This manual is valid for the Incontinence Treatment Device LT2061

This instruction manual is published by Shenzhen Dongdixin Co.,Ltd.

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Conformity to safety standards

Shenzhen Dongdixin Co.,Ltd. declares that the device complies to the following normative documents:

IEC60601-1, IEC60601-1-2, IEC60601-2-10, IEC62366, IEC60601-1-11
ISO10993-5, ISO10993-10, ISO10993-1, ISO7010
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1. Introduction

Congratulations on your purchase and welcome to Dongdixin! Read this user manual carefully before you use the incontinence treatment device. To achieve optimal treatment success with LT2061, we recommend that you use it according to the treatment instructions in this user manual. If you need further information or have questions, please contact with us.

1.1 Feature
The LT2061 is a ME system. The ME EQUIPMENT is the main device (vaginal probe), the non-ME EQUIPMENT including the storage case and the adapter. Features are shown below:
- Through the Bluetooth to achieve wireless control, and makes it convenient to use.
- The main device contains electrical stimulation teat, kegel exercise and vibration massage three functions. Not only
- can be used for treatment also can bring pleasure to you.
- Ergonomic design, effectively prevent the vaginal probe off and rotation, to ensure that treatment effect.
- The flange part is wrapped with silicone to ensure a comfortable touch when Treatment.
- The waterproof level rating of the main device reaches IP56, to ensure that convenient to clear.
- Special storage case, set of charging and admission for one, improved privacy and at the same time, also ensure that the probe is clean and sanitary.

1.2 Intended Use
This device is used for the treatment of stress, urge and mixed urinary incontinence, weakening of the pelvic floor muscles and pain relief.
2. Important Safety Precautions and Warning

It is important that you read all the warning and precautions included in this manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the device.

2.1 Contraindications
This stimulator must not be used in combination with the following medical devices:

- Internally transplanted electronic medical devices, such as a pacemaker.
- Electronic life support equipment, such as respirators.
- Electronic medical devices attached to the body, such as electrocardiographs.
- Using this stimulator with other electronic medical devices may cause erroneous operation of those devices.

2.2 Warning
DO NOT USE THIS DEVICE UNDER THESE CONDITIONS:

- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances in certain susceptible individuals.
- Pregnant women must not be treated with this device.
- People with extra-urethral incontinence (fistula, ectopic ureter) must not be treated with this device.
• People with overflow incontinence due to outflow obstacle must not be treated with this device.
• People with serious retention of urine in the upper urinary tract must not be treated with this device.
• People with complete peripheral denervation of the pelvic floor must not be treated with this device.
• Do not use this device for treatment during menstruation, vaginal or urinary tract inflammation or infection.
• The vaginal probe and silicone sleeve for single patient use, in order to avoid mutual infection, do not cross-use.
• Stimulation should not take place while the user is connected to high-frequency surgical equipment, it may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
• Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.

DO NOT USE ON THESE INDIVIDUALS
• Pregnant women, because the safety of electrical stimulation during pregnancy has not been established.
• Children or infants, because the device has not been evaluated for pediatric use.
• Persons incapable of expressing their thoughts or intentions.

DO NOT USE THIS DEVICE DURING THESE ACTIVITIES
• When in the bath or shower;
• While sleeping;
• While driving, operating machinery, or during any activity in which electrical stimulation can put you at risk for injury.
2.3 Caution

- The LT2061 device is intended for use by one person. Do not share with another person.
- Patients with total/subtotal prolapsed uterus/vagina should be stimulated with greatest caution.
- Patients with urinary tract infections must be treated and clear of infection before starting therapy with this device. Consult your doctor.
- If tissue irritation should occur, treatment should be temporarily discontinued. If problems continue, contact your health care provider. Hypersensitivity can occur in isolated cases. The problem usually disappears when the LT2061 device or the silicone sleeve changed to another type.
- Always turn the power off before removing or changing the location.
- If the stimulator is not functioning properly or you feel discomfort, immediately stop using the device.
- Do not use for any other purpose except for what it is intended for.
- Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- The service life of the device may vary by the frequency of washing, vaginal condition, and storage state.
- Be careful to strangulation due to cables and hoses, particularly due to excessive length. Keep unit out of the reach of young children/pets. The electrode cord can cause strangulation.
- The typical service life of the main device, the adaptor and the charging box is 2 years; and the silicone sleeve is 1 year.

