PATH MEDICAL

Instructions for Use (IFU)

nanoAudio®

Manufacturer

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IFU Reference Information

Language:	English
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Applies to:	nanoAudio, Model NA101414 nanoAudio Software version 1.0 and above Medical electrical system consisting of the nanoAudio device and a computer or tablet on which the nanoAudio software is installed

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All information, illustrations, and specifications provided within this IFU are based on the latest product information available at the time of publication. PATH MEDICAL reserves the right to make changes at any time without notice.

The latest revision of the instructions for use (IFU) is available online at www.pathme.de/downloads.

Errors and omissions excepted.

Copyright Notice

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Table of Contents

1 Introducing nanoAudio

The nanoAudio device consists of an audiometric headphone (left), a central unit (middle), and a USB cable (right). It is also operated through software called nanoAudio.

1.1 This Instructions for Use (IFU)

This Instructions for Use (IFU) or “user manual” contains information pertinent to the use of the screening audiometer “nanoAudio” and its software made by PATH MEDICAL GmbH. Please read the entire Instructions for Use (IFU) carefully before using the nanoAudio for the first time. Use this device only as described in this IFU. We recommend taking particular note of the safety (see the section *12: Notes on Safety*), intended use (see section *3: Authorized Use*), cleaning (see the section *11: Cleaning and Disinfection Recommendations*) and maintenance (see section *10: Service and Maintenance*) instructions.

1.2 Customer Feedback

PATH MEDICAL is dedicated to producing quality work at affordable prices, and we support everything we sell. All our products are designed to balance expert performance and ease of use. Your feedback is valued. If there’s something you love, hate, or think would be better if it were just a little different, please let us know. Your input directly influences the course of development and future features of PATH MEDICAL products.

2 Explanation of Symbols

This section explains all symbols used within this Instructions for Use and/or on the device label.

Symbols within this Instructions for Use (IFU):

Symbol	Explanation
	Reading the Instructions for Use is mandatory. Follow the instructions in this Instructions for Use.
CE	CE mark to declare conformity with applicable European directives and regulations as stated in the declaration of conformity on the PATH MEDICAL website www.pathme.de/certificates. The number below the CE mark refers to the identifier of the notified body.
	Important notice: Please read this paragraph for important information.
	Warning: Please read the safety-relevant information carefully. Failure to follow these instructions may result in risk of injury to persons and/or damage to the device.

Table 1: Symbols within this IFU (Instructions for Use)

Symbols on the device label (depending on the device manufacturing date and target market, not all symbols listed below may appear on the actual label):

Symbol	Explanation
	Reading the Instructions for Use is mandatory. Follow the instructions in this Instructions for Use (IFU).
	Consult Instructions for Use (IFU)
SN	Serial number
REF	Article number
MD	Medical device
	Manufacturer name and address, production date
	Compliance with applied part type B (body) requirements according to IEC 60601-1
	Device with safety class II according to IEC 60601-1

⎓	Direct current input
	The device is electronic equipment covered by the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). When discarded, it must be sent to separate collection facilities for recovery and recycling.
CE	CE mark to declare conformity to directives and regulations as stated in the Declaration of Conformity on the PATH MEDICAL website www.pathme.de/certificates. The number below the CE mark refers to the identifier of the notified body.
	2D code, Unique Device Identifier (UDI). Information next to the UDI represents: (01) identifier, (11) manufacturing date, (21) serial number; additional codes on other labels: (17) expiration date
PATH MEDICAL	PATH MEDICAL company logo

Table 2: Symbols on the device label

3 Authorized Use

3.1 Intended use

The nanoAudio is a pure-tone, air-conduction, portable audiometer. The audiometric tests on the nanoAudio are mainly indicated for use with cooperative patients starting at adequate development age or having sufficient mental maturity, enabling them to participate in interactive audiometry.

The nanoAudio is intended for audiologists, ear-nose-throat (ENT) specialists, hearing health care professionals, and audiologically trained technicians in a medical environment. Please consider local regulations regarding the qualification requirements for performing measurements with a specific test module.

The nanoAudio is not intended for operational use by untrained personnel. All test procedures must be supervised or conducted by qualified personnel. In the United States of America, federal law restricts this device to sale by or on the order of a licensed physician.

The nanoAudio is intended for indoor use only and must be operated under defined environmental conditions. The nanoAudio is not intended for use in oxygen-rich environments. See also operating conditions in the section *13: Technical Specifications* and information about environmental conditions regarding electromagnetic disturbances in the section *12: Notes on Safety*.

The nanoAudio consists of a hardware component and a PC software. Neither is intended to be used as a standalone component without the other.

3.2 Contraindications

Audiometric tests are contraindicated if the headphone cannot be placed on the patient's head, the patient doesn't cooperate or hasn't reached the adequate age or mental maturity to undergo interactive audiometry.

3.3 Side Effects

There are no known undesirable side effects for using nanoAudio.

See also section *12: Notes on Safety*.

4 Basics of Screening Audiometers

4.1 IEC 60645-1:2017 Type 4 Audiometer

An IEC 60645-1:2017 type 4 screening/monitoring pure-tone air-conduction audiometer assesses whether an individual's hearing thresholds at specific frequencies meet a predefined criterion. The audiometer presents pure-tone stimuli through air-conduction at selected frequencies and hearing levels, typically using headphones. The patient's ability to hear these tones determines whether their hearing is within the normal range or if further diagnostic testing is necessary. The screening process is efficient, focusing on identifying potential hearing loss without determining precise hearing thresholds. This type of audiometer, known as a type 4 screening/monitoring audiometer according to the IEC 60645-1:2017 standard, ensures consistent and reliable screening results.

4.2 Interpretation of Results

The audiogram visually represents the patient's hearing sensitivity across different frequencies and hearing levels.

Disclaimer: PATH MEDICAL is not responsible for the interpretation of these results. The users are solely responsible for interpreting the results on their own.

4.3 Clinical Relevance

IEC 60645-1:2017 Type 4 audiometers are crucial hearing screening and monitoring tools. Designed for use in diverse settings like schools and workplaces, these audiometers offer reliable and standardized performance according to international guidelines. They are user-friendly and cost-effective, making them suitable for initial assessments. While they provide essential detection of hearing issues, they are not as detailed as diagnostic audiometers. Their adherence to the IEC standard ensures consistent and accurate results, supporting early identification of hearing loss.

5 Requirements of nanoAudio

5.1 Computer Requirements

The nanoAudio can only be used in combination with a PC, laptop, or tablet computer running the nanoAudio software or application. This section describes requirements to consider when choosing a suitable computer.

5.2 Electrical Safety Requirements

The nanoAudio and the computer constitute an electrical system as defined in IEC 60601-1. The medical electrical system must fulfill the electrical safety requirements described in IEC 60601-1. While the nanoAudio meets all applicable requirements, it remains the responsibility of the operator's organization to ensure that the computer used to operate the nanoAudio is also compliant.

This can be achieved in several ways

- Using a medically (IEC 60601-1) approved computer
- Using a standard computer in combination with an isolating transformer
- Using a standard battery-powered computer (not connected to any charger or other mains-powered equipment like printers)
- Using a standard computer that is kept outside of the patient environment

The nanoAudio itself is suitable for use within the patient environment in any of the above-listed scenarios.

See also section *12.5: Electrical Safety*.

The term *standard computer* refers to a typical computer suitable for office use according to the requirements of IEC 60950-1 / IEC 62368-1.

5.3 Software and System Requirements

The nanoAudio software can be used on any computer running Microsoft Windows 10 or higher. The nanoAudio device requires at least one free USB port. For the patient-controlled tests, one more USB port is required to connect the patient response button.

Minimum system requirements to install nanoAudio:

- Windows 10 or higher
- RAM: 4 gigabytes (GB)
- Display resolution: 1024 x 768
- USB port
- Minimum 5 GB of available disk space

5.4 Cybersecurity Requirements

For data privacy and cybersecurity reasons, both physical and network access to on-site computers, as well as remote access to personal data (e.g., patient test results), must be adequately secured. This may include, e.g., the computer(s) on which nanoAudio is running, the computer(s) on which the nanoAudio database (or any backup of the database) is stored, and the computer(s) on which relevant data files (e.g., test result exports or printouts) are stored.

Please use up-to-date anti-virus and firewall software on the computer(s) running nanoAudio or the computer(s) on which the nanoAudio database (or any backup of the database) is stored. Install the latest service packs and security patches for the operating system on which nanoAudio is running and ensure the operating system is still actively supported with security updates.

Please implement an appropriate backup policy to prevent the loss of relevant data (e.g., patient test results).

5.5 Environmental Requirements

Follow routine check procedures for audiometric equipment to ensure proper device operation. The nanoAudio should be operated in a quiet room (e.g., soundproof cabin, room with low ambient noise).

Check the sections *3.1: Intended use*, *12: Notes on Safety* and *13: Technical Specifications* for other information, too.

6 Unpacking and Accessories

We recommend that you unpack the nanoAudio carefully, ensuring all components are removed from the packing materials. Verify that all components listed below are included in your shipment. If any component is missing, contact your distributor immediately to report the shortage. This will ensure that a proper claim is made. If any component appears damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged. Any missing part or malfunction should be reported immediately to the supplier of the device, along with the invoice, serial number, and detailed report of the problem. Save all the original packing material and the shipping container so the device can be packed appropriately if it needs to be returned for service or calibration.

