

Dental Implant Motor (Elite)

USER MANUAL

File No.: WDL/CE-01-B6-IFU, A/0

MODEL: V-IM-1



CE: The EU directive 93/42/EEC was applied in the design and production of this medical device.

Thank you for purchasing the Dental Implant Motor (Elite).

◆ Classification of equipment

- Type of protection against electric shock:
 - Class II equipment
- Degree of protection against electric shock:
 - Type B applied part
- Degree of protection against ingress of water as detailed in the current edition of IEC60529:
 - Foot Control: IPX7 (Protected against the effects of continuous immersion in water)
 - Main Unit: IP21

IMPORTANT



For correct operation please read this manual before use.

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Cautions for handling and operation

- Read these safety cautions thoroughly before use and operate the product properly.
- These indicators are to allow you to use the product safely and prevent danger and harm to you and others. These are classified by degree of danger, damage and seriousness. All indicators concern safety, be sure to follow them.

CLASSIFICATION	Degree of Danger or Danger and Seriousness
 WARNING	Explains an instruction where personal injury or physical damage may occur
 CAUTION	Explains an instruction where minor to medium injury or physical damage may occur

1.Safety Precautions

WARNING

- The system may present a possibility of malfunction when used in the presence of electromagnetic interference wave. Do not install the system in the vicinity of the device which emits magnetic waves. Turn off the power switch of the Control Unit of this system when an ultrasonic oscillation device or an electrode knife located in the vicinity is used.
- No modification of this equipment is allowed.
- Do not modify this equipment without authorization of the manufacturer.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- EQUIPMENT is supplied with a POWER SUPPLY CORD having three conductors, the third conductor is only a functional earth.

CAUTION

- It is intended for use in dental, oral surgical procedures, should not be used for other purposes.
- For people: adults aged 18-70 years old.
- User: dental implant motor should be operated by an implantology dentist who has been specially trained to do it.
- Patient safety is a priority.
- Read this User Manual before use, and fully understand the functions of each part for starting use.
- Inspect the operation status of the equipment before use, and use only after confirming that no abnormalities exist.
- Test run the product to ensure its correct operation prior to using it.
- If the product should ever malfunction (excessive vibration, noise, heat, etc) please turn it off immediately.
- When the product is very frequently used, please consider the maintenance of a small stock of replaceable parts.
- We recommended to prepare spares for consumable parts.
- Use an electrical outlet that is grounded.
- To avoid possible injury or product damage, ensure that the Motor has completely stopped before changing burs.
- Severe shock-Eg. Dropping the product may cause damage.
- Do not bend the Irrigation Tube while the water pump is operating. It could cause tube breakage.
- Never attempt to disassemble the Control Unit, the Foot Control or the Motor.
- Do not lubricate the Motor. Oil could generate excessive heat and cause damage.
- The equipment cannot work for a long time, which will cause the motor temperature to be too high and the continuous work will not exceed 30s.
- The Control Unit and the Foot Control cannot be sterilized by any method.
- The Control Unit may be cleaned with a moist cloth. Disconnect the power supply before cleaning.
- Do not clean the Control Unit with any solvent solutions.
- The system functions normally in the environment where the temperature is at 0-40°C (32-104°F) , humidity at 10-75%RH, atmospheric pressure at 700-1060hPa, and no moisture condensation in the Control Unit. Use at outside of these limits may cause malfunction.
- This equipment should not be used in the presence of flammable anesthetic gas mixed with air or with

oxygen or nitrous oxide.

- The disposal method of the equipment and the disposable irrigation tube must comply with the regulations of the local government, otherwise it will cause the confusion of environmental sanitation.
- An effective coolant supply is required when the equipment is in use because the drill may burn the bone at a high speed.

