Soniquence®

Soniquence RF Generator

Instructions for Use Manual

1. INTRODUCTION

The generator enhanced capability Radiosurgery Devices are a compact source of high radiofrequency energy employed for a variety of procedures. This action is achieved by front panel selection of waveforms and power level. All selection is effected through push buttons and lamps which give the operator feedback of status. Power level for each mode is indicated by front panel digital displays which also show the status of self-test and monitoring. This display is interlocked with controls to prevent operation when an error code is displayed. The final output power control is made through foot and/or hand switches. Both Monopolar and Bipolar electrodes are offered. This device is designed to comply with international safety standards. The atraumatic nature of electrosection provides a noteworthy advantage. The lack of trauma results in tissue healing without fibrous contractile scar tissue, which characterizes the healing of wounds created by manual cutting. Read Instructions for Use in details before use.

INDICATIONS FOR USE

The Soniquence RF Generator is intended to provide high frequency energy for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels during surgical procedures and is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

1.1 SYMBOL DEFINITIONS

The following symbols are used on the equipment and/or labels

1.1.1 Classification Class IIb, according to European Council Directive 93/42/EEC concerning medical devices.

Classification = Class I, according to the type of protection against electric shock as per IEC 60601-1.

Nominal Line Voltage:	100V - 240V AC
Line Frequency:	60Hz/50Hz
Power Consumption at max output power:	360 VA
Input current at max output power:	100V - 240V, 2.3A
Rating of two fuses in the main supply power:	F4.0 (250V) T4.0A (250V) optional

1.1.2 Supply Input Power = 100V AC - 240V AC ~ 50/60 Hz

1.1.3 Alternating current

1.1.4 Defribrilation-Proof Type CF applied part

1.1.5 MR Unsafe - Device should not enter the MRI Scanner room

1.1.5 Refer to Instruction Manual/Booklet

1.1.6 Protective earth (ground)

1.1.7 Neutral electrode referenced to ground

1.1.8 Neutral plate

1.1.9 Fingerswitch control

1.1.10 Footswitch

1.1.11 Bipolar

1.1.12 Volume control

1.1.13 Non-ionizing radiation

1.1.14 UL Mark E504261 ELECTROSURGICAL GENERATOR

AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH

ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1-2:, IEC 60601-2-2.

1.2 LIST OF AUTHORIZED ACCESSORIES BY PRODUCT FAMILY

Bayonet Tip, Malleable Tip, Microincision Tip, SP-Tips, SP-Kit, Fiber Tip, Tip Set, Neutral Plates, Suction Coagulator, Footswitch, Fingerswitch Wand, Bipolar Cable, RF Cobb Tip, and Bipolar Wand

II. TECHNICAL INFORMATION

2.1 OUTPUT CHARACTERISTICS

Output Power ± 20%

Mode/Character	Output Waveform	120W	170W	Max Output Power	Activation
CUT	4.0 MHz Square Wave Envelope	120W @ 500 Ω	150W @ 500 Ω	2.3A	via footswitch or via fingerswitch
BLEND	4.0 MHz Square Wave Envelope	90W @ 500 Ω	110W @ 500 Ω	2.3A	via footswitch or via fingerswitch
HEMO	4.0 MHz Square Wave Envelope	60W @ 500 Ω	60W @ 500 Ω	2.3A	via footswitch or via fingerswitch
BIPOLAR	1.7 MHz Square Wave Envelope	40W @ 200 Ω	40W @ 200 Ω	2.3A	via footswitch
BIPOLAR TURBO	1.7 MHz Square Wave Envelope	120W @ 200 Ω	170W @ 200 Ω	2.3A	via footswitch

For technical information, refer to Service Manual (item # IN S0006). The information provided in instruction manual does not replace the information provided in service manual (item # IN S0006).

