

## URGENT – Safety Notice on Temperature Probes for TECOTHERM NEO

Measures against possible mixing up of Disposable Temperature Probes

Dear Ladies and Gentlemen,

the TEC COM GmbH places great emphasis on highest reliability and safety, therefore our products are monitored continuously. Recently we have identified a potential problem which in the case of insufficient attention can lead to a situation where inadvertently the skin probe instead of the rectal probe is used for the automatic temperature control of the patient.

This letter is intended to inform our distribution partners and users,

- what the problem is
- the actions you can take
- the corrective actions planned by manufacturer and distribution to rectify the problem.

**This document contains important information for the continued safe and proper use of your equipment.**

Please review the following information with all members of your staff and customers who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instructions for Use.

Should you require further information or support concerning this issue, please contact

- your local service provider

or directly

- TEC COM GmbH, +49 (0) 345 1205204.

The German competent authority “Bundesinstitut für Arzneimittel und Medizinprodukte“ is informed and has received a copy of this Field Safety Notice.

With best regards

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Affected products	All TECOTHERM NEO operated with Disposable Skin Probe of type <b>FMT 400/AS-D</b> and adapter cable <b>FMT 400/AEC-THT</b> .
Problem description	<p>The adapter cable of type FMT 400/AEC-THT is featured with a connection jack of the same type as the standard adapter cable for the disposable rectal probe. Thus a mix-up of rectal and skin probe is possible. On the unit side a mix-up of the probes is impossible; the different connection jacks are unique.</p> <p>If in preparing the treatment one does not sufficiently careful follow the Instruction for Use, which points out several times that the rectal probe must be connected to the socket "R", instead the skin sensor could be unintentionally plugged into the cable that fits into the socket "R".</p> <p>At the same time, as a result of the confusion, the rectal probe would then be connected to the socket "S", which however would not have any consequences, as temperatures measured on this input are only displayed, but not used.</p> <p>The problem, therefore, is that due to the possible confusion the skin temperature would be used as the reference variable for temperature control.</p>
Potential hazard	It is known that the abdominal measured skin temperature does not have a well-defined correlation with the rectal temperature, which is actually intended as the reference variable for the automatic temperature control. Deviations up to several degrees in both directions are possible. If the device now would regulate the skin temperature to the set point value, the rectal temperature could differ by a few degrees from the intended treatment temperature. This represents an unacceptable risk to the patient.
How to identify affected products	<p>Check whether your device is equipped with the following accessories:</p> <ul style="list-style-type: none"> <li>• Disposable Skin Probe of type FMT400/AS-D with Reusable Extension cable FMT400/AEC-THT.</li> </ul> <p>If present, your system is affected.</p>
Action to be taken by customer / user	<ul style="list-style-type: none"> <li>• Skin Probe of type <b>FMT 400/AS-D</b> and adapter cable <b>FMT 400/AEC-THT</b> must not be applied to or used with the TECOTHERM Neo.</li> <li>• If the optional skin probe can not be spared, only the reusable skin probe type is allowed to be used.</li> </ul>
Actions planned by TEC COM GmbH and Inspiration Healthcare	<ul style="list-style-type: none"> <li>• Dispatch of instructions to avoid this confusion to all affected customers within 2 weeks.</li> </ul>
Further information and support	<p>Should you require further information or support concerning this issue, please contact TEC COM GmbH, Dr. Schoepke, by E-Mail to <a href="mailto:QM@teccom-halle.de">QM@teccom-halle.de</a> or by phone: +49 (0) 345 1205204. Fax: +49 (0) 345 1205211.</p>