Operating Instructions

ATMOS Audio Cube 31

English

$C \epsilon$ 0483

Table of contents

1 Introduction

1.1 Notes on operating instructions

These operating instructions contain important notes on how to operate your ATMOS Audio Cube 31 safely, correctly and effectively.

The manual is used to train and instruct operating personnel and also as a reference manual. This document may be reprinted, either in part or in whole, only with the written permission of ATMOS.

These operating instructions must always be kept available near the device.

Care, period tests, regular cleaning and appropriate application are indispensable. They guarantee the operational safety and usability of the ATMOS Audio Cube 31.

Maintenance, repairs and period tests may be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. The person in question must possess the necessary test devices and original spare parts required to carry out these measures.

Read chapter "2 Notices for your safety" on page 8 before using the device for the first time. This will help you avoid potentially dangerous situations.

The product ATMOS Audio Cube 31 bears the CE marking CE 0483 according to the EC directive of the council for medical products 93/42/EEC and meets the basic requirements of appendix I of this directive.

The ATMOS Audio Cube 31 meets all the applicable requirements of the directive 2011/65/EC on restricting the use of certain hazardous substances in electrical and electronic equipment ("RoHS").

The declarations of conformity and our general terms and conditions can be found on our website at www.atmosmed.com.

The quality management system applied at ATMOS has been certified according to the international standard EN ISO 13485.

These operating instructions are valid for the following devices:
- ATMOS Audio Cube 31   512.2100.0

1.2 Explanation of pictograms and symbols

In the operating instructions

⚠ **DANGER**

Warning of a danger resulting in immediate fatal or serious injury. Observe the necessary measures.

⚠ **WARNING**

Warning of a danger that can cause fatal or serious injury. Observe the necessary measures.

⚠ **CAUTION**

Warning of a danger that can cause minor injury. Observe the necessary measures.

ATTENTION

Notice of a danger that can damage the product or other objects. Observe the necessary measures.

⚠	Warning of a danger which can cause death or serious injury.
❶	Notice of potential material damage.
☞	Useful information on the handling of the device.
1.	Action. Proceed step by step.
•	List.
»	Result of an action.

On the device and type plate

🧍	Applied part type B	CE 0483	This product meets the relevant requirements of the EU directives.
SN	Serial number		Observe the operating instructions
REF	Article number		Manufacturing date
	Dispose of properly		Manufacturer

⚠₁	WARNING! Danger of fatal injury from electric current. Please observe the safety instructions for the mains supply of your device.
⚠₂	CAUTION! Danger from electric current, incorrect measurement results or excess levels. Please observe the safety instructions for the connection of the acoustic transducers.
⚠₃	CAUTION! Danger due to products that do not comply with EN 60601-1. Electric shock is possible. Please observe the safety instructions on the combination of the audiometer with other devices.

1.3 Intended use

Name: ATMOS Audio Cube 31

Main function: Quantitative and qualitative electro-acoustic hearing test

Medical indications/ application: Test and determination of the hearing ability

Specification of the main function: Determination of the hearing ability (tone and speech audiometry, suitable for the diagnostic and clinical application).

Application organ: Ear

Application time: For the short-term application on patients (max. 60 minutes).

Application environment: In clinics and practices for ENT doctors. The examination may be performed only by healthcare professionals.

Contraindications: None

The product is: active

Sterility: Not necessary

Single-use product/re-sterilisation: Not a single-use product

1.4 Function

Principle: Audiometry is the subjective examination of the hearing ability, for which there are several different methods. Unlike objective audiometry (tympanography/OAE/BERA), the active cooperation of the person to be examined is required. The audiometric tests are performed in a soundproof room.

Measuring method: The ATMOS Audio Cube 31 applies tone and speech audiometry by means of air and bone conduction as well as in the free field.

Tone audiometry: The auditory threshold is determined by a tone audiogram. The patient is presented with tones of different frequencies. The volume of the tone is gradually increased until the patient can perceive the tone, the so-called threshold. Initially this test is performed by means of air and then by bone conduction. Together, they result in the tone audiogram.

Now it can be determined whether there is a conductive hearing loss (hearing defect in the middle ear) or a sensorineural hearing loss (hearing defect in the inner ear) or if it is a combination of both. If there is a difference in hearing between both sides, the non-test ear is subjected to masking.

All the important supra-threshold tests are integrated in the ATMOS Audio Cube 31. They indicate where there is damage to the acoustic organ in the inner ear.

Speech audiometry: Speech audiometry is not only the hearing of tones but also the perception of complex acoustic information, such as words, numbers or sentences, which the patient must then repeat.

Country-specific language assessment tests can be used via CD or hard drive.

Significance: From the combination of tone and speech audiometry, the physician knows in which frequency ranges the patient has hearing problems and what therapeutic approaches are to be taken as a result.

Precise clarification of the hearing ability is enabled by the measurement of the tone and speech audiometry together with the measurement of the otoacoustic emissions (OAE) and the derivation of acoustically evoked potentials (BERA) as well as the tympanometry with a stapedius reflex measurement. With the help of these tests it is possible to elicit the location, type and extent of a hearing loss.

The measurement results are stored in a patient-related database and can be printed or integrated into a physician's practice software system or a hospital information system (HIS).

1.5   Scope of delivery

This chapter describes the standard scope of delivery in the full version. The scope of delivery of your device can be found in the delivery note.

ATMOS Audio Cube 31	1x power cable	1x headphones	1x bone vibrator	1x headset with examiner microphone
1x patient response button	1x USB 2.0 cable	1x software (USB flash drive)	1x operating instructions	Optional: DD450 headphones, high-frequency option

1.6   Transport and storage

ⓘ Transport at low temperatures can damage the device.

1. Before starting up the device, allow it to acclimatise for up to six hours at room temperature.

Transport the device only in a shipping carton that is padded and offers sufficient protection.

If damage occurs during transport:

1. Document and report the damage to ATMOS.
2. Fill in the form QD 434 "Customer Complaint / Return Shipment". It is enclosed with the product.
3. Send the device to ATMOS (see chapter "6.6 Sending in the device" on page 55).

Ambient conditions for transport and storage

- Temperature: −10 to +45 °C
- Air humidity: 30 to 90%
- Air pressure: 70 to 106 kPa

2   Notices for your safety

The safety of the ATMOS Audio Cube 31 complies with the recognized rules of technology and the directives of the MPGG (Medical Devices Implementation Act).

Nevertheless, read and follow the safety instructions carefully before using the product.

General safety instructions

If you wish to operate the ATMOS Audio Cube 31 in combination with non-medical products (e.g. PC, printer), you must observe chapter "3.5 Combined use with other devices" on page 13.

The device has applied parts of type B.

Dangers to users, patients and third parties

Protect yourself against an electric shock!

Burns, cardiac arrhythmia and even fatal injuries are possible.

- Prior to each use, check whether the device or power cable is damaged. Never operate the device if it exhibits any obvious safety defects. In this case clean the device and send it to ATMOS for repair.
- Disconnect the device from the mains power supply prior to cleaning or disinfection.
- Prior to switching the device on or off, remove all transducers from the patient or examiner.
- Plug out the transducer before you repair it. First remove the transducer cable from the audiometer before you loosen the cable from the transducer itself.
- Do not operate the device if it has been dropped. In this case clean the device and send it in to ATMOS for repair.
- Connect the device only to a mains power supply with a correctly installed protective conductor.
- Only use accessories and spare parts from ATMOS.
- Assembly, new settings, alterations, extensions and repairs may be carried out only by authorized persons.
- Pay attention to the period tests in chapter "6.1 Period tests" on page 50.

Explosion and fire hazard!

Burns and injuries are possible.

- Never operate the product ATMOS Audio Cube 31 in potentially explosive or oxygenated areas.
- Use only original accessories and spare parts from ATMOS.

Reduce the risk of infection for you and your patients!

Diseases could be transmitted.

- Clean and disinfect the product as described in chapter "5 Cleaning and disinfection" on page 47.
- Use standard protective covers for headphones.
- Replace the ear cushions and headband pads at regular intervals.

Avoid misapplication or incorrect diagnosis.

The patient's ear and hearing can be contaminated, injured or damaged.

- The product may be used only by medically trained staff.
- A diagnosis may only be made by persons with the appropriate medical training.
- Use the product only in a soundproof, audiological room with an acoustic level below 40 dB SPL.
- Prior to use, a daily function check must be performed.
- Adjust the level to above 80 dB HL only if prescribed by the physician.
- Only remove or connect the transducer to the audiometer when it is switched off. Otherwise, the transducers will crackle.
- Connect the acoustic transducers only to the jacks provided.
- As soon as you have to replace an acoustic transducer or wish to use a different acoustic transducer, the device must be recalibrated. In this case, please contact ATMOS.
- Please observe the information on period tests in chapter "6.1 Period tests" on page 50.
- Use only original accessories and spare parts from ATMOS.
- Assembly, new settings, alterations, extensions and repairs may be carried out only by persons authorized by ATMOS.

Only a fully functional product meets the safety requirements of users, patients and third parties. Therefore, observe the following instructions on your product:

Avoid damage to the device

Observe the ambient conditions regarding transport, storage and operation.

Take care to ensure that no liquid gets into the device. The device may no longer be used if liquid gets into it. In this case clean the device and send it to ATMOS for repairs.

The device may be connected to the mains power supply only if the mains voltage and frequency of the device correspond to the mains power supply.

Use only appropriate mains supplies and extension cords.

Do not twist or bend the wires.

Protect the device from shock and vibration.

3 Installation and start-up

3.1 Device overview

Front side

❶ Status LED
❷ Mains/power LED

Rear side

❸ Power cable connector
❹ On/off switch

3.2 Minimum requirements for your PC

⚠ **CAUTION**

Inappropriate hardware

The patient cannot be examined and treated.

• Observe the minimum requirements for the hardware.

Operating system	Windows Vista / 7 / 8
Free hard drive capacity	At least 50 GB
CPU performance	At least 2 GHz
Available RAM	At least 4 GB RAM
Graphic resolution	At least 1600 x 900 pixels
Connectors	Min. 1 USB port, another port for printer if necessary

3.3 Installing the device

⚠ **CAUTION**

Incorrect measurement results due to incorrect device installation.

The patient's ear and hearing can be contaminated, injured or damaged.

- Before starting up the device, check whether it and the charging accessories or other accessories are damaged.
- Use the product only in a soundproof, audiological room with an acoustic level of below 40 dB SPL.
- You can achieve the best measurement results in a special hearing test booth.
- The connections between the audiometer, hearing test booth and applied parts may be established only by a service technician authorized by ATMOS.
- Free field loudspeakers must always be calibrated on site. As soon as you change the position or orientation of the free field loudspeakers, the device must be recalibrated. In this case, please contact ATMOS.

ATTENTION

Heat and humidity.

Damage to the device is possible.

- Observe the ambient conditions for operation.
- Never place the device in direct sunlight, beside radiators, in poorly ventilated rooms or in damp rooms.

3.3.1 Audiometer with free field loudspeaker

Please observe the following standards:

- DIN EN ISO 8253-2 (July 2010): Acoustics – Audiometric test methods – Part 2: Sound field audiometry with pure-tone and narrow-band test signals.
- DIN EN ISO 8253-3 (August 2012): Acoustics – Audiometric test methods – Part 3: Speech audiometry.
1. The installation of the free field loudspeaker may only be performed by a service technician authorized by ATMOS. Free field loudspeakers must always be calibrated on site.

3.3.2 Audiometer with headphones

ⓘ Damage to the device due to incorrect connections.

1. Connect the transducer and the patient response button only to the audiometer. They must not be connected to other system components.
2. Connect the transducer and external devices. Observe chapter "3.4 Connection diagram" on page 12.

3.3.3 Hearing test booth

1. Have the audiometer connected to the hearing test booth only by a service partner authorized by ATMOS.

3.4 Connection diagram

> ⚠ **CAUTION**
>
> **Wrong measurement results due to incorrectly calibrated transducers.**
>
> Damage to the patient's hearing is possible.
>
> • As soon as you replace or use a different transducer then the device must always be recalibrated. In this case, please contact ATMOS.
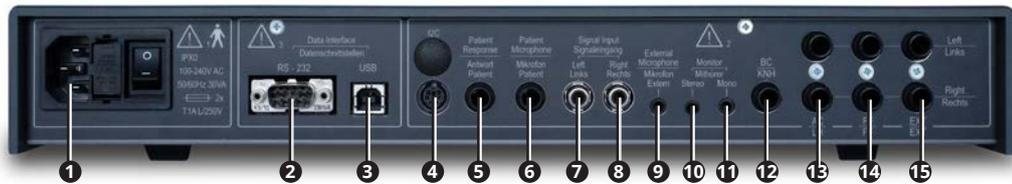
No.	Name	Connection	Note
1	Mains supply	Mains power supply	
2	RS - 232		Service interface
3	USB	PC	
4	I2C		No function
5	Patient response	Patient response button	
6	Patient's microphone	Patient microphone	
7	Left signal input	Audio input from sound card / PC	Left signal input: white/black connector
8	Right signal input	Audio input from sound card / PC	Right signal input: red connector
9	External microphone	Headset (Stereo)	Red connector. The microphone in the front panel is automatically switched off as soon as a headset is plugged in.
10	Monitor earphones, stereo	Headset (stereo)	Green connector. If the monitor earphones (mono) are simultaneously plugged in, the left side of the headset will not work.
11	Monitor earphones, mono	Control earphones (mono)	The left side of the headset is switched off.
12	BC	Bone vibrator	RadioEar B71
13	AC	Headphones (audiometer headphones)	Sennheiser HDA280: AC left: blue connector; AC right: red connector.
14	FF	Passive free field loudspeaker	Loudspeaker positioned on the left: FF left. Loudspeaker positioned on the right: FF right
15	EXT	Output for RF headphones or special accessories such as "in-ear speakers"	Loudspeaker positioned on the left: EXT left; loudspeaker positioned on the right: EXT right

3.5 Combined use with other devices

A medical system is created if you connect additional devices to the audiometer.

ATMOS recommends: do not use portable multiple sockets.

If you still have to use portable multiple sockets, please observe the following:

- The portable multiple sockets must comply with IEC 60601-1.
- The portable multiple sockets must not be extended repeatedly.
- Do not exceed the permissible nominal load of the multiple socket.
- Only devices which are part of the medical system may be connected to the multiple socket. Otherwise, the leakage currents could exceed the permissible limits.

PC to USB interface

The USB interface is electrically isolated and therefore complies with the requirements of EN 60601-1.

If your PC does not comply with IEC 60601-1, please observe the following:

- Your PC must comply with the IEC 60950 and the applicable EMC standards.
- If your PC is positioned in the immediate vicinity of the patient, you must operate it with an isolation transformer that complies with IEC 60601-1.

Active free field loudspeaker, printer

If other devices do not comply with IEC 60601-1, please observe the following:

- The devices must be operated with an isolation transformer or power supply unit that complies with IEC 60601-1.
- The devices must comply with EMC standards.

Connecting the system

1. Observe the notes in this chapter.
2. Connect the device.
3. Ensure that it does not present a tripping hazard e.g. cables, multiple socket etc.
4. Protect the connecting cables between the system components from mechanical damage.
5. Measure and document the leakage currents on site. The leakage current must comply with the following conditions (IEC 60601):

Housing leakage current from or between parts of the system within the vicinity of the patient (normal condition)	< 0.1 mA
Housing leakage current from or between parts of the system within the vicinity of the patient (single fault condition)	< 0.5 mA
Patient leakage current (normal condition)	< 0.1 mA

6. Measure and document the following values (IEC 62353):

Protective earth conductor resistance: Accessible conductive parts – power cable connector to wall socket (including multiple distributor)	≤ 0.3 Ω
Housing leakage current: Accessible conductive parts, no protective earth connection + protective earth conductor	≤ 0.5 mA

3.6 Connecting the device

1. Connect the device to a PC with a USB cable.
2. Connect the device with the power cable to an earthing socket installed properly.