2.2 DUTY CYCLE

The supplier suggested operational duty cycle is 10 seconds ON / 30 seconds OFF. The yellow CUTTING MODE Activation Indicator will be ON when CUTTING MODE circuit is energized. The blue COAGULATION MODE Activation Indicator will be ON when COAGULATION MODE circuit is energized. A continuous tone will alert user of activation. After 55 seconds of continuous applied power (at any power level, in any mode), the tone will change and energy will cease 5 seconds after. The tone continues to alert of footswitch depression even though energy will not be emitted.

2.3 CLASSIFICATION

2.3.1 According to the type of protection against electric shock: the equipment is energized from an external electrical power source and is Class I equipment

2.3.2 According to the type of protection against electric shock: DEFIBRILLATION-PROOF TYPE CF APPLIED PART

2.3.3 Degree of protection against harmful ingress of water: ordinary equipment, or IPX0 according to IEC 60529.

2.3.4 Cleaning and Disinfection of the Unit Before Each Use:
Cleaning and disinfection of the unit should only be done with non-flammable and non-explosive agents. Make sure that no moisture or detergents enter the unit. If cleaning or disinfection of the unit with flammable or explosive agents is unavoidable, these must be completely evaporated from the radiosurgical generator before it is switched on.

2.3.5 The mode of operation is continuous operation with intermittent loading, duty cycle 10 seconds ON / 30 seconds OFF.

2.3.6 The permissible operational environment conditions:
Ambient temperature range ------ +10°C ~ +40°C
Relative humidity range ------ 30% ~ 75%

2.3.7 The following specifications are applicable to the extent called out herein:
EN IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

EN IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility.

EN IEC 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for safety of high frequency surgical equipment.

ELECTROSURGICAL GENERATOR
WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1-2:2014 (4th edition), IEC 60601-2-2 2017 (6th edition).

2.3.8 Over voltage category II: Equipment of OVER VOLTAGE CATEGORY II is energy-consuming equipment to be supplied from the fixed installation.

2.3.9 Flammability Material Classification according to UL 94-V1.

2.3.10 Pollution Degree Classification II: Normally only non-conductive pollution occurs. Temporary conductivity caused by condensation is to be expected.

2.3.11 Normal operating conditions for the generator is within an Altitude range of up to 2000 meters.

2.4 PREVENTIVE INSPECTION AND MAINTENANCE

2.4.1 By Customer;
Regular preventative inspection should be carried out to avoid reduced performance of the unit due to aging, wear, deterioration, etc. Cables, electrodes, and other products must be checked before each use. The recommended preventative inspections are:

- Inspection for any damage to the unit and its accessories
- Inspection of proper function of the unit

2.4.2 By Soniquence or authorized personnel;
Technical safety inspections should only be carried out by Soniquence. Soniquence assumes no responsibility for improper

changes or repairs carried out on the unit or its accessories by unauthorized persons. Improper changes or repairs carried out by unauthorized personnel voids the warranty. The recommended technical safety inspections are:

- Inspection of electrical safety in compliance with 60601-2-2
- Inspection of high frequency output power in the variety of modes
- Line Fuses - The unit is protected with two lines fuses. If a fuse blows, the unit should be checked for possible fault before the fuse is replaced and the unit is operated again. Always replace with a fuse of the same type and rating.

2.5 ENVIRONMENTAL PROTECTION

Disposal of the equipment and accessories must follow or comply with local disposal rules.

2.6 TECHNICAL INFORMATION

For technical information, refer to service manual (item # IN S0006). The information provided in instruction manual does not replace the information provided in the service manual (item # IN S0006).

III. CAUTIONS, WARNINGS AND SAFETY INSTRUCTIONS

3.1 CAUTIONS:

3.1.1 Do not use the Soniquence RF Generator in the presence of flammable anesthetics or other flammable gases, liquids, or objects.
For transportation and storage:
Ambient temperature range ------ -10°C ~ +50°C
Relative humidity range ------ 10% ~ 95%
Atmospheric pressure range ------ 500 hPa ~ 1060 hPa

3.1.2 Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or are hot from use may cause a fire.

