



MEDIROLL
ORVOSTECHNIKAI KFT.

innovative solutions

SA-7

mini screen audiometer

Instruction manual



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Read the instructions before using the device.

1 INSTRUCTIONS

This manual was made for the **SA-7** audiometer.

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

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

1.1 Purpose of the device

The portable audiometer, type **Sa-7** is suitable for the measurement of air conduction hearing loss, and recording audiograms. The hearing threshold information may be recorded during 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 measurement is based on the examination of the Hughson-Westlake test. The audiometer - like all the other audiometers - may primary be used in a silent cabin (an audiometric booth) but the use of the noise cancelling headphones provides correct measurement data in a bit noisier environment as well.

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

Targeted patients: This device can be used to examine any kind of patients from the age of 1, regardless their sex, age and state of health. There isn't any known hazard of the examination.

User profile:

The Sa-7 audiometer can be used by an audio specialist doctor, an otolaryngologist or a trained specialist. The success of the hearing loss screening depends on the accurate cooperation of the patient. In case of a non-accurately responding patient there is a possibility of executing other tests, which give at least some useable data. In these cases –when diagnosing “normal hearing” - we cannot leave out of consideration other possible sings that point to a controversial result. If there are any further doubts of the hearing sensitivity, a full audiological examination must be carried out.

1.2 Safety instructions

The Sa-7 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.

Please pay attention to the following requirements in order to avoid damages and accidents:

- Check the mains voltage before connecting to the mains
- Check the cable before connecting (not damaged in any way)
- The device can only be used for maintained purposes
- Clean the device regularly according to the instructions
- Connecting any accessories except the standard ones is strictly prohibited!
- Keep the device in dry places
- Keep the device away from heat, oil, sharp objects, rough places, and be sure of the good state of the cable
- Do not expose the device to direct sunlight, or strong light (more than 1500 lux)
- Do not use the device in a dusty environment
- Do not use the device in a vibrating environment
- Do not use the device in an environment where liquid can fall onto it
- Pay attention to the assurance of the all-time environmental conditions



ATTENTION!

Check the mains voltage before connecting to the mains.

Connecting the device to protective earth is strictly prohibited!

REQUIREMENTS REGARDING SAFE OPERATION

- ***The device may only be used with the attached adapter!***
- **To disconnect the device 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 device or any of the accessories when cleaning or disinfecting!**



Attention!

The device is fragile therefore it needs to be protected from damages (falling, crashing). The touchscreen can be used by lightly pressing it (max. 250 g). The handling does not require another device it can be easily operated manually. In case of using another device, it must be an equipment that is designed specifically for touchscreens (available in stores). Avoid the usage of sharp tools as they can damage the screen, and in this case the warranty is not valid.

2 INSTALLATION

2.1 Unpacking, installation, operation

If the device was delivered or stored in a cool environment it must be kept in its original package until its warm-up to room-temperature.

The device is packed in one case along with all its accessories. After the unpacking check the accessories according to point 4.4. In case of damage or faulty accessories inform the manufacturer or its representative by stating the product number as well. The device can be used by the attached headphone. The product number is stated on the headphone as well.

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

The following chart contains the permissible noise levels measured in the patient's environment that do not disturb accurate pure sound hearing threshold determination yet supposing a headphone-covered ear during the examination. The alleviation of the headphones of the SA-7 is in the second and third row. In the fourth row there is the highest permitted sound level of the measuring.

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
Noise cancelling headphones	dB	47	27	33	42	36	39	43

