User manual
Version 1.21

Oscilla®

SM930 Screening Memory Audiometer
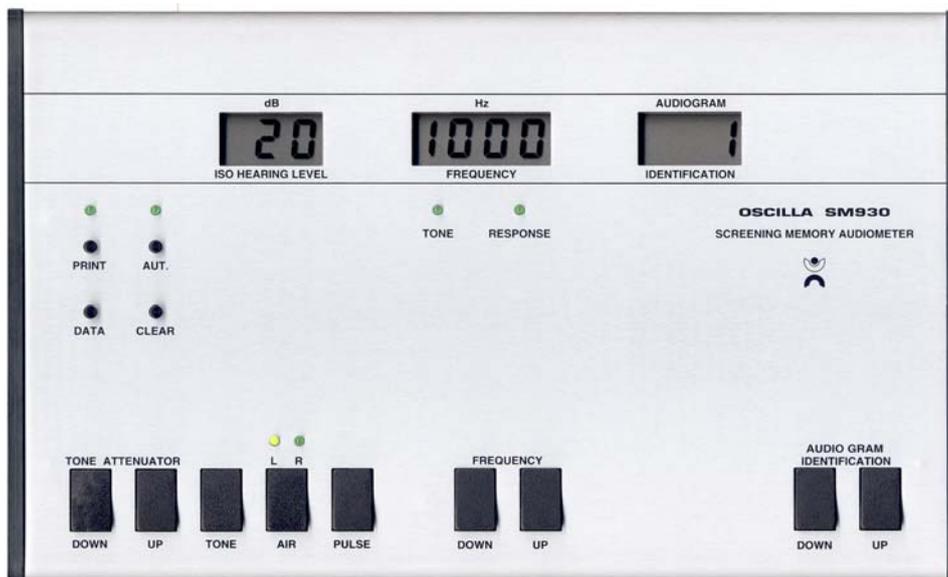
Firmware version 1.16, 1.17
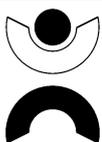
CE -0543

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1 General description

The SM930 is a fully automatic audiometer equipped with many useful features, which are of great use in the daily work.

The audiometer is capable of memorizing the results obtained during a hearing test. Therefore it is not necessary to register the threshold values for each frequency during the test, but the operator can wait to fill out the audiogram by the time the test is completed. During the manual hearing test, the values, which are presented to the patient, will be stored in the audiometer. Values not responded to, are displayed with a special symbol on the print out. If the operator leaves out some frequencies, these will not be shown neither on the screen nor on the print out.

When changing frequency or channel the stored threshold values for each frequency are shown in the tone attenuator display for both left and right ear.

The audiometer may be connected to a 9 or 24 pin dot printer, a thermo printer or a PCL 5 compatible laser printer in order to print out complete audiograms.

The audiometer may optionally be used with the software program AudioConsole. In AudioConsole you can display and save recorded audiograms stored within the audiometer and manage patients.

The audiometer is capable of conducting several automatic hearing threshold tests. While the audiometer conducts the automatic tests there is time for the operator to finalize the necessary paperwork and possibly prepare and instruct the next patient. In the program there is also a SETUP function, which makes it possible to change some of the features of the audiometer. The functions selected will be remembered until SETUP is changed again.

