

English

Operating instructions

ATMOS Strobo 21 LED



CE

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1.1 Notes on operating instructions

 In the following all device versions, as well as all modules and table-top devices are named ATMOS Strobe 21 LED!



These operating instructions contain important notes on how to operate the ATMOS Strobe 21 LED safely, correctly, and effectively. Their reading helps to avoid risks and also to reduce repair costs and down-times. This increases, among other things, the reliability and service life of the device.

These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. Reprints, also in extracts, only with permission in written form by ATMOS.

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



Care and safety inspections in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS Strobe 21 LED and are therefore a must besides regular cleaning.

Repair work and safety inspections may be carried out only by expert personnel authorized by ATMOS. By applying only original spare parts you will have the guarantee that operational safety, readiness for work and the value of your ATMOS Strobe 21 LED will be preserved.



- The product ATMOS Strobe 21 LED bears CE marking CE according to the EC Directive 93/42/EEC and meets the basic requirements of Annex I of the directive.
- The product ATMOS Strobe 21 LED 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 viewed on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 13485.
- Prior to start-up please peruse chapter 2.0 "For your safety" in order to be prepared for any possible dangerous situations.

These operating instructions are valid for the following devices:

ATMOS Strobe 21 LED (S 61 Servant vision)	REF 531.2050.0
ATMOS Strobe 21 LED	REF 507.4700.0

1.2 Intended use

Product name:	ATMOS Strobe 21 LED
Main functions	Recording and analysis of frequency and sound pressure level of a voice. Appropriate control of a light source. Adjustment of phase shift and pulse width regulation.
Intended purpose:	Diagnostics of the anatomy and the movement of the vocal folds.
Intended Users / User profile:	Doctors and medical specialists
Intended Patient population:	All patients without any restrictions
Medical conditions to be diagnosed, treated or monitored:	General examination of the larynx, voice problems
Application organ:	Larynx / vocal folds
Application time:	< 60 min.
Application site:	Outpatient medical facilities, e.g., ENT practices, hospital outpatient departments, medical care centers

1.0 Introduction

Patient selection criteria:	None
Indications:	General examination of the larynx, voice problems
Medical contra-indications:	None
Other contra-indications:	None
Warnings:	None
The product is:	Active
Sterility / specific microbial status:	Non sterile
Single use product / reprocessing:	No single-use product. Reprocessing according to instructions for use.

1.3 Function

The device is intended to record and analyze the frequency and sound pressure level of a voice. It can trigger a light source accordingly. The device allows phase shift adjustment and pulse width control for the illumination.

The device is an electrically driven device and takes medical effect by triggering a light source according to the recorded frequency of a voice. By using the triggered light source the movement of the vocal folds is visible at a lower speed and can be examined with the human eye.

1.4 Explanation of pictures and symbols

	Consult operating instructions		Humidity limitation
	Follow operating instructions (blue)		Atmospheric pressure limitation
	Warning; pay special attention		Temperature limit
	This device complies with the relevant requirements of EU regulations.		Professional disposal
	This device complies with the relevant requirements of the Eurasian Economic Union.		Keep dry
	Manufacturer		Fragile, handle with care
	Date of manufacture		Handle with care
	Country of manufacture		Keep away from heat
	Reference number		
	Serial number		
	Unique Device Identifier of a medical device		
	Medical device		
	Type BF applied part		
	2x T2A/H 250 V		
		UDI application identifier	
		(1)	04250365167832
		(11)	210322
		(21)	11223344



General safety instructions

- ATMOS neither guarantees for fault-free operation nor for personal injuries and damage to property if:
 - no original ATMOS parts are being used
 - the advice for use in these operating instructions is not being observed,
 - assembly, new settings, alterations, extensions and repairs have been carried out by personnel not authorized by ATMOS.
- The ATMOS Strobo 21 LED is:
 - designed in line with IEC 601 / EN 60601.
 - assigned to VDE safety class I
 - and the class I (93/42/EEC).
- The ATMOS Strobo 21 LED meets the immunity to interference requirements of IEC 601-1-2 / EN 60601-1-2 "Electromagnetic Compatibility – Medical Electrical Devices".
- Please check the delivery on completeness and intactness.
- **Please note:**
A medical insulating transformer with earth leakage monitor or any similar safety system acc. to EN 60 601-1 is required if
 - several devices are connected over one common power supply. The transformer must correspond to the power consumption of all the devices to be connected.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- You can only disconnect the device from the power supply by pulling out the power plug.
- Position the device in such a way that you can easily disconnect it from the power supply at any time.
- The ATMOS Strobo 21 LED may only be used under the supervision of skilled staff who have been authorized by ATMOS and trained in its operation (IEC 601-1 / EN 60601-1).
- There are no warranty claims whatsoever on defects which arise from the use of third-party accessories or consumables.
- When connecting several devices on one grounding receptacle, the allowed strain and leakage current have to be observed.
- Pay also attention to the safety information of the attached devices / parts as well as to the safety information in the following chapters.
- The ATMOS Strobo 21 LED may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen-rich environments.
- All additional equipment which is connected to the analogue and digital interfaces of the device must meet the requirements of relevant EN specifications (e.g. EN 60950 for data processing equipment and EN 60601 for electrical medical equipment). In addition, configurations must satisfy system specification EN 60601-1. When additional equipment is connected to the signal input or signal output section on the device, the person carrying out the connection is deemed „a system configuration operator“ and as such is responsible for meeting the requirements of system specification EN 60601-1. For answers to additional questions, please contact your local specialist supplier or the ATMOS Technical Service.
- Report all serious incidents that have occurred in connection with this product to the manufacturer and your national competent authority.



