# DENOPS

DENTIS No Pain System

# DENOPS User Manual

# Contents


1. Purpose & Environment
    - 1.1 Purpose 3
    - 1.2 User & Patient 3
    - 1.3 Environment (Transport and Storage, Use) 3
2. FCC Statement
    - 2.1 FCC Statement 4
    - 2.2 FCC Radiation Exposure Statement 4
3. Caution & Symbol
    - 3.1 Caution 5
    - 3.2 Symbol 6
4. Configuration and Specification
    - 4.1 Configuration 8
    - 4.2 Specification 9
5. Function & Use
    - 5.1 Function (Main Body) 10
    - 5.2 Function (LCD) 11
    - 5.3 Function (Sound) 12
    - 5.4 Function (CRADLE) 13
    - 5.5 Use(Basic function) 15
    - 5.6 Use(Change amount of inject medicine, injection speed, mode) 16
    - 5.7 Use(Change USER setting) 17
6. Disinfection, Sterilization and Storage
    - 6.1 Disinfection 18
    - 6.2 Sterilization 18
    - 6.3 Storage 18
7. Trouble shooting and Warranty
    - 7.1 Trouble shooting 19
    - 7.2 Warranty & Expected Service Life 19


**"Warning : Changes to this product are not allowed"**

# 1. Purpose & Environment

## 1.1 Purpose

- This device is used for injection of medicine such as local anesthesia.
- This device is classified as a internally powered medical device.

| Device name | Model name | Equipment Part |
|---|---|---|
| Anesthesia injection system | AN100 | Type B |

## 1.2 User & Patient

- Only a doctor or specialist should use this device.
- A doctor or specialist may permit a nurse to manage the device but they should not operate it. For example, they may charge, assemble and hold the product before using, and sterilize and store after using.
- There is no limit on the gender and age of the patient, but it can be applied differently depending on the doctor's prescription.

## 1.3 Environment(Transport and Storage, Use)

- Temperature : 0 - 40 ℃
- Relative humidity : 30 - 90 %RH
- Humidity : 0 - 2,000 m (106 - 80 Kpa)

# 2. FCC Statement

## 2.1 FCC Statement

Federal Communication Commission Interference Statement

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 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.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

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.

## 2.2 FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This equipment should be installed and operated with minimum distance 15cm between the radiator & your body.

This device and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.

# 3. Caution & Safety regulations

## 3.1 ⚠ Caution

- Be sure to read the user manual before using this product.
- Please use this product only for licensed dentists.
- When injecting the anesthetic solution into the patient using this product, adjust the injection amount according to the decision of the physician.
- Do not use on uneven floors, sloping areas or when there's vibration.
- Do not use in water or humid areas.
- Do not touch the main body and power plug with wet hands.
- Be careful not to move or get external shock when operating the machine.
- If the product smells of smoke or burning, please contact the place of purchase.
- This device complies with electromagnetic specifications. However, this equipment can cause improper operation due to loss of performance or degradation due to external electromagnetic disturbances.
- Please check if all the components are present after opening this product.
- Please do not use any adapter other than the one provided by the manufacturer.
- Unplug the adapter connected to the cradle in case of abnormal operation or problems with the product.
- If the wire is damaged, please stop using it and contact the place of purchase to replace it.
- Never use this product for anything other than its intended use.
- Do not disassemble or modify unless by a technician from the place of purchase. No warranty shall be granted for arbitrary disassembly and modification.
- Please do not use the used ampoule again.
- Store the product in a CRADLE when not in use.
- This device has obtained electromagnetic compatibility KC, CE, FCC certification.
- In case of malfunction or damage, please contact the place of purchase
- Please dispose of the product in accordance with the laws of your country.
- When replacing the battery, contact the manufacturer of the product.
- Electric shock hazard, do not saturate the Pump with liquids. Protect the Pump from exposure to condensed humidity, moisture, and liquid.
- When used in the vicinity of an electric scalpel (medical scalpel is an incision and resurfacing device using high-frequency current), check the following before use - The distance from the pump to the electric scalpel (scalpel, scalpel and return electrode) and the scalpel should be kept at least 25cm.
  - The electric scalpel and this pump should operate with the power from separate system and connect them safely.

