MANUALE D'ISTRUZIONI / INSTRUCTION'S MANUAL / MANUAL DE INSTRUCCIONES

DIATERMO 106

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MA126IGBEa

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IMPORTANTE / *IMPORTANT* / *IMPORTANTE*

Queste istruzioni operative costituiscono una parte fondamentale dell'apparecchiatura per chirurgia ad alta frequenza, in quanto ne descrivono il funzionamento e l'uso, pertanto devono essere lette attentamente prima di iniziare l'installazione e l'uso dell'apparecchiatura.
Tutte le istruzioni di sicurezza o note di avvertimento devono essere osservate. Siate certi che queste istruzioni operative siano fornite insieme all'apparecchiatura quando è trasferita ad altro personale operativo.
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In caso di necessità di Assistenza Tecnica, contattare il proprio rivenditore.

These operating instructions form an integral part of the equipment and must be available to the operating personnel at all times.
All the safety instructions and advice notes are to be observed. Be sure that these operating instructions is furnished together the equipment when this is transferred to other operating people.
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Las presentes instrucciones operativas forman parte indisoluble del equipo y han de estar a disposición del personal que lo utiliza, en todo momento.
Todas las instrucciones de seguridad y las notas de advertencia se han de cumplir al pie de la letra. Cerciórese de que estas instrucciones operativas se adjunten al aparato, si el mismo es utilizado por otros miembros del personal operativo.
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1. INTRODUCTION

1.1 CHECK-LIST

Check that all the items and accessories which had been ordered have been delivered, according to the following list:

Ref.Nr.GMA10100.05A	**DIATERMO 106** Unit
Ref.Nr. 00100.03	Unit mains cable 2 meters long
Ref.Nr. 00404.08	Cable for connection of the reference electrode
Ref.Nr. 5365	Reference electrode
Ref. Nr. 00301.00	Pedal switch
Ref. Nr. 00500.03	Kit of 6 assorted tip
Ref. Nr. MA126IGBE	Instruction's Manual

1.2 GENERAL DESCRIPTION

DIATERMO 106, High Frequency Surgical Equipment, provides the facility to carry out monopolar minor surgery.
The equipment is designed for desk-top use.
The most advanced electronic components and circuitry including LSI microcontrollers are applied to provide all the prerequisite for safe and reliable operation.
In this way most of the thermic problems, and the need for cooling fans, very dangerous for the batterium diffusion in the health care rooms, have been overcome.
Control of the unit is via the front panel keys and display; mains inlet and on/off switch are on the rear panel.
The type of surgical operation which can be carried out are those where monopolar minor electrosurgical cutting or coagulation is requested.
Use of **DIATERMO 106** is restricted to trained medical personnel, and it is to be used only for the purposes set down by the manufacturer.
DIATERMO 106 consists of the following components:

- the generator, or unit
- the handpiece
- the electrodes
- the dispersive plate
- the pedal switch

1.3 MONOPOLAR CUTTING

Monopolar cutting is the sectioning of the biological tissue caused by the passing of high density, high frequency current concentrated by the tip of the active electrode. When the high frequency current, by the tip of the active electrode, is applied to the tissue, it creates intense molecular heat in the cell so that the cell explodes. The cutting effect is achieved by moving the electrode through the tissue and destroying the cell one after the other. The movement of the electrode prevents the propagation of the heat laterally in the tissue, thus limiting the destruction to a single line of cells.
The best current for cutting is pure sine wave without any modulation which cuts very smoothly and provides the least thermal effect with poor hemostasis while cutting. Because its effects can be precisely controlled, it can be used safely without damage to the bone, but since good coagulation while cutting is one of principal benefits of using electrosurgery a current with a certain amount of modulation is desirable.

DIATERMO 106 allows cutting with pure sine wave form as well as with two degrees of moderate modulation producing blend wave form with different crest-factor, so more hemostatic effect than with pure sine wave form is achieved.

The following rules help the operator to obtain good cutting, however every user must follow first of all his professional judgement as he does every time in his practice.

