Dermopen HOMEUser Manual

Dermopenworld

TABLE OF CONTENTS

TABLE OF CONTENTS (CONTINUED)

Dermopenworld

I - GENERAL INFORMATION

It is the responsibility of the user to carefully read all information presented in this manual before starting to use Dermapen HOME™. This includes warranty information.

It is always the responsibility of the user to adhere to the instructions in this manual.

It is the responsibility of the user/purchaser to be aware of local laws and regional restrictions for microneedling.

Read this user manual carefully and in full.

Keep this Instruction for Use in a place that it is always accessible.

II - INTELLECTUAL PROPERTY

Dermapen HOME™ is a trademark of Equipmed USA LLC. 4695 MacArthur Court, Suite 1100, Newport Beach, CA 92660

III - DISCLAIMER

Equipmed USA LLC or its representatives hold no responsibility for treatment outcomes as individual results may vary. The Dermapen HOME $^{\text{TM}}$ device or protocols are not designed to cure diseases. The Dermapen HOME $^{\text{TM}}$ is to be used as directed.

IV - CONTACT DETAILS

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Website www.EquipmedUSA.com

1 - WARNING SYMBOLS USED IN THIS USER MANUAL



Indicates a hazardous situation which, if not avoided, could result in injury, death or serious injury.



Sharp hazard.



Read the user manual before use.

1.1 - OTHER SYMBOLS USED IN THIS USER MANUAL AND ACCESSORIES



Device capacity for Bluetooth Connectivity, Battery (DC) Operation or Mains Power (AC) Operation.



Dermapen HOME™ App is downloadable on the Apple App Store. Search for Dermapen HOME.



Set up and Syncing of Dermapen HOME™ is completed via Bluetooth Connectivity.



Speed Dial as seen on the LCD Screen. (Refer to section 9.1, page 21.)



Product may not be thrown into the household waste. Dispose properly as electronic waste.



Date of manufacture.



Manufactured by.



Lot / batch code.



Use by / expiry date.



Do NOT reuse.



Do NOT resterilise.

STERILE EO

Sterilised by Ethylene Oxide.



Humidity range (lower and upper range) for safe storage.



Temperature range (lower and upper range) for safe storage.



Keep dry.

2 - LIMITATIONS OF LIABILITY



Do NOT use the Dermapen HOME™ microneedling device in any way that is not as exactly specified in this Instructions for Use user manual.

Use of Dermapen HOME™ in any other way or for any other indication other than those specified in this Instructions for Use has not been tested and the risk is unknown

This device may ONLY be operated for the purpose stated in this user manual

Contraindications must be observed without exception. The user is obligated to adhere to the principles of cleanliness and hygiene (refer to section 6, page 9, and section 10.1, page 25).

It is the responsibility of the user/purchaser to be aware of local laws and regional restrictions for microneedling.

3 - INDICATIONS OF USE

Dermapen HOME™ is a microneedling device and accessory intended to be used as a treatment to improve the appearance of wrinkles in adults aged 22 to 65 years.

3.1 - USAGE ENVIRONMENT

Dermapen HOME™ is suitable for use in the following environments:

- Domestic (home) environments for personal use by lay users to perform the treatment on themselves.
- Not intended for commercial or clinical use on patients.
- Treatment must be performed in a dry, clean and smoke-free environment and under hygienic conditions. The device must be used and maintained as set out in this user manual.

4 - DEVICE DESCRIPTION

The Dermapen HOME™ system consists of the following components:

- Dermapen HOME™ Device
- Dermapen HOME™ Needle Cartridge
- Dermapen HOME™ Battery Charger
- Dermapen HOME™ Power Charging USB cable
- Dermapen HOME™ Batteries x2

The Handpiece contains a drive train, a digital display to relay information to the operator, an ON/OFF button to power the device on and off and two separate toggle buttons to adjust frequency (speed) and needle level (depth).

The Handpiece receives its power via removable lithium-ion battery (3.7 VDC).

The drive train encompasses a DC motor, eccentric cam and rotational to linear drive converter to oscillate the Needle Cartridge.

The digital display shows battery status, cartridge status, sync/update notifications and Bluetooth connectivity. The display also contains a digital dial to convey frequency or motor speed and a 3-figure display showing current needle level.

The frequency of oscillation (speed) can be set from 80-120Hz (+/-10 Hz) and the needle level from 0.2mm to 0.5mm (0.1mm to 0.3mm ANZ).

