

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 Radiometer has been working on a solution, which involved a hardware redesign of the TCM5 monitoring system.

Affected product:

TCM5 FLEX/BASIC monitor – all serial numbers.

Permanent countermeasure provided by Radiometer:

Radiometer can now announce that the permanent countermeasure to this issue is to exchange your TCM5 monitoring system with a redesigned device.

Radiometer plans to provide replacement devices starting in May 2019 and to be completed by the end of this year. Your Radiometer representative will contact you when a redesigned TCM5 monitoring system is available for you.

Please note that the short term countermeasures are still valid until your TCM5 monitoring system has been replaced.

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>