URGENT FIELD SAFETY NOTICE

Audiolyser ADL Connect – software / firmware update

FSCA reference	FSCA-2026-01
Date	2026-10-22
Distributor / local contact	PROCARE / Tjalle Dijkstra

Dear Customer,

You are receiving this notice because you use one or more **Audiolyser ADL Connect** audiometers. We have identified a fault that can occur on some devices, and we have released an update that corrects it. Please read this notice and take the simple actions described below.

1. Information on affected devices

1.1 Device type	Pure-tone audiometer
1.2 Commercial name	Audiolyser ADL Connect
1.3 Basic UDI-DI / UDI-DI	376025345FF1166TY / 3760253450638
1.4 Primary clinical purpose	Computerised digital audiometer intended solely for the exploration of hearing function, used to detect possible defects in patient hearing (as stated in the IFU).
1.5 Model / catalogue reference	ADL Connect / FF1166
1.6 Affected software versions	Audiowin ≤ 01.02.00 – firmware ≤ 01.04.00
1.7 Affected serial numbers	See attached list – your device(s): S/N […]
1.8 Associated devices	Audiowin software (PC); headphones Holmco PD-81 or DD65v2

2. Reason for the Field Safety Corrective Action (FSCA)

2.1 Description of the product problem	FIM MEDICAL has received two reports in which an ADL Connect audiometer emitted a tone at 250 Hz at a level much higher than the level selected in the Audiowin software. The built-in Sound Protect safety function detects the excessive level and interrupts the tone, in up to approx. 1.5 seconds. Our investigation identified the cause: an error when writing the calibration data to the device memory during calibration. This error occurs only on some devices.
2.2 Hazard giving rise to the FSCA	This may cause discomfort and tinnitus (ringing or buzzing in the ears). No permanent damage has been reported. Residual risk once the corrective version is installed: none expected – the error can no longer occur and an affected device is detected.
2.3 Probability of the problem arising	Low – two reports on the same frequency (250Hz) for approx. 1,130 devices in the field;
2.4 Background on the issue	A corrective software and firmware version (Audiowin 01.03.00 / firmware 02.00.00). It prevents this memory write error (Audiomanager version 02.02.00) and shortens the reaction time of the Sound Protect function. It also detects devices already affected: a wrongly calibrated frequency is blocked and reported on screen. Because any device running the affected versions may be concerned the update applies to all of them.

3. Type of action to mitigate the risk

3.1 Actions to be taken by the user

1. Check the Audiowin and firmware current versions of each ADL Connect audiometer you use.
2. Install the corrective version as described in the attached instructions, or arrange the update with your distributor / FIM MEDICAL.

   If the corrective version is not yet installed: Perform a listening check once on receipt of this notice. With the earphones held away from the ear (not on the head), present a tone at 60 dB HL on each earphone at each frequency you use in practice. If a tone is louder than expected, do not use the device and contact FIM MEDICAL or your distributor.
3. After the update, if a frequency is reported as blocked on the screen, that frequency can no longer be presented and the device can continue to be used at all other frequencies. No recalibration is required if you do not use the blocked frequency. If you need it, contact FIM MEDICAL or your distributor to arrange a recalibration.
4. If your device has already been updated by FIM MEDICAL or your distributor, no further action is required other than returning the acknowledgement form.
5. Return the completed acknowledgement form by 2026-11-20.
6. Report any adverse event related to this issue to FIM MEDICAL and to your national competent authority.

Distributors and calibration service providers

- Forward this notice to all your customers using ADL Connect audiometers and confirm completion to FIM MEDICAL (list of customers informed).
- Install the corrective version before any calibration of an ADL Connect device.

3.2 By when should the user action be completed?	2026-11-20
3.3 Is follow-up of patients recommended?	No
3.4 Is a customer reply required?	Yes – acknowledgement form attached
3.5 Action being taken by the manufacturer	Software / firmware update of affected devices. Technical support is available from FIM MEDICAL and its distributors.
3.6 By when should the manufacturer action be completed?	2027-01-15
3.7 Is the FSN required to be communicated to the patient / lay user?	No

4. General information

4.1 FSN type	New
4.2 Further advice expected in a follow-up FSN?	No
4.3 Manufacturer	FIM MEDICAL SAS – 51 rue Antoine Primat, 69100 Villeurbanne, France
4.4 Competent authority	The competent authority of your country has been informed about this communication to customers.
4.5 Attachments	Acknowledgement form; list of affected serial numbers; update instructions (Quick guide - ADL Connect update)
4.6 Contact	Jérôme ARGOD – Quality & Regulatory Affairs Manager –**quality-regulatory@fim-medical.com**– +33 4 72 34 89 89

Transmission of this Field Safety Notice

- This notice needs to 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.
- Please transfer this notice to other organisations on which this action has an impact.
- Please maintain awareness of this notice and the resulting action for an appropriate period to ensure the effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and to the national competent authority if appropriate, as this provides important feedback.

We apologise for any inconvenience and thank you for your cooperation.

Name / signature	Jérôme ARGOD, Quality & Regulatory Affairs Manager

ACKNOWLEDGEMENT FORM

FSN FSCA-2026-01 – Audiolyser ADL Connect

Please return to your distributors and/or to quality-regulatory@fim-medical.com by 2026-11-20.

Organisation	
Address / country	
Contact name / function	
Email / phone	
Serial number(s) of ADL Connect in use	
Corrective version installed?	☐ Yes, on (date): _____ ☐ No – update requested
Blocked frequency reported after update?	Blocked frequency reported after update? ☐ No ☐ Yes – frequency: _____ *Recalibration is needed only if you use the blocked frequency.* Recalibration requested: ☐ Yes (blocked frequency used) ☐ No (blocked frequency not used)
Notice forwarded to (distributors only)	
I confirm I have read and understood this FSN	Signature: _____ Date: _____