



# REPRIEVE

*Pain Relief by* **REGENESIS<sup>®</sup>**



## **Reprieve by Regenesi<sup>™</sup>**

Instruction Manual

Regenesi Medical Customer Service

1-877-970-4970

Save this manual for future reference

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## Introduction

The Reprive by Regensis™ (Reprive) 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.

This device is designed for use by the individual to whom it is prescribed. At start up, the device requires registration of the device to the prescribed user.

If you have any questions, please contact Regensis Medical:

Phone: 1-877-970-4970

Website: [www.regenesismed.com](http://www.regenesismed.com)

Email: [support@regenesismed.com](mailto:support@regenesismed.com)

## About Shortwave Diathermy

Shortwave diathermy (SWD) uses electromagnetic energy to produce a thermal effect in tissues. The Relieve by Regenesi<sup>TM</sup> 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 Relieve device is factory-set to an initial recommended setting.

## Glossary and Symbol Definitions

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

## Contraindications

- **NEVER use Reprive 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 Reprive 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 any of the above contraindications, call your clinician to discuss your situation before using this device.

## Warnings and Precautions



**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)

## Potential Adverse Reactions

- 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 Reprive:

- 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 Regenes 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.

## Product Description



1	Base Unit	5	Fingerprint Sensor
2	Treatment Applicator Pads	6	LCD Screen
3	Applicator Cables	7	Control Panel
4	A/C Power Supply (not pictured)	8	Indicator Light

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

1-877-970-4970

## Instructions for Use: SETUP

- 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.



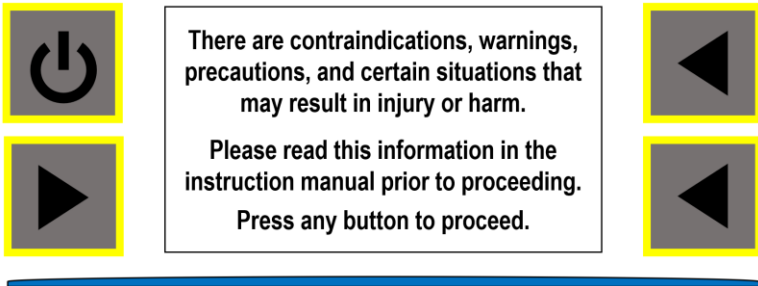
**WARNING: Choking and Strangulation Hazard – Keep the device and cables out of the reach of children and pets.**

## Instructions for Use: PREPARE DEVICE

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



- The following message will display 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.

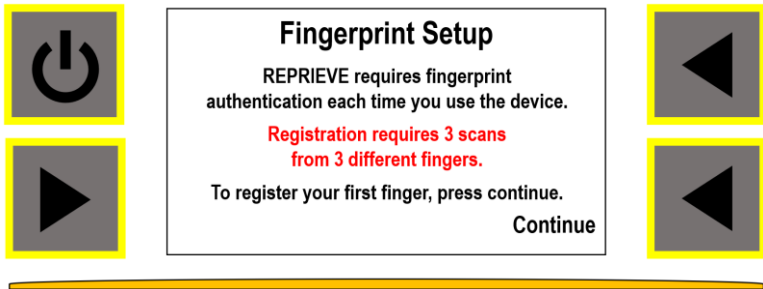
If this is **your first-time** using Reprive, continue to **page 13**.

If this is **NOT your first-time** using Reprive, continue to **page 16**.

