

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


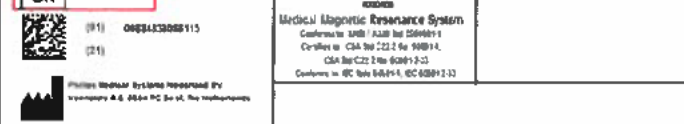



Intended Use:

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:

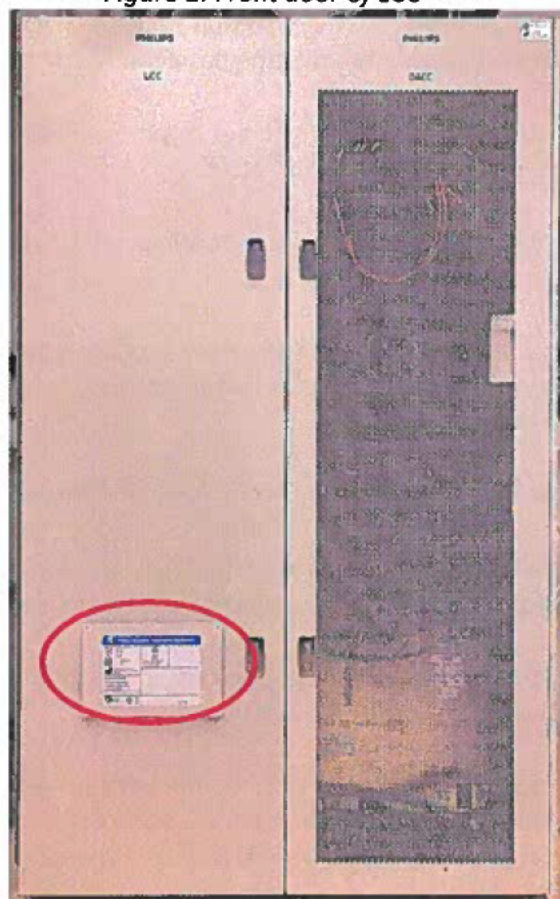
The Affected 3T MR Systems including product number, name and serial number are listed in Appendix A and/or Appendix B. Figure 1 illustrates the location of the product number, name, and serial number.

| Figure 1. Example System Label | Product Name | Model |
|---|--------------------------------|--------------------------------------|
|  | 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:

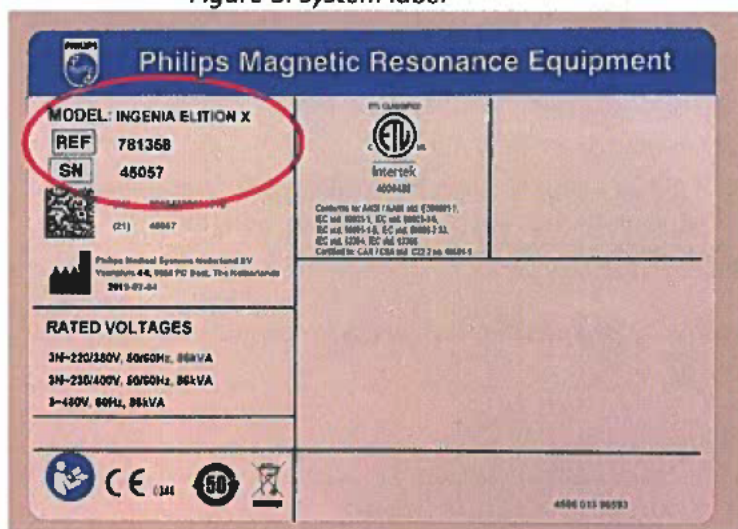
1. Enter the Technical Room
2. Locate the CombiCabinet
3. On the front door of the LCC part of the system locate the system label (see figure 2)

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.

PHILIPS

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).

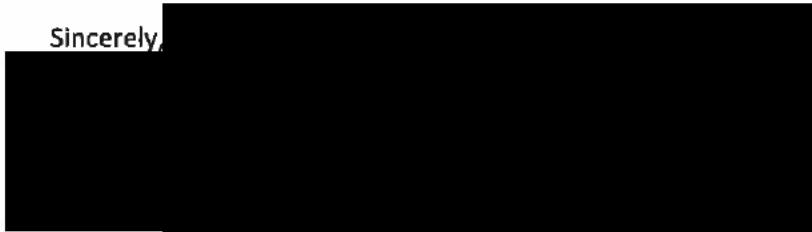
Philips is committed to addressing the issue and continues to investigate this issue. We will provide regular updates to you on the development of our plan to address the issue. The first update will be provided no later than January 20, 2023.

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,



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 |

