MAICO Diagnostic GmbH

Operating Instructions
MB 11 Classic

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1 Introduction

Thank you very much for purchasing a quality product from the MAICO family. This automatic ABR-test system MAICO MB 11 Classic is manufactured to meet all quality and safety requirements, and has been certified with the CE-symbol according to Medical Directive 93/42/EEC.

In designing the MAICO MB 11 we placed particular importance in making it a user-friendly device, meaning its operation is simple and easy to understand. And because all functions are software controlled, upgrading later to new, extended measurement functions will be simple and inexpensive. That means that you have invested in a device that will adjust to your future needs.

This user manual should make it as easy as possible for you to become familiar with the functions of the MAICO MB 11 Classic. Please open out the flap of illustrations on the last page. The description of the position (e.g.) of controls, displays and connections, found again in the text, will make it easier for you to learn how to operate the MAICO MB 11 Classic.

If you have problems or have ideas for further improvements, please get in touch with us. Simply call.

Your MAICO-team

2 Important safety instructions

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

The MAICO MB 11 Classic 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 computers power supply accords to IEC 601-1 or IEC 950-1 safety regulations.

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.

Disclaimer

The MAICO MB 11 Classic Test Instrument is designed to be a screening device for hearing loss. Sensitivity and specificity of this type of device are based on the test parameters defined by the user, and may vary depending on environmental and operating conditions. The presence of normal evoked potentials suggests normal hearing. However, a passing result using this instrument is not an indication that the full auditory system is normal. Thus, a passing result should not be allowed to override other indications that hearing is not normal. A full audiological evaluation should be administered if concerns about hearing sensitivity persist. A REFER test result should not be assumed to be an indicator of a lack of auditory function; however it should be followed with full audiological diagnostic testing.

3 Description

MB 11 tests hearing function by measuring the auditory evoked potentials of the auditory pathway. It records the appropriately filtered EEG in certain electrode configurations on the skull.

Repeated stimulation and averaging the corresponding EEG sections allows the signal/noise ratio to be improved. The spontaneous, non-stimulation related fluctuations in the EEG are reduced to a level that makes it possible to detect the element of the EEG evoked by the acoustical stimulation. This permits "objective audiometry", the hearing threshold can be identified without participation from the patient (babies, infants).

3.1 Auditory Brainstem Response (ABR) audiometry

Brainstem potentials, BERA (brainstem evoked response audiometry) or ABR (auditory brainstem response) do not require the patient to be awake. ABR measurements can also be taken while the patient is asleep or under anaesthetics, whereas the late cortical potentials require the patient to be awake and alert. For click-evoked brainstem potentials (see Figure 1) 5 to 6 typical waves (each marked with Roman numerals after Jewett) are received with the following approximated source points in the auditory pathway:

I	**Spiral ganglia**
II	**Auditory nerve (cranial nerve VIII) leaving the internal meatus**
III	**Ventral cochlear nucleus (VCN)**
IV	**Superior olivary complex (SOC) and initial section of lateral lemniscus (LL)**
V	**Lateral lemniscus (LL), ascending section**
VI	**Inferior colliculus**

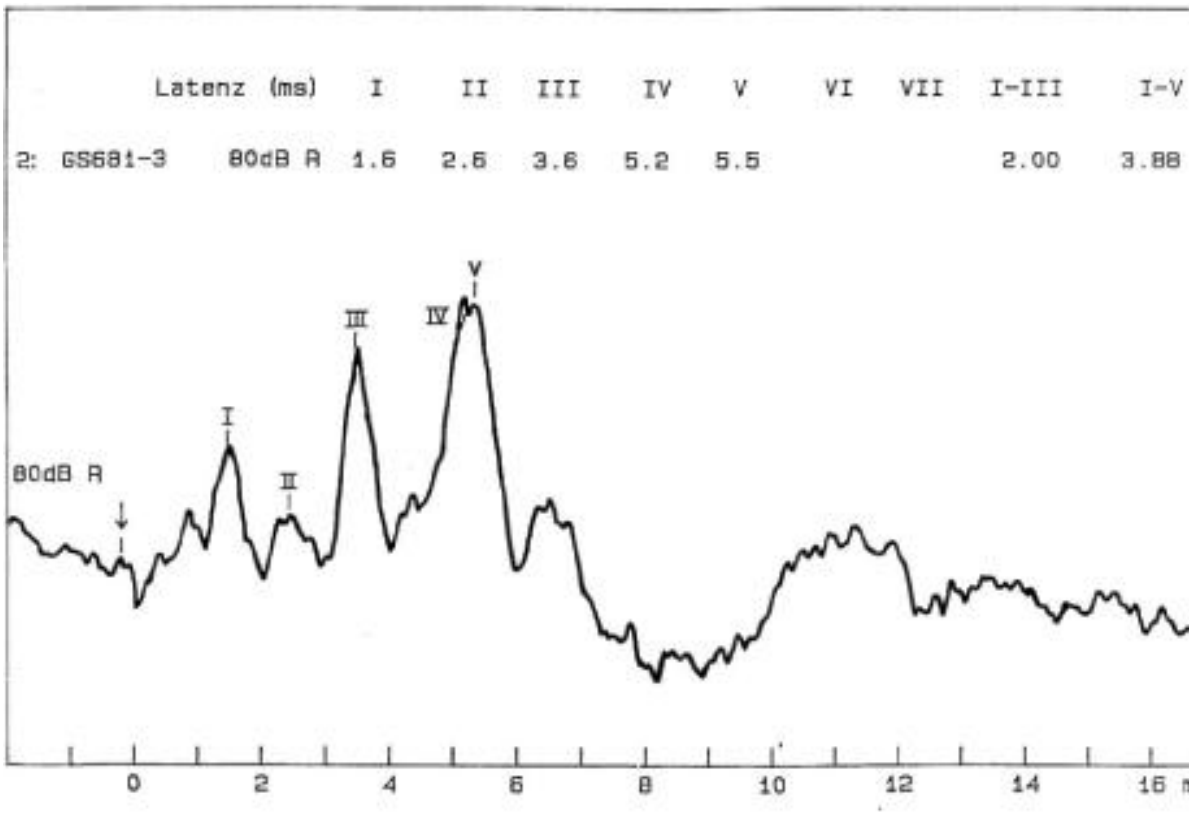


Figure 1 – Example of a typical, low filter ABR potential

Important for diagnoses are waves I, III and V with approximate latencies of 2ms, 4ms and 6ms. Wave V is generally the largest and is the only one that can be recorded at levels near the hearing threshold (see Figure 1).

The latency of all waves increases with decreasing stimulation intensity (sound pressure) and is generally a better indicator than the wave amplitude, which decreases with the stimulation intensity but with a less characteristic pattern. The inter-peak latency (the temporal interlude) of waves I and III (I-III) and I and V (I-V) is, as a particular characteristic of the ear, independent of the click stimulus intensity (see Figure 2). A value exceeding 4.5 ms for I-V is generally regarded as pathological, indicating need for follow-up examinations.

The largest potentials are obtained, when the electrodes are positioned in the direction of the propagation of the excitation in the auditory pathway: wave V in line with its origin in the ascending section of lateral lemniscus is measured best with a "vertical" electrode placement. Accordingly, an ipsilateral mastoid versus vertex (or hairline on the forehead) is chosen for electrode placement. The mastoid ipsilateral to stimulation side supplies wave I for this ear. For detection of wave III to VI the contralateral mastoid is just as suitable for electrode positioning.

The short click stimulus (100 µs) excites auditory nerve fibres in the region of 1 to 3 kHz, ABR responses are therefore not frequency specific.

		Latenz (ms)	I	II	III	IV	V	VI	VII	I-III	I-V
0:	B-1	90dB R	1.6		3.9		5.6	7.2		2.32	4.00
1:	B-2	[illegible]dB R	1.6		4.0		5.6	7.3		2.32	4.00
2:	B-3	70dB R	2.0		4.2		5.9	7.4		2.28	3.96
3:	B-4	60dB R	2.2		4.6		6.2	7.7		2.40	4.00
4:	B-5	50dB R	2.4		4.8		6.4	8.0		2.36	4.00
5:	B-6	40dB R	2.6		5.3		6.8	8.5		2.44	3.96
6:	B-7	30dB R	3.3		5.7		7.3	8.8		2.40	4.00
7:	B-8	20dB R			6.3		7.8				
8:	B-9	10dB R			8.9		8.6				

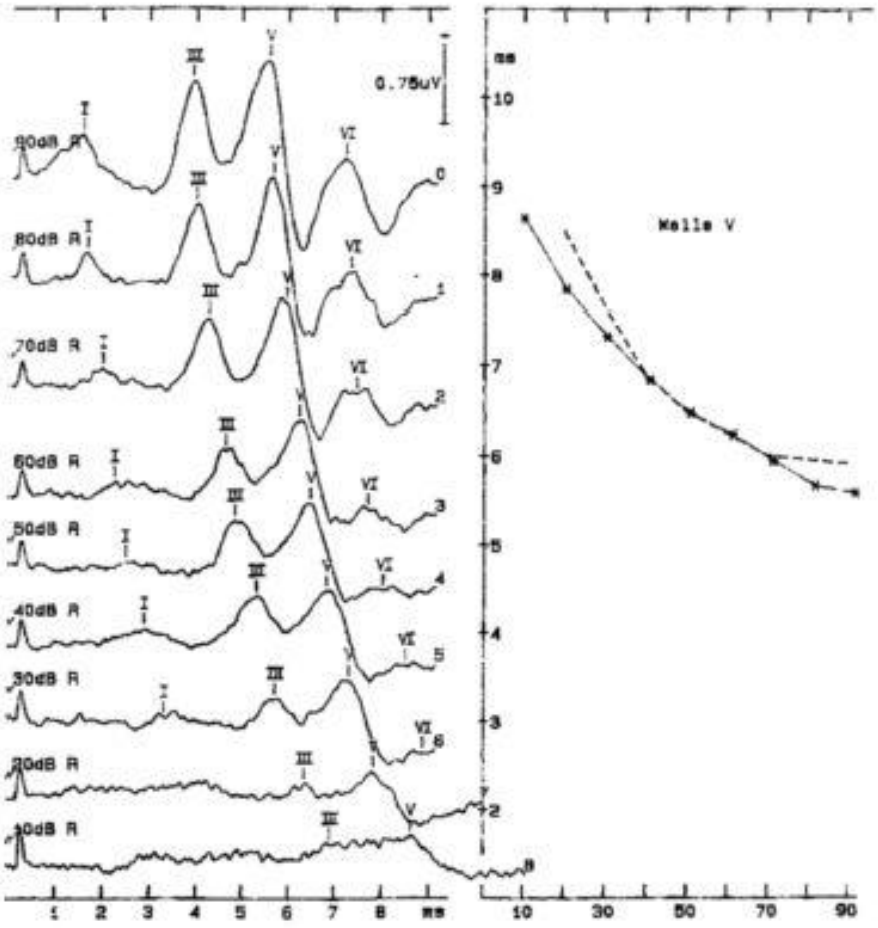


Figure 2 - Threshold detection from 90 to 10 dB HL with Latency/Level diagram (---=standard)

3.2 The MB 11 Classic

EEG for brainstem audiometry was obtained by sticking electrodes to different points of the head of the patient. The electrodes detect and record brainstem response evoked by acoustical signal delivered via the MB 11 Classic insert-phone (as shown in Figure 3).

Figure 3
Testing with MB 11 Classic

The MB 11 Classic, with its flexibility, can be used on any patient.

The MB 11 Classic can be used very advantageously with the patented, fast reliable built-in automatic ABR-"**A**uditory **S**teady **S**tate" (ASS) test and the new CE-Chirp®. Fast test time, simple to use, a high sensitivity of > 99,9% and a high immunity against electrical interference and hum are the most important benefits of this algorithm. The AABR test is described in details in chapter 6.1, and further diagnostic test like ABR and Time Step Stimulus are described in Chapter 7.

Figure 4
MB 11 "PASS" test result

3.3 Automatic Screening with the "Auditory Steady State Algorithm"

For Universal Newborn Hearing Screening (UNHS) current test methods include Otoacustic Emissions (OAE) and Auditory Brainstem Response (ABR). With OAE, the preparation and the test time are fast. But a significant handicap of OAE is a rather insufficient sensitivity and specificity.

With ABR hearing screening, the sensitivity and specificity are very high, but testing traditionally takes significantly more time than OAE screening. With the patented ASS ABR-algorithm, which is implemented in the MB11, it is now possible to achieve test times that are comparable to OAE´s.

The acoustical CE-Chirp® stimuli are applied with a high repetition rate (93 clicks/second). At this click rate a so called "**A**uditory-**S**teady-**S**tate **R**esponse" (**ASSR**) occurs. The objective statistical recognition of the ASSR is done after the transformation of this strict periodic time function in the frequency domain. The ASSR is described in the frequency domain by a few spectral lines (harmonics), the position in the spectrum is determined by the stimulus repetition rate and therefore well known. The statistical test uses the phase and amplitude information of the harmonics below 800 Hz. The spectral lines between the harmonics of the ASSR contain no signal, but only noise or harmonics of the electrical interference. These spectral lines will not be considered in the test result. Beside the short test time another benefit of this method is the high immunity against distortion from electrical hum and ripple.

The statistical test is done in 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 critical value (the green marked PASS criteria, see Figure 5). Then the test will be stopped with the test result “PASS”. If the PASS criteria is not achieved after 180 seconds, the test is stopped with the test result “REFER”.

4 Getting started

All Notebooks delivered by MAICO have the correct settings and the MB 11 software is already installed. If you use not a Notebook delivered by MAICO please follow the instruction in chapter "Installation and Settings" or contact your local dealer.

4.1 Unpacking your instrument

Your MB 11 Classic 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 Classic. 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.

Standard accessories - MB 11 Classic:

1 MB 11 Classic with amplifier
with jacks for three electrodes and two sound transmitters
1 set of Vertex, Ground and Mastoid electrode cables
1 set Left and Right Insert Phones
1 packet of 25 single-use, adhesive electrodes
4 additional disposable ear tips of different sizes
1 USB connection cable
1 Carrying bag
1 CD Installation Software
1 User Manual

4.2 Preparing the MB 11 for use

The MB 11 unit is supplied in a grey box connected with the MB 11 Classic through a cable®.

A USB-cable connects the MB 11 with a USB port of a Notebook or desktop computer.

