

## TECHNICAL INFORMATION

HF ELECTROSURGICAL

# DIATERMO 106



### 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.

**DIATERMO 106** consists of the following components:

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

### *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.



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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.

### **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.

## **Technical Specifications**

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

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 VAC, 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 1: 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%



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COAG: 40 W +/- 10%

Reference Load Resistance: 400Ω

No Load Max Voltage: 900 V<sub>pp</sub> +/-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

Protection IP21

#### **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)

#### **Standard accessories**

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1 REF GMA10100.05A **DIATERMO 106** Unit  
 1 REF 00100.03 Unit mains cable 2 meters long  
 1 REF 00404.01 Cable for connection of the reference electrode  
 1 REF 5046 Reference electrode  
 1 REF 00301.00 Pedal switch  
 1 REF 00500.01 Kit of 5 assorted tip  
 1 REF MA126IGBa Instruction's Manual italian /english

#### **Manufacturer**

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LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE



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**Declaration of Conformity (fac-simile)**

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PROGETTAZIONI E PRODUZIONI ELETTRONICHE

**DICHIARAZIONE CE DI CONFORMITA'**  
*EC Declaration of Conformity*

per la marcatura CE in accordo all'Allegato II della  
Direttiva 93/42/CEE  
for CE-marking according to Annex II of MDD 93/42/EEC

**Produttore:** LED SpA - Via Secchia, 11 - 04011 APRILIA (LT) ITALY  
*Manufacturer:*

**Categoria del Prodotto:** Apparecchiatura per elettrochirurgia ad alta frequenza / HF Electrosurgical Unit  
*Product Category:*

**Prodotto:** DIATERMO 106  
*Product:*

**Classificazione:** Classe II b  
*Classification:*

**Direttive e Norme Applicate**  
*Applied Standards*

**Direttive applicate**  
*Applied Directives*

- Direttiva Dispositivi Medici 93/42/CEE (D.Lgs. 24/02/87 n.46) / MDD 93/42/EEC

**Norme di Assicurazione Qualità applicate**  
*Applied Quality Assurance Standard*

- UNI EN ISO 9001 (1994)  
- UNI CEI EN 46001 (1996)

**Norme di Sicurezza applicate**  
*Applied Safety Standard*

- EN 60601-1 (1991) + A1 (1995) + A2 (1997)  
- EN 60601-2-2 (1993)  
- EN 60601-1-2 (1993)  
- EN 1441 (1998)

*Claudio Meuti*

Claudio Meuti  
(Resp. Assicurazione Qualità)  
(Quality Assurance Manager)

Aprilia, 23 Ottobre 1998  
October 23, 1998



Mod. 101-0002 rev. 0

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