VRN

DA–1

Endo Ultra Activator

Operation Manual

Contents

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This document is an English translation of the original Chinese version.

Congratulations on your purchase of DA–1 Endo Ultra Activator from URIT Medical Electronic Co., Ltd. .It will bring you a new experience and convenience.

The manual is compiled in accordance with the relevant laws and regulations of China and the specific conditions of the DA–1 manufactured by URIT Medical Electronic Co., Ltd.

The manual includes the latest information as of the time of printing. URIT Medical Electronic Co., Ltd. is solely responsible for the revision and explanation of the simplified Chinese version of the manual, and reserves the right to change the relevant content after the manual is printed without prior notice.The pictures involved in this manual are schematic diagrams and are for reference only. If the pictures do not match the actual product, the actual product shall prevail.

Medical Electronic Co., Ltd., any form of reproduction, photocopying, or translation of any content in the manual is not allowed to be translated into other languages.

The operator must strictly follow this manual to operate. Otherwise, URIT Medical Electronic Co., Ltd. shall not be responsible for any errors and equipment failures caused by illegal operations.

NOTICE：URIT Medical Electronic Co., Ltd. does not promise that the device will be used for a certain special purpose and make any implied guarantee for its marketability and applicability.

If you need after-sales service support, please contact Guilin Veirun Medical Technology Co., Ltd. or an authorized agent.

1. Introduction

1.1. Overview

DA-1 adopts piezoceramic ultrasonic technology，which has the function of root canal washing and has the following characteristics:

- The product produces a cavitation effect through ultrasonic vibration to effectively clean the inside of the root canal. The working vibration frequency can reach 40,000 Hz, which can significantly improve the performance of root canal washing;
- The tip, wrench and silicone sleeve can be sterilized at a high temperature of 135℃ and a high pressure of 0.22 MPa.
- The product service life is five years.

1.2. Equipment description

The product is mainly composed of unit, tip, wrench, silicone sleeve and power cord.

1.3. Intended use

The product is intended use for root canal washing.

Applicable people:people except for contraindications.

Place of use:professional dental clinics and hospitals

1.4. Contraindications

- Patients with hemophilia is forbidden.
- Patients with heart pacemaker is forbidden.
- Doctors with heart pacemaker is forbidden.
- Use with caution in patients with heart disease, pregnant women and young children

1.5. Technical parameters

- Input Power：DC 5 V 1 A
- Batteries：3.7 V/1400 mAh
- Tip amplitude：minimum,1 μm, deviation –50%
  maximum, 100 μm, deviation +50%
- Half deflection force：minimum, 0.1 N, deviation –50%
  maximum, 5 N，deviation +50%
- Vibration frequency of tip：18 kHz ~ 45 kHz；

Note：The vibration frequencies of different types tips are different, but they are all distributed within the described range.

- Output Power of tip：3 W MAX
- Weight of main unit：116 g
- Operation modes：discontinuous running
- Protection against electric shock rating：Class Ⅰ equipment
- Protection against electric shock degree：B–type application part
- Ingress protection rating：Ordinary equipment (IPX0)
- Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide:Non–AP,APG type equipment

1.6. Operation environment

a) Ambient temperature：5 ℃ to 40 ℃

b) Relative humidity：≤80%

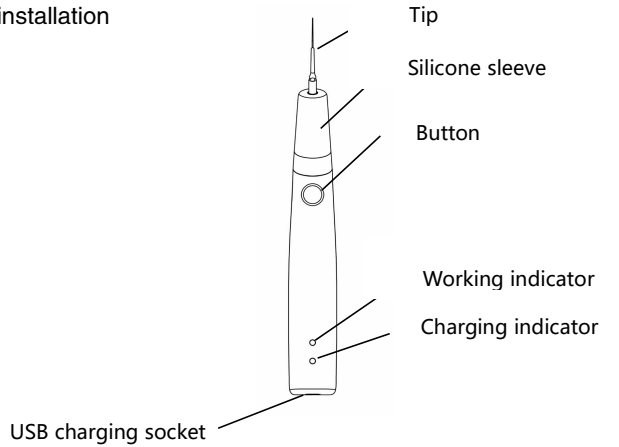
c) Atmospheric pressure：70 kPa to 106 kPa

2. Installation

2.1. Installation steps

Put on the black silicone sleeve manually, screw the tip into the thread of the unit, and tighten the tip with a wrench.

2.2. Diagram after installation



3. Operating instruction

3.1. Root canal washing function

1) Press the black ON/OFF button, the working indicator will be on, and it will shut down when not in use.

2) Inject the root canal sealing liquid, and the needle will move vertically up and down in a small width (2–3mm) and keep a distance of 2mm from the working length.

3) Activate the sealing liquid in the root canal. Every 20 seconds of working is an operating cycle, which automatically stops, and then the root canal is rinsed.

4) Reciprocating working 2 or 3 times for 30 seconds~60 seconds to achieve the best root canal cleanliness.

