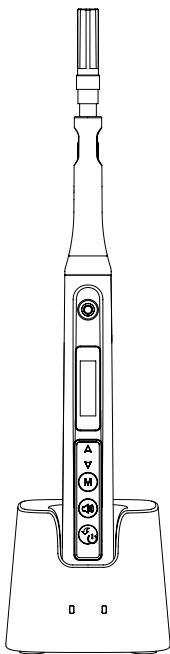


Dental Anesthesia Device Instruction Manual

Please read this manual before operating



MODEL: Super Pen
Star Pen

www.glwoodpecker.com

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

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1 Product introduction

1.1 Preface

Guilin Woodpecker Medical Instrument Co., Ltd is a professional manufacturer researching, developing, and producing dental products. Woodpecker owns a sound quality control system. Guilin Woodpecker Medical Instrument Co., Ltd has two brands, Woodpecker and DTE. Its main products include Ultrasonic Scaler, Curing light, Apex locator, Ultrasurgery, Endo Motor, etc.

1.2 Product description

This device features:

- 1) Wireless portable, wireless charging, one-key start, easy to use
 - 2) Equipped with 3 modes with 9 injection speeds, precise control, choose according to your need
 - 3) Automatically aspirate when the injection is stopped, avoiding the risk of getting into the blood
 - 4) Dual pressure dynamic feedback technology, uniform drug delivery in different density tissues, patented technology
 - 5) Periodontal ligament injection mode (PDL)
- (Note: Only Super Pen models have 4), 5) functions)

1.3 Model and specification

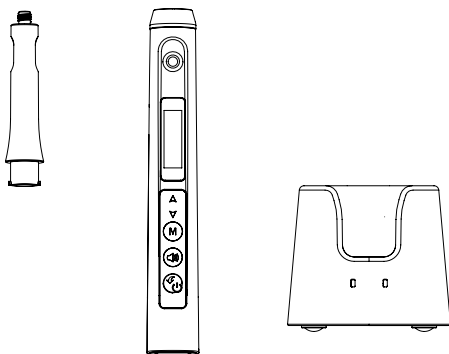
Super Pen: There is a battery in the charging base, with dual pressure feedback, periodontal ligament(PDL) injection mode.

Star Pen: There is no battery in the charging base.

Please refer to packing list for device configurations.

1.4 Structure and composition

The device is composed of charging base, handpiece, Cartridge Holder, power adapter, etc.



1.5 Scope of application

This device is intended for use only in subcutaneous or intramuscular injections of local anesthetic for dental applications. It should not be used for intravascular (IV) or other routes of administration. This device should be used only by practitioners who are familiar with, and observe applicable labeling regarding the use of local anesthetics for dental applications.

This device needs to be used in conjunction with local anesthetics and syringe needles.

1.6 Contraindication

- (1) The doctor with a pacemaker is disabled.
- (2) Patients with cardiac pacemakers (or other electrical equipment) and warned not to use small appliances (such as Electric razors, hair dryers, etc.) are disabled.
- (3) Hemophilia patients are banned.
- (4) Patients with allergic constitution and history of drug allergy are prohibited from using this device.
- (5) Use with caution in patients with heart disease and young children.
- (6) Pregnant women or lactating women, women of childbearing age who have recently had a birth plan should be cautious to use this device.

(7) Patients with oral and maxillofacial infections, unhealed oral mucosal diseases, periapical periodontitis, gum disease, periodontal disease, oral tumors, etc. should be cautious to use this device.

(8) Patients with mental disturbance should be cautious to use this device.

(9) Patients with severe systemic or systemic diseases such as heart, liver, kidney, hematopoietic system, digestive system and endocrine system should be cautious to use this device.

(10) Patients with active periodontal disease are prohibited from intra-ligament injections.

1.7 Warnings

1.7.1 Please carefully read this Instruction Manual before first operation.

1.7.2 This device should be operated by professional and qualified dentist in qualified hospital or clinic.

1.7.3 Do not directly or indirectly place this device near heat source. Operate and store this device in reliable environment.

