



ISA

User's guide

DECLARATION OF CONFORMITY

The manufacturer G.COMM
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20872 Cornate D'Adda (MB)
Italy,

DECLARES

under its sole responsibility that the equipment of

Model: ISA

complies with the requirements of the Italian Law D.Lgs. 46 dated 24/02/97 which enacts the European Directive 93/42/EEC, amended with the Italian Law D.Lgs. 37 dated 25/01/10 which enacts the European Directive 2007/47/EC on medical devices of Class I.

This product complies with the following norms:

- EN 60601-1 :1990 “Medical electrical equipment – Part 1 : General requirements for safety ” + A1 :1993 + A2 :1995
- EN 60601-1-2:2001 “Medical electrical equipment - Part 1: General norms on safety - 2: Collateral standard: Electromagnetic Compatibility - requirements and tests” + A1:2006
- EN ISO 14971:2007 “Application of risk management to medical devices”
- UNI EN ISO 9680:1996 “Dental operating light”

G.COMM also states that this declaration of conformity is valid provided that:

1. periodical servicing is performed only by G.COMM's instructions and by G.COMM's authorised personnel;
2. no part of these products is replaced with spares which are not approved by G.COMM;
3. no appliance is connected to these products after their first delivery without prior G.COMM's authorisation.

As stated in DPR 224/1988 and Dir. 85/374/EEC, any responsibility for damages resulting from defective products stops 10 years after the date of the first delivery of this product by manufacturer; successively, the user undertakes this responsibility.

Giaffreda Nicola

Amministratore Unico














This certificate is a reproduction of the original on file at the manufacturer's premises.

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SYMBOLS USED IN THE MANUAL AND IN THE PRODUCT

	Type B applied part
	Alternating current
	Attention, look at instruction manual
	Ground
	Prohibition (this icon identifies what to prevent doing not to cause damage to the device)
	Warning (this symbol warns to be very careful in order to avoid any situation that could cause damage to the device)
	Switch Open (partial)
	Switch Closed (partial)
	Low light intensity
	High light intensity
	RAEE symbol

SAFETY WARNINGS

Before using the operating light system, please read the instructions contained in this manual and please pay attention to the following indications:

- dental operating light has to be used to illuminate patient oral cavity and must be utilized only for this purpose by medical staff;
- device installation must be realized only by

authorized staff;

- dental operating light must be installed on appropriate medical devices such as dental treatment unit, or supplied in conformity to electric supply specifications exposed in this manual and with wiring in conformity to laws applied for medical local;
- the light system must be supplied with a net isolation transformer;
- do not stare into beam;
- do not realize maintenance or light cleaning during light switched on;
- do not introduce any object in the ventilation holes that could realize a contact with in voltage point;
- clean light surface according to the indications contained in this manual;
- do not cover the ventilation light holes; clean and control periodically holes to assure a correct ventilation;
- do not leave unguarded the light switched on for long period;
- spray or liquid vapour entry in the light envelope has to be avoid.

INTRODUCTION

Thank you for purchasing the dental operating light "ISA".

"ISA" has been designed on 3 main basis: aesthetic, functionality and simplicity, putting particular attention to research in design and materials.

The result is a modern operating light, with a soft, fresh, pleasant design, but also very stable and functional. "ISA" will give you high level performances and will surely meet with any of your professional requirements.

FUNCTIONS

The operating light "ISA" permits excellent illumination of the oral cavity thanks to a bright light pattern without shadows, and emission of a cold white light. To ensure maximum security the light is equipped with a protection shield and the bulb mounted is a low pressure UV STOP bulb.


If you're still experiencing difficulties please call our Helpline +39 039 6060420

INSTRUMENT CLASSIFICATION

(CE 93/42 "Medical device" directive)

Our operating light is classified as a CLASS I equipment.

Protection degrees:

- against direct and indirect contact: instrument which applies to type B part , i.e. instrument that has a specific protection degree against electrical dangers

TECHNICAL DESCRIPTION

SPECIFICATIONS

external aspect:

fig. 1

dimensions:

fig. 1

weight:

light head 1.750Kg. operating light arm 5.150 Kg

possible movements:

fig. 1

PRODUCT CHARACTERISTICS

illumination, colour temperature, light pattern:

As per ISO 9680 regulations.