The Needle Cartridge is a sterile, single-use consumable designed to create micro incisions in the epidermis and dermis. Each cartridge contains 16, 33-gauge surgical grade stainless steel needles, arranged in a circular pattern. Each Needle Cartridge employs a bayonet feature to securely connect it to the Handpiece during operation. Internal and external seals assist in the prevention of cross contamination, while a safety cap helps avoid needle stick injury. Each Needle Cartridge contains an RFID tag encoded with a unique ID and a needle level correction factor. This information is read from the cartridge when it is first inserted into the Handpiece and prevents reuse of the cartridge once the cartridge is removed from the Handpiece.

The battery charger is capable of charging 1x 14500 Lithium cell. The system batteries can only be charged when removed from the Handpiece and inserted into the battery charger.

The equipment is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat.

The Dermapen HOME™ is intended to be used by lay users.

5 - CONTRAINDICATIONS



You should not use the Dermapen HOME[™] device in the following cases:

- You suffer from Hemophilia or other blood clotting disorders.
- You take high doses of anti-coagulants or blood-thinning substances; e.g., aspirin, warfarin, heparin, acetylsalicylic acid.
- You have unregulated diabetes.
- You suffer from systemic infections or acute local skin infections (such as Hepatitis disorders type A, B, C, D, E, F or Human Immuno deficiency virus (HIV) infection).
- You suffer from any forms of active acne in the treatment area or are currently taking acne medication with the ingredient isotretinoin (such as Accutane™).
- You are on courses of high dose of chemotherapy, radiotherapy, or high-dosage corticosteroid therapy.
- · You have an allergy to topical (local) anesthetics.
- · You have an allergy to stainless steel.
- You are suffering from eczema, skin rashes or have open wounds/broken skin in the treatment area.
- You have undergone plastic surgery of the face or dermal fillers within the last 12 months or have any facial surgical scars less than 12 months old
- You have undergone Botox or other neuromodulator injections in the face within the last 3 months.
- You are under the age of 22 or over the age of 65.

Furthermore, do not use the Dermapen HOME™:

- To treat the delicate skin around the eye (inside the orbital rim).
- To treat skin inside the mouth or nostrils (mucous membranes).
- If you are suffering from any of the following in the treatment area; skin cancers, keloids or in case of predisposition to keloids, solar keratosis, warts, or birthmarks.

6 - WARNINGS AND PRECAUTIONS



Dermapen HOME™ is intended for personal use only and NOT intended to be used to deliver treatment to patients in a commercial setting. **Keep out of reach of children and pets as**; some small parts may pose a choking hazard.

Do not use Dermapen HOME™ with Topical Local Anaesthetic (TLA) if you are pregnant or nursing.

NOT to be used by people under the age of 22 or over 65.

As the clinical supporting documentation for Dermapen HOME™ was based on patients between the ages of 22 to 65, it is recommended to seek medical before utilising this device if outside this age range.

Dermapen HOME™ must ONLY be used with the authorised accessories. Using Dermapen HOME™ with unauthorised accessories will void any warranty and may lead to harm.

Dermapen $HOME^{m}$ is not intended to be used with topical products such as cosmetics, drugs, or biologics.

Before use, with the device switched OFF, check the Handpiece and Needle Cartridge. Do NOT use the Handpiece and/or Needle Cartridges if there are any visible signs of damage.

ALWAYS switch OFF the device before attempting to clean or inspect any part of the device.

Before and after each use, clean the Dermapen $HOME^{TM}$ device according to cleaning instructions (refer to section 10.1, page 25).

NEVER share Dermapen HOME™ with others. This may result in infection or transmission of diseases.



Take care when handling Needle Cartridges as there is a risk of a sharps injury. When the Handpiece is switched OFF, all needles of the Needle Cartridge should be fully retracted into the cartridge. If all needles are NOT fully retracted, the Needle Cartridge is faulty and must be immediately replaced. Take care when handling a faulty Needle Cartridge as there is a greater risk of a sharps injury.

6 - WARNINGS AND PRECAUTIONS (CONTINUED)

Do NOT use a Needle Cartridge if its sterile pack is damaged or ripped or the use-by date has been exceeded. Needle Cartridges are sterile single-use products (consumables) and must ONLY be used once. Discard Needle Cartridge immediately after use.

Do NOT use the Needle Cartridge more than once. Repeated use of the Needle Cartridge may result in infection or injury. Discard the needle immediately after use in household waste.

Do NOT use a device, that is contaminated; e.g., with bodily fluids or other substances. Use of a device contaminated with bodily fluids is not permitted due to the risk of cross-contamination. Follow cleaning instructions (refer to section 10.1, page 25).

NEVER modify the device, the Needle Cartridges or other accessories. A modification may lead to an electrical shock or a needle stick injury with a contaminated needle.