Risk of injury!

- Do not allow any liquid to get into the device. If liquids have penetrated the device, it may not be operated again until it has been checked by the customer service centre.
- If the endoscope is used combined with energetic operated accessories the patient leakage current can sum up.
- Never look directly into the light source!
- Never touch the device's interfaces and the patient at the same time!
- Prior to first starting up, all connecting leads must be checked on damage. Damaged cables must be replaced! Check functions of the device prior to use.
- The treating doctor is responsible for the proper procedure and technology! The appropriateness and the kind of application must be decided by a trained doctor on a case-by-case basis.
- Prior to cleaning, switch off the device and separate it from the mains supply respectively from other devices.
- The fixation of microphone may just be tightened enough as absolutely necessary for the function.
- Only endoscopes which previously have been cleaned and disinfected may be stored in the endoscope quivers.
- To disconnect the device from the mains supply, first remove the plug from the wall outlet. Then disconnect the power cable from the device. Never touch plug or cable with wet hands!
- The ATMOS Strobo 21 LED may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards.
- Explosion-hazardous areas may be caused by the use of flammable anaesthetics, skin cleansing products and skin disinfectants.
- Prior to each use check the outer surface of all endoscope parts and endoscopic used accessories parts which are implemented in the patient. Make sure no harsh surface, sharp-edged angles or salient parts are existing, they may cause a danger.
- Please observe, it could happen that body parts get caught in the foot controller!



Danger to the device!

- Switch off the device when you finish your daily business.
- When installing the unit, make sure that there is enough cooling air supply.
- The ATMOS Strobo 21 LED System may not be operated with devices not complying with the requirements of standard EN 60601-1 "Medical Electrical Equipment" and EN 60601-1-2 "Electromagnetic Compatibility" (Medical Electrical Equipment).
- The device may only be connected to a properly installed protective contact socket.
- For mains supply, only use the power cable supplied (or an equivalent one).
- Pay attention to the ambient conditions specified in chapter 8.0.
- Please pay attention to the period tests in chapter 6.0 „Maintenance and service“.
- Prior to first starting up, check whether the mains voltage specified on the type plate matches the local mains voltage.
- Check proper assignment when assembling country-specific connections:
 - green/yellow: protective conductor (PE)
 - blue: neutral conductor (N)
 - black or brown: phase (L)
- Protect the device against direct solar radiation and keep it away from heaters.
- Always set up the device in such a way that the operating elements are in clear view and within easy reach of the operator. The device must be placed on a stable, level surface.

3.0 Setting up and starting up



3.1 Scope of supply

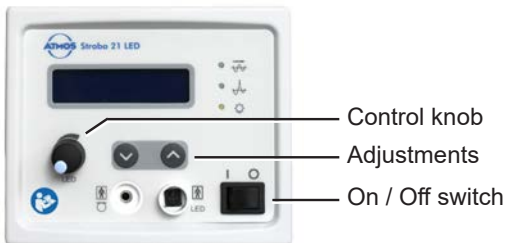
- Control unit
- Airborne sound microphone incl. clip for laryngoscope
- Light handle ATMOS LS 21 LED incl. adapter Wolf
- Holder for light handle ATMOS LS 21 LED with switching function
- Foot controller
- Audio cable
- Power cable

Optional:

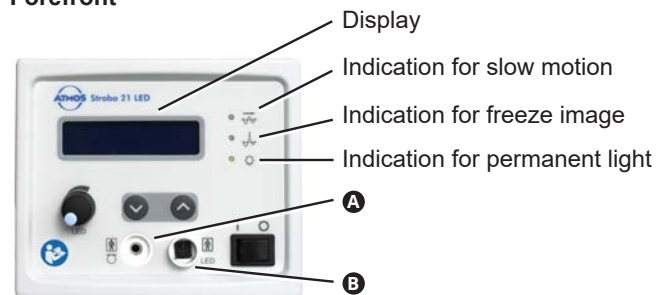
- Impact sound adaptor for airborne microphone
- Data cable (Strobo 21 LED)

3.2 Connections

Control panel



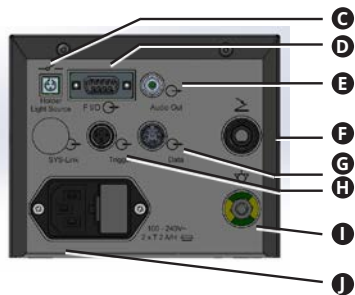
Forefront



A Connection for microphone

B Connection for LED light handle

Backside



C Connection holder for light handle ATMOS LS 21 LED with switching function

D Optional connection for the MediaStroboscope

E Audio output (Line-out)

F Connection for foot controller

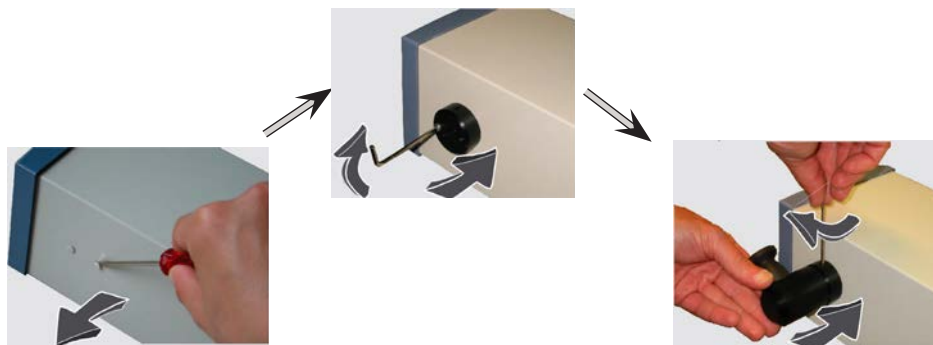
G DATA Interface

H No function

I Connection for potential equalisation

J Nut for mains supply

3.3 Mounting the holder for light handle



3.0 Setting up and starting up



3.4 Starting up

i Please pay attention, just to switch on the devices after they have been completely wired.

