



MB 11

- Patented **CE-Chirp**[®] stimulus reduces test times
- Virtually “no cost” or low cost supplies reduce program costs
- Classic and **BERAphone**[®] hardware models offer choices to meet your program needs

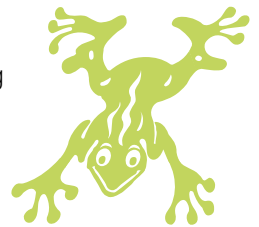
ABR Screener

Excellence in Newborn Hearing Screening

MB 11 BERAphone® - No Costly Disposables



- Re-usable electrodes and integrated earphone reduce operating costs significantly
- Eco-friendly technology reduces medical waste
- Baby-friendly - no discomfort caused by pulling adhesive disposables off of baby's skin



child friendly / eco-friendly

The Only Automatic ABR Screener without Adhesive Electrodes



Apply electrode gel at the 3 electrode sites on the baby's head



Place a drop of electrode gel on the integrated electrodes



Position the BERAphone® ear cushion around the baby's ear, resting the electrodes on the prepared sites

Why Screen with Automatic ABR?

The auditory brainstem response (ABR) reflects the function of the entire auditory pathway up to the brainstem. While both ABR and the alternate screening technology of otoacoustic emissions (OAE) detect cochlear hearing loss, only ABR detects auditory neuropathy.

Fast Test Times

Fast rate ABR technology with patented CE-Chirp® stimulus leads to faster test times

Compatible with NHS Databases

Comply with reporting requirements (HiTrack, OZ eSP™, Auris, California Data Management Service)

USB-Powered Hardware

Combine MB 11 with a laptop PC to test on battery power; avoid rebooting as you move the system

Custom Cart Package (optional)

Easy transport from room to room; locked compartment for laptop security and storage for supplies



User-Friendly Software



Simple user interface enhances ease of training.



“Traffic light” display for electrode contact and test quality provides easy to understand feedback to screeners.



Patented chirp stimulus and advanced response detection algorithm allow fast test times.



Oz and HiTrack compatible export functions available.

MB 11 Classic - Advanced Technology, Familiar Technique



**Test both ears
simultaneously
to save time**

- Familiar hardware and disposables streamline training of screeners
- Choose between EarCups or in-the-ear tips based on your preference and budget
- Combine Classic and BERAphone® hardware on one system for ultimate flexibility

MAICO's Long History of Hearing Instrument Manufacturing

The Medical Acoustic Instrument Company (later shortened to MAICO) was founded in 1937 in Minneapolis, MN. MAICO designed and produced the first hearing test instrument with a "zero reference level", coining the term "audiometer". For the first time it was possible to accurately measure hearing loss.

Since then, MAICO has continued to design and manufacture screening and diagnostic test instruments for the hearing healthcare industry. The MB 11 BERAphone® and Classic evolved over 12 years of research and development. They are intended to generate auditory brainstem response (ABR)-based measurements for newborn hearing screening, providing a Pass/Refer result. Use of the MB 11 Screener does not require special technical skills or interpretation of results.

MB 11 Combo System – 2 ABR screening devices on one platform

Combine the advantages of the BERAprone® and the Classic into one mega system for an affordable price. The MB 11 Combo includes both device types that connect to one laptop and are supported by the same software. Switch back and forth easily between the BERAprone® and Classic to accommodate the needs of the baby or the screener's preference. Plus, in case of a service issue with one device, you have a built-in back up system so that no baby is discharged without being screened.

Big Savings with the MB 11

How much money can YOUR newborn hearing screening program save by using a MAICO MB 11 BERAprone® or Classic?

**Think your current system is too new for replacement?
Think again!**

Let's See!

Even if Popular Brand X new system price is significantly discounted, the major savings using MB 11 is in the cost of disposables over the life of the system



MANUFACTURER & MODEL	POPULAR BRAND X	MAICO MB 11 CLASSIC USING EARCUPS	MAICO MB 11 CLASSIC USING IN-THE-EAR TIPS	MAICO MB 11 BERAprone®
List price	\$23,995	\$19,190	\$19,190	\$20,390
Disposable cost per baby	\$12.00	\$7.00	\$2.50	\$0.25
Babies screened per year	2000	2000	2000	2000
Annual disposable costs	\$24,000	\$14,000	\$5,000	\$500
Estimated cost savings 1st year	————	\$14,805	\$23,805	\$27,105
Estimated cost savings over 5 years	————	\$54,805	\$99,805	\$121,105
Cost/baby amortized over 5 years	\$14.40	\$8.92	\$4.42	\$2.29
Disposables required	Disposable ear couplers and electrodes	Disposable ear couplers and electrodes	Disposable eartips and electrodes	Electrode gel and disinfectant wipes
Advantages/Challenges		<ul style="list-style-type: none"> • Test both ears at the same time • Very fast test times • Fast learning curve and easy transition for screeners that are experienced using ABR systems using ear couplers • Cost savings = \$\$ 	<ul style="list-style-type: none"> • Fast learning curve for screeners that have experience using in-the-ear tips • Fast test times especially if testing both ears at the same time • Cost savings = \$\$\$ 	<ul style="list-style-type: none"> • Fast test times • Cost savings = \$\$\$\$ • No other ABR device like this in the market; requires learning a new technique & procedure

FDA:

The MB 11 BERAphone® and Classic (Standard) received a FDA 510k number of K082035 in January 2009 with an indications for use statement as follows: The Maico MB 11 with BERAphone® and the MB 11 Standard (Classic) are intended to generate evoked auditory brainstem response (ABR) – based measurements for newborn hearing screening, providing a PASS/REFER result. This does not require special technical skills or interpretation of the results.