6.1 Supplied Parts

Your nanoAudio set should consist of the following items:

- This “Instructions for Use” (IFU) or “user manual”
- The nanoAudio device, including audiometric headphone (either DD45 or DD65v2)
- Lanyard for hands-free testing
- A USB flash drive containing software and an electronic version of this “Instructions for Use” (IFU)

6.2 Accessories

- Patient response button “PB-03” (optional for manual audiometry and required for Hughson-Westlake procedure)

7 Installation and Setup

7.1 Hardware Installation

Connect the nanoAudio and the patient response button, if available, to a USB host (e.g., PC) through separate USB connections.

7.2 nanoAudio Software Installation

To start using your nanoAudio, install the software from the accompanying USB flash drive. If the USB flash drive is unavailable, the software can be found in the support/download section of www.pathme.de.

To install the software, run the installer and follow the on-screen instructions.

The nanoAudio device itself does not require special installation procedures. It is ready to operate when connected to a computer's USB port.

To disconnect power from the instrument (e.g., before cleaning), the nanoAudio must be unplugged from the USB port. Therefore, the USB port should be easily accessible.

7.3 Noah (HIMSA) Integration

The nanoAudio installer will automatically register nanoAudio as a Noah module if the Noah System is present. If you intend to use nanoAudio within Noah, it is recommended that Noah be installed and configured before installing the nanoAudio software.

7.4 Storage

To fully power off nanoAudio, disconnect the USB cable. When nanoAudio is not in use, store it in a location where it will be safe from damage to the acoustic transducer and cable. Store according to the recommended temperature conditions described in the section *13.4: Storage, Transport, and Operating Conditions*.

7.5 Connecting the Device

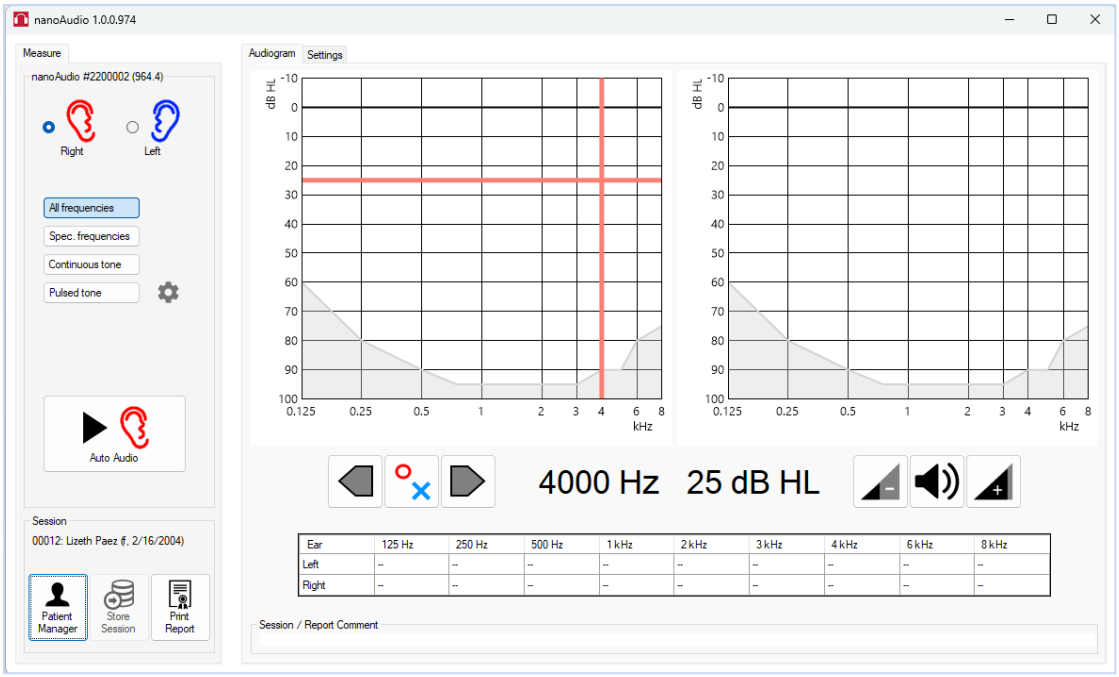
A USB cable connects the nanoAudio to a laptop or desktop computer's USB port. The nanoAudio's power is directly supplied through the computer's USB port, so no external power supply is needed. This makes the nanoAudio system easy and safe to use.

Device Status: The green LED indicates a proper connection between the device and the software. If the software is not connected, the light turns off.

7.6 Starting the software

After starting the computer, launch the nanoAudio software by clicking on the icon  "nanoAudio" on the desktop or directly from the program menu. The program launches with

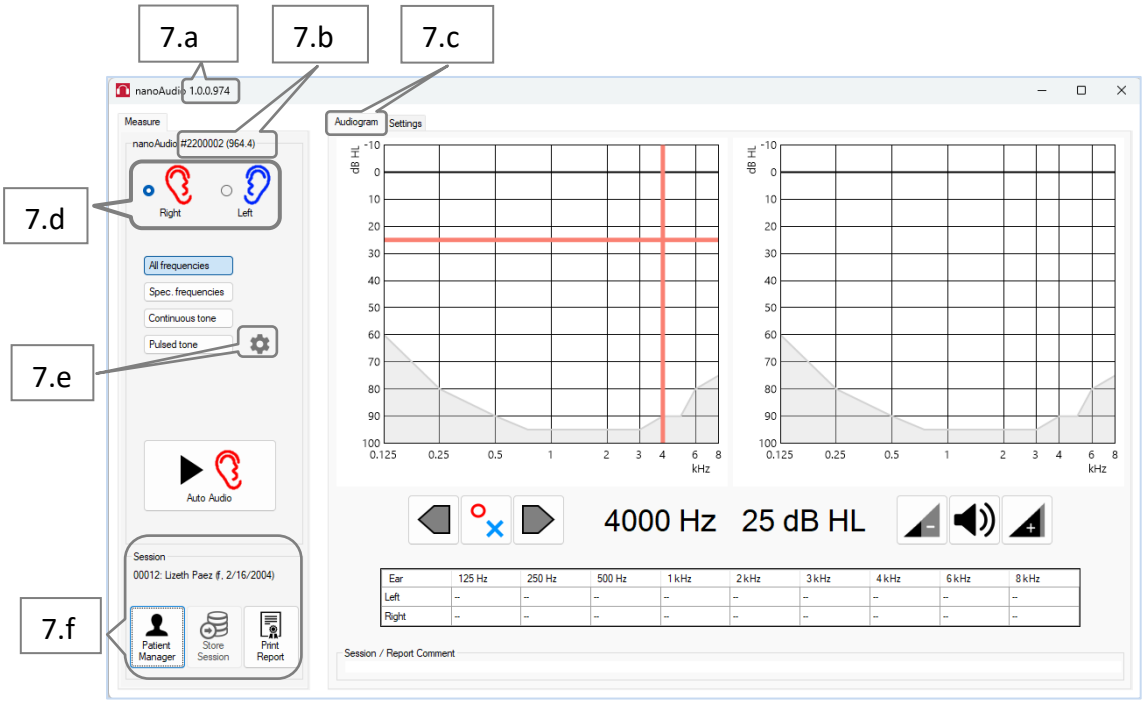
the start screen (see figure below), which displays the buttons controlling the nanoAudio's pure-tone audiometry test functions.



The picture above depicts two audiograms, one for the right and one for the left ear. The gray regions inside the audiograms are beyond the maximum output level of the connected nanoAudio device.

To close the program, click the X at the top right corner of the screen. Additional functions are located at the top left of the screen.

7.7 Main Interface Overview

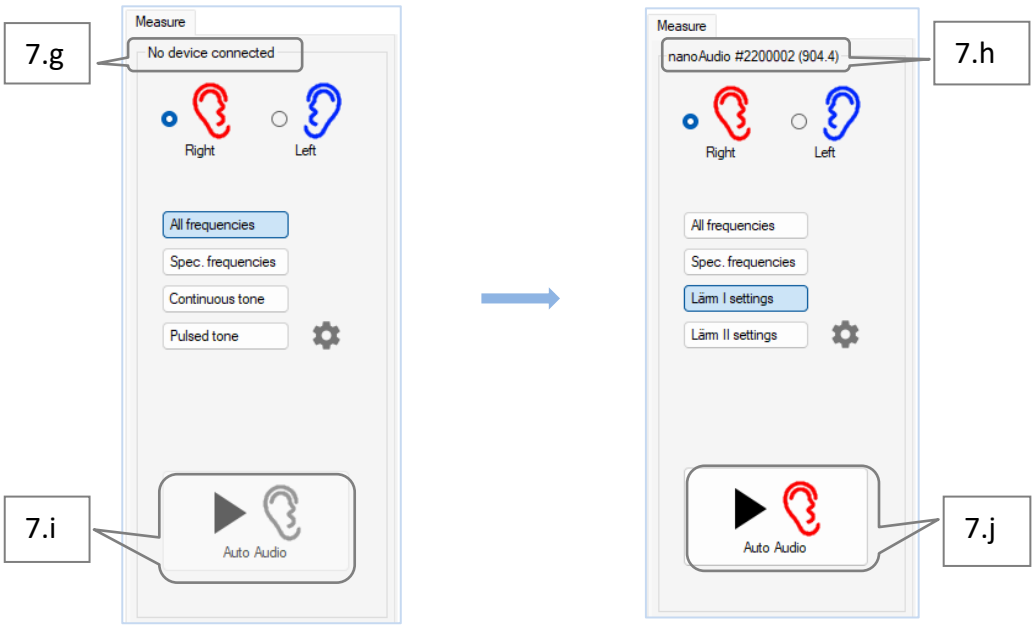


7.a. PC Software Version
7.b. Device serial number (Device firmware version)
7.c. Display of right and left ear results
7.d. Ear Selection
7.e. Settings: Modify protocol parameters
7.f. Patient data management: Add/Select patient, save result and print

