Newborn Hearing Screening gets a "touch" more intuitive





Another giant step for Newborn **Hearing Screening**

Allow us to present the new MADSEN AccuScreen, a complete redesign of the AccuScreen that thousands of hearing care professionals around the world have used in their Newborn Hearing Screening (NHS) programmes.

You might say that the new

Designed by you

AccuScreen was designed by you. We started with all the great feedback you gave us during the first wave of NHS programmes. Then we incorporated what we learned into the new device - making improvements in everything from the device's physical size and charging system, to the user interface, navigation system and administrator control capabilities.

Fast, accurate and intuitive

Brought to you by the same people who developed the first AccuSceen, the new version of this legendary NHS device is fast. accurate and intuitive. The new touch screen user interface helps speed up the whole screening process - while delivering all the

accuracy you expect from the AccuScreen name.

A proud heritage

As different as the new AccuScreen looks, it offers the same precision and workflow integration that's made MADSEN AccuScreen a first choice for NHS programmes around the world. In fact, doctors, nurses and hearing care professionals have screened more than 36 million newborns using AccuScreen - making our name one of the most trusted in the industry. And at Otometrics, we're more than just device manufacturers. We're an experienced partner in NHS programmes, and our products come with a full range of support and service options.



More than

newborns tested with AccuScreen





Accuracy

- Phenomenal track record
- Preferred by leading screening programmes
- Combined OAE/ABR device enabling two-step screening
- More than 36,000,000 newborns screened
- Low maintenance costs
- Durable probe
- Probe and ear couplers for ABR

Intuitive accuracy

- + Breakthrough touch screen display
- + Easy and intuitive data entry
- + Detailed test and result screens
- + On-screen help menu
- + Reliable and faster screening
- + Small and lightweight
- + Docking station for data transfer, instrument updates and charging
- + Angled probe with improved probe tip
- + New improved ear couplers
- + Quality tests of probe and cables
- + Comprehensive software offering patient, test and device management

Your workflow has never been so simple



Quality tests

Checking to make sure your Accu-Screen is working properly is easy and fast, saving time and improving the validity of test results.

With its slimmed-down profile, intuitive touch screen display, new probe and convenient docking station, the new AccuScreen is all about design. But at Otometrics, "design" really means usability, and the way a given tool fits into and supports your unique workflow.

Breakthrough touch screen

The first thing you'll notice about the new AccuScreen is its striking touch screen display. Touch screen technology has enabled us to take a quantum leap in user-friendliness. You always have an overview of all the main commands right at your fingertips, and tasks like

accessing test results, entering data and adding comments have never been easier – allowing you to focus on the infants you're screening instead of the technology.

Easy to learn, guess and remember

With easy access to all functions and big bright icons providing strong visual cues, learning to use the new AccuScreen is fast and easy. This means you can get new screening personnel up to speed very quickly and without costly training courses. And if a user ever does get stuck, AccuScreen offers a comprehensive on-screen help menu to resolve the problem on the spot.

Vastly improved workflow

AccuScreen's convenient docking station takes the hassle out of battery charging, data transfers, device settings and firmware updates and label printer connections by handling all of it, while also keeping your device right where you need it. An improved, angled probe ensures a secure fit, and even allows you to screen infants in car seats, for example.



Angled probe for better fit Based on your feedback, we've redesigned the AccuScreen probe to make testing a smoother experience for all concerned.



Dual-density ear couplersA new dual-density ear coupler design adapts to the shape of the baby's head, ensuring an easy fit, optimal sealing and accurate stimulus presentation for more reliable results.



