

Hinge Health Enso

Transcutaneous nerve stimulator for pain relief

User Manual



Table of Contents

Indications for Use	2	Checking battery	16
Warnings and Precautions	4	Bluetooth range	17
Introduction	8	Gel pad care	17
Setting Up Your Enso	9	Troubleshooting	18
Using Your Enso	12	Contact Us	21
Ending treatment	13	Appendix A: Technical specifications	22
Resuming treatment	14	Appendix B: Label symbols	24
Switching devices	15	Appendix C: Radio information	26
Storing the gel pad	16	Appendix D: Electromagnetic compatibility	27
Hinge Health App compatibility	16	Appendix E: Parts and accessories	33

Indications for Use

The Hinge Health Enso device is intended for the symptomatic relief and management of chronic pain. It provides temporary relief of pain associated with sore and aching muscles stemming from strains in the shoulder, waist, back, neck, upper extremities (arms), and lower extremities (legs). Enso gel pads should be applied to the normal, healthy, dry, clean skin of adult patients.



Warnings and Precautions

Contraindications

- › Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
- › Do not use if you are pregnant.
- › Device is not intended for use with children.

Warnings

- › Do not apply stimulation across your chest; the introduction of electrical current to the area may cause rhythm disturbances in your heart, which could be lethal.
- › Do not apply stimulation near the eyes or to the side or front of the neck, head, or face.
- › Do not apply stimulation over your throat, which could cause severe muscle spasms resulting in closure of your airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.
- › Do not apply stimulation over open wounds or rashes or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).

- › Do not apply stimulation over or near cancerous lesions.
- › Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when Enso is in use.
- › Do not apply stimulation when in the bath or shower to avoid risk of shock.
- › Do not apply stimulation while sleeping.
- › Do not apply stimulation while driving or operating machinery or during any activity when electrical stimulation can put you at risk of injury.
- › Do not allow the device or any of its accessories to get wet. Do not immerse them in water or other liquids, which could damage the device and accessories.
- › Do not use the device on children. It has not been evaluated for pediatric use.
- › Apply stimulation only to normal, intact, clean, healthy skin to avoid causing an infection.
- › Remove gel pads between treatments.

- › Attach gel pads to the protective liner between uses, and store in a clean place to avoid contamination.
- › Ensure the gel pad lays flat along the surface of the skin. Sweat or intense exercise/activity can cause gel pad to detach and generate a shock.
- › If your pain does not improve, stop using the device and consult with your physician.
- › If you have had medical or physical treatment for your pain, consult with your physician before using this device to avoid issues with contraindications.
- › Consult with your physician before using this device, as it may cause lethal rhythm disturbances in the heart in susceptible individuals.
- › Do not insert sharp objects into, disassemble, or tamper with the device in any way, as the electronics inside may pose a safety risk.
- › Do not use or integrate with accessories, detachable parts, or materials not described in the User Manual, which could cause a risk of injury.
- › Do not use with gel pads past their expiration date, which could cause discomfort or unpleasant sensations.
- › Consult your doctor about the use of the stimulator if you recently had surgery or are planning to have surgery, as stimulation may disrupt the healing process.
- › If you are under the care of a physician, consult with your physician before using the device to avoid misuse.

Warnings and Precautions

Adverse reactions

- › In rare cases, you may experience skin irritation or burns beneath a gel pad applied to your skin. If you experience an adverse reaction, please stop using the device and consult your physician.

Precautions

- › To prevent increased chances of skin irritation or infection, discard gel pads after 30 uses.
- › Transcutaneous electrical nerve stimulation is not effective for pain of central origin, including headache.
- › Pain reduction is dependent on pain area being treated
- › The long-term effects of electrical stimulation are unknown.
- › Since the effects of stimulation of the brain are unknown, stimulation should not be applied on your head.
- › The safety of electrical stimulation during pregnancy has not been established.
- › You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium gel.
- › If you have suspected or diagnosed heart disease, you should follow all precautions recommended by your physician.
- › If you have suspected or diagnosed epilepsy, you should follow all precautions recommended by your physician.
- › If you have a tendency to bleed internally, such as following an injury or fracture, please use the device with caution.
- › Use caution if stimulation is applied over a menstruating uterus or if pregnant.
- › Use caution if stimulation is applied over areas of skin that lack normal sensation.
- › Keep this device out of the reach of children.
- › Use the device only with Enso-branded gel pads and accessories.
- › No modification of the Enso device is allowed.
- › Patients with particularly small limbs or body parts may be at increased risk of discomfort from the electrical pulses delivered by Enso.
- › Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Introduction

How does Enso work?

