ATMOS MedizinTechnik

English

Operating Instructions

ATMOS® Strobo 21 LED

CE

These operating instructions are valid for ATMOS® Strobo 21 LED 2nd generation.

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1.0 Introduction

1.1 Notes on operating instructions

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

These operating instructions contain important notes on how to operate the ATMOS® Strobo 21 LED, correctly and effectively. Their reading helps to avoid risks, and also to reduce repair costs and down-times. This increases, amongst 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® Strobo 21 LED and are therefore a must besides regular cleaning.

Repair work and safety inspections may be carried out only by expert personnel authorised 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® Strobo 21 LED will be preserved.

- The product ATMOS® Strobo 21 LED bears CE marking CE according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of Appendix I of the directive.
- The product ATMOS® Strobo 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 obtained on our website at www.atmosmed.com.
- The quality management system 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.

1.2 Intended use

Name: ATMOS® Strobo 21 LED

Main functions: Stroboscopic diagnostics of the larynx

Medical indications / application:

Examination of the larynx

Specification of the main function:

The adjustment of requested phases or slow motion for examination is set by means of a foot regulator. Along with corresponding endoscopes and video components, the sequence of examination can be watched on a monitor and be recorded.

Application organ: Examination of the larynx

Application time:

The duration of the examination (stroboscopy) is set as “temporary” (max. 60 minutes).

Application site:

In clinics and practices for ENT doctors and phoniatricians. The stroboscope may only be operated and applied by medically trained staff.

Contraindications:

Not for use outside of medical areas.

Not for use in explosion-hazardous areas of medically-used rooms.

The product is: active

Sterility: Not necessary

Single-use product / reprocessing:

No single use product

1.3 Function

The product consists of a control module with control elements, the set off LED light emitter and the microphone. The emitter and the microphone are both connected to the control element with an electric cable. Another control element is the foot controller which is also connected to the control element. The activation of a video recorder is possible with the connection of the optionally available professional foot controller.

The device has two different modi, these are permanent light mode or stroboscopy mode. As soon as there is no microphone trigger signal, the device automatically switches over from the stroboscopy mode to permanent light mode. There are two functions in the stroboscopy mode: freeze-image and slow-motion. In the permanent light mode the LED stroboscope can be used as light source.

An airborne sound microphone (alternatively a structure-borne sound microphone – stethoscope microphone) picks up the sound signal produced by the proband. With this sound signal a trigger signal is produced to activate the light source, the basic frequency respectively the sound-pressure level is obtained In the display the determined values for the basic frequency respectively the sound-pressure level and the operation mode (freeze image, slow motion resp. permanent light) are indicated.

1.4 Explanation of pictures and symbols

Short cuts / symbols contained in these operating instructions


Follow the arrows


Please press where dot indicates


Activate the optional foot switch


Please read, important information


Check


Move, plug... in this direction


Turn, shift ... in this direction


Replace

Engage, check correct fit

Graphic symbols contained in this manual


Warning, special diligent notice


Follow operating instructions (blue)


Fuse according to IEC 417/5016, DIN 30600/0186


Application part type BF


Potential equalisation


Freeze (Storage)


Signal output


Signal input and output


Foot switch


Ground wire connection

~ Alternating current

| On (feed-in, power connection)

○ Off (feed-in, power connection)

2.0 For your safety

General safety information

- 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 authorised 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/EWG).
- 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.
- The ATMOS® Strobo 21 LED may only be used under the supervision of skilled staff who have been authorised 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 informations 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 (for inst. EN 60950 for data processing equipment and EN 60601 for electrical medical appliances). In addition, configurations must satisfy system specification EN 60601-1-1:2001. When additional equipment is connected to the signal input or signal output section on the device, the person carrying out the connection is deamed „a system configuration operator“ and as such is responsible for meeting the requirements of system specification EN 60601-1-1:2001. For answers to additional questions, please contact your local specialist supplier or the ATMOS Technical Service.

Risk of injury!

- Do not allow any liquid to get into the unit. If liquid has penetrated the unit, 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 using it!
- The treating doctor is responsible for the proper procedure and technology! The adequacy and the kind of application must be decided by a trained doctor according to circumstances.
- Prior to cleaning, switch off the device and separate it from the mains supply resp. 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 quivers.
- To disconnect the device from the mains supply, first remove the plug from the wall outlet. Disconnect the connection line on the device afterwards only. 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.
- This environment 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 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 9.0.
- Please pay attention to the period tests in chapter 6.0 „Service and maintenance“.
- 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 unit in such a way that the operating elements are in clear view and within easy reach of the operator.
  Pay attention to maximum stability of the installation surface.

