



M STUDIO Software

OTOWAVE TYMPS
FAST, ACCURATE
MIDDLE EAR MEASUREMENTS

MedRx

Studio Software Impedance Module Training Manual





0123

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*This manual explains the IMP Studio Software Module.
Refer to the manual that came bundled with your TYMPANOMETER for instructions on use and safety requirements.*

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This manual will familiarize you with the features and software for the Otowave Tympanometers. Tympanometry has multiple purposes in a hearing assessment.

- Measuring the compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures
- Measuring stapedial and ipsilateral reflexes
- Detecting abnormalities to the tympanic membrane and middle ear

Always perform a tymp exam of the ear prior to testing to determine if there are any abnormalities with the TM/middle ear that will interfere with testing. If there is a problem, the patient should be referred to an appropriate resource for further medical evaluation. It is recommended that the patient be cleared from the medical referral before you can proceed with the hearing evaluation.

Always use ear tips with the system. The ear tips must be cleaned or replaced between patients per accepted medical practice procedures. (Reference section: "Cleaning and Disinfecting" for more information)

Getting to Know Your Otowave Tymps

Intended Use Statement:

The Otowave Tympanometers are used to measure the compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures. They are also used to measure stapedial reflexes. The Tymps measures ipsilateral reflexes and when selected, reflex measurement is automatically carried out after a tympanogram is taken. These devices are to be operated by professionals with education and/or training in the field of audiometry. The device consists of a Tympanometer connected to a computer via USB cable or IR Link that can send the Tympanometer data to the computer.

Indication for Use Statement:

The Otowave Tympanometers is for use by professionals with education and/or training in the field of audiometry to provide detailed examinations of the middle ear and tympanic membrane. The Tymps are designed to perform middle ear measurements.

 **CAUTION:** The Otowave Tympanometers are to be used by a person qualified in the use of a Tympanometer. Misuse can cause a patient pain and possible injury.

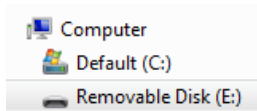
This manual explains the IMP Studio Software Module. Refer to the manual that came bundled with your TYMPANOMETER for instructions on use and safety requirements.

INSTALLATION

Drivers & TYMP Software Key

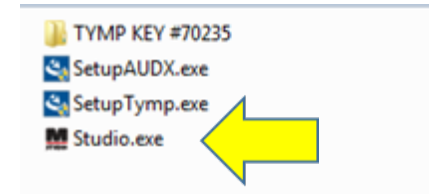


1. Insert the MedRx USB Flash Drive into a USB port:
 - Launch **My Computer**
 - Locate USB Drive



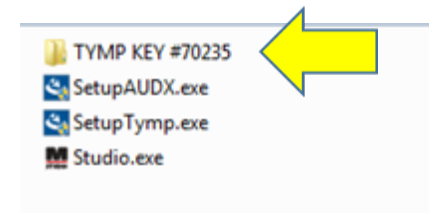
(E:) may vary depending on the USB port selected.
Consult your computer's documentation.

2. Double click on **Studio.exe** to download MedRx Studio Software. Full Instructions to download Studio software can be found in the MedRx Studio Installation Manual.



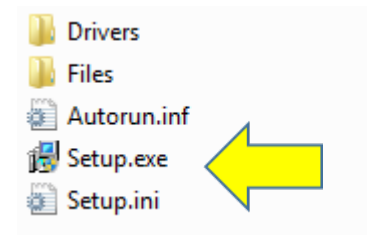
NOTE: If requested, *Accept Permission to Install Software.*

