OzoneDTA

Dental OZONE GENERATOR

USER'S MANUAL

CE 1639

● Read all instructions in this USER'S MANUAL before installation or operation.

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NOTE

Use only the specified accessories.

 : Caution and Read before use.

 : Type BF applied part.

 : Double insulated equipment.

1. APPLICATIONS

The main purpose of this unit is to produce pure ozone in focused area for medical treatment. Due to its unique effects, it can reach a concentration ranging from 10 to more than 100μg/ml required for the treatment area. The properties of pure ozone in sanitize fungi, viruses, and bacteria, make the unit into a novel and important therapeutic tool in dental treatment, with the hopes of resisting illnesses that are caused by bacteria, such as gingivitis. Moreover, ozone is a strong oxidizing agent currently used nowadays, and has a strong sterilizing power so that it can even disinfect tough bacteria, fungi, and viruses.

PROPERTIES OF OZONE

Ozone is a poignant gas. If a high concentration of ozone is inhaled, this will cause injuries to the human body. The inhaled ozone will inflict injuries to the lungs, come into contact with the eyes, or irritate the mucous membrane.

The German government stipulates that the maximum workplace concentration of ozone (i.e. MAK value) shall not exceed 0.2mg/m^3 for a weekly inhalation of 42 hours and a daily inhalation of 8 hours. At just one tenth of the MAK value, the odor of ozone can be perceived. However, within a shorter inhalation period, a higher concentration of ozone is allowed. Once formed, ozone will quickly be absorbed into oxygen molecules. Studies have shown that low ozone concentration actually does not harm the human body but has a therapeutic effect.

BIOCHEMICAL BASIS OF OZONE REACTIONS

After observing the sterilization action of ozone water, it is found that oxidation is primarily the action on the constantly dripping water drainage. In other words, when microbes come into contact with a sufficient amount of ozone, this will produce sterilization effects. Through oxidation, the cell envelopes of microbes are decomposed, and then their DNA or RNA is also attacked, in order to kill bacteria or viruses; such observations have already been proposed by several scholars. If such observations have been applied in medical treatment, they are considered ozone action in focused area simply.

As for cellular healing, oxidation action will deactivate viruses, and discharged peroxides which produce synergism within the cells and kill the microbes that invade into cells. As a rule, inflammation will occur only when white blood cells no longer can kill bacteria, so that hydrogen peroxide (H_2O_2) is unable to be produced or a less than normal quantity of hydrogen peroxide is produced.

⚠ CAUTION:

OzoneDTA is the model name of dental ozone generator. It stands for the full name of dental ozone generator in this user manual.

2. SAFETY INSTRUCTIONS and CONTRAINDICATIONS

Prior to use, it is imperative that the instruction manual and safety standards have been read thoroughly.

SAFETY INSTRUCTIONS

1》 Before using the equipment for the first time, it is important that the probe has to be cleaned and disinfected.

2》 This equipment shall not be used in a moist environment. Only dry probes could be used with the unit.

⚠ CAUTION:

- **It is prohibited to turn on power of the unit if the unit, handpiece, and probe are not 100% dry. Otherwise, it might cause injury and damage.**
- **Turn off the power before cleaning the unit or the probes.**

3》 The untrained operator shall not operate this equipment.

4》 It is necessary for each treatment to conform to the safety standards specified for dental treatment.

※ For further details, please refer to SAFETY and HEALTH STANDARDS

5》 It is necessary to be familiar with indications and contraindications of ozone therapy.

6》 No alcohol or ether shall be used, because these two solutions are combustible in electro surgery.

7》 No foreign object shall be plugged into the opening of the ozone generating handpiece.

8》 It is suggested that empirical values can be taken as intensity values primarily used for therapy. The release of an electric current will not cause any injuries to the human body as long as a contraindication is not involved.

9》 When an electric current passes through an allergic patient, the patient may have a trembling feeling, especially when the patient's lips come into contact with probe. However, the probe handle has been highly insulated.