3.1.3 Electrical shock hazard. Do not remove cover. Refer to authorized personnel for service.

3.1.4 May present a hazard to patients with all active electrical implants. Consult qualified medical personnel.

3.1.5 Soniquence strongly recommends the use of Corneal Shields for any procedure involving Radiofrequency around the eyelid and the immediate surrounding areas.

3.1.6 This equipment complies with IEC 60601-1-2:2014 EMC standard for medical devices. This equipment generates, uses, and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and radio communications. To provide reasonable protection against such interference, this product complies with the radiated emission as per CISPR11 Group1 Class A standard limits. However, there is no guarantee that interference will not occur in a particular installation. If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem by one or more of the following measure(s):

- Reorient or relocate the affected device(s)
- Increase the separation between the equipment and the affected device
- Power the equipment from a source different from that of the affected device
- Consult the point of purchase or service representative for further suggestions

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment. All interconnect cables to peripheral devices must be shielded and properly grounded, except when technologically prohibited. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (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.

3.1.7 When being used in Monopolar Cut and Blend, never increase the power setting without first checking the proper connections of both the active electrode and the neutral plate.
Important: Please read Sections 5.1, 5.2 and 5.3 before operating the device.

3.1.8 When multiple monopolar energy sources are to be used in a procedure, Soniquence recommends activating only one (1) energy source at a time.

3.1.9 When multiple neutral plates are applied to a patient for multiple energy sources, Soniquence recommends applying our disposable neutral plate on a separate side of the patient, with no wires being crossed.

3.1.10 The Soniquence RF generator requires special precautions regarding EMC. Install and use the Soniquence RF generator according to the guidelines of the EMC declaration tables. (REFER TO: TABLES 1-4)

3.1.11 Portable and RF communications equipment may affect the Soniquence RF generator. Always observe the recommended separation distances as defined in the EMC declaration tables. (REFER TO: TABLES 1-4)

3.1.12 This device is suitable for hospitals and doctor/physician offices.

3.2 WARNINGS:

3.2.1 Hazardous electrical output. This equipment is for use only by qualified personnel.

3.2.2 Never increase the power setting without first checking the proper connections of both the active electrode and the neutral plate.

3.2.3 Only Soniquence supplied and/or approved accessories should be used to ensure proper operation. The Soniquence generator and its accessories are identified with the manufacturer information and reference identification number for proper traceability.

3.2.4 Failure of the RF SURGICAL EQUIPMENT could result in an unintended increase of output power.

3.2.5 Read the instruction manual in detail before use.

3.2.6 The Generator will retain the latest power output settings. When using Monopolar and Bipolar techniques, always start at the lowest setting.

3.2.7 Keep the electrode tips clean at all times. Prevent eschar build-up, which increases resistance and contributes to arcing. Eschar can ignite and cause a fire.

3.2.8 Use of accessories or cables other than Soniquence specified, as replacement parts for internal components, may result in increased emissions or decreased immunity of the Soniquence RF generator.

3.2.9 The use of external cables and leads that exceed 3.5 meters, may result in increased emissions or decreased immunity of the Soniquence RF generator. The maximum permissable cable length is 3.5 meters.

3.2.10 Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.

3.2.11 DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.

3.2.12 Prior to increasing the intensity, check the adherence of the neutral electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections.

3.2.13 Connect adaptors and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

3.2.14 Do not use with hybrid trocar systems. This may result in alternate site burns due to capacitive coupling. Use only all metal or all plastic trocar systems.

3.3 SAFETY INSTRUCTION

Please review the below cautionary instructions to reduce the incidence of accidental burns.

3.3.1 When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertant contact with patient may result in burns.

3.3.2 Continuity Monitor / Contact Quality Monitor
It is recommended to place the Neutral Plate as close to the surgical site as possible (usually in opposition to the surgical site). If you are operating on the chest area, place the plate on the back. The Neutral Plate's entire area must be in contact with the patient's clean, bare skin which is free of hair. Proper contact of the Neutral Plate to the patient should be monitored, during a procedure. If the neutral place is not place correctly and it is not in contact with the patient skin an alarm will sound. Continuity above 1000 ohms will also activate the audible alarms.

