Dr.pen®

Auto Microneedle System

User Manual

Dr.pen Microneedling System A20

Please read this User Manual before use

Doc.: A20H14
Rev.: 2208A

Table of Contents

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1. DEVICE DESCRIPTION

The Dr.pen Microneedling device consists of a microneedling pen handpiece, and a sterile needle cartridge.The accessories are a base, a charging adapter and a protective sleeve.Each component and accessory will be explained to understand how Dr.pen works.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Dr.pen Components

A. Handpiece Charging Socket

B. Charge Level Indicator/Power Indicator Light

C. Power On/Off Button

D. Dr.pen Handpiece

E. Depth Setting Ring

F. Microneedling Connector

G. Dr.pen Cartridge (Applied Part)

H. Power adapter with cable

I. Base

Detailed Description

The Dr.pen Microneedling System is a minimally invasive microneedlingdevice that mechanically creates microscopic punctures in the epidermal and dermal layers of the skin by means of micro-needles in a reciprocating cartridge head. The Dr.pen Microneedling System is comprised of a reusable pen body, a sterile, single use microneedling cartridge, an AC adapter, a charging cable and a disposable Protective Sleeve.

Dr.pen Handpiece

The microneedling cartridge is attached to the pen body and activated with an On/Off button. The depth of needle penetration can be adjusted by the user depending on the condition of the skin being treated. Charging is accomplished by connecting the adapter and charging cable to the handpiece charging socket.

Dr.pen Cartridge

EO (Ethylene Oxide) Sterilized, disposable needle cartridge packaged and labeled individually.
Proprietary needle cartridge.
*Cartridges are not to be re-sterilized or reused.

Dr.pen Protective Sleeve

The Dr.pen and needle cartridge interface with a non-sterile and disposable Protective sleeve to prevent contamination of the Dr.pen Device.

2. INDICATIONS FOR USE

The Dr.pen Microneedling System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years or older. This device is for prescription use only.

3. CONTRAINDICATIONS

The use of the Dr.pen Microneedling System should not be used on patients who:

- Have active skin cancer in the treatment area(s)
- Have open wounds, sores, or irritated skin in the treatment area(s)
- Have an allergy to stainless steel or anesthetics
- Have a hemorrhagic (bleeding) disorder or hemostatic (bleeding) dysfunction
- Are pregnant or nursing
- Are currently taking drugs with the ingredient isotretinoin (such as Accutane)

Note: This product is not intended for transdermal (under the skin) delivery of topical products such as cosmetics, drugs, or biologics.

4. WARNINGS

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Do not use any equipment not designed specifically for Dr.pen as to avoid interference with the device's intended performance.

5. PRECAUTIONS

Safety and Effectiveness for setting greater than 1.5 mm has not been evaluated.
The Dr.pen Microneedling System has not be evaluated in the following patient populations (i.e.patients with the following conditions or taking the following medications): Actinic (solar) keratosis; active acne; collagen vascular diseases or cardiac abnormalities; diabetes; eczema, psoriasis and other chronic conditions in the treatment area or on other areas of the body; immunosuppressive therapy; history of contact dermatitis; raised moles in the treatment area; rosacea; active bacterial, fungal, orviral (i.e.herpes,warts); keloidscars (a scar that grows outside of the boundaries of an original scar); patients on anticoagulants; scars and stretch marks less than one year old; scleroderma; and wound-healing deficiencies.

PLEASE NOTE: The Dr.pen device allows for incremental increase in settings of up to 2.0 mm to allow for the variability in thickness of healthy skin and acne scar tissue. However, the cartridge settings greater than 1.5 mm has not been clinical tested for this type of device. As there are fine structures (i.e., nerve branches and accompanying blood vessels) that run under the skin and are essential to proper tissue function, it is not recommended to treat at needle depths greater than 1.5mm. It is essential that the thickness of the patient's skin in each anatomical area to be treated is assessed by a qualified clinician to address any potential risk of injuring these structures. Such structures include (but are not limited to)the supra orbital nerve (the terminal branch of the frontal nerve that provides the sensory innervations for the skin of the forehead, mucosa of frontal sinus, and the skin of the upper eyelid) and the temporal, buccal and marginal mandibular branches of the facial nerve (motor nerve that controls facial muscle movement). Please refer to Ekai provided training module on superficial nerve and vessel facial anatomy for additional information.