ATMOS Strobe
21 LED



ATMOS Cam 31 DV Data
3. Generation



(Not applicable for
ATMOS Cam 21 / 31,
2. Generation)

1



2



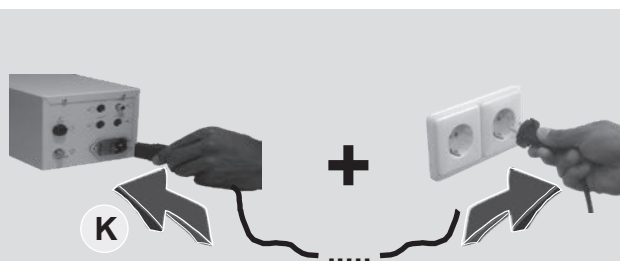
3



4



5



i The ATMOS Strobe 21 LED has a potential equalization connector on the rear, which can be connected to the potential equalization rail of the room if necessary. This connector can be used with protection class I devices to avoid potential differences between the protective earth of the device and the protective earth of other devices or parts of a system that can be used or touched on the patient at the same time.

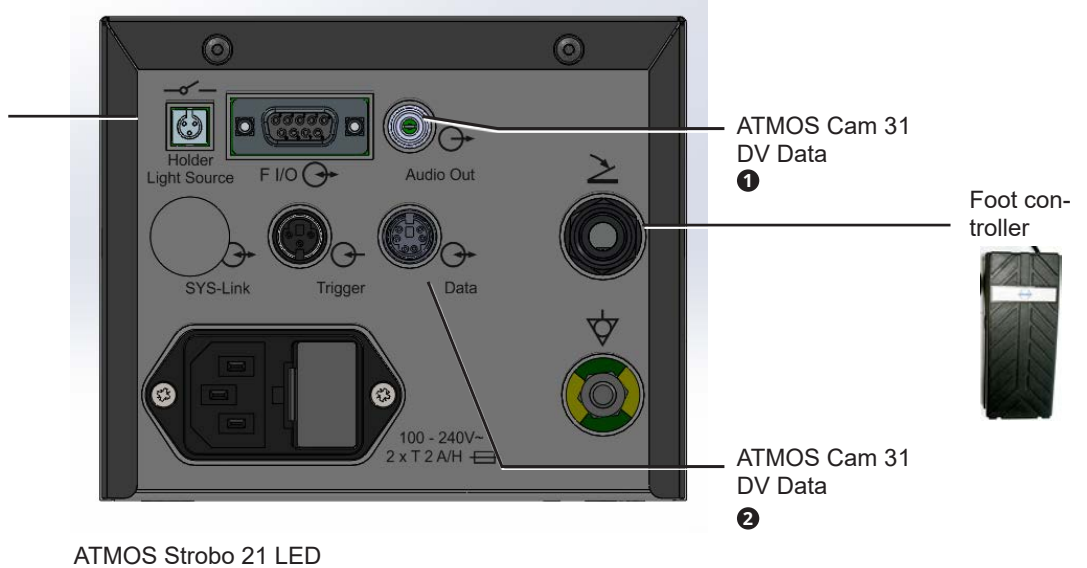
3.0 Setting up and starting up



3.4.1 Connection diagram ATMOS Cam 31 DV Data, 3. Generation and ATMOS Strobo 21 LED



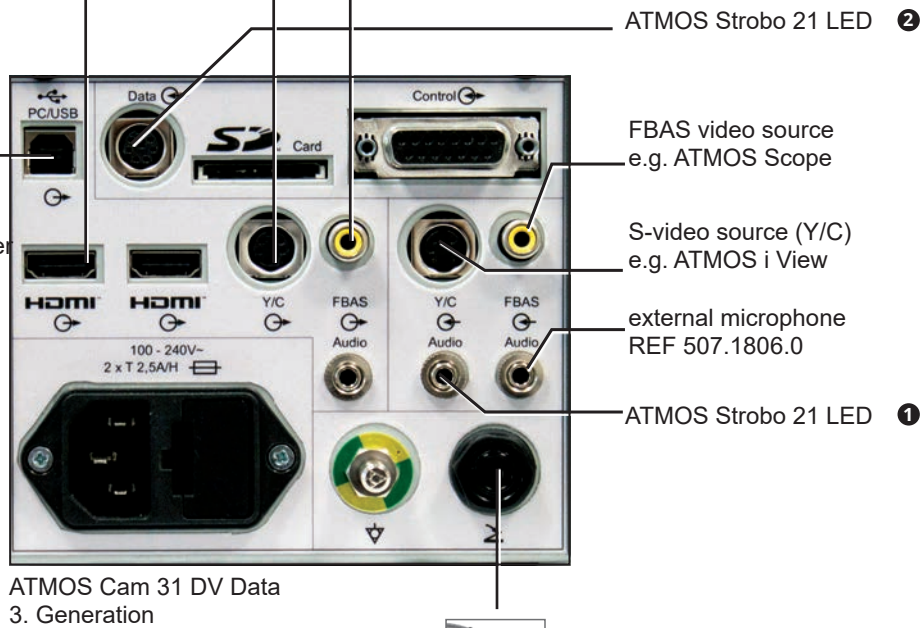
Handle support
LED light source
ATMOS Strobo
LED



