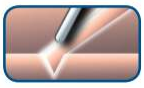
French leader in electrosurgery since 1947

SEAL II

Universal electrosurgical platform with latest generation microprocessors for the providing of energies which are in real time adapted to the evolution of the tissues (Power Feedback).
Reference: V10GMS



Full electrosurgical unit 370 W

Complete electrosurgical units 370 W with a wide range of monopolar and bipolar effects

Endo 1 / Endo 2

Specific waveforms dedicated to endoscopic polypectomy

Argon system

Argon module for a complete solution: Argon Plasma Coagulation for the hepatic and endoscopic surgery

PLASMA EDGE

The gold standard of bipolar plasma resection power dedicated for bipolar TUR and hysteroresection procedures

THERMOCISION

A unique system which can seal, dissect and cut in one instrument, dedicated for Thyroid and delicate procedures

VESSEL SEALING

Safe and efficient up to 7 mm vessel diameter with Validation
signal after sealing process

FT_SEAL-EN (draft)
Date de révision: 5/12/2019

Tél : +33 (0)1 69 20 69 69, Fax : +33 (0)1 60 13 97 47, Mail : info@lamidey-noury.fr, www.lamidey-noury.com
LAMIDEY NOURY MEDICAL, Z.A. Les godets, 3, rue des petits ruisseaux, F-91370 Verrières le Buisson, France
RCS Evry 445 145 105 Siret 445 145 105 00018 TVA FR 49445145105 Code APE 3250A

French leader in electrosurgery since 1947

Special features:

- Friendly user interface digital
- Saving **100 personal programs**.
- 3 High Frequency outputs : 1 monopolar, 1 bipolar ans 1 vessel sealing
- Saline cut with PLASMA technology : - TURP/TURV
  - Intra-uterine resection TCRE
- Full range of single use Plasma EDGE compatible electrode

- Argon capability with the Argon Module System
- Recognition of the vessel sealing intruments
- **Reusable Cutting and Sealing** forceps :

*** THERMOCISION** forceps :

- Completely **reusable**
- **Dissection, sealing and cutting** in one act

*** THERMOCUT** forceps :

- Completely **reusable** and autoclovable
- Safe and efficient sealing up to 7 mm Ø vessels
- Completely dismountable for safer cleaning
- Single use blade
- Cable **not** attached

*** THERMOCLAMP** forceps:

- Completely **reusable**
- open surgery clamps in **16, 22 and 32 cm**

FT_SEAL-EN [draft]
Date de révision: 5/12/2019

Tél : +33 (0)1 69 20 69 69, Fax : +33 (0)1 60 13 97 47, Mail : info@lamidey-noury.fr, www.lamidey-noury.com
LAMIDEY NOURY MEDICAL, Z.A. Les godets, 3, rue des petits ruisseaux, F-91370 Verrières le Buisson, France
RCS Evry 445 145 105 Siret 445 145 105 00018 TVA FR 49445145105 Code APE 3250A

French leader in electrosurgery since 1947

INPUT FEATURES	
Main supply	220-240 V~ 50 or 60 Hz
Safety	Class 1 type CF
Maximum power	1200 VA (600 W)
OUTPUT FEATURES	
Waveform	Pure Sinewave and Pulsed Sinewaves
Frequency emitted	450 KHz
Modulation frequency	21 KHz

MONOPOLAR CUT
FORCED PURE CUT : 370 W / 450 Ω, forced cut
BLEND 1 : 340 W / 450 Ω, forced cut with light haemostatic effect
BLEND 2 : 330 W / 450 Ω, forced cut deep haemostatic effect
ENDO 1/ ENDO 2 : 200 W / 250 Ω for gastrointestinal endoscopy (polypectomy)
MONOPOLAR CUT UNDER IRRIGATION *(glycine)*
MONOPOLAR RESECTION : 350 W / 450 Ω for transurethral resection of prostate (TURP/ TURB / TCRE)
MONOPOLAR COAGULATIONS
SOFT COAG : 170 W / 250 Ω, soft contact coagulation for vascular surgery, pediatric and micro surgery
DESSICATE : 210 W / 450 Ω, forced contact coagulation for all surgeries
FULGURATE : 100 W / 900 Ω, spray coagulation for haemostasis of large area

Tél : +33 (0)1 69 20 69 69, Fax : +33 (0)1 60 13 97 47, Mail : info@lamidey-noury.fr, www.lamidey-noury.com
LAMIDEY NOURY MEDICAL, Z.A. Les godets, 3, rue des petits ruisseaux, F-91370 Verrières le Buisson, France
RCS Evry 445 145 105 Siret 445 145 105 00018 TVA FR 49445145105 Code APE 3250A

French leader in electrosurgery since 1947

Coagulation with ARGON (in option), gasflow : 0 to 10 L/min	
Argon Plasma Coagulation	Coagulation by ionized gas, 100 W / 900 Ω (open surgery)
Pulsed Argon Plasma	Coagulation by ionized gas, 100 W / 900 Ω (gastrointestinal endoscopy)
PLASMA EDGE CUT UNDER SALINE LIQUID (NaCl 0,9%)	
THIN LOOP / Needle	TURB & uterine resection
THICK LOOP	TURP
VAPORIZATION	TURP & uterine resection
BALL	TURP; TURB & TCRE, for coagulation in saline
BIPOLAR COAGULATION	
SOFT Coagulation	100 W / 25 Ω soft coagulation, for neurosurgery and laroscopic surgery
FORCED Coagulation	170 W / 75 Ω for all tissues *(vascularized and adipose tissues)*
SALINE plasma coagulation	180 W / 75 Ω for coagulation under saline liquid

VESSEL SEALING SYSTEM

Maximum power: 150 W / 30 Ω

Vessel sealing until 7mm of diameter with reusable forceps.

Jaws are completely insulated: thermal spread doesn't exceed 2mm.

Action reverse mode for Thermocut handle: clamping pressure is superior to 700mmHG.

Automatic output power adjustment following forceps connected

THERMOCLAMP forceps for open surgery, with a vessel clamping device

THERMOCUT 10 mm forceps for open surgery (28cm with handle) and laparoscopy (36cm with handle), with vessel autoclamping system and integrated cut system, straight jaws (10 mm)

THERMOCUT (5 mm) forceps for open surgery (28cm with handle), laparoscopy (36cm with handle), with vessel autoclamping system and integrated cut system

THERMOCISION forceps for dissection, haemostasis and cutting in one act (thyroidectomy)

Tél : +33 (0)1 69 20 69 69, Fax : +33 (0)1 60 13 97 47, Mail : info@lamidey-noury.fr, www.lamidey-noury.com
LAMIDEY NOURY MEDICAL, Z.A. Les godets, 3, rue des petits ruisseaux, F-91370 Verrières le Buisson, France
RCS Evry 445 145 105 Siret 445 145 105 00018 TVA FR 49445145105 Code APE 3250A

French leader in electrosurgery since 1947

ERGONOMY	
User's interface	KEYBOARD
HF power display	Digital display in maximum Watts
Adjustments	1 W / step
MEMORIZATIONS	Storage of interventions parameters :mode of cut and coagulation, power adjustments.
Automatic bipolar coagulation	Automatic start and stop by impedance contact sensing on forceps.
Personal programs	Memorization of surgeons' adjustments *(Possible memorization of several thousand adjustments).*
MONOPOLAR OUTPUTS	International plugging for hand switches with a 3 pins in line plug and for cable with one 4mm male plug
BIPOLAR OUTPUTS	Plugging for wire with two 4 mm diameter male plug (interaxial spacing 28.5 mm)
Twin footswitches	1 socket for : Monopolar and bipolar cut Monopolar and bipolar coagulation
Single footswitches	2 sockets for : Bipolar coagulation Vessel sealing system
Hand control	Monopolar cut and coagulation control on handswitch

Tél : +33 (0)1 69 20 69 69, Fax : +33 (0)1 60 13 97 47, Mail : info@lamidey-noury.fr, www.lamidey-noury.com
LAMIDEY NOURY MEDICAL, Z.A. Les godets, 3, rue des petits ruisseaux, F-91370 Verrières le Buisson, France
RCS Evry 445 145 105 Siret 445 145 105 00018 TVA FR 49445145105 Code APE 3250A

French leader in electrosurgery since 1947

SAFETIES	
Neutral Electrode Safety	- Monitoring of skin contact with single use adhesive double plate - Audible and visual alarm in case of contact failure or short circuit, or electrical discontinuity with inhibition of HF power. - Compatible with adult and children plates
Single plates	Monitoring of electrical continuity between unit and neutral electrode.
HF control power	Monitoring of HF power emitted, with automatic power shutdown in case of excessive HF Power *(IEC 60601-2-2)*.
HF leakage	I_{hf} < 100mA / 200 Ω (< 130 mA / 200 Ω in fulgurate mode)
Electrical safeties	class 1, CF type (*I <1µA in Normal Conditions*) Defibrillation proof device Short circuit protection > 10 s
Thermal safety	Forced ventilation
HF voltage	Regulated (automatic limitation of maximum voltage)
Limited activation	Automatic stop after 1 minute of continuous activation. Normal working is restored after interruption of the control.
Auto check starting	When power on, the unit is checking all accessories connected and internal circuits

Tél : +33 (0)1 69 20 69 69, Fax : +33 (0)1 60 13 97 47, Mail : info@lamidey-noury.fr, www.lamidey-noury.com
LAMIDEY NOURY MEDICAL, Z.A. Les godets, 3, rue des petits ruisseaux, F-91370 Verrières le Buisson, France
RCS Evry 445 145 105 Siret 445 145 105 00018 TVA FR 49445145105 Code APE 3250A

ELECTROSURGICAL UNIT

SEAL

REF : V10GMS

EN

Ref : NU-SEAL.Rev2
Revision Date : 01/10/2020
Year of affixing CE marking : 2004

LAMIDEY NOURY MEDICAL
Z.A. Les Godets - 3, rue des Petits Ruisseaux
91370 Verrières-Le-Buisson (France)
Tél : (33) 01.69.20.30.21 - Fax : (33) 01.60.13.97.47
E-mail: info@lamidey-noury.fr

CE 0459

INDEX

1 INTRODUCTION

THE INSTRUCTIONS BELOW ARE AN INTEGRAL PART OF THE HIGH-FREQUENCY SURGICAL DEVICE THAT YOU HAVE JUST ACQUIRED. THEY DESCRIBE ITS OPERATION AND USE AND MUST BE READ CAREFULLY BEFORE THE GENERATOR IS INSTALLED AND USED.

All safety instructions and warning notes must be scrupulously complied. Make sure that they are transferred whenever the device is used by new personnel. No portion of this document may be photocopied, reproduced, or translated without the written approval of ***LAMIDEY-NOURY MEDICAL***.

When the power is switched on, the digital display of the unit briefly shows the following information:
- The software version appearing on the bipolar coagulation display.
- The serial number of the device appearing on the monopolar displays (the coagulation display for hundreds, the cut display for thousands).

Technical data on electrical features, preventive maintenance and routine troubleshooting are available in the units Service Manual. Biomedical services of hospitals can obtain this manual from LAMIDEY NOURY Medical or its authorized representative, on request.

2 FIELD OF APPLICATION

THE UNIT MUST ONLY BE USED AS DESCRIBED IN THESE OPERATING INSTRUCTIONS. ANY OTHER USE IS IMPROPER AND DANGEROUS. THE MANUFACTURER CANNOT BE CONSIDERED RESPONSIBLE FOR DAMAGE CAUSED BY IMPROPER, ERRONEOUS OR WRONG USE.

THE USE OF SEAL UNIT IS EXCLUSIVELY RESERVED FOR SURGEONS. This electrosurgical unit (ESU) is designed to be used intermittently for surgical operations in the operating room, through open way or laparoscopic way, and for resection under liquid. It can be associated with a gas flow control device for performing coagulations under an ionized argon jet.

This unit is intended for electrosurgical cutting and coagulation in monopolar and bipolar mode, for vessel sealing with THERMOCLAMP®; THERMOCUT® and THERMOCISION® forceps, and for bipolar resection in saline, with Plasma Edge® electrodes.

The unit can be used in the following specialties (non exhaustive list): Ambulatory surgery; Gynaecological and obstetric surgery; Cardiac and thoracic surgery; Orthopaedic surgery; Paediatric surgery; Plastic and reconstructive surgery; Vascular surgery; Visceral and digestive surgery; Digestive endoscopy; Urology; Neurosurgery; Oto Rhino Laryngology; Odontology; Dermatology.

Table below details commonly used functions and their applications

Modes	Functions	Applications
MONOPOLAR	**CUT** *(Pure ; Blend1 ; Blend 2)*	Soft tissue incisions and coagulations in all surgical specialties
	COAGULATION *(Soft ; Dessicate ; Fulgurate ; Argon; Pulsed Argon)*	
	CUT *(Resection)*	Resection under Glycine irrigation, in Urology and Gynecology, for Prostate (TURP); Bladder (TURB); cervico-prostatic incisions, and operative hysteroscopy for myomectomies and endometrial ablations.
	CUT *(Endo 1 : Endo 2)*	Digestive endoscopy (Polypectomy; Mucosectomy)
BIPOLAR	**COAGULATION** *(Soft ; Forced)*	Soft tissue incisions and coagulations in all surgical specialties, with bipolar forceps.
	SALINE PLASMA COAGULATION	Coagulations in bipolar resection procedures under saline irrigation, with electrodes of the PLASMA EDGE™ range, Thin loop, Thick loop and Ball type, for Prostate and Bladder resection procedures (TURP and TURB); cervico-prostatic incisions, and operative hysteroscopy for myomectomies and endometrial ablations.
	CUT (Plasma Edge Resection)	Cuts and vaporization in bipolar resection procedures under saline irrigation, with electrodes of the PLASMA EDGE™ range, Thin loop, Thick loop, Needle and Vaporization type, for Prostate and Bladder resection procedures (TURP and TURB); cervico-prostatic incisions, and operative hysteroscopy for myomectomies and endometrial ablations.
VESSEL SEALING	**SEAL** *(Thermocut 5 ; Thermocut 10 ; Thermoclamp ; Thermocision)*	Sealing of vessels and tissues, using sealing forceps such as THERMOCUT™ or THERMOCLAMP™. Haemostatic tissue dissection using THERMOCISION™ forceps.

3 CONTRAINDICATIONS

Modes	Description of contraindications
ALL MODES	ALCOHOLIC ANTISEPTICS: the use of electrosurgical devices is contraindicated in the presence of flammable gases and vapors, such as the vapors released by alcoholic antiseptics. If alcoholic antiseptics are used, the treated skin surface must be dry before applying the active electrodes.
MONOPOLAR	HIGH CURRENT MODE USE: The unit is not intended for high current mode procedures such as radiofrequency tissue ablation, nor for long activation (recommended duty cycle less than or equal to 10 s on for 30 s off). The device is not intended for short-circuit operation.
	PATIENT WITH AN ACTIVE IMPLANTABLE DEVICE: Some active implantable devices have relative or absolute contraindications for electrosurgical techniques due to the risk of electromagnetic interference (see precautions for use). It is important that the surgeon consults the relevant and recent medical literature and makes his decision based on his assessment of the benefit/risk ratio for the patient.
	PATIENT EQUIPPED WITH ELECTRICALLY CONDUCTIVE IMPLANTS: Conduction of HF current in a conductive implant can present a risk of burns. It is important to position the neutral electrode so that the implant is not placed between this plate and the surgical site.
	IRRIGATION OR SALINE INFILTRATION: The use of monopolar mode is not recommended on tissues irrigated or infiltrated with saline. Conductive fluids disperse HF current, which may cause burns away from the point of contact with the tissue. In arthroscopic procedures, the use of an arthropump activated simultaneously with the HF current is essential to avoid burns due to the heating of the saline solution.
RESECTION	OPERATIVE HYSTEROSCOPY, known contraindications: Pelvic inflammation and infection; Acute cervico-vaginitis; Significant metrorrhagia; Pregnancy; Cervical or uterine malignancy.
	PATIENT AGE: The use of PLASMA-EDGE™ bipolar resection electrodes is restricted to adult patients, excluding pregnant women.
VESSEL SEALING	CONTRAINDICATION OF VESSEL SEALING: The age of the patient and certain co-morbidities (cancer, coronary artery disease) may compromise the healing process and the integrity of the fusion zone. These factors should be considered in the surgical risk assessment prior to applying vessel sealing technique. Vascular pathologies (atherosclerosis, aneurysms, irradiated tissue...) present a high risk of failure of the fusion and healing processes. It is important to avoid applying sealing to the affected areas. The diameter of the vessels or tissues caught in the forceps must not exceed 7mm. Above this dimension, the reliability of sealing is not guaranteed.
	CONTRAINDICATION OF THERMOCISION : do not use the THERMOCISION™ forceps on vessels larger than 2mm in diameter.
	PATIENT AGE: use of THERMOCUT™ forceps with their blades is restricted to adult patients, excluding pregnant women.