6. ELECTRICAL SAFETY WARNINGS

- No modification of this equipment is allowed. Only use included Dr.pen adapter and charging cable.
- Do not plug product into outlet with a voltage other than specified on the adapter. (100-240 Vac).
- Never force plug into an outlet if it does not easily fit into the outlet, discontinue use.
- Discontinue use if product appears damaged in anyway.

- Do not use or charge if cord or plug is damaged.
- Keep cord away from heated surfaces.
- Do not store the pen and/or power adapter near a sink or where it can fall or be pulled into water.
- For your safety from electrical shock, the Dr.pen and/or Dr.pen power adapter should not be opened or disassembled for trouble-shooting purposes. There are no user serviceable parts.
- Do not use any equipment not designed specifically for Dr.pen as to avoid interference with the device's intended performance.
- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- WARNING: Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Dr.pen device is suitable for use in industrial areas and hospitals.

7. INSTRUCTIONS FOR USE

- Only use this device for the commended applications. This device should only be used under medical supervision.
- Before administering any treatment, you should become acquainted with the operating procedures for the treatment, as well as the indications, contraindications, warnings, and precautions. Consult other resources (ie. IFU) for additional information regarding the application of microneedling therapy.

PRE-PROCEDURE PRECAUTIONS

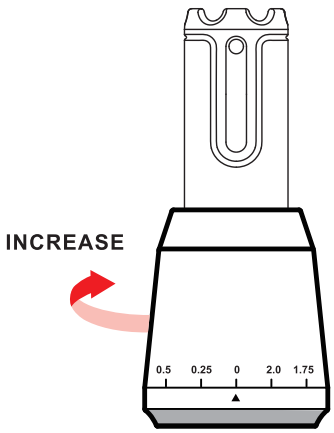
- Avoid excessive sun exposure/burns 24 hours prior to procedure.
- Discontinue use of topical retinoids 24 hours prior to procedure.
- Avoid treatment on patients with active breakouts or open lesions.
- Allow at least 24 hours after autoimmune therapies before a Dr.pen treatment.
- Wait six months following oral isotretinoin use.

PROCEDURE INSTRUCTIONS

1. Have patient complete consent form.
2. Explain the Dr.pen procedure to the patient and set expectations.
3. Apply single use, non-latex gloves.
4. Cleanse patient’s face with a gentle cleansing complex to effectively remove makeup, sunscreen and surface oils.
5. Take “before” pictures of the procedure area.
6. Apply the disposable Protective Sleeve.
7. Install the cartridge onto Dr.pen handpiece.
8. Ensure the needle is set to “0” before starting a new procedure.

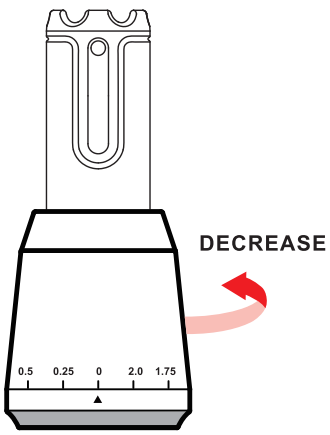
9. Power on by pressing and holding the on/off button on the front of Dr.pen for one second.
10. Adjust needle depth settings on the Dr.pen cartridge. New settings will be indicated by a “click” into place.

Instructions: How to adjust needle length:



- Adjust the depth setting ring to increase/decrease the needle depth, The scale number which the symbol pointing to shows the current depth

- Needle settings should be selected based on patient needs.

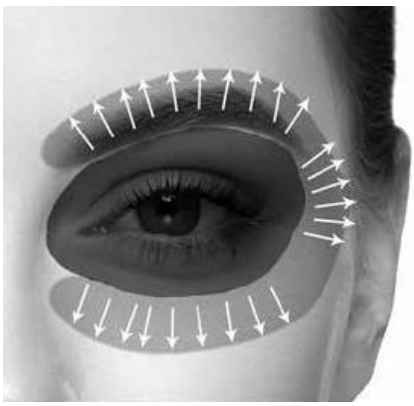


- It is recommended to start at a depth setting of 0.25mm.