3. Once you are finished installing the MedRx Studio Software



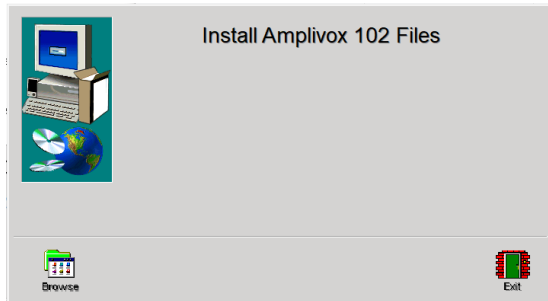
4. Click on TYMP Key

5. Click on Setup.exe

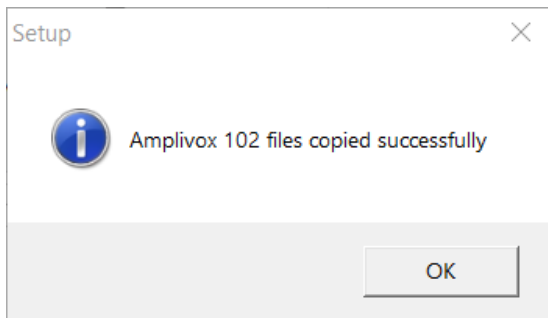


Otowave 102

To Install Otowave 102 Files:



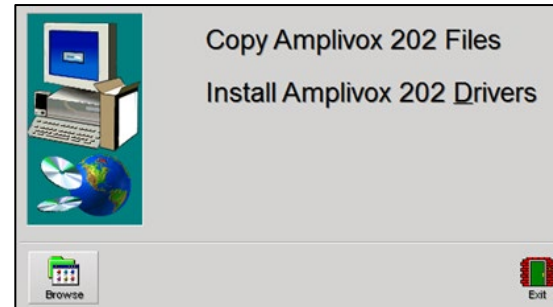
1. Click Install Amplivox 102 Files.



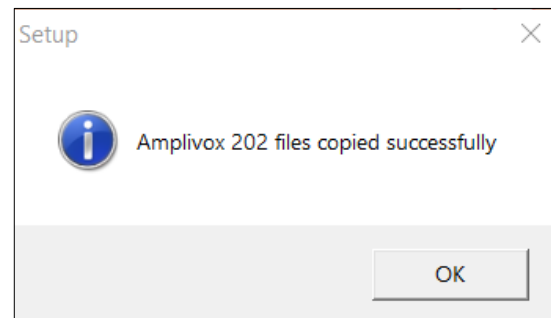
2. A pop-up will appear if the files were copied successfully. Click OK.

Otowave 202 and 202H

To Install Otowave 202 or 202H Files and Drivers:



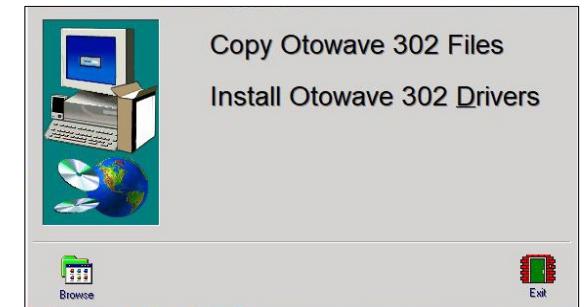
1. Click Copy Amplivox 202 Files.



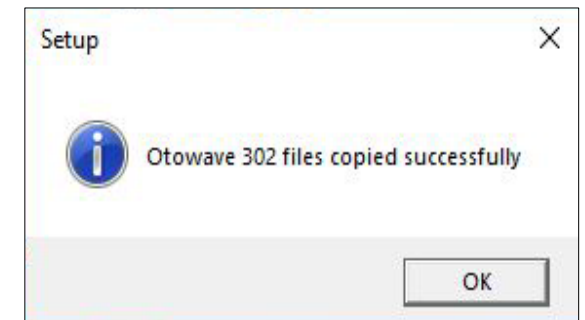
2. A pop-up will appear if the files were copied successfully. Click OK.
3. Click Install Amplivox 202 Drivers and follow the prompts.

Otowave 302 and 302+

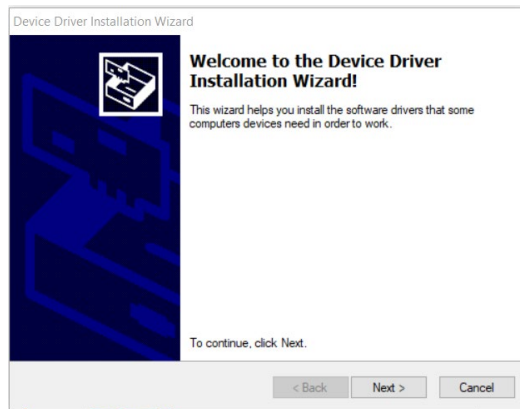
To Install Otowave 302 or 302+ Files and Drivers:



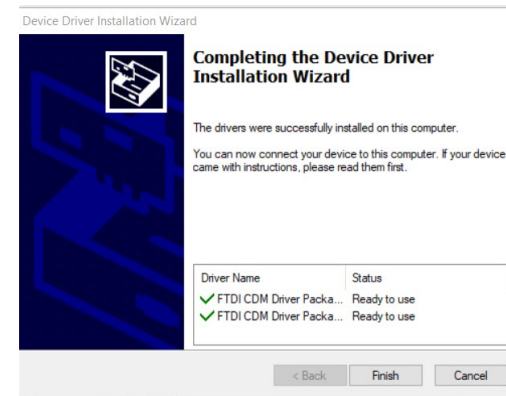
1. Click Copy Otowave 302 Files.



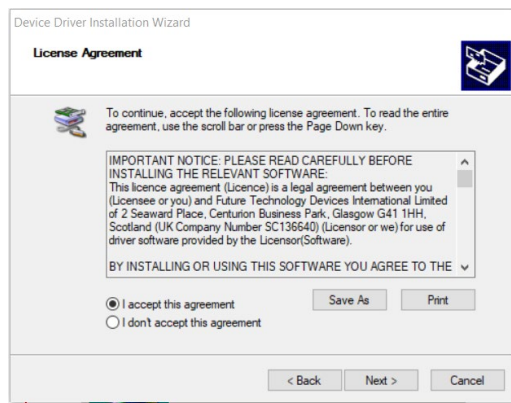
2. A pop-up will appear if the files were copied successfully. Click OK.
3. Click Install Otowave 302 Drivers and follow the prompts.



1. This is the Welcome Screen
 - To continue, click **Next**



3. When the installation is complete.
 - Click **Finish**.



2. Read the Software License Agreement. This important document defines the acceptable usage of the Tymp Software.

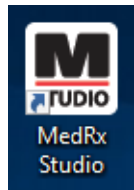
- After reading the agreement, select **I accept this agreement**.
- Click **Next**.

IMP MODULE

Studio Software Overview

The MedRx Studio software can run stand-alone or from Noah System or the TIMS® Noah-Compatible Office System.

Launching the MedRx Studio Software



Stand Alone

- Double click the MedRx Studio shortcut on your Windows desktop.



Noah

- Launch Noah.
- Select a patient.
- Launch MedRx Studio module following Noah procedures.

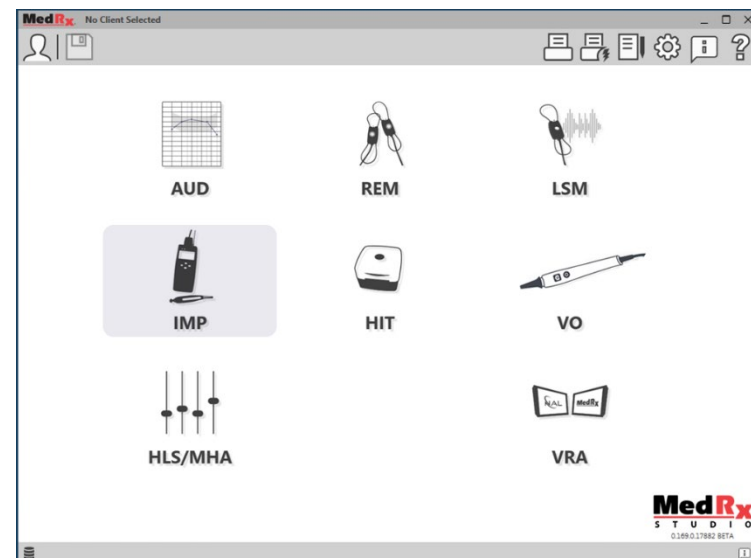
This manual explains the IMP Studio Software Module. Refer to the manual that came bundled with your TYMPANOMETER for instructions on use and safety requirements.

Basic Software Options

Several options are available which allow the user to customize the MedRx Studio software to meet their needs.