MAINTENANCE OF THE DEVICE DURING USE: No part of the device should be serviced or maintained when the device is used with a PATIENT.

4 GENERAL INFORMATIONS

4.1 USER TRAINING

- Knowledge of the contents of this manual by surgeon is sufficient to begin using the generator in monopolar and bipolar cutting and coagulation modes without additional training.

The use in Vessel Sealing modes requires prior knowledge of the contents of the instructions for use of the THERMOCUT, THERMOCLAMP and / or THERMOCISION forceps.

Use in bipolar resection modes requires prior knowledge of the contents of the PLASMA-EDGE resection electrodes operating instructions and their associated working handles.

Representatives or distributors of the company LAMIDEY NOURY MEDICAL, remain available, at the request of the users, to assist them in their first use of the equipment and for any additional information.

4.2 OPERATING ENVIRONMENT

SEAL unit is designed for use in the operating room, connected to the mains supply network dedicated to the operating theatre and insulated from the public network (medical rooms of group 2 of the IEC 60364-7-710 standard, with insulated power supply according to the medical IT diagram). It is recommended that these operating rooms be equipped with an antistatic conductive floor and that the relative humidity be close to 50%, to prevent the risk of electrostatic discharges and the risk of explosion of flammable medical gases.

- Environmental conditions

Environmental conditions	Temperatures	Relative humidity	Atmospheric pressure
For transport and storage	-20 to +70°C	0 – 95%	500 – 1060 hPa
For use	+10°C to +40°C	0 – 85%	620 – 1060 hPa

Do not leave the unit exposed to atmospheric agents (rain, sun, etc.), even in its transport packaging.

- Specifications of the mains supply network

Mains supply insulated from the public mains	220 - 240 V ~ ; 50/60 Hz (or option 110-120 V~ ; 50/60 Hz)
Maximum apparent power input	95 VA in stand-by ; 1200 VA
Overcurrent protection	2 external fuses T 6,3 AH, 250 V (or T 10 AH, 250 V for 110-120 V option)

- Exclusions: SEAL device is suitable for operation in a hospital environment (operating rooms), except installations near active HF SURGICAL EQUIPMENT and the CONTROLLED ACCESS AREA of a MAGNETIC RESONANCE SYSTEM, where the intensity of ELECTROMAGNETIC DISTURBANCES is high.

USE OF THIS EQUIPMENT ADJACENT TO OR STACKED WITH OTHER EQUIPMENT SHOULD BE AVOIDED BECAUSE IT COULD RESULT IN IMPROPER OPERATION. IF SUCH USE IS NECESSARY, THIS EQUIPMENT AND THE OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THAT THEY ARE OPERATING NORMALLY.

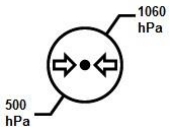
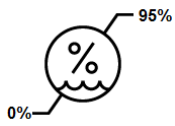
NOTE: *the operation of the unit in Argon Plasma mode requires an ARGON module ref V11A100, designed and tested to operate with the SEAL unit superposed on the module*.

4.3 MEDICAL DEVICE CLASSIFICATION

According to the classification criteria for medical devices mentioned in IEC 60601-1, the table below specifies the classifications applicable to the SEAL unit:

Classification criteria	**Classification**
Protection against electric shock	Class I
Type of applied parts	CF type, protected against defibrillation shock
Protection against ingress of water according to IEC 60601-2-2 (art. 201.11.6.3)	The device is protected against the harmful effects of a reasonable quantity of water spilled on the unit
Sterilization method	Non-sterilizable device
Suitability for use in an OXYGEN RICH ENVIRONMENT	 **Not applicable:** use prohibited in an oxygen-rich environment
Mode of operation	Non continuous operation 10 s ON / 30 s OFF

4.4 MEANING OF SYMBOLS AND INDICATORS USED

	Mains switch : Power up (light on)		Mains switch : Power off (light off)
	Single-phase AC mains supply voltage		Equipotential terminal
	Reference code		Serial number
	Device including RF transmitter		Connection socket for a footswitch
	Manufacturer's identification		Manufacturing year YYYY
	At the end of its service life, the device must be disposed of in a state-approved recycling facility.		Protective earth terminal (on the mains power cord)
	Instructions for use		Warning
	the instruction manual must be read before operating		CF type applied parts, protected against defibrillation shock
	High HF voltage (risk of burns). Do not touch the plugs or connected conductors.		Patient circuit insulated in HF (neutral electrode without earth connection)
	Assignment of double pedal controls (Bipolar / Monopolar modes)		Plate-patient contact monitoring mode selections (single or split plate mode)
	Automatic bipolar coagulation disabled		Automatic bipolar coagulation enabled
	Selection key		Adjustment of the sound level (4 levels)
	Cut power output controls		Coagulation power output controls
	Vessel sealing power output controls		Confirmation key for resection electrode replacement
	Key for loading a stored program		Key for storing program in memory
	Transport conditions : FRAGILE		Storage and transport conditions: KEEP DRY
	Transport and storage position : TOP		Transport and storage conditions Temperature limits (-20°C - 70°C)
	Transport and storage conditions Atmospheric pressure limits (500-1060 hPa)		Transport and storage conditions Humidity limits (0-95%)

	Weight of the empty unit (Installation on trolley)		Maximum safe load (Installation on trolley)
	Service manual: maintenance instructions		Dangerous voltage, DO NOT TOUCH

5 INSTALLATION OF THE ELECTROSURGICAL UNIT

5.1 MAINS CONNECTION

- TO AVOID RISK OF ELECTRIC SHOCK, THIS UNIT SHOULD ONLY BE CONNECTED TO A MAINS SUPPLY EQUIPPED WITH A PROTECTIVE EARTH. The continuity of the earth connection must be checked regularly. If in doubt, replace the mains power cord and have the installation checked by qualified personnel. Lamidey Noury Medical cannot be held responsible for damage caused by an installation that does not have an effective earth connection.
- Before connecting the unit to the mains power supply, make sure that the voltage indicated on the nameplate matches the local network voltage. For proper use of the equipment, the specified environmental conditions must be respected (see § 4.2).
- The unit is supplied with a power cord with a standard 10 / 16 A & Ground plug. Connect the power cord to the corresponding socket on the rear panel of the unit. In the event of incompatibility between the power outlet and the power cord, replace only with connectors and accessories that comply with current standards. Using adaptors, multiple outlets, or extensions is not recommended. If it is impossible to do otherwise, make sure they comply with current safety standards.
- Do not leave the device connected if not needed. Switch off the unit as soon as it is no longer being used.

5.2 INSTALLATION PRECAUTIONS

- Do not use the device and its accessories near a source of flammable gas or vapors.
- INGRESS OF WATER: The enclosure of the device does not provide protection against the penetration of water or material particles. The user must take all necessary measures to avoid any contact with water, which, as with any electrical equipment, could cause injuries (electric shocks).
- Inappropriate storage and/or physical stress during transport could lead to a failure or malfunction likely to induce harm. Therefore, it is required for the user to check the proper operation of device before use and to strictly follow the mandatory verification operations as described in IFU.
- EMERGENCY STOP: In use, the device must be positioned so that the On/Off switch, on the rear panel, remains accessible at all times.
- Do not stack the unit with other electro-medical devices. Doing so may result in malfunctions of the individual devices. The operation of the electro-surgical generator may be affected by disturbances from other electronic equipment in the operating room (see § 5.5)
- FORCED CONVECTION COOLING: Do not obstruct ventilation openings or cover the unit with surgical drapes.
- The SEAL unit is a portable unit, thanks to the carrying handle on the rear panel. It must be installed on a flat and stable surface with dimensions at least equal to its own and capable of withstanding its weight.

-The unit must not be placed on the ground except in its packaging box.

5.3 INSTALLATION ON TROLLEY

Trolley
ref V10GALP

trolley
ref V10GA2

2 models of trolleys are available for installation in the operating room (photos above).

The castors on the trolley are designed to make it easy to move the unit around within the operating room for convenience. THEY ARE NOT INTENDED FOR MOVEMENT WITH THRESHOLD CROSSINGS OR FOR ROLLING ON CABLES. It is therefore necessary to take all necessary precautions to prevent the trolley from tipping over in the event of an obstacle in its path.

The trolley is not designed to support a person's load. There is a risk of falling when standing on its base.

5.4 OPERATING ACCESSORIES

- Before using the unit in monopolar mode, it is necessary to bring the neutral electrode into contact with the patient and connect it to the unit. This one is designed to be used with plates divided into 2 conductive areas for monitoring skin patient contact. The operating circuit is floating in low and high frequency (neutral electrode not referenced to earth): any electrical connection between the neutral electrode and the operating table is prohibited.

- Footswitches are connected on the rear panel.

- All other active operating accessories are connected on the front panel.

5.5 ELECTROMAGNETIC INTERFERENCES

ELECTROMEDICAL EQUIPMENTS require special precautions with regard to Electro-Magnetic Compatibility (EMC). They must be installed and commissioned in accordance with the EMC information provided in the ACCOMPANYING DOCUMENTS.

SEAL unit is designed to provide the following performances:

- During the activation of HF current, the output power must not be interrupted and the unit must not be resetted into stand-by mode, unless this is indicated on the devices display.

- The output power delivered must remain within ±20% of the power graphs provided in the technical description of the unit.

Possible alterations in performance, due to electromagnetic disturbances, could be non operation of a safety device, false alarms, uncontrolled power activations, interruptions of operation.

WARNING: PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SEAL unit, including cables specified by LAMIDEY NOURY MEDICAL. Otherwise, degradation of the performance of this equipment could result.

The EMISSIONS characteristics of this equipment make it suitable for use in hospital setting (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The equipotential terminal on the rear side of the unit can be connected to another equipotential terminal in the electrical installation. This connection is recommended as a preventive measure against the risk of malfunctions caused by electromagnetic interference.

WARNING: It is not recommended that the electrosurgical generator be used near from another electrosurgical generator in operation, or that both generators be used on the same patient. Interference may result.

6 PRECAUTIONS FOR USE

6.1 OPERATING INSTRUCTIONS ACCORDING TO IEC/EN 60601-2-2

A) THE FOLLOWING INSTRUCTIONS FOR USE ARE ESSENTIAL PRECAUTIONS TO REDUCE THE RISK OF BURNS.

1) The entire area of the NEUTRAL ELECTRODE should be reliably attached to a suitably prepared and appropriate area of the PATIENT'S body:

- It is recommended to use in priority disposable and adhesive NEUTRAL ELECTRODES, split into two conductive parts, and complying with the patient's weight (see the labeling of NE). These ones are the only models compatible with the monitoring of the skin contact.

- When the NEUTRAL ELECTRODE is reusable, this one must be clean, without damaged surface, and it must be attached to the patient's body with a bandage, to ensure the largest possible area of skin contact.

- Choose a muscle location (thigh, buttock, abdomen, eg.). The location must be clean, dry, cosmetics free, shaved and without antiseptic. Do not use alcohol solution to clean the skin. Do not add any gel.

- Avoid hairy parts, scars, bone parts, joints, proximity to metal prosthesis or other electrodes (eg ECG.), or parts of the body subject to a buildup of fluid. Avoid lumbar site, sacrum, ischial, and Scapula.

- Do not reduce the contact surface of the NEUTRAL ELECTRODE by cutting this one or by overlapping. NEUTRAL ELECTRODE should not be folded. Do not interpose a surgical drape or other tissue between the NEUTRAL ELECTRODE and the patient

- Remove air inclusions under the NEUTRAL ELECTRODE by hand pressure from the end of the plate to the connecting tab

- Avoid any risk of liquid infiltration beneath the NEUTRAL ELECTRODE. This could compromise the adhesion of the electrode and the efficiency of the skin contact monitoring

- Do not remove and reposition an adhesive NEUTRAL ELECTRODE. If the patient is moved during the operation, make sure there is still proper skin contact with the NEUTRAL ELECTRODE.

- Do not exceed expiration date of adhesive NEUTRAL ELECTRODEs, and comply with storage temperature limits specified on labelling.

- In the event of a NEUTRAL ELECTRODE alarm, replace the electrode and its connector

2) The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.)

3) Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze.

4) When HF SURGICAL EQUIPMENT and physiological monitoring equipment are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating HIGH FREQUENCY current limiting devices are recommended.

5) The PATIENT leads should be positioned in such a way that contact with the PATIENT or other leads is avoided. Temporarily unused ACTIVE ELECTRODES should be stored in a location that is isolated from the PATIENT.

6) For surgical procedures where the HF current could flow through parts of the body having a relatively small cross sectional area, the use of BIPOLAR techniques may be desirable in order to avoid unwanted tissue damage.

7) The output power selected should be as low as possible for the intended purpose.

Certain devices or ACCESSORIES may present an unacceptable RISK at low power settings. For example, with argon beam COAGULATION, the risk of gas embolism rises if there is insufficient HF power to produce a rapid, impermeable eschar on the target tissue.

In gastrointestinal endoscopy, if the power setting is too low to initiate immediately the cut during a polypectomy or a mucosectomy, the thermal diffusion in the tissues can cause tissue necrosis with a risk of perforation.

8) Apparent low output or failure of the HF SURGICAL EQUIPMENT to function correctly at the normal operating settings may indicate faulty application of the NEUTRAL ELECTRODE or poor contact in its connections. In this case, the application of the NEUTRAL ELECTRODE and its connections should be checked before selecting a higher output power.

9) The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (NO2) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

Non-flammable agents should be used for cleaning and disinfection wherever possible.

Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling of flammable solutions under the PATIENT or in body depressions such

as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF SURGICAL EQUIPMENT is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton and gauze, when saturated with oxygen may be ignited by sparks produced in NORMAL USE of the HF SURGICAL EQUIPMENT.

10) For PATIENTS with electrically conductive implants, a possible HAZARD exists due to concentration or re-direction of HF currents. In case of doubt, qualified advice should be obtained.

B) INTERFERENCE PRODUCED BY THE OPERATION OF HF SURGICAL EQUIPMENT MAY ADVERSELY INFLUENCE THE OPERATION OF OTHER ELECTRONIC EQUIPMENT.
For PATIENTS with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.

C) MAXIMUM OUTPUT VOLTAGE FOR EACH ELECTROSURGICAL HF MODE, VARIES DEPENDING ON THE OUTPUT SETTING. CHAPTER 9.1 INCLUDES THE MAXIMUM OUTPUT VOLTAGE DIAGRAMS ACCORDING TO THE SETTING FOR EACH MODE. THE ASSOCIATED EQUIPMENT AND ACTIVE ACCESSORIES SHOULD BE SELECTED IN THESE ONES HAVING A RATED VOLTAGE ACCESSORIES HIGHER OR EQUAL TO THE MAXIMUM OUTPUT VOLTAGE

D) Failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power. *In such a case, switch off the power supply to the unit immediately, either by using the main switch on the rear panel or by unplugging the power cord.*

E) LAMIDEY NOURY MEDICAL declares that the SEAL (or OPTIMA) generators are compatible with the MONITORING NEUTRAL ELECTRODES, from SKINTACT™ brand, with references RS25;RS25/5 (adult plates) and RS26 (pediatric plate), manufactured by Leonhard Lang GmBH.

Unless a compatible MONITORING NEUTRAL ELECTRODE is used, loss of safe contact between the Neutral Electrode and the PATIENT will not result in an auditory alarm.

F) When the HF SURGICAL EQUIPMENT is used with a NEUTRAL ELECTRODE including a single conductive area, such as SILIPLAQUE C (Ref. V11IS1C), a poor application of this NEUTRAL ELECTRODE induces a risk of severe burns, without auditory alarm. To mitigate this risk, the following tips must be scrupulously followed.

- The electrode must be fixed to the patient's thigh with a bandage. All the electrode surface must ensure a direct contact with the naked skin. The location where apply the electrode must be clean, shaved, without antiseptic. Do not add any gel on the skin.