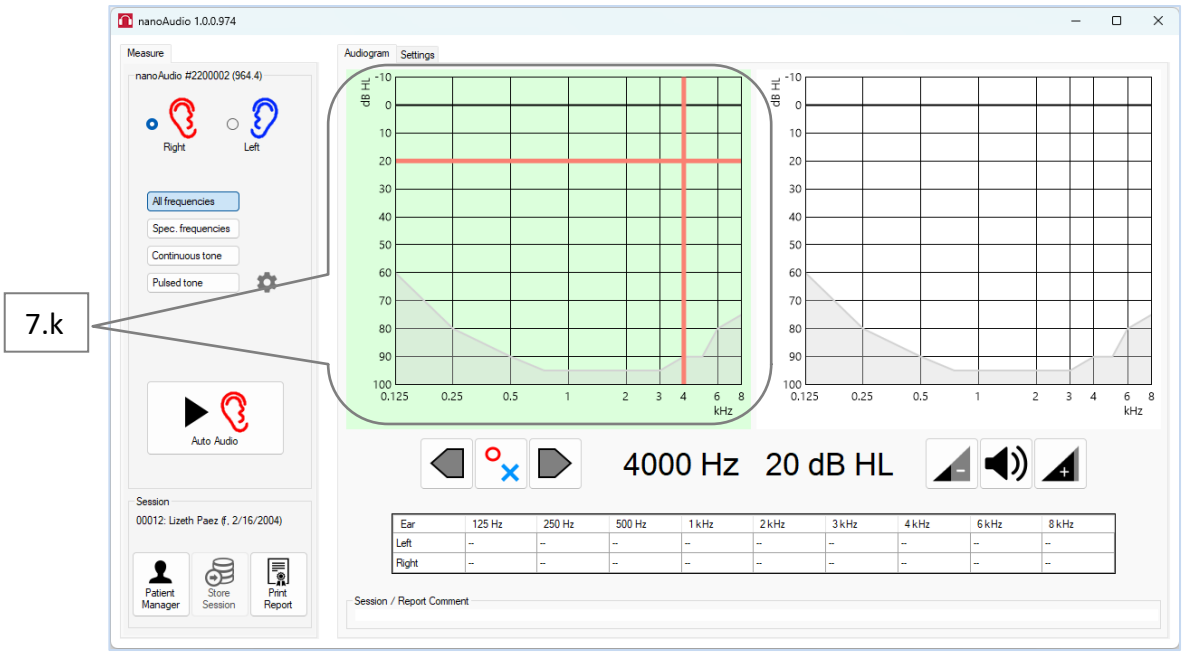
7.7.1 Connectivity Status

The menu bar at the left contains the **Measure** tab.

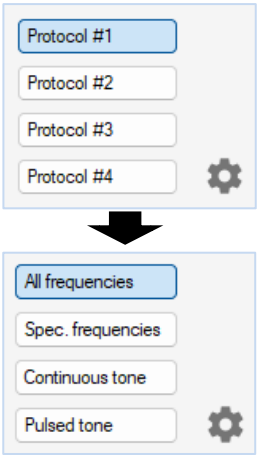
- Directly beneath the **Measure** tab, the device's connectivity status will be displayed as Device Connected / Device Not Connected.



7.g. Before the device is connected.
7.h. After the device is connected, the device serial number (device firmware version) is displayed.
7.i. Before the device and patient response button are connected, the **Auto Audio** button is disabled.
7.j. After the device and patient response button are connected, the **Auto Audio** button is enabled.



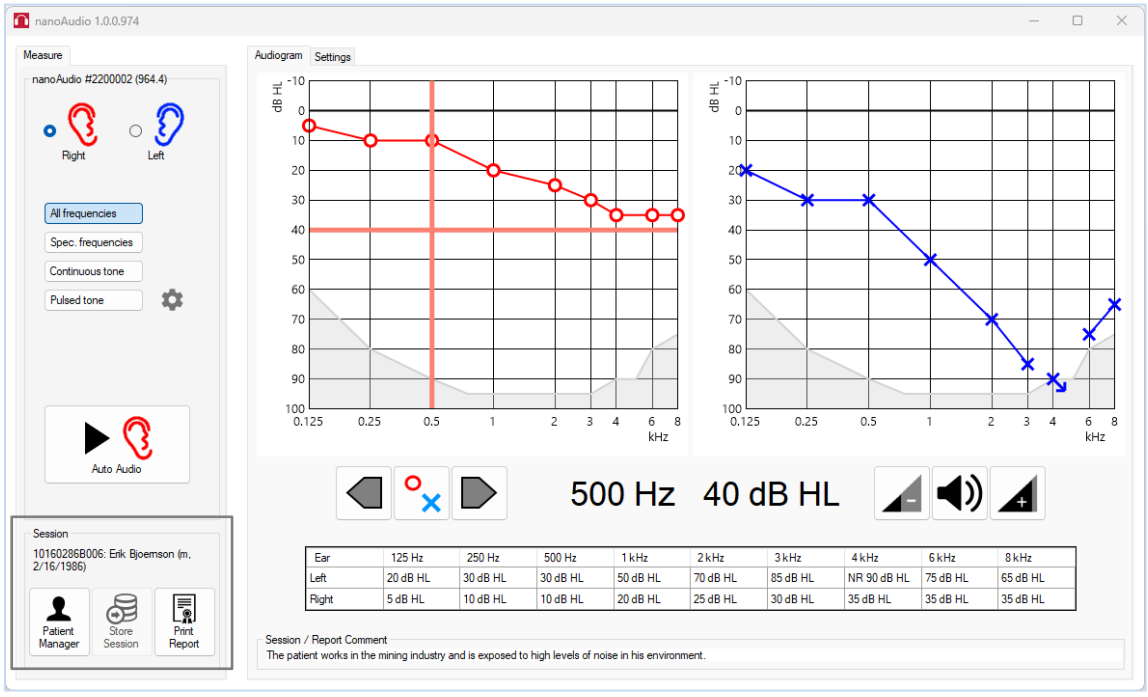
7.k. A green background confirms proper connection of the patient response button while it is pressed.



- Radio buttons allow for the selection of the right ear and the left ear
- **Select protocol** allows you to select preset or factory default protocols or to customize them according to your testing preference. If one of the protocols is selected, it will be shaded in blue. The protocol names can be changed as well.
- The Settings button can be selected to view or change the settings related to the specific protocol.
- The **Auto Audio** button is used for automated audiometry only. It can be pressed when the headphones are correctly positioned and both the patient and the clinician are ready for the measurement to start. The color of the ear icon matches the selected test ear—blue for the left ear and red for the right ear.

7.8 Patient Management

Under Session, you can view the patient information, store a session, and select to print a report.



If the **Patient Manager**  block is selected, the Patient Manager screen appears:

This screen allows you to capture new patient information or search for a stored patient to load information from the database. You can highlight a patient and load the stored data by pressing the **Patient Manager** button or double-clicking on the desired patient name with the

mouse. To load data for a specific session, select that session from the session list and double-click it with the mouse or press the **Load Session** button.

If you run a computer with the Noah System installed, nanoAudio will store patient and test data within the Noah database. In this case, you will not see the patient browser as shown above; instead, you will be presented with the Noah patient browser.

The **Store Session** button 

saves the results for the patient that is already loaded from the database. If a patient's name appears under Session, then the data will be assigned to the active patient automatically when the store button is pressed. If the measurements were performed before loading the patient, the patient should be created or selected first (see **Patient Manager**).

