BREAS

FSN Ref: REC-008478 (rev.0) FSCA Ref: CAPA-21 / 6.6.2-2020-6255

Date: 6 February 2020

Urgent Field Safety Notice
Protective Cover Vivo 55/65 (part no 006344)

For Attention of*:Distributors, Customers and Clinical Users of Protective Covers for Vivo 55 and Vivo 65

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)*
	Protective cover for Vivo 55 and Vivo 65 series ventilators. Supplied non-sterile.
1.	2. Commercial name(s)
	Protective Cover Vivo 55/65 (part/catalog number 006344)
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not applicable.
1.	4. Primary clinical purpose of device(s)*
	The protective cover is intended for additional protection of the Vivo 55/65 during transportation, and in hospital, institutional and home care environments. It can be used while the Vivo 55/65 is operating, for example mounted on a wheelchair, in a personal vehicle, or carried by hand.
1.	5. Device Model/Catalogue/part number(s)*
	006344
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	Protective covers (006344) distributed between 2018-01-11 and 2019-12-17. (Protective covers do not have serial or lot number.)
1.	8. Associated devices
	Protective Covers when used together with Vivo 55 and Vivo 65 series ventilators in combination with an active exhalation valve circuit or dual limb circuit. Use with a single limb circuit with leakage port is NOT affected.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	When the Protective Cover is used with the Vivo 55/65 ventilator and exhalation valve patient circuits, the interior of the Protective Cover may under certain circumstances, i.e. if significant force is applied to the Protective Cover, obstruct the outlet orifice for the exhalation valve control pressure, located at the bottom of the ventilator. This may cause exhaled air to remain in the patient circuit and the ventilator will consequently alarm for Rebreathing (if alarm is set to ON) and subsequently an Exhalation Valve Failure alarm with high priority audible and visual signals after approximately 60 seconds.
2.	2. Hazard giving rise to the FSCA*
	The hazardous situation associated with this problem is: Excessive carbon dioxide or carbon dioxide build up during ventilation (insufficient carbon dioxide removal). The risk is to patient only, and may only arise if ALL of the following conditions are fulfilled: 1. The device is used in a Protective Cover; 2. The device is used with an exhalation valve circuit or a dual limb patient circuit; 3. Significant force is applied to the Protective Cover; 4. The alarm for Rebreathing is ignored; 5. The Exhalation Valve Failure alarm (with high priority audible and visual signals) is ignored.

2.	3. Probability of problem arising
	From complaint data analysis, the probability of occurrence of the problem is estimated to be Remote.
2.	4. Predicted risk to patient/users
	The potential harm to the patient, should the hazard occur, is hypercarbia. This is deemed possible only under certain conditions when using the Protective Cover with the ventilator, with an exhalation valve patient circuit or dual limb patient circuit, with significant force applied to the Protective Cover AND the supervising person(s) failing to respond to the alarms that will be triggered. The high priority Exhalation valve failure alarm cannot be set to OFF. Responding to alarms and good clinical practices, checking the function prior to use per labeling, would likely prevent a serious adverse patient outcome. The risk assessment has therefore concluded the hazard is not likely to cause or contribute to a serious adverse patient outcome. With the FSN actions/advice taken, the residual risk is deemed acceptable.
2.	5. Further information to help characterise the problem
	No serious incidents have been reported pertaining to this issue.
2.	6. Background on Issue
	Breas was informed by the German medical device authority BfArM about one (1) event in Germany, where a Vivo 55 used with the Protective Cover had alarmed repeatedly for Rebreathing and Exhalation Valve Failure. The patient involved was not injured. Breas' investigation identified the most likely root cause to be that the design of the Protective Cover outlet hole for the exhalation valve control pressure tube under certain circumstances, e.g. if force is applied to the top of the Protective Cover. If this occurs, the ventilator will alarm as intended with Rebreathing after 10 breaths and Exhalation Valve Failure within approx. 60 seconds.
2.	7. Other information relevant to FSCA
	Existing mitigations currently in place to reduce the risk include: •Rebreathing alarm •Technical alarm, exhalation valve control failure •CO2 and EtCO2 alarm (optional) •Instructions for use on checking exhalation valve prior to use •Instructions for use on patient surveillance

	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 1) Identify users/patients using Protective Covers (p/n 006344) with a Vivo 55 or Vivo 65 ventilator. 2) Check if the Protective Cover is used with an exhalation valve circuit or dual-limb circuit. If this is the case, advise users to be observant of Rebreathing alarms and Exhalation Valve Control Error alarms. Inform them that if any of these alarms occur, the small hole at the back cover of the ventilator may be obstructed. This may be

	resolved by ensuring that no force is applied to the front or back side of the Protective Cover. With this precaution, the Protective Covers can continue to be used. 3) If a user prefers, Breas offers to replace Protective Covers (p/n 006344) with new Protective Covers free-of-charge. We can provide you up to the number of the Protective Covers purchased according to our records. The replaced Protective Covers must be destroyed, and confirmation must be provided to Breas via the Distributor/Customer reply form.	
3.	2. By when should the action be completed?	13 March 2020
3.	3. Particular considerations for: (No particular considerations.) Is follow-up of patients or review of patients' previous results recommended? No The hazardous situation is transient in nature and is resolved by the user without need for further intervention.	
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 to be observant of alarms and adjusting use of the product. 2. Optional replacement of affected product. 3. Improvement of the design of the Protective Cover.	
3	6. By when should the action be completed?	Latest by 30 November 2020
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 Choose an item.	

	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 Distributor Reply Form
4.	10. Name/Signature	**xxx** Datum: 2020.02.06 00:38:22 +01'00'

	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.