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Instructions for Use – EN

MT10

Interacoustics

D-0134732-B – 2023/06

Table of Contents

1 Introduction

1.1 About this manual

This manual is valid for the handheld tympanometer MT10.

Manufacturer:

Manufactured for:
Interacoustics A/S
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Denmark
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E-mail: info@interacoustics.com
Web: www.interacoustics.com

1.2 Intended use

The MT10 is a handheld screening tympanometer offering Tympanometry and optional Ipsi reflex testing. The MT10 allows storing of data by printing (optional printer) or by transferring data to a computer (optional software module).

The MT10 tympanometer is intended to be used by an audiologist, hearing healthcare professional, or trained technician in a quiet environment (tymp and reflexes).

1.3 Product description

The MT10 is designed for use by audiologists, general practitioners, hearing aid dispensers and child health professionals. The instrument performs two types of measurement:

Tympanometry is used to measure the compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures.

Optional:
Reflex tests are used to measure stapedial reflexes. The MT10 measures ipsilateral reflexes and, when selected, reflex measurement is automatically carried out after a tympanogram is taken.

The system includes the following included and additional parts:

Included Parts MT10:
MT10 Tympanometer [1] [2]
4 x 1.5V ‘AA’ Batteries
Instructions for Use Calibration certificate
Warranty card

Additional Parts:
4 in 1 test cavity assembly
Carrying case
Portable thermal printer
2 rolls of thermal paper
Diagnostic Suite and OtoAccess®
Infra-red USB Adapter
Additional probe tip
Additional sets of ear tips [1]

[1] Applied part according to IEC60601-1

[2] The probetip of MT10 is considered applied part by definition, whereas the remaining part of the device may unintentionally come into contact with the patient (clause 4.6)

1.4 Warnings and precautions

	**WARNING** indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	**CAUTION**, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in damage to the equipment.
NOTICE	**NOTICE** is used to address practices not related to personal injury or damage to the equipment.

2. Unpacking and installation

2.1 Unpacking and Inspection

Check box and contents for damage

When the instrument is received, please check the shipping box for rough handling and damage. If the box is damaged it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty, please contact your local distributor. Keep the shipping material for the carrier's inspection and insurance claim.

Keep carton for future shipment

The MT10 comes in its own shipping carton, which is specially designed for the MT10. Please keep this carton. It will be needed if the instrument has to be returned for service.
If service is required, please contact your local distributor.

Reporting Imperfections

Inspect before connection

Prior to connecting the product it should once more be inspected for damage. All of the cabinet and the accessories should be checked visually for scratches and missing parts.

Report immediately any faults

Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. In the back of this manual you will find a "Return Report" where you can describe the problem.

Please use "Return Report"

Please realise that if the service engineer does not know what problem to look for, he/she may not find it, so using the Return Report will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.

2.2 Safety Regulations

Electrical Safety:

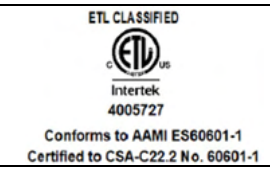
This audiometer is specified to comply with the international standard IEC 60601-1.

1. The instrument is not intended to be used in oxygen rich environments or use in conjunction with flammable agents.
2. Do not position the power supply in a position so that it is difficult to disconnect the device.

2.3 Marking

The following marking can be found on the instrument:

Symbol	Explanation
	Type B applied parts. Patient applied parts that are not conductive and can be immediately released from the patient.
	WEEE (EU-directive) This symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection for facilities for recovery and recycling.
 0123	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.
	Medical device
	The number next to the symbol indicates the year of manufacture.
	Manufacturer
	Reference number
	Serial number
	Do not re-use Parts that are marked with this symbol are for single use only.
	Keep dry
	Transport and storage temperature range

Symbol	Explanation
	Transport and storage humidity limitations
	ETL listing mark

Label to be found in the battery compartment beneath the battery.

2.4 Connections

Infrared adapter (the MT10 has been tested with Actysis ACTIR2000U USB adapter and it is recommended by Interacoustics to use this device).

3. Operating instructions

This instrument is equipped with a real-time clock. Before use, please set the date and time to local values in order to ensure that test data and calibration status are correctly identified.

Careful handling of instrument whenever in contact with patient should be of high priority. Calm and stable positioning while testing is preferred for optimal accuracy.

