

Comfort-Sonic®

Ultrasonic Scaler

P6 Plus
Instruction for Use



Beyes®
The Next Standard

Table of Contents

1. The installation and components of equipment

1.1 Introduction	P3
1.2 Components	P3
1.3 The main technical specifications.....	P3-4
1.4 Installation of the main components.....	P4-7

2. Product function and operation

2.1 Scaling funtion.....	P7-9
2.2 Endo function.....	P9

3. Sterilization and maintenance

3.1 Sterilization of detachable handpiece.....	P9
3.2 Sterilization of scaling tips and endochuck.....	P10
3.3 Serilization of torque wrench and edo wrench.....	P10
3.4 Cleaning of tips, endochuck, torque wrench and endo wrench.....	P10
3.5 Sterilization and cleaning of LED lamp and Light pipe	P10
3.6 Troubleshooting and notes	P10-12

4. Precaution

4.1 Notice when using equipment	P12
4.2 Contraindication.....	P12
4.3 Storage and maintenance	P13
4.4 Transportation	P13
4.5 Working condition.....	P13

5. After service.....

P13

6. Symbol instruction

P13

7. Environmental Protection.....

P14

8. Manufacturer's rights

P14

9. Warranty

P14-15

1. The installation and components of equipment

1.1 Introduction

Beyes Dental Canada Inc. Is a professional manufacturer in researching , developing and producing ultrasonic piezo scalers. This product is mainly used for teeth cleaning and is also an indispensable equipment for tooth disease preventions and treatments. The new product COMFORT-SONIC ultrasonic piezo scaler has scaling, perio, endo functions. It contains the following features:

1.1.1. Optical handpiece, more convenient for clinical operation.

1.1.2. Automatic frequency tracking ensures that the machine always works on be the best frequency and performs more steadily.

1.1.3. The handpiece is detachable and can be autoclaved to the temperature of the 135°C and the pressure of 0.22Mpa.

1.1.4. Controlled by PC, easy operation and more efficient for scaling.

These features make COMFORT-SONIC become a new generation product in the world dental market.

1.2 Components

1.2.1.The components of the machine are listed in the packing list.

The scaling tips and their accessories are not listed in this instruction manual completely. The detail can be found in the instruction for tips and packing list attached to the machine.

1.2.2. Product performance and structure

Ultrasonic piezo scaler is composed of electro circuit, water way and ultrasonic transducer.

1.2.3. Scope of application

Ultrasonic piezo scaler COMFORT-SONIC is used for the dental calculus elimination and root canal treatment.

1.3 The main technical specifications

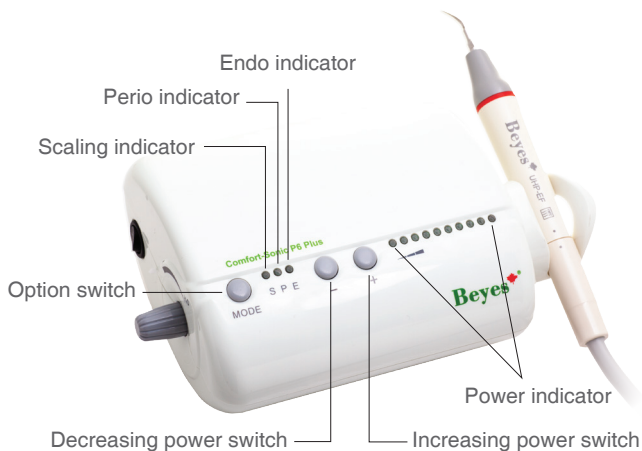
- Power supply Input: 220V to 240V~ 50Hz/60Hz 150mA
- Main unit input: 24V~50Hz/60Hz 1.3A
- Output primary tip Vibration excursion: $\leq 100\mu\text{m}$
- Output half-excursion force: $< 2\text{N}$
- Output tip vibration frequency: 28kHz $\pm 3\text{kHz}$
- Output power: 3W to 20W
- Main unit fuse: T1.6AL 250V
- Adapter fuse:T0.5AL 250V
- Water pressure: 0.1bar to 5bar(0.01Mpa to 0.5 Mpa)