## Instructions for Use: PREPARE DEVICE (First time use)

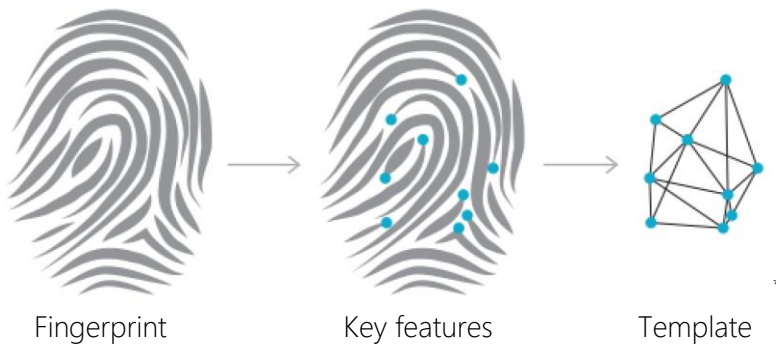
First time use: Reprive is a prescription device, therefore, as a patient safety feature, you **MUST** register three different fingers on the Reprive device as the authorized user before first use.

- The following message will display on the LCD screen and the indicator light will flash amber:



- Press lower right button to continue.

Note: For your security, actual fingerprints are not scanned nor stored in the Reprive device. Electronic reference templates are created and stored using the unique pattern of a fingerprint (see below) to assure that only the authorized user is able to use the Reprive device.



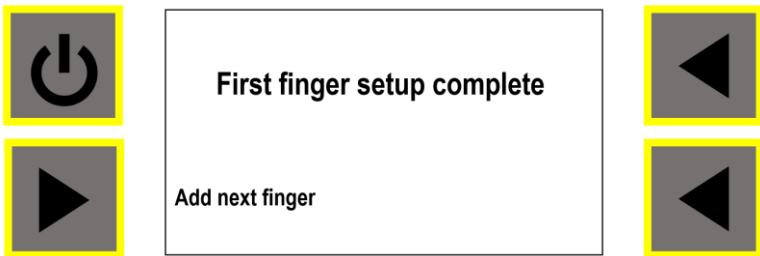
\* Image credit: Fingerprint Cards AB

## Instructions for Use: PREPARE DEVICE (First time use)

- Ensure your hands are clean prior to registration.
  1. Choose the first finger you would like to register.
  2. Place and remove your first finger on sensor.
    - A beep will sound when the fingerprint scan has been accepted.



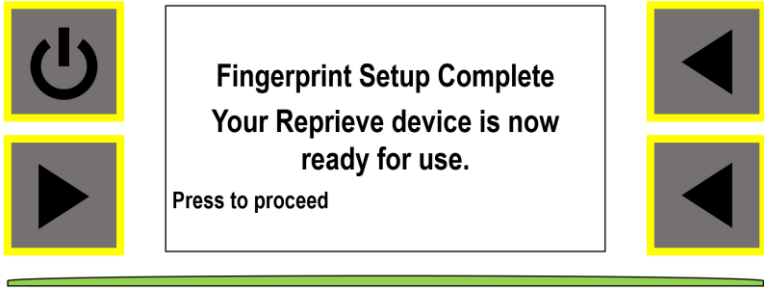
3. Place and remove the same finger on the sensor until a total of three (3) scans are accepted.
  - When all 3 scans are accepted the LCD screen will display "First finger setup complete" and the indicator light will be solid green.



4. Press lower left button to continue.
5. Repeat steps 1-4 above with a second and third finger.

## Instructions for Use: PREPARE DEVICE (First time use)

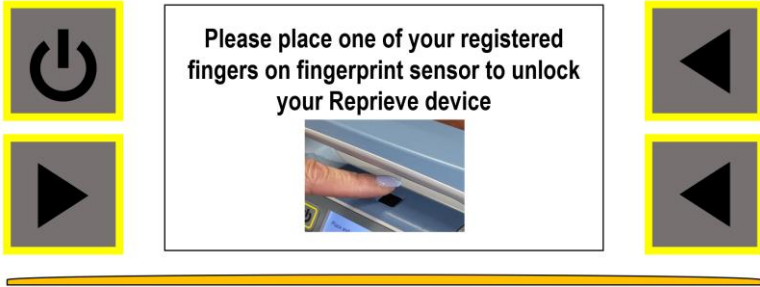
- When all three fingers are registered the LCD screen will display "Fingerprint Setup Complete, Your Reprive device is now ready for use." and the indicator light will be solid green.