Enso is designed to deliver electrical pulses through the skin and produce natural pain relieving endorphins.

What does it feel like?

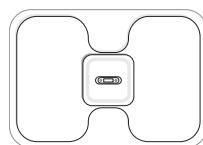
Enso treatment may feel different to each user. It may feel like a light tingling sensation. At stronger intensities, it may feel like a strong tingling sensation combined with a massaging sensation.

What's included?

1) Enso Device



2) Gel Pads x 3
(large or standard)



3) Charger



4) AC Adapter



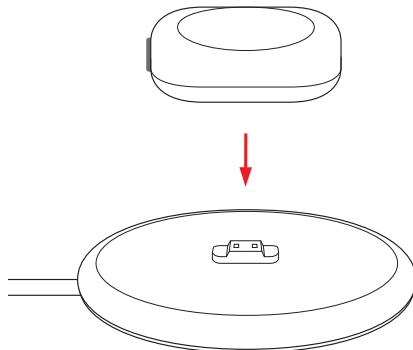
5) Nylon Bag



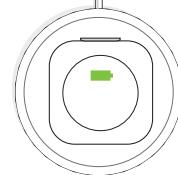
Setting Up Your Enso

Charging Enso

- › Enso arrives already charged. To charge your Enso, position it on the charger so that it attaches magnetically.
- › Plug the charger into the AC adapter, and then plug the AC adapter into a wall outlet.
- › For a quick charge, charge Enso for 30 minutes.
For a full charge, charge Enso for one hour.
- › Enso will last around 3 hours on a full charge.



Solid Green LED



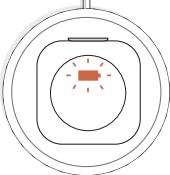
Fully charged

Pulsing Green LED



Charging

Pulsing Red LED



Low battery

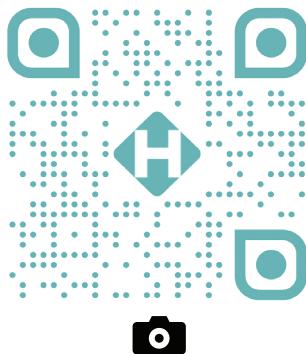
Setting Up Your Enso

Download the Hinge Health app

› Enso is controlled wirelessly using the Hinge Health app on your iPhone or Android device.

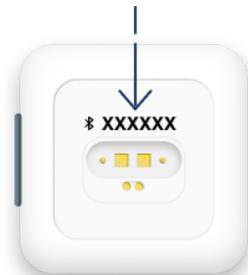
› To download the app:

On your iPhone or Android device take a picture of the QR code below or open the Apple App Store or Google Play Store and search for “Hinge Health.”



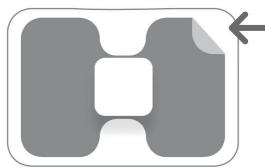
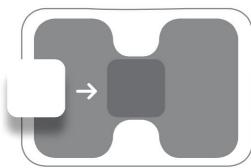
Pairing Enso

- › Open the Hinge Health app and tap “Set Up Enso” on the home screen.
- › Make sure Bluetooth is enabled. If it isn’t, select “allow” when the app asks permission to use the phone’s Bluetooth.
- › Put Enso on your phone screen with the six-digit code facing you. Tap the button to confirm.
- › Input the six-digit pin when prompted to do so.
- › Flip Enso over to confirm that the status light on Enso is displaying solid green. Bluetooth is now successfully connected.