3.7 Installing the software

☞ The partition where the software is to be installed must have read and write access.

☞ You will require administration rights in order to install the software on your PC.

1. Check whether your computer meets the system requirements.
2. Connect the supplied USB flash drive to the PC.
3. Right click on the file INSTALL.EXE and select the RUN AS ADMINISTRATOR menu item.
4. The portable multiple sockets must not be extended repeatedly.
» The software starts.
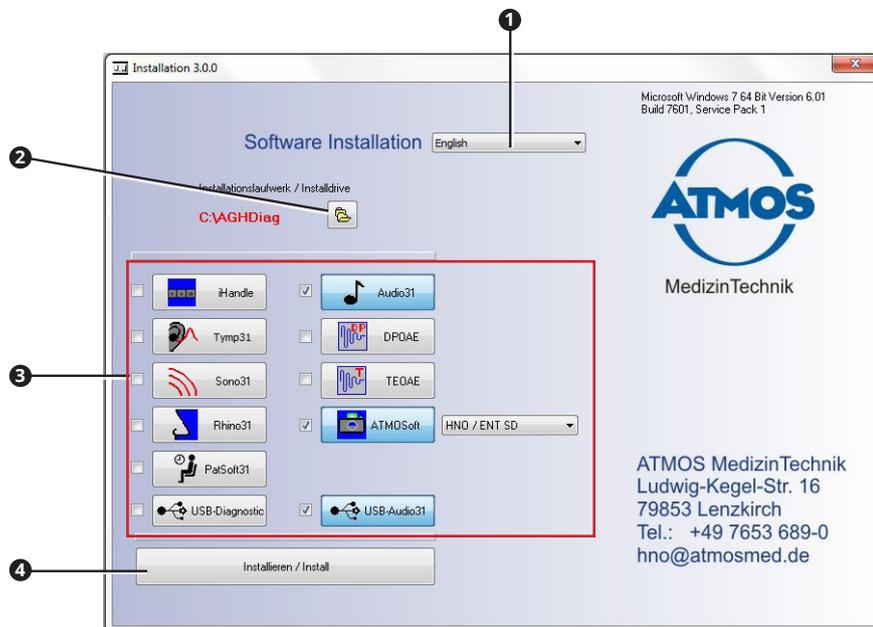
5. Set the following:
   - Language ❶
   - Installation path ❷
   - Software to be installed ❸

☞ The program automatically selects the necessary software components (driver), depending on the selected software.

6. Click on the INSTALL button ❹.

» The software is installed. The current status is displayed at the bottom left.

» The message INSTALLATION COMPLETE appears at the bottom left as soon as the installation is complete.

7. Perform a function check. See chapter "6.3 Weekly function check" on page 52.

3.8   Setting up the ATMOS PatSoft 31

☞   As soon as you exit the OPTIONS section, you will be asked if you want to save the settings. Click on the YES button to save the settings or on the NO button to not do so.

3.8.1 Opening the OPTIONS section

1.   Start the PatSoft 31.
2.   Click on the ATMOS ❶ button at the top right.
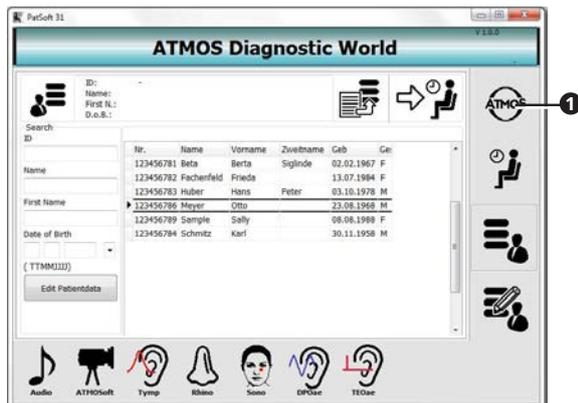
»   The OPTIONS section is opened.

3.8.2 Selecting the start window

You can select which section is to be displayed after opening the PatSoft 31.
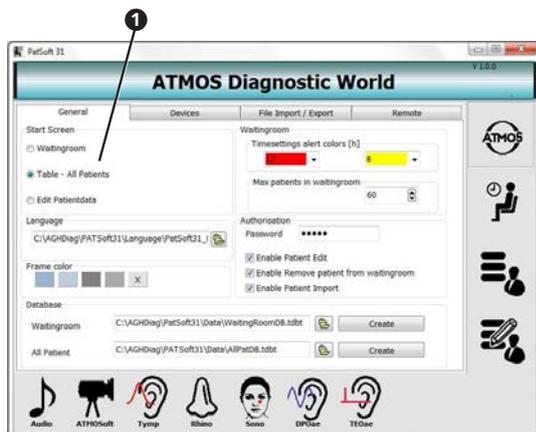
1.   Go to the OPTIONS section.
2.   Click on the GENERAL tab.
3.   Select the desired start screen in the START SCREEN selection area ❶.

ATMOS recommends selecting the following start window, depending on the workplace situation:

Reception	• TABLE - ALL PATIENTS
Treatment room	• WAITING ROOM

3.8.3 Setting the WAITING ROOM section
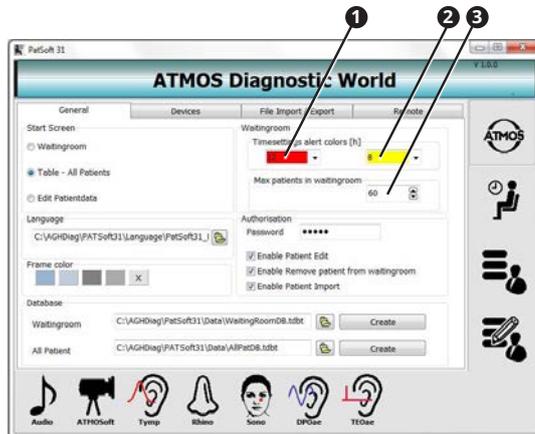
1. Go to the OPTIONS section.
2. Click on the GENERAL tab.

Using colours to highlight patient data

1. Use the left selection box ❶ of the TIME SETTINGS ALERT COLOURS section to define how many hours are to elapse before the patient data in the WAITING ROOM section are highlighted in red.

2. Use the right selection box ❷ of the TIME SETTINGS ALERT COLOURS section to define how many hours are to elapse before the patient data in the WAITING ROOM section are highlighted in yellow.

Maximum amount of patient data

1. In the MAX PATIENTS IN WAITING ROOM text field ❸, enter the maximum amount of patient data permitted in the WAITING ROOM section.

3.9 Setting up the ATMOS Audio Cube 31 software

User and practice data

1. Click on the OPTIONS button.
» The Options window appears.
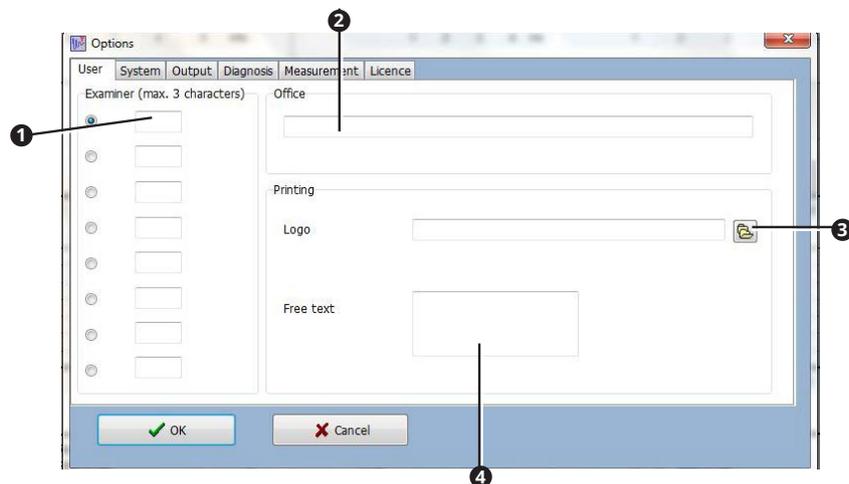
2. Enter the user initials ❶. They are then available for selection in the main window.
☞ By default, the selected user is displayed in the main window as examiner.
3. Enter the name of the practice ❷.
4. If necessary, select the praxis logo in *.bmp or *.jpg format ❸.
5. Enter the address of the practice ❹.
☞ Information on the practice appears on the printout.
6. Click on the OK button.
» The entries are saved.
» The window is closed.

4   Operation

4.1   Ambient conditions during operation

- Temperature: +15 to +35 °C
- Air humidity: 30 to 90% humidity without condensation
- Air pressure: 98 kPa to 104 kPa

4.2   Switching on the device

1. Switch on the device with the on/off switch.
» The green indicator lamp lights up on the front side.
2. Start the software if it does not start automatically.

4.3   Switching off the device

1. Close the software with the CLOSE button or with the X on a red background at the top left.
2. Switch off the device with the on/off switch.

4.4   Patient management with the ATMOS PatSoft 31

4.4.1 Starting the ATMOS PatSoft 31

☞ The PatSoft 31 is automatically started during the boot up. If necessary, you can start the PatSoft 31 also with an icon on the desktop.
1. Start the PatSoft 31 via the Windows menu START - ALL PROGRAMS.
» The PatSoft 31 is started.

4.4.2 Exiting the ATMOS PatSoft 31

1. Click on the EXIT button at the top right (red X).
» The PatSoft 31 is closed.

4.4.3 Recommended procedure at workplaces

ATMOS recommends importing, creating, editing and searching for patient data at the reception workplace and sending it from there to the WAITING ROOM section.

At the treatment room workplace, the patient data should be retrieved from the WAITING ROOM section and the diagnostic software launched. After treatment, the patient data can be removed from the WAITING ROOM section.

4.4.4 Going to a section

The software is divided into four sections:

- OPTIONS ❶: Settings
- WAITING ROOM ❷: Waiting area for patient data
- TABLE - ALL PATIENTS ❸: All patient data
- EDIT PATIENT DATA ❹: Editing the patient data

1. Click on the respective button to go to a section.
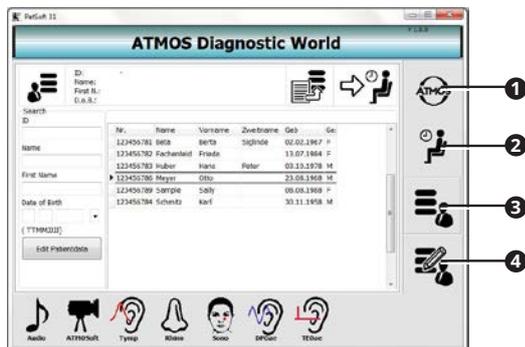
Creating a patient
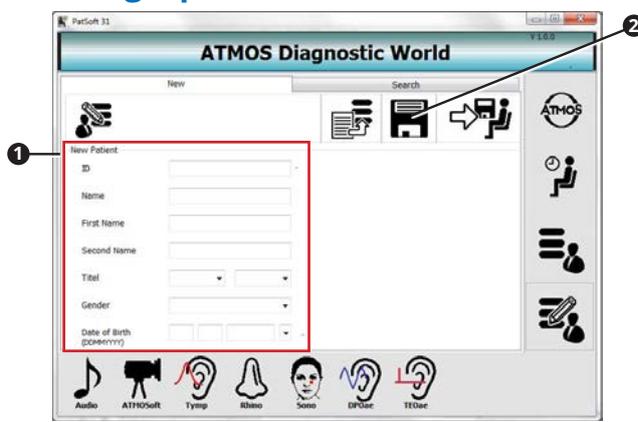
2. Go to the EDIT PATIENT DATA section.
3. Open the NEW tab.
4. Enter the patient data in the NEW PATIENT section ❶.
5. Save the data by clicking on the SAVE button ❷.

4.4.5 Importing patient data manually
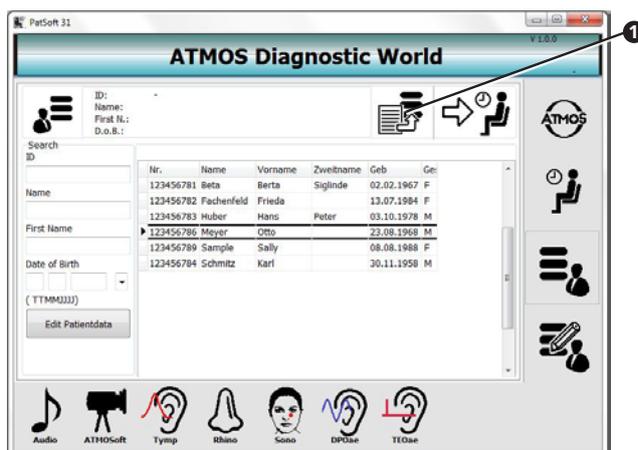
1. Go to the TABLE - ALL PATIENTS or EDIT PATIENT DATA section.
2. Click on the IMPORT button ❶.
» The patient data are updated.

4.4.6 Searching for patient data

In the section TABLE - ALL PATIENTS
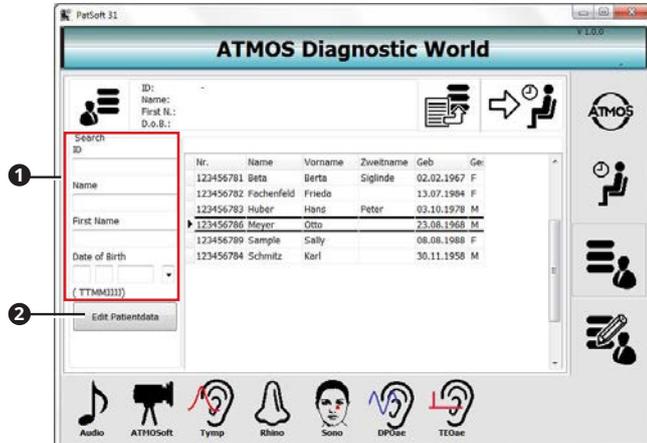
1. Go to the section TABLE - ALL PATIENTS.

2. Enter the patient data you are searching for in the SEARCH section ❶.

» As soon as you enter the first character, a corresponding hit is highlighted in the table.

☞ If you want to edit the patient data, click on the EDIT PATIENT DATA button ❷.

In the EDIT PATIENT DATA section
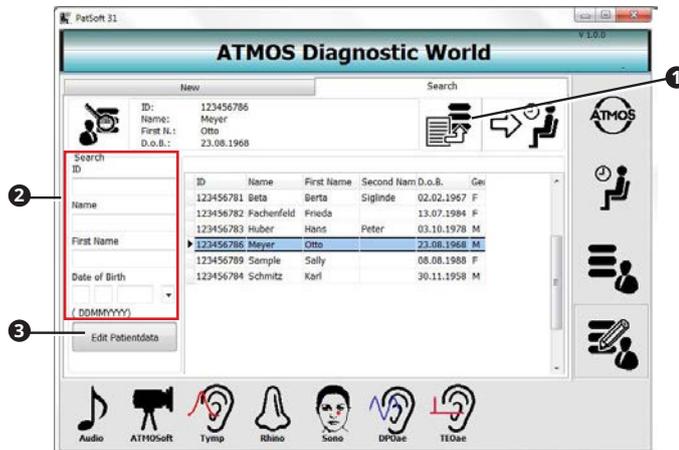
1. Go to the EDIT PATIENT DATA section.

