



GIMA

PROFESSIONAL MEDICAL PRODUCTS

FONTE DI LUCE LED PORTATILE 200.000 LUX

PORTABLE LED LIGHT SOURCE 200.000 LUX

- È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

- All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

REF

AGS-PL100 (GIMA 30796)



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AGS-PL100COLDLIGHTSOURCE

Instruction Manual



You must use a network outlet with a protective grounding wire and ensure a good grounding.



Do not alter this device without authorization from the manufacturer.

Overview

The cold light source for endoscopy is mainly composed of LED cold light source, control circuit and battery, which can be connected with endoscope through optical fiber for clinical endoscopy or deep surgical illumination, etc. Using LED light as the light source, there are three grades of brightness, with convenient and simple adjustment, low temperature and long life.

Classification

Electrical safety classification	Internal power supply equipment
Operation mode	Continuous
Device	Non-AP or APG type equipment

MainParameters

N°	Main Specifications	Parameters	Number	Main Specifications	Parameters
1	Battery	18650 Lithium battery	4	Luminous flux	110lm
2	Multiple-power supply Time	>5h	5	Color temperature	5700K
3	Product-netweight	90g	6	Light-source	LEDLamp

WorkingCondition

Operating environment	Temperature	+5℃ ~ +40℃
	Relative humidity	30% ~ 80%
	Atmospheric pressure	700hPa ~ 1060hPa
Power requirements	Operating voltage	DC3.7V

TechnicalIndicators

1	Light output hole	Diameter (10±0.1mm)
2	Color Index	≥90
3	Color temperature	5700K±500K
4	Luminous flux	110lm
5	Illumination Limit	≤2
6	Ratio of irradiation flux to luminous flux in the wavelength range of 300nm-1700nm	≤6mW/lm

Structure and Principle

Composition

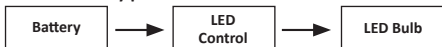
The cold light source for endoscope consists of LED cold light source, control circuit, and battery.

Principle

After the battery output DC3.0-4.2V to the control circuit, the control circuit gives power to the light source bulb, and then the light from the bulb is transmitted to the optical fiber. Use optical fiber as the light transmission medium to transmit the light energy to the illuminant or other lighting systems.

The electrical block diagram shown below:

Internal battery power status



Scopes of Application and Contraindications

AGS-PL100 cold light source for endoscope has low power consumption, high efficiency, stable performance and long service life.

Scope of application: It can be connected with endoscope through light guide bundle for clinical endoscopy or deep surgical illumination, etc.

Precautions: Do not exposure to the human eye directly during use.

Caution and Precaution

- Please carefully read the security warning and precaution provided in this manual to ensure safe and efficient use of cold light sources.
- Please do not overcharge and discharge to avoid affecting the service life of the cold light source battery.
- Do not touch the ends of the battery with wet hands or short circuit the battery.
- If you do not use it for a long time, please remove the battery and store it.

- Fiber optic cable can not be too curved, and the radius of curvature should not be less than 5CM, otherwise it will break the fiber optic cable, affecting the light rate.
- Before each use, the user must check whether there is any rough surface, sharp edges or protrusions on the endoscope, especially the part inserted into human body, which would cause safety hazards probably.
- If the endoscope equipment is damaged (broken or fractured, etc.), please replace the endoscope equipment in time, otherwise the endoscope will likely overheat.
- When connecting an interoperable device (endoscope, guide bundle, etc.), select the interoperable device with the applicable connection specifications (e.g., guide bundle with Wolf connector).
- Please do not look directly at the light outlet to avoid permanent damage to the eyes.
- Please do not replace the LED lights by yourself, so as not to cause irreparable damage to the equipment. If you have a need for replacement, please contact your local agent or manufacturer.
- The output part of cold light source may exceed 41°C. It is advisable to reduce the brightness as well as to avoid prolonged exposure to the same site in case of the burns when used with endoscope simultaneously.
- For your safety and the safety of others, please do not disassemble the cold light source.
- If there is abnormal smell and noise in running when using it, immediately turn off the power and contact the local dealer or our after-sales service department.
- Since this is a medical electronic product, there would be electronic pollution to the environment after disposal. Therefore, it should be disposed of strictly in accordance with the rules and regulations in your country when your product reaches its end of life. The user should contact the one whose qualification is available for disposal. It is prohibited that users dismantle and dispose of discarded product unauthorized.
- If the LED lamp is suddenly off during use, anyone who wants to repair it should have relevant knowledge and ability, and sunglasses, a good insulated glove and electrostatic bracelet is required as well as the power supply should be cut off. It is not allowed to look directly at the lamp with naked eyes and touch the lamp with hand. Or contact the manufacturer or local distributor for help. Any parts of the machine should not be disassembled or replaced without authorization.
- When used together with high frequency surgical equipment,

