ellune

freedom from period pain*

User Manual

Read carefully before using this device

Model No. KTR-2302

*pain relief is temporary

paingone

Fast, effective pain relief

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The serious stuff

Indications for use

For temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over the-counter pain medications.

Intended user

Ellune should be used only by those aged 16 and above, that are still having menstrual periods. If you experience new, unexpected or worsening pain, seek medical advice.

Who should NOT use Ellune?

⚠ CONTRAINDICATIONS DO NOT USE:

- If you have suspected or confirmed epilepsy or heart disease, malignant tumour, serious cerebrovascular disease or other acute disease, unless specialist medical authorisation has first been obtained.
- If you are fitted with a pacemaker or other active implanted electrical device. Such use could cause electric shock, burns, electrical interference, or death.
- In case of epilepsy or suspicion of epilepsy because electro stimulation could promote the occurrence of epileptic seizures.
- This device is not intended for and should not be used by those who are pregnant, in labour, or breastfeeding.
- Ellune should not be used while fertility problems are being evaluated, diagnosed, or treated.
- Do not use in areas with staples, implants or any metal parts in order to avoid the risk of burns or pain.
- On children or people with no ability to express their own consciousness.
- If you have been diagnosed with or have any reason to believe that you may be suffering from, Deep Vein Thrombosis (“DVT”).
- If suffering from haemorrhage after acute trauma or fractures, or if recovering from surgery.

⚠ ADVERSE REACTIONS

- Risk of cardiac arrest if you are fitted with a pacemaker or other implanted electrical device.
- Risk of electric shock if you attempt to open up the device.
- Risk of epileptic seizure if you have epilepsy.

- Risk of adverse effects on breathing, heart rhythm or blood pressure if you apply the electrodes to the front of the neck.
- Risk of lethal rhythm disturbances to the heart if you place the electrodes across your chest.
- Risk of affecting eyesight or causing headaches if you place the electrodes over your eyes.
- Use of the device may cause irritation to the skin beneath the electrodes.
- Burns beneath the electrodes have also been reported in the literature.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Allergic reactions to the gel adhesive may be possible.
- Long-term stimulation of the same area may cause skin irritation.

⚠ WARNINGS

- Do not place electrodes over the neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.
- Do not place electrodes across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart which could be lethal.
- Do not place electrodes over open wounds, rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, and varicose veins).
- Do not place electrodes over, or in proximity to, cancerous lesions.
- Do not place electrodes on the genitals.
- Electrodes should be applied only to normal, intact, clean and healthy skin.
- Incorrect application of electrodes could result in discomfort or burning of the skin.
- Do not share electrodes with other persons because of the risks of adverse skin reactions and disease transmission.
- As Ellune is a TENS device, it is intended for symptomatic treatment and has no curative effect.
- Electronic devices (such as an ECG and others) may not operate properly when TENS stimulation is in progress.
- Do not attempt to clean or maintain the device during use.
- Using the Ellune device and High Frequency (HF) equipment at the same time could result in burns and it may also damage the device or equipment. Using Ellune within 1 metre of short wave or microwave therapy equipment could result in an unstable output from the Ellune device.

- Only Ellune branded electrodes must be used with the Ellune device.
- Keep Ellune within reach during use in order to deactivate the device promptly if this becomes necessary.

⚠ CAUTIONS

- Turn Ellune off before applying or removing the electrodes.
- TENS is not recommended for patients with heart disease who have not received a medical evaluation of possible adverse effects.
- TENS should not be used to alleviate an undiagnosed pain syndrome until the etiology has been well established.
- Ellune should not be used for ovulation pain (mid-cycle pain).
- Batteries are rechargeable; batteries should not be replaced by unauthorised personnel.
- To avoid potential contamination, use the electrodes only on intact skin for no longer than 10 hours at a time.
- Keep Ellune dry. Do not expose the device to a wet environment and do not use when bathing or showering.
- Use caution while using Ellune in tandem with any monitoring equipment with body-worn electrode pads. Ellune may interfere with the signals being monitored.
- Strong electromagnetic fields may affect the correct operation of this device. If unusual phenomena are observed, move away from electromagnetic fields.
- Use caution following recent surgical procedures. Electrical stimulation may disrupt the healing process.
- Since the effects of stimulation of the brain are unknown, stimulation electrodes should not be placed on opposite sides of the head.
- The long-term effects of cutaneous electrodes for electrical stimulation on the human body are unknown.
- Keep electrodes out of the reach of children.
- Use caution if electrodes are applied over areas of skin that lack normal sensation.
- Replace self-adhesive electrodes if they no longer stick firmly to the skin.
- Do not charge the device while using it.
- Do not operate the device when electrodes are not connected. Make sure the device is off before removing or connecting the electrodes.
- Use caution, if operating machinery or driving, to ensure that electrical stimulation or involuntary muscle contraction is not dangerous.

