



User Manual

nanoTymp[®]



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 Medical electrical system consisting of TY-MU and (tablet) computer

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All information, illustrations, and specifications provided within this manual 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 user manual is available online at www.pathme.de/support.

Errors and omissions excepted.

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Table of Contents

1	Overview	5
1.1	Introduction	5
1.2	Authorized Use	6
1.2.1	Intended Use	6
1.2.2	Contraindications	7
1.2.3	Side Effects	7
2	Explanation of Symbols	9
3	Impedance Audiometry Basics.....	11
3.1	Tympanometry	11
3.1.1	Eustachian Tube Function (ETF) Test	12
3.2	Acoustic Reflexes	12
4	Operational Description.....	15
4.1	Computer Requirements	15
4.1.1	Requirements regarding electrical safety	15
4.1.2	Requirements to run the nanoTymp Software	16
4.2	Unpacking and Installation	16
4.3	Operating the Device	17
4.4	Preparing for Testing	17
4.4.1	Starting the software and menu	17
4.4.2	Preparing the patient	20
4.5	Performing the Test	21
4.5.1	Handling the Eartips	21
4.5.2	Performing a measurement: Tympanometry	21
4.5.3	Performing a measurement: Acoustic Reflexes	22
4.6	Settings	23
4.7	Storage.....	25
4.8	Troubleshooting.....	25
5	Service and Maintenance.....	27
5.1	General Service Information.....	27
5.2	Routine Maintenance and Calibration	27

5.3	Repair.....	29
6	Cleaning and Disinfection Recommendations	31
7	Accessories.....	33
8	Notes on Safety.....	35
8.1	General Usage.....	35
8.2	Customer Responsibility	36
8.3	Manufacturer’s Liability.....	36
8.4	Handling, Transport, and Storage.....	36
8.5	Electrical Safety	37
8.6	Electromagnetic Compatibility	37
8.7	Accessories	38
8.8	Waste Disposal	39
9	Technical Specifications	41
9.1	General Device Information	41
9.2	Device Characteristics.....	41
9.3	Power Supply	41
9.4	Storage, Transport, and Operating Conditions	42
10	Electromagnetic Compatibility Information.....	45

1 Overview

1.1 Introduction

Thank you for purchasing a quality product from the PATH MEDICAL product family. The nanoTymp is designed and manufactured to meet all quality and safety requirements. When designing the nanoTymp, PATH MEDICAL placed importance on making it a user-friendly device. The intent was to make its operation easy-to-learn, making the device simple and easy to operate. This manual is your guide for safely operating and maintaining your device, meant to simplify the process of becoming familiar with the operation and functions of the nanoTymp when performing the tests.

The nanoTymp (TY-MU) consists of a hardware device and software, used to conduct tests and to display the results on a computer. Throughout this manual, for identification, the term TY-MU will be used when referring to the hardware itself and the term nanoTymp will be used when referring to the software or to the system as a whole.



This operation manual contains information pertinent to the use of the PATH MEDICAL TY-MU device and the nanoTymp software. Please read the entire operation manual carefully before using the nanoTymp for the first time. Use this device only as described in this manual. We recommend taking particular note of the safety (see section [8: Notes on Safety](#)), intended use (see section [1.2: Authorized Use](#)), cleaning (see section [6: Cleaning](#)) and maintenance (see section [5: Service and Maintenance](#)) instructions.



The TY-MU device consists of the USB cable (left), the main unit (middle) and the probe (right). It is operated via the nanoTymp Software.

1.2 Authorized Use

1.2.1 Intended Use

The TY-MU is an electroacoustic test instrument that produces controlled levels of test tones and signals in order to obtain information on medical conditions affecting the middle ear as well as other afferent and efferent auditory pathways. This testing forms a valuable component of the screening and diagnostic audiometric evaluation, assisting in the diagnosis of possible otologic disorders. It features

- Tympanometry
- Auditory reflexes

All physiological test modules are suitable to be used for all ages elder than infants from 34 weeks (gestational age) that are ready for discharge from the hospital.



TY-MU is intended for use by audiologists, ear-nose-throat (ENT) specialists, and other hearing health care professionals and audiologicaly trained technicians in a medical environment. Please consider local regulations and professional guidelines regarding the qualification requirements for performing measurements with a specific test module.



TY-MU is not intended for operational use by the general public. 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.



TY-MU is intended for indoor-use only and must be operated at defined environmental conditions. See also operating conditions in section [9: Technical Specifications](#) and information about environmental conditions regarding electromagnetic disturbances in section [10: Electromagnetic Compatibility Information](#). TY-MU is not intended for use in oxygen-rich environments.



The nanoTymp consists of a hardware component (TY-MU) and a PC application. Both are not intended to be used as standalone device without the other.

1.2.2 Contraindications



Visual inspection for obvious structural abnormalities of the external ear structure as well as the external ear canal should be performed before testing. Testing should not be performed on patients with one of the following symptoms without a medical doctor's approval:

- Recent middle ear surgery
- Discharging ear
- Acute external auditory canal trauma or infection
- Occlusion of the external auditory canal
- Presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used

1.2.3 Side Effects



There are no known undesirable side effects for using TY-MU.

See also section [8: Notes on Safety](#).













2 Explanation of Symbols

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



Symbols within this manual:

Symbol	Explanation
	Important notice: please read for important information.
	Warning: please read for safety-relevant information, which may cause risk of danger to persons and/or device if not followed.

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

Symbol	Explanation
	Consult instruction for use, i.e. this manual
	Serial number
	Article number
	Medical device
	Manufacturer name and address, production date
	Compliance with applied part type B (body) requirements according to DIN EN 60601-1
	Device with safety class II according to DIN EN 60601-1
	Direct current input
	The device is electronic equipment covered by the directive 2012/19/EC on waste electrical and electronic equipment (WEEE). When discarded, the item must be sent to separate collection facilities for recovery and recycling.
	CE mark to declare conformity to directives and regulations as stated in the Declaration of Conformity (see https://pathme.de/support/#certificates) The number below the CE mark (if any) 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 company logo

For further symbols, e.g. on accessory labels, please refer to the respective manual or data sheet of the accessory. Important symbols may include:

Symbol	Explanation
	Single use only. Do not reuse the respective item.
	Expiration date. Do not use the respective item after the specified date.