1. Use this device only as described in this manual.
2. Use only the disposable Sanibel ear tips designed for use with this instrument.
3. Always use a new ear tip for each patient to avoid cross-contamination. The ear tip is not designed for reuse.
4. Never insert the probe tip into the ear canal without affixing an ear tip as omission may damage the patient's ear canal.
5. Keep the box of ear tips outside the reach of the patient.
6. Be sure to insert the probe tip in a way which will assure an airtight fit without causing any harm to the patient. Use of a correct and clean ear tip is mandatory.
7. Be sure to only use stimulation intensities acceptable to the patient.
8. It is recommended to conduct a probe test at the beginning of each day to ensure that the probe and/or cable is functioning correctly.
9. Clean the probe tip regularly to ensure wax or other debris stuck in the probe tip does not affect the measurement.
10. Contraindications to testing include recent stapedectomy or middle ear surgery, a discharging ear, acute external auditory canal trauma, discomfort (e.g, severe otitis externa) or occlusion of the external auditory canal. Testing should not be performed on patients with such symptoms without a medical doctor's approval.
11. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.
12. No parts of the device must be serviced while in use with a patient.

NOTICE

1. Careful handling of the instrument whenever in contact with a patient should be given high priority. Calm and stable positioning while testing is preferred for optimal accuracy.
2. The MT10 should be operated in a quiet environment, so that measurements are not influenced by outside acoustic noises. This may be determined by an appropriately skilled person trained in acoustics. ISO 8253 Section 11, defines a quiet room for audiometric hearing testing in its guideline.
3. It is recommended that the instrument be operated within an ambient temperature range of 15°C / 59°F – 35°C / 95°F.
4. Never clean the transducer housing with water or insert non-specified instruments into the transducer.
5. Do not drop and avoid other undue impact to this device. If the instrument is dropped or otherwise damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.
6. Although the instrument fulfils the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones, etc. If the device is used adjacent to other equipment, caution must be taken to observe that no mutual disturbance appears.
7. The instrument is not intended to be used in environments exposed to fluid spills.

Malfunction

In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has caused, or potentially could cause such harm, it must be quarantined immediately.
Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to include as many details as possible, e.g. the type of harm, serial number of the product, software version, connected accessories and any other relevant information.

In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Interacoustics and the local national competent authority.

Disposal of the product

Interacoustics is committed to ensuring that our products are safely disposed of when they are no longer usable. The cooperation of the user is important to ensure this. Interacoustics therefore expects that local sorting and waste regulations for disposal of electric and electronic equipment are followed, and that the device is not discarded together with unsorted waste.
In case the distributor of the product offers a take-back scheme, this should be used to ensure correct disposal of the product.

3.1 Installing and replacing batteries

The MT10 may be powered from Alkaline 'AA' / LR6 batteries (e.g. Duracell MN1500) or rechargeable Nickel-Metal Hydride (NiMH) batteries. Four batteries are required.

If the MT10 is to be used infrequently, we recommend alkaline cells are fitted. NiMH batteries have a high self-discharge rate and are likely to need recharging if left unused for several weeks. To fit the cells, remove the battery compartment cover on the base of the MT10. Fit the cells as indicated inside the battery compartment.

Batteries should only be changed outside the patient environment. The operator should not touch the battery connectors and the patient simultaneously.

You must set which type of cell is fitted in the CONFIGURATION menu. By default this is set to ALKALINE. To change the setting, select CONFIGURATION from the main menu and scroll to BATTERY TYPE as described later in this manual.

A battery state indicator is shown in the top right corner of the display (except when showing test results). This shows the battery state as a progressively emptying battery. The batteries should be replaced when the symbol has an **!** in front of it, or when advised to do so at switch-on. Removing the batteries does not affect the configuration, the contents of the database, the calibration settings or the results of the last test.

NOTICE Remove the batteries, if the instruments will not be used for some time.

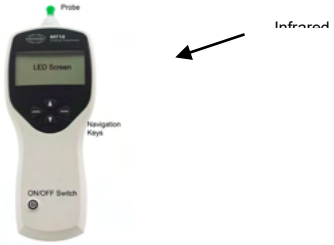
3.2 Controls and indicators

Press the On/Off key momentarily to turn the MT10 on (refer to the diagram below).

No warm-up time is required, although a short diagnostic routine will run for a few seconds. During this time the internal pump will operate. To switch off, again press the On/Off key momentarily.

