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Instructions for Use - US

# PA5



8530526 – D-0131335-A – 2021/09



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# 1 Introduction

## 1.1 About this manual

This manual is valid for the PA5. The product is manufactured by:

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## 1.2 Intended use

The PA5 handheld paediatric screening audiometer is designed to be a device for screening for hearing loss primarily amongst children. Output and specificity of this type of device are based on the test characteristics defined by the user and may vary depending on environmental and operating conditions. The screening for hearing loss using this kind of audiometer depends on the interaction with the patient. However, for children not responding well, various test possibilities allow the tester of having at least some evaluative result. Thus, a “normal hearing” result should not allow for ignoring other contra indications in this case. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist.

## 1.3 Product description

### Delivered items with PA5:

- PA5 Paediatric Free Field Audiometer
- 3 AA Batteries
- PA5 Handbag
- Instructions for Use
- Service Manual

### Optional parts:

- TDH39 Headphone
- TDH39S Headphone

### Check numbers on PA5 and manual:

The identification label on the rear plate holds the serial number. This should be checked with the manual number and written down for later service claims.

## 1.4 Warnings

Throughout this manual the following meaning of warnings, cautions and notices are used:



The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.



**CAUTION**, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in damage of the equipment.

**NOTICE**

**NOTICE** is used to address practices not related to personal injury or damage of the equipment.





## 2 Unpacking and installation

### 2.1 Unpacking and inspection

#### **Check box and contents for damage**

When the instrument is received, please check the shipping box for rough handling and damage. If the box is damaged it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty, please contact your local distributor. Keep the shipping material for the carrier's inspection and insurance claim.

#### **Keep carton for future shipment**

The PA5 comes in its own shipping carton, which is specially designed for the PA5. Please keep this carton. It will be needed if the instrument must be returned for service.

If service is required, please contact your local distributor.

#### **Reporting Imperfections**

##### **Inspect before connection**

Prior to connecting the product it should once more be inspected for damage. The cabinet and the accessories should be checked visually for scratches and missing parts.

##### **Report immediately any faults**

Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. In the back of this manual, you will find a "Return Report" where you can describe the problem.

##### **Please use "Return Report"**

Please realise that if the service engineer does not know what problem to look for, he may not find it, so using the Return Report will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.







#### **Storage**

If you need to store the PA5 for a period, please ensure it is stored under the conditions specified in the section for technical specifications:



## 2.2 Marking

The following marking can be found on the instrument:

Symbol	Explanation
	Type B applied parts. Patient applied parts that are not conductive and can be immediately released from the patient.
	WEEE (EU-directive) This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745. Approval of the quality system is made by TÜV – identification no. 0123.
	Medical Device
	Year of manufacture
	Manufacturer

## 2.3 General warnings and precautions

### NOTICE

Be sure to use only stimulation intensities, which will be acceptable for the patient.

### NOTICE

The transducers (headphones, bone conductor, etc.) supplied with the instrument are calibrated to this instrument - exchange of transducers require a recalibration.

### NOTICE

It is recommended that parts which are in direct contact with the patient (e.g., earphone cushions) are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognised disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.

### NOTICE

Always remove the batteries when the instrument is left unused for more than a month.





## NOTICE

Although the instrument fulfils the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones etc.

If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

Disposal of batteries must be made according to national regulations.

Although the instrument fulfils the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears. Please also refer to EMC consideration in the appendix.



Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore must be collected separately. Such products will be marked with the crossed-out wheeled bin shown below. The cooperation of the user is important to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

## 2.4 Malfunction



In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has caused, or potentially could cause such harm, it must be quarantined immediately.

Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to include as many details as possible e.g., the type of harm, serial number of the product, software version, connected accessories and any other relevant information.

