

# easyScreen Operation Manual



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All available operation manuals can be found in the download center on the MAICO homepage:

Germany:



International:



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## Compliance

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**Caution for USA:** Federal Law restricts this device to sale by or on the order of a licensed medical professional.

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NuPrep® is a U.S. registered trademark of Weaver and Company.

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Sanibel® is a trademark of Sanibel supply registered in the USA, the European Union, Argentina, Brazil, Canada, the UK, Mexico, Australia, China, Japan, South Korea, and the Russian Federation.

# 1 Introduction

This section offers you important information about:

- the intended use inclusive indications of use of the device
  - contraindications of use
  - essential performance
  - features and benefits
  - a description of the device
- 

## 1.1 Intended Use Statement

### Indications for Use

The device TEOAE and DPOAE modules are intended for use in the audiologic evaluation and documentation of ear disorders using Transient Otoacoustic Emissions technology or Distortion Product Otoacoustic Emissions.

The device ABR module is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. It is to be used by trained personnel only, such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted. Hearing screenings are most successfully and efficiently performed in acoustically quiet surroundings. While this is not always achievable in a hospital environment, the screener should be aware of acoustic noise and control it to the extent that this is feasible.

### Target population

The target population for the TEOAE and DPOAE modules includes all ages. The population for the ABR module is newborns and infants up to 6 months of age. The TEOAE probe fit procedure is optimized for infant ears. Some ears with larger ear canal volume may not achieve a good probe fit.

It is recommended that screening should be performed when the newborn is medically stable and is at least 32 weeks postmenstrual age in the case of preterm infants.

The BERAphone® ABR transducer is optimized in size and shape for newborns up to approximately 3 months of age. Older infants with larger ears may be difficult to test with the BERAphone®. The key to an acceptable fit is to achieve contact of the ear cushion all around its edge with no gaps between the skin and the cushion. Any gaps can lead to a reduction in the stimulus intensity increasing test time and the chance of a Refer outcome.

### Clinical Use of the Measurement and Clinical Outcome

The easyScreen is a screening device used for audiologic evaluation and documentation of ear and nerve disorders. In case of a positive result the patient shall be referred for follow-up diagnostic examination. Infants who have risk factors for hearing loss should be referred for follow-up and periodic re-screening of hearing even if the result of the hearing screening is a Pass.

## 1.2 Contraindications

Contraindications to testing include recent stapedectomy or middle ear surgery, a discharging ear, acute external auditory canal trauma, discomfort (e.g., severe otitis externa) or occlusion of the external auditory canal. Testing should not be performed on patients with such symptoms without a medical doctor's approval. The BERAphone® is intended for use on intact, external skin around the ears and on the scalp. It should not be used if the skin is not intact or if the baby has a contagious dermatological condition.

## 1.3 Features and Benefits

### 1.3.1 General Information About the easyScreen

The easyScreen features:

- Touchscreen operation
- Long battery life
- Wireless charging in cradle
- Screening ABR with patented CE-CHIRP® stimulus<sup>1</sup>
- Multiple ABR transducer choices including the unique, patented BERAphone® which eliminates the need for disposable electrodes and EarCups™
- DPOAE and/or TEOAE option
- Powerful response detection algorithms
- Simple Pass/Refer outcome

The easyScreen is available with or without a wireless label printer.

### 1.3.2 Licenses

The following functions are available:

- ABR
- TEOAE
- DPOAE

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**NOTE:** Each license key is specific for the serial number of your device.

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In case you want to purchase another license, please, contact MAICO or your local distributor to determine eligibility. Additional licenses are installed by the distributor.

### 1.3.3 easyScreen Cradle

The easyScreen cradle allows you to:

- Charge the easyScreen battery

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<sup>1</sup> Screening ABR is also possible using a standard Click stimulus. See Section 6.6 for more information.

## 1.3.4 easyScreen HearSIM™ PC Application (Configuration Dependent)

The HearSIM™ PC application in combination with the OtoAccess® Database application allows you to:

- Store, view and manage patient information
- Store, view and manage test data transferred from the easyScreen
- Transfer names of patients requiring testing to the easyScreen
- Print test results on a standard PC-compatible printer
- Export patient and test data (HiTrack, OZ Systems, CSV and XML formats supported)
- Configure various easyScreen device settings including screening protocols
- Manage easyScreen users
- Manage easyScreen custom lists (e.g. Screening facility names, risk factors)
- Manage HearSIM™ (OtoAccess®) user accounts

## 1.3.5 Printing Options

Printing test results from the easyScreen is accomplished in a variety of ways:

- Print directly from easyScreen using the optional wireless label printer that is available from MAICO.
- Transfer easyScreen test data into the optional HearSIM™ with OtoAccess® database PC applications and print results using your standard printer attached to the PC.

## 1.4 Description

### 1.4.1 General

The easyScreen features a touchscreen display and user-friendly user interface in a compact hardware design. It can be purchased with various licenses allowing you to perform different hearing screening tests.

### 1.4.2 ABR

easyScreen uses fast rate automatic auditory brainstem response (ABR) technology to screen patients for hearing loss. Using the default protocol, a modified click stimulus, the CE-CHIRP<sup>®</sup> of 35 dB nHL, is delivered into the patient's ear while electrodes placed on the patient's head measure EEG activity. Alternate protocols with different stimulus intensity levels as well as a click stimulus are available. See section 6.6.

The EEG is processed and analyzed automatically using the easyScreen's powerful, response detection algorithm. When a response is detected, the screening is stopped automatically, and a Pass result is assigned to the ear tested. When no response is detected after 3 minutes of EEG activity has been processed, a Refer result is assigned.

### 1.4.3 BERAphone<sup>®</sup>

The BERAphone<sup>®</sup> contains both a one-channel preamplifier for recording EEG from re-usable electrodes placed on the patient's skin as well as a transducer for delivery of the acoustic stimulus. It eliminates the need for traditional disposable electrodes and ear couplers.

The BERAphone<sup>®</sup> is a non-critical, patient care item since it comes into contact with intact skin, but not mucous membranes. For such devices, guidelines from both the US Center for Disease Control<sup>12</sup> (CDC) and the Robert-Koch-Institut Bundesinstitut für Infektionskrankheiten und nicht übertragbare Krankheiten (Berlin, Germany) recommend cleaning and disinfection with a hospital-grade, surface disinfectant.

### 1.4.4 TEOAE

Transient Evoked Otoacoustic Emissions (TEOAE) technology uses a click stimulus to screen patients for cochlear hearing loss. The emissions are clearly related to the stimulus and therefore can be measured via a sensitive microphone placed in the patient's ear canal. The responses can be divided into frequency bands for assessment.

### 1.4.5 DPOAE

Distortion product otoacoustic emissions (DPOAE) technology uses pairs of pure tones presented in sequence to screen patients for cochlear hearing loss. The emissions are clearly related to the stimulus and therefore can be measured via a sensitive microphone placed in the patient's ear canal.

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<sup>2</sup> Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. CDC, Department of Health and Human Services, USA

## 2 Warnings and Cautions

This section offers you important information about:

- how to read the operation manual
- where to spend special attention
- the customer responsibility
- the explanation of all regulatory symbols used
- important cautions and warnings that have to be considered during the whole time handling and operating your device

### 2.1 Reading this Operation Manual

This operation manual contains information pertinent to the use of the easyScreen system including safety information as well as maintenance and cleaning recommendations.

It is highly recommended that users read the manual in its entirety prior to use of the easyScreen device on a patient.



**READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!**

Use this device only as described in this manual.

All images and screenshots are only examples and may differ in appearance from the actual device settings.

In this manual the following two labels identify potentially dangerous or destructive conditions and procedures:



**WARNING**

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



**CAUTION**

The **CAUTION** label identifies conditions or practices that could result in damage to the equipment

**NOTE:** Notes help you identify areas of possible confusion and avoid potential problems during system operation.

## 2.2 Customer Responsibility

All safety precautions given in this operation manual must be observed at all times. Failure to observe these precautions could result in damage to the equipment and injury to the operator or subject.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this device, the more stringent rules should take precedence.



This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from MAICO.

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**NOTE:** Customer responsibility includes proper maintenance and cleaning of the device (see sections 3.2 and 3.3). Breach of the customer responsibility can lead to limitations of Manufacturer's Liability and Warranty (see sections 2.3 and 3.1).

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**NOTE:** In the unlikely case of a serious incident, inform MAICO as well as the competent authority of the Member State in which the user is established.

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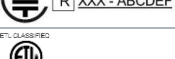


## 2.3 Manufacturer's Liability

Usage of the device in a way deviant from the intended use will lead to a limitation or termination of the manufacturer's liability in case of damage. Improper use includes disregarding the operation manual, the operation of the device by underqualified personnel as well as making unauthorized alterations on the device.

## 2.4 Regulatory Symbols

The following Table 1 gives an explanation of the symbols used on the device itself, on the packaging and the accompanying documents including the Operation Manual.

Table 1 Regulatory Symbols

REGULATORY SYMBOLS	
SYMBOL	DESCRIPTION
	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Return to authorized representative, special disposal required
	Reference number
	Medical Device
	Patient applied part type BF according to IEC 60601-1
	Refer to operation manual (mandatory)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
	Voltage transformer
	Do not reuse
	Conforms to Medical Device Regulation (EU) 2017/745
	Turns the device on or off. Long press to turn off. Short press to wake the device from sleep mode (display off).
	Non-ionizing electromagnetic radiation
	Label Marking of Radio Equipment based on Certified Type
	ETL listed mark
	Logo

## 2.5 General Precautions



Before starting a measurement make sure, that the device works properly.

Use and store the device indoors only. For operation, storage and transport conditions see table in section 6.



Do not drop or otherwise cause undue impact to this device. If the device is dropped or otherwise damaged, return it to the manufacturer for repair and/or calibration. Do not use the device if any damage is suspected.



Equipment is not user repairable. Repairs must be performed by a qualified service representative only. No modifications of the equipment are allowed by anyone other than a qualified MAICO representative. Modification of the equipment could be hazardous.

No parts of the equipment can be serviced or maintained while in use with the patient.

## 2.6 Electrical and Electrostatic Safety



This icon indicates that patient applied parts of the device conform to IEC 60601-1 Type BF requirements.

The system is internally powered.



In case of emergency, disconnect the device from the computer.

In Case of Emergency



In case of emergency, disconnect the device from power supply. Position the device in such a way that it can be easily disconnected from the power supply at any time.

In Case of Emergency

Do not use the device if the mains cable and/or the plug is damaged.



To transfer data to a PC, establishing a PC-connection via USB is required. See section 4.4.11 on how to safely establish a connection with a power supplied PC or laptop (medical device/non-medical device) or to a battery-driven laptop.

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.



If the device is connected to a PC (IT equipment forming a system) assembly and modifications shall be evaluated by qualified medical technician according to safety regulations in IEC 60601-series.



Do not touch the contacts of the device and the patient at the same time.

If the device is connected to a PC (IT equipment forming a system) do not touch the patient and the IT equipment at the same time.

The consequence of not following this warning could be a too high leakage current to the patient.



Do not touch the contacts of the device and the patient at the same time.

The consequence of not following this warning could be a too high leakage current to the patient.



The device is not intended for operation in areas with an explosion hazard. Do NOT use the device in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc. If the device is not used switch it off and disconnect it from the power supply.

Never short-circuit the terminals.



To avoid the risk of electric shock, this equipment must only be connected to the medical power supply originally delivered by MAICO. Using another power supply can also lead to electrical damage on the device.

Prevent cable breakage: cables must not be bend or buckled.



Before performing any service to the insert earphones, such as disconnecting the transducer boxes from the cable, you must uncouple the easyScreen transducers and electrodes from the patient.



Do not open the case of the easyScreen device. Refer servicing to qualified personnel.

## 2.7 Electromagnetic Compatibility (EMC)



This device is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

The device fulfills the relevant EMC requirements.

Avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc.



Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.



Patients with Ventriculoperitoneal Shunts must observe a safety separation of 5 cm between the shunt and the active part of the transducer. See section 6.5.



Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The list of accessories, transducers and cables can be found in the section 6.5 of this operation manual.



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the easyScreen, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

## 2.8 Use in Home Healthcare Environment



This device is intended to be used in home healthcare environments (outside professional healthcare facilities). The device is only intended to be charged in professional healthcare facilities. This means that only the hand-held unit is intended for home healthcare environments. The charger, power supply and cradle are not to be used in home healthcare environments.

## 2.9 Battery Safety and Capacity

### 2.9.1 Safety Information



#### **Explosion hazard**

The internal battery must be only replaced by an authorized service representative. Damage to the electronics resulting from an attempt to change the battery by someone other than an authorized representative will not qualify for repair under the product warranty.



#### **Device damage due to overheating**

Foreign materials (e.g., metal objects, magnets, and magnetic stripe cards ) between the device and the wireless charger as well as labels or stickers on the backside of the device can disturb the charging process and cause damage due to overheating.

- Do not place foreign materials between the device and the charger.
- Do not apply stickers on the backside of the device.

### 2.9.2 Battery Capacity

The capacity of the battery will degrade over time with repeated charging/discharging cycles. The need to replace the battery due to diminishing capacity depends on usage patterns.

To extend battery capacity, do not allow the battery to fully discharge. Instead, place the easyScreen back in the cradle after use even if the battery has not been fully depleted.

## 2.9.3 Battery Life per Charge

- Estimated Battery Life for ABR Screening - > 50 ABR screens
- Estimated Battery Life for OAE Screening - >150 OAE screens

Test duration effects battery life. Test duration depends on the state of the baby and test technique issues that can vary widely. Therefore, the number of screens per battery charge may vary significantly in your facility.

## 3 Warranty, Maintenance and After-Sales Service

This section offers you important information about:

- **warranty conditions**
  - **maintenance**
  - **cleaning and disinfection recommendations**
  - **handling disposables**
  - **troubleshooting**
  - **recycling and disposal of the device**
- 

### 3.1 Warranty

The MAICO device is guaranteed for at least one year. Ask your authorized local distributor for more information.

This warranty is extended to the original purchaser of the device by MAICO through the distributor from whom it was purchased and covers defects in material and workmanship for a period of at least one year from date of delivery of the device to the original purchaser.

The device shall only be repaired and serviced by your distributor or by an authorized service center. Opening the device case will void the warranty.

We urgently advise you against attempting to rectify any faults by yourself or commissioning non-experts to do so.

Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

In the event of repair during the guarantee period, please, enclose evidence of purchase with the device.

The expected service life for the device is 7 years.

Accessories like eartips and electrodes have no service life guarantees.

### 3.2 Maintenance

In order to ensure that your device works properly, the easyScreen should be checked and calibrated at least every 12 months. If these checks are not done legal regulations may be violated and warranties may be void. The use of non-calibrated devices can lead to incorrect test results and is not advisable. The service and calibration must be performed by your dealer or by a service center authorized by MAICO.

When returning the device for repairs or calibration it is essential to send the acoustic transducers with the device. Please, include a detailed description of faults. In order to prevent damage in transit, please, use the original packing if possible when returning the device.

## 3.3 Cleaning and Disinfection Recommendations

### 3.3.1 General



Also, check-out our training videos:

[MAICO Training | easyScreen with earCups™ | ABR | 6/6 Disinfection - YouTube](https://www.youtube.com/watch?v=UFTWCKxJ5Eo)

<https://www.youtube.com/watch?v=UFTWCKxJ5Eo>



[MAICO Training | easyScreen | OAE | 6/6 Disinfection - YouTube](https://www.youtube.com/watch?v=avQL0AWMMms)

<https://www.youtube.com/watch?v=avQL0AWMMms>

It is recommended that parts (device and accessories like insert phones and probe tips, ear cushions, reusable electrodes) which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedures between patients.

Recommendations for cleaning and disinfection of MAICO device presented in this document are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.

If there is not a high infection potential, MAICO recommends:

- Before cleaning always switch off and disconnect the device from power supply.
- Remove disposable EarCup™, EARturtle™, eartips or electrodes prior to disinfection.
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the easyScreen and its accessories by wiping the surfaces with wet disinfection wipes. Follow the instructions on the specific disinfection product.
  - Wipe before and after each patient
  - After contamination
  - After infectious patients



**CAUTION**

To avoid damage of the device and its accessories, please mind the following:

- Do not autoclave or sterilize the device or probes.
- Do not use the device in the presence of fluid that can come into contact with any of the electronic components or wiring.

Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by a MAICO certified service technician.

Do not use hard or pointed objects on the device or its accessories.

For more detailed cleaning recommendations see the following sections 3.3.2 to 3.3.8 and follow the instructions on the items that are relevant for your system.

### 3.3.2 Cleaning and Disinfecting the Touchscreen

Use a lens cleaning or microfiber cloth to clean the easyScreen touchscreen. Disinfect the touchscreen of the easyScreen by wiping the surfaces with wet disinfection wipes.

### 3.3.3 Cleaning and Disinfecting the Case and Cables



**CAUTION**

Use caution while cleaning.

Before cleaning, remove the easyScreen from the cradle and unplug the cradle from AC power.

Use a damp cloth to clean the plastic parts of the easyScreen and cradle.

For disinfection use a disinfectant wipe rather than a spray product. Make sure that excess liquid from the wipe does not seep into any sensitive areas such as connectors, BERAphone<sup>®</sup> speaker and seams where plastic pieces connect such as the edges around the touch screen.

Follow the instructions on the disinfection product.

### 3.3.4 Cleaning and Disinfecting the BERAphone<sup>®</sup>



Also, check-out our training videos:

[MAICO Training | easyScreen BERAphone<sup>®</sup> | 8/8 Disinfection - YouTube](https://www.youtube.com/watch?v=Xqz3__BgsvQ)

[https://www.youtube.com/watch?v=Xqz3\\_\\_BgsvQ](https://www.youtube.com/watch?v=Xqz3__BgsvQ)

The BERAphone<sup>®</sup> features stainless steel electrodes and a silicone ear cushion designed to make direct contact with the baby's skin. Assuming intact skin on the baby, the device is considered non-critical according to the CDC guidelines for minimizing cross-infection, meaning that the device contacts the patient only externally on intact skin. Therefore, sterilization is not required. However, the device must be cleaned and disinfected with a medical or hospital-grade disinfectant prior to re-use.

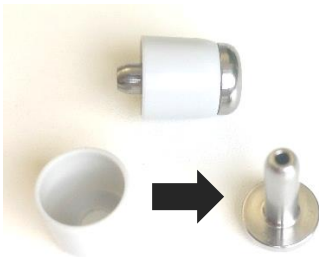
Use of a non-alcohol based disinfectant is recommended. Non-alcohol based products contain the active ingredient referred to as quaternary ammonia compound. The quaternary ammonia compound is specifically designed to disinfect rubber, plastic, silicone and acrylic products which are commonly used in hearing evaluation devices.

