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.

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 PHILIPS	Xhale Assurance is voluntarily initiating a correction consisting of: • Distribution of this Field Safety Notice (FSN) and the attached IFU Addendum providing the updated instructions.
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. The information provided in the Nasal Alar SpO2 Sensor IFU Addendum must be reviewed with all members of your staff whom need to be aware of the updated instructions. Complete and return the attached Customer Reply Form.

Nasal Alar SpO_2™ Sensor

Addendum - Directions For Use

Check and Change Application Site Periodically

The sensor application site should be inspected at least every 4 hours and changed every 8 hours or as necessary if circulation or skin integrity is compromised. For patients with low perfusion or other medical conditions that would increase the risk for skin necrosis, the site should be inspected at least every 2 hours and application site changed every 4 hours.

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

CE 0086

Rx only

Manufactured by:
Xhale Assurance, Inc.
3630 SW 47th Ave., Suite 100
Gainesville, FL 32608, USA
www.xhale.com/assurance
(855) 743-4589

Vérification et changement réguliers du site d'application

Le site d'application du capteur doit être inspecté au moins toutes les 4 heures et modifié toutes les 8 heures, ou dès que cela est nécessaire, en cas d'altération de la circulation ou de l'intégrité de la peau. Pour les patients présentant une faible perfusion ou toute autre pathologie susceptible d'accroître les risques de nécrose cutanée, le site d'application doit être inspecté au moins toutes les 2 heures et modifié toutes les 4 heures.

Regelmäßiges Kontrollieren und Wechseln des Messorts

Der Messort des Sensors sollte mindestens alle 4 Stunden untersucht und mindestens alle 8 Stunden bzw. nach Bedarf gewechselt werden, falls Durchblutung oder Hautintegrität beeinträchtigt sind. Bei Patienten mit Minderdurchblutung oder anderen Erkrankungen, die die Gefahr einer Hautnekrose erhöhen, sollte der Messort mindestens alle 2 Stunden untersucht und alle 4 Stunden gewechselt werden.

10412_7_EUAddendum

Nasal Alar SpO_2™ Sensor

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Customer Reply for FSN20190508

Nasal Alar SpO2 Sensor IFU

Please complete and fax to +1 (352) 375-3133 or email to jeffrey.hoebelheinrich@philips.com

Customer ID #	
Contact Name	
Telephone Number	
Email Address	
Facility Name	
Street Address City, State, Zip	

Please fax or email this completed form to the number or email address provided above.

CUSTOMER ACKNOWLEDGEMENT:

The enclosed Nasal Alar SpO2 Sensor IFU Addendum must be inserted into each case of sensors for ready reference.

The information provided in the Nasal Alar SpO2 Sensor IFU Addendum must be reviewed with all members of your staff whom need to be aware of the updated instructions.

_____ _____

CUSTOMER NAME (please print) **TITLE**

_____ _____

CUSTOMER SIGNATURE **DATE**

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Please email the completed reply form to jeffrey.hoebelheinrich@philips.com or fax it to +1 352-375-3133. If you experience difficulty carrying out the instructions contained in this communication, Jeffrey Hoebelheinrich at +1 352-271-2734.