

Operating Instructions

ATMOS

Diagnostic Cube

English



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These operating instructions are valid from software version

Rhino 31: V 2.1.5

TEOAE 31: V 1.0.5

Sono 31: V 2.0.15

DPOAE 31: V 1.0.5

Tymp 31: V 2.1.6

PatSoft 31: V 1.0.0.4

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1 Introduction

1.1 Notes on operating instructions



These operating instructions contain important instructions on how to operate your product safely, correctly and effectively.

These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. Any reprint - even in extracts - only after written permission from ATMOS.

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



Care, period tests, regular cleaning and proper application are indispensable. That increases, among other things, the reliability and service-life of the device.

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



Peruse chapter „2 Hints for your safety“ on page 13, before using the product for the first time. This helps you avoid potentially dangerous situations.

The product bears CE marking CE 0124 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 product complies with all applicable requirements of the Directive 2011/65/EC restricting the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).

The declaration of conformity and our general standard terms and conditions can be obtained on our website at www.atmosmed.com.

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

These operating instructions are valid for the following devices:

- | | |
|---|------------|
| • ATMOS Diagnostic Cube | 512.0000.0 |
| • ATMOS Rhino 31 with olive measuring probe | 512.1000.0 |
| • ATMOS Rhino 31 with mask measuring probe | 512.1600.0 |
| • ATMOS Sono 31 | 512.1200.0 |
| • ATMOS Tymp 31 | 512.1100.0 |
| • ATMOS Tymp 31 D | 512.1700.0 |
| • ATMOS TEOAE + DPOAE 31 | 512.2000.0 |
| • ATMOS TEOAE 31 | 512.1800.0 |
| • ATMOS DPOAE 31 | 512.1900.0 |

1.2 Explanation of pictures and symbols

Icons and symbols in the operating instructions

 DANGER	Warning of a danger which causes immediate death or serious injury. Observe the necessary measures.
 WARNING	Beware of a danger which can cause death or serious injury. Observe the necessary measures.
 CAUTION	Beware of a danger which can easily hurt you. Observe the necessary measures.
ATTENTION	Indication of a danger where the product or other items can be damaged. Observe the necessary measures.
	Warning of a danger which can cause death or serious injury.
	Information regarding possible material damage which can be caused.
	Useful information on the handling of the device.
1.	Action. Go step by step.
»	Result of an action.

Icons and symbols on device and type plate

	Follow operating instructions (blue)		Observe operating instructions
	Manufacturer		Manufacturing date
SN	Serial number	REF	Order number
	This product complies with the relevant requirements of EU Directives		Application part type BF
	For single use only (symbol is on the consumables)		Application part type B
	Caution! Pay attention to the safety instructions in the operating instructions		Professional disposal
	Foot switch		

1.3 Intended use

1.3.1 ATMOS Rhino 31

Name: ATMOS Rhino 31

Main functions:	Determination of the nasal flow resistance
Medical indications / application:	Diagnostic of the nasal flow resistance
Specification of the main function:	<ul style="list-style-type: none"> • Determination of the nasal flow resistance • Nasal provocation test (allergology)
Application organ:	Nose
Application time:	For the short-term application on patients (max. 60 minutes)
Application site:	In clinics and practices for ENT doctors. The examination may only be performed by healthcare professionals.
Contraindications:	None
The product is:	active
Sterility:	Not necessary
Single-use product / reprocessing:	No single use product

1.3.2 ATMOS Sono 31

Name:	ATMOS Sono 31
Main functions:	Diagnostics of the paranasal cavities including secretion and tissue status
Medical indications / application:	Determination of diagnostic findings e.g. sinusitis, tumours, cysts, mucositis
Specification of the main function:	Generation of echoes by means of ultrasonic waves for application on the maxillary sinus (sinus maxillaris) or on the frontal sinus (sinus frontalis)
User profile:	Doctors and medical assistants
Patient groups:	Patients of all ages with and without restrictions
Application organ:	Head
Application time:	For the short-term application on patients (max. 60 minutes)
Application site:	In clinics and practices for ENT doctors. The examination may only be performed by healthcare professionals.
Contraindications:	None
The product is:	Active
Sterility:	Not necessary
Single-use product / reprocessing:	No single use product

1.3.3 ATMOS Tymp 31

Name:	ATMOS Tymp 31
Main functions:	Determination and display of the eardrum's mobility
Medical indications / application:	Diagnostic of the middle ear

Specification of the main function:	<ul style="list-style-type: none"> • Determination and display of the eardrum's mobility, • Determination of the minimum triggering level of the stapedius reflex (ipsi and contralateral), • Reflex decay • Eustachian tube function test • High frequency tympanometry for children
Application organ:	Ear
Application time:	For the short-term application on patients (max. 60 minutes)
Application site:	In clinics and practices for ENT doctors. The examination may only be performed by healthcare professionals.
Contraindications:	<ul style="list-style-type: none"> • Perforated/injured eardrum • Inflamed auditory canal • Inflamed eardrum • During recovery after ear surgery • Injuries and foreign body
The product is:	active
Sterility:	Not necessary
Single-use product / reprocessing:	No single use product

1.3.4 ATMOS TEOAE + DPOAE 31

Name:	ATMOS OAE 31
Main functions:	Determination of TEOAE and DPOAE
Medical indication / application:	TEOAE: Test of the outer hair cells DPOAE: frequency specific test of the outer hair cells
Specification of the main function:	Determination of transient evoked otoacoustic emissions (TEOAE) and distortion product otoacoustic emissions (DPOAE). The doctor is responsible for the interpretation of the indicated values. The device is not a screening device.
User profile:	Doctors and medical assistants
Patient groups:	Patients of all ages with and without restrictions
Application organ:	Ear
Application time:	For the short-term application on patients (max. 60 minutes).
Application site:	In clinics and practices for ENT doctors. The examination may only be performed by healthcare professionals.
Contraindications:	None
The product is:	active
Sterility:	Not necessary
Single-use product / reprocessing:	No single use product

1.4 Function

1.4.1 ATMOS Rhino 31

The ATMOS® Rhino 31 is used for determining the respiration flow, this is performed by means of an annular diaphragm spiroceptor which is connected to the patient by means of a breathing mask or nasal olives. The differential pressure determination is then taken by means of the anterior method (choana versus mask interior pressure/olive pressure).

Data are shown in real time as a rhinogram and afterwards as a flow-pressure-diagram, as a value table and bar graph. The data processing is done by the ATMOS Rhino 31 software and the obtained values and results are saved. For printing a Windows printer connected to the device can be used.

For an easy evaluation of the results up to three examinations can be graphically displayed simultaneously. For easy evaluation a comparison of the curves is shown both tabularly and graphically. The results of the calculation include a patented data processing system CAR (computer aided rhinomanometry). This process supports the rejection of artefacts. This provides the examiner with more objective examination results.

The results are saved in an individual patient data file out of which they can be printed via a Windows printer. The ATMOS Rhino 31 diagnostic software is network-compatible and can be integrated into a patient EDP or a hospital information system.

1.4.2 ATMOS Sono 31

The quick and easy to perform ultrasound examination with the ATMOS Sono 31 computer module is an examination method for detecting the condition of the maxillary sinuses. For each of the four cavities there is a corresponding graph which shows the echo performance of the ultrasound. Echoes develop when the acoustic impedance changes, this occurs on the border between bones, tissue, liquids (secretion) and air. The bigger the impedance difference, the stronger is the reflection. An ultrasound probe is used both as a sender and receiver for ultrasonic waves.

Ultrasonic waves are almost completely reflected on the transition areas between bones or tissue and air. This fact is used for the diagnostic evaluation. Consequently in a healthy and air-filled frontal or maxillary sinus only a front wall echo can be seen. Mucosal swelling, secretion accumulation, cysts or neoplastic changes produce additional characteristic late echoes.

Free text comments can be added to the graphical display of the examination results, whereby here a dialogue field for each individual sinus is available. Furthermore there is also a dialogue field for the overall assessment. Apart from that every sinogram can be reworked by a distance measurement. All test readings and evaluations are saved in a database and are available for later viewing.

For printing a Windows printer connected to the device can be used. The ATMOS Sono 31 diagnostic software is network-compatible and can be integrated into a patient EDP or a hospital information system.

1.4.3 ATMOS Tymp 31

The ATMOS Tymp 31 is a diagnostic device for the objective measurement and examination of the eardrum, the ossicular chain, the stapedius reflex and the Eustachian tube. Here the ear of the test subject is exposed to precise pressure conditions and is filled with acoustic sound in different frequencies and levels. The aim of this examination is to determine the flexibility (compliance, reciprocal value of the acoustic impedance), the pressure in the middle ear at maximum impedance (peak), the minimum triggering level of the stapedius reflex by four different frequencies (500, 1000, 2000 and 4000 Hz) and in order to determine the function of the eustachian tube.

In order to perform this diagnostic investigation a probe is placed into the entrance of the subject's auditory canal. It is then sealed with the help of an adapter. A tone is sent via the probe into the ear (probe tone). At the same time it is exposed to an increase and decrease in pressure. The reflected echoes are determined and calculated by the ATMOS Tymp 31 software and are shown both as a graph and in tabular form. According to the preselected examination method, a result is shown on the monitor. Due to a variety of adjustment possibilities, it can be adapted to suit the examination on the physiology of the test subjects as well as the preferences of the examiner. In the everyday clinical life freely selectable standard parameters simplify the application of the ATMOS Tymp 31.

The ATMOS Tymp 31 corresponds to the current requirements for correct accounting with the insurance companies, all data is available for assessment and is documented electronically for verification. The ATMOS Tymp 31 diagnostic software is network-compatible and can be integrated into a patient EDP or a hospital information system.

1.4.4 ATMOS TEOAE + DPOAE 31

Principle:

Otoacoustic emissions, abbreviated OAE, are acoustic emissions from the inner ear. They are created by the vibration of the outer hair cells in the cochlea and can be detected with a microphone.

Measuring method:

The ATMOS OAE 31 uses two of the most frequently applied measuring methods, the transient evoked otoacoustic emissions (TEOAE) and the distortion product otoacoustic emissions (DPOAE).

TEOAE:

A succession of broadband acoustic stimuli (clicks) are radiated into the outer ear via a small loudspeaker in the probe. Via the microphone in the probe an acoustic response of the inner ear is registered and via a measuring computer evaluated and displayed.

TEOAE reflect the hearing capacity in the range of 1000 Hz to 5000 Hz and are considered to be proven if a reproducibility of at least 50% is at a signal level of 3 dB SPL or more. By around 99% of all young adults with a hearing threshold of 20 dB or better TEOAE are detectable. With a hearing loss of 30 dB or more TEOAE cannot be detected.

DPOAE:

The measurement is carried out analogous to TEOAE, except that in addition to the microphone two loudspeakers are used in the probe. This way two pure tones (primary tones) are generated, whose frequencies are so near to one another that their waves overlap. In this overlap area, existing and functional outer hair cells will produce measurable distortion products (tones). The detection presupposes the presence and the functionality of the outer hair cells in the specific measured frequency range.

Significance:

The measurement of otoacoustic emissions, together with the derivation of acoustically evoked potentials (BERA) and the tympanometry with stapedius reflex measurement, is one of the three important methods of the objective hearing test.

The measurement results can be saved in a patient related database, be printed or integrated into a doctor's office computer system respectively into a hospital information system (HIS).

1.5 Scope of delivery

All modules



ATMOS Diagnostic Cube with modules and probe holder



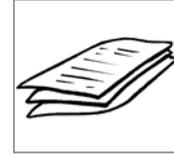
Power supply unit with power cord



USB cable, 2 m



Software (CD)



Operating Instructions

ATMOS Rhino 31 with olive measuring probe



Measuring probe with olives in 3 sizes



2 x set of filter plates each 50 pieces



Test block

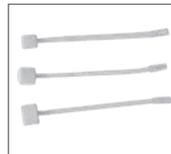
ATMOS Rhino 31 measuring probe with nose mask



Measuring probe with nose mask



50 x filter plates



3 x set of nose adapters each 50 pieces



Test block

ATMOS Sono 31



Ultrasonic probe



Ultrasonic gel



Test block

ATMOS Tymp 31



Tymp probe



Ear plugs



Contra head-
phone

ATMOS TEOAE + DPOAE



Measuring
probe



Probe tip can
be exchanged



Ear plugs



Cleaning cord



Probe holder
(magnetic)

Optional



Foot switch



iHandle

1.6 Transport and Storage

Only transport the device in a shipping carton, which is padded and offers sufficient protection.

If damage occurs during transport:

1. Document and report the transport damage.
2. Send the device to ATMOS, see chapter „6.2 Sending in devices“ on page 61.

Ambient conditions for transport and storage:

- Temperature: -30...+50 °C
- Relative air humidity: 5...85% without condensation
- Air pressure: 700...1060 hPa

2 Hints for your safety

The safety of the ATMOS Diagnostic Cube complies with all the recognized rules of technology and the Directives of the Medical Devices Act.

Please read and observe the safety instructions prior to using the product.

2.1 General safety information

The device may only be operated in rooms used for medical purposes.

A PC is required in order to operate the ATMOS Diagnostic Cube. If the PC is in close proximity to the patient then it must comply with the standards IEC 60601-1.

As a user of the diagnostics software you are responsible for the data backup.

2.2 Dangers for users, patients and third parties

Protect yourself against an electric shock!

Burns, cardiac arrhythmias and even death are possible.

- Check before each use if the device, power supply unit or the power cord are damaged. Never operate the unit, if it shows any obvious safety defects. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Disconnect the device from the mains supply prior to cleaning or disinfection.
- Do not operate the device if it has been dropped. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Only connect the device to a power supply with a correctly installed protective conductor.
- Only use proper power connections and extension cords.
- The device can be disconnected from the power supply only by pulling the plug out. Unplug the power cable from the wall socket first. Then separate the power cable from the device.
- Never touch the plug or power cable with wet hands.
- Only use original accessories and original spare parts from ATMOS. Only use the supplied medical power supply unit (manufacturer: GlobTek Inc., model: GTM91099-6015-3.0-T2A).
- Assembly, new settings, modifications, extensions and repairs may only be carried out by persons who are authorized by ATMOS.

Reduce the risk of infection for you and your patients!

Diseases could be transmitted.

- Never use components marked with  more than once. These components are intended for single use only.
- Clean and disinfect the product as described in chapter „5 Cleaning and disinfection“ on page 54.

Avoid misapplication or incorrect diagnosis.

The patient can be injured.

- Prior to each use a function check has to be performed.
- The product may only be applied by medically trained staff.
- A diagnosis may only be made by persons with the appropriate medical training.
- The control panel should always be clearly in view for the operators and be easy to reach.

- Only probes which are not damaged may be used.
- Only use original accessories and original spare parts from ATMOS.
- Assembly, new settings, modifications, extensions and repairs may only be carried out by persons who are authorized by ATMOS.

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

- Only use the module TEOAE + DPOAE in a soundproof, audiological room with an acoustic level <40 dB.
- For examination with the modules TEOAE + DPOAE or Tymp always use a suitable earplug.
- Only use the modules TEOAE + DPOAE and Tymp on patients with a normal outer ear.
- Clean the patient's ear prior to the examination with the modules TEOAE + DPOAE and Tymp.

The patient may suffer burns.

- The ultrasonic device should not be used in HF surgery.

Harmful materials!

The Rhino twin tube contains phthalates which are categorised as toxic for reproduction in category 2. This applies particularly to children, pregnant and breastfeeding women. The residual risk, which may arise through possible exposure and due to the short term application, can be valued as insignificant compared to the benefit of the product.

- Avoid direct skin contact with the Rhino twin tube.

Explosion and fire hazard!

Burns and injuries are possible.

- Never operate the device in explosion-hazardous areas or areas which are oxygenated.
- Only use original accessories and original spare parts from ATMOS.

Only a fully functional product meets the safety requirements of users, patients and third parties. Please read the following instructions carefully:

2.3 Damage to the device

ATMOS TEOAE + DPOAE 31: Always slide the ear tip straight onto the probe and pull the ear tip straight from the probe. In doing so never twist the ear plug. The probe tip could be damaged.

ATMOS Sono 31: Use the ultrasonic probe very carefully. Avoid any vibration, blows, impacts or other mechanical effects. Otherwise the ultrasound probe could be damaged

Please observe the ambient conditions regarding transport, storage and operation.

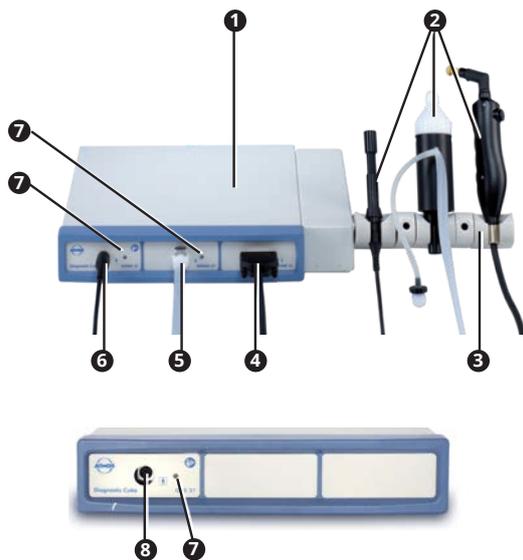
Take care that no liquid penetrates the device. If liquid has penetrated the device it may no longer be operated. In this case, clean and disinfect the device and send it to ATMOS for repair.