pments.

It is advisable to keep the working part of the live electrode within the operator's range of vision to prevent accidental high-frequency burns. In order to guarantee a right position for the charged electrode during surgery, there should be enough distance between electrode and endoscopic head. Before the high-frequency output is excited, avoid contact with the metal parts and conductors of endoscope, including liquid nozzles that may be a conductor. Insulation accessories without high-frequency stimulus may be exposed to live electrode protection during surgery. Avoid contralateral high-frequency burns. Use the high-frequency current for the lesion but not for the normal mucosa. Use non-conductor eyepiece cap to reduce the risk of high-frequency burns around the face of eye. Choose the output power that suits the intended operation, especially avoiding a too low output power which leads to a tissue thermal damage and avoiding a too high output power which leads to much bleeding caused by an ineffective blood clotting.

● Working conditions

If you need to replace the battery, please use the standard voltage DC3.7V cylindrical 18650 lithium battery. (The working time of this product is affected by the capacity of the replaced battery.)

The battery of this product is rechargeable, please use the DC3.7V cylindrical 18650 lithium battery charger that meets the local standard.

Electromagnetic Compatibility



Caution:

- AGS-PL100 cold light source for endoscope meets the YY0505-2012 standard on electromagnetic compatibility requirements.
- The user should install and use the device according to electromagnetic compatibility information offered in the instruction.
- Portable and mobile RF communication equipment may affect AGS-PL100 coldlight source for endoscope. Avoid strong electromagnetic interference when use, such as mobile phone, microwave ovens.
- The guide and the manufacturer's statement are detailed in the attachments.



Warning:

- The device should not be stacked with other equipment or be too close to other equipment. If you have to, you should

check if it can function normally in the right configuration.

- Class A equipment is intended for use in industrial environment. As AGS-PL100 cold light source for endoscope would transmit with interference, there may be potential difficulties to ensure electromagnetic compatibility in other environments.

- The use of accessories, transducers and cables that is not manufactured or authorized by the manufacturer may result in the increase cost of maintenance of the device and the decrease of the immunity.

- Place the cold light source away from electromagnetic interference, such as portable and mobile wireless communication devices.

- The cold light source should in accordance with the requirements of transmission and immunity to unrelated electromagnetic wave. Any incorrect replacement of original parts of the device may result in decreases of immunity to unrelated electromagnetic wave and failure of the cold light source even.

Attachment:

Guidance and manufacturer's statement - Electromagnetic emission		
AGS-PL100 cold light source for endoscope is expected to be used in the following specified electromagnetic environment, the user should ensure the device is used in this electromagnetic environment:		
Emission Test	Compliance	Electromagnetic Environment-Guide
GB4824 RF Emission	1set	AGS-PL100 cold light source for endoscope use RF energy only for its internal function. As a result, its RF emissions are low and will not cause any interference to nearby electronic equipment theoretically.
GB4824 RF Emission	AClass	AGS-PL100 cold light source for endoscope is suitable for use in all non-home facilities and the facilities that are not connected to the residential public low - voltage power supply network directly.
GB17625.1 Harmonic Emission	Not applicable	
GB17625.2 Voltage Fluctuation/ Flashing Emission	Not applicable	

