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Endo A1

Endo Activator user manual

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1. Symbols

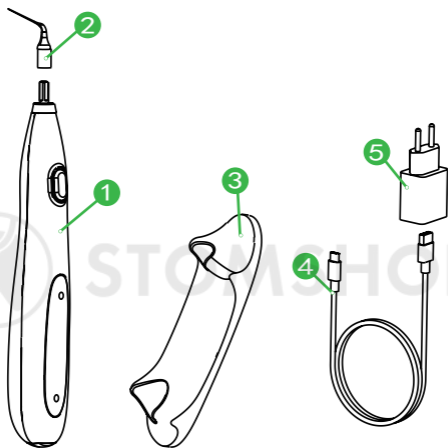
 Warning	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
 NOTE	Additional information, explanation of operation and performance.
	Do not dispose of with normal household waste.(WEEE)
	Serial number
	Catalogue number
	Manufacture
	Date of manufacture
	Type B applied part
	Direct current
	Safety class II device
	Store in a dry place
	Can be autoclaved up to a maximum temperature of 135° Celsius
	Temperature limitation
	Relative humidity
	Transport and storage pressure conditions: 70 kPa - 106 kPa

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2. Technical Data

Model	Endo A1
Package Size	211mmX151mmX91mm
Package weight	Approx. 662g,±10%
Power supply	ICR14500, 3.7V 800mAh ±10%
Charger power supply	5VA
Degree of Protection	IPX 0
Electrical safety class	Class II
Applied part	B
Speed range	400Hz
Operating conditions	Use: in enclosed spaces Ambient temperature: 5° C ~ 40 ° C Relative humidity: <80% Operating altitude < 2000m above sea level Atmospheric pressure: 70kPa ~ 106kPa
Transport and storage conditions	Ambient temperature: -20 ° C ~ +55 ° C Relative humidity: 20% ~ 80 % Atmospheric pressure: 70kPa ~ 106kPa

3. Parts Identification



Components and Accessories

① Main unit	1 (pcs)	② Tips	40(pcs)
③ Base	1(pcs)	④ USB Cable	1 (pcs)
⑤ Adapter	1 (pcs)	User manual	1 (pcs)

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3.1 Scope of application

Endo A1 is used in endodontic treatment by application of sonic energy. The Endo A1 can provide the energy for tip oscillation and vibration required to create sufficient acoustical streaming and cavitation necessary to effectively clean, penetrate, and remove vapor lock. A cleaned root canal system makes for better outcomes and reduces retreatment rate.

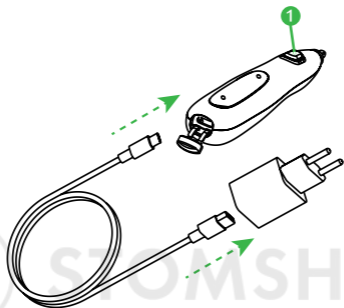
This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.



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4. Installation and Use

4.1 Battery charge



Remove the shost from the packaging and short press the power button **1** on the machine. After the machine emits a beep, turn it on and enter standby mode.

Plug the charging cable into the host socket and connect the other end to the adapter USB socket. At this time, the device will make a beep sound and turn on the adapter LED . The battery LED will turn on and breathe.

When the battery is fully charged, the charging Progress bar stops, the battery LED will be always green, and the battery is full. It takes approximately 2.5 hours for this device to fully charge from the lowest level.

The time varies depending on the battery usage times and the remaining battery level. The battery life of the product is approximately 400 to 500 charging and discharging cycles, and the battery level will decrease there after.

Please stop using and charge immediately when the battery level is LED in red.

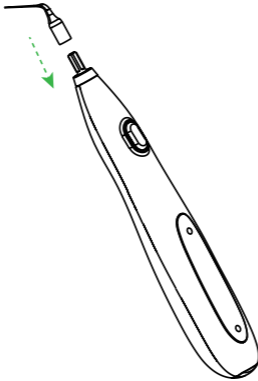
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Warning

1. Before using the product for the first time, please charge the host for at least 4 hours.
2. Do not use batteries or charging cables outside of our company, otherwise risks may arise. We are not responsible for any issues arising from the use of accessories outside of our company.
3. Do not use this device during the charging process.
4. Please ensure the use of our company's original accessories.

4.2 Accessories Installation

Make sure the tip aligning to the handpiece. Plug them together.

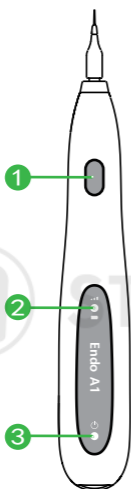


NOTE

1. Please use the original or recommended tips
2. Before installing the tips, ensure that the equipment is in a stopped.
3. After the installation of the tips is completed, gently pull to confirm whether the installation is secure.

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4.3 Interface and use



- ① Power button
- ② Battery LED / power Display
- ③ Adapter led

Power On

Short press the power button ① for more than 0.5 seconds to turn on the machine and it will enter standby mode. Short press again to start/stop this device.

Power adjustment

When the motor is running, long press the button to adjust the output power.

Power Off

Long press the power button ① When the device is stopped , then the machine will automatically shut down.



NOTE

1, This device automatically shuts down after 8 minutes of inactivity.

