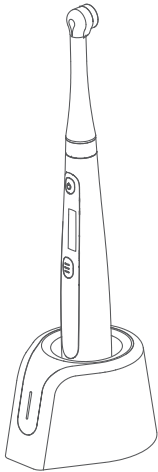


LED Curing Lights
DB686
Q1



User Manual

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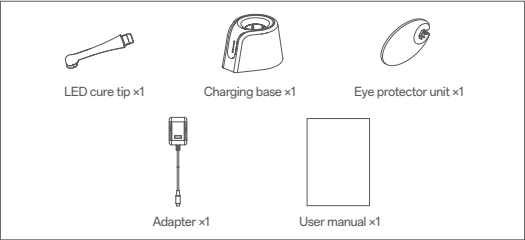


Fig1: Accessories List

1. Safety

Safety notes

Be aware of the following general safety notes and the special safety notes in other chapters of these Instructions for Use.



Warning

This alerts the user of possibility of extremely serious injury or complete destruction of the instrument as well as other property damage including the possibility of fire.



Caution

This alerts the user of possibility of minor or moderate injury or damage to the instrument.



Note

Informs the user of important points concerning operation or the risk of instrument damage.



Caution

- Any patient who have retinal disease should consult an ophthalmologist before operating the device and follow all necessary safety precautions.
- Do not use the device for intraoral illumination or transillumination of teeth; excessive heat may be generated, resulting in mucosal burns or pulpal irritation.
- Check the device if there's worn, loose or damaged parts before every time using it, also check the light output if it is normal.
- Before using, a disposable protective sleeve should insert the head of the host to prevent the host or other parts from contacting the patient's skin or mouth mucosa.
- After finishing to use it, the disposable protective sleeve should be removed from the head of the host and disposed of in accordance with relevant regulations. Disposable protective sleeves are prohibited from being reused to prevent cross- infection.
- Blue light, ultraviolet protection measures: it is forbidden to shine the light into the eyes. The light reflected from the surface of the teeth may also injure the eyes of doctors, nurses and patients. Please standardize and correctly install the eye protector unit, wear eyes protector glasses.
- Precautions for Heat Radiation: All dental curing light devices will generate a certain heat. Long-term operation in the area near the pulp or soft tissue may cause severe injury.
- The light source should be directly irradiated on the resin material to be cured to prevent improper irradiation position and affect the curing effect when it is in clinical use. It is forbidden to directly irradiate the oral soft tissue at close range to avoid thermal damage. Repeated long-term irradiation is not recommended for avoiding light hazards such as thermal radiation.
- Precautions against overheating: When the device is continuously operated for a long time (multiple curing cycles), the surface temperature of the LED cure tip may exceed 43°C, and it should not contact the skin or mucous membranes for a short time. Avoid long-term irradiation and stop using the equipment when it has a significant increase in temperature.
- Failure to comply with relevant environmental operating conditions may cause injury to patients or users.
- After every time using it, please clean and disinfect reusable parts according to the instructions.



Note:

- The LED cure tip can rotate 360°.
- If the LED cure tip is not connected or connected improperly, an error message will be displayed when the device is started: the handpiece will emit 10 beeps. And the display screen will show "E1" which means error caution, please check the LED cure tip and reconnect it.
- Using a disposable protective sleeve can protect the LED cure tip from contamination.
- Please ensure that the disposable protective sleeve is installed flat on the LED cure tip to avoid wrinkles at the light source output, which will affect the curing effect.



Caution:

The LED cure tip contains glass products, please do not contact with hard objects and vigorously flung, so as to avoid cuts and damages after dislodging.

5.2 Charging

When you need to charge, take out the charging base and adapter, the adapter is connected to 100V-240V, the output plug of the power adapter is inserted into the charging jack on the charging base, the machine adopts the wireless magnetic charging technology, put the handpiece into the charging base to carry out the wireless inductive charging. When you don't need to charge, please unplug the power adapter. Steps: Refer to "Figure 3".

