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Field Safety Notice

Achieva 1.5T, Achieva 1.5T Conversion, Ingenia 1.5T CX, Intera 1.5T, Intera 1.5T Power/Pulsar, SmartPath to dStream for 1.5T

Gradient Coil component failure may act as a heat source with potential to produce smoke and/or fire.

October 23, 2023

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 identified an issue with certain models of its 1.5T MR systems, the Achieva 1.5T, Achieva 1.5T Conversion, Ingenia 1.5T CX, Intera 1.5T, Intera 1.5T Power/Pulsar, and SmartPath to dStream for 1.5T systems ("Affected 1.5T MR Systems"), that could pose a risk for patients and/or users. 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 an issue where a specific component failure in the Gradient Coil of the affected 1.5T MR Systems listed in this letter may act as a heat source with a potential to produce smoke and/or fire.

If the component failure occurs, the user may observe the following:

- Repeated scan abort error messages due to gradient amplifier fault detection, described in Section 4.
- Unusual noise from the system in the examination or technical room
- Smoke and/or fire from within the system

Philips has received one (1) complaint of smoke/fire caused by this issue which is associated with the Gradient Coil type used in the MR Systems identified in this letter. There was no report of injury or serious harm to hospital staff or patients, however, damage to property has occurred.

2. Hazard/harm associated with the issue

If smoke or a fire occurs, the risk to patients or operators may include inhalation of smoke, burns, and/or asphyxia which may lead to injury or even death. This issue could also lead to property damage.

3. Affected products and how to identify them

Identification of Impacted Systems:
The affected 1.5T MR Systems including product number (REF), name (Model) and serial number (SN) are listed in Appendix A. Figure 1 illustrates the location of the product number (REF), name (Model), and serial number (SN).

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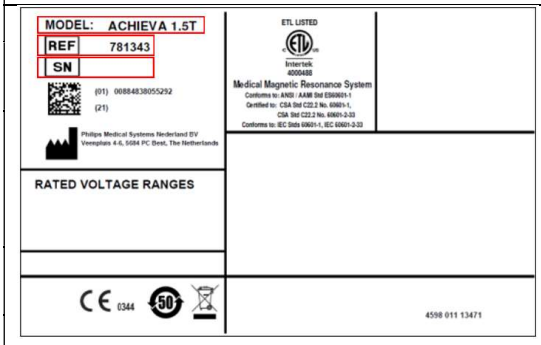
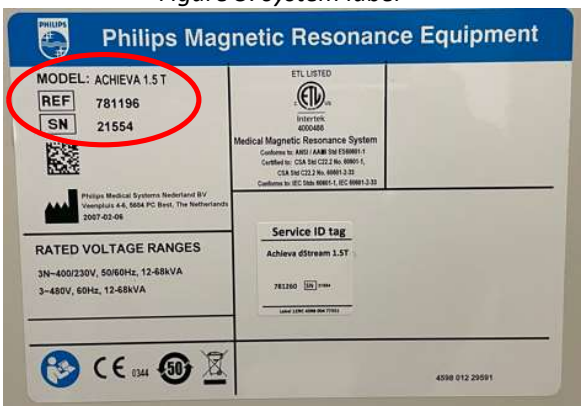
Figure 1. Example System Label	Product Name (Model)	Product Number (REF)
	Intera 1.5T Power/Pulsar	781105
	Intera 1.5T	781195 781295
	Achieva 1.5T	781178 781196 781296 781343
	Achieva 1.5T Conversion	781283 781346
	Ingenia 1.5T CX	781261 781262
	SmartPath to dStream for 1.5T	781260 782112

Please locate the serial number of your impacted MR system by:

3.1. Enter the Technical Room
3.2. Locate the general Mains Distribution Unit (gMDU)
3.3. The system label is located on the front door of the gMDU (see figure 2)
3.4. Locate the serial number on the system identification label (see figure 3)

Figure 2: Front door of GMDU

Figure 3: system label



Intended Use:
Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device.

These MR systems enable trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body or extremities, in any orientation, representing the spatial distribution of protons or other nuclei with spin.