Guidance and manufacturer's statement-Electromagnetic immunity			
AGS-PL100 cold light source for endoscope is expected to be used in the following specified electromagnetic environment, the user should ensure the device is used in this electromagnetic environment:			
Immunity Test	IEC60601 Test Level	Match Level	Electromagnetic Environment-Guide
Electrostatic Discharge (ESD)GB/T 17626.2	±6kV Contact Discharge ±8kV Air discharge	±6kV Contact Discharge ±8kV Air Discharge	The ground should be wood, concrete or tiles, if the ground is covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient GB/T 17626.4	Not applicable		
Electrical Surge GB/T 17626.5	Not applicable		
Voltage sag, short interrupt and change in power input line GB/T 17626.11	Not applicable		
Frequency Magnetic Field (50/60Hz)GB/T 17626.8	3A/m	3A/m	The electromagnetic field should have the frequency characteristics applied in typical commercial or hospital environment.
Note: U_T refers to the AC voltage before applying the test voltage.			

Guidance and manufacturer's statement-Electromagnetic immunity			
AGS-PL100 cold light source for endoscope is expected to be used in the following specified electromagnetic environment, users should ensure the device is used in this electromagnetic environment			
Immunity Test	IEC60601 Test Level	Match Level	Electromagnetic Environment-Guide

RF Trans- mit GB/ T17625.6	3Vrms 150kHzto80 MHz	3Vrms	Portable and mobile RF commu- nication equipment as well as cables should not be used more closely to any parts of AGS-PL100 cold light source for endoscope than the recommended isolation distance. The distance should be calculated by the formula corresponding to the transmitter frequency.
RF Radia- tion GB/ T17626.3	3V/m 80MHzto2,5 GHz	3V/m	Recommended isolation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ Where P is the maximum output rated power provided by the tran- smitter manufacturer in watts and d is the recommended isolation distance in meters. ① The field strength of the fixed RF transmitter is determined by the investigation ② of the electromagnetic field, which should be lower in each frequency range than the coincidence level. Interference may occur near the device marking the following symbols. 

Note 1: At frequencies of 80 MHz and 800 MHz, the formula in the higher frequency band is used.

Note 2: These guidelines may not be suitable for all situations where electromagnetic transmission is affected by the absorption and reflection of buildings, objects and humans.

① Fixed field strength, such as: wireless (cellular / cordless) telephones and terrestrial mobile radio base stations, amateur radio, AM (AM) and FM (FM) radio and television broadcasts, the field strength in theory can not be accurately Predicted. If the field strength of the AGS200/AGS100 medical cold light source for endoscope is higher than the RF compliance level given above, the device should be observed to verify its normal operation. If abnormal performance is observed, the supplement may be necessary, such as re-positioning or positioning the AGS200/AGS100 medical cold light source for endoscope.

② In the 150KHz ~ 80MHz the entire frequency range, the field strength should be less than 3 V / m.

Recommended isolation distance between portable and mobile RF communication equipment and AGS-PL100 cold light source for endoscope.

AGS-PL100 cold light source for endoscope is expected to be used in radiated RF harassment controlled electromagnetic environments. According to the maximum output power of the communication equipment, the user of AGS-PL100 cold light source for endoscope can prevent electromagnetic interference by keeping the recommended minimum distance listed following between portable and mobile RF communication equipment(transmitter) and AGS-PL100 cold light source for endoscope.

Transmitter rated maximum output power /W	Isolation distance at different frequency transmitter/m		
	150kHz~80 MHz $d = 1.2\sqrt{P}$	80MHz~800 MHz $d = 1.2\sqrt{P}$	800MHz~2,5GHz $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the table above, the recommended isolation distance d , in meters (m), can be determined using the formula in the corresponding transmitter frequency bar, where P is transmitter maximum output rated power provided by the transmitter manufacturer in watts (W).

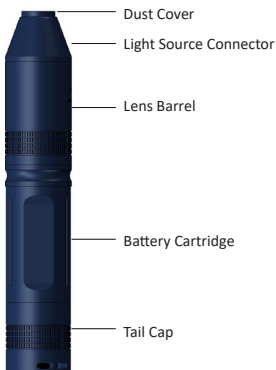
Note 1: At frequencies of 80 MHz and 800 MHz, the formula in the higher frequency range is used.

