

Denjoy TieApex Apex Locator User Manual

Home » Denjoy » Denjoy TieApex Apex Locator User Manual







Contents

- 1 TieApex Apex Locator
- **2 GENERAL INTRODUCTION**
- **3 MAIN TECHNICAL INDEX**
- **4 COMPONENTS**
- **5 FUNCTIONS**
- **6 OPERATION**
- **7 SAFETY PRECAUTIONS**
- **8 MANTENANCE & SERVICE**
- 9 TOUBLESHOOTING GUIDE
- **10 ENVIRONMENTAL**

REQUIREMENTS

- 11 PACKING LIST
- 12 WARRANTY
- 13 Documents / Resources
 - 13.1 References

TieApex Apex Locator

TieApex Apex Locator

- *The unit must be installed by a qualified engineer.
- *Only for use by dental professionals.
- *Read this operation manual carefully before installation or operation.



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.

GENERAL INTRODUCTION

1.1. CONTACT INFORMATION

Apex Locator is manufactured by: DENJOY DENTAL CO., LTD

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

Website: www.denjoy.cn
E-mail: denjoy@denjoy.cn

Manufacturing:

Company name: DENJOY DENTAL CO., LTD

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

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

1.2. PRODUCT DESCRIPTION

Thank you for purchasing our apex locator.

Model: TieApex

Trade Name: FreePex

For optimum safety and performance, read this manual carefully before use for operation instruction, care and maintenance. Please keep this user's manual for future reference.

Our company 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 our device use is suitable for national regulation and our FreePex's requirement.
- 3. The operation of our device should be operated by licensed professions; the operator should be specialized in medical applied skill. The whole operation process should according to user's manual strictly.

Working Principle:

FreePex apex locator adopts the most up-to-date multi-frequency, ARM, DSP and auto-calibration technology. And the accuracy can reach 95% or more in clinical cases.

Product application range and features FreePex apex locator is a kind of highly precise device used for determining the position of apex of root canal.

Features:

- 1. Self-Calibration, 98.4% accuracy.
- 2. Beeps determine the apex location.
- 3. Adjustable display of apical constriction .
- 4. Built-in buzzer with adjustable volume.
- 5. New probe cable with long operating life.
- 6. Ergonomic design, adjustable viewing angle.
- 7. Multi-frequency circuit technology and foldable body.
- 8. Power-saving, timing automatism power off function.
- 9. Built-in high-capacity lithium battery and low power consumption

1.3. SYMBOL DESCRIPTIONS

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 apex locator and its use.

V	Caution: Consult accompanying documents
M	Date of manufacture.
	Manufacturer
SN	Specifies serial number
*	Type BF applied part
	Refer to instruction manual / booklet
===	Direct current
135°C	Sterilizable up to the temperature specified at most
\Box	The device should not be used after the end of the shown or the day
Z	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such wast e separately for special treatment is necessary.
山)))	Alarm indicator displayed on the LCD screen
	Battery indicator displayed on the LCD screen

MAIN TECHNICAL INDEX

- 1. Classification: Internally powered equipment
- 2. Degree of protection against electric shock —Type BF applied part



- 3. Degree of protection from ingress of liquids: None
- 4. Operation mode: Continuous
- 5. Display mode: LED Display
- 6. Charger: Input voltage: AC 100-240V, 50/60Hz, 0.2A Chargeable battery: 3.7V, 800mAh
- 7. Dimension: 120×110×25mm
- 8. Weight: about 420g
- 9. Indication range and accuracy Indication range: from 1.0 to ov Accuracy: 95% or more

COMPONENTS



- 1 Power On/Off
- 2 Charger Socket
- 3 Cable Socket
- 4 Supporter

- 5 Sound Adjustment Button6 Apical Constriction Area Adjustment
- 7 LCD Display

Main Accessories



Probe Cable



File Holder



Mouth Hook



Calibrator

FUNCTIONS

LCD Description:

- a. Green WL Bar: Represents approaching apical constriction of apex of root-canal.
- b. Yellow WL Bar: Reach apical constriction of root-canal.
- c. Red Bar: File over the apex.
- d. Digit Display: the distance between the file and apex.