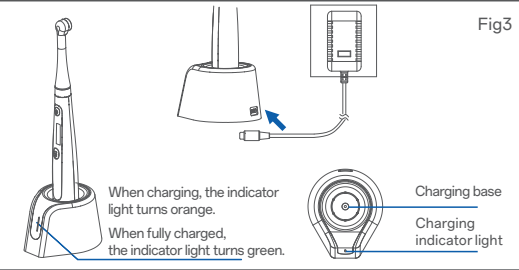


Fig3

2. Intended use

- For dental clinics treatment to irradiate polymer-based restorative materials to cure them.
- The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

3. Composition

It consists of a handpiece, LED cure tip, power adapter, charging base, eye protector unit.

4. Contraindications

- Systemic diseases (tumors, severe cardiovascular diseases, blood system diseases, immune system diseases, etc.).
- Undergoing certain systemic and local treatments (anticoagulant therapy, chemotherapy, radiotherapy, etc.).
- Use with caution in patients with cardiac disease, pregnant women and children.
- Use with caution if allergic to LED light.

5. Preparation before using

5.1 Install Accessories

Refer to "Fig2"

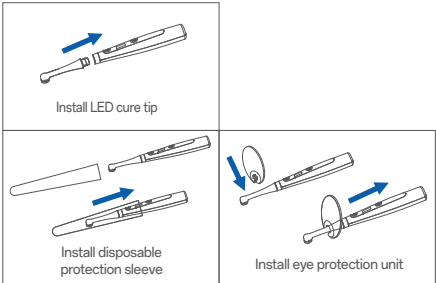


Fig2



Note:

- It is recommended to charge the device in time when it is at a lower battery level. When the device's battery level is too low, the handpiece emits 3 beeping beeps, while the handpiece display shows the E3 Low Battery Alert.
- When the handpiece is charging, indicator on the charging base turns orange. When it is fully charged, it will turn green.



Caution:

- The handpiece will automatically shut down when its battery level of is too low, Please be sure to check the battery level before use to avoid affecting normal use.
- Please use the original charging base and power adapter to charge, otherwise it may cause damage to the lithium battery and control circuit.
- It is forbidden to charge in a humid environment.
- If the battery is not used for a long time, it may cause a decrease in battery life. The handpiece should be charged at least once a month.

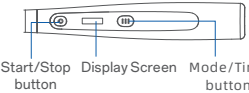
6. Operation



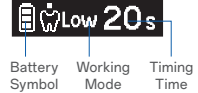
Caution:

The light generated by the device may damage eyes. Before using, please standardize and correctly install the eye protector unit and wear eyes protector to avoid unnecessary harm to you.

Explanation



Handpiece screen display



6.1 Power On/Off

When the device is in off state, long press " " start/stop button for more than 0.5 second to power it on.
When the device is in standby mode, long press " " start/stop button for more than 0.5 seconds to power it off.



Note:

When the device is not operated for a long time, it will automatically enter the shutdown state.

6.2 Functions /Modes Selection

The device has two functions: resin curing and caries detection. And resin curing function has three modes: Low-temperature curing, Standard curing and Fast curing. You could long press " " Mode/Time button to switch functions / working modes.

A. Resin curing function:

| Mode | Screen Display | Functionality |
|----------------------|----------------|--|
| Low-temperature Mode | | Variable illumination output with illumination values pulsed at 600/1300mW/cm² cycles |
| Standard Mode | | Light output at a constant illumination of 1000~1200mW/cm², used for conventional resin curing |
| Fast Mode | | Light output at a constant illumination of 2300~2500mW/cm² fast resin curing |

B. Caries Mode:

Use the fluorescent reaction produced by irradiating teeth with purple light to check caries or dental calculus. The single working time is 60s. The screen display:

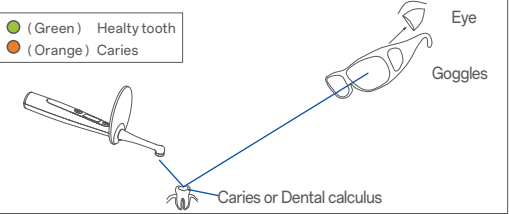


During the detection process, the fluorescent color is displayed as follows:



Note:

- Turn off the external light source during the caries test to ensure accurate results;
- After removing the decayed tooth, it is recommended that the mouth be examined again.