- Clean the neutral electrode before use (cleaning with soapy water, then rinsing with clean water and drying). The electrode surface must not be damaged and it must be dry, without residues of antiseptics. The electrode SILIPLAQUE cannot be steam sterilized. It can be decontaminated with a spray for surface, and then rinsed and dried.

G) Neuromuscular stimulations can occur especially with modes which produce electrical arcs between the ACTIVE ELECTRODE and tissue, such as Fulguration mode, Argon Plasma Coagulation, and resections under liquid. These stimulations can induce a secondary risk of injury. It is advised to apply the following means of mitigation of risk:

- *Use the lowest power setting as possible for the intended effect.*
- *Use fasteners to maintain the patient on the operating table.*
- *In the event of muscular or nerve stimulations of the patient, check all the ESUs connections. If none of them is defective, have an electrical safety check performed on the device.*

H) The AUTOMATIC BIPOLAR COAGULATION MODE presents risks of nuisance tripping, and burning on contact with active electrodes. To mitigate these risks, the automatic mode should not be selected when electrodes are irrigated with saline, or when laparoscopic bipolar forceps are connected to the device. After use, do not put the bipolar forceps on the patient: it could result in a skin burning.

I) The maximum length of cables and accessories compatible with the generator is specified below:

	Monopolar	Bipolar	Neutral Electrode
Cables	4 m		5 m
Accessories	0.5 m		0.3 m

The use of cables or accessories of greater length can have a harmful influence on the risks of interferences of electro-medical equipments, and on the risks of burns by leakage currents.

6.2 ADDITIONAL SAFETY RECOMMENDATIONS

A) RISKS OF MISUSE

- The unit must only be used for the purpose for which it was specifically designed. All other use is improper and dangerous. The manufacturer may not be held responsible for damage caused by improper, erroneous, or incorrect use.
- Non observance of IFU in general & in particular warnings, such as the strict application of verification and maintenance operations, or for device disposal can lead to misuse, dysfunction/malfunction likely to induce harm (Adverse Events or Serious Adverse Events) or non-effective device (intended use not reached), or hazardous situations for environment.
- The device shall be used strictly according to IFU, by persons corresponding to the user profile, for indications and intended use as described. All other use are prohibited and contraindicated by the manufacturer because it could lead to Hazardous Situations likely to induce Harm (Adverse Events or Serious Adverse Events) or non-effective device (intended use not reached), or hazardous situations for environment.
- Before starting an intervention, systematically check configurations of use, modes of cut and coagulation selected, and the output power settings. Pay attention to check the right configuration of the double footswitch: it can be assigned to monopolar mode or bipolar mode.
- Do not touch simultaneously the patient and the pedal connector contacts on the device.
- Making contact between a monopolar active electrode and non-insulated metal forceps held by the surgeon exposes the surgeon to the risk of a skin burn through the gloves: these are not designed to protect the surgeon against high-voltage HF currents.

B) DYSFUNCTION RISKS - MAINTENANCE

- As any device, dysfunction and/or Failure can occur during the device lifecycle. Therefore, it is necessary to ensure proper operation of device before use and to strictly follow the periodic maintenances as described in IFU. Non-Observance of operations mentioned in IFU could lead to Hazardous Situations likely to induce Harm (Adverse Events or Serious Adverse Events) or non-effective device (intended use not reached), or hazardous situations for environment.
- It is dangerous to modify or attempt to modify the properties of the device OPTIMA - In the event of damage or poor operation, turn off the generator and have it repaired by a support center approved by Lamidey-Noury Medical.
- Before any cleaning or maintenance operation, disconnect the unit by unplugging the power cord.
- In the event of damage or malfunction, turn off the power by flipping the M / A switch on the rear panel, or disconnecting the AC power cord. For a repair call a service center approved by the manufacturer, requiring original spare parts. Any other solution may compromise the safety of the device and especially that of its user.
- Avoid checking the function of the unit by making a short circuit between the active and neutral electrode, or by contact between the active electrode and metal parts.

C) MINOR ADVERSE EVENTS.

The benefits of the device outweigh the probability of adverse events. However, minor adverse events could occur during use of the device, such as superficial burns. It is recommended that a physician be consulted if symptoms persist for more than 2 weeks, or if symptoms worsen.

D) SERIOUS ADVERSE EVENTS.

Benefits outweight Serious Adverse Events (SAE) occurrence. However, SAE are reported in scientific and medical literature and reviewed periodically to ensure adherence to state of art. SAE reported and known are listed here below. - These Serious Adverse Events need to be addressed immediately by medical staff.

1) SOUND LEVEL MUST BE ADJUSTED TO BE HEARD DESPITE AMBIENT NOISE. If the sound level is too low, an unintentional activation of HF current may not be perceived, which could lead to serious injury. It is recommended to adjust the sound volume according to the ambient noise level, and / or to reduce the ambient noise.

2) SKIN BURNING RESULTING FROM A HF CURRENT LEAKAGE, THROUGH LIQUIDS: the HF current can pass to the metal parts of the operating table via a conductive liquid (antiseptic, blood, saline, amniotic fluid ...). Avoid basting the patient with excessive amounts of antiseptic solution, so as not to cause accumulation of fluid under the patient. A waterproof liner covering the operating table can reduce the risk of conduction to the table.

3) INJURY RESULTING FROM AN INDUCTED HF CURRENT: Do not form loops with the electrosurgical cables during use. Loops crossed by a HF current are creating an inductive coupling with other cables nearby. It can make burns located at the applied parts in contact with these cables, and or dysfunctions to the devices connected to these cables.

4) JEWELLING, PIERCING: before surgery, it is necessary to remove any jewelry or piercing worn by the patient, to avoid burning by the passage of HF current through the metal of these items.

5) ELECTROSURGERY IN LIQUID:

a) Use of resection under liquid may cause an accumulation of explosive gases in the bladder. Care must be taken to evacuate any gas pockets formed during resection and to avoid activation of the HF current when the active end of the electrode is in the gas. Otherwise the bladder may rupture due to ignition of the gas mixture.

b) the activation of HF current in saline risks burning by heating the liquid:

- Infiltration of tissues by a conductive liquid such as saline, induce a risk of diffusion of monopolar RF current through the liquid. This could cause burns away from the point of application of the active electrode. The use of bipolar mode is recommended to avoid current diffusion.
- In arthroscopy, it is recommended to use an arthropump, to replace liquid heated by fresh liquid with each activation of HF current.
- Monopolar resection procedures in gynecology and urology using a resectoscope require irrigation with a non-conductive liquid (Glycine).
- Bipolar resection procedures require continuous saline irrigation throughout the duration of electrosurgery, using a double flow resectoscope. Check irrigation before and during surgery.

6) STIMULATION OR MONITORING ELECTRODES: avoid proximity and contact between an active electrosurgical electrode and a stimulation or monitoring electrode connected to the patient. Transmission of HF current via a stimulating electrode, or a monitoring electrode, is likely to cause irreversible damage, including damages to cardiac or nerve tissues.

7) LESIONS TO BONE TISSUES: avoid applying HF current to the Periosteum. This can impair the healing process. Necrosis of the tissues may ensue.

8) As a precaution, against unexpected HF power activations, deactivate or adjust to the minimum power all unused functions during surgery. Disconnect all foot switches or hand switches, not used during the procedure.

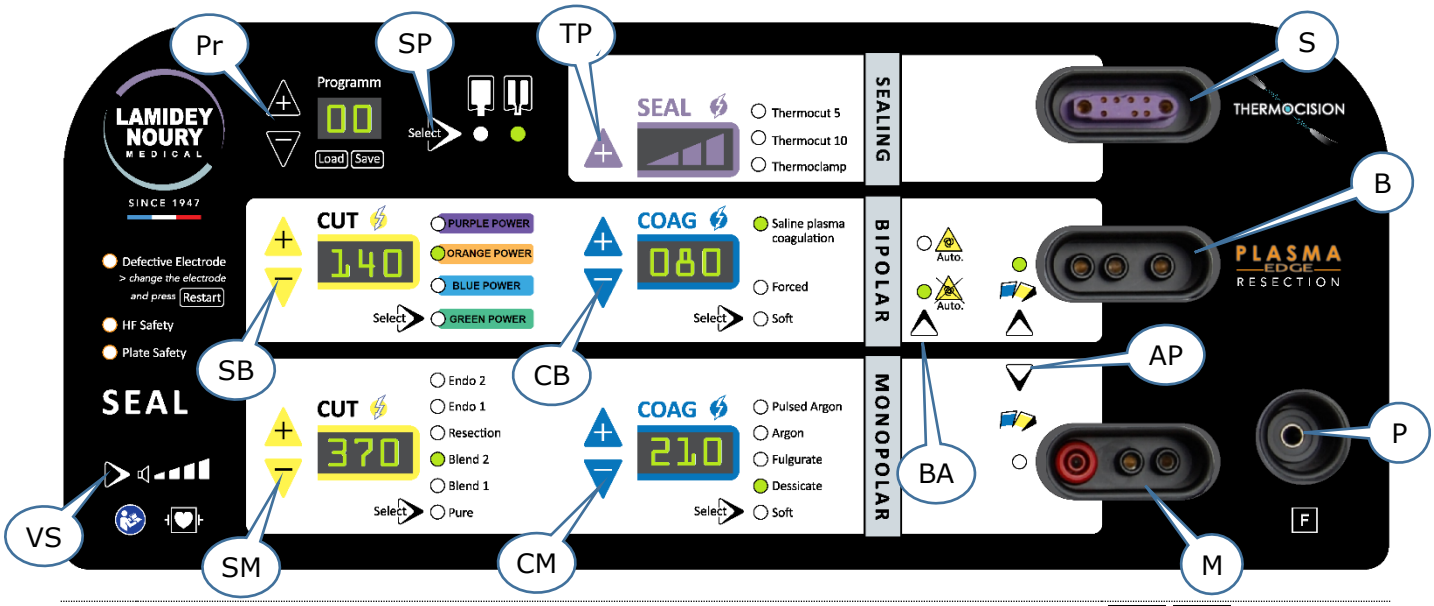
9) Never touch the device with wet or damp hands or feet. Do not use the device with bare feet. It could result in a skin burning for user.

10) RISK OF FIRE OR EXPLOSION: The use of the generator is prohibited in flammable or explosive atmosphere. Keep a safe distance of at least 25 cm between the electrosurgical equipment, including accessories, and anesthesia equipment or their pipes. Do not cover the electrosurgical cables with drapes. The cables should remain visible throughout their length.

11) Contact or proximity between a monopolar active electrode and a non-insulated electrically conductive device may result in a risk of burns on contact with the device. A safety distance of more than 5 mm is recommended.

7 DESCRIPTION AND OPERATION OF THE UNIT

7.1 DESCRIPTION OF FRONT PANEL



Pr – Selection of personal programs by registration number

Loading and saving personal programs

SP - Selection of the monitoring mode of the plate/patient contact

R - Reset the "Defective electrode" alarm.

TP - Vessel sealing power level selection and display

Vessel sealing output power activation indicator light

S – Active outlet for Vessel sealing / Thermocision

SB – Bipolar cut power adjustment keys

Bipolar cut output power activation light

CB - Bipolar coagulation power adjustment keys

Bipolar coagulation output power activation light

SM - Monopolar cut power adjustment keys

Monopolar cut output power activation light

CM - Monopolar coagulation power adjustment keys

Monopolar coagulation output power activation light

VS – Volume control key

BA – Selection of automatic bipolar coagulation mode (on / off)

B – Active bipolar outlet

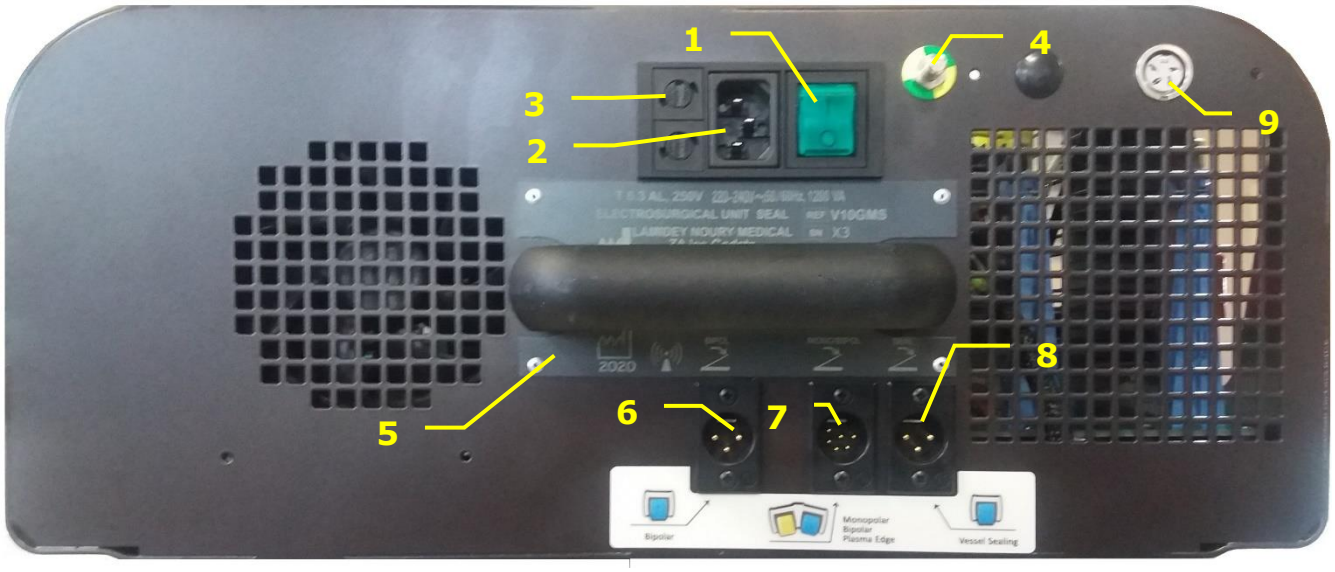
AP – Double pedal assignment selection keys (2 selections)

M – Active monopolar outlet (triple)

P – Neutral electrode outlet (Plate)

Digital power displays: The output powers delivered adapt to variations in tissue impedance. Therefore, the numerical values displayed are relative power levels. In the case of SEAL mode, the display is in 3 levels represented by increasing bars.

7.2 DESCRIPTION OF REAR PANEL



1 Mains power switch
2 Mains power socket
3 Mains fuses
4 Equipotential terminal
5 Nameplate
6 Single pedal socket (for outlet B)
7 Double pedal socket (for outlet B et red monopolar outlet)
8 Single pedal socket (for outlet S)
9 Outlet for Argon module control (option)

7.3 EXPECTED POSITION NEAR FROM THE UNIT IN USE

- The device should be placed close to the operating table to allow the use of active accessories in the operating field, but as it is not sterile, it should not come into contact with either the patient or the operator.
- It must be oriented in such a way that the operator can see the indications displayed on the front panel at all times.
- Mains switch on the rear panel must remain accessible to the personnel at all times.

7.4 UNIT OPERATION

This section provides a brief description of the operation of the device. For a detailed description of the operating modes, see § 9.

7.4.1 DEFINITIONS

HF CURRENTS: High Frequency currents ($f \geq 200$ KHz) delivered by electrosurgical units (or HF surgical equipments) to provide cutting and coagulation effects.

ACTIVE ELECTRODE: an active electrode is an electrode whose contact with tissues produces conversion of HF energy into thermal energy inside tissues, in order to produce cutting or coagulation effects.

ACTIVE PART: non insulated part of an active electrode, that comes onto contact with tissues to cut or coagulate.

NEUTRAL ELECTRODE: also called an indifferent electrode, dispersive electrode, or plate, this is a large-surface-area electrode that is brought into contact with the patient and is intended to close the HF circuit without producing any noteworthy thermal effect.

MONOPOLAR MODE: an HF current application mode in which the HF current passes through the patient between an active electrode and a neutral electrode.

BIPOLAR MODE: an HF current application mode in which the HF current passes through the tissues located between two active electrodes.

