
Essenlite[®] Pen

Battery Type User Manual

Document No.:2020118601

Software Version: 1.1.1.20201118_Release

Suitable for Model: (Q1 / Q3 / Q5 / Q7)

Parts name



-
- 1.DC jack
 - 2.Power switch and speed control
 - 3.Needle length adjustment
 4. Needle connector to install the needle cartridge

Presentation

Congratulations!, You have acquired a high-quality apparatus for Microneedling Therapy, which, together with your knowledge, will give you better results for your treatments.

Manual

This user manual describes the entire operation process and technical characteristics of the Essenlite Pen[®], in addition to guiding the microneedling technique with regard to indications, contraindications, storage and warranty.

About Essenlite Pen[®]

Essenlite Pen[®] is an electronic device in the form of a pen that allows to perform the technique of microneedle and is characterized to present some advantages:

- It is portable equipment, with adaptor drives and battery drives (wireless station) ways
- It has an intensity circuit in the pen itself that provides agility in the procedure.
- It has speed control and needle size, adjusting the need length for the procedure.
- AC110V- 240V power supply to the adaptor, with lithium battery inside.
- Two types uses, battery drives, or adaptor drives, when use adaptor drives, same time to charge the battery.
- Pen designed exclusively for the professional, as it offers ergonomic, light and practical design to carry out the procedures.

How to operate Essenlite Pen[®]

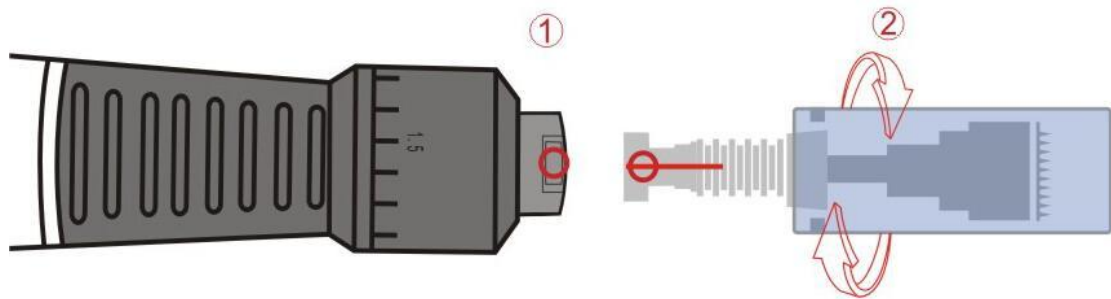
1. Adapter

- (1) Plug DC adapter into the jack
- (2) Plug DC adapter into the AC outlet
- (3) When connect the adaptor, the PCBA board light will turn red to charge the battery, at same time if turn on the pen, the green light will flash with different frequency according to the

speed, the red light will not turn off, till the battery is fully charged, then the indicator light be green.

2. Preparation

- (1) Take out the needle cartridges from the sterilized packing
- (2) Fitting round slots 1 into 2 of the machine, push needle cartridges horizontally up to the end.
- (3) Lock the cartridge by turning it to the counter clockwise
- (4) Needle length adjustment should be done after turning on the machine
- (5) If you want to remove the needle cartridge, turn it to the clockwise and push out horizontally, fitting round slots (1 and 2) together



3. Speed and needle length adjustment

- (1) ON/OFF

Press the button 3 seconds to turn ON/ OFF the pen

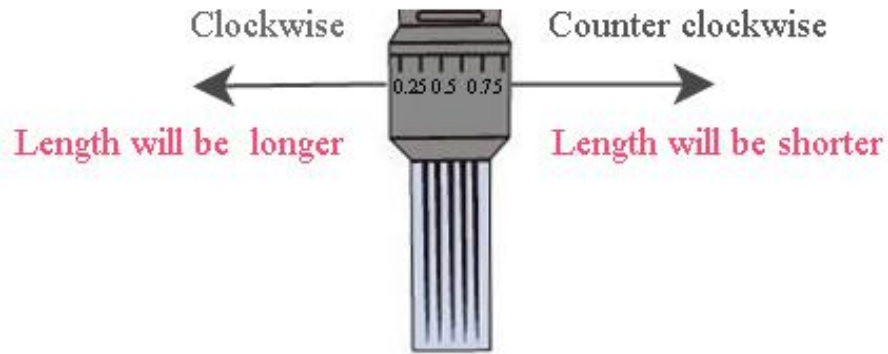
- (2) Speed control

Press the button for 3 seconds, pen will start, press the button again, the speed will add from lowest level to the highest level, the speed cycles low-high-low-high.

