

Reference: FSN 2021-003

Wednesday, 26 May 2021

Urgent Field Safety Notice

OrganOx *metra* Retained Unit (D0003)

Dear Valued Customer,

OrganOx Ltd is issuing a Field Safety Corrective Action (FSCA) for the OrganOx *metra* Retained Unit (P/N D0003). This FSCA affects all serial numbers in the OrganOx *metra* fleet.

OrganOx has identified that under certain circumstances electrical noise generated in the battery charging network may cause the device to switch erroneously from mains power to battery power. The noise issue results in the batteries discharging at a slow rate and/or prevents batteries charging at the normal rate during use. This erroneous switching may also stress charging components leading to premature device failure.

An FSCA is being implemented immediately to eliminate the noise and prevent erroneous switching.

A design change has been implemented that restores the performance of the printed circuit board assembly. As such, this design change does not introduce additional risks but will reduce the likelihood of the hazardous situation when compared to the initial risk assessment.

OrganOx requests that you take the following actions:

Given this risk, we ask that you quarantine your device immediately and unplug it from the mains power. You will be contacted by OrganOx Senior Team to advise on the timing and logistics of the field correction for this failure.

OrganOx has notified the appropriate regulatory agencies of this action.

On behalf of OrganOx, we thank you sincerely for your assistance in completing this action and apologise for any inconvenience caused. We would like to assure you that OrganOx is committed to ensuring the ongoing safety and quality of our products.

If you have any questions about this notice, please contact OrganOx at reporting@organox.com or +44 (0) 1865 504054

Sincerely,

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Global Director of Quality and Regulatory Affairs

Field Safety Notice Customer Reply Form

Customer Reply Form

Field Safety Notice (FSN) information	
FSN Reference number*	FSN 2021- 003
FSN Date*	26 th May 2021
Product/ Device name*	OrganOx <i>metra</i> Retained Unit
Product Code(s)	D0003
Batch/Serial Number (s)	All devices could be affected.

Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

Customer action undertaken on behalf of Healthcare Organisation				
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY)
				:
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
	N/A	Comments:		

Registered Address

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+44 (0) 1865 784156

organox.com

<input type="checkbox"/>	Other Action (Define):	
<input type="checkbox"/>	I do not have any affected devices.	
<input type="checkbox"/>	I have a query please contact me	
Print Name*		
Signature*		
Date*		

Return acknowledgement to sender	
Email	reporting@organox.com
Customer Helpline	+44 (0) 1865 504054
Postal Address	Oxford Science Park, Oxford, OX4 4GA
Deadline for returning the customer reply form*	15 TH June 2021

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

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