6.3 Curing time selection

Various curing times could be set for different functions / working modes by short pressing " " .

| Mode | Curing time (seconds) |
|----------------------|-----------------------|
| Low-temperature Mode | 5s、10s、15s、20s |
| Standard Mode | 5s、10s、15s、20s |
| Fast Mode | 1s、3s |
| Caries Mode | 60s |

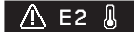
6.4 Start the work

After completing the settings, short press " " start/stop button to start light curing, and press again to turn off the device.



Caution:

- The user must use eyes protector and wear goggles during the operation, otherwise it will cause injury to the eyes.
- The recommended distance between the LED cure tip and the curing surface is 3mm-5mm.
- When the temperature of the handpiece is too high, the handpiece will stop working, emits 5 beeps and the handpiece screen shows E2 overheating prompt. Please wait until it cools down completely cooled before using it.



7. Maintenance

- 1) Before each use, check the handpiece and LED cure tip for any damage. If so, stop using them immediately and contact our company or authorized dealers for assistance.
- 2) Before the first use and after each use, you must clean and disinfect handpiece, LED cure tip and eye protector unit.
- 3) After each use, please check whether there is any resin left on the lens surface of the LED cure tip to avoid affecting the service life of the LED cure tip or the curing effect.

8. Cleaning and Disinfection

| | |
|--|---|
| Device | Handpiece, LED cure tip, charging base, eye protector unit. The procedure for cleaning, disinfection applies only to the accessories handpiece, LED cure tip, charging base, eye protector unit. |
| Advice | Reprocessing procedures have only limited implications to this dental instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation. In case of damage the device should be reprocessed before sending back to the manufacturer for repair. |
| Reprocessing Instructions | |
| Preparation at the Point of Use: | Disconnect the disposable protective sleeve and LED cure tip from the handpiece. Store the instruments in a humid surrounding. |
| Transportation: | Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment. |
| Preparation for Decontamination: | The devices must be reprocessed in a disassembled state. All parts cannot be cleaned and disinfected in a washer/disinfectior. Only a general wipe decontamination is possible! |
| Manual Cleaning of handpiece, LED cure tip, charging base, eye protector unit: | Do a manual cleaning, until the instruments are visually clean. <ul style="list-style-type: none">● Recommend using 3M multi-enzyme cleaning agent at a concentration of 5mL /1L distilled water.● Soak the soft cloth in detergent and wring it out.● Wipe the outer surface of the eye protector unit with the soft cloth.● Rinse eye protector unit with tap water until all visible contaminants have been removed.● Remove any liquid residue with a lint-free cotton cloth, then dry at 30°C. |

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9. Troubleshooting

If the product functions abnormally, please refer to the following instructions for troubleshooting first. If cannot be resolved, please contact your local dealer or our company.

