

MB 11 BERAphone® Operating Instructions



Operating Instructions MB 11

TABLE OF CONTENTS

PAGE

1 INTRODUCTION 1

2 IMPORTANT SAFETY INSTRUCTIONS 2

3 DESCRIPTION 3

3.1 AUDITORY BRAINSTEM RESPONSE (ABR) AUDIOMETRY	3
3.2 THE BERAPHONE®	3
3.3 AUTOMATIC SCREENING WITH THE "FAST STEADY STATE ALGORITHM"	4

4 INSTALLATION AND SETTINGS 5

4.1 USB SPECIFICATIONS	5
4.2 INSTALLATION OF MB 11 SOFTWARE	5
4.3 MINIMUM COMPUTER SPECIFICATIONS	5
4.4 OPERATING SYSTEM SETTINGS	6
4.4.1 Deactivate "save power" (USB hubs).	7
4.4.2 Change Power Options:	8
4.4.3 Change visual effects:	12
4.4.4 Change Display Properties:	13
4.4.5 BIOS Setup	13

5 GETTING STARTED 15

5.1 UNPACKING YOUR INSTRUMENT	15
5.1.1 Standard accessories - MB 11 with BERAPHONE®:	15
5.2 GETTING FAMILIAR WITH THE MB 11	16
5.3 DEVICE RECOGNITION	16
5.4 STARTING THE SOFTWARE AND MENU	16
5.5 MENUS	18
5.5.1 Menu "File"	18
5.5.2 Menu "Settings" (Figure 8)	19
5.5.3 Menu "About"	21
5.6 OPERATION WITH MOUSE AND KEYBOARD OR TOUCH-SCREEN	22
5.8 LOADING OF STORED PATIENT DATA	24
5.9 WORKING WITH A "TODAY'S LIST"	25

6 AUTOMATIC TESTING IN THE AABR SCREENING MODE26

6.1 PREPARING THE BABY FOR MEASUREMENTS WITH BERAPHONE®	26
6.2 PLACEMENT OF THE BERAPHONE®	27
6.3 PERFORMING THE SCREENING TEST	28
6.3.1 Impedance Test	29
6.3.2 The signal quality control indicators	31
6.3.3 EEG-Display	32
6.3.4 The function buttons	33
6.3.5 Test result "Pass"	34
6.3.6 Test result "Refer"	35
6.3.7 Test result "Abort"	36

7 TRACKING37

7.1 TRACKING SETTINGS	37
7.2 INPUT OF TRACKING DATA	38
7.3 ADVANCED TRACKING DATA	39
7.4 THE EXPORT FUNCTIONS OF THE MB 11 DATABASE (NO TRACKING ENABLED)	39
7.5 THE EXPORT FUNCTIONS OF THE MB 11 DATABASE (TRACKING ENABLED)	40

Operating Instructions MB 11

8 CARE AND MAINTENANCE OF THE BERAPHONE®	41
8.1 ROUTINE CLEANING AND INFECTION CONTROL RECOMMENDATIONS	41
8.2 TIPS REGARDING USE OF THE ELECTRODE GEL	41
9 TROUBLESHOOTING	43
9.1 INSTRUMENT DOES NOT TURN ON	43
9.2 POOR IMPEDANCE AT ONE OR MORE ELECTRODE SITES.	43
9.3. HIGH ARTIFACT (POOR SIGNAL QUALITY) DURING THE SCREENING.....	43
9.4. SCREENING RESULT IS NOT PROGRESSING UPWARD TOWARD THE PASS CRITERIA/HIGH REFER RATE.	43
10 TECHNICAL DATA	44
11 SCIENTIFIC BACKGROUND INFORMATION	45
11.1 CE-CHIRP STIMULUS™	45
12 WARRANTY, MAINTENANCE AND AFTER-SALES SERVICE	48
13 SAFETY REGULATIONS	49
APPENDIX A	50
APPENDIX B	52
APPENDIX C	53

Operating Instructions MB 11

1 Introduction

The MAICO MB 11 is a screening device for hearing loss. It uses fast rate auditory brainstem response (ABR) technology and a sophisticated, automatic response detection algorithm to determine the presence or absence of the ABR response to a 35 dB nHL chirp stimulus. The screening test culminates in a Pass or Refer result, requiring no interpretation by the user.

A PASS result is highly correlated with normal hearing. However, a passing result is not an indication that the full auditory system is normal since ABR technology does not test the full auditory system up to the level of the cortex of the brain. Therefore, a passing result should not be allowed to override other indications or concerns that a hearing problem exists. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist.

A REFER result does not confirm the presence of hearing loss since a variety of conditions can cause a REFER result. However, it is important that the child be referred for a follow-up evaluation to rule out or confirm the presence of a hearing impairment.

Operating Instructions MB 11

2 Important safety instructions

The Maico MB 11 BERAphone® is intended for use on intact, external skin around the ears and on the scalp. It should not be used if the skin is not intact or if the baby has a contagious dermatological condition. The MB 11 BERAphone® is considered a non-critical, patient care item since it comes into contact with intact skin, but not mucous membranes. For such devices, guidelines from the US Center for Disease Control (CDC) recommend cleaning and disinfection after use with a hospital-grade, surface disinfectant.



The MAICO MB 11 BERAphone® is specified according to IEC 601-1 safety against electrical hazard. This is only guaranteed, when the connected notebook computer is powered by batteries or the computer's power supply accords to IEC 60950-1 safety regulations and an isolation transformer meeting requirements of IEC 61558-2-1 or 60601-1 is used. The complete system must meet the leakage current requirements of IEC 60601-1-1. This complete system consisting of the MB11 BERAphone®, computer and isolation transformer, is suitable for use in the patient environment. Equipment not complying with IEC 60601 shall be kept outside the patient environment. Additional equipment not specified as part of the system shall not be connected.

Precautions



READ THE ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS UNIT. Use this device only as described in this manual.

Before measurement make sure, that the device works properly.



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

Do not immerse the unit in any fluids. See the Cleaning section of this manual for proper cleaning procedures.

Use and store the instrument indoors only. Do not expose this instrument or its accessories to temperatures below 59°F (15°C) or above 95°F (35°C), or to relative humidity of more than 75%.

Do not attempt to open or service the instrument. Return the instrument to the manufacturer for all service. Opening the instrument case will void the warranty.

Operating Instructions MB 11

3 Description

MB 11 tests hearing function by measuring the brainstem auditory evoked response of the auditory pathway.

Processing of EEG samples allows the auditory brainstem response generated by the delivery of the acoustic stimulus and present in the EEG to be differentiated from generalized EEG activity.

3.1 Auditory Brainstem Response (ABR) audiometry

Brainstem potentials, BERA (brainstem evoked response audiometry) or ABR (auditory brainstem response), are optimally measured on a quiet, sleeping patient. In fact, sleep is conducive to improving the quality of the recording and reducing test time.

3.2 The BERAPhone®

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), 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 instrument after each baby is tested.

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.

The MB 11 BERAPhone® performs a fixed intensity (35 dB nHL) ABR screening.



Figure 1
Testing with BERAPhone®



Figure 2
BERAPhone® with integrated
electrodes and speaker

Operating Instructions MB 11

3.3 Automatic Screening with the "Fast Steady State Algorithm"

The MB 11 uses a patented Fast Steady State ABR-algorithm. This state-of-the-art technology makes it possible to achieve faster test times than typical ABR screening devices.

The acoustical CE-Chirp stimulus is presented at a high repetition rate (93/second). At this rate a so-called "Steady-State Response" (SSR) occurs. The objective statistical determination of the presence of the SSR is performed after the EEG is processed to determine its frequency content. The SSR is described in the frequency domain by a few spectral lines (harmonics), mathematically related to the stimulus rate of 93 Hz. The statistical test uses the phase and amplitude information of the harmonics below 1200 Hz. Frequencies in the processed EEG that are not related to the stimulus rate contain no response to the auditory stimulus, but only contain generalized EEG activity or "noise". These spectral lines will not be considered in the test result. This signal detection algorithm is associated with short test times as well as high immunity against distortion from electrical interference.

The statistical test is performed using repeated EEG samples of one second. The first test is done after passing the impedance test and then the test is repeated every second, until the overall test result arrives at the critical value (the green marked PASS criteria, (see figure 3). Then the test will be stopped with the test result "PASS". If the PASS criterion is not achieved after 180 seconds of artifact-free EEG sampling, the test is terminated with a "REFER" result.

Please see section 12 for additional scientific background on the stimulus and algorithm used with the MB-11 device.

Neither the algorithm nor critical test values are adjustable by the user.



Figure 3
MB 11 - program test result - "PASS"

Operating Instructions MB 11

4 Installation and Settings

4.1 USB Specifications

The MB11 is a high-powered device that requires a USB port with 500 mA dc current over the V_{USB} - line. Passive USB hubs without an internal or separate power supply do not work with the MB 11 BERAphone®. We recommend using a USB port directly on the PC or notebook 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 MB11 does not work or interferes with the function of simultaneously-used USB devices, try another USB port to change the USB hub output.

4.2 Installation of MB 11 Software

Boot the PC and wait until the operating system finishes the start-up process. Please note that the MB11 is only supported by MS Windows 2000 SP4 and above and MS Windows XP SP1 and above* and Windows 7 Professional. The following installation guide is based on the use of MS Windows XP. MS Vista is not supported.

Install the MB 11 Software with the USB driver files. Please note that you need administration rights for software installation. Install the MB 11 software before connecting the MB 11 to the USB port on the computer. After installation of the MB 11 software, connect the MB 11 to the USB port of your PC and check that the red LED on the BERAphone® 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 4.1 above about using USB ports. After a few seconds, the system will show a message about a newly found USB device "MAICO MB 11". Allow the wizard to install the MB 11 driver if necessary.

4.3 Minimum computer specifications

- Processor: Intel Pentium 800 MHz compatible or better
 - RAM: 256 MB
 - Hard disk: 2 GB
- Interface: USB 1.1 or 2 (MB 11 requires a USB port with 500 mA dc current over the V_{USB} – line)
 - Display: SVGA (800x600)
 - Grounded power supply
- Operating system: Windows XP SP 1 or later, Windows 2000 SP 4 or later and Windows 7 Professional.

4.3.1 Power supply:

NOTE: PC or Laptop must either be grounded, or laptop must be in battery mode.

Use only protective earth conductor plugs and wiring for the power supply. The lack of grounding will lead to enhanced humming noise with a large affect on the measurement quality. The buzzing noise also affects the audio output of computers and produces a masking noise signal. This will falsify the results of the measurements.

PC battery Mode:

To assure the most undisturbed (humming noise free) measurement and masking noise free stimuli, it is necessary to disconnect all external accessory PC devices, such as those with external power supply like USB Units, printers and local area network cables (LAN).

Operating Instructions MB 11

If it is necessary to use accessory devices while you operate in the battery mode, ensure a separate continuous and sufficient grounding of your PC.

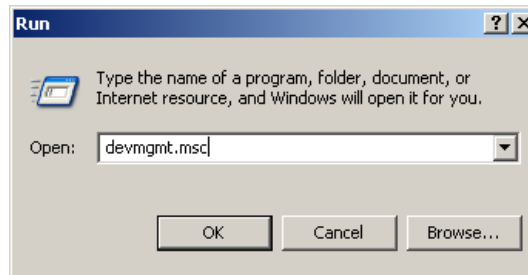
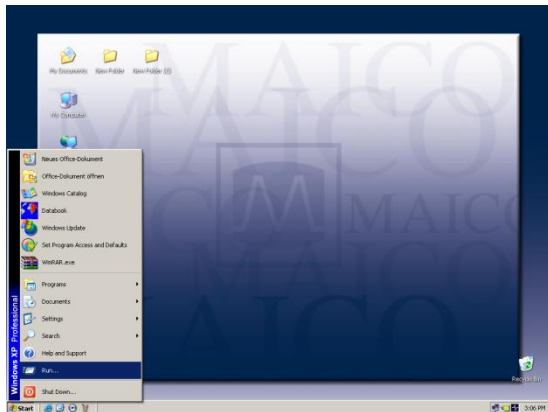
4.4 Operating system settings

To get the best possible performance for the MB 11 BERAphone®, it might be necessary to change the properties of the computer / notebook systems used. A description of these settings is provided below for Windows XP computers.

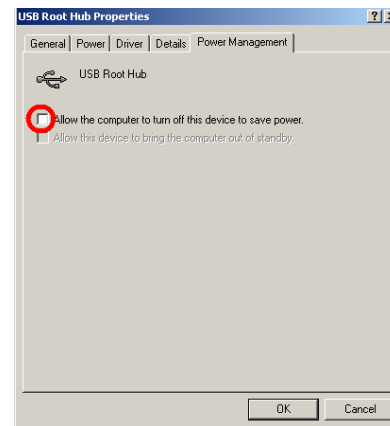
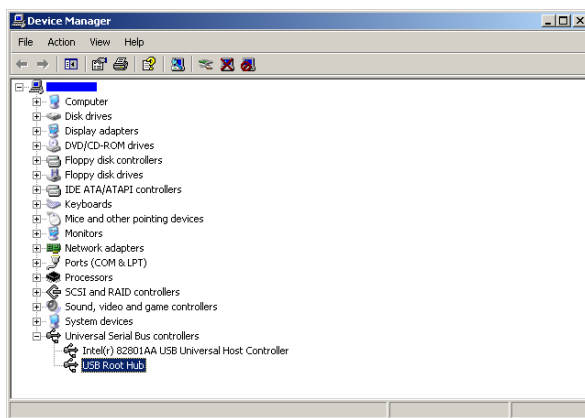
Operating Instructions MB 11

4.4.1 Deactivate "save power" (USB hubs).

Therefore select **Run** within the "START" column, type **devmgmt.msc** and confirm



Select **Universal Serial Bus controllers** and then select a listed **USB Root Hub**. Double-click to open and take out the check mark if preselected. (Don't allow the computer to turn off this device to save power.)