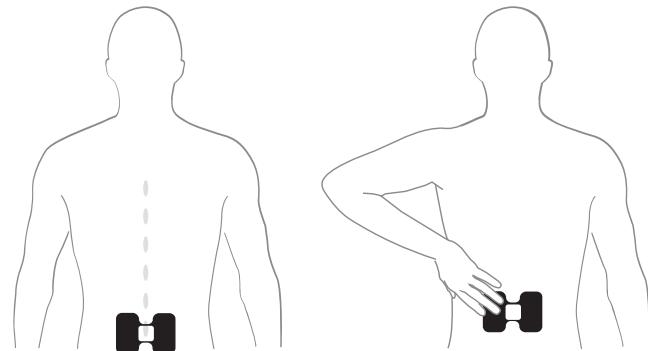


Placing the Gel Pad

- › Remove a gel pad from its pouch.
- › Position your Enso device onto the black tray of the gel pad until it attaches magnetically.
- › Remove the protective liner. Save the protective liner and use it to store the gel pad between uses.



(Large gel pad shown. Your kit may alternatively include standard gel pads).



- › Grip the center tray and position it directly over your pain area or the source of your pain.
- › Use your hand to smooth out the surface of the gel pad so it securely adheres to your skin.

Using your Enso

Starting treatment

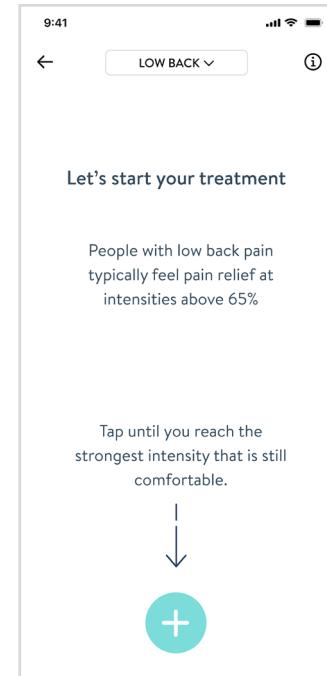
Tap the **+** button to start treatment and to increase treatment intensity.

Recommended treatment time

For optimal results, use Enso for at least 1 hour per session. Studies show that using Enso for at least 1 hour a day provides effective relief. Experiment with placement and usage times to find what works best for you.

Recommended intensity

The app provides recommended intensity levels for different body areas. For optimal results, try to increase intensity to be as close to the recommended level as you feel comfortable doing.



Adjusting treatment intensity

Once treatment intensity has been set, tap the **+** **button** to increase intensity. Tap the **-** **button** to decrease intensity.

Ending treatment

At any time, tap the **■** **button** on the treatment control screen, or the button on the device, to end your treatment session

Note: always stop treatment before removing the gel pad to prevent uncomfortable stinging

Battery status

The current battery status of Enso is displayed at the bottom right of the treatment control screen.



Using your Enso

During treatment

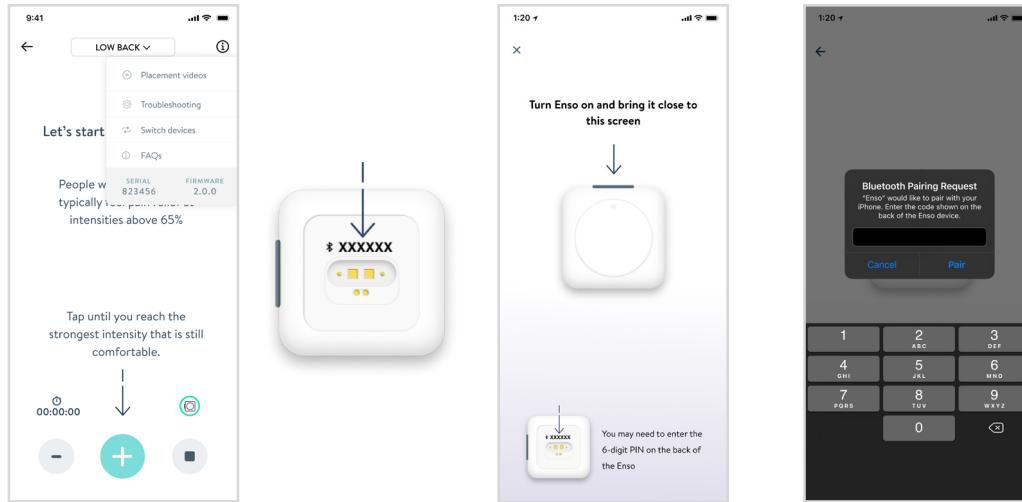
After starting a treatment session, you can go about your normal daily activities. Enso may be worn under clothing or exposed. It is not waterproof, so do not shower, bathe, or swim while wearing Enso.