3 Impedance Audiometry Basics

The primary purpose of impedance audiometry is to determine the status of the tympanic membrane and middle ear via tympanometry. The secondary purpose of this test is to evaluate acoustic reflex pathways, which include cranial nerves (CN) VII and VIII and the auditory brainstem. This test cannot be used to directly assess auditory sensitivity, although results are interpreted in conjunction with other threshold measures.

3.1 Tympanometry

Tympanometry is an objective measurement of middle ear mobility (compliance) and pressure within the middle ear system. The function of tympanometry is to provide one way of diagnosing and monitoring problems in the middle ear system. Tympanometry is one type of test used to identify and diagnose disorders that may lead to or have already caused a hearing loss. Performing tympanometry and acoustic reflex testing can help with making decisions about referring for further medical treatment and can help differentiate between different pathologies such as:

- Middle ear infection (otitis media)
- Perforation of the eardrum
- Fluid in the middle ear
- Tumor of the middle ear
- Ossicular fixation or discontinuity
- Eustachian tube dysfunction

Before the test, visual inspection with an otoscope for structural abnormalities, obstructions, or cerumen (ear wax) should be done. A common classification system for interpreting tympanograms with a 226 Hz probe can be seen below:

Type	Characteristics	Indication
A	Peaks at 0daPa	Normal
Ad	Unusually high peak	Suggests ossicular dislocation.
As	Reduced peak	Suggests ossicular fixation.
B	Flat, no peak	Indicates reduced movement, usually a sign of middle ear fluid or a space-occupying tumor.
Type B with an abnormally large volume	>2.0 cc volume	Indicates a perforation or patent ventilation tube.
Type B with an abnormally small ear canal volume	<1.0 cc	Indicates faulty probe function, usually the probe is against the ear canal wall or blocked with cerumen.
C	Negative pressure	Indicates abnormal negative peak.
D	Shows a dip in the peak	Indicates scarred eardrums or a hypermobile tympanic membrane (TM).

3.1.1 Eustachian Tube Function (ETF) Test

There are a number of eustachian tube (ET) abnormalities that can be identified with a eustachian tube function (ETF) test. Some of the most common ET dysfunctions are obstructions (such as an anatomic abnormality), local mucosal changes as a result of allergies or otitis media, or patulous eustachian tubes. The ET dysfunction can be transitory, caused by an upper respiratory infection resulting in negative pressure, or poor veli palatini muscle function commonly seen in children. ET dysfunction can also be due to chronic conditions such as palatal muscle dysfunction (i.e. from a cleft palate) or structural changes from radiation. Other conditions that can result in ET dysfunctions include stroke and muscular dystrophy.

An ETF test can be done using conventional tympanometry. A Type C, or >-250 daPa middle ear pressure, tympanogram indicates that the ETF is abnormal. However, the absence of negative pressure does not necessarily imply normal ETF.

If the tympanogram is normal and if the tympanic membrane is intact, have the patient perform a Toynbee (hold nose and swallow) procedure, and redo the tympanogram. If ETF is normal you will see a negative shift in pressure. Then, have the patient perform a Valsalva (hold nose and blow) procedure, and redo the tympanogram. If ETF is normal you will see a positive shift in pressure. The total shift in pressure should be at least 15 - 20 daPa. It is important to note that only about 80% of adults (and a lower percentage of children) can properly perform these procedures. If there is a tympanic membrane perforation or patent ventilating tube, introduce positive (or negative) pressure of approximately 400 daPa. If the ET opens as a direct result of the pressure (i.e. the pressure returns toward 0 daPa) the ET is most likely working properly.

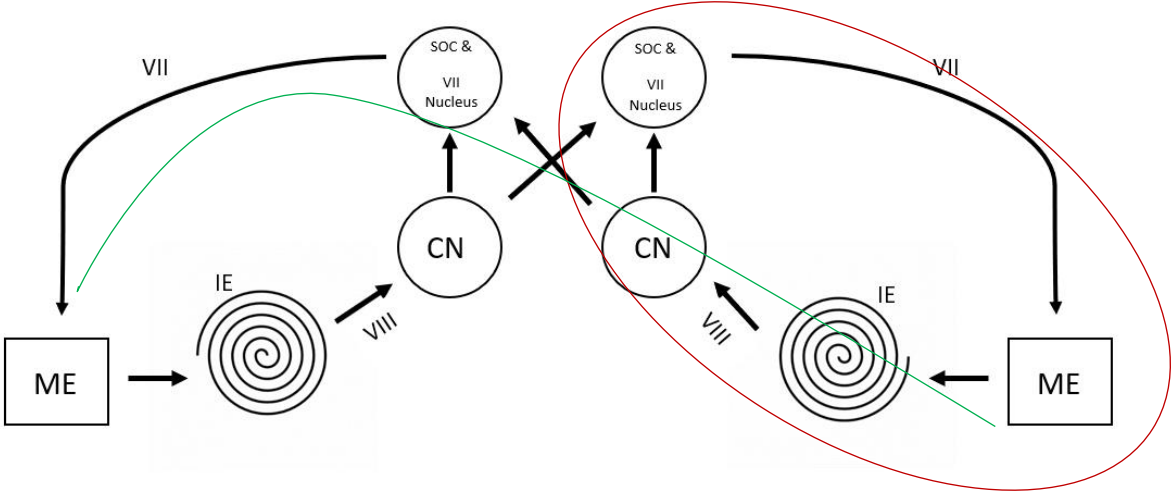
3.2 Acoustic Reflexes

An acoustic reflex is the contraction of the stapedial muscle which occurs under normal conditions when a sufficiently intense sound is presented to the auditory pathway. Acoustic reflex measurements provide information about the middle and inner ear, in addition to the eighth and seventh cranial nerve and brainstem function. The contraction of the muscle causes a stiffening of the ossicular chain which changes the compliance of the middle ear system and is measured using a probe tone in the same way as with tympanometry. There is an afferent limb to the acoustic reflex involving the TM, middle ear, cochlear, and eighth cranial nerve, and also an efferent limb involving the seventh cranial nerve, middle ear, and TM with cross-over in the brainstem at the level of the superior olive complex. An ipsilateral acoustic reflex is measured when the stimulus presentation and measurement are made in the same ear by means of the probe. Contralateral Acoustic Reflex is measured when the stimulus presentation is made in the opposite ear of where the measurement is made. Stimulus tones of varying high intensities (70-115 dB SPL) at 500 Hz, 1000 Hz, 2000 Hz or 4000 Hz are presented as short bursts. An acoustic reflex will either be present, elevated or absent, depending on whether a change in compliance was measured or not.

