

Augustine Temperature Management, LLC
4 December 2024

Field Notification: HotDog® Temperature Management Controllers

Dear Valued HotDog Customer,

The purpose of this Field Notification is to advise you that there is an update to the User and Technical Manual to further clarify existing instructions for the following Augustine Temperature Management devices: HotDog Temperature Management Controllers Models WC71, WC77, and Temperature Management Controller MP Model 2083516. Updating these manuals is considered a voluntary recall for these devices. This letter is a notification and not a product removal.



WC7X

Product and Distribution Information Table			
Unique Device Identifier	Manufacturer's Product Number/Catalog Number	Serial Number	Distribution Dates
00850011479018	WC71	20080004-23060141	01 August 2020 – 08 July 2024
00850011479025	WC77	20080060-24060065	01 August 2020 – 08 July 2024
00850011479285	WC71R	20080004-23060141	01 August 2020 – 08 July 2024
00850011479292	WC77D	20080060-24060065	01 August 2020 – 08 July 2024
00850011479308	WC77R	20080060-24060065	01 August 2020 – 08 July 2024
00850011479247	WC71V	20080007-24030075	01 August 2020 – 08 July 2024
00850011479254	WC77V	20080090-24020097	01 August 2020 – 08 July 2024
00850011479582	2083516	22120000-24030030	26 January 2023 – 08 July 2024

Background

In approximately 4 out of every 100,000 uses, a Controller has alarmed at start-up (Alarm “EA POST”). This alarm makes the Controller inoperable for a maximum of 6 minutes unless properly re-started. There are no reported incidences of risk to health, although we recognize that it could theoretically result in briefly delayed temperature management therapy.

Root Cause

Through rigorous investigation, a Root Cause Analysis revealed that the alarm only occurs if an already warm blanket or mattress is plugged-in when the Controller is powered-on in Controllers manufactured between 01-Aug-2020 to 08-Jul-2024. The alarm circuitry’s timing was affected by the device being warm, resulting in a rare alarm at start-up under these unusual conditions. Devices manufactured after 08-Jul 2024 are not susceptible to this issue.

What action should I take?

Medical Facilities:

This EA POST alarm is quickly resolved by turning on the Controller *without* a blanket or mattress plugged in. To ensure this instruction is followed, an additional clarifying sentence has been added to the User and Technical Manuals:

“Turn on the Controller with no blankets or mattress connected to prevent possible alarm.”

Furthermore, information about troubleshooting this EA POST alarm has been added to the Alarms and Alerts section (the additional language is underlined):

“Please turn off the Controller, disconnect blankets and/or mattress, then restart.”

Labeling Change: Updates to the User and Technical Manuals (IFU)					
Controller PN	Description	Manual PN	Additional IFU Language	IFU Section	eIFU Link
WC71	Temperature Management Controller – Single Port	D11367	“Turn on the Controller with no blankets or mattress connected to prevent possible alarm.”	Instructions for Use	US: https://hotdogwarming.com/D11367EN O-US (English): https://hotdogwarming.com/D11367EU
WC77	Temperature Management Controller – Multiport		“Please turn off the Controller, <u>disconnect blankets and/or mattress</u> , then restart.”	Alarms and Alerts	
WC71V	Temperature Management Controller – Single Port (Veterinary)	3489	“Turn on the Controller with no blankets connected to prevent possible alarm.”	Instructions for Use	https://vetwarming.com/3489EN
WC77V	Temperature Management Controller – Multiport (Veterinary)		“Please turn off the Controller, <u>disconnect blankets</u> , then restart.”	Alarms and Alerts	
2083516	Temperature Management Controller MP (Hillrom-branded)	3713	“Turn on the Controller with no blankets or mattress connected to prevent possible alarm.”	Instructions for Use	https://hotdogwarming.com/3713EN
			“Please turn off the Controller, <u>disconnect blankets and/or mattress</u> , then restart.”	Alarms and Alerts	

If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.

Distributors:

If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Field Notification in accordance with your customary procedures.

For all consignees:

Please complete the attached medical device correction return acknowledgement and receipt form and return it to customercare@aug surg.com as soon as possible. If you do not respond, you will be contacted again.

Our goal is to ensure that all customers get the best results for their patients with the latest information and technology available. Optional hardware upgrades are available for controllers manufactured before July 8, 2024; however, following the instruction in this Field Notification makes the upgrade unnecessary. If you have any concerns or issues with this alarm, please contact us at customercare@aug surg.com.

Authorized by:

BRENT AUGUSTINE



President

IVONA DOMNISORU



RA/QA Director

Contact Information:

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Website: <https://www.hotdogwarming.com>

Available 8:00 AM to 5:00 PM Central Time for calls.

MEDICAL DEVICE CORRECTION RESPONSE

Acknowledgement and Receipt Form

Response is Requested

Customer Information:

Customer Name	
Street Address	
Town, State, Zip Code	

HotDog Temperature Management Controllers

Affected Product Information:

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I have read and understand the field safety notice instructions provided in the 4 December 2024 letter. Yes ☐ No ☐

Instructions for Distributors:

If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Field Notification in accordance with your customary procedures.

I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**) _____

For questions or concerns regarding this notice, please contact customercare@aug Surg.com

☐ Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE EMAIL COMPLETED RESPONSE FORM TO: customercare@aug Surg.com