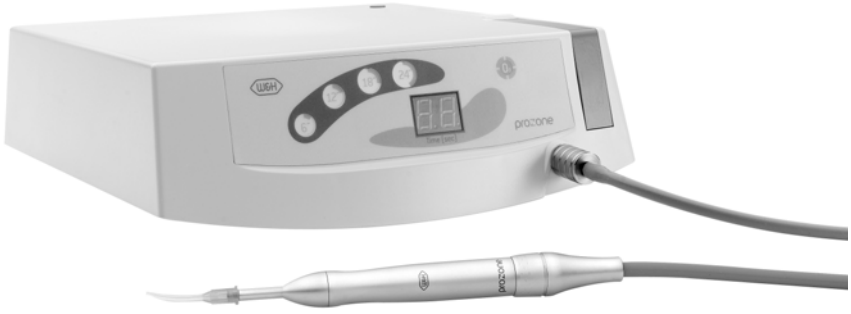
PEOPLE HAVE PRIORITY

Instructions for use



prozone

Symbols

WARNING!
(Risk of injury)

ATTENTION!
(to prevent damage occurring)

General explanations,
without risk to
persons or objects

Thermo washer disinfectable

Sterilizable
up to the stated temperature

Data Matrix Code for product
identification e.g. in hygienic
maintenance process

Only for USA
Caution: Federal law restricts this device to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the device.

Contents

1. Introduction

For your safety and the safety of your patients
These Instructions for Use explain how to use your product. However, we must also warn against possible hazardous situations. Your safety, the safety of your team, and of course, the safety of your patients are of paramount importance to us.

It is therefore essential to read the safety notes.

Intended use
The Prozone is an electrical device which produces ozone for use in various dental applications.

Qualifications of the user
The Prozone has been designed and developed for the dental profession.
Only suitably qualified medical, technical and specialist staff may use the Prozone unit after specific training.

Production according to EU-Directives
EU-Directive 93/42/EEC has been used as a basis in the design and manufacture of this medical product and this applies to the Prozone unit. This declaration does not apply to non-specified fittings, mountings etc.

Introduction

Responsibility of the manufacturer
Tip Top Tips (TTT) can only accept responsibility for the safety, reliability and performance of the Prozone when there is compliance with the following directions:

> The Prozone must be used in accordance with these Instructions for use.

> The Prozone has no components which can be repaired by the user. Assembly, modifications or repairs must only be undertaken by skilled personnel authorized by TTT.

> The electrical installation at the premises must comply with the regulations of ÖVE-EN 7 »Installation of electrical equipment in rooms used for medical purposes« or with the regulations applicable in your country.

> Unauthorized opening of the Prozone invalidate all claims under warranty and any other claims.

2. Ozone generation

Generation of ozone is created with a high voltage applied on a ceramic plate, principle called corona discharge.

To produce ozone with the Corona effect, it is very important that the air inside the ozone generator chamber is dry.

The device will purge for 30 secs each time it is turned on (up to 90 sec if the air flow is reduced; for example with an Prozone tip Endo connected).

This purge will ensure that the humidity that could remain in the Prozone while the device is not in use will be evacuated.

The purge can also be performed manually by depressing the O_3 button while the device is in standby.

 Only use the Prozone with a yellow filter

Humidity inside the ozone generator will:
> reduce the production of ozone.
> reduce the life time of the ceramic plate.

yellow = good
blue/yellow = to be exchanged
blue = expired (error CF)

The device will display an error (E2) when there is a low output of ozone. In this case, the Prozone will have to be re-calibrated by a TTT appointed distributor.