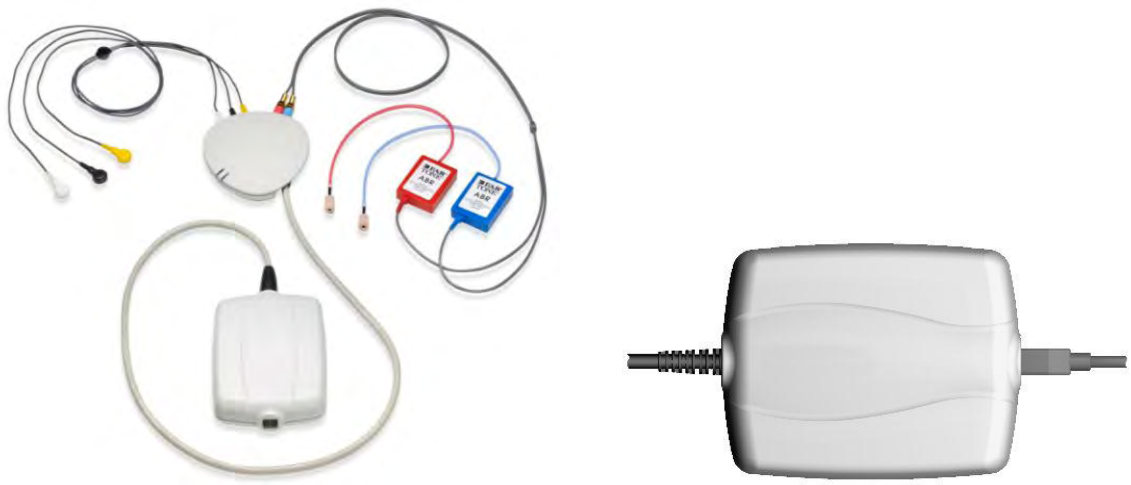


Figure 5
Classic with electrodes and MB 11 box

The MB 11´s power is directly supplied through the computer via the USB port. No external power supply is needed. This makes the MB 11 Classic easy and safe to use.

4.3 Getting familiar with the MB 11 Classic

The MB 11 Classic should be operated in a quiet room, so that the examinations are not 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 Classic. Therefore the use of these instruments is not allowed in close proximity to the MB 11 Classic.

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.

4.4 Starting the software and menu

The Operating System of the Notebook or PC should first be started. After successful booting, launch the MB11 Classic software by clicking the icon "MB 11 USB Version" at the desktop or direct from the program menu. The program launches with the start screen (see Figure 6).

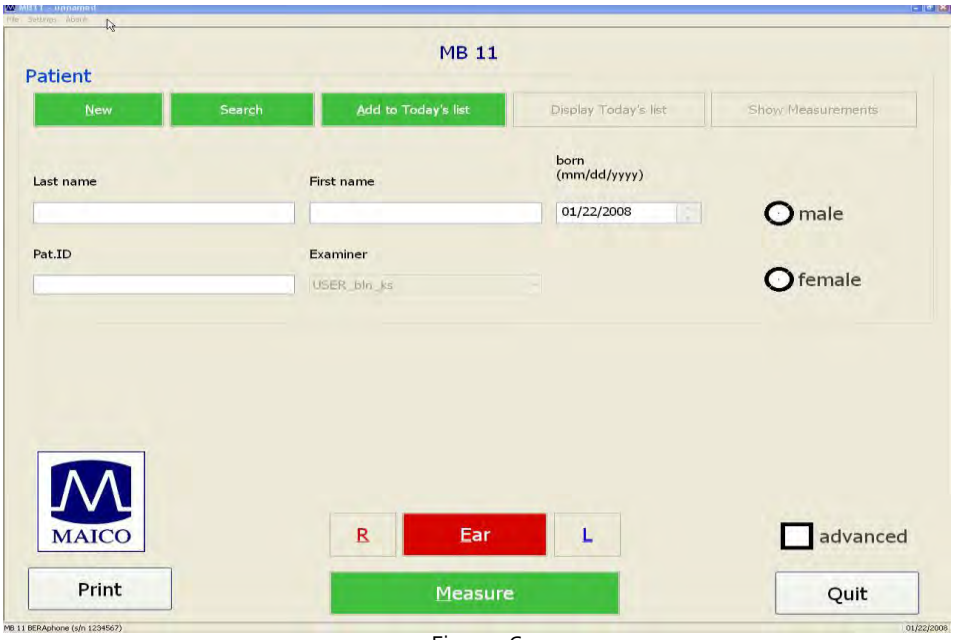


Figure 6
Start screen of the MB 11 program

Device recognition: You can connect up to 3 MB 11 Classic/ Beraphone® devices. A pop-up window displays the connected instruments. If more than one MB 11 is connected, you can choose the device you want to work with by mouse click. To change the instrument during the measurement, press CTRL + U and the pop-up window opens.

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".

4.4.1 Menu "File"

Figure 7
File Menu

"New" – Entry of a new patient (see also Tracking – Patient data)

"Search" - Launches a dialogue field that allows selection of a patient out of the integrated database. In this field, a patient can be chosen by clicking the patient's name with the mouse or by typing the name. The corresponding patient data appears in the fields of the start screen.

"Print" - The window "Print Measurement" opens. Choose the measurement you want to print out.

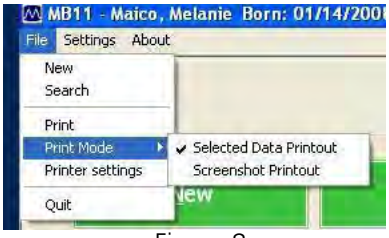


Figure 8
Print Mode

"Print Mode" – This allows the type of printout to be selected, choose "selected Data printout" to print a list of chosen measurement results. Choose "screenshot printout" to print the graphical display on the complete measurement.

"Printer Settings" - The settings of the printer can be individually set with the "Printer Settings" menu.

"Quit" – Exits the MB 11 program.

4.4.2 Menu "Settings"

"Language" - The program language can be changed i.e. to English, German, French, Chinese or Japanese.

"Default Mode" – Options: "Screening only" and "advanced". The advanced mode offers additional diagnostic tests: Time Step Stimulus and Standard ABR.

"Tracking System" – For a brief screening test choose "no tracking". "HI*TRACK": The MB 11 software is full HI*TRACK compatible and supports secured quality tracking.

Figure 9
Settings Menu

"Tracking Settings" - Define the export directory for the tracking data and insert clinic data. Default setting for Examiner/Screener is the user of the computer (login identification).

Figure 10 – Tracking Settings

4.4.3 Menu "About"

Clicking on "About" to see product information about the software version and contact information.

4.5 Operation with mouse, keyboard or touch screen

The MB 11 Classic-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. The actual position is shown as highlighted. Pressing the Enter key activates the actual field or button.

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

Very fast operation is possible by using the keyboard short cuts. Press the <ALT> key together with the underlined letter of the required button. I.e. to start the measure press the keys <ALT> and <M> together.

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 devices)
Ctrl+B	Beep at the end of the measurement

4.6 Registry of new patient data

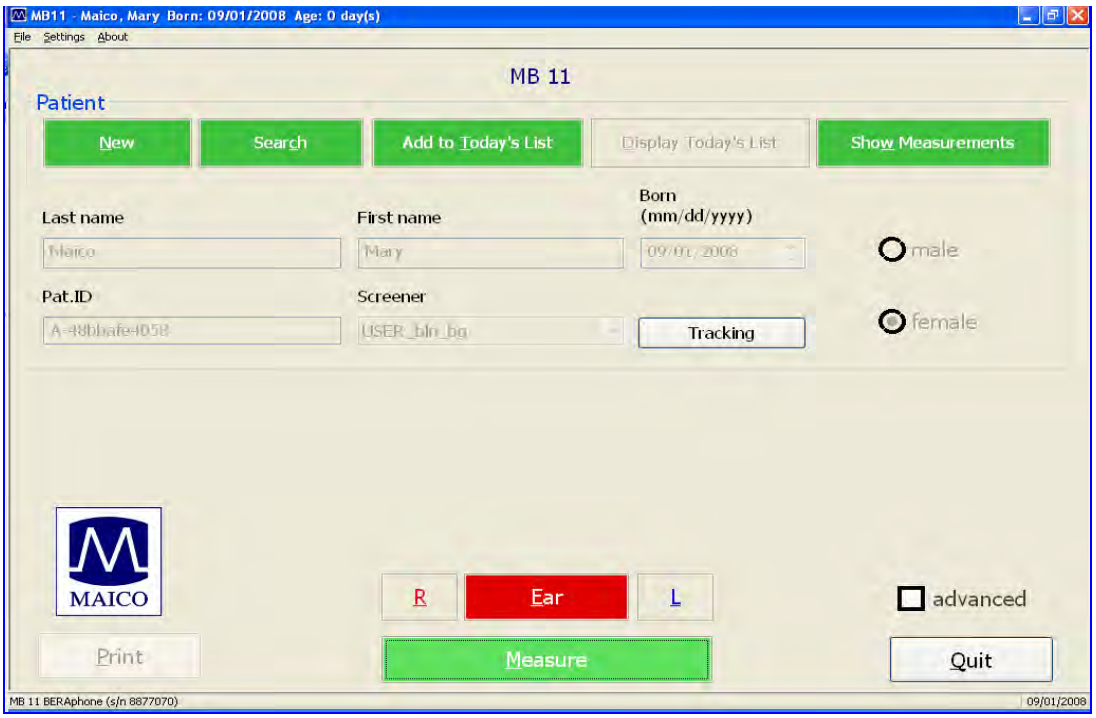


Figure 11 - MB 11 - program start screen with patient data

For a fast screening test without tracking it will be enough to register the name, birthday, gender and Patient-ID. Tracking may require more detailed data. (Read more in Chapter 6 Tracking).

Enter the surname and first name of the patient/baby with the keyboard. Move between the different entry fields using the <tab> key or a mouse click in the required data field. The current date is displayed as the default value for the date of birth. The arrows on the right of the date field can be operated with the mouse to increase or decrease the value, alternatively use the ▲ and ▼cursor buttons of the keyboard or enter the date with the numeric keyboard. Mark the sex of the patient by clicking the box male or female. The <Del> key can be used to delete the default setting prior to entering a different value.

When "Tracking System" is activated it is possible to mark the patient as outpatient.

Additionally you can load stored patient data (see chapter 4.7) or create a "today's list" of the patients to be tested today (see chapter 4.8).

Select the side of the ear to be tested, < R > for right or < L > left, using the Ear button or the R/L slide just above the "Measure" button.

Now you are ready for testing. The test procedure is described in chapter 5.

4.7 Loading stored patient data

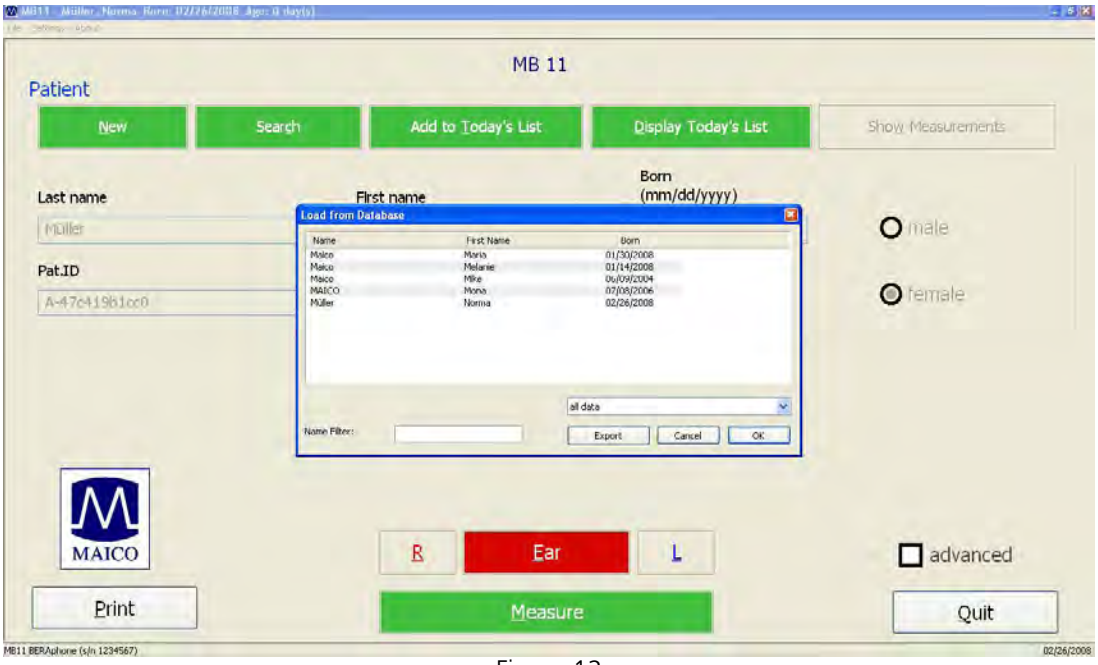


Figure 12
Load from database

After clicking on the button "Search", all stored patients will be shown (see Figure 12).

Select a patient with the cursor buttons or the mouse and load the stored data by pressing the Enter button or double click with the mouse.

If a test result of this patient already exists, the button "Show Measurements" on the right of the screen (see Figure 13) becomes active. By clicking on this button you can scroll through these test results and load them.

