



MEDIROLL Medico Technical Ltd.
H-4025 DEBRECEN Postakert u. 10.
Tel.:(52) 533-737, 533-738 Fax.: (52) 534-446

Sa-52

Portable screening/diagnostic audiometer

User manual



Serial number:

CE 1979

WARNING! The apparatus is operated by technical system and a computer program under legal protection of copyright.

The computer program remains in the possession of MEDIROLL Co. recording, changing, lending of the program and its usage otherwise without the written permission of MEDIROLL is forbidden.

CONTENTS

	<i>Page</i>
I. INTRODUCTION	
1.1./ Function	4
1.2./ Safety instructions	4
Descriptions of the safety instructions	4
II. INSTRUCTIONS FOR INSTALLATION AND MAINTENANCE	
2.1./ Unpacking, installation, putting into operation	5
2.2./ Controls and terminals	6
2.3./ Switching on, setting of controls into basic operation	7
2.4./ Trouble free operation	8
2.5./ Operation, signs of malfunction	8
III. OPERATION	
3.1./ General instructions for operation	9
3.2./ Patient threshold determination	10
3.3./ Bone conduction threshold determination	10
3.4./ Masking	11
3.5. / Using menu	11
3.5.1./ Delete of actual measuring	12
3.5.2./ Saving, recalling and delete data from the memory	12
3.5.3./ Modification of the settings	12
a./ Adjusting the rhythm of pulsed sound	13
b./ Frequency selection	13
c./ Language selection	13
d./ Setting „Reverse” mode	14
e./ Calibration	14
3.6./ Signs of malfunction	14
IV. INSTALLATION AND SERVICING INSTRUCTION	
4.1./ Marks, symbols	15
4.2./ Maintenance, repair	15
4.3./ Technical data	16
4.4./ Acoustic data	17
4.5./ Accessories	18
4.6./ Packing, delivery	18
4.7./ Storage	19
4.8./ Warranty	19
4.9./ Supplement	19

INTRODUCTION

1.1./ FUNCTION

The portable audiometer, type **Sa-52** is suitable for the measurement of air and bone conduction hearing loss, recording audiograms. Hearing threshold information may be recorded with the use of the regular process (according to ISO 8253-1), and may be recalled and stored in the memory even when the audiometer is switched off.

The audiometer may be connected to a PC and data processing is possible (e.g. printing). The audiometer — like all the other audiometers — may primary be used in a silent cabin (an audiometric booth) but the use of the noise protected headphones gives correct measurement data in a low level of environmental noise as well.

The measurement of the audiometer can be recalled on PC, saved and printed with the Maudio program.

1.2./ SAFETY INSTRUCTIONS

The portable audiometer type Sa-52 belongs to patient safety class II. (interpreted with the mains adapter) and double insulated between „patient parts” and the mains. Putting into operation doesn't require any precautionary measure.

ATTENTION!

Check up the mains voltage before connecting to the mains.

Connecting the apparatus to protective earth is strictly prohibited!

REQUIREMENTS REGARDING SAFE OPERATION

- *The apparatus may only be used with the attached adapter!*
- **For disconnecting the apparatus from the mains pull-out the mains adapter from the mains socket!**
- **Dismantling the mains adapter cover is dangerous and therefore *PROHIBITED!***
- **Maintenance and calibration may only be done by an expert in electrics and audiometers!**
- **Connecting any accessories except the standard ones is strictly prohibited!**
- **No liquid can fall into the apparatus or any of the accessories when cleaning or disinfecting!**

II. INSTRUCTIONS FOR INSTALLATION

2.1./ UNPACKING, INSTALLATION, PUTTING INTO OPERATION

In case of delivered or stored in a cool environment the apparatus must be kept in the original package until its warm-up to room-temperature.

The apparatus is packed in one case along with all its accessories. After the unpacking check the accessories according to point **4.5**. In case of damage or faulty accessories inform the manufacturer or its representative by stating the product number as well.

The primary condition for installation and operation is the silent environment.