Function
This device supports pure-tone and can perform screening hearing tests in order to determine the hearing ability of a person.
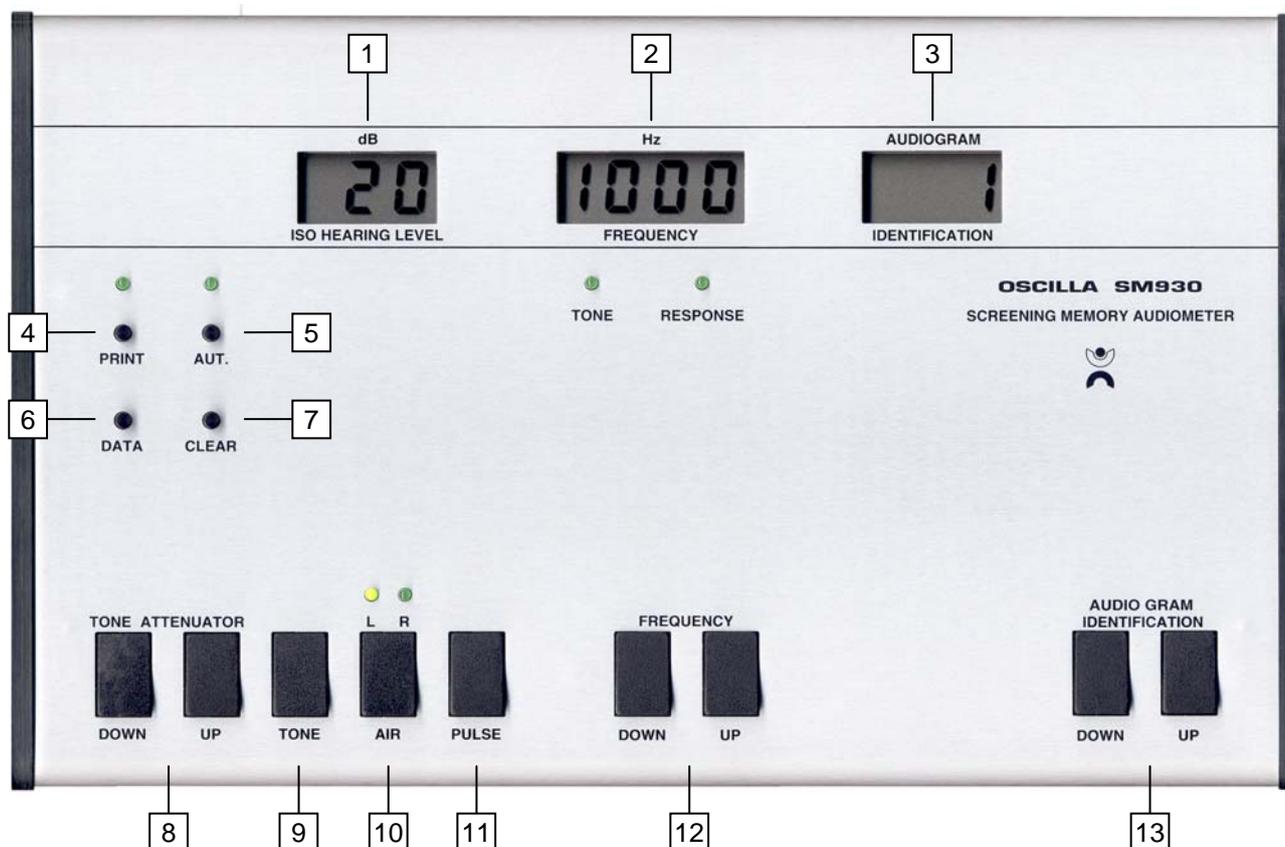
Intended application
The intended application of the device is to be used within a screening environment operated by trained health personal or likewise.

Classification
Type 4 - Screening Audiometer

For additional information refer to the technical specifications on page 14.

2 Description of front panel

1 **ISO hearing level** - The actual sound pressure in dB

2 **Frequency** - The actual frequency in Hz

3 **Audiogram Identification** - The active audiogram

4 **Print** - Prints the active audiogram

5 **Aut.** - Starts 1 of 4 possible automatic tests

6 **Data** - Transmits the test results to a connected PC

7 **Clear** - Erases the current audiogram

8 **Tone attenuator** - Push the DOWN/UP to change sound level

9 **Tone** - Sends tone to the patient

10 **AIR** - Determines whether the tone is going to the right or left ear

11 **Pulse** - Sends a pulsing tone to the patient, with a modulation frequency of 2.5 Hz

12 **Frequency** - Pushing one of the buttons changes the frequency to the next fixed value

13 **Audiogram Identification** - Push one of the buttons to select which audiogram to be active

Default: if the device has not yet been in use, the FREQUENCY display shows 1000 Hz, the TONE ATTENUATOR display shows **-**, and the IDENTIFICATION DISPLAY shows 1.