3.0 Setting up and starting up

3.1 Scope of supply

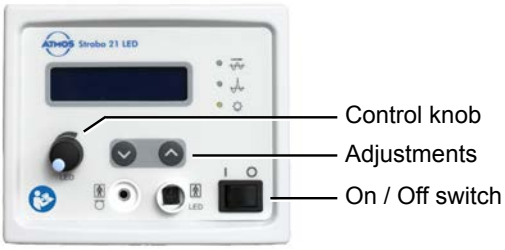
- Control unit
- Airborne sound microphone incl. clip for laryngoscope
- Light handle ATMOS® LS 21 LED incl. adapter Wolf
- Holder for light handle LS 21 LED with switching function (not applicable for ATMOS® Roadster)
- Foot regulator
- Audio cable
- Power supply cord

Optional:

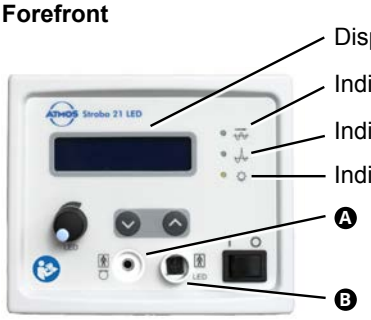
- Impact sound adaptor for airborne microphone
- Holder for laryngoscope (1 quiver)

3.2 Connections

Control panel



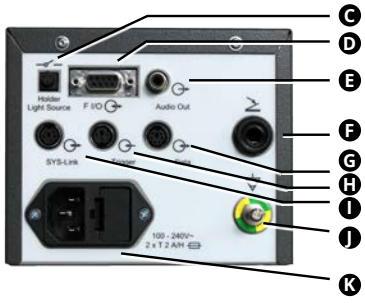
Forefront



Ⓐ Connection for microphone

Ⓑ Connection for LED light handle

Backside



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

Ⓓ Optional connection for the MediaStroboscope

Ⓔ Audio output (Line-out)

Ⓕ Connection for foot regulator

Ⓖ DATA Interface

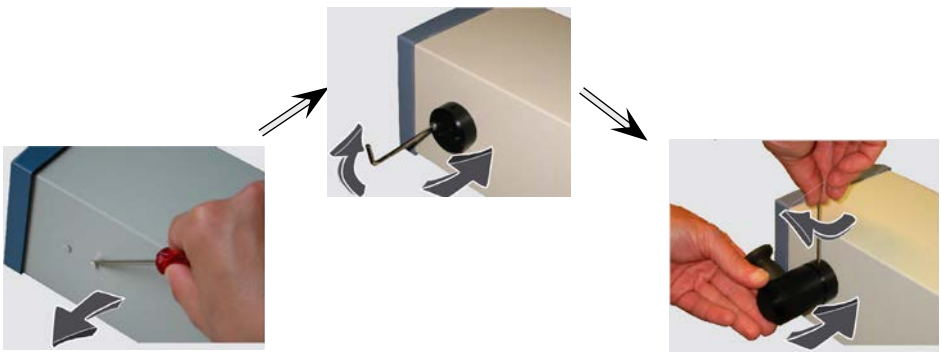
Ⓗ No function

Ⓘ No function

Ⓙ Connection for potential equalization

Ⓚ Nut for mains supply

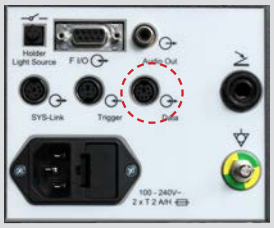
3.3 Mounting the holder for light handle (not applicable for ATMOS Roadster)



3. 4 Starting up

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

ATMOS®
Strobo 21 LED



ATMOS® Cam 31 DV Data
3. Generation

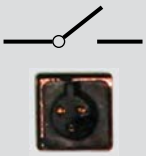
(not applicable for ATMOS® Cam 21 / 31, 2. Generation)

1

F

(not applicable for ATMOS® Roadster)