Follow this process for cleaning and disinfection of the BERAphone<sup>®</sup> after use:

1. Clean residual gel from the electrodes and ear cushion using a tissue or a disinfectant wipe.
2. Disinfect the electrodes, ear cushion and other components that made contact with the baby or the baby's bedding by wiping them with a fresh hospital-grade disinfectant wipe.
  - a. Follow the directions for use and precautions on the disinfectant product.
  - b. If the disinfectant wipe is very wet, do not allow disinfectant to drip down into the black, perforated speaker inside the BERAphone<sup>®</sup> ear cushion area.
3. Disinfect any other components that touched the baby or the baby's bedding such as the cable, BERAphone<sup>®</sup> handle, etc.
4. Allow the disinfectant to dry thoroughly according to the manufacturer's instructions for maximum efficiency before using it on the next patient.

Daily routine periodic inspection inside the electrode gel protectors and beneath the ear cushion is recommended:

1. Remove the electrodes from the fixed electrode posts by pulling them straight out.
2. Inspect the inside of the gel protectors looking for residual electrode gel.
  - a. The presence of gel inside the gel protector is generally an indication that the screeners are applying an excessive amount of gel to the electrode and/or the baby.
  - b. Re-instruct the screeners to use only a small amount of gel on the electrode and to reduce the amount of gel used to prepare the baby's skin.
3. If gel is observed inside the gel protector, remove it from the stainless-steel part of the electrode by sliding it off (Figure 1).



**Figure 1**

4. Clean the stainless-steel part of the electrode with a disinfectant wipe. The stainless-steel part of the detached electrode can be autoclaved if desired.
5. Clean the gel protector with a disinfectant product using a cotton-tipped applicator to reach into the cavity to remove any gel inside.
6. Allow the gel protector and stainless-steel electrode to dry thoroughly and then re-assemble.
7. Inspect the inside of the fixed electrode post for any sign of electrode gel.
8. If the stainless-steel electrodes or the gel protectors cannot be adequately cleaned, replace them with a new set of electrodes.
9. Remove the ear cushion from the BERAPhone® and inspect the plastic beneath it for residual gel. Clean it with a tissue and disinfectant wipe being careful not to drip excess liquid into the speaker.
10. Inspect the ear cushion for cracks or changes in the softness or colour of the material.
11. Replace the ear cushion with a new one as needed.

### 3.3.5 Cleaning the OAE Probe Tip – Standard OAE Probe

In order to achieve accurate measurements it is important to make sure that the probe system is kept clean at all times. Therefore, check the probe for debris in the channels after each use and clean them as needed. It is critical to remove cerumen from the probe tip's small acoustic channels. Therefore, please follow the illustrated instructions below.



Never clean the probe tip while the tip is still attached to the probe!



Use the Bridge & Implant Floss or the ProxySoft 3 in 1 Floss for cleaning (Figure 2).

Discard floss after use.

**Figure 2**



Unscrew the probe cap by turning it in a counter clockwise direction. (Figure 3).

**Figure 3**



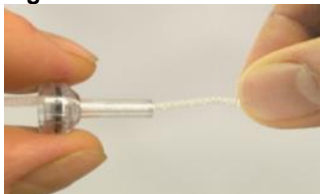
Take the plastic probe tip out of the probe (Figure 4).

**Figure 4**



Insert the blue end of the floss from back to front through one of the probe channels (Figure 5).

**Figure 5**



Pull the floss along its entire length through the channel (Figure 6).

Proceed in the same way with all 4 probe channels. Use the floss only once.

**Figure 6**



Use a thick or a thin floss depending on the size of the channel (Figure 7).

**Figure 7**



Figure 8

To access and clean the larger channel it is necessary to remove the gasket from inside the probe tip. You can do this using a fine pin. Push the gasket back into place after cleaning (Figure 8).



Figure 9

Place the probe tip back onto the probe. Make sure that the plastic pegs are inserted into the appropriate corresponding cavities (Figure 9).



Figure 10

Screw the probe cap back on the probe. The force of tightening the cap will tighten the screw sufficiently. Never use tools to fix the probe cap! Use only your fingers and screw it on until secure (Figure 10).

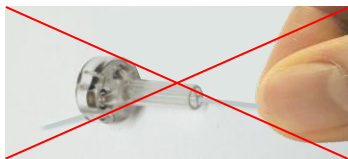


Figure 11

Only insert the cleaning floss or wire into the base of the probe to ensure wax/debris is pushed out of the probe tip instead of into it. This also protects the gasket from being damaged (Figure 11).

If the inside of the probe, beyond the removable probe tip, is clogged or damaged, only a MAICO authorized distributor can repair the parts. For further information ask your authorized local distributor or MAICO.

### 3.3.6 Replacing Wax Guards – SnapPROBE™



Also, check-out our training videos:

[easyScreen SnapPROBE™ Wax Guard Replacement - YouTube](https://www.youtube.com/watch?v=b2m3EuT386w)

<https://www.youtube.com/watch?v=b2m3EuT386w>

To achieve accurate measurements, it is important to keep the probe system clean at all times. Therefore, the infant SnapPROBE™ is operated with disposable single-use eartips.

The probe uses replaceable wax guards to prevent clogging of the probe itself. It is critical to replace the wax guards if they show signs of debris inside. Therefore, follow the illustrated instructions below.



**CAUTION**

Make sure no liquid enters the openings of the probe to avoid any damage to the sensitive components.



Figure 12

The SnapPROBE™ uses a special Sanibel® eartip that couples the probe to the ear and provides 3 separate acoustic channels.

To enhance infection control, each acoustic channel is protected with a wax guard. It prevents earwax from entering the probe body (Figure 12).

The wax guards must be regularly checked for earwax in the openings. If you see earwax in the wax guard, replace it.

If there is any cerumen or debris in one of the 3 acoustic channels after testing the first ear a new eartip needs to be used for testing the other ear.

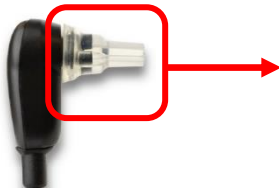


Figure 13

Remove the eartip from the probe by simply snapping it off the probe (Figure 13).

Discard the disposable eartip. It is for single use only.

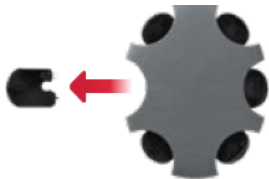


Figure 14

Pull out a probe wax guard replacement tool from the dispenser (Figure 14).



Figure 15

The tool has 2 pins (Figure 15):

- Empty pin (1): Push this pin in the wax guard and pull the wax guard straight out of the probe body. Discard the wax guard as it cannot be cleaned or reused.
- Pin with new wax guard (2): Press the new wax guard into this hole and pull the tool out again, to keep the new wax guard in place. Discard the tool.

**NOTE:** If the inside of the probe, beyond the replaceable filters, is clogged or damaged, only a MAICO authorized distributor can repair the parts. For further information ask your authorized local distributor or MAICO's technical customer support.

### 3.3.7 Disposables

Use only the Sanibel Supply disposable supplies that are supplied with your easyScreen system.



Eartips, EarCups™, EARturtle™ and adhesive electrodes are intended for single-use only. They shall be discarded after use. They cannot be cleaned.



**WARNING**

In case of re-use of the single-use disposables, you enhance the risk of cross-contamination!

Always apply new eartips, EarCup™, EARturtle™ and adhesive electrodes for each patient.



**CAUTION**

If you use heavily clogged or cleaned wax guards, the probe may become damaged.



**WARNING**

The use of clogged or cleaned wax guards can lead to incorrect measurement results.

Check regularly if the wax guards are clogged and replace them with new ones if necessary and discard those that are clogged. Always use new wax guards.

### 3.3.8 Accessories/Replacement Parts

Some reusable components are subject to wear with use over time. We recommend that you keep these replacement parts available (as appropriate for your easyScreen device configuration).

## 3.4 Troubleshooting – ABR Issues

In case of problems see below for symptoms, possible causes and suggested troubleshooting.

**Table 2 Troubleshooting**

SYMPTOM	POSSIBLE CAUSE	SUGGESTED TROUBLESHOOTING
Cannot pass impedance for one or more electrodes	Ineffective skin preparation	Remove electrode and use NuPrep® or other skin preparation product to prepare the skin.
	Electrode has lost contact with the skin	Check contact of electrodes to the skin at the prepared sites.
	Electrode lead wire is not fully attached to the preamplifier	Check connections at the preamplifier cable jack and try again.
	Electrode lead wire has a short in the wire	Replace the electrode lead wire with a new one (may need to replace more than one of the electrode wires).
	Connection of preamplifier or BERAphone® cable to the easyScreen ABR/OAE connector is not secure	Check the connection of the preamplifier or BERAphone® cable to the easyScreen; remove it and re-insert it verifying that it is securely attached.

SYMPTOM	POSSIBLE CAUSE	SUGGESTED TROUBLESHOOTING
Excessive artifacts are observed during the measurement	Baby is too active, moving, sucking, crying, muscle tension, etc.	Pause the recording and calm the baby. Swaddle the baby in a blanket. Resume recording only when the baby is quiet.
	Electrode is losing contact with the skin	Check electrode contact to skin making sure it is contacting the prepared skin.
	Electrode lead wire is broken or BERAphone® electrode has poor internal contact which may lead to intermittent contact to skin	Replace the electrode lead wire with a new one (may need to replace more than one of the electrodes).
	Electrical interference is interfering due to AC connection	If easyScreen is being used in the cradle with AC attached, unplug the cradle power supply from the outlet to run on battery only.
	Electromagnetic interference is present from other electronic devices in the environment	Shut down all unnecessary devices near the test area including cell phones, tablets, lights, TVs, etc. Move as far away as possible from devices that cannot be powered off. Ask the baby's doctor or nurse to assist with troubleshooting if the baby is connected to monitoring devices to determine if they can be powered off temporarily for troubleshooting. RFID devices used for security that are attached to or near the baby may cause interference. Ask the nurse or doctor if they can be temporarily removed. Try testing in a different location.
High refer rate	Screening babies when they are too active	Perform screenings only when the baby is quiet – preferably sleeping, comfortable, and recently fed. Screen just after feeding when Mom is still holding the baby.
	Screening babies within a few hours after birth when the ear canals are still wet and possibly occluded with vernix	Wait to screen until at least 12 hours after birth when it is more likely that the ear canals are clear.
	Environment is too acoustically noisy	Switch off all sources of acoustic noise such as TVs, radios. Ask others in the environment to stop talking. Ask parents to remove noisy siblings from the test room. Close the door to reduce acoustic noise coming from the hallway or nearby rooms. Move away from acoustic noise sources such as air conditioning vents, devices that have motors that turn on and off.

SYMPTOM	POSSIBLE CAUSE	SUGGESTED TROUBLESHOOTING
	EarCup™, EARturtle™, BERAprone® or eartip is not applied to the ear properly	<p>Make sure that the EarCup™, EARturtle™ or BERAprone® ear cushion is surrounding the ear and that there are not big gaps between the coupler and baby's skin.</p> <p>For eartips make sure that the eartip is securely inserted into the baby's ear canal</p>
	Stimulus is not coming through the transducer	<p>Check the connection of the transducer cable into the preamplifier; remove it and re-insert it verifying that it is securely attached.</p> <p>Check the connection of preamplifier or the BERAprone® cable to the easyScreen ABR/OAE connector.</p> <p>Check the connection of the insert earphone cable to the red and blue transducers.</p> <p>Check the insert earphone adapter to see if it is cracked or occluded. The insert earphone clear adapter may need to be cleaned. Refer to the cleaning instruction that was packaged with the insert earphones.</p> <p>Make sure the insert earphone tubes are free of any crimping or compression; replace the tube with a new one.</p> <p>Replace the insert earphone cable with a new one.</p>
Data collection is stalled in "Reconnect Electrode" message	Electrostatic discharge event	Stop the measurement and start again.
"Reconnect Electrode" message during testing	Electrode is not contacting skin	Reapply electrode to prepared skin site.
"Check Cables" message during screening	Electrode contact may be poor	Check electrode contact to skin.
Touchscreen is non-responsive to touch	Software is frozen in a process	Hold the easyScreen power button for 10 seconds to force a power off and then reboot the system.
easyScreen battery is not charging when device is in the cradle	Poor connection of power supply; wrong power supply	Verify that you are using the correct power supply for the easyScreen and it is fully connected.
"Mains Noise Detected" in status area of main test screen; artifacts occurring	easyScreen has detected a high level of electrical noise at frequencies that could cause an inaccurate test result	Check electrodes for good contact; check environment for sources of electrical interference and try to control them; move to a new location.

## 3.5 Recycling and Disposal



Within the European Union it is illegal to dispose of electric and electronic waste as unsorted municipal waste. According to this, all MAICO products sold after August 13, 2005, are marked with a crossed-out wheeled bin. Within the limits of Article (9) of DIRECTIVE 2002/96/EC on waste electrical and electronic equipment (WEEE), MAICO has changed their sales policy. To avoid additional distribution costs we assign the responsibility for the proper collection and treatment according to legal regulations to our customers.

Non-European countries

Outside the European Union, local regulations should be followed when disposing of the product after its useful life.



Batteries may explode or cause burns, if disassembled, crushed or exposed to fire or high temperatures.



The internal battery should only be replaced by an authorized service representative. Damage to the electronics resulting from an attempt to change the battery by someone other than an authorized representative will not qualify for repair under the product warranty.

## 4 Unpacking and Hardware Orientation

This section provides information on:

- **unpacking the system**
  - **becoming familiar with the hardware inclusive connections**
  - **system assembly**
  - **using the label printer**
  - **how to power the easyScreen**
  - **how to store the device**
- 

### 4.1 Unpacking the System

#### Check Box and Contents for Damage

- It is recommended that you unpack your easyScreen carefully making sure that all components are removed from the packing materials.
- Verify that all components are included as shown on the packing slip included with your shipment.
- If any component is missing, contact your distributor immediately to report the shortage.
- If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.

#### Reporting Imperfections

Notify the carrier immediately if any mechanical damage is noted. This will ensure that a proper claim is made. Save all packaging material so the claim adjuster can inspect it as well.

#### Report Immediately any Faults

Any missing part or malfunction should be reported immediately to the supplier of the device together with the invoice, serial number, and a detailed report of the problem.

#### Keep Packaging for Future Shipment

Save all the original packing material and the shipping container so the device can be properly packed if it needs to be returned for service or calibration (see section 3.2).

The easyScreen comes with different components (see Table 3). The availability of configurations with the following components are country-specific. Contact your local distributor for more information.

Table 3 List of Components

List of Components		
<b>Components – General</b>	easyScreen Cradle	
	Cradle Power Supply – Model UES12LCP-050160SPA	
	Stylus Pen	
	Neckstrap	
	Hardware Pass-Checker	
	Infant Ear Simulator	
	Label Printer HM-E200 Kit (Includes 2 Rolls of Thermal Label Paper)	
	USB Cable	
	EARturtle™ Adapter Kit	
	Carrying Case	
	Operation Manual	
	Quick Guides	
	<b>ABR-Related Components</b>	Preamplifier*
		Electrode Lead Wires*
NuPrep® Skin Preparation Gel		
<b>Transducers (One or More Included as Selected at Time of Purchase)</b>	IP30 (50 Ω) Insert Earphone With Eartip Adapters Kit*	
	IP30 (50 Ω) Insert Earphone With EarCup™ Adapters Kit*	
	Standard OAE Probe	
	SnapPROBE™ (OAE)	
<b>Disposables Supplied – With Insert Earphones With EarCups™</b>	BERAphone® (Transducer & Preamplifier)*	
	ABR EarCup™ Accessory Kit	
<b>Disposables Supplied – With Insert Earphones With EARturtle™</b>	ABR EARturtle™ Accessory Kit	
<b>Disposables Supplied – With Insert Earphones With Eartips</b>	IP30/Probe Accessory Kit	
	Sanibel® Eartip Starter Kit*	
<b>Disposables Supplied – With OAE Probe</b>	Probe Tip Kit*	
	Sanibel® Eartip Starter Kit*	
	SnapPROBE™ Accessories Box	
	Probe Cleaning Kit	
	IP30/Probe Accessory Kit (ABR only)	
<b>Supplied with BERAphone®</b>	BERAphone® Accessory Kit*	
	BERAphone® Hardware Tester	
<b>Software/Electronic Files</b>	HearSIM™ with OtoAccess® Database PC applications (separate optional purchase)	
	HearSIM™ Installation Instructions	
	USB drive with Operation Manuals and Quick Guides.	

\* Applied part according to IEC 60601-1

## 4.2 Use of Equipment After Transport and Storage

Make sure the device is functioning correctly before use. If the device has been stored in a colder environment (even for shorter time) allow the device to become acclimatized. This can take a long time depending on the conditions (like environmental humidity). You can reduce the condensation by storing the device in its original packaging. If the device is stored under warmer conditions than the use conditions no special precaution are required before use. Always ensure proper operation of the device by following routine check procedures for audiometric equipment.

## 4.3 Hardware Orientation

### 4.3.1 Display, Switch and Charging Light Indicator on the easyScreen

Viewing your easyScreen from the front side, you will see the touch screen display, the On/Off/Home switch, and a charging light indicator (Figure 16). For detailed information on the light modes in different conditions see section 4.4.12.4.



Figure 16

### 4.3.2 Connection on the easyScreen

The top view shows the connector for attaching the ABR preamplifier, BERAPHone® or the OAE probe cable (Figure 17).



Figure 17

The bottom view shows the micro-USB connector (1) and the built-in slot for attaching a neck lanyard (2) for transport of the device (Figure 18).



Figure 18

### 4.3.3 Connections and Light Indicator on the Cradle

Cradle features are shown below.

The LED (1) indicates the power status of the cradle (on = connected to power supply, off = not connected) (Figure 19).



Figure 19

Figure 20 shows the power supply connector.

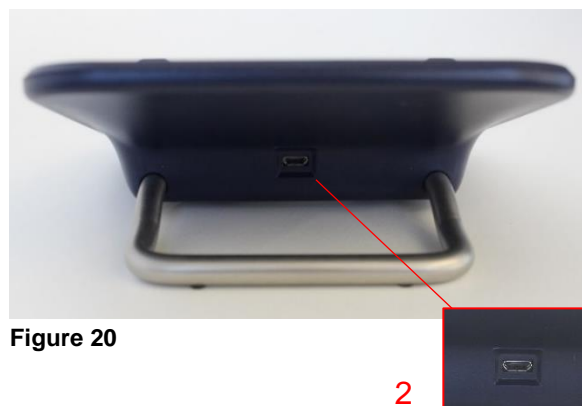


Figure 20

### 4.3.4 Display and Further Components



Figure 21

#### Display

The display on the easyScreen is a resistive touch screen that allows operation with gloves (Figure 21). It responds to the pressure of touching the icons. This can be accomplished with a finger or a pointing device. Care should be taken not to scratch the surface of the touch screen overlay.



Figure 22

#### easyScreen BERAphone® (Only for ABR)

The BERAphone® has reusable, stainless-steel electrodes, transducer and preamplifier integrated in one unit so that no disposables are needed. A button let you start the test and LED's provide feedback about the selected ear, impedance and test status. The spring-loaded electrodes adapt to the shape of the haead and the forehead electrode can be rotated or replaced by a longer electrode for smaller baby heads.



Figure 23

#### Preamplifier Cable (for ABR Only)

The preamplifier cable connects to the top of the easyScreen when using some of the available transducers. It is not used with the BERAphone®. Electrode lead wires and the acoustic transducer connect to the jacks at the top of the preamplifier cable for performing ABR screenings (Figure 23).