2. Open the SEARCH tab ❶.

3. Enter the patient data you are searching for in the SEARCH section ❷.

» As soon as you enter the first character, a corresponding hit is highlighted in the table.

☞ If you want to edit the patient data, click on the EDIT PATIENT DATA button ❸.

4.4.7 Editing the patient data

1. Search for the patient data in the TABLE - ALL PATIENTS or EDIT PATIENT DATA section.

2. Click on the EDIT PATIENT DATA button.

»   The CHANGE PATIENT DATA view is displayed.
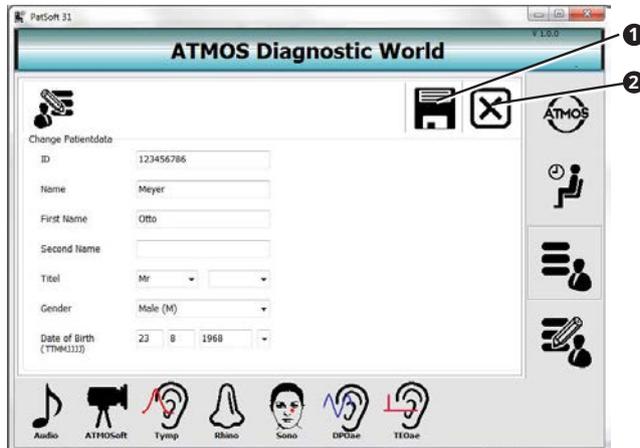
3. Change the patient data.

4. Click on the SAVE button ❶ to save the data.

☞   If you do not wish to save the data, click on the ABORT button ❷.

4.4.8 Placing patient data in the WAITING ROOM section
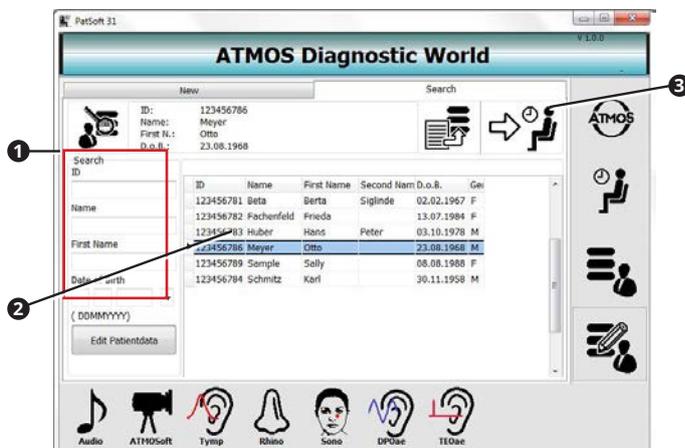
1. Go to the TABLE - ALL PATIENTS or EDIT PATIENT DATA section.

2. Search for the patient data in the SEARCH section ❶.

3. Double-click on the desired patient data ❷.

4. Click on the button ADD TO WAITING ROOM ❸.

»   The patient data are available in the WAITING ROOM section.

4.4.9 Opening up the patient software
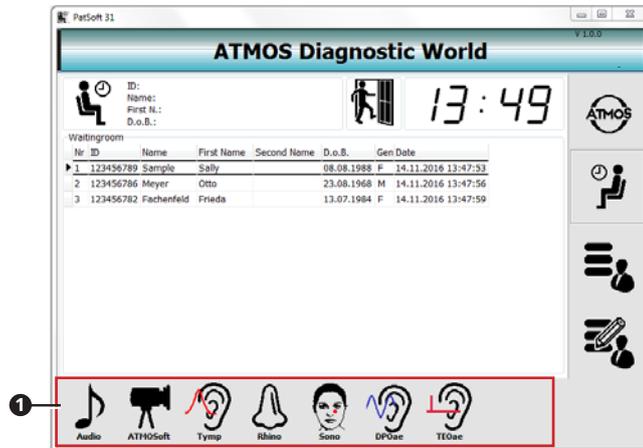
☞ You can open the patient software from any section. For the examination, we recommend opening the patient software from the WAITING ROOM section.

1. Go to the WAITING ROOM section.
2. Double-click on the patient data of the current patient.
3. Click on the button for the patient software ❶ you want to use.
» The patient software starts.
☞ The patient data are automatically adopted.

4.4.10 Removing patient data from the WAITING ROOM section
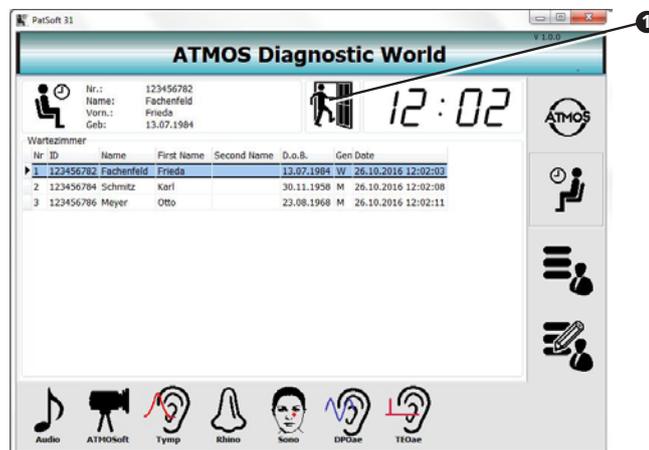
1. Double-click on the patient data.
2. Click on the REMOVE FROM WAITING ROOM button.
» The patient data are deleted from the WAITING ROOM section.

4.5   ATMOS Audio Cube 31 software

4.5.1 Software overview

☞   You can operate the software on a touch screen or with the keyboard or mouse.
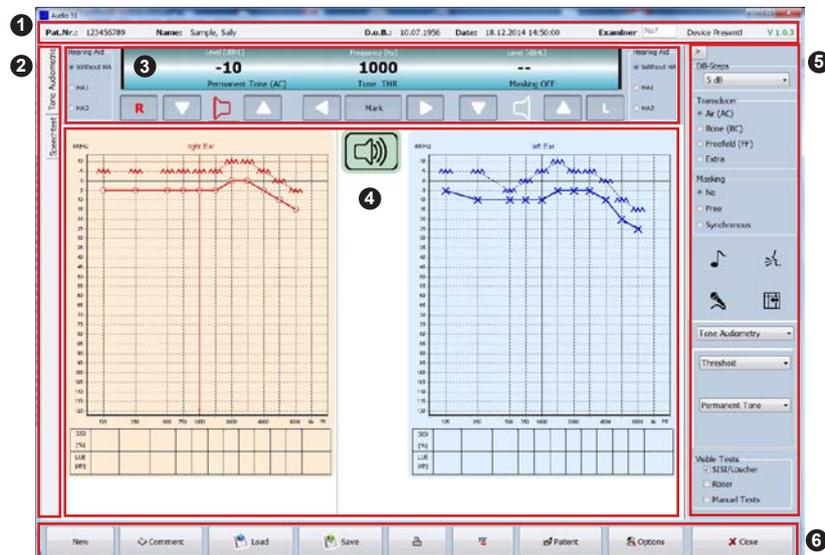
❶   Patient data, examiner and status indication

❷   Speech/tone audiometry selection

❸   Current settings during the test

❹   Display of the measurement data

❺   General measurement settings

Transducer ○ Air (AC) ○ Bone (BC) ○ Freefield (FF) ○ Extra	Transducer used for the test	Masking ○ No ○ Free ○ Synchronous	Masking settings
♪ ≋ᘯ ☖ 🎙 ⊞	Tone audiometry Speech audiometry Speaking to the patient Measure high tone	DB-Steps 5 dB	Level increment
Tone audiometry Tone Audiometry Threshold Permanent Tone	Set signal type	Speech audiometry Discrimination Loss Test Freiburger 1 track01 (Zweisilber)	Select speech test
Visible Tests ☑ SISI/Lüscher ☐ Röser ☐ Manuel Tests	Activate additional tests		

New	Start new measurement	PDF	Save measurement as PDF file	
Comment	Enter diagnosis, findings for the measurement	Patient	Start patient management	
Load	Load measurement	Options	Set up software – Only instructed persons may change settings	
Save	Save measurement	Close	Close program	
	Print measurement			

4.5.2 Making default settings

Diagnosis/comments

If you wish to comment on the measurements, you can create standardised selection texts.

1. Click on the OPTIONS button.

» The Options window appears.

2. Select the DIAGNOSIS tab.
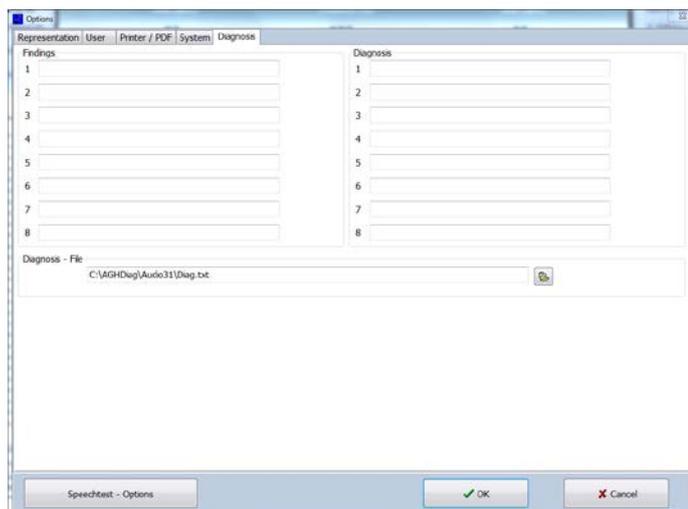
3. Enter the texts to be available for the diagnosis and findings.

4. Click on the OK button.

» The entries are saved.

» The Options window is closed.

Software representation / measurement settings

1. Click the button OPTIONS.

» The Options window appears.

2. Select the REPRESENTATION tab.

» Further tabs are under the tab REPRESENTATION.
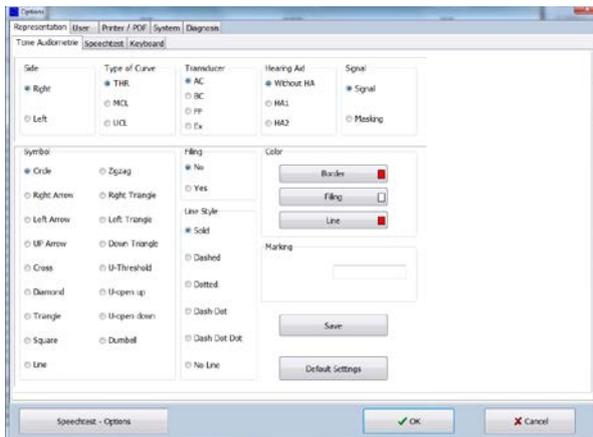
You can make the following settings on the individual tabs:

Tab	Setting options
Tone audiometry	Display of the measurement of the tone audiometry
Speech test	Display of the measurement of the speech audiometry
Keyboard	Function of the loudspeaker sign

Standard keyboard

In the STANDARD KEYBOARD section, you can define the level and hotkeys for changing pages and for various markers in the audiogram.

Signal presentation

You can switch the tone standard on or off in the SIGNAL REPRESENTATION section. If the SPACE BAR box is selected, the function is reversed during audiometry by pressing the space bar. Mouse functions can be activated or deactivated.

Speaker Position

In the SPEAKER POSITION section, you can specify the position of the free field loudspeakers for speech tests. Their position is displayed in the audiogram.
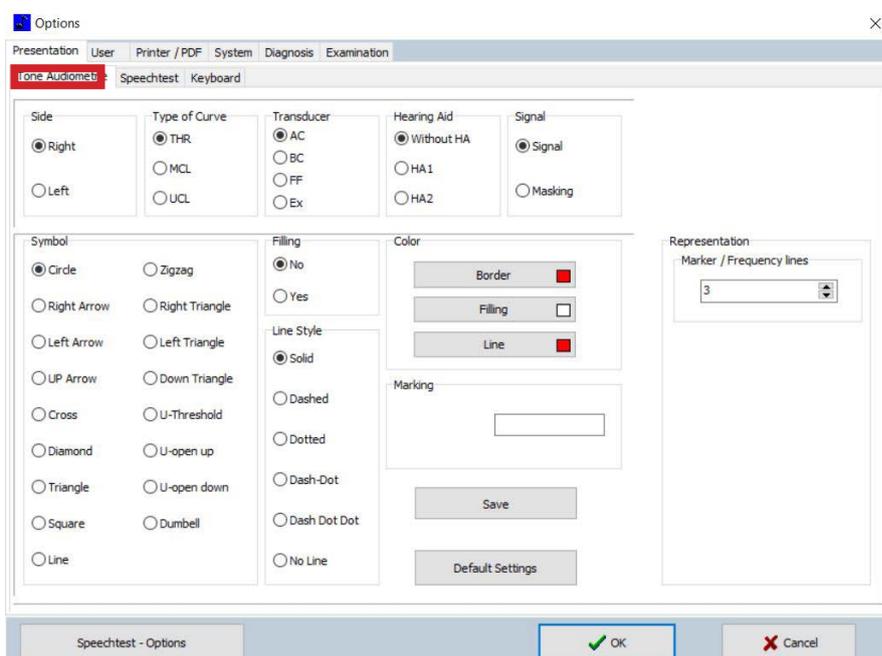
You can make individual settings for the left and right tone audiometry on the TONE AUDIOMETRY tab.

☞ With ipsilateral masking (sound in noise), the colour value of the marking can be inverted (red to blue / blue to red).
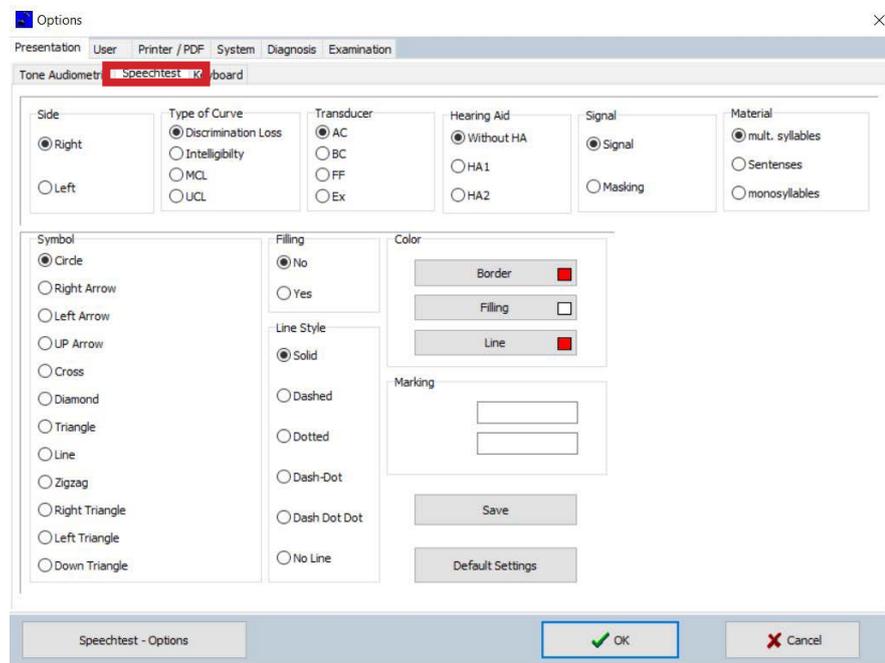
You can make individual settings for the speech audiometry on the SPEECH TEST tab.

