

<To the person in charge of the unit where the SIEMENS product is operated, and the administrative head of organization>

Contact person of  
the Regional Unit  
Department

Telephone  
Fax  
E-Mail

Date

### Field Safety Notice

To all users of the SIEMENS Mobilett Mira

Contact person of  
the Business Unit  
Department

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Date

20.09.2012

### **Mobilett Mira: risk of lost images during examination**

Dear customer,

This letter is to inform you of a potential hazard to patients when using the Mobilett Mira.

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

When the imaging system of Mobilett Mira (i.e. the computer with touch screen) is running for a long period of time without interruption, it might occur in rare cases that images are not stored correctly despite the fact that X-ray was released. In this case the imaging system would have to be restarted and the examination would have to be repeated, leading to increased examination time and additional radiation dose for the patient.

#### **What steps can the user take to avoid the potential risk?**

- As the probability of the described problem increases over time, the operator(s) should make sure that the imaging system of Mobilett Mira is shut down or restarted whenever Mira is not being used, but latest after 10 hours of continuous uptime. This is performed by switching off the Mobilett Mira with the key.
- On request, a service technician from Siemens can deactivate the software component which causes the error. This makes the previous advice to frequently restart the system unnecessary, but will result

#### **Siemens AG**

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Siemens Aktiengesellschaft: Chairman of the Supervisory Board: Gerhard Cromme;  
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Joe Kaeser, Barbara Kux, Hermann Requardt, Siegfried Russwurm, Peter Y. Solmssen, Michael Suess  
Registered offices: Berlin and Munich, Germany; Commercial registries: Berlin Charlottenburg, HRB 12300, Munich, HRB 6684  
WEEE-Reg.-No. DE 23691322

in a slightly impaired functionality (no display of WLAN connectivity in the status bar of the imaging system).

**How will the issue finally be resolved ?**

Siemens is preparing a modification of Mobilett Mira which will resolve this potential malfunction permanently. The field modification (Update Instruction XP054/12/S) will be released in October 2012, and your system will be updated free of charge by a Siemens Service technician.

We ask you to immediately instruct your personnel accordingly. Please ensure that this field safety notice is placed in the System's instructions for use. Your personnel should maintain awareness until the final solution is available.

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

We apologize for the issue and any inconvenience it might have caused.

Sincerely Yours

Siemens Aktiengesellschaft

20.09.2012



Andre Hartung  
CEO  
Siemens AG Healthcare  
X-ray Products



Jürgen Buckow  
Head of Quality Management  
Siemens AG Healthcare  
X-ray Products

### Acknowledgement of receipt

Customer address:

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I hereby confirm as the owner / responsible operator of the Mobilett Mira with the Serial number \_\_\_\_\_ (optional) that I received the following document:

#### **Field Safety Notice**

**Mobilett Mira: risk of lost images during examination**

Place, Date \_\_\_\_\_

Name \_\_\_\_\_

Signature \_\_\_\_\_