

VITAL INJECTOR 2™



Operator Manual

Ver. 1.0

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EUNSUNG GLOBAL CORP.

#1102~1105, Hanrasigma Valley 345-90,

Gasam-Dong, Geumcheon-Gu,

Seoul, Korea

Tel. : +82-2-514-9713

Fax. : +82-2-514-9716

E-mail : es@esglobal.co.kr

Website : www.esglobal.co.kr

Manufactured by EUNSUNG GLOBAL CORP.

1) **#1316~1317, Daeryung Techno Town 12Cha,**
Gasam Digital 2ro 14, Geuncheon-Gu, Seoul, Korea

2) **#1302~1305, Hanrasigma Valley, Gasam Digital 2ro**
53, Geuncheon-Gu, Seoul, Korea

Tel. : +82-2-514-9713

Fax. : +82-2-514-9716

E-mail : es@esglobal.co.kr

Website : www.esglobal.co.kr

Authorized representative:

EUNSUNG GLOBAL CORP.

#1302~1305, Hanrasigma Valley Gasam Digital 2ro 53,

Geumcheon-Gu,

Seoul, Korea



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1. Introduction

1.1. About the Manual

- Vital Injector2 is designed to meet international safety and performance standards.
- Personnel operating the system must have a thorough understanding of the proper operation of Vital Injector2.
- This manual has been prepared to aid medical and technical personnel to understand and operate the system.
- Do not operate the system before reading this manual and gaining a clear understanding of system operation.
- If any part of this manual is not clear, please contact your local representatives of Eunsung Global for further clarification.
- The information provided in this manual is not intended to replace the professional training on the clinical use of the system. Please contact your local representatives of Eunsung Global whether there are any updated information on available training.
- For information on technical guideline, refer to the respectively offered treatment guideline manual.
- This manual should always accompany the system and all operating personnel must know its location.

1.2. About the Device

Vital injector2 system is a meso injection device using a separately offered syringe to safely inject drugs within it into the skin.



WARNING

Use of controls, adjustments or performance of procedures other than those specified herein may put the operator and/or the patient at risk. Therefore, before attempting to use or operate the system, personnel operating Vital Injector2 should read this manual and become thoroughly familiar with all its safety requirements and operating procedures.

2. Equipment Safety

2.1. About Equipment Safety

This chapter describes general safety issues regarding the use of Vital Injector2. With proper operation and maintenance, trained and qualified medical practitioners can use the Vital Injector2 safely. The supervising physician and all other personnel operating or maintaining Vital Injector2 must be familiar with the safety information provided in this chapter.

The primary consideration should be for the safety of the patient, the physician and other personnel. Patient safety is mainly assured with a well trained staff and a well laid out treatment room.

Patient education is also important, including information about the nature of the given treatment.

2.2. General Precaution & Caution

2.2.1. General

- Physicians and clinicians should read this manual thoroughly before attempting to operate the system
- While not in use, injector & multi-needle should be detached from each other and store separately for the safety.
- There are no user-serviceable parts inside the system. Only Eunsung Global-authorized personnel may service the system, especially inside its cabinet.
- The system, inclusive of console & a injector, weighs approximately 2.4kg (5.3lbs.) and may cause injury if proper care is not used when moving it. The system is well balanced and is designed to be moved, but should always be moved carefully and slowly.
- Verify that the Vital Injector2 is wired for the appropriate electrical voltage of your country (110 VAC - 240 VAC).

2.2.2. Injector & multi-needles

- Do not twist or pull the connecting cable. This could cause damage to internal wires and connections.
- Do not use the injector if any it is dropped or if any other type of excessive force has been applied. Injectors may be permanently damaged if dropped onto the hard surface. The system must be examined for safe operation after such an occurrence.
- Multi-needle comes in different packet. Be sure to have needle first prior to make treatment.
- Keep new multi-needle in a sterilized pouch until ready for use.
- Multi-needle is a disposable item. Do not reuse.

2.3. Electrical Hazard

- Do not arbitrarily untighten the screws, keep all covers and panels of the system closed. Removing the covers creates a safety hazard.
- Always make sure the system is turned off before connecting/disconnecting the Injector to/from the system and before cleaning the system.
- Do not immerse any part of the system into liquids.
- It is forbidden to connect any third-party equipment to the system.
- Disconnect the power cord from the outlet by pulling on the plug not the cord.
- No modification of this equipment is allowed.