- Weight of main unit: 0.64kg
- Weight of adapter: 1kg
- Main unit volume: 196mmx134mmx80mm
- Operating mode : Continuous operation
- Type of protection against electric shock: Class II
- Degree of protection against electric shock: Type BF applied part
- Applied part of the equipment: handpiece and tip
- Degree of protection against harmful ingress of water : Ordinary equipment(IPX0) Protection degree against water(used on the foot switch):IPX1
- Degree of safety of application in the presence of a Flammable Anesthetic Mixture with air or with Oxygen or Nitrous Oxide: Equipment is not suitable for being used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

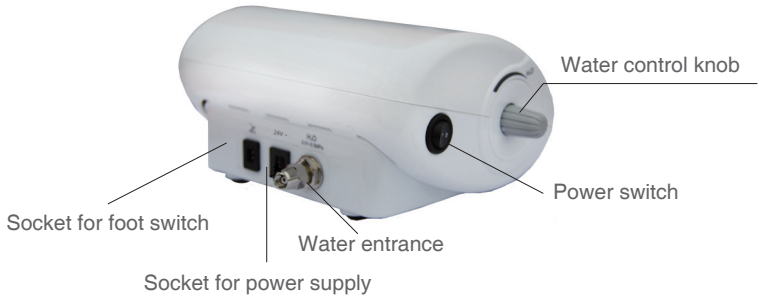
1.4 Installation of the main components

1.4.1. Installation and connection.

a) The components of the equipment are showed in picture 1 (a,b)

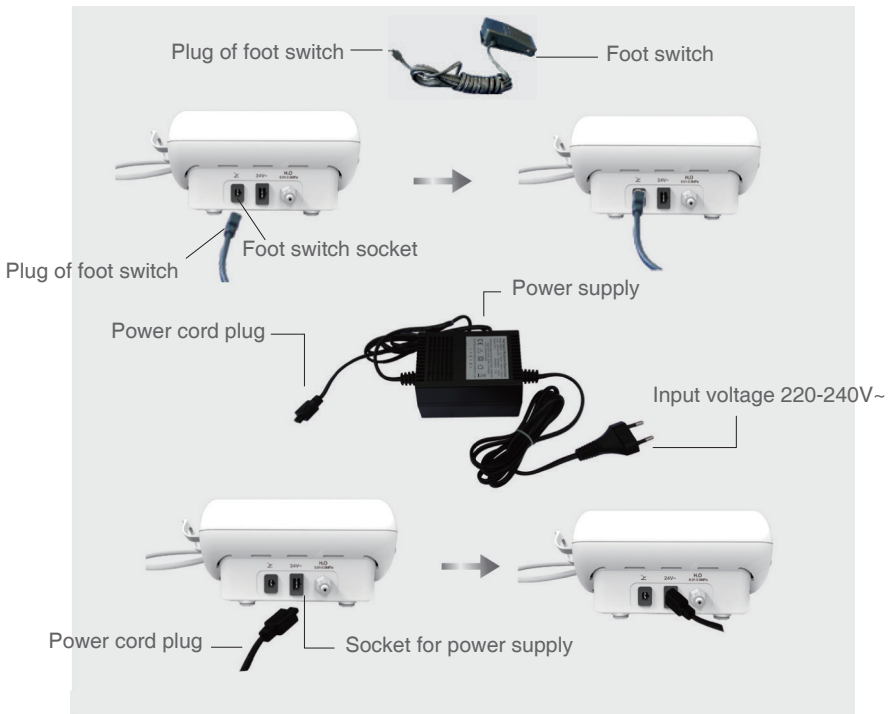


picture 1 (a)



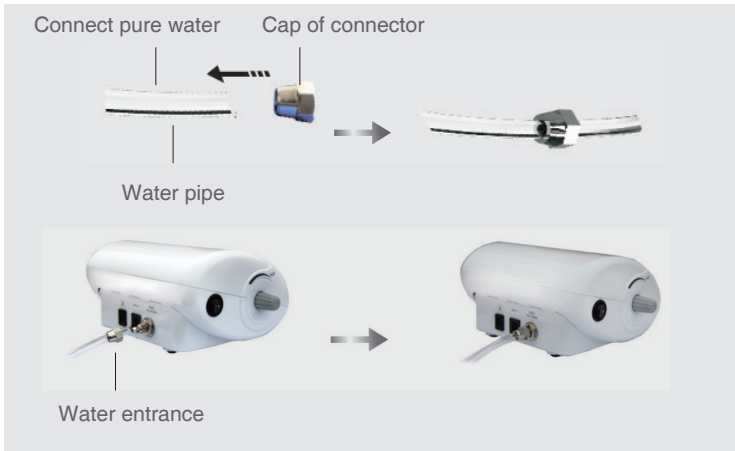
picture 1 (b)

b) Sketch map for connection of foot switch, power supply and main unit are showed in picture 2