☞ Always confirm the changes by clicking on the OK button before you close the window.
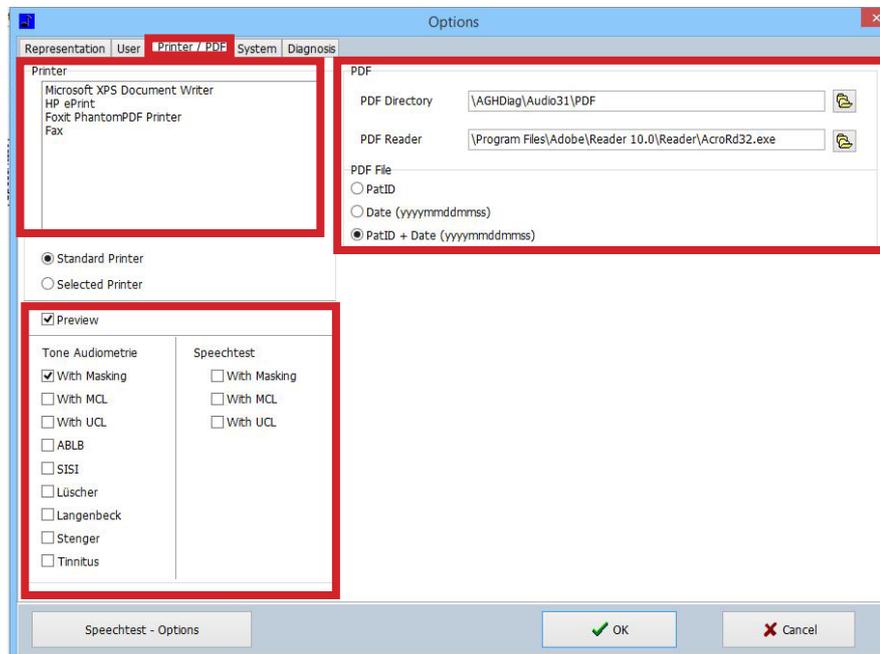
Printer

You can select an installed/connected printer in the PRINTER section.

PDF

In the PDF section, you can select the folder used to store the PDF files that contain the evaluation. Furthermore, you can determine the format of the PDF file.

Tone Audiometry / Speech test

In the section TONE AUDIOMETRY/SPEECH TEST, you can select the contents to be printed in the evaluation.
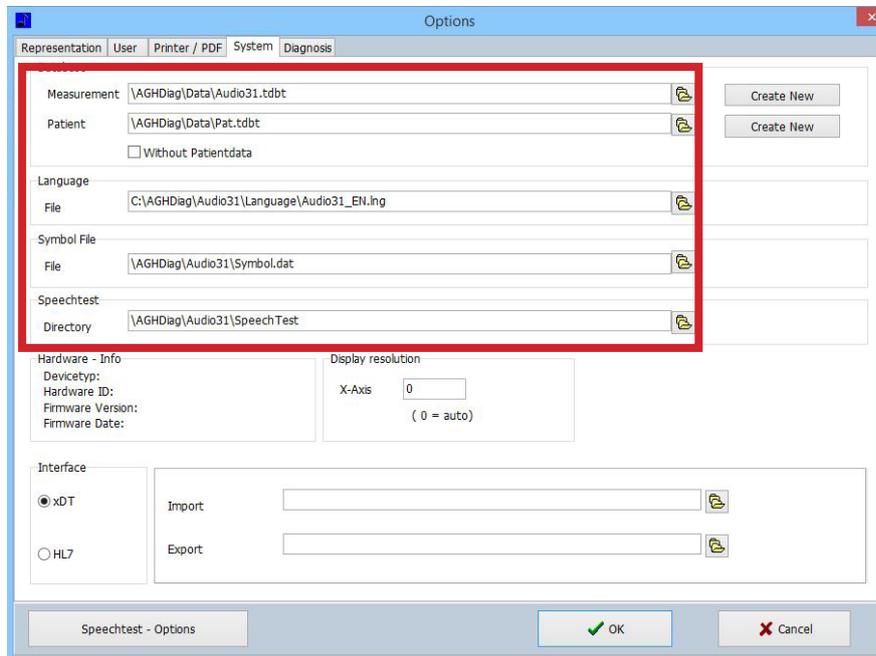
In the sections on the SYSTEM tab, you can make administrative settings for the databases, the language of the user interfaces and the import and export folders for the GDT interfaces.
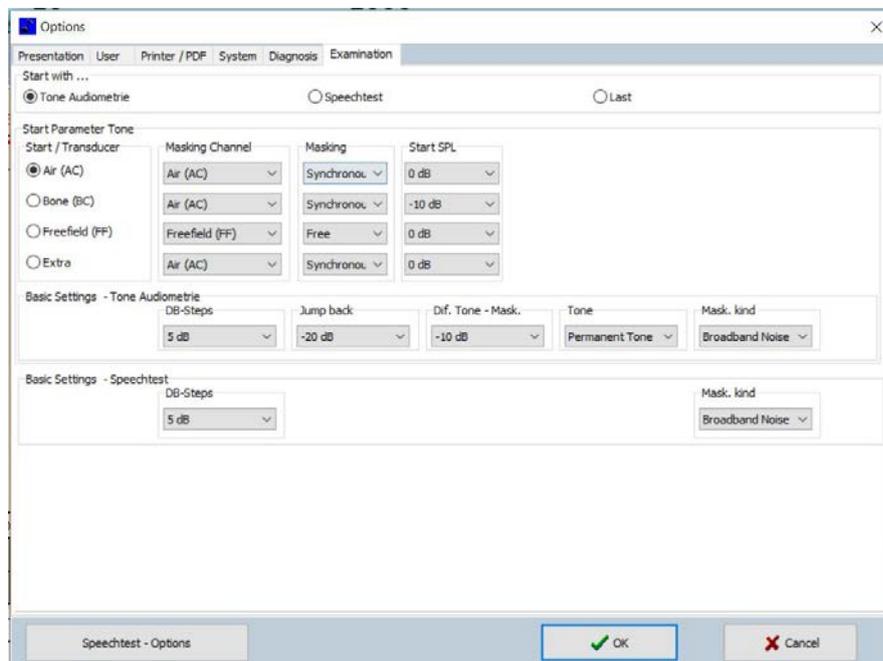
☞ On the EXAMINATION tab, you can define the start parameters, e.g. level, masking, jump back in the event of frequency change, measurement type and level steps.

☞ The set parameters are active when opening the interface and can still be changed at the beginning of each measurement.

☞ Click on the button SPEECH TEST - OPTIONS to go to the settings and set up speech tests.

4.5.3 Configuration of the audiometer for speech tests, implementation of speech tests and calibration of the audiometer und PC audio output

Click on the button SPEECH TEST - OPTIONS to configure the audiometer for speech tests and calibrate it.

Available speech tests and importing new speech tests

On the tab TEST ADMINISTRATION, it is possible to make settings for the existing and new speech tests.

Available Tests

This list includes the available tests implemented for the application.

Directory

In this section, the folder can be defined in which the tests are stored after importing a CD.

New Test

A new test of the CD can be added (test ripped from a CD) in this section.
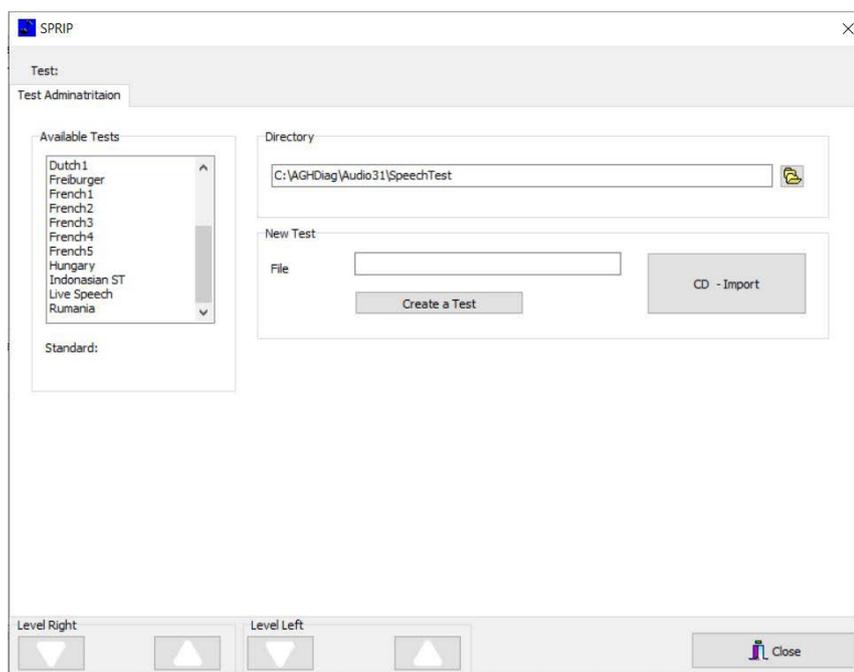
Calibrating a test

After selecting one of the available tests, the next tab is opened. On the EDIT SPEECH FILE tab, the test is defined with regard to words, length of lines, masking and one-sided or dichotic test. Tests should be created by the audiologist in cooperation with an expert from ATMOS MedizinTechnik.
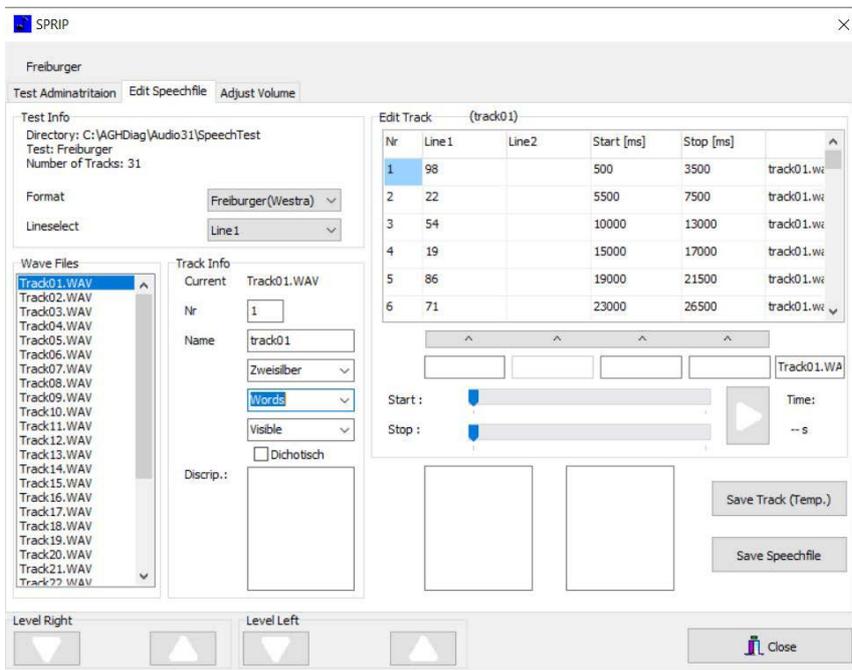
To calibrate existing tests with the audiometer and the PC sound card, select the calibration tone from the test tracks.
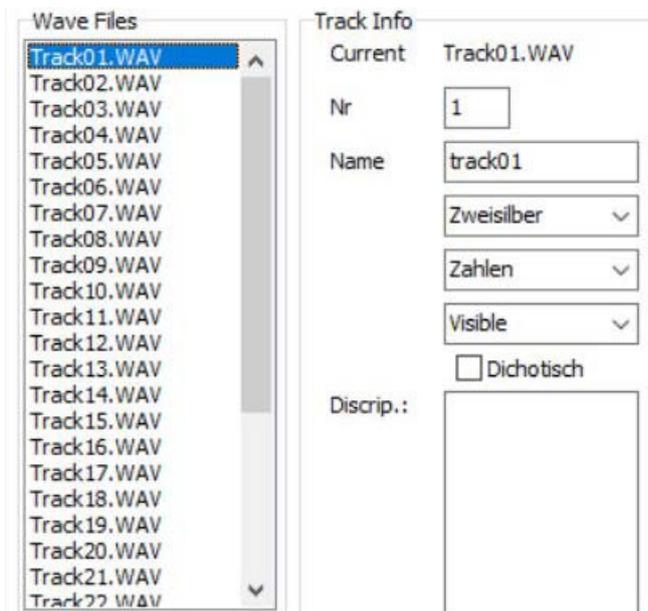
The next tab is activated, on which the track recording level, the PC sound card and the Audio 31 software can be calibrated. The calibration must be performed once for each test before being used for the first time.
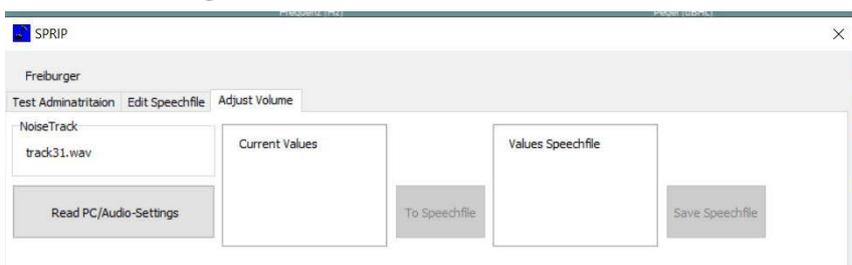
Begin the calibration procedure by clicking on the READ PC/AUDIO-SETTINGS button.

☞ The settings are adopted for the test file in the .idx file. Then start the test tone.

☞ Each channel must be calibrated to 0 dB with the left and right arrows.
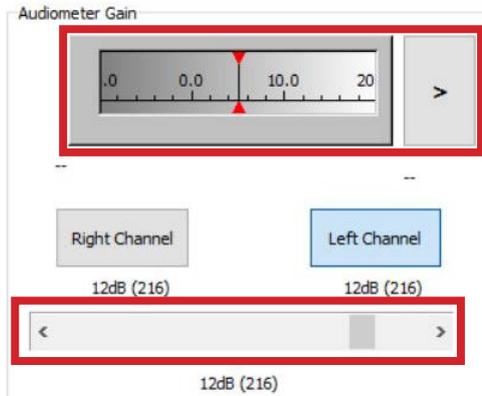
After calibrating the left and right channel to 0 dB, click on the SAVE SPEECH FILE button to save the compensation values in the .idx file.
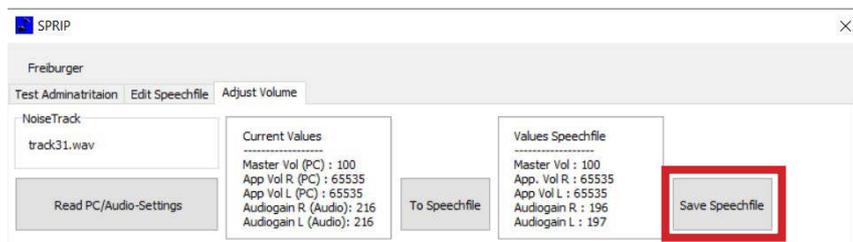
The calibration of the speech test has been completed and the settings can be closed. Click on the CLOSE button.
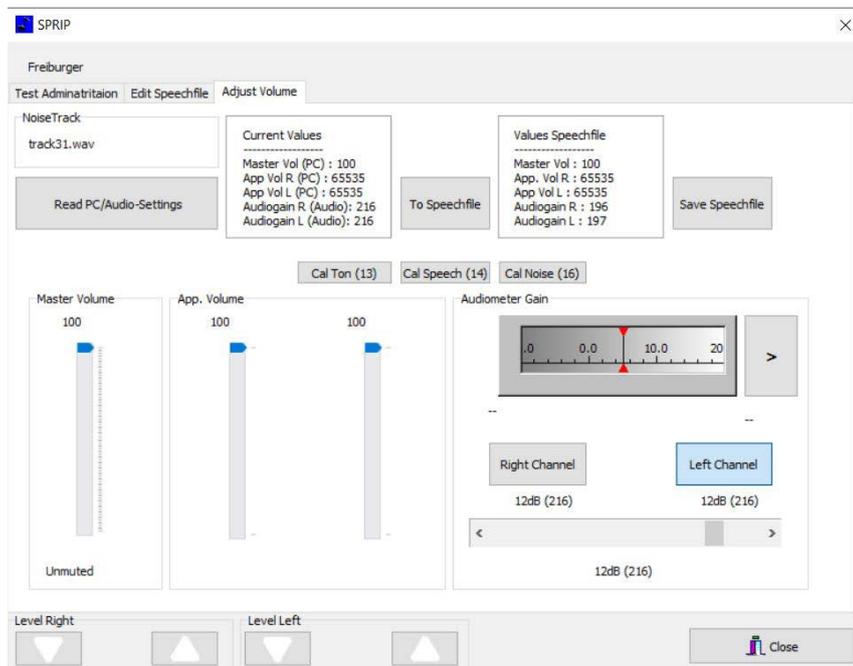
4.5.4 Speech tests

