

Customer
Hospital
City
Postal code
Country
Attn.: XXX

URGENT Field Safety Notice

TCM5 monitor

Dear Customer

This communication replaces any previous communication that you may have received relating to this issue. Please discard previous communication.

Background

Radiometer has become aware of an issue with the TCM5 monitor.

The issue is that the TCM5 application in monitors with software versions 1.5.0 and 1.5.0.1 may freeze and not update the display with new values or send new values to a central monitoring system. This means that the last measured values remain displayed unchanged on the TCM5 screen and in a central monitoring system and may not reflect patient status.

The countermeasure is to install an unaffected software version.

Radiometer requests that you immediately stop using the affected product, as detailed below. Once the unaffected software version has been installed, the monitor may be taken into use again.

Affected product

All TCM5 monitors with software versions 1.5.0 or 1.5.0.1 are affected. However, it has been assessed that if used in sleep studies, non-critical patients will not experience harm.

For EU Countries only the following is to be included in the translated letter:

EU Basic UDI-DI: 57006900001MB

(UDI = Unique Device Identifier – DI = Device Identifier)

Risk for the patient

The described error has a risk of leading to serious adverse health consequences for the patient. The described error may, in a reasonably foreseeable worst-case scenario, cause a delayed measurement of pCO₂ in a critically ill patient with unknown severe or life-threatening hypercapnia. This may lead to delayed necessary change of patient management

in a patient with unknown severe or life-threatening hypercapnia, which may put the patient at risk of experiencing respiratory failure, coma, or death.

Your actions

Radiometer kindly requests you to:

- Immediately stop using the affected product, as detailed above, until the unaffected software is installed.
- Complete the Recall Response Form (on the last page of this letter) and return it to your Radiometer representative within one week of receiving it.
- For TCM5 monitors used in sleep studies only:
 - If the application freezes, switch the monitor off and then on again to restart the application.

Solution provided by Radiometer

Radiometer will contact you to schedule a visit to install an unaffected software version.

Your help is appreciated

If you are not the end-user of the affected product, please ensure that this letter is distributed to the final end-user.

If you have any questions, please contact your Radiometer representative.

Radiometer sincerely apologizes for the inconvenience this situation may cause you.

Best regards,

<State Radiometer distributor name>

Recall Response Form

Concerning:

TCM5 monitor

- I have received the customer advisory letter and can confirm that we have ceased using the affected TCM5 monitor(s) until the unaffected software is installed. The affected products are all TCM5 monitors with software versions 1.5.0 or 1.5.0.1. However, it has been assessed that if used in sleep studies, non-critical patients will not experience harm.

- I have no TCM5 monitors with software versions 1.5.0 or 1.5.0.1 in my institute.

Hospital Name:	
Your Name:	
Date:	
Signature:	
Email Address:	