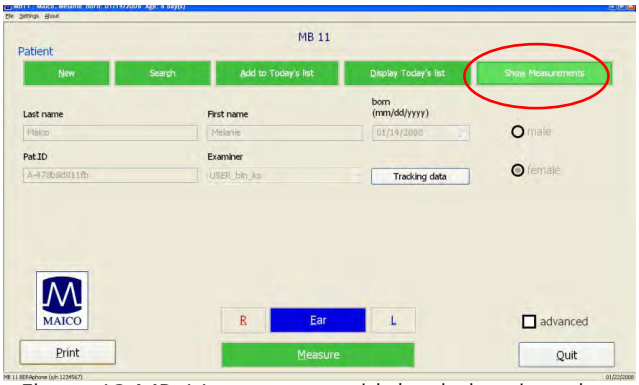


Figure 13 MB 11 - program with loaded patient data and active "Show Measurement" button

4.8 Working with a "Today's list"

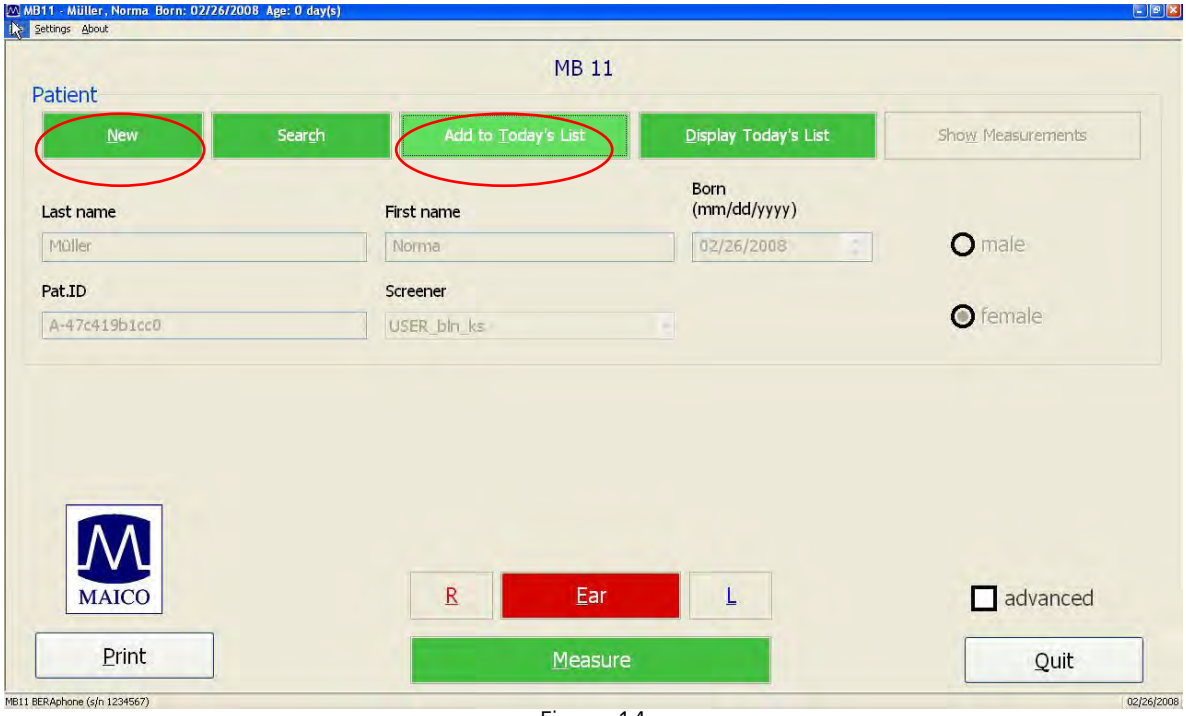


Figure 14
MB 11 - Today's list

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 data" and enter the name, birth data and sex, as described in chapter 4.6. After the data is entered click on the button "Add to 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 testing, you just have to click the button Display "Today's list". The list of the babies to be tested today appears on the screen.

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 chapter 5.

The today's list will be erased automatically at midnight of the next day to avoid misunderstandings. Of course the stored test results remain in the database.

5 Automatic testing in the AABR screening mode

It is easy and fast to screen with the built-in patented automatic Auditory Steady State Algorithm. Screening means that during the test it will just be determined if the newborn/patient has the possibility of a significant hearing loss and needs further evaluation.

PASS: As soon as the indication mark reaches the green area (100% Pass criteria), the result is "PASS".

REFER: If no response at the test level of 35 dBnHL is found, the test result is "REFER". In this case a "Follow Up" with diagnostic measurements should be done by a specialist (see chapter 7).

ABBORT: If the test is aborted, a pop-up window with reasons appears. (I.e. Test aborted, because … Technical Problems, Invalid…). The reason will be stored in the database for quality- controlled tracking.

Because no judgements or interpretations of the screening results are necessary, the test can be easily done by properly trained personnel. Additional information and results are available at any time for the doctor or specialist (see chapter 5.4).

5.1 Preparing the Patient for measurements

Before any measurement, the patient should be informed of the test procedure:

Electrodes will be fixed onto three different points of the patient's head, i.e. the top of the forehead (vertex), the temple, and the mastoid.

The test will cause neither harm nor discomfort.

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

A comfortable reclining armchair that supports the head, neck, shoulders and arms is most suitable.

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

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

5.2 Placement of the Electrodes

For electrode placement, the skin should be cleaned with cotton pad dipped in alcohol or acetone to remove any oil and dirt from skin surface to minimize any potential skin impedance. Using the finger, rub the skin lightly until it turns slightly red, this will help to reduce skin impedance and ensure accurate BERA result.

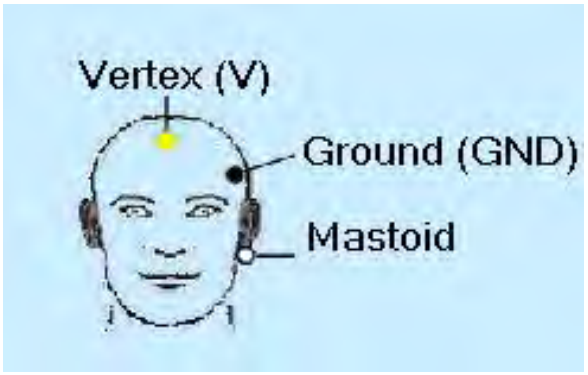


Figure 15
Placement of the Electrodes

If the patient has very rough or dry skin, rubbing the mastoid area with cotton pad soaked in salted water will help to improve the BERA result.

After skin preparation, apply one disposable electrode sticking pad on each of the three electrode placement points, the vertex, the ground, and the mastoid.

An optimal BERA measurement can be achieved by having good electrode-skin contact and accurate positioning of the electrodes.

5.3 Placement of the eartips

As human grow, so do the ears and the ear canals. Hence it is important to choose the right ear tip according to the patient's age and the size of the ear canal.

5.3.1 Placement of eartips for infants

As the ear canals for newborn infants are very small, it is important to choose suitable ear tips especially designed for babies (Figure 16). Before inserting the ear tips, connect them to the insert-phone, and rub the soft rubber tip between the thumb and the index finger to warm it up slightly before putting them into the ears of the babies. This will help to avoid discomfort and thus facilitates the screening process.

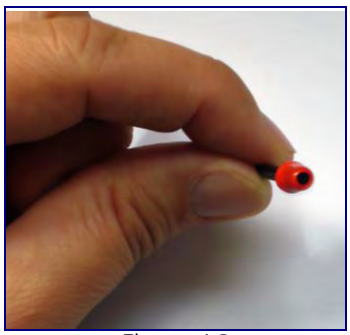


Figure 16
Moulding of the earphones

5.3.2 Placement of eartips for adults

Before inserting the eartips, the soft and pliable noise-excluding form surrounding the sound tube should be shaped and moulded by pressing using the fingers to fit the size of the outer ear canal of the patient (Figure 17). Ensure that the form does not obstruct the sound tube in any way. It is recommended to connect the earphone to the respective insert-phone of the MB 11 Classic before inserting the foam eartips into the patient's ears to avoid any discomfort.

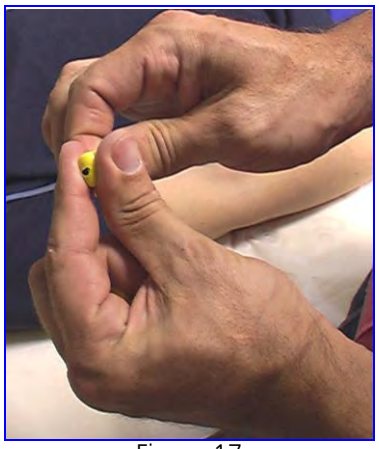


Figure 17
Moulding of the earphones

If the patient is laying down, place the left and right insert-phones next to the patient. If the patient is sitting, clip both the left and right insert phones onto the patient's clothes, or any pockets if available to avoid pulling of the sound tube. As this may distort the sound quality delivered.

When the eartip is in place, the flexible noise-excluding form will slowly expand to fit the ear canal and thus exercising its noise-excluding property. When in doubt, ask the patient if external sound appeared muffled. If the patient answers "Yes", then the eartips are properly placed.

ATTENTION

After the test all three of the electrodes and the eartips should be removed carefully to avoid any discomfort or pain of the patient.

First remove the eartips to resume normal communication with the patient, subsequently remove the insert-phones clipped onto the patient's clothes.

Unclip all the electrodes cables.

For removal of the electrodes, inform the patient in advance and ask for the patient's cooperation. Then, using the thumb and the index finger, stretch the skin surrounding the electrode pad lightly, and with the other hand, using a gentle force to pull the electrode pads off the patient's skin with a down-upward movement.

For hygienic reason the electrodes and earphones are for single-use only. Please use brand new electrode pads and earphones for every new patient to avoid any contamination or transmission of diseases.

5.4. Doing the screening test

Figure 18
MB 11 - program start screen

Enter or load patient data.

Next click on "Measure": The measurement screen opens (see Figure 19).

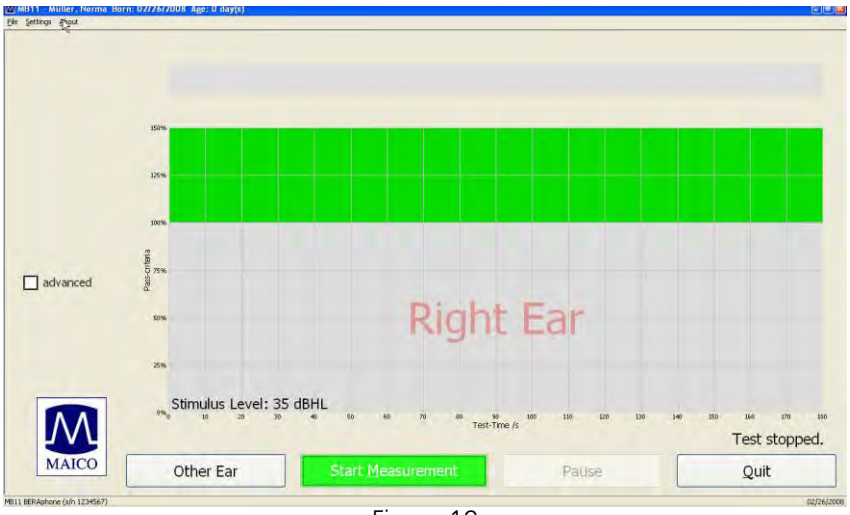


Figure 19
Start measurement

Prepare the patient and as described in chapter 5.1 and place the electrodes as described in chapter 5.2.

Select the ear to be tested. The ear(s) selected (Right Ear, Left Ear, Binaural) are displayed on the measuring screen.

Start the test by clicking on "Start Measurement" button.

Before measurement is started an automatic impedance test is performed.

5.4.1 Impedance Test

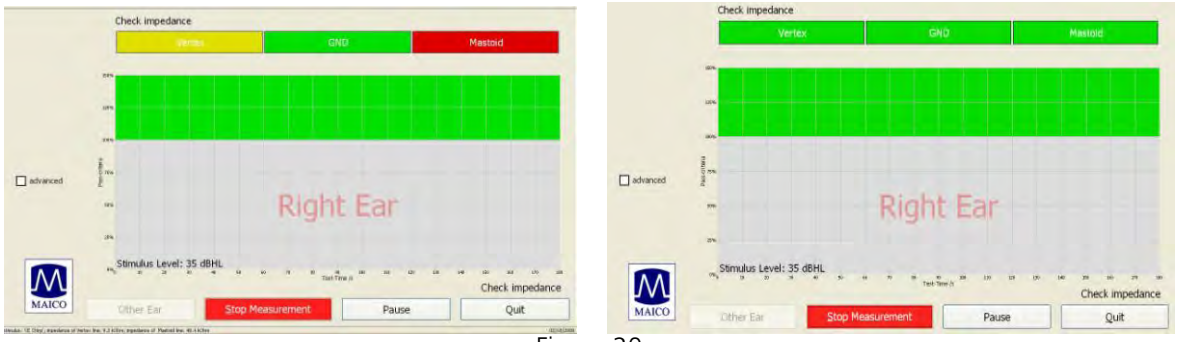


Figure 20
Start measurement

The impedance is the resistance between the measuring electrodes (Vertex Mastoid) and the ground electrode. This impedance is influenced by the resistance of the electrodes and more important of the resistance of the skin. The impedance should be in the range of 250 Ohm to 15.000 Ohm for each electrode per (Mastoid / Ground and Vertex / Ground). Impedance in this range will allow the best EEG quality.

The top of the test screen shows the impedance traffic light (Figure 20). Here the tester can see easily the status of the impedance test for each of the three electrodes. The green colour symbolizes good impedance, yellow means not optimal and red signals bad impedance.

The impedance values measured for Vertex / Ground and Mastoid / Ground lines are shown in the status line in the lower left corner at the screen.

In case of red light the impedance needs to be corrected. Please repeat the preparation with the electrode gel for lowering the impedance of the skin.

In some cases it takes some time until the electrode gel takes into effect.

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

5.4.2 The signal quality control

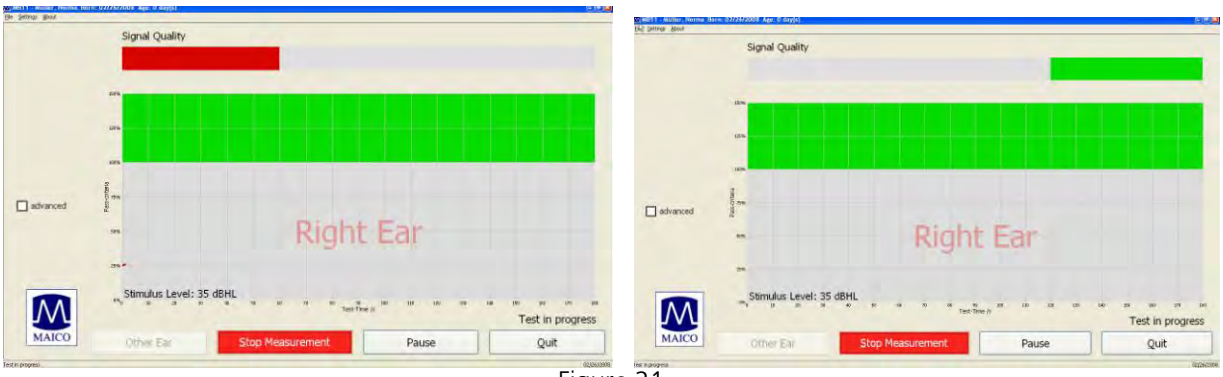


Figure 21
MB 11 - program test screen showing bad and good signal quality

The signal quality in the screening mode is determined by the ratio of artifact and accepted signals. Artifacts are big potentials caused by electrical noise, muscle activity or muscle tension. The quality is low if at a time scale of 1 second the amplitude of the response is at 300 time points bigger than the artefact level (it is possible to change the artifact level in the advanced mode), indicating a high electrical noise level or muscle activity of the patient. Signal quality depends strongly on the correct position of the electrodes and on electrical noise in the surrounding environment. Also potentials from muscle activity disturb the measurements.

The signal quality "traffic light" is located at the top of the test screen. Red indicates low, yellow indicates fair and green indicates good signal quality. As soon as the signal quality turns yellow or green the test starts.