Three different types of speech tests are available:

- Tests conducted with single word resolution (must be implemented by the audiologist together with an ATMOS technician)
- Test with track resolution (as CD copied from the hard drive) or free speech test presented by the tester using a microphone
- Execution of speech test for word resolution: Each word can be selected individually or with one or multiple syllables. Individual words can be presented repeatedly until a "correct" or "incorrect'" decision is made.
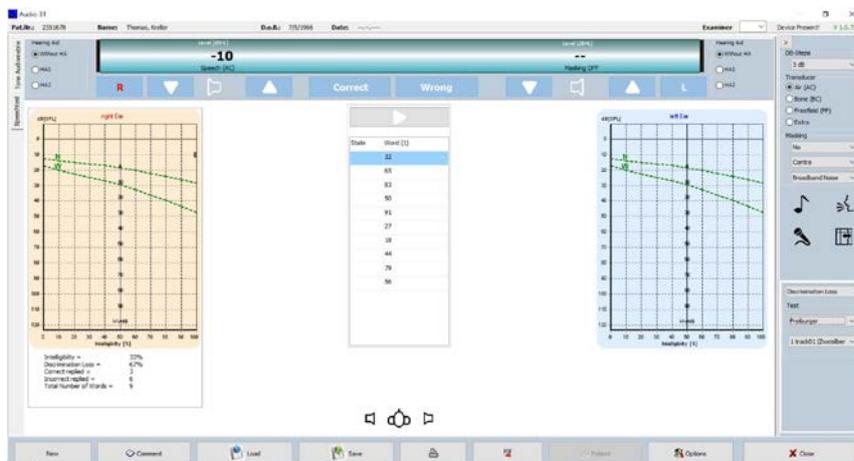
Presentation of the speech test with track resolution

The test is presented track by track as recorded. The presentation can be stopped and continued (like playing a CD player). Individual words can NOT be presented repeatedly. The assessment is adapted to the total number of "correct" and "incorrect" decisions entered. The track can be named and the content entered in a presentation list so that the tester can see the words of the test on the monitor.
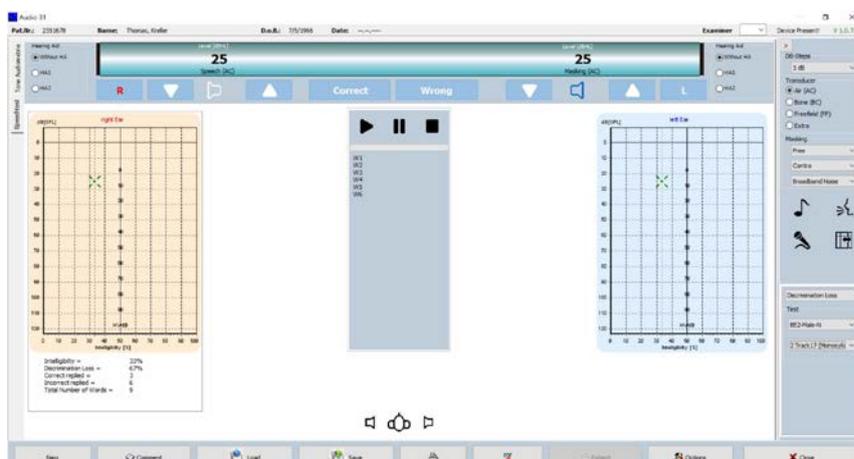
Dichotic speech test

Dichotic speech tests are presented with the option to set the SPL (sound pressure level) downwards and upwards separately for each page with the arrow buttons on the keyboard.
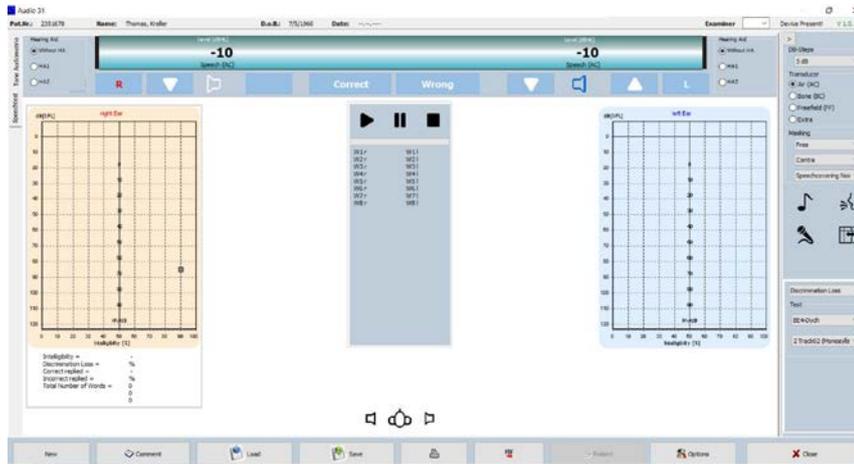
Live speech test with microphone

In the options, a test pattern can be created and the words displayed on the screen for the tester. The assessment is adapted to the number of "correct" and "incorrect" entries after completing the test. The result can be stored with the "report" symbol.
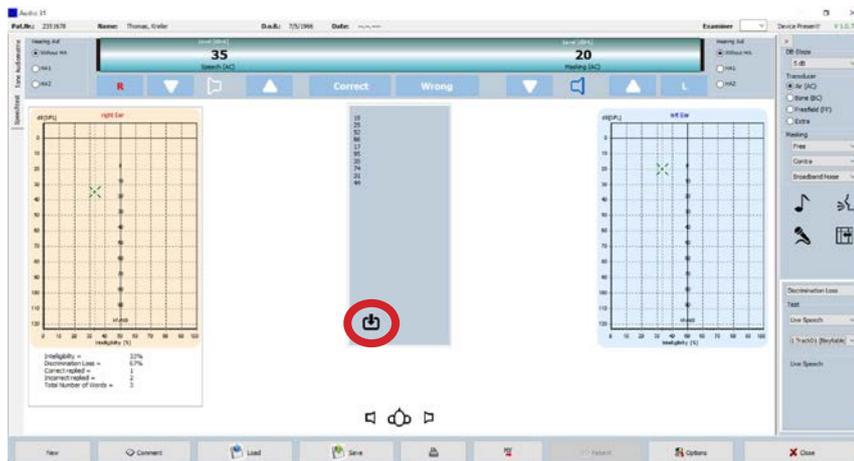
☞ **Important:** The live speech test depends on the SPL of the speaker conducting the test. The speaker must speak with an SPL of approximately 70 dB, which corresponds to normal speaking volume. The speaker may have to practice with an SPL meter to obtain reliable results.

4.5.5 Expert manual for creating speech tests
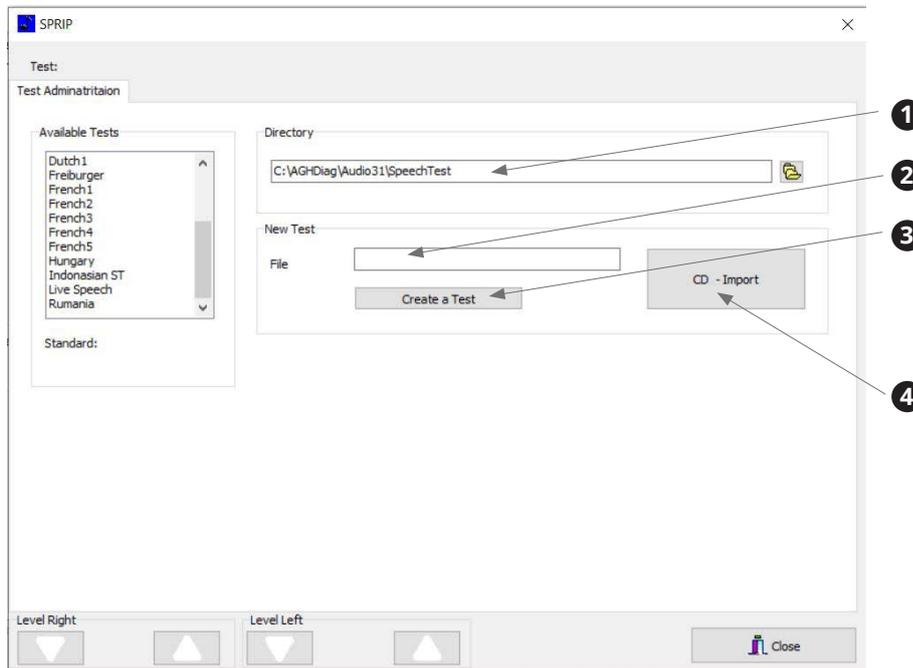
1. Folder in which all speech tests are stored.

2. Enter the name of the test ("English" in this example).

3. Click on the CREATE A TEST button.

☞ A folder with the test name is created, including the .idx files.

4. Click on the CD - IMPORT button. A window appears from which you can select the CD drive or the data source as well as the tracks to be copied into the folder.

5. After selecting the source and tracks, click on the RIP CD button.
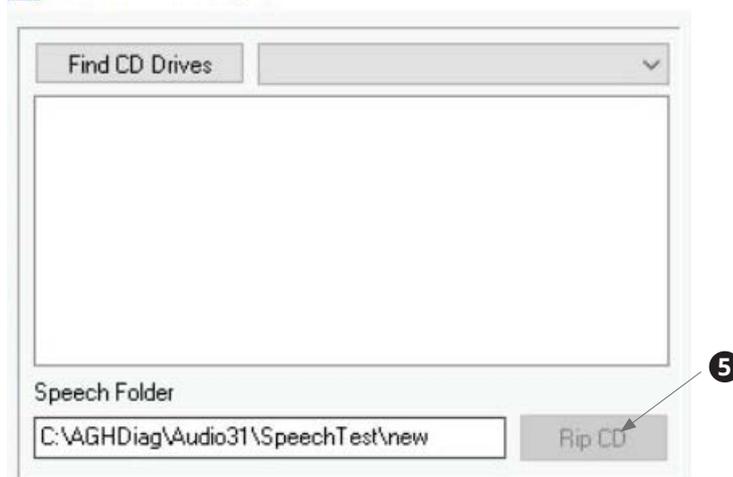
Folder example for speech tests with ripped tests

The folder for the tests is automatically installed and can be moved into a released folder within a network.
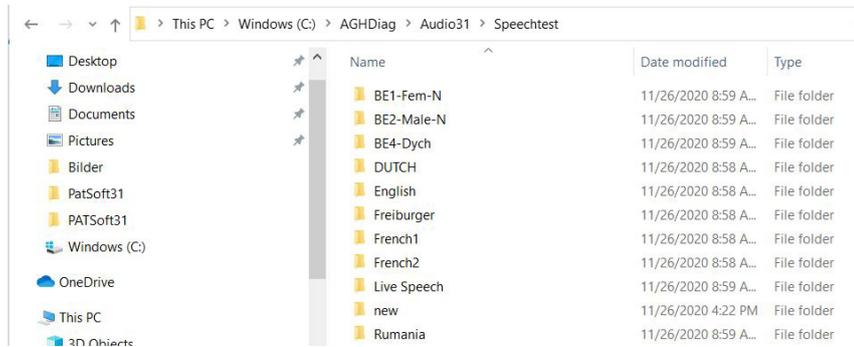
☞ **Important:** When moving the speech test folder, the path must be adapted within the audio settings! See chapter "4.5.2 Making default settings" on page 24.

Example for the content of a speech test folder ("English" test name here)

You find two .idx files, which are required to calibrate and work through the test, and all implemented test tracks and a calibration sound test track. A calibration tone is required to adapt the SPL output to the recording level of the original test. This calibration track is always part of the original test CD (see test CD description).
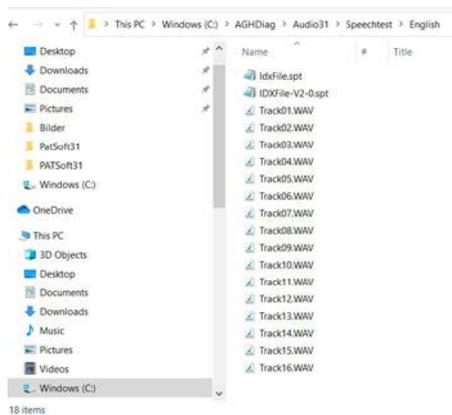
4.5.6 Creating speech tests

Three different test situations are possible:

1. **Speech test with word resolution:** Each word within a test track can be presented separately and repeated if necessary. Creating this method is the most time-consuming procedure of the three versions. Each word or sentence of the test must be defined by the start and stop time as well as the duration. This method should be implemented only in cooperation with an ATMOS specialist.

2. **Resolution of the speech test track:** Each track can be played separately and is presented to the patient as recorded on the original test CD. It is much easier to conduct this test than method no. 1 and it can be carried out by the audiologist according to the following instructions.

3. **Free speech using a microphone:** This test can be used if there is no audio test CD and the words/sentences are presented with the tester microphone. This test is the least reliable one due to the different SPLs created by the different testers during the oral test procedure.