2.4 General precautions

- Inspect the equipment prior to use.
- The long-term effects of electrical stimulation are unknown.
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
• If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
• Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
• Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
• This stimulation should not be applied over the menstruating or pregnant uterus.
• After use, the part of electrode contact with human and silicone sleeve should be cleaned.
• △ Keep unit away from young children. The unit contains small pieces that may be swallowed. Immediately contact your physician.
• Use this device only with the silicone sleeve, adaptor and storage case recommended by the manufacturer. Do not maintain or service the device while the device is in use.
• Do not modify this device without authorization of the manufacturer.
• Do not use the device if it is damaged. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
• Do not store the device to extreme temperature (below -10°C or over 50°C) (at least 30 min required of equipment to warm from the minimum storage temperature between uses until it is ready for intended use at least 30 min required for me equipment to cool from the maximum storage temperature between uses until it is ready for intended use) or extreme humidity (below 0%RH or over 93%RH). Failing to do so may affect the performance of the stimulator.
• Please report to your agency if any unexpected operation or events occur.
• If you have any problems with this device, such as setting up, maintaining or using, please contact with SERVICE PERSONNEL of SDT.
changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.
-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the 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.
• You should stop using the device and consult with your physician if you experience adverse reactions from the device.
• The materials (e.g. ABS) of expect contact with patient had passed the ISO 10993-5 and ISO10993-10 standards test, no toxicity, allergy and irritation reaction. However, based on the current science and technology, other potential allergic reactions are unknown. If you have allergic reaction to materials, please stop treatment immediately and consult your physician.

2.5 Installation and Usage Precautions
• Before use, check and ensure the main device and all accessories are intact.
• If you feel any discomfort, stop treatment immediately.
• Placed the storage case away from splashing water.
• Connect the main device and APP correctly and securely.
• Always adjust the output intensity in the comfort level. If you feels uncomfortable, adjust the output intensity or stop treatment.
• Do not use gasoline, hot water or chemicals to clean the main device and accessories. Use a dry cloth to clean accessories.
• Vaginal Probe can be reused, but should be cleaned it after use, and single patient use only.
3. Product overview

Your LT2061 is supplied with a gift box containing:

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Main device/Vaginal probe</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Storage case</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Adaptor</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>User manual</td>
<td>1</td>
</tr>
</tbody>
</table>

- **Main device/Vaginal probe**
  - Stainless steel electrode
  - Power Key and indicate
  - Silicone massage part
- **Storage and charge case**
  - Charging contact
- **Charging indicator**
  - Micro-USB socket
4. Product overview

4.1 Indicator Description

LT2061 have two different indicator light, one is orange / blue light on the vaginal probe, other one is orange/green light on the charging case.

1. What’s the function of indicator light on probe?
   - When device is turn on and without connect Bluetooth, blue light is flash;
   - When device successful connect with Bluetooth, blue light keep turn on;
   - Orange light means with low battery, it will flash 10s then device will turn off.

2. What’s the function of indicator light on the charging case?
   - Still under charging mode---Orange light;
   - Charging completed---Green light;
   - When probe is not good place, green light will last for long time and orange light will flash, you should better to replace probe in charging case and connect USB cable again.
4.2 Power on/off
1. Power on
Take the main device from the shortage case, turn on the main device by press Power key, blue light will flash, device is under standby mode.
2. Power off
- Device will automatic power off when there is no connecting Bluetooth within 5 minutes under standby mode or connection after 5 minutes without treatment;
- In the Power on mode, turn off the main device by Long press the power button.
- When orange light is flash to indicate lower battery, device will power off after 10s.
  Remark: App also can pop up a tips to remind low battery during working time

4.3 Charging
To be able to use the device, you first have to charge it. Charging the device takes approx. 3 hours at room temperature. When the Lithium-ion battery is fully charged, it contains sufficient energy for use about four times electrical stimulation treatment .
Note:
- If the device is not fully charged when you start a treatment, the battery may run out during the treatment.
- Treatment is not possible when the device is charging.
- To ensure normal use, please charge before the first time use!
- If the indicator light turn to orange, or the APP prompt that the batter is in empty state, please charge.
1. Place the main device to the storage case correctly.
2. Insert the micro-USB plug of the adapter cable into the micro-USB socket of the storage case.
3. Insert the USB plug into the socket of the adapter and insert the adapter into a wall socket.