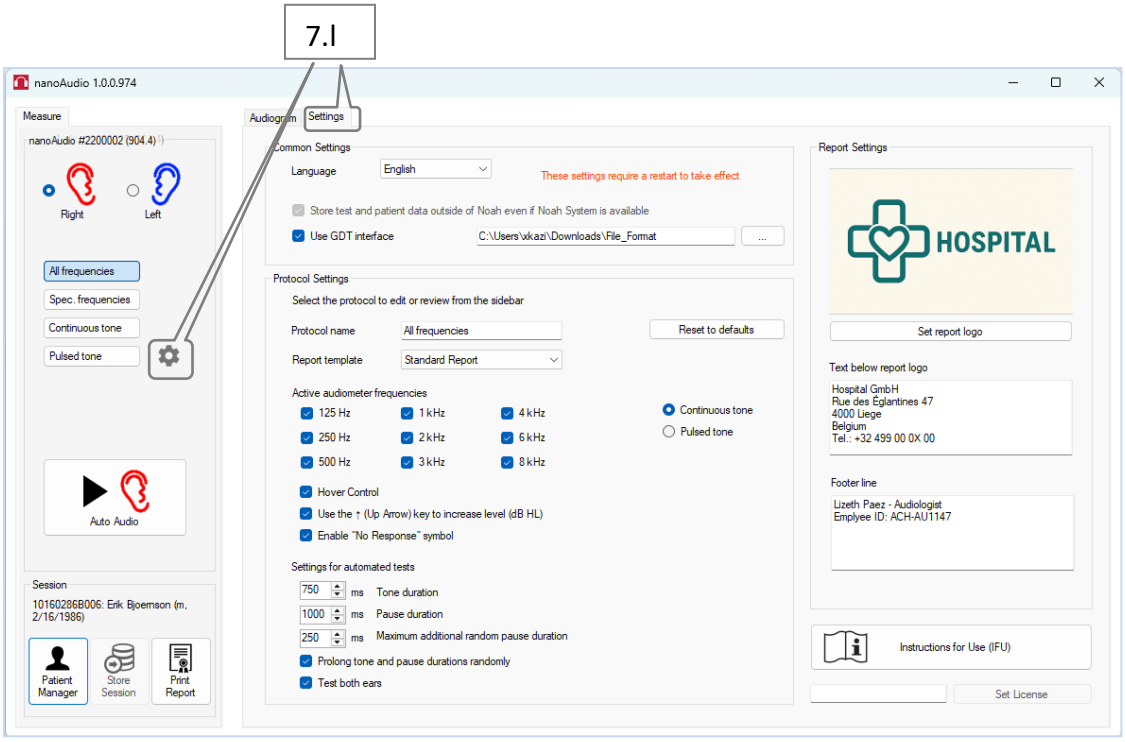
Select the **Print Report** button 

to print out a copy of the results. The report will be generated in PDF format, which can be saved or sent to a printer if a printer is available.

A **Session / Report Comment**, which will be added to the printed report, can be entered in the corresponding box. When entered *before* storing the session, the comment will be stored with the session. If entered *after* storing the session, the comment will just appear on the printout and not be kept on record.

7.9 Settings

The settings can be accessed via the icon  next to the last protocol on the Home screen or via the **Settings** tab next to the audiogram tab.

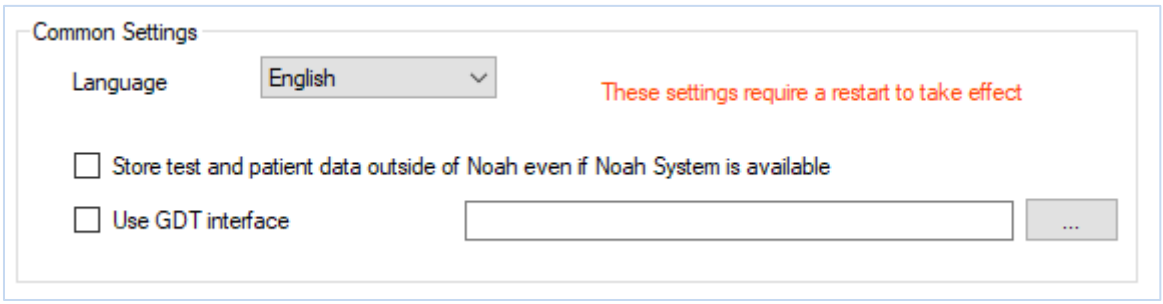


7.l. Access the Settings

The following settings are available: Common Settings, Protocol Settings, and Report Settings.

7.9.1 Common Settings

Under **Common Settings,** you have the option to change the user interface language.

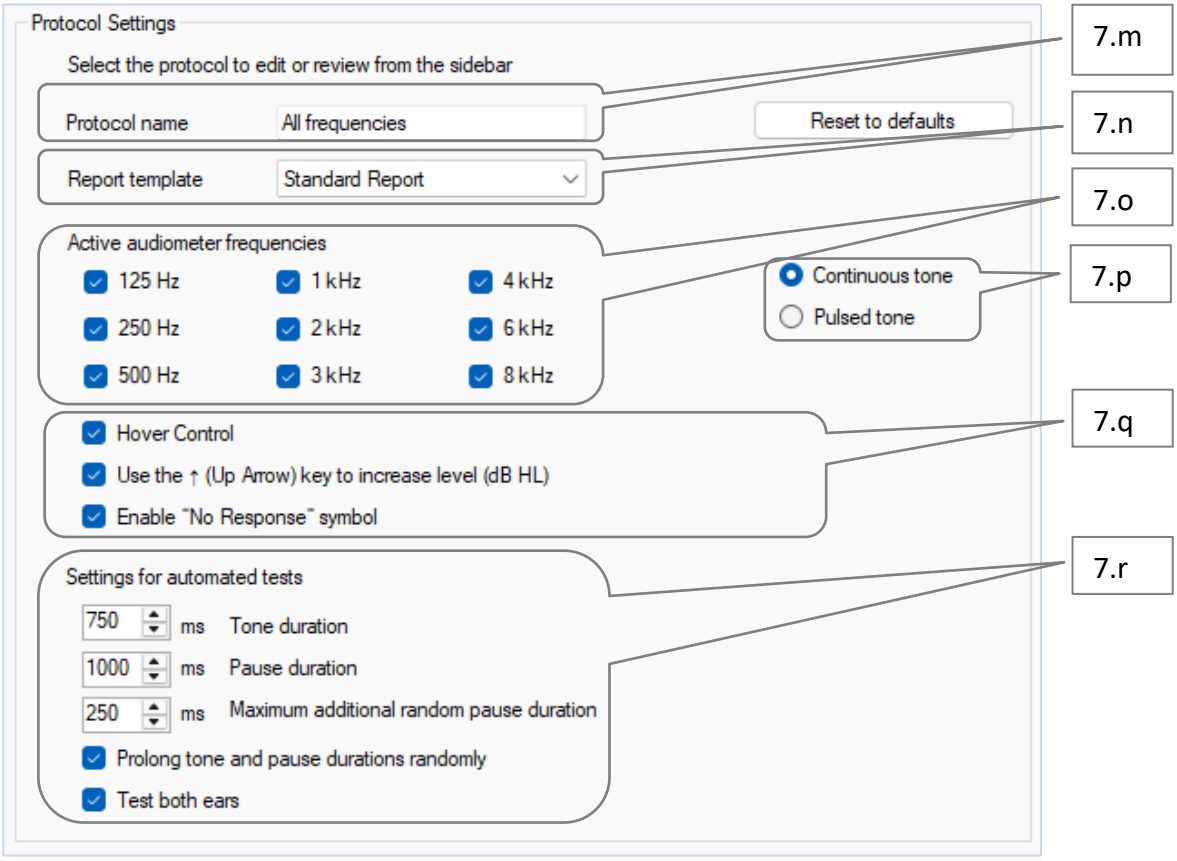


If running on a system with Noah installed, the user can choose not to use Noah and instead store data in a local database.

Alternatively, a GDT data exchange folder can be configured. In that case, test results are exported as PDF documents for storage in the GDT host application. No data will be stored in Noah or nanoAudio's local database.
Changes to these settings will only become effective the next time the application is started.

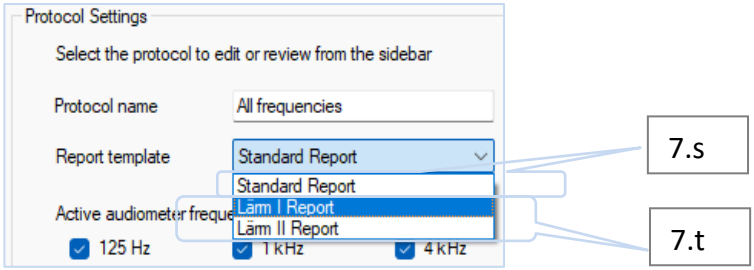
7.9.2 Protocol Settings

You can customize the protocols under Protocol Settings. From the sidebar, select the protocol to edit or review.



The protocol settings include a **Protocol name** (7.m), which is displayed in the sidebar for protocol selection. The protocol names can be changed.

The **Report template** (7.n) option allows users to select the format used for generating reports under a pre-selected protocol. This ensures that reports are created in a consistent and predefined layout according to user requirements.



- **Standard report** (7.s): Selecting this option generates reports using the system's standard report format.
- **Additional reports** (7.t): These report templates can be selected for specific reports when needed. They provide flexibility to generate reports in specific formats or styles to suit particular requirements (e.g., Lärm I or Lärm II Report for Germany).

Once a report template is selected, all subsequently generated reports under that protocol will use the chosen template format. The structure and content of the generated reports are described in detail in Section *8.4: Printing Report*.

Parameters within the (7.o) define the **Active audiometer frequencies** for the selected protocol. Any frequency can be enabled or disabled by setting the checkbox accordingly. If a frequency is disabled, it will not be tested during automated testing and will not be available as a crosshair position in manual testing either.

Under the (7.p), the **continuous tone** or **pulsed tone** can be selected for a pre-selected protocol.

The **Hover Control** (7.q) option allows control of frequency, level, and tone presentation silently without clicking the mouse or pressing any key. While it's activated, simply hover the cursor over the buttons to use them.

The ↑ (Up Arrow) key decreases the stimulus level by default. To invert this function, activate the checkbox **Use the ↑ (Up Arrow) key to increase level (dB HL)** (7.q).