- Keep the tissues moist but not wet
- Survey the stroke before activate the electrode
- Keep the electrode perpendicular to the tissue
- Activate the electrode before making contact with the tissue
- Keep the electrode clean
- Wait at least five seconds before to repeat a stroke.

When the output power is properly set there should be:

- no resistance to the electrode movement through the tissue
- no change in the cut surfaces color
- no fibers of tissue remained onto the electrode

1.4 MONOPOLAR COAGULATION

Monopolar coagulation is the hemostasis of small blood vessel of the bodily tissue through the passing of high frequency current in correspondence of the active electrode.When the current density is reduced and a broad-surfaced electrode is used to dissipate the energy over a larger area, the effect is to dry out the surface cells, without deep penetration, resulting in coagulation. These coagulate surface cells then serve as a layer of insulation, preventing heat from successive applications of current from penetrating too deeply.

The current normally used for coagulation is modulated and depending from the modulation percentage is the smoothness of cutting, goodness of hemostasis and likelihood of tissue destruction. Deeper current modulation brings to somewhat roughly cutting and the chance of some slight depth of tissue destruction but more efficient coagulation.

DIATERMO 106 allows coagulation with deep modulation producing blend wave form with high crest-factor so more thermal effect and consequently hemostatic effect than with pure sine current has achieved.

The following rules help the operator to obtain good coagulation: however every user must follow first of all his professional judgement as he does every time in his practice.

- Select a ball or heavy wire electrode
- Locate the bleeder, after have wiped the excess blood from the area, contact lightly the bleeder before activating the electrode
- Stop the electrode activation as soon as the tissue blanches to avoid tissue damage.

2. SAFETY

WARNING These operating instructions form an integral part of the equipment and must be available to the operating personnel at all times. All the safety instructions and advice notes are to be observed. Be sure that these operating instructions is furnished together the equipment when this is transferred to other operating people.
Electrosurgery can be dangerous. Careless use of any element in the electrosurgical system may subject the patient to a serious burn. Read and understand all warnings, precautions, and directions for use before attempt to use any active electrode. Neither LED S.p.A., Frosinone, Italy nor any of the subsidiary sales organisations can be considered responsible for personal, material or consequential injury, loss or damage that results from improper use of the equipment and accessories.

2.1 GENERAL

- Persons fitted with a heart pacemaker must not operate the equipment nor approach the same while it is in operation.
- The patient does not must be in contact with metal parts that are connected to the earth or have a large electrical coupling capacity to the earth (for example: operating-table or metallic support). The use of antistatic sheets is advised.
- Avoid the skin to skin contact (for example between arm and body of the patient). Insert an interface material like dry surgical gauze.
- When high frequency electrosurgical unit and phisiological monitoring devices are used at a time in the same patient, all the monitoring electrodes, that has not resistive or inductive elements suitable to high frequency interferencies, must be as far as possible from the electrodes of the electrosurgical unit.
- Avoid the use of monitoring needles.
- The connection to the electrodes should be located in such a way to avoid the contact both with the patient and with other cables.
- The power level should be the lowest useful to the work to do.
- Always check the dispersive plate whenever the electrosurgical unit fails to produce the desired effect. Reason for a low output power level, or for an uncorrect functioning of the electrosurgical unit when arranged for a normal output, may be lack of connection of the dispersive plate or its imperfect placement.
- The use of flammable anesthetics, of oxygen and of nitrogen protoxyde should be avoid in the case of operation at the head or at chest level except the possibility of evacuating gas.
- Flammable materials used to clean, or to disinfect, should be let to evaporate before the use of the electrosurgical unit.
- There is risk of stagnation of flammable solutions under the patient or in body cavities as the umbilicus and the vagina. The fluid which deposits in these areas should be removed before the equipment use. The danger of endogenous gas ignition has to be considered.
- Some materials like cotton wool or gauze, when saturated with oxygen, may burst into flames because of the sparks produced by the equipment in the normal use.
- There is a risk for the patients fitted with heart pace-maker, or other stimulation electrode: an interference may occur with the stimulator signal or the stimulator itself can be damaged. Please refer to the cardiologic department when in doubt.
- The use of electrosurgery is not recommended in patients:
- with serious unbalance of arterial pressure
- with serious illness of the nervous system
- with serious renal insufficiencies
- in state of pregnancy
- Inadvertent stimulation of a patient's muscle and nerves can be caused by low frequency currents originating in electric sparks between the electrode and the tissue of the patient. Should neuromuscular stimulation occur stop the surgery and check all the connections to the generator. If this does not solve the problem the generator must be inspected by qualified service personnel.