Note:
- Insert the USB plug into a wall socket that is properly accessible so that the USB plug can be removed easily. The device is only connected to the mains during charging.
- When charging, the indicator light of the storage case turn to orange, and it will turn to green when the battery is in full state.

4. When charging is finished, remove the micro-USB plug from the microUSB socket of the storage case.

Note:
- The USB socket may only be used for charging with the adapter supplied. Do not use this socket for any other purpose.
- If you do not use the device for a long time, please charging every 2~3 months.
4.4 Installing and setting up the Treatment App
Note: System requirement IOS 7.0 +
   Internet download
   In the APP Store, customer can search “My pelvic” to download app;
   Scan QR code
   Scan the QR code on gift box or the QR code below.

5. Instructions for use

5.1 Use the Main device
1. Remove the main device from the storage case, turn on the main device by press power key, and the indicator light turn to blue flashing. The main device is in standby mode.
Note:
   ● If the indicator light turn to orange flashing, it means it need charge.
   ● If you can’t turn on the main device, please try again after charging.
2. Cleaning of the device by use clean water;
3. Try to use a comfortable treatment gesture, for example, you can lay on the bed;
4. First of all, to make sure device is power on, slowly and gently insert into vaginal cavity until the flange at the base of electrode is located between labia. Make sure no bare metal of pins is exposed (If vaginal environment is dry, a approved thin coating of lubricating gel is suggested, don’t use cream or lubricating oil, because lubricating gel should be conduct electricity).
Remark:  
- When customer do electrical stimulation and Kegel exercise, vaginal probe have to be in requested position. If not, it will influence treatment result.  
- During vibration mode, people can hold the handle by hand.  

5. Open the APP, device will connect with APP automatically.  

Note:  
- People need to charge the vaginal probe at first use time.  
- The electrode probes are designed for single patient use only.  
- Please keep clean of vaginal probe, it should be cleaned before first use and after each use.
5.2 APP operation

1. Open the Blue tooth mobile device;
2. Find App named “My pelvic”, sign as below:

3. Your mobile need to be bound to device at first time before use, please check below picture, press “select for binding”, then you can reach main interface. You can enter to main interface directly during next time of treatment.

4. After you successful bind your mobile phone with our device, when device is power on, Deice can connect with your phone automatically. When devices correct connect with APP, the sign on the top right of interface will turn to the sign like this:

Remark: If you are fail to connect the device, please check device is power on or not, or you can double check Blue tooth on APP is open or not.
5. Pelvic floor electric stimulation treat

Press “Treat” button to enter into treatment choose interface, it shows as below picture, please select different program based on different symptom:

Remark: There are 7 pre-set programs as below:

<table>
<thead>
<tr>
<th></th>
<th>Stress Incontinence</th>
<th>Urge Incontinence</th>
<th>Mixed Incontinence</th>
<th>Pain Relief</th>
<th>Lack of Sensitivity</th>
<th>Pelvic Floor Work Out</th>
<th>Frequency</th>
</tr>
</thead>
</table>
Press the specific treatment procedures, enter the treatment display interface, As shown below:

1. Work /Rest indicator of stimulator
2. The phase prompt of this program
3. Pause button.
4. Increase intensity
5. Decrease intensity
6. Output intensity
7. Treatment time

Press start treatment. Next, press “+” or “-” to adjust the intensity

Remark:
• At operating mode, you can press to pause treatment. Then, you can press again to continue treatment, also can press “End” to end of treatment.
• If APP pop-out an error tips as “Poor contact” during working time, maybe it caused by Vaginal dryness, we suggest to use a thin coating of lubricating to avoid this error tips. Below picture for your reference.
Press the specific treatment procedures, enter the treatment display interface, as shown below:

- Customer can adjust the intensity based on their own bearable stress, if people feels comfortable and no pain when she contraction and relax the muscle of Pelvic floor during treatment at some intensity, she can use this intensity to do treatment.
- The output intensity of stimulation may be adjusted depending upon the individual requirement of the user. After a long time use, user need to increase intensity to get best treatment effect.