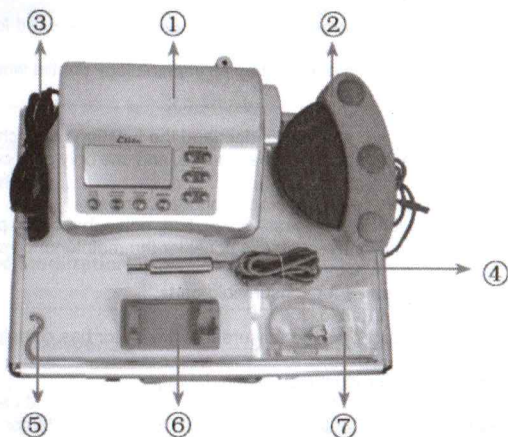
2. Contraindications

- 2.1 Systemic diseases (cancer, cardiovascular diseases serious diseases, the blood system, the immune system disease...);
- 2.2 Ongoing and topical treatment of certain systems (anticoagulant therapy, chemotherapy, radiotherapy...);
- 2.3 Poor quantity or quality of bone;
- 2.4 Doctors and patients with cardiac pacemakers shall not use them.

3. Package Contents

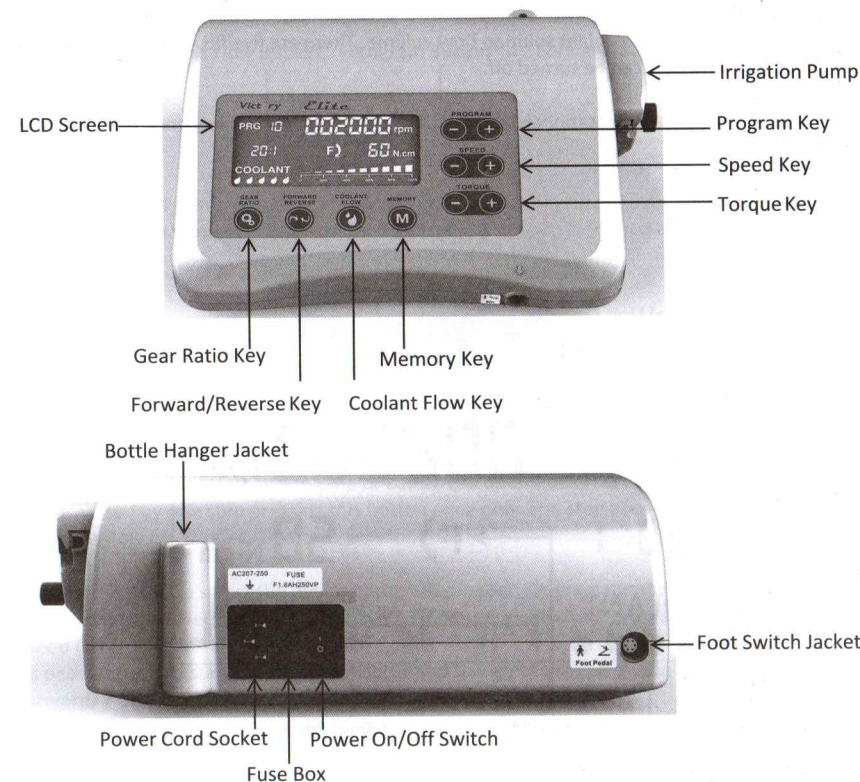
⚠ CAUTION:

- The handpiece is not included in the product configuration and customers need to buy it from other manufacturers.
- Foot Control and Motor Handle with Cable are the applied parts.



Item No.	Description	Item No. Quantity
①	Control Unit	1pc
②	Foot Control	1pc
③	Power Cord	1pc
④	Motor Handle with Cable	1pc

⑤	Bottle Hanger Post	1pc
⑥	Silicon Rubber Stand	1pc
⑦	Irrigation Tube	10packs



4. Control Unit and Foot Control

4.1 Keys on the Control Unit

(1) Program Key (- +)

This key is used to select any one of 10 available programs. Press [+] to ascend program numbers and [-] to descend the numbers. By pressing either [+] or [-] the numbers rotate continuously through all available programs.

(2) Speed Key (- +)

This key is used to set the Motor speed. Press [+] to increase speed by one step and [-] to decrease speed by one step.

(3) Torque Key (- +)

This key is used to set the torque. Press [+] to increase torque by one step and [-] to decrease torque

by one step. The range of torque setting steps vary according to the gear ratio selected to match the handpiece attachment in use.

(4) Gear Ratio Key

This key is to select match ratio of the handpiece attachment, before use, to the unit. Press this key until the LCD display exhibits the correct gear ratio of the handpiece attachment.

(5) Coolant Flow Key

This key is used to select the coolant solution flow volume. There are five flow volume rates available for selection, plus the flow can be turned off.

