DIROS
TECHNOLOGY INC

OPERATOR'S MANUAL

OWL® UNIVERSAL RF SYSTEM

MODEL URF-3AP

INCLUDING THE MULTI-LESION ADAPTOR MODEL MLA-4

Diros Technology Inc.
www.dirostech.com
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Serial No. _____

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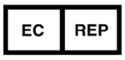
Table of Contents

1 DIROS TECHNOLOGY INC. GENERAL INFORMATION

Diros Technology Inc. is dedicated to providing service and support to its customers. If there are any questions concerning the use of OWL® Universal RF System and Accessories, please contact your local sales representative/distributor. To replace any accessories or detachable parts please contact your sales representative or distributor. If you are unable to reach them, please contact Customer Service at one of the following:

Manufacturer:

Diros Technology Inc.
120 Gibson Drive,
Markham, ON
L3R 2Z3 CANADA
Tel: (905) 415-3440
Fax: (905) 415-0667
E-mail: info@dirostech.com
Web Site:www.dirostech.com



Authorized Representative for Europe:

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Basic UDI-DI Information

Model Number	Basic UDI-DI
URF-3AP	0825114GN3APMLF8
MLA-4	0825114GNMLA4M9

This manual has been drafted in the English language.
Document is also available in other languages (as required by member states).
Contact manufacturer or your local distributor for details.

2 WARNINGS, PRECAUTIONS, AND RECOMMENDATIONS

2.1 GENERAL WARNINGS AND PRECAUTIONS

CAUTION:
Federal law restricts this device to sale by or on the order of a physician.

DO NOT *attempt to operate the OWL® Universal RF System before thoroughly reading this manual. To assure safe and effective use of RF energy, it is important that the equipment's operating instructions are read, understood and followed. Retain this Manual in a convenient, readily accessible place for future reference.*

- *Use only accessories provided by Diros Technology Inc.*
- Risk of electric shock: This equipment is classified as Class 1 Type CF applied parts as a measure of the degree of shock protection. Qualified personnel only should perform all servicing and calibration. Disconnect supply before servicing.
- Risk of injury: Radio-frequency procedures should be performed in a fully equipped operating room environment and only by physicians who are thoroughly trained in RF procedures.
- Risk of Fire: Do not use in the presence of flammable anesthetics, other flammable gases, near flammable fluids (such as skin prepping agents and tinctures), flammable objects, or with oxidizing agents. Observe appropriate fire precautions at all times.
- Risk of Fire: The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the area where the instrument is in use. This device is not rated for anesthetic proof (AP) or anesthetic proof gases (APG). If required, the use of smoke-plume extraction is advised.
- Risk of Fire: Do not use this device in oxygen enriched atmospheres, nitrous oxide (N_20) atmospheres, or in the presence of other oxidizing agents.
- Risk of RF burns to the patient: While using this device during a procedure, the patient should not be allowed to come into direct contact with grounded metal objects such as the surgical table frame, the instrument table, etc.
- Risk of RF burns to the patient: Place monitoring electrodes as far away from the treatment site as possible, to avoid burns or interference with other equipment. The use of needle monitoring electrodes (or small-area electrodes) during RF output is not recommended. In all cases, monitoring systems incorporating high frequency current limiting devices are recommended.
- Risk of RF burns to the patient: Failure of the equipment could result in an unintended increase of output power.
- Risk of RF burns to the patient**:** Use only Diros GD Pad Return Path Electrode. Always select a return path electrode that is designed to be compatible with the available contact quality monitor.
- Risk of RF burns: Unless a compatible monitoring return electrode that meets or exceeds IEC 60601-2-2:2017 is used with a contact quality monitor, loss of safe contact between the return electrode and the patient will not result in an auditory alarm.
- Risk of Fire: Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. Any fluid pooled in these areas should be mopped up before HF surgical

equipment is used. There is a danger of ignition of endogenous gases which should be considered prior to initiation of RF Therapy.

- Risk of RF burns to the patient: Use only with a return electrode that meets the IEC 60601-2-2 standard. The entire area of patient return electrode should be reliably attached to a suitably prepared and appropriate area of the patient's body as defined by the manufacturer.
- Interference with active implants: During RF output, electrically conductive implanted devices such as pacemakers may be affected due to concentration or re-direction of HF currents. Patients that have sensing pacemakers need consultation with a cardiologist to convert the pacemaker to a fixed rate device for the duration of the procedure. Patients with electrically conductive implants, a possible hazard exists due to the concentration or re-direction of HF current. In case of doubt, qualified advice should be obtained as necessary, to minimize the risk of injury from implanted device malfunction. These devices include cardiac pacemakers, implanted defibrillators, implanted neurostimulators or any active electrical implant.
- Interference with other equipment: During RF output (lesion modes), the conducted and radiated fields may interfere with other electrical medical equipment. For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the active implant may occur, or the active implant may be damaged. In case of doubt, qualified advice should be obtained.
- Risks Associated with Disposal and Waste Products: Do not dispose in the household waste and follow the disposal regulations.
- Risk of electric shock: Grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked "HOSPITAL ONLY" or "HOSPITAL GRADE".
- Risk of Neuromuscular Stimulation: Inadvertent Neuromuscular stimulation may occur during treatment.
- Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
- 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.
- 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.
- The output power selected should be as low as possible for the intended purpose.
- Certain devices or accessories may present a safety hazard at low power settings (e.g., with argon beam coagulation, risk of gas embolism rises when there is insufficient HF power to produce a rapid impermeable scar on the target tissue.
- Non-flammable agents should be used for cleaning and disinfection wherever possible.
- This device provides an automatic mode of operation. Use of automatic modes requires constant monitoring of the patient and generator status throughout treatment. Do not leave the device operating while unattended.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

PRECAUTIONS:

- Do not remove the cover/case. Removing the cover/case may result in personal injury and/or damage to the OWL® Universal RF System. Qualified personnel only should perform all servicing and calibration. Disconnect supply before servicing.
- ELECTRODE INSULATION coating should be checked and visually inspected on all needles, cannulae or electrodes before each procedure, to be sure it is not cracked, chipped, cut, missing or exhibiting any other damage. If damage is detected they must not be used to prevent personal injury for both patient and user. Such damage could lead to exit of RF current at a point along the shaft, producing unwanted tissue heating at unspecified points and possibly burns. In general, a sign of unwanted RF current loss either by cut insulation or other means, would be revealed by unusually high RF current values to achieve a desired tip temperature. Extremely high currents could produce heating and possibly burns at the dispersive electrode.
- CABLE INSULATION for both active and dispersive electrode cables should be checked prior to each procedure to be sure it is not damaged or cut. Regularly inspect and test re-usable cables and accessories.
- USE OF COMPONENTS AND ELECTRODES not of Diros Technology Manufacture together with Diros Technology equipment seriously compromises the safety and efficiency of the equipment. Always use only manufacturer recommended equipment and accessories.
- USE OF SINGLE USE COMPONENTS. Do not reprocess or reuse cables, needles or cannulae etc., which have been designed for or have been designated as disposable (single patient use only). Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- USE OF STERILE COMPONENTS. Sterile packaging should always be inspected prior to use. Do not use these components beyond expiry date.
- Do not connect any probe/electrode to the patient through which treatment is not intended to be delivered.
- Do not initiate treatment while any probe/electrodes connected to the device are not inserted into the patient.
- Do not insert any electrodes into the patient or remove any electrodes from the patient while lesioning or stimulating.
- Care must be taken when operating around other equipment to avoid reciprocal interference. Potential non- ionizing electromagnetic or other interference could occur to this or to the other equipment near it.
- 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.
- Avoid output settings of generator exceeding 150Vrms at 480 kHz.
- For large tip sizes longer ramp time is recommended.
- For small tip sizes lower power settings are recommended.

2.2 CONTRAINDICATIONS

Contraindications: radiofrequency treatment is contraindicated on patients with a cardiac pacemaker, implanted defibrillator, implanted neurostimulator, or any active electrical implant.

The MLA-4 multi-lesion adaptor is not intended for use in brain surgery.

There is insufficient clinical data demonstrating safe and effective use of radiofrequency treatment in pediatric and pregnant patient populations.

RF procedures should be reconsidered in persons with poor psychological capacity, and among those receiving anticoagulation therapy or with anticoagulopathy.

2.3 CARE AND MAINTENANCE FOR NEEDLE SET COMPONENTS

Carefully clean the components of each set after each procedure. Flush out re-usable cannulae vigorously using a syringe and needle inserted into the hub end, and remove all coagulum from the bare tip and tip hole.
In cases where there is a flexible or spring tip electrode there are special precautions for care and maintenance. Excessive bending or kinking of curved flexible tip electrodes may damage internal wires. The distal tip of these electrodes should be cleaned after each procedure to eliminate any coagulum. Gently wash the flexible or spring tip free of coagulum, and carefully scrape off any crusted or charred matter from the tip. Note that a crust on the spring tip, over the thermistor sensor, can thermally insulate it to be cooler during lesioning than another tip area that is clean. For further guidelines refer to the information supplied with these electrodes.

2.4 RECOMMENDATIONS FOR RETURN PATH (REFERENCE) ELECTRODES

Patient or operator injury can result from improper handling of the OWL® Universal RF System and the indifferent (dispersive) electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.

Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the disposable indifferent (dispersive) electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.

Use only with a return electrode that meets the IEC 60601-2-2 standard. (e.g. OWL GD-Pad Patient Return Electrode).

The entire area of the patient return electrode should be reliably attached to a suitably prepared and appropriate area of the patient's body as defined by the manufacturer.

Read and follow the disposable indifferent (dispersive) electrode manufacturer's instructions for use.

Use of a Return Path electrode is required in all cases unless bipolar RF lesioning is being performed.

The URF-3AP is designed with a built-in contact quality monitor that detects the impedance between the two conductors of the return electrode. If a single plate electrode is connected, it will detect if there is a fault with either one of the conductors. If a dual plate is connected, it will detect the impedance between the two plates. If the impedance between the dual plate is greater than 135 ohms it will prevent the lesion from starting. Table 2- 1 outlines the expected CQM icons based on the impedance between the two conductors.

A CQM error will be triggered based on the trigger conditions outlined in Table 2- 2. Once the CQM error is triggered, the lesion will be stopped, the CQM LED and CQM Error icon on the screen will start to flash, a message of high impedance will be displayed, and an alarm tone as described in Table 2- 3 will also be outputted.

Impedance between both Conductors (ohms)	Expected CQM icon	CQM LED STATUS
0 < R < 10	Good Single Plate	OFF
10 < R < 135	Good Dual Plate	OFF
135 < R < 150	Bad Dual Plate	ON
R > 150	No Pad	ON

Table 2- 1 CQM Thresholds and expected CQM icon and CQM LED status.

Initial State	Change in Impedance
Single Plate	An impedance increase of 20 ohms will cause an alarm.
Split Plate	An impedance increase of 30% + 10 ohms or an impedance greater than 150 ohms will cause an alarm.

Table 2- 2 CQM Alarm Triggers

Alarm Characteristic	Description
Sound Level	>65dB at 1m from the generator
Frequency	700 & 900 Hz

Table 2- 3 CQM Alarm Tone Characteristics

CQM Measurement Current <10uA

Note: CQM will only be present in monopolar RF modes.

2.5 List of Accessories and Detachable Parts

All Diros Probes	(patient applied part)
All Diros Cannulae	(patient applied part)
Diros GD Pad Return Electrode	(patient applied part)
Diros MLA-4 Multi-Lesion Adaptor	
Diros Foot-Switch	

Note: For new accessories contact Diros Technology or your distributor to confirm compatibility.

2.6 PATIENT POPULATION

The target population of the Diros radiofrequency system are adult patients suffering with neurological disorders or chronic pain mediated by the central nervous system which have not adequately responded to non-invasive treatment approaches and who are eligible and willing to undergo interventional techniques according to a treatment plan devised by a qualified clinician. Treatment may involve repeat lesioning without any restrictions as to the number of said repeated lesions as deemed appropriate by the qualified clinician.

3 INTRODUCTION

The medical device presented in this Operator's Manual consists of the OWL® URF-3AP Radio Frequency Lesion Generator and its Multi-Lesion Adaptor. This manual is designed to provide instructions for use and will act as a quick reference for features available to the operator such as Stimulus, R.F Lesioning and DiscPlasty™ modes. DiscPlasty™ when using the URF-3AP, refers to thermal annuloplasty techniques.

The URF-3AP Operator's Manual provides the user with a complete description of the physical appearances, controls, and displays. Due to the essential use of an R.F. Probe / Temperature Sensor, this manual explains which probes can be used, and for what treatment. The URF-3AP will inform the user of any incorrect usage of probes, by prompting the user with an error message.

A glossary of terms has been added to the remaining pages of this manual to assist the OWL® User with any terminology provided with any instructions, or explanations.

The Instructions for Use are divided into two sections based on whether or not a Multi-Lesion Adaptor is present, as the user interface is substantially different in these two cases. The URF-3AP senses the presence of the Multi-Lesion Adaptor and adjusts its user interface accordingly.

4 DEVICE DESCRIPTION & INDICATED USE

Device Description: The OWL® Universal RF System consists of the generator URF-3AP and the multi-lesion adaptor MLA-4. The URF-3AP generator can be used as a stand-alone single lesion device. The multi-lesion adaptor MLA-4 is an accessory to URF-3AP generator and cannot be used alone. When the MLA-4 adaptor is attached to the URF-3AP generator, it allows connection of up to 4 lesion probes/electrodes. The RF energy that is produced by the URF-3AP generator, is then multiplexed by the MLA-4 adaptor between probes/electrodes to create multiple lesion locations.
The URF-3AP is used by qualified medical personnel to make heat ablative lesions in central or peripheral nerve tissue for the treatment of movement disorders or for the relief of pain. The lesions are ablative in order to be therapeutic; i.e. the destruction of a small portion of the thalamus within the brain interferes with the motor pathway causing the tremor of Parkinson's disease, thereby relieving the tremor; or the destruction of the facet joint nerves in the lumbar vertebrae to block pain transmission by these nerves and thereby relieve certain types of low back pain. The lesion is made by radiofrequency electro coagulation by a high frequency sine wave current, generally between 450-500 kilohertz, applied directly to the tissue via the uninsulated tip of a RF lesion probe. Radiofrequency current does not heat the probe tip; rather the tissue heats itself as a result of the frictional effect of rapid movement of tissue ions produced by the rapidly oscillating RF current. The RF lesion technique has been accepted for over 40 years as the method of choice for making well controlled, targeted, percutaneously guided lesions in the nervous system.

Intended User: The URF-3AP is used by qualified medical personnel to make heat ablative lesions in central or peripheral nerve tissue for the treatment of movement disorders or for the relief of pain.

Intended Use: The Diros / OWL Universal RF System URF-3AP is intended for use in radiofrequency (R.F) lesioning during neurosurgical and interventional pain management procedures.

Clinical Benefits: The URF-3AP along with its other accessories such as MLA-4, Probes, Cannula and Cables are used by qualified medical personnel to make heat ablative lesions in central or peripheral nerve tissue for the treatment of movement disorders or for the relief of pain. The lesions are ablative in order to be therapeutic; i.e. the destruction of a small portion of the thalamus within the brain interferes with the motor pathway causing the tremor of Parkinson's disease, thereby relieving the tremor; or the destruction of the facet joint nerves in the lumbar vertebrae to block pain transmission by these nerves and thereby relieve certain types of low back pain.

5 INSTALLATION

5.1 PREPARING THE GENERATOR FOR USE

In a packaging box, you will find:

- Generator, URF-3AP
- MLA-4 Multi-Lesion Adaptor (optional)
- Power Cord
- Footswitch
- Operator's Manual

Place the OWL® URF-3AP generator on any sturdy table or platform.
Do not obstruct the air-cooling vents on the rear panel and the underneath of the Generator. Leave at least 10cm (4") of space around the device for free air flow.

Check the Generator, Power Cord and Footswitch for any signs of physical damage that may have occurred during transportation.

The URF-3AP must be used only with an approved hospital-grade power cord.
Do not use extension cords or adapters.
Periodically check main power cord assembly for signs of excessive wear, kinking or any other damage to cable and connectors.

- If any physical damage is found DO NOT USE THE GENERATOR.
- To isolate the device from MAINS Power, disconnect power cord.
- Ensure that the instrument is positioned so that the MAINS power cord can be easily disconnected.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- If the instrument fails to operate when plugged into a proper AC POWER receptacle and the (POWER) button is pressed
  DO NOT ATTEMPT TO REPAIR.

Contact your local representative or Diros Technology Inc. for instructions on returning the instrument for repair or replacement. All returns must be approved by Diros Technology Inc.

The OWL Universal RF System URF-3AP does not contain any user-serviceable parts.
Disassembly and attempted repair by unqualified personnel may create a hazardous condition and will void the warranty. Do not modify the device in any way. Any device modification may cause serious injury or death to patient or operator.

5.2 PREPARING THE MULTI-LESION ADAPTOR FOR USE

In the packaging box, you will find:

- MLA-4 Multi-Lesion Adaptor
- Operator's Manual

Inspect the MLA-4 for any physical damage.

- **If any physical damage is found DO NOT USE THE ADAPTOR.**
- **If the Adaptor fails to operate DO NOT ATTEMPT TO REPAIR.**

5.3 GENERATOR & ADAPTOR CLEANING AND DISINFECTION INSTRUCTIONS

With the instrument turned off and unplugged, periodically or as necessary use a damp cloth moistened in isopropyl alcohol (70%) to disinfect the instrument. Where disinfection is not required, a mild cleaning solution can be used to carefully wipe the various surfaces of the instrument. Avoid caustic or abrasive cleaners.
Never pour or spray any liquids or cleaning solutions on any part of the instrument directly. The generator is not sterilizable.

5.4 GENERATOR MAINTENANCE & CALIBRATION

The Generator requires no routine service or maintenance. Generator verifies functionality during Self-Test. If the unit repeatedly fails self-test on boot up, it will need to be returned to the factory for repairs.

Preventative maintenance can be performed annually such as cleaning, a test for electrical safety, check if red LED illuminates with absence of Return Path electrode and verification that rear fan is operational.

There are no calibration adjustments accessible to the user, therefore the instrument does not require any calibration to be performed by user or service personnel. During every both startup, the instrument performs a self-test, this process is automatic; computer controlled and is done using built in references. The internal references are set and can only be reset by the factory personnel during factory calibration process. In the unlikely event of a failure of the instrument, it must be returned to the factory for repair.

5.5 PROBES AND CONNECTOR CABLES

Upon connection, the Generator recognizes the probe and cable type, and highlights the appropriate menu in the main screen.

An error message is displayed when an unrecognized probe type is detected. The Generator issues a warning message when the probe or connector cable is disconnected. The Generator will transfer to the Main Menu if the probe chosen does not coincide with the treatment method.

5.6 PROBES AND NEEDLE SETS

The Generator supports several types of probes for use in neural stimulation and RF lesioning treatments. A unique connector cable is required to interface each type of probe to the Generator. The connector cable is recognized by the Generator. The available treatment modes depend upon the recognized probe type.

5.7 FOOTSWITCH

The OWL® pneumatic footswitch allows the operator to turn the Generator output on and off from outside the sterile field. This is a non-sterile device.

Keep the OWL® pneumatic line away from wheels and other equipment which may kink, squeeze or otherwise obstruct the line.

Use a mild detergent and damp cloth, followed by a disinfectant to clean the footswitch and guard. The footswitch is not sterilizable.

6 USER INTERFACE OVERVIEW

6.1 INTRODUCTION

The user interface consists of:

- Main POWER switch
- Flat-panel LCD display
- START button
- STOP button
- STIMULUS button
- LESION button
- 6 Soft Keys along the right side of the display
- OUTPUT CONTROL knob

6.2 FRONT PANEL

The flat panel display is the central feature of the user interface. The display is separated into several functional blocks as shown in Figure 6-1, and explained in Table 6-1. Variable-function Soft Keys are provided along the right of the display, using "labels" which are adjacent to the membrane panel keys. By changing the "labels", the functions of the keys can be configured for different modes of operation.
Soft Keys along the right side are used to select treatment mode and treatment parameters. During RF output, the screen displays and graphs, in real-time, the measured parameters. Error/Fault messages are displayed in pop-up windows, which appear near the center of the display.

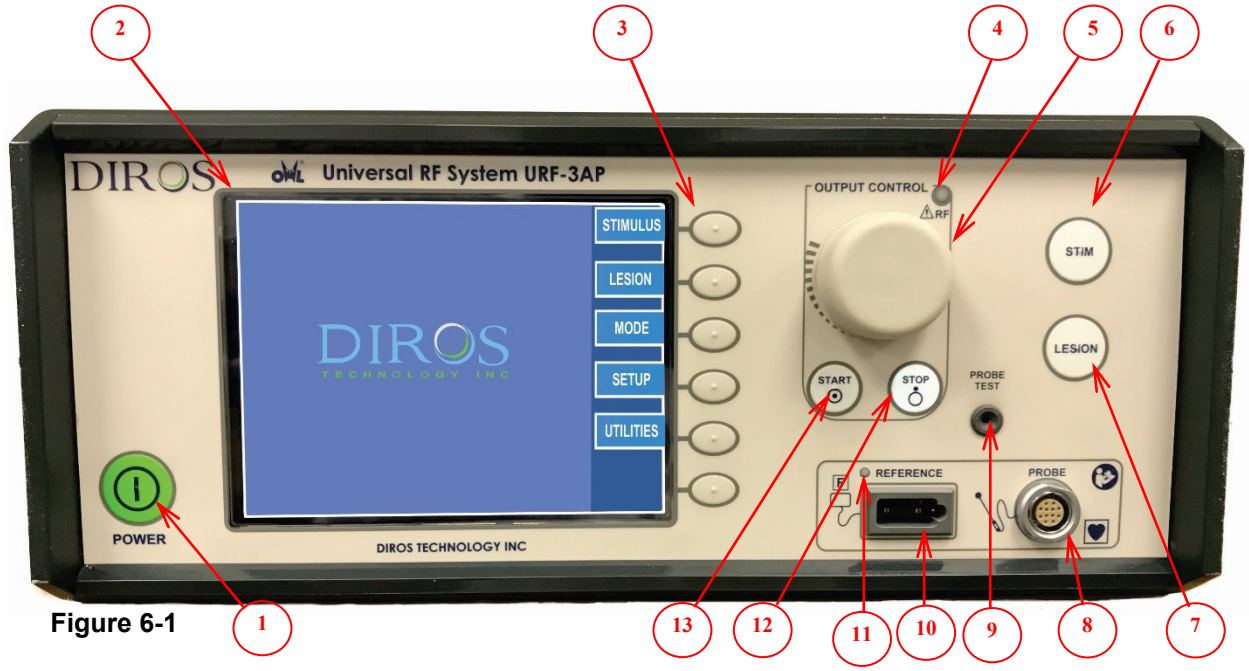


Figure 6-1

	Item	Function
1	**Power ON/OFF Button and Indicator**	This button turns the RF Generator ON and OFF. The green LED indicator light indicates that the system power is on.
2	**Display Screen**	The flat panel LCD shows various measurements, and timeline illustrations of wave cycles and temperature increments. It is also used in menu navigations and parameter settings.
3	**Soft Keys**	The Soft Keys are used to select and adjust various menu options, treatment modes, settings, and parameters in different modes.
4	**RF Output Indicator**	This blue LED indicator is active when RF power is being generated and delivered to the electrode.
5	**OUTPUT CONTROL knob**	This control is used for manual ramp of output signal in LESION and STIMULUS.
6	**Stimulus Button**	This button is a short-cut to the STIMULUS mode screen. The STIMULUS mode screen can also be accessed by navigating the menu using the Soft Keys. Button is illuminated when STIMULUS menu is chosen.
7	**Lesion Button**	This button is a short-cut to the LESION mode screen. The LESION mode screen can also be accessed by navigating the menu using the Soft Keys. Button is illuminated when LESION menu is chosen.
8	**Probe Connector**	This patient isolated connection is for attachment of the connector cable for bipolar and monopolar probes. This connector can accept multiple types of cables to be used in different procedures.
9	**Probe Test Jack**	When the Probe Test mode is selected, this jack accepts the probe for testing and calibration.
10	**Return Electrode Connector**	This patient isolated connection is for attachment of industry standard Electrosurgical return electrodes. Use only with a return electrode that meets the IEC 60601-2-2 standard.
11	**CQM LED**	This LED will illuminate red if the return pad is not connected or if the CQM alarm triggers.
12	**STOP Button**	This button terminates procedure related to mode of operations. Button is illuminated when outputs are disabled.
13	**START Button**	This button initiates the procedure related to mode of operations. Button is illuminated when outputs are energized.

Table 6-1

6.3 REAR PANEL

Descriptions of the rear panel features, and their functions are shown in Figure 6-2, and outlined in Table 6-2.

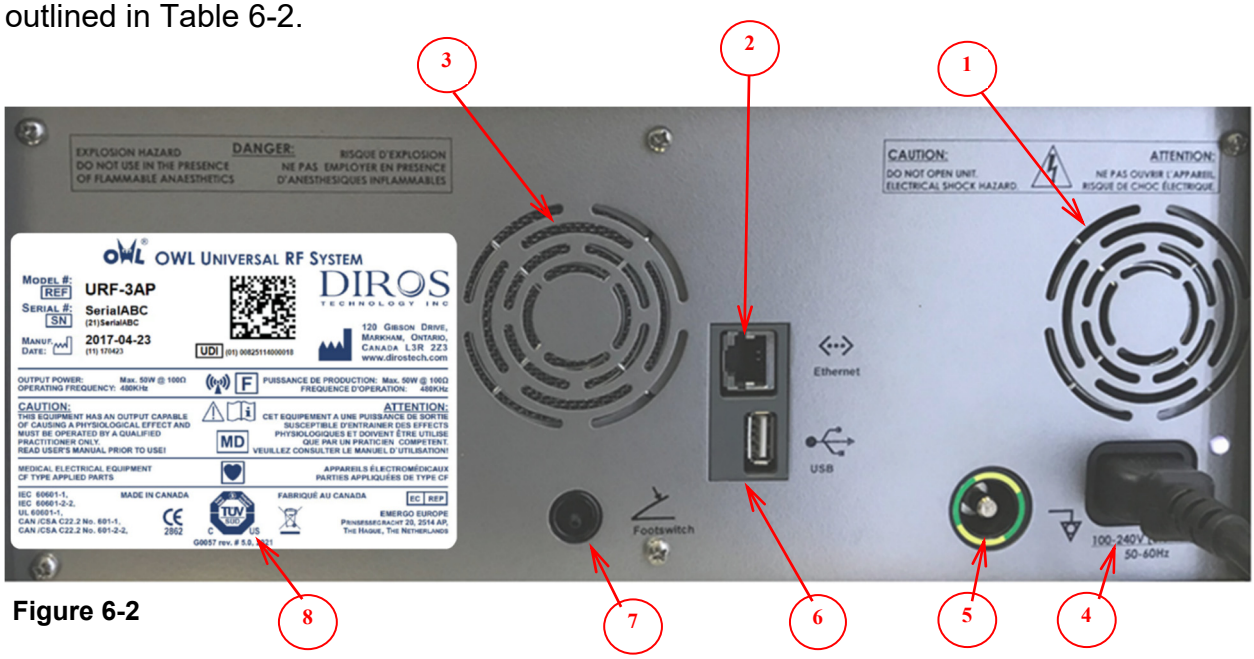


Figure 6-2

	Indication	Function
1	**Fan**	A DC fan is used to force air circulation to cool the URF-3AP.
2	**Ethernet Connection**	This is an isolated connection to a standard Ethernet port. This port is currently not used.
3	**Speaker**	Used to deliver audible feedback that aids operation of URF-3AP.
4	**AC Main Outlet**	This outlet is the initial AC power input to the system.
5	**Equipotential Ground Connection**	This is attached to the chassis / earth ground. It is intended for earth reference connection in environments where Equipotential Ground cabling is used.
6	**USB Port**	This is an isolated connection to a standard USB port. Only attach a USB Key for the purpose of storing history to this port.
7	**Footswitch**	This pneumatic barb connects to the hose of the pneumatic footswitch. Acts as a START/STOP switch.
8	**Name Plate**	Serial Number, Ratings, Model, Standards and Approvals,

Table 6-2

6.4 MLA-4

The MLA-4 consists of 5 ports and 4 LEDs on the front panel. Each port is indicated with its corresponding channel number. The functionality of the black port as indicated by the sigma, is reserved for future use. Each channel has a corresponding LED (Figure 6-3) that is used to indicate the state of that channel which is described in section 8.2.2. The features of the MLA-4 are described in Table 6-3. Figure 6-4 depicts the MLA-4 attached to the URF-3AP.

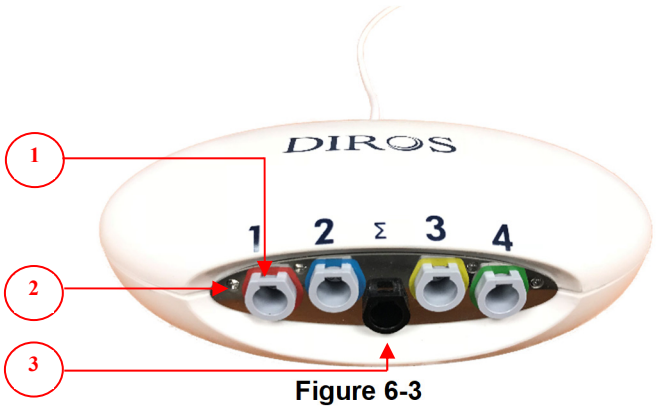


Figure 6-3

Feature	Description
1	Channel Ports
2	Channel LED
3	Reserved for Future Use

Table 6-3

Figure 6-4

6.5 Equipotential Ground Connection

The URF-3AP is supplied with a terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR according to IEC 60601-1. During installation and use ensure that:
– The terminal shall be accessible to the operator.
– The risk of accidental disconnection shall be minimized.

7 INSTRUCTIONS FOR USE WITHOUT MULTI-LESION ADAPTOR

7.1 INTRODUCTION

This section of the Operator's Manual will provide working explanations for the OWL® R.F Generator, URF-3AP when operating without the Multi-Lesion Adaptor. Section 7 has been designed to explain screens, specifications, functions, instructions, and will summarize the screen illustrations that one will view during operation of the URF-3AP.

During Stimulus, Lesioning, and DiscPlasty operations, the screens provided by the URF-3AP offer the Treatment screen, and the Setup menu. The Setup menu allows the user to set up values for their preferred operation, and the Treatment screen provides the user with real-time feedback during most Treatments. All screen explanations in this section illustrate the Treatment, and Set up screens, and will state all the available changes that can be made during the operation (Run mode), Standby (Idle mode), and Setup modes. The screen explanations match the order of sequence in that of the URF-3AP.

The URF-3AP has been designed to work with several types of probes (R.F Probe / Temperature Sensors) through a patient-isolated, universal probe connector. Each probe type is connected to the Generator through a unique interface cable, which allows the Generator to identify the probe. When monopolar probes are used, the return electrode is connected to an industry-standard patient-isolated receptacle.

The URF-3AP is intended as a portable device that consists of a power cord, the Generator box, a footswitch and, the Operator's Manual.

7.2 GENERATOR POWER-UP

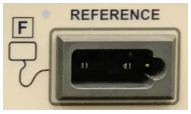
7.2.1 POWER-UP

Plug the Generator into a grounded receptacle (extension cords and/or adapter plugs must not be used). The power can be turned on/off using the POWER button on the front panel. Turn the power on by pressing the POWER button.

After powering on the Generator, it will conduct a Self-Test with active time indicator to ensure proper operation of the URF-3AP. Following successful completion of the self-testing screen, the user will be prompted with a Passed indication, and the Generator will automatically transition to the Main Menu Screen (See Figure 7-1).

The Generator remains in the Main Menu screen until treatment is chosen. The operation modes available will depend on the type of probe connected to the device.

7.2.1.1 RETURN ELECTRODE CONNECTION



Connect the commercial return electrode by inserting the plug into the rectangular receptacle on the front panel of the Generator.

7.2.1.2 PROBE CONNECTION

The probe is connected by an intermediate cable, to the universal probe receptacle on the front panel of the Generator.

7.2.1.3 FOOTSWITCH CONNECTION

Connect the pneumatic hose of the footswitch to the barb on the rear panel of the Generator. Slide the hose onto the barb to create a secure friction fit.

7.3 MAIN SCREEN START UP

Figure 7-1 illustrates the initial start-up screen of the URF-3AP when no cable is connected to the Probe Connection port of the RF generator.

Labels adjacent to the Soft Key are numbered and

Table 7-1 outlines the function of each selection

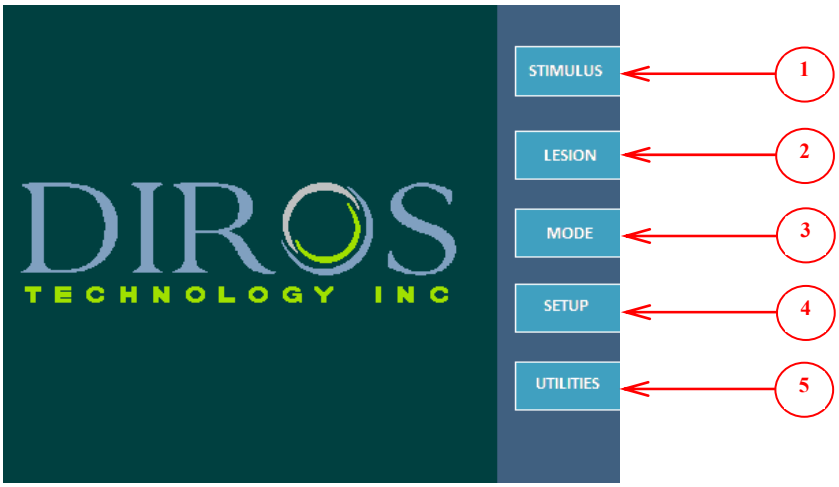


Figure 7-1

	Soft Key	Function		Location
1	STIMULUS	Stimulus Single Probe	Voltage and Current Controlled Stimulation MOTOR and SENSORY modes	7.3.1
		Stimulus Multiple Probes	Voltage and Current Controlled Stimulation MOTOR and SENSORY modes	8.4
2	LESION	Continuous RF Lesion (Single Probe)	HIGH temperature RF Lesion procedure One RF Probe/Temperature Sensor and Dispersive Return Electrode is used	7.3.2.1
		Continuous RF Lesion (Multiple Probes)	HIGH temperature RF Lesion procedure Multiple RF Probes/Temperature Sensors and Dispersive Return Electrode are used	8.7
		Pulsed RF Lesion (Single Probe)	LOW temperature RF Lesion procedure One RF Probe/Temperature Sensor and Dispersive Return Electrode is used	7.3.2.4
		Pulsed RF Lesion (Multiple Probes)	LOW temperature RF Lesion procedure Multiple RF Probes/Temperature Sensors and Dispersive Return Electrode are used	8.7
	DiscPlasty®	DiscPlasty Type 1 DiscTRODE®	Thermal Annuloplasty Technique	7.3.3
		DiscPlasty Type 2 IDET™	Thermal Annuloplasty Technique	7.3.4
3	MODE	This key is enabled only without the cable attached; it allows the user to select various modes of operations.		-----
4	SETUP	• User information entry • Change/Add/Delete user • Audio setup • Date and Time entry		10
5	UTILITIES	• HISTORY (Save latest procedures on USB Flash Memory) • PROBE TEST (Test RF Probe and cable)		11

Table 7-1

7.3.1 STIMULUS MODES

7.3.1.1 VOLTAGE STIMULATION

During the VOLTAGE STIMULATION procedure, output is manually controlled by varying voltage of the stimulus signal.