Resuming treatment

Enso is designed to pause treatment if the gel pad or Enso device becomes disconnected during treatment. If you reapply the gel pad or reattach Enso within 60 seconds, treatment will resume and the intensity level will gradually increase to the previously set level.

Switching devices

If you receive a replacement Enso, you can switch to the new Enso device by tapping on the menu (i.e., three lines) located on the top right of the treatment control screen. From the menu, tap **switch devices**. Follow the instructions to place the new Enso device onto the phone screen with the six-digit code facing you. Tap the button to confirm. Input the six-digit pin when prompted to do so. Flip Enso over to confirm the status light on Enso is displaying solid green. Bluetooth is now successfully connected.



Useful Tips

Storing the gel pad

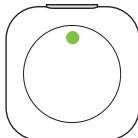
Place a gel pad onto its protective liner between uses to preserve its life and to prevent contamination by dirt or dust.

App compatibility

› Hinge Health app is compatible with iPhones running iOS 12+ and most Android devices running Android 7+.

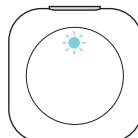
The Enso device LED light will display the following states:

Solid
Green LED



Connected

Pulsing
Blue LED



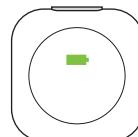
Treatment
is on

Checking battery level, when not on charger

Press the gray power button on top of Enso to check the current battery level while treatment is inactive.

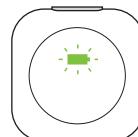
On Enso, the battery light will display one of the following when the status button is pressed:

Solid
Green LED



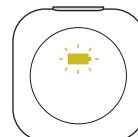
Full charge

Pulsing
Green LED



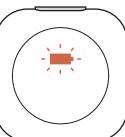
Charged

Pulsing
Amber LED



Low
charge

Pulsing
Red LED



Needs
charge

Bluetooth range

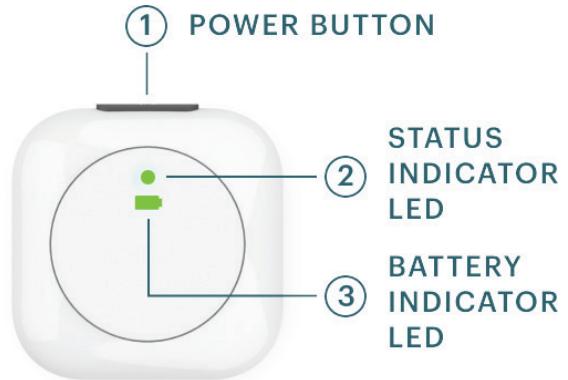
Enso has a Bluetooth range of around 30 feet depending on environment and radio interference. If your iPhone or Android device is out of your Enso device's range during treatment, treatment will continue but the Hinge Health app controls will be suspended until your device is back in range.

Gel pad care

When a gel pad can no longer stick effectively to the body, the risks of electrical discomfort from treatment and skin infections may increase. Replace the gel pad when it becomes dirty or when it does not stay fully adhered to your skin. Always store gel pads in a cool, dark place between uses. The temperature limits are 5° C to 27° C (41° F to 80.6° F). The shelf life for gel pads is 12 months from the date of manufacture.

Power button

Press the power button to pair Enso with the Hinge Health app or to stop treatment.



Troubleshooting

I can't pair my Enso.