Below is a table that can be used for interpreting acoustic reflex thresholds (ART). For this example, pathologies of the right ear have been used.

Ear	Ipsilateral ART	Contralateral ART
Bilateral normal ART		
Right	Present	Present
Left	Present	Present
Cochlear pathology (right ear)		
Right	Elevated/Absent	Elevated/Absent
Left	Present	Present
Vestibulocochlear nerve pathology (right ear)		
Right	Elevated/Absent	Elevated/Absent
Left	Present	Present
Facial nerve pathology (right ear)		
Right	Absent	Present
Left	Present	Absent
Mild middle ear pathology (right ear)		
Right	Elevated/Absent	Present/Elevated
Left	Present	Elevated
Severe middle ear pathology (right ear)		
Right	Absent	Absent
Left	Present	Absent
Intra-axial brainstem pathology (small)		
Right	Present	Absent
Left	Present	Absent
Intra-axial brainstem pathology (large)		
Right	Absent	Absent
Left	Absent	Absent

Below is a diagram of the acoustic reflex pathway indicating the ipsilateral and contralateral pathways.



Key	
—	Ipsilateral pathway
—	Contralateral pathway
ME	Middle ear
IE	Inner ear
CN	Cochlear nucleus
SOC	Superior olivary complex
VIII	Vestibulochoclear nerve
VII	Facial nerve

4 Operational Description

PATH MEDICAL is dedicated to producing quality work at affordable prices, and we support everything we sell. All our products are designed with the balance of expert performance and ease of use in mind. Your feedback is valued. If there's something you love, hate or just 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.

4.1 Computer Requirements

The TY-MU can only be used in combination with a PC, laptop or tablet computer running the nanoTymp Software. This section describes requirements to consider when choosing a suitable computer.

4.1.1 Requirements regarding electrical safety



The TY-MU together with the computer constitutes a medical electrical system as defined in EN 60601-1. Electrical safety requirements as described in EN 60601-1 have to be fulfilled by the medical electrical system as a whole. While the TY-MU itself meets all applicable requirements, it remains the responsibility of the operator's organization to ensure that the computer used to operate the TY-MU is compliant as well.

This can be achieved by several ways

- Using a medically (EN 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 which is kept outside of the patient environment

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

See also section [8.5: 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.

4.1.2 Requirements to run the nanoTymp Software

The nanoTymp software can be used on any computer running Microsoft Windows 10 or higher. At least one free USB port is required to connect the TY-MU instrument.

Minimum system requirements to install nanoTymp:

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



For data privacy and cybersecurity reasons please make sure to secure the physical and network access to computers which locally store or have remote access to personal data (e.g. patient test results). This may include e.g. the computer(s) on which nanoTymp is running, the computer(s) on which the nanoTymp 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 nanoTymp or the computer(s) on which the nanoTymp database (or any backup of the database) is stored. Install the latest service packs and security patches for the operating system nanoTymp is running on and ensure the operating system still is actively supported with security updates.



Please make sure to implement an appropriate backup policy in order to avoid loss of relevant data (e.g. patient test results).

4.2 Unpacking and Installation

We recommend that you unpack your TY-MU carefully, making sure that all components are removed from the packing materials. Verify that all components as listed below are included with 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 to be 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 together with the invoice, serial number, and a detailed report of the problem. Save all the original packing

material and the shipping container so the device can be properly packed if it needs to be returned for service or calibration.

Your nanoTymp set should consist of the following items

- This manual
- The TY-MU instrument
- Lanyard for hands free testing
- A USB Stick containing Software and an electronic version of this manual
- Starter Sets of ear tips and probe tips (see also section [7: Accessories](#)).
- A calibration cavity block

To start using your nanoTymp, install the nanoTymp software from the accompanying USB Stick. In case the USB stick is not available, the nanoTymp software can be found in the support / download section of www.pathme.de.

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

The TY-MU device itself does not require any special installation procedures. It is ready to operate as soon as connected to a USB port of the computer.



To remove supply voltage from the instrument, e.g. when performing cleaning procedures, the TY-MU needs to be disconnected from the USB port. The USB port used should therefore be located easily accessible to allow for disconnection of the TY-MU.

4.3 Operating the Device

Always ensure proper operation of the device by following routine check procedures for audiometric equipment. The nanoTymp should be operated in a quiet room.