Press the On / Off key momentarily to turn the MT10 on or off.
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.



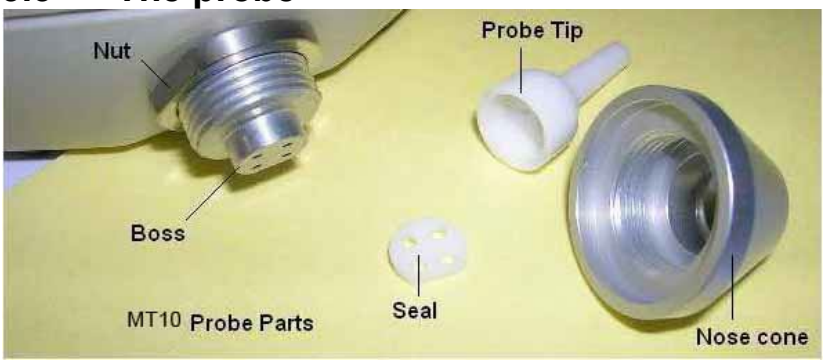
Operating Language
To set the operating language (English, French or German), use the options within the CONFIGURATION menu.

The function of the left and right keys is usually shown on the bottom line of the display. When not performing a test, the MT10 will switch off automatically if no key is pressed for 90 seconds. This time can be extended to 180 seconds in the CONFIGURATION menu.

The LEDs indicate the status of the system:

Green LED	Yellow LED	Status
Off	Off	MT10 turned off
On	Off	Idle & ready to use
Off	Slow flash	Attempting to obtain an ear seal
Slow flash	Off	Taking a measurement
Off	Fast flash	Pump error at switch on
On	Flickering	Sending data to a PC

3.3 The probe



The small holes through the MT10 probe tip must be kept clear. If these become blocked, a warning message will be displayed. The tip must be removed and cleaned or replaced.

To remove the tip, unscrew the nose cone and pull the tip off the probe boss. A small seal will be found in the base of the probe tip. This should be examined and replaced if it is damaged.

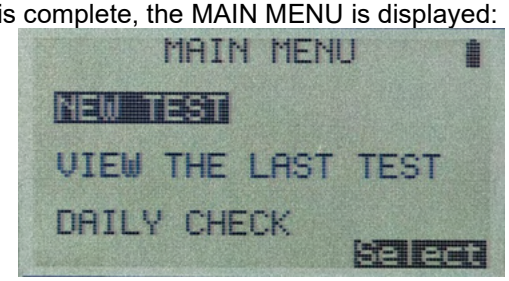
When replacing the tip, ensure that the seal is correctly inserted with its flat aligned with the flat on the probe tip. Push the probe tip over the boss and replace the nose cone. Make sure that the nose cone is screwed home firmly, but do not over-tighten. Do not use any tools to tighten the nose cone.

After replacing the tip, a Daily Check should be carried out.

3.4 Start up and menu display

When the MT10 is turned on, the start-up screen is shown while internal tests are performed and the pump is initialised.

When the start up sequence is complete, the MAIN MENU is displayed:



Menu items and instructions are shown in upper case text.
Information and error messages are generally in lower case.

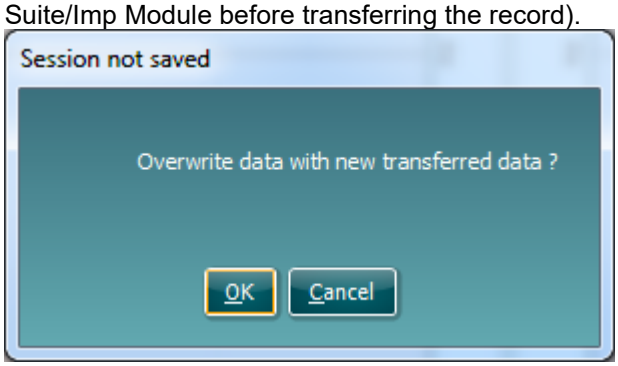
3.5 MT10 – menu summary

3.5.1 Main menu selections

Menu	Sub-Menu
MAIN MENU	NEW TEST
	VIEW THE LAST TEST
	DAILY CHECK
	DATA MANAGEMENT
	CONFIGURATION
	SYSTEM INFORMATION

3.5.2 Sub-menu selections

Sub-Menu	Option	Choices/Description
NEW TEST	SELECT EAR	Open which ear(s) to test and start the test. A tympanogram is taken followed by reflex measurements, if selected. On-screen messages & LED's indicate progress. Graphical display are shown automatically at the end.
VIEW THE LAST TEST	SELECT EAR	Recalls the last stored test for the selected ear. Shows the tympanogram and reflex respones, if available. Also allows the last test to be printed, sent to a PC or saved in the internal database.
DAILY CHECK		Shows the volume in ml measured by the probe.
DATA MANAGEMENT	LIST RECORDS	Lists the test results stored in the internal database. Allows individual records to be viewed, printed, sent to a PC or deleted.