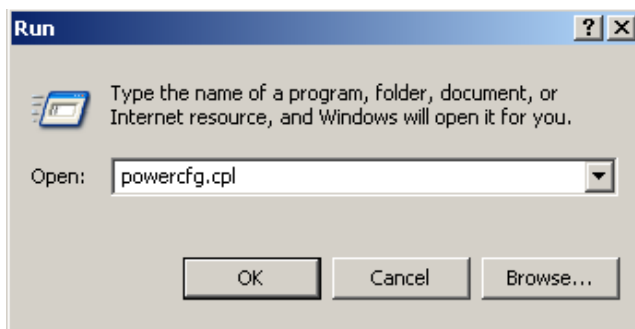
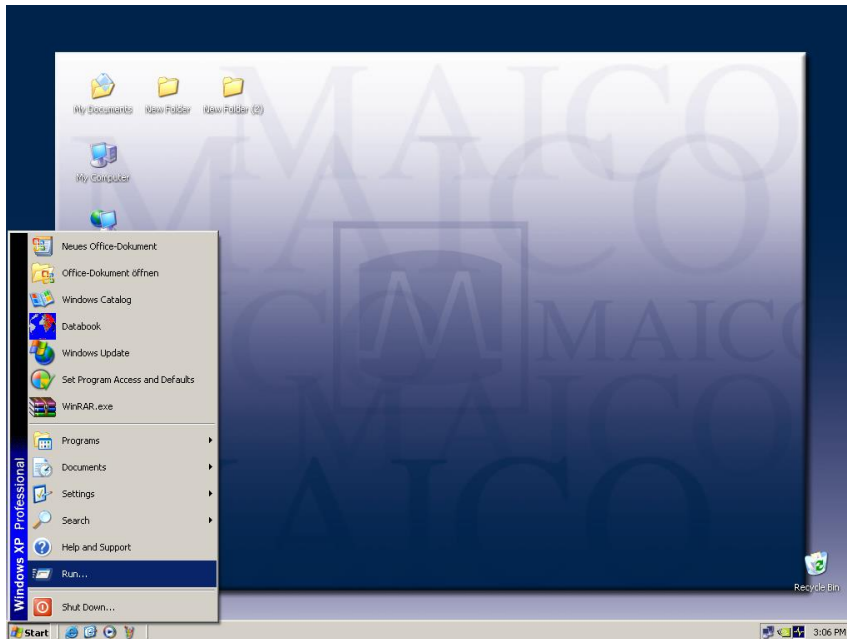


If there are more than one listed USB Root Hubs, please repeat the procedure as described above and take out the check mark if preselected. (Do not allow the computer to turn off this device to save power).

Operating Instructions MB 11

4.4.2 Change Power Options:

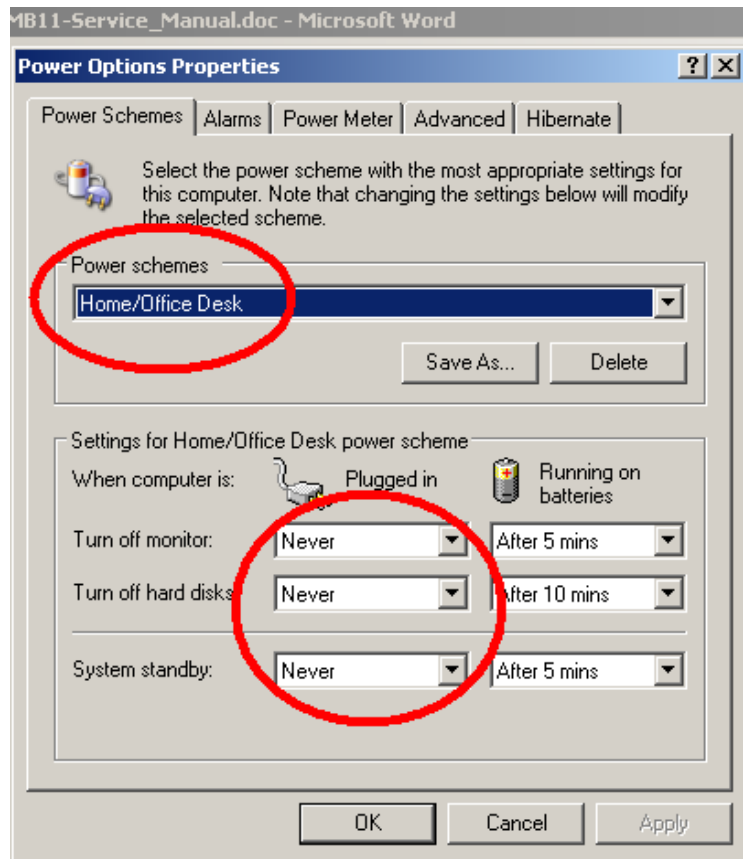
To change power options select **Run** within the “START” column, type **powercfg.cpl** and confirm



Operating Instructions MB 11

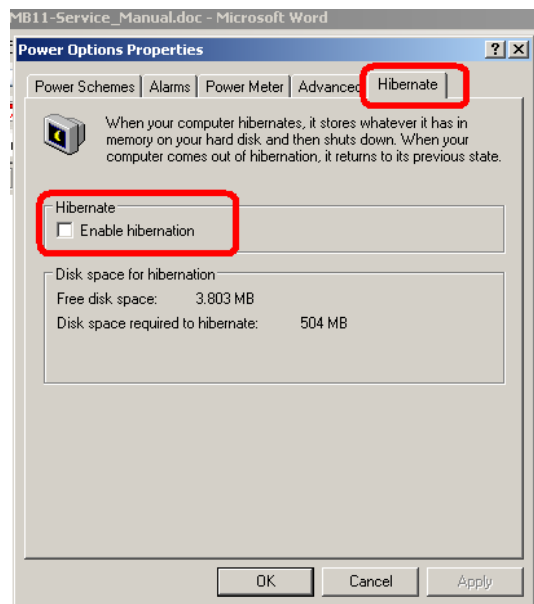
If you use a desktop computer, select **Home/Office Desk** within the Power Schemes and select **never**:

Turn Off monitor: **never**
Turn off hard disk: **never**
System on standby: **never**



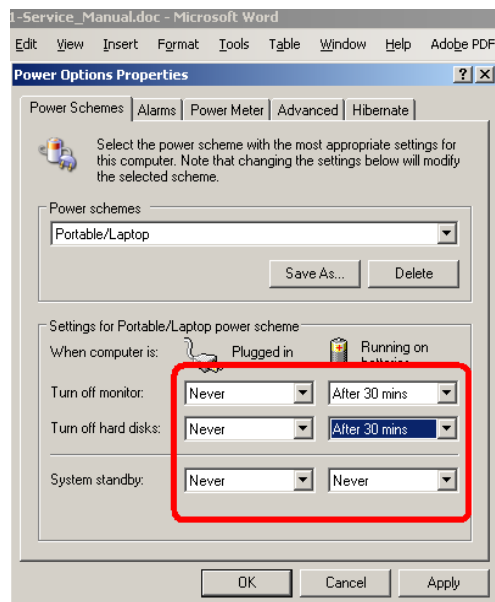
Operating Instructions MB 11

Select **Hibernate** within the menu bar and change Hibernate settings to off as shown in the picture.



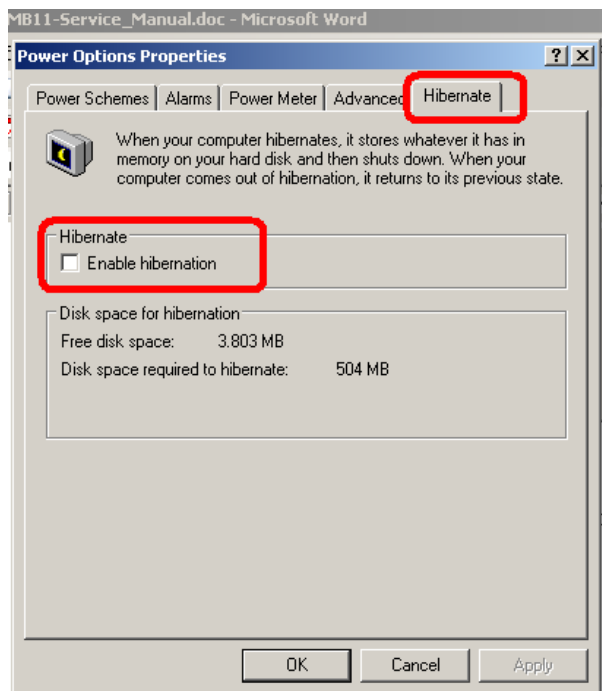
If you use a Notebook computer select **Portable/Laptop** within the Power Schemes and select **as follows**:

Plugged in	Running on batteries
Turn off monitor	never after 30min
Turn off hard disk	never after 30min
System standby	never never
System hibernates	never never

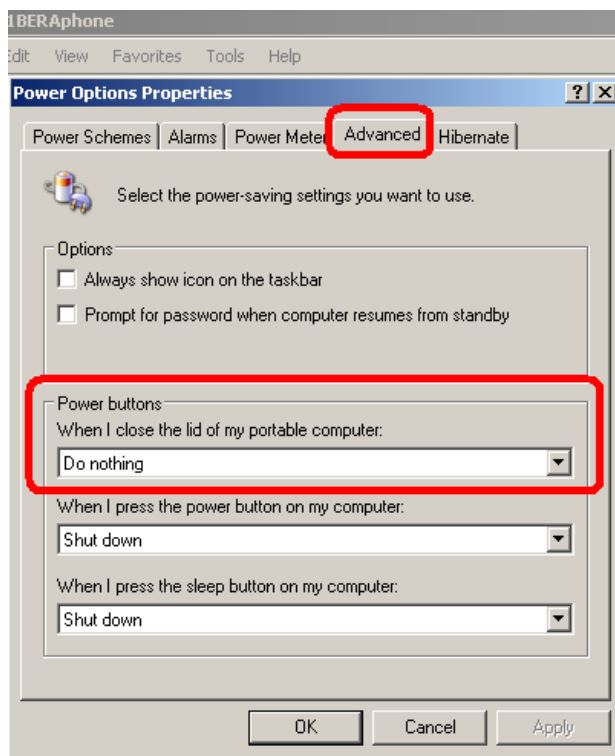


Operating Instructions MB 11

Select **Hibernate** within the menu bar and change Hibernate settings to off as shown in the picture.



Select **Advanced** within the menu bar and change Advanced settings to “When I close the lid of my portable computer” **Do nothing** as shown in the picture.

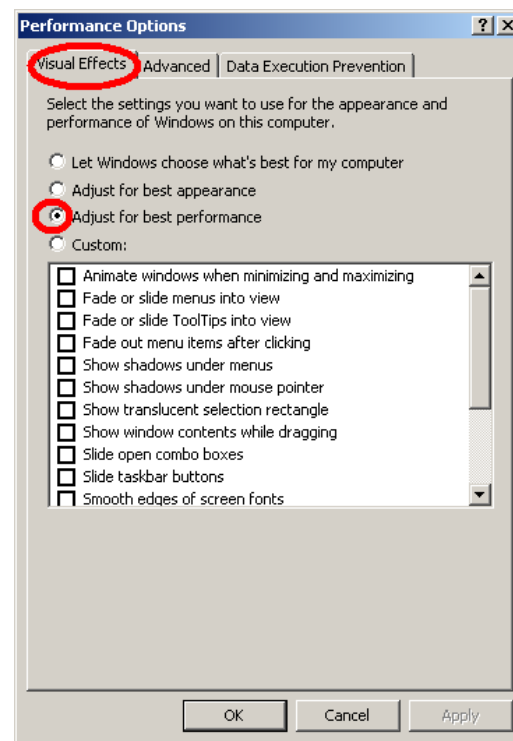
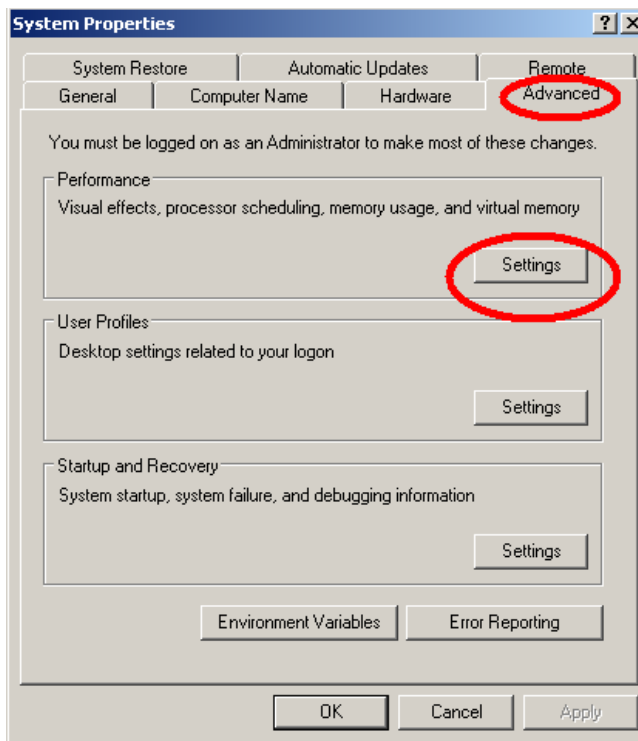
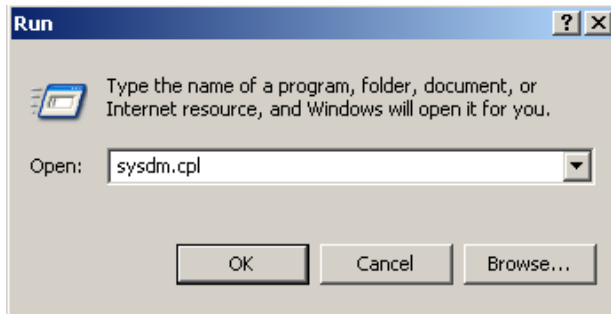


