



# SKIN BOOSTER II



operating manual

Ver. 1.2



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# 1. Introduction

## 1.1 About the Device

- SKIN BOOSTER II system is designed to meet international safety and performance standards of medical devices which is making Vital injector-3 system safe, durable and easy to use.



**Please read this operators manual carefully before use the system.**

- Please read this operators manual carefully before use the system.
- Always keep this user manual near the Vital injector-3 system.
- The contents of the manual may be changed or improved.
- All relevant standards and regulations referenced in the User Manual are valid versions when creating the User Manual.
- Eunsung Global provides training for customer about safety and proper use of our product . Please inform us if it is necessary.
- EunSung Global take no responsibility for product damage caused by failure to comply with the requirements of the user manual.

WARNING: Incorrect of use the device can cause hazards and device defects. Therefore, before attempting to use or operate the system, should read this manual and become thoroughly familiar with all its safety requirements and operating procedures.

# 1. Introduction

## 1.2 About the Glossary of Symbols and Abbreviations

| 기 호   | 내 용  |
|---|--|
|    | <p><b>Warning</b></p> <p>Indicates that there are certain risks that could result from improper conditions and actions that could result in serious or fatal accidents, regardless of whether they involve substantial property damage.</p>  |
|    | <p><b>Caution</b></p> <p>Indicates the need for the user to consult the instruction for use for important cautionary information such as warning and precautions that cannot, for a variety of reason be presented on the medical device itself</p>  |
|    | <p><b>Note</b></p> <p>Notes designate information of special interest especially on device.</p>  |
|   | <p><b>Good Manufacturing Practices</b></p> <p>Good manufacturing practices (GMP) are the practices required in order to conform to guidelines recommended by agencies which control authorization and licensing for manufacture and sale of products. These guidelines provide minimum requirements that this product is of high quality and do not pose any risk to the consumer or public.</p> |
| <b>MFDS</b>   | <p><b>Ministry of Food and Drug Safety</b></p> <p>Complying with MFDS's legitimate quality standard</p>  |
|  | <p><b>Manufacturer</b></p> <p>Indicates the medical device manufacturer as defined in EU directives</p>  |
|  | <p><b>Authorized representative in the European Community</b></p> <p>Symbol marking that shows Authorized representative in the European Community</p>   |
|  | <p><b>Waste Electrical and Electronic Equipment Directive</b></p> <p>This item must be disposed of properly. Contact your local representative or authorized distributor for disposal instructions</p>   |



**WARNING**

Unlike those described in this manual, operating or using the instrument may result in serious damage due to hazardous high voltages.

## 2. Equipment Safety

### 2.1 General Precaution

- The administrator is responsible for ensuring that the user operating the device has read and understood the Safety Precautions section of this manual. However, reading this manual does not entitle the user to operate, inspect, test, align, calibrate, troubleshoot, repair, or modify the system. The administrator should ensure that only properly trained and fully qualified operators perform the operation, installation, maintenance, troubleshooting, calibration and repair of the equipment.
- If anyone who wants to use or patients with this device, should be fully informed on detailed safety & regulation information.
- The administrator of the device must ensure that only fully qualified users are authorized to operate the system with appropriate training. Before you give the operator permission to operate the system, make sure that the operator has read and understood the instructions contained in this manual. If the device does not work correctly, please contact the manufacturer, Eunsung Global AS Center.
- EunSung recommends that all qualified personnel who operate Vital Injector system first seek training and also after determining suitability, the physician should inform the patient of the detailed cautionary information prior to the treatment
- Use this device only with the intention described in this User Manual.
- If anyone who wants to use this device, should be fully informed on detailed safety & regulation information.
- Unauthorized use of accessories may results in merchandise defect..
- Do not disassemble, repair the device. Merchandise-defect due to this act may void the warranty.
- Pregnant women should Consult with a specialist before treatment.
- Do not use or contact device to anyone who has infectious diseases or injuries.
- To avoid personnel injury, do not operate the system before ensuring that the exterior panels are properly closed.

