

FSN Ref: 2021-01

FSCA Ref: 2021-01

Date: 09:FEB:2021

Urgent Field Safety Notice
Vapotherm Oxygen Assist Module

For Attention of*: Clinicians trained to use the Vapotherm Oxygen Assist Module



Contact details of local representative (name, e-mail, telephone, address etc.)*
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Urgent Field Safety Notice (FSN)
Vapotherm Oxygen Assist Module
Risk addressed by FSN

1. Information on Affected Devices*	
1	<p>1. Device Type(s)*</p> <p>Automatic Oxygen Controller for Vapotherm's Precision Flow® System</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>Vapotherm Oxygen Assist Module</p>  </div> <div style="text-align: center;">  <p>Vapotherm Precision Flow</p> </div> </div>
1	2. Commercial name(s)
.	Vapotherm Oxygen Assist Module (OAM)
1	3. Unique Device Identifier(s) (UDI-DI)
.	Complete when this becomes available.
1	4. Primary clinical purpose of device(s)*
.	The OAM is an optional module consisting of electronic hardware and software that is compatible only with Vapotherm Precision Flow, used to aid the clinician in maintaining a target SpO2 value, determined by the clinician in a patient-specific manner, by automatically increasing or decreasing the FiO2 setting on the Precision Flow based on pulse oximetry readings.
1	5. Device Model/Catalogue/part number(s)*
.	PF-OAM-MAS; PF-OAM-NEL
1	6. Software version
.	2.5.0
1	7. Affected serial or lot number range
.	Any units upgraded to Version 2.5.0 which began on 29-Jan-2021
1	8. Associated devices
.	None

2 Reason for Field Safety Corrective Action (FSCA)*	
2	<p>1. Description of the product problem*</p> <p>If the user ends a case while the OAM is in auto mode, although the OAM screen indicates it is in manual mode, the OAM is still automatically controlling the FiO2 setting on the Precision Flow.</p>
2	<p>2. Hazard giving rise to the FSCA*</p> <p>If the OAM is still automatically controlling the FiO2 setting on the Precision Flow when the clinician is trying to pre-oxygenate a neonate in preparation for intubation, the OAM would be decreasing the oxygen being delivered to the patient rather than allowing the clinician to increase the oxygen as desired. This could lead to desaturation. Another potential hazard could occur when the clinician is doing a probe change or otherwise thinks they have manual control, the OAM may direct PF to deliver inappropriate FiO2, leading to either desaturation or in neonates, over delivery of oxygen.</p>
2	<p>3. Probability of problem arising</p> <p>If the OAM device exits an active case while in AUTO mode and remains in manual mode while the Precision Flow continues to deliver therapy to the patient it will in all cases continue to control the delivered oxygen. The likelihood of this sequence of events occurring is occasional given clinical use of the device.</p>
2	<p>4. Predicted risk to patient/users</p> <p>Risk is anticipated as being moderate while probability of injury occurring as unlikely but possible. This results in a moderate risk.</p>
2	<p>5. Further information to help characterise the problem</p> <p>None</p>
2	<p>6. Background on Issue</p> <p>Vapotherm became aware of this issue when its International Director of Medical Education installed version 2.5.0 of the software on an OAM device as part of training customers. There have been no incidents of the OAM remaining in automatic mode after ending a case and therefore, no patient injury. The root cause is an inadvertent bug introduced in the 2.5.0 version of the software as this issue was not present in the previous version (2.2.0). The problem will be able to be contained as no additional OAM devices will be upgraded to the version 2.5.0 software.</p>
2	<p>7. Other information relevant to FSCA</p> <p>None</p>

3. Type of Action to mitigate the risk*			
3.	<p>1. Action To Be Taken by the User*</p> <p><input checked="" type="checkbox"/> Identify Device</p> <p><input checked="" type="checkbox"/> On-site device modification/inspection</p> <p>A Vapotherm representative will perform the on-site device modification/inspection to remove the version 2.5.0 software and replace it with the prior software version (2.2.0).</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%; text-align: center;">2. By when should the action be completed?</td> <td style="text-align: center;">This action should be completed as soon as possible but no later than 2021-Feb-19</td> </tr> </table>	2. By when should the action be completed?	This action should be completed as soon as possible but no later than 2021-Feb-19
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3.	<p>3. Particular considerations for: Choose an item.</p> <p>Is follow-up of patients or review of patients' previous results recommended? Choose an item.</p>		

	The OAM is not an implantable device, diagnostic imaging device or IVD so this section is not applicable.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes 19-Feb-2021
3.	5. Action Being Taken by the Manufacturer <input checked="" type="checkbox"/> On-site device modification/inspection <input checked="" type="checkbox"/> Software upgrade A Vapotherm representative will perform the on-site device modification/inspection to remove the version 2.5.0 software and replace it with the prior software version (2.2.0).	
3	6. By when should the action be completed?	This action should be completed as soon as possible but no later than 2021-Feb-19
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
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*	New
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? *	No
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	Vapotherm
	b. Address	100 Domain Drive, Exeter, NH 03833, USA
	c. Website address	www.vapotherm.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	OAM Version 2.5.0 Correction Process
4.	10. Name/Signature	

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.