- The electrosurgical equipment does emit unnoticed radiation of high frequency energy that may effect other medical equipments, unrelated electronics, telecommunications, navigational systems.

2.2 INSTALLATION

- The electric safety of **DIATERMO 106** is insured only when the same is correctly connected to an efficient net linked to the earth in conformity with the actual safety requirements. It is neccessary to verify this fundamental safety requisite and, in case of doubt, to require an accurate control of the plant from part of qualified personnel. The manufacturer cannot be considered responsible for possible damages caused from the lack of efficient connection to earth of the installation. Operation without a protective earth connection is forbidden.
- Before connect the equipment ascertain that the required voltage (showed on the rear panel) corresponds to the available mains. The fuse holder is installed on the mains input connector module.
- In case of incompatibility between the available wall socket and the feeding cable of the equipment, replace only with legally approved connectors and accessory items. The use of adapters, multiple connections or cable extensions are not advised. Should their use become necessary it is mandatory to use only simple or multiple adapter conforming to the actual safety requirements.
- The use of any electric apparatus involves the observance of some fundamental rules. Particularly:
- don't touch the apparatus with wet or damp feet or hands.
- don't use the apparatus with naked feet
- don't let the apparatus exposed to atmospheric agents
- Don't obstruct openings or cracks of ventilation or heathsink.
- Don't leave the equipment uselessly inserted. Switch off the equipment when not in use.
- **DIATERMO 106** must be destined only to the use for the which has been expressly designed. Any other use is to be considered improper and dangerous. The manufacturer can not be considered responsible for possible damages due to improper, wrong and unreasonable uses.
- It is dangerous to modify or try modify the characteristic of the equipment.
- Before effect any operation of cleaning or maintenance, disconnect the apparatus from the electric net, either unplugging it from the mains or switching off the mains switch of the plant.
- In case failure and/or bad operation of equipment switch off it. For the possible reparation address only to a authorized service center and ask for the the use of original spare parts. The lack to follow the above requirements could risk the safety of the equipment and can be dangerous for the user.
- Never lay the pen on the patient drape. Set it on the instrument tray when not in use. Accidental activation can cause patient burns beneath the blade of the active electrode.
- Do not reduce or disable the audible signal warning the activation of the generator. A functioning activation signal can minimize or prevent patient or staff injiury in the event of accidental activation.

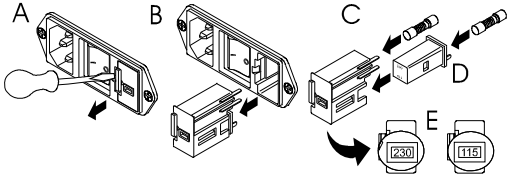
2.3 APPLICABLE SAFETY STANDARDS

DIATERMO 106 conforms to the safety requirements of IEC 601-1/ EN 60601-1 (Medical electrical equipment-General requirements for safety), and of IEC 601-2-2 / EN 60601-2-2 (Medical electrical equipment - Particular requirements for the safety of high frequency surgical equipment).

3. INSTALLATION

- Inspect the equipment for damage during transit. Any damage should be reported to the carrier immediately.
- Unpack the equipment and carefully study the documentation and operating instruction supplied. The mains input voltage, indicated up the equipment mains input, must agree with the local mains voltage (mains frequency: 50-60 Hz). The correct voltage setting is selected as shown in fig. E
- Insert the correct fuses in the module according to the following table:

  Mains Voltage 110-120 V Fuse 2 x 2AT (Anti-surge) Type 5 x 20 mm
  Mains Voltage 220-240 V Fuse 2 x 1AT (Anti-surge) Type5 x 20 mm
- To insert the fuses pull out the fuse holder from the mains module with the help of a screwdriver (Fig.1 and Fig. 2) - clip the fuses into the holder (Fig. 3) - replace the holder into the module.



