Service Manual – EN

Impedance Tympanometer

MT10

Interacoustics

Item no. 8100015 - D-0100404 D – 2018/01

Table of Contents

1. Introduction

1.1 About this manual

This manual is for our Impedance Tympanometer, MT10. The contents of this manual cover instrument related data, such as calibration, technical specifications and a parts & accessories list.

1.2 About warnings and cautions

Where applicable, the below warning, caution and notice symbols are used throughout the manual, indicating the level of attention required for a given action:

 WARNING	The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.
 CAUTION	The **CAUTION** label identifies conditions or practices that could result in damage to the equipment.
NOTICE	**NOTICE** is used to address practices not related to personal injury.

1.3 General information

We continuously strive to improve our products and their performance, hence the specifications in this service manual are subject to change without further notice.

The performance and specifications of our products can only be guaranteed if technical maintenance is conducted routinely every year. Technical maintenance should be carried out by qualified personnel authorized by Interacoustics.

We are happy to receive any inquiries about our products. Our contact details are:

Interacoustics A/S	Phone:	+45 6371 3555
Audiometer Allé 1	Fax:	+45 6371 3522
5500 Middelfart	Mail:	info@interacoustics.com
Denmark	Web:	www.interacoustics.com

2. MT10

2.1 Basic operation

The left and right key function is usually shown on the bottom line of the display. When not performing a test and no key is used for 90 seconds, the MT10 switches off automatically. It is possible to extend this to 180 seconds (refer to configuration menu).

The LEDs indicate the status of the system:

Green LED	Yellow LED	Status
Off	Off	MT10 switched off
On	Off	Idle and ready to use
Off	Slow flash	Attempting to obtain an ear seal
Slow flash	Off	Conducting a measurement
Off	Fast flash	Pump error upon switch on
On	Flickering	Sending data to a PC

Table 1

2.2 Language settings

MT10 offers the language options English, French and German. The options are found in the configuration menu.

2.3 Probe

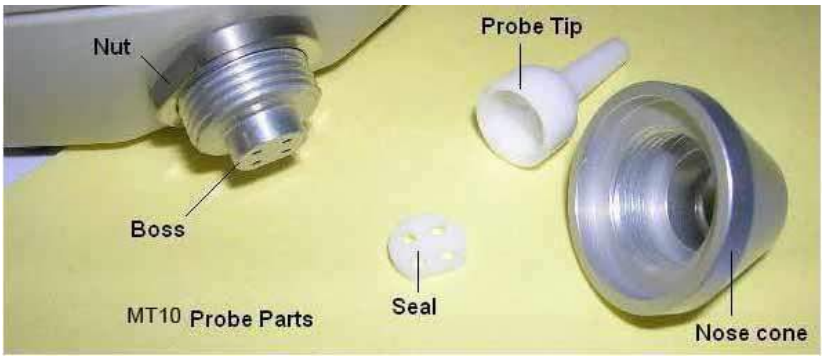


Figure 1

The small holes through the MT10 probe tip must be kept clear. If these are blocked, a warning message pops up. The tip must then be removed and cleaned, or replaced.

For probe tip removal, unscrew the nose cone and pull the tip off of the probe boss. The small seal found in the base of the probe tip should be examined and replaced if damaged.

When replacing the tip, ensure that the seal is correctly inserted with its flat side aligned with the flat side on the probe tip. Push the probe tip over the boss and replace the nose cone. Make sure that the nose cone is screwed on firmly but not over-tightened.

NOTICE

Never use tools of any kind to tighten the nose cone.

After tip replacement, a daily check should be conducted.

2.4 Menu description

2.4.1 Start up and menu display

When switching on MT10, the start screen is displayed while internal tests are performed and the pump is initialized.

When the start-up sequence is complete, the *Main Menu* is displayed:

The menu items and instructions are shown in upper case.

Information and error messages are generally shown in lower case.