It is recommended to place Enso on your phone's screen during pairing to ensure reliable pairing. Also, in your phone settings, please make sure that Bluetooth is turned on. If that doesn't work, please contact us at help@hingehealth.com.

I don't see any lights on my Enso device.

This often means the battery is too low. For a quick charge, charge Enso for 30 minutes. For a full charge, charge Enso for one hour.

What should I do if the treatment feels like a stinging sensation?

Stop treatment by pressing stop button in the app or press the Enso power button. Reapply the gel pad more securely onto your skin. If the gel pad is coming off your skin or has become dirty, please use a new gel pad.

Treatment stopped and I noticed the status light on my Enso device is displaying a blinking blue light. What does this mean?

This indicates that Enso has poor contact with the gel pad or the gel pad is not fully adhered to your skin. Make sure the gel pad is completely adhered to your skin and reattach Enso. If it is reattached within 60 seconds, treatment will resume and gradually increase to the intensity set previously.

What should I do if I get muscle cramps from treatment?

Decrease treatment intensity by tapping the **- button** on the treatment control screen of the Hinge Health app.

My skin is irritated or feels itchy after treatment.

In some cases, mild skin irritation may occur. Remove the gel pad between treatments to allow your skin to breathe. If this does not help, use a new gel pad.

How about maintenance or service for Enso?

Your Enso device is designed to be maintenance free, and there are no user-serviceable parts. Please contact us at help@hingehealth.com if your Enso device is not operating properly or if you need any assistance. Do not disassemble Enso or any of its accessories, as doing so may cause damage.

Use only the provided AC adapter and charger to charge Enso. Using other AC adapters may damage Enso.

Use a damp cloth to clean the outside of the Enso device. Do not use cleansers, which may damage it. Always make sure Enso is completely dry before starting treatment.

Do not allow Enso to get wet or immersed in water or any other liquid. If your Enso device has been immersed, do not attempt to continue using it. Please contact support at help@hingehealth.com.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Store Enso in a cool, dry place. Please keep it out of direct sunlight.

Limitation of liability

THE SERVICE IS PROVIDED “AS IS” AND “AS AVAILABLE” WITHOUT WARRANTY OF ANY KIND TO THE USER. EXCEPT TO THE EXTENT REQUIRED BY LAW, HINGE HEALTH EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

EXCEPT TO THE EXTENT REQUIRED BY LAW, HINGE HEALTH SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR INDIRECT DAMAGES ARISING FROM THE USE OF THIS PRODUCT, OR IN CONNECTION WITH THIS AGREEMENT, RESULTING FROM ANY BREACH OF EXPRESSED OR IMPLIED WARRANTY OR CONDITION, OR UNDER ANY OTHER LEGAL THEORY, EVEN IF HINGE HEALTH HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EXCEPT TO THE EXTENT REQUIRED BY LAW, HINGE HEALTH’S LIABILITY ARISING FROM USE OF OR INABILITY TO USE ENSO WILL AT ALL TIMES BE LIMITED TO THE GREATER OF \$100.00 OR THE AMOUNT PAID BY THE USER FOR THE DEVICE.

Some jurisdictions do not allow exclusion or limitation of incidental, special, consequential, indirect, or direct damages, so the above limitations may not apply to you.

Contact Us

help@hingehealth.com

Hinge Health
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Suite 700
San Francisco, CA 94105

(855) 902-2777

hingehealth.com/enso

Appendix A: Technical Specifications

Power

- › Power Source: Internally powered by fixed, rechargeable battery
- › Battery Type: Lithium-polymer battery, 3.7V nominal
- › Battery Life: >80% of initial capacity after 500 cycles (estimated two to three years of typical use)
- › Input Voltage: 5V DC
- › Input Current: 100mA (maximum)
- › Charging Source: AC adapter
- › AC Voltage: 100–240V AC
- › AC Frequency: 50–60Hz
- › Battery Compliance: IEC 62133-2:2017

Line Current Isolation: Treatment is not possible during charging because the Enso device must be disconnected from the gel pad while it is charging.

