AveCure Microwave Generator Operations Manual

Model MWG881-003
Lung Menu

MedWaves, Inc may make improvements or changes in the product(s) or programs described in this publication at any time.

Please read this entire manual before Operating the generator

Table of contents

General warnings and cautions

1.1. Electrical safety

The generator must be tested to verify that it meets your facility's electrical safety requirements for patient contact equipment upon receipt and on regular schedule prescribed by the hospital.

Warning: If the generator fails to meet patient safety requirements, replace it with another one that does, and contact the factory for a replacement and return authorization.

1.2. Prescription and restricted

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

1.3. Stop usage

If generator fails to power up, contact the factory for replacement and return authorization immediately.

If generator shows signs of physical damage, contact the factory for replacement and return authorization immediately.

If generator is dropped from more then 6 inches in height, contact the factory for replacement and return authorization immediately.

1.4. Warning

- DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g. cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

- INSPECT instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.
- The surface of the antenna may remain hot enough to cause burns after the microwave energy is deactivated.
- Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Connect adaptors and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
- This device is not argon enhanced.
- DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.
- This is not a monopolar instrument.
- Use strict sterile procedures during surgical use when handling this device to prevent patient contamination.
- Always use this device under direct visual observation to verify that the ablation/coagulation process progresses as intended and the delivered power selected is correct for the surgical result desired.
- Stop ablation/coagulation when the desired result is achieved.
- **Do not apply microwave power to the probe until the antenna is properly positioned within the tissue to be ablated. Unintentional patient thermal injury could result from misplacing the antenna within the target area or if laid down on the patient between uses.**

If the yellow-orange LED above the front panel power switch fails to blink when microwave is on or stop blinking when microwave is off, Remove AC power from the unit immediately and replace the generator. Contact the factory for return authorization and a replacement.

US 858-946-0015 and ask for customer service.

1.5. Precautions

- Prior to the procedure, all equipment should be checked to verify proper function and integrity.
- Do not place surgical instruments like forceps, hemostats and retractors in the immediate area where the microwave energy is emitted.
- The time setting should be set as low as necessary to achieve the desired effect.

1.6. Use with endoscopic equipment

Warnings:

- Interconnections conditions require the applied parts of other medical equipment used within the configuration for endoscopic application to be Type BF applied parts or Type CF applied parts.
- Risks resulting from gas embolism caused by, for example, overinsufflation of air, inert gas prior to use of our ablation system are present.
- When the ablation system is used with energized endoscope, patient leakage currents may be additive. This is particularly important if a Type CF applied part endoscope is used.
- If the ablation system is used with laser equipment, ensure proper safety precautions are taken, including avoidance of potential eye damage to the operator. Suitable protective filtering spectacles or eyepieces are recommended.
- Before use with endoscopic equipment, the ablation system should be checked for compatibility with the equipment to ensure there is no damage. Ensure the active microwave antenna does not come into contact with the endoscopic equipment, and the tip does not penetrate into the endoscopic equipment.
- Before use, check the ablation device to ensure there are no unintended rough surfaces, sharp edges, or protrusions which may cause harm.

1.7. MRI Safety Information

MR Unsafe: Keep the Microwave Generator outside the MRI scanner room.

2 . Agency requirements

MedWaves surgical microwave generator and system meet the requirements outlined by IEC 60606-1, IEC 60601-2-2, IEC 60601-1-2

3 . Purpose of the device

This surgical microwave generator shall be used only with MedWaves proprietary ablation probes to ablate soft tissue under order of a qualified physician for the indication specified.

Indications for use: The MedWaves AveCure Ablation System is intended for use in percutaneous, laparoscopic, and intraoperative coagulation-ablation of soft tissue. It is not intended for use in cardiac procedures.

4 . System overview

4.1. System components

MedWaves, Inc., microwave surgical ablation system consists of the following:

Sterile ablation probe not shown.

