

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.

November 22, 2022

This document is address two populations:

- **If the serial number for your device is listed in Appendix A: Please immediately stop use of your impacted MR system (see also section 4 Actions to be taken by customer).**
- **If the serial number for your device is listed in Appendix B: this letter contains important information for the continued safe and proper use of your equipment (see also section 4 Actions to be taken by customer).**

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.

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 where 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

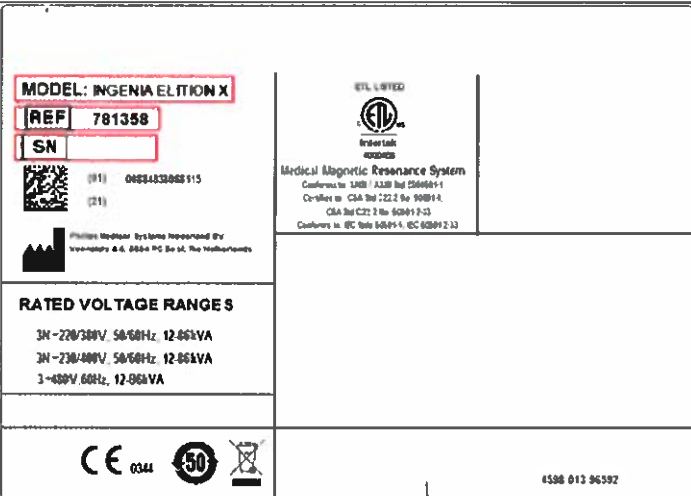
Intended Use:

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:

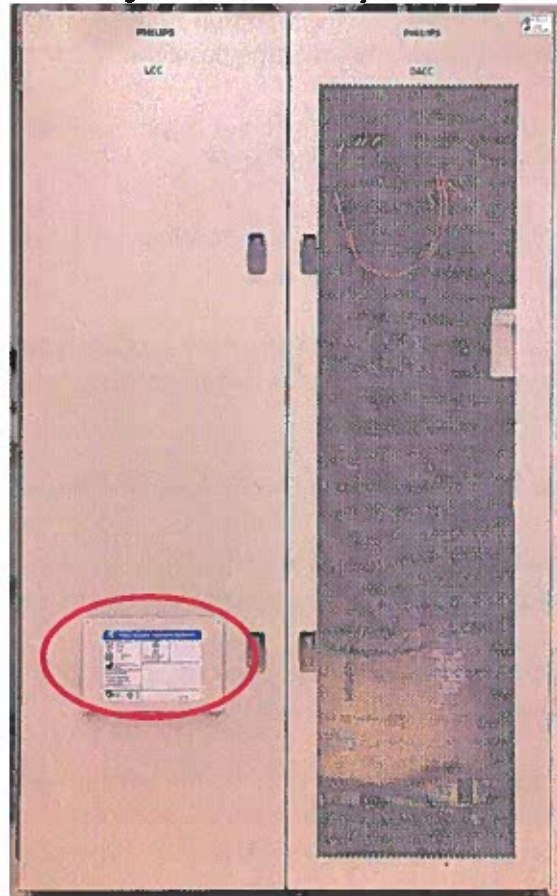
The Affected 3T MR Systems including product number, name and serial number are listed in Appendix A and/or Appendix B. Figure 1 illustrates the location of the product number, name, and serial number.

Figure 1. Example System Label		Product Name	Model
 <p>MODEL: INGENIA ELITION X REF: 781358 SN: [redacted]</p> <p>Philips Medical Systems Incorporated 3800 Central Expressway Redwood City, CA 94063-1000</p> <p>RATED VOLTAGE RANGES 3M - 220/380V, 50/60Hz, 12-06kVA 3M - 230/400V, 50/60Hz, 12-06kVA 3 - 400V, 60Hz, 12-06kVA</p> <p>CE 0344 50</p> <p>4598 012 96392</p>		Ingenia Elition X	781358 782107 782119 782136
		Ingenia Elition S	781357 782106 782137
		SmartPath to Ingenia Elition X	782118 782132 782144
		MR 7700	782120
		Upgrade to MR 7700	782130

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

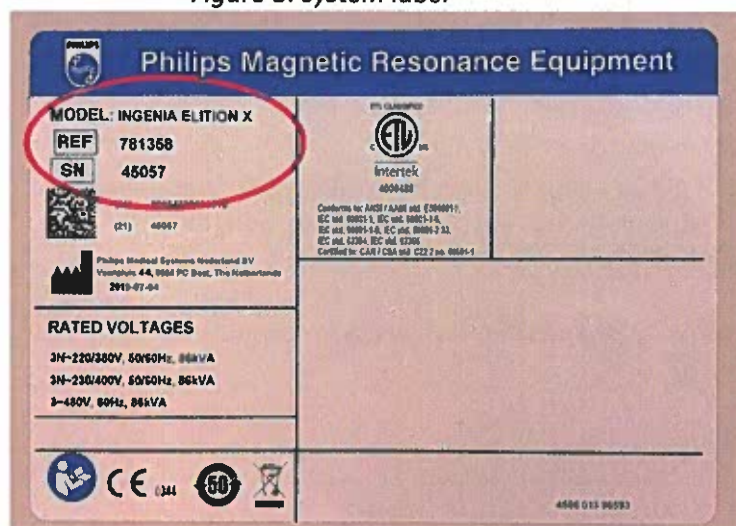
1. Enter the Technical Room
2. Locate the CombiCabinet
3. On the front door of the LCC part of the system locate the system label (see figure 2)

Figure 2: Front door of LCC



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

Figure 3: system label



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

1. Systems that do not yet have the SmokeDetector Interlock feature installed are identified in **Appendix A**. **If your system is listed in Appendix A immediately discontinue use of your impacted MR system(s) until Philips has installed the SmokeDetector Interlock.**
 - Post a “Do not use” notice on or near the impacted MR system(s)
 - 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.
 - **Note:** Once your system has the SmokeDetector Interlock installed, please follow the advice in steps 2 through 5.
2. Philips has installed a SmokeDetector Interlock feature on the systems listed in **Appendix B**. **Immediately confirm if your system has the SmokeDetector Interlock installed by confirming your serial number is listed in Appendix B.**
- 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.
3. 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
4. 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
5. Ensure all users are aware of facility specific Emergency Procedures as outlined in Section 2: Safety of 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.

