

# Instructions for Use

Oscilla® SM960-C Clinical Audiometer



Specifications are subject to change without notice  
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## 1 General Description

**OSCILLA® SM960-C CLINICAL MEMORY AUDIOMETER** is a two channel audiometer with click-free buttons and sound pressure level between -10 to 120 dB, equipped with three different types of masking, among others Narrow Band Masking, which means effective masking.

The device has a built-in memory of 17 audiograms, and the option of connection to PC or printer. The SM960-C is programmable featuring a range of useful tests including various automatic threshold tests.

Display: The device has four LCD displays, three of them for traditional use: Attenuator and frequency display. The fourth display, referred to as the VU display, is meant for different purposes, mainly as a VU meter and during standard use, as an intensity indicator of ex. level of talk back, sensitivity of the microphones etc.

### Function

This device can perform clinical hearing tests in order to determine the hearing threshold of a person. It supports pure-tone and speech and masking.

### Intended application

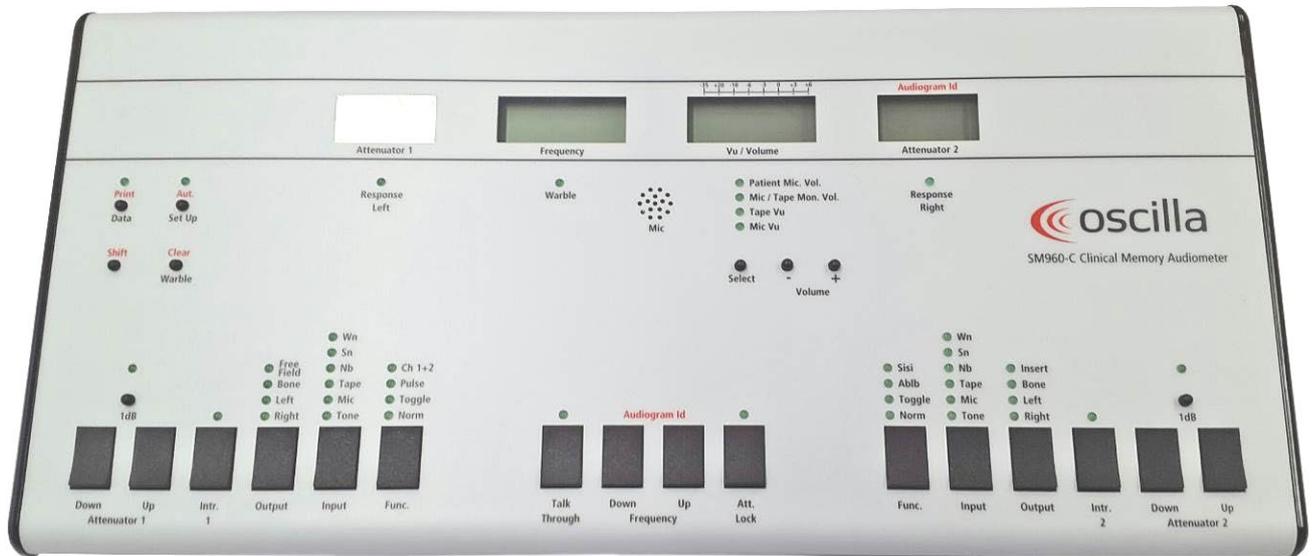
The intended application of the device is to be used within a diagnostic environment operated by ear doctors or likewise.

### Classification

Type 2 - Clinical Audiometer

For additional information refer to the technical specifications.