Operating Instructions MB 11

4.4.3 Change visual effects:

(Optional at low-power PC)

To change visual effects select **Run** within the "START" column, type **sysdm.cpl** and confirm



Operating Instructions MB 11

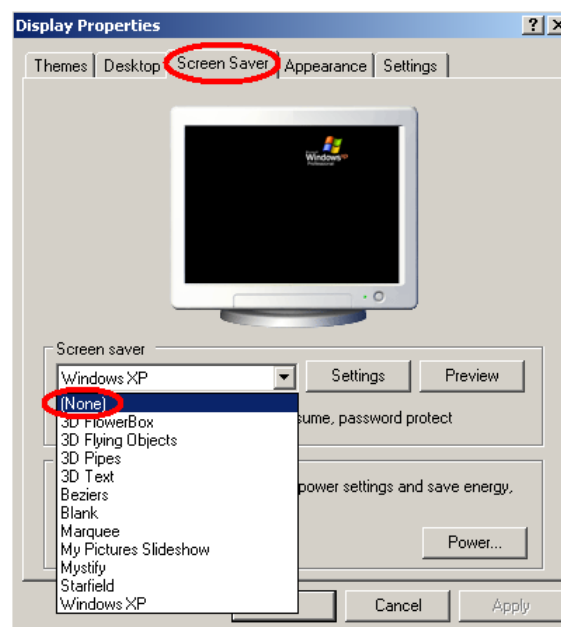
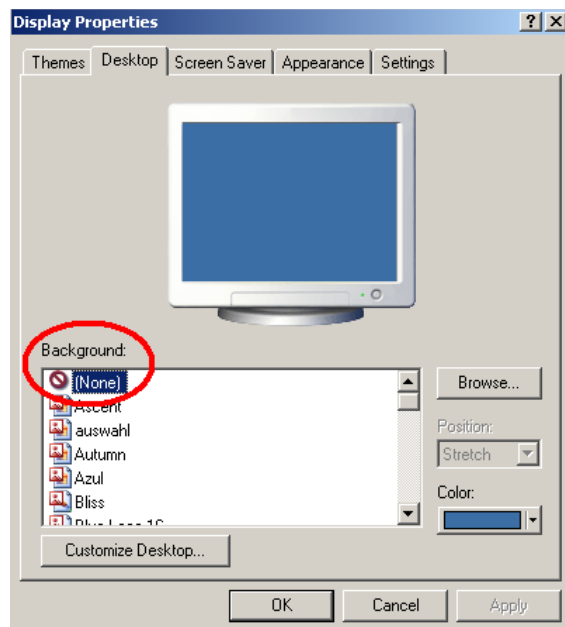
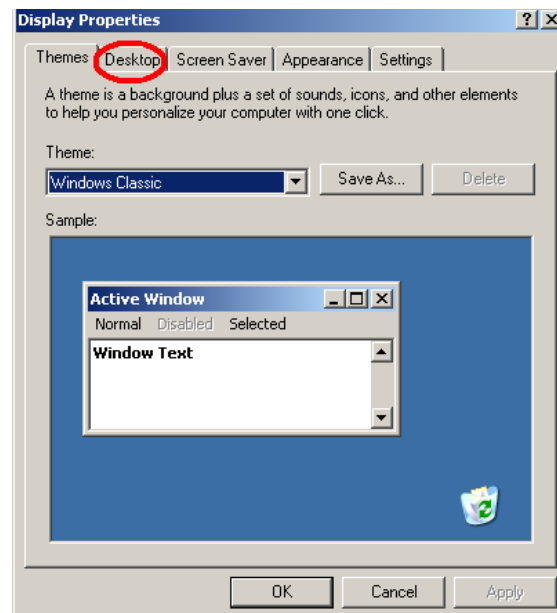
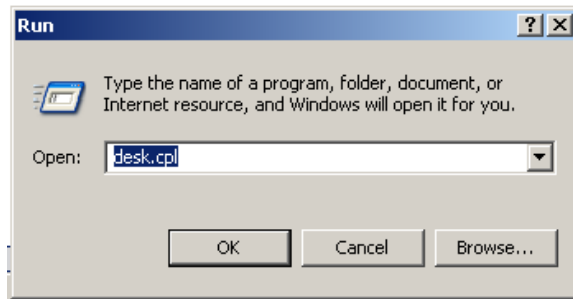
4.4.4 Change Display Properties:

(Optional at low-power PC)

To change display properties select **Run** within the "START" column, type **desk.cpl** and confirm.

Select **Desktop** and change background settings to **none**.

Select **Screen Saver** setting to **none**.



4.4.5 BIOS Setup

Because the MB 11 software uses real-time and processor-intensive algorithms, we recommend disabling energy saving processor settings in the BIOS, like "throttling" on Intel Pentium or "Power Now" on AMD Athlon.

For further details, consult the documentation for your main board or ask your local computer dealer.

Additionally it is recommended to adjust the value of system performance inside the system control to "optimal".

Operating Instructions MB 11

Operating Instructions MB 11

5 Getting started

5.1 Unpacking your instrument

Your MB 11 was carefully inspected and packed for shipping. However, it is good practice to thoroughly inspect the outside of the shipping box for signs of damage. Carefully remove the instrument from the shipping box. Remove the plastic bag from the instrument and inspect the case for any damage.

If any damage is noted, please notify the carrier immediately. This will assure that a proper claim is made. Save all packing material so the claim adjuster can inspect it as well. Notify your dealer or MAICO when the adjuster has completed the inspection.

SAVE ALL THE ORIGINAL PACKING MATERIAL AND THE SHIPPING CONTAINER SO THE INSTRUMENT CAN BE PROPERLY PACKED IF IT NEEDS TO BE RETURNED FOR SERVICE OR CALIBRATION.

All accessories are already packed in the compartment connected with the MB 11. Please check that all accessories listed below are received in good condition. If any accessories are missing or damaged, immediately notify your dealer or MAICO.

5.1.1 Standard accessories - MB 11 with BERAphone®:

BERAphone® unit

Additional set of stainless steel electrodes with gel protectors

USB connection cable

Carrying bag (not provided with cart option)

Electrode gel (2 bottles)

Disinfectant wipes (1 tub)

MB-11 software on USB Flash Drive or CD

Operation Manual

Laminated Quick Guide

Cradle for BERAphone® (may be provided depending on other options purchased with your order)

Operating Instructions MB 11

5.2 Getting familiar with the MB 11

The MB 11 unit is supplied with a Transducer/USB Interface Box that is connected to the BERAphone® through a non-removable cable.

A USB-cable then connects the Interface Box to a USB port of a computer.

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

The MB 11, like any hearing screening device, should be operated in a quiet room, so that the screening results



Figure 4
BERAphone® and MB 11 box

are not negatively influenced by outside acoustic noises.

Electro-medical instruments with strong electromagnetic fields (e.g. microwaves - radiotherapy devices), can influence the function of the MB 11. Therefore the use of these instruments is not allowed in close proximity to the MB 11.

The test room must be at normal temperature, usually 15°C / 59°F to 35°C / 95° F. If the device has been cooled down (e.g. during transport), please wait until it has warmed up to room temperature.

5.3 Device recognition

You can connect multiple MB 11 devices to a single computer. When more than one MB 11 device is attached to the PC, a pop-up window displays the connected instruments when the software is launched. At that time you can choose the device you want to use with a mouse click. The most common scenario in which you would experience this pop-up window is if you have purchased a combination system including both the MB 11 BERAphone® and the MB 11 Classic hardware.

To change between the BERAphone® and the Classic hardware between screenings, after the software has been launched, press CTRL + U and the pop-up window opens allowing you to select your alternate hardware.

To close the program, just click on the "QUIT" <Q> button located on the bottom right of the screen. Additional functions are located in the Menu bar at the top of the screen. It contains the menus "File", "Settings" and "About".

5.4 Starting the software and menu

After starting the computer, launch the MB11 software by clicking the shortcut icon "MB 11 USB Version" on the desktop or direct from the program menu.

The program launches with the start screen (see figure 5).

Operating Instructions MB 11

MB11 - unnamed

File Settings About

MAICO MB 11

Patient

New Search Add to Today's List Display Today's List Show Measurements

Last name First name Born (M/d/yyyy)

Pat.ID Screener

male female

Print Measure Quit

MB 11 Classic with EAR-3A (s/n 0047594) 10/27/2011

Figure 5
Start screen of the MB 11 program

Operating Instructions MB 11

5.5 Menus

5.5.1 Menu “File”

“New” – Entry of a new patient (see also Tracking – Patient data). Clears all fields if they contain information on a previously tested patient.

“Search” - Launches a dialogue that allows selection of a patient from the integrated database. In this window, a patient can be selected by clicking the patient’s name with the mouse. Various means are provided to filter the patient database so that fewer names appear in the list. After clicking on the desired patient, the patient’s information appears in the fields of the start screen.

Data Filter options in the Search dialog include:

“Last Name Filter”: Entry of a last name will filter the database to show only those with a matching last name.

Range of date filter: Use of the drop down allows you to filter the database for baby’s screened within a certain time period (all data, data from today, data from last 3 days, data from last 7 days, data from last 30 days, data from the past year). The computer’s current date and test dates for the patients are used to make this determination.

Test Result filter: Use of the drop down allows you to filter the database for screening test outcomes (Pass, Refer, Abort, Not Measured). This filter will limit the names of the babies displayed in the list to those that have a test in the database that matches the displayed outcome. This filter does not filter for the last or “best” test result. In other words, a baby that ultimately passed a screening but at some point had a Refer result will be displayed in the list when the “Refer” filter is enabled.

Examiner/Screeners Name filter: Use of this drop down allows you to filter the database for babies screened by a specific screener.

Number of cases field: This read-only field displays a count of the number of babies in the database that match the data filtering definitions.

Data export function: The Data Export controls allow you to set a data range using calendar controls and export patients and tests performed in this date range to a file that can be read in a spreadsheet program such as MS Excel. A Windows browser will appear to allow you to define the path and filename to which the data will be saved. This file can be opened for viewing using a text editor or a spreadsheet application. Information contained in the .txt file includes: ID No. (as entered by the user), Name (last), First name, Sex, Birthdate (Born), Date of test (date and time), Screener, Ear (side), Test type (Mode), Result (Note). If additional fields are completed using the Hi*Track tracking feature, these fields are not exported through this function. In a spreadsheet this file should be viewed as a comma delimited file structure.

Tracking export function: The Tracking Export controls allow you to set a data range using calendar controls and export patients and tests performed in this date range to a file that is formatted according to the selection of either OZ or HiTrack set in the Options dialog. A Windows browser will appear to allow you to define the path and filename to which the data will be saved. This file can be merged into HiTrack or OZ. You must have purchased these third party databases from HiTrack or OZ and you must follow their procedures for merging the data in these export files into their databases.

“Print” – The function implemented by selection of the Print item depends on which “Print Mode” setting is enabled in the Options dialog.

“Quit” – Exits the MB 11 program.



Figure 6
File Menu

Operating Instructions MB 11

5.5.2 Menu “Settings” (Figure 8)

“**Save Test settings**” – Saves configurable test settings as user-selected defaults. Menu item is only available for selection from within the Measurement screen.

“**Reset settings to default**” – Resets configurable test settings to the original defaults. Menu item is only available for selection from within the Measurement screen.

“**Options**” (Figure 9) – This dialog allows you to define a number of user-selectable settings. The item is only selectable from within the Main screen.

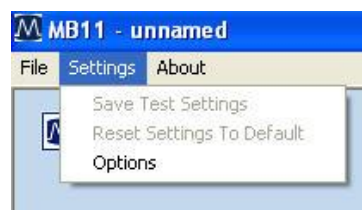


Figure 7
Settings Menu

The fields in the **Options** dialog include:

“**Language**” - The program language can be changed to any of the available languages that are supported by the fonts installed on your PC.

“**Database Path**” – The path for the saving of the MB 11 database can be defined in this field. The MB 11 database file includes all patient and test information as well as screener, physician, screening location and birth hospital entries entered in the List Field Setup area.

“**Print Mode**” – This allows the type of printout to be selected.

Enable “**Label**” to print to a supported label printer. In this mode, the “best” result for both ears will print out by default even if it is not the most current one performed. If there is no Pass result for one or both ears, then the most current Refer and then Aborted test will print. Use the “Selected Data Printout” setting to override this default printing scheme and choose your desired screening tests for printing to the label printer.

Enable “**Selected Data Printout**” to choose from a list of results for the current patient and print these results. These results can be printed to either a standard printer or to a label printer. When using a standard printer the results will print in lines on one print out. When printing to a label printer, each selected test will print out on an individual label.

Enable “**Screenshot Printout**” if you wish to print the graphical display of the final result for a chosen screening test. This is the same view of the measurement screen that you see at the conclusion of a screening. (It does not print an ABR waveform.)

“**Printer Settings**” – This control opens a standard Windows printer dialog from within the MB 11 software. For efficiency it is recommended that you set the typical printer you will use to print your MB11 results as the default printer in the operating system settings.