digital analogue



Computer
MS-Windows 7 or higher
USB Streaming
ATMOSoft



4.1 Switching on and off



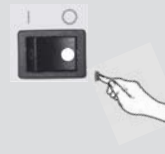
Prior to each use, a function check has to be performed. See chapter 6.0 "Service and Maintenance".

Switching on



After switching on the device it takes a few seconds until it is ready for operation.

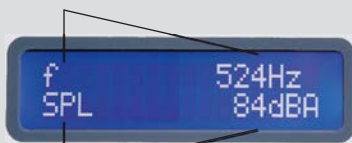
Switching off



4.2 Functions of display

4.2.1 Indication during examination

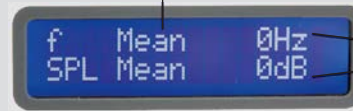
Frequency (pitch)



Volume
(Sound pressure level)

4.2.2 Indication after examination

Ø-value



mean frequency
and Ø-volume
after phonation

Change of contrast



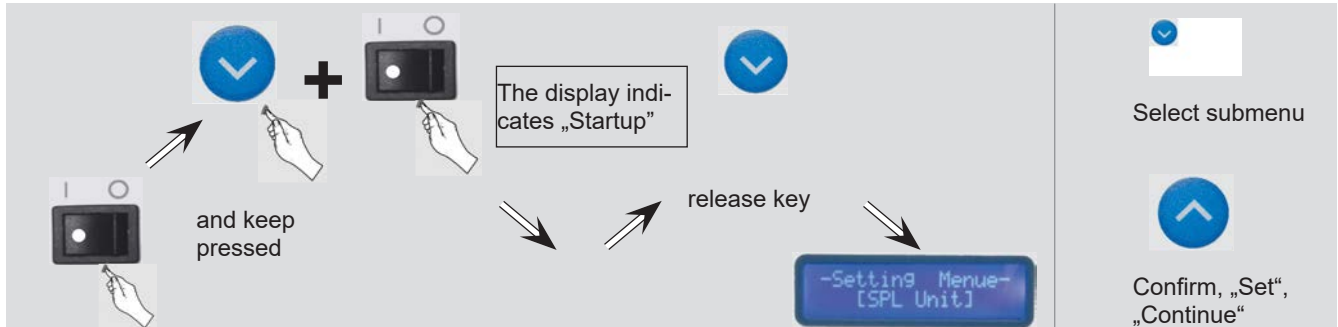
...or...