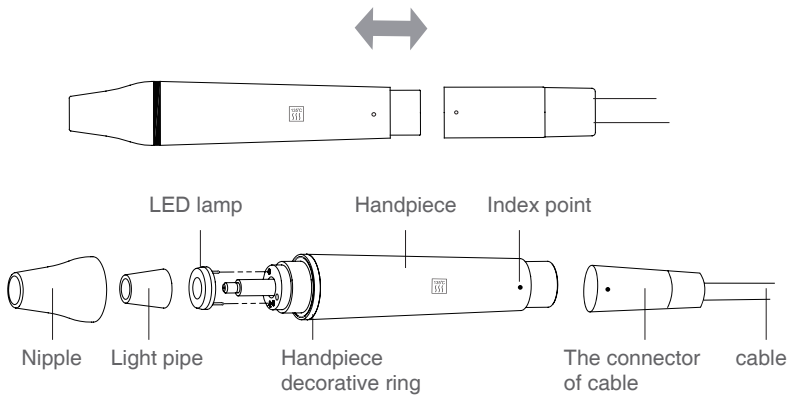
picture 2

c) Sketch map for connection of water supply system are showed in picture 3



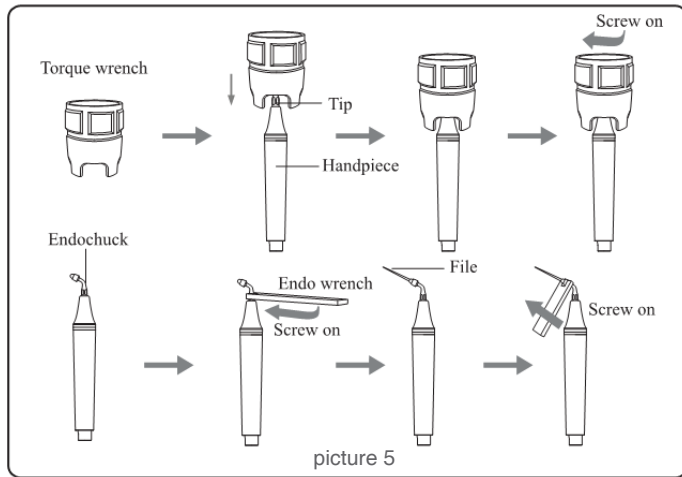
picture 3

d) Sketch map for connection of detachable handpiece are showed in picture 4



picture 4

e) Sketch map for how to install tip and endpckchuck with wrench are showed in picture 5



2. Product function and operation

2.1 Scaling function

2.1.1 Operation

- Open the packaging box, make sure that all the parts and accessories are completed according to the packing list. Take the main unit out of the box and put it on a stable place.
- Turn the water control knob to the maximum based on symbols as shown in 3.5.2[*note 1*]
- Insert the plug of the foot switch to its socket (See picture 2).
- Connect one end of the water pipe to the water entrance , and the other end to the purified water source (See picture 3)
- Screw the scaling tip tightly to the handpiece by torque wrench, then connect the handpiece and the connector of cable correctly.
- Insert the plug of the power source to its socket, then get through to the power (See picture 2)
- Switch on the main unit , then the scaling indicator and the leading five lights of power regulator shine.
- Step on the foot switch, the tip begins to vibrate, and the LED lamp on the top of the handpiece shines. Release the foot switch, the LED lamp keep shining for 10 seconds.
- Select a suitable scaling tip as you need, screw it on the handpiece tightly by the torque wrench (See picture 5)
- The normal frequency is extremely high. Under the normal working state of scaling tips, a light touch and a certain to-and-fro motion will eliminate the tartar without heating. Overexertion and long-time lingering are forbidden.
- Vibrating intensity: Adjust the vibration intensity as you need, generally turn the knob to the middle grade. According to patient's different sensitivity and the rigidity of the gingival tartar, adjust the vibration intensity during the clinical treatment.