Position the device to ensure that the recommended safe distance from possible sources of electrical interference is maintained. Prevent sources of interference by avoiding the use of other portable or mobile wireless devices near the device (section 13).

When not using the device, store it in a clean, dry environment. Do not place on an unsterile surface.

Read the technical data specified in this user manual and ensure that the conditions for operation and storage are met.

Use only the Dermapen HOME™ Needle Cartridges supplied with this product. The device is not compatible with other cartridges. The cartridge product code is prominent on the packaging, contact your supplier to reorder. Use of non-approved accessories may damage the device, cause risk to the user and will void your warranty.

6.1 - WARNING AND PRECAUTIONS: BATTERIES

Use only the Battery, Battery Charger supplied with this product.

Incorrect installation of the Battery in Dermapen HOME™ or Battery Charger is hazardous and may result in fire, personal injury and damage to property. Always carefully check the polarity before installing or using batteries.

Do NOT dispose of the Dermapen HOME $^{\rm m}$ batteries in household waste. Follow local guidelines for correct disposal.

6.2 - MEDICAL PRECAUTIONS



If you are unsure if the Dermapen HOME™ device is suitable for you, please seek advice from your doctor or qualified medical practitioner.

Take care when using the device if you have a history of post-inflammatory hyperpigmentation (PIH) (darkening of the skin). People with a history of PIH are more likely to pigment after microneedling.

Before use, ensure your skin has been thoroughly cleaned and is free from products or contaminants.

Do not add any products to the skin during or after the procedure other than those listed in this manual.

Protect freshly treated skin areas against physical stress, contamination. UV radiation and sunlight.

Do not use the Dermapen HOME™ device on any skin area except the facial zones described in this manual.

Do not perform more than one treatment per week.

To ensure that the required intensity of treatment is not exceeded, avoid the risk of injury by using the correct levels (refer to section 9.3, page 23).

Avoid the risk of injury from excessive puncture frequency (refer to section 9.2, page 22).

Ensure that the Needle Cartridges do NOT come into contact with contaminated or unclean objects such as clothing or worktop.

Dispose of contaminated Needle Cartridges immediately after use in household waste

6.3 - WARNINGS: ELECTRICAL SHOCK



Dermapen HOME™ is an electrical device, which under certain circumstances could present an electrical shock hazard to the user.

Please read this user manual and follow directions stated to assure maximum safety during operation.

NEVER use the Dermapen HOME $^{\text{\tiny{TM}}}$ device where it can fall or be pulled into water.

There are no self-serviceable parts on the Dermapen HOME™ device.

Do NOT modify the Dermapen HOME™ device in any way. Modifying the device in any way will void the manufacturer's warranty and could pose a risk to the user.

6.4 - WARNINGS: USE OF THE NEEDLE CARTRIDGE



The Dermapen HOME™ microneedling device requires the use of Needle Cartridges, which under certain circumstances pose the risk of a sharps injury. Injuries from contaminated needles in Needle Cartridges may lead to the transmission of diseases.

Dermapen HOME™ contains a re-use protection feature built into the Needle Cartridge. Do NOT attempt to reuse the Needle Cartridge.

Do NOT attempt to attach or remove the Needle Cartridge to or from the Handpiece while the device is ON. The Needle Cartridges may ONLY be attached and removed when the Handpiece is switched OFF. Failure to follow this precaution may lead to a sharp's injury.

Do NOT touch the needles and tip of the cartridge at any time. Contact with the needles may lead to a sharp's injury or contamination.

Use ONLY original Needle Cartridges for the device that fit your Handpiece.

ALWAYS dispose of a used or contaminated Needle Cartridge in household waste immediately after use.

7 - INSTRUCTIONS & SETUP INSTRUCTIONS

7.1 - INITIAL SETUP

Upon receipt of your Dermapen $HOME^{m}$, unpack the device and accessories and check them off using the list in Section 4. Contact your distributor or supplier if any parts are missing or appear damaged.

Dermapen HOME™ is powered by a single Lithium-ion Turbo-Cut battery. Do not use any other type of rechargeable Lithium-ion battery.

7.2 - DERMAPEN HOME™ TURBO-CUT BATTERY

Dermapen HOME™ is supplied with 2x rechargeable Lithium-ion batteries - Turbo-Cut

Before commencing use of the device, you will need to charge the Turbo-Cut batteries

Turbo-Cut batteries are specific for Dermapen HOME™. Do not use any other type of rechargeable Lithium-ion battery. Use of other batteries may damage the device and will void your warranty.

