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Urgent Field Safety Notice (FSCA NOV 20141 EN)

Product:	**Breas Vivo 50 Home Care Ventilator**
Affected devices:	**All Devices (with firmware versions 2.04 or below)**
Action:	**Mandatory firmware upgrade**

Date: November 18, 2014

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 50 ventilators [215YXX] with firmware version 2.04 or below.

Description of problem:
Breas Medical AB has identified a potential risk associated with its Vivo 50 ventilators. In very rare instances, a series of unusual conditions can combine to cause a malfunction in the keypad of the Vivo 50 ventilator that could result in an unintended treatment termination. This malfunction is erroneously interpreted by the device as a *Stop treatment* instruction from the user and thus an alarm will not sound or be registered. Accessories and monitoring equipment connected to the Vivo 50 will stop functioning as the device enters stand-by mode.

Since this issue has been identified, Breas has been able to confirm only a very low number of reports world-wide in the last 5 years where a malfunction of the type described above has occurred and has determined the probability for occurrence to be *Improbable*. Although improbable, a failure would result in complete loss of mechanical ventilation without the sounding of any alarms, which could lead to a critical situation for the patient if the *General User Precautions* outlined in the Vivo 50 Operating Manual are not strictly followed.

Investigations have shown that devices that have been cleaned or sanitized using excessive amounts of liquids or sprays may be more likely to experience this malfunction. However, use of excessive amounts of liquids or sprays does not appear to be the sole or primary cause of this malfunction in all cases.

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 50 Operating Manual are strictly followed.

Breas has developed a new firmware version (2.07) to resolve this issue. This firmware version will include a change to the procedure for *Stop treatment*, which eliminates the risk of the device erroneously entering *Stand-by mode* without alarm.

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

1. **Until the device has been updated to firmware version 2.07 or above, the *Remote Alarm* and *Nurse Call* system accessories should not be used.**

2. **Strictly adhere to the *Instructions for Use* in respect to cleaning the Device: Never apply any liquids directly on a Vivo 50 ventilator by spraying, splashing or pouring. Use a moistened lint-free cloth when cleaning. Do not use an excessive amount of liquid when cleaning a Vivo 50 ventilator.**

3. **Strictly adhere to the General User Precautions outlined in the Vivo 50 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.**

   Note: Do not use the Vivo 50 ventilator in the event of suspected damage to the device. In these cases, contact the patient's responsible care provider for an inspection.

4. **All Vivo 50 ventilators with firmware version 2.04 or below should immediately be upgraded to firmware version 2.07 or above.**

   Note: The firmware upgrade can be performed in the device's current use environment (e.g. home, hospital or care facility) and should be performed by an authorized representative.

   Note: A leaflet explaining the resulting changes in the Vivo 50 Operating Manual will be distributed

   Note: After the device is updated to firmware version 2.07 or above, the Remote Start/Stop accessory can only be used to start treatment and pause alarm sound indications.

5. **The upgrade of each unit detailed to the serial number must be confirmed using a Customer Reply Form.**

   Note: The firmware upgrade should be completed and confirmed urgently, at the latest within 6 months.

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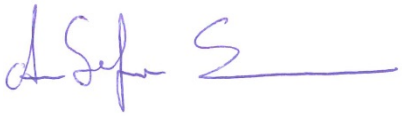
Transmission of Field Safety Notice (if appropriate):
This notice needs be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Also, please transfer this notice to other organizations on which this action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



Ann-Sofie Svensson, VP Quality and Regulatory Affairs
Breas Medical AB
Foretagsvagen 1
SE-435 33 Molnlycke
Sweden
Email: quality@breas.com