

**GIMA**

Operative Manual

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Observation lamp with flexible support

SIMPLEX

**GIMA**

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Introduction

Dear Client,

GIMA congratulates you for having purchased a product from its range and invites you to read carefully every part of the present Operative Manual, subdivided into installation, use and maintenance phases.

You will find all the necessary instructions for a correct use of the product within. Please observe the warnings contained carefully, keep it unaltered and easy to find and be accessible to the operator. In the case of sale or transfer of the used apparatus, this manual and its attachments must always accompany it.

GIMA can modify the content of the present Manual, without previous notice or further obligations, in order to include variations and improvements.

The reproduction or translation of any part of the present manual is forbidden without the written agreement of GIMA.

We inform you that our Company remains completely available to you for further information and clarifications of everything concerning the installation, use and maintenance of the product.



The symbol to the side and used in the present manual means that when it is shown it is to be considered “compulsory” in order to install and use the device correctly.



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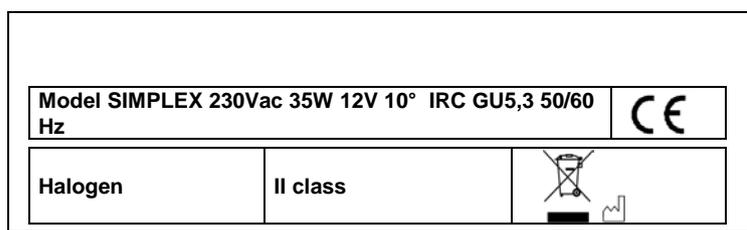
General information

	<p><i>GIMA does not assume any responsibility for eventual damage to people or things as a result of failure to respect the safety regulations and recommendations contained in the present document.</i></p>
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1.1 Identification data of the apparatus, EC marking and re-traceability

Conformity is documented by the plate with the EC mark (portrayed below) and by the declaration of conformity accompanying the present manual.

Device SIMPLEX: re-traceability plate



The plate is positioned on the device on the basement. The re-traceability of the SIMPLEX is guaranteed by the series number positioned on the label in fulfilment of the internal company PO 7.5 Operative Procedure.

Description of the symbols on the plate, the product and in the present manual:

	Graphic symbol confirming the EC product mark		All electrical and electronic products should be disposed of separately from the municipal waste stream
	Symbol indicating the manufacturing date (year).		Attention → ADVICE
	Fragile package		Warning → COMPULSORY
	Device Class II		Read enclosed warning

1.2 Classification and destination of use of the device

Classification according to a general regulation (CEI EN 60598-1 section 2)

- On the basis of the type of protection against electrical danger: class II apparatus
- On the basis of protection against penetration of water: IP20
- On the basis of the level of safety of use in the presence of an inflammable anaesthetic mixture with air or oxygen or hydrogen protoxide: apparatus considered not suitable for use with the above described elements.
- On the basis of the conditions of use: apparatus for continuous functioning.

- malfunctions or faults due to the fact that the electrical system of the premises where the machine is installed is not in compliance with International or local standards for electrical systems in premises used for medical purposes and similar standards.
- 7. GIMA shall repay direct damages suffered by the buyer and which are documented as attributable to its product, caused within the warranty period, for an amount not above 40% of the net value of the product as indicated on the buyer's invoice. GIMA's liability is expressly ruled out for indirect damages or consequential damages (including cases of the lamp not being used) deriving from the supply.
- 8. This warranty certificate replaces legal warranties for faults and non-conformities and rules out any other possible liability of GIMA originating from the supplied products.
- 9. The payment of any damages to persons or things due to product malfunction or faults shall be limited to the maximum amount of GIMA's insurance coverage for civil liability.
- 10. The warranty shall be automatically invalidated in the event of:
 - the product having been tampered with or modified by the buyer or third parties;
 - the product having been repaired by the buyer or third parties, without following the instructions in the instruction manuals;
 - the product serial number having been cancelled, defaced or removed;
 - the buyer not being up to date with payments.
- 11. For jobs to be done under warranty, the buyer shall contact GIMA only.
- 12. The component parts replaced under warranty must only be returned to GIMA, if so requested by GIMA, carriage free and suitably packed.
- 13. In case of failure to return a part requested by GIMA, the cost of the component part will be charged.
- 14. GIMA cannot accept returns from end users or in any case from parties other than the buyer.
- 15. Products returned to GIMA must be complete with documentation authorising such return and another document describing the malfunction.
- 16. For everything not indicated on this warranty certificate, reference shall be made to the laws of Italy.
- 17. For all disputes deriving from or related to the orders to which this warranty certificate applies and which cannot be amicably settled between the parties, the only competent law court shall be that of Milan.