1.7.4 This device requires special precautions regarding electromagnetic compatibility (EMC) and must be in strict accordance with the EMC information for installation and use. Do not use this equipment especially in the vicinity of fluorescent lamps, radio transmitting devices, remote control devices, handheld and mobile high frequency communication devices.

1.7.5 Long time use of this device may result in handpiece overheat, thus it should be left to cool for use. If the handpiece is overheated frequently, please contact local distributor.

1.7.6 Please use the original cartridge holder. Otherwise it will be unusable or cause adverse consequences.

1.7.7 Please do not make any changes to the device. Any changes may violate safety regulations, causing harm to the patient. There will be no promises of any modification.

1.7.8 Please use original power adapter. Other power adapter will result in damage to lithium battery and control circuit.

1.7.9 The handpiece cannot be autoclaved. Use disinfectant of neutral pH value or ethyl alcohol to wipe its surface.

1.7.10 Before the handpiece stops working, the cartridge holder cannot be installed or removed, otherwise the device may be damaged.

1.7.11 This device needs to be used in conjunction with local anesthetics and syringe needles.

1.7.12 Use a cartridge that conforms to ISO 11499 (a container for local anesthetics).

1.7.13 Before starting the handle, please confirm that the cartridge holder has been installed correctly.

1.7.14 Please choose the injection speed of this device according to clinical needs.

1.7.15 The lithium battery of this device is not replaceable, and the wrong replacement of the lithium battery will lead to unacceptable risks.

1.7.16 If the device is not used for a long time, please charge it according to the standard charging and discharging method every 3 months.

1.7.17 Please fully charge the device before using it for the first time.

1.7.18 It is strictly forbidden to insert metal or other conductors into the charging socket of the charging base and the small holes at the end of the handle to avoid short-circuiting the internal circuit or burning the lithium battery.

1.7.19 Do not squeeze, vibrate or shake the battery, do not short-circuit the battery, or put the battery together with metal objects.

1.7.20 It is strictly forbidden to disassemble the battery without authorization, otherwise it will cause a short circuit or electrolyte leakage

1.7.21 Wireless charging will generate heat, and the surface temperature of charging base and handpiece will rise. It is

recommended that the time of contacting handpiece and charging base during wireless charging should not exceed 120 minutes.

1.8 Device safety classification

1.8.1 Type of operation mode: Continuous operating device.

1.8.2 Type of protection against electric shock: Class II equipment with internal power supply.

1.8.3 Degree of protection against electric shock: BF type applied part.

1.8.4 Degree of protection against harmful ingress of water: Ordinary equipment (IPX0).

1.8.5 Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

1.8.6 Applied part: Cartridge Holder.

1.8.7 The contact duration of applied part: 1 to 5 minutes.

1.9 Primary technical specifications

1.9.1 Battery:

Super Pen:

Lithium battery in charging base: 3.7V /2000mAh

Lithium battery in handpiece: 3.7V /200mAh

Star Pen: Lithium battery in handpiece: 3.7V /200mAh

1.9.2 Power adapter:

Input: ~100V-240V 50Hz/60Hz 0.4A Max

Output: DC5V/1A

1.9.3 Injection speed:

Super Pen	
Mode	Injection time of single anesthetic
H	35~105s
L	120~170s
PDL	190~310s

Star Pen	
Mode	Injection time of single anesthetic
H	45~150s
L	170~310s

1.10 Environment parameters

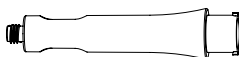
1.10.1 Environment temperature: +5°C ~ +40°C

1.10.2 Relative humidity: 30% ~ 75%

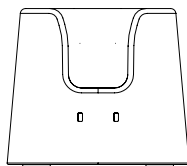
1.10.3 Atmospheric pressure: 70kPa ~ 106kPa

