

USER'S MANUAL



DY310 Pulp Tester

The unit must be installed by a qualified dental engineer.

The unit is only for use by dental professionals.

Read this operation manual carefully before operation.



CONTENTS

SECTION I. CONTACT INFORMATION

SECTION II. DESCRIPTION

SECTION III. COMPONENTS AND FEATURES

SECTION IV. SYMBOL

SECTION V. MAIN TECHNICAL INDEX

SECTION VI. OPERATION

SECTION VII. SAFETY PRECAUTIONS

SECTION VIII. MAINTENANCE

SECTION IX: TROUBLESHOOTING GUIDE

SECTION X. PACKING LIST

SECTION XI. STORAGE & TRANSPORT

ENVIRONMENT

SECTION XII. WARRANTY STATEMENT

REMARKS:

**The pictures here are for reference only.
Real products shall prevail. The parameters
and pictures in this manual are subject to
change without prior notice.**

SECTION I. CONTACT INFORMATION

Thank you for purchasing our device. Before operating the device, please fully read the manual and this manual should be saved for later use.

DENJOY DENTAL CO., LTD will take the responsibility for the security, reliability, capability under the following conditions:

1. The installation, debugging, maintenance should be adjusted by the approbatory technician by our company or obtained related nation quality level license professions.
2. The power supply shall be in conformity with the relevant provisions of the state and the use requirements of device itself.
3. The device should be operated by licensed dental professionals with medical applied skill. The whole operation process should follow user's manual strictly.

DENJOY DENTAL CO., LTD has right to improve shape and structure of the device, change any information and technical specification of this manual all the time, and no need to notice the user in advance.

CONTACT INFORMATION

The device is manufactured by:

DENJOY DENTAL CO., LTD

Address: F4, Building A4, Lugu Medical Device Park,
No.229 Guyuan Road, Changsha, 410205 P. R. China

Authorized European Representative:

Company name: LANDLINK GMBH

Address: DORFSTRASSE 2/4, 79312 EMMENDINGEN,
GERMANY

SECTION II. DESCRIPTION

Pulp Tester DY310 is a device to examine the vitality of dental pulp using the electrical stimulation. During the pulp test, the current stimulates intradental nerve, and give severe pain to patients. Some studies were accomplished to measure the responses of subjects by stimulating over the sensory threshold to determine whether the nerve of pulp in the tooth remains alive. So It can accurately read the pulp's livingness in a very highly efficiency way.

SECTION III. COMPONENTS AND FEATURES



- A. Test electrode
- B. Stainless hook
- C. Control part
- D. Probe cable



Test electrode 2pcs,
Probe cable 1pc

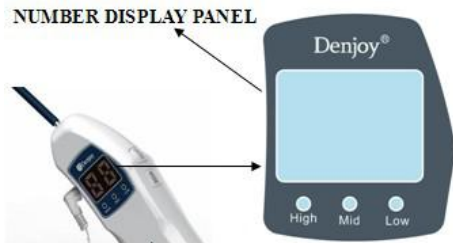
Stainless hook 4pcs,



Press ON/OFF button for 2S to turn on the device.



Press MODE button to set the speed of number change.



“High” “Mid” “Low” stands for different modes for speed of number change.

Features

- Preset speed mode (high-mid-low speed)

A gentle, pulsed stimulus begins to increase at a rate of high-mid-low speed

- Specifically designed for patient comfort

If the patient indicates perception, simply release the button. The stimulus stops immediately, but the numbers remain frozen on the face for about 3 minutes.

- Convenient to operate

Peak of stimulus current reaction numerical value---80.

Between 0-39, the patient feels ache and anesthesia, it means alive teeth nerve






Between 40-79, with above-mentioned reaction, it means part of teeth nerve dead








Reach 79, no above-mentioned reaction, dead teeth nerve

- The device turns itself off three minutes later after operation (No wasted batteries.)

SECTION IV. SYMBOL

The following symbols may appear in this manual, on the label, or on it's accessories. Some of the symbols represent standards and compliances associated with the endo motor and its use.

	Consult accompanying documents
	Cautions
	Authorized Representative in the European Community
	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Sterilizable up to the temperature specified at most

	Date of manufacture.
	Manufacturer
SN	Specifies serial number
	Type BF applied part
	Refer to instruction manual / booklet
	Direct current
	The device should not be used after the end of the shown or the day
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

SECTION V. MAIN TECHNICAL INDEX

Model Name DY310

Anti-shock type internally powered equipment



Anti-shock level

Class BF

Degree of protection from ingress of liquids: None

Operation mode

Continuous Operation

Rated voltage:

9.0V DC

Net weight:

about 100g

Gross weight:

about 350g

SECTION VI. OPERATION

1. Make the probe cable link with the cable socket of the control part; afterwards insert the stainless hook and the test electrode into the interface of the device.

