SYLFIRM X™ User Manual

Victory of Life
ViOL

Serendia, LLC
Exhibit 2083
EndyMed v. Serendia
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Ex. 2083-001

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Chapter 1. Product Introduction

1.1 Introducing SYLFIRM X™

This device is intended for coagulating skin tissue by emitting high frequency electricity (2MHz). The product consists of a Main device, Hand-piece(Probe), Foot switch and Bi-polar electrode.

- Name– SYLFIRM X™
- Manufacturer–VIOL Co., Ltd.
- Country of Origin –South Korea

1.2 Indications for use

The SYLFIRM X™ is intended for use in dermatologic procedures for electrocoagulation and hemostasis.

1.2.1 Prescription only

SYLFIRM X™ is intended for prescription only device

⚠ Caution: Federal law restricts this device to sale by or on the order of a word "physician", or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device;

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Chapter 2. Information on Safety and Handling

2.1 Safety Precautions

2.1.1 Safety Precautions before application and for Operating Room

⚠ **Before application, the doctor must explain cautions to the patient**

1) Operate the product in the correct order as described in this manual.
2) Be cautious when installing the product.
   ① Vibration and shock, for example, while transporting.
   ② Inappropriate voltage for power supply.
   ③ Unstable contact with the ground.
3) This product generates electrical arcs during operation, which can damage tissues such as neuromuscular. Therefore, only be operated by personnel that has completed relevant training approved by the manufacturer.
4) It is considered normal for this product to cause noise to other electric medical devices (e.g. monitor noise) during its operation.
5) Patients must not make contact with any grounded metal part or elastic conductor.
   ① Use dry materials to insulate body parts that give out excessive secretion or contact the skin (e.g. arm, torso).
6) Since this product is a medical device, instructions are required to properly dispose of it. Contact the deputy or manufacturer for such instructions. Improper disposing of this device can lead to legal consequences.
7) The conducting wire for patients should be situated in ways that do not make contact with either the patient or other wires. Any active electrode that is temporally not in use should be stored in locations that are insulated from the patient.
8) Crusting, Edema may be observed right after application, however these symptoms are temporary and normally expected during and after the application.

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2.1.2 General Safety Precautions for Users, Staff and Patients

1) Patients with electrically conductive implants(artificial cardiac pacemaker, cardioverter defibrillator, or other implantable electric devices) should qualified advice before use.
2) Beware of the following as for power supply.
   ① Always ensure the supplied voltage is AC 100-240V before plugging in the device.
   ② Turn off the power switch after using the device and pull out the plug when off-work.
3) The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment
4) Ensure that the distance between the product and the wireless device is at least 0.3 m.
5) If the safety standards are not met when installing this product or operating table, it may be highly dangerous to use the device.
   ① Do not use "multiple-tap" for power supply.
   ② If multiple devices are supplied by a single outlet source, consult a professional electrician on the appropriateness of such configuration before operating this product.
6) It can be risky to use components that are second-hand or not supplied by the manufacturer.
7) Be aware that patient medical equipment (e.g. assistance device) may become damaged or broken down when operating this product.
8) In addition to removing every metallic object such as rings and chains, patients need to avoid contact with metallic parts that are grounded or contain enough capacitance for grounding (e.g. the supporting area of an operation table).
9) Do not use flammable anesthetic gas when operating within cavum (e.g. membrane, organ).
10) Make sure not to use or vaporize detergent, sterilizer, or inflammable solvent before operation.
11) Operating the product may lead to a "spark" which can flare intestinal gas or oxygen-containing objects (such as cotton and gauze).
12) As this product is electrically operated and can be interfered by electromagnetic waves, do not use other electric devices like cell phone when this product is in use.
13) To avoid risks associated with electric shock, connect this product to a power supply using the protective ground connector.
14) Adhere to the following for safely turning off the product.
    ① Reset the device to its default settings when finished operating it.
    ② Do not pull out the plug with one hand using excessive force.
15) Do not set this equipment up at closed place and narrow place, and power plug placed difficult place to remove.
16) If the equipment fails, the unintended output power may increase or decrease. In this case, contact the manufacturer.
17) Contact the manufacturer if the product functions abnormally, problematically, or not at all.

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Any attempt to repair without the manufacturer's guide is not recommended.

18) Reuse of the tip is prohibited in any circumstances due to the infection.
19) Re-sterilization is prohibited in any circumstances.
20) Properly shut down, disconnect and secure the Hand-piece(Probe) and foot switch connector before moving it. Failure to do so may damage the system or cause someone to trip over a loose cable.
21) If any abnormality occurs during use, please contact Manufacturer. Our information is on the Chapter 8.
22) The safety load weight is as follows.
    A. Hand-piece holder: 0.5 kg
    B. Hand-piece cable holder: 0.5 kg
    C. Cart tray: 10 kg
    D. Cart handle: 5 kg

2.1.3 Table of Risk and Benefit Analysis to Users, Staff and Patients

Risk / Benefit analysis Table	
Risk	**Benefit**
User and Patient' Electric Shock	Bipolar type is safer than monopolar type to limit electric field in a target regionally to prevent systemic electric shock. Hand-piece, connecting cable, and Bi-polar electrode body are materials insulated to prevent an electric leakage. SYLFIRM X™ has No ground plate to prevent systemic electric shock.
Patient' skin Burn, Scarring	RF generator PCB board has a design of hardware-limitation not to generate over the Max Power limitation. Max output power and conduction time (duration) of software of SYLFIRM X™ are limited and fixed not to induce unexpected burn due to errors. GLP study shows that it doesn't induce burn, and scarring in treated face with all mode and power level.
User and Patient' Infection	EO gas sterilization is performed for Bi-polar electrode. To prevent a risk of infection due to reuse of tip, it is clearly marked to prohibit reuse through the labels and manuals. Manufacturer gives operator training specially for single use.
Patient' Metal Allergy, and Contact hypersensitivity	Electrode' material is 24k gold plated Surgical Stainless steel(SUS304) which is used commonly for surgical instruments due to low risk of metal allergy and lowest Nickel. Bi-polar electrode body' material is PC not to induce contact hypersensitivity.