- Increase by increments of 0.25 mm or 0.5 mm for the desired amount of erythema with a maximum depth of 1.5mm on the face.

***Lower the setting of the cartridge to 0.25-0.5mm to perform the procedure around the orbital rim.**

Acne Scar Procedure Depth (Suggested Guidelines)	
Forehead (0.25-1.0 mm)	Nose (0.25-0.75 mm)
Around the Orbital Rim* (0.25-0.5 mm)	Facial Acne Scars (up to 1.5 mm)
*Note: treatment can be performed around but not within the orbital rim.	

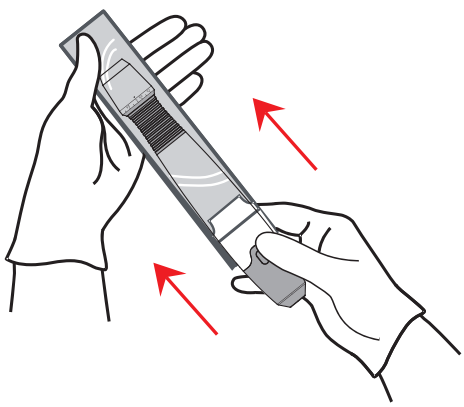


Orbital Rim Guide

Orbital Rim Treatment area

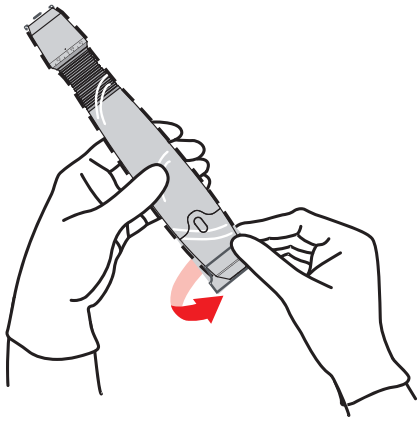
Microneedling should not be used within the orbital rim

How to apply Protective Sleeve:



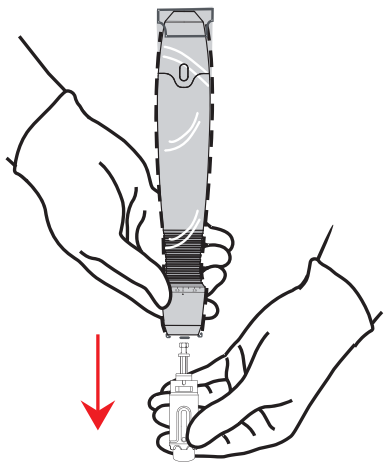
- While wearing non-latex gloves, obtain a single use Protective Sleeve and ensure the Dr.pen is clean/disinfected as Section 8 CLEANING OF DR.PEN SYSTEM.

- While Dr.pen is powered off, install the Protective Sleeve on the Handpiece. Make sure that the front part of the protective sleeve is longer so that it can be easily inserted into the inside of the front end of the pen to prevent bacteria from invading into the pen.

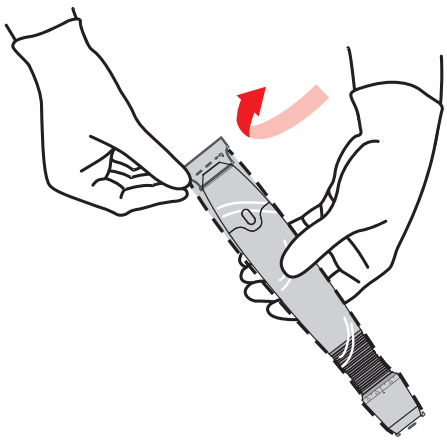


• Attach the adhesive strip at the end of the pen case. Dr.pen is now protected and ready to use.