3.3.3 The patient should not come into contact with metal parts which are earthed or which have appreciable capacitance to earth.

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

3.3.5 When the generator is used simultaneously with physiological monitoring equipment on the same patient, the monitoring electrodes should be placed as far as possible from the surgical electrodes and the Neutral Plate. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating high-frequency current-limiting devices are recommended

3.3.6 The cables to the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored segregated from the patient.

3.3.7 For surgical procedures where the High Frequency current could flow through parts of the body having a relatively small cross-sectional area, the use of Bipolar techniques may be desirable to avoid unwanted coagulation.

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

3.3.9 The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.

3.3.10 Apparent low output or failure of the surgical equipment to function correctly at the normal operating settings may indicate faulty application of the Neutral Plate or poor contact in its connection. In this case, the application of the Neutral Plate and its connections should be checked before selecting a higher output power.

3.3.11 Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before application of the generator.

3.3.12 Any flammable fluid pooled in the body depressions and/or body cavities or under the patient should be mopped up prior to using the generator. Attention should be called to the danger of ignition of endogenous gases.

3.3.13 Some materials, such as cotton, wool, and gauze when saturated with oxygen may be ignited by sparks produced in normal use of the High Frequency surgical equipment.

3.3.14 Before each use, inspect the accessories, electrode cables and probes for possible physical damage.

3.3.15 The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

3.4 CONTRAINDICATION

3.4.1 Device is not to be used for female sterilization or come in contact with the central nervous system or central circulatory system.

IV. DESCRIPTION OF CONTROL ELEMENTS

4.1 SPECIAL FEATURES

The Soniquence generator will comprise unique accessories that include retractable mode and power output level setting, a waterproof Triple Footswitch for both Monopolar and Bipolar applications, and a 3-Button Fingerswitch Handpiece for activation of Monopolar (CUT, BLEND, and HEMO) modes.

Detailed descriptions follow:

4.1.1 Mode and Power Output Level memory

4.1.1.1 Mode and power output levels are stored in a non-volatile memory and recalled upon turning the device on.

4.1.1.2 The memory is set to default zero (0) values upon shipment. To reset to the default values, while the generator is in off position hold both mode select buttons simultaneously while turning on the device until “CLR ALL” is seen in the display.

4.1.1.3 To reset to the default Cutting values only, press and hold both the + and - Cutting Mode Power Selector buttons (see fig. 2.3 - 11 &12) simultaneously while turning on the device and continue to hold the buttons until “CLR YEL” is seen in the display.

4.1.1.4 To reset to the default Coagulation values only, press and hold both the + and - Coagulation Mode Power Selector buttons (see fig. 2.3 - 18 & 19) simultaneously while turning on the device and continue to hold the buttons until “CLR bLU” is seen in the display.

4.1.2 Triple Footswitch and 3-Button Fingerswitch Handpiece

4.1.2.1 Triple Footswitch:

A heavy duty waterproof triple footswitch for CUT and COAG modes of both Monopolar and Bipolar applications. The specific selection of each function (CUT, BLEND, HEMO, BIPOLAR , and BIPOLAR TURBO) is manually selected by pressing the function selector button (with the exception of the center button on the footswitch which will always activate BIPOLAR TURBO). The control function of the Triple Footswitch is described below. It can be summarized as “what you see is what you get”, which means each specific footswitch can only activate the corresponding setting on the display.

a) The far left yellow footswitch controls CUT and BLEND.
b) The far right blue footswitch controls HEMO, BIPOLAR, and BIPOLAR TURBO.
c) The center button footswitch ONLY controls BIPOLAR TURBO

4.1.2.2 Three-Button Fingerswitch Handpiece:

This patented, unique handpiece is utilized to activate CUT, BLEND, and HEMO modes via fingerswitch for delicate procedures. The depressed button function will be the actual output function and disregards the front display settings. The fingerswitch operational features are as follows:

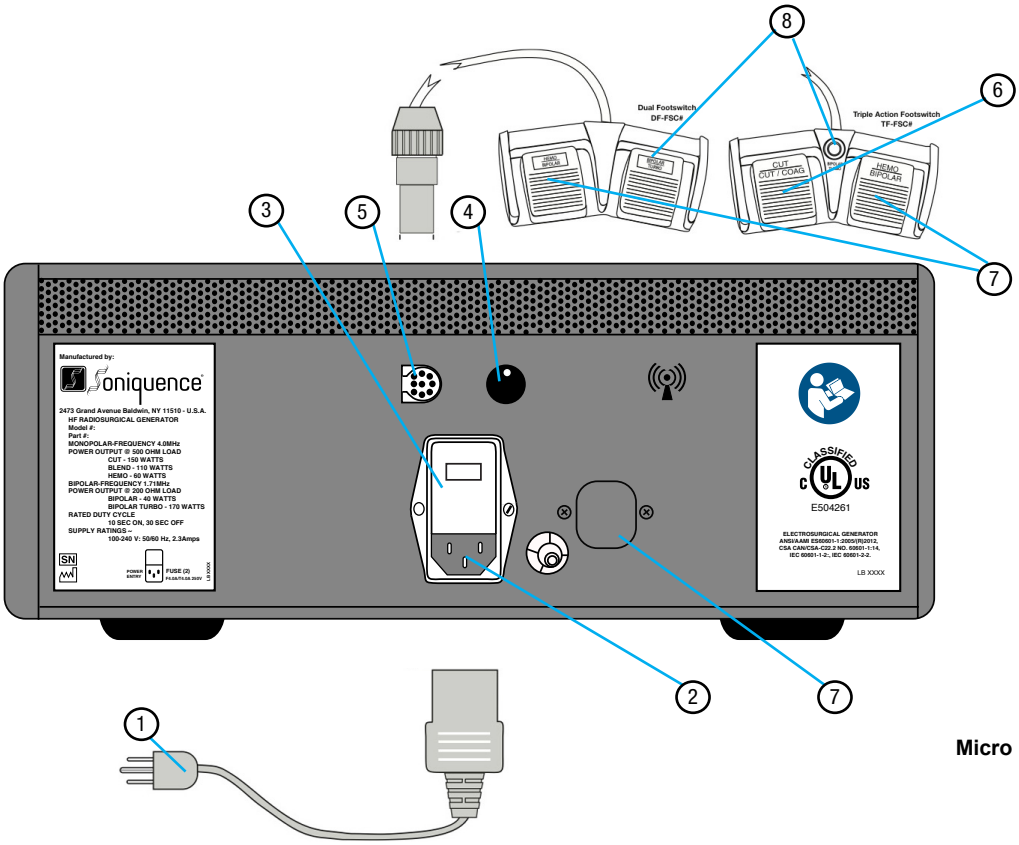
a) The CUT button will activate CUT mode. When depressed, the yellow indicator (CUT) illuminates.
b) The BLEND button will activate BLEND mode. When depressed, the yellow indicator (BLEND) illuminates.
c) The HEMO button will activate the HEMO mode. When depressed, the blue indicator (HEMO) illuminates.

4.1.2.3 Dual Footswitch:
A heavy duty waterproof Dual Footswitch for Coagulation Modes of both Monopolar and Bipolar applications. The specific selection of each mode (HEMO, BIPOLAR and BIPOLAR TURBO) is manually selected by pressing the mode selector button. The control function of the Dual Footswitch is described below. Each specific footpedal can only activate the corresponding setting on the display.
a) The left, blue footpedal controls whatever mode is displayed on the Coagulation Mode (HEMO, BIPOLAR or BIPOLAR TURBO)
b) The right, black footpedal ONLY controls BIPOLAR TURBO