| Fault status | Possible cause | Solutions |
|--|--|--|
| No response from the handpiece | The battery needs to be charged | Please increase the charging time, especially when using it for the first time or not used for a long time |
| | Battery damaged | Contact the dealer or manufacturer |
| Not charging after connecting to the adapter | Poor power contact | Check the connection between the adapter and the charging base |
| | Wrong use of the adapter | Check the specifications of adapter |
| | Damaged power adapter | Replace the power adapter |
| | Dirty magnetic connection | Wring out a clean, damp cloth and wipe off the soiled area |
| Usage time becomes shorter after charging | Battery aging | Contact the dealer or manufacturer to replace the battery |
| Insufficient light intensity | The light outlet is offset or not vertically close to the surface of the dental adhesive | Use after adjusting the position |
| | Residue on the end face of the LED cure tip | Clean the LED cure tip emitting surface |
| | The LED cure tip is damaged | Replace the LED cure tip |
| | Battery power is too low | Use after charging |
| Handpiece screen displays E1 | LED light is damaged | Contact the dealer or manufacturer |
| | The LED cure tip is not installed or has poor contact with the handpiece | Install the LED cure tip according to the instructions |
| | A non-original LED cure tip is used | Make sure to use the original LED cure tip provided by the manufacturer |
| Handpiece screen displays E2 | Device failure | Contact the dealer or manufacturer |
| | The continuous working time is too long or the working interval is too short the handpiece prompts overheating | Please stop using it immediately until the device is completely cooled before using it |
| Handpiece screen displays E3 | The device power is too low, and the low power prompts | Automatically recover after charging |

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11. Operating, storage and Transport conditons

| | |
|---------------------------|----------------|
| Operating Environment | |
| Environmental temperature | +5°C ~ +40°C |
| Relative humidity | 20%RH ~ 80%RH |
| Atmospheric pressure | 80kPa ~ 106kPa |
| Altitude | ≤2000m |


| | |
|----------------------------------|----------------|
| Transport and storage conditions | |
| Environmental temperature | -10°C ~ +55°C |
| Relative humidity | ≤93% RH |
| Atmospheric pressure | 50kPa ~ 106kPa |

12. Product Warranty

- 1) The warranty period for the handpiece, LED cure tip, charging base is 24 months from the date of purchase, the adapter is 6 months, the rest of accessories are not warranted.
- 2) This device cannot be repaired on-site by the customer, and equipment repair should be performed by professionals designated by the manufacturer.
- 3) Upon request, the supplier will provide circuit diagrams, component lists, legends, calibration details, or other information necessary for qualified technicians to help users repair equipment parts designated by the manufacturer for repair.
- 4) The following situations are not covered by the free warranty:
- Damage caused by human factors;
 - Damage caused by force majeure;
 - Customers make unauthorized changes, dismantle or repair privately;
 - Any damage caused by failure to use and maintain in accordance with the instructions for use;
 - Failure or damage caused by forcible use of this product beyond normal conditions of use.

13. Recycling and Disposal

The device and its packaging are designed to be as environmentally friendly as possible.

-  Ensure that the parts are not contaminated on disposal. Follow your local and country specific laws, directives, standards and guidelines for disposal.
- Medical device
 - Waste electrical equipment
 - Packaging

13

⚠ Caution:


- This device conforms to IEC 60601-1-2, the relevant international standard for electromagnetic compatibility (EMC). The following is the Guidance and Manufacturer's Declaration which is required by IEC 60601-1-2, the relevant international standard for electromagnetic compatibility.
- This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
- Portable and mobile RF communication equipment can effect the device.
- Use of other than those accompanied or specified by COXO may result in increased EMC emissions or decrease EMC immunity of the device.
- This device should not be used adjacent to with other equipment. If adjacent use is necessary, the device should be observed to verify normal operation.

| Serial number | Name | Cable Length (m) | Shielded wire | Remarks |
|---------------|------------------|------------------|---------------|---------|
| 1 | AC adapter cable | 1.5 | No | / |

| Guidance and Manufacturer's Declaration-Electromagnetic Emissions | | |
|--|------------|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment-guidance |
| RF emissions CISPR 11 | Group1 | The device use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The device is suitable for use in all establishments other than domestic 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 | |

| Guidance & Declaration — Electromagnetic Immunity |
|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are used in such an environment. |