The signal quality indicator light on the MB 11 Classic also shows whether the signal quality is good or not. As long as the signal quality on the screen is red, the signal quality indicator lights red, too. As soon as the signal quality is better and the test starts, the signal quality indicator on the MB 11 Classic changes to green.

If the signal quality decreases for a certain time the signal quality indicator on the MB 11 Classic changes to red again and the test is paused. Try to increase the signal quality again by moving the MB 11 Classic slightly to improve the impedance. If the bad 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.

IMPORTANT: It is recommended to advise patient to close his/her eyes during the test and not to wink, frown, laugh, swallow or make any facial movement as this will result in muscle potential that subsequently impedes the signal quality.

5.4.3 Advanced display mode - EEG-Display

The advanced display mode can be entered by clicking on the box "advanced" on the left of the test screen. Artefact limits can be selected from the pull-down menu located to the left of the EEG display. Choices include 40µV, 50 µV and 60 µV.

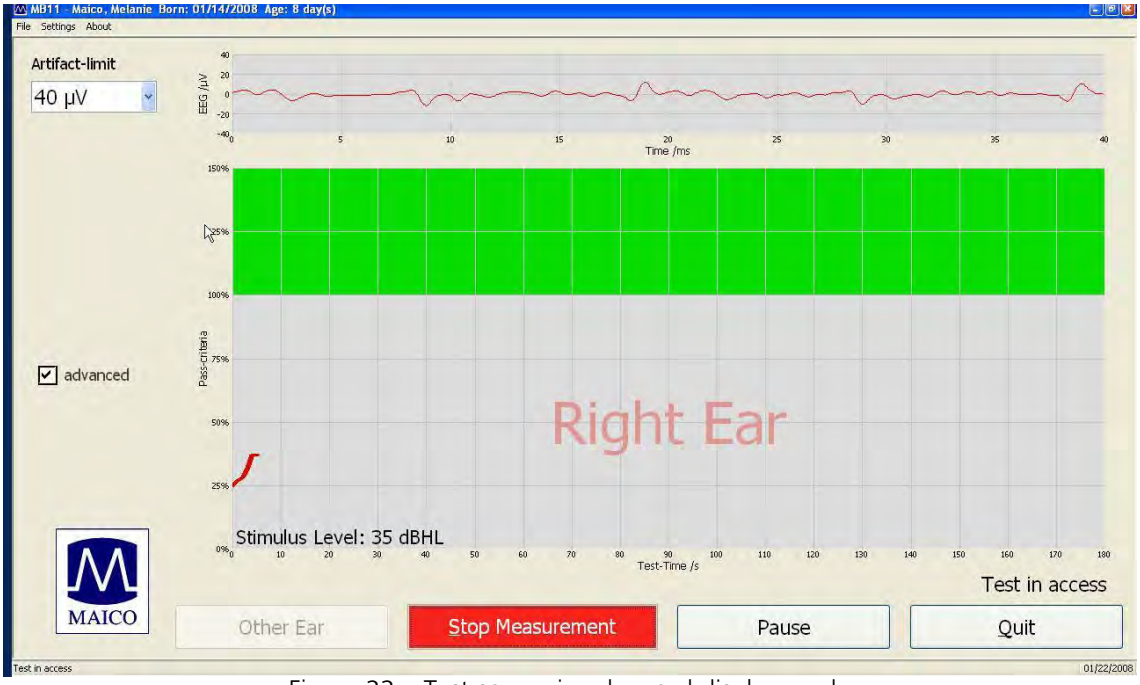


Figure 22 – Test screen in advanced display mode

5.4.4 The function buttons

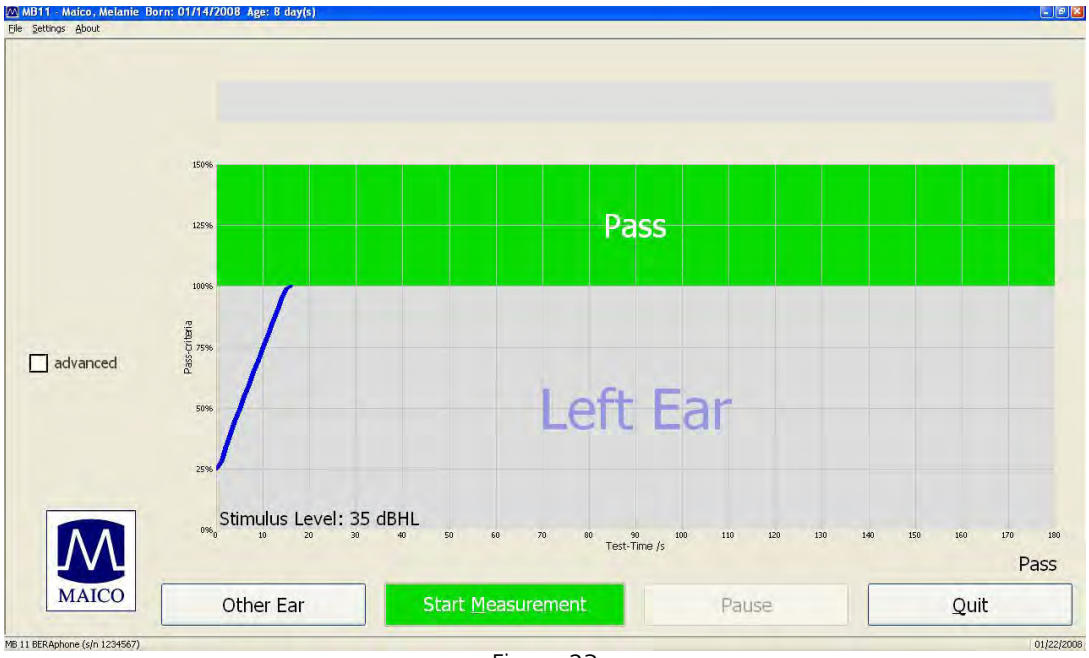


Figure 23
MB 11 - program "Test stop"

At the bottom part of the test screen are the function buttons.

Other EAR: To select the ear(s) for testing, Left (blue), Right (red) or Binaural (purple).

Start Measurement: Clicking on the "Start Measurement" button starts 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 pop-up window "Test aborted, because…" opens. The result (Abort and the reason) will be displayed and stored in the database for quality- controlled tracking.

Pause: Stops the ongoing test. In this case this button changes to "Continue.." and the status indication at the bottom of the screen shows "Test in progress".

Quit: Finishes the measurement and returns to the start screen.

Advanced: The advanced display mode shows the EEG. Artefact limits can be selected from the pull-down menu located to the left of the EEG display.

5.4.5 Test result “Pass”

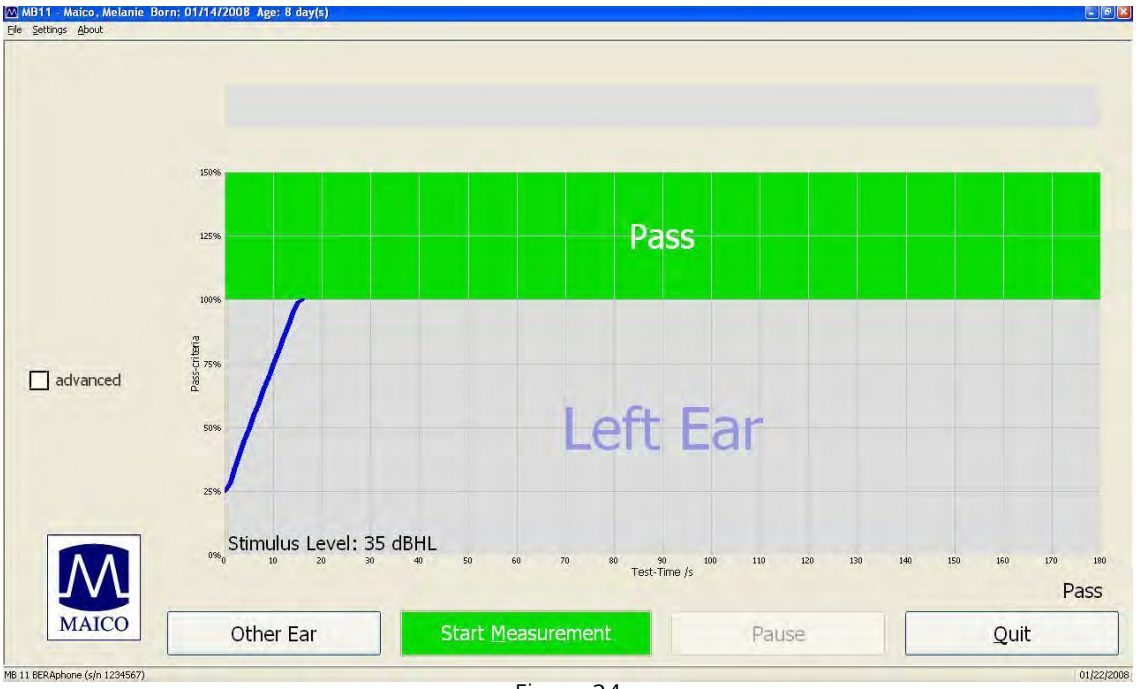


Figure 24
MB 11-program “Test result PASS”

During the test, the indication line for pass criteria in the diagram continues to move upward on the graph until the green area is reached. Then 100% of the pass criteria is fulfilled and the test was passed successfully. The result "PASS" is shown in the green area (see Figure 24).

However, a “PASS” result using this instrument is not an indication that the full auditory system is normal. Thus, a passing result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about normal hearing persist.

When you leave the test screen by clicking on the button “QUIT” the test result will be stored automatically in the data base.

5.4.6 Test result "Refer"

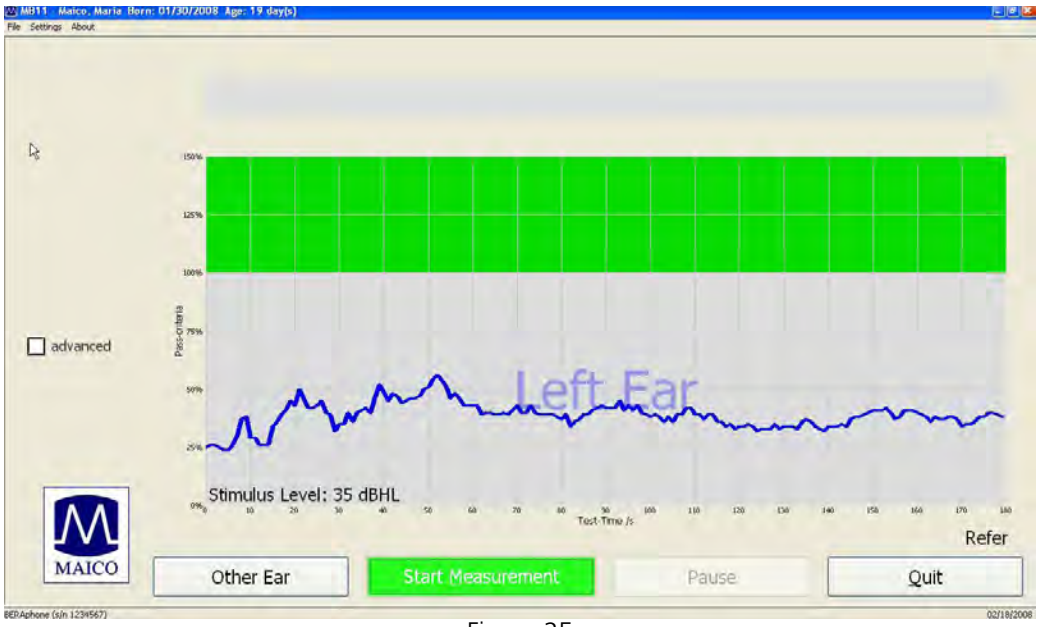


Figure 25
MB 11–program Test result "REFER"

If 100% of the pass criteria is not reached after three minutes test time, the probability for a hearing loss is very high. This needs to be assessed by a follow-up diagnostic. The small status window in the lower right of the screen shows the test result as "Refer". (Figure 25)

If you cannot exclude bad test conditions as a reason for the "Refer" you should retest. If the test was done without any errors, the newborn should be referred for a "follow up" audiological examination by experts.

If parents are watching the test, they should be instructed that the test result is not a detection of an eventual hearing loss. **But to exclude the possibility of a hearing loss a "follow up" is mandatory.**

When you leave the test screen by clicking on the button "QUIT", the test result will be stored automatically in the data base.

5.4.7 Test result "Abort"

Figure 26
Test result "Abort"

If the test is aborted, a pop-up window with reasons appears. After confirming a reason the result "Abort" with reason is shown in the green area (see Figure 26). When you leave the test screen by clicking on the button "QUIT", the test result will be stored automatically in the data base.

5.5 Binaural Screening

With the MB 11 Classic a binaural testing is made possible. This allows both ears to be screened at the same time, with screening time generally under 20 seconds for both ears.

5.5.1 Preparing for a Binaural Screening

Preparing the patient as described in chapter 5.1.

When the patient is ready, click on "Other Ear" on the measuring screen until "Binaural" (in pink letter) is displayed. Click on "Start Measurement" to begin measurement.

5.5.2 Binaural Screening Result

Unlike monaural test, the binaural measurement will display two coloured lines, red for the right ears and blue for the left. Both ears are screened for hearing loss at 35dBnHL. If responses are detected from both ears, the lines move upward until it reaches the 100% area coloured green, then the result will be shown as "PASS".

If no response is detected, the lines do not reach the 100% green area after 180 seconds, the result will be "REFER".

NOTE: For Binaural Testing, a "PASS" result can only be obtained when the 100% pass criteria are reached by **both ears** (Figure 27). If either of the ears fails to reach the 100% pass criteria after three minutes, even if the other ear had reached the 100% pass criteria, the screening result will be shown and recorded as "REFER" for proper follow-up actions (Figure 28).