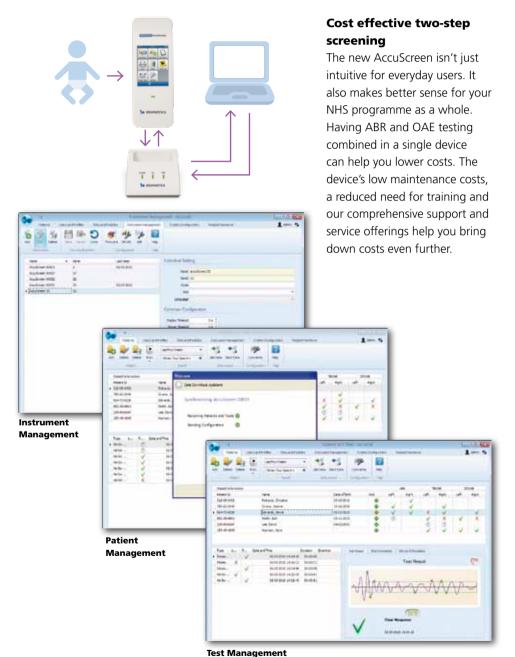
Intuitive touch screen
The breakthrough touch screen
interface puts patient setups, testing, printing and much more right
at your fingertips.



Improved workflow
It's now much easier to transfer
data, upload patient lists to the
device and download patient data,
including test results, comments
and risk factors.



The intuitive solution for a more efficient NHS program



Powerful software

Enhanced AccuLink software delivers several new benefits, including a comprehensive settings menu that lets you define settings on the computer and transfer them to the device simply by placing the device in the docking station. Via the docking station, you can also easily upload patient lists to the device and download patient data – including test results, comments and risk factors – for convenient data processing.

Enhanced governance and security features

AccuScreen and the AccuLink software make it easy to manage user profiles, with test management functionality ensuring that only the required tests are performed, and a deletion management system taking care that no child's test results are lost. The optional mandatory field system is used to make sure all required patient details are recorded, allowing administrators to easily customise patients' demographic data setup in the device.

All this and more at your fingertips



Daily probe and cable tests have never been easier thanks to new quality tests.

2 Entering patient details is far less cumbersome with the large touch screen keypad.





Handling probes is much easier thanks to new angled probes that ensure easy placement and optimal fit.

4 The intuitive test menu gives you a clear overview of the different testing options.





5 Monitor test progress with easy-to-read graphical displays.



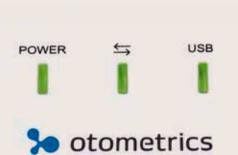
6 Get answers you understand, with no need for interpretation.



The comprehensive on-screen help menu is always ready to assist you.



AccuScreen Full size.



Leaders in paediatric hearing care

Audiometry MADSEN Astera

Is a two-channel clinical audiometer based on state-ofthe-art technology and modern paediatric audiology practice.



MADSEN Astera

Tympanometry MADSEN OTOflex 100

Is a compact immitance device that provides both tympanometry and acoustic-reflex testing using the recommended 1000Hz infant probe tone.



MADSEN OTOflex 100

EP/ASSR **ICS Chartr EP 200**

Is Otometrics' system for Auditory Evoked Potential testing, and was built with the paediatric population in mind.



ICS Chartr EP 200

Otometrics is the world's leading manufacturer of hearing and balance instrumentation and software, providing solutions ranging from infant screening applications and audiologic diagnostics to balance testing and hearing instrument fitting.

For more information about MADSEN AccuScreen, please visit www.otometrics.com/accuscreen











MADSEN AccuScreen®



Technical specifications:

Measurement techniques

Evaluation method: Noise-weighted averaging, counting of significant signal peaks

Stimulus: Non-linear click sequence

Stimulus level: 70-84 dB SPL (45-60 dB HL), self calibration depending on ear canal volume

Click rate: Approx. 60 Hz

Frequency range: 1.5 to 4.5 kHz

Display: Statistical waveform, measurement progress, TEOAE detection level, noise level

DPOAF

Evaluation method: Noise-weighted phase statistics

Stimulus: Primary tone pair, f2/f1 = 1.24 Available test frequencies: Configurable, f2 range 1 to 6 kHz

Default test frequencies: f2 = 2, 3, 4 and 5 kHz (PASS at 3 out of 4)