The following table contains the permissible noise levels measured in the patient's environment that do not disturb accurate pure sound hearing threshold determination yet with an uncovered ear during examination. The alleviation of the headphones of the apparatus Sa-52 is in the second and the third row. In the fourth and the fifth row there is the highest voice level of the measuring.

An average attenuation of Sa-52 headphone completed with a Pelton noise excluder are in **line 2**. The permissible noise levels with a Pelton noise excluder are in **line 3**.

Test frequency	Hz	125	250	500	1K	2K	4K	8K
Permissible noise with uncovered ear (SPL) *	dB	36	14	11	8	4	4	9
TELEPHONICS TDH-39 attenuation	dB	11	13	22	34	32	35	34
Permissible noise with a Pelton noise excluder (SPL)	dB	47	27	33	42	36	39	43

*: according to ISO 8253-1, (1/3 octave)

Generally the **module system silent cabins** satisfy these requirements of the place if the place of setting is not especially noisy.

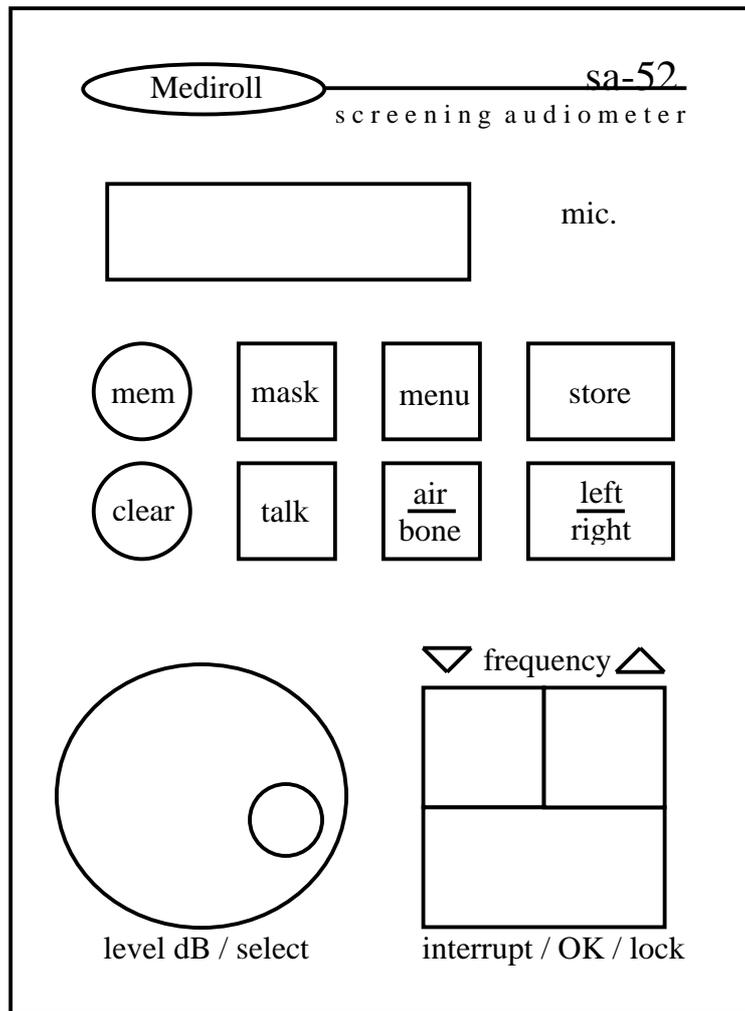
If the apparatus is installed in a silent cabin a suitable installation of the accessories is of major importance. Be sure that during the installation neither of the cables touches the apparatus or the cabin. Do not contract cables which appear to be on the same potential (e.g.: the cold points of the headphones).

Under normal conditions silent cabins are not in use. This time try to make sure that the environment has the lowest noise level possible. The test results can differ from the result measured in a silent cabin from 5 to 15 dB. (Mainly at the low frequencies of 250 and 500 Hz.)

The apparatus doesn't require special arrangements when installed and after completing the process described in point 2.41 it is ready for operating. No further warm-up-time is required.