3   Description of rear panel

The earphone- and patient answer button cables are mounted with phone jacks who are hooked up to the appropriate input connectors on the rear side of the device. The power adapter is inserted into the POWER connector at the rear side of the device and plugged into an electrical outlet.
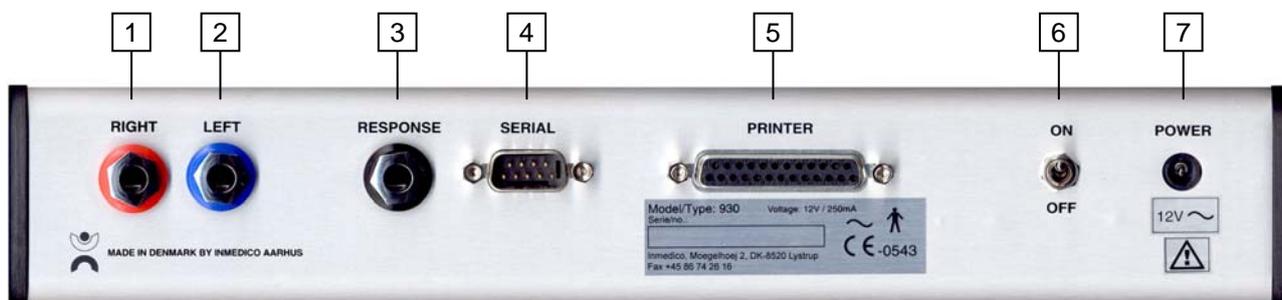
1 **Right** - Right earphone

2 **Left** - Left earphone

3 **Response** - Patient response

4 **Serial** - Connection for PC, or serial printer

5 **Printer** - Connection for parallel printer

6 **On/off** - Device on/off

7 **Power** - Power connector

4 Operation

4.1 Tone attenuator

By applying light pressure to the DOWN/UP buttons the attenuator steps up or down in 5 dB

The actual sound pressure can be read in the display

Holding down one of the buttons, the sound pressure is increased or decreased until the button is released. Increments: in the range from -10 dB to 110 dB (refer to max. intensities under Technical Specifications).

When the attenuator is in its lowest position - one step below -10 dB - the display will show minus (-). In this position no data will be stored in the memory and should a print out be performed no values will be shown for these frequencies. If the patient does not respond to the tone, even at maximum sound level, this information should be stored in memory by pressing the attenuator UP button one extra time. This will make the hearing level display flash, and thereby indicate that the tone was not heard. If it is decided to store the threshold values shown in the display, it is important not to activate the two attenuator keys before print out, unless a correction of the sound pressure is desired.

4.2 Tone

With the interrupter button a tone is sent to the patient.

The light will shine as long as the tone is present.

It is possible to select fixed tone duration of 0.5, 1.0 or 1.5 seconds. This means that independently of how long the interrupter button is depressed the selected tone duration remains unchanged.

4.3 AIR

The output button AIR determines whether the tone is going to the right or left ear.

When the **L** (left) lamp is on, the tone is sent to the left ear.

Oppositely, the tone is sent to the right ear, when the **R** (right) light is on.

For each touch of the AIR key, ears are changed.

4.4 Pulse

By pushing the PULSE button a pulsing tone with a modulation frequency of 2.5 Hz is emitted.

Pulse modulation may be used during an automatic test too, by holding down PULSE while starting the auto test.

4.5 Frequency

Pushing one of the buttons changes the frequency to the next fixed value.

The actual frequency can be read in the display

When holding either of the buttons, the frequency is repeatedly changed to lower (DOWN) or higher (UP) values until the key is released. If desired, some frequencies can be disabled (see **SETUP**, **MODE 1**).

4.6   Memory

The built-in memory is capable of storing 83 separate audiograms, numbered from 1 to 83 by an identification number. The desired audiogram number is chosen by means of the AUDIOGRAM IDENTIFICATION up and down buttons.