## 2. Equipment Safety

### 2.2 Electrical and fire Hazards

- The system utilizes high voltage electrical current. To avoid personnel injury, do not operate the system before ensuring that the exterior panels are properly closed.
- Do not disassemble, repair the device. Removed exterior panels are causing Merchandise-defect and may severe electric shock.
- Water and electricity are a dangerous combination! Do not place Vital Injector in wet surroundings. Keep the device and hand-piece dry.
- Do not use this device near devices that generate strong electric fields, such as televisions, micro-electromagnetic devices.
- Do not use adjacent or stacked to other devices. May cause malfunction due to inter-product electromagnetic interference.
- This device must not be operated when the main power cable is damaged or worn out.
- Please unplug the device and keep it clean when not in use for a long time. May cause electric shock, electric short or fire.
- If the device had been severely wet and if you suspect strange noises, burning smell, smoke etc., turn off the AC power switch immediately and call to the customer support center.
- Vital Injector-3 should not be used near flammable substances. Fire or explosion can result.
- Do not operate Vital injector-3 with the cloth on the device. .



#### NOTE

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Eunsung Global is liable for the damages limited to the device defectives. All or any damages caused by the user's lack of experience or carelessness shall not be included.

## 2. Equipment Safety

### 2.3 Contraindications

- Prior to using this device, the operator must read this manual carefully and be familiar with the relevant points. Eunsung Global recommends that operators should seek continuing education in practical cases and are strongly advised to consult medical journals specific to their practice to ensure clinical updates on existing and new treatment procedures.



Vital Injector-3 is clinically proven safe device, yet therapy that using the Vital injector-3 system is contraindicated for those patients who have following condition and/or diseases

Besides following cases, if the physician decides not to use on certain other conditions, you may stop immediately.

- Malignant cancer
- Children
- Pregnant or lactation women
- Herpes
- Epileptic, Infection, Rash
- Inflammation
- Bleeder's disease(Hemophilia)
- cardiovascular disease
- Nephrological Disorders
- Implant pacemaker
- Implant metal stent
- Hypertension
- Diabetes mellitus
- Dermatologic disease
- Anticoagulant treatment
- Self-immune disease
- Facial nerve paralysis
- Lupus, Leukoplakia, Albinism Fever
- Caution of treatment at abdominal area during menstrual period
- Dermal filler
- Implant (including Dental, plastic surgery Orthopedic use)
- Be careful to use cuts or stab wounds, orbital, pre-orbital, ears, etc.
- A skin condition that affects the entire body or does not heal locally
- keloid skin
- Susceptible for electric stimulation
- patients with disease accompanied by more than 38 degrees of fever
- Patients with other specific diseases

Do not use this product with the following electronic medical devices:

- Transplantable electronic medical devices such as pacemakers
- Life-supporting electronic system, such as an artificial heart-lung apparatus
- portable electronic medical device, such as EKG.
- Do not connect any other therapeutic electric stimulator together.



Depending on the patient's condition, you can adjust the level of the procedure..

This device can be adjusted to an appropriate level depending on the patient's condition.

The results of the procedure may vary depending on the condition of each patient.