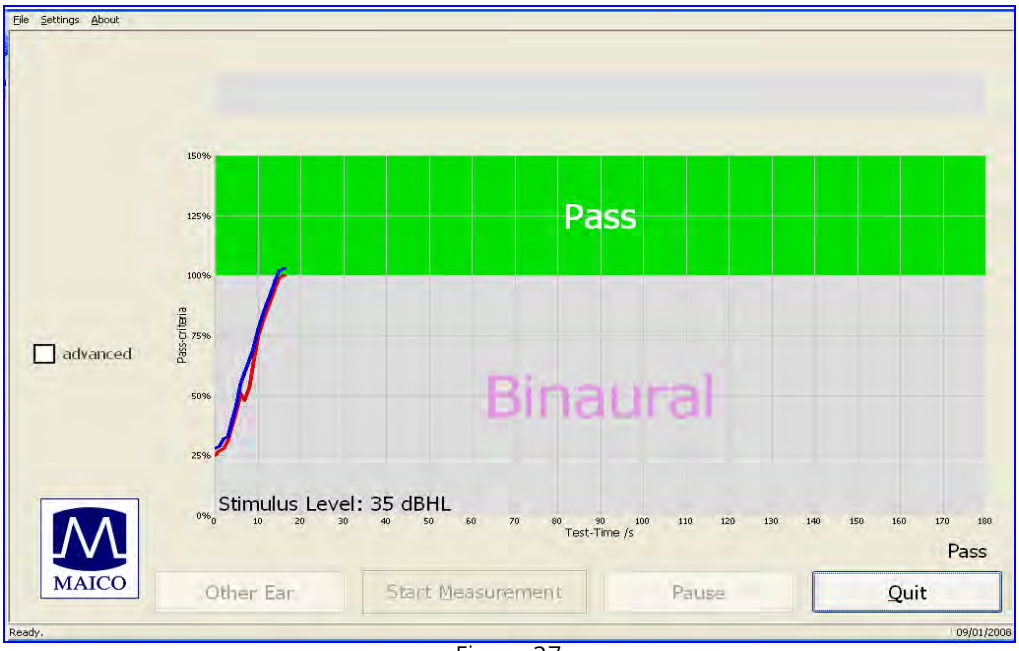


Figure 27
MB 11 – Binaural screening program Test result "PASS"

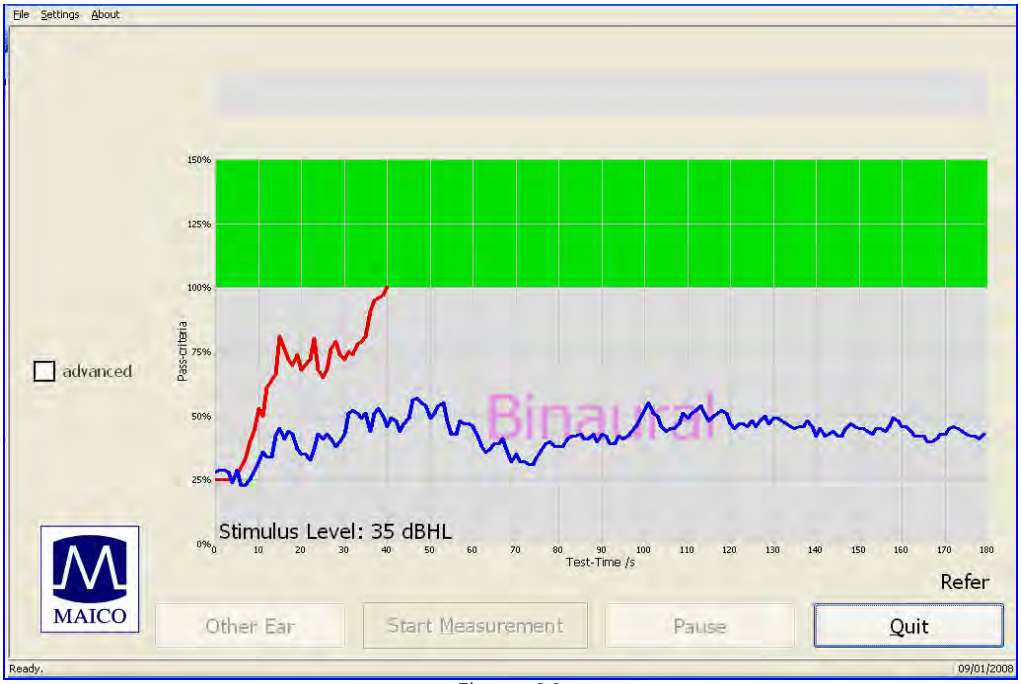


Figure 28
MB 11–Binaural screening program Test result "REFER"

6 Tracking

The MB 11 Classic has been designed for Newborn Hearing Screening (NHS). Vital to the success of NHS Programs is an effective tracking and follow-up protocol of the tested patients.

The new MB 11 software has an export function which allows export of relevant data into different database programs and into HI*TRACK, a database designed specifically to support Early Hearing Detection and Intervention programs.

All patient data from the start screen or the Today's list and the measurement results will be stored automatically in the tracking export file. If you are working with tracking software this software will recall your tracking data. The file will be renamed to make sure, that the data will not be sent twice.

For further information contact the producer of your tracking software or your tracking center.

6.1 Tracking Settings

Choose "Settings", Sub menu

"Tracking System", option

"HI*TRACK"(Figure 29).

Figure 29
Menu setting HI*TRACK

Then click Settings/Tracking System/Settings and the input window (Figure 30) will open.

Define the settings of the database directory. Put in the name of the clinic, screening location and physician.

The examiner-id will be assigned automatically.

The patient-id can be generated by the system (automatic pat.id). The system can also check the patient id by check sum (check pat.id)

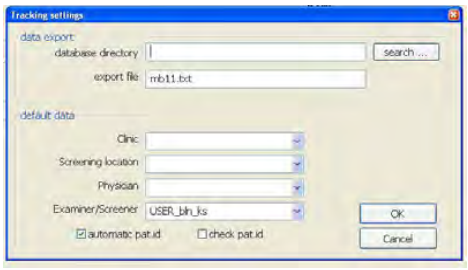


Figure 30
Input window Tracking settings

6.2 Input of Tracking data

If Settings/HIGH*TRACK is activated, the function button "Tracking" appears on the start screen:

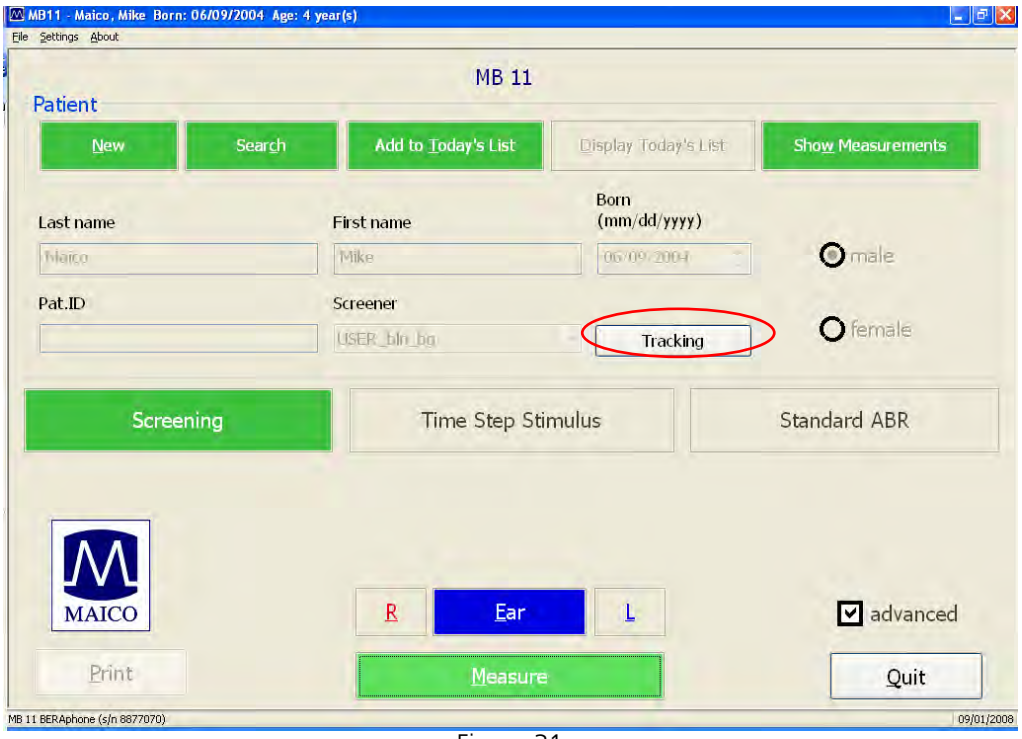


Figure 31
Start screen with function button Tracking

Click on Tracking to open the input window (Figure 32).

Patient data will be copied from the start screen.

Fill out the form. Activate the check box "Parents permission for screening"

Depending on your tracking system even more data may be required. Click on the "advanced" button to open the next input window:

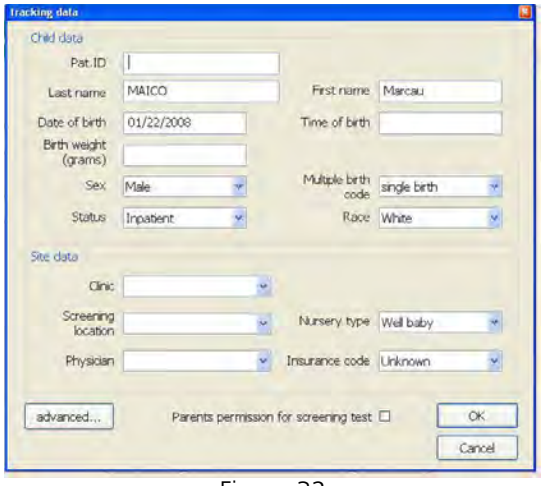


Figure 32
Tracking data

6.3 Advanced Tracking data

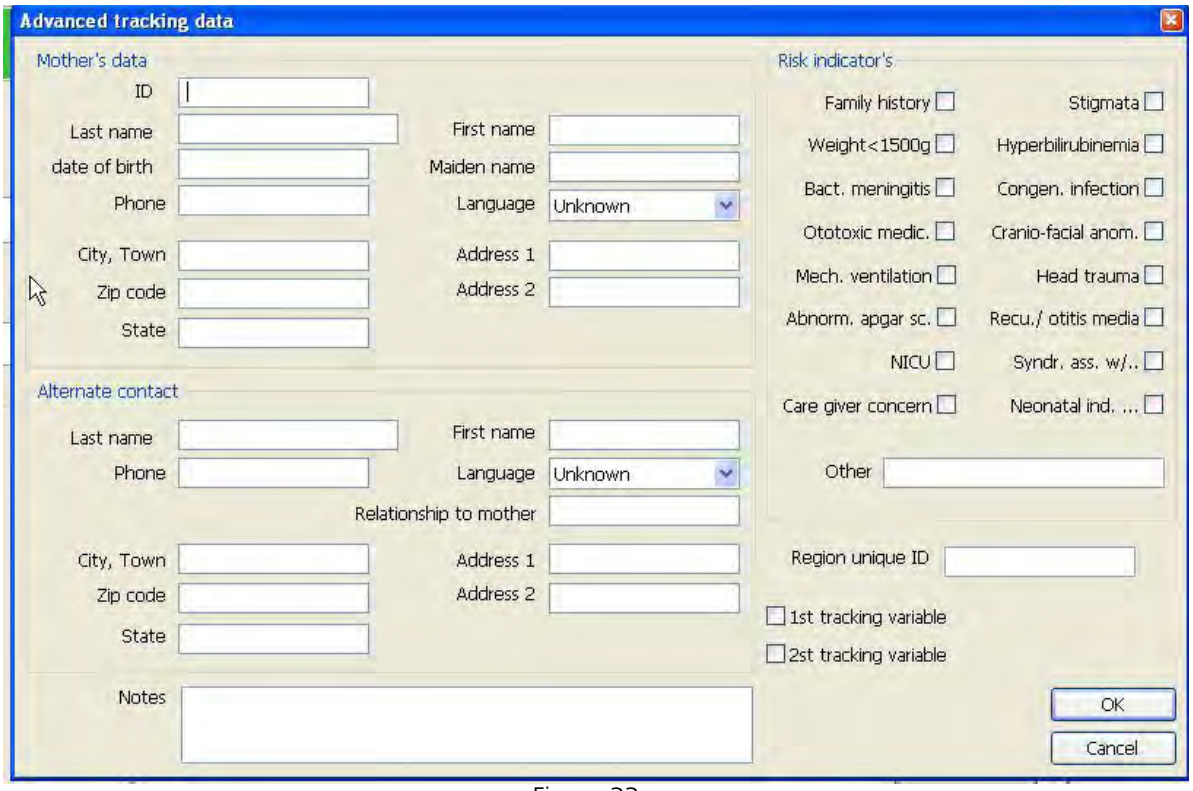


Figure 33
Advanced tracking data

Input of advanced tracking data is optional and depends on the requirements of the responsible tracking center.

6.4 The export functions of the MB 11 database

The MB 11 Classic software allows the export of data from the database for detailed analyzing. 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. Choose the data for export and click "Export" Type in the name of the export file and the location for storage. Click "ok".

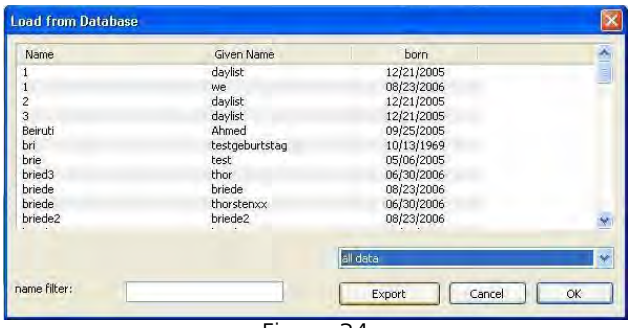


Figure 34
Load from Database

7 Follow up measurements

Not available for the MB 11 Classic Screener.

Diagnostic test for the “follow up” after a REFER result can be enabled by clicking on the box "advanced" on the lower right of the start screen. The start screen now displays two additional tests: “Time Step Stimulus” and “Standard ABR”.