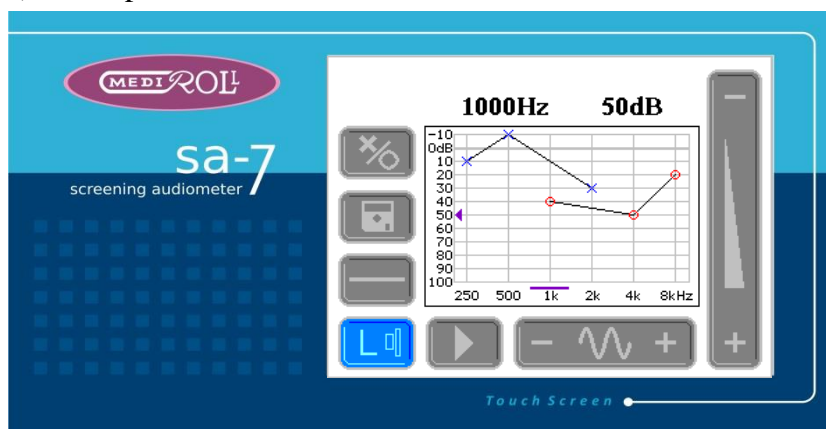
*: according to ISO 8253-1, (1/3 octave)

** : producing data

Generally the **silent cabins** satisfy these requirements if the place of operating is not especially noisy. If the device is installed in a silent cabin a suitable installation of the accessories is of major importance. Make sure that during the installation neither of the cables touches the apparatus or the cabin. Do not connect cables that appear to be on the same potential (e.g.: the cold points of the headphones). When connecting the headphone to the device, only the connection cable provided by the producer can be used. In most cases there is no silent cabins to use. In these cases 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 10 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 2.1. it is ready to use. The warm-up-time is 2 seconds. If you want to connect the device to a PC, you must use the connection cable provided by the producer.

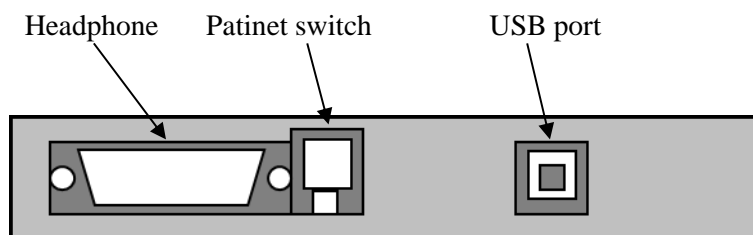
2.2 Controls and ports

Controls and ports of Sa-7 are illustrated below. The device must be operated through a film (touch sensitive) that is placed on the multicolour screen:



Picture 1

In the second picture the ports of the audiometer is shown.



Picture 2

The plugs can only be connected to the ports in 1 way. The headphone plug can be fixed to the terminal by two screws, it is not necessary to unscrew the device when transporting. When connecting the plugs to the terminals always make sure it is the right way. Forcing the plugs is prohibited.

Frequently used functions:

Functions that are meant to be used frequently according to the producer

- installation, switching on
- measuring of hearing threshold
- memory handling
- data valuation
- cleaning, disinfection

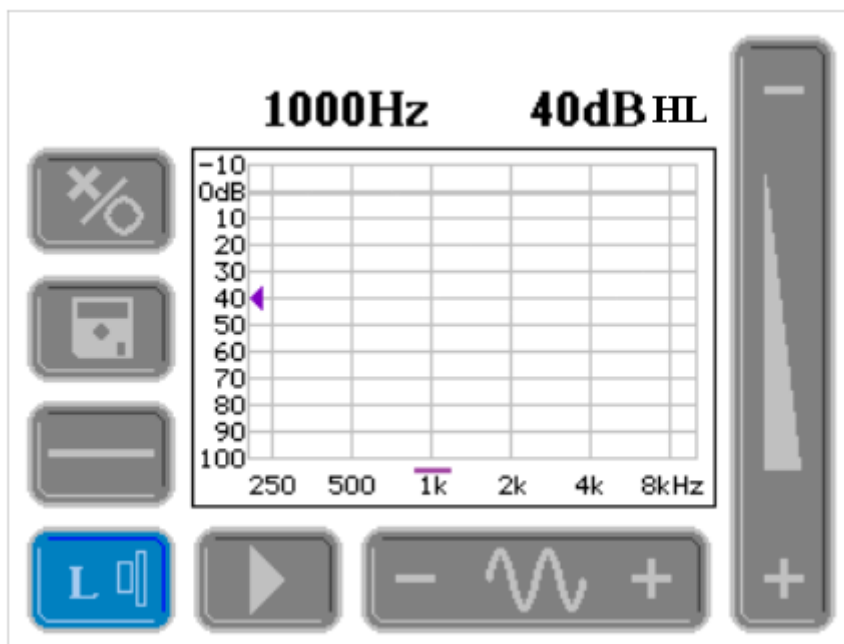
2.3 Switching on, setting the controls into basic operation

The device doesn't have a main switch. First connect the main adapter and the headphone to the device then the adapter to the wall socket and the equipment will be automatically switched on. The order of the plugging is important, otherwise the apparatus will not operate authentically.

