natus®

ALGO® 7i

User Manual

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Manual Information

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All information, illustrations, and specifications provided within this manual are based on the latest product information available at the time of publication. PATH MEDICAL reserves the right to make changes at any time without notice.

Errors and omissions excepted.

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1 Overview

1.1 Introduction

Thank you for purchasing the ALGO 7i. This manual is your guide for safely operating and maintaining your device.

Please read this manual carefully before using the ALGO 7i the first time. We recommend taking particular note of the safety (see section *8: Notes on Safety*), intended use (see section *1.2: Intended Use*), cleaning (see section *5: Cleaning*) and maintenance (see section *4: Service and Maintenance*) instructions.

ALGO 7i devices are reliable, easy-to-use, and mobile medical devices. All devices provide easy navigation via touch-screen and are intended for hearing examinations (see section *1.2: Intended Use*).

1.2 Intended Use

1.2.1 Intended Purpose

The ALGO® 7i Newborn Hearing Screener is a hand-held, portable hearing screener intended to objectively determine the hearing status of a newborn/infant from 34 weeks gestational age to 6 months old. Babies should be well enough for hospital discharge and should be asleep or in a quiet state at the time of screening. The test methodology contains:

- stimulus delivery
- EEG processing
- ambient noise processing
- PASS/REFER determination
- screening conditions assessment
- ability to screen ears individually, simultaneously and sequentially
- screening test condition monitoring

ALGO 7i devices are intended for use by audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals, nurses and audiologically trained personnel. It is not intended to be operated by lay users.
Given the simple operating principle of the ALGO device, basic training with the device is sufficient for performing screening of patients in good health. This is considered audiologically trained in this context.
Please consider local regulations regarding the qualification requirements for performing hearing screening.

The ALGO 7i is not intended for operational use by the general public. All test procedures must be supervised or conducted by qualified personnel. In the United States of America, Federal law restricts this device to sale by or on the order of a licensed physician.

The ALGO 7i is intended for indoor-use only and must be operated at defined environmental conditions. ALGO 7i devices are designed for use in clinical environments, such as the well-baby nursery, neonatal intensive care unit (NICU), mother's bedside, audiology suite, outpatient clinic, or doctor's office. as well as in community settings. See also operating conditions in section *9: Technical Specifications* and information about environmental conditions regarding electromagnetic disturbances in section *10: Electromagnetic Compatibility Information*. The ALGO 7i is not intended for use in oxygen-rich environments.

1.2.2 Contraindications

There are no known contraindications to the use of the ALGO 7i device.

1.2.3 Exclusion Criteria

The following criteria should be used to exclude an infant from screening with the Natus ALGO hearing screeners:

▪ Infants not between 34 weeks gestational and 6 months of age ▪ Infants on ventilators or in incubators ▪ Infants on CNS (central nervous system) stimulants ▪ Infants receiving ototoxic medications ▪ Infants with compromised skin or jaundice	Such infants may be screened once they are 34 weeks gestational age, and healthy enough for discharge from the hospital, but standard-of-care protocols should be followed as some of these conditions may be associated with delayed onset hearing loss.
▪ Infants exhibiting cranio-facial head abnormalities, including structural abnormality of the outer, middle, or inner ear ▪ Infants with known or suspected neurological conditions	Such infants should not be screened with the ALGO screener, as screening results may be misleading. Such infants require a comprehensive medical, audiological, and neurological assessment performed by qualified professionals.
▪ Infants in an agitated state	Perform the ALGO screening when the infant has settled down to ensure accurate results.

1.2.4 Side Effects

There are no known undesirable side effects for ALGO 7i devices.

See also section *8: Notes on Safety*.

1.3 Performance Characteristics

The ALGO screener delivers faint click sounds at 35 or 40 dBnHL ("normal hearing level" scale) to the baby's ears through disposable earphones. Each click evokes a series of identifiable brain waves from the infant's auditory brainstem. This brain wave activity is called the ABR (auditory brainstem response). Each click from the ALGO coupled with a response to that click is called a "sweep".

The ALGO 7i hearing screener offers the user the option to screen both ears simultaneously, both ears sequentially or each ear individually. This single technology device uses Natus's patented AABR® (Automated Auditory Brainstem Response) Screening technology to determine the status of the hearing pathway from the outer ear up to the brain stem. The device offers an automatically created result, which can have the values "PASS" (Clear Response), "REFER" (No Clear Response) or "INCOMPLETE".

The ALGO screener will issue a PASS result when it collects sufficient data to establish with > 99% statistical confidence that an ABR signal is present and consistent with the template. This confidence level can be reached at a minimum of 1000 sweeps for 35dBnHL screening, and 2000 sweeps for 40dBnHL screening. The ALGO screener will continue to collect data up to 15,000 noise-weighted sweeps. If it has not established with > 99% statistical confidence that the ABR signal is present after 15,000 noise-weighted sweeps, it will issue a REFER result.

The ALGO 7i hearing screener uses patented signal processing technology to separate the ABR from background noise and other brain activity. These responses are matched against a stored pattern called a "template", derived from the ABRs of normal-hearing infants. The ALGO screener must detect the ABR with very high statistical confidence in order to issue a PASS result. The ALGO technology includes a patented dual-artifact rejection system to prevent non-ABR activity from contributing toward a PASS result. This ensures a very high degree of accuracy of the PASS result issued by an ALGO device.

The ALGO 7i has no essential performance as related to DIN EN / IEC 60601-1.

2 Explanation of Symbols

This section explains all symbols used within this manual and on the device label.

Symbols within this manual:

Symbol	Explanation
	Important notice: please read for important information.
	Warning: please read for safety-relevant information, which may cause risk of danger to persons and/or device if not followed.

Symbols on the device label:

Symbol	Explanation
	Consult instruction for use, i.e. this manual.
	Serial number
	Article number
	Medical device
	Manufacturer name and address, production date
	Compliance with applied part type BF (body floating) requirements according to DIN EN 60601-1
	Device with safety class II according to DIN EN 60601-1
	Direct current input
	The device is electronic equipment covered by the directive 2012/19/EC on waste electrical and electronic equipment (WEEE). When discarded, the item must be sent to separate collection facilities for recovery and recycling.
	CE mark to declare conformity with medical device directive 93/42/EEC. The number below the CE mark refers to the identifier of the notified body.

For further symbols, e.g. on accessory labels, please refer to the respective manual or data sheet of the accessory. Important symbols may include:

Symbol	Explanation
	Single use only. Do not reuse the respective item.
	Expiration date. Do not use the respective item after the specified date.

3 Basic Operation

After switching on the device, the device can be operated via a touch-sensitive display. In the following section, the most important device functions and screen elements are explained.

Please note that screen shots or references to test modules in this manual may not reflect the actual configuration of your device.