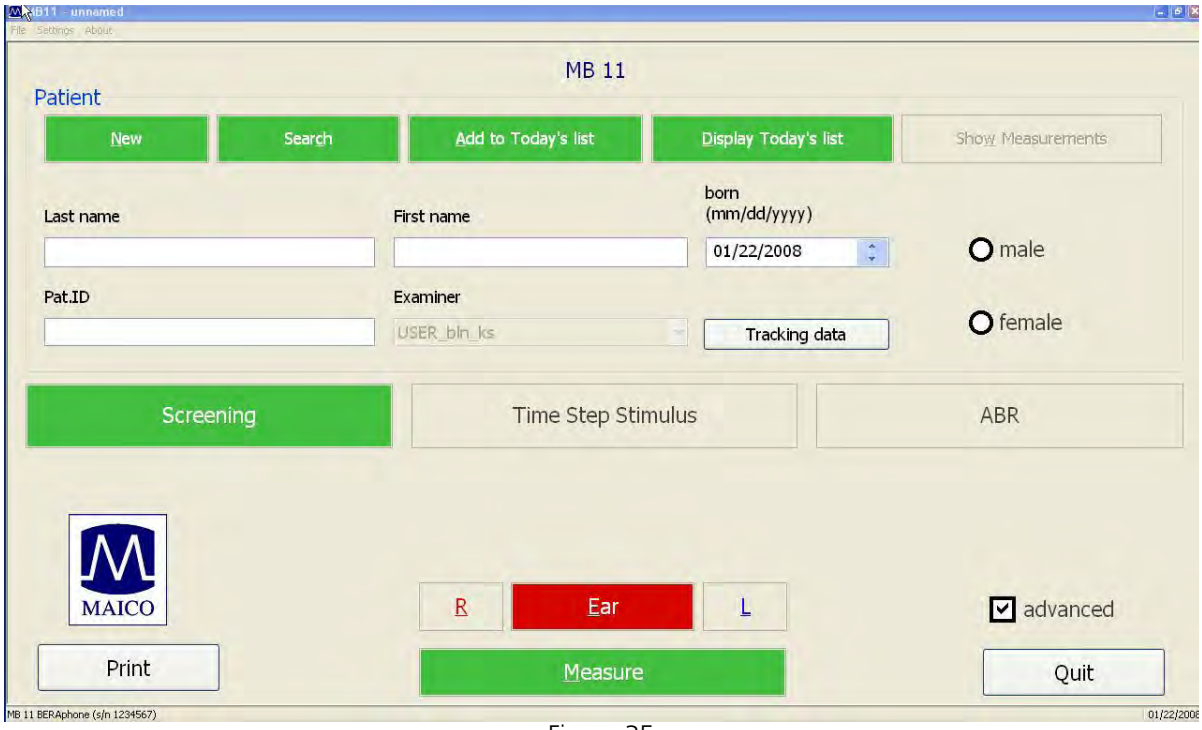


Figure 35
MB 11 – program start screen in advanced mode

IMPORTANT NOTE: These two diagnostic tests are only available for single-ear testing and should only be used by an experienced expert! This offers the possibility of an immediate diagnostic evaluation of hearing after a screening result of “REFER” has occurred. Using the Standard, these tests are done under the same test conditions as the screening test. For this purpose, you can choose between Standard ABR with adjustable intensity or the Time Step Stimulus method which tests six intensities simultaneously.

Unlike screening, the electrode behind the Mastoid should be placed accordingly, corresponding to the ear being tested (i.e. right Mastoid for right ear and left mastoid for left ear). Under good test conditions it is possible for an advanced tester to perform these measurements with a calm or sleeping baby or patient. If you are not able to get good test results you should keep the baby calm by possibly feeding or sedating it. You could also consider testing the baby another time when the baby is sleeping.

7.1 Testing with the Time Step Stimulus

7.1.1 The Time Step Stimulus

In the "Standard ABR" test the evoked potential is measured for individual clicks of a defined sound intensity. Instead of individual clicks, the step stimulus uses "packets" of 6 clicks following each other very rapidly in which the intensity increases in 10 dB increments for each click in the packet (Figures 36 and 37). As the entire "click packet" is presented in only 25 ms, the patient is not aware of the complex composition but it is still processed with a high level of time precision in the brainstem. If the six sound pressure levels of the click chain are arranged in such a way that the hearing threshold lies within this sound pressure range, then a single averaging suffices to "objectively" determine the hearing threshold, as those clicks below this level of course do not evoke any potential.

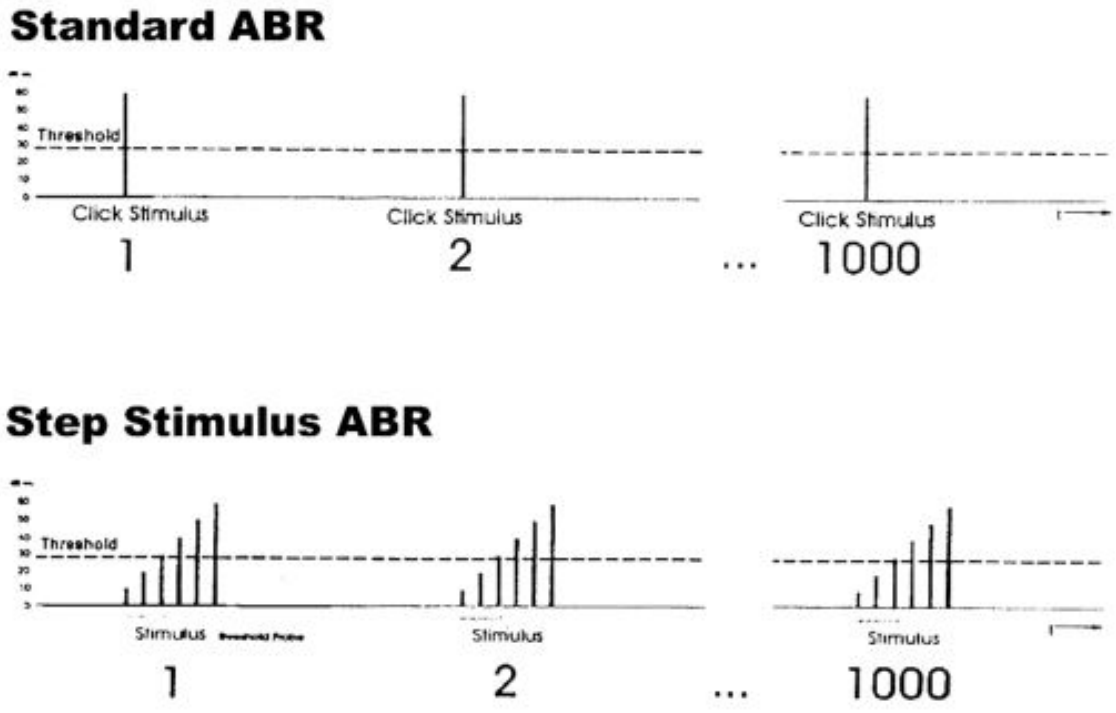


Figure 36
Stimuli Presentation with Standard ABR and Time Step Stimulus ABR

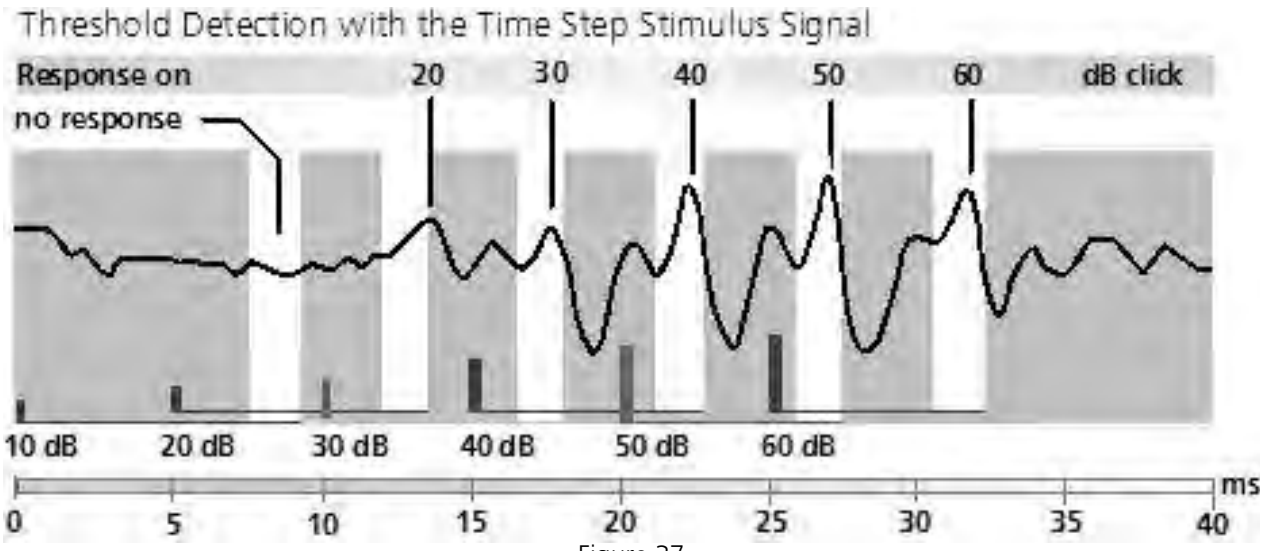


Figure 37
Typical ABR-Response with the Time Step Stimulus Signal

The white bars show the frame within which wave V for each of the evoking clicks is expected. Click intensities are located above the corresponding column (white bar).

The step stimulus curves permit a direct reading of the ABR hearing threshold. The white bars with the anticipated latency of the relevant wave V are very useful. The center of these white bars is set for the timing of the normal latency intensity function and is shifted according to the age of the patient (as entered in the patient data).

Therefore: The latencies of the wave V's for an individual must always be in the same temporal relationship to the bars. It is not possible for wave V at 50 dB for example to be at the end of the 50 dB bar but for 40 dB at the beginning of the 40 dB bar.

From the highest intensity onwards, waves must be traceable without a gap through to the threshold. The amplitude of the highest intensity can turn out to be slightly smaller but must still be recognisable. It is not possible for the 60 dB and 50 dB waves and also the 30 dB wave for example to be clearly recognizable but no response identifiable at 40 dB. In this case, the wave at 30 dB is determined to be artefact and not a reliable evoked potential. If necessary, repeat the measurement to clarify the situation. A good indication for genuine ABR-potentials is a peak one column width before the wave V. This is the wave III, but it is not always well formed.

7.1.2 Testing with the Time Step Stimulus

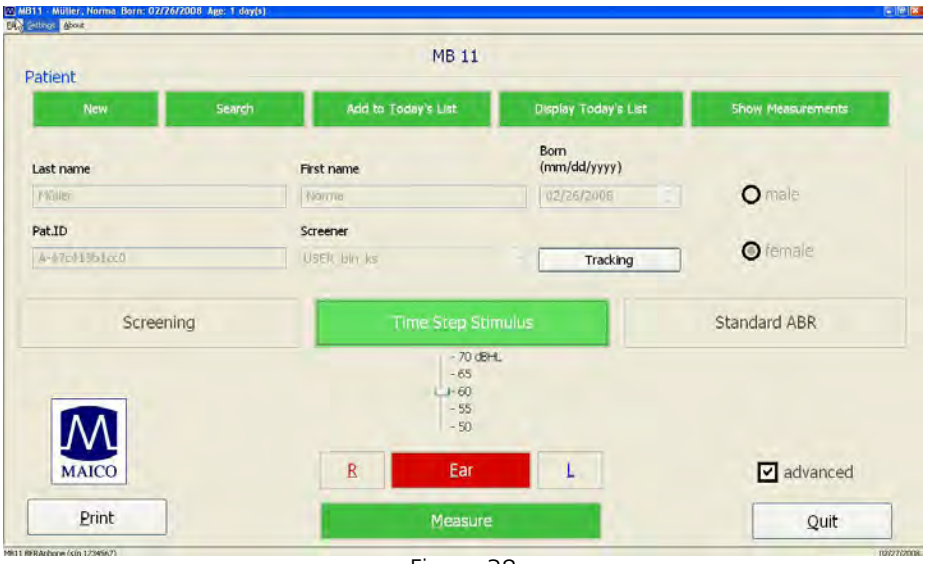


Figure 38
Program start screen with Time Step Stimulus

After clicking on the button "Time Step Stimulus" the start screen, shown in Figure 38 is displayed. You can select the maximum intensity of the time step stimulus test signal with the "Level slider" between 50 dBnHL and 70 dBnHL. The default value is 60 dBnHL . If the baby reacts sensitively to loud signals, you should select 50 dBnHL.

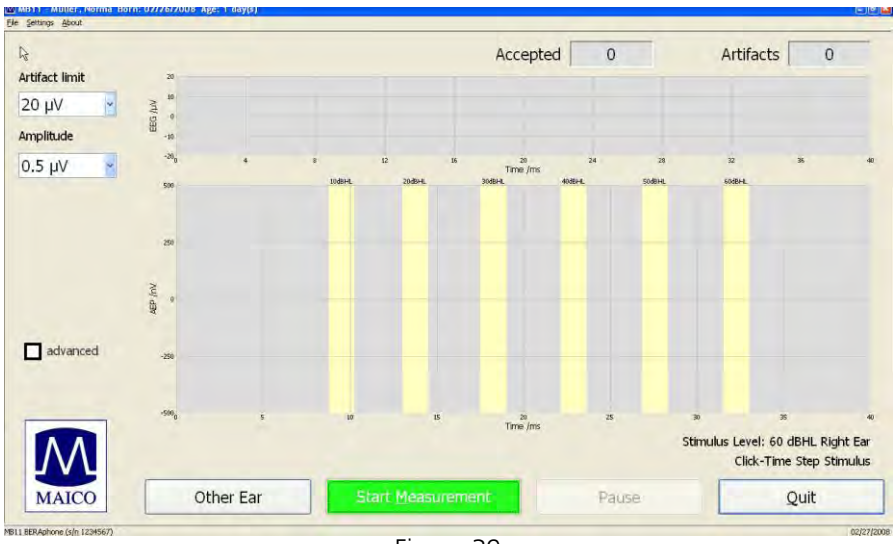


Figure 39
MB 11 - TSS Test Screen with Measurement

After entering or loading the patient data select the ear to be tested. Click on the "Measure" button and the test screen as shown in Figure 39 appears.

The EEG scaled in µV is displayed at the top of the screen. If the EEG level is within the selected Artifact-limit (see box at the top left of the screen) a measurement is performed and the number in the box "Accepted" increases by one.

If the EEG signal is larger than the Artifact-limit, this measurement will not be used and the numeric value indicated as" Artifacts" increases by one.

If the evoked potentials are large you can change the Artifact-limit with the mouse by clicking on the arrow right of the Artifact-limit box on the top left of the screen. Values between 5 µV and 50 µV are selectable.

It is important to have a good quality EEG during the test. This is especially important when there is a suspected hearing loss or the estimated evoked potentials are low.

In this case, do not increase the artifact threshold, but try to calm the baby. You could also consider testing the baby at another time when the baby is sleeping.

Figure 40 shows an example of a test screen for the Time Step Stimulus. The analysis time is 40 ms. The corresponding wave V responses should occur in the range of the respective white areas. Above the white areas are the corresponding click levels. Blue stands for the left ear and red for the right ear. The magnitude of the curve can be adjusted by changing the Amplitude value from the pull-down menu on the left side of the screen. Values between 0.1 µV and 1.1 µV are selectable.