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

3 Setting up and starting up

3.1 Device overview

Front view



- ❶ Diagnostic Cube
- ❷ Probes
- ❸ Probe holder or iHandle
- ❹ Connection for the ATMOS Tymp 31 probe
- ❺ Connection for the ATMOS Rhino 31 probe
- ❻ Connection for the ATMOS Sono 31 probe
- ❼ LED status
- ❽ Connection for the ATMOS TEOAE + DPOAE 31 probe

☞ Only connect the probes provided.

Rear view



- ❶ Connection power supply unit
- ❷ Connection PC (USB 2.0)
- ❸ Date for the next safety-related check. The punchings indicate the date.
- ❹ Connection foot switch (USB 2.0)
- ❺ Connection contralateral head-phone (jack socket)

3.2 Minimum requirements for the hardware

⚠ WARNING

Inappropriate hardware

The patient cannot be examined and treated.

- Observe the minimum requirements for the hardware.

☞ As a user of the software you are responsible for the data backup.

Operating system	Windows 10 (64 bit)
Free hard-drive capacity:	1 GB.
CPU performance	min. 1 GHz
Available RAM	1 GB RAM for Rhino 31, Sono 31, Tymp 31 4 GB RAM for TEOAE + DPOAE 31

Graphic resolution	min. 800 x 600 for Rhino 31, Sono 31, Tymp 31 min. 1024 x 800 for TEOAE + DPOAE 31
Connections	min. 2 x USB 2.0 (Diagnostic Cube, iHandle), optionally other USB connections for printer and connection to the network

3.3 Preparing the device

Prior to first operation peruse the safety notes in chapter „2 Hints for your safety“ on page 13.

i Damaged device due to cold transport temperatures.

1. In case the device was transported at temperatures below 0 °C: let the device stand at room temperature for at least 6 hours before proceeding with the next steps.
2. Check the device for any damage in transport. If the device is damaged: Document and report the transport damage. Send the device to ATMOS (Chapter „6.3 Sending in the device“ on page 41).

⚠ Injuries and allergic reaction due to contamination and production residue.

3. Prior to first use, clean the device. Observe chapter „5 Cleaning and disinfection“ on page 54.

i Damaged electronics due to incorrect mains voltage or mains frequency.

4. Check whether mains voltage and frequency of the device match with voltage and frequency of the supply network. The device data are on the type plate.
5. Place the device on a safe and even surface.
6. Connect the probes:

- ATMOS Rhino 31:

⚠ Incorrect measurement due to a leaky connector. Check that the sealing rings are available on the connector and are undamaged. Press down the metal lever on the jack and connect the probe. The connector engages.



- ATMOS Sono 31: Connect the probe and turn the connector to the right as far as it will go. The connector engages.



- ATMOS Tymp 31: Connect the probe and tighten the screw.



- ATMOS TEOAE + DPOAE 31: connect the probe.



7. Gently pull the connector and check if it is still loose.
8. Connect the foot switch on the rear side to the USB-A-connection or to a PC.
- ☞ The device must **not yet** be connected to the PC.
9. Connect the device to the mains supply.

3.4 Installing and connecting the iHandle

Only persons who have the necessary knowledge and are familiar with the product may install the iHandle. On request a detailed installation plan is available.



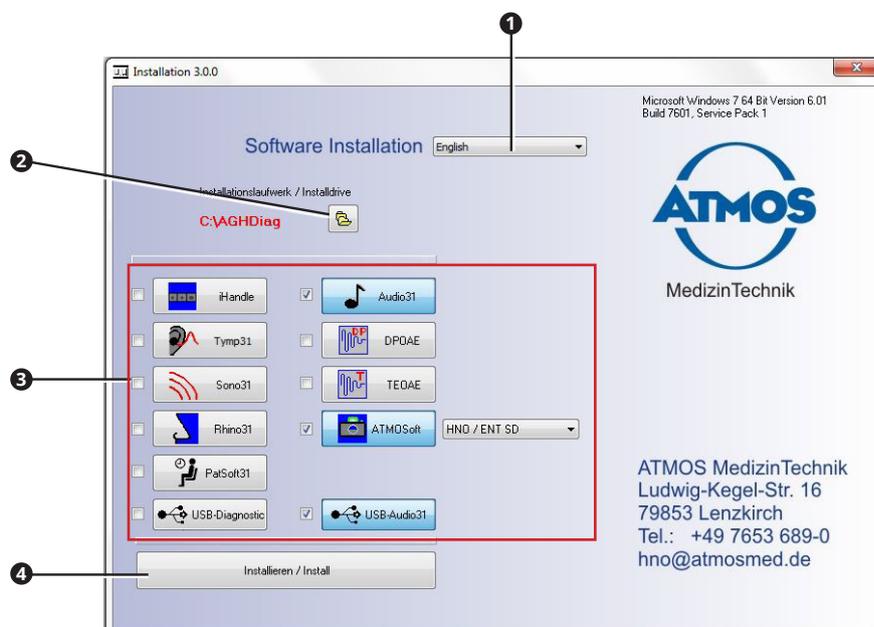
The iHandle is connected to the PC via the USB connection ❶.

- ☞ The sequential order of the measuring probes on the iHandle must correspond to the sequential order of the connections on the ATMOS Diagnostic Cube.

3.5 Installing the software

Only persons who have the necessary knowledge and are familiar with the product may install and configure the ATMOS software. On request a detailed installation plan is available. ATMOS recommends: work should be carried out by an authorised ATMOS service partner. This will ensure that the software is installed and configured properly.

- ☞ You will require administration rights in order to install the software on your computer.
 - ☞ The hardware must not be connected.
1. Check whether your computer meets the system requirements.
 2. Insert the supplied CD into the computer.
 3. Right click on the file INSTALL.EXE and select the menu item RUN AS ADMINISTRATOR .
 4. Enter your administrator login details.
- » The software starts.



5. Set the following:
 - Language ❶
 - Installation path ❷, important for the installation of the network.
 - Software to be installed ❸

- » Depending on the software the programme automatically selects the necessary software components (driver).
- 6. Click on the button **INSTALLIEREN / INSTALL** ④.
- » The software will be installed. The current status is displayed below on the left .
- » As soon as the installation is complete the message **INSTALLATION COMPLETE** appears below on the left.

Possible problems during the installation

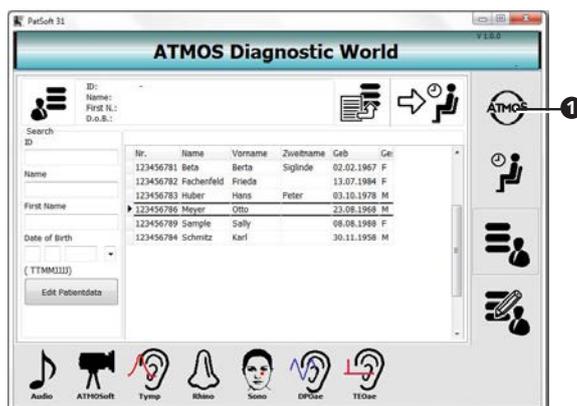
Problem	Possible cause	Remedy
Message START AS ADMINISTRATOR appears.	Installation was not started as administrator.	7. Shut down the software. 8. Right click on the file INSTALL.EXE and select the menu item RUN AS ADMINISTRATOR . 9. Enter your administrator login details
Button INSTALLIEREN / INSTALL not available.	No software selected.	1. Select which software should be installed.
	Installation was not started as administrator.	1. Close the software. 2. Right click on the file INSTALL.EXE and select the menu item RUN AS ADMINISTRATOR . 3. Enter your administrator login details

3.6 Installation of the ATMOS PatSoft 31

- » As soon as you exit the section **OPTIONS**, you will be asked if you want to save the settings. Click the button **Yes**, to save the settings or the button **No**, not to save the settings.

3.6.1 Call up **OPTIONS**

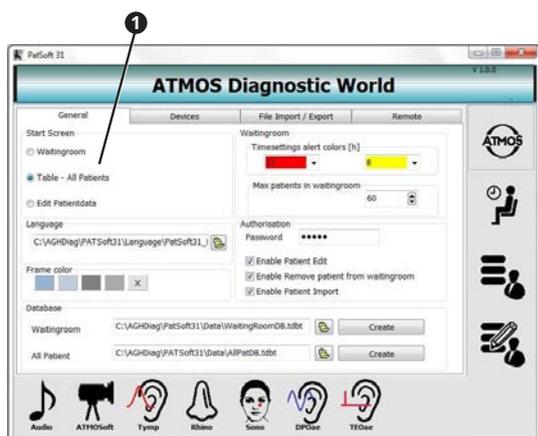
1. Start the PatSoft 31.
2. Click the button **ATMOS** ①, above on the right.



- » The section **OPTIONS** is opened.

3.6.2 Select the start window

After opening the PatSoft 31 you can select which section should be displayed.

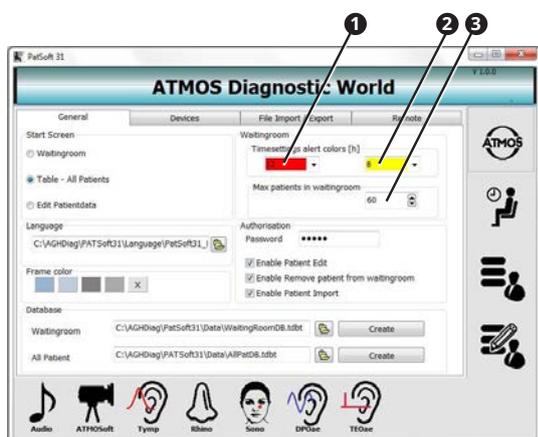


1. Go to the section OPTIONS.
2. Click on the tab GENERAL.
3. Select in this section the requested start screen under START SCREEN ❶.

Depending on the workplace situation ATMOS recommends you to select the following start window:

Reception	• TABLE - ALL PATIENTS
Treatment room	• WAITINGROOM

3.6.3 Setting the section WAITINGROOM



1. Go to the section OPTIONS.
2. Click on the tab GENERAL.

Patient data can be highlighted in colour

3. Select from the left choice box ❶ in the section TIMESETTINGS ALERT COLORS, after how many hours the patient data in the section waitingroom should be highlighted in red.
4. Select from the right choice box ❷ in the section TIMESETTINGS ALERT COLORS, after how many hours the patient data in the section waitingroom should be highlighted in yellow.

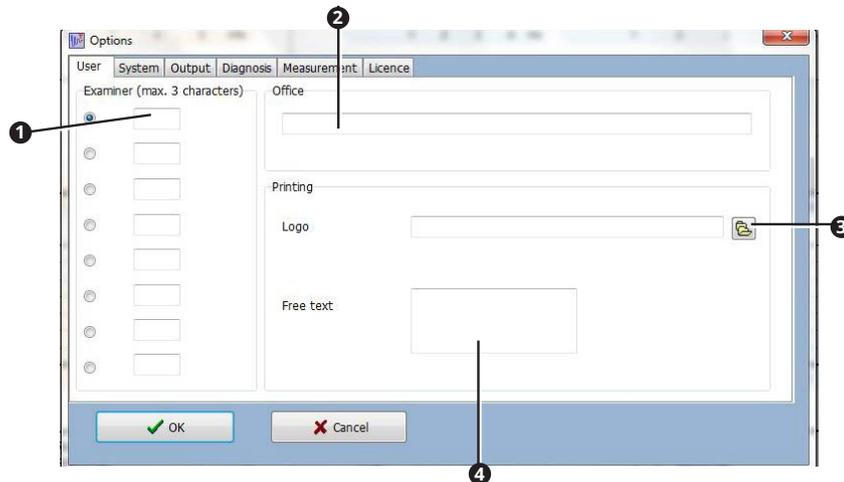
Maximum amount of patient data

5. Select in the text field MAXIMUM PATIENTS IN WAITINGROOM ❸ how many patient data may be in the section waitingroom.

3.7 Installation of the diagnostic software

3.7.1 User and practice data

1. Open the window OPTIONS.



2. Enter the user initials ①. This is represented in the main window for selection.
 - ☞ The user who is selected is, by default, displayed in the main window as the examiner.
3. Enter the practice name ②.
4. If required select the practice logo ③.
5. Enter the practice address ④.
 - ☞ The practice information appears on the printout.
6. Click the button OK.
 - » The entries are saved.
 - » The window is closed.

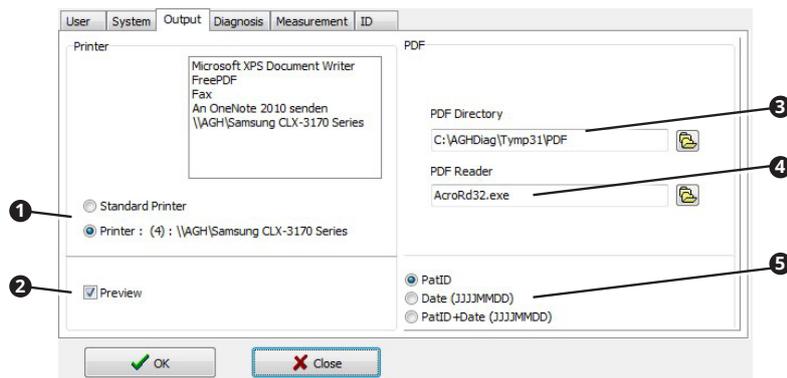
3.7.2 Setting up the printer and PDF output

- ☞ In each diagnosis software the printer and PDF output must be set individually.

1. Click on the button in the main window OPTIONS ①.



- » The window OPTIONS is opened.
 - ☞ The menu bar is slightly different in the individual diagnostic software. In some of the software the button SETTINGS is used to open the window OPTIONS.
2. Select the tab OUTPUT.



3. Select in the section PRINTER ❶, which printer should be used: Select the Windows standard printer or a printer, which you have marked above.
4. If you wish to have a print preview prior to every printing, activate the check box PREVIEW ❷.
5. State the directory in which PDF files should be saved ❸.
6. Select the programme with which PDF files should be displayed ❹.
7. Select how the PDF file name should be composed of ❺.

4 Operation

WARNING

Electric shock

Burns and cardiac arrhythmia and even death are possible.

- Check before each use if the device, power supply unit or the power cord are damaged.
- If the device shows any obvious safety defects, clean and disinfect the device and send it to ATMOS for repair. Never operate the unit, if it shows any obvious safety defects.

4.1 Ambient conditions during operation

- Temperature: +10...+32 °C
- Relative air humidity: 20...80% without condensation
- Air pressure: 700...1060 hPa

4.2 Starting the diagnostic software

Depending on whether the diagnostic software is integrated to an existing patient software or whether the iHandle is connected to your PC, the software can be started in various ways.

- ☞ If the software PATSOFT 31 was installed, the diagnostic software must be started from the PATSOFT 31 software.
- ☞ Prior to each use a function check has to be performed.
- 1. Start the software over one of the following possibilities:
 - Over an icon or a key combination in the integrated patient software.
 - Over an icon on the desktop.
 - Over the Windows Menu **START - ALL PROGRAMMES**.
 - By removing the probe on the iHandle.
- » The software is started.
- ☞ You may operate the software via a touch screen, keyboard or mouse.

4.3 Exit the diagnostic software

1. Click on the button **EXIT** above right (red X).
 - » The diagnostic software is closed.
 - ☞ You may also use the button **CLOSE**.

4.4 Patient management with the ATMOS PatSoft 31

4.4.1 Starting the ATMOS PatSoft 31

- ☞ The PatSoft 31 automatically starts during boot up. If need be you can also start the PatSoft 31 over an icon on the desktop.
- 1. Start the PatSoft 31 over the Windows menu **START - ALL PROGRAMMES**.
 - » The PatSoft 31 is started.

4.4.2 Exit the ATMOS PatSoft 31

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

4.4.3 Recommended procedure at workplaces

ATMOS recommends that at the workplace reception the patient data are imported, created, processed, searched and stored in the waiting room.

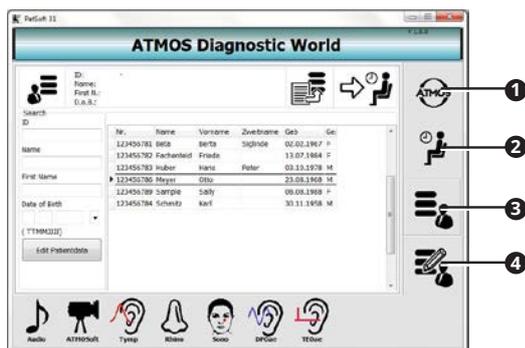
At the workplace treatment room the patient data should be called up from the waiting room and the diagnostic software started. After treatment the patient data can be removed from the waiting room.

