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The AccuScreen Screening Device

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| 1. What is AccuScreen? | AccuScreen is a handheld newborn hearing screening device that features a combination of TEOAE, DPOAE and ABR screening. AccuScreen is fast, accurate and intuitive and features a touch screen for easy navigation and a docking station for data transfer and charging. |
| 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 configuration); Docking station; Battery; AccuLink software; AccuScreen manual; USB cable for data transfer; Power supply and adaptor plug kit; Starter kit including ear tips and probe tips; cleaning cloth; carrying case. AccuScreens configured for ABR screening include the electrode cable, electrodes and the ABR test fixture for performing quality tests. The Ear Coupler cable is sold separately as an optional accessory. |
| 3. Which optional accessories are available? | Ear coupler cable for ABR screening; Ear couplers; Label printer and labels; External charger, Spare battery. |
| 4. Is AccuScreen limited for screening newborns? | The algorithms for AccuScreen have been optimized for newborns up to 6 months of age however the AccuScreen can be used to screen patients older than 6 months. |
| 5. How many patients can be stored on the AccuScreen? | The AccuScreen stores up to 250 patients or approximately 500 tests. |
| 6. Does the AccuScreen need calibration? | Yearly calibration of the AccuScreen is recommended to ensure reliable screening results. Please contact your local sales representative to learn more about Natus / Otometrics service plans. |
| 7. What is the purpose of the docking station? | The docking station is used for: data transfer to/from the AccuScreen and the AccuLink software (on your computer); battery charging; and label printer connection. The docking station also 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 the same type of screen used in many GPS devices. Each screen point withstands a minimum of 1 million repetitive strokes. |
| 10. What are the quality tests? | Quality tests offer fast testing of the probe, ear coupler cable and electrode cable to ensure the AccuScreen is working properly. 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 ABR test fixture. |
| 11. How often should the quality tests be performed? | Quality tests are recommended once daily to verify the probe and ABR cables. |

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| 12. What if the built-in test cavity is contaminated? | The probe test should be completed without an ear tip on the probe nozzle. If the probe nozzle has been contaminated with debris after removing the probe tip and it has been inserted into the probe test cavity on the back of the device, the probe cavity should be replaced. Cover the probe test cavity with tape to make sure that the test cavity cannot be used, and contact your authorized service department for replacement of the test cavity. |
| 13. Which screening methods are available with AccuScreen? | The AccuScreen can be purchased with any combination of TEOAE, DPOAE and/or ABR. |
| 14. Can I use AccuScreen for simultaneous ABR screening? | Yes, you have the option of screening ABR simultaneously or sequentially when using the ear couplers and ear coupler cable. |
| 15. What ABR levels are available in AccuScreen? | 30, 35, 40 and 45 dB. The default ABR level is 35 dB. |
| 16. How do I add other ABR levels than the default (35 dB)? | Screening protocols are added to the AccuScreen via connection from the docking station to the AccuLink Software on your computer. |
| 17. What is the stimulus level with TEOAE? | 70-84 dB SPL (45-60 dB HL). AccuScreen is self-calibrating depending on ear canal volume. |
| 18. What is the frequency range with TEOAE? | 1.5 – 4.5 kHz. |
| 19. What frequency range is covered with DPOAE? | There are 19 different DPOAE protocols available for the AccuScreen, covering frequency ranges between 1.5 kHz and 6 kHz, and with several different selectable Pass/Refer criteria. For information about how to add DPOAE protocols to your AccuScreen, please see the AccuLink user manual. |
| 20. How do I add other DPOAE protocols than the default protocol? | Screening protocols are added to the AccuScreen via connection from the docking station to the AccuLink Software on your computer. |

The AccuScreen Battery

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| 21. 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). |
| 22. How is the battery charged? | The AccuScreen battery automatically charges when the AccuScreen is placed in the docking station and the docking station is plugged in. Screening is not possible during charging. An external battery charger is available as an accessory. |