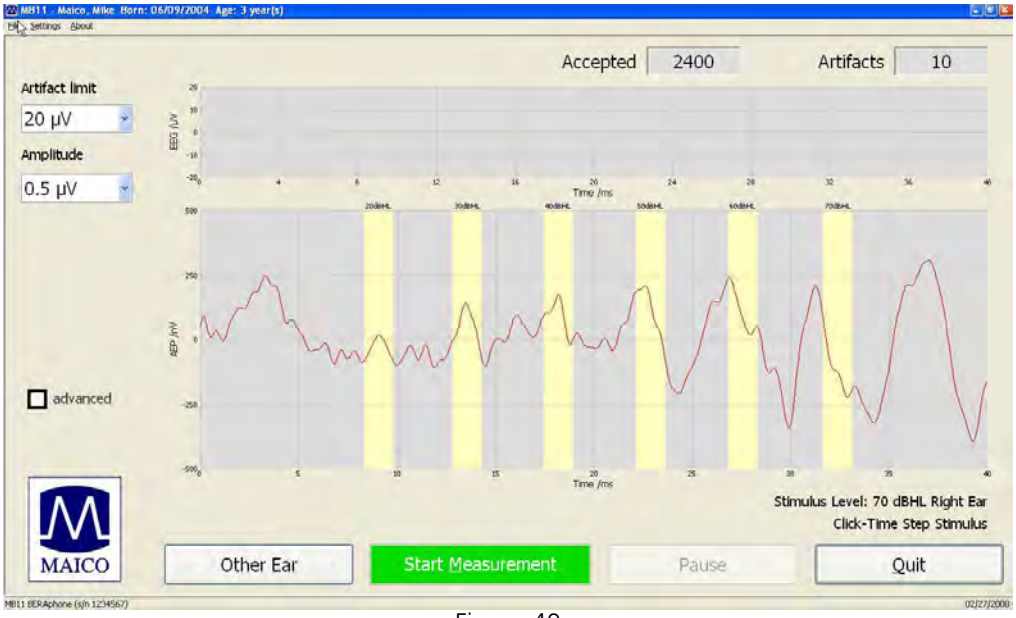


Figure 40
MB 11 - program result "Time Step Stimulus"

7.1.3 Advanced display Time Step Stimulus Test

The advanced display mode can be entered by clicking on the box **"advanced"** on the left side of the test screen. This test screen contains additional information and features. This mode is available for the current test result as well as for the stored data.

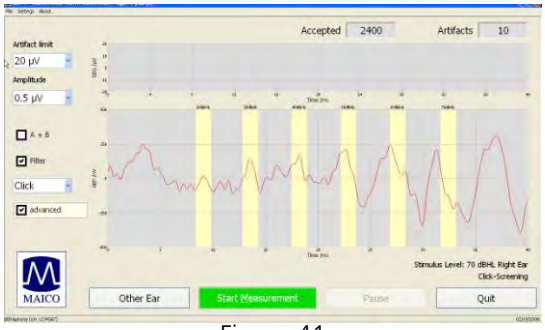


Figure 41
Test screen advanced

Figure 42 and 42 display the test result shown in chapter 7.1.2, Figure 41, in the advanced display format.

During the test, the single measurement sweeps are stored alternatively in the A- and B-Buffer. It is possible to display data within the A- and B-Buffers separately, by selecting the "A+B" function located at the left of the test screen. When this is selected, the averaged data will be displayed at the bottom and the data stored within the separate A- and B-Buffers will be displayed at the top.

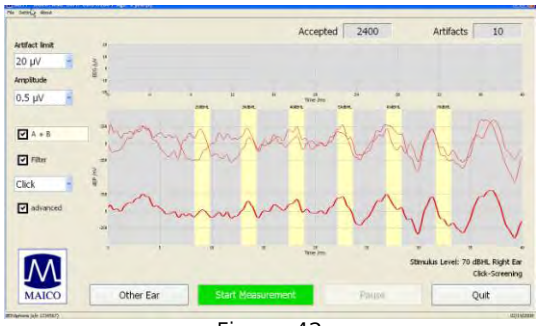


Figure 42
Test screen advanced A+B

The "Filter" function allows you to smooth the curves on the screen. The cut-off frequencies of the filter are 163 Hz and 1930 Hz.

The boxes for the adjustment of the artifact limit and the amplitude of the AEP display are located on the upper left part of the screen (see Figure 43).

The actual value of the artifact limit is shown under **"Artifact-limit"**. For example, in Figure 36 the actual artifact limit is 20 µV. The artifact limit can be adjusted by clicking on the arrow right of the Artifact-limit box. Values between 5 µV and 50 µV are selectable. The display magnitude of the AEP's (waves) is shown under **"Amplitude"**. For example, in Figure 36 the actual amplitude is 1.1 µV.

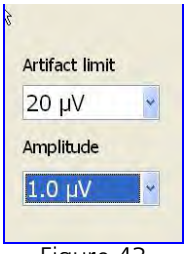


Figure 43
EEG-Quality window

The amplitude can be adjusted by clicking on the arrow right of the Amplitude box. Values between 0.1 µV and 1.1 µV are selectable.

7.2 Testing with Standard-ABR

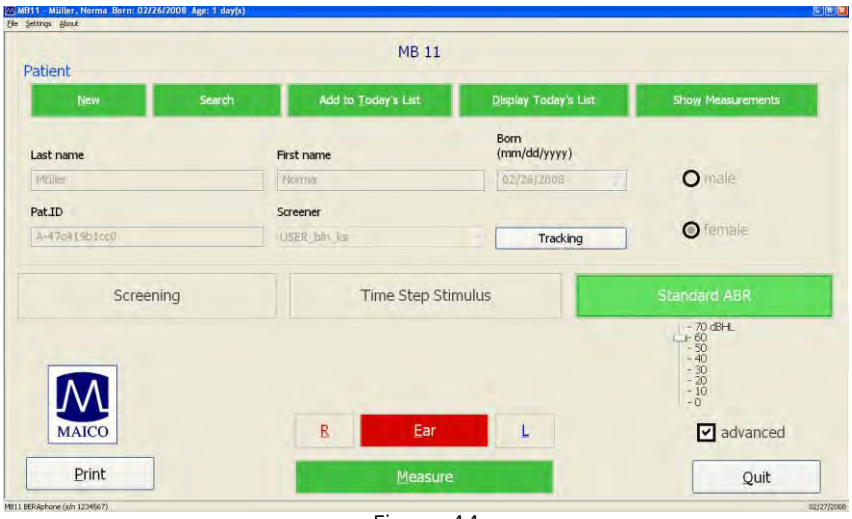


Figure 44
MB 11 - program start screen in expert mode "Standard ABR"

After clicking **"Standard ABR"** on the start screen, an intensity level selector appears as shown in Figure 44. The intensity level for the click can be adjusted between 0 and 70 dBnHL using the slider adjustment. Next, select the Ear to be tested by clicking "R" for right or "L" for left ear, and then click "Measure" to begin the test. The screen shown in Figure 45 will appear.

In contrast to the time-step stimulus, the Standard ABR will only test at a single intensity. When sufficiently high Stimulus levels are used, all waves I – V should be visible. Other options and displays shown in this Standard ABR screen are explained in detail in chapter 7.1.2 of this manual.

Figure 45
MB 11 - program test screen "Standard ABR"

8 Recommended literature

Audiometric Interpretation:	A Manual of Basic Audiometry Lloyd, Lyle L. and Kaplan Harriet, Baltimore: University Park Press, 1980
Auditory Disorders:	A Manual for Clinical Evaluation Jerger, Susan and James Jerger, Boston: College Hill Press, 1981
Handbook of Clinical Audiology	Katz, Jack Baltimore: William & Wilkins, 1994
s Audiology Desk Reference	Roeser, Ross J. New York /Stuttgart: Thieme, 1996
Auditory Diagnosis	Silam, Shlomo and Silvermann Carol A., San Diego/London: Singular Publishing Group,1997
Rapid threshold estimation using the "chained-stimuli" technique for auditory brain stem response measurement 1991	Hamill T.A., Hussung R.A. and Sammeth C.A., Ear and Hearing, 12(4): 229 - 234,
Automated auditory response detection: statistical problems with repeated testing	Stürzebecher E, Cebulla M and Elberling C. Int J Audiol, 42(2): 110-7, 2005
Objective Detection of Auditory Steady-State Responses: Comparison of One-Sample and q-Sample Tests	Cebulla M, Stürzebecher E and Elberling C. J Am Acad Audiol 17:93-103,2006
New efficient Stimuli for Evoking Frequency-Specific Auditory Steady State Responses	Stürzebecher E, Cebulla M, Elberling C and Berger T J Am Acad Audiol 17: 448-461, 2006
New Click-like Stimuli for Newborn Hearing Screening	Cebulla M, Stürzebecher E and Elberling C. J Am Acad Audiol,

9 Installation and Settings

9.1 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 Classic. 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 bothers the function of parallel used USB devices, try another USB port to change the USB hub output.

9.2 Installation of MB 11 Software

Boot the PC and wait until the operating system finishes the start process. Please note that the MB11 is only supported by MS Windows 2000 SP4 on up and MS Windows XP SP1*. We strongly recommend MS Windows XP. The following installation guide bases on the use of MS Windows XP.

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 with the USB port. Connect the MB 11 with the USB port of your PC and check that the red LED lights up.

If this LED does not light up, ensure that your USB port supports high-powered USB devices or change the USB port and try again. Also see the note above about using USB ports. After a few seconds, the system will show a message about a newly found USB device “MAICO MB 11”. Put in the installation CD and follow the instructions. You can also install the software by start of the “setup.exe” direct from CD.

9.3 Computer Settings for optimal performance

To get the best possible power for the MB 11 Classic, it might be necessary to change the properties of the used computer / notebook systems. For questions please contact your local dealer.

10 Care and maintenance of the instrument

Cleaning the instrument

The MB 11 Classic requires minimal cleaning. However, it is a good practice to always check and make sure the instrument is clean and the tubing are free of clogging from dirt or oil.

Make sure that the cables are not broken or tangled or oppressed in any manner, as this may destroy the wire embedded within.

To clean the MB 11 and other accessories use a damp soft cloth with some warm soapy water or detergent. Please ensure that no liquid run into the instrument.

11 Trouble shooting

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

1. Instrument does not turn on.
Solution:
Are all cords and the plugged in correctly and the USB plug well fitted in the jack?

Please check the USB specification.

2. The measurement is running properly but with large regular EEG fluctuations.
Solution:
Can an improvement be effected via slightly moving the electrodes?

3. No potential or only unclear potential is registered.
Solution:
Listen briefly to the earphone and verify that the click stimulation is present.

Ensure that the EEG was not interrupted by polarization of the electrodes, which is easy to identify by extremely smooth curves shown in the "EEG" section and without any reaction to gentle movements of the MB 11 on the baby's head.

A simple test is to place the electrodes of the MB 11 on the inner side of your left arm. The skin of the arm should be prepared by cleaning. The current variation is determined by the muscle potentials of the arm. It is important to test that the muscle potentials of the arm are being recorded correctly, that means contraction yields larger potentials, relaxation smaller ones.

12 Technical Data

CE 0123 The MB 11 Classic is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.

Standards:	**IEC 601-1, IEC 645-3**
Test signals:	**Screening: CE-Chirp® Stimulus** **Time Step Stimulus (Opt.): Click** **ABR (Opt.): Click**
Stimulus rate:	**Screening 93/s; 20/s** **Time Step Stimulus, Standard ABR 14/s**
EEG filter:	**125 Hz - 1,25 kHz**
Sample rate:	**16 kHz**
Quality control:	Integrated indicator in Standard and display in software with signal quality display or with EEG
Environmental conditions:	**+ 15 ... + 35 C / + 59 ... + 95° F (operation)** **+ 5 ... + 50 C / + 41 ... + 122° F (storage)** **Maximum humidity 75 % (operation)** **Maximum humidity 90 % (storage)**
Probe (Standard):	
Speaker:	**Integrated, dynamic wideband speaker (8 Ω)**
Electrodes:	**Reusable, stainless-steel electrodes with gel protectors**
Level range:	**0 to 70 dBnHL**

Preamplifier:	**Integrated, 87 dB Amplification (23.000x)**
Quality control:	**Integrated indicator red (signal quality low), green (signal quality OK)**
Weight:	**300 g**
Instrument (MB 11 Box):	
Power Supply:	**via USB port of computer**
Power Consumption:	**max. 400 mA**
Weight:	**165 g**
Dimensions:	**W x D x H: 12 x 9 x 3 cm**

Computer requirements (computer not included):

Type:	**Intel Dual Core, Atom 1.5 GHz**
RAM:	**Minimum 1 GB RAM, 2 GB RAM with Windows 7**
Hard disk:	**Minimal 5 GB free diskspace**
Interface:	**USB 1.1 or 2**
Display:	**1024 x 768**
Operating system:	**Windows XP Professional (min. SP 3)** **Windows 7, Professional 32/64 Bit or Ultimate 32/64 Bit** **.NET-Framework 3.5 SP 1**

Mains supply:

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).

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.

Standard accessories:

1	**MB 11 Classic with amplifier with jacks for three electrodes and two sound transmitters**
1	**set of Vertex, Ground and Mastoid electrode cables**
1	**set Left and Right Insert Phones**
1	**packet of 25 single-use, adhesive electrodes**
4	**additional disposable ear tips of different sizes**
1	**USB connection cable**
1	**Carrying bag**
1	**CD Installation Software**
1	**User Manual**

Connecting plugs:	Connection	Specification
USB socket	USB	USB 1.1 max 400 mA

Figure 46
Connector of MB 11

13 Scientific Background Information

13.1 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.

Up to now 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.

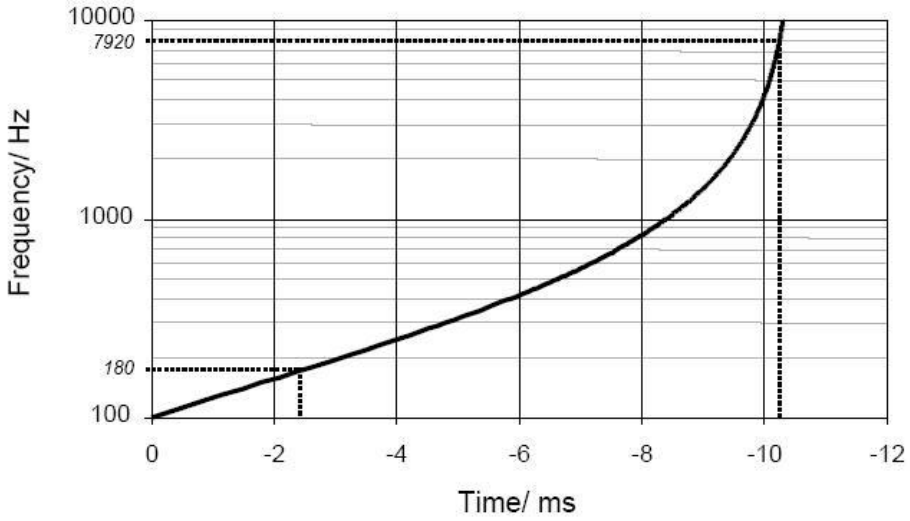


Figure 47

Figure 47 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 the amplitude that would result from a more synchronous excitation.