To implement the test for methods no. 1 and no. 2, please open the Audio 31 options and then click on the button Speech test - Options.
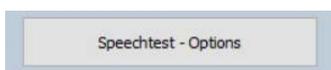
The Test Administration tab is opened. Then enter the name of the test to be conducted ("English" in this example).
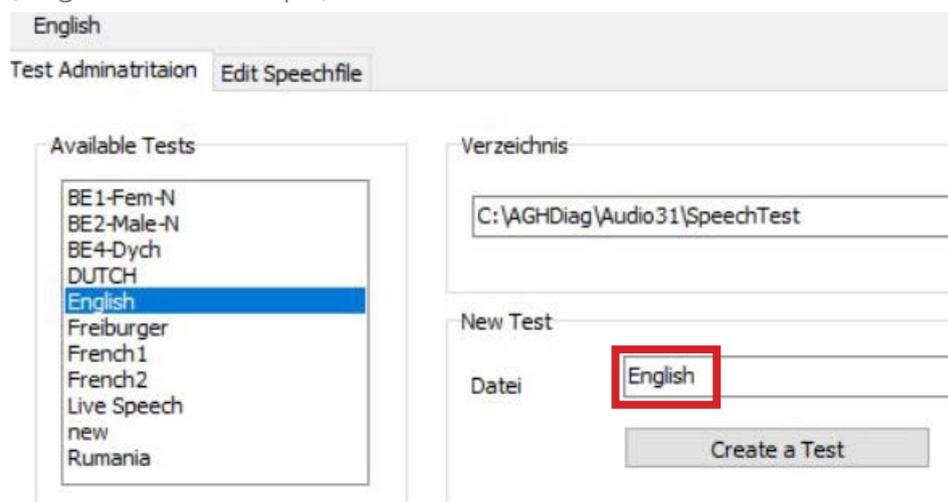
- Please click on the Create a Test button.
- Insert the CD in the CD-ROM drive.
- Click on the CD - Import button.
- Select the CD drive and the tracks to be imported and then click on the Rip CD button.
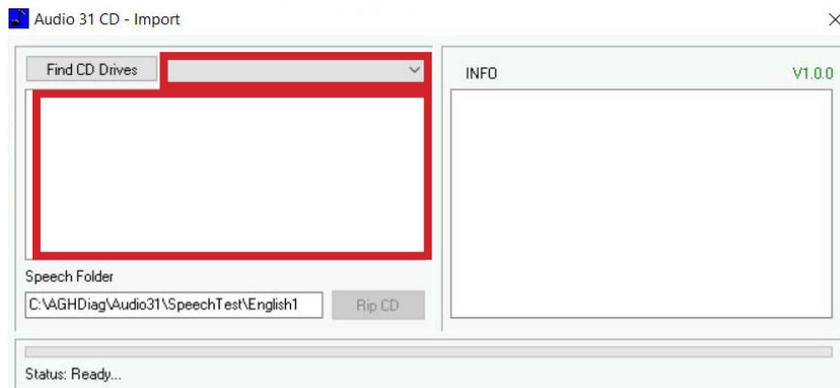
- Close the window after completing the procedure. Then click on the EDIT SPEECH FILE tab.
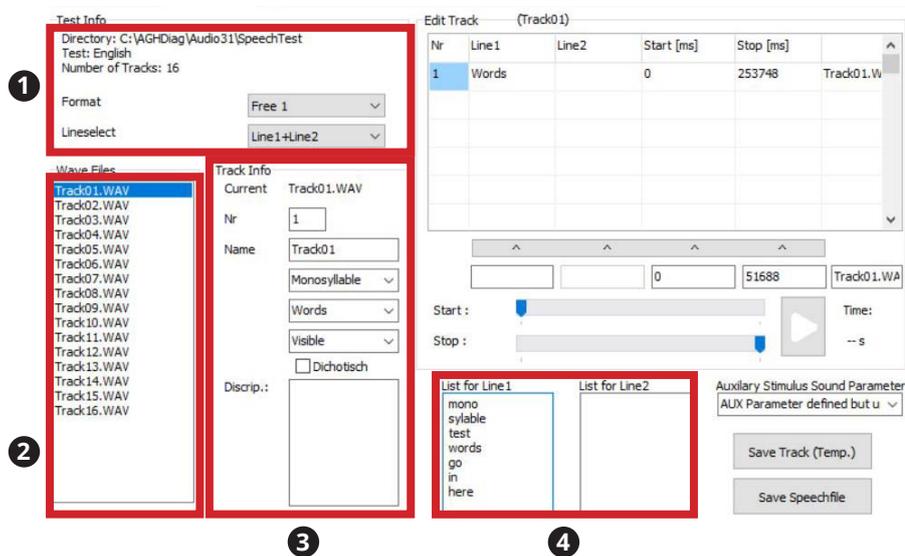
❶ Please select the format of the track: FREIBURGER for German speech test, FREE 1 with implemented PDF evaluation form, FREE 2 only with screen evaluation and LIVE SPEECH for the presentation using the tester microphone. Then select the signal source from which the tone is to be presented.

❷ Select a track from the list of ripped and available tracks in the WAVE FILES section.

❸ Enter the information required for each track in the TRACK INFO section.

❹ Enter the words from the test for each line in the LIST FOR LINE1 section.

☞ **Important:** The track information for the calibration noise in section ❸ must be as follows:

Name:	• Track number (normally the first or last track on the CD)
	• Masking
	• (Leave empty)
	• Not visible (as a result, the calibration line is not visible for the test)
Description:	• Please enter the type of calibration noise for documentation reasons

4.5.7 Speech test format #1

To present the test word by word, repeat words or skip a word, the test must be "decomposed" into its individual segments. The structure of each tracks looks like this:
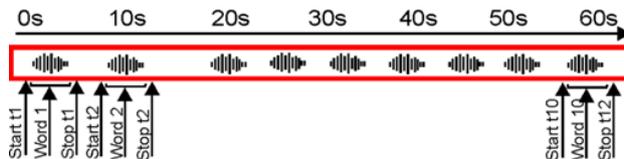
The start and stop time must be defined and adopted in the .idx file on the Edit Track tab.

Line 1: The word or number that is presented.

Start [ms]: Start time of the word in ms on the line.

Stop [ms]: End time in ms if the word ends on the line.

☞ **Important:** Dichotic tests cannot be presented with this word resolution method, but only by playing the complete track!

Sample for track 01 of the German Freiburger speech test

❶ Enter the text for line 1 and line 2 as well as the start time and end time of the word in the fields under ❶

❷ Click on the bar ❷ to add it to the track list.

This procedure must be repeated for each word within the track.

❶ Once you have finished a track, click on the Save Track button to save the test temporarily.

❷ After you have finished all tracks, click on the Save speech file button to adapt the .idx files and save the speech test.

4.5.8 Speech test format #2

The format for the test presentation is based track by track on the track structure below. Words/sentences may be on both lines of the track (left and right) for dichotic tests:
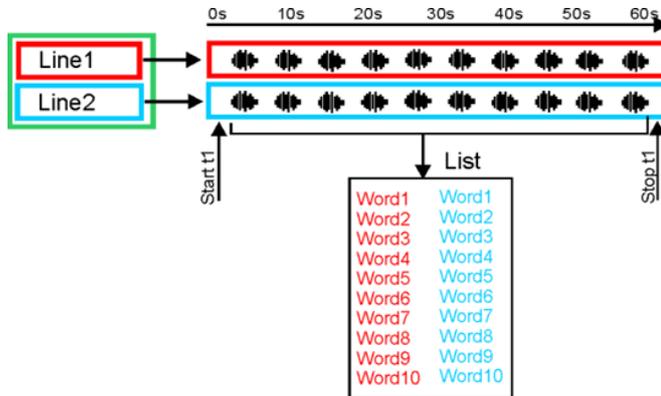
But there may also be words/sentences on a line and a masking noise on the other line:
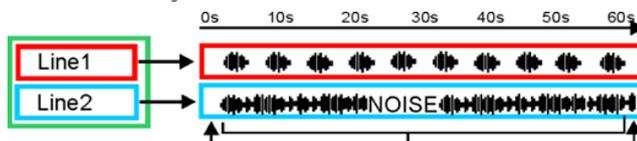
Another option is that words/sentences may be on one line and nothing on the other line:

To implement a test track by track, go through all ripped tracks. Define all tracks (apart from calibration noises), set the start and stop times and enter the list of presented words/sentences in the LIST FOR LINE 1 and LIST FOR LINE 2 fields.

❶ Select the track to be implemented.

❷ Define the structure of the test and whether it is to be visible in the presentation list.

❸ Click on the blue marker at the beginning to set the start time. Drag the stop marker to the end of the scale to set the stop time of the track.

❹ Click on the APPLY VALUE BAR button to enter the parameters for the line length in the list.

❺ Enter the words/sentences for each line (optionally) to present them on the test screen.

❻ Click on the SAVE THE TRACK button to save the track just defined. Click on the SAVE SPEECH FILE button to save the parameter finally in the .idx file and complete the implementation.

Repeat the procedure to implement each track (apart from the calibration line).

☞ To use the test, carry out the calibration procedure "4.5.3 Configuration of the audiometer for speech tests, implementation of speech tests and calibration of the audiometer und PC audio output" on page 28. Close the Audio 31 settings and restart the Audio 31 software. The test is now available.
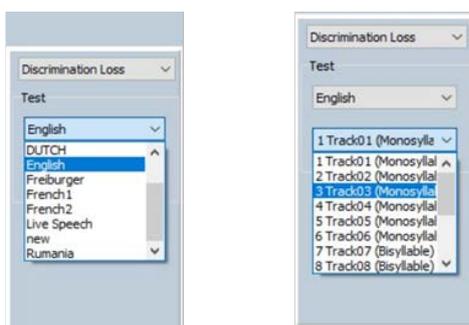
☞ To use a test, first select the test and then the track number with the necessary method.

4.5.9 Speech test format #3

The third method for the speech test presentation is a live speech test, which is spoken by the examiner using the intercom microphone of the examiner headset. There are ten "falsified" tracks without tone and the calibration noise in the "Live Speech" folder. The live speech test allows ten live tests to be conducted with words/numbers. The words/numbers can be displayed on the test screen to enable the tester to read them on the screen during the test procedure.
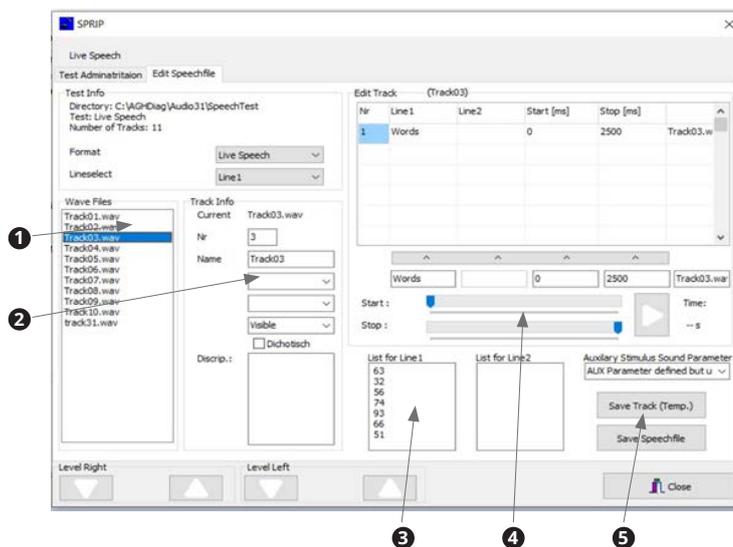
1. Select a track from the list ❶. The list contains ten "empty" tracks as placeholders for saving test parameters as an .idx file. Track 31 is the calibration tone used to synchronise the Audio 31 software and the PC sound card.

2. Define the word, number or sentence representation in section ❷ (optionally).

3. Enter spaces when entering words/numbers in section ❸ to allow the tester to read the test screen.

4. Click on the blue start marks in section ❹ and then drag the blue stop mark to the end of the scale. Then click on the Apply value bar button to adopt the parameters.

5. Click on the Save Track ❺ and Save speech file buttons to save the values as an .idx file.

☞ **Important:** The live speech test depends on the SPL of the speaker conducting the test. The speaker must speak with an SPL of approximately 70 dB, which corresponds to normal speaking volume. The speaker may have to practice the presentation with an SPL meter to obtain reliable results.

4.5.10 Patient management

Please observe: If you are only going to document the measurements electronically, you must store them related to the patient. There is an obligation to back up the data as evidence for the health insurance.

If the audiometer software is not integrated in practice software, you must manage the patient data with the audiometer software.

If the audiometer software is integrated in practice software, the patient management will be disabled for the audiometer software.

Selecting a patient

1. Click on the PATIENT button in the main window to open the patient management.
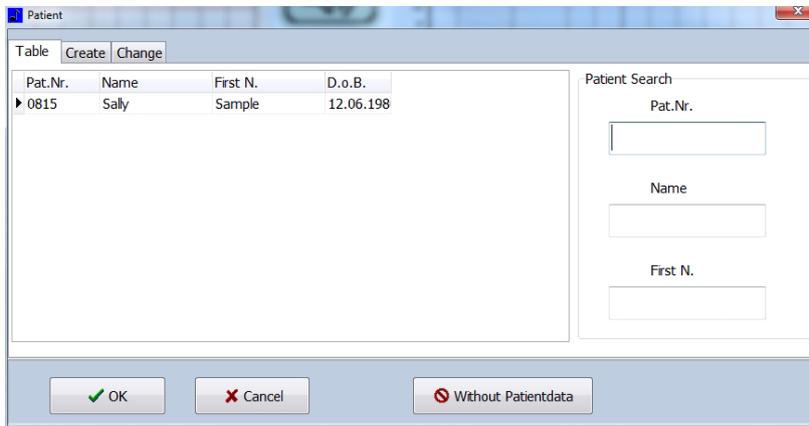
2. Select the patient from the table or enter the surname in the NAME field in the SEARCH section.

3. Click on the OK button.

» The patient data appear at the top of the main window.

Creating a new patient

1. Click on the PATIENT button in the main window to open the patient management.

2. Click on the NEW tab.
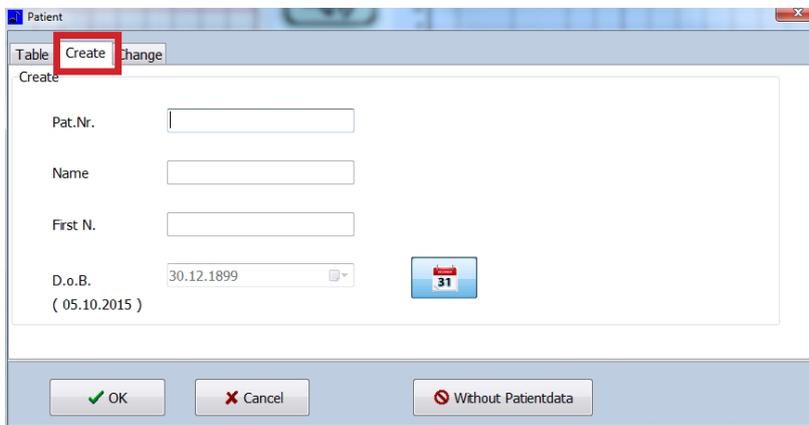
3. Enter the patient number, surname, first name and date of birth. Only the patient number is mandatory.

4. Click on the OK button.
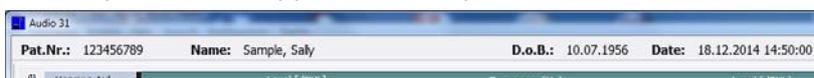
» The patient data appear at the top of the main window.

Changing or deleting a patient

☞ The patient number cannot be changed.

1. Click on the PATIENT button in the main window to open the patient management.

2. Select the patient.

3. Click on the CHANGE tab.
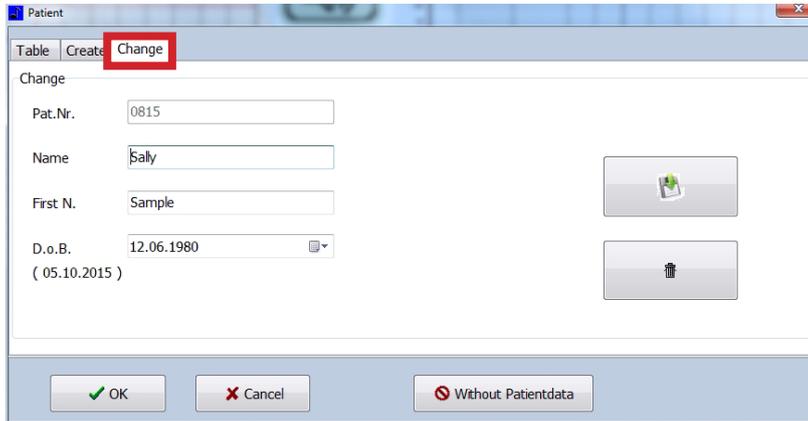
4. Change the patient data.

5. Click on the SAVE (diskette symbol) button to save the changes.

6. If you want to delete the patient data: Click on the DELETE (bin symbol) button.

4.5.11 Preparing the measurement

1. Switch on the PC.

2. Switch on the device.

⚠ Incorrect measurement results due to a cold device. The patient's hearing can become damaged by inappropriate treatment.

3. Wait at least five minutes. The device must warm up.

4. Adjust the desired parameters for the measurement.

5. Select the patient in the audiometer software.

☞ If you do not select a patient, the measurement can be printed, but not saved.