Access these options by clicking the settings wheel in the top right menu bar.



The MedRx Studio software main screen.

Icons are selectable depending on your equipment.



The Main Screen settings allow you to set the default modules, database, print templates defaults and more.



If you have more than one MedRx product you can show/hide modules in the Main Screen settings.

NOTE: Remember, more information is always available in the Interactive Help System by clicking the “?” Icon in the top right corner of the software or pressing the F1 key.

Tympanometry



Select IMP from the main menu.

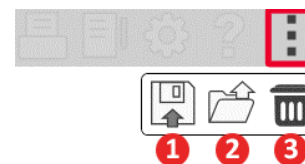
Top Tool Bar

The **Tool Bar** icons have the following functions:



1. Save Session and Exit
2. Save Session
3. Print
5. Show Journal
6. Show Settings
7. Show Help
8. More Options

The **More Options** icons have the following functions:



1. Save the current session to a file
2. Open session from a file
3. Clear Data from Current Test

Configuring the Tympanometer Software

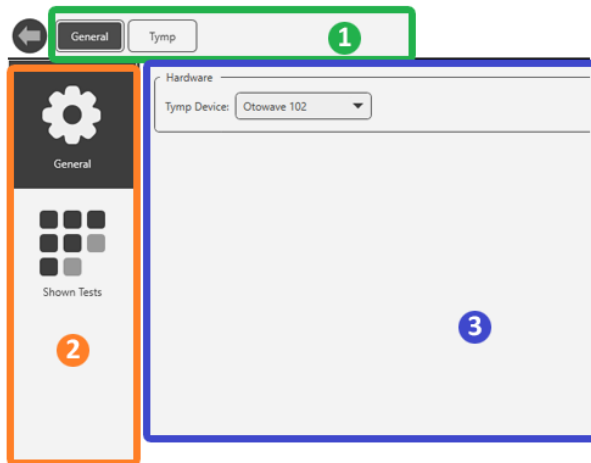


It is important to note that each module will have different settings available for customization.

Once you have installed the Files and Drivers select the IMP module from the main screen.



Click the settings wheel in the top right corner to customize.



The Tympanometry module has unique settings for the module. To navigate the settings you will:

- Select the group of settings from the header (1).
- Then choose the setting options from the left sidebar (2).
The customization options will change based on the group and settings chosen in the main body (3).

Choosing your Tympanometer



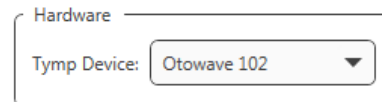
Click the settings wheel in the top right corner of the Tymp main screen



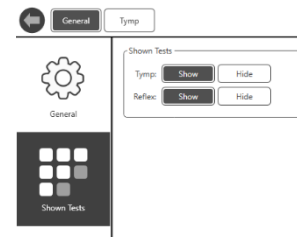
Click the General Button in the top Left Corner



Click the General Settings wheel in the top Left Corner



Select the model of your Tympanometer from the drop-down menu.



Select which tests are visible within the Tymp module.



Go back to the Tympanometer main screen by clicking the back arrow on the menu bar top left.

Tymp Menu Controls on the Tympanometer:

- Press the up ▲ and down ▼ navigation keys to scroll through the menus or set values.
- Press the right navigation key ► to accept a menu choice or go to the next step.
- Press the left navigation key ◀ to cancel an operation or go back to the previous step.

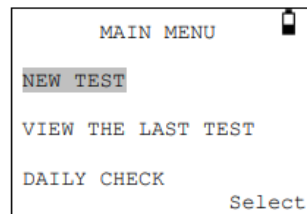
Performing Tymps & Reflexes

See operations manual for detailed use of devices.

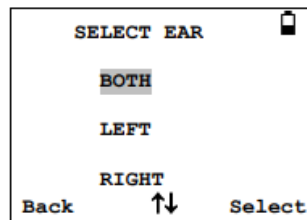
Always use a clean ear tip for each new patient.



- Make sure your Tymp is turned on by using the power button in the bottom left hand side of the device.
- Click the IMP Icon on the MedRx Studio software main screen.