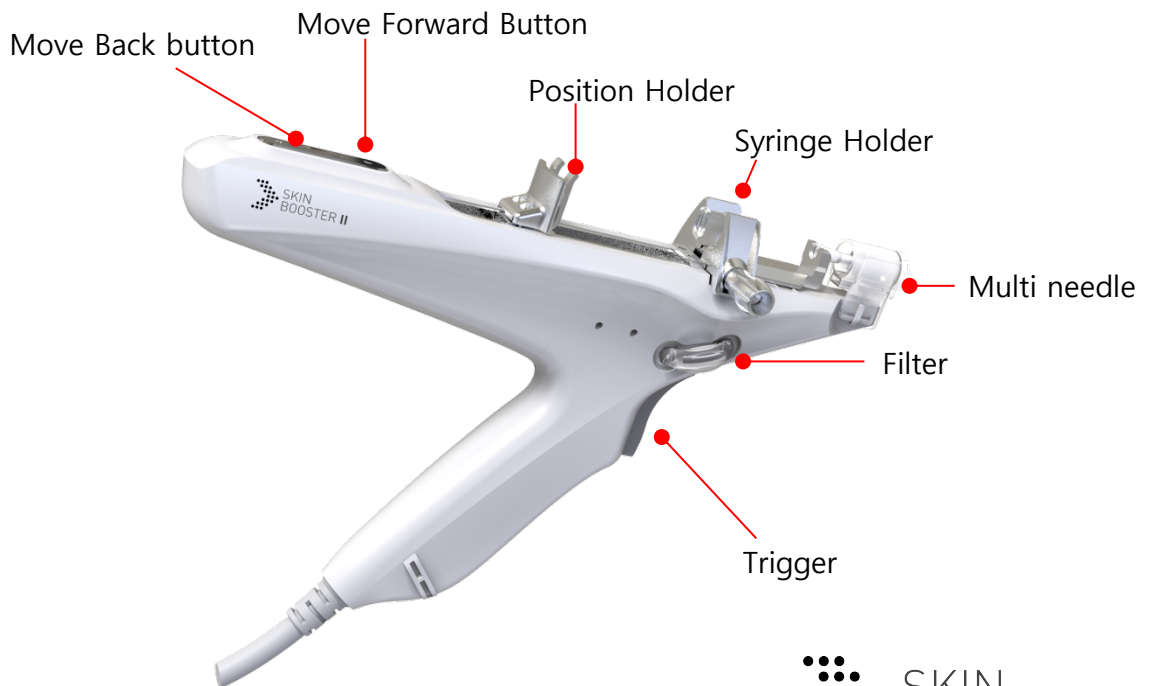
# 3. Device Description

## 3.1 Exterior and Function

### Main Body



### Injector



## 3. Device Description








### 3.2 Display Screen



| No | Name                             | Description  |
|----|----------------------------------|--|
| ①  | Current shot display             | Current shot count shown in display.   |
| ②  | Shot count reset                 | Reset shot count.  |
| ③  | Syringe type                     | Syringe type selection– 1 cc / 2 cc / 3 cc / 5 cc  |
| ④  | Depth                            | Set needle Penetration depth   |
| ⑤  | Dose                             | Set Drug Dosage.   |
| ⑥  | Viscosity                        | Needle Delay time( vital injector 2: 'Speed')  |
| ⑦  | Vacuum                           | Vacuum Level   |
| ⑧  | Select level                     | Level setting button of mode number 4~7  |
| ⑨  | Setting Button                   | Main screen setting option selection<br>– starting point adjustment/ LCD calibration   |
| ⑩  | Sound On/Off                     | Sound On/Off   |
| ⑪  | SK / HR Mode button              | SK / HR mode button<br>- SK mode: start vacuum<br>- HR mode: stop Vacuum   |
| ⑫  | Shot D / Shot C Selection button | Shot D / Shot C selection mode<br>- Shot D: Vital injector 2-intermittent mode<br>- Shot C: Vital injector 2-continuous mode |
| ⑬  | Standby/Ready                    | Standby / Ready  |

# 3. Device Description

## 3.3 Components

| Main Body   |   |   |
|---|---|---|
|   |   |   |
| Handpiece   | Handpiece Filter  | Filter cotton ball  |
|   |   |    |
| Cotton Swab   | User's manual   | Power cable   |
|  |  |  |

# 4. Installation

## 4.1 About the Installation

### Delivery

- The device is heavy so When in move, take an extra caution and do it slowly.
- Do not lay on side or impact on the device. It may occur damage to the interior of the device.
- Do not drop & minimize shock and vibration.

### About Site Preparation and environment

- Flooring should be flat.
- Install the machine in a well-ventilated area where appropriate temperature and humidity are maintained. Avoid sunlight and humidity.
- Keep the ambient temperature between 50°F and 105°F (10° to 40° C), humidity is between 10% and 90%, atmospheric pressure between 500 and 1060hPa.
- Keep distance from other machines that occur heat.
- Do not install the product in an environment where there is a possibility of flammable gas and volatile organic gases leaks possible explosion.
- when selecting the installation location for the device, must consider space, electricity, environmental, mobile condition, and even storage.
- The space to install the device must be well ventilated Also, check the "product specifications" in the back to see if the size of the space is suitable for the device's specifications. For proper ventilation, always position the machine at a distance of 0.2m from the wall or other object.
- This device may be affected if it is too close to a computer or other electronic device, so please keep a distance of about 2 meters.

### Caution

- Make sure that the wall outlet input voltage matches the rated voltage.
- Make sure that the ground terminal of the wall outlet is valid. If the outlet grounding terminal is not valid, install a separate ground on the ground terminal on the back of the Main body.
- This device is designed to operate normally at rated voltage, so check the voltage condition before installing the product.
- Take care not to wet the power cable.
- Do not connect to the main body if the power cable is damaged.
- Do not connect and use in one power strip with other products. Using multiple products with single power strip can cause abnormal heat generation.