6. Kegel Exercise
Press “Exercise” button to enter into Kegel exercise program:

Remark: There are 2 pre-set programs and 2 self-setting program. Pre-set program as below.
1. Speed Kegel (use for fast muscle exercise)
2. Endurance Kegel (use for slow muscle exercise)
Press the specific treatment procedures enter into treatment display interface, as shown below: it include the function of timer, period and voice indicator.

1. Exercise time
2. The prompt of Kegel training
3. Pause button
4. Increase of vibration strength
5. Decrease of vibration strength
6. Voice prompt switch

Or user can select the self-setting program and set the treatment parameter by themselves, they can set the contraction / relax time and cycle times, then press OK button to finish setting.

User exercise interface, press “ ” button to start exercise, follow the voice or vibration intensity to contraction and relax the Pelvic muscle (for example, vibration time to contraction pelvic and relax pelvic muscle if there is no vibration). When user is doing contraction, it will be better to contract urethra, anus and perineum at the same time keep relax of your ham and abdominal muscles, press “+” or “-” to adjust vibration strength.
Remark:
- When user in process of contraction, try to use pelvic muscle to against the vibration, when muscle is weak, it will be better to decrease intensity of vibration.
- When the timer is goes to ‘‘0’’, treatment will be end automatically.

7. Vibration massage
Press “Massage” to enter into treatment interface.
Chose a vibration program, there are 7 pre-set mode as below:
Press “ ” button to start vibration, press “+” and “-” button to adjust the vibration intensity. Press “ ” button again to pause vibration.

6. Cleaning
After user finish treatment, please close the app, shutdown the device, clean the device with clean water or mild soap water, keep the Main device and the Silicone Sleeve clean and dry, store the device in the storage case for next treatment.
Cautions: Clean the main device and silicone sleeve by soap water and wiping them with dry cloth, do not cleaning with boiling water or corrosive cleaning agents.
## 7. specifications

<table>
<thead>
<tr>
<th>Model</th>
<th>LT2061</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rated input - adapter</td>
<td>100-240V</td>
</tr>
<tr>
<td>Rated output - adapter</td>
<td>5V 0.3A</td>
</tr>
<tr>
<td>frequency (Hz) - adapter</td>
<td>50/60Hz</td>
</tr>
<tr>
<td>Class Medical –the main device</td>
<td>Class IIA</td>
</tr>
<tr>
<td>Ingress of water - the main device</td>
<td>IP56</td>
</tr>
<tr>
<td>Battery type - the main device</td>
<td>3.7V /200mAh Li-ion</td>
</tr>
<tr>
<td>Size- the main device</td>
<td>Φ31mm*128.5mm</td>
</tr>
<tr>
<td>Weight- the main device</td>
<td>50g</td>
</tr>
<tr>
<td>Service life of the device</td>
<td>2 years</td>
</tr>
</tbody>
</table>
### TENS output parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency range</td>
<td>2~100Hz (±10%)</td>
</tr>
<tr>
<td>Pulse width range</td>
<td>50~350us (±10%)</td>
</tr>
<tr>
<td>Maximum output voltage</td>
<td>80V</td>
</tr>
<tr>
<td>Output Intensity Level</td>
<td>0~80 levels</td>
</tr>
<tr>
<td>Treatment time</td>
<td>1~99 minutes</td>
</tr>
</tbody>
</table>

### Kegel output parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract time</td>
<td>1-99S</td>
</tr>
<tr>
<td>Relax time</td>
<td>1-99S</td>
</tr>
<tr>
<td>Cycle period</td>
<td>1-99S</td>
</tr>
<tr>
<td>Preset programs</td>
<td>4 (Contains 2 custom modes)</td>
</tr>
</tbody>
</table>
### Massage output parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output Intensity Level</td>
<td>1~10 levels</td>
</tr>
<tr>
<td>Preset programs</td>
<td>7</td>
</tr>
<tr>
<td>Working noise</td>
<td>&lt;40dB(Measuring distance is 50cm)</td>
</tr>
</tbody>
</table>

### Operating conditions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>From +5°C to +40°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>From 15% to 90% non-condensing, but not requiring a water vapour partial pressure greater than 50hPa.</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>From 700hPa to 1060hPa</td>
</tr>
<tr>
<td>Wireless maximum separation distance</td>
<td>10m (In the opened environment )</td>
</tr>
<tr>
<td>Wireless recommended separation distance</td>
<td>3m</td>
</tr>
</tbody>
</table>
### Storage and transport conditions