Incorrect installation of the battery in the Dermapen HOME $^{\rm m}$ is hazardous and may result in fire, personal injury and damage to property.

If the Dermapen $HOME^{TM}$ is not likely to be used for an extended period, the battery should be removed.

7.3 - INSTALLING & REMOVING THE TURBO-CUT BATTERY

- 1. Remove the battery cover.
- 2. Insert battery into battery bay, ensuring correct polarity is observed.
- 3. Replace the battery cover and ensure that it is securely closed.
- 4. When it comes time to remove the battery, remove the battery cover.
- 5. Remove the battery from the battery bay.

7.4 - CHARGING THE TURBO-CUT BATTERY

Before charging the batteries, inspect the battery charger and cable. Do NOT use the battery charger or cable if they are damaged in any way.

- 1. Plug the USB charger into a suitable AC power adapter.
- The charger displays a red LED while the battery is charging. Once fully charged, a green LED will be displayed.
- 3. The battery takes approximately 2 hours to fully charge.
- 4. The supplied battery provides enough charge for 4 typical treatments of 15 minutes duration each (total 1 hour).
- 5. If the battery charge drops below a threshold level, the Dermapen HOME™ device will alert the user by flashing the yellow status LED and battery indicator. The device will emit an audible double-beep every 10 seconds.
- 6. If the battery is no longer capable of supplying sufficient power, the Dermapen HOME™ will provide a Critical Battery Alert. The device will display a red status LED, display a flashing battery symbol, emit three audible tones and power off after 10 seconds.

During charging, keep the power cable away from hot surfaces.

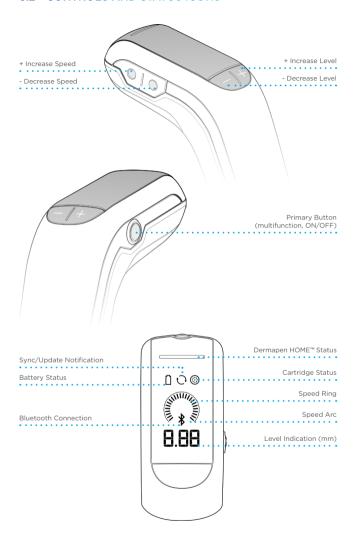
8 - GETTING STARTED

To get started with Dermapen HOME $^{\text{TM}}$, first register your device with the Dermapen HOME $^{\text{TM}}$ Companion App. The App must be first downloaded to a compatible smartphone or device.

8.1 - APP SYSTEM REQUIREMENTS

- · iPhone/iPad with iOS 10/11 and Bluetooth functionality, or
- Android Phone with Android 6/7/8 and Bluetooth functionality

8.2 - CONTROLS AND STATUS ICONS



8.3 - POWERING ON THE DEVICE

- Press and hold the Primary Button until the Dermapen HOME™ beeps. This should take around 3 seconds. The Status LED lights blue and the Speed Indicator Ring will begin to flash.
- 2. Once the device is powered on, the Speed Indicator Ring and Level Indicator Digits will be displayed. The Status LED will light blue to indicate device is ready for normal operation.
- Adjust the Speed Indicator Ring and Level Indicator Digits as required.
- 4. Press the Primary Button once to activate Treatment Mode.

8.4 - STATUS LED AND AUDIBLE TONES

The status LED displays 3 different states:

- Blue: Normal Operation
- Orange: Attention
- · Red: Critical Attention

The Dermapen HOME™ emits the following audible tones (beeps):

- Single Beep: Indicates a button press
- Double Beep: Indicates Speed/Level setting has been set, or there is an alert requiring attention
- Triple Beep: Indicates a Critical Battery Alert or Motor Error (refer to section 11, page 26).

8.5 - INSTALLING AND DOWNLOADING THE DERMAPEN HOME™APP

- Open the Apple or Android App Store on your compatible smartphone.
- 2. Search for "Dermapen HOME".
- Tap the 'Get' or 'Install' button on the app page to install the app. The App is free and will not cost any money to download or use.

8.6 - CREATING AN ACCOUNT

- Open the Dermapen HOME™ app.
- 2. On the opening screen, tap Create new account.
- On the Create Account screen, enter your first name, last name, account email address, account password, confirm your account password, and tap to confirm the privacy policy. Then tap Next.
- Enter in your address details and select the appropriate address result. Then tap Done. If you need to overwrite the address, tap Edit, then manually enter in the correct address. Then tap Save changes. Then tap Next.
- 5. Review your Account details (tap Edit to make changes).