3.1 Screen Layout

The device screen is divided into three main sections (see *Figure 1*):

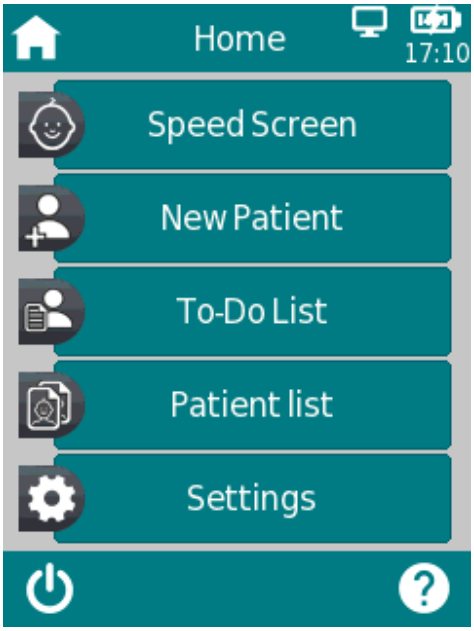


Figure 1: Device screen layout

① **Header**, including the following elements:

- Device time (e.g. 12:00)
- Screen-related information (e.g. Tab you are currently viewing)
- USB connection (is shown if USB cable is connected to a PC)
- Battery status (charging status indicator from empty to full)

② **Main screen**, including screen-related elements (e.g. Speed Screen, Patient list, Patient Selection or Settings)

③ **Footer**, including control elements (e.g. for switching off the device) and help

3.2 Online Help

Content-sensitive help screens allow intuitive handling of the device. Automatically generated message boxes may present additional content-sensitive warnings or information.


The content-sensitive help screens are available via the question mark icon, which is displayed in the footer. The help screens explain the currently available symbols and their functions.

3.3 Test Result Status Icons

In the test history list, test results are shown with an overall test result status icon. The icons correspond to the following definitions:

	**Test result PASS** Screening passed successfully; no further testing necessary
	**Test result incomplete** Screening should be repeated (e.g. when baby is sleeping or in a calm state)
	**Test result REFER** Screening referred. Please consult your local facility protocol for next steps with rescreening or audiological referral

3.4 Device Hardware

3.4.1 On/Off Switch

The on/off switch is located at the right side of the device housing (see *Figure 2*). The on/off switch can be used to switch on or off the device. For switching on the device, press the switch briefly. The welcome screen appears. For switching off the device, press the switch for approximately 10 seconds.

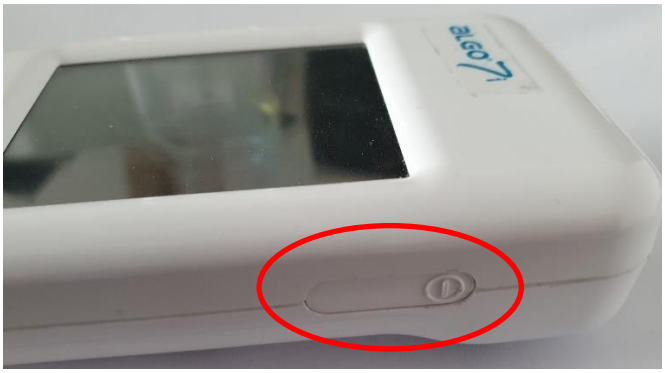
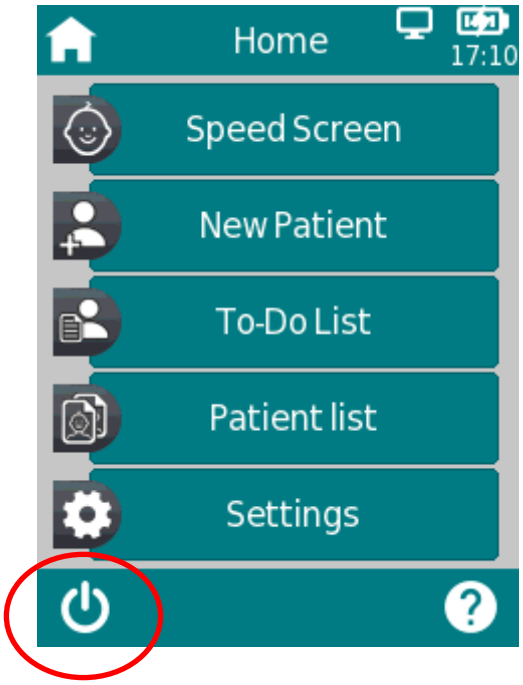


Figure 2: On/off switch

Alternatively, the device can be switched off via the off-switch icon in the footer of the device display.



3.4.2 Device Reset

If the touch screen is unresponsive (i.e., no reaction when pressing an icon), reset the device by pressing the on/off switch for several seconds. The reset does not change any device or test module settings or affect any other saved data on the device.

3.4.3 Device Cable Connectors

Multiple cables can be connected to the device. This includes The Acoustic Transducer Assembly (ATA), Patient Cable, and the Multi-Data Cable (for connecting the label printer, USB communication cable, and power cable for charging purpose). For further information, see section *6: Accessories*.

The sockets can be used as described in *Table 1*.

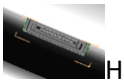
Socket	Cable
ODU Grey 	ATA Cable
ODU Black 	Patient Cable
 Hirose	Multi-Data Cable/ Docking station for Charging, USB connection and label printer.

Table 1: Device socket overview

For the Docking Station and the Multi-Data Cable, following sockets are displayed:

	Label printer, modem
	USB cable with type B connector
	Power supply

Table 2: Device socket overview for Docking Station and Multi-Data Cable

3.4.4 Charging the Device

Connect the Multi-Data Cable to the device (see section *3.4.3: Device Cable Connectors*). For charging the device, connect the power supply to the power supply outlet and plug it to a power mains socket with appropriate output voltage and frequency. For more information about power supply units please see section *9: Technical Specifications* and information provided on the power supply unit. When using a Docking Station, make sure that the power supply is connected to the Docking Station and to a power mains socket. Simply slide the device into the Docking Station. The charging process starts automatically and completes within about 5 - 8 hours. The battery status can be derived from the battery status icon symbol: charging  status indicator from empty to full. The Docking Station and the Multi-Data Cable will feature a LED indicating when the device is charging.

3.5 Device Functions

3.5.1 User Management

With the ALGOLink software you can activate or de-activate the user management on your device (see ALGOLink online help for more information). If the user management is activated, after switching on the device, you will be asked to select a user and to enter the user password. Please follow the explanations on the device. If you would like to change a user you need to logoff from the device and restart the device. If the user management is active, you are only enabled to change module parameters when logged in as administrator.

Please make sure that local data protection requirements are met. When user management is deactivated on ALGO 7i device, the device does not provide any inherent access protection (i.e. no login with password).

3.5.2 Patient Management

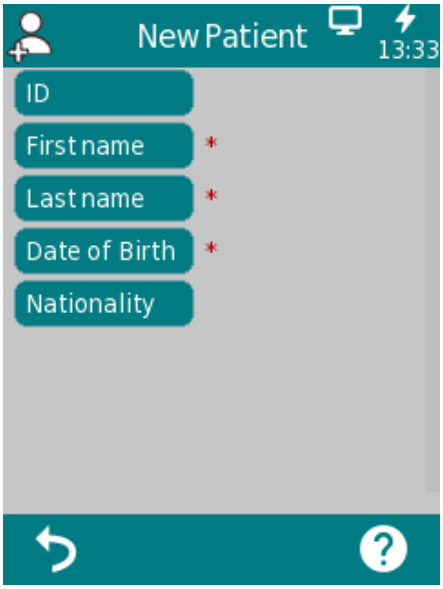
After switching on the device (and if applicable after login) a patient can be added, selected from the list of patients or the test screen can be entered directly in “Speed Screen” mode, i.e. without adding or choosing a patient. Depending on user rights, it is also possible to delete a single patient, all patients or patients by date range (Device Settings → Data Management).

In “Speed Screen” mode, tests can be conducted and patient data can be entered and saved simultaneously. This may be helpful e.g. for quickly testing a sleeping child if there is no time to enter the patient data in advance. When conducting test in “Speed Screen” mode, always make sure that you assign the test data to the correct patient.

