FSN Ref: FSN 0925 R300_500

FSCA Ref: FSCA 0925 R300_500

Date: 06-October-2025

Urgent Field Safety Notice (FSN)
REANIBEX 300/ REANIBEX 500

For attention of:

- Medical devices surveillance
- External Defibrillators distribution companies
- Users of External Defibrillators

Contact details of local representative
Osatu, S.Coop Edificio Zearrekobuelta, Subida de Areitio 5 48260 Ermua-Bizkaia Spain Phone: +34 943 170 220 Email: calidad@bexencardio.com

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REANIBEX 300 / REANIBEX 500
See section 2.2

1. Information on Affected Devices	
1.	1. Device type(s)
	The **Reanibex 300** is an Automated External Defibrillator (AED) with colour display, incorporating 3D animated graphics and the ability to view the ECG signal. Main options: • Manual overdrive. • GSM. The **Reanibex 500** is specially designed to perform advanced monitoring and resuscitation functions. For this purpose, it has four operating modes: Monitor, Manual Defibrillator, Automated Defibrillator and Non-invasive Transcutaneous Pacemaker (Optional). Main options: • 12 ECG leads • Interpretation • SpO2 • Capnography (EtCO2) • Non Invasive Blood Pressure (PNI) • Transmission (GSM, Bluetooth, USB). • "Push Pad" device 
1.	2. Commercial name(s)
	REANIBEX 300 / REANIBEX 500
1.	3. Primary clinical purpose of device(s)
	The REANIBEX 300 is a portable, lightweight Defibrillator designed to carry out advanced monitoring and resuscitation functions. It offers three operating modes: Manual Defibrillator (optional), Automated Defibrillator and ECG Mode (optional). The REANIBEX 500 is a portable, lightweight Monitor/Defibrillator designed to carry out advanced monitoring and resuscitation functions. It offers four operating modes: Monitor, Manual Defibrillator, Automated Defibrillator and Non-Invasive Transcutaneous Pacemaker (optional).
1.	4. Model (s)
	REANIBEX 300 REANIBEX 500

1.	5. Software versions
	Not applicable
1.	6. Affected serial numbers
	Not applicable

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the problem
	Bexen Cardio has been notified that in certain situations, some users have experienced problems turning on REANIBEX 300 / REANIBEX 500 devices, even to the point of being unable to turn them on. Our investigation of the reports received from customers did not identify any anomalies or non-compliance with the product. All devices were manufactured according to the established specifications. Bexen Cardio has modified the instructions for use provided with the devices to add additional explanations to prevent this situation (see Annex to this FSN).
2.	2. Hazard giving rise to the FSCA
	The potential danger that could arise is that the equipment may not turn on, and therefore cannot be used with a patient.
2.	3. Probability of problem arising
	Based on market experience and considering the number of units in use and the frequency of switching on, the probability of the problem occurring is estimated to be low.
2.	4. Predicted risk to patient/users
	Potential risk of patient death due to inability to turn on or delay in turning on the equipment, which may result in failure to perform or delay in performing defibrillation therapy.
2.	5. Background on Issue
	Two reports have been received from customers in Sweden indicating that they have encountered difficulties or found it impossible to switch on the equipment. Bexen Cardio, in its checks on the equipment and its components as part of its quality system, has not detected any problems with the equipment.

3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User/Distributor** ☐ Identify the device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations X Take note of the amendment/reinforcement of Instructions for Use (IFU) ☐ Other: ☐ None Provide further details of the action(s) identified • Distribute and post this notice to all persons within your organization who need to be aware of it and to any organization to which the affected product has been transferred or distributed. • Complete and submit the attached customer/distributor confirmation form