<table>
<thead>
<tr>
<th><strong>Temperature - device</strong></th>
<th>-10°C to + 5 °C, and + 5 °C to +35 °C at a relative humidity up to 90 %, non-condensing; +35 °C to 50 °C at a water vapour pressure up to 50hPa</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relative humidity</strong></td>
<td>from 0% to 93% non-condensing</td>
</tr>
<tr>
<td><strong>Atmospheric pressure</strong></td>
<td>from 700hPa to 1060hPa</td>
</tr>
</tbody>
</table>

### Bluetooth features

<table>
<thead>
<tr>
<th><strong>RF Frequency</strong></th>
<th>2.4GHZ-2.48GHZ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Channel Bandwidth</strong></td>
<td>2 MHz (-20db)</td>
</tr>
<tr>
<td><strong>Types of spread spectrum</strong></td>
<td>FHSS</td>
</tr>
<tr>
<td><strong>Modulation type</strong></td>
<td>GFSK</td>
</tr>
<tr>
<td><strong>Number of channel</strong></td>
<td>40</td>
</tr>
<tr>
<td><strong>Channel spacing</strong></td>
<td>2 MHz</td>
</tr>
<tr>
<td><strong>Channel frequency</strong></td>
<td>0-39 Channel 2.402-2.480GHZ</td>
</tr>
<tr>
<td><strong>Dwell time (if FHSS)</strong></td>
<td>400ms</td>
</tr>
<tr>
<td><strong>Hopping rate (if FHSS)</strong></td>
<td>1600HZ</td>
</tr>
<tr>
<td><strong>Maximum Output Powers</strong></td>
<td>0dBm</td>
</tr>
</tbody>
</table>
## 8. Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Check points</th>
<th>Possible solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>LED of the main device turn to orange flashing, and then turn off automatically</td>
<td>The battery is exhausted</td>
<td>Charging in time</td>
</tr>
<tr>
<td>LED of the main device turn to orange flashing in the working mode</td>
<td>low power</td>
<td>Battery less than 25% after use, charging in time</td>
</tr>
<tr>
<td>Stimulation is uncomfortable</td>
<td>Is the intensity too high or too low?</td>
<td>Adjust the output intensity</td>
</tr>
<tr>
<td></td>
<td>The electrode poor contact with vaginal of subject</td>
<td>Use a lubricant</td>
</tr>
<tr>
<td></td>
<td>The placement of the vaginal probe is not correct</td>
<td>Adjust the placement according to this USER MANUAL</td>
</tr>
</tbody>
</table>
9. Maintenance

1. Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
2. The user must not attempt any repairs to the device or any of its accessories. Please contact the retailer for repair.
3. Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.
4. Check the device before each use for signs of wear and/or damage. Replace wear items as required.
5. In order to ensure the safety and effectiveness of the use, please use the main device and accessories provided by the manufacturer.
6. If you do not use the machine for a long time, to ensure lithium battery performance, please charging every 2–3 months.
10. Disposal

Please dispose of the device in accordance with the directive 2012/19/EU – WEEE (Waste of Electronic Equipment). If you have any queries, please refer to the local authorities responsible of waste disposal.

11. Glossary of symbols

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Disposal icon" /></td>
<td>Disposal in accordance with Directive 2012/19/EU (WEEE)</td>
</tr>
<tr>
<td><img src="image" alt="Type BF icon" /></td>
<td>Type BF Applied Part</td>
</tr>
<tr>
<td><img src="image" alt="Instruction Manual icon" /></td>
<td>Refer to instruction manual.</td>
</tr>
<tr>
<td><img src="image" alt="Compliance icon" /></td>
<td>Complies with MDD 93/42/EEC and amended by directive 2007/47/EC requirements. Notified body TÜV Rheinland (CE0197)</td>
</tr>
<tr>
<td><strong>IP20</strong></td>
<td>Only for storage case, The first number &quot;2&quot;: Protected against solid foreign objects of 12.5 mm Φ and greater. The second number &quot;0&quot;: non water-proof.</td>
</tr>
<tr>
<td>----------</td>
<td>---------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>IP56</strong></td>
<td>Only for main device/probe. Protect against the effects of powerful water jets.</td>
</tr>
<tr>
<td><strong>SN</strong></td>
<td>Represent the manufacture date and Serial number.</td>
</tr>
<tr>
<td><strong>EC REP</strong></td>
<td>The name and the address of the Authorized EC representative in Europe</td>
</tr>
<tr>
<td><strong>-10°C</strong> to <strong>50°C</strong></td>
<td>Transportation and storage temperature from -10°C to 50°C</td>
</tr>
<tr>
<td><strong>0%</strong> to <strong>93%</strong></td>
<td>Transportation and storage humidity limits from 0% to 93%</td>
</tr>
<tr>
<td><strong>70.0 kPa</strong> to <strong>106.0 kPa</strong></td>
<td>Transportation and storage atmospheric pressure limits from 70.0 kPa to 106.0 kPa</td>
</tr>
</tbody>
</table>
12. Electromagnetic emissions and immunity