- Do not use this device while you sleep to avoid the risk of pain, inflammation, or burns due to excessive intensity adjustment that you would not be able to control for lack of alertness.

⚠ Do not place electrodes:

- On broken skin.
- On skin which does not have normal sensation. If the skin is numb, too great a strength may be used in the Ellune and this could result in skin inflammation.
- On the front of the neck. Doing so could cause the airway to close, affecting breathing, or causing a sudden drop in blood pressure (vasovagal response).
- Over the eyes. Doing so may affect eyesight or cause headaches.
- Across the front of the head. The effect on patients who have had strokes or seizures is unknown.
- Over, or in proximity to, cancerous lesions.

⚠ Do not:

- Ignore any allergic reaction to the electrodes. If skin irritation develops, stop using the device.
- Immerse your device unit in water or place it close to excessive heat – this may cause the device to cease operating correctly.
- Attempt to open up the device - there are no serviceable components and there is a risk of electric shock.
- Use this device with electrodes other than those recommended by the manufacturer – performance and safety may be compromised.
- Attempt to modify this product.

Contents of your Ellune pack

Ellune device

The main unit that lets you control the therapy.

Silicone cover

This fits over your Ellune. Different colours are available allowing you to customise your device.

Charging cable

Lets you connect your Ellune to a USB point to charge the battery.

2x electrode pads

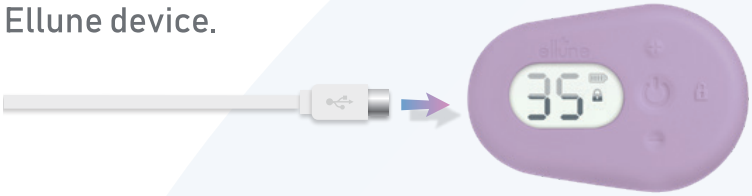
These pads are placed on your skin, at the point of pain, where they deliver Ellune's therapy. They are connected by cable to the Ellune unit.

6x gel pads

These replaceable gel pads help the electrode pads adhere to your skin.

Connecting cable

Connects the electrode pads to the Ellune device.

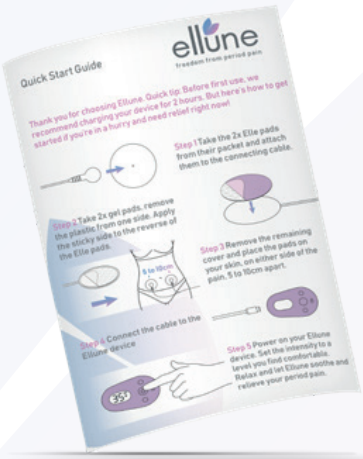


Carry bag

Keep Ellune and its accessories in this bag for protection and easy transport.

User manual

The manual you have in your hands right now!



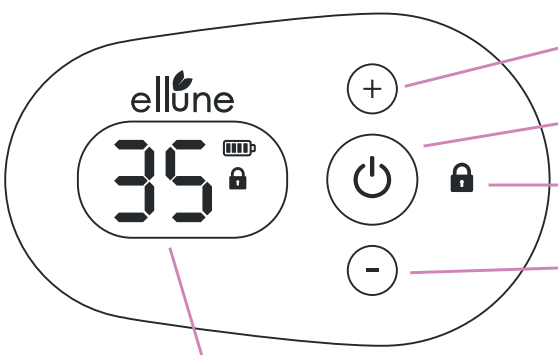
Quick start guide

If any part is missing, or to purchase accessories for your Ellune, contact your local distributor or visit

www.paingone.com

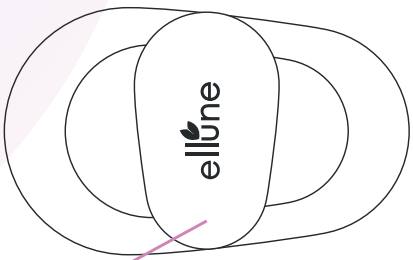
Device overview and diagrams

Device front view



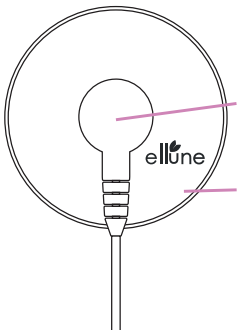
- Increase Intensity button
- Power On/Off button
- Lock function button
- Decrease Intensity button
- Display screen