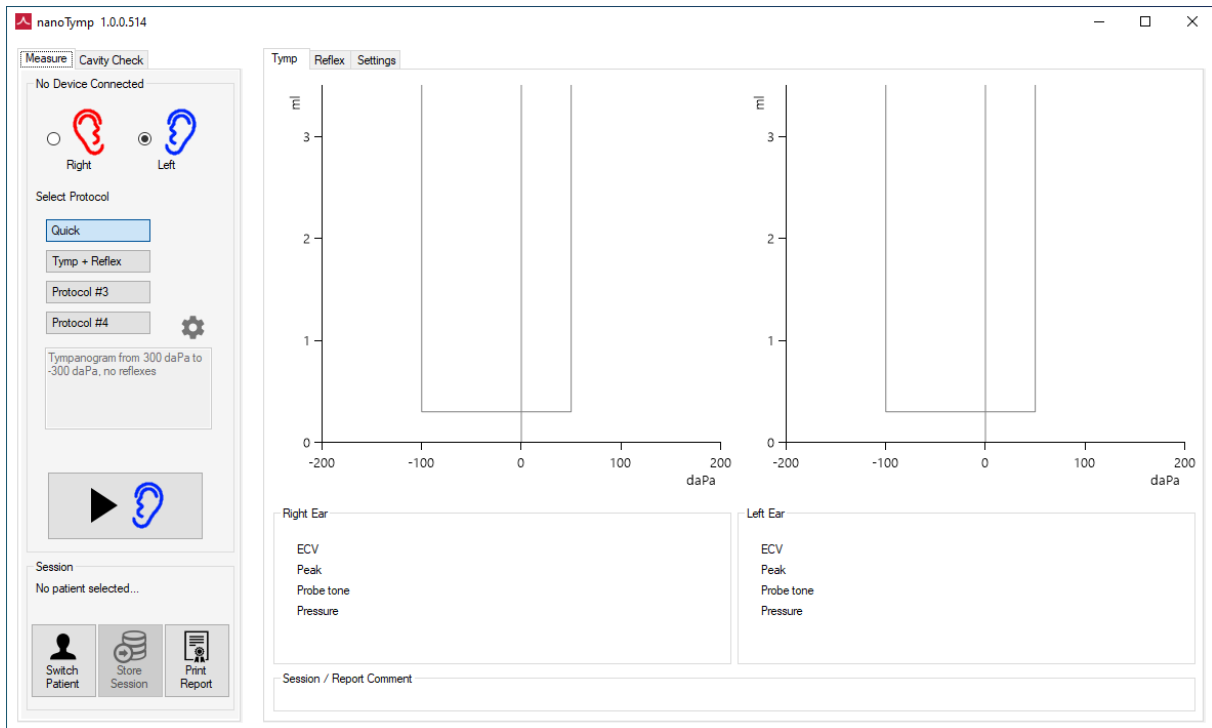
4.4 Preparing for Testing

A USB-cable connects the TY-MU with a USB port of a laptop or desktop computer. The TY-MU's power is directly supplied through the computer via the USB port. No external power supply is needed. This makes the nanoTymp system easy and safe to use.

4.4.1 Starting the software and menu

After starting the computer, launch the nanoTymp software by clicking on the icon "nanoTymp" on the desktop or direct from the program menu. The program launches with the start screen (see figure below). The start screen displays the buttons controlling entry

into the major functions of the nanoTymp. To access the test, select the module from the start screen.







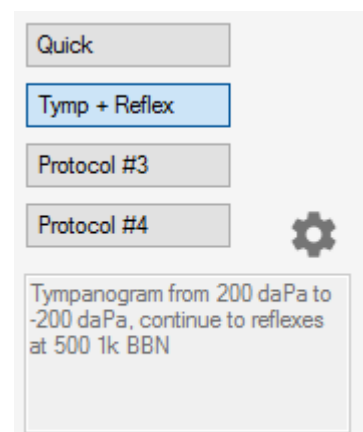
To close the program, click onto X located on the top right corner of the screen. Additional functions are located at the top left of the screen.


The menu bar at the left contains the tabs “Measure” and “Cavity Test”.

This section describes the Measure tab. The cavity test and calibration procedure is described in section [5.2: Routine Maintenance and Calibration](#).

The different functions under each tab will be discussed starting from the top or first line.

- Directly beneath the “Measure” tab the status of the device in terms of connectivity will be displayed as Device Connected / Device not Connected
- 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 according to your testing preference. When one of the protocols is selected it will be shaded in blue and a short description of the test will appear in the info box below the last protocol. The Setting  button can be selected to either view or change the settings related to the specific protocol.



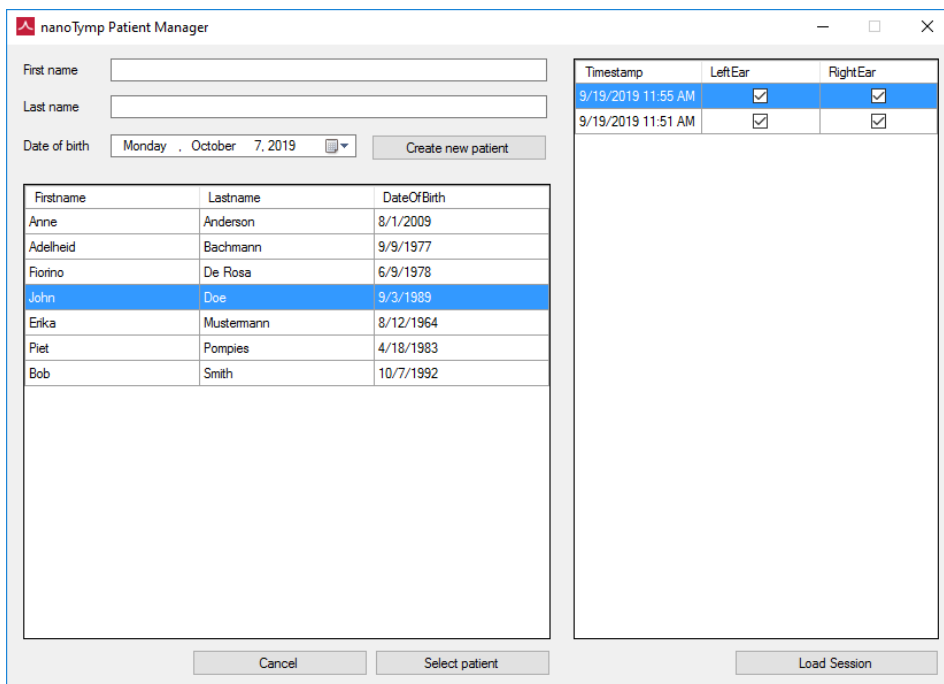
- The **start** test button  can be pressed when the probe is in position as both patient and clinician is ready for the measurement to commence. The color of the ear will match the ear selected for testing **blue** for left ear and **red** for right ear.
- Under **Session** you will be able to view the patient information, store a session and select to print a report.