3. Equipment supplied

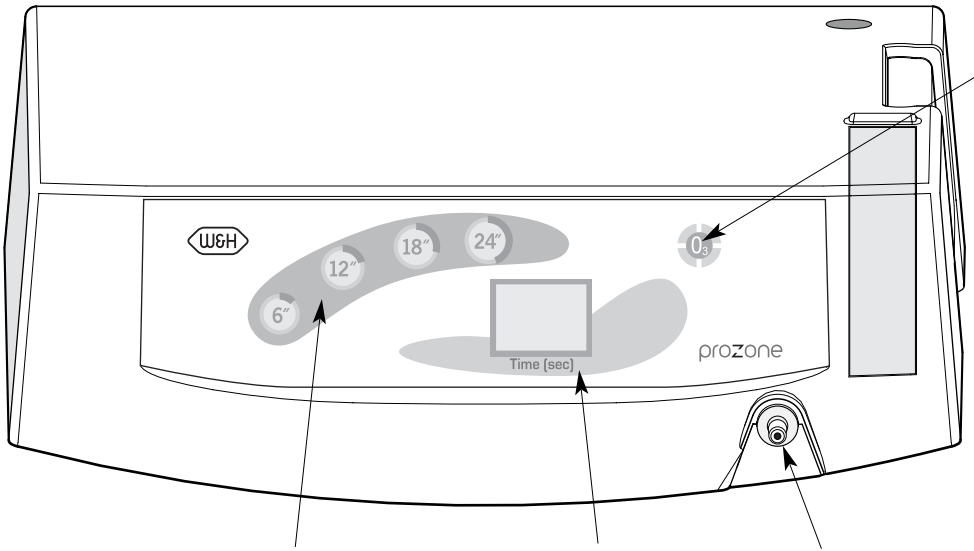
- ❍ REF 12930100 Prozone unit
  - ❍ Prozone handpiece tube with connector
  - ❍ Prozone handpiece
  - ❍ Prozone filter cartridge
  - ❍ Prozone foot control
  - ❍ Prozone tips Coro (20 pcs)
  - ❍ Prozone tips Endo (20 pcs)
  - ❍ Prozone tips Perio (20 pcs)
  - ❍ IFU 50631 Prozone Instruction for use

Only one supplied:

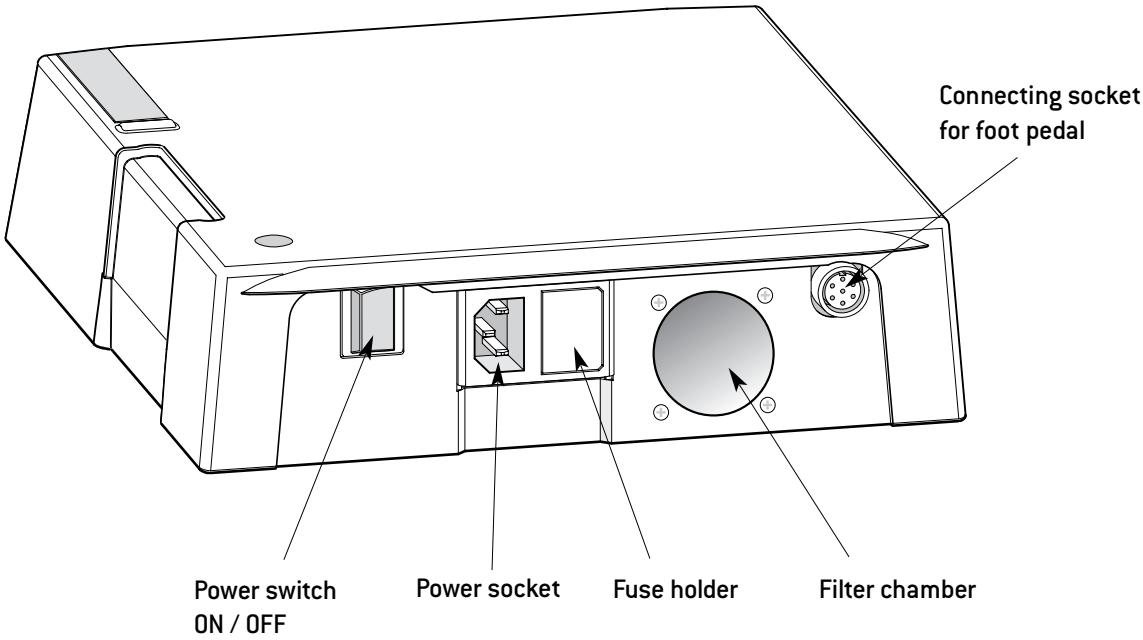
- ❍ REF 01343700 Mains cord EUR
- ❍ REF 03212700 Mains cord UK
- ❍ REF 04280600 Mains cord CH
- ❍ REF 02909300 Mains cord AUS, NZ
- ❍ REF 02821400 Mains cord USA
- ❍ REF 05901800 Mains cord DK

Handpiece and handpiece tube are not delivered sterile and therefore must be sterilized to prior first use.