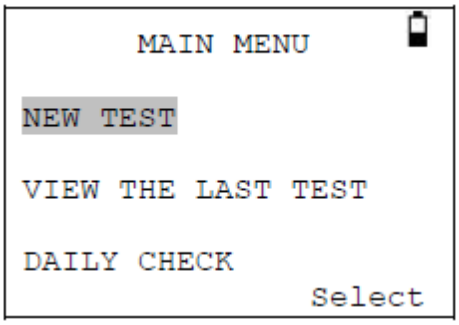


Figure 2

2.5 Menu summary

2.5.1 Main menu selections

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

2.5.2 Sub menu options

The options in **BOLD** are the default settings.

Sub-Menu	Option	Options/Description
NEW TEST	SELECT EAR	Open ear(s) up for testing and start the test. A tympanogram is taken followed by reflex measurements, if selected. On-screen messages and LEDs indicate progress. Graphical display is shown upon completion.
VIEW THE LAST TEST	SELECT EAR	Recalls the last stored test for the selected ear. Shows the tympanogram and reflex response, if available. Allows print of latest test, and sending it to a PC or saving it 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.
	DELETE RECORDS	Delete stored records. Select: *All Printed Records* for deleting all printed records. *All Sent Records* for deleting all records sent to a PC. *All Records* for deleting all records.
	PRINT RECORDS	Print stored records. Select: *Unprinted Records* for printing not previously printed records. *All records* for printing all records.
	SEND RECORDS TO PC	Transfer records to a PC. Select: *Unsent Records* for sending all records not previously sent. *All Records* for sending all records.
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* for always measuring reflexes. *Never Measure* for never measuring reflexes.

		Only Peak If Found for measuring reflexes only when MT10 detects a peak on the tympanogram. *Prompt to Measure* prompts 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.
	REFLEX FREQUENCIES (optional)	Choose to perform the reflex test at **1 KHz** only **or** **500, 1000, 2000 and 4000 Hz**
	REFLEX THRESHOLD	Select the change in compliance determining reflex detection. 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 smooths the plot more.
	PRINTER	Select Martel (Sanibel MPTII)
	BATTERY TYPE	Select **Alkaline** or NiMH (this effects the battery state display and low battery warning).
	POWER-OFF DELAY	The time span before the unit switches 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	Adding the hospital name enables personalized print outs.
	DEPARTMENT	Adding the department name enables personalized print outs.
	RELOAD DEFAULTS	The above options are reset to their default values.
	SELECT LANGUAGE	Select between English, German or French as operating language.
SYSTEM INFORMATION		Displays: Battery voltage Software version Date calibrated Next calibration date Instrument serial number Current date and time

2.6 Maintenance

2.6.1 General maintenance procedure

MT10 is a precision instrument. Handling it carefully ensures its continued accuracy and service. Prior to cleaning the instrument, remove the batteries. Use a soft damp cloth and mild detergent to clean the instrument panel and case, ensuring no moisture enters the instrument.

2.6.2 Cleaning the accessories

Being single use items, ear tips should be replaced after use. Handle the probe and accessories with care.

The probe tip and its accompanying sealing washer are disposable items. Check that the probe tip is intact before insertion, and none of the tubes through it are blocked. Always replace if necessary.

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

NOTICE Do not allow moisture, condensation, fluids or debris to enter the probe.

3. Calibration

This chapter includes the various tests and calibration procedures applying to MT10.

Equipment requirements

- Digital pressure meter
- Sound level meter including an IEC126 acoustic coupler
- CAT50 cavities complete
- 2.0 mL syringe
- Tube to tube Tee T210 1/16”

3.1 Calibration mode

Hold down ▲ and the left ▬ key and press the *On* key.

Select *Tymp Calibration* from the *Main Menu*.

Enter the unique calibration code for the unit. The calibration code is stated on the *Test and Calibration Results Report.* See example below:

Test and Calibration Results Report
According to instruction I07028401

Interacoustics
leading diagnostic solutions

ACCEPTANCE TEST RESULTS FOR MT10 TYMPANOMETER				
	Calibration code: xxxx		Serial number: xxxxxxxxx	
Para	**Test**	**Min limit**	**Max limit**	**Result**

Figure 3

The *Calibration* menu is then displayed.