Figure 24

### Insert Earphone Cable (for ABR Only)

The insert earphone cable connects to the jack on the top edge of the preamplifier cable. For testing, the insert earphone EarCup™ adapters at the end of the red and blue tubes are inserted into the foam edge of the EarCups™ or the EARturtle™ adapters into the opening of the silicon ear pieces when using EARturtle™. If eartips are used, disposable eartips are attached to the clear eartip adapters at the end of the tubes (Figure 24).



Figure 25

### Standard OAE Probe (for ABR and OAE)

The OAE ear probe must be used for OAE screening. However, it can also be used as the transducer to deliver the acoustic stimulus for ABR screening as well. In this case the OAE probe connects to the preamplifier cable. For testing connect a disposable eartip of the proper size for the patient's ear onto the probe tip (Figure 25).



Figure 26

### OAE SnapPROBE™ (for ABR and OAE)

The SnapPROBE is a dedicated OAE probe for screening of newborns. For testing connect a disposable eartip of the proper size for the patient's ear onto the probe tip (Figure 26).



Figure 27

### Electrode Lead Wires (for ABR)

Electrode lead wires are provided with the system purchase when ABR is included and the preamplifier is needed. The color-coded plugs connect to the jacks on the top of the preamplifier cable (Figure 27).



Figure 28

### Home Health Care Transport

Use the carrying bag that is provided with the delivery of your easyScreen (Figure 28).



Figure 29

### Label printer

The wireless thermal printer (Figure 29) allows the direct printing of labels from the easyScreen.

Pairing to the easyScreen is required in preparation for wireless printing (see section 5.14).

## 4.4 System Assembly

### 4.4.1 General



Also, check-out our training videos:

[MAICO easyScreen - Components and Setup - YouTube](https://www.youtube.com/watch?v=E-NJ8wIIP3E)

<https://www.youtube.com/watch?v=E-NJ8wIIP3E>

The easyScreen will require some assembly before use including one of the following depending on your system purchase and test method:

- Connecting the BERAPhone® for ABR  
OR
- Connecting the ABR preamplifier cable, ABR transducer and electrode lead wires  
OR
- Connecting a OAE probe to easyScreen for OAE testing

### 4.4.2 Connecting the BERAPhone®, Preamplifier Cable or OAE Probe to easyScreen



Figure 30



Align the dot on the plug at the end of the BERAPhone® cable, the preamplifier cable or OAE probe with the socket at the top of the easyScreen which also has a small dot to assist with alignment. Insert the plug and push it securely into place (Figure 30).

The plug contains a series of small metal pins that insert into corresponding jacks in the socket. Be careful that the plug and socket are properly aligned so that the pins are not bent or broken during insertion. **Do not twist the connector in the socket.**

Align the plug at the end of the preamplifier cable with the socket at the top of the easyScreen with the dot on the preamplifier connector on the top. Insert the plug and push it securely into place.

### 4.4.3 Connecting the Insert Earphone Cable or OAE Probe to the Preamp



Align the plug at the end of the insert earphone cable or OAE probe with the socket at the top of the preamplifier cable marked with the graphic . Insert the plug and push it securely into place (Figure 31).

Figure 31



The plug contains a series of small metal pins that insert into corresponding jacks in the socket. Be careful that the plug and socket are properly aligned so that the pins are not bent or broken during insertion. **Do not twist the connector in the socket.**

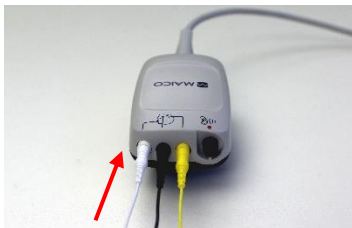
### 4.4.4 Connecting the Electrode Lead Wires to the Preamp



Also, check-out our training videos:

[MAICO Training | easyScreen with earCups™ | ABR | 1/6 Setup - YouTube](https://www.youtube.com/watch?v=1ix1u0Gy34s)

<https://www.youtube.com/watch?v=1ix1u0Gy34s>



Connect the 3 electrode lead wires securely into the electrode jacks on top of the preamplifier, matching the color of the lead wire with the jack. Be sure they are fully inserted into the jack (Figure 32).

Figure 32

Fully assembled cables for an ABR tests using insert earphones are shown in Figure 33 (eartips), Figure 34 (EarCups™), and Figure 35 (EARturtle™).



Figure 33

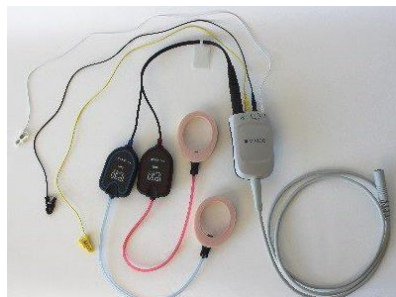


Figure 34

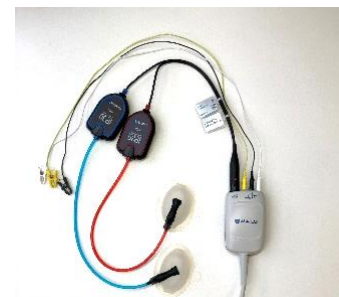


Figure 35

## 4.4.5 Connecting the EARturtle™ adapter

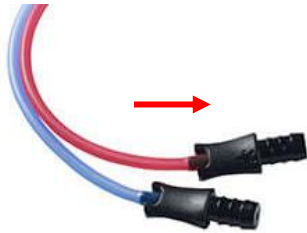


Figure 36

Remove the EarCup™ adapters from the red and blue tube of the IP30 by pulling them off (Figure 36).



Figure 37

Insert the metal part of the EARturtle™ adapter into the red and blue tube of the IP30 transducers until it is fully covered (Figure 37).

---

**NOTE:** To ensure correct stimulus levels, do not replace the transparent eartip adapter with the black EarCup™ or EARturtle™ adapter.

---

## 4.4.6 Connecting the BERophone® to the Hardware Tester (Optional Use)



Figure 38

To perform a hardware integrity test, connect the BERophone® to the hardware tester (Figure 38). Hold it in place while performing a measurement. The impedance values at all electrodes should be acceptable and the end result of the test should be a “Refer”.

## 4.4.7 Connecting to the Pass-Checker for ABR Using the Preamplifier (Optional Use)



Figure 39

To perform a hardware integrity test, connect the insert earphone adapters into the holes in the sides of the Pass-Checker. The black EarCup™ and EARTurtle™ adapters fit directly into the holes (Figure 39).

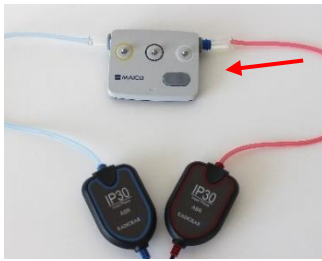


Figure 40

If your system has the clear, eartip adapters, you will need to install an eartip onto the adapters for a good fit into the holes. Be sure that the adapters are fully inserted into the holes of the Pass-Checker (Figure 40).

---

**NOTE:** The Pass-Checker is not required for patient testing.

---

With the Pass-Checker turned on, perform a standard ABR test. The impedance values should be low enough to begin the measurement and the measurement should provide a “pass” within 30 seconds.

## 4.4.8 Handling of easyScreen and Cradle



Figure 41

Place the easyScreen into the cradle so that it sets within the U-shaped placement guides (Figure 41). Proper placement in the cradle is needed to ensure charging of the battery.

If the battery is being charged the LED on the front of the easyScreen will light up when the display is turned off. If it does not light, check that the device is properly positioned in the cradle.



Figure 42

Grasp the upper portion of the easyScreen above the cradle placement guides and lift it out of the cradle to remove it (Figure 42).

## 4.4.9 Handling of BERAphone® and Cradle



Figure 43

Place the BERAphone® into the cradle so that top part is inserted first between the insertion guides. Then lower the ear cushion portion into the cradle (Figure 43).



Figure 44

The left and right insertion guides hold the BERAphone® centered in the cradle (Figure 44). To remove it, lift the lower part of the BERAphone® first.

The cradle can be mounted to a table or other flat surface with two screws.

## 4.4.10 Components of the BERAphone®

The BERAphone® components are as follows (Figure 45 and Figure 46):

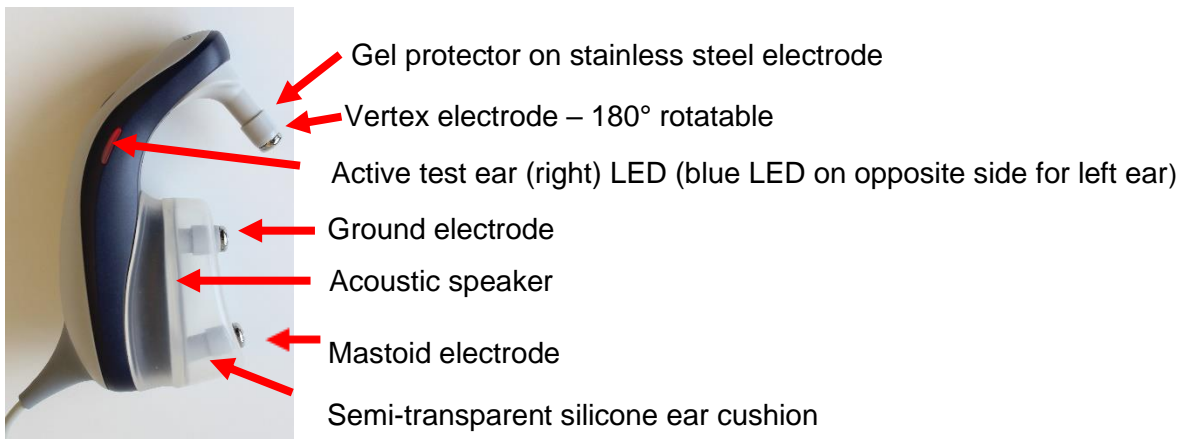


Figure 45

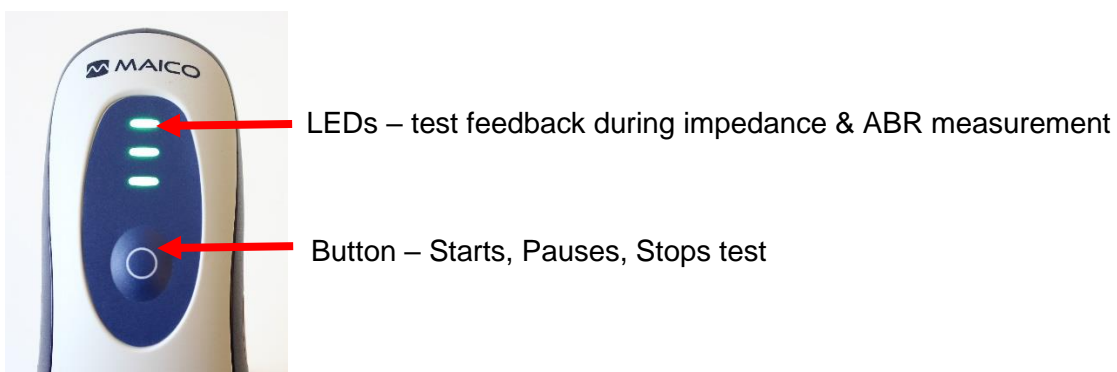


Figure 46

**Table 4 BERAphone® LED Behavior**

Phase	Status	LED Appearance
Impedance test	Good impedance	
	Poor impedance – vertex	
	Poor impedance – all electrodes	
Testing	Test running – quality OK	
	Artifacts occurring	
	Paused	
	Electrode off	
	Test complete	

### 4.4.11 Establishing a PC-Connection

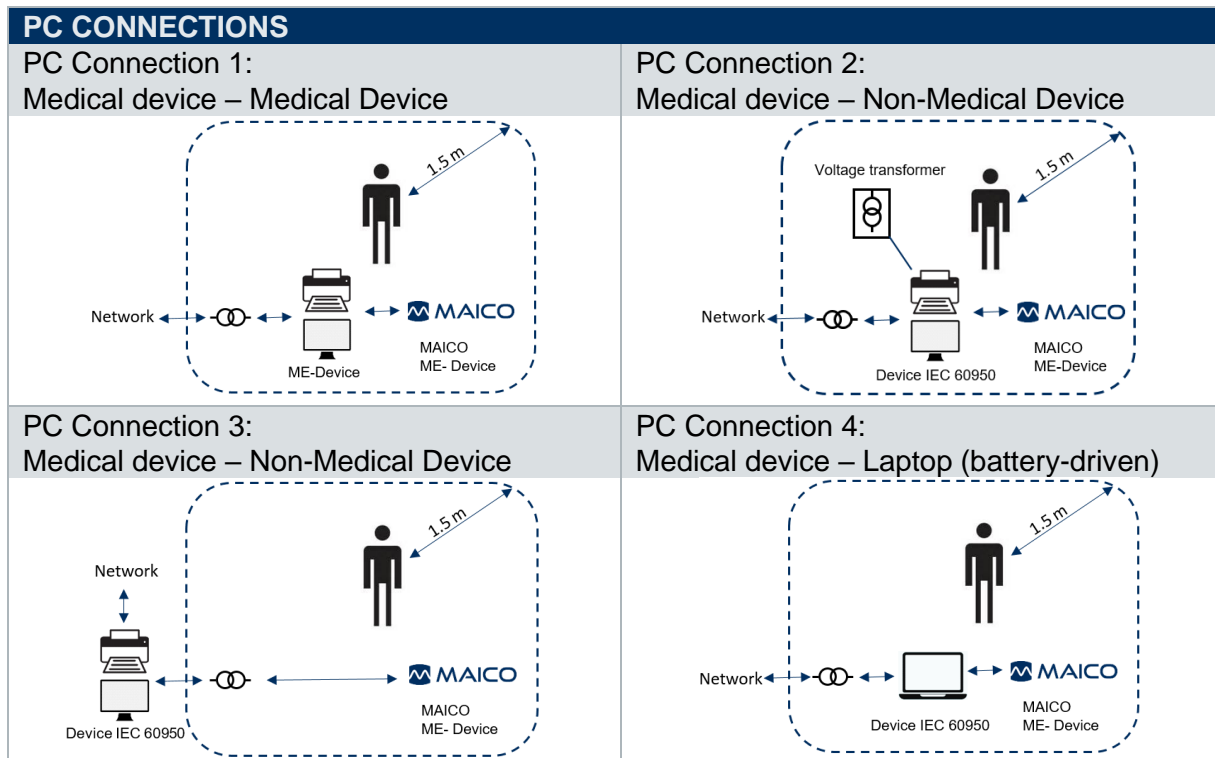
To transfer data to a PC, establishing a PC-connection via USB is required. If the easyScreen is used with office equipment that is not a medical device itself (see Table 5, PC-Connection 1), make sure to establish the PC-connection in one of the following ways (see Table 5, PC Connection 2, 3 or 4).



**WARNING**

Make sure you use only office equipment with the device that is a medical device itself or meets the requirements of IEC 60950. If a non-medical device is used within the patient environment (1.5 m from patient as defined in IEC 60601) a voltage transformer must be used (exception: a battery driven laptop is used).

**Table 5 PC-Connections**



## 4.4.12 Powering easyScreen

### 4.4.12.1 General

The device is powered by a rechargeable Lithium-ion (Li-ion) battery. The battery is charged by placing the device in the AC powered cradle.

The battery can also be charged by:

- Connecting the device to a powered PC using the supplied USB cable. Charging this way will be slower than charging with the cradle.
- Connecting the device to mains using the power supply from the cradle directly plugged into the micro-USB port of the easyScreen.

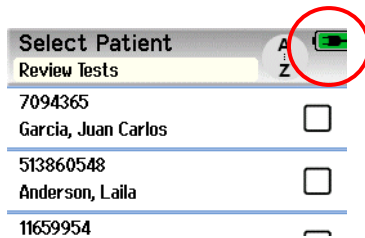


**WARNING**

**USE ONLY UES12LCP-050160SPA- POWER SUPPLY.**

**NOTE:** The USB connection on the device has insulation protections to the patient connections.

### 4.4.12.2 Battery status



The charge status of the battery is represented graphically in the status bar at the top of the easyScreen touchscreen when it is powered on.

The explanation of the charge status symbols is given in Table 6.

Figure 47

Table 6 Battery status

SYMBOL	CHARGE STATUS
	Charging
	100 % to 11 %
	10 % (approx. 30 minutes of active test time remaining)
	5 % (testing cannot be performed; recharge ASAP)
	3 % (automatic shutdown)

**NOTE:** The easyScreen will shut down automatically when the battery charge is too low to avoid data loss.

### 4.4.12.3 Powering the Cradle

The cradle is powered by plugging the power cable into the micro-USB connector on the back of the cradle and plugging the other end into an AC outlet using the appropriate adapter for your region. The cradle LED will light up when it is powered on.

Use only the power supply delivered by MAICO for powering the cradle.

### 4.4.12.4 Charging the Battery

Keep the battery fully charged for the longest battery life.

With the cradle plugged into AC, insert the easyScreen into the cradle. This begins the battery charging process. Charging time from under 10% to above 90 % is approximately 6 hours.

Charging via the USB cable to a powered PC alone (no cradle used) or with the cradle power supply directly plugged into the easyScreen will take approximately 9 hours.

The Charging Light Indicator on the front of the easyScreen will light differently depending on conditions (see Table 7).

**Table 7 Device Status**

Device status	OFF		ON		Power Save (Standby)	
	Battery charging	Battery not charging / full	Battery not full	Battery status	Battery charging	Battery not charging / full
USB charge	Blue solid	Green solid	Off	Off	Blue blink	Green blink
Cradle charge	Blue solid	Green solid	Off	Off	Blue blink	Green blink
Not charging	Off	Off	Off	Off	N/A	Green blink
Battery fault	Green+ blue solid	Green+ blue solid	Off	Off	Green+ blue blink	Green+ blue blink

### 4.4.12.5 Screening During Charging



**CAUTION**

Testing while charging may cause the device to overheat and result in damage.

Avoid charging the device during testing.

Screening can be performed when easyScreen is connected to the powered PC via the USB cable or with the power supply plugged directly into easyScreen. However, electrical interference may introduce noise into the recording prolonging the screening time and increasing the chance of a refer result. Therefore, screening while the device is connected via USB to a powered PC or into mains power is not recommended.

## 4.5 Using the Label Printer

### 4.5.1 Connecting the label printer to easyScreen

The connection of the easyScreen and the label printer is made via wireless pairing. See section 5.13.2.

## 4.5.2 Powering the Label Printer



Figure 48

The label printer is powered by a Lithium-ion battery. Use the micro USB power supply delivered by MAICO to power the label printer (Figure 48).

## 4.5.3 Insert Label Rolls Into the Label Printer

The printer indicates that it has run out of paper by displaying the message **"Out of paper"** on the screen and the blue LED (ERROR) flashes (Figure 49).

Open the printer by pressing the small latch button (Figure 50).

Insert the label roll into the printer with the paper end placed towards the open cover. Hold the paper end in place and close the cover. Turn the printer on and press the feed button on the left side so that the printer can properly align the labels with the print head (Figure 51).