4. Description of front panel



5. Description of rear panel



Description of rear panel

CE symbol refers to Directive 93/42/EEC

Equipment of Protective Class II

REF Catalog number

Follow operating instructions

Type BF appliance (not suitable for intracardiac application)

SN Serial Number

O I ON and OFF positions marked

Foot control connector

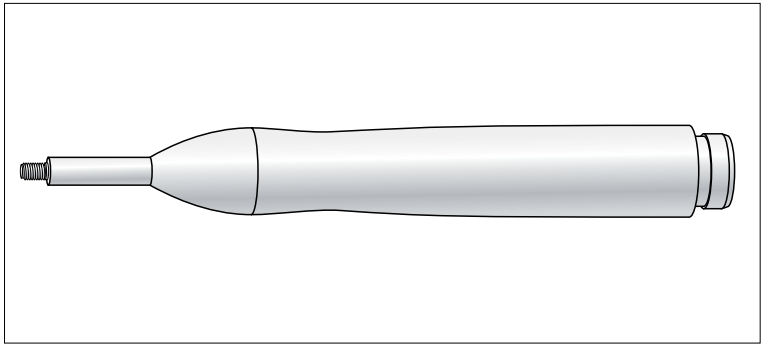
Fuse

Separate collection for electrical and electronic equipment waste per Directive 2002/96/EEC in the European Union

Year of manufacture

Functional Earth

6. Description of Prozone handpiece



CE symbol refers to Directive 93/42/EEC

SN Serial Number

Sterilizable up to 135° C in autoclave

Thermo washer disinfectable

7. Description of Prozone tip marking

CE symbol refers to Directive 93/42/EEC

Single use

Lot Batch number

EC REP EC European Representative

8. Safety notes

Please ensure that you carry out the following instructions before operating the unit:

> Only operate the Prozone when you have high volume aspiration (~50l/min) and at the point of application.
> Never operate unit if any tubing is damaged or worn.
> Use only original parts and accessories, as recommended by the manufacturer. The use of non-original parts will invalidate any claims under warranty.

Inappropriate Use
Improper use in addition to assembly, installation, modifications or repairs of the unit or non-compliance with an instruction, invalidates all claims under warranty and any other claims.

Patients at risk
Do not use the Prozone on patients with respiratory conditions.

Cardiac Pacemaker Patients
The use of the Prozone involves generation of magnetic fields, which are below the interference threshold limit according to EN 60601-1-2. We do however advise that the Prozone is not used on such patients.

Pregnant Women and Infants
Do not use the Prozone on these patients as the VME value is not available.

Safety notes

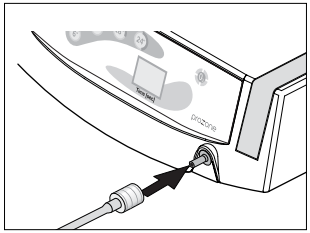
Mains
The power supply should be connected to a hospital grade power outlet as applicable in your country. Only connect to an earthed socket outlet.

Power Failure
In the event of a power failure while the Prozone is in use, the unit will reset itself once the mains power has been restored.

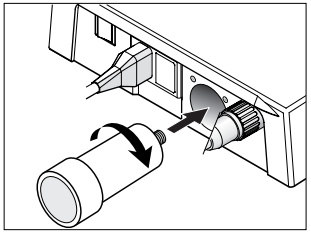
Safety in presence of a flammable substance

In accordance with EN 60601-1, the control unit is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.

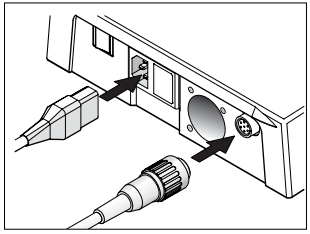
9. Starting operation – General



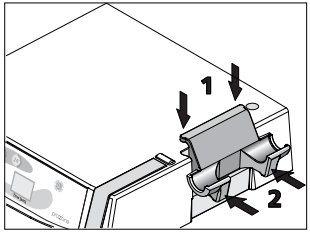
❶ Connect the end of the handpiece tube to the unit by sliding it over the connector until it is fully inserted.