## 3.2 Symbol

| Part | Symbol | Explanation |
|---|---|---|
| Instruction Manual | | - Be sure to read this instruction manual before using it to prevent safety accidents and understand essential performance before using It. (ISO 7010-M002) (show on Label) |
| Electricity | | - Be careful not to touch the charging adapter with wet hands, as there is a risk of electric shock. (ISO 7010- W012) |
| No activated Mobile phone | | - Do not use wireless equipment such as mobile phones within 30 cm during the procedure as malfunctions may occur due to external electromagnetic forces. (ISO 7010-P013) |
| Sharp | | - Be careful not to get stung. (ISO 7010-W022) |
| Warning | | - Be careful not to drop the body on the floor during use. (ISO 7010-W001) |
| Wash your hand | | - Make sure to wash your hands before and after use. (ISO 7010-M011) |
| This side up | | - Indicates the correct direction of the package. (show on label) |
| Keep dry | | - Indicates a medical device that needs to be protect from moisture. (ISO 15223-1: 2012) (show on label). |
| Fragile | | - The contents of the packaging are fragile, so be careful and handle them. (ISO 15223-1: 2012) (show on label). |
| Stand-by | | - To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition. (IEC 60417-5009) |
| Serial number | SN | - Indicates the manufacturer's serial number so that a specific medical device can be identified. (ISO 15223-1)(show on label) |
| Date of manufacture | | - Indicates the date when the medical device was manufactured. (ISO 15223-1)(show on label) |

## 3.2 Symbol

| Part | Symbol | Explanation |
|---|---|---|
| Use no hand hooks | | - Do not use hooks when handling packing cargo. (show on label) |
| Recycling | | - Indicate Recycling box location. (ISO 7001: 2007) (show on label) |
| Atmospheric pressure limitation | 106Kpa 80Kpa | - Indicates the range of atmospheric pressure to which the medical device can be safely exposed. (ISO 15223-1:2012) (show on label) |
| Temperature limit | 40°C 0°C | - Indicates the temperature limits to which the medical device can be safely exposed. (ISO 15223-1:2012)(show on label) |
| Humidity limitation | 90%RH 30%RH | - Indicates the range of humidity to which the medical device can safely exposed. (ISO 15223-1:2012) (show on label) |
| Sterilization | 132°C | - After use, make sure to sterilize the AMPOULE CASE with steam in the autoclave and store it in a sterilization bag for the next use. (ISO 7000-2868) |
| Discard | | - Do not dispose of this device with unsorted waste. Please separate recyclable parts and throw than away separately Classify recyclable parts and throw them away. (Directive 2002/96/EC) (show on label) |
| Type B Equipment Part | | - This medical device corresponds to type B Equipment part . (IEC 60417-5840) (show on label) |
| Class 2 | | - This device is a 2-class medical device. (IEC 60417-5172) (show on label) |
| Manufacturer | | - Indicates the medical device manufacturer (Directives 90/385/EEC, 93/42/EEC and 98/79/EC)(show on label) |
| EU representative | EC REP | - Indicates the authorized representative in the European Community. |

# 4. Configuration & Specification

## 4.1 Configuration

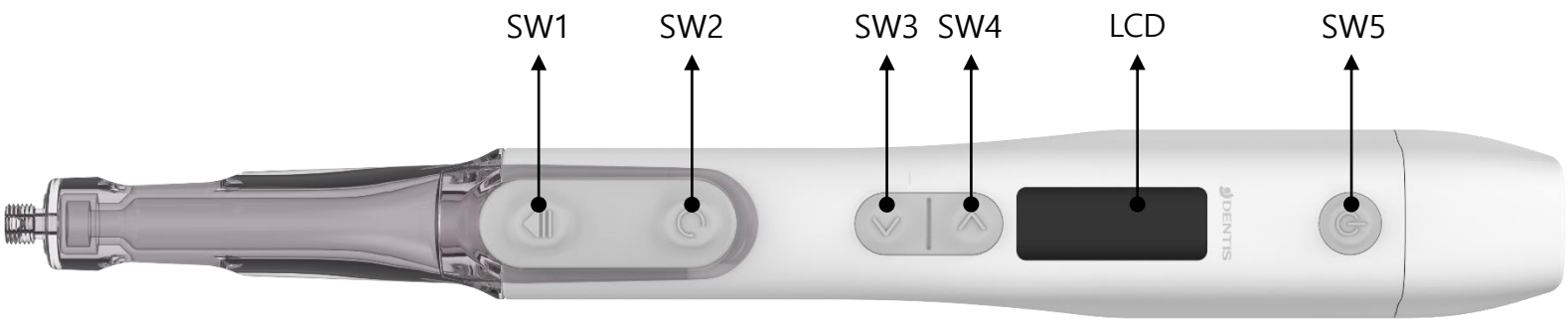
| | | |
|---|---|---|
| | | |
| AMPOULE CASE | Main Body | CRADLE |

