



Urgent Field Safety Notice - ReoAmbulator

Device Name: ReoAmbulator

Date: June 20, 2017

Type of action: modification of the ReoAmbulator

To whom it may be concerned

Details on affected devices:

The following ReoAmbulator systems of catalogue number REOAA002, require modification:

Product and Distribution Information Table		
Serial Number	Manufacturing Date	Expiry Date
REOAMB-4914-01	02-Dec-2014	Dec-2024
REOAMB-4914-03	02-Dec-2014	Dec-2024
REOAMB-0815-03	18-Feb-2014	Feb-2024
REOAMB-0415-03	21-Jan-2015	Jan-2025
REOAMB-0815-02	18-Feb-2015	Feb-2025
REOAMB-0815-04	29-Jul-2015	Jul-2025
RA-3115012	16-Sep-2015	Sep-2025
RA-3815014	07-Oct-2015	Oct-2025
RA-4115015	07-Oct-2015	Oct-2025
RA-4115017	18-Feb-2015	Feb-2025

Description of the problem:

Following a procedure, the Hoist Crane (the part which holds the patient) fell down and hit the patient's head.

Risk to Health:

The Hoist Crane is the part which holds the patient. Therefore, its fall during a procedure may result in an injury to the patient or the caregiver.

Root Cause of the Fault:

Motorika performed an extensive and comprehensive investigation in order to find the root cause of the problem. It was concluded that the Hoist Crane fell due to a failure mode in the pin that secures it into place. This mode is related to a weak point along the shaft axis of the pin.

Advise on action to be taken by the user:

- Locate the ReoAmbulator device from the affected Serial Numbers.
- Immediately verify the integrity of the device/s in your site according to the attached instructions (see appendix A of this document).
- In the following days a representative of Motorika will contact you in order to set a date for the technician visit, in which the faulty part will be replaced by an improved part, eliminating the weak point.

Motorika Medical (Israel) Ltd.

15 Alon HaTavor Street, PO Box 3562, Caesarea 38900, Israel

Tel: 04-6275559 Fax: 04-6275560

E-mail: info@motorika.com



- Complete the questionnaire at the end of this notice and return to Motorika.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

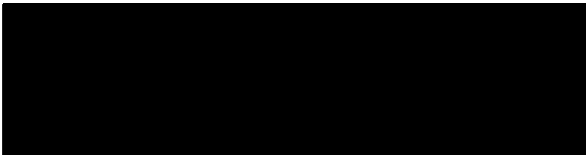
Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Din Hadass
Motorika Medical (Israel) Ltd.
Cell: +972 55 8874775
Email: din@motorika.com
Address: 15 Alon HaTavor Street, Caesarea, 3088900, Israel

The undersign confirms that this notice has been notified the appropriate Regulatory Agency



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Field notice questionnaire – For Customers

Please complete the questionnaire and return it utilizing:

e-mail: din@motorika.com

Fax to: +972 4 627-5560

1. Do you have a ReoAmbulator system of one of the aforementioned serial numbers in your clinic? Yes No
(If NO, terminate questioning, sign the form and return to Motorika)
2. Please fill-in the serial number of the ReoAmbulator system in your facility _____
3. Did you verify the integrity of the ReoAmbulator (Hoist Crane bushing fixation, as detailed in appendix A of this document)? Yes No

Individual completing this form:

Signature

Date

Print Name/Title

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APPENDIX A (document 16WIP074, rev. 1)

ReoAmbulator Hoist Bushing Placement

1. Purpose

The purpose of this document is to provide instructions for the fixation of the hoist bushing into place, and decrease the movement of the hoist crane axis.

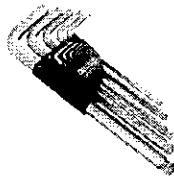
2. Scope

These instructions are related **only** to ReoAmbulator systems of model REOAA002, in which the hoist bushing is visible beneath the hoist covers.

