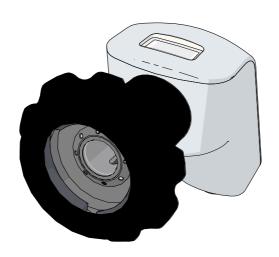


Operating Instructions

ATMOS iQam

English





GA1GB.150405.0

2020-07 Index 03



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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 are designed for training and instructing new operating personnel in the use of the system and are also intended for use as a reference manual. This document may only be reprinted, either in part or in whole, with written permission from ATMOS.

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



Care, periodic tests, regular cleaning, and proper application are essential. They ensure the operational safety and usability of the product.

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



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

The product bears the CE marking CE in accordance with EC Council Directive 93/42/EEC concerning medical devices and meets the basic requirements of Annex I of this directive.

The product complies with all the applicable requirements of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS").

The Declarations of Conformity and our General Terms and Conditions can be viewed on our website at www.atmosmed.com.

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

These operating instructions are valid for the following products:

ATMOS iQam

507.6000.0



1.2 Explanation of pictures and symbols

In the operating instructions

- 10			

Warning of a danger that will result in immediate fatal or serious injury. Observe the necessary measures.

▲ WARNING

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

A CAUTION

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

ATTENTION

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

- Marning of a danger that can cause fatal or serious injury.
- Notice of potential material damage.
- Useful information on the handling of the device.
- 1. Action. Proceed step by step.
- » Result of an action.
- Move, plug in this direction.



On device and type plate



Follow operating instructions (blue)



This product complies with the relevant requirements of the EU Directives



This product may be used in Canada and the USA with a UL-listed product.



Manufacturer



	Manufacturing date
SN	Serial number
REF	Order number
IP68	Degree of protection
	Protection class (EN 60601-1) II
X	Professional disposal

Intended use 1.3

Name: ATMOS iOam

Medical indications /

application:

Imaging of diagnostic endoscopy in ENT medicine

Specification of the

main function:

Endoscopic camera for the digitalization of the endoscopic image and subsequent transmission for process-

ing and representation on a PC

User profile: Doctors and medically trained personnel

Patient groups: Patients of all ages without restrictions

Application organ: Ear, mouth and pharynx, nose

Application time: <60 min

Outpatient medical facilities, e.g., ENT practices, hospi-Area of application:

tal outpatient clinics, ambulatory healthcare centers

Contraindications: No contraindications

The product is: Active

Sterility: Not sterile

Single-use product /

reprocessing:

Not a disposable product. Options for reprocessing

according to the operating instructions.



1.4 Function

The ATMOS iQam is a camera for digitizing an endoscopic image. Via the endoscope coupler a medical endoscope can be fitted single-handedly, this is detected automatically and the optimal camera settings are used. The camera will switch on automatically when you move or change the image and will automatically go into standby mode after use. A status indicator on the camera head and a vibration indicate the operating status of the camera.

The endoscopic image is transferred to a PC and displayed on a monitor. When using the ATMOS Capture Suite software, recordings can be documented as a photo or video. The ATMOS Capture Suite software also allows individual camera settings.

1.5 Intended users

Doctors and medically trained personnel

1.6 Scope of delivery



ATMOS iQam with camera cable



ATMOS Software demo version; Operating instructions (USB flashdrive)



Ouick Guide

1.7 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 damages in transit.
- 2. Send the device to ATMOS; see chapter "6.3 Sending in the device" on page 22.

Ambient conditions for transport and storage:

• Temperature: -40...+80 °C

• Relative humidity: 5...90 % air humidity without condensa-

tion

• Air pressure: 700...1060 hPa



2 Notes for your safety

Please read and pay attention to the safety instructions prior to using the product.

2.1 General safety instructions

Only use accessories and options that are specifically suited for combination with the product and that meet the performance and safety requirements.

The PC used must comply with the standard IEC 60950-1.

If you wish to connect more than one device or application part, you must always observe their safety instructions.

The product uses vibration as haptic feedback. When used in combination with the ATMOS Capture Suite software, the vibration can be deactivated.

2.2 Danger for users, patients, and third parties

Electric shock due to unsuitable power connection, incorrect handling of the product, or damage to product components

Slight injuries are possible.