4.1.3 Monopolar and Bipolar Electrodes

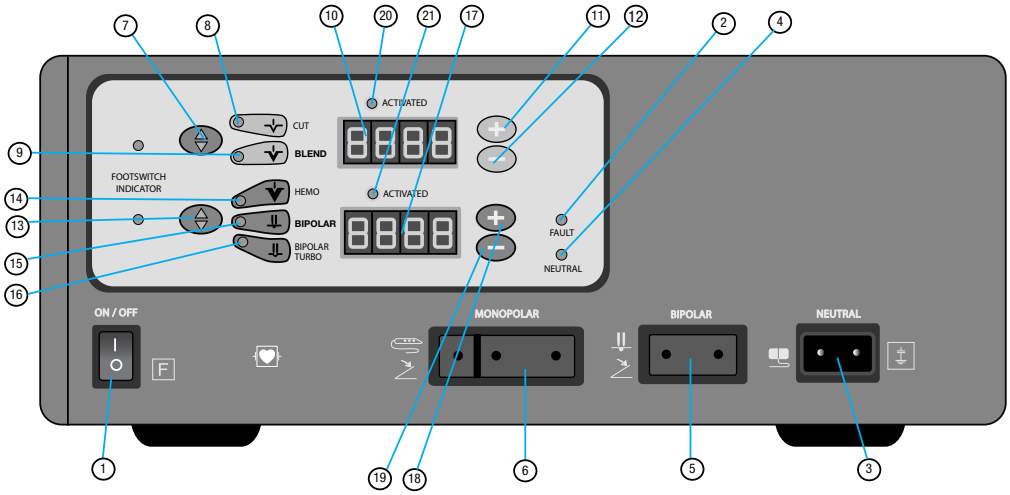
4.1.3.1 The Soniquence RF generator is intended to be used only with Soniquence monopolar and biploar electrodes.
Refer to the instruction manuals for the individual electrodes which include all applicable cautions, safety instructions and warnings.

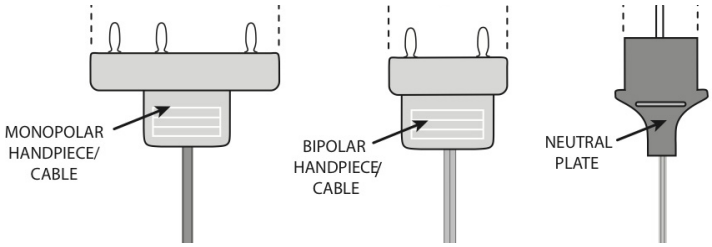
FIGURE 4A: REAR PANEL CONTROL ELEMENTS



Power Plug	1
Power Socket	2
Line Fuses	3
Audio Volume Control	4
Footswitch Receptacle	5
Cutting Mode Activation Pedal	6
Coagulation Mode Activation Pedal	7
BIPOLAR TURBO Activation Pedal	8
Micro USB Port (For Services Purposes Only)	9

FIGURE 4B: FRONT PANEL CONTROL ELEMENTS





ON/OFF Power Switch	1
FAULT Indicator	2
NEUTRAL Receptacle	3
NEUTRAL Indicator	4
BIPOLAR Receptacle	5
MONOPOLAR Receptacle	6
Cutting Mode Selector	7
CUT Mode Indicator	8
BLEND Mode Indicator	9
Cutting Mode Output Power Indicator	10
Cutting Mode Power Increase Selector	11
Cutting Mode Power Decrease Selector	12
Coagulation Mode Selector	13
HEMO Mode Indicator	14
BIPOLAR Mode Indicator	15
BIPOLAR TURBO Mode Indicator	16
Coagulation Mode Output Power Indicator	17
Coagulation Mode Power Increase Selector	18
Coagulation Mode Power Decrease Selector	19
Cutting Mode ACTIVATED Indicator	20
Coagulation Mode ACTIVATED Indicator	21

V. OPERATING THE DEVICE

5.1 GENERAL INFORMATION

5.1.1 The device will retain the latest power output settings. When using Monopolar and Bipolar techniques, always start at the lowest setting and increase in 1-2 point increments to reach desired tissue effect.

