

white PC version



FIGURE 1

ALGO[®]5

Newborn Hearing Screener

QUICK GUIDE

Intended Use

The ALGO 5 Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses AABR[®] (Automated Auditory Brainstem Response) technology. The ALGO 5 also includes Natus Medical's audible[®] Data Management software pre-installed.

The screener is intended for babies between the ages of 34 weeks (gestational age) and six months. Babies should be well enough to be ready for discharge from the hospital, and should be asleep or in a quiet state at the time of screening.

The screener is simple to operate. It does not require special technical skills or interpretation of results. Basic training with the equipment is sufficient to learn how to screen infants who are in good health. A typical screening process can be completed in 15 minutes or less. Sites appropriate for screening include the well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.

Precautionary Information

WARNING: Do not turn screener off while baby is still connected.

WARNING: Any misuse of the earphones or the earphone cable (that is, any use other than what is described here) may result in screening at unknown and uncontrolled decibel levels.

WARNING: Never apply pressure to the ear canal or compress the tragus (the prominence in front of the external opening of the ear).

WARNING: Never insert the acoustic transducers directly into an ear.

CAUTION: Failure to shut down properly may lead to problems with the stability of the database containing patient data. Patient data could potentially be lost if the device is shut down improperly. Care should be taken to ensure all staff are following proper shutdown procedures.

TURNING ON THE ALGO 5 NEWBORN HEARING SCREENER

1. Push the Main Power Switch on the back of the column to the on (I) position.

Note: If the Main Power is on but the ALGO 5 Hearing Screener appears off, the device may be in Hibernate mode. In this case, press the Computer Power Switch on the computer to wake the system.

2. Press the Printer Power Switch located on the front of the label printer. The printer will also automatically turn on when printing the first label.

TURNING OFF THE ALGO 5 NEWBORN HEARING SCREENER

1. Select "F10 - Exit" from the Main Window of the ALGO 5 user interface.
2. Select "F2 - Power Off" and confirm the choice (or press cancel).
3. Wait a moment for the system to power off and then switch off Main Power.

HIBERNATING THE ALGO 5 NEWBORN HEARING SCREENER

1. Select "F10 - Exit" from the Main Window of the ALGO 5 user interface.
2. Select "F1 - Hibernate"

SELECTING OPTIMAL SCREENING CONDITIONS

The ALGO screener is indicated for use with babies meeting the following criteria:

- Term, healthy newborns
- NICU graduates, 34 weeks gestational age or older
- Newborns with normal outer ear anatomy and no obvious deformities of the head or neck
- Ready for discharge, or scheduled to go home within a few days
- Receiving no central nervous system stimulants
- In an open crib
- Sleeping or in a relaxed state

PROPER SENSOR PLACEMENT

1. Attach sensor cable clips to sensors: clip onto purple tab section of sensors (Refer to Figure 2)
2. Place sensors with colored cable clips to the correct site on the baby (Refer to Figure 3):

- **Vertex site:** centered on the forehead, as high as possible.
- **Nape site:** centered on back of neck, not on skull and not on infant's back.
- **Common site:** back of either shoulder, not on cheek.

Correct clip attachment: Clip is (1) attached to the purple tab portion of sensor only and (2) with wire of PCA clip aligned with bottom side on electrode.

Incorrect clip attachment: Clip touches hydrogel portion of sensor.

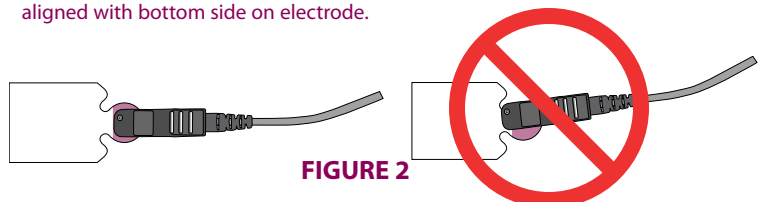


FIGURE 2

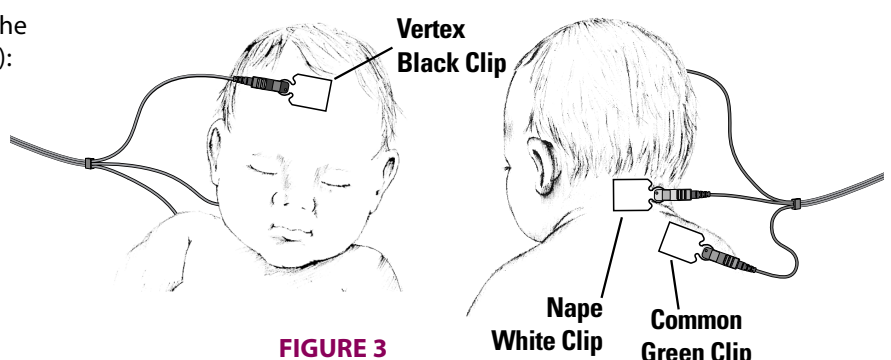


FIGURE 3

Note: Orient PCA clip so that wire is closest to baby.

[Continued on Reverse Side]

Note: Ensure the tab portion of all sensors are pointed towards the same side of baby.

