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Rev 1: September 2018
FSN Ref: CAPA-00105_FSN_AccuScreen DPOAE Probe
Date: 09.Sept.2025

FSCA Ref: CAPA-00105

Urgent Field Safety Notice (FSN)
AccuScreen DPOAE Probe PN 8-69-41100

For Attention of*:AccuScreen DPOAE Users

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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Urgent Field Safety Notice (FSN)
AccuScreen DPOAE Probe PN 8-69-41100
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	AccuScreen DPOAE Probes,
1.	2. Commercial name(s)
	MADSEN AccuScreen TEOAE/DPOAE/ABR Probe
1.	3. Unique Device Identifier(s) (UDI-DI)
	04260223141355
1.	4. Primary clinical purpose of device(s)*
	Intended use:The ear probe is intended as an application part for audiological measuring systems which use evoked signal responses (e.g. DPOAE, ABR) for estimating the hearing function. It is intended for use with instruments adapted to their mechanical and electrical properties. The generation and recording of sound signals in the auditory canal is possible. The connection to the auditory canal is made by ear tips in various sizes, which are available as separate disposable items.
1.	5. Device Model/Catalogue/part number(s)*
	PN 8-69-41100
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	1008850 - 1009896
1.	8. Associated devices
	Within context of the FSCA: MADSEN AccuScreen

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	This letter pertains to a performance issue with certain lot of probes which could result in increased artificially generated acoustic distortion signals when used for Distortion Product Otoacoustic Emission (DPOAE) testing in combination with specific software protocols to be chosen deviating from the standard protocol.
2.	2. Hazard giving rise to the FSCA*
	The issue could result in decreased DPOAE test sensitivity due to potential false negative (i.e. False 'Pass' or False 'Clear Response') results when used for Distortion Product Otoacoustic Emission (DPOAE) testing using certain DPOAE Protocols in AccuScreen.
2.	3. Probability of problem arising
	The occurrence rate of the issue is significantly increased initially for users switching from the standard default DPAOE protocol to one of the affected DPAOE Protocols. The protocols added last also do not show this effect, additionally reducing the occurrence. It also will to a certain extent be covered by regular check-ups in early ages and use of different methods for risk babies. Occurrence rate shall be evaluated as medium, since the exact number is not

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	known.
2.	4. Predicted risk to patient/users
	Overall, there is already an inherent risk of a false pass with the DPOAE testing protocol with AccuScreen for a child with a hearing disorder and this cannot be eliminated. This inherent risk of false negative answers was increased when deviating from the AccuScreen factory default DPAOE Protocol (DP-1).
2.	5. Further information to help characterise the problem
	In General, DPOAE Screening has a risk of false negative results of about 11%, as latest scientific literature shows. 80% of prelingual hearing loss is attributed to genetic causes. To address this, the new-born having parents with hearing loss are categorized as "new-borns with risk factors", which usually are screened using the more reliable (A)ABR method, to identify potential hearing losses. This significantly reduces the actual risk occurrence in clinical use.
2.	6. Background on Issue
	Due to obsolescence of parts, PATH MEDICAL replaced the probe speakers with the successor model as suggested by the supplier in their EP-DP ear probes. Although initially tested as suitable according to testing procedures and standards in place, PATH MEDICAL's DPOAE probes for AccuScreen could induce technical distortions on high sound levels. These kinds of unwanted, technical distortions are indistinguishable from the biological distortion product the DPOAE test bases on and may lead to an erroneous recognition of an answer at specific test frequencies.
2.	7. Other information relevant to FSCA
	The issue only occurs in combination with specific DPOAE Protocols of AccuScreen.

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None - Please check your device configuration on the screening protocol in use. If the default factory settings are used, no action is needed. - If another protocol is used, please provide information on rationale for changing and state the protocol in use. Then change the protocol using AccuLink Software to one of the protocols listed in the reply form. Make sure that the protocol is in accordance with your local screening program. Please also note, that the EP-DP Earprobe has an expected lifetime of two (2) years. Please adhere to this duration of use. The manufacturing date is stated on the

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	product labelling	
3.	2. By when should the action be completed?	At your earliest convenience.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Notification of users about compliant protocols to be chosen for DPOAE Screening.	
3	6. By when should the action be completed?	At your earliest convenience
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**PATH MEDICAL GmbH**
	b. Address	**Landsberger Str. 65, 82110 Germering, Germany**
	c. Website address	**www.pathme.de**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**Customer Reply Form**
4.	10. Name/Signature	**Florian Peters** **Head of QM/RA** **Quality Management Representative** **Responsible Person acc. Art. 15 MDR**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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CUSTOMER REPLY FORM
TO BE COMPLETED BY RECIPIENT

Customer Name:	
Facility Name:	
Facility Address:	
Contact Name:	
Email:	
Phone Number:	
Device Serial Number:	
Probe Serial Number(s):	
Did you change the device's default configuration? If yes, please explain why and state the protocol(s) currently in use:	

Please mark as appropriate:

Director/Geschäftsführer:
Dr.-Ing. Hans Oswald

Amtsgericht: München
HRB 167243

Sales Tax Identification
No: DE 254491320

☐ We do not have any of the affected products (returned/scrapped)
☐ We still have the affected product(s) in use.
We confirm to have changed the AccuScreen device to the following protocol. Other protocols are removed:

☐	DP-1
☐	DP-2
☐	DP-3
☐	DP-4
☐	DP-17
☐	DP-18
☐	DP-19
☐	DP-20

Name of Person completing these actions:_____

Signature: _____ **Date:** _____

Title: _____

Director/Geschäftsführer:
Dr.-Ing. Hans Oswald

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