2.2./ CONTROLS AND TERMINALS

Controls and terminals of Sa-52 are illustrated below:

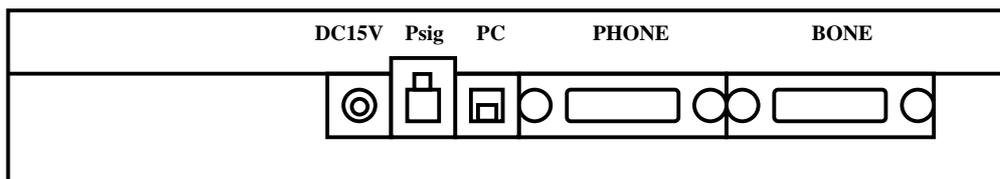


2.figure

Functions of the buttons:

- | | |
|---------------------|---|
| - level dB / select | -Sound level/menu select knob |
| - interrupt/OK/lock | -Tone interrupted/menu OK/lock on-off |
| - frequency | -Increasing/ decreasing the frequency |
| - mem | -Functions of memory |
| - clear | -Delete data |
| - mask | -Mask setting |
| - talk | -Press it to talk to the patient |
| - menu | -Entering menu |
| - air/bone | -Change between air and bone conduction |
| - store | -To store the threshold |
| - left/right | -Change between left and right |

Terminals at the back side of the audiometer are shown on Fig. 3.



3.fig.

Functions of the terminals:

DC15V	Mains adapter terminal
Psig.	Patient response switch terminal
PC	PC terminal (not USB)
PHONE	Headphones terminal
BONE	Bone (vibrator) terminal

The plugs are „one-way to connect” to the terminals. The headphone plug can be fixed to the terminal by two screws.

When connecting the plugs to the terminals always make sure it is the right way. Forcing the plugs is prohibited.

2.3./ SWITCHING ON, SETTING OF CONTROLS INTO BASIC OPERATION

The apparatus doesn't have mains switch. Connecting the mains adapter and headphone to the apparatus then the adapter to the wall socket the equipment will be automatically switched on.

For switching off the apparatus pull out the mains adapter from the wall socket.

Attention!!

The order of the connecting is important, and if the operator deflects from it, than the apparatus will work, but the voice levels won't be authentic.

When the audiometer is switched on it is set in basic mode and displayed:

Mediroll Ltd. v1.0

Then the following text is displayed in 1 sec

Sa52 screening audiometer

This text will be seen for 1 sec. Then the following text appears automatically.

Air 1	1000Hz
Tone Left	40dB

This is the **test menupoint**. In the manual the description of the operation always starts from here.

2.4./ TROUBLE FREE OPERATION

The process detailed in point 2.4. may also serve to check safe operation. Although calibration is properly ensured by a measuring instrument only, an expert with the necessary experience will be able to detect faults by listening.

2.5./ OPERATION, SIGNS OF MALFUNCTION

The apparatus is stable for continuous operation, no over load is possible. malfunction during operation may be identified on the basis of point 3.6.

Incorrect installation may be the cause of incorrect level attenuation. It can be caused by the unproper extension of cables (eg. in the case of connections to the silent cabin). During the installation of these see instructions in point 2.1.

ATTENTION! Using a mobile telephone when operating the apparatus is strictly prohibited!

III. OPERATION

3.1./ GENERAL INSTRUCTIONS FOR OPERATION

In the following you can read about the handling of the apparatus. On the left there's the instruction, and on the right there are the signs which can be read on the screen during the operations. Of course these signs will change with the examination. In the examples we proceed from the base situation after turning on.

After turning on – after doing the internal tests- the audiometer will be in a base mode and in the left headphone you will hear a voice of 1000 Hz, of 40 dB.

Air 1	1000Hz
Tone Left	40dB

This is the control to set the sound level in the headphone. **Turning the knob** clockwise the sound level will increase with steps of 5 dB. Turning the knob anticlockwise the sound will decrease with steps of 10 dB. The volume in the middle frequencies can be changed between -10dB and 100dB.

