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220-00123 Rev A

User Manual

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User manual

Hinge Health™ Enso® 3

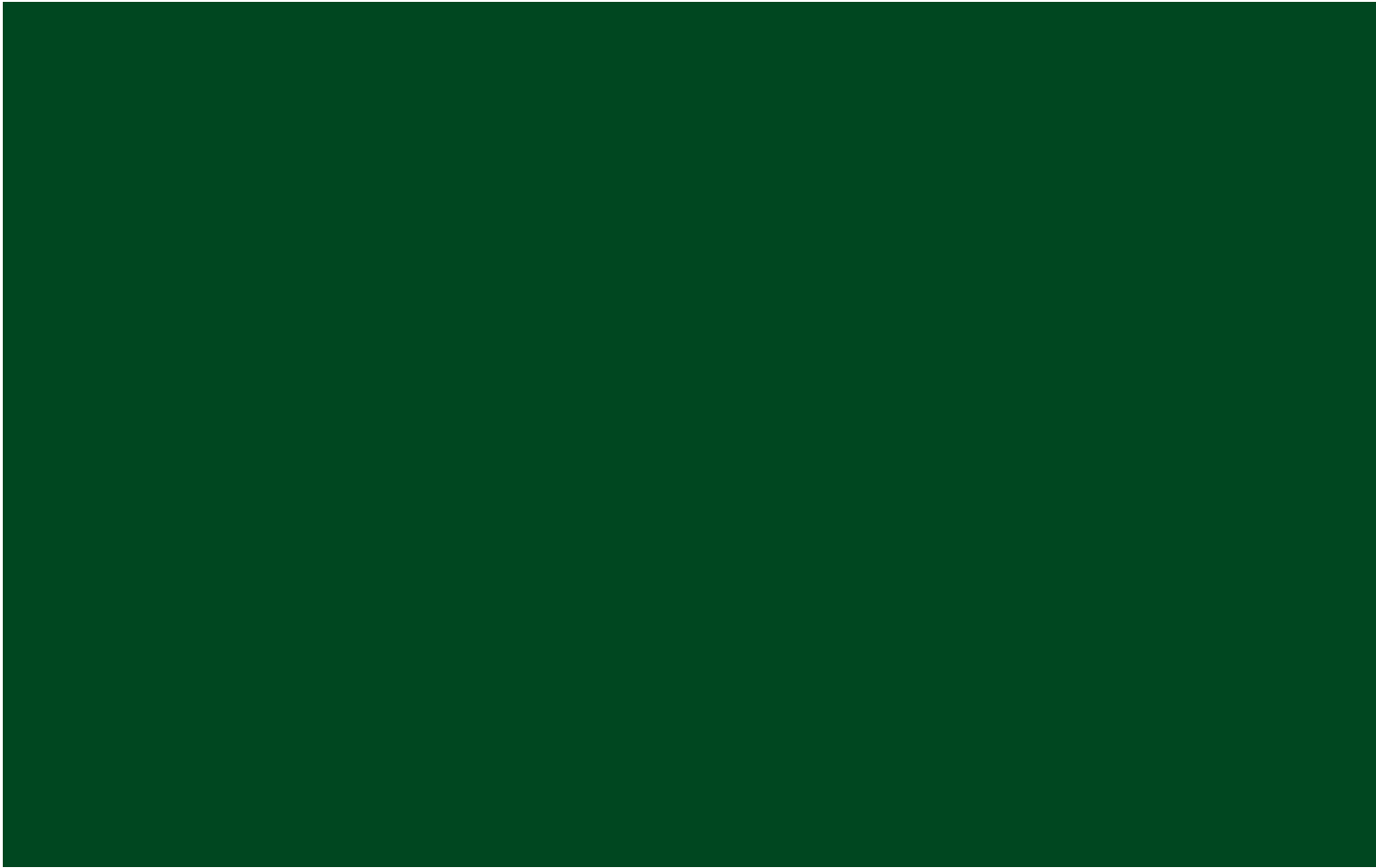


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Indications for use

The Hinge Health Enso device is intended for the symptomatic relief and management of chronic intractable 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) from exercise or normal household or work activities. Enso gel pads should be applied to the normal, healthy, dry, clean skin of adult users.