4.4.4 Go to a section

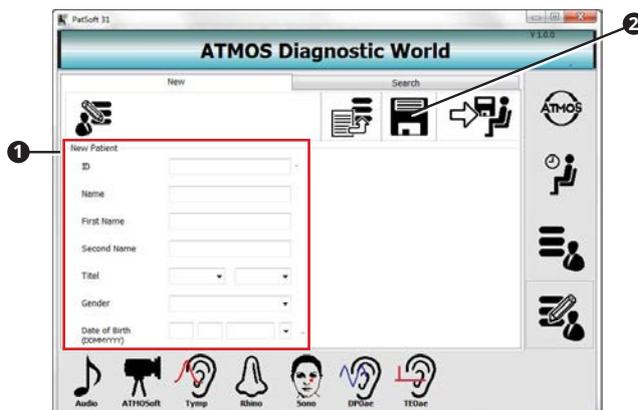
The software is divided into four sections:

- OPTIONS **1**: Settings
- WAITING ROOM **2**: Waiting area for patient data
- TABLE - ALL PATIENTS **3**: All patient data
- PATIENT DATA - EDIT **4**: Processing the patient data

1. Click on the respective button in order to enter a section.

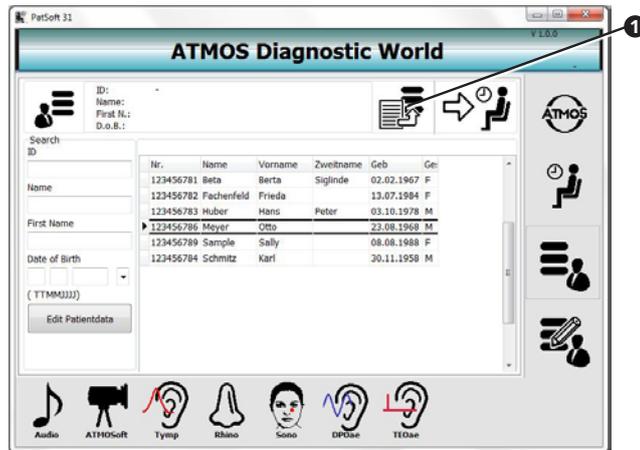


4.4.5 Creating a patient



1. Go to the section EDIT PATIENTDATA.
2. Go to the tab New.
3. Go to the section NEW PATIENT **1** and enter the patient data.
4. Save the data by clicking on the button SAVE **2**.

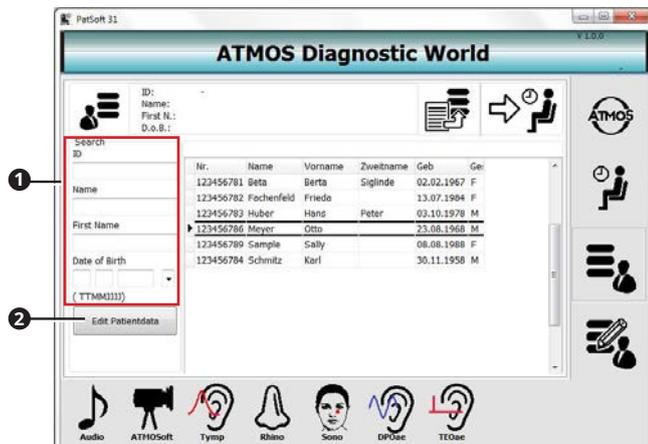
4.4.6 Importing patient data manually



1. Go to the section TABLE - ALL PATIENTS or in the section EDIT PATIENTDATA.
 2. Click on the button IMPORT ①.
- » The patient data will be updated.

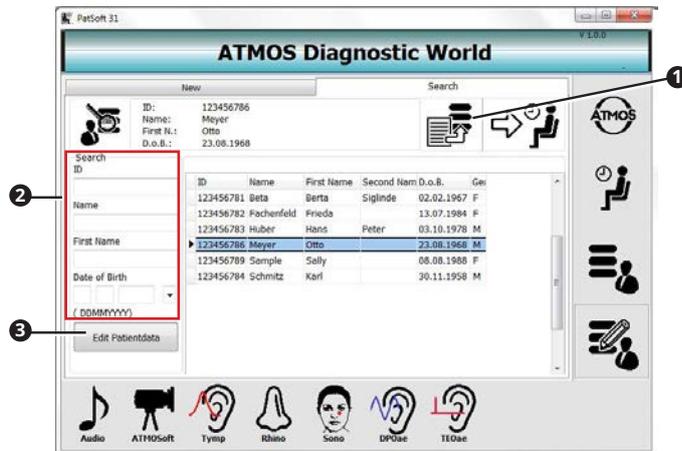
4.4.7 Searching patient data

In the section TABLE - ALL PATIENTS



1. Go to the section TABLE - ALL PATIENTS.
 2. Enter in the section SEARCH ① the patient data which you are searching for.
- » As soon as you enter the first character, a corresponding hit will be highlighted in the chart.
- » If you want to edit the patient data, click on the button EDIT PATIENTDATA ②.

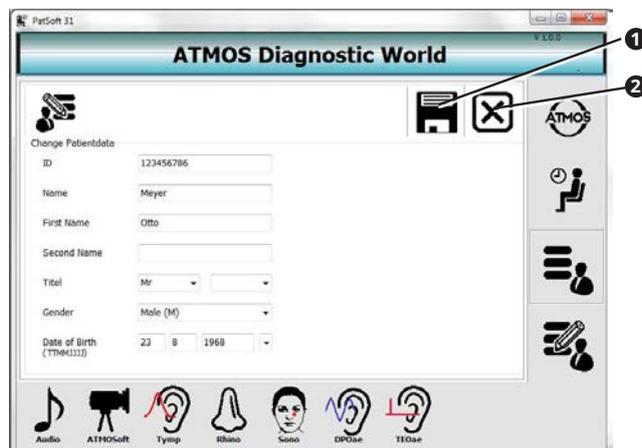
In the section EDIT PATIENTDATA



1. Go to the section EDIT PATIENTDATA.
2. Go to the tab SEARCH ①.
3. Enter in the section SEARCH ② the patient data which you are searching for.
 - » As soon as you enter the first character, a corresponding hit will be highlighted in the chart.
- ☞ If you want to edit the patient data, click on the button EDIT PATIENTDATA ③.

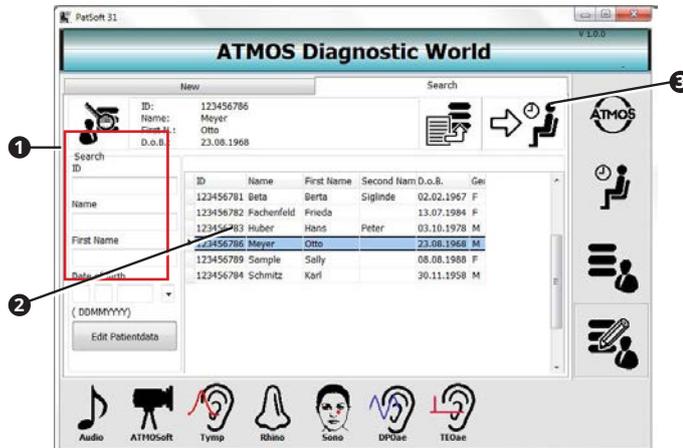
4.4.8 Editing patient data

1. Go to the section TABLE - ALL PATIENTS or in the section EDIT PATIENTDATA.
2. Click on the button EDIT PATIENTDATA.
 - » The view CHANGE PATIENTDATA is displayed.



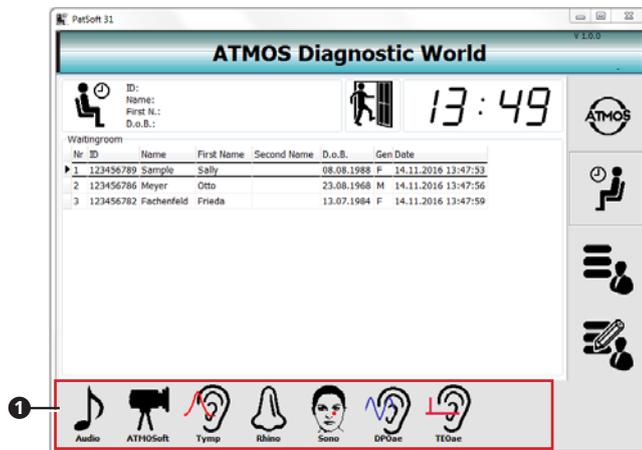
3. Change the patient data.
4. Click on the button SAVE ①, to save changes.
 - ☞ If you do not wish to save the data, click on the button ABORT ②.

4.4.9 Place the patient data in the section WAITINGROOM



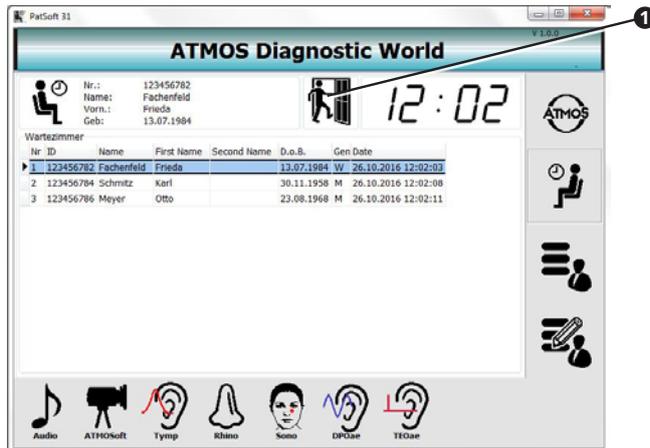
1. Go to the section TABLE - ALL PATIENTS or in the section EDIT PATIENTDATA.
 2. Look for the patient data in the section search ❶.
 3. Double click on the desired patient data ❷.
 4. Click on the button ADD TO WAITINGROOM ❸.
- » The patient data is available in the section WAITINGROOM .

4.4.10 Calling up the diagnostic software



- ☞ You can call up the diagnostic software from every section. For the examination we recommend to start the diagnostic software from the section WAITINGROOM .
1. Go to the section WAITINGROOM.
 2. Double click on the patient data of the current patient.
 3. Click on the diagnostic software Date button ❶, which you want to use.
- » The diagnostic software is started.
- ☞ The patient data is automatically adopted.

4.4.11 Remove the patient data from the waitingroom



1. Double click on the desired patient data .
 2. Click on the button REMOVE FROM THE WAITING ROOM.
- » The patient data is deleted from the section WAITING ROOM .

4.5 Patient management with the diagnostic software

- ⚠ Please note: If you are only going to document the measurements electronically, then they be saved, patient related. The data are subject to the obligation to backup data as proof for the health insurance.

If the diagnostic software is not integrated to the patient software, then the patient data must be managed over the diagnostic software.

If the diagnostic software is integrated into another patient software, then the patient management of the diagnostic software is deactivated.

4.5.1 Open the patient management

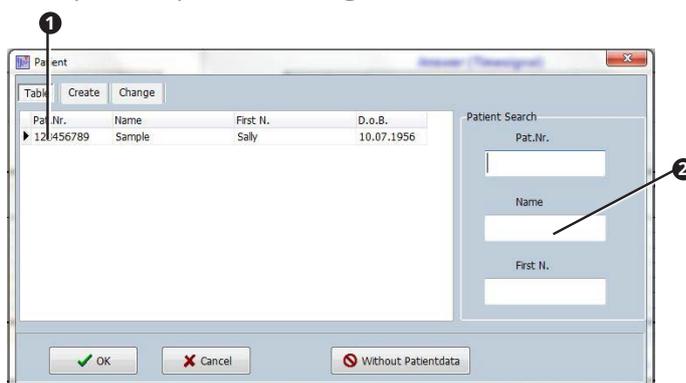
1. Click on the button PATIENT **1** in the main window .



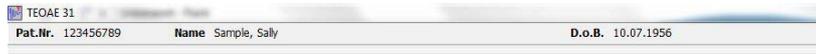
- » The patient management is opened.
- ⚠ The menu bar is slightly different in the individual diagnostic software.

4.5.2 Selecting a patient

1. Open the patient management.

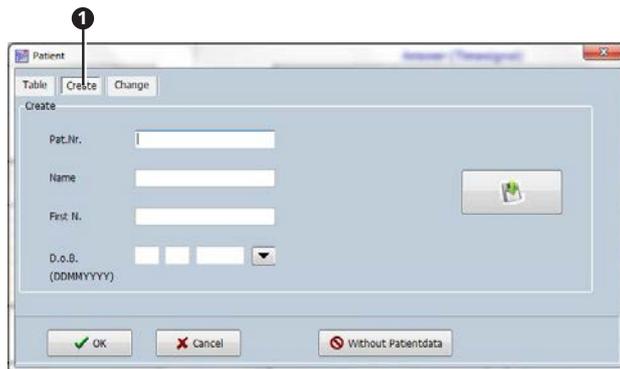


2. Select the patient from the table **1** or enter the surname in the field NAME **2**.
3. Click the button OK.
- » The patient data appear in the main window.

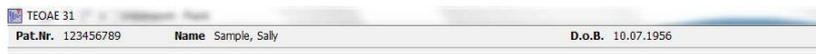


4.5.3 Creating a new patient

1. Open the patient management.
2. Click on the tab NEW **1**.



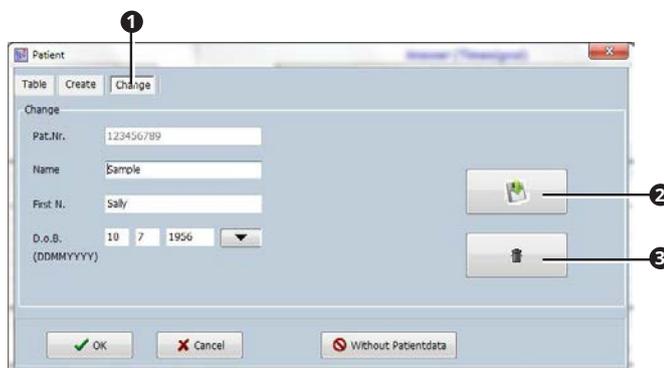
3. Enter the patient number, surname, first name and date of birth. Only the patient number is mandatory.
4. Click the button OK.
- » The patient data appears in the main window.



4.5.4 Changing or deleting a patient

⚠ The patient number cannot be changed.

1. Open the patient management.
2. Select the patient.
3. Click on the tab CHANGE **1**.



4. Change the patient data.
5. Click on the button SAVE **2**, to save the changes.
6. If you want to delete the patient data, click on the BUTTON Delete **3**.

4.6 Setting the standard values

☞ The standard values must be individually set in every diagnostic software.

4.6.1 Open the window OPTIONS

1. Click on the button in the main window OPTIONS **1**.



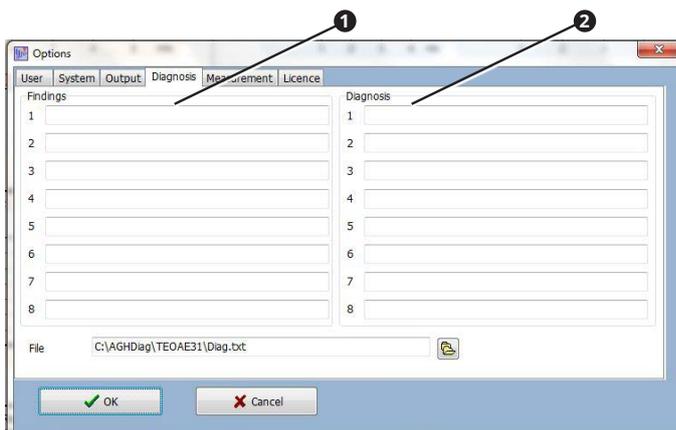
» The window OPTIONS is opened.

☞ The menu bar is slightly different in the individual diagnostic software. In some of the software the button SETTINGS is used to open the window OPTIONS.

4.6.2 Diagnosis texts and findings texts

Texts which you create here are available as comments to the measurements, see chapter „4.11.1 Comments“ on page 51.

1. Open the window OPTIONS.
2. Select the tab DIAGNOSIS.

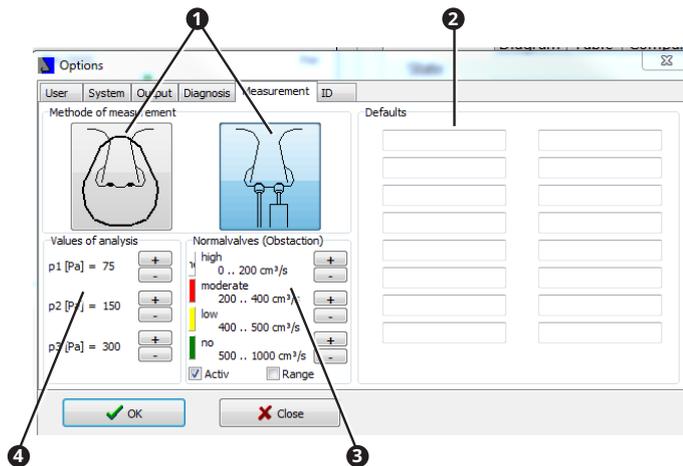


3. Enter the texts for findings **1** and diagnosis **2** which should be available to you for selection.
4. Click the button OK.
 - » The entries are saved.
 - » The window is closed.

4.6.3 Measurement

ATMOS Rhino 31

1. Open the window OPTIONS.
2. Select the tab MEASUREMENT.

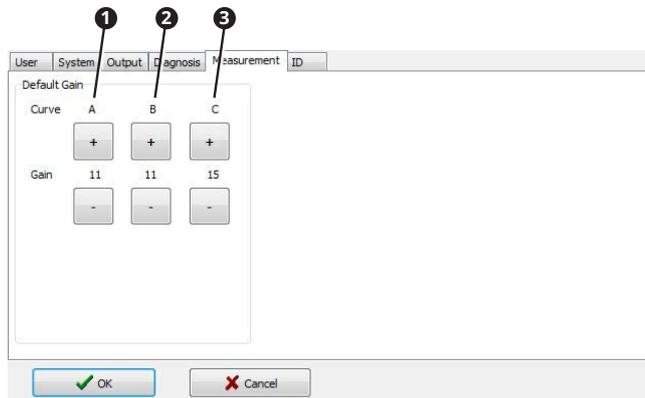


- ❶ Type of probes used.
- ❷ Descriptions of examinations.
- ❸ Classification of the measuring values.
- ❹ Print parameters for evaluation.

