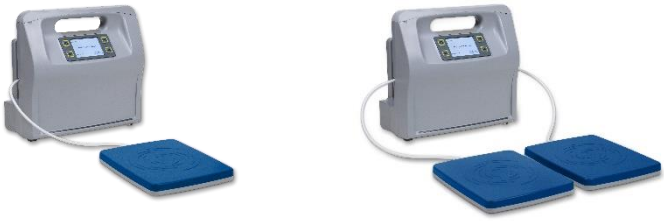
REPRIEVE

Pain Relief by REGENESIS®



Reprieve 60 by Regenesis

Compliance and Compatibility Assessment (CCA) device

Instruction Manual

Regenesis Medical Customer Service

1-877-970-4970

Save this manual for future reference.

Table of Contents

Introduction

The Reprieve 60 by Regenesis (Reprieve 60) is a home-use shortwave diathermy device designed to relieve pain and alleviate muscle spasms.

Please read this entire instruction manual carefully before using this device.

The Reprieve 60 device assesses compliance and compatibility with Reprieve therapy and is active for 60 days from the first time you plug the device in.

You will be notified of the remaining number of active days on the Reprieve 60 device. At the end of the 60-day assessment period, contact Regenesis Medical to return the device.

If you have any questions, please contact Regenesis Medical:

Phone: 1-877-970-4970

Website: www.regenesismed.com

Email: support@regenesismed.com

About Shortwave Diathermy

Shortwave diathermy (SWD) uses electromagnetic energy to produce a thermal effect in tissues. The Reprieve 60 by Regenesis device can operate in continuous or pulsed wave modes with varying power levels. As the pulsed mode has lower average power, potential hazards typically associated with the continuous wave mode may not apply.

Transmission Profile	Continuous Wave	Pulsed Wave*
Pulse Duration	N/A (Continuous)	20, 40, 60, 80, and 100 microseconds
Pulse Frequency	N/A (Continuous)	200, 400, 600, 800, and 1000 Hz
Duty Cycle	100%	0.4% to 10%
Signal Strength	9W	0.3 W to 7.0 W

* The Reprieve 60 device is factory-set to an initial recommended setting.

- Contraindications: Conditions under which the device should not be used as the risk of use outweighs potential benefit (e.g., reasons not to use this device).
- EMC: Electromagnetic Compatibility – the ability of the Reprieve 60 device to operate effectively in the presence of other electronic devices.

Precaution: Hazard that may result in minor to moderate injury to the user or damage to the equipment or other property

Warning: Hazard that may lead to death or serious injury

There are important operating, maintenance and service instructions in the literature accompanying the product.

The presence of uninsulated dangerous voltage within the product's enclosure may be of sufficient magnitude to constitute a risk of electric shock.

This device intentionally applies electromagnetic energy for medical treatment.

This device is a Type BF applied part. The Treatment Applicator Pads are safe to place against a living body.

This device is Magnetic Resonance (MR) unsafe – keep away from magnetic resonance imaging (MRI) equipment

IP21

This device carries an Ingress Protection (IP) Rating of 21 – is protected from touch by fingers or similar objects and from water spray less than 15 degrees from vertical.

Indications and Contraindications for Use

Indications for Use

- The Reprieve 60 by Regenesis device (Reprieve 60) is indicated to generate deep heating within body tissues for the treatment of conditions such as relief of pain and muscle spasms.
- Reprieve 60 is intended for adults only (22 years of age and older).

Contraindications

- NEVER use Reprieve if you:
  - Are pregnant
  - Have a blood clotting disorder
  - Have impaired cognition (an inability to comprehend how to use device or follow instructions for use)
- NEVER use Reprieve 60 over the following locations or conditions:
  - Active implanted deep brain stimulators, spinal cord stimulators, and cardiac pacemakers
  - Active cancer
  - Developing fetus
  - Developing gonads
  - Active inflammation or infection
  - Metal implants, not including metal screws, rods, and plates
    - i.e., it is safe to use over metal screws, rods, and plates

If your prescribing clinician is not aware of the any of the above contraindications, call your clinician to discuss your situation before using this device.

WARNING: Choking and Strangulation Hazard – Keep the device and cables out of the reach of children and pets.

WARNING: Consult your physician if the intended area of treatment is a prior cancer site.

WARNING: Do not administer more than one treatment every two hours. Exceeding the recommended time limits can result in tissue becoming overheated and damaged.

WARNING: Do not use this device:

- Unless you are the prescribed user.
- If the cable(s), power supply, and/or Treatment Applicator Pad(s) are damaged.
  - Inspect regularly for possible damage.
- In the presence of flammable anesthetic mixtures or in oxygen rich environments.