2 Installation

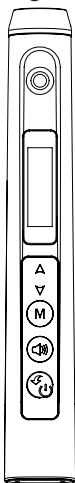
2.1 Basic accessories of product



Cartridge holder



Charging base

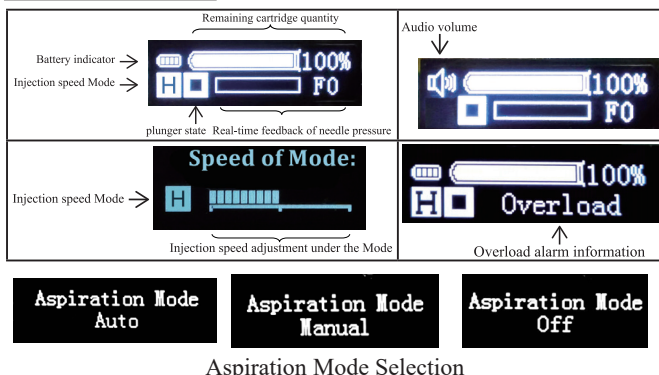


Handpiece



Power adapter

2.2 Display Screens



Aspiration Mode:

Auto: Auto aspiration starts once the injection stops.

Manual: During injection, short press the "start" button to stop the injection and then long press the "start" button to start aspiration manually

Off: The aspiration function is turned off.

2.3 Assembly and use of the cartridge holder

2.3.1 Before the first use and after treatments, please clean and disinfect the cartridge holder with disinfectant of neutral PH value, and sterilize it under high temperature and high pressure (134°C, 2.0bar ~ 2.3bar (0.20MPa~0.23MPa)).

2.3.2 The cartridge holder can only be used cooperatively with this device. Otherwise the cartridge holder or the handpiece will be damaged.

2.3.3 Before installing or removing the cartridge holder, please confirm that the handpiece has been shut down or stopped working, and the plunger has been reset to the initial state.

2.4 Installation of the cartridge holder

According to clinical needs, select the specifications of the disposable injection needle for oral cavity, install the

needle on the front end of the cartridge holder, and rotate it to tighten. [Figure 1]

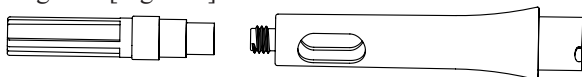


Figure 1

According to the clinical needs, put the anesthetic into the cartridge holder. [Figure 2]



Figure 2

Align the cartridge holder with the groove in the front hole of the handpiece, and then push it to the end [Figure 3], after the cartridge holder is pushed in to the end, turn the cartridge holder clockwise to lock the boss and the groove structure of the handpiece [Figure 4]. Gently pull the cartridge holder out to confirm that the cartridge holder is firmly installed.

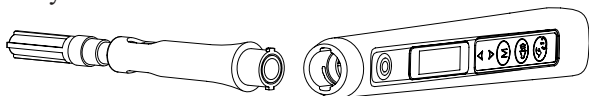


Figure 3



Figure 4

2.5 Removal of the cartridge holder

After the cartridge holder is shut down or stopped working, turn the cartridge holder counterclockwise to disengage the boss from the groove clamping structure of the handpiece, and then pull the cartridge holder out along the axis of the handpiece [Figure 5].

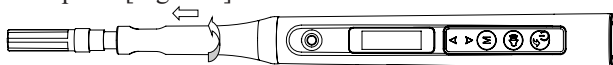


Figure 5

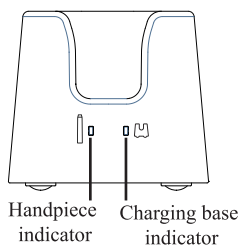
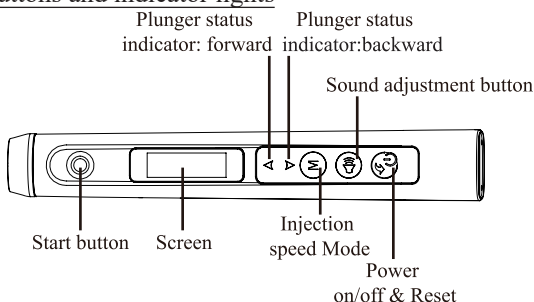
⚠ Warnings

