Admn/Prop/29/2022-AIIMS.JDH Dated: - 01st July, 2022

Subject: Purchase of 01 Nos. Automated ABR Screener without Disposable Electrodes with BERA Phone Plus OAE for Department of Pediatrics & 01 Nos. Automated ABR Screener without Disposable Electrodes with BERA Phone for Department of Neonatology at AIIMS Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the process of purchasing 01 Nos. Automated ABR Screener without Disposable Electrodes with BERA Phone Plus OAE for Department of Pediatrics & 01 Nos. Automated ABR Screener without Disposable Electrodes with BERA Phone for Department of Neonatology at AIIMS Jodhpur on proprietary basis from M/s MAICO Diagnostics GmbH, Sickingenstr, Berlin, Germany and PAC certification by user are attached.

The above document are being uploaded for open information to submit objection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21 days of issue giving reference Admn/Prop/29/2022-AIIMS.JDH. The comments should be received by office of Deputy Director (Administration), Medical College at AIIMS, Jodhpur on or before 21st July, 2022 upto 03:00 PM failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Deputy Director (Administration)

Enclosed: Related documents enclosed.

Annexure 2

COMBINED ABR + OAE NEWBORN HEARING SCREENER:

AUTOMATIC OAE + ABR SCREENER WITHOUT DISPOSABLE ELECTRODES RATHER WITH INTEGRATED ELECTRODES WITH BERAPHONE WHICH DO NOT REQUIRED TO BE PASTED OR FIXED ON THE SCALP AND COMPATIBLE SOFT WARE

An electro acoustic instrument **OAE + ABR combo-screener** designed to evaluate the activity of the auditory pathway of the brain in response to an acoustic signal [auditory brainstem response (ABR) and OAE] it provides at the ear, without need of patient cooperation.

The signal, detected without the device's scalp electrodes requiring fixation and is measured using computer averaging and signal processing techniques.

This device is typically used to assess the function of the auditory pathways and to differentiate coma due to metabolic factors from structural damage.

TECHNICAL CHARACTERISTICS

1. Lightweight & Portable Design
2. Combined OAE (TEOAE and DPOAE) with AABR BERAphone
3. Inbuilt reusable electrodes make it easy to screen New Born and young Children
4. Unique BERAphone technology
5. Fast and automatic ABR-screening, reliable automatic display of results within seconds.
6. Integrated electrodes requiring no fixation over the scalp of the baby and should have no disposable electrodes
7. Automatic Impedance Check indicating impedance conditions
8. Stimulation level should start at 35 dBnHL. Variable stimulus level desirable
9. Cleaning gel required before placing the electrodes.
10. No Sticking of Electrodes
11. Results should be stored in computer
12. User's interface electrodes and computer
13. The screening test should culminate in a Pass or Refer result, requiring no interpretation by the user
14. Data should be captured on a user friendly screen which in turn can export the data to a proper computer
15. Software and/ standard of communication (where ever required) in built. The software should include step up frequencies
16. Label printer

12. Accessories (mandatory, standard, optional);

- **Stainless steel electrodes (Nos) 1**
- **Stainless steel electrodes for pre-matures (Nos) 1**
- **Gel protection for electrodes 1 set of 3 pieces 2 set**
- **Electrode gel bottle (ml) 250 ml 5 such**
- **OAE probe with comfortable ear tip for newborns: 1 box**
- **options for the best fit in infant ear canals.**
- Additional set of stainless steel electrodes with gel protectors
- USB connection cable
- Carrying bag
- Disinfectant wipes (1 tub)

- MB-11 software on USB Flash Drive or CD
- Operation Manual
- Laminated Quick Guide

Minimum computer specifications (optional)

- Configuration Type: Intel Pentium P4 compatible or better
- RAM: minimum 2 GB; Hard disk: Minimal 5 GB free disk space
- Interface: USB 1.1 or 2
- Grounded power supply
- Operating system: Windows XP SP 3 Professional and Windows 7 32/64bit Professional or Ultimate
- Software and/ standard of communication (where ever required) in built. The software should include step up frequencies
- Display: SVGA-Colour Display 800x600 or better
- Power Requirements 220-240Vac; 50/60 HZ
- Battery operated Desirable
- Tolerance (to variations, shutdowns

Current

MAICO

PROPRIETORY ARTICLE CERTIFICATE

1. Name of the Item: Combines AABR Screener without Disposables
2. Description of goods: easyScreen OAE + AABR combo-screener with unique BERAphone
3. Name of the Original Author/Inventor: MAICO Diagnostics GmbH
4. Name of the Original Equipment Manufacturers (OEM) with certification that they are the sole and the Original Equipment Manufacturers. (Attachment: CE Certificate)
5. No other make or model/supplier/service provider is acceptable/available to supply the above goods which could be used in lieu for the following reasons :
   a. MAICO Diagnostics GmbH is the owner of this product and OEM
   b. .....
   c. .....
6. M/s Auditivo Hearing Services Pvt. Ltd., 309, 19-Oriental Apartment, Community Centre, Yusuf Sarai, New Delhi – 110049, India are the authorized dealer/stockiest/distributor of the OEM in India.

