

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice: TCM4 series Base Unit does not comply with Medical Safety Standard IEC 60601-1

Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware that the TCM4 series Base Unit does not comply with the Medical Safety Standard IEC 60601-1, 2nd edition, subclause 15(b).

The implication is that there is a potential risk of receiving an electrical shock under certain conditions as follows:

- The monitor is connected to the mains outlet and the mains switch is ON
- The battery is fully charged (or no battery is present)
- The operator disconnects the line cord (at either end) without first switching the mains switch on the back of the monitor OFF
- The operator touches the two metal pins on the mains plug or on the monitor's line cord receptacle after disconnecting the line cord

The above situation could occur e.g. when moving the monitor between sites.

The shock is considered non-harmful for normal, healthy individuals.

Affected product:

TCM4 series Base Unit with serial numbers starting with: 000-154, 391-876, 391-878, and 391-880.

RADIOMETER has developed a hardware upgrade that will prevent the above from happening. The upgrade will be installed as soon as it becomes available.

Your Radiometer representative will contact you to schedule the upgrade.

Workaround:

Until the upgrade has been implemented on your monitor(s) we strongly recommend to implement the following workaround, which effectively eliminates the above risk of receiving an electrical shock:

- Switch the mains switch OFF (on the back of the monitor)
- Then disconnect the line cord

If you have any questions, please contact your Radiometer representative.

Best regards,
<Radiometer distributor>