- Before installing or removing the cartridge holder,

confirm that the handpiece has been shut down or stopped working, and the plunger has been reset to the initial state.
b) When installing the cartridge holder, confirm that the cartridge holder has been installed correctly. After installation, gently pull the cartridge holder out to confirm that the cartridge holder is firmly installed.

3 Function and operation of product

3.1 Buttons and indicator lights



3.2 Buttons operation instructions

a. Turn power on

Short press Power on/off & Reset button to  turn on the handpiece.

b. Turn power off

Long press the Power on/off & Reset button  to turn off the handpiece. If the plunger is not in the initial state before turning off, the plunger will first reset to the initial

state, and then the handpiece turns off.

c. Injection speed mode switch

Short press the Injection speed Mode button to (M) switch the injection speed.

d. Sound adjustment

Long press the sound adjustment button (C) to enter the sound adjustment, short press the sound adjustment button (C) to choose different volume levels, whether to play background music.

e. Injection speed mode setting

Long press the injection speed mode button (M) to enter the injection speed mode setting, then short press the speed mode button (M) to switch the mode that needs to be set, and short press the sound adjustment button (C) to adjust the injection speed of this mode.

f. Start injection

Short press the start button to start the injection.

g. Stop injection/Aspiration

When the injection is in progress, short press the start button to suspend the injection and aspiration at the same time.

h. Reset

After the injection is suspended, short press the Power on/off & Reset button (R) to reset the plunger to the initial state.

i. Aspiration Mode Selection

Long press the (M) button and at the same time short press the start button 3 times to enter the aspiration mode selection, Short press the (C) button to select different modes, short press the start button to confirm and exit.

3.3 Indicator lights status

Super Pen's indicator lights:

Indicator lights	Lights' status	Status description
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Plunger status indicator	The forward indicator flashes and the backward indicator is off	The plunger is advancing (injection is in progress)
	The forward indicator is off and the backward indicator flashes	The plunger reverses (resetting or aspiration)
	Both forward and backward indicators are off	The plunger is suspended
Handpiece indicator	off	The handpiece is not detected; or the handpiece is fully charged and the charging ends
	Flashing orange	The handpiece is charging
	Steady green (Turn off after 1min)	The handpiece is fully charged
Charging base indicator	off	The handpiece is not detected; or the handpiece is fully charged and the charging ends; or the internal battery of the charging base is low
	Flashing orange	The battery inside the charging base is charging
	Steady green	The battery inside the charging base is fully charged
	Steady orange	The battery level inside the charging base is 40% or less

Star Pen's indicator lights:

Indicator lights	Lights' status	Status description
Plunger status indicator	The forward indicator flashes and the backward indicator is off	The plunger is advancing (injection is in progress)
	The forward indicator is off and the backward indicator flashes	The plunger reverses (resetting or aspiration)
	Both forward and backward indicators are off	The plunger is suspended

Handpiece indicator	off	The handpiece is not detected; or the charging base is not connected to power
	Flashing orange	The handpiece is charging
	Steady green	The handpiece is fully charged
Charging base indicator	off	The charging base is not connected to power
	Steady green	The charging base is connected to the power supply

Cautions

1. When the handpiece battery sign indicates low battery, the battery may not be enough to support the handpiece to reach the maximum thrust value, and may not be able to complete a single working cycle, please charge in time.
2. If the handpiece is always in working condition, the machine may automatically stop due to overheating protection. If this happens, turn off the handpiece for a period of time until the handpiece's temperature has dropped before using it.
3. Please choose the injection speed of this device according to clinical needs.