2



C

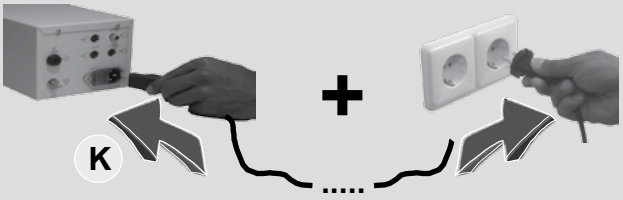
3

B

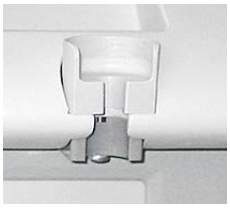
4

A

5



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

ATMOS® Cam 31
DV Data
❶

Foot
controller

ATMOS® Cam 31
DV Data
❷

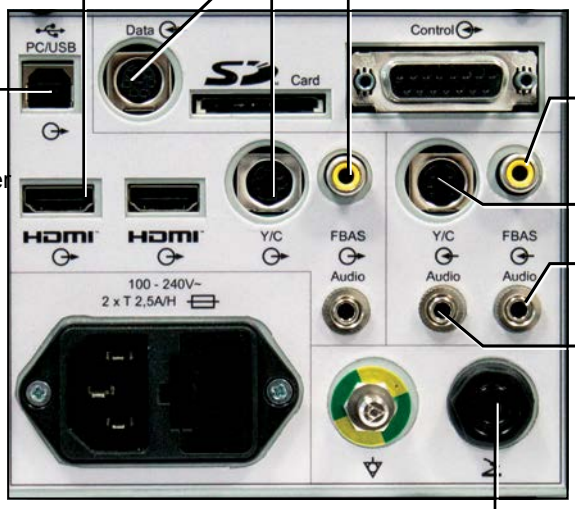
ATMOS® Strobo 21 LED

digital

analogue

ATMOS® Strobo 21 LED ❷

Computer
MS-Windows 7 or higher
USB Streaming
ATMOSoft



FBAS video source
e.g. ATMOS® Scope

S-video source (Y/C)
e.g. ATMOS® i View

external microphone
REF 507.1806.0

ATMOS® Strobo 21 LED ❶

ATMOS® Cam 31 DV Data
3. Generation

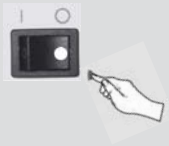
4.1 Switching on and off

⚠ Prior to each use a function check has to be performed. See chapter 6.0 “Service and Maintenance”.

Switching on

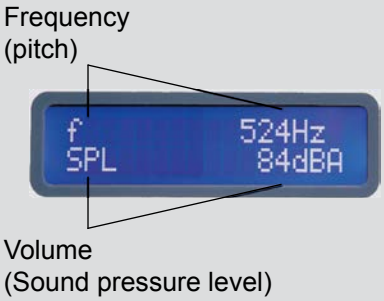
After switching on the device it takes a few seconds until it is ready for operation.