- Connect the mains cable to a mains outlet that has good earth connection.

OPERATION OF THE EQUIPMENT WITHOUT EARTH CONNECTION IS FORBIDDEN

- Position the equipment such that there is sufficient room around it. Air circulation must not be restricted in any way.
- Operate the equipment only in dry surroundings. Any condensation that occurs must be allowed to evaporate before putting the equipment into operation. Do not exceed the permissible ambient temperature or humidity.
- Environmental conditions:
- Temperature: from 10°C up to 40 °C
- Relative moisture: from 30% up to 75%
- Atmospheric pressure: from 70 kPa up to 106 kPa (10 PSI up to 15 PSI)

4. CONNECTORS AND CONTROLS

4.1 LABEL ON THE REAR PANEL

The requirements for the safety of H.F. surgical equipment ask that some technical data and graphic symbols must be printed on the cabinet or on at least one of the panels of the generator unit to define its features and oversee its condition of work.

4.1.1 DEALER'S IDENTIFICATION DATA

The **DIATERMO 106** H.F.Electrosurgical unit is dealered by GIMA SpA Via Marconi, 1 I-20060 Gessate (MI) -ITALY-

4.1.2. TECHNICAL DATA

OUTPUT COAG:	40 W – 400Ω	FREQUENCY:	600 kHz
OUTPUT CUT:	50 W - 400Ω	FREQUENCY:	600 kHz
MAIN POWER:	115 V~ - 50/60 Hz	FUSE:2 x 2 AT (Antisurge)	
	230 V~ - 50/60 Hz	FUSE:2 x 1 AT (Antisurge)	
DUTY-CYCLE:	intermittent 10 seconds output / 25 seconds pause.		
CLASS:	I CF		

4.1.3 GRAPHIC SYMBOLS' MEANING.

The meaning of the graphic symbols printed on the DIATERMO 106 's cabinet is the following:
1. Floating Patient's plate: not connected to the earth neither at low-frequency nor at high frequency.
2. The equipment is protected against H.V. discharge due to the use of a Cardiac Defibrilator.
3. Not Ionizing Radiation emitted
4. Read carefully the INSTRUCTION's MANUAL before to attempt the use of the equipment.

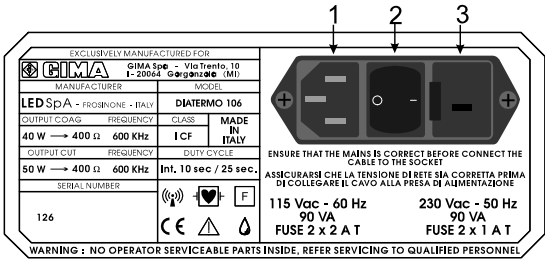
1

2

3

4

4.2 REAR PANEL



1 - IEC MAINS INPUT CONNECTOR
2 - MAINS SWITCH
3 - FUSE HOLDER AND VOLTAGE SELECTOR

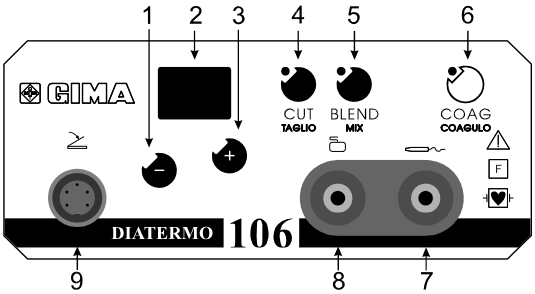
4.2.1 EQUIPMENT MAINS INPUT MODULE AND VOLTAGE SELECTOR

The equipment mains input module provides the connection point for the power of the equipment's internal electronics. The mains input module incorporates the mains input socket, the main input voltage selector and in-line mains fuses.
WARNING: Before the unit is powered up the operator should check that the mains input voltage indicated on the power input module corresponds to the mains voltage supply to which it is to be connected, and that the correct mains fuse type for the selected mains voltage has been inserted.

