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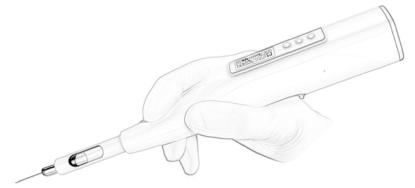
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The User Instruction of Dental Anesthesia Delivery Equipment Easy-IV



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- 5. During transportation and using, the product shall be protected from violent vibration, drop, impact or extrusion.
- 6. If the product reaches the scrapping period, the machine and accessories shall be disposed in accordance with relevant national regulations.
- 7. The adapter should meet the requirements of IEC 60601-1.
- 8. The product can not use in Oxygen-enriched state, is not available for flammable anesthetic.

XI. Warnings and Tips:

- 1. Make sure the O-ring installed and complete before aspiration.
- 2. Lithium-ion batteries are recommended to be charged once every 3 months according to standard charging and discharging methods.
- 3. Each main machine must be charged with the matching power adapter. The main machine will not work when charging. Other cables and accessories may negatively affect EMC performance.
- 4. If the equipment is abnormal, please contact our company for repair, do not disassemble it without authorization, and provide the circuit diagram, component list, drawing note and correction rules as required by our company.
- 5. For your safety ,do not modify the ME EQUIPMENT without authorization.

XII, Date of Produce: Show on the Label

XIII. The period of Use: 5 years

Standard		Test methods and levels	
Radiated Emissions CISPR 11	Group 1 Cla	ss B	
Conducted Emissions CISPR 11	Group 1 Class B (only charging mode)		
Harmonic emissions IEC 61000-3-2	Class A, (only charging mode)		
Voltage fluctuations/ flicker Emissions IEC 61000-3-3	Complies, (only charging mode)		
Electrostatic discharge (ESD) IEC 61000-4-2	8 kVcontact 2 kV, 4 kV, 8 kV, 15 kVair		
Electrical fast transient/burst IEC 61000-4-4	2 kV 100KHz repetition frequency (only charging mode)		
Surge input AC power port IEC 61000-4-5	1kV Line-to-Line (only charging mode)		
Voltage dips IEC 61000-4-11	0% UT for 0.5 cycle At 0°45°900°135°180°225°270°and 315° 0% UT for 1 cycle and 70% UT for 25 cycles Single phase at 0° (only charging mode)		
Voltage interruptions IEC 61000-4-11	0 % UT; 250/300 cycle (only charging mode)		
Power frequency(50/60Hz) Magnetic fieldIEC-61000-4-8	30 A/m 50Hz / 60Hz		
Conducted RFIEC 61000-4-6	6Vrms in IS	MHz~80MHz M bands between 0,15MHz and 80MHz 1kHz (only charging mode)	
	For EM fields: 3V/m 80MHz~2.7GHz For Proximity fields from RF wireless communications equipment:		
	Freq MHz	Test Level P: max power, d:distance, E:Immunity Level	
	385	P=1.8W d=0.3m E=27V/m for TETRA400	
	450	P=2W d=0.3m E=28V/m for GMRS460; FRS460	
Radiated RFIEC 61000-4-3	710 745 780	P=0.2W d=0.3m E=9V/m for LTE Band 13, 17	
	810 870 930	P=2W d=0.3m E=28V/m for GSM800/900; TETRA800; iDEN820; CDMA850;LTE Band 5	
	1720 1845 1970	P=2W d=0.3m E=28V/m for GSM1800, CDMA1900; GSM1900; DECT; LTE Band 1,3,4,35;UMTS	
	2450	P=2W d=0.3m E=28V/m for Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	
	5240	P=0.2W d=0.3m E=9V/m for WLAN 802.11 a/n	
	5500	802.11 a/n	
	5785		

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I, Name of Product:

Dental Anesthesia Delivery Equipment

II、Medical Use

This device is intended for use only in local anesthetic agents for dental applications. It's appropriate for local anesthesia during the treatments of oral diseases, such as intraoral cure, repair, reform, small size of surgical operation and so on . The device is use with 1.8ml standard card local anesthetics (Primacaine, Scandonest) and Disposable Dental Needle.