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Patient' Bleeding, Erythema, Edema, Crust, folliculitis, and severe inflammation	Electrode' thickness is 0.3mm which is thin not to induce severe bleeding. Pin point bleeding is possible which is self-limited in a few minutes. Immediate erythema and edema can happen as normal thermal response induced by high frequency to induce neocollagenesis and dermal remodeling after wound healing. They are self-limited within a few hours normally. Rarely those symptoms can last during a few days but it is transient and temporary without any medical application. Crust on the electrode mark can happen and is self-limited within a few days without any medical application. Mild folliculitis can happen after application on incomplete cleaning face. Folliculitis is self- limited symptom without medical application within a few days. Severe inflammation doesn't happen. In conclusion of GLP study, the SYLFIRM X™ device appears to be well tolerated by the animals at the various level of RF tested as evidenced by the absence of edematous, and presence of only low grade erythema that was resolved within twenty-four(24) hours after application in all the animals.
User' Physical injury	When device fall over, user have a physical injury. Device has wheel-lock to prevent the device fallen over and designed with long legs not easy to fall over. During moving device, locking wheel and fixing device are recommended in User manual. All margins and corners of metallic parts are smoothed out to prevent an injury.
User and Patient' Electronic device malfunction	No contact of any electronics to the device is recommended in User manual to prevent a damage on user and patient electronics. Manufacturer provides Information on EMC in User manual. Main device' material is steel to prevent a leakage of electromagnetic wave minimally.

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2.2 Prohibited Usage

1) Pregnant or breast-feeding mothers
2) A current sign or medical history of skin cancer, other cancer types, and/or precancerous wart.
3) Critically ill patients (for example, with a heart-related disease).
4) Compromised immune system due to AIDS, HIV, and/or drug.
5) Heat-sensitive disease; for instance, preventive drug applications are needed for remedying recurrent herpes simplex.
6) Endocrine disorders that are hardly manageable (e.g. diabetes).
7) Patients who currently undergo progressive acute disease (e.g. eczema, psoriasis, decubitus, rash & etc)
8) Those with a history of impeded recovery from skin disorder, keloid, and/or any injury.
9) Patients with impaired blood clotting or who have consumed or injected an anticoagulant drug in the last 10 days.
10) Those who are deemed unsuitable for such operation at the surgeon's discretion.

2.3 Usage and Storage Conditions

2.3.1 Conditions for Usage

1) Temperature: 10℃-30℃
2) Relative humidity: 30%-75%
3) Atmospheric pressure: 700hPa-1060hPa

2.3.2 Conditions for Storage

1) Temperature: −20℃-60℃
2) Relative humidity: 10%-90%
3) Atmospheric pressure: 500hPa-1060hPa

2.3.3 Conditions for cleaning

1) The system should be dusted off before use
2) Before using the system, please cover the hand-piece with a FDA cleared sanitized disposable sheet and attach a sterilized and sealed Bi-polar electrode after opening it.
3) The Bi-polar electrodes must be used only once for each treatment

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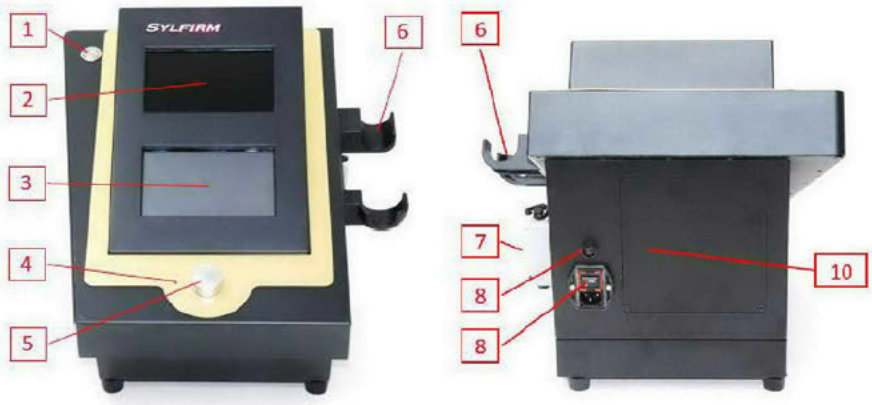
Chapter 3. Components and Installation of SYLFIRM X™

3.1 Main Device Components



No.	Name	Description
1	ON/OFF Switch	For turning the power on and off
2	Display LCD	A display that shows current operational settings
3	Operation Touch Screen	For configuring operational settings or functions
4	Power LED	Led for check the power
5	Jog Dial	A dial that changes functional values or equip mode for Bi-polar electrode.
6	Hand-piece Holder	A part that holds the Hand-piece in place
7	Hand-piece Connector	Connector between the Hand-piece and the main device
8	Foot switch Connecter	Connector between the foot switch and the main device
9	Power Inlet	For turning the main power on and off
10	Back Cover	A cover that can be removed when repairing or replacing components of the main device

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3.2 Accessory Components

1) Hand-piece

No.	Name	Description
1	Bi-polar Hand-piece	Component that equips the Bi-polar electrode
2	Hand-piece Connector	Connector to the main device
3	Flexible Cable	Cable protector