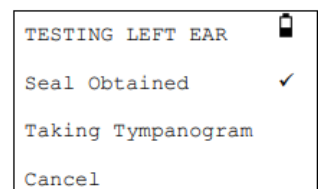
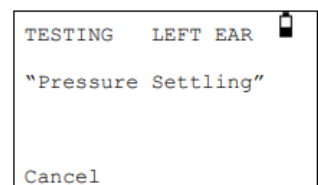
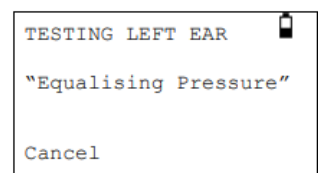
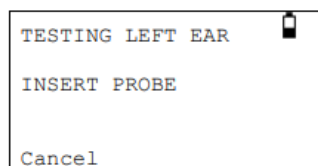


- At the MAIN MENU select NEW TEST.



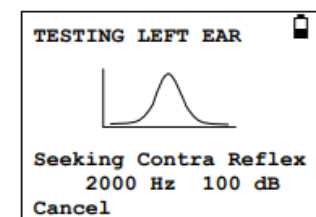
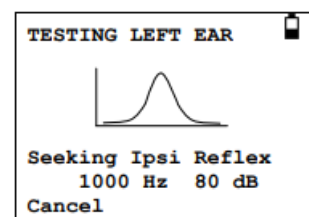
- Select the ear(s) you are want to test.

A message will appear that says “Deleting last test” then you will be asked to insert the probe. Be sure to insert both the ipsi and contra probes if applicable.

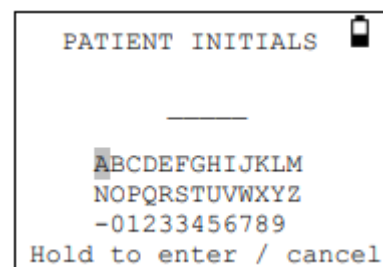


- As long as you have a good seal on the probe in the ear you will see:
 1. “Equalizing Pressure”
 2. “Pressure Settling”
 3. “Seal Obtained”

The device will perform the tympanogram portion of the examination first. The Tymp will then perform reflex measurements if selected in the configuration menu. The Tymp 102 can perform Ipsi reflex measurements and the Tymp 202/202H/302/302+ can perform Ipsi and Contra reflex measurements.



Saving Results



- Once the PROCESS RESULTS window comes up you will select SAVE RESULTS. You will enter the patient's initials and hold the right arrow to save.
- After you have entered the patient's initials you will be able to transfer the data to the PC.

Transferring Data to Studio

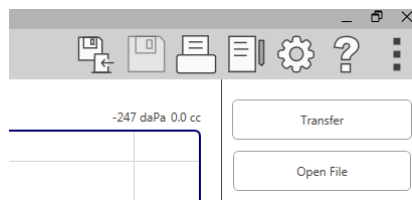


Otowave 102

- Position your MedRx 102 Tymper within range of the IR Link (as shown). The IR Link should be within a few inches of the Tymper's IR port.
- On the MedRx 102 Tymper you will click on Send to Computer and then click the ► navigation key to transfer. You will see the tracing on the screen in Studio.

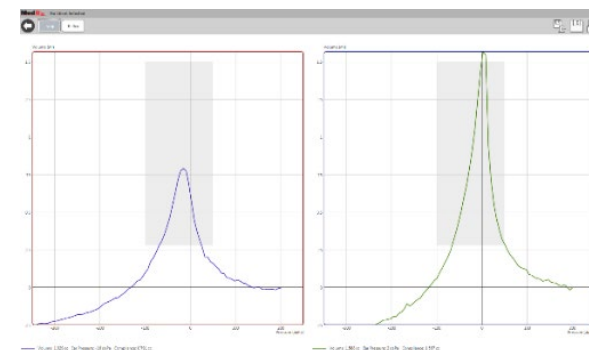
Otowave 202 and 302

- Plug the MedRx 202/202H/302/302+ Tymper into the Computer via a USB cable.
- Select Transfer in the top right corner of Studio. It will transfer the data for you right to the screen.



- In the top left of the Tymper Software you can toggle between your Tymps and Reflexes.