Figure-1: MWG 881 front panel

Figure-2: MWG 881 rear panel

Figure-3: Microwave power cable and signal extension cable (supplied sterile and wrapped together). On the power cable, the large type-N connector connects to the generator. The small SMA connector connects to the probe. Cables not included with generator.

4.2. Key features

4.2.1. Temperature controlled ablation:

The generator uses temperature feedback to control the ablation process. Based upon real time tissue temperature readings, the generator will automatically control the forward power applied to the tissue. The set temperature in the ready screen determines the highest target temperature the ablation will reach.

4.2.2. Over temperature check:

The generator monitors temperature from embedded senor in probe antenna and halts the microwave energy application when it exceeds 140 ºC ± 3 ºC and displays "Temperature Over Limit, Check Connections".

4.2.3. Reverse power check:

The generator monitors both reverse and forward microwave power ratios and selects the frequency that generates the lowest ratio for ablation process.

4.2.4. Maximum power check:

The generator monitors forward microwave power and halts if the microwave power exceeds maximum allowed.

4.2.5. System check

The generator performs self-check and halts if it encounters hardware or configuration errors during power up and operations.

5 . Environmental conditions

5.1. General

The surgical microwave generator is design to be used by trained personnel under the supervision of a prescribing physician in hospital surgical theater. The surgical operation could be invasive or minimally invasive in nature. The generator must be powered from a grounded hospital outlet with a hospital grade power cord (one is supplied). The generator should be place on a table or a cart adequate to support its weight (12 kilos) without any signs of instability, and within easy of the user so that disconnection becomes difficult.

5.1.1. Operating/storage temperatures

The generator operating room temperature must not exceed 30°C for a prolonged period.

The generator storage temperature must not exceed 40°C for a prolonged period.

5.1.2. Recommended electrical setup

The generator is shipped with a hospital grade, 10ft AC power cable which should be used. In the event that a longer distance is needed, please use a hospital grade power cable.

The ablation operation should be performed at a minimum distance of 1meter from any sensitive wireless communication system.

The AveCure System requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the rest of this document. Portable and mobile RF communications equipment may be affected by medical electrical equipment.

If stacked or adjacent use with other equipment is necessary, the AveCure System should be observed to verify normal operation in the configuration in which it will be used.

5.1.3. AC power requirements

AC Power input range
100 VAC to 240 VAC, 50/60 Hz, 3 Amperes (shown selected)

6 . Installation

6.1. Unpacking

6.1.1. Before unpacking the generator, check the overall condition of the shipping box for obvious shipping damage.

If there is shipping damage, record the damage, contact the factory for a replacement, and return authorization.

6.1.2. If there is no visible shipping damage, open the box.

6.1.3. Remove power cord, the generator and the remaining foam cushions from the shipping box.

6.1.4. Remove foam and set the generator on an appropriate-stable working surface.

6.1.5. Check the power cord for damage.

6.1.6. Check the generator for damage.

6.1.7. Perform electrical safety tests as your facility requires.

The generator is ready for use if it has met your facility's electrical safety test requirements.

6.2. Check-out

6.2.1. Connect the system to an appropriate AC power source and toggle the rear AC inlet filter I/O switch to On (I).

Connect the medical grade AC power cord to the AC inlet filter assembly.

Toggle the front panel On/OFF Toggle switch to 'ON' and observe that the generator performs proper power up sequence and indicates ready for ablation.

Check for proper operation of cooling fans on the rear panel.

Front panel switch OFF:

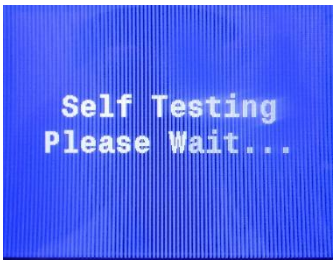
Front panel switch ON:

(Green power on indicator in the switch)

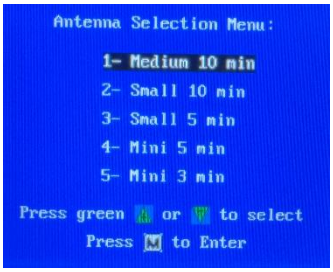
The first power up screen is the MedWaves logo and firmware version for ~1 second.

