



# THE INHIBITOR™

*An Ultrasonic Tinnitus Treatment Device*



**Melmedtronic**

*"Where ideas become reality"*

## Please read these instructions completely prior to using this device!

The following warnings and caution statements should be heeded to avoid patient/user injury. This manual contains detailed instructions and warnings on the use of **The Inhibitor™**. It is intended only to reinforce instruction provided by a trained health care professional or an authorized Melmedtronics representative.

### Warnings and Cautions

**Never allow others to use your device. They could have a medical condition that they may be unaware of and could incur serious side effects. You are the only person for whom this device is intended.**

- Melmedtronics will assume no responsibility for incidents that may occur if the product is not used in accordance with product labeling.
- Do not operate this device in environments where there is an explosion hazard! A possible explosion hazard exists if **The Inhibitor™** is used in the presence of flammable anesthetics.
- To avoid mechanical or electronic damage, do not steam autoclave or immerse the Inhibitor in any fluids or cleaning solutions.
- Always disconnect the battery charger from the device before cleaning to prevent electrical shock or damage to the device.
- **Only** the supplied battery charger can be used to charge **The Inhibitor™**

#### **DO NOT UTILIZE THIS DEVICE IF:**

- You have a pacemaker.
- You are pregnant.
- You have any thrombosis.
- You have a metal bonded retainer.
- You are prone to migraines or headaches.
- You have any metal implants in your head or neck.
- You have had any recent surgeries (last six months) and are still recovering.
- Your physician advises against its use because of any other medical condition.

#### **DISCONTINUE USE IF:**

- Your Tinnitus becomes louder.
- You get a headache after using the device.
- You become nauseous after using the device.
- You notice any discomfort at the treatment site.

**Use of this device is restricted to the mastoid bone behind the ear. DO NOT use it on any other area of the body.**

## **Warning Statement!**

**THIS IS A MEDICAL DEVICE!  
THE INHIBITOR® MAY ONLY BE USED IF THE FOLLOWING  
CONDITIONS ARE MET:**

1. You are 18 years of age or over, and
2. The device has been **prescribed** by a physician, audiologist or licensed hearing instrument specialist, either with a medical referral or a signed medical waiver.
3. Qualified medical personnel have informed you of possible counter indications and instructed you on proper usage.

**If cracks are observed in the case, if the transducer head is loose or if you have any questions, contact:**

**Melmedtronics, Inc.**

1550 Norwood Dr., Suite 100, Hurst, TX 76054 / U.S.A.

[www.TinnitusTreatment.com](http://www.TinnitusTreatment.com)

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## Intended Use and Effectiveness

**The Inhibitor™** is intended to be used for the temporary relief of Tinnitus. The device will not “cure” your Tinnitus. Approximately 70-75% of patients treated with the device notice either a total or partial reduction in the loudness of their Tinnitus, while 25-30% report no effect. The benefit of treatment varies considerably between individuals, with the duration of relief lasting from several minutes, to hours, to days and in some cases, as long as weeks. Individual benefit amount and duration cannot be predicted. Relief is always temporary and after some duration of time Tinnitus will return. Most patients, who receive benefit, find the amount and duration of relief similar each time the device is used. If you do not experience initial benefit after several one-minute treatments, the device may not be effective in alleviating your tinnitus. You should refrain from using the device more than 16 times per day.

## Specifications

Mechanism.....	Piezoelectric ultrasonic signal generator, 20-60kHz
Dimensions WxHxD.....	1.4" (35mm) x 4.8" (122mm) x 2.4" (62mm)
Weight.....	0.22 lbs. (100gm)
Power Requirements.....	5V DC, 1000 mA, 5 Watts
Leakage Current.....	10 $\mu$ A (Max)
Battery.....	3.7V, 780 mAh, Li-Ion (Rechargeable)
Battery Operating Time.....	30-60 treatments
Battery Charge Time.....	4 hours (approx.)
Operating Temp Range.....	59° F to 86° F (15° C to 30° C)
Operating RH Range.....	45% to 85% relative humidity, non-condensing
Operating Pressure Range.....	10.51 PSI to 15.37 PSI (70 kPa to 106 kPa)
Storage Temp Range.....	23° F to 95° F (-5° C to 35° C)
Storage RH Range.....	45% to 85% relative humidity, non-condensing
Storage Pressure Range.....	10.15 PSI to 15.37 PSI (70 kPa to 106 kPa)
Power Output.....	<100mW/cm <sup>2</sup>

## Device Identification

There is a label on the device that shows the serial number and lot number. When reporting a problem with your device always provide the serial number on the label.

## Instructions on Use

**Inspection on Delivery:** Despite careful packaging, risk of damage during transport cannot be entirely excluded. Upon receipt, please ensure that nothing is missing. **Do NOT** use a damaged device. If the device is damaged, please contact Melmedtronics before use.

**Packaging:** The device packaging is reusable, please retain.

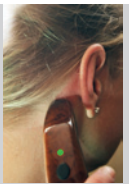
**Package Contents:** The Inhibitor™ device, battery charger, warning insert, user manual.

### Unpacking and charging the unit for the first time:

1. Remove the device from the box.
2. Plug the recharging adaptor into the wall electrical outlet and then plug the adapter into the device. The status light will blink yellow while charging and go out when charging is complete (about 4 hours).
3. The device does not have to be recharged every night. Waiting until the battery is fully discharged and the status light is yellow (about 60 treatments) will extend the battery life.
4. Always disconnect the battery charger from the device before cleaning to prevent electrical shock or damage to the device.