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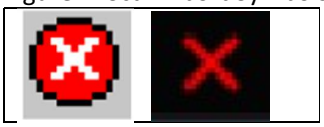
4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

4.1. When using any affected system identified according to the information in section 3, follow the instructions below.

4.2. Pay particular attention if a scan interruption occurs and a 'scan abort' symbol is encountered, which may appear in the user interface (UI) with the symbols shown in Figure 4 below:

Figure 4. Scan Abort Symbols



4.3. When scan aborts occur the symbol is shown and applicable messages are presented in the message box (see Figure 5 and Figure 6 examples)

4.3.1. Check the status of the error messages in the User Interface (UI) screen. Click to expand the message box in case previous messages are hidden, see orange box in Figure 5 and Figure 6 below. If possible, correct the issue that is relevant to the error shown, and continue scanning, for example:

- "RF door must be closed while performing scan. Scan aborted."
- "Patient support is moved while scanning, scan stopped."
- "Coil A (*or B*) failure, coil disconnected?".

Figure 5. UI example SW Version R11.

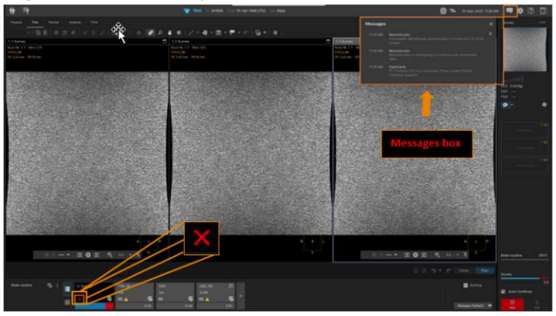
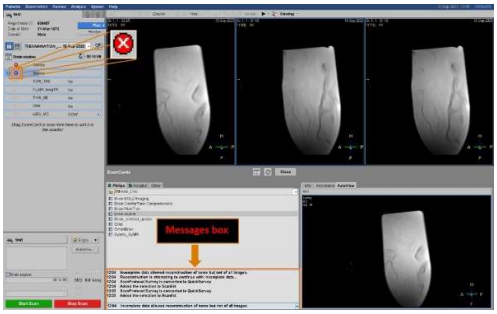


Figure 6. UI example SW Version R5.



4.3.2. If, after a scan abort, one of the following conditions occur five times in a row stop scanning immediately and contact Philips Service to describe the problem:

- If there is no error message in the message box
- If the error message meaning is not clear

4.3.3. If the error message "Gradient amplifier Rack Fault" is received two times in a row, or if the error message "Gradient amplifier Rack Fault" is preceded or followed by an aborted scan with no message, then stop scanning immediately and contact Philips Service to describe the problem.

4.3.4. If you encounter any of these conditions described in 4.3.2 or 4.3.3 do not attempt any additional/further scans, including without limitation do not attempt any phantom scanning until your system has been checked and released by a Philips Service representative.

4.4. If smoke and/or fire is detected:
- Immediately stop scanning and evacuate the patient and staff from the Examination Room.
- If a developing fire is detected adhere to established hospital fire emergency procedures, which may include switching off power to the complete system and/or removing the magnet field by using the Emergency Magnet Off button.
- Do not attempt to continue scanning.
- Immediately contact Philips Service.

4.5. Ensure all users are aware of facility specific Emergency Procedures as outlined in *Chapter 2: Safety* in the Instructions for Use:

Emergency procedures

The User is required to establish emergency procedures for the following situations:
- *A medical emergency*
- *A fire*
- *An emergency that requires immediate removal of the magnetic field*
- *The release of helium gas into the examination room*

Philips MRI systems have an Emergency Table Stop button in case there is an emergency during tabletop movement.

4.6. Post the attached Appendix B – Actions for Customer / User: Post with System near the affected MR system(s) for ease of reference.

4.7. Circulate this notice to all users of this device so that they are aware of the product issue and associated hazard/harm until this issue has been resolved.

4.8. Please complete and return the attached updated customer response form to Philips **promptly** and no later than 30 days from receipt of this letter.

5. Actions planned by Philips to correct the problem

Philips is providing this customer letter containing guidance until the investigation into this issue is complete.