2) Foot switch

No.	Name	Description
1	Foot switch Stepper	RF Energy Start/Stop during operation
2	Foot switch Connector (2p)	Connector to the main device
3	Foot switch cable	Cable for connecting with foot switch stepper and connector
4	Foot switch case	Case for protecting and using the foot switch stepper

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3) Bi-polar electrode(Applied part)

	① Cap	② Body

No.	Name	Description
1	Cap	Removable Cap
2	Body	Bi-polar electrode

- This Bi-polar electrode is blister-packaged and EO-sterilized. If the tip is unclean or exposed to the air due to damage to its package, do not use the tip. When it scraps, do not mix up with other wastes.
- The Bi-polar electrode is <u>disposable</u> and can be used only once for each patient.
- The part which touches the skin consists of 18 ~ 25 pins.

No.	Model name	Type
A	J25BM	5x5 2.0 mm needle
B	J25BS	5x5 1.5 mm needle
C	J18BS	3x6 1.5 mm needle
D	Consumable TIP	5X5 2.0 mm needle

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- Detailed specifications of the Bi-polar electrode are as follows.

No.	Item	Description
1	Electrode Material	SUS 304 with gold coating
2	Electrode Quantity	25 pins(consumable tip, J25BM, J25BS) 18 pins(J18BS)
3	Molded Assembly Quantity	4 pieces (cap, housing, PCB holder, PCB holder support)
4	Mold Material	PC (Polycarbonate)
5	Sterilization Method	EO gas
6	Number of Usage	Once (disposable)
7	Depth	0.3 mm – 4.0 mm

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4) Cart

No.	Name	Description
1	Tray	For mounting Main body
2	Caster	For moving or anchoring the main device
3	Connector hole	For power cord and foot switch connection hole
4	Handle	Handle for moving the main device
5	Hand-piece cable hanger	Hanger the Hand-piece cable
6	Drawer	Space to store accessories

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5) User Manual

No.	Name	Description
1	User Manual	Manual for safe and efficient usage

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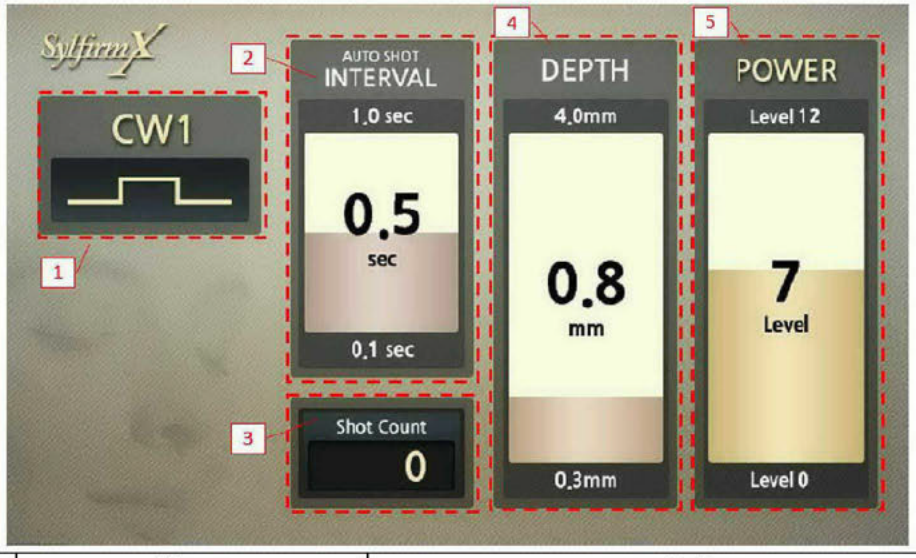
3.3 User Interface (UI)

i. Operation UI– Upper screen



No.	Name	Description
1	Current operation mode display	The mode being operated
2	Auto Shot Interval display	Display of interval time between motor movements in Auto Shot (**0.1 ~ 1.0 sec**)
3	Shot Count display	Display total number of shot count
4	Depth display	Display microneedle penetration depth (**0.3 ~ 4.0 mm**)
5	Power display	Display RF output power level (**Level 0 ~ Level** 12) - Level 0: No RF output - Level 1 ~ 12: As the level increases, the output increases.

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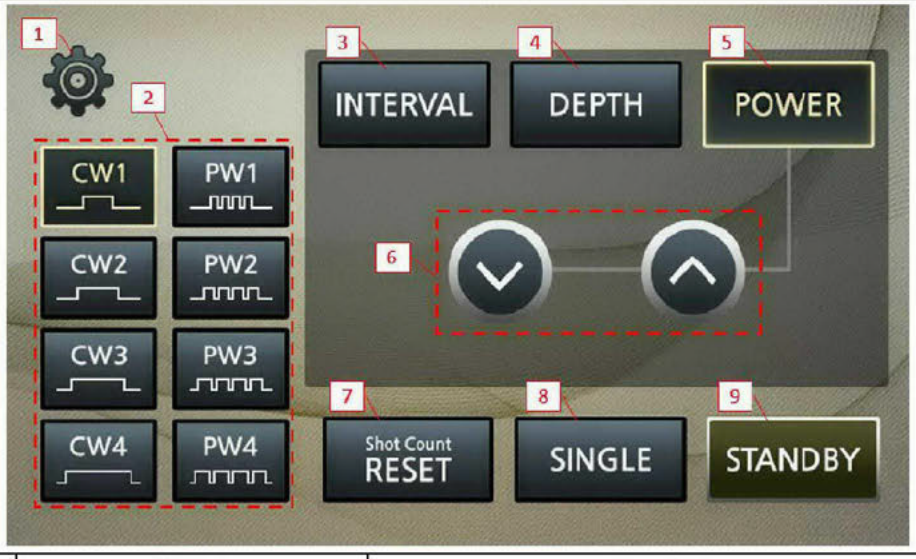
ii. Operation UI –Lower screen