Figure 49



Figure 50



Figure 51

## 4.6 Storage

When the easyScreen is not in use, store it in the carry case or in a location where it will be safe from damage to the touchscreen or other sensitive components such as the acoustic transducers and cables. Store according to the recommended temperature conditions described in section 6.

## 5 Operating the Device

This section offers you information about:

- how to get started with the easyScreen
  - the easyScreen screen format
  - preparing for testing
  - performing screenings
  - managing the test results
  - settings to be made in the setup menu
  - using the pass-checker (optional use)
  - using the Infant Ear Simulator (optional use)
- 

### 5.1 Getting Started with easyScreen

#### 5.1.1 General



Also, check-out our training videos:

[MAICO easyScreen - how to operate the device - YouTube](https://www.youtube.com/watch?v=-9HYLn1Eq3I)

<https://www.youtube.com/watch?v=-9HYLn1Eq3I>

#### 5.1.2 Switch on easyScreen

The easyScreen can be operated in or out of the cradle. Briefly press the **Home** button on the front of the easyScreen to turn on the device. The boot-up process will take a few seconds. During this time the display will show the splash screen.

Important information or reminders may be displayed during the boot-up process. This could include:

- Calibration expiration reminder
- Low battery charge warning

#### 5.1.3 Power-Saving Mode and Power-off

When the easyScreen is inactive for some time period, the device will go into **Power Save mode** (standby) and the display will turn off. Pressing the **Home** button briefly will awaken the device. Upon awakening from standby, the screen will display as it was when it went into standby mode. (If **User Login** is enabled, you will need to enter your password again when the device awakens from standby.)

Finally, after another period of inactivity, the device will power off automatically.

The time periods for power save and power off can be set in the **Energy Settings** on the easyScreen.

---

**NOTE:** To manually power off easyScreen press and hold the **Home** button for more than 10 seconds. Or, while in the Home screen press the **Home** button and a message will display allowing you to shut off the device or cancel.

---

## 5.2 The easyScreen Screen Format

The general easyScreen screen format (Figure 52) includes:



- 1 – Screen title
- 2 – Status/subheader
- 3 – Main screen
- 4 – Battery charge & Function buttons
- 5 – Bottom control bar with common function buttons

Figure 52

## 5.3 Common Function Buttons

The common function buttons are explained in Table 8.

Table 8 Common Function Buttons

	OK (accept/save)		Cancel		Add comment
	Change logged in user		Search		Enter setup
	Page up		Page down		Go Back (previous screen)
	Test list		View Test Fields		Print
	Test		Pause (test)		Stop (test)
	Resume (test)		Save	-	-
	Sort order (chronological)		Sort order (alphabetical)		View details
	Right ear		Left ear		Both ears (test)

## 5.4 Entering Special Characters

To access special characters, proceed as follows:

- Touch and briefly hold the letter that contains the alternative you want to access.
- Wait for the special characters to appear.
- Touch the special character you want to insert.
- Special characters are available in both lower and upper case. The table shows only the lower case choices.

Table 9 Entering Special Characters

Standard character	Special characters	Standard character	Special characters
e	è é ê ë ê ð	d	d' đ
r	ř ř	g	ğ ğ
u	ú û ü	l	ł
i	ì í î ÿ	z	ž ž ž
o	õ ö ó ô ø	c	ç ć ċ
a	à á â ã ä å æ ç	n	ñ ñ
s	ß ş ș		

## 5.5 Selecting the User (Optional)



Figure 53

The easyScreen can be set to require screener login via the optional HearSIM™ PC application. This is disabled by default.

When login is enabled, a list of screeners that you created in the HearSIM™ PC application and transferred into easyScreen will display after the device boots up.


Select your name from the list to proceed to the password entry screen. **UP** and **Down** arrow buttons in the bottom control bar allow you to move through pages of names if there are more than 8 users in the list.

Select the **Search** button in the bottom control bar in order to type in the beginning characters of your screener name using the on-screen keyboard. Then select the check control in the bottom control bar to return to view a shortened list of screener names.

## Entering the Password



Figure 54

Enter your password in the **Enter Password** screen using the on-screen keyboard and select the **Check**  button in the bottom control bar (Figure 54).

If the password is correct, the **Home** screen will display.

## Incorrect Password

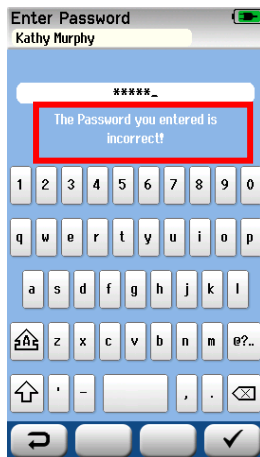


Figure 55

If an incorrect password is entered, a message will appear indicating that the password you entered was incorrect.

The message will display for several seconds and then disappear, clearing the entry field so that you can try again to enter the password (Figure 55).

## 5.6 The Home Screen

### 5.6.1 General

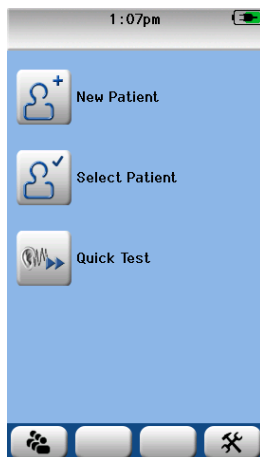








Figure 56

The Home screen displays the buttons controlling entry into the major functions of the easyScreen: **New Patient** , **Select Patient**  and **Quick Test**  (Figure 56). It is also possible to access the **Setup**  and to access the **User selection**  if it is enabled via the optional HearSIM™ PC application.


## 5.6.2 New Patient

Select **New Patient** to enter demographics for a new patient. After entry of the patient's information you can save the name to the database for screening later or immediately proceed with the screening.



## 5.6.3 Select Patient

Select **Select Patient**  to review the list of patients saved on the device. Select a patient to review detailed demographic and test information for this patient or to begin a screening.


## 5.6.4 Quick Test

Select **QuickTest**  to proceed immediately to perform a test without entry of patient information. Quick tests performed in a session are saved temporarily under the patient name of Quick Test. Later if you want to save a Quick Test session you can save it by editing the **Patient Information**.

## 5.6.5 Change Screener


The **Change Screener**  control will be unavailable for selection if user login is disabled. Select **Change Screener**  to log out the current screener and display the list for selection of a new screener.

## 5.6.6 Setup

Select **Setup**  to access a list of the device settings that can be made directly on easyScreen. Some settings can only be made via use of the optional HearSIM™ PC application.

## 5.7 Entering or Choosing a Patient for Testing

### 5.7.1 Adding a New Patient

Patient information can be entered manually into the easyScreen via the **Enter Details** screen. Select the **New Patient**  button on the **Home** screen.

In the **Enter Details** screen, select a field for data entry by touching the desired field. The appropriate data entry control such as the keyboard, calendar or drop-down list will open. Enter the patient's data for the field. Select another field and enter the data until all desired fields are completed. The Patient ID field must be completed in order to save the data or proceed to a screening.

It is possible to configure the device to input an automatic ID number into this field so that you do not have to enter an ID. This ID can be overwritten when entering the patient data. Configuring easyScreen to use an automatically entered ID number is accomplished via the optional HearSIM™ PC application (Figure 57).

Use the **Page up** / **Page down** buttons to access all fields.

The orange framed fields must be filled in before starting a test (Figure 58). If you use the optional HearSIM™ PC application, you can use it to determine which fields shall be displayed on the **Enter Details** screen and which of the fields should be mandatory. Some fields cannot be set mandatory.

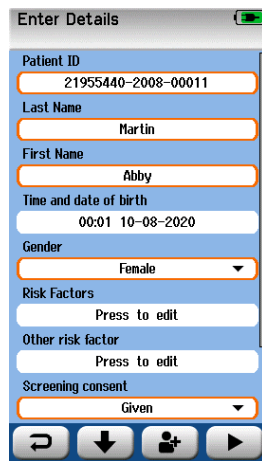


Figure 57

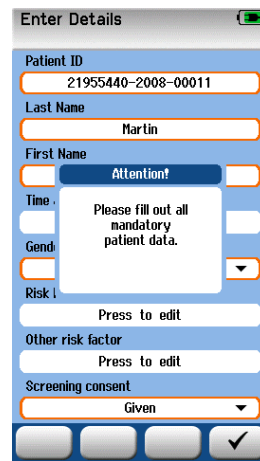


Figure 58

**NOTE:** *Risk factors* and *Ethnicity* fields can be customized using the optional HearSIM™ PC application. The *Ethnicity* field can be turned off if not needed. Refer to the HearSIM™ Instructions for use for more information.

When you have completed entry of data, you can proceed immediately to screen the patient.

## 5.7.2 ID Conflict



Figure 59

The Patient ID must be unique. If you attempt to enter a duplicate patient ID into the database, an ID conflict message will display (Figure 59). After dismissing the message by selecting the **Check** in the bottom control bar, edit the ID to a different number.

If the ID number is correct, then this patient's information may already be present on the device. Return to the **Home** screen and select the **Select Patient** button to search the device for this patient's name/ID.

## 5.7.3 Selecting From the Patient List

A patient can be selected from the Patient list. Press the **Select Patient** button on the **Home** screen.



You can find the desired patient in the patient list in several ways (Figure 60):

- Use the **Search** button to open a screen in which you can enter all or part of the patient's ID, last or first name to search for matching patients. The patient list will be shortened to include only matching entries.
- Scroll the page using the **UP** and **Down** arrow buttons to find the desired patient name.

Select the patient of interest to open the **Patient information** screen.

Figure 60

After selecting the patient you can proceed to:

- **Review** the patient's test history
- **Test** the patient.

In the **Select Patient** list at the right side of the row with the patient's name, a square is present and the appearance of the square reflects the test status as described below.



No tests are saved in the device for this patient (Figure 61).

Figure 61



Tests are saved in the device (between 1 and 49) (Figure 62).

Figure 62



The maximum number of tests is saved (50). No additional tests can be performed for this patient (Figure 63).

Figure 63

Use HearSIM™ with OtoAccess® Database to transfer the tests to your PC database. This will automatically delete all patients and tests saved on easyScreen.

To delete all patients and tests manually from the easyScreen, navigate to Setup/Device and select **Delete all patients and test data** to clean the internal device database.

Only when a full device has been cleared of data you can transfer or enter this patient's ID again to the device and perform more tests.

**NOTE:** Manually deleted patient and test data are irreversibly removed from the device and cannot be recovered afterwards.

## 5.8 Preparing for Testing

### 5.8.1 Test Environment

#### 5.8.1.1 General



Also, check-out our training videos:

[MAICO Training | easyScreen BERophone® | 3/8 Test environment - YouTube](https://www.youtube.com/watch?v=wYT2PdmBQcQ)

<https://www.youtube.com/watch?v=wYT2PdmBQcQ>

The ideal environment for hearing screening is one that is acoustically quiet with minimal potential for electrical interference (for ABR). This is not easily achieved in a hospital, where most newborns are screened.

Nevertheless, the screener should be aware that the environment can impact the testing process and results and should attempt to control the environment to the extent that this is possible.

#### 5.8.1.2 Acoustic Noise

Acoustic noise in the screening environment can be so loud that the low-level stimulus delivered by the hearing screening system is overwhelmed by the background noise. Acoustic noise can also awaken the baby causing less than optimal recording conditions and artifacts that prolong the test time. Acoustic noise can lead to a Refer result even for a baby with normal hearing.

What can the screener do to reduce acoustic noise?

- Find a location for the screening that is as quiet as possible, such as an unoccupied patient or procedure room.
- Close the door to the test room to reduce the acoustic noise from others walking in the hallway who may be talking or pushing equipment that is noisy.
- Be aware of “hidden” sources of acoustic noise, such as air conditioner vents, motors from devices. Try to avoid them by moving as far away as possible.
- Ask others in the test room to suspend talking and mute or turn off radios or TVs while the test is being performed.
- Ask parents to take other children out of the mother’s room during the test.

#### 5.8.1.3 Electrical Noise & ABR

Electrical noise in the screening environment can cause high artifact levels and generally noisy EEG, prolonging ABR test times and increasing the chance of a refer result. Electrical noise issues can be very difficult to troubleshoot and avoid in a hospital environment.

The following can be sources of electrical noise:

- Other electrical equipment in the test room, especially devices attached to the baby such as other monitoring equipment.
- Nearby cell phones, tablets, computers, walkie-talkies.
- MRI or other radiographic equipment located near the nursery, even on the floors above or below.
- RFID tracking devices especially if attached to the baby or mother holding the baby.

If the screener notices high levels of electrical artifact during testing or an increase in refer rates, these sources of electrical interference should be considered and eliminated if possible. The screener may need help from the infant's nurse or physician to troubleshoot electrical interference issues if it involves other types of monitoring equipment attached to the baby that are critical to the child's care.

## 5.8.2 Preparing the Patient



**WARNING**

Keep in mind the indications and contraindications of use given in sections 1.1 and 1.2.

Hearing screening is most successfully and efficiently performed on a quiet, sleeping baby. If the baby is awake but quiet or sucking intermittently, testing is possible though the test time may be affected. If the baby is crying, moving or sucking vigorously and constantly then the test will be prolonged and the chance of a Refer result will be increased. In this case it would be best to terminate the screening and return when the baby is sleeping.

Screening can be performed when the baby is lying in a crib, in a car seat or is being held by the screener or parent. The key is to make the baby comfortable and quiet for the screening. Swaddling the baby in a blanket with the arms wrapped inside is recommended. This will calm the baby and keep the baby from interfering with the screening device components.



**WARNING**

### **Risk of choking.**

Always keep eartips and similar small pieces out of reach of the baby.

**IMPORTANT NOTE:** All disposable supplies included with easyScreen are produced by Sanibel® Supply. The system has only been tested using disposables supplied by Sanibel® Supply. Use of other supplies could alter the behavior and results obtained with the device and is not recommended. Sanibel® disposables are latex, DEHP and BPA free and have been tested for bio-compatibility. Data sheets are available upon request.

## 5.8.3 Preparing for ABR Testing with BERAphone®



Also, check-out our training videos:

[MAICO Training | Auditory Brainstem Response Test with the easyScreen BERAphone® | Full Version - YouTube](https://www.youtube.com/watch?v=SCnUWoMPMhw&list=PLonl5JzuDcd7UI1slmclx_3cislbGp91q&index=5)

[https://www.youtube.com/watch?v=SCnUWoMPMhw&list=PLonl5JzuDcd7UI1slmclx\\_3cislbGp91q&index=5](https://www.youtube.com/watch?v=SCnUWoMPMhw&list=PLonl5JzuDcd7UI1slmclx_3cislbGp91q&index=5)

Optimal ABR recording requires low skin-electrode resistance (electrode impedance). To achieve low electrode impedance, electrode gel must be massaged into to the skin in the areas where the electrodes will make contact as seen in (Figure 64). You can also repair the skin with a skin preparation product such as NuPrep®.



**Figure 64**

**IMPORTANT NOTE:** If any lotion has been applied to the baby's skin in the area of the electrodes then this should be removed with soap and water or other electrode skin preparation products such as NuPrep®. The “ground” electrode is positioned above the ear. The vertex electrode is placed on the forehead at the hairline, at a distance from the ground electrode of approximately 3 fingers width. The mastoid electrode is placed below the ear lobe. Depending on the size of the baby’s head, the position of the BERAphone®’s vertex electrode can be adjusted by rotating the disc in which the electrode is mounted. Place a small quantity (approx. 0.1 to 0.2 ml) of electrode gel on the tip of a finger or gauze swabs and rub back and forth approximately 10 to 15 times at each of the areas described above (rub the gel in the direction as indicated in Figure 69).

The baby should be in a relaxed and comfortable position to minimize any potential muscular artifact and ensure optimum test outcome in the shortest time.

Make sure that the face, neck and shoulder of the baby are relaxed and free of any obstructions.

**IMPORTANT NOTE:** Make sure that the gel areas remain separate from each other. This can be achieved by always rubbing in the direction from the face towards the back of the head (see Figure 69) to ensure three distinct gel areas that do not contact each other. Particularly critical is the distance between the electrode above the ear (ground electrode) and the vertex electrode. Ensure that at least a finger-wide area between electrodes remains free of electrode-gel. Merging of gel from one site into the other will cause very poor recordings and increase the likelihood of “Refer” results.

Finally, using your finger to control the quantity of gel, apply a small drop of electrode-gel on the tip of each electrode of the BERAphone®.

Place the BERAphone® on the baby's head (Figure 65). First position the mastoid electrode below the ear. If the baby moves, follow the head movements with the BERAphone®. When the baby has stopped moving, lower the other two electrodes into place making sure to achieve good contact with the prepared skin sites.



**Figure 65**

## IMPORTANT

- The easyScreen BERAphone® does not require pressure to hold it in place. You are supporting the BERAphone® only to maintain the position of the electrodes and ear cushion on the baby's head. The ear cushion must be placed so that it is surrounding the ear. Make sure there are no obvious gaps between the cushion and the baby's skin as this may reduce the intensity of the acoustic stimulus delivered to the baby's ear and increase the chance of a "Refer" test outcome. If necessary reposition the BERAphone® or change the position of the vertex electrode in its rotating housing to achieve a better fit.
- Never place the electrodes in the ear canal.
- All electrodes must contact the skin well.

### 5.8.4 Preparing for Classic ABR Testing



Also, check-out our training videos:

[MAICO Training | How to conduct an ABR hearing measurement with the easyScreen | Full Version - YouTube](https://www.youtube.com/watch?v=aPqIZAIM5HI&list=PLonI5JzuDcd7UI1slmcLx_3cisbGp91q&index=4)

[https://www.youtube.com/watch?v=aPqIZAIM5HI&list=PLonI5JzuDcd7UI1slmcLx\\_3cisbGp91q&index=4](https://www.youtube.com/watch?v=aPqIZAIM5HI&list=PLonI5JzuDcd7UI1slmcLx_3cisbGp91q&index=4)

ABR recording requires placement of 3 electrodes. The ideal electrode positions are:

- Center of the forehead at the hairline
- Cheek (either side) or shoulder
- Nape of the neck

An alternate electrode montage can be used as seen below. However, the screening time for the right ear may be prolonged when using this montage.

- Center of the forehead at the hairline
- Right mastoid
- Left mastoid

Regardless of the electrode placement you choose, the skin at the electrode locations must be cleaned with an electrode skin preparation product. Rub the product gently, but briskly on the skin at each position.

**NOTE:** Skin preparation products vary in terms of abrasiveness. Be sure to follow the instructions on the product to avoid damage to the skin.

Preparing the skin helps to achieve good contact (i.e. low impedance) between the skin and the electrode. After cleaning, remove any residue of the skin prep product so that the skin is dry. This will help to ensure good adhesion of the disposable electrode to the skin.



#### **Risk of strangulation.**

Keep cables away from baby's neck.



**Avoid contact between the unused electrodes and any other conductive parts.**

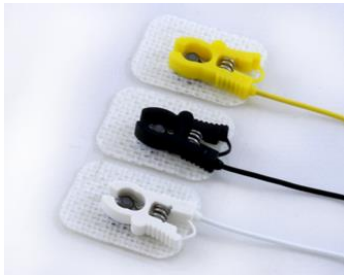


Figure 66

Connect the white, black and yellow pinch clip electrode lead wires to a snap electrode (Figure 66).