Switching off

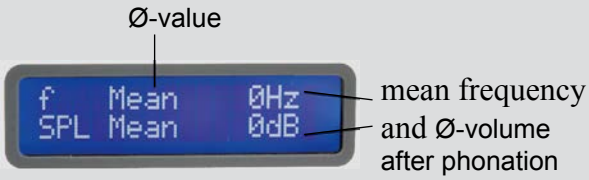


4.2 Functions of display

4.2.1 Indication during examination



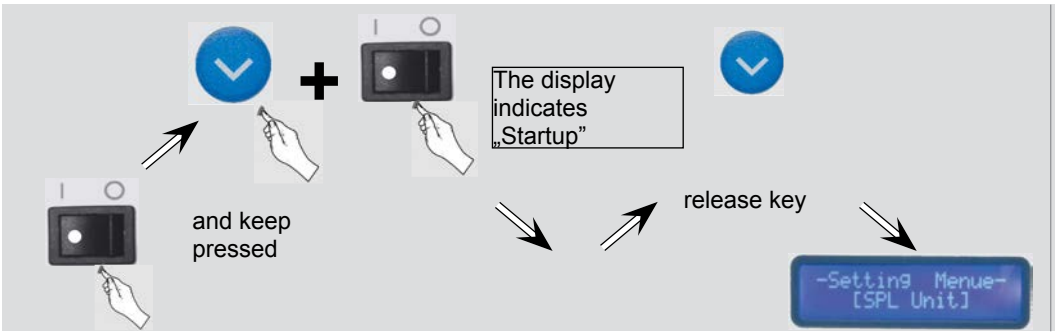
4.2.2 Indication after examination



Change of contrast

4.2.3 Setting menu

Access „Setting Menu“



Select menu

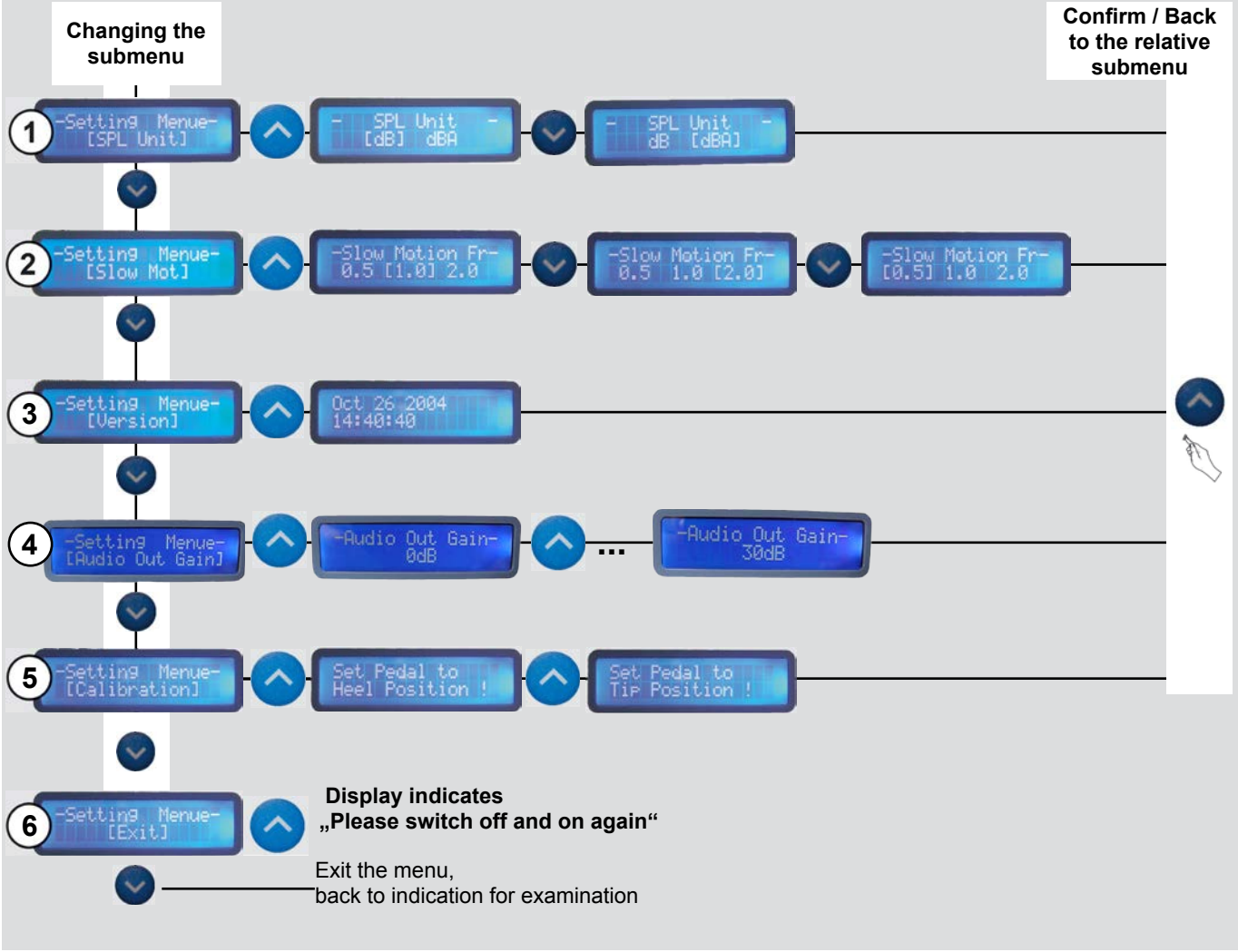
Select submenu

Confirm, „Set“, „Continue“

Adjustable submenus (see next page)

