Operation Manual
MB 11
BERAphone®/Classic

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Title: Operation Manual MB 11

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1 Introduction

This section offers you important information about:

- **the intended use of the device**
- **indications and contraindications of use**
- **features and benefits**
- **a description of the device**

1.1 General

This operation manual is for MB 11 BERAphone® and Classic versions. If sections or parts of sections of this operation manual apply only to certain versions of the device, they are marked with the version names.

1.2 Intended Use Statement

The MAICO MB 11 BERAphone® and MB 11 Classic are intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the auditory nerve and the brainstem.

The devices are intended to be used for Newborn Hearing Screening (NHS) using automated auditory brainstem response tests. The aim is to detect those babies with possible auditory or hearing-related deficits and to refer them on for further testing to confirm or rule out a disorder.

Target population

The MB 11 Classic is intended to be used for hearing screening of newborns and infants up to 6 months.

The MB 11 BERAphone® includes components that are 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.

Indications for Use

The MAICO MB 11 BERAphone®/Classic is designed to be used only by trained personnel (Audiologists, Physicians or other trained, supervised personnel). No person should attempt to use this instrument without the necessary knowledge and training to understand how this equipment is to be properly utilized and interpreted.

The device shall be used in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in standard ISO 8253-1. 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.

1.3 Contraindications of Use

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®/Classic 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.

1.4 Features and Benefits

1.4.1 General Information About the MB 11

The MB 11 features (dependent on version):

- Screening ABR with patented CE-CHIRP® stimulus and automatic impedance check
- Powerful response detection algorithm
- BERAphone® with reusable spring-mounted, stainless-steel electrodes, preamplifier and speaker integrated in one unit
- Use of MB 11 Classic with EarCup™, EARturtle™, or eartips
- Simple Pass/Refer outcome
- Optional label printer

1.4.2 MB 11 Software

The MB 11 Software allows you to:

- Add new patients, select patient from database or days list
- Perform automated ABR based hearing screening tests
- Print test results on a standard PC, label printer or store as PDF
- Enter test information
- Configure various MB 11 Software settings
- File based database integration via GDT or XML file
- MAICO Center for standalone database and tracking configurations
- Option to use with HearSIM™ software to manage newborn hearing screening data
- Option to use with OtoAccess® Worklist HL7

1.4.3 Cradle for MB 11 BERAPHONE®

The cradle for MB 11 BERAphone® allows you to store the MB 11 BERAphone® when not in use.

1.5 Description

1.5.1 General

The MB 11 features a user-friendly user interface via the MB 11 Software for ABR testing. The MB 11 Classic can be used with EarCup™, EARturtle™ or eartips. With integrated electrodes and speaker, the MB 11 BERAphone® provides a cost-effective and environmentally friendly alternative for ABR-based hearing screening.

1.5.2 ABR Screening

The MB 11 uses fast rate auditory brainstem response (ABR) technology to screen patients for hearing loss. A modified click stimulus, the CE-CHIRP®, is delivered into the patient's ear while electrodes placed on the patient's head measure EEG activity.

The EEG is processed and analyzed automatically using the MB 11's state-of-the-art, powerful, response detection algorithm. When a response is detected, the screening is stopped automatically, and a ***PASS*** result is assigned to the ear tested.

If no response is detected after a maximum 3 minutes of EEG activity has been processed, a ***REFER*** result is assigned.

In some cases, a ***REFER*** result will occur after 2 minutes if the progress toward the pass criterion is so poor that the likelihood of a pass in the last 60 s is negligible.

By default, the MB 11 performs ABR screening at a fixed intensity of 35 dB nHL. Users with administrator rights can change the screening level in the range from 25 dB nHL to 45 dB nHL. It is particularly suited for newborn hearing screening.

1.5.3 Interpretation of the Results

A Pass result that was obtained with the MB 11 devices is not an indication that the full auditory system is normal. A Pass result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist. A Refer result should not be assumed to be an indicator of a lack of auditory function, however, it should be followed with full audiologic diagnostic testing.

1.5.4 MB 11 BERAphone®

Figure 1

Traditional ABR screening of infants uses disposable electrodes that adhere to the baby's skin for recording the response. The patented BERAphone® has spring-mounted, stainless-steel electrodes, a headphone and preamplifier integrated in one unit (see Figure 1 and Figure 2) which is held to the infant's head after the three electrode sites on the head have been rendered more conductive by the application of electrode gel. The only disposable supplies needed for screening with the BERAphone® are electrode gel and disinfectant wipes to clean and disinfect the device after each baby is tested.

Figure 2

The BERAphone® hardware is especially suited for infants. The vertex electrode is located in an adjustable mounting, allowing the distance to the ground electrode to be varied to adjust for different head sizes.

1.5.5 MB 11 Classic with EarCup™, EARturtle™, or Eartips

The MB 11 Classic uses standard disposable electrodes to record an ABR. To deliver the acoustic stimulus it is possible to use either Sanibel® EarCup™ (Figure 3 and Figure 4), EARturtle™ or insert earphones with eartips.

Figure 3

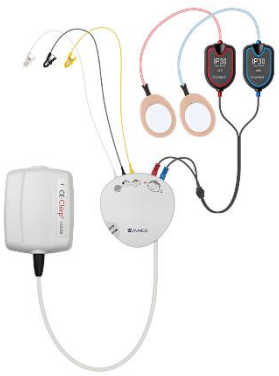


Figure 4

2 For Your Safety

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 MB 11 system including safety information as well as maintenance and cleaning recommendations.

It is highly recommended that users read the operation manual in its entirety prior to use of the MB 11 device on a patient.

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

Use this device only as described in this operation manual.

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

In this operation 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.
	The information sign displays alternative documents or sections in this operation manual that provide more detailed information.

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

NOTE: For more information on the use of the MB 11 application with HearSIM™ and/or OtoAccess® Database, refer to:
Instructions for Use : OtoAccess® Database
Instructions for Use: HearSIMTM
Brochures | Manuals | Software | OtoAccess®
https://www.otoaccess.com/downloads

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.

Customer responsibility includes proper maintenance and cleaning of the device.

Section 3.2 Maintenance

Section 3.3 Cleaning and Disinfection Recommendations

Breach of the customer responsibility can lead to limitations of Manufacturer's Liability and Warranty.

Section 2.4 Manufacturer's Liability

Section 3.1 Warranty

NOTE: In the unlikely case of a serious incident, inform MAICO as well as the competent authority in the country where the user is established.

2.3 Cyber Security and Data Protection

To ensure data protection it is essential to follow common practice in terms of cyber security. This involves:

1. Ensure operating systems are security patched.
2. Keep your software up to date.
3. Install only apps and software from trusted sources.
4. Install an antivirus protection and anti-malware software and a firewall from a trusted vendor and keep them up to date.
5. Utilize the unique PC login settings and use safe passcodes.
6. Ensure secure physical and network access to computers with local data storage.
7. Implement an appropriate backup policy.
8. Do not use public WiFi.
9. Learn about phishing scams: Be very suspicious of emails and calls.
10. To avoid data from being misused if stolen, the data must be encrypted. All users should have a unique login to the PC.
11. When using a third-party networked software, the communication to the database should be secure (encrypted) to avoid client information being captured during network transmission.
12. When using a third party networked software, all users should have a unique login to the database to ensure traceability and identification of data when updated or deleted from the database.

For details see:

Third-party instructions for use

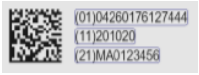
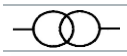
2.4 Manufacturer’s Liability

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.

2.5 Regulatory Symbols

The following Table 1 explains 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
SN	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Information sign (reference for more detailed information)
	Return to authorized representative, special disposal required
REF	Reference number
MD	Medical Device
	UDI information: (01) GTIN (Global Trade Item Number), (11) Date, (21) Serial number
	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
CE 0123	CE label with notified body ID
	Non-ionizing electromagnetic radiation
	Direct Current (DC)
	ETL listed mark
MAICO	Logo

2.6 General Precautions


WARNING

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 Technical Data


WARNING

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.


WARNING

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.


WARNING

Connect only accessories purchased from MAICO to the MB 11. Only accessories which have been stated by MAICO as being compatible are allowed to be connected to the device.


WARNING

Before performing any service to the device or insert earphones, you must uncouple the MB 11 transducers and electrodes from the patient.


WARNING

Do not open the case of the MB 11 Device. Refer servicing to qualified personnel.

2.7 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.


WARNING

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

In Case of Emergency

In Case of Emergency

In case of emergency, disconnect the device from the USB cable. A laptop should not be connected to power supply during testing.

Position the device in such a way that it can be easily disconnected from the USB cable at any time.

Do not use the device if the USB cable is damaged.

To use the device, establishing a connection via USB is required.

To learn how to safely establish a connection with a power supplied PC or laptop via USB-connection (medical device/non-medical device) or to a battery-driven laptop see:

Section 4.3.4 Establishing a PC-Connection

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 62368-1 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.

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.

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.


WARNING

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.


WARNING

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.


WARNING

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

2.8 Electromagnetic Compatibility (EMC)


WARNING

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.


WARNING

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.


WARNING

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

Section 6.4 Electromagnetic Compatibility (EMC)

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:

Section 6.4 Electromagnetic Compatibility (EMC)

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 MB 11, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result in improper operation.

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

3.1.1 General

The MAICO device is guaranteed for at least 1 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 1 year from date of delivery 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.

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

3.1.2 Ownership, Warranty and Disclaimer (Software)

Ownership

The MB 11 Software (hereinafter the “SOFTWARE”) is solely owned by MAICO Diagnostics GmbH, Sickingenstr. 70-71, D-10553 Berlin, Germany. By purchasing the SOFTWARE the buyer is entitled the right of usage, but not ownership of the SOFTWARE. The SOFTWARE is to be used in accordance to the agreed terms of usage provisioned by MAICO.

Copyrights

MAICO’s ownership of the SOFTWARE covers worldwide and is therefore, protected against any unauthorized copying of the SOFTWARE. Nonconformity of use of the SOFTWARE is strictly prohibited.

Restrictions

You may not:

Reverse engineer or attempt in any manner to discover the source code of the SOFTWARE.

Attempt to defeat any mechanisms in the SOFTWARE, including those mechanisms responsible for password protection of data and limiting the number of concurrent users.

Rent, lease, sublicense or in any manner, copy or transfer (except as permitted above) the SOFTWARE.

Obscure or obliterate any MAICO copyright or trademark notices which appear on the SOFTWARE, the documentation, the screen-display, or otherwise in connection with the SOFTWARE.

MAICO specifically calls your attention to the fact that, any violation or infringement of above restrictions will result in legal action.

The SOFTWARE can be used by any number of users, on any number of computers, and in any place, provided but not on more than one display screen at the same time.

Limited Warranty

MAICO warrants that any physical media and physical documentation provided by MAICO are free of defects in materials and workmanship. This limited warranty is effective for a period of ninety (90) days from the original purchase date.

If MAICO receives notification within the warranty period of defects in materials or workmanship and determines that such notifications are correct, MAICO will replace defective media or documentation.

Do not return any product until you have obtained authorization to do so from your supplier. The entire and exclusive liability and remedy for breach of this limited warranty shall be limited to replacement of defective media or documentation supplied by MAICO, and shall not include or extend to any claim for or right to recover any other damages, including but not limited to, loss of profit, data, or use of the SOFTWARE, or special, incidental or consequential damages, or other similar claims, even if MAICO has been specifically advised of possibility of such damages. In no event will MAICO's liability for any damages to you or any other person ever exceed the lowest list price or the actual price paid for the license to use the SOFTWARE, regardless of the form of the claim.

Disclaimer

MAICO covers; including but not limited to; all warranties, representations and terms and conditions, either expressed or implied; under specified terms of use and application of the SOFTWARE for its specific purpose. All other terms and conditions shall not apply.

Furthermore, MAICO does not guarantee that the SOFTWARE or Documentation is free of bugs, or fulfill the relevant standards, requirement or needs of a user. In this case, all the warranties, guarantees and terms and conditions on all MAICO delivered physical disk and documentation shall be limited to the 90 days warranty period.

MAICO is not liable for any third party's product, disks, SOFTWARE or documentation that is used in conjunction with MAICO's SOFTWARE or programs, but is not directly manufactured or supplied by MAICO.

NOTE: A list of applied third party's software can be found in the About screen.

Section 5.9 About

General Terms and Conditions

Any change made to this Agreement shall be notified in writing, agreed and signed between both parties, namely the purchaser of the SOFTWARE and a representative of MAICO.

In the event that the essential purpose of the above remedy (limited warranty) is not fulfilled, all other limited liability including the liability limits and exclusions of damage claims shall continue to apply.

This SOFTWARE License Agreement shall be interpreted and construed according to, and governed by, the laws of Jurisdiction of Federal Republic of Germany.

In the event that any legal or commercial dispute or controversy arising out of, or relating to this agreement; provided MAICO is in all case violated of the rights, to the SOFTWARE or other intellectual property protection right related to the SOFTWARE; shall be presented under the Jurisdiction of Federal Republic of Germany in the court of Berlin.

The SOFTWARE is protected under both Copyright Law and the International Copyright Treaties. Copying of the SOFTWARE is strictly prohibited except for copies made of the SOFTWARE for backup purposes to protect data loss.

3.2 Maintenance

To ensure that the device works properly, it must 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 distributor, or 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. Include a detailed description of faults. To prevent damage in transit, use the original packaging, when returning the device.

3.3 Cleaning and Disinfection Recommendations

3.3.1 General

It is recommended that parts (device and accessories like insert earphones and ear cushions, reusable electrodes) which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedure 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 MB 11 and its accessories by wiping the surfaces with wet disinfection wipes or a comparable product. Follow the instructions on the specific disinfection product.
    - Wipe before and after each patient
    - After contamination
    - After infectious patients

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

- Do not autoclave or sterilize.
- 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 and follow the instructions on the items that are relevant for your system.

3.3.2 Cleaning the Case and Cables

CAUTION

Use caution while cleaning.
Before cleaning, unplug MB 11 from USB connector.

Use a damp cloth to clean the plastic parts of the device.

If disinfection is required, 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 and seams where plastic pieces connect.

Follow the instructions on the disinfection product.

3.3.3 Cleaning and Disinfecting the BERAphone®

3.3.3.1 General

Also, check-out our training videos:

MB 11 BERAphone® | ABR | MAICO Training | Hearing Screening Diagnostic Tests – How to disinfect the equipment

https://youtu.be/FPQsk__HisU?si=cuZRoImTgOuJaSb5&t=331

The BERAphone® features stainless-steel electrodes and an 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.

For a detailed description of cleaning and disinfection of the BERAphone®, see the following sections.

3.3.3.2 Disinfectants

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.

Many common disinfectant wipes present in hospitals contain alcohol as a main disinfection ingredient. However, alcohol chemically denatures certain materials, such as the material used in the BERAphone® ear cushion. With repeated exposure to alcohol-based disinfectants, the material of the cushion will harden, crack and breakdown over time. The higher the alcohol content of the disinfectant, the faster the ear cushion will be affected.

If alcohol disinfectant wipes are used to disinfect the BERAphone®, the earphone cushion will need to be replaced more frequently than if a non-alcohol-based disinfection product is used.

3.3.3.3 Cleaning & Disinfection between Examinations of Different Patients

Follow this process for cleaning and disinfection of the BERAphone® after each 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 contacted 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 speaker inside the BERAphone®.
3. Disinfect any other components that touched the baby or the baby's bedding such as the cable, BERAphone® 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.

3.3.3.4 Routine Periodic Inspection and Cleaning

Figure 5 shows the design of the BERAphone®.

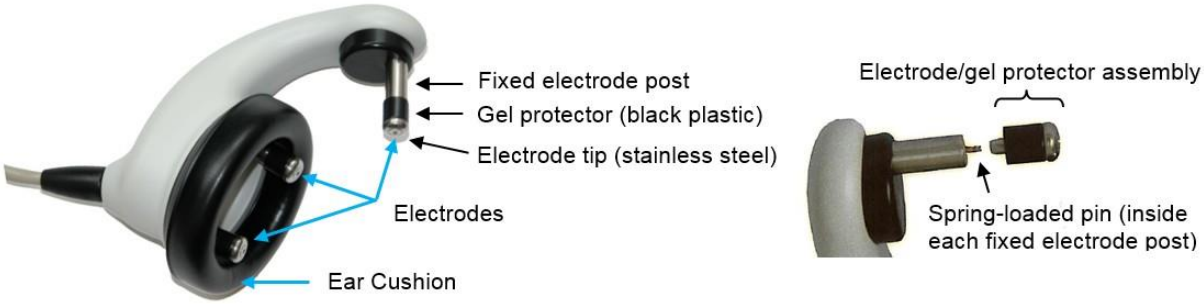


Figure 5

Daily routine periodic inspection and cleaning 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 (Figure 6 and Figure 7).

Figure 6

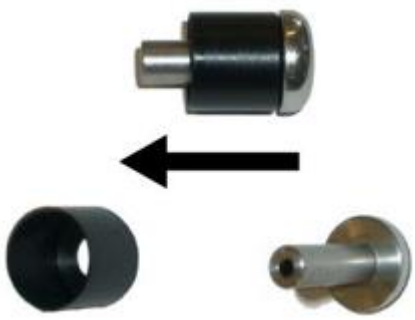


Figure 7

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 7).
4. Clean the stainless-steel part of the electrode with an alcohol or disinfectant wipe.
   a. 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 of the material.

3.3.4 Disposables (MB 11 Classic Only)

Use only the Sanibel Supply disposable supplies that are supplied with your MB 11 system.

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

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.

3.3.5 Accessories/Replacement Parts

3.3.5.1 General

Some reusable components are subject to wear with use over time. We recommend that you keep theses replacement parts available (as appropriate for your MB 11 device configuration).

3.3.5.2 Replacement of Stainless-steel Electrodes (MB 11 BERAphone® Only)

Replacement of the removable electrodes is recommended at least every 3 months. More frequent replacement of electrodes may be required based on the cleaning and maintenance practices of the facility. Replacement electrodes are available from MAICO.

1. Remove the electrode tip/gel protector assemblies from the fixed electrode posts by pulling each one straight out from the fixed post.
2. Discard the old electrodes.
3. Connect a new set of electrodes to the posts by aligning them with the spring-loaded pin and pressing them fully onto the pin.

3.3.5.3 Replacement of Ear Cushions (MB 11 BERAphone® Only)

Replace the ear cushion with a new one as needed. Replacement of the ear cushion is recommended at least every 3 months. More frequent replacement of the ear cushion will be required if the facility uses an alcohol based disinfectant product. Replacement cushions are available from MAICO or your local distributor.

1. Remove the ear cushion by pulling it off the BERAphone®.
2. If there is any debris on the plastic mounting for the ear cushion, clean and disinfect the area using a disinfectant wipe and allow the disinfectant to dry thoroughly.
3. Attach a new ear cushion to the BERAphone®.
    a. A small notch at the top of the plastic mounting for the ear cushion can be used to start the connection of the ear cushion followed by a counter-clockwise rotation of the ear cushion until it is fully attached to the plastic mounting.
    b. The ear cushion can also be attached by stretching it around the plastic mounting until it is fully seated in place.

3.4 Troubleshooting

In case of problems see below for symptoms, possible causes and suggested troubleshooting (Table 2).

Table 2 Troubleshooting

SYMPTOM	POSSIBLE CAUSE	SUGGESTED TROUBLESHOOTING
Device does not turn on	Connections are not working	1. Verify that the USB cable is connected securely into both the USB box of the MB 11 hardware as well as the computer USB port.Verify that the USB port on the PC meets the specifications described in section 4.3.5. 2. Verify that the PC is powered on.
Error Message: EEG quality	Humming noise with a large affect on the measure-ment quality	1. Remove the disturbance source or attempt to test at another place. 2. Press OK and the test starts automatically.
Start button in HearSIM™ is disabled	Error in application launch	1. Start the MB 11 Software from the Windows® start menu and close it again. This ensures, that the software is running in the background and can be launched by HearSIM™.
Only for BERAphone®		
Impedance indicator remains orange	Poor fit or insufficient skin preperation	1. Shift the position of the BERAphone® electrode(s) with poor impedance slightly making sure it is in contact with the area of the skin that was prepared with the electrode gel. 2. Remove the BERAphone® and massage a little more gel at the site. Apply a little more gel. 3. Use an electrode skin preparation product such as NuPrep® or an electrode skin prep pad at the site, wipe it off and then re-apply gel to the site.
Measureme nt is running properly but with noise bar in orange	Electrical artifact in environment or poor electrode contact	1. Check the connection of the electrodes to the baby's skin and reapply if necessary. 2. Look for sources of electrical noise in the room, cell phones, other equipment nearby or attached to the baby. 3. Change location if necessary.
High artifact (poor signal quality) during the screening	Baby is unsettled and produces noises	1. Check the state of the baby. A quiet, sleeping baby is most conducive to a high quality screening. Calm the baby with a pacifier if appropriate. 2. Position the baby so he/she is comfortable and in a way to release any tension in the neck. A rolled up blanket tucked at the baby's side and in the curve of the back and neck can help to release any tension in this area.