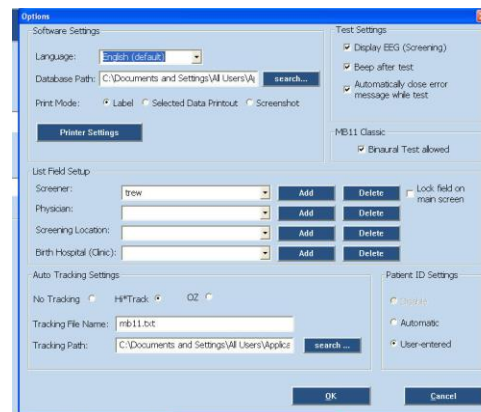


Figure 8
Options

The **List Field Setup** area allows you to add and delete names from the drop down fields. Use the Add control to add new names to the drop down list. Use the Delete control to remove the displayed name from the drop down field.

“**Examiner/Screener**” – a default name is present based on the PC name. Names added to the Examiner/Screener drop down list field will be accessible in the main screen. The check box control locks and unlocks the screener field on the main screen. When locked, then the screener field is ghosted on the Main screen with the default name displayed and cannot be changed. When entering these names to be used with merging data to HiTrack, they must be entered in exactly the same format as they are entered in the HiTrack application or there will be merge errors upon importing the tracking file into HiTrack.

“**Physician**” – this is a HiTrack field. The list of physicians is accessible for selection when HiTrack is enabled and when the user enters the Tracking dialog by selecting the “Tracking” control on the main screen. When entering these names to be used with merging data to HiTrack, they must be entered in exactly the same format as they are entered in the HiTrack application or there will be merge errors upon importing the tracking file into HiTrack.

Operating Instructions MB 11

“Screening location” – this is a HiTrack field. The list of screening locations is accessible for selection when HiTrack is enabled and when the user enters the Tracking dialog by selecting the “Tracking” control on the main screen.

“Birth Hospital” – this is a HiTrack field. The list of hospitals is accessible for selection when HiTrack is enabled and when the user enters the Tracking dialog by selecting the “Tracking” control on the main screen. It is referred to as the Hospital code in the Tracking window.

The **Auto Track Settings** area allows you to set your tracking preference.

“No tracking” – no tracking file will be saved.

“HiTrack” – during collection a file will be continuously saved and appended to with each screening test. This file will be in the format required by the HiTrack third party database which the customer must purchase from the HiTrack provider. This setting also impacts the Tracking export function that is accessed in the Search dialog. So there are two ways to create a HiTrack tracking file. One occurs automatically when the HiTrack tracking function is enabled. One is performed through a manual process by exporting based on a manually entered date range entered in the Search dialog Tracking Export area.

“OZ” – during collection a file will be continuously saved and appended to with each screening test. This file will be in the format required by the OZ third party database which the customer must purchase from OZ. This setting also impacts the Tracking export function that is accessed in the Search dialog. So there are two ways to create an OZ tracking file. One occurs automatically when the OZ tracking function is enabled. One is performed through a manual process by exporting based on a manually entered date range entered in the Search dialog Tracking Export area.

“Tracking File Name” – Allows the user to define the desired name for the tracking file that is saved automatically during data collection.

“Tracking Path” – Allows the user to define the desired data path for saving of the automatically created tracking file.

The **Test Settings** area allows the user to enable (checked) or disable (unchecked) the following features that occur during a measurement:

“Display EEG (Screening)” – sets the EEG view as the default when enabled; otherwise the quality indicator bar is displayed above the measurement graphic during data collection.

“Beep after test” – enables an audible “beep” that occurs when a measurement is complete. The quality and audibility of the beep may be affected by the specific PC that is used and the operating system.

“Automatically close test distortion message” – enabling of this control causes a pop up message regarding test distortion to disappear after 7 seconds. When disabled, the user must manually close this message that occurs immediately after an impedance test when cyclical noise is detected in the EEG signal.

The **MB 11 Classic** area allows the user to set preference related to testing when the hardware being used is the MB 11 Classic rather than the BERAphone. This control will only show up in the dialog if an MB 11 Classic is attached to the PC when the software is launched.

“Binaural test allowed” – Enabling this setting allows access to a “binaural” test option during data collection with the MB 11 Classic. If this control is disabled, then only the right ear or left ear can be selected and only a monaural test can be performed.

The **Patient ID Settings** area allows the user to set preferences regarding the handling of the patient ID.

“Disable” – disables the field for the patient ID. Control is not available when Tracking is enabled. Disabling the Patient ID field allows you to collect and save test data without entering a patient ID. Disabling the patient ID can make it difficult to differentiate patients with the same name.

“Automatic” – disables the Patient ID field for user entry, but automatically assigns a random ID number upon entry of a new patient.

“User-entered” – the default setting; requires user to enter an ID for each patient.

Operating Instructions MB 11

5.5.3 Menu “About”

Click on “About” to see product information about the software version and contact information.

Operating Instructions MB 11

5.6 Operation with mouse and keyboard or touch-screen

The MB 11 program can be operated with the mouse by pointing and clicking on the required input field or button on the screen.

It is also possible to jump with the <TAB> key from field to field. Pressing the Enter key activates the selected field or button.

If you use a touch-screen you can run the program by touching the appropriate field on the screen.

Keyboard short cuts can also be used for fast operation. Press the <ALT> key together with the underlined letter of the required button. i.e. to start the measurement press the keys <ALT> and <M> together.

Keyboard short cuts:

Alt+F	File
Alt+S	Settings
Alt+A	About
Alt+N	New
Alt+C	Search (Load from Database)
Alt+T	Add to Today's list
Alt+R	Right Ear
Alt+L	Left Ear
Alt+E	Change Ear
Alt+D	Display Today's list
Alt+M	Start Measurement
Alt+S	Stop Measurement
Alt+Q	Quit
Alt+W	Show Measurements
Alt+P	Print
Ctrl+U	USB (Pop-up window with the connected MB 11 devices)
Ctrl+B	Beep at the end of the measurement
Ctrl+E	Open/close the screener field
Ctrl+W	Automatic closing of test distortion message

There are also several shortcuts accessible by using the Function keys:

F1	Help
F2	Add to Today's List
F3	Display Today's List
F4	Ear/Other Ear
F5	Measure/Start Measurement
F6	Advanced Display On/Off
F7	Pause (Continue)
F8	Stop Measurement
F9	Print
F10	Quit
F11	Beep (at end of test) On/Off

Operating Instructions MB 11

5.7 Registry of new patient data

The screenshot shows the MB 11 program interface. At the top, a title bar reads "MB 11 - Carpenter, BG Born: 9/13/2011 Age: 44 day(s)". Below this is a menu bar with "File", "Settings", and "About". The main window has a header with the MAICO logo and "MB 11". A "Patient" section contains several buttons: "New", "Search", "Add to Today's List", "Display Today's List", and "Show Measurements". Below these are input fields for "Last name" (Carpenter), "First name" (BG), "Born (M/d/yyyy)" (9/13/2011), "Pat.ID" (3), and "Screener" (Mary Smith). There are also radio buttons for "male" and "female", with "female" selected. A "Tracking" button is also present. At the bottom, there are buttons for "Print", "Measure", and "Quit". Above the "Measure" button are three buttons labeled "R", "Ear", and "L". The "Ear" button is highlighted in red. The status bar at the bottom left reads "MB 11 Classic with EAR-3A (s/n 0047594)" and the bottom right shows the date "10/27/2011".

Figure 9
MB 11 - program start screen with patient data

For a fast screening test without tracking, only a name, birthdate, gender and Patient-ID are required to run and save a test. If you do not enter this information but continue with collection anyway, the patient and tests performed will not be saved in the database.

Tracking may require more detailed data. (Read more in Section 7 Tracking).

Enter the last name and first name of the patient/baby with the keyboard. Move between the different entry fields using the <tab> key or with a mouse click in the required data field. The current date (based on the PC date) is displayed as the default value for the date of birth. A calendar control allows you to select an earlier birthdate. Mark the sex of the patient by clicking the male or female radio button. The key can be used to delete the default setting prior to entering a different value.

When "Tracking System/HiTrack" is activated, it is possible to select the Tracking button and complete many other patient demographic fields.

Additionally you can load stored patient data (see Section 5.8). or create a "today's list" of the patients to be tested today (see Section 5.9).

Select the ear to be tested, < R > for right or < L > left, using the Ear button or the R/L buttons just above the "Measure" button. The color displayed in the background of the Ear button is indicative of which ear is currently selected, red for right ear and blue for left ear.

Operating Instructions MB 11

5.8 Loading of stored patient data

Clicking on the "Search" button will display all stored patients (see Figure 11).

ID	Name	First Name	Sex	Born
1	Abby	Abby	f	9/27/2011
2	Burns	Burns	f	9/1/2011
2	Carey	Carey	m	5/4/2011
4	Dirks	Dirks	m	9/25/2011
4	Early	earlyh	f	9/27/2011
	eeueu	ueueu	m	9/29/2011
6	Fred	Fred	f	9/25/2011
10	Garvin	Garvin	f	10/3/2011
4	Grow	Grow	m	9/5/2011
11	Hanna	Hanna	m	10/2/2011
12345678	Malco	Mike	m	1/1/2008
edf6-4f	edf6-4f	edf6-4f	m	10/6/2011

Figure 10
Load from database

Select a patient by double-clicking on the name with the mouse or highlight the desired name and select the OK button. This will return you to the Main screen with the patient fields displaying the selected patient. The fields will be greyed out since they cannot be edited once the information is saved in the database.

If a test result for this patient already exists, the button "Show Measurements" on the right of the screen (see Figure 12) becomes active. By clicking on this button, you can view a list of all tests performed on this patient and review each test result.

MAICO MB 11

Patient

New Search Add to Today's List Display Today's List Show Measurements

Last name: [text box] First name: [text box] Born (MM/yyyy): [dropdown] [male] [female]

Pat.ID: [text box] Screener: [dropdown]

Tracking

Print Measure Quit

Figure 11
MB 11 - program with loaded patient data and active "Show Measurement" button

Operating Instructions MB 11

5.9 Working with a "Today's list"

If several tests will be conducted in one day, it may be easier to enter the data of all babies before you start to test. In this case, click on the button "New" and enter the name, ID, birthdate and sex, as described in Section 5.7. If you are saving additional information for Hi*Track, click on the Tracking button and enter this additional data as well. After the data is entered click on the button "Add to Today's list".

The screenshot shows the MAICO MB 11 software interface. At the top, a status bar displays "MB11 - Carpenter, BG Born: 9/13/2011 Age: 44 day(s)". Below this is a menu bar with "File", "Settings", and "About". The main window has a title bar "MAICO MB 11". Under the "Patient" heading, there are five buttons: "New", "Search", "Add to Today's List" (circled in red), "Display Today's List", and "Show Measurements". Below these buttons are input fields for "Last name" (Carpenter), "First name" (BG), "Born (M/d/yyyy)" (9/13/2011), "Pat.ID" (3), and "Screener" (Mary Smith). There are also radio buttons for "male" and "female", with "female" selected. A "Tracking" button is located below the "Screener" field. At the bottom, there are buttons for "Print", "Measure" (with "R" and "L" sub-buttons), and "Quit". The status bar at the bottom left shows "MB 11 Classic with EAR-3A (s/n 0047594)" and the date "10/27/2011" is on the right.

Figure 12
MB 11 - Today's list

Now click again on the button "New" data and proceed as described before. Repeat this until you have entered the data of all babies to be tested.

Later on, when you are ready to test one of these babies, click the button "Display Today's list". The list of the babies you entered appears on the screen so that you can select the desired name.

After selecting the baby to be tested, select the ear to be tested, right (R) or left (L), and start the test by clicking on the button "Measure". For the test procedure refer to Section 6.

Names entered into "today's list" will remain until at least one test has been initiated on the patient or after 48 hours with no tests initiated.

Operating Instructions MB 11

6 Automatic testing in the AABR screening mode

It is fast and easy to screen patients with the built-in patented automatic Fast Steady State Algorithm. At the conclusion of the test or when the test is manually terminated, one of the following results will display and be saved with the screening.

Test Result Definitions

PASS: As soon as the indication mark reaches the green area (has met the Pass criteria), the result is "PASS".

REFER: If no response at the test level of 35 dB nHL is present after 180 seconds of data collection, the test is automatically terminated with a "REFER" result. In this case, follow your screening program protocol to determine whether another screening should be performed or whether the baby will be referred for a diagnostic follow-up test.

ABORT: If the test is aborted ("Stop Measurement" is pressed during the test), the test is labeled as "ABORT". If any tracking is enabled, then a pop-up window appears for selection of a reason for stopping the test.

6.1 Preparing the baby for measurements with BERAphone®

Optimal ABR recording requires low skin-electrode resistance (electrode impedance).

To achieve low electrode impedance, electrode gel must be applied to the skin in the areas where the electrodes will make contact as seen in (Figure 14). You can also prepare the skin with an alcohol pad or with a skin preparation product such as NuPrep.

IMPORTANT! 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.



Figure 13
Apply electrode-gel at the shown locations in direction of the arrows

The "ground" electrode is positioned above the ear (Figure 15, Step 1). The vertex electrode is placed on the forehead at the hairline, at a distance from the ground electrode of approximately 3 fingers width. (Step 2). The mastoid electrode is placed below the ear lobe (Step 3). Depending on the size of the baby's head, the position of the BERAphone®'s vertex electrode can be adjusted by rotating the black disc in which the electrode is mounted.