**Note: These instructions should only be performed by a site qualified person (Maintenance engineer etc.).*

3. Recommended Tools

- Set of Alan keys



- Wrench (open 20 mm)



4. Instructions

4.1 Run the system, enter technician screen and:

4.1.1 Verify that the Patient Weight (see figure 4.1) value (in the load cell section) is between ± 1 kg when the hoist isn't loaded at all.

4.1.2 Verify that the covers don't interfere with the hoist measurements:

- Apply a load of 30-40 kg on the hoist.
- Release the load and verify that the reading returns to its initial value within ± 0.5 kg tolerance.

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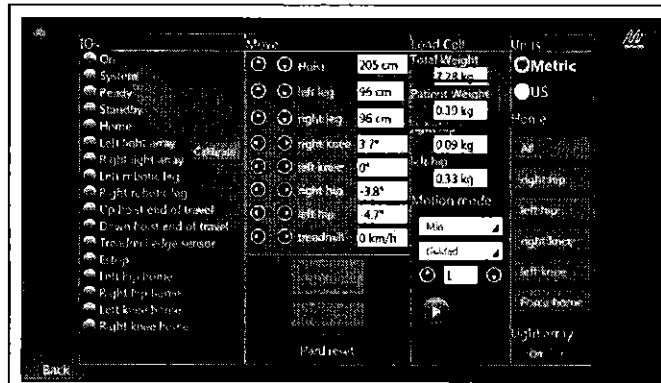


Figure 4.1: Enter technician and check the Patient Weight value

4.2 Turn off the system

4.3 Disassemble the hoist covers, as illustrated in figure 4.2.

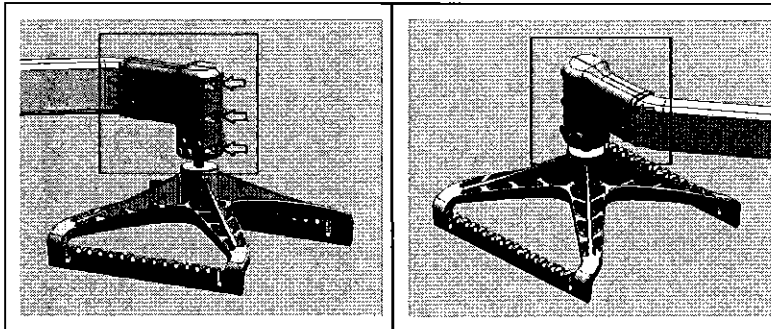


Figure 4.2: Disassemble the hoist covers

4.4 Check whether the bushing is visible. Use figures 4.3 and 4.4 for better understanding of where a loosed bushing may be.

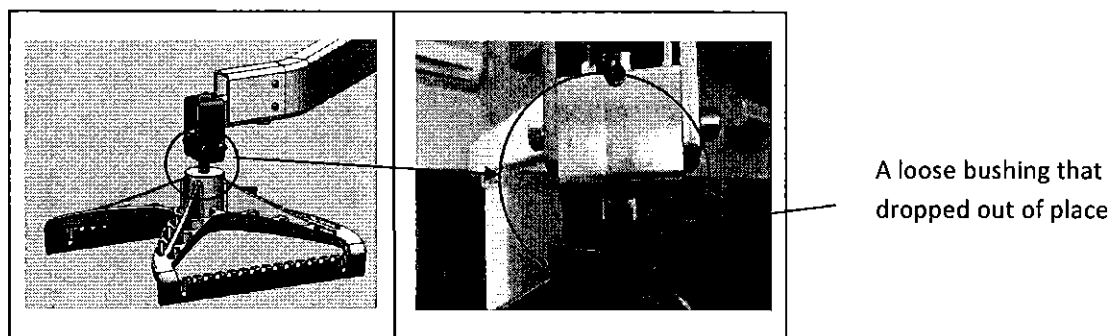


Figure 4.3: (left) the location of the bushing, (right) a bushing that dropped out of its place