When the **Switch Patient**



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 **Select Patient** button or double clicking on the desired patient name with the mouse. To load data of 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 Noah System installed, nanoTympanic 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 can be used to store results of a patient that has already been loaded on the database. If a patient 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, a patient should be created or selected first (see **Switch Patient**).



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

A **Session / Report Comment** text, 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 and maintained with the session. If entered *after* storing the session, the comment will just appear on the printout and not be kept on record.

4.4.2 Preparing the patient

- Make sure that the patient is comfortable on a chair or on an examination table if necessary. Small children may feel more comfortable sitting on a parent's lap.
- Check the external ear canal for cerumen (wax) with an otoscope. Excessive wax should be removed by a qualified professional to prevent the probe opening from clogging, which will inhibit testing. Excessive hairs may have to be cut for a seal to be obtained.
- Show the probe to the patient and explain that the eartip will be inserted into the ear canal. A seal must be achieved for the test to progress, so it is important to explain the effect of coughing, talking and swallowing on the test and test results.
- For Tympanometry, the purpose of the test can be explained as a test to measure the movement of the eardrum as well as the health of the middle ear. A small amount of air will flow through the probe to move the eardrum; it produces a sensation equal to pressing a finger slightly into the ear canal. One or more tones will be heard during the test. No participation is expected from the patient.
- For Acoustic Reflexes, the purpose of the test can be explained as a test to access the muscle (Musculus stapedius) in the ear's ability to protect the ear from loud sounds. One or more tones varying in intensity will be heard during the test. No participation is expected from the patient.

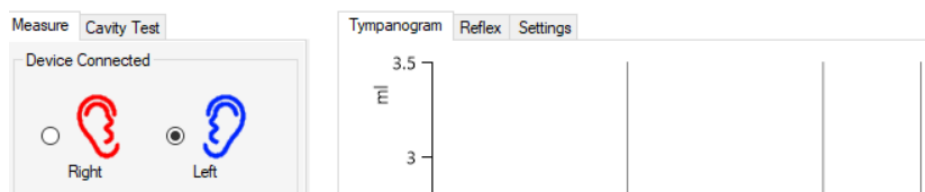


4.5 Performing the Test



4.5.1 Handling the Eartips

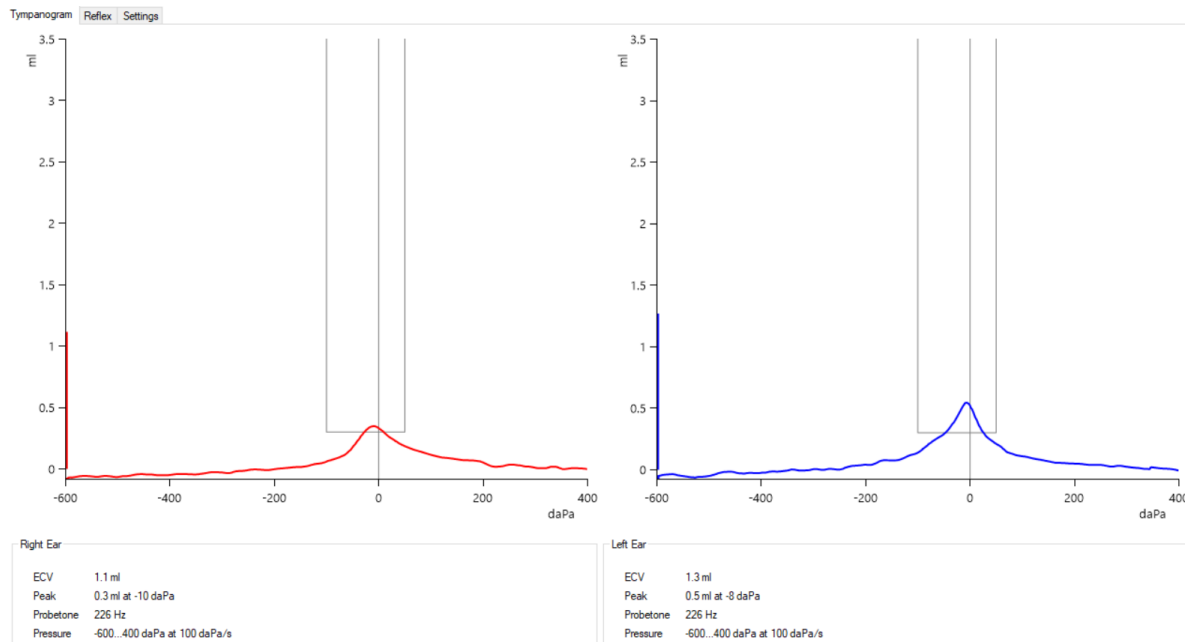
Choose the proper size of eartip based on your inspection of the size of the patient's ear canals. Do not insert the probe without having an eartip attached, this is to prevent damage to the patient's ear canals. Put the eartip tightly on the probe tip making sure it is pushed all the way down. Insert the probe with eartip attached into the patient's ear. For children and adults, pull gently up and back on the outer ear during insertion to straighten the ear canal. Hold the adapter and aim and twist (gently) the eartip into the ear canal. The fit of the eartip should be secure. Release the earlobe. When testing infants, gently pull the pinna down and back to straighten the ear canal. Each eartip should only be used once.

4.5.2 Performing a measurement: Tympanometry



Choose the test ear by pressing on the corresponding tympanogram ear buttons.

The measurement will be started as soon as the probe is properly placed in the ear and the test button   is selected. The measured curve will be displayed simultaneously to the ongoing test. Below the graphic the numerical values are shown:



Ear Canal Volume (ECV): indicates the volume of the section of the auditory canal between the eartip and the eardrum in ml.