RATED ACCESSORY VOLTAGE: maximum peak HF output voltage which may be applied to a MONOPOLAR HF SURGICAL ACCESSORY with respect to a Neutral Electrode connected to the PATIENT. For a BIPOLAR HF SURGICAL ACCESSORY, the maximum peak HF output voltage which may be applied to pairs of opposite polarity

7.4.2 GENERAL DESCRIPTION

SEAL unit is an Electro-Surgical Unit (ESU) generating HF currents intended to produce the following effects:
- In the Monopolar mode: cutting, haemostatic cutting, and coagulation
- In the Bipolar mode: cutting, coagulation, VESSEL SEALING and BIPOLAR RESECTION in saline

The APPLIED PARTS to the patient are as follows:
- Monopolar patient circuit: 1 neutral electrode output (including 2 poles), and 1 monopolar active output.
- Bipolar patient circuit: 1 output dedicated to cuts and coagulations with 2 poles (including resection in saline), and 1 output dedicated to coagulation and Vessel Sealing / THERMOCISION™ modes with 2 poles.

Use in the Monopolar mode requires the application of a NEUTRAL ELECTRODE (the plate). The device can be used with a single plate, or with a plate whose conductive surface is divided into two parts (split plate).

Systems automatically controlling the internal parameters will report any detected anomalies.

The last power settings used are automatically saved and retrieved when the device is switched on.

Users can save the current settings. Saved settings can be recalled at any time using the number under which they were saved.

The volume of the activation tone is adjustable.

HF currents are activated using hand-switches, pedals, or by contact with the tissues in automatic Bipolar coagulation.

7.4.3 MONOPOLAR CUTTING

The application of a high HF current density on a fine active electrode produces the bursting of the cells by the thermal effect. The cutting effect is obtained by moving the electrode on the tissues and thus vaporizing the cells one after the other

If the device is used in MONOPOLAR RESECTION, via a Urethroscope or a Hysteroscope, the operating cavity must be filled with a solution of Glycine. This operating technique requires specific precautions to be taken to avoid the risk of TURP syndrome. Bipolar resection in a saline environment is an alternative that avoids this risk, especially for long-term operations

7.4.4 MONOPOLAR COAGULATION

Monopolar coagulation causes haemostasis of the capillary vessels by contact with a large electrode (knife, ball, thick needle), or haemostasis of a bleeding surface, without contact by means of an electric arcing (with Fulgurate function or Argon Plasma Coagulation)

MONOPOLAR COAGULATION UNDER ARTHROSCOPY involves a risk of heating the saline irrigation solution. It requires the use of an arthropump, synchronised with the activation of HF current, in order to cool the operating cavity.

7.4.5 BIPOLAR RESECTION (PLASMA EDGE™ MODE)

Bipolar resection in saline solution, or PLASMA EDGE™ mode, is intended for Trans-urethral resections of the Prostate or Bladder, and Hystero-resections. A bipolar cutting current is applied between the 2 poles of a bipolar resection electrode immersed in saline solution (0.9% NaCl). A bubble of ionised vapour (plasma) is created around the active pole to vaporise tissues in contact. When the active electrode takes the form of a loop or a needle, the displacement of the electrode is accompanied by an incision. If the electrode is hemispherical in shape, it will cause tissues vaporization

Saline irrigation of the operating cavity requires precautions against the risk of heating of the conductive fluid. It is imperative to have continuous irrigation, with a double flow resectoscope, throughout the operation.

The risks known to date are a lack of irrigation and heating of the external jacket of the resectoscope. LAMIDEY NOURY offers bipolar resection electrodes without any current return through the resector sheaths, in order to avoid any heating of the external sheath.

7.4.6 BIPOLAR COAGULATION

Bipolar coagulation uses bipolar forceps, or a bipolar resection loop to heat the cells up to the point of coagulation at about 80°C with soft coagulation. Above 100 ° C, it dehydrates the cells (Desiccation). The depth of coagulation depends on the application time of the HF current. Tips for use:

- Do not submerge the jaws of bipolar forceps in blood. Blood should be removed before coagulation.
- To perform tissue coagulation, the 2 poles must not be in contact with each other (short-circuit malfunction)
- SALINE PLASMA COAGULATION mode is intended exclusively for resection procedures under saline irrigation, in UROLOGY and GYNECOLOGY. It should not be used with bipolar forceps.
- In Soft and Forced modes, SALINE IRRIGATION using bipolar forceps with irrigation channel, connected to a pouch of saline solution (irrigation by gravity effect or using a peristaltic pump) facilitates the coagulation of adipose tissue, and avoids carbonization of the tissue. It is essential in neurosurgery, to preserve neurons from excessive heating.

7.4.7 SEALING

Bipolar VESSEL SEALING is a bipolar application intended to seal the walls of an artery or vein by fusion of collagen and elastin, thanks to the thermal energy produced in tissues by the HF current.

THERMOFUSION requires the use of dedicated forceps, THERMOCLAMP™, THERMOCISION™ or THERMOCUT™. The connection to the multifunction socket with recognition allows the output power to be automatically adjusted according to the connected forceps.

VESSEL SEALING process is monitored by a microprocessor: a sound signal alerts the surgeon when fusion has been completed. The surgeon can then release the activation control. Operating incidents are signaled by repetitive beeps.

Section 9.1.5 details the use and usage precautions of VESSEL SEALING.

8 START-UP PROCEDURE

8.1 VERIFICATION UPON RECEIPT

Upon receipt, inspect the device and note any damage having occurred during transport. Claims will only be accepted if they are reported to the deliverer or directly to the shipper. If the unit is returned, it is imperative to use its original packaging or any other packaging capable of maintaining its integrity during its return shipment.

8.2 INITIAL OUTPUT SETTINGS

In general, output power settings are dependent on multiple factors:

- The impedance of the tissue through which the HF current flows (adipose tissue offers a high resistance to current, especially with respect to the plate).
- The size of the active electrodes (thin electrodes require less power to cut).
- The patient's mass and the distance between the plate and the monopolar active electrode (pediatric surgery requires much less power than adult patient surgery).
- The selected coagulation mode (Fulgurate mode requires less power than Desicate mode).

Therefore, to reduce the risk of misadjustment, it is necessary to set the power to 0 for all unused modes, and to increase the power gradually for used functions until the correct setting is found.

Special cases:

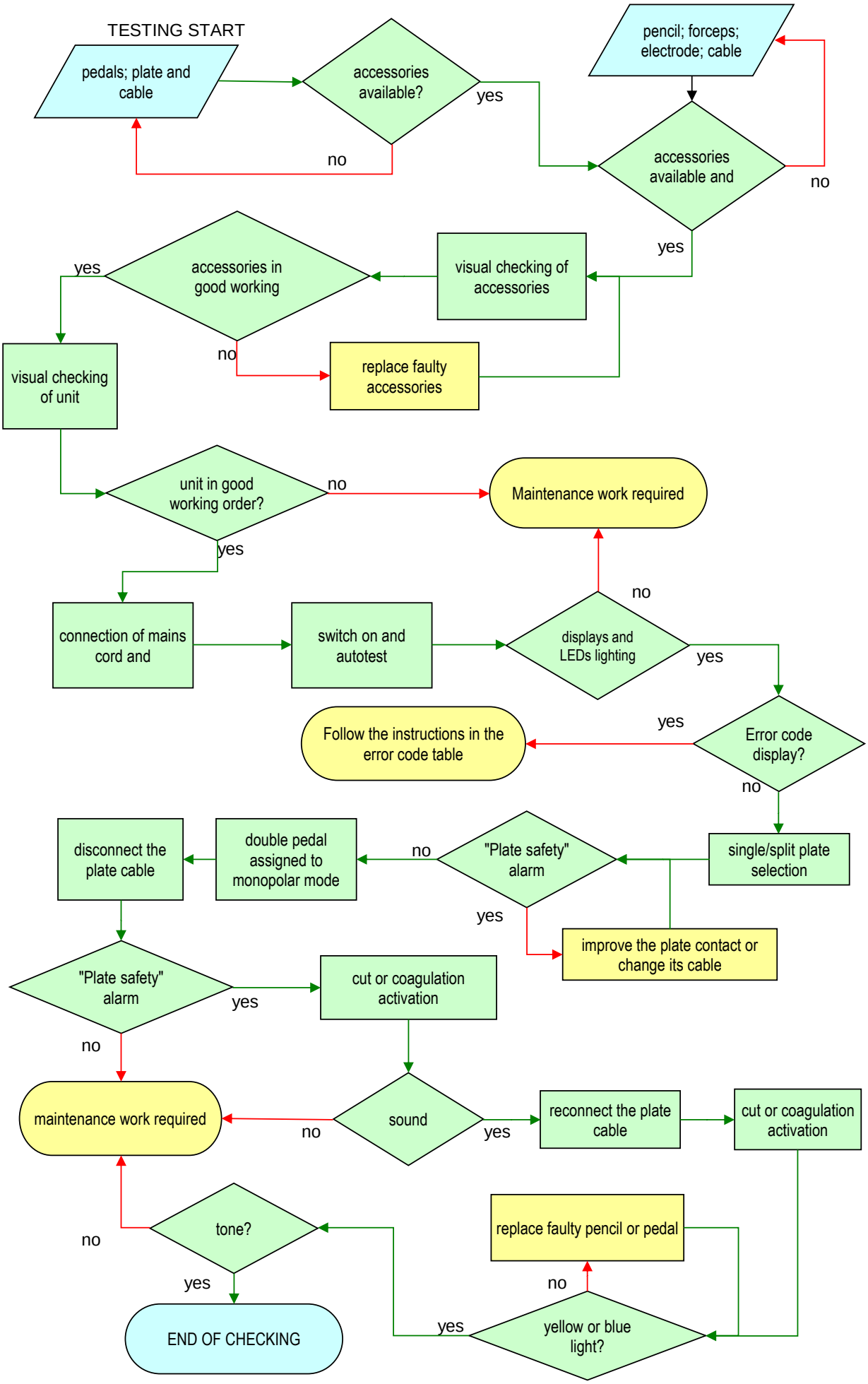
- In digestive endoscopy (Endo 1/Endo 2 functions), a minimum cutting power of 100 is necessary to avoid thermal diffusion in the tissues which could cause necrosis of the intestinal wall.
- When using Argon Plasma coagulation, it is recommended to use sufficient coagulation power to ionize the gas immediately to cause rapid hemostasis of the tissues.
- In Vessel Sealing mode, the basic setting is determined by connecting the cable associated with the forceps to the generator. The operator can choose between 3 levels. The minimum level will be chosen on vascularized tissue with small plugs between the forceps jaws. The maximum level for adipose tissue or for large tissue intakes.
- In bipolar resection, the power range is framed according to the selected resection electrode. Limits are set to ensure efficient cutting and coagulation.

8.3 CHECKS BEFORE USE

A daily check of the ESU and its accessories is recommended. The following flow chart describes checking steps. CAUTION: ACTIVE ELECTRODES MUST NOT COME INTO CONTACT WITH ANYONE DURING CHECKING!

The patient to be operated has to be placed on the operating table in such a way as to remain isolated from the metal parts of the table. If conductive liquids can flow over the table, an impermeable sheet covering the table can prevent the HF current from being conducted to the operating table via the liquid.

- The correct application of the neutral electrode on the patient, and its connection to the generator before starting the operation, is essential for use in monopolar mode.
- Connect foot pedals or touch control handles.
- Activate the ON/OFF switch on the rear panel: the unit switches on by performing a self-test phase and displaying the serial number on monopolar power display (cut and coagulation), and software version on bipolar coagulation power display.
- At the end of this phase, if no fault is detected, display switches to operating mode.
- - If a message indicates a fault, the unit cannot be used until the cause has been eliminated.

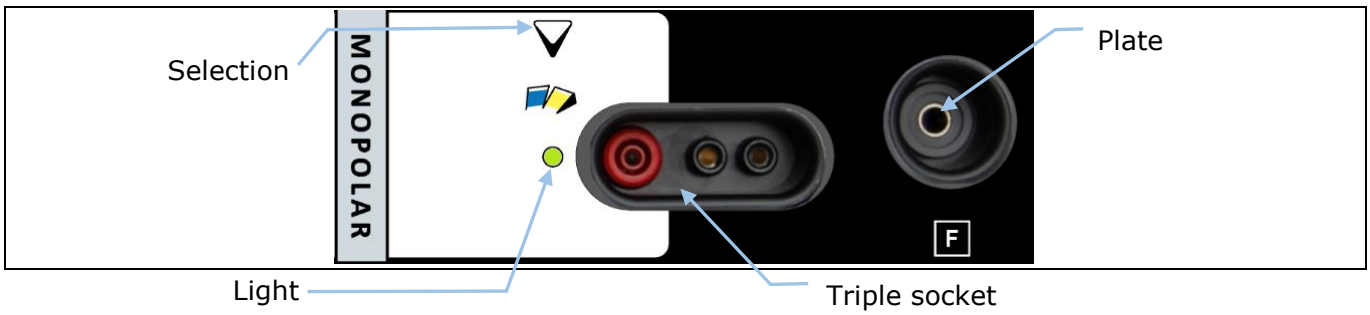

TESTING START
pedals; plate and cable
accessories available?
yes
no
pencil; forceps; electrode; cable
accessories available and
no
yes
visual checking of accessories
accessories in good working
yes
no
replace faulty accessories
visual checking of unit
unit in good working order?
no
Maintenance work required
yes
connection of mains cord and
switch on and autotest
displays and LEDs lighting
no
yes
Error code display?
yes
Follow the instructions in the error code table
no
single/split plate selection
"Plate safety" alarm
no
double pedal assigned to monopolar mode
disconnect the plate cable
yes
improve the plate contact or change its cable
"Plate safety" alarm
yes
cut or coagulation activation
no
maintenance work required
sound
no
yes
reconnect the plate cable
cut or coagulation activation
tone?
no
yes
END OF CHECKING
replace faulty pencil or pedal
no
yellow or blue light?
yes

9 USAGE - FUNCTIONS

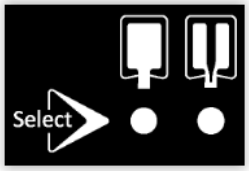
9.1 MODES OF USE - DESCRIPTION

9.1.1 Monopolar cutting modes

CONNECTIONS AND SELECTIONS:



- Connect the plate cable to the generator on the one hand, and with the plate applied to the patient on the other hand.
- Select plate safety mode: single or split plate



If using the double pedal control:
- Press the select key: the LED should light up.
- Connect the active cable Ref V11FM40 in the red socket:

If using handswitches controls:
- Plug the hand-operated pencil into the triple socket

Note: If a bipolar cut is selected, the monopolar mode will be automatically disabled: all LEDs and monopolar displays will turn off.

PURE CUT	Select Pure	Maximal power: 370 W / 450 Ω Maximal voltage: 900 V_p

PRESS SELECT KEY TO TURN ON "PURE" INDICATOR

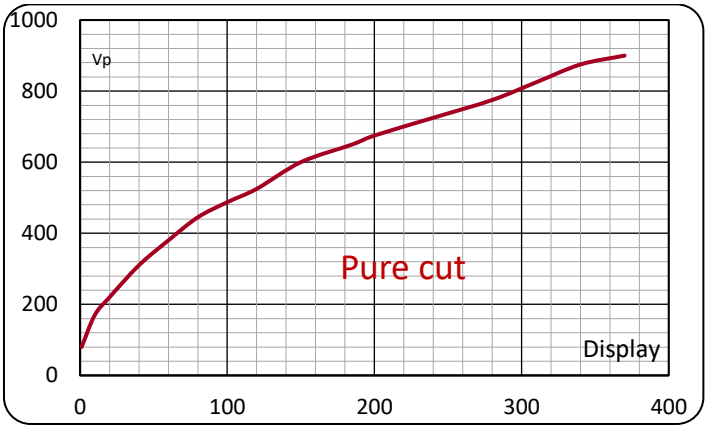
Use : cutting in open or laparoscopic surgery (all specialties)

Special features: minimal thermal spread at the edges of the incision.

Recommended electrode : thin needle, or loop

Applications: Incision of all kind of soft tissues, including adipose tissues. LLETZ of the cervix.

Precautions for use: see general recommendations (see section 6)



BLEND 1

Select Blend 1

Maximal power: 340 W / 450 Ω
Maximal voltage: 1 575 V_p

PRESS SELECT KEY TO TURN ON "BLEND 1" INDICATOR

Use: cutting in open or laparoscopic surgery (all specialties)

Special features: Light hemostasis effect of the edges of the incision.

Recommended electrode: medium needle or knife.

Applications: Incision of all kind of soft tissues, including adipose tissues.