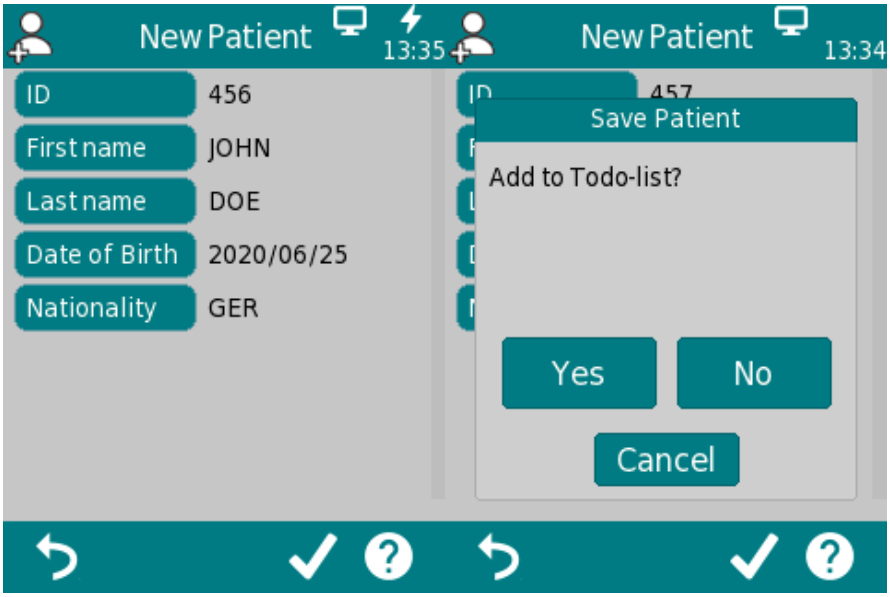
Patient Data can also be added retrospectively once the test is complete by going to Patient List and selecting the BLANK Patient that has just been screened. It is essential to enter patient data after a Speed screen to ensure tests are assigned to the correct patient.

To add patients, tap the “New Patient” Button on the home Screen.

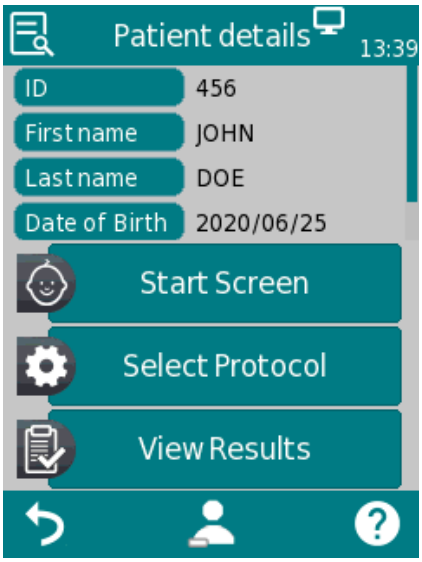
Following information then can be entered using the keyboard on the touch display:



When done, confirm by tapping the check mark. You'll be automatically asked if you want the patient added to the To-Do List.



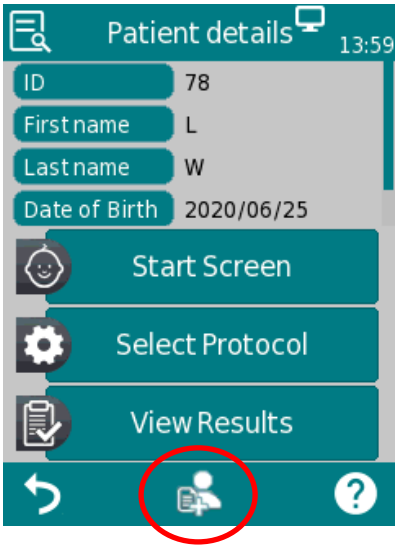
Once a Patient has been saved to the Patient and/or To-Do list, following options are available: "Start Screen", "Select Protocol" and "View Results"



- "Start Screen" directs you to the Screening menu (see 3.5.7),
- "Select Protocol" allows you to adapt screening settings prior to your measurements (Stimulus level and Screen method, i.e. which ear, or both ears (if enabled),
- "View Results" shows any screening result already existing to the patient.
- Tapping the icon in the middle of the footer:  allows you to remove this patient from the To-Do List (depending on potential user rights).

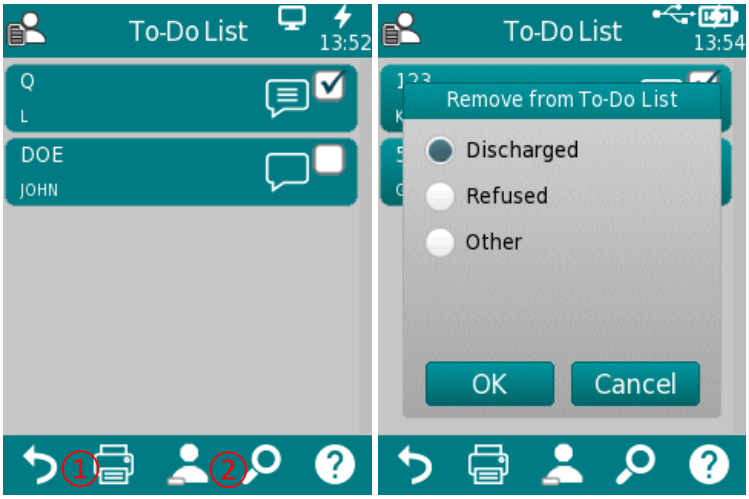
For further questions, please also use the device online help by tapping the question mark in the patient screen.

When adding Patient to the To-Do- List, you can create your individual work list for each day. Either load your To-Do- list using the ALGOLink PC Software onto your device, or choose from the patient database on your ALGO 7i device and tap on the "add patient" button in the footer of the Patient Details screen.



When using the To-Do- list, you can enter the patient details by tapping on the individual patient. From there, you can operate as described above. Additionally, by tapping on the speech bubble, you can enter or read already existing comments to this patient. Tapping the Checkbox activates the Patient-

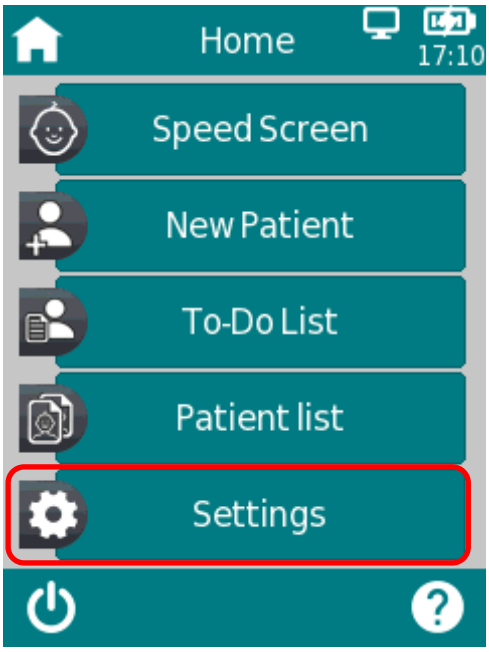
related options in the Footer (① Print Record, ② Remove Patient from To-Do List). When Removing a Patient, please choose the reason for removal.

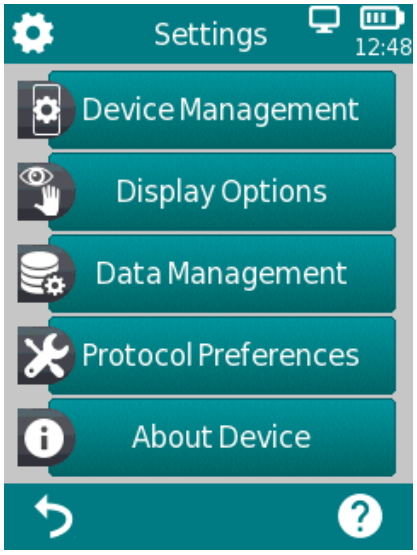


3.5.3 Device Settings

There are multiple options to configure the device to your needs.