The second power up screen is “Initializing Please Wait” for ~1 second.

The third power up screen is “Self-testing Please Wait”. Five hexadecimal check sum numbers will flash consecutively.



The final default screen shows the antenna selection menu with five antenna options to choose from.

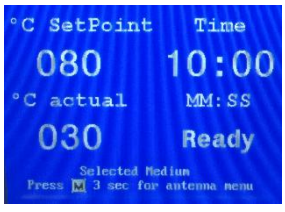


Press the green up/down arrows to select the desired antenna and press the M button to enter that selection.

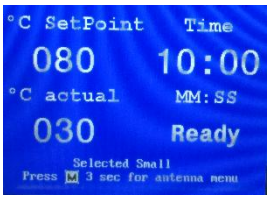
Each antenna has different default settings listed below:

1. Medium 10 min – 80°C, 10 minutes, 30 Watts
2. Small 10 min – 80°C, 10 minutes, 26 Watts
3. Small 5 min – 80°C, 5 minutes, 26 Watts
4. Mini 5 min – 80°C, 5 minutes, 16 Watts
5. Mini 3 min - 80°C, 3 minutes, 16 Watts

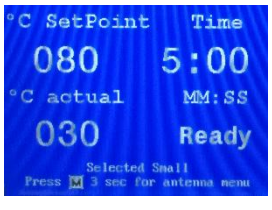
Medium 10min



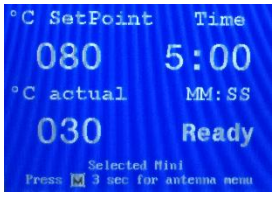
Small 10min



Small 5min

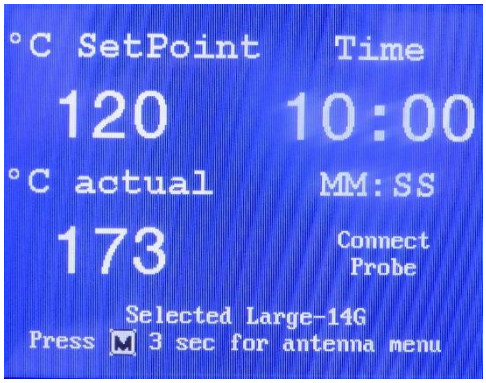


Mini 5min

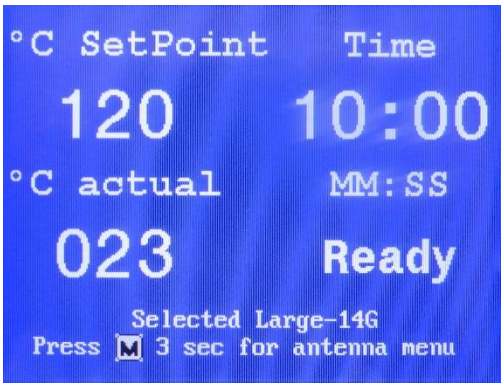


Mini 3min

Please note if a probe is not connected, a reminder is shown to connect the probe. Otherwise, the real-time temperature will be displayed along with the “Ready” message:



Not Ready



Ready

The generator is ready for use if it has met your facility’s electrical safety test requirements.

