

Date: November 22, 2021

Urgent Field Safety Notice

DAESUNG MAREF CO.,LTD.

Commercial name of the affected product: **LX9 & LF900**

FSCA-identifier: CAPA-2021-10

Type of action: Firmware update through importers

Attention: To Whom It May Concern:

1. Details on affected devices:

- a. Type of device : Intermittent Pneumatic Compression system
- b. Firmware version of affected devices : 2.00.06
- c. Model Name & S/N

Model Name	Serial No.
LX9	2026322~2026701, 2032416~2032465, 2032713~2032792
LF900	20112942~20113341, 20114559~20114618, 20117885~20117954, 20129599~20129918

2. Description of the problem:

It was observed that the pressure applied to the cuff(sleeve) was higher than the pressure set on the device. It has been confirmed that this is intermittently occurring in the firmware version 2.00.06 of this model.

Potential hazard and possible risk - Among the potential risks for continued use of the device, the serious risk is mild pain, which is evaluated as "minor". This is based on the fact that the maximum pressure caused by the problem is lower than the maximum pressure range of the product, and there have been no adverse events of serious side effects of patient injury or death from IPC equipment worldwide..

3. Advise action to be taken by the user and importer:

- Check S/N of products in use or sold
- Check the inventory of the product
- Inspection of the product
- **Sign and return the "Field Safety Corrective Action Acknowledgement Form"**
- Notify the manufacturer of the implementation plan and actions
- Schedule consultation and implementation of firmware update
- Check if there were any adverse events including side effects that occurred during use

4. Transmission of this Field Safety Notice:

This notice should be passed on all those who needs to know about a product issue. Also, please maintain awareness on this FSCA and its consequences so that it can remain effective.

5. Contact reference person:

For questions or additional information, please contact:

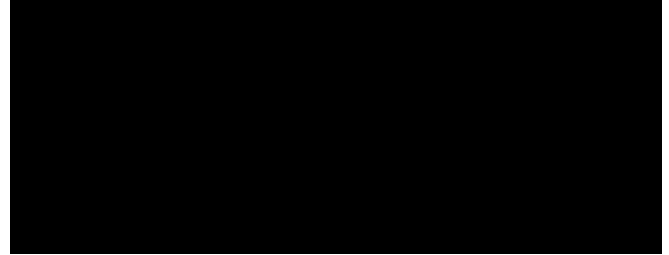
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Field Safety Corrective Action Acknowledgement Form

DAESUNG MAREF CO.,LTD.

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Device list:

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I confirm that I have received and read this FSN

Name	
Company Name	
Address	
Country	
Phone Number	
E-Mail Address	

Date:

Signature:

Please return signed form to: danny@dsmaref.com & qcqms@dsmaref.com