10》 We suggested that the foot pedal had better to be used. For example, when the probe comes into contact with the to-be-treated "area" inside the gingival pocket, start the unit with foot pedal and by the end of the treatment. While the probe is still in contact or within the mouth, the foot pedal can be used to stop the treatment. Its advantage lies in its capability to avoid overly sensitivity (that is, the patient's tactile sensation of the electric current when coming into contact with the current.)

The Safety Rod at the patient's end for dental treatment conforms to the regulations stipulated by manufacturers. All treatment specifications, especially data related to time and power, are all related to the Safety Rod at the back of the unit. We sincerely suggest that the patient to hold the Safety Rod, especially during using the # 1 probe, so that it is possible to recognize any fracture at the tip of the probe caused by negligence during therapy, and thus for stopping the signals immediately.

11》 Electro surgery is a treatment in which the to-be-treated area is treated by probe sparking (For example, while applying probes in pus treatment, the probes are kept at a distance of 1 mm apart.)

12》 The probe shall not come into contact with the open eyes or shall not be placed at close range to the eyes.

13》 In order to enable the # 1 probe to penetrate into the gingival pocket, its diameter at the tip is set to be smaller, so as to avoid excessive force or a lever action (to prevent it from being broken.) Hence, it is necessary to widen the gingival pocket prior to using as the probe is secure for general applications in gingival pocket treatment. If the probe really breaks, the unit power will automatically be cut off within 0.1 second if the output is over 100μA.

14》 It is suggested to gradually increase the output power from lower to higher within the patient's endurance to prevent any injury or danger.

15》 Probes must be used regularly, idle time of non-usage should not exceed 2 months.

CONTRAINDICATIONS

For the following conditions, the unit should not be used or can only be used under specific conditions:

1》 Patients using cardiac stimulators (pacemakers).

2》 Epileptic patients or patients suffering from other serious neurological illnesses.

3》 Patients suffering from psychological problems.

4》 Mucous membrane of infants (under one year old).

5》 Patients who are overly sensitive to electric currents.

6》 Patients suffering from serious asthma.

7》 Pregnant women.

This therapy will not have any negative effects on the illnesses specified in the above-mentioned contraindication # 2, 3, and 5. These are considered contraindications merely because these may cause patients uncontrollable secondary mechanical reactions.

To those patients suffering from contraindication # 1, it is only possible to apply a light electric current for the therapy because this electric current will not cause any interference to a normally functioning cardiac stimulator.

To those patients suffering from the contraindication # 4 and # 7, it is prohibited to apply an electric current at a power level above 2.

Moreover, dentists shall decide whether those suffering from the above-mentioned contraindications should receive therapy.

SAFETY and HEALTH STANDARDS

1》 Ozone is applied for therapy on focused area only. Its concentration is required to be within acceptable medical range.

2》 The generated ozone is less than the MAK volume at 0.2mg/m^3, even the volume generated in the oral cavity. Inhalation in a very short time will not have any injury on the respiratory tract. However, it is necessary to avoid an extended direct inhalation of ozone within the treatment range

3》 The therapy room should be well ventilated because ozone may stimulate the respiratory tract and mucous membrane for allergic patients.

4》 The glass probe should be prevented from directly coming into contact with emulsion gloves, because some products have poor tolerance toward ozone, which may thus damage the emulsion layer of the gloves.

5》 The unit should be cleaned every time after use. Probes should be wiped with a sterilized, soft and dry cloth after and before each therapy.

⚠ CAUTION:

- **It is prohibited to turn on power of the unit if the unit, handpiece, and probe are not 100% dry. Otherwise, it might cause injury and damage.**
- **Turn off the power before cleaning the unit or the probes.**

6》 Steam sterilization is allowed to the probes.

7》 Only original accessories made by the original manufacturer should be used, including control box, probes and all other components. Otherwise, it will cause warranty invalid.

8》 Glass probes have major safe function and concern. Consequently, accessories or probes not made by the original manufacturer shall not be used for this product, and are not covered by the warranty.

3. FEATURES

1》 Ozone has good performance in disinfection, killing bacteria, and helping healing wounds.

2》 High concentration but low volume ozone is simply generated in the focused area.

