Rev 1: September 2018
FSN Ref: NEO201905-005 FSCA Ref: NEO201905-005

Date: 18, June 2019

Urgent Field Safety Notice
TECOtherm NEO

For Attention of*: Distributors and End Users of the TECOtherm NEO.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Inspiration Healthcare Ltd., info@inspiration-healthcare.com, +44(0)1455840555, 2 Satellite Business Village, Fleming Way, Crawley, West Sussex, RH10 9NE

TEC COM GmbH

Rev 1: September 2018

FSN Ref: NEO201905-005 FSCA Ref: NEO201905-005

Urgent Field Safety Notice (FSN)
TECOtherm NEO
Release of new Information for Use (IFU) version

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Hypo-/ Hyperthermia device, non-sterile
1.	2. Commercial name(s)
	TECOtherm NEO
1.	3. Unique Device Identifier(s) (UDI-DI)
	04260498580002
1.	4. Primary clinical purpose of device(s)*
	Hypo- and Hyperthermia
1.	5. Device Model/Catalogue/part number(s)*
	TECOtherm NEO
1.	6. Software version
	063/2.18
1.	7. Affected serial or lot number range
	All.
1.	8. Associated devices
	--

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	Change of the instructions for use (IFU).
2.	2. Hazard giving rise to the FSCA*
	Without a rectal temperature probe, the automatic treatment mode (servo mode) can not be used. Cause: partly no availability of previously released temperature probes. Possible confusion of the user when selecting new temperature probes for safe use with the TECOtherm NEO.
2.	3. Probability of problem arising
	Unlikely. (Other available temperature probes are also listed in previous IFU.)
2.	4. Predicted risk to patient/users
	It is necessary to use alternative forms of treatment. For this, the manual treatment mode is available in the TECOtherm NEO. For inexperienced users, this could delay the therapy.
2.	5. Further information to help characterise the problem
	Introduction of an internationally identical selection of available temperature probes. Better overview through well-structured listing of released accessories in Annex I of the new IFU.
2.	6. Background on Issue
	Introduction of an internationally identical set of available, approved accessories in the instructions for use (based on market research).
2.	7. Other information relevant to FSCA
	No relation to previous FSN.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	--
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. --	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer**	
	☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None New IFU version.	
3	6. By when should the action be completed?	Immediately
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	**Update**
4.	2. For updated FSN, reference number and date of previous FSN	**NEO201905-005 from 04.06.2019**
4.	**3.** For Updated FSN, key new information as follows:	
	Typing error in the APPENDIX I of the IFU 21 corrected, new IFU version 21.1 released and sent to the distributors.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	--	
4	6. Anticipated timescale for follow-up FSN	--
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**TEC COM GmbH**
	b. Address	**Am Krümmling 1, D-06184 Kabelsketal**
	c. Website address	**--**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**IFU TECOtherm NEO TN 300 – 21.1**
4.	10. Name/Signature	**Steffen Nebelung, Safety Officer**

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.