| | |
|---|---|
| | |
| Adapter | User Manual |

## 4.2 Specification

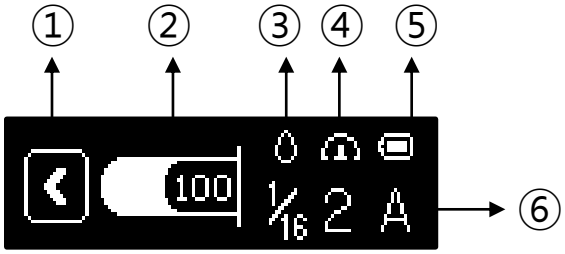
| List | Category | Unit | Specification | Etc. |
|---|---|---|---|---|
| Main body (+ AMPOULE CASE) | Weight | g | 85 | |
| | Amount of inject medicine | ml | Adjust 5 Steps<br>(Check the steps with the LCD)<br>1/16 : 0.11ml, 1/8 : 0.22ml, 1/4 : 0.45ml,<br>1/2 : 0.90ml, Full : 1.8ml | |
| | Injection time | s | Manual - 1step : 320s, 2step : 160s, 3step : 30s<br>Auto - 1step : 320s, 2step : 170s, 3step : 48s | 1.8ml |
| | Mode | - | AUTO, MANUAL, USER | |
| | Battery | V | 3.7 | Lithium Polymer |
| | | mAh | 550 | |
| | Charging time | h | 6 | |
| | Size | mm | 202.5 X 24.7 X 28 | |
| CRADLE | Weight | g | 140 | |
| | Size | mm | 176 X 41.4 X 75.3 | |
| Adapter | Rated input | V | AC 100 – 240 | |
| | | Hz | 50/60 | |
| | Rated output | V | DC 5 | |
| | | A | 2.0 | |
| | Weight | g | 104 | |
| Dental needle (Disposable, Separately sold) | Size | mm | 27G/16, 25, 30<br>30G/ 12, 16, 25<br>31G/ 12 | |

## 5.1 Function(Main body)




| Part | Name | Function |
|---|---|---|
| LCD | LCD | - Show main body status |
| SW1 | Operation button | - Injection of medication / Stop<br>- Aspiration (Over 2 seconds) |
| SW2 | Reset button | - Remove bubble<br>- Initialization(Over 2 seconds) |
| SW3 | Select button | - Move menu : Amount of inject medication , Injection speed , Select Injection mode<br>- Sound Setting(Over 2 seconds) |
| SW4 | Adjust button | - Step Setting<br>- Save User mode(Over 2 seconds) |
| SW5 | Power button | - Power On/Off(Over 2 seconds) |
| SW3+SW4 | Connect hook | - Hook the motor pin to the back of the ampule (Setting before using the aspiration) |