Infection Control:

The BERAphone® is considered a noncritical patient care item since it comes into contact with intact skin, but not mucous membranes. Another example of a noncritical patient care item is a blood pressure cuff. For such devices, guidelines from the US Center for Disease Control (CDC)[1] recommend cleaning and decontamination with a low-level disinfectant which can be performed at the location where it is used.

A statement by the CDC in the Guideline document concluded that “virtually no risk has been documented for transmission of infectious agents to patients through noncritical items when they are used as noncritical items and do not contact non-intact skin and/or mucous membranes”.

The BERAphone® has been used in Europe for over 15 years and in the US since 2009. There has never been a report or complaint raised to MAICO regarding cross-contamination of an infectious agent between patients.

Loaner Program:

MAICO will make every attempt to provide loaner equipment when a warranty repair is needed on a Customer’s device. Once a loaner agreement form is completed and returned by an authorized individual at the facility, loaner equipment will be shipped to the Customer via UPS Next Day Air service at no charge.

[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



MB 11 - Specifications

Technical Data

MB 11 BERAphone®

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: + 59 to +95°F, (+15 to +35°C);

Maximum humidity 75%

Storage conditions: +41 to +122°F, (+5 to +50°C);

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: 10.59 oz, (300 g)

USB box weight: 5.83 oz, (165 g)

USB box dimensions: 4.73 x 3.55 x 1.19 in, (12 x 9 x 3 cm)

Power supply: via USB port of computer

Power consumption: max 400 mA

STANDARD COMPONENTS - MB 11 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

Quick Guide

Cradle for BERAphone®

MB 11 Classic

Standards: IEC 60601-1, IEC 60645-3

Stimulus type: CE-Chirp Stimulus

Stimulus rate: 93/s

Stimulus Intensity: 35 dB nHL

Sample rate: 16 kHz

Quality control: Integrated LED on Amplifier hardware and display in software with signal quality or with EEG display

Operation conditions: + 59 to +95°F, (+15 to +35°C);

Maximum humidity 75%

Storage conditions: +41 to +122°F, (+5 to +50°C);

Maximum humidity 90%

Transducer: ER3A insert earphones

Electrodes: Disposable snap

Preamplifier: Integrated, 87 dB amplification (23,000 x)

USB box weight: 5.83 oz, (165g)

USB box dimensions: 4.73 x 3.55 x 1.19 in, (12 x 9 x 3 cm)

Power supply: Via USB port of computer

Power consumption: Max 400 mA

STANDARD COMPONENTS - MB 11 Classic

MB 11 Classic with preamplifier and USB box

USB cable

Set of 3 pinch clip electrode leads

Ear-tone ER3a insert earphones with either EarCup adapters and tubes or with the infant eartip adapters and tubes

Sanibel EarCup couplers, snap electrodes and electrode skin prep pads (1 box of 20 sets) OR

Disposable eartips (3-5 mm and 4-7 mm sizes) and snap electrodes

NuPrep skin preparation gel (1 tube)

MB 11 software on USB flash drive

Operating Manual

Quick Guide

Testimonials

"Our nurses have been performing ABR hearing screening tests for many years at our hospital. Since our equipment was old and needed to be replaced, I decided to try the Maico MB 11 Classic that I had seen at a recent nursing conference. It took our nurses a few days to transition to some differences in the hardware and software. Very soon, however, the fast speed of the screenings convinced everyone that using the MB 11 Classic was a time-saver compared to screening with our old device. Plus my Director of Maternal & Child Health is thrilled that the MB 11 EarCups and electrodes cost so much less than the other manufacturer's disposables. I am so happy that we tried the Maico MB 11 Classic. We found an ABR hearing screener that is faster to use and more economical for our program."

- Newborn Hearing Screening Program Manager

"I have been doing hearing screens for over 10 years. When my program administrator told me we were going to try out a different device, I was not happy about having to learn a new system. But now that I have been using the Maico MB 11 BERAphone for a few weeks, I have to admit that I am blown away by the speed of the screenings. It takes so much less time to complete a "refer" test and the passes are also generally much faster than with the previous equipment. I now have more time to spend with my patients. I'm happy that I tried something new."

- Staff nurse – newborn nursery

"I received a brochure in the mail regarding the Maico MB 11 ABR newborn hearing screener. The Nurse Manager of our Newborn Nursery had recently contacted me about replacing our current hearing screening device, which was 7 years old. Since the brochure said there was a big potential for cost-savings on disposables using the Maico screener, I suggested the Nurse Manager give it a try. Her nurses trialed the MB 11 Classic. The nurses transitioned easily to using the Classic since the screening procedure was very similar to the device they were currently using. They really liked the device because the tests are so much faster to perform. We purchased the Classic and now the hospital is saving approximately 30% in disposable costs, which was a major goal from my perspective."

- Hospital Purchasing Director



MAICO Diagnostics

10393 West 70th Street
Eden Prairie, MN 55344

Tel.: 888.941.4201
Fax: 952.903.4100

e-mail: info@maico-diagnostics.com
Web: www.maico-diagnostics.com