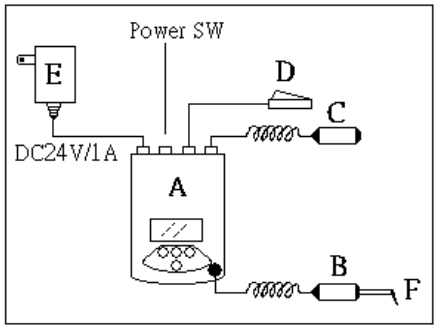
3》 Disinfection effect of ozone lasts long.

4》 It eliminates worry of antibiotics misuse.

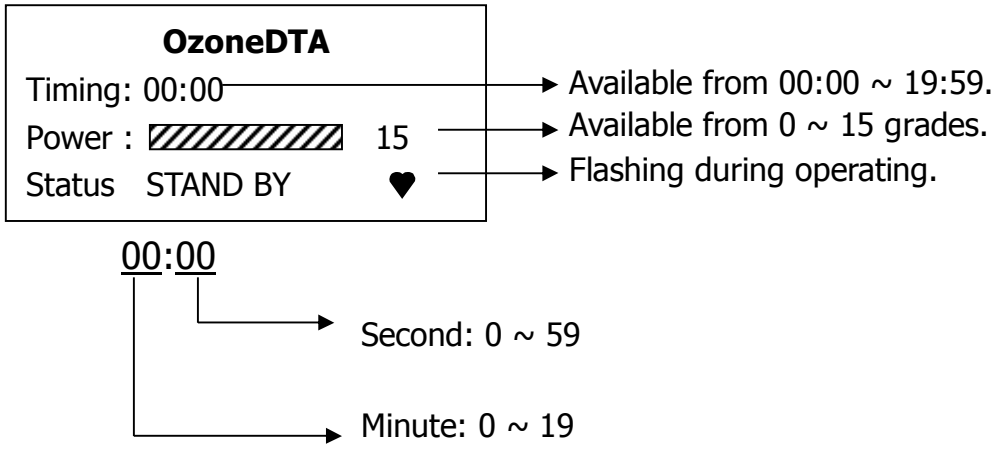
4. COMPONENT ILLUSTRATION and PANEL FIGURES

COMPONENT ILLUSTRATION

A : Control Box
B : Ozone Generating Handpiece
C : Safety Rod (Patient Ground)
D : Foot Pedal
E : Switching Power Adapter
F : Probe



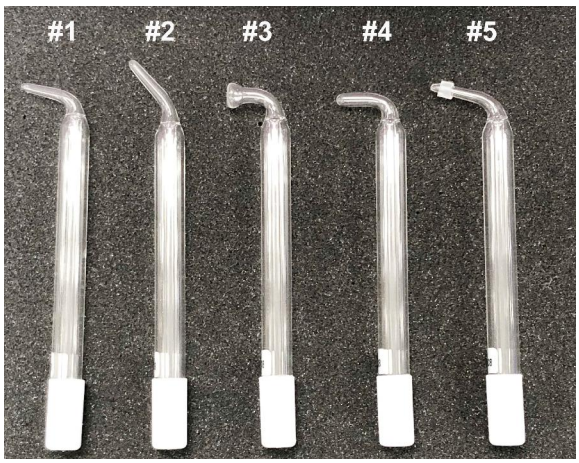
CONTROL PANEL



: DOWN
: UP
: ON / OFF
: ENTER

PROBES

 # 1 Probe: Pointed probe 10°
For treatments of gingivitis.
 # 2 Probe: Pointed probe 50°
For treatments of gingivitis.
 # 3 Probe: Flat probe
For treatments of skin and mucous membrane.
 # 4 Probe: Conical probe
For alveolar therapies after tooth extraction.
 # 5 Probe: Pointed probe 10° with conical plastic
For root canal treatments.



5. INSTALLATION and OPERATION

⚠ CAUTION:

- **It is prohibited to turn on power of the unit if the unit, handpiece, and probe are not 100% dry. Otherwise, it might cause injury and damage.**
- **Turn off the power before cleaning the unit or the probes.**

1》 Connect properly the Safety Rod and the foot pedal with the control box.