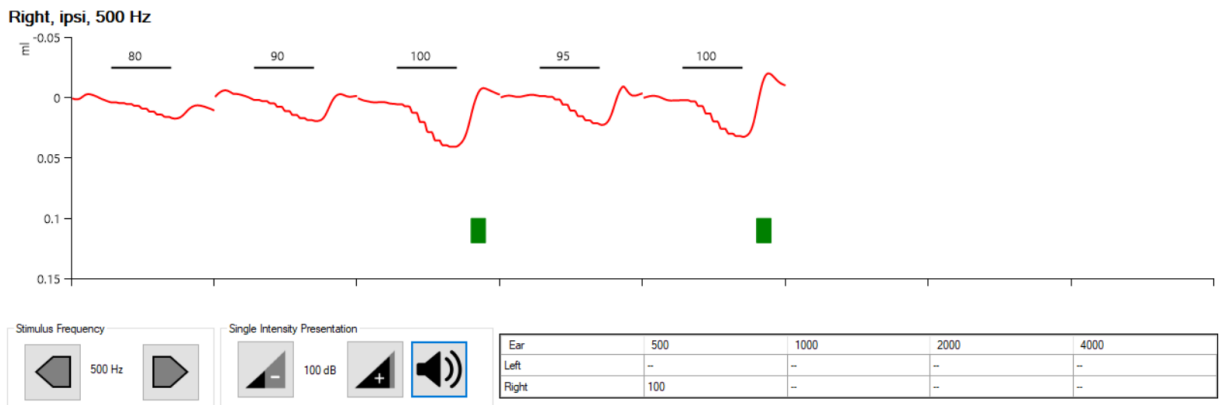
Compliance (Peak): indicates the maximum value of the movement from the tympanic membrane (eardrum) in ml. The pressure in daPa at the highest measured Compliance is also indicated here.

Pressure: indicates the pressure setting of the protocol in daPa/s.

4.5.3 Performing a measurement: Acoustic Reflexes

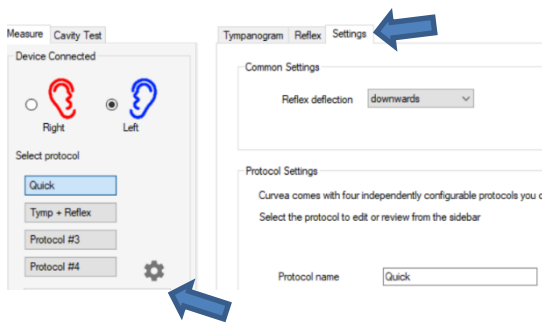
The screen shows the buttons for Ipsi reflexes with the different frequency buttons. They are always presented according to the default setting in the setting menu and from low to high frequencies. It is possible to select or deselect one of the frequencies by pressing on it. A frequency will be selected if the box is ticked . To present the sequence of selected frequencies press the start / play button . To present frequencies and intensities manually select the frequency and intensity and press the present button .

The evaluation of the Acoustic Reflex test results depends on the configuration and is displayed as a graph. The measured curves are displayed simultaneously to the ongoing test. For easier evaluation the pass criterion threshold and the zero line are shown in the graph. Above each diagram the intensity level in dB HL is displayed. When the reflex is present there is a green block below the reflex response. The deflection of the graph (going up or going down) can be modified in the settings.



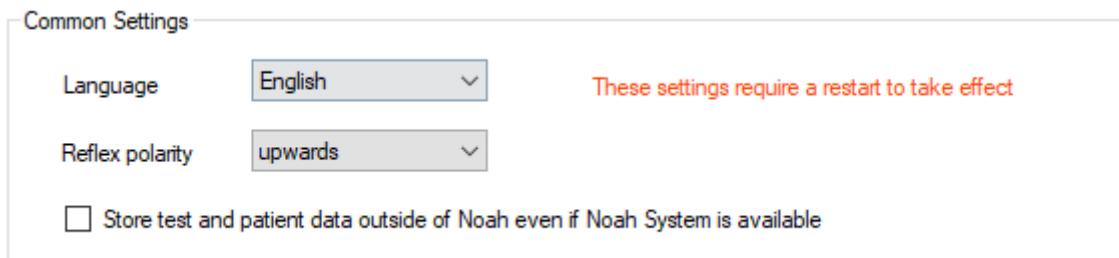
4.6 Settings

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 reflex tab.

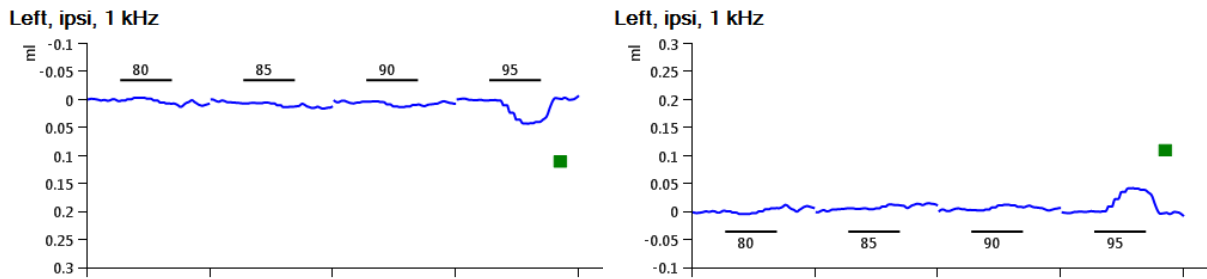


The following settings are available: Common Settings, Protocol Settings, and Report Settings

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



Furthermore, the reflex deflection can be changed from downwards to upwards. Below find an example of downward and upward deflection of the same reflex responses.



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

Changes to any of these settings will only become effective the next time the application is started.

Under **Protocol Settings** you can customize the protocols. Select the protocol to edit or review from the sidebar.