## 5.2 Function(LCD)



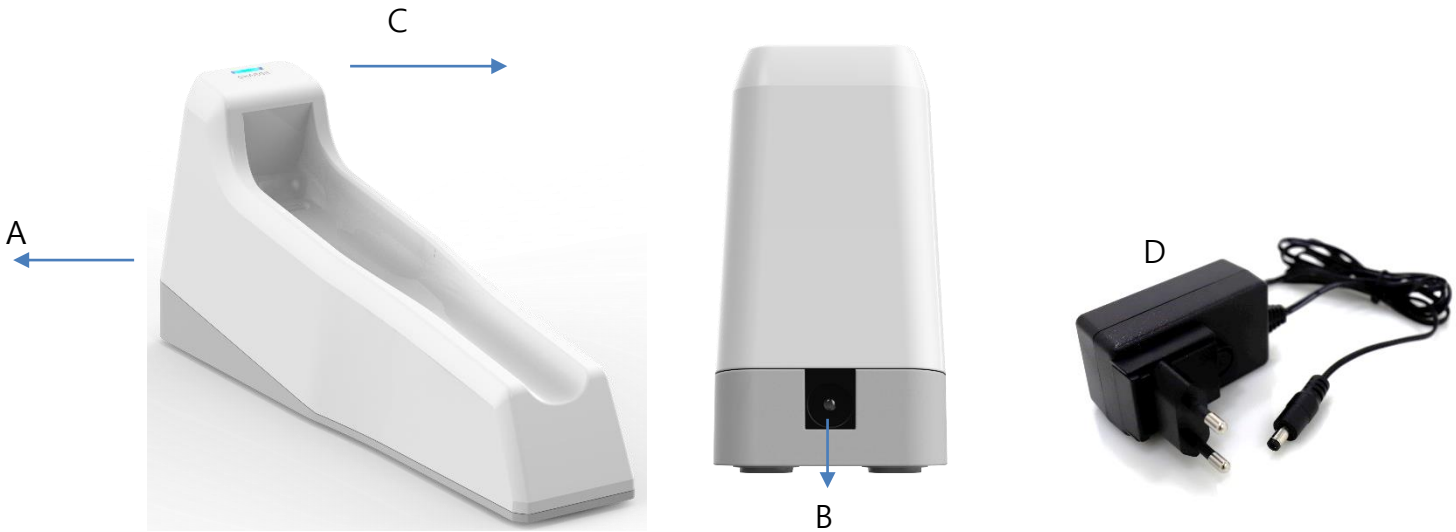

| No. | Part | Function |
|---|---|---|
| ① | Motor movement direction | - Show forward( ), backward( ), stop( ) |
| ② | Current amount of inject medicine | - Show current amount of inject medicine(1 ~ 100%). |
| ③ | Amount of inject medicine | - Amount of inject medicine icon |
| | Adjust amount of inject medicine | - Show amount of inject medicine such as FULL, 1/2, 1/4. 1/8, 1/16. |
| ④ | Injection speed | - Injection speed icon. |
| | Adjust Injection speed | - Show injection speed(1 ~ 3 Step). |
| ⑤ | Battery | - Show current battery status. |
| ⑥ | Mode | - Auto(A) : Low-speed to high-speed injection. |
| | | - Manual(M) : Inject constant speed. |
| | | - User(U1~U5) : Save user-specified amount of inject medicine and injection speed and use. |

## 5.3 Function(Sound)

| Part | Order | IMAGE | | Explanation |
|---|---|---|---|---|
| Sound | 1 | Setting Mode<br>SOUND ON | Setting Mode<br>SOUND OFF | Press Select button (SW3) for more than 2 seconds to enter setting mode. |
| | 2 | | | Set ON/OFF with Adjust Button (SW4) |
| | 3 | SOUND ON | SOUND OFF | Press the SELECT button (SW3) for more than 2 seconds to exit the setup mode. |
| Language | 1 | LANGAUGE<br>KOREAN | LANGAUGE<br>ENGLISH | Press Select button (SW3) for more than 2 seconds to enter setting mode. |
| | 2 | LANGAUGE<br>CHINESE | | Press the SELECT button (SW3) to change to LANGUAGE SELECT mode. |
| | 3 | | | Press the adjustment button (SW4) to select the language (KOR, ENG, CHN). |
| | 4 | Language(KOR, ENG, CHN) | | Press Select button (SW3) for more than 2 seconds to enter setting mode. |

| Voice Guidance | | | | | |
|---|---|---|---|---|---|
| 1 | POWER ON | Start pain-free anesthesia. | 5 | Low Battery | Please charge the battery. |
| 2 | POWER OFF | Treatment complete. | 6 | Reay to Aspiration | Ready for Aspiration. |
| 3 | AMPOULE RESET | Reset the ampoule position. | 7 | Remove Bubble | Remove air bubbles. |
| 4 | SOUND ON | Activate voice assistant. | 8 | SOUND OFF | Turn off voice assistant. |

