URGENT – FIELD SAFETY NOTICE. PRODUCT ADVISORY
ASRA Curve Screening Audiometer

FSN # GMI-FSN-001

FSCA # GMI-FSCA-001

Date: 05th April 2022

Product / Model: ASRA Curve Screening Audiometer

Problem Summary Statement: Wrong HSE Categorisation assigned for Male subjects

For the Attention of: Occupational Health Department Manager

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

This notice must be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

You must maintain awareness of this notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

Please retain a copy with the equipment Instruction for Use

Information on Affected Device
Device Type:
Audiometer
Primary Clinical purpose of the device:
Screening audiometer used to provide baseline hearing levels and trends to help identify the possibility of Noise-Induced Hearing Loss (NIHL)
Device Model:
ASRA Curve Screening Audiometer
Software Version:
Software Version 1.0 Revision 4195
UDI:
5060485270065

Dear Customer,

GM Instruments Ltd has identified an issue with the ASRA Curve Audiometer Software. This Field Safety Notice (FSN) is intended to inform you about:

1. What the problem is and under what circumstances it can occur

The ASRA Curve Audiometer ('the device') is a screening audiometer used to provide baseline hearing levels and trends to help identify the possibility of Noise-Induced Hearing Loss (NIHL), which may be associated with the persons working environment.

The ASRA Curve is a stand-alone product and is not intended to be used with other medical devices.

The device contains software that converts the results of the hearing test into a graph showing frequency (kHz) and hearing level (dB) for the subject. One of the functions of the ASRA Curve Audiometer software, is to present the results of the hearing test in one of 4 categories as defined by the UK Health & Safety Executive (HSE) Categorisation Scheme:

Category 1 - Acceptable Hearing Ability
Category 2 - Mild Hearing Impairment
Category 3 - Poor Hearing
Category 4 - Rapid Hearing Loss

The HSE Categorisation Scheme classification table is based on subjects age, and then split into Male & Female, and Warning & Referral levels as shown below:

Classification Table

Sum of hearing levels 1, 2, 3, 4 and 6 kHz				
	Males		Females	
Age	Warning level	Referral level	Warning level	Referral level
18-24	51	95	46	78
25-29	67	113	55	91
30-34	82	132	63	105
35-39	100	154	71	119
40-44	121	183	80	134
45-49	142	211	93	153
50-54	165	240	111	176
55-59	190	269	131	204
60-64	217	296	157	235
65	235	311	175	255

We have identified an issue within the software that can result in the HSE categorisation for male subjects potentially being wrongly overstated by the device, as the software references the female table only when determining the classification warning and referral thresholds. The female thresholds are around 30% lower than male thresholds. We have verified that the actual hearing test results over the range of the audiometer are correct. Therefore, it is only the way in which the software categorises the results against the HSE classification levels for male subjects which has been determined to be incorrect.

In the case of a male subject being tested, the affected device software will compare his results with the female classification table and potentially provide a false (negative) result. For example: a male subject aged 42 with a hearing level of 110 would be classified as HSE Category 1 (threshold 121), whereas using the female classification for a 42-year-old male he would be HSE Category 2 (threshold 80). This would falsely provide a warning-level categorisation. Female subjects are not affected by this issue.

2. A description of the hazard/harm associated with the issue

As defined in the user manual, the operator of the device is expected, as a minimum, to be a competent person who has completed courses with syllabi determined by the British Society of Audiology. These courses familiarise them with audiology, the methods of performing hearing testing and how to operate and maintain audiometers. Other users may be more skilled experts in audiology, such as Occupational Health nurses and audiologists.

Based on the intended use of the device, and expected competence of the user, the risk to the subject is low, as the software generated category is not the only method the user will use to determine any Noise-Induced Hearing Loss issues. If hearing loss issues are identified, the subject would potentially be referred to a clinical specialist for further review.

We strongly believe most clinical practices will reference the results of the hearing test with the HSE Categorisation Scheme tables found in the HSE Controlling Noise at Work Regulation 2005 and the ASRA Curve user manual, and therefore record the correct hearing level category for the subject.

As the ASRA Curve is a screening audiometer the risk to male subjects is wrong HSE category levels noted in his records and the possibility of unnecessary action taken by the employer to address suspected work-related noise levels.

The potential false-negative categorisation would either trigger a warning level, or referral level, where further investigation of the subject's hearing level would be examined by a clinical specialist. According to the user manual, no direct intervention should be undertaken solely on the ASRA Curve software classification.