Figure 7-2 and Figure 7-3 exemplify Voltage Stimulus Sensory Treatment and Setup screens. Table 7-2 outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Sensory sub-mode

Treatment Screen

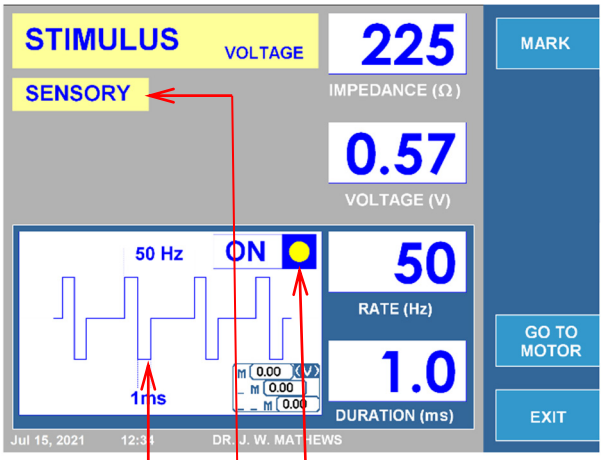


Figure 7-2

Setup Screen

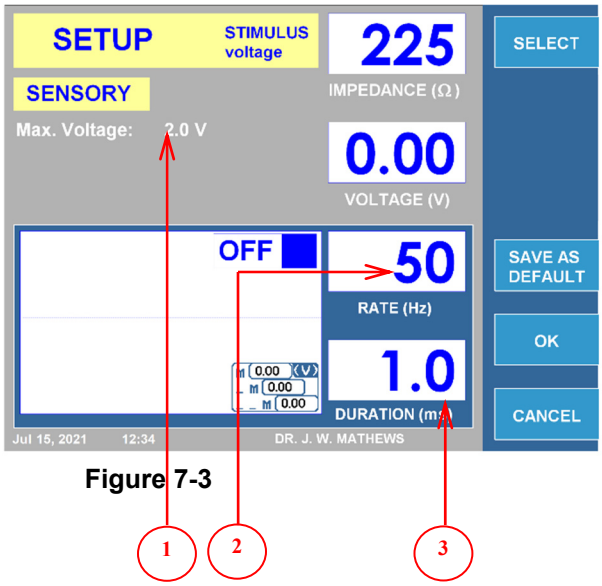


Figure 7-3

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Max Voltage			✓	0.2V to 10V	2V
2	Rate (Hz)			✓	10Hz-200Hz	50Hz
3	Duration (ms)			✓	0.1ms-3.0ms	1.0ms
4	*Sensory/Motor menu	✓	✓		Sensory / Motor	Sensory
5	Waveform illustration	Simulated output waveform.				
6	ON/OFF indicator	Repeatedly alternating while stimulus output is activated				

Table 7-2

**Note: Output signal will be set to "0", if MOTOR/SENSORY key is used during treatment.*

Figure 7-4 and Figure 7-5 exemplifies Voltage Stimulus Motor Treatment and Setup screens. Table 7-3 outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Motor sub-mode

Treatment Screen

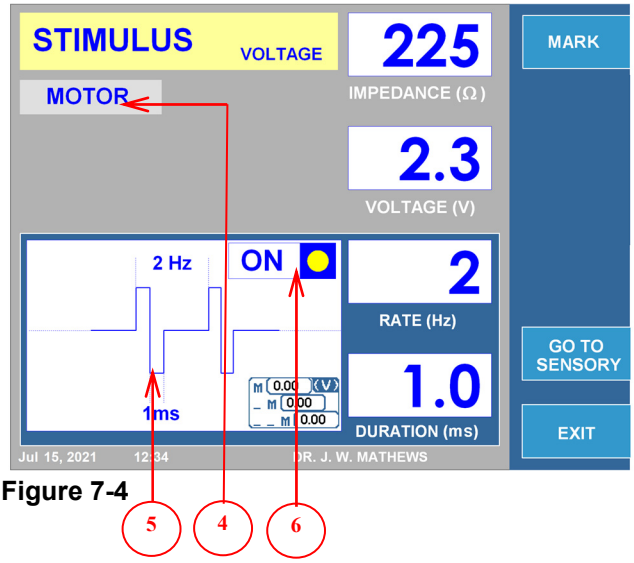


Figure 7-4

Setup Screen

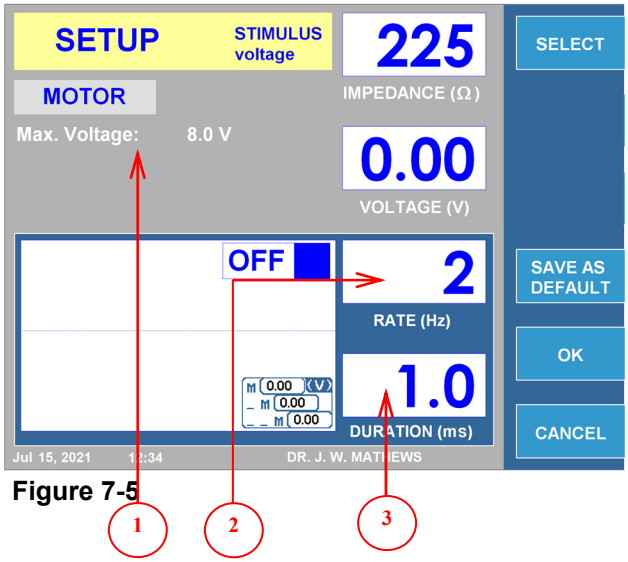


Figure 7-5

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Max Voltage			✓	0.2V to 10V	8V
2	Rate (Hz)			✓	1 SHOT, 1Hz-10Hz	2Hz
3	Duration (ms)			✓	0.1ms-3.0ms	1.0ms
4	*Motor/Sensory menu	✓	✓		Motor/Sensory	Sensory
5	Waveform illustration	Simulated output waveform.				
6	ON/OFF indicator	Repeatedly alternating while stimulus output is activated				

Table 7-3

**Note: Output signal will be set to "0", if MOTOR/SENSORY key is used during treatment.*

7.3.1.2 INSTRUCTIONS FOR VOLTAGE STIMULUS USE

VOLTAGE STIMULUS OPERATION FLOW CHART

Step 1: Press the STIM button or alternatively navigate the Soft Keys on the side of LCD display to bring up the Voltage Stimulus Treatment screen.

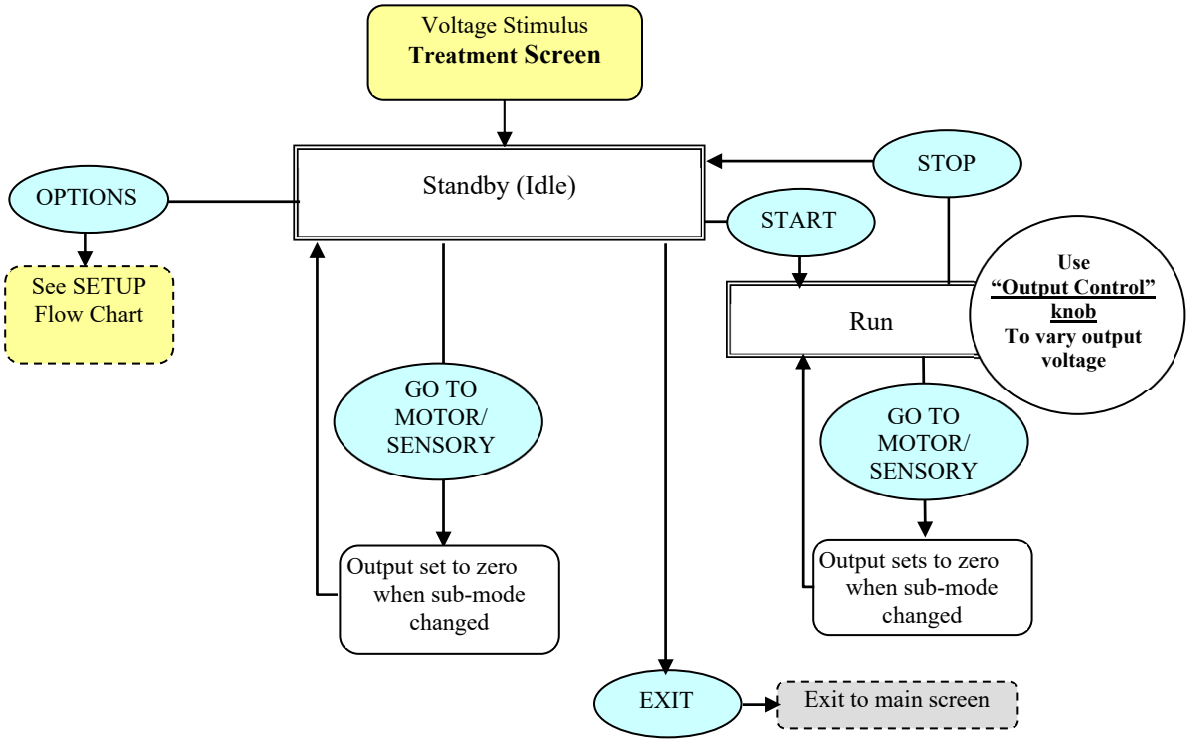
Step 2: Verify that the settings for treatment are correct. Make all necessary changes, if needed, before starting treatment.

Step 3: Check patient connections and electrode placement. Press the START button to begin treatment.

Step 4: Use the OUTPUT CONTROL knob to vary signal strength.

Step 5: Press the STOP button to terminate treatment. During treatment, the MOTOR/ SENSORY key can be used to alternate between the stimulus options.

The footswitch can be used instead of the START and STOP buttons.
To start, depress and hold footswitch, release footswitch to stop.



VOLTAGE STIMULUS SETUP FLOW CHART

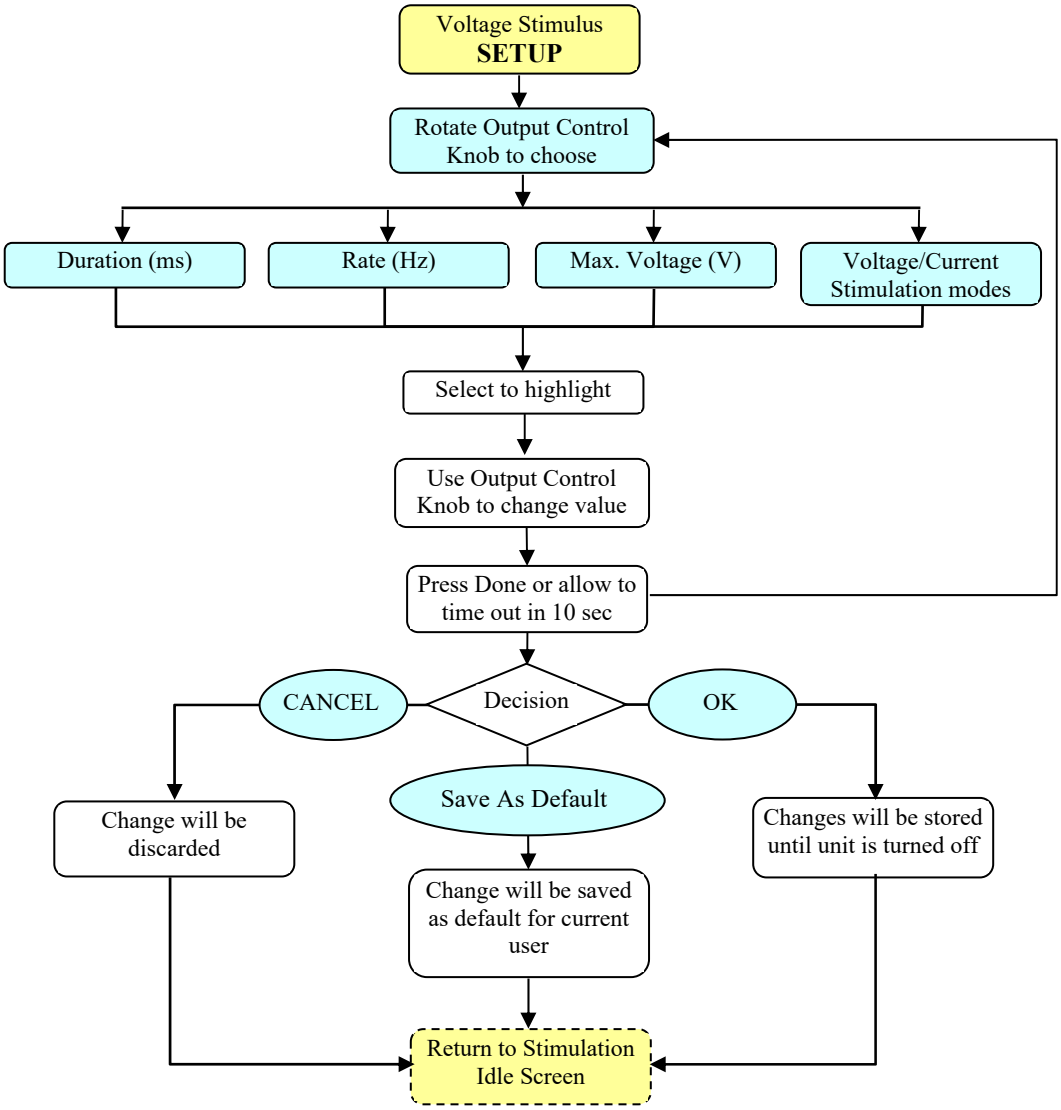
From the Voltage Stimulus Treatment screen press OPTIONS key to initiate the mode setup menu.

Step 1: Use OUTPUT CONTROL knob to outline required parameter.

Step 2: Press SELECT key to highlight parameter, and then use the OUTPUT CONTROL knob to change it to the correct value. Repeat steps 1 and 2 for other parameters as needed.

Step 3: Choose either of the 3 options available:
OK key - keep changes until instrument is turned OFF
CANCEL key - discard all changes
SAVE AS DEFAULT key- save changes as default values for treatment

Note: All settings have an effect on current user and treatment only.



7.3.1.3 CURRENT STIMULATION

During the CURRENT STIMULATION procedure, output is manually controlled by varying current of the stimulus signal.

Figure 7-6 and Figure 7-7 exemplify the Current Stimulus Sensory Treatment and Setup screens. Table 7-4 outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Sensory sub-mode

Treatment Screen

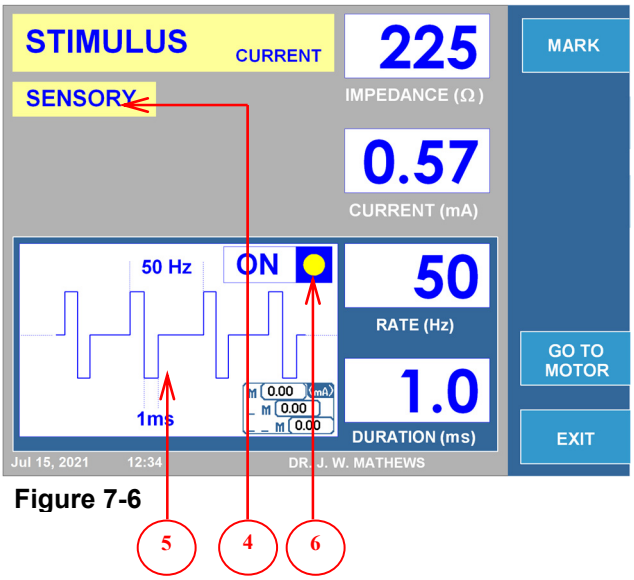


Figure 7-6

Setup Screen

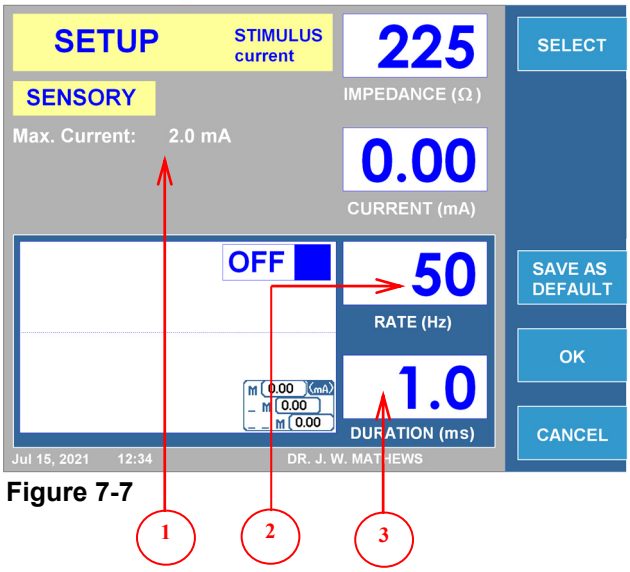


Figure 7-7

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Max Current			✓	0.2mA to 10mA	2mA
2	Rate (Hz)			✓	10Hz-200Hz	50Hz
3	Duration (ms)			✓	0.1ms-3.0ms	1.0ms
4	*Sensory/Motor menu	✓	✓		Sensory / Motor	Sensory
5	Waveform illustration	Simulated output waveform.				
6	ON/OFF indicator	Repeatedly alternating while stimulus output is activated				

Table 7-4

**Note: Output signal will be set to "0", if MOTOR/SENSORY key is used during treatment.*

Figure 7-8 and Figure 7-9 exemplifies Current Stimulus Motor Treatment and Setup screens. Table 7-5 outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Motor sub-mode

Treatment Screen

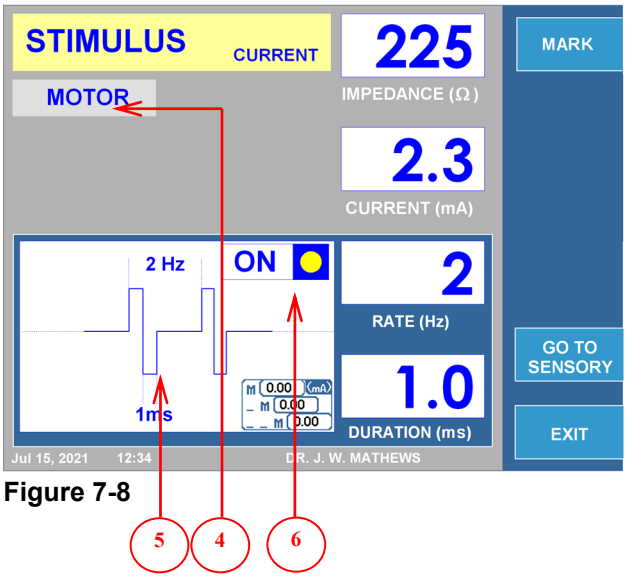


Figure 7-8

Setup Screen

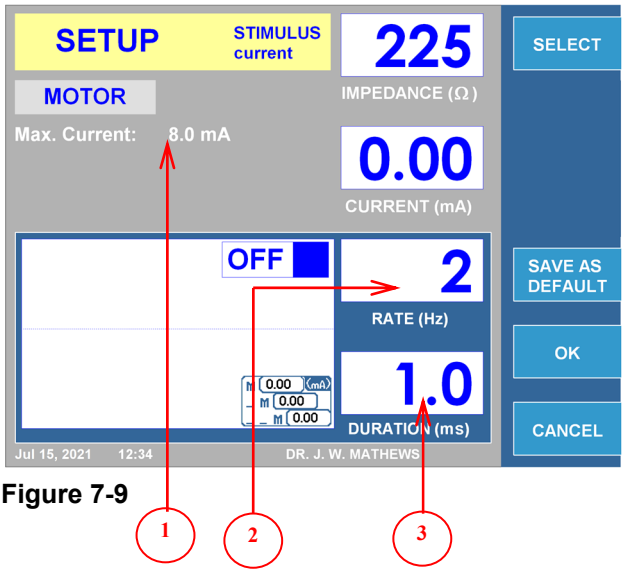


Figure 7-9

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Max Current			✓	0.2mA to 10mA	8mA
2	Rate (Hz)			✓	1 SHOT, 1Hz-10Hz	2Hz
3	Duration (ms)			✓	0.1ms-3.0ms	1.0ms
4	*Motor/Sensory menu	✓	✓		Motor/Sensory	Sensory
5	Waveform illustration	Simulated output waveform.				
6	ON/OFF indicator	Repeatedly alternating while stimulus output is activated				

Table 7-5

**Note: Output signal will be set to "0", if MOTOR/SENSORY key is used during treatment.*

7.3.1.4 INSTRUCTIONS FOR CURRENT STIMULUS USE

CURRENT STIMULUS OPERATION FLOW CHART

Step 1: Press the STIM button or alternatively navigate the Soft Keys on the side of LCD display to bring up the Current Stimulus Treatment screen.

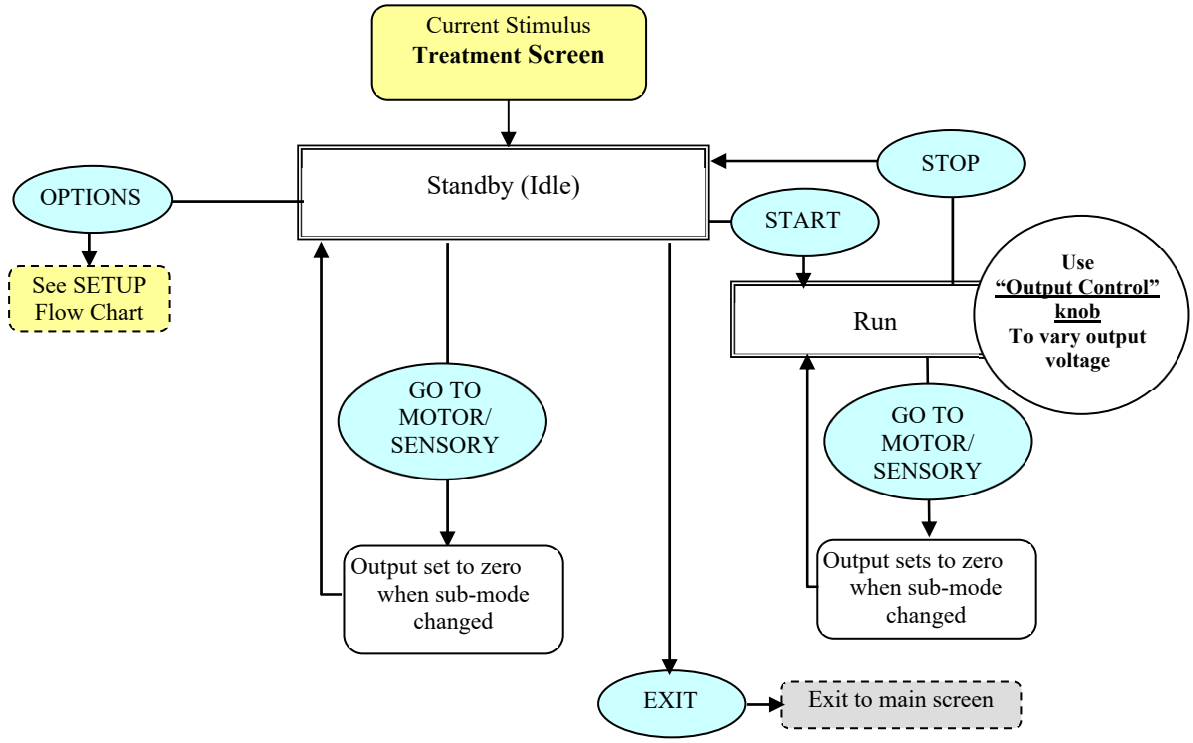
Step 2: Verify that the settings for treatment are correct.
Make all necessary changes, if needed, before starting treatment.

Step 3: Check patient connections and electrode placement. Press the START button to begin treatment.

Step 4: Use the OUTPUT CONTROL knob to vary signal strength.

Step 5: Press the STOP button to terminate treatment.
During treatment, the MOTOR/SENSORY key can be used to alternate between stimulus options.

The footswitch could be used instead of the START and STOP buttons.
To start, depress and hold footswitch, release footswitch to stop.



CURRENT STIMULUS SETUP FLOW CHART

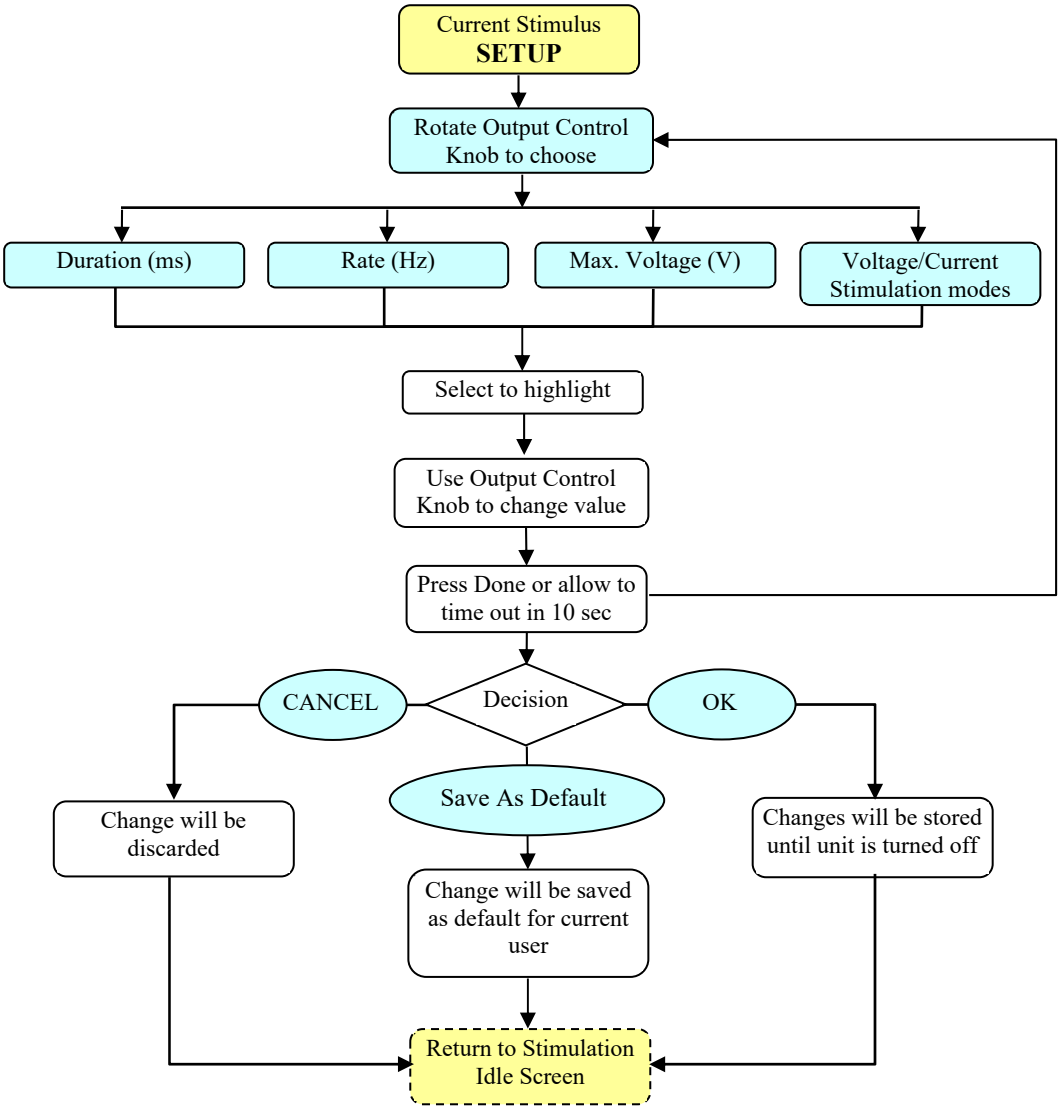
From the Current Stimulus Treatment screen press the OPTIONS key to initiate the mode setup menu.

Step 1: Use the OUTPUT CONTROL knob to outline the required parameter.

Step 2: Press the SELECT key to highlight the parameter, and then use OUTPUT CONTROL knob to change it to correct value. Repeat steps 1 and 2 for other parameters as needed.

Step 3: Choose either of the 3 options available:
OK key- keep changes until instrument is turned OFF
CANCEL key- discard all changes
SAVE AS DEFAULT key- save changes as default values for treatment

Note: All settings have an effect on current user and treatment only.



7.3.2 RF LESION MODES

7.3.2.1 CONTINUOUS RF MODE (MONOPOLAR)

The Automatic CONTINUOUS RF LESION procedure is controlled by software following the previously preset parameters.

The Manually controlled CONTINUOUS RF LESION is also available to the operator and requires controlling signal strength using the OUTPUT CONTROL knob.

Figure 7-10 and Figure 7-11 exemplify the Monopolar Continuous RF Lesion Treatment and Setup screens. Table 7-6 outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Treatment Screen

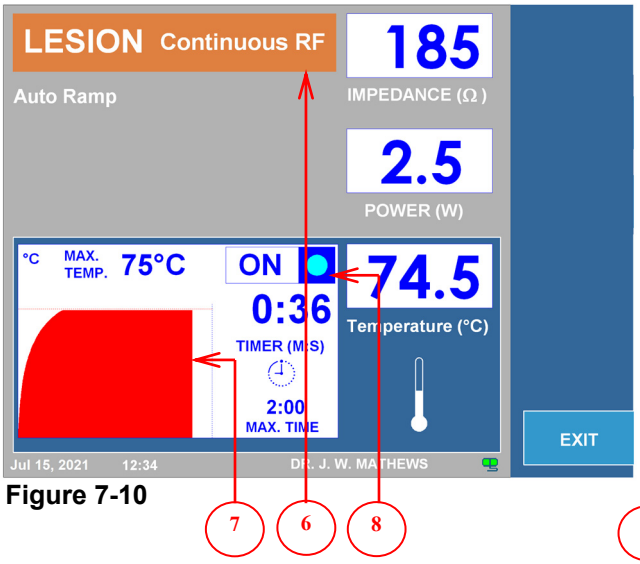


Figure 7-10

Setup Screen

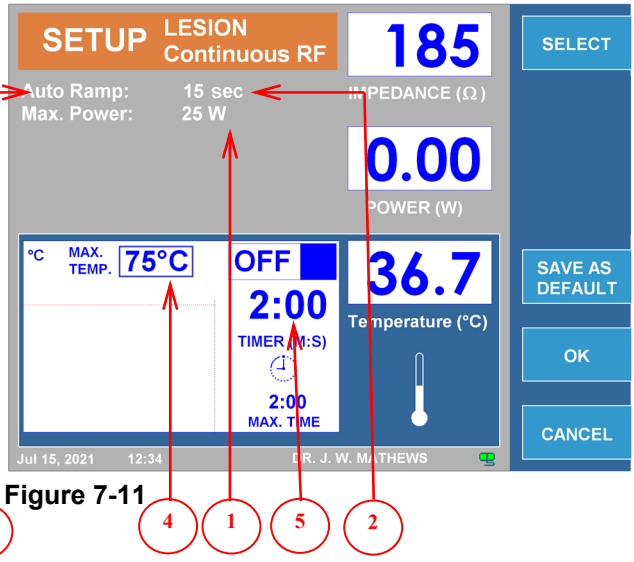


Figure 7-11

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Max. Power (W)			✓	1w to 50w	25W
2	Auto Ramp (s)			✓	10s to 30m	15s
3	Automatic/Manual menu			✓	Automatic/Manual	Auto.
4	Max. Temperature (°C)			✓	40°C to 95°C	75°C
5	Timer (M:S)			✓	30s to 30m	120s
6	Continuous/Pulsed menu		✓		Continuous/Pulsed	
7	Graph	Visual presentation of temperature change during procedure				
8	ON/OFF indicator	Blue indicator will stay on while RF output is active				

Table 7-6

7.3.2.2 CONTINUOUS RF MODE (BIPOLAR)

Bipolar intermediate cable will be required for correct operation in this mode.

The Automatic CONTINUOUS RF LESION procedure is controlled by software following previously preset parameters.

The Manually controlled CONTINUOUS RF LESION is also available to the operator through the OUTPUT CONTROL knob.