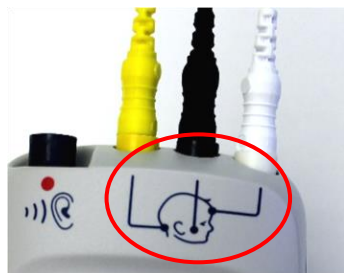


Figure 67

Peel the electrodes from the backing card and place them on the electrode positions following this color scheme. A graphic near the electrode jacks on the preamplifier illustrates proper placement for the nape montage as a reminder (Figure 67, see also Table 10 for nape and mastoid montage).

Table 10 Nape and Mastoid Montage



Figure 68

Press gently around the entire surface of each electrode to help secure its adhesive to the skin (Figure 68).

	<b>Nape Montage (recommended)</b>	<b>Mastoid Montage (alternate)</b>
<b>White</b>	Forehead	Forehead
<b>Black</b>	Cheek (either side) or shoulder	Right mastoid
<b>Yellow</b>	Nape of the neck	Left mastoid

**5.8.4.1 Preparing for Classic ABR Testing with EarCups or EARturtle™**



Also, check-out our training videos:

[MAICO Training | easyScreen with earCups™ | ABR | 2/6 Patient preparation - YouTube](https://www.youtube.com/watch?v=X5YL53tmUSM)

<https://www.youtube.com/watch?v=X5YL53tmUSM>

At the time of purchase you chose your preferred style of acoustic transducer. If insert earphones were selected you also chose your preferred ear coupling method, the EarCup™ or eartips. Both use single-use disposable supplies.



**WARNING**

In case of re-use of the single-use disposable, you enhance the risk of cross contamination!

The EarCup™ and EARturtle™ are around-the-ear coupler that connects to the tubing of the IP30 insert earphones using adapters. The EarCup™ and EARturtle™ adhere to the skin around the baby's ears.

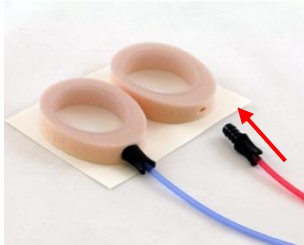


Figure 69

Insert the EarCup™ adapter at the end of each of the insert earphone tubes into the hole in the foam at the top of the EarCup™ so that it is fully inserted (Figure 69).

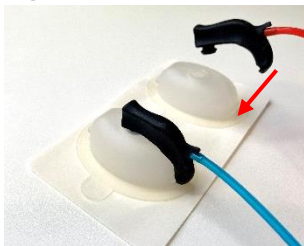


Figure 70

Insert the EARturtle™ adapter at the end of each of the insert earphone tubes into the hole of the silicon EARturtle™ and clip the lower part of the EARturtle™ adapter onto the EARturtle™ (Figure 70).



Figure 71

Peel the EarCup™ or EARturtle™ attached to the red tubing from the backing card. Place it around the baby's right ear with the adapter and tubing pointing toward the top of the head (Figure 71 and Figure 72). Press around the entire circumference of the EarCup™ or EARturtle™ to ensure adhesion to the baby's skin.



Figure 72

You can also couple the EarCup™ or EARturtle™ to the head with the insert earphone tubing pointing below the ear. In either case be sure that the tubing is not crimped and that the black adapter opening into the EarCup™ cavity is not occluded by any contact with the ear.

Peel the EarCup™ or EARturtle™ attached to the blue tubing from the backing card. Place it around the baby's left ear. Press around the entire circumference of the EarCup™ or EARturtle™ to ensure adhesion to the baby's skin.

Place the insert earphone transducer boxes above or to the side of the baby's head.

## 5.8.4.2 Preparing for Classic ABR Testing with Eartips

The eartip is a small tip that is installed on the infant eartip adapter attached to the tubing of the insert earphones. The eartip is inserted into the baby's ear canal.

Choose the proper size of eartips based on your inspection of the size of the baby's ear canals. The Sanibel® red flanged eartip fits most newborn ears. The Sanibel® green preemie tip is another good option for smaller canals. Other sizes are available for larger ear canals.

### Eartips with Insert Earphones



**WARNING**

Do not insert the eartip adapter into the baby's ear without an eartip installed. The adapter could scratch the baby's ear.



Figure 73

Apply the eartips onto the eartip adapters at the end of the insert earphone tubing (Figure 73).



Figure 74

Insert the eartip attached to the red tubing into the baby's right ear. Do this by pulling gently down and out on the baby's ear lobe to open the ear canal. Hold the adapter and twist (gently) the eartip into the ear canal (Figure 74). The fit of the eartip should be secure; not superficial. Release the earlobe. Repeat this procedure inserting the eartip attached to the blue tubing into the baby's left ear.

If you find that it is difficult to keep both eartips securely in the baby's ear canals at the same time, you can choose to test one ear at a time.

Place the insert earphone transducer boxes above or to the side of the baby's head.

**IMPORTANT NOTE:** The calibration value for the insert earphone is saved in the connector at the end of the insert earphone cable. Calibration values for inserts with eartips are different from calibration values for inserts used with EarCup™ and EARturtle™.

**Never modify an insert earphone by replacing the original tubes and adapters with the other adapter type. This will result in incorrect stimulus levels causing inaccurate screening results.**

**NOTE:** When using insert earphones, you cannot use the same transducer for testing both ears. Only use the red colored transducer for the right ear and the blue transducer for the left ear.

## 5.8.5 Preparing for OAE Testing



Also, check-out our training videos:

[MAICO Training | easyScreen | OAE | 4/6 Preparations - YouTube](https://www.youtube.com/watch?v=t5vT1-K8rzA)

<https://www.youtube.com/watch?v=t5vT1-K8rzA>



**WARNING**

Do not insert the OAE probe tip into the baby's ear without an eartip installed. The adapter could scratch the baby's ear.



Figure 75



Figure 76

Apply the eartips onto the OAE probe tip (Figure 75) or the SnapPROBE™ (Figure 76).

Insert the eartip into the baby's first ear to test. Do this by pulling gently down and out on the baby's ear lobe to open the ear canal. Hold the probe and aim and twist (gently) the eartip into the ear canal. The fit of the eartip should be secure; not superficial. Release the earlobe. You should not hold the OAE probe during the measurement since this can cause acoustic noise.

## 5.9 Testing

### 5.9.1 General Information






Also, check-out our training videos:

[MAICO Training | easyScreen BERAPhone® | 2/8 Start up - YouTube](https://www.youtube.com/watch?v=Ct9oD0xo4ow)


<https://www.youtube.com/watch?v=Ct9oD0xo4ow>

A screening can be initiated in several ways:

- **Quick Test**  (in **Home** screen)
- After entering **New Patient**  information
- From the Patient Information screen after you have chosen a patient from the **Select Patient**  list.

The following processes are the same regardless of the type of screening you perform.

### 5.9.2 Quick Test Button

Quick test functionality can be enabled/disabled by an administrator using the optional HearSIM™ PC application. If Quick Test is disabled on your device, then the **Quick Test**  button will not appear on the **Home** screen.

### 5.9.3 Select the “Test” Button

Press the **Test**  button to start the process toward screening.

Depending on the configuration of your device, some screens may appear before the actual measurement screen is displayed.

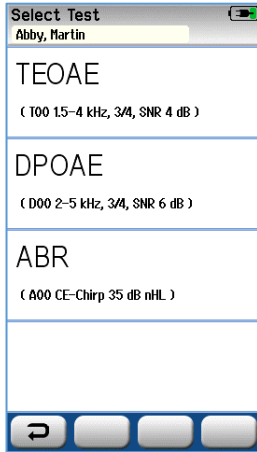


Figure 77

If your device has both **ABR** and **OAE** functionality or if you have transferred multiple protocols of one test type to the device, then a **Select Test** screen may appear for you to select which screening protocol to use (Figure 77).

This screen will only appear if the hardware attached to your easyScreen support more than one protocol present on your device.

**NOTE:** Different test protocols are available. See section 6.7 for more information.

It is only possible to display up to 4 protocols at a time.

### 5.9.4 Edit Test Fields

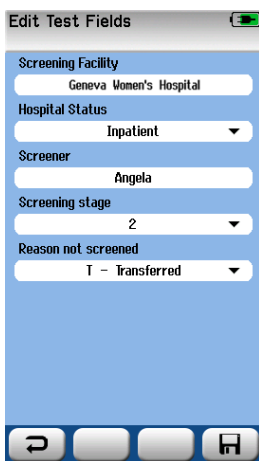



Figure 78

Using the optional HearSIM™ PC application, your easyScreen can be configured to save information with each test (Figure 78) regarding:

- **Screening Facility** name
- **Hospital Status**
- **Screener** name
- **Screening stage**
- **Reason not screened:**

Selecting a reason not screened will not progress to a measurement, as the field is stating that a measurement could not be performed.

When this function is enabled, an **Edit Test Fields** screen will appear so you can complete these fields for the current patient. Since these fields are often the same from patient to patient, your selection will be recalled so that you only need to confirm the entry by proceeding with selection of the **Test**  button if the current items displayed in the fields are correct.

If you have logged into the device upon boot-up, then your screener name will also be saved with the test. The selection is then disabled on the **Edit Test Fields** screen.

### 5.9.5 Hearing Screening Result Symbols

The explanation of the screening result symbols is shown in Table 11.

Table 11 Screening Result Symbols

Symbol			
Screening result	Pass	Refer	Incomplete

### 5.9.6 Reason for Incomplete Test



Figure 79

Using the optional HearSIM™ PC application, the administrator can enable a feature in easyScreen for automatically displaying a **Select Stop Reason** screen (Figure 79) when a test is manually stopped. This information is saved with the test.

## 5.10 ABR Measurement Screen

### 5.10.1 General

During the **ABR** process the screens will change to reflect the processes taking place and the options available to the screener.

### 5.10.2 Initial ABR Measurement Screen

The **ABR** start screen displays some setup instructions (Table 12).

Table 12 ABR Initial Test Screen

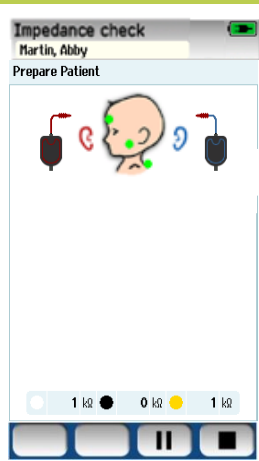
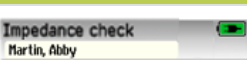
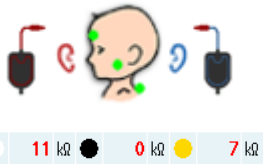


Screen	Screen Area/ Graphic	Function Name	Description
		Patient information	Shows current patient name
		Instruction	Describes how to prepare patient
		Ear selection button	Choose desired ear here
		Back button	Returns to prior screen
		Test button	Proceed to next phase of test

Figure 80

## 5.10.3 Impedance Check Screen

During the impedance check, the electrode positions on the graphic of the baby's head will display in green or yellow with the impedance value in kΩ shown toward the bottom of the screen (Table 13). Once the impedance values at all locations remain "green" (<50 kΩ) for a few consecutive seconds, the impedance check stops and the response detection phase begins automatically (Table 14).

**Table 13 Impedance Check Screen**

Screen	Screen Area/ Graphic	Function Name	Description
 <p><b>Figure 81</b></p>		Screen title & Patient information	Shows current patient name and process taking place
		Impedance check feedback	Feedback about the impedance values: Green = good impedance Yellow = poor impedance
		Stop (test) button	Stops the test
		Pause /continue screening button	Pause/continue the measurement

If any impedance indicator remains yellow, the screener must improve the impedance at this electrode position by:

- Making sure that the electrode is placed properly on the prepared skin site.
- If poor impedance persists, it may be necessary to remove the electrode and use the skin preparation product to clean the skin again. It may be possible to reapply the same electrode but if the adhesion is poor then a new electrode may be required.

An impedance time out message will appear after:

- approximately 180 s of impedance checking if the BERAphone® is connected.
- approximately 60 seconds of impedance checking if the preamplifier is used.

Upon dismissing the message, the initial test screen appears again. No test is saved if the impedance was not completed.

## 5.10.4 ABR Measurement Screen

During the **ABR** measurement, a bar graph shows the progress toward a Pass result. A red bar reflects the test progress for the right ear. A blue bar reflects the test progress for the left ear (see Table 14). At the end of the test, the screening result symbol appears at the top of the bar graph (see Table 11).

Table 14 ABR Measurement Screen

Screen	Screen Area/ Graphic	Function Name	Description
		Heading & Patient information	Shows current patient name and measurement status taking place
		Test progress feedback	<p><b>Noise:</b> checkmark = collects acceptable data</p> <p><b>Time:</b> duration of test; ends at 180 sec.</p> <p><b>Bar graph:</b> progress toward pass (red for right ear; blue for left ear)</p>
		Stop (test) button	Stops the test
		Pause/continue screening button	Pause/continue the measurement

Figure 82

### Status Bar

During measurement, the Status area at the top of the screen will show helpful information about the testing status.

- **Testing...**: Test is proceeding.
- **Done!**: Test is complete.
- **Reconnect electrode**: Electrode has fallen off; reconnect it.
- **Too noisy**: Artifacts are occurring; consider pausing the test to improve the situation. Too much electrical noise may mean an electrode is loose or the baby is too active.
- **Paused**: Displays when you have manually paused the recording.
- **Mains Noise Detected**: System has detected electrical interference at frequencies that could cause inaccurate test results. Check electrodes for good contact, assess the area for electrical interference and control it if possible, move system to a new location.

### Noise Bar

During measurement, a **Noise** bar will display the amplitude of the incoming EEG samples. A checkmark will appear at the back of the bar when the incoming signals are low enough to be accepted and processed in the response detection algorithm. If the incoming EEG signals have a high amplitude due to myogenic or electrical noise, the check will disappear and the EEG bar indicates that the artifact rejection threshold has been exceeded.

## Time Bar

During measurement, an **Elapsed time** bar will fill in as good samples of data are processed. When 180 seconds of acceptable EEG samples have been acquired, the bar will be filled in completely and the test will terminate automatically.

## Troubleshooting

Refer to section 3.4 for troubleshooting suggestions.

### 5.10.5 Test Done Screen



Also, check-out our training videos:

[MAICO Training | easyScreen BERophone® | 7/8 ABR result - YouTube](https://www.youtube.com/watch?v=cdHSRzV1OAg)

<https://www.youtube.com/watch?v=cdHSRzV1OAg>

At the end of a hearing screening, the result of the most recently completed screening will continue to be visible (Table 15). The ear selection control will return so that the user can select the other ear for testing or can repeat a screening measure on the same ear.

The ear selection control can also be used to toggle between the last ABR test performed on the right and left ear during the session.

Table 15 Test Done Screen

Screen	Screen Area/ Graphic	Function Name	Description
<p><b>Figure 83</b></p>		Patient information	Shows current patient name
		Ear selection button returns	Choose ear to test
		Test result bar, result symbol and other measurement information	Green check & bar = Pass Black ? = Incomplete Yellow X = Refer Artifact = % "bad" samples Time = duration of test in "good" samples
		Test list button	Shows the list of tests from this session to select for printing
		Start button	Begins next screening test on this patient
		Comment	Select to enter a comment that saves with this test.
		Back button	Returns to prior screen

## 5.11 OAE Measurement Screen

### 5.11.1 General



Also, check-out our training videos:

[MAICO Training | easyScreen | OAE | 5/6 OAE screening - YouTube](https://www.youtube.com/watch?v=oAZAUEjgvEU)

<https://www.youtube.com/watch?v=oAZAUEjgvEU>

During the OAE process the screens will change to reflect the processes taking place and the options available to the screener.

### 5.11.2 Initial OAE Measurement Screen

The initial OAE screen displays instructions for preparation of the patient (Table 16).

Table 16 OAE Initial Test Screen

Screen	Screen Area/ Graphic	Function Name	Description
<p>Figure 84</p>		Patient information	Shows current patient name
		Ear selection buttons	Choose ear to test
		User instruction	See notes about preparing the patient for testing
		Start button	Starts the probe check fit process
		Back button	Returns to prior screen

## 5.11.3 Probe Check Screen

During the probe check information is displayed regarding the quality of the fit of the probe in the ear canal and acoustic background noise (Table 17). Once the probe fit is good and the acoustic noise is below the threshold level the probe check terminates and the OAE measurement phase begins automatically.

**NOTE:** The information displayed about the probe fit depends on the measurement type (DPOAE and TEOAE).

Table 17 Probe Check Screen

Screen	Screen Area/ Graphic	Function Name	Description
<p>The screenshot shows a 'Test: Probe check' screen. At the top, it says 'Prepare Patient' and shows a cartoon baby with a probe in its ear. Below this are three progress bars for 'Seal', 'Stimulus', and 'Noise', each with a green checkmark. At the bottom, there are four buttons: a square, a pause button, a play button, and another square.</p>		Patient information	Shows current patient name
		Probe fit feedback:	In ear & seal = good Out of ear = poor fit Too noisy = poor fit or conditions Off levels = poor stimulus quality
		Stop (test) button	Stops the test
		Pause/continue screening button	Pause/continue the measurement

Figure 85

If either the fit or the noise level is not acceptable you need to improve the situation before the screening begins:

- Make sure the probe tip is inserted securely into the ear canal.
- Quiet the baby or attend to any acoustic noise in the test environment.

After approximately 20 seconds of probe checking, a time out message will appear. Upon dismissing the message, the initial test screen will appear again. No test will be saved in this case.

The TEOAE process includes an “adjusting level” phase immediately after the probe fit check.

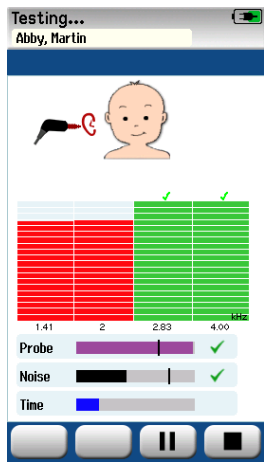





**NOTE:** The TEOAE probe fit and “adjusting level” process is optimized for infant ears. Some ears with larger canal volume may not pass through this phase of the TEOAE process. These ears cannot be screened.

## 5.11.4 OAE Measurement Screen

During the **OAE** measurement, a bar graph for each of the frequencies in the test protocol reflects the progress toward a Pass (Table 18). The bar will fill in completely with color and a checkmark will appear above the bar when the criteria for a pass is achieved at that frequency. Additionally, horizontal bars for probe stability, noise and test progress appear. When noise and probe stability are acceptable, a checkmark appears next to the horizontal bar.

**NOTE:** Probe stability during the measurement displays only for TEOAE. For DPOAE a probe stability measurement comparing the probe output pre- and post-test will be available with the test record once it is saved, but not during the measurement.