SYMPTOM	POSSIBLE CAUSE	SUGGESTED TROUBLESHOOTING
		3. Check that the BERAphone® has not slipped away from the prepared electrode sites and the electrodes are in contact with the skin. If so, shift it back into place.
BERAphone® does not make contact well on the baby's head	Different head sizes	Depending on the size of the head the position of the vertex electrode can be adapted by rotating the black disc in which the electrode is mounted.
	Moving of the vertex electrode does not allow ideal contact	For this special case an extra long electrode is available to replace the vertex electode. This can be ordered (stainless-steel electrode for premature babies).
Only for MB 11 Classic		
Impedance indicator remains orange	Poor fit or insufficient skin preperation	1. Check the contact of the electrode on the skin. 2. Check that the electrode lead wire is properly and securely connected to the electrode. 3. Remove the electrode and prepare the skin again with a skin preparation product such as NuPrep® or an electrode skin prep pad at the site, wipe it off and then re-apply the electrode to the site.
High artifact (poor signal quality) during the screening		1. Check the state of the baby. A quiet, sleeping baby is most conducive to a high quality screening. Calm the baby with a pacifier if appropriate. 2. Position the baby so he/she is comfortable and in a way to release any tension in the neck. A rolled up blanket tucked to support the baby's back and in the curve of the back and neck can help to release tension in this area. 3. Check that the electrodes remain in contact with the skin. If any electrode has become detached or loosened from contact, press it back into place or replace it. 4. Observe the ***EEG*** signal displayed above the measurement diagram. If there is high amplitude noise or cyclical noise evident in the EEG then there may be electromagnetic interference in the test environment. Try moving the system to a different location in the room or into another room.
Screening result is not progressing		1. Check that the insert earphone eartip remains securely inserted into the baby's ear canal(s). If you are using the EarCup™ or EARturtle™, check that they are in contact with the baby's skin around the entire circumference of the baby's ear. 2. Check the state of the baby and quiet the baby if possible.

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 2012/19/EU of the European Parliament and of the Council of 4 July 2012 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.

4 Unpacking and Hardware Orientation

This section provides information on:

- **unpacking the system**
- **becoming familiar with the hardware inclusive connections**
- **system assembly**
- **how to install the PC software**
- **how to power the MB 11**
- **how to store the device**

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your MB 11 carefully making sure that all components are removed from the packaging materials.
- Verify that all components are included as shown on the packing list 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 packaging material and the shipping container so the device can be properly packed if it needs to be returned for service or calibration.

The MB 11 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	
Components – General	Carrying case
	USB-B Cable
	Operation Manual**
	Quick Guides**
	Label Printer for MB 11 incl. Power Supply
MB 11 BERAphone® Components	MB 11 USB Box with BERAphone® *
	Cradle
	Set of Replacement Stainless-steel Electrodes with Gel Protection
	Stainless-steel Electrode for NICU Babies
	Hygienic Protection for Ear Cushion
	Electrode Gel
MB 11 Classic Components	MB 11 USB Box with Preamplifier
	Insert Earphones – RadioEar IP30*
	Pinch Clip Cable Kit for Snap Electrodes (3 Cables Yellow, White and Black)*
	NuPrep® Abrasive Skin Preparation Gel
… with EarCup™	Infant EarCup™ with Snap Electrodes
	EarCup™ adapter set
… with EARturtle™	Infant EARturtle™ with Snap Electrodes
	EARturtle™ Adapter Set
… with eartip	Pack of Disposable Snap Electrodes
	Disposable Eartips of Different Sizes
	Eartip Adapter Set
Software/Electronic Files	USB Drive with MB 11 Software

***Applied part according to IEC 60601-1**

****As download from the download center – see accompanying leaflet**

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 is 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 Powering MB 11

The MB 11´s power is directly supplied through the computer via the USB port. No external power supply is needed.

4.3.2 MB 11 BERAphone® Hardware

Also, check-out our training videos:

MB 11 BERAphone® | ABR | MAICO Training | Hearing Screening Diagnostic Tests – How to setup the MB11 with PC and BERAphone®

https://youtu.be/FPQsk__HisU?si=4J6bexwL4h97hPYe&t=5

The MB 11 unit consists of the MB 11 USB Box that is connected with the BERAphone® through a non-removable cable (see Figure 8 and Figure 9).

Connect the MB 11 BERAphone® to the computer using the USB cable.

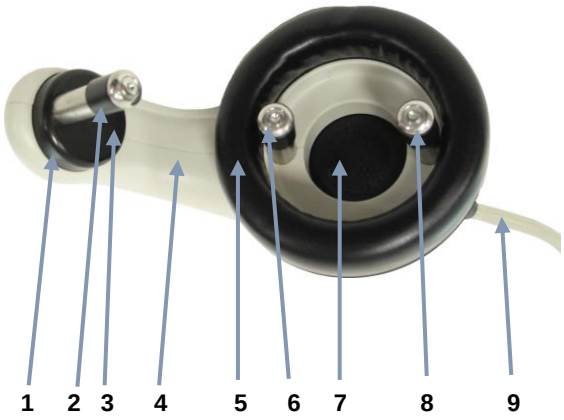


Figure 8

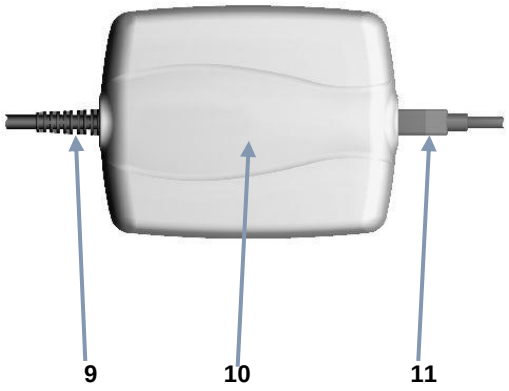


Figure 9

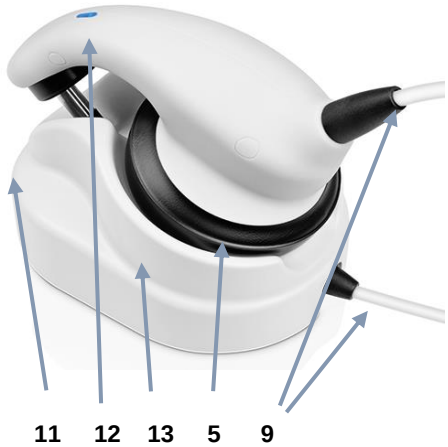


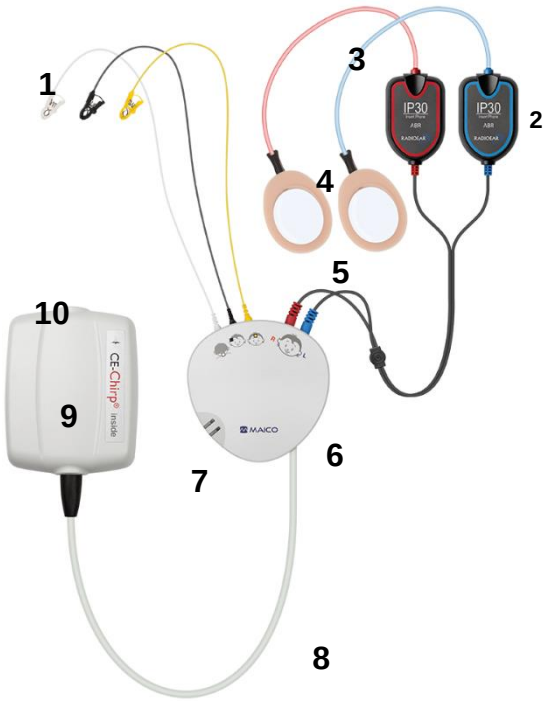
Figure 10

1	Vertex electrode rotator
2	Gel protection
3	Vertex electrode
4	Handle
5	Ear cushion
6	Ground electrode
7	Speaker
8	Mastoid electrode
9	Connection cable
10	MB 11 USB box
11	USB cable
12	Power/Signal quality indicator
13	Cradle

4.3.3 MB 11 Classic Hardware and System Assembly

The MB 11 Classic unit consists of a USB box connected with the MB 11 Classic preamplifier by a cable. The insert earphones and electrode leads plug into jacks in the preamplifier (Figure 11). The red plug of the insert earphone cable plugs into to the jack with the label R for the right ear and the blue plugs into the jack with the label L for the left ear on the back side of the preamplifier. For the EarCup™ and EARturtle™ versions, the black adapters are installed at the end of the red and blue tubes of the insert earphone. For the MB 11 Classic with eartips, the transparent eartip adapters are attached to the red and blue tubes.

Connect the electrode lead wires to the color-coded jacks on the side of the preamplifier.



1. Electrode lead wires
2. Insert Earphones IP30
3. Red and blue tubes
4. Tube adapters (black for EarCup™ and EARturtle™ or clear for eartips)
5. Sanibel® EarCup™, EARturtle™ or eartips
6. Preamplifier
7. Power / Signal quality indicator
8. Connection cable
9. MB 11 USB box
10. USB socket

Figure 11

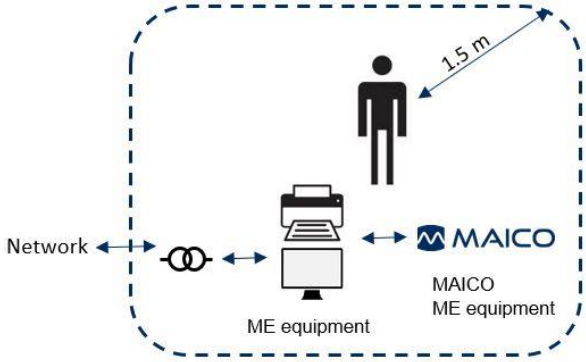
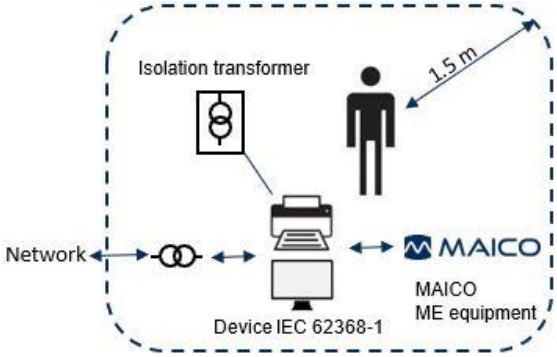
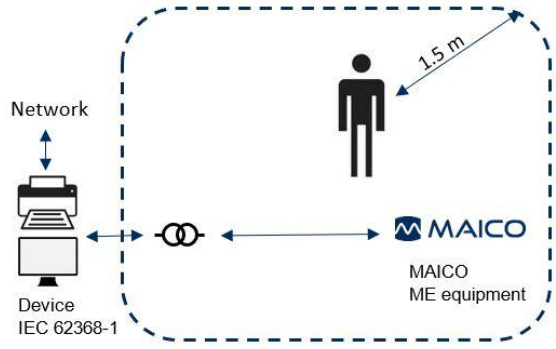
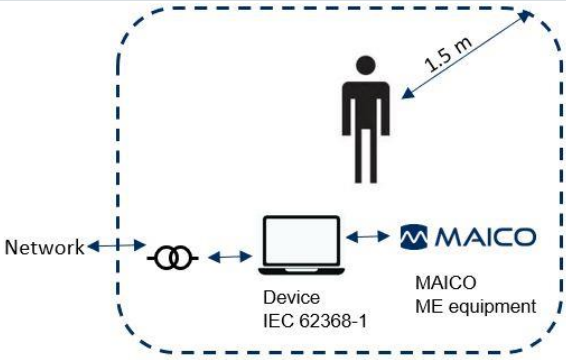
4.3.4 Establishing a PC-Connection

To perform measurements with the MB 11 device, establishing a PC-connection via USB is required. If the MB 11 is used with office equipment that is not medical electrical equipment (ME equipment) itself (see Table 4, PC-Connection 1), make sure to establish the PC-connection in one of the following ways (see Table 4, 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 62368-1. If non-medical electrical equipment is used within the patient environment (1.5 m from patient as defined in IEC 60601-1) a isolation transformer must be used (exception: a battery-driven laptop is used).

Table 4 PC-Connections

PC CONNECTIONS	
PC Connection 1: ME equipment – ME equipment	PC Connection 2: ME equipment – Non-ME equipment
	
PC Connection 3: ME equipment – Non-ME equipment	PC Connection 4: ME equipment – Laptop (battery-driven)
	

4.3.5 PC and System Requirements

System Requirements

NOTE: You need administrator privileges to install the MB 11 Software.

MB 11 Software can be run under the following systems:

- Windows® 11 64 Bit
- Windows 10 Pro, Enterprise 64 Bit (No "N" Edition)

NOTE: If you have been using the previous MB 11 Software version 3.48 and below, there are tools available for converting the MB 11 screening results into

- the local database or
- HearSIM™ with OtoAccess® Database

Minimum PC Requirements

The minimum PC requirements are as follows:

- Intel Core i5, i7 or equivalent
- 8 GB RAM
- Hard disk: 10 GB free disk space
- Display 1360 × 768
- Interface: 1 free USB Port

NOTE: In case you use the MB 11 Software with the OtoAccess® Database and HearSIM™ find the PC requirements in:
Instructions for Use: OtoAccess® Database
Instructions for Use: HearSIM™
Brochures | Manuals | Software | OtoAccess®
https://www.otoaccess.com/downloads

Display Requirements

- Minimum resolution supported is WXGA (1280x768).

Needed Components

The following components are needed to perform measurements with the MB 11:

- USB A to B cable

4.3.6 USB Specifications

The MB 11 is a high-powered device that requires a USB port with 500 mA DC current over the V_{USB}-line. Do not use USB hubs with the MB 11 device. We recommend connecting the device directly on the computer. In most cases, these ports allow the use of high-powered functions/devices.

If you use additional USB devices on your PC and the MB 11 does not work or influences the function of USB devices used in parallel, try another USB port or disconnect the other devices while using the MB 11.

4.4 Storage

When the MB 11 is not in use, store it in a location where it will be safe from damage to sensitive components such as the acoustic transducers and cables.

Store according to the recommended temperature conditions described in:

Section 6.1 MB 11 Hardware

4.5 Installation

4.5.1 Starting the Installation Process

NOTE: Make sure that the device is not connected with your computer while installing. The update process is the same as the installation process.

Close all open or running programs. To start the installation process, double-click ***MB 11 Setup.exe*** from the USB. Press ***Cancel*** if you want to cancel the installation.

After starting the installation process and pressing ***Next***, the ***End User License Agreement*** is shown. ***Enable software updates***, if you want to perform software updates directly when a new version is available Accept the terms in the License agreement by setting the check mark. Press ***Install*** to start the installation process (Figure 12).

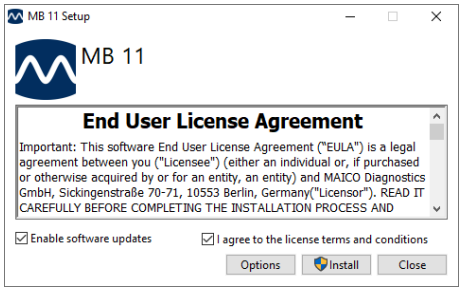


Figure 12

The User Account Control ask if you want to allow this app to make changes to your PC. Press ***Yes*** to proceed (Figure 13).

Figure 13

The installation process starts (Figure 14).

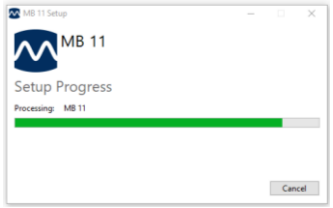


Figure 14

When 100 % is reached, an Installation Successfully Complete message will be shown. Press ***Launch*** to open the MB 11 Software or ***Close*** (Figure 15).

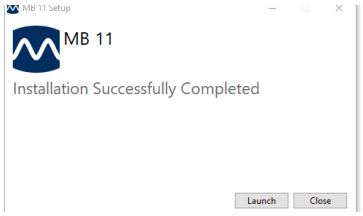


Figure 15

4.5.2 Automatic Update

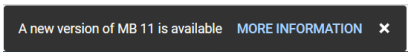


Figure 16

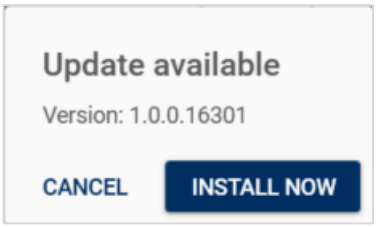


Figure 17

If ***Enable software updates*** was selected during the installation, a notification is displayed at the bottom of the MB 11 Software when a new version is available.

Press ***MORE INFORMATION*** at the bottom of the MB 11 Software to review details about the new version. Press ***INSTALL NOW*** to start the download and installation process.

Follow the installation process as described in:

Section 4.5 Starting the Installation Process

To change update settings see:

Section 5.6.2 Settings – GENERAL

4.5.3 Check Success of Installation Process

Connect the MB 11 with the USB port of your PC and check that the LED on the BERAphone® or Classic preamplifier lights up.

If this LED does not light up, ensure that your USB port supports high-powered USB devices or change the USB port and try again. Also see the note above about using USB ports. After a few seconds, the system will show a message about a newly found USB device ***MAICO MB 11***.

4.5.4 Repair or Remove

In case a repair or removal of MB 11 Software is required, start the process with ***MB 11 Setup.exe*** or the Windows Apps and Features list and press ***Uninstall***.

You are asked to ***Repair*** or ***Uninstall*** (Figure 18) the program. Select one of the options to proceed and start the repair or the removal. The process is displayed, and the final Uninstall screen as shown in Figure 19.

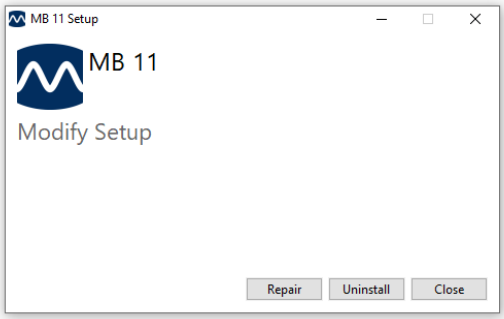


Figure 18

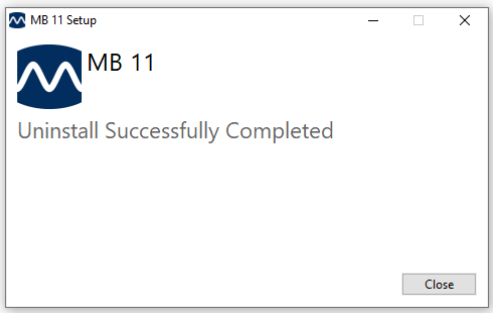


Figure 19

4.6 Database Connection

4.6.1 General

The MB 11 Software can be used in different setups:

- Local database with MAICO Center (integrated in MB 11 Software installation process)
- File based integration with GDT or XML
- HearSIM™ with OtoAccess® Database integration (optional)
- OtoAccess® Database integration (optional)

4.6.2 Connection to Practice Management Software

4.6.2.1 General

If you want to connect the MB 11 Software to an existing practice management software, this is possible via:

- XML interface with import and export file according to the MAICO format
- GDT interface

4.6.2.2 Connection via XML or GDT Interface

Proceed as follows to connect the MB 11 Software as stand-alone version to your existing practice management software:

1. Install the MB 11 Software.
2. Open the MB 11 Software by navigating to the MAICO folder in the start menu, the Windows® search function or icon on the desktop.
3. Select ***Settings*** – ***File Integration***
4. Select ***XML*** or ***GDT*** as integration type and follow the instructions below.

Integration Type – GDT or XML

To use the MB 11 Software with an external database via GDT or XML interface, the import and export settings must be made. Select GDT or XML (Figure 20, **1**) and make the settings as described below.