Precautions for use: see general recommendations (see section 6)

BLEND 2

Select Blend 2

Maximal power: 330 W / 450 Ω
Maximal voltage: 1825 V_p

PRESS SELECT KEY TO TURN ON "BLEND 2" INDICATOR

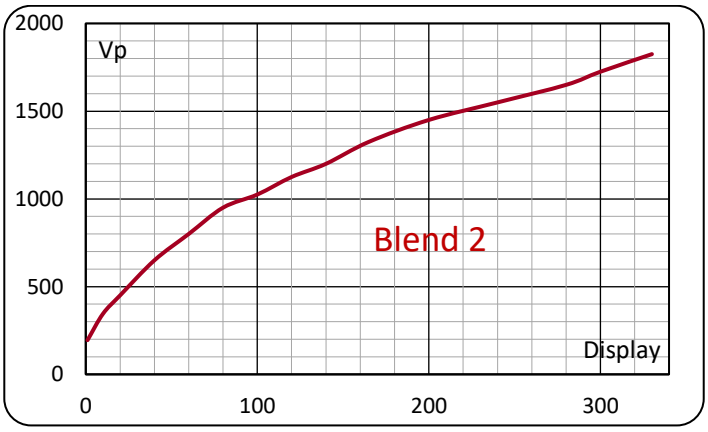
Use: cutting in open or laparoscopic surgery (all specialties)

Special features: deep hemostasis effect of the edges of the incision

Recommended electrode: knife.

Applications: Incision of all kind of soft tissues, including adipose tissues.

Precautions for use: see general recommendations (section 6)



ENDO 1

Select Endo 1

Maximal power: 200 W / 250 Ω
Maximal voltage: 430 V_p

PRESS SELECT KEY TO TURN ON "ENDO 1" INDICATOR

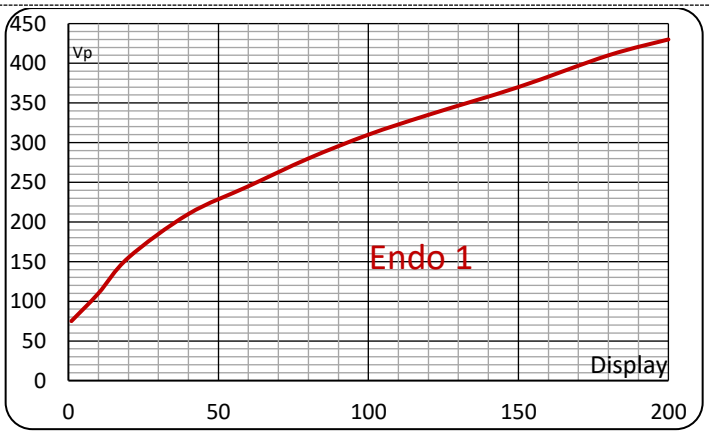
Use : digestive endoscopy

Special features: Fractionated cut self-regulated. 800 ms cycles; cutting phase, 60% of the cycle; coagulation phase 40% of the cycle.

Recommended electrode: Polypectomy snare.

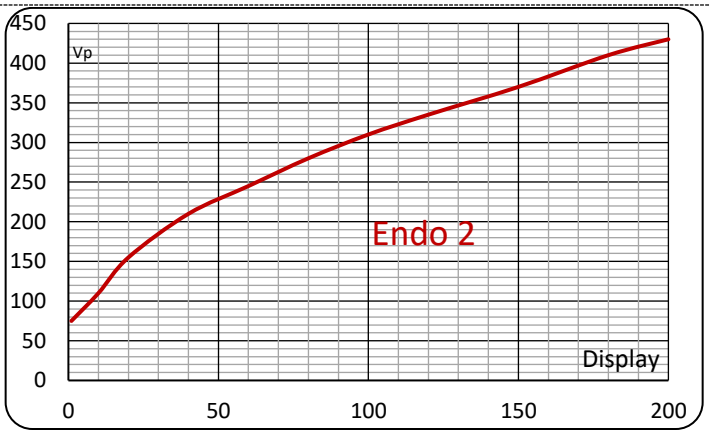
Applications : Polypectomy (pedicled polyps or not)

Precautions for use: recommended power, 100 ≤ P ≤ 120. Risk of thermal diffusion and tissue necrosis if the power setting is too low.



ENDO 2 Select Endo 2

Maximal power: 200 W / 250 Ω
Maximal voltage: 430 V_p



PRESS SELECT KEY TO TURN ON "ENDO 2" INDICATOR

Use : digestive endoscopy

Special features: Fractionated cut self-regulated. 800 ms cycles; cutting phase, 40% of the cycle; coagulation phase 60% of the cycle.

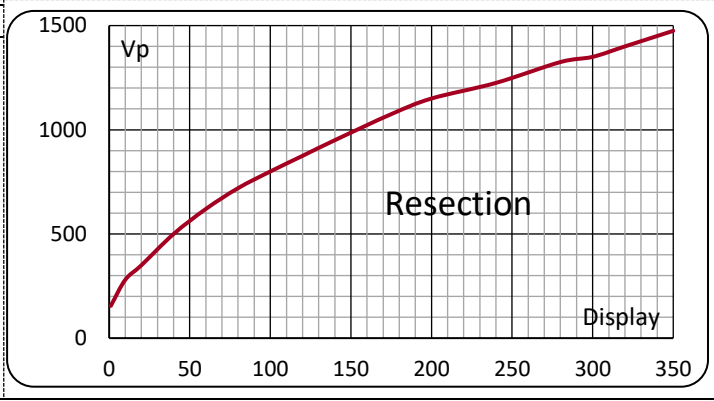
Recommended electrode: Polypectomy snare.

Applications : Polypectomy (pedicled polyps or not)

Precautions for use : recommended power, 100 ≤ P ≤ 120. Risk of thermal diffusion and tissue necrosis if the power setting is too low.

RÉSECTION Select Resection

Maximal power: 350 W / 450 Ω
Maximal voltage: 1 480 V_p



PRESS SELECT KEY TO TURN ON "RESECTION" INDICATOR

Use : urological and gynaecological surgery

Special features: light hemostatic effect

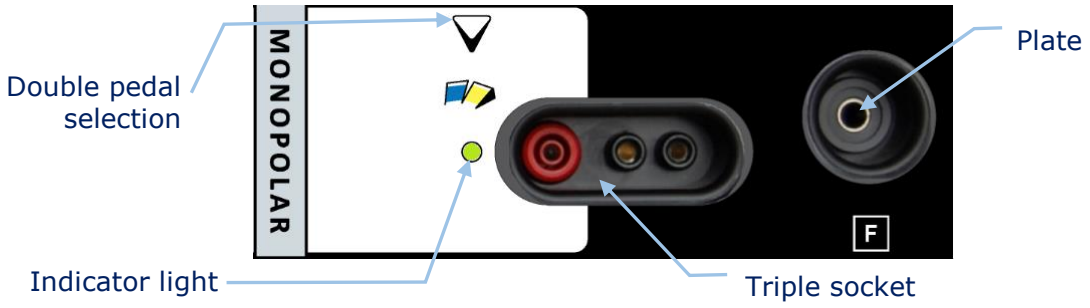
Recommended electrode: loop monopolar electrode for resectoscope.

Applications : transurethral resection of the prostate (TURP), operative hysteroscopy

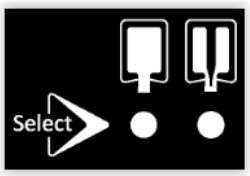
Precautions for use: requires continuous GLYCINE irrigation (Saline irrigation is at high risk of burns).
Recommended settings: 120 ≤ P≤ 150

9.1.2 Monopolar coagulation modes

CONNECTIONS AND SELECTIONS:



- Connect the plate cable to the generator on the one hand, and with the plate applied to the patient on the other hand.
- Select plate safety mode: single or split plate



<u>If using the double pedal control:</u>

- Press the select key: the LED should light up.
- Connect the active cable Ref V11FM40 in the red socket:

<u>If using handswitches controls:</u>

- Plug the hand-operated pencil into the triple socket

<u>Note:</u> If a bipolar cut is selected, the monopolar mode will be automatically disabled: all LEDs and monopolar displays will turn off.

Soft coagulation 

Maximal power: 170 W / 250 Ω
Maximal voltage: 1600 V_p

PRESS SELECT KEY TO TURN ON "SOFT" INDICATOR

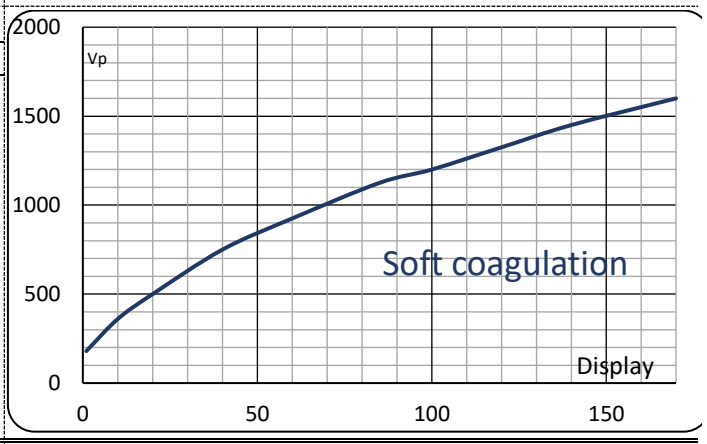
Use : Pediatric surgery, digestive endoscopic surgery

Special features: white coagulations without carbonization. Automatic RF power shutdown as soon as coagulation occurs.

Recommended electrodes: ball or monopolar insulated forceps.

Applications: contact coagulation for vascularized tissues, coagulation with hot biopsy forceps (endoscopy).

Precautions for use : see general recommendations (section 6)



Dessicate 

Maximal power:210 W / 450 Ω
Maximal voltage:2 250 V_p

PRESS SELECT KEY TO TURN ON "DESSICATE" INDICATOR

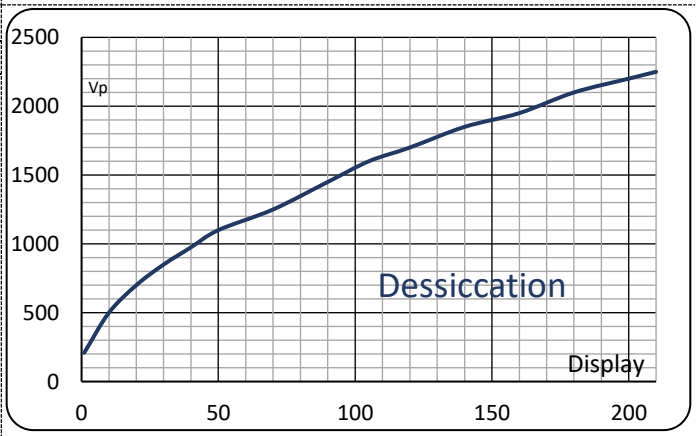
Use : all surgical specialties, except digestive endoscopy

Special features: current suitable for high impedance tissues (eg. adipose tissues).

Recommended electrodes: ball, knife, or monopolar insulated forceps.

Applications: contact coagulation for all kind of soft tissues.

Precautions for use : see general recommendations (section 6)



Fulgurate 

Maximal power: 100W / 750 Ω
Maximal voltage: 3600 V_p

PRESS SELECT KEY TO TURN ON "FULGURATE" INDICATOR

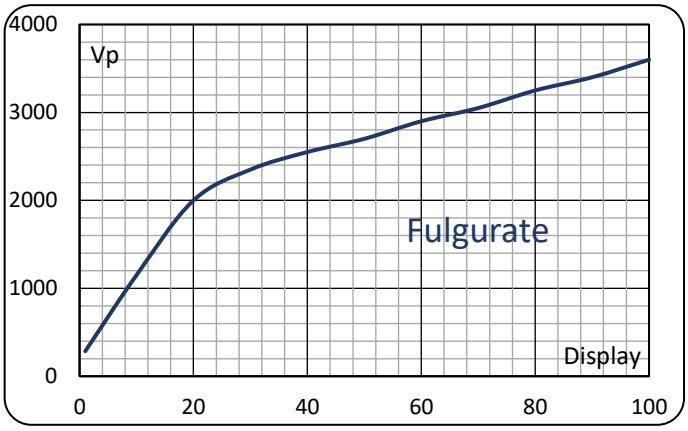
Use: Visceral, hepatic and thoracic surgery.

Special features: Non-contact coagulation by electrical sparking

Recommended electrode: needle or ball electrode.

Applications: Coagulation of diffuse bleeding surface, by scanning the electrode above the tissues.

Precautions for use: maintain a safety distance of at least 10 mm with all tissues that need to be preserved from the effects of coagulation. Check the compatibility between the fulguration setting and the rated voltage of the connected accessory. Not recommended for use with monopolar forceps or laparoscopic surgery electrodes. In case of use in contact with tissues, make progressive adjustments lower than 50W.



Argon Select Argon

Maximal power: 100W / 750 Ω
Maximal voltage: 3600 V_p

PRESS SELECT KEY TO TURN ON "ARGON" INDICATOR

Use: Visceral, hepatic and thoracic surgery, digestive endoscopy.

Special features: non-contact coagulation through an ionized gas flow. The generator must be equipped with a compatible argon distribution module.

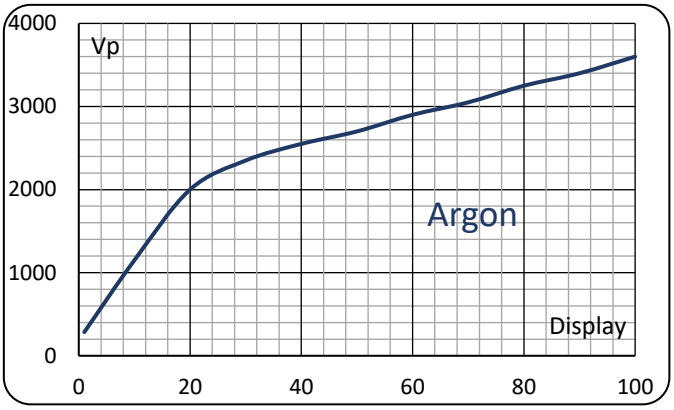
Recommended electrode: argon electrodes for open surgery, or endoscopic Argon probes.

Applications: coagulation of diffuse bleeding surfaces, tissue devitalization.

Precautions for use: RISKS OF GAS EMBOLISM - Do not direct gas into a vascular lumen. Not recommended for laparoscopic surgery. The risk of gas embolism rises if there is insufficient power to produce a rapid impermeable eschar on the target tissue.

Do not put the electrode in contact with the tissues. Contact with tissues involves the following risks:

- Obstruction of the electrode.
- Injection of gas into the tissues.
- Necrosis or perforation caused by electric sparks within tissues.



Pulsed Argon Select Pulsed Argon

Maximal power: 100W / 750 Ω
Maximal voltage: 3600 V_p

PRESS SELECT KEY TO TURN ON "PULSED ARGON" INDICATOR

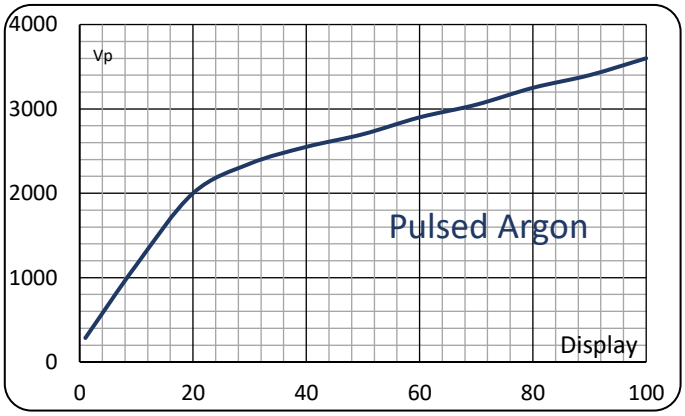
Use: Visceral, hepatic and thoracic surgery, digestive endoscopy.

Special features: non-contact coagulation through an ionized gas flow. The generator must be equipped with a compatible argon distribution module. The effect of coagulation is mitigated by a discontinuous HF current emission. Emission time 150 ms / downtime 250ms.

Recommended electrode: argon electrodes for open surgery, or endoscopic Argon probes.