Air 1	1000Hz
Tone Left	45dB

Air 1	1000Hz
Tone Left	35dB

Change frequency. Press the **frequency button** on the left and the audiometer will decrease the value of the frequency, press the other one on the right you can increase it. The frequency can be changed between 250 Hz and 8000 Hz in each octave.

Air 1	500Hz
Tone Left	35dB

Air 1	2000Hz
Tone Left	35dB

To examine the other ear, press the **left/right** button, so the apparatus will give the voice to the other ear. On the screen the operator will see in which ear the voice can be heard.

Air 1	2000Hz
Tone Right	35dB

If you want to be sure that the patient really hears the voice, and not only pretend it, press the **interrupt** button and hold it. Until you keep it pressed there's no voice in the headphone.

Air 1	2000Hz
Mute Right	35dB

Connect the response switch to the audiometer. You can follow the patient's signals on the screen.

Air 1 Pac	2000Hz
Tone Right	35dB

If the patient does not understand the task, you can talk to the patient without putting off the headphone. Press the **talk** button, and hold it. The connection is signed by this sign on the screen: **mic**. The voice of the operator appears in both headphones. You can settle the intensity with the button **level dB/select**.

Air 1	2000Hz
Tone Mic.	35dB

3.2. Recording the air conduction data

-Put the headphone onto the head of the patient.

-The audiometer in the basic situation makes a voice of 1000 Hz and 40 dB. The patients generally can hear it, but if it is necessary we can increase the volume. We explain the patient that he/she has to press the patient response switch as soon as he/she hears the voice, but he/she does not hear it, the patient has to release it. Change the volume, and be sure that the patient understands the task.

-**Start the measuring with 1000 Hz.** Control the volume with 30 dB under the expected hearing threshold. The standard method (IEC8253) is the following:

-**Increase the level** in every **5 dB**, until the patient hears it, and signs the voice.

-**Decrease the level** with **10 dB** (the patient does not have to sign the voice) and increase it with 5 dB again. If the patient signs again at the same level that he/she did before than the apparatus automatically accepts it as a threshold.

-If the patient signs at a different level continue the measuring until we get two signs at the same level, which level is accepted as a threshold.

-If this level is correct, the operator does not have to do anything else, than change the frequency.

-If the operator does not accept that level, settle the right correct (in his opinion) and record it with the **store** button and after it change the following frequency. If he wants to delete this threshold settle the volume to this threshold and press the **store** button.

-The regular frequency order is from 1000 Hz to 8000 Hz, and again from 1000 Hz to 250 Hz. (the second measuring in 1000 Hz is a control measuring). Repeat this measuring order in the right ear as well.

-For the audiometer the only accepted patient sign is, which is come when the voice appears. The audiometer does not accept the sign which is given in the mute.

Important! All the time we switch a measured frequency the audiometer shows the measured threshold value (and this level is given to the headphone). If there's no recorded threshold level, the last value will appear on the screen.

3.3. Recording bone conduction threshold data

Connect the bone conduction headphone (vibrator) to the “bone” terminal of the audiometer. Switch the audiometer on.

Press the **air/ bone** button. The audiometer changes to bone conduction headphone. Press this button again, and the apparatus will be again air conducted.

Bon 1	1000Hz
Tone Left	40dB

Put the bone conducted headphone on the back of the ear (mastoid). The measuring has to be done like the air conduction one. The bone conducted threshold values are signed by another symbol (“>” left, “<” right ear).

3.4. Masking

This function inhibits the crosstalk. In normal case the crosstalk is around 40- 60 dB. It means the patient hears a voice of 50 dB given into one of the ears and with 10 dB in the other one. The big difference between the thresholds of the 2 ears may cause confusion. That's why you may need the masking. In case of the bone conduction measuring the hearing difference is a lot smaller: 0-10dB. Because of the little difference in case of the bone conduction measuring the masking is almost every time needed. The right level of the masking is important. If it's too low we do not inhibit the crosstalk, and if it's too high the covering voice may cause crosstalk. It lifts the threshold of the examined ear and creates an overmasking.

To settle the masking function, press and hold the button **mask**. On the screen you will see the parameters of the masking.