Philips is committed to addressing the issue and continues to investigate its root cause. We anticipate providing an update to you on the development of our plan to address the issue in early 2024.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this issue, please contact your local Philips representative at the Philips Customer Care Service Centre on:

Telephone: UK : +448000260086
NI: +448000260430
ROI: +3531800832340

Email : ukisfco@philips.com

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This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

David Hanly
Head of Quality, Magnetic Resonance (MR)

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Field Safety Notice Response Form

Reference: Achieva 1.5T, Achieva 1.5T Conversion, Ingenia 1.5T CX, Intera 1.5T Power/Pulsar, Intera 1.5T, SmartPath to dStream for 1.5T: Gradient coil may act as a heat source with a potential to produce smoke and/or fire.

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:

A. Post this notice near the affected MR unit(s) for ease of reference.

B. Circulate this notice to all users of this device so that they are aware of the product issue and associated hazard/harm until this issue has been resolved.

C. 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 system.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please complete and return the attached acknowledgment form to Philips MR via email to: **safetynoticeuki@philips.com**

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Appendix A – Units Affected List

Product number (REF): 781105	Product name (Model): Intera 1.5T Power/Pulsar
8187	

Product number (REF): 781195					Product name (Model): Intera 1.5T				
18510	18516	18529	18550	18564	18567	18578	18583	18592	18657
18660	18667	18678	18701	18709	18711	18714	18725	18727	18769
18773	18776	18787	18812	18820	18854	18856	18857	18870	18873
18878	18884	18889	18890	18905	18906	18907	18913	18917	18920
18923	18931	18935	18947	18948	18950	18965	18973	18986	18998
20402	20403	20404	20409	20426	20441				

Product number (REF): 781295					Product name (Model): Intera 1.5T				
30004	30030	30037	30038	30064	30079	30081	30082	30131	30187
30190	30199	30200	30206	30213	30218	30219	30223	30234	30235
30236	30238	30255	30256	30265	30266	30267	30268	30272	30274
30277	30278	30279	30280	30281	30284	30285	30288	30293	30296
30297	30298	30303	30311	30312	30315				

Product number (REF): 781178			Product name (Model): Achieva 1.5T
21034	21605	21695	

Product number (REF): 781196					Product name (Model): Achieva 1.5T				
21035	21082	21083	21133	21158	21165	21178	21184	21205	21209
21212	21225	21237	21240	21242	21246	21247	21249	21262	21265
21269	21271	21292	21299	21320	21327	21333	21343	21345	21359
21369	21396	21397	21428	21431	21438	21448	21458	21480	21503
21530	21540	21552	21556	21577	21580	21607	21647	21677	21682
21684	21686	21688	21690	21704	21706	21711	21713	21724	21725
21848	21851	21876	21879	21895	21900	21913	21914	21935	21961
21988	21994	21995	21996	22019	22026	22051	22052	22053	22055
22065	22078	22080	22085	22103	22117	22119	22133	22135	22147
22152	22158	22165	22175	22176	22179	22193	22201	22210	22224
22233	22234	22246	22251	22254	22257	22259	22262	22273	22281
22313	22316	22318	22323	22326	22328	22330	22361	22379	24184
32086	33022								

Product number (REF): 781296					Product name (Model): Achieva 1.5T				
8524	32039	32052	32083	32087	32097	32103	32118	32123	32150
32153	32154	32186	32223	32226	32228	32230	32231	32243	32247
32255	32265	32288	32289	32306	32350	32375	32376	32385	32387
32390	32392	32413	32435	32439	32452	32459	32463	32474	32505
32531	32533	32537	32567	32584	32591	32595	32603	32608	32610
32631	32655	32675	32684	32708	32720	32727	32728	32739	32748
32764	32769	32776	32789	32795	32799	32802	32806	32807	32812
32815	32816	32820	32823	32832	32842	32843	32844	32848	32850
32871	32878	32894	32897	32899	32903	32905	32907	32916	32925

