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1. DESCRIPTION AND INTENDED USE OF CLINIPORATOR VITAE

Cliniporator *VITAE* is the most advanced medical device for electroporation of tissues.

Electroporation is a physical phenomenon that induces an alteration of cell membrane structure through the exposure of cells to a short high intensity electric field; this alteration of the cell membrane leads to an increase of the permeability. Molecules that normally do not go past the cell membrane either in diffusion or active transport, after electroporation can reach the intracellular environment.

Electroporation is the basis for Electrochemotherapy [ECT].

Cliniporator *VITAE* enables the application of electroporation applying high voltage electric pulses that allow the intracellular transfer of molecules not or little permeant the cell membrane.


During the electroporation procedure, Cliniporator *VITAE* measure the voltage and current the waveforms and displays them in real time. The treatment data are stored in the device's archive.

CLINIPORATOR *VITAE* consists of a main unit characterised by:

- a control section called console, on which the application that manages the system is installed
- a power unit which generates pulses
- an incorporated radio section to automatically recognise the electrodes that can be used (only PRE-SET section).

CONSOLE FEATURES		
Operating System	Linux	
Display	17" XVGA Touch screen resistive - resolution 1280 x 1024 pixels	
Power Supply	115/230 VAC	
Electrode Radiofrequency Identification (only PRE-SET section)	RFID ISO15693	
POWER UNIT FEATURES	PRE-SET	CUSTOM
Pulses number	8 (Linear, Finger and Plate Electrode) 24 groups of 4 pulses with polarity inversion (Hexagonal Electrode)	8 ÷ 320 groups of 4 pulses with polarity inversion
Pulses amplitude	400/730/960 Volt	[500 ÷ 3000] Volt
Pulses length	100 µs	100 µs
Rise up time	< 2 µs a 1000 Volt	< 4 µs a 1000 Volt
Pulses repetition frequency	5000 Hz	[1000] Hz
Maximum supplied current	20 Ampere	50 Ampere
Pulse amplitude precision	±5%	±5%
Pulse length precision	±3 µs	±2µs
Commutation interval for each couple of needle/electrodes	<60 ms	3,1 s
ECG signal Synchronization through Norav 1200T (Optional) or a device with same characteristics.		


2. ACCESSORIES

CODE	APPEARANCE	DESCRIPTION
HANDLES IGOM910 (blue) IGOM915 (green)		The handle (two different models) allows the connection with some of the sterile disposable electrode used in the PRESET section. The handle tolerates up to 20 sterilisation cycles in autoclave [caoutchouc cycle, minimum of 15 and maximum of 20 minutes at 121°C]. Process performed not according to the specifics above mentioned, can wear down the handles and jeopardize the effectiveness as stated by the manufacturer, which declines any responsibility.







3. STERILE SINGLE PATIENT'S ELECTRODES

CLINIPORATOR VITAE must be used together with electrodes, disposable sterile devices manufactured by IGEA and specifically designed as applied parts of CLINIPORATOR VITAE. The electrodes allow the application of electroporation to the tissues.


CUSTOM SECTION ELECTRODES

Model	Series VGD Electrode	Description
VGD-aaxxZyy		<p>aa is the electrode diameter (0.8 / 1,2 / 1,8 mm); xx is the length of the active part (10/20/30/40 mm); Z is the tip type: "T" Trocar, "C" Chiba; yy is the total electrode length (12/16/20/24* cm).</p> <p><i>*24 cm only for models VGD-08xxCyy e VGD-12xxTyy</i></p>