- Water volume adjust: Step on the foot switch, and the tip will begin to vibrate, then turn the water control switch to form fine spray to cool down the handpiece and clean the teeth.
- The handpiece can be handled in the same gesture as a pen in hand.
- During the clinical treatment, be sure not to make the end of tip touch the teeth vertically and not to make the tip overexert on the surface of the teeth in case of hurting the teeth and damaging the tip
- After finishing operation, keep the machine working for 30 seconds on the water supply condition in order to clean the handpiece and the scaling tip.
- Unscrew the scaling tip and pull out handpiece, then sterilize them.

Notice

Don't pull the handpiece out when the foot switch is stepped on and the ultrasonic vibration is produced from the machine.

2.1.2 Instruction for main components of detachable handpiece (See picture 4):

- Nipple: The nipple can be removed. You can screw out the nipple and clean the pole with alcohol termly.
- Handpiece seal: The seal can't be removed.
- Handpiece: The main part of the whole handpiece, can be autoclaved under the high temperature and pressure.
- The connector of the cable: Connect the handpiece with the water source and power supply of the main unit.
- LED lamp, Light pipe: Clean them with purified water and sterilize them under the high temperature of 135 °C and high pressure of 0.22Mpa.

Notice

Keep dry when the detachable handpiece connects to the connector of the cable.

2.1.3 Instruction of torque wrench (See picture 5)

- The torque wrench's structure is designed in special way which can control the strength of the scaling tip's installation properly and correctly. It also can guarantee the operator screw or unscrew the scaling tip effectively and keep their hands away from being scratched.
- Operation
 - a. Take the scaling tip into the torque wrench as showed in picture 5.
 - b. Tip installation: Hold the handpiece, turn the tip toward direction as showed in figure 7 with the torque wrench. Turn twice more circles when the tip stops, then the tip will be installed.
 - c. Tip's uninstillation: Hold the handpiece, turn the wrench in anti-clockwise direction direction.
 - d. Serilize it in sterilizer after each treatment.
 - e. The torque wrench must be cooled down naturally after sterilization to avoid scald when using for the next time.
 - f. Keep the torque wrench in a cool, dry and ventilated place and keep it clean.

Notice

We are not responsible for any damage of the torque wrench directly or indirectly made by any way in the above items.

2.2 Endo function

2.2.1. Usage process

- Fix endochuck to handpiece by endo wrench.
- Unscrew the screw cap on the endochuck.
- Put the ultrasonic file into the hole in the front of endochuck.
- Screw down the screw cap with endo wrench to tight up the ultrasonic file.
- Press option key, turn to endo function.
- When ultrasonic scaler turns into endo function, only the first lead light will be on and the power will be at the 1st grade. Put the ultrasonic file into the patient's root canal slowly, step on the foot switch, during the treatment, turn up the power gradually according to the needs.

2.2.2 Notice

- When fixing endochuck, it must be screwed down.
- The screw cap on the endochuck must be screwed down.
- Don't press it too much when the ultrasonic file is in root canal.
- Don's step on the foot switch until the ultrasonic file is in root canal.
- The power ranged from the 1st to the 5th grades.

3. Sterilization and maintenance

3.1 Sterilization of detachable handpiece

3.1.1 Autoclaved in high temperature/pressure:

- 121°C/1bar (0.1 Mpa)
- 135°C/2.2 bar (0.22Mpa)
- Pull out the handpiece and unscrew scaling tip and endochuck after each operation.
- Pack the handpiece with sterile gauze or sterile bag before sterilizing.
- Reuse handpiece after it cools naturally in case of scalding hand.

3.1.2 Notice

- Dry the cleaning liquid in the handpiece with compressed air before sterilization.
- Ensure that the scaling tip has been unscrewed from the handpiece and it could not be sterilized with others.
- Please notice whether the outer part of the handpiece is damaged during the treatment or sterilization, don't smear any protective oil on the surface of handpiece.
- There are two waterproof "o" rings at the end of handpiece. Please lubricate them with dental lube frequently, as sterilization and repeated pulling and inserting will reduce their life. Change a new one once it is damaged or worn excessively.