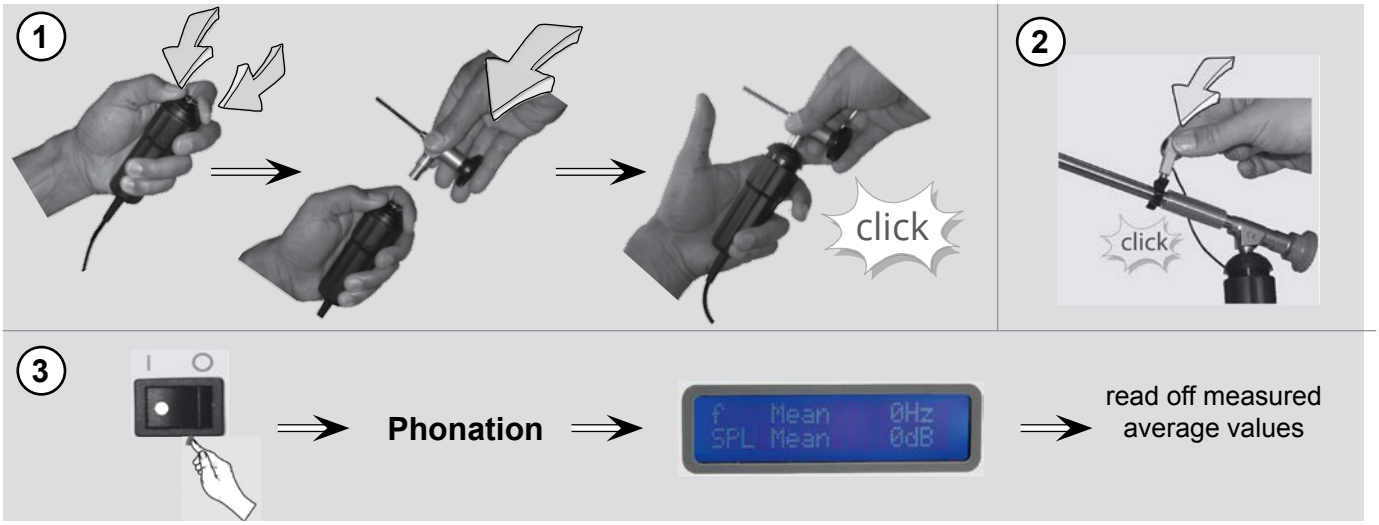
1. **SPL Unit:**
   Setting dB or dBA
2. **Slow Motion:**
   Setting speed of slow motion →
   0.5: 1 oscillation / 2 sec
   1.0: 1 oscillation / sec
   2.0: 2 oscillations / sec
3. **Version:**
   Information about software version
4. **Audio Out Gain:**
   Amplification of the audio signal can be adjusted 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



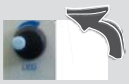
4.3.2 Resolution / Brightness control

After switching on

turn right until limit stop

turn left slowly until requested picture adjustment is obtained

Adjustments



→ LED gets darker

→ LED gets lighter

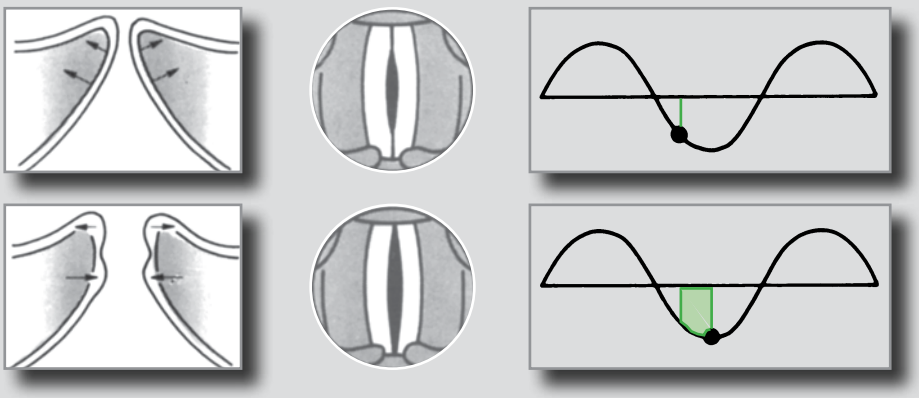
Operating mode of brightness control:

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

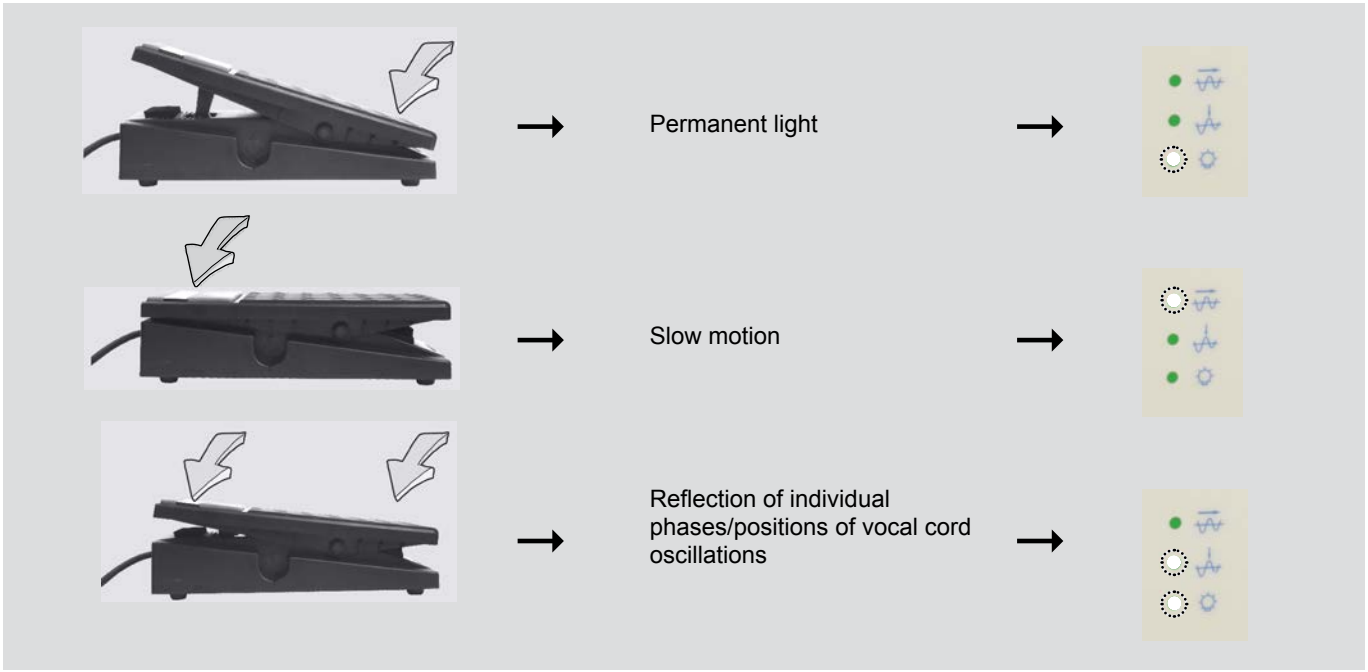
The ATMOS® Strobo 21 LED flashes with 2 Watt. For generating a brighter image, the illumination has to be longer. This entails that the vocal cord oscillates fractionally at this moment.

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 regulator



4.3.4 Operation with other light sources

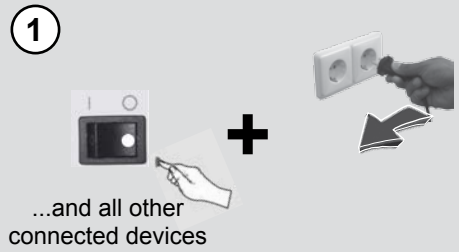
The device can be operated with other ATMOS® light sources or other ATMOS® devices with integrated light sources e.g. with an ATMOS® Scope. During the operation with other devices the light handle ATMOS® LS 21 LED can remain in the light source holder.

5.0 Cleaning and care

5.1 General information on cleaning and disinfection

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



- If required, wipe the camera 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!

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

Cleaning supplies,
→ see page 15

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 Nonionic tensides Solvents, complexing agents	26.0 g	Ecolab, Düsseldorf
Dismozon® pur (Application concentrate) End of product 2014-12	magnesium monoperoxyphthalate hexahydrate	80 g	Bode Chemie, Hamburg
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.

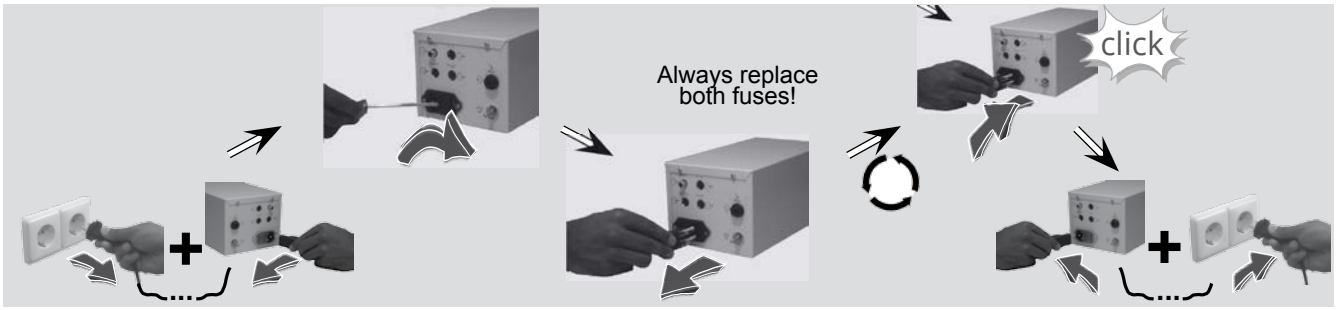
6.0 Maintenance and Service

Medical devices like the ATMOS® Strobo 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 switch works as described in chapter 4.2.3.