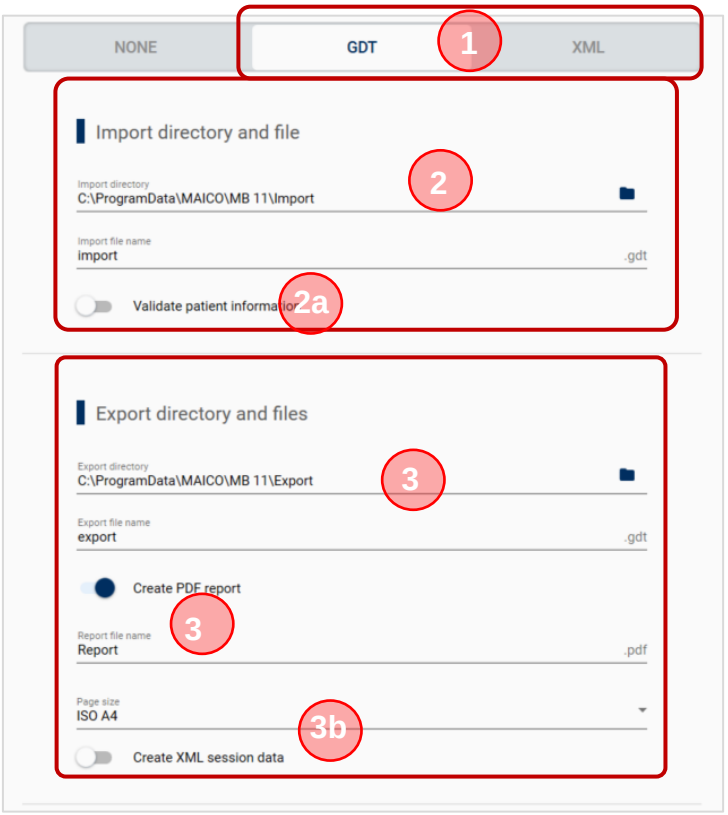


Figure 20

Import Directory and File (Figure 20**, 2):** Press  to select the directory for the data-based communication with the Practice Management Software. Changes will be activated after restart of the application.

Validate Patient Information (Figure 20**, 2a**, for GDT only): Activate this setting if only those patients are to be transferred to MB 11 Software for whom the first name, last name, ID and date of birth are valid.

Note: By default, an asterisk ***** is selected in the ***Import file name*** field. This means that the data from the first valid XML file in the selected folder is automatically imported.

Export Directory and Files (Figure 20, 3): Press  to select an export file. ***Patient*** is automatically offered as ***Export File Name*** and can be changed if necessary.

If you activate the ***Create PDF report*** (**3a**) or the ***Create XML session data*** (**3b, GDT only**) function, you can make further settings for file name and PDF page format.

NOTE: The PDF report is based on the report settings.

 Section 5.6.5 Settings – PRINT 

4.6.3 Connection to OtoAccess® Database

The OtoAccess® Database 2.1 or higher must be installed prior to installation of MAICO MB 11 Software.

4.6.4 Connection to HearSIM™ (Optional)

The MB 11 Software is compatible to HearSIM™ version 3.3 and higher. HearSIM™ allows the user to navigate to MB 11 Software while this is running in the background. Results of all performed tests get stored by HearSIM™, when closing the MB 11 Software.

If you want to use the MB 11 Software with HearSIM™ and OtoAccess® Database, these software products must be installed before starting the MB 11 Software installation.

4.6.5 Connection to MB 11 Device

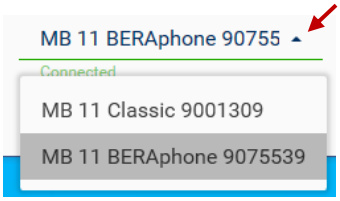


Figure 21

The MB 11 Software connects automatically to the connected MB 11 device. The device type and serial number are displayed in the lower left area (Figure 21).

If more than one MB 11 is connected, you can select another device from the drop-down menu or use the shortcut ***CTRL + U.***

5 Operating the MB 11

This section offers you information about:

- **how to get started with the MB 11 BERAphone®/Classic**
- **general information about the MB 11 Software**
- **preparing for testing**
- **performing screenings**
- **managing the test results**
- **settings to be made in the setup menu**

5.1 Getting Started with MB 11 Software

5.1.1 Starting the MB 11 Software

5.1.1.1 Starting the MB 11 Software with the MAICO Center

After starting the computer, launch the MB 11 Software by pressing the ***MB 11*** icon on the desktop or from the program menu. The program launches with the ***NEW PATIENT*** screen.

Section 5.1.4 Patient Management (MB 11 With MAICO Center)

5.1.1.2 Starting the MB 11 Software from HearSIM™ (Optional)

In HearSIM™ the MB 11 Software can be started in one of the following ways:

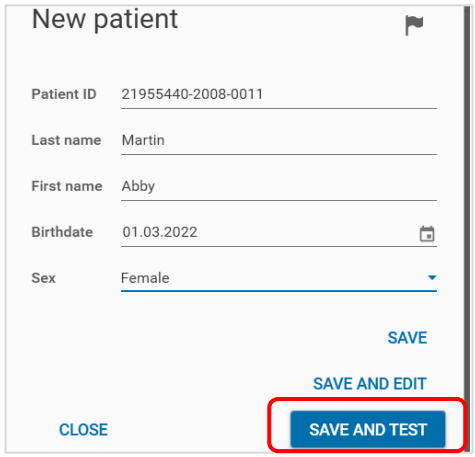


Figure 22

Starting From the *New patient* Dialog

Press , enter the patient details and select ***SAVE AND TEST*** (Figure 22).

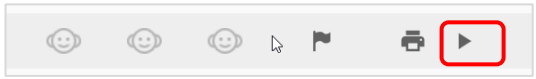


Figure 23

Starting From the Patient List

Move the mouse curser over a patient in the patient list and press ▶ (Figure 23).

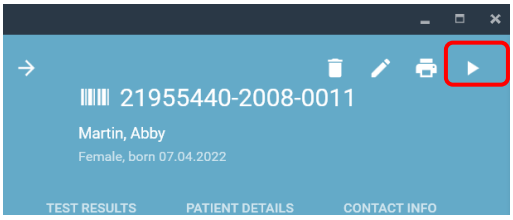


Figure 24

Starting From the Patient Details

Select a patient in the list to display the patient details. Press ▶ in the upper right corner (Figure 24).

Note the following:

- The MB 11 Software is started and the ID, last and first name of the selected patient is displayed. The patient details cannot be edited in MB 11 Software.
- If the option ***Test fields*** is enabled in the MB 11 Software and configurations lists for screener and facilities created in HearSIM™, the items from the HearSIM™ list can be selected on the ***Edit test information*** dialog.
- HearSIM™ is blocked in the background and cannot be operated until the MB 11 Software is closed.
- If the button to start the MB 11 Software is disabled, start the MB 11 Software from the Windows® start menu and close it again. This ensures, that the software is running in the background and can be launched by HearSIM™.

5.1.1.3 Starting the MB 11 Software from OtoAccess® Database (Optional)

Select a patient and press the MB 11 icon at the module selection to start the MB 11 Software (Figure 25).

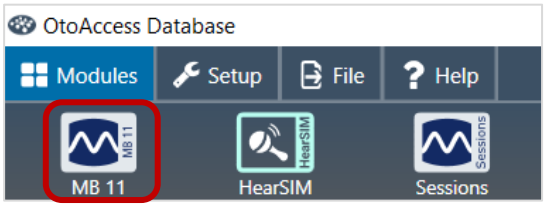


Figure 25

5.1.1.4 Starting the MB 11 Software via integrated GDT or XML Interface

Section 4.6.2 Connection to Practice Management Software

After configuration, patient and test data can be exchanged with external practice management software via XML or GDT.

To do this, place the import file in the configured input directory. The data is read out automatically when the MB 11 Software is started.

Accordingly, the export file can be taken from the export directory.

5.1.2 Preparation Screen

The preparation screen displays the buttons, fields, and menu of all the major functions of the MB 11. See Figure 26 as well as Table 5 for explanation.

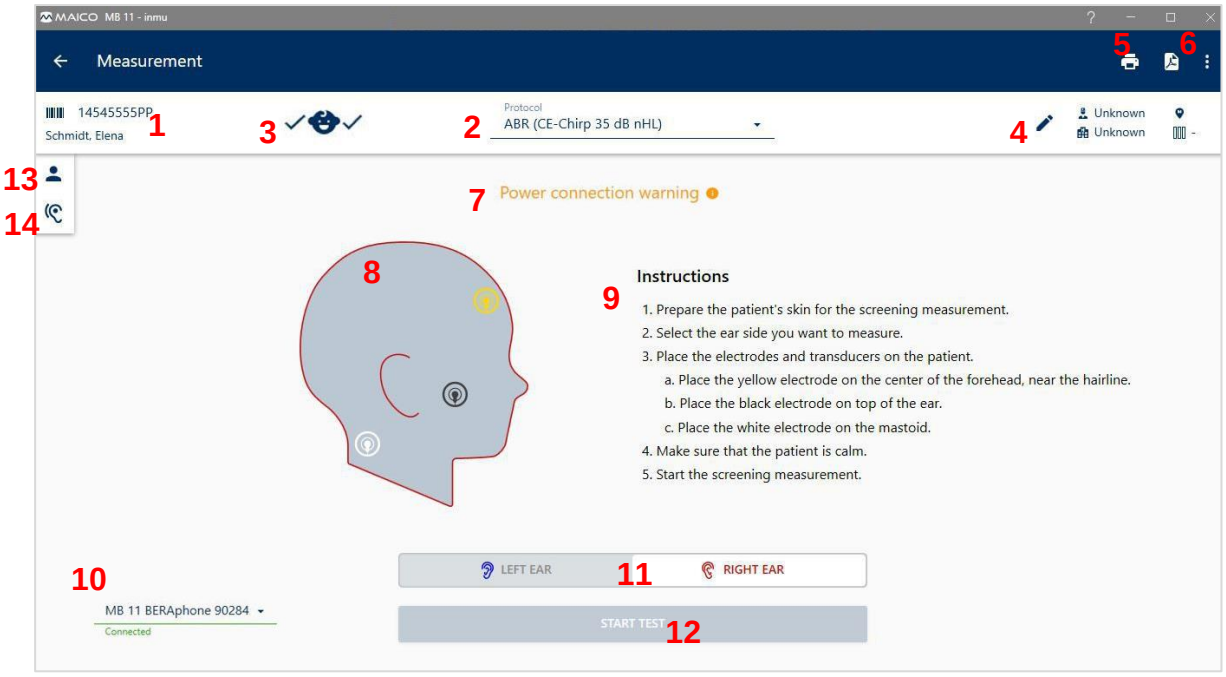


Figure 26

Table 5 Explanation of Preparation Screen

1 ***Patient information*** – show information of current patient	**8** Indication of electrode positions and selected ear side
2 ***Protocol*** – no selection if only one level available	**9** **Instructions**
3 ***Last result*** – displays last screening result of the left and right ear for the current patient	**10** **Device with serial number** – device selection if more than one connected via USB
4 ***Test information*** – editable only available if enabled in settings	**11** **Ear side selection**
5 **Print** and **export PDF** – when result available	**12** **Start test** – starts electrode impedance test
6 ***Ellipsis*** – to enter **Settings**, ***Feedback*** and ***About***	**13** **Patient details** – opens the patient details to review and edit
7 **Power connection warning** – The measurement quality is negatively affected if the laptop is connected to the power supply during the measurement.	**14** **Results** – opens screen to review existing results

5.1.3 Connection to MB 11 Device

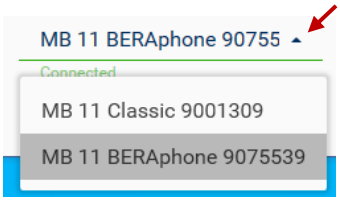


Figure 27

The MB 11 Software connects automatically to the connected MB 11 device. The device type and serial number are displayed in the lower left area (Figure 21).

If more than one MB 11 is connected, you can select another device from the drop-down menu or use the shortcut ***CTRL + U.***

5.1.4 Patient Management (MB 11 With MAICO Center)

5.1.4.1 General

When starting the MB 11, the input mask for new patients opens (Figure 28). Existing patients can be selected from the ***PATIENT LIST*** and the ***DAYLIST*** (**1**).

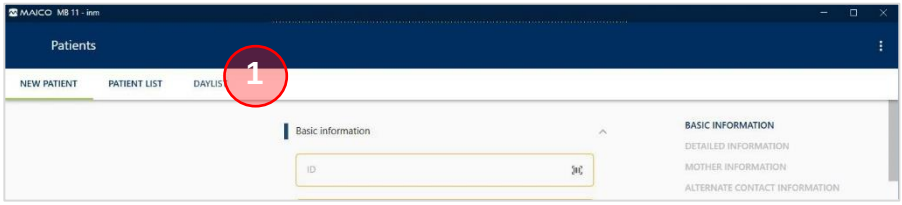


Figure 28

5.1.4.2 Add New Patient

The ***NEW PATIENT*** screen allows you to create a new patient in a mask. See Figure 29 as well as Table 6 for explanation.

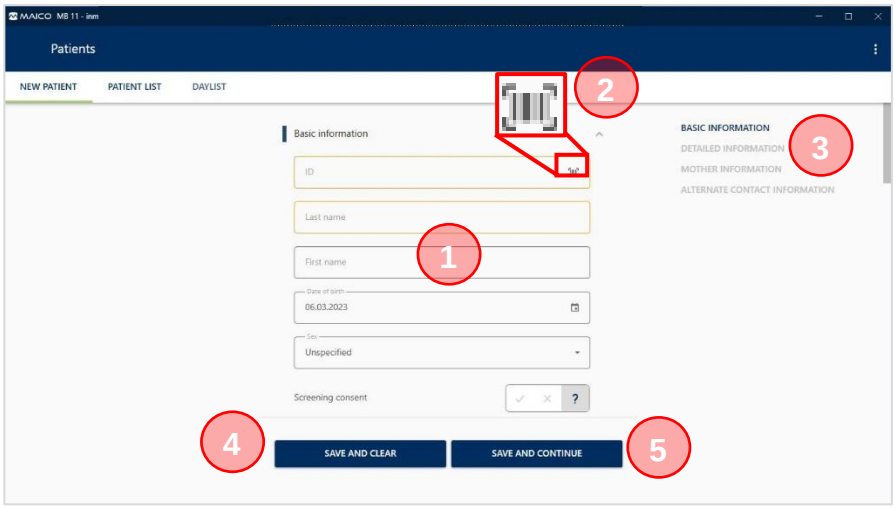


Figure 29

Table 6 Explanation of NEW PATIENT Screen

No.	Explanation
1	Mask for adding a new patient (mandatory field: orange, optional fields: black; according to settings in the MAICO Center).
2	Press to use the Barcode Scanner.
	Section 5.1.7 Using the Barcode Scanner
3	Shortcuts to the patient data categories.
4	***SAVE AND CLEAR:*** press to save patient data and proceed with a new empty patient mask.
5	***SAVE AND CONTINUE:*** press to save patient data and proceed to the start test screen.

5.1.5 Patient List

The ***PATIENT LIST*** screen allows you to sort and search for patients. See Figure 30 as well as Table 7 for explanation.

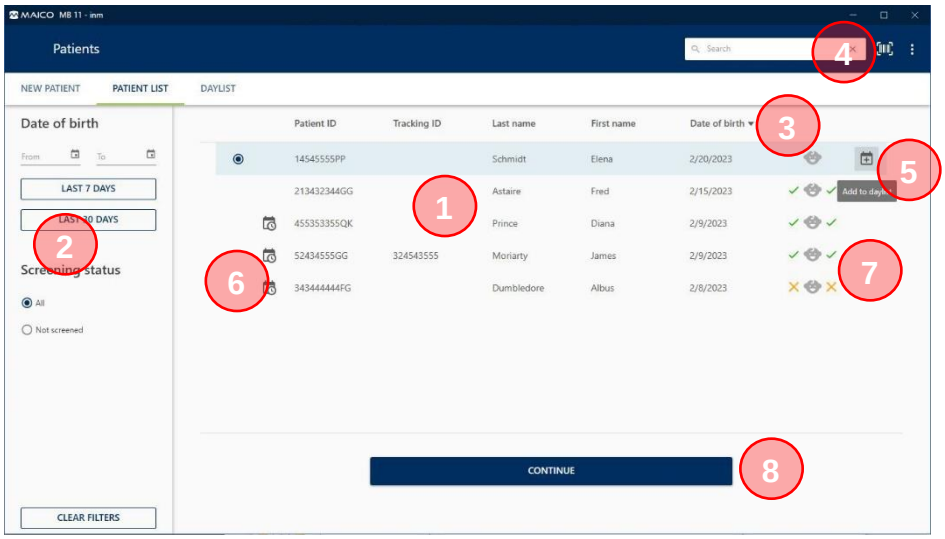


Figure 30

Table 7 Explanation of PATIENT LIST Screen

No.	Explanation
1	Patient list with entered patient data. Select a patient by clicking on the line.
2	Filter options (including shortcuts)
3	Sorting options
4	Search options (search by fields or scan a barcode).
	Section 5.1.7 Using the Barcode Scanner
5	***Add to daylist*** (hover over it to display): press to add the patient to the daylist. Select a daylist in the dialog and save.
	 **Figure 31**
	Section 5.1.6 Daylist
6	: Hovering over the symbol shows the daylist the patient is currently added to.
7	Existing test results for each ear: = ***PASS***, = ***REFER***, = ***INCOMPLETE***
8	***CONTINUE:*** press to proceed to the preparation screen.

5.1.6 Daylist

NOTE: Daylists can be managed either in the MB 11 Software or the MAICO Center. They are synchronized automatically in both systems.

The ***PATIENT LIST*** screen allows you to sort and search for patients. See Figure 32 as well as Figure 30 for explanation.

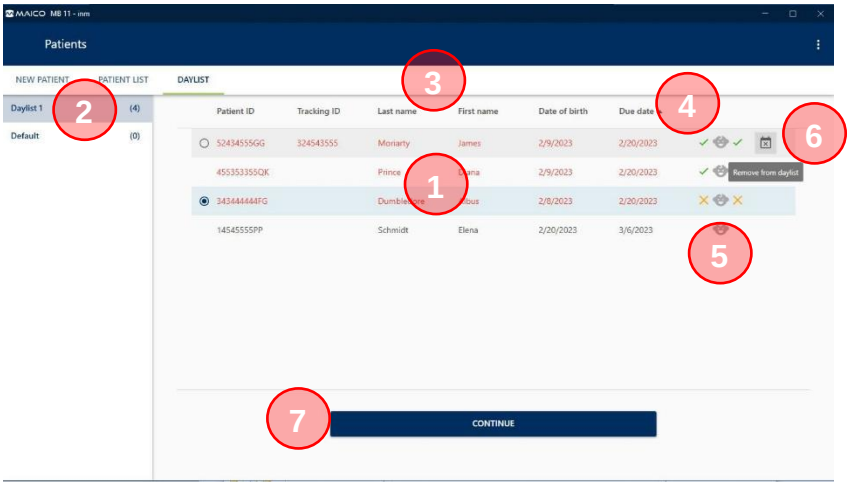


Figure 32

Table 8 Explanation of DAYLIST Screen

No.	Explanation
1	Daylist with entered patient data. Select a patient by clicking on the line.
2	Selection of daylist
3	Sorting options
4	***Due date***: When adding the patient, the current day is automatically set as the due date. When the due date is exceeded, the patient's line is displayed in red.
5	Existing test results for each ear: ✓ = ***PASS***, ✗ = ***REFER***, ? = ***INCOMPLETE***
6	***Remove from daylist*** (hover over it to display): press to remove the patient from the daylist.
7	***CONTINUE****:* press to proceed to the preparation screen.

5.1.7 Using the Barcode Scanner

To scan a barcode with patient data, proceed as follows (Figure 33):

1. Select a camera (**1**).
2. Hold the barcode in front of the camera and press START (**2**). The barcode is automatically captured and marked with a green line (**3**). The captured code is displayed for control (**4**).
3. Optionally, activate the option to flip the image horizontally or vertically (**5**).
4. Press CONFIRM (**6**) to save the data and return to the respective screen.

NOTE: After confirmation, the code can still be adjusted manually in the respective screen.