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32930	32931	32938	32958	32959	32964	32970	32971	32974	32983
32985	32988	32989	32991	32992	32994	32995	32998	33000	33008
33010	33021	33043	33051	33055	33058	33060	33064	33066	33067
33068	33070	33071	33073	33074	33082	33083	33087	33088	33091
33093	33097	33099	33101	33103	33109	33115	33117	33119	33126
33128	33132	33133	33136	33138	33144	33148	33149	33150	33156
33158	33162	33163	33170	33173	33177	33178	33180	33182	33183
33185	33186	33187	33189	33190	33198	33202	33205	33207	33215
33218	33219	33221	33222	33223	33225	33227	33234	33235	33240
33244	33248	33251	33252	33253	33254	33255	33262	33264	33269
33272	33274	33275	33283	33287	33302	33305	33312	33313	33314
33318	33328	33330	33334	33335	33338	33340	33347	33348	33364
33367	33368	33369	33371	33377	33382	33388	33392	33393	33394
33396	33398	33399	33402	33404	33408	33413	33423	33435	33438
33449	33451	33453	33459	33463	33470	33471	33474	33477	33478
33489	33493	33497	33516	33518	33523	33525	33526	33527	33534
33541	33543	33544	33545	33547	33548	33550	33553	33558	33561
33562	33563	33564	33565	33566	33567	33570	33582	33587	33591
33603	33604	33608	33609	33611	33625	33628	33632	33635	33636
33639	33648	33650	33651	33655	33662	33669	33673	33677	33678
33679	33683	33684	33686	33687	33690	33692	33695	33696	33699
33700	33702	33704	33717	33718	33722	33723	33726	33740	33748
33749	33750	33751	33752	33755	33767	33772	33775	33777	33784
33785	33787	33788	33789	33794	33797	33805	33823	33838	33839
33848	33850	33854	33858	33867	33897	33909	36062	39068	

Product number (REF): 781343					**Product name (Model): Achieva 1.5T**				
72005	72007	72008	72013	72016	72019	72020	72022	72032	72036
72038	72040	72048	72053	72055	72058	72063	72066	72080	72083
72100	72103	72114	72118	72119	72120	72124	72127	72128	72131
72134	72138	72139	72141	72144	72149	72150	72153	72154	72157
72170	72173	72175	72180	72185	72189	72190	72192	72201	72204
72208	72222	72239	72240	72247	72290	72306	72322		

Product number (REF): 781283					**Product name (Model): Achieva 1.5T Conversion**				
39001	39027	39028	39030	39032	39039	39053	39059	39061	39062
39064	39065	39066	39067	39072	39073	39074	39075	39078	39080
39081	39082	39083	39084	39086	39088	39090	39091	39093	39094
39095	39097	39098	39100	39102	39105	39106	39107		

Product number (REF): 781346					**Product name (Model): Achieva 1.5T Conversion**				
5243	5547	8020	8276	8289	8361	8367	8371	8415	8714
8727	8740	8782	10189	10194	10219	10821	18505	18737	75000
75003	75004	75007	75008	75009	75015	75031	75068	75087	75092

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Product number (REF): 781261			Product name (Model): Ingenia 1.5 CX
77008	77016	77018	

Product number (REF): 781262					Product name (Model): Ingenia 1.5 CX				
77032	77034	77035	77038	77040	77041	77046	77049	77050	77054
77056	77058	77059	77061	77062	77065	77066	77067	77071	77072
77074	77075	77078	77081	77083	77084	77087	77093	77094	77097
77100	77101	77106	77109	77110	77111	77119	77120	77121	77124
77126	77129	77130	77131	77137					

Product number (REF): 781260					Product name (Model): SmartPath to dStream for 1.5T				
5447	5463	5479	5490	5537	5546	8012	8025	8054	8086
8087	8091	8092	8110	8118	8178	8260	8311	8318	8365
8378	8387	8392	8395	8427	8554	8566	8578	8611	8616
8639	8642	8667	8706	8713	8746	8750	8752	8779	8783
8786	8831	8840	8851	8857	8884	8895	8896	8923	8942
8948	9004	9013	10029	10044	10075	10079	10130	10151	10164
10170	10174	10185	10191	10458	10511	10513	10554	10906	10915
11031	11047	11062	11076	11085	11091	11102	12030	13011	13029
13032	13062	18038	18670	18761	18957	20071	20111	20226	21062
21213	21576	21582	21801	21814	22013	22017	22031	22086	22098
22102	22144	22157	22248	30033	32218	33044	33246	39003	39024
39031	39037	72054	72243	72250					