- The following sterilizing methods are forbidden:
 - a. Putting handpiece into any liquid for boiling.
 - b. Dipping handpiece in disinfectors such as iodine, alcohol and glutaraldehyde.
 - c. Sterilizing handpiece into oven or microwave oven for baking.

3.2 Sterilization of scaling tips and endochuck.

All the scaling tips and endochuck can be autoclaved to 135°C.

3.3 Sterilization of torque wrench and edo wrench

- The torque wrench and endo wrench can be sterilized in high temperature and pressure.
- The following sterilization ways for torque wrench are forbidden:
 - a. Baise in liquor.
 - b. Dipping in iodine, alcohol or glutaraldehyde.
 - c. Sterilizing in oven or microwave oven.

Notice

We are not responsible for any damage of the torque wrench directly or indirectly made by any ways which indicated in above items.

3.4 Cleaning of tips, endochuck, torque wrench and endo wrench

The scaling tip, endochuck, torque wrench and endo wrench can be cleaned by ultrasonic cleaner.

3.5 Sterilization and cleaning of LED lamp and Light pipe

Clean the LED lamp and Light pipe with purified water and sterilize them under high temperature and high pressure after every operation.

3.6 Troubleshooting and notes

3.6.1 Troubleshooting

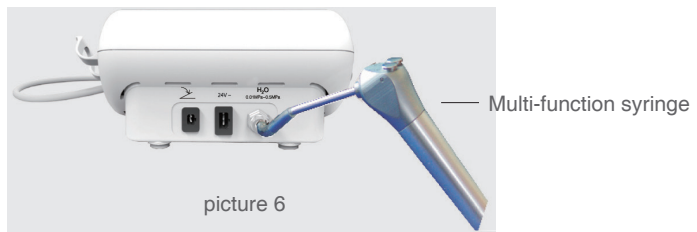
Fault	Possible cause	Solutions
The scanning tip doesn't vibrate and there is no water flowing out when stepping on the foot switch	The power pipe plug is in loosen contact	Make the plug insert to the socket well
	The foot switch is in loosen contact	Insert the foot switch to its socket tightly
	The fuse in the main unit is broken	Contact our dealers or us
The scaling tip doesn't vibrate but there is water flowing out when stepping on the foot switch	The tip is in loosen contact	Screw the tip on the handpiece tightly (see picture 5)
	The connect plug between the handpiece with the circuit board is in loose contact.	Contact our dealers or us
	Something wrong with the handpiece	Send the handpiece to our company to repair
	Something wrong with the cable	Contact our dealer or us
The scaling tip vibrates but there is no spray when stepping on the foot switch	The water control switch is not on	Turn on the water control switch [note 1]
	There is impurity in the electric-magnetic valve	Contact our dealers or us
	The water system is blocked	Clean the water pipe by multi-function syringe[note 2]

There is still water flowing out after the power is off	There is impurity in the electric-magnetic valve	Contact our dealers or us
The handpiece generates heat	The water control switch is in a low setting	Turn the water control switch to a higher grade[note2]
The amount of spouting water is too little	The water pressure is not high enough	Make the water pressure higher
	The water pipe is blocked	Clean the water pipe by multi-function syringe[note2]
The vibration of tip becomes weak	The tip hasn't been screwed on to the handpiece tightly	Screw the tip on the handpiece tightly (see picture 5)
	The tip is loosen because of vibration	Screw on the tip tightly (see picture 5)
	The coupling between the handpiece and the cable isn't dry	Dry it by the hot air
	The tip is damaged[note 3]	Change to a new tip
There is water seeping from the coupling between the handpiece and the cable	The waterproof "O" ring is damaged	Change to a new "O" ring
The ultrasonic doesn't vibrate	The screw is loosen	Tighten it
	Endochuck is damaged	Change to a new endochuck
LED light doesn't work	Poor contact	Contact tightly
	Something wrong with LED light	Change a new one
	LED lamp installed backwards	Please install the "+" of the LED lamp to the "+" of the handpiece
There is noise coming from the endochuck	The screw cap is loosen	Tighten it

If the problem still can't be solved, please contact with local dealer or manufacturer.

