

**URGENT – Medical Device Correction
Ingenia 1.5T and Ingenia 3.0T**

Reported Skin Reddening During Scanning of Large Patients

Dear Customer,

A problem has been detected with Philips Ingenia 1.5T and Ingenia 3.0T MR systems (Software Release 4.1.1) that during scanning some reddening of the skin of the patient may occur in certain instances due to RF heating when the torso is positioned within the body coil. This may only affect a small group of large patients (>106kg/234lbs).

This Field Safety Notice is intended to inform you about:


- The problem and the circumstances under which it can occur
- The actions that should be taken by the customer / user in order to prevent risks for patients and users
- The actions planned by Philips Healthcare to correct the problem.

Philips has revised the system software to address the problem. To prevent the above stated problem from occurring, a software upgrade will be installed within 30 days on your system by a Philips field service engineer.

If you need any further information or clarification, please contact your local Philips field service representative:

<Philips representative contact details to be completed by the KM / country>

Sincerely,


Senior Director Quality & Regulatory Affairs
Magnetic Resonance Imaging Systems
Philips Healthcare



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AFFECTED PRODUCTS	Ingenia 1.5T and 3.0T Systems on Software Release 4.1.1
PROBLEM DESCRIPTION	Skin reddening during scanning observed in population of large patients (>106kg/234lbs) when the torso is positioned within the body coil during scanning.
HAZARD INVOLVED	Patient heating with skin reddening and discomfort
HOW TO IDENTIFY AFFECTED PRODUCTS	All Ingenia 1.5T and 3.0T Systems
ACTION TO BE TAKEN BY CUSTOMER / USER	Read the Application Notes 4.1.1 SP1. Ensure that patient weight is entered correctly during scan set-up. The system software uses patient weight in calculation of the SAR.
ACTIONS PLANNED BY PHILIPS	To prevent the above stated problem from occurring, Philips has revised the system software and added an 'Ultra Low' SAR mode, which allows the user to operate the system at a lower SAR level. A corresponding software upgrade will be installed on all Ingenia systems by a Philips field service engineer.
FURTHER INFORMATION AND SUPPORT	If you need any further information or clarification, please contact your local Philips field service representative: <Philips representative contact details to be completed by the KM / country>