No.	Name	Description
1	Setup button	Administrator screen activation button
2	RF output selection button	Select one of 8 types of RF output signals Continuous Wave(CW1, CW2, CW3, and CW4) and Pulsed Wave(PW1, PW2, PW3, and PW4)
3	Interval button	Set the interval time between motor movements in Auto Shot
4	Depth button	Set the depth of microneedle penetration depth (0.3 ~ 4.0 mm)
5	Power button	Set the RF output power level (Level 0 ~ Level 12)
6	Interval/Depth/Power control button	Control button to increase or decrease the Interval/Depth/ Power settings
7	Shot Count RESET button	Reset the total shot count number to 0
8	AUTO/SINGLE Shot Mode selection button	Set single shot or auto shot (automatically repeated shots)
9	STANDBY/READY selection button	STANDBY button to configure all settings and READY button for operation (configuring of settings is not available if the READY button is activated)

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3.4 How to install SYLFIRM X™

1) Connection of Hand-piece

< Hand-piece >

< Main device >

i. Connect the Hand-piece's female connector (2) to the Hand-piece connector (7) on the right side of the main device.

ii. The Hand-piece connector is a directional connector and must be gently fastened in the correct direction. Be careful when inserting forcibly while the direction is not correct because it may damage the equipment.

iii. After inserting the connector, check the fastened state (if it is tightened vertically, it is properly fastened). When the fastening is completed, fasten the securing latch (7.1).

iv. If the Hand-piece connector is installed incorrectly, the following error message will be generated when setting up the equipment.

< Error message >

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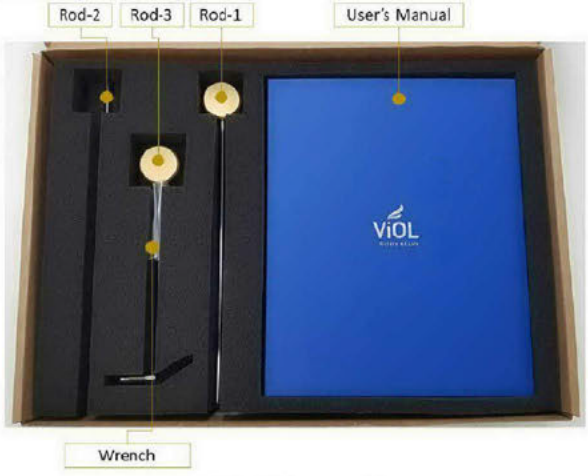
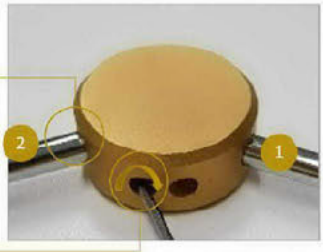
2) Connection of Hand piece hanger



< in side of Accesory box >

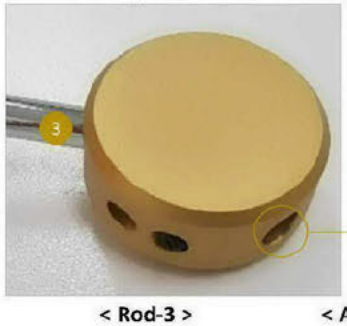
i. Insert the Rod-2 into the Rod-1's upper hole indicated in the image above. Use the wrench to tighten(clockwise) the bolt inside Rod-2 to secure it.

< Rod-1 >



< Assemble Rod-1 and Rod-2 >

ii. Insert the Rod-3 into the Rod-2's upper hole indicated in the image above.



< Rod-3 >

< Assemble Rod-2 and Rod-3 >

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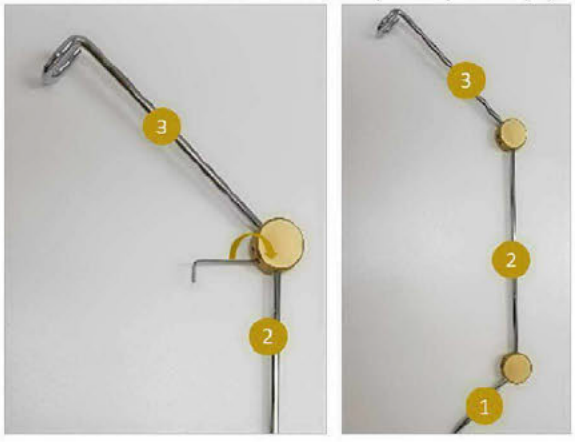
iii. Connect the Rod-3 to the Rod-2's open end. Use the wrench to tighten the bolt inside the Rod-3.
※ Note that the hook at the end of the Rod-3 should face upward ("U" shape)



iv. Use the wrench, rotate clockwise <u>to tighten the bolt inside</u> the lower hole of the main component as shown in the image above.

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3) Connection of Foot switch

< Foot switch >

< Main device >

i. Connect the foot switch's male connector (2) to the foot switch female connector (8) at the rear of the mains.

ii. The foot switch connector is a directional connector that must be gently pinned in the correct direction. Forcibly inserted in the wrong direction may cause damage to the equipment.

iii. The foot switch controls the output operation of the system. When the SYLFIRM X™ system is in the READY state, pressing the foot pedal of the foot switch will cause the output action to occur, leading to tip exposures and high frequency energy emissions. In the STANDBY state, pressing the foot switch does not activate the RF output operation.

iv. To clean the foot switch, use a soft cloth with alcohol and use it after the alcohol has completely dried.