- Prior to each use, check for damage to the device and the camera cable.
 Do not operate the device if you notice any damage. In this case, clean and disinfect the device and send it to ATMOS for repair.
- The device can only be disconnected from the power supply by pulling out the camera cable.
- Position the device so that it can always be disconnected from the power supply easily.
- Never touch the plug or power cable with wet hands.
- Never touch the device's interfaces and the patient at the same time!
- Only use original accessories and original spare parts from ATMOS.
- Follow the instructions regarding periodic tests in chapter "6.1 Periodic tests" on page 21.
- Assembly, new settings, alterations, extensions, and repairs may only be carried out by authorized persons.
- Do not modify the device without the manufacturer's permission.



Keep the device fully functional at all times.

Malfunctions could cause injury to you and your patients.

- Please observe the notes on the electromagnetic compatibility (EMC) of the device.
- If the camera fails, then use the endoscope without the camera.
- ATMOS recommends: Use only software from ATMOS.

Risk of infection by germs on the product!

Diseases could be transmitted.

- Always wear disposable gloves when using the product.
- Clean and disinfect the product according to the operating instructions.

2.3 Avoiding damage to the device

Unsuitable mechanical stress.

Risk of damage to the camera cable.

- Make sure that the camera cable is not pinched, squeezed, knotted, or clamped off.
- Do not pull on the camera cable.

Storage and operation in an unsuitable environment.

Risk of damage to the product.

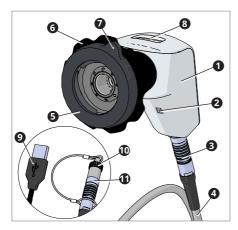
• Please observe the ambient conditions regarding transport, storage, and operation.



3 Setting up and starting up

Device overview 3.1

Front view



- Camera head
- 2 Unique Device Identification (UDI)
- 3 ATMOS connector plug
- 4 Camera cable
- **6** Endoscope coupler
- **6** Focusing ring
- Release lever
- Status indicator
- USB connector (optional)
- Protection cap
- **1** ATMOS connector plug (optional)

3.2 Using with other devices

Only qualified personnel are authorized to install electrical systems. The manufacturer of an electrical medical system is responsible for ensuring that the performance, safety, technical data, and intended use of the ATMOS iQam are not impaired.

Observe the following information when connecting the device in the required combination:

- Refer to the specifications of IEC 60601-1 on medical electrical systems.
- Pay particular attention to the information on the patient environment, multi-outlet power strips, and leakage currents.



3.3 Preparing the device

A Risk of injury and risk of infection due to production residues.

- Prior to first use, prepare the product according to the operating instructions.
- 2. Connect the camera cable to the camera head. Make sure that the red dots on the ATMOS connector plug and camera head are facing each other.
- 3. Perform a function check after connecting.

Connecting to a PC

1. Connect the camera cable (USB connector) to a PC.

Connecting to an ENT treatment unit (ATMOS S 61 Servant vision or ATMOS S 61 CORIAN® integral)

1. Connect the camera cable (ATMOS connector plug) to the corresponding connection on the respective ENT treatment unit.

Corian® is a registered trademark of E. I. du Pont de Nemours and Company or its affiliated companies.

3.4 Installing the software

Observe the operating instructions for the ATMOS Capture Suite software.



4 Operation

4.1 Ambient conditions during operation

• Temperature: +10...+35 °C

• Relative humidity: 20...80 % air humidity without condensa-

tion

• Air pressure: 700...1060 hPa

4.2 Switching on the device

1. Remove the camera from the camera mount or from the shelf.

- » The camera turns on.
- » The camera vibrates 2x.
- » The status indicator lights up blue.

4.3 Switching off the device

- 1. Attach the camera to the camera mount or place the camera on the shelf.
- » The camera goes into standby mode.
- » A hint symbol appears momentarily on the monitor.
- » The status indicator lights up blue at regular intervals ("Breathing").
- To disconnect the camera from the power supply the plug of the camera cable must be pulled.

4.4 Connecting and removing the endoscope



4.4.1 Connecting the endoscope

- 1. Launch the software.
- 2. Press the eyepiece lens of the endoscope into the endoscope coupler of the camera.
- » The camera automatically selects the appropriate settings for the endoscope.
- » The camera vibrates 2x.
- » The recognized endoscope profile appears on the monitor.





4.4.2 Removing the endoscope

- Securely hold the endoscope and turn the release lever 1 to the right.
- » The endoscope is released from the camera.

4.5 Adjusting the image

4.5.1 Focusing the image

- 1. Launch the software.
- 2. Turn the focusing ring.

4.5.2 Zooming

You need the ATMOS Capture Suite software to use this function.

- 1. Launch the software.
- 2. Zoom in on the live image display of the ATMOS Capture Suite software.
- Observe the operating instructions for the ATMOS Capture Suite software.

