

Field Safety Notice

FSN Number: FSN-BMT-2023-001

Name of the affected products: The Belmont® Rapid Infuser, RI-2 Model Numbers 903-00037A and 903-00039A, manufactured prior to November 2022, software version 2.16 or lower.

February 24, 2023

To the attention of:

Head of Biomedical Engineering
Medical Device Safety Officer

Dear Customer,

Belmont Medical Technologies is notifying you of a particular issue that can arise when the Belmont Rapid Infuser RI-2, models and date of manufacture described above, is used differently than instructed by the Operator's Manual.

Description of the Problem:

According to the instructions for use, the sequence for powering up the device starts with plugging the device into AC power mains and then turning the power on by pressing the power up button on the device.

If the power up button is switched on before the device is plugged into AC power mains, the device reverts to the factory default of operating on 60 Hz. This may lead to insufficient power during use and trigger the device to display error 101. The error is removed only if the device is powered down, unplugged and the process restarted using the proper power up sequence.

If the user does not follow these steps, the device may become unavailable for use.

Required Actions for Users:

1. Ensure users of these devices are made aware of this notification.
2. Should an error 101 message be displayed on the device, power down the device, unplug the device, plug the device into AC mains power, and restart the power up sequence.
3. Provide users with Quick Reference Guide (702-00201) that describes the correct power up sequence. The Quick Reference Guide is provided electronically with this notice.

4. Please complete the attached acknowledgement form and return to Belmont via email UKFSNRI2replies@belmontmedtech.com

Note: Error 101 may be caused by other factors, such as residue on the temperature sensor. In case where error 101 is not resolved by powering up the device per the instructions described above, please refer to Chapter 3: Alarms and Troubleshooting Guide HEATING ALARMS of Instructions for Use, 702-00190, or the Heating Alarms section of the Quick Reference Guide, 702-00201 on how to resolve the error.

The Instructions for Use can be accessed through Belmont's website at:

<https://belmontmedtech.com/resources>

If the error cannot be resolved by performing the steps described above, please contact Belmont Technical Support.

Follow up Actions by Belmont Medical Technologies:

1. Belmont developed a new software, version 2.17, which ensures that the device remembers the line frequency it was last powered up which prevents error 101 from occurring due to the incorrect power up sequence.
2. Your device will be updated to the latest software version during your next scheduled service visit or during any unscheduled service visit. If Belmont does not normally provide scheduled preventive maintenance, Belmont will reach out to you to schedule the update of your device.
3. Belmont expects to complete the software update activities within 12 months of distributing this notice.

Contact information:


For any questions regarding this action, technical assistance, or to report an adverse event or product complaint, please contact Belmont Medical Technologies technical support using the following information:

Telephone: 0 870 600 9940

euroserviceuk@belmontmedtech.com

Belmont Medical Technologies is committed to patient and user safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Respectfully,



Lida Reed

Director, Quality Assurance and Regulatory Affairs

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Company Registration Number 10460858



Customer Response Form

RI-2 Belmont Rapid Infuser, Error 101

Please assist Belmont Medical Technologies by acknowledging this notice. Please email the completed form to:

UKFSNRI2replies@belmontmedtech.com

Name of Facility: _____

Address: _____

☐ I have read and understood the attached notice and agree to notify users

Completed by:

Print Name Signature Date

Title Phone Number e-mail

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