Protocol Settings

nanoTymp offers four protocols which can be configured independently here

Select the protocol to edit or review from the sidebar

Protocol name

Pressure range

Min	Max	Speed
-300 <input style="width: 30px;" type="text"/>	300 <input style="width: 30px;" type="text"/>	200 <input style="width: 30px;" type="text"/>
daPa	daPa	daPa/s

Continue to reflexes after tympanogram

Require type A tympanogram for auto proceed to reflexes

Select stimuli for automatic reflex threshold

500 Hz 1 kHz 2 kHz 4 kHz BBN

Level range for automatic reflex threshold

dB HL

Always perform reflex testing at 0 daPa (pump deactivated)

daPa Perform reflex testing at the following offset to tympanometric peak pressure

The protocol settings consist of a protocol name, which will appear on the sidebar to choose protocols from (blue box).

Parameters within the green box define pressure range and pump speed for recording the tympanogram.

Additionally, the settings allow for the option of reflexes to automatically be measured after recording the tympanogram. The automatic reflex recording can also be restricted to type A (i.e. normal) tympanogram results.

In the **purple box**, stimulus frequencies and level range can be defined for automatic reflex testing.

By default, reflex testing is performed at peak pressure, i.e. the point of maximum compliance in the tympanogram. You can however disable pressurization during reflex recording, or specify a custom pressure offset here.

The **Report Settings** allow you to customize the nanoTymp reports by adding

- Your logo
- Text below the logo, like an address
- Additional text at the end of the report, such as a motto or payment information

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

4.7 Storage

To fully power off the TY-MU, simply disconnect the USB cable. When the TY-MU is not in use, store 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 section [9.4: Storage, Transport, and Operating Conditions](#).

4.8 Troubleshooting

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

Issue	Possible reason	Suggesting
System shows "Leaky. Please Retry"	The probe fit to the ear canal is not airtight.	Check the probe and ear tip. Make sure ear tip size is appropriate. Re-position the probe in the patient's ear canal.
System shows "No patient selected"	No patient has been selected	Select a patient from the patient browser or create a new patient
System shows "No device connected"	TY-MU not connected	Make sure the TY-MU is connected to a USB port. Try different USB ports. Avoid using hubs.

<p>Reflex measurement does not start</p>	<p>Probe fit is unstable/leaky or hypermobile eardrum</p>	<p>Reflex measurements require a stable probe fit. Try to re-position the probe in the patient's ear canal.</p> <p>On patients with hypermobile eardrum, try specifying offsets like 20-50 daPa to tympanometric peak pressure.</p>
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5 Service and Maintenance

5.1 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 online help or associated manuals. General information on your device and on PATH MEDICAL can be found at www.pathme.de.

Updates to software, firmware and documentation (e.g. user manual) 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/support 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 from PATH MEDICAL with 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. 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.

5.2 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 correct system function. A warning message is shown on the device if the device service date or a transducer calibration date has expired. Please return the device or accessory immediately to your distributor or service partner.

EXPLANATION:

The device and its accessories contain parts, which are exposed to environmental impacts and contamination. In order 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.

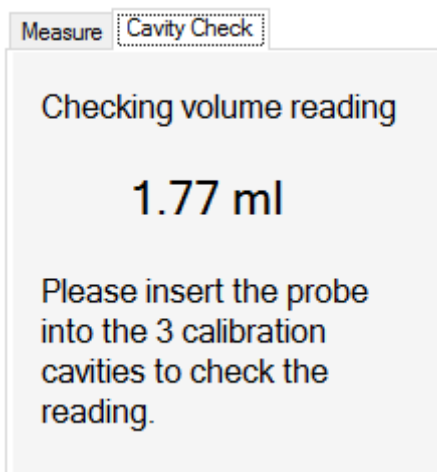


For acoustic transducers differences in environmental conditions between the point of calibration and the point of use may influence the calibration accuracy. For more information please refer to section [8.4: Handling, Transport, and Storage](#)



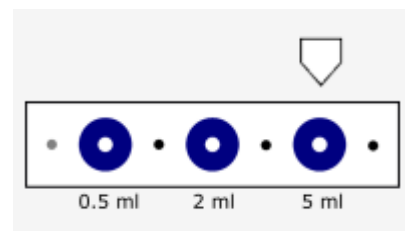
In addition to the annual metrological inspection, a regular visual inspection and a regular check for correct operation of the device and its accessories is recommended. Before using the middle ear analyzer module each day, use the calibration volume cavities provided with your device to check the calibration of the ml/mmho meter. Please follow local regulations or guidelines.

To check volume calibration, switch to **Cavity Check** tab in start screen. Then insert the probe into any of the three volumes of the cavity block. The current volume reading will be displayed on screen.



If any of the volume readings deviate from the nominal volume by more than 10% (e.g. 1.7 ml is shown for 2.0 ml volume) – the calibration should be repeated.

For this procedure, press the **Re-calibrate** button and then insert the probe into all of the three cavities as indicated on screen:



5.3 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 in speeding up the repair process and failure analysis and in excluding issues that can be solved without sending the device. Additional information may be requested by your service partner.

See also section [5.1: General Service Information](#).

6 Cleaning and Disinfection Recommendations



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

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



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



Disposable accessories (e.g. ear tips and other accessories marked for single use only on the package label or data sheet) must be replaced between patients (or ears of the same patient) to avoid cross-infection. It is recommended that any other parts which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedure between patients.

The ear probe test cavity must be used with a disinfected and clean new probe tip. In case of contamination with pathological material or suspected dirt inside the cavity, please discontinue the use of the test cavity. For external cleaning, please use a sterile alcohol wipe, typically containing 70% isopropyl alcohol.

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



To avoid damage of 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 of the 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 also disinfect computer, keyboard, transport trolley etc. once a week or after contamination. Refer to the respective operating instructions for appropriate cleaning procedures.

Recommendations for cleaning and disinfection of the device presented in this manual are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.

7 Accessories

Available accessories for nanoT ymp include:

Picture	Part number	Description
	100734	Tipbox, 10 of each size, 14 sizes
	100587	AB04 – Accessory box T ymp
	100369	Probe clip
	100549	Calibration cavity block

	<p>100013</p>	<p>Probe tips PT-A (transparent) available in different package sizes</p>
	<p>upon request</p>	<p>Lanyard</p>

This list of accessories may be subject to change. Accessories may be available only upon request, may be replaced by comparable equipment, or may be discontinued without prior notice. Please contact your distributor for an up-to-date list of available accessories.