The new CEC Stimulus implemented in the MB 11 Classic 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.

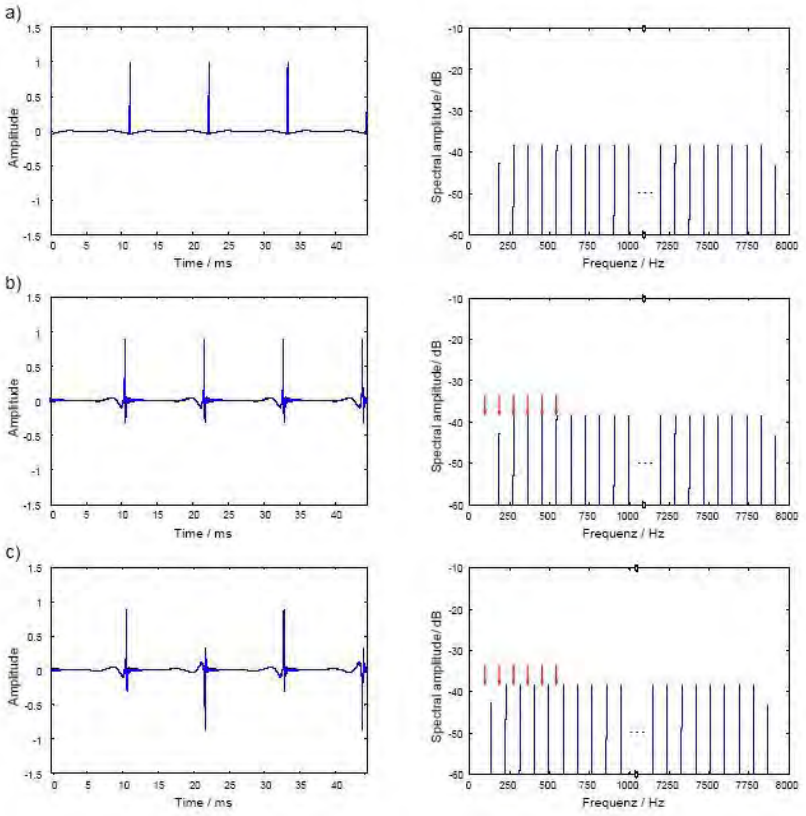


Figure 48

Figure 48 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 48 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.

Figure 48 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 Classic 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 at ears of dead bodies 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 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 48 c) 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.

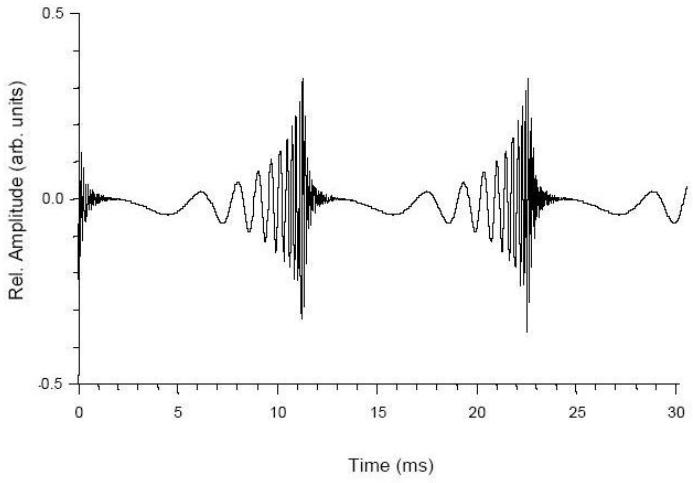


Figure 49 – CE-Chirp®

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 dBnHL stimulus level, usually used for AABR newborn hearing screening, we found a high specificity and short test time in newborns. The combination of the CE-Chirp® and the Standard leads to very short examination times for newborn hearing screening.

13.2 Sensitivity and specificity of the Auditory Steady State algorithm

For a successful universal newborn hearing screening (UNHS) program, it is essential to have a high rate of detection of severe hearing losses and a low referral rate of babies with normal hearing.

For better understanding, the terms Sensitivity and Specificity are explained below in general and also specifically related to the ASS algorithm, which is implemented in the MB 11.

Sensitivity = **Percentage of positive results (Refer/Fail) for newborns with severe hearing disorder.**

Specificity = **Percentage of negative results (Pass) for normal hearing newborns.**

The ASS regarding <u>specificity</u>:
Clinical investigations of newborns in a hearing screening program do normally not produce data from which an unbiased estimate of the specificity can be calculated. Therefore the precise value of the Specificity cannot be given.

Besides Hearing Loss, restless babies during the test or electrical distorting fields in the test facility can lower the Specificity.

Regarding <u>sensitivity</u>:
To assess the sensitivity, usually a significantly high number of babies with known hearing loss must be tested.

Sensitivity estimate of the ASS:

Due to the high stimulus repetition rate of 93 Hz, a periodic signal (ASS response), will be generated from the auditory system (see Figure 34). The averaging result in the time domain shows a clearly visible wave between 8 and 10ms with a broader part between 2 and 6ms.

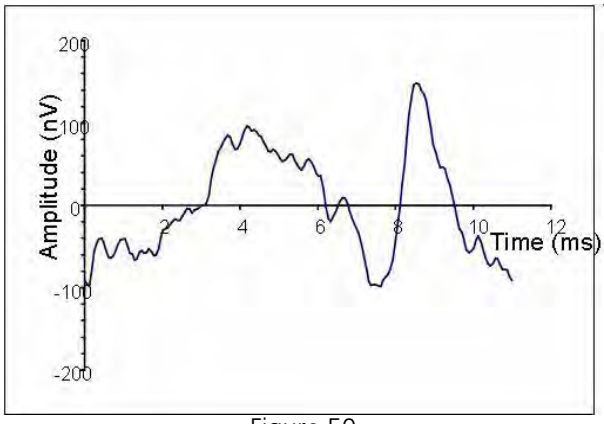


Figure 50
Example of one period of a "Auditory Steady State" response in the time domain (stimulus repetition rate 93 Hz).

The ASS detection algorithm operates in the frequency domain. After transformation of the measured response into the frequency domain, the periodical response is represented by a relatively low number of harmonics (see Figure 51).

All harmonics below 800 Hz are considered by the test statistic (at a click rate of 93/s, 8 harmonics are included). Between the harmonics a large

number of spectral components (at a resolution of 1 Hz approx. 90 spectral components) are located which contain no information about the response, only noise.

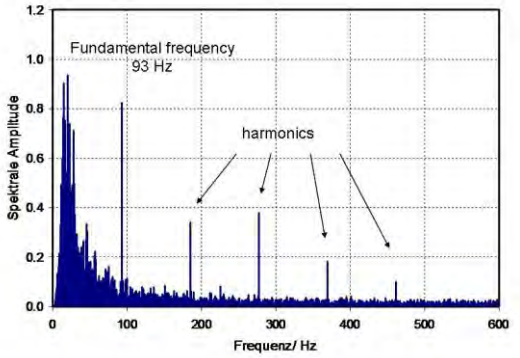
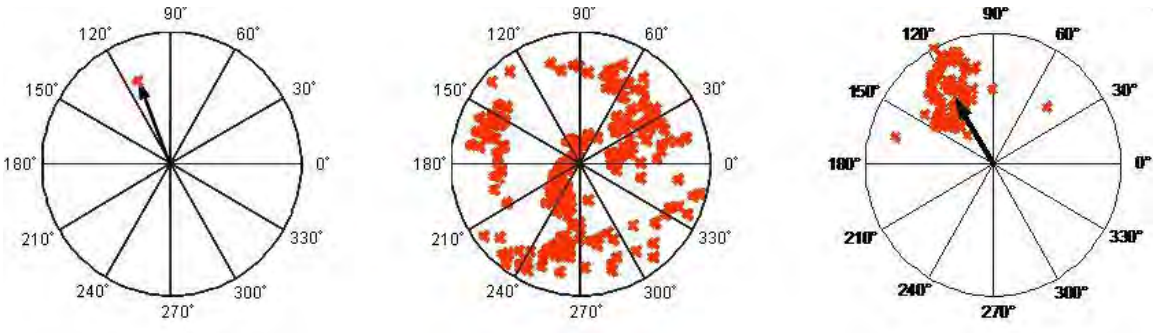


Figure 51
"Auditory Steady State" Response in the frequency domain.

In normal hearing newborns with a good ASS-response the amplitude of the response harmonics are significantly higher than the noise components. (If a hearing loss is present, the harmonics would not be present significantly higher than the noise components, and so would just blend in with the noise floor.)

The statistical test decision is based on a comparison of calculated test values from the measured data with a so called critical test value. To perform this calculation the continuous recorded EEG is separated into epochs of one second. Only epochs having passed the artefact criterion will be used for further analyzing. Each accepted epoch is transformed into the frequency domain by Fast Fourier Transformation (FFT). In the frequency domain the evoked response is described by a certain number of spectral harmonics as described above. Each spectral component is characterized by a phase angel and amplitude of the corresponding sinusoidal wave. These data can be displayed as vectors in a polar coordinate system (see Figure 52A). If no response to the stimulus is present the epoch contains only noise. If this is the case, the vector endpoints in the polar display show a random distribution (see Figure 52 B).



A: single spectral component

B: "No response" random disribution

C: "Response present" spectral lines of harmonics grouped together

Figure 52 - Amplitude and phase angel of the sinusoidal waves corresponding to the spectral lines displayed in the polar coordinate system

Calculate the critical test value:
The algorithm uses the phase angle and the amplitude of the first eight harmonics of the response to calculate the test value. The statistical test is carried out in the following way: The first test value will be calculated with a sample of the first 15 epochs. If the test value is less than the critical test value the sample will be increased by one epoch and tested again. This procedure will be continued until the test value is equal to or greater than the critical test value. Then the testing is stopped with a "Pass" result. If the critical test value is not reached after 120 epochs, the test will stop with a "refer" result. The critical test value used by the algorithm was calculated by a Monte Carlo simulation. A very large amount of random data was generated. The critical test value was then determined with the frequency distribution of the test values calculated for this data.

The frequency distribution of the test values is a good estimate of the probability density function of the null hypothesis H0 (no response present).

With the H0 the critical test value for a given error of the first kind (error probability α, 100- α = sensitivity) can be determined. To ensure a high sensitivity, the implemented algorithm works with a critical test value which realizes the very low error probability α = 0,004% (see Figure 53).

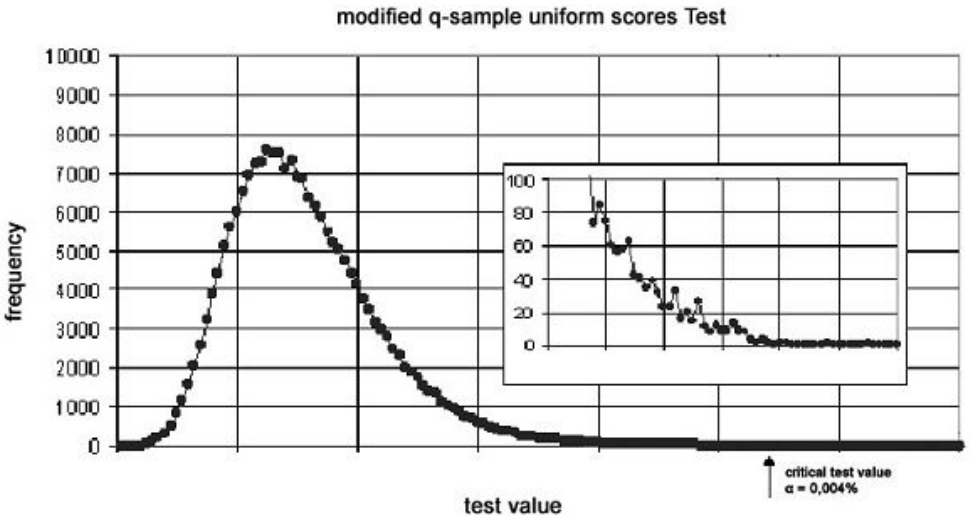


Figure 53
Estimated probability density

In general with a statistical test the reduction of the error of the first kind increases the error of the second kind (the increase of the sensitivity creates a decrease of the specificity), because the probability density functions of the null hypothesis and the alternative hypothesis overlap more or less. But with the ASS algorithm this overlap is very low. The test power is very high because even with the extremely low probability of error the sensitivity for precise response detection is very high.

With the given exact critical test value a sensitivity of nearly 100% (99.99%) is maintained.

A detailed description of the used statistical tests is published by Stürzebecher et al 2003. A procedure to determine the critical test value with using a sequential test procedure is described in Stürzebecher et al 2005.

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

Automated auditory response detection: statistical problems with repeated testing

Stürzebecher E, Cebulla M and Elberling C. Int J Audiol, 42(2): 110-7, 2005

14 Warranty, Maintenance and After-Sales Service

The MB 11 Classic 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 Classic may be repaired only by your dealer or by a service centre recommended by your dealer. We urgently advise you against attempting to rectify any faults yourself or commissioning non-experts to do so.

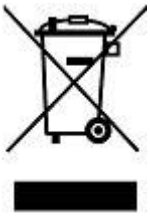
In the event of repair during the guarantee period, please enclose evidence of purchase with the instrument.

In order to ensure that your instrument works properly the audiometer should be checked and calibrated at least once a year. This check has to be carried out by your dealer.

When returning the instrument for repairs it is essential to send all the components, as well.

Send the device to your dealer or to a service center authorized by your dealer. Please include a detailed description of faults.

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



The customer is committed to dispose of the delivered goods according to the rules stipulated by law. The costs for disposal have to be paid by the end-user.

15 Safety Regulations

15.1 Electrical Safety: The MB 11 Classic 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.

15.2 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 centre. In accordance with the regulations of the EU medical directive we will drop our liability if these checks are not done.

15.3 Device control: The user of the instrument should perform a subjective instrument check once a week. For your own security, you should copy the printout of the test and store it in your files.

15.4 User Instruction: The MAICO MB 11 Classic is designed to be used only by skilled personnel (Audiologists, physicians or other trained personnel. No person should attempt to use this instrument without the necessary knowledge and training to understand how this equipment is to be properly utilized and interpreted.

Specifications are subject to change.

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