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4) Connection of Power cable

< Main device – Front >

< Main device – Side >

< Electric outlet >

< Power cables>

i. Make sure that the power switch on the main device power inlet (9) is OFF (I: ON, O: OFF).
ii. Make sure that the front power switch (1 is in the OFF state (the switch is in the extruded state).
iii. Plug the power cable receptacle ('Power cable' Figure, 1) into the power inlet of the main device ('Main device - Side' Figure, 9).
iv. Connect the plug of the power cable ('Power cable' Figure, 2) to the electric outlet ('Electric outlet' Figure, 3).

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5) Connection of Bi-polar electrode

i. When connecting the Bi-polar electrode to the Hand-piece, it should be capped. Be careful not to connect the needle assembly to the motor when connected with the cap removed.

ii. Insert the Bi-polar electrode in the direction of the arrow as shown in the figure below.
- Insert (1) into (2).

iii. Turn the Bi-polar electrode counterclockwise to complete the tightening, and when removed, operate the opposite.

iv. Remove the cap of the Bi-polar electrode when starting the procedure.

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6) Power on

< Main device – Front >

< Main device - Side >

i. After connecting all the components to the main device, turn on the power.
ii. Turn the power switch on the main device's power inlet (9) to ON (I: ON, O: OFF).
iii. Press the main device power switch (1) to turn it on (switch pressed).
iv. Check if the upper and lower LCD screen lights up. If the LCD screen does not turn on, contact the sales company.

※ LCD panel is vulnerable to impact, so be careful when using it. (Lower LCD is a touch panel frequently used by practitioners. Gentle use is required)

3.5 Precautions ⚠

1) Do not install the Main Device too near the patient, adjacent to a wall, or in a closed space.
2) Do not expose the device to direct sunlight.
3) After using the device, wipe dust and other foreign substances using a dry cloth.

3.6 Power off

Turn off the power by following the reverse order of turning on the power.

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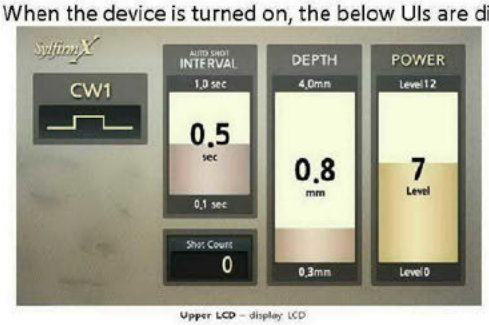
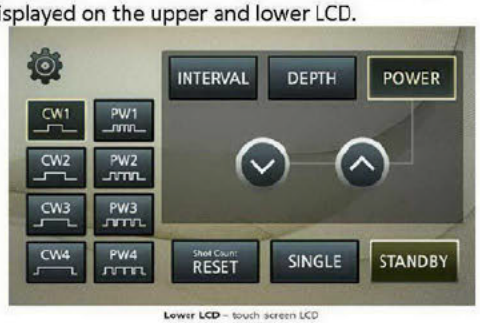
Chapter 4. Using and Operating SYLFIRM X™

4.1 How to operate SYLFIRM X™

1) Install the device in the order described in this manual (refer to "3. How to install SYLFIRM X™")
2) When the device is turned on, the below UIs are displayed on the upper and lower LCD.



Upper LCD – display LCD



Lower LCD – touch screen LCD

4.1.1 UI operation

i. Selection of operation mode of RF

- If you select one of the eight RF operation modes 'CW1, CW2, CW3, CW4, PW1, PW2, PW3, and PW4' on the left side of the lower LCD, the currently selected mode is displayed on the left side of the upper LCD.
- The RF operation mode selection is available only in 'STANDBY' state.

ii. POWER level setting

- The following shows how to set the RF output power level (Level 0 ~ Level 12).
- If you select the 'POWER' button on the upper right side of the lower LCD, you can see that the 'POWER' of the upper LCD is selected.
- Press the Up and Down arrows / buttons on the lower LCD to adjust the POWER level. Press briefly to switch to step 1 level, press and hold to switch continuously.
- You can also adjust the POWER level by turning the jog dial located on the front panel.
- POWER level adjustment is available only in 'STANDBY' state.

iii. DEPTH setting

- Next, set the penetration depth of the microneedle electrodes (0.3 ~ 4.0 mm).
- If you press the 'DEPTH' button in the upper center of the lower LCD, 'DEPTH' of the upper LCD is selected.
- Press the Up and Down arrows / buttons on the lower LCD to adjust the DEPTH. Press briefly to switch to step 0.1 mm, press and hold to switch continuously in increments of 0.3 mm.
- You can also adjust DEPTH by rotating the jog dial located on the front panel.
- DEPTH control is available only in 'STANDBY' state.