5) It is recommended to use no more than 20 root canals per tip.

NOTICE：

1) Please tighten the tips when installation；

2）When the root canal is washed, do not apply heavy pressure.

3.2. Charging

1） When working, the working indicator flashes, indicating that the battery is low and needs to be charged.

2） When charging, the charging indicator is yellow, and it changes to green after charging.

3.3. Precautions

1）Keep the device clean and dry before or after use.

2）Before each use, please sterilize the tip, silicone sleeve, wrench and other accessories at 135℃ temperature and 0.22MPa by high pressure sterilizer.

3）The operator should be equipped with adequate protection (such as goggles, mask, etc.) to prevent cross-infection.

4）Using the product must comply with the requirements of the relevant operating specifications and relevant laws and regulations of the medical department, and it is limited to trained doctors or

technicians.

5）Do not tighten or loosen the tips when the handpiece is activated.

6）Tighten the tips.

7）When the tip is damaged or worn, the vibration intensity will decrease. The operator should replace the tip with a new one according to the clinical situation.

8）Don’t bend or sharpen the tips.

9）It is recommended to use no more than 20 root canals per tip.

10）Stop using the tips when there is a harsh whistling sound during using.

11）Our company specializes in producing medical devices and we're responsible for its security only when the device maintained, repaired and modified by URIT or Distributor authorized by the our Company, and the replacement accessories are made by our Company and operating follow the user manual.

12）The internal thread of the tips produced by some manufacturers is rough, rusty, chipped or adopts other standard threads. When used with the handpiece, it is easy to damage and slip the

teeth, and even cause irreparable damage to the product. Please use the original tip.

4. Cleaning and sterilization

4.1. Unit

When using alcohol for sterilization, use 70%~80% (volume ratio) ethanol to soak a piece of clean dry gauze, and then use this gauze to wipe the surface to be sterilized twice for 3 minutes. Dry or wipe the residual alcohol with a clean, dry cloth.

4.2. Tip

The tips can be sterilized in high temperature and pressure environment.

4.3. Wrench

The wrench can be sterilized in high temperature and pressure environment.

4.4. Silicone sleeve

The silicone sleeve can be sterilized in high temperature and pressure environment.

5. Troubleshooting

Error	Possible causes	Solutions
Turn up the device but the tip is not working.	Batteries are out of power.	Please charge the device in time or change new batteries.
	Tip is not tightened.	Tighten the tip.
	Worn or bent tip.	Replace the tip.
	Unit is damaged.	Contact your local dealer or our company.

NOTICE：If the fault still cannot be resolved, please contact your local dealer or our company.

6. Storage, maintenance and transportation

6.1. Storage and maintenance

- The device should be handled with care, far away from the earthquake source, and should be installed or stored in a cool, dry and ventilated place.
- Do not mix with toxic, corrosive, flammable and explosive materials during storage.
- Store temperature from –20℃ to 55℃,relative humidity from 0% to 90%，atmospheric pressure from 70kPa to 106kPa.

6.2. Transportation

- Transport should not be mixed with dangerous goods.
- Avoid excessive shock and vibration during transportation, handle with care and avoid upside–down.
- Keep away from rain, sunlight or snow during transportation.

7. Maintenance

Maintenance list as follow:

No.	Name	Specification/model
1	Main board	/
2	Wrench	/
3	Tip	/
4	Silicone case	/
5	Power cord	/

NOTICE： The manual does not exhaustively list the accessories and specifications of the DA–1. Please refer to the random delivery materials and packing list for details.

8. After–sale service

This device is guaranteed by the warranty card from the date of sale, and is responsible for lifetime

maintenance. Irreparable device damage caused by non–designated dedicated maintenance personnel is not covered by the free warranty.

9. Symbols

Symbol	Description
VRN	Trademark
	Caution
	Refer to instruction manual/ booklet

Symbol	Description
ON/OFF	Switching on (ON) / Switching off (OFF)
POWER	Charging indicator
DC 5V 1A	USB charging socket
	Manufacturer
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Symbol	Description
	Date of manufacture
	Use by date
	Temperature Limit
	Atmospheric pressure limitation
	Humidity limitation
	Serial number
	This way up

Symbol	Description
	Fragile, handle with care
	Keep away from rain
	Type B applied part
	Sterilisation at 135 ℃ in an autoclave

10. Environmental Protection

Name	Toxic and harmful substances or elements					
	Pb	Hg	Cd	Cr（Ⅵ）	PBB	PBDE
Plastic shell	O	O	O	O	O	O
Circuit board	O	O	O	O	O	O
Stamping parts	O	O	O	O	O	O
Tips	O	O	O	O	O	O
Silicone sleeve	O	O	O	O	O	O