→ push repeatedly

4.2.3 Setting menu

Access „Setting Menu“

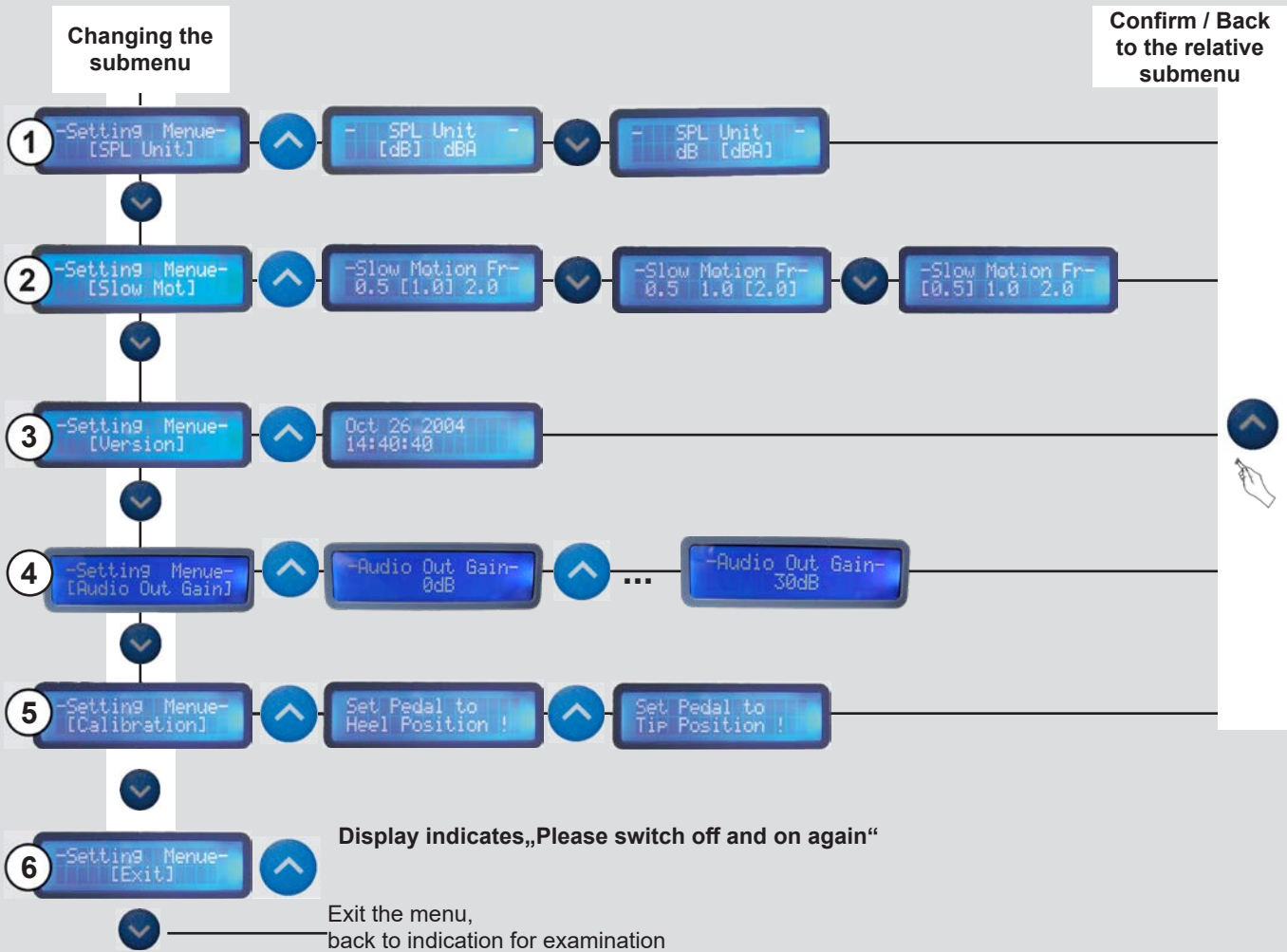


Adjustable submenus (see next page)

- 1 SPL Unit:**
Setting dB or dBA
- 2 Slow Motion:**
Setting speed of slow motion

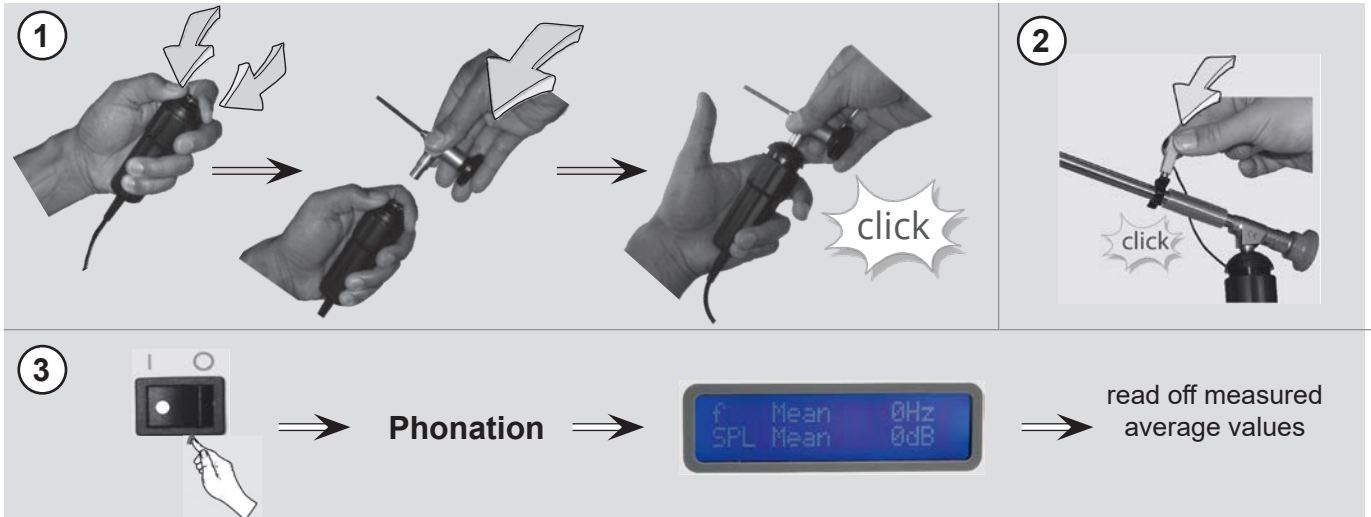
→ 0.5: 1 oscillation / 2 sec
1.0: 1 oscillation / sec
2.0: 2 oscillations / sec
- 3 Version:**
Information about software version
- 4 Audio Out Gain:**
Amplification of the audio signal can be adjusted at the LINE-OUT audio output.
Attention! In case the audio signal of the LINE-OUT is amplified, that is to say for all adjustments other than 0 dB, the audio signal no longer corresponds to the sound level of the input signal which is shown in the display respectively emitted at the data interface.
- 5 Calibration:**
Calibration of foot controller. Your supplied foot controller is already calibrated to your stroboscope. Please follow the instructions in the display. Please take care to apply only low pressure for the stop positions. Prior to confirming the reached stop position please wait for 2 seconds.
- 6 EXIT:**
End adjustments of menu