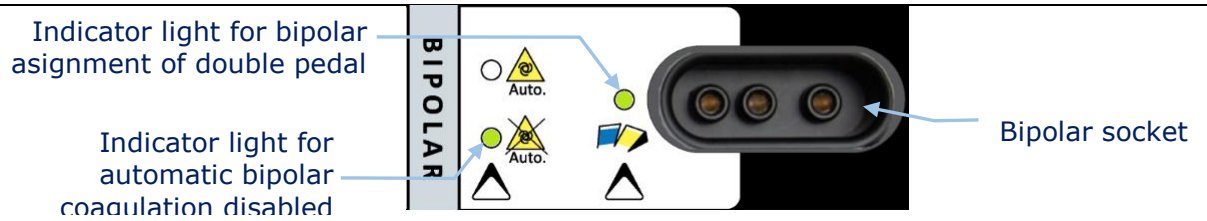
Applications: coagulation of diffuse bleeding surfaces, tissue devitalization.

Precautions for use : see above, precautions for Argon Plasma Coagulation

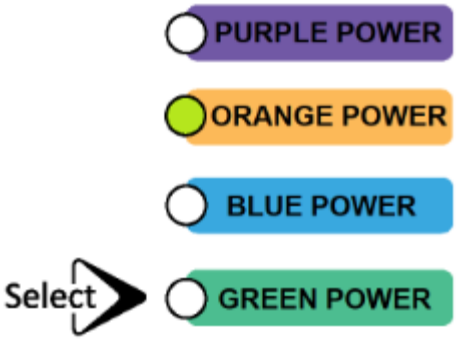


9.1.3 Bipolar cutting modes - PLASMA EDGE RESECTION

CONNECTIONS AND SELECTIONS:



- Connect the bipolar resection electrode in the bipolar socket
- Select a bipolar cut of your choice
- NOTES: The following configurations are automatically selected
- Automatic bipolar coagulation mode is disabled,
- Assignment of the double pedal to bipolar mode
- Extinction of the LEDs and displays dedicated to monopolar mode
- Illumination of the text "PLASMA EDGE RESECTION".



Maximal power: 230 W / 350 Ω
Maximal voltage: 500 V_p

PRESS THE SELECT KEY TO LIGHT THE LED CORRESPONDING TO THE ELECTRODE COLOUR IN USE.

- *Use* : Urological and Gynecological Surgery
- *Special features*: Cells are vaporized by the vapor plasma coating the resection loop, producing a cutting effect.
- *Recommended electrodes* : thin bipolar resection loops PLASMA EDGE of LAMIDEY NOURY MEDICAL
- *Applications* : hysteroscopic resection, transurethral resection of Prostate and Bladder (TURP / TURB)
- *Recommended electrodes*: Plasma Edge electrodes from Lamidey Noury Medical. For TURB, it is recommended to use only thin loop electrodes; thick loop electrodes are intended for long term resections (> 30min), in particular TURP; needle electrodes are intended for incisions (cervix incision, synechia cure); Vaporization electrodes are intended to vaporize tissues, ball electrodes only allow coagulation, enucleation electrodes are intended for enucleation of the Prostate.

Precautions for use :

- Use of non-validated electrodes can cause risks of malfunctions, neuromuscular stimulations or serious injury.
- Use a double flow resectoscope. The irrigation flow must be operational throughout all the duration of the intervention, to avoid excessive heating of the liquid.
- Use a saline irrigation (NaCL 0.9%) at room temperature. Temperature of the solution should not exceed 37 ° C (risk of burns).
- Any attempt to resect with a defective electrode may cause patient stimulation and injury. Any defective electrode must be replaced immediately.

9.1.4 Bipolar coagulation modes

CONNECTIONS AND SELECTIONS:

Bipolar socket

Selection of automatic bipolar coagulation

Selection key for double pedal asignment

- Connect bipolar forceps or Plasma Edge electrode in bipolar socket *(bipolar cable V11F242 has only 2 pins).*

Control by single pedal :
- Connect single pedal on rear panel.
- Automatic bipolar coagulation must be disabled.

Control by double pedal :
- Press selection key for double pedal: indicator must light on.
- Automatic bipolar coagulation must be disabled.

Automatic bipolar coagulation
- Press selection key for automatic bipolar coagulation. Indicator must light on
- Activation will be initiated when the forceps will touch tissues

Soft 

Maximal power: 100 W / 30 Ω
Maximal voltage: 125 V_p

PRESS SELECT KEY TO TURN ON "SOFT" INDICATOR

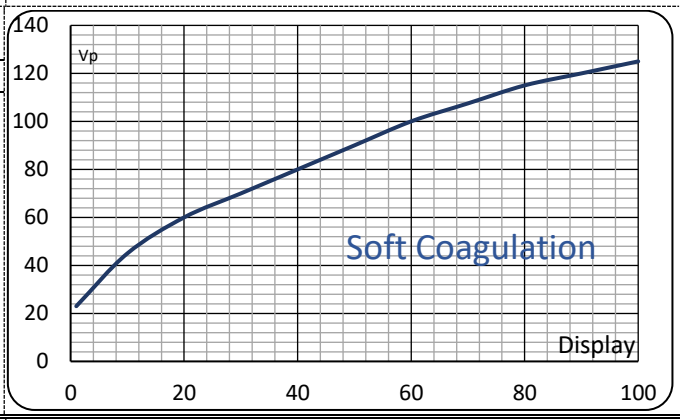
Use: open and laparoscopic surgery, neurosurgery.

Special features: white coagulations, without carbonization. Optimum efficacy with saline irrigation on the forceps tips.

Recommended electrodes : insulated bipolar forceps

Applications : Coagulation of vascularized tissues

Precautions for use : see general recommendations (section 6)



Forced 

Maximal power: 170 W / 75 Ω
Maximal voltage: 225 V_p

PRESS SELECT KEY TO TURN ON "FORCED" INDICATOR

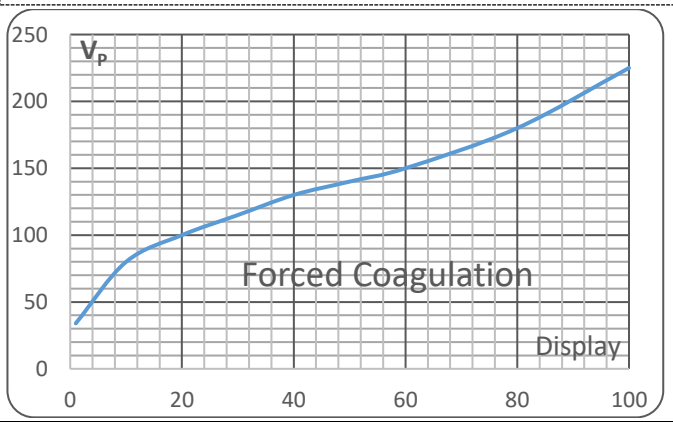
Use: open and laparoscopic surgery.

Special features: efficiency on all kind of tissues.

Recommended electrode: bipolar forceps with wide tips (2 to 5 mm width).

Applications: bipolar coagulation of vascularized or adipose tissues.

Precautions for use: adjust the power very gradually (carbonization risks). This mode is not recommended for neurosurgery.



Saline plasma coagulation	Automatic Selection	Maximal power: 130 W / 75 Ω Maximal voltage: 150 Vp

Selection of Saline coagulation is in effect as soon as a bipolar cut is selected

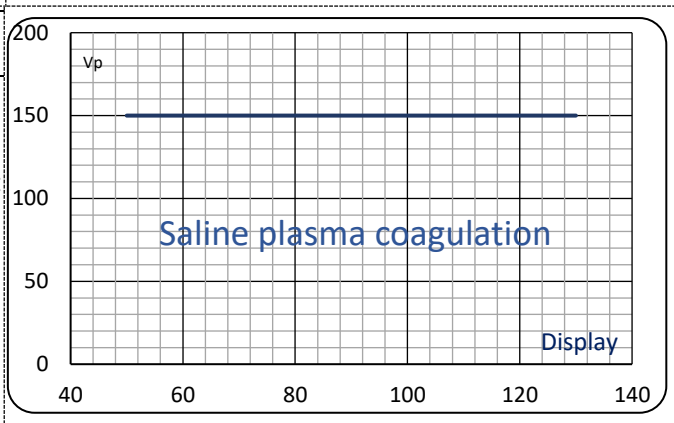
Use : Urological and Gynecological Surgery

Special features: Resection electrode is heated by the HF current. Coagulation is obtained by thermal diffusion in contact with the tissues.

Recommended electrode: Plasma Edge electrodes (REF VRUxx), or ball electrode (REF VRUB; VRUB1)

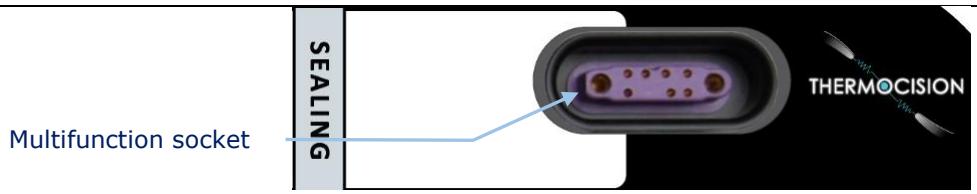
Applications : Hysteroscopic resection, TURP, TURB

Precautions for use: see recommendations for Plasma Edge mode



9.1.5 Sealing modes

CONNECTIONS



THERMOCLAMP™ ; THERMOCUT™ ; AND THERMOCISION™ forceps must be connected on se connectent multifunction socket.

- LED corresponding to the connected forceps will light up (THERMOCUT™ Ø 5; THERMOCUT ™ Ø 10; THERMOCLAMP™)
- If you connect a THERMOCISION™ forceps, the text THERMOCISION will light up.
- The output power setting is automatically adjusted to a predetermined level. The operator can adjust the power between 3 levels (3-bar display)
- Output power is activated by a single footswitch connected to the rear panel, or by a fingerswitch, if the cable has one.
- If a bipolar cable is connected without a valid recognition plug, the output cannot be activated.

Special features:

- With Thermocision forceps, the current allows haemostasis and dissection of tissues and small vessels, with the forceps.
- With Thermoclamp and Thermocut forceps, the current allows the sealing of tissues and vascular walls. Monitoring of the sealing cycle beeps to indicate whether the sealing cycle is complete (one beep), or if tissue fusion cannot be confirmed (several beeps).

Applications : Sealing of tissues or vessels to perform surgical removal of affected tissues. The applications mentioned for each forceps are given by way of example. The choice of the forceps to use is the responsibility of the surgeon.

Precautions for use: Vessel sealing process has been validated only with the THERMOCLAMP, THERMOCUT and THERMOCISION forceps of LAMIDEY NOURY MEDICAL, specified below. The use of any other forceps can cause serious injuries (burns, haemorrhages). Refer to the instructions for use of the vessel sealing forceps: Failure to follow the instructions for use of the vessel sealing forceps can lead to serious injury. Precautions for use of the vessel sealing mode are detailed in section 9.5 of this manual.

	**THERMOCISION**	Maximal power: 80 W / 20 Ω Maximal voltages: - Level 1 : 145V_p - Level 2 : 195 V_p - Level 3 : 245 V_p

Use : Open surgery

Recommanded forceps: REF V11CLPBS6 ; V11CLPBS62 ; V11CLPBS62L ; V11CLPBS63 avec câble V11F343D

Applications: Thyroidectomy, removal of salivary glands, lymph node dissection.

Precautions for use: Do not use on vessels larger than 4mm in diameter.

	**THERMOCLAMP 16CM**	Maximal power: 60 W / 20 Ω Maximal voltages: - Level 1 : 112 V_p - Level 2 : 142 V_p - Level 3 : 180 V_p

Use : Open surgery

Recommanded forceps: REF V11CLPBS6, V11CLPBS61

Applications : Hemorrhoidectomy, vein removal (for bypass surgery), salpingectomy, oophorectomy, mastectomy

Precautions for use: Do not use on vessels larger than 4mm in diameter.

	**THERMOCLAMP 22-32CM** **Wide jaws**	Maximal power: 125 W / 20 Ω Maximal voltages: - Level 1 : 80 V_p - Level 2 : 90 V_p - Level 3 : 95 V_p

Use : Open surgery

Recommanded forceps: Ref. V11CLPBS1 ; V11CLPBS2 ; V11CLPBS21 ; V11CLPBS22 ; V11CLPBS4

Applications : Colectomy; Gastrectomy; Liver resection; Total abdominal hysterectomy

Precautions for use: Do not use on vessels larger than 7mm in diameter.

	**THERMOCUT Ø 5mm**	Maximal power: 60W / 30 Ω Maximal voltages: - Level 1 : 80 V_p - Level 2 : 95 V_p - Level 3 : 100 V_p

Use : Open and laparoscopic surgery

Recommanded forceps: Ref. V12PBN523 (lg 20cm), et V12PBN524 (lg 33cm)

Applications : Salpingectomy; Ovariectomy; Radical Prostatectomy

Precautions for use: Do not use on vessels larger than 7mm in diameter.

	**THERMOCUT Ø 10mm**	Maximal power: 150 W / 30 Ω Maximal voltages: - Level 1 : 120 V_p - Level 2 : 135 V_p - Level 3 : 160 V_p

Use : Open and laparoscopic surgery

Recommanded forceps: V12PBN21P; V12PBN22P

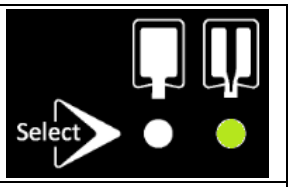
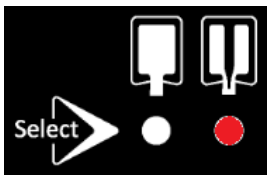
Applications : Colectomy; Gastrectomy; Liver resection; Upper hysterectomy

Precautions for use: Do not use on vessels larger than 7mm in diameter.

9.2 UNIT CONFIGURATIONS

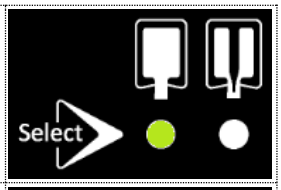
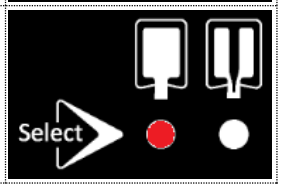
9.2.1 Selection of the neutral electrode monitoring mode

When the unit is switched on, the default monitoring mode of the unit is double plate mode (split into 2 conductive areas):

DOUBLE PLATE WITH NO CONTACT OR CONNECTION FAULTS: The indicator on the double plate lights up green.	
DOUBLE PLATE WITH FAULTY CONTACT OR CONNECTION The light on the double plate turns red in the following cases, - a skin contact failure of the plate - a short circuit between the 2 conductive parts of the plate. - a failure in the plate cable or its connections *The device will not be able to operate in monopolar mode in this state (see § 10.3).*	

THE DOUBLE-PLATE MODE is compatible with 2-zone adhesive plates for adult patients, and with adhesive plates with conductive surface ≥ 73 cm², for children from 2.7 to 11.4 kg

If only a single plate is available, press the "Select" key to light the left indicator.

SINGLE PLATE WITH NO CONNECTION FAULTS: the single plate indicator lights up green WARNING: with a single plate, the colour of the indicator only concerns the connection to the plate. NO ALARM WILL SIGNAL A PLATE-PATIENT CONTACT FAULT.	
SINGLE PLATE WITH CONNECTION FAULT: the single plate indicator light turns red: - A fault has been detected in the continuity of the plate cable or its connections. *The device will not be able to operate in monopolar mode in this state (see § 10.3).*	

Precaution when using the plates: read the operating instructions for the plate carefully when in use. See also section 6.1 of this manual (points A and F). Non-observance of the instructions for use of the neutral electrodes can cause malfunctions and serious burns.

9.2.2 Double pedal assignment

	Assignment to the MONOPOLAR mode controls: Press the select button near the MONOPOLAR socket. The green LED next to the socket should light up.	
	Assignment to the BIPOLAR mode controls: Press the select button near the BIPOLAR socket. The green LED next to the socket should light up.	

BEFORE STARTING AN INTERVENTION, SYSTEMATICALLY CHECK THE CONFIGURATION OF THE DOUBLE FOOTSWITCH.
THIS ONE CAN BE ASSIGNED TO MONOPOLAR MODE OR BIPOLAR MODE.

NOTE: IF BIPOLAR CUTTING (PLASMA EDGE) IS SELECTED, THE DOUBLE PEDAL ASSIGNMENT AUTOMATICALLY SWITCHES TO BIPOLAR MODE.