Figure 7-12 and Figure 7-13 exemplify Bipolar Continuous RF Lesion Treatment and Setup screens. Table 7-7, outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Treatment Screen

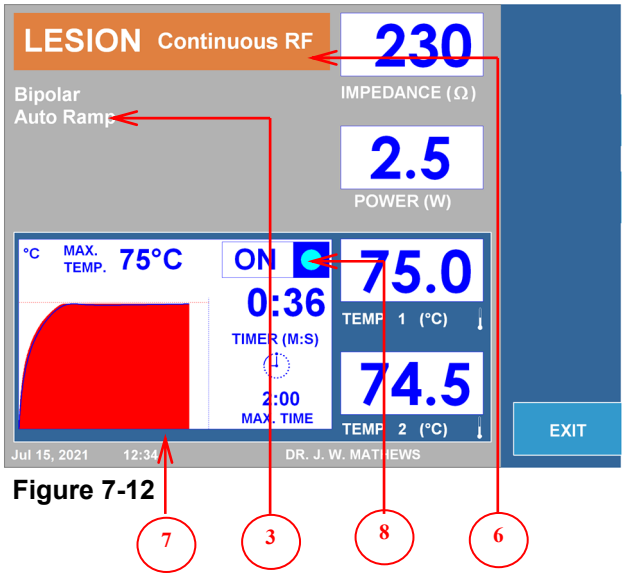


Figure 7-12

Setup Screen

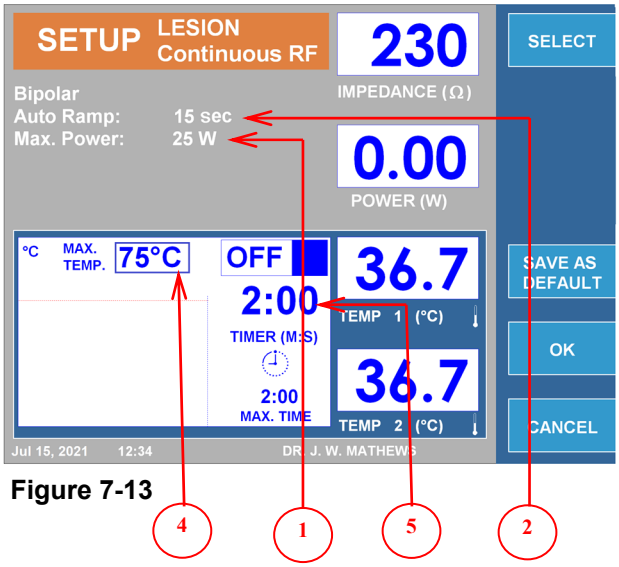


Figure 7-13

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Max. Power (W)			✓	1w to 50w	10W
2	Auto Ramp (s)			✓	10s to 30m	15s
3	Automatic/Manual menu			✓	Automatic/Manual	Auto.
4	Max. Temperature (°C)			✓	40°C to 95°C	75°C
5	Timer (M:S)			✓	30s to 30m	120s
6	Continuous/Pulsed menu		✓		Continuous/Pulsed	Continuous
7	Graph	Visual presentation of temperature change during procedure				
8	ON/OFF indicator	Blue indicator will stay on while RF output is active				

Table 7-7

7.3.2.3 INSTRUCTIONS FOR CONTINUOUS RF USE

CONTINUOUS RF LESION OPERATION FLOW CHART

Step 1: Press the LESION button or alternatively navigate the Soft Keys on the side of LCD display to bring up the Continuous RF Lesion Treatment screen.

Step 2: Verify that the settings for treatment are correct. Some treatment parameters are available only in the setup menu. Make all necessary changes, if needed, before starting the treatment.

Step 3: Check patient connections and electrode placement.

Press the START button to begin the treatment.

If automatic control was selected:

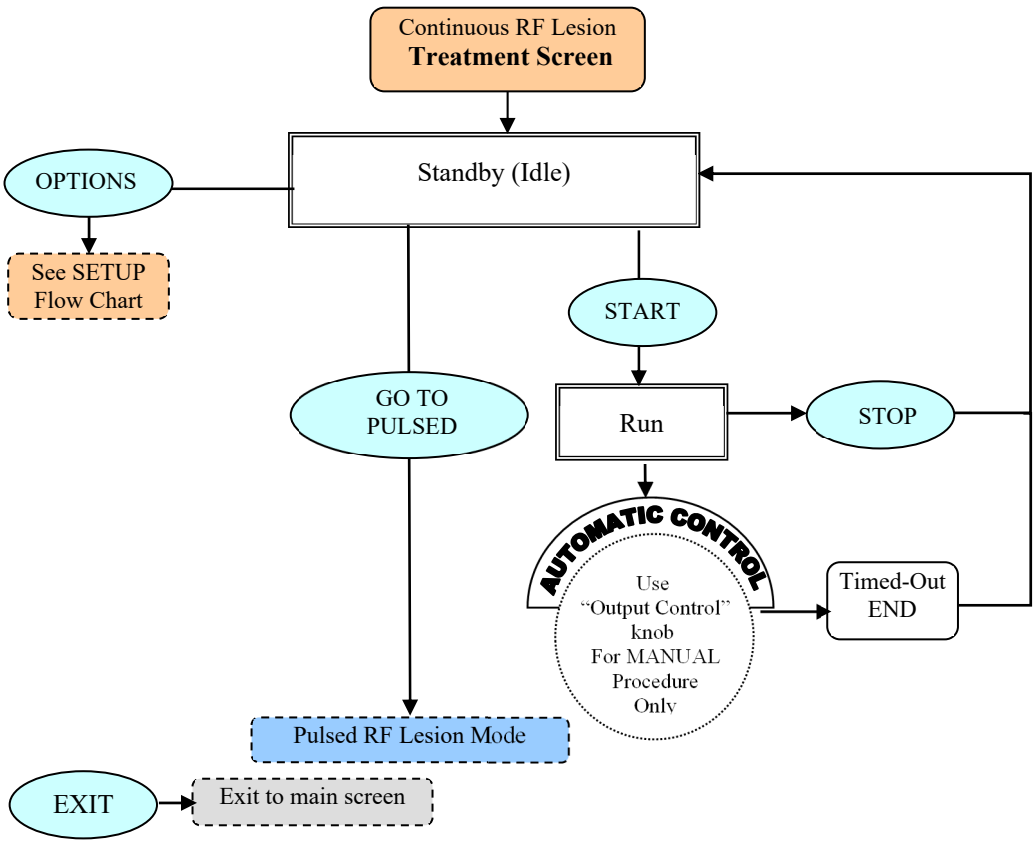
- The Generator will perform treatment using preset parameters.

If manual control was selected:

- Use the OUTPUT CONTROL knob to vary signal strength.

Allow timer to timeout to "0" or press the STOP button to terminate treatment.

The footswitch could be used instead of the START and STOP buttons.
To start, depress and hold footswitch, release footswitch to stop.



CONTINUOUS RF LESION SETUP FLOW CHART

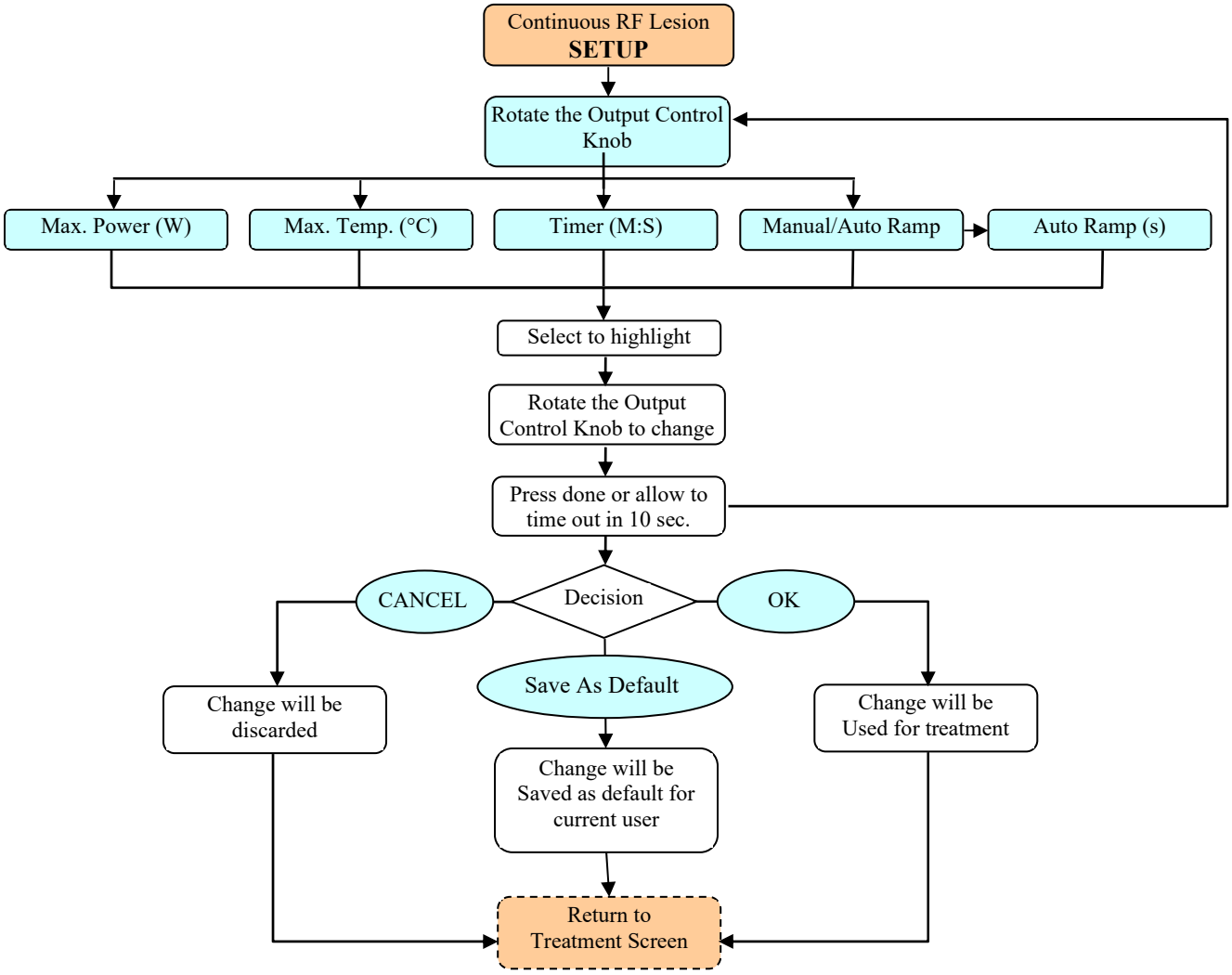
From the Continuous RF Lesion Treatment screen press the OPTIONS key to initiate the mode setup menu.

Step 1: Use OUTPUT CONTROL knob to outline the required parameter.

Step 2: Press the SELECT key to highlight the parameter, and then use OUTPUT CONTROL knob to change it to the correct value.
Repeat steps 1 and 2 for other parameters as needed.

Step 3: Choose either of the 3 options available:
OK key- keep changes until instrument is turned OFF
CANCEL key- discard all changes
SAVE AS DEFAULT key- save changes as default values for treatment

Note: All settings have an effect on current user and treatment only.



7.3.2.4 **Pulsed RF MODE (MONOPOLAR)**

The automatic PULSED RF LESION procedure is controlled by software following the previously preset parameters.

The manually controlled PULSED RF LESION is also available to the operator through the OUTPUT CONTROL knob.

Figure 7-14 and Figure 7-15 exemplify Monopolar Pulsed RF Lesion Treatment and Setup screens. Table 7-8 outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Treatment Screen

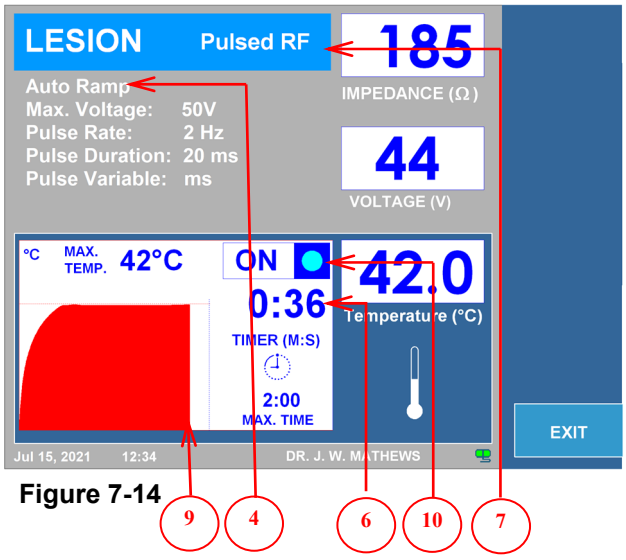


Figure 7-14

Setup Screen

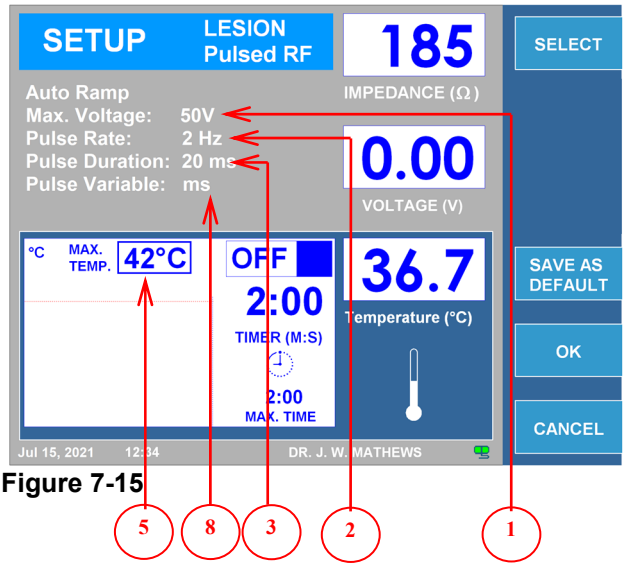


Figure 7-15

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Max. Voltage (V)			✓	5V to 100V	50V
2	Pulse Rate (Hz)			✓	1Hz to 20Hz	2Hz
3	Pulse Duration (ms)			✓	5ms to 50ms	20ms
4	Automatic/Manual menu			✓	Automatic/Manual	Auto.
5	Max. Temperature (°C)			✓	40°C to 95°C	42°C
6	Timer (M:S)			✓	30s to 30m	120s
7	Pulsed/Continuous menu		✓		Pulsed/Continuous	Continuous
8	Pulse Variable			✓	ms, V, Hz	ms
9	Graph	Visual presentation of temperature change during procedure				
10	ON/OFF indicator	Blue indicator will stay on while RF output is active				

Table 7-8

7.3.2.5 **Pulsed RF MODE (BIPOLAR)**

Bipolar intermediate cable will be required for correct operation in this mode.

The automatic PULSED RF LESION procedure is controlled by software following previously preset parameters.

The manually controlled PULSED RF LESION is also available to the operator through the OUTPUT CONTROL knob.

Figure 7-16 and Figure 7-17 exemplify Bipolar Pulsed RF Lesion Treatment and Setup screens. Table 7-9, outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Treatment Screen

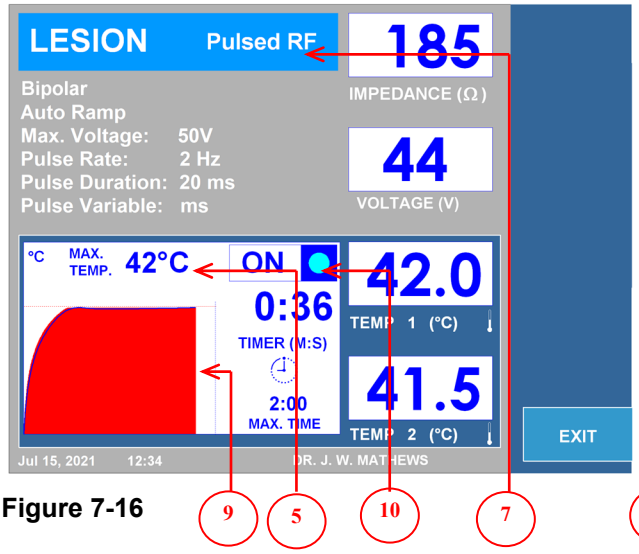


Figure 7-16

Setup Screen

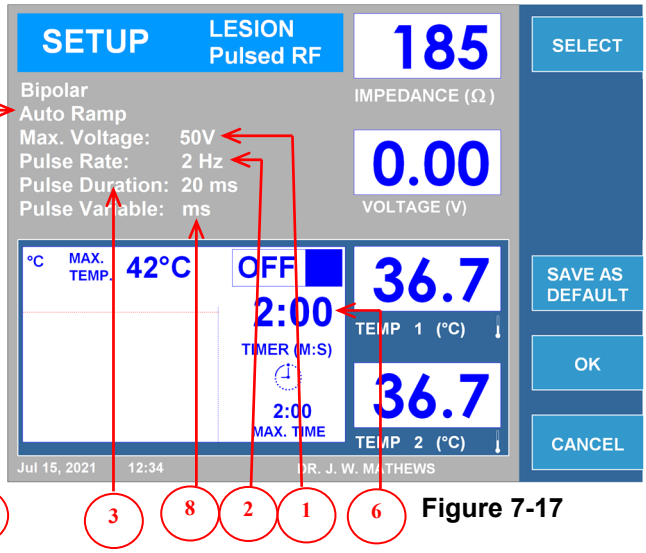


Figure 7-17

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Max. Voltage (V)			✓	5V to 100V	50V
2	Pulse Rate (Hz)			✓	1Hz to 20Hz	2Hz
3	Pulse Duration (ms)			✓	5ms to 50ms	20ms
4	Automatic/Manual menu			✓	Automatic/Manual	Auto.
5	Max. Temperature (°C)			✓	40°C to 95°C	42°C
6	Timer (M:S)			✓	30s to 30m	120s
7	Pulsed/Continuous menu		✓		Pulsed/Continuous	Continuous
8	Pulse Variable			✓	ms, V, Hz	ms
9	Graph	Visual presentation of temperature change during procedure				
10	ON/OFF indicator	Blue indicator will stay on while RF output is active				

Table 7-9

7.3.2.6 INSTRUCTIONS FOR PULSED RF USE

PULSED RF LESION OPERATION FLOW CHART

Step 1: Press the LESION button or alternatively navigate the Soft Keys on the side of LCD display to bring up the Pulsed RF Lesion Treatment screen.

Step 2: Verify that the settings for treatment are correct.

Step 3: Make all necessary changes, if needed, before starting the treatment. Check patient connections and electrode placement.

Step 4: Press the START button to begin the treatment.

If automatic control was selected:

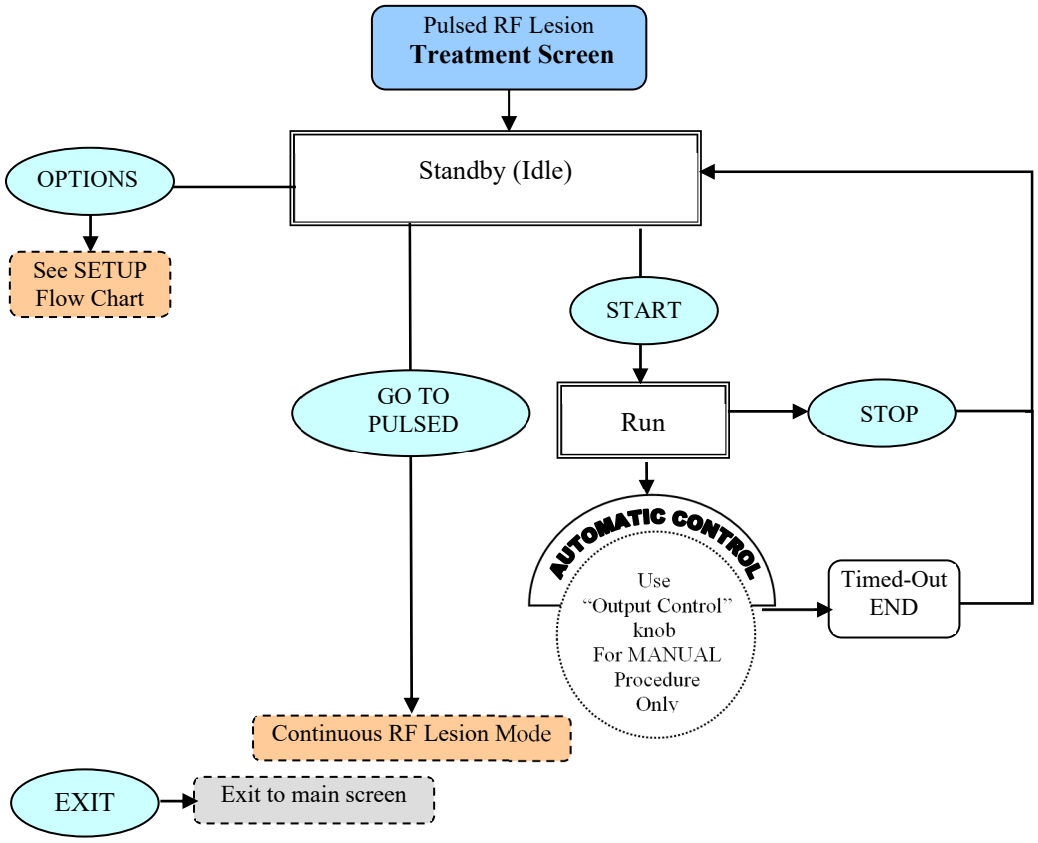
- The Generator will perform treatment using preset parameters.

If manual control was selected:

- Use the OUTPUT CONTROL knob to vary signal strength.

Allow timer to timeout to "0" or press the STOP button to terminate treatment.

The footswitch could be used instead of the START and STOP buttons.
To start, depress and hold footswitch, release footswitch to stop.



PULSED RF LESION SETUP FLOW CHART

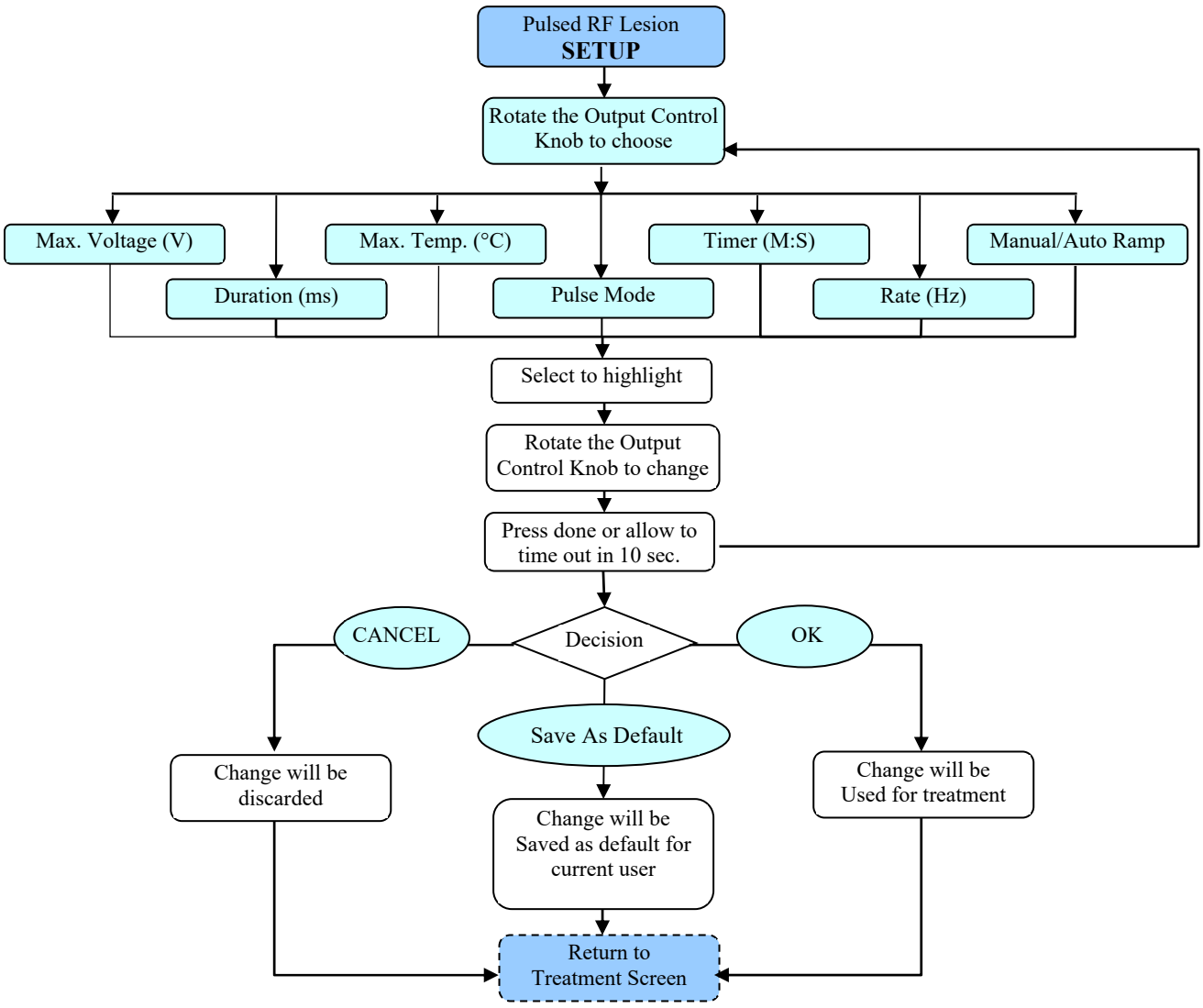
From the Pulsed RF Lesion Treatment screen press the OPTIONS key to initiate the mode setup menu.

Step 1: Use the OUTPUT CONTROL knob to outline the required parameter.

Step 2: Press the SELECT key to highlight the parameter, and then use the OUTPUT CONTROL knob to change it to the correct value.
Repeat steps 1 and 2 for other parameters as needed.

Step 3: Choose either of the 3 options available:
OK key- keep changes until instrument is turned OFF
CANCEL key- discard all changes
SAVE AS DEFAULT key- save changes as default values for treatment

Note: All settings have an effect on current user and treatment only.



7.3.3 DISCPLASTY TYPE 1 MODE (IDET™)

DiscPlasty Type 1 intermediate cable will be required for correct operation in this mode.

DiscPlasty Type 1 is an IDET™ Thermal Annuloplasty Therapy, controlled by software following previously preset parameters.

Figure 7-18 and Figure 7-19 exemplify DiscPlasty Type 1 Treatment and Setup screens. Table 7-10 outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Treatment Screen

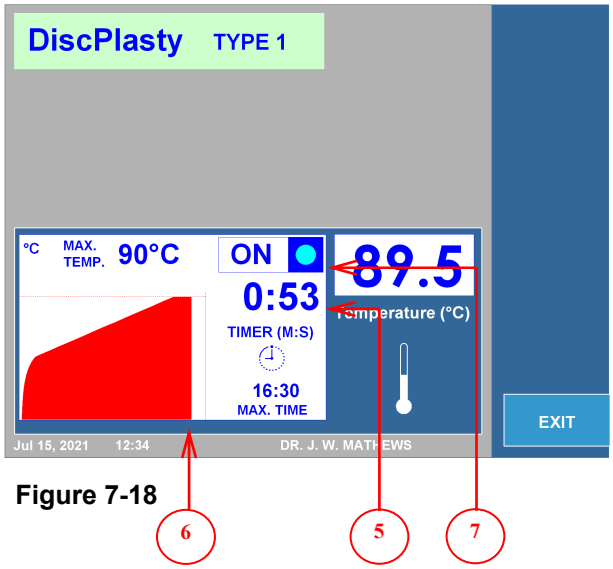


Figure 7-18

Setup Screen

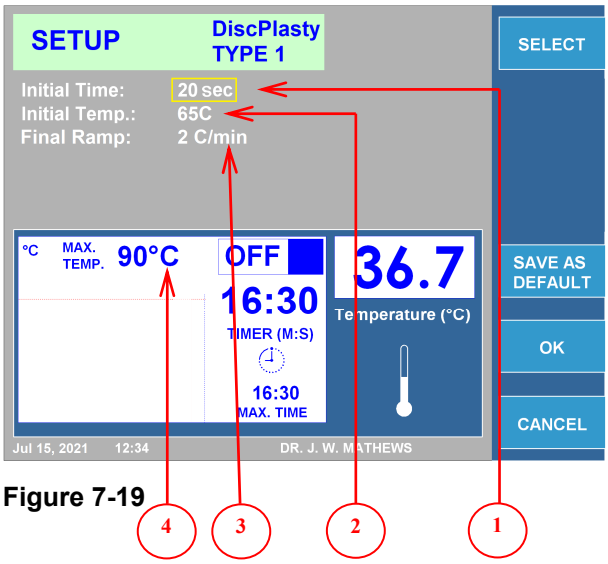


Figure 7-19

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Initial Time (s)			✓	15s-30s	20s
2	Initial Temperature (°C)			✓	40(°C)-80(°C)	65(°C)
3	Final Ramp (°C/min)			✓	0.5(°C/min) - 10(°C/min)	2(°C/min)
4	Max. Temperature (°C)			✓	40°C to 95°C	90°C
5	Timer (M:S)			✓	30s to 30m	16m:30s
6	Graph	Visual presentation of temperature change during procedure				
7	ON/OFF indicator	Blue indicator will stay on while RF output is active				

Table 7-10

7.3.3.1 INSTRUCTIONS FOR DISCPLASTY TYPE 1 USE

DISCPLASTY TYPE 1 OPERATION FLOW CHART

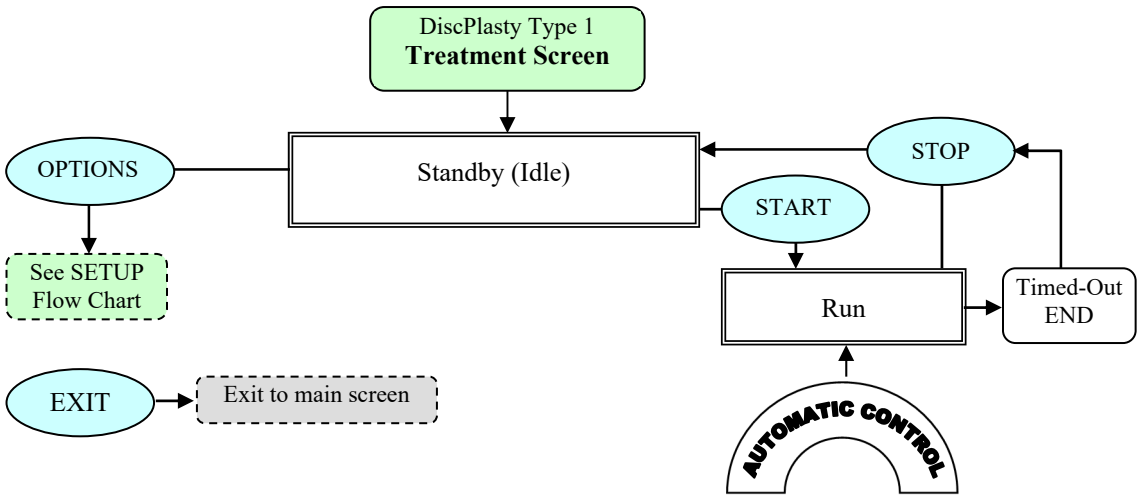
Step 1: Navigate the Soft Keys on the side of LCD display to bring up the DiscPlasty Type 1 Treatment screen.

Step 2: Verify that the settings for treatment are correct. All treatment parameters are available in the setup menu only.
Make all necessary changes, if needed, before starting the treatment.

Step 3: Check patient connections and electrode placement.

Step 4: Press the START button to begin treatment.
The Generator will perform treatment using preset parameters.
Allow timer to timeout to "0" or press the STOP button to terminate treatment.

The footswitch could be used instead of the START and STOP buttons.
To start, depress and hold footswitch, release footswitch to stop.



DISCPLASTY TYPE 1 SETUP FLOW CHART

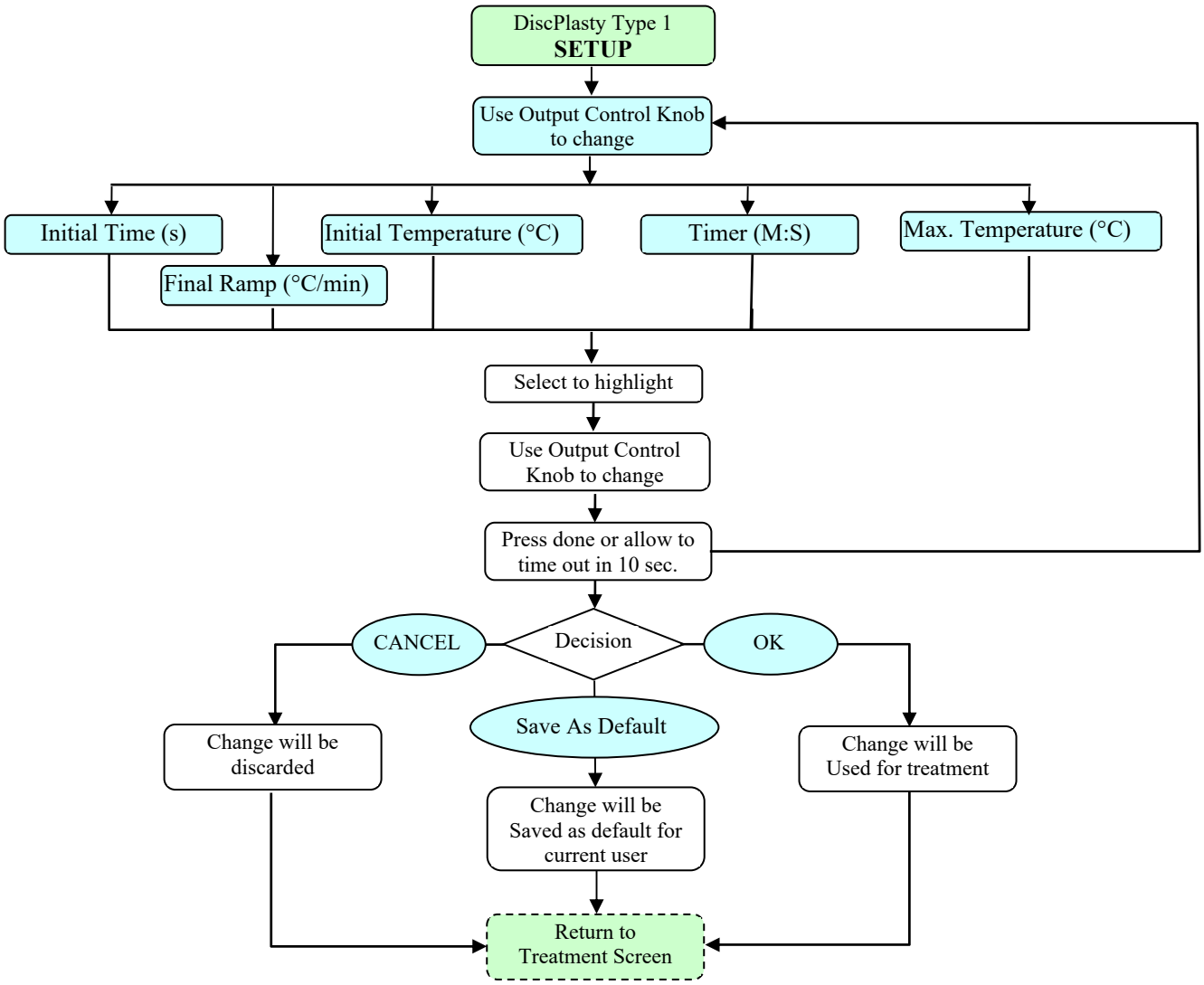
From the DiscPlasty Type 1 Treatment screen press the OPTIONS key to initiate the mode setup menu.

Step 1: Use the OUTPUT CONTROL knob to outline the required parameter.

Step 2: Press the SELECT key to highlight the parameter, and then use the OUTPUT CONTROL knob to change it to the correct value.
Repeat steps 1 and 2 for other parameters as needed.

Step 3: Choose either of the 3 options available:
OK key- keep changes until instrument is turned OFF
CANCEL key- discard all changes
SAVE AS DEFAULT key- save changes as default values for treatment

Note: All settings have an effect on current user and treatment only.