Operating Instructions MB 11



Figure 14
Application of electrode gel

Step 1:
Application of electrode-gel above
the ear

Place a small quantity (approx. 0.1 to 0.2 ml) of gel on the tip of a finger and rub back and forth approximately 10 to 15 times at the areas described above (rub the gel in the direction as indicated in Figure 14). It is advisable to start with the position above the ear, then prepare for the vertex electrode and then finally apply electrode-gel below the earlobe.

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

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

Proper EEG measurements require a low skin-electrode resistance (electrode impedance).

IMPORTANT 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 from the face towards the back of the head (see Fig. 14) 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 each electrode of the BERAphone®.

6.2 Placement of the BERAphone®

Place the BERAphone® on the baby's head (Figure 16).

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 sites.

Select the Start Measurement button.

The impedance test will show you if the electrodes are making good contact with the skin. (see Section 6.3.1). After passing the impedance test,



1162-0906 REV. D

Figure 16
Placement of the BERAphone®

Operating Instructions MB 11

the measurement starts and the impedance display changes into the signal quality display.

If the impedance remains poor (shown by a red background color at one or more of the electrode indicators on the screen), slightly reposition the BERAphone® to insure good contact with the prepared electrode sites. It may take a few seconds to achieve optimal impedance results. If any electrode impedance continues to be “red” you may need to reapply gel to the skin and/or to the electrode and try again.

If impedance remains poor after several attempts it may be necessary to use an electrode skin preparation product, such as NuPrep which is slightly abrasive, to achieve good contact or to wash the area in case lotion was applied to the skin. If washing is needed, then reapply the gel to the site and to the electrode and try again.

IMPORTANT

- 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.
- Never place the electrodes in the ear canal.
- All electrodes must contact the skin well.

ATTENTION

After the screening is completed for a baby, the electrodes and the ear cushion should be cleaned and disinfected with a disinfectant wipe (see Section 8). The stainless steel portion of the electrodes can be autoclaved if desired. The electrodes can be removed by pulling them straight out of the MB 11 BERAphone®. The black plastic gel protector on the electrode must be removed before the stainless steel portion is autoclaved.

To reapply electrodes to the BERAphone®, replace the gel protector onto the stainless steel portion and couple an electrode to the pin visible in each of the three electrode shafts. Press them gently but securely into place.

6.3 Performing the screening test

Enter or load patient data, then select the ear to be tested by clicking on “R” for right ear and on “L” for left ear (see Figure 17).

Figure 17
MB 11 - program start screen

Next click on “Measure”. The measurement screen opens (see Figure 18).

Operating Instructions MB 11

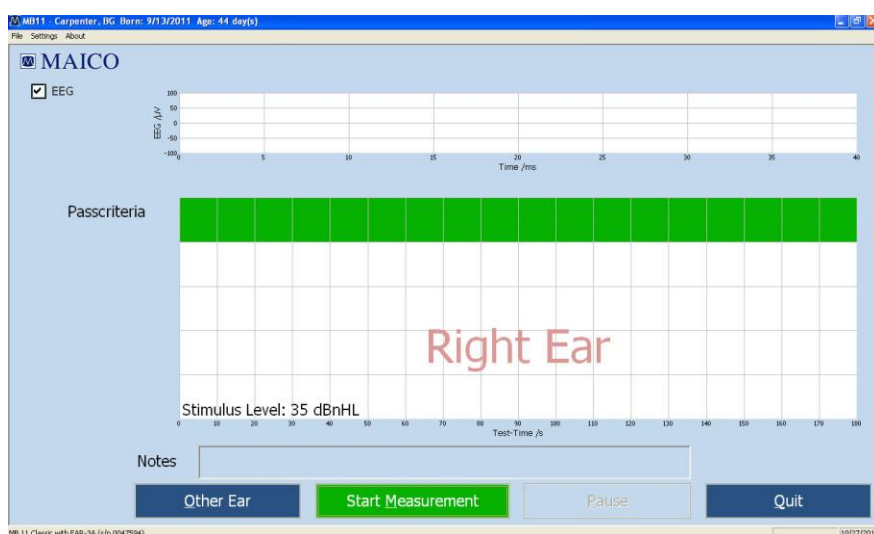


Figure 18
Start measurement

Prepare the baby and BERAphone® as described in Section 6.1 and place the BERAphone®, as described in Section 6.2.

Start the test by clicking on “Start Measurement” button.

Before starting the measurement, an automatic impedance test is performed.

6.3.1 Impedance Test



Figure 19
MB 11 – impedance test

The impedance is the resistance between the measuring electrodes and the ground electrode. Impedance is influenced by the resistance of the electrodes and the resistance of the skin. The impedance is improved by the application of the electrode gel. Low electrode impedance is optimal for the best quality recording.

The top of the test screen shows the impedance indicator lights (Figure 19). Here the tester can see the status of the impedance test for each of the three electrodes in a stoplight (red/yellow/green) type display. The green color symbolizes good impedance. Yellow means not optimal, but sufficient to perform the screening. Red indicates poor impedance and the test will not proceed. The impedance will need to be improved before the test will run.

In some cases, it may take a few seconds for the electrode gel to penetrate the skin and take effect.

The impedance can sometimes be improved by shifting the position of the electrode at that site slightly, making sure to be in contact with area of the skin which was prepared with the electrode. If this is not successful then it may be necessary to massage additional gel to the baby's skin or apply more gel to the electrode itself.

Operating Instructions MB 11

If these measures have been attempted and impedance remains poor, then use of a more abrasive skin preparation product, such as Nuprep or an electrode skin prep pad, may be needed. Poor impedance can occur if lotion has been applied to the baby's skin.

The impedance test is passed when all three electrodes show green or yellow for seven seconds. After passing the impedance test, the ABR measurement starts automatically and the impedance indicator lights change into the signal quality light.

Operating Instructions MB 11

6.3.2 The signal quality control indicators

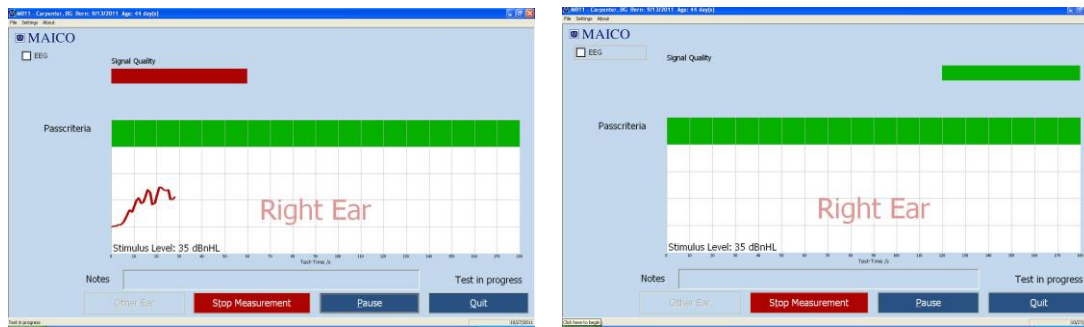


Figure 20
MB 11 - program test screen showing bad and good signal quality

The signal quality is determined by the ratio of artifacts versus accepted samples of EEG data. Artifacts are large potentials that are rejected during the recording. They can be caused by electrical noise in the environment, muscle activity related to movement of the baby, muscle tension or loss of acceptable electrode impedance. Excessive periods of artifact can prolong the test time and may increase the chance of a “Refer” result.

After the impedance test is completed and data collection begins, the signal quality light is displayed at the top of the test screen (Figure 20). Red indicates poor recording quality (artifact), yellow indicates fair quality and green indicates good signal quality. When the signal quality meets conditions to display a yellow or green bar, the test proceeds. When the signal quality is poor (red light) then artifacts are occurring which, in effect, pauses data collection.

The signal quality indicator light on the MB 11 handle also shows a color indicator of signal quality that matches the display on the screen.

If the signal quality remains poor for a prolonged period, try to improve it by moving the MB 11 BERAphone® slightly to improve the impedance. If poor signal quality is caused by movements from the baby and muscle artifact, the test will continue automatically as soon as the baby is calm and the signal quality is good again. If necessary due to excessive agitation of the baby, consider manually pausing the data collection by pressing the “PAUSE” button and allow the baby to calm down before continuing the screening.

Operating Instructions MB 11

6.3.3 EEG-Display

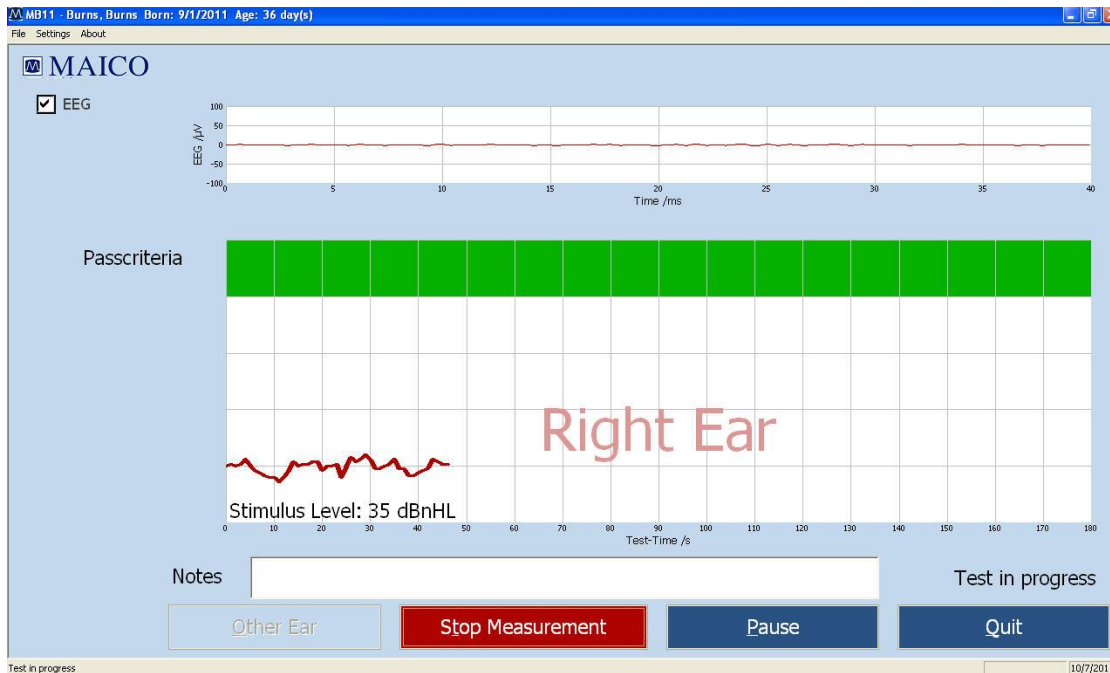


Figure 21
Test screen with EEG view enabled

The EEG display mode can be accessed by clicking on the “EEG” checkbox on the left of the test screen.

The EEG view at the top of the screen allows you to monitor the ongoing real-time EEG activity. The EEG in this view will be relatively flat when the baby and electrical conditions in the environment are quiet. 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. This may be improved by checking the placement of the electrodes on the baby’s head. View of a rolling, cyclical waveform in the EEG can indicate that the electrode gel from two sites on the baby’s head have merged. This can negatively affect the quality of the recording.

Operating Instructions MB 11

6.3.4 The function buttons



Figure 22
MB 11 - program "Test termination with a Pass result"

At the bottom of the test screen are several function buttons:

Other Ear: After the test is completed on one ear, use this button to change to the other ear. Then select "Start Measurement" when ready.

Start Measurement: Click on the "Start Measurement" button to begin a new test. The function button changes to "Stop Measurement".

Stop Measurement: An ongoing test can be aborted by clicking on the button "Stop Measurement". The result (Abort) will be displayed and stored in the database for quality- controlled tracking. If tracking is enabled, then a pop-up window will open allowing you to choose the reason for the test termination.

Pause: Stops the collection and processing of EEG samples although the acoustic stimulus continues to be presented. The function button changes to "Continue" and the status indication at the bottom of the screen shows "Test in progress". Select the "Continue" button to resume data processing.

Quit: Completes the screening phase and returns to the main screen. If pressed before the screening has automatically come to a stop, then this will Abort the test in progress.

EEG: Enabling the EEG checkbox replaces the signal quality indicator light with a display of ongoing EEG activity.

Operating Instructions MB 11

6.3.5 Test result "Pass"



Figure 23
MB 11-program "Test result PASS"

During the test, a small segment of a line is drawn after each 1 second of data collection. The line displays as blue for a left ear test and red for a right ear test. Progress toward reaching the criteria for a "Pass" result is indicated by the movement of the line upward toward the green area of the graph. When the line reaches the green area, a "PASS" result displays inside the green area. (see Figure 23).

Operating Instructions MB 11

6.3.6 Test result "Refer"



Figure 24
MB 11-program Test result "REFER"

If 100% of the pass criteria is not reached after 180 (artifact-free) seconds of data collection time, the test is automatically terminated and a "REFER" will be displayed below and to the right of the graph. (Figure 24)

In this case, follow your screening program protocol to determine whether another screening should be performed or whether the baby will be referred for a diagnostic follow-up test.

Operating Instructions MB 11

6.3.7 Test result "Abort"



Figure 25
Test result "Abort"

If the test is aborted by manual selection of the "Stop Measurement" button by the screener, the test will be documented as an Abort. If tracking is enabled, a pop-up window will display to allow selection of a reason for termination. After confirming a reason, the result "Abort" with reason is shown in the green area (see Figure 25).

Operating Instructions MB 11

7 Tracking

The MB 11 software has an export function which allows export of patient and test data into files that are compatible with a few data management programs designed specifically to track newborn hearing screening information (HI*TRACK, OZ or an ascii file).