If the checkbox **Enable "No Response" symbol** (7.q) is activated, each click on a point in the audiogram cycles through three states:

1. Response marking – Sets a normal threshold symbol for the selected frequency and level. Adds a threshold level, for example, "30 dB HL" on the audiogram table.
2. No-response marking – Changes the symbol to a "No Response"  (left ear) and  (right ear) symbol at the same frequency and level. Adds a threshold level, for example, "NR 30 dB HL" on the audiogram table.
3. Remove marking – The next click removes the symbol from the audiogram. Adds "--" instead of a threshold level on the audiogram table.

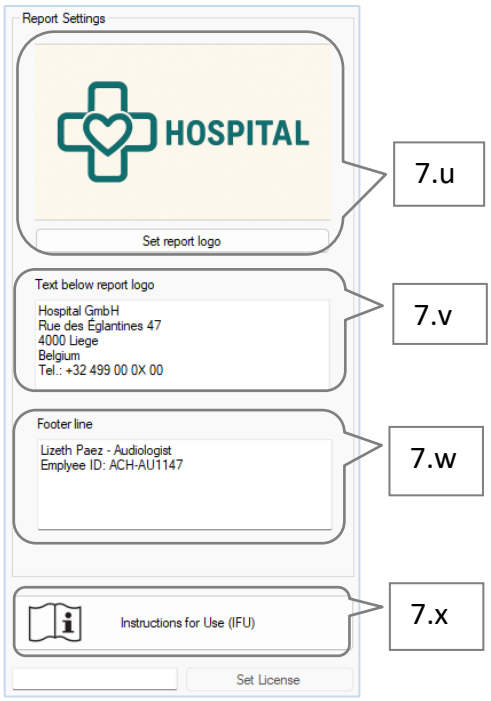
Under the **Settings for automated tests** (7.r), the stimulus timing parameters (**Tone duration**, **Pause duration**, and **Maximum additional random pause duration** for automated testing can be configured. The **Prolong tone and pause durations randomly** option may be selected to enable automatic audiometry with randomized timing and minimal user intervention. The option **Test both ears** will continue the test with the other ear, once all thresholds for the currently active ear have been obtained.

7.9.3 Report Settings

The **Report Settings** allow you to customize the nanoAudio standard report by adding:

- Your logo
- Text below the logo, e.g., an address
- Additional text at the end of the report, e.g., a motto or payment information

These settings are entirely optional. It is possible to use all three in combination or individually.



7.u. Customize your standard report by adding a logo, which will appear in the printed document under the report area 8.d of *8.4.1: Standard Report.*

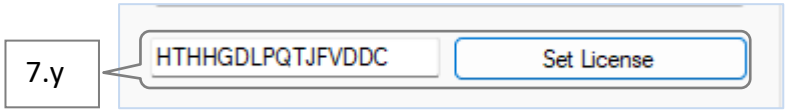
7.v. Customize text below the logo and header, printed under the report area 8.d of *8.4.1: Standard Report.*

7.w. Customize the footer in Report Settings, printed under section 8.d of *8.4.1: Standard Report*.

7.x. Access the Instructions for Use (IFU) or User Manual

Note: The elements (7.u, 7.v, 7.w) mentioned above will appear in the **Standard Report**. But, some of those may or may not appear on the additional reports (e.g., Lärm I and Lärm II for Germany).

7.9.4 Set Additional Licenses



If your distributor has provided an additional license key (e.g., Automated Test or Hughson-Westlake procedure), you can add it as follows:

- Connect the nanoAudio device to your computer.
- Navigate to Section 7.y. and enter the license key provided by your distributor.
- Click **Set License** to activate the license.

When activation is successful, the corresponding functionality is enabled and ready for use..

Note: Enter the license key exactly as provided.

8 Performing the Test

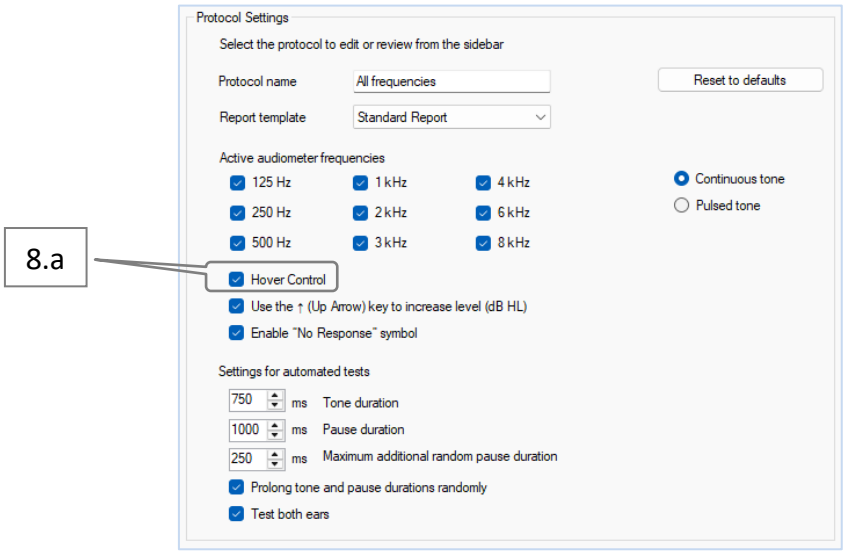
8.1 Preparing the Patient

- If necessary, ensure that the patient is comfortable in a chair or on an examination table. Small children may feel more comfortable sitting on a parent's lap.
- Use an otoscope to check the external ear canal for cerumen (wax build-up), hair, infections, or foreign objects. Excessive wax might influence test results or contaminate the headphones and should be removed by a qualified professional before testing.
- Show the headphone cushions to the patient and explain that those will be carefully positioned over the ears.
- Familiarize the patient with the patient response button, if available, and explain how to hold and when to press it.

8.2 Manual Audiometry / Test

You can choose the test ear by pressing the corresponding ear buttons or using the TAB key to switch between test ears.

Protocol settings can be configured through the Settings menu (see Section *7.9.2: Protocol Settings*).



8.a. Hover control allows silent tone selection during manual audiometry.

The manual audiometry test can be controlled by mouse or keyboard using the following controls.

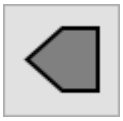
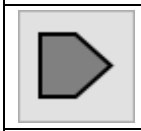
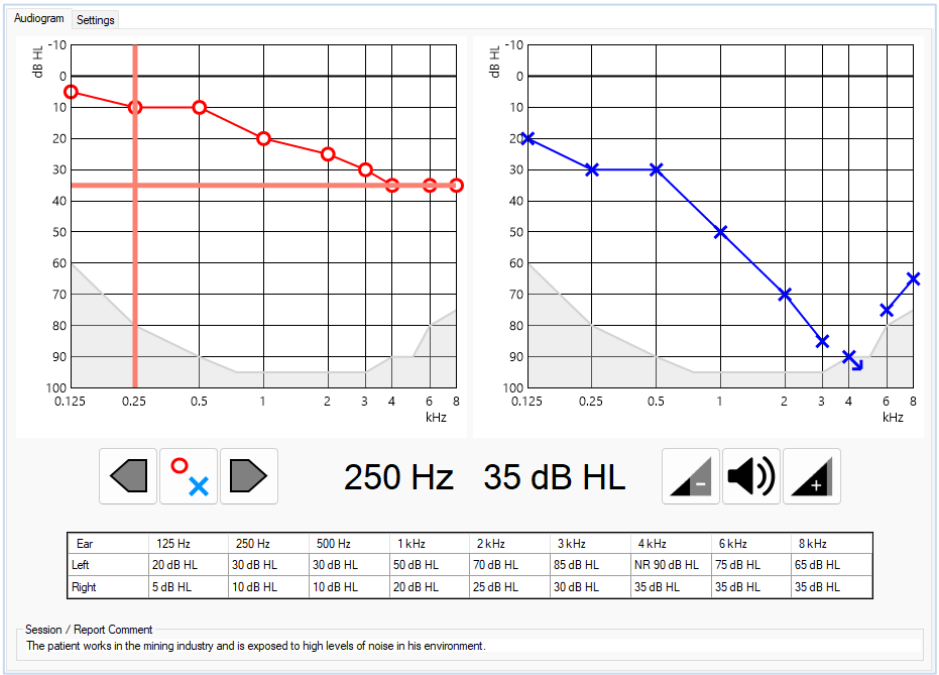
Button	Keyboard shortcut	Function
	ARROW LEFT	Decrease test frequency (crosshair moves left)
	ARROW RIGHT	Increase test frequency (crosshair moves right)
	ARROW UP / DOWN (configurable, see 7.9.2)	Decrease test level (crosshair moves up)
	ARROW DOWN / UP (configurable, see 7.9.2)	Increase test level (crosshair moves down)
	SPACE	Present a tone. The tone is presented as long as the button is being pressed.
	ENTER (configurable, see 7.9.2)	Sets or clears a threshold (and if configured, “No Response” symbol) at the current crosshair position.
No button available	SHIFT + ENTER	Sets “No Response” symbol