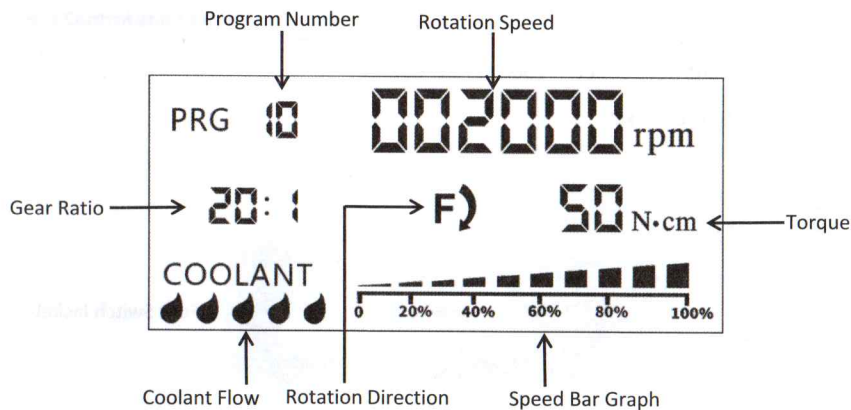
(6) Forward / Reverse Key

This key is used to change the rotational direction of the Motor. Press this key once to change the rotational direction.

(7) Memory Key

This key is used to memorize the program parameters set by the operator. Press this key for approx. three times to memorizes parameters. An audible beep confirms that new program parameters have been memorized.

4.2 LCD Display on the Control Unit Console



(A) Coolant Flow

Display the selected coolant solution flow volume level. The selected flow volume level is indicated by one of 5 levels of illuminated indicators. No light indicates the coolant solution flow is off.

(B) Program Number

Display the selected program number.

(C) Gear Ratio

Display the gear ratio of the handpiece.

(D) Forward / Reverse indicator

Display the rotational direction of the Motor.

(E) Speed / Torque

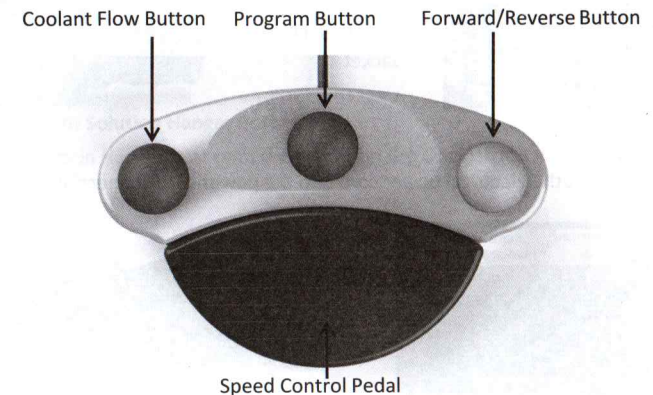
Display the selected speed and torque. Normal speed is shown when the unit is switched on and also when a program is changed. To display speed, press the [Speed] key on the Control Unit. To display torque, press the [Torque].

* When using the 1:1 direct drive or Speed Increasing Handpiece, the torque is not displayed.

(F) Speed / Torque Bar Graph

During operation displays an approximate percentage indication of the actual operation speed or torque relevant to the preset maximum speed or torque. When all bars illuminate, the operating speed or torque is at maximum. When bars are half illuminated then the operating speed is approximately 50% of the preset speed.

4.3 Foot Control



(a) Coolant Solution Flow Volume Button

This button is used to select the volume of coolant solution flow. Five levels are available and each level may be increased by one step pressing this button once only. The step above level five and below level one turns the flow off.

(b) Program Button

This button is used to select the desired program number. Program numbers will always ascend each time this button is pushed and will roll from No.10 program onto No.1 program.

(c) Speed Control Pedal

This pedal is used to start and stop the Motor and to vary the speed during operation.

(d) Forward/ Reverse Button

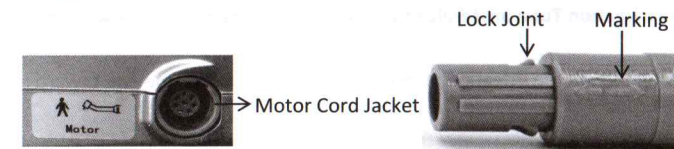
This button is used to change the rotational direction of the Motor. Push once to change the rotational direction.