Test level: |1/|2 = 59/50 dB SPL

Display: DPOAE level, test progress, noise level, DP-Gram

Result display: Overall PASS/REFER, DP-Gram with DPOAE and noise level

Evaluation method: Noise-weighted averaging and template matching

Stimulus: 35, 40 or 45 dB nHL click

Click rate: Approx. 80 Hz

Impedance sense signal: 1 kHz square way

Impedance test range: 1 to 99 kO

Impedance accepted for test: $< 12 \text{ k}\Omega$

Impedance control:

Before test, periodically during test, stimulus continues during impedance control

Display: Statistical graph, test progress, EEG-level, ABR detection probability

Electrodes: Disposable hydrogel electrodes

Approx. 202 x 73 x 30 mm (8 x 2.8 x 1.2 inches)

Weight

Approx. 240 g (8.5 oz) excluding battery

280 g (9.9 oz) including battery

Type: Color, TFT, touch screen with adjustable LED backlight

Dimensions: 89.4 mm (3.5 inches)

Resolution: 240 x 320 pixels

Keystroke durability: min. 1 million repetitive strokes per screen point

Resistive Touch Screen (can be used with gloves)

Memory

Patient memory capacity: Max. 250 patients / Min. 500 tests

Connectors

OAE probe connector: 14 pin ODU Medisnap - For OAE Probe or ABR ear coupler cable

ABR (ABR version only): 4 pin ODU Medisnap - For ABR electrode cable

Real time clock

Integrated real-time clock for time-stamping of measurements

The clock is automatically synchronized with PC clock when docked.

Backup: Min. 5 days, when battery is removed from unit

PC: IR data transmission to Docking Station - USB interface from Docking Station to PC

Transport and storage environment

Temperature range: -20 - +60°C (-4 - 140 °F)

Humidity range: 20-80 % rel., non-condensing Air pressure 500 hPa to 1060 hPa

Operating environment

Temperature range: 10 - 40°C (50 - 104°F)

Humidity range: 30-80 % rel., non-condensing Air pressure 600 hPa to 1060 hPa

Standards

Otoacoustic emissions: EN 60645-6, Type 2

Auditory evoked potentials: EN 60645-7, Type 2

Patient Safety:

• EN 60601-1, Internally Powered, Type BF, IPXO

• U2601-1; CAN/CSA-C22.2 NO 601.1-90,

• IEC 60601-2-26

• IFC 60601-2-40 FMC: FN 60601-1-2

Power supply and battery

Battery type: Rechargeable Li-ion 3.7 V/1800 mAh (6.7 Wh), fully charged

Estimated battery life: 8 hours of continuous use (based on a typical use scenario.

Actual use can influence the battery life time)

Battery level indicator: 5-step battery level indicator Charge time in AccuScreen docking station: 80% charged 4½ hours. Fully charged 6 hours

PC interface

Interface type: USB 2.0, Full-speed

USB Power: Uses <100 mA of current from the USB interface

Printer interface

Interface type: RS232

Connector type: 6-pol Mini Din

DC power input

Input voltage: 5 V DC ±5%

Max. power consumption when AccuScreen is docked: 5VA (5V, 1.0 A)

Max. power consumption when AccuScreen is not docked: 0.25 VA (5V, 50 mA)

Power adapter

Input voltage/range: 100-240 V AC, 50-60 Hz

Output voltage: 5.0 V DC/min. 1.0A

Mains plug types: US, UK, Europe and Australia

Flexible, shielded cable, approx. length: 120 cm (approx. 55 inches)

Probe body: 20 mm Ø x 23 x 11 mm (0.8" Ø x 0.9" x 0.43")

Probe tip: 3.3 mm Ø x 10 mm (0.13" Ø x 0.4") Weight

Probe incl. probe tip: Approx. 4.5 grams

Standard (cylindric): 4 sizes (3.7 - 5 mm)

Tree tip: 1 size (4 - 7 mm)

Foam tip: 1 size (13 mm) ABR electrode cable

Flexible, shielded cable, approx. length: 140 cm (approx. 55 inches)

ABR ear coupler cable (optional)

Flexible, shielded cable, approx. length: 145 cm (approx. 57 inches)

IIa (according to Council Directive 93/42/EEC Appendix IX)

The MADSEN AccuScreen comes with customized Carrying case, Docking station including Power Adaptor and USB Cable, Starter kit, OAE probe (DPOAE/TEOAE or TEOAE only), Battery, ABR electrode cable (ABR version only), ABR Tester (ABR version only), Cleaning cloth and User Manual

Optional accessories

Label Printer with printer cable, ABR ear coupler cable and External battery charger. Standard accessories and optional accessories may vary from country to country - please consult your local distributor.