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5. Maintenance and sterilization

5.1 Foreword

For hygiene and sanitary purpose, the components must be cleaned,disinfected and sterilized before each usage to prevent any contamination . This occurs the first use as well as the subsequent uses.

Comply with your national guidelines,standards and requirements for cleaning, disinfection and sterilization.

5.2 General recommendations

1. The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.

2. For your own safety,please wear personal protective equipment

3. Use only a disinfecting solution which is approved for its efficacy(VAH/DGHM listing,CE marking,and FDA approval) and in accordance with DFU of the disinfecting solution manufacturer.

4. The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.

5. Thoroughly clean and wash the components before autoclaving.

6. Do not lubricate the motor handpiece.

7. Do not clean the prophy angle with an ultrasonic cleaning device.

8. Do not use bleach or chloride disinfectant materials.

5.3 Autoclavable Components

N/A

5.4 Cleaning and disinfection

N/A

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5.5 Disinfection components

Handpiece



Base



USB cable



Wipe all the surfaces with a cloth lightly moistened with Ethanol for Disinfection (Ethanol 70 - 80vol%) at least 2min, repeat for 5 times.



NOTE

1. Do not use anything except Ethanol for disinfection.



Warning

The included work tip is for one-time use and should be disposed of as medical waste after use and cannot be reused.

5.6 Battery Maintenance

Charge the battery when the battery LED in RED .

If you do not use the device for a long time, you need to keep the device fully charged at least once a month to ensure that the battery is not too low.

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6. EMC table

Guidance and manufacturer' s declaration –
electromagnetic emissions

The **Endo A1** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Endo A1** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Endo A1 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 Endo A1 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 IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer' s declaration –electromagnetic immunity

The **Endo A1** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Endo A1** 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	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 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 transients/ bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
Electrostatic discharge (ESD) IEC 61000-4-2	+8 kV contact +/-2 kV, +/-4 kV, +/-8 kV, +/-15 kV air	+/- 8 kV contact +/-2 kV, +/-4 kV, +/-8 kV, +/-15 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 %.
Voltage dips, Short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% UT; 0.5 cycle at 0° , 45° , 90° , 134° , 180° , 225° , 270° , and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5 cycle at 0° , 45° , 90° , 134° , 180° , 225° , 270° , and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continue operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT: rated voltage(s); E.g.
25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz

Guidance and manufacturer' s declaration –electromagnetic immunity

The **Endo A1** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Endo A1** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Endo A1 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended minimum separation distances. See the RF wireless communication equipment table in "Recommended minimum separation distances".
Radiated RF EM fields IEC 61000-4-3	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz See the RF wireless communication equipment table in "Recommended minimum separation distances"	3V/m Complies	
Proximity fields from RF wireless communication equipment IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"		

Recommended minimum separation distances

Nowadays, many RF wireless equipment have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **Endo A1** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the **Endo A1** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM \pm 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9



NOTE

1. Use of accessories and cable other than those specified or provided by the manufacturer of the **Endo A1** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **Endo A1** and result in improper operation.

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Cable information			
Cable Name	Cable Length (m)	Shielded or not	Remark
Cable	0.5	No	/

7. Warranty

1. The main unit of **Endo A1** enjoys a **12-month warranty period**, which starts on the day of delivery to the customer.
2. The host and other parts of the **Endo A1** are repaired by authorized repair service partners.
3. If it is proved that the damage is caused by improper daily maintenance by the user, it is not covered by the warranty.

8. Service life

The service life of the **Endo A1** main unit is **5 years**.

9. Declaration

In the following cases, the manufacturer does not assume any responsibility:

1. Use **Endo A1** for purposes other than those specified in this manual.
2. The cleaning, disinfection or sterilization operation is not carried out according to the method stated in this manual.
3. Use or maintenance by untrained personnel.
4. If you have any questions, please contact your local dealer.

10. Environmental protection

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. The lithium batteries are disposed as special refuse. Please deal with them according to the local environmental protection laws and regulation.

11. Right

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to the manufacturer. The industrial design, inner structure, etc, have claimed for several patents by the manufacturer, any copy or fake product must take legal responsibilities.



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12. Warranty Card

Name of customer:	Tel:	Purchase date:
Address detail:		
Product name:	Model:	
Serial number:		
Maintenance record	Date	Fault cause

Thank you very much for using our products;This table is considered as the Protection to fix warranties,so please reserve them carefully,Loose don' t repair

1. Calculated from the date of purchase,our company' s product warranty period is **_1_ year**.During this any belongs to under normal usage circumstance cause because of the product.

Quality' s problem of breakdown, our company will be responsible for giving free maintain.

2. In protect fix the period,if there is any breakdown,please return the faulty device and completed warranty card to our company for repair.

3. Those machines that has refitted or added other functions by yourself will not be accepted to repair.

4. Once the protect to fix card has been changed,the protection to fix immediately expired.

Free maintain won't be given under the following circumstance:

1. Without Protection to fix warranties.

2.Failure caused by improper installation,operation,and sterilization (Don' t comply with the user manual).

3. The breakdown caused by the dismantle movement of non-our-company authorized maintain.

4. The damage caused by customer inappropriate preservation,-maintain,breakdown,or the usage.

5. Easy damage pieces and present accessories are not concerned.

6. The breakdown and the damage caused by the force majeure.

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