7.3.4 DISCPLASTY TYPE 2 MODE (DISCTRODE™)

DiscPlasty Type 2 intermediate cable will be required for correct operation in this mode.

DiscPlasty Type 2 is a DiscTRODE™ Thermal Annuloplasty procedure, controlled by software following previously preset parameters.

Figure 7-20 and Figure 7-21 exemplify DiscPlasty Type 2 Treatment and Setup screens. Table 7-11 outlines the adjustable parameters during Run, Idle, and Setup modes. Default values and modification ranges for parameters are shown.

Treatment Screen

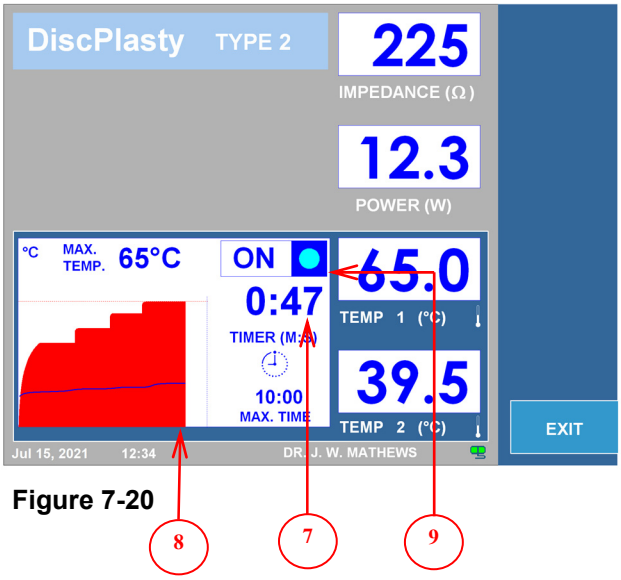


Figure 7-20

Setup Screen

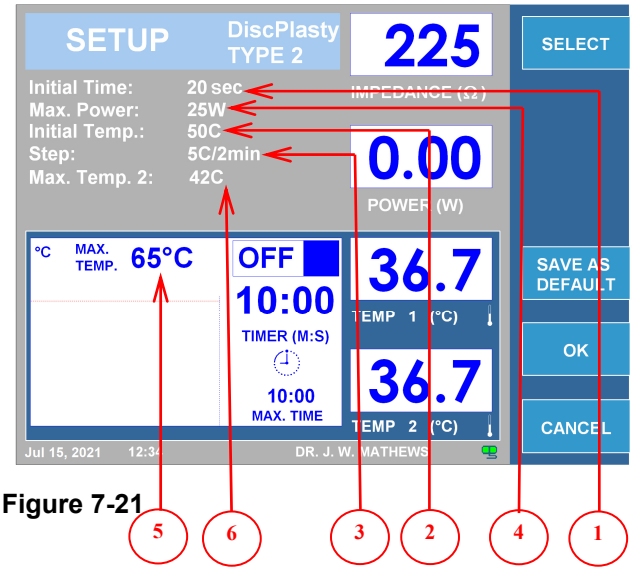


Figure 7-21

	Parameter	Adjustable During			Range	Default
		Run Mode	Idle	Setup		
1	Initial Time (s)			✓	15s-30s	20s
2	Initial Temperature (°C)			✓	40(°C)-80(°C)	50(°C)
3	Step (°C/2 min)			✓	1.0(°C/2min)-10(°C/2min)	5(°C/2min)
4	Max. Power (W)			✓	1W-50W	25W
5	Max. Temperature 1(°C)			✓	40°C to 95°C	65°C
6	Max. Temperature 2(°C)			✓	37°C to 45°C	42°C
7	Timer (M:S)			✓	30s to 30m	10:00m
8	Graph	Visual presentation of temperature change during procedure				
9	ON/OFF indicator	Blue indicator will stay on while RF output is active				

Table 7-11

7.3.4.1 INSTRUCTIONS FOR DISCPLASTY TYPE 2 USE

DISCPLASTY TYPE 2 OPERATION FLOW CHART

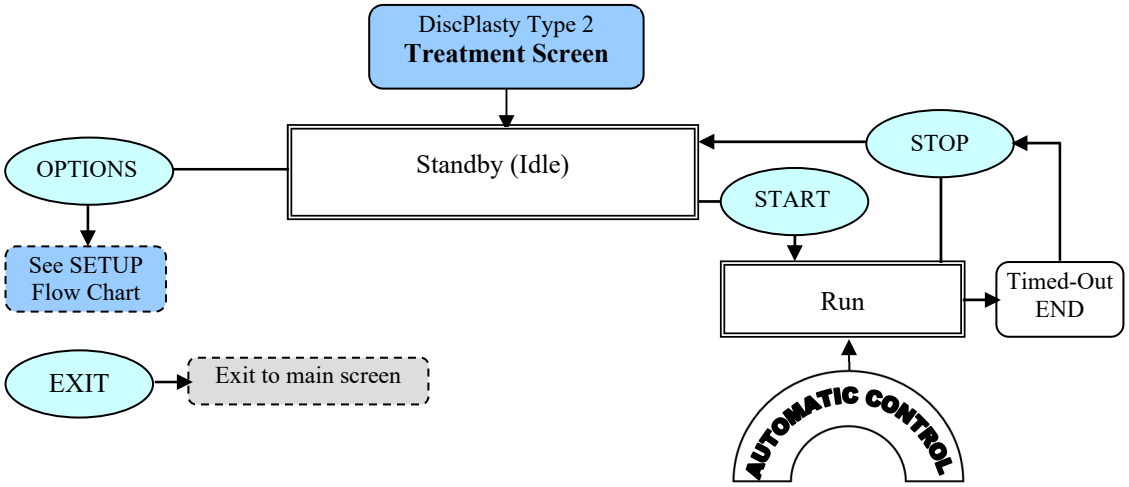
Step 1: Navigate the Soft Keys on the side of the LCD display to bring up the DiscPlasty Type 2 Treatment screen.

Step 2: Verify that the settings for treatment are correct. All treatment parameters are available in the setup menu only. Make all the necessary changes, if needed, before starting the treatment.

Step 3: Check patient connections and electrode placement.

Step 4: Press the START button to begin the treatment.
The Generator will perform the treatment using preset parameters.
Allow timer to timeout to "0" or press the STOP button to terminate the treatment.

The footswitch could be used instead of the START and STOP buttons.
To start, depress and hold footswitch, release footswitch to stop.



DISCPLASTY TYPE 2 SETUP FLOW CHART

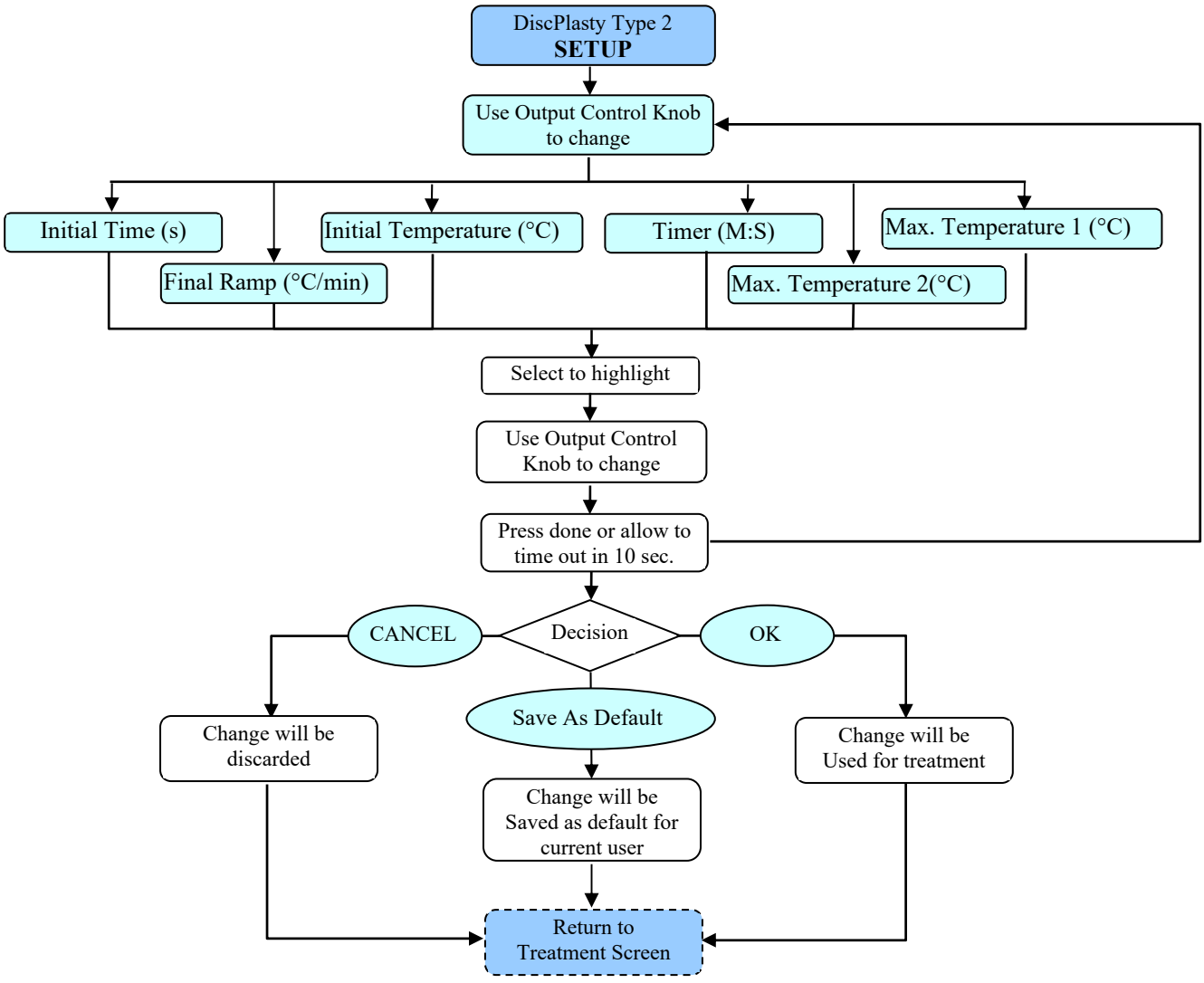
From the DiscPlasty Type 2 Treatment screen press the OPTIONS key to initiate the mode setup menu.

Step 1: Use the OUTPUT CONTROL knob to outline the required parameter.

Step 2: Press the SELECT key to highlight the parameter, and then use the OUTPUT CONTROL knob to change it to the correct value.
Repeat steps 1 and 2 for other parameters as needed.

Step 3: Choose either of the 3 options available:
OK key- keep changes until instrument is turned OFF
CANCEL key- discard all changes
SAVE AS DEFAULT key- save changes as default values for treatment

Note: All settings have an effect on current user and treatment only.



8 INSTRUCTIONS FOR USE WITH THE MULTI-LESION ADAPTOR

8.1 INTRODUCTION

This section of the Operator's Manual will provide working explanations for the OWL® R.F Generator, URF-3AP when operating with the Multi-Lesion Adaptor (MLA-4). Section 8 explains screens, specifications, functions, instructions, and details about the user interface when the MLA-4 is connected to the URF-3AP.

The Multi-Lesion Adaptor delivers a maximum total of 50W to up to 4 channels. The maximum power supplied will depend on total power required for all 4 channels combined. The MLA-4 Adaptor is alternating power between 4 channels quickly, so that each channel is delivered the required RF energy.

8.2 INSTALLATION & POWER-UP

If the URF-3AP is to be operated with the Multi-Lesion Adaptor, ensure the Adaptor is installed prior to powering on the system.

8.2.1 INSTALLING THE MULTI-LESION ADAPTOR

Prior to powering on the system, attach the Multi-Lesion Adaptor to the port labeled PROBE on the front panel of the generator.

8.2.2 MLA-4 LED STATES

Each channel on the MLA-4 has a LED indicator. The LED indicator will only be on, if that channel is delivering a stimulation or creating a lesion. The table below (Table 8-1) shows the different states for the channels depending on the colour of the LED.

STATE	LED
Not stimulating or lesioning	Off
Stimulation (Sensory and Motor)	Green
Continuous Lesion	Solid Blue
Pulsed Lesion	Flashing Blue

Table 8-1

8.2.3 POWERING THE SYSTEM

Ensure that the Multi-Lesion Adaptor is installed for Multi-Lesion operation. Plug the Generator into a grounded receptacle (extension cords and/or adapter plugs must not be used). Turn the power on using the POWER button located on the front panel.

After powering on the Generator, it will implement a Self-Test screen with an advancing time indicator that ensures proper operation of the URF-3AP. Following successful

completion of the self-testing screen, the user will be prompted with a Passed indication, and the Generator will automatically transition to the Main Menu Screen. The Generator remains in the Main Menu screen until a menu item is chosen.

8.2.4 PROPER PROBE SEPARATION FOR MULTIPLE LESIONING

The operator must ensure that there is adequate spacing between probes when performing multiple probe lesioning to prevent lesions from overlapping. A spacing of at least 2x the exposed probe tip is recommended. *(Appl. Neurophysiol. 1976-1977; 39(2):69-7)*

8.2.5 RETURN ELECTRODE CONNECTION

Connect the dispersive return electrode by inserting the plug into the rectangular receptacle on the front panel of the Generator marked REFERENCE.

8.2.6 FOOTSWITCH CONNECTION

Connect the pneumatic hose of the footswitch to the barb on the rear panel of the Generator. Slide the hose onto the barb to create a secure friction fit.

8.3 USING THE MAIN SCREEN

Figure 8-1, shows the main screen that is presented to the operator upon start up. The following sections describe the function of each of the four Soft Keys available to the user.

Figure 8-1

8.3.1 MULTI-STIMULUS SOFT KEY (1)

The MULTI-STIMULUS Soft Key initiates the stimulus part of the treatment which is described in section 8.4.

8.3.2 MULTI-LESION SOFT KEY (2)

The MULTI-LESION Soft Key initiates the lesion part of the treatment which is detailed in section 8.5.

8.3.3 SETUP SOFT KEY (3)

The SETUP Soft Key allows the operator to enter the setup screen and perform operations such as configuring the date and time of the device, the device operating language, and the audio level. A complete description of the setup screen is available in section 10.

8.3.4 UTILITIES SOFT KEY (4)

The UTILITIES Soft Key allows the operator to enter the utilities screen and perform operations such as storing patient history and testing probes. The utilities screen is described in section 11. Instructions for storing patient history and testing probes are available in 11.1 and 11.2 respectively.

8.4 MULTI-STIMULUS

The Multi-Stimulus mode provides the user with the ability to perform motor/sensory stimulation on 4 separate channels.

8.4.1 ACCESSING MULTI-STIMULUS SCREEN

To access this mode:

Step 1: Connect the MLA-4 into the URF-3AP and press the MULTI-STIMULUS soft key from the main menu or press the STIM button on the front panel. This will put the generator in Multi-Stimulus mode.

Step 2: To move between motor and sensory stimulation press the Go to Motor/Sensory soft key. To identify which stimulation mode the generator is in, refer to section 8.4.2

8.4.2 READING THE MULTI-STIMULUS SCREEN

The Multi-Stimulus screen displays a variety of information that helps the operator understand what state the generator is in. When there is no probe connected to a channel on the MLA-4, that channel will be greyed out. Once a probe is connected to a channel on the MLA-4, the display for that channel will become *alive* and turn white on the generator screen. The channel that is enlarged is the channel which will be stimulated once START is pressed. Figure 8-2 showcases the Multi-Stimulus screen when the user has started a Motor stimulation. As depicted in the figure below, all four probes are connected and channel 3 is being stimulated.

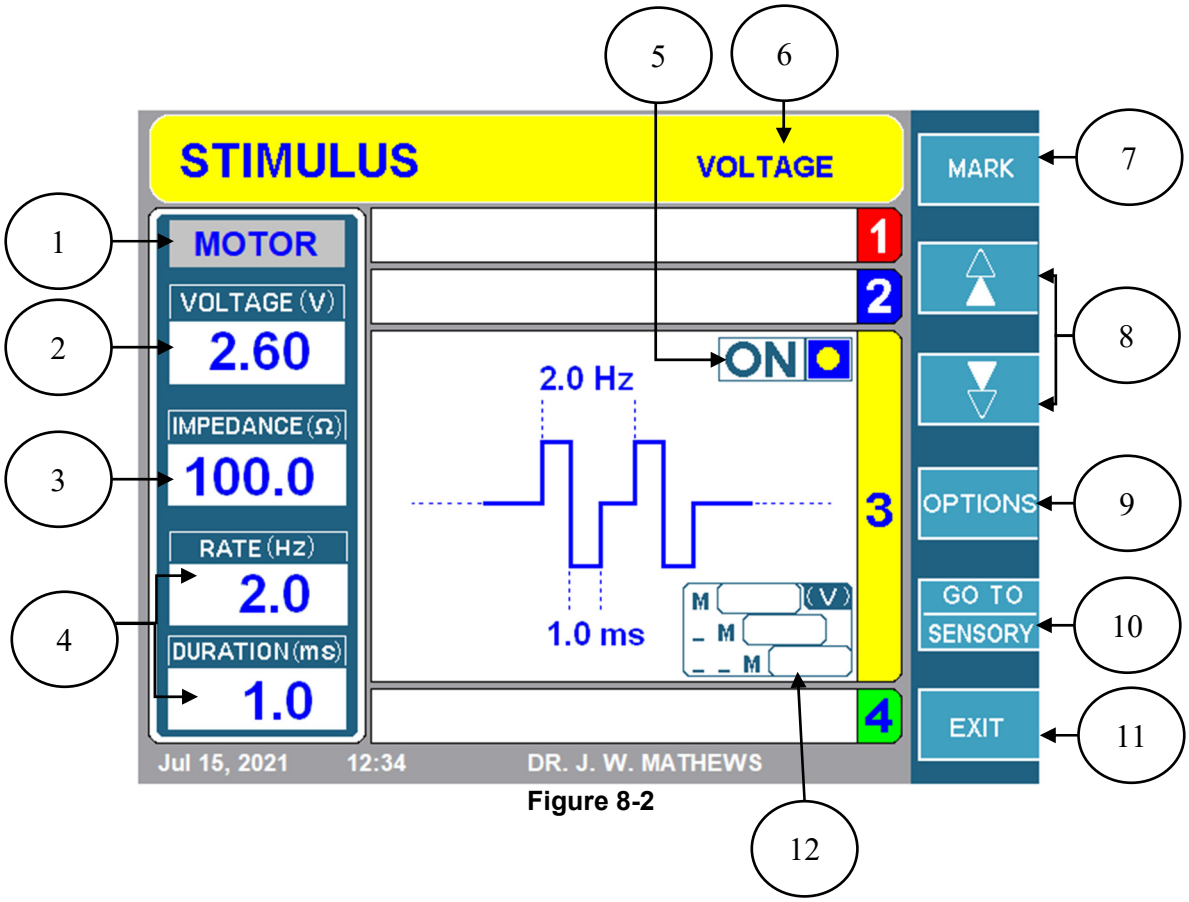


Figure 8-2

1. STIMULATION TYPE LABEL

This region of the screen indicates if the user is in Motor or Sensory Stimulation. This label will have a grey background for Motor Stimulation and yellow background for Sensory Stimulation.

2. STIMULUS AMPLITUDE DISPLAY

The actual voltage/current amplitude being delivered to the patient is displayed in this area.

3. IMPEDANCE DISPLAY

Displays the impedance of the channel into which a stimulus signal is being delivered.

4. STIMULUS PULSE DISPLAY

The repetition frequency and duration of the stimulus pulses is displayed in this area.

5. ON/OFF INDICATOR

This region of the screen indicates if the stimulation has started or not. If it has started, it will display ON with a flashing yellow circle. If it did not start, it will display OFF with no yellow circle.

6. VOLTAGE/CURRENT MODE

This region indicates if the generator is in constant voltage or current mode.

7. MARK SOFT KEY

This soft key allows the user to mark the amplitude of the signal. The last three marked amplitude values will be stored in the Mark Box (12).

8. CHANNEL SELECTION SOFT KEYS

These Soft Keys allow the operator to select the channel into which the URF-3AP will send a stimulus signal. Only one channel is active at a time and is indicated by the enlarged tab. Pressing the ▲ or ▼ Soft Keys will move the active channel to the next in sequence number in closed loop fashion one by one. Note that channels with no probes connected are greyed out and cannot be selected.

9. OPTIONS SOFT KEY

Pressing this button opens the Multi-Stimulus Setup Screen described in section 8.4.4. This screen allows configuration of all stimulus parameters and selection of the stimulus mode (voltage/current).

10. GO TO SENSORY/ GO TO MOTOR SOFT KEY

Pressing the GO TO SENSORY/MOTOR Soft Key, switches between sensory and motor stimulus modes. If the system is currently in Sensory Mode, this soft key will be labeled as GO TO MOTOR and vice versa.

11. EXIT SOFT KEY

Pressing the EXIT Soft Key opens the main menu as described in section 8.3.

12. MARKING STIMULUS EVENTS BOX

During stimulus, events can be marked and later retrieved. To mark a stimulus event, press the MARK Soft Key (7). The voltage or current, as well as the time of the marking are recorded. Up to three stimulus events per channel can be stored in memory locations named M, _ M, and _ _M. The M being the most recent event, and _ _M the oldest.

Note: Stimulation screens can be identified with a yellow banner.

8.4.3 MULTI-STIMULUS PARAMETERS

There are a variety of parameters that can be changed depending if the stimulation mode is set to sensory/current and if the stimulation type is motor/sensory.

Table 8-2 and Table 8-3 show the parameters and the values that can be changed for Voltage stimulus mode. Table 8-4 and Table 8-5 lists the parameters and the values that can be changed for Current stimulus mode.

Stimulus Mode: Voltage

Stimulation Type: Motor

Parameter	Range	Default
Max Voltage (V)	0.2-10	8.0
Pulse Rate (Hz)	1 shot, 1, 2, 5, 10	2
Pulse Duration (ms)	0.1, 0.2, 0.5, 1.0, 2.0, 3.0	1.0

Table 8-2

Stimulation Type: Sensory

Parameter	Range	Default
Max Voltage (V)	0.2-10	2.0
Pulse Rate (Hz)	10, 20, 50, 100, 200	50
Pulse Duration (ms)	0.1, 0.2, 0.5, 1.0, 2.0, 3.0	1.0

Table 8-3

Stimulus Mode: Current

Stimulation Type: Motor

Parameter	Range	Default
Max Current (mA)	0.2-10	8.0
Pulse Rate (Hz)	1 shot, 1, 2, 5, 10	2
Pulse Duration (ms)	0.1, 0.2, 0.5, 1.0, 2.0, 3.0	1.0

Table 8-4

Stimulation Type: Sensory

Parameter	Range	Default
Max Current (mA)	0.2-10	2.0
Pulse Rate (Hz)	10, 20, 50, 100, 200	50
Pulse Duration (ms)	0.1, 0.2, 0.5, 1.0, 2.0, 3.0	1.0

Table 8-5

8.4.4 CHANGING PARAMETERS IN MULTI-STIMULUS

Since Motor and Sensory Stimulations share the same setup menu, there is only one setup screen. To access the Multi-Stimulus setup screen, press the OPTIONS key while in the Multi-Stimulus mode.
From this screen all stimulus parameters can be modified. The tables in section 8.4.3 define each of the parameters that can be edited in the Multi-Stimulus Setup Screen (Figure 8-3). By changing the Stimulus Mode from current to voltage, the list of parameters that can be adjusted is also changed.
To change the parameters in Multi-Stimulus, follow the steps below:

Step 1: From the Main Menu, press the Multi-Stimulus soft key, or press the STIM button on the front panel.

Step 2: Press the OPTIONS soft key. This will display the Multi-Stimulus setup screen.

Step 3: Use the OUTPUT CONTROL knob and outline the parameter to edit, with the yellow box.

Step 4: Press the SELECT soft key. This will highlight the parameter and allow for editing.

Step 5: Use the OUTPUT CONTROL knob to change the value of the parameter and then press the DONE soft key. If there are more parameters to be edited, repeat steps 3-5.

Step 6: Once all parameters are edited press one of the three options:
i.) OK key- keep changes until instrument is turned OFF
ii.) CANCEL key- discard all changes
iii.)SAVE AS DEFAULT key- save changes as default values for treatment

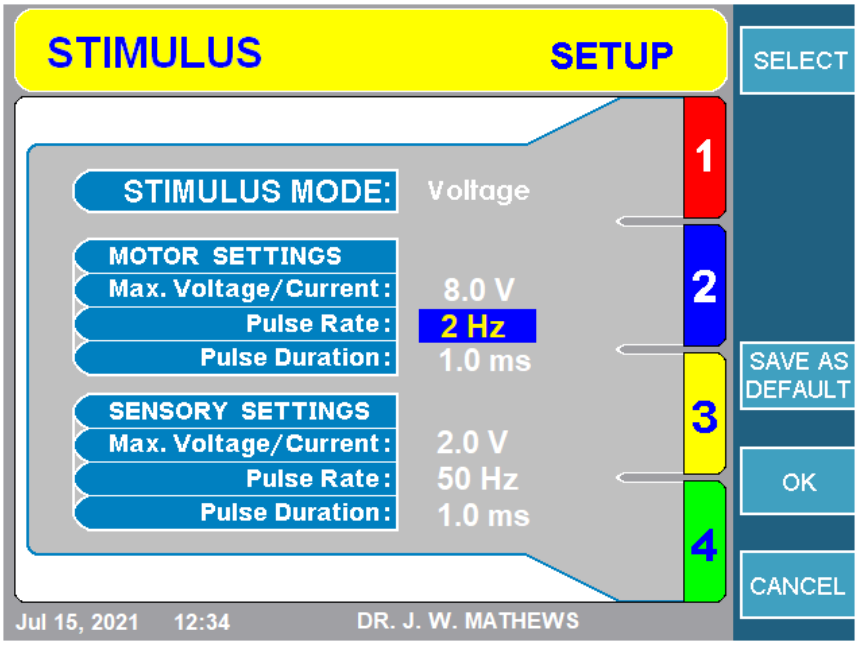


Figure 8-3

8.4.5 STARTING STIMULATION

1. SENSORY STIMULATION

Step 1: Go to Sensory Stimulation mode.

Step 2: Select the channel to stimulate by using the ▲/▼ soft keys. The channel which is enlarged is the channel that will be stimulated.

Step 3: Press the START button on the front panel to initiate the stimulation. Figure 8-4 illustrates a Sensory Stimulation being applied to the probe connected to channel 1.

Note: If an error message appears address that issue before pressing start again.

Step 4: Use the OUTPUT CONTROL knob to adjust the amplitude of the signal. On the screen the ON/OFF indicator will switch to ON and a flashing yellow circle will appear. Also, on the MLA-4, a green LED will illuminate beside the channel that is being stimulated.

Step 5: To stop the stimulation, press the STOP button on the front panel. This will set the amplitude of the signal back to zero.

Note: Changing the active stimulus channel or changing between sensory/motor stimulation returns the stimulus amplitude to zero.

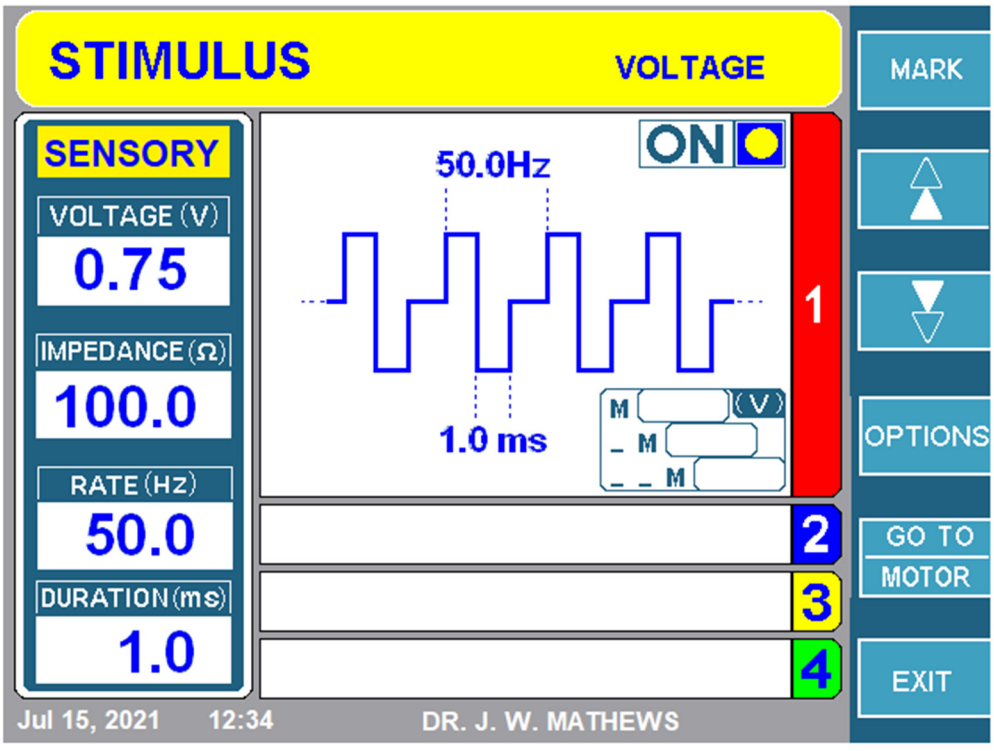


Figure 8-4

2. MOTOR STIMULATION

Step 1: Go to the Motor Stimulation screen.

Step 2: Select the channel to stimulate by using the ▲/▼ soft keys. The channel which is enlarged is the channel that will be stimulated.

Step 3: Press the START button on the front panel to initiate the stimulation. Figure 8-5 illustrates a Motor Stimulation being applied to the probe connected to channel 3.

Note: If an error message appears, address that issue before pressing start again.

Step 4: Then use the OUTPUT CONTROL knob to adjust the amplitude of the signal. On the screen the ON/OFF indicator will switch to ON and a flashing yellow circle will appear. Also, on the MLA-4, a green LED will illuminate beside the channel that is being stimulated.

Step 5: To stop the stimulation, press the STOP button on the front panel. This will set the amplitude of the signal back to zero.

Note: Changing the active stimulus channel or changing between sensory/motor stimulation returns the stimulus amplitude to zero.

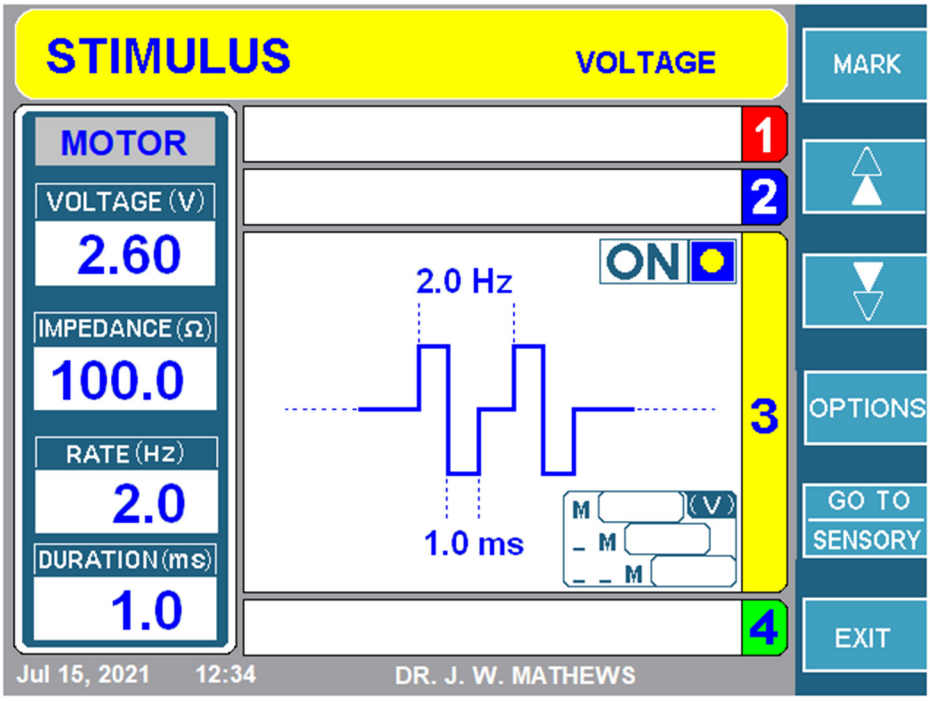


Figure 8-5

8.5 MULTI-LESION MODE

The URF-3AP + MLA-4 can perform 5 types of lesions in the continuous and pulsed variety. Each of these lesions can store its unique parameters which will be discussed in section 8.5.1. Sections 8.6-8.10 will go over how to access each mode, change its parameters and start the lesion.

8.5.1 LESION PARAMETERS

The URF-3AP allows the user to change/store parameters based on the type of lesion. This section explains the parameters that can be edited in the setup menu for each lesion type. Table 8-6 gives an overview of the various parameters that can be changed depending on whether it is a continuous or pulsed lesion.

Parameter	Available in Pulsed Mode	Available in Continuous Mode	Customizable Per Channel	Range	Default Value
Max Power W (per channel)	No	Yes	No	1W to 50W	50W
Ramp Type	Yes	Yes	No	Auto, Manual, Stagger	Auto
Ramp Time (only available in auto-ramp mode)	No	Yes	No	10s to a Max. Time	15s
Stagger Time (only available in staggered mode)	Yes	Yes	No	0s to 120s	0s
Maximum Time	Yes	Yes	No	30s to 30m	2:00 mins
Max Temperature for RF probes	Yes	Yes	Yes	40°C to 95°C	75°C
Max Temperature for Monitoring Channel	Yes	Yes	Yes	37°C to 45°C	42°C
Pulse Rate	Yes	No	No	1Hz to 20Hz	2 Hz
Pulse Duration	Yes	No	No	5ms to 50ms	20ms
Max Voltage	Yes	No	No	5V to 100V	50V
Pulse Variable	Yes	No	No	ms, V, Hz	ms

Table 8-6

1. MAX POWER

Max Power can only be set for Continuous type lesions. It has a range of 1W to 50W. By default, the max power is set to 50 W.

2. RAMP TYPES

There are three ramp types to choose from depending on the type of lesion selected. The ramp type indicates how each channel will reach the maximum temperature.

a) Auto Ramp Type

In Automatic Ramp Mode, the URF-3AP will automatically increase the temperature for each channel to the maximum temperature by the end of the ramp time. Figure 8-6 showcases the treatment screen for a Monopolar Continuous Lesion with an Automatic ramp type. As depicted in the figure below all channels start and reach a maximum temperature of 75˚C at the same time.