3.2 Software Calibration

3.2.1 Probe tone level

1. Select *Probe Tone*.

   Select *226 Hz.*

   Select *Set Tone Level*.

2. Verify that the *Attenuation* shown is between 33 dB and 38 dB, and record the setting on the results sheet.
   Failure of this test indicates a problem with the microphone or loudspeakers.

3. Verify that the *Mic. Gain* shown is between 18dB and 22 dB, and record the setting on the results sheet.
   Failure of this test indicates a problem with the microphone or loudspeakers.

4. Now connect the tympanometer to the sound level meter, and set the sound level meter to display the frequency spectrum by pressing the *f<>t* key.

   Set the measurement frequency of the sound level meter to 250Hz using the left ▬ and right ▬ keys. Press *Next* on the tympanometer to display the *Set Tone Level* screen.

   Use the up/down keys on the tympanometer until the level displayed on the meter is between 84.5 dB and 85.5 dB SPL. Record the level on the results sheet.

   Press *Save.*

3.2.2 Reflex tone levels

Always calibrate all four reflex frequencies.

1. Press *Back* twice to return to the calibration menu.

   Select *Reflex Tone,* and then *500 Hz.*

2. Set the measurement frequency of the sound level meter to 500 Hz.

   Press *Next* on the tympanometer to display the set level screen.

   Set the level shown on the meter to between 85.0 dB and 86.0 dB SPL. Then press *Save*. This displays the *Reflex Tone* menu.

3. Select *1000 Hz* from the *Reflex Tone* menu.

4. Set the measurement frequency of the sound level meter to 1.0 KHz.

   Press *Next* on the tympanometer to display the *Set Level* screen, then set the level shown on the meter to between 79.5 dB and 80.5 dB SPL.

   Press *Save*. The *Reflex Tone* menu is displayed.

5. Then select *2000 Hz.*

6. Set the measurement frequency of the sound level meter to 2.0 KHz.

   Press *Next* on the tympanometer to display the *Set Level* screen, and then set the level shown on the meter to between 82.5 dB and 83.5 dB SPL.

   Record the level on the results sheet, and press *Save*.

   The *Reflex Tone* menu is displayed.

7. Scroll down and select *4000 Hz*.

8. Set the measurement frequency of the sound level meter to 4.0 KHz.

   Press *Next* on the tympanometer to display the *Set Level* screen.

   Set the level shown on the meter to between 85.0 dB and 86.0 dB SPL.

   Record the level on the results sheet.

   Press *Save*. The *Reflex Tone* menu is displayed.

9. Press *Back* to return to the *Calibration* menu.

   Disconnect the tympanometer from the sound level meter.

3.2.3 Pressure calibration

1. Set the pressure testing syringe to 1.0 mL.

   Connect the tympanometer to the pressure testing system.

   Select *Pressure Levels* from the *Calibration* menu.

   Set Pressure to -400 daPa pops up.

2. Pull the syringe plunger back slowly and when a reading between +3.95 kPa and +4.05 kPa is shown on the pressure meter, press *Select*.

   NOTICE

   As the pressure inside the syringe is sensitive to temperature, keep your hands away from the body of the syringe.

   Note that the meter shows a negative value for a positive pressure and vice versa. This is due to the meter connection.

3. *Set Pressure to +200 daPa* pops up.

   Push the syringe plunger in slowly and when a reading between –1.95 kPa and -2.05 kPa is shown on the pressure meter, press *Select*.

   Record the pressure level on the results sheet.

   NOTICE

   As the pressure inside the syringe is sensitive to pressure, keep your hands away from the body of the syringe.

4. Press *Next* to display the *Expose to an Atmosphere* message.

   Disconnect the tympanometer from the pressure measurement arrangement, and press *Save* to complete the pressure calibration.

   NOTICE

   Incorrect pressure calibration may cause the tympanometer to start up erroneously.

   For units with firmware 1.71.C and higher, hold the left and up-keys during start-up. Then hold the left, up and down-keys and select *Next* to bypass the error message. Reload default calibration levels.

