

URGENT Field Safety Notice

**Ingenia Elition X, Ingenia Elition S, SmartPath to Ingenia Elition X,
MR 7700 and Upgrade to MR 7700**

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

June 05, 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 3T MR systems, the Ingenia Elition, SmartPath to Ingenia Elition X, MR 7700 and Upgrade to MR 7700 MR systems (“Affected 3T MR Systems”), that could pose a risk for patients and/or users. This *URGENT Field Safety Notice* is intended to inform you about:

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

Issue 1: Gradient Coil: Philips has identified an issue where a specific component failure in the Gradient Coil of the affected 3T MR Systems identified 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:

- Severe image quality issues (image artifacts caused by electrical disturbances)
- Scan abort
- Smoke and/or fire

Philips has received two (2) complaints of fire associated with the Ingenia Elition MR system. In both cases there was no report of injury or serious harm, however damage to property has occurred.

Issue 2: System Power Cycle: The system operator is able to bypass the SmokeDetector Interlock system locking mechanism after a smoke detection by power-cycling the system. If the operator completes a MR System power-cycle the SmokeDetector Interlock is reset. Although the operator received the SmokeDetector Interlock warning, the warning is inadvertently cleared, and the operator could begin to scan again. The SmokeDetector Interlock will continue to engage and shut the system down if it detects smoke again.

There have been no reports of adverse events reported to Philips regarding this issue as of May 2023.

Issue 3: Insecure Cable: A connecting cable, between the SmokeDetector Interlock and the host PC, may not have been properly installed. This connection is used for service diagnostics and does not impact the functionality of the system and/or the SmokeDetector Interlock system.

There have been no reports of adverse events reported to Philips regarding this issue as of May 2023.

2. Hazard/harm associated with the issue

Issue 1: Gradient Coil: If smoke or a fire were to occur, 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.

Issue 2: System Power Cycle: If smoke or a fire were to occur, 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.

Issue 3: Insecure Cable: This issue poses no safety risk to patients, operators, or service personnel.

3. Affected products and how to identify them

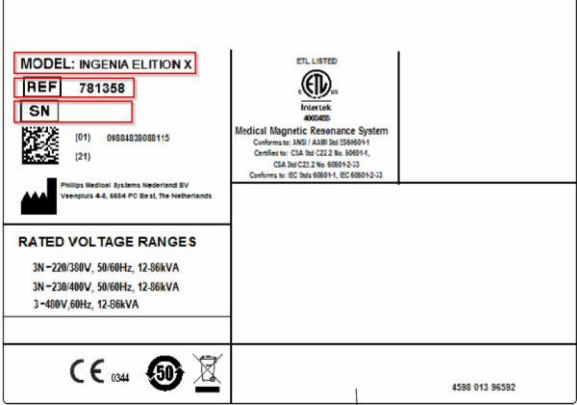
Intended Use:

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

This MR system enables 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.

Identification of Impacted Systems:

The Affected 3T MR Systems including product number, name and serial number are listed in Appendix A. Figure 1 illustrates the location of the product number, name, and serial number.

Figure 1. Example System Label	Product Name	Model
	Ingenua Elition X	781358 782107 782119 782136
	Ingenua Elition S	781357 782106 782137
	SmartPath to Ingenua Elition X	782118 782132 782144
	MR 7700	782120
	Upgrade to MR 7700	782130

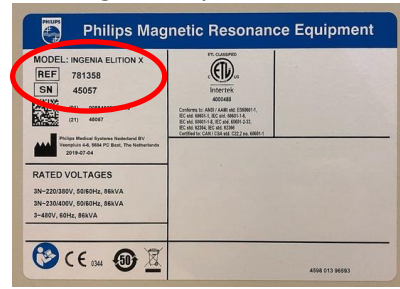
Please locate the serial number of your impacted MR system by:

- 3.1. Enter the Technical Room
- 3.2. Locate the CombiCabinet
- 3.3. On the front door of the LCC part of the system locate the system label (see figure 2)
- 3.4. Locate the serial number on the system label (see figure 3)