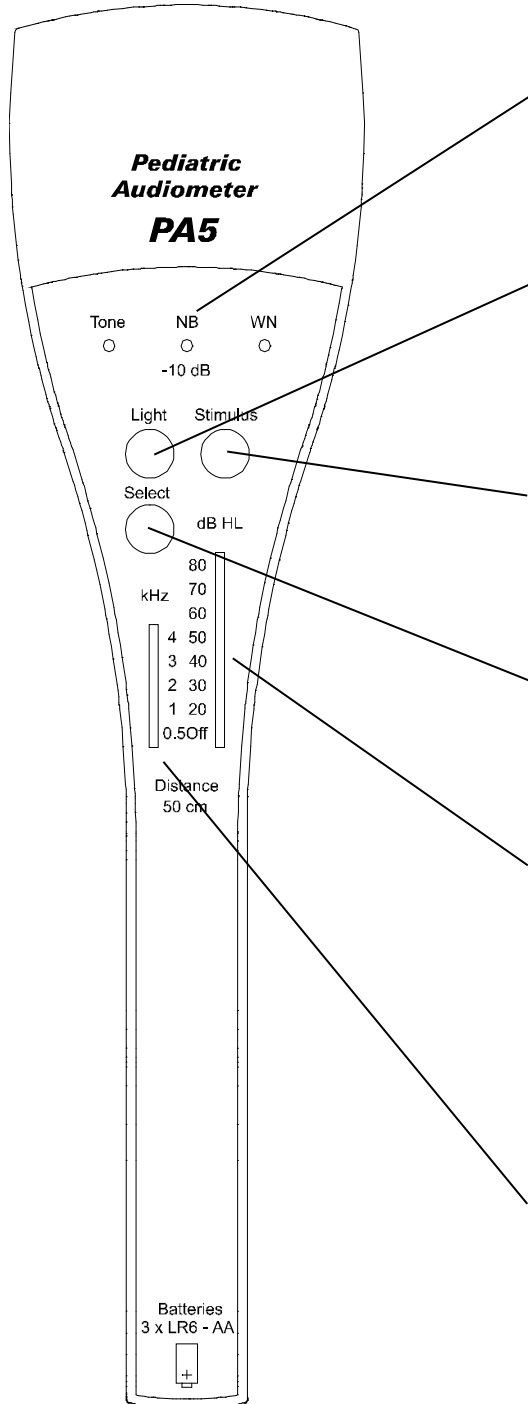
In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Interacoustics and the local national competent authority.





### 3 Getting started - setup and installation

The instructions included in this manual describe the general functions of the instrument.



#### Description of Control Panel

##### Indication of stimulus mode:

Indication LEDs informing the user of the present stimulus mode: Tone, NB or WN.

##### Light:

Light button to control the three red LEDs, which are arranged in a triangle above the speaker to condition the orientation reflex.

##### Stimulus:

Stimulus button to present the selected stimulus Tone, NB or WN.

##### Select:

Select button to select between the three different stimuli Tone, NB or WN.

##### Intensity dB HL:

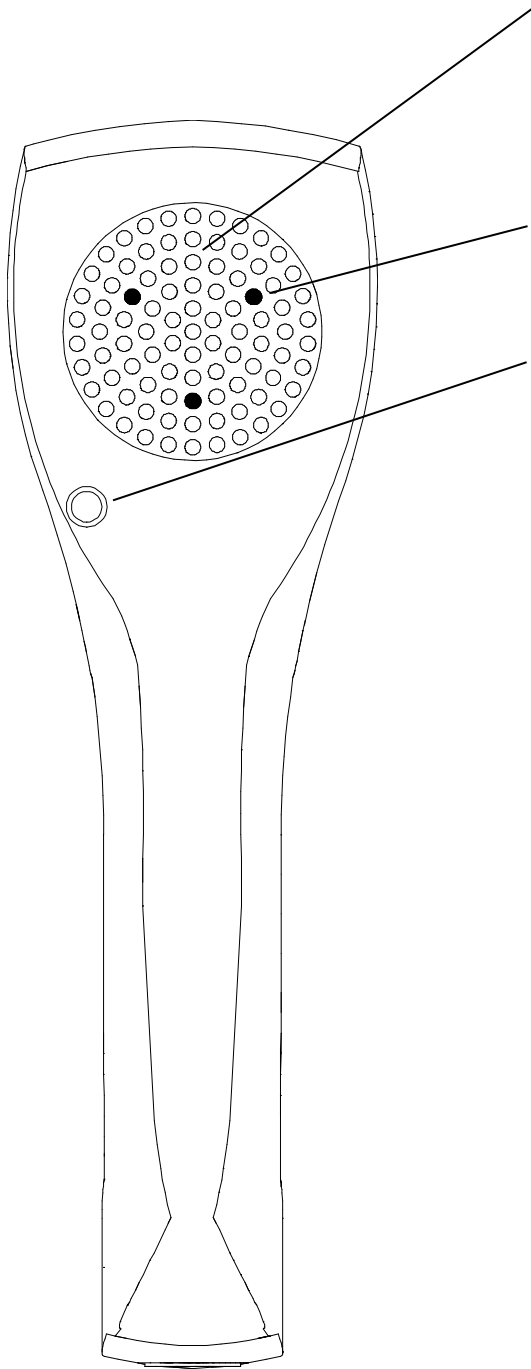
With the intensity control switch intensities between 20 and 80 dB, HL can be selected in steps of 10 dB when the distance between the ear and the loudspeaker of the PA5 is 50 cm or the PA5 is switched off by leaving the intensity control switch in the "Off" position. When the PA5 is not activated for two minutes it will switch off automatically.

