

Field Safety Notice
High-Frequency Jet Ventilator monsoon 4

For Attention of*:End user/customer/Distributor

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Field Safety Notice (FSN)
monsoon 4
Potential contamination of the internal pneumatic system of
specific devices

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	High-Frequency Jet Ventilator
1.	2. Commercial name(s)*
	monsoon 4
1.	3. Unique Device Identifier(s) (UDI-DI)
	04260758890018 – monsoon 4 SingleJet 04260758890025 – monsoon 4 DoubleJet
1.	4. Primary clinical purpose of device(s)*
	The universal jet ventilator monsoon 4 is designed for jet ventilation of patients in the operating theatre during laryngoscopy, rigid bronchoscopy or microsurgery with or without a laser. The aim offset ventilation is to secure patient's oxygenation using compressed air, medical oxygen or a combination of both. The minimum body weight for using the monsoon 4 is 3 kg.
1.	5. Device Model/Catalogue/part number(s)*
	MS4-SJ-001 (214011), MS4-DJ-001 (214012)
1.	6. Software version
	1.5
1.	7. Affected serial or lot number range
	MS41153 MS41155 MS41159 MS41166
1.	8. Associated devices
	none

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* Due to a malfunction within the compressed-air supply system, there is a possibility that small quantities of compressor oil may have entered the compressed air supplied during manufacturing of the affected devices. As a result, a potential exposure of the affected devices to these fluids cannot be excluded.
2.	2. Hazard giving rise to the FSCA* The identified hazard is the potential exposure of patients and/or users to devices that may have been exposed to compressor oil residues. In a worst-case scenario, such exposure could potentially lead to impaired device performance or unintended exposure to trace substances during clinical use.
2.	3. Probability of problem arising Low, based on initial follow-up investigations which indicated that visible oil residues did not reach the outlet of the gas pathways. However, as contamination cannot be fully excluded, a precautionary FSCA was initiated.
2.	4. Predicted risk to patient/users Depending on the type of device and clinical application, this may potentially result in a risk to the patient, such as reduced treatment efficacy, unintended physiological effects, or exposure to residues of compressor oil. Risk to the user, particularly through handling or inhalation of contaminated aerosols, if applicable.
2.	5. Further information to help characterise the problem N/A
2.	6. Background on Issue The fault was noticed when the compressed-air supply system failed during the release test of a device. The responsible technician identified a defect in the compressed-air supply system and confirmed the presence of compressor oil within the compressed-air supply system.
2.	7. Other information relevant to FSCA N/A

3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* Please identify whether your device is affected based on the serial number listed above and follow the instructions applicable to your country below. Germany: <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input checked="" type="checkbox"/> On-site device modification / inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None Immediately stop using the affected device. Quarantine the device to prevent further use. A manufacturer technician will contact you to arrange an on-site inspection.

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
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	Thora Tech GmbH
	b. Address	Gutfleischstraße 3-5, 35390 Gießen
	c. Website address	https://thoratech.de/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
	Yes	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Fatih Yüksel, CEO (PRRC)
		Date: 18.12.2025

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>