ORGAN ASSIST

subject: Field Safety Notice
date: 16-04-2020
FSN ref: FSN-CAP-264
FSCA ref: FSCA-CAP-264

To whom it may concern

Dear valued customer,

With this letter, we would like to inform you about a potential issue that could arise while using the following devices: Liver Assist, Kidney Assist and/or Lung Assist.

The Liver Assist, Kidney Assist and Lung Assist are intended to be used for isolated temperature controlled ex-situ oxygenated machine perfusion of donor livers, kidneys and lungs resp.

To guarantee that the Organ Assist devices are safe for the perfused organs in all circumstances, several safety features are implemented. Warnings and errors preventing too high perfusion temperature are programmed in the embedded software of the device. In the unlikely event of non-responsive software, essential performance is safeguarded by a hardware safety circuit.

It has come to our attention that this hardware safety circuit to alarm the user when unintentionally **perfusion temperature rises above 43°C** is NOT implemented correctly. In the next pages you will find detailed information on which devices it concerns, which actions should be taken by the user and which actions will and have been taken by Organ Assist.

Taking these measures into account, Organ Assist feels the device can still be safely used when the recommended actions are taken by you as user. If you have any doubt, or do not feel comfortable continuing using the device, please contact your Client Service Manager.

It is our promise to correct this issue as soon as possible so you continue to feel comfortable with safe use of your Organ Assist device.

Yours sincerely,

W den Hartog (CEO)

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9723 AZ Groningen
The Netherlands

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www.organ-assist.nl

Urgent Field Safety Notice (FSN)

Temperature hardware alarm not fully effective

1	Affected Serial Numbers in Switzerland		
	Liver Assist 11.01.101	Kidney Assist 21.01.101	Lung Assist 41.01.101
	111804M108 111804M109	-	-
2	Problem Description		
	To guarantee that the Organ Assist devices are safe for the perfused organs in all circumstances, several safety features are implemented. Warnings and errors preventing too high perfusion temperature are programmed in the embedded software of the device. In the unlikely event of non-responsive software, essential performance is safeguarded by a hardware safety circuit. It has come to our attention that this hardware safety circuit to alarm the user when unintentionally perfusion temperature rises above 43°C is NOT implemented correctly. This safety measure should shut down the Thermo Unit and generates a medium priority alarm with buzzer, yellow and cyan LED and display text: !! Error !! Temp high limit. In the products identified above, this is not the case.		
3	Hazards		
	The embedded software of the device controls the perfusion temperature by controlling the Thermo Unit. If measured temperature deviates too much from the set temperature, the embedded software generates a low priority alarm and controls the Thermo Unit. In the unlikely event of non-responsive embedded software control and alarming, the Thermo Unit could continue to warm the perfusion solution and the temperature of the perfusion solution could become higher than 43°C. This could eventually lead to an injured organ.		
4	Actions to be taken by the user		
	While using your device, the embedded software safety circuit safeguards your perfusion settings. We do ask you, especially during normothermic procedures, to be vigilant, perform extra checks on perfusion temperature readings and actual values before transplanting the perfused organ. If the temperature of the temperature rises above 43°C, turn off the device and switch to cold storage. This notice needs to be passed on all those who need to be aware within your organization. Please complete the return-form and return to: info@organ-assist.nl		
5	Actions being taken by Organ Assist		
	A corrective action plan is defined to update your device to fully comply with the intended safety specifications. Your Client Service Manager will contact you to schedule a repair action as soon as possible. Depending on COVID-19 measures, this might be by sending the device back to Organ Assist.		
6	Other information		
	If you have any doubt, or do not feel comfortable continuing using the device, please contact your Client Service Manager.		

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Return form

I confirm that this field safety notice, FSN-CAP-264, is read, understood and passed on all those who are working with the Organ Assist perfusion machines.

Name	
Hospital / Institution	
Device	
Serial Number	
Protocol	normothermic / hypothermic / research
Email	
Signature	
Date	

Please return this form as soon as possible to your Organ Assist Client Service Manager or to info@organ-assist.nl.

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