5.1.2 CAUTION: Power level must be adjusted in response to tissue effects. If there is tissue dragging, power should be raised and if there is sparking, power should be lowered.

5.2 MONOPOLAR CUT AND BLEND

5.2.1 SETTING POWER LEVEL: Press the yellow Cutting Mode Select Button until the matching mode indicator illuminates. Use Cutting Mode Power Increase Selector button or Cutting Mode Power Decrease Selector button to set the desired power level.

5.2.2 ENERGY ACTIVATION: For energy emission, press the CUT or BLEND button on the 3-Button Handpiece or the yellow footswitch (if available).

5.3 MONOPOLAR HEMO, BIPOLAR HEMO and BIPOLAR TURBO

5.3.1 SETTING POWER LEVEL: Press the blue Coagulation Mode Select button until the matching mode indicator illuminates. Use Coagulation Mode Power Increase Selector button or Coagulation Mode Power Decrease Selector button to set the desired power level.

5.3.2 CAUTION: Prior to energy activation, BIPOLAR must always be selected.

5.3.3 ENERGY ACTIVATION: For BIPOLAR or TURBO, use the corresponding footswitch. MONOPOLAR HEMO is activated using the HEMO button on the handpiece.

5.3.4 ATTENTION: To turn off MONOPOLAR safety alarm when using only the (2) BIPOLAR modes, all (3) MONOPOLAR modes (CUT, BLEND and HEMO) must be set at 0 (zero).

5.4 ERROR CODES TABLE / SINGLE FAULT CONDITION

DESCRIPTION	ERROR CODE
Interface to displays failed	1
Interface to LEDS failed	2
Interface to keypad failed	3
Processor had a warm reset	4
A/D converter error	7
Foot/Fingerswitch interface failed	8
Bond sensor interface failed	9
Keypad pressed during power up protection failed	10
Foot or Fingerswitch pressed during power up protection failed	11
Temperature out of limits	12
Output power test failed	13
Linearization Table in Error	15
EEPROM Read	16
EEPROM Write	17
Oscillator Control Monopolar/Bipolar Enable	18
Processor Master/Slave Error	20
Fram CRC Error	21
Foot/Finger Comparator A/D Error	22
Main Monitor Loop Error	23
SMB Comm is Hung	24
SMB did not reach idle before RF	25
SMB Comm Error to RFID Processor	26
SMB Comm Error RTC	27

TABLE 1

Guidance and manufacturer's declaration – electromagnetic emissions		
This RF Generator is intended for use in the electromagnet environment specified below. The customer or the end user of this RF Generator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This RF Generator must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	This RF Generator is suitable for use in all establishements, other than domestic establishments and those directly connected to the public low=voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

TABLE 2

Guidance and manufacturer's declaration – electromagnetic immunity			
This RF Generator is intended for use in the electromagnet environment specified below. The customer or the end user of this RF Generator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electromagnetic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC61000 - 4-6	Conducted disturbances induced by RF fields	3V 0,15 MHz - 80 MHz 6V/m in ISM bands between 0.15 and 80 MHz 80% AM at 1 kHz	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RF Generator requires continued operation during power mains interruptions, it is recommended that the RF Generator be powered from an uninterruptible power supple or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

TABLE 3

Guidance and manufacturer's declaration – electromagnetic immunity			
This RF Generator is intended for use in the electromagnet environment specified below. The customer or the end user of this RF Generator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	[*3*] V [*3*] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the RF Generator, including cables, than the recommended seperation distance calculated from the equation applicable to the frequency of the transmitter. ***Recommended separation distance*** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electrom magnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RF Generator is used exceeds the applicable RF compliance level above, the RF Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the RF Generator. b) Over the frequency range 150 kHz to 80 MHz, field strenghts should be less than [V_1] V/m.			