Use the ID DOWN/UP buttons, to select which one is the active audiogram.

The number is shown in the ID display

The memory may be disabled in the SETUP mode 3, and this will prevent the memory related functions from working, and make the device act exactly like an "old-fashioned" audiometer. These memory related functions are:

PRINT
AUT.
DATA
CLEAR
ID DOWN, UP buttons, and the audiogram ID display.

4.7   Print

A push on the PRINT button causes the device to print the active audiogram to a connected printer.

The light above the button will light up during the printing, and the program automatically selects the correct symbols. If the printer is not connected or shows an error (e.g. out of paper), the light turns off after 20-25 seconds. To select the correct printer driver, refer to the SETUP section under mode 5 and 6.

The following symbols will be used:
X   :   LEFT ear
O   :   RIGHT ear

When the patient does not hear the tone, it is marked with a little arrow on the X & O respectively. Frequencies left out are not shown on the audiogram. Under the audiogram a table is printed, containing the dB numbers of the test. This table also includes two fields for each channel named MID and HI. The MID field is the average of the three midrange frequencies 500, 1000 and 2000 Hz. And HI is the average of the three treble frequencies 3000, 4000 and 6000 Hz.

4.8   Automatic mode

A push on the AUT. button causes the device to start 1 of 4 possible tests

If on one or more frequencies has not been answered, the light above the AUT. button will flash when the test ends.

The 20 dB test

The 20 dB test gives the option of performing a quick automatic screening test, with a fixed sound pressure of 20 dB. After each answer the frequency will change, and the sound level will return to 20 dB. The test is started at 1000 Hz in the left channel, and goes up in frequency. When the highest frequency is reached it returns to 1000 Hz, and continues down, and the sequence is repeated with the right ear. After the test has been performed, you may recall the values in the display by pressing FREQUENCY UP and DOWN, and transmit them to a printer or a computer.

The 20 dB RANDOM test:

An extremely useful automatic test has been added: selects RANDOMLY frequency and channel, avoiding that the test person will find a system and therefore be prepared for the next signal. The test is started at 1000 Hz, left channel, and then 1000 Hz right channel. After this the frequency and channel is selected randomly, with a new sequence each time the test is started.

When a 20 dB test is finished

1. If all frequencies are answered at 20 dB, you will hear 1 BEEP after the test, and you will know that all frequencies have been heard at 20 dB.
2. If one or more frequencies are not responded to at 20 dB, 3 Beeps' will be heard, as well as the AUT lamp will flash, telling you that one or more frequencies have not been heard at 20 dB. When you go through the frequencies, the attenuator display will tell you which frequencies were not heard. Those that shows anything other than "20" was responded to at the sound level shown, rather than 20 dB. If the display flashes, it means that the automatic test proceeded all the way up to maximum sound level at this frequency, without the patient responding at all.

4.8.1

Variable automatic test

This is an automatic threshold test. The frequency is set to 1000 Hz and a tone is automatically given to the left ear at an intensity of 30 dB. As long as there is no response from the patient, intensity will increase 10 dB each time the tone is presented to the patient. For each response the intensity will decrease 5 dB, and conversely, increase 5 dB when there is no answer.

When the test has accepted the answer, the frequency is automatically changed to the next level above 1000 Hz and the procedure is repeated until all frequencies above 1000 Hz have been tested. The frequency drops down to 1000 Hz, and all frequencies below 1000 Hz are tested following the same procedure, as described above.

4.9   The Hughson Westlake automatic test

This is an automatic threshold test. The frequency is set to 1000 Hz and a tone is automatically given to the right ear at an intensity of 30 dB. As long as there is no response from the patient, intensity will increase 5 dB each time the tone is presented to the patient. For each response the intensity will decrease 10 dB, and conversely, increase 5 dB when there is no answer. The test uses the 2-of-3 answer method to determine when to proceed to the next frequency. This means that it looks at the two first answers, and if they are at the same sound levels, the next frequency is selected. If they are not equal, it tests a third time and compares the answer with the two previous answers. If it matches one of those, it proceeds to the next frequency. If all three answers are different from each other, the test continues until two out of three following answers are equal. The sequence of the frequencies is different from that of the 20 dB test: After the initial 1000 Hz has been tested, the frequency will go down to the next frequency, instead of up. When the lowest frequency has been tested, the test returns to 1000 Hz and goes up from here. This sequence is repeated on the left ear.