Sub-Menu	Option	Choices/Description
	DELETE RECORDS	Delete stored records. Select: ”ALL PRINTED RECORDS” – Delete all records that have been printed. ”ALL SENT RECORDS” – Delete all records that have been sent to a PC. ”ALL RECORDS” – Delete all records.
	PRINT RECORDS	Print stored records. Select: ”UNPRINTED RECORDS” – Print all records not previously printed. ”ALL RECORDS” – Delete all records.
	SEND RECORDS TO PC	**NOTE:** **It is advised not to transfer several records to the PC at the same time (Diagnostic Suite) as the system is not prepared for this.** If you select ”Send records to PC” and transfer “all records”/”Unsent records”, you get the message in the Diagnostic Suite view: “Overwrite data with new transferred data?”. Hence, all the records will be sent to the dedicated folder on the PC, and the Diagnostic Suite will ask if you want to overwrite the current data on the screen. So it is recommended to send the individual records by selecting “List records” (in “Data Management”) and select the preferred record. (NB: Remember to start Diagnostic Suite/Imp Module before transferring the record). 

NOTE:
Please be aware that when connecting the USB IR receiver and the Sanibell II printer at the same time, the printer may start printing out nonsense data from the PC, because the Infrared receivers may interfere with each other. However, it does not happen often that users will send data to their PC as well as print out the data on the wireless printer. IF the scenario occurs, please see that the two IR windows on these devices are not pointed directly at each other.

CONFIGURATION	TODAY’S DATE	Set the internal clock date and time.
	REFLEX SELECTION (if your version has this feature)	Select when reflexes will be measured: ”ALWAYS MEASURE” – Reflexes are always measured. ”NEVER MEASURE” – Reflexes are never measured.

Sub-Menu	Option	Choices/Description
		”**ONLY IF PEAK FOUND”** – Reflexes will be measured only if MT10 detects a peak on the tympanogram. ”PROMPT TO MEASURE” – The user is asked whether to perform a reflex at the start of at each test.
	REFLEX LEVELS	Select the maximum tone level to be used for the reflex test. Set to 100 dB (with 5 dB or 10 dB steps) or **95 dB**, 90 dB or 85 dB with **5 dB** steps.
	Optional: REFLEX FREQUENCIES	Choose to perform the reflex test at **1 KHz** only **or 500, 1000, 2000 and 4000**.
	REFLEX THRESHOLD	Select the change in compliance that determines that a reflex has been detected. Adjustable in 0.01 ml steps from 0.01 to 0.5 ml. **Default 0.03 ml.**
	REFLEX AUTO-STOP	If selected, reflex measurement at each frequency stops as soon as a reflex is found. **Default YES.**
	REFLEX FILTER	Select either **2 Hz** or 1.5 Hz. The lower value smoothes the plot more.
	PRINTER	**Sanibel MPTII**
	BATTERY TYPE	Select **Alkaline** or NiMH (This effects the battery state display and low battery warning).
	POWER-OFF DELAY	The time before the unit turns off automatically if no key is pressed. Select **90** or 180 seconds.
	LCD CONTRAST	Change the display contrast 0-15. **Default 7.**
	EAR SEAL CHECK	Select ”**QUICK”** or ”THOROUGH”.
	REPORT CAL. DATES	Select ”**PRINT CAL. DATES”** or ”HIDE CAL.DATES”.
	SET DATE FORMAT	Select ”**DD/MM/YY”** or ”MM/DD/YY”
	HOSPITAL NAME	Allows the hospital name to be entered (this will appear at the top of the print out).
	DEPARTMENT	Allows the department name to be entered (this will appear at the top of the print out).
	RELOAD DEFAULTS	The options above are reset to their default values.
	SELECT LANGUAGE	Select ”**ENGLISH”,** ”GERMAN” or ”FRENCH” for operating language.