8.7 - REGISTRATION OF DERMAPEN HOME™ ACCOUNT

- Ensure the Dermapen HOME™ is powered off.
- Ensure Bluetooth is enabled on your smart device.
- If you are using an Apple iPhone or iPad, ensure that Bluetooth is enabled for the Dermapen HOME™ app.
 (Settings - Privacy - Bluetooth - Dermapen HOME)
- If you are using an Android device, ensure that Location Services is enabled. (Settings - Location)
- Login to the Dermapen HOME™ app with your email and password.
- 6. On the Homepage, tap + Register Device.
- Select your address from the list that you want to register your Dermapen HOME™ to.
- When prompted, power on your Dermapen HOME™ and hold it near to your smart device.
- The app will display the serial number of the Dermapen HOME™ that is ready to be registered.
- 10. Tap Connect device.
- The Dermapen HOME[™] has now been registered to your Account.

8.8 - TO SYNC AND UPDATE DERMAPEN HOME™

- Ensure Bluetooth is enabled on the smart device being used. Ensure Dermapen HOME™ is turned off at this point.
- 2. Login to the app with the account email address and password.
- 3. The app should open on the products page, which will list the available pens.
- 4. Find the required pen in the list (the serial number in the list will match the serial number on the back of the pen under the battery lid).
- 5. Turn the pen on ensuring it is in pairing mode.
- 6. Tap Connect and Sync.
- 7. The app will display Pen synchronising. Do not power off the Dermapen HOME™ while updates are in progress. Interruptions will require the device to be re-synced to resume normal use. It is recommended to use the Power Adaptor during this process.
- 8. When the app displays **Pen Successfully Updated**, tap **Done** to complete the syncing and updating process.

8.9 - DURING BLUETOOTH SYNCING/UPDATING

- Dermapen HOME™ will display a blue Status LED, a Sync Symbol, a Bluetooth Symbol, and the Speed Indicator Ring will spiral to indicate updating is in progress.
- 2. Once successfully updated, the device is ready to be used.
- 3. If it has been more than 2 months since the last update of the device, Dermapen HOME™ will remind you by emitting an audible tone, displaying a Sync/Updating Symbol, and displaying the time remaining to sync/update on the level Indication Digits (in days, or in hours if less than 48 hours remaining). Sync/Update the device or press the Primary Button to continue operation.
- Once the Sync/Update reminder period has elapsed, the device will:
 - Display an orange Status LED
 - Display a pulsing Sync/Update Symbol
 - · Display 'SYN' on the Level Indication Digits
 - · Emit a double tone

9 - FITTING THE NEEDLE CARTRIDGE



The microneedle cartridge is sterile and for single-user, single use ONLY. Discard each and every safety Needle Cartridge after use.

- Switch OFF the Handpiece before attempting to attach or remove a Needle Cartridge.
- Check that the Needle Cartridge package is not damaged and torn.
- 3. Do NOT use a Needle Cartridge if the sterile pack is damaged in any way.
- Do NOT use a Needle Cartridge if the USE-BY date has been exceeded.
- The sterility of the Needle Cartridges is ONLY guaranteed if the packaging is undamaged and the cartridge is within its USE-BY date.
- 6. With clean hands, remove the Needle Cartridge from its sterile pouch.
- 7. Insert the drive ball end of the cartridge into Dermapen HOME™.
- 8. Turn cartridge a quarter-turn clockwise to securely lock it in place.



9. To remove needle, turn the cartridge a quarter-turn anti-clockwise to unlock it and gently remove.



9 - FITTING THE NEEDLE CARTRIDGE (CONTINUED)

- 9. Keep the protective cap in place until immediately before treatment
- 10. Switch ON the device.
- 11. If the Needle Cartridge is not installed properly, the LCD screen will display the Cartridge symbol flashing on and off. The Dermapen HOME™ will not operate until the cartridge is installed correctly.
- 12. Switch OFF the device, remove the Needle Cartridge and re-install. If the problem persists, refer to section 11 -Troubleshooting Dermapen HOME™ Device, page 26.
- 13. Only install a genuine Dermapen HOME™ cartridge at all times. Installation of any other cartridge will risk damage to the device and pose risks to the user and will void your warranty.
- 14. Remove the protective needle cap prior to commencing a treatment.