Name, Signature and designation of Certifying Officer:

Mr. Uwe Ledworuski, Quality Manager: .....

Name of the Organization: MAICO Diagnostics GmbH

VAT number: DE 170899958

Contact details:

MAICO Diagnostics GmbH
Sickingenstraße 70-71
10553 Berlin
Germany
Tel:+49 30- 70 71 46-50 Fax: +49 30- 70 71 46-99

MAICO Diagnostics GmbH
Sickingenstr. 70/71
10553 Berlin
Germany
Phone: +49 30 7071 4650
E-Mail: sales@maico.biz

Date: 25th February 2021

All India Institute of Medical Sciences, Jodhpur
Department of Neonatology

Enclosures: 1. Technical specifications

AUTOMATIC ABR SCREENER WITHOUT DISPOSABLE ELECTRODES (rather with Integrated Electrodes), and stimulation level at least 35 dB HL including software for screening AABR, with compatible Laptop computer

Clinical Purpose: to evaluate the activity including the integrity of the auditory pathways of the brain in response to an acoustic signal [auditory brainstem response (ABR)], signal provided at the ear (e.g., clicks), without need of patient cooperation and without sticking any electrodes on the baby's scalp. To evaluate the activity of the auditory pathway of the brain in response to an acoustic signal [auditory brainstem response (ABR)]

TECHNICAL CHARACTERISTICS

1. Screening and follow-up with ABR Screener inclusive software for screening AABR, additional follow-up measuring modes: standard ABR, compatible with notebook or PC with USB port, including carrying bag.
2. For frequency specific screening test feature with two bands of 135 – 1500 Hz and 1500 – 8000 Hz
3. Lightweight & Portable Design, Hand held and portable
4. Integrated electrodes requiring no fixation over the scalp of the baby and should have no disposable electrodes' i.e. Do not require any Electrode to be pasted or fixed on the scalp
5. Inbuilt reusable steel electrodes make it easy to screen New Born and young Children
6. Fast and automatic ABR-screening, reliable automatic display of results within seconds. Facility to edit the protocol used for screening. Stimulus: Click/Chirp
6. Automatic Impedance Check indicating impedance conditions
7. Stimulation level should start at 35 dB NHL. Variable stimulus level desirable
8. User's interface electrodes and computer
9. Automatic impedance check indicating impedance conditions
10. Cleaning gel required before placing the electrodes
11. No sticking of Electrodes
12. Results should be stored in computer
13. User interface: Electrodes and computer
14. Software and /or standard of communication (where ever required): Inbuilt
15. The screening test should culminate in a Pass or Refer result, requiring no interpretation by the user

Minimum computer specifications

- Configuration Type: Intel processor latest
- RAM: minimum 4 GB;
- Hard disk: 500 GB SSD
- Interface: USB 1.1 or 2
- Grounded power supply
- Operating system: Windows XP SP 3 Professional and Windows 7 32/64bit Professional or Ultimate
- Software and/ standard of communication (where ever required) in built. The software should include step up frequencies
- Display: SVGA-Colour Display 800x600 or better
- Power Requirements 220-240Vac; 50/60 HZ
- Battery operated Desirable
- Tolerance (to variations, shutdowns)

12. Accessories (mandatory, standard, optional);

- Additional set of stainless steel electrodes with gel protectors
- Stainless steel electrodes – (1 pc.)
- Stainless steel electrodes for pre-matures – (1 pc.)
- Gel Protection for electrodes – (1 set of 3 pieces)
- Electrode gel, bottle 250ml (2 bottles)
- USB connection cable
- Carrying bag
- MB-11 software on USB Flash Drive or CD
- Operation Manual
- Laminated Quick Guide

Current

MAICO

PROPRIETORY ARTICLE CERTIFICATE

1. Name of the Item: AABR Screener without Disposables
2. Description of goods: AABR Screener without disposables named as BERAphone (model MB 11)
3. Name of the Original Author/Inventor: MAICO Diagnostics GmbH
4. Name of the Original Equipment Manufacturers (OEM) with certification that they are the sole and the Original Equipment Manufacturers. (Attachment: CE Certificate)
5. Nó other make or model/supplier/service provider is acceptable/available to supply the above goods which could be used in lieu for the following reasons :
   a. MAICO Diagnostics GmbH is the owner of this product and OEM
   b. .....
   c. .....
6. M/s Auditivo Hearing Services Pvt. Ltd., 309, 19-Oriental Apartment, Community Centre, Yusuf Sarai, New Delhi – 110049, India are the authorized dealer/stockiest/distributor of the OEM in India.

Name, Signature and designation of Certifying Officer:

Mr. Uwe Ledworuski, Quality Manager: Uwe Ledworuski .....