Table 3: Keyboard shortcuts for manual audiometry



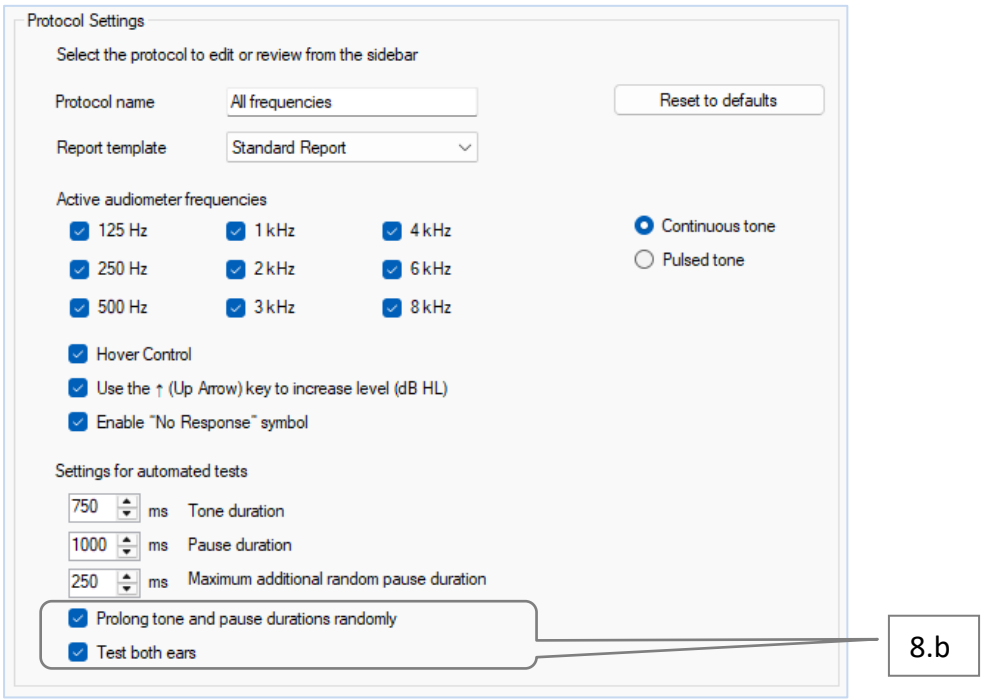
The crosshair position indicates the current frequency and level settings, which are presented in text form below the audiogram graphs.

8.3 Automatic / Patient-controlled Audiometry (Hughson-Westlake)

Automated testing requires the patient response button and an additional software license. If you are missing this additional software license, please contact your service provider to provide you with a license key and see Section *7.9.4: Set Additional Licenses* for instructions.

Since the test will run automatically, it is essential that the patient has been appropriately instructed and understands how to handle the patient response button and when to press and release it. If in doubt, a few tone presentations to familiarize the patient should be carried out in manual audiometry mode before commencing the actual test.

You can choose the test ear by pressing the corresponding ear buttons or using the TAB key to switch between test ears.



8.b. Randomly vary tone and pause durations in automatic audiometry. Supports automatic testing of both ears with minimal user input.

The **Auto Audio** button becomes active as soon as the nanoAudio and patient response buttons are connected and ready to operate. The color of the ear icon matches the selected test ear—blue for the left ear and red for the right ear.

Depending on your preferences, automated testing will be performed on one ear only or on both ears, one after the other. Protocol settings can be configured through the Settings menu (see Section *7.9.2: Protocol Settings*).

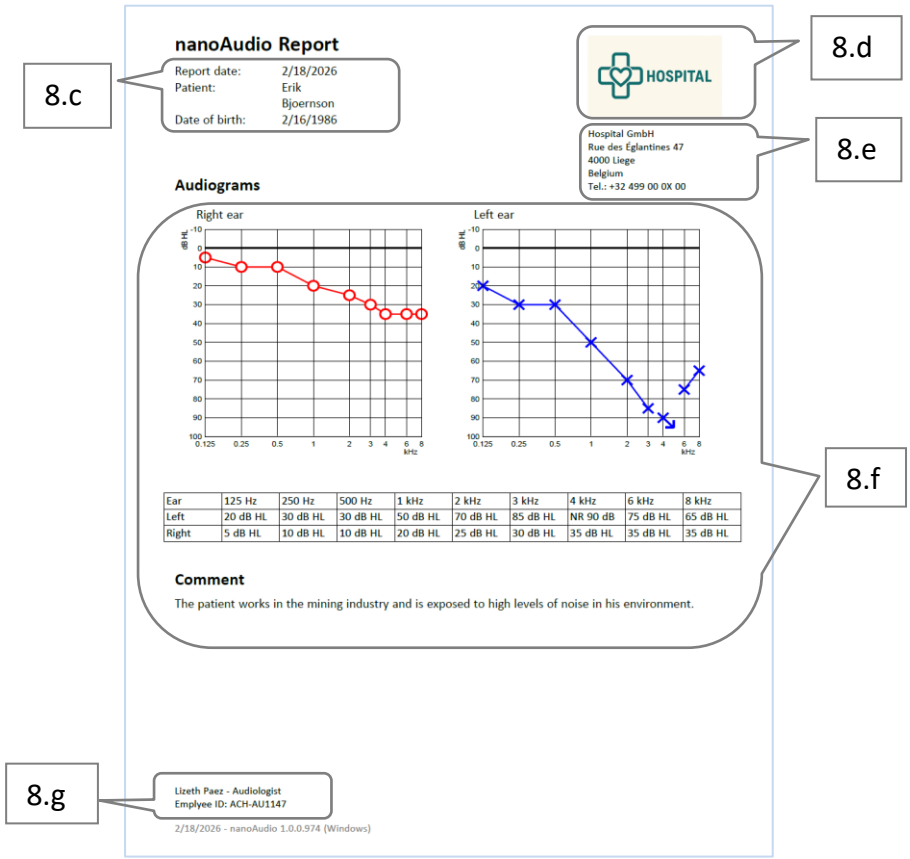
Press the **Auto Audio** button to start the automated test as configured (see Section *7.7.1: Connectivity Status*). The actual test progress is visualized using the crosshair and onscreen controls in the same way as during manual audiometry. If the patient feels uncomfortable at any time during the test, you can pause it by clicking the Auto Audio Pause button.

It is recommended that the progress of the test be monitored until a few thresholds have been obtained to ensure that the patient has understood the procedure. The automated test will be interrupted if patient responses are implausible.

8.4 Printing Report

Select the **Print Report** button Print Report to print out a copy of the results. The report will appear in PDF format, which can be saved or sent to the available printer.

8.4.1 Standard Report



8.c. Patient Database.

8.d. Print your report with a logo added under the GUI area (7.u) of *7.9.3: Report Settings.*

8.e. Hospital address: Includes the hospital's address or other custom text as required by the facility added under GUI area (7.v) of *7.9.3: Report Settings.*

8.f. Audiogram and Comments.

8.g. Footer line: Displays context-specific information such as audiologist notes or general reference details added under the GUI area (7.w) of *7.9.3: Report Settings.*

8.4.2 Additional Reports

The printed report reflects the format and layout of the selected template. The available **Report template**s are displayed in the drop-down list.

9 Troubleshooting

If any problems occur while operating your device, try to solve the problem by consulting the table below.

Issues	Possible reasons	Suggestions
The system shows “No patient selected”.	No patient has been selected.	Select a patient from the patient browser or create a new patient.
The system shows “No device connected”.	nanoAudio is not connected.	Make sure the nanoAudio device is connected to a USB port. Try different USB ports, and avoid using unpowered USB hubs.
The play button does not become active.	No patient response button is connected.	Make sure the patient response button is connected to a USB port. Try different USB ports. Avoid using USB hubs.
Certain frequencies cannot be tested.	The frequency is configured as inactive in the preset.	Review the preset and make sure the frequency is active, or choose another preset.
A message about licenses is shown.	The automated tests require an additional license.	Contact your distributor to clarify whether your nanoAudio license includes automated tests and how to upgrade if it doesn’t.
The automated test stops amid testing.	Implausible patient response.	Make sure the patient has understood the procedure.
The device failed to run on a tablet.	The tablet or system can’t supply enough power through the USB port to the device.	Use an active (powered) USB hub.

Table 4: Some possible issues, their reasons, and the troubleshooting

10 Service and Maintenance

10.1 General Service Information

PATH MEDICAL is committed to customer satisfaction. Please contact your PATH MEDICAL authorized distributor for ordering supplies, obtaining information on training courses and service contracts, getting help with device-related problems, suggesting desired features, or finding answers not addressed in the device's online help or associated Instructions for Use. General information on your device and on PATH MEDICAL can be found at www.pathme.de.

Updates to software, firmware, and documentation (e.g., Instructions for Use) are available on the PATH MEDICAL homepage. If updates are available, PATH MEDICAL distributors will be informed. It is the responsibility of the local distributor to inform the end customer. If you are not sure whether your software, firmware, or documentation is up-to-date, please check www.pathme.de/downloads or contact your distributor.

Service activities and repairs of the device and its electro-medical accessories must only be conducted by PATH MEDICAL or its authorized service partners. Authorized service partners are enabled by PATH MEDICAL with the necessary documentation and training in order to conduct specified service activities and repairs.

PATH MEDICAL reserves the right to decline any responsibility for the safety in operation, reliability, and capability of the device or accessory if any service activities or repairs were conducted by a non-authorized service partner (see also section *12.3: Manufacturer's Liability).* If in doubt, please contact PATH MEDICAL (service@pathme.de) before commissioning a service activity or repair. Please send the device or accessory in its original packaging to your distributor.

10.2 Routine Maintenance and Calibration

To ensure safe operations and to keep measurements valid, it is stipulated by PATH MEDICAL to check the device and calibrate its transducers at least once a year. Additional checks or calibrations might be required by local regulations or if there is any doubt about the correct system function. A warning message is shown on the device if the device service date or a transducer calibration date has expired. In this instance, please contact your distributor or service partner.