After switching on, the device will be in basic operation mode and display:

SA-7 screening audiometer
Mediroll Co. V4.02

After executing the automatic settings the following picture will appear.



Picture 3: Incoming image/ Home screen

This is the home screen. In the manual the operating description always starts from this picture.

Attention! If you switch on the audiometer without connecting the headphone, a warning will appear on the screen. Switch off the device, connect the headphone, and switch it on again. After this, the device will operate correctly.

2.4 Trouble free operation

The process detailed in point 2.1. may also serve to check safe operation. We listen to the audiometer in several frequencies, and we make sure that the touchscreen works well. Although the calibration can only be properly executed by a measuring instrument, an expert with the necessary experience will be able to detect faults by listening.

2.5 Operation, signs of malfunction

The device is stable for continuous operation, no over load is possible. Malfunction during operation may be identified on the basis of point 2.1. and 2.3.

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 2.4.

The system needs to be set in a way so the patient can be at least 1,5 meter away from the tools that are in electrical connections with the computing equipments.






















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

To switch off, unplug the USB power adapter or, if you are using a computer, close the application and then unplug the cable from the PC's USB port.

3 OPERATING INSTRUCTIONS

3.1 General description

The Sa7 screening audiometer has only one operative item controlled by a touchscreen. With this operative item you can set the frequencies, the level and the different settings. The screen displays two options: there are buttons and a controlling item. The buttons make their effects when we release them right after having them pushed. Releasing the sign + next to the controlling icon increases, while the – decreases the desired quantity. Pressing and sliding the controlling icon into the chosen direction gives the same result (for sliding the icon can be pressed anywhere, only the direction counts. The sliding controls the quantity until the icon is pressed).

	Threshold test		Delete data		Slow pulse	
	Automatic threshold		Left side		Medium pulse	
	Melody test		Right side		Fast pulse	
	Memory		Mute		Slow melody	
	Data store		Sound		Normal melody	
	Data recall		continuous sound		Fast melody	
			frequency controller		Settings	

Picture 4 : Controls on the display

3.2 PC program

The "Maudio7 receiver program" user manual can be downloaded from the MEDIROLL.hu website. It contains the computer configuration, installation and operation steps required to run the PC program.

3.3 Descriptions of the tests

3.3.1 Measuring of the hearing threshold

Put the headphone on the patient's ear, and ask them to signal (press the button, or raise their hand), if they can hear the sound, and do not sign, if they doesn't hear it. When turning on there's a sound in the left headphone (blue). We show what's needed to be heard (with changing the level of the sound) and we set the level under the expected hearing threshold. Increase the level with 5 dB steps, till the patient signals, and after that decrease the level with 10 dB steps, and increase it again with 5 dB steps. The patient has to sign if they hear the voice again. After two signals at the same level the audiometer saves that level as a hearing threshold and marks it with a **blue x** on the audiogram (the sign of the left air conducted threshold). This is the **automatic threshold recognition**.



If the operator doesn't agree with the threshold sign of the audiometer, than they can settle the right one and with a "click" they can modify the audiometer's one. To do so, press the audiogram anywhere. To clear the threshold sign, press the audiogram twice.

The automatic threshold recognition works only with the response switch. If there's no response switch, the operator can record the hearing threshold by touching the audiometer.

We search the hearing threshold of 1000 Hz, and continue the examination with 2000 Hz. To do so press the "+" side of the controlling icon. The frequency will change to 2000 Hz.