WARNING

- Unattended use of Vital Injector2 with and/or without the multi-needle attached on, by children or incapacitated persons may be dangerous.

3. Medical Safety

3.1. About Medical Safety

This chapter describes various cases of safety issue while using the device in clinical setting.

3.2. Indication for Use

Vital Injector2 is a multi-use meso injector for various medical use. This advanced capacity machine now featuring with a detachable hygienic- filter technology promises better controlled hygienic treatment. Vital Injector2 is originally developed to assist in the delivery of stabilized hyaluronic acid filler to restore hydrobalance in the skin and improve skin elasticity and tone to create a revitalized look.

3.3. Patient Safety

- Delivering excessive amount of drug not considering individual's skin sensitivity would result in side effect or some adverse events.
- Trial test should be done before making full facial treatment.



WARNING

- Use this system only if you are trained and qualified to do so.
- If any problems occur during the system operations, take immediate actions; lift the injector off the patient's skin, press the button to STOP to discontinue treatment in progress.

4. Device Description

4.1 Main Console

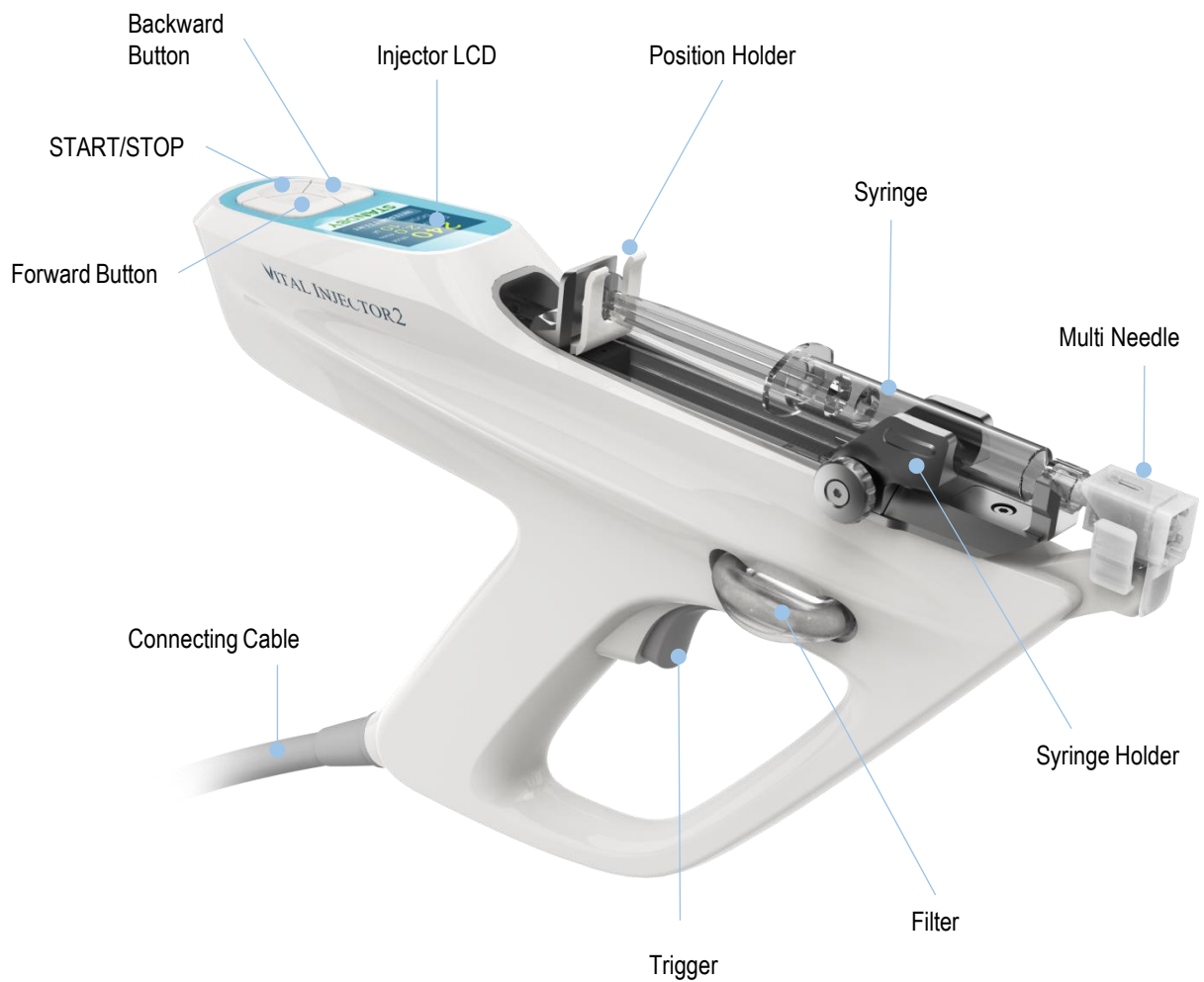


- Main Body & Trolley -

4. Device Description

4.2. Injector

The device is conveniently designed easily operated. LCD panel on the device enables an operator to check the operation during treatment.



- Injector -

4. Device Description

4.3. Equipment List

The following equipment is delivered in the shipping pack:

① Device	② Injector
	
③ Power Cable & Adaptor	④ Filter
	
⑤ Filter cotton ball	⑥ Manual
	
⑦ Multi Needle(20psx/box) [Option]	⑧ Trolley [Option]
	



NOTE

Call your local dealer if you want to purchase additional equipment of Vital Injector2

5. Site Preparation

5.1. About Site Preparation

When preparing the site, operators should consider the spatial, electrical, environmental, transportation and storage requirements of the system. Before unpacking, ensure that the site meets the requirements described in the following sections.

5.2. Spatial Requirements

- Space should be allocated with adequate ventilation and free airflow.
- After positioning the system, lock the breaks (along with the use of trolley) on the front wheels by pressing the pedals on top of each wheel.