The flicker frequency of the light faster, the speed higher.

- (3) Needle length adjustment

Adjust the needle length by turning the adjustment ring clockwise or counter clockwise. Needle length will be longer, when clockwise; shorter when counter clockwise.



Operation instructions

1. Evaluate the patient situation, to see if he or she is suitable for the treatment, and confirm the treatment purpose and plan
2. Operator wears the rubber gloves, cleaning the treatment part with cleaner. For the facial part, attention to discharge makeup first.
3. Wash the treatment part and dry after step 2.
4. Sterilize the treatment parts with medical use alcohol.
5. Choose the appropriate treatment supplement, and daub evenly on the treatment part
6. Start the pen and check if it functions well, set the appropriate needle length according to the reference chart, and start the treatment
7. During the treatment, please make sure the needle cartridge contacts the skin vertically each time.
8. Treatment is forbidden on the eyelid
9. After the treatment, clean the treatment parts with medical absorbent cotton dipped with medical use alcohol
10. Routing the cables during use of the product, to avoid strangulation due to cables.
11. The pen is designed to be driven by adaptor or battery separately, which means you can use adaptor to drive the motor at same time to charge the battery, or only use battery to drive.
12. During the charging station, the light will be red, till the battery is fully charged.
13. When the battery is end discharging, the pen will stop work, that means you need use the adaptor to charge or operate the pen
14. Even the battery is over the service life, still the PCBA board is designed to use the adaptor to supply power, just without wireless condition.

Pre-use check

1. Check the needle cartridge package, do not use if it is broken
2. Check the cartridge connection part, to see if it is blocked
3. Assemble the adapter or directly use the battery type, and needle cartridge, take off the needle cartridge cap, start the pen to check if every speed level functions well
4. If everything is fine, cover the cartridge cap, and standby for use

Essenlite Pen® User Manual Version: V2.0.2

Date: 2020-11-18

5. If with the finer needle cartridges(shorter type), there is no cap, so be careful not damage the needle tips.

After treatment nursing

1.After the following 7 days, please wash treatment part with warm water(cold water will stimulate the skin). Recommend not to use other cosmetics or makeup .

2. If makeup is necessary , recommend with light makeup after 3 days following the treatment

3.Recommend to use the supplement that helps skin recover morning and night, such as the EGF, or following your doctor suggestions.

4.Drink water and take rest on time to help recover.

5. Avoid exposing under the strong sunlight. Keep away from spicy food.

6.Any other situation after the treatment, please consult with your doctor.

Reference chart

During the operation, choose the right needle length according to the real situation, to ensure the needle will not touch the bone or veins

(suggestion – each patient must be evaluated prior the use)

REGIN	THIN SKIN	THICK SKIN
Forehead	0.25-0.5mm	0.5-0.75mm
Between eyebrow	0.25-0.5mm	0.5-1.0mm
Nose	0.25mm	0.5mm
Eye area	0.25mm	0.25-0.5mm
Cheek bone	0.5mm	0.5-1.0mm
Check and chin	0.5-1.0mm	1.0-2.0mm
Upper lip	0.25mm	0.25-0.75mm
Facial scars	1.0-1.25mm	1.5-2.0mm
Stretch mark	1.5-2.0mm	1.5-2.0mm
Surgical/ burn scars	2.0-3.0mm	

Needle length and speed recommendation

DEPTH	SPEED
Under 0.5mm	1-2
0.5~1.0mm	2-3
1.0~1.5mm	3-4
1.5~2.0mm	4-5
2.0~3.0mm	5

Instructions

1. Object

Device for applying the micro-needle therapy by vibration

2. Performance

A device for puncturing skin-penetrating drugs or cosmetics supports with a micro needle guided between extended retracted positions

3. Classifications

Type of protection against electric shock: Class II equipment

Degree of protection against electric shock: Floating applied part

Dust and water resistance level : IP22

Operation mode : continuous operation

4. Intended Operator

-Who has got the cosmetologist certificate, and read the manual

-who has learned the full training process from the agent or the distributor, and passed the training process as a skilled operator

-Who has already operated such kind of pen skillfully, and read the manual

-Operation place: hospital, clinic, salon, SPA, home ,which places meet the demands of environmental conditions.