REGULATORY BACKGROUND:

The Medical Device Operator Act (MPBetreibV, Germany) requires that audiometric equipment undergo an annual metrological inspection, which must be conducted by authorized and trained personnel. An annual inspection interval is also suggested by EN ISO 8253-1 for audiometers.

EXPLANATION:

The device and its accessories contain parts that are exposed to environmental impacts and contamination. To ensure an accurate measurement function, the fault tolerance provided by the manufacturer or defined by applicable standards needs to be controlled by specifically designed instrumentation and defined procedures. Therefore, metrological inspection must be conducted by authorized service partners instructed and trained by PATH MEDICAL.

For acoustic transducers, differences in environmental conditions between the point of calibration and the point of use may influence the accuracy of the calibration. For more information, please refer to section *12.4: Handling, Transport, and Storage.*

In addition to the annual metrological inspection, a regular visual inspection and a regular check for the correct operation of the device and its accessories are recommended. Guidelines for routine inspections are provided, e.g., in EN ISO 8253-1 for pure-tone audiometry. Before using the audiometer each day, check that the tone output and patient response button are functional. Please follow local regulations or guidelines.

10.3 Repair

In case a device or accessory is defective or differs in any way from its original setup, PATH MEDICAL or an authorized service partner will repair, re-calibrate or exchange the device or accessory. All repairs are subject to parts and material availability. Please contact your distributor to find out about the lead time of any repair activity.

Prior to sending any equipment for repair, please provide relevant information to your service partner (e.g. model, serial number, firmware version, contact information, shipping information, detailed description of experienced issue or defect). This may help speed up the repair process and failure analysis and exclude issues that can be solved without sending the device. Additional information may be requested by your service partner.

See also section *10.1: General Service Information*.

11 Cleaning and Disinfection Recommendations

11.1 General Cleaning Procedures

Cleaning the device and its accessories is very important to comply with hygienic requirements and avoid cross-infection. Please always consider local regulations and read this section carefully.

Before cleaning the device, it must be switched off and removed from all connected components.

Wipe the device's surface with a cloth slightly dampened with mild detergent, normal hospital bactericides, or an antiseptic solution. The following quantities of chemical substances are allowed: ethanol: 70-80%, propanol: 70-80%, and aldehyde: 2-4%. Do not immerse the device, and ensure no liquid gets into it. Dry the device with a lint-free cloth after cleaning.

When using a cleaning agent, please refer to the manufacturer's data sheet for the minimum time period during which the wipe must be in direct contact with the surface of the device or accessory to ensure the effectiveness of cleaning.

To avoid damage to the device and its accessories, please mind the following:

- Do not sterilize the unit
- Do not use the device in the presence of fluid that can come into contact with any electronic components or wiring.

Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by a PATH MEDICAL certified service technician.

Do not use hard or pointed objects on the device or its accessories. The device and its accessories are provided non-sterile and are not intended to be sterilized.

Remember to disinfect the computer, keyboard, mouse, transport trolley, etc., once a week or after contamination. Refer to the respective operating instructions for appropriate cleaning procedures.

11.2 Cleaning of Patient Contact Parts

It is recommended that parts in direct contact with the patient or user (e.g., headphone cushions and patient response buttons) be subject to physical cleaning using recognized disinfectants as defined in section *11.1 General Cleaning Procedures* before being used for the next patient. Hygiene protective covers are recommended for headphones (if available for the used headphone model).

11.3 Infection Control Measures at Facilities

Recommendations for cleaning and disinfecting the device provided in this Instructions for Use (IFU) are not intended to replace or contradict any policies or procedures for infection control in effect at the facility.

12 Notes on Safety

In order to allow safe performance of the nanoAudio, please read the following notes on safety carefully and follow the provided instructions. If not followed, risks of danger to persons and/or the device may be the consequence. Retain this “Instructions for Use” (IFU) for later use, and make sure to hand over this IFU to any person who uses this device. Applicable local government rules and regulations must be followed at all times. Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

12.1 General Usage

Follow relevant regulations in your facility regarding the maintenance and calibration of audiometric equipment. This includes regular servicing of the device and calibration of transducers. See section *10: Service and Maintenance*.

Do not try to open or service the device and its components yourself. Return the device to the authorized service partner for all services.

Do not operate the device if any of the cables (including cables of the PC) show a damaged cord or plug.

The device is capable of producing high stimulus levels. Always make sure to use only stimulus levels that will be acceptable for the patient. Do not present high stimulus levels to a patient if it could cause hearing damage.

For pure-tone audiometry, the patient is allowed to press the patient response button during the test according to instructions from qualified personnel. Supervision by qualified personnel is required for all subjects at all times.

The device needs to be operated in a quiet environment so that measurements are not influenced by ambient noise. This may be determined by an appropriately skilled person trained in acoustics. EN ISO 8253-1 section 11 defines maximum ambient noise levels for audiometric hearing testing. If not followed, measurement data may not reliably represent the actual hearing status. See also section *5.5: Environmental Requirements.*

For calibrated transducers, differences in environmental conditions between the point of calibration and the point of use may influence the calibration accuracy. For more information, please refer to section *13.4: Storage, Transport, and Operating Conditions*.

There are no device parts that can be serviced during use with a patient. There are no device parts that can be serviced by the patient. See also section *10: Service and Maintenance*.

12.2 Customer's Responsibility

All safety precautions given in this Instructions for Use must always be observed. Failure to observe these precautions could result in damage to the equipment and injury to the operator or subject. The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury. It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this IFU and the rules of the organization using the instrument, the more stringent rules should take precedence.

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this IFU and accompanying labels. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from PATH MEDICAL.

12.3 Manufacturer's Liability

Usage of the device in a way deviant from the intended use will lead to a limitation or termination of the manufacturer's liability in case of damage. Improper use includes disregarding the Instructions for Use, the operation of the device by underqualified personnel as well as making unauthorized alterations on the device.

12.4 Handling, Transport, and Storage

Do not drop or otherwise cause undue impact to the device or any accessory. If any damage is suspected (e.g., loose parts inside the device), do not use the device or accessory anymore and return it to your local service partner for repair and/or calibration.

Do not modify the device and its components in any way without written consent of the manufacturer. Failure to do so may result in a reduced level of safety of the system and/or degradation of functionality.

Do not transport, store or operate the device at environmental conditions exceeding those stated in section *13: Technical Specifications*. If the device is moved from a cold location to a warmer one, there will be a risk of condensation. If condensation occurs, the device must be allowed to achieve normal temperature before it is switched on.

Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the device and its components is adequate, sturdy, and safe. PATH MEDICAL is not responsible for

any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces.

Do not allow any fluid to infiltrate the device. Do not immerse the device in fluids as e.g. cleaning agents.

Do not place the device next to a radiator or any other heat source.

12.5 Electrical Safety

The device is intended for connection to the USB port of a standard PC or laptop computer. Do not use any power supply such as USB chargers. Other power supplies made for other electronic devices may cause damage to the device.

When operating the device with a standard mains-powered PC (protection class I), in order to avoid the risk of electrical shock, the PC power supply unit must only be connected to a supply mains with protective earth.

Do not use the device in close proximity to shortwave or microwave therapy equipment, as it may produce instability in the applied parts.

If the device is used during surgery, the connectors must not touch conductive items, including ground.

If a connection is established from the device to a standard PC that is powered through the mains network, the PC must be located outside the patient's close range.

Alternatively, the PC may be running on battery, be medically approved, or powered via a medically approved safety transformer.

In order to completely disconnect the nanoAudio from the supply voltage, the USB plug has to be disconnected. The USB port used should therefore be easily accessible to allow for the disconnection of the nanoAudio.

The computer used to operate nanoAudio must not be serviced while working with a patient. Specifically, the operator must not touch the internal parts of the computer simultaneously while touching the patient. This includes parts accessible by removing covers or enclosure components that can be opened without tools.

Only connect items that have been specified as part of the medical electrical system or specified as being compatible with the medical electrical system.

12.6 Electromagnetic Compatibility

The use of nanoAudio devices next to other electronic equipment or with other electronic equipment in a stacked form should be avoided, as this could result in improper operation (nanoAudio: e.g., occurrence of unwanted noise). Electronic equipment may include, e.g., mobile phones, pagers, walkie-talkies, or RFID systems. If such an application cannot be avoided, nanoAudio and the other electronic devices should be observed to make sure they are working properly. It may be necessary to implement suitable corrective measures (e.g., new

orientation or positioning of nanoAudio or shielding). Please also refer to section *13.5: Information on Electromagnetic Compatibility.*

This device is suitable for use in medical environments, except in high-intensity electromagnetic disturbances such as near-active high-frequency (HF) surgical equipment and RF-shielded rooms used for Magnetic Resonance Imaging (MRI) systems. It is not intended for use in the Magnetic Resonance (MR) environment. It has not been evaluated for safety in the MR environment, including risks such as heating or unintended movement. Therefore, bringing or operating this device in the MR environment may result in injury or device malfunction.

Portable radio frequency communications equipment (radio equipment), including their accessories such as antenna cables and external antennas, should not be used closer than 30 cm (12'') to nanoAudio and its accessories.

During testing, it is recommended to keep low-power radio equipment (≤ 2 W) at a distance of at least 3 m (118'') from nanoAudio and its accessories.