8 Notes on Safety



In order to allow safe performance of the nanoTymp 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 manual for later use and make sure to hand over this manual 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.

8.1 General Usage



Follow relevant regulations in your facility regarding maintenance and calibration of audiometric equipment. This includes regular servicing of the device and calibration of transducers. See section [5: 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 service.

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

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

The enclosure of the device (not the ear probe) may reach surface temperatures above 41°C (and below 48°C) during prolonged operation at high ambient temperatures, or under single fault condition. Direct skin contact should therefore be avoided.



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 [9.4: Storage, Transport, and Operating Conditions](#).

There are no device parts, which can be serviced during use with a patient. There are no device parts, which can be serviced by the patient. See also section [5: Service and Maintenance](#).

8.2 Customer Responsibility



All safety precautions given in this operation manual 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 manual 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 manual 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.

8.3 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 operation manual, the operation of the device by underqualified personnel as well as making unauthorized alterations on the device.

8.4 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 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 [9: 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.

8.5 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 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 which 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 TY-MU from supply voltage, the USB plug has to be disconnected. The USB port used should therefore be located easily accessible to allow for disconnection of the TY-MU.

The computer used to operate the TY-MU must not be serviced while working with a patient. Specifically, the operator must not touch internal parts of the computer at the same time as touching the patient. This includes parts accessible by removing covers or enclosure components which 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.

8.6 Electromagnetic Compatibility



The use of TY-MU 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 (TY-MU: 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, TY-MU 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 TY-MU or shielding). Please also refer to section [10: Electromagnetic Compatibility Information](#).

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 TY-MU 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 TY-MU 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 TY-MU (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 other accessories than the ones 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.

8.7 Accessories



The probe tip of the ear probe must not be inserted into an ear without a disposable ear tip properly affixed to the probe tip. Make sure that the ear tip size corresponds to the patient's ear canal size.

Ear probes must not be used in cases of external otitis (outer ear canal infection) or in any case which yields to pain for the patient when inserting the ear probe.

Disposable accessories (e.g. ear tips and other accessories marked for single use only on the package label or data sheet) must be replaced between patients (or ears of the same patient) to avoid cross-infection. Do not clean or reuse these items.

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 which 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 [6: 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. ear probe microphone and loudspeakers) may get damaged and deteriorate measurement performance. Do not use a cable or transducer if any damage is suspected.

Keep small parts (e.g. ear tips) out of patient's range (especially children) in order to prevent accidental swallowing.

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



Inspect the transducer channels of the ear probe (including probe tip and ear tip) before use. A blocked loudspeaker and/or microphone channel may deteriorate measurement performance.

8.8 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 which depends on electric currents or electromagnetic fields. The device and accessories to which the definition is applicable are electronic equipment covered by the 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 proper disposal of any packaging material.

9 Technical Specifications



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

9.1 General Device Information


Device classification	Class II a (93/42/EEC) Class II (21CFR874.1090) Class II (MDR Canada)
Applied part classification Applied part	Type B (body) ear probe
Ingress protection rating (IP code)	IP20
Safety class (EN 60601-1)	II
Applied standards	DIN EN ISO 389-2 (transducer calibration), DIN EN ISO 10993-1 (biocompatibility), DIN EN ISO 15223-1 (manual), DIN EN 60601-1 (electrical safety), DIN EN 60601-1-2 (EMC), DIN EN 60601-1-4 (PEMS), DIN EN 60601-1-6 (usability), DIN EN 60645-5 (tympanometry), DIN EN 60645-6 (OAE, where applicable), DIN EN 62304 (software lifecycle)

9.2 Device Characteristics

Device dimension	150 x 72 x 55mm
Device weight	ca. 170g
Cable length	180 cm / 90 cm (probe part)
Probe tone	226 Hz ± 1 % at 85.3 dB SPL ± 3 dB
Additional probe tone	1000 Hz ± 1 % at 69 dB SPL ± 3 dB
Compliance Range	0.2 to 5 ml
Compliance Accuracy	± 5 % or 0.1 ml (whichever is greater)
Pressure Range	-600 to +400 daPa
Pressure Accuracy	± 10 % or 10 daPa (whichever is greater)
Pump speed	50, 100, 150, 200 daPa/s ± 10 daPa/s


9.3 Power Supply


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 risk of electrical shock, the PC power supply unit must only be connected to a supply mains with protective earth.

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

9.4 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 in order to protect all components against external forces and environmental impacts as e.g. mechanical stress (scratches), dust or moisture. Extreme storage and operating conditions may result in malfunction or in impairment of the device and/or transducer calibration.

 If the device is moved from a cold location to a warmer one, there will be a risk of condensation. In this case, the device must be allowed to achieve normal room temperature before it is switched on. Also make sure that the below operating conditions 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 point of calibration p_c	Air pressure at 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 DIN EN 60645-1 5.3 and Soares et al.: "Audiometer: Correction factor for atmospheric pressure", Inter-Noise 2016.

10 Electromagnetic Compatibility Information

Electromagnetic compatibility (EMC) as stated by standard DIN EN 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 *Table 1* and in *Table 2*.

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 1: Compliance with electromagnetic emission guidelines and resulting requirements for electromagnetic environment

Tests for immunity to interference	IEC 60601 test level	Concurrent 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 6000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency shall correspond to typical hospital or commercial environment.

Table 2: Compliance with immunity to interference tests and resulting requirements for electromagnetic environment



The user must take care, that the device is used in an environment with minimum distances to potential radiators as described in *Table 3*.

Tests for immunity to interference	IEC 60601 test level	Concurrent level	Electromagnetic environment
Conducted high-frequency disturbance according to IEC 61000-4-6	3 V (150 kHz – 80 MHz) 6 V (ISM 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).
<p>* 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;</p>			

Table 3: Minimum distance to potential radiators

The device is intended for use in an environment in which high-frequency disturbances are controlled.

Contact information from distributor/service partner:

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