3. Enter the values which should be selected by default for a new measurement.
4. Click the button OK.
 - » The entries are saved.
 - » The window shuts down.

ATMOS Sono 31

1. Open the window OPTIONS.
2. Select the tab MEASUREMENT.

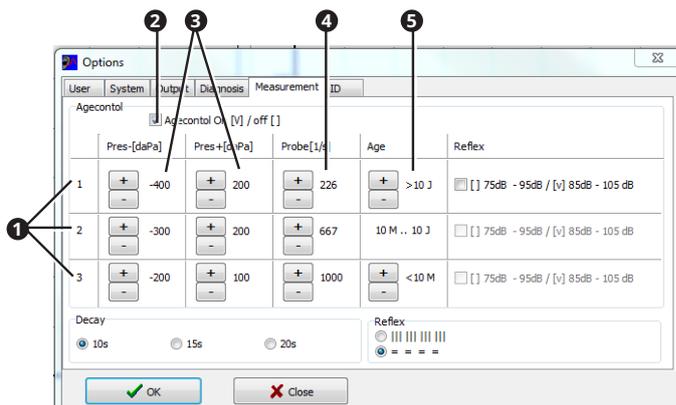


- ❶ Gain curve A: Depth regulation for a maxillary examination.
- ❷ Gain curve B: Depth regulation for a frontal examination.
- ❸ Gain curve C: Centre amplification for cysts, inclusions (bell-shaped curve).

3. Enter the values which should be selected by default for a new measurement.
4. Click the button OK.
 - » The entries are saved.
 - » The window shuts down.

ATMOS Tymp 31

1. Open the window OPTIONS.
2. Select the tab MEASUREMENT.

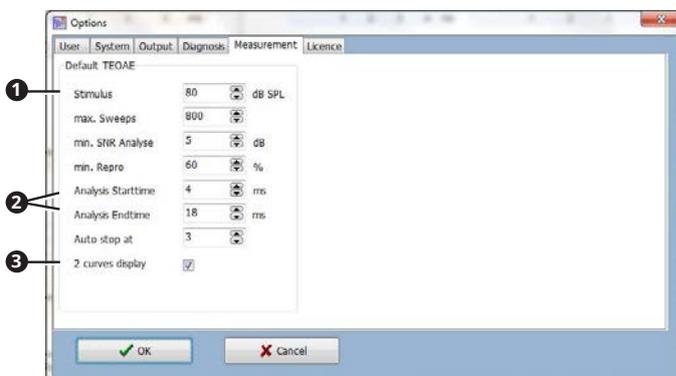


- 1 Age groups
 - 1: Upper age group
 - 2 Middle age group
 - 3: Lower age group
- 2 Activating and deactivating the age control
- 3 Printing per age group
- 4 Probe frequency per age group
- 5 Age per age group

- ☞ If the age control is deactivated the values from the upper age group are used.
- 3. Enter the values which should be selected by default for a new measurement.
- 4. Click the button OK.
- » The entries are saved.
- » The window shuts down.

ATMOS TEOAE 31

1. Open the window OPTIONS.
2. Select the tab MEASUREMENT.

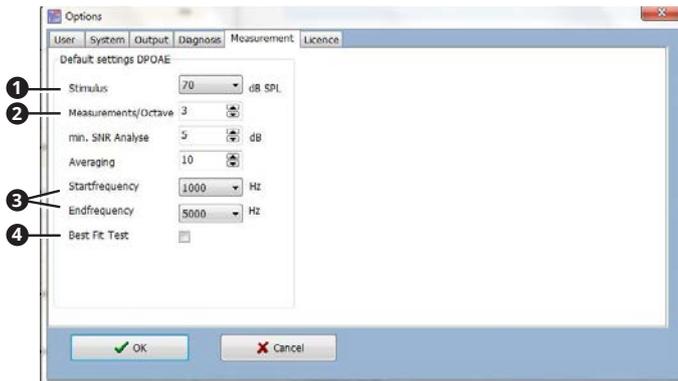


- 1 Stimulus: Volume
- 2 Start and End of the analysis
- 3 Illustrated as 2 curves

3. Enter the values which should be selected by default for a new measurement.
4. Click the button OK.
- » The entries are saved.
- » The window shuts down.

ATMOS DPOAE 31

1. Open the window OPTIONS.
2. Select the tab MEASUREMENT.

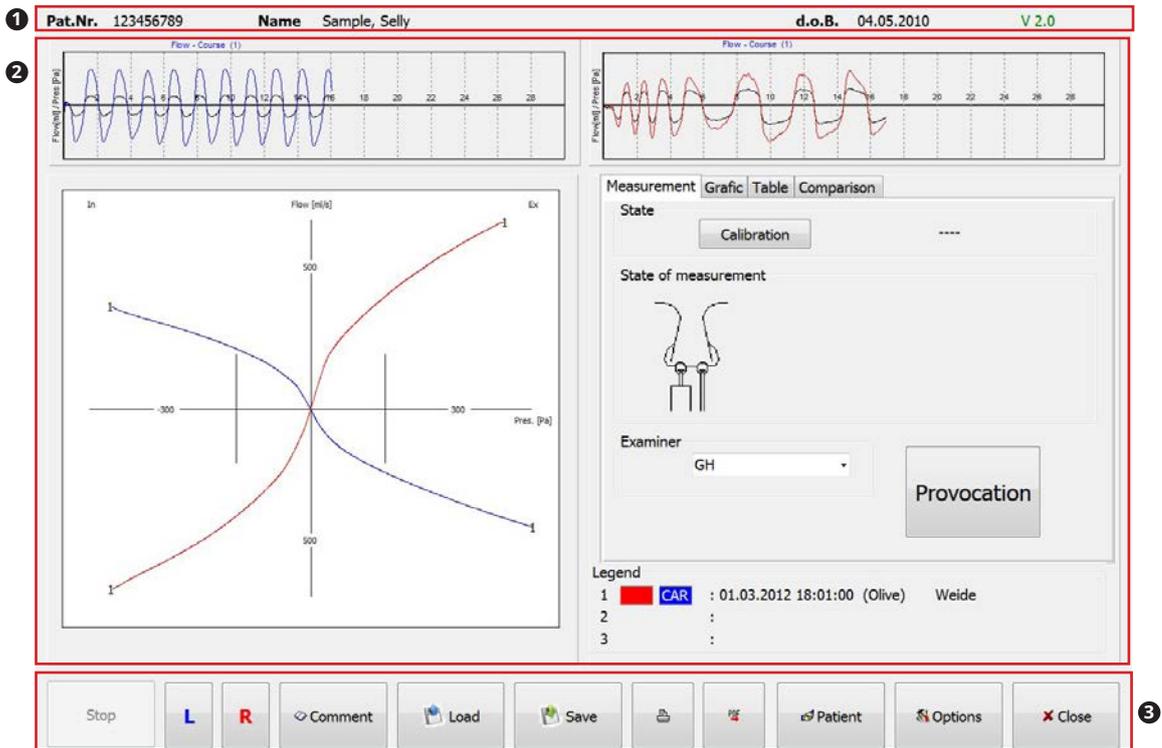


- ❶ Stimulus: Volume
- ❷ Amount of measurements per octave
- ❸ Start and End of the analysis
- ❹ Activate / deactivate best-fit-test

- 3. Enter the values which should be selected by default for a new measurement.
- 4. Click the button OK.
 - » The entries are saved.
 - » The window shuts down.

4.7 ATMOS Rhino 31

4.7.1 Software overview



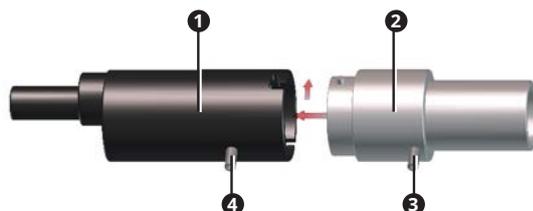
- ❶ Patient data
- ❷ Display of the measurement data
- ❸ Operation

	Start measurement.		Save measurement.
	Cancel measurement.		Print measurement.
	Select right nostril.		Save measurement as a PDF.

	Select left nostril.	 Patient	Start patient management.
	Enter a comment regarding the measurement.	 Options	Set up the software.
	Load the measurement.	 Close	Close the programme.

4.7.2 Function check

Prior to each use a function check has to be performed.



1. Insert a filter plate. The filter plate must be inserted no deeper than to the sealing ring.
2. Affix the test piece **2** onto the handle **1**.
3. Affix the measuring hose to the connection **3**.
4. Affix the connection hose to the connection **4**.
5. Start a measurement for the **right** side and breathe in and out of the test piece with your mouth.
6. Stop the measurement.
7. Start a measurement for the **left** side and breathe in and out of the test piece with your mouth.
8. Stop the measurement.
9. Compare the illustrated curves. They must comply with the following criteria:
 - The curves are symmetrical on both sides.
 - The values in the chart are the same for both the left and right side.
 - The difference Fl. L/R must not be > 1 .
- » The function check was passed.
10. Clean and disinfect the test piece.
11. Replace the filter plate.

4.7.3 Perform the measurement

⚠ WARNING

Contaminated filter plates, nose adapter, nose olives and nose masks.

Inflammation and infections could be caused or transmitted

- Use new single use products for each patient.
- Clean and disinfect all application parts after use.

Careless handling of the application parts.

The patient's nose could be injured.

- Apply nose olives and nose adapters very carefully.
- Never insert the nose olives into the nostrils.

Incorrect measuring values as a result of unsuitable application parts.

The patient can be injured due to a wrong diagnosis and treatment.

- Select the size of the nose mask and nose olives according the patient.
- Ensure that the probe is air-tight.
- Prior to the measurement the patient must be informed regarding the measuring procedure.

- ☞ As soon as the software is started an automatic pressure balance is performed. You can repeat this by pressing the button **CALIBRATION** . This is important in the case of air pressure variations due to extreme weather conditions.

Measurement with nose olives

⚠ Injury to the patient with a device which is not ready to use.

1. Check whether the device is in good order and condition. If it is obviously defective or not ready for operation, it must not be used.
2. Start the software.
3. Select the patient, if this has not already been done.

⚠ Damage to the patient's nose due to the incorrect allocation of measurement data.

4. Check whether the correct patient is displayed in the main window.
 - ☞ The software always starts automatically with a measurement on the right side. You can change the side by clicking on the button **L** .
5. Inform the patient regarding the measurement procedure.
6. Select the size of the nose olives according to the patient. The nostril must be completely sealed so that no air can pass through the olive.
7. Hold the handle with the nose olive to the nose. Pay attention that the nose olive is held to the nostril which is to be measured. The contra olive seals the other nostril.
8. Make sure that it does not interfere with the nose form or nasal breathing.
9. The patient should breathe in and out several times so that they get used to the slightly increased breathing resistance.
10. Start the measurement by clicking on the button **START** .
 - ☞ You may also start and end the measurement with the foot switch.
11. Conduct the measurement for at least the duration of the recording of the flow-process.
12. End the measurement by clicking on the button **STOP** .
 - » The measurements are adopted in the value table.

- » The software automatically changes the side.
- 13. Hold the handle with the nose olive to the other nostril.
- 14. Make sure that it does not interfere with the nose form or nasal breathing.
- 15. The patient should breathe in and out several times so that they get used to the slightly increased breathing resistance.
- 16. Start the measurement by clicking on the button **START** .
- 17. Conduct the measurement for at least the duration of the recording of the flow-process.
- 18. End the measurement by clicking on the button **STOP** .
- » The measurements are adopted in the value table.
- 19. Click on the button **SAVE** to save changes.
- 20. Clean and disinfect the handle (spiroceptor), measuring probe and nose olives.
- 21. Replace the filter plate.

Measurement with nose mask

- ⚠ Injury to the patient with a device which is not ready to use.
 1. Check whether the device is in good order and condition. If it is obviously defective or not ready for operation, it must not be used.
 2. Start the software.
 3. Select the patient, if this has not already been done.
- ⚠ Damage to the patient's nose due to the incorrect allocation of measurement data.
 4. Check whether the correct patient is displayed in the main window.
 - ☞ The software always starts automatically with a measurement on the right side. You can change the side by clicking on the button **L** .
 5. Inform the patient regarding the measurement procedure.
 6. Select the size of the nose mask according to the patient. The nose area must be completely covered and airtight so that no air flows past the nose mask.
 7. Choose the size of the nose adapter according to the patient. The nose adapter must be easy to insert into the nostril but still close it tightly.
 8. Attach the nose adapter and nose mask. Make sure that the nose adapter seals the nostril which is not to be measured.
 9. The patient should breathe in and out several times so that he gets used to the slightly increased breathing resistance.
 10. Start the measurement by clicking on the button **START** .
 - ☞ You may also start and end the measurement by pressing the foot switch.
 11. Conduct the measurement for at least the duration of the recording of the flow-process.
 12. End the measurement by clicking on the button **STOP** .
 - » The measurements are adopted in the value table.
 - » The software automatically changes the side.
 13. Attach the nose adapter and nose mask. Make sure that the nose adapter seals the other nostril.
 14. The patient should breathe in and out several times so that they get used to the slightly increased breathing resistance.
 15. Start the measurement by clicking on the button **START** .

16. Conduct the measurement for at least the duration of the recording of the flow-process.
17. End the measurement by clicking on the button STOP .
- » The measurements are adopted in the value table.
18. Click on the button SAVE to save changes.
19. Clean and disinfect the handle (spiroceptor) and nose mask.
20. Dispose of the bacterial filter.
21. Replace the filter plate.

Provocation measurement

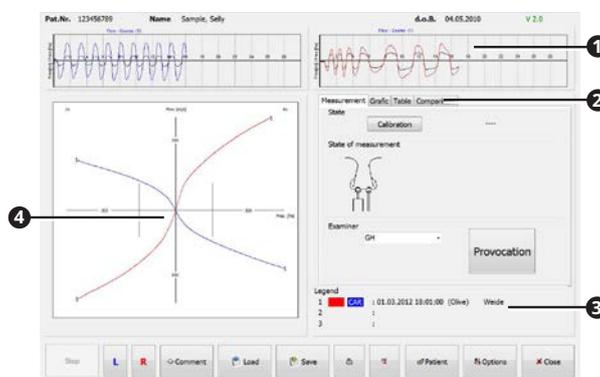
The software records the results of the provocation measurement and documents them. Observe the manufacturer's instructions for the provocation test in regard to procedure and process of the provocation.

Observe the following:

- The provocation must be active in the software.
- Each of the three measurements is saved individually.
- You can compare three measurements to one another see chapter „4.11.3 Load“ on page 51.

4.7.4 Measurement representation

You can evaluate an individual measurement or several measurements simultaneously, see chapter „4.11.3 Load“ on page 51.



- 1 Flow-process during the measurement
- 2 Different representations of the measurement results.
- 3 Date, time, type of probe and description of the examination
- 4 Real-time recording of the rhinogram and graphic illustration of the measurement.

☞ When several measuring curves are illustrated, they are listed in the legend 3 and are simultaneously illustrated in the diagram 4 .

Register TABLE

	Inspiration			Expiration			Unit
Pres.	75	150	300	75	150	300	Pa
Fl. L	135	205	300	131	197	285	ml/s
Fl. R	147	211	307	128	198	306	ml/s
Fl. L+R	282	416	607	259	395	591	ml/s
Fl. L/R	0.92	0.97	0.98	1.02	0.99	0.98	
Fl. L-R	-12.0	-6.0	-7.0	3.0	-1.0	-21.0	ml/s
Fl. inc L	52	46		50	45		%
Fl. inc R	44	45		55	55		%
Fl.L/(R+L)	48	49	49	51	50	48	%
Fl.R/(R+L)	52	51	51	49	50	52	%
Res L	1.87	2.47	3.37	1.93	2.57	3.55	
Res R	1.72	2.40	3.30	1.98	2.56	3.31	
Res L+R	0.90	1.22	1.67	0.98	1.28	1.71	

- ① Measurements:
 - ② Inspiration results at different pressure levels
 - ③ Expiration results at different pressure levels
 - ④ Pressure levels
- ☞ When several curves are illustrated, the chart shows the values of the first measuring curve according to the legend.

Display	Measuring value:
Fl. L	Flow left nostril
Fl. R	Flow right nostril
Fl. L+R	Sum of the flow of the left and right nostril
Fl. L/R	Relation between left and right nostril
Fl. L-R	Relation between left and right nostril
Fl inc L	Percentage increase of the flow value of the individual nostril from 75 to 150 Pa and 150 to 300 Pa
Fl inc R	
Fl.L/(R+L)	Relation between left flow and total flow
Fl.R/(R+L)	Relation between right flow and total flow
RES L	Resistance value of the left nostril
RES R	Resistance value of the right nostril
RES L + R	Resistance value of the left and right nostril

Register DIAGRAM

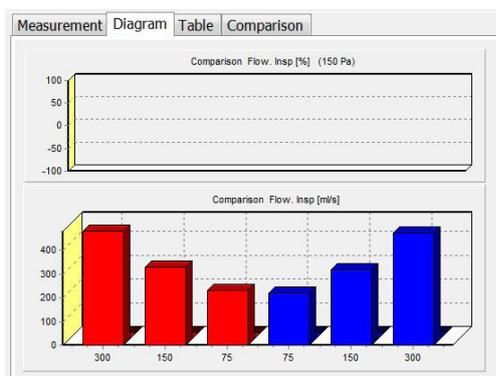


Illustration of the measuring results as a bar graph.

- ☞ When several curves are illustrated, the graph shows the measured values as well as the difference between the individual curves.