❸ Install the filter cartridge by screwing in clockwise.



❷ Connect the mains cord. Connect the foot control and secure it by turning the locking sleeve clockwise.



❹ Fit the handpiece holder. It can also be used on a mobile basis.

10. Starting operation – Control Unit

Immediately after switching the unit »ON«, a purge (30sec-90sec) is automatically performed and all four programmes (6"-24") will be illuminated by a blue LED accompanied by a single beeping sound. Then the unit is in »Standby« mode.

For all procedures, please observe the following:

❶ Press desired program select button. The unit goes to »Ready« mode.

❷ Cycle button illuminated and flashing, allowing user 30 seconds preparation time to place aspiration and Prozone tip. (Pressing the program select button return to »Standby« mode.)

❸ Activate foot control briefly. After a 3 second warmup. O_3 LED is ON, indicating ozone generator is active.

❹ Treatment Countdown + Fast beeping. Pressing program button will interrupt the treatment.

❺ There is a system flush for 10 seconds at the end of each treatment. Keep aspiration and Prozone tip in place, until the fast beeping has been replaced by slow beeping.

❻ Unit returns to »Ready« mode for 30 seconds during which time treatment may be continued by reactivating foot control. After 30 seconds, or pressing the program select button, the unit return to »Standby« mode.

Before treatment, ensure high volume aspiration is used (~50l/min) prior to activating foot control.

11. Clinical applications

Please use high volume aspiration (~50l/min.)
Place Prozone tip as close as possible to the treatment area (1-2mm)

Apply only the prescribed time of application. Do not »over ozonate« tissues.

PROGRAM 6" (seconds)
Cavity disinfection technique:

> Prozone tip Coro
> Prepare cavity as per standard procedure
> Select 6" on display panel
> Follow steps 2-5 to disinfect cavity
> Place restoration

Program 6" can also be utilized directly for the following conditions:
Herpes
Gingivitis
Stomatitis

Clinical applications

PROGRAM 6" (seconds)
Acid etch bonding technique for composite restoration:
(inlays-onlays-veneers)

> Prozone tip Coro
> Prepare tooth surface as per standard procedure
> Apply and rinse etching gel
> Select 6" on display panel
> Follow steps 2-5, injecting 03 directly into the cavity to disinfect
> Apply bonding agent and restoration as normal

PROGRAM 12" (seconds)
Surgical disinfection:

> Prozone tip Coro
> Extraction, implant placement
> Disinfection of crowns, posts, inlays-onlays-veneers
> Dental hypersensitivity

Clinical applications

PROGRAM 18" (seconds)
Periodontal treatment:

> Prozone tip Perio
> Debride and irrigate pocket as usual
> Select 18" on display panel
> Follow steps 2-5, applying to disinfect

PROGRAM 24" (seconds)
Endodontic treatment:

> Prozone tip Endo
> Prepare and clean the canal system as per standard procedure
> When the canals are ready for obturation, dry with paper points
> Select 24" on display panel
> Follow steps 2-5 injecting gas directly into canal to disinfect
> Complete obturation procedure
> Should bleeding from the pulp chamber occur, utilize ozone gas to coagulate bleeding

Clinical applications

Which tips to use?
Prozone tips are specifically designed and manufactured for use with the Prozone.
We suggest you use the following tips for each specific treatment:

Prozone tip Coro: general use, cavity preparation, surgical disinfection etc.
Prozone tip Endo: endodontics (needle tip for endodontics).
Prozone tip Perio: fine capillary tip for periodontal pockets.

12. Disinfection, Cleaning, Sterilization

Wear protective gloves.
Disinfect and clean the handpiece immediately after every treatment.

Control unit, foot control
The front panel of the control unit is sealed and may be wiped clean.
Disinfect using surface disinfectants.
Use certified surface disinfectants (e.g. DGHM-tested).