6. Position the patient.

7. Explain the test sequence to the patient.

⚠ Risk of infection due to contaminated headphones. Cross infection is possible.

8. Use standard protective covers for headphones.

9. If necessary, put the required transducer on the patient and give him the patient response button.

4.5.12 Tone audiometry measurement

⚠ **CAUTION**

Level is too high.

Damage to the patient's hearing is possible.

• Only adjust the level to > 80 dB HL if it was prescribed by the doctor.

1. Start with the right ear.

2. Press the arrow key to the right or left to adjust the first frequency. The arrow buttons are either on the keyboard or at the centre of the screen.

» The software displays the frequency currently set.

3. Change the level by pressing the up or down arrow buttons. The arrow buttons are either on the keyboard or at the top left of the screen. Increase the level gradually.

4. As soon as the patient presses the patient response button, Mark. or the Enter-button.

» The software marks the frequency and the corresponding level.

☞ To interrupt the tone, press the loudspeaker sign 🔊. You can also invert the loudspeaker function so that the sound is only heard when you go over the loudspeaker sign (see chapter "Software representation / measurement settings" on page 24).

5. Change the frequency.

» The level is automatically reduced.

6. Increase the level until the patient presses the patient response button and mark the point.

7. By doing so, you can check all the desired frequencies.

8. Continue with the left ear. Please observe: You can change the level on the left ear with the buttons PICTURE ↑ and PICTURE ↓.

4.5.13 Speech audiometry measurement

⚠ CAUTION

Level too high.

Damage to the patients hearing is possible.

• Only adjust the level to > 80 dB HL if it was prescribed by the doctor.

1. Start with the right ear.

2. Play the first word by pressing the button ▶.

3. Change the level by pressing the up or down arrow buttons. The arrow buttons are either on the keyboard or at the top left of the display. Increase the level gradually.

4. As soon as the patient repeats the text, press the Correct or Incorrect button.

» The software then marks the comprehensibility rate at each level.

5. By doing so, you can check all the desired texts.

6. Continue with the left ear. Please observe: You can change the level on the left ear with the buttons PICTURE ↑ and PICTURE ↓.

4.5.14 Illustration of the measurement

Tone audiometry
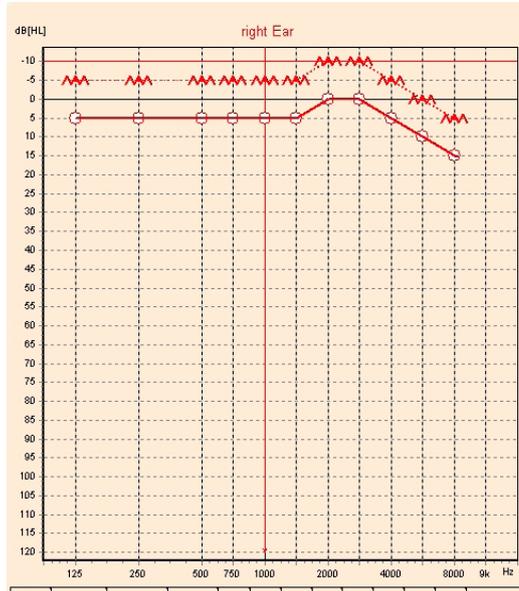
This diagram shows the frequencies heard at the respective levels.

Speech audiometry
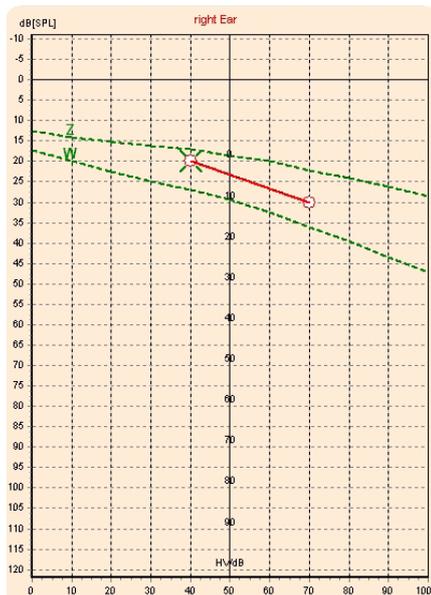
This diagram shows the comprehensibility rate as a function of the level.

Z: numbers

W: words

4.5.15 Organize measurement data

Comments

If you wish to comment on the measurements you can create standardized selection texts (see chapter "Comments" on page 45).

If you have loaded several measurements, you cannot comment on them. Therefore, load the measurements individually.

1. Click on the button COMMENT.

» The comment window appears.
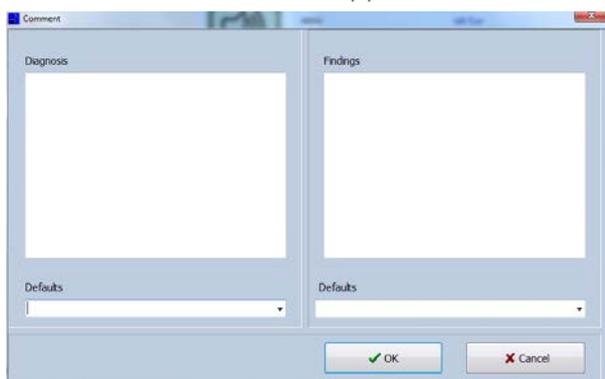
2. Enter the diagnosis and/or the findings.

3. Click on the OK button.

» The comments are saved.

Saving

Measuring data can only be stored when it is assigned to a patient.

1. Click on the button SAVE.

» The measurement is saved to the database.

Load

1. Select a patient.

2. Click the button LOAD.

» The Load window appears:
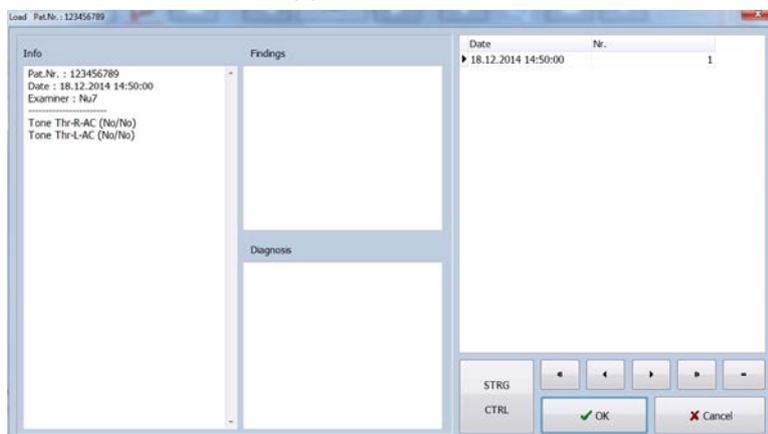
» Only measurements regarding the selected patient are displayed.

3. Navigate with ⏮ ◀ ▶ ⏭ .

4. Select the measurement by clicking on it.

☞ You can select up to five measurements simultaneously by clicking on the measurements while pressing the CTRL button.

5. Click on the OK button.

» The measurement is displayed in the main window.

Deleting

1. Select a patient

2. Click on the LOAD button.

» The Load window appears:
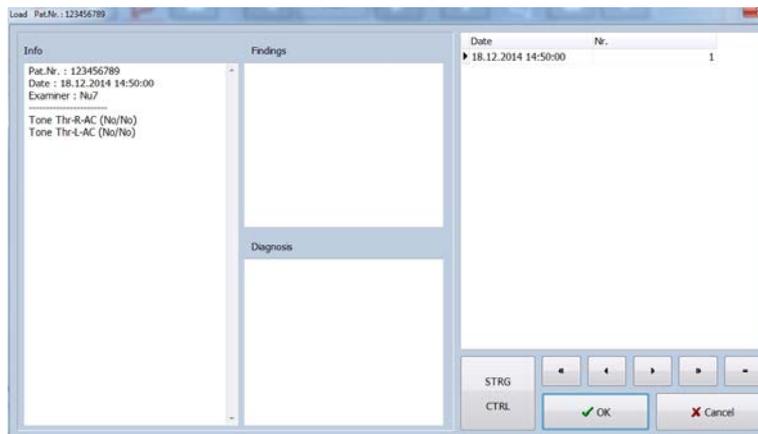
» Only measurements regarding the selected patient are displayed.

3. Navigate with [◄◄] [◄] [►] [►►].

4. Select the measurement by clicking on it.

5. Click on the MINUS button.

6. Confirm the question with OK.

» The measurement is deleted.

Exporting

1. Click on the PDF button.

» The PDF is opened.

2. Save the PDF.

Printing

1. Click the button PRINT.

» The printer dialogue appears.

2. Set the printing conditions.

3. Print the document.

5 Cleaning and disinfection

We recommend that you always document all maintenance work and part replacements in writing.

5.1 Cleaning and disinfection

⚠ **CAUTION**

Risk of infection.

Cross infection is possible. Diseases could be transmitted.

- Clean and disinfect the product according to the operating instructions.
- Always wear disposable gloves during all cleaning operations.
- Clean the device and accessories after each use.
- Observe the valid guidelines.

ATTENTION

Material damage due to liquids or incorrect disinfection.

- The cleaning cloth must not be wet.
- Never spray disinfectant directly onto the device or accessories, always on the cloth.
- Do not rinse the device or accessories under running water and do not immerse it into any liquids.
- Do not autoclave the device.
- Take care that no liquid penetrates the device. Pay particular attention to the connectors. If liquid gets into the device, it must no longer be operated and must be checked by an authorized ATMOS service partner.
- Observe the operating instructions of the disinfectant manufacturers. Pay particular attention to the information regarding the concentration and material compatibility.
- Use only disinfectants recommended by ATMOS (see chapter "5.3 Recommended disinfectants" on page 49). Other disinfectants may damage the device.

ATMOS Audio Cube 31

Clean the ATMOS Audio Cube 31 after each patient.

⚠ Electric shock due to liquid in the device.

1. Disconnect the device from the mains power supply.

ⓘ Porous plastic due to detergents containing solvents.

2. Dampen a soft cloth with water and mild, solvent-free detergent.
3. Clean the device with a damp (not wet) cloth.
4. Disinfect the housing with a recommended disinfectant.
5. Make sure the ATMOS Audio Cube 31 is dry before you switch it back on.

Headphones, bone vibrator and patient response button

Replace the ear cushions and headband pads at regular intervals.

Clean the headphones, bone vibrator and patient response button after each patient.

❶ Porous plastic due to detergents containing solvents.

1. Dampen a soft cloth with water and a mild, solvent-free detergent.

❶ Damaged headphone capsules due to water.

2. Make sure that the headphone capsules do not come into contact with water.

3. Clean the following items with a damp cloth:
   - Headphone bow
   - Headphone ear cushions
   - Bone vibrator capsule
   - Patient response button

5.2   Overview of hygiene measures

Device part	Cleaning	Disinfection	Notice	After each patient
Device	x	x	Mild solvent-free detergent	x
Headphone bow	x		Mild solvent-free detergent	x
Ear cushions	x		Mild solvent-free detergent	x
Bone vibrator capsule	x		Mild solvent-free detergent	x
Patient response button	x		Mild solvent-free detergent	x

5.3 Recommended disinfectants

If you use aldehyde and amine-containing disinfectants on the same object, this may cause discolouration.

> **ATTENTION**

Housing damage due to unsuitable detergent.

Corrosion damage and stress cracks are possible.

- Only use the recommended disinfectant or disinfectant solutions with the same ingredients.
- Do not use disinfectants containing alcohol.
- Do not use disinfectants containing organic and inorganic acids or bases.
- Do not use disinfectants containing chloramides or phenol derivatives.

Disinfectant	Ingredients	in 100 g	Manufacturer
Green & Clean SK	Dialkyl dimethyl ammonium chloride	< 1 g	Metasys, Rum (Austria)
	Alkyl dimethyl ethyl benzyl ammonium chloride	< 1 g	
	Alkyl dimethyl benzyl ammonium chloride	< 1 g	
Dismozon® plus (Granulate)	Magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Kohrsolin® FF (application concentrate)	Glutaral	5 g	Bode Chemie, Hamburg
	Benzyl-C12-C18-alkyldimethyl-ammonium chloride	3 g	
	Didecyldimethylammonium chloride	3 g	
Perform®	Pentapotassium-bis(peroxymonosulphate)-bis(sulphate)	45 g	Schülke & Mayr, Norderstedt
Terralin® Protect (Application concentrate)	Benzyl-C12-16 alkyldimethyl-chloride	22 g	Schülke & Mayr, Norderstedt
	2-phenoxyethanol	17 g	
	Aminoalkyl glycine	0.9 g	
	Non-ionic surfactants, perfumes		
Mikrobac® forte (Application concentrate)	Benzyl-C12-18-alkyldimethyl-ammonium chloride	19.9 g	Bode Chemie, Hamburg
	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	5 g	

6 Maintenance and service

Maintenance, repairs and period tests may be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. The person in question must possess the necessary test devices and original spare parts required to carry out these measures.

ATMOS recommends: Commission an authorized ATMOS service partner. This will ensure that the repairs and tests are carried out professionally, original spare parts are used and warranty claims remain unaffected.

6.1 Period tests

⚠ **WARNING**

Electric shock or incorrect measurement results due to a defective device.

Electric shock: Cardiac arrhythmia is possible.

Incorrect measurement results: The patient's hearing can be damaged.

- Please observe the intervals in this chapter.
- If you notice any errors or defects on the audiometer: Please contact ATMOS.

Mandatory check	Period	Tester
Daily function check	Daily prior to use	User
Weekly function check	Every week When the device is rarely used: prior to each use	User
Metrological check including repeat test of the electrical safety (Germany: metrological check according to the Medical Device Operator Ordinance)	Every 12 months.	Person with the appropriate technical knowledge and the necessary testing devices Recommended: ATMOS service partner

☞ ATMOS recommends:

- Document all tests carried out.
- Create an audiogram for the subjective examination of the hearing threshold for each examiner.

6.2 Daily function check

Visual check

1. Visually check the following condition of the device:
   - ☐ All operating controls easy to move; nothing is bent or twisted; no damage to plugs and power and accessory cables; no signs of ageing.
   - ☐ The headphone ear cushions have no cracks, breaks or any signs of ageing. Replace them if necessary.
   - ☐ The serial number of the device (SN) is indicated on the headphones and bone vibrator:
     Headphones SN: _____
     Bone vibrator SN: _____
     Audiometer SN: _____
     If the serial number on the transducer does not correspond to the serial number on the audiometer then you cannot use the transducer with that audiometer!

2. Switch on the device.

3. Wait at least five minutes. The device must warm up.

Checking tone audiometry

1. Check subjectively the hearing threshold via air conduction and bone conduction.
   - ☐ The hearing threshold is within normal limits.

2. Test the following conditions of the air conduction and bone conduction:
   - ☐ No disturbing noises, no signal from the other channel, no difference in tone quality when the masking noise is switched on
   - ☐ dB splitter weakening is all right
   - ☐ dB splitter without mechanical and electrical noises
   - ☐ Tone switch (mute button) mechanically silent
   - ☐ The emitted noise from the audiometer cannot be heard by the test person

3. Test the following condition at **60 dB HL** air conduction and **40 dB HL** bone conduction:
   - ☐ Proper function on both sides of the headphone / free field speakers and bone vibrator at all frequencies and settings, distortion-free, no switch noises.

4. Test the patient response button:
   - ☐ Patient response button can be pressed, the signal is displayed

_____   _____
 Date   Signature

6.3 Weekly function check

<table>
<tr>
<td rowspan="3">Visual check</td>
<td>
1. Visually check the following condition of the device:

  □ All operating controls easy to move; nothing is bent or twisted; no damage to plugs and power and accessory cables; no signs of ageing.