Mask type:off
Lock:off 40dB

With the **frequency buttons** you can settle the type of the masking noise and with it you can turn on/off the masking. You can choose between two types of noises: NBN and WN.

Mask type:NBN
Lock:off 40dB

With the volume button you can settle the level if the masking voice between -10 dB and 80 dB. Press the button **interrupt/ OK/ lock** to switch on/off the lock. The lock is needed if the operator wants to change together the level of the pure tone and the masking tone. In case of locking during the changing of the level of the pure tone the difference between the pure tone and the masking tone is the same. To settle the difference, settle a level on the pure tone (e.g. 50dB) and press the **mask** button to settle the mask level (e.g. 25dB). In this case the level of the pure tone in the bone conducted headphone can be settled from 5dB to 60dB. The minimum level is changed to 5dB instead of -10dB, because the apparatus can not decrease any more the level of the masking noise.

Mask type:NBN
Lock:on 40dB

Bon 1 [] 1000Hz
Tone Left 50dB

Mask type:NBN
Lock:on 25dB

Important! The lowest and the highest limits of the volume are shown by the sparkling square next to the dB value.

Bon 1 [] 1000Hz
Tone Left 5 ■ B

3.5.Menu point selection

In the audiometer the functions and settings are controlled by a menu system. A sparkling square shows the chosen menu points on the screen. The square can be moved by the volume controller or the frequency- setting button. They can be selected by the button **OK**.

3.5.1.Delete measuring

Before the measuring of a new patient, delete the previous measuring data so you will not have confusing data on the screen. To delete actual measuring press the **clear** button. The audiometer calls the attention of the operator that the actual patient data may be lost. Turning the knob to **No**, measuring data will stay alive. Turning knob to **Yes**, data will be deleted. The data stored in the memory will not be changed.

<p>Are you sure? Yes No</p>
--

3.5.2.Save, recall, and delete data from the memory

Pressing the memory button data will be stored in the actual memory position. The apparatus saves the data when you release the **mem** button into the memory position which can be seen on the screen. The empty threshold table is not saved. If you would like to save the measuring results to another memory position, hold the **mem** button and choose a new memory position with level knob. After the data saving the apparatus will be automatically in the data-reading menu point and it will turn to the next memory position. During the data - reading the apparatus will sign if there's stored data in the memory position, and from which measuring it comes. With the knob the operator can select a new position. Press the **OK** button and the apparatus recalls the data from the memory and shows it on the screen.

<p>Air14 x 1000Hz Tone Left 40dB</p>
--

<p>Data save: 14</p>

<p>Data read: 15 air</p>

The data can be deleted from the memory, if you don't need them anymore. To delete them enter the memory. In the data-reading menu point press the button **clear**. The apparatus will turn to the data-deleting menu point. Next to the memory position on the screen can be seen, if the memory contains valid data on this position. To delete the memory position, press the button **OK**. The apparatus will ask that you are sure about the deleting. Press Yes.

<p>Air15 x 1000Hz Tone Left 25dB</p>
--

<p>Data clear: 15 air</p>

<p>Are you sure? Yes No</p>
--

You can quit from the deleting menu by pressing the button **mem**.

3.5.3/ Modifying the settings

The other functions can be changed by pressing the **menu** button. On the screen will appear the settings menu points. From this menu you can escape by pressing the **menu** button again or by clicking to this sign:←. The apparatus will remember the settings after you escape. Between the menu points you can choose by moving the sparkling square. You can enter to the selected menu point by pressing the button **OK**.

Pulse Freq.Lang.	
Rev. Cal.	←

a, Pulsed tone

In basic situation the audiometer gives continues tone. After a certain time the continuous sound can be heard difficultly, that's why the apparatus has a pulsed tone mode, which means that the patient can hear the voice with pauses. To settle it, select the **pulse** menu point in the setting menu. Choose the right rhythm and press the **OK** button.

Pulsed sound
1/2s 1s 2s No

b, Setting frequency:

Basically the apparatus uses 7 frequencies. If there's any frequency that is not used, you can turn it off in this menu point. In the setting menu choose the **Freq.** menu point. In the appearing menu select the frequency with the level knob or with the frequency buttons (e.g. 2000Hz). Press the **OK** button to switch on/off the frequency. To escape from this setting, choose the **Return** menu at the end of the frequency row or press the **menu** button. The 1000Hz can not be turned off.