The device settings can be reached via Settings Tab with the gearwheel symbol on the main screen:





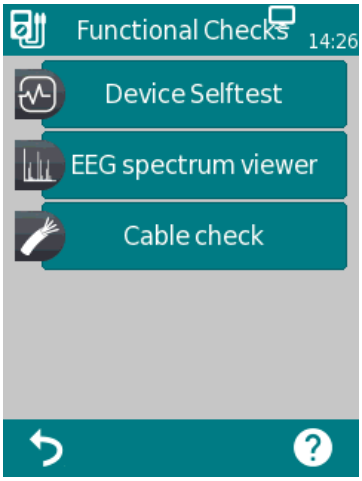
The following device settings are available:

- Device Management, date and time format
- Display Options: Language, sound (key click, result sound), display brightness, power options, keyboard preferences
- Data Management: Patient Removal, Factory Presets
- Test preferences: To-Do-List Removal Criteria

For further information about device settings please see device online help on the “Settings” screen and its submenus.

3.5.4 Hardware Tests

The main device functions can be tested with the “Functional Checks” option in “About Device”.



The **device self-test** examines several device properties such as internal power supply, codec function, and memory integrity. If a device property is correctly working, test status is indicated as “OK”. If not all device properties are tested successfully, please contact your distributor or Natus Sales representative. To perform the device self- test, simply touch the device self- test button. The test will start automatically.

The **Cable Test** checks the ATA Cable and Patient Cable functionality. Please use the ALGO 7i Check Kit to test the Impedance levels with your cable. To do so, plug in your Patient Cable in the black socket of your ALGO 7i device and attach all three clips to the metal bar of your Check Kit. Then plug in your ATA Cable in the grey socket and connect to the left and right opening of the Check Kit. Tap the “Cable Check” button and follow the on-screen instructions. Please note: Please do not run this test without connecting cables to the ALGO 7i Check Kit. If your ATA Cable fails the Cable Check, Screening will be disabled with this particular cable until a successful Cable Check has been passed.

If anything other than those values listed for each test step are displayed, please contact Natus Technical Service or your Natus authorized service representative.

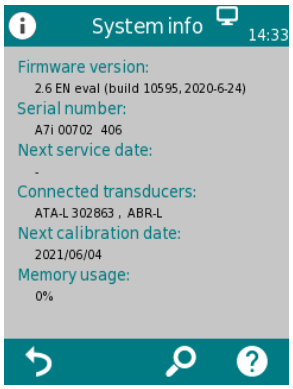
It might happen that one of the error messages shown in *Table 3* occurs. Please follow the recommended actions for troubleshooting mentioned in *Table 3*.

Error message	Recommended actions for troubleshooting
No transducer found	Check if the ATA Cable is properly connected to the device. → If not, connect the ATA Cable to the device.
Test Result “FAIL”	Check if the ATA Cable is placed correctly and tightly in the test cavity. → If not, place the ATA Cable hooks in the cavities.

Table 3: Probe test error messages and recommended actions

If the recommended actions in *Table 3* do not help in solving the problem, please contact Natus Technical Service or your Natus authorized service representative.

3.5.5 System Information



On the system information screen, general information about the device and firmware version is displayed. Information about connected transducers is also displayed if the respective transducer has been connected before the system information screen is entered. On the second page, the next service date of the device and the next calibration dates of the known transducers are listed. When contacting your distributor regarding any service request (e.g. error message or module update) this data should be at hand.

3.5.6 Test Module Information

Auditory brainstem responses (ABR) Screening tests are performed with the device. Options include 2 Stimulus intensity levels (35dB nHL and 40dB nHL).

When conducting a measurement, please consider the following aspects:

Ambient noise levels should be minimized to avoid interference with screening. Myogenic interference from a restless baby or environmental factors will affect the screening and should be kept to a minimum.
For ABR measurements also make sure to test in an environment with low electromagnetic disturbance from electronic devices (e.g. computers, lights, other electronic medical devices) as electromagnetic radiation may deteriorate ABR test performance. Please consider local regulations regarding requirements for the test environment.

3.5.7 Performing Measurements

3.5.7.1 Prepare the baby

Before starting a measurement, the baby needs to be prepared for screening.

Prepare the infant for screening by ensuring that no exclusion criteria are present, and that the infant is in a quiet state. Evaluate skin and prep if necessary.

Connect the cables:

The ATA Cable (gray strain relief) plugs into the gray port, and the Patient Cable (black strain relief) plugs into the black port. Align the double ridges on the bottom of each plug with the slots in the appropriate port, and then press the cable in until it clicks into place.

Carefully align the ridges on the plug to the slots in the port to reduce the chance of bending the metal pins inside the plug. You must insert the plugs completely into the corresponding ports for the device to operate properly. Never twist the plugs during insertion or removal. Twisting a plug in the port can damage the metal pins and cause system malfunctions. Handle the ATA transducers with care at all times and avoid striking against any surface. Shock to the transducers can result in damage to their sensitive acoustic components.

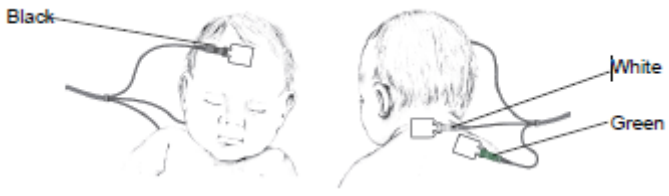
Apply the Jelly Tab® sensors:

Skin preparation reduces impedance, allowing for better conductivity of the AABR signals.
Prior to applying the Jelly tab sensors, Prepare the 3 sensor sites by wiping with water and mild soap (as per your facility's protocol). Be sure to wipe the soap from the skin with damp gauze, leaving the skin moist.

Note: Alcohol dries the skin and is not recommended as a skin preparation method.

Do not use soap or alcohol on an infant's skin unless permitted by your facility's standard protocol. If your facility's protocol does not permit mild soap, wash the skin with water or approved skin preparation gel such as NuPrep. If a skin preparation gel is used, be sure to remove it with damp gauze, leaving the skin moist before applying the sensors.
Do not prepare skin or apply Jelly Tab sensors to damaged or compromised skin. Always remove and dispose of the Jelly Tab sensors when screening is completed.
Jelly Tab sensors are designed for single-patient use. Do not reuse. Do not use damaged or expired sensors.
Attach the clips of the Patient Cable to 3 disposable Jelly Tab sensors:
Attach the clips to all 3 Jelly Tab Sensors before removing the sensors from the adhesive liner card. Squeeze each clip open and place it on the purple tab of the sensor. Keep the cable side of the clip and the gel side of the sensor facing the same way. Do not allow the clip to come in contact with the hydrogel portion of the sensor. Hold the sensors by the clips and remove one at a time from the liner card and attach the sensors to the baby, orienting all 3 sensors in the same general direction:

- Black clip: Vertex (center forehead, as high as possible, nearest to the hairline and away from eyebrow and eye area.)
- White clip: Nape (centered on back of the neck, not on the skull or back.)
- Green clip: Common (back of either shoulder, not touching the nape sensor.)