Note: The display on the front panel 1.0, 0.5, etc. does not indicate to the apical distance unit is 1.0mm, 0.5mm it prompts the operator which is close to the root canal apical needle.

OPERATION

- 5.1. The plug of the probe cable should be completely inserted into the socket on the right side of the main body.
- 5.2. Extended pressing power on/off button. Extended pressing power on/off button for 2 seconds to turn on/off the device.
- 5.3. Please connect the file holder to probe cable and insert the mouth hook into the interface, then hang it up at any side of the sufferer's mouth.
- 5.4. Clip the metal part of the endodontic file with the holder. Then insert the endodontic file into the root-canal with the file holder.



5.5. Hang the mouth hook up at any side of the patient's mouth, insert the file into the teeth, when the endodontic file reaches the position which the number indicated in the color screen is 0.5. Then please fasten the file with the rubber positioning ring on the reference point of the tooth crest. And this means that the file has reached the position of the apical constriction. (Generally we suggest to use 0.5 for measurement the length of root canal). Note: Please do not make the measurement when in charge.

5.6. IMPORTANT STEP

Deciding the working length of root canal Measure the distance from the bottom of rubber positioning ring to the tip of the file. Note down this number. So this number need to minus 0.1-0.5mm is the most suitable working length of root-canal.

REMARKS: The working length of root canal varies from each other for the reason of different shapes of teeth and root-canal.

5.7. After operation, please switch off the device. If the dentists forgot to switch off the device, the device will automatically be power off.

Self-Calibration:

Insert the calibrator test instrument into the socket, if the LCD shows 0.5, it means that the control part (mainbody) work normally.

Insert the probe cable into the cable socket, then connect the file holder, mouth hook and calibrator as a circle. if the LCD shows 0.5, it means that the accessories work normally. Please see the image below.



For ACCURATE MARESUREMENT:

- Make sure that stainless hook entirely contact patient's mouth mucosa.
- · Check all connections
- Make sure that when the device is switched on, the device can complete self-checking procedure automatically and successfully.
 - When following situations appear, please use paper point part to make root canal dry to increase accuracy of measurement.
- It will cause bad electrical conduction between root canal and metal or dental crown if overfull liquid.

Other problems need to check:

- Make sure that endodontic file was getting through the top hole of the root canal, the loose file will lead to measure incorrectly.
- If the diameter of apical is more than 0.4mm, it will affect the accuracy.
- Complicated root canal environment also will affect the accuracy.
- Make sure that the battery is not too low, or it will lead to faulty measurements.
- Avoiding endodontic file and probe contacting metal prosthesis, or it will form the earth current and lead to inaccurate indicating root tip.
- If the root canal is too dry, please inject the NaOCI into the apical foramen.

SAFETY PRECAUTIONS

CAUTIONS:

- **6.1.** Before operation, you have to read user manual carefully.
- **6.2.** Like all of the other electric facilities, this device has an electromagnetism disturbance. When there is a patient who is now using the cardiac pacemaker, or there is an electronic operation, please don't put the machine around. The cardiac pacemaker sufferer, viz. the serious cardiac pulse abnormality sufferer, is forbidden to use this machine.
- **6.3.** Please put in the battery before use. Make sure that the power of the battery is in sufficient supply to guarantee the correct measurement result.

When change the battery, do not mix the old battery with the new one and mix the alkali battery with the manganic one.

Please take off the battery in the event of longtime nonuse or long –distance transit.

- **6.4.** Please use the file with the resin handle rather than mental one. Even when using the file with the resin handle, please notice that the fingers should be avoided touching the mental part of file.
- **6.5.** Please clip the upper portion of the file rather than the down portion with the holder, other wise, the metal part of the holder and the resin part of the file would be damaged. The damaged holder will affect the measure result.
- **6.6.** When the file accidentally touches the inner part of the root-canal, the reading of scale will get a bit abnormality, then will get right automatically a few seconds later.
- **6.7.** The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- **6.8.** The enclosure of the main body of device is not designed to give any protection against ingress of water. Please keep the device away from any harmful ingress of water.

MANTENANCE & SERVICE

7.1. MANTENANCE

The device is maintained free of charge and doesn't require any routine maintenance within warranty period. The device cannot be repaired.