7.1 Tracking Settings

Choose "Settings", Sub menu

"Options" (Figure 26). See the area titled "Auto Tracking Settings" in the dialog.

Tracking choices in this dialog are:

"No Tracking" - no tracking file will be saved.

"HI*TRACK" – A Tracking button will be added to the main screen. Selection of this button opens a window providing access to a wide variety of fields that are compatible with the HI*TRACK data management application. The entered information and test findings are saved in a file that can be exported into the HI*TRACK application. (see section 7.2)

"OZ Systems" – As data is collected the patient and test information is saved automatically in a file that can be exported into the OZ web-based data management system.

"Tracking File Name" – Here you can define the desired name for the tracking file.

"Tracking Path" - Here you can define the path for the tracking directory.



Figure 26
Menu setting - Options

Operating Instructions MB 11

7.2 Input of Tracking data

If Settings/HI*TRACK is activated, the function button “Tracking” appears on the start screen:



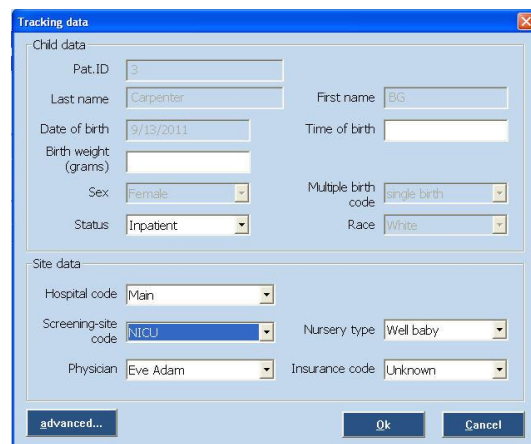
The screenshot shows the MB 11 application window. At the top, there's a menu bar with 'File', 'Settings', and 'About'. Below it, the title bar says 'MB 11'. The main area is titled 'Patient' and contains several buttons: 'New', 'Search', 'Add to Today's List', 'Display Today's List', and 'Show Measurements'. Below these buttons are input fields for 'Last name', 'First name', 'Born (M/d/yyyy)' (with a date picker showing 10/5/2011), 'Pat.ID', and 'Screener' (with a dropdown menu showing 'USER_mis_ksm'). There are also radio buttons for 'male' and 'female'. A 'Tracking' button is located at the bottom right of the patient input section.

Figure 27
Start screen with function button Tracking data

Click on the Tracking button to open the input window (Figure 28).

Patient data will be copied from the main screen.

Fill out the form with the information your program tracks. Click on the “advanced” button to open the next input window which contains additional fields as seen in Figure 29.

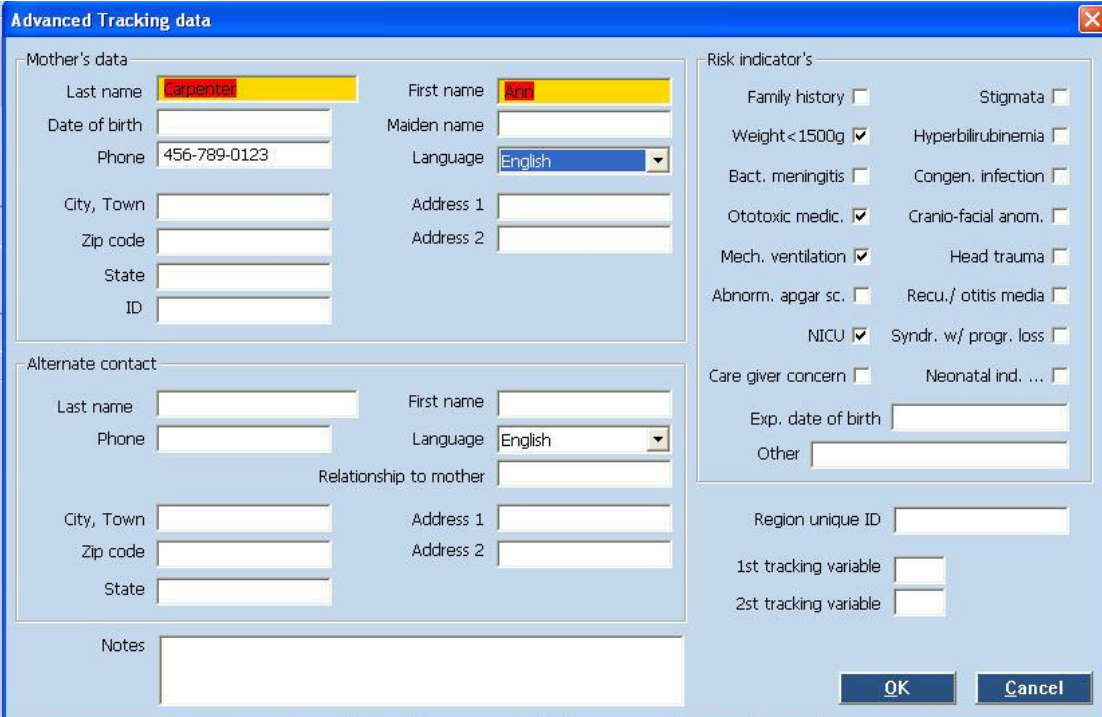


The screenshot shows the 'Tracking data' input window. It has a title bar with 'Tracking data' and a close button. The window is divided into two main sections: 'Child data' and 'Site data'. The 'Child data' section includes fields for 'Pat.ID' (with a value of 3), 'Last name' (Carpenter), 'First name' (BG), 'Date of birth' (9/13/2011), 'Time of birth', 'Birth weight (grams)', 'Sex' (Female), 'Multiple birth code' (single birth), 'Status' (Inpatient), and 'Race' (White). The 'Site data' section includes fields for 'Hospital code' (Main), 'Screening-site code' (NICU), 'Nursery type' (Well baby), 'Physician' (Eve Adam), and 'Insurance code' (Unknown). At the bottom, there are three buttons: 'advanced...', 'Ok', and 'Cancel'.

Figure 28
Tracking data

Operating Instructions MB 11

7.3 Advanced Tracking data



The "Advanced Tracking data" dialog box is divided into several sections for data entry:

- Mother's data:** Includes fields for Last name (Carpenter), First name (Ann), Date of birth, Maiden name, Phone (456-789-0123), Language (English), City, Town, Address 1, Address 2, Zip code, State, and ID.
- Alternate contact:** Includes fields for Last name, First name, Phone, Language (English), Relationship to mother, City, Town, Address 1, Address 2, Zip code, and State.
- Notes:** A large text area for additional information.
- Risk indicator's:** A grid of checkboxes for various medical and social risk factors:
 - Family history ☐
 - Stigmata ☐
 - Weight < 1500g ☒
 - Hyperbilirubinemia ☐
 - Bact. meningitis ☐
 - Congen. infection ☐
 - Ototoxic medic. ☒
 - Cranio-facial anom. ☐
 - Mech. ventilation ☒
 - Head trauma ☐
 - Abnorm. apgar sc. ☐
 - Recu./ otitis media ☐
 - NICU ☒
 - Syndr. w/ progr. loss ☐
 - Care giver concern ☐
 - Neonatal ind. ... ☐
- Exp. date of birth:** A date field.
- Other:** A text field.
- Region unique ID:** A text field.
- 1st tracking variable:** A text field.
- 2st tracking variable:** A text field.

Buttons for "OK" and "Cancel" are located at the bottom right.

Figure 29
Advanced tracking data

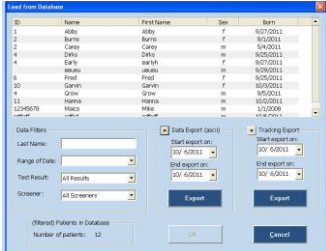
The Advanced tracking dialog allows entry of Mother's data, an Alternate Contact's information as well as documentation of the relevant risk factors for the baby.

7.4 The export functions of the MB 11 database (no tracking enabled)

The MB 11 software allows the export of patient and test data from the database. The export file will be exported as text file (*.txt) in the Excel compatible CSV format. The CSV format allows easy import into Excel or other software.

To export the data, click "Search" on the start screen:

The "Load from Database" dialogue appears (Fig 30). Choose the data for export using the filter fields and set the date range in the Date Export area. Then click on the Export button below. A browser dialog will open allowing you to type in the name of the export file and the location for storage. You can limit the list of exported data using the various search filters described in section 5.5.1.



The "Load from Database" dialog box displays a table of patient data with columns for ID, Name, First Name, Sex, and Birth. Below the table are filter fields for Last Name, Range of Date, Test Results, and Screens. On the right, there are sections for "Data Export (CSV)" and "Tracking Export" with start and end date/time pickers. At the bottom, there are "Export" buttons and a status bar showing "Number of patients: 12".

Figure 30
Load from Database

Operating Instructions MB 11

7.5 The export functions of the MB 11 database (Tracking enabled)

The MB 11 software allows the export of patient and test data from the database into an OZ or HiTrack compatible format. To do this, the OZ or HiTrack Tracking option must be enabled in the Settings/Tracking settings menu..

To export the data, click "Search" on the start screen:

The "Load from Database" dialogue appears (Fig 30a). Choose the data for export using the filter fields, set the date range in the "Tracking Export" area and click the "Export" button in the Tracking Export area. A browser dialog will open allowing you to type in the name of the export file and the location for storage. Be sure that the filename and extension you enter here is the one that OZ or HiTrack will be looking for to merge the data. You can limit the list of exported data using the various search filters described in section 5.5.1.

ID	Name	First Name	Sex	Born
1	Abby	Abby	f	9/27/2011
2	Burns	Burns	f	9/1/2011
3	Carley	Carley	m	5/4/2011
4	Doris	Doris	m	9/25/2011
4	Early	earlyn	f	9/27/2011
	esau	esau	m	9/28/2011
6	Fred	Fred	f	9/25/2011
10	Garvin	Garvin	f	10/9/2011
4	Grow	Grow	m	9/5/2011
11	Hanna	Hanna	m	10/2/2011
12345678	Maico	Mike	m	1/1/2008

Data Filters: Last Name: Range of Date: Test Result: All Results Screener: All Screeners

Data Export (sec1) Tracking Export: Start export on: End export on: Export

(Filtered) Patients in Database: Number of patients: 11 OK Cancel

Figure 30a
Load from Database

Operating Instructions MB 11

8 Care and maintenance of the BERAphone®

8.1 Routine cleaning and infection control recommendations

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

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

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 earphone material will harden, crack and breakdown over time. The higher the alcohol content of the disinfectant, the faster the earphone 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.

8.2 Tips regarding use of the electrode gel

It is important to avoid getting electrode gel into the inner parts of the MB 11 BERAphone®. For this reason, gel protectors are put on to the electrodes. Only a small amount of gel placed on the electrode is typically required to perform a screening. Avoid use of excessive amounts of gel that can seep down below the gel protector and into the critical components inside the electrode housing.

Never apply the electrode gel to the electrodes directly from the gel bottle or tube. It is not always possible to control the flow of gel from the bottle and you want to avoid accidentally squeezing a large quantity of gel on the electrodes or on the sensitive earphone.

At frequent intervals the MB 11 BERAphone® electrodes should be removed and cleaned thoroughly with a hospital grade disinfectant.

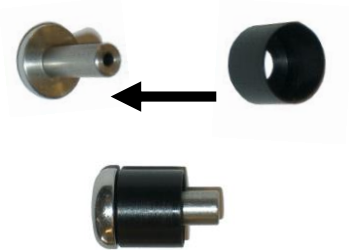
Operating Instructions MB 11

You can easily remove/exchange the stainless steel electrodes.

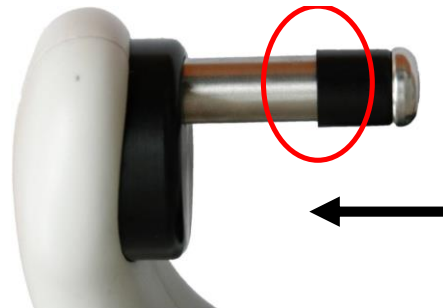


Remove electrodes carefully
Electrodes and gel protection can be cleaned and sterilized. It is possible to sterilize the stainless steel electrodes (not the gel protectors) in an autoclave. Alternatively you can perform a plasma sterilization of electrodes and gel protectors after cleaning.

When replacing the electrodes onto the BERAphone®, verify that the electrode with gel protection is plugged correctly and completely into the MB 11 BERAphone®.



Push the gel protector back on the electrode



Plug the electrode with gel protection into the BERAphone®.

Figure 32

Operating Instructions MB 11

9 Troubleshooting

If you should find that your instrument is no longer working properly during a test run, please check the following points:

9.1 Instrument does not turn on

Verify that the USB cable is connected securely into both the USB box of the BERAphone® as well as the computer USB port.

Verify that the USB port on the PC meets the specifications described in Section 4.

Verify that the PC is powered on.

9.2 Poor impedance at one or more electrode sites.

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.

Remove the BERAphone® and massage a little more gel at the site.

Apply a little more gel onto the electrode itself.

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.

9.3. High artifact (poor signal quality) during the screening.

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.

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 neck can help to release any tension in this area.

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.

9.4. Screening result is not progressing upward toward the Pass criteria/High refer rate.

Pause the screening and hold the BERAphone® to your ear to verify that you can hear the acoustic stimulus.

Enable the "advanced" checkbox on the measurement screen and view the EEG signal. Do you see evidence of a rolling wave travelling along the EEG? This can be evidence that gel from one electrode site had merged with gel at another site which can cause poor recordings and refer results. Check sites and remove gel from areas between the electrode sites.