CAUTION: When using over the following areas or conditions:

- Breached or compromised skin (i.e., open wound, surgical incision)
- The ocular and orbital regions (eye area)
- The head or neck
- Poorly vascularized tissue(s)
- Areas of thermal insensitivity
- Areas of impaired sensation
- Implanted metal lead wires
- Noncopper, metallic intrauterine devices (IUDs)

- Shortwave diathermy applied to the lower back in women can result in increased menstrual flow during menses.
- Consistent and vigorous heating can result in edema of the skin, subcutaneous fat, and muscle tissue.

Discontinue device use and consult a physician or qualified individual if adverse effects occur.

General Usage and Safety Guidelines

Federal law restricts this device to sale by, or on the order of, a licensed health care practitioner.

Follow these guidelines for the safe and effective use of Reprieve:

- The therapy administrator should not be within 3 inches of the treatment area for more than 6 minutes.
- Any persons with a pacemaker should not be within 6 inches of the treatment area.
- Follow your clinician's instructions for best results.
- Do not use an alternate A/C power supply other than the one supplied by Regenesis Medical (P/N 315-2000-00).
- Remove all jewelry, watches, hearing aids, or metallic items that are on the area to be treated before use.
- Treatments can be given through clothing or dressings without removing them.
  - Never treat over wet skin or clothing.
- Do not stand on Treatment Applicator Pad(s).
- Do not submerge this device in water or other liquids.
- Do not use this device while driving.
- Keep this device away from other electronic devices. If this is not possible, monitor nearby devices to avoid interference. Take these steps to avoid disrupting other medical equipment:
  - Keep the Treatment Applicator Pad(s) away from other electronics or cables,
  - Move the devices further apart,
  - Untangle cables,
  - Plug the device into a different outlet.

1	Base Unit	5	LCD Screen
2	Treatment Applicator Pads	6	Control Panel
3	Applicator Cables	7	Indicator Light
4	A/C Power Supply (not pictured)		

If any items are missing or appear damaged,
Contact Regenesis Medical Customer Service

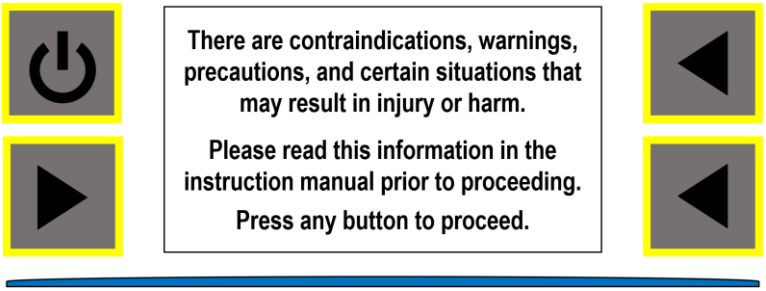
1-877-970-4970

- Read Contraindications, Warnings, and Precautions sections before using.
- Unbox the device and check for damage or missing parts.
- Choose a stable location for the device with easy access to Control Panel.
- Ensure cables are not a tripping hazard.

WARNING: Choking and Strangulation Hazard – Keep the device and cables out of the reach of children and pets.

- Firmly plug in A/C Power Supply and Cable.

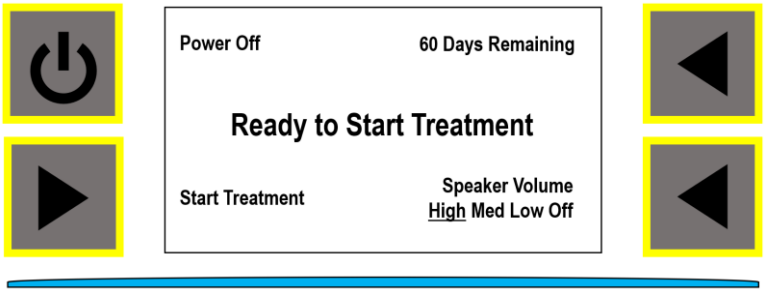
- The following message will appear on the LCD screen and the indicator light will flash blue:



You MUST read the contraindications, warnings, and precautions before proceeding.

- Press any button to proceed.

- Find a comfortable position with easy access to the treatment site.
- Remove all jewelry, watches, hearings aids, or metallic items that are on the area to be treated before use
- To turn on the device from sleep mode press any button
- The LCD screen will display "Ready to Start Treatment," a countdown of remaining treatment days, and the indicator light will be a solid blue.