3.4 Battery Charging

The handpiece has a rechargeable lithium battery inside. The Super Pen type charging base has a rechargeable lithium battery inside, while the Star Pen type charging base does not have a rechargeable lithium battery.

Insert the power adapter plug into the power socket of the charging base and confirm that the connection is complete, then align the front of the handpiece and put it into the charging base. According to the description of the indicator light in 3.3, judge whether it is being charged or fully charged.

Please unplug the power adapter in time when charging is complete.

3.5 Replacing Battery

If the use time of the device is significantly shorter than

the original time, you can contact the local distributor and manufacturer to replace the battery.

3.6 Cleaning and Sterilization

3.6.1 Cartridge holder cleaning

(1) Remove the cartridge holder from the handpiece.

(2) Use a cleaning brush to remove stains from holes and surfaces.

Cautions:

·Only the cartridge holder of this device can be cleaned and sterilized.

·The handpiece and charging base cannot be sterilized by autoclave (high temperature and high pressure), only neutral disinfectant or alcohol can be used to wipe the surface.

3.6.2 Cartridge holder sterilization

3.6.2.1 Sterilization of cartridge holder by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO17665) under consideration of the respective country requirements. Minimum requirements: 3 min at 134°C (in EU: 5 min at 134°C) Maximum sterilization temperature: 137°C.

3.6.2.2 After each use, it should be autoclaved according to the following steps:

1) Use a cleaning brush to remove stains on the surface of the cartridge holder. Do not use a metal brush. Clean the cartridge holder with pure water.(or distilled water/deionized water)

2) Put the cleaned cartridge holder into a sterilization packaging and seal it. (only when using autoclave)

3) The sterilization time is at least 4 minutes at a temperature of 132°C/134°C and a pressure of 2.0 bar ~ 2.3 bars. Allow a maximum sterilization time of 20 minutes at 134°C.

4) The cartridge holder that has been sterilized should be placed in a sterilization packaging, and then taken out before use.

Cautions:

- If there are chemicals remaining in the cartridge holder, do not perform sterilization, otherwise, it may cause damage.
- Please store the cartridge holder in a place where it will not be affected by dust, sulfide or salt in the air.
- Do not touch it immediately after autoclaving to avoid burns.

4 Troubleshooting

Failure	Possible cause	Solutions
The plunger in handpiece does not work	The plunger has reached the maximum stroke; there is a foreign object stuck in the plunger	Short press the Power on/off & Reset button  to reset the plunger to the initial state, and then test; remove the cartridge holder, check the plunger, and then start and test
The handpiece is overheat	It's been in continuous use too long	Turn off the handpiece for a period of time until the handpiece's temperature has dropped
The handpiece cannot be charged	The handpiece is not correctly placed on the charging base; the charging base is not connected to a power supply	Align the front of the handpiece and put it into the charging base before charging; connect the charging base to the power adapter and connect to the power supply
No sound	The volume is set to mute	Refer to 3.2d adjusting the volume as needed

5 Storage, maintenance and transportation

5.1 Storage

- 5.1.1 This equipment should be stored in a room where the

relative humidity is 10% ~ 93%, atmospheric pressure is 70kPa to 106kPa, and the temperature is -20°C ~ +55°C.

5.1.2 Avoid the storage in a too hot condition. High temperature will shorten the life of electronic components, damage battery, reshape or melt some plastic.

5.1.3 Avoid the storage in a too cold condition. Otherwise, when the temperature of the equipment increases to a normal level, there will be dew that will possibly damage PCB board.

5.2 Maintenance

5.2.1 This device do not include accessories for repair usage, the repair should be carried out by authorized person or authorized after service center.

5.2.2 Keep the equipment in a dry storage condition.

5.2.3 Do not throw, beat or shock the equipment.

5.2.4 Do not smear the equipment with pigments.

5.2.5 Replace the battery if it seems to be running out of power sooner than it should.

5.3 Transportation

5.3.1 Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and don't invert it.