Operating Instructions MB 11

10 Technical Data

Standards:	IEC 601-1, IEC 645-3
Stimulus type:	CE-Chirp Stimulus
Stimulus rate:	93/s
Stimulus intensity:	35 dB nHL
Sample rate:	16 kHz
EEG filter:	125 Hz – 1.25 kHz
Quality control:	Integrated LED on BERAphone® and display in software with signal quality or with EEG display
Operating conditions:	+15 to +35°C (+ 59 to +95°F); Maximum humidity 75%
Storage conditions:	+5 to +50°C (+41 to +122°F); Maximum humidity 90%
Speaker:	BERAphone®: integrated, dynamic wideband speaker (8Ω)
Electrodes:	BERAphone®: reusable, stainless steel electrodes with gel protectors.
Preamplifier:	Integrated, 87 dB amplification (23,000 x)
BERAphone® weight:	300 g (10.59 oz)
USB box weight:	165 g (5.83 oz)
USB box dimensions:	12 x 9 x 3 cm (4.73 x 3.55 x 1.19 in)
Power supply:	via USB port of computer
Power consumption:	max 400 mA

Operating Instructions MB 11

11 Scientific Background Information

11.1 CE-Chirp Stimulus™

The stimulus for an AABR-newborn hearing screening should generate auditory evoked brainstem responses with an amplitude as great as possible at the level of 35 dB HL. High response amplitudes allow a fast objective detection with high specificity and short measuring time.

Previously in the field of hearing screening the standard click was used as stimulus. The standard click is generated by delivering a short rectangular electrical impulse to a transducer. This click generates a traveling wave along the basilar membrane. The traveling wave runs from the basal part of the cochlea along the basilar membrane to the tip of the cochlea (apex). Hereby it excites each of the frequency areas of the cochlea starting with high frequency part and ending with the low frequency part. The velocity of the traveling wave is the greatest at the basal part of the cochlea and slows exponentially towards the apex.

Figure 33 shows the delay of the travelling wave for reaching the various frequency bands in the cochlea calculated from the cochlea model of de Boer. The Figure shows a delay shorter than 2 ms for the region from 10 kHz to 1 kHz but a delay of 8 ms from the area of 1 kHz to 100 Hz. Due to the resulting greater synchronization of excitation in the basal part of the cochlea, only the higher frequency range contributes effectively to the click-evoked activity. The travelling wave delay in the more apical part of the cochlea is responsible for considerably dispersed responses from this area. For this reason, the spatio-temporally summated response does not achieve

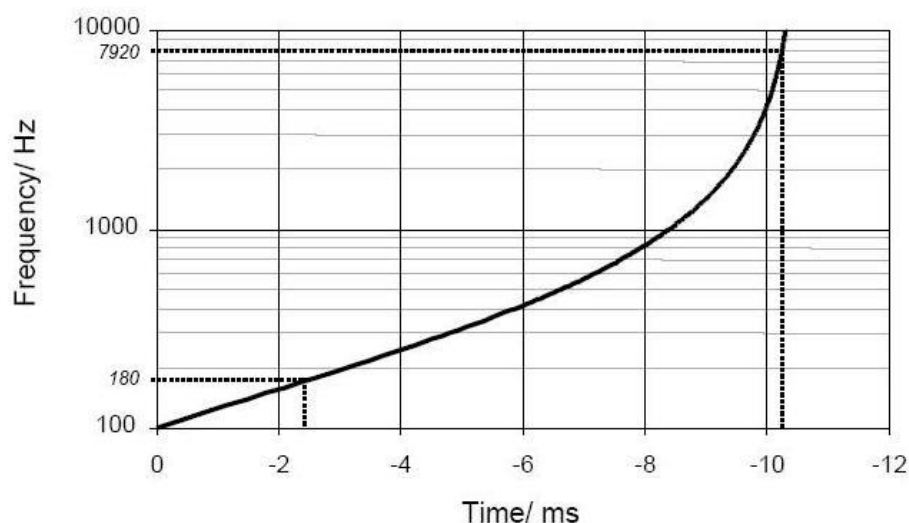


Figure 33

the amplitude that would result from a more synchronous excitation.

The new CE-Chirp Stimulus implemented in the MB 11 BERAphone® allows a well synchronized activation of the whole cochlea.

In contrast to the conventional generation of a click in the time domain, in the frequency domain a click-like stimulus can be created through the addition of a large number of cosines with a fixed frequency difference. The frequency difference is selected in accordance with the desired stimulus repetition rate.

Figure 34 a) shows in the right panel the frequency spectrum of such a click. Every component of the spectrum represents a cosine. The difference between the single cosines is 90 Hz and is equal to the stimulation rate of 90 /s. A ripple between the individual pulses of the stimulus in the time domain shown in the left panel of Figure 34 a) can be effectively reduced by halving the amplitudes of the cosines with the lowest and the highest frequency. In contrast to the standard click generated in the time domain the new stimulus is a steady-state signal.

The patented stimulus constructed from individual cosines offers the possibility of introducing a frequency-dependent phase correction in order to compensate for the propagation time in the cochlea. From this phase correction a synchronized activation of the whole basilar membrane can be expected.

Operating Instructions MB 11

Figure 34 b) shows to the left the time course of a phase corrected click. The corresponding amplitude spectrum is shown at the right side. The red arrows mark the position of the first six spectral harmonics of the brainstem response evoked by the phase corrected stimulus. These harmonics were analyzed by the objective statistical test implemented in the automatic test algorithm of the MB 11 BERAphone® software. It is easy to see that five of the six harmonics of the brainstem responses are overlapping with the stimulus frequencies. This overlapping could lead to false results of the statistical test when electrical stimulus artefacts occur. For elimination of this source of error a frequency offset is introduced into the cosines. This frequency offset causes a displacement of the stimulus frequency spectrum. In the time domain, the frequency offset leads to an alternating stimulus. With this stimulus a better detection time and shorter test time could be realized.

For further optimization the question of the adequate cochlea model for calculating the phase correction was addressed. The cochlea model from de Boer is based on measurements on ears of cadavers with non physiological high stimulus levels. Due to this fact the cochlea delay derived from the de Boer model has to be considered as not optimal. For this reason a new model function of the frequency-dependent propagation time in

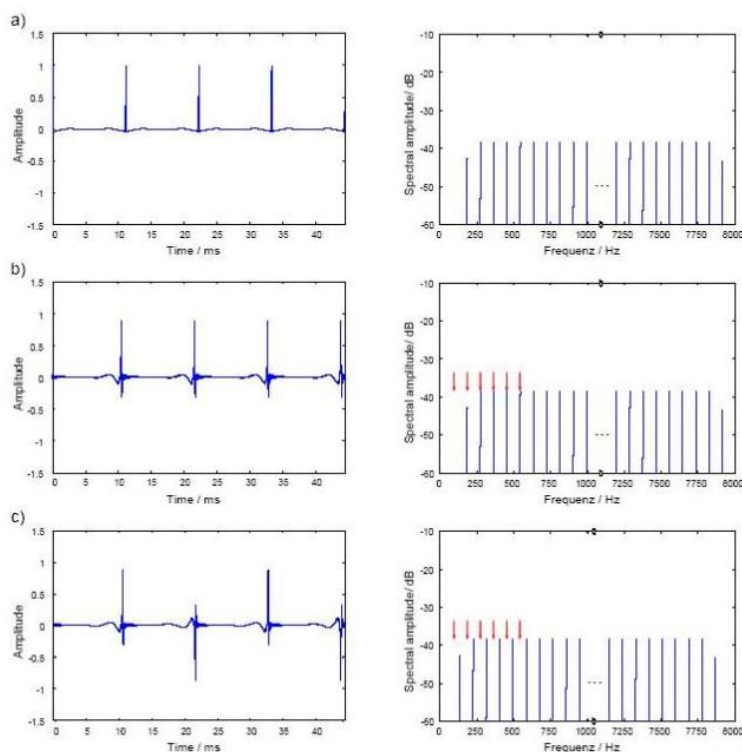


Figure 34

the cochlea was calculated based on the latency data of frequency specific ABR recorded at low stimulus levels.

In this context the question arises as to whether the delay of the different models has to be considered to reflect the group delay or the phase delay of the cochlea. The phase delay describes how much a steady-state cosine of a specific frequency is delayed from the input to the output of a system (of the cochlea). The group delay describes how much the envelope of a signal formed by a narrow group of frequencies is delayed through the system.

The results of a study confirmed the assumption that the latencies of the frequency-specific ABR reflect the group delay. Since the stimulus shall compensate for the cochlear delay of single frequencies, the phase delay calculated from the group delay was used for the phase correction of the individual cosines of the stimulus.

Figure 35 shows the time course of the resulting CE-Chirp™ Stimulus. For preventing an overlapping of response harmonics by electrical artefacts, the above-described frequency offset has to be added, too.

Operating Instructions MB 11

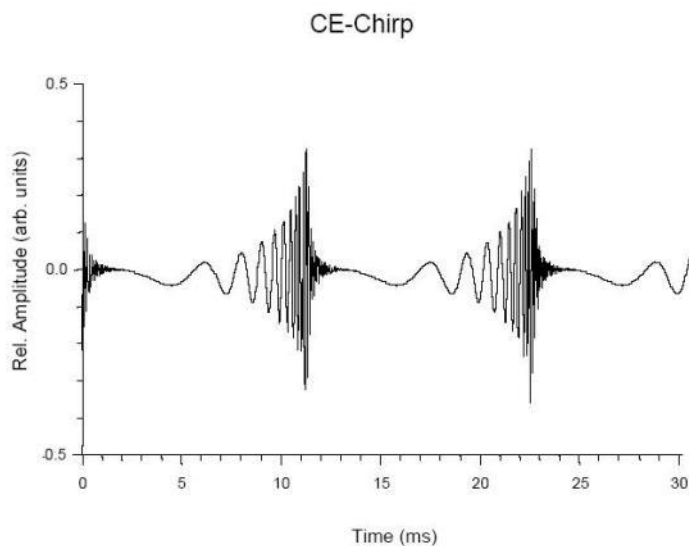


Figure 35

Extensive investigations on newborns have shown that the CE-Chirp™ Stimulus generates significant better results than other acoustical stimuli used for newborn hearing screening. At 35 dB_{HL} stimulus level, usually used for AABR newborn hearing screening, we found the combination of the CE-Chirp™ and the BERAphone® leads to very short testing times for newborn hearing screening.

Reference documents:

“Click-evoked ABR at high stimulus repetition rates for neonatal hearing screening”.

Stürzebecher E, Cebulla M and Neumann K. Int J Audiol, 42(2):59-70, 2003

Operating Instructions MB 11

12 Warranty, Maintenance and After-Sales Service

The MB 11 BERAphone® ABR-Screener is guaranteed for 1 year. This warranty is extended to the original purchaser of the instrument by MAICO through the Distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser.

The MB 11 may be repaired only by your dealer or by an authorized service center recommended by your dealer. We urgently advise you against attempting any repairs to the instrument yourself or commissioning non-experts to do so.

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

In order to ensure that your instrument works properly the MB 11 should be checked and calibrated at least once a year. This check must be carried out by an authorized Maico distributor.

When returning the instrument for repairs it is essential to send all of the system components.

Send the device to your dealer or to a service center authorized by your dealer. Please include a detailed description of the issues you are experiencing.

In order to prevent damage in transit, please use the original packing if possible when returning the instrument.

Operating Instructions MB 11

13 Safety Regulations



13.1 Electrical Safety: The MB 11 BERAphone® ABR-Screener is specified to comply with the international standard IEC 601-1 (EN 60601-1).

The MAICO MB 11 is guaranteed according to IEC 601-1 safety against electrical hazard only when the connected notebook computer is powered by batteries or the computers power supply accords to IEC 601-1 or IEC 950-1 safety regulations.

The instruments are not intended for operation in areas with an explosion hazard.

13.2 Measuring security: To guarantee that the instrument works properly, it has to be checked at least once a year.

The service and calibration must be performed by an authorized service center. We will drop our liability if these checks are not done.

13.3 Device control: It is recommended that the system user perform a subjective check of the stimulus intensity on a regular basis.

Operating Instructions MB 11

APPENDIX A

Tips for Screening with the MB11 BERAphone®

- 1) A baby who is quiet, comfortable and, preferably, sleeping is in the ideal state for screening. While screening can be successful on a baby who is awake, sucking intermittently on a pacifier or nursing, the test time will be longer and the chance of a refer result will be higher. However, if the pacifier or nursing ultimately calms an agitated baby, by all means, try anything you can think of to calm a fussy baby.
- 2) Screening within a few hours after birth can be successful because the baby is often sleeping very soundly at this time. However vernix blocking the ear canal can cause a refer result when screening is performed early. Try to clear the canal by grasping the ear, gently pulling and rotating the ear. Massage the area just in front of the ear canal opening. These maneuvers can help to open up the ear canal, improving the chance for a Pass result.
- 3) It will be difficult to place the BERAphone® ear cushion around the baby's ear when the baby is tightly swaddled with the blanket obstructing the ear and neck area.
 - a) Loosen the blanket so that you can achieve better access to the baby's ear.
 - b) Swaddle the baby so that the shoulders are not pushed up tightly toward the neck and ears.
- 4) A baby who is tense in the neck and shoulder area will take longer to screen since muscle tension near the electrodes can cause artifacts, slowing the test and increasing the chance for a refer result. Position the baby in a way that promotes neck and shoulder relaxation.
 - a) This might be achieved by rolling the baby slightly on his/her side with a rolled up blanket tucked along the back and into the curve of the neck.
 - b) Grasping the baby's hand and gently guiding the arm down and toward the midline of his/her body can promote relaxation of the shoulder and neck. A tightly fistted hand is a sign that the baby is tensing the shoulder and neck muscles.
 - c) A baby is likely to initially react to the placement of the BERAphone® by tensing up the shoulder and neck. Typically, however, after a few seconds of continuing to hold the device in place, following the baby's head movements, the baby will begin to relax. Beginning the collection can sometimes distract or relax the baby as they "listen" to the soft chirp sound. If the baby is moving or tense, start the screening so that the stimulus begins and then Pause the test until the baby quiets and relaxes. The stimulus continues when the screening is Paused. When the baby is quiet, Continue the test.