When a threshold test is finished:
When the automatic threshold test is completed, the audiometer gives 1 beep. If some of the frequencies have not been answered, then the lamp above the **AUT** button will flash. Going through the frequencies step by step, the attenuator display will flash for the frequencies not heard. It is now possible to conduct a manual test for those frequencies. For safety reasons the maximum test level is fixed at 80 dB (125 Hz to 70 dB) during the automatic tests. For the Hughson Westlake test, this maximum level may be decreased in the setup.

4.9.1

Patient notification of an automatic test finishing:
When an automatic test is finished, the patient is notified by three beep sounds in the earphones. This is done for all the test types, both 20dB and threshold tests.

4.9.2

Pulse tone and automatic test combined:
It is possible to use the pulse tone within the automatic tests. The test will then keep pulsing the tone until the patient responds, then stop it so the patient knows his response is acknowledged. When the next tone is given, the test starts pulsing again, and waits for a response. To use this feature, hold down the PULSE button while you start the automatic test, by pressing AUT.

4.10 Data
A push on the DATA button causes the device to transmit the test results stored in the active audiogram to a connected PC.

The time of transmission is about 200 milliseconds.

There are 3 options for datatransmission which can be chosen from SETUP mode 3:
Frequency display shows OFF: Memory is off, datatransmission is not possible.
Frequency display shows ON: Every push on the DATA button will transmit results to PC.
Frequency display shows AUTO: Data will automatically be transmitted everytime the soundpressure is changed, also when an automatic test runs.

Following symbols will be shown on the screen:

X : left ear
O : right ear

If a tone is not answered, the audiogram will show a little arrow on X and O.
If some frequencies has been left over they will not be shown on the audiogram.

4.11 Erase an audiogram
The CLEAR button erases the active audiogram selected by the ID buttons.

Use it to ensure that there is no old data stored in the audiogram, before you perform a new hearing test. Only one audiogram may be erased at a time.

4.12 Setup

The **SETUP** function is selected in the following way: Press **DATA** - and hold it while pressing **CLEAR.**
Release **CLEAR** and then release **DATA.** The **RESPONSE** light will flash 5 times and then stay on
constantly as long as **SETUP** is active.

With the **ID** buttons it is possible to select the 15 different modes, which can be programmed individually.
The mode selected is shown in the **ID** display. In addition, a brief text is shown in the hearing level display, to
make it easier to remember the purpose of the different modes.
In all modes the **ATTENUATOR** buttons are used to select the desired state of each mode. The middle box
indicates the default value in each mode.

Mode 1: Frequency selecting

		AUDIOGRAM
FRE	125-8000	1
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

This gives the option of selecting or deselecting single frequencies by means of the TONE ATTENUATOR.
One press on the UP button selects the frequency and the TONE lamp will light up. On the other hand,
pushing the DOWN button will deselect the frequency and the lamp will be off. The deselected frequencies
are then skipped over in normal operation.

Mode 2: Tone length

		AUDIOGRAM
LEN	OFF	2
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

In this mode fixed tone duration of 0.5 - 1.0 - 1.5 seconds may be chosen. The individual tone durations are
selected with the tone attenuator buttons and are shown in the frequency display as: OFF - 0.5 - 1.0 - 1.5.
When set to OFF the tone is on as long as the interrupter is held down. The fixed tone duration selected is
not affected by the length of time the interrupter button is depressed.

Mode 3: Recall mode

		AUDIOGRAM
REC	ON	3
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

This determines if the threshold values are stored in the memory of the audiometer, for printout, transfer to
PC or recall in display. There are three different choices, shown in the frequency display as "OFF", "ON", or
"AUTO":

OFF: The memory is disabled. Use this if you want the unit to operate as a "traditional" audiometer without
memory and recall capabilities. When memory is disabled it is not possible to use the printer port, the serial
port and the automatic hearing tests.

