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PATH MEDICAL GmbH, Landsberger Str. 65, 82110 Germering, Germany

Attention: SENTIERO users

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URGENT: MEDICAL DEVICE RECALL SENTIERO

26. September 2023

Dear valued customer,

In accordance with our manufacturing regulations and guidelines, we are sending you this letter to advise you of a product recall on the SENTIERO OAE device. You are receiving this letter, since we identified you have purchased at least one SENTIERO product built with the PCB revision 74 (for SENTIERO handheld devices) or 600 (for SENTIERO TYPE DESKTOP devices).
This notice needs to be passed on to any other organization to which one of those devices has been forwarded.

Please forward this letter to such organizations.

Items Affected:

Model Number	Part Number	Serial Number
SOH100098		

Description of condition:
Otoacoustic emissions (OAE) measured for hearing screening or hearing diagnostics are basically "biological distortions" that occur in the inner ear during the processing of sound stimuli. An OAE measurement system registers these distortions with a

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Director/Geschäftsführer:
Dr.-Ing. Hans Oswald

Amtsgericht: München
HRB 167243

Sales Tax Identification No:
DE 254491320

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sensitive microphone. Technical distortions, i.e., distortions that arise in the measurement system itself, generally occur in OAE measurement systems at higher stimulus levels and limit the possible level range because they cannot be reliably distinguished from physiological stimulus responses.
The threshold above which distortion can increasingly occur is influenced by many factors, such as the design of the ear probe, the microphone used, handling or electronical equipment in the near proximity and the amplifier circuitry.
In the course of adapting the SENTIERO circuit boards due to components no longer being available, minor modifications had to be made to the microphone amplifier, among other things. In hardware tests carried out for commissioning, the boards were in-conspicuous in this respect.
However, during regression tests as part of a further development of the firmware, it was noticed that technical distortions occur to a greater extent than was the case with previous board revisions.

<u>Predicted risk to patient or user:</u>

The risk scenarios of incorrect screening results and incorrect diagnosis are considered very unlikely.

TEOAEs, which are predominantly used for OAE-based hearing screening, show no abnormalities and can be used normally. When using DPOAE in hearing screening programs, moderate stimulus levels are used (see e.g. ASHA guidelines). These are preset accordingly on the device. Measurements at these stimulus levels showed no distortions. Furthermore, DPOAE-based hearing screening always consists of measurements at multiple frequencies. Therefore, false positive DPOAE detections at a single frequency, which are already considered unlikely, would not necessarily falsify the overall screening result (e.g., pass criterion 3 out of 4).

For diagnostic purposes, the device allows the use of higher

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stimulus levels compared to those used in screening. Here, sporadic false positive OAE detections may occur. However, in the overall picture (consideration of multiple frequencies and multiple levels), even when using DPOAE exclusively without adding other diagnostic procedures, there is no scenario in which a severe hearing impairment would be falsely missed.

Since all metrological diagnostic procedures involve a certain probability of error, which can be due both to errors in the application and to unnoticed equipment defects or similar, comparable scenarios have already been documented and evaluated in the risk analysis.

In summary, there are no hazard scenarios other than those already documented in the risk analysis for the effect of faulty diagnosis, which have been classified as being low risk. Thus, the hazard can be considered negligible, as it is already considered in the products risk- benefit evaluation.

<u>Advice on Action to be taken by the user:</u>
Even though the risk to the user and patient is considered neglectable, those technical distortions can influence the specified performance of the device when performing diagnostic DPOAEs at high stimuli. Therefore, PATH MEDICAL chose to voluntarily recall affected products for modification as a precautionary measure.

Please return your device(s) affected to your local distributor or PATH MEDICAL directly to have your PCB replaced.

Please be aware that your local competent authority may have been informed of this recall, if required by law.

Thank you for your cooperation.
In case there are additional questions, please contact us under:
Mail: qm@pathme.de
Phone: [redacted]

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[redacted]
Quality Management Representative
Head of Quality Management &Regulatory Affairs
Responsible Person acc. Art. 15, MDR

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