

## **URGENT Field Safety Notice**

**Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 3.0T, Ingenia Elition X Magnetic Resonance System**

Wrong psi relief valve (42 psi instead of 3.75 psi)

**This document contains important information for the continued safe and proper use of your equipment**

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.

14-JUL-2021

Dear Customer,

A problem has been identified in the Philips Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 3.0T, and Ingenia Elition X Magnetic Resonance (MR) systems, that could pose a risk for patients or users. This URGENT Field Safety Notice letter is intended to inform you about:

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

Philips has detected an issue with a pressure relief valve in the magnet assembly where a 42 psi pressure relief valve was installed, instead of a 3.75 psi valve. The relief valve is used for controlling the pressure of helium when the magnet is not attached to a working cryo-system and is off-cooling. In a system where a 3.75 psi valve is installed the helium pressure can be released as intended.

In a system where a 42 psi valve has been installed the helium pressure would not be released until the pressure reaches 42 psi. However, all MR systems in the scope of this notification have a secondary pressure relief valve at 5 psi which alleviates high pressure release of helium gas, releasing instead a moderate amount of helium gas.

No customer complaints were reported related to this issue as of July 2021.

### **2. Describe the hazard/harm associated with the issue**

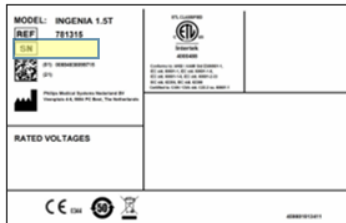
It is unlikely that the sequence of events leading to system off-cooling and release of a moderate amount of helium gas occurs, however if this issue does occur, it may lead to the following harms:

If a patient, operator or service engineer is adjacent to the system during off-cooling skin burns or cold burns of eyes may occur.

If the moderate release of helium depletes the oxygen in the room and the exposure is for an extended period of time, a patient, operator or service engineer may experience asphyxia.

### 3. Affected products and how to identify them

The systems with a potentially affected 42 psi relief valve are listed in Appendix A, below, with System S/N (Serial Number) and UDI (Unique Device Identifier). To determine whether your system is affected, please check your MR System label.



**Figure 1. System Label**

Product Name	Product Number
Ingenia 1.5T	781341
Ingenia 3.0T	781342
Ingenia 1.5T Evolution	781315
Ingenia Elition X	781358

**Table 1. Affected Products**

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

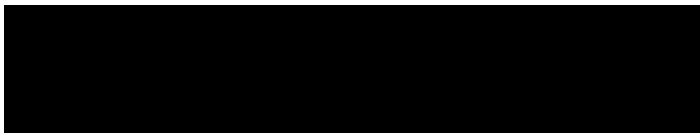
The Philips Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 3.0T, and Ingenia Elition X MR systems can continue to fulfill clinical use as normal. However, in case of technical problems related to off-cooling of the magnet, magnet pressure or Helium boil-off, please stop use and contact your local Philips service representative immediately and reference FCO78100530.

### 5. Describe the actions planned by Philips MR to correct the problem

A Philips Field Service Engineer (FSE) will contact you to schedule an on-site visit to resolve the issue by inspecting the potentially affected system(s) to confirm if the non-conforming pressure relief (42 psi) has been installed (reference FCO78100530). If your system has a 42 psi valve, the Phillips FSE will replace the valve with the correct 3.75 psi valve.

This notice has been reported to the appropriate Regulatory Agencies.

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 the Customer Care Solutions Center 1-800-722-9377 and reference FCO78100530.