6.1 Replacing the fuse



6.2 Period tests

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 authorized 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 and properly dispose of consumables.
- Clean and disinfect the product and accessories according to the operating instructions.
- Place used accessories with the product.
- 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.

- The device must be well padded and packed in suitable packaging.
- Place the 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 to your dealer.

7.0 Troubleshooting

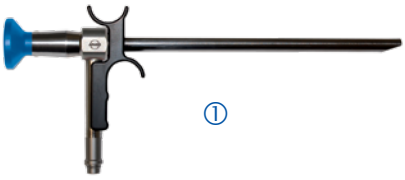
Description	Possible causes of error	Measures
No indication from the device	Power plug is fitted badly	Check fitting of the power plug at the mains power and at the device
	No mains voltage available	Check main fuse
	Defect fuse	Check fuses
Indication is illegible	Insufficient contrast	Adjust contrast 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.
	Acoustic signal cannot be evaluated at all resp. cannot be evaluated properly.	Use the optional obtainable contact microphone.
Image is too dark	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 regulator does not work	Foot regulator is not connected properly.	Check if foot regulator is connected properly. Switch off the device and wait 5 sec until switching it on again.
	Foot regulator has not been calibrated.	Implement calibration. (Enter the submenu ‚Calibration' (see chapter 4.1.3, „Adjustable submenus") and follow the indicated advices.)

8.0 Accessories and spare parts

8.1 Accessories

Impact sound adaptor for airborne microphone	507.4775.0
Holder for laryngoscope (1 quiver)	507.2209.0
Dongle connector for interlink ATMOS® Cam 21 / 31	507.4781.0

Optical instruments



Laryngoscopes

① Laryngoscope 70°, Ø 10 mm, working length 176 mm, autoclavable, without light guide	950.0209.0
Laryngoscope 90°, Ø 10 mm, working length 174 mm, autoclavable, without light guide	950.0210.0
Laryngoscope 70°, Ø 8 mm, working length 166 mm, autoclavable, without light guide	950.0246.0
Tele-magnifying laryngoscope 70°, Ø 10 mm, working length 147.5 mm, can be immersed, without light guide	950.0211.0
Tele-magnifying laryngoscope 90°, Ø 10 mm, working length 145 mm, can be immersed, without light guide	950.0212.0

Ear endoscopes

Wide-angle optic, 0°, working length: 50 mm, Ø 4 mm, autoclavable	950.0213.0
② Wide-angle optic, 30°, working length: 50 mm, Ø 4 mm, autoclavable	950.0214.0
Wide-angle optic, 0° working length: 34 mm, Ø 2,7 mm, can be immersed incl. adapter for ear-speculum	950.0215.0

Nose / Pharynx endoscopes Ø 4 mm

Wide-angle optic, 0°, working length: 180 mm, Ø 4 mm, autoclavable	950.0216.0
Wide-angle optic, 30°, working length: 180 mm, Ø 4 mm, autoclavable	950.0217.0
③ Wide-angle optic, 45°, working length: 180 mm, Ø 4 mm, autoclavable	950.0218.0
Wide-angle optic, 70°, working length: 180 mm, Ø 4 mm, autoclavable	950.0219.0

Nose/Pharynx endoscopes wide angle Ø 2.7 mm

Wide-angle optic, 0°, working length: 110 mm, Ø 2.7 mm, autoclavable	950.0220.0
④ Wide-angle optic, 30°, working length: 110 mm, Ø 2.7 mm, autoclavable	950.0221.0

Flexible endoscopes

⑤ High-resolution naso-pharyngoscope Ø 3.2 mm, working length: 300 mm, 0°, angle of field of view: 80°, depth of focus: 5 mm – infinite, angle: 125° / 125° Scope of delivery includes aluminium transport case and leak tester	950.0243.0