Newborn Hearing Screening gets a "touch" more intuitive

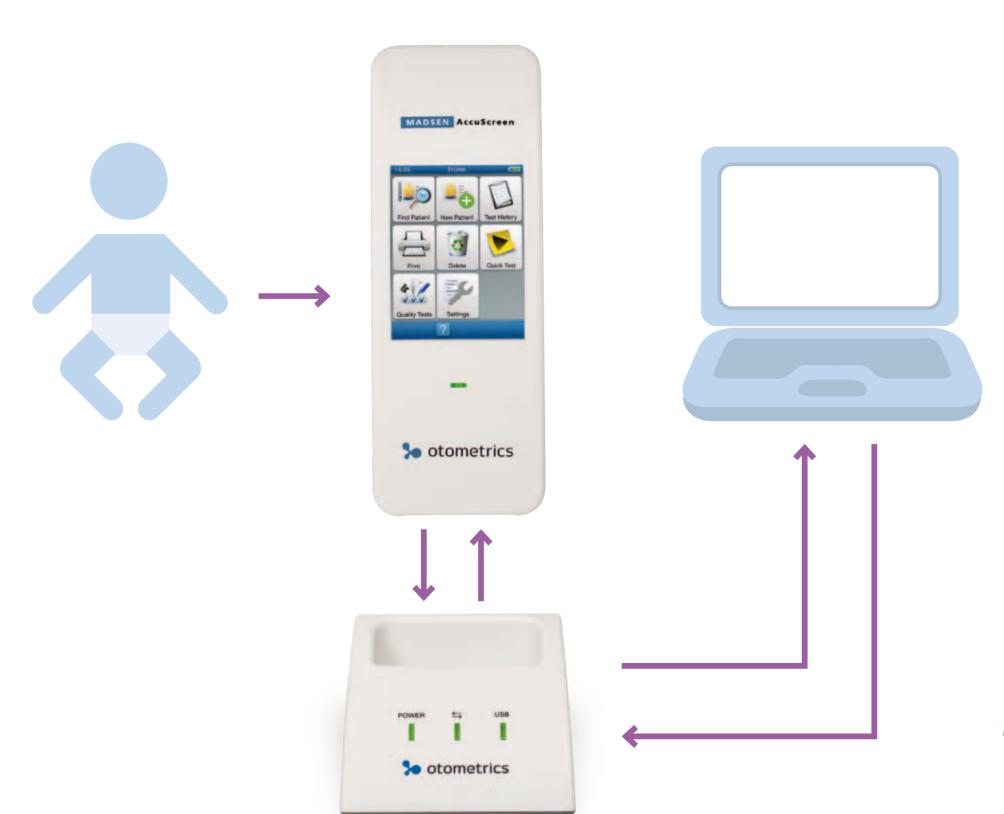






O Hearing Assessment Fitting Systems Balance Assessment

Your workflow has never been so simple





The new MADSEN AccuScreen

- + Developed by the same people who developed the first MADSEN AccuScreen
- + Combined OAE/ABR device enabling two-step screening
- + Quality tests
- + Small and lightweight
- + Angled probe for better fit
- + Probe and ear couplers for ABR
- + Dual-density earcoupler design for more reliable results
- + User login option for data security
- + Low maintenance costs

Breaktrough touch screen display

- + Easy and intuitive data entry
- + Easy and intuitive navigation
- + Detailed test and result screens
- + On-screen help menu

AccuLink software

- + Patient management
- + User management
- + Device management
- + Test management
- + Comprehensive settings menu

MADSEN AccuScreen docking station

- + Upload patient lists to the instrument
- + Download patient data including test results, comments and risk factors, to the AccuLink software
- + Transfer instrument settings defined in the AccuLink PC software
- + Transfer firmware updates
- + Charge battery
- + Connect label printer
- + Store instrument