Sub-Menu	Option	Choices/Description
SYSTEM INFORMATION		Shows: Battery voltage Software version Date calibrated Next calibration date Instrument serial number Current date and time.

4. Maintenance

4.1 General maintenance procedure

The MT10 is a precision instrument. Handle it carefully in order to ensure its continued accuracy and service. Before cleaning the instrument, remove the batteries. Use a soft damp cloth and mild detergent to clean the instrument panel and case. Ensure no moisture enters the instrument.

4.2 Cleaning the accessories

Ear tips should be replaced after a single use.

Handle the probe and accessories with care.

The probe tip and its associated sealing washer are disposable devices. The probe tip should be checked before each ear insertion to ensure it is undamaged and that none of the tubes through it are blocked. It should be replaced if necessary.

The sealing washer should be replaced if it shows signs of wear, or if a pressure leak is suspected.

Important note: Do not allow moisture, condensation, fluids or debris to enter the probe.

4.3 Calibration and return of the instrument

It is recommended that the MT10 is calibrated annually. Please contact Interacoustics for details.

When returning the instrument for re-calibration, please use the original shipping packing materials. Place the instrument in a plastic bag before packing to stop dirt and dust getting into the probe. Do not return the batteries with the instrument.

Calibration procedure is available in service manual which is available on request.

Do not modify this equipment without authorization.

Interacoustics will make available on request relevant circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of this tympanometer that are designated by the Interacoustics as repairable by service personnel.

4.4 How to clean Interacoustics products

If the surface of the instrument or parts of it are contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or similar. The use of organic solvents and aromatic oils must be avoided. Be careful that no fluid is entering the inside of the instrument or the accessories.

Before cleaning, always switch off and disconnect from the power supply.

- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces.
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid.
- Do not use hard or pointed objects to clean any part of the instrument or accessory.
- Do not let parts that have been in contact with fluids dry before cleaning.
- Rubber ear-tips or foam ear-tips are single use components.

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap).

Procedure

- Clean the instrument by wiping outer case with a lint free cloth lightly dampened in cleaning solution.

4.5 Concerning repair

Interacoustics is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment, if:

1. assembly operations, extensions, readjustments, modifications or repairs are carried out by authorised persons,

2. a 1 year service interval is maintained

3. the electrical installation of the relevant room complies with the appropriate requirements, and

4. the equipment is used by authorised personnel in accordance with the documentation supplied by Interacoustics.

The customer shall reach out to the local distributor to determine the service/repair possibilities including onsite service/repair. It is important that the customer (through local distributor) fills out the **RETURN REPORT** every time when the component/product is sent for service/repair to Interacoustics.

4.6 Warranty

Interacoustics warrants that:

- The MT10 is free from defects in material and workmanship under normal use and service for a period of 24 months from the date of delivery by Interacoustics to the first purchaser.
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service centre to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Interacoustics shall be at purchaser's risk.
In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- repaired by anyone other than an authorized Interacoustics service representative;
- altered in any way so as, in Interacoustics judgement, to affect its stability or reliability;
- subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability in connection with the sale of Interacoustics products.

INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

5. Technical specifications

The technical specifications provided here cover the general aspects of the instrument. The MT10 Tympanometer is classified as a Class II a device under Annex IX (Section 1) of the EU Medical Devices Directive. It is intended for transient use as a screening tympanometer instrument.

Tympanometry

Instrument type	Screening tympanometer
Analysis performed	Compliance peak level (in ml). Pressure of same; Gradient (in daPa); Ear Canal Volume (ECV) @ 200 daPa.
Probe tone levels and accuracy	226Hz +/-2%; 85dB SPL +/-2dB over range 0.2ml to 5 ml.
Pressure levels and accuracy	+200daPa to -400 daPa +/-10daPa or +/-10% (whichever is larger) over range.
Ear volume measurement range and accuracy	0.2ml to 5ml +/-0.1ml or +/-5% (whichever is larger) over entire range.
Sweep speed	Typically 200-300daPa/sec; dependant on ear&cavity volume.
Pressure limits (safety cutout)	+600 to -800daPa
Number of samples stored	100 per tympanogram

