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Urgent Field Safety Notice (FSCA OCT20171 EN)

Product:	**Breas Vivo 60 Home Care Ventilator**
Affected devices:	**Vivo 60 devices delivered to Japan, Sweden and Germany between 4-12 April 2017**
Action:	**Replace Outlet Cover**

Date: October 19, 2017

Attention: Home Respiratory Care, Subacute Respiratory Care, Nursing, Risk Manager, Home Care Providers, DMEs, Service Providers, Biomedical Engineering, Sales Offices

Details on affected devices:
All Vivo 60 ventilators [2161XX/ 2163XX] delivered to Japan, Germany and Sweden between 4-12 April 2017

Description of problem:
Breas Medical AB has identified a potential risk associated with its Vivo 60 ventilators in configurations with a dual limb circuit or a single limb circuit with exhalation valve. Due to an error in the molding process of the Outlet Cover in one batch, there may be a risk that the hole in the center of the outlet tube (controlling the exhalation valve) may be partially or completely obstructed by residual plastic material.

Statistical analysis of production records has revealed that this issue may have occurred in a limited number of devices produced and shipped in the period 4-12 April 2017 and that these devices were shipped to three countries only (Japan, Sweden and Germany).

In case the hole in the outlet cover is obstructed, the device will not pass the pre-use test and the error will be detected prior to patient treatment. This only affects the performance when using Vivo 60 with dual limb circuit or single limb circuit with exhalation valve. Vivo 60s used with leakage circuits will still work correctly.

> **Note:** The Instructions for Use stipulate that the pre-use test must be performed when preparing the ventilator for use and in other cases, e.g. when changing the type of patient circuit or insert. Moreover, the Vivo 60 ventilator always reminds the user to perform a pre-use test when starting the device.

The risk assessment concluded that the probability of these events is remote. Although remote, a failure could lead to a critical situation for the patient if the *General User Precautions* outlined in the Vivo 60 Operating Manual are not strictly followed. Breas concludes that continued use of the device is not likely to cause any immediate hazard to the patient, user, care giver, or any other person if the ***General User Precautions*** **outlined in the Vivo 60 Operating Manual are strictly followed**.

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Solution to the problem

To solve this potential problem, Breas initiates a mandatory replacement of the Outlet Covers in all devices that have been identified as potentially involved. This replacement may be done by authorized service providers or by Breas service department. Breas will provide an instruction for the replacement of the Outlet Covers.

Actions to be taken by the distributor, caregiver and user:

1. **Identify the location of all devices identified as potentially involved following the list of serial numbers provided by Breas.**

2. **Strictly adhere to the General User Precautions outlined in the Vivo 60 Operating Manual: When a patient is treated there should always be a trained caregiver present to respond to alarms or conditions the patient is unable to solve on his or her own. If used as life support ventilator, requirements in ISO 10651-2 (Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 2: Home care ventilators for ventilator-dependent patients) needs to be followed including, but not limited to, that emergency equipment (e.g., a resuscitation bag) should be available at all times.**

3. **Replace the Outlet Covers in all potentially involved devices. This may be done by authorized service providers or by Breas Service department. Breas will agree on the preferred option with each customer.**

   Note: Breas will provide an instruction for the replacement of the outlet cover.

4. **The replacement of the Outlet Cover, detailed to the serial number of the ventilator must be confirmed using a Replacement Confirmation Form.**

   Note: The replacement of the Outlet Cover should be completed and confirmed urgently, at the latest within 6 months after reception of the notification.

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Transmission of Field Safety Notice (if appropriate):
This notice needs be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Also, please transfer this notice to other organizations on which this action has an impact.

Should you have any concerns or if you require further clarification please contact your local Breas representative.

The undersigned confirms that the appropriate regulatory agency will be notified consistent with applicable regulations.

Breas Medical strives to develop, manufacture and distribute products with the utmost quality. We thank you for acting promptly on this Field Safety Notice despite any inconvenience this may cause you or your organization. Furthermore, so that we may adequately track the status of the implementation of the actions specified in this notice, we request that you acknowledge your receipt of this notice and then confirm once you have completed the steps outlined above. We truly appreciate your assistance and cooperation with our efforts to further improve patient safety.

Sincerely,

[redacted]

Breas Medical AB
Foretagsvagen 1
SE-435 33 Molnlycke
Sweden
Email: quality@breas.com