3.2.4 Volume calibration

1. Select *Probe Tone* from the *Calibration* menu.
   Select 226 Hz, and then *Volume Calibration*.
   Press the right — key to start the calibration. *Insert into 0.2 mL* is displayed.
2. Insert the tympanometer probe into the 0.2 mL calibration cavity.
   Make sure the nozzle is pressed firmly in place and the probe is perpendicular to the end of the cavity.
   Verify that a raw volume between 0.5 mL and 0.7 mL is shown on the screen.
1. Press the right — key to start the volume calibration. Shortly after, the message *Insert into 1 mL* pops up.
4. Insert the tympanometer nozzle into the 1.0 mL calibration cavity.
   Make sure the nozzle is pressed firmly in place and the probe is perpendicular to the end of the cavity.
   Verify that a raw volume between 0.9 mL and 1.2 mL is shown on the screen.
2. Press the right — key to start the volume calibration. Shortly after, the message *Insert into 5 mL* is displayed.
3. Insert the tympanometer nozzle into the 5.0 mL calibration cavity.
   Make sure the nozzle is pressed firmly in place and the probe is perpendicular to the end of the cavity.
   Verify that a raw volume greater than 3.5 mL is shown on the screen.
   Press the right — key to start the volume calibration. Shortly after, the *Calibration* menu is displayed.
7. Press the left — key to return to the main menu.
   Select *Daily Check.*
   Wait until *Open* is shown on the display.
   Insert the tympanometer nozzle into the 1.0 mL test cavity.
   Verify that the display shows a volume of 1.0 mL.
   If the tympanometer fails to show the correct volume, repeat this section (E) up to three times. This error is often a result of poor alignment with the cavity during calibration.
8. Insert the tympanometer nozzle into the 0.5 mL test cavity.
   Verify that the display shows a volume of 0.5 mL.
   If the tympanometer fails to show the correct volume, repeat this section (E) up to three times. This error is often a result of poor alignment with the cavity during calibration.
9. Press the left — key to return to the main menu.

3.2.5 Set calibration date

1. Select *Tymp Calibration* from the main menu.
   Select *Set Cal. Date.*
   After a short pause the message *Cal. date updated* is displayed.
   Switch off the tympanometer.

3.2.6 Functional tests and inspection

1. Switch on the tympanometer. Listen for a smooth pump start up operation, with no abnormal noises. Abnormal operation may not always generate an error message.
   Verify that the tympanometer goes straight to the main menu showing no error messages and with only the green led illuminated.
2. Select *New Test* from the *Main Menu*.
   Select *Left* from the *Select Ear* menu.
   When prompted to *Insert probe*, insert the tympanometer probe firmly into a 1.0 mL calibration cavity.
   Verify that the tympanometer test messages are displayed.
   Verify that the right hand led flashes yellow while the *Insert Probe* message is displayed.
   Verify the left hand led flashes green while the test is conducted.
3. Wait for the test to be completed and the tympanogram to be displayed.
   Verify that an ECV of 1.0 mL is shown and the graph shows a solid, straight line across the screen with no more than 1 step variation from the 0 mL line. Record this on the results sheet.
   Greater variations from the 0 mL line or separated solid and dotted lines indicate a pump (noise), seal or microphone problem. If any part of the line is dotted rather than solid, pressure is being lost. If ECV is not 1.0 mL, suspect incorrect probe tone level or volume calibration.
   Press *Next* to exit the tympanogram.
   The *Process Results* menu pops up. If this is not the case, the instrument has failed the test.
4. If applicable, first choose the appropriate printer via *Configuration* and *Printer*. Place the tympanometer on the bench approximately 15 cm in front of the infra-red printer.
   Make sure that the infra-red windows of the two devices point directly at each other.
   Make sure that the printer is switched on.
   Select *Send to Printer* from the process results menu.
   Verify that the stored tympanogram is printed correctly. Attach the print-out to the test results sheet.
5. Press *Quit* to return to the main menu.
   Select *Configuration*.
   Select *Reload Defaults.*
   Select *Yes*.
   Press *Back* to return to the main menu.
4. Select *Data Management* from the *Main Menu.*
   Select *Delete Records.*
   Select *All Records.*
   Select *Yes.*
   Press *Back* to return to the main menu.
5. Select *New Test* from the main menu.
   Select *Both.*
   Press *Cancel*.
   Press *Back* to return to the main menu. Switch off MT10.