## Appendix A – Units Affected List (RoW)

System Code	Serial Number	Unique Device Identifier (UDI#)
781271	78189	(01)00884838068452
781271	78272	(01)00884838068452
781271	78294	(01)00884838068452
781271	78295	(01)00884838068452
781271	78332	(01)00884838068452
781271	78335	(01)00884838068452
781271	78340	(01)00884838068452
781271	78345	(01)00884838068452
781271	78249	(01)00884838068452
781271	78324	(01)00884838068452
781271	78326	(01)00884838068452
781277	34264	N/A
781315	61028	(01)00884838099715
781315	61008	(01)00884838099715
781315	61025	(01)00884838099715
781315	61026	(01)00884838099715
781315	61034	(01)00884838099715
781315	61035	(01)00884838099715
781315	61042	(01)00884838099715
781315	61046	(01)00884838099715
781315	61040	(01)00884838099715
781315	61041	(01)00884838099715
781315	61018	(01)00884838099715
781315	61017	(01)00884838099715
781315	61032	(01)00884838099715
781315	61043	(01)00884838099715
781315	61033	(01)00884838099715
781315	61064	(01)00884838099715
781341	87171	(01)00884838055322
781341	84943	(01)00884838055322
781341	87142	(01)00884838055322
781341	87249	(01)00884838055322
781341	87252	(01)00884838055322
781341	87195	(01)00884838055322
781341	87129	(01)00884838055322
781341	87136	(01)00884838055322
781341	87175	(01)00884838055322
781341	87196	(01)00884838055322
781341	87197	(01)00884838055322
781341	87235	(01)00884838055322
781341	87187	(01)00884838055322
781341	87212	(01)00884838055322
781341	84572	(01)00884838055322
781341	87116	(01)00884838055322
781341	87152	(01)00884838055322
781341	87161	(01)00884838055322
781341	87237	(01)00884838055322
781341	87244	(01)00884838055322
781341	87090	(01)00884838055322
781341	87093	(01)00884838055322
781341	87259	(01)00884838055322
781341	87209	(01)00884838055322
781342	85393	(01)00884838055339
781342	85332	(01)00884838055339
781342	85334	(01)00884838055339
781342	85336	(01)00884838055339
781342	85349	(01)00884838055339
781342	85350	(01)00884838055339
781342	85355	(01)00884838055339
781342	85370	(01)00884838055339
781342	85371	(01)00884838055339

System Code	Serial Number	Unique Device Identifier (UDI#)
781342	85382	(01)00884838055339
781342	85384	(01)00884838055339
781342	85385	(01)00884838055339
781342	85398	(01)00884838055339
781342	85348	(01)00884838055339
781342	85149	(01)00884838055339
781342	85367	(01)00884838055339
781342	85388	(01)00884838055339
781357	46083	(01)00884838088108
781357	46084	(01)00884838088108
781357	46086	(01)00884838088108
781357	46061	(01)00884838088108
781357	46054	(01)00884838088108
781357	46058	(01)00884838088108
781357	46082	(01)00884838088108
781358	45215	(01)00884838088115
781358	45284	(01)00884838088115
781358	45253	(01)00884838088115
781358	45313	(01)00884838088115
781358	45265	(01)00884838088115
781358	45297	(01)00884838088115
781358	45218	(01)00884838088115
781358	45272	(01)00884838088115
781358	45281	(01)00884838088115
781358	45231	(01)00884838088115
781358	45278	(01)00884838088115
781358	45279	(01)00884838088115

**URGENT FIELD SAFETY NOTICE  
RESPONSE FORM****Reference:**

Wrong psi relief valve (42 psi instead of 3.75 psi) in Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 3.0T, and Ingenia Elition X systems (FCO78100530).

**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:**

The Philips Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 3.0T, and Ingenia Elition X MR systems can continue to fulfill clinical use as normal. However, in case of technical problems related to off-cooling of the magnet, magnet pressure or Helium boil-off please stop use and contact your local Philips service representative immediately and reference FCO78100530.

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 Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 3.0T, and Ingenia Elition X systems.

**Name of person completing this form:**

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Date  
(DD/MM/YYYY): \_\_\_\_\_

Please email completed form to: [<email: to be completed by the Market>](#)