-Operator must wash the hands, and wear the disposable sterilized medical use rubber gloves

5. Environmental operating conditions

- A temperature range of +5°C to + 40 °C
- A relative humidity range of 15%-93%,no condensing and
- An atmospheric pressure range of 700hPa to 1060hPa

6. Environmental conditions of transport and storage between use

- A temperature range of -20°C to +70°C
- A relative humidity range up to 93%,no condensing
- Without atmospheric pressure range control

7. Storage room conditions

Room wall and ceiling keep clean, structure of door and windows keep tighten

Environment around the store should be clean, no dust, harmful gas, and pollution sources

Store should be light avoid, ventilation, dust proof, fire protection, moisture proof, mildew proof, anti-pollution, insect prevention and rat proof.

8. Transport conditions

Avoid sun light enclosure, forbidden to be mixed with any other harmful goods,

Stacking layer:8

Avoid to been exposed to the rain

9. Specifications

Product name: Essenlite Pen®

Adapter input voltage: AC 110V-240V,50Hz-60Hz









Adapter output voltage: 5V,2A

Weight: main body 86g

Size: 152*22.3mm

Needle Cartridge: for single use, the method of sterilization: Sterilized by ethylene oxide gas .ME expected Service Life: Three years (Over the life, extend the life according to the pen situation)

Precautions

	The tracking ID of the pen, each ID is unique
	Produce date: Month/ Date/ Year
	Expiry date (Pen expected service life three years)
	Please dispose of the device in accordance with the legal obligation in your area
IP22	Protected against vertically falling water drops when enclosure tilted up to 15°
	TYPE BF APPLIED PARTS
	Sterilized by ethylene oxide gas for the needle cartridges
	Please read the manual carefully before operation
	Do not use with power over AC240V
	Do not use it around the place with high temperature, dust or humidity (near humidifier)
	Do not repair, disassemble or alter the controller or the body
	Do not touch the adapter or device with wet hands
	Do not wash device ,or clean with wet cloth
	Do not use the stripped cord or the propped cord
	If do not use for a long time, unplug it from the outlet
	Inspection and test before operation are necessarily to avoid trouble
No one can operate without the full training	
	Do not use for micro pigmentation, except with the dedicated micro pigmentation needles



Precautions

1. Do not use with other supplements ,if you are not sure of the effect
2. If the skin is bleeding during and after the treatment, stop the treatment and consult the doctor for help
3. It is common effect that the skin become redness after the treatment
4. Any other abnormal effect, please consult the doctor
5. Do not use the needle cartridges from the damaged sterilized packing. Cartridges are for single use
6. Do not use the equipment if you notice a change in operating system performance, the system is damaged, or any of its components are worn or frayed.
7. Use of the equipment is not recommended in the presence of one of the following conditions:
 - a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
 - operating during transit;
 - magnetic resonance imaging (MRI)equipment;
 - used adjacent to or stacked with other equipment. If necessary, verify normal operation in the configuration.
8. Keep unit out of the reach of children/pets.
9. To prevent any damage to equipment, use only accessories, detachable parts and materials described in this user manual.
10. Be careful to strangulation due to cable, particularly due to excessive length



Contraindications

Patients with a medical condition, skin condition or taking prescription medication should consult their doctor or dermatologist prior to use this system

Do not use if pregnant or breastfeeding

Do not use on skin cancer

Do not use if you have a bleeding disorder or taking anti-coagulating medication

Do not use if you are prone to keloid scarring

Do not use if you have taken Accutane for the last 12 months

Do not use if taking any medication that causes photosensitivity

Do not use on areas any topical medication is been applied

Do not use on raised moles or warts

Do not use on open skin wound, broken skin, scabs, bleeding skin or blisters

Do not use on cold sores or prone to cold sores

Do not use on active inflamed pustular acne

Do not use on rashes,eczema or psoriasis ,pustular rosacea ,contagious skin infection or fungal infections

Do not use post micro dermabrasion,botulinum toxin, dermal fillers,IPL,chemical peels, or cosmetic surgery until inflammation from those treatment has resolved

Do not perform on sun burned skin until resolved

Do not use of self tanning lotion

Do not use if you are sensitive for the metal penetration

Do not use on who has acute disease or bloody disease
Do not use on body temperature over 38C

Do not use on who has allergy and hemophilia

Do not use on who has melanosis of the face

Do not use on who is under 12 years old

Adverse effects

Ablative procedures can cause several unwanted side effects on ethnic or darker skin.