Note: Hold sensors in place for a few seconds to warm and activate sensor adhesive.

Note: Route the ATA cables on the baby such that they do not overlap an electrode. This may aid in reducing interference during screening.

PROPER EARPHONE PLACEMENT

1. Insert colored acoustic transducers of earphone cable into earphones (Refer to Figure 4)
2. Place earphones with colored transducers over baby's ears by rolling from behind the ear to the front (Refer to Figure 5).

Blue transducer: **Left** ear **Red** transducer: **Right** ear

The earphone tab should be directed towards the back of the infant's head.

The earphone cable may emerge either up or down from the earphone (Refer to Figure 5)

Note: Hold earphones in place for a few seconds to warm and activate earphone adhesive.

Note: Removal of the earphones and sensors can be aided with the use of wet gauze.

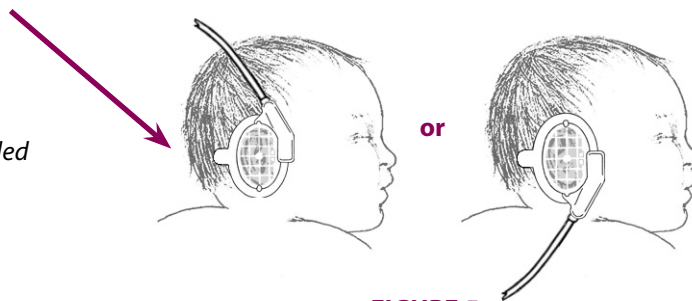


FIGURE 5

ENTERING PATIENT INFORMATION

Babies without Previous Screening History:

1. Type the patient's medical record number and press the tab key. Repeat for Last Name, First Name, Gender and DOB fields.
2. Enter information into any additional fields as required.
3. If information is entered in error, use the backspace key to delete.

Note: The screener only saves patient information after you select "Continue". If before selecting "Continue", you turn off the screener, press "F8 – Clear All Fields", or select "F10 – Main Window", then the information you have entered will be lost.

4. Enter the Risk Factors information.
5. Select a screening method.

Babies with Previous Screening History:

1. Type the patient's medical records number and press the tab key.
2. Confirm that you are entering the correct patient and medical record number.
3. You may also choose **Search Patient (press F3 key)** to load a patient based on any mandatory field partially filled in.
4. Review all information that automatically appears in the data fields; correct and/or update entries, as necessary.
5. Enter the Risk Factors information.
6. Select a screening method.

STARTING THE HEARING SCREEN

After the sensors and earphones are properly connected to the baby, begin the screening:

1. Select **Begin Screening (press F1 key)** from the Baby Preparation display.
2. Monitor the screening progress. As the screen proceeds, the status is indicated on the Screening display (Refer to Figure 6).
3. At the completion of the screen, the "Screen completed" message will appear. Select **OK** to continue. Once you select **OK**, you will see the results displayed in the Screening window.

Refer to the ALGO 5 User Manual for further information and all applicable precautionary information.

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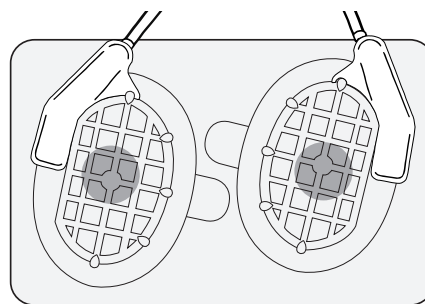


FIGURE 4

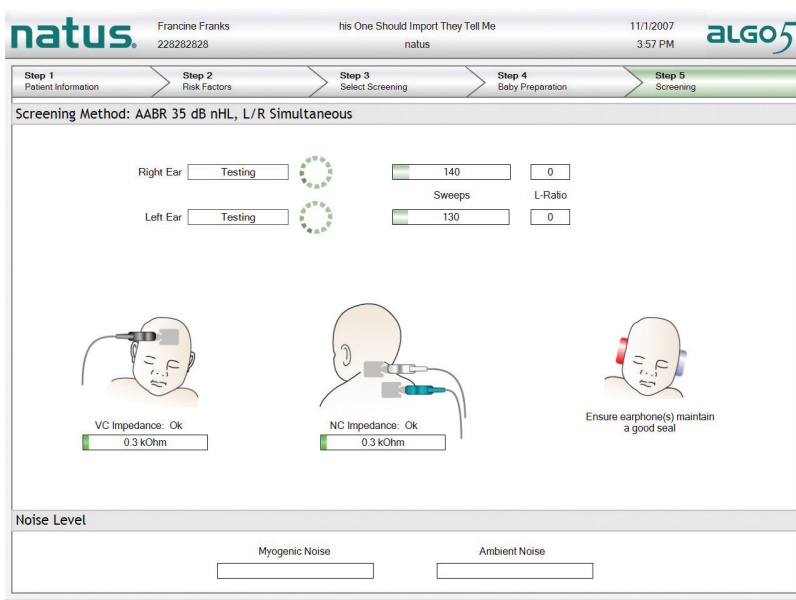


FIGURE 6



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