4.6 Recording videos

You need the ATMOS Capture Suite software to use this function.

Starting and stopping a recording

- 1. Launch the software.
- 2. Select the appropriate mode for video recording.
- 3. Tap 2x on the status indicator (you need the ATMOS Capture Suite software to use this function).
- » The video recording starts.
- » The status indicator lights up red.
- » The camera vibrates 2x.
- » A red dot appears on the monitor.



- 4. Tap again 2x on the status indicator (you need the ATMOS Capture Suite software to use this function).
- » The video recording stops.
- » The status indicator lights up blue.
- You can also start and stop the video recording via the software or a foot switch (only with the ATMOS Capture Suite software).

Pausing a recording

You need the ATMOS Capture Suite software to use this function.

- 1. Pause the recording. Follow the operating instructions for the ATMOS Capture Suite software.
- » The status indicator flashes red.
- » Two red vertical bars appear on the monitor.

4.7 Capturing a photo

- 1. Launch the software.
- 2. In the software, select the appropriate mode for recording photos.
- 3. Tap 2x on the status indicator (you need the ATMOS Capture Suite software to use this function).
- » The photo is taken.
- » The status indicator lights up blue briefly.
- » The camera vibrates 2x.
- You can also record a photo via software or a foot switch (only with the ATMOS Capture Suite software).

4.8 Setting the white balance

You need the ATMOS Capture Suite software to use this function.

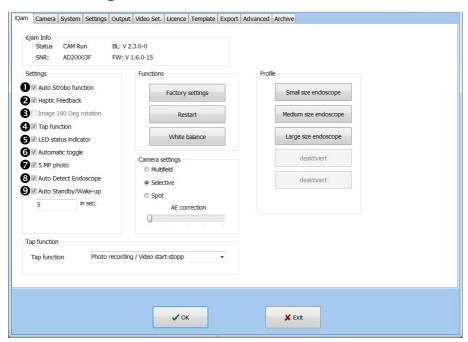
- Do not set the white balance under fluorescent light because otherwise the result may not be satisfactory.
- 1. Launch the ATMOS Capture Suite software.
- 2. Turn on the light source and wait until the light has stabilized.
- 3. Set the white balance preferably under natural lighting conditions. (If possible, point the camera out of the window.) Otherwise, use a white-gray surface.
- 4. Open the window Settings.
- 5. Select the ATMOS iQam tab.
- 6. Click on the white balance button.



Changing the settings 4.9

You need the ATMOS Capture Suite software to use these functions. Observe the operating instructions for the ATMOS Capture Suite software.

Disabling functions 4.9.1



You can disable the following functions:

0	Auto strobo function Haptic feedback	Display of the stroboscope parameters and the corresponding camera settings while stroboscoping Vibration of the camera
8	Image 180° rotation	Rotation of the image by 180° if the camera head is rotated by 180°
4	Tap function	Response when tapping camera head
6	LED status indicator	Status indicator
6	Automatic changeover	Automatic changeover of video source
7	Save 5 MP photo	Saves photo in highest possible resolution
8	Auto Detect Endoscope	Automatic endoscope detection
9	Auto Standby/Wake-up	Automatic transition to standby mode



- 1. Launch the ATMOS Capture Suite software.
- 2. Open the window Settings.
- 3. Select the ATMOS iQam tab.
- 4. Remove the check mark in the corresponding check box.

Changing actions by tapping on the camera head

- 1. Launch the ATMOS Capture Suite software.
- 2. Open the window Settings.
- 3. Select the ATMOS iOam tab.
- 4. Select the appropriate entry in the TAP FUNCTION choice box:
 - Photo recording / video start-stop: Snapshot mode: Capture snapshot, video mode: Start/stop video recording
 - Selection / Pause video: Snapshot mode: Switch to next storage location, Video mode: Pausing and continuing a recording
 - Toggle Photo / Video: Toggling Photo/Video mode
 - White BALANCE: Set the white balance

4.9.3 Setting the time until standby mode is activated

- 1. Launch the ATMOS Capture Suite software.
- 2. Open the window Settings.
- 3. Select the ATMOS iOam tab.
- 4. Select the desired time (in seconds) in Auto STANDBY.

4.9.4 Restoring factory settings

- 1. Launch the ATMOS Capture Suite software.
- 2. Open the window Settings.
- 3. Select the ATMOS iOam tab.
- 4. Click the Factory settings button.



