

Customer
Hospital
City
Postal code
Country
Attn.: XXX

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

Dear Customer

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 instructions for use includes 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

The described effect may potentially lead to:

- Incorrect measurement results by 3rd party devices, such as an ECG 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. Thus, in a worst-case scenario, the described error may result in insufficient or no treatment for a critically low heart rate or critical arrhythmias.

Affected product:

TCM5 FLEX/BASIC monitor – all serial numbers.

What you must do:

You are not affected by this field safety notice in case you only perform measurements using the TCM5 FLEX/BASIC and never combine this measurement with an ECG measurement.

Otherwise, Radiometer kindly requests you to implement one of the counter measures listed below to reduce/prevent the interference.

These countermeasures are to be considered as an interim change of labeling as they will be incorporated in the instructions for use with the next revision.

1. Disconnect the TCM5 FLEX/BASIC from the mains supply and run it on battery only. This will prevent the interference from occurring on an ECG monitor.

2. Do not use both the TCM5 FLEX/BASIC and an ECG monitor simultaneously on the same patient.

Once the above has been done please complete the form on page 3 of this letter and submit to your Radiometer representative.

Final Solution provided by Radiometer:

You will be contacted by your Radiometer representative when the revised instructions for use are available.

Radiometer is working on a solution 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 monitor

- I have received the customer letter and have concluded that:
 - We are not affected by this field safety notice as we never combine the TCM5 FLEX/BASIC measurement with an ECG measurement
 - We are affected by this field safety notice and have now implemented the following counter measure:
 - TCM5 FLEX/BASIC is disconnected from the mains supply during the combined measurement.
 - TCM5 FLEX/BASIC and an ECG monitor are not used simultaneously on the same patient.

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