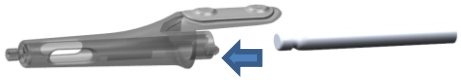
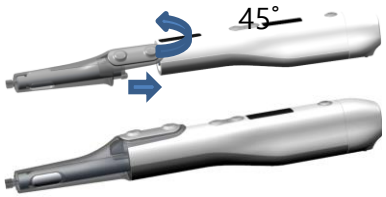
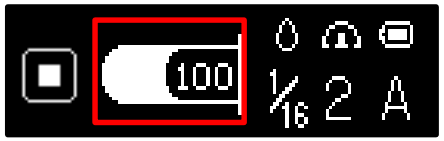
## 5.4 Function(CRADLE)



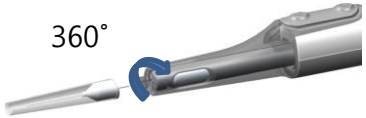
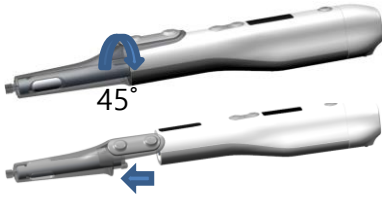
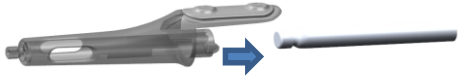

| Part | Name | Explanation |
|---|---|---|
| **A** | CRADLE | - When the main body is not in use, put it on a CRADLE and charge it.<br>- Store the Main body before and after use. |
| **B** | DC power Port | - Port to which the adapter jack can be connected. |
| **C** | LED | - Show charging status<br>Charging light(GREEN) : Standby charging<br>Charging light(BLUE) : Charging |
| **D** | Adapter | - Connect Plug to Outlet after connect charging DC JACK to DC power port |

**Only use the supplied charging adapter for charging.**

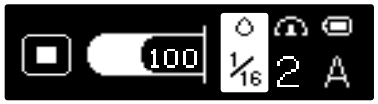
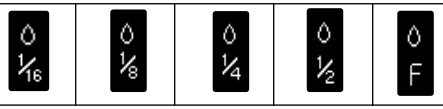
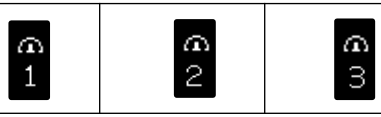
## 5.5 Use(Basic function)

| Order | Image | Explanation |
|---|---|---|
| 1 | | ▪ Check the entire DENOPS component.<br>(Main body, AMPOULE CASE, Adapter, CRADLE, User manual) |
| 2 |  | ▪ Connect the ampoule to the AMPOULE CASE. |
| 3 |  | ▪ Rotate the AMPOULE CASE 45 degrees to connect the AMPOULE CASE and the main body. |
| 4 | <br>SW5 | ▪ Press SW5 (over than 2 seconds) to turn on the power and display. |
| 5 | <br>SW3 SW4  | ▪ After checking amount of inject medication (100%) on LCD and the ampoule reset, press SW3 and SW4 at the same time to connect hook.<br>※ Use only when using aspiration (optional) |
| 6 | - | ▪ Set amount of inject medicine, injection speed, mode<br>※ Note page 14 |
| 7 | | ▪ Turn the needle 360 degrees to connect it to the main body.<br>※ Before using DENOPS, keep the needle covered with a cap. |
| 8 | <br>SW2 | ▪ Press SW2 to remove air bubble.(remove bubble after remove cap) |

## 5.5 Use(Basic function)

| | | |
|---|---|---|
| 9 | SW1 | ▪ Press SW1 (over than 2 seconds) to operate aspiration. |
| 10 | SW1 | ▪ Remove the needle cap and press SW1 to start injection. |
| 11 | SW2 | ▪ Press SW2 (over than 2 seconds) to initialize ampoule after completion of inject medication. |
| 12 |   | ▪ Turn the needle 360 degrees in the reverse direction to separate the needle. |
| 13 |   | ▪ Disconnect the AMPULLE CASE by turning the AMPOULE CASE to 45 degrees on the main body. |
| 14 |  | ▪ Separate AMPOULE CASE and ampoule. |
| 15 | | ▪ Attach the main body to the CRADLE and charge and store it. |

