FSN Ref: FSN-MDR-2020-001_KSA

Date: 2021-01-16

Urgent Field Safety Notice
FreeO2 automated oxygen therapy device

For Attention of*:All customer having a FreeO2 device. Refer to list provided

Contact details of local representative (name, e-mail, telephone, address etc.)*
Please contact your distributor

Techno Orbits

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web:www.technoorbits.com.sa

Urgent Field Safety Notice (FSN)
FreeO2 automated oxygen therapy device
Unwanted Fluctuation of O2 delivery

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The FreeO2 Automated Oxygen Therapy Device is a multi-use, nonsterile, non-invasive, active therapeutical device that provides oxygen therapy on demand, based on continuous, non-invasive monitoring of oxygen saturation.
1.	2. Commercial name(s)
	FreeO2 automated oxygen therapy device
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not available
1.	4. Primary clinical purpose of device(s)*
	The FreeO2 device is indicated for use under the direction of a physician in a clinical or hospital environment, on spontaneously breathing pediatric, and adult patients who are prescribed supplemental oxygen via a nasal cannula or oxygen mask.
1.	5. Device Model/Catalogue/part number(s)*
	Model : FO2-110-00
1.	6. Software version
	1.2.3
1.	7. Affected serial or lot number range
	Refer to Appendix
1.	8. Associated devices
	Not applicable.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	When the flow rate calculated by the device reaches the maximum threshold, i.e. 20L / min for adult patients or 10L / min for paediatric patients, the device generates a critical alarm and triggers a safety protocol with the result of temporarily reducing the oxygen supply at 8L / min for adult patients and at 7L / min for paediatric patients. This reduction is only temporary (a few seconds). However, if the calculated flow rate reaches the limit again, the alarm will be triggered again, and several cycles of flow fluctuations may occur.
2.	2. Hazard giving rise to the FSCA*
	Degradation of the patient's state of health which may lead to intubation. However, it is important to note that the patient's state of health is at the origin of the severity of the situation. The behavior of the device could in some cases accelerate the time of intubation by a few minutes, but in no case could it be the root cause of the intubation. The risk is to patient. There is no risk for the user. There will be no residual risk if the FSN advice/action is taken.
2.	3. Probability of problem arising
	This will happen each time a patient requires the maximum threshold i.e. 20L / min for adult patients or 10L / min for paediatric patients. However, the FreeO2 device is used to treat spontaneously breathing patients who require between 0.1L / min and 20L / min of oxygen and the ratio of patient requiring the maximum threshold is low.
	4. Predicted risk to patient/users

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2.	Reasonably acceptable, No new harm to patient. However, intubation could be required more quickly than if the device had not had this behaviour (momentary decrease in oxygen dosage)
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	We became aware of the issue after receiving a communication from a user of the device. A COVID-19 patient requiring high dosage of Oxygen (up to the limit of 20L/min) required an intubation. The patient's state of health is at the origin of the severity of the situation. The behaviour of the device could in some cases accelerate the time of intubation by a few minutes, but in no case could it be the root cause of the intubation. The root cause of the reduction of oxygen supply when the maximum is reach is a deficiency in the software
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.OxyNov has taken two steps to resolve this issue: 1) implement a short-term solution by modifying the software parameters. 2) implement a long-term solution by modifying the software.	
3.	2. By when should the action be completed?	Ideally, within one month of receiving the letter
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No N/A	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.OxyNov has taken two steps to resolve this issue:	

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	1) implement a short-term solution by modifying the software parameters. 2) implement a long-term solution by modifying the software.	
3	6. By when should the action be completed?	1) implement a short-term solution by modifying the software parameters. (Available now) 2) implement a long-term solution by modifying the software (To be available in about 90-120 days).
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
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.	

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item. Yes, when the long-term solution becomes available
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Providing the long-term solution, new software update	
4	6. Anticipated timescale for follow-up FSN	In about 90 days
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Appendix 1. List of S/N distributed within the Kingdom of Saudi Arabia
4.	10. Name/Signature	**Nathalie Racette** **Quality Assurance and Regulatory Affairs Manager**
		

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

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Appendix 1. List of S/N distributed within the Kingdom of Saudi Arabia

Serial Number
11001-2001-0022
11001-2001-0023
11001-2001-0024
11001-2001-0025
11001-2001-0026
11001-2001-0027
11001-2001-0028
11001-2001-0029
11001-2001-0030
11001-2002-0002
11001-2002-0003
11001-2002-0004
11001-2002-0005
11001-2002-0006
11001-2002-0007
11001-2002-0008
11001-2002-0009
11001-2002-0010
11001-2002-0011
11001-2002-0012
11001-2002-0013

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