Freq.selection
2000Hz on

c, Setting language

Basically there are 5 languages in the apparatus. To settle a language, choose the **Language** menu point, and press **OK**.

Select:
English

d, Setting „Reverse” mode:

When „Reverse” mode is switched **on** there is **no sound** in the headphone unless the **interrupt button** is pressed. When the „Reverse” mode is **off** the sound will appear in the headphone immediately. In this case press the **interrupt button** and the sound goes **off**.

For setting Reverse mode turn **knob select** to **Rev.** Press button **OK**.

Turning **knob select** either **off** or **on** may be set. Pressing button **OK** the apparatus will turn back to **menu setup**.

Reverse mode:
off on

e, Calibration.

Calibration should preferably be done by the manufacturer or a maintenance service expert. If you decide doing the calibration yourself set to **Cal.** by turning **knob select**. Press **button OK** and enter the **code** by turning **knob select**. If the **code** is then you can enter to the calibration. If the code is incorrect the level can not be changed.

Pressing **button OK** again the newly adjusted levels may be stored and returns back to **menu setup**.

3.6./ SIGNS OF MALFUNCTION

Bellow there is a list of errors and how they should be dealt with.

Pull out the adapter from the mains socket, and connect the headphone to the audiometer. Connect the adapter to the mains again, in case error signal is still on, call the service.

Error! See Oper. Manual

Recalibration should be done by service!

Recalibration needed!

During the use of the memories can appear the “Memory error” sign. Try the previous operation again. If the problem is still on, call the service.

Memory error!

IV. Command of the maintenance

4.1./ MARKS, SYMBOLS

All the marks and symbols may be seen in the previous point.

There is a rating label on the back side of the audiometer with the following informations on it:

- The name of the manufacturer
- Company plant
- The type of the apparatus
- Mains supply
- Power consumption



Sign of the double isolation (according to IEC 60-1-1 for both the apparatus and the adapter).



B patient protection



sign of 93/42 EU Directive (Minister of Health for Decree No. **4/2009. (III.17)**) and the code of certification office (SGS)

4.2./ MAINTENANCE, REPAIR

Maintenance:

The audiometer doesn't need regulator maintenance but the occasional checkup of calibration may be necessary according to the effective rules.

The occasional checkup must be carried out by the producer or by an expert service company.

Measuring instrument required for calibration.

- artificial ear (according to standard IEC 303)
- measuring microphone
- calibrated instrument for measuring sound-pressure level

Technical description for calibration may be seen in point 3.4.6.

Repair:

Repairing is advisable to be done by the manufacturer or by an expert service company.

In case of repairing the following points must be taken into consideration:

- Respect rules of shock protection.
- The apparatus may only be used with the attached calibrated headphone.
- When repairing a soldered point out it must resoldered to the same point.

When the continuously shining green light is extinguished, than there's a problem with the adapter.

Important!

In this case do not try to replace it with a similar adapter! Turn to the service!

4.3./ SPECIFICATION, TECHNICAL DATA

Classification according to the Medico-technical directiva: II. a

Standard applied: EN 60645-1
 EN ISO 389-1
 EN ISO 389-3
 EN ISO 389-4
 EN 60601-1
 EN 60601-1-2
 93/42 EEC (4/2009. (III.17) Minister of Health for Decree)

General data

Operating temperature range	+ 5 °C ... + 40 °C
Reference temperature range	+ 15 °C ... + 40 °C
Storage temperature range	- 25 °C ... + 70 °C
Protection	IP 20
Dimensions	195 x 150 x 50 mm
Weight	0,45 kg
Warming up time	2 s
Lifetime	10 years

Electrical data.

Audiometer:

Nominal power supply:	+ 15 V DC
Power consumption	2 VA max.