9.1 - ADJUSTING PUNCTURE FREQUENCY (SPEED)

- Use the Speed +/- buttons to increase or decrease the needle speed (puncture frequency). A single beep will be produced for each successful button press.
- The Dermapen HOME™ will produce a double beep when the new speed value has been set, and the selected speed will be displayed on the Speed Indicator Arc.
- 3. The speed can be adjusted without a cartridge connected to the device.
- 4. The device can operate at different speed levels according to user comfort

Speed 1 80hz - 80 revolutions per sec



Speed 3 105hz - 105 revolutions per sec



Speed 2 90hz - 90 revolutions per sec



Speed 4
120hz - 120 revolutions per sec

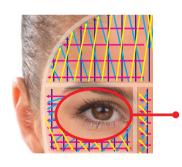


9.2 - ADJUSTING NEEDLE LEVEL

- Use the Level +/- buttons to increase or decrease the needle level (respectively). A single beep will be produced for each successful button press.
- The device will produce a double beep to indicate the new level value has been set and the selected level will be displayed on the Level Indication Digits.
- 3. The level can be adjusted without a Cartridge connected to the device.

We recommend the following suggested needle level ranges:

- Forehead (levels 1-4)
- Between eyebrows (levels 1-4)
- Nose (levels 2)
- Cheek bone (levels 1-4)
- · Cheek (levels 1-4)
- Lip area (levels 1-4)
- Facial scars (levels 1-4)
- Around the orbital rim* (levels 1-4)



*Note: Treatments can be performed around the eye socket (orbital rim), but do not treat the sensitive skin within the orbital rim.

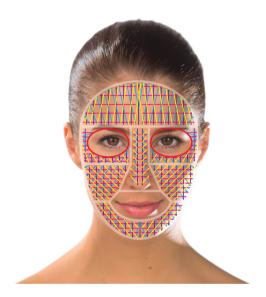
9.3 - CARRYING OUT A TREATMENT

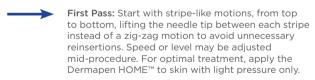
- 1. Thoroughly cleanse the skin with an appropriate cleanser.
- 2 Remove all residue of the cleanser with water
- 3. Thoroughly wash and dry hands prior to performing a treatment and handing the sterile Needle Cartridge.
- 4. Attach a new sterile Needle Cartridge (refer to section 9, page 19).
- 5. Power on the device (refer to section 8.3, page 16). If required, sync the device via Bluetooth (refer to section 8.8, page 18).
- 6. Remove the protective needle cap from the Needle Cartridge and throw it away into general household waste.
- 7. Select the needle level and speed of the Dermapen HOME™ (refer to section 9.2, page 21, and section 9.3, page 22).
- 8. Apply light pressure and move the Dermapen HOME™ in stripe-line motions across each region. lifting the needles between each stripe to avoid unnecessary reinsertions.

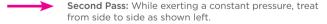


9.3 - CARRYING OUT A TREATMENT (CONTINUED)

- For each region, complete a pass of all four directions as shown below. Repeat these three to five times before moving to another region.
- 10. Needle level may be increased within guidelines if necessary.
- 11. After the treatment, cleanse the skin with warm water.
- 12. Apply a suitable sunblock.







Third Pass: While exerting a constant pressure, treat in a diagonal direction as shown left.

Fourth Pass: While exerting a constant pressure, treat in the other diagonal direction as shown left.

10 - CARING FOR YOUR DEVICE

10.1 - CLEANING PROCEDURE FOR DERMAPEN HOME™

Do NOT attempt to clean the Needle Cartridge. The Needle Cartridges are for single use ONLY.

The technique described below is a validated cleaning procedure and must be followed to ensure effective cleaning of the device.

Before and after each treatment, follow the cleaning procedure.

Prior to cleaning the device, visually inspect the device. If you see signs of contamination in the inside of the Handpiece or you suspect contamination in the inside of the Handpiece please contact your local distributor.



Using a disinfectant wipe or clean cloth damped with soap and water, thoroughly wipe over all areas of the device. Apply pressure with your finger and wipe the whole surface of each part.

Wipe the outer casing of the device, paying particular attention to the following:

- · Wipe all joints between the device casings.
- Wipe joint between the screen area and device casing.
- Wipe edges and crevices around the area where the Needle Cartridge attaches.

Allow the device to dry before storing in a clean, dry location.

11 - TROUBLESHOOTING: DERMAPEN HOME™ DEVICE

If the suggested actions fail to fix the problems listed below, or the problem reoccurs, please contact your local distributor.

Do NOT attempt to investigate any of the problems further. The device has no parts that you can repair.