- Press the lower left button (▶) to proceed.
- Please proceed to page 17.

## Instructions for Use: UNLOCK DEVICE

- If the device is in sleep mode, press any button to turn on the device.
- The LCD screen will display “Please place one of your registered fingers on fingerprint sensor to unlock your Reprise device” and the indicator light will flash amber.

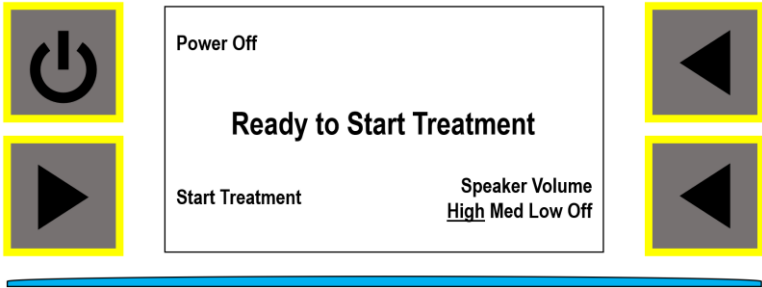


You **MUST** unlock the device by placing one of your registered fingers on the fingerprint sensor.



## Instructions for Use: PREPARE FOR TREATMENT

- Find a comfortable position with easy access to the treatment site.
- Before use, remove all jewelry, watches, hearings aids, or metallic items on the area to be treated.
- The LCD screen will display "Ready to Start Treatment" and the indicator light will be 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(s) you are treating.
- Treatments can be given through clothing or dressings without removing them.



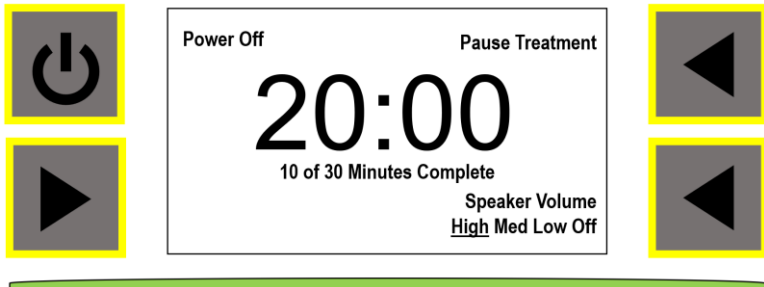
**CAUTION:** Do not apply Treatment Applicator Pad directly to breached or compromised skin (i.e., open wound, surgical incision).

## Instructions for Use: START TREATMENT

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



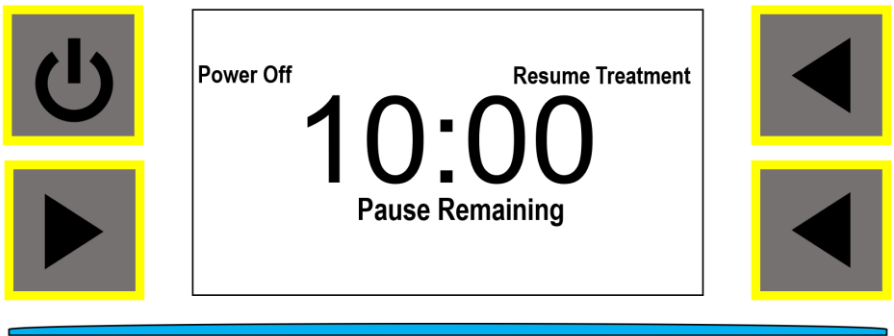
- During treatment the LCD screen will display a Countdown Timer and active buttons (Power Off, Pause Treatment, and Speaker Volume) and the indicator light will flash green.



## Instructions for Use: PAUSE or END TREATMENT

- **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, Storage, and Disposal

- **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.
    - Wipe dry the fingerprint sensor with a lint free cloth.
  
