

Customer
Hospital
City
Postal code
Country
Attn.: XXX

[ISSUE
DATE]

Urgent Field Safety Notice: TCM Incorrect pO₂ measurement

Dear "Customer"

Background

Radiometer has recently become aware that there is a potential problem relating to the calibration of the TCM modules: TCM4 Combi, TCM CombiM and TCM Tosca, that may lead to a wrong calibration of the pO₂.

Risk for the patient

The described error may lead to wrong reporting of the pO₂ value for a patient. In the case of a wrongful higher tcpO₂ and a correct measurement that would be below normal range, the patient will be at risk for wrongfully not receiving necessary treatment. In a worst-case scenario, the described error may result in severe overestimation of the actual pO₂ in a critically ill neonatal patient with actual severe hypoxia.

The calibration problem will occur in the following scenario:

- Step 1: The operator inserts the calibration bottle meant for the TCM5 monitor into the TCM module.
- Step 2: The operator inserts the sensor into the calibration chamber and thereby starts the calibration of the sensor
- Step 3: The sensor is calibrated using the gas from TCM5 gas bottle, which have a significantly lower pO₂ value than the gas for TCM modules.

This causes the measured pO₂ value to be reported significantly higher than the correct value.

Please note that inserting a TCM4 gas bottle into the TCM5, will not have the same consequence, as the TCM5 will not allow calibration on this gas.

Affected products:

TCM4 Combi module (item #902-778), Combi M module (item #903-111) and TCM Tosca module (item #903-044)

What you should do:

- Inform operators of the TCM modules to always check that the correct gas bottle (Item # 962-187) is inserted into the gas bottle chamber of the TCM module. This can easily be identified by the dark blue handle at the bottom of the bottle and the item # 962-187 on the side of the gas bottle. See also pictures below.
- Radiometer recommends that you review previous patient results.

Permanent countermeasure provided by Radiometer:

Radiometer is currently looking into a permanent solution for this problem. When this is available your Radiometer representative will contact you in order to introduce this permanent solution to your TCM system.

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.

Radiometer sincerely apologizes for the inconvenience this situation may cause you.

If you have any questions, please contact us.

Best regards,
<Radiometer distributor>

Correct bottle for TCM Combi module, TCM CombiM and TCM Tosca



Correct bottle for TCM5 only, DO NOT use for TCM4 modules



Recall Response Fax Form no. 1

Fax No.:

Concerning:

TCM Incorrect pO2 measurement

- I have received the customer letter, and informed users of TCM4 systems to be aware of only using 962-187 gas bottles when inserting gas bottles.

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