ON: The memory is active. Sound levels are stored in memory each time the attenuator setting is changed.
When frequency or channel is changed, the sound level previously stored in memory is recalled to the
display.

AUTO: The memory is active. Works like when ON is selected, but in addition the unit will transmit the
audiogram data to the serial port each time the attenuator setting is changed. This setting is useful if you
want to watch the audiogram on a PC during the test, and will work when automatic tests are performed, too.

Mode 4: Auto mode

AUDIOGRAM

AUT	RND	4
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

Selecting one of the four automatic tests. The four tests are shown as "20", "20r", "VARI" and "HUGH", and the choice is made by means of the attenuator buttons.

20: The quick and simple 20 dB screening test.
20r: The randomized version of the 20 dB test.
VARI: An automatic threshold test
HUGH: The Hughson Westlake 2-of-3 automatic threshold test.

The different tests are described in the **Automatic mode** section.
Note that the memory must be enabled in mode 3, for the automatic modes to work.

Mode 5: Printer type selection

AUDIOGRAM

PRT	24	5
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

If you want to use a printer connected directly to the audiometer, the correct type of printer must be selected. There are 5 printer type selections that work with a variety of printers:

9: Used with most Epson compatible 9 pin matrix printers.
24: Used with most 24 pin printers and many inkjet printers such as Canon.
PRO: Used with IBM Pro Printers. Some other printers can emulate a Pro Printer.
HP: Used with PCL 2 to PCL 5 compatible laser printers such as HP DeskJet and LaserJet printers. Many other laser printers may emulate HP laser printers and will work with this setting.
THER: Used with the Kyosha Thermo printer. When this printer is used, MODE 15 must be set to "SERI", because it is connected to the serial port.

Note that printers designed specially for Microsoft Windows will not work when connected directly to the audiometer. It is, however, perfectly possible to use them together with a PC, when the audiometer is connected to the PC via the serial port. If you don't know which 'language' your printer works with, you may just try the different settings and see if it works. There is no risk of damage to neither the printer nor the audiometer by selecting a wrong printer type. You may also consult the printer manual for further information as to what the printer may emulate. (E.g. HP printers which may emulate PCL 2 will work)

Mode 6: Carriage return on/off

AUDIOGRAM

CR	OFF	6
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

Some matrix printers may make horizontal blank lines in the printout. If this occurs, try to set this setting to OFF. Others will fail to return the printhead to the start of the next line, and then often only print one line. If this occurs, set this setting to ON. In some cases you will see blank lines, even with the setting set to OFF. This can occur if a 9 pin printer is used in the 24 pin or PRO mode. Try to change mode 5 (Printer type) to 9 pin printer.

Mode 7: Audiogram selection

		AUDIOGRAM
AUD	SNGL	7
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

This is used to determine if the audiograms printed out should be single or dual. The two choices are shown as "SNGL" or "DUAL" in the attenuator display.
SNGL: Both ears are shown on one single audiogram on the printout.
DUAL: Two separate audiograms are printed out, one with the left ear and one with the right ear.

Mode 8: Automatic printout

		AUDIOGRAM
APR	OFF	8
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

APR=automatic print out after finished an automatic test. The SM930 will automatically print out the test result and during this you may prepare for the next patient.

Mode 9: Top-Margin

		AUDIOGRAM
POS	0	9
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

If you want to use a certain formula for printing your test data, you are able to determine the top-margin from 0 to 30 lines. POS = Position.

Mode 10: Automatic attenuator reset

		AUDIOGRAM
AAR	OFF	10
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

Automatic reset of attenuator in the Hughson Westlake test. (AAR=automatic attenuator reset).
If this mode is ON the attenuator will be reset to the level which is set in mode 13.

Mode 11: Hughson Westlake minimum

		AUDIOGRAM
LO	-10	11
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

Hughson Westlake minimum sound level in the range of: -10 to 40dB. The value can not be higher than the value chosen in mode 13.

