

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Urgent Field Safety Notice:
TCM5 FLEX/BASIC used with ECG and EEG monitor

Dear Customer

This is a follow-up on previous communication, January 2018.

Radiometer has now introduced revised versions of the instructions for use including a separate paragraph relating to “Electromagnetic interference” under Limitations of use. The new paragraph is given overleaf.

Affected product:

TCM5 FLEX/BASIC monitor – all serial numbers.

What you must do:

You are kindly requested to:

1. Ensure that copies of previous revisions of instructions for use are discarded and replaced by the new ones.
2. Once the above has been done please complete the Recall Response Fax Form (last page of this letter) and submit to your Radiometer representative.

Final solution provided by Radiometer:

Radiometer is working on a solution, which involves a hardware redesign of the TCM5 monitoring system, for this issue. You will be contacted by your Radiometer representative when the final solution is available.

Please Note:

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.

Best regards,
<Radiometer distributor>

New paragraph in revised instructions for use:

Electromagnetic interference

⚠ WARNING – Risk of interference

Instruments sensitive to electromagnetic interference may be affected by TCM5 measurements. A list of devices that may be affected by interference from the TCM5 monitoring system can be seen in the table below. If the below-mentioned options in *To reduce or remove electromagnetic interference* are not possible, do not use both the TCM5 monitoring system and such sensitive instruments simultaneously on the same patient.

Abbreviation	Device
ECG	Electrocardiography
EEG	Electroencephalography
EMG	Electromyogram
MMG	Mechanomyogram
EOG	Electrooculography
GSR	Galvanic Skin Response
MEG	Magnetoencephalogram
ICG	Impedance Cardiography

Note: Some instruments offer means against electromagnetic interference. Please refer to the manufacturer and/or manufacturer's documentation.

To reduce or remove electromagnetic interference

1. Choose one of the options listed in order of priority below:

Option	Description
1.	Connect the TCM5 monitoring system to a grounded Ethernet network using a shielded Ethernet cable. Please contact your Radiometer representative if this option is selected. Radiometer will assist in verifying that your Ethernet network is indeed grounded and in selecting types of Ethernet cables verified by Radiometer.
2. If a grounded Ethernet network is not available, option 2 may be selected.	Disconnect the TCM5 monitoring system from the mains supply and run it on battery power only. You can use the monitor for up to 4 hours with a fully charged battery.
3. If you need to measure continuously for more than 4 hours, option 3 may be selected.	If an alternative monitoring system is available, consider using that one while waiting for the final solution from Radiometer. Your Radiometer representative may make a TC loaner device available.

Recall Response Fax Form

Fax No.:

Concerning:

TCM5 FLEX/BASIC used with ECG and EEG monitor

- I have received the customer advisory letter and the required quantity of revised instructions for use. Further, I have performed the following action:
 - All copies of previous revisions of the instructions for use have been collected, discarded and replaced by the new revision just received.

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