More than

36,000,000

newborns tested with AccuScreen



The AccuScreen

1. What is AccuScreen?	AccuScreen is a handheld newborn hearing screening device that features any combination of TEOAE, DPOAE and ABR. It has been developed by the same people that developed the old AccuScreen and builds on our reputation of having one of the most trusted infant screeners in the world. The new AccuScreen is fast, accurate and intuitive and features a touch screen for intuitive navigation, a docking station for data transfer, instrument updates and charging and an angled probe for easy probe handling, while the powerful software secures administrator control.
2. What is delivered with the AccuScreen?	The following items are supplied with all versions of Accuscreen: AccuScreen device, Probe (EP-TE or EP-DP depending on AccuScreen version), Docking station, Battery, AccuLink software (on DVD), AccuScreen manual, USB cable for data transfer, Power supply and adaptor plug kit, Starter kit including e.g. ear tips and probe tips, Cleaning cloth For ABR versions the following is supplied also:
	Electrode cable, Electrodes, ABR tester, Carrying case
3. Which optional accessories are available?	Ear coupler cable for ABR tests, Ear couplers, Label printer and labels, External charger, Spare battery
4. Which age groups can be tested with AccuScreen?	The algorithms for AccuScreen have been optimized for newborns up to 6 months of age. However, AccuScreen can be used for patients older than 6 months. A longer test time and a slightly higher refer rate caused by test time-out should be expected.
5. How many patients can be stored on the AccuScreen?	You can store up to 250 patients on the AccuScreen and approx. 500 tests.
6. Does the AccuScreen need calibration?	Yes, it is recommended to perform a yearly calibration of the AccuScreen to ensure reliable test results. Please contact your local sales representative to learn more about Otometrics service offers.
7. What is the docking station used for?	The docking station is used data transfer to/from the PC (AccuLink software), battery charging and label printer connection. Furthermore, it serves the purpose of storing the AccuScreen when not in use.
8. Can the touch screen be used with gloves?	Yes.
9. What is the durability of the touch screen display?	The touch screen display used on the AccuScreen is also used in several GPS devices. Each screen point withstands a minimum of 1 million repetitive strokes.
10. What are the quality tests?	To make sure your AccuScreen is working properly, the quality tests offer very fast testing of the probe, ear coupler cable and electrode cable. This saves time and improves the validity of the test results. The probe is tested in the built-in test cavity on the back of the AccuScreen. The electrode cable and ear coupler cable are tested with the supplied ABR tester.
11. How often should the quality tests be performed?	It is recommended to run probe and cable tests before starting the daily tests and at the end of the day to make sure the probe and cables are working correctly.
12. What if the built-in test cavity is contaminated?	It is recommended always to replace the probe tip with a clean one before inserting it in the test cavity. If the test cavity has been contaminated with debris from the probe tip, make sure that the test cavity cannot be used, for instance by sticking a piece of tape across the entry hole, and contact your authorized service department for cleaning and/or replacement of the test cavity. Spare test cavities are available for replacement by technical staff.





Question	Answer
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Test methods

13. Which test methods are available with AccuScreen?	The AccuScreen is available with any combination of TEOAE, DPOAE and/or ABR
14. What ABR levels are available in AccuScreen?	30, 35, 40 and 45 dB. The default ABR level is 35 dB.
15. How do I add other ABR levels than the default (35 dB)?	Via AccuLink's device management other ABR levels can be uploaded to AccuScreen. The default ABR level can also be removed via AccuLink's device management.
16. What is the stimulus level with TEOAE?	70-84 dB SPL (45-60 dB HL). AccuScreen is selfcalibrating depending on ear canal volume.
17. What is the frequency range with TEOAE?	1.5 – 4.5 kHz
18. What frequency range is covered with DPOAE?	There are 4 different protocols available for DPOAE on AccuScreen:
	Protocol 1 (default protocol): 5, 4, 3, 2 kHZ, Pass/Refer criterion 3/4, Test stops when 3 frequencies pass or 2 refer.
	Protocol 2: 6, 5, 4, 3.5, 3, 2 kHZ, Pass/Refer criterion 4/6, Test stops when 4 frequencies pass or 3 refer.
	Protocol 3: 4, 3, 2, 1 kHZ, Pass/Refer criterion 3/4, All frequencies are tested.
	Protocol 1: 6, 5, 4, 3, 2, 1 kHZ, Pass/Refer criterion 4/6, All frequencies are tested.
	L1/L2 levels are 60/50 dB SPL for all protocols.
19. How do I add other DPOAE protocols than the default protocol?	Via AccuLink's device management other DPOAE protocols can be uploaded to AccuScreen. The default DPOAE protocol can also be removed via AccuLink's device management.