Continue the measuring until 8000 Hz, and after from 1000 Hz to 250 Hz (this is the regular method). Measuring on 1000 Hz again has a checking purpose.

In order to switch sides, press the blue L button. After releasing the button turns red, and marks R, and the sound will be displayed in the right part of the headphone. **When switching sides there is a silent click in the headphone, which is automatic, it is a characteristic of the construction.**



Do the examination on the right side again from 1000 Hz to 8000 Hz, then from 1000 Hz to 250 Hz. The sign of the threshold here is a red "o".

The two ears' audiograms are displayed on the screen at the same time. If it bothers the operator, he/she can separate the left and the right audiogram. In this case, only the current one will be visible (L or R).

In case of uncertain signals of the patient, or if they continuously signal at a low volume, they did not understand the task correctly, or maybe they are trying to cheat. In this case (e.g.: low volume) we can switch the sound off in the headphone by the mute button. In place of the play sign, the pause sign will appear. If the patient signals again, explain the task once more. By pressing the pause sign, the sound will be played again.

We can continue the examination with the next patient, but we will lose the data of the previous patient, so it's useful to save or delete the data after the examination. Also: the appearance of the previous threshold on the screen can confuse the operator. That's why it is recommended to save or delete the data after the examination. In case of saving the data will be placed in a background memory, where it can be recalled from. In case of delete the data will be lost forever.

The examinations can be done without delete or save. In this case use the response switch, don't write the hearing threshold into the audiometer, just note it down.

3.3.2 Fast screen

The aim of this examination is to check that the patient hears a pre-set level in different frequencies, or not. Here, the patient has to signal with their hands (the automatic threshold does not apply in case of the fast screening). If the patient signs with the switch, the audiometer will sense it and will write the “x” or the ”o” sign. If the patient raises their hand, the operator has to record the fact of the hearing by touching the screen.

The 25 dB and the 30 dB are often used (30 dB is almost a hearing loss). Switch all of the frequencies one after another on both ears. The audiometer saves the answers (the signals of the patient, or the touch of the operator), similarly to the threshold measuring. We can delete or save data here as well.

3.3.3 Melody test, child examination

The audiometer can examine children and has nursery songs; a song is like a pure toned measuring frequency. The level can be changed, just like the middle frequency of the songs. The operator watches and records the reactions of the child. To select the test, choose the Threshold menu point. The device will list the options. Select the Melody option. The melody button will replace the Threshold button, and the first row of the given song belonging to the relevant frequency will appear on the top of the screen. Choose the relevant frequency with its song, and it will be played by pressing the pause button. It will be played, until the operator does not stop it by pressing the play button. At the end of the song, the device will repeat it. During the play time the volume can be changed. When examining children it is better to use the decreasing volume method. It means that for the first time we need to set the volume to a certain level that the patient will surely hear. We can also make sure by asking the patient. After this we decrease the volume by 5dB until the patient cannot hear it. This value will be the threshold. Generally it is not recommended to use a switch with children, as it distracts their attention from the task. Record the thresholds manually. The operator can see on the screen the flying note during the play (a part of the lyrics), so he/ she can follow the song without hearing it.

Change the melody and the volume level in order to get the sound level data. These will be the results of the examination that can be saved, or recalled. The operator can settle the rhythm of the songs (in chapter 3.5.4.) and the middle frequency of the songs (chapter 3.5.5.).

3.3.4 Automatic hearing threshold examination

In this function the audiometer changes automatically the volume and the frequency according to the signs of the patient. This examination can only be done by an audiometer that has a response switch. To choose the test press the threshold measure button. The device will list the possible options. Press the “automatic threshold” button. In this case the “automatic measuring” button will replace the threshold measure button.

Tell the patient that they will hear an increasing level. As they hear the sound, press the switch and do not let it go until they can hear the sound. To the sign of the patient the level will decrease. Upon losing the sound (cannot hear it anymore), they have to release the switch. This time the level will increase again. The examination continues and if the patient signals two times at the same volume, the audiometer will save the data as a threshold. After saving the threshold, the device changes the frequency and it decreases the level by 20 dB.