## 2 Description of front panel



**Attenuator 1** - The actual sound pressure in dB

**Frequency** - The actual frequency in Hz

**Vu/Volume** - VU meter and volume indicator for speech section

**Audiogram Identification** - The active audiogram

**Attenuator 2** - The sound pressure for channel 2

**Print** - Prints the active audiogram

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

**Aut.** - Starts 1 of 3 possible tests

**Setup** - Enters the setup function

**Shift** - Select the "RED" functions

**Clear** - Erase audiogram

**Warble** - This adds a frequency modulation to the tone, at a modulation frequency of 5 Hz

**Select** - Select the volume or sensitivity to adjust

**Volume** - Adjust the selected volume or sensitivity

**1 dB** - Change channel 1 attenuator to 1dB steps

**Attenuator 1** - Push the DOWN/UP to change channel 1 sound pressure

**Intr. 1** - Sends channel 1 signal to the patient

**Output** - Selects the output for channel 1

**Input** - Selects the input for channel 1

**Func.** - Selects the interrupter mode for channel 1

**Talk through** - Communicate with the patient

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

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

**Att. Lock** - Makes attenuator 2 follow channel 1

**Func.** - Selects the interrupter mode for channel 2

**Input** - Selects the input for channel 2

**Output** - Selects the output for channel 2

**Intr. 2** - Sends channel 2 signal to the patient

**Attenuator 2** - Push the DOWN/UP to change channel 2 sound pressure

**1 dB** - Change channel 2 attenuator to 1dB steps

### 3 Description of back panel

The earphones, bone conductor and patient answer button cables are mounted with jack plugs which are hooked up to the appropriate sockets on the back side of the device. The power adapter is inserted into the **POWER** socket at the back of the audiometer and plugged into an electrical outlet.

When the device is turned on, the version number is shown shortly, and the FREQUENCY display shows **1000 Hz**. If the devices' memory function is enabled in SETUP, the attenuator displays will show the last used sound levels, or, if memory is disabled, the attenuators will show 20.



**Insert earphone** - Mono insert phone

**Right** - Right earphone

**Left** - Left earphone

**Bone conductor** - Bone conductor

**Free Field** - Free field loudspeaker

**Operator headphones** - Operator headphone

**Line-in** - Tape or CD input

**Talkback Back microphone** - Patient microphone

**Patient responder** - Patient answer buttons

**RS-232** - Connection for PC

**Printer** - Connection for printer

I / O - Device on/off

**Power supply** - Power connector

## 4 Operation

If nothing else mentioned, the description will be for both channels.

### 4.1 Attenuators

By applying light pressure to the DOWN/UP buttons the attenuator steps up or down.

The actual sound level can be read in the two attenuator displays.



Normally the steps are 5 dB, but by means of the 1 dB button the steps can be changed to 1 dB. Held down for a while, the attenuators will repeat.

The attenuators are click free, meaning that you may change sound level while the attenuators are active, without losing the signal. However, there is a reservation to this: Say you start at 60 dB at 1000 Hz and hold down the interrupter while increasing the hearing level. In this case you will not be able to rise hearing level to 120 dB, without releasing the interrupter.

This has the following reason:

In order to decrease amplifier noise at low hearing levels, the signal to the earphones is attenuated by 20 dB by a resistor. When a high level is needed the resistor is shorted by a relay. This must happen while the earphone is silent, or a loud click will be heard. If the operator wants to increase hearing level near to maximum you need to release the interrupter, increase hearing level, and activate the interrupter again. The same applies when you want to decrease from a high to a low level - you also need to release the interrupter. In this case it will be at a sound level 25 dB lower than when increasing the level.

To be able to increase hearing level without the relay shortening, you must do the following:

**An example:** Anticipate that the attenuator is set on 40 dB; consequently the relay is switched off. You want to perform a manual tone decay test which moves over 20 dB and starts at 85 dB. Press the attenuator up to 105 dB (20 dB higher than the starting point) to ensure the relay will short. Now set the attenuator back to 85 dB where you want the test to start. Because of the 25 dB difference in the relay switching point, the relay will stay shorted. You may now activate the interrupter and move attenuator from 85 to 105 dB without any cut-offs.

#### The 1 dB button

By means of the 1 dB button you may select steps of 1 dB for the attenuator.



The light will shine as long as the 1 dB function is active.



As mentioned you may change hearing level while interrupters are active. When the 1 dB steps are active the change is made over 200 msec. instead of the usual 50 msec. making it impossible to hear any sharp increase of hearing level. Please note that the attenuator may be a little slow when running 1 dB, and the interrupter is activated.

#### 5 dB:

The 5 dB is performed over 50 msec. smooth as the 1 dB increase, e.g. for tone decay tests.

#### 4.2 Interrupter

With the interrupter button you activate the signal.