It is recommended to keep very strong sources of radio frequency emissions (e.g., high-power transmitting antennas from radio or TV stations) at a distance of at least 2 km (6560 ft.) from nanoAudio (minimum required distance depends on signal power and directional characteristics of the sender).

Failure to do so may result in a reduction of device performance.

Use of accessories other than those specified or provided by PATH MEDICAL may result in higher electromagnetic emission or reduced immunity to interference of the device and may result in improper device operation.

12.7 Accessories

Headphones must not be used in cases of open wounds or in any case that yields pain for the patient when placing the headphones.

Do not connect any accessories other than those provided by PATH MEDICAL. Other accessories are not compatible with the device and may result in improper functionality of the device. If connecting accessories that do not comply with the same safety requirements as this product, this may lead to a reduction in the overall system safety level.

Cleaning the device is very important for compliance with hygienic requirements and to avoid any cross-infection. For further information, please refer to section *11: Cleaning*.

Always handle cables and transducers with care. Do not excessively bend or twist any cable. The cable may break and hence deteriorate overall device functionality or reduce the overall system safety level. Do not drop, throw, or hit any transducer on a hard object. Sensitive parts (e.g., headphones) may get damaged and deteriorate measurement performance. Do not use a cable or transducer if any damage is suspected.

Keep small parts out of the patient's range (especially children) to prevent accidental swallowing.

No parts may be eaten, burnt, or in any other way used for purposes other than audiometry.

12.8 Waste Disposal

Within the European Union, the device and its accessories, which are electrical or electronic equipment, must not be disposed of in your normal household waste bin since electronic waste may contain hazardous substances. Electrical or electronic equipment is defined as equipment that depends on electric currents or electromagnetic fields. The device and accessories to which the definition is applicable are electronic equipment covered by Directive 2012/19/EC on waste electrical and electronic equipment (WEEE). The device and applicable accessories may be returned to your service partner or PATH MEDICAL for disposal. Please contact your service partner or PATH MEDICAL for proper disposal of the device and its accessories. Please follow your local regulations for proper disposal of the device and its accessories.

Please follow your local regulations for the proper disposal of any packaging material.

13 Technical Specifications

This section provides a summary of the most important technical specifications.

13.1 Standards and Compliance

Device classification	Class IIa (MDR 2017/745) Class II (21 CFR § 874.1050) Class II (MDR Canada)
Applied part classification Applied part	Type B (body) Headphone
Ingress protection rating	IP20
Safety class	II

Audiometry	IEC 60645-1:2017, Pure-tone type 4 (Screening) ANSI/ASA S3.6-2018 (R2023), Pure-tone type 4
Safety of medical electrical equipment	IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014 + A2:2020 ANSI/AAMI ES60601-1:2005 (R2012) with amendments ANSI/AAMI ES60601-1:2005/A2:2021 CAN/CSA-C22.2 NO. 60601-1:14 + A2:22 (R2022) (consolidated)
Electromagnetic compatibility (EMC)	IEC 60601-1-2:2014 + A1:2020
Usability	IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 62366-1:2015 + Cor1:2016 + A1:2020

13.2 Device Characteristics

Device dimension	150 x 72 x 55 mm
Device weight	ca. 170 g
Cable length	180 cm (USB) / 180 cm (headphone) / 170 cm (PB)
Warm-up time	The warm-up time is negligible if the device has acclimatized to the ambient temperature.
Frequencies	125, 250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz ±2 %
Output levels	Ranging from -10 dB HL to a maximum of 100 dB HL (depending on headphone model and frequency)
Headphone models	DD45 or DD65v2 (for further details, refer to the corresponding datasheet)

13.3 Power Supply

The device is intended to connect to the USB port of a standard PC or laptop computer. Do not use any power supply, such as USB chargers. Other power supplies made for other electronic devices may damage the device.

⚠ When operating the device with a standard mains-powered PC (protection class I), the PC power supply unit must only be connected to a supply main with protective earth to avoid the risk of electrical shock.

Input rating of nanoAudio	5V DC, 0.6A
Connector	Standard USB type A plug with standard pin assignment

13.4 Storage, Transport, and Operating Conditions

⚠ For storage and transport, please keep the device and its accessories in the provided carrying case or a similar closable container to protect all components against external forces and environmental impacts, such as mechanical stress (scratches), dust, or moisture. Extreme storage and operating conditions may result in malfunction or impairment of the device and/or transducer calibration.

⚠ If the device is moved from a cold location to a warmer one, there is a risk of condensation. In this case, it must be allowed to achieve normal room temperature before it is switched on. Also, make sure that the operating conditions below are fulfilled.

TRANSPORT AND STORAGE CONDITIONS:

Transport temperature	-20 to 60 °C (-4 to 140 °F)
Storage temperature	0 to 40 °C (32 to 104 °F)
Relative air humidity	10 to 90 % non-condensing
Barometric pressure	50 to 106 kPa

OPERATING CONDITIONS:

Temperature	10 to 40 °C (50 to 104 °F)
Relative air humidity	20 to 90 % non-condensing
Barometric pressure	70 to 106 kPa

In the following cases, a transducer recalibration at the point of use is recommended:

Air pressure at the point of calibration p_c	Air pressure at the point of use p_u
98 to 104 kPa	< 92 kPa
92 to 98 kPa	< p_c – 6 kPa
<92 kPa	< p_c – 6 kPa or > p_c + 6 kPa

See also IEC 60645-1 5.3 and Soares et al.: “Audiometer: Correction factor for atmospheric pressure”, Inter-Noise 2016.

13.5 Information on Electromagnetic Compatibility

Electromagnetic compatibility (EMC), as stated by standard IEC 60601-1-2 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), was certified by an accredited laboratory. Information on the full report is available from PATH MEDICAL upon request.

The user must take care that the device is used in an environment with electromagnetic radiation, as specified in Tables 5 and 6.

Emitted interference measurement	Compliance	Electromagnetic environment
High-frequency emission, according to CISPR11	Group 1	The medical electric device uses high-frequency (HF) energy only for internal operation. Hence, its HF emissions are very low and it is unlikely that adjacent electronic devices are disturbed.
	Class B	The medical electric device may be used in all establishments, including those in residential environments and those that are directly connected to a public power network that also supplies buildings used for residential purposes.

Table 5: Compliance with electromagnetic emission guidelines and resulting requirements for electromagnetic environment

Tests for immunity to interference	IEC 60601 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	To reduce ESD effects, the ground floor shall consist of wood, concrete, or ceramic tiles.
Magnetic field at mains frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency shall correspond to typical hospital or commercial environment.
Proximity magnetic field according to IEC 61000-4-39	8 A/m: 30 kHz 65 A/m: 134.2 kHz ± 2.1 kHz PM 7,5 A/m: 13.56 MHz ± 50 kHz PM	8 A/m: 30 kHz 65 A/m: 134.2 kHz ± 2.1 kHz PM 7,5 A/m: 13.56 MHz ± 50 kHz PM	Proximity magnetic fields at the mains frequency shall correspond to typical hospital or commercial environment.

Table 6: Compliance with immunity to interference tests and resulting requirements for the electromagnetic environment

The device is intended for use in an environment in which high-frequency disturbances are controlled. The user must ensure that the device is used in an environment with minimum distances to potential radiators, as described in *Table 7*.

Tests for immunity to interference	IEC 60601 test level	Compliance level	Electromagnetic environment
Conducted high-frequency disturbance according to IEC 61000-4-6	3 V (150 kHz – 80 MHz) 6 V (ISM and amateur radio frequencies)	3 V 6 V	Portable and mobile radio units shall not be used closer than 30 cm (12'') to the device and its components (i.e., connected cables).
Radiated high-frequency disturbance according to IEC 61000-4-3	3 V/m (80 MHz – 2.7 GHz) 9-28 V/m* (wireless RF communication)	3 V/m 9-28 V/m*	Portable and mobile radio units shall not be used closer than 30 cm (12'') to the device and its components (i.e., connected cables).
* Wireless RF communication frequencies and levels: 28 V/m: 450 MHz, ±5 kHz FM, 1 kHz sine; 810 MHz, 50% PM at 18 Hz; 870 MHz, 50% PM at 18 Hz; 930 MHz, 50% PM at 18 Hz; 1720 MHz, 50% PM at 217 Hz; 1845 MHz, 50% PM at 217 Hz; 1970 MHz, 50% PM at 217 Hz; 2450 MHz, 50% PM at 217 Hz; 27 V/m: 385 MHz, 50% PM at 18 Hz; 9 V/m: 710 MHz, 50% PM at 217 Hz; 745 MHz, 50% PM at 217 Hz; 780 MHz, 50% PM at 217 Hz; 5240 MHz, 50% PM at 217 Hz; 5500 MHz, 50% PM at 217 Hz; 5785 MHz, 50% PM at 217 Hz; RF: radio frequency, FM: frequency modulation, PM: pulse modulation			

Table 7: Minimum distance to potential radiators

13.6 Performance Characteristics

ESSENTIAL PERFORMANCE according to IEC 60601-1

- This device does not possess any ESSENTIAL PERFORMANCE.
- The absence or loss of ESSENTIAL PERFORMANCE will not result in any unacceptable immediate risk.
- Final diagnoses should always be based on clinical expertise and knowledge.

Contact information from distributor/service partner:

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