Rev 2: February 2020

FSN Ref: FSN-BMT-2022-001 FSCA Ref: FSCA-BMT-2022-001

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 Physical City: FREIENBACH Physical Zip Code: 08807 Physical Country: Switzerland Contact Information: gabriel.duerst@gdmedical.ch

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Urgent Field Safety Notice (FSN)
CritiCool®
Risk of premature circulation pump failure

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	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.
1.	2. Commercial name(s)*
	CritiCool®
1.	3. Unique Device Identifier(s) (UDI-DI)
	08961280020000108E
1.	4. Primary clinical purpose of device(s)*
	The CritiCool® is a thermal regulating system, indicated for monitoring and controlling patient temperature.
1.	5. Device Model/Catalogue/part number(s)*
	CritiCool®/ 200-00236
1.	6. Affected serial or lot number range
	Site Serial numbers will be provided by the in country distributor

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	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.
2.	2. Hazard giving rise to the FSCA*
	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.

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 1. Ensure users of these devices are made aware of this notification. 2. If the device is operating properly, it is acceptable to continue to use the device as intended, with increased oversight of the device during use while awaiting inspection and repair. 3. Should a HALT 4 message be displayed on the device, turn off the device immediately. Check for obstruction preventing water flow in the water hoses or wrap tubing, especially near the hose connection. Disconnect the wrap and hoses and then reconnect, listening for a click with each insertion, and tugging lightly to be sure the connection is tight. Wait at least ten minutes before restarting the device. If the actions described above do not resolve the situation, discontinue use of the device, and contact your service provider. 4. While you are waiting to have your device(s) to be inspected and repaired, Belmont Medical Technologies recommends that you evaluate your current situation and clinical needs and consider planning for alternative methods of thermoregulation in case of failure, such as a secondary thermoregulation device.	
3.	2. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No *Tracking to be completed by in country distributor.
3.	**3. Action Being Taken by the Manufacturer*** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None 1. We have developed a repair kit for the pump that once installed will prevent premature failure of the pump (P/N 405-00002, Kit Fasteners, 5 sets per each kit)) 2. Developed instructions on inspection and rework of the pump (799-00028). The instructions are included with the Kit Fasteners. 3. Instructed distributors to inspect and service customer units.	
3.	4. Is the FSN required to be communicated to the patient /lay user?	No

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
	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.