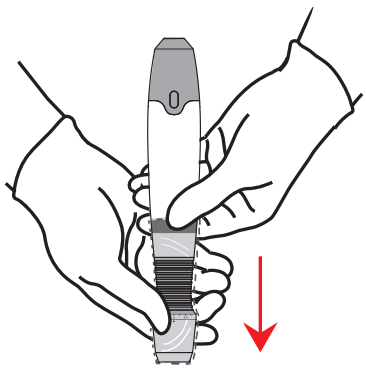
How to remove the Protective Sleeve and clean the Dr.pen Device:



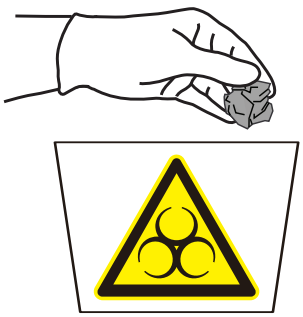
• Hold the Dr.pen perpendicular to the floor, or with the cartridge attachment tip pointing down wards. Use one hand to remove the cartridge and dispose of the cartridge in a sharps container.



• Continue to hold the Dr.pen device perpendicular to the floor, with the cartridge tip pointed downwards, and pull apart the adhesive strip of the Protective Sleeve.



• Remove the Protective Sleeve by carefully rolling it down the Dr.pen to prevent soiling the handpiece.



• Dispose of the Protective Sleeve in a biohazard container. Protective Sleeve are not intended to be reused.

• Cleaning and Disinfection of the Dr.pen should be completed with the use of near-neutral pH detergent solution and Super Sani-Cloth® Germicidal Disposable Wipes, See section 8. CLEANING OF DR.PEN SYSTEM.

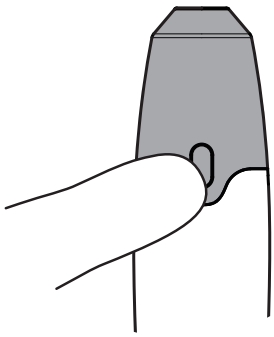
• After removal of the Protective Sleeve, the Handpiece should be cleaned with a near-neutral pH detergent solution and disinfected with the PDI Super Sani-Cloth® Germicidal Disposable Wipes, users' gloves should be removed, hands cleaned, and a new pair of clean gloves worn before proceeding to the next patient.

• Clean and disinfect the base after each patient`s treatment. Cleaning and Disinfection of the base should be completed with the use of near-neutral pH detergent solution and Super Sani-Cloth Germicidal Disposable Wipes

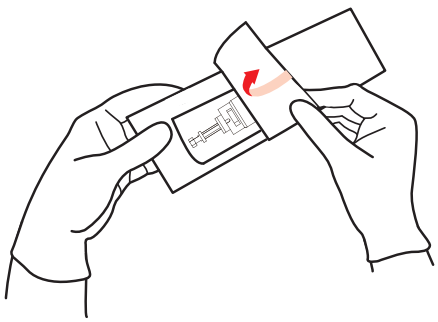
Note: Soiled gloves should always be disposed of in a biohazard container. Do not reuse disposable gloves.

Note: The purpose of a protective sleeve is to provide a covering that helps prevent the transmission of pathogens from one patient to another. Dr.pen is intended to be used only with provided Protective Sleeve.

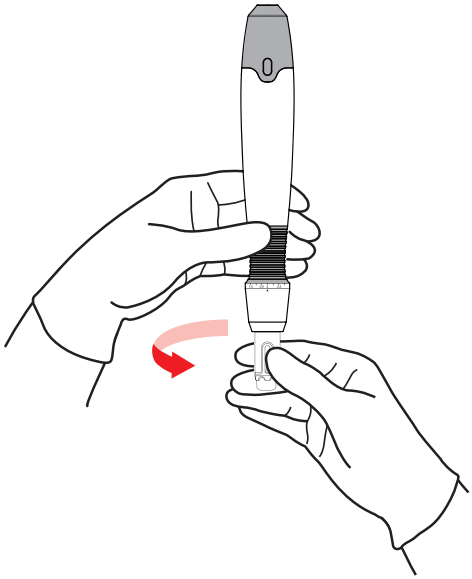
How to install/uninstall disposable Dr.pen cartridge:



• Ensure Dr.pen is powered off.