Figure 2: Front door of LCC



Figure 3: system label



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

4.1. Philips has installed a SmokeDetector Interlock feature on all the systems listed in **Appendix A**.

- Post this notice near the affected MR system(s) for ease of reference.
- 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.
- Please complete and return the attached updated customer response form to Philips **promptly** and no later than 3 days from receipt of this letter. **Philips is requesting that even if you acknowledged a previous version of this letter that you also respond with an acknowledgment to this updated letter.**

4.2. The SmokeDetector Interlock feature is integrated with the MR System and powers off the relevant part of the system (Gradient Amplifier) when smoke is detected in order to prevent further development of smoke and/or fire. If the SmokeDetector Interlock has detected smoke and has powered off the Gradient Amplifier:

- Remove patient from the system according to the instructions for use because power to the tabletop will still be active
- Scanning is disabled until Philips service has checked the system. Do not attempt to continue scanning.
- Immediately inform Philips Service
- DO NOT attempt to restart or perform a power-cycle of the system

4.3. If a user experiences smoke, fire, or severe image quality issues (image artifacts caused by electrical disturbances):

- Immediately stop scanning and evacuate the patient from the Examination Room.
- Check Examination Room for a developing fire.
- If a developing fire is sensed, adhere to established 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
- Scanning is disabled until Philips service has checked the system. Do not attempt to continue scanning
- Immediately contact Philips Service

4.4. Ensure all users are aware of facility specific Emergency Procedures as outlined in *Section 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.

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:

Issue 1: Gradient Coil:

- Philips has equipped all impacted systems with the SmokeDetector Interlock as of January 2023 (Reference FCO78100529).
- Philips plans to improve the SmokeDetector Interlock system reaction time from ten (10) seconds to one (1) second (Reference FCO78100562). Philips plans to start implementing beginning in Q4 2023.
- Install a heat detector on the gradient coil to test/monitor your system to determine if the Gradient Coil has a defect and requires replacement (Reference FCO78100560). Philips plans to start implementing beginning in Q4 2023.

Issue 2: System Power Cycle:

Install a software Service Pack to prevent the bypass of the SmokeDetector Interlock system and update the SmokeDetector Interlock error message to provide more detailed instructions for the operator. As part of this installation, Philips will be providing an electronic IFU Addendum to include the SmokeDetector Interlock, Heat Detector system, and align with the instructions provided in sections 4.2 and 4.3 of this letter.

Based on your systems software the table below indicates when the solution will become available.

Reference number	Current Software release affected:	Philips plans to release solution:
FCO78100565	SW R5.x China: SW R6.1.x	Beginning in Q3 2023
FCO78100567	SW 5.9, R10.x and R11.x	Beginning in Q4 2023

Issue 3: Insecure Cable:

- Philips will inspect your system and install the correct cable connector if necessary. (Reference FCO78100560). Philips plans to start implementing beginning in Q4 2023.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative.

Telephone 80 30 30 35
Email philips.service@philips.com

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)

Updated: URGENT Field Safety Notice Response Form

Reference: Ingenia Elition X, Ingenia Elition S, SmartPath to Ingenia Elition X, MR 7700 and Upgrade to MR 7700. 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 3 days from receipt. **Philips is requesting that even if you acknowledged a previous version of this letter that you also respond with an acknowledgment to this updated letter.** Completing this form confirms receipt of the updated Urgent Field Safety Notice Letter, 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 Urgent Field Safety Notice Letter.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter 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 via email to FCO.Nordic@philips.com.