Warnings and precautions

Contraindications

- Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted 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).
- Apply stimulation only to normal, intact, clean, healthy skin to avoid causing an infection.
- Do not apply stimulation over or near cancerous lesions.
- Do not apply stimulation over or near metallic implants.
- 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 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 apply stimulation when in the bath or shower to avoid risk of shock.
- 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.
- Remove gel pads between treatments.
- Do not use with gel pads past their expiration date, which could cause discomfort or unpleasant sensations.
- Attach gel pads to the protective liner and store within the resealable pouch between uses, and store in a clean place to avoid contamination.
- Ensure the gel pad lies flat along the surface of the skin. Sweat or intense exercise/activity can cause gel pad to detach and generate a shock.
- 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; doing so could cause a risk of injury.
- 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.
- If your pain does not improve, stop using the device and consult with your physician.

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 hydrogel.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- 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 been stationary while using Enso, use caution upon moving again due to rare instances of temporary weakness (for example, use caution when standing up).
- 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.
- 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.
- Users 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 to Enso

How does Enso work?

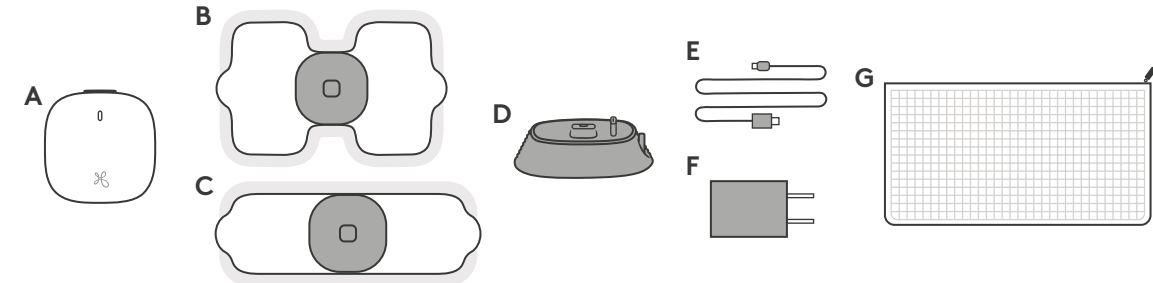
Enso delivers targeted relief through your skin via gel pads. It may produce natural pain-relieving endorphins during treatment to help you move with more confidence at home or on the go.

What does Enso feel like?

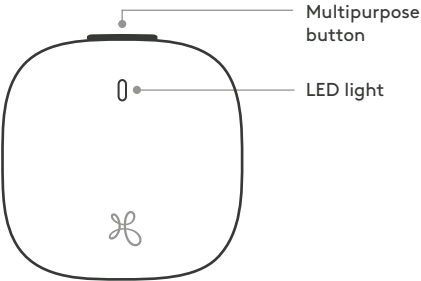
There are a variety of treatment types available for pain relief which may result in different tingling sensations for each user.

What's included?

- A.** Enso device
- B.** Large gel pad
- C.** Standard gel pad
- D.** Charging dock
- E.** Charging cable
- F.** AC adapter
- G.** Storage bag



Enso overview



Multipurpose button interaction	Command
Press & hold for 1 second	Power on/off
Quick press during treatment	Pause
Quick press while device is idle	Check battery
Hold for 10 seconds	Hard reset

Tip: Store Enso in a cool, dry place.

LED light indications

Light state	Device state
LED off	Off
Pulsing blue	Disconnected/pairing
Solid white	Idle/connected
Pulsing white	Treating
Solid green*	Battery charged
Solid orange*	Battery low
Pulsing yellow**	Caution
Pulsing red**	Error

*To view battery status, make sure your Enso is turned on and in idle mode—then quick-press the multipurpose button.
**See Troubleshooting on page 11 for more information.

Getting started with Enso

Download the Hinge Health app

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

To download the app:
Scan the QR code below to download the Hinge Health app from the Apple App Store or Google Play Store.

Note: The Hinge Health app is compatible with Apple devices running iOS 15+ and most Android devices running Android 9+.



Pairing Enso with your iPhone or Android device

1. Open the Hinge Health app.
2. Tap the Enso card on the home screen.
3. Follow the setup instructions.

Bluetooth range

Enso has a Bluetooth range of around 30 feet (10 meters), depending on the environment and radio interference. If your mobile device is out of your Enso’s range or experiences radio interference from nearby devices, treatment will continue but in-app controls will be unavailable until the issue contributing to the poor connection is resolved.