4.2.2 POWER ON-OFF SWITCH

POWER ON/OFF mechanical switch is used to control power to the equipment. To power the equipment, press the switch in the direction of the 1 (i.e. right side).
When the equipment is powered the front panel will illuminate. Pressing the switch in the 0 direction will cut power to the equipment, this operation allows the switch to be used as a emergency stop switch, in the event of any fault.

4.3 FRONT PANEL



1 Key for output power decrease
2 Output power display
3 Key for output power increase
4 CUT 1 key
5 BLEND key
6 COAG key
7 Pen-holder connector
8 Patient Plate connector
9 Foot-switch connector

4.3.1 USER KEYS

The keys are split into two groups, the four operative keys, positioned at the left of the unit, and the two output power control keys under the digital display.
The two output power control keys are used to increase (+) or decrease (-) the output current.
The function of each of the operative keys is as follows:

Pressing this key Cut current, i. e. pure sine current is preset, to be delivered when the foot-switch output control is activated. Crest factor of the Cut current is 1.5. Cut current preset condition is indicated by green LED which will illuminate.

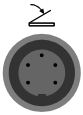
Pressing this key Blend current, i.e. modulated current is preset, to be delivered when the foot-switch output control is activated. Crest factor of the Blend current is 1.8. Blend current preset condition is indicated by green LED which will illuminate.

Pressing this key presets Coag current, i.e. modulated current is preset, to be delivered when the foot-switch output control is activated. Crest factor of the monopolar Coag current is 2.5. Coag current preset condition is indicated by green LED which will illuminate.

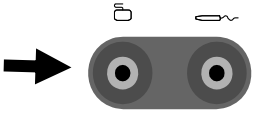
4.3.2 CONNECTOR

Pedal Connector

This is the connection point for the foot-switch. The pedal switch is allowed to control the output current delivering of the operative condition.

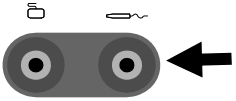


Monopolar Patient Plate Connector



This is the connection point for the Patient Plate.

Handpiece Connector



This is the connection point for the handpiece.

4.3.3 WARNING SIGNALS

Should the unit's inside temperature rise above 75 °C i.e. the save working level, the digital display blinks. Stop the output emission until the normal condition is restored.

5. TECHNICAL SPECIFICATIONS

5.1 GENERAL

Equipment Description:
H.F. Electrosurgery Equipment for monopolar minor surgery. The unit provides the facilities to fine preset the output power level and choose the coagulating effect through the appropriate Crest Factor.
Cabinet:
Bench-top, metal housing, with the frontal and rear panel covered by lexan sheet.

Height:	100 mm	Width:	180 mm
Depth:	180 mm	Weight:	2,8 Kg

Equipment Mains Input: Selectable 115 or 230 V~, 50/60 Hz.
Maximum Current: 0,5 A (230V) or 1A (115V)
IEC socket with in-line fuses, voltage selector and mechanical mains switch.
Displays:
LED Digital Displays provide the indication of the preset output level as follows:

CUT:	0 – 50	BLEND:	0 – 45
COAG:	0 - 40		

Output Power Control by two keys
The use of the control keys allows the user to control very accurately the output power since it is possible to vary the
preset output power in step as low as just 1 watt.
Max Output Power:

CUT:	50 W +/- 10%	BLEND:	45 W +/- 10%
COAG:	40 W +/- 10%		

Reference Load Resistance: 400Ω
No Load Max Voltage: 900 Vpp +/-10%
Crest Factor:

CUT:	1.5	BLEND:	1.8
COAG:	2.5		

Output Frequency: 600 kHz +/- 10%
Modulation Frequency:

CUT:	NONE	BLEND:	10 kHz
COAG:	10 kHz		

Allowed output time:
Duty Cycle: 10 seconds output-25 seconds pause

6. PREVENTIVE MAINTENANCE

6.1 GENERAL

No user adjustable parts are within the equipment, either for calibration or service purposes. The equipment housing must not be opened: the warranty is invalidated by any unauthorized entry into the unit. In the event any repair or adjustment work being necessary, the whole equipment should be returned to the LED S.p.A. Service Centre 04011 APRILIA (LT) - ITALY, or to a other Authorized Centre, together with a description of the fault.
Maintenance work by the user is mainly the cleaning of the exterior of the cabinet, cleaning and sterilization of the accessory items and checking of the equipment before each use. Carrying out function and safety check for verification of the parameters is demanded to specialized technical people.

6.2 CLEANING OF THE CABINET

Switch the equipment off complitely and disconnect the mains supply before any cleaning is undertaken. Clean the outside of the cabinet with a damp cloth. No chemical should be used; a mild non abrasive cleanser may be used when necessary.

6.3 CLEANING AND STERILIZATIONOF THE ACCESSORY ITEMS

The best thing to do is to use only one time use accessories and discard them after use. Since some of the accessory items are to be used more than once it is mandatory to clean carefully and sterilize those accessories before the new use. The best way to clean and sterilize the reusable items is to follow the direction of the supplier of each item. When original reusable accessories supplied by LED S.p.A. are applied, the cleaning by using soft cleanser and sterilization through steam sterilization at 134 °C is recommended.

6.4 CHECKING OF THE EQUIPMENT BEFORE EACH USE

Each time the use of the electrosurgical equipment is planned a check of the most important safety aspects has to be implemented considering at least the following:

- Check the integrity of cords, connections, wire breakage, etc.
- Assure that all the electrical equipment is properly grounded
- Assure that all the accessories that should be used are available and sterilized.

6.5 FUNCTION AND SAFETY CHECK AND TEST

At least once a year, the following check and test should be done by the biomedical engineering department or other qualified personnel:

- Check of the connectors and mains supply cord conditions;
- Visual check of the mechanical protections;
- Check of the protections against the danger due to liquid's pouring, dripping, moisture, liquid's penetration, cleanliness, sterilization and disinfection.
- Check of the Equipment's Datas on the Label
- Check of the availability of the Instruction's Manual
- Check the functioning of the H.F. output controls
- Check the uniformity of the resistance through the surface of the patient plate.
- Test the earth conductivity resistance.
- Test the earth leakage current. Test H.F. leakage current.
- Control of the neuromuscular stimulation. Control of the accuracy of the output power.