Problem	Possible Cause	Action
Once powered on, the Dermapen HOME™: • Displays an orange Status LED • Displays a pulsing Cartridge symbol • Emits a double beep.	No Needle Cartridge detected	Remove and refit Needle Cartridge to ensure it is installed correctly. If problem persists, replace Needle Cartridge with a new one.
Once powered on, the Dermapen HOME™: • Displays an orange Status LED • Displays a flashing Cartridge symbol • Emits a double beep.	Needle Cartridge Error due to invalid Cartridge	Replace Needle Cartridge with a new one.
Once powered on, the Dermapen HOME™: • Displays a solid Sync Symbol • Displays days or hours on the Level Indication Digits • Emits a beep.	Sync Warning	Sync the Dermapen HOME™ via Bluetooth at earliest opportunity.
Once powered on, the Dermapen HOME™: • Displays an orange Status LED • Displays a pulsing Sync symbol • Displays 'SYN' on the Level Indication Digits • Emits a double beep.	Too long since last sync	Sync the Dermapen HOME™ via Bluetooth to continue operation.

11 - TROUBLESHOOTING: DERMAPEN HOME™ DEVICE (CONTINUED)

Problem	Possible Cause	Action
Once powered on, the Dermapen HOME™: • Displays an orange Status LED • Displays a flashing Sync symbol • Emits a double beep.	Configuration Error	Sync the Dermapen HOME™ via Bluetooth.
During operation, the Dermapen HOME™: • Displays an orange Status LED • Displays a Battery symbol • Emits a double beep every 10 seconds.	Low Battery	Replace or recharge the battery at the earliest opportunity to continue.
Once powered on, the Dermapen HOME™: • Displays a red Status LED • Displays a flashing Battery symbol • Emits three beeps • Powers off after 10 seconds.	Critical Battery - the device has insufficient battery charge to continue operation	Charge the battery before recommencing use, or switch to the Power.
App displays Error Code 303.	Issue communicating to device via Bluetooth	Ensure Bluetooth is enabled on your smartphone and tap Retry.
App displays Error Code 304.	Registration Error	Ensure Bluetooth is enabled on your smartphone and tap Retry.

12 - SPECIFICATIONS

Dermapen HOME™

Input Voltage/Current: 5V DC, 2.4A

Dimensions: 180mm x 40mm x 70mm

Weight: 155g IP Rating: IP22

Needling Motor ranges: from 80-120Hz

Level Ranges: 0.2-0.5mm

Dermapen HOME™ Needle Cartridge

Needle count: 16

Needle size/shape: 33G, solid needle

Cartridge contact zone: Fluted Shroud Needle Material: Surgical

grade stainless steel

Battery

Type: 14500, Lithium-ion, rechargeable Voltage/Current: 3.7V DC, 800mAh

Battery Charger

Input Voltage/Current: 90-250V AC, 1.0-0.5A, 50-60Hz

Output Voltage/Current: 4.2V DC, 500mA per cell

Acceptable environmental conditions

Storage and Transportation

Temperature: -18 to +70°C (0.4°F-158°F)

Humidity: 30-95%, non-condensing

Pressure: 573 to 1013hPa (8.3 to 14.7psi)

Operation

Temperature: +0°C to +30°C (32°F-86°F)

From Humidity: 30-95%, non-condensing

To: 15-90% RH, non-condensing

Pressure: 795 to 1013hPa (8.3 to 14.7psi)

13 - ELECTROMAGNETIC COMPATIBILITY

FCC Class B Statement

This product contains FCC ID: SH6MDBT42Q

The Dermapen HOME™ is intended for use in an electromagnetic environment in which radiated Radiofrequency (RF) disturbances are controlled.

The Dermapen $HOME^{TM}$ has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- 1. This device may not cause harmful interference.
- 2. This device must accept any interference received, including interference that may cause undesired operation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference to radio communications or devices that use radiofrequency.

The operator of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF communications equipment (transmitters) and the device of 3 metres.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment in proximity should be observed to verify that they are operating normally.

Changes or modification not expressly approved by the manufacturer could void the user's authority to operate the equipment.

If this equipment does cause harmful interference, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the device.
- Increase the separation distances between equipment.
- Connect the equipment into an outlet on a different electrical circuit or run the device using the battery option.
- Consult the manufacturers of the equipment.

13.1 - ELECTROMAGNETIC COMPATIBILITY GUIDELINES

The device is ONLY intended for operation with original accessories. in an environment like the one described below. The user of the device must ensure that it is operated in such an environment.

Essential Performance

The Dermapen HOME™ microneedling device has been tested for electromagnetic immunity and emissions. The basic safety and essential performance of the device is maintained if the user follows the rules distances and exclusions described in the information and tables that follow.

The essential performance of the Dermapen HOME™ microneedling device is defined as:

 Needle protrusion: Maximum needle protrusion is a needle protrusion setting of 0.5mm.

