Date: 2022-Dec-12

Field Safety Notice
HCTronic Heater-Cooler system HCS-1

Waardenburg, 12 December 2022

Dear Customer,

We would like to inform you about a software bug we found because of feedback we received on 21 November 2022.
Below you find the necessary information about this bug including a short description of the problem found, a solution/action to be taken by the user/perfusionist, and the affected devices.
We are working on a solution in the form of a software update.
Please contact us if you have any questions, remarks, or suggestions.
Feel free to call us if a malfunction occurs: we will be happy to help you resolve the malfunction.

Best regards,

Bastiën van der Hoeff
Heater Cooler B.V.
Head of Quality Assurance
+31 6 20 93 9595

For Attention of: perfusionist

Contact details
Heater Cooler B.V. Bastiën van der Hoeff Koeweistraat 1 4181 CD Waardenburg The Netherlands +31 (0418) 78 25 43 info@hctronic.nl www,hctronic.nl

Field Safety Notice
HCTronic Heater-Cooler system HCS-1
Software bug

1. Information on Affected Devices	
1.	1. Device Type and Commercial Name
	Technical Unit which is part of the HCTronic Heater-Cooler system HCS-1.
1.	2. Unique Device Identifier(s) (UDI-DI)
	Technical Unit (/TU) UDI-DI/GTIN: 8720165944019.
1.	3. Primary clinical purpose of device(s)
	Used as Heater-Cooler system in conjunction with a Heart-Lung Machine to cool and heat patients during cardiac surgery.
1.	4. Device Model/Catalogue/part number(s)
	HCS-1 Technical Unit reference (REF): H-TU1.
1.	5. Software version
	Regin controller: 01.04.
1.	6. Affected serial or lot number range
	SNs: TU00005 TU00006 TU00007 TU00008 TU00009 TU00010 TU00011 TU00012 TU00013 TU00014.

2. Reason for Field Safety Notice	
2.	1. Description of the product problem
	In a specific setting, the system may keep on heating or cooling and the setpoint may not be reached or maintained. This situation will only occur if the Pause button is used, and the system is in Pause Mode. Only in Pause Mode the following four scenarios may happen: <u>Scenario 1</u> When the user ends the heater-cooler procedure in Pause Mode by pressing the "End Procedure" button. <u>Scenario 2</u> When the system is in Pause and goes into malfunction while being in Pause Mode, the system will automatically go to Safety Mode. The user gets an alarm to switch to the other unit (as described in the IFU). <u>Scenario 3</u> When the system is in Pause Mode and the user enters Safety Mode manually by pressing the "Safety Mode" button. In this case there is no alarm. The system cannot be used immediately in Safety Mode because it is filled with water. The System must first be put into Drying Mode before you can proceed. **For scenarios 1-3, the next time when the user (re)starts the system** and during preparation/priming of the system when there is no patient connected to the Heater-Cooler system, there may be three unwanted consequences, see the three Consequences mentioned below under Scenario 4. <u>Scenario 4</u> When the system is in Pause Mode and the user changes the setpoint.

	For scenario 4, when resuming the system—with or without a patient connected—there may be three unwanted consequences. These three Consequences also apply to Scenarios 1-3: <u>Consequence 1</u> The system may not reach the setpoint temperature and the system gives an alarm that the setpoint temperature is not reached. <u>Consequence 2</u> The system is cooling instead of heating. <u>Consequence 3</u> The system keeps on heating.
2.	2. Hazard giving rise to the FSN.
	The system does not behave as expected under the above-described conditions and the user must switch to the second unit to start with the procedure as described in the IFU.

3. Type of Action to mitigate the risk

3. **1. Action To Be Taken by the User**

Preferably, the user should not use the Pause button until the system software is upgraded (Regin controller software will be upgraded to version 01.05). **When the Pause button is not used, the problem will not occur.**

If the Pause button is used, do not change the setpoint in Pause Mode.
(Changing the setpoint during Pause is useless, and unlikely for a user to do.)