2. Strictly separate the tooth which will be measured from the saliva , blow the surface of the tooth until it is dry , so as to forbid the stimulation electric current to conduct from the gum, or else there will appear a false stimulus current. You have to particularly pay attention to the near joint's dryness, for forbidding the current conduct from the near joint to the near tooth, or else there will appear a false stimulation current signal.

3. Hang the stainless hook on any side of the mouth, then select different speed mode (different speed: high means high speed, mid means middle speed, low means

low speed)

4. Paste a spot of conducting glue or toothpaste on the contact interface (1/3 slice side) between test electrode and selected tooth.

Then press the power switch.

Then lay the test electrode on the on the surface of selected tooth. Afterwards, the unit will be activated and simultaneously the figure keeps rising on the screen.

5. When the patient slightly feels toothache, or anesthesia, you should take the test electrode away from the tooth and observe the figure on the screen in order to record it; this figure is the tooth's stimulation current reaction number.

6. Peak of stimulus current reaction numerical value is 80. Between 0-40, the patient who has the reaction of ache and anesthesia, the dentist can be sure that the nerve is still alive. Only the numerical value go up to 40-80, the patient has the above-mentioned reaction, the dentist can be sure that part of the teeth nerve has been dead! When the numerical value has reached 80, but the tooth has no above-mentioned reaction, this shows the nerve has already been dead!


7. After operation, the measuring result remains frozen


on the surface of LCD screen for 3 minutes and then the unit will switch off automatically.


* After switch the machine on, while the display screen shows LO, its means the battery needs to be charged.


SECTION VII. SAFETY PRECAUTIONS

a). Before operation, you have to read this usage manual carefully.


b).  CAUTION: Persons having a history of photosensitive reactions or who are using photosensitizing drugs should not be exposed to light from this unit.


c).  CAUTION: Set the battery in a properly way connecting positive with negative pole.


d).  CAUTION: Keep away from bump into hard stuff!


e).  CAUTION: Equipment not suitable for use in

the presence of flammable anesthetic mixture with air or nitrous oxide.

f).  To keep the safety operation, we suggest that check your local AC power supply voltage before you buy this product oversea.

g).  CAUTION: Persons having a history of photosensitive reactions or who are using photosensitizing drugs should not be tested by pulp tester.

h).  CAUTION: Only experienced professional and well-trained operator can use this machine.

i).  The pulp tester should be placed in the original packing box in a dry and clean cupboard. Please take out the battery of the unit during the long period of nonuse!

SECTION VIII. MAINTENANCE

1. This device cannot be dismantled privately; otherwise the unit will be damaged wholly.

2. Please use the original charger, any other charger may result in the damage of the battery and the controlled electric circuit; even the machine will be greatly damaged.

3. After using this unit, the dental professionals must cover the machine with sterilized sheet.

4. The unit should be scrubbed by pure water or ethanol and follow the standard disinfection procedure to disinfect the materials. Then the pulp tester should be placed in the original packing box in a dry and clean cupboard, in case of its drop onto the floor.

SECTION IX: TROUBLESHOOTING GUIDE

When trouble is found, check the following again before contacting your dealer. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. In this case, please contact your dealer.

Problems	Cause & Solution
The device can not be	The batteries out of power. Charge the batteries

turned on.	Batteries disorder. Reinstall the batteries.
The light indicator has no changes	Button of speed mode (high-mid-low speed) is broken.
The device can not work normally during the operation.	Make sure that connection plug of probe cable is in good contact with cable socket of control part.
	Make sure that all connection cables are in good order.
	Make sure that test electrode connection is well and stable. The front part of test electrode can seamlessly contact with teeth facing.
	Make sure that stainless hook connection is well and stable.
	Make sure that the preparation treatment of teeth has been made before operation.