5. Installation

CAUTION: Install the cord/plug only power is OFF.

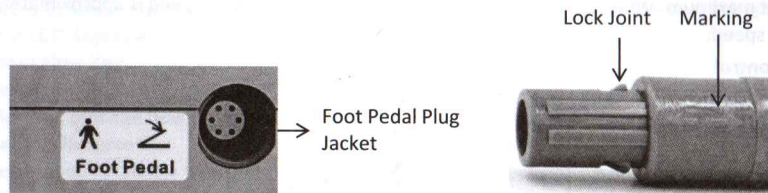
5.1 Connecting the Motor Cord

Face the [▲] mark on the Motor Cord plug upward then insert the plug into the Motor Cord Jacket on the Control Unit. A click is heard when the motor cord plug is correctly inserted into the control unit. To disconnect the plug, pull back the lock joint, then disconnect the cord.



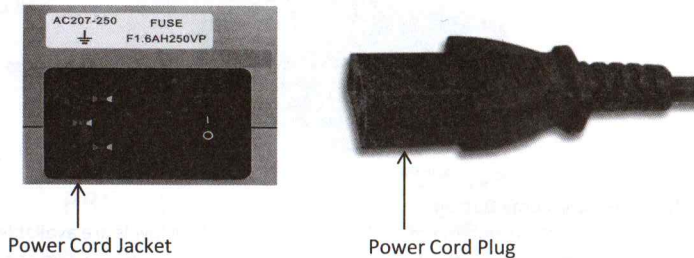
5.2 Connecting the Foot Control

Face the mark on the Foot Pedal control cord plug downward then insert the plug into the Foot Control Cord Jacket on the control unit. Secure the plug by fastening the lock nut.



5.3 Connecting the AC Power Cord

Align correctly then insert the electrical power cord into the power cord connection at the back of the control unit.

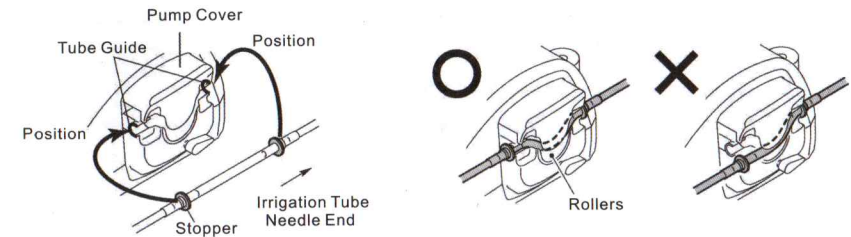


5.4 Installing of the Irrigation Tube

⚠ CAUTION:

- Make sure that the tube is securely set on the rollers when closing the pump cover.
- If the tube is not correctly positioned on the rollers or the cover is closed, the tube could be cut or sheared.
- Only after the tubes are correctly positioned, close the pump cover lever 18 degrees to the left.
- Suggestions for the use of Irrigation Tube:
- Irrigation Tube: It is composed of medical polymer material, which consists of a cork puncture device, a dropper, a liquid channel, a funnel, a switch and a silicone peristaltic tube etc. It is used to provide water coolant when doing the dental implanting operation.
- Requirements:
- Length of Irrigation Tube: $\geq 2\text{m}$, Diameter of the Channel: $> 3\text{mm}$, Peristaltic tube should be made of silica gel tube with diameter of 6mm, wall thickness of 0.5mm, length of 12mm and inner diameter of the handpiece connecting tube of 1mm. The product should be sterilized by ethylene oxide and packed separately.
- The use of an Irrigation Tube unsterilized with ethylene oxide may cause worsening of symptoms.

Mount the irrigation tube in the irrigation pump, with the irrigation tube needle toward backside of the unit Position the stoppers of the tube in the guide securely.



5.5 Mounting the Coolant Solution Hanger Post

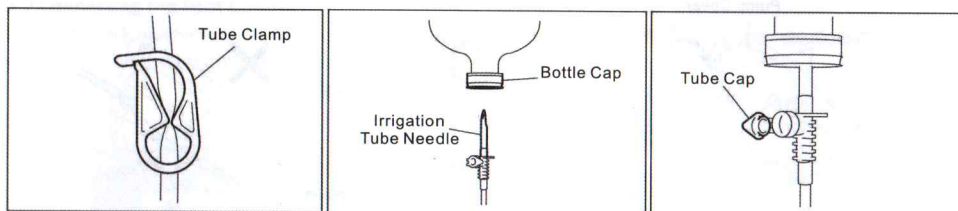
Mount the Coolant Solution Hanger Post onto the holder on the Control Unit. Place the bottle as shown in the picture.