Battery

20. What is the battery operating time?	When fully charged the AccuScreen battery lasts for 8 hours of continuous use (based on a typical use scenario)
21. How is the battery charged?	The AccuScreen battery is automatically charged in the docking station if this is connected to mains. The battery should not be removed from the device for charging. Testing is not possible during charging. It is possible to charge the battery with an external charger (optional).

PC Software

22. Does the AccuScreen come with PC software?	Yes, the AccuLink software is delivered with the AccuScreen.
23. Which features does AccuLink software provide?	The enhanced AccuLink software delivers several new benefits including a comprehensive settings menu that lets you define settings on the PC and transfer them to the device simply by placing the device in the docking station. Via the docking station, you can also easily upload patient lists to the device and download patient data – including test results, comments and risk factors – for convenient data processing.
	User profiles are easily managed with AccuLink and the test management functionality ensures that only the required tests are available and performed by the users. Comments and risk factor lists are maintained and managed in AccuLink and a special mandatory field system is used to make sure all required patient details are recorded. AccuLink provides easy update of AccuScreen, when new free-of-charge firmware updates are available.

Question	Answer
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Printing

24. How is printing done with AccuScreen?	The AccuLink software offers a number of basic and detailed reports that are printed on the printer connected to the PC. Basic reports include patient demographics and test results, whereas the detailed reports also include waveforms and test details. Smaller label prints including basic patient details and test results can be printed via the docking station on a label printer. The AccuLink software is not needed for this.
25. Is the label printer supplied with AccuScreen?	The label printer is an optional accessory.

Probe

	<u></u>
26. Why are there two versions of the AccuScreen probe?	AccuScreen comes in 7 different versions depending on the combination of test methods (TEOAE, DPOAE and ABR). For TEOAE and ABR only one speaker is needed to generate the stimulus whereas two speakers are needed for DPOAE stimulus. Therefore, there are two versions of the AccuScreen probe: version EP-TE for all AccuScreens with TEOAE and/or ABR and version EP-DP for all AccuScreens including DPOAE.
27. Can the DPOAE probe (EP-DP) be used for TEOAE testing?	Yes.
28. Is it possible to test both OAE and ABR with the same probe?	Yes. Please note that for TEOAE/ABR testing it is sufficient to have the EP-TE probe, whereas for DPOAE testing the EP-DP probe is needed.
29. Why is the new AccuScreen probe angled?	The improved angled probe ensures a secure and stable fit in the ear canal and even allows screening of infants in car seats and bassinets.
30. Why is the probe shielded?	To ensure the fastest test results it is important to record as little noise as possible. When cables are shielded they obtain less external noise from e.g. baby movements.
31. How should the probe be placed in the baby's ear?	The probe can be inserted with the probe cable pointing either upwards or downwards, depending on which direction fits best.
32. How is the probe fitted properly?	To fit the probe, gently pull the pinna back and slightly down and insert the probe in the ear canal, twisting the probe slightly as you insert it. NEVER insert the probe without an ear tip fitted on the probe tip.
33. How should the probe tip be cleaned?	The probe tip usually does not come into contact with the skin or secretion from the ear canal, as it is covered by the ear tip, but always check the sound channels in the probe tip every time you have used the probe. Even small amounts of cerumen or vernix can block the probe channels or be deposited on the probe tip. Before testing a baby remove the probe tip from the probe. Use the cleaning wire to clean the sound channels of the probe tip from the rear. Note: remember to clean the cleaning wire when it protrudes from the probe tip. When you have finished using the cleaning wire, remember to disinfect it. Make sure that the sound channels are completely dry before fitting the probe tip on the probe body.