Register COMPARISON

Measurement	Inspiration			Expiration			Unit
	150 (1)	150 (2)	150 (3)	150 (1)	150 (2)	150 (3)	
Pres..							Pa
Fl. L	278	318	205	272	337	197	ml/s
Fl. R	275	324	211	276	337	198	ml/s
Fl. L+R	553	642	416	548	674	395	ml/s
Fl. L/R	1.01	0.98	0.97	0.99	1.00	0.99	
Res L	1.82	1.59	2.47	1.86	1.50	2.57	
Res R	1.84	1.56	2.40	1.83	1.50	2.56	
Res L+R	0.92	0.79	1.22	0.92	0.75	1.28	

Comparison: Fl. Insp (150 Pa)						
Dif. in	Right			Left		
	1..2	1..3	2..3	1..2	1..3	2..3
ml/s	-49	64	113	-40	73	113

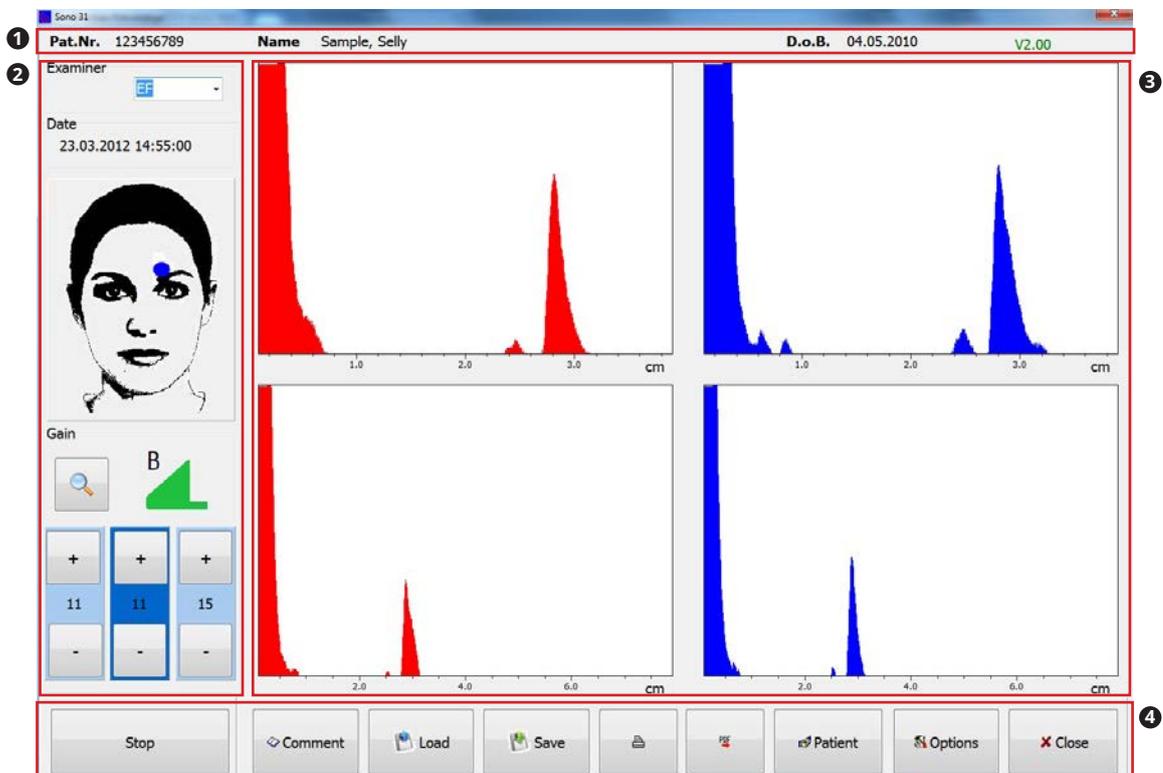
- ❶ Comparison of several measurement results: Inspiration at 150 Pa
- ❷ Comparison of several measurement results: Expiration at 150 Pa
- ❸ Pressure condition
- ❹ Ratios of measurements to one another in %.

4.7.5 Replace the filter plate

1. Remove the nose olive or the nose mask from the handle.
2. Remove the filter plate with a tweezers.
3. Insert a filter plate. The filter plate must be inserted no deeper than to the sealing ring.

4.8 ATMOS Sono 31

4.8.1 Software overview



The screenshot shows the ATMOS Sono 31 software interface. At the top, patient data is displayed: Pat.Nr. 123456789, Name Sample, Selly, D.o.B. 04.05.2010, and V2.00. Below this, there are sections for Examiner, Date (23.03.2012 14:55:00), a patient photo, Gain settings (B, 11), and a control panel with buttons for Stop, Comment, Load, Save, Patient, Options, and Close. The main area contains four plots showing measurement data for inspiration and expiration, with red and blue traces respectively. The x-axis represents distance in cm, ranging from 0 to 6.0.

- ❶ Patient data
- ❷ Settings for measuring.
- ❸ Display of the measurement data
- ❹ Operation

	Start measurement.		Print measurement.
	Cancel measurement.		Save measurement as a PDF.
	Enter a comment regarding the measurement.		Start patient management.
	Load the measurement.		Set up the software.
	Save measurement.		Close the programme.

4.8.2 Function check

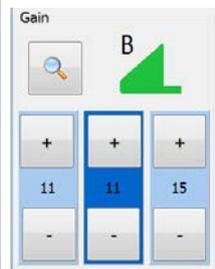
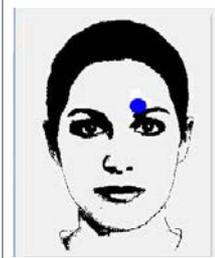
Prior to each use a function check has to be performed.



1. Start a measurement.
 2. Apply ultrasonic gel onto the ultrasonic probe.
 3. Put the test piece onto the probe.
 4. Stop the measurement.
 5. Test the illustrated curve. They must comply with the following criteria:
 - The peak of the curve must be at 2 cm.
- » The function check was passed.

4.8.3 Perform the measurement

Settings for measuring.

	<p>Set gain.</p> <p>Gain curve A: Depth regulation for a maxillary examination.</p> <p>Gain curve B: Depth regulation for a frontal examination.</p> <p>Gain curve C: Centre amplification for cysts, inclusions (bell-shaped curve).</p>		<p>Sinus to be measured.</p> <p>☞ You can set the sinus by clicking on the respective sinus.</p>
---	---	---	--

☞ By clicking on the button **MAGNIFIER** you can change the scale.

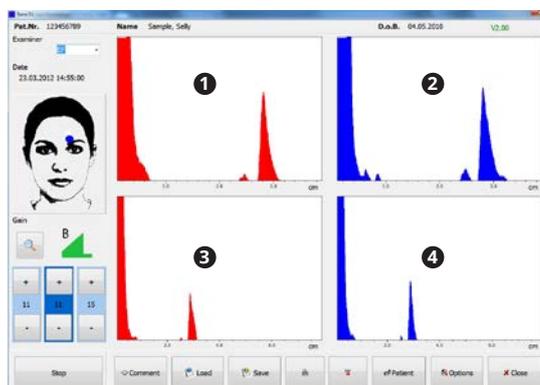
The following standard values are set:

Start measuring point:	Maxillary right
Gain factor:	12
Gain curve	A
Scaling:	Frontal: 4 cm, Maxillary: 8 cm
Magnifier:	Off

Perform the measurement

- ⚠ Injury to the patient with a device which is not ready to use.
 1. Check whether the device is in good order and condition. If it is obviously defective or not ready for operation, it must not be used.
 2. Start the software.
 3. Select the patient, if this has not already been done.
- ⚠ Injury to the patient due to the incorrect allocation of measurement data.
 4. Check whether the correct patient is displayed in the main window.
 5. Set the parameter for the measurement in the left bar of the main window.
 6. Put enough ultrasonic gel onto the ultrasonic probe, otherwise the ultrasonic waves cannot invade loss-free into the body.
- ☞ The software always starts automatically with the measurement of the right maxillary sinus. You can change the sinus by clicking on the person's face illustrated.
- 7. Put the ultrasonic probe onto the sinus.
- 8. Start the measurement by clicking on the button **START** .
 - » The measuring values are illustrated.
- ☞ You may also start the measurement by pressing the foot switch.
- 9. After the first measurement is finished place the ultrasonic probe on the next sinus.
- 10. Click on the sinus of the person's face illustrated or activate the foot switch to start the next measurement.
 - » The measurement starts immediately.
 - » The measurements are illustrated.
- 11. Perform all measurement in the same way.
- 12. Click on the button **SAVE**, to save measurements.
- 13. Clean and disinfect the ultrasonic probe.
- ☞ If you wish to repeat a measurement, select the respective sinus and click again on the button **START**.

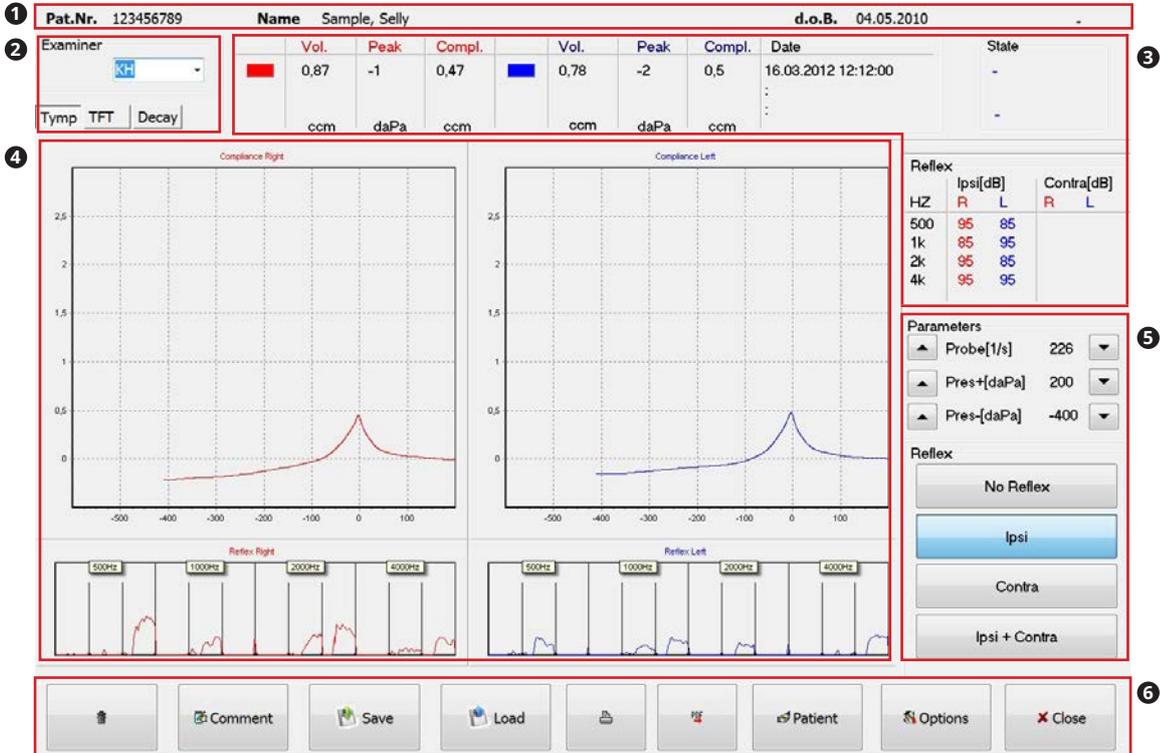
4.8.4 Illustration of the measurement



- ① Frontal right
- ② Frontal left
- ③ Maxillary right
- ④ Maxillary left

4.9 ATMOS Tymp 31

4.9.1 Software overview



The screenshot shows the ATMOS Tymp 31 software interface with the following components:

- 1 Patient data:** Pat.Nr. 123456789, Name Sample, Selly, d.o.B. 04.05.2010
- 2 Selection of measurement and examiner:** Examiner KH, Tymp TFT Decay
- 3 Display of the measuring data, numerical:**

	Vol.	Peak	Compl.	Vol.	Peak	Compl.	Date	State
Right	0.87	-1	0.47	0.78	-2	0.5	16.03.2012 12:12:00	-
Left								
- 4 Display of the measuring data, graphic:** Compliance Right, Compliance Left, Reflex Right, Reflex Left plots.
- 5 Settings for measuring:**

Reflex	
Hz	Ipsi[dB]
	R L R L
500	95 85
1k	85 95
2k	95 85
4k	95 95

Parameters	
Probe[1/s]	226
Pres+[daPa]	200
Pres-[daPa]	-400

Reflex	
No Reflex	
Ipsi	
Contra	
Ipsi + Contra	
- 6 Operation:** Comment, Save, Load, Print, Patient, Options, Close buttons.

- 1 Patient data
- 2 Selection of measurement and examiner
- 3 Display of the measuring data, numerical
- 4 Display of the measuring data, graphic
- 5 Settings for measuring
- 6 Operation

	Reset display		Save measurement as a PDF.
	Enter a comment regarding the measurement.		Start patient management.
	Load the measurement.		Set up the software.
	Save measurement.		Close the programme.
	Print measurement.		

4.9.2 Function check

Prior to each use a function check has to be performed.



1. Start the software.
 2. Hold the measuring probe to the test volume of the probe holder.
 3. Check the illustrated curve. It must comply with the following criteria:
 - The volume is 0.85 - 1 ccm.
- » The function check was passed.

4.9.3 Perform the measurement

WARNING

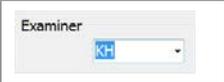
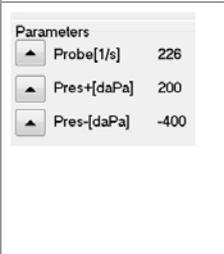
Contaminated ear plugs or pre-existing illnesses.

Inflammation, infection and injury could be caused.

- Only use ear plugs which are in a perfect hygienic condition.
- Examine the eardrum and ear canal prior to the measurement.
- Prior to the measurement remove any foreign objects, water or cerumen from the ear.
- Do **not** perform the examination if the eardrum and ear canal are infected, injured or perforated.
- Do **not** perform the examination during recovery after ear surgery.

Settings for measuring.

☞ If you wish to change the values it must be done prior to the measurement.

	Select an examiner.		Select a measurement.
	Settings for measuring. <ul style="list-style-type: none"> • Probe frequency • Pressure 		Only for tymp measurements: Method for the reflex measurement
	Only for TFT measurements: Method for the tympanometry measurement		

The following standard values are set:

Method tymp: Ipsi lateral (Ipsi)

Compliance, peak and stapedius reflex measurement

⚠ Injury to the patient with a device which is not ready to use.

1. Check whether the device is in good order and condition. If it is obviously defective or not ready for operation, it must not be used.
2. Start the software.
3. Select the patient, if this has not already been done.

⚠ Injury to the patient's ear due to the incorrect allocation of measurement data.

4. Check whether the correct patient is displayed in the main window.
5. If necessary select the measurement T_{VMP} .
6. Set the measurement in the right bar of the main window.

⚠ Injury or damage to the ear canal due to unsuitable ear plugs.

7. Select a suitable ear plug.
8. Insert the ear plug directly onto the probe.



- » As soon as the LED on the probe blinks red, the device is ready for the measurement on the right side.
9. Explain to the patient, that there could be an uncomfortable feeling in the ear during the measurement e.g. pressure, vacuum or loud tones.
 10. Insert the probe with the earplug into the patient's right ear.
 - » The measurement starts automatically.
 - » The LED on the probe is continuously red.
 - » As soon as the measurement is concluded, the LED on the probe is continuously green.
 11. Remove the probe from the ear.
 - » The measurements are illustrated.
 - ☞ When the device aborts the measurement, the LED on the probe blinks lilac. In this case the ear plug is not sealed. Try again or select another ear plug in another size.
 12. Press the button on the probe.
 - » The software switches to the left ear.
 - » As soon as the LED on the probe blinks blue, the device is ready for the measurement on the left side.
 13. Insert the probe with the earplug into the patient's left ear.
 - » The measurement starts automatically.
 - » The LED on the probe is continuously blue.
 - » As soon as the measurement is concluded, the LED on the probe is continuously green.
 14. Remove the probe from the ear.
 - » The measurements are illustrated.
 15. Remove the ear plug from the probe and dispose of it.
 16. Clean and disinfect the probe.

Eustachian tube function test (TFT)

- ⚠ Injury to the patient with a device which is not ready to use.
 1. Check whether the device is in good order and condition. If it is obviously defective or not ready for operation, it must not be used.
 2. Start the software.
 3. Select the patient, if this has not already been done.
- ⚠ Injury to the patient`s ear due to the incorrect allocation of measurement data.
 4. Check whether the correct patient is displayed in the main window.
 5. Select the measurement TFT and the method T_{YMP}.
 6. Set the measurement in the right bar of the main window.
- ⚠ Injury or damage to the ear canal due to unsuitable ear plugs.
 7. Select a suitable ear plug.
 8. Insert the ear plug directly onto the probe.
- ☞ Never twist the earplug onto the probe!