7 . Summary Instruction

7.1. Keypad

7.1.1. Keypad functions prior to microwave application:

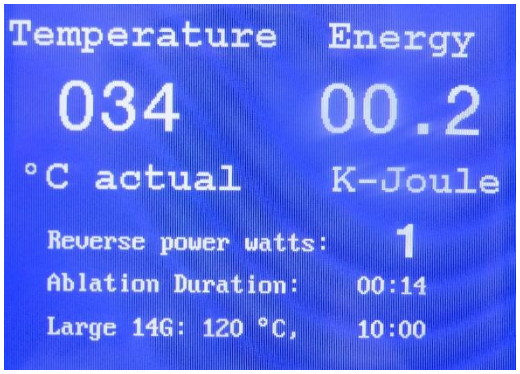
The **Green +/-** keys are used to adjust ablation temperature setting on the ready screen.

The **Blue +/-** keys are used to adjust the ablation time duration on the ready screen.

The **Grey M** key is used to return to the antenna selection menu and also to toggle between displays during an ablation.

7.1.2. Microwave energy control:

The Yellow I/O key toggle activates microwave energy on and off.

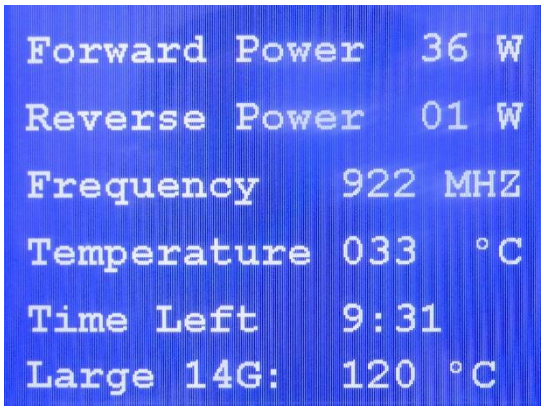


Default ablation display

7.1.3. Keypad functions during microwave application:

The **Grey M** is the only key function available during microwave energy application to toggle select between normal or alternate ablation displays.

Alternate ablation display



The yellow-orange LED above the front panel **power switch will blink when microwave is on. It is off when microwave is not being applied.**

All other keys are non-functioning for the duration of microwave energy application cycle.

The front panel on/off switch can be used anytime to shut off the microwave energy application.

Operating instructions

7.2. Preparation for operation

7.2.1. Place the generator on a sturdy surface approximately level with the patient table in the operating room where it is in easy reach of the MW and Signal extension cable and AC power source.

7.2.2. Connect the system to an appropriate AC power source and toggle the rear AC inlet filter I/O switch to On (I).

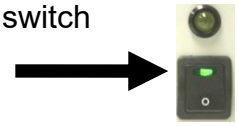
Connect the medical grade AC power cord to the AC inlet filter assembly.

Check for proper operation of cooling fans on the rear panel.

Toggle the front panel ON/OFF Toggle switch to on and observe that the generator performs proper power up sequence and indicates ready for ablation.

Front panel switch Off:

Front panel switch On:



If the system fails to conform to local electrical safety test requirement, replace it immediately and call the factory for return authorization.

7.2.3. Obtain appropriate number of sterile microwave power cable, temperature cable and ablation probes as necessary for procedure plan.

7.2.4. When ready, remove the sterile probe from the sterile pouch and place it in the sterile field.

Care should be taken not to contaminate the sterile field

7.2.5. Remove the extension cables from the sterile pouch and identify the probe end of the cables. Connect the small SMA connector of the microwave cable to the probe in the sterile field.

7.2.6. Connect one end of the temperature cable to the probe in the sterile field by lining up the arrows, pushing in the connector, and securing the locking mechanism.

7.2.7. Place the other end of the temperature cable out of the sterile field and connect it to the receptacle on the generator rear panel marked “accessory connector”. The temperature reading on the generator should drop from a high value to probe-reading temperature.