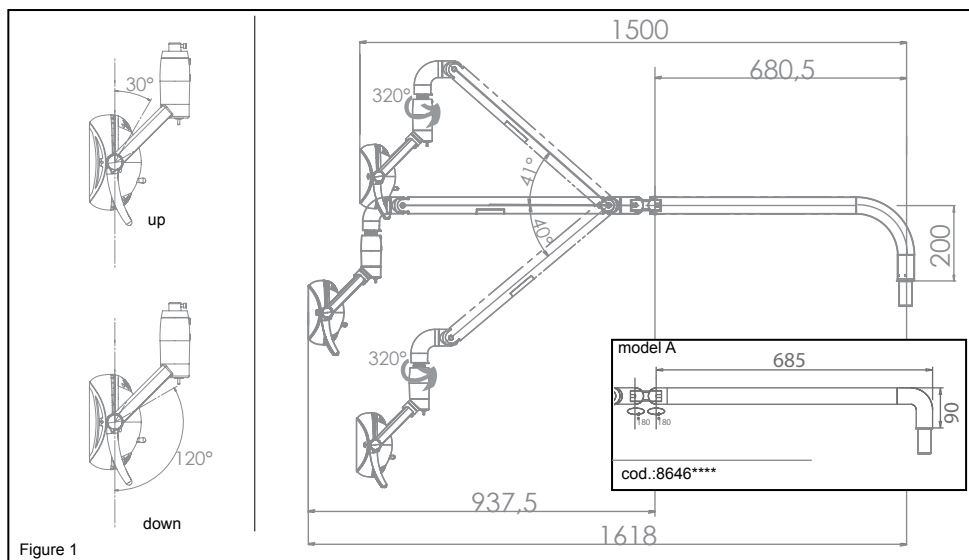
focal distance:

70 cm

bulb:

OSRAM halogen tungsteno UV STOP IRC

Low pression H-Star 12V-50W



with particular care for admissible currents dissipation and reliability of the ground connection.

- against water infiltration: IPXO

Security degrees:

- instrument not suitable for the momentary use of inflammable anaesthetic mixtures with air, oxygen or nitrogen protoxide.

Terms and conditions of use:

- instrument for continuous work.

ELECTRICAL WIRING

"ISA" must be electrically connected as follows (feed voltages intended 50 W load):

SWITCH version (see fig. 2):

Pos. 1 GREEN WIRE 0 Volt

Pos. 2 BLACK WIRE 13.2 Volt ~ (alternating current)

Pos. 3 WHITE WIRE 11.5 Volt ~ (alternating current)

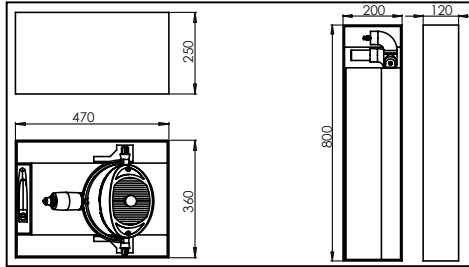
Power : 65 Watt.

Minimum power of the transformer for all applications: 60VA 50 Hz

It is necessary to use an insulated transformer from the net 230 V 50Hz and, that will ensure stiffened insulation ,in the respect of safety regulations also make sure that, during the primary winding of the transformer, a bipolar switch would be put before in accordance with its regulations with a power of 10 A-250 V and that in series during the secondary windings would be put 2 rapid fuses 5 A.

INSTALLATION

The operating light "ISA" is delivered as one **LIGHT HEAD** and one **ARM** packed separately.
The complete installation of the light requires the assembly of these two parts.

PACKAGING:

Proceed as follows:

1. Take the arm out of the box.
2. Use an eyelet to connect the ground cable at the bottom of the pivot (M3 thread). See picture 3.
3. Connect the cable of the arm with the cable that comes out from the dental unit column. Place the arm with mounted pivot in the bushing of the column. Check the movements of the dental operating light and the stability of the entire structure.
4. Carefully take the "ISA" light head out of its protective package not to cause damage to glass reflector or other parts.
5. As per fig.5 connect the male connector placed in the arm to the female connector placed in the light head. Insert the light head pivot in the bend (called light head bend); make sure that the threaded hole of the pivot is in line with the small one on the arm. Place the M5 screw supplied with the light into the hole and screw it all the way until locking position. Check for stability.
6. Attach the handles inserting hooks into handle (see Figure 4). There are two possible configurations (side view):