9.2.3 Automatic bipolar coagulation

The unit is configured with the automatic bipolar coagulation activation mode deactivated when the power is turned on. To activate the automatic mode, press the selection key (triangle), to light the upper indicator light, corresponding to the icon without a cross.

Once the automatic bipolar mode is activated, the contact of the 2 jaws of a bipolar forceps on the tissue triggers the coagulation current at the displayed power level. As soon as the forceps are removed, the activation stops.

The double foot pedal assignment can then remain in monopolar mode.

SELECTION OF THE AUTOMATIC BIPOLAR COAGULATION ACTIVATION, BY CONTACT OF THE FORCEPS ON TISSUES, INVOLVES RISKS OF UNEXPECTED ACTIVATIONS

- NEVER PLACE THE FORCEPS ON THE PATIENT: the slightest contact with the skin, or on a wet field, could initiate activation and cause skin burns.
- DO NOT TOUCH THE JAWS WITH FINGERS UNPROTECTED BY GLOVES. Cleaning of the tips, with a compress soaked with saline, will cause automatic activations.
- DO NOT USE WITH LAPAROSCOPIC BIPOLAR FORCEPS WITH NORMALLY CLOSED JAWS: these are not compatible with automatic bipolar coagulation.
- THE AUTOMATIC BIPOLAR MODE IS NOT COMPATIBLE WITH SALINE IRRIGATION ON THE FORCEPS. Irrigation may cause untimely and continuous coagulation activation.
- BIPOLAR RESECTION IN SALINE IS NOT COMPATIBLE WITH AUTOMATIC BIPOLAR ACTIVATION. The automatic bipolar mode is disabled if bipolar saline resection is selected.

FOR GOOD OPERATION

- FREQUENTLY CLEAN THE TIPS OF THE BIPOLAR FORCEPS WITH A MOIST COMPRESS.
- DO NOT USE EXCESSIVE POWER: Too much power can cause automatic bipolar coagulation dysfunctions.

9.2.4 Sound volume

To adjust the volume, press the select key:

- 4 sound levels are available.
- There is no level 0, as sound is essential to signal HF current activations.
- Safety related tones (plate alarm, HF safety) are not adjustable.

9.3 OUTPUT POWER SETTING

Monopolar cutting and coagulation power settings

The + and - keys are used to increase or decrease the displayed output power from 0 to the maximum value.

The displayed value corresponds to a maximum value, as the output power constantly varies according to tissue impedance variations. These values cannot be compared with those of other equipment that do not have the same output characteristics.

REMINDER: EXCEPT IN SPECIAL CASES (SUCH AS POLYPECTOMY / MUCOSECTOMY, OR ARGON PLASMA COAGULATION), THE OUTPUT POWER SELECTED SHOULD BE AS LOW AS POSSIBLE FOR THE INTENDED PURPOSE.

Bipolar cutting and coagulation power settings

The + and - keys are used to increase or decrease the displayed output power from 0 to the maximum value, in "Soft" or "Forced" coagulation.

For bipolar resection, the range of available powers is framed for optimal efficiency. It is therefore not possible to reduce the power to levels incompatible with the efficiency of cutting or coagulation.

Power settings in THERMOCLAMP™ ; THERMOCUT™ ET THERMOCISION™ modes

For each forceps, 3 power levels are available. This is displayed by 3 vertical bars. Choose the maximum level (3 bars) when sealing involves fat tissues, or when tissue intake seems to be thick, or when the sealing cycle is particularly long.

9.4 OUTPUT POWER ACTIVATION

The table below summarizes the activation possibilities according to the modes of use:

Use modes	 Single pedal	 Double pedal	Handswitches 		 Auto. Automatic control
Monopolar cut		Yes (Yellow footswitch)	Yes (Yellow handswitch)		
Monopolar coagulation		Yes (Blue footswitch)	Yes (Blue handswitch)		
Bipolar cut		Yes (Yellow footswitch)			
Bipolar coagulation	Yes	Yes (Blue footswitch)			Yes
Sealing	Yes			Yes	

- Activation of the HF current is signalled by a distinct sound for cutting and coagulation.

- The activation indicators light up: yellow for cutting, blue for coagulation, purple for SEALING mode.

9.5 SEALING / THERMOCISION ACTIVATIONS

Vessel Sealing is only available on the B2 socket controlled by a single pedal ref. V11SM1DN, or by fingerswitch on Thermocut forceps. Vessel Sealing process is monitored by "THERMOCONTROL" program. Sound signals inform the surgeon about results:

- A single beep occurs when sealing cycle has ended with a complete tissue fusion cycle detection.
- A series of repetitive short beeps indicates that fusion cycle has probably not been ended.

Possible causes of a Sealing failure may be:

- Tissues intake is too thick.
- Activation control was interrupted before the end of the sealing cycle
- Forceps was opened before the end of the sealing cycle
- Forceps tips are immersed, or in short circuit
- Cable is cut or incorrectly connected

RECOMMENDATIONS FOR SUCCESFULL VESSEL SEALING:

WITH THERMOCLAMP FORCEPS,

- Tighten THERMOCLAMP forceps on the tissues until contact with the internal stop. The area to be sealed must not exceed from jaws.
- Keep the forceps closed, thanks to the clamping integrated in the cable connector, until the end of the fusion cycle.
- It is recommended to carry out at least two sealing before cutting the tissues between the two sealed areas. Do not cut beyond the fused area.

WHATEVER THE FORCEPS,

- Activate Vessel Sealing continuously without releasing the activation control, until the sound signal indicating Sealing result has occurred.
- Do not Seal at less than one centimeter from a bifurcation between 2 vessels.
- To ensure that Sealing is successful, examine the slices cut. If necessary, it is possible to restart a new seal.
- AVOID ANY CONTACT BETWEEN THE FORCEPS AND COLLATERAL TISSUES during Sealing. If necessary, use a retractor to protect tissues against the risk of thermal diffusion.
- Immersion of the forceps may compromise Sealing. Evacuate liquids by aspiration or with a compress.
- Any damaged forceps must be replaced: regularly check the forceps (see the Instructions for use of the forceps)

- Only use the Sealing forceps offered by LAMIDEY NOURY MEDICAL. The use of inappropriate forceps is dangerous and can cause lesions and hemorrhages

NOTE: *there is no detection of sealing cycle with THERMOCISION forceps mode*

9.6 DIGESTIVE ENDOSCOPY (POLYPECTOMIES / MUCOSECTOMIES)

Insufficient cutting power can cause deep tissue coagulation with risk of perforation. Too much power can cause too fast cutting without enough haemostasis.

ENDO-CUT 1 and 2 provide the possibility of successive step cuts phases, which slow down the cutting effect and effectively coagulate tissues, as the diathermy snare tightens around the polyp. A POWER OF LESS THAN 100 W IS NOT RECOMMENDED because the power may not be enough to start the cut properly, and may lead to necrosis of the intestinal wall. A power of 120 W gives good results on the majority of polyps.

9.7 STORAGE OF PERSONNAL SETTINGS

To save the current settings, perform the following steps:

- Press the "save" button continuously for 1 second: the digital display will start flashing slowly.
- Use the + or - key to display the desired registration number.
- Press the "save" button again for 1 second: the display stops flashing. The program is now saved.

The unit can store 99 separate programs. It is recommended that the numbers used and the associated programs are noted on a sheet of paper accompanying the unit.
Recording a program with a number that has already been used will erase the previous program.

9.8 SEARCHING FOR STORED SETTINGS

The steps for loading a program into memory are as follows:

- Press the " Load " key for 1 second: the " Program " display flashes rapidly.
- Use the + and - keys to scroll to the desired number. The corresponding parameters are displayed as the number is changed.
- Press the "Load" key to confirm the program selection: the "Program" display stops flashing.

If you do not confirm the choice with the "Load" key, after 5 seconds, the unit returns to the previous configuration.

Program "00" is used to set all values to 0.

10 MALFUNCTIONS – ALARMS AND INFORMATION CODES

10.1 THE DEVICE IS RESPONDING TO COMMANDS

BUT THE ELECTRODES REMAIN INACTIVE UPON CONTACT WITH THE PATIENT: make sure the asignment of the dual pedal for the Monopolar and Bipolar modes is correct. If so, check the usage accessories (outlets, cables, electrodes, etc.). Replace if necessary.

If there is no result regardless of the power value settings, contact LAMIDEY NOURY MEDICAL or its authorized representative.

10.2 THE DEVICE IS NOT RESPONDING TO COMMANDS

10.2.1 The device remains off

Lights and displays do not illuminate: Check the power supply connectors and cables and the mains fuses. If the fuses are damaged, contact LAMIDEY-NOURY MÉDICAL or its authorized representative.

10.2.2 The device comes on:

Check the control components (pedal, tactile-control electrode holder) using, if necessary, the TESTELEC testing box.

10.2.3 If no anomaly is detected in the external components :

Turn off the generator for a few seconds, then turn it back on.

- If normal operation is restored after doing this, report the observed fault to the manufacturer and the circumstances under which it occurred.
- If normal operation is not restored, refrain from any internal operation prior to contacting LAMIDEY NOURY MEDICAL or its authorized representative.

10.3 PLATE SAFETY

When the plate monitoring circuit reports a fault with an orange light, any attempt to activate the HF current in monopolar mode will trigger an audible and visual alarm:

The output power is then inhibited.

Recommendations in case of plate defect:

- Check whether the selection of the plate monitoring mode corresponds to the plate model used (single plate / split plate)
- If the selection is correct, and the plate is of the split type, apply hand pressure on the plate from the end towards the connector to improve the contact.
- If the alarm persists, replace the plate and its connecting cable.

10.4 HF SAFETY

The "HF Safety" indicator lights up orange with an audible signal.

This alert indicates a malfunction of the device. Turn off the power for a few seconds and then turn it back on.

If the fault reappears immediately or the first time the device is used, the unit is operating abnormally and the device needs to be checked by LAMIDEY-NOURY MEDICAL or its authorized.

10.5 DEFECTIVE ELECTRODE

If during the activation of bipolar cutting, or bipolar saline coagulation, the device emits a degressive beep, with an interruption of the output power, it means that an electrical arcing has been detected on the electrode.

Before restarting footswitch activation, visually check the electrode to ensure that there is no breakage of a white ceramic at the end of the electrode, nor any tissue residue remaining on the electrode. If necessary, replace the electrode or remove the tissue causing the arc.

If 2 electrical arcings are detected during 3 successive activations, the "Defective electrode" indicator lights up and the HF current emission is inhibited. The "Defective electrode" light may also illuminate during activation if a short circuit is detected in the electrode.

In the event of an alarm, it is imperative to replace the defective electrode and press the [RESTART] key to restore normal operation.

10.6 SEALING SOUND SIGNALS

Surgeon is assisted in the Sealing process by means of sound signals:

- 1 long beep means that a complete cycle of sealing has been detected: if all precautions have been followed, Sealing has been completed correctly, and the surgeon will be able to section the tissue by visually checking the state of the tissue section.

- If a series of short beeps are heard, it is strongly recommended that the tissue not be cut. Possible causes of sealing failure are detailed below :

- ***a) if the beeps occur immediately upon activation of the HF current***	
Possible causes	*Actions required to resolve the problem*
Activation took place before the forceps were closed.	Restart sealing activation.
Bipolar cable breakage	Replace cable
The forceps are immersed in the blood	Evacuate blood by suction
The forceps are short-circuited	Open the forceps to make sure it is not closed on a staple or clip. Otherwise replace the forceps.
Tissues caught are too thin.	Take up more thickness of tissue between the jaws
There's a deposit of dry residues on the jaws	Clean the jaws with a damp compress.

b) if the beeps occur after a few seconds of HF current activation	
Possible causes	*Actions required to resolve the problem*
The system requires more time to complete the sealing process.	If possible, increase output power. Restart sealing cycle.
Tissue intake is too thick.	Take less thickness of tissues
The forceps were opened before the end of the sealing cycle.	Restart sealing cycle

10.7 MEANING OF INFORMATION CODES

Some anomalies detected by the unit cause all the lights and displays to go out, except for the monopolar cut display, which indicates a fixed code. The codes displayed have the following meanings :

Codes	Meanings	Causes	Actions required
001	Double pedal error, coag	When switching on, the foot pedal has a short circuit in the coagulation control.	Disconnect the double pedal and send it to an authorised service centre.
002	Double pedal error, cut	When switching on, the foot pedal has a short circuit in the coagulation control.	
003	Single pedal 1 error	When switching on, the foot pedal has a short circuit on the Sealing control.	Disconnect the single pedal and send it to an authorised service centre.
004	Automatic bipolar control errotr	When switching on, an abnormal detection occurs.	Turn on the generator. If this happens again, have the generator serviced by an authorised service centre.
005	Handswitch error	When switching on, a short circuit was detected on the handswitch.	Replace the cable with its handswitch
006	Safety stop	If an error is detected 10 times in a row, the device goes into safety shutdown.	- Turn off the unit - Remove the cause of error - Turn on the unit
007	HF alarm	HF power control failure and safety shutdown	- Switch off the unit a few seconds - Switch on the unit If the fault persists, take the unit to an approved service centre.
008	Automatic bipolar fault	Automatic bipolar power activation without selection of automatic mode	Turn on the generator. If this happens again, have the generator serviced by an approved maintenance service.

Codes	Meanings	Causes	Actions required
014 (*)	Test mode	Activation with output power set to 0	Power activation requires the selection of a non-zero output power.
015	Resection ignition failure	It is not possible to obtain ignition of the cutting plasma in a saline environment.	- Check the concentration of saline - Check that 2 conductive poles of electrode are well immersed. - If in doubt, replace the electrode
016	Short-circuit in resection	Resection electrode is in short-circuit	Always replace the resection electrode and confirm the replacement by pressing [Restart] key.
017	Too long activation time	Activation for more than 60 seconds (or more than 12s in sealing mode)	Stop activation
018	Handswitch error, coag	The handswitch is short-circuited on the coagulation control during start up	Replace the faulty handswitched pencil.
019	Handswitch error, cut	The handswitch is short circuited on the cutting control when starting up.	
023	Single pedal 2 error	The pedal has a short circuit when starting up.	Disconnect the pedal and send it to an approved maintenance service.
024 (*)	Bipolar cut activation fault	Activation of the cut in standard bipolar mode	Release the footswitch
025 (*)	Sealing activation fault	Activation of sealing without connected accessories	Plug a sealing forceps before activation
> 100	Internal errors	Internal technical failure of the device	Turn the generator off for a few seconds, then turn it back on. If the fault persists, take the generator to an approved maintenance service.
(*) Codes 014; 024; and 025 are accompanied by a degressive beep to indicate the error of use.			

10.8 SHUTDOWN PROCEDURE

Emergency stop:

Switch OFF the device on the rear panel or disconnect mains cable.

Stop at the end of the intervention

- Switch OFF the device on the rear panel.
- Disconnect the accessories of use

11 CLEANING, DISINFECTION, STERILIZATION

11.1 CLEANING AND DISINFECTION OF UNIT

DO NOT SPRAY LIQUID ON THE REAR SIDE INTO THE AIR VENTS.

THE FOLLOWING CHEMICAL COMPOUNDS ARE INCOMPATIBLE WITH THE GENERATOR: Aldehydes, Aromatic Amines, Ketones, Esters, Polyglycol Ethers, Essential Oils, Aromatic and Chlorinated Hydrocarbons

CLEANING: Before cleaning, turn off the generator. It does not require any particular maintenance. The body and front panel can be cleaned with a cloth soaked in a cleaning product that does not contain any of the compounds listed above.

DECONTAMINATION: use a surface decontaminant such as Cidalkan towelettes (Alkapharm laboratory) or WIP Anios or Linget Anios towelettes (Anios Laboratory).

THE UNIT CANNOT BE STERILIZED.

11.2 PEDALS

CLEANING: Waterproof pedals can be cleaned under a faucet with liquid soap.

DECONTAMINATION: the pedals can be decontaminated with a surface decontaminant such as Cidalkan towelettes, or by spraying a decontaminant such as SURFA'SAFE (Anios Laboratory) or Alkasurf 750 (Alkapharm laboratory). The pedals cannot be sterilized.