The screenshots below are examples of Tymp and Reflex results



Right	Left
Pressure: 0.00	Pressure: 0.00
Time: 0.00	Time: 0.00
Volume: 0.00	Volume: 0.00
Compliance: 0.00	Compliance: 0.00
Resistance: 0.00	Resistance: 0.00
Phase: 0.00	Phase: 0.00
Quality: 0.00	Quality: 0.00
Gain: 0.00	Gain: 0.00
Offset: 0.00	Offset: 0.00
Scale: 0.00	Scale: 0.00
Units: 0.00	Units: 0.00
Mode: 0.00	Mode: 0.00
Filter: 0.00	Filter: 0.00
Gain: 0.00	Gain: 0.00
Offset: 0.00	Offset: 0.00
Scale: 0.00	Scale: 0.00
Units: 0.00	Units: 0.00
Mode: 0.00	Mode: 0.00
Filter: 0.00	Filter: 0.00

Saving Session Data



Click on the save session icon located in the top right menu bar. It will prompt you to save the current session to your patient file.

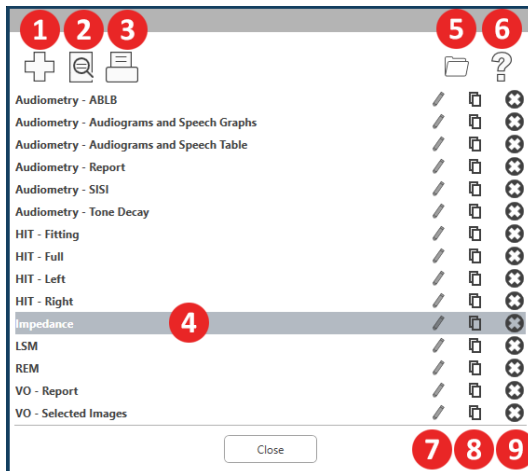


Turn-off your tympanometer when you exit the IMP module by pressing the on/off button located on the bottom left hand side of the device

Printing

Printing within the MedRx Studio software. You can use the templates provided at installation or create your own templates to suit your needs.

Icons in the Print Window

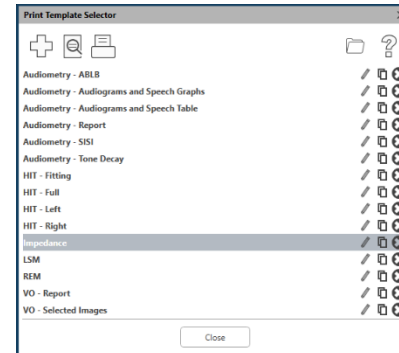


1. Create a new template.
2. Preview template icon.
3. Print template icon.
4. Select the template you would like to use.
5. Shortcut to templates folder on your desktop.
6. Studio Help icon.
7. Edit the template with the pencil icon. Editing a template will open the print editor and allow you to adjust print elements.
8. Duplicate existing templates icon.
9. Delete template icon.

To Use an Existing Print Template

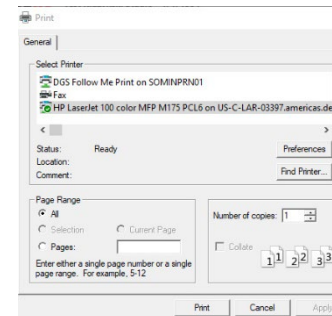


1. Click the print icon in the top tool bar or hold down the Ctrl key and click the P key on your keyboard.



4. Click the print icon.

2. Select the template you would like to use.
3. Click the print preview icon to see the patient's data & images on the template before printing.



5. The printer options box will pop-up.
6. Click print.
7. Or click Ctrl+Shift+P to print the modules default template.

Create New Print Templates



1. Select the printer icon.



2. Select the + icon to create a new template.

New Template

3. Name the template you are creating.



4. Choose page orientation.

Letter

- A3
- A4
- A5
- B4
- B5
- Executive
- Legal
- Letter
- Tabloid

5. Use the drop-down menu to choose the size of paper you will be using.

6. In the bottom left, Page Zoom will allow you to zoom in/out of the template for easier editing.

Page Zoom: 75%

Page Margins

Left: [Slider]

Top: [Slider]

Right: [Slider]

Bottom: [Slider]

7. In the bottom left, the Page Margin is set by default to the ideal level. Adjusting this will determine how far items will print from the edges.

