# SIEMENS

#### Healthcare

Contact person of The Regional Unit Department

Telephone Fax Mobil E-Mail Date

### Safety Advisory Notice

To users of the SIEMENS Ysio Systems

Contact person of Volker Biermann

the Business Unit

H CP XP MK RFU

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Date

2014-04-25

Re: Ysio systems

Possible unintended release of X-Ray due to liquid infiltration into generator console

Dear Customer.

This letter is to inform you about a potential issue and a possible hazard to persons due to excessive usage of liquids for cleaning the Ysio Control Room Module.

# When does this malfunction occur and what are the potential risks?

Due to excessive usage of liquid for cleaning, it has been reported that some liquid may infiltrate the generator console cause a short circuit which may lead to an unintended release of radiation. To date, one customer has reported this occurrence.

Attention needs to be taken to the recommended procedure for cleaning the system detailed in the user manual of the system. Inobservance of the relevant caution notice in the user manual may lead to unintended release of x-ray.

## What steps can the user take to avoid the potential risk of this issue?

Until the modification is available, please follow strictly the recommended procedure detailed in the user manual to avoid liquid infiltration into generator console:

- Do not let cleaning liquids seep into the openings of the system (e.g. air openings, gaps between covers)
- Wipe system parts with a damp cloth (squeeze out wet cloth before using it)
- Remove any watery residues immediately

Siemens AG

Healthcare Sector; Leitung: Hermann Requardt Clinical Products Division; Leitung: Britta Fuenfstueck X-Ray Products; Leitung: Andre Hartung

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## How will the issue finally be resolved?

Siemens has prepared a modification that will resolve this potential issue by preventively sealing the generator consoles of the Ysio Systems against infiltration of liquid. The field modification will be available in the second quarter of 2014 and is expected to be completed in all systems in the field in the fourth quarter of 2014.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is placed in the system's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

The relevant National Competent Authority has been informed of this notice.

Sincerely Yours

2014-04-25

CEO H CP XP

Jürgen Backow H CP XP QM

# Acknowledgement of receipt

Customer address:
I hereby confirm as the owner / responsible operator of the product name with the Serial number (optional) that I received the following document:
Safety Advisory Notice
Ysio systems Possible unintended release of X-Ray due to liquid infiltration into generator console
Place, Date
Name
Signature