Operating Instructions MB 11

- 5) Before applying the BERAprone® to the baby's skin make sure that the electrodes and ear cushion are completely dry after using the disinfectant wipe to clean the device. The disinfectant is not good for the baby's skin and can also affect the quality of the recording if the electrodes are still wet.
- 6) When using the MB 11 BERAprone® it is easier to monitor the correct positioning of the BERAprone® on the baby's head when the screener is positioned looking into the face of the baby. It is more challenging to achieve good electrode and earphone placement on the baby when the screener is positioned looking at the back of the baby's head.
- 7) During screening, be watchful that the ear cushion surrounding the baby's ear is constantly in contact with the baby's head around its entire perimeter. Gaps between the ear cushion and the baby's skin will allow some of the stimulus intensity to leak out of the earphone cavity reducing the volume of the stimulus reaching the baby's ear.
- 8) Screenings can be successfully performed even in relatively noisy places, like a NICU. However, a quieter test environment is desirable when it can be achieved. Awareness of the noise level in the test room and attempts to control it will help you achieve better and quicker screening results.
 - a) In Mother's room, or multi-purpose rooms when other people are present, ask others to suspend conversations or talk quietly and mute the TV/radio during the screening.
 - b) If a room or hallway adjacent to your screening room is noisy, close the door to reduce the background noise.
 - c) Try to avoid testing in a location near concentrated noise, such as air conditioner vents.
- 9) Some environments in the hospital are very "noisy" in terms of electrical interference from other pieces of equipment nearby or even on adjacent floors of the hospital. If you are experiencing poor signal quality (as seen by viewing the Signal Quality indicator in the software or on the BERAprone® LED lights) when the baby appears to be relaxed and free of muscle tension in the neck/shoulder, the source of the degraded signal quality may be electrical interference.
 - a) Enable the "EEG" checkbox on the collection window so you can view the incoming electrical signal from the electrodes (EEG).

Operating Instructions MB 11

- b) Do you see any rolling, cyclical waves present in the EEG? If so,
 - i) Check to be sure that the electrode gel from 2 electrode sites on the baby's head have not merged into one large gel area. This "salt bridge" condition can produce this rolling electrical artifact, poor signal quality and poor recordings. If you suspect this may be the case, terminate or pause the test and clean the electrode gel off the baby and start again.
 - ii) Change the power condition of the system. That is, if you are running on PC battery, plug the PC into an outlet. Or, if you are running on AC power, unplug the system (printer too!) and run on PC battery power only. See if the rolling artifact in the EEG quiets with this change.
 - iii) Move to a different location for screening. Sometimes moving to a different power outlet in the wall and moving the system and baby across the room can position the system in a part of the room that is electrically quieter.
- 10) Screening is in progress on a quiet baby with good signal quality (green light on BERAphone®), but the red or blue data progress line is remaining flat and is not, over time, trending upward toward the GREEN "Pass" area.
 - a) See #7 above
 - b) See #9 above
 - c) Was the baby initially active when you started the screening and now has become quiet? Sometimes a period of mildly "noisy" data collection at the beginning of the recording can prolong the test and delay the progress toward the Pass area even after the baby has become quiet. That is, the data collection during the quiet time has to overcome the beginning of the data collection that was noisy. It may actually save time to Stop the recording in progress if you note that time is going by and it is not trending upward and Start a new measurement now that the baby has quieted down. Don't remove the BERAphone® when you Stop and Start again as this movement may awaken the baby. The point is to start the recording again when the baby is now quiet so that the data quality is better from the beginning of the screening.
- 11) **Ultrasound gel is NOT recommended for use with the MB 11 BERAphone®.** It's is chemically different from the recommended electrode gel (Parker SignaGel Electrode gel or Sonaville Electrode gel). Additionally, it is thinner in viscosity and therefore is more prone to spreading out on the baby's skin perhaps causing the gel from different electrode sites to merge causing poor recording conditions.
- 12) Switching to a new screening device or technology often requires some change in technique. Even a seasoned screener will experience higher refer rates as she adjusts to a new device. A screener who tests lots of babies will gain experience and improve the refer rate quickly. Screeners in low volume birthing hospitals who screen babies infrequently will take longer to reach the optimum refer rate. In low birth rate hospitals it may be wise to limit the number of individuals performing the screening so that each one gets more practice, rather than attempting to have all staff members perform screening.

APPENDIX B

Competency Evaluation for use of the MB 11 BERAphone® ABR Screener

Screener name: _____

Examiner name: _____ Date: _____

	MB 11-specific screening tasks	Performs task competently	Needs training	Not observed
1	Plugs in equipment			
2	Turns on computer			
3	Launches the software			
4	Demonstrates understanding of optimal baby state for screening			
5	Enters all required demographic information			
6	Correctly matches the chosen test ear in the software to the actual ear being screened			
7	Properly chooses the electrode sites on the baby's head			
8	Properly prepares the electrode sites on the baby's head using an appropriate amount of gel and keeping the gel between sites separated			
9	Massages the gel into the skin rubbing back and forth 15-20 times at each site			
10	Applies an appropriate amount of gel to the electrodes			
11	Positions the baby in a way to allow good positioning of the BERAphone® on the baby's head			
12	Positions the BERAphone® on the baby's head making sure that the ear cushion is surrounding the ear and making contact with the baby around its entire circumference			
13	Shows ability to begin the measurement in the software			
14	Positions the BERAphone® electrodes on the prepared electrode sites or			

Operating Instructions MB 11

	modifies as needed to make adequate contact for acceptable impedance			
15	Understands the impedance traffic lights regarding the terms "vertex", "mastoid" and "ground" and which sites on the baby's head corresponds to these terms			
16	Supports the BERAphone® on the baby's head to maintain its position but does not apply force while holding the device in place			
17	Observes the baby and the quality light on the BERAphone® and on the software screen to identify prolonged periods of "noisy" behavior (red light showing) and calms the baby or pauses testing until the baby quiets			
18	At conclusion of test for first ear, repositions baby for testing opposite ear			
19	Prints results			
20	Cleans BERAphone® appropriately with designated disinfectant product after each baby.			
21	Clears demographics in main screen when preparing to test next baby			
22	Makes sure the electrodes are dry of disinfectant before use on next baby			
23	Shows ability to "Search" the database to find a previously tested baby			
24	Exits the MB 11 software correctly			
25	Shuts down the computer correctly			
26	If required, exports data correctly			
General screening program tasks				
1	Transports babies according to facility protocol			
2	Follows facilities infection control procedures			
3	Displays appropriate baby handling techniques			
4	Provides appropriate information to parents regarding the results of the screening for both Passing and Referring results			
5	Documents results in accordance with screening program requirements			
6	Works cooperatively with other nursery/hospital staff			
7	Handles equipment with proper care, leaving instrument in order for other screening staff			
8	Understands the importance of newborn screening and can explain the reason for it and describe the test adequately to family members			
9	Follows hospital's privacy regulations			
10	Follows screening program screening protocol in regards to limiting the number of rescreens			
11	Follows screening program protocol with regards to ears to screen on a rescreening (i.e. are both ears rescreened in case of Refer in one ear?)			
12	Demonstrates awareness of the possible negative impact of moderate-high levels of acoustic noise on the hearing screening process and outcome; attempts to manage the noise level to the extent possible			

APPENDIX C

Cleaning, Disinfection & Maintenance Recommendations

The MB 11 BERAphone® is considered a non-critical, patient care item since it comes into contact with intact skin, but not mucous membranes. For such devices, guidelines from both the US Center for Disease Control¹ (CDC) and the Robert-Koch-Institut Bundesinstitut für Infektionskrankheiten und nicht übertragbare Krankheiten (Berlin, Germany) recommend cleaning and disinfection with a hospital-grade, surface disinfectant.

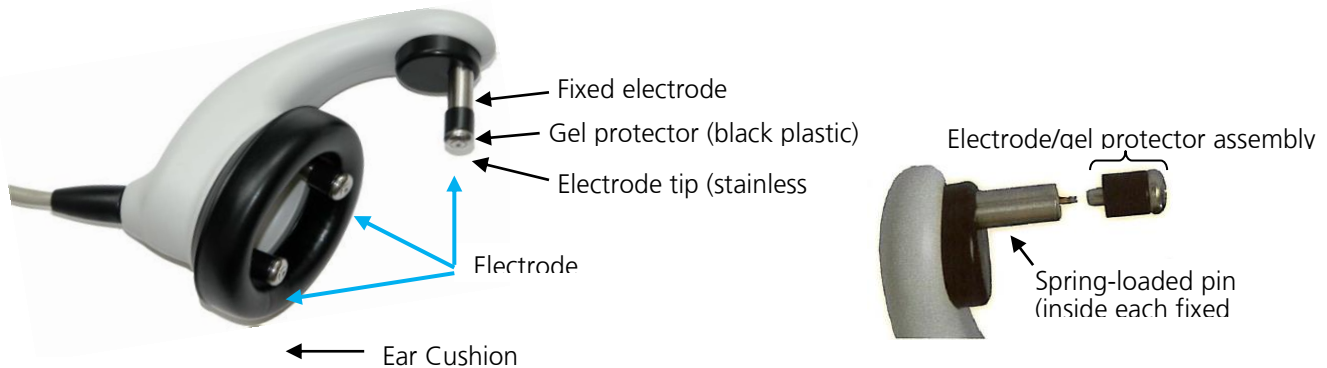
Important information

- The Maico MB 11 BERAphone® is intended for use on intact, external skin around the ears and on the scalp. It should not be used if the skin is not intact or if the baby has a contagious dermatological condition.
- Recommendations for cleaning and disinfection of the BERAphone® presented in this document are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.

Definitions of terms

¹ Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. CDC, Department of Health and Human Services, USA

Operating Instructions MB 11



Cleaning & disinfection after screening each baby

The BERAphone® must be cleaned and disinfected after use on each baby.

1. Clean off residual gel from the electrodes and ear cushion using a tissue or disinfectant wipe.
2. Disinfect the electrodes, ear cushion and other components that made contact with the baby or the baby's bedding by wiping them with a fresh hospital-grade disinfectant wipe designed for use on hard surfaces.
 - a. Use of a non-alcohol based disinfectant product is recommended in order to preserve the material of the ear cushion. Non-alcohol based disinfectants contain the active ingredient referred to as quaternary ammonia compound.
 - b. If an alcohol-based disinfectant is used repeatedly on the ear cushion, the material will be chemically denatured over time, causing it to harden and crack. It will need to be replaced on a more frequent basis. The higher the alcohol content of the disinfectant product, the faster the ear cushion will be denatured, requiring replacement. Replacement ear cushions are available from Maico or your local distributor.
 - c. Follow the directions for use and precautions on the disinfectant product.
 - d. If the disinfectant wipe is very wet, do not allow disinfectant to drip down into the black, perforated speaker inside the BERAphone® ear cushion area.
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 on the BERAphone® before using it on the next patient.

Routine periodic inspection inside electrode gel protectors and stationery electrode post

For new users, daily inspection inside the gel protector and fixed electrode post is recommended. If the inspection is routinely showing no indications of gel inside the gel protectors or posts, the frequency of this inspection process can be reduced.

1. Remove the electrode tip/gel protector assemblies from the fixed electrode posts by pulling them straight out.
2. Inspect the inside of the gel protectors looking for any sign of electrode gel.

Operating Instructions MB 11

- 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.
 - i. 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.



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 wipe 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.
 - a. Gel inside the fixed electrode post is an indication that the screeners are applying an excessive amount of gel to the electrode and/or the baby.
 - i. 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.
8. If gel is observed inside the fixed electrode post, use a dry cotton-tipped applicator to gently swab around the spring-loaded pin to remove the gel.
 - a. Be careful not to bend the spring-loaded pin so that it is no longer centered in the electrode post.
 - b. A bent pin may cause the electrode to "stick" in the fully pushed-in position. If this happens you may have to manually release the electrode so it will spring out to make contact with the baby's skin.
 - c. A bent pin can sometimes be manually pushed back into a centered position; however a repair may be required if the electrode is constantly sticking in the pushed in position.
9. When the disinfection product has thoroughly dried, reconnect the removable electrodes to the fixed posts by aligning them with the spring-loaded pin and pressing them fully onto the pin.

Replacement of electrodes

Replacement of the removable electrodes is recommended on a yearly basis. It may be convenient to change the electrodes at the time of the device annual calibration. 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.

Replacement of the ear cushion

Replacement of the ear cushion is recommended on an annual basis. It may be convenient to change the ear cushion at the time of the device calibration. 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.

1. Remove the ear cushion by pulling it off of the BERAprone®.
2. If there is any debris on the plastic mounting for the ear cushion, clean and disinfect the area using a disinfectant wipe.
3. Allow the disinfectant to dry thoroughly.
4. Attach a new ear cushion to the BERAprone®.
 - 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.

Annual calibration

Annual calibration by a qualified Maico distributor is recommended. Contact your local Maico representative for scheduling information.

Operating Instructions MB 11

Specifications are subject to change.



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