complete and return the attached acknowledgement form to Philips DXR via email to:

<Market to insert local contact information>.



Appendix A – Impacted System Serial Numbers

Model Name: ProxiDiagnost N90									
Model Number: 706110									
10001185	10001205	10001220	10001224	10001225	10001227	10001228	10001229	10001230	10001231
10001234	10001235	10001236	10001237	10001239	10001245	10001247	10001248	10001249	10001250
10001251	10001253	10001256	10001257	10001258	10001261	10001262	10001264	10001265	10001266
10001269	10001270	10001271	10001272	10001273	10001274	10001275	10001276	10001277	10001278
10001282									

Model Name: CombiDiagnost R90									
Model Number: 709031									
100001385	100001402	100001409	100001412	100001415	100001416	100001417	100001424	100001426	100001432
100001449	100001460	100001464	100001476	100001480	100001483	100001488			

Model Name: DigitalDiagnost 4 High Performance							
Model Number: 712031							
10001181	10001182	10001185	10001186	10001188	10001189	SN16000022	SN20000013

Model Name: DigitalDiagnost 4 Flex / Value			
Model Number: 712032			
10001179	19000341	19000342	19000343

Model Name: DigitalDiagnost C90 High Performance									
Model Number: 712034									
22860131	22860392	22860404	22860437	22860556	22860559	22860578	22860581	22860583	22860584
23860409	23860424	23860428	23860607	23860625	23860632	23860652	23860656	23860658	23860665
23860667	23860668	23860669	23860680	23860684	23860693	23860700	23860717	23860769	23860780
23860812	23860820	23860823	23860824	24860041	24860042	24860043	24861002	24861010	24861018
24861020	24861021	24861031	24861036	24861039	24861040	24861041	24861042	24861055	24861063
24861072	24861076	24861083	24861086	24861088	24861091	24861105	24861106	24861107	24861108



Model Name: DigitalDiagnost C90 High Performance (continued)									
Model Number: 712034 (continued)									
24861110	24861112	24861114	24861118	24861121	24861123	24861124	24861125	24861126	24861128
24861130	24861132	24861133	24861135	24861136	24861137	24861138	24861140	24861141	24861142
24861143	24861150	24861153	24861155	24861160	24861162	24861165	24861175	24861203	24861206
24861207	24861208	24861216	24861225	24861226	24861233	24861234	24861237	24861238	24861239
24861240	24861241	24861242	24861243	24861245	24861254	24861255	24861256	24861257	24861258
24861259	24861261	24861262	24861263	24861264	24861265	24861268	24861269	24861271	24861285
24861286	24861290	24861291	24861294	24861295	24861297	24861298	24861299	24861300	24861301
24861305	24861308	24861314	24861317	24861318	24861319	24861320	24861321	24861324	24861326
24861327	24861328	24861329	24861331	24861340	24861341	24861342	24861343	24861344	24861346
24861352	24861360	24861361	24861362	24861363	24861364	24861365	24861366	24861367	24861369
24861370	24861372	24861373	24861378	24861381	24861382	24861385	24861386	24861387	24861388
24861389	24861391	24861397	24861398	24861399	24861400	24861401	24861404	24861405	24861407
24861408	24861410	24861411	24861412	24861413	24861414	24861418	24861419	24861420	24861421
24861423	24861424	24861428	24861429	24861435	24861436	24861438	24861439	24861440	24861441
24861442	24861443	24861446	24861450	24861451	24861455	24861456	24861459	24861460	

Model Name: DigitalDiagnost C90 Flex/Value/Chest/ER									
Model Number: 712035									
23860438	24861021	24861023	24861037	24861044	24861045	24861046	24861047	24861054	24861055
24861061	24861062	24861063	24861064						

Model Name: Radiography 7300 C									
Model Number: 712037									
6	7	8	9	11	12	13	14	15	17
24860004	24860006	24860008	24860009	24860010	24860011	24860012	24860013	24860014	24860015
24860017	24860018	24860019	24860021	24860034	24860036	24860037	24860038	24860039	24860040
24860044	24860045	24860047	24860049	24860051	24860053	24860055	24860056	24860057	24860058
24860059	24860060	24860061	24860062	24860064	24860065	24860066	24860067	24860068	24860069



Model Name: Radiography 7300 C (continued)									
Model Number: 712037 (continued)									
24860070	24860072	24860073	24860074	24860075	24860076	24860077	24860078	24860079	24860080
24860081	24860082	24860083	24860084	24860085	24860086	24860087	24860088	24860089	24860090
24860091	24860092	24860093	24860094	24860096	24860098	24860099	24860100	24860101	24860102
24860103	24860104	24860105	24860106	24860107	24860108	24860109	24860110	24860111	24860112
24860113	24860115	24860116	24860117	24860118	24860119	24860120	24860121	24860122	24860123
24860124	24860125	24860126	24860128	24860129	24860130	24860131	24860133	24860135	24860137
24860139	24860141	24860142	24860143	24860144	24860145	24860146	24860148	24860149	24860150
24860153	24860157	24860158	24860159	24860163	24860164	24860165	24860166	24860167	24860168
24860169	24860170	24860172	24860173	24860174	24860175	24860177	24860178	24860179	24860180
24860181	24860182	24860183	24860184	24860185	24860186	24860187	24860191	24860192	24860193
24860196	24860197	24860198	24860200	24860203	24860204	24860205	24860207	24860208	24860209
24860210	24860211	24860212	24860213	24860214	24860216	24860217	24860218	24860219	24860220
24860221	24860222	24860223	24860224	24860225	24860226	24860227	24860228	24860229	24860232
24860233	24860234	24860235	24860236	24860237	24860238	24860239	24860240	24860241	24860248
24860252	24860254	24860255	24860256	24860257	24860259	24860260	24860261	24860262	24860264
24860265	24860266	24860267	24860268	24860269	24860270	24860271	24860272	24860273	24860275
24860276	24860277	24860278	24860280	24860281	24860282	24860283	24860284	24860286	24860288
24860289	24860290	24860294	24860295	24860296	24860297	24860298	24860299	24860302	24860306
24860308	24860310	24860311	24860312	24860314	24860315	24860317	24860318	24860319	24860321
24860322	24860324	24860325	24860328	24860332	24860337	24860338	24860339	24860340	24860342
24860343	24860344	24860352	24860355	24860356	24860357	24860361	24860363	24860365	24860366
24860367	24860368	24860369	24860370	24860372	24860373	24860376	24860382	24860383	24860384
24860388	24860390	24860391	24860392	24860393	24860394	24860401	24860404	24860407	24860410
24860411	24860416	24860420	24860425						