

[Name Surname]
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Atos Medical AB
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242 22 Hörby
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March 24, 2021
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PLEASE NOTE, THIS LETTER CONTAINS IMPORTANT INFORMATION WHICH REQUIRES YOUR ATTENTION.

Urgent Field Safety Notice – 2021-03-24

Provox Life Night HME - Device may be inserted sideways and, in rare cases, be pushed through the adhesive coupling.

This Field Safety Notice concerns the following product codes:

8262 Provox Life Night HME
8224DK Provox Life Coming Home Denmark
8224FI Provox Life Coming Home Finland
8224NL Provox Life Coming Home Netherlands



This FSN concerns the following LOT numbers

2001187, 2008128, 2009130, 2009237, 2009246, 2010128, 2011019, 2011094, 2011159, 2012003, 2012123, 2012124, 2012158, 2101064, 2102147, 2102148, 2102149

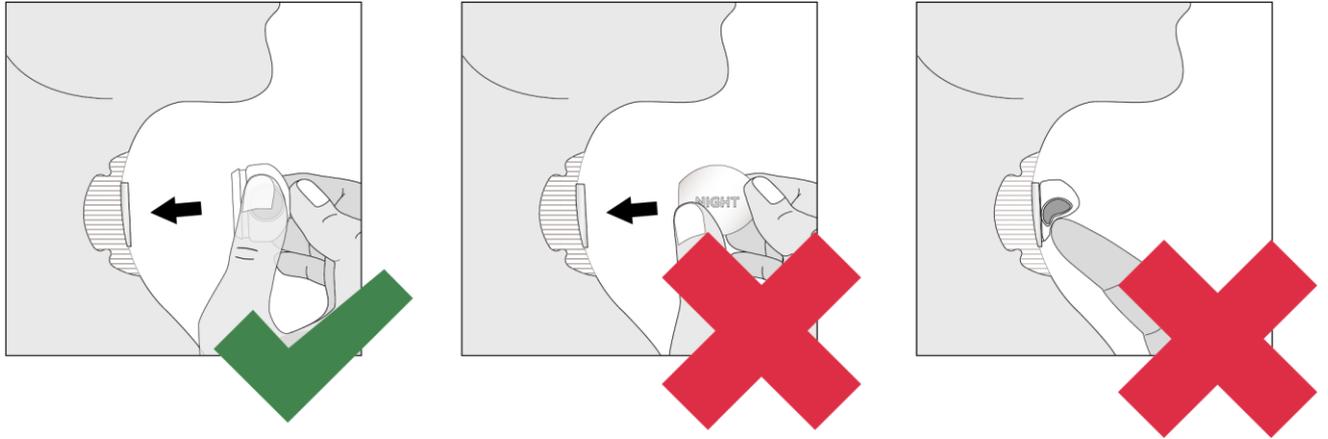
Why are you receiving this notice?

You are receiving this notice because our records indicate you are using a heat and moisture exchanger (HME) named Provox Life Night. Because your safety is our top priority, we are making you aware of a potential risk if the HME is inserted incorrectly or forcefully.

Atos Medical is proactively sending you this notification to ensure safe use of the Night HME.

Problem description

It has come to our attention that Provox Life Night HME may be inserted sideways through the adhesive coupling. Provox Life Night HME is designed to be soft and comfortable so that it does not interfere with your sleep. As a result, the material is pliable and the HME may (in rare cases) be inadvertently pushed through the adhesive coupling if held sideways when attaching or if inserted forcefully.

