Rev 1: September 2018

FSN Ref: 3746_FSN_EU_EN_v1.1 FSCA Ref: 3746_FSCA

Date: 2024-12-17

Urgent Field Safety Notice
MSOT Acuity Echo CE
MSOT Acuity Echo Research Systems
MSOT Acuity Research Systems

For Attention of: Operators of the MSOT devices listed above, persons responsible for laser safety at your location (e.g. Laser Safety Officers)

Contact details of iThera representative
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HypoVereinsbank München
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Managing Director: Christian Wiest
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USt-IdNr.: DE270036658

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Error in information relevant to laser safety considerations

	1. Information on Affected Devices
1.	1. Device Type(s)
	 The MSOT Acuity is a mobile assembly of electrically-powered components intended for imaging and analysis of soft-tissue and soft tissue vasculature using combined optoacoustic (photoacoustic) and ultrasound (US) imaging. It includes a processing unit with a monitor, controls, and integrated software, and a dedicated laser-emitting extracorporeal ultrasound transducer. Pulsed near-infrared laser light of various wavelengths is emitted, and the associated acoustic feedback (photoacoustic effect) provides complementary information regarding tissue composition/functionality based on the presence of endogenous chromophores, such as haemoglobin; this photoacoustic data can be overlaid on the associated US image.
1.	2. Commercial name(s)
	MSOT Acuity Echo CE, MSOT Acuity Echo Research Systems, MSOT Acuity Research Systems
1.	3. Unique Device Identifier(s) (UDI-DI)
	04262380070004 – No UDI-DI available for older devices, check serial numbers below (1.7.)
1.	4. Primary clinical purpose of device(s)
	Combined ultrasound and optoacoustic imaging of soft tissue.
1.	5. Device Model/Catalogue/part number(s)
	MSOT Acuity Echo CE, MSOT Acuity Research Systems, MSOT Acuity Echo Research Systems
1.	6. Software version
	N/A
1.	7. Affected serial numbers
	2-17-01, 2-17-02, 2-17-05, 2-18-01, 2-18-02, 2-19-01, 2-19-04, 2-20-01, 2-20-03, 2-20-05, 2-21-01, 2-21-02, 2-21-03, 2-21-04, 2-21-05, 2-21-06, 2-21-07, 2-22-01, 2-22-02, 2-22-03, 2-22-04, 2-22-05, 2-22-06, 2-23-01 2-24-01, 2-24-03
1.	8. Associated devices
	N/A

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	2 Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem
	The previous version of the user manuals contained the wrong value for the Nominal Ocular Hazard Distance (NOHD). The actual value of the NOHD is "~ 6km" and therefore higher than the previously value communicated in the Instructions for Use.
2.	2. Hazard giving rise to the FSCA
	Laser safety hazards for the eyes for bystanders or persons other than operators and patients. Safety of patients and safety of operators using the device is not impacted – the defined safety measures for patients and for operators are sufficient to safely operating the device.
2.	3. Probability of problem arising
	No incidents have been reported that indicate any harm occurred.
2.	4. Predicted risk to patient/users
	Safety of patients and safety of operators using the device is not impacted - Laser safety hazards for the eyes for bystanders or persons other than operators and patients cannot be excluded by the manufacturer as those hazards are based on the specific laser safety precautions chosen by the local person responsible for laser safety.
2.	5. Further information to help characterise the problem
	The NOHD value is used by the person responsible for laser safety on site to define additional safety measures with regard to occupational safety based on the local conditions, which may go beyond the measures defined by the manufacturer. Other relevant data for laser safety, such as laser class (4), laser energy, wavelengths, laser pulse lengths do not change.
2.	6. Background on Issue
	No incidents were reported. Issue was detected when reassessing the values for NOHD.
2.	7. Other information relevant to FSCA
	None

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other Forward this information and the updated IFU to the person responsible for laser safety at your location (such as Laser Safety Officer) Consult with the person responsible for laser safety at your location to identify any additionally required work safety related measures and precautions to safely operate the MSOT Acuity Echo device in the presence of bystanders and other people, if applicable.	
3.	2. By when should the action be completed?	N/A not critical to patient safety or operator safety
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No N/A	
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	No

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3.	**5. Action Being Taken by the Manufacturer** ☒ IFU or labelling change iThera will provide an updated user manual (IM_2.03_EN_III) with the corrected value for NOHD.		
3	6. By when should the action be completed?	2024-12-20	
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?		
	N/A	N/A	

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	4. General Information	
4.	1. FSN Type	Update
4.	2. For updated FSN, reference number and date of previous FSN	3746_FSN_v1.0 (not distributed to customers
4.	**3.** For Updated FSN, key new information as follows:	
	Paragraph 2.5 filled	
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:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**iThera Medical GmbH**
	b. Address	**Zielstattstr. 13, 81379 Munich, Germany**
	c. Website address	**www.ithera-medical.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	**User Manual MSOT Acuity Echo Part III (IM_2.03_EN_III)**
4.	10. Name/Signature	**Ingmar Thiemann, VP QM & RA**

	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.

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