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| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|--------------------------|---|---|--|
| Conducted RF 1000-4-6 | 3 Vrms 150 kHz to 80 MHz | 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. Recommended separation distance $d = [(3.5) \sqrt{P}] / 3$ $d = [(3.5) \sqrt{P}] / 3$ 80 MHz to 800MHz $d = [(7) \sqrt{P}] / 3$ 800 MHz to 2.7GHz 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). 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:  |
| | 6 Vrms in ISM and amateur Radio bands | 6 Vrms in ISM and amateur Radio bands | |
| | 3 V/m, 10 V/m | 3 V/m, 10 V/m | |
| Radiated RF 61000-4-3 | 80 MHz to 2.7 GHz | 80 MHz to 2.7 GHz | Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not be applicable in every case. The propagation of electromagnetic waves is subject to absorption and reflection by buildings, objects, and people. |
| | 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1) | 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1) | |

- a: The field strength of stationary transmitters such as base stations of mobile telephones and land mobile radio devices, amateur radio stations, AM and FM radio and television broadcasting stations cannot be determined based on theoretical considerations. A site study should be considered to determine the electromagnetic environment in terms of stationary transmitters: if he field strength measured at the site, at which the Device is used, exceeds the compliance levels shown above, the device should be monitored to demonstrate proper function. Should unusual performance features be observed, additional measures may be required, such as, e.g., a different alignment or different location for the Device.
- b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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| | |
|--|---|
| | <ul style="list-style-type: none">● Checked that if the devices were clean or broken after cleaning. If the cleaning is not good enough, repeat the cleaning procedure. |
| Manual Disinfection of handpiece, LED cure tip, charging base, Eye protector unit: | After cleaning, wipe all device surfaces with a new single-use cloth in combination with an alcohol-based, tuberculocidal, quaternary ammonium solution.5 minute contact time, use according to disinfectant solution manufacturer's Instruction for Use. Use a separate wipe for LED cure tip and handpiece. Ensure direct contact of device and disinfectant by pressing the wet wipes on the device after half of the required contact time. Use fresh wipes to disinfect the LED Cure Tip o-ring area, handpiece mating cavity and battery/handpiece mating seam for the entire contact time. Immediately absorb excess fluid with a dry disposable towel Wipe the devices with a sterile, clean, lint-free cloth that is well dampened with deionized water for 30 seconds to remove all disinfecting agent. Pay special attention to all seems, especially around the LED cure tip /handpiece junction. Ensure cloth is damp with deionized water for the entire 30 seconds. Discard used cloth and repeat rinsing with a new, second dampened cloth for 30 seconds. Discard second cloth and rinse with a new, third dampened cloth for a final 30 seconds. Wipe device with a fourth dry, sterile lint-free cloth to remove all fluid. Allow the devices to air dry for at least 5 minutes. |
| Manual Drying: | Use compressed air to blow dry the internal pipes and external surfaces separately. |
| Functional Testing, Maintenance: | Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. Defective accessories should be immediately discarded. The defects include: plastic deformation and corrosion. Maintenance is not required. Instruments oil must not be used. |
| Storage: | Storage of disinfected instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use. |
| Additional Instructions: None | |
| It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly. | |

























10

10. Technical Parameters


| | |
|--|--|
| Adapter | Input: 100-240V ~ 50/60HZ Output: 5V --- 1.5A |
| Input power | 10VA |
| Li-ion battery | 3.7V/1400mAh |
| Light curing classification | Class II |
| LED source | Voltage:3V LED Light Power:10W |
| Wavelength range | 385nm~515nm |
| Peak wavelength | 460nm |
| 385nm ~ 515nm (blue light) | ≥ 200mW/cm² |
| Irradiance in the wavelength range 200nm ~ 385nm | ≤ 200mW/cm² |
| Irradiance in the wavelength range above 515nm | ≤ 100mW/cm² |
| Diameter of light guide element | 10mm |
| Optical effective area | 78.5mm² |
| Operation mode | Duty cycle: Max.T_ON: 3min, Min.T_OFF: 3min |
| Degree of Protection (IEC 60529) | IPX0 |
| Classified by security | Non-AP/APG type |
| Protection against Electric Shock | Type B |
| Classified of protection against Electric Shock | Class II device when charging, does not work when charging, internal power supply class when working normally. |
| Overvoltage category | Class II |
| Pollution degree | Class 2 |
| Applied part | Disposable protective sleeve, material: PP (order code: 4031013) |

