FSN Ref: COM-009299 Rev. 1 EN FSCA Ref: SCAR-342 / 6.6.2-2023-85030

Date: 2023-10-06

Field Safety Notice
Vivo 1, Vivo 2, Vivo 3 Ventilators

For Attention of*:Distributors, Customers and Clinical Users of Vivo 1, Vivo 2, Vivo 3 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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Field Safety Notice (FSN)
Vivo 1, Vivo 2, Vivo 3 Ventilators
Replacement of blowers in specific S/N ranges

1. Information on Affected Devices*

1. 1. Device Type(s)*

Portable Pulmonary Ventilator

1. 2. Commercial name(s)*

Vivo 1, Vivo 2, Vivo 3

1. 3. Unique Device Identifier(s) (UDI-DI)

07321822270000, 07321822279003, 07321822280009, 07321822289002, 07321822290008, 07321822299001, 07321820076413

1. 4. Primary clinical purpose of device(s)*

Vivo 1 and 2 are intended to provide non-invasive ventilation for patients weighing over 10 kg (22 lbs) who require long-term support or mechanical ventilation for respiratory impairment, with or without obstructive sleep apnea. Vivo 1 and 2 are intended for spontaneously breathing patients.

Vivo 3 is intended to provide non-invasive or invasive ventilation for 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 3 is intended for spontaneously breathing patients.

1. 5. Device Model/Catalogue/part number(s)*

REF 227000, 227900, 228000, 228900, 229000, 229900, 007641

1. 6. Software version

Not applicable

1. 7. Affected serial or lot number range

Devices and spare parts distributed between 21 July 2023 and 12 September 2023, according to the following table:

REF	Description	Affected serial no ranges	Affected ship dates from – to
227000	Vivo 1 main unit	F290441 – F330676	24 Jul 2023 – 12 Sep 2023
227900	Vivo 1 main unit CN	F310061 – F360380	21 Jul 2023 – 12 Sep 2023
228000	Vivo 2 main unit	F300070 – F360056	27 Jul 2023 – 12 Sep 2023
228900	Vivo 2 main unit CN	F320097 – F360363	11 Aug 2023 – 12 Sep 2023
229000	Vivo 3 main unit	F200266 – F360141; M290007 (repaired)	25 Jul 2023 – 12 Sep 2023
229900	Vivo 3 main unit CN	F310283 – F350563	04 Aug 2023 – 12 Sep 2023
007641	Blower assembly Vivo 1-2-3	2327521369001 - 2331520842073	25 Jul 2023 – 12 Sep 2023

1. 8. Associated devices

Not applicable

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Breas Medical was informed by the supplier of the Vivo 1/2/3 blower in mid-September about a deviation in the Supplier's assembly process affecting the hardening of parts of the adhesive joint on the blower housing. The affected blowers have been used in devices and spare parts shipped from Breas from 21st July 2023 up until 12th September 2023.
2.	2. Hazard giving rise to the FSCA*
	Breas Medical has urgently investigated this issue together with the Supplier. Tests have shown that the affected blowers are performing as intended and maintaining their strength prior to, and upon delivery. However, the Vivo 1/2/3 are specified for a service life of 5 years or 20,000 hours, and Breas Medical cannot accept any uncertainty about the long term durability of the affected blowers. The adhesive has been tested for biocompatibility in final hardened form, however there is a possibility that inadequately hardened adhesive may cause irritation. At this time Breas has no reports of such effects from the market. Out of an abundance of caution, Breas Medical is implementing a Field Safety Corrective Action for the affected Vivo 1, Vivo 2 and Vivo 3 ventilators and will be replacing affected devices and blower spare parts in the field.
2.	3. Probability of problem arising
	Improbable ($p < 10^{-6}$)
2.	4. Predicted risk to patient/users
	Probability of Harm has been estimated to Improbable ($p < 10^{-6}$).
2.	5. Further information to help characterise the problem
	The deviation is not detectable by the user, as the affected devices have passed manufacturing tests and are performing as intended after delivery. The corrective action is implemented while the devices are at the beginning of their service life.
2.	6. Background on Issue
	No other device models or ranges are affected by this problem.
2.	7. Other information relevant to FSCA
	Not applicable.

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 Contact Breas local representative to arrange repair or replacement of affected device.	
3.	2. By when should the action be completed?	Initial response by 31 October 2023. Arrange repair or replacement by 30 November 2023.

3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No N/A	
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. Identification and remediation of affected devices on stock. 2. Communication to distributors/users of Field Safety Notice/Field Safety Corrective Action. 3. Arrange for the repair or replacement of affected devices. 4. Supplier Corrective Action to prevent recurrence.	
3.	6. By when should the action be completed?	31 December 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
	c. Website address	breas.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Cover letter, FSN Customer Response Form
4.	10. Name/Signature	[redacted], SVP Global Quality Assurance and Regulatory Affairs

	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.