1.5 Technical assistance and qualification of the personnel

For any requests, clarifications or interventions contact the numbers below.

Telephonic assistance is guaranteed from Monday to Friday, from 8.30 a.m. to 5.30 p.m.

GIMA TECHNICAL ASSISTANCE OFFICE FOR CLIENTS

Via Marconi, 1 – 20060 GESSATE (MI) ITALY

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1.6 Packing, Transport, Stockage, Characteristics of the installation premises, Dismantling

The packing for the SIMPLEX model consists of one box:

Packing	Content	Dimensions LxWxH	Weight (Kg)
1	Medical device + Operative Manual	60x47x12	3,300

Transport is carried out by GIMA or by any carrier as long as the following characteristics are respected:

Temperature	(-15/+60)°C
Humidity	(10/75) %
Atmospheric pressure	(500/1060) h/Pa

Stockage (storage) of the packaged devices must take place in a dry place and at the following temperature:

Temperature	(-15/+60)°C
Humidity	(10/75) %
Atmospheric pressure	(500/1060) h/Pa

The premises designated for setting up the apparatus must have the following characteristics:

Temperature	(+10/+40) °C
Humidity	(30/75) %
Atmospheric pressure	(700/1060) h/Pa

Method for dismantling product at the end of life:

dismantle Medical Device separating plastic parts from glass, electric wires and iron dismantling following national laws.



Before proceeding with installation, check that all the packages are present and in good condition, without damage due to transportation and that the contents coincide with what has been reported above.

Complaints will be considered only if the vendor or the forwarder is immediately advised. Every complaint must be made in written form. The goods always travel at the risk and danger of the purchaser.

Keep the original packing in case there is the need to return the lamp.

Using the apparatus

2.1 Safety indications (undesired secondary effects)

- The lamp is not designed to function in a zone with a risk of explosion.
- Do not look directly at the lit lamp and do not insert reflecting objects in the way of the rays. There exists the danger of blinding in view of the high potency of illumination.
- The distance between the surface of emission of the light of the lamp and the surface of the patient should not be less than 10 cm so as to guarantee an efficient illumination.
- Do not place any objects on the body of the lamp nor hang objects on the arm or the body of the lamp.
- Avoid collisions with the body of the lamp. The lamp might be damaged with a violent collision or pieces of magnifying glass might break off and fall into the operating field of the patient zone.
- The alimentation wire cannot be substituted. In case of damage you have to contact GIMA.

2.2 Description of the apparatus, working principle and lighting

The lamp is constituted of a lamp of 35W 12V 10° IRC settled inside the reflector end protected by a temperate glass. The reflector is little in order to give more freedom for the movement. There's a flexible arm (70cm).

2.3 Cleaning and disinfecting



Before proceeding to the operations of cleaning removing feeding to the lamp parading the thorn from the net electrical worker

All the parts of the lamp can be cleaned up with common detergents on all the superficial ones and can be disinfected with common disinfectants in use passing a humid soft cloth to you with frequency of 3 months or before if famous that the reflector is being opacified or the lamps cover of one powder layer.

	<p><i>Not to pour never directly the content of bottle the detergents and disinfectants on the lamp also through atomizer and not to spray never the liquids to the inside of the device.</i></p>
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2.4 Technical data and performance of the apparatus

Technical data	Mod.SIMPLEX
Maximum radiation at 50cm [Lux]	30.000
Technical data on power supply	
Nominal voltage [Volt ac]	230
Frequency [Hz]	50/60
Power supply [VA]	35
Class emergency electrical worker	II
General data	
Lamp	35W
Life fluorescent bulbs [h] (this data can vary in base to a tension advanced supply to that one indicated, from tension peaks and from the frequency of use)	5.000 c.ca