<u>In case of Scenarios 1-3</u>
The actions below to be taken by the user, depend on the above-described Consequences 1-3 in section 2.1. These three Consequences can occur in above-described Scenarios 1-3 in section 2.1, and **after the first (re)start**.

The user must if Scenarios 1-3 occur, always restart the system to see if Consequences 1-3 occur. This to be sure that the Heater-Cooler system is ready for the next use. In case Consequence 1-3 occur, the actions to be taken by the user are as follows:

<u>For Consequences 1 or 2</u>

1. Start the system in Cardioplegia Mode and set the setpoint to 4 °C when Priming Mode is about 90 seconds active.
2. Wait about 20 seconds and set the desired setpoint at 36.5 °C. (The PID needs some time to go to heating.)
3. Normally the measured temperature will go to the desired setpoint, and the desired temperature will be maintained when reached. If not, please start a Self-test.
4. If the Self-test is passed, the system is ready for use. If the Self-test is not passed because there is a malfunction, please contact Heater Cooler B.V.'s service department.

	For Consequence 3 1. Start Self-test. 2. If the Self-test is passed, the system is ready for use. If the Self-test is not passed because there is a malfunction, please contact Heater Cooler B.V.'s service department. In case of Scenario 4 If the Pause button is used, and the setpoint is changed in Pause Mode (Scenario 4), and after resuming, the user may experience one of the three Consequences described (see Consequences 1-3 in section 2.1). The action to be taken by the user is either 1. to start up the second unit and switch to the second unit or 2. in case of Consequences 1 and 2, to set the setpoint for about 10 seconds to 4 °C when in Cardioplegia Mode or set the setpoint for 10 seconds to 15 °C when in Oxygenator mode. The action to be taken by the user in the case of Consequence 3 is to set the setpoint for about 10 seconds to 39 °C.	
3.	**2. Is customer Reply Required?** **(If yes, form attached specifying deadline for return)**	Yes
3.	**3. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None As soon as software V1.05 is finished, all systems will be upgraded to this version. This is planned for Q2/2023.	

4. Transmission of this Field Safety Notice

Measures to be followed:

This notice needs to be passed on to all those who need to be aware within your organization, that is at least all perfusionists working with the HCS-1 system.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to Heater Cooler B.V. as this provides important feedback.

Customer Reply Form

5. Field Safety Notice information	
FSN Reference number	HC-FSN-001
FSN Date	2022-Dec-05
Product/ Device name	HCTronic Heater-Cooler system HCS-1
Product Code(s)	Technical Unit (/TU) UDI-DI/GTIN: 8720165944019
Batch/Serial Number(s)	TU00005 TU00006 TU00007 TU00008 TU00009 TU00010 TU00011 TU00012 TU00013 TU00014.

6. Customer Details	
Account Number	
Healthcare Organization Name	
Organization Address	
Department/Unit	
Contact Name	
Title or Function	
Telephone number	
Email	

7. Customer action undertaken on behalf of Healthcare Organization

- ☐ I confirm receipt of the Field Safety Notice and that I read and understood its content. *
- ☐ I performed all actions requested by the Field Safety Notice. *
- ☐ The information and required actions have been brought to the attention of all relevant users and executed. *
- ☐ Other Action (Define): *

Name:
Signature:

Date:
* Customer to complete or enter "N/A".

8. Return acknowledgement to sender	
Email	bastien.vanderhoeff@hctronic.nl
Customer Helpline	+31 418 78 25 43
Postal Address	Heater Cooler B.V. Koeweistraat 1 4181 CD Waardenburg The Netherlands
Web Portal	www.hctronic.nl
Deadline for returning the customer reply form	2022-Dec-20

It is important that your organization takes the actions detailed in the Field Safety Notice and confirms that you have received the Field Safety Notice.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.