ATMOS® Scope

⑥ Flexible video naso-pharyngoscope with integrated LED light source	950.0300.0

8.2 Spare parts

Airborne sound microphone	507.4780.0
Light handle ATMOS® LS 21 LED	507.4600.0
Light handle ATMOS® LS 21 LED, warm white	507.4602.0
Holder for light handle ATMOS® LS 21 LED with switching function	507.4605.0
Foot regulator	507.4771.0
Power supply cord	507.0859.0
Audio cable	008.0858.0

9.0 Technical data

Operating voltage	100 - 240V, 50/60Hz
Current consumption (max.)	0.3 A/m
Input power	30 VA
Flash frequency	70 - 1000 Hz
Accuracy of displaying flash frequency	+/- 1 Hz
Metering range of sound level	70 - 125 dB
Accuracy of the sound level display	+/- 1dB
Power supply cord	2 m length, earthing contact plug, non-heating
Microphone	Airborne sound microphone, Impact sound adaptor optional
Modes of operation	Continuous light; slow motion 0,5 up to 2 Hz; freeze image 0°- 400° displacement of phase
Operation time	Continuous operation
Models	Table top unit (507.4700.0) Assembly module for S 61 Servant (531.0159.0)
Fuse	2 x 2.0 A/H
Enclosure leakage current (max.)	0.1 mA NC
Patient leakage current (max.)	0.1 mA NC
Earth leakage current (max.)	0.5 mA NC
Heat release	max. 30 Joule/s
Noise level	No noise emission
Ambient conditions Transport / storage	-30° up to 50° 5 bis 90% humidity without condensation at an air pressure of 700 - 1060 hPa
Ambient conditions Operation	5° up to 35° 20 bis 80% humidity without condensation at an air pressure of 700 - 1060 hPa
Dimensions HxWxD	118 x 139 x 280
Weight	5 kg
Period tests	Repeat test of the electrical safety every 24 months. Recommended: inspection according to the manufacturer‘s specifications.
Protection class (EN 60601-1)	I
Degree of protection	BF 
Protection class	IPX1
Classification in accordance with appendix IX EC Directive 93/42/EEC	I
CE marking	CE
UMDNS code	12-346
GMDN code	30008

10.0 Disposal

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

11.0 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, converters and cables other than those stated may lead to an increased emission or a reduced interference immunity of the equipment or system.
- The device may not be used directly next to other devices or piled up with other devices. If operation next to or piled with other devices is necessary, please observe the device to check its intended operation in this arrangement

11.1 Guidelines and Manufacturer´s Declaration - Emissions

The ATMOS® Strobo 21 LED is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® Strobo 21 LED should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The ATMOS® Strobo 21 LED uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions according to CISPR 11	Class B	The ATMOS® Strobo 21 LED is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Inapplicable	
Flicker IEC 61000-3-3	Inapplicable	

11.2 Guidelines and Manufacturer´s Declaration - Immunity

The ATMOS® Strobo 21 LED is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® Strobo 21 LED should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD 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 %.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV common-mode ± 2 kV differential mode	± 1 kV common-mode ± 2 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips / Dropout IEC 61000-4-11	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 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 % 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS® Strobo 21 LED requires continued function during interruptions of the energy supply, it is recommended to supply the ATMOS® Strobo 21 LED from an uninterruptible power supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

11.3 Guidelines and Manufacturer´s Declaration - Immunity

The ATMOS® Strobo 21 LED is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® Strobo 21 LED should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff} 150 kHz to 80 MHz 80 % AM 1kHz	Portable and mobile communications equipment should be separated from the ATMOS® Strobo 21 LED incl. the cables by no less than the distances calculated/listed below. Recommended distances: d = 1.17 √ P d = 1.17 √ P 80 MHz to 800 MHz d = 2.33 √P 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 RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies. NOTE 2 These guidelines may not be applicable in every case. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects and people.
a The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. 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® Strobo 21 LED is used exceeds the above compliance level, the ATMOS® Strobo 21 LED 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 device. b Within the frequency range of 150 kHz to 80 MHz the field strength should be below 3 V/m.

11.4 Recommended safety distance between portable and mobile RF Communications equipment and the ATMOS® Strobo 21 LED

The ATMOS® Strobo 21 LED is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS® Strobo 21 LED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS® Strobo 21 LED as recommended below, according to the maximum output power of the communications equipment.

	Safety distance, depending on transmit-frequency m		
Nominal output of the transmitter W	150 kHz to 80 MHz d = 1.17 √ P	80 MHz to 800 MHz d = 1.17 √ P	800 MHz to 2.5 GHz d = 2.33 √ 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 may not be applicable in every case. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects and people.			

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