FSN Ref: COM-009266 EN v.0 FSCA Ref: CAPA-154 / 6.6.2-2022-28574

Date: 6 April 2022

Urgent Field Safety Notice
Vivo 45, Vivo 45 LS Ventilators

For Attention of*:Distributors, Customers and Clinical Users of Vivo 45 and Vivo 45 LS Ventilators

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Portable Ventilator
1.	2. Commercial name(s)
	Vivo 45, Vivo 45 LS
1.	3. Unique Device Identifier(s) (UDI-DI)
	07321822200007, 07321822300004
1.	4. Primary clinical purpose of device(s)*
	Vivo 45: Vivo 45 is intended to provide non-invasive or invasive ventilation for adult or pediatric patients weighing over 10 kg (22 lbs) who require long-term support or mechanical ventilation for respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea. Vivo 45 is intended for spontaneously breathing patients. **Vivo 45 LS:** The Vivo 45 LS ventilator (with or without the SpO2 and CO2 sensor) is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for paediatric through adult patients weighing more than 5 kg (11 lbs.) The Vivo 45LS with the SpO2 is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The Vivo 45LS with the CO2 sensor is intended to measure CO2 in the inspiratory and expiratory gas. The device is intended to be used in home, institution, hospitals and portable applications such as wheelchairs and gurneys. It may be used for both invasive and non-invasive ventilation. The Vivo 45LS is not intended to be used as an emergency transport or critical care ventilator.
1.	5. Device Model/Catalogue/part number(s)*
	220000, 230000
1.	6. Software version
	Vivo 45: firmware version 1.1.4 or earlier (i.e. lower number) Vivo 45 LS: firmware version 3.1.4 or earlier (i.e. lower number)
1.	7. Affected serial or lot number range
	Vivo 45 serial number ranges Y******, D******, K*******, M01**** – M1403** Vivo 45LS serial number ranges Y******, D******, K*******, M01****- M1403** (* asterisk denotes any digit 0-9)
1.	8. Associated devices
	Not applicable.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The Vivo 45 and Vivo 45 LS ventilators are designed with two processors which monitor each other continually during treatment. Each processor is programmed to generate an alarm if it does not get a signal from the other processor within milliseconds range.

	During an internal bench test of this processor monitoring function, Breas has discovered an exceptional condition where a forced shutdown of one of the processors in the ventilator could cause the ventilator to stop treatment without alarming. The test was performed as a challenge test using a special, internal version of the ventilator firmware, which contains code that is not present in any released version of the firmware.
2.	2. Hazard giving rise to the FSCA*
	Breas has not received any complaints that can be linked to this exceptional condition, and we are not aware of any defect in the current hardware or firmware that could cause this condition in the released device configurations. Out of an abundance of caution, Breas has decided to correct this potential issue with a mandatory firmware upgrade even if there is no confirmed complaint or incident.
2.	3. Probability of problem arising
	Probability of harm has been estimated to Improbable, less than 2×10^{-8}
2.	4. Predicted risk to patient/users
	If the defect would develop into a failure AND the instructions to monitor a ventilator dependent patient are NOT followed, the health consequences could potentially be Permanent impairment or life threatening if medical intervention is not obtained.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The issue was found during an internal bench test.
2.	7. Other information relevant to FSCA
	N/A

3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☒ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

Firmware upgrade to the following firmware versions:

Vivo 45: Version 1.1.7 or later
Vivo 45 LS: Version 3.1.7 or later

3.	2. By when should the action be completed?	Initial response within 30 (thirty) days. Firmware upgrade within 12 (twelve) months.
3.	3. Particular considerations for:	(No particular considerations.)

Is follow-up of patients or review of patients' previous results recommended?
No

3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None 1. Communication to distributors/user of Field Safety Notice/Field Safety Corrective Action. 2. Release of updated firmware versions.	
3	6. By when should the action be completed?	30 April 2023
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Not appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Breas Medical AB**
	b. Address	**Företagsvägen 1, SE-435 33 Mölnlycke, Sweden**
	c. Website address	**www.breas.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	Cover letter, FSN Customer Reply Form
4.	10. Name/Signature	**xxx**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.