

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.

January 20, 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 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

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)
- 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.

2. Hazard/harm associated with the issue

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.

3. Affected products and how to identify them



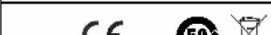
Intended Use:

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:

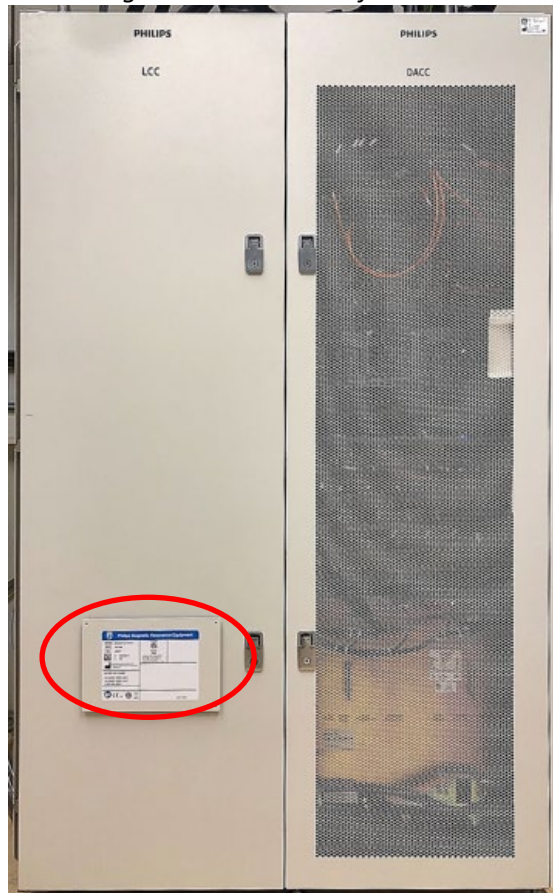
The Affected 3T MR Systems including product number, name and serial number are listed in Appendix A. Figure 1 illustrates the location of the product number, name, and serial number.

Figure 1. Example System Label	Product Name	Model
	Ingenia Elition X	781358 782107 782119 782136
	Ingenia Elition S	781357 782106 782137
<p>RATED VOLTAGE RANGES</p> <p>3N-220/380V, 50/60Hz, 12-86kVA 3N-230/400V, 50/60Hz, 12-86kVA 3-480V, 60Hz, 12-86kVA</p>	SmartPath to Ingenia Elition X	782118 782132 782144
	MR 7700	782120
<p>4598 013 96592</p>	Upgrade to MR 7700	782130

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

1. Enter the Technical Room
2. Locate the CombiCabinet
3. On the front door of the LCC part of the system locate the system label (see figure 2)

Figure 2: Front door of LCC



4. Locate the serial number on the system label (see figure 3)

Figure 3: system label



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

1. Philips has installed a SmokeDetector Interlock feature on 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 customer response form to Philips **promptly** and no later than 30 days from receipt of this letter.
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
 - Immediately inform Philips Service
3. If a user experiences smoke, fire, or severe image quality issues:
 - Immediately stop scanning and remove patient from the system
 - Switch off power to the complete system
 - Remove magnet field by using the Emergency Magnet Off button (EMO)
 - Follow local fire regulations (e.g. evacuation, inform firefighters)
 - Immediately inform Philips Service
4. Ensure all users are aware of facility specific Emergency Procedures as outlined in Section 2: Safety of the Instructions for Use:

5.

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

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

Philips is committed to addressing this issue. Work on a solution to identify affected systems is in process and will be deployed once it has been confirmed. Once deployed, a Philips Field Service Engineer (FSE) will visit your site to complete a test to determine if your system has the defect. If the defect is identified, Philips will replace the Gradient Coil (Reference FCO78100560).

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.

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)

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 30 days from receipt. Completing this form confirms receipt of the 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 Medical Device Correction Letter.

We acknowledge receipt and understanding of the accompanying Urgent Medical Device Correction 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 MR via email to:
PD.CNR@philips.com

**Updated Appendix A –
Units Affected List - as of 20JAN2023**

Elition X									
Product number: 781358					Product name: Ingenia Elition X				
45000	45058	45106	45145	45184	45222	45279	45333	45379	45435
45001	45061	45107	45148	45185	45224	45280	45339	45381	45437
45008	45062	45109	45149	45186	45227	45281	45340	45382	45438
45009	45064	45111	45151	45187	45228	45282	45342	45390	45439
45025	45065	45114	45153	45188	45229	45284	45344	45391	45441
45028	45066	45115	45154	45189	45231	45289	45345	45392	45442
45029	45067	45116	45155	45190	45241	45290	45348	45393	45443
45030	45070	45118	45156	45191	45242	45292	45349	45394	45444
45033	45072	45119	45157	45192	45244	45293	45350	45396	45446
45034	45076	45120	45158	45193	45246	45294	45352	45397	45447
45036	45077	45121	45159	45195	45248	45295	45354	45406	45448
45037	45080	45122	45160	45197	45249	45298	45359	45407	45450
45039	45081	45123	45162	45203	45250	45300	45360	45408	45451
45040	45084	45127	45163	45204	45253	45302	45362	45409	45456
45041	45085	45128	45165	45205	45257	45311	45363	45410	45459
45042	45088	45129	45168	45207	45259	45312	45367	45411	45461
45043	45090	45131	45169	45210	45260	45313	45368	45412	45463
45044	45091	45134	45170	45211	45262	45314	45369	45416	45464
45045	45093	45136	45171	45212	45265	45317	45370	45417	45467
45046	45094	45137	45174	45215	45267	45319	45371	45419	45469
45047	45095	45138	45176	45216	45268	45320	45372	45421	45471
45048	45096	45139	45177	45217	45272	45323	45374	45426	45473
45049	45097	45140	45180	45218	45274	45328	45376	45428	45474
45050	45098	45141	45181	45219	45276	45330	45377	45432	45476
45052	45102	45142	45183	45220	45278	45332	45378	45434	45480
45056	45105	45144	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Elition X									
Product number: 782107					Product name: Ingenia Elition X				
45500	45510	45521	45533	45545	45559	45568	45589	62017	62031
45501	45511	45523	45534	45546	45560	45572	45594	62019	62033
45503	45514	45524	45536	45547	45561	45573	45595	62021	62038
45504	45516	45525	45538	45550	45562	45574	45596	62023	62039
45506	45517	45528	45540	45552	45564	45577	45600	62024	62040
45507	45518	45530	45542	45554	45565	45578	62011	62027	62073
45508	45519	45531	45543	45555	45566	45580	62012	62030	62080
45509	45520	45532	45544	45556	45567	45583	62016	N/A	N/A

Upgrade to Elition X systems									
Product number: 782118					Product name: SmartPath to Ingenia Elition X				
42054	42085	42113	42306	42329	71019	71025	71050	71535	N/A

Elition S									
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

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

MR 7700									
Product number: 782120					Product name: MR 7700				
65000	65002	65003	65004	65009	65019	65020	N/A	N/A	N/A

MR 7700									
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