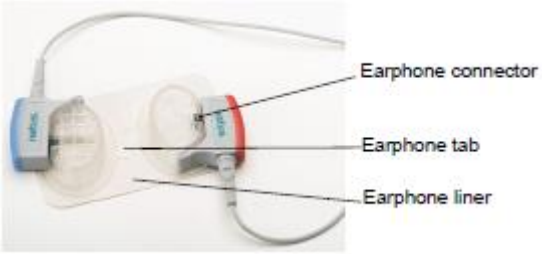


Gently hold each sensor in place for a few seconds to allow them to warm and create good adhesion to the baby's skin.

TIP: Attach the white and green sensor clips first, and attach the black clip last as you about to commence the screen. This allows you to move the baby as needed to attach the sensors and ear couplers without dislodging the forehead sensor.

Apply Flexicoupler® Disposable Ear Couplers:

Before removing the Flexicouplers from the adhesive liner, attach the ATA Cable transducers by inserting the transducer into the round opening, and clicking it into place along the side of the Flexicoupler.



One at a time, remove a Flexicoupler from the liner and place it securely over the baby's ear:

Position the Flexicoupler tab at the back of the ear with the cable emerging either toward the top of the head or toward the baby's body. Roll the earphone from the back of the ear to the front as you attach it to the baby. The earphone must completely enclose the external ear and form a good seal all the way around.

Ensure that the transducer is in the front, i.e., towards the baby's face. This ensures that the screening stimulus is directed into the infant's ear.

Avoid applying Flexicouplers to hair if possible.

Ensure that the colored transducer is in front of the baby's ear and the Blue transducer is positioned on the left ear and the Red transducer is positioned the on right ear.

3.5.7.2 Perform a Screening

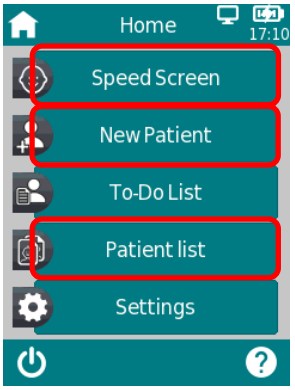
Options to start screening include the Speed Screen function (if enabled by your administrator), or via the New Patient button or by selecting a patient from the To-Do List.

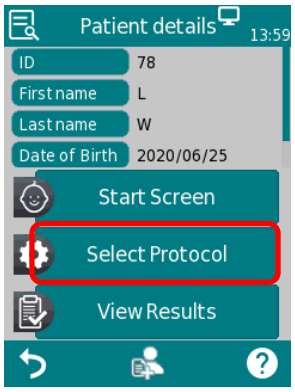
The screening options appearing on your device are set by your program administrator. The ALGO 7i device supports simultaneous, sequential, or single screening of each ear individually.

Start screening:

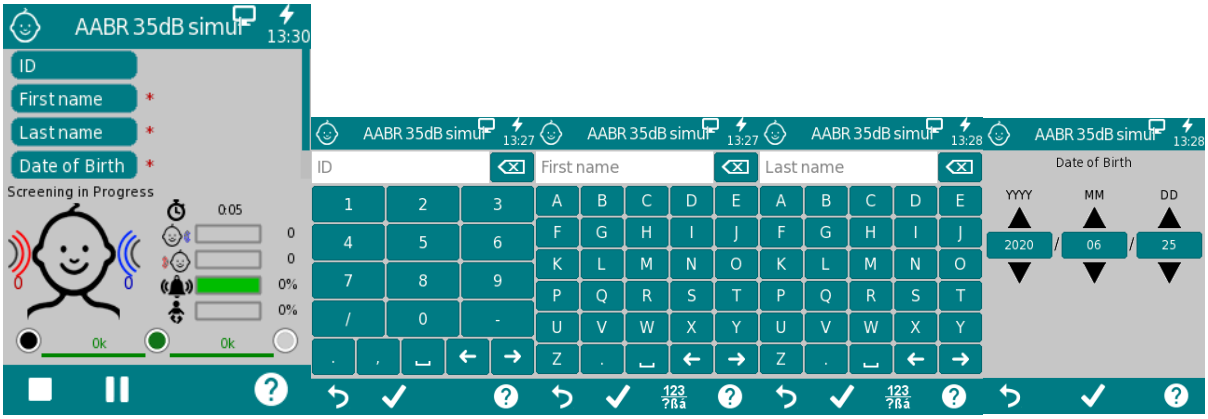
Select the Patient to be screened:

- To select a Patient already added to the To-Do list, on the Home screen, tap To-Do List and select the patient, and select start screen, or select protocol, and start screen depending on your device settings
- To select a patient already on the device but not yet in the To-Do list, on the Home screen, tap Patient List, select the baby by tapping on the Patient Name, and select start screen, or select protocol, and start screen depending on your device settings
- To add a new patient to the device and then start screening, tap New Patient and enter the patient information and select start screen, or select protocol, and start screen depending on your device settings.





If you want to start screening immediately and enter Patient data during screening, touch “Speed Screen”. You will be directed to the Screening display and measurement will automatically start, if ATA Cable and Patient Cable are connected properly to the device. You can then enter the patient’s data by tapping on the individual field using the touch screen display.



3.5.8 Troubleshooting

If an error occurs with your device please check the below list and proceed as recommended in *Table 4*. Further information about Troubleshooting can be found in section *3.5.4: Hardware Tests* or in the online FAQ (www.pathme.de/support/faq).

Error	Recommended action for troubleshooting
Black display	The display is automatically deactivated after 2 minutes (time span configurable) without user activity in order to increase use time without recharging. Touch the display in order to leave the power saving mode.
No feedback, black display	After 10 minutes (time span configurable) without user activity the device automatically powers down completely. Start the device by pressing the on-switch.
No feedback, black display, device stalled	If the device does not respond to user action you might need to restart the device by pressing the reset switch (see section *3.4.2: Device Reset*). Charge the battery if necessary.
Error message: "Battery is too low for testing."	Connect the device to the power supply unit or place into the Docking Station to charge the battery. Do not perform any measurement during charging.
Device stops test and/or shuts down during test.	Connect the device to the power supply or place into Docking Station unit to charge the battery. If a test is stopped due to low battery and the device is shut down, the test data is saved before shut down.
Error message: "Remove cable"	Remove the Multi-Data Cable.
Error message: "Touch screen error"	The error message appears if there is a permanent pressure on the touch screen during startup of the device. Check if there is a particle between the display and the surrounding display frame. Remove the particle with a small and soft tool (e.g. paper strip).
Error message: "Calibration/service interval expired"	The error message appears if the calibration interval of a transducer or the service interval of the device has expired. Please send the transducer and/or the device to your service partner.
"Error *[Error-ID]*"	Device error recognized by device self-test. Contact your service partner for more information.

Table 4: Errors and recommended actions

If the recommended actions in *Table 4* or in the online FAQ do not help in solving the problem, please contact Natus Technical Service or your Natus authorized service representative.

3.6 ALGOLink PC Software

The ALGOLink PC software will be delivered with your system. The ALGOLink PC Software can be used for creating user accounts, exporting data from the device, uploading and downloading patient information to and from the device, reviewing and archiving test data, printing test data to a standard PC printer. The ALGOLink Software comes with a built-in online help for further information about correct usage and for troubleshooting.

This software also includes the latest firmware for updating the ALGO 7i device. Please contact Natus Technical Service or your Natus authorized service representative to obtain the latest version of this software.

4 Service and Maintenance

4.1 General Service Information

Natus Medical is committed to customer satisfaction. Please contact your distributor or Natus Sales representative for ordering supplies, obtaining information on training courses and service contracts, getting help with device-related problems, or finding answers not addressed in the device online help or associated manuals. General information on Natus Medical can be found at www.natus.com.