Table 18 OAE Measurement Screen

Screen	Screen Area/ Graphic	Function Name	Description
 <p>Figure 86</p>		Patient information	Shows current patient name
		Test process info	Shows test process information.
		Test progress information	Feedback about the progress toward reaching a Pass result; test result symbol; elapsed time indicator, noise level feedback and probe fit feedback
		Stop (test) button	Stops the test; assigns an incomplete result
		Pause/resume screening button	Pause/resume the measurement

### 5.11.4.1 Probe Stability

During TEOAE measurement, a **Probe** stability bar will reflect the status of the probe in the ear canal. A check will appear at the back of the bar when the probe stability is adequate. If the probe stability drops below an acceptable level suggesting that the probe is falling out of the ear, the check will disappear. If this happens you should check the fit of the probe in the ear.

#### 5.11.4.2 Status Bar

During measurement, the Status area at the top of the screen will show helpful information about the testing status.

- **Testing...:** Test is proceeding.
- **Done!:** Test is complete.
- **Too noisy:** Artifacts are occurring; consider pausing the test to tend to the situation. Too much noise may mean the baby is too active or the test environment is too noisy for good testing conditions.
- **Paused:** When you have manually paused the recording.
- **Off levels:** Probe position in the ear canal has changed.

#### 5.11.4.3 Noise Bar

During measurement, a **Noise** bar will display the amplitude of the incoming acoustic noise. A check will appear at the back of the bar when the incoming signals are quiet enough to be accepted and processed in the response detection algorithm. If the incoming data sample contains high noise the check will disappear and the noise bar will reflect noise exceeding the threshold for rejection of those samples.

If this occurs, you should Pause the test and attend to the acoustic noise by calming the baby or managing other sources of ambient noise. The fit of the probe should also be checked.

#### 5.11.4.4 Time Bar

During measurement, an **Elapsed time** bar will fill in as good samples of data are processed. When the maximum test time has been reached, the bar will be filled in completely and the test will terminate automatically.

#### 5.11.4.5 Time Out

If test conditions are consistently poor for 60 seconds due to high noise or poor probe instability so that good data samples cannot be acquired, then the test will time out with an incomplete result displayed.

#### 5.11.4.6 Troubleshooting

Refer to section 3.4 for troubleshooting suggestions.

## 5.11.5 Test Done Screen

At the conclusion of a hearing screening, the result of the most recently completed measurement will continue to be visible. The ear selection control will return so that the user can select the other ear for testing or can repeat a screening measure on the same ear.

The ear selection control can also be used to toggle between the last **OAE** test performed on the right and left ear during the session (Table 19).

Table 19 Test Done Screen

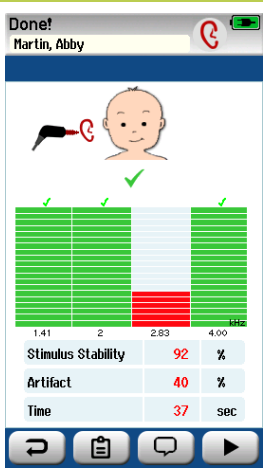







Screen	Screen Area/ Graphic	Function Name	Description
 <p>Done! Martin, Abby</p> <p>1.41 2 2.83 4.00 kHz</p> <p>Stimulus Stability 92 %</p> <p>Artifact 40 %</p> <p>Time 37 sec</p>		Patient information	Shows current patient name
		Ear selection buttons	Choose ear to test
		Test result bars, symbols and test feedback	Feedback about the result(s) of the most recent screening performed per ear in this test session
		Test list button	Displays test performed in the session for printing
		Start button	Begins probe fit check for next test
		Comment	Select to enter a comment that saves with this test.
		Back button	Returns to prior screen

Figure 87

## 5.12 Quick Test

### 5.12.1 General

Selection of **Quick Test** from the **Home** screen bypasses entry of patient information or selection of a patient from the database.

The process of a **Quick Test** is identical to that of a standard test.

Quick tests can be printed immediately after the test is completed, but no identifying information will appear on the print-out.

One Quick Test session is saved temporarily in the **Patient List** of the easyScreen until the next time that the **Quick Test** button is selected on the **Home** screen. When **Quick Test** is selected, the previous Quick Test session is immediately and permanently deleted from easyScreen.

### 5.12.2 Saving a Quick Test

If it is your standard practice to save screening tests, it is highly recommended that you first enter the patient information or select an existing patient in the database **before** performing the screening.

However, if you want to save a **Quick Test** session (all tests) immediately after it was performed, follow these steps:

1. At the **Home** screen, choose **Select Patient**.
2. Select the “Quick Test” patient.
3. Enter the patient’s data in the **Patient Information** screen.
4. Select the checkmark in the bottom control bar.

The **Quick Test** session is now saved under the patient ID and name you entered.

## 5.13 Managing Test Results

### 5.13.1 General

Test results from easyScreen can be printed on the wireless printer.

Use of the optional HearSIM™ with OtoAccess® Database PC applications support transfer, storage and management of easyScreen data and clears the easyScreen database.

Refer to the HearSIM™ and OtoAccess® Database Instruction for Use that are provided on the USB flash drive if you purchased the HearSIM™ with OtoAccess® Database option.

In the easyScreen Settings/Device screen, it is possible to clear the database of all patients and tests.

### 5.13.2 Reviewing Patients and Tests

#### 5.13.2.1 Select Patient

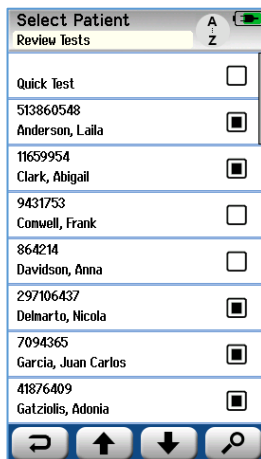






Figure 88

Select the **Select Patient**  button on the **Home** screen to view the list of patients contained in the device database (Figure 88). The list can be sorted alphabetically by last name or by test date in reverse chronological order using the sort  icon at the top right corner.

In both modes, the “Quick Test” patient appears at the top of the list if one is present. Also patients without tests appear at the top of the list for easy access.

Use the **Up**  and **Down**  arrow buttons in the bottom control bar to page through the list.

You can use the **Search**  button in the bottom control bar to open a keyboard screen. Type in all or a portion of the patient’s last name or ID number and select **Search**  again to return to a shortened list containing only matching patients. Select the desired patient on the list to proceed to the **Patient Information** screen showing this patient’s details.

### 5.13.2.2 Patient Information

When you have selected a patient from the list that patient's details will display for review.

### 5.13.2.3 Edit Patient Information

Patient information saved in easyScreen can be edited only before tests are performed. Once a test is saved for this patient, edits cannot be made directly on the device. If an edit is required after a test is saved on the device, it can only be performed in the optional HearSIM™ with OtoAccess® Database PC application, after transfer of the data from the device.


Patient information transferred from the HearSIM™ PC application to the device can be edited on the device until a test is saved.

In both cases, the Patient ID is the exception to the rule. Once it is entered and saved, it cannot be edited on the device even if no tests were performed.

### 5.13.2.4 Proceed to Test

Select the **Test**  button in the bottom control bar to proceed with testing this patient.

### 5.13.2.5 View Test List

Select the **Test List**  button in the bottom control bar of the **Patient information** screen to see a list of tests performed on this patient.

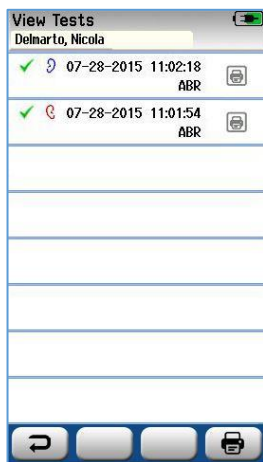




Figure 89

The test list is sorted chronologically with the most recent test at the top (Figure 89). Each row represents one test.

If more than 8 tests are saved then use the **Up**  and **Down**  arrow buttons in the bottom control bar to page through the list.

You can select one or more tests from this list and print them (see section 5.13.3.2).



Figure 90

Each row in the **View Test List** screen shows the following information:

- Result symbol for Pass, Refer or Incomplete
- Test ear symbol for Right, Left or Both ears
- Test date & time
- Technology type (ABR, DPOAE or TEOAE)

### 5.13.2.6 Review Test Details

Select one of the tests in the list to view its details. See sections 5.10 to 5.11.5 for descriptions of the information displayed in the **View Details** screens.

### 5.13.2.7 View Test Fields

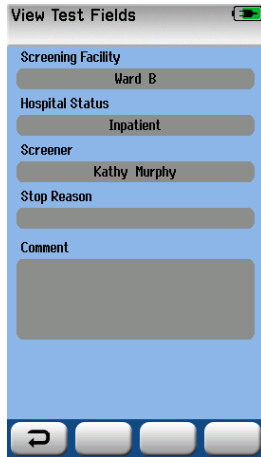



Figure 91

Select the **View Test Fields**  button in the bottom bar of the **View Details** screen to view the test fields. This screen will be available only if the **Test Fields** option is enabled on the device via the HearSIM™ PC application.

The test fields cannot be edited on the easyScreen. If edits are needed, the test data must be transferred into the optional HearSIM™ PC application and the edits can be made there.

### 5.13.3 Printing Test Results

#### 5.13.3.1 General

Use only the recommended label printer from MAICO. It is possible to share one printer with multiple easyScreen devices.

Pairing of the wireless printer and the easyScreen is accomplished in the **Setup/Printer** screen.

**NOTE:** Do not power off the easyScreen during printing to avoid incomplete label printing.

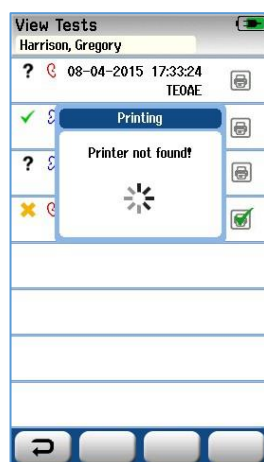



Figure 92

An attempt to print when the wireless label printer is powered off or is out of range to the easyScreen will result in the appearance of an error message (Figure 92).

Dismiss the message by selecting the **Back**  button in the bottom control bar. Try again after turning on the printer or moving into range.

### 5.13.3.2 Start Print Process

Printing of screening results on the label printer can be accomplished either directly after screening from the **Test Done** screen or at a later time from the **View Tests** screen (entered from the **Patient information** screen).

#### Start Print Process from the View Tests Screen

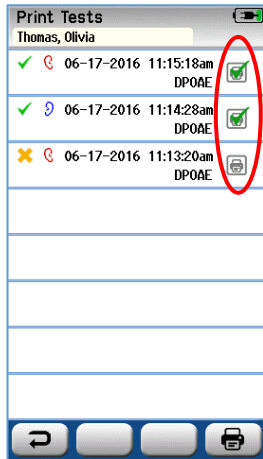


Figure 93

Touch the Printer box to the right of the test to select the test for printing. When selected the print icon box will contain a green checkmark. Select as many tests as you want to print. Then select the **Print** button in the bottom control bar.

Each test will be printed on a separate label except in the case where you have selected only one right and one left ear test of the same technology type. In that case, both tests will be printed on a single label.

**NOTE:** Printer boxes and the **Print** button only appear on the screen if your easyScreen has the Wireless and Printer settings enabled via the optional HearSIM™ PC application and if a printer has been paired with the device. Otherwise these controls are hidden from view.

#### Start Print Process After Screening from the Test Done Screen

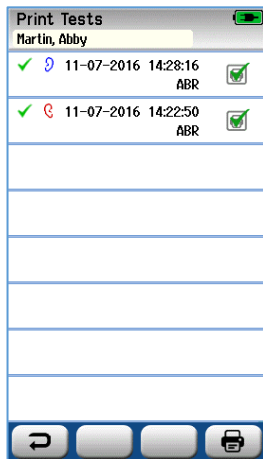


Figure 94

Printing of test results on the label printer can be performed at the **Test Done** screen by selecting the **Test List** button in the bottom control bar. The full list of screening tests performed for this patient will appear in reverse chronological order (Figure 94).

For your convenience, the most recently performed right and left ear screening in the current session will be pre-selected for printing. This is reflected by a small green checkmark appearing on a printer icon at the right side of the row. You can deselect by touching the symbol. You can select other tests in the list for printing according to your preferences.

If only one right and one left ear screening is selected for printing in the list, then both ears' results will be printed out on a single label. When more than 2 tests are selected for an ear, then each screening will be printed out on a separate label.

**NOTE:** The print icons will not appear on easyScreen under certain conditions. If label printing or wireless communication is not enabled on the device via the HearSIM™ PC application or if a label printer has not been paired to the easyScreen, the icons will not appear.

### 5.13.3.3 Understanding the Print-Out

The label print-out displays the following information (Figure 95).

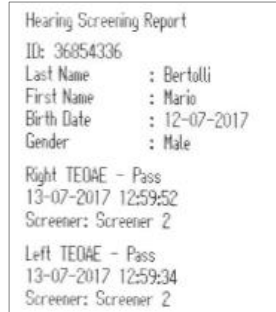


Figure 95

## 5.14 Setup

Select the **Setup** button on the bottom control bar of the **Home** screen to access a list of the settings that can be made directly on the easyScreen.



Figure 96

### Setup Language

A list of available languages displays. Use the **Up** and **Down** arrow buttons in the bottom bar to page through the list.

Select the desired language so that a checkmark appears in the checkbox next to the language.

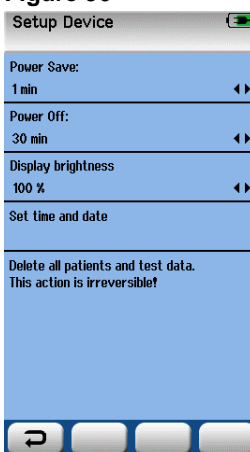


Figure 97

### Setup Device

Set your time preference for **Power Save** and **Power Off** features (Figure 97):

- **Power Save** (Standby): can be set to Never, 1-5 minutes or 10 minutes.
- **Power Off**: can be set to Never or 1, 5, 10, 15 or 30 minutes.
- **Display brightness**: set a value between 10 % and 90 %.
- **Set time and date**: allow setting of date format, 12/24 hour clock format, date and time
- **Delete all patients and test data**: allows clearing the internal device database after confirming the action.

**NOTE:** Manually deleted patient and test data are irreversibly removed from the device and cannot be recovered afterwards.

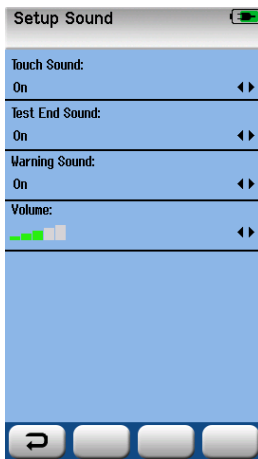


Figure 98

## Setup Sound

Setup your preferences for the presentation of a sound as feedback under various conditions as well as the setting of the **Volume**. Conditions for which you can choose to present a sound are (Figure 98):

- **Touch Sound:** plays a sound when touching a function button or keyboard key
- **Test End Sound:** plays a sound when a test is completed
- **Warning:** plays a sound when an electrode becomes detached during ABR
- **Volume:** Select the volume at which the sounds are to be played back.

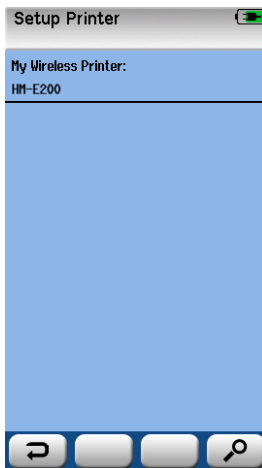


Figure 99

## Setup Printer


To pair to the optional wireless printer, select the **Search**  button in the bottom control bar. Be sure that the printer is powered on. The names of any “HM-E200” printers discovered in the search will display. Select the one you want to pair with easyScreen. Then the screen will show the printer to which it is successfully paired (Figure 99).



Figure 100

## About

Select the **About** item to view information about the easyScreen (Figure 100) including:

- Software versions
- Serial numbers and calibration dates
- Battery information
- Licenses

## 5.15 License Upgrade

License upgrades to a MAICO easyScreen can be added after the original purchase. One example of a license upgrade is adding TEOAE or DPOAE technology to a device that was purchased with ABR only.

License upgrades require entering a 23-character license key onto the device via a PC software tool. Additional hardware/accessories may also be required to support the added technology.

**Following information are required to order a license upgrade key:**

- Sales part number for the desired upgrade
- easyScreen device Serial Number (SN)
- easyScreen Mainboard SN

The device SN can be found on the type label at the back of the device and the Mainboard SN can be found in the **About**  view (Figure 101).

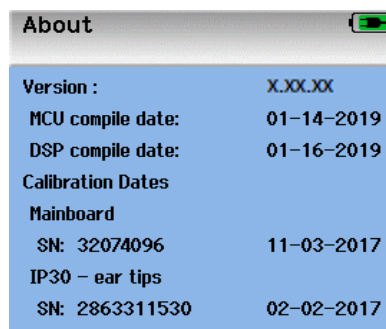



Figure 101

After receiving the license code, connect the easyScreen device with your computer using the Micro-USB cable. Copy the **ErisLicenseManager.exe** utility program from the provided USB flash drive onto the PC's and power on the easyScreen. Open the **ErisLicenseManager.exe** application. Licenses that already exist on your device will display in the appropriate field. Be careful not to alter or overwrite these license codes. In the Licenses table add the provided 23-character code to the correct license field by copying and pasting the code from the USB flash drive to the correct license field. If you received the license code on a paper certificate, enter the number manually into the correct license field being careful to match the numbers exactly. Press the **Set license** button behind the new license number to program the easyScreen.

Close the License Manager, disconnect the easyScreen from the USB cable and restart the device. The requested feature is now activated in the device. Select the **Setup** button on the device start screen and navigate to **About**  in the **Setup** to see the active licenses.

If additional hardware and accessories were included with your upgrade package, you will need to connect the proper cables to the easyScreen to use the new technology. Make sure the correct probe or transducer is connected to the device before turning on the device.

Check the functionality of the activated feature in the device by performing the test.

## 5.16 Pass-Checker (Optional Use for ABR Hardware Testing)

The Pass-Checker accessory can be optionally used to perform a quality check of the ABR components of the easyScreen. This can be done on a regular basis or can be performed if you suspect a problem with the easyScreen hardware. The Pass-Checker can be purchased from your MAICO representative.



Figure 102

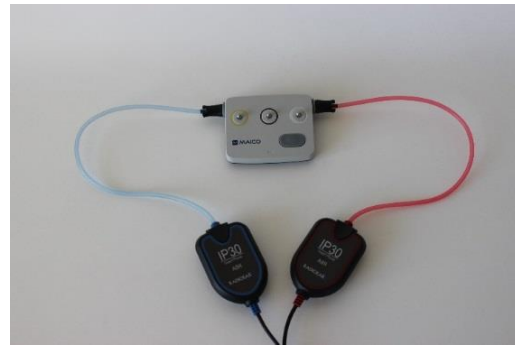


Figure 103

The quality check is performed as follows:

- Verify that the electrode lead wires and the insert earphones are connected to the easyScreen preamplifier cable and that the preamplifier cable is attached to the easyScreen.
- Connect the 3 electrode lead wires to the posts on the Pass-Checker matching the colors of the wires to the ring around the posts (Figure 102).
- Insert the insert earphone adapters securely into the holes on either side of the Pass-Checker (Figure 103).
- If the black EarCup™ or EARturtle™ adapters are used with your system these will fit into the hole directly.
- If the clear eartip adapters are used with your system you will need to place a disposable eartip onto the adapters before inserting them into the Pass-Checker holes.
- Switch on the Pass-Checker by pressing the power button. The amber LED lights up when the Pass-Checker is turned on.
- The Pass-Checker has an auto-off function. If you perform repeated tests during troubleshooting, make sure that the Pass-Checker is still switched on during your tests.
- Perform a standard binaural (both ears) ABR test with the Pass-Checker attached.
- The test should proceed quickly through the impedance and measurement phases ending in a Pass result for both ears.