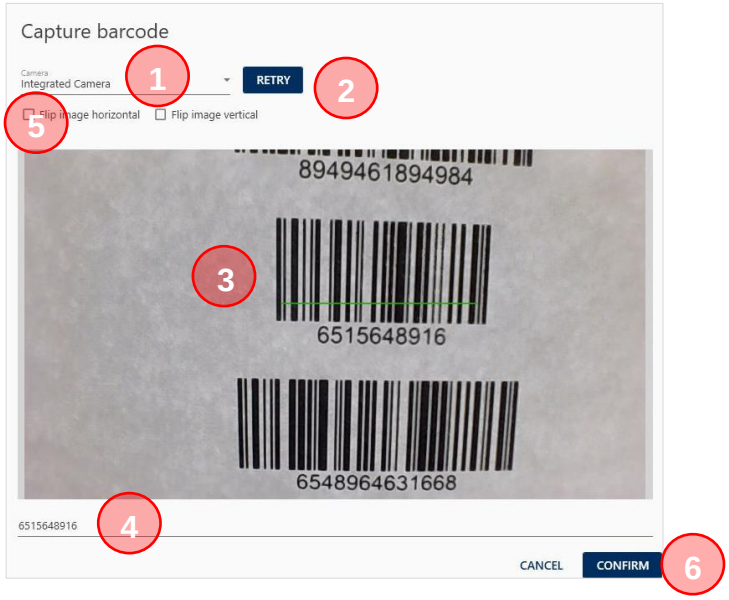


Figure 33

5.1.8 Operation with Mouse and Keyboard or Touchscreen

The MB 11 program can be operated with the mouse by pointing and clicking on the required input field or button on the screen. If you use a touchscreen, you can run the program by touching the appropriate field on the screen.

Keyboard shortcuts can also be used for fast operation. See Table 9 for explanation of function keys and shortcuts.

Table 9 Function keys and shortcut

FUNCTION KEYS	SHORTCUT	DESCRIPTION
	Ctrl + U	USB MB 11 device change
F5	Ctrl + M	Measurement starts
F6	Ctrl + E	Ear change (toggle)
F7	Ctrl + H	Hold on (pause)/continue measurement
F8	Ctrl + S	Stop measurement
F4	Ctrl + N	New measurement
F9	Ctrl + P	Print
F10	Esc	Quit
F11	Ctrl + B	Beep feedback sound on/off

5.1.9 Edit Patient Information (With MAICO Center Only)

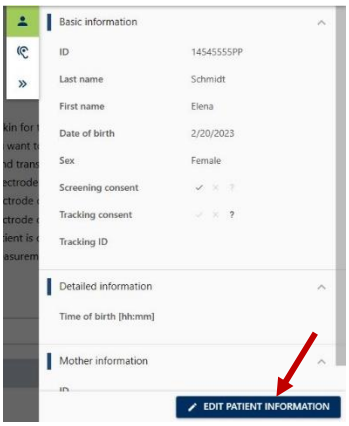


Figure 34

Press below the patient details to open the dialog to enter patient details (Figure 34). Press EDIT PATIENT INFORMATION to make the fields editable.

5.1.10 Edit Test Information

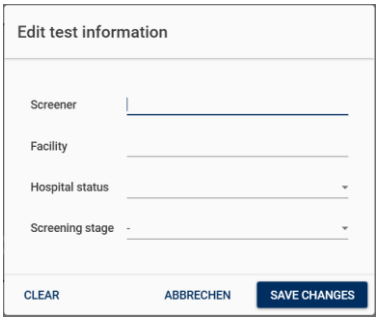


Figure 35

Press ✎ next to the test information to open the dialog to enter test information (Figure 35).

NOTE: If you start the MB 11 Software from HearSIM™, you can select the screener and facility from a list as configured in HearSIM™.

This option is only available if the setting ***Test fields*** is enabled.

ⓘ 5.6.3 Settings – MEASUREMENT ⚙

5.1.11 Quit the MB 11 Software

Press the cross in the upper right corner of the software to quit ▭ ▭ ✕.

5.2 Hearing Screening with MB 11

Also, check-out our training videos:

MB 11 BERAphone® | ABR | MAICO Training | Hearing Screening Diagnostic Tests – How to set up the test environment for hearing screening

https://youtu.be/FPQsk__HisU?si=yvEpjMvU0sbjoZQ4&t=79

5.2.1 Testing Environment

5.2.1.1 General

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 disconnecting the electrode lead wires or insert earphone tubes during the screening (MB 11 Classic only).

⚠ WARNING

Risk of choking.

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

IMPORTANT NOTE: All disposable supplies included with MB 11 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 biocompatibility. Data sheets are available upon request.

5.2.1.2 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.

5.2.1.3 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 in the vicinity of 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.

5.2.2 Preparing the Patient for Testing with BERAphone®

Also, check-out our training videos:

MB 11 BERAphone® | ABR | MAICO Training | Hearing Screening Diagnostic Tests – How to prepare the baby

https://youtu.be/FPQsk__HisU?si=hMJ5D82-CpVqBxyb&t=106

5.2.2.1 Preparing the Skin for Electrodes

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. You can also prepare the skin with an alcohol pad or with a skin preparation product such as NuPrep®.

Figure 36

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 (about 0.1 ml to 0.2 ml) of electrode gel on the tip of a finger 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 36).

The baby should be in a relaxed and comfortable position to minimize any potential muscle 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: Avoid fluid bridges caused by electrode-gel connections between the three gel sites on the skin. This can be avoided by always rubbing in the direction as seen in Figure 36 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®.

5.2.2.2 Placing the BERAphone®

Place the BERAphone® on the baby's head (Figure 37). First position the mastoid electrode below the earlobe. 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 37

When you start the test, the impedance test will show you if the electrodes are making good contact with the skin. After passing the impedance test, the measurement starts.

IMPORTANT NOTE: The MB 11 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.

All electrodes must contact the skin well.

5.2.3 Preparing the Patient for Testing with MB 11 Classic

5.2.3.1 General

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™, EARturtle™ 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™ is an around-the-ear coupler that connects to the tubing of the insert earphones using the EarCup™ black adapters at the end of the tubes. The EarCup™ and EARturtle™ adhere to the skin around the baby's ears.

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

The sections below offer the following information (see Table 10):

Table 10 Overview Preparing the Patient for Testing with EarCup™, EARturtle™ and Eartips

Section	Use with	Information
5.2.3.2	EarCup™, EARturtle™ and eartips	Placing electrodes for ABR testing
5.2.3.3	EarCup™, EARturtle™	Placing the EarCup™, EARturtle™ on the patient
5.2.3.4	eartips	Placing the eartips on the patient

5.2.3.2 Placing Electrodes for ABR Testing with MB 11 Classic (EarCup™, EARturtle™ and Eartips)

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

- Center of the forehead at the hairline
- Cheek (either side)
- 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.

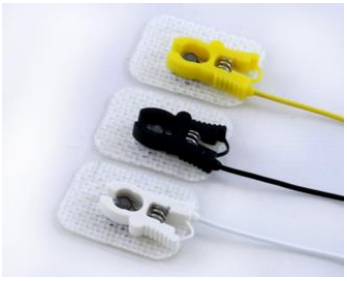


Figure 38

Connect the white, black and yellow pinch clip electrode lead wires to a snap electrode (Figure 38).

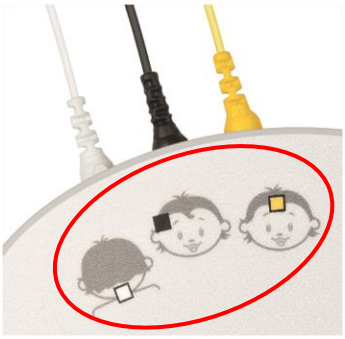


Figure 39

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 39, see also Table 11 for nape and mastoid montage).

Table 11 Nape and Mastoid Montage

	Nape Montage (recommended)	**Mastoid Montage (alternate)**
Yellow	Forehead	Forehead
Black	Cheek (either side)	Right mastoid
White	Nape of the neck	Left mastoid

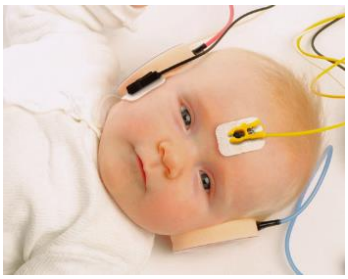


Figure 40

Press gently around the entire surface of each electrode to help secure its adhesive to the skin (Figure 40).

5.2.3.3 Placing EarCupTM or EARturtle™ (with Insert Earphones) on the Patient

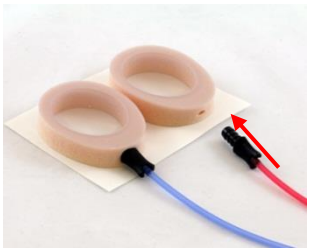


Figure 41

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 41).

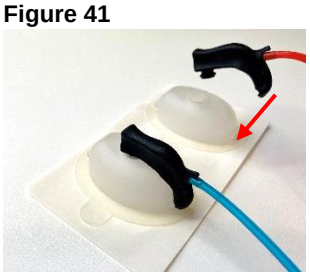


Figure 42

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 42).

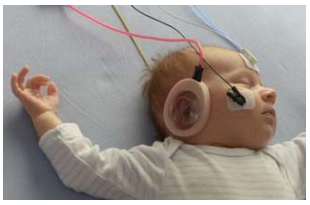


Figure 43

Peel the EarCup™ 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 43). Press around the entire circumference of the EarCup™ or EARturtle™ to ensure adhesion to the baby's skin.

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 cavity is not occluded by any contact with the ear.

Figure 44

Peel the EarCup™ or EARturtle™ attached to the blue tubing from the backing card. Place it around the baby's left ear with the adapter and tubing pointing toward the top of the head. 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.

5.2.3.4 Placing Eartips into the Patient's Ear Canal (Eartips Only)

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.

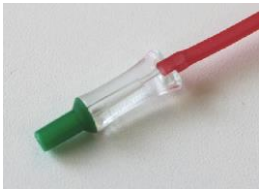


Figure 45

Apply the eartips onto the eartip adapters at the end of the insert earphone tubing (Figure 45).

Figure 46

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 46). 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 device. Calibration values for inserts with eartips are different from calibration values for inserts used with EarCup™ or 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.

5.3 Automatic ABR Screening

The MB 11 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® 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 are available.

Section 5.6.4 Settings – PROTOCOLS

The EEG is processed and analyzed automatically using the MB 11'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 maximum 3 minutes of EEG activity has been processed, a ***REFER*** result is assigned.

5.4 Performing the Hearing Screening Test

5.4.1 Select Ear Side and Start Test

Also, check-out our training videos:

MB 11 BERAphone® | ABR | MAICO Training | Hearing Screening Diagnostic Tests - How to start a measurement

https://youtu.be/FPQsk__HisU?si=5oSdw4Tp8byjAAY1&t=211

Select the ear to be tested by pressing ***LEFT EAR*** or ***RIGHT EAR***. When using the MB 11 Classic also the option ***BINAURAL*** is available (Figure 47) or toggle between ears with the shortcut ***Ctrl + E*** or ***F6***.

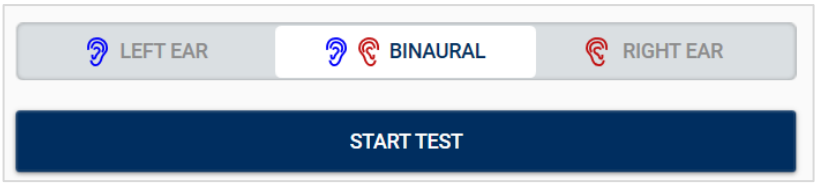


Figure 47

As soon as the baby is prepared, and calm press ***START TEST***. Before the actual data ABR screening test starts an automatic check of the skin impedance is performed.

NOTE: If the option ***Test fields*** is enabled and set to ***mandatory***, the test information need to be entered as described in Section:

Section 5.1.2 Preparation Screen

5.4.2 Test Protocol

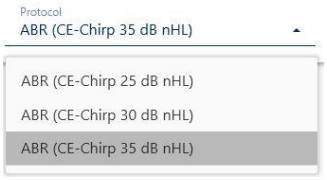


Figure 48

When starting the MB 11 Software, the default protocol is displayed at the top center of the measurement screen.

If more than 1 protocol was selected in the protocol settings, they can be selected in the drop-down menu (Figure 48).

5.4.3 Skin Impedance Check

The skin impedance is the resistance between the measuring electrodes (vertex and mastoid for MB 11 BERAphone® or forehead and nape for MB 11 Classic) and the ground electrode.

This impedance is influenced by the resistance of the skin. Ideally, the impedance should be in the range of 1 to 8 kΩ for each electrode (***Mastoid*** and ***Vertex***) and the difference between both shall be smaller than 5 kΩ.

Impedance in this range will allow the best EEG quality. The impedance is improved by the application of the electrode gel or preparation with NuPrep®.

Section 5.2 Hearing Screening with MB 11

The current impedance values are displayed next to the color-coded electrodes and the impedance status in green or orange color (Figure 49). Once the impedance status at all locations remains “green” for about 5 s, the impedance is acceptable, and the ABR screening starts automatically.

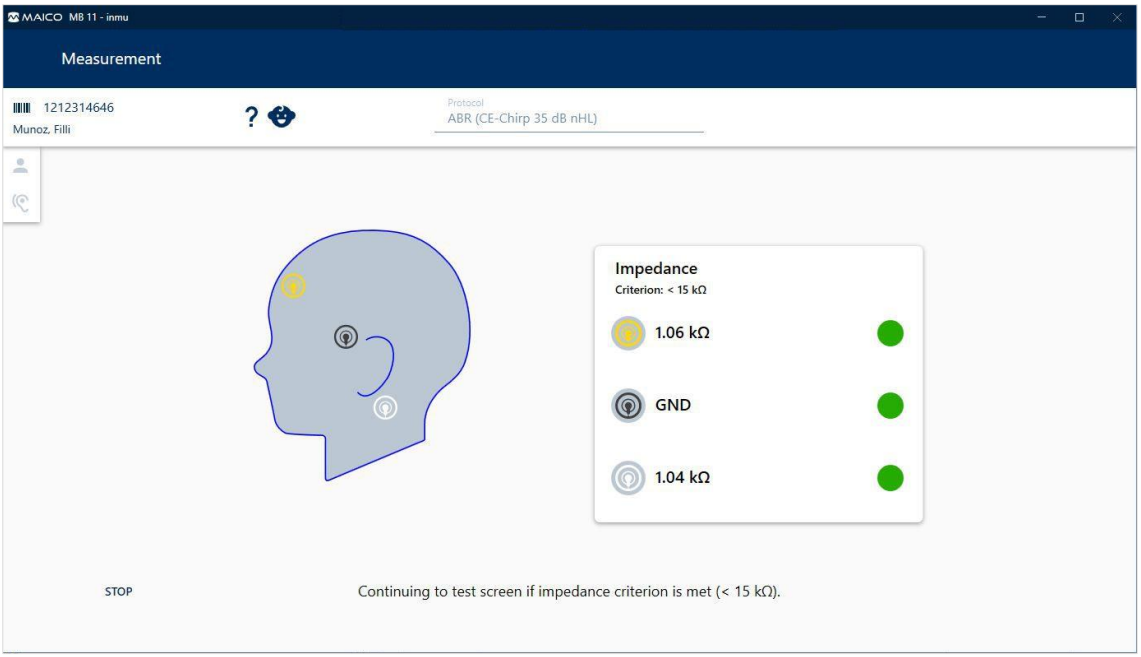


Figure 49

If any impedance indicator remains orange, the impedance at this electrode position needs to get improved 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.
- For the BERAphone® make sure all electrodes are in contact to the skin.
- If the impedance is below 0.25 kΩ two electrodes are in contact or connected through gel.

After approximately 180 s of impedance checking, an Impedance time out message will appear. You can return to the preparation screen at any time by pressing ***STOP***.

After passing the impedance check, the ABR test starts automatically, and the EEG signal and measurement diagram is displayed.

5.4.4 ABR Screening Test

During the test, a measurement diagram is displayed with progress line(s) in red for the right ear and blue for the left ear. Every second of data collection is reflected as a progress of the test line. The test time is displayed in the horizontal direction from 0 s to maximum 180 s.

A green line at the top of the diagram indicates the ***PASS*** criterion, which need to get reached by the line for a ***PASS*** result. If the measurement setting ***Reduced test time*** is enabled a box at 60 % and 120 s is displayed in the diagram. In that case the measurement will end after 120 s, when the test line did not reach more than 60 % until then.

Above the measurement diagram is the real-time EEG signal displayed. For good testing condition the line is nearly flat. When the baby becomes active you will note higher amplitude activity in the EEG representing myogenic activity from the baby. If there is electrical interference in the room, you may note spikes of activity showing in the EEG.

On the right of the EEG view is a noise bar. While the EEG signal is below the artifact rejection threshold it remains gray and the amount which is exceeding the artifact rejection threshold is displayed in orange.

Artifacts are large potentials caused by electrical noise, muscle activity or muscle tension and are not evaluated by the MB 11 response detection and the test progress is interrupted until the EEG signal is in the normal rage again.

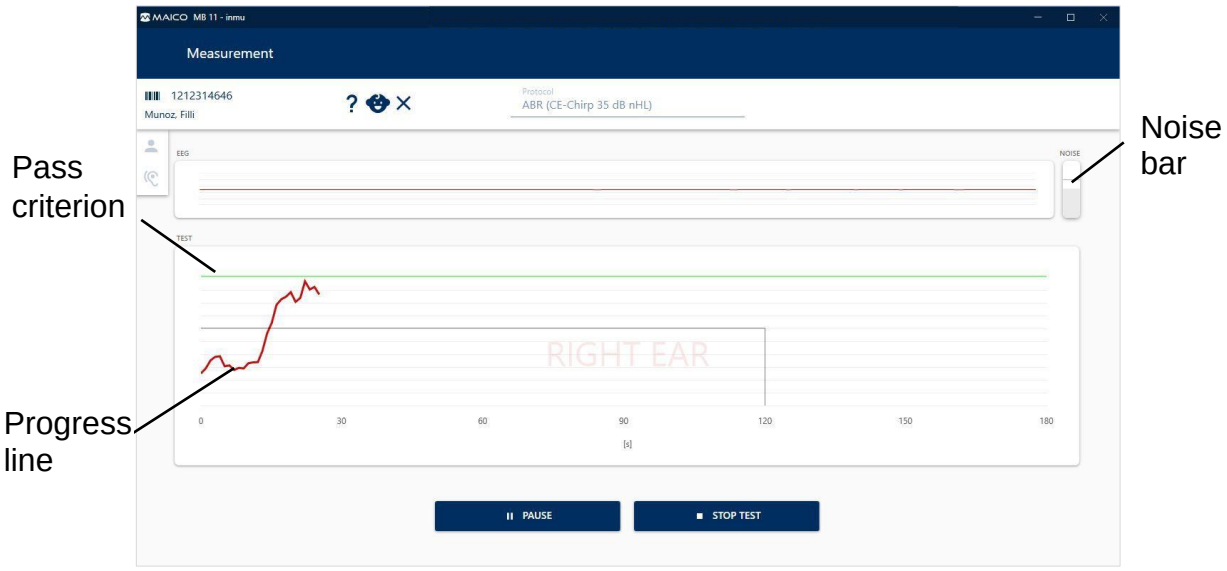


Figure 50

Press ***PAUSE*** to pause the test and allow the baby to calm down before continuing the screening (Figure 50).

If the baby is too active and constant artifacts occur, consider stopping the test by pressing the ***STOP TEST*** button and repeat the hearing screening when the conditions are better. The test result will be ***INCOMPLETE*** when the test is stopped. If the setting ***Reason for Incomplete outcome*** is enabled a dialogue will be displayed to select the reason for stopping the test (Figure 51).

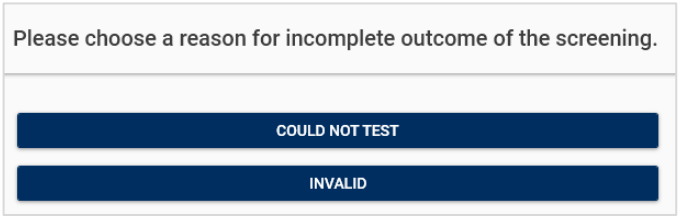


Figure 51

5.4.5 Electrode Disconnected

In case an electrode loses contact to the skin, during the measurement the test interrupts. Pause the test and ensure that all electrodes are in contact to the skin (Figure 52). As soon as the contact is reestablished, continue the test.