5.6 Insertion of the Irrigation Tube

⚠ CAUTION: Do not operate the irrigation pump if the tube is bent or the Tube Clamp is in the closed position. This could cause the tube to burst or slip out of the bottle.

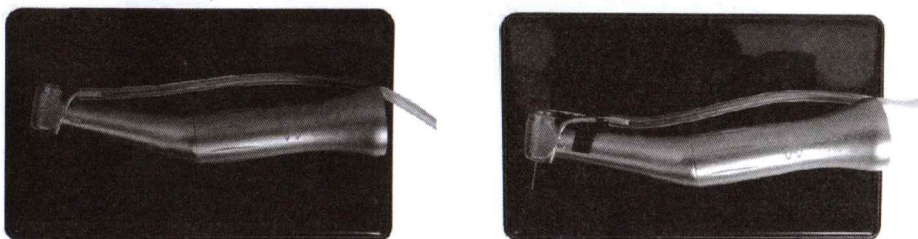
- 1) Close the tube clamp, between the irrigation tube needle and the irrigation pump.
- 2) Insert the irrigation tube needle into the bottle cap.
- 3) Open the tube cap to supply air into the bottle.
- 4) Open the tube clamp also.



5.7 Installation of the Nozzle Needle

⚠ CAUTION: The handpiece is not included in the product configuration and customers need to buy it from other manufacturers. The handpiece in the picture below is 20:1 handpiece, just for example reference.

Water can be connected both to the external coolant pinhole and the internal coolant pinhole .



6. Operation

6.1 Motor Operation:

⚠ CAUTION: Repeat the above steps 1) – 7), there are 10 available programs can be compiled.

Control panel can store 10 programs. Each program contains the functions as below. Select the appropriate program number, these functions can run automatically.

Handpiece Gear Ratio→Rotation Speed→Rotation Direction→Torque Limit→Coolant Flow

- 1) Push the main power switch to [I].
The program number will always display what the operator chose last time on this machine; Push the main power switch to [O]. The device will shut down.
- 2) Select program number through the process of a) or b):
 - a) Press the [Program + -] key on the control panel until it displays the program number needed, or;
 - b) Push the [Program] button on the foot control until it displays the program number needed.
- 3) Select the handpiece gear ratio related to the program. Press the [Gear Ratio] key to display the gear

Power On/Off Switch Mark	○	I
Function	OFF	ON

ratio needed;

- 4) Speed setting. Press the [Speed + -] key until it displays the program number needed;
 - Each time you press this key, it will display the next speed level. Press and hold this key more than one second, the speed will rapidly transfer to the next level, until it reaches the maximum or minimum speed;
 - When the speed reaches the maximum or the minimum level, beep sound will appear. In this case, the speed will not change anymore;
- 5) Torque Limit Setting. Press the [Torque + -] key until it displays the torque value needed;
 - Each time you press this key, it will display the next torque level. Press and hold this key more than one second, the torque will rapidly transfer to the next level, until it reaches the maximum or minimum torque.
 - When the torque reaches the maximum or the minimum level, beep sound will appear. In this case, the torque will not change anymore.
- 6) Coolant Flow Setting. Press the [Coolant Flow] key to set the coolant flow;
 - There five grades for the coolant flow and one "no coolant flow".
- 7) Memory Function Setting. After completing steps 1)--6), press the [Memory] key more than one second until you hear the beep sound, beep indicates that the program set up is completed.

6.2 Standard Operation:

All standard operation can be completed by foot control.