Output characteristics

- › Waveform: Biphasic, asymmetrical
- › Regulation: Current regulated
- › Current: 0–80mA ($\pm 10\%$, into 500Ω load)
- › Voltage: 90V ($\pm 10\%$, maximum, into open circuit)
- › Pulse Duration: 90us +/- 4%
- › Pulse Frequency: 2–160Hz ($\pm 4\%$, modulated according to lookup table)
- › Operating Mode: Continuous
- › Phase Charge: $16.2\mu\text{C}$ (maximum)
- › Maximum Current Density: 0.51mA/cm^2 into 500Ω load
- › Maximum Average Current: 2.33mA into 500Ω load
- › Maximum Average Power Density: 3.6mW/cm^2 into 500Ω load

Environmental

- › Temperature, Operating: 5° C to 40° C
- › Temperature, Transport and Storage: 5° C to 45° C (device); 5° C to 27° C (gel pads)
- › Atmospheric Pressure: 50kPa to 106kPa
- › Relative Humidity: 10% to 95%
- › Water Ingress (device): IP22

Physical

- › Dimensions (device): 36 mm x 36 mm x 8.5 mm
- › Weight: 14g

Gel pads

- › Type: Self-adhering, single-patient use, multiple applications
- › Materials: Hydrogel; silver ink; polyester film; cotton fabric
- › Number of Hydrogel Electrodes: Two
- › Electrode Area: 40.91cm² (each)
- › Connector: Proprietary magnetic connector
- › Dimensions: 5mm x 50mm x 145mm
- › Shelf Life: 12 months from date of gel manufacture

Operating and storage conditions

- › Atmospheric Pressure Limits: 50kPa to 106kPa
- › Relative humidity (RH) = 10% to 95% for operation and storage
- › Temperature: 5° C to 27° C

Appendix B: Label Symbols



Read user manual



Type BF applied part



Shelf life

IP22

Ingress Protection rating



Non-sterile



Immunity test / RF transmitters



Serial number



Temperature limits

(Store and use between specified temperatures)



Relative humidity limits



Atmospheric pressure limits



Manufacturer



Class 2 equipment



Warnings and cautions



Part number



WEEE (Waste Electrical and Electronic Equipment)

This symbol on the product means that used electrical and electronic products should not be mixed with general household waste, according to the Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC). For proper treatment, recovery, and recycling, please take this product to designated collection points, where it will be accepted free of charge. Alternatively, in some countries you may be able to return your products to your local retailer upon purchase of an equivalent new product. Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment. Please contact your local authority for further information about your nearest designated collection point.

Appendix C: Radio Information

Enso device is FCC ID: 2AQLG-40895051

This device complies with part 15 of FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation of the device.

FCC RF radiation exposure statement

This equipment complies with FCC radiation exposure limits for an uncontrolled environment. This transmitter meets portable and mobile limits.

Appendix D: Electromagnetic Compatibility

Guidance and manufacturer's declaration—electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The user of the device should assure that it is used in such an environment.

Emission test		Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration—electromagnetic immunity

This device is intended for use in the electromagnetic environment specified below. The user of the device should assure that it is used in such an environment.

Immunity test		Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	
Surge IEC 61000-4-5	Not applicable	
Voltage dips, short interruptions, and variations on power supply input lines IEC 61000-4-11	Not applicable	
Power frequency (50/60 Hz) field IEC 61000-4-8	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Appendix D: Electromagnetic Compatibility

Immunity test		Electromagnetic environment—guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	<p>Recommended separation distance $d = 1.2 \sqrt{P}$</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <p></p>

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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Appendix D: Electromagnetic Compatibility

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below:

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (meters)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz d $= 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4

Recommended separation distances between portable and mobile RF communications equipment and the device (continued)

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.

Appendix E: Parts and Accessories

**The following are the parts and accessories included with Enso.
Please use these part numbers when requesting replacements.**

Part	Part number
Enso Device	100-365
Standard Gel Pad	100-276
Large Gel Pad	100-252
Charger	100-366
AC Adapter	100-385
Quick Start Guide	100-440
User Manual	100-441
Nylon Bag	100-434



PN 100-441