## 4. Site Preparation

### 4.2 Installation Guide

- 1) Connect power cable and check the power supply.
- 2) If the power connector is connected to a multiple outlet, remove any other connections.
- 3) Make sure that the power plug is properly inserted. Please be careful not to connect the product with moist hands, as this may cause an electric shock.
- 4) Push the On button in the back side of the device and turn on the device.

## 5. Operation

### 5.1 About the Operation

- This device needs to be operated by only with authorized personnel who are correctly trained to use it.
- Before use, check all risks, warnings, cautions, and important points in the user manual provided.
- If anyone who wants to operate this device, should be fully informed on detailed safety & regulation information. .
- Check whether the power voltage, power input is correct.
- Make sure that the body and each part are properly assembled.
- Make sure that the handpiece and device are cleaned and disinfected.
- Do not place the device close to easily flammable anesthetics or solvents.
- There are no age or gender limitations in the application of this device to patients, but please follow the specialist's judgment about condition of patient to determine for treatment.
- If a failure is found with the device, stop using it and turn off the power.
- If there is a power outage, turn off the power immediately and place the switch in its original position.
- Make sure the handpiece cables are not tangled.
- Make sure that the power cable is connected properly.
- Make sure that the body and handpiece are positioned and secured in place.

# 5. Operation

## 5.2 Operation Guide

### 5.2.1 Type of syringe selection

- 1) Select the type of syringe operator wants to use.
- 2) Selectable types of syringe: 1cc, 2cc, 3cc, 5cc

### 5.2.2 Set Needle penetration depth

- 1) Range: Min. 0 mm ~ Max. 5.0 mm (Interval : 0.2mm)

### 5.2.3 Set Drug dosage

- 1) Shot D Mode
  - 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, 25, 30, 40, 50, 60, 70, 80, 90  $\mu$ l
- 2) Shot C Mode
  - 1 cc : 4, 8, 12 cc/min
  - 2 cc : 5, 10, 15 cc/min
  - 3 cc : 6, 12, 18 cc/min
  - 5 cc : 6, 12, 18 cc/min
- 3) Shot D mode guide (Minimum 50 shot / Maximum 120 shot applicable capacity range)
  - 1 cc: 8, 9, 10, 11, 12, 13, 14, 15, 20  $\mu$
  - 2 cc: 15, 20, 25, 30, 40  $\mu$
  - 3 cc: 25, 30, 40, 50, 60  $\mu$
  - 5 cc: 40, 50, 60, 70, 80, 90  $\mu$ l

### 5.2.4 Set Viscosity

- 1) Set the speed level at which the needle stays within the tissue after injection
- 2) 1 ~ 6 Level (Slower as number increases)

### 5.2.5 Set Vacuum

- 1) Set the level at which operator wants to apply.
- 2) 1 ~ 6 Level (Stronger as number increases)

# 5. Operation

## 5.2 Operation Guide

### 5.2.6 Set SK / HR Mode

- 1) SK Mode: All functions normal operation
- 2) HR Mode: Stop Vacuum function operation

### 5.2.7 Set Shot D / Shot C Mode

- 1) Shot D Mode: Each time when a trigger pulled, the loaded drug is injected 1 time.
- 2) Shot C Mode: While when a trigger is being pulled, the loaded drug is injected continuously.

### 5.2.8 Reset

- 1) Why the device needs to be reset?: Long term device use or external environmental factors may lead to errors of position holder control. You can restore the factory status to the pre-shipment state by running reset function.
- 2) Adjustment Method
  - ① Touch the Settings button on the UI screen to go to Setup screen.
  - ② Press 'Reference position' button to run reset.
  - ③ on the UI screen displaying 'CAUTION! Returning to the reference position ?' message.
  - ④ Pressing the move forward button of the injector (It matches 'Yes' button) 1 time then automatically moves the position holder to its original position.
  - ⑤ When the reset is completed, the UI screen displays the message 'CAUTION! The reset completed. Please start the positioning.'
  - ⑥ Short press the move back button of the injector, the message disappears, completing the reset

### 5.2.9 Injector Button

- 1) Move Forward button
  - Move forward position holder
- 2) Move Back button
  - Move back position holder
  - Keep pressing 2 seconds and it automatically move back. Press button once to stop movement.