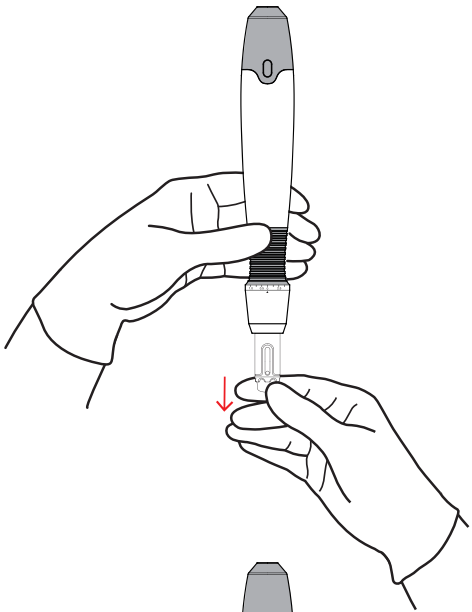


• Open the cartridge package by holding it right-side up and pulling back the protective covering at the sealed chevron.

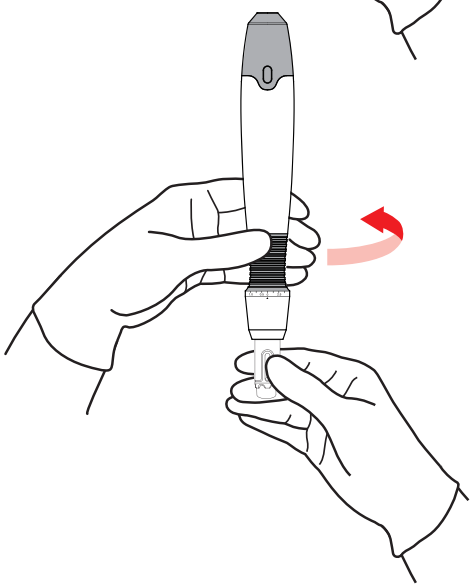


• slightly push the Dr pen microneedling cartridge into microneedling connector and lock it by clockwise

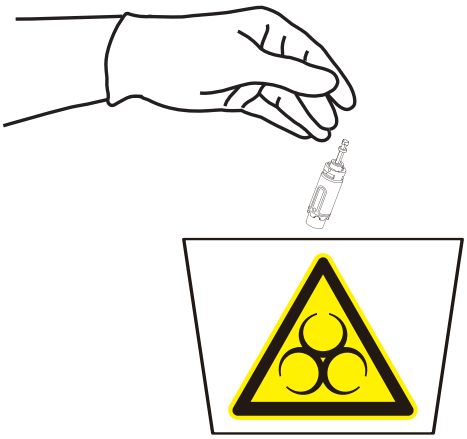
• The Dr.pen cartridge is designed for single use.



• Remove cartridge cap and then the Dr.pen is ready for use.



• To remove the cartridge, contrarotate until the cartridge is removed.



• Dispose of used Dr.pen cartridge via a Sharps container.