Reverse view



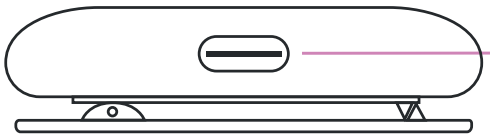
- Attaching clip – Allows you to attach Ellune to your waistband

Electrode pads



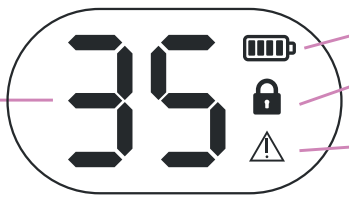
- Connecting Cable
- Electrode Pad

Side view



- USB-C Connection point

Display screen



- Intensity level
- Battery level
- Lock function indicator
- Connection error indicator

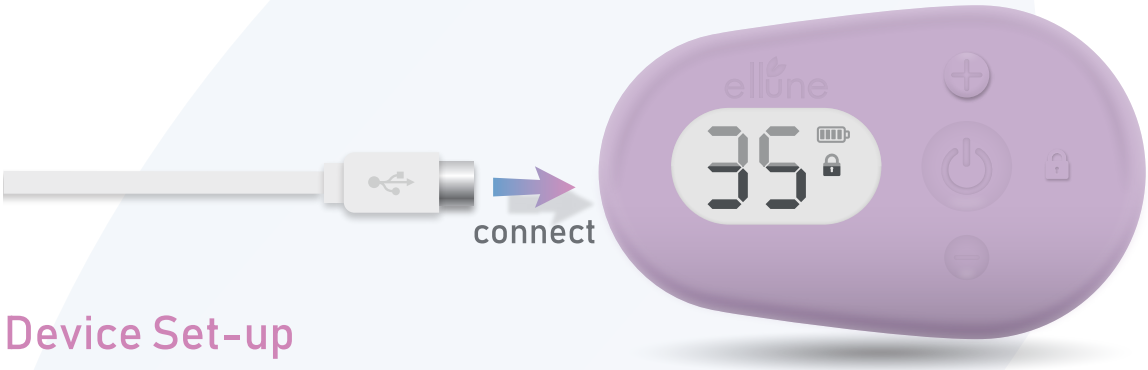
Everything you need to know about using Ellune

Before using for the first time

Scan the QR code to watch a 'how-to' video

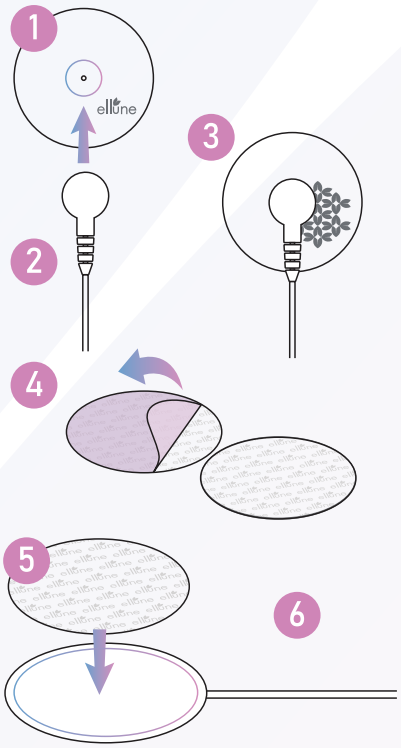
We recommend charging your Ellune before using for the first time. This will give your device the best possible start and ensure it performs optimally.

1. Connect the charging cable to Ellune.
2. Connect the cable to a USB charger.
3. We recommend charging for 2 hours this first time. All future charges take approximately 1 hour.