Updated Appendix A – Units Affected List

Product number: 781358					Product name: Ingenia Elition X				
45000	45058	45106	45145	45185	45228	45289	45332	45379	45437
45001	45061	45107	45148	45186	45229	45290	45333	45381	45438
45008	45062	45109	45149	45187	45231	45292	45339	45382	45439
45009	45064	45111	45151	45188	45241	45293	45340	45390	45441
45023	45065	45114	45153	45189	45242	45294	45342	45391	45442
45025	45066	45115	45154	45190	45244	45295	45344	45392	45443
45028	45067	45116	45155	45191	45246	45300	45345	45393	45444
45029	45070	45118	45156	45192	45248	45302	45348	45394	45446
45030	45072	45119	45157	45195	45249	45303	45349	45396	45447
45031	45073	45120	45158	45197	45250	45304	45350	45397	45448
45033	45076	45121	45159	45203	45257	45305	45352	45406	45450
45034	45077	45122	45160	45204	45259	45306	45354	45407	45451
45036	45080	45123	45162	45205	45260	45307	45359	45408	45456
45037	45081	45127	45163	45207	45262	45308	45360	45409	45459
45039	45084	45128	45165	45210	45265	45309	45362	45410	45461
45040	45085	45129	45168	45211	45267	45310	45363	45411	45463
45041	45088	45131	45169	45212	45268	45311	45367	45412	45464
45042	45090	45134	45170	45215	45272	45312	45368	45416	45467
45043	45091	45136	45171	45216	45274	45313	45369	45417	45469
45044	45093	45137	45174	45217	45276	45314	45370	45419	45470
45045	45094	45138	45176	45218	45278	45317	45371	45421	45471
45046	45095	45139	45177	45219	45279	45319	45372	45426	45473
45047	45096	45140	45180	45220	45280	45320	45374	45428	45474
45048	45097	45141	45181	45222	45281	45323	45376	45432	45476
45049	45098	45142	45183	45224	45282	45328	45377	45434	45480
45050	45102	45144	45184	45227	45284	45330	45378	45435	45481
45056	45105	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Product number: 782107					Product name: Ingenia Elition X				
45500	45514	45528	45543	45559	45572	45595	62021	62039	62073
45501	45516	45530	45544	45560	45573	45596	62023	62040	62080
45503	45517	45531	45545	45561	45574	45599	62024	62041	62081
45504	45518	45532	45547	45562	45577	45600	62027	62042	62082
45506	45519	45533	45550	45564	45578	62011	62030	62044	62083
45507	45520	45534	45552	45565	45580	62012	62031	62046	62088
45508	45521	45536	45554	45566	45583	62016	62033	62056	62091
45509	45523	45538	45555	45567	45589	62017	62037	62070	62120
45510	45524	45540	45556	45568	45594	62019	62038	62071	62147
45511	45525	45542	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Product number: 782118					Product name: SmartPath to Ingenia Elition X				
42054	42085	42113	42306	42329	71019	71025	85661	N/A	N/A

Product number: 781357					Product name: Ingenia Elition S				
46001	46012	46020	46030	46039	46049	46058	46069	46084	46095
46003	46013	46021	46031	46041	46050	46059	46075	46085	46101
46004	46015	46023	46032	46042	46052	46060	46076	46086	46104
46005	46016	46024	46033	46044	46053	46061	46078	46089	46107
46007	46017	46026	46034	46045	46054	46066	46081	46092	46111
46008	46018	46027	46036	46046	46055	46067	46082	46093	46119
46011	46019	46029	46037	46048	46057	46068	46083	46094	46121

Product number: 782106					Product name: Ingenia Elition S				
46200	46205	46211	46217	46226	46235	46242	46252	46281	46310
46201	46206	46212	46218	46228	46237	46243	46258	46282	46315
46202	46207	46213	46219	46231	46239	46245	46263	46289	46324
46203	46208	46214	46220	46233	46240	46247	46264	46304	61010
46204	46209	46215	46222	46234	46241	46249	46268	46305	61017

Product number: 782120					Product name: MR 7700				
65000	65003	65009	65019	65020	65023	65025	65030	65031	65041
65002	65004	65013	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Product number: 782130					Product name: Upgrade to MR 7700				
45007	45297	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A