6. Actions planned by Philips to correct the problem

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



If your system has not yet been equipped with the SmokeDetector Interlock, Philips will contact you by November 29, 2022 to schedule installation (Reference FCO78100529).

Philips is committed to addressing the issue and continues to investigate this issue. We will provide regular updates to you on the development of our plan to address the issue. The first update will be provided no later than January 20, 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. <Customer Service contact information will be added by country representative>

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

A handwritten signature in blue ink that reads "David Hanly" followed by the date "22nd Nov 2022".

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 (and a "Do not use" notice, if applicable) near the affected MR unit(s) for ease of reference. Please confirm by checking the appropriate box below that you have completed the actions requested:

<input type="checkbox"/>	I confirm that for my affected system(s) listed in Appendix A have been removed from clinical use and we have posted the customer letter and a do not use notice on or near the impacted MR system(s).
<input type="checkbox"/>	I confirm that for my affected system(s) listed in Appendix B we have posted the customer letter on or near the impacted MR system(s).

- 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 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

**Appendix A –
Units Affected List - Devices without SmokeDetector Interlock Installed as of 20-Nov-2022**

Elition X									
Product number: 781358					Product name: Ingenia Elition X				
45000	45045	45107	45129	45159	45187	45218	45289	45307	45317
45008	45052	45109	45134	45177	45190	45227	45292	45308	45350
45009	45065	45111	45137	45180	45193	45246	45303	45309	45379
45036	45085	45121	45142	45181	45207	45253	45304	45310	45392
45040	45088	45127	45145	45183	45215	45257	45305	45311	45407
45043	45096	45128	45154	45184	45217	45259	45306	45312	45408
45044	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Elition X									
Product number: 782107					Product name: Ingenia Elition X				
45506	45509	45520	45525	45543	45546	45554	N/A	N/A	N/A

Elition S									
Product number: 781357					Product name: Ingenia Elition S				
46001	46012	46031	46049	46052	46061	46093	46094	46101	46119
46008	46029	46045	46050	46060	46086	N/A	N/A	N/A	N/A

Elition S									
Product number: 782106					Product name: Ingenia Elition S				
46200	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

**Appendix B –
Units Affected List - Devices with SmokeDetector Interlock Installed as of 20-Nov-2022**

Elition X									
Product number: 781358					Product name: Ingenia Elition X				
45001	45064	45106	45155	45195	45249	45300	45359	45396	45442
45025	45066	45114	45156	45197	45250	45302	45360	45397	45443
45028	45067	45115	45157	45203	45260	45313	45362	45406	45444
45029	45070	45116	45158	45204	45262	45314	45363	45409	45446
45030	45071	45118	45160	45205	45265	45319	45367	45410	45447
45031	45072	45119	45162	45210	45267	45320	45368	45411	45448
45033	45076	45120	45163	45211	45268	45323	45369	45412	45450
45034	45077	45122	45165	45212	45272	45328	45370	45416	45451
45037	45079	45123	45168	45216	45274	45330	45371	45417	45456
45039	45080	45131	45169	45219	45276	45332	45372	45419	45459
45041	45081	45136	45170	45220	45278	45333	45374	45421	45461
45042	45084	45138	45171	45222	45279	45339	45376	45426	45463
45046	45090	45139	45174	45224	45280	45340	45377	45428	45464
45047	45091	45140	45176	45228	45281	45342	45378	45432	45467
45048	45093	45141	45185	45229	45282	45344	45381	45434	45469
45049	45094	45144	45186	45231	45284	45345	45382	45435	45471
45050	45095	45148	45188	45241	45290	45348	45390	45437	45473
45056	45097	45149	45189	45242	45293	45349	45391	45438	45476
45058	45098	45151	45191	45244	45294	45352	45393	45439	45474
45061	45102	45153	45192	45248	45295	45354	45394	45441	45480
45062	45105	N/A	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	45514	45524	45536	45550	45562	45573	45594	62017	62031
45501	45516	45528	45538	45552	45564	45574	45595	62019	62033
45503	45517	45530	45540	45555	45565	45577	45596	62021	62038
45504	45518	45531	45542	45556	45566	45578	45600	62023	62039
45507	45519	45532	45544	45559	45567	45580	62011	62024	62040
45508	45521	45533	45545	45560	45568	45583	62012	62027	62073
45510	45523	45534	45547	45561	45572	45589	62016	62030	62080
45511	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Elition S									
Product number: 781357					Product name: Ingenia Elition S				
46003	46015	46021	46032	46041	46053	46059	46075	46083	46095
46004	46016	46023	46033	46042	46054	46066	46076	46084	46104
46005	46017	46024	46034	46044	46055	46067	46078	46085	46107
46007	46018	46026	46036	46046	46057	46068	46081	46089	46111
46011	46019	46027	46037	46048	46058	46069	46082	46092	46121
46013	46020	46030	46039	N/A	N/A	N/A	N/A	N/A	N/A

Elition S									
Product number: 782106					Product name: Ingenia Elition S				
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	46222	46233	46239	46245	46258	46281	61017
46205	46211	46217	N/A	N/A	N/A	N/A	N/A	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	71052	71535	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