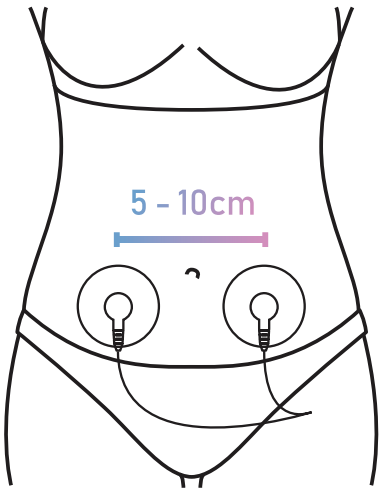


Device Set-up

1. Take the electrode pads.
2. Attach the first pad to the connecting cable. The pads connect via metal press studs. Press until the connection snaps firmly into place.
3. Repeat this action with the second pad.
4. Take a gel pad. Remove a plastic liner from one side of the pad (be sure to retain liners for later).
5. Apply the gel pad to the reverse (the black side) of an electrode pad.
6. Repeat the above with the second gel pad, applying it to the second electrode pad.



Positioning the electrode pads



In the next step we will apply the pads to the required area. You can apply them on the abdomen or the lower back, depending on where you have the most pain.

Aim to position the pads on either side of the painful area, at the same height, and at a distance of 5-10cm apart from each other.

Applying the electrode pads

1. Ensure that your desired area of application is clean and dry.
2. Remove the remaining plastic liners from the gel pads.
3. Apply the pads as required on the abdomen or lower back.

Connecting the pads to Ellune

1. Now, take the connecting cable and connect this to your Ellune device.

Using Ellune

1. Press the power button to activate Ellune.
2. Set the intensity to a level you find comfortable. Use the "+" button to increase the intensity. You can tap it to increase by just one level. Or hold the button down to change levels rapidly. If the intensity becomes too strong, press the "-" button to reduce intensity.
3. The screen displays your chosen intensity level. There are 35 levels in total.
4. Once you are comfortable, you can attach Ellune to your waistband using the clip on the reverse of the device.
5. Let Ellune do it's work while you get on with the things you love. The device will run until you press the power button or the battery is exhausted.

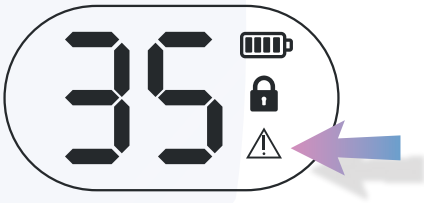
Note: Ellune is intended for use by you. All functions can be safely operated without intervention or supervision from a specialist.

Note: If the device has been stored at a temperature that is outside of the specified storage limits, allow 15 minutes for the device to reach normal ambient temperature before using.

Lock function

To avoid accidentally changing the intensity or turning the device off during use, press the 'lock' button to activate lock mode. This will disable all the other buttons. Simply press the 'lock' button once more to exit lock mode.

Connection error



If Ellune detects that there is a connection error, it will pause therapy and display the connection error symbol on the display screen.

To resolve a connection error, check that:

- The gel pads are applied firmly to your skin
- The connecting cable is correctly attached to the pads and Ellune device

Once connection is re-established, Ellune will automatically resume therapy and return to the intensity level that was previously selected.

Over time, the connecting cable and/or electrode pads may deteriorate from daily wear and tear. These parts can be replaced. Contact your local distributor or visit www.paingone.com for replacements.

Finishing a session

1. To stop the Ellune therapy, simply press the power button.
2. Carefully remove the pads from your skin.
3. Place a plastic liner back over each gel pad. This will keep them in optimum condition for their next use.
4. You can store Ellune and its accessories in the carry bag supplied.

Taking Care of Your Ellune

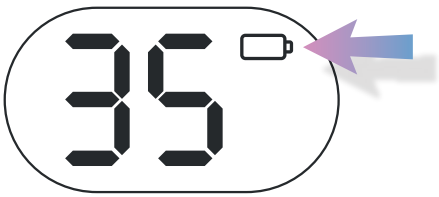
Replacing the gel pads

For optimum effectiveness and hygiene, we recommend using one set of gel pads per menstrual cycle.

At the start of your menstrual cycle, remove and dispose of the used gel pads and replace with brand new pads. Only use Ellune branded gel pads with the device.

Ensure your device is switched off when changing the gel pads.

Charging your Ellune



When Ellune's battery is getting low, the device will beep and the battery symbol on the display will flash. This indicates that it is time to recharge your device.

Take the charging cable supplied. Connect this into your Ellune device, and connect the other end to a USB charger.

The battery symbol on the screen will show that the device is charging. Once fully charged, the battery symbol will display 4 solid bars.

Ellune is compatible with fast-chargers. It takes approximately 1 hour to fully charge the battery.

Cleaning and maintenance

Switch off Ellune before cleaning. Use a disinfectant or anti-microbiological wipe.