2》 Clean and disinfect the selected probe and the ozone generating handpiece. All the unit and accessories must be 100% dry before next step.

3》 Screw properly the ozone generating handpiece with the control box.

4》 Connect the switching power adapter with the control box.

5》 Assure the electric power on the unit is turned off.

6》 Slightly and properly insert the selected probe into the probe seating on the ozone generating handpiece, and make sure the probe is seated steadily.

7》 Pre-operation test of function as follows:

(1) Turn on the power.

(2) Press ↵ to set the timing by pressing ⌒ or ⌒. Press ↵ to go on next.

(3) Set the power. Press ↵ to save the setting.

(4) Put the probe close to the arm by keeping around 1mm from the skin. Press ◈ (on/off) to start program.

(5) Gas inside the probe turns slight red color while operating.

(6) There's a sparking sound and ozone smell on the skin.

(7) Press ◈ (on/off) again to stop program.

8》 If the Safety Rod and the Ozone Generating Handpiece are held in the hands of the same person, it might trigger off the inner safeguard and show "WARNING: Sys. Locked". This is a protection design. Just re-start the power and it will work fine.

9》 When the probe is broken, it will be automatically cut off within 0.1 second and then the switch will be turned off. In order to enable the automatic cut-off mechanism to achieve its function, **the Safety Rod must be held in hand of patient. This can thus prevent allergic patients from feeling trembling.**

10》 Before treatment, the patient must hold the Safety Rod.

11》 Repeat step 2》, step 5》 and step 6》.

12》 Operation can be started after checking the above instructions.

13》 Operation for treatment:

(1) Turn on the power.

(2) Press ↵ to set the timing by pressing ⌒ or ⌒. Press ↵ to go on next.

(3) Set the power. Press ↵ to save the setting.

(4) Put the probe close to the to-be-treated focus. Press ◈ (on/off) to start program.

(5) Program will be stopped automatically once the setting time ends.

(6) To interrupt the operation, just press ◈ (on/off) again to stop program.

14》 **The foot pedal has the same function as ◈ (on/off).**

15》 For power-related information, please refer to APPLICABLE SCOPE.

16》 Gradually increase the output power to meet with patient's comfort.

17》 By the end of therapy, it is imperative to turn off the power of the unit.

18》 Apply a force slightly and then screw out the glass probe in a clockwise direction.

19》 Clean the unit and probe (referring to **6. MAINTENANCE**) and then carefully place all the parts to their original locations.

APPLICABLE SCOPE

When the probe comes into contact with the focus, for example, during the therapy of gingivitis, oxygen will be converted into ozone inside and on the surface of gingiva, because oxygen molecules can also be oxidized in solutions. Consequently, it can arrest the oozing hemorrhage, relative to traditional therapy, so that therapy can be continued. Moreover, a high-frequency electric current can promote lymph flow and metabolism on the to-be-treated focus. Furthermore, a wide range of replaceable probes is used so that probes can extend to the source of the illness and thus achieve the required sterilization effect. Hence, the unit can be described to achieve its effects as follows:

⚠ ※ IMPORTANT NOTE ※

- Aspirator should be used together with the unit during therapy so that free ozone molecules are separated.
- **Test on patient's hand before setting output power.**
- It is necessary to gradually increase the output power to meet with patient's comfort.

Oxidation reaction rate means the conversion of oxygen molecules per time unit, which is related to pH value. In an alkaline environment, oxidation reaction is faster but is slower in an acidic environment. Consequently, we suggest that an oxygen accelerator is used together with this equipment in an acidic therapeutic environment. For the oxidization accelerator, substances containing catalytic copper ions can be used.

I. DEPARTMENT OF GINGIVA

❖ Gingival Pocket Treatment

The diameter of probe #1 (or #2) Tip is approximately 1.5mm and at approximately 8 mm by length. The glass tip will not be easily broken if it is normally used, for example at the gingival pocket. In order to prevent the probe from being broken, please don't over-exert a force and a lever action on the probe.