5.3.2 Don't put it together with dangerous goods during transportation.

5.3.3 Avoid solarization and getting wet in rain and snow during transportation.

6 Environmental protection

Please dispose according to the local laws. Waste disposal of Dental Anesthesia Device should be in accordance with the sanitary management regulations of the medical institutions.

7 After service

From the date this equipment has been sold, based on the warranty card, we will repair this equipment free of charge

if there are quality problems. Please refer to the warranty card for the warranty period.

8 Symbol instruction



Follow Instructions for Use



Serial number



Date of manufacture



Manufacturer



Type B applied part



Class II equipment

IPX0 Ordinary equipment



Recovery



Used indoor only



Keep dry



Handle with care



Appliance compliance
WEEE directive



Humidity limitation



Temperature limitation



Atmospheric pressure
for storage

9 Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by WOODPECKER, any copy or fake product must undertake legal responsibilities.

10 EMC-Declaration of conformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee

in any way that this device will not be effected by electromagnetic interference Avoid using the device in high electromagnetic environment.

Technical Description Concerning Electromagnetic Emission

Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The model Super Pen and Star Pen are intended for use in the electromagnetic environment specified below. The customer or the user of the model Super Pen and Star Pen should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model Super Pen and Star Pen are use 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 CISPR11	Class B	The model Super Pen and Star Pen are suitable for used in all establishments, including domestic establishments 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	

Technical Description Concerning Electromagnetic Immunity

Table 2: Guidance & Declaration - electromagnetic immunity

Guidance & Declaration — electromagnetic immunity			
The model Super Pen and Star Pen are intended for use in the electromagnetic environment specified below. The customer or the user of the model Super Pen and Star Pen 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	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±2, ±4, ±8, ±15kV 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 transient/burst IEC 61000-4-4	$\pm 2\text{kV}$ for power supply lines $\pm 1\text{kV}$ for Input/output lines	$\pm 2\text{kV}$ for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 0.5, \pm 1\text{kV}$ line to line $\pm 0.5, \pm 1, \pm 2\text{kV}$ line to earth	$\pm 0.5, \pm 1\text{kV}$ line to line $\pm 0.5, \pm 1, \pm 2\text{kV}$ line to earth	Mains power quality should 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	$<5\%$ UT ($>95\%$ dip in UT.) for 0.5 cycle $<5\%$ UT ($>95\%$ dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles $<5\%$ UT ($>95\%$ dip in UT) for 250 cycles	$<5\%$ UT ($>95\%$ dip in UT.) for 0.5 cycle $<5\%$ UT ($>95\%$ dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles $<5\%$ UT ($>95\%$ dip in UT) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Super Pen and Star Pen requires continued operation during power mains interruptions, it is recommended that the models Super Pen and Star Pen be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3: Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

Guidance & Declaration - Electromagnetic immunity			
The model Super Pen and Star Pen are intended for use in the electromagnetic environment specified below. The customer or the user of the models Super Pen and Star Pen should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band 3 V/m 80 MHz to 2.7 GHz	3V 6V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models Super Pen and Star Pen, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \times P^{1/2}$ $d = 2 \times P^{1/2}$ $d = 1.2 \times P^{1/2}$ 80 MHz to 800 MHz $d = 2.3 \times P^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 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 end 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 model Super Pen and Star Pen are used exceeds the applicable RF compliance level above, the model Super Pen and Star Pen should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Super Pen and Star Pen.

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

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the model Super Pen and Star Pen

Recommended separation distances between portable and mobile RF communications equipment and the model Super Pen and Star Pen			
The model Super Pen and Star Pen are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Super Pen and Star Pen can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Super Pen and Star Pen 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		
	150kHz to 80MHz $d=1.2 \times P^{1/2}$	80MHz to 800MHz $d=1.2 \times P^{1/2}$	800MHz to 2,7GHz $d=2.3 \times P^{1/2}$
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 meters (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) accordable 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.