## 5.6 Use(Change amount of inject medicine, Injection speed, Mode)

| Order | Image | | Explanation |
|---|---|---|---|
| 1 | SW3 |  Amount of inject medicine<br> Injection speed<br> Mode | - Press SW3 to select the desired setting.<br>change amount of inject medicine, injection speed, mode<br>※ Change User mode setting (Note P15) |
| 2 | SW4 |  Change amount of inject medicine<br>  Change injection speed<br> Change mode | - Press SW4 to select the desired step.<br>Amount of inject medicine : 1/16, 1/8, 1/4, 1/2, FULL<br>Injection speed : STEP 1, 2, 3<br>Mode : AUTO, MANUAL, USER 1 ~ 5 |

## 5.7 Use(Change User mode setting)

| Order | Image | | Explanation |
|---|---|---|---|
| 1 | SW3 | 100 1/16 2 A | - Press SW3 to select the desired mode. |
| 2 | SW4 | 100 1/16 2 U1 | - In the Change Mode screen, press SW4 to select U1 to U5. |
| 3 | SW4 | 100 1/16 2 U1 | - Press SW4 for more than 2 seconds to change the USER setting. |
| 4 | SW3 | 100 1/16 2 U1<br>Amount of inject medicine | - Press SW3 to select the desired mode change.<br>Amount of inject medicine, Injection speed<br>- Press SW4 to select the desired step.<br>Amount of inject medicine : 1/16, 1/8, 1/4, 1/2, FULL<br>Injection speed : STEP 1, 2, 3 |
| 5 | SW4 | 100 1/16 2 U1<br>Injection speed | |
| 6 | SW4 | 100 1/16 2 U1 | - Save the User mode by pressing SW4(over than 2 seconds) after changing the amount of inject medicine and injection speed. |

# 6. Disinfection, Sterilization and Storage

## 6.1 Disinfection(Main Body)

- Before and after use, wipe with just a dry cloth or with a cloth using Enzyssept.
- Please dilute the QUAT disinfectant and pour it into Dry Wipes.

## 6.2 Sterilization (AMPOULE CASE)

- The use of the following substances is not permitted.
  - High concentrations of organic acids and inorganic acids, hydrocarbons chlorinated
- Sterilization condition(Please refer to the sterilization method for each country.)

| Sterilization condition | |
|---|---|
| Operating Condition | Autoclave |
| • Temperature : 132 ℃(270 ℉)<br>• Pressure : 150 kPa (1.6 kgf/㎠)<br>• pre vacuum: 8 min(Wrapped)<br>• Dry : 30 min | |

## 6.3 Storage

- Place DENOPS on CRADLE to charge after use.
- Please keep it away from places where there is humidity or water.
- Do not store near firearm.
- Store the product at room temperature and out of direct light.

# 7. Trouble shooting and Warranty & Expected Service Life

## 7.1 Trouble shooting

| Num. | Problem | Cause | Matter of management |
|---|---|---|---|
| 1 | The display does not turn on | Drained battery | Please charge the battery and use it again. |
| | | Etc. | Contact the customer service center. |
| 2 | Button does not operate | Button failure | Contact the customer service center. |
| 3 | Not Charging | CRADLE breakdown | Contact the customer service center. |
| | | faulty adapter | Contact the customer service center. |
| 4 | Device is running hot | - | Contact the customer service center. |
| 5 | Damage to the device and other problems | - | Contact the customer service center. |

## 7.2 Warranty & Expected Service Life

- The warranty period of this product is 1 year.
- The expected service life of this product is 3 years.
- The expected service life of a lithium-polymer charging battery is 300 charging cycles, 4.1V full charge and 3.1V full discharge.
- Free maintenance will be provided during the warranty period if a user has unexpected problems while following instructions correctly.
- If there is a problem due to user carelessness or product modification or disassembly, you need to pay for the repair

**DENTIS Co., LTD.**
**HEADQUARTER :** 99, SeongSeoseo-ro, Dalseo-gu, Daegu, Republic of Korea
**FACTORY** : 6, Yuram-ro, Dong-gu, Daegu, Republic of Korea
KOREA +82-2-869-6020 / USA +1-323-677-4363

ⓒ2021 DENTIS CO.,LTD. All Right Reserved.
Specifications are subject to change without notice.
Trademarks are the property of DENTIS CO., LTD. Or their respective owners.

(Ver 1.0) Jun/30/2021
Document No. : UEF-A1-11