- **Storage:**
  - Store the device in its original box.
  - Do not expose to extreme temperatures or humidity beyond the specified ranges:
    - During treatment:
      - Temperature: 41°–104°F (5°–40°C)
      - Humidity: 15%–90%, non-condensing
      - Atmospheric Pressure: 700–1060 hPa/mbar
    - While transporting or storing:
      - Temperature: -13°–158°F (-25°–70°C)
      - Humidity: 15%–90%, non-condensing
  
- **Disposal:**
  - Please contact Regenesys Medical at 1-877-970-4970 for proper disposal of your Reprieve device.

## Troubleshooting

- **Do not attempt to disassemble, service, or repair this device.**
  - Call Regensis 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 recognize your fingerprints:**
  - Ensure you are using one of the 3 registered fingerprints.
    - If your first fingerprint is not recognized, try using another registered fingerprint
  - Make sure your hands are clean.
  - Clean the fingerprint sensor following the instructions on page 21 and retry.
  - If the problem persists, call Regensis Medical Customer Service at 1-877-970-4970.
- **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 Regensis Medical Customer Service at 1-877-970-4970.

For further troubleshooting assistance, call:  
Regensis 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.

## Troubleshooting

- If you see “SERVICE REQUIRED” message:
  - Please call Regensis 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:  
Regensis 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.

## Electromagnetic Compatibility (EMC) User Information

- 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 Regenes 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.

Guidance and manufacturer's declaration Electromagnetic Emissions		
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.		
Emissions Test	Compliance	The REPRIEVE BY REGENESIS DEVICE must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted RF emissions – CISPR 11	Group 2, Class B	
Radiated RF emissions – CISPR 11	Group 2, Class B	
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.		



**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.


<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment Guidance</b>
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.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment guidance</b>
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 150 kHz 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. <b>Recommended separation distance</b> $d = [3.5/\sqrt{f}] \sqrt{P}$ $d = [3.5/E1] \sqrt{P}$ 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	10 V/m 80 MHz to 2,7 GHz 80% AM 1kHz	10 V/m 80 MHz to 2,7 GHz 80% AM 1kHz	

Radiated RF IEC 61000-4-3 Proximity Fields from RF Wireless Communications Equipment	27 V/m (385MHz)	27 V/m (385MHz)	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 <sup>a</sup> , should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 
	28 V/m (450MHz)	28 V/m (450MHz)	
	9 V/m (710MHz, 745MHz, 780MHz)	9 V/m (710MHz, 745MHz, 780MHz)	
	28 V/m (810MHz, 870MHz, 930MHz)	28 V/m (810MHz, 870MHz, 930MHz)	
	28 V/m (1720MHz, 1845MHz, 1970MHz)	28 V/m (1720MHz, 1845MHz, 1970MHz)	
28 V/m (2450MHz)	28 V/m (2450MHz)		
9 V/m (5240MHz, 5500MHz, 5785MHz)	9 V/m (5240MHz, 5500MHz, 5785MHz)		

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.

<sup>a</sup> 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.

<sup>b</sup> 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 $d = [3.5/\sqrt{P}] \sqrt{P}$	80 MHz to 800 MHz $d = [3.5/\sqrt{E}] \sqrt{P}$	800 MHz to 2.5 GHz $d = [7/\sqrt{E}] \sqrt{P}$
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 Reprive by Regenesi<sup>TM</sup> 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 Reprive by Regenesi 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	40W 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	<u>Continuous</u>	<u>Pulsed</u>
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*



\* Signal strength derived using peak to peak voltage measured with oscilloscope into a 50-ohm RF load termination.



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Website: [www.regenesismed.com](http://www.regenesismed.com)

Email: [support@regenesismed.com](mailto:support@regenesismed.com)

Phone: 1-877-970-4970

250-2000-00 A