You're at risk if you have:

- Light olive to darker skin tones
- Tanned skin (from natural sunlight and tanning beds)

This is because these skin types contain more melanin (the pigment causing skin color). The more melanin you have, the higher your risk. Sometimes, the skin damage can last several months to several years.

Common side effects of ablative procedures are:

- Skin discoloration (hypo/hyper pigmentation)
- Burning
- Blistering
- Scarring
- Infection (due to the removal of the epidermis)
- Thinning of the skin

Warranty

1.90 days warranty for free repair, from the day it is purchased. If any product has damages or natural troubles, offer repairs or replacements for free.

2.Battery charge - discharge circle life time warranty 500 times, over 500 times, the battery still can use, just the electric discharge time will be shorter.

3.Even the battery is over the service life, still the PCBA board is designed to use the adaptor to supply power, just without wireless condition.

4.If the trouble or damage is from the followings, nothing is free even during the warranty period:

-Troubles due to the users careless operation, voluntary repair or alteration

-
- Troubles due to the repairs rather than the technicians from the dealer shop or the customer center appointed by the manufacture
 - Troubles due to the shocks in the transport
 - Troubles due to the accessories or the options not appointed by the manufacture
 - Troubles due to the other natural disaster

Maintenance

1.General maintenance

- Keep it power off when no use. Wipe its surface with the dry cloth.
- Keep it away from the direct sunlight or high temperature / humidity
- Do not leave it to the repair or alter from no-professional stuff
- Avoid the high force pressure
- When the battery is fully charged, do not still charge for longer time.

2.Routine inspection

- Inspection needle/ adapter/ battery station / pen body before use, better to pre-test before use
- After a long time no use, please inspect fully when use again.

3. Cleaning and Disinfection

- Please clean the pen surface with the dry cloth, please do not with the wet cloth
- Please use cotton soaked in alcohol 95% to gently clean the surface and the needle connection par. Strictly forbid using any liquid to soak or hard objects to dig. Ensure no liquid flow back into the pen
- Each time before the patient is treated, please use the 95% concentration of medical alcohol to wipe the pen tip (connection part to the needle)

4. Disposal

The device and accessories are to be disposed of according to local regulations after their service lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

Troubleshooting

Faults	Causes	Solutions
No power	Adapter or wire connection malfunction; fun out of battery	Please check the AC part to the adapter, or the Micro tip to the pen, if connect well; charge the battery

Needle does not in and out	Connecting rod blocking	Check if the connecting rod is blocked by foreign matter, or if the needle is fixed well
----------------------------	-------------------------	--

We will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of ME equipment that are designated by the manufacturer as repairable by service personnel.

This device must only be serviced, repaired and opened by individuals at authorized sales centers. Don't open or repair the device by yourself.

EMC Guide

1. During the pen working, it will generate a certain small electromagnetic noise, if any other device is sensitive to the electromagnetic noise, please keep the distance
2. The other strong electromagnetic noise will affect the pen working, please keep distance from those device.

Guidance and manufacture's declaration – electromagnetic emission		
The Essenlite Pen is intended for use in the electromagnetic environment specified below. The customer of the user of the Essenlite Pen should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Essenlite Pen use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The Essenlite Pen is suitable for use in all establishments, including domestic establishments and those directly connected to the public 110V-240V power supply network that supplies buildings used for domestic purposes.
RF emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity
The Essenlite Pen is intended for use in the electromagnetic environment specified below. The customer or the user of Essenlite Pen should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±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	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/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 manufacture's declaration – electromagnetic immunity			
The Essenlite Pen is intended for use in the electromagnetic environment specified below. The customer or the user of Essenlite Pen should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz Outside ISM bands ^a	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Essenlite Pen, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 26 MHz to 800 MHz 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 26 MHz to 2.5 GHz	3V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^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 26 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>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.</p> <p>b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in these frequency ranges.</p> <p>c 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</p>			

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 Essenlite Pen is used exceeds the applicable RF compliance level above, Essenlite Pen should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Essenlite Pen.

- d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Packaging list

Pen body	1pcs
Adapter	1pcs(with wire)
Instructions	1pcs
Cartridges	2pcs

European Authorized Representative info

Company: SUNGO Europe B.V.

Add: Olympisch Stadion 24, 1076DE, Amsterdam, Netherlands

Email: EC.REP@sungogroup.com

Phone: +31 08 5029 0204