Ear couplers and ear coupler cable

34. Can I have ear couplers for ABR testing?	Yes, you can use both the probe and ear couplers for ABR testing.
35. Why are the transducers on the ear coupler cable colored?	The transducers are colored to make sure the ABR test results are given for the correct ears. The coloring is according to the international standard: BLUE for left ear and RED for right ear.
36. Can the transducers be placed directly in the ear canal?	NO. The red and blue transducers SHOULD NEVER be placed in the ear canal. They are to be used with the AccuScreen ear couplers only.
37. How should the ear couplers be placed on the baby?	The ear couplers should be placed with the transducer entry hole pointing upwards over the baby's ears.
38. Why are the cables shielded?	To ensure the fastest test results it is important to record as little noise as possible. When cables are shielded they obtain less external noise from e.g. baby movements.

Question Answer

Eartips

39. What ear tip sizes are available for the AccuScreen?	The ear tip range covers: 4 cylindrical silicone ear tips in 3.7, 4.0, 4.5 and 5.0 mm 1 tree tip silicone ear tip covering 4-7 mm 1 foam ear tip covering 8-12 mm
40. What material are the ear tips made of?	There are 5 ear tips made of silicone and one made of foam.
41. Do the ear tips contain latex?	No.
42. How is the correct ear tip size selected for a baby?	Selecting the correct ear tip is a matter of training, but in general one of the 4 cylindrical ear tips should fit the ears of a newborn baby. If you are in doubt choose a smaller ear tip rather than a bigger one. For TEOAE and ABR you don't need a tight seal as long as the environment is quiet. For DPOAE however, a tight seal is needed, but the AccuScreen checks the fit during the calibration. If it is difficult to get a test through, try replacing the ear tip with a smaller or bigger one and retest the baby.
43. Should the ear tip be replaced between ears?	No, it is not necessary as long as the sound canals in the probe tip are clean and it is used on the same patient. Remember to follow local screening procedures as they might require replacing ear tips between ears.
44. Should ear tips be replaced between patients?	Yes, always replace with a clean ear tip between patients.
45. Can the ear tips be cleaned?	No, the ear tips are single use items and should be disposed after use.

Electrodes

46. What is the optimal electrode placement?	The shortest possible distance between the three electrodes ensures the fastest testing for both ears. Therefore, it is recommended to place the electrodes on the cheek, high on the forehead and on the nape of the neck. The three clips on the electrode cable are attached as follows: black on the cheek, white on the forehead and red on the neck. The correct placement and clip connection is illustrated on the electrode cable.
47. Can the neck electrode be placed on either mastoid?	If the nape of the neck is difficult to reach it is possible to place the electrode behind the ear on the mastoid. The other electrodes are still placed on the cheek and forehead. Please note that if both mastoid and cheek electrode are placed on the same side of the face, testing of the ear on that side will be faster than testing of the other ear due to the electrodes being closer together. The optimal placement of the electrodes is illustrated on the electrode cable.
48. Can the cheek electrode be placed on either mastoid?	It is possible to place the cheek electrode on either mastoid keeping the other electrodes on the forehead and neck. However the test time will be extended since the 3 electrodes are not placed optimally. The shorter the distance between the electrodes the faster the response is recorded. The optimal placement of the electrodes is illustrated on the electrode cable.
49. Can the cheek electrode be placed on either shoulder?	If everything else is impossible the cheek electrode can be placed on either shoulder, but the test time will be extended since the 3 electrodes are not placed optimally. The shorter the distance between the electrodes the faster the response is recorded. The optimal placement of the electrodes is illustrated on the electrode cable.
50. What material are the electrodes made of?	The surface that gets in contact with the skin is a biocompatible hydrogel approved to be used on babies' skin.

