MESI
Simplifying Diagnostics

MESI, development of medical devices, Ltd
Leskoškova cesta 11A, SI-1000 Ljubljana
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SAFETY NOTICE

Medical device trade name: Automated Ankle-Brachial Index measuring device (MESI ABPI MD)
Security corrective action code (for example date): 05/07/2019
Type of corrective action (e.g. definition of safety corrective action): Further clarification regarding the correct calibration of the Automated Ankle-Brachial Index measuring device (MESI ABPI MD).

Date: 05/07/2019

Subject: Further clarification regarding the correct calibration of the Automated Ankle-Brachial Index measuring device (MESI ABPI MD).

Detailed information about the affected medical devices:
Generic Name: Noninvasive Ankle-Brachial Pressure Index measurement unit
Trade name: Automated Ankle-Brachial Pressure Index measuring device
Model: ABPIMDD
Alternative name: ABPI MD

Issue description:
After recently performed calibrations of the ABPI MD, our UK distributor noticed that the cuffs are overinflating. This does not represent any additional risk for the patient, but it may cause slight discomfort. The distributor reported the problem to MESI. We proposed a detailed examination of the manometers, which are parts of the Calibration kits with which the devices were calibrated. During the inspection, the distributor noticed that the measurement units on some of the manometers were changed from millimeters of mercury (mmHg) to millibars (mbar), resulting in inadequate calibration of the ABPI MD. The distributor notified the affected users and organised re-calibration of their devices. If the incorrectly calibrated devices were used, the calculation of the Ankle-Brachial Indices was still correct. However, the individual blood pressures in each extremity were measured incorrectly.

Recommended corrective actions the user should take:
We recommend the users do the following:

- Before performing the calibration, they should double check that the units on the manometer are set correctly (to mmHg).
- If they notice the units on their manometer are currently set to mbar, they should reach out to the customers whose devices were recently calibrated and calibrate them once again.
- In case their customers report the cuffs on a particular device are overinflating, the calibration should be performed once again using the correctly set units.

Forwarding of the security notice:

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This notice must be sent to anyone within your organization that sells or calibrates the ABPI MD device. Please also communicate this notification to other organizations if the external contractor is responsible for the calibration procedure.

Contact person:

Nina Polak
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Leskoškova cesta 11a
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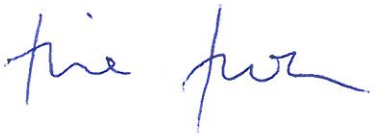
TEL: 00386 1 620 34 87

The signature below confirms that the appropriate authority for medical devices has been informed of this notice.

Signature:



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