Adjustment of menu



4.3 Examination

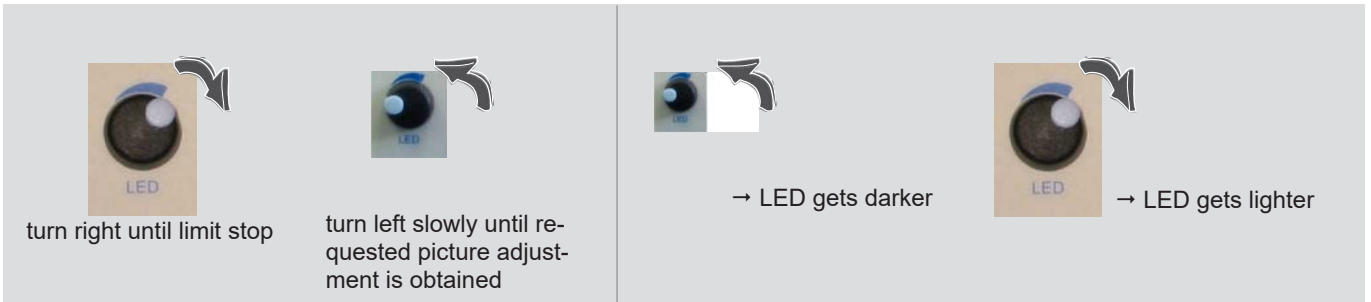
4.3.1 Operating sequence



4.3.2 Resolution / Brightness control

After switching on

Settings



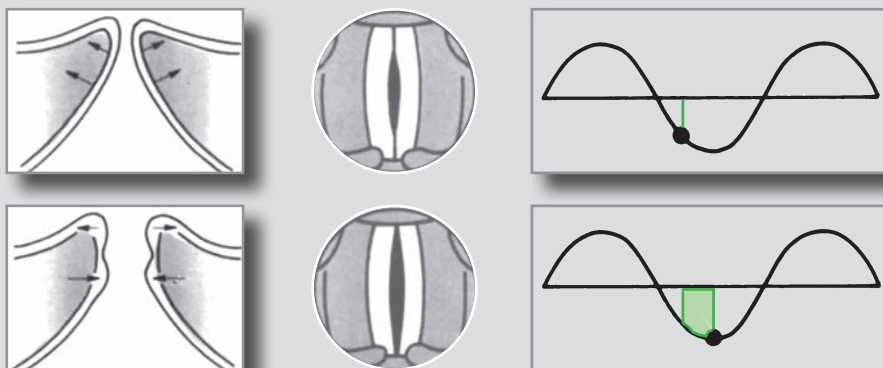
i Operating mode of brightness control:

In case the picture becomes more blurred when the brightness is increased:

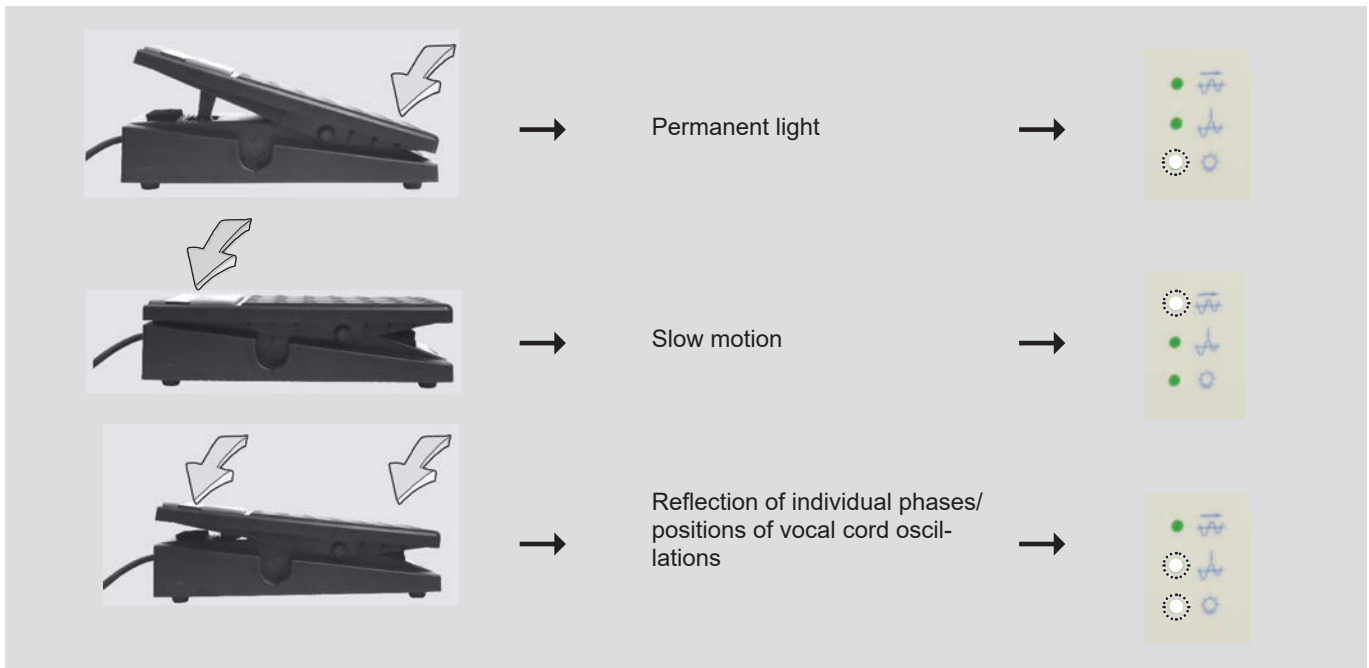
The ATMOS Strobe 21 LED flashes with 2 Watt. For generating a brighter image, the illumination has to be longer. This entails that the vocal cord oscillates fractionally at this moment.

The tiny movement reclined during the exposure time is perceived blurred.