- Make sure to keep an enough distance between the patients & device so as not to be touched/operated by the patients.

5.3. Electrical Requirements

Please consider the following electrical requirements before installing the system:

The AC power line power requirements for the system are:

- 110 - 240 VAC
- 50 - 60 Hz

5.4. Environmental Requirements

Air Quality:

The system should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components and the surfaces of treatment components.

Metallic dust is destructive to electrical equipment.

Temperature:

To ensure that the system performs optimally, maintain room temperature between 50° to 80°F (10° to 27°C) and relative humidity at 30% to 75%, non-condensing.



NOTE

Any damage to the packaging or to the system found prior to opening the package should be reported to your Eunsung Global local representative.

5. Site Preparation

5.5. Storage & Transportation Requirements

To maintain the system properly during storage and transport, follow these requirements.

- Keep the room temperature between 40° and 105° F (5° to 40°C) to optimally store the main console.
- Keep the system in a location where the humidity is between 10% and 80%, non-condensing.
- Store the system where the air is free of corrosive substances, such as salts or acids.
- Store the system where there is a minimum of dust particles.
- Air pressure: 500hpa ~ 1,060hpa
- Minimize shock and vibration during the transportation.
- Do not drop.

6. Installation

6.1. About the Installation

Vital Injector2 is designed for installation in an office or a clinic and requires minimal site preparation.

System installation is carried out by clinic personnel, who will do the following:

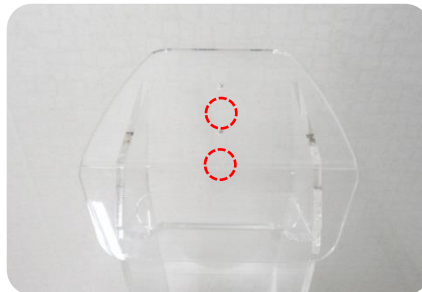
- 1) Unpack the system and position the items in their pre-selected locations.
- 2) Needles are packaged separately from the main unit and injector, in ready-to-use, small pouch.
- 3) Verify the integrity of the system and all components.
- 4) Connect the injector and required multi-needle.
- 5) Plug the Injector connecting cable into the system's cable receptacle.
- 6) Plug the system's power cable into an appropriate electrical outlet.
- 7) Turn the system on.
- 8) Test the system for functional operation of all components and software.