Instructions for Use: POSITION TREATMENT APPLICATOR PAD(S)

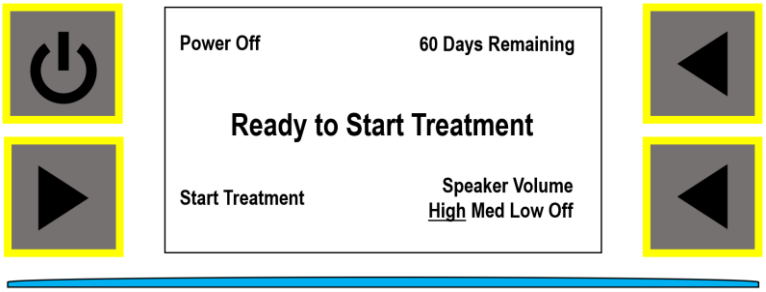
- Position the Treatment Applicator Pad(s) on the treatment site(s).
  - Use the Treatment Pad Positioning Guide for assistance.
  - Ensure the Treatment Applicator Pad(s) are separated from any metallic surface with padding.
  - Ensure the dark colored side of the Treatment Applicator Pad(s) are facing the area being treated.

The dark colored side of the Treatment Applicator Pad(s) should be facing the area you are treating.

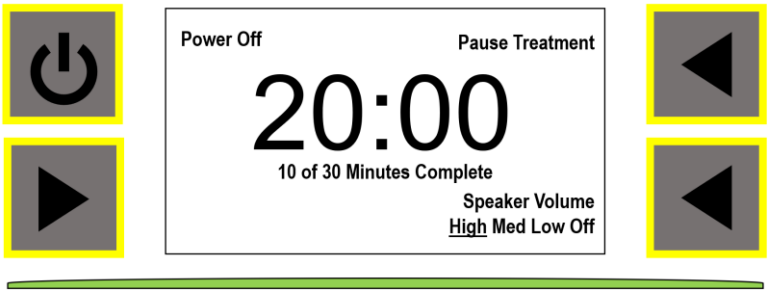
- Apply only one Treatment Applicator Pad to the specific area you are treating.
- Treatments can be given through clothing or dressings without removing them.

⚠ CAUTION: Do not apply Treatment Applicator Pad directly to breached or compromised skin (i.e., open wound, surgical incision).

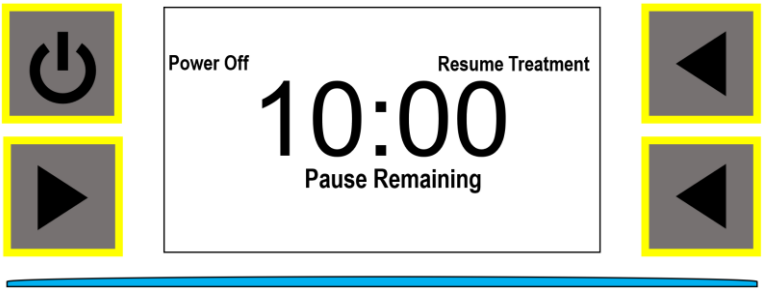
- Press "Start Treatment" (▶) on the Ready to Start Treatment Screen and listen for a beep.



- During treatment, the LCD screen will display a Countdown Timer and active buttons (Power Off, Pause Treatment, and Speaker Volume) and the indicator light will flash green.



- Pause Treatment
  - Press "Pause Treatment" (◀) on the top right to temporarily halt the treatment.
    - You will have 10 minutes to resume treatment.
    - The LCD screen will show a "Pause Remaining" timer and the indicator light will be solid blue.
  - To resume treatment, press "Resume Treatment" (◀) on the top right before the 10-minute countdown finishes.



- End Treatment
  - If you need to end the session early, press "Power Off" (⏻) and confirm with "YES" to stop the treatment.
  - Treatment ends automatically when the prescribed time is up.
  - The device will enter sleep mode (LCD screen turns off).
  - To fully power down the device, unplug the A/C Power Cable after the LCD screen turns off.

Cleaning and Storage

- Cleaning:
  - DO NOT SUBMERGE this device in water or other liquids.
  - Before cleaning, unplug the device from the electrical outlet.
  - The device can be cleaned using a damp cloth moistened with 70% rubbing alcohol, as needed.

