



Date: 2022:11:11

Urgent Field Safety Notice
CritiCool®

For Attention of*: Director of Biomedical Engineering, Director of Risk Management, Medical Device Safety Officer.

Contact details of local representative (name, e-mail, telephone, address etc.)*

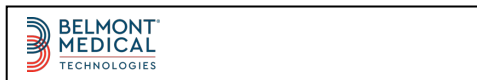
Account Name: Mediq Suisse AG
Physical Street: SCHWERZISTRASSE 6
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Physical Country: Switzerland
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Urgent Field Safety Notice (FSN)
CritiCool®
Risk of premature circulation pump failure

| 1. Information on Affected Devices* | |
|--|--|
| 1. | <p>1. Device Type(s)*</p> <p>CritiCool® Thermoregulation device, used for regulating patient’s temperature as determined by the physician. The device is an autonomous semi stationary unit connected to VAC supply. Its purpose is to supply water at a desired temperature to a garment that is worn by the patient, CureWrap. The device or the garment are not sterile.</p> |
| 1. | <p>2. Commercial name(s)*</p> <p>CritiCool®</p> |
| 1. | <p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>08961280020000108E</p> |
| 1. | <p>4. Primary clinical purpose of device(s)*</p> <p>The CritiCool® is a thermal regulating system, indicated for monitoring and controlling patient temperature.</p> |
| 1. | <p>5. Device Model/Catalogue/part number(s)*</p> <p>CritiCool®/ 200-00236</p> |
| 1. | <p>6. Affected serial or lot number range</p> <p>Site Serial numbers will be provided by the in country distributor</p> |

| 2. Reason for Field Safety Corrective Action (FSCA)* | |
|---|--|
| 2. | <p>1. Description of the product problem*</p> <p>The pump that circulates the water from the CritiCool® device into the CureWrap® may experience premature failure due to loose hardware on the pump component. This premature failure leads to the CritiCool® device displaying a HALT 4 error, from which the device cannot recover even after a device reboot.</p> |
| 2. | <p>2. Hazard giving rise to the FSCA*</p> <p>The hazard is that the failure could occurred during thermoregulation procedure and the interruption in the thermoregulation could potentially have severe impact on the state of the patient, with the highest assessed impact on neonates and then potentially on cardiac patients. There is no risk to the user.</p> |

| 3. Type of Action to mitigate the risk* | |
|--|---|
| 3. | <p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input 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) </p> |



| 4. General Information* | | |
|--------------------------------|--|---|
| 4. | 1. FSN Type* | New |
| 4. | 2. Further advice or information already expected in follow-up FSN? * | No |
| 4. | 3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Belmont Medical Technologies |
| | b. Address | 780 Boston Road, Billerica, MA 01821, USA |
| | c. Website address | Belmontmedtech.com |
| 4. | 4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 5. Name/Signature | Lida Reed Director, Quality Assurance and Regulatory Affairs |

| 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> |

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