Set the output power at level 3-6. Prior to the insertion of the probe, it is necessary to open the gingival pocket, so that oxygen molecules can enter the to-be-treated area. Then the probe is extended into the opened gingival pocket. However, it is not necessary to extend the tip to the bottom of the gingival pocket, because through the conversion of oxygen, ozone will rapidly diffuse in the opened gingival pocket.

As a rule, it takes 1 to 2 minutes for the treatment of every to-be-treated area, so that the bacteria at that to-be-treated area can become oxidized, thereby killing the bacteria. A thorough gingivitis therapy covers both gingival pocket therapy and gingival therapy outside the gingival pocket.

For gingival therapy, use # 1 (or #3) probe, set the output power at level 3-9 for the same timing on the to-be-treated area. It is suggested to repeat the same therapy a few days later, until gingivitis recedes noticeably. Moreover, it is also suggested that regular preventive treatment should be conducted every half year.

❖ Gingival Surgery Applications

Use # 1 (or # 3) probe. Set the output power at the same level as gingival pocket treatment, and the timing at 1 minute for each treatment. In order to assure that the wider opening can receive a sufficient ozone concentration, it is necessary to select longer action timing than gingival pocket treatment requires.

❖ Necrotizing Gingivitis Treatment

Use # 1 (or # 3) probe according to the size of to-be-treated area. Set the output power at level 3-6, and the timing at 2 minutes for each treatment so that the pus-filled portion can become fully oxidized. The follow-up therapy after three days is recommended.

❖ Pericoronitis Treatment

For serious dental caries, use # 3 (or # 1) probe, setting the output power at level 1-3 for timing 1~3 minutes. For the treatment, ozone that inhibits inflammation, as well as a high-frequency electric current that circulate blood circulation and lymphatic fluid, is applied. After treatment, patient's symptoms are relieved.

II. MAINTENANCE & PREVENTIVE TREATMENT

❖ Dental Cavity Disinfection

Use # 4 (or # 5) probe according to the size and shape of the to-be-treated area.

It is more suitable to use # 4 probe to the to-be-treated area for the cavity formed by tooth extraction. As for the dental cavity with a smaller opening, it is more suitable to dispose the # 5 probe in the opening, so that ozone can be diffused in the cavity. It is suggested to set the output power at level 3-6, and timing at 1.5~3 minutes. As for bleeding cavities, it is suggested to set the output power at level 12, and timing approximately at 5 minutes based on the severity of bleeding.

❖ Root Canal Disinfection

Use # 5 probe. Prior to ozone therapy, it is necessary to remove the residual soft tissues inside the root canal, so that oxygen molecules can enter the root canal. Then slightly place # 5 probe into the root canal. Set the output power at level 6, and timing at 0.5~1 minute.

Moreover, it is possible to use # 1 probe , but care should be taken to prevent the probe from being stuck and to prevent the tip of the probe from being broken while patient is moving. Ozone will then diffuse to all the branches and kill the bacteria.

❖ Tooth Root Disinfection

Use # 3 and # 4 probe. Place the probe on the tooth root, and set the output power at level 6-9, and timing at 30 seconds.

❖ Oral Candidiasis Treatment

Place # 3 (or #4) probe along the affected area for therapy. Set the output power at level 6. Place the probe at the to-be-treated area, then set the timing acting for 2 minutes for every $8mm^2$ of to-be-treated area. Repeating the therapy two times after few days is suggested.

❖ Herpetic Treatment

Place the # 3 (or #4) probe along the affected area for therapy. Set the output power at level 6-9. Place the probe at the to-be-treated area, then set the timing acting for 2 minute for every $8mm^2$ of to-be-treated area. It is suggested that therapy is administered twice daily until the condition recovers. Therapeutic effects will appear after therapy has been administered for several times. However, viral nervous necrosis (Type 2 / Herpes Zoster) may take a longer therapeutic time.