Optional:
Reflex measurements

Measurement modes	Ipsilateral optional
Reflex tone levels and accuracy	500Hz, 1kHz, 2kHz, 4kHz Frequency +/-2%, configurable over range 70dB to 100dB HL (4kHz restricted to 95dBHL) +/-2dB, referenced to 2ml calibration volume; Compensates for measured ear volume.
Reflex measurement range and accuracy	0.01ml to 0.5ml +/-0.01ml configurable in 0.01ml steps.
Number of reflex levels	Four: 100dB with 5dB or 10dB steps; 95dB, 90dB or 85dB with 5dB steps.
Reflex analysis	Reflex pass/fail at each level tested; Maximum amplitude of each reflex (seen on printed report and PC report); Pressure at which reflex was performed.
Pressure used for reflex measurement	Pressure at Tympanogram peak, or 0daPa (Always and Prompt Before Each Test modes).
Reflex level cut-off	Optionally, Auto-stop when reflex found.
Reflex threshold detection	Configurable 0.01-0.50ml in 0.01ml increments.
Reflex tone duration	0.6 seconds.
Number of records stored in Patient Database	30
Data storage	Any recording can be stored once the tympanogram is viewed. Patient Initials (A-Z, 0-9, “-“) must be entered before storage.
Data held	Patient Initials, Tympanogram and Reflex graphs and analysis for Left Ear and/or Right Ear, Time and Date of recording, which ears were tested, whether or not the record has been printed and/or sent to a PC, parameters printed and/or sent to a PC, parameters used for analysis, 128 bit Globally Unique Idenfitier (GUID).
Display mode	Records listed in reverse chronological order (latest first), with indication of date stored as described above.

Real Time Clock

Time stamps	Time and date stamp applied to all recordings, and to the last calibration date.
Backup power supply	>30 days without main batteries fitted.

Languages

Operating languages	English, German or French

Printing

Supported printer	Sanibel MPTII.
Interface	Infra-red, IrDA hardware, 9600 baud.
Information printed	Space for patient and clinician's details, Tympanogram analysis parameters, Tympanogram, Reflex analysis parameters, Reflex graph, Serial Number of device, Last and Next Due Calibration dates.

Serial Interface to PC

Interface	OBEX (Object Exchange) service running on top of IrDA stack. Auto-selects rate between 9600 – 115200 baud.
Information sent	Patient header, full left or right ear data.

Power Supply

Battery types	4 Alkaline AA Cells or; 4 NIMH rechargeable batteries which must be larger than 2.3Ah capacity.
Warm-up period	None at room temperature.
Number of recordings from one set of cells	Approx. 200 (Alkaline AA)
Auto power-off delay	90 or 180 seconds.
Idle current	70mA
Current while testing	230mA

Physical

Display	128x64 pixels / 8 lines of 21 characters
Dimensions	190mm long x 80mm wide x 40mm high excluding probe 225mm long including probe.
Weight (without batteries)	285g
Weight (with batteries)	380g

Environmental

Operating temperature range	+15°C - +35°C
Operating humidity range	30% to 90% RH, non-condensing
Operating atmospheric pressure range	980 to 1040 mb
Storage temperature range	-20°C to +50°C
Storage humidity range	10% to 95% RH, non-condensing. Keep dry.
Storage atmospheric pressure range	900 to 1100mb

Standards conformance

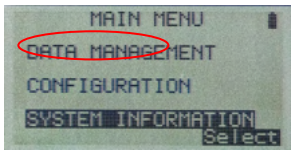
Safety	IEC 60601-1 ANSI/AAMI ES60601-1, CAN-CSA C22.2 No 60601-1
EMC	IEC 60601-1-2+AMD1:2020
Performance	IEC 60645-5, Type 2 Tympanometer
CE mark	To the EU Medical Device Directive.

5.1 Electromagnetic Compatibility (EMC)

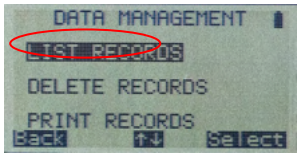
See Appendix in English in the back of the manual.

Data transfer guide – existing measurements

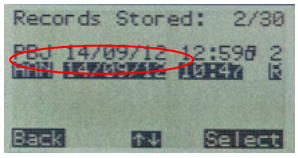
1. Launch the Database (OtoAccess® or NOAH)
2. Select the right patient
3. Launch Diagnostic Suite (via OtoAccess® or NOAH)
4. Select the IMP tab
5. Turn on the MT10
6. Select ”Data Management”.