##### Frequency kHz:

With the frequency control switch it is possible to select between the following frequencies: 0.5, 1, 2, 3, and 4 kHz.



## Description of Stimulus Panel



### Loudspeaker:

The loudspeaker is to be found underneath the black grid. When used on a patient the grid should be positioned in 50 cm (20 inches) from the ear to obtain the intensities printed on the Control Panel.

### LEDs:

Three LEDs arranged in a triangle for conditioning of the orientation reflex.

### Headphone Connector:

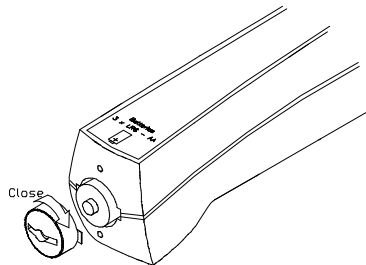
Connector for single Headphone TDH39S (optional). When the headphone is connected PA5 will automatically go to Pure Tone stimulation and correct calibration for Pure Tone Audiometry will be applied.

## Battery Description

### Replacing Batteries:

To replace old batteries, unscrew the small black lid in the narrow end of PA5 and the batteries can be taken out.

Replace with three new AA batteries. When inserting the new batteries make sure that they are inserted correctly according to the small drawing in the bottom part of the control panel.



PA5 contains 3 batteries, size LR6, AA or Mignon.

### Approximate Battery Lifetime:

The battery lifetime using Alkaline battery type:

With the instrument switched off: 12 months

With 80 dB tone switched on: 10 hours

With 80 dB tone and light switched on: 4 hours

### Battery Level indication:

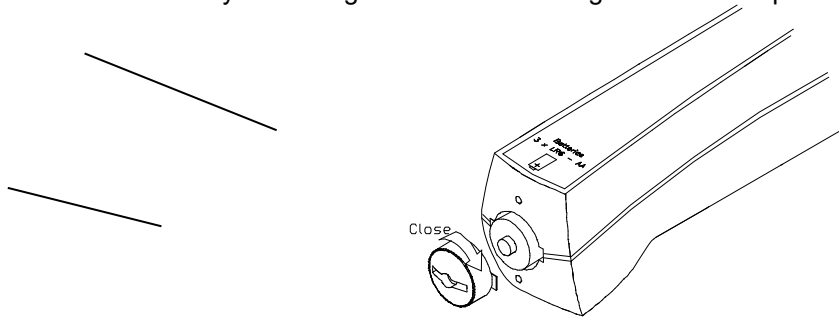
When the batteries need to be replaced the LED indication for the present used stimulus will gradually reduce in light intensity and finally switch off.

**Note:** Always remove the batteries when the instrument is left unused for a longer period.



### 3.1 Replacing batteries

To replace old batteries, unscrew the small black lid in the narrow end of PA5 and the batteries can be removed. Replace with three new AA batteries. When inserting the new batteries please make sure that they are inserted correctly according to the small drawing in the bottom part of the control panel.



PA5 contains 3 batteries, size LR6, AA or Mignon. Alkaline or rechargeable (NiMH or NiCa).

#### 3.1.1 Approximate battery lifetime

The battery lifetime using alkaline battery type:

With the instrument switched off:	12 months
With 80 dB tone switched on:	10 hours
With 80 dB tone and light switched on:	4 hours

#### Battery Level indication:

When the batteries need to be replaced the LED indication for the present used stimulus will gradually reduce in light intensity and finally switch off.