Abnormal Operation

It may not be possible to maintain normal operation under the following conditions:

- In the event an electromagnetic field, not in accordance with those listed in the EMC table, affects Dermapen HOME™, the device may shut off or the speed setting may change without the user pressing buttons. If either of these are observed, use of the Dermapen HOME[™] should be temporarily postponed until the source of the interference can be eliminated or reduced. It may be necessary to relocate the device to an area with lower levels of electromagnetic fields.
- If a large electrostatic discharge (ESD) occurs while the device is in operation, the device may power off. If this happens, it may be necessary to relocate the device in an area with a relative humidity greater than 50% to reduce the likelihood of ESD and then continue the procedure.
- If the device shuts down unexpectedly, is unable to be restarted, or the desired speed cannot be set, a fault condition has occurred. If this happens the device has an internal failure and should not be used. Contact your supplier.

13.1.1 - ELECTROMAGNETIC EMISSIONS

Emissions Test	Compliance	Notes
Radiated Emissions (FCC Part 15, Subpart B)	Class B	
Conducted Emissions (FCC Part 15, Subpart B)	Class B	
RF Emissions (CISPR 11)	Group 1, Class B	
Conducted Emissions - Mains Terminal Disturbance Voltage (CISPR 11)	Group 1, Class B	
RF Emissions (EN55032)	Class B	
Harmonic Current Emissions (IEC 61000-3-2)	Class A	
Voltage Change, Fluctuation and Flicker (IEC 61000-3-3)	Complies	

13.1.2 - ELECTROMAGNETIC IMMUNITY

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) (IEC 61000-4-2)	±8kV Contact ±15kV Air	±8kV Contact ±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%.
Radiated RF Electromagnetic Field (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz 3 V/m 2.7 to 6 GHz	10 V/m 80 MHz to 2.7 GHz 3 V/m 2.7 to 6 GHz	Minimum separation from portable and mobile RF communications equipment should be more than: E=6/d \P where P = maximum power in W, d = minimum separation distance in m, E = immunity level in V/m.
Electrical Fast Transients/Burst (IEC 61000-4-4)	±2 kV AC Power Ports	±2 kV AC Power Ports	Mains power quality should be that of a typical commercial or hospital environment.
Surges (IEC 61000-4-5)	±0.5 kV, ±1 kV Line-to-line	±0.5 kV, ±1 kV Line-to-line	Mains power quality should be that of a typical commercial or hospital environment.
Conducted Disturbances induced by RF fields (IEC 61000-4-6)	3 V 150 kHz to 80 MHz 6 V in ISM bands between 150 kHz and 30 MHz 80% AM at 1 kHz	3 V 150 kHz to 80 MHz 6 V in ISM bands between 150 kHz and 30 MHz 80% AM at 1 kHz	Minimum separation from portable and mobile RF communications equipment should be more than: E=6/d \P where P = maximum power in W, d = minimum separation distance in m, E = immunity level in V/m.
Power Frequency Magnetic Field 50/60Hz (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.
Voltage Dips, Short Interruptions and Voltage Variations (IEC 61000-4-11)	Various, as specified in Table 5 of IEC 60601-1-2: 2014	Various, as specified in Table 5 of IEC 60601-1-2: 2014	Mains power quality should be that of a typical commercial or hospital environment.

14 - WARRANTY INFORMATION

This product is manufactured under strict quality control and inspection processes.

Standard warranty of the Dermapen HOME™ device is to cover the operating period 2 years after the purchase.*

Standard warranty for Battery Charger and Battery is 12 months. Use of other batteries will void your warranty.

If this product goes out of order under normal customer use, it will be repaired/replaced free of charge during the warranty period (not including return costs).

The damages prescribed below are NOT covered by warranty:

- User faults by lack of care and responsibility (e.g., exposure to water, dropping device).
- Unauthorised electric current connection faults.
- Faults caused by the user's own intention or unauthorised repair.
- Damages caused by natural disaster (fire, flood, earthquake, lightning, etc).

Full warranty details can be found on www.EquipmedUSA.com

15 - DISPOSAL

Performance testing has supported a maximum lifetime of the Dermapen HOME[™] of 3 years. Depending on the frequency of use, this correlates to:

- 1. 10 uses per month for 3 years
- 5 uses per month for 6 years

To ensure user safety, please discontinue use of the device after it has reached the maximum lifetime.

At the end of the product lifetime, dispose of the Dermapen HOME™ microneedling device in accordance with applicable regulations for waste electronic equipment. If necessary, ask your dealer or the competent authorities about the applicable regulations.

^{*}Terms and conditions apply.

NOTES



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