Rev 1: September 2018
Voluntary extension FSN 2023-BM-1020-001

Date: 07:AUG:2024

# Urgent Field Safety Notice
# TEE Care System BM-33T



For Attention of*: General Directorate
Health Directorate
Clinical Engineering
Vigilance Supervisor Officer

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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| **Manufacturer: S.I.D.EM. S.p.A. Via Bergamo 94, 20882 Bellusco (MB) Italia** |
| **Contact person: Lorenzo Oscar Maria Banfi**<br>**Quality Manager and Management Representative**<br>**Signal Officer on behalf of P.R.R.C.** |
| **E-Mail: quality@sidemspa.it**<br>**Telephone: +390396067732 +393518009161**<br>**Website: https://www.sidemspa.com/** |

Rev 1: September 2018
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# Voluntary extension Urgent Field Safety Notice (FSN)
# TEE Care System BM-33T
# Turbine flow sensor 0,05-15 L/min. code BMI03078's possible malfunction



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| | 1. **Information on Affected Devices*** |
| 1. | 1. Device Type(s)* |
| | BM-33T TEE Care System is a medical device designed for reconditioning (cleaning, high disinfection and final rinsing) transesophageal ultrasonic probes and similar excluding thermolabile ducted flexible endoscopes. |
| 1. | 2. Commercial name(s) |
| | BM-33T TEE Care System |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 805062419BM33TZF |
| 1. | 4. Primary clinical purpose of device(s)* |
| | Cleaning and reconditioning of the distal part of transesophageal and similar transducers to the excluding thermolabile ducted flexible endoscopes. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | BM-33T |
| 1. | 6. Software version |
| | 7.0, not relevant for the purposes of this document. |
| 1. | 7. Affected serial or lot number range |
| | 4417B00501, 4417B00502, 1818B00503, 2518B00504, 3718B00505, 2019B00507, 1420B00508, 1420B00509, 1520B00510, 1520B00511, 1620B00512, 1720B00514, 4320B00515, 0522B00517, 0922B00518, 3822B00519, 3822B00520, 1123B00521, 1223B00522, 1723B00523, 2323B00524, 2423B00525, 3323B00526, 3423B00527, 0524B00528. |
| 1. | 8. Associated devices |
| | Not applicable. |

| 2. **Reason for Field Safety Corrective Action (FSCA)*** | |
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| 2.1. | 1. Description of the product problem* |
| | Turbine flow sensor 0,05-15 L/min. code BMI03078 went into short circuit causing an overheating of the same and an abnormal increase in temperature in the adjacent section, which caused the melting of the hydraulic and electric circuitry. |
| 2.2. | 2. Hazard giving rise to the FSCA* |
| | Turbine flow sensor 0,05-15 L/min. cod. BMI03078's malfunction can lead to::<br>• an anomaly related to disinfection phase, medical device's blocking and cycle's interruption.<br>• a possible liquid's leakage<br>• an internal temperature's increase and a possible adjacent componentry's fusion. |
| 2.3. | 3. Probability of problem arising |
| | Described problem arising probability is really low: from 13 April 2017 (first placing on the market date) to date we find a single isolated global case. |
| 2.4. | 4. Predicted risk to patient/users |
| | Coming from health hazard assessment's output, damage to the patient/end user's (direct or indirect) expected risk (product of severity by probability) is considered acceptable. Appropriate control measures shall be established, implemented and verified to eliminate or minimize risk while always taking into account the benefits related to device's performance. |
| 2.5. | 5. Further information to help characterise the problem |
| | During dosing of the sporicidal high level disinfectant's phase (21) of peracetic and acetic acid with hydrogen peroxide mod. SIDEM-1SH (CAS No. 79-21-0 UFI UE00-G06U-R00G-Y92G), medical device detected phase process anomaly (21) and blocked reconditioning cycle and the release of disinfectant. |
| 2.6. | 6. Background on Issue |
| | Manufacturer S.I.D.EM. S.p.A. became aware of the medical device's problem following notification performed by user and end user. As a precaution, Manufacturer S.I.D.EM. S.p.A. has voluntarily decided to extend this Field Safety Notice to all units produced with the Turbine Flow Sensor 0.05-15 L/min. code BMI03078 from the date of first placing on the market to date. |
| 2.7. | 7. Other information relevant to FSCA |
| | Competent Authorities for each country where device has been installed, Authorized Distributors and End User have been contacted. Preliminary instructions have been provided to prevent the occurrence of risks for patients and operators. Operational instructions have been drawn up to implement corrective action in the field (FSCA). |

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| | **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

S.I.D.EM. S.p.A. has developed corrective action to prevent occurrence of described problem. Final user can continue to use TEE Care System following Instructions for Use (IFU) and taking following precautions, waiting for planned implementation..

We encourage you to identify areas within your healthcare facility where inappropriate materials are present within medical device's perimeter.

Whether a disinfection cycle's anomaly gets detected, please contact S.I.D.EM. S.p.A. Technical Assistance Service. by phone number +39039606771 or its Authorized Dealer to receive immediate support.

Attache this Field Safety Notice together with your medical device documentation.

Distribute this Field Safety Notice to every medical device's operators so that they are aware of the problem described.

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| 3. | 2. By when should the action be completed? | 14/Aug/2024 |
| 3. | 3. Particular considerations for: | Not applicable |

Is follow-up of patients or review of patients' previous results recommended?
No

Appropriate control measures shall be established, implemented and verified to eliminate or minimize risk while always taking into account the benefits related to device's performance.

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| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes<br>07/Sep/2024 |

**3. 5. Action Being Taken by the Manufacturer**

☐ Product Removal ☒ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

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| | S.I.D.EM. S.p.A. has developed related Field Safety Corrective Action action and will replace, free of charge, hardware components associated with this problem. S.I.D.EM. S.p.A. or its Authorized Dealer will contact your department staff in order to schedule a visit from our technical specialists. | | |
| 3 | 6. By when should the action be completed? | 07/Oct/2024 | |
| 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? | | |
| | No Not appended to this FSN | | |

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| | **3. General Information*** | |
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | Not applicable. |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | Not applicable. | |
| 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: | |
| | Not applicable. | |
| 4 | 6. Anticipated timescale for follow-up FSN | Not applicable. |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | **S.I.D.EM. S.p.A.** |
| | b. Address | **Via Bergamo 94, 20882, Bellusco (MB) Italia** |
| | c. Website address | **https://www.sidemspa.com/** |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | **Template for a Field Safety Notice**<br>**Customer Reply Form** |
| 4. | 10. Name/Signature | **Lorenzo Oscar Maria Banfi** |

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