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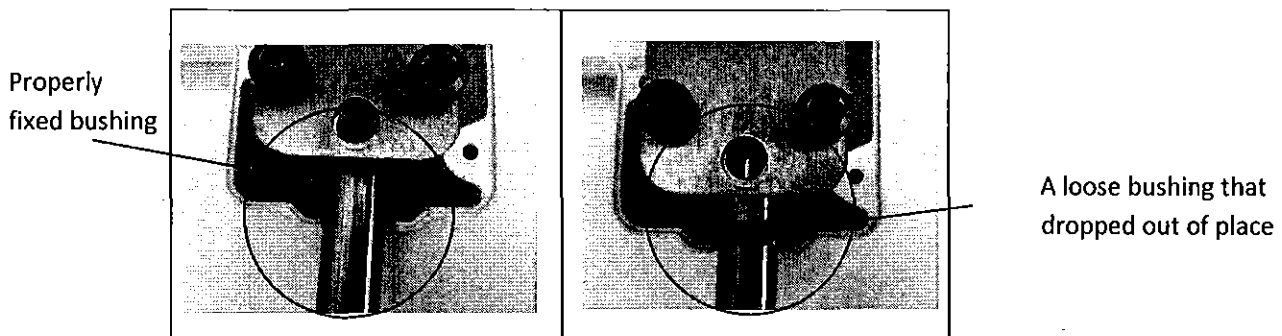


Figure 4.4: (left) a bushing that is fixed properly to its place, (right) a bushing that dropped out on the open hoist cover

IN CASE THE BUSHING IS NOT VISIBLE, NO FURTHER FIXATION IS REQUIRED, CONTINUE TO STEP 4.7.

4.5 If the bushing is loose, insert it back to its place by using your fingers first, and then tight it to its place by using an open 20 mm wrench (see figure 4.5).

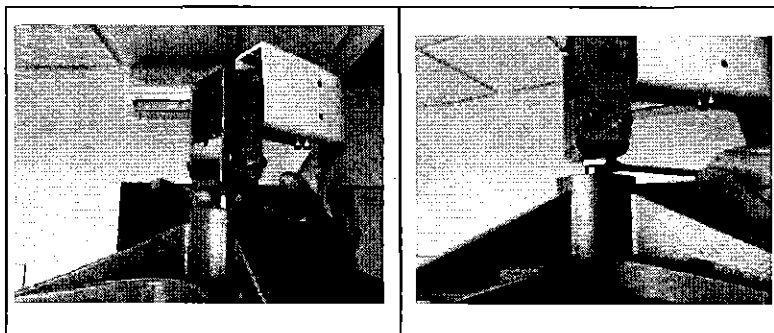


Figure 4.5: insert the bushing back into place by using your fingers, and then using a wrench to tight it in its place

4.6 If the bushing is still loose after inserting it as mentioned above, put one of the following glues on the bushing before inserting it into place: Loctite 638, 5 seconds Superglue, or Epoxy glue.

4.7 Re-assemble the Hoist's covers, and verify they don't interfere with the readings of the Hoist's load cell by doing the following:

- 4.7.1 Enter technician screen and check that the value presented as the patient weight in the load cell section, is less than $\pm 1\text{kg}$ when there is no load on the hoist.
- 4.7.2 Apply a load of 30-40 kg on the hoist.
- 4.7.3 Release the load and verify the reading returns to its initial value within a tolerance of $\pm 0.5\text{kg}$ tolerance.
- 4.7.4 If the deviation between the load cell readings is higher than 0.5kg, or if the initial reading isn't in the range of $\pm 1\text{kg}$, re-organize the hoist covers - make sure the covers don't touch the hoist load cell this time. After each time you rearrange the covers, repeat step 4.7 and check the reading of the hoist load cell.

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