❖ Treatment of Aphtha

Place the # 3 (or #4) probe along the affected area for therapy. Set the output power at level 6-9. Place the probe at the to-be-treated area, then set the timing acting for 30 seconds to 1 minute for every 5mm^2 of to-be-treated area. It is suggested that therapy is administered twice daily for the first few days. Therapeutic effects will appear after therapy has been administered for several times. However, keratinized aphtha (herpes zoster) may take a longer therapeutic time.

❖ Stomatitis Treatment

Place the # 3 probe along the affected area for therapy. Set the output power at level 9. Place the probe at the to-be-treated area, then set the timing acting for 1 minute for every 5mm^2 of to-be-treated area. It is suggested that therapy is administered twice for the first few days.

❖ Dental Caries (CP, P) Therapy

Use the # 1, # 4, or # 5 probe to further sterilize the dental cavity after dental caries have been treated. Set the output power at level 6 and timing approximately for 30 seconds to 1 minute according to the size of cavity. Especially for pulp therapy (endodontics), once the caries have been incised and extracted, power at level 12 is able to alleviate the blocking caused by homeostasis and thus increases the success rate of alleviating the inflamed focus.

III. JAW SURGERY APPLICATIONS

❖ Pre-operation Oral Disinfections

Use the # 3 probe. Set the output power at level 3-9 for treatment of entire oral cavity. It takes approximately 10 minutes to complete the treatment (with long-term action timing).

❖ Post-operation Oral & Wound Disinfections

Use # 1 (or #3)probe. Set the output power at level 6-9 for treatment of entire oral cavity. It takes no less than 3~10 minutes to complete the treatment (with medium to long-term timing). A shorter therapeutic timing can be selected for individual wounds.

❖ Wound Inflammation Treatment

Place # 1 (or #3) probe along the affected area for therapy. Set the output power at level 9. Place the probe at the to-be-treated area, then set the timing acting for 1 minute for every 5mm^2 of to-be-treated area. It is suggested that therapy is repeated twice on the next day.

❖ Homeostasis of Oozing Hemorrhage

Use # 4 or # 1 probe to arrest the oozing gingival hemorrhage. Use # 4 probe for the hemorrhage in the dental cavity, setting the output power at level 9~15 for timing 1~5 minutes.

❖ Tooth Extraction Follow-up Treatment

Use # 4 probe. It is suggested to extend the probe into the dental cavity in order to prevent inflammation. Set the output power at level 9 for timing 1~2 minutes.

INDICATIONS FORM

The applications of this form are excerpted from APPLICABLE SCOPE on the Instruction Manual. The time setting, intensity settings, and the frequency of repeating the treatment can provide average empirical values for your reference. However, the setting may change according to the size of the area of the focus, pH value, and the severity of illnesses. Moreover, dentists should decide the intensity used for individual therapy.

Diagnosis	Probe Type	Output Power	Time (minute)	Frequency of Treatment	The no. of times
Gingival Pocket Therapy	# 1 # 2	3-6	1-2 min.	Once to twice per week, every three days	3~5
Gingival Treatment	# 1 # 3	3-9	1-2 min.	Once to twice per week	3~5
Gingival Surgery Applications	# 1 # 3	3-9	1 min.	Once per week	2~5
Necrotizing Gingivitis Treatment	# 1 # 3	3-6	2 min.	Once per week	5
Pericoronitis Treatment	# 1 # 3	1-3	1-3 min.	Twice per week	1
Dental Cavity Disinfections & Dental Cavity Hemorrhage Treatment	# 4 # 5	3-6 12	1.5-3 min. 5 min.	Once Twice per week	1 2
Root Canal Disinfections	# 5	6	0.5-1 min.	Once per week	2
Tooth Root Disinfections	# 3 # 4	6-9	0.5 min.	Once	1
Oral Candidiasis Treatment	# 3 # 4	6	2 min.	Twice per week	3~5
Herpetic Treatment	# 3 # 4	6-9	2 min.	Twice per week	1~3