	See Annex 1 of this document.	
3.	2. By when should the action be completed?	Taking note of the modification/application of the instructions for use (IFU) must be completed as soon as possible after receiving/becoming aware of the FSN.
3.	3. Is customer Reply required?* (If so, attached form specifying the return period)	Yes See attached customer/distributor reply form
3.	**4. Actions being taken by the Manufacturer** ☐ Product removal ☐ On-site device modification/inspection ☐ Software upgrade X Change in labelling or instructions for use (IFU) ☐ Others ☐ None Provide further details of the action(s) identified.	
3	5. By when should the action be completed?	When all affected users are notified of the modification to the instructions for use.
3.	6. Is the FSN required to be communicated to the patient /lay user?	YES
3	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Yes Appended to this FSN	

4. General Information		
4.	1. FSN type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer Information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	OSATU, S. COOP.
	b. Address	Edificio Zearrekobuelta, Subida de Areitio 5 48260 Ermua-Bizkaia (España)
	c. Website	www.bexen.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of annexes attached:	*Customer/distributor Reply form* for confirmation of FSN receipt and answers on

		actions to be taken by the Customer / Distributor
4.	6. Name/Signature	Silvia Almaraz Hernández Responsible Technician and PRRC

	Transmission of this Field Safety Notice
	This notice should be forwarded to all persons who need to be informed within your organisation or to any organisation to which the potentially affected equipment has been transferred (as applicable). Please, forward this notice to other organisations that may be affected by this action (as applicable). Please remain aware of this notice and resulting action for an appropriate period of time to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and to the national Competent Authority if applicable, as this provides important information.

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ANNEX 1:
MODIFICATION OF THE INSTRUCTIONS FOR USE

The purpose of this document is to inform you that Osatu S.Coop. (trademark Bexen Cardio) has published an update to the instructions for use of the REANIBEX 300 and REANIBEX 500 devices. You are receiving this information because our records indicate that you have REANIBEX 300/REANIBEX 500 devices

The updated version of the instructions for use for these devices is:

- REANIBEX 300: Revision U
- REANIBEX 500: Revision J

The modification to the instructions for use is described below:

1. In section '2.1.1 Front view' of both the REANIBEX 300 and the REANIBEX 500 user manual, where the operation of the ON/OFF key is explained, the underlined information is added:

ON/OFF BUTTON. This button is used to switch the equipment on and off. When the equipment is on, this button is illuminated with an LED.

To turn on the equipment, press and hold this key for a few seconds until the power on screen is displayed.

To turn off the equipment, press and hold this key for a few seconds until the power off screen is displayed.

2. In section '2.5 STATUS INDICATOR' of both the REANIBEX 300 and the REANIBEX 500 user manual, where the icons are explained, the following information is added:

   The status of the equipment is only checked during automatic tests (daily, weekly or monthly), at start-up or during operation

3. In section '9.7.5 Auto-Tests' of the REANIBEX 300 user manual and in section '11.7.5 Auto-Tests' of the REANIBEX 500 user manual, the following information is added:

   At the end of the first paragraph

   (temperature range condition only applicable to the monthly tests).

   After explaining how it works in the event that a auto-test could not be performed:

   During the automatic tests, if the device detects that the measured temperature is outside the operating range the daily and weekly tests are carried out normally, but the monthly test is delayed for the next day and a daily test is carried out instead. In this situation, if the automatic test result is OK, the indication TEMP will be saved as the tests result to indicate that the temperature was outside the operating range. If the automatic test result is an error, the error code will be saved.

   The monthly test is only carried out if the temperature is within the operating range.

4. The following information is added to section '11.1 Overview' (11. Maintenance) of the REANIBEX 300 user manual and section '13.1 Overview' (13. Maintenance) of the REANIBEX 500 user manual:

   If the REANIBEX 300/REANIBEX 500 detects a problem that requires service during the auto-test, the status indicator shows the  icon. If his symbol appears try to use the defibrillator if needed for an emergency cardiac situation. However, you should contact authorized service personnel as soon as possible. The icon is displayed until the problem is fixed.

   At the end of the first section:

   If during operation the REANIBEX 300/REANIBEX 500 detects that the measured temperature is outside the operating range, a warning message is periodically displayed.