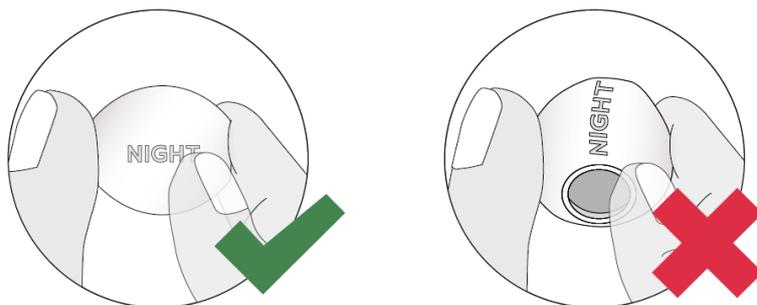
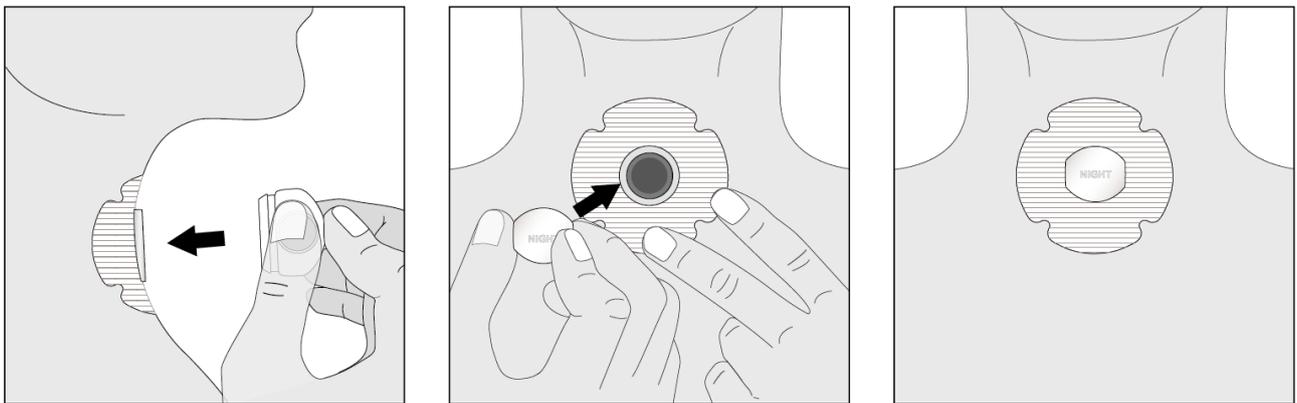


Potential risk

Inserting the HME sideways may result in the stoma being occluded and may restrict your breathing. Pushing the HME forcefully through the adhesive coupling may block your stoma and windpipe.

What should you do?

Please pay close attention when connecting Provox Life Night HME to the adhesive. Start by holding the HME by the occlusion holes (side openings) between your thumb and middle finger. With your index finger on the top of the HME (where the word 'Night' is imprinted), press lightly until the HME clicks onto the adhesive coupling.





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Do not squeeze the sides of the HME and do not force it into place. Connecting to the adhesive should not require force. Use a mirror when first learning how to use the product or when in doubt.

You can continue using your products safely when following the guidelines above.

Forwarding of this safety information

Our records show that you have received the products listed above which are affected by this safety information. Please let us know if this information is incorrect.

Contact

We appreciate your time and attention in reading this important notification and apologize for any inconvenience this may have caused. Please know that your safety and satisfaction are our top priority.

As always, we are here to support you. Please contact us immediately if you have any questions or concerns or need assistance.

Your local representative is:

Placeholder line for automatic insert of customer specific local contact during mail merger.

John Wennborg
Vice President Quality Assurance & Regulatory Affairs
T. +46 415 19888
John.Wennborg@atosmedical.com

Atos Medical AB

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<https://www.atosmedical.com>



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Customer acknowledgement and reply form

Re: Urgent Field Safety Notice – 2021-03-24

Provox Life Night HME - Device may be inserted sideways and pushed through the adhesive coupling

Notification ID:

GB-21-003

Please acknowledge that you have received and that you understand the information provided.

You can provide your acknowledgement in one of two ways:

1. Via Email

send an email to: quality.se@atosmedical.com with the above acknowledgement

Notification ID-number in the subject line (click the link)

2. Via Telephone

to your local Atos Medical office. Please call your local Atos Medical on the below number and give them the **Notification ID-number upon request**.

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Please note that the Notification ID provided above is a sample code that will be replaced during the mail merger process.