- 6.2.1 Turn on the main switch. Control panel is ready to execute the program 1 stored in the programs.
- 6.2.2 Select the desired program number. Push the PROG button by foot, program numbers will always ascend to the next. Selected program number displays on the LCD screen and it will roll from No.10 program onto No.1 program.
- 6.2.3 Verification program details. Verify the details of displayed programs. Maximum number displayed shows the set up of the speed.
- 6.2.4 Run the micro-motor. Step on the central part of the speed pedal of the foot control, the micro-motor starts running. If the coolant flow is also incorporated into the program, the cooling pump will run automatically. The pedal is stepped more heavily, the speed will be faster. When the pedal is stepped on the bottom, speed reaches the set maximum value.
- 6.2.5 Torque limit. In the running of the micro-motor, if the load on moving of the drilling reaches the maximum torque, then the micro-motor will stop working automatically. Re-push the foot pedal to let the motor start working again.
- 6.2.6 Stop the micro-motor. Release the foot control, micro-motor will stop automatically.
- 6.2.7 Change the rotation direction of the motor. Change the rotation direction of the micro-motor (and the drill), just push the Forward/ Reverse button. When the rotation direction is under reverse mode, warning beep sound can be heard.

6.3 Power Off

In the use of ME equipment, if there is a fault or emergency, please immediately turn off the power switch (Push the main power switch to [O]), and unplug the power plug. Therefore, the equipment should be located where the power supply can be easily turned off and disconnected.

7. Protection Circuit

When the micro-motor overloaded works, the circuit will run automatically to protect the micro-motor. Power supply for the micro-motor will be cut off automatically.

8. Error Code& Troubleshooting

⚠ CAUTION: If maintenance is needed, it must be done by a professional, please do not replace the parts by different specifications. If you need to replace, please contact the dealer or our company, we will provide circuit diagrams, parts list, qualified parts and assist maintenance personnel in repairing them. If the unqualified parts are replaced by yourselves, the equipment will not be able to be used normally or cause serious damage to the equipment, and all the consequences will be borne by the individual, our company will not be responsible.

If the device is not working properly, please check in accordance with the table before contacting with your dealer.

Phenomenon	Reason Analysis	Problem Shooting
Cannot power on?	Power cord is not well plugged in.	Re-plug the power cord.
	Fuse burned out.	Replace it by the spare fuse.
	Power Cord is broken.	Replace the Power Cord.
	Main PCB board of the Control Unit is broken.	Contact your dealer.
Micro-motor vibration?	Motor Handle Cable is not connected to the Control Unit.	Re-connect the Motor Handle Cable.
	Micro-motor is broken.	Replace the micro-motor.
Excessive heat from the motor handle?	Micro-motor is broken.	Replace the micro-motor.
	Main PCB board of the Control Unit is broken.	Contact your dealer.
Micro-motor doesn't run?	Micro-motor is broken.	Replace the micro-motor.
	Main PCB board of the Control Unit is broken.	Contact your dealer.
	Foot Control is not well connected to the Control Unit.	Re-connect the Foot Control.
	Foot Control is broken.	Replace the Foot Control.
Fuse burned out repeatedly?	Main PCB board of the Control Unit is broken.	Contact your dealer.

9. Fuse Replacement

9.1 If the Control Unit does not function, check the fuses (Fuse Box lock located on the rear of the Control Unit). To access the Fuse, use a pointed tool push on the fuse locking latch and the drawer will spring open.

9.2 During the inspection or replacement of the fuse, please cut off the power to avoid electric shock. The fuse should be qualified and meet the requirements. The wrong fuse will cause damage to the equipment.

9.3 Inspection and replacement of fuses must be performed by a professional.

The device has two fuses, one beside the power switch, the other inside the machine, two fuse type consistent, fuse type for $\phi 5*20\text{mm}$ F1.6AH250VP.

Fuse Ratings	
$\phi 5*20\text{mm}$	F1.6AH250VP

10. Cleaning, Disinfection and Sterilization

⚠ CAUTION: The handpiece is not included in the product configuration and customers need to buy it from other manufacturers. The sterilization method mentioned below is suggested for the handpiece. Please refer to the sterilization method provided by the manufacturer of the purchased handpiece for the specific sterilization method. The user should sterilize the handpiece, cleaning and disinfecting the motor handle before the first use and after use of the device.

10.1 Cleaning and Disinfection of the Control Unit and Foot Control:

If blood or saline solution has stained the Control Unit or Foot Control, remove the AC Electrical Cord, wipe Control Unit or Foot Control with a damp cloth, then with an alcohol-absorbed cloth.

10.2 Cleaning of the Motor Handle

The dentist should clean and disinfect the motor handle with medical alcohol before and after use.

