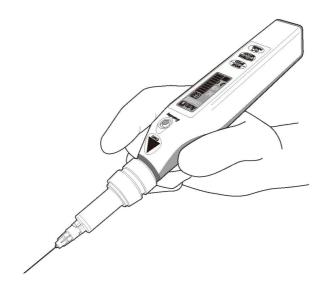
The User Instruction of Local Anesthesia Boosting Instrument

TR-LAI02



Catalogue

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I. Name of Product:

Local Anesthesia Boosting Instrument

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 Dispossable Dental Needle.

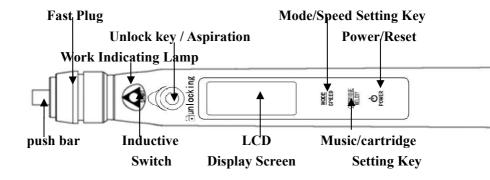
III, Model, Specification:

TR-LAI02

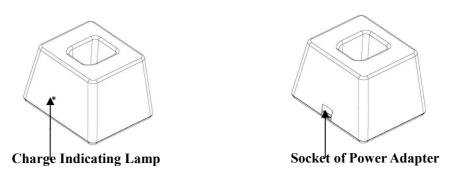
IV, Configuration and Composition:

- 1.One main machine
- 2.Four boosting pipes (NO.1 British system, NO.2 Metric system)
- 3.One battery charging base
- 4.One power adapter(With One USB Cable)
- 5.O-ring ten pieces

Main Machine



Battery Charging Base



V . Performance:

1. Basic performance of local anesthesia boosting instrument:

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 device is in accordance with the provisions of IEC 60601-1-2.
- 6.Environmental test: The environmental test of the local anesthesia boosting instrument is in accordance with the requirements of IEC 60601-1 and meets the standard requirements.
- 7. The unique features of EASY II
- 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:

1. Security feature:

Type classification of electric shock protection: For cure: Internal

electric source, For charge: Class II (wireless)

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

Working system: continuous operation

No signal input and output, No anti-defibrillation function

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

Water proof grade: IPX-0

- 2. Applied parts specified: Disposable Dental Needle connected with me equipment is chosen according doctor's needs.
- 3 Working environment: the equipment is applied for general environment and locations .it is used at an altitude under 3000meters above with temperature of 5-35°C ,relative humidity of 30-80%.
- 4. Power adapter input: AC 100-240V, 50/60Hz Output: DC 5V,1A.
- 5. Input Power: 10VA
- 6. Working power: DC 3.7V, 350mAh ,Rechargeable lithium battery
- 7. Working voltage: DC 3.7V.
- 8. Working current: 800mA MAX
- 9. Stand-by time: 30 days.
- 10. Working hours: 4hours.
- 11.LCD display time: 60 seconds; The host standby time 120 seconds, Press any button to wake up.
- 12. Working instructions: LED light indication, Alarm indication: alarming of bibi...
- 13. Product dimension: main machine: 185mm×25mm×30mm

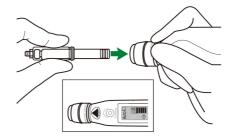
14. Product weight: main machine: about 120g.

WI. Operation Instructions:

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

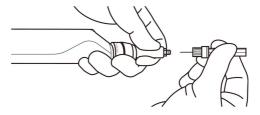


2. Insert the booster tube into the quick plug of the main machine and prove that it is inserted after hearing a sound. like the pic 2.



Pic 2

3. Install a Dispossable Dental Needle.see the pic 3



Pic 3

4. When finish injection and need to remove the anesthetic, use the index finger to pull the quick plug back and the booster tube will pop up automatically, see the pic 4°.



Pic 4

- 5. Press and hold the Power for 2-5 seconds to power on/off, when the power on, the host enter standby mode. Double click the Power to reset the push rod.
- 6. Press and hold the Mode/Speed for 2-5seconds, to set the Auto mode or Constant mode. See the pic 5.



Pic 5

7. Press the Mode/Speed for one time to select <u>High speed</u>, <u>Medium speed or Low speed</u>, see the table 1.

Table 1

Mode	Auto mode (injection time)		Constant Mode	(injection time)
Speed	1.8ml	1.0ml	1.8ml	1.0ml
Н	90s	50s	75s	40s
M	150s	85s	145s	80s
L	310s	180s	310s	180s

8 press the UNLOCKING key 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 UNLOCKING key for 2-5 seconds in working state to do aspiration.



Pic 6

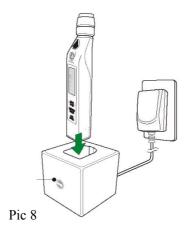
9. Music: Press the CARTRIDGE/MELODY to switch music or the prompt tone (a sound injected every 0.1ml)or mute mode, see the pic 7.



- 10. Long press the CARTRIDGE/MELODY for 2-5 second to set the dose of anesthetic 1.8ml or 1.0ml.
- 11. Aspiration: Press the UNLOCKING 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 UNLOCKING 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.

12. Charging method :Connect the power adapter with the charging base, the indicator lights red on the front of the charging base ,put the main machine into the charging base (Inductive charging), The LCD screen of the machine shows the charging status, and the green light at the front of the charging base flashes. It is take 3 Hours to finish charge. When the battery is fully charged, the charger indicator lights green .,see the pic 8.



VII. 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: When the main machine crashes, Press and hold the power button to turn off the power, then press and

hold the power button to restart the factory settings.

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

X . Attention:

- 1. This product is used at an altitude under 3000meters above with temperature of 5-35°C, relative humidity of 30-80%. 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.
- 3. The storage products warehouse environment temperature for $10 \,^{\circ}\text{C}$ to + 45 $\,^{\circ}\text{C}$ 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.

Standard	Test methods and levels
Radiated Emissions CISPR 11	Group 1 Class B
Conducted Emissions CISPR	Group 1 Class B
11	(only charging mode)
Harmonic emissions	Class A, (only charging mode)

IEO 04000 0 0			
IEC 61000-3-2			
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	3Vrms 0.15MHz~80MHz 6Vrms in ISM bands between 0,15MHz and 80MHz 80% AM at 1kHz (only charging mode)		
	For EM fields: 3V/m 80MHz~2.7GHz For Proximity fields from RF wireless communications equipment:		
Radiated RFIEC 61000-4-3	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	
	710 745 780	P=0.2W d=0.3m E=9V/m for LTE Band 13, 17	
	810	P=2W d=0.3m E=28V/m for	

870	GSM800/900; TETRA800;
930	iDEN820; CDMA850;LTE Band 5
1720	P=2W d=0.3m E=28V/m for
1845	GSM1800, CDMA1900;
1970	GSM1900; DECT; LTE Band
1970	1,3,4,35;UMTS
	P=2W d=0.3m E=28V/m for
2450	Bluetooth, WLAN 802.11 b/g/n,
	RFID 2450, LTE Band 7
5240	P=0.2W d=0.3m E=9V/m for
5500	WLAN 802.11 a/n
5785	VVLAIN 002.11 a/II

- 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 charger and 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 charging base and 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. The period of Use: 5 years