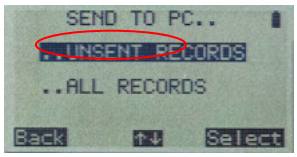
7. Select “List Records”.



8. From the list of records, select the one you wish to transfer and select “send to computer”.



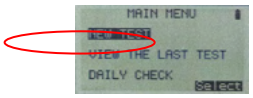
9. Connecting (”handshake” between MT10 and IR-receiver)



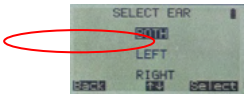
10. Data transferred to Diagnostic Suite (5 sec.)
    (Data/measurements shown in front view)
11. Save the data.

Data transfer guide – after a measurement

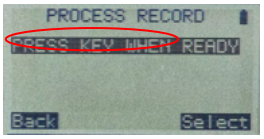
1. Launch the Database (OtoAccess® or NOAH)
2. Select the right patient
3. Launch Diagnostic Suite (via OtoAccess® or NOAH)
4. Select the IMP tab
5. Turn on the MT10
6. Select ”New Test”



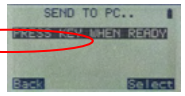
7. Select ear (Left/Right/Both)



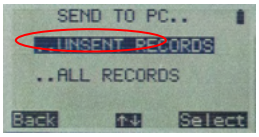
8. Process results (send to Computer (or save & send))



9. Press ”select” when ready (point at the IR-receiver)



10. Connecting… (”handshake” between MT10 and IR-receiver)



11. Data transferred to Diagnostic Suite (5 sec.)
    (Data/measurements shown in front view)
12. Save the data.

Appendix

5.1 Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the MT10. Install and operate the MT10 according to the EMC information presented in this chapter.
The MT10 has been tested for EMC emissions and immunity as a standalone instrument. Do not use the MT10 adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.
The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.
Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard+AMD1:2020, emission class B group.

Guidance and manufacturer's declaration - electromagnetic emissions		
MT10 is intended for use in the electromagnetic environment specified below. The customer or the user of MT10 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	MT10 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	MT10 is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and MT10.			
MT10 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of MT10 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MT10 as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
MT10 is intended for use in the electromagnetic environment specified below. The customer or the user of MT10 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Spot freq. 385-5.785 MHz Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of MT10.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not applicable +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.

Surge IEC 61000-4-5	+1 kV Line to line +2 kV Line to earth	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% *U*T (100% dip in *U*T) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *U*T (100% dip in *U*T) for 1 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 250 cycles	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of MT10 requires continued operation during power mains interruptions, it is recommended that MT10 be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If MT10 contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
MT10 is intended for use in the electromagnetic environment specified below. The customer or the user of MT10 should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any parts of MT10, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.)	3 Vrms 6 Vrms	$d = \frac{3,5}{Vrms}\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	3 V/m 10 V/m (If Home Healthcare)	$d = \frac{3,5}{V/m}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{V/m}\sqrt{P}$ 800 MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which MT10 is used exceeds the applicable RF compliance level above, MT10 should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating MT10.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Return Report – Form 001

Opr. dato:	af:	Rev. dato: 30.01.2023	af:	Rev. nr.:	
2014-03-07	EC		MHNG	5	

Company: _____

Address: _____

_____

Phone: _____

e-mail: _____

Address
DGS Diagnostics Sp. z o.o.
Rosówek 43
72-001 Kołbaskowo
Poland

Mail:
rma-diagnostics@dgs-diagnostics.com

Contact person: _____ Date: _____

Following item is reported to be:

☐ returned to INTERACOUSTICS for: ☐ repair, ☐ exchange, ☐ other: _____

☐ defective as described below with request of assistance

☐ repaired locally as described below

☐ showing general problems as described below

Item: Type: _____ Quantity: _____

Serial No.: _____ Supplied by: _____

Included parts: _____

Important! - Accessories used together with the item must be included if returned (e.g. external power supply, headsets, transducers and couplers).

Description of problem or the performed local repair:

_____

_____

_____

Returned according to agreement with: ☐ Interacoustics, ☐ Other : _____

Date : _____ Person : _____

Please provide e-mail address to whom Interacoustics may confirm reception of the returned goods: _____

☐ **The above mentioned item is reported to be dangerous to patient or user** [1]

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.
Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

[1] EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user.