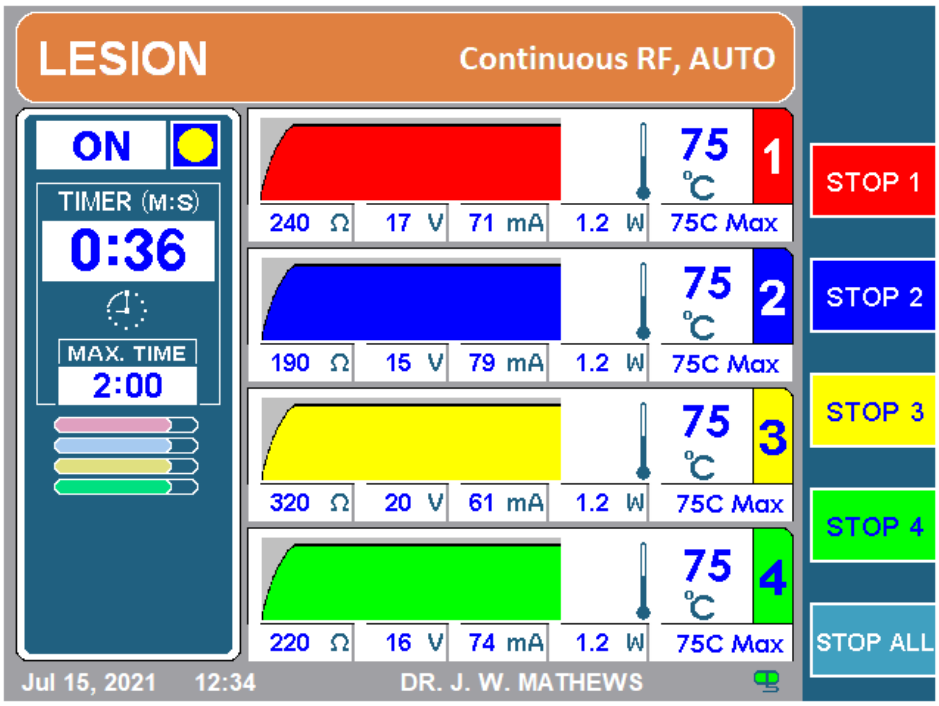


Figure 8-6

Note: For continuous lesions, the ramp time can be set between 10s to the Max Time. For pulsed lesions there is no defined ramp time.

b) Manual Ramp Type

In Manual Ramp Mode, the user controls the target temperature (indicated by the black arrow in Figure 8-7) by adjusting the OUTPUT CONTROL knob located on the front panel. The target temperature lets the generator know what temperature each of the channels should be at. If the target temperature is higher than the current temperature of each channel, the generator will output more power to reach the target temperature. Likewise, if the target temperature is lower than the current temperature, the generator will ease off the power and allow the temperature to drop towards the target temperature. This mode is beneficial if the operator requires more control in terms of how fast/slow they would like to reach the maximum temperature.

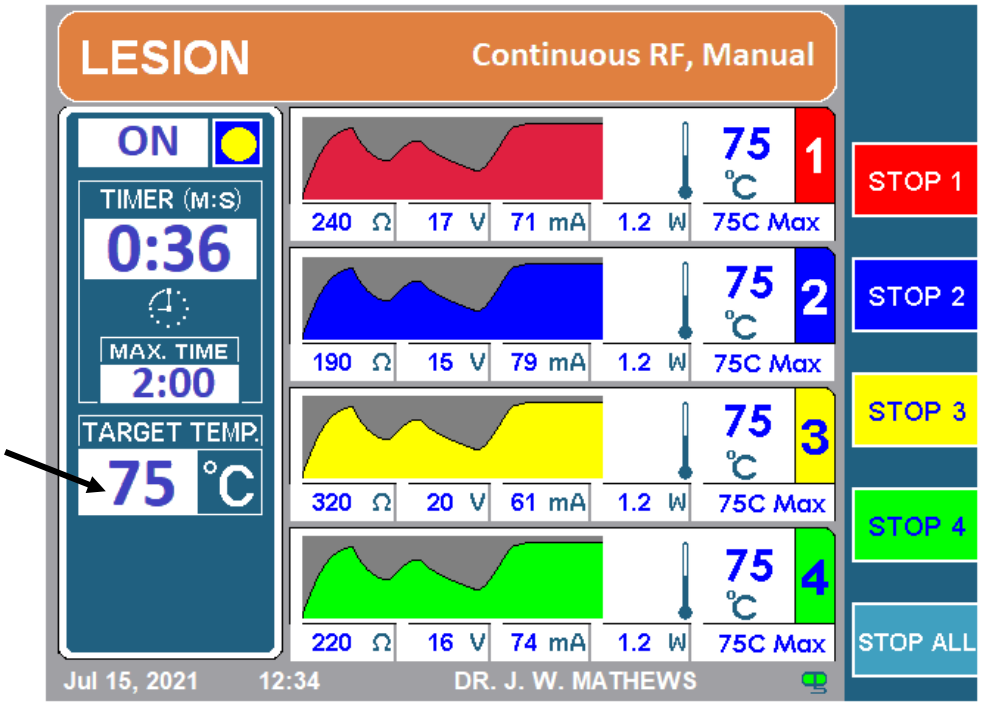


Figure 8-7

c) Staggered Ramp Type:

Staggered start is available whenever more than one simultaneous lesion is being generated. In this mode, the first lesion is started while the following lesions are delayed. The start of each sequential lesion is delayed by a time equal to a sum of "Ramp time + Stagger time". Each lesion temperature is increased until it reaches its pre-defined maximum temperature. Temperature is maintained at the target for a duration that is set as a maximum duration time. After the maximum duration time is elapsed, the first lesion is terminated and then the next in the order of lesions are terminated with predetermined "Ramp Time + Stagger Time" delays. Figure 8-8, illustrates a monopolar staggered lesion type.

Figure 8-9 shows how staggered lesion affects the total lesion time. The maximum time was set to 1:30 min (90s), ramp time 20s and stagger time of 10s. This means each channel will do a lesion for 90s in which the first 20s it will take to reach maximum temperature. Also, since it is staggered, each channel will not start at the same time,

instead the next channel will start after the ramp time and stagger time of the previous channel is completed.

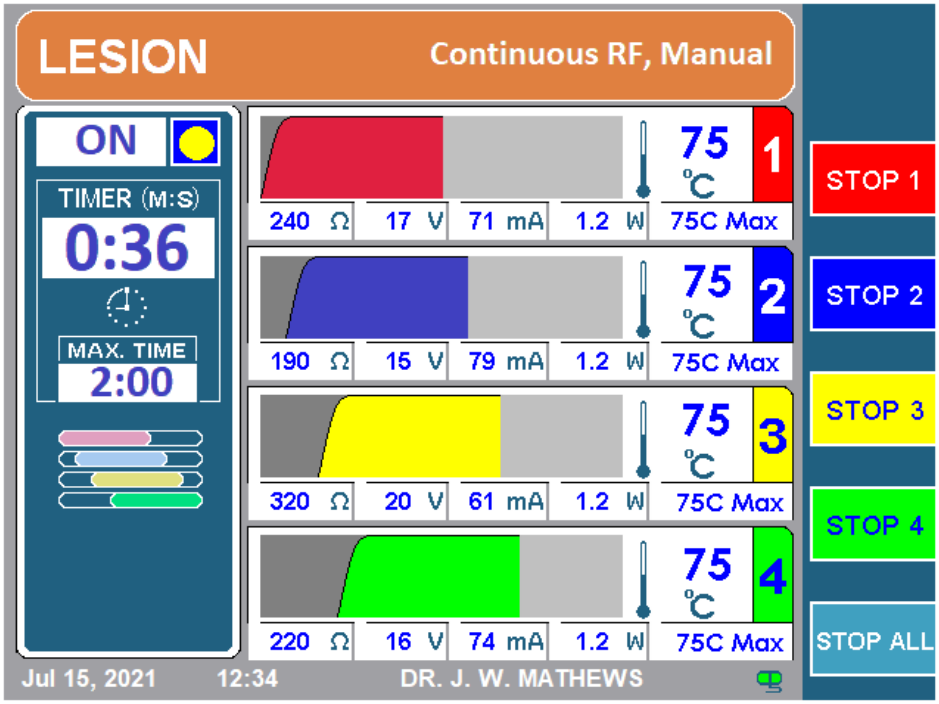


Figure 8-8

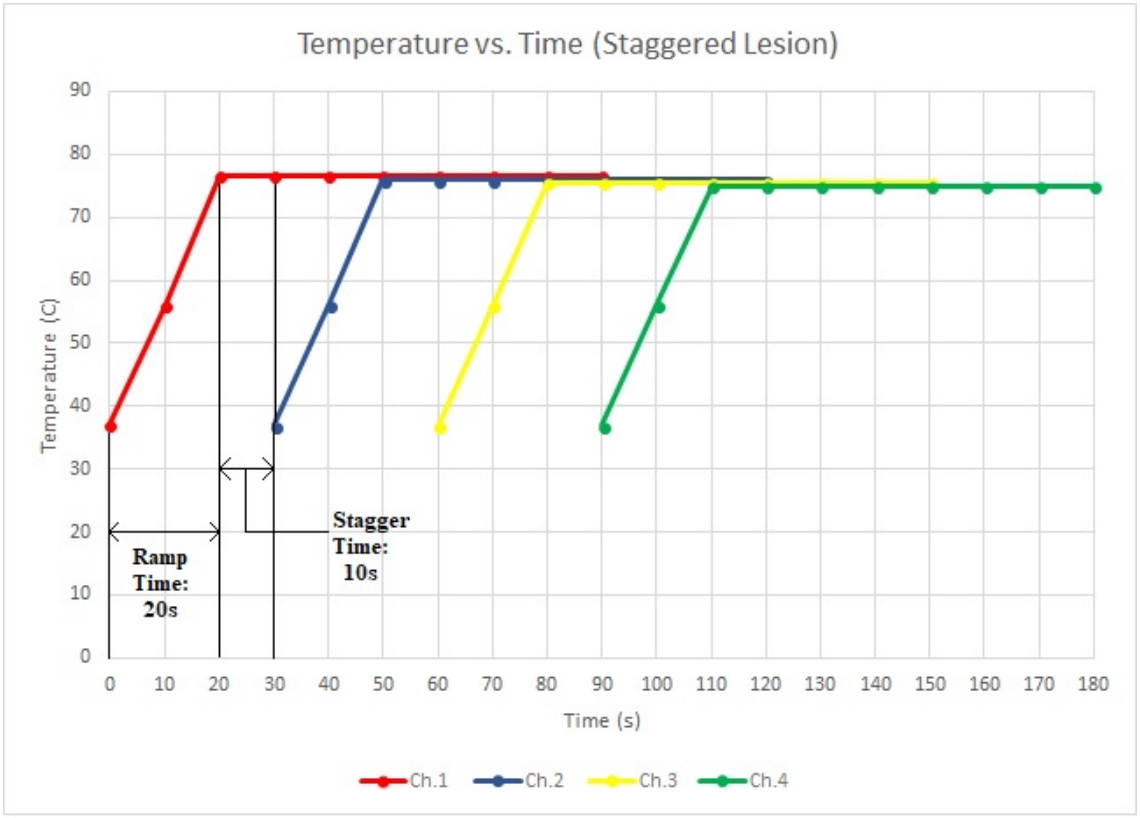


Figure 8-9

3. RAMP TIME

This is the amount of time that it takes the generator to ramp the channel to the maximum temperature. If the ramp time is 20s, it will take 20 seconds from when the lesion starts to reach maximum temperature. The ramp time can be set as low as 10s to as high as the maximum time. The default ramp time is 15 seconds.

4. STAGGER TIME

As described in the previous section, the stagger time is the amount of time between the previous channel reaching maximum temperature and the next channel starting. The stagger time can be set anywhere between 0 and 120s. The default stagger time is 0s. If the stagger time is set to 0s, the next channel will start once the previous channel has completed its ramp time. As depicted in Figure 8-9, the stagger time is set as 10s because channel 2 starts 10 seconds after channel 1 reaches max temperature.

5. MAXIMUM TIME

The maximum time is the amount of time each channel will do a lesion for. This timer can be set between 30s and 30 minutes. The default maximum time is 2:00 mins.

6. MAXIMUM TEMPERATURE

The maximum temperature for probes delivering RF can be set between 40 – 95˚C. The default maximum temperature for continuous lesion is 75˚C and pulsed lesions is 42˚C. The maximum temperature for the temperature monitoring probes can be set between 37-45˚C. The default maximum temperature for the monitoring probes is 42˚C.

7. PULSE RATE

The pulse rate dictates how fast the pulses are delivered during a pulsed lesion. This is only available in pulsed lesion type and can be set between 1Hz to 20Hz. The default pulse rate is 2 Hz.

8. PULSE DURATION

The pulse duration indicates the width of the pulse. Like pulse rate, this parameter is only available in pulsed lesion types and can be set between 5ms to 50ms. The default pulse duration is 20ms.

9. MAX VOLTAGE

The max voltage indicates the amplitude of the pulses delivered during pulsed lesions. The max voltage can be set between 5V to 100V. The default max voltage is 50V.

10. PULSE VARIABLE

The pulse variable indicates which pulse parameter will be adjusted during the pulsed procedure in the event the probe temperature nears the max temperature. The pulse variable can either be set to ms (pulse duration), V (pulse voltage) or Hz (pulse rate). The default pulse variable is ms.

8.5.2 LESION TYPES

The URF-3AP + MLA-4 has 5 lesion types to select from:

1. Monopolar Lesion
2. Temperature Monitoring Monopolar Lesion
3. Dual Bipolar Lesion
4. Quadrapolar™ Lesion
5. Temperature Monitoring Bipolar Lesion

Each of these lesion types have a continuous and pulsed variant. Section 8.5.3 will explain how to identify the differences on the screen.

To access Dual Bipolar Lesion, Quadrapolar™ Lesion and Temperature Monitoring Bipolar Lesion, the Bipolar option must be enabled in the setup menu (refer to section 11).

Table 8-7 outlines the different lesion mode icons that can be seen on the lesion screen depending on the lesion and ramp type.

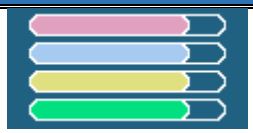
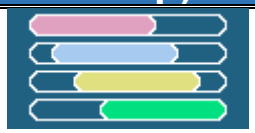
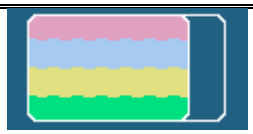
Lesion Type	Lesion Mode Icon (AUTO ramp)	Lesion Mode Icon (Stagger Ramp)
Monopolar Lesion		
Temperature Monitoring Monopolar Lesion		
Dual Bipolar Lesion		
Quadrapolar™ Lesion		**N/A**
Temperature Monitoring Bipolar Lesion		**N/A**

Table 8-7

Note: If the ramp type is manual, there will be a target temperature indicator that will replace the lesion mode icon on the screen.

Also, due to the nature of Quadrapolar™ and Temperature Monitoring Bipolar modes only one lesion is being formed therefore, there is no option to stagger.

Each lesion type has its own setup menu which will be discussed in sections 8.6-8.10. Table 8-8 outlines the setup icon that will be displayed depending on the Bipolar Type.

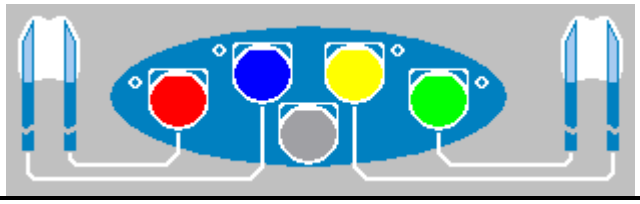
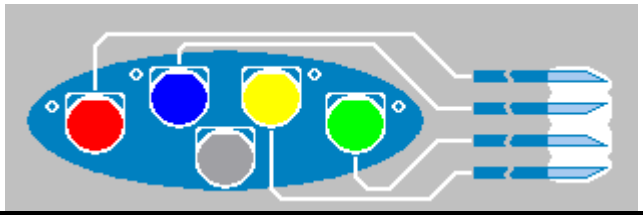
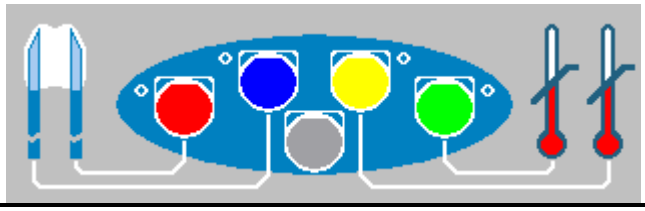
Bipolar Type	Setup Icon
Dual Bipolar	
Quadrapolar™	
Temperature Monitoring Bipolar	

Table 8-8

Note: Temperature Monitoring Bipolar setup icon will only be shown if the temperature monitoring probe is connected to ch3/ch4.

8.5.3 DIFFERENTIATING CONTINUOUS AND PULSED LESIONS

As mentioned in the previous section, each lesion type has a continuous and pulsed variant. For instance, there is Continuous Dual Bipolar and Pulsed Dual Bipolar, Continuous Monopolar and Pulsed Monopolar.

Table 8-9 outlines the differences that the operator will see on the screen depending if they are in Continuous or Pulsed lesion.
Figure 8-10 illustrates a Continuous Dual Bipolar Lesion and Figure 8-11 showcases a Pulsed Dual Bipolar Lesion.

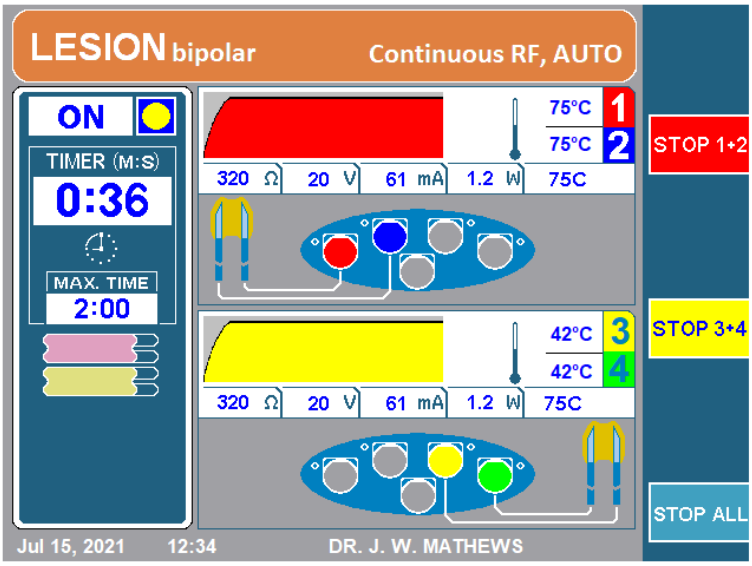


Figure 8-10

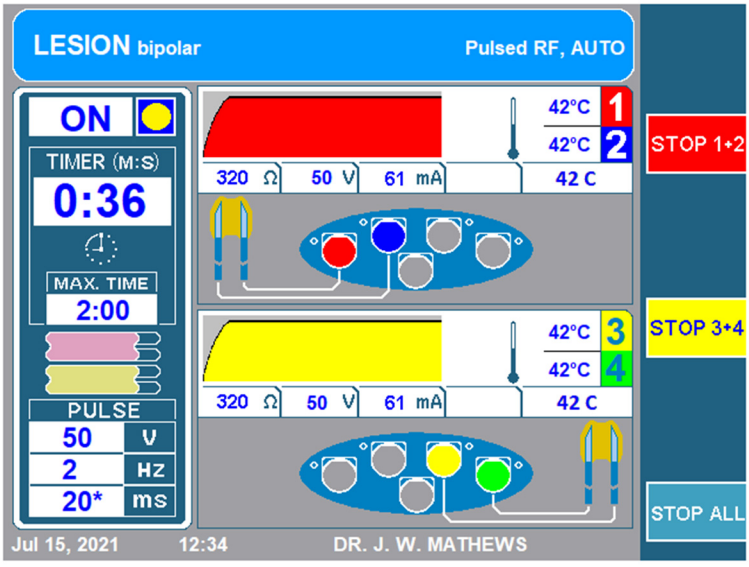


Figure 8-11

Feature	Continuous	Pulsed
Top Banner	LESION bipolar Continuous RF, AUTO *Colour*: Orange/Red *Label*: Continuous RF	LESION bipolar Pulsed RF, AUTO *Colour*: Blue *Label*: Pulsed RF
Pulse Box	N/A	Bottom left of lesion screen: PULSE V Hz ms
Soft Key	GO TO PULSED	GO TO CONTINUOUS
Audio Tone	Lower pitch	Higher Pitch
MLA-4 Channel LED	Solid blue light	Flashing blue light

Table 8-9

In addition to the above features, whenever the user switches between Continuous and Pulsed lesion, there is a notification message that pops up that lets the user know they are switching from one mode to another. The notification illustrated in Figure 8-12 appears when switching from pulsed to continuous and when switching from continuous to pulsed Figure 8-13 will appear. There is also a time delay, so the user can surely recognize the switch.

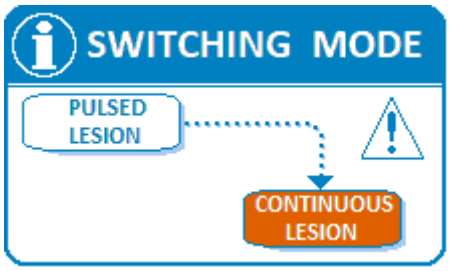


Figure 8-12

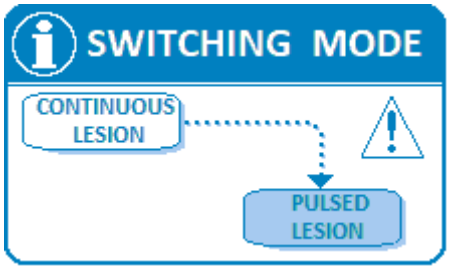


Figure 8-13

8.6 MONOPOLAR LESION

This mode creates a monopolar lesion around the active tip of the cannula. The MLA-4 allows the ability to create up to 4 independent monopolar lesions at the same time. This type of lesion requires a return path electrode to be connected as the current flows from the active tip to the return pad.

8.6.1 ACCESSING MONOPOLAR LESION

To access this mode:

Step 1: Connect the MLA-4 into the URF-3AP and press the MULTI-LESION soft key from the main menu or press the LESION button on the front panel.

Step 2: Identify the generator is in the correct mode.

To do this, check:

- Top banner:
  - LESION bipolar → The generator is in Bipolar mode, press the top soft key that displays, GO TO MONOPOLAR. This will take the generator to Monopolar mode.
  - LESION → The generator is in Monopolar mode, now check the Lesion Mode Icon.

- Lesion Mode Icon: Refer to Table 8-7
  - Monopolar Lesion Icon → Continue to step 3.
  - Temperature Monitoring Monopolar Icon → Remove the temperature monitoring probes from the MLA-4 and move onto step 3.

Step 3: Check whether the generator is in continuous or pulsed mode by reading the top banner. To switch between the two, press the GO TO CONTINUOUS/PULSED soft key.

8.6.2 READING MONOPOLAR LESION SCREEN

Depending if the Generator is in Continuous/Pulsed Lesion or if it is in Automatic or Manual ramp type the screen will be slightly different.

Figure 8-14 displays a Continuous Monopolar lesion with Automatic ramp type and Figure 8-15 displays a Pulsed Monopolar lesion with Manual ramp type.

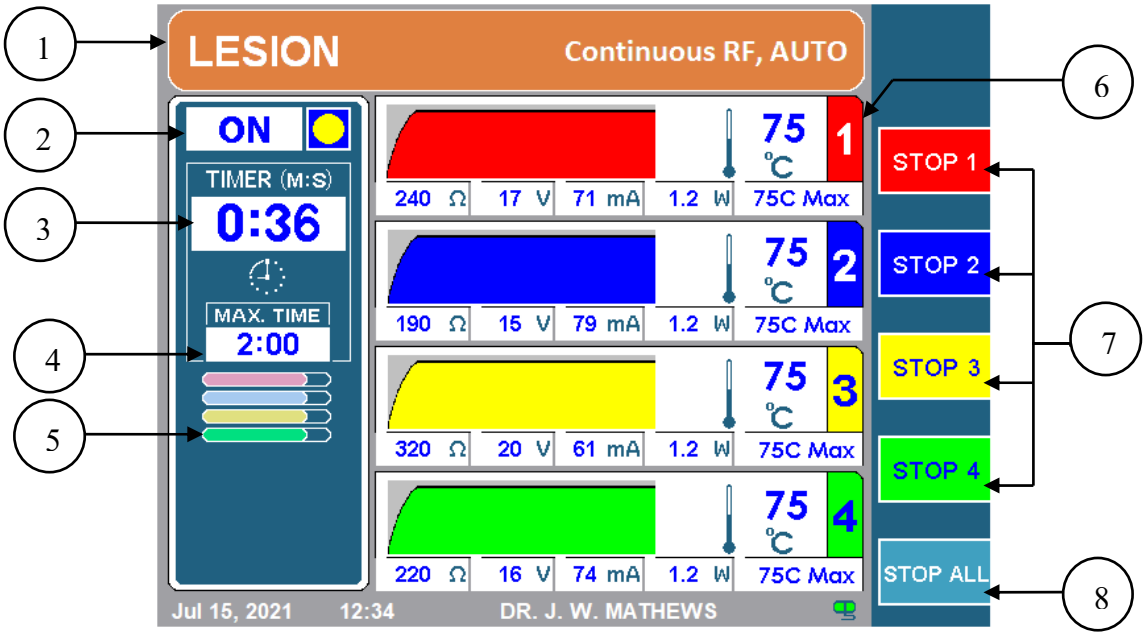


Figure 8-14

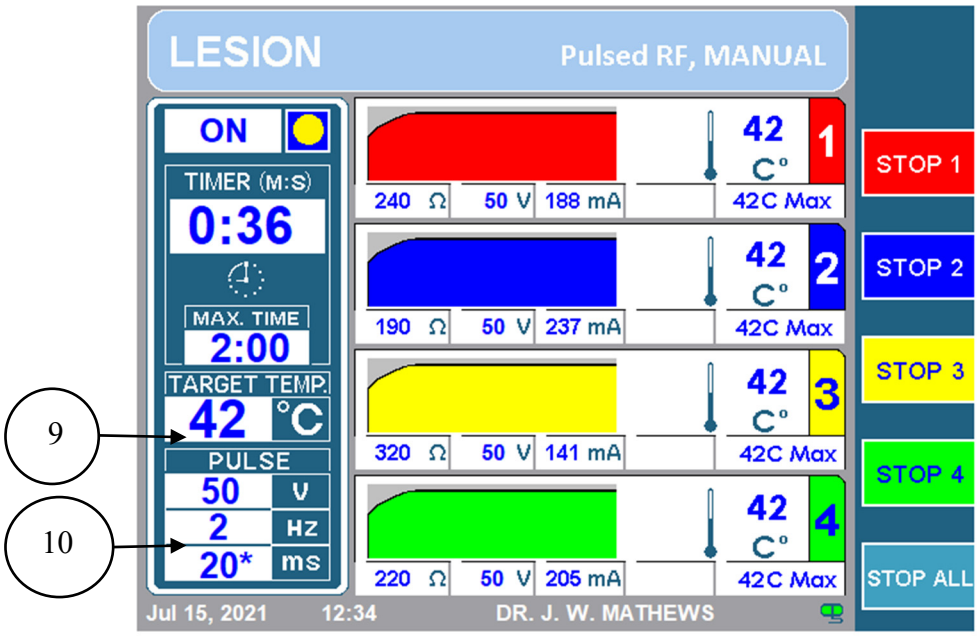


Figure 8-15

1. TOP BANNER

The Top Banner lets the operator know what type of lesion is being performed. The colour will either be orange for continuous lesion or blue for pulsed lesion. It will also explicitly display Continuous RF or Pulsed RF accordingly. Additionally, it will also mention the ramp type. It will display AUTO for automatic and staggered ramp types, or Manual for manual ramp type. Also, for monopolar lesions it will read LESION and for bipolar lesions it will display LESION bipolar.

2. ON/OFF INDICATOR

The on/off indicator lets the operator know if a lesion has started or not. While the lesion is off, the indicator will display OFF and there will be no yellow circle. If the lesion is on, it will display ON with a yellow circle.

3. TIMER

The timer lets the user know the total time it will take for all channels to finish.

4. MAX TIME

This timer lets the user know the total time each channel will do a lesion.

5. LESION MODE ICON

The lesion mode icon will indicate the type of lesion as well as the ramp type, refer to Table 8-7 to correspond the lesion type with its icon. If the ramp type is set as Manual, the lesion mode icon will be replaced with the Target Temperature Indicator (9).

6. CHANNEL DISPLAY

Each channel displays its current status and configuration throughout the lesioning process. The following figure (Figure 8-16) shows the channel status display for channel one. The features of this status display are described in Table 8-10.

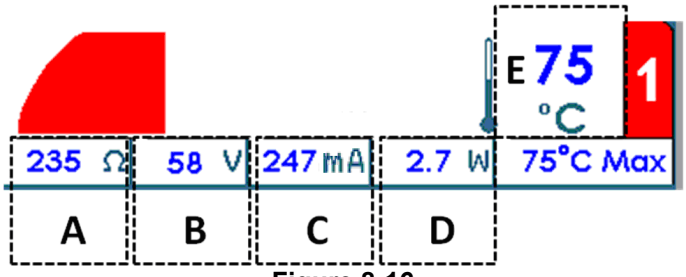


Figure 8-16

Label	Description
A	**Ω,** the impedance between probe attached to the channel and the return electrode
B	**V,** the RMS voltage being delivered through the probe attached to the channel in continuous mode. In pulsed lesion mode, the peak voltage is displayed
C	**mA,** the RMS current being delivered through the probe attached to the channel in continuous mode. In pulsed lesion mode, the peak current is displayed.
D	**W,** the average AC power being delivered through the probe attached to the channel. Note that average power is not displayed in pulsed lesion mode.
E	**°C,** Current Probe temperature. In the figure above, the current probe temperature is 75°C. Beside the current probe temperature is a graph that plots the temperature history. The graph has a darker background shading while RF energy is being delivered to the patient and a lighter background shading when it is not.

Table 8-10

7. STOP CHANNELS 1, 2, 3 AND 4

These soft keys allow the operator to stop individual channels during a lesion.

8. STOP ALL

The STOP ALL soft key stops all lesions and returns the Generator back to the idle screen.

9. TARGET TEMPERATURE INDICATOR

The target temperature lets the generator know what temperature all the connected channels should be at. The target temperature can be adjusted by rotating the OUTPUT CONTROL knob after pressing start. The target temperature indicator will replace the Lesion Mode Icon (5) if the ramp type is set as Manual.

10. PULSE BOX

The pulse box will only be displayed for pulsed lesions. This box showcases what the set max voltage, pulse rate, and pulse duration are for this pulsed lesion. The asterisk indicates the pulse variable.

8.6.3 CHANGING PARAMETERS IN MONOPOLAR LESION

To change parameters for a monopolar lesion, follow the steps below:

Step 1: Go to Monopolar Lesion Mode

Step 2: Press the OPTIONS key.

Note: If the generator is Continuous Monopolar it will go to the setup menu for Continuous Monopolar as shown in Figure 8-17. Likewise, if the generator is in Pulsed Monopolar it will go the setup menu for Pulsed Monopolar, as illustrated in Figure 8-18.

Step 3: To change a parameter, rotate the OUTPUT CONTROL knob to move the yellow box to the parameter that needs to be changed.

Step 4: Once the desired parameter is outlined, press the SELECT key. This will highlight the outlined parameter and allow for editing.

Step 5: Rotate the OUTPUT CONTROL knob to change the value of the parameters.

Step 6: Press the DONE soft key and repeat steps 3-6 for other parameters.

Step 7: Then press one of the following three options:

i) OK – This will store these parameters for this lesion type until the generator is powered off.
ii) SAVE AS DEFAULT – This will store these parameters for this lesion type even after the generator is rebooted.
iii) CANCEL – This will not store any of the changed parameters and will return to the previously saved parameters.

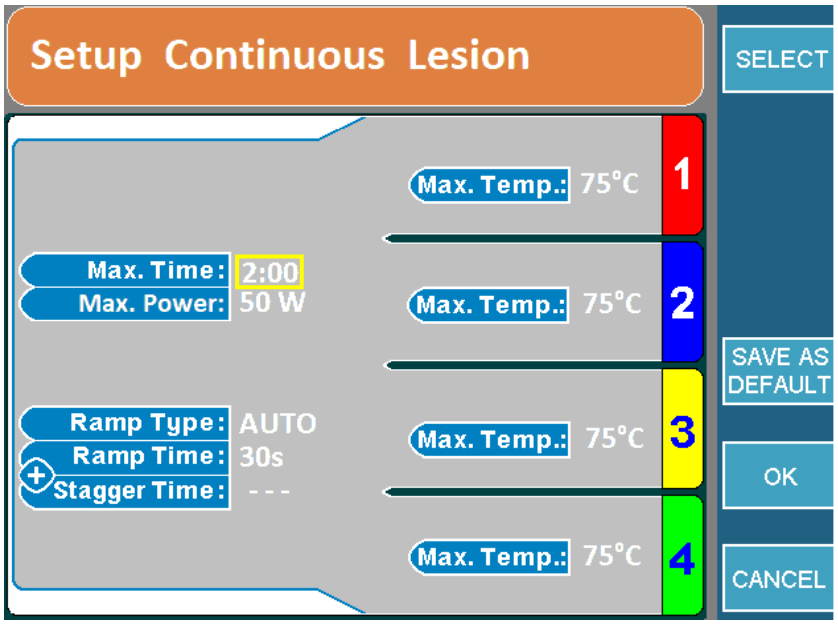


Figure 8-17

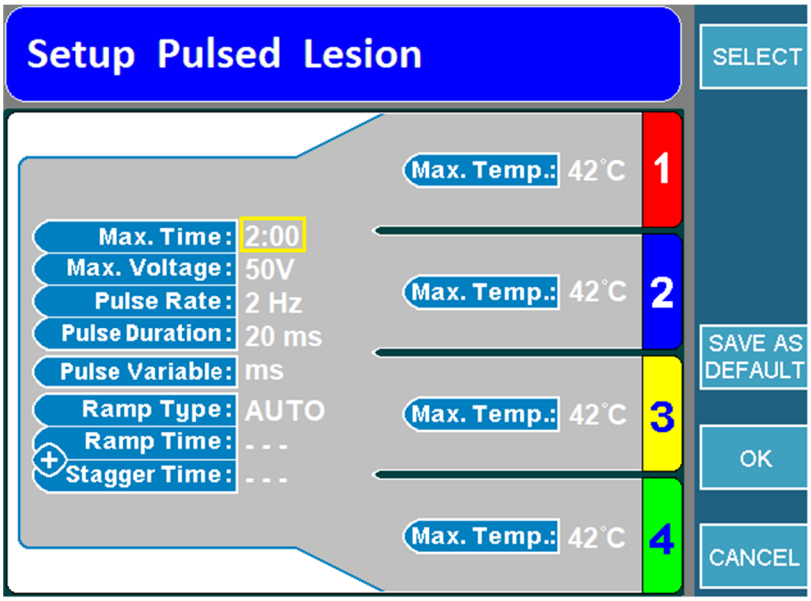


Figure 8-18

8.6.4 STARTING MONOPOLAR LESION

Step 1: Go to Monopolar Lesion screen.