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iv. INTERVAL setting

- Next, set interval time between motor movements in Auto Shot (0.1 ~ 1.0 sec).
- If you press the 'INTERVAL' button in the upper left of the lower LCD, 'AUTO SHOT INTERVAL' of the upper LCD is selected.
- Press the Up and Down arrows / buttons on the lower LCD to adjust the INTERVAL. Press briefly to switch to step 0.1sec, press and hold to switch continuously.
- You can also adjust INTERVAL by rotating the jog dial located on the front panel.
- INTERVAL control is available only in 'STANDBY' state.

v. Selection of AUTO and SINGLE shot

- This section describes how to control motor movement. 'SINGLE' will operate one shot each time the foot switch is pressed, and 'AUTO' will continue to operate when press and hold the foot switch down.
- The button locates at the bottom center of the lower LCD. The currently displayed button indicates the current status. There is no display on the upper LCD.
- Press button to switch 'SINGLE' to 'AUTO'. Press again to switch 'AUTO' to 'SINGLE'.
- Only available in 'STANDBY' state.

vi. Selection of STANDBY and READY

- All settings and selections are available only in the 'STANDBY' state and not in the 'READY' state.
- In 'READY' state, pressing the foot switch will activate the system.
- The button locates at the bottom right of the lower LCD. The currently displayed button indicates the current status. There is no display on the upper LCD.
- Press button to switch 'STANDBY' to 'READY'. Press again to switch 'READY' to 'STANDBY'.
- If you are in the 'READY' state, you can see 'Shot Count' activated at the bottom center of the upper LCD.

vii. Reset of Shot Count

- When you press the 'Shot Count RESET' button located at the lower left of the lower LCD, 'Shot Count' of the upper LCD is initialized to '0'.

viii. Error Message

<ERROR Message>

- If the Hand-piece is not connected properly or has a failure, the lower LCD will display the ERROR message as shown above.
- In this case, after disconnecting the power, check the Hand-piece connection status or reconnect and turn on the power.
- If the same error message occurs again, contact the sales company.

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4.1.2 Application Procedure

1) When you complete to configure all settings, click on "STANDBY" icon to change from "STANDBY" to "READY". Then, LED lights of Hand-piece are turned on.
2) Lightly place Hand-piece on target region at 90°.
3) Stepping on Foot switch starts delivery of RF signal, and each shot of delivery sounds an alarm.
4) Check target region response immediately.
5) Confirm the configuration of all settings.
6) When you stop, keep "STANDBY" icon activated.

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4.2 Specifications and S/W of SYLFIRM X™

1) SYLFIRM X™ Specifications

No.	Name	Description
1	Type	General-purpose electric surgical device
2	Input Voltage	AC 100-240 V, 50/60 Hz
3	Max Power Consumption	100 VA ± 10 %
4	Output Frequency	2 MHz ± 10 %
5	Electrode Type	Bipolar
6	Output Power	Max 16.0 W ± 20 %
7	RF Conduction Time	Fixed (CW1: 120 msec, CW2: 160 msec, CW3: 200 msec, CW4: 300 msec, PW1: 120 msec, PW2:160 msec, PW3: 200 msec, PW4: 240 msec)
8	Output Energy per Electrode(mJ/pin)	See table 1 below for details.
9	Interval(auto shot)	0.1 ~ 1.0 Sec(0.1 sec unit)
10	Electrode Penetration Depth	0.3 mm – 4.0 mm (0.1mm unit)
11	Electrode No.	25 Pins(Consumable tip, J25BM, J25BS) 18 Pins(J18BS)
12	Weight	about 40 Kg
13	Dimension	400 mm(W) * 450 mm(D) * 1580 mm(H)

2) S/W Specifications

Classifications	Contents
SW version	V1.1.0
MCU	ATSAM4E8EB-AN
Memory Type	Program: FLASH type / Data: SRAM type
Compiler	AtmelStudio 7

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[Table 1. Output Energy per Electrode[mJ/Electrode](CONSUMABLE TIP, J25BM, J25BS)]

	RF type							
	CW1		CW2		CW3		CW4	
Level	50 Ω	500 Ω	50 Ω	500 Ω	50 Ω	500 Ω	50 Ω	500 Ω
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1	41.65	9.14	55.54	12.18	69.42	15.23	104.13	22.84
2	44.42	9.78	59.22	13.03	74.03	16.29	111.04	24.44
3	47.31	10.41	63.08	13.88	78.85	17.35	118.28	26.03
4	50.30	11.06	67.07	14.75	83.83	18.43	125.75	27.65
5	53.42	11.73	71.23	15.64	89.04	19.54	133.56	29.32
6	56.55	12.41	75.40	16.55	94.25	20.69	141.37	31.04
7	59.76	13.13	79.68	17.50	99.60	21.88	149.40	32.82
8	62.91	13.86	83.89	18.48	104.86	23.10	157.29	34.66
9	66.25	14.60	88.33	19.47	110.42	24.34	165.63	36.50
10	69.78	15.36	93.04	20.48	116.29	25.60	174.44	38.40
11	73.13	16.15	97.51	21.54	121.88	26.92	182.82	40.38
12	76.72	16.96	102.30	22.61	127.87	28.26	191.81	42.40

	RF type							
	PW1		PW2		PW3		PW4	
Level	50 Ω	500 Ω	50 Ω	500 Ω	50 Ω	500 Ω	50 Ω	500 Ω
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1	41.65	9.14	55.54	12.18	69.42	15.23	83.31	18.27
2	44.42	9.78	59.22	13.03	74.03	16.29	88.83	19.55
3	47.31	10.41	63.08	13.88	78.85	17.35	94.63	20.82
4	50.30	11.06	67.07	14.75	83.83	18.43	100.60	22.12
5	53.42	11.73	71.23	15.64	89.04	19.54	106.85	23.45
6	56.55	12.41	75.40	16.55	94.25	20.69	113.09	24.83
7	59.76	13.13	79.68	17.50	99.60	21.88	119.52	26.26
8	62.91	13.86	83.89	18.48	104.86	23.10	125.83	27.73
9	66.25	14.60	88.33	19.47	110.42	24.34	132.50	29.20
10	69.78	15.36	93.04	20.48	116.29	25.60	139.55	30.72
11	73.13	16.15	97.51	21.54	121.88	26.92	146.26	32.31
12	76.72	16.96	102.30	22.61	127.87	28.26	153.45	33.92