The darker the image, the shorter the exposure time, the shorter the reclined movement of the vocal cord, the well-defined the image.



4.3.3 Operate the foot controller



4.3.4 Operation with other light sources

The device can be operated with other ATMOS light sources or other ATMOS devices with integrated light sources e.g. with an ATMOS Scope. During the operation with other devices the light handle ATMOS LS 21 LED can remain in the light source holder.

5.1 General information on cleaning and disinfection

- i** The composition of plastic, varnish and colours as well as cleansers and disinfectants change continuously. Therefore, prior to first use always test the cleaning agent on the underside of the device!

Prior to cleaning

1

...and all other connected devices

- If required, wipe the device with a cloth moistened with a cleaning solution and disinfect the application parts which come into contact with the patient. Do not spray the liquid directly on the device.
- For cleaning / disinfecting the optics please pay attention to the respective cleaning instructions.
- For disinfection, you may use all surface disinfectants listed on page 15.
- Always observe the concentration specifications and instructions by the respective manufacturer!

i **Do not use:**

- Disinfectants which contain organic or inorganic acids or bases as they could cause corrosion damage.
- disinfectants containing chloramides, phenol derivatives or anionic tensides, as these may cause stress cracks in the material used for the housing of the unit.

5.2 Unit

5.3 Chemical disinfection

- Avoid liquid residues in the snap-in connection of the video adaptor.
- Upon drying avoid liquid residues and spots on the lens of the image sensor.
- All surfaces may be cleaned with the disinfectants listed on page 15.

5.4 Surface disinfectants

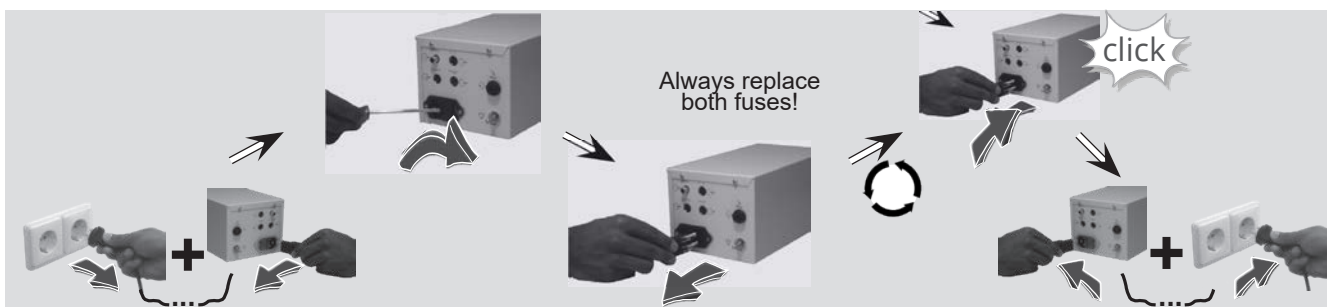
Disinfectant	Ingredients	(in 100 g)	Manufacturer
Incidin® Plus (Application concentrate)	Glucoprotamin Non-ionic tensides Solvents, complexing agents	26.0 g	Ecolab, Düsseldorf
Dismozon® plus (Application concentrate)	Magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Green & Clean SK (Application concentrate)	alkyl-dimethyl-benzyl-ammonium chloride dialkyl-dimethyl-ammonium chloride	< 1 g	Metasys, Rum (Austria)

- When using disinfectants containing aldehyde and amine at the same object colour changes may occur.

Medical devices like the ATMOS Strobe 21 LED must be fail-safe at all times. Do not use the device if it is obviously damaged. Prior to each use a **function check** has to be performed:

- Check whether the device or its cables are visibly damaged. Damaged cables have to be replaced immediately.
- Connect the microphone and sing a tone. The device has to show a constant frequency. As soon as you change the pitch level, the frequency changes.
- Check whether the foot controller works as described in chapter 4.2.3.

6.1 Replacing the fuse



6.2 Period tests

Maintenance, repairs, and periodic 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.

At least every 24 months a repeat test of the electrical safety should be performed according to IEC 62353.

ATMOS recommends an inspection according to the manufacturer's specifications.

Scope of test:

- Visual inspection of device and accessories on function-related mechanical defects.
- Checking the readability of safety-related labellings.
- Controlling the melt insert of the miniature fuse on the nominal current and the melting characteristics.
- Function control in compliance with the operating instructions.
- Measuring the ground wire resistance
- Measuring the earth leakage current: NC and SFC
- Measuring the patient leakage current: Type BF, NC and SFC

6.3 Sending in the device




- Remove all consumables and dispose of them properly.
- Clean and disinfect the product and accessories in accordance with the operating instructions.
- Place any used accessories with the product.
- Fill in form QD 434 "Delivery complaint / return shipment" and the corresponding **Decontamination certificate**.
☞ This form is enclosed with each delivery and can be found at www.atmosmed.de.
- The device must be well padded and packed in suitable packaging.
- Place form QD 434 "Delivery complaint / return shipment" and the respective **decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or your dealer.