Step 2: Press the START button on the front panel to start the lesion. If an error message appears, address that issue before pressing start again.

Step 3: The lesion will start and then automatically stop when the timer expires. Once the timer expires, the generator will output 3 audible beeps.

Step 4: To stop the lesion before the timer expires, press the STOP button on the front panel or STOP ALL soft key as this will stop all 4 channels. To stop a single channel, press the channel specific STOP soft key.

8.7 TEMPERATURE MONITORING MONOPOLAR LESION

This mode can create one or two monopolar lesions with one or two temperature monitoring probes. If the temperature sensed by the monitoring probes near its threshold, it will reduce the RF output in the RF probes. If the temperature for the monitoring probes continues to rise and reaches its limit, the lesion will stop.. This type of lesion requires the temperature monitoring probe(s) and a return path electrode to be connected as the current flows from the active tip to the return pad.

8.7.1 ACCESSING MONOPOLAR TEMPERATURE MONITORING LESION

To access this mode:

Step 1: Connect the MLA-4 into the URF-3AP and press the MULTI-LESION soft key from the main menu or press the LESION button on the front panel.

Step 2: Identify the generator is in the correct mode.

To do this, check:

- Top banner:
  - LESION bipolar → Press the top soft key that displays GO TO MONOPOLAR. This will take the generator to Monopolar mode.
  - LESION → Generator is in Monopolar Mode, check lesion mode icon.

- Lesion Mode Icon: Now that the generator is in monopolar mode, check the lesion mode icon (Table 8-7).
  - Monopolar Lesion Icon → Insert the temperature monitoring probes into the MLA-4. This will take the generator to Monopolar Temperature Monitoring Lesion mode. Continue to step 3.
  - Temperature Monitoring Monopolar Icon → Move onto step 3.

Step 3: Check whether the generator is in continuous or pulsed mode by reading the top banner. To switch between the two, press the GO TO CONTINUOUS/PULSED soft key.

8.7.2 READING TEMPERATURE MONITORING MONOPOLAR LESION SCREEN

Depending if the Generator is in Continuous/Pulsed Lesion or if it is in Automatic or Manual ramp type, the screen will be slightly different.

Figure 8-19 displays a Continuous Monopolar lesion with Automatic ramp type and Figure 8-20 displays a Pulsed Monopolar lesion with Manual ramp type.

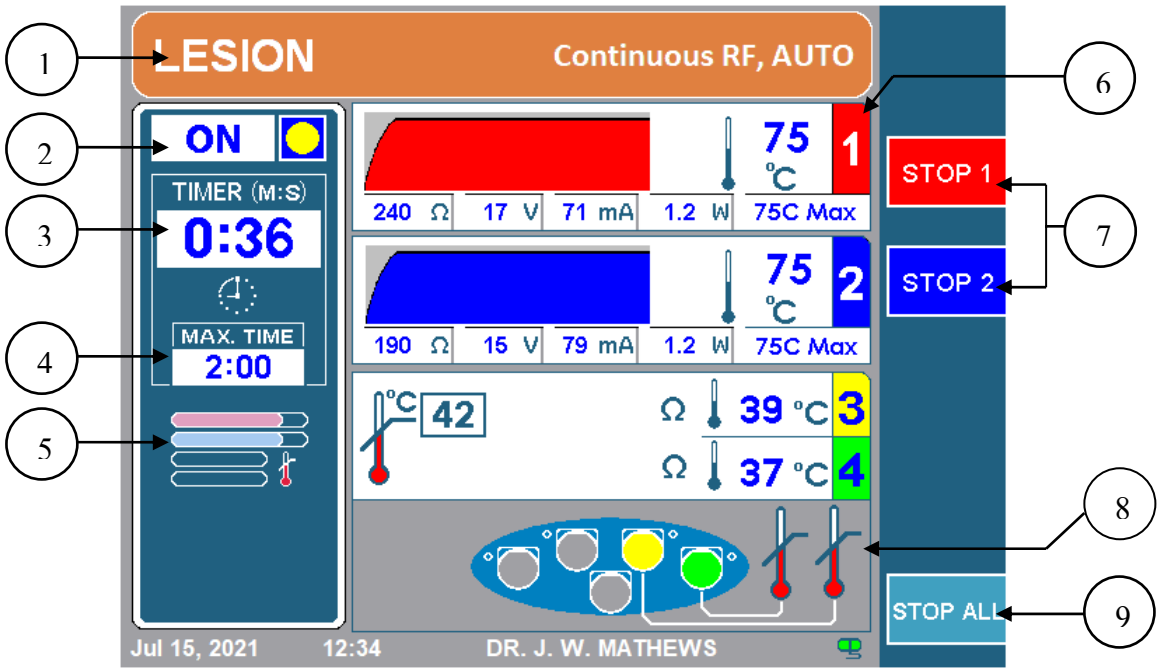


Figure 8-19

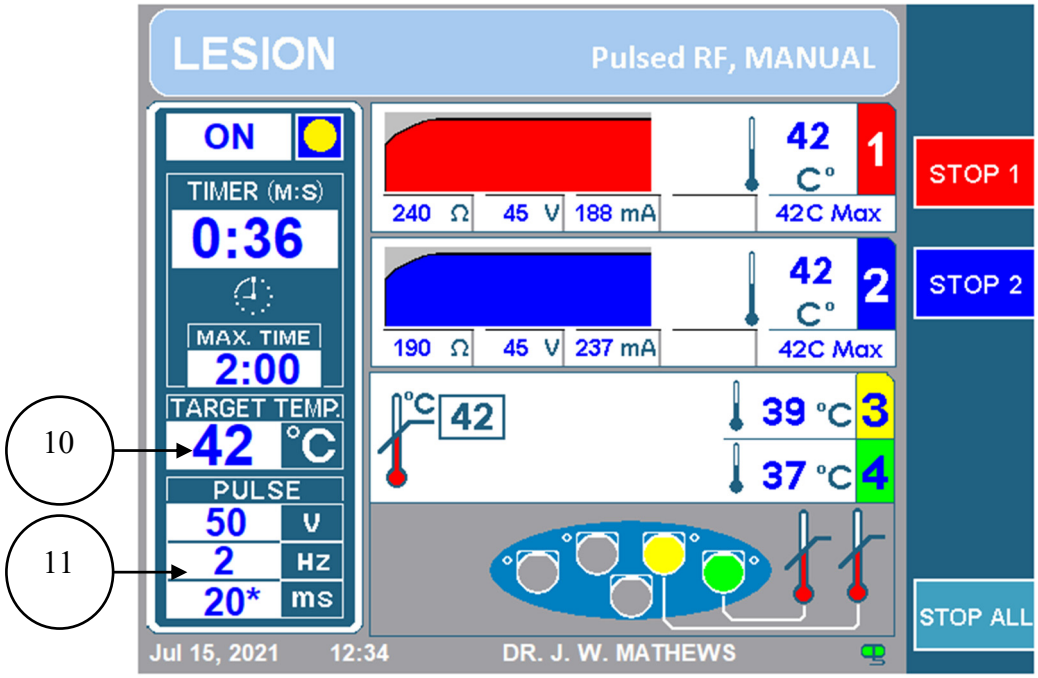


Figure 8-20

1. TOP BANNER

The Top Banner lets the operator know what type of lesion is being performed. The colour will either be orange for continuous lesion or blue for pulsed lesion. It will also explicitly display Continuous RF or Pulsed RF accordingly. Additionally, it will also display the ramp type. It will display AUTO for automatic and staggered ramp types, or Manual for manual ramp type. Also, for monopolar lesions it will display LESION and for bipolar lesions it will display LESION bipolar.

2. ON/OFF INDICATOR

The on/off indicator lets the operator know if a lesion has started or not. While the lesion is off, the indicator will display OFF and there will be no yellow circle. If the lesion is on, it will display ON with a yellow circle.

3. TIMER

The timer lets the user know the total time it will take for all channels to finish.

4. MAX TIME

This timer lets the user know the total time each channel will do a lesion.

5. LESION MODE ICON

The lesion mode icon will indicate the type of lesion as well as the ramp type, refer to Table 8-7 to correspond the lesion type with its icon. If the ramp type is set as Manual, the lesion mode icon will be replaced with the Target Temperature Indicator (10).

6. CHANNEL DISPLAY RF PROBES

Each channel displays its current status and configuration throughout the lesioning process. The following figure (Figure 8-21) shows the channel status display for channel one. The features of this status display are described in Table 8-11.

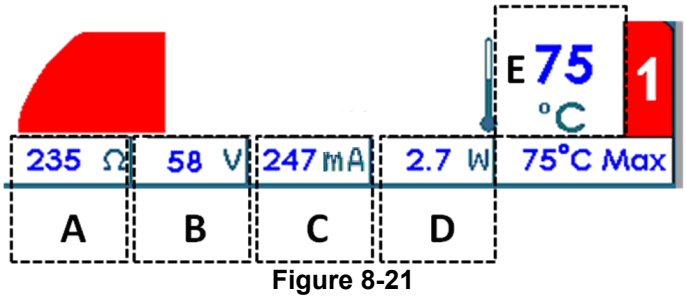


Figure 8-21

Label	Description
A	**Ω,** the impedance between probe attached to the channel and the return electrode
B	**V,** the RMS voltage being delivered through the probe attached to the channel in continuous mode. In pulsed lesion mode, the peak voltage is displayed
C	**mA,** the RMS current being delivered through the probe attached to the channel in continuous mode. In pulsed lesion mode, the peak current is displayed.
D	**W,** the average AC power being delivered through the probe attached to the channel. Note that average power is not displayed in pulsed lesion mode.
E	**°C,** Current Probe temperature. In the figure above, the current probe temperature is 75°C. Beside the current probe temperature is a graph that plots the temperature history. The graph has a darker background shading while RF energy is being delivered to the patient and a lighter background shading when it is not.

Table 8-11

7. STOP CHANNELS 1, 2

These soft keys allow the operator to stop the channels creating the lesion.

8. CHANNEL DISPLAY TEMPERATURE MONITORING PROBES

Channels 3 and 4 only monitor temperature and have their own display on the screen as shown in Figure 8-22. The features of this display are explained in Table 8-12

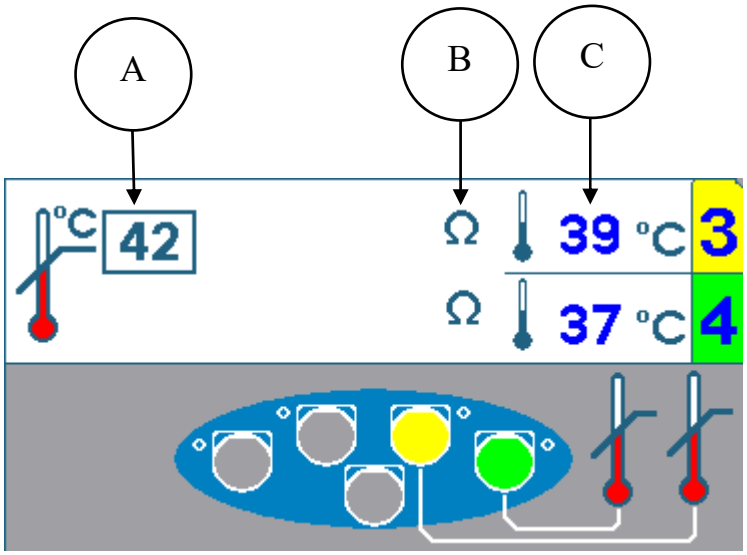


Figure 8-22

Label	Description
A	**°C,** Maximum temperature for temperature monitoring probes. If either of the temperature monitoring probes go above this maximum temperature the lesion will stop.
B	**Ω,** The impedance of the probes are indicated by the ohm symbol. If the impedance is in a suitable range, there will be an ohm symbol. If the impedance is not in a suitable range, there will be an ohm symbol with a red x marked though it. In the above image both channels 3 and 4 are in suitable range. If either of the temperature monitoring channel's impedance goes to an unsuitable range, the lesion will stop.
C	**°C,** Current Probe temperature. The current temperature read for both probes will be displayed here. In the above image channel 3 reads 39˚C and channel 4 reads 37˚C.

Table 8-12

9. STOP ALL SOFT KEY

The STOP ALL soft key stops all lesions and returns the Generator back to the idle screen.

10. TARGET TEMPERATURE INDICATOR

The target temperature lets the generator know what temperature all the connected channels that are delivering RF should be at. The target temperature can be adjusted by rotating the OUTPUT CONTROL knob after pressing start. The target temperature indicator will replace the Lesion Mode Icon (5) if the ramp type is set as Manual.

11. PULSE BOX

The pulse box will only be displayed for pulsed lesions. This box showcases what the set max voltage, pulse rate, and pulse duration are for this pulsed lesion. The asterisk indicates the pulse variable.

8.7.3 CHANGING PARAMETERS IN TEMPERATURE MONITORING MONOPOLAR

Step 1: Go to Temperature Monitoring Monopolar Lesion Mode

Step 2: Press the OPTIONS key.

Note: If the generator is in the Continuous Temperature Monitoring Monopolar mode it will go to the setup menu for Continuous Monopolar as shown in Figure 8-23. Likewise, if the generator is in Pulsed Monopolar it will go the setup menu for Pulsed Temperature Monitoring Monopolar as illustrated in Figure 8-24.

Step 3: To change a parameter, rotate the OUTPUT CONTROL knob to move the yellow box to the parameter that needs to be changed.

Step 4: Once the desired parameter is outlined, press the SELECT key. This will highlight the outlined parameter and allow for editing.

Step 5: Rotate the OUTPUT CONTROL knob to change the value of the parameters.

Step 6: Press the DONE soft key and repeat steps 3-6 for other parameters.

Step 7: Then press one of the following three options:

i) OK – This will store these parameters for this lesion type until the generator is powered off.
ii) SAVE AS DEFAULT – This will store these parameters for this lesion type even after the generator is rebooted.
iii) CANCEL – This will not store any of the changed parameters and will return to the previously saved parameters.

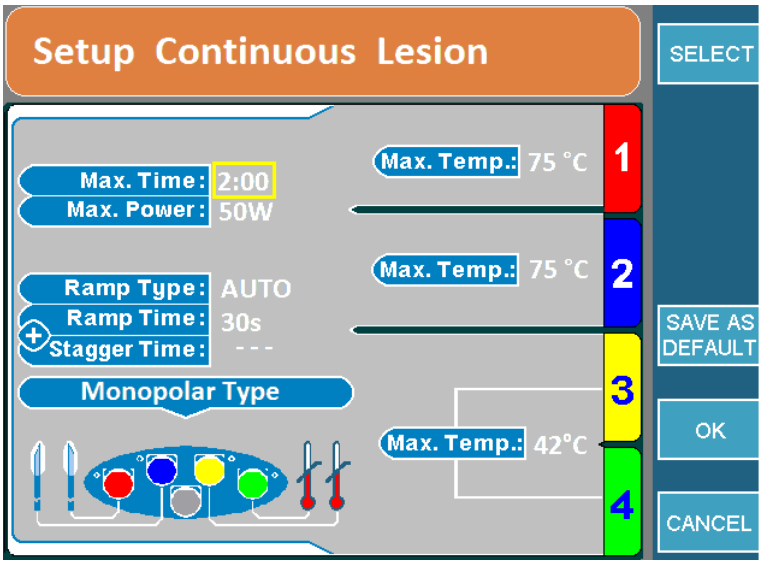


Figure 8-23

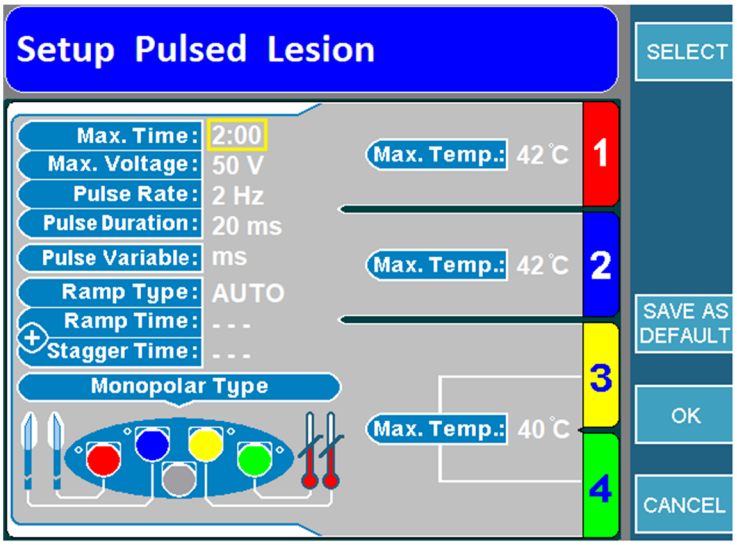


Figure 8-24

8.7.4 STARTING TEMPERATURE MONITORING MONOPOLAR LESIONS

Step 1: Go to Temperature Monitoring Monopolar Lesion screen.

Step 2: Press the START button on the front panel to start the lesion. If an error message appears address that issue before pressing start again.

Step 3: The lesion will start and then automatically stop when the timer expires. Once the timer expires, the generator will output 3 audible beeps.

Step 4: To stop the lesion before the timer expires, press the STOP button on the front panel or the STOP ALL soft key as this will stop all channels. To stop a single channel, press the channel specific STOP soft key.
Note: The Lesion will stop if one of the temperature monitoring probes exceeds the max set temperature.

8.8 DUAL BIPOLAR LESION

This mode can create one or two bipolar lesions at the same time. Bipolar lesions can only be made between channels 1 and 2 or channels 3 and 4. This type of lesion requires 2 or 4 probes and does not require a return pad.

8.8.1 ACCESSING DUAL BIPOLAR LESION

To access this mode:

Step 1: Connect the MLA-4 to the URF-3AP and press the MULTI-LESION soft key from the main menu or press the LESION button on the front panel.

Step 2: Identify the generator is in the correct mode.

To do this, check:

- Top banner:
  - LESION → Press the top soft key that displays GO TO BIPOLAR. This will switch the generator from monopolar mode to bipolar mode and the top banner will now display LESION bipolar.
  - LESION bipolar → The generator is already in bipolar mode, check the lesion mode icon.

- Lesion Mode Icon: Now that the generator is in bipolar mode, check the lesion mode icon (Table 8-7).

  - Temperature Monitoring Bipolar Icon → Remove the temperature monitoring probes from the MLA-4 and this will take the generator to Dual Bipolar mode. Move to step 3.
  - Quadrapolar™ Icon → Press the Options key and change the Bipolar Type setting to Dual Bipolar and then move to step 3.
  - Dual Bipolar Icon → Generator is in the correct mode move to step 3.

Step 3: Check whether the generator is in continuous or pulsed mode by reading the top banner. To switch between the two, press the GO TO CONTINUOUS/PULSED soft key.

8.8.2 READING DUAL BIPOLAR LESION SCREEN

Depending if the Generator is in Continuous/Pulsed Lesion or if it is in Automatic or Manual ramp type the screen will be slightly different.

Figure 8-25 displays a Continuous Monopolar lesion with Automatic ramp type and Figure 8-26 displays a Pulsed Monopolar lesion with Manual ramp type.

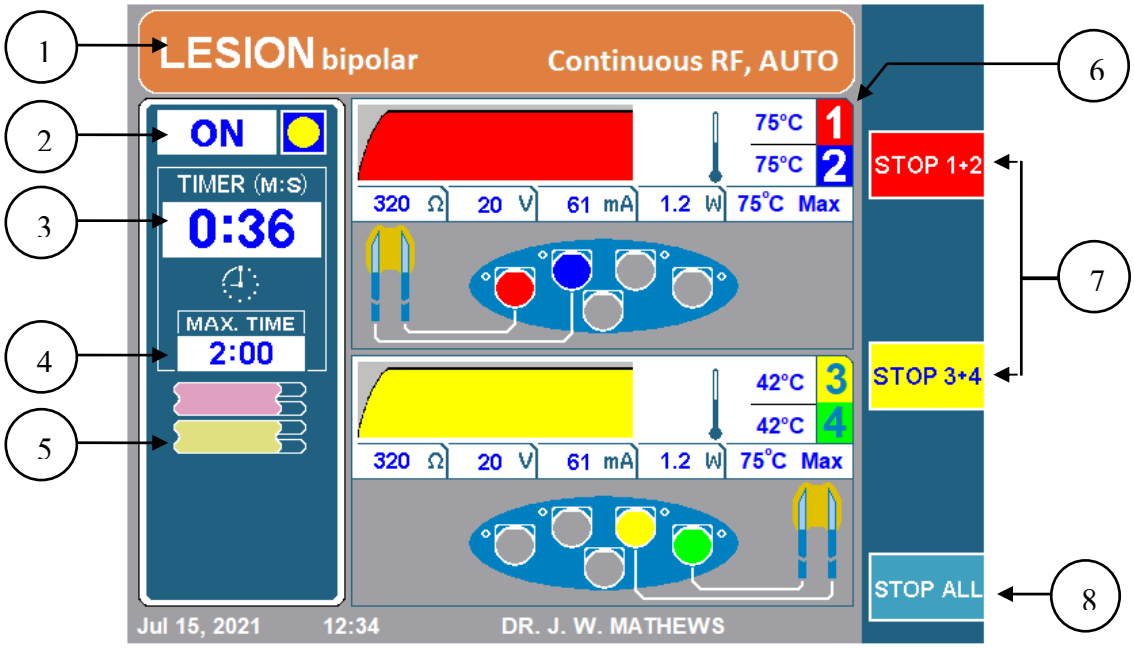


Figure 8-25

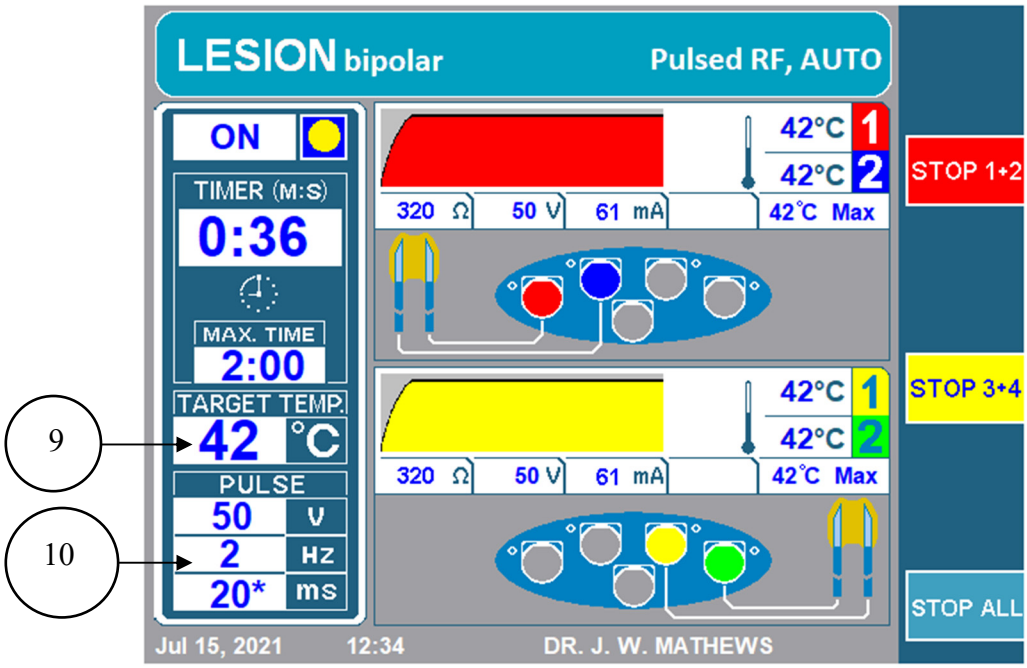


Figure 8-26

1. TOP BANNER

The Top Banner gives the operator a lot of information regarding the type of lesion that is being performed. The colour will either be orange for continuous lesion or blue for pulsed lesion. It will also explicitly display Continuous RF or Pulsed RF accordingly. Besides that, it will mention the ramp type. The top banner will display AUTO for automatic and staggered ramp types, or Manual for manual ramp type. Also, for bipolar lesions it will read LESION bipolar and for monopolar lesions, it will display only LESION.

2. ON/OFF INDICATOR

The on/off indicator lets the operator know if a lesion has started or not. While the lesion is off, the indicator will display OFF and there will be no yellow circle. If the lesion is on, it will be labeled ON with a yellow circle.

3. TIMER

The timer lets the user know the total time it will take for all channels to finish.

4. MAX TIME

This timer lets the user know the total time each channel will do a lesion for.

5. LESION MODE ICON

The lesion mode icon will indicate the type of lesion as well as the ramp type, refer to Table 8-7 for corresponding lesion type with icon. If it is set to manual ramp type the lesion mode icon will be replaced with the Target Temperature Indicator (9).

6. CHANNEL DISPLAY RF PROBES (BIPOLAR)

Each bipolar pair (ch 1-2 & ch 3-4) displays its current status and configuration throughout the lesioning process. The following figure (Figure 8-27) shows the channel status display for one bipolar pair (ch1-2). The features of this status display are described in Table 8-13.

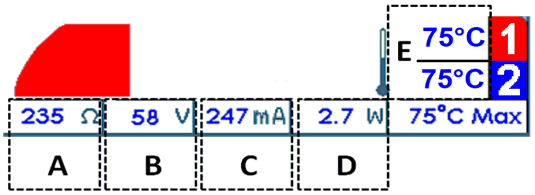


Figure 8-27

Label	Description
A	**Ω,** the impedance measured between the two probes. The figure above has an impedance reading of 235 ohms.
B	**V,** the RMS voltage being delivered to the bipolar pair in continuous mode. In pulsed lesion mode, the peak voltage being delivered to the bipolar pair is displayed. The picture above displays an RMS voltage of 58 V.
C	**mA,** the RMS current being delivered to the bipolar pair in continuous mode. In pulsed lesion mode, the peak current is displayed. The figure above displays a RMS current of 247mA being delivered.
D	**W,** the average AC power being delivered to the bipolar pair in continuous mode. The figure above displays an average AC power of 2.7 W delivered to the bipolar pair. Note that average power is not displayed in pulsed lesion mode.
E	**°C,** Current Probe temperature. This displays the temperature for each channel. In the figure above both ch1 and ch2 are reading a temperature of 75˚C

Table 8-13

7. STOP CHANNELS 1+2/3+4

These soft keys allow the operator to stop the bipolar pair between channel 1-2 or 3-4.

8. STOP ALL SOFT KEY

The STOP ALL soft key stops all lesions and returns the Generator back to the idle screen.

9. TARGET TEMPERATURE INDICATOR

The target temperature lets the generator know what temperature all the connected channels should be at. The target temperature can be adjusted by rotating the Output

Control knob after pressing start. The target temperature indicator will replace the Lesion Mode Icon (5) if the ramp type is set as Manual.

10. PULSE BOX

The pulse box will only be displayed for pulsed lesions. This box showcases what the set max voltage, pulse rate, and pulse duration are for this pulsed lesion. The asterisk indicates the pulse variable.

8.8.3 CHANGING PARAMETERS IN DUAL BIPOLAR

Step 1: Go to Dual Bipolar Lesion Mode

Step 2: Press the OPTIONS key.

Note: If the generator is in the Continuous Dual Bipolar Mode, it will go to the setup menu for Continuous Dual Bipolar as shown in Figure 8-28. Likewise, if the generator is in Pulsed Dual Bipolar Mode, it will go to the setup menu for Pulsed Dual Bipolar as illustrated in Figure 8-29.

Step 3: This will take the generator to the setup menu for dual bipolar lesion. To change a parameter, rotate the OUTPUT CONTROL knob to move the yellow box to the parameter that needs to be changed.

Step 4: Once the desired parameter is outlined, press the SELECT key. This will highlight the outlined parameter and allow for editing.

Step 5: Rotate the OUTPUT CONTROL knob to change the value of the parameters.

Step 6: Press the DONE soft key and repeat steps 3-6 for other parameters.

Step 7: Then press one of the following three options:

i) OK – This will store these parameters for this lesion type until the generator is powered off.

ii) SAVE AS DEFAULT – This will store these parameters for this lesion type even after the generator is rebooted.

iii) CANCEL – This will not store any of the changed parameters and will return to the previously saved parameters.

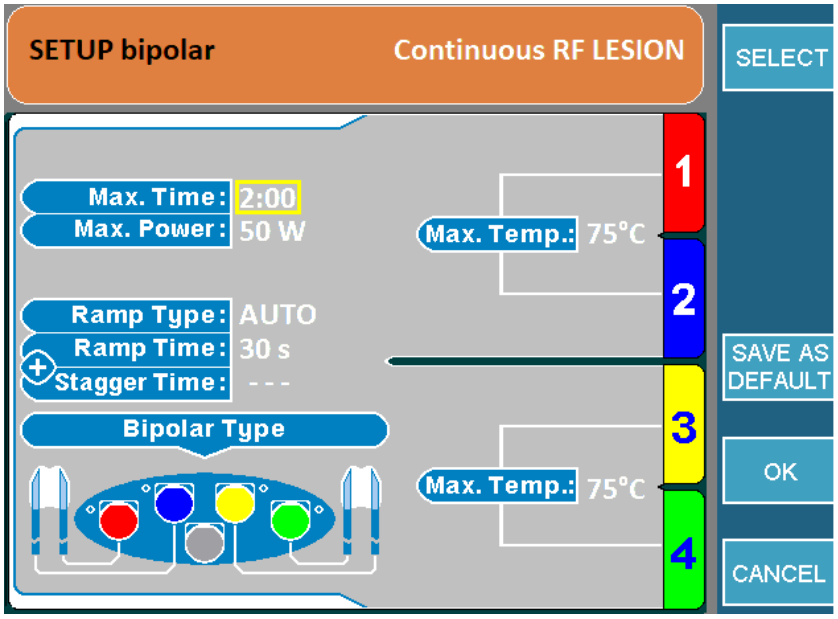


Figure 8-28

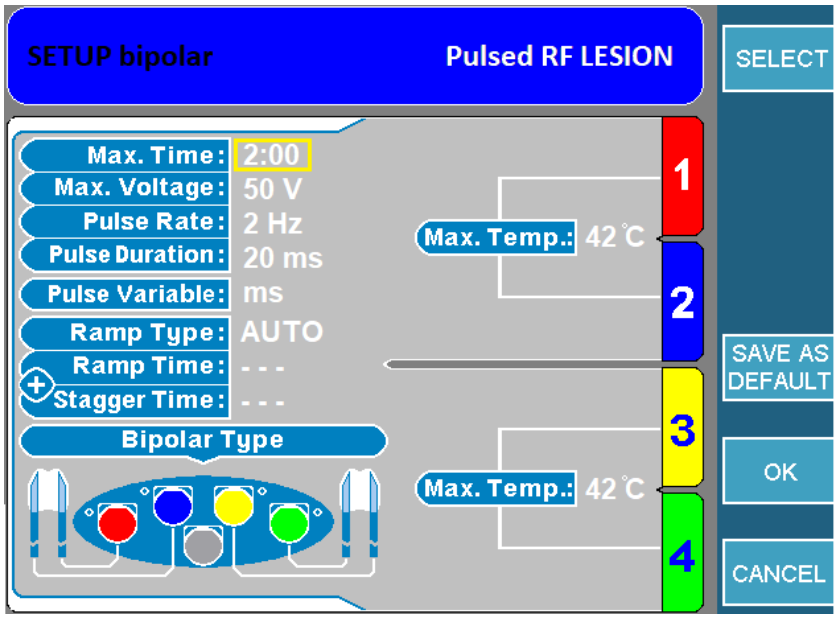


Figure 8-29

8.8.4 STARTING DUAL BIPOLAR LESIONS

Step 1: Go to Dual Bipolar Lesion screen.

Step 2: Press the START button on the front panel to start the lesion. If an error message appears address that issue before pressing start again.

Step 3: The lesion will start and then automatically stop when the timer expires. Once the timer expires, the generator will output 3 audible beeps.

Step 4: To stop the lesion before the timer expires, press the STOP button on the front panel or the STOP ALL soft key as this will stop all channels. To stop a single bipolar pair, press the STOP 1+2/3+4 soft key.

8.9 QUADRAPOLAR™ LESIONS

This mode creates one thorough strip lesion between all four probes. This type of lesion requires the use of 4 probes and does not require a return pad.

8.9.1 ACCESSING QUADRAPOLAR™ LESION SCREEN

To access this mode:

Step 1: Connect the MLA-4 to the URF-3AP and press the MULTI-LESION soft key from the main menu or press the LESION button on the front panel.

Step 2: Identify the generator is in the correct mode.

To do this, check:

- Top banner:
  - LESION → Press the top soft key that displays GO TO BIPOLAR. This will switch the generator from monopolar mode to bipolar mode and the top banner will now display LESION bipolar.
  - LESION bipolar → The generator is in bipolar mode, check the lesion mode icon.

- Lesion Mode Icon: Now that the generator is in bipolar mode, check the lesion mode icon (Table 8-7).

  - Temperature Monitoring Bipolar Icon → Remove the temperature monitoring probes from the MLA-4. This will take the generator to Dual Bipolar mode. Then press the Options key and change the Bipolar Type setting to Quadrapolar™ and move to step 3.
  - Dual Bipolar Icon → Press the Options key, change the Bipolar Type setting to Quadrapolar™ and move to step 3.
  - Quadrapolar™ Icon →Move to step 3.

Step 3: Check whether the generator is in continuous or pulsed mode by reading the top banner. To switch between the two, press the GO TO CONTINUOUS/PULSED soft key.

8.9.2 READING QUADRAPOLAR™ LESION SCREEN

Depending if the Generator is in Continuous/Pulsed Lesion or if it is in Automatic or Manual ramp type, the screen will be slightly different.