**Use of this device is restricted to the mastoid bone behind the ear. DO NOT use it on any other area of the body.**



### How to use the Device:

1. Press the recessed "ON" button to begin treatment; the status LED should become green indicating the device is operating optimally.
2. Apply the device to either mastoid bone, behind the right or left ear (see picture).
3. Move the device slightly in this area to determine the "Treatment Spot" (where it is loudest) and then press firmly until the sound goes off.

The device will reach max loudness after 10 seconds and maintain this for 60 seconds more. More than one treatment may be necessary.

## Care and Maintenance

- Do not clean, disinfect, or sterilize any part of the device with ethylene oxide gas (EtO) or by autoclaving. Doing so may damage the device and void the warranty.
  - Do not use acetone solutions containing glutaraldehyde or abrasive cleansers on the device.
  - Do not use abrasive cleaning tools or pressurized spraying devices as these may damage the device.
  - Your device can be cleaned with a soft dry cloth. The part that is placed behind the ear during treatment can be wiped with a standard alcohol wipe pad.
  - Keep your device in a cool, dry location. Avoid excessive heat, cold, or humidity
- There are **NO** serviceable parts. The rechargeable battery should last for approximately five years.

## Instructions on How to Safely Dispose of the Device

The Model 1-R device contains one 3.7 V Li-Ion rechargeable battery and has a circuit board. If necessary, please dispose of the device and its components according to your local laws.

## Safety Data

The University of Illinois Bioacoustics Research Laboratory measured the ultrasound energy emitted by a similar instrument at maximum output power levels against known injury mechanisms. The output intensity data were calculated against a standard thermal model supported by theoretical and experimental studies on blood and intact tissues. The ultrasound energy has been shown to be too low to produce thermal damage and too low to produce any other known damaging bio-effects. The output satisfies the safety limits of IEC 61689.

Studies conducted at the Hearing & Balance Research Center in Hurst, TX from 2005-2007 found:

1. No change in hearing among any of the subjects treated with **The Inhibitor™**.
2. No increase in skin surface temperature after treatment.
3. No change in hearing with as many as 16 treatments in a 1.5 to 6 hour period.
4. No adverse events were reported, with one exception. Three patients who had a history of frequent migraines also reported a mild headache after treatment. It is **NOT** recommended for persons with a history of migraines.

## Troubleshooting Information

If your device does not activate, make sure the battery has been fully charged. Once the “ON” button is depressed, the status light should be green. If the battery has been fully charged and the device still does not activate and/or the status light remains red, return the device. If the device does not automatically turn off after 60-90 seconds – return the device.

### Status Indicator Light

When the “ON” button is pushed, a small LED light on the device will indicate the current operating status of the unit.

Green Light ..... Operating normally

Yellow Light ..... Device needs charging

Blinking Yellow ..... Device is charging

Red Light ..... Charge is too low for treatment or unit is not functioning

No Light ..... Unit is off or not functioning

Symptom	Cause	Possible Solution
No sound <b>OR</b> Red status light	Battery is fully discharged	Charge device
Red status light (After re-charging)	Internal malfunction	Return device for repair
Weak sound <b>OR</b> Yellow status light	Low battery	Charge device
Weak sound (After re-charging)	Internal malfunction	Return device for repair
Intermittent sound	Wrong placement of transducer	Reposition Inhibitor
Short battery life	Battery not fully charged	Charge battery longer
Will not hold charge	Battery malfunction	Return device for repair
Internal problem		Return device for repair

- **DO NOT** drop your device as this could cause internal damage to the device.
- Avoid exposing your device to extreme temperatures, such as in your car.
- Do not leave your device where it can be reached by small children or pets.
- Do not get your device wet.
- If you experience any skin irritation or discomfort at the treatment site, **stop using the device and consult your healthcare provider.**

## Compliance

**The Inhibitor™** complies with the following:

- IEC/EN 60601-1-2 for CE Mark EMI/EMC.
- 47 CFR, Part 15, Subpart B, Class B, FCC Emissions.
- ICES-003 Issue 4 CAN/CSA-CEI/IEC CISPR22;02, Class B ITE Emissions.
- ISO 10993-1 for Biocompatibility.
- IEC 60529-1 for IPX0 Fluid Ingress Rating.
- Directive 2002/95/EC (RoHS).

The internal Li-Ion Battery complies with all tests in UL 1642 per UL file number MH28232.

The AC Adapter / Battery Charger complies with IEC/EN 60950-1 for LPS supplies

## Classification

US FDA Medical Device: Class II

Canada Medical Device: Class II

European Union Medical Device: Class IIa

Protection Against Electrical Shock Hazard: Class II

Protection Against Fluid Ingress per IEC 60529-1: IPX0

Applied Part: B

## Limited Warranty

**The Inhibitor™** has a one year repair warranty that also includes the battery and charger. You may not transfer the Warranty. Either you or your dispenser must register your device with the correct serial number within 30 days of purchase. Failure to register will automatically nullify any Warranty. If any malfunctions occur within the one-year time period, you may return the device to your dispenser or directly to:

**Melmedtronic, Inc.** 1550 Norwood Dr., Suite 100, Hurst, TX 76054 / U.S.A.

\*Patent Notice: There is a U.S. and International Patent Pending.