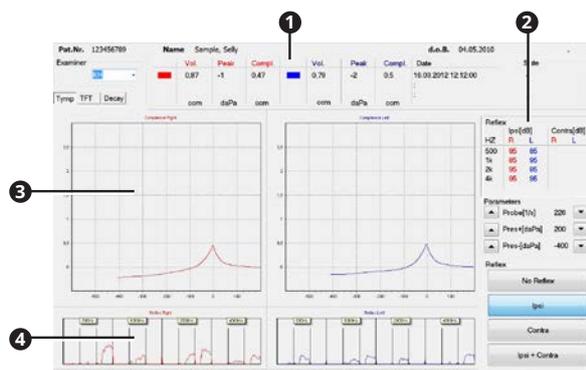


- » As soon as the LED on the probe blinks red, the device is ready for the measurement on the right side.
- 9. Insert the probe with the earplug into the patient's right ear.
 - » The tympanometry measurement starts automatically.
 - » The LED on the probe is continuously red.
 - » As soon as the measurement is concluded, the LED on the probe is continuously green.
- 10. Remove the probe from the ear.
 - » The measurements are illustrated.
- ☞ When the device aborts the measurement, the LED on the probe blinks lilac. In this case the ear plug is not sealed. Try again or select another ear plug in another size.
- 11. Select the method VALSALVA.
 - ☞ During the next measurement the patient may not swallow or move his chin.
- 12. The patient should breathe out by closing one's mouth and pinching one's nose shut, so that a positive pressure develops in the inner ear.
- 13. Insert the probe with the earplug into the patient's right ear.
 - » The measurement starts automatically.
 - » The LED on the probe is continuously red.
 - » As soon as the measurement is concluded, the LED on the probe is continuously green.
- 14. Remove the probe from the ear.
 - » The measurements are illustrated.
- 15. Select the method SWALLOW.
- 16. Allow the patient to swallow and move their chin. This supports the Eustachian tube during pressure equalization.
- 17. Insert the probe with the earplug into the patient's right ear.
 - » The measurement starts automatically.

- » The LED on the probe is continuously red.
 - » As soon as the measurement is concluded, the LED on the probe is continuously green.
18. Remove the probe from the ear.
- » The measurements are illustrated.
19. Press the button on the probe.
- » The software switches to the left ear.
 - » As soon as the LED on the probe blinks blue, the device is ready for the measurement on the left side.
20. Perform a measurement on the left ear.
21. Remove the ear plug from the probe and dispose of it.
22. Clean and disinfect the probe.

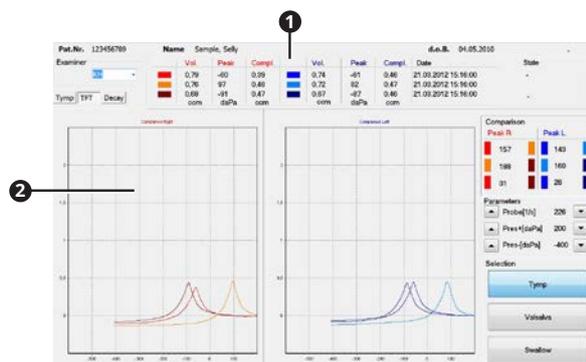
4.9.4 Illustration of the measurement

Compliance, peak and stapedius reflex measurement



- 1 Measuring values, volume, peak, compliance
- 2 Measuring values stapedius reflex measurement
- 3 Tympanogram
- 4 Stapedius reflex measurement

Eustachian tube function test

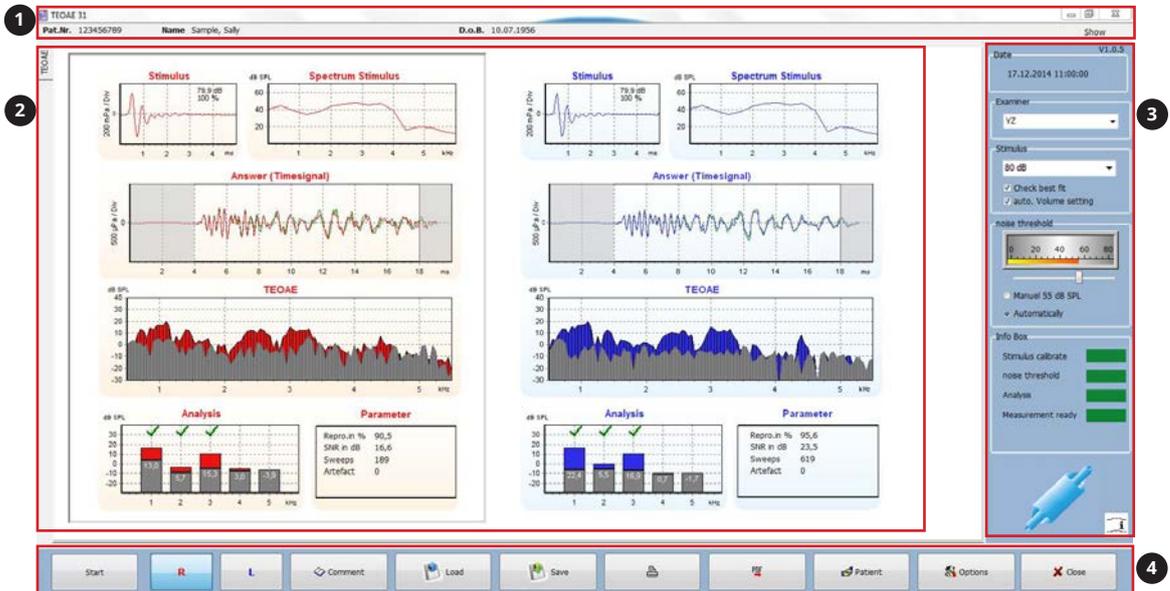


- 1 Measuring values, volume, peak, compliance
- 2 Tympanogram of the three measurements

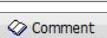
4.10 ATMOS TEOAE + DPOAE 31

4.10.1 Software overview

TEOAE

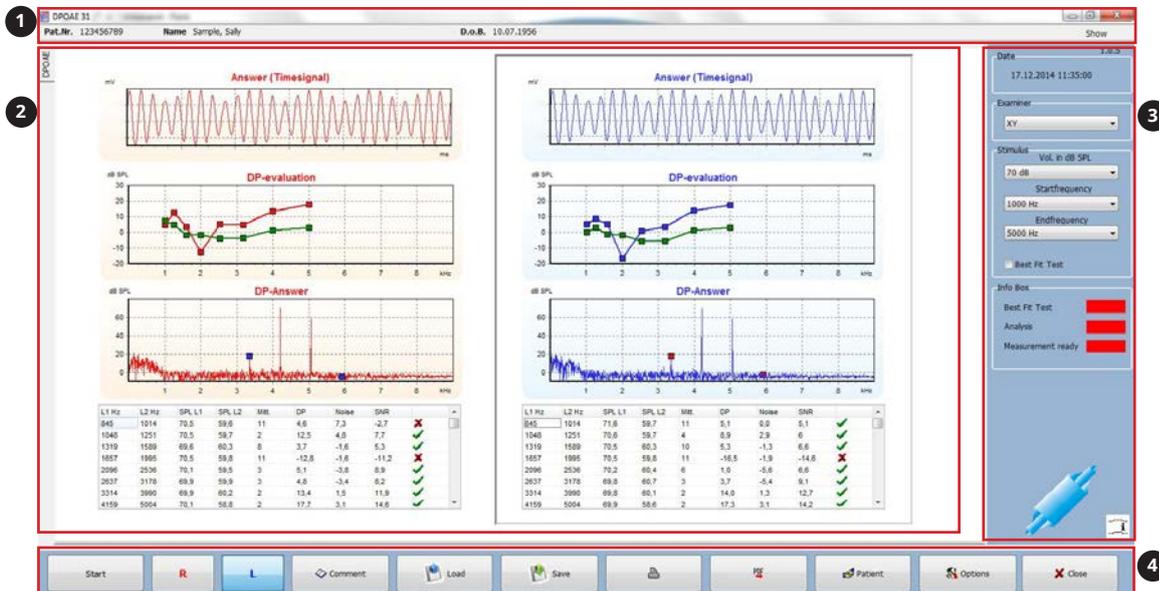


- ① Patient data
- ② Display of the measurement data
- ③ Settings for measurement and status display
- ④ Operation

	Start measurement.		Save measurement.
	Cancel measurement.		Print measurement.
	Select right ear.		Save measurement as a PDF.
	Select left ear.		Start patient management.
	Enter a comment regarding the measurement.		Set up the software.
	Load the measurement.		Close the programme.

DPOAE

You may operate the software via a touch screen, keyboard or mouse.



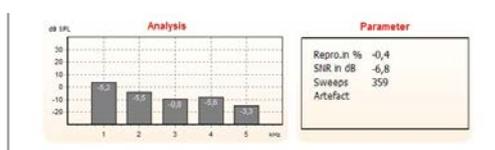
- 1 Patient data
- 2 Display of the measurement data
- 3 Settings for measurement and status display
- 4 Operation

	Start measurement.		Save measurement.
	Cancel measurement.		Print measurement.
	Select right ear.		Save measurement as a PDF.
	Select left ear.		Start patient management.
	Enter a comment regarding the measurement.		Set up the software.
	Load the measurement.		Close the programme.

4.10.2 Function check

Prior to each use a function check has to be performed.

1. Start the software TEOAE or DPOAE.
 2. Insert the probe to the probe tip.
 3. Start the measurement by clicking on the button **START**.
- After some time the device will automatically cancel the measurement.
4. Check the measurement results. The measurement results must be negative:



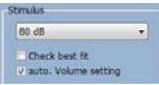
TEOAE



DPOAE

4.10.3 Perform the measurement

Settings for measuring

TEOAE		DPOAE	
	Examiner		Examiner
	Noise threshold.		Stimulus. Activate / deactivate Best-Fit-Test.
	Stimulus. Automatic volume = 80 dB. Activate / deactivate Best-Fit-Test.		

Perform the measurement

⚠ CAUTION

Contaminated ear plugs or pre-existing illnesses.

Inflammation and infections could be caused.

- Only use ear plugs which are in a perfect hygienic condition.
 - Only use ear plugs which are not damaged or worn.
 - Only perform the examination when the patient's outer ear is inconspicuous.
- ☞ OAE measurements should be performed in a quiet environment. Even moderate noise or the inherent patient noise can negatively influence a measurement.
- ⚠ Injury to the patient with a device which is not ready to use.**
1. Check whether the device is in good order and condition. If it is obviously defective or not ready for operation, it must not be used.
 2. Start the software.
 3. Select the patient, if this has not already been done.
- ⚠ Injury to the patient's ear due to the incorrect allocation of measurement data.**
4. Check whether the correct patient is displayed in the main window.
 5. Set the measurement in the right bar of the main window.
- ⚠ Injury or damage to the ear canal due to missing or unsuitable ear plugs.**
6. Select a suitable ear plug.
- ⓘ Damaged probe tip due to the incorrect attachment of the ear plug.**
7. Insert the ear plug directly onto the probe.
- ☞ Never twist the earplug onto the probe!



8. Insert the probe with the earplug into the patient's ear.
9. Select the ear in the software:
 - Button R, if the probe is in the right ear.
 - Button L, if the probe is in the left ear.
10. Click on the button **START**, to start the measurement.
 - » If the best-fit-test is activated, the probe will be tested.
 - » If the probe is intact and fitted properly the measurement will start automatically.
 - » Colour fields in the right-hand bar visualize the measuring process:
 - Green: Was carried out successfully.
 - Yellow: Is in progress.
 - Red: Has not been carried out yet.

TEOAE

Info Box	
Stimulus calibrate	Yellow
noise threshold	Red
Analysis	Red
Measurement ready	Red

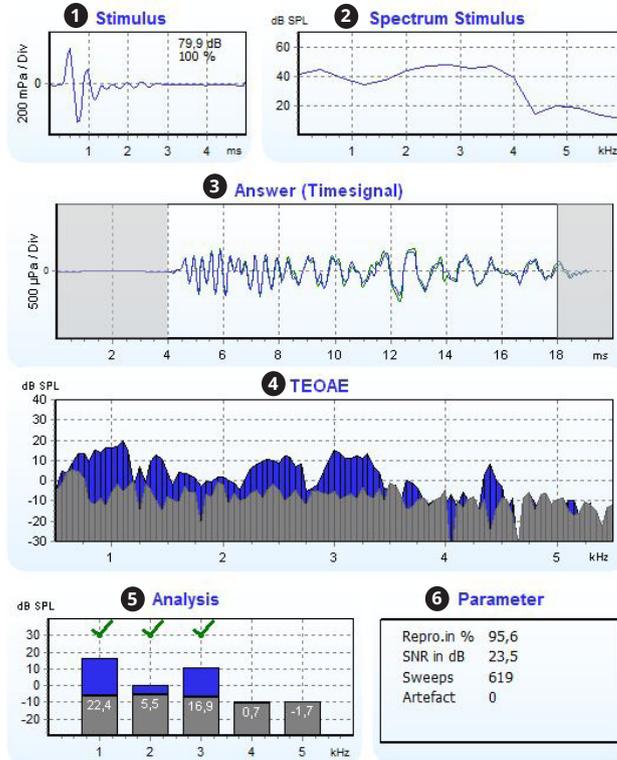
DPOAE

Info Box	
Stimulus calibrate	Yellow
noise threshold	Red
Analysis	Red
Measurement ready	Red

11. If the software indicates an error: Check the ear plug and probe.
12. To cancel the measurement press the button **STOP**.
 - » Once all the measurements are successfully carried out all the colour fields are green.

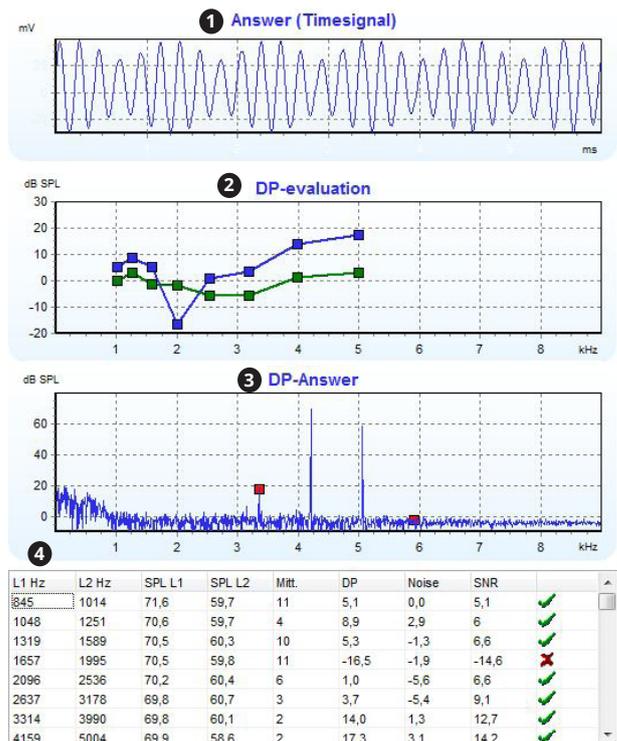
4.10.4 Illustration of the measurement

TEOAE



- 1 Stimulus within time range with display of reproducibility and volume.
- 2 Spectrum of the stimulus (probe fit).
- 3 Measurement raw data of the outer hair cells.
- 4 Display of the TEOAEs with noise component.
- 5 Evaluation of the measured data at 1-5 kHz.
- 6 Results and parameters of the measurement.

DPOAE



- 1 Measurement raw data in time domain.
- 2 DPOAEs with noise component.
- 3 Spectrum of a measurement.
- 4 Evaluation of a measurement.

4.11 Manage the measuring data

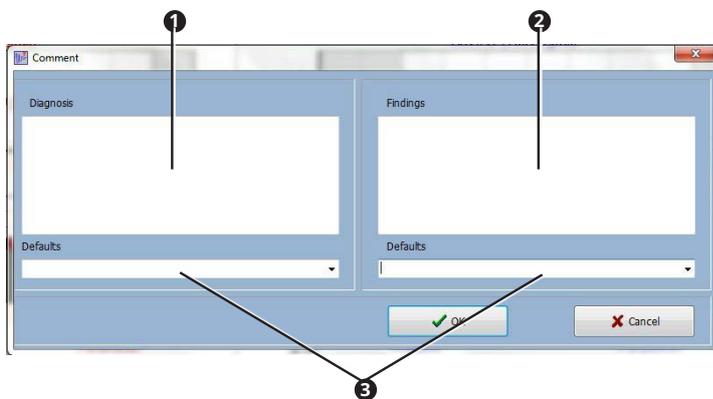
4.11.1 Comments

If you wish to comment on a measurement, you may use the preset diagnosis texts and findings texts (chapter „4.6.2 Diagnosis texts and findings texts“ on page 29) or enter an individual comment.

1. Click on the button COMMENT **1**.



- ☞ The menu bar is slightly different in the individual diagnostic software.
- » The window COMMENT is opened.



- ☞ In the text fields **DIAGNOSIS** **1** and **FINDINGS** **2** you may enter the individual comments. Via the selection fields **DEFAULTS** **3** you may select the preset diagnosis texts and findings texts.

2. Enter the diagnosis and findings:
3. Click the button OK.
- » The comments are saved.

4.11.2 Save

Measuring data may only be saved if they are allocated to a patient.

1. Click on the button SAVE **1**.



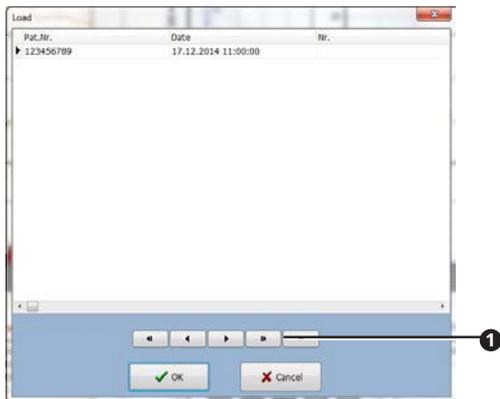
- ☞ The menu bar is slightly different in the individual diagnostic software.
- » The measurement is stored in the database.