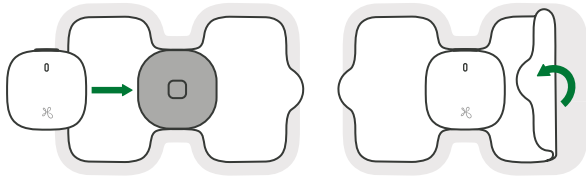
Gel pad care

When a gel pad can no longer stick 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 41° F to 81° F (5° C to 27° C).

Placing the gel pad

It's recommended that you clean your skin with soap and water before an Enso treatment session. Do not use any lotions, moisturizers, or creams before use.

Be sure to follow the in-app guidance on gel pad selection.



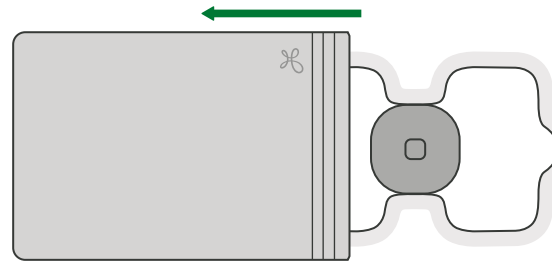
Pictured: Placing Enso in the center of the gel pad (left). Using the pull tabs to remove the gel pad from the protective liner (right).

1. Remove the gel pad from its pouch.
2. Position your Enso device onto the center tray of the gel pad until it attaches magnetically.
3. Remove and save the protective liner.

4. Use the pull tabs on the gel pad to place it directly over your pain area or the source of your pain. Avoid touching the hydrogel.
5. Use your hand to smooth out the surface of the gel pad so it securely adheres to your skin.

Removing the gel pad

Before removing the gel pad, make sure your Enso device is turned off. Then, using the indicated pull tab, gently peel the pad away in one smooth direction. Be sure to avoid touching the hydrogel.



Pictured: Resealable pouch to store gel pad in between uses.

Storing the gel pad

Place the gel pad onto its protective liner and place in the resealable pouch between uses. This helps to preserve the usability of the gel pad and to prevent contamination by dirt or dust.

Replacing the gel pad

The expiration date is located on the back of the gel pad pouch. If your gel pads are expired, dirty, or no longer sticky, please contact support at help@hingehealth.com to request a replacement.

Beginning treatment

Follow the in-app instructions to choose your treatment details and start your first Enso session.

Recommended treatment time

For optimal results, use Enso for at least one hour per session. Studies show that using Enso for at least one hour a day provides effective relief. We recommend experimenting 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, set your intensity level to the recommend level for your body area if it's comfortable for you.

During treatment

You can do normal daily activities or exercise therapy. The device is wireless and can be worn under your clothing. It is not waterproof, so do not shower, bathe, or swim while wearing Enso. Additionally, do not remove your Enso or its gel pad without first pausing your treatment session.

Stopping treatment

You can stop your treatment by pressing the multipurpose button on the Enso device or by pressing the pause button in the app.

Battery life

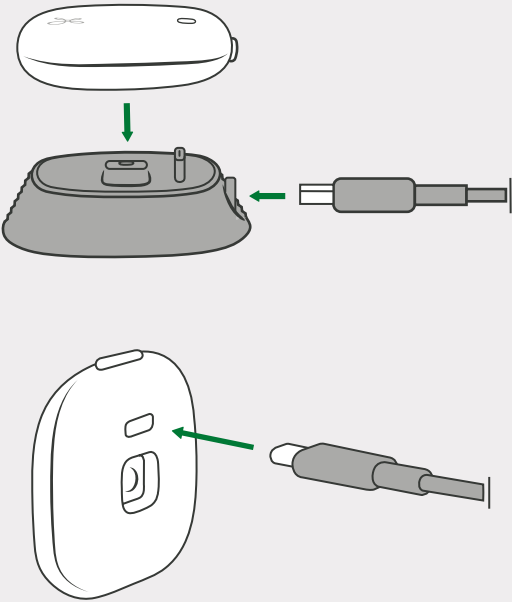
Your Enso arrives charged and ready to use. Enso's battery life will vary depending on your selected treatment intensity.

Charging

- For at-home charging, place Enso onto the charging dock and connect the charging dock to a wall outlet using the charging cable and AC adapter.
- For charging on the go, connect the charging cable to the charging port on the bottom of the device and connect to a wall outlet using the AC adapter.
- For a quick charge, charge Enso for 30 minutes. For a full charge, charge Enso for 2 hours and 30 minutes.
- Enso’s battery life will vary depending on your selected treatment type and intensity.

