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C.F./P.IVA 01063890394 · Registro Imprese di Ravenna n. 01063890394
Capitale Sociale € 98.800,00 interamente versato

16th June 2016

Urgent Field Safety Notice

Affected Product: **DEAS Autofeed Humidification Chamber**
Affected Part Numbers: **1035609, 1045770, 1044015, 1044016**
FSCA reference: **2016-00088**
FSCA action: **Revision of the Instructions for Use (IFU)**
Concerned Document: **Instructions for Use, p/n 05383 Rev 5, 2015-05**

DEAS is sending you this important safety communication to inform you that additional warnings are being implemented in the Instructions for Use (IFU) for our Autofeed Humidification Chamber. This Field Safety Notice is only for information purpose and no devices need to be returned. All future devices will include the updated Instructions for Use.

Reason for this field safety notice

The updates to the IFU are being made to better emphasize the destination of use of our Autofeed Humidification Chamber and that it is not intended to be used during patient transportation, in response to a recent adverse incident report about a tracheostomised patient transported into the hospital on a heated wire breathing circuit with humidification chamber connected to a Philips Respironics Trilogy ventilator and a Intersurgical humidifier.

Actions to be taken by the user

1. Use DEAS Autofeed Humidification Chamber only in accordance with the revised indications for use in the IFU as set out below.
2. Complete the return slip and forward it to our UK distributor, Philips Respironics (UK) Ltd., to confirm receipt of this Field Safety Notice.
3. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.
4. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Adjustment in the Instructions for Use

The safety-related changes are listed below, as additions to current Warnings that can be found in the product's IFU:

a. Humidification chamber with autofeed system for invasive (patients that have bypassed airways) and non invasive ventilation **for patients being treated in hospital or home environment.**

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b. Warning! Do not use the humidification chamber during the transport of patients as undulating and sudden movements and the airflow of the ventilator could cause water to spill out of the breathing circuit chamber, which may reach the patient's airways.

Please share this notice with others in your organization who may be affected by this action. Please also note that DEAS has informed the relevant Competent Authorities about this Field Safety Notice and the updated Instructions for Use.

We apologize for any inconvenience this may cause, however we find it important to assure that you are aware of these recommendations for optimal care of patients in your practice. If you need any further information or support concerning this information, please contact our UK distributor, Philips Respironics (UK) Ltd.

Yours Faithfully

Domenico Scardovi
Quality Assurance manager
DEAS s.r.l.

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Confirmation of receipt

I / We confirm receipt of the Field Safety Notice relating to DEAS Autofeed Humidification Chamber, distributed by Philips Respironics (UK) Ltd.

Product Part Numbers: **1035609**
1045770
1044015
1044016

I / We will ensure that all necessary personnel will be made aware of this notice.

Name of Organisation / Hospital: _____

Department: _____

Name and Title: (please print) _____

Signed: _____

Date: _____

Please return this form as soon as possible to:

Philips Respironics (UK) Ltd Customer Services

Fax: 0800 1300 845

Or email: rukcustomerservices@philips.com

THANK YOU