4.11.3 Load

1. Select a patient.
2. Click the button LOAD.



- ☞ The menu bar is slightly different in the individual diagnostic software.
- » The window LOAD is opened:



- » Only measurements on the selected patient are displayed.
- 3. Navigate with the ARROW ❶ buttons.
- 4. Select the measurement by clicking on it.
- 5. Click the button OK.
- » The measurement is displayed in the main window.
- ☞ In some diagnosis software you may select several measurements simultaneously by pressing the STRG button and simultaneously clicking on the requested measurements.

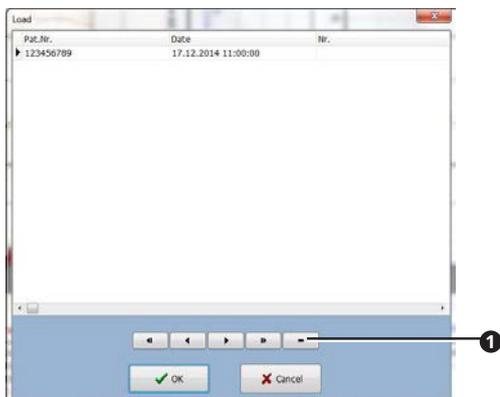
ATMOS Rhino 31 and ATMOS Tymp 31:

You may filter the type of measurement ❶.



4.11.4 Delete

1. Select a patient.
2. Load the measurement.
3. Select the measurement by clicking on it.



4. Click on the button MINUS ❶.
- ☞ In some diagnostic software a trash can be pictured instead of a minus.
5. Confirm the question with OK.
- » The measurement is deleted.

4.11.5 Export

Requirements: A PDF reader has to be installed. If PDF reader is not installed, the PDF will not be opened. An error message appears.

1. Click the button PDF **1**.



☞ The menu bar is slightly different in the individual diagnostic software.

2. The PDF is opened.
3. Save the PDF.

4.11.6 Print

Requirements: A printer has to be installed. If printer is not installed, the dialogue will not be opened. An error message appears.

1. Click the button PRINT **1**.



☞ The menu bar is slightly different in the individual diagnostic software.

2. The printer dialogue is opened.
3. Select printer settings.
4. Print the document.

5 Cleaning and disinfection

5.1 Cleaning and disinfecting

We recommend that you always document all maintenance work and exchange of parts in writing.

It is the responsibility of the operator to ensure that the required results for cleaning and disinfection are adhered to. Generally validation and routine monitoring of the procedure is necessary.

In addition to the instructions in this manual, please observe the applicable regulations for operating the device.

⚠ CAUTION

Hazardous fumes and ingredients.

Allergic or toxic diseases of the respiratory tract and skin as well as burns and irritation are possible.

- Use only approved disinfectants.
- Observe the manufacturer's usage information for each disinfectant.
- Check the cleaned objects after cleaning and disinfection to detect residues of disinfectants. Remove them if necessary.

5.1.1 Device surface

⚠ Danger to life by electric shock.

1. Disconnect the device from the mains supply prior to cleaning or disinfection.
2. Clean the device with a damp cloth. The cloth may not be wet!
3. If liquid has penetrated the device: Send in the device to ATMOS or a service partner authorized by ATMOS.

ⓘ Corrosion damage, stress cracking and discolouration caused by unsuitable disinfectants.

4. Disinfect the device with a recommended surface disinfectant.
5. Check whether there are still any residues on the unit or whether it is still dirty. Remove them if necessary.

5.1.2 Probe tip ATMOS TEOAE and DPOAE 31

☞ The probe tip consists of two parts.

ⓘ Damaged loudspeaker and damaged microphone due to the contact of the cleaning cord with the electronics of the probe.

1. Gently unscrew the probe tip from the probe.
2. Put the probe aside so that it cannot be damaged by the cleaning cord.
3. Insert the cleaning cord through the front part of the probe:



4. Reassemble the probe tip after cleaning.

5. Screw the probe tip to the probe:



5.2 Hygienic plan

Cleaning and disinfection plan ATMOS® Diagnostic Cube

	What	How		Details	When			Who
		C Cleaning	D Disinfection		After each application	Daily	Weekly	
ATMOS® Rhino 31								
	Test block	X	X	Manual cleaning and disinfection	X			Qualified and trained staff who are familiar with reprocessing. (Please fill in the responsible person -> use a water-based overhead marker)
	Measuring olive	X	X	Manual cleaning and disinfection, exchange of olives after each patient	X			
		X	X	Machine reprocessing, 93°C, with recommended agents (see below)		X		
	Pressure probe and hose		X	Manual cleaning and disinfection, exchange of olives after each patient	X			
		X	X	Machine reprocessing, 93°C, with recommended agents (see below)			X	
	Measuring probe mask	X	X	Wipe cleaning and disinfection	X			
		X	X	Machine reprocessing, 93°C, with recommended agents (see below)		X		
	Nose adapter			Single-use product	X			
	Annular diaphragm spiroceptor		X	Wipe cleaning and disinfection	X			
		X	X	Machine reprocessing, 93°C, with recommended agents (see below)			X	
	Hose system		X	Wipe cleaning and disinfection		X		
	Filter hygiene pad			Single-use product	X			
ATMOS® Sono 31								
	Ultrasonic probe	X	X	Wipe cleaning and disinfection	X			
ATMOS® Tymp 31								
	Handle	X	X	Wipe cleaning and disinfection	X			
	Ear plugs			Single-use product	X			
ATMOS® TEOAE + DPOAE 31								
	Probe tips	X		Cleaning with cleaning cord if contaminated				
	Ear plugs			Single-use product	X			

Manual cleaning and disinfection: In the case of coarse contamination, clean the cavities with a small brush. Immerse in cleaning and disinfectant solution; pay attention to the manufacturer's instructions regarding the duration of effect. Rinse with demineralised water.

Recommended disinfectants

Surface disinfection for coated surfaces:

Tested:

- Green & Clean SK (ATMOS)

Experience with:

- Dismozon® plus (Bode Chemie)
- Perform® (Schülke & Mayr)
- Terralin® Protect (Schülke & Mayr)

Other surfaces:

- Dismozon® plus (Bode Chemie)
- Bacillocid® rasant (Bode Chemie)
- Mikrobac® forte (Bode Chemie)
- Perform® (Schülke & Mayr)
- Terralin® Protect (Schülke & Mayr)
- Surface disinfectant FD 312 (Dürr Dental)
- Quick disinfection B 30 (Orochemie)

Manual disinfection of instruments:

- Korsolex® extra (Bode Chemie)
- Sekusept® aktiv (Ecolab)
- Gigasept FF neu (Schülke & Mayr)

Automatic disinfection of instruments:

- Dismoclean® 28 alka one (Bode Chemie)
- Dismoclean® twin basic/twin zyme (Bode Chemie)
- Thermostept® alka clean forte (Schülke & Mayr)
- Thermostept® RKN-zym (Schülke & Mayr)



Wrong concentration of disinfectants may lead to material damage!

For concentrations, contact time, temperature, material compatibility, please see the relevant information from the manufacturer.

The above stated hygiene requirements are based on the regulations according to the Medical Devices Act, the Medical Devices Operator Ordinance, §18 IfSG and the recommendations of the Robert Koch Institute.

Definition of the required reprocessing steps result from the recommendations of the Robert Koch Institute: „Requirements for the reprocessing of medical products“, from Robert Koch Institute. The medical products were categorised in the risk groups uncritical, semi-critical and critical. The reprocessing steps stated in this diagram have to be performed. Any additional reprocessing measures are at the operator's discretion.

All the recommended disinfectants which are stated herein are listed disinfectants (VAH/RKI) and have been tested on their suitability of use on the ATMOS® Diagnostic Cube. ATMOS MedizinTechnik cannot be held liable for any damage caused by wrong concentration of the disinfectants or by the application of any other disinfectants.

Patients with suspicion of a clinical disease or who developed a transmissible spongiform encephalopathy (CJK, vCJK, etc.) have to be treated at facilities which are able to provide for the necessary preventive measures against infection. The reprocessing of the reusable instruments and material may only be performed at facilities which have an externally certified QM Management acc. to DIN EN ISO 13485.

The Medical Devices Act, IfSG, the RKI directives, BGR 250 and TRBA 250 always have to be considered.

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5.3 Preparing and completing reprocessing

Prior to reprocessing

- Disassemble the product into the following items for reprocessing:
 - Device
 - Hoses
 - Accessories

After reprocessing

- Perform a function check.

5.3.1 Preparing surfaces

5.3.2 Overview

Surface	After each use	After each patient	Daily	Weekly	Every 14 days	Monthly	Pre-cleaning	Wipe cleaning	Wipe disinfection	Spray disinfection	Remarks
Housing	x						x		x		
Hose system			x					x			Max. reprocessing cycles

ATTENTION

Unsuitable disinfectant.

Stress cracks and corrosion damage is possible.

- Do not use disinfectants containing organic or inorganic acids or bases.
- Do not use disinfectants containing alcohol, chloramides or phenol derivatives.
- Observe the exposure times and concentration data of the disinfectant manufacturer.

5.3.3 Surface disinfectant

- ☞ If you are using aldehyde and amine-containing disinfectants on the same object, this may be discoloured.
- ☞ The surfaces of the ATMOS Diagnostic Cube can be cleaned with disinfectants which have QAC (quaternary ammonium compound) as an ingredient.

Disinfectant	Ingredients	in 100 g	Manufacturer
Green & Clean SK	Di alkyl dimethyl ammonium chloride	< 1 g	Metasys, Rum (Austria)
	Alkyl dimethyl ethyl benzyl ammonium chloride	< 1 g	
	Alkyl dimethyl benzyl ammonium chloride	< 1 g	

Disinfectant	Ingredients	in 100 g	Manufacturer
Dismozon® plus (Granulate)	magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Perform®	Potassium-bis(peroxymonosulfate)-bis(sulfate)	45 g	Schülke & Mayr, Norderstedt
Terralin® Protect (Application concentrate)	Benzyl-C12-16 alkyldimethyl-, chloride 2-phenoxyethanol aminoalkylglycine non-ionic surfactants, perfumes	22 g 17 g 0.9 g	Schülke & Mayr, Norderstedt

5.3.4 Pre-cleaning

1. Disconnect the device from the mains power supply.
2. Clean the surface evenly with a suitable cloth and clear water. Pay particular attention to hard-to-reach areas.
 - » No more residue is visible.

5.4 Reprocessing the accessories

5.4.1 Overview

Observe the hygienic plan, see chapter „5.2 Hygienic plan“.

5.4.2 Wipe disinfection

Follow the manufacturer’s instructions for the process chemical.

Pre-treating at the site of use <ul style="list-style-type: none"> • Flushing: For 60 s • Rinsing: For 60 s 	<ul style="list-style-type: none"> • Disassemble all accessories • Clean the accessories under cold, running water. • Rinse the hollow spaces and lumina of the accessories thoroughly under running water. <p>No more residue is visible.</p>
Collecting and transporting	<ul style="list-style-type: none"> • Label any damaged accessories. • Place the accessories in a canister. • Transport the canister to the reprocessing site.
Disassembly	<ul style="list-style-type: none"> • See chapter ‘5.3 Preparing / completing reprocessing’ • Dispose of disposable products
Pre-cleaning <ul style="list-style-type: none"> • Flushing: 1x/30s • Rinsing: For 60 s <p>Brush: Circular brush Size: 7 mm, Material: Nylon</p> <p>Brush: Circular brush Size: 11 mm, Material: Nylon</p> <p>Brush: Circular brush Size: 15 mm, Material: Nylon</p> <p>Brush: Angular Size: 40 x 10 mm, material: nylon, characteristics: With angled head</p>	<ul style="list-style-type: none"> • Make the following hollow spaces accessible: <ul style="list-style-type: none"> – Test block – Measuring olive – Pressure probe • Make the following lumina accessible: <ul style="list-style-type: none"> – Double hose connector • Clean the accessories evenly with a suitable brush under running water. • Rinse the hollow spaces and lumina of the accessories thoroughly under running water.

Mechanical cleaning and disinfection Pre-rinse: 1 min Clean: 5 min, 50°C / 122°F Neutralise: 2 min Intermediate rinse: 1 min Disinfect: 5 min, 93°C / 199°F Drying: 12 min, 110°C / 230°F	<ul style="list-style-type: none"> • Secure the accessories on a suitable load carrier. • Clean and disinfect using a suitable programme: <ul style="list-style-type: none"> – Pre-rinse with cold water – Cleaning with cleaning agent – Neutralise with neutralising agent – Intermediate rinse with softened, cold water – Disinfection with demineralized water – Drying • Cleaning and disinfection device: In accordance with EN ISO 15883-1 • Program: Miele Vario TD
Checking and maintaining	<ul style="list-style-type: none"> • Check whether reprocessing was successful with a suitable light magnifier. They must be free of particles and organic material. • If reprocessing was unsuccessful, reprocess the accessories again. • Dispose of damaged accessories or have them repaired.
Assembly	<ul style="list-style-type: none"> • Not necessary.
Function check	<ul style="list-style-type: none"> • Not necessary.
Packaging	<ul style="list-style-type: none"> • Label the accessories. • Pack the accessories using a packaging system according to DIN EN ISO 11607.
Sterilisation	<ul style="list-style-type: none"> • Please observe the manufacturer's operating instructions.
Storage	<ul style="list-style-type: none"> • Observe the ambient conditions, see chapter '11 Technical data'.

5.4.3 Hoses

☞ Take particular care when reprocessing hard-to-reach areas.

Pre-treating at the site of use	<ul style="list-style-type: none"> • Clean the accessories under cold, running water. • Thoroughly rinse the hollow spaces of the accessories with running water. <p>No more residue is visible.</p>
Collecting and transporting	<ul style="list-style-type: none"> • Label any damaged accessories. • Place the accessories in a canister. • Close the canister. • Transport the canister to the reprocessing site.
Pre-cleaning	<ul style="list-style-type: none"> • Clean the accessories evenly under running water. • Thoroughly rinse the lumina of the accessories with running water.
Disassembly	<ul style="list-style-type: none"> • Not necessary.

<p>Mechanical cleaning and disinfection Pre-rinse: 1 min Clean: 5 min, 55°C / 131°F Neutralise: 2 min Intermediate rinse: 1 min Disinfect: 5 min, 93°C / 199°F Drying: 12 min, 110°C / 230°F</p>	<ul style="list-style-type: none"> • Secure the accessories on a suitable load carrier. • Clean and disinfect using a suitable programme: <ul style="list-style-type: none"> – Pre-rinse with cold water – Cleaning with cleaning agent – Neutralise with cold water – Intermediate rinse with softened, cold water – Disinfection with demineralized water – Drying • Cleaning and disinfection device: In accordance with EN ISO 15883-1 • Adapter: Miele E366/E446 • Program: Miele Vario TD
<p>Checking and maintaining</p>	<ul style="list-style-type: none"> • Check whether reprocessing was successful with a suitable light magnifier. • If reprocessing was unsuccessful, reprocess the accessories again. • Dispose of damaged accessories or have them repaired.
<p>Assembly</p>	<p>Not necessary.</p>
<p>Function check</p>	<p>Not necessary.</p>
<p>Packaging</p>	<ul style="list-style-type: none"> • Label the accessories. • Pack the accessories using a packaging system according to DIN EN ISO 11607.
<p>Sterilisation Pre-fractionated vacuum: 3x Temperature: 134°C / 273°F Time: 5 min Dry: 10 min</p>	<ul style="list-style-type: none"> • Sterilise the accessories using a suitable procedure: <ul style="list-style-type: none"> – Steam sterilisation / autoclaving Steriliser: in accordance with EN 285.
<p>Storage</p>	<ul style="list-style-type: none"> • Observe the ambient conditions, see chapter '11 Technical data'.

6 Maintenance and Service

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

ATMOS recommends: work should be carried out by an authorised ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used and warranty claims remain unaffected.

6.1 Period tests

Please comply with the country-specific guidelines regarding regular testing especially for the electrical safety.

ATMOS recommends a test every 24 months.

6.2 Sending in devices

1. Remove and properly dispose of consumables.
 2. Clean and disinfect the products and accessories according to the operating instructions.
 3. Place used accessories with the device.
 4. Fill in the form QD 434 „Delivery complaint / return shipment“ and the respective **Decontamination certificate**.
- ☞ This form is enclosed to 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 form QD 434 „Delivery complaint / return shipment“ and the respective **decontamination proof** in an envelope.
 7. Stick the envelope on the outside of the package.
 8. Send the product to ATMOS or to your dealer.

7 Troubleshooting

The product was subjected to a thorough quality control in the factory. Nevertheless, if a problem should occur you can possibly solve it yourself.