5 Reprocessing

5.1 Safety instructions for reprocessing

5.1.1 General safety instructions

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

It is the responsibility of the user to ensure that the required results of cleaning and disinfection are achieved. Validation and routine monitoring of the procedure will usually be necessary.

Reprocessing may only be carried out by persons who have the necessary expertise. The person in question must have the necessary test devices required to carry out these measures.

5.1.2 Danger for users, patients, and third parties

Risk of infection due to unsuitable accessories.

Deadly diseases could be transmitted.

- Always wear your own personal protective equipment. The protective equipment consists of protective gloves, protective clothing, safety glasses and mouth and nose protection for all steps for which the product components are contaminated.
- Only use accessories which can be easily sterilized or use disposable products.

5.1.3 Avoiding damage to the device

Unsuitable accessories.

Risk of damage to the product.

- Only use lint-free, soft cloths.
- Always use demineralized water for the final rinse.
- Follow the corresponding operating instructions of all accessories and devices used.



Unsuitable cleaning agents and disinfectants.

Risk of damage to the product.

- Do not use any process chemicals containing the following ingredients **on** plastic parts:
 - · Chloramide or phenol derivatives

5.1.4 Further cleaning instructions

Image quality could be affected even by the slightest contamination, such as fingerprints. After use, the camera can be protected from dust by storing it on the designated camera mount or by covering it. The external surfaces of optical components should only be cleaned when necessary. Dust which has accumulated on the optical surfaces can be blown off or removed with a soft, clean brush.

Preparing and completing reprocessing 5.2

After reprocessing

1. Perform a function check.

Preparing surfaces 5.3

5.3.1 **Overview**

Surface	After each application	After each patient	Daily	Weekly	Every 14 days	Monthly	Pre-cleaning	Wipe cleaning	Wipe disinfection	Immersion disinfection	Remarks
camera head		χ							χ	χ	



5.3.2 **Selecting process chemicals**

Observe the manufacturer's specifications for the process chemicals.

Product			Surface 1
	Active ingredients in 100 g	Art	Su
	manual reprocessing		
Tristel Wipes® (Tristel GmbH)	Oxidizing agent Propan-2-ol	Wipes Ready-to-use	Х
neodisher® MediClean forte (Dr. Weigert)	Enzymatic <5 % nonionic and anionic surfactants, enzymes	Liquid Concentrate	Χ
mikrozid® sensitive wipes (Schülke & Mayr)	Quaternary ammonium compounds 0.26 g alkyl (C12-16) dimethylbenzylammonium chloride Didecyldimethylammonium chloride (DDAC), 0.26 g Alkyl (C12-14) ethylbenzyl ammonium chloride	Wipes Ready-to-use	Х
mikrozid® universal wipes (Schülke & Mayr)	Alcohols Propan-2-ol Ethanol	Wipes Ready-to-use	Χ
Gigasept® pearls (Schülke & Mayr)	Peroxide compound Sodium percarbonate, citric acid, sodium carbonate	Granulate	Х
Helipur® H plus N (BBraun)	Aldehydes Glutaraldehyde 12.0 g, propan-2-ol, 7.5 g, ethylhexanol 0.5 g, anionic surfactants	Liquid Concentrate	Х
Cidezyme® / Enzol® (Advanced Steriliza- tion Products)	Enzymatic Subtilisins (proteolytic enzymes)	Liquid Concentrate	Χ
Disinfectants - m	anual reprocessing		
Tristel Wipes® (Tristel GmbH)	Oxidizing agent Propan-2-ol	Wipes Ready to use	Х
mikrozid® sensitive wipes (Schülke & Mayr)	Quaternary ammonium compounds 0.26 g alkyl (C12-16) dimethylbenzylammonium chloride Didecyldimethylammonium chloride (DDAC), 0.26 g alkyl (C12-14) ethylbenzylammonium chloride	Wipes Ready-to-use	Х
mikrozid® universal wipes (Schülke & Mayr)	Alcohols Propan-2-ol Ethanol	Wipes Ready-to-use	Х
Gigasept® pearls (Schülke & Mayr)	Peroxide compound Sodium percarbonate, citric acid, sodium carbonate	Granulate	Х



Product (manufacturer)	Active ingredients in 100 g	Art	Surface 1
Gigasept® FF (Schülke & Mayr)	Aldehydes Reaction product of DMO-THF, ethanol and water, Phosphonates, anionic and non-ionic surfactants, perfumes, methylisothiazolinones	Liquid concentrate	Χ
Revital-Ox® Resert® (Steris)	Enzymatic 2-furancarboxylic acid, hydrogen peroxide, potassium hydroxide, phosphoric acid, 1-hydroxyethane-1, 1-diphosphonic acid	Liquid Concentrate	χ
Cidex OPA (ASP)®	0.55 % ortho-phthalaldehyde	Liquid Ready to use	Х