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The AccuLink Software

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| 23. Does the AccuScreen include software? | Yes, the AccuLink software is included with the purchase of AccuScreen. |
| 24. Which features does AccuLink software provide? | <p>AccuLink software allows users to define AccuScreen settings on their computer and transfer these settings to the AccuScreen device when placed in the docking station. Patient lists can be sent from the computer to the handheld screener and screening results can be transferred from the screener to the AccuLink Software.</p> <p>User profiles and password management are defined within the AccuLink software. Choices of screening protocols are also defined within the AccuLink software so that only the desired screening protocols are available for use when screening babies. 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 entered prior to screening.</p> |
| 25. Under the ABR and DPOAE configuration, what does Basic and Enhanced mean? | <p>Basic and enhanced refer to access levels or permissions. A facility may choose to have more than one ABR protocol available on their device. They can limit access by defining a protocol as enhanced. For example, a 35dB protocol would be categorized as a basic protocol and thus would be visible and available to all screeners. A 45 dB protocol would be categorized as enhanced and thus visible and available only to screeners with administrative privileges. A screener's access level defines which protocols can be selected for screening.</p> |

Printing with the Accuscreen / AccuLink

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| 26. How do I print AccuScreen screening results? | <p>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 screening results, whereas the detailed reports include more information about the screening results, stimulus, calibration and conditions. The optional label printer prints results directly from the docking station. Information on the label includes basic patient details and screening results. The AccuLink software is not used for printing labels.</p> |
| 27. Is the label printer supplied with AccuScreen? | The label printer is an optional accessory. |

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The AccuScreen Probe

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| 28. Why are there two versions of the AccuScreen probe? | AccuScreen is available in 8 different configurations depending on the combination of screening modalities (TEOAE, DPOAE and ABR). There are two versions of the AccuScreen probe. The TEOAE probe (EP-TE) has a single speaker in the probe housing and cannot be used for DPOAE. The DPOAE probe (EP-DP) has two speakers in the probe housing and can be used for both DPOAE and TEOAE. Both probes can be used for stimulus delivery for ABR. |
| 29. Can the DPOAE probe (EP-DP) be used for TEOAE screening? | Yes. |
| 30. Is it possible to screen with OAE and ABR using the same probe? | Yes. Please note that for TEOAE/ABR screening it is sufficient to have the EP-TE probe, whereas for DPOAE screening the EP-DP probe is needed. |
| 31. Why is the new AccuScreen probe angled? | The angled probe ensures a secure and stable fit in the ear canal and also facilitates placing the probe in the baby's ear if the baby is being screened while in a car seat or small bassinet. |
| 32. How should the probe be placed in the baby's ear? | The probe can be inserted with the probe cable pointing either up-wards or downwards, depending on which direction fits best. |
| 33. 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. |
| 34. How should the probe tip be cleaned? | Always cover the probe tip with an appropriately sized disposable ear tip before screening. After screening, remove and dispose of the ear tip. Check the sound channels in the probe tip after every screening to ensure there is no debris or blockage. The probe tip can be removed and cleaned with the probe cleaning wire. If necessary, disinfect the probe tip using an approved disinfectant and ensure the probe is completely dry before placing it on the probe. |

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The AccuScreen Ear Couplers and Ear Coupler Cable

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| 35. Can I use ear couplers for ABR screening? | Yes, the ABR stimulus can be delivered with ear couplers or the probe. |
| 36. Why are the transducers on the ear coupler cable colored? | The color of the transducer identifies the ear being screened. Red on the right ear and blue on the left ear. |
| 37. 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 only with the AccuScreen ear couplers. |
| 38. How should the ear couplers be placed on the baby? | Ensure the ear coupler completely encases/surrounds the ear and the adhesive is firmly attached to the skin at all points. |

AccuScreen Ear Tips

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| 39. What ear tip sizes are available for the AccuScreen? | Individual ear tip sizes range from 3.7 mm to 5 mm. The tree tip is designed to fit most full term newborns. |
| 40. What material are the ear tips made of? | The ear tips are silicone. |
| 41. Are the ear tips latex-free? | Yes |
| 42. How is the correct ear tip size selected for a baby? | Choose an ear tip that will fit snugly in the baby's ear canal. A loose fit may result in longer screen times and increased refer rates. |
| 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, the ear tips are single use only and should be disposed after use. |

AccuScreen Electrodes

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| 45. Where are the electrodes placed? | 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. |
| 46. Can the nape electrode be placed on either mastoid? | No, always place the electrodes as directed in the instructions for use. |
| 47. Can the cheek electrode be placed on either shoulder? | No, always place the electrodes as directed in the instructions for use. |
| 48. What material are the electrodes made of? | The surface of the electrode is hydrogel, approved for use on infants. |