Mains adapter FW 7555 M/15 (MPP15), Friwo:

Power supply:	100 - 240 V ~ 50-60 Hz
Output Voltage:	5 V stabilized, polarized: -  +
Output current:	1A max.
Patient safety:	Class II.
Patient protection:	B (MSZ EN 60601-1)
Protection:	IP 40

PC connection: optically separated RS- 232/ C

4.4./Acoustic data:

Frequency and sound-level maxima:

Frequency	AC	BC
250 Hz	80 dB HL	30 dB HL
500 Hz	100 dB HL	60 dB HL
1000 Hz	100 dB HL	60 dB HL
2000 Hz	100 dB HL	60 dB HL
3000 Hz	100 dB HL	60 dB HL
4000 Hz	100 dB HL	60 dB HL
6000 Hz	100 dB HL	40 dB HL
8000 Hz	80 dB HL	40 dB HL

Level minimum		- 10 dB
Level steps:		5 dB
Level accuracy:		+/- 3 dB
Frequency accuracy:		jobb mint 1 %
Distortion:		THD < 0,5 % (IEC 645)
Interrupted:		manual and automatic, 0.5, 1, 2 imp/s
Level interrupt:		> 100 dB
Calibration:		ISO 389/1991

Sign of masking**Narrow Band Noise (NBN)**

Frequency and level maximum:

Frequency	AC
250 Hz	60 dB EM
500 Hz	80 dB EM
1000 Hz	80 dB EM
2000 Hz	80 dB EM
3000 Hz	80 dB EM
4000 Hz	80 dB EM
6000 Hz	80 dB EM
8000 Hz	60 dB EM

White noise

WN	80 dB SPL
----	-----------

4.5./ ACCESSORIES

Accessories included in Price (Standard)

Headphone:	Telephonics TDH-39/100 Ω (in a Pelton noise excluder)	1 pair
Mains adapter FW 7555M/15, MEDICAL, Friwo		1 piece
Operating Manual		1 piece
Carrying case		1 piece
Patient response switch		1 piece

Accessories on order (Optional)

Extra pieces of the items included in price

Bone (B-71) headphone

PC connecting cable

PC Program (MAudio)

On order of accessories and spare parts state the apparatus product number as well!

4.6./Cleaning, disinfecting:

Parts of the apparatus (headphone cushion, patient response switch) coming in direct contact with the patient may be disinfected **by wiping it with detergent**. All the detergents normally used in the institute can be applied. Don't use any detergent containing active chlorine, phenol or formaldehyde components!

After cleaning the apparatus **operation is prohibited**. Let the solution dry on the surface for about one hour!

Disinfection:

The apparatus may only be used when it is disconnected from the mains socket.

Dip a clean cloth used solely for this purpose into the freshly made solution, squeeze it lightly wipe the surface with it thoroughly. Let the solution dry on the surface and wipe it with a clean textile cloth.

Always comply with these instructions when cleaning **the apparatus**.

4.7./ PACKING, DELIVERY

Conditions for packing and delivery are regulated in the Terms of Delivery. SA-52 transported in its own case is suitable for field application. Climatic conditions and the operating temperature range of transport in this case stated in point 4.3.

STORAGE

Storage conditions are given in Terms of Delivery in regard of the concerning regulations. Storage climatic conditions are given in point 4.3. In case the apparatus is stored in extreme temperature it is important to keep it stored in its own package on the temperature of later use for one day before installation.

4.8./ WARRANTY

Warranty is provided by the manufacturer based on the „Delivery Contract” in case conditions of the Operation Manual have fully been taken into regard. In case transport within the country the Terms of Warranty is 24 months starting on the day of installation.

The product meets the requirements of the Minister of Health for Decree No. 4/2009. (III.17) 1 regulations, meets the requirements of standards applied and the technical specification given out by the manufacturer.

The apparatus has a CE 1979 mark, certified by SGS.

ATTENTION! The owner of the apparatus is kindly requested to supply the number of Quality and Warranty Certificate issued by the producer, the date of issue and product number of SA-52 when bringing in a claim, asking for a service or spare-parts.

4.9./ SUPPLEMENT

Quality and Warranty Certificate (a document separately attached to the Operating Manual).

Note: