NOT APPLICABLE IN THE UNITED STATES

Subject: URGENT FIELD SAFETY NOTICE – Firmware Version 3.2.1/7.2.1 for Vivo 45 LS (non-US (CAPA-385)

FSN Reference number:	CAPA-385 / 6.6.2-2026-032810
FSN Date:	17 April 2026
Affected Products:	Vivo 45 LS (non-US) (REF 230000)
Affected units:	• Devices distributed between 23 March 2026 and 02 April 2026, with serial numbers between 1R070KF and 1R100F9, manufacturing date between 2026-02-13 and 2026-03-05, and firmware version 3.2.1 or 7.2.1. • Devices updated on or after 23 March 2026 to firmware version 3.2.1 or 7.2.1.
Manufacturer:	Breas Medical AB

Dear valued Healthcare Provider,

Breas Medical AB is issuing this Field Safety Notice to inform affected customers, distributors, and healthcare providers of a firmware-related defect affecting a limited number of Vivo 45 LS (non-US) ventilators with firmware version 3.2.1 or 7.2.1 which was released for distribution 23 March 2026. Earlier or later distributed devices and firmware versions are not affected by this issue. The issue does not affect Vivo 45 or Nippy 4 models, or Vivo 45 LS firmware versions for the United States, Japan, Malaysia, or Singapore.

In devices with the affected firmware versions, treatment in volume-controlled ventilation modes (VCV, VCV-SIMV and VCV-MPV) can, under specific trigger conditions, result in delivered tidal volume being reduced significantly below set value. The issue can only occur during active VCV therapy and may be triggered following clearance of a disconnection alarm or high-pressure condition, or after certain stop/start treatment sequences. Pressure ventilation modes are not affected by this issue.

If this condition is triggered, the device will remain in a low tidal-volume state and continue to alarm. The condition will generate an immediate low-pressure alarm and may also trigger low tidal volume, low minute volume, and obstruction alarms, if these alarms are configured appropriately for the patient. If this condition occurs, first attempt to stop and then start treatment. If this does not clear the condition, then contact your responsible care provider.

The issue was identified internally by Breas, and has been corrected in firmware versions 3.2.3 / 7.2.3 released on 16 April 2026. Breas is not aware of any reported incidents related to this issue.

Breas Medical advises notified healthcare providers to update affected Vivo 45 LS (non-US) devices to the corrected firmware versions as soon as possible and within thirty (30) days. This notice does not apply to devices that have any other firmware version. Please note, however, that the Instructions for Use require that device firmware be updated to the latest released firmware version during scheduled maintenance.

Please forward this notice to all relevant staff within your organization and, where applicable, to any customers and users to whom you have supplied potentially affected devices.

IMPORTANT: Please acknowledge receipt of this notice by completing and returning the attached Response Form within 30 (thirty) days.

Advice to Users

- Affected devices may continue to be used pending firmware update, provided they are used in accordance with the Instructions for Use, the alarm settings are configured appropriately for the patient and therapy, and any alarms are responded to immediately in accordance with the Instructions for Use. Contact your responsible care provider in the event that the device does not perform as expected.

Action Required by Distributors and Healthcare Providers

Distributors and healthcare providers should take the following actions on receipt:

- identify and quarantine all Vivo 45 LS (non-US) devices in your possession that are running firmware version 3.2.1 or 7.2.1 until they have been updated to corrected firmware;
- identify and delete all downloaded copies of Upgrade Tool (UGT) versions 1.6.77 and 1.6.78, and instruct any party to whom you have provided these copies to do the same;
- identify all customers and users who may have received an affected device or may have updated a device using UGT version 1.6.77 or 1.6.78 on or after 23 March 2026, and determine whether those devices are used in VCV mode;
- for devices used in VCV mode, ensure that users are informed, that the low pressure alarm and low tidal volume alarm are checked and set appropriately for the specific patient, and that users are reminded to respond to alarms in accordance with the Instructions for Use;
- update of all affected devices to corrected firmware version 3.2.3 / 7.2.3 using UGT versions 1.6.82 and 1.6.83 as soon as possible and no later than thirty (30) days from receipt of this notice; and
- complete and return the attached Response Form within thirty (30) days.

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

- On the front panel, press the navigation button labelled “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.

Sincerely,

Vishnu Vardhan Pully

Therapy Area Director, Life Support Solutions

Breas Medical

Field Safety Notice Response Form

Please complete, sign and return this form within 30 (thirty) days via email to fsn@breas.com .

1. Field Safety Notice (FSN) information	
FSN Reference number:	CAPA-385 / 6.6.2-2026-032810
FSN Date:	17 April 2026
Affected Product:	Vivo 45 LS (non-US) (REF 230000)
Affected units:	Devices distributed between 23 March 2026 and 02 April 2026 (serial numbers between 1R070KF and 1R100F9, manufacturing date between 2026-02-13 and 2026-03-05) with firmware version 3.2.1 or 7.2.1. Devices updated to firmware version 3.2.1 or 7.2.1 on or after 23 March 2026.

2. Respondent Details (* mandatory fields)		
Organization/Company Name*		
Address*	Line 1:	
	Line 2:	
	Postcode:	
	City:	
	Country:	
Contact Name*		
Title or Function		
Telephone number*		
Email*		

3. Actions taken (* mandatory fields)		
3.1	*I confirm that we have received, read and understood this Field Safety Notice.	☐ **YES**
3.2	*We have forwarded this information to relevant staff and customers, as applicable.	☐ **YES** ☐ **NO, please explain:**
3.3	*We have identified and deleted all downloaded copies of Upgrade Tool versions 1.6.77 and 1.6.78, and instructed any party to whom we provided these copies to do the same.	☐ **YES** ☐ **NO, please explain:**
3.4	*We have Vivo 45 LS devices affected by this FSN.	☐ **YES** ☐ **NO**
3.5	*If YES to 3.4: We have identified affected users using the devices in VCV mode, and ensured that those users are informed and that alarm settings have been checked and set appropriately for the specific patient.	☐ **YES** ☐ **NO, please explain:**
3.6	*If YES to 3.4: We have updated all affected devices to corrected firmware version 3.2.3 / 7.2.3.	☐ **YES** ☐ **NO, please explain:**

Printed Name and signature*.	
Date *	