10.3 Sterilization:

The handpiece can be autoclavable up to Max.135°C.

Autoclave sterilization is required for the first time use and after each patient as noted below.

Remove blood and debris from the handpiece;

Clean inside the handpiece by using the spray lubricant;

Place those in autoclave pouch and seal it.

Autoclavable up to max. 135°C. (autoclave for 20 min. at 121°C, or 3 min. at 134°C)

Keep the handpiece in the autoclave pouch to keep it clean until you use it.

11. Specification

11.1 Control Unit with Coolant Pump

Model	V-IM-I
Power Supply Voltage	AC 207-250V
Frequency	50 / 60Hz
Rated Power	60VA
Maximum Output of the Pump	100ml/min.

Dimension	L290mm x D240mm x H114 mm
Weight	2.6Kg

11.2 Micro-motor

Motor Rotation Speed Range	500-40,000min-1(rpm) (under 1:1 gear ratio)
Torque Range	10-60N.cm (under 20:1 gear ratio)
Dimension	ø24 x L116 mm
Weight	240g (include the cable weight)

11.3 Foot Control

Cord Length	2m
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12. Storage, Maintenance and Transportation

12.1 Storage and Maintenance

12.1.1 Do not store with toxic, corrosive, flammable and explosive articles.

12.1.2 The equipment should be carefully placed, away from the source and should be installed or stored in a cool, dry and ventilated place indoors.

12.1.3 Store the equipment in the place where the temperature is at-10-50°C (14-122°F), humidity at 10-85%RH, atmospheric pressure at 500-1060hPa and the equipment is not subject to air with dust, sulfur or salinity.

12.1.4 When the equipment is not in use, turn off the power switch and unplug the power plug. When not in use for a long time, the equipment should be powered up by the equipment manager once a month for five minutes each time.

12.1.5 The service life of this equipment is five years.

12.2 Transportation

12.2.1 During transportation, excessive shock and vibration should be prevented, it should be handled with care.

12.2.2 Transport should not be mixed with dangerous goods.

12.2.3 Avoid sun or rain or snow during transportation.

13. EMC Information

Guidance and manufacturer's declaration - electromagnetic emissions – for all ME EQUIPMENT and ME SYSTEM.

Table 1: Guidance and manufacturer's declaration – electromagnetic emissions


The V-IM-I is intended for use in the electromagnetic environment specified below. The customer or the user of the V-IM-I should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The V-IM-I 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 emissions CISPR 11	Class B	The V-IM-I 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 emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity - for all ME EQUIPMENT and ME SYSTEM.

Table 2: Guidance and manufacturer's declaration – electromagnetic immunity			
The V-IM-I is intended for use in the electromagnetic environment specified below. The customer or the user of the V-IM-I should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance.
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	±2 kV For power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line 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% U_T (>95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycle 70% U_T (30% dip in U_T) For 25 cycle <5% U_T (>95% dip in U_T) For 5 cycle	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycle 70% U_T (30% dip in U_T) For 25 cycle <5% U_T (>95% dip in U_T) For 5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of V-IM-I requires continued operation during power mains interruptions, it is recommended that the V-IM-I be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity for ME EQUIPMENT and ME SYSTEM that are not LIFE-SUPPORTING.

Table 3: Guidance and manufacturer's declaration – electromagnetic immunity			
The V-IM-I is intended for use in the electromagnetic environment specified below. The customer or the user of the V-IM-I 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	3 Vrms 150 kHz to 80MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800MHz to 2.5GHz
Radiated RF IEC 61000-4-3	3 Vrms 80MHz to 2.5GHz	3V/m	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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT and ME SYSTEM – for ME EQUIPMENT and ME SYSTEM that are not LIFE-SUPPORTING.

Recommended separation distances between portable and mobile RF communications equipment and the V-IM-I			
The V-IM-I is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the V-IM-I can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the V-IM-I 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		
	150kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80MHz to 800MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800MHz to 2.5GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

14.Symbols



Manufacturer



Consult Instructions
for Use



AUTHORISED
REPRESENTATIVE
IN THE EUROPEAN
COMMUNITY



Type B Applied Part



Use by

CE 0123

CE Marking in
Accordance with
Medical Device
Directive 93/42/EEC



Date of manufacture



Caution



Foot Pedal



Motor