Description	Possible causes of error	Measures
No indication from the device	Power plug is fitted badly	Check fitting of the power plug at the mains power and at the device
	No mains voltage available	Check the main fuse
	Defective fuse	Check fuses
Indication is illegible	Insufficient contrast	Adjust contrast by pressing the ‚up‘ and ‚down‘ button (see chapter 4.1.1).
Blurred image	For technical reasons the vocal fold oscillations / vocal fold position are blurred if there is an increase in brightness during stroboscopy with the LED light source, (see chapter 4.2.2 Resolution / brightness control).	Reduce the brightness of the LED light source.
	Foot controller is positioned at „heel“, thereby the signal for permanent light is generated.	Change to freeze image mode respectively slow motion mode by moving the foot controller, see chapter 4.2.3).
	The acoustic signal is not picked up properly / microphone has not been connected correctly.	Make sure, the microphone is properly connected to the device, that it is affixed close enough to the acoustic source and correctly aligned. Make sure the operational reliability of the microphone is given.
Image is too dark	Acoustic signal cannot be evaluated at all resp. cannot be evaluated properly.	Use the optional obtainable contact microphone
	Brightness of the LED light source is too low.	Enhance the brightness of the LED emitter by triggering the control knob (see chapter 4.2.2). Please observe the information there regarding „Resolution / Brightness control“.
Foot controller does not work	Foot controller is not connected properly.	Check if foot controller is connected properly. Switch off the device and wait 5 sec until switching it on again.
	Foot controller has not been calibrated.	Implement calibration. (Enter the submenu, ‚Calibration‘ (see chapter 4.1.3, „Adjustable submenus“) and follow the indicated advices.)

8.0 Technical data



Input voltage	100-240 V~ ± 10%; 50/60 Hz
Current consumption	0.3 A
Power consumption	max. 30 VA
Fuses	2 x T 2.0 A/H 250 V
Flash frequency	70 – 1000 Hz
Accuracy of displayed flash frequency	± 1 Hz
Metering range of sound level	70 – 125 dB
Accuracy of the sound level display	± 1 dB
Power cable	2 m length, schuko rubber connector
Microphone	Airborne sound microphone, body sound adapter optional
Operation modes	continuous light, slow motion 0.5 –2 Hz, freeze image 0°C – 400°C displacement of phase
Protective earth conductor resistance	max. 0.1 Ω
Earth leakage current	max. 5 mA
Touch current	max. 0.1 mA
Patient leakage current	max. 0.1 mA
Ambient conditions: Transport/storage	
- Temperature range	-30...+50 °C
- Air humidity without condensation	5...90%
- Air pressure	700...1060 hPa
Ambient conditions: Operation	
- Temperature range	+5...+35 °C
- Air humidity without condensation	20...80%
- Air pressure	700...1060 hPa
Maximum operating altitude	3000 m
Contamination level	2
Overvoltage category	II
Dimensions H x W x D	118 mm x 139 mm x 280 mm
Weight	5 kg
Periodic tests	Repeat test of electrical safety every 24 months. Recommended: inspection according to manufacturer's specifications.
Protection class against electric shock (acc. to EN 60601-1)	I
Classification of applied parts	ATMOS LS 21 LED type BF  Microphone type BF 
Degree of protection	IPX0
CE marking	
Reference number (REF)	507.4700.0 ATMOS Strobo 21 LED 531.2050.0 ATMOS Strobo 21 LED (S 61 Servant Vision)

9.0 Disposal



- The materials of the housing can be recycled completely.
- The ATMOS Strobo 21 LED does not contain any hazardous goods.
- The component parts of the ATMOS Strobo 21 LED must be disposed of correctly and the materials are to be separated carefully.





☞ Medical electrical equipment is subject to special precautions with regard to EMC and must be installed according to the following EMC notes.

Guidance and manufacturer's declaration – ambient conditions

The ATMOS Strobe 21 LED is intended for use in the following environments:

- In fields of home health care in any buildings, outdoor areas and means of transport.
- In professional healthcare facilities such as medical practices, hospitals/clinics, first-aid facilities and operating theatres/ rooms.

The following environments are not suitable:

- It in the vicinity of HF surgical devices and in settings outside of an HF-shielded room of a magnetic resonance imaging system.
- Special environments such as factory or military facilities and medical areas near HF surgical devices, short-wave therapy equipment, or within an HF-shielded room of a magnetic resonance imaging system.

The customer or user of the ATMOS Strobe 21 LED must ensure that the device is used in a prescribed environment.

Guidance and manufacturer's declaration – key features

☞ Please note the technical data in this manual. The essential features are fully usable even in the presence of electromagnetic disturbances.

Guidance and manufacturer's declaration – removable components that can be replaced by the operator

The ATMOS Strobe 21 LED has the following removable components that can be replaced by the operator:

Type	REF	Max. cable length
Microphone	507.4780.0	2.5 m
ATMOS LS 21 LED / ATMOS LS 21 LED	507.4600.0	2.0 m
Foot controller	507.4771.0	2.0 m
Data cable	507.5016.0	0.5 m
Audio cable	008.0858.0	1.2 m
Trigger cable	507.4838.0	1.0 m

Guidance and manufacturer's declaration – warnings

WARNING

The use of electrical components and accessories other than those specified or provided by the manufacturer may cause increased electromagnetic interference or reduced immunity to electromagnetic interference and result in faulty operation of the device.

WARNING

Portable RF communications equipment (e.g., radios, antenna cables) should be used no closer than 30 cm* to any part of the ATMOS Strobe 21 LED, including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

☞ *The distance may be reduced at higher immunity test levels.

WARNING

Avoid placing the device on top of or next to another device. This could result in faulty operation. If such placement cannot be avoided, the proper functioning of the device must be monitored regularly. If possible, please switch off any nearby devices that are not in use.









MedizinTechnik

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