Electromagnetic Compatibility (EMC)
1. This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2. Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3. Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4. Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

- Refer to further guidance below regarding the EMC environment in which the device should be used.
Guidance and manufacture’s declaration – electromagnetic emission

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

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 1</td>
<td>Group 1</td>
<td>The device use 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.</td>
</tr>
<tr>
<td>RF emission CISPR 11</td>
<td>Class B</td>
<td></td>
</tr>
</tbody>
</table>
| Harmonic emissions  
IEC 61000-3-2 | Class A | The device 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. |
|--------------------------------|---------|----------------------------------------------------------------------------------------------------------------------------------|
| Voltage fluctuations/  
flicker emissions  
IEC 61000-3-3 | Complies |                                                                                                                                 |


Guidance and manufacture’s declaration – electromagnetic immunity

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact ±8 kV air</td>
<td>±8 kV contact ±15 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV line(s) to ± 1 kV differential line(s)</td>
<td>± 2 kV line(s) to earth</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------------------------------------</td>
<td>--------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>± 1 kV differential mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>I&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the DEVICE requires continued operation during power mains interruptions, it is recommended that the DEVICE be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40% UT (60% dip in UT) for 5 cycles</td>
<td>40% UT (60% dip in UT) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% UT (30% dip in UT) for 25 cycles</td>
<td>70% UT (30% dip in UT) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5% UT (&gt;95% dip in UT) for 5 sec</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 5 sec</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50Hz/60Hz) magnetic field</td>
<td>3 A/m</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>-------</td>
<td>--------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>

NOTE UT is the a.c. mains voltage prior to application of the test level.
The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of the DEVICE should assure that it is used in such an environment.

Table 4

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>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. Recommended separation distance</td>
</tr>
<tr>
<td>Conducted RF</td>
<td>Radiated RF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>IEC 61000-4-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Conducted RF**
- 3 Vrms
- 150 kHz to 80 MHz

**Radiated RF**
- 3 V/m
- 80 MHz to 2.5 GHz
- 3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur radio bands

- 3 V/m

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 metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:
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 re-orienting or relocating the DEVICE.

b  Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
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, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>transmitter (W)</td>
<td>150 KHz to 80 MHz ( d = 1.2\sqrt{P} )</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 800 MHz ( d = 1.2\sqrt{P} )</td>
</tr>
<tr>
<td></td>
<td>800 MHz to 2.5 GHz ( d = 2.3\sqrt{P} )</td>
</tr>
</tbody>
</table>
For transmitters rated at a maximum output power not listed above, the recommended separation distance \( d \) in metres (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.

<table>
<thead>
<tr>
<th>Power (W)</th>
<th>Distance (m)</th>
<th>Power (W)</th>
<th>Distance (m)</th>
<th>Power (W)</th>
<th>Distance (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.12</td>
<td>0.12</td>
<td>0.23</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
<td>0.38</td>
<td>0.73</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
<td>1.2</td>
<td>2.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
<td>3.8</td>
<td>7.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>12</td>
<td>12</td>
<td>23</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
13. Warranty

Shenzhen Dongdixin Technology Co., Ltd., provides a warranty to the original purchaser that this product will provide for a period of 1 years from the date of purchase. In advance, the liability of Shenzhen Dongdixin Technology Co., Ltd., under this limited product warranty does not extend to any misuse or abuse such as dropping or tampering with the device or normal wear and tear. Any evidence of tampering will nullify this warranty.