7.2.8. Place the type-N (larger) connector end of the microwave cable out of the sterile field and connect it to the receptacle on the generator rear panel marked “Microwave output”

Generator connections:

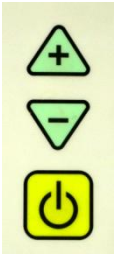
Care should be taken not to contaminate the sterile field

7.3. System test prior to probe insertion

Once the microwave probe is connected to the generator with the extension cables, place the distal 6cm of the probe antenna into a container of saline solution on the surgical tray. Both container and saline need to be sterile. Select the appropriate antenna selection from the generator menu and input desired ablation settings. While ablating into the sterile saline, confirm the correct forward power level of the antenna. Monitor the reverse power and ensure it remains low (<5 watts). The temperature reading should be stable and increase steadily. Use caution handling the probe and avoid damage to the device.

7.4. Applying microwave energy

Once the microwave probe is positioned in a patient for ablation, Microwave energy can be applied by pressing Yellow-I/O key once.

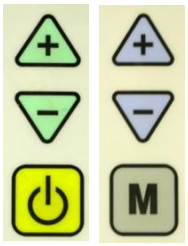


The Yellow-I/O key toggles the microwave power on and off.

Ablation process can be halted any time during the ablation cycle by pressing the Yellow-I/O key or by toggling the front panel power switch to off.

7.5. Control settings

7.5.1. The **Green +/-** keys are used to adjust set temperature or power.



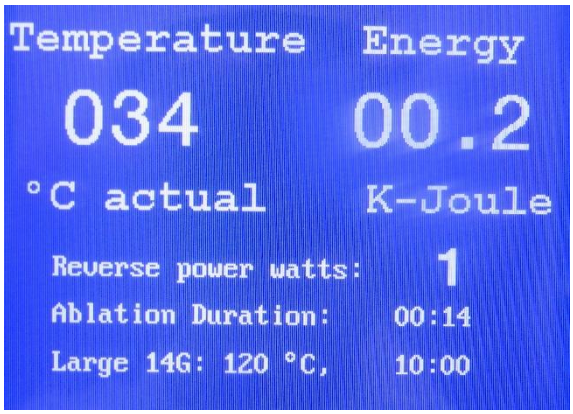
7.5.2. The **Blue +/-** keys are used to adjust the ablation duration. In the antenna menu, these buttons are used to highlight the desired probe model.

7.5.3. In the Ready screen, if the **Grey M** key is pressed for 3 seconds, the generator will return to the antenna selection menu. In the antenna menu, this key selects the desired probe model.

7.5.4. Microwave Ablation

Select the desired temperature and time settings for ablation (ablation guidelines found on probe instructions for use).

Start microwave ablation process by pressing the **Yellow I/O** key.



The display shows the temperature (°C) and energy delivered (kJ) on the upper half.

Reverse power is displayed in watts.

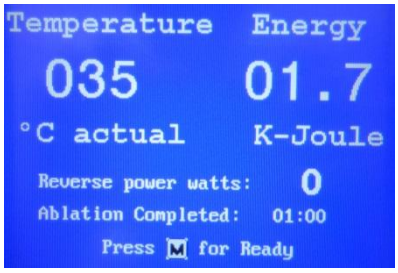
Ablation duration is displayed in minutes and seconds.

Initial settings are displayed on the last line of the display.

The yellow-orange LED over the power switch also blinks on and off when microwave energy is applied.

The generator will complete the ablation cycle as specified if no halt conditions are encountered.

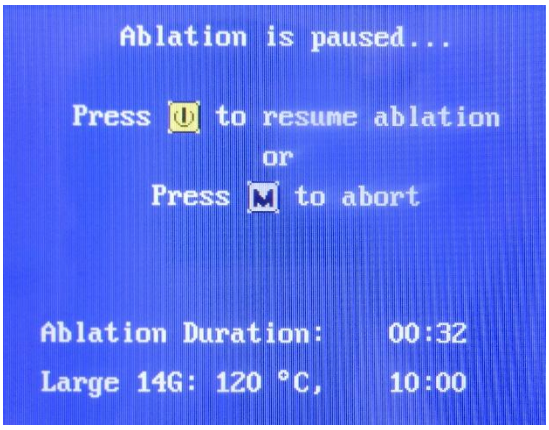
When the generator completes the ablation process as specified, the display will show the “Ablation Completed” message and total energy delivered. Press the **Grey M** button to return to the Ablation Ready screen.