After recording the hearing threshold of the left ear the audiometer changes to the right ear, it does the recording of the threshold, and the examination stops. . During the examination the frequencies change from 1000 Hz to 8000 Hz, after it from 1000 Hz to 250 Hz. First the left side is examined, then the right side. It is not obligatory to start the examination by 1000 Hz on the left side. Before the examination the operator can choose the starting frequency. The device monitors only the order of the frequencies. **The examination starts by pressing the mute button (it turns into the play button), and can be stopped here at any time.**

3.4 Memory

At the end of the examination the measuring results will appear on the screen. Any of the results can be modified or repeated if needed. The new data replaces the old one. We can notice the measuring results. Further handling is needed, because the data of the previous measuring can be confusing on the screen. In order to handle the data, press the memory handling button. The necessary buttons will appear on the screen: store data, recall data, delete data.



3.4.1 Delete data

After the examination the measuring data will be in the memory of the screen. If you don't need them anymore you can delete them with the **Delete** function. The data will be deleted for good. To start the deleting, choose the Delete menu point (the bin). The device will ask whether you are sure about the process. If you are sure, press the Yes button. If you change your mind, or you just pressed this option by accident, press the No button.



3.4.2 Store data

If you want to use the data later, you can store them in a background memory. Maximum 50 patients' two side hearing threshold data can be stored. The audiometer saves the data even when it's switched off. The patient can be identified by a number.

To save data, choose the Save menu point. Create an ID number of the memory, where you want to save the data – using the icon on the right side. Note down this number next to the patient's name (in case you have it). Press the Yes button. The device saves the measuring results under the given memory number, and then erase the audiogram from the screen. If you don't want to store the data in the memory, press the Cancel button. The audiogram stays on the screen.



3.4.3 Reading data

The operator can recall all the data to the memory of the screen. To read choose the Read menu point.

Settle the number of memory where you want to read the data from, and press Yes. The previously displayed results will disappear, and the stored data will replace them on the screen. If you don't save the data before recalling them, they will be lost. The data in the background memory will not change by reading. If you don't want to read from the memory choose the Cancel button. The previous data will appear on the screen.



3.5 Settings

The operator can change some of the parameters of the examination. These parameters are the following:

- automatic pulse
- melody tempo
- frequency on/off
- middle frequency of melodies
- language
- brightness of the screen
- others

Changing the listed parameters does not have an effect on every examining method. We list at each setting the examination methods that are in connection with the given parameter. To reach the settings press the “test selection” button, and then the “settings” button. The pulse and the tempo can be set with separate buttons. The set parameters are saved even if the audiometer is switched off, therefore one setting is enough. Of course the settings can be modified at any time, the audiometer saves the last one.



3.5.1 Pulsed sound

During the examinations there might be a need not to examine the patient with a continuous sound, but with a pulsed sound (the patient has more attention to the pulsed sound than the continuous sound). The audiometer can settle 3 types of pulsing rhythm: 0.5, 1, 2 pulse/second. The 1 pulse/second means that in the headphone the sound can be heard for 1 second and then there is 1 second silence.

To set the pulsed tone, choose the “automat pulse” button. 4 options will be displayed on the screen: fast, middle, slow, and turned off. After selecting the desired tempo a button will appear next to the audiogram (that shows the measure or the mode of the pulse) and the selected kind of sound will be played in the headphone. **The pulse can only be used in case of the threshold, the screen and the auto examinations.**



3.5.2 Melody tempo

The melody tempo can be changed. When selecting a memory test the “auto pulse” button turns into a “tempo” button. To set a tempo, press the tempo button and choose from the 3 appearing options: slow, middle, fast. **The time signature is only valid in case of the melody test.**



3.5.3 Frequency selection

The examinations do not need to be done in every frequency. The audiometer makes it possible to switch off frequencies from the frequency row. These switched off frequencies won't be shown during the examination.

To set a frequency, select the Frequencies menu in the Setup. In the appearing list you can switch on/off the frequencies by touching the frequency values. You can finish the setting by touching the “Exit” button at the bottom of the list. The turned off frequencies will appear in grey on the audiogram. **The frequency at 1000 Hz can't be switched off.**

3.5.4 Transpose

Every song can be assigned to a frequency.