Wipe all external surfaces of the device control unit and all cables.

Care should be taken not to clean the cable connectors.

Cleaning should be carried out at least once a month.

Frequently Asked Questions

How long can I use Ellune for?
Ellune can be used as long as you are experiencing period pain.
The electrode pads should be removed and the site of application adjusted at least every 10 hours. Regularly changing the site of application will reduce the risk of skin irritation.

What is the right intensity level for me?
The right intensity level is one that feels comfortable for you and where it begins to match the intensity of your pain.

How does Ellune work?
Ellune works by sending high-frequency electrical signals that are both continuous and mild to block out the pain signals being delivered to the brain. This is sometimes known as the “gate” control effect because it reduces transmission of pain. When these pain signals are halted, pain is not felt by the reactive area and the patient gets relief. Electrotherapy also helps activate the natural pain control response, releasing beta endorphins that ease the pain felt by the patient.

Can I use Ellune in combination with medication?
Yes, you can use Ellune in combination with medication you may be taking

Where can I obtain replacement parts and accessories?
Visit www.paingone.com or contact your local distributor

Can I place one pad on my abdomen and one on my back?
The maximum distance apart the electrode pads can be placed is 10cm.
To apply Ellune to the abdomen and the back at the same time requires 2x Ellune devices.

Troubleshooting

Issue	Suspected cause	Suggested action
No stimulation from pads	Low battery or connection error.	Fully charge Ellune's battery. Check that the connection cable is properly connected to the electrode pads and to your Ellune device, and that the cable is not damaged.
No stimulation from electrode pads. Screen displays 	Connection error. The electrode pads may have come loose from the skin. Or the connecting cable may have detached or be damaged.	Firmly press the electrode pads against your skin. Check that the connection cable is properly connected to the pads and to your Ellune device. Replace cable if there are signs of damage.
Stimulation feels weak	Poor connection or worn gel pads.	Firmly press the electrode pads against your skin. If this does not improve stimulation, apply brand new gel pads to the electrode pads.
Device beeps	Low battery. The beep sound indicates that battery is running out.	Fully charge Ellune's battery.
Nothing displayed on screen	Exhausted battery.	Fully charge Ellune's battery.
Gel does not adhere to the skin	Gel pads have become overused.	Replace the gel pads.
Stimulation is felt more strongly through one electrode pad	Poor positioning of electrode pads.	Ensure the electrode pads are positioned on either side of your pain and at the same height on your body.
Buttons are not responsive	Lock function may be active.	Press the lock button once to reactivate the other buttons.

If you have followed the recommendations above but find that your device is still not functioning correctly please contact your local distributor or the manufacturer. Do not attempt to disassemble or repair this device.

Technical Details

Device specification

Model No:	KTR-2302
Output:	0-45V
Intensity:	35 levels
Frequency:	100Hz
Pulse width:	120μS
Load impedance:	500Ω, tolerance is ±20%
Weight:	44g
Dimensions:	75×50×19.8mm
Power consumption:	About 0.2W
Power source:	3.7V DC 500mAh
Power supply:	Type-C USB 5V/9V DC
Input Power:	1.5W

Battery life cycles: Under normal use, the battery life is ≥500 recharge cycles, about 2-3 years of use (30 minutes per day).

a. Environment for operation

Temperature:	+5°C~+40°C
Humidity:	0%~80%
Barometric pressure:	86kpa~106kpa

a. Environment for storage:

Temperature:	-25°C~+55°C;
Humidity:	0-93%RH
Barometric pressure:	50kpa~106kpa

a. Environment for transport

Temperature:	-25°C~+55°C;
Humidity:	0-93%RH
Barometric pressure:	50kpa~106kpa

Glossary of Graphic Symbols

Symbol	Explanation
LOT	Production Batch
REF	Model/catalogue number
	Manufacturer
	DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture
	Caution
	Applied part of type BF
EC REP	European Authorized Representative
	Do not dispose in household waste. Separate collection for waste electric and electronic equipment (WEEE) is required
CE 2862	CE marking with the Registration Number of the Notified Body. This denotes compliance with (Regulation (EU) 2017/745 for Medical Devices)
IP22	Level of protection against the insertion of solid bodies of size/diameter ≥ 12 mm and liquids in the presence of dripping water when tilted at 15° compared with products.
	Refer to instruction manual/ booklet
MD	Indicates the item is a medical device
	Single-patient multiple use device
	Importer name and address
UDI	Unique device identifier
	Use by date

Safety and compliance standards

The product conforms to the following standards and laws:

1. IEC 60601-1:2005+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.

2. IEC 60601-1-11:2020 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment.

3. IEC 60601-2-10: 2012+A1:2016 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.

4. IEC 60601-1-2:2014+A1:2020 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.

5. ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

EMC & electrical standards/requirements

IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

The equipment is intended for use in the electromagnetic environment specified below.