Diagnosis	Probe Type	Output Power	Time (minute)	Frequency of Treatment	The no. of times
Treatment of Aphtha	# 3 # 4	6-9	0.5-1 min.	Twice per week	1~3
Stomatitis Treatment	# 3	9	1 min.	Twice per week	3
Dental Caries Treatment (CP, P)	# 1 # 4 # 5	6	0.5-1 min.	Once	1
Pre-operative Extensive Oral Disinfections	# 3	3-9	10 min.	Once	1
Post-operative Oral & Wound Disinfections	# 1 # 3	6-9	3-10 min.	Once	1
Wound Inflammation Treatment	# 1 # 3	9	1 min.	Twice per week	3
Homeostasis of Oozing Hemorrhage	# 1 # 4	9~15	1-5 min.	Once	1
Tooth Extraction Follow-up Treatment	# 4	9	1-2 min.	Twice per week	2

For those highly allergic patients, if an injection is not to be administered, it is necessary to tightly attach the probe at close proximity to the treatment body portions. Operating the equipment by using Foot Switch is effective.

6. MAINTENANCE

⚠ CAUTION:

- **It is prohibited to turn on power of the unit if the unit, handpiece, and probe are not 100% dry. Otherwise, it might cause injury and damage.**
- **Turn off the power before cleaning the unit or the probes.**

1》 The unit should be cleaned every time after use. Probes should be wiped by soft cloth with surgical ethyl alcohol or disinfected by autoclave within 134℃(highest temperature) after and before each therapy. Never soak the unit, handpiece and probe into any surgical liquid for disinfection to prevent remain liquid in it.

2》 Only original accessories made by the original manufacturer should be used, including probes and plug-connected parts.

3》 Probes have major safe functionalities. Consequently, non-packaged accessories or other probes not supplied by manufacturers shall not be used for this unit.

4》 Probes shall not be soaked into solutions for disinfection or sterilization.

※ IMPORTANT NOTE ※

Steam sterilization is allowed for the probes.

5》 Prevent the glass from being broken while handling.

6》 Change the probe according to the frequency of usage as the power of the glass probe will be reduced with time. Generally, # 1, # 2, and # 5 probes needs to be replaced around every 6 months, and around every 12 months for # 3 and # 4 probes.

7》 **For any defect found, don't disassemble and don't use the unit** because this may cause injury to the patients when the equipment does not conform to the required safety regulations and this would cause warranty invalid.

8》 If the unit could be reasonably, properly used, stored and all necessary maintenance could be taken, it could be used safely for five years from date of manufacturer. The lifespan would be affected if the device is used with any component or accessory which is not made by the original manufacturer.

9》 Environmental Conditions:

Storage temperature : -10℃ / +50℃

Operating temperature : +15℃ / +45℃

10》 Insert and Remove the glass probe in one direction only, and it is prohibited to move in the pocket during oral therapy.

11》 Any instrument (including but not limited to mirror and tools) should be removed from oral before removing the glass probe.

12》 Prevent the glass probe to touch solid object (tooth, mirror, tools utensil, etc.)

7. TROUBLE SHOOTING

Users could simply check over the device with the following chart. For any other unlisted fault, please contact the dealer immediately for further check. Any self-repairing might raise worse condition and sever damage or injury.

FAULT	POSSIBLE CAUSE	SOLUTION
Display is not working.	Electric power is not connected properly.	Re-connect properly the electric power and re-start.
"**WARNING: Sys. Locked**" shows on the display.	A. The glass probe is damaged while operating. B. The Safety Rod and the Ozone Generating Handpiece are held in the hands of the same person.	A. Turn off the device and replace with a new glass probe before restarting the operation. B. The Safety Rod should be held by the patient while the doctor is holding the Ozone Generating Handpiece for treatments. (Hands must be dry)
Probe doesn't work	A. Improper connection of cable line. B. Improper connection between handpiece and probe. C. The probe is damaged or broken.	A. Reconnect the cable line. B. Reconnection the probe into handpiece C. Replace the probe
Weak output power on probe	Probe is damaged or broken	Replace the probe.
The light in the probe is sluggish	The air in probe become inactive	Wake up the air – power level : 15 and turn on the power for 30 seconds. If the light doesn't become stronger. Replace the probe.