Figure 8-30 displays a Continuous Monopolar lesion with Automatic ramp type and Figure 8-31 displays a Pulsed Monopolar lesion with Manual ramp type.

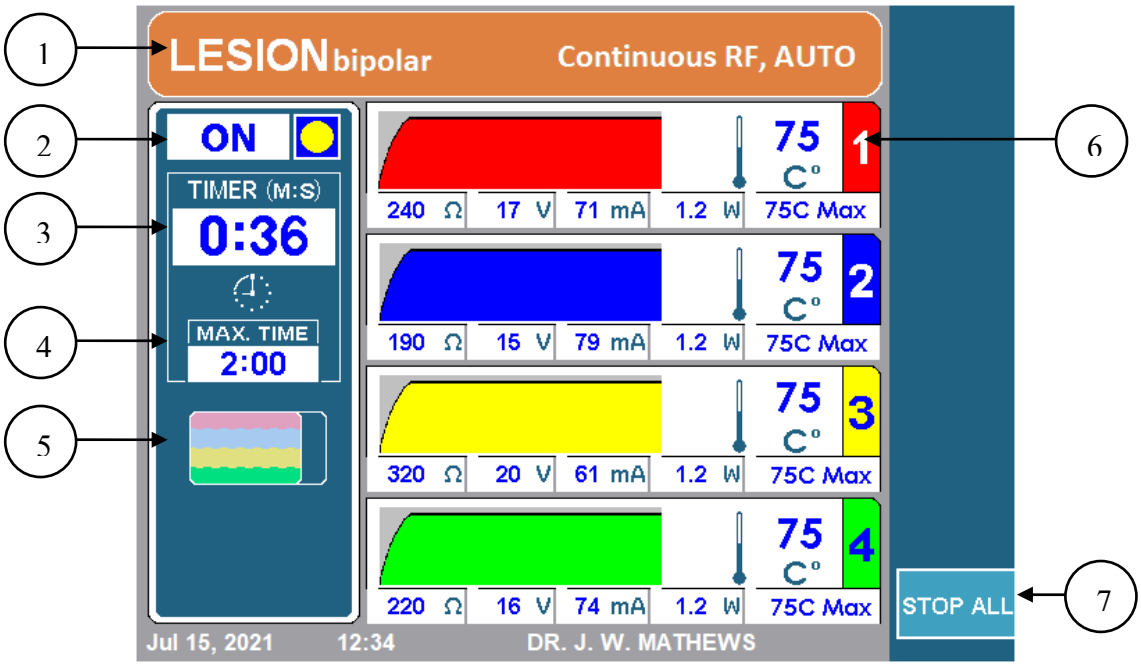


Figure 8-30

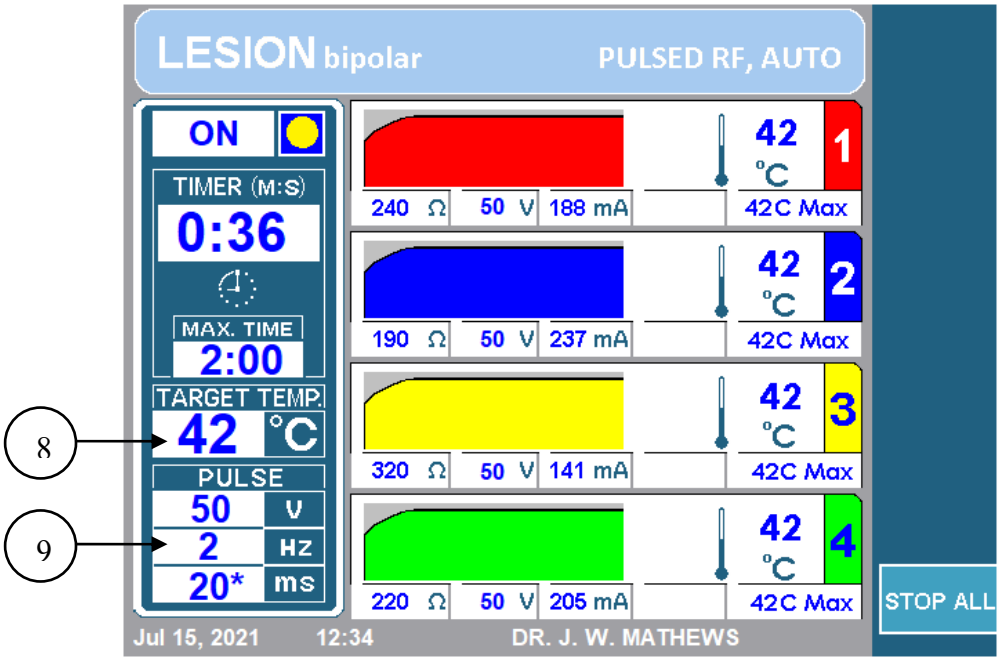


Figure 8-31

1. TOP BANNER

The Top Banner gives the operator a lot of information regarding the type of lesion that is being performed. The colour will either be orange for continuous lesion or blue for pulsed lesion. It will also explicitly display Continuous RF or Pulsed RF accordingly. Besides that, it will mention the ramp type. The top banner will display AUTO for automatic and staggered ramp types or Manual for manual ramp type. Also, for bipolar lesions it will read LESION bipolar and for monopolar lesions it will display only LESION.

2. ON/OFF INDICATOR

The on/off indicator lets the operator know if a lesion has started or not. While the lesion is off, the indicator will display OFF and there will be no yellow circle. If the lesion is on, it will be labeled ON with a yellow circle.

3. TIMER

The timer lets the user know the total time it will take for all channels to finish.

4. MAX TIME

This timer lets the user know the total length of time each channel will do a lesion for.

5. LESION MODE ICON

The lesion mode icon will indicate the type of lesion as well as the ramp type, refer to section 8.9 for the corresponding lesion type with icon. If it is set to manual ramp type, the lesion mode icon will be replaced with the Target Temperature Indicator (8).

6. CHANNEL DISPLAY

Each channel displays its current status and configuration throughout the lesioning process. The following figure (Figure 8-32) shows the channel status display for channel one. The features of this status display are described in Table 8-14.

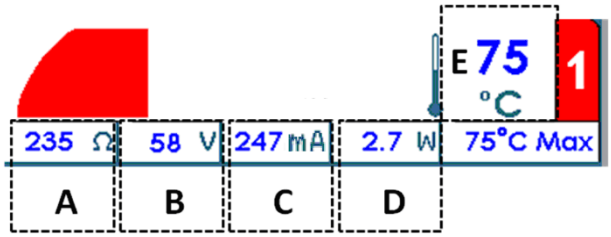


Figure 8-32

Label	Description
A	**Ω,** the impedance between probe attached to the channel and the return electrode
B	**V,** the RMS voltage being delivered through the probe attached to the channel in continuous mode. In pulsed lesion mode, the peak voltage is displayed
C	**mA,** the RMS current being delivered through the probe attached to the channel in continuous mode. In pulsed lesion mode, the peak current is displayed.
D	**W,** the average AC power being delivered through the probe attached to the channel. Note that average power is not displayed in pulsed lesion mode.
E	**°C,** Current Probe temperature. In the figure above, the current probe temperature is 75°C. Beside the current probe temperature is a graph that plots the temperature history. The graph has a darker background shading while RF energy is being delivered to the patient and a lighter background shading when it is not.

Table 8-14

7. STOP ALL SOFT KEY

The STOP ALL soft key stops all lesions and returns the Generator back to the idle screen.

8. TARGET TEMPERATURE INDICATOR

The target temperature lets the generator know what temperature all the connected channels that are delivering RF should be at. The target temperature can be adjusted by rotating the OUTPUT CONTROL knob after pressing start. The target temperature indicator will replace the Lesion Mode Icon (5) if the ramp type is set as Manual.

9. PULSE BOX

The pulse box will only be displayed for pulsed lesions. This box showcases what the set max voltage, pulse rate, and pulse duration are for this pulsed lesion. The asterisk indicates the pulse variable.

8.9.3 CHANGING PARAMETERS FOR QUADRAPOLAR™

Step 1: Go to Quadrapolar™ Lesion Mode

Step 2: Press the OPTIONS key.

Note: If the generator is in the Continuous Quadrapolar™ Mode, it will go to the setup menu for Continuous Quadrapolar™ as shown in Figure 8-33. Likewise, if the generator is in Pulsed Quadrapolar™, it will go to the setup menu for Pulsed Quadrapolar™ as illustrated in Figure 8-34.

Step 3: This will take the generator to the setup menu for Quadrapolar™ lesion. To change a parameter, rotate the OUTPUT CONTROL knob to move the yellow box to the parameter that needs to be changed.

Step 4: Once the desired parameter is outlined, press the SELECT key. This will highlight the outlined parameter and allow for editing.

Step 5: Rotate the OUTPUT CONTROL knob to change the value of the parameters.

Step 6: Press the DONE soft key and repeat steps 3-6 for other parameters.

Step 7: Then press one of the following three options:

i) OK – This will store these parameters for this lesion type until the generator is powered off.
ii) SAVE AS DEFAULT – This will store these parameters for this lesion type even after the generator is rebooted.
iii) CANCEL – This will not store any of the changed parameters and will return to the previously saved parameters.

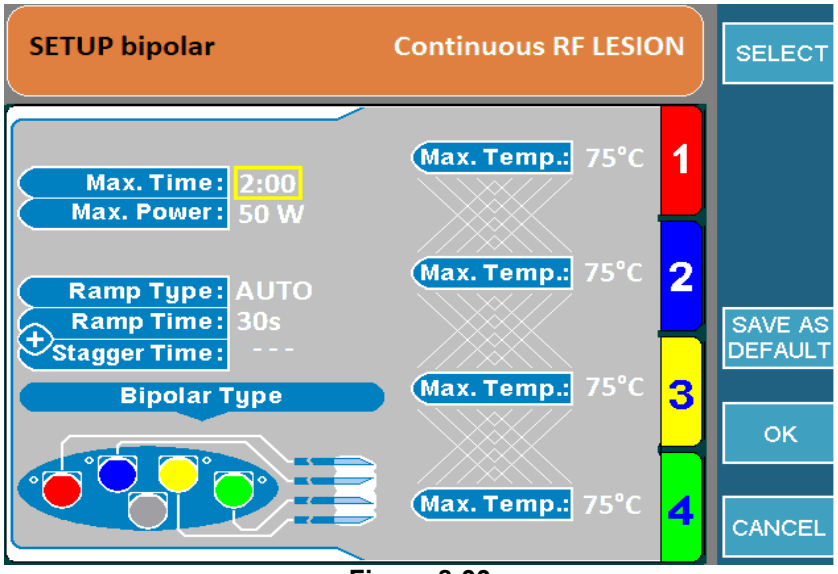


Figure 8-33

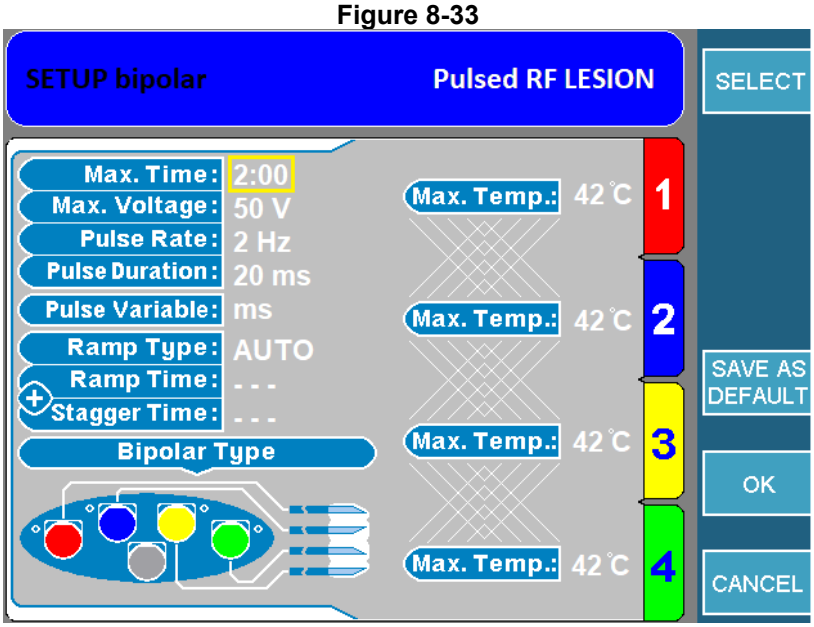


Figure 8-34

8.9.4 STARTING QUADRAPOLAR™ LESION

Step 1: Go to Quadrapolar™ Lesion screen.

Step 2: Press the START button on the front panel to start the lesion. If an error message appears, address that issue before pressing start again.

Step 3: The lesion will start and then automatically stop when the timer expires. Once the timer expires, the generator will output 3 audible beeps.

Step 4: To stop the lesion before the timer expires, press the STOP button on the front panel or the STOP ALL soft key as this will stop all channels.

8.10 TEMPERATURE MONITORING BIPOLAR LESION

This mode creates one bipolar lesion with one or two temperature monitoring probes. If the temperature sensed by the monitoring probes near its threshold, it will reduce the RF output in the RF probes. If the temperature for the monitoring probes continue to rise and reaches its limit, the lesion will stop. This type of lesion requires the temperature monitoring probe(s) to be connected to the MLA-4.

8.10.1 Accessing Temperature Monitoring Bipolar Lesion Screen

To access this mode:

Step 1: Connect the MLA-4 to the URF-3AP and press the MULTI-LESION soft key from the main menu or press the LESION button on the front panel.

Step 2: Go to Temperature Monitoring Bipolar mode.

To do this, check:

- Top banner:
  - LESION → Press the top soft key that displays GO TO BIPOLAR. This will switch the generator from monopolar mode to bipolar mode and the top banner will now display LESION bipolar.
  - LESION bipolar → Generator is in bipolar, check lesion mode icon.

- Lesion Mode Icon: Now that the generator is in bipolar mode, check the lesion mode icon (Table 8-7).

  - Dual Bipolar Icon → Continue to step 3.
  - Temperature Monitoring Bipolar Icon → Continue to step 4.
  - Quadrapolar™ icon → Press the OPTIONS key and change the Bipolar Type to Dual Bipolar and move to step 3.

Step 3: Once the generator is in Dual Bipolar mode, connect the temperature monitoring probes and the generator will go to Temperature Monitoring Bipolar mode.

Step 4: Check whether the generator is in continuous or pulsed mode by reading the top banner. To switch between the two, press the GO TO CONTINUOUS/PULSED soft key.

8.10.2 READING TEMPERATURE MONITORING BIPOLAR LESION SCREEN

Depending if the Generator is in Continuous/Pulsed Lesion or if it is in Automatic or Manual ramp type, the screen will be slightly different.

Figure 8-35 displays a Continuous Temperature Monitoring Bipolar lesion with Automatic ramp type and Figure 8-36 displays a Pulsed Temperature Monitoring Bipolar lesion with Manual ramp type.

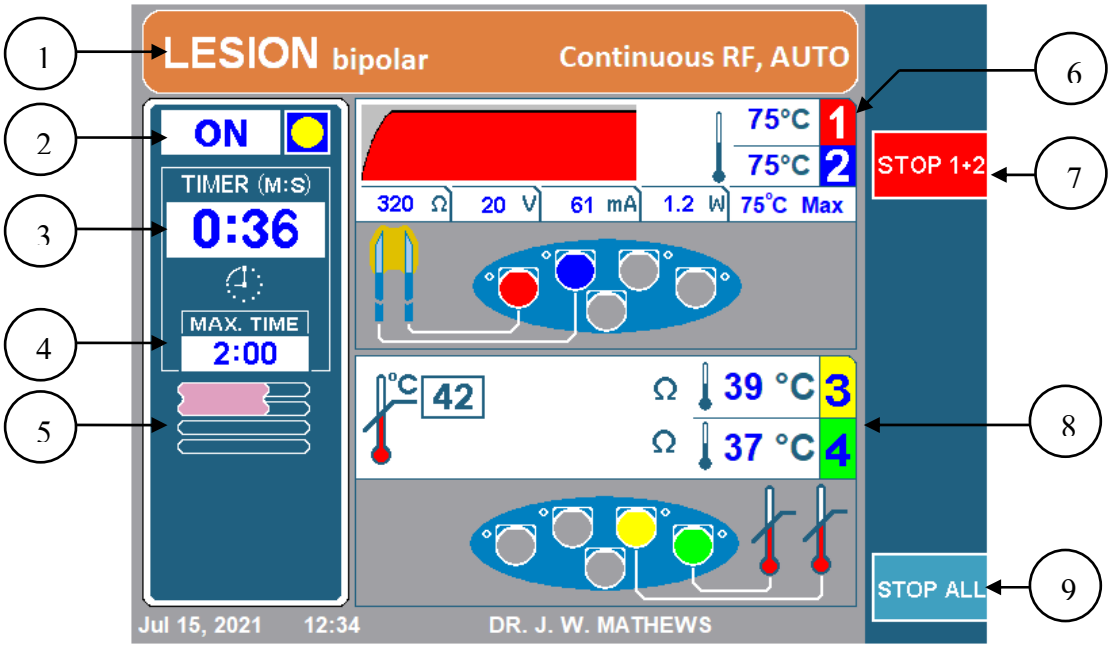


Figure 8-35

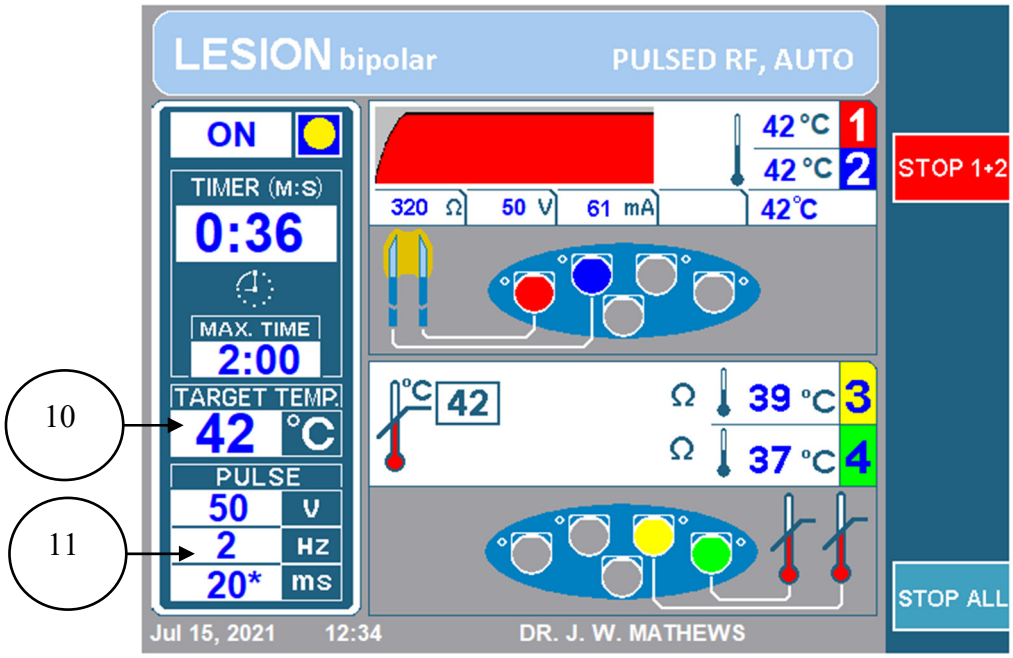


Figure 8-36

1. TOP BANNER

The Top Banner gives the operator a lot of information regarding the type of lesion that is being performed. The colour will either be orange for continuous lesion or blue for pulsed lesion. It will also explicitly display Continuous RF or Pulsed RF accordingly. Besides that, it will mention the ramp type. The top banner will display AUTO for automatic and staggered ramp types or Manual for manual ramp type. Also, for bipolar lesions it will read LESION bipolar and for monopolar lesions it will display only LESION.

2. ON/OFF INDICATOR

The on/off indicator lets the operator know if a lesion has started or not. While the lesion is off, the indicator will display OFF and there will be no yellow circle. If the lesion is on, it will be labeled ON with a yellow circle.

3. TIMER

The timer lets the user know the total time it will take for all channels to finish.

4. MAX TIME

This timer lets the user know the total time each channel will do a lesion for.

5. LESION MODE ICON

The lesion mode icon will indicate the type of lesion as well as the ramp type, refer to section 8.9 for corresponding lesion type with icon. If it is set to manual ramp type the lesion mode icon will be replaced with the Target Temperature Indicator (10).

6. CHANNEL DISPLAY RF PROBES

Each channel displays its current status and configuration throughout the lesioning process. The following figure (Figure 8-37) shows the channel status display for channel one. The features of this status display are described in Table 8-15.

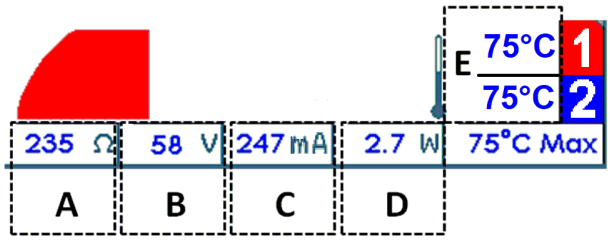


Figure 8-37

Label	Description
A	**Ω,** the impedance measured between the two probes. The figure above has an impedance reading of 235 ohms.
B	**V,** the RMS voltage being delivered to the bipolar pair in continuous mode. In pulsed lesion mode, the peak voltage being delivered to the bipolar pair is displayed. The figure above displays an RMS voltage of 58 V.
C	**mA,** the RMS current being delivered to the bipolar pair in continuous mode. In pulsed lesion mode, the peak current is displayed. The figure above displays a RMS current of 247mA being delivered.
D	**W,** the average AC power being delivered to the bipolar pair in continuous mode. The figure above displays an average AC power of 2.7 W delivered to the bipolar pair. Note that average power is not displayed in pulsed lesion mode.
E	**°C,** Current Probe temperature. This displays the temperature for each channel. In the figure above both ch1 and ch2 are reading a temperature of 75˚C

Table 8-15

7. STOP CHANNELS 1+2

This soft key allows the operator to stop the lesion being created between channel 1 and 2.

8. CHANNEL DISPLAY TEMPERATURE MONITORING PROBES

Channels 3 and 4 only monitor temperature and have their own display on the screen as shown in Figure 8-38. The features of this display are explained in Table 8-16

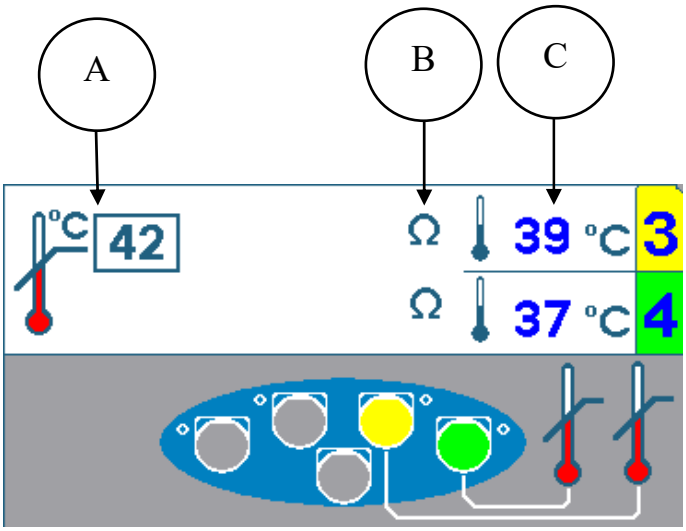


Figure 8-38

Label	Description
A	**°C,** Maximum temperature for temperature monitoring probes. If either of the temperature monitoring probes go above this maximum temperature the lesion will stop.
B	**Ω,** The impedance of the probes are indicated by the ohm symbol. If the impedance is in a suitable range there will be an ohm symbol. If the impedance is not in a suitable range there will be an ohm symbol with a red x marked though it. In the above image both channels 3 and 4 are in suitable range. If either of the temperature monitoring channel's impedance goes to an unsuitable range, the lesion will stop.
C	**°C,** Current Probe temperature. The current temperature read for both probes will be displayed here. In the above image channel 3 reads 39˚C and channel 4 reads 37˚C.

Table 8-16

9. Stop All Soft Key

The STOP ALL soft key stops all lesions and returns the Generator back to the idle screen.

10. TARGET TEMPERATURE INDICATOR

The target temperature indicator will replace the Lesion Mode Icon (5) only if the ramp type is set as Manual. This temperature can be adjusted by rotating the OUTPUT CONTROL knob. The target temperature is the temperature all four channels will move towards when the lesion has started.

11. PULSE BOX

The pulse box will only be displayed for pulsed lesions. This box showcases what the set max voltage, pulse rate, and pulse duration are for this pulsed lesion. The asterisk indicates the pulse variable.

8.10.3 CHANGING PARAMETERS FOR TEMPERATURE MONITORING BIPOLAR LESION

Step 1: Go to Temperature Monitoring Bipolar Mode

Step 2: Press the OPTIONS key.

Note: If the generator is in the Continuous Temperature Monitoring Bipolar Mode, it will go to the setup menu for Continuous Temperature Monitoring Bipolar as shown in Figure 8-39. Likewise, if the generator is in Pulsed Temperature Monitoring Bipolar it will go to the setup menu for Pulsed Temperature Monitoring Bipolar as illustrated in Figure 8-40.

Step 3: This will take the generator to the setup menu for Temperature Monitoring Bipolar lesion. To change a parameter, rotate the OUTPUT CONTROL knob to move the yellow box to the parameter that needs to be changed.

Step 4: Once the desired parameter is outlined, press the SELECT key. This will highlight the outlined parameter and allow for editing.

Step 5: Rotate the OUTPUT CONTROL knob to change the value of the parameters.

Step 6: Press the DONE soft key and repeat steps 3-6 for other parameters.

Step 7: Then press one of the following three options:

i) OK – This will store these parameters for this lesion type until the generator is powered off.
ii) SAVE AS DEFAULT – This will store these parameters for this lesion type even after the generator is rebooted.
iii) CANCEL – This will not store any of the changed parameters and will return to the previously saved parameters.

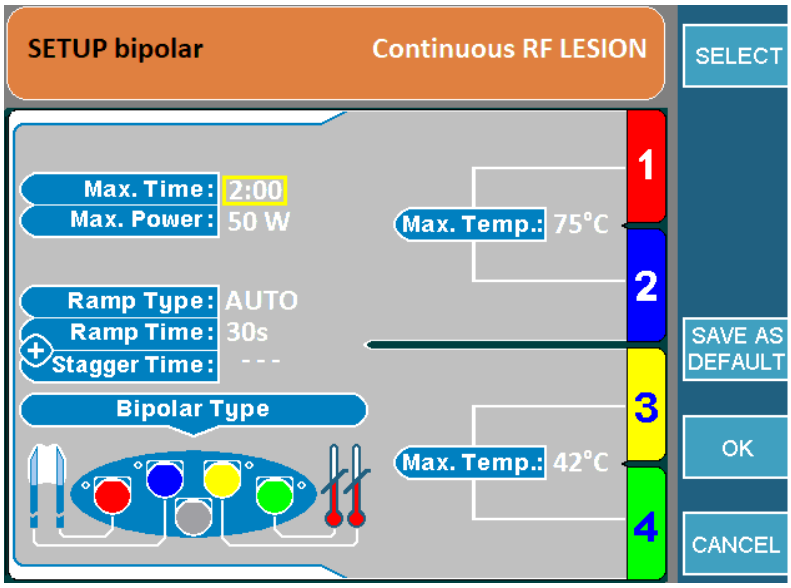


Figure 8-39

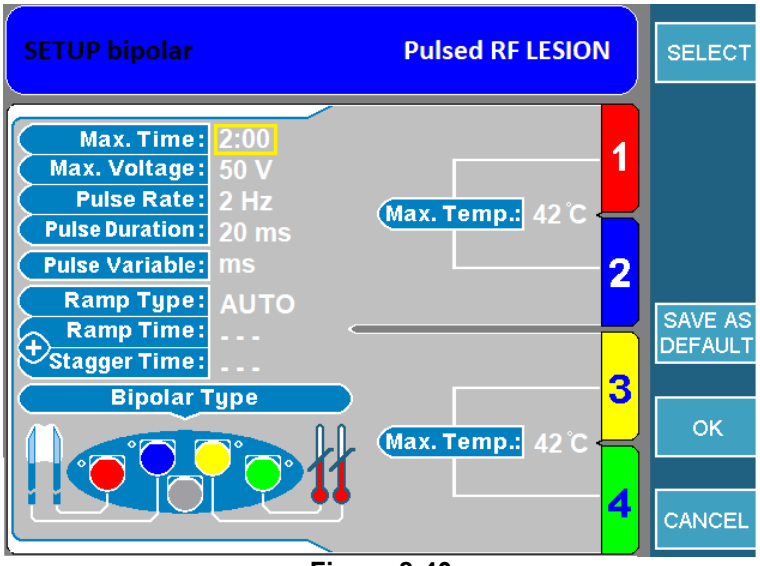


Figure 8-40

8.10.4 STARTING TEMPERATURE MONITORING BIPOLAR LESIONS

Step 1: Go to Temperature Monitoring Bipolar Lesion screen.

Step 2: Press the START button on the front panel to start the lesion. If an error message appears, address that issue before pressing start again.

Step 3: The lesion will start and then automatically stop when the timer expires. Once the timer expires, the generator will output 3 audible beeps.

Step 4: To stop the lesion before the timer expires, press the STOP button on the front panel or the STOP 1+2/STOP ALL soft key, as this will stop all channels.

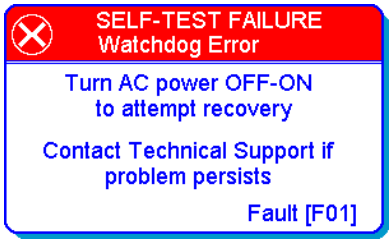
Note: Lesion will stop if one of the temperature monitoring probes exceed the maximum temperature set.

9 ERROR AND WARNING MESSAGES

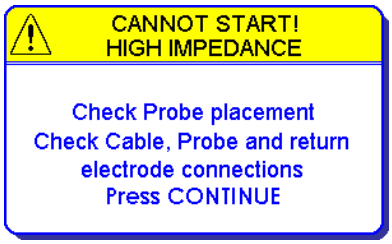
9.1 GENERAL WARNING MESSAGES

The URF-3AP provides the user with error, warning and information messages. Messages are triggered by various conditions and require specific user actions. Messages come up on the screen describing the condition that caused the message and the action that is expected to correct it.

Example of Error Message



Example of Warning Message



Example of Information Message

9.2 MULTIPLE LESION SPECIFIC WARNING MESSAGES

In addition to the general warning messages displayed during single probe operation, the Multi-Lesion Adaptor delivers channel specific error and warning messages. When a channel specific error occurs, lesioning will stop on the channel with the problem and continue on all other channels not experiencing an error condition. Figure 9-1 below shows an example of a channel specific error message indicating that RF energy is no longer being delivered to channel 2 as the impedance is above the defined safety limit.

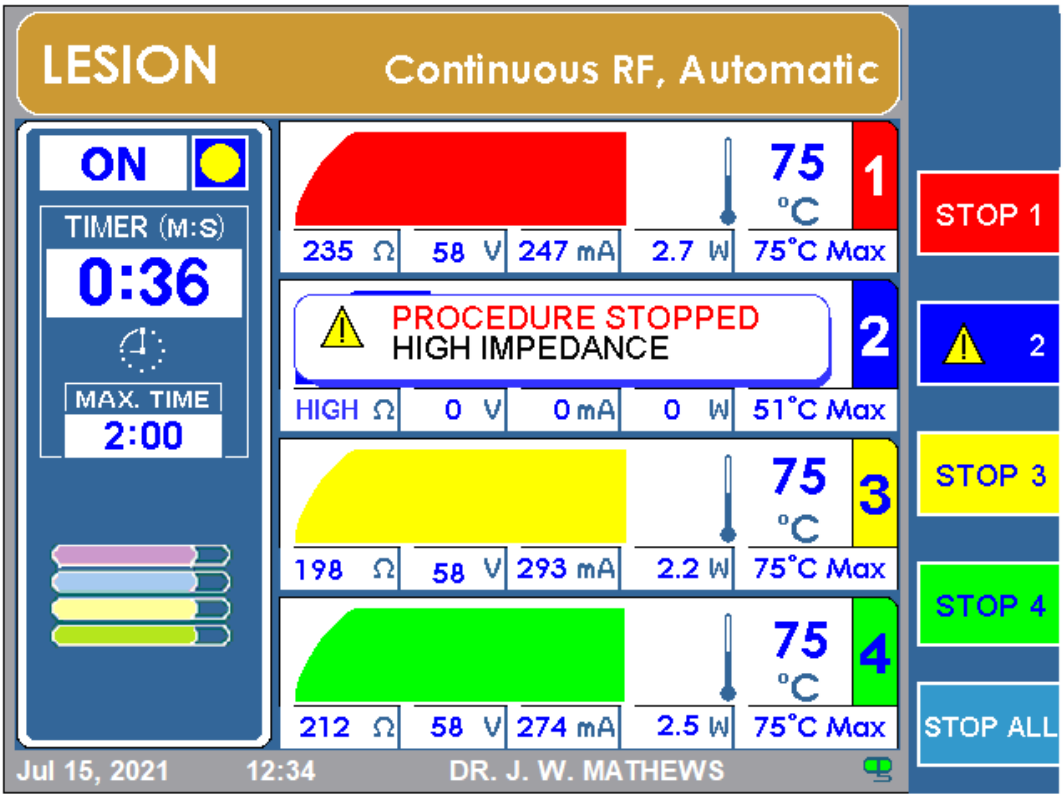


Figure 9-1

10. USING THE SETUP SCREEN

Figure 10-1 below shows the setup screen which consists of a list of parameters that can be edited by using the OUTPUT CONTROL knob. The available options and default values are detailed in Table 10-1.