Figure 3

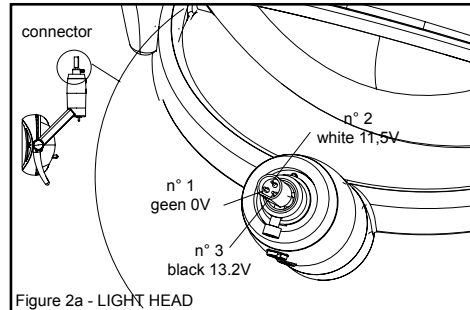
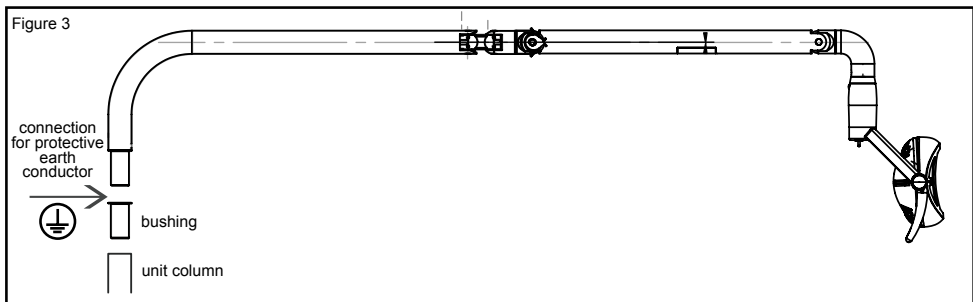


Figure 2a - LIGHT HEAD

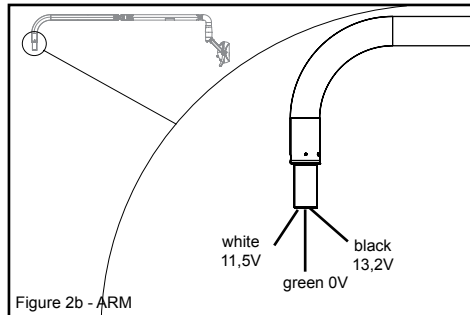




Figure 2b - ARM

"ISA" is now installed. Before switching the light ON check the electrical data with those of your transformer. Make sure the arm is properly placed and still.

Rotate arm and light head in order to check proper fixation and free movements.

USE

1. **Switch version.** Switch the operating light ON with the switch placed on the upper part of the light head; the central position indicates OFF mode ; the position on the left selects minimum light intensity, indicates with symbol:  ; the position on the right selects the maximum light intensity, indicates with symbol: .

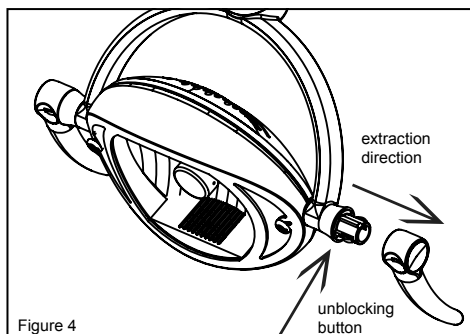


Figure 4

2. An increase of temperature can occur depending on the time of use.

! ATTENTION: NEVER TOUCH THE BULB WHILE THE LIGHT IS ON OR IMMEDIATELY AFTER USE. WAIT AT LEAST 30 MINUTES. GLASS REFLECTOR AND BULB PROTECTION GO THROUGH TEMPERATURE INCREASE DURING USE, TOO. WAIT AT LEAST 30 MINUTES BEFORE TOUCHING THEM.

3. Move the operating light **only by holding the handles** of the light head. This guarantees perfect working conditions of the dental light.

4. To ensure good operating light conditions avoid any scratch on the protection shield and always keep it clean. To take out the protection shield go to section "MAINTENANCE", in particular go to point 2, section "REPLACEMENT OF THE BULB".

! ATTENTION: radiotelephones may cause interferences with electromedical instruments. To guarantee the correct working of electromedical instruments, it is forbidden to use radiotelephones in medical offices and hospitals.

MAINTENANCE

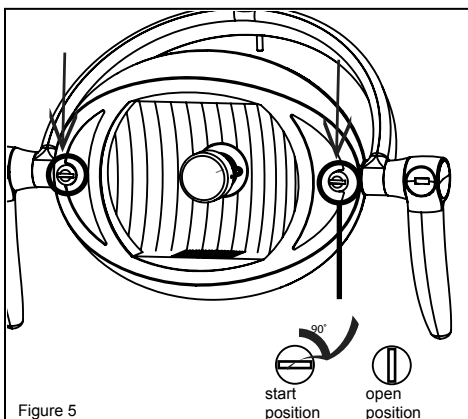


Figure 5

"ISA" has been designed to permit easy disinfection, with particular attention to hygiene. The following advices will simplify the cleaning process on your dental operating light.