Name of the Organization: MAICO Diagnostics GmbH

VAT number: DE 170899958

Contact details:

MAICO Diagnostics GmbH
Sickingenstraße 70-71
10553 Berlin
Germany
Tel.: +49 30- 70 71 46-50 Fax: +49 30- 70 71 46 99

MAICO Diagnostics GmbH
Sickingenstr. 70/71
10553 Berlin
Germany
Phone: +49 30 7071 4650
E-Mail: sales@maico.biz

Date: 25th February 2021

MAICO

Confirmation

To whom it may concern,

We, Maico Diagnostic GmbH, who are official manufacturers of Maico Audiometers, Impedance Meters, Otoacustic Emissions Systems OAE and Auditory Brainstem Measuring Systems ABR having factories at Salzufer 13/14, 10587 Berlin, Germany do hereby confirm that we are the sole and original equipment manufacturer for AABR Screener without disposables.

Berlin, 19th March, 2015

Yours faithfully,

MAICO Diagnostic GmbH

Uwe Ledworuski
Quality Manager

For and on behalf of:
Messrs Maico Diagnostic GmbH
Salzufer 13/14
10587 Berlin
Germany

Pg353.

MAICO

EC Certificate of Conformity

Product:

Product category	**Objective Audiometer**
Trademark	**MB 11 BERAphone®**
Description	**ABR Test System**
Serial number beginning with	**MA9014798**

Manufacturer:

Name	MAICO Diagnostic GmbH		
Address	Salzufer 13/14		
Area code/Area	D-10587 Berlin	Country	Germany
Phone no.	(+49) 30 70 71 46 0	Fax no.	(+49) 30 70 71 46 99

is in conformity with:

- Council Directive 93/42/EEC of 14 June 1993 including all amendments concerning medical devices, fulfilling the essential requirements in appendix I through application of a full quality system according to appendix II 3.
- The product is graded as active diagnostic medical product in class IIa, see also rule 10 of the MDD 93/42/EEC
- 2011/65/EU & Regulation (EC) 1907/2006 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

The conformity is achieved by fulfilling the following main standards:

- EN 60601-1 (General safety)
- EN 60601-1-1 (Safety of systems)
- EN 60601-1-2 (EMC)
- EN 60645-3 (Audiologic Devices)

Notified body:

TÜV SÜD Product Service GmbH

Ridlerstr. 65, Germany – 80339 München

CE 0123

This declaration is made by:

Name	U. Ledworuski		
Title	Quality Manager		
Company	MAICO Diagnostic GmbH		
Address	Salzufer 13/14		
Area code/Area	D-10587 Berlin	Country	Germany
Phone no.	(+49) 30 70 71 46 61	Fax no.	(+49) 30 70 71 46 99

Signature

Date 24. March 2015

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 06 63429 008

Manufacturer:

MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
GERMANY

Facility(ies):

MAICO Diagnostics GmbH
Sickingenstr. 70-71, 10553 Berlin, GERMANY

Product Category(ies):

Subjective Audiometer, Objective Audiometer, Impedance Meter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713084013

Valid from: 2016-08-26
Valid until: 2021-07-08

Date, 2016-08-26

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 5472-2-2019

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	Name of Manufacturer/Distributor, Address
See Attached List	See Attached List
(One Page)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from February 19, 2019 to February 18, 2021.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 5472-2-2019
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer
MAICO Diagnostics GmbH
Sickingenstr. 70-71
Berlin, Berlin GERMANY 10553

Name of Distributor
DIAGNOSTIC GROUP LLC
Doing Business As
Maico-Diagnostics
10393 W 70th St
EDEN PRAIRIE, MN USA 55344

----END OF MANUFACTURER/DISTRIBUTOR LIST----

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA ·

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 5472-2-2019

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer

MAICO Diagnostics GmbH
Sickingenstr. 70-71
Berlin, Berlin GERMANY 10553

Name of Distributor

DIAGNOSTIC GROUP LLC

Doing Business As

Maico-Diagnostics
10393 W 70th St
EDEN PRAIRIE, MN USA 55344

Name of Product(s)

PILOT TEST (Audiometer)
MA 1 (Audiometer)
MA 25 (Audiometer)
MA 27 (Audiometer)
MA 28 (Audiometer)
MA 33 (Audiometer)
MA 41 (Audiometer)
MA 42 (Audiometer)
easyTymp (Tympanometer)
easyTymp Pro (Tympanometer)
touchTymp MI 24 (Tympanometer)
touchTymp MI 24 RaceCar (Tympanometer)
touchTymp MI 26 (Tympanometer)
touchTymp MI 26 RaceCar (Tympanometer)
touchTymp MI 34 (Tympanometer)
touchTymp MI 36 (Tympanometer)
ERO SCAN (OAE)
ERO SCAN Pro (OAE)
easyScreen (ABR)
MB 11 (ABR)

----------END OF PRODUCT LIST----------