TABLE 4

Recommended seperation distance between Portable and mobile RF communications equipment for the RF Generator

The RF Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RF Generator can help prevent electromagnetic interference by maintaining minimum distance between portable and mobile RF communications equipment (transmitters) and the RF Generator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

TABLE 5

Guidance and manufacturer's declaration - enclosure port immunity

This RF Generator is intended for use in the enclosure port immunity specified below.
The customer or the end user of this RF Generator should assure that it is used in such an environment.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

WARRANTY STATEMENT

Soniquence warrants the Soniquence RF generator against defects in materials and workmanship for a period of two (2) years from the date of purchase.

During the warranty period, Soniquence will replace, at its discretion, any defective Soniquence RF generator, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event that an Soniquence RF generator is replaced, the warranty period will not be extended.

This warranty is valid only if the Soniquence RF generator is used in accordance with the manufacturer's instructions. This warranty will not apply:

- If damage results from changes or modifications made to the Soniquence RF generator by the user or third persons after the date of manufacture.
- If damage results from service or repairs performed by any person or entity other than the manufacturer or approved technical service by Soniquence.
- If damage results from a Force Majeure or other event beyond the control of the manufacturer
- If damage results from negligence or improper use, including but not limited to: improper storage, deliberate submersion in water, physical abuse, such as dropping or otherwise.

Use of any and all third-party products and accessories, not specifically authorized by Soniquence® for use in combination with our manufactured RF generator units, shall automatically void any and all warranties on our products and accessories. Moreover, any such unauthorized use shall release Soniquence® and its affiliates, and their respective officers, directors, members, agents and employees from (i) any and all liability for personal injuries, property damage, regulatory violations, fines and penalties proximately caused by, or related to, the unauthorized third-party products and accessories, as well as, (ii) any indemnification obligations owed and/or expenses incurred by Soniquence®.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Soniquence nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product. Any statutory rights granted to consumers under any applicable legislation are reserved.

All other warranties, express or implied, except any applicable mandatory statutory warranties, are excluded, including the warranties of merchantability and fitness for a particular purpose.

FCC COMPLIANCE STATEMENT

CAUTION: Changes or modifications not expressly approved could void your authority to use this equipment.
This device complies with Part 15 of the FCC Rules. Operation to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

QUICK REFERENCE GUIDE

(PLEASE READ INSTRUCTION MANUAL BEFORE USE)

- The device will retain the last power output settings. When using Monopolar and Bipolar Techniques, always start at the lowest setting and increase in 1-2 point increments to reach desired tissue effect.

- **CAUTION:** Power level must be adjusted in response to tissue effects. If the tissue is not cutting cleanly (i.e. dragging), power should be raised. If there is sparking at the electrode tip, power should be lowered.

MONOPOLAR CUT and BLEND

- When using MONOPOLAR modalities, a disposable neutral plate must be used.

- N.B. The unit will not work in MONOPOLAR until a neutral plate is inserted into the unit and is properly placed on the patient.

SETTING POWER LEVEL: Press the Yellow MODE SELECT button until the matching mode indicator illuminates. Use POWER (+) or (-) to set the desired power level.

ENERGY ACTIVATION: For energy emission, press the CUT or BLEND button on the 3-Button Handpiece or the yellow footswitch pedal (if available)

MONOPOLAR HEMO, BIPOLAR BLEND and BIPOLAR TURBO

- When using BIPOLAR modalities, a disposable neutral plate is NOT needed (i.e. when ONLY using Disc-FX and Trigger-Flex products)

- N.B. All three (3) MONOPOLAR Modalities must be set at zero (0) to avoid sounding the alarm when using BIPOLAR.

SETTING POWER LEVEL: Press the Blue MODE SELECT button until the matching mode indicator iluminates. Use POWER (+) or (-) to set the desired power level.

CAUTION: Prior to energy activation, BIPOLAR BLEND must always be selected.

ENERGY ACTIVATION: For energy emission, press the CUT or BLEND button on the 3-Button Handpiece or the yellow footswitch pedal (if available)

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