PRESET SECTION ELECTRODES

Model	Series EPS, Needle Electrode	Description
N – 10 – HG		Needle length 10 mm, hexagonal configuration, to be used with green handle
N – 20 – HG		Needle length 20 mm, hexagonal configuration, to be used with green handle
N – 30 – HG		Needle length 30 mm, hexagonal configuration, to be used with green handle
N – 10 – 4B		Needle length 10 mm, linear configuration, to be used with blue handle
N – 20 – 4B		Needle length 20 mm, linear configuration, to be used with blue handle
N – 30 – 4B		Needle length 30 mm, linear configuration, to be used with blue handle
Model	Series EPS, Plates Electrode	Description
P – 30 – 8B		Plates length 30 mm, linear configuration, to be used with blue handle
Model	Series EPSA, Adjustable Needle Electrode	Description
H-30-ST		Hexagonal configuration (H), Needle length adjustable in steps of 5mm, 30 mm maximum length (30), Standard not insulated needles (ST)
H-40-IN		Hexagonal configuration (H), Needle length adjustable in steps of 5mm, 40 mm maximum length (40), Insulated needles (IN)
L-30-ST		Linear configuration (L), Needle length adjustable in steps of 5mm, 30 mm maximum length (30), Standard not insulated needles (ST)
L-40-IN		Linear configuration (L), Needle length adjustable in steps of 5mm, 40 mm maximum length (40), Insulated needles (IN)
Model	Series NFD, Wearable Finger Electrode	Description
F-15-NO		Orthogonal configuration, Needle length 15 mm
F-10-NL		Longitudinal configuration, Needle length 10 mm
F-20-NL		longitudinal configuration, Needle length 20 mm

Model	Series EGPS, Expandable Electrode	Description
E-L2-00-S4-2		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 20 cm (2), zero divergence (00), square needle configuration (S), maximum needle exposure 40 mm (4), active part length 20 mm (2).
E-L2-02-S2-2		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 20 cm (2), 2° divergence (02), square needle configuration (S), maximum needle exposure 20 mm (2), active part length 20 mm (2).
E-X2-00-S4-2		Expandable Electrode (E), shaft diameter 10 mm (X), shaft length 20 cm (2), zero divergence (00), square needle configuration (S), maximum needle exposure 40 mm (4), active part length 20 mm (2).
E-X2-03-S2-2		Expandable Electrode (E), shaft diameter 10 mm (X), shaft length 20 cm (2), 3° divergence (03), square needle configuration (S), maximum needle exposure 20 mm (2), active part length 20 mm (2).
E-L5-00-S4-2		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 50 cm (5), zero divergence (00), square needle configuration (S), maximum needle exposure 40 mm (4), active part length 20 mm (2).
E-L5-02-S2-2		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 50 cm (5), 2° divergence (02), square needle configuration (S), maximum needle exposure 20 mm (2), active part length 20 mm (2).
E-L2-10-SA-B		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 20 cm (2), 10° divergence (10), square needle configuration (S), maximum needle exposure 25 mm (A), active part length 15 mm (B).
E-L5-10-SA-B		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 50 cm (5), 10° divergence (10), square needle configuration (S), maximum needle exposure 25 mm (A), active part length 15 mm (B).
E-X2-10-SB-B		Expandable Electrode (E), shaft diameter 10 mm (X), shaft length 20 cm (2), 10° divergence (10), square needle configuration (S), maximum needle exposure 15 mm (B), active part length 15 mm (B).



4. TECHNICAL DATA

Manufacturer	IGEA S.p.A. Via Parmenide 10/A Carpi, 41012, Modena, Italy. ISO 13485 certified Quality System
Model	VGP02
Product name	Cliniporator <i>VITAE</i>
Field of use	Tissue electroporation
Certifications	Cliniporator <i>VITAE</i> complies with electrical safety standards IEC60601-1 complies with the requirements of the European directives for medical devices 93/42/CEE and 2007/47/CEE and it is marked CE0051 under the control of the Notification Body IMQ.
Italian Medical Device Repertory	Number: 425494/R
CND Classification	K0299: Electrosurgery devices - others
Physical specifications:	Dimensions [width x length x height]: 52 x 71 x 152 cm Weight: 85 kg
Technical specifications	<ul style="list-style-type: none"> Output: 6 CUSTOM section, 7 PRE-SET section Maximum Energy delivered per pulse [nominal]: 2 J PRE-SET section - 15 J CUSTOM section
Power supply specifications	<ul style="list-style-type: none"> Mains Voltage: 115/230 VAC Mains frequency: 50 / 60 Hz Maximum input power: 280 VA
Operating conditions	<ul style="list-style-type: none"> Room temperature: 10°C to 40°C Relative humidity: 30% to 75% Atmospheric pressure: 700 hPa to 1060 hPa
Electromagnetic compatibility	Complies with requirements of Standard EN60601-1, EN60601-1-2.
Transportation and storing conditions	<ul style="list-style-type: none"> Room temperature: -20°C to +50 °C Relative humidity: 10% to 90% Atmospheric pressure: 500 to 1060 hPa
Classification	<ul style="list-style-type: none"> EN 60601-1: Class I, BF MDD 93/42 CEE: IIb