Figure 52

5.4.6 Test Results

When the test is finished, the result is displayed above the measurement diagram (Figure 53).

The latest result of the left and right ear is displayed as checkmark for ***PASS***, cross for ***REFER*** or question mark for ***INCOMPLETE***, next to the little baby head at the top area, next to the patient information.

The test result is stored when the application is closed, or if a new screening is started. Press the ***NEW SCREENING*** button to return to the preparation screen. For left or right ear tests is automatically the other ear selected.

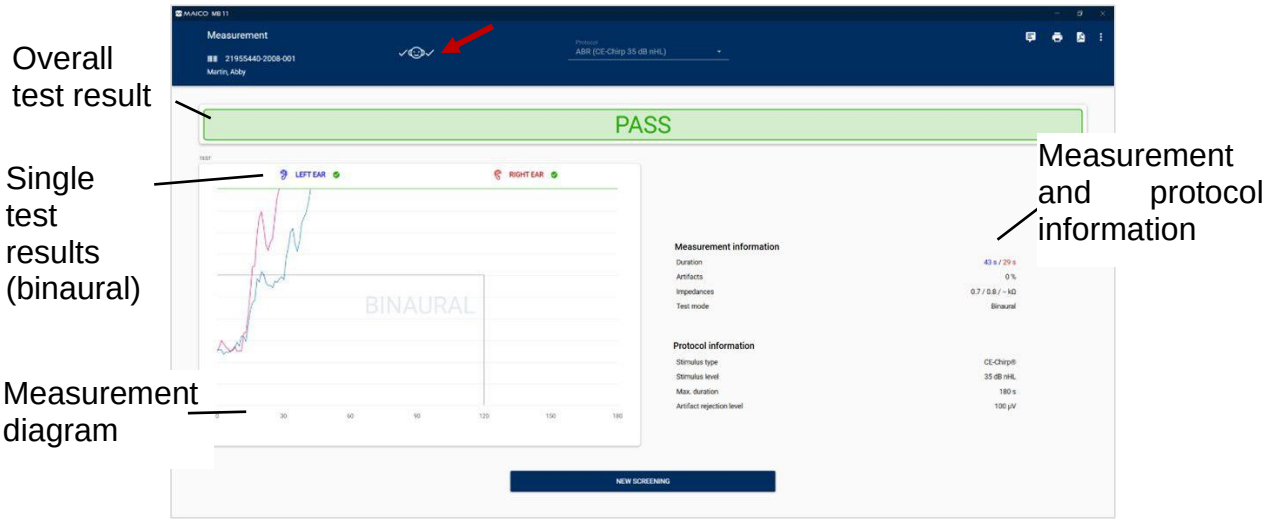


Figure 53

Possible Test Results

Figure 54

As soon as the progress line of the corresponding ear reaches the green line on top of the measurement diagram, the ***PASS*** criterion has been met and a ***PASS*** result is assigned to the corresponding ear**.**

For binaural tests, the overall result is a ***PASS*** if the progress lines of both ears reached the green area at the top of the diagram and the result of each ear is displayed above the diagram with the ***PASS*** result symbol next to the ear side.

Figure 55

If no response is detected for the maximum test duration of 180 s or with the setting ***Reduced test time*** enabled already after 120 s when the progress line did not exceed the box displayed in the diagram, the test result is ***REFER***.

For binaural tests is the overall result a ***REFER*** if the progress lines of one or both ears did not reach the green area at the top of the diagram. The result of each ear is displayed above the diagram with the ***REFER*** result symbol next to the ear side.

Figure 56

If the test is stopped during the test and depending on the settings also during the impedance measurement, the test result of the selected ear(s) is an ***INCOMPLETE***.

The result of each ear is displayed above the diagram with the ***INCOMPLETE*** result symbol next to the ear side which did not reach the ***PASS*** when the test was stopped.

5.4.7 Edit Notes

Press to open the ***Edit notes*** dialog. Type in the notes for the current measurement with the computer keyboard and press ***SAVE CHANGES*** to keep the notes with the test details or ***CANCEL*** to abort (Figure 57).

Figure 57

5.4.8 Autosave

In case the application gets stopped unexpectedly and some patient data are not yet transferred to the database, Autosave files are generated. Restarting the application will give the pop-up window (Figure 58), where you can choose which autosave files you want to restore.

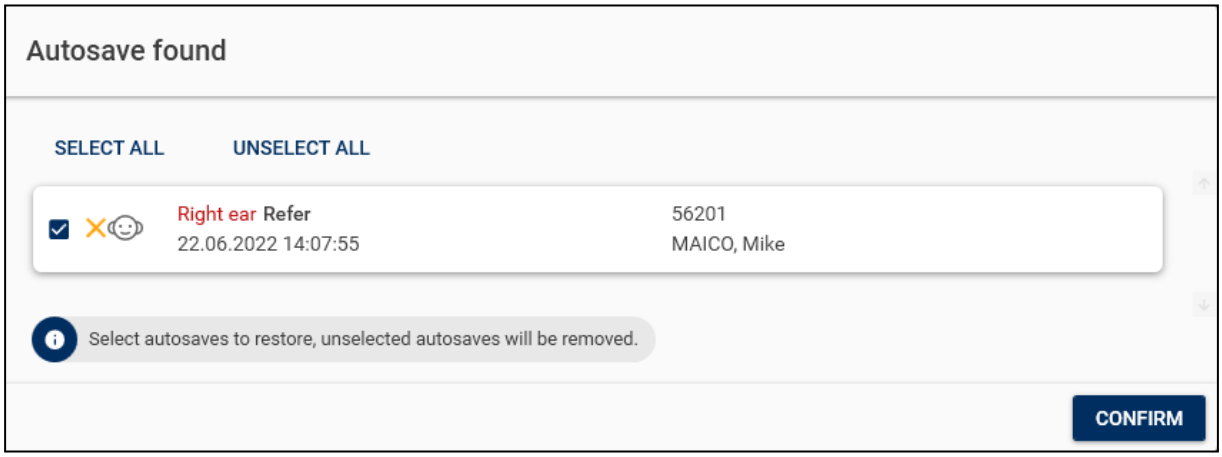


Figure 58

5.5 Printing

5.5.1 Print Preview

Press the print button , to print the results. If more than one test was performed, select the tests in the dialog (Figure 59) and press ***CONTINUE*** to display the print preview. Press ***CANCEL*** to close the dialog.

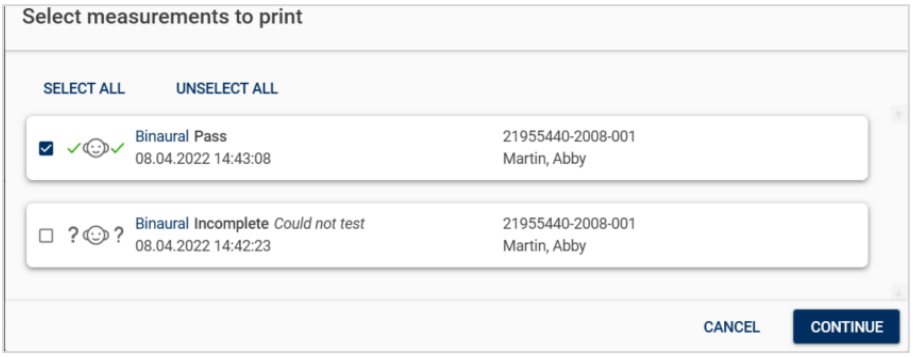


Figure 59

Depending on the ***Report format*** setting either the ***Basic*** (Figure 60) or ***Detailed*** (Figure 61) report is displayed in the preview.

Basic Report

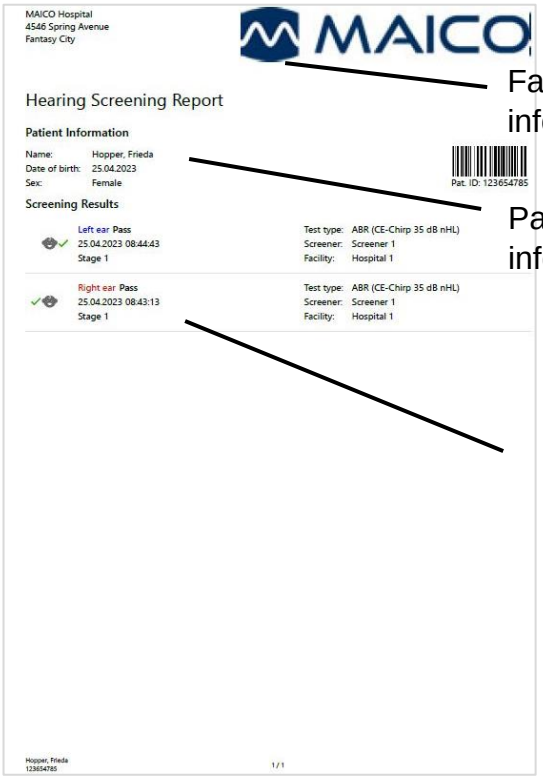
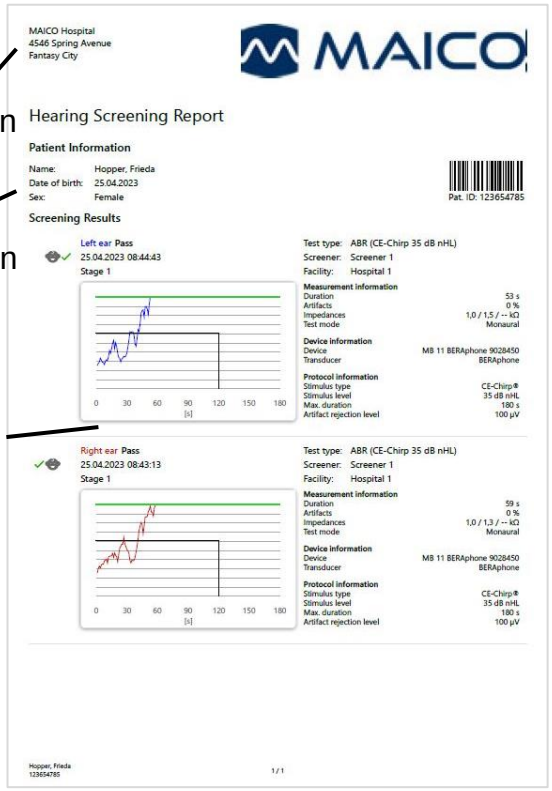


Figure 60

Detailed Report



Facility information

Patient information

Test results

Figure 61

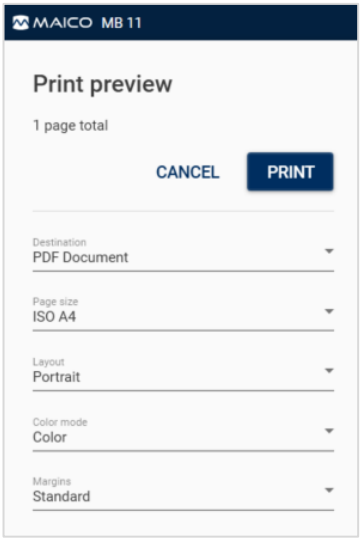


Figure 62

At the left side of the print preview the printer or file format can be selected as destination, the page size, layout, color mode and margins selected.

When selecting a label printer is selected as destination, the content of the preview is adjusted to a label printout.

Make sure the correct label format is selected in the Windows printer settings.

Section 5.5.2 Label Printer Setup

Press ***PRINT*** to print the results with the selected printer.
Press ***CANCEL*** to close the print preview.

5.5.2 Label Printer Setup

For label printing from the MB 11 Software, use either the Dymo LabelWriter 450 or the Brother QL810W label printer can be used.

Install the according printer driver and navigate to the extended printer options:

Navigate to the ***Printers & Scanners*** menu in the Settings App of the PC (Figure 14).

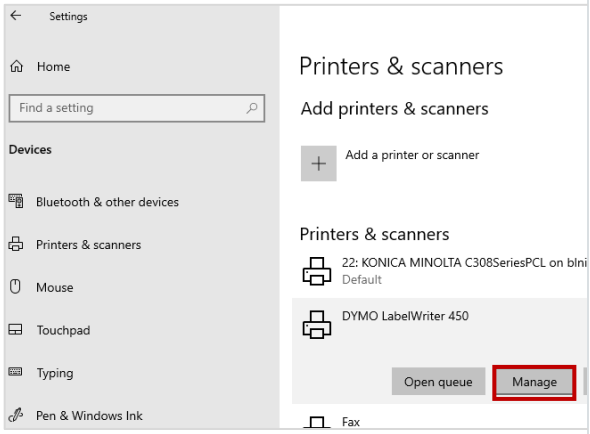


Figure 63

Select the label printer and press ***Manage*** to open the printer properties (Figure 15).

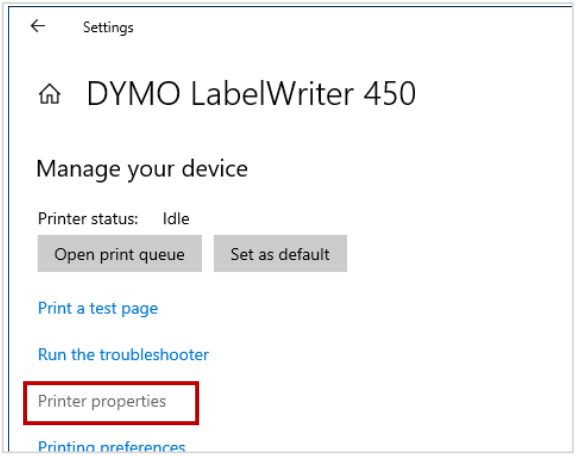


Figure 64

Press ***Printing Defaults…*** to open the label writer's printing defaults (Figure 65).

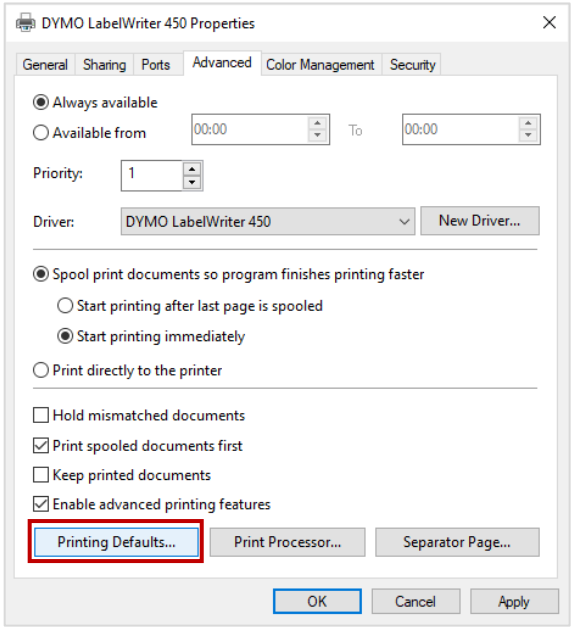


Figure 65

Press ***Advanced*** to open the advanced options (Figure 66).

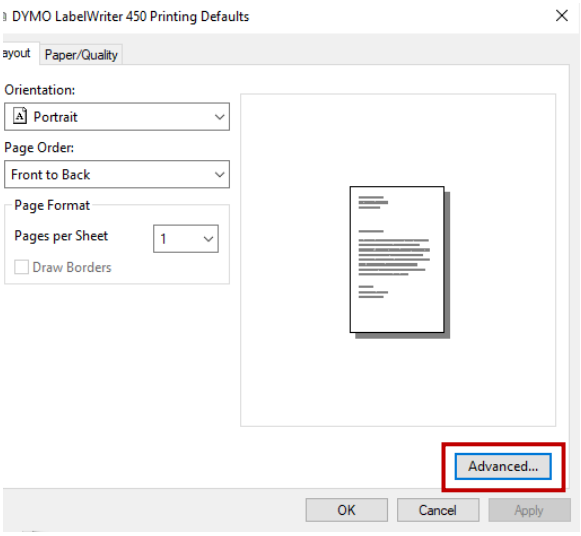


Figure 66

Select the ***Paper Size*** under ***Paper/Output*** (Figure 67):

- Dymo LabelWriter 450: ***99015 floppy disc***
- Brother QL810W: ***DK1202 labels***

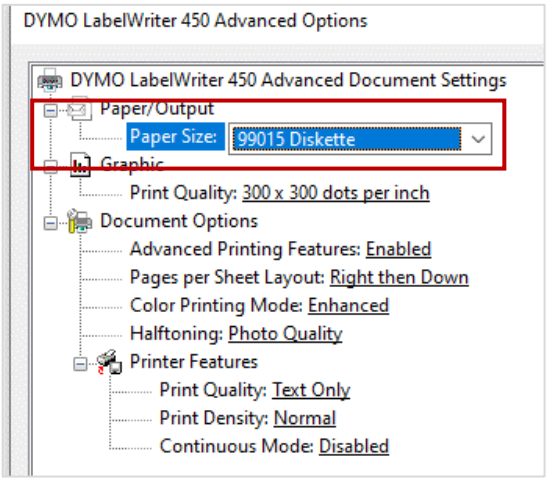


Figure 67

Respective printer manual

5.6 Settings

5.6.1 About the Settings Menu

NOTE: Some of the settings are only accessible for users with MAICO Center or OtoAccess® Administrator permissions (when used with OtoAccess® Database).

This symbol indicates that the setting/submenu is only accessible for users with Administrator rights.

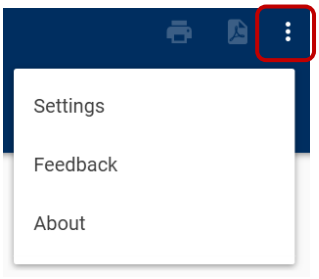


Figure 68

Open the Setting Menu

Press ⋮ to extend the menu and select ***Settings***. Press on a tab to select a submenu (Figure 69).

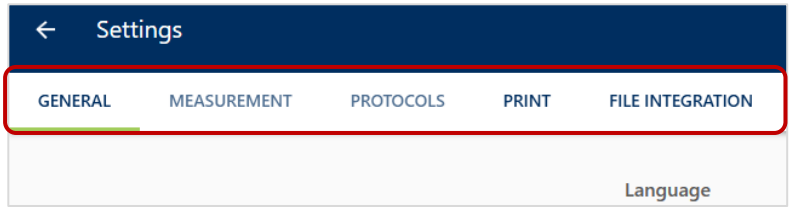


Figure 69

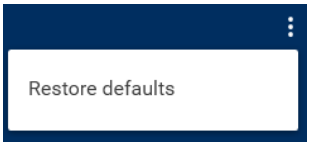


Figure 70

Reset Settings

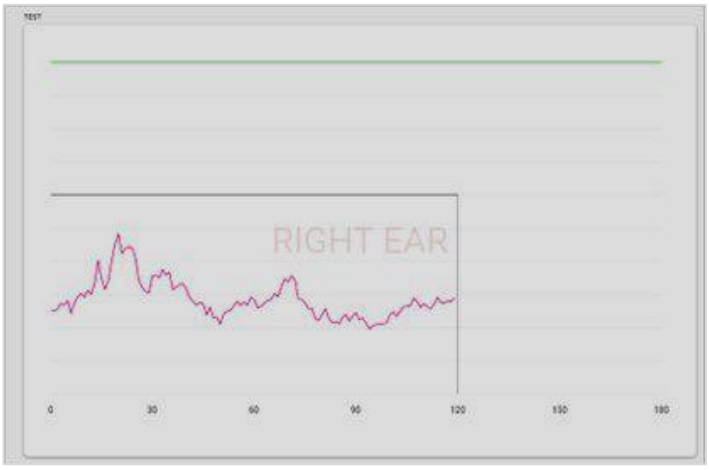
Press ⋮ to extend the menu and press ***Restore defaults*** if you want to reset the settings.

5.6.2 Settings – GENERAL

Language	Select the preferred language from the drop-down menu. If the MB 11 Software was started from HearSIM™ or OtoAccess® Database this setting is deactivated, and the language is automatically set to the language set in the OtoAccess® Database.
Theme	Select the layout of the application (Figure 71).  Figure 71
Automatic update check	Activate this setting to get a notification when a new version of the MB 11 Software is available.
Update	Press CHECK FOR UPDATE to manually search for an updated software version.