5.3.3 Procedure

Pretreatment at the site of use	Not necessary				
Pre-clean	Not necessary				
Dismantle	Not necessary				
Manual cleaning and disinfection	1. Clean the device evenly with a suitable cloth and a suitable detergent under running water.				
	2. Immerse the device in the cleaning solution (follow manufacturer's instructions) and clean it in the solution evenly with a suitable cloth.				
	3. Disinfect the device evenly with a suitable cloth and a suitable disinfectant. Wait for the exposure time to work.				
Checking and maintaining	1. Check the success of the reprocessing with a suitable light magnifier.				
	If reprocessing was unsuccessful, the procedure must be repeated.				
Assembly	Not necessary				
Function check	Other: Coupler shoe function				
Packaging	Not necessary				
Sterilizing	Not necessary				

There are material compatibilities for the sterilization process from STERIS for thermolabile flexible endoscopes.



Maintenance and service 6

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

For design reasons it is not possible to repair the ATMOS iQam on site. Always send defective devices to an authorized ATMOS Partner for repair. ATMOS does not accept any liability for damage resulting from unauthorized interventions.

Maintenance, repairs, and periodic tests **may not** be carried out while the product is being used on the patient.

6.1 **Periodic tests**

Observe the specifications for the individual components.

Function check 6.2

Always perform a function check when connecting the camera cable. Perform a function check at least once a week.

- 1. Check if the following items are obviously damaged, missing, or not properly connected:
 - · camera head
 - · camera cable
 - Accessories
- 2. Check whether the parts mentioned above are hygienically harmless.
- If you find any damage, please remedy it. 3.
- 4. Connect the camera cable if it is not already connected.
- 5. Connect an endoscope.
- 6. Check the connection camera head - endoscope.
- 7. Check if the status indicator light up blue.
- Check if the image is displayed on the monitor.
- 9. Focus the image.
- 10. Check if the image is sharp.
- 11. Take a photo or make a video and check whether the camera vibrates 2x when activated



6.3 Sending in the device

- 1. Clean and disinfect the product and accessories in accordance with the operating instructions.
- 2. Place any used accessories with the product.
- 3. Fill in the form QD 434 "Delivery complaint / return shipment" and the respective **decontamination certificate**.
- This form is enclosed with each delivery and can be found at www.atmosmed.com.
- 4. The device must be well padded and packed in suitable packaging.
- 5. Place the QD 434 "Delivery complaint / return shipment" form and the respective **decontamination certificate** in an envelope.
- 6. Affix the envelope to the outside of the package.
- 7. Send the product in to ATMOS or your dealer.



Troubleshooting

The product has been subjected to a thorough quality control in the factory. If a fault should occur despite this check, you may be able to resolve it yourself.

Error symptom	Possible cause	Remedy
The status indicator lights up yellow.	Technical defect.	Contact an authorized ATMOS service partner.
The camera does not display the colors correctly.	Color settings are optimized for LED light sources.	Colors may be displayed incorrectly when affected by extraneous light. Check color fidelity when using an endoscope without ambient light (e.g., during use); see "4.8 Setting the white balance" on page 14
Camera does not vibrate.	Function has been deactivated.	Activate the function in the ATMOS Capture Suite soft-
Status indicator does not work.		ware; see page 15.
Endoscope is not detected automatically.		
Camera does not go into standby mode.		
Camera does not respond when the camera head is tapped on.		



8 Accessories

Accessories	REF
ATMOS Capture Suite HD License Dongle	700.0047.0
Software for displaying and archiving video signals on a PC. Up to 8 single frames can be temporarily frozen and saved in a PDF or Word document.	
Further functions:	
 Saving and editing photos (JPG format) 	
 Saving and editing video sequences (mp4 format) 	
Selection of different cameras	
ATMOS patient database for processing diagnostic results. Optimizing the video signal (brightness, definition, contrast).	
Scope of delivery:	
 Right of use for the ATMOS Capture Suite HD 	
 Licensing via dongle 	
ATMOS Controller for visualization	507.6200.0
High-performance compact PC for the medical environment. Aluminum housing in small format and with noiseless cooling.	
Scope of delivery:	
 Compact PC (Windows IoT Enterprise) 	
External power supply unit	
Power cable EU 2.5 m (angled)	
 VESA assembly kit for mounting behind the monitor 	