3.6.2 Notes

- [Note 1] Turn the water control switch can adjust the water volume according to the symbol.
- [Note 2] Clean the water pipe with the Multi-function syringe of the dental unit (see picture 6)



- Cut the water pipe from a distance of 10cm to 20cm from the water entrance.
- Turn on the electricity and get through to the power.
- Connect the multi-function syringe of dental unit to the water pipe.
- Disassemble the tip or handpiece
- Step on the foot switch.
- Turn on the switch of the multi-function syringe, press the water into the machine and the impurity blocked in the water pipe can be eliminated.

- [Note 3] If the scaling tip has been screwed on tightly and there is fine spray too, the following phenomena show that the scaling tip is damaged:
 - a. The vibrating intensity and the water atomization degree become weak obviously.
 - b. During treatment, it produces the sound like "buzz" from the scaling tip.

4. Precaution

4.1 Notice when using equipments

- 4.1.1 Keep the scaler clean before and after operation.
- 4.1.2 The handpiece, scaling tip, torque wrench, endo wrench and endochuck must be sterilized before each treatment.
- 4.1.3 Don't screw or unscrew the scaling tip and endochuck when stepping on the foot switch.
- 4.1.4 The scaling tip must be fastened and there must be fine spray or dripped from the tip when operating.
- 4.1.5 Change to a new one when the tip and ultrasonic file are damaged or worn excessively.
- 4.1.6 While scaler working, the heat of scaling tip will become higher if there is no water flowing out. Please keep the water flow smoothly.
- 4.1.7 Don't twist the tip and endo chuck or rub them.
- 4.1.8 Don't use impure water source and be sure not use normal brine instead of pure water source.
- 4.1.9 If using the water source without hydraulic pressure, the water surface should be one meter higher than the head of patient.
- 4.1.10 Ensure the connector of handpiece and the socket of the cable are dry before installing the handpiece.
- 4.1.11 Don't pull the cable forcibly in case of the handpiece falling off the cable.
- 4.1.12 Don't knock or rub the handpiece.
- 4.1.13 Please put the power plug into the socket easy to pull out, to make sure it can be pull out in emergency.
- 4.1.14 The device can only be equipped with the special power supply of original manufacturer.
- 4.1.15 The power supply is NOT waterproof. Please keep it dry and away from the water.
- 4.1.16 After operating, turn off the power, then pull out the plug.
- 4.1.17 We are only responsible for the safety on the following conditions:
 - The maintenance, repairment and modification are made by the manufacturer or the the authorized dealer.
 - The changed components are originated of "BEYES" and are operated according to instruction manual.
- 4.1.18 The internal screw thread of the scaling tips produced by some manufactures is coarse, rusty and collapsed. This will damage the external screw thread of the handpiece irretrievably. Please use "BEYES" brand scaling tips.

4.2 Contraindication

- 4.2.1 The hemophilia disease patient is not allowed to use this equipment.
- 4.2.2 The patients or doctors with heart pacemaker are forbidden to use this equipment.
- 4.2.3 The patient with heart disease, pregnant women and children should be cautious with using the equipment.

4.3 Storage and maintenance

4.3.1 The equipment should be handled carefully and lightly. Be sure that it is far from the vibration, and install or keep in a cool, dry and ventilated place.

4.3.2 Don't store the machine together with the articles that are combustible, poisonous, caustic, and explosive.

4.3.3 This equipment should be stored in a room where the relative humidity is $\leq 80\%$, atmospheric pressure is 50kPa to 106kPa, and the temperature is -10°C to $+50^{\circ}\text{C}$.

4.3.4 If it has not been used a long time, please ensure the machine gets through to the power and water once per month for five minutes.

4.4 Transportation

4.4.1 Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and don't invert it.

