Field Safety Notice

Xhale Assurance, Inc.

Nasal Alar SpO2 Sensor
FSN20190508

May 2019

URGENT - Medical Device Correction
Nasal Alar SpO2 Sensor – Updated Instruction in IFU

Dear Customer,

An update has been made to the Xhale Assurance Nasal Alar SpO2 Sensor Instructions for Use (IFU) for revisions 10412_7 and prior (i.e. 10412_6, 10412_5, etc.) as well as 10358_6 and prior. Your Nasal Alar SpO2 Sensors remains safe to use.

These IFUs are missing instruction related to the checking and changing of the application site procedure.

This instruction is developed to reduce the risk of patient developing pressure injuries at the application site of the Nasal Alar SpO2 Sensor.

This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients
- the actions planned by Xhale Assurance to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please refer to the following pages, which provide information on the missing warnings and instructions for actions to be taken. Follow the “Action to be taken by Customer/User” section of this notice. This issue has been reported to the appropriate regulatory agencies.

It is imperative that all end-users with affected Xhale Assurance Nasal Alar SpO2 Sensors as identified in the “AFFECTED PRODUCTS” section of the FSN, receive this Device Correction Notice. Because Xhale Assurance sells these products through distributors, including your organization, we may not have the information to contact all users. Therefore, send a copy of the attached Field Safety Notice to any customer to whom you have distributed one of the affected devices.

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I sincerely regret the inconvenience that this may cause you. Your satisfaction with Xhale Assurance products and with our response to this issue is very important to us. Please contact Xhale Assurance at 1-352-271-2734 with questions or concerns about this correction.

Sincerely,

Jeffrey Hoebelheinrich
Head of Quality & Regulatory Affairs
Xhale Assurance, Inc

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AFFECTED PRODUCTS	The Xhale Assurance Nasal Alar SpO2 Sensor **REF Code** 0303 0201-A01
PROBLEM DESCRIPTION	Updated instruction for checking and changing the application site is missing from the Nasal Alar SpO2 Sensor revisions 10412_7 and prior as well as 10358_6 and prior.
HAZARD INVOLVED	If the user is not aware of the appropriate check and change site procedure, the patient is at an increased risk to develop pressure injuries at the application site.
HOW TO IDENTIFY AFFECTED PRODUCTS	Nasal Alar SpO2 Sensor Instructions for Use for revisions 10412_7 and prior (i.e. 10412_6, 10412_5, etc) as well as 10358_6 and prior. This reference number is found on the lower right corner of the IFU.
ACTIONS PLANNED BY XHALE ASSURANCE	Xhale Assurance is voluntarily initiating a correction consisting of: • Distribution of this Field Safety Notice (FSN) and an IFU Addendum that provides the updated instruction.
ACTION TO BE TAKEN BY CUSTOMER / USER	The enclosed Nasal Alar SpO2 Sensor IFU Addendum must be inserted into each case of sensors for ready reference. A copy of the attached Field Safety Notice and IFU Addendum must be sent to any customer to whom you have distributed one of the affected devices. Complete and return the attached Customer Reply Form.