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URGENT Field Safety Notice

Panorama 1.0T HFO, All Serial Numbers

Potential for serious injury resulting from structural integrity failure following a magnet quench

17-NOV-2023

Please immediately stop use of your impacted MR system
(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.

Please retain this letter for your records.

Dear Customer,

Philips has become aware of a potential issue with Panorama 1.0T HFO 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 been informed of an event in which the structural integrity of the Panorama 1.0T HFO system components failed due to unintended excessive pressure buildup of helium gas during a magnet quench.

   During a quench, a large amount of helium evaporates and is vented outside the building through a venting system. If an unknown blockage is present in the venting system and the pressure exceeds design limits, the structural integrity of the system may be compromised. The magnet may experience an unsolicited quench during normal use or will quench when initiated in an emergency situation by the operator pressing the Magnet EMERGENCY STOP button.

   Philips has received one (1) complaint of system and property damage after quenching the magnet on Panorama 1.0T systems as of November 2023. There was no report of injury or serious harm.

2. **Hazard/harm associated with the issue**

   If the system is unable to contain the pressured helium gas due to an unforeseen blockage in the system the following are risks to patients and/or operators that may lead to injury or death:
   - Chemical exposure (i.e. helium gas); may expand to surrounding rooms
   - Asphyxia
   - Barotrauma
   - Mechanical trauma caused by debris, for example:
     - Traumatic brain injury
     - Laceration
     - Fracture
     - Eye injury
     - Contusion

   This issue could also lead to system and/or property damage.

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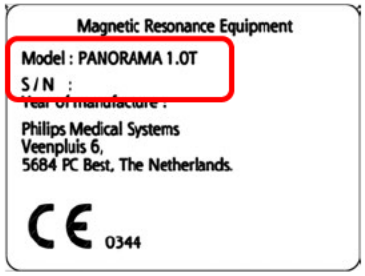
3. Affected products and how to identify them

Identification of Impacted Systems:
The affected Panorama 1.0T HFO systems including product number, name and serial number are listed in Appendix A. Figure 1 illustrates the location of the product name and serial number.

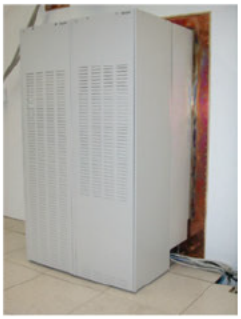
Figure 1. Example System Label	Product Name	Model
	Panorama 1.0T HFO	781250 781350

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) (see Figure 2) or the Filter Control Cabinet (FCC) (see Figure 3)
3.3. The system label is located on the front door of the gMDU or on side panel of the FCC.
3.4. Locate the serial number on the system identification label.

Figure 2. General Mains Distribution Unit

Figure 3. Filter Control Cabinet



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.

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

- **If your system is listed in Appendix A immediately discontinue use of your impacted MR system(s).**
- DO NOT initiate manual quench of the magnet, unless there is an emergency
- Post a "Do not use" notice on or near the impacted MR system(s)

- Post this notice near the affected Panorama 1.0T HFO 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 30 days from receipt of this letter.

5. Actions planned by Philips to correct the problem

Philips is requesting that customers immediately stop using the MR systems until an inspection can be completed.

Philips will contact you to schedule time for a Field Service Engineer (FSE) to visit your site to inspect your system starting in December 2023. (Reference FCO78100572)

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.

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Appendix A

781250 Panorama 1.0T									
19002	19004	19006	19013	19015	19017	19022	19025	19026	19029
19030	19033	19037	19040	19042	19043	19044	19052	19059	19067
19069	19070	19071	19073	19076	19078	19080	19081	19082	19083
19084	19090	19096	19097	19098	19100	19101	19109	19112	19113
19114	19115	19120	19121	19122	19127	19131	19132	19137	19138
19139	19140	19143	19146	19155	19157	19158	19159	19160	19161
19163	19167	19168	19175	19176	19179	19183	19187	19192	19197
19202	19205	19206	19215	19221	19222	19224	19225	19227	19228
19229	19232	19233	19240	19243	19245	19246	19247	19249	19251
19255	19256	19258	19260	19261	19267	19277	19278	19281	N/A

781350 Panorama 1.0T									
37009	37010	37011	37013	37015	37016	37019	37020	37022	37023
37024	37026	37027	37030	37031	37032	37034	37036	37044	37050
37055	37058	37060	37064	37066	37067	37068	37069	37070	37071
37073	37075	37080	37081	37082	37085	37088	37089	37093	37096
37097	37098	37100	37105	37106	37109	37116	37119	37121	37122
37124	37126	37127	37129	37132	37133	37134	37135	37137	37138
37139	37140	37141	37143	37145	37146	37147	37149	37150	37153
37154	37156	37157	37160	37161	37162	37167	37170	37171	37173
37174	37175	37176	37177	37178	37180	37181	37182	37183	37184
37185	37187	37188	37192	37193	37194	37195	37196	37197	N/A

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URGENT Field Safety Notice Response Form

Reference: Panorama 1.0T HFO System: Potential for serious injury resulting from structural integrity failure following a magnet quench

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 Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

_____

Customer Actions:
Follow the instructions provided in Section 4 of the Field Safety Notice Letter.

We acknowledge receipt and understanding of the accompanying Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please complete and return the response form to Philips promptly and no later than 30 days from receipt via email to: pd.cnr@philips.com.