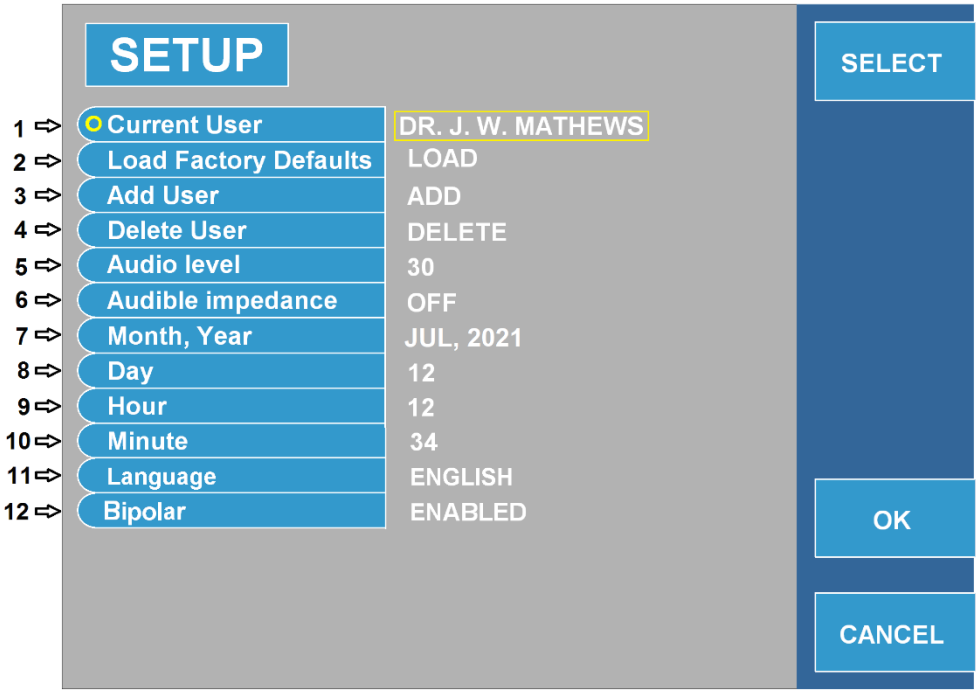


Figure 10-1

	Field name	Function	Default
1	Current User	• To **CHANGE** user, press SELECT, then switch users by rotating the OUTPUT CONTROL knob. • To **EDIT** user, press EDIT. The "Edit user" screen will be displayed, as shown in Figure 10-2: Edit User Screen (Password may be required, see Figure 10-4: Password Entry Screen)	"Default User"
2	Load Factory Defaults	• Loading Current User with factory default parameters	N/A
3	Add User	• Allows the input of up to 5 new users • By selecting the **ADD** tab on the right of the screen, the URF-3AP will display the add user screen shown in Figure 10-3: Add User Screen	N/A
4	Delete User	• Any user can be deleted. (Will not delete last user)	N/A
5	Audio Level	• Audio level set. Range from 0-50	30
6	Audible Impedance	• Impedance related audio response. Audio frequency directly related to measured impedance	"OFF"
7-10	Month, Year, Day, Hour, Minute	• Allows user to set system Date and Time	Current Date and Time
11	Language	• Allows user to select the language in which menus and messages are displayed.	English
12	Bipolar	• Allows user to Enable or Disable bipolar modes.	Disabled

Table 10-1

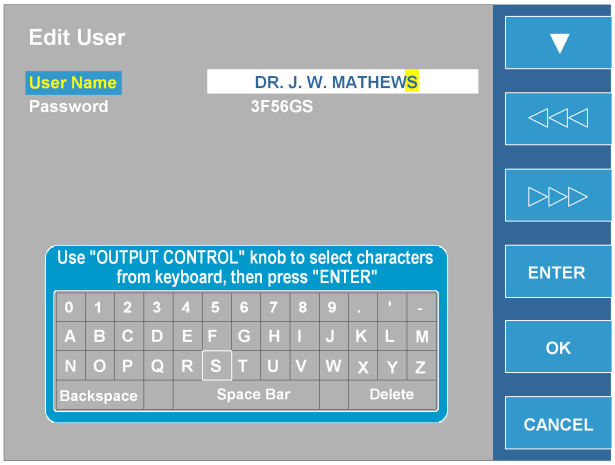


Figure 10-2: Edit User Screen

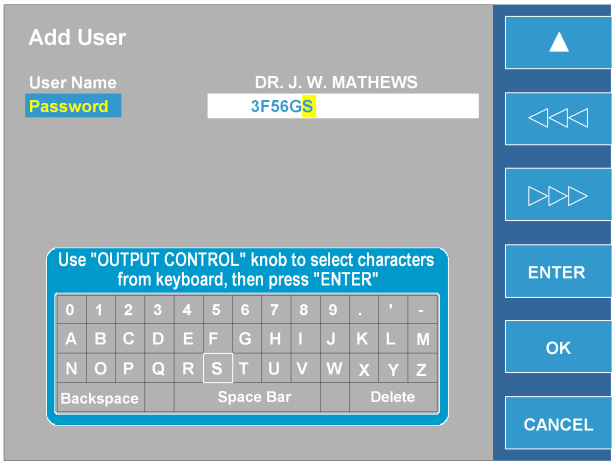


Figure 10-3: Add User Screen

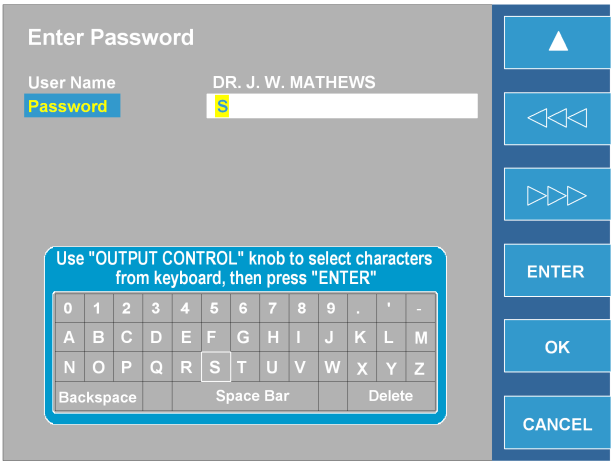


Figure 10-4: Password Entry Screen

11. USING THE UTILITIES SCREENS

Figure 11-1, exemplifies the utility screen options. Table 11-1 explains each function. The Utilities menu offers the user two features, HISTORY and PROBE TEST.

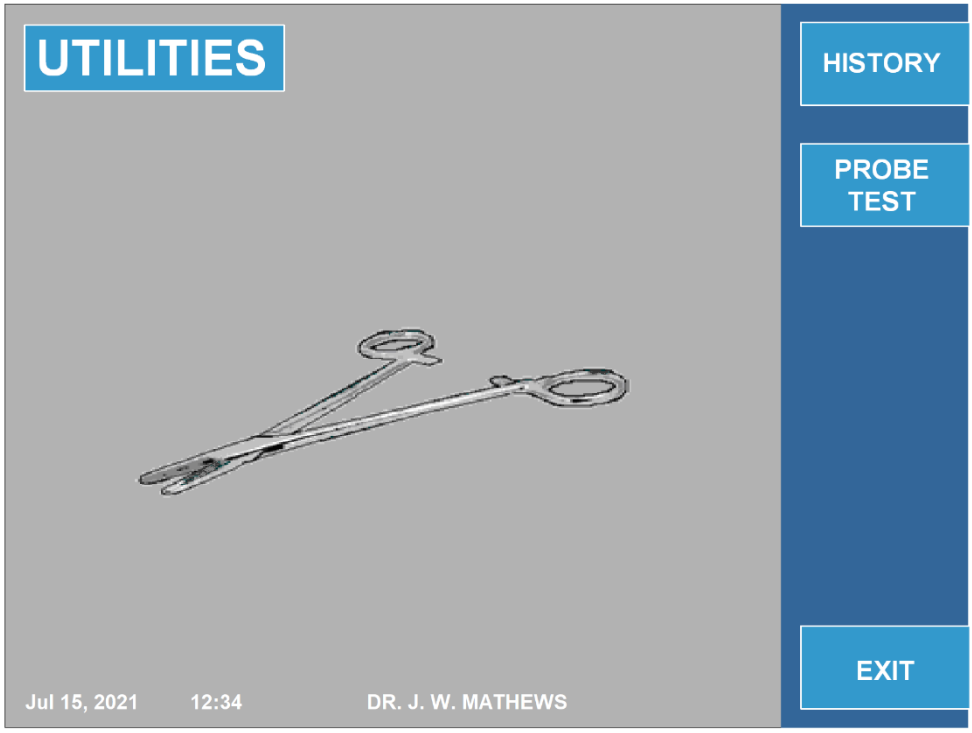


Figure 11-1

	Specification	Function
1	HISTORY	• Allows user to upload previous operation details. • See Figure 11-2
2	PROBE TEST or 4 PROBE TEST	• Allows user to test OWL R.F Probe/Temperature Sensor to determine the correct functionality. • See Figures 11-3 and 11-4

Table 11-1

11.1 USING THE HISTORY FUNCTION

The HISTORY menu allows the user to save procedural data onto a Flash Memory Stick.

Figure 11-2: History Screen exemplifies the HISTORY screen.

To save data on external media, plug the USB Flash Memory Stick into the socket on the rear panel then select: SAVE LAST or SAVE ALL. The SAVE LAST option allows the user to upload all data for the last patient to be operated on. The SAVE ALL option allows the user to upload up to 127 of the most recent operations performed using the device.

The HISTORY menu also provides the user with the ability to identify each patient by name or other ID. By pressing NEW PATIENT a new patient name will be automatically created. This feature gives the user the ability to differentiate between prior patients' data stored, while allowing the user the flexibility to edit the name of the patient by using the EDIT NAME feature. In addition, history records can be erased from the system by pressing the ERASE RECORDS soft key. This will delete all history records stored on the system.

HISTORY Screen

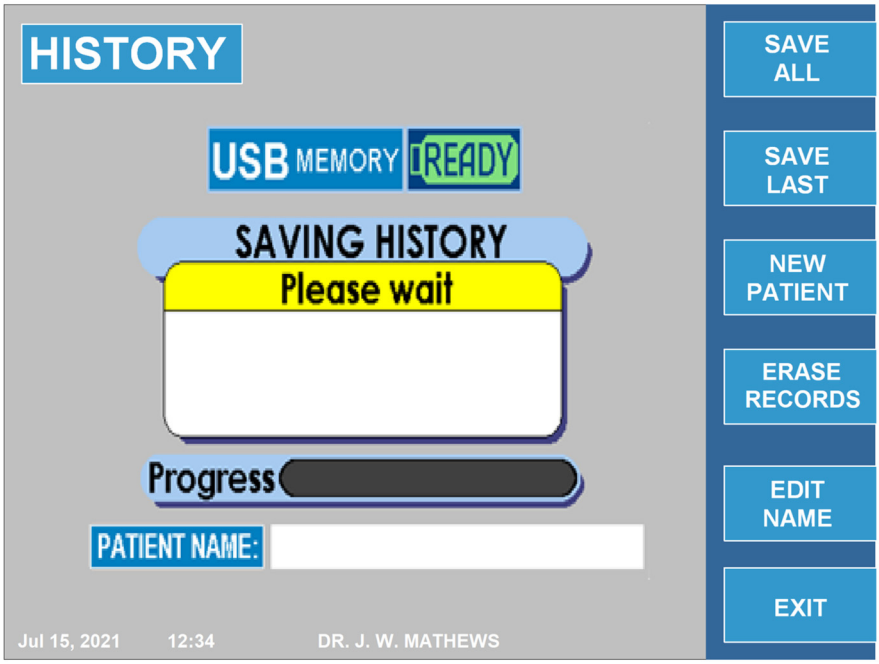


Figure 11-2: History Screen

11.2 PROBE TEST

The probe test feature is designed to test the functionality of reusable probes. It will test the sensor of the probe and continuity of probe and cable. To access this mode, press the UTILITIES soft key from the main menu. Then press the PROBE TEST/ 4 PROBE TEST soft key. The 4 PROBE TEST option will only appear if the MLA-4 is connected.

To maintain sterility of the probe, use a sterile DIROS Probe Test Adapter when testing.

11.2.1 INSTRUCTIONS FOR USING PROBE TEST

Step 1: Insert the test adapter into the Probe Test port on the URF-3AP. Go to the Probe Test mode which can be accessed from the UTILITIES screen.

Step 2: Wait a few moments to let the generator warm up the internal reference temperature. Once the reference temperature reaches 60°C, it will prompt the user to insert the probe.

Step 3: Insert the probe into the adapter and ensure it is fully inserted. The test will automatically begin once the probe is inserted.

Step 4: Once the timer is complete, a PASSED or FAILED messages will appear accordingly.

Step 5: To retest a probe, press the TEST or TEST AGAIN Soft Key to retest the probe.

Note: If there is no MLA-4 connected, the probe test screen will appear as in Figure 11-3. If there is an MLA-4 connected, the probe test screen will display Figure 11-4.

If the MLA-4 is being used, the URF-3AP will automatically identify which probe is being tested and highlight it in a graphic on the screen

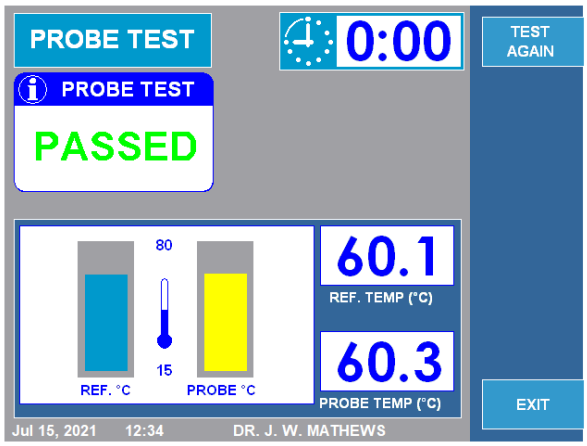


Figure 11-3: Probe Test Screen (without MLA-4)

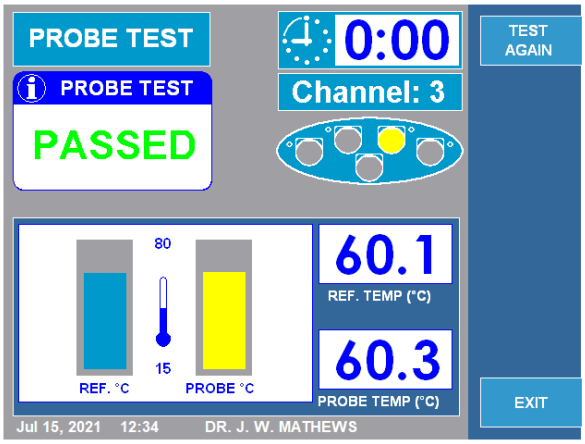


Figure 11-4: Probe Test Screen (with MLA-4)

12 SPECIFICATIONS

SPECIFICATIONS FOR MULTI-LESION SYSTEM URF-3APWITHOUT MLA-4

Impedance

Range (Constantly Measuring Biological Impedance)	0 to 5000Ω

Stimulation

Pulse Repetition Rate	One Shot, 1, 2, 5, 10, 20, 50, 100, 200Hz
Pulse Duration	0.1, 0.2, 0.5, 1, 2, 3ms
Constant Voltage Mode	0 – 10V
Constant Current Mode	0 – 10mA
Pulse Shape	Rectangular. Balanced biphasic, with negative leading pulse.

RF Lesion Generator

Power	0 – 50W
Frequency	480kHz
RF Voltage	0-150V rms
RF Current	0 - 0.7A
RF Mode Conventional RF	Continuous
RF Mode Pulsed RF	1, 2, 3, 5, 8, 10, 15, 20Hz 5, 10, 20, 30, 50ms
Bipolar Lesioning / DiscPlasty	IDET®, DiscTRODE®

Built-in Comprehensive R.F Probe/ Temperature, Power, and Cable Tester

Double Channel Temperature Monitor

Device	Thermistor and/or Thermocouple
Range	20 – 110ºC

Automatic and Manual Temperature Control

Timer

Timer Range	0 to 30 minutes

Output/Input

Color VGA Screen, USB, Ethernet, Footswitch

Operating Voltage

100VAC to 240VAC, 50 – 60Hz
All Active Accessories rated to 150V rms.

Physical Characteristics

Cabinet	Light gauge aluminum, off-white powder coat paint
Dimension	6" (15cm) high x 14" (35cm) wide x 15" (38cm) deep
Weight	17lbs (7.5kg)

Accuracy

± 10% unless otherwise specified

SPECIFICATIONS FOR MULTI-LESION SYSTEM URF-3AP WITH MLA-4

Impedance

Range (Constantly Measuring Biological Impedance)	0 to 5000Ω

Stimulation

Pulse Repetition Rate	One Shot, 1, 2, 5, 10, 20, 50, 100, 200Hz
Pulse Duration	0.1, 0.2, 0.5, 1, 2, 3ms
Constant Voltage Mode	0 – 10V
Constant Current Mode	0 – 10mA
Pulse Shape	Rectangular. Balanced biphasic, with negative leading pulse.

RF Lesion Generator — Number of Simultaneous RF Channels: 4

Power	0 – 50W
Frequency	480kHz
RF Voltage	0-150V rms
RF Current	0 - 0.7A
RF Mode Conventional RF	Continuous
RF Mode Pulsed RF	1, 2, 3, 5, 8, 10, 15, 20Hz 5, 10, 20, 30, 50ms
Bipolar Lesioning / DiscPlasty	IDET®, DiscTRODE®

Built-in Comprehensive R.F Probe/ Temperature, Power, and Cable Tester

Double Channel Temperature Monitor

Device	Thermistor and/or Thermocouple
Range	20 – 110ºC

Automatic and Manual Temperature Control

Timer

Timer Range	0 to 30 minutes

Output/Input

Color VGA Screen, USB, Ethernet, Footswitch

Operating Voltage

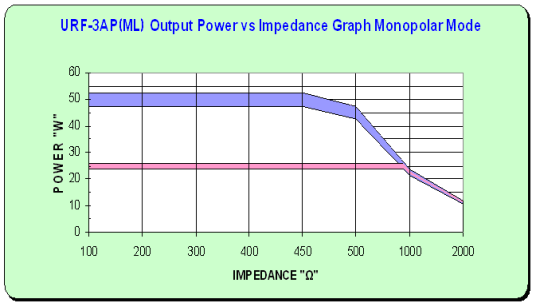
100VAC to 240VAC, 50 – 60Hz
All Active Accessories rated to 150V rms.

Physical Characteristics

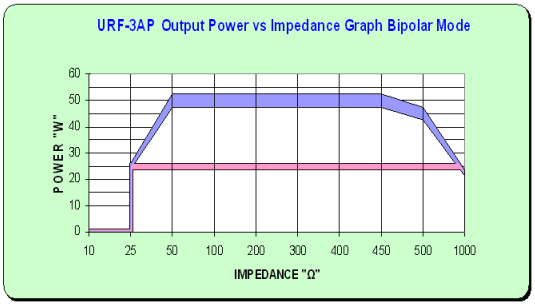
	URF-3AP Generator	MLA-4 Multi-Lesion Adaptor
Cabinet	Light gauge aluminum, off-white powder coat paint	Elliptical molded plastic, Grey V94-0
Dimension	6" (15cm) high x 14" (35cm) wide x 15" (38cm) deep	2" (5cm) high x 7.5" (18cm) wide x 4" (10cm) deep
Weight	17lbs (7.5kg)	

Accuracy

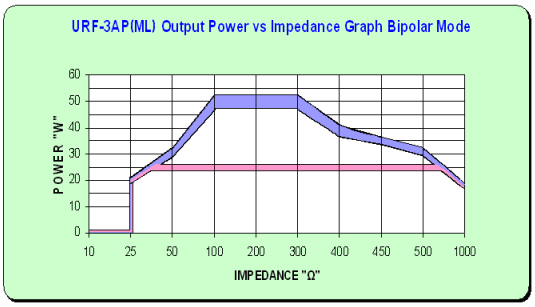
± 10% unless otherwise specified



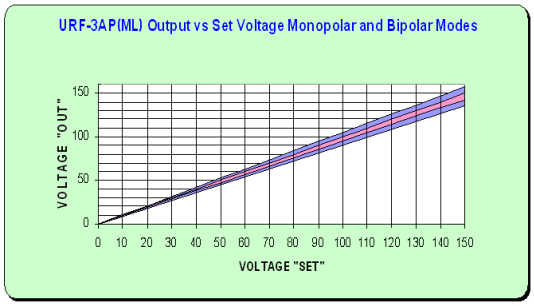
POWER OUTPUT AT FULL AND HALF OUTPUT CONTROL SETTINGS OVER THE RANGE OF 100 TO 2000Ω



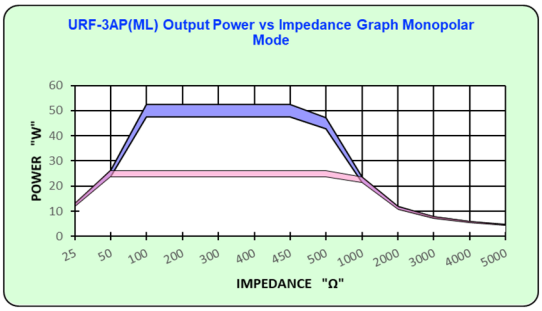
POWER OUTPUT AT FULL AND HALF OUTPUT CONTROL SETTINGS OVER THE RANGE OF 10 TO 1000Ω



POWER OUTPUT AT FULL AND HALF OUTPUT CONTROL SETTINGS OVER THE RANGE OF 10 TO 1000Ω (WITH MLA-4 ATTACHED)



OUTPUT VS SET VOLTAGE IN MONOPOLAR AND BIPOLAR MODES OVER THE FULL RANGE OF RATED VOLTAGE



POWER OUTPUT AT FULL AND HALF OUTPUT CONTROL SETTINGS OVER THE FULL RANGE OF RATED LOAD

13 LABELING SYMBOLS

SYMBOL	SYMBOL NAME	MEANING/DESCRIPTION/USE
	POWER	POWER ON/ POWER OFF
	---	ALTERNATING CURRENT (AC)
	CAUTION	ATTENTION, CONSULT ACCOMPANYING DOCUMENTS
	---	REFER TO INSTRUCTION MANUAL
	---	CONSULT INSTRUCTIONS FOR USE, OPERATOR'S MANAUL; OPERATING INSTRUCTIONS
	---	NEUTRAL ELECTRODE ISOLATED FROM EARTH AT HIGH FREQUENCY
	---	CF TYPE APPLIED PARTS
	TIME	REMAINING TIME DISPLAY, PROGRAMMABLE TIMER
	OUTPUT CONTROL	VARIABILITY
	START (ON)	"ON" FOR A PART OF EQUIPMENT
	STOP (OFF)	"OFF" FOR A PART OF EQUIPMENT
	STIM.	NEGATIVE – GOING PULSES
	TEMPERATURE	TEMPERATURE
	MAX. °C	TEMPERATURE LIMITATION
	ELECTRODE	ACTIVE ELECTRODE
	REFERENCE	RETURN ELECTRODE
	---	NON-IONIZING RADIATION
	EQUIPOTENTIAL GROUND CONNECTION	THIS CONNECTOR IS ATTACHED TO THE CHASSIS/EARTH GROUND. IT IS INTENDED FOR EARTH REFERENCE CONNECTION IN ENVIRONMENTS WHERE EQUIPOTENTIAL GROUND CABLING IS USED.
 2862	CE MARK	THIS PRODUCT COMPLIES WITH REGULATION MDR 2017/745 AND CAN BE MARKETED LEGALLY IN THE VARIOUS EU COUNTRIES. ALL REQUIREMENTS OF THIS REGULATION HAVE BEEN CONSIDERED AND THE PRODUCT COMPLIES WITH THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS.
	---	MANUFACTURER
	---	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

	---	CAUTION, RISK OF ELECTRICAL SHOCK
	---	FOOTSWITCH
	---	UNIVERSAL SERIAL BUS (USB) PORT/PLUG
	---	WEEE MARKING
	---	DATE OF MANUFACTURE
	---	CATALOG NUMBER
	---	SERIAL NUMBER

14 ENVIRONMENTAL CONDITIONS

14.1 TRANSPORT AND STORAGE RANGE

Temperature:	0-50 ºC
Relative Humidity:	15-80% non-condensing RH
Atmospheric Pressure:	500-1060 hPa

14.2 OPERATING RANGE

Temperature:	10-40 ºC
Relative Humidity:	15-80% non-condensing RH
Atmospheric Pressure:	500-1060 hPa

If the unit is outside the operating range it should be gradually returned to the operating environmental range and must be stabilized for at least one hour before use.

15 COMPLIANCE

15.1 CLASSIFICATIONS

CLASS I ME EQUIPMENT, externally powered with detachable cord set
Type CF - patient applied parts
IPX0 - Ingress Protection Rating
Input: 100-240 V, 50-60 Hz, 3-1.5 A
RF Output: 0-150V, 0-50W, 480 kHz
Intended for continuous use in dry pollution degree 2 environments.

15.2 CE MARKING

The OWL Diros Universal RF System, including a RF Generator URF-3AP and Multi-Lesion Adaptor, MLA-4 bears the CE mark "CE-2862", Intertek Medical Notified Body AB, indicating its conformity with the provisions of the Council Regulation 2017/745, concerning medical devices and fulfills the General Safety and Performance requirements of this regulation.
Any other directive(s) and all the standards the product complies to are listed in the general information of the operator manual for the product following this page.
The country of manufacture can be found on the equipment labeling.
The safety and effectiveness of this device has been verified against previously distributed devices. Although all standards applicable to presently marketed devices may not be appropriate for prior devices (i.e. electromagnetic compatibility standards), this device will not impair the safe and effective use of those previously distributed devices.

15.3 ELECTROMAGNETIC COMPLIANCE

15.3.1 GENERAL INFORMATION

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided. This Product is intended for use in the electromagnetic environments as specified.

a. The end user of this product should assure it is used in the environment consistent with the levels characteristic of a typical commercial or hospital environment and NOT used in an environment such as:

i. Near portable and mobile RF Communications equipment.
ii. Near active HF surgical equipment and the RF shielded room of a ME Equipment for magnetic resonance imaging, where the intensity of EM disturbances is high.

b. Portable and mobile radio frequency (RF) communications equipment including antennas, can effect the performance of this equipment. For recommended minimum separation distances, follow the table in section 15.3.6, where distances specified are applicable to any part of the equipment including the cables and other accessories specified by Diros Technology Inc.

c. All cables and accessories connected to the device must be certified to the respective IEC standards. Furthermore, all configurations shall comply with Diros's recommendations. Use cables and accessories only those recommended and manufactured by Diros Technology Inc.. Anyone who connects additional equipment to the signal input or signal output, configures a medical system, and is therefore, responsible that the system complies with the requirements of the standards.

d. The 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:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet or a circuit different from that to which the other device(s) are connected.
- Do not use accessories and cables other than those specified and sold by the manufacturer. Failing to do so may result in the increased emissions or decreased immunity of the Diros OWL Universal RF System, URF-3AP.
- The URF-3AP system should not be used adjacent to or stacked with other equipment, and that if adjacent or stacked use is necessary, the URF-3AP system be observed to verify normal operation in the configuration in which it will be used.
- Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.
- Consult the manufacturer or field service technician for help.

Changes or modifications to this system not expressly approved by Diros Technology Inc. can cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulations regarding EMC and must be installed and put into service according to the EMC information stated in this supplement.

15.3.2 BASIC SAFETY AND ESSENTIAL PERFORMANCE

Operation of the URF-3AP should not cause fire, burns, shocks, mechanical hazards or electromagnetic disturbances for its intended use and environments.
When subjected to EM disturbances, equipment shall not be damaged. No loss of performance or loss/corruption of any settings is allowed. Temporary Degradation during the event, shall be self-recoverable. Power and temperature limits shall not exceed claimed tolerance of +/- 10%.

15.3.3 EMISSION CLASS AND GROUP COMPLIANCE

Guidance and manufacturer's declaration

The URF-3AP is intended for use in the electromagnetic environment specified below. The customer or the user of the URF-3AP should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions (radiated) CISPR 11	Group 1	The URF-3AP uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions (conducted) CISPR 11	Class A	The URF-3AP is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the URF-3AP or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

15.3.4 IMMUNITY TEST LEVELS COMPLIANCE

Guidance and manufacturer's declaration

There are technological limitations in the ability of the system to perform as intended when subjected to interference from electrostatic discharges (ESD) at above the values specified in the table. The following guidelines can greatly reduce the potential for ESD interference prior to connecting any cables to the device:

- Discharge any electrostatic charge from your body prior to connecting any cables to the device.
- You can discharge electrostatic charge by touching the exposed metal equipotential terminal on the back of the device.

The URF-3AP is intended for use in the electromagnetic environment specified below. The customer or the user of the URF-3AP should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic 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 should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line & ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line & ±0.5 kV, ±1 kV, ±2 kV line to ground	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% *UT* (100% dip in *UT*) for 0.5 cycle 0% *UT* (100% dip in *UT*) for 1 cycle 70% *UT* (30% dip in *UT*) for 25 cycles 0% *UT* (100% dip in *UT*) for 5 sec	0% *UT* (100% dip in *UT*) for 0.5 cycle 0% *UT* (100% dip in *UT*) for 1 cycle 70% *UT* (30% dip in *UT*) for 25 cycles 0% *UT* (100% dip in *UT*) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the URF-3AP requires continued operation during power mains interruptions, it is recommended that the URF-3AP be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 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.			

15.3.5 ELECTROMAGNETIC IMMUNITY TEST LEVEL COMPLIANCE

Guidance and manufacturer's declaration

The URF-3AP is intended for use in the electromagnetic environment specified below. The customer or the user of the URF-3AP 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 6 Vrms ISM bands inside 150 KHz to 80 MHz 3 V/m 80 MHz to 2.7 MHz RF communication equipment inside 80 MHz to 6 GHz	3 Vrms 150 KHz to 80 MHz 6 Vrms ISM bands inside 150 KHz to 80 MHz 3 V/m 80 MHz to 2.7 MHz RF communication equipment inside 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the URF-3AP including cables, than the recommended separation 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].

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 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 electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the URF-3AP is used exceeds the applicable RF compliance level above, the URF-3AP should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the URF-3AP

b) Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Additional test frequencies used for URF-3AP immunity compliance:

The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz, 433.05 MHz to 434.79 MHz

Table 9
IEC 60601-1-2:2014

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, FRS460	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						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

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 6100-4-3.

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.

15.3.6 RECOMMENDED SEPARATION DISTANCES

The table below provides the recommended separation distances (in meters) between portable and mobile RF communications equipment and the URF-3AP.

Recommended separation distances between portable and mobile RF communications equipment and the URF-3AP			
The URF-3AP is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the URF-3AP can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the URF-3AP 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	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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 power 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.			

15.3.7 COMPLIANT CABLES AND ACCESSORIES

The use of accessories and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

The table below lists applicable accessories with which the URF-3AP generator is EMC compliant.

Category	Description	Maximum cable length
Adaptor	Multi-Lesion Adaptor MLA-4	2.5 m / 8ft
Cable	Intermediate connection cables	2.5 m / 8ft
Cable	Intermediate adaptor cables	2.5 m / 8ft
Neutral Electrode	GD-PAD Neutral Electrodes	3.0 m / 10ft
RF Electrode	RF Lesion Electrodes with cable	2.5 m / 8ft
RF Probe	RF Lesion Probes with cable	2.5 m / 8ft
RF Cannula	RF Cannulae with cable	2.5 m / 8ft
Hybrid device	RF Hybrid devices with cable	2.5 m / 8ft

NOTE:
Any supplied accessories that do not affect EMC compliance are not included.

16 WARRANTY

Diros Technology Inc. warrants its products against defects in workmanship and materials. This Warranty applies for one year from date of delivery to original purchaser. Obligations under this Warranty are limited to repairing or replacing, at our option, products proven to be defective, in our opinion, and returned prepaid to our factory after prior authorization by an authorized representative of Diros Technology Inc.

This Warranty shall not apply to any instrument, which our inspection discloses to our satisfaction to have become defective due to mishandling, accident, alteration, improper installation or operation, or other causes beyond our control.

Diros Technology reserves the right to make design changes at any time without any obligation to update units previously purchased.

In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Diros Technology Inc. shall not be liable for damages for loss of profits or revenues, loss of use of the product, loss of facilities or services, any downtime costs, or for claims of buyer's customers for any such damages. Diros Technology Inc.'s sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Diros Technology Inc. to buyer which give rise to the claim for liability.

This Warranty is in lieu of and excludes all other warranties expressed, implied or statutory. Diros Technology Inc. is not liable for special or consequential damages.

The buyer's use of this product shall be deemed acceptance of the terms and conditions of this warranty, exclusion, disclaimer and limitations of liability for money damages.

17 GLOSSARY

Term	Definition
Bipolar	Method of RF energy application where the energy delivering and return paths to complete the RF circuit are provided only via introduced electrodes. This method does not require a separate dispersive pad.
DONE	State of the Generator when RF energy has been terminated.
DiscPlasty	Thermal Annuloplasty Technique
Impedance	The effective resistance to the flow of current in a circuit.
Lesion	A localized pathological change in a bodily organ or tissue.
Mode	States of the machine which comprise the necessary steps to complete a procedure. This Generator include: Sensory Voltage or Current Stimulation, Motor Voltage or Current Stimulation, Pulsed Lesion with manual or automatic control, Continuous Lesion with manual or automatic control, DiscPlasty Type1, DiscPlasty Type2, Bipolar Continuous, Bipolar Pulsed and Manual Lesion without temperature sensor.
Monopolar	Method of RF energy application using RF probe and a separate return pad to complete the RF circuit.
ON	State of the Generator when the power is ON.
OFF	State of the Generator when the power is OFF.
START	State of the Generator when RF energy is applied.
STOP	State of the Generator when the RF energy to the Probe (and return electrode if in the Monopolar Mode) has been terminated.
Pulse Duration	A setting which applies to Voltage Stimulation, Current Stimulation and Pulsed Lesion modes. In the Stimulation modes, it describes the length of time of single stimulus pulse. In Pulsed Lesion mode it describes the length of time of single RF burst. It is measured in ms.
Pulse Rate	A setting which applies to Voltage Stimulation, Current Stimulation and Pulsed Lesion modes. In the Stimulation modes it describes the number of stimulus pulses delivered in a second. In Pulsed Lesion modes it describes the number of RF bursts delivered in a second. It is measured in Hz.
Ramp Rate	Setting which is adjustable in Advanced Settings and applies to DiscPlasty mode. It is the rate at which the Generator heats from the initial temperature to the peak temperature.
Ramp Time	A setting which is adjustable in Advanced Settings and applies to the Auto Temp. and Pulsed Lesion modes. It describes the amount of time the Generator takes to reach the Set Temperature.
READY	State of the Generator where settings can be adjusted, and other modes of operation can be chosen prior to RF application.
RF	Radio Frequency
RF Probe	A slender, flexible surgical instrument used to deliver stimulation and RF output to body tissue.
STANDBY	State of the Generator when a valid probe must be connected prior to proceeding to the applicable READY state for the probe.
State	A function of the Generator where a basic task is performed. For instance, the READY state for any mode allows settings to be changed and allows RF energy to be initiated.