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



#### 4.3 Output selector

The output from the device is chosen by means of the output selector, which allows the choice of 5 different ways of output.



The lamps will indicate which output is selected.



For both channels you may choose:

- Right and left telephone
- Bone conductor

Channel 1:

- Free field

Channel 2:

- Insert phone

The output selector on channel 1 is operated in a special way: By pressing the button you choose between right and left earphone. To select bone conductor hold down SHIFT while activating the output selector. The bone indicator lamp will light up, whereas right or left indicator lamp will remain ON.

When you activate the output selector again without SHIFT, you toggle between right and left BONE CONDUCTOR. The reason is that the device will have to 'know' at which side the bone conductor is placed, to get the correct symbols on the screen and/or on the printout. This also means that the signal will always be through the same output, no matter if right or left bone conductor is chosen.

To choose FREE FIELD once again you should hold down the SHIFT while activating the output selector. The RIGHT-LEFT lights will turn off, as there is no option of right or left FREE FIELD.

#### 4.4 Input selector

By means of input selector you choose the input signal, which gives you 6 different options. May be used on both channels.



The lamps will indicate which input is selected.



TONE: Standard sinus tone for threshold test.

MIC: Build-in microphone meant for either speech audiometric or for communication to the patient.

TAPE: The connector marked with "TAPE" on the back of the device, for either tape-recorder or CD player.

NB: "Narrow Band" noise for masking.

SN: "Speech Noise" for masking.

WN: "White Noise" also for masking.

For technical reasons: If one channel is on TAPE you can not at the same time choose MIC on the opposite channel. When performing a standard threshold test channel 2 should be used for masking, if you want to store data.

#### 4.5 Function

By activating this button you determine how the interrupter reacts when activated.



The lamps will indicate which mode is selected.



You have the following possibilities on channel 1:

**MAN:**  
Standard operation.

**TOGGLE:**  
Interrupter toggles between active and inactive, when you push the button.

**PULSE:**  
Enables pulse tone - push the interrupter to present the pulse tone.

**CH1+CH2:**  
Simultaneously activation of both interrupters

You have the following possibilities on channel 2:

**MAN:**  
Standard operation.

**TOGGLE:**  
Interrupter toggles between active and inactive, when you push the button.

**ABLB:**  
Will initiate the ABLB test (see special description).

**SISI:**  
Will initiate the SISI test (see special description).

#### 4.6 Talk Through

The TALK THROUGH button provides a quick and easy way to communicate with the patient.



The light will shine as long as the button is held down.



When holding down the button the MIC signal will be transmitted to both earphones at the same time. Holding down the talk through button, you may adjust the sound pressure by means of the channel 1 attenuator. Actual sound level will be shown in Channel 1 display. The set level will be stored for later communication to the patient - therefore you do not have to adjust sound level for each communication during the test. Before using the talk through, make sure that the sensitivity of the microphone is on an appropriate level (see paragraph: Tape/Mic).

#### 4.7 Frequency

With the DOWN/UP buttons one of the 11 frequencies is selected.



Actual frequency will always be shown in frequency display.



Holding one of the buttons down the frequency is repeatedly changed to lower (DOWN) or higher (UP) values until the key is released (see **SETUP, MODE 1**).

#### 4.8 Attenuator lock

By means of the ATT LOCK, you may lock the channel 2 attenuator to the attenuator on channel 1, but you may still use channel 2 separately.



The lamp above the ATT. LOCK lights up when the lock function is active.



The lock is a one-way lock, which is valuable for masking.

#### 4.9 Tape/Mic

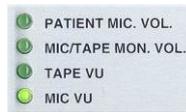
The device has a built-in memory for 17 audiograms. Each audiogram is identified by an ID number from 1 to 17.

This section in the device is used for setting the sensitivity of the build-in microphone as well as the Tape input, and in addition to set the volume for Talk Back and monitoring.

By means of SELECT you choose what you want to change.



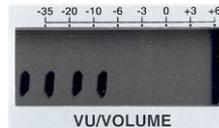
The lamps will show which setting will be adjusted.



VOLUME + or - for correction of the setting.



Actual setting is shown in the bottom part of the VU display.