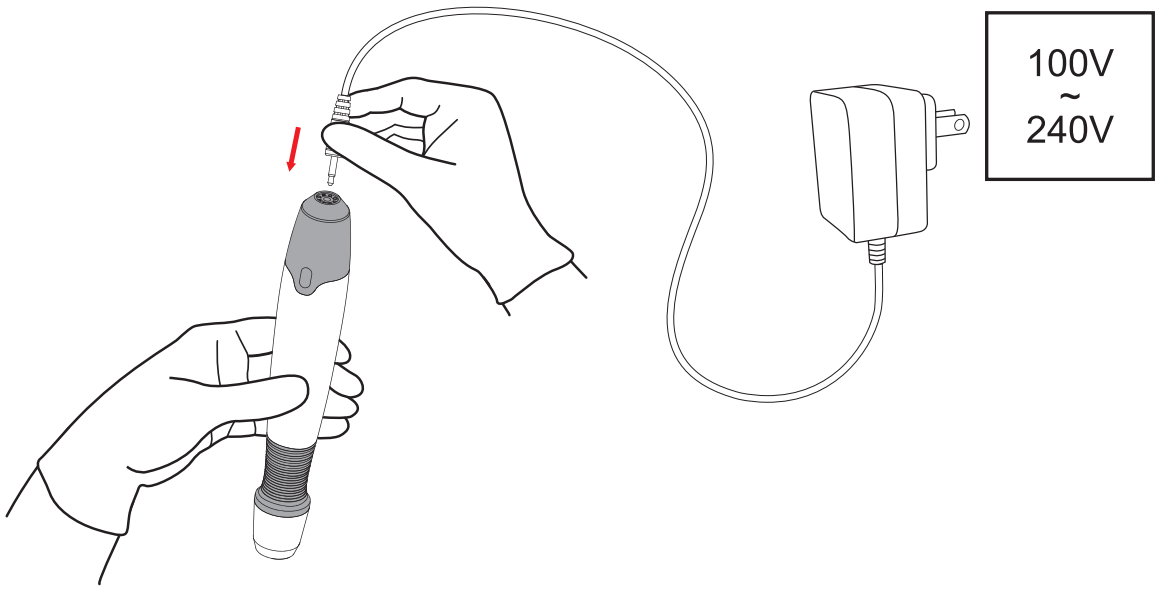
*** If a Dr.pen Cartridge becomes inadvertently contaminated before or during installation (ie. Dropped on floor, open/broken package, needles subjected to possible contamination), discard, and obtain new Dr.pen Precision cartridge.**

DR.PEN DEVICE CHARGING:

How to charge:

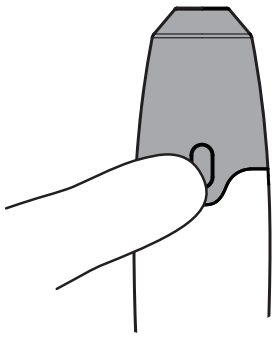
• Connect the cable of power adapter to the charging socket on the handpiece

• Connect the power adapter to mains power (100-240V). See “FAQ/Troubleshooting” for additional battery information. Battery charge percentages in “FAQ/ Troubleshooting”.



Power:

*** Powering ON/OFF should only be done with the Dr.pen device disconnected from the charging cable and power adapter.**



• ON: Press and hold power button for 3 seconds.

• OFF: Press and hold power button for 3 seconds.

8. CLEANING OF DR.PEN SYSTEM

***Ensure Dr.pen device is powered down before cleaning.**

Cleaning

- Place the handpice (or charger) on a clean cloth.
- Wear new clean gloves, use several soft cloth, moistened with near-neutral pH detergent solution with proteases for 5 minutes., to clean the handpiece/charger until they are visibly clean. the device should be cleaned while holding the Dr. pen straight down while wiping the rotary area).
- Use a new soft cloth, moistened with water for 15 seconds, to remove detergent residue.
- Use a dry soft cloth to dry the handpiece/charger surface.
- If soil residues are not fully removed, repeat the above cleaning steps.

Disinfection

- Put on new, clean gloves. Use a PDI Super Sani-Cloth® Germicidal Disposable Wipe to remove contaminants (clean the rotating area with the Dr.pen facing down while wiping the handle, and carefully wipe any gaps and joints). If one wipes cannot completely remove contaminants, use more than one until visually clean and contaminant free.
- If the contaminant remains are not completely removed, repeat cleaning step f-h.
- Unfold a new unused Super Sani-Cloth® Germicidal Disposable Wipe and use it to completely wipe and wet the surface of the device (gaps and joints need to be wiped and moistened).

- Allow treated surface remain visibly wet for a full 2 minutes (use additional wipe(s) if needed to assure continuous 2 minute wet contact time).
- Ensure that the device is moistened for 2 minutes and place the device until the liquid on the surface dries.
- Let air dry.

9. STORAGE

- For optimal performance of your Dr.pen, ensure the device is turned off and store the device when not in use.

