

## **Medical Devices Safety Notice**

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Vivo 45 LS
Device Model	230480
Serial No.	K370396 M180089 M180186
Manufacturer	Breas Medical SB
Country of Origin	Sweden
Reference	<u><a href="#">Attached</a></u>
Reason of Alert	NHRA initiates this FSN due to firmware issues in Vivo 45 LS devices, where earlier versions may trigger unnecessary Internal Function Failure 2 alarms, potentially delaying treatment initiation.
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative Skype Medical Equipment at <a href="mailto:INFO@SKYPMED.COM">INFO@SKYPMED.COM</a> & <a href="mailto:SUPPORT@SYPMED.COM">SUPPORT@SYPMED.COM</a> .

**Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.**

For more information please contact [Medical\\_Devices@nhra.bh](mailto:Medical_Devices@nhra.bh)

Mölnlycke, 18 November 2024

**NOT APPLICABLE IN THE UNITED STATES****Subject: FIELD SAFETY NOTICE – Firmware Version 3.1.10 and Later for Vivo 45 LS (non-US) Devices**

Dear valued Healthcare Provider,

Breas Medical advises healthcare providers to update Vivo 45 LS (non-US) devices to firmware version 3.1.10 or later during the next scheduled regular maintenance, or within 12 months, in accordance with the Instructions for Use and the Service Manual. This update was introduced in all markets except Singapore and Malaysia in September 2023 and includes an enhanced detection of Internal Function Failure 2 conditions prior to start of treatment.

The above notice is not applicable to devices that already have firmware version 3.1.10 or later. However, please note that the instruction to update device firmware to the latest released firmware version during scheduled regular maintenance applies to all Vivo 45 LS devices.

Breas Medical announced the 3.1.10 firmware to distributors and authorized service centers through a Product bulletin in September 2023. The firmware update tool was made available for download on Oct 2<sup>nd</sup>, 2023.

It has come to our attention through reports from users that earlier software versions may cause Vivo 45LS ventilators to unnecessarily generate Internal Function Failure 2 alarms, inhibiting the start of treatment and requiring a manual reset. Breas Medical wants to ensure that healthcare providers are informed about the firmware update with enhanced Internal Function Failure 2 detection. Therefore, please distribute this notice to all personnel responsible for maintenance of Vivo 45 LS devices in your organization.

**Description of the Firmware Enhancement**

The Vivo 45 LS performs a check of the pressure sensors before start of treatment, as part of a process to ensure accurate pressure measurements. If the main pressure sensor fails this check, the device will alarm with Internal Function Failure 2. The updated firmware makes the check less susceptible to non-zero readings which are unrelated to a main sensor fault condition, thereby reducing the likelihood of triggering the Internal Function Failure 2 alarm unnecessarily. This does not affect the accuracy or reliability of the pressure measurement, which are ensured through calibration and continuous checks during treatment.

Please note that Internal Function Failure 2 alarms can only occur before treatment has started and not during treatment. There is no anticipated risk to patients associated with



Internal Function Failure 2 alarms when the device is used in accordance with the Instructions for Use.

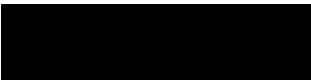
**How to check the firmware version on the Vivo 45 LS device**

**Make sure the device is in Ventilator Standby mode and not connected to a patient.**

On the front panel, press the navigation button labeled “Others”. Press the Up button until “Device Information” is highlighted, then press the Right button. The Firmware Version is displayed in the menu.

If you require assistance with the firmware upgrade process or need further information, please contact your supplier of the Vivo 45 LS device, your local Breas representative or Breas technical support at [techsupport@breas.com](mailto:techsupport@breas.com).

Sincerely,



Global Product Manager, Ventilation

Breas Medical