

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, distributed March 2018, relating to this issue where there is a possibility that TCM5 FLEX/BASIC can cause interferences to ECG or EEG measurements, however, only when applied on the same patient. The problem may also concern other highly sensitive devices.

As informed earlier the permanent countermeasure provided by Radiometer is to exchange your TCM5 monitoring system with a redesigned device.

Affected product:

TCM5 FLEX/BASIC monitor – all serial numbers.

Permanent countermeasure provided by Radiometer:

Radiometer has now exchanged your TCM5 FLEX/BASIC with a redesigned device.

As a result the short term countermeasures implemented earlier may now be lifted.

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

Fax No.:

Concerning:

TCM5 FLEX/BASIC used with ECG and EEG monitor

- Radiometer has now exchanged my TCM5 FLEX/BASIC with a redesigned device.

The serial numbers of the devices involved are:

Original device	Redesigned device
393-500R _____ N _____	393-500R _____ N _____

- I have received the customer advisory letter

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