**Note:** Always remove the batteries when the instrument is left unused for more than a month



### 3.2 Description of various tests

As found by Professor Sanford E. Gerber complex signals like White Noise (WN) assure better responsiveness on neonates and up to the age of approximately seven months than e.g., pure tones and Narrow Band Noise. Therefore, PA5 has the possibility of stimulating with WN.

#### **The APR Test:**

The Auropalpebral Reflex is a startle reflex of the eyelid elicited by relatively strong sounds, approximately 80 - 100 dB SPL (PA5 is calibrated in dB HL).

The test can be performed on neonates from the day of birth, and it is not based on co-operation with the new-born child. Other responses than the APR can be arousal from sleep, crying or diminished activity.

#### **The COR Test:**

The Paediatric Audiometer PA5 can perform Conditioned Orientation Audiometry based on a technique described by Suzuki and Ogiba (1961). The phenomenon called "Orientation Reflex" is not a learned response, but a natural reflex movement elicited by sound or visual stimulation.

If the visual stimulation elicits a reflex which is conditioned by a tone, the child will look towards the visual stimulation, e.g., flashing light, as soon as the tone is heard. If the conditioning is effective the child will look in the direction of the sound source even before the visual stimulation is presented. The COR method requires cooperation from the child.

#### **The VRA Test:**

The Paediatric Audiometer PA5 can perform the Visual Reinforcement Audiometry (Liden and Kankunen, 1969), which is an extension and modification of COR, where the co-operation with the child is less important. Liden and Kankunen accept not only the sound localisation orientation reflex, but also four other reactions: reflex reactions (body and face), search reactions, orientation reactions and spontaneous reactions.

### 3.3 Reflex audiometry by Neonates

The reflex pattern elicited by sound can be divided into the following types of reflexes (Relke and Frey 1966). The sound intensity is 75 – 90dB.

#### **Breathing Reflex**

The breathing rhythm is changing when the sound is heard and should stabilise after 5-10 seconds.

#### **Auropalpebral Reflex (APR)**

The open eyelids will be closed fast and clear.

#### **Moving Reflex**

The neonatal child will move heavily after a quiet period.

#### **Crying Reflex (Scream)**

The face of the child will indicate discomfort and shortly after followed by weeping or a scream.

#### **Astonishment Reflex**

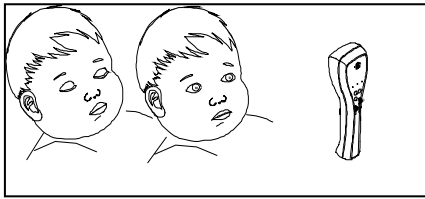
Crying and body movements stop momentarily as if the child is asking: "What is going on"?

#### **Waking up Reflex**

The breathing rate is accelerating; the child starts moving, wakes up and opens the eyes.

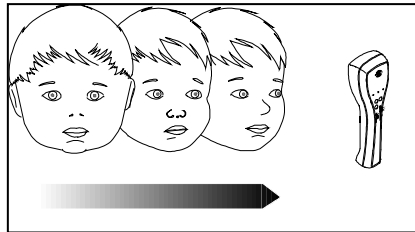


### 3.4 Maturation of auditory response



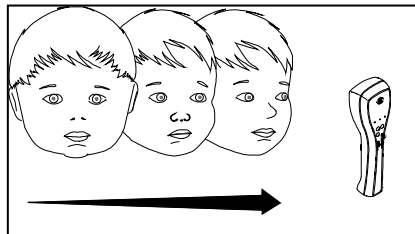
New-born to 2 months of age

Arousal from sleep. MRL<sup>1</sup> in quiet surroundings 50-70 dB.



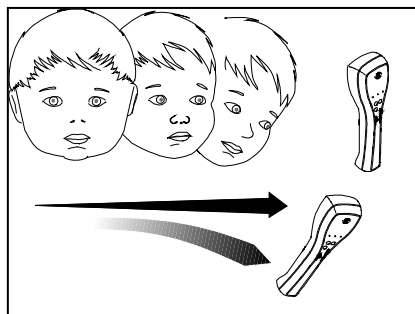
MRL in noisy surroundings: 90 d 3-4 months of age

Rudimentary head turn, horizontally.  
MRL: 50-60 dB.