4.4.2 Don't put it together with dangerous goods during transportation.

4.4.3 Avoid solarization and getting wet in rain and snow during transportation.

4.5 Working condition

- Environment temperature: 5°C to 40°C
- Relative humidity: $\leq 80\%$
- Atmosphere pressure: 70kPa to 106kPa

5. After service

We offer one year's free repair to the equipment according to the warranty card. The repair of the equipment should be carried out by our professional technicians. We are not responsible for any

6. Symbol instruction



Consult the accompanying documents



Type BF applied part



Socket for the foot switch



Atmospheric pressure for storage



Date of manufacture



Used indoor only

~24V

24VAC power supply socket



Appliance compliance WEEE directive



Water entrance pressure 0.01MPa to 0.5MPa



Class II equipment



Alternating current



Adjustment for the water flow



Humidity Limitation



Manufacturer



Can be autoclaved

IPX1

Anti-drip device



Temperature

7. Environmental Protection

There is no harmful factor in our product. You can deal with it based on the local law.

8. Manufacturer's rights

We reserve the rights to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

9. Beyes Limited Warranty Statement

9.1 SCOPE OF WARRANTY

BEYES Dental Canada Inc. ('BEYES') warrants to the original retail purchaser that it will be at BEYES option to repair or replace components of the dental products manufactured by BEYES (except for components not warranted under 'Exclusions') that are defective in material or workmanship under normal use and service. BEYES' obligation under this limited warranty is limited to the repair or replacement of the applicable components.

This limited warranty shall only apply to defects that are reported to BEYES within the applicable warranty period and which, upon examination by Beyes, prove to be defective. This warranty extends only to the first retail purchaser of a product and is not transferable or assignable. Replacement components or products may be used and/or refurbished components or products, provided they are of like quality and specifications as new components or products.

9.2 APPLICABLE WARRANTY PERIOD

The applicable warranty period, measured from the date of invoice to the original user, shall be warranted for a period of 12 months

9.3 EXCLUSIONS

This limited warranty does not cover and BEYES shall not be liable for the following;

- (1) Defects, damage or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, negligent storage, tampering or failure to seek and obtain repair or replacement in a timely manner;
- (2) Products which are not installed, used, and properly cleaned and maintained as required or recommended in the BEYES 'Installation' and/or 'Installation/User's Manual' for the applicable product, including the specified structural and operational environment conditions and electrical power requirements;
- (3) Products considered to be of a consumable or sterile nature;
- (4) Accessories or parts not manufactured by BEYES;

- (5) Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing in advance by BEYES;
- (6) Costs and expenses of routine maintenance and cleaning;
- (7) Representations and warranties made by any person or entity other than BEYES;
- (8) Matching of color, grain or texture except to commercially acceptable standards;
- (9) Changes in color caused by natural or artificial light;
- (10) Custom manufactured products;
- (11) Alterations or modifications to the product by any person or entity other than BEYES;
- (12) Products that would otherwise be covered under Sections 1 and 2 of this limited warranty, but are acquired: (i) from a person or entity that is not BEYES or one of its authorized dealers; or (ii) from a BEYES dealer that is not authorized to sell the product at issue in the geographic territory where the purchaser is located, or is not authorized to sell the product at issue within the medical, animal health or dental market, as the case may be, in which purchaser intends to use the product.

9.4 EXCLUSIVE REMEDY; CONSEQUENTIAL DAMAGES DISCLAIMER

BEYES' OBLIGATION UNDER THIS LIMITED WARRANTY IS THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS. BEYES SHALL NOT BE LIABLE FOR AND HEREBY DISCLAIMS ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OR DELAYS, INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS OR INCOME, LOSS OF USE, DOWNTIME, COVER AND EMPLOYEE OR INDEPENDENT CONTRACTOR WAGES, PAYMENTS AND BENEFITS.

9.5 WARRANTY DISCLAIMER

THIS LIMITED WARRANTY IS BEYES ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. BEYES MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS.

Beyes[®]

The Next Standard



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 states in which he or she practices to use or order the use of this device.

Beyes Dental Canada Inc.

23-595 Middlefield Road
Toronto, Ontario, M1V 3S2
Canada

Tel: 1-855-603-1888

Fax: 1-855-720-1228

Email: info@beyes.ca

Website: www.beyes.ca



MEDevice Union Ltd.

26 York Street
London, W1U 6PZ
United Kingdom

Tel: 44-20-3514-0949

Email: info@beyes.ca

Website: www.beyes.ca



Printed in Canada
ENI014R1