Select the Transpose option in the Setup menu. From the appearing frequency list choose the value you need. A song list will appear, choose your preference. Press “OK”. Every song can be transposed. **The setting of the transpose is valid only in case of a melody test.**

3.5.5 Language selection

To set the language, select the Language option from the menu. Select the language from the appearing list.

3.5.6 Brightness

Press the Brightness option in the menu. Set the right brightness by the appearing controller button, then press “OK”.

3.5.7 Decreasing step size

In a basic state the device increases the volume by 5 dB, and decreases it by -10 dB. This step size adjusts to the increasing volume method. If the operator wants to apply the decreasing volume method, they can set the decreasing step size to -5 dB.

To do so, press the “**Other**” button in the settings menu. In the appearing list touch the “10 dB to decrease” in order to set the quantity of the decrease. This function can only be used with the threshold measurement and the auto test.

3.5.8 Detection threshold

Touch the “Detection threshold” button under the “Other” menu point in order to switch this function on/off. This function can only be used with the threshold measurement and the auto test.

3.5.9 Double side audiogram

Touch the “2 side audiogram” button under the “Other” menu point. You can choose to see both sides’ audiograms or only the currently examined one.

3.5.10 Calibration

Calibration should preferably be done by the manufacturer or a maintenance service expert. It is highly recommended to have the device calibrated bi-yearly. Please contact the manufacturer about this.

3.6 Signs of malfunction

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

“The headphone is not connected to the audiometer!” (When switching on).

You can skip the error message by touching the “Ok”, but **in this case the device will not be calibrated**. Disconnect the adapter from the mains socket. Connect the headphone to the audiometer. Connect the adapter to the mains again. In case the error signal is still on, call the service.

„Calibration error!”

Recalibration should be done by the manufacturer!

„Memory error!”

There was an error in the background memory. Try the operation again. If it is not successful, the data will be stored in the memory of the screen, and it can be noted.

“Data error!”

Invalid data has been recalled from the background memory.

3.7 Training

The device does not require any special training.

4 MAINTENANCE

The command of the maintenance gives instructions to the technical staff.

4.1 Marks, symbols

All the marks and symbols are in the 2.2. point.

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

- The name of the manufacturer
- The address of the manufacturer
- The type of the device
- Mains supply
- Power consumption

Sign of the double isolation (according to IEC 60-1-1 for both the device 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 (NEO EMKI)



The producer of the device (MEDIROLL Ltd.)



serial number



Read the manual before using



The unwanted device should be recycled in a selective waste bin. Do not throw it away for environmental protection reasons.

The unwanted device can be placed at the producer’s site for free.

4.2 Maintenance, repair

4.2.1 Maintenance

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

There is a 3-year warranty on the device.

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 3.4.10.

4.2.2 Repair

It is advised to contact the manufacturer for repair.

The wiring diagrams, the list of the parts and the instructions for the calibration are accessible at the manufacturer's site.

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

- Respect the rules of shock protection.
- The device 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 off, than there's a problem with the adapter.



Important!

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

4.2.3 Cleaning, disinfecting:

In all cases the device must be disconnected from the main socket when cleaning it. Keep liquids away from the device and its attachments.

Those parts of the device that are touched by the patients need to be disinfected from time to time. You can use the usual tinctures of your establishment if it does not contain active chlorine, fenol or formaldehyde.

If you do not know the effect of the tincture, apply it only on a small surface (test cleaning). You can continue the cleaning if there is no damage/ change.

When cleaning the touchscreen use a soft tissue with some izopropile alcohol, or ethanol, do NOT use water or aromatic diluent. Do not work with the device right after cleaning it – let it dry for an hour at least.

Disinfecting:

Put a special tissue (produced only for this purpose) into the tincture, and when it is slightly wet rub the surface that you want to disinfect.

4.2.4 Alarms

Serious adverse events related to the SA-7 screening audiometer should be reported immediately to the manufacturer and the competent authority of the Member State where the user and/or patient is established.