Following options:

##### MIC VU

Sets sensitivity for the build-in microphone. Choose MIC on one of the input selectors, and adjust to appropriate deflection on the VU display.

##### TAPE VU

Sets sensitivity for TAPE input. Choose TAPE by means of one of the INPUT selectors, and adjust to appropriate deflection on the VU display.

##### MIC/TAPE MON. VOL.

Sets sound level in the operator's earphone. Select MIC or TAPE on one of the INPUT selectors, and then adjust to appropriate sound level.

##### PATIENT MIC. VOL.

Sets sound level of the patients microphone (talk back), should be adjusted while the patient is talking.

#### 4.10 Memory

The storage capacity is 17 audiograms each with an ID number between 1 and 17. Following test results will be stored:

- Sound level for LEFT and RIGHT earphone
- Sound level for LEFT and RIGHT bone conductor
- Sound level for FREE FIELD loudspeaker
- Sound level for masking together with earphone
- Sound level for masking together with bone conductor
- SISI test scores for LEFT and RIGHT earphone

The channel 1 attenuator display will show the stored value for the chosen frequency and output. The channel 2 attenuator will show the masking level, used by either earphone or bone conductor.

#### 4.11 Audiogram ID

Use the SHIFT + ID DOWN/UP buttons, to go through the audiograms to find one specific test.



The number is shown in the ID display, which is the same as the channel 2 attenuator.



#### 4.12 Shift

All function written in red on the front panel is activated by using the SHIFT button.



In addition you have the following possibilities:

- Shows actual ID number when held down.
- Changes "direction" of the various features, as they are so called wrap-around. If you hold down the SHIFT and press SELECT, you will go back-wards instead of forwards, which is practical instead of having to go through all functions to get the one you want. This options goes for the INPUT selectors as well as the FUNCTION selector and the channel 2 OUTPUT selector.

#### 4.13 Print

Use the SHIFT + PRINT buttons 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 a couple of seconds.

For selection of printer type see special paragraph in setup.

#### 4.14 Data

A push on the DATA button causes the device to transmit the test results stored in the active audiogram to a connected PC. Transmission time is 0.2 seconds.



#### 4.15 Automatic hearing tests

The program contains three different automatic tests. To choose between the three types of test, enter the SETUP function, and change mode 5. See the SETUP section for more information.

Use the SHIFT + AUT. buttons to start 1 of 3 possible tests



#### The three automatic tests

##### 20 dB test

This performs a quick automatic screening test with fixed sound pressure of 20 dB. The test chooses 1000 Hz, the sound pressure will be set to 20 dB and increase in steps of 5 dB until the patient responds. Immediately hereafter, the frequency changes and the sound pressure starts at 20 dB again.

##### 20 dB RANDOM test

This is an extremely useful automatic test. It starts by selecting 1000 Hz, first at the left, then the right ear. It then randomly selects frequency and channel in the rest of the test until all frequencies has been tested at both channels, and thereby makes it hard for the patient to 'cheat'. In both the 20 dB and the 20 dB random test there is a slight variation in the duration of the tones presented, and the pause between the tones. These variations are also chosen randomly.

#### When a 20 dB test is finished

1. If all frequencies are answered at 20dB, you will hear **1 BEEP** after the test, to indicate that all frequencies have been heard.
2. If one or more frequencies was not responded to at 20 db, you will hear **3 BEEPS** and the AUT lamp will flash, telling you that not all frequencies have been heard. Press the **AUT.** button to stop the flashing, and go through the frequencies to see which of them was not heard. All frequencies that displays "20" was heard at 20 dB, and other levels tells you at what level the patient responded. If a frequency was not responded to even at 80 dB, the attenuator display will flash when this frequency is selected.

### **Variable automatic 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 to the tone, the intensity will increase 10 dB each time the tone is presented, until the patient signal button is pressed. For each response the intensity is reduced 5 dB and conversely increased 5 dB when there is no answer.

When the software program has accepted the answer, the frequency is automatically changed to the next level and the procedure is repeated until all frequencies have been tested for both the left and the right ear.