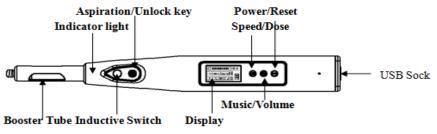
.III、Model、Specification:

Easy -IV

IV, Configuration and Composition:

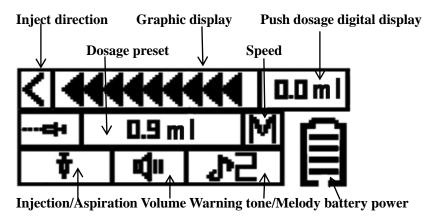
- 1.One main machine
- 2. Four boosting pipes
- 3.One base
- 4.One power adapter (With One USB Cable)
- 5.O-ring ten pieces

Main Machine



USB Sock: connect the USB power adapter(DC5V,1A)to charge or connected to the computer through the USB cable to change the music.

Display:



Button Instruction

Picture	Button Instruction
\Diamond	Inductive switch: When the inductive switch is unlocked, use the finger to block the inductive switch to start inject medicine, and the finger leaves the inductive switch to stop pushing the medicine.
(a)	The aspiration/inductive switch unlock button: press the button to unlock (or lock) the inductive switch, the blue work indicator lights up and enters the working state; press and hold the the button for 2-5 seconds to do aspiration.
(E)	Speed/Dose: Press and hold for 2-5 seconds to set the dosage needed: 0.1ml、0.3ml、0.6ml、0.9ml、1.8ml;Press the button one second to set the High speed/Medium speed/Low speed.
	Music/Volume: Press and hold for 2-5 seconds to set the Mute mode. Volume(low or high); Press one second to set the warning tone (beep every 0.1ml) Or melody.
(Press and hold the button for 2-5 seconds to turn on /off the power, Double click the button to reset the push rod.

VIII、Maintenance and Care:

- 1. Check the O-ring every day. If there is a worn O-ring, it should be replaced immediately. If the aspiration function is not used for a long time, it is recommended to remove the O-ring with a dental probe.
- 2.In order to extend the battery life, it is recommended to charge the battery when there is still one grid remaining.
- 3. Restore the original factory settings: If there is a continuous alarm or other fault status during use, connect the host to the power adapter or remove the battery and plug it in again. After the prompt tone is heard, the original factory settings will be restored.

IX、Contraindication: Intraligamentary injection is prohibited in patients with active periodontal disease.

X. Attention:

- 1. This product is only applied for the local anesthesia in the Stomatology Department. The selection of anesthetic and needle shall be purchased according to doctors' clinical requirements. Any results caused by misuse of anesthetic and needle have nothing to do with the product.
- 2. The machine and charger should be disinfected after use, It is recommended to spray the disinfectant onto a clean paper towel to wipe the machine. Do not spray the disinfectant directly onto the machine. The boosting tube is disposable.
- 3. The storage products warehouse environment temperature for 10 °C to + 45 °C of indoor cleaning ,to avoid contact with corrosive substances, stay away from fire and heat source.
- 4. Please keep away from strong magnetic field and alternating current equipment to avoid electromagnetic interference.

Electromagnetic compatibility statement as follows: The products for Professional health care facility environment.

- 8. press the button to turn the inductive switch on/off. when the inductive switch on, the blue work indicator lights up and enters the working state; use the finger to block the inductive switch to start inject medicine, and the finger leaves the inductive switch to stop pushing the medicine when the inductive switch off, the machine will stop inject the medicine. Press and hold the button for 2-5 seconds in working state to do aspiration.
- 9. **Music Function:** Built-in music (8M memory can be connected to the data cable to download MP3 format music or record MP3 format caring language, etc.)

Change music method:

After the main machine is connected to the computer through the Micro USB cable. You can find the internal music storage space. It contains four music files: "001key.mp3" and "002prompt.mp3". "003music.mp3""004alarm.mp3", if you want to change "003music.mp3", you can rename the mp3 music file name to 003music.mp3, and then replace the original "003music.mp3" (It is recommended to copy the internal four files before replacing, and then format the storage space, then move the four files into the music storage space)

NOTE: The files of 001key.mn3 and 002alarm.mp3 MUST BE RETAINED!