DO NOT PULL THE PEDAL BY ITS CABLE. DO NOT BEND THE CABLE, OR WRAP IT TIGHT AROUND THE PEDAL: MAKE WIDE LOOPS

Connect the pedal to the unit before turning it on. SEAL unit performs a checking of the commands connected at startup. After starting, the pedals can be tested directly on the generator provided not to connect the active electrodes for safety measure.

11.3 REUSABLE INSTRUMENTS IN CONTACT WITH PATIENT

SILIPLAQUE reusable neutral electrodes, and UNIPLAC connection cables for single-use neutral electrodes, are not sterilizable. However, they can be cleaned with soapy water and rinsed thoroughly with clean water before drying. These accessories can be treated with a surface decontaminant

Each electrosurgical accessory used in the surgical field must have been checked, decontaminated, cleaned, rinsed, dried and sterilized before use. Consult the instructions for use of electrosurgical accessories for more detailed information.

FAILURE TO FOLLOW THE INSTRUCTIONS FOR USE OF THE ACCESSORIES MAY RESULT IN SERIOUS INCIDENTS FOR THE PATIENT AND / OR OPERATING ROOM STAFF.

CLEANING: Do not clean electrosurgical accessories in an ultrasonic machine. Reusable accessories can be immersed in a pre-decontamination solution, cleaned with soft bristle brushes and swabs.

DO NOT USE ABRASIVE OR SHARP OBJECTS WHEN CLEANING.

DECONTAMINATION: The soaking time and temperature of the bath must not exceed the recommendations of the laboratory manufacturing the product. Careful rinsing with filtered running water must be carried out and followed by complete drying, if necessary with compressed air. Sterilizable accessories can be decontaminated and machine washed at 90°C.

STERILIZATION: Instruments and cables in contact with the patient can be sterilized in an autoclave at 134°C for 18 minutes.

12 CHECKS AND MAINTENANCE

12.1 DAILY CHECKS

See paragraph 8.3, including control flowchart

12.2 CHECKING OF ELECTROSURGICAL ACCESSORIES

Regularly inspect the ACCESSORIES. In particular, electrode cables and HF ENERGIZED ENDOTHERAPY DEVICES should be checked (e.g. under magnification) for possible damage.

- A visual inspection of all electrosurgical accessories before use, can detect damage that may cause accidental injury such as burns.
- Carefully check the condition of the electrical insulations, tensile strength of removable electrodes, the condition of the connectors, the appearance of the cables: any damaged accessories must be replaced. Connecting uninsulated accessories or those with deteriorated insulation can cause burns. The rupture of an electrosurgical cable can cause electric arcing and ignite the materials in contact with the cable.
- SEAL unit automatically checks the controls connected to the device during self-test phase and signals any commands in short-circuit. The operation of the controls can be tested on the unit.
- The operation of bipolar forceps and their cable can be tested on a compress soaked with saline: with an average output power, the passage of the HF current through the compress will cause the liquid to evaporate between the jaws of the forceps.

12.3 SAFETY INSTRUCTIONS

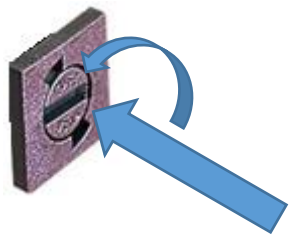
- It is dangerous to modify or attempt to modify the properties of the device.
- Before any cleaning or maintenance operation, disconnect the generator either by unplugging the power plug or by turning off the main switch.
- In the event of damage or poor operation, turn off the generator and have it repaired by a support centre approved by LAMIDEY-NOURY MEDICAL.
- Avoid checking the function of the device by making short circuits between active electrodes.
- No maintenance on the device is allowed while it is being used on a patient.

12.4 MAINTENANCE

The device must not be opened: Warranty would be voided if any modification were to be made to the generator. If repair or adjustment is needed, the device must be sent to the technical assistance centre of LAMIDEY NOURY MÉDICAL Company with a description of the observed incident.

Maintenance required by user essentially consists of cleaning and sterilizing the accessories and checking for proper operation of the device before it is used. The periodic annual inspections as well as safety inspections and verification of parameters may be done by specialized technicians.

LAMIDEY NOURY MEDICAL recommends periodic annual preventive maintenance action for checking the electrical properties (electrical safety, output power, HF leakage current, operation, and alarms). Spare parts are only replaced in the event of failure within the context of corrective maintenance.



Fuse replacement: The 2 mains power fuses are the only components that can be replaced by service personnel. If necessary, they must be replaced by timed fuses of the same size and intensity. However, in such a case, we recommend checking the generator before it is put back into service.

Indeed, it is likely that the power supply circuit of the generator has a failure.

To remove the mains fuses, turn the fuse cap counterclockwise a quarter of a turn, using a suitable screwdriver.

13 ACCESSORIES

13.1 USE PRECAUTIONS

a) Pedals :

Connect the pedal to the generator before turning it on. The SEAL performs a self-check of the connected controls at startup to ensure that no controls are shorted. However, it is recommended to test the pedals for safe operation without connecting the monopolar or bipolar active instruments:

- SINGLE PEDAL IN BIPOLAR COAGULATION OR SEALING MODE: the action on the pedal must switch on the corresponding indicator light and operate the audible indicator.

- TO TEST THE DOUBLE PEDAL IN MONOPOLAR MODE, the plate should be connected and the plate selection lights should be lit green. Otherwise, perform the test in bipolar mode, selecting a bipolar cut. Pressing the yellow lever, it should illuminate

the cut indicator. Pressing the blue lever should illuminate the coagulation indicator. In each case, an audible signal should sound.

Regularly check the condition of the anti-slip pads: the absence of a pad makes the pedal unstable and may prevent its normal operation.

AFTER USE:

- Always disconnect the foot pedal as soon as the surgeon has finished the operation to avoid any risk of accidental triggering.
- Do not pull the pedal by its cable.
- Do not bend the cable or wrap it tightly around the pedal: make wide loops.

b) Selection of electrosurgical accessories

The use of ACCESSORIES, and cables other than those specified or provided by the MANUFACTURER of this device may cause increased electromagnetic emissions or decreased immunity of this device and cause improper operation.

The patient's and user's safety depends not only on the generator, but also on the application accessories and instruments. It is imperative to use only accessories or consumables whose compatibility with the generator is demonstrated.

The ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES should be selected in these ones having a RATED VOLTAGE ACCESSORIES higher or equal to the MAXIMUM OUTPUT VOLTAGE (see paragraph 9.1 that includes maximal voltage graphs as function of output setting)

In Bipolar Saline Resection or Sealing modes, the connection of non-validated accessories to the unit presents a risk of failure relative to expected performances, and may seriously compromise patient and operator safety.

PLASMA EDGE™ system of LAMIDEY NOURY MEDICAL, uses electrodes without any electrical connection on the working elements or on the external resector sheath. LAMIDEY- NOURY MEDICAL declines any responsibility in case of use of resection electrodes that would require an electrical connection on the working handle, in contact with the external resector sheath.

The list of compatible accessories proposed by LAMIDEY NOURY corresponds to the accessories whose use has been validated with the SEAL generator. If you are in doubt about an accessory, ask LAMIDEY NOURY or its authorised representative.

c) Vessel sealing forceps - number of uses

Connecting THERMOCLAMP, THERMOCUT or THERMOCISION forceps to the multifunction socket may result in a momentary display on the unit of the type [PPP – XXX], where XXX is a number indicating the number of uses remaining for the forceps or its insert.
If the countdown drops to [PPP – 000], the HF current will not operate on the multifunction socket until the forceps (or THERMOCUT insert) and its recognition cable have been replaced.
This countdown function does not exempt you from the necessary visual inspection before use, as it is still possible that a forceps may be accidentally degraded before the end of its expected life.

13.2 LIST OF COMPATIBLE ACCESSORIES

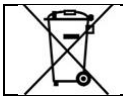
The accessories listed below have been tested for compatibility with SEAL electrosurgical unit.

Part number	Description	Rated voltage
Lamidey Noury medical's footswitches		
V11SM2FN	Twin Footswitches for Monopolar and Bipolar controls	5 Vdc
V11SM1DN	Single footswitch for bipolar coagulation and vessel sealing controls	
Lamidey Noury medical's cables		
V11K250	Connection cable for single-use adhesive plate	2.1 kVp
V11FM40	4-meter Monopolar cable for pencil11MD25 and for Monopolar forceps	5 kVp
V11FM40P	Monopolar cable 4m length, male 4mm protected plug/ female Ø 4.0mm	5 kVp
V11FM43	Monopolar cable lg 4m tri-pins plug for diathermic loop	7.5 kVp
V11F242	Bipolar cable lg 4m plug BCP / connector EU	2 kVp
V11F242C	Bipolar cable lg 4m plug BCP / connector EU short	2 kVp
V11F242TC	Bipolar cable lg 4m plug BCP / connector EU very short	2 kVp
V11F342D	Bipolar cable 4m length BCP plug for THERMOCISION forceps (plug & play)	2 kVp

Part number	Description	Rated voltage
V11F343D	Bipolar cable 4m length BCP plug for THERMOCLAMP forceps (plug & play)	2 kVp
V12PBS25DM	Bipolar cable lg 4 m for Thermocut forceps Ø10mm with detection and figerswitch	2 kVp
V12PBS26DM	Bipolar cable lg 4 m for Thermocut forceps Ø5mm with detection and figerswitch	2 kVp
Lamidey Noury medical's Monopolar accessories		
V11MD25	Electrosurgical pencil for 2.4-mm diameter electrodes, without cable	4.5 kVp
V11MD40	Electrosurgical pencil for 4-mm diameter electrodes, without cable	4.5 kVp
V11MCT9N	Electrosurgical pencil with hand switches for 2.4-mm diameter electrodes	4.5 kVp
V11MCT94N	Electrosurgical pencil with hand switches for 4-mm diameter electrodes	4.5 kVp
V11xxxx	Monopolar electrodes Ø 2.4mm, all dimensions (see catalog)	1.6 kVp
V14xxxx	Monopolar electrodes Ø 4.0mm, all dimensions (see catalog)	1.8 kVp
VPMxxxxx	Monopolar forceps, all lengths (see catalog)	2.1 kVp
Lamidey Noury medical's Vessel sealing accessories		
V11CLPBSx	THERMOCLAMP™ & THERMOCISION™ vessel sealing forceps (laparotomy)	350 Vp
VR11CLPBSx	THERMOCLAMP™ & THERMOCISION™ vessel sealing forceps with automatic recognition cable	
V12PBN5xx	THERMOCUT™ vessel sealing forceps, 5mm diameter	106 Vp
V12PBN2xx	THERMOCUT™ vessel sealing forceps, 10 mm diameter	223 Vp
Lamidey Noury medical's Bipolar accessories		
VRUxx/VFUxx	Plasma Edge® bipolar resection electrodes (see catalog)	700 Vp
VPBxxxxx	Bipolar forceps, all lengths (see catalog)	1.76 kVp
Trading: Unmarked CE products by Lamidey Noury		
RSxx	Single-use adhesive split plates, SKINTACT® brand	N.A.
VSUT1 / VSUTL1*	Electrosurgical pencil, with handswithces, single-use + short / long needle	4.5 KVP
VSUC1 / VSUCL1*	Electrosurgical pencil, with handswithces, single-use + short / long knife	4.5 KVP
VSUT2 / VSUC2*	Single-use pencils without controls + short needle / shot knife	4.5 KVP

14 ENVIRONMENTAL PROTECTION

Studies have shown that the SMOKE-PLUMES generated by electrosurgical procedures, may contain toxic gases and vapors, cell fragments and viruses. These smokes have a mutagenic potential hazard. The most effective way to protect medical staff and patients, is a suction system for the smoke-plumes extraction on the operating field.



DIRECTIVE 2012-19-EU : Electronic equipment at the end of lifetime, must be disposed of according to law. They must be collected separately and be given to a recycling center approved by the authorities.

LAMIDEY NOURY MEDICAL undertakes to take back at its own expense all of its electrosurgical generators, installed on the french market. Contact LAMIDEY NOURY MEDICAL at 01 69 20 69 69 for any pick up request. For generators placed on the European market, contact the local distributor of LAMIDEY NOURY MEDICAL.
After use, end-of-life reusable electrosurgery accessories and single-use accessories pose a risk of contamination for hospital staff. They must be collected in suitable protective containers for safe disposal.

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 7753 rev. 9

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

LAMIDEY NOURY MEDICAL
3 Rue des Petits Ruisseaux ZA les Godets
91370 Verrières-le-Buisson FRANCE

pour les activités
for the activities

Conception, fabrication, ventes et réparation d'appareils d'électrochirurgie à courant haute fréquence et leurs accessoires stériles et non stériles, d'appareils d'aspiration médicale et leurs accessoires. Fabrication des accessoires d'instruments électro-chirurgicaux.

Design, manufacturing, sales and repairing of high frequency surgical equipments and sterile and not sterile accessories, medical and surgical suction equipments and accessories. Manufacture of electrosurgical instruments accessories.

réalisées sur le(s) site(s) de
performed on the location(s) of

LAMIDEY NOURY MEDICAL
3 rue des Petits Ruisseaux ZA les Godets 91370 Verrières-le-Buisson FRA
LAMIDEY NOURY MEDICAL
4, rue des Petits Ruisseaux ZA les Godets Verrières-le-Buisson 91370 FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité */ Effective date :* **April 6th, 2020 (included)**
Valable jusqu'au */ Expiry date :* **October 3rd, 2023 (included)**
Etabli le */ Issued on :* **April 6th, 2020**

On behalf of the President
Béatrice LYS
Technical Director

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

GMED N° 7753–9
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 7753-8

Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites :

French version:

- **Conception, fabrication, ventes et réparation d'appareils d'électrochirurgie à courant haute fréquence et leurs accessoires stériles et non stériles, d'appareils d'aspiration médicale et leurs accessoires.**
- **Fabrication des accessoires d'instruments électro-chirurgicaux**

English version:

- *Design, manufacturing, sales and repairing of high frequency surgical equipments and sterile and not sterile accessories, medical and surgical suction equipments and accessories.*
- *Manufacture of electrosurgical instruments accessories.*

****

Identification des sites couverts et des activités /

Identification of locations and activities

LAMIDEY NOURY MEDICAL 3 rue des Petits Ruisseaux ZA les Godets 91370 Verrières-le-Buisson France
Siège social, Conception, fabrication, vente et réparation / *Headquarter, Design,manufacturing, sales and repairing.*

LAMIDEY NOURY MEDICAL 4 rue des Petits Ruisseaux ZA les Godets 91370 Verrières-le-Buisson France
Fabrication / Manufacturing.

****

2 sites / *2 sites*

On behalf of the President
Béatrice LYS

Technical Director

DocuSigned by:

ATTESTATION / *CERTIFICATE* **N° 7752 rev. 13**

Délivrée à Paris le 07 mai 2020

Issued in Paris on May 7th, 2020

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

LAMIDEY NOURY MEDICAL

3 Rue des Petits Ruisseaux ZA les Godets

91370 Verrières-le-Buisson FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

- Appareils d'électrochirurgie à courant haute fréquence et leurs accessoires stériles et non stériles

- Appareils d'aspiration médicale et leurs accessoires

- High frequency surgical equipments and sterile and not sterile accessories

- Medical and surgical suction equipment and accessories

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600866 / P601472-2, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P600866 / P601472-2, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **May 7th, 2020 (included)**

Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED SAS GMED SAS GMED GROUPE LNE

DocuSigned by: Beatrice Lys EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

GMED_b2p3-F-V0-07-2018

GMED - 7752 rev. 13
Modifie le certificat 7752-12

Identification des dispositifs / *Identification of devices*

Les produits couverts par ce certificat sont référencés sur la liste des produits (3 pages) datée du 7 mai 2020 et authentifiée par GMED le 7 mai 2020.
The products covered by this certificate are listed on the manufacturer's list of products (3 pages) dated May 7th 2020 and authenticated by GMED on May 7th, 2020.

Ce certificat couvre le site et les activités / *This certificate covers the site and activities* :

LAMIDEY NOURY MEDICAL
Za les Godets 3 Rue des Petits Ruisseaux 91370 Verrières-le-Buisson :
Conception, fabrication et contrôle final / *Design, manufacture and final control*

LAMIDEY NOURY MEDICAL
Za les Godets 4, rue des Petits Ruisseaux 91370 Verrières-le-Buisson
Fabrication/M*anufacture.*

GMED	0459

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director