Dr.pen®

Auto Microneedle System

User Manual

Dr.pen Microneedling System A11

Please read this User Manual before use

Doc.: A11H14
Rev.: 2208A

Table of Contents

1. DEVICE DESCRIPTION

The Dr.pen Microneedling device (A11) consists of a microneedling pen handpiece, and a sterile needle cartridge. The accessories are a charging adapter, a handpiece holding base 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. Charging/Power/Puncture Rate Indicator Light

C. Puncture Rate Adjusting Button

D. Power On/Off Button

E. Handpiece Holding Base

F. Scale Point Mark

G. Depth Setting Ring

H. Dr.pen Cartridge (Applied Part)

I. Power Adapter

J. Charging Cable

Detailed Description

The Dr.pen Microneedling System (A11) is a minimally invasive microneedling device 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, a handpiece holding base and a disposable Protective Sleeve.

Dr.pen Handpiece

The microneedling cartridge is attached to the pen body. The Dr.pen device can be activated and the puncture rate can be adjusted 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. INTENDED USE

The Dr.pen Microneedling System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of wrinkles of the neck for Fitzpatrick skin types II - IV and to improve the appearance of facial acne scars in adults with all Fitzpatrick skin types aged 22 years and older.

This device is for prescription use only.

3. CONTRAINDICATIONS 

The use of the Dr.pen Microneedling System (A11) 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.

- Microneedling should not be used within the orbital rim. Treatment can be performed around but not within the orbital rim.
- Microneedling should not be used in the nose area.

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 

The Dr.pen Microneedling System (A11) 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, or viral (i.e. herpes, warts); keloid scars (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 1.5 mm for acne scars and 2.5 mm for wrinkles on the neck to allow for variability in thickness of the skin. 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). No adverse events were observed relating to such structures in the clinical studies when treating at needle depths up to 1.5 mm (acne scars) and 2.5 mm (wrinkles on the neck).

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.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).
- 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

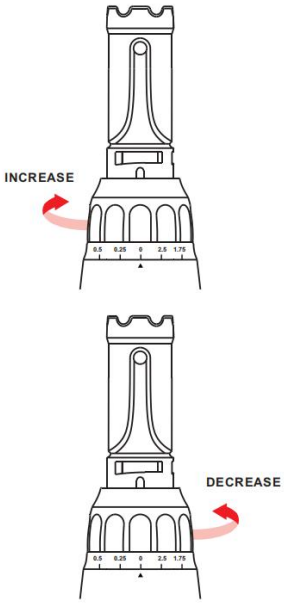
- Avoid excessive sun exposure/burns 24 hours prior to procedure.
- Discontinue use of topical retinoids 24 hours prior to procedure.
- Avoid treatment on patients with active breakouts or open lesions.
- Allow at least 24 hours after autoimmune therapies before a Dr.pen treatment.
- Wait six months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

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. If a numbing agent was applied to provide patient comfort, the numbing agent must be removed from the skin with an antiseptic solution prior to the microneedling procedure.
9. Ensure the needle is set to “0” before starting a new procedure.
10. Power on by pressing and holding the on/off button on the front of Dr.pen for one second.
11. Adjust needle depth settings on the Dr.pen cartridge. New settings will be indicated by a “click” into place.

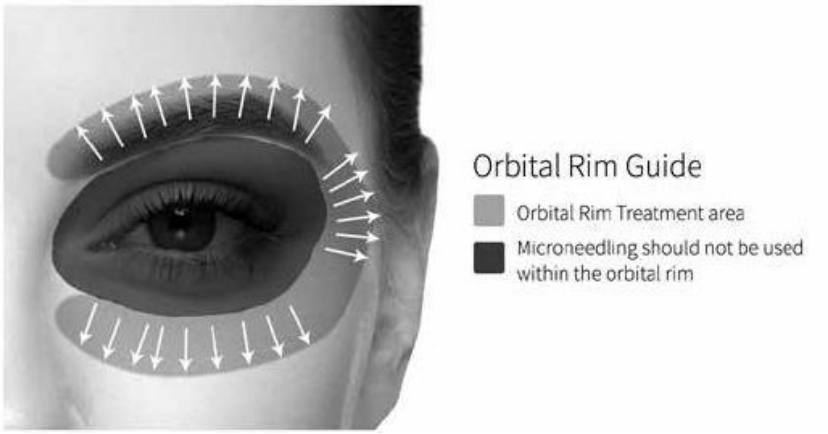
Instructions: How to adjust needle length:



- 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 2.5mm on the face and neck areas.

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

Procedure Depth (Suggested Guidelines)	
Forehead (0.25-1.0 mm)	Facial Acne Scars (up to 1.5 mm)
Around the Orbital Rim* (0.25-0.5 mm)	Neck Wrinkles (up to 2.5 mm)
*Note: treatment can be performed around but not within the orbital rim.	



12. When treating the face for Acne Scars divide the face into four quadrants. Start with the right cheek, move to the chin/perioral, then to left cheek, and finish with forehead. When treating the neck region, divide the neck into right and left halves and begin treating at the right jawline, moving downward and across into the left half of the neck and finishing at the left jawline.
13. Hold the skin taut and glide the pen in controlled horizontal motions. Repeat with vertical motions in the same area. Repeat the pattern if the erythema endpoint is not reached. Depth may

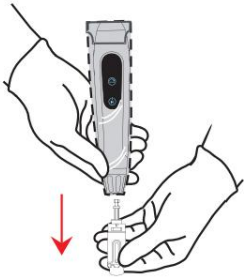
be increased within guidelines if necessary. Gentle, one-directional circular motions in small targeted areas is acceptable if needed to assist in reaching the erythema endpoint.