Picture

Text

Journal

AUD

Audiogram

Audiogram Legend

Audiogram Table

Speech Graph

Speech Legend

Speech Results

QuickSIN

Stenger

ABLB

IMP

Tymp Graph

Tymp Table

Reflex

REM

Rem Graph

Lsm Graph

HIT

Hit Graph

Battery Current Graph

Input/Output Graph

Attack Release Graph

VO

VO Image

All Selected VO Images

1. Drag and drop elements onto the page to create your template.

- a. You can combine data from multiple modules into a single template.
- b. Elements may overlap and will stack/cover previously added elements.
- c. Certain elements will have settings that can be adjusted after dropping onto the page.
- d. You can resize all elements. The contents of each element will resize within the box depending on the amount of data in the element.



2. Use the + button to add additional pages if needed.



3. After template completion, use the Save, Save As, Preview and Print Icons for your template.

- a. Saved templates will be available for future sessions.
- b. Print a template to ensure that all elements print as expected.

Cleaning & Disinfecting

Your MedRx Tympanometer has been designed to provide years of trouble-free service. Do not remove or open the Tympanometer housing, as there are no user serviceable components inside.

Cleaning

To keep your system looking new, wipe the exterior of the components with a soft cloth. Stubborn stains may be removed using a cloth moistened with water and mild detergent. Do not allow debris or fluid to enter into the components. Use an alcohol wipe to clean the probe on the end of the tympanometer/probe pencil, or a common disinfectant.

Tympanometer Disinfecting

The Tympanometer is sealed so that it may be wiped between patients with the following surface cleaners to disinfect; 70% Alcohol, Chlorhexiderm, Cidex, Nolvasan, Parvocide, Parvosol, Roccal or Synphenol. Follow instructions provided with the disinfectant.

The scope should NEVER be heat sterilized, gas sterilized or soaked in liquid because damage may result.

Ear Tip Replacement

The ear tip is always to be replaced between patients.

Transportation & Storage

When transporting or storing your Tympanometer, it is best to use the original packing case or similar packaging. Store the system in a cool, dry location and do not place your system in direct sunlight. Care must be taken to protect the system from shock, moisture damage and mishandling. Do not place heavy objects on any of the system's components. To assure proper operation and warranty protection, use manufacturer's replacement components only.

Technical Specifications

Tymp 102-4

Analysis Performed: Compliance peak level (in ml), Ear canal volume (ECV) at 200 daPa, Ipsilateral reflex

Probe Tone Levels: 226 Hz $\pm$ 2%, 85 dB SPL $\pm$ 2 dB. Over range 0.2 ml to 5 ml

Pressure Levels: +200 daPa to – 400 daPa. $\pm$ 10 daPa

Ear Volume Measurement Range: 0.2 ml to 5 ml $\pm$ 0.1 ml or $\pm$ 10% (whichever is larger) over entire range

Reflex Tone Levels: 500 Hz, 1 kHz, 2 kHz, 4 kHz Frequency $\pm$ 0.1%, Configurable over range 85 dB to 100 dB HL (programmable in 5 – 10 dB steps)

Reflex Measurement Range: 0.01 ml to 0.5 ml $\pm$ 0.01 ml configurable in 0.01 ml steps

Power: Battery specification: 4 Alkaline AA cells or 4 NiMH rechargeable

Dimensions: Approx. 21 x 8 x 4 cm (L x W x H)

Weight: 380 g / < 1 lbs

Tymp 202 – 202H

Analysis Performed: Compliance peak level (in ml), Ear canal volume (ECV) at 200 daPa, Ipsilateral reflex or $\pm$ 10 daPa or $\pm$ 10% (whichever is larger) over range 0,1 ml to 5 ml

Probe Tone Levels: 226 Hz $\pm$ 2%, 85 dB SPL $\pm$ 2 dB 1000Hz $\pm$ 2%; 79 dB SPL $\pm$ 2 dB (202-H only) over ear canal volume range