Name	Toxic and harmful substances or elements					
	Pb	Hg	Cd	Cr（Ⅵ）	PBB	PBDE
The table is compiled in accordance with the provisions of SJ/T 11364. O：It means that the content of this toxic and hazardous substance in all homogeneous materials of this part is below the limit requirement of GB/T 26572. X：It It means that the content of the toxic and hazardous substance in at least one of the homogeneous materials of the part exceeds the limit requirement of GB/T 26572. (This product complies with the requirements of EU RoHS environmental protection: currently there is no mature technology in the world that can replace or reduce the lead content in electronic ceramics, optical glass, steel and copper alloys) In accordance with *Administrative Measures on the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products*, *Regulations on the Management of the Recycling and Disposal of Waste Electrical and Electronic Products* and related standards, please observe the safety and use precautions of the product, and recycling or disposal of this product please apply appropriate measures in accordance with local laws and regulations after the product is used.						

11. Manufacturer's rights

The company reserves the right to modify the design, technology, accessories, user manual content and packing list content of the product at any time without notice. In case of discrepancies, the actual product shall prevail.

12. Electromagnetic compatibility

NOTICE：

1）Without the express consent of URIT, unauthorized changes or modifications to the device may cause electromagnetic compatibility(EMC) problems of the device or other device.

2）The design and test of device comply with the operating regulations related to EMC.

3）WARNING：Even if other devices meet the launch requirements of the corresponding national standards,the device or system may interfere with other electronic devices.

12.1. Cable length

Cable name	Type	Length

Power Cord	Unshielded parallel line	1.5 m

12.2. Key components of EMC

The product key components of EMC are the scaler's main board chip and adapter. The use or replacement of accessories, cables, transducers, etc. that are not designed to match will cause the electromagnetic emissions and immunity performance to be significantly reduced.Do not replace device parts without authorization.

12.3. Electromagnetic emissions

GUIDANCE AND MANUFACTURER’S DECLARATION– ELECTROMAGNETIC EMISSIONS		
DA–1 is designed for use in the electromagnetic environment described in the table below. The user or purchaser must ensure that the medical device is used in the environment described below.		
Emissions Test	Compliance	Electromagnetic environment – guidance

RF emissions GB 4824	Group 1	DA–1 uses radiofrequency energy for its internal operation. Consequently, its radiofrequency emissions are very low and are not likely to create any interference with other nearby equipment.
RF emissions GB 4824	Class B	DA–1 is suitable for use in all establishments, including domestic and those directly connected to the low voltage energy supply public network supplying buildings used for domestic purposes.
Harmonic emissions GB 17625.1	N/A	
Voltage fluctuation and flickers GB 17625.2	Conforming	

12.4. Electromagnetic immunity

GUIDANCE AND MANUFACTURER'S DECLARATION– ELECTROMAGNETIC IMMUNITY			
DA–1 is designed for use in the electromagnetic environment described in the table below. The user or purchaser must ensure that the medical device is used in the environment described below.			
Immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment – guidance

Electrostatic discharge (ESD) GB/T 17626.2	± 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, relative humidity should be at least 30%.
Electrical fast transient/burst GB/T 17626.4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for link cable	Main power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	± 1 kV differential mode ± 2 kVcommon mode	± 1 kV differential mode	Main power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines. GB/T 17626.11	< 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 seconds	< 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 seconds	Main power quality should be that of a typical commercial or hospital environment. If the user of DA−1 requires continued operation during power main interruptions, it is recommended that the DA−1 be powered from an UPS or battery supply.

Power frequency (50–60 Hz) magnetic field GB/T 17626.8	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.
NOTE:U_T is the A.C. mains voltage prior to applications of the test level.			

12.5. Electromagnetic immunity

GUIDANCE AND MANUFACTURER’S DECLARATION– ELECTROMAGNETIC IMMUNITY			
DA–1 is designed for use in the electromagnetic environment described in the table below. The user or purchaser must ensure that the medical device is used in the environment described below.			
Immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment – guidance

Conducted RF GB/T 17626.6 Radiated RF GB/T 17626.3	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 DA–1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V1}\right]\sqrt{p}$ $d = \left[\frac{3.5}{E1}\right]\sqrt{p} 80MHz \sim 80MHz$ $d = \left[\frac{7}{E1}\right]\sqrt{p} 800MHz \sim 2.5GHz$ Where P is the maxi mum 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] 

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) telephone 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 theDA–1 is used exceeds the applicable RF compliance level above, DA–1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating DA–1.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

12.6. RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND DA–1

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND DA–1

DA–1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of DA–1 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DA–1 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 ~ 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{p}$	80 MHz ~ 800 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{p}$	800 MHz ~ 2.5 GHz $d = \left[\frac{7}{E1}\right]\sqrt{p}$
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

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 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.

DA–1 has passed test according to the standard YY 0505–2012 and standard IEC 60601–1–2：2004, but it cannot guarantee in any way that it is not affected by electromagnetic interference. DA–1 should be avoided using in high electromagnetic environments.

www.urit.com

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