Handpiece, Handpiece tube
Wrap handpiece in sterilization bag, according to EN 868-5.
TTT recommends sterilization according to EN 13060, class B

Vacuum sterilization
Steam vacuum sterilization according to EN 13060, using a sterilization holding time of a minimum of 3 minutes at 134 (+3) °C (273.2 +5.4 °F)

Gravity sterilization
Steam gravity sterilization using a sterilization holding time of a minimum of 4 minutes at 134 (+3) °C (273.2 +5.4 °F)

Before starting operation again, wait until the handpiece is completely dry.

13. Maintenance

Filter Cartridge
The filter is a key element for the generation of ozone.
The functions are:
> Air drying
> Dust prevention

Life time of the filter cartridge will depend on relative humidity conditions and number of treatments: average 500 applications.

The top of the filter cartridge is fitted with a special indicator which will change colour with using:
yellow = good for use
blue/yellow = needs to be replaced
blue = expired (error CF)


When Prozone is not in use for more than 2 days, place the black rubber cover over the filter cartridge.

Changing the filter
> For easy access to the filter, remove the foot control connector.
> Unscrew the used filter.
> Install the new filter.
> Reattach the foot control connector.


If the filter is not attached correctly, error E1 will appear on the digital display when the Prozone is put into operation.

Maintenance

Checking the ozone concentration level
W&H recommends sending in the Prozone every 12 months for a safety inspection.

14. Warnings

Warnings only appear in »Standby« or »Ready« mode and never interrupt a treatment.
Activating any button will erase the warning display and the Prozone will return to »Standby« mode after a purge of the air circuit.

Display: CF
After every hour of ozone generator working time, »CF« will be indicated on the display panel, as a reminder to check the filter status. Refer to »Maintenance / Filter« section.

Display: CO
After up to 100 hours of ozone generator working time, »CO« will be indicated on the display panel, as a remainder to check the ozone generation values. Contact your distributor to arrange an inspection of the ozone concentration levels.

Display: OU
The device will limit the amount of ozone produced in case it runs continuously (Over Used). The allowed continuous running time is 15 minutes, then the device allow to run as many time as the time it stay in standby.

15. Errors

When an error is detected, the Prozone immediately returns to »Standby« mode. An error will interrupt a running treatment. Activating any button will erase the error display and the Prozone will return to »Standby« mode.

Display: E1
Air leakage detected. Check for correct connection of:
> Filter cartridge
> Handpiece tube
> Handpiece
> Prozone tip

If the error remains, refer to your Prozone dealer.

Display: E2
Ozone detection: No presence of ozone detected by the internal ozone sensor.
Check the filter status (refer to Maintenance/Filter) and purge the air circuit with dry air by manually by pushing the O_3 switch while the device is in standby.
If the error remains, a re-calibration of the device could be necessary due to the ageing of the Corona ceramic plate.
Refer to your Prozone dealer to proceed with re-calibration.

Display: E3
Hardware fault: Hardware problem detected during the automatic self-testing of the unit. Switch ON/OFF the unit and re-start a treatment. If the error remains, refer to your Prozone dealer.

Errors

Display: E4
Ozone sensor fault: Hardware problem detected during the automatic self-testing of the unit. Switch ON/OFF the unit and re-start a treatment. If the error remains, refer to your Prozone dealer.

Display: E5
Over pressure fault: Over pressure inside the ozone chamber detected during the automatic self-testing of the unit. Re-start the device with the handpiece cord removed. If the error is cleared, check if the air is blocked inside the tube, handpiece or the tip. If the error remains, refer to your Prozone dealer.

16. Environmental Conditions

Operation

Temperature:	5°C to 40°C (41°F to 104°F)
Altitude:	-390 m to 3,012 m (-1,254 ft. to 9,882 ft.)
Atmospheric Pressure:	70 kPa to 106 kPa (20.6 in. Hg to 31.3 in Hg)
Relative Humidity:	15 % to 95 % non-condensing to be compliant with IEC 60601-1, sub-clause 44.5

Transport and Storage

Temperature:	-20°C to 60°C (-2°F to 140°F)
Altitude:	-390 m to 5,574 m (-1,280 ft. to 18,288 ft.)
Atmospheric Pressure:	50 kPa to 106 kPa (14.7 in. Hg to 31.3 in Hg)
Relative Humidity:	15 % to 95 % non-condensing

Recycling

Prozone:	The equipment contains many valuable materials. Therefore return your equipment for material recycling via the relevant public collection system. Main unit must be disposed as »special electronic waste«
Foot control:	When the foot control is to be scrapped, it must be disposed of - if necessary - as »special electronic waste« in accordance with local regulations.