5.6.3 Settings – MEASUREMENT

Ear side	Select ***Left ear*** or ***Right ear*** as default ear side for MB 11 BERAphone®, when starting the MB 11 Software. For MB 11 Classic ***Binaural*** is set as default.
Binaural measurements	For the MB 11 Classic only: Activate this setting to allow the user to select ***Binaural*** on the start screen, to test both ears at the same time.
Test fields	Activate this option to allow the user to enter test information. If activated, select: • ***Optional*** to let the user decide to enter test information as needed or • ***Mandatory*** to allow only to start a measurement if the user entered test information before. Section 5.1.9 Edit Patient Information (With MAICO Center Only)
Lock screener	Activate this option to set the screener automatically to the HearSIM™/OtoAccess® Database user if the MB 11 Software is started from HearSIM™/OtoAccess® Database. If activated, it is not possible to change the ***Screener*** in the ***Edit test information*** window in the MB 11 Software.
Impedance criterion	The default impedance criterion for both measurement electrodes is 15 kΩ. Select a value between 5 kΩ, 10 kΩ and 15 kΩ. Allowing the test to start at a lower skin impedance requires more skin preparation – the better the skin contact, the better the test quality and shorter the test time.
Impedance balancing	Activate this setting to start a test only when the impedance difference between both measuring electrodes is less than 5 kΩ. This ensures good test conditions – the lower the difference in skin impedance between the two measuring electrodes, the better the noise suppression of the preamplifier.

Reduced test time	If deactivated, a ***REFER*** outcome will be recorded after 180 s of data collection when the algorithm detects no response. If activated, a box is displayed in the diagram of the measurement screen (Figure 72). If the test progress line(s) remain(s) below the horizontal line of the blue box, the test ends after 120 s with a ***REFER*** result. Otherwise, the test continues for the full 180 s.  **Figure 72**
Artifact rejection threshold	This setting defines at which level of EEG amplitude caused by electrical noise or muscle artifacts, the test is interrupted, and the EEG is rejected. Select a value between 80 µV to 150 µV (default: 100 µV): • Select a lower value to guarantee a better data quality. The test might be interrupted more often. • Select a higher value if the test is too often interrupted and "***Incoming EEG signal is too high"*** displayed.
Stop test definition	Select: • ***Data collection***, to store the test as incomplete if stopping the test AFTER impedance check OR • ***Impedance test***, to store the test also as incomplete if stopped DURING impedance check.
Reason for incomplete outcome	If activated, the user must select a reason when the test is stopped and stored as incomplete.
Acoustic feedback	Select: • ***No sound***, to avoid acoustic feedback, OR • ***Asterisk, MAICO Sound*** or ***Hand***, to activate an acoustic notification when the test finishes. Use the level slider to set the preferred sound level and press to play back the selected sound.

5.6.4 Settings – PROTOCOLS

Default protocol	Select the default protocol that is preselected when the software is started.
Protocol selection	If activated, the user can change the protocol in the measurement screen. Select/deselect protocols according to your needs. Selected protocols are available as default protocols (see above). Section 5.4.2 Test Protocol

5.6.5 Settings – PRINT

Report header

Enter the preferred header text.

Press to select a logo from your network. Press to remove the logo again if needed (Figure 73).

If you only want to use an image without entering your facility information manually, activate the ***Use image only*** feature and proceed as indicated. (Figure 74).

Figure 73

Figure 74

NOTE: With the ***Use image only*** feature, the image is centered on the head of the printout. If you want it to be displayed at a different position, you have to work with white space accordingly.

If you want to use the image over the maximum available space, we recommend an aspect ratio of 12:1.

Report format

Select:

- ***Basic*** report format OR
- ***Detailed***, to also include the result diagram and test information.

Section 5.5 Printing

5.6.6 Settings – FILE INTEGRATION

Section 5.1.1.4 Starting the MB 11 Software via integrated GDT or XML Interface

Here you can select an integration type for the connection to your practice management software and choose the corresponding settings (Figure 75).

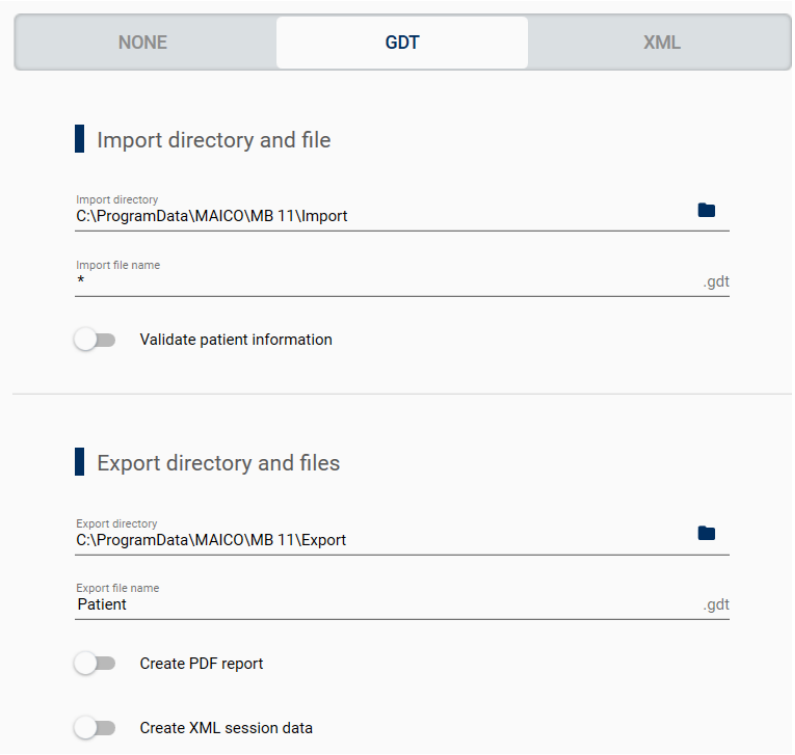


Figure 75

Integration Type – NONE

Select the integration Type ***NONE*** if you want to use the MB 11 Software with local database integration (MAICO Center).

Integration Type – GDT or XML

Section 4.6.2 Connection to Practice Management Software

5.7 Feedback

To navigate to the feedback dialog, press ⋮ and select ***Feedback***.

If you want to provide MAICO feedback on your experiences with the MB 11 Software, you can use the integrated Feedback form. Leave a star rating (**1**) and let us know how what you like and what can be improved (**2**). Press ***SEND*** (**3**) to share your ideas with MAICO (Figure 76).

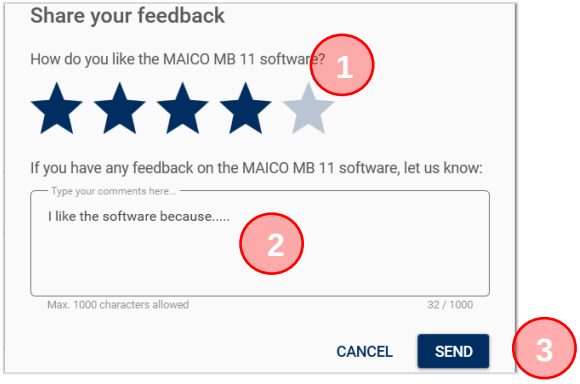


Figure 76

5.8 Managing Test Results

5.8.1 General

Test results from MB 11 can be printed on the wireless printer.

It is possible to use the optional HearSIM™ with OtoAccess® Database PC applications support transfer, storage and management of MB 11 data.

HearSIM™ and OtoAccess® Database Instruction for Use Settings – PROTOCOLS

5.8.2 Printing Test Results

Printing test results is possible from

- MAICO Center
- MB 11 Software
- OtoAccess® Database/HearSIM™
- Practice Management Software

Printing from the MB 11 Software

Test results can be printed from MB 11 Software on the wireless label printer or other printers.

Section 5.5 Printing

Printing from OtoAccess® Database/HearSIM™/Practice Management Software

Refer to respective Software Manual

5.8.3 Deleting Test Results

Deleting test results is possible from

- MAICO Center
- OtoAccess® Database/HearSIM™
- Practice Management Software

Refer to respective Software Manual

5.8.4 Tracking with Local Database Integration (MAICO Center)

5.8.4.1 Automatic Tracking

Automatic tracking allows management of the acquired health data without additional manual steps. It can only be configured and managed by an administrator in the MAICO Center.

OM MAICO Center

5.8.4.2 Manual Tracking

Regardless of the automatic tracking options, you can also perform manual tracking without owning administrator rights.

Press ⋮ and Manual tracking to open the ***Test export*** screen of the MAICO Center (Figure 77). See Table 12 for explanation of the screen.

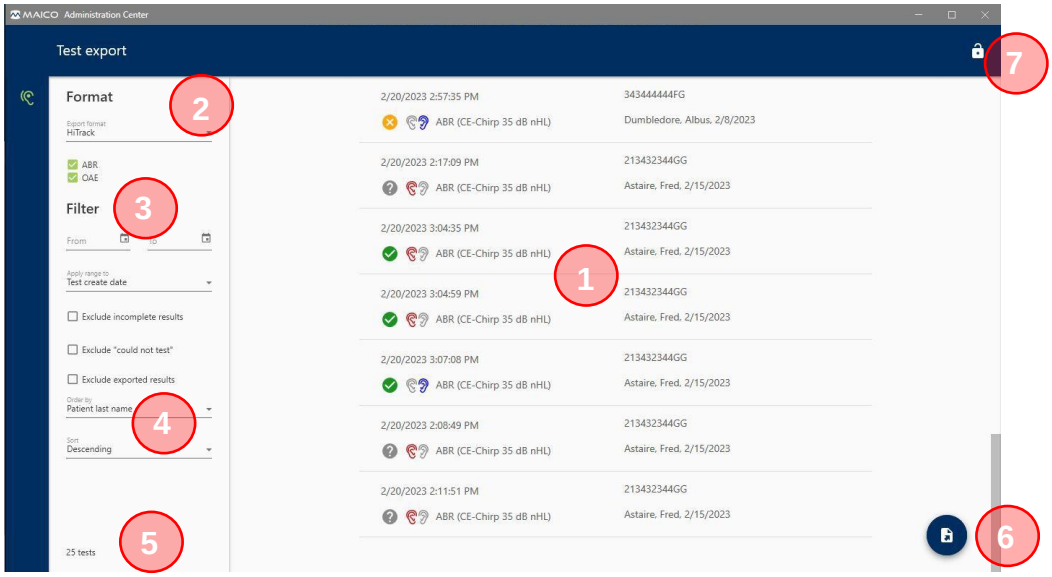


Figure 77

Table 12 Explanation of Test Export Screen

No.	Explanation
1	List of test result
2	Selection of export format
3	Filter options
4	Sorting options
5	Number of selected tests
6	Press to select an export path and safe export file.
7	**For administrators only**: Press to access the full MAICO Center.

5.9 About

To navigate to the ***About*** screen (Figure 78), press ⋮ to extend the menu and select ***About***.

Selecting ***About*** in the ***Screen selection*** area opens the ***Product information*** screen. It shows diverse product information (e.g., Manufacturer information).

It is possible to ***Allow usage statistics*** (**1**) or not it is moving the slider to the left or the right (● = allowed, ○ = not allowed). Change of this setting requires a restart of the application.

Third-party software is displayed by pressing the arrow (**2**).

NOTE: The MB 11 Software logs data about the PC on which it is installed for support reasons. Further, the MB 11 Software may log data about its usage patterns and anonymous usage data from test sessions on the manufacturer's servers administered by the manufacturer. They are used for future development.

All data logged is anonymous and is therefore not covered by EU GDPR consent. No individual can be identified and therefore the manufacturer is not able to or obliged to erase data requested by individuals or groups.

You can set ***Allow usage statistics*** to off.

44

Figure 78

6 Technical Data

This section offers you important information about

- **the MB 11 hardware specifications**
- **the pin assignment**
- **calibration values**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated standards**

6.1 MB 11 Hardware

CE 0123

The MB 11 is an active, diagnostic medical product according to the class IIa of the Medical Device Regulation (EU) 2017/745.

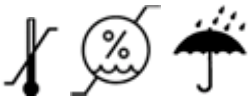
General Information About Specifications

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	
Device Safety	IEC 60601-1: 2012 reprint ANSI/AAMI ES60601-1: 2005 / A2:2010 CAN/CSA-C22.2 No. 60601-1:14 Type BF applied parts The protection class according EN 60601-1 depends on the used computer (USB connection). IEC 60601-2-40:2016
EMC	IEC 60601-1-2:2014 (EMC test done with default settings)
Calibration	ISO 389-6:2007
ABR	IEC 60645-7:2009, Type 2

DEVICE SPECIFICATIONS

Operation environment 	Temperature	+5 °C to +40 °C / + 41 °F to +104 °F
	Relative Humidity	15 % to 93 % (non-condensating)
	Ambient Pressure	98 kPa to 104 kPa
	Boot-up Time	depends on connected PC
	Warm-up Time	< 1 min
Transport & Storage environment	Storage Temperature:	0 °C to 50°C, 32 °F to 122°F
	Transport Temperature:	-25 °C to 70 °C, -13 °F to 158 °F
	Storage and Transport rel. Humidity	10 % to 95 % (non-condensating)
Altitude rating	Max. operating altitude	2000 m / 6561 ft. above sea level
Dimensions		120 mm x 93 mm x 30 mm / 4,7 in x 3,7 in x 1,2 in
Weight		142 g / 0.3 lb
Mode of operation		Continuous
Language Settings		English, Chinese, French, German, Polish, Turkish, Hungarian, Japanese, Russian, Spanish
Data Interfaces	PC connection	USB
Connectors	USB	USB-B to PC
Power Supply	USB	Approximately 310 mA

ABR

Stimulus	Type	CE-CHIRP® (135 Hz to 7.5 kHz)
	Level range	25 dB nHL to 45 dB nHL, default: 35 dB nHL
	Stimulus rate	88 /s left ear, 92.5 /s right ear
	Transducers	IP30 ABR for EarCup™ and EARturtle™ IP30 ABR for eartips BERAphone®
	Test modes	Binaural (only with IP30) or monaural
Recording	Analysis time	Maximum 180 s of artifact-free data samples
	A/D resolution	16 bit
	Artifact reject system	Peak rejection level
	Artifact rejection levels	80 µV to 120 µV, default: 100 µV
	Display	Test result (PASS, REFER or INCOMPLETE), test diagram with line towards PASS, signal quality and EEG, electrode positions and impedance
	Measurement frequency	183 Hz, 73 Hz

ABR

Electrode impedance measurement	Measurement current	200 nA
	Waveform	Rectangular
	Acceptable Impedance Range	Customizable in settings
Accuracy of Measurement	Sensitivity	> 99.6 %
	Specificity	97.9 %[1]

TRANSDUCER

Radioear IP30	Type	ABR insert earphones (50 Ω)
	Versions	With EarCup™, EARturtle™ or eartip adapter
	Supported tests	Binaural or monaural ABR
	Max. input voltage	5.0 V RMS
	THD	< 2% (125 Hz – 4 kHz)
	Cable length	37 cm / 14.5 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

[1]Cebulla, M., & Shehata-Dieler, W. (2012). ABR-based newborn hearing screening with MB11 BERAphone® using an optimized chirp for acoustical stimulation. *International Journal of Pediatric Otorhinolaryngology*, *76*(4), 536-543.

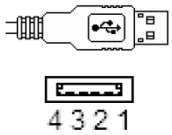
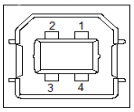
BERAPHONE®

Preamplifier	Channels	One
	Gain	69.3 dB
	Frequency response	43 Hz to 4 kHz
	Noise	<25 nV/√Hz
	CMR Ratio	> 110 dB at 80 Hz
	Input impedance	42 MΩ at 50 Hz
	Power supply	Isolated, from USB box
Speaker	Integrated	Dynamic, 8 Ω
Electrodes	3pcs. with gel protectors	Stainless-steel, reusable, rotatable vertex electrode
Properties	Weight	285 g/ 10.1 oz
	Dimensions	160 mm x 87 mm x 60 mm / 4.7 in x 3.4 in x 2.4 in
	Cable length	190 cm / 7.5 in
Cradle	Weight	270 g/ 9.5 oz
	Dimensions	119 mm x 160 mm x 74 mm / 4.7 in x 6.3 x 2.9 in

ABR PREAMPLIFIER

Channels	One
Connectors	3 electrode lead wires (black, yellow, white)
	Transducer (IP30) left and right
Gain	69.8 dB
Frequency response	35 Hz to 3.9 kHz
Noise	<25 nV/√Hz
CMR Ratio	>115 dB at 80 Hz
Input impedance	1100 MΩ / 32pF, 98 MΩ at 50 Hz
Power supply	Isolated, from main unit
Weight	100 g / 3.5 oz
Dimensions	100 mm x 100 mm x 22 mm / 3.9 in x 3.9 in x 0.9 in
Cable length	187 cm / 73.6 in
Electrode lead wire length	50 cm / 20 in

6.2 Pin Assignment

USB A		USB B	
	1. +5 VDC 2. Data - 3. Data + 4. Ground		1. +5 VDC 2. Data - 3. Data + 4. Ground

Connecting plugs: Connection Specification

USB socket: USB-B max 400 mA

Figure 79

6.3 Calibration Values

RadioEar IP30 with Coupler IEC 60318-4 (IEC 711):

TRANSDUCER	CE-CHIRP® pe RETSPL [dB re. 20 µPa]
Radioear IP30 with eartips	30
Radioear IP30 with EarCup™ or EARturtle™	56.5

RadioEar IP30 with Coupler IEC 60318-5:

TRANSDUCER	CE-CHIRP® pe RETSPL [dB re. 20 µPa]
Radioear IP30 with eartips	20.5
Radioear IP30 with EarCup™ or EARturtle™	47

The calibration values for eartips are according to PTB report from 2008-05-19, in compliance to the calibration procedure defined in standard EN 60645-3. Correction values for EarCup™ and or EARturtle™ calibration are defined as MAICO standard values.

BERAphone® with coupler 60318-3:

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

The calibration values for the BERAphone® are according to the PTB Report from 2008-05-19. The values are equal to the click stimulus calibration values for the MB 11 BERAphone® regarding the standard ISO 389-6. Both stimuli have the identical amplitude magnitude spectrum. A special calibration adapter is needed to mount the BERAphone® onto the coupler with a pressure of 5 N.

Sound Attenuation Characteristics

Frequency[Hz]	Sound Attenuation [dB] ISO 4869-1 RadioEar IP30
125	33.5
250	34.5
500	34.5
1000	35.0
2000	33.0
4000	39.5
8000	43.5

Stimulus

The ABR stimulus is different from the one specified in the standard IEC 60645-3. This CE-CHIRP® stimulus has the same linear magnitude frequency response as the click stimulus specified in the standard. However, it is designed 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 are delayed according to the cochlear delay of the according frequency in order to achieve a more effective stimulus design. The frequency range of the stimulus is from 135 Hz to 7500 Hz.

Screening Algorithm

The MAICO's MB 11 presents the CE-Chirp® stimulus periodically with a repetition rate of about 90 Hz. During stimulation, the EEG is continuously recorded and analyzed. The evoked ABR has the same periodicity as the fixed stimulus repetition rate. A statistical test [1] is performed to detect the response automatically. The amplitude and phase values of the first eight harmonics of the stimulus repetition rate are extracted from the spectrum of the EEG signal. All the amplitude and phase values of harmonics of all previous and the current epochs are included in the calculation of a test value. After every calculation of the test value it is compared with a critical test value to determine presence or absence of a

response. Since the critical test value varies with each new calculation, to maintain a constant sensitivity throughout the test a look up table is used. The critical test values in this table were calculated by the method described by Stürzebecher et al [1] to keep the error probability constant [2]. If the currently calculated test value is higher or equal to the critical test value, the test result is a PASS. The test continues through collection of 120 epochs if the test value remains < 60 % and continues for 180 s if the test value remains smaller than the critical test value but exceeded the 60 %, the test stops with a REFER after 180 s.

[1] Automated auditory response detection: Statistical problems with repeated testing (2005). Stürzebecher, Cebulla, Elberling. International Journal of Audiology.

[2] Automated auditory response detection: Improvement of the statistical test strategy (2013). Stürzebecher and Cebulla. International Journal of Audiology, 52:12, 861-864, DOI: 10.3109/14992027.2013.822995

6.4 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.