For treatment of facial acne scars, a needle depth of 1.5mm may be used on the face and up to a depth of 2.5mm on the neck under the discretion of the physician.

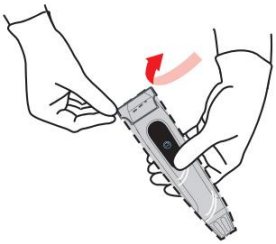
How to apply Protective Sleeve:

- 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, push Dr.pen through the Protective Sleeve until the device is snug inside the Protective Sleeve.
- Remove adhesive backing and seal end. Dr.pen is now protected and ready to use.

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

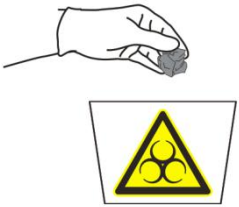


- Hold the Dr.pen perpendicular to the floor,or with the cartridge attachment tip pointing down wards. Use one hand to remove the cartridge and dispose of the cartridge in a sharps container.



- 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.

- Disinfection of the Dr.pen should be completed with the use of near-neutral pH detergent solution and PDI 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.

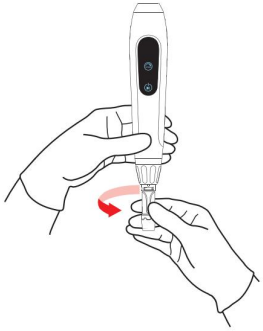
Note: Soiled gloves should always be disposed of in a biohazard container. Do not reuse disposable gloves.

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.

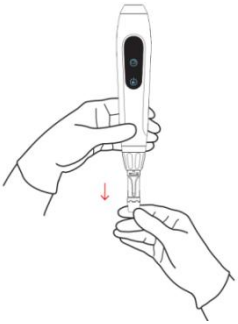
How to install/uninstall disposable Dr.pen cartridge:

- Ensure Dr.pen is powered off.

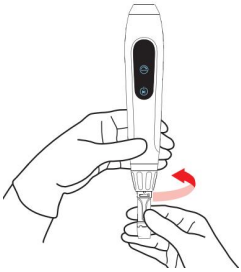
- Open the cartridge package by holding it right-side up and pulling back the protective covering at the sealed chevron.



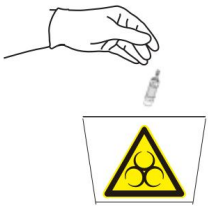
- slightly push the Dr pen microneedling cartridge into microneedling connector and lock it by clockwise
- The Dr.pen cartridge is designed for single use.



- 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.

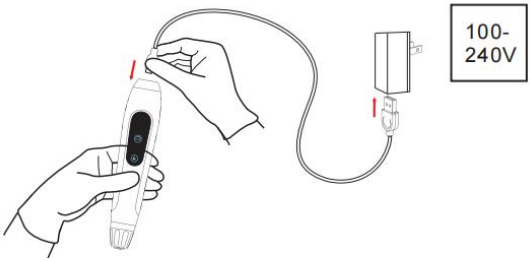
*** If a Dr.pen Cartridge becomes inadvertently contaminated before or during installation (ie. Dropped on floor, open/broken package, needles subjected to possible contamination), discard, and obtain new Dr.pen Cartridge.**

DR.PEN DEVICE CHARGING

How to charge:

- Connect one end of charging cable to the power charging socket on the handpiece and the other end to the power adapter.

- 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 2 seconds.

- **OFF**: Press and hold power button for 2 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 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 steps.
- 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**

Long press power button for 2 seconds. The power indicator light will be in blue.

- **SUSPEND**

The Dr.pen (A11) will be suspended from working, press again to return working state.

- **LOW BATTERY**

When the battery of Dr.pen (A11) is 10% capacity left, the Puncture Rate on LED Indicator flashes slowly.

The Dr.pen (A11) will turn OFF automatically after 1 minute quick flash of the LED Indicator.

Restarting the Dr.pen (A11) after the automatic power off, the LED Indicator will be in "L".

LED Indicator in Charging state:

- **CHARGING**

When the Dr.pen (A11) is connected to main power, The LED Indicator will be spinning "0" to indicate it is in charging state.

- **BATTERY CHARGE=100%:**

LED Indicator will be in "F" when the Dr.pen (A11) is fully charged.

Puncture Rate Level:

- **Puncture Rate:**

The puncture rate level of Dr.pen (A11) can be adjusted from Level 1 to Level 6 after each short press of the Rate Adjusting Button. The LED Indicator light will be in numbers to indicate Puncture Rate Level.

13. SPECIFICATIONS

Technical Information of Dr.pen

Product Name	Dr.pen Microneedling Device
Model Number	A11 (Handpiece) H14 (Cartridge)
Weight and Unit	Handpiece: 107.5g /170mm length and max. Outer diameter of 35mm Handpiece Holding Base: 146.6g /138mm length and max. Outer diameter of 56mm
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 (Adjustable Speed Level 1-6)
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 2.75mm

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.

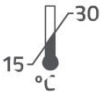
Refer to the Dr.pen Instructions for Use for additional information on the Procedure Instructions.

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. 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