Mode 12: Hughson Westlake maximum

		AUDIOGRAM
HI	70	12
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

Hughson Westlake maximum sound level in the range of: 50 to 80dB.

Mode 13: Hughson Westlake start

		AUDIOGRAM
INI	30	13
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

Hughson Westlake start level in the range of: 0 to 50dB. May not be set to a lower value than the minimum value in mode 11.

Mode 14: Identification transmit

		AUDIOGRAM
ID	ON	14
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

When this mode is on, the audiometer transmits an identification key when turned on. This is required when the audiometer is used with the AudioConsole PC program. If the audiometer is used with other programs, it is possible that this ID key will cause problems. If you experience this, the ID transmission can be turned off here.

Mode 15: Printer Port selection

		AUDIOGRAM
PP	PARA	15
ISO HEARING LEVEL	**FREQUENCY**	**IDENTIFICATION**

This mode selects if a printer is connected to the parallel port, or the serial port. If you use the Kyosha Thermo printer, this mode must be set to SERI. This printer is connected to the socket marked "SERIAL" on the audiometer. For printers with parallel port, select PARA, and connect the printer to the socket marked "PRINTER".

Finishing SETUP
The DATA button terminates the SETUP function. The software program stores the modes selected, until changes are made.

Reset to **DEFAULT** values is performed manually by using the below listed values.

Mode 1: All frequencies available
Mode 2: OFF
Mode 3: ON
Mode 4: RND
Mode 5: 24
Mode 6: OFF
Mode 7: SNGL
Mode 8: OFF
Mode 9: 0
Mode 10: OFF
Mode 11: -10
Mode 12: 70
Mode 13: 30
Mode 14: OFF
Mode 15: PARA

5 Technical specifications

Standards compliance:

Audiometer	EN 60645-1, EN 60601-1, EN 60601-1-1, EN 60601-1-2
TDH-39 sound pressure:	EN ISO 389-1
Safety:	EN 60601-1:1990 + A1:1993 + A2: 1995 + A13:1996
Electromagnetic compliance:	EN 60601-1-2:2001 + EMC Directive 89/336/EEC
Medical Instrument Directive: (CE Mark)	MDD 93/43/EEC

Classification: Group 1, class B EN 60601-1-2:2002

Type of protection against electric shock:	Class I equipment
Degree of protection against electric shock:	Type B applied part
Degree of protection against liquid penetration:	IPO, ordinary equipment
Degree of safety of application in the presence of flammable anaesthetics:	N/A
Mode of operation:	Continuous operation

Medical CE- mark: Inmedico A/S is approved for medical CE marking, by DGM.
Identification number 0543

Transducers: TDH-39 air conduction

Power Supply: 12 VAC, approx. 200mA max.

Adaptor: Primary: 230 VAC, 50/60 Hz, 60mA max.
Secondary: 12 VAC, 7 VA, ± 10 %

Environmental Conditions for Operation
Ambient Temperature: +15 to +35 degree Celsius.
Relative Humidity: 30 % to 90 %
Surrounding pressure: 80 kPa to 120 kPa

Environmental Conditions for Storage
Ambient Temperature: -10 to +50 degree Celsius
Relative Humidity: 95% or less (non-condensing)
Surroundings pressure: 50 kPa to 120 kPa

Physical Attributes
Dimensions: 295 (W) x 180 (D) x 55 (H) mm
Weight: ~ 1,2 kg including accessories
Casing material: Aluminium

Calibration: Data is saved in eeprom memory, EN 60604-1

Parallel port: Automatic or manual printout of complete audiogram, 60-75 dpi.

Serial port: Automatic, manual Computer data transmission (RS-232) to patient file or serial printer. 9600 baud, 8 bit, no parity, 1 stop bit.

Warm-up time:	< 3 seconds.
Included parts:	1 audiometer, 1 set of Peltor H7A headphones with TDH-39, 1 response button, 1 mains adapter, 1 user manual and calibration certificate.
Accessories:	carrying bag, serial cable, printer cable, AudioConsole software and Thermo-Printer

Measurement specifications

Measurement Method   Manual and automatic threshold test **without** storage of data.