Error indication	Possible cause	Remedy
Measurement does not start.	Diagnostic software is not opened.	1. Start the software.
	Power supply or mains cable are not connected properly.	1. Check the connection to the mains supply. The LED at the power supply has to be illuminated.
	The USB connection from the ATMOS Diagnostic Cube and computer is not available.	1. Check the connection between the PC and ATMOS Diagnostic Cube.
	Measuring probe is not connected properly or not connected to the right connection.	1. Check the connections of the measuring probe. The plugs may not be loose.
	USB port is switched off due to the energy saving option.	1. Supply the USB port permanently with power.
	ATMOS Tymp 31: The ear plug does not fit tightly.	1. Check the size of the ear plug and repeat the measurement.
	ATMOS Tymp 31: The probe head is aligned with the ear canal or upper auditory wall	1. Check the alignment and repeat the measurement.
ATMOS TEOAE + DPOAE: During the measurement: Error message MAXIMUM NUMBER REACHED.	Probe with earplug is not fitted properly.	1. Check the fitting and if necessary use another ear plug.
Software error message: Database error	With network connection: No connection to the network.	1. Restart the computer. Contact the network administrator if the error persists.
Measurement starts but no diagram is recorded.	ATMOS Rhino 31 ,ATMOS Tymp 31: Probe hose has insufficient connection to the measuring probe and to the Diagnostic Cube	1. Check the connections of the measuring hose.
	ATMOS Rhino 31, ATMOS Tymp 31: Measuring probe or probe hose are contaminated or blocked	1. Clean the measuring probe and the probe hose.
Measurement cannot be printed.	Incomplete measurement.	1. Complete the measurement. 2. Print the measurement.
Measurement cannot be printed (no error message)	Printer is not installed.	1. Install a printer. 2. Select in the software the printer under OPTIONS - OUTPUT.

Error indication	Possible cause	Remedy
PDF cannot be exported (no error indication).	There is no PDF reader installed or PDF reader is not recognized by the OAE software.	<ol style="list-style-type: none"> 1. Install the PDF reader. 2. Select in the OAE software the installed PDF reader under OPTIONS - OUTPUT.
Apparently the software does not respond.	Patient management window is still open and possibly in the background.	<ol style="list-style-type: none"> 3. Simultaneously press the buttons ALT and TAB and put it forward.
Software crashes.	Already opened software has been started a second time via iHandle.	<ol style="list-style-type: none"> 1. Make sure that all manually started software programmes are closed before you start the programme using the iHandle.
ATMOS Rhino 31: The measured curves are too steep	Hose connection measuring and pressure side are mixed up at the probe.	<ol style="list-style-type: none"> 1. Remove the hose from the measuring probe and change the pressure side with the measuring side.

☞ If other errors occur, then turn off the device and disconnect it from the mains supply. Contact your ATMOS service partner.

8 Accessories

8.1 ATMOS Diagnostic Cube

Article	REF
iHandle - automatic control for handle support	512.0500.0
Support arm for integration to the ATMOS S 61 Servant	512.1300.0
Support arm for integration to the ATMOS C 21/C 31/Servant 5	512.1350.0
Foot switch to control the modules Rhino 31 and Sono 31	512.0600.0

8.2 ATMOS Rhino 31

Article	REF
Measuring olive, size 3	512.1054.0
Pressure olive, size 3	512.1058.0
Measuring olive, size 2	512.1055.0
Pressure olive, size 2	512.1059.0
Measuring olive, size 1	512.1056.0
Pressure olive, size 1	512.1060.0
Nose mask, large, for adults	105.2014.5
Nose mask, small, for children	105.2012.5

8.3 ATMOS Tymp 31

Article	REF
Contralateral headphone Scope of delivery: Headphone and connection kit	512.1120.0

8.4 ATMOS TEOAE + DPOAE 31

Article	REF
Set of ear plugs with cleaning cord	On request

9 Spare parts and consumables

9.1 ATMOS Diagnostic Cube

Spare parts	REF
Power supply unit GTM91099-6015-3.0-T2A	011.1334.0
Power cable H05VVH2-F 2x0.75mm ²	008.0920.0
Cable USB, type A / B, 2 m	950.0324.0

9.2 ATMOS Rhino 31

Consumables	REF
Filter for olive measurement, set of filter plates (50x large, 50x small)	512.1030.0
Filter for mask measurement, filter plates (50x large)	512.1040.0
Nose adapter for mask measurement size 1, d = 12 mm (50 pieces)	512.1061.0
Nose adapter for mask measurement size 2, d = 15 mm (50 pieces)	512.1062.0
Nose adapter for mask measurement size 3, d = 18 mm (50 pieces)	512.1063.0

Spare parts	REF
Measuring probe with measuring olive	512.1020.0
Measuring probe with nose mask for adults	512.1010.0

9.3 ATMOS Sono 31

Consumables	REF
Ultrasonic gel, bottle 250 ml	507.0603.1

9.4 ATMOS Tymp 31

Consumables	REF
Set of ear plugs with cleaning cord	On request

9.5 ATMOS TEOAE + DPOAE 31

Spare parts	REF
OAE probe with 1400 mm probe cable and patient clip	512.1810.0

10 Disposal

Packaging

1. Please recycle the packing.

ATMOS Diagnostic Cube

Do not dispose of the device with household waste.

The product does not contain any hazardous materials.

1. Clean and disinfect the device.
2. Dispose of the product properly and in accordance with country-specific laws and regulations.

In principle, the housing is fully recyclable. Refer to the country-specific laws and regulations.



11 Technical data

11.1 ATMOS Rhino 31, ATMOS Sono 31, ATMOS Tymp 31

Voltage power supply unit (REF 011.1334.0)	Globtek GTM91099-6015-3.0-T2A 100-240 V~; 50/60 Hz
Supply Diagnostic Cube	12 V DC, max. 5 A
Current consumption	Max. 0.5 A
Power consumption	Max. 6 W
Other power sources	Via USB for "intelligent handle control"
Mains cable	Euro socket on power supply unit
Device variations	Unit to be installed as stand-alone unit or for system integration on support arm
	Holder for hand grip mountable on unit or support arm
	Optional iHandle for "intelligent handle control" for automatic programme call up
Interfaces	1 x USB 2.0 exit to PC, socket type B 1 x USB 2.0 i.e. for "intelligent handle control", socket type A 1 x voltage supply DC in 2.5 x 5.5 mm of the power supply
System requirements PC For installation in patients surrounding only medical approved PC are permitted	Operating system Windows 10 (64 bit) Free hard-disk capacity (patient and measuring database): 1 GB CPU performance: min. 2 GHz Available working memory: 2 GB RAM Graphic resolution: min. 1024x768 At least 2 USB-2.0 connections, optionally further USB interfaces for printer Non-medical PC can only be connected to the unit via USB coupler or over a medical isolation transformer to the power supply system!
PC software in general	For device control and data archiving (also independent from a practice EDP) Program start via icons or "intelligent handle control" or activation from the practice EDP system (e.g. MediStar) Start/stop and store over foot switch Input of the examiner Transfer of patient data via xDT Data transfer after end of measurement via xDT interface to the practice PC system Patient-related storage in data base Print-out over windows printer possible Graphic output for transfer into the clinical information system (PDF format)

ATMOS Rhino 31	<p>Measuring the nasal breathing resistance under use of a nose mask or nose olives</p> <p>Real-time display of the development curve</p> <p>Pressure measuring range: -500 Pa to 500 Pa (+/-5%)</p> <p>Flow measuring range: -700 ml/s to 700 ml/s (+/-5 %)</p> <p>After measuring presentation of the breathing development curve and the tabular values</p> <p>Averaging of the curve acc. to the CAR algorithm</p> <p>Automatic measuring sequence control</p> <p>Comment line (diagnosis and findings/measurement)</p>
ATMOS Sono 31	<p>Ultrasonic A-mode</p> <p>Pulse frequency ultrasonic probe 100 Hz</p> <p>Probe measuring frequency 3.5 MHz</p> <p>Transmitting performance: 0.06 mW / cm²</p> <p>Thermal index TI < 1</p> <p>Mechanical index MI < 1</p> <p>Amplification setting: 80 dB</p> <p>Switching between the depth ranges 8 and 4 cm within the automatic measuring sequence control or manually</p> <p>Permanent 4-picture presentation</p> <p>Comment line (diagnosis and findings/measurement picture)</p>
ATMOS Tymp 31	<p>Measuring of the tympanic membrane flexibility (compliance) with probe sound</p> <p>226 Hz (+/-1%), 667 Hz (+/-1%) and 1000 Hz (+/-1%)</p> <p>Pressure range +200 daPa (+/-5%) to - 600 daPa (+/-5%), in 100 daPa steps after age classification or manually.</p> <p>Compliance-range 0.4 to 5 ml (cm³)</p> <p>Measuring the stapedius reflex with 500/1000/2000 and 4000 Hz at 75/85/95 dB SPL, or 85/95/105, dB SPL ipsi and optionally contra (+/-5 dB)</p> <p>Automatic start and measuring sequence control</p> <p>Display of the compliance curves, the significant measuring data and reflex charts</p> <p>Tube function test (L and R)</p> <p>Optional decay-measurement</p> <p>Comment line (diagnosis and findings/measurement)</p>
Support arm	<p>Mountable at system frame of ATMOS S 61 Servant and at the microscope column of the ATMOS C 21, ATMOS C 31 and ATMOS Servant 5.</p> <p>Radius 50 cm, rotatable over mounting point at system frame, inclusion of the housing, handle holder mountable, optional "intelligent handle control", monitor attachment VESA 100, inclination adjustable +/- 15°</p>
Operating time	Continuous operation
Touch current (NC)	Max. 0.1 mA

Patient leakage current (NC)	Max. 0,1 mA AC
Ambient conditions Transport / storage	-30...+50°C 5...85% air humidity without condensation at air pressure 700...1060 hPa
Operation	+10...+32°C 20...85% air humidity without condensation at air pressure 700...1060 hPa
Maximum operational altitude	3000 m (NN)
Contamination level	Class 2
Dimensions H x W x D Diagnostic Cube Power supply unit Support arm	62 x 280 x 270 mm, without holder 35 x 60 x 120 mm Radius: 50 cm between rotating points Max. width: 78 cm
Weight Diagnostic Cube Power supply unit Foot switch Support arm (without equipment)	approx. 4 kg (with full equipment) 0.5 kg 0.4 kg 5 kg
Period tests	Recommended: Testing every 24 months.
Protection class (EN 60601-1)	II
Degree of protection	Application parts type B
Type of protection	IP X0
Classification in accordance with Appendix IX EC Directive 93/42/EEC	Class IIa
CE marking	CE 0124
GMDN code	15737 (ATMOS Rhino 31) 35526 (ATMOS Tymp 31) 40766 (ATMOS Sono 31)
UMDNS code	15-737 (ATMOS Rhino 31) 15-634 (ATMOS Tymp 31) 15-659 (ATMOS Sono 31)
Ident No.	512.0000.0 512.1000.0 (ATMOS Rhino 31) 512.1100.0 (ATMOS Tymp 31) 512.1200.0 (ATMOS Sono 31)

11.2 ATMOS TEOAE + DPOAE 31

Voltage	12 V 5 A switching power supply 100 V-240 V ~ 5060Hz Manufacturer: GlobTek GTM91099-6015-3.0-T2A
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Current consumption	max. 200 mA (12 V)
Power consumption	max. 2.5 W
Other power sources	USB to power the USB controller
Fuses	Polyswitch 250 mA in the device
Mains cable	Over socket (IEC) on power supply
Interfaces	USB 2.0 A-B cable
System requirements PC For installation in patients' surrounding only medical approved PC are permitted	<p>Operation system Windows 10 (Pro 32 bit/64 bit)</p> <p>For software:</p> <p>Free hard-drive capacity: 1GB</p> <p>Available working memory: min. 4 GB</p> <p>Graphic resolution: min. 1024x800</p> <p>Min. 1 USB 2.0 connection</p> <p>Network connection possible over galvanic isolated network coupler.</p> <p>Non-medical PC can be connected only via USB coupler to the unit or over a medical isolation transformer to the power supply system!</p>
PC software in general	<p>For device control and data archiving (also independent from a practice EDP by means of the ATMOS PatSoft 31)</p> <p>Programme start via icons or starting from the practice EDP or HIS</p> <p>Start/stop and store of diagnostics</p> <p>Input of the examiner</p> <p>Transfer of patient data via GDT interface or via ATMOS PatSoft 31</p> <p>Data transfer after end of measurement via GDT interface to the practice PC system or document export (PDF)</p> <p>Patient-related storage in data base</p> <p>Print-out over windows printer possible</p> <p>Graphic output for transfer into the clinical information system</p>
DP-OAE	<ul style="list-style-type: none"> • Measuring otoacoustic emissions • Real-time display of the data curve • Frequency range: 550Hz to 8kHz (+/-5%) • Test frequencies: max. 4/octave • Sound level: max. 75 dB • Illustration of the data curve and the table values • Automatic measuring sequence control - "guided diagnostics"

TE-OAE	<ul style="list-style-type: none"> • Measuring otoacoustic emissions • Real-time display of the data curve • Frequency range: 1000 Hz to 5 kHz (+/-5%) • Sound level: max. 80 dB • Illustration of the data curve and the table values • Automatic measuring sequence control
Operating time	Continuous operation
Patient leakage current	max. 0.1 mA
Ambient conditions Transport / storage	-30...+50°C 5...85 % air humidity without condensation at an air pressure of 700...1060 hPa
Operation	+10...+32°C 20...80% air humidity without condensation at an air pressure of 700...1060 hPa
Maximum operating height	3000 m (NN)
Contamination level	Class 2
Overvoltage category	I
Dimensions HxWxD	62 x 280 x 270 mm
Weight	3.5 kg
Period tests	Recommended: Testing every 24 months.
Protection class (EN 60601-1)	Protection class II
Degree of protection	Application parts type BF
Type of protection	IP x0
Classification in accordance with Appendix IX EC Directive 93/42/EEC	Class IIa
CE marking	CE 0124
GMDN code	36908
UMDNS code	16-303
ID No. (REF)	512.0000.0 512.2000.0 TE + DPOAE 512.1900.0 DPOAE 512.1800.0 DPOAE

12 Notes on EMC

- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.
- The electrical medical device must not be stacked next to or with other devices. When operation is required close to or in combination with other equipment, the electrical medical equipment must be observed to verify its intended operation in this arrangement.

Guidance and manufacturer's declaration - electromagnetic emissions

The ATMOS Diagnostic Cube is designed for operation in the electromagnetic environment specified below. The customer or user of the ATMOS Diagnostic Cube should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
HF transmission according to CISPR 11	Group 1	The ATMOS Diagnostic Cube uses HF energy only for its internal function. Therefore, its HF emissions are very low and it is unlikely that nearby electronic devices will be affected.
HF transmission according to CISPR 11	Class B	The ATMOS Diagnostic Cube is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Inapplicable	
Voltage fluctuations/ flicker according to IEC 61000-3-3	Inapplicable	

Guidance and manufacturer's declaration - electromagnetic immunity

The ATMOS Diagnostic Cube is designed for operation in the electromagnetic environment specified below. The customer or user of the ATMOS Diagnostic Cube should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramics tile. If floors are synthetic, the relative humidity should be at least 30%.
Fast electrical transient/burst IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Impulse voltage/surges according to IEC 61000-4-5	± 1 kV common-mode ± 2 kV differential mode	± 1 kV common-mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations according to IEC 61000-4-11	<5% U_T (>95% Dip of the U_T) for 0.5 Cycles 40% U_T (60% Dip of the U_T) for 5 Cycles 70% U_T 30% Dip of the U_T for 25 Cycles <5% U_T (>95% Dip of the U_T) for 5 s	<5% UT (>95% Dip of the UT) for 0.5 Cycle 40% UT (60% Dip of the UT) for 5 Cycles 70% UT (30% Dip of the UT) for 25 Cycles <5% UT (>95% Dip of the UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS Diagnostic Cube requires continued operation even in case of interruptions of the energy supply, it is recommended that the ATMOS Diagnostic Cube be powered by an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be that of a typical commercial or hospital environment.

NOTE: U_T is the mains alternating current prior to application of the test levels.

Guidance and manufacturer's declaration - electromagnetic immunity

The ATMOS Diagnostic Cube is designed for operation in the electromagnetic environment specified below. The customer or user of the ATMOS Diagnostic Cube should ensure that it is used in such an environment.

Immunity Test	IEC 60601-Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted interference according to IEC 61000-4-6	3 V _{Effective value} 150 kHz to 80 MHz	3 V _{Effective value}	Portable and mobile communications equipment should be separated from the ATMOS Diagnostic Cube, including the cables, by no less than the recommended safety distance, which is calculated according to the equation applicable to the transmission frequency. Recommended distances: $d = 1.17 \cdot \sqrt{P}$ $d = 1.17 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33 \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz where „P“ is the max. power in watts (W) and D is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b). Interference may occur in the vicinity of equipment containing following symbol: 
Radiated HF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 Hz	3 V/m	
NOTE 1: With 80 MHz and 800 MHz the higher frequency range applies. NOTE 2: These guidelines might 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 radio telephones and land mobile radio devices, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be accurately predicted theoretically. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS Diagnostic Cube is used exceeds the above compliance level, the ATMOS Diagnostic Cube is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e.g. a changed arrangement or another location for the ATMOS Diagnostic Cube. (B) Over the frequency range of 150 kHz to 80 MHz, field strengths should be lower than 3 V/m.			

Recommended safety distances between portable and mobile RF Communications equipment and the ATMOS Diagnostic Cube

The ATMOS Diagnostic Cube is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS Diagnostic Cube can thereby help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communication equipment

(transmitters) and the ATMOS Diagnostic Cube as recommended below, according to the maximum output power of the communications equipment.

Power of transmitter W	Safety distance, depending on transmit-frequency m		
	150 kHz to 80 MHz $d = 1,17 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters for which the maximum nominal output is not indicated in the above table, the recommended safety distance d in meters (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) acc. to manufacturer's specification.

NOTE 1 By 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines might not be applicable in any case. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects and people.



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