3.3 Calibration mode

Hold down ▲ and the left ▬ key and press the *On* key.

3.4 Tests

3.4.1 Pressure test

1. Switch on the pressure meter, and set the pressure test syringe to 1.0 mL.
2. **I**nsert the tympanometer probe firmly into the silicone tube and connect to the digital pressure meter. Pull the syringe back gently until the pressure meter displays a pressure of 2.50 kPa.
3. Wait 5 seconds. Verify that the pressure indicated on the meter is equal to or greater than 2.45 kPa. A slow gradual drop in pressure is acceptable. A continuous drop in pressure require further investigation.
4. Disconnect the tympanometer from the pressure meter.

3.4.2 Pump test

Fit test batteries to the tympanometer.

Press the *On* key.

Verify that the green LED is on and the yellow LED is off.

Listen for a smooth pump start-up operation, with no abnormal noises.
Abnormal operation may not always generate an error message.

If a pump fault pops up, this must be fixed before continuing.
Failure, other than the pump, at this stage, indicates a PCB fault.

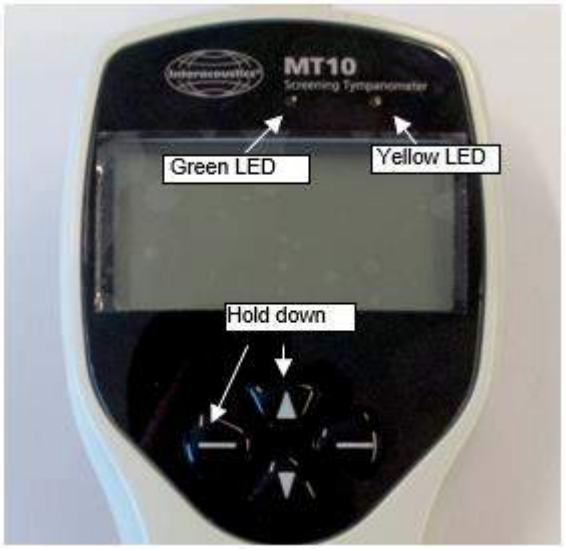


Figure 4

3.4.3 Software test

WARNING

If *Device Uncalibrated* pops up, the instrument requires a complete calibration.

Select *System Information* from the main menu. The current software version is then displayed on the screen.

Figure 5

3.5 Initialize data

6. Select *Configuration* from the *Main Menu*.
   Select *Today's Date.*
   Set the current time and date. Confirm the setting on the results sheet.
   Press *Back* to return to the main menu.
7. Select *Back* to return to the main menu and select *System information*.

Appendices

Appendix A - General technical specifications

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 0.2 mL to 5 mL
Pressure levels and accuracy:	+200 daPa to -400 daPa +/-10 daPa or +/-10% (whichever larger) over range.
Ear volume measurement range and accuracy:	0.2 mL to 5 mL +/-0.1 mL or +/-5% (whichever is larger) over entire range.
Sweep speed:	Typically 200-300 daPa/sec; dependent on ear & cavity volume.
Pressure limits (safety cut-out):	+600 to -800 daPa
Number of samples stored:	100 per tympanogram

Optional:

Reflex measurements

Measurement modes:	Ipsilateral optional
Reflex tone levels and accuracy:	500 Hz, 1 kHz, 2 kHz, 4 kHz Frequency +/-2%, configurable over range 70 dB to 100 dB HL (4 kHz restricted to 95 dB HL) +/-2 dB, referenced to 2 mL calibration volume; compensates for measured ear volume.
Reflex measurement range and accuracy:	0.01 mL to 0.5 mL +/-0.01 mL configurable in 0.01 mL steps.
Number of reflex levels:	Four: 100 dB with 5 dB or 10 dB steps; 95 dB, 90 dB or 85 dB with 5 dB 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 0 daPa (always and prompt before each test modes).
Reflex level cut-off:	Optionally, auto-stop when reflex detected.
Reflex threshold detection:	Configurable 0.01-0.50 mL in 0.01 mL increments.
Reflex tone duration:	0.6 sec.
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 Identifier* (GUID).
Display mode:	Records listed in reverse chronological order (latest first), and 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 2.3 Ah capacity.
Warm-up period:	None at room temperature.
Number of recordings from one set of cells:	Approximately 200 (alkaline AA).
Auto power-off delay:	90 or 180 sec.
Idle current:	70 mA
Current while testing:	230 mA

Physical

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

Environmental

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

Standards conformance

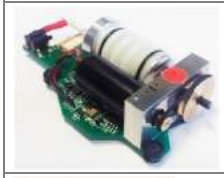
Safety:	IEC 60601-1 ANSI/AAMI ES60601-1, CAN-CSA C22.2 No. 60601-1
EMC:	IEC 60601-1-2
Performance:	IEC 60645-5, Type 2 tympanometer.
CE marking:	To the EU Medical Device Directive.

Appendix B - Parts & accessories

Accessories	Part number	Description
	8101787	MT10 MPT-II printer kit Includes: 2 rolls of Sanibel MPT-II thermal paper and power supply
	8029346	USB adapter IR2000UL
	8011296	CAT50 calibration cavities open/closed
	8102184	1.0/0.5 cc cavity

Consumables	Part number	Description
	8012892	BET55 Ear tip box Complete ear tip assortment and cleaning tool
	8011348	Probe cleaning tool Assembled / open
	8002028	Ear tip 3-5 mm, flanged
	8002029	Ear tip 4-7 mm, flanged
	8002030	Ear tip 5-8 mm, flanged
	8002010	Ear tip 7.5 mm, umbrella
	8002011	Ear tip 9 mm, umbrella
	8002012	Ear tip 10 mm, umbrella
	8002013	Ear tip 11 mm, umbrella
	8002014	Ear tip 13 mm, umbrella

Accessories	Part number	Description
	8002015	Ear tip 15 mm, umbrella
	8002016	Ear tip 19 mm, umbrella
	8002017	Ear tip 22 mm, umbrella
	8002018	Ear tip 7 mm, mushroom
	8002019	Ear tip 8 mm, mushroom
	8002020	Ear tip 9 mm, mushroom
	8002021	Ear tip 10 mm, mushroom
	8002022	Ear tip 11 mm, mushroom
	8002023	Ear tip 12 mm, mushroom
	8002024	Ear tip 13 mm, mushroom
	8002025	Ear tip 14 mm, mushroom
	8002026	Ear tip 15 mm, mushroom
	8002027	Ear tip 19 mm, mushroom
	8029305	Sanibel MPT-II thermal paper
	8011226	Battery 1,5Volt LR6 14,5x50,5m
	8012959	Cleaning cloth

Spare parts	Part number	Description
	8002592	Probe tip
	8001156	Probe cone
	8001157	Probe nut
	8002009	Sealing part probe tip
	8103278	Probe boss (includes tubes)
	8103125	MT10 display
	8103128	Mainboard (w/ reflex) – including microphone/speakers and tubes
	8103129	Mainboard (w/o reflex) – including microphone/speakers and tubes
	8100479	Pump assembly
	8001925	Drive belt
	8103130	Pump bellows and o-rings kit
	8103134	Reservoir kit (includes dampers and comb)
	8103139	Microphone kit (includes hose and wires)
	8103271	Speaker kit (includes hose and wires)

Spare parts	Part number	Description
	8103135	Bottom cabinet kit Includes: battery terminals and cable
	8002678	Top cabinet kit
	8103315	Silicone pad

Appendix C - Update news

The following modifications have been made to this instrument and/or service manual:

Date	Action	Remarks
2018/01	New tech specs added Update of service manual to new format and content quality	