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[Table 2. Output Energy per Electrode[mJ/Electrode] (J18BS)]

	RF type							
	CW1		CW2		CW3		CW4	
Level	50 Ω	500 Ω	50 Ω	500 Ω	50 Ω	500 Ω	50 Ω	500 Ω
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1	57.85	12.69	77.14	16.92	96.42	21.15	144.63	31.72
2	61.69	13.58	82.25	18.10	102.82	22.63	154.23	33.94
3	65.71	14.46	87.62	19.28	109.52	24.10	164.28	36.15
4	69.86	15.36	93.15	20.48	116.43	25.60	174.65	38.40
5	74.20	16.29	98.93	21.72	123.66	27.14	185.50	40.72
6	78.54	17.24	104.72	22.99	130.90	28.74	196.34	43.10
7	83.00	18.23	110.67	24.31	138.33	30.39	207.50	45.58
8	87.38	19.25	116.51	25.67	145.64	32.09	218.45	48.13
9	92.02	20.28	122.69	27.04	153.36	33.80	230.04	50.70
10	96.91	21.33	129.22	28.44	161.52	35.56	242.28	53.33
11	101.57	22.44	135.42	29.91	169.28	37.39	253.92	56.09
12	106.56	23.55	142.08	31.41	177.60	39.26	266.40	58.88

	RF type							
	CW1		CW2		CW3		CW4	
Level	50 Ω	500 Ω	50 Ω	500 Ω	50 Ω	500 Ω	50 Ω	500 Ω
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1	57.85	12.69	77.14	16.92	96.42	21.15	115.70	25.38
2	61.69	13.58	82.25	18.10	102.82	22.63	123.38	27.15
3	65.71	14.46	87.62	19.28	109.52	24.10	131.42	28.92
4	69.86	15.36	93.15	20.48	116.43	25.60	139.72	30.72
5	74.20	16.29	98.93	21.72	123.66	27.14	148.40	32.57
6	78.54	17.24	104.72	22.99	130.90	28.74	157.08	34.48
7	83.00	18.23	110.67	24.31	138.33	30.39	166.00	36.47
8	87.38	19.25	116.51	25.67	145.64	32.09	174.76	38.51
9	92.02	20.28	122.69	27.04	153.36	33.80	184.03	40.56
10	96.91	21.33	129.22	28.44	161.52	35.56	193.82	42.67
11	101.57	22.44	135.42	29.91	169.28	37.39	203.14	44.87
12	106.56	23.55	142.08	31.41	177.60	39.26	213.12	47.11

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4.3 Error Message and Alarm

Cause	Classifications	Contents
Hand-piece equipped incorrectly or not at all.	Error message	The below message is displayed on the lower operation touch screen.
	Alarm	Loud warning sound
	Solution	Alarm disappears if the Hand-piece is successfully reconnected.

4.4 Troubleshooting

1) When the device fails to turn ON
- Check the power cord is correctly inserted into the main power inlet.
- Check the main power switch to the ON position.
- Check the condition of the fuse inside the device.

2) When the device is powered on but RF energy fails to be delivered
- Check the foot switch is correctly inserted into its socket.
- Check the Hand-piece is correctly inserted into its socket.
- Check the UI READY icon is activated.

If RF energy is still not emitted after several attempts, turn off the device and wait two minutes before turning it on again. If the problem persists, do not disassemble the device or take any inadequate or unauthorized actions of your own. Always contact an authorized our distributor or VIOL Co., Ltd. for assistance.

3) When the RF output is delivered with insufficient output power
- Check whether the needles in the Bi-polar electrode are damaged or dirty. If they are damaged, or are contaminated, discard and replace the tip.
- If the problem persists after taking the above actions, contact your authorized our distributor or Manufacturer for assistance.

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Chapter 5. Labels and Packaging

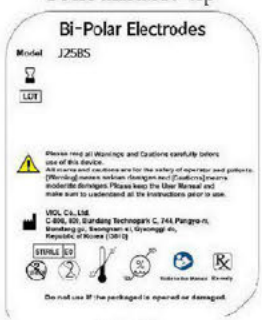
5.1 Labels

5.1.1 Label for Main Device

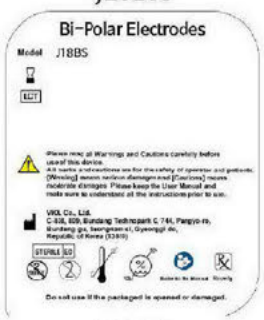
5.1.2 Label for Bi-polar electrode

Consumable tip

J25BM



J25BS



J18BS

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5.1.3 Label for Hand-piece

5.1.4 Label for Foot Switch

5.1.5 Label for CART

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- Descriptions on the visual symbols of the label

No.	Symbol	Description
1	SN	The serial number that identifies the object.
2		Date of manufacture
3		Manufacturer
4		Caution / Warning
5		Instruction for User Manual
6	Rx only	Prescription only
7		Type of applied part
8		WEEE Mark
9		Protective earth terminals
10		Expire Date
11	STERILE EO	EO sterilized unit
12		Disposable unit
13	STERILIZE	Do not re-sterilize
14	LOT	Batch code
15		Temperature limitation
16		Humidity limitation
17		General prohibition sign
18		NRTL Mark

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5.2 Packaging

5.2.1 Package List

Classifications	Components	Quantity
Main Box	SYLFIRM X™ Main Body	1
Accessory Box	Hand-piece	1
	Foot switch.	1
	Power cord	1
	User Manual	1

5.2.2 Package Units

1) Main Box

①The box and the main device are prepared.	②The device is covered with a plastic wrap.
③The device is anchored with PE foams.	④The box cover is placed.