Product number (REF): 782112				Product name (Model): SmartPath to dStream for 1.5T
10128	21893	32580	32798	

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

4.1. When using any affected system identified according to the information in section 3, follow the instructions below.

4.2. Pay particular attention if a scan interruption occurs and a 'scan abort' symbol is encountered, which may appear in the user interface (UI) with the symbols shown in Figure 4 below:

Figure 4. Scan Abort Symbols

4.3. When scan aborts occur the symbol is shown and applicable messages are presented in the message box (see Figure 5 and Figure 6 examples)

4.3.1. Check the status of the error messages in the User Interface (UI) screen. Click to expand the message box in case previous messages are hidden, see orange box in Figure 5 and Figure 6 below. If possible, correct the issue that is relevant to the error shown and continue scanning, for example:

- "RF door must be closed while performing scan. Scan aborted."
- "Patient support is moved while scanning, scan stopped."
- "Coil A (or B) failure, coil disconnected?".

Figure 5. UI example SW Version R11.

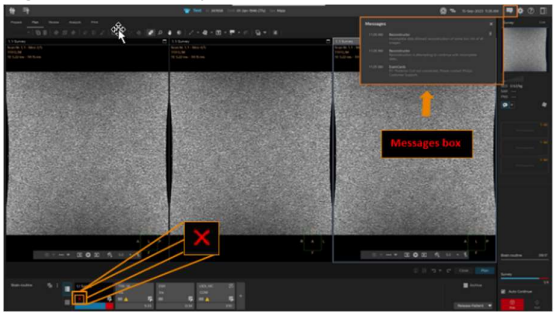
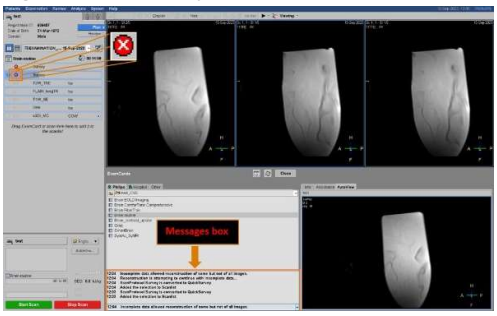


Figure 6. UI example SW Version R5.



4.3.2. If one of the following conditions occur five times in a row stop scanning immediately and contact Philips Service to describe the problem:

- If there is no error message in the message box
- If the error message meaning is not clear

4.3.3. If the "Gradient amplifier Rack Fault" error message is received two times, or if the error message "Gradient amplifier Rack Fault" is received followed by an aborted scan with no message, then stop scanning immediately and contact Philips Service to describe the problem.

4.3.4. If you encounter any of these conditions described in 4.3.2 or 4.3.3 do not attempt any additional/further scans, including without limitation do not attempt any phantom scanning until your system has been checked and released by a Philips Service representative.

4.4. If smoke and/or fire is detected:
- Immediately stop scanning and evacuate the patient and staff from the Examination Room.
- If a developing fire is detected adhere to established hospital fire emergency procedures, which may include switching off power to the complete system and/or removing the magnet field by using the Emergency Magnet Off button.
- Do not attempt to continue scanning.
- Immediately contact Philips Service.

4.5. Ensure all users are aware of facility specific Emergency Procedures as outlined in Chapter 2: Safety in the Instructions for Use:

Emergency procedures
The User is required to establish emergency procedures for the following situations:
- *A medical emergency*
- *A fire*
- *An emergency that requires immediate removal of the magnetic field*
- *The release of helium gas into the examination room*

Philips MRI systems have an Emergency Table Stop button in case there is an emergency during tabletop movement.

4.6. Keep this Appendix B near the affected MR system(s) for ease of reference.

4.7. Circulate this notice to all users of this device so that they are aware of the product issue and associated hazard/harm until this issue has been resolved.