17. Characteristics

Electrical

Supply voltage:	100 - 240 V AC
Frequency:	50 - 60 Hz
Power:	30 VA
Fuse:	2x 250V T1AH
Operating mode:	Continuous
Protection class:	Class II (with functional earth connection)
Applied Part:	Type BF
Degree of Safety in presence of a flammable anesthetic:	Not suitable

Ozone

Ozone production:	140ppm @ 2L/min

Protection again ingress of water

Prozone:	The control unit is classed as conventional equipment (closed equipment without protection against the ingress of water).
Foot control:	IPX1 - Drip-Proof

Physical Characteristics

Weight:	1.8 kg
Dimensions:	24 cm x 26.5 cm x 6.5 cm

18. Electromagnetics compatibility

Manufacturer's Declaration
WARNING: The use of accessories, cables other than those specified may result in increased emission and/or decreased immunity.

Cables Length:

Cables and accessories	Maximum length	Complies with
Handpiece cord	1.80 m	RF emissions, CISPR 11, Class B / Group 1
Foot control	3.00 m	Harmonic emissions, IEC 61000-3-2
Mains cord	2.50 m	Voltage fluctuations/flicker emission, IEC 61000-3-3 Electrostatic discharge (ESD), IEC 61000-4-2 Electric fast transient/burst, IEC 61000-4-4 Surge IEC 61000-4-5 Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11 Power frequency (50/60Hz) magnetic field, IEC 61000-4-8 Conducted RF, IEC 61000-4-6 Radiated RF, IEC 61000-4-3

Electromagnetics compatibility

Electromagnetic Emissions
The Prozone is suitable for use in the specified electromagnetic environment. The customer and/or user of the Prozone should assure that it is used in an electromagnetic environment as described below:

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

Electromagnetic Immunity

Immunity Test	IEC 60601-1-2	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 1 kV common mode	± 1 kV differential mode ± 1 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment

Electromagnetic Immunity

Immunity Test	IEC 60601-1-2	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 %U_T (>95 % dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 %U_T (>95 % dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic Immunity, RF portable equipment

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 environment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
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.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 0 MHz to 2.5 GHz	3 Vrms 3 V/m	Recommended separation distance d = 1.2 P d = 1.2 P 80 MHz to 800 MHz d = 2.3 P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)
Field strengths form 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 : 			

Electromagnetic Immunity, RF portable equipment

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.

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 product 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.
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separations Distances

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter M**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

19. Accessories

Use only original or approved by TTT accessories and spare parts.

- REF 05864100 Prozone handpiece tube with connector
- REF 05875200 Prozone handpiece
- REF 05863400 Prozone filter cartridge
- REF 05863500 Prozone foot control
- REF 05863700 Prozone tips Coro (20 pcs)
- REF 05863800 Prozone tips Endo (20 pcs)
- REF 05863900 Prozone tips Perio (20 pcs)

20. Warranty

As manufacturer, TTT is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase.

TTT accepts no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by TTT. Parts subject to normal wear, such as bulbs, are excluded from the warranty.

Claims under warranty - accompanied by proof of purchase - must be sent to the vendor or to an authorized TTT service point.

The provision of service under warranty extends neither the warranty period nor any other guarantee period.

CERTIFICATION OF TRAINING

Name of the customer / user _____

Adress _____

Distributor _____

Prozone Serial Number _____

The user / customer have been trained in all functions of the unit in accordance with current Instructions for Use. Particular attention was shown to Safety notes, Disinfecting, Cleaning, Sterilization and Servicing.

Name of the instructor _____

Address _____

Date _____ Signature _____

Appendix 1: Copy for the distributor.

Prozone follow up

User Control Prozone	
Date	**Drager 10/a Visa / OK**

Note:

Distribution

W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Straße 53, 5111 Bürmoos, **Austria**

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Manufacturer

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CE 1254 ISO 13485

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