The yellow-orange LED over the power switch should be off.

If not, remove AC power immediately

During an active ablation, the cycle can be paused by pressing the **Yellow I/O** key. The display will show the ablation settings and ablation duration:



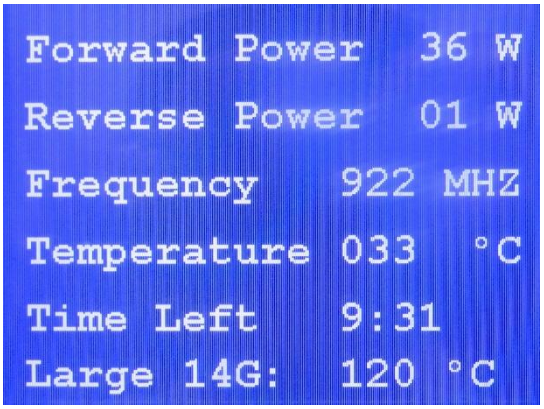
The yellow-orange LED over the power switch is off.

Press the **Yellow I/O** key to resume the ablation or the **Grey M** key to abort. If aborted, the generator will return to the ready screen for the next ablation.

Alternate Display

During the ablation process, display can be toggled between regular display and alternate display modes by pressing the **Grey M** key.

The alternate display shows forward power, reverse power, operating frequency, current temperature, time left, and antenna setting.



If the **Grey M** key is pressed again, the display reverts to regular screen.

7.6. Reverse Power Control

7.6.1. General information

Reverse power is a direct indication of microwave energy returning back to the generator. This occurs when the microwaves have trouble propagating from the antenna into the tissue, usually because there is not enough tissue contact, or if the tissue type is not conductive to microwaves. The generator provides reverse power feedback so the user knows how well the ablation is progressing and what type of environment the antenna is in. The generator will automatically select the best operating frequency with the lowest reverse power.

7.6.2. High reverse power

When the reverse power climbs up to 3-4 watts, the generator buzzer will beep with double pulses. If the reverse power climbs up to 5 or more watts, the buzzer will beep with triple pulses. If the reverse power stays above the threshold of 5 watts for more than 20 consecutive seconds, the reverse power alarm will sound and the following error message will be displayed:

This message will also be displayed if the reverse power increases to more than 40% of the forward power.

7.6.3. Correcting Reverse Power

If the reverse power starts high immediately at the start of an ablation, the antenna is in a poor microwave environment or the microwave extension cable is not fully connected. After checking the connections, the best way to mitigate reverse power is through antenna repositioning. By finding a new environment where the antenna has better contact, the reverse power will be improved.

It is common to see the reverse power increase as the ablation progresses and tissue dries out. Tissue shrinkage around the antenna may also result in an increased reverse power. Antenna repositioning is still the best approach to obtain better contact. It may be necessary to account for high reverse power by ablating for additional time.

Halt conditions

7.7. System Error

This halt condition will occur if the generator encountered a hardware or configuration error during initialization or operation.

When “System Error, Contact Maintenance” occurs:

Cycle the front panel power switch to off, wait ~3 seconds, and to on to clear it.

If it occurs more than once, replace the generator immediately and contact the factory for return authorization and a replacement.

US 858-946-0015 and ask for customer service.

7.8. Power Detect Error

This halt condition will occur if the reveres power to forward power ratio is larger the 40%.

When “Power Detect Error” condition occurs:

Cycle the front panel power switch to off, wait ~3 seconds, and to on to clear it.

Verify all microwave connections are secure.

If it occurs again, replace microwave power cable or probe

Return to ablation process.

If the halt condition persists, replace the generator immediately and contact the factory for return authorization and a replacement.