Updates to software, firmware and documentation (e.g. user manual) may be done as needed. If updates are available, Natus distributors and Sales representatives will be informed. It is the responsibility of the local distributor or Sales Representative to inform the end customer. If you are not sure whether your software, firmware, or documentation is up-to-date, please contact Natus Technical Service or your local Natus representative.

Service activities and repairs of the device and its electro-medical accessories must only be conducted by Natus, its authorized service partners or PATH MEDICAL. Authorized service partners are enabled from Natus and PATH MEDICAL with necessary documentation and training in order to conduct specified service activities and repairs.

Natus Medical and the manufacturer of this device, PATH MEDICAL reserve the right to decline any responsibility for the safety in operation, reliability, and capability of the device or accessory if any service activities or repairs were conducted by a non-authorized service partner (see also section *7: Warranty*). If in doubt, please contact Natus before commissioning a service activity or repair. Please send the device or accessory in its original packaging to your distributor.

4.2 Routine Maintenance and Calibration

To ensure safe operations and to keep measurements valid, it is stipulated by PATH MEDICAL to check the device and calibrate its transducers at least once a year or more frequently if required by local regulations or if there is any doubt about correct system function. A warning message is shown on the device if the device service date or a transducer calibration date has expired. Please return the device or accessory immediately to your distributor or service partner.

Please note that it is easy to exchange transducers individually and recalibrate them separately. This will help you to increase uptime and availability of your device. The ALGO 7i screener electronically reads the calibration date of the ATA Cable. If the calibration date cannot be read, the ALGO 7i screener will not allow screening with that ATA Cable. Calibration dates are read at start-up and also prior to starting the screening, and are displayed in the System Info in the Device Settings Tab.

Note: The ATA calibration date is not related to the current time and date values in the ALGO 7i screener. Changing the current time and date will not affect the calibration clock.

The calibration clock will count down to 0 days until calibration due, and will award a 90-day grace period before disallowing hearing screening with that ATA Cable.

REGULATORY BACKGROUND:

For the device and its transducers, an annual metrological inspection following §11 Clause 2 of the medical device operator act (MPBetreibV, Germany) must be conducted by a service partner who is authorized by PATH MEDICAL. The measurement principle of acoustically evoked potentials (AEP) is not explicitly described in MPBetreibV. Therefore, the manufacturer is obliged to define metrological inspection instructions. DIN EN 60645-7 (AEP) suggests an annual inspection interval.

EXPLANATION:

The device and its accessories contain parts, which are exposed to environmental impacts and contamination. In order to ensure an accurate measurement function, the fault tolerance provided by the manufacturer or defined by applicable standards needs to be controlled by specifically designed instrumentation and defined procedures. Therefore, metrological inspection must be conducted by authorized service partners instructed and trained by PATH MEDICAL.

For acoustic transducers differences in environmental conditions between the point of calibration and the point of use may influence the calibration accuracy. For more information please refer to section *8.2: Handling, Transport, and Storage*.

In addition to the annual metrological inspection, a regular visual inspection and a regular check for correct operation of the device and its accessories is recommended. Guidelines for routine inspections are provided e.g. in DIN EN ISO 8253-1 for pure-tone audiometry. Please follow local regulations or guidelines.

4.3 Repair

If a defect of any kind is suspected, or calibration of cables is due, Natus, or an authorized service partner will repair, re-calibrate or exchange the device or accessory. All repairs are subject to parts and material availability. Prior to sending any equipment for repair, please provide relevant information to your service partner (e.g. model, serial number, firmware version, contact information, shipping information, detailed description of experienced issue or defect). In the United States and in countries where Natus Medical directly distributes the device, ALGO 7i ATA Cable calibration and repair service is performed by Natus Medical through Natus Technical Service. Outside the above- mentioned territories, local distributors can organize ATA7i Cable calibration service and repair service through an authorized Natus technical service center. There are no user serviceable parts inside the ALGO 7i screener. Disassembling the ALGO 7i screener or any of its components will void the manufacturer warranty.

In the United States, contact Natus Technical Service at (888) 496-2887 or (650) 802-0400. Outside the United States, please contact your authorized service representative.

See also sections *4.1: General Service Information* and *7: Warranty*.

5 Cleaning

Cleaning the device and its accessories is very important for compliance with hygienic requirements and to avoid any cross-infection. Please always consider local regulations and read this section carefully.

Before cleaning the device, the device must be switched off and removed from all connected components (e.g. power supply unit).

Wipe the surface of the device with a cloth slightly dampened with mild detergent or normal hospital bactericides or antiseptic solution. The following quantities of chemical substances are allowed to clean the device:

- ethanol: 70-80%,
- propanol: 70-80%,
- aldehyde: 2-4%.

Approved cleaning solutions for cleaning ATA Cables are 70% isopropyl alcohol and mild soapy water solution. The ATA Cable transducer body contains sensitive components. Never attempt to clean the sound apertures on the transducer body with cleaning solution or by inserting an object in the sound apertures.

Do not immerse the device into liquid and ensure that no liquid gets inside the device. Dry the device with a lint-free cloth after cleaning.

Disposable accessories (Jelly Tab sensors and Flexicouplers) must be replaced between patients to avoid cross-infection.

It is recommended that parts which can have direct contact with the patient are subject to standard disinfecting procedures between patients. This includes physical cleaning and use of recognized disinfectants.

When using a cleaning agent, please refer to the manufacturer's data sheet of the cleaning agent for the minimum time period in which the wipe has to be in direct contact with the surface of the device or accessory to ensure effectiveness of cleaning.

The device and its accessories are provided non-sterile and are not intended to be sterilized.

6 Accessories

Available accessories for ALGO 7i devices include:

Type	Model examples	Applied part	Max. cable length*
ATA Cable		yes	1.83 m (72'') or 0.91m (36")
Related accessories: Flexicoupler			
Patient Cable	Patient Cable	yes	1.83 m (72'') or 0.91m (36")
Related accessories: - Sensor testing device - Jelly Tab sensors			
Label printer	Seiko SLP 650 SE, Able AP1300	no	---
Related accessories: printout paper rolls			
Multi-Data Cable	USB, Charging, Label Printer, Modem Connection	no	0.2 m (8'')
Modem	---	no	---
Transportation bag	---	no	---
PC software	---	no	---
Power supply unit	Friwo FW7662	no	1.83 m (72'')
Docking Station	--	no	---

* Maximum cable length rounded in metrics units.

The above list of accessories may be subject to change. Accessories may be available only upon request, may be replaced by comparable equipment, or may be discontinued without prior notice. Please contact your distributor for an up-to-date list of available accessories.

7 Warranty

Natus Medical warrants that the supplied device and its accessories are free from defects in material and workmanship and, when properly used, will perform in accordance with applicable specifications during the defined warranty period.

The ALGO 7i is covered under a one-year warranty. The rechargeable battery pack, the touch screen and wearable parts (e.g. Patient Cable) are covered under a six months warranty. The warranty period begins on the date of shipment.

This warranty is only valid for devices and accessories purchased from an authorized distributor. This warranty is not valid in cases of breakage, malfunction due to manipulation or unintended usage, negligence, non-observance of manufacturer's instructions including cleaning instructions, crashes or accidents, damages by external causes (e.g. flood, fire) or damages due to shipment (see also disclaimer of warranty). This warranty is not valid for normal deterioration of wearing parts and cosmetic damages (e.g. scratches). Opening the device case or any accessory housing voids this warranty.