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14. Symbols Identification

| | | | |
|---|---|---|--|
|  | General warning |  | Caution |
|  | Refer to operating instructions |  | Serial number |
|  | Type B applied part |  | Note |
|  | Keep dry |  | Fragile, handle with care |
|  | Keep upright |  | Class II equipment |
|  | Direct current |  | Alternating current |
|  | Do not dispose of the product into the ordinary municipal waste or garbage system |  | Indoor use only |
|  | Start/Stop button |  | Mode/Time button |
|  | Do not reuse |  | Manufacturer |
|  | Wireless device |  | Authorized representative in the European Community/European Union |
|  | Medical device |  | Catalogue number |
|  | CE marking |  | Date of manufacture |

15. EMC

-  **Note**
- Based on IEC 60601-1-2 concerning the electromagnetic compatibility of electrical medical devices, we must draw your attention to the following points:
 - Medical electrical devices are subject to special precautions concerning the electromagnetic compatibility and must be installed and operated in accordance with the Manufacturer assembly instructions.
 - High-frequency communications devices may interfere with electrical medical devices.
 - Manufacturer cannot guarantee the compliance of accessories, cables, and other components not supplied by manufacturer with the EMC requirements of IEC 60601-1-2.

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| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|--|--|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air | Floor 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 | +2kV for power supply lines ±1 kV for Input/output lines | ±2kV for power lines | Mains power quality should be that of atypical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground | ±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2 kV common mode | Mains power quality should Be that of atypical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11. | <5 % U _i (>95% dip in U _i) for 1 cycle 70% U _i (30% dip in U _i) for 25/30 cycles <5% U _i (>95 % dip in U _i) for 5/6 sec | <5 % U _i (>95% dip in U _i) for 0.5 cycle <5 % U _i (>95% dip in U _i) for 1 cycle 70% U _i (30% dip in U _i) for 25/30 cycles <5% U _i (>95 % dip in U _i) for 5/6 sec | Mains power quality should be that of atypical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that device be powered from a unit eruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m, 30 A/m | 3 A/m, 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: U _i is the a.c. mains voltage prior to application of the test level. | | | |

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| Guidance & Declaration — Electromagnetic Immunity |
|---|
| 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. |

| Recommended separation distances between portable and mobile RF communications device 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 device (transmitters) and the device as recommended below, according to the maximum output power of the communications device. | | | | |
| Rated maximum output power of the transmitter/W | Separation distance according to frequency of transmitter / m | | | |
| | 150 kHz to 80 MHz d=1.2√P | 80 MHz to 800 MHz d=1.2√P | 800 MHz to 2.7 GHz d=2.3√P | |
| 0.01 | 0.12 | 0.12 | 0.23 | |
| 0.1 | 0.38 | 0.38 | 0.73 | |
| 1 | 1.2 | 1.2 | 2.3 | |
| 10 | 3.8 | 3.8 | 7.3 | |
| 100 | 12 | 12 | 23 | |
| For transmitter rated maximum output power not listed in the table above, the recommended isolation distance, d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is the maximum output power rating of the transmitter in watts (W) as supplied by the transmitter manufacturer. | | | | |
| Note 1: At 80 MHz and 800 MHz frequencies, the formula for the higher frequency range is used. | | | | |
| Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | | |

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User manual version:1.3
Date:20250716
User manual No.:AE1212
Software version:Ver 1.0