Pressure Levels: +200 daPa to – 400 daps. $\pm$ 10 daPa or $\pm$ 10% (whichever is larger) over range 0,1 ml 5 ml

Ear Volume Measurement Range: 226 Hz: 0.2 ml to 5 ml; 1000 Hz: 0.1 ml to 5 ml $\pm$ 0,1 ml or $\pm$ 5% (whichever is larger)

Reflex Tone Levels: 500 Hz, 1 kHz, 2 kHz, 4 kHz Frequency $\pm$ 2%, Configurable over range 70 dB to 100 dB HL (4 kHz restricted to 95 dB HL) $\pm$ 2 dB, referenced to 2 ml calibration volume; compensates for measured ear volume

Reflex Measurement Range: 0.01 ml to 0.5 ml $\pm$ 0.01 ml configurable in 0.01 ml steps

Power: Mains: 100-240 V AC; 50/60 Hz via mains adapter (approved in medical safety standards); Batteries: 4 x AA (either Alkaline or NiMH, the latter recharged external to the instrument)

Dimensions: Base unit: Approx. 19 x 8,5 x 4 cm (L x W x H) Probe: 13 x 2.5 cm (max.) diameter

Weight: Base unit: 330 g (without batteries, using mains power), 430 g (with batteries) Probe: 110 g (incl. connecting cable)

Tymp 302 - 302+

Analysis Performed: Compliance peak level (in ml), Ear canal volume (ECV) at 200 daPa or -400 daPa, Ipsilateral reflex or $\pm$ 10 daPa or $\pm$ 10% (whichever is larger) over range 0.1 ml to 6 ml

Probe Tone Levels: 226 Hz $\pm$ 2%, 85 dB SPL $\pm$ 2 dB; 1000Hz $\pm$ 2%, 79 dB SPL $\pm$ 2 dB (302-H only) over ear canal volume range
Pressure Levels: +200 daPa to – 400 daPa, $\pm$ 10 daPa or $\pm$ 10% (whichever is larger) over range 0.1 ml to 6 ml

Ear Volume Measurement Range: 226 Hz: 0.2 ml to 6 ml; 1000 Hz: 0.1 ml to 6 ml $\pm$ 0,1 ml or $\pm$ 5% (whichever is larger)

Ipsilateral Reflex Tone Levels: 500 Hz; 1000 Hz, 2000 Hz, 4000 Hz, Frequency $\pm$ 2%, Configurable over range 70 dB to 100 dB HL (4,000 Hz restricted to 95 dB HL)* $\pm$ 2 dB, referenced to 2 ml calibration volume, compensates for measured ear volume

*2kHz level is restricted to maximum 95dBHL for ear canal volumes greater than ~3.5ml

Contralateral Reflex Tone Levels: 500 Hz; 1000 Hz, 2000 Hz, 4000 Hz, Frequency $\pm$ 2%, Configurable over range 70 dB to 110 dB HL (4,000 Hz restricted to 95 dB HL)

* $\pm$ 2 dB, referenced to 2 ml calibration volume, compensates for measured ear volume *2kHz level is restricted to maximum 105dBHL for ear canal volumes greater than ~3.5ml

Reflex Measurement Range: 0.01 ml to 0.5 ml $\pm$ 0.01 ml configurable in 0.01 ml steps

Power: Mains: 100-240 V AC; 50/60 Hz via mains adapter (approved in medical safety standards)

Dimensions: Base Unit: 270 x 60 x 165 mm / 10.63 x 2.36 x 6.49 inch (excluding connections), Probe: 130 x 25 mm / 5.11 x 0.98 inch

Weight: Base unit: 760 g / 1.68 lbs, Probe: 115 g / 0.25 lbs

Complaints/Safety Reporting

Please contact your local distributor in case of any incidents related to product defects (hardware defects or software bugs) or adverse events (which does not necessarily have a causal association to the product). It is recommended for a user to report all the known facts about the incident. Upon receipt of any serious incident with serious health impact for the patient or user (serious adverse events), local distributor shall report to MedRx through its appropriate vigilance system. MedRx shall ensure that the regulatory authority in patient's home country is informed according to the vigilance requirements. MedRx shall handle all the product complaints and adverse events as per the internal procedure.