This warranty includes material and labor costs in accordance with the manufacturer specifications. Natus Medical reserves the right to credit, repair or replace (with a new or refurbished product) an "in-warranty" device or accessory.

Warranty repairs for the ALGO 7i are handled in the same manner as other repairs and service.

See also section *4.1: General Service Information*.

DISCLAIMER OF WARRANTY:

The warranty contained herein is exclusive. Natus Medical disclaims all other warranties expressed or implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose or application. Natus Medical shall not be liable for any incidental, indirect, special or consequential damages whether resulting from the purchase, use, misuse or inability to use of the device or accessory or relating in any way to the defect in or failure of the device or accessory, including, but not limited to, claims based upon loss of use, lost profits or revenue, environmental damage, increased expenses of operation, cost of replacement goods.

8 Notes on Safety

In order to allow safe performance of the ALGO 7i, please read the following notes on safety carefully and follow the provided instructions. If not followed, risks of danger to persons and/or the device may be the consequence. Retain this manual for later use and make sure to hand over this manual to any person who uses this device. Applicable local government rules and regulations must be followed at all times. Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

8.1 General Usage

Follow relevant regulations in your facility regarding maintenance and calibration of audiometric equipment. This includes regular servicing of the device and calibration of transducers. See section *4: Service and Maintenance*.

Do not try to open or service the device and its components yourself. Return the device to the authorized service partner for all service.

Do not operate the device if its power supply is connected to the device and shows a damaged cord or plug. Likewise, this is true for any accessory with a separate power supply (e.g. label printer).

The device needs to be operated in a quiet environment, so that measurements are not influenced by ambient noises. This may be determined by an appropriately skilled person trained in acoustics. DIN EN ISO 8253-1 section 11 defines maximum ambient noise levels for audiometric hearing testing. If not followed, measurement data may not reliably represent the actual hearing status. See also section *3.5.6: Test Module Information*.

The device needs to be operated in an environment with low electromagnetic disturbance. If not followed, measurement data may be deteriorated by electrical noise.

For calibrated transducers differences in environmental conditions between the point of calibration and the point of use may influence the calibration accuracy. For more information, please refer to section *8.2: Handling, Transport, and Storage*.

There are no device parts, which can be serviced during use with a patient. See also section *4: Service and Maintenance*.

8.2 Handling, Transport, and Storage

Do not drop or otherwise cause undue impact to the device or any accessory. If any damage is suspected (e.g. loose parts inside device), do not use the device, contact Natus Technical Service or your local Natus authorized service partner for repair.

Do not modify the device and its components in any way without written consent of the manufacturer. Failure to do so may result in a reduced level of safety of the system and/or degradation of functionality.

Do not transport, store or operate the device at environmental conditions exceeding those stated in section *9: Technical Specifications* If the device is moved from a cold location to a warmer one, there will be a risk of condensation. If condensation occurs, the device must be allowed to achieve normal temperature before it is switched on.

Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the device and its components is adequate, sturdy, and safe. Neither Natus Medical nor PATH MEDICAL is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces.

Do not allow any fluid to infiltrate the device. Do not immerse the device in fluids or cleaning agents.

Dust particles may corrupt the touch pad. Please make sure to keep the touch pad clear of dust particles.

Do not put excessive pressure on the device display or allow any item to puncture the device display.

Do not place the device next to a radiator or any other heat source.

8.3 Electrical Safety

The power supply is specified as a part of the device. Do not use any power supply other than the ones defined in section *9: Technical Specifications*. The use of alternate power supplies designed for other electronic devices such as notebook computers or printers may cause damage to the device. Likewise, using the ALGO 7i power supply on other types of devices may cause damage to those devices.

Avoid accidental contact between connected but unused applied parts and other conductive parts including those connected to protective earth. Conductive parts of sensors and their connectors including the neutral sensor are not allowed to contact other conductive parts and earth.

Do not use the device during the application of high-frequency surgical devices, cardiac pacemakers, defibrillators or other electrical stimulators. This may result in burns at the site of sensors and possible damage to the applied parts.

Do not use the device in close proximity to shortwave or microwave therapy equipment as it may produce instability in the applied parts.

Do not connect the Multi-Data Cable to the device during testing.

If a connection is established from the device to a standard PC which is powered through the mains network, special precautions must be taken in order to maintain medical safety. The Multi-Data Cable can only be used for PC connection if the connected PC is outside the patient's close range or if the PC is running on battery, is medically approved, or is powered via a medically approved safety transformer or is compliant to EN 60950. In all other cases, a galvanic separator must be inserted in the USB connection.

8.4 Electromagnetic Compatibility

The use of ALGO 7i devices in close proximity to other electronic equipment or with other electronic equipment in a stacked form should be avoided, as this could result in improper operation (e.g. occurrence of unwanted noise). Electronic equipment may include e.g. mobile phones, pagers, walkie-talkies, or RFID systems. If such an application cannot be avoided, ALGO 7i and the other electronic devices should be observed to make sure they are working properly. It may be necessary to implement suitable corrective measures (e.g. new orientation or positioning of ALGO 7i or shielding). Please also refer to section *10: Electromagnetic Compatibility Information.*

Portable radio frequency communications equipment (radio equipment) including their accessories such as antenna cables and external antennas should not be used closer than 30 cm (12'') to the ALGO 7i and its accessories.

During testing it is recommended to keep low-power radio equipment (≤ 2 W) at a distance of at least 3 m (118'') from the ALGO 7i and its accessories.

It is recommended to keep very strong sources of radio frequency emissions (e.g. high-power transmitting antennas from radio or TV stations) at a distance of at least 2 km (6560 ft.) from ALGO 7i (minimum required distance depends on signal power and directional characteristics of the sender).

Failure to do so may result in a reduction of device performance.

Use of other accessories than the ones specified or provided by PATH MEDICAL may result in higher electromagnetic emission or reduced immunity to interference of the device and may result in improper device operation.

8.5 Accessories

The Flexicouplers and Jelly Tab sensors are marked "single use only" and must be replaced between patients to avoid cross-infection. Do not clean or reuse these items.

Do not connect any accessories other than those supplied by Natus Medical. Accessories other than those specified by the manufacturer are not compatible with the device and may result in device damage or improper functionality of the device. If connecting accessories which do not comply with the same safety requirements as this product, this may lead to a reduction in the overall system safety level.

Cleaning the device and its accessories is very important for compliance with hygienic requirements and to avoid any cross-infection. For further information please refer to section *5: Cleaning*.

Always handle cables and transducers with care. Do not excessively bend or twist any cable. The cable may break and hence deteriorate overall device functionality or reduce the overall system safety level. Do not drop, throw or hit any transducer on a hard object. Sensitive parts (e.g. ATA Cable microphone and loudspeakers) may get damaged and deteriorate measurement performance. Do not use a cable or transducer if any damage is suspected.

Keep small parts out of patient's range in order to prevent accidental swallowing.

No parts may be eaten, burnt, or in any other way used for purposes other than specified in the intended use.

The sockets are intended to connect to the respective accessories (ATA Cable, Patient Cable, Multi-Data Cable). Do not connect any other item to these sockets. For correct connections see section *3.4.3: Device Cable Connectors*.

Do not try to insert any plug into a device socket with excessive force. A plug fits only into a device socket if the mechanical coding of the plug is corresponding to the device socket. Cables are color-coded to assist with selecting the correct device socket. See section *3.4.3: Device Cable Connectors*.

When pulling a plug out of a socket always pull at the plug and not at the cable to avoid cable break.

Do not expose the label printout to sunlight or heat. Printing on thermal paper fades with exposure to light or heat.