Note 2: These guidelines may not be suitable for all situations where electromagnetic transmission is affected by the absorption and reflection of buildings, objects and humans.

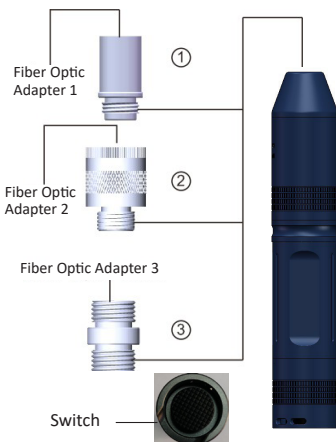
The AGS-PL100 cold light source for endoscope has been tested in accordance with YY0505-2012/EN 60601-1-2, which, however, is not guaranteed that the device will not be affected by electromagnetic interference in every ways. The medical cold light source should use avoiding a high electromagnetic environment.

Instructions for use

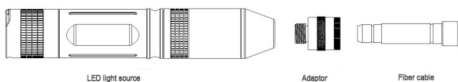
1. Description



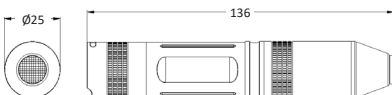
Configuration diagram



Cold light source and light guide bundle connection schematic



LED cold light source structure diagram



2. Installation

Take out the cold light source and battery from the box, loosen the tail cap, put the battery into the battery barrel when positive pole facing forward and then put back the tail cap. Remove the dust cover, and then according to the lens specifications to choose the appropriate adaptor into the light source connector. After pressing the switch, you will hear a beep when the light turns up. Press the switch a second time to increase the brightness and a third time to reach the brightest brightness, and then press the switch again to turn off the LED light.

The brightness is adjusted by the switch behind the tailcap (Note: adjusted by the user according to the following). The brightness adjustment range has 4 grades, each grade is 33%. Please see the following table for the illumination value corresponding to each 33% grade.

Number	Position	Luminous flux
0	0	0
1	1	≥25lm
2	2	≥65lm
3	3	≥110lm

- Get the sterilized optical fiber threaded to the light source connector through a fiber optic adaptor to start working.
- Note: Connect the optical fiber correctly before turning on the cold light source. Looking into the optical fiber can seriously damage your eyes. The use place must be explosion-proof area.

3. Turnoff

Press the cold light switch until the off state after use.

Maintenance and Cleaning

1. Use hydrogen-containing disinfectant to clean the outside of the equipment.
2. To keep the system clean, gently wipe the surface of the equipment with a soft damp cloth (gauze) that is warmed by warm water or that is with a cleaning agent. The cleaning should be at least once a month, and should avoid liquid infiltration into the cold light source.
3. Do not use dilute ethylene oxide or other organic solution, nor use any solvent or polishing agent, preventing damage to the cold light source shell.
4. Do not use flammable and explosive liquids to clean and disinfect. If you must, these liquids must have gone from the equipment before the equipment start.

Store

The packed cold light source should be stored in where the ambient temperature is $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$ and where the relative humidity is within the range of 10% to 80% and where is cool and dry with a well ventilated clean environment without corrosive gases.

Fault and Repair

When there are some problems with your cold light source, it will works usually by troubleshooting follow the table below if the cold light source fails. If problems remain the same, please contact our company or the authorized after-sales service.

Problems	Solutions
After turning on, the light does not light up	1. Check whether the batteries are installed backwards. 2. Check whether the battery is charged
LED lamp is off during running.	1. Replace the battery. 2. Return for replacing the LED.
Brightness cannot be adjusted after power on	Return for repair

Production Date and Period of Use

The production date is shown in the laser engraving on the front of each cold light source shell, and the use period is 5 years from the date of use.

Symbols

	Caution: read instructions (warnings) carefully		Follow instructions for use
	Keep in a cool, dry place		Keep away from sunlight
	Product code		Lot number
	Medical Device compliant with Regulation (EU) 2017/745		WEEE disposal
	Medical Device		Manufacturer
	Authorized representative in the European community		Date of manufacture
	Temperature limit		Humidity limit
	Unique device identifier		Imported by



Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.