USER MANUAL

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.

CE

Contents

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 1: 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.


Caution: Consult accompanying documents


Date of manufacture.


Manufacturer

Specifies serial number


Type BF applied part


Refer to instruction manual / booklet


Direct current

Sterilizable up to the temperature specified at most


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.

Alarm indicator displayed on the LCD screen

Battery indicator displayed on the LCD screen

SECTION 2: 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

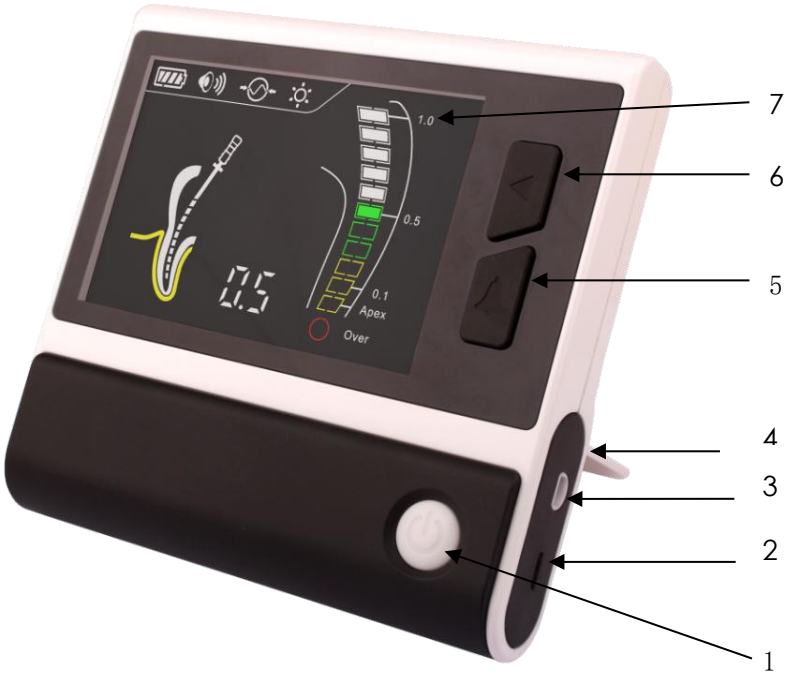
6. Charger:
   Input voltage: AC 100-240V, 50/60Hz , 0.2A
   Chargeable battery: 3.7V, 800mAh

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

SECTION 3: COMPONENTS

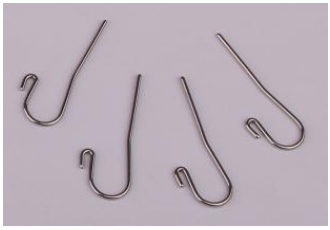


1 Power On/Off
2 Charger Socket
3 Cable Socket
4 Supporter
5 Sound Adjustment Button
6 Apical Constriction Area Adjustment
7 LCD Display

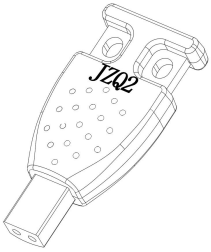
Main Accessories

Probe Cable

File Holder



Mouth Hook



Calibrator

SECTION 4: FUNCTIONS

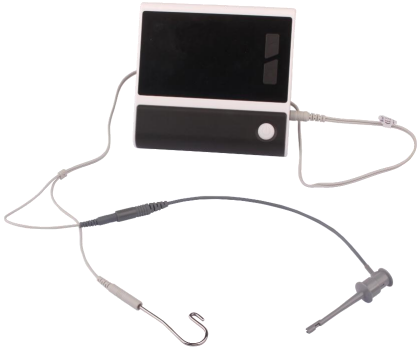
LCD Description:

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.

SECTION 5: 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 NaOCl into the apical foramen.

SECTION 6: 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.

SECTION 7: 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℃ 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.

SECTION 8: 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.

SECTION 9: ENVIRONMENTAL REQUIREMENTS

OPERATING CONDITIONS
Ambient temperature: 5℃ ~ 40℃
Relative humidity range: ≤80%
Atmospheric pressure: 70kPa~ 106kPa

STORAGE AND SHIPPING CONDITIONS

Ambient temperature: -40℃ ~ 55℃
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 10. 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

SECTION 11：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 after-sale 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	**Compliance**	**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 interference in nearby electronic equipment.
RF emissions CISPR 11	Class [B]	The [TieApex] is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

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	±8 kV	±8 kV	Floors should be

discharge (ESD) IEC 61000-4-2	contact ±15 kV air	contact ±15 kV air	wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/burst IEC 61000-4-4	Power supply lines： ±2 kV input/output lines： ±1 kV	Power supply lines：±2 kV input/output lines：±1 kV	Mains power quality should be that 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. 100 kHz repetition	line(s) to line(s)：±1 kV. line(s) to earth：±2 kV. 100 kHz repetitio	Mains power quality should be that of a typical commercial or hospital environment.

	frequency	n frequen cy	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	Mains power quality should be that of a typical commercial or hospital environment.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	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. mians voltage prior to application of the test level.			

Table 3

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**
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio	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

	amateur radio bands) 80% Am at 1kHz	bands) 80% Am at 1kHz	the equation appropriate for the frequency of the transmitter. Recommended separation distances: d=0.35$\sqrt{P}$; d=1.2$\sqrt{P}$	
Radiated RF IEC61000-4-3	10V/m, 80% Am at 1kHz	10V/m, 80% Am at 1kHz	80MHz to 800MHz： d=1.2$\sqrt{P}$ 800MHz to 2.7GHz： d=2.3$\sqrt{P}$	Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is 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 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 [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.

Table 4

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 output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz **$d=3.5\sqrt{p}$**	**80MHz to 800MHz** **$d=1.2\sqrt{p}$**	**800MHz to 2.7GHz** **$d=2.3\sqrt{p}$**
0,01	/	0.12	0.23
0,1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	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.

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							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless	**Test Frequency** (MHz)	**Band a)** (MHz)	**Service a)**	**Modulation b)**	**Modulation b)** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
	385	380–390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380–390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	810 870	800 –	GSM 800/900,	Pulse modulati	2	0,3	28

com munic ations equip ment)	930	960	TETRA 800, iDEN 820, CDMA 850, LTE Band 5	on b) 18 Hz			
	1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulati on b) 217 Hz	2	0,3	28
	2450	2 400 – 2 570	Bluetoot h, WLAN, 802.11 b/g/n, RFID 2450, LTE	Pulse modulati on b) 217 Hz	2	0,3	28

			Band 7				
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
	5240						
	5785						

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:

$$E = \frac{6}{d}\sqrt{P}$$

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