- Storage:
  - Store the device in its original box.
  - Do not expose to extreme temperatures or humidity beyond the specified ranges:
    - During treatment:
      - Temperature: 41º–104ºF (5º–40ºC)
      - Humidity: 15%–90%, non-condensing
      - Atmospheric Pressure: 700–1060 hPa/mbar
    - While transporting or storing:
      - Temperature: -13º–158ºF (-25º–70ºC)
      - Humidity: 15%–90%, non-condensing

- Do not attempt to disassemble, service, or repair this device.
  - Call Regenesis Medical Customer Service at 1-877-970-4970 for assistance.
  - If your problem involves a health issue and you need emergency assistance, please call 911 and/or contact your health care professional.

- If device does not start and/or there are no indicator lights:
  - Make sure the A/C Power Supply is firmly plugged into both:
    - The electrical wall outlet
    - The Base Unit
  - If the problem persists, call Regenesis Medical Customer Service at 1-877-970-4970.

- If you see "SERVICE REQUIRED" message:
  - Please call Regenesis Medical Customer Service at 1-877-970-4970.

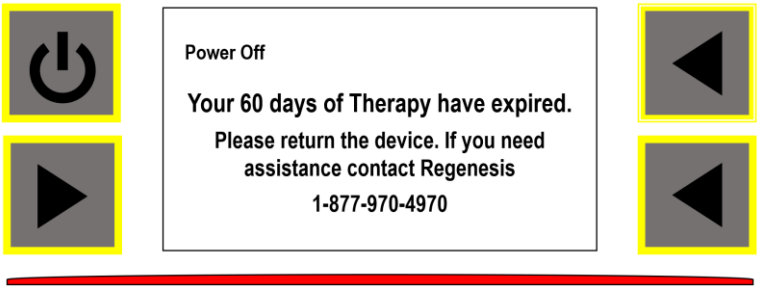
- If device interferes with other electronic devices:
  - Move the devices further apart,
  - Untangle cables,
  - Plug the device into a different outlet.

- USB port is not powered and is used for manufacturing purposes only.

For further troubleshooting assistance, call:
Regenesis Medical Customer Service
1-877-970-4970

IMPORTANT: Please have the Serial Number, located on the label on the back of the Base Unit, ready for Customer Service.

- If there are no treatment days left, the device will not activate. Follow the return instructions provided in the Patient Treatment Information Folder or contact Regenesis Medical to return the device.



- Radiofrequency communications equipment may affect Reprieve.
- Keep portable communications equipment at least 30 cm (12 in) away from any part of Reprieve to prevent performance degradation.
- Only use Regenesis Medical-specified accessories and cables with Reprieve as it could result in increased electromagnetic emissions or decreased immunity of the Reprieve device and could result in improper operation.
- Avoid using Reprieve adjacent to or stacked with other equipment.

NOTE: The EMC tables and other guidelines that are included in the Instruction Manual provide information that is essential in determining the suitability of the equipment or system for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the equipment or system to perform its intended use without disturbing other equipment and systems or non-medical electrical equipment.

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration Electromagnetic Emissions</td></tr>
<tr><td colspan="3">The REPRIEVE BY REGENESIS DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of the REGENESIS REPRIEVE DEVICE should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td rowspan="2">The REPRIEVE BY REGENESIS DEVICE must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>Conducted RF emissions – CISPR 11</td><td>Group 2, Class B</td></tr>
<tr><td>Radiated RF emissions – CISPR 11</td><td colspan="2">Group 2, Class B</td></tr>
<tr><td colspan="3">The REPRIEVE BY REGENESIS DEVICE is suitable for use in all establishments including those directly connected to the public low-voltage power supply networks which supplies buildings used for domestic purposes, but not near active HF SURGICAL EQUIPMENT or MAGNETIC RESONANCE IMAGING EQUIPMENT.</td></tr>
</table>

