

## FIELD SAFETY NOTICE

**Commercial name of the affected product:** REANIBEX 300 y REANIBEX 500

**FSCA-Identifier:** RECALL 0118 R300-500

**Type of action:** FSCA Field Safety Corrective Action

---

**Date:** 30/01/2018

**Attention to:** Distribution companies and users of external defibrillators.

### Details on affected devices:

Products: REANIBEX 300 y REANIBEX 500 (see Serial Numbers of affected equipment).

### Description of the Problem:

We have received a customer complaint informing us that several equipment, less than one year old, have their batteries exhausted, without having been used. These are disposable batteries (reference DIS 3100) and are installed in the equipment.

The investigation is started and the manufacturer of these batteries is consulted to analyze them. The study is made on several equipment and it is observed that the equipment in off state has a consumption of 850uA, being this value very high that it entails to the exhaustion of the capacity in a year more or less. Said consumption is insufficient for the battery monitor to be able to count it (<200mA), so that the equipment indicates a higher battery charge value than the real one.

The potential risk that can occur is that the equipment indicates that the battery has enough charge capacity to perform a defibrillation therapy and that, in reality, the battery does not have enough charge to perform the defibrillation therapy.

It is concluded that the functionality of the equipment is not affected, but internally the equipment has a resistive divider that is always consuming around 816uA and it is the cause of the batteries losing their capacity prematurely as long as they are installed in the equipment defibrillator.

The correction that is made is a change in the values of two electronic components (resistors) to reduce the consumption of the equipment in off to approximately 110uA, which allows the batteries to have a self-discharge of more than 7 years. This correction is also made in the defibrillator model REANIBEX 500 because it has the same resistive divider.

## Actions:

1. Check that the serial number of your REANIBEX 300 or REANIBEX 500 is in the List of affected Serial Numbers.
2. If so, remove it, along with its battery (if it is disposable reference DIS 3100) and put them in quarantine, not being able to be used in defibrillation therapy.
3. Contact with your distributor or directly with the manufacturer Osatu S. Coop.
4. Send the REANIBEX 300 or REANIBEX 500, together with its battery if it is disposable (DIS 3100) following the instructions indicated by them.
5. Our After Sales Technical Service will make the correction and the corrected equipment will be returned, along with a new DIS 3100 disposable battery if applicable.
6. All received batteries will be removed and sent for recycling.

## List of affected Serial Numbers:

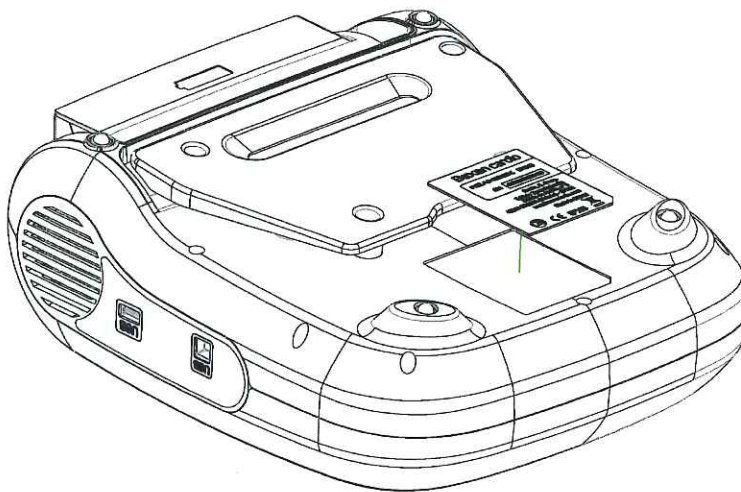
### **Reanibex-300, N/S 2004----:**

20040510, 0531, 0539..0540, 0557, 0583..0584, 0632..0633, 0635, 0639, 0641..0642, 0646, 0655, 0669, 0672..0673, 0714, 0733, 0736, 0774..0775, 0785, 0792, 0822, 0829, 0845, 0896, 0917..0919, 0996..0997, 1006..1007, 1026, 1031, 1037, 1055, 1067, 1190, 1209, 1234, 1281, 1308, 1366, 1377, 1490..1493, 1499..1505, 1507..1514, 1520, 1522..1993

### **Reanibex-500, N/S 2005----:**

20050505, 0525, 0579, 0620, 0625, 0637, 0640, 0642, 0667, 0675, 0676..0746

The Serial Number is found on the label indicated on the drawing and is indicated by the symbol "SN"



**Contact reference person:**

Miguel Angel Aguado Villazán, Responsable Técnico  
Osatu, S. Coop.  
Edificio Zearrekobuelta,  
Subida de Areitio 5  
48260 Ermua (Vizcaya)  
Spain

Teléfono: +34 943 170 220

Fax: +34 943 170 227

Email: [maaguado@bexencardio.com](mailto:maaguado@bexencardio.com)



Signature: Miguel Angel Aguado Villazán