10. DISPOSAL 

- Dispose of cartridges/needle tips as medical waste via a sharps container.
- Properly dispose of all items in accordance with local regulations.
- You must dispose of Dr.pen, Dr.pen adapter, and all other Dr.pen components properly according to local laws and regulations. Because Dr.pen contains electronic components and a Lithium Ion rechargeable battery, Dr.pen must be disposed of separately from household waste. When Dr.pen reaches its end of life, contact local authorities for proper disposal and recycling options.

11. WARRANTY

- One year under normal use after its original purchase.
- Warranty extends only to the original purchaser and purchase date.

- Contact Guangzhou Ekai Electronic Technology Co.,Ltd. Customer Service at 0086-020-81177539 for warranty inquiries.
- Warranty does not cover:

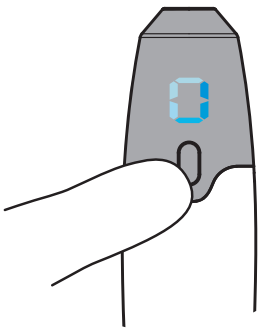
- Defects due to negligence, alteration, modification, or installation by any one other than factory authorized personnel.
- Abuse or misuse.
- Attempted or actual dismantling, disassembling, service, or repair not specifically authorized by Guangzhou Ekai Electronic Technology Co.,Ltd.

12. FAQ/TROUBLESHOOTING

Fault Indications:

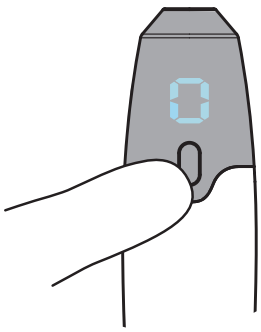
For your safety from electrical shock, the Dr.pen and/or Dr.pen power adapter should not be opened or disassembled for trouble-shooting purposes. There are no user serviceable parts.
If there's any help needed with the Dr.pen device and /or Dr.pen power adapter, please contact Customer Service Center at 0086-020-81177539 or e-mail at gzekai@163.com for assistant.

LED indications in Running state:



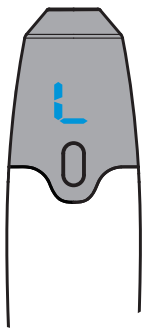
• ON

The LED Indicator on screen will blink sequentially in circles to indicate it's normal running.



• SUSPEND

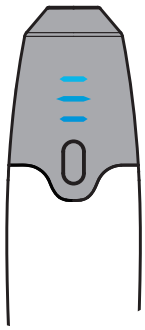
Short press the power button for once to suspend the Dr.pen, and press again to resume running. When the Dr.pen is suspended, the symbol " " on LED screen will blink.



• LOW BATTERY

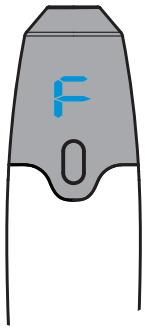
The symbol " " will blink on LED screen for 5 times when the battery is low, and then the Dr.pen will be turned off automatically.

LED Indicator in Charging state:



• CHARGING

When the Dr.pen is connected to main power, LED stripes will blink sequentially to indicate it is in charging state.



• BATTERY CHARGE=100%:

LED Indicator will be in “ F ” when the Dr.pen is fully charged.

13. SPECIFICATIONS

Technical Information of Dr.pen

Product Name:	Dr.pen
Dr.pen Handpiece Model Number:	A20
Weight and Unit	93.06g /150mm length and max. Outer diameter of 35mm
Output voltage:	1.5 W (max)
Charger Time From 10% charge to 100%	Charge within 3.5 hours
Working Time	1 hours (under extreme use conditions); 2 hours (under normal use conditions)
Speed	6300RPM – 7700RPM
Needles	• 14 total solid needles • 32 BWG (gauge) • <32 RMS (roughness) • Medical grade Stainless Steel • Sharpness specification within the Radius 0.005mm (Max) • Maximum extension of the needles from the needle head surface is less than 2.3mm
Operation	Cordless
AC Adapter	Medical Grade, Universally compatible power requirements: 100-240VAC at 50-60Hz