See below for symptoms, possible causes and suggested troubleshooting (Table 20).

**Table 20 Pass-Checker – Troubleshooting**

SYMPTOM	POSSIBLE CAUSE	SUGGESTED TROUBLESHOOTING
Cannot pass impedance for one or more electrodes.	Electrode lead wire is not fully attached to the preamplifier or to the Pass-Checker.	Check connections at the preamplifier cable jack and on the Pass-Checker and try again.
	Electrode lead wire is broken.	Replace the electrode lead wire with a new one (may need to replace more than one of the electrode wires).
	Connection of preamplifier or BERAPhone® cable to the easyScreen jack is not secure.	Check the connection of the preamplifier or BERAPhone® cable to the easyScreen; remove it and re-insert it verifying that it is securely attached.
Excessive artifacts are observed during the measurement.	Electrode lead wire is broken or has poor internal contact which may lead to intermittency.	Replace the electrode lead wire with a new one (may need to replace more than one of the electrodes).
Test does not pass in one or both ears.	Connection of insert earphone cable into the preamplifier cable jack is not secure.	Check the connection of the insert earphone connector into the preamplifier cable; remove it and re-insert it verifying that it is securely attached.
	Insert earphone cable is not securely attached to the transducer box.	Check the connection of the insert earphone cable to the red and blue transducers.
	Insert earphone adapter is occluded with debris or is cracked; more likely to occur with the clear Eartip adapter.	Clean the adapter using the Infant Eartip Cleaning brush. Or replace the adapter with a new one.
	Tubing of insert earphone is crimped shut or has a rip in the tube.	Make sure the tubes are free of any crimping or compression; replace the tube with a new one.
	Insert earphone cable has a short-circuit in the cable or is broken causing no output.	Replace the insert earphone cable with a new one.
	Low battery on the Pass-Checker? Is the LED flickering?	Contact your MAICO Service representative regarding change of battery on the Pass-Checker. We recommend annual battery change at the time of calibration of your easyScreen device.



The Pass-Checker battery should only be replaced by an authorized Maico representative. Damage to the Pass-Checker electronics resulting from an attempt to change the battery by someone other than an authorized representative will not qualify for repair under the product warranty.

If these troubleshooting suggestions do not resolve the problem you are experiencing with your easyScreen device, allowing you to pass a screening using the Pass-Checker, contact your local MAICO representative for assistance. It is recommended that you keep replacement cables and accessories for your easyScreen available to perform these troubleshooting procedures (see Table 21).

**Table 21 Descriptions Replacement Parts**

DESCRIPTIONS
Insert earphone tubes & adapters for EarCups™ (around the ear)
Insert earphone tubes & adapters for EARturtle™ (around the ear)
Insert earphone tubes & adapters for eartip (in-the-ear)
Electrode lead wires (black, yellow, white)
Preamplifier cable

## 5.17 Infant Ear Simulator (Optional Use for OAE Probe Testing)

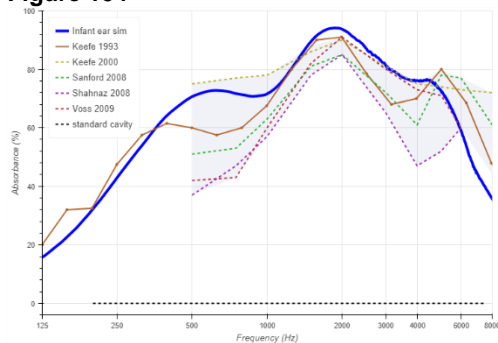
The performance of the probe is critical for acquiring accurate results so that newborns with possible cochlear hearing loss are not missed. To ensure that your device is performing accurately, regular testing of the probe is essential.

Until now, the only method available to assess the probe was to perform a test in a hard-walled cavity. It is well known that such a cavity does not reflect the properties of an infant ear. Testing this way can produce false responses due to the resonance characteristics of the hard-walled cavity, making it difficult to assess how accurately the probe will perform in a real infant ear.



With the Infant Ear Simulator (Figure 104) it is possible to test your OAE probe in a cavity specifically designed to mimic the acoustic absorbance properties of a real infant ear including the ear canal and middle ear.

**Figure 104**



**Figure 105**

Figure 105 shows how accurately the Infant Ear Simulator mimics the acoustic absorbance of an infant ear based on data from several published studies.

The shaded area displays the range from all of the referenced studies.

The blue line at the bottom of the graph shows how poorly a standard cavity simulates an infant ear.

Using the Infant Ear Simulator, it is possible to perform an OAE probe quality check in a realistic test cavity. Use the Infant Ear Simulator as follows:

1. Attach a clean disposable eartip of the smallest size to your OAE probe.
2. Insert the probe with eartip into the Infant Ear Simulator.
3. Perform a standard OAE screening.
4. The screening outcome should be a Refer.
5. If the screening outcome is a Pass, contact your distributor to replace or repair your probe.

## 6 Technical Data

This section offers you important information about

- the easyScreen hardware specifications
- the pin assignment
- calibration values
- electromagnetic compatibility (EMC)
- electrical safety, EMC and associated Standards
- screening protocols available via the optional HearSIM™ PC application

### 6.1 easyScreen Hardware



The easyScreen is an active, diagnostic medical product according to the class IIa of the Medical Device Regulation (EU) 2017/745.

#### General Information About Specifications

The performance and specifications of the device can only be guaranteed if it is subjected to technical maintenance at least every 12 months.


MAICO Diagnostics puts diagrams and service manuals at the disposal of authorized service companies.

#### STANDARDS

<b>Device Safety</b>	IEC 60601-1:2012 reprint/ANSI/AAMI ES60601-1:2005+A2:2010 +A1:2012/ CAN/CSA-C22.2 No. 60601-1:14, Internally powered, BF applied parts IEC 60601-2-40:2016
<b>Cradle Safety</b>	IEC 60601-1:2012 reprint, Class II
<b>EMC</b>	IEC 60601-1-2:2014 (EMC test done with default settings)
<b>Calibration</b>	ISO 389-2:2017 ISO 389-6:2007
<b>Test Signal</b>	IEC 60645-3:2007
<b>OAE</b>	IEC 60645-6:2009, Type 2 <sup>3</sup>
<b>ABR</b>	IEC 60645-7:2009, Type 2

<sup>3</sup> OAE Standard is met by transferring IEC protocols from HearSIM™ to the easyScreen. For detailed information, see section 6.7 of this manual.

## DEVICE SPECIFICATIONS

<b>Operation environment</b> 	Temperature	+15 °C to +35 °C / + 59 °F to +95 °F
	Relative Humidity	30 % to 90 % (non-condensating)
	Ambient Pressure	98 kPa to 104 kPa
<b>Transport &amp; Storage environment</b>	Storage Temperature	0 °C to 50°C, 32 °F to 122°F
	Transport Temperature	-20 °C to + 50 °C / -4 °F to +122 °F
	Storage and transport rel. humidity	10 % to 95 % (non-condensating)
<b>Altitude rating</b>	Max. operating altitude	5000 m / 16404 ft. above sea level On-site calibration is needed at altitudes above 2000 m / 6561ft.
<b>Markings</b> <b>IP02</b> <b>IP20</b>	<p>IP marking is an ingress protection marking. The marking specifies the protection provided against ingress of particle matter and liquids. This device has different IP marking with the follow impact:</p> <p>IP02: To protect the device against rain and water always use the carrying bag during transport.</p> <p>IP20: This marking can be found on the device parts meaning that the parts are not protected against water</p> <p><b>NOTE:</b> The charger, power supply and cradle are not to be used in home healthcare environments.</p>	
<b>Warm-up time</b>	Less than 1 minute after power on (incl. boot-up time)	
<b>Dimensions</b>	160 mm x 85 mm x 21 mm / 6.4 in x 3.3 in x 0.8 in	
<b>Weight</b>	265 g / 0.5 lb	
<b>Display</b>	Display Size	95 mm x 56 mm / 3.7 in x 2.2 in
	Resolution	272 x 480
<b>Mode of operation</b>	Continuous	
<b>Data Interfaces</b>	PC connection	USB
	Wireless printing	Transmit frequency: 2400 MHz to 2483.5 MHz Modulation types: GFSK, π/4-DQPSK and 8DPSK Radiated power: 2.5 mW (Class 2)
<b>User Feedback</b>	Acoustical	Integrated speaker
	Visual	Color display and LED
<b>User Interface</b>	Resistive touch screen	
<b>Language Settings</b>	English, German, Spanish, French, Italian, Dutch, Turkish, Chinese, Japanese, Korean, Romanian, Norwegian, Russian, Polish, Portugese	
<b>Battery</b>	Type	Li-ion battery
	Capacity	3.7V/3850 mAh
	Expected life time	Depending on use – typically > 3 years
<b>Memory</b>	1 GB (max. 250 patients can be stored with 50 tests each)	
<b>Connectors</b>	OAE/ABR	For OAE Probe, SnapPROBE™, ABR preamplifier or BERAPHONE®
	USB	Micro USB to PC

## ABR

<b>Stimulus</b>	Type	CE-CHIRP® (default) 200 Hz to 11 kHz Click 200 Hz to 11 kHz
	Level range	30 dB nHL to 45 dB nHL
	Default level	35 dB nHL <sup>4</sup>
	Stimulus rate	88 /s left ear, 92.5 /s right ear
	Transducers	IP30 ABR insert phones IP30 ABR for EarCup™ and EARturtle™ Standard OAE probe SnapPROBE™ BERAphone®
	Test modes	Binaural (only with IP30) or monaural
<b>Recording</b>	Analysis time	Maximum 180 s of artifact-free data
	A/D resolution	24 bit
	Artifact rejection system	Artifact rejection level (Peak, Min RMS, Max RMS) & Clipping (Saturation)
	Artifact rejection level	100 µV
	Display	View of progress bars toward Pass, feedback about EEG Noise and recording Time
<b>ABR impedance measurement</b>	Measurement frequency	33 Hz
	Measurement current	11.25 µA
	Waveform	Rectangle
	Acceptable Impedance Range	1 kΩ to 50 kΩ

## DPOAE

<b>Stimulus</b>	Frequency range	1500 Hz to 6000 Hz
	Frequency accuracy	< 1 %
	Default frequencies	2000, 3000, 4000, 5000 Hz
	Nominal frequency	F2
	F2/F1 Ratio	1.22
	Level range	50 dB SPL to 65 dB SPL
	Level accuracy	± 1.5 dB
	Default level (L1/L2)	65 dB SPL / 55 dB SPL with in-ear calibration <sup>5</sup>
	Level tolerance	7 dB
	Transducer	Standard OAE probe, SnapPROBE™
<b>Recording</b>	Maximum test time	60 s

<sup>4</sup> See section 6.7 for more information about the available protocols with different levels and stimuli.

<sup>5</sup> The easyScreen uses an alternative stimulus level control procedure, which is optimized for a large range of ear canal volumes from newborn ears with small ear canal volumes to adult ears with large volume. This is beyond the range required by the standard. See section 6.7 for details about the protocols which comply with the standard.

## DPOAE

	A/D resolution	24 bit
	Artifact rejection level	30 dB SPL
	Probe fit check	Frequency response of the ear canal with click stimulus
	Residual noise	RMS measurement in frequency domain, average of frequency components around the DP frequency (26 bins < 2500 Hz and 60 bins ≥ 2500 Hz)
	Display	Progress bar towards Pass, feedback about Noise, recording Time
<b>Pass criteria:</b>	SNR criteria	Depends on protocol Default: Minimum 6 dB
	Response criteria	Depends on protocol Default: Minimum -5 dB SPL
	#Freq for pass	Depends on selected protocol Default: 3 of 4

## TEOAE

<b>Stimulus</b>	Stimulus type	Non-Linear click (according to IEC 60645-3)
	Level range	60 dB peSPL to 83 dB peSPL
	Default level	83 dB peSPL (peak to peak calibrated), auto in-ear calibration
	Level tolerance	± 3 dB
	Click rate	~70 /s
	Transducer	Standard OAE probe, SnapPROBE™
<b>Analysis bands</b>	Frequency range	1000 Hz to 4000 Hz
	Default center frequencies	1400, 2000, 2800, 4000 Hz
<b>Recording</b>	Maximum test time	60 s
	Maximum noise level	55 dB SPL
	Averaging method	Bayesian weighted averaging
	Display	Progress bar towards Pass, feedback about Probe stability, Noise and recording Time
<b>Pass criteria</b>	SNR criteria	Depends on protocol Default: Minimum 4 dB
	Response criteria	Depends on protocol Default: Minimum -5 dB SPL
	#Freq bands	Depends on protocol Default: 3 of 4

## TRANSDUCER

<b>Radioear IP30</b>	Type	ABR insert phone (50 Ω)
	Versions	Calibrated for EarCup™ and EARturtle™ or eartips Auto detection by device
	Supported tests	Binaural or monaural ABR
	Max. input voltage	5.0 V RMS
	THD	< 2 % (125 Hz - 4 kHz)
	Memory	Calibration values and transducer ID
	Cable length	22 cm / 8.66 in
	Tube length	25 cm / 9.8 in
	Tube colors	Red (right ear) and blue (left ear)
	Weight (incl. cables)	53 g / 1.87 oz
<b>Standard OAE Probe</b>	Supported tests	DPOAE, TEOAE and monaural ABR
	Cable length	120 cm / 47 in
	Memory	Calibration values and transducer ID
	Probe tip	Replaceable
	Weight (incl. cables)	19 g / 0.67 oz
<b>SnapPROBE™</b>	Supported tests	DPOAE, TEOAE and monaural ABR
	Cable length	120 cm / 47 in
	Memory	Calibration values and transducer ID
	Eartip	Replaceable, with 3 acoustic channels
	Weight (incl cables)	20 g / 0.71 oz

## BERAphone®

<b>Supported tests</b>		ABR (monaural)
<b>Preamplifier</b>	Channels	One
	Gain	72 dB
	Frequency response	0.5 Hz to 5000 Hz
	Self Noise	<25 nV/√Hz
	CMR Ratio	> 100 dB at 100 Hz
	Max input offset voltage	2.5 V
	Input impedance	10 MΩ/170 pF
	Power supply	Isolated, from main unit
<b>Speaker</b>	Integrated	Dynamic, 8 Ω
<b>Electrodes</b>	3pcs. with gel protectors	Stainless-steel, reusable, rotatable vertex electrode
<b>Feedback</b>	LEDs	LEDs to indicate right or left ear, 3 RGB LEDs for impedance and test status (running, paused or artifacts)
<b>User Interface</b>	Push button	To start, pause or stop test
<b>Properties</b>	Weight	254 g/ 8.96 oz
	Dimensions	148 mm x 75 mm x 65 mm / 5.83 in x 2.95 in x 2.56 in
	Cable length	120 cm / 47 in
<b>Memory</b>		Calibration values and transducer ID
<b>Cradle</b>	Weight	300 g/ 10.6 oz
	Dimensions	94 mm x 171 mm x 90mm /3.7 in x 6.7 x 3.5 in

## ABR PREAMPLIFIER

Channels	One
Connectors	3 electrode lead wires (black, yellow, white) Transducer (IP30 or OAE Probe)
Gain	72 dB
Frequency response	0.5 Hz to 5000 Hz
Inherent Noise	<25 nV/ $\sqrt{\text{Hz}}$
CMR Ratio	> 100 dB at 100 Hz
Max input offset voltage	2.5 V
Input impedance	10 M $\Omega$ /250 pF
Power supply	Isolated, from main unit
Weight	85 g / 3 oz
Dimensions	85 mm x 50 mm x 25 mm / 3.4 in x 1.9 in x 0.9 in
Cable length	112 cm / 44 in
Electrode lead wire length	51 cm / 20 in

## CRADLE

Charging	Wireless (inductive charging)	
Dimensions	142 mm x 140 mm x 62 mm / 5.6 in x 5.5 in x 2.4 in	
Weight	270 g / 0.6 lb	
Power supply	Type	UES12LCP-050160SPA
	Input	100 to 240 V AC, 50/60 Hz, 0.5 A
	Output	5.0V DC, 1.6A MAX
	Safety	IEC 60601-1, Class II

## PRINTER

Label printer	Type	HM-E200
	Connection	Wireless
	Battery	7.4 V rechargeable Li-polymer battery, 1300 mAh
	Weight	234 g / 8.3 oz
	Paper	Label
	Paper size	Label 57.5 mm $\pm$ 0.5 mm x 60 mm (width x length) Thermal paper 57.5 mm $\pm$ 0.5 mm (width)
	Printing time	<5 seconds per test result
Power supply	Type	UES12LCP-050160SPA
	Input	100 to 240 V AC, 50/60 Hz, 0.5 A
	Output	5.0V DC, 1.6A MAX
	Safety	IEC 60601-1, Class II

## 6.2 Pin Assignment

### easyScreen Cradle Connection

MICRO USB B (IN)	
	1. VBUS from external host system
	2. Ground connection for external power supply
	3. External power supply, 5V/1.5A DC
	4. Not used
	5. Ground connection for external power supply

### easyScreen ABR/OAE Connector for ABR Preamplicifier Probe/Transducer connector, BERAprone® and Insert earphones

PROBE CONNECTOR	PIN	FUNCTION
<p>12 pol connector</p>	1	CH1 out
	2	CH1 GND
	3	DGND
	4	GND A / GND Microphone
	5	Microphone – input / Analog balanced in
	6	Microphone + input / Analog balanced in
	7	Power supply +3/+5V
	8	CH2 out
	9	CH2 GND
	10	I2C CLK
	11	I2C DATA
	12	I2C Interrupt

EASYSscreen CONNECTOR			
USB A (OUT)		MICRO USB B (IN)	
<p>4 3 2 1</p>	1. +5 VDC		1. +5 VDC
	2. Data -		2. Data -
	3. Data +		3. Data +
	4. Ground		4. ID
			5. Ground

## 6.3 Calibration Values

### RadioEar IP30 with Coupler IEC 60318-4 (60711).

TRANSDUCER	CE-CHIRP® pe RETSPL [dB re. 20 µPa]	Click pe RETSPL [dB re. 20 µPa]
Radioear IP30 with eartips	32.0	35.0
Radioear IP30 with EarCups™ and EARturtle™	58.5	61.5

Calibration values are defined as MAICO standard values.