SECTION X. PACKING LIST

Standard accessories contain:

. Control part	1pc
. Test electrode	2pcs
. Probe cable	1pc

. Stainless hook	4pcs
. User manual	1pc

SECTION XI. STORAGE & TRANSPORT ENVIRONMENT:

OPERATING CONDITIONS

Ambient temperature: 5°C ~ 40°C

Relative humidity range: ≤80%

Atmospheric pressure: 70kPa ~ 106kPa

STORAGE AND SHIPPING CONDITIONS

Ambient temperature: -40°C ~ 55°C

Relative humidity range: ≤80%

Atmospheric pressure: 50kPa~ 106kPa

Equipment is not suitable for storage in the presence of sunlight, rain, dust, corrosive gasoline and volatile without poor ventilation.

Transportation is applicable to all common methods.

SECTION XII. WARRANTY STATEMENT

This device described below has been fully inspected and confronts to the current products specification.

This device is guaranteed for its designated use, against original defects in materials and workmanship for a period of 12 months from date of purchase.

Products warranty or service will not be extended if

(1) The product is repaired, modified, misused, disassembled, or using the parts are not provided by the manufacturer. (2) The serial number of the product is defaced or missing.

The guarantee for accessories is 6 months. All accessories of the device are damaged or needed to be renewed, the user can purchase new accessories from the seller.

WARNING

The device is not repairable by user and contains no user serviceable parts. No modification of this equipment is allowed. The user must check that the equipment functions safely and see that it is in proper working condition before being used. The manufacturer does not require such preventive inspections by other persons.

Please contact the sales distributor directly from whom you have purchased this device for user's record and further after-sale service.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The [DY310] is intended for use in the electromagnetic environment specified below. The customer or the user of the [DY310] should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The [DY310] 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 [DY310] is suitable for use in all establishments other than domestic, and may be used in domestic
Harmonic emissions	Class A	

IEC 61000-3-2		establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	<p>Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [DY310] or shielding the location.</p>

Table 2

Guidance and manufacturer's declaration - electromagnetic emissions			
The [DY310] is intended for use in the electromagnetic environment specified below. The customer or the user of the [DY310] 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	±2 kV for power	±2 kV for power	Mains power quality should

transient/burst IEC 61000-4-4	supply lines ± 1 kV for input/output lines	supply lines	be that of a typical commercial or hospital environment. The electrical fast transient burst (EFT) is generated by the switching of inductive loads. Separation between the equipment and other loads shall be considered before installation. Mains filter is required, if necessary.
Surge IEC	± 1 kV line(s) to	± 1 kV line(s) to	Mains power quality should

61000-4-5	line(s) ± 2 kV line(s) to earth	line(s)	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	<p>$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle</p> <p>$40\% U_T$ (60% dip in U_T) for 5 cycle</p> <p>$70\% U_T$ (30% dip in U_T) for 25 cycle</p> <p>$< 5\% U_T$ ($> 95\%$ dip in U_T)</p>	<p>$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle</p> <p>$40\% U_T$ (60% dip in U_T) for 5 cycle</p> <p>$70\% U_T$ (30% dip in U_T) for 25 cycle</p> <p>$< 5\% U_T$ ($> 95\%$ dip in U_T)</p>	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [DY310] requires continued operation during power mains interruptions, it is recommended the [DY310] be powered from an

	for 5s	for 5s	uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	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 application of the test level.			

Table 3

Guidance and manufacturer's declaration - electromagnetic emissions
The [DY310] is intended for use in the electromagnetic environment specified below. The customer or the user of

the [DY310] 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	3V(rms) 150KHz to 80MHz	3V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the [DY310], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d \neq 1.2 \sqrt{P}$ $d \neq 1.2 \sqrt{P} \quad 80 \text{ MHz} \sim 800$

-4-6	3 V/m		MHz
	80MHz		$d=2.3\sqrt{P}$ 800 MHz~2.5
	to		GHz
Radiat	2.5GHz	3 V/m	where p is the maximum
ed RF			output power rating of the
IEC			transmitter in watts (W)
61000			according to the transmitter
-4-3			manufacturer and d is the
			recommended separation
			distance in metres (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
			Interference may occur in
			the vicinity of equipment
			marked with the following
			symbol:



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) telephones 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 the [DY310] is used exceeds the applicable RF compliance level above, the [DY310] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [DY310].

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the [DY310]			
<p>The [DY310] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [DY310] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [DY310] as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
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 metres (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 separation distance for 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.

WARRANTY REGISTRATION FORM

Item Name: _____

Model Name: _____

Serial No.: _____

Date of Purchase: _____

Name: _____

Address: _____

Phone: _____

Email: _____

Name of Distributor: _____

Authorized Distributors: _____

Stamp and Signature