6.2. Assemble Main Body & Trolley

- 1) Remove the two bolts on the bottom of the device.
- 2) Match the connection holes in the top of the trolley and the holes in the bottom of the device.
- 3) Using the bolts to firmly tighten the device to the trolley.



- Back side of device-



- Top of the trolley -



6.3. Assemble Main Body & Injector

Mount the injector to the cradle and connect the cable to the socket on the main unit.



CAUTION

Locate the injector horizontally position with cradle then gently push forward to correctly mount on it. If injector is not correctly inserted it may cause to drop & lead to equipment failure.

6. Installation

6.4. Power On/Off

Connect AC power cable by simply inserting to the device then press the switch to the position of [I] to power on.



- Power Off -



- Power On -

6.5. Mounting filter

Mount filter to injector.



6.6. Multi-needle mounting and exchanging

Remove safety guard on multi-needle prior to use.



- Connect the needle to injector -



- Remove the safe guard -



CAUTION

Remove safety guard immediately after mounting the multi needle to injector . If not, It may cause to equipment & clinical failure.

6. Installation

6.7. Mounting Syringe

Place syringe on injector and place the end of the pistol into the position holder as shown below.



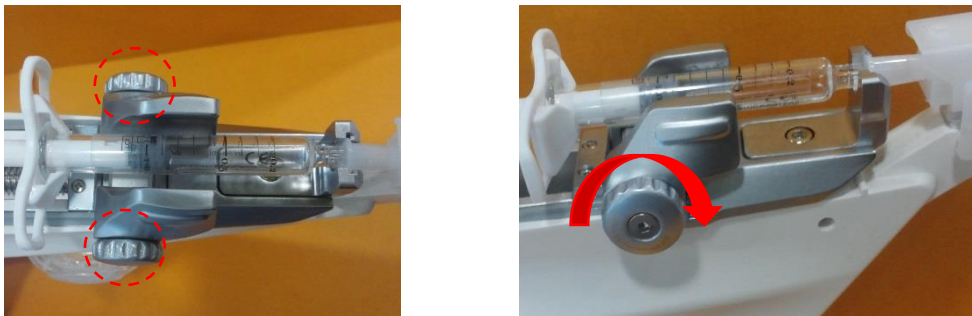
6.8. Connect Syringe to Multi-needle

Press the forward button and insert syringe into needle hole. Hold syringe with hand in order to accurately connect syringe in needle hole. Slightly push syringe once more to finish up the connection tightly.



6.9. Tighten syringe holder screw

Fasten up the syringe with screw dials at both sides.



NOTE

Once all preparation process is done, pull the trigger couple of times to deplete of remaining air inside the syringe.

7. Operating Instructions

7.1. About Operating Instructions

This section of the manual explains how to start and operate the system inclusive of possible warning & caution at each level of the procedure.

Prior to use the system, make sure that following conditions are all met.

- Are Injector, syringes, needle and body clean ?
- Is the caster fixed?
- Is the power cable connected properly?
- Are the syringe and needle ready?

7.2. System Operation

7.2.1. Prepare the system for operation

- 1) Plug the AC power cable on the back of the system into the wall socket.
- 2) Press the main power switch (on the rear panel) to the ON position. (The main power switch may be left in the ON position when the system is not in use)

7.2.2. Loading

Loading screen will be shown up when turning on the device



7. Operating Instructions

7.2. System Operations

7.2.3. LCD Monitor & Control Panel



NOTE

DOSAGE

- Intermittent mode [Preset : 10 μ l]
5,6,7,8,9,10,11,12,13,14,15,20,25,30 μ l
- Continuous mode [Preset : 1 cc/min]
1 cc : 1, 2, 3 cc/min
2, 3, 5 cc : 1, 3, 5 cc/min

