

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 earlier this year.

Radiometer has recently received reports of occurrences of the TCM5 causing interferences on ECG and EEG monitors.

Radiometer acknowledges that there is a possibility that TCM5 FLEX/BASIC can cause interferences to ECG or EEG measurements, however, only when applied on the same patient.

For this reason the current instructions for use include the following warning:

⚠ WARNING – Risk of interference

Other instruments sensitive to electromagnetic interference may be affected by the TC measurement. If this is the case, contact authorized service personnel.

Risk for the patient

In a worst-case scenario, the described error may result in insufficient or no treatment for a critically low heart rate or critical arrhythmias.

The reason is that the described effect may potentially lead to:

- Incorrect measurement results by 3rd party devices, such as an ECG and EEG monitor, due to interference by the TCM5 FLEX/BASIC monitor. These incorrect measurement results may potentially lead to incorrect treatment or incorrect management of the patient.

In an absolutely worst-case scenario, where the actual heart rate of the patient is critically low, or the patient is experiencing critical arrhythmias, this may not be discovered due to the described interference.

Affected product:

TCM5 FLEX/BASIC monitor – all serial numbers.

Please note that there is no risk of interference in case you only perform measurements using the TCM5 FLEX/BASIC and never combine this measurement with an ECG or EEG measurement.

What you must do:

If you combine the TCM5 FLEX/BASIC measurement with an EEG or ECG measurement, Radiometer kindly requests you to:

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

Option 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.

If grounded Ethernet network is not available option 2 may be selected:

Option 2: Disconnect the TCM5 monitoring from the mains supply and run it on battery only. You can use the monitor for up to 4 hours with a fully charged battery.

If it is required to measure continuously beyond 4 hours option 3 may be selected:

Option 3: If alternative monitoring system is available consider to use that while waiting for the final solution from Radiometer. Your Radiometer representative may make a TC loaner device available.

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

In case none of the above options are feasible Radiometer kindly requests you to refrain from combining the TCM5 FLEX/BASIC measurement with an EEG or ECG measurement.

2. Once the above has been done please complete the form on page 4 of this letter and submit to your Radiometer representative.**Temporary solutions provided by Radiometer:**

You will be contacted by your Radiometer representative to schedule a visit to assist you with Option 1 or 3, if selected.

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>

Recall Response Fax Form no. 1

Fax No.:

Concerning:

TCM5 FLEX/BASIC used with ECG and EEG monitor

- I have received the customer letter and have concluded that:
 - We are not affected by the risk of interference as we never combine the TCM5 FLEX/BASIC measurement with an ECG or EEG measurement.
 - We are not affected by the risk of interference as the means against electromagnetic interference offered by the third party device effectively eliminates any interference.
 - We were affected by risk of interference but we have now implemented the following counter measure:
 - TCM5 FLEX/BASIC is connected to a grounded Ethernet network using a shielded Ethernet cable.
 - TCM5 FLEX/BASIC is disconnected from the mains supply and runs on battery only.
 - Since continuous measurement beyond 4 hours is required I have:
 - Taken an alternative monitoring system into use.
 - Requested a TCM4 loaner unit from my Radiometer representative.
 - TCM5 FLEX/BASIC and an ECG or EEG monitor are not used simultaneously on the same patient.

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