When the test is completed, the audiometer gives a beep. If some of the frequencies have not been heard, the lamp above the **AUT** button will flash. Press the **AUT** button and check the frequencies. The attenuator display will flash for the frequencies not heard. It is possible to conduct a manual test for those frequencies.

**Please note** that for safety reasons the maximum intensity is fixed at 80 dB during the automatic test.

Please note that frequencies left out will not be included in the automatic threshold tests.

### **SISI test: (Short Increment Sensitivity Index)**

In addition to the three automatic tests the SM960-C is equipped with an automatic SISI test. The test has three pulse amplitudes it operates at, which can be selected while it runs. The three amplitude modes are as follows:

#### **5dB:**

The test starts in this mode, and is intended only for familiarizing the patient with the test method. The patient responses and pulses are not counted in this 5dB mode, and the mode continues until the next mode is selected, or the test is terminated.

#### **2dB:**

This mode presents 20 pulses of 2dB increments before it continues to the 1dB mode. It counts the patient responses, but does not store the count in memory. If the patient has responded to every pulse, or did not respond to any of them after 10 pulses, the test will continue to 1dB mode.

#### **1dB:**

This presents 20 pulses of 1dB increments. It also counts the patient responses, but this time it is stored in memory as the test result in percent. This happens when 20 pulses has been presented, or if there was either 0% or 100% responses to the first 10 pulses.

The patient is allowed to respond within a period of 3 seconds after each pulse. The response lamps will always show the responses, but they are not counted up if they occur later than 3 seconds after the pulse.

While the test is running, the frequency display is used for pulse counting and the VU display is used for patient response counting. The channel 2 attenuator display shows the sound level and the pulse increment, when it happens every 5 seconds.

### **Using the test:**

The test is controlled on the audiometer's channel 2. When the FUNCTION setting is set to SISI, then the VU will display changes to show the test results. Also the attenuator to channel 2 is preset to a level 20dB higher than channel 1. This is just for convenience, as a SISI test is usually performed at 20dB higher level than the patient's hearing threshold. The level can be changed freely with the attenuator buttons before the test is started.

After setting the INPUT to TONE and the OUTPUT and FREQUENCY to the desired channel and frequency, the test is started by pressing the INTERRUPTER. A brief "SISI TEST" is displayed, followed by "5 dB", to indicate that the 5dB amplitude mode is running. While the test runs, the ATTENUATOR keys are used to change the amplitude mode. UP

selects the next mode and DOWN selects the previous. The mode is displayed briefly when changed, and the pulse and response counters are reset. The test can be terminated manually with the interrupter.

**The memory:**

Test results are stored in every audiogram, and for every frequency as a percent figure. There is memory for the left and the right earphone. It is possible to run a SISI test using the bone conductor and the mono insert phone too, but the results are not stored separately, they use the same memory as left and right. When SISI is selected on the channel 2 function selector, the VU display recalls the stored test results when the frequency and channel is changed. These results may be erased by pressing CLEAR (with shift). This only clears the single result that corresponds to the currently selected frequency and channel. When a printout is done, all the SISI test results are shown in a table below the audiogram.

**ABLB: (Alternate Bilateral Loudness Balance)**

ABLB involves both channels by activating the two interrupters twice on each channel, in the following way:

INPUT and OUTPUT is selected for both channels. The two attenuators are set on the wanted soundpressure. On the channel 2 FUNCTION choose ABLB.

To start the test: press the channel 2 interrupter.

Duration of tone as well as the pause in between may be programmed individually, SETUP no. 7.

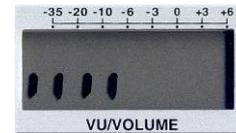
**4.16 Setup**

You may individually change the basic function of the SM960-C by programming one or more of the 11 SETUP functions.

The setup function is entered by pressing the SETUP button.



Two short beeps will be heard, and the VU display will show "SETUP" briefly.



To change between each SETUP mode press the channel 2 attenuator, and selected mode is shown in the channel 2 attenuators display as a figure between 1 and 11.

**Mode 1: Frequency selecting**

FRE  
FREQUENCY

125-8000  
VU/VOLUME

**AUDIOGRAM ID**  
1  
**ATTENUATOR 2**

In this mode you may leave out one or more frequencies. Select the frequency with the frequency buttons, and use the channel 1 attenuator to include or leave out the selected frequency. The VU display says ON when the frequency is included and OFF if it is left out.