8.6 Waste Disposal

The device includes a rechargeable lithium ion battery pack. Replacement of the battery pack must be completed by an authorized service partner. The service partner is responsible for the correct disposal and storage of the battery pack. Do not dispose of the batteries in your normal household waste bin. Please follow your local regulations for proper disposal.

Within the European Union, the device must not be disposed of in your normal household waste bin since electronic waste may contain hazardous substances. The device is electronic equipment covered by the Directive 2012/19/EC on waste electrical and electronic equipment (WEEE). Please follow your local regulations for proper disposal of the device and its accessories.

9 Technical Specifications

This section provides a summary of the most important technical specifications.

9.1 General Device Information

Device classification (93/42/EEC, 745/2017)	Class II a
Applied part classification Applied parts	Type BF (body floating) ATA Cable, Patient Cable
Ingress protection rating (IP code)	IP30
Applied standards	DIN EN ISO 10993-1, -5, -10 (biocompatibility), DIN EN ISO 15223-1 (manual), DIN EN 60601-1 (electrical safety), DIN EN 60601-1-2 (EMC), DIN EN 60601-1-4 (PEMS), DIN EN 60601-1-6 and DIN EN 62366 (usability), DIN EN 60601-2-40 (AEP equipment), DIN EN 60645-3 (short-term test signals), DIN EN 60645-7 (ABR), DIN EN 62304 (software lifecycle)

9.2 Device Characteristics

Device dimension	ca. 209 x 98 x 52 mm (8.22 x 3.86 x 2.05'')
Device weight (including battery pack)	ca. 500 g
Display properties	240 x 320 pixel, graphic LCD, 3.5''
Maximum power consumption from battery	ca. 4 V, 0.5 A = 2 W
Typical power consumption from power supply unit during charging	ca. 12 V, 0.17 A = 2 W

9.3 Power Supply

For medical applications the following power supply units are exclusively allowed when used with ALGO 7i devices:

- Friwo FW7662M/12

TRANSPORT AND STORAGE CONDITIONS:

Transport temperature	-20 to 60 °C (-4 to 140 °F)
Storage temperature	0 to 40 °C (32 to 104 °F)
Relative air humidity	10 to 90 % non-condensing
Barometric pressure	50 to 106 kPa

OPERATING CONDITIONS:

Temperature	10 to 40 °C (50 to 104 °F)
Relative air humidity	20 to 90 % non-condensing
Barometric pressure	70* to 106 kPa

* In the following cases a transducer recalibration at the point of use is recommended:

Air pressure at point of calibration p_c	Air pressure at point of use p_u
98 to 104 kPa	< 92 kPa
92 to 98 kPa	< p_c – 6 kPa
<92 kPa	< p_c – 6 kPa or > p_c + 6 kPa

See also DIN EN 60645-1 5.3 and Soares et al.: “Audiometer: Correction factor for atmospheric pressure”, Inter-Noise 2016.

10 Electromagnetic Compatibility Information

Electromagnetic compatibility (EMC) as stated by standard DIN EN 60601-1-2 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests) and 60601-2-40 (Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment) was certified by an accredited laboratory. Information on the full report is available from PATH MEDICAL upon request.

The user must take care that the device is used in an environment with electromagnetic radiation as specified in *Table 5* and in *Table 6*.

Emitted interference measurement	**Compliance**	**Electromagnetic environment**
High-frequency emission according to CISPR11	Group 1	The medical electric device uses high-frequency (HF) energy only for internal operation. Hence, its HF emissions are very low and it is unlikely that adjacent electronic devices are disturbed.
	Class B	The medical electric device may be used in all establishments, including those in residential environments and those that are directly connected to a public power network that also supplies buildings used for residential purposes.
Emission of harmonic components according to IEC 61000-3-2	Class A	---
Emission of voltage fluctuation / flicker according to IEC 61000-3-3	Compliant	---

Table 5: Compliance with electromagnetic emission guidelines and resulting requirements for electromagnetic environment

Tests for immunity to interference	**IEC 60601 test level**	**Concurrent level**	**Electromagnetic environment**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	To reduce ESD effects, the ground floor shall consist of wood, concrete or ceramic tiles.
Fast transient electric disturbance; bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines	The quality of supply voltage shall correspond to typical hospital or commercial environment.
Impulse voltage, surges according to IEC 61000-4-5	± 1 kV voltage outer conductor – outer conductor ±2 kV voltage outer conductor – earth	± 1 kV voltage outer conductor – outer conductor	The quality of supply voltage shall correspond to typical hospital or commercial environment.

Tests for immunity to interference	IEC 60601 test level	Concurrent level	Electromagnetic environment
Voltage drop, short interruption and fluctuation of supply voltage according to IEC 61000-4-11	0 % U_T (>95 % U_T drop) for ½ and 1 period 0 % U_T for 300 periods 70 % U_T (30 % U_T drop) for 30 periods	0 % U_T (>95 % U_T drop) for ½* and 1 period 0 % U_T for 300 periods 70 % U_T (30 % U_T drop) for 30 periods	The quality of supply voltage shall correspond to typical hospital or commercial environment. If the user of the medical electric device also demands continued proper functioning of the device during an interruption of energy supply, the connection of the device to an uninterrupted power supply (UPS) or battery is recommended.
Magnetic field at mains frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency shall correspond to typical hospital or commercial environment.
Note: U_T is the mains AC voltage before applying the test level. *Test conducted with phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°			

Table 6: Compliance with immunity to interference tests and resulting requirements for electromagnetic environment

The user must take care, that the device is used in an environment with minimum distances to potential radiators as described in *Table 7*.

Tests for immunity to interference	IEC 60601 test level	Concurrent level	Electromagnetic environment
Conducted high-frequency disturbance according to IEC 61000-4-6	3 V (150 kHz – 80 MHz) 6 V (ISM frequencies)	3 V 6 V	Portable and mobile radio units shall not be used closer than 30 cm (12‘‘) to the device and its components (i.e. connected cables).
Radiated high-frequency disturbance according to IEC 61000-4-3	3 V/m (80 MHz – 2.7 GHz) 9-28 V/m* (wireless RF communication)	3 V/m 9-28 V/m*	Portable and mobile radio units shall not be used closer than 30 cm (12‘‘) to the device and its components (i.e. connected cables).
* Wireless RF communication frequencies and levels: 28 V/m: 450 MHz, ±5 kHz FM, 1 kHz sine; 810 MHz, 50% PM at 18 Hz; 870 MHz, 50% PM at 18 Hz; 930 MHz, 50% PM at 18 Hz; 1720 MHz, 50% PM at 217 Hz; 1845 MHz, 50% PM at 217 Hz; 1970 MHz, 50% PM at 217 Hz; 2450 MHz, 50% PM at 217 Hz; 27 V/m: 385 MHz, 50% PM at 18 Hz; 9 V/m: 710 MHz, 50% PM at 217 Hz; 745 MHz, 50% PM at 217 Hz; 780 MHz, 50% PM at 217 Hz; 5240 MHz, 50% PM at 217 Hz; 5500 MHz, 50% PM at 217 Hz; 5785 MHz, 50% PM at 217 Hz;			

Table 7: Minimum distance to potential radiators

The device is intended for use in an environment in which high-frequency disturbances are controlled.

Contact information from distributor/service partner:

Distributed By:

Natus Medical Incorporated

3150 Pleasant View Road,
Middleton, WI 53562 USA
Toll-free: +1-800-303-0306
Telephone: +1-650-802-0400
Fax: +1-650-802-8680
E-mail: technical_service@natus.com
www.natus.com

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