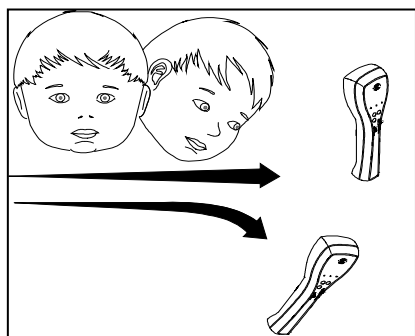
4-7 months of age

Sound localisation to the side only, not above or below eye level.  
MRL: 40-50 dB.



7-9 months of age

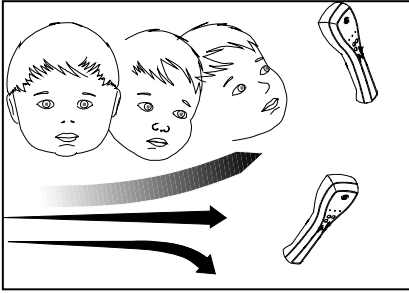
Sound localisation to the side and Indirect below. (Not above).  
MRL: 30-40 dB.



9-13 months of age

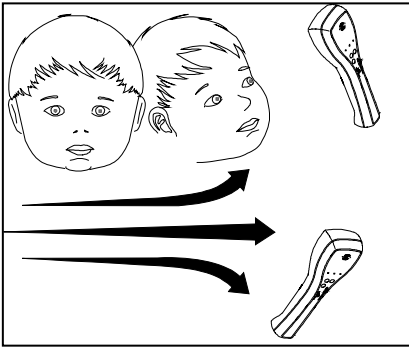
Sound localisation to the side and direct below.  
MRL: 25-35 dB.

<sup>1</sup> Minimum response level, dB HL. The MRL levels are recorded in sound cabins. In noisy surroundings the levels will have to be correspondingly higher.



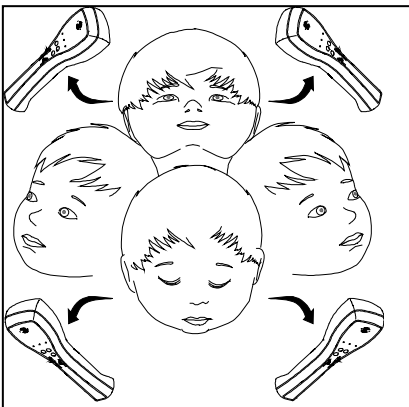
13-16 months of age

Sound localisation to the side, below and indirect above.  
MRL: 25-35 dB.



16-21 months of age

Direct sound localisation to the side, below, indirect above.  
MRL: 25-35 dB.



21-24 months of age

Locates directly sound at any angle.  
MRL: 25-30 dB.





## 4 Maintenance

The performance and safety of the instrument will be kept if the following recommendations for care and maintenance are observed:

- It is recommended to let the instrument go through at least one annual overhaul, to ensure that the acoustical, electrical, and mechanical properties are correct. This should be made by an authorised workshop to guaranty proper service and repair.
- Do not site the instrument next to a heat source of any kind and allow sufficient space around the instrument to ensure proper ventilation.
- To ensure that the reliability of the instrument is kept, it is recommended that the operator at short intervals, for instance once a day, perform a test on a person with known data. This person could be the operator him/herself.
- If the surface of the instrument or parts of it are contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or similar. The use of organic solvents and aromatic oils must be avoided. Always be careful that no fluid is entering the inside of the instrument or the accessories.
- After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. General precautions must be observed to avoid that disease from one patient is conducted to others. If ear cushions or ear tips are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. By frequent cleaning water should be used, but by severe contamination it may be necessary to use a disinfectant. The use of organic solvents and aromatic oils must be avoided.
- Great care should be exercised by the handling of earphones and other transducers, as mechanical shock may cause change of calibration.

### 4.1 How to clean Interacoustics products

If the surface of the instrument or parts of it are contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or similar. The use of organic solvents and aromatic oils must be avoided. Always disconnect the USB cable during the cleaning process and be careful that no fluid is entering the inside of the instrument or the accessories.