**Mode 2: Tone length**

LENG  
FREQUENCY

OFF  
VU/VOLUME

**AUDIOGRAM ID**  
2  
**ATTENUATOR 2**

The duration of the ON-TIME of the interrupter. To change the ON-TIME, use the channel 1 attenuator. The selected length is shown in the VU display. Options are: OFF, 0.5, 1.0, or 1.5 second.

If one of the three numbers are programmed the tone will last for this period, no matter how long you press the interrupter. If the display says OFF, the interrupter is operated manually.

**Mode 3: Recall mode**

RCAL  
FREQUENCY

ON  
VU/VOLUME

AUDIOGRAM ID  
3  
ATTENUATOR 2

Connects or disconnects the storage function. To include or exclude storage capacity press the channel 1 attenuator. The VU display will show ON or OFF for connected or disconnected. If the memory function is disconnected the device will operate as a standard manual audiometer, and printer, serial port and automatic tests are not accessible. A special setting here is "AUTO". If this is selected, the audiometer will transmit the audiogram to the serial port each time the channel 1 attenuator is changed. It also transmits when the ID number is changed, and when an automatic test is run, each time the frequency is changed. Note that the channel 1 attenuator will be acting a bit slow while this "AUTO" transmit feature is enabled.

#### Mode 4: Reset

RSET  
FREQUENCY

OFF  
VU/VOLUME

AUDIOGRAM ID  
4  
ATTENUATOR 2

Connects or disconnects the RESET option. The programming of this feature is done by means of the channel 1 attenuator, and the VU display says ON or OFF. When reset is ON the tone is disconnected when you change frequency or channel.

#### Mode 5: Auto mode

PRNT  
FREQUENCY

HP  
VU/VOLUME

AUDIOGRAM ID  
5  
ATTENUATOR 2

By means of programming mode 5 you may choose the type of printer which is connected to the device. Selection is made by pressing the channel 1 attenuator. The selected printer type is shown in VU display. Options are:

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 ProPrinters. Some other printers can emulate a ProPrinter.

HP: Used with HP DeskJet and laser printers. Many other laser printers may emulate HP lasers, and will work with this setting.

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 printers' manual for information about what the printer can emulate.

#### Mode 6: Auto mode

AUTO  
FREQUENCY

RND  
VU/VOLUME

AUDIOGRAM ID  
6  
ATTENUATOR 2

Selecting one of the three automatic tests. In the VU display is shown which of the three automatic tests is selected: 20dB, Random 20dB (RND) or variable (VARI) and the choice is made by means of the attenuator 1 buttons. Please note that any frequencies left out as a result of programming mode 1, will also be skipped over in the AUTO test.

#### Mode 7: ABLB test timing

ON

0.6

AUDIOGRAM ID  
7

**FREQUENCY**

**VU/VOLUME**

**MASKING LEVEL dB**

Programming of ON and PAUSE time for the ABLB test. Select between ON and PAUSE time with the channel 1 interrupter button. The FREQUENCY display will show ON = ON TIME or PAUS = PAUSE. Then use the channel 1 attenuator to select a time between 0.1 and 1 second.

**Mode 8: Carriage return on/off**

**FREQUENCY**

**VU/VOLUME**

**AUDIOGRAM ID**  
  
**MASKING LEVEL dB**

Some printers may not print a full audiogram, or make blank horizontal stripes. This is usually caused by either sending a carriage return to a printer programmed to automatically return the printhead at a new line (blank stripes occur), or by sending no carriage return to a printer that expects it (only one line is printed). By means of the channel 1 attenuators you may connect or disconnect carriage return. The VU display will say ON or OFF for connected or disconnected. This setting has no effect if the printertype (mode 5) is set to HP.

**Mode 9: Bone audiogram on/off**

**FREQUENCY**

**VU/VOLUME**

**AUDIOGRAM ID**  
  
**MASKING LEVEL dB**

On the printout you may choose to have the bone test results printed in a separate audiogram frame, or have both air and bone printed in the same frame. By selecting ON in this mode, a separate bone audiogram is printed. If this mode is on, and no air tests have been performed, only a single audiogram is printed, containing the bone test results. Also, if no bone results exist in memory, no extra audiogram is printed.