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⑤The box is fastened with screws.	⑥Linking the bands finishes packaging.

2) Accessory Box
   - The components consist of the lower and upper compartment.
   - This box is in the main box at the time of shipment.

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Chapter 6. Information on EMC

6.1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

- The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.

Immunity test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The EUT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF Emissions CISPR 11	Class A	The EUT is 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
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

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6.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

- The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air	± 8kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 1kV, ± 2kV @PRF 100kHz, meet BS /EP requirements	± 1kV, ± 2kV @PRF 100kHz, meet BS /EP requirements	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1kV, ±2kV common mode, ± 0.5 kV, ± 1kV differential mode	± 0.5 kV, ± 1kV, ±2kV common mode, ± 0.5 kV, ± 1kV 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 s power interruption, meet BS requirements and meet EP requirements	<5% U_T 5 s power interruption, meet BS requirements and meet EP requirements	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EUT image intensifier requires continued operation during power mains interruptions, it is recommended that the EUT image intensifier be powered from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m, meet BS requirement	30 A/m, meet BS requirement	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the A.C. Mains voltage prior to application of the test level.			

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6.3 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

- Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power(W)	Distance(m)	Immunity Test level(V/m)
385	380 ~ 390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430 ~ 470	GMRS 460, FRS 460	FM[c] ± 5 kHz deviation 1 kHz sine	2.	0.3	28
710	704 ~ 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800 ~ 960	GSM 800/900, TETRA 800, iDEN 820, CMDA 85-, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700 ~ 1990	GSM 1800; CMNA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 ~ 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100 ~ 5800	WLAN 820.11 a/n	Pulse Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

Note. If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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Chapter 7. Findings of Pre-Clinical Study

The pre-clinical study was designed to evaluate the safety and effectiveness of SYFLIRM X™ as a radiofrequency(RF) heating device to treat dermal conditions and hemostasis. Three (3) Yucatan Mini-pigs were used in this study. Animal G1 was euthanized 3 h after treatment on Day 1; Animal G2 was euthanized on Day 5; and Animals G3 was euthanized on Day 22.

Treatment with the SYLFIRM X™ device did not result in erythema or edema formation within 1-hour post treatment, nor at any other scheduled timepoints on all animals. The treatment-related microscopic findings consisted of minimal to moderate, multifocal deep dermal collagen necrosis in animals euthanized on Days 1 and 5, and minimal to mild multifocal deep dermal fibrosis on animal euthanized on Day 22.

Test results including histology data demonstrated that the subject device is substantially equivalent to the predicate devices in the market for its intended use.

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Ex. 2083-040

CX-0823C.40

Chapter 8. Product Life time and Warranty

8.1 Product Life time

- SYLFIRM X™ is guaranteed to last for a minimum of four years.

8.2 Product Warranty

- The warranty covers a year.
  However, the conditions excluded by the warranty are as follows.
  - Natural aging of the product from daily usage
  - Product damage due to improper storage
  - Product damage due to improper usage
  - Second-hand products (which are not covered by the warranty)
  - Products that are not in their original locations to which the manufacturer had initially sent them.
  - Products that are repair or change without the manufacturer's confirmation
  - Bi-polar electrode is not covered under the warranty

You should use it just one time and then discard to avoid infection. The company cannot accept liability for damage caused by re-use.
Bi-polar electrode is valid for three years from the date of manufacture.

Chapter 9. Manufacturer Information

Company name: VIOL Co., Ltd.
Address: C-808, 809, Bundang Technopark C, 744, Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do (13510), South Korea
E-mail: info@celfirm.com
Tel: +82-31-8017-7893

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Chapter 10. SYLFIRM X™ patent list

This product is protected by the following patents.

No.	Title	National	Publication No.	Patent No.
1	Device for acupuncture	KR		10-0863269
2	Electric Skin Treatment Device	KR		10-1013581
3	Method, system, and apparatus for dermatological treatment	KR		10-1169747
4	Method, system, and apparatus for dermatological treatment	KR		10-1363000
5	Method, system, and apparatus for dermatological treatment	US		8979912
6	Method, system, and apparatus for dermatological treatment	US		9320536
7	Method, system, and apparatus for dermatological treatment	US		9630002
8	Method, system, and apparatus for dermatological treatment	US	2017-0014305	
9	Method, system, and apparatus for dermatological treatment	US		9775774
10	Method, system, and apparatus for dermatological treatment	US		10869812
11	Method, system, and apparatus for dermatological treatment	US	2021-0128404	
12	Method, system, and apparatus for dermatological treatment	US	2021-0077350	
13	Skin treatment apparatus and method	US		9480836
14	Electrically based medical treatment device and method	US		10058379
15	Electrically based medical treatment device and method	US		10799286
16	Apparatus and method for improving skin using a RA-EFFECT or RA PLUS-EFFECT	EP	2722072	

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Document History

Revision No.	Date	Description
Rev 00	2019-03-13	Initial release User Manual R00 (Software SYLFIRM X_Ver1.0.0)
Rev 01	2020-04-09	Revising 1.2.1 prescription only
Rev 02	2020-04-09	Replacing the term of probe with Hand-piece
Rev 03	2020-04-09	Revising 2.3.3 condition for cleaning
Rev 04	2020-07-24	Update Label information(marked NRTL)
Rev 05	2021-03-05	Adding Bi-polar electrode information
Rev 06	2022-04-20	Revising 1.2 Indications for use