Treatment intensity	Battery life*
100%	Up to 4 hours
75%	Up to 4 hours, 20 minutes
50%	Up to 4 hours, 35 minutes
25%	Up to 5 hours, 25 minutes

*Tested under typical usage conditions. Your experience may vary depending on treatment mode.



Pictured: Place Enso onto the charging dock and connect to a wall outlet for at-home charging (above). Connect the charging cable to the charging port on the bottom of Enso for on-the-go charging (below).

Charging indications

Light state	Battery percentage
Pulsing orange	0%-20%
Pulsing green	21%-99%
Solid green	100%

Troubleshooting

I can’t pair my Enso.

In your device settings, make sure that Bluetooth is turned on, and hold Enso close to your device when pairing. If you need more help, email 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 2 hours and 30 minutes.

My treatment stopped and Enso is pulsing yellow.

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 five minutes, treatment will resume and gradually increase to the intensity set previously.

My treatment stopped and Enso is pulsing red.

Turn your Enso device off and then back on. If this does not resolve the issue, please contact support for additional help at help@hingehealth.com.

My treatment feels like a stinging sensation.

Stop treatment in the app or press the Enso multipurpose 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. If the stinging sensation continues after adjusting or replacing the gel pad, please contact your health coach for assistance.

I get muscle cramps from treatment.

Decrease treatment intensity on the treatment control screen of the Hinge Health app. Please contact your health coach if this issue continues after adjusting treatment intensity.

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 or use a new gel pad. If irritation continues, discontinue treatment and contact your health coach for assistance.

I would like maintenance or service for my 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 use Enso if your device has become damaged.

Do not disassemble Enso or any of its accessories, as doing so may cause damage.

Use only the provided AC adapter, charging dock, and

charging cable to charge Enso. Outside charging solutions may damage Enso.

Use a dry cloth to clean the outside of the Enso device. Do not use cleansers; they may damage it.

Do not allow Enso to get wet or immersed in water or any other liquid, as this may damage it. Do not continue using your Enso if it has been immersed in water or any other liquid.

If your Enso device has been damaged for any reason, 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.

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.

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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

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Suite 700
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hingehealth.com/enso

Appendix A: Technical specifications

Power

- Power Source: Internally powered by fixed, rechargeable battery
- Battery Type: Lithium-polymer battery, 3.85V nominal
- Battery Life: >80% of initial capacity after 300 cycles (estimated two to three years of typical use)
- Input Voltage: 5V DC
- Input Current: 220mA (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 500 Ω load)
- Voltage: 90V ($\pm 10\%$, maximum, into open circuit)
- Max Pulse Duration: 93.6 μ s
- Pulse Frequency: 166.4Hz
- Operating Mode: Continuous Phase Charge: 40 μ C (maximum)
- Maximum Current Density: 0.51mA/cm² into 500 Ω load
- Maximum Average Current: 2.33mA into 500 Ω load
- Maximum Average Power Density: 3.6mW/cm² into 500 Ω load

Environmental operating and storage conditions

- 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): 42.0mm x 42.0mm x 11.0mm
- Weight: 13.5g


Bluetooth/wireless communication

- Operating distance 30 feet (10 meters)
- Transmit power +4 dBm - Output watts 0.0016W
- Frequency range: 2402-2480 MHz
- Security: AES Encryption
- Quality of Service (QoS) Packet Loss: < 50%
- QoS Data Integrity: 100%
- Data Latency: < 1 sec and Data Throughput: > 0.2 kbit/s
- Accessibility and Signal Priorities: equal priority with other BLE devices


Gel pads

- Type: Self-adhering, single-patient use, multiple applications
- Materials: Hydrogel; Polyethylene terephthalate; Thermoplastic polyurethane
- Number of Hydrogel Electrodes: Two
- Expiration: See date on gel pad pouch


Appendix B:
Label symbols




Temperature limits
(Store and use between specified temperatures)




Relative humidity limits



Atmospheric pressure limits



Refer to instruction manual/booklet



Type BF applied part

IP22

Ingress protection rating

The Enso product should be disposed of in accordance with local, state, regional, and federal regulations.

Appendix C:
Radio information

See Enso device label for FCC ID

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	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	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.

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.

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.

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</p> $d = 1.2 \sqrt{P} \quad d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <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, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</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.

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 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.5 GHz d = 2.3 √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.