Dimension	
Measures of block[cm]	70x8x8
Weight [Kg]	3,0
Colour	White
Marks	
	

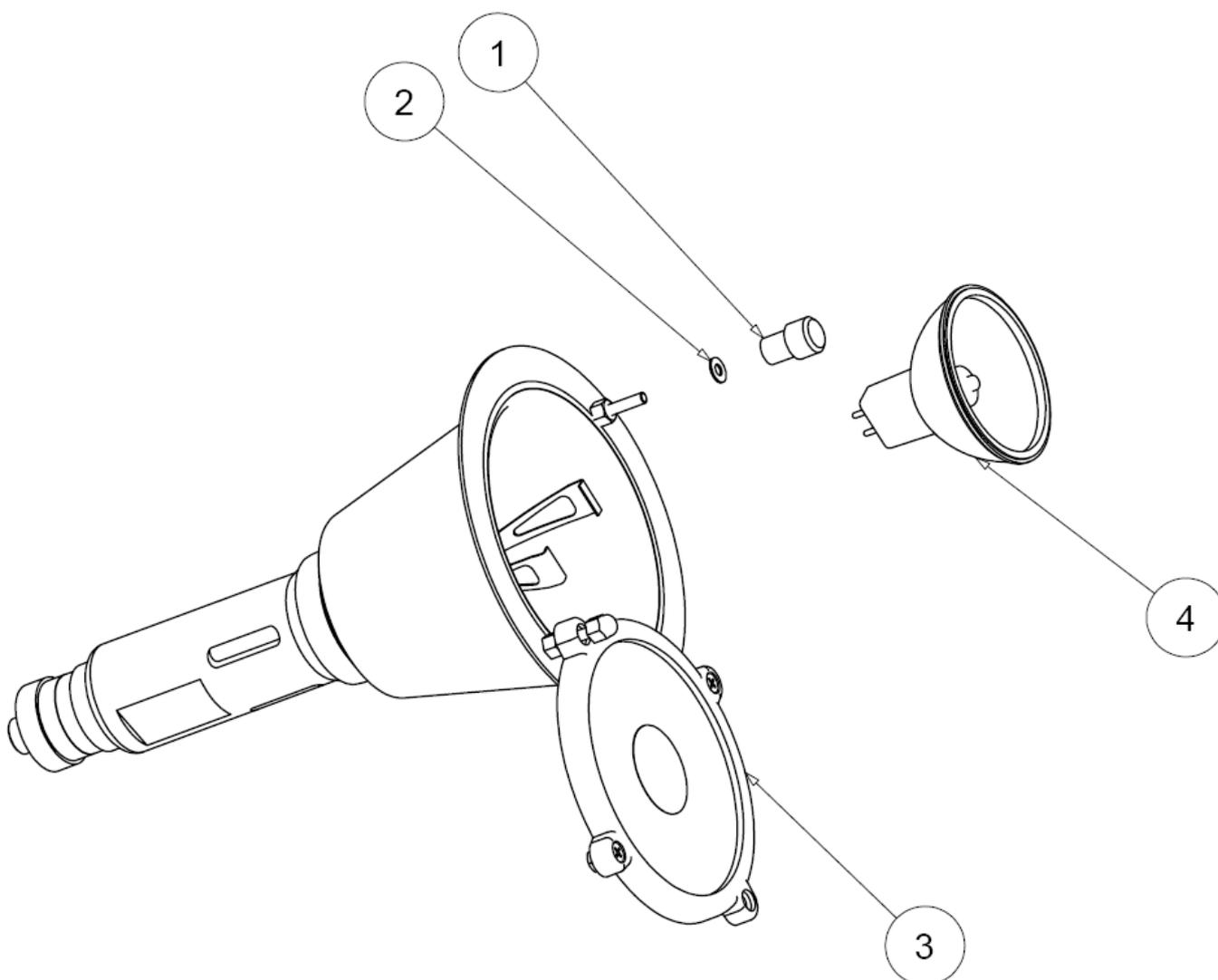
Maintenance

3.1 Repairing faults and anomalies

n	Problem	Solve problem
1	Device do not light	To verify the presence of tension to the net of feeding (taken electrical worker), integrity of the fuse inside, the presence of the lamps and their condition

3.2 Bulb sostitution

First of all you have to unscrew the screw (1). Taking out the washer (2), you have the opportunity to rotate the cover (3). Now you can take out the dicroic bulb and substituted it (4).



3.3 Electric diagram