Measurement Range
Maximum Intensities:

Frequency	Air
125 Hz	70 dB
250 Hz	90 dB
500 Hz	110 dB
750 Hz	110 dB
1000 Hz	110 dB
1500 Hz	110 dB
2000 Hz	110 dB
3000 Hz	110 dB
4000 Hz	110 dB
6000 Hz	100 dB
8000 Hz	90 dB

Measurement Accuracy
Tolerance frequency: ± 1 %.
In/output impedance: Left / Right channel ~ 4,7- 144,7 ohm, Patient response ~ 1 K ohm
Distortion speaker: TDH-39: **<** 1 %, 4. and higher harmonic + sub harmonic < 0,3 %.

Single signal channel:
Air conductor: ± 4 dB (125 Hz – 4 kHz)
                              ± 5 dB (6 kHz – 8 kHz)

Measurement Durations and Times
Data transmission: RS-232C protocol
Storage space: 83 audiograms

6 Please note

6.1   Safety precaution

Medical electrical equipment need special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Interruptions of the mains adapter must be carried out on the outlet.

If the audiometer / personal computer are exposed to a powerful static discharge, this can cause interruption of the signal without interruption of the device.
Should this rare state occur, then turn the audiometer off and then on. Under normal conditions the device should function again.

Neither the patient nor user will be exposed to any danger; likewise the calibration settings or other functions would be affected.

If a failure should occur, meaning the device is missing a function or has a fault, please contact the seller of the device or the manufactor.
Repair of the device must be accomplished by Inmedico A/S or a specially trained person with a given permission to repair the product.

PC, printers or other equipment there are used together with the audiometer, must meet the specified demands given in standard EN60601-1 § 14.1a

6.2   Packing guidance

By shipment, the device must be wrapped into bubble plastic and put into an ordinary export case.
None of the audiometer parts must be able to touch the sides in the box.
The audiometer withstand ordinary air freight and similar.

6.3   Calibration
It's recommended to get the device calibrated every 2nd year, by qualified personal.

6.4   Cleaning / disinfection
Audiometer parts that are in contact with the patient include patient response and headset.
Both can be cleaned with a cloth wrung in lukewarm water and a little soap. Disconnect both parts from the audiometer before cleaning and make sure they are dry before connecting them again.

6.5   Product Warranty
2 years – device only

6.6   Product Life
20 years - estimated

6.7 Symbols

$\sim$	AC - 12V alternating current
⚠	Caution
🧍	Type B, EN60601-1
🗑	Must be properly disposed

7 EMC

<table>
<tr><td colspan="3" align="center">Guidance and declaration of the manufactor – electromagnetic emission</td></tr>
<tr><td colspan="3">The audiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the audiometer should assure that it is used in such an environment.</td></tr>
<tr><td align="center">Emissions test</td><td align="center">Compliance</td><td align="center">Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td align="center">Group 1</td><td>The audiometer 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td align="center">Class B</td><td rowspan="3">The audiometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td align="center">Complies</td></tr>
<tr><td>Fluctuations/flicker emissions

IEC 61000-3-3</td><td align="center">Complies</td></tr>
</table>

Guidance and declaration of the manufactor – electromagnetic immunity			
The audiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the audiometer should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-5	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycle 70 % UT (30 % dip in UT) for 25 cycle <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycle 70 % UT (30 % dip in UT) for 25 cycle <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the audiometer requires continued operation during power mains interruptions, it is recommended that the audiometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC mains voltage prior to application of the test level.			

Guidance and declaration of the manufactor – electromagnetic immunity			
The audiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the audiometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the audiometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $$d = 1,17\sqrt{P}$$ $$d = 1,17\sqrt{P} \quad 80\,\text{MHz to } 800\,\text{MHz}$$ $$d = 2,33\sqrt{P} \quad 800\,\text{MHz to } 2,5\,\text{MHz}$$ 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:
NOTE 1 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.			