- Before cleaning always switch off and disconnect from power
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to get in contact with the metal parts inside the earphones / headphones
- Do not autoclave, sterilize, or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory
- Do not let parts that have been in contact with fluids dry before cleaning
- Rubber ear-tips or foam ear-tips are single use components

#### Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)

#### Procedure:

- Clean the instrument by wiping outer case with a lint free cloth lightly dampened in cleaning solution
- Clean cushions and patient hand switch and other parts with a lint free cloth lightly dampened in cleaning solution
- Make sure not to get moisture in the speaker portion of the earphones and similar parts



## 4.2 Concerning repair

Interacoustics is only considered to be responsible for the validity of the CE marking, effects on safety, reliability, and performance of the equipment if:

1. assembly operations, extensions, readjustments, modifications, or repairs are carried out by authorised persons,
2. a 1-year service interval is maintained
3. the electrical installation of the relevant room complies with the appropriate requirements, and
4. the equipment is used by authorised personnel in accordance with the documentation supplied by Interacoustics.

The customer shall reach out to the local distributor to determine the service/repair possibilities including onsite service/repair. It is important that the customer (through local distributor) fills out the **RETURN REPORT** every time when the component/product is sent for service/repair to Interacoustics.

## 4.3 Warranty

Interacoustics warrants that:

- The PA5 is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service centre to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Interacoustics shall be at purchaser's risk.

In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- repaired by anyone other than an authorized Interacoustics service representative;
- altered in any way so as, in Interacoustics judgement, to affect its stability or reliability;
- subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced, or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability in connection with the sale of Interacoustics products.

**INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.**



## 5 Technical specifications

<b>Medical CE-mark</b>	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745. Approval of the quality system is made by TÜV – identification no. 0123.
<b>Standards</b>	Sound Pressure Level of the loudspeaker: ISO 389-7 Sound Pressure Level of the headphone: ISO 389
<b>Power</b>	Batteries 3 x 1.5 AA or 3 x 1.2V NiMH
<b>Frequencies</b>	500, 1000, 2000, 3000, 4000 Hz
<b>Stimuli</b>	Warble Tone, NB, WN
<b>Intensities</b>	Distance 50 cm 20 - 30 80 dB HL in 10 dB steps, Warble Tone and WN-10 dB in NB distance 16 cm+ 10 dB
<b>Warble Frequency</b>	5 Hz, □ 5%
<b>Sound Source</b>	Built in loudspeaker or headphone TDH39
<b>Light Stimulation</b>	3 LEDs arranged in a triangle; flash speed 5 Hz
<b>Tone and light stimulation</b>	Silent touch switches with automatic battery switch
<b>Dimensions</b>	L x W x H: approx. 25 x 7,5 x 5 cm Weight: approx. 0,4 kg



## 5.1 Calibration values

Values used by calibration of the output levels for the applied transducers are generally found in international, national and/or in some cases internal product standards.

It is the responsibility of the person who makes the calibration, that the correct set of values is used here. The calibration charts for the test setup in question is used to ensure that the correct correction values are considered.

By the initial factory calibration, it is required that the standardized output levels are reached as close as possible, and they should in general be within a reading of  $\pm 1$  dB for all type of signals.

By follow-up control of calibration, the allowed deviation of the output levels for the common signal types according to IEC 60645 and ANSI S3.6-2004 are:

	<b>IEC 60645</b>	<b>ANSI S3.6-2004</b>
Air conduction:	$\pm 3$ dB at 125 Hz to 4000 Hz	$\pm 3$ dB at 125 Hz to 5000 Hz
	$\pm 5$ dB at higher frequencies	$\pm 5$ dB at 6000 Hz and higher

## 5.2 Standards for production and calibration

Standards used:

For Sound Pressure Level of the loudspeaker: ISO 389-7

For Sound Pressure Level of the headphone: ISO 389

Values for Loudspeaker:

Frequency (Hz)	ISO 389-7 Tone (dB re. 20 $\mu$ Pa)	ISO 389-7 NB (dB re. 20 $\mu$ Pa)	White Noise in SPL
500	4,0	3,5	0 dB
1000	2,0	0,5	
2000	-1,5	-1,5	
3000	-6,0	-4,0	
4000	-6,5	-5,0	

Values for Headphone TDH39:

Frequency (Hz)	ISO 389 (dB re. 20 $\mu$ Pa)
500	11,5
1000	7,0
2000	9,0
3000	10,5
4000	9,5