Portable and mobile RF communications equipment can affect the MB 11. Install and operate the MB 11 according to the EMC information presented in this section.
The MB 11 has been tested for EMC emissions and immunity as a standalone MB 11. Do not use the MB 11 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 MAICO as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *MB 11* is intended for use in the electromagnetic environment specified below. The customer or the user of the *MB 11* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The *MB 11* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *MB 11* is suitable for use in all commercial, industrial, business, and residential environments.
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 MB 11.			
The *MB 11* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *MB 11* can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *MB 11* 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. **Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** 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 *MB 11* is intended for use in the electromagnetic environment specified below. The customer or the user of the *MB 11* 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 fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not applicable +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	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	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the *MB 11* requires continued operation during power mains interruptions, it is recommended that the *MB 11* 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.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The *MB 11* is intended for use in the electromagnetic environment specified below. The customer or the user of the *MB 11* 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 *MB 11*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}2\sqrt{P}$
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,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
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.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *MB 11* is used exceeds the applicable RF compliance level above, the *MB 11* should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *MB 11*. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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 13).

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.

Table 13 EMC Requirements – Accessories

ITEM	MANUFACTURER	MODEL	EMF Level
ABR Preamplifier	MAICO	MB 11	LOW
IP30 50 Ω Insert Earphones	RadioEar	IP30	LOW
BERAphone®	MAICO	MB 11	LOW

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 14.

Table 14 EMC Requirements – Cable types and lengths

EUT SUPPORT EQUIPMENT						
Item	Manu-facturer	Model	Cable		SIP/SOP	
			Length [m]	Screened [Y/N]	Socket ID	Type
Cable USB A & B (for MB 11 Classic only)	Sanibel® Supply		1.80	Y	USB	DC supply Data
Insert Earphones (50 Ω)	Radioear	IP30	0.25	Y	On the preamp: Socket marked with ear symbol	Analog output Serial data
Non-removable cable	MAICO	-	1.80	Y	Fix connected to USB box	Analog output and input Serial data
Electrode cables (for MB 11 Classic only)	Sanibel® Supply	-	0.51	N	On the preamp: Colour marked sockets with head symbol	Analog input for Physiological signals

6.5 Electrical Safety, EMC, and Associated Standards

- IEC 60601-1:2012 reprint/ANSI/AAMI ES60601-1: 2005 / A2:2010: Medical Electrical Equipment, Part 1 General Requirements for Safety
- CAN/CSA-C22.2 No. 60601-1:14: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC/EN 60601-2-40:2016: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
- IEC/EN 60601-1-2:2014: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests
- ISO 14971:2012 - Application of risk management to medical devices
- General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
- DIRECTIVE 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Specifications are subject to change without notice.

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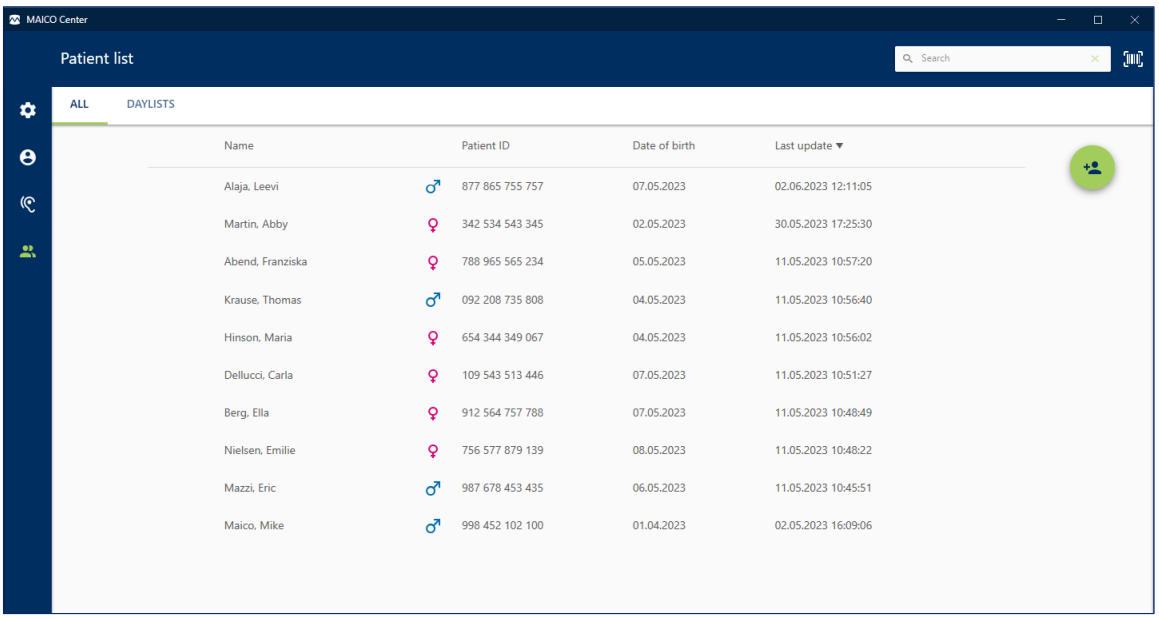
Operation Manual
MAICO Center



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Title: Operation Manual MAICO Center

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Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

Trademark Notice

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HITRACK® is a U.S. registered trademark of the Utah State University.

1 Introduction

1.1 General

This operation manual is meant to make it as easy as possible for the operator to become familiar with the operation and functions of the MAICO Center. If you have questions or suggestions for further improvements, do not hesitate to contact MAICO.

The information sign displays alternative documents or sections in this operation manual that provide more detailed information.

NOTE: Figures shown in the operation manual are exemplary and may vary depending on the device used.

The MAICO Center is a database that can be run together with

- MB 11 Software (VERSION 4.1 and higher)

MAICO Center supports tracking with the following export formats:

- HiTrack/Ecrypted HiTrack
- OZ/Encrypted OZ
- MS EHDI/Encrypted MS EHDI
- Audio_CL/ Encrypted Audio_CL
- NHS CSV/Encrypted NHS CSV

1.2 Intended Use Statement

The intended use of the MAICO Center application is to provide a platform for storing and retrieving hearing screening data. The application can be used to manage patient records, store hearing screening results, and generate tracking reports. Additionally, it offers functions to set up a user management based on Windows PC users and advanced features like the selection of offered patient fields.
The application is not a medical product itself but is only responsible for the storage of sensitive patient information.

1.3 PC and System Requirements and Installation

The MAICO Center is installed together with the MB 11 software. For PC and system requirements and installation refer to:

Operation Manual MB 11

1.4 Safe Use of the MAICO Center

To ensure data protection it is essential to follow common practice in terms of cyber security. This involves:

1. Ensure operating systems are security patched.
2. Keep your software up to date.
3. Install only apps and software from trusted sources.
4. Install an antivirus protection and anti-malware software and a firewall from a trusted vendor and keep them up to date.
5. Utilize the unique PC login settings and use safe passcodes.
6. Ensure secure physical and network access to computers with local data storage.
7. Implement an appropriate backup policy.
8. Do not use public WiFi.
9. Learn about phishing scams: Be very suspicious of emails and calls.
10. To avoid data from being misused if stolen, the data must be encrypted. All users should have a unique login to the PC.
11. When using a third-party networked software, the communication to the database should be secure (encrypted) to avoid client information being captured during network transmission.
12. When using a third party networked software, all users should have a unique login to the database to ensure traceability and identification of data when updated or deleted from the database.

For details see:

Third-party instructions for use

2 Operation

2.1 General

The MAICO Center is installed with your device application, like the MB 11 Software. It provides the possibility to configure database and tracking export related settings, manage users and user permissions, manually export hearing screening results, review audit logging data and the list of patients stored in the database and to manage daylists. The icons on the left-hand side are used to navigate to the different sections:

- access the ***Settings*** menu, including audit logging and backup.
- manage ***Users*** and user permissions.
- review and ***Export*** hearing screening tests.
- review the stored ***Patients*** and manage day lists.

Figure 1

The following chapter will describe the available settings.

2.2 Settings

2.2.1 About the Settings Menu

Press to access the ***Settings*** menu. Press on a tab to select a submenu (Figure 2).

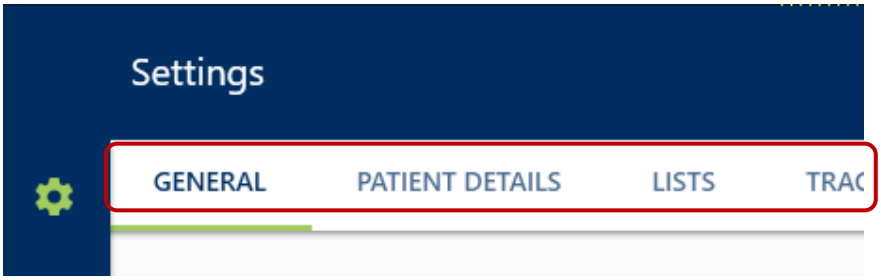


Figure 2

2.2.2 Settings – GENERAL

Language	Select the preferred language from the drop-down menu.
Import settings / configuration	Press IMPORT... to import settings or configuration lists saved to the directory.
Export settings / configuration	Press EXPORT... to export and save settings or configuration lists to the directory.

2.2.3 Settings – PATIENT DETAILS

In the ***PATIENT DETAILS*** you can set which patient data can/must be entered before it is saved. Figure 3 shows the ***Settings – PATIENT DETAILS*** screen. Table 1 gives explanation.

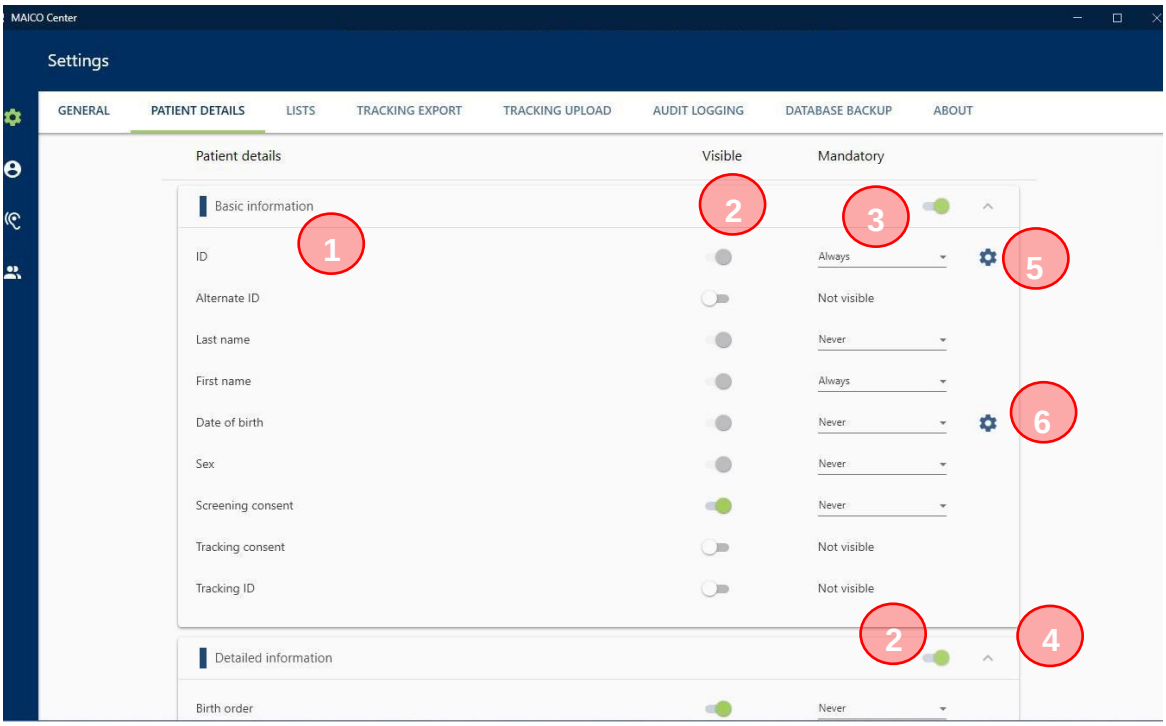


Figure 3

Table 1 Explanation of the Settings – PATIENT DETAILS screen

No.	Explanation
1	Categories and Items
2	**Visible**: Set the whole category/single item visible ( ) or invisible ( ) in MB 11 Software. Some items are always visible ( ).
3	**Mandatory**: Select when a visible item shall be mandatory. ***Mandatory if refer***: Field is mandatory in case of a ***Refer*** or ***Could not test*** result.
4	**/ :** Fold/unfold category
5	**Press to enter the *Configure ID validation* window:** **Regular expression**: Create a regular expression if you want to determine the way IDs shall be created. **Test input**: Try the regular expression with a test entry. **Example:** Regular expression: ^[A-Za-z][A-Za-z][A-Za-z][A-Za-z][A-Za-z]_\d\d\d\d$ for an ID like MAICO_1937 (5 letters, underscore, 4 digits, no case sensitivity)
6	Press to enter the ***Configure default date of birth*** window: Set the default date of birth to ***Today*** or ***Empty*.**

2.2.4 Settings – Lists

Figure 4 shows the ***Settings – LISTS*** screen.

Select a list on the left (**1**). The lists ***Screeners***, ***Facilities*** and ***Physicians*** must be created completely new. The other lists are HiTrack® standard tracking lists. They can be customized if necessary.

NOTE: You need to restart the MB 11 Software to display new fields/categories.

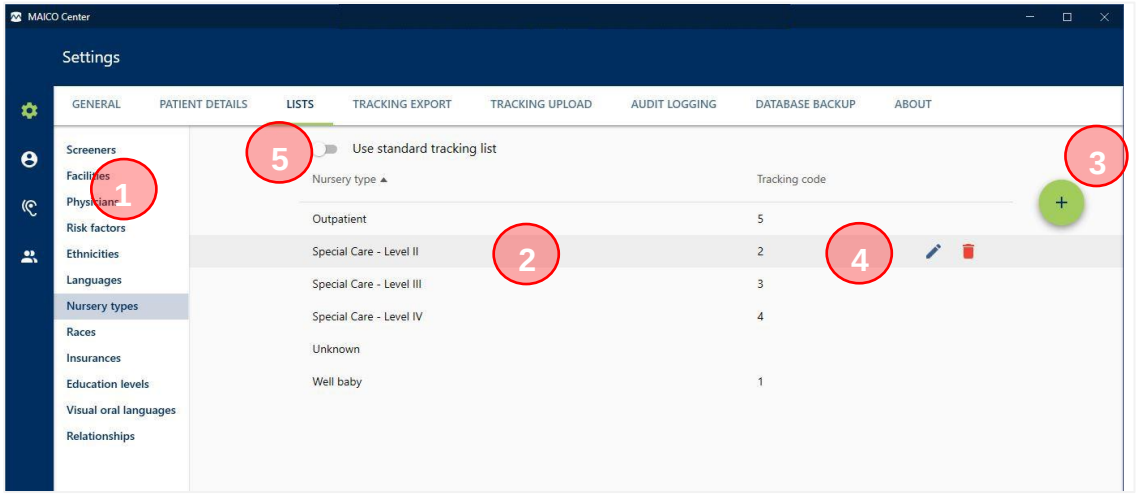


Figure 4

Table 2 Explanation of Settings – LISTS Screens

No.	Explanation
1	Selection of lists
2	Single categories and items
3	Press + to add a new item.
4	Press to edit or to delete an item.
5	**Use standard tracking list**: If activated ( ), the list is reset to default. If deactivated ( ), the list can get customized.

Table 3 gives an overview of the patient data fields.

Table 3 Patient Details Fields – Overview

Basic information	Detailed information	Mother information	Alternate contact information
ID	Birth order	ID	Last name
Alternate ID	Birth weight	Last name	First name
Last name	Gestational age	First name	Address line 1
First name	Time of birth [hh:mm]	Maiden name	Address line 2
Date of birth	Expected birth date	Date of birth	City
Sex	Race	Address line 1	Zip / Postal code
Screening consent	Ethnicity	Address line 2	State / Province /Region
Tracking consent	Birth facility	City	Country / Area
Tracking ID	Nursery type	Zip / Postal code	Phone
	Insurer	State / Province /Region	Mobile
	Insurance number	Country / Area	Fax
	Physician	Phone	Email
	Referred by	Mobile	Language
	Regional unique id	Fax	Relationship to patient
	Tracking variable 1	Email	
	Notes	Language	
	Risk factors	Education level	
	Other risk factor	WIP participation	
		ADA communication required	
		Visual oral language	

2.2.5 Settings – TRACKING EXPORT

Filter export formats

Press CONFIGURE... to select/deselect the export formats that shall be available for manual and automatic export (Figure 5).

Figure 5

Anonymization configuration

Define when and how patient data should be anonymized when exporting tracking data.

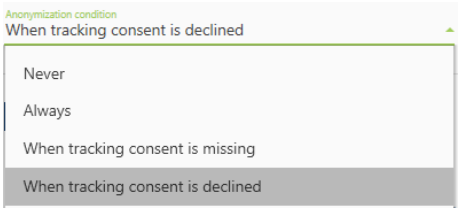


Figure 6

It is possible to either clear all personal data or replace them by randomly generated data sets.

Automatic tracking export

Automatic tracking allows the automatic creation of tracking files. Activate ( ) or deactivate ( ) automatic tracking. If activated, you can make further settings:

Export format: Select one of the export formats you have activated under ***Filter export formats***.

Destination file: Press to save the export file to another destination.

Exclude incomplete results: Activate to exclude all incomplete results from the export.

2.2.6 Settings – TRACKING UPLOAD

2.2.6.1 General

The Tracking Upload allows the automatic transmission of data to a tracking center.

Figure 7 shows the ***Settings – TRACKING UPLOAD*** screen. Table 4 gives explanation.

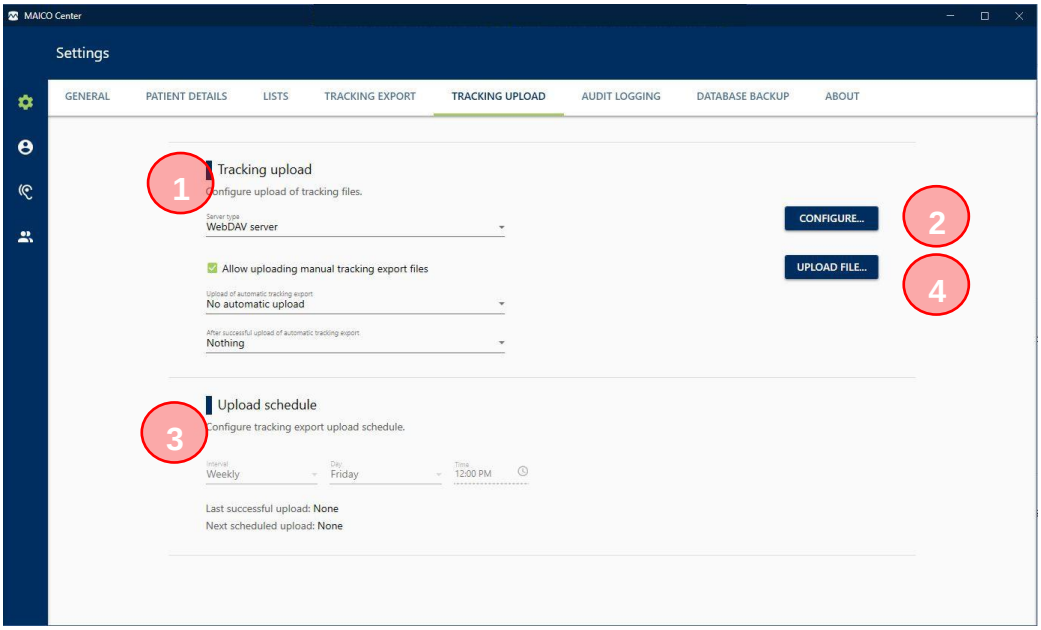


Figure 7

Table 4 Explanation of the Settings – TRACKING UPLOAD Screen

No.	Explanation
1	Tracking upload configurations: • select a server type. • decide if you want to allow manual upload of tracking export files. • select if/when automatic uploaded shall take place (see also **3**). • define what shall be done with the export files after successful upload.
2	Press CONFIGURE... to make the detailed configuration. For more information refer to: Section 2.2.6.2 Configure Upload
3	If scheduled upload is selected (**1**), configure the upload schedule.
4	Press UPLOAD FILE... to manually upload the tracking export file.