7. Operating Instructions

7.2. System Operations

7.2.3. LCD Monitor & Control Panel

No	Item	Description
1	Number of Shots	Displays currently treated number of shots. (after mounting the syringe to the injector)
2	Syringe Volume(cc) & Type	Select desired volume of syringe for operator's medical needs. The volume changes as the user presses the touch screen. (Range: 1cc, 2cc, 3cc, 5cc / Default: 1cc)
3	Needle Depth	Select the appropriate depth of the needle to penetrate into the skin. Press the 'DEPTH' touch screen to select then adjust the depth by using upward/downward arrows on the right. (Range: 0.0mm ~ 5.0mm / Interval: 0.2mm)
4	Drug Dose (cc/min) per a shot	Select to adjust total amount of drug per one shot. Tab the 'DOSE' to select then adjust the amount by using upward/downward arrows on the right <ul style="list-style-type: none"> ▪ Range: 5µl ~ 30 µl (5Pin Total)
5	Mute	Press the icon once to mute the sound of the buttons. Press again to set back to normal.
6	Treatment Mode	Two types of treatment mode is programmed. Press the tab to change between 'INTERMITTENT' & 'CONTINUOUS'
7	Reset	Reset the currently delivered number of shots to '0'
8	Speed	Select to adjust the time of needle to be inserted/stayed onto the skin. <ul style="list-style-type: none"> ▪ Range: 1 ~ 6 (The staying time of needle on the skin progresses longer from '1' to '6') ▪ Default: 3
9	Level Adjustment	By using this upward/downward button, the operator can adjust, syringe volume, needle depth, needle staying time, drug dosage, vacuum level. <ul style="list-style-type: none"> ▪ ^ Increase button ▪ v Decrease button
10	Vacuum	Select to adjust the vacuuming power of needle in treatment. <ul style="list-style-type: none"> ▪ Range: 1 ~ 5 (weakest to strongest) ▪ Default: 4
11	Setting	Press the 'Setting' button to adjust Syringe, check F/W upgrade and LCD calibration.

7. Operating Instructions

7.2. System Operations

7.2.3. LCD Monitor & Control Panel

Intermittent Mode [Preset : 10 µl]

Type	Dose	Available Shot	Dose	Available Shot
1 cc Syringe	7 µl (1.4µl/pin)	143	13 µl (2.6µl/pin)	77
	8 µl (1.6µl/pin)	125	14 µl (2.8µl/pin)	72
	9 µl (1.8µl/pin)	111	15 µl (3.0µl/pin)	67
	10 µl (2.0µl/pin)	100	20 µl (4.0µl/pin)	50
	11 µl (2.2µl/pin)	90	25 µl (5.0µl/pin)	40
	12 µl (2.4µl/pin)	83	30 µl (6.0µl/pin)	33

Continuous Mode [Preset : 1 cc/min]

Type	Dose
1 cc	1 cc/min, 2 cc/min, 3 cc/min
2 cc	1 cc/min, 3 cc/min, 5 cc/min
3 cc	
5 cc	

7.2.4. Alert on drug used

- 1) The audible alarm signal is activated when the drug within the syringe is almost used up.
- 2) In case of the standard (syringe), total 5 number of alarm signals are to be activated. Except for the standard, in case of others, at least two times of alarm signals would be heard.
- 3) Upon hearing the alarm signal, the operator needs to immediately stop the treatment and check the residual amount of drug & the condition of the needles. If syringe rubber is reached to the end of the syringe, stop advancing to any further treatment.
- 4) Unless stop, the syringe rubber is compressed to abraded which result in functional & physical impair to the injector. Also the needles are to be protruded and major damage to the patient's skin condition resultingly.