- 10. **Aspiration**: Press the to unlock the button and the blue work indicator lights up to enter working state when you need to do aspiration during the clinical injection; Long press the For 2-5 seconds , the push rod will return 0.1 ml, At the same time, observe whether there is blood return in the anesthetic bottle through the transparent booster tube. If the aspiration function is not used for a long time, it is recommended to remove the O-ring with a dental probe.
- 11. **Charging method**: Connect the power adapter to the charging hole at the rear of the main machine. The battery on the main machine screen shows that it is charging. At the same time, the blue indicator light on the back of the main unit lights up. It takes around 3 hours to finish charging. When the battery is full charged, the main unit screen battery shows 4 grids. The blue LED is off. It is recommended to charge the battery when it has one space left, which will extend the battery life.

V. Performance:

- 1.Basic performance of dental anesthesia delivery equipment:booster tube: There is no damage when falling at a height of 1.5 meters easy to insert and pull; push time: push time error does not exceed $\pm 10\%$; push dose: push dose 1.8ml, The error does not exceed $\pm 10\%$.
- 2.The connection situation: the booster tube and fast plug connection should be reliable; the button should be flexible and reliable.
- 3. Appearance: The outer surface of the machine should be smooth, and there should be no defects such as corrosion spots, dirt, scratches, sharp edges and burrs.
- 4.Safety requirements: electrical safety performance fully implements the requirements of IEC 60601-1; electromagnetic compatibility should comply with the provisions of IEC 60601-1-2.
- 5.Electromagnetic compatibility: The electromagnetic compatibility of the local anesthesia delivery equipment is in accordance with the provisions of IEC 60601-1-2.
- 6.Environmental test: The environmental test of the dental anesthesia delivery equipment is in accordance with the requirements of IEC 60601-1 and meets the standard requirements.
- 7. The unique features of Easy -IV
- 7.1 The display should show clear, no black screen, defects, display confusion and other defects.
- 7.2 When the battery is low, the warning light flashes with an audible alert function.
- 7.3 When you making injection, you can select a music playback function to play a song, or you can choose to mute or tone.

VI, Technical Parameters:

• Security feature::

Type classification of electric shock protection: For cure: Internal electric source. For charge: Class II.

Degree classification of electric shock protection: BF type of application part

Working system: continuous operation

No signal input and output , No anti-defibrillation function $% \left(1\right) =\left(1\right) \left(1\right)$

Network power isolation: Unplug power adapter (DC 5V,1A)for network power isolation.

Water proof grade:IPX-0

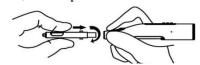
- Applied parts specified: Disposable Dental Needle connected with me equipment is chosen according doctor's needs.
- Working environment: the equipment is applied for general environment and locations .it is used at an altitude under 3000meters above with temperature of 5-40°C, relative humidity of 30-80%.
- Power adapter input: AC 100-240V,50/60Hz Output: DC 5V,1A
- Input Power: 10VA
- Working power: DC 3.7V, 480mAh ,Rechargeable lithium battery
- Working voltage: DC 3.7V.
- Working current: 800mA MAX
- Stand-by time: 30 days.
- Working hours: 4hours.
- OLED display time: 60 seconds
- Working instructions: LED blue light indication
- Alarm indication: LED red light indication and alarming of bi..bi
- Size: Main machine: 178mm×28mm×32mm
- Weight: Main machine: about 120g.

VII, Operation Instructions:

1. Insert the 1.8ml card-type anesthetics (Primacaine, Scandonest.) into the booster tube according to the clinical needs, like the pic 1.

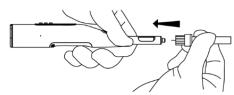


2. Insert the booster tube into the fast plug of the machine,Rotate 45 degrees clockwise,like the pic 2.



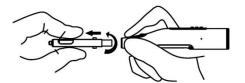
Pic 2

3. Install a Disposable Dental Needle, like the pic 3.



Pic 3

4. After finish injection, turn the booster counterclockwise and pull it out, like the pic 4



Pic 4

- 5. Press and hold 2-5seconds to turn on/off the power, turn the power on,the host enter standby state.double click to reset the push rod.
- 6. Press and hold 2-5 seconds to set the dosage of anesthetic 0.1ml, 0.3ml, 0.6ml 0.9ml, 1.8ml; Press once to set the speed High speed, Medium speed, Low speed like the table 2.

Table 2

Speed	1.8ml Inject time
Н	108s
M	150s
L	310s

7. Press and hold 2-5seconds to set the Mute mode . Volume(Low or High); Press once to set the warning tone (beep every 0.1ml) Or Melody.