Guidance and manufacturer's declaration Electromagnetic Immunity			
The REPRIEVE BY REGENESIS DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of the REPRIEVE BY REGENESIS DEVICE 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 ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	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 @ 100kHz	±2 kV @ 100kHz	Suitable for use in all establishments including those directly connected to the public low-voltage power supply networks.
Surge IEC 61000-4-5	±0.5, 1.0, 2.0 kV common mode high/low to ground ±0.5, 1.0 kV common mode high to low	±0.5, 1.0, 2.0 kV common mode high/low to ground ±0.5, 1.0 kV common mode high to low	Suitable for use in all establishments including those directly connected to the public low-voltage power supply networks.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0,5 cycle 0% U_T (100% dip in U_T) for 1 cycle 30% U_T (70% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 250 cycles	0% U_T (100% dip in U_T) for 0,5 cycle 0% U_T (100% dip in U_T) for 1 cycle 30% U_T (70% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 250 cycles	Suitable for use in all establishments including those directly connected to the public low-voltage power supply networks. While not necessary to maintain ESSENTIAL PERFORMANCE, if the user of the REPRIEVE BY REGENESIS DEVICE requires continued operation during power mains interruptions; it is recommended that the REPRIEVE BY REGENESIS DEVICE be powered from an uninterruptible power supply.
(50 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical domestic establishment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			
ESSENTIAL PERFORMANCE: None other than that related to basic safety.			
The REPRIEVE BY REGENESIS DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of the REPRIEVE BY REGENESIS DEVICE 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	3 Vrms 0,15 MHz to 80 MHz 6 Vrms 0,15 MHz to 80 MHz 6 Vrms ISM and Amateur Radio bands 150 kHz to 80 MHz	3 Vrms 0,15 MHz to 80 MHz 6 Vrms 0,15 MHz to 80 MHz 6 Vrms ISM and Amateur Radio bands 0,15 MHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the REPRIEVE BY REGENESIS DEVICE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [3.5/V1]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz 80% AM 1kHz	10 V/m 80 MHz to 2,7 GHz 80% AM 1kHz	$d = [3.5/E1]\sqrt{P}$ 80 MHz to 800 MHz $d = [7/E1]\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in

Radiated RF IEC 61000-4-3 Proximity Fields from RF Wireless Communications Equipment	27 V/m (385MHz) 28 V/m (450MHz) 9 V/m (710MHz, 745MHz, 780MHz) 28 V/m (810MHz, 870MHz, 930MHz) 28 V/m (1720MHz, 1845MHz, 1970MHz) 28 V/m (2450MHz) 9 V/m (5240MHz, 5500MHz, 5785MHz)	27 V/m (385MHz) 28 V/m (450MHz) 9 V/m (710MHz, 745MHz, 780MHz) 28 V/m (810MHz, 870MHz, 930MHz) 28 V/m (1720MHz, 1845MHz, 1970MHz) 28 V/m (2450MHz) 9 V/m (5240MHz, 5500MHz, 5785MHz)	watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the 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 REPRIEVE BY REGENESIS DEVICE is used exceeds the applicable RF compliance level above, the REPRIEVE BY REGENESIS DEVICE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the REPRIEVE BY REGENESIS DEVICE.

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

Recommended separation distances between portable and mobile RF communications equipment and the REPRIEVE BY REGENESIS DEVICE

The REPRIEVE BY REGENESIS DEVICE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the REPRIEVE BY REGENESIS DEVICE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the REPRIEVE BY REGENESIS DEVICE 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 = [3.5/V1]√P	80 MHz to 800 MHz d = [3.5/E1]√P	800 MHz to 2.5 GHz d = [7/E1]√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.39
100	11.67	11.67	23.33

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.

System Technical Specifications

OVERVIEW

The Reprieve by Regenesis™ is a shortwave diathermy device designed to operate at the Federal Communications Commission authorized medical device frequency of 27.12 MHz. During treatment, the device transmits a fixed dose of electromagnetic energy via one or two applicator pads that are placed adjacent to the area to be treated. This device automatically delivers and monitors a preset energy level per your clinician's prescription during each preset treatment. The Reprieve by Regenesis device complies with the following standards: IEC 60601-1, IEC 60601-2-3, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 62366-1, IEC 62304, and ISO 10993-1.

DETAILED SPECIFICATIONS

Unit Weight	9.5 pounds
Packaged Weight	12.0 pounds
Treatment Applicator Pad size	8.8" x 10.5" x 1.2"
A/C Power Supply	48W (24.0V DC) Medical Grade Class II Wall-plug, 57" length
Treatment Applicator Cable(s)	Coaxial cable, 96.75" length
Power Requirements	AC 100-240V, 50-60 Hz
Circuit Protection	AC 0.75 Amp Slow Blow
Power Consumption	15 Watts
Expected Service Life	2 years

RADIOFREQUENCY (RF) SPECIFICATIONS

Operating Frequency	27.12 MHz	
Transmission Profile	Continuous	Pulsed
Pulse Duration	N/A (Continuous)	20, 40, 60, 80, and 100 microseconds
Pulse Frequency	N/A (Continuous)	200, 400, 600, 800, and 1000 Hz
Duty Cycle	100%	0.4% to 10%
Signal Strength	2 to 26 A/m @ surface of Treatment Applicator Pad(s)	
Effective Radiated Power	9W using a 50-ohm matched load*	0.3 to 7.0W using a 50-ohm matched load*

* Effective radiated power was derived using peak to peak voltage measured with oscilloscope into a 50-ohm RF load termination.

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