14. ENVIRONMENTAL CONDITIONS

Operating conditions:	Temperature: 17-30°C Relative humidity: 30-75% relative humidity non-condensing Atmospheric Pressure: 70 -106 kPa
Transportation conditions:	Temperature: -20-60°C Relative humidity: 10-98% relative humidity non-condensing Atmospheric Pressure: 70 -106 kPa

The EMISSIONS characteristics of the Dr.pen make it suitable for use in industrial areas and hospitals (CISPR 11 class A).
This user manual is valid for Dr.pen Handpiece (with power adapter), Dr.pen Protective Sleeve and Dr.pen Cartridge.
Refer to the Dr.pen Instructions for Use for additional information on the Procedure Instructions.
This user manual is published by Guangzhou Ekai Electronic Technology Co.,Ltd. Guangzhou Ekai Electronic Technology Co.,Ltd. Does not guarantee its contents and reserves the right to improve and amend it at any time without prior notice. Amendments will however be published in a new Edition of this manual.

Declaration of Conformity

Guangzhou Ekai Electronic Technology Co.,Ltd. Declares that the Dr.pen device complies with the following normative documents: IEC62133, IEC60601-1, IEC60601-1-2, IEC62366, ISO14971:2012, IEC62304, MDD93/42/EEC, IEC60601-1-6, IEC60529, ISO10993-1.

15. EMC INFORMATION

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The Dr.pen Handpiece (A20) is intended for use in the electromagnetic environment specified below. The customer or the user of Dr.pen Handpiece (A20) should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Dr.pen Handpiece (A20) uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The Dr.pen Handpiece (A20) suitable for use 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The Dr.pen Handpiece (A20) is intended for use in the electromagnetic environment specified below. The customer or the user of the Dr.pen Handpiece (A20) 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 ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 %.
Electrostatic transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode	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	0 % UT; 0,5 cycle g) At 0° , 45 ° , 90 ° , 135° , 180° , 225 ° , 270 ° and 315° 0 % UT; 1 cycle and 70 % UT ; 25/30 cycles Single phase: at 0° 0 % UT ; 250/300 cycle	0 % UT; 0,5 cycle g) At 0° , 45° , 90 ° , 135 ° , 180 ° , 225 ° , 270 ° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model + Name requires continued operation during power mains interruptions, it is recommended that the Model + Name be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Dr.pen Handpiece (A20) is intended for use in the electromagnetic environment specified below. The customer or the user of the Dr.pen Handpiece (A20) should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Dr.pen Handpiece (A20), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	3 Vrms 150 kHz to 80 MHz	3V 150 kHz to 80 MHz	**Recommended separation distance**
IEC 61000-4-6	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	$d = [\frac{3.5}{V_1}]\sqrt{p}$ $d = [\frac{12}{V_2}]\sqrt{p}$

Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d=[\frac{3.5}{E_1}]\sqrt{p}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{p}$ 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 metres (m).b 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 is affected by absorption and reflection from structures, objects and people.

a. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b. 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 Dr.pen Handpiece (A20) is used exceeds the applicable RF compliance level above, the Model + Name should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dr.pen Handpiece (A20).

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

Recommended separation distances between portable and mobile RF communications equipment and the Dr.pen Handpiece (A20).				
The Dr.pen Handpiece (A20) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Dr.pen Handpiece (A20) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model + Name as recommended below, according to the maximum output power of the communications equipment				
	Separation distance according to frequency of transmitter (m)			
Rated maximum output of transmitter W	150 kHz to 80 MHz outside ISM and amateur radio bands $d=[\frac{3.5}{V_1}]\sqrt{p}$	150 kHz to 80 MHz in ISM and amateur radio bands $d=[\frac{12}{V_2}]\sqrt{p}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{p}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{p}$

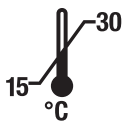
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70

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.

16. SYMBOL LEGEND

Manufacturer's trade name and address		Batch code	
Do not re-sterilize		Single use only	
Consult Instructions for Use		Sterilized using ethylene oxide	
Caution		Do not use if package is damaged	
Temperature shipment limits		Humidity limitation	
Keep dry		Not for general waste	
Direct Current		Positive Polarity	
Use-by date		Prescription use only