Accessories	REF
ATMOS Medical Monitor 21.5" Touch	507.3128.0
The ATMOS Medical Monitor 21.5" Touch is an especially flat compact monitor for use in the medical environment. Completely enclosed metal housing, double-coated safety glass plate, backlit keypad with power switch, status indicator, and brightness control.	
Remote On for the ATMOS Compact PC and ATMOS Controller.	
Scope of delivery:	
ATMOS Medical Monitor Touch	
Display port cable	
 Power cable EU 2.5 m (angled) 	
• 2.5 mm cinch-cinch	
• USB cable	
360° diagnostics foot switch for controlling	512.0600.0
ATMOS LS 31 LED	531.2100.0
Endoscopic LED light source.	507.4800.0



9 Spare parts

Spare part	REF
ATMOS iQam camera head	507.6036.0
♡ Without camera cable	
ATMOS iQam camera cable USB	507.6028.0
 For connection to a PC. For transmission of image and control information of the ATMOS iQam. 	



10 Disposal

Packaging

1. Please recycle the product packaging.

Product

Do not dispose of the product together with household waste.

The product does not contain any hazardous materials.

- 1. Clean and disinfect the product.
- 2. In Germany: Send the product back to ATMOS or your specialist dealer. They will dispose of the device professionally.
- 3. In other countries: Dispose of the product properly and in accordance with country-specific laws and regulations.

In Germany, the device is excluded from the Electrical and Electronic Equipment Act (ElektroG) in accordance with the National Register for waste electric equipment because it may be contaminated. Do not discard the product in electronic waste.

The housing is fully recyclable. Refer to the country-specific laws and regulations.





11 Technical data

ATMOS iQam

Voltage	5 V (USB 2.0)
Current consumption	Max. 0.5 A (USB 2.0; 5 V ===)
Power consumption	Max. 2.5 W
Other power sources	None
Fuses	n/a
Other safety equipment	n/a
Performance parameter 1	n/a
Performance parameter 2	n/a
Operating time	Continuous operation
Protective earth conductor	n/a
resistance	n/a
Earth leakage current	n/a
Housing leakage current	n/a
Patient leakage current	
Ambient conditions for transport/storage	
Temperature:	-40+80 °C
Air humidity:	590 % air humidity without condensation
• Pressure:	at an air pressure of 7001060 hPa
Ambient conditions for operation	
Temperature:	+10+35 °C
Air humidity:	2080 % without condensation
Pressure:	at an air pressure of 7001060 hPa
Maximum operational altitude	4000 m (NN)
Contamination level	Class 2
Overvoltage category	I
Dimensions H x W x D	7.7 x 5.7 x 9.0 cm
Weight	0.183 kg
Periodic tests	None



Protection class (EN 60601-1)	II
Degree of protection	Application parts type BF 🛕
Type of protection	IP 68
Classification according to Annex IX, EC Directive 93/42/ EEC	Class I according to regulation 12
CE marking	CE
GMDN code	17002
UMDNS code	17-002
MD/MDS code	MDA 0204
ID No. (REF)	507.6000.0

Updated: November 2019



12 Notes on EMC

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

Guidance and manufacturer's declaration – ambient conditions

The ATMOS iQam is suitable for use in the following environments:

 Environment in professional healthcare facilities such as doctor's practices, clinics, or first-aid facilities as well as operating rooms and outside of the HF-shielded room of a magnetic resonance imaging system.

The customer or user of the ATMOS iQam 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 – for accessories, transducers. and cables

The ATMOS iQam has the following accessories, transducers and cables:

Туре	REF	Max. cable length
ATMOS iQam camera cable with USB connector	507.6028.0	2 m

Guidance and manufacturer's declaration - warnings



The use of accessories, transducers, and cables other than those specified or provided by the manufacturer may cause increased electromagnetic emissions or reduced immunity to electromagnetic interference and result in faulty operation.



Portable HF communications equipment (e.g., radios, antenna cables) should not be used within 30 cm* of any parts or cables of the ATMOS iQam as specified by the manufacturer. Failure to do so may result in a reduction in the device's performance.

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



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MedizinTechnik

🖬 ATMOS MedizinTechnik GmbH & Co. KG

Ludwig-Kegel-Straße 16

79853 Lenzkirch/Germany

Phone: +49 7653 689-0

info@atmosmed.de

www.atmosmed.com