2.2.6.2 Configure Upload

Set up the upload configuration under the 3 tabs:

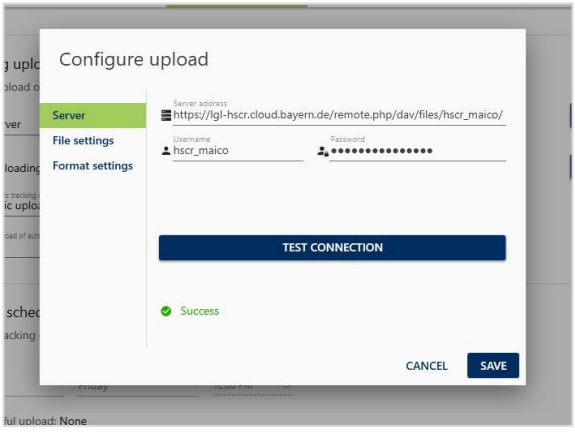


Figure 8

Server (Figure 8):

Server address: Enter a valid Uniform Resource Identifier (URI).

Authentication: Choose between ***Anonymous*** and authentication with username and password.

TEST CONNECTION: Press to test if the connection/URI is valid.

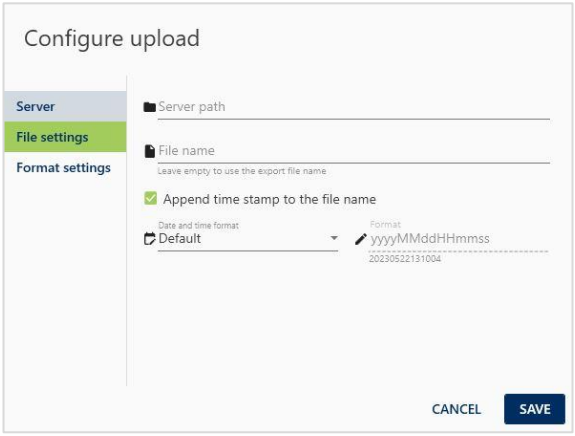


Figure 9

File settings (Figure 9):

Enter:

- a ***Server path*** and
- a ***File name*** if you want to use a file name other than the export file name.

Time stamp: Select if you want to append a time stamp to the file name. Select ***Default*** format or customize the format.

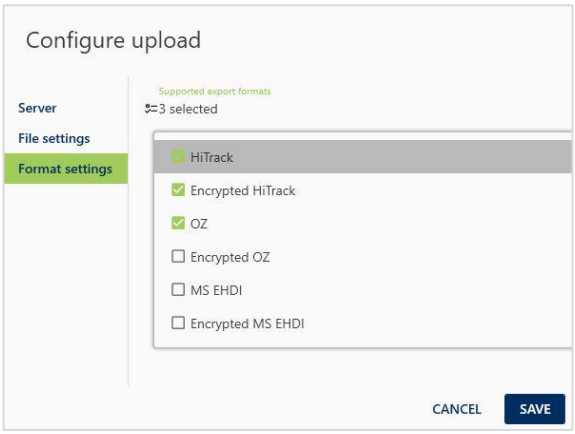


Figure 10

Format settings (Figure 10):

Select one or more of the export formats you have activated under ***Filter export formats.***

Section 2.2.5 Settings – TRACKING EXPORT

2.2.7 Settings – AUDIT LOGGING

Figure 11 shows the ***Settings – AUDIT LOGGING*** screen. Table 5 gives explanation.

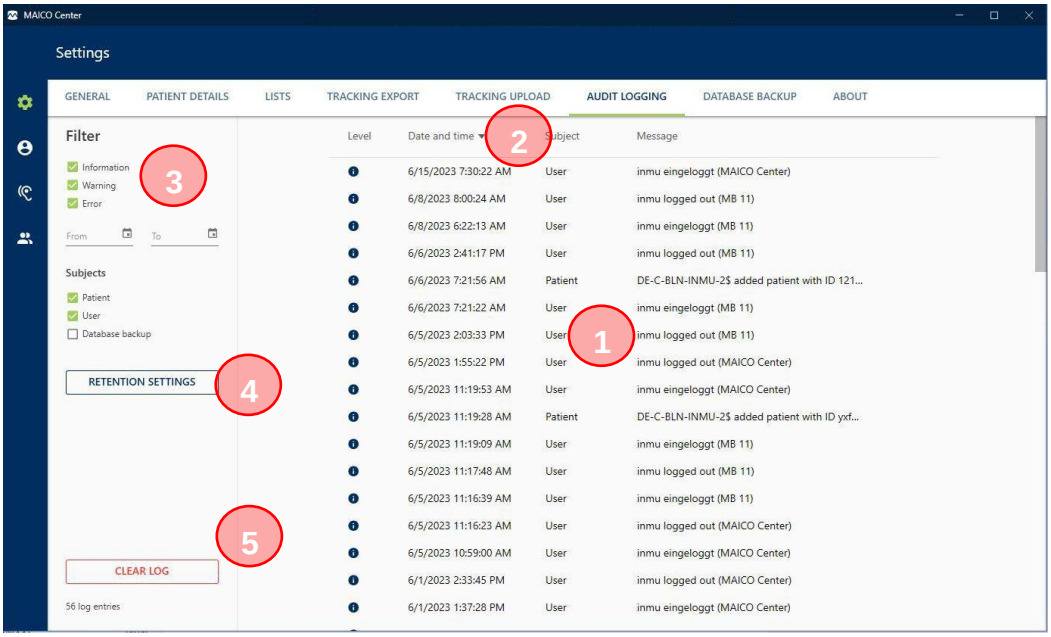
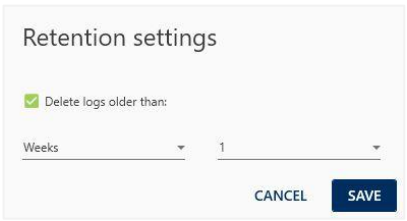


Figure 11

Table 5 Explanation of Settings – AUDIT LOGGING screen

No.	Explanation
1	List of the recorded processes
2	Sort the list by level, date and time or subject.
3	Filter the list by level, date and/or subject.
4	Press RETENTION SETTINGS to open the ***Retention settings*** window. Define a rule at which time intervals the logs shall be automatically deleted (Figure 12).  **Figure 12**
5	Press CLEAR LOG to clear all logs.

2.2.8 Settings – DATABASE BACKUP

Automatic backups can be configured for the database. Figure 13 shows the ***Settings – DATABASE BACKUP*** screen. Table 6 gives explanation.

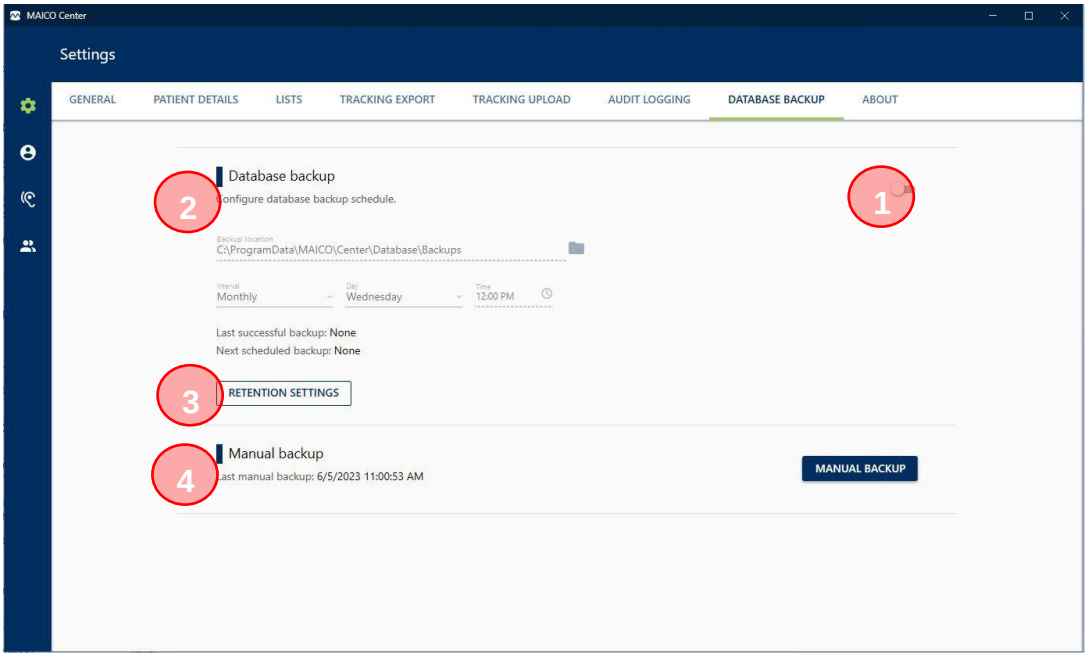


Figure 13

Table 6 Explanation of Settings – DATABASE BACKUP screen

No.	Explanation
1	Activate ( ) Database backup if you want to save automatic backups.
2	Press to change the location in the directory. Define a rule at which time intervals automatic backups should be saved.
3	Press RETENTION SETTINGS to open the ***Retention settings*** window. Define a rule at which time intervals the logs shall be automatically deleted
4	Press MANUAL BACKUP to save a manual backup file to the directory. To restore the database proceed as follows: 1. Open the directory: ***C:\ProgramData\MAICO\Center\Database*** 2. Remove the existing file in the existing database file. It is advisable to store it in another place. 3. Copy/paste the backup file into the directory and rename it with the name of the previous file.

2.2.9 Settings – ABOUT

To navigate to the ***About*** screen (Figure 14), press ⋮ to extend the menu and select ***About***.

Selecting ***About*** in the ***Screen selection*** area opens the ***Product information*** screen. It shows diverse product information (e.g., Manufacturer information).

It is possible to ***Allow usage statistics*** (**1**) or not it is moving the slider to the left or the right (● = allowed, ○ = not allowed). Change of this setting requires a restart of the application.

Third-party software is displayed by pressing the arrow (**2**).

NOTE: The MAICO Center logs data about the PC on which it is installed for support reasons. Further, the MAICO Center may log data about its usage patterns and anonymous usage data from test sessions on the manufacturer's servers administered by the manufacturer. They are used for future development.

All data logged is anonymous and is therefore not covered by EU GDPR consent. No individual can be identified and therefore the manufacturer is not able to or obliged to erase data requested by individuals or groups.

You can set ***Allow usage statistics*** to off.

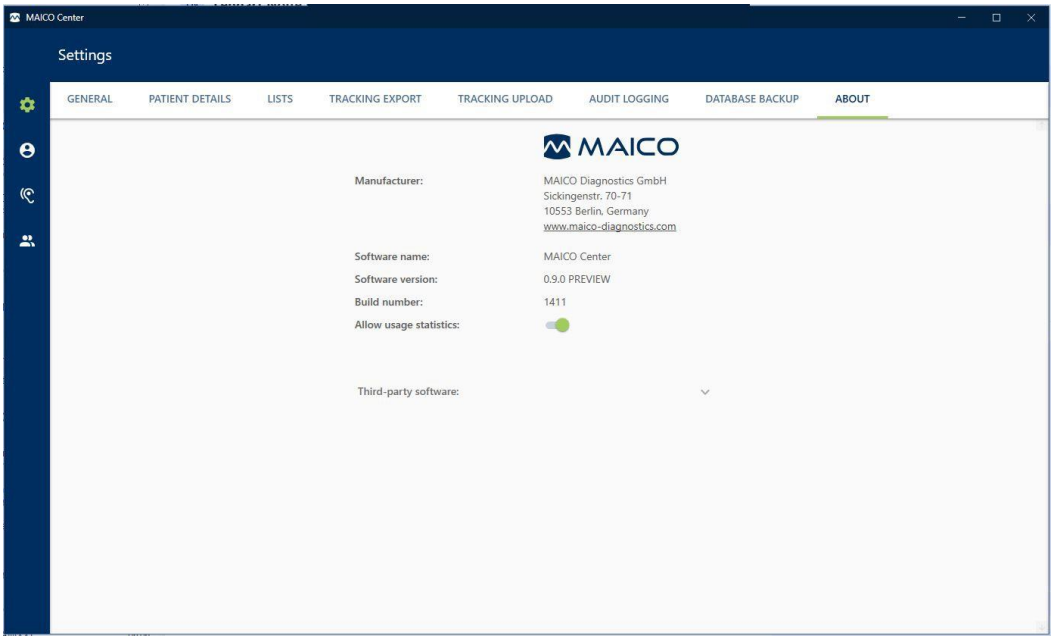


Figure 14

2.3 User Management

2.3.1 General

Press to access the User management screen (e.g., Figure 15). Select a tab:

- **USERS**: to add, edit and remove users.
- **GROUPS**: to configures privileges.

2.3.2 User Management – Users

Figure 15 shows the ***User Management – USERS*** screen. Table 7 gives explanation.

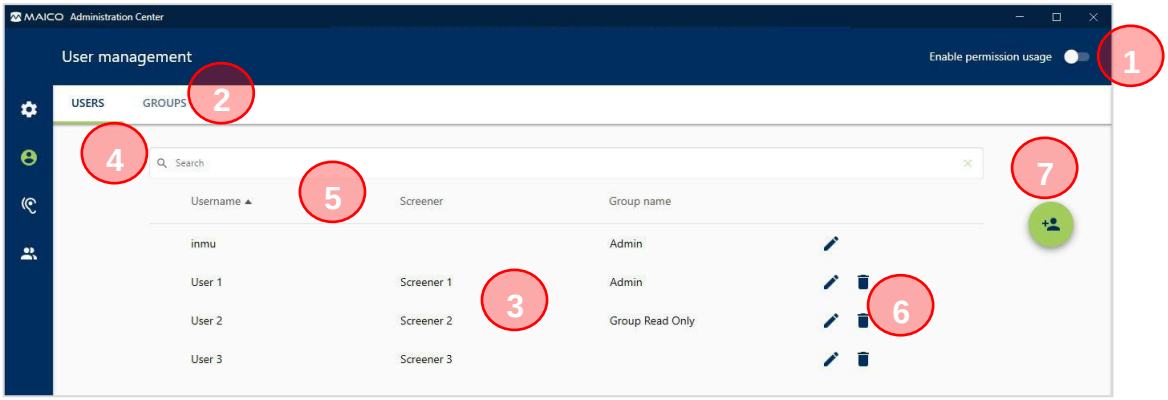


Figure 15

Table 7 Explanation of User Management – USERS Screen

No.	Explanation
1	**Enable permission usage**: Activate ( ) to enable the user management. The currently locked-in user is automatically added as an administrator. **NOTE**: A minimum of 2 Windows® users is necessary to use this function.
2	Tabs ***USERS*** and ***GROUPS***
3	User List: Each user can be assigned a screener name and a group name. By assigning a group, the permissions for the user are set. Section 2.3.3 User Management – GROUPS Section 2.2.4 Settings – Lists
4	Search all fields.
5	Sorting options
6	Press to edit or to delete a user.
7	Press to add a new user. Enter the Windows username as ***Username***. You can assign an already created screener or enter a new screener name. This is automatically added to the screener list. Assign a group to define the user rights.

2.3.3 User Management – GROUPS

Figure 16 shows the ***User Management – GROUPS*** screen. Table 8 gives explanation.

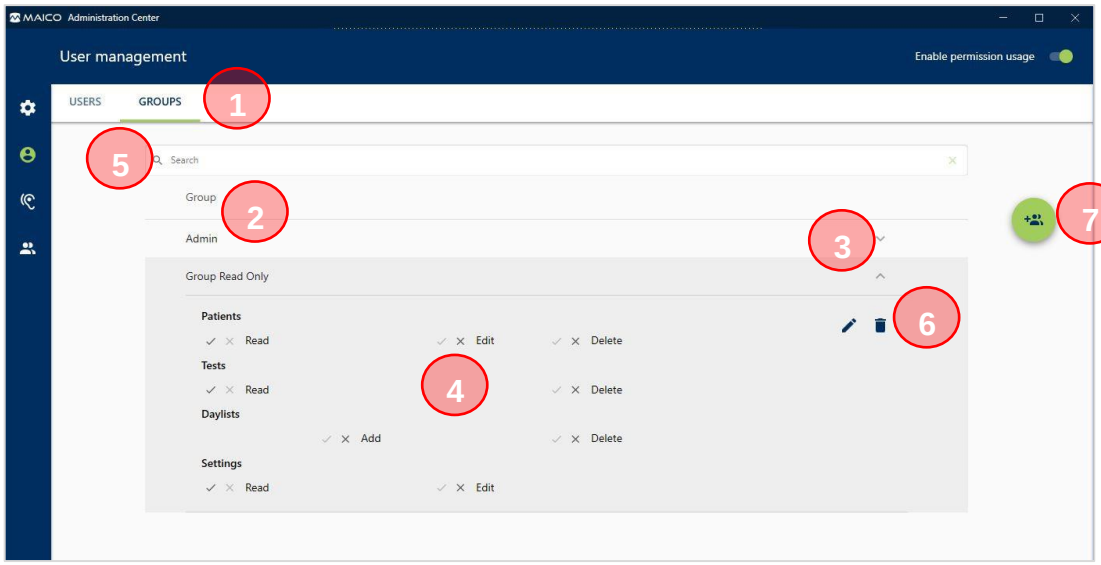


Figure 16

Table 8 Explanation of User Management – GROUPS Screen

No.	Explanation
1	Tabs ***USERS*** and ***GROUPS***
2	Group names
3	Fold or unfold the group to see the permissions and edit or delete the group if necessary.
4	Permissions of the group
5	Search per group name.
6	Press to edit or to delete a group. **NOTE**: Group Admin cannot be altered or deleted.
7	Press to add a new group. Enter a ***Group name***. Assign the rights for the group in each category by pressing the check mark or the cross (e.g., Read).

2.4 Test Export

Press to access the ***Test Export*** screen (Figure 17). See Table 9 for explanation.

NOTE: You can also access the ***Test Export*** screen from the ***Manual Tracking*** screen of the MB 11 Software. Press to access the full MAICO Center.

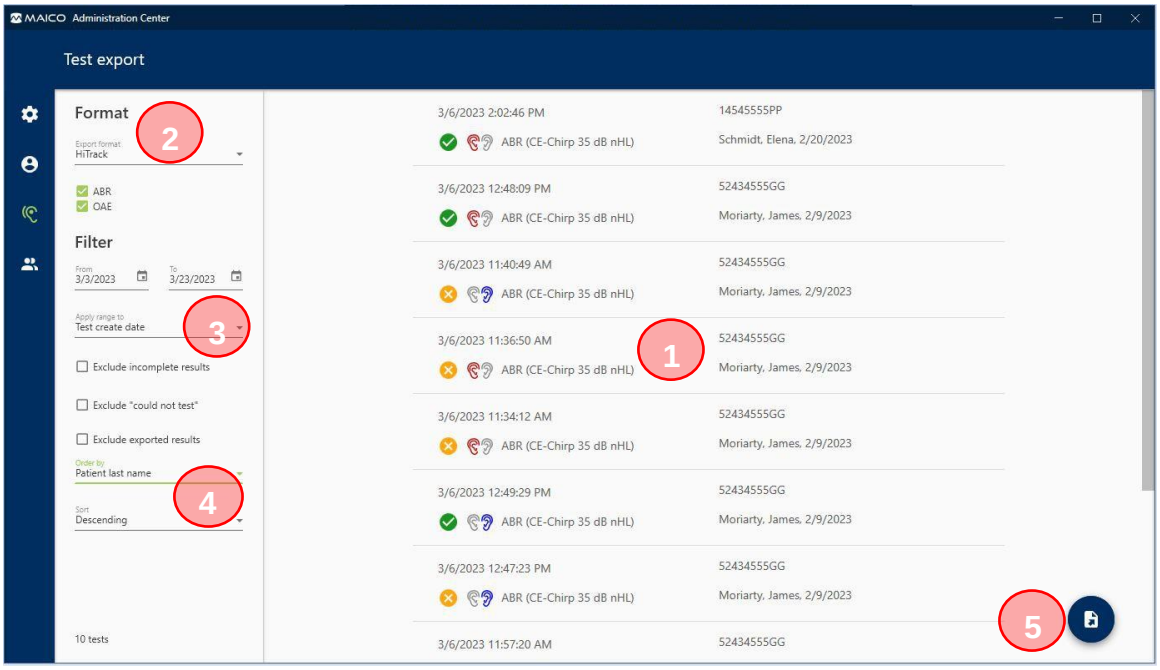


Figure 17

Table 9 Explanation of Test Export Screen

No.	Explanation
1	List of test result
2	Selection of export format
3	Filter options
4	Sorting options
5	Number of selected tests
6	Press to select an export path and safe export file.

Specifications are subject to change

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