

16/08/2019

REFERENCE: NEO201905-005

FIELD SAFETY NOTICE
[Tecotherm Neo]

Dear Customer,

This letter is to inform you of a field safety notice relating to the Tecotherm Neo thermoregulation device, manufactured by TEC COM GmbH.

Reason for the notice:

TEC COM GmbH have released new Instructions for Use (IFU) for the Tecotherm Neo.

As part of the new IFU, TEC COM GmbH recommend the use of an improved rectal probe adaptor cable and disposable rectal probe, as per the table below:

Inspiration Healthcare Part Number	Description
TCFMT400/AEC-P2	Mono Connector Rectal Probe adaptor cable
TCFMT400/AOR-D5	3.0mm Single Use Rectal Probe
TCFMT400/AOR-D6	2.3mm Single Use Rectal Probe

The above parts will replace the previously supplied equivalent Inspiration Healthcare parts (TCFMT400/AEC-P adaptor cable, TCFMT400/AOR-D 3.0mm disposable rectal probe, TCFMT400/AOR-D2, 2.3mm disposable rectal probe) with immediate effect.

Below are the pictures of the products to help users identify the two types of rectal probes and adaptors.



New adaptor cable



Currently used adaptor cable (discontinued)

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New rectal probe connection



Currently used rectal probe connection (discontinued)

Inspiration Healthcare will provide one rectal temperature probe adaptor cable per Tecotherm Neo device and two rectal temperature probes free of charge.

Inspiration Healthcare will make suitable arrangements through our Sales and Service representatives to supply the items listed above.

Inspiration Healthcare will only be supplying the new cables and probes with immediate effect and will convert any orders of the current products to the new ones, as suggested in the table on page 1.

Potential Risks:

None identified. It is safe to use the existing IFU and cables.

Required actions for you and your Healthcare Facility:

None.

We appreciate your cooperation and assistance and sincerely apologise for any inconvenience that may result from this action. Should you have any questions or require assistance in this matter, please contact: info@inspiration-healthcare.com, stating the reference 'NEO201905-005' in the email title.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact.

Alex Angelopoulos
Product Manager

For and on behalf of Inspiration Healthcare Limited.