Date: 2023-09-06

Field Safety Notice

AutoMer 2

For Attention of*:Importers and healthcare professionals in Austria that uses the AutoMer 2

Contact details of local representative (name, e-mail, telephone, address etc.)*
Ace Medical 33, Naeyoo-Road 124, Deogyang-Gu, Goyang-Si, Gyeonggi-Do, Korea Postcode: 10264 Phone:+82-31-960-9206 E-mail: shhan@ace-medical.com

Field Safety Notice (FSN)
AutoMer 2
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The AutoMer 2 is a class Ⅱb medical device. It is a blood/fluid warming system designed to warm blood/fluid. 
1.	2. Commercial name(s)*
	AutoMer 2
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	AutoMer 2 is AC 220V external powered equipment for blood/fluid warming.
1.	5. Device Model/Catalogue/part number(s)*
	E2MZ00001 / AutoMer 2
1.	6. Software version
	Rev.1
1.	7. Affected serial or lot number range
	LOT No.: A230214-E2MZ0000AT-1
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	A non-conformity was found in a temperature sensor of the same LOT complaint device.
2.	2. Hazard giving rise to the FSCA*

	The device is not used to the patient. So there is no harm to the patient. If the device is not returned and is used, the patient may not receive the proper temperature of the blood.
2.	3. Probability of problem arising
	N/A
2.	4. Predicted risk to patient/users
	N/A
	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	AutoMer 2 (A230214-E2MZ0000AT-1 was returned as a complaint device. Through the tests, Ace Medical found a problem with a material (Temperature sensor). By tracking the material, the LOT A230214-E2MZ0000AT-1 device was the only one that used the defective material.
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***	
	☐ 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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer***	
	☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☒ None Provide further details of the action(s) identified.	

3.	6. By when should the action be completed?	N/A
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?	
	Choose an item. Choose an item.	

4. General Information*		
4.	1. FSN Type*	Update
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? *	Not planned yet
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	Ace Medical
	b. Address	
	c. Website address	http://ace-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:	N/A
4.	10. Name/Signature	

	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.