  □ The headphone ear cushions have no cracks, breaks or any signs of ageing. Replace them if necessary.

  □ The headphones fit perfectly and do not slip. All the joints move freely.

  □ The serial number of the device (SN) is indicated on the headphones and bone vibrator. If the serial number on the transducer does not correspond to the serial number of the audiometer, you must not use the transducer with this audiometer! Headphones SN: _____

  SN bone vibrator: _____ Audiometer SN: _____

2. Switch on the device and wait at least five minutes. The device must warm up.
</td>
</tr>
</table>

<table>
<tr>
<td rowspan="4">Tone audiometry test</td>
<td>
1. Check subjectively the hearing threshold via air conduction and bone conduction.

  □ The hearing threshold is within normal limits.

2. Test the following condition at levels just above the hearing threshold:

  □ No disturbing noises, no signal from the other channel, no difference in tone quality when the masking noise is switched on

  □ dB splitter weakening is all right

  □ dB splitter without mechanical and electrical noises

  □ Tone switch (mute button) mechanically silent

  □ The emitted noise from the audiometer cannot be heard by the test person

3. Test the following condition at **60 dB HL** air conduction and **40 dB HL** bone conduction:

  □ Perfect function on both sides of the headphones / free field speakers and bone vibrator at all frequencies and settings, distortion-free, no switch noises, no cross-talk of the channels, no humming or other disturbing noises.

  □ Signal is not interrupted, even if the cable is moved.

4. Test the patient response button:

  □ Patient response button can be pressed; signal is displayed.
</td>
</tr>
</table>

<table>
<tr>
<td rowspan="2">Speech audiometry test</td>
<td>
1. Check the following condition of the device:

  □ The level meter is at the set point (0 dB HL on the VU meter for speech-simulating noise or CCITT noise of the speech CD).

  □ Speech signal and masking noises at levels just above the hearing threshold.

  □ No disturbing noises at all sound transducers (e.g. intrinsic noises of the playback device or humming)

  □ No "cross-talk" from the other channel (e.g. left signal can be heard on the right)

  □ No change in the tone quality when the masking noise is switched on, level control weakens the speech and masking signal over the entire dB splitter range.

2. Test the following condition at **50 dB HL** air conduction and **30 dB HL** bone conduction:

  □ Perfect function and no distortion

  □ Test signals and test person response can be heard perfectly at the audiometrist's place.
</td>
</tr>
</table>

Date: _____   Signature: _____

6.4 Metrological check / electrical safety

Only persons with the appropriate technical knowledge may perform this test. International and country-specific regulations must be complied with. ATMOS recommends: Commission an authorized ATMOS service partner.

When the test is completed, make sure the following is available:

- Test report with the target and actual value of all parameters as well as the error limits
- Seal of approval with information on the testing organization and the date for the next check

At least the following is tested during the metrological check:

- Visual check, wear parts will be replaced
- Function check
- Patient response button and patient communication check
- Test for disturbing noises, cross-talk, distortion
- Pressing force of the headphones
- Frequency accuracy of the test tone
- Total harmonic distortion (THD) of the air conduction
- Tone level attenuation
- Deviation of the sound pressure level tone and noise masking per air conduction setting frequency
- Total harmonic distortion of the bone conduction
- Deviation of the force level of the bone conduction per setting frequency
- Speech sound level measurement
- Measurement of the frequency response for speech reproduction via the headphones
- Deviation of the tone sound level / speech in free field
- Repeat test of the electrical safety according to IEC 62353

6.5 Replacing parts

Only the parts described in this chapter may be replaced by the user. All the other parts must be replaced by a service partner authorized by ATMOS.

6.5.1 Head bow of the bone vibrator B71

1. Switch off the device.
2. Unclip the bone vibrator capsule from the old head bow.
3. Insert the new bone vibrator into the new head bow.

6.5.2 Bone vibrator cable B71

1. Switch off the device.
2. Loosen the cable of the bone vibrator from the audiometer.
3. Gently pull the cable plug from the bone vibrator capsule.
4. Plug the new cable into the bone vibrator capsule.
5. Plug in the new bone vibrator cable into the audiometer.

6.5.3 Mains fuses

⚠ **WARNING**

Fire hazard due to unsuitable fuses.

Burns and injuries are possible.

- Only use glass tube fuses type T1A L/250V 5x20 mm.
- Always replace the fuses in pairs.
- If the fuses blow within a short period of time then an authorized service partner must be contacted immediately.

1. Switch off the device.
2. Remove the power cable from the device.
3. Undo the fuse holder at the top and bottom with a screwdriver.
4. Remove the fuse holder.
5. Replace both glass tube fuses.
6. Reattach the fuse holder. Press until it audibly locks.

6.6 Sending in the device

1. Remove all consumables and dispose of them properly.
2. Clean and disinfect the product and accessories in accordance with the operating instructions.
3. Enclose any used accessories with the product.
4. Fill in the QD 434 form "Delivery Complaint / Return Shipment" and the corresponding **decontamination certificate**.
☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.
5. The device must be well padded and packed in suitable packaging.
6. Place the QD 434 form "Delivery Complaint / Return Shipment" and the corresponding **decontamination certificate** in an envelope.
7. Affix the envelope to the outside of the package.
8. Send the product to ATMOS or your dealer.

7   Troubleshooting

The ATMOS Audio Cube 31 was subjected to thorough quality control at the factory. If a fault occurs nevertheless, you may be able to resolve it yourself.

Error symptom	Possible cause	Remedy
Measurement does not start.	No USB connection between PC and audiometer.	1. Check whether the PC is connected to the device. 2. If necessary, connect the PC and ATMOS Audio Cube 31 with the USB cable.
The software does not respond.	Patient management window is still open in the background.	1. Keep the Alt and Tab keys pressed and select the patient management using the arrows. 2. Close the patient management.

8   Accessories

> ⚠ **CAUTION**
>
> **Incorrect measurement results or level is too high caused by incorrectly calibrated transducers.**
>
> Damage to the patient's hearing is possible.
>
> - As soon as you replace or use a different transducer then the device must always be recalibrated. In this case, please contact ATMOS.
> - Free field loudspeakers must always be calibrated on-site. In this case, please contact ATMOS.

Accessories	REF
Patient microphone	512.2118.0
Cable harness, acoustic booth	512.2114.0
Loudspeaker active*	512.2115.0
Loudspeaker cable, 2m	512.2116.0
Loudspeaker cable, 3 m	512.2117.0
High tone-audiometry option incl. headphones HDA 300	512.2120.0

*Free field loudspeakers must always be calibrated on site. In this case, please contact ATMOS.

9 Spare parts and consumables

Spare part	REF
Sennheiser HDA 280 headphone cushions	512.2123.0
Sennheiser HDA 300 headphone cushions	512.2124.0
Sennheiser HDA 280 / HDA 300 headphones, bow cushion	512.2122.0
Spare bow for Sennheiser HDA 280	512.2125.0
Head bow, bone vibrator B71	512.2121.0
Patient response button	512.2112.0
Headset Stereo	512.2113.0

10 Disposal

Device

- Do not dispose of the device with household waste.
- The ATMOS Audio Cube 31 does not contain any hazardous goods.

Disposal in Germany

1. Clean and disinfect the device.
2. Send the device to ATMOS or your authorized dealer. They will dispose of the device appropriately.

Disposal within the EU

1. Clean and disinfect the device.
2. The device must not be disposed of in the domestic waste (EU directives WEEE and RoHS).
3. Dispose of the device appropriately in accordance with the national regulations.

Disposal in countries that do not belong to the European Union

1. Clean and disinfect the device.
2. Please observe the national regulations.
3. The materials can be separated. The housing is fully recyclable.

11 Technical data

Voltage	100 to 240 VAC ± 10%
Mains frequency	50 to 60 Hz ± 3 Hz
Power consumption	30 VA ± 10 %
Fuses	2 X T1A L/250V glass tube
Weight	Approx. 4.5 kg without accessories
Dimensions	approx. 505 x 355 x 110 mm (W x H x D)
Life cycle	approx. 11 years
Warm-up time	<10 min full acclimatization at the specific operating environment
Ambient conditions Transport and storage	Temperature: -10°C to +45°C
	Air humidity without condensation: 30 to 90 % relative humidity
	Air pressure: 70 kPa to 106 kPa
Operation	Temperature: +15°C to +35°C
	Air humidity without condensation: 30% to 90 % relative humidity
	Air pressure: 98 kPa to 104 kPa
Signal output	Headphones (audiometer headphones)
	Bone vibrator
	Free field: 2 loudspeakers, active or passive
	External: additional headphones or earphones or 2 additional loudspeakers
	Monitor Mono: monaural listener
	Stereo monitor: binaural listener
Signal inputs	Left and right: external signal source
	Microphone external: Headset (electret or dynamic)
	Patient microphone: Patient microphone (electret or dynamic)
Data interfaces	RS 232: Printer (8 data bits, 1 stop bit / no parity / no flow control / 115200 baud)
	USB: PC (galvanically isolated, USB 2.0, 12 Mb/s)
Number of signal channels	2 separate and identical signal channels
Attenuator	1dB or 5 dB steps over the entire range
Total harmonic distortion	Headphones: < 2.5%
	Bone vibrator: < 5.5 %
Frequency range, tone test	Headphone: 125 - 8000 Hz
	Bone vibrator: 250 - 6000 Hz
Frequency accuracy, tone test	Better ± 1%

Signal types, tone test	
Continuous tone	
Pulse tone	0.25 - 2.5 Hz in steps of 0.25 Hz
Frequency modulation (Wobbel)	1 - 20 Hz in steps of 1 Hz
	Wave form of modulation: sine
Complexity of sound (Wobbel)	1 - 25% in steps of 1%
Amplitude modulation (SISI)	5, 3, 2, 1 dB steps
Masking tone test	
Contralateral free or synchronous	
Broadband noise	
Narrowband noise	(acc. to EN 60645-1 chapter 6.4, 8.5 and table 4) Spectrum: 1/3 octave
Masking, speech test	
Contralateral free or synchronous	
Broadband noise	
Speech-simulating noise	Frequency-weighted noise acc. to EN 60645-2 chapter 13
Speech test	
Monaural and binaural	
External speech test	Via HDD or microphone
Supra-threshold tests	SISI, FOWLER, Lüscher, Langenbeck, Stenger and tinnitus
Output level	Max. 120 dB HL
Bone vibrator B 71	Pressing force: 5.4 N
	Coupling type IEC 373
Sennheiser headphones HDA 280	Pressing force: 5.0 N
	Coupling type IEC 303
Protection class	I
Applied part	Type B
Operation mode	Continuous operation
Type of protection	IPX0
Classification according to Appendix IX EC Directive 93/42/EEC	II a
Classification acc. to EN 60645-1 (2002-09)	Class 2
Classification according to EN 60645-2 (1997-04)	Sennheiser HDA 280: Class B-E
	Sennheiser HDA 300: Class B
	Radioear DD45 for B-E
	Radioear DD450 for B
Period tests	Daily function check
	Weekly function check
	Metrological check including repeat test of the electrical safety every 12 months. (Germany: Metrological check according to Medical Device Operator Ordinance).

12 Notes on EMC

Medical electrical devices are subject to special precautions with regard to EMC and must be installed according to the following EMC instructions.

Portable and mobile HF communication facilities can influence medical electrical devices.

The use of accessories, transducers or cables other than those specified can lead to the increased emission or reduced interference immunity of the device or system.

Guidelines and manufacturer's declaration - electromagnetic emissions

The product ATMOS Audio Cube 31 is intended for operation in the environment specified below. The customer or user of the audiometer should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guideline
RF emissions according to CISPR 11	Group 1	The audiometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and it is unlikely that nearby electronic devices will be affected.
RF emissions according to CISPR 11	Class B	The audiometer is suitable for use in all facilities, including domestic ones and those directly connected to the public mains power supply that also supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Inapplicable	
Emission of voltage fluctuations/ flickering according to IEC 61000-3-3	Inapplicable	

Guidelines and manufacturer´s declaration - electromagnetic immunity

The product ATMOS Audio Cube 31 is intended for use in the electromagnetic environment specified below. The customer or user of the audiometer should ensure that it is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or covered with ceramic tiles. If floors are synthetic, the relative humidity should be at least 30%.
Fast electrical transient/bursts according to IEC 61000-4-4	± 2 kV Mains ± 1 kV for input and output cables	± 2 kV for power cables ± 1 kV for input and output cables	The quality of the mains power should correspond to that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common-mode voltage	± 1 kV differential-mode voltage ± 2 kV common-mode voltage	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage dips, temporary interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5% UT (> 95% dip of the UT) for ½ cycle	complies	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the user of the audiometer requires continued function during interruptions of the energy supply, it is recommended to supply the audiometer from an uninterruptible power supply or a battery.
	40% UT (60% dip of the UT) for 5 cycles	Fulfilled	
	70% UT (30% dip of the UT) for 25 cycles	Fulfilled	
	< 5 % UT (> 95 % Dip of the UT) for 5 s	Fulfilled (criteria B)	
Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of the mains frequency should correspond to that of a commercial or hospital environment.
NOTE UT is the alternating mains voltage prior to application of the test levels			

Guidelines and manufacturer´s declaration - electromagnetic immunity

The product ATMOS Audio Cube 31 is intended for operation in the electromagnetic environment specified below. The customer or user of the audiometer should ensure that it is used in such an environment.

Immunity Test	IEC 60601-Test Level	Compliance level	Electromagnetic environment – Guidelines
Conducted RF interference according to IEC 61000-4-6	3 V_{rms}	3 V_{rms}	Portable and mobile communications equipment should be separated from the audiometer including the cables by no less than the distances calculated/listed below.
Radiated RF interference according to IEC 61000-4-3	3 V/m 80 MHz to 1.0 GHz	3 V/m	Recommended safety distance: $d = 1.17 * \sqrt{P}$ $d = 1.17 * \sqrt{P}$
			where "P" is the nominal power in watts (W) of the transmitter according to the information of the transmitter manufacturer and d is the recommended safety distance in metres (m).
			Field strengths from fixed transmitters, as determined by an electromagnetic site[a] survey, should be less than the compliance level[b].
			Interference is possible near devices with the following symbol. $((\cdot))$

NOTE 1

At 80 and 800 MHz, the higher frequency range applies.

NOTE 2

These guidelines may not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects and people.

a

The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, AM and FM broadcast and TV stations cannot be theoretically pre-determined exactly. To determine the electromagnetic environment with regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the audiometer is used exceeds the above compliance level, the audiometer must be monitored to verify the intended use. If unusual performance characteristics are observed, additional measures may be required, such as re-orienting or relocating the audiometer.

b

Within the frequency range of 150 kHz to 80 MHz, the field strength should be below 10 V/m.

Recommended safety distances between portable and mobile RF communications equipment and the audiometer

The product ATMOS Audio Cube 31 is intended for operation in an electromagnetic environment in which RF disturbances are controlled. The customer or user of the audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the audiometer, depending on the output power of the communications equipment as specified below.

Nominal power of the transmitter W	Safety distance, depending on the transmission frequency m		
	150 kHz to 80 MHz $d = 1.17 * \sqrt{P}$	80 to 800 MHz $d = 1.17 * \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 * \sqrt{P}$
0.01	0.12	0.12	0.233
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters of which the maximum nominal output is not indicated in the above table, the recommended safety distance d in metres (m) can be determined using the equation belonging to the respective column, whereas P is the maximum nominal output of the transmitter in watts (W) according to the manufacturer of the transmitter.

NOTE 1

With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2

These guidelines may not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects and people.

13 For your notes

www.atmosmed.com