

MEDIVA

Svetonedeljska 62/a

HR-10431-SVETA NEDJELJA.-(KERESTINEC) CROACIA

Tel: 385 1 619 1579 Fax:

E-mail: draga.toth@mediva.hr

Ermua, February 8, 2018

IMPORTANT SAFETY NOTICE

FSCA identifier: RECALL 0118 R300-500

Product trade name: REANIBEX 300 & REANIBEX 500

Required action: Review, in factory, of the affected products

Target group: Distribution companies and users of external defibrillators.

Dear Sirs,

This letter is to inform you about Safety Corrective Action (see Annex) to perform in the defibrillators purchased by you:

<i>Model</i>	<i>Serial Number</i>	<i>Date</i>	<i>Battery</i>
REANIBEX-300	20041877	24-07-2017	Disposable

Please read the letter carefully and follow the steps below:

- 1) Inform customers that you have sold defibrillators, whose serial number is in the above table, the contents of this action through the enclosed LETTER TO FINAL CLIENT.
- 2) Check to see if you have any REANIBEX 300 or REANIBEX 500 whose serial number is in the above table.
- 3) If so, remove it, together with its battery if it is disposable (reference DIS 3100) and put them in quarantine, not being able to be used in defibrillation therapy.
- 4) Contact our Sales Department to specify the collection. Tel: **+34 943170220**, Email: **info@bexencardio.com**. Shipping charges are by OSATU.
- 5) Send the REANIBEX 300 or REANIBEX 500, together with its battery if it is disposable (DIS 3100) following the instructions indicated by them:

- 6) 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.
- 7) All received batteries will be removed and sent for recycling.

We apologize for any inconvenience caused by this issue. However, to allow patients and users to safely utilize our products, these measures have to be taken immediately. We assure you that safety and quality are our first and foremost priorities. Please do not hesitate to contact our sales staff with any questions you may have.

Yours sincerely,



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

LETTER TO FINAL CLIENT

<p>From: MEDIVA Svetonedeljska 62/a HR-10431 SVETA NEDJELJA (KERESTINEC) CROACIA Telefona: 385 1 619 1579 Fax: Email: draga.toth@mediva.hr</p>	<p>To: Name of final client Address Tel: _____ Fax: _____ E-mail: _____</p>
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Place, date

IMPORTANT SAFETY NOTICE

FSCA identifier: RECALL 0118 R300-500

Product trade name: REANIBEX 300 & REANIBEX 500

Required action: Review, in factory, of the affected products

Target group: Distribution companies and users of external defibrillators.

Dear Sirs,

This letter is to inform you about Safety Corrective Action (see Annex) to perform in the defibrillators purchased by you:

<i>Model</i>	<i>Serial Number</i>	<i>Date</i>	<i>Battery</i>
Reanibex-300 and / or Reanibex-500		Sale dates	Disposable And / or Rechargeable

Section 3 explains how to identify the serial number of the product.

Please read the letter carefully and follow the steps indicated in section 2.

1. Description of the defect

Summary: In the affected equipment, it is observed that the equipment in off state has a higher electrical consumption than normal, which leads to the exhaustion of the capacity of the disposable battery in a year or so. This consumption is not enough for the battery monitor to account for it, so the device indicates a higher battery charge value than the real one.

Potential risk: There is a risk that the equipment indicates that the battery has enough charge capacity to perform a defibrillation therapy and, in fact, the battery does not have enough power to get to perform defibrillation therapy.

The correction to be made in the factory is to modify the values of two electronic components (resistors) to reduce consumption of the equipment in off, which allows the batteries to have a self-discharge of more than 7 years.

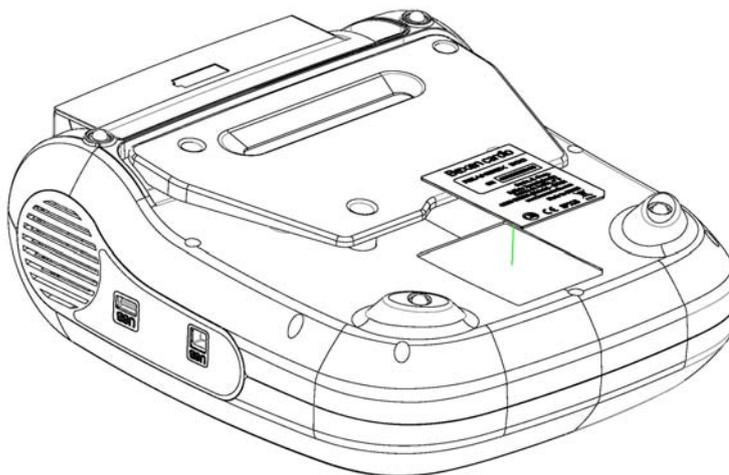
Safety information: With this letter, Osatu S. Coop. informs you of the fact that this safety notices will also be forwarded to the competent authorities. Please note that under existing legislation you are obliged to comply with the requirements of this recall action.

2. Actions

- 1) Check to see if you have any REANIBEX 300 or REANIBEX 500 whose serial number is in the above table.
- 2) If so, remove it, together 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:
MEDIVA
Tel: [385 1 619 1579](tel:38516191579), email: draga.toth@mediva.hr
Or directly with the manufacturer **Osatu S. Coop:**
Tel: [+34 943170220](tel:+34943170220), email: info@bexencardio.com
- 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.

3. Identification of the serial number

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



We apologize for any inconvenience caused by this issue. However, to allow patients and users to safely utilize our products, these measures have to be taken immediately. We assure you that safety and quality are our first and foremost priorities. Please do not hesitate to contact our sales staff with any questions you may have.

Yours sincerely,

Contact person

Position

MEDIVA

Svetonedeljska 62/a

HR-10431 SVETA NEDJELJA (KERESTINEC) CROACIA

Telefona: 385 1 619 1579

Fax:

Email: draga.toth@mediva.hr

Annex



Osatu s.coop
Edificio Zearekobuelta
Subida de Areitio 5
48260 Ermua (Vizcaya) Spain

Tel: +34 943 170 266
Fax: +34 943 170 227
export@bexencardio.com
www.bexencardio.com

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: 26/01/2018

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:

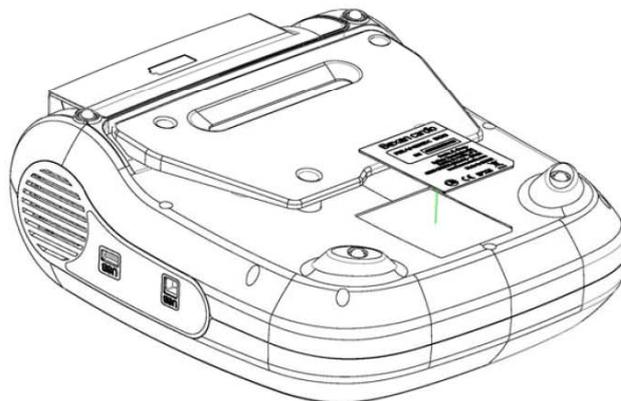
Reanibex-300, N/S 2004----

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"



Bexen cardio

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Edificio Zearrekobuelta
Subida de Areitio 5
48260 Ermua (Vizcaya) Spain

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Contact reference person:

Miguel Angel Aguado Villazán, Responsable Técnico
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Fax: +34 943 170 227
Email: maaguado@bexencardio.com

Signature: Miguel Angel Aguado Villazán