8. SPECIFICATION and ACCESSORIES

SPECIFICATION

1》 **Control Box**

Input	:	24V DC 500mA
Output	:	500Hz, 2~59μs
Max. Output Current	:	Imax<=100μA
Safety Output Lock Current	:	>100μA (Duration: t>=0.1s)

2》 **Switching Power Adapter**

Input	:	100V~240V AC, 50/60Hz
Output	:	24V DC 1.25A

STANDARD ACCESSORIES

Control Box	x 1pc
Ozone Generating Handpiece	x 1pc
Safety Rod (Patient Ground)	x 1pc
Foot Pedal	x 1pc
Switching Power Adapter	x 1pc
Probes	x 5pcs
Autoclavable probe box	x 1pc

9. WARRANTY

1》This product has been fully inspected and conformed to current product specification. It is
warranted for its designated usage, against original defects in materials and workmanship for period of 18 months from date of purchase. Charges applied to following conditions：

a. Incorrect or improper operation caused by not following the User Manual instructions.

b. Disassemble, repair or modify the accessories without approval.

c. Damage caused by consumption parts, accessories or natural disasters.

We will charge partly cost or inspection fee after the warranty period. Please refer to warranty statement for more details.

2》Special Condition :

The following conditions are **not included** in Apoza warranty:

a. The damage was caused by user's mistake. (e.g. unsuited power voltage, overheat location of the unit, fallen down by accident ,pressed by hard force or other unusual situations.)
b. "Apoza specification" or parts had been replaced, disassembled, disposition of the goods or serious damage of shell.
c. The damage was caused by accidents such as fire, explosion, flood, war riots, earthquake or other irresistible situations.
d. Damage during transportation.

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10. Declaration for Electromagnetic Compatibility

Note:

1. This product needs special precautions regarding electromagnetic compatibility and needs to be installed and put into service according to the note "electromagnetic compatibility.
2. Certain types of mobile telecommunication equipment could potentially interfere with this product. The separation distances recommended in the note "electromagnetic compatibility" must be taken into account.

Warning:

1. This product should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
2. The use of accessories and cables other than those specified or sold by manufacturer as replacement parts may result in increased emissions or decreased immunity of this product.

Table 1

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration . electromagnetic emissions</td></tr>
<tr><td colspan="3">The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 2</td><td>The product must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The product must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded location, a minimum RF filter attenuation of 80 dB from 10 MHz to 20 MHz, 100 dB from 20 MHz to 80 MHz and 80 dB from 80 MHz to 100 MHz. (The minimum at 20 MHz is 100 dB and the minimum at 80 MHz is 80 dB.)

The product when installed in such a shielded location, 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601	test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 % .
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 004 image intensifier requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position the image intensifier further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment . guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz～80 MHz 3 V/m 80 MHz～2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz 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, [a] should be less than the compliance level in each frequency range. [b] 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 product is used exceeds the applicable RF compliance level above, the Model 006 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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WARRANTY STATEMENT

This instrument described below has been fully inspected and conforms to the current products specification.
This instrument is guaranteed for its designated use, against original defects in materials and workmanship for a period of 18 months from **shipment date**. Repairs necessitated by misuse or disassembling of the equipment, or by the parts not provided by the manufacturer, are not covered by this warranty.
The following parts are not included in the warranty:

1) Curing Light : Light guide
2) Autoclave : Filter
3) J-500/J-500 plus unit : Air tip, Air tip cover, Root canal tip
4) BT Cool plus : Distance guide with supporter, Goggles(orange)

* Following parts warranty for 3 months: probes of ozone generator, lithium battery *

ITEM NAME _____

SERIAL NO. _____ INSPECTOR _____

POWER _____ VOLTAGE _____

(TEAR OFF HERE)

RETURN INFORMATION CARD

ITEM NAME _____

SERIAL NO. _____ DATE PURCHASED _____

POWER _____ VOLTAGE _____

CUSTOMER NAME _____

ADDRESS _____

_____

_____

Please fill in this "Return Information Card" to the sales representative for user's record and future service.