Do not modify and disassemble the device. 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. Expected life time: 5 years.

7.2. CLEANING AND DISINFECTION

MAIN BODY CLEANING INSTRUCTION

When the surface of main body is polluted, please rub the surface with dry soft cloth ONLY.

REMARKS: Any liquid lotion like ethanol, banana oil and light oil are not allowed.

PROBE CABLE CLEANING INSTRUCTION

Please wipe the probe cable with the soft cloth stained with ethanol and reuse it after it is completely dry.

MOUTH HOOK AND FILE HOLDER DISINFECTION INSTRUCTION

The front part of the file holder, which is easily get polluted with rubbish and liquid medicine, should be disinfected by the ethanol.

Mouth hook and file holder should be disinfected at temperature 135°C for 10 minutes and disinfection by autoclave is preferred. The disinfection can be repeated 200 times. The effect of repeated disinfection on the product has been verified and has no effect on the performance and normal use of the product.

TOUBLESHOOTING GUIDE

Question: After switch on, the LCD screen has no reaction.

Answer:

- a. Check that the power of the battery is in sufficient supply.
- b. Check that hold the power on/off key for at least 2 seconds.
- c. Check that the device can not be switched on when charging.

Question: No alarm sound

Answer:

- a. Check the sound adjustor button of panel on top of unit.
- b. The file has not reached the point less than 2.0 at which the machine will give an alarm.

Question: NO changes or incorrect reading on the LCD screen Answer:

- a. Do not clip the file with the holder firstly and switch on the device secondly.
- b. Remember to hang mouth hook up at any side of the sufferer's mouth.
- c. Check probe cable connections both at unit and at AC outlet to be sure they are properly seated.
- d. The mental part of the file holder may be polluted or corroded.

Question: The device can't be charged normally.

Answer:

a. The charger is not connected properly.

b. The charger is broken.

c. The battery is broken.

Question: Error Code E1

Answer: calibration error, please restart the device.

Question: Error Code E2

Answer: Short circuit indication for accessories.

ENVIRONMENTAL REQUIREMENTS

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.

PACKING LIST

Mainbody	1pc	Probe Cable	1 pc
File Holder	2 pcs	Mouth Hook	4 pcs
Probe Needle	2 pcs	Calibrator	1 pc
Charger	1 pc	User manual	1 pc

WARRANTY

The device is maintained free of charge and doesn't require any routine maintenance within warranty period. Do not modify and disassemble the device.

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

This instrument 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 from the manufacturer.

WARNING

Disposal Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being. Battery Disposal: Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

Lithium battery is intended to be changed only by service personnel using a tool. Replacement by inadequately trained personnel could result in burn or explosion hazard.

The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.

The device is not repairable 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 sales representative from whom you have bought this device for user's record and further aftersale service.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions

The [TieApex] is intended for use in the electromagnetic environment specified below. The customer or the user of the [TieApex] should assure that it is used in such an environment

Emissions test	Complianc e	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The [TieApex] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any int erference in nearby electronic equipment.
RF emissions CISPR 11	Class [B]	
Harmonic emissions IEC 61000-3-2	Class A	The [TieApex] is suitable for use in all establishments oth er than domestic and those directly connected to the public low-voltage power supply network that supplies building
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	s used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic emissions

The [TieApex] is intended for use in the electromagnetic environment specified below. The customer or the user of the [TieApex] 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 ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthet ic material, the relative humidity should be at least 30 %
Electrical fast transient/ burst IEC 61000-4-4	Power supply lines: ±2 kV input/outp ut lines: ±1 k V	Power supply lines: ±2 k V input/out put lines: ±1 kV	Mains power quality should be t hat of a typical commercial or hospital environment.
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV. line(s) to earth: ±2 kV.1 00 kHz repetition freque ncy	line(s) to line(s): ±1 kV. line(s) to earth: ±2 kV. 1 00 kHz repetition freque ncy	Mains power quality should be t hat of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltag e variations on power s upply input lines IEC 61000-4 -11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 7 0% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 27°0° and 315°0% 1 cycle A nd 70% 25/30 cycles Single phase: at 0 0% 300 cycle	Mains power quality should be t hat of a typical commercial or hospital environment.
Power frequency (50/6 0Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60H z	30 A/m 50Hz/60 Hz	Power frequency magnetic field s should be at levels characteristic of a typical locatio n in a typical commercial or hos pital environment.