US 858-946-0015 and ask for customer service.

7.9. Over temperature

This halt condition will occur if temperature sensed by the embedded sensor in probe antenna experiences temperature above 140 ºC ± 3 ºC,

When this condition occurs:

Ensure all cable connections are securely attached.

Cycle the front panel power switch to off, wait ~3 seconds, and to on to clear it.

If it reoccurs, replace the probe or temperature cable and try again.

If the halt condition persists, replace the generator immediately and contact the factory for return authorization and a replacement.

US 858-946-0015 and ask for customer service.

7.10. Over Power

This halt condition will occur if output power reaches maximum limit of the generator.

When “Over power contact maintenance" condition occurs:

Cycle the front panel power switch to off, wait ~3 seconds, and to on to clear it.

If it reoccurs, replace the probe or microwave power cable and try again.

If the halt condition persists, replace the generator immediately and contact the factory for return authorization and a replacement.

US 858-946-0015 and ask for customer service.

8 . Specification

Microwave:	
Power:	40 watts maximum (36 watts selectable)
Temperature control range:	60°C to 130°C ± 3°C
Frequency:	902-928 MHz
Maximum temperature:	140°C ± 3°C
Power control range:	16 watts to 36 watts
Timing:	0seconds- 16 min, 35 seconds; ±3% or 2sec
Connections:	
Microwave:	Type N
Temperature:	8 Pin DIN
Display:	5.5” LCD display, color
Power:	100-240 VAC (auto-select)
Dimensions:	40.7 x 45.7 x 15.9 cm
Weight:	12.5 kg

9 . Cleaning

The generator should be cleaned with damp cloth or sponge wetted with hospital detergent disinfectant followed by a damp cloth or sponge wetted with water for wipe.

1 0 . Troubleshooting

IF the generator fails to function safely, not power up, check out, or persistently halts with error messages, replace the faulty unit immediately.

Call the factory for return authorization and for immediate shipment of a replacement unit.

Warning: the faulty generator should never be opened or tampered with unless by a factory authorized maintenance personnel.

11. Fuse

On those rare occasions when fuses located inside the AC inlet filter fuse-box would open:

Disconnect the generator from AC power.

Gently pry open fuse-box with a small screw-driver.

Replace the damaged fuse(s) with 8X20MM 5A 250V fuse.

Contact the hospital's maintenance department for assistance if this problem persisted.

12. Maintenance and repair

All internal parts will be maintained/repaired by MedWaves Inc.'s factory authorized service center.

Currently, the only factory that is an authorized service center is located at:

MedWaves, Inc., 16760 W Bernardo Drive, San Diego, CA 92127

Phone number: US 858-946-0015

Each system should be checked for calibration per schedule date on the calibration label adhered to the generator by a factory authorized service center, or verified with calorimetric methods below.

1. The temperature reading should be verified using room-temperature and boiling-water baths with a standard ablation antenna. A calibrated temperature gauge must be used as a reference to verify generator temperature readings of the room-temperature and boiling-water baths. A care should be taken to limit the standard ablation antenna handle from being exposed to the rising steam from the boiling-water bath. Both baths should be deep enough to cover the temperature sensor position of the standard antenna and large enough in volume to maintain stable temperatures. The temperature readings should be recorded approximately 5 to 10 seconds after the antenna is placed in the baths. The temperature readings should be within ±3°C for room-temperature bath, and +1°C and -3°C at boiling-water bath.

2. The ablation energy should be verified using pieces of exvivo tissue such as, beef or pork muscle cut to 7cm x 7cm x 10cm and equilibrated to 24°C. The verification should include at least one Medium antenna and one other antenna (small or mini), and their default settings are to be used. The antennas should be inserted in the test tissue along it long axis to depths deep enough to cover the temperature sensor location plus the 2cm minimum. The ablation zone created with each antenna should be compared with the ablation guidelines provided with each probe.