OUTPUT POWER DIAGRAMS

Diagramma valori a metà potenza / Half power diagram

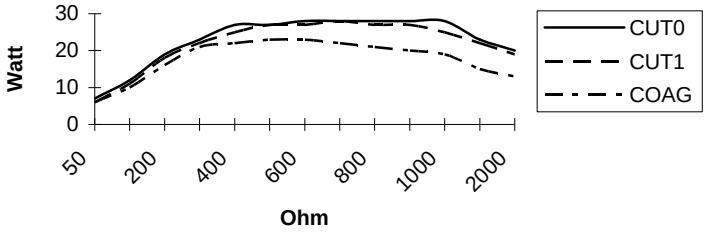


Diagramma valori alla potenza massima / Max power diagram

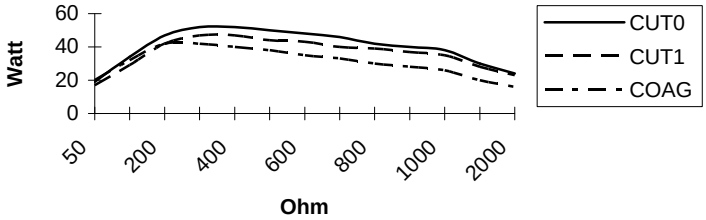


Diagramma linearità CUT / CUT linearity diagram

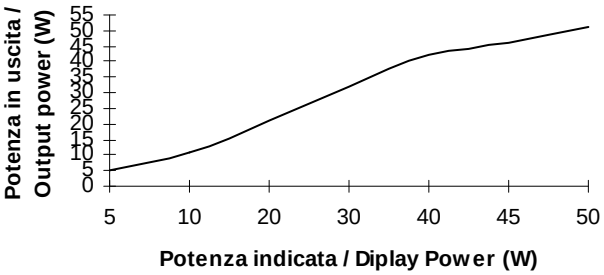


Diagramma linearità BLEND / BLEND
linearity diagram

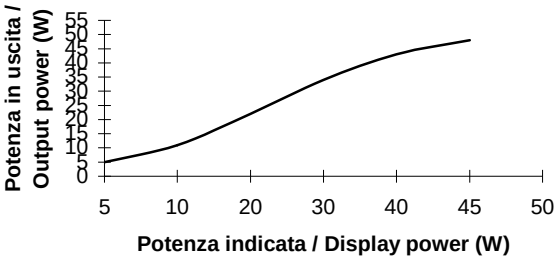
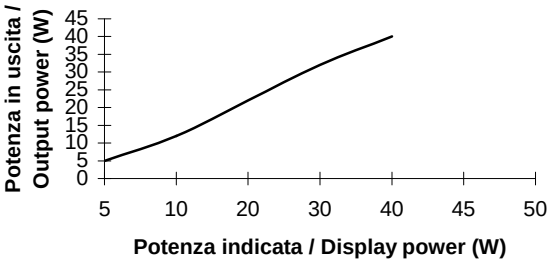
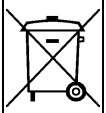


Diagramma linearità COAG / COAG
linearity diagram

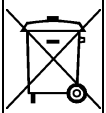


Informazioni in base all'Art. 13 del D.Lgs. 151/05 del 25/07/2005 "Attuazione delle Direttive 2002/95/CE e 2003/108/CE, relative alla riduzione di sostanze pericolose nelle apparecchiature elettriche ed elettroniche, nonché allo smaltimento dei rifiuti.



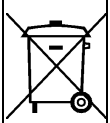
A fine vita il presente prodotto non deve essere smaltito come rifiuto urbano, lo stesso deve essere oggetto di una raccolta separata.
Se il rifiuto viene smaltito in modo non idoneo è possibile che alcune parti del prodotto (ad esempio eventuali accumulatori) possono avere effetti potenzialmente negativi per l'ambiente e sulla salute umana.
Il simbolo a lato (contenitore di spazzatura su ruote barrato) indica che il prodotto non deve essere gettato nei contenitori per i rifiuti urbani ma deve essere smaltito con una raccolta separata.
In caso di smaltimento abusivo di questo prodotto sono previste delle sanzioni.

Information about elimination of this product (Applicable in the European Union and other European countries with separate collection systems)



On the end of the life, the present product mustn't be eliminated as urban refusal, but it must be eliminated in a separated collection.
If the product is eliminated in unsuitable way, it is possible that some parts of the product (for example some accumulators) could be negative for the environment and for the human health.
The symbol on the side (barred dustbin on wheel) denotes that the products mustn't throw into urban refuses container but it must be eliminated with separate collection.
In case of abusive elimination of this product, could be foreseen sanctions.

Información sobre la eliminación de este producto (Aplicable en le Unión Europea y en países europeos con sistemas de recogida selectiva de residuos)



En el final de la vida, el actual producto no se debe eliminar como denegación urbana, sino que debe ser eliminado en una colección separada.
Si el producto se elimina de manera inadecuada, es posible que algunas partes del producto (por ejemplo algunos acumuladores) podrían ser negativas para el ambiente y para la salud humana.
Este símbolo indica que el presente producto no puede ser tratado como residuos domésticos normales, sino que deben entregarse en el correspondiente punto de recogida de equipos eléctricos y electrónicos.
En caso de que de eliminación abusiva de este producto, podrían estar las sanciones previstas.