## 6. Maintenance

### 6.1 Maintenance Precaution

- When the procedure is finished, remove the cartridge and store it separately, and keep the handpiece in the holder.
- Do not twist or tangle the handpiece.
- Do not store the device in humid or wet conditions.
- Power off in case of not in use for a day or more.
- For long time storage, remove the power cable and wrap the device.
- For long time storage, disassemble the handpiece connectors.
- Do not store in direct sunlight areas which may increase the temperature of the device.
- Be careful that the handpiece falls on the floor and is not damaged.
- Remove the power cable from the outlet and store.
- Keep the device away from children.
- To protect the device from bad influence of environment, do not store the device in locations exposed to high temperature, high humidity, dust and corrosive gas etc.
- Keep the device away from physical impacts, wobbling and slope locations.
- Do not store the device in locations with chemicals or which may generate gas.
- Carrying out a periodical inspect is strongly recommended.
- Safety check is strongly required before resume the device which has not used a month or more.

### 6.2 Cleaning and Storage

#### Storage

- Optimal temperature for storage is 5~40°C.
- Optimal humidity for storage is 10~90%.
- Indoor ventilation for storage is required.
- Minimize physical impacts or wobbling of the device.
- The optimal storage temperature for cartridges is -5°~ 30°C. (Low temperature storage)



Please turn off the power switch and disconnect a power cable before conduct the maintenance. It causes serious damages to the user or device unless power off.



## 6. Maintenance

### 6.2 Cleaning and Storage

#### Cleaning

- If foreign matter is stained, do not wipe it with strong force. Wipe it several times to remove foreign matter.
- Wipe it with a soft cloth. If it is not cleaned well, please do not rub hard and gently wipe it several times.
- Do not wipe with paint thinner, benzene, alcohol, etc. as it may cause discoloration or deformation..

#### Cleaning Main Body

- Wipe the screen and main body with a soft cloth to remove foreign materials and dirt.

#### Cleaning Handpiece

- Wipe with a wet tissue and then wipe with a dry cloth once more.

### 6.3 Trouble Shooting

#### 6.3.1 Syringe Usage Completion Message

- ❖ If the syringe was empty during the procedure, display the following message on the UI:
  - Warning ! This syringe is empty. Please move back the holder.
- ❖ Press the move back button on the injector to move back the position holder and remove syringe.

#### • 6.3.2 When the position holder reached at the end of injection.

- ❖ When operator press the move back button to move back the position holder, in case of the position holder reached at the end display the following message on the UI:
  - CAUTION ! The holder reached at the end..
- ❖ The message would be disappear when press the move forward button to move position holder forward.

# 7. Warranty

## 7.1 About Warranty

- Eunsung Global Corp. provides the following assurance for products in accordance with the Consumer Dispute Resolution Criteria by Item (Fair Trade Commission Notice)
- In the event of a break down in normal use (according to the user's manual only) within 1 year from the date of purchase, customer service is granted without charges.
- The warranty covers a main body of the device only.
- The warranty excludes any problems caused by the cases that users are not following the guides for operation and safety.
- The warranty excludes any damages caused by the cases that users moved the device by holding the connected cable or handpieces.
- The warranty excludes the cases of misuse, disassemble and modification which are not identified in the manual.
- The warranty excludes consumable components.

## 7.2 Exclusion

- Compensatory guarantees is provided after 1-year warranty above. Within the warranty period, compensatory guarantees is applied to the cases of a break down caused by consumer's faults or natural disasters such as fire, salt damages, flood, shocks, earthquakes, lighting etc.
- Compensatory guarantees is applied to damages caused by disassemble, modification and careless handlings of the user.
- Compensatory guarantees is applied to damages due to the third party repairs which is not authorized by Eunsung Global Corp.
- Compensatory guarantees is applied to damages caused by using inappropriate consumable goods or the user's misconduct of the manual.
- Compensatory guarantees is applied to the case that the free warranty period approved by Eunsung Global Corp. for consumable goods is expired.



- The authorized person must provide the repair service for free warranty. The warranty strictly excludes the cases that the device is used for the purpose which is not identified in the manual.
- The service request for any cases other than the damage of the device, it shall be charged regardless of free warranty period. Please read and understand all guidelines in the manual

## 8. Customer Service

### Sales Manager

### Distributor

Australia and New Zealand

Cryomed Aesthetics / Cryomed NZ Limited

[www.cryomed.com.au](http://www.cryomed.com.au) / [www.cryomed.nz](http://www.cryomed.nz)



The V3 Project a joint venture between Eunsung and Cryomed