If the generator fails to verify per above methods, Please contact the factory for return material authorization (RMA) to return it for service and to obtain a replacement unit.

Warning: the faulty generator should never be opened or tampered with unless performed by a factory authorized maintenance personnel.

1 3 . Guidelines and Manufacturer's Declaration – Emissions

The AveCure™ Microwave System is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.

Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 2	The AveCure System uses RF energy within the ISM Band 902-928MHz and has an unrestricted limit for emissions within this band
RF Emissions CISPR 11	Class A	The AveCure System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonics IEC 61000-3-2	Class A	
Flicker IEC61000-3-3	Pass	

14. Guidelines and Manufacturer's Declaration – Immunity

The AveCure™ Microwave System is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.

Immunity Test	**IEC 60601 – Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
ESD EN61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%
EFT EN61000-4-4	±2 kV Mains ±1 kV I/Os	±2 kV Mains ±1 kV I/Os	Mains power quality should be that of a typical hospital environment
Surges EN61000-4-5	±2 kV Common ±1 kV Differential	±2 kV Common ±1 kV Differential	Mains power quality should be that of a typical hospital environment
Magnetic Field EN61000-4-8	3 A/m Continuous field	3 A/m Continuous field	Power frequency magnetic fields should be that of a typical hospital environment
Voltage Dips/Dropout EN61000-4-11	<5% U_T for 0.5 Cycle 40% U_T for 5 Cycles 70% U_T for 25 Cycles <5% U_T for 5 sec	<5% U_T for 0.5 Cycle 40% U_T for 5 Cycles 70% U_T for 25 Cycles <5% U_T for 5 sec	Mains power quality should be that of a typical hospital environment. It is recommended to supply the AveCure system from an uninterruptible current supply

1 5 . Guidelines and Manufacturer's Declaration – Immunity

The AveCure™ Microwave System is intended for use in the electromagnetic environment specified below. The customer or user should ensure 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	$3V_{eff}$ 150kHz - 80MHz	3V	Portable and mobile communications equipment should be separated from the AveCure System by no less than the distances calculated/listed below Recommended distances: d= 1,167*√(p) d= 1,167*√(p) d= 2.33*√(p) where P is the max. power in watts (W) and D is the recommended separation in meters (m). Interference may occur in the vicinity of equipment containing following symbol 
	3V/m 80 MHz - 2.5GHz	3V/m	

European Authorized Representative

EC REP

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16. Symbol Glossary

Symbol	Title	Description	Standard	Reference No.
STERILE EO	Sterilized using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements	5.2.3
⚠	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO-15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.4.4
EC REP	Authorized European Representative	Indicates the authorized representative in the European Community.	ISO-15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.1.2
	Manufacturer	Indicates Device Manufacturer. Includes name and address of the Manufacturer.	ISO-15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.1.1

	MR Unsafe	This item should not be brought into the MRI Environment.	ASTM F2503 – 13 Standard Practice for making medical devices and other items for safety in the magnetic resonance environment.	7.3.1
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.1.5
	Use by	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.1.4
	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.2.6
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.4.2

	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.4.3
Rx Only	Prescription Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.	21 CFR 801.109 – Labeling – Prescription devices.	NA
CE	CE Marking	Signifies European Technical Conformity	Directive 93/68/EEC	N/A
	Non-ionizing electromagnetic radiation	There are elevated, potentially hazardous, levels of non-ionizing radiation. This equipment intentionally applies RF electromagnetic energy for treatment	IEC 60601-2-6 Particular requirements for the basic safety and essential performance of microwave therapy equipment	201.7.2.101
	Keep Dry	Keep equipment away from rain or other liquids	ISO 15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.3.4
	Do not use if package is damaged	Do not use if the product sterilization barrier or its packaging is compromised	ISO 15223-1 Medical Devices – Symbols to be used with medical devices labels, labeling and information to be supplied – Part 1: General requirements.	5.2.8