Please inform the manufacturer in writing to mediroll@mediroll.hu and at the same time by telephone +36/30 458 1354.

5 STORAGE, TRANSPORTING



Attention, the device is fragile

SA-7 should be transported in its own case. This device is suitable for field application. Put the parts into the convenient pockets of the carrier. The touchscreen and the metal part of the headphone cannot touch each other.

Conditions when transporting

Air temperature:	-10 °C ÷ +50 °C
Relative humidity:	10-95%
Atmospheric pressure:	950 ÷ 1060 mbar

Sa7 is a mobile device. Climatic conditions and the operating temperature range of transport is stated in point 4.3.

After transporting check the condition of the package. If the package is damaged alert the transporter or Mediroll Ltd.

5.1 Storage

Conditions of storage

Air temperature:	-10 °C ÷ +50 °C
Relative humidity:	10-95%
Atmospheric pressure:	950 ÷ 1060 mbar

If the device is stored in extreme temperature it is important to keep it stored in its own packaging and keep it at the operation location for a few hours before use.

6 TECHNICAL DATA

Classification according to the MDD: II. a
 Classification according to EN 60645-1: type 4 audiometer

Operating environmental conditions/ conditions of use:

Operating temperature range	+ 5 °C ... + 40 °C
Reference temperature range	+ 15 °C ... + 40 °C
Storage temperature range	- 25 °C ... + 70 °C
Relative humidity	10-75%
Atmospheric pressure range	960-1060 hPa

In order to do a proper measurement, apply the ISO 8253-1 standard, to ensure a noiseless environment.

EMC information

Although the device adheres the corresponding regulations, make sure you do not put the device under unnecessary electromagnetic radiation, e.g.: do not use mobile phones next to it. Do not use other cables apart from the ones that we provide you with. The usage of other cables can increase the radiation and decrease the protection. Length of the cable: maximum 3 meters. If you use the device next to another device, make sure that there is no interference. If you connect other devices to the ports and you configure the device, it will be your responsibility to make the device correspond to the regulation IEC/EN60601-1-2.

General data

Protection	IP 20
Dimensions	146 x 91 x 30 mm
Weight	0,22 kg
Weight of the headphone with cable	0,57 kg
Cable length	1.5 metres
Warming up time	2 s
Lifetime	10 years

Electrical data

Audiometer:

Nominal power supply:	5 V DC
Power consumption	2 VA max.

Mains adapter

USB network adapter	Friwo FOX6M-USB
Power supply:	100 - 240 V ~ 50-60 Hz
Output Voltage:	5 V stabilized
Output current:	1A max.
Patient safety:	Class II.
Patient protection:	B (EN 60601-1)

Acoustic data:

Frequency and sound-level maxima:

250 Hz	80 dB	Sound level minimum:	- 10 dB
500 Hz	100 dB		
1000 Hz	100 dB	Sound level steps:	5 dB
2000 Hz	100 dB		
4000 Hz	100 dB	Sound level accuracy:	< 3 dB
6000 Hz	100 dB		
8000 Hz	80 dB	Frequency accuracy:	better than 1 %

Distortion:	THD < 0,5 % (IEC 645)
Pulsed sound:	manual or automatic, 0.5, 1, 2 imp/s
Sound presentation:	by pressing the required button
Sound interruption level:	> 100 dB
Calibration:	ISO 389/1991

6.1 Accessories

Accessories included in the price:

Headphone: Telephonics TDH-39/100 Ω (or RadioEar (DD45/10 Ω))	1 pair
Mains adapter ((Friwo FOX6M-USB)	1 piece
USB cable	1 piece
Operating Manual	1 piece
Carrying case	1 piece

Extra Accessories (Optional)

Extra pieces of the basic accessories

Patient response switch

When ordering spare parts, state the device's serial number as well!