The customer or the user of the EQUIPMENT should assure that it is used in such an environment.

This Transcutaneous Electrical Nerve Stimulators is suitable for use in a professional health care environment, not including areas where there are sensitive equipment or sources of intense electromagnetic disturbances, such as the RF shielded room of a magnetic resonance imaging system, in operating rooms near active AF surgical equipment, electrophysiology laboratories, armored rooms or areas where short wave therapy equipment is used.

- Do not use the system around strong electric fields, electromagnetic fields (e.g. MRI scan room) and mobile wireless communication devices. Using the device in an improper environment may cause malfunction or damage.
- The compliance with EMC and EMI regulation cannot be guaranteed by the use of modified cables or those which do not comply with the same standards under which the equipment was validated.
- The system must not be used adjacent to or supported by other equipment.
- The recommendations of this manual must be followed.
- Do not use accessories, transducers, internal parts of components and other cables other than those previously specified by the manufacturer. This may result in increased emission or decreased electromagnetic immunity and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should by used no closer than 30cm to any part of the ultrasound system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- To maintain basic safety in relation to electromagnetic disturbances during the expected service life, always use the system in the specified electromagnetic environment and follow the maintenance recommendation described in this manual.

The following tables provide information on compliance of the equipment according to the standard EN 60601-1- 2:2015.

Lifespan

Ellune has an expected lifespan of approximately three years. At the end of its useful life, the device should be discarded according to local law for disposal of electrical and electronic devices.

Electromagnetic emissions table

Table 1 compliance class

Emissions Test	Compliance	Electromagnetic Environment and Guidance
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 compliance standards

Phenomenon	Basic Standard of	Immunity Test	Level of
Electrostatic discharge	IEC 61000-4-2	±8 KV contact ±2 KV, ±4 KV, ±8 KV,±15KV air§	±8 KV contact ± 2 K V, ± 4 K V, ± 8 KV, ±15KV air
Radiated RF EM fields1	IEC 61000-4-3	3V/m 80 MHz-2.7 GHz 80% AM at 1 KHz	3V/m 80 MHz-2.7 GHz 80% AM at 1 KHz
Proximity fields from RF wireless communication equipment	IEC 61000-4-3	See table	See table
Electrical Fast/ Transients bursts	IEC 61000-4-4	±1 KV 100 KHz repetition frequency	±1 KV 100 KHz repetition frequency
Conducted disturbances induced by RF fields.	IEC 61000-4-6	3V 0.15 MHz-80 MHz 6 Vm in ISM bands between 0 .15 MHz and 80 MHz 80% AM at 1KHz	3V 0.15 MHz-80 MHz 6 Vm in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1KHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz

Table 3- Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipments

Test Frequency	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5 KHz deviation 1KHz sine	2	0.3	28
710 745 780	704-787	LTE 13, 7 Band	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800 , iDEN 820, CDMA 850, LTE 5 Band	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800 , CDMA 1900, GSM 1900, DECT,LTE 1, 3, 4 , 25 Band, UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450,	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Warranty

This product is warranted to be free from manufacturing defects for 2 years from date of purchase.

This warranty refers to the unit only. It does not cover the electrodes, gel pads, charging cable, or connecting cables.

This warranty is void if the product is modified or altered, is subject to misuse or abuse; damaged in transit; lack of responsible care; is dropped; if the unit has been immersed in water; if damage occurs by reason of failure to follow the written instructions for use booklet enclosed; or if product repairs are carried out without authority from the manufacturer.

Contact us info@paingone.com

Shenzhen Kentro Medical Electronics Co. Ltd.
2nd Floor, No. 11, Shanzhuang Road, Xikeng Village,
Yuanshan Street, Longgang District, Shenzhen City,
Guangdong Province, China.

EC REP WellKang Ltd (www.CE-marking.eu), Enterprise Hub,
NW Business Complex, 1 Beraghmore Road, Derry, BT48
8SE, Northern Ireland

PGELLUNE

10.01.24 version 0002