### OAE Probe with Coupler IEC 60318-4 (60711).

TRANSDUCER	CE-CHIRP® pe RETSPL [dB re. 20 µPa]	Click pe RETSPL [dB re. 20 µPa]
OAE Probe	35.0	33.5
SnapPROBE™	34.0	37.5

Calibration values are defined as MAICO standard values.

### BERAphone® with coupler 60318-3.

TRANSDUCER	CE-CHIRP® pe RETSPL [dB re. 20 µPa]	Click pe RETSPL [dB re. 20 µPa]
BERAphone®	32.5	37.5

The calibration values for the BERAphone® are according to the PTB Report from 2008-05-19. A special calibration adapter is needed to mount the BERAphone® onto the coupler with a pressure of 5 N.

## Stimulus

### ABR

The ABR stimulus is different from the click specified in the standard IEC 60645-3. This CE-CHIRP® stimulus has the same linear magnitude frequency response like the click stimulus specified in the standard. However, it is generated as a sum of cosine functions in the frequency domain. The frequencies of the cosines are multiples of the stimulus repetition rate – with equal intensity for each frequency, to achieve the same linear magnitude frequency response. However, the phase of the cosine components is delayed according to the cochlear delay of the according frequency in order to generate a more effective stimulus design. The frequency range of the stimulus is from 200 Hz to 11,000 Hz.

## TEOAE

The IEC 60645-6 standard allows the use of manufacturer specific stimuli waveform shapes. However, the current IEC 60645-6 standard refers to the IEC 60645-3 standard on the specific topic of a reference stimulus characteristic for TEOAE measurements (i.e. the use of short duration stimuli).

The IEC 60645-3 standard documents the electrical characteristics of a reference short duration stimulus which is a rectangular, unipolar signal of 100  $\mu\text{s}$  duration (with a tolerance of 10  $\mu\text{s}$ , and specified rise and fall times). Note that this reference pulse is an 'electrical signal' that is used to generate an acoustic stimuli and as such is heavily modified by the electro-acoustic nature of the probe transducer, the acoustic design of the probe, and the ear simulator or other cavity that it used during acoustic calibration of the equipment.

The easyScreen utilises an optimised TEOAE stimulus that avoids the inherent difficulties that arise during TEOAE measurements when using a simple unipolar rectangular pulse such as the IEC 60645-3 specified reference pulse. This optimised stimulus is bipolar so that it contains no DC component. DC and low frequency energy (i.e. below 400 Hz or so) increase the risk of contamination of the TEOAE response with residual stimulus energy – this typically occurs up to 4 ms after the electrical pulse is applied. It is possible to reduce this risk of contamination by only measuring the TEOAE response after say 5 ms has elapsed. However, the high frequency components of the TEOAE (which originate at the basal end of the cochlea) will then be considerably diminished and the test will take longer and be less effective. Furthermore, the optimised stimulus concentrates the energy of the pulse in the frequency region that is most relevant to infant hearing screening.

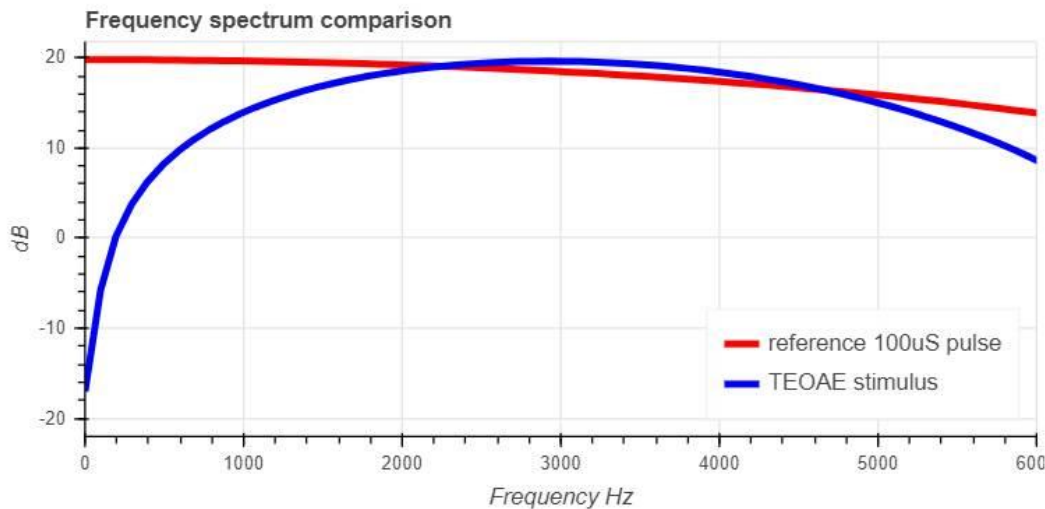
In order to permit comparisons of electrical calibration between the easyScreen and the IEC 60645-3 reference stimulus, this document provides a comparison of the energy contained within the electrical characteristics of both the reference and the optimised stimulus. This was calculated using an 'area under the curve' method, in other words a simple integral of voltage over time for each of the stimuli shapes. Please note that a pure rectangular electrical pulse is rarely measurable at any accessible point on OAE equipment since there will usually be filtering applied to the signal once it has been generated by the DAC long before it reaches the OAE probe. Fast edged signals contain considerable high frequency energy and cause problems with no benefits at all in OAE measurements. Furthermore, sometimes this filtering is included in the DAC internal circuitry making the original signal unavailable outside of the integrated circuit.

The comparison of the reference pulse and our bipolar optimised stimulus requires careful attention to the use of 'peak' and 'peak to peak' measurements since one is a unipolar signal and the other is bipolar. Although this is the case at the exact source of electrical generation, both signals will be bipolar when delivered acoustically due to the inherent high-pass filtering of the transducers and any high-pass filtering present in the signal chain. This document provides comparison using both methods of measurement. In practice, an acoustic comparison will fall somewhere between these two extremes due to the filtering.

Using a 'peak' measurement: I.e. the rectangular pulse has a height equivalent to only the positive excursion of the optimised bipolar pulse, the optimised stimulus used in the easyScreen delivers 5.18 dB additional energy for equivalent peak voltages.

Using a 'peak to peak' measurement: I.e. the rectangular pulse has a height equivalent to the full positive to negative excursion of the optimised bipolar pulse, the optimised stimulus used in the easyScreen delivers -0.84 dB energy relative to the reference rectangular pulse.

Finally, the graph below shows a comparison of the frequency response of the reference pulse and the optimised stimulus. The relative levels of the two pulse types has been adjusted to reflect the typical resulting levels when acoustic calibration is performed (i.e. peak-to-peak acoustic levels in an adult ear simulator). The graph clearly illustrates the severe reduction of low frequency and DC components and the slight enhancement in the required OAE screening frequency region.



## 6.4 Coupler Types Used for Calibration

**DPOAE:** Probe tones L1 and L2 are calibrated individually in SPL values using the IEC 60711 ear simulator made in accordance to IEC 60318-4.

**TEOAE:** Probe tones are calibrated in peSPL values using the IEC 60711 ear simulator made in accordance to IEC 60318-4.

## 6.5 Electromagnetic Compatibility (EMC)

ESSENTIAL PERFORMANCE for this device is defined by the manufacturer as:

- This device does not have an ESSENTIAL PERFORMANCE.
- Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk. Final diagnosis shall always be based on clinical knowledge.

This device is in compliance with IEC 60601-1-2:2014, emission class B group 1

*NOTICE:* There are no deviations from the collateral standard and allowances uses.

*NOTICE:* All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

### Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the **easyScreen**. Install and operate the **easyScreen** according to the EMC information presented in this chapter.

The **easyScreen** has been tested for EMC emissions and immunity as a standalone **easyScreen**. Do not use the **easyScreen** adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.


The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The <b>easyScreen</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>easyScreen</b> should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The <b>easyScreen</b> 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.  The <b>easyScreen</b> is suitable for use in all commercial, industrial, business, and residential environments.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the easyScreen.			
The <b>easyScreen</b> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <b>easyScreen</b> can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <b>easyScreen</b> as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
<b>Note 1</b> At 80 MHz and 800 MHz, the higher frequency range applies.			
<b>Note 2</b> These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The <b>easyScreen</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>easyScreen</b> should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical transient/burst IEC61000-4-4	± 2 kV for power supply lines 100kHz repetition frequency ± 1 kV Line-to-line 100kHz repetition frequency	Not applicable ± 1 kV Line-to-line	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	± 1 kV Line-to-line ± 2 kV Line-to-ground	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% $UT$ for 0.5 cycle 0 % $UT$ for 1 cycle and 70% $UT$ for 25/30 cycles Single phase: at 0°	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the <b>easyScreen</b> requires continued operation during power mains interruptions, it is recommended that the <b>easyScreen</b> be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
<b>Note:</b> $UT$ is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The <b>easyScreen</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>easyScreen</b> should assure that it is used in such an environment.			
Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any parts of the <b>easyScreen</b> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b>  $d = 1,2\sqrt{P}$
	6 Vrms in ISM bands 150kHz to 80 MHz 80 % AM at 1 kHz	6 Vrms	
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz  $d = 2,3\sqrt{P}$ 800 MHz to 2.7 GHz  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:  
	80 % AM at 1 kHz		
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<sup>a</sup> ) 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 <b>easyScreen</b> is used exceeds the applicable RF compliance level above, the <b>easyScreen</b> should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <b>easyScreen</b> .			
<sup>b</sup> ) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

This device is in compliance with IEC 60601-1-2:2014, emission class B group 1.

**NOTE:** There are no deviations from the collateral standard and allowances uses

**NOTE:** All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories (see Table 22).

**Table 22 EMC Requirements – Accessories**

ITEM	MANUFACTURER	MODEL
ABR Preamplifier	MAICO	-
Standard OAE Probe	RadioEar	-
SnapPROBE™	RadioEar	-
IP30 50 Ohm stereo ID headset	RadioEar	IP30
BERAphone®	MAICO	easyScreen

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified in Table 23.

**Table 23**

EUT SUPPORT EQUIPMENT						
Item	Manu- facturer	Model	Cable		SIP/SOP	
			Length [m]	Screened [Y/N]	Socket ID	Type
Power Supply	UE / Fuhua	UES12LCP- 050160SPA	-	-	Mains power	AC supply
			1.5	N	Micro USB on the wireless charger/cradle	DC supply
Wireless charger/cradle	MAICO	-	-	-	-	-
Audiometric Insert-Headset (50Ω)	RadioEar	IP30	0.25	Y	On the preamp: Socket marked with ear symbol	Analog output Serial data
Ear Probe	RadioEar	Standard OAE Probe	0.48	Partial	On the preamp: Socket marked with ear symbol or top socket on the easyScreen	Analog output Mic input Serial data
SnapPROBE™	RadioEar	SnapPROBE™	1.2	Partial	On the preamp: Socket marked with ear symbol or top socket on the easyScreen	Analog output Mic input Serial data
Preamp	MAICO	-	1.15	Partial	Top socket on the easyScreen	Analog output Mic input Serial data
Electrode cables	Sanibel Supply	-	0.51	N	On the preamp: Colour marked sockets with head symbol	Analog input for Physio- logical signals

Compliance with the EMF exposure guidelines as specified by ICNIRP, (HEALTH PHYSICS 96(4):504-514; 200) is ensured when using the following accessories: The accessories are classified (EMF level) according to the maximum strength of the permanent magnetic field.

Patients having magnetically programmable cerebral shunts must observe the precautions stated by the manufacturer of the shunt if the accessories with a HIGH magnetic field are used. No special precautions are necessary with accessories which emit a LOW magnetic field.

ITEM	MANUFACTURER	MODEL	EMF Level
ABR Preamplifier	MAICO	-	LOW
Standard OAE Probe	RadioEar	-	LOW
SnapPROBE™	RadioEar	-	LOW
IP30 50 Ohm stereo ID headset	RadioEar	IP30	LOW
BERAphone®	MAICO	easyScreen	LOW

## 6.6 Electrical Safety, EMC and Associated Standards

- IEC 60601-1:2012 reprint/ANSI/AAMI ES60601-1:2005+A2:2010+A1:2012/ CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment, Part 1 General Requirements for Basic Safety and Essential Performance
- UL/IEC/EN 60950-1: Information Technology Equipment - Safety - Part 1: General Requirements
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests
- ISO 14971 - Application of risk management to medical devices
- General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)

## 6.7 Screening Protocols

easyScreen is delivered with default screening protocols already present on the instrument as seen in section 6.1. MAICO recommends use of these protocols.

If your NHS program requires different screening parameters additional protocols can be installed if you purchased the optional HearSIM™ with OtoAccess® Database applications. Follow these instructions.

1. In HearSIM™, go to the Device menu and the Protocols tab.
2. Select the **Add protocol** control.
3. Review the list of available protocols residing in the default browser path.
4. Select the desired protocol and select **Open**. The protocol will be added to the Protocols list.
5. Follow the instructions in the HearSIM™ manual to transfer the desired protocols to your easyScreen.

The following table shows the protocols that can be installed via the optional HearSIM™ with OtoAccess® PC applications.

PROTOCOL FILE NAME	PARAMETERS	SENSITIVITY
ABRIS A00 CE-Chirp 35 dB nHL	CE-Chirp® stimulus of 35 dB nHL (default)	≥ 99.6 %
ABRIS A01 CE-Chirp 30 dB nHL	CE-Chirp® stimulus of 30 dB nHL	≥ 99.6 %
ABRIS A02 CE-Chirp 40 dB nHL	CE-Chirp® stimulus of 40 dB nHL	≥ 99.6 %
ABRIS A03 CE-Chirp 45 dB nHL	CE-Chirp® stimulus of 45 dB nHL	≥ 99.6 %
ABRIS A04 Click 35 dB nHL	Click stimulus of 35 dB nHL	≥ 99.6 %
ABRIS A05 Click 30 dB nHL	Click stimulus of 30 dB nHL	≥ 99.6 %
ABRIS A06 Click 40 dB nHL	Click stimulus of 40 dB nHL	≥ 99.6 %
ABRIS A07 Click 45 dB nHL	Click stimulus of 45 dB nHL	≥ 99.6 %
ABRIS A08 CE-Chirp 25 dB nHL	CE-Chirp® stimulus of 25 dB nHL	≥ 99.6 %
ABRIS A09 Click 25 dB nHL	Click stimulus of 25 dB nHL	≥ 99.6 %
DPOAE D00 2-5 kHz, 3_4, SNR 6 dB	F2 Frequencies: 5k, 4k, 3k, 2kHz (default) Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s # Freq. for pass: 3 / 4 Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Artifact rejection level: 30 dB SPL	≥ 99.6 %
DPOAE D01 1.5-4 kHz, 3_4, SNR 6 dB	F2 Frequencies: 4k, 3k, 2k, 1.5k Hz Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s # Freq. for pass: 3 / 4 Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Artifact rejection level: 30 dB SPL	≥ 99.6 %
DPOAE D02 1.5-6 kHz, 3_5, SNR 6 dB	F2 Frequencies: 6k, 4k, 3k, 2k, 1.5k Hz Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s # Freq. for pass: 3 / 5 Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Artifact rejection level: 30 dB SPL	≥ 99.6 %
DPOAE D05 1.5-6 kHz, 3_6, SNR 7 dB	F2 Frequencies: 6k, 5k, 4k, 3k, 2k, 1.5k Hz Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s # Freq. for pass: 3 / 6 Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 7 dB Artifact rejection level: 30 dB SPL	≥ 99.6 %

PROTOCOL FILE NAME	PARAMETERS	SENSITIVITY
DPOAE D06 2-5 kHz, 3_4, SNR 8 dB	F2 Frequencies: 5k, 4k, 3k, 2k Hz Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s # Freq. for pass: 3 / 4 Pass criteria for each frequency: Min OAE level: -25 dB SPL Min SNR: 8 dB Artifact rejection level: 30 dB SPL	≥ 99.6%
DPOAE D07 1.5-6 kHz, 3_6, SNR 6 dB	F2 Frequencies: 6k, 5k, 4k, 3k, 2k, 1.5k Hz Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s # Freq. for pass: 4 / 6 – auto stop Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Artifact rejection level: 30 dB SPL	≥ 99.6%
TEOAE T00 1.5-4 kHz, 3_4, SNR 4 dB	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz (default) Stimulus type: Click (non-linear) Level: 83 dB peSPL Max. test time: 60 s # Freq. for pass: 3 / 4 Min OAE level: -5 dB SPL Pass criteria for each frequency band: Min SNR: 4 dB Band mandatory for Pass: None	≥ 99.6%
TEOAE T01 1.5-4 kHz, 2_4 SNR 6 dB	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz Stimulus type: Click (non-linear) Level: 83 dB peSPL Max. test time: 60 s # Freq. for pass: 2 / 4 Min OAE level: 0 dB SPL Pass criteria for each frequency band: Min SNR: 6 dB Band mandatory for Pass: None	≥ 99.6%
TEOAE T02 1.5-4 kHz, 3_4, 80 dB SPL	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz Stimulus type: Click (non-linear) Level: 80 dB peSPL Max. test time: 60 s # Freq. for pass: 3 / 4 Min OAE level: -5 dB SPL Pass criteria for each frequency: Min SNR: 4 dB Band mandatory for Pass: None	≥ 99.6%

The following table lists the IEC 60645-6 compliant OAE protocols available to install into your HearSIM™ software. To install these protocols into HearSIM™ follow these steps:

1. In HearSIM™, go to the Device menu and the Protocols tab.
2. Select the **Add protocol** control.
3. Find the **IEC** sub-folder located in the default browser path.
4. Select the desired protocol and select **Open**. The protocol will be added to the Protocols list.
5. Follow the instructions in the HearSIM™ manual to transfer the desired protocols to your easyScreen.

PROTOCOL FILE NAME	PARAMETERS	SENSITIVITY
DPOAE D03 2-5 kHz, 65_55 dB SPL, IEC	F2 Frequencies: 5k, 4k, 3k, 2kHz Level (L1/L2): 65/55 dB SPL F2/F1 ratio: 1.22 Max. test time: 60 s # Freq. for pass: 3 / 4 Mic correction: disabled to comply with standard Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Artifact rejection level: 30 dB SPL	≥ 99.6 %
DPOAE D04 2-5 kHz, 60_50 dB SPL, IEC	F2 Frequencies: 5k, 4k, 3k, 2kHz (same as default) Level (L1/L2): 60/50 dB SPL F2/F1 ratio: 1.22 Max. test time: 60 s # Freq. for pass: 3 / 4 Mic correction: disabled to comply with standard Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Artifact rejection level: 30 dB SPL	≥ 99.6 %
TEOAE T03 1.5-4 kHz, 60 dB SPL, IEC	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz Stimulus type: Click (non-linear) Level: 60 dB peSPL Max. test time: 60 s # Freq. for pass: 3 / 4 Min OAE level: -5 dB SPL Pass criteria for each frequency: Min SNR: 4 dB Band mandatory for Pass: None	≥ 99.6 %
TEOAE T04 1.5-4 kHz, 70 dB SPL, IEC	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz Stimulus type: Click (non-linear) Level: 70 dB peSPL Max. test time: 60 s # Freq. for pass: 3 / 4 Min OAE level: -5 dB SPL Pass criteria for each frequency: Min SNR: 4 dB Band mandatory for Pass: None	≥ 99.6 %

Specifications are subject to change without notice.



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