**Mode 10: Identification on/off**

**FREQUENCY**

**VU/VOLUME**

**AUDIOGRAM ID**  
  
**MASKING LEVEL dB**

This mode is for enabling or disabling the identification sent to the PC when turning on the device. This must be turned on for use with the AudioConsole program. If you encounter problems when the device is used to transmit data to other programs, try turning ID off.

**Mode 11: Select supra phones or inserts phones calibration**

**FREQUENCY**

**VU/VOLUME**

**AUDIOGRAM ID**  
  
**MASKING LEVEL dB**

This mode selects between supra aural earphones or insert phones. The selected type of phones is displayed briefly when the device is turned on. Select "PHON" if supra aural phones (TDH 39) are used, and "INST" if insert phones (usually Eartone 3A or 5A) are used. The selection affects the calibration and the maximum output level.

**Mode 12:**

**FREQUENCY**

**VU/VOLUME**

**AUDIOGRAM ID**  
  
**MASKING LEVEL dB**

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 programming**

To exit the SETUP, press the SETUP button again. The software program stores the selected settings, 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: OFF.  
Mode 5: HP.  
Mode 6: RND.  
Mode 7: ON TIME: 0.6 seconds. PAUSE: 0.3 seconds.  
Mode 8: ON.  
Mode 9: OFF  
Mode 10: ON  
Mode 11: PHON  
Mode 12 :PARA

## 5 Technical specifications

**Standards compliance:** EN 60645-1: 1996  
 EN 60601-1:1990 + A1:1993 + A2: 1995 + A13:1996  
 EN 60601-1-2:2002

**Classification:** Group 1, class A 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, B-71 bone (calibrated via mastoid)

**Power Supply:** 18 VAC, 800mA max.

**Adaptor:** Primary: 230 VAC, 50/60 Hz, 170mA max.  
 Secondary: 18 VAC, 20 VA,  $\pm 10\%$

### 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: 389 (W) x 180 (D) x 55 (H) mm

**Parallel port:** Automatic printout of complete audiogram, 60/72 dpi.

**Serial port:** Computer data transmission (RS-232) to patient file. 9600 baud.

**Warm-up time:** < 10 minutes

**Included parts:** audiometer, Peltor H7A headphones with TDH-39, response button, bone conductor, power supply, user manual and calibration certificate

**Accessories:** carrying bag, serial cable, printer cable, AudioConsole software

## Measurement specifications

**Measurement Method** Manual and automatic threshold test **with** storage of data.

## Measurement Range

Maximum Intensities:

Frequency	Air		Bone	
	Pure Tone	Narrow Band	Pure Tone	Narrow Band
125 Hz	80 dB	70 dB	10 dB	0 dB
250 Hz	100 dB	90 dB	40 dB	30 dB
500 Hz	120 dB	110 dB	70 dB	60 dB
750 Hz	120 dB	110 dB	70 dB	60 dB
1000 Hz	120 dB	110 dB	70 dB	60 dB
1500 Hz	120 dB	110 dB	70 dB	60 dB
2000 Hz	120 dB	110 dB	70 dB	60 dB
3000 Hz	120 dB	110 dB	70 dB	60 dB
4000 Hz	120 dB	110 dB	60 dB	50 dB
6000 Hz	110 dB	100 dB	50 dB	40 dB
8000 Hz	100 dB	90 dB	40 dB	30 dB

White Noise: 110 dB (same for all frequencies)

Speech Noise: 115 dB (same for all frequencies)

## Measurement Accuracy

Tolerance frequency:

$\pm 1 \%$ .

In/output impedance:

Left / Right channel ~ 4,7- 144,7 ohm, Patient response ~ 1 Kohm

Distortion speaker:

TDH-39: < 1 %, 4. and higher harmonic + sub harmonic < 0,3 %.