NOTE UT is the a.c. mians voltage prior to application of the test level.

Table 3

Guidance and manufacturer's declaration – electromagnetic emissions				
	ded for use in the electro d assure that it is used in	•	pecified below. The customer or the user	
Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance	

onduced RF IEC6100 0-4-6	150KHz to 80MHz: 3 Vrms 6Vrms (in ISM and a mateur radio bands) 80% Am at 1kHz	150KHz to 80MHz: 3V rms 6Vrms (in ISM and am ateur radiobands) 80% Am at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the [TieApex], including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: d=0.35 \[\frac{P}{P} \] ;d=1.2 \[\frac{P}{P} \]	
Radiated RF IEC61000-4-3	10V/m, 80% Am at 1k Hz	10V/m, 80% Am at 1k Hz	80MHz to 800MHz d=1.2 \$\sqrt{P}\$ 800MHz to 2.7GHz d=2.3	Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, dis the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. 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 w ith accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site s urvey should be considered. If the measured field strength in the location in which the [TieApex] is used exceeds the applicable RF compliance level above, the [TieApex] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [TieApex]. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V /m.

Recommended separation distances between portable and mobile RF communications equipment and the [TieApex]

The [TieApex] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [TieApex] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [TieApex] as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter m				
output power of transmit ter W		80MHz to 800MHz	800MHz to 2.7GHz		
	MHz d=3.5 √ <i>P</i>	d=1.2 √P	d=2.3 √P		
0,01	1	0.12	0.23		
0,1	1	0.38	0.73		
1	1	1.2	2.3		
10	1	3.8	7.3		
100	1	12	23		

For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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.

Table 5

Guidance and manufacturer's declaration - electromagnetic emissions

The [TieApex] is intended for use in the electromagnetic environment specified below. The customer or the user of the [TieApex] should assure that it is used in such an environment

	Test Freq uency (M Hz)	Ban d a) (M Hz)	Service a)	Modulat ion b)	Modulati on b) (W)	Distance (m)	IMMUNIT Y TEST LE VEL (V/m)
Radiated RF IEC6 10004- 3	385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
(Test specific ations for ENCLOSUR E POR TIMM	450	380 -39 0	GMRS 460,F RS 460	FM c) ± 5 kHz d eviation 1 kHz s ine	2	0,3	28
UNITY to RF wireles	710			Pulse			
S	745	704 – 787	LTE Band 13 ,17	modulation b) 2	0,2	0,3	9
	780			17 Hz			
	810	800 –	GSM 800/90 0,	Pulse modulati	2	0,3	28
	870						20
	930	960	TETRA 800, iDEN 820, CDMA 850, LTE Band 5	on b) 18 Hz			
	1720	1 700– 1990	GSM 1800;	Pulse modulation b) 217 Hz		0,3	28
	1845		CDMA 1900; GSM 1 900; DECT; LTE B and 1, 3, 4, 2 5; UMTS		2		
communicati ons	1970						
equipment)	2450	2 400 – 2 57 0	Bluetooth, W LAN, 802.11 b/g/n, RFID 2450, LTE	Pulse modulation b) 2 17 Hz Band 7	2	0,3	28
	5240	5 100 – 5 80 0	WLAN 802.1 1 a/n	Pulse	0,2	0,3	9
	5240			modulation b)			
	5785			217 Hz			

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the

ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
- c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not

represent actual modulation, it would be worst case.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

WARRANTY REGISTRATION FORM

Item Name:
Model Name:
Serial No.:
Date of Purchase:
Name:
Address:
Phone:
Email:
Name of Distributor:
Authorized Distributors:
Stamp and Signature

alandental.com

Documents / Resources



<u>Denjoy TieApex Apex Locator</u> [pdf] User Manual FreePex, TieApex Apex Locator, TieApex, Apex Locator, Locator

References

- | Dental Instruments Australia | Dental Equipment Supplies For Sale Alandental.com
- © Endo Devices, Dental Consumables, Biological Material | Denjoy
- User Manual

Manuals+, Privacy Policy

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