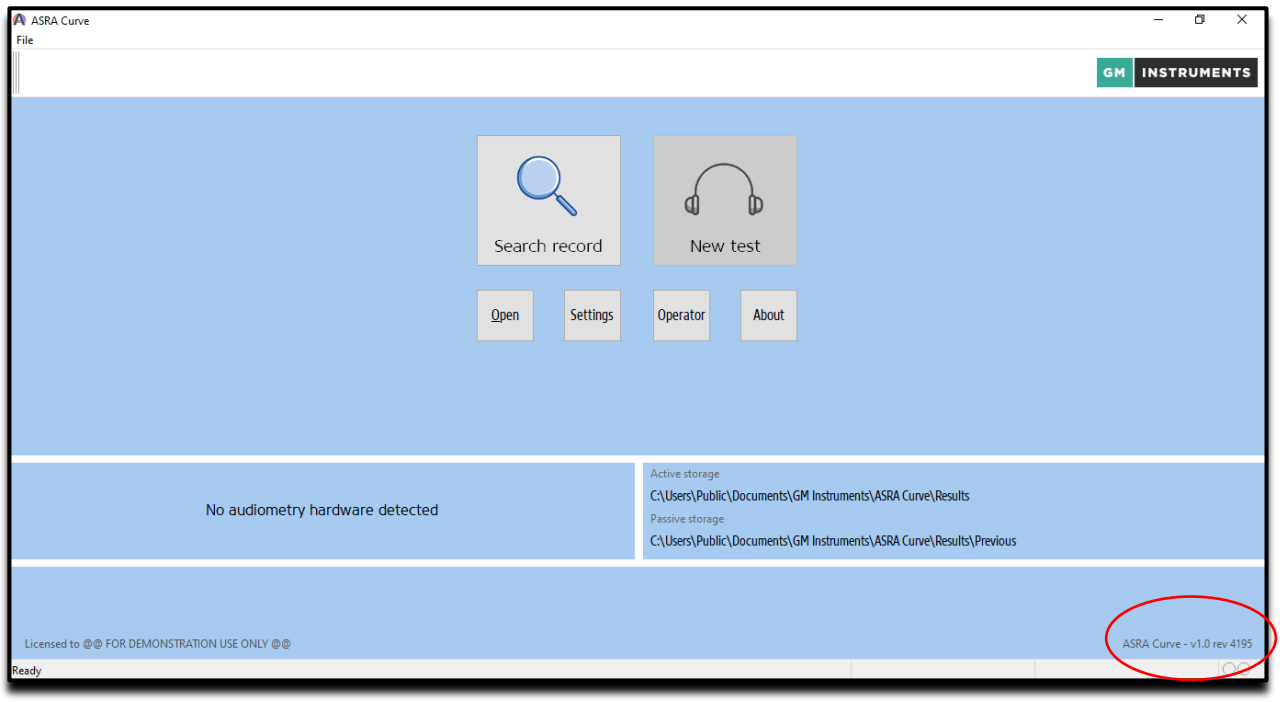
There is no risk to the user of the equipment, or public health risk, and after the Field Safety Notice advice / action is taken, the residual risk of wrong categorisation will be eliminated.

The device has been on the market for just over 2 years, and this is the only reported issue with the software to date.

3. Affected products and how to identify them

This Field Safety Notice is limited to ASRA Curve Audiometers running **Software Version 1.0 Revision 4195**. To identify if your model of ASRA Curve has the affected software, the version and revision are shown at the bottom right-hand corner of the screen as shown in figure 1:

Figure 1



4. Actions to be taken by the customer / user in order to prevent risks for subjects or users

- Identify the ASRA Curve Audiometer(s) in your facility and determine if it includes the affected software version and revision (ref. Section 3).
- Determine if any affected devices have been sold to a third-party or transferred to any other organisation and identify the current owner/user of those devices and share the contents of this FSN with them.
- Review all results of previous testing of male subjects taken using affected ASRA Curve audiometer and verify the categorisation levels are correctly assigned. Update results if necessary and schedule a follow-up consultation if appropriate.

Please send an acknowledgment to GM Instruments Ltd promptly upon receipt of this FSN with confirmation that the above actions have been taken, no later than 30 days from receipt via email to: support@gm-instruments.com

NOTE: You may continue using affected devices to test male subjects, according to the intended use and user manual, however the software-displayed Categorisation level for male subjects must be disregarded, and instead you should refer to the HSE Categorisation Scheme table shown in the user manual.

5. The actions planned by GM Instruments Ltd to correct the problem

We are currently working with our software developer who has identified the source of the issue and already has a software update under test that is expected to resolve the problem.

Once the testing is complete, we will perform a full software revalidation to ensure the issue has been resolved, no regression has been introduced, and that the software continues to operate as per the user manual and intended use.

The updated software will then be distributed to all affected ASRA Curve Audiometer customers, using a method convenient to their operation. This may include sharing via USB drive, Dropbox or an on-site visit by our Service Engineer. We will be in contact with you in due course to ensure a timely and efficient software update.

A full and thorough investigation has already begun to identify the root cause of occurrence and non-detection of the issue described in this FSN. Our internal processes will be updated as necessary.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

We will, without charge, remedy the issue and bring all affected devices into compliance with each applicable standard / regulation in accordance with a plan to be approved by the General Manager, the details of which are communicated in this letter.

Please be assured that maintaining a high level of safety and quality for all our products is our highest priority. If you need additional information or support concerning this issue, please contact GM Instruments Ltd Customer Support on +44 [0] 1294 554 664 or email support@gm-instruments.com and reference GMI-FSN-001

Sincerely,

Hugh Templeton

Quality and Technical Manager

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FIELD SAFETY NOTICE – ACKNOWLEDGEMENT FORM

FSN # GMI-FSN-001

Please complete this form then print, scan and email to GM Instruments Ltd using the link below to acknowledge receipt of this Field Safety Notice (FSN) no later than 30 days from receipt. This will confirm acceptance and understanding of the Medical Device FSN.

support@gm-instruments.com

Please also confirm the actions listed on the cover page and in section 4 have been completed.

Comments:……
……
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……
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Name:……

Position:……..

Date:……..

Signed:……..