☐ Use water, DO NOT USE ABRASIVE SUBSTANCES AND/OR MATERIALS.

Please put particular care while cleaning protection shield, handles and reflector. Please read as follows:

- Handles: very easy to clean; if needed the handle can be dismantled and cleaned separately.
- Reflector: use a very soft cloth soaked with distilled water, with very soft movements. Dry with a soft cloth.
- Protection shield: use a very soft cloth soaked with distilled water, with very soft movements. Dry with a soft cloth.

! Check monthly the working order of the cooling fan; its malfunction could cause an overheating of the operating light.

REPLACEMENT OF THE BULB

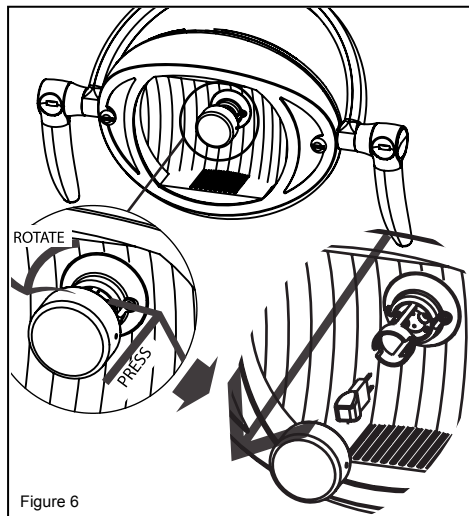


Figure 6

The bulb needs to be periodically replaced. Proceed as follows:

1. **Wait at least 30 minutes after switching off the dental operating light.**
2. Rotate the plastic knob placed on the protection shield 90° in a clockwork sense as per fig.5 and take it out.
3. Press the front metal bayonet cap, rotate it anti-clockwise and take it out. (fig.6)

4. Take the bulb and remove it with caution.
 5. Insert the new bulb in the socket **without touching the glass with your fingers**, use the proper tool given.
 6. Reinsert the front metal bayonet cap and make sure that it is properly fixed. Put on the protection shield and fix it by rotating anticlockwise the plastic knobs. (Fig. 5)
- Use proper glass containers for the disposal of used bulbs.

STORAGE

Please keep the dental operating light "ISA" in a closed, covered and dry place. Do not subject it to thermal stress and do not expose it out of the following limits:

- temperature : -10 to +50°C
- relative humidity : from 10 to 90%
- atmospheric pressure : from 700 to 1060 hPa.

REPAIRS

G.COMM is not responsible to unauthorized repairs made by third parties. Please, contact us directly to have the address of authorized distributors and technicians.

G.COMM responsibility is limited to:

- assembly operations, extensions, adjustments, modifications or repairs made by authorized staff;
- electrical installation made in accordance with the instructions given in this guide;
- use of the light in accordance with the instructions given.

WARRANTY

G.COMM guarantees to the end user a **12-month** warranty from the date of the purchase invoice.

Repairs under warranty should be done exclusively by **G.COMM or authorized service personnel**.

Transport costs and risks will be on the customer's charge. Repairs under warranty, during the period of validity, will be done only if the product is accompanied by shipping document, delivery note or purchase invoice. The warranty covers failures due to defects in material or manufacturing. In case of legitimate claim the product that is under warranty will be repaired or exchanged free of charge. **Any other claim, in particular for damages and/or interests is excluded.** Warranty shall be null if the damage and its consequences are due to improper manipulation, incorrect use and maintenance or wearout. Bulbs are not covered by warranty.

We hope you'll enjoy your new "ISA" operating light.

WARNING RAE

Indications about disposal

The European directives 2002/95/CE, 2002/96/CE and 2003/108/CE foresee the dental operating light in the category of electrical and electronic products that should be disposed separately from the municipal waste stream (RAEE).

The disused product shall be disposed separately to optimise the recovery and re-cycle of materials that compose the unit, in order to obtain a significant energy saving and to prevent potential negative consequences for environment and human health.

This crossed-out bin symbol is shown to all products that request to be disposed via designated collection facilities.

The user can hand over the disused dental operating light to his/her city office or to the designated collection facilities appointed by his/her government or local authorities.

The illegal or inadequate disposal of disused product by the user implies the application of economic / administrative sanctions accordingly to the Law.





G.COMM srl è un'azienda certificata ISO 13485:2003 e ISO 9001:2000

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