CAUTION

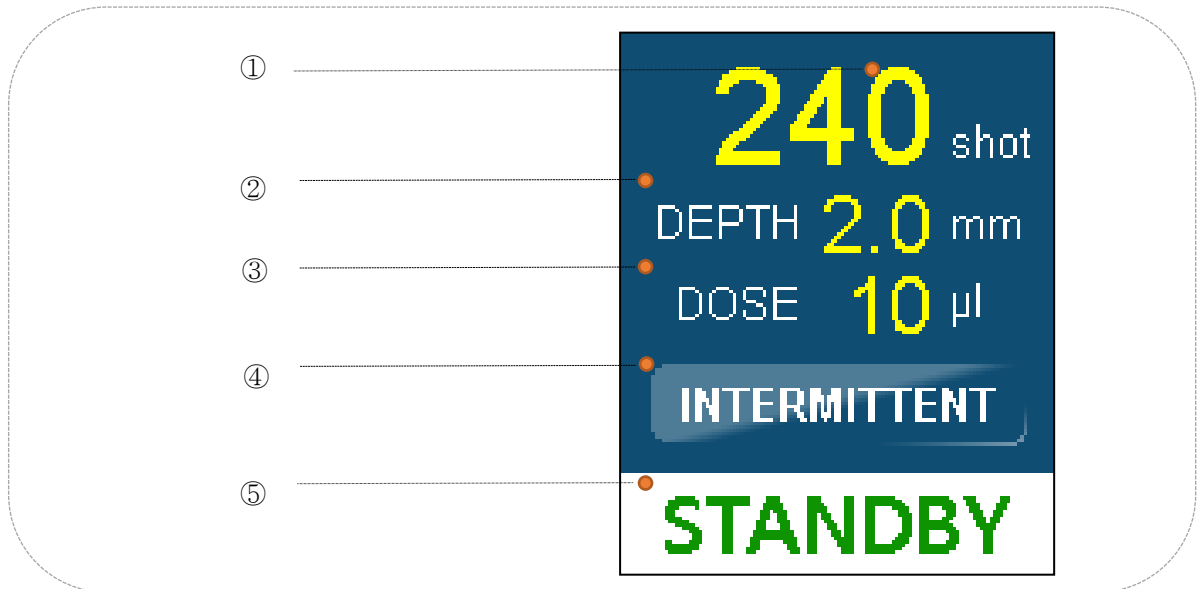
Alert on drug used

- Final alarm signal rings at the state when the drug (within the syringe) is almost used up.
- 5 times and below number of alarm signals will be activated when using non-standard syringe.

7. Operating Instructions

7.2. System Operations

7.2.5. Injector Button & LCD

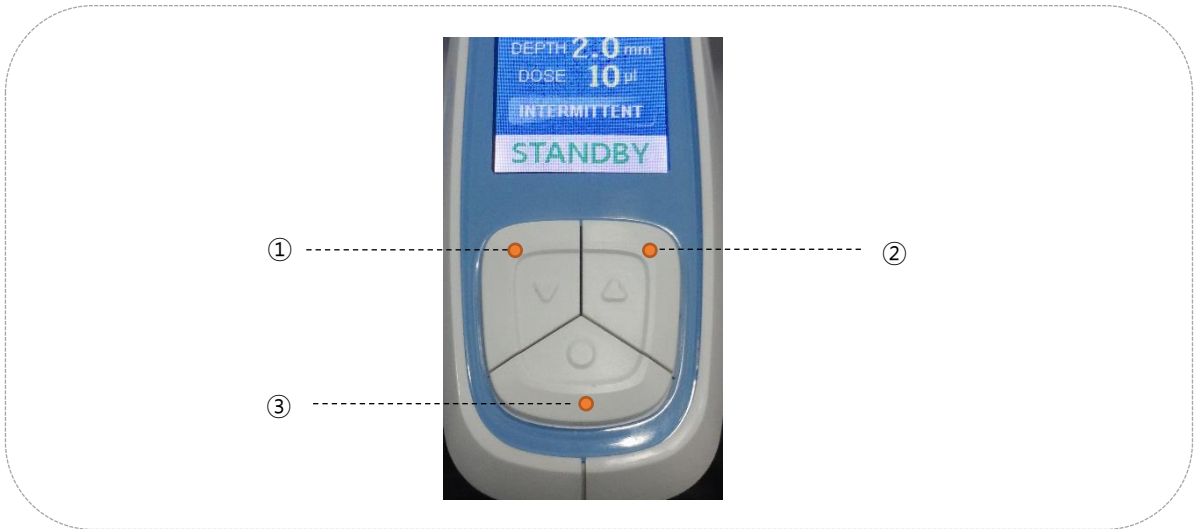


No	Item	Description
1	Number of Shots	Displays currently treated number of shots. (after mounting the syringe to the injector)
2	Needle Depth	Select the appropriate depth of the needle to penetrate into the skin. Press the 'DEPTH touch screen to select then adjust the depth by using upward/downward arrows on the right. (Range