Single signal channel:

Air conductor:

$\pm 4$  dB (125 Hz – 4 kHz)

$\pm 5$  dB (6 kHz – 8 kHz)

Bone conductor:

$\pm 4$  dB (125 Hz – 4 kHz)

$\pm 5$  dB (6 kHz – 8 kHz)

Multiple signal channels:

$\pm 1$  dB (125 Hz – 4 kHz)

$\pm 2$  dB (6 kHz – 8 kHz)

## Measurement Durations and Times

Data transmission:

RS-232C protocol

Storage space:

17 audiograms

## **6 Warning and safety notices**

### **6.1 Warning**

- No modifications of the device nor accessories are allowed.

### **6.2 Safety notices**

- Place the audiometer at least 1 meter from the patient.
- Always use accessories supplied by the manufacturer.

### **6.3 Maintenance & calibration**

It is recommended to have the device calibrated every other year by Inmedico A/S or a technician authorised by Inmedico A/S. Contact your Oscilla® distributor for further information regarding calibration.

### **6.4 Cleaning**

The patient responder and patient headset need to be cleaned on a regular basis for hygienic reasons. Both can be cleaned with disinfecting wipes or a cloth wrung in lukewarm water with soap or dishwashing liquid. Disconnect the parts from the audiometer before cleaning. Ensure that they are dry before re-connecting.

### **6.5 Shipping recommendations**

The audiometer should be packed in a manner, which prevents it from being damaged during transportation. For example, the device can be packed in bubble wrap and shipped in an ordinary cardboard box – or similar.

### **6.6 Disposal**

According to Directive 2012/19/EU (WEEE) and local regulations, the device including accessories can be disposed of as normal electronic waste.

## 7 Symbols



Manufacturer



Serial number



Catalogue/product number



Caution



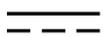
Follow instruction for use



Consult instruction for use



Type B applied part



Direct current



Medical device according to Medical Device Directive 93/42/EEC.



Humidity limitation



Atmospheric pressure limitation



Temperature limit



The device must be recycled or disposed of in a proper manner in accordance with the WEEE Directive 2012/19/EU.

## 8 EMC

- SM960-C is an electro-medical device and is therefore subject to special safety precautions. For this reason, the installation and operating instructions provided in this document must be followed closely.
- Portable and mobile high-frequency communication devices, such as mobile phones, may interfere with the functioning of SM960-C.

### Guidance and manufacturer's declaration – electromagnetic emission

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	This device 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 A	The device is suitable for use in all establishments other than domestic and those connected to a low voltage power supply network which supplies buildings used for domestic purposes. Class A covers devices for usage in all establishments other than domestic and that are not directly connected to a low voltage power supply network, which supplies domestic environment.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

### Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 6$ kV contact $\pm 8$ kV air	$\pm 6$ kV contact $\pm 8$ 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	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1$ kV differential mode $\pm 2$ kV common mode	$\pm 1$ kV differential mode $\pm 2$ 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 requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.
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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

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**Recommended separation distance**

$$d = 1.17 \sqrt{P}$$

$$d = 1.17 \sqrt{P} \text{ 80 MHz to 800 MHz}$$

$$d = 1.23 \sqrt{P} \text{ 800 MHz to 2.5 MHz}$$

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, <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup>. Interference may occur in the vicinity of equipment marked with the following

symbol: 

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**Note:**

- $U_T$  is the AC mains voltage prior to application of the test level.
  - At 80 MHz and 800 MHz, the higher frequency range applies.
  - 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 the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## 9 Responsibility of the manufacturer

The manufacturer is only responsible for the safety, reliability and performance of the device if:

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by the device manufacturer or by personnel authorized by the manufacturer.
- The electrical installation, to which the device is connected, complies with EN/IEC requirements.
- The device is used in accordance with the instructions for use.

The manufacturer reserves the right to waive all responsibility for the operating safety, reliability and performance of devices serviced or repaired by unauthorised parties.

Service manual may be supplied upon request.

## 10 Manufacturer

Inmedico A/S  
Johann Gutenbergs Vej 3  
DK-8200 Aarhus N  
Denmark



+45 86 74 26 22



[www.oscillahearing.com](http://www.oscillahearing.com)



[support@oscillahearing.com](mailto:support@oscillahearing.com)