7 EC DECLARATION OF CONFORMITY

MEDIROLL Kft.
4025 Debrecen,
Postakert u. 10.
HUNGARY



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Fax: +36/52-534-446
E-mail: mediroll@mediroll.hu
Internet: www.mediroll.hu

EU MEGFELELŐSÉGI NYILATKOZAT EC DECLARATION OF CONFORMITY



- | | |
|--|--|
| <p>1. A gyártó neve, címe: Mediroll Kft.
Name, address 4025 Debrecen, Postakert u. 10. Hungary
egyedi regisztrációs szám/SRN: HU-MF-000006368</p> | |
| <p>2. A nyilatkozat tárgya: Termék és kereskedelmi név/Product and trade name: Szűrő audiométer/Screening maudiometer
Subject of declaration: maudiometer
Termékkód, katalógusszám/Product code, catalogue number: SA-7
Alapvető UDI/Basic UDI: nincs (öröklött termék)/ none (legacy device)
Az eszköz rendeltetése/ Intended purpose: audiometriás szűrő hallásvizsgálat/ audiometric filter hearing test</p> | |
| <p>3. A gyártó kizárólagos felelősséggel kijelenti, hogy a fent megnevezett termék MEGFELEL következő jogszabályok követelményeinek:
- az orvostechikai eszközökről szóló 93/42/ EGK irányelv
- korlátozott anyagok jegyzékéről szóló (EU) 2011/65/EU irányelv
Minden ezt igazoló dokumentáció a gyártónál elérhető.</p> | <p>The manufacturer hereby declares that the above mentioned product MEETS the requirements of the following legislation</p> <ul style="list-style-type: none"> - Directive (EU) 93/42 on medical devices - Directive (EU) 2011/65 on the restricted substances list <p>All supporting documentation is available from the manufacturer.</p> |
| <p>4. A termékek megfelelőségét a következő harmonizált szabványok, egységes előírások alkalmazásával biztosított:
The conformity of products in the following harmonized standards, common specifications assured:</p> <p>EN 60645-1:2017
EN 60601-1:2006
EN 60601-1-2:2007,
EN 60601-1-6:2010, EN 62304:2006,
EN 62366:2008
EN ISO 14971:2012, EN 60601-1-4:1996
EN 1041:2008</p> | |
| <p>5. Megfelelőség-értékelési információk
Kockázati osztály II.a
Besorolási szabály(ok): 6.2.10 szabály alapján
Megfelelőség-értékelési eljárás: A minőségirányítási rendszer és a műszaki dokumentáció MDD szerinti értékelésével az NB szervezet által
Bejelentett szervezet neve : NeoEMKI Kft
Címe: 1097 Budapest Albert Flórián út 3/a. (Postal address)1463 Budapest, Pf. 853.)
Bejelentett szervezet azonosító száma: 1011
EU tanúsítvány azonosítója: 5-878-200-2003
Érvényes: 2024.05.26</p> | <p>Conformity assessment informations
Risk class II.a
Rule(s): 6.2.10
Conformity assessment route: The assessment of the quality management system and the technical documentation according to the MDD by the NB
Name of Notified Body: NeoEMKI Ltd.
Adress: 1097 Budapest Albert Flórián út 3/a. (Postal address)1463 Budapest, Pf. 853.)
Identifier of Notified Body: 1011
Identifier of the EU Certificate: 5-878-200-2003
Valid: 26/05/2024</p> |

Dátum/Date

aláírás/signo

8 WARRANTY

Warranty is provided by the manufacturer based on the „Delivery Contract” if the Operation Manual have fully been taken into regard. Terms of Warranty is 36 months starting on the day of installation. The lifetime of the device is guaranteed in case of regular checkings and calibrations by the producer (in every 2 years).

The warranty is not valid and the Mediroll Ltd. does not take any responsibility in case of the following:

- reparation done by anyone else than the Mediroll Ltd.
- Modifications that effect the stability and the reliability of the device
- careless usage (e.g. falling) or usage against the rules
- the serial number has been modified, became unreadable or is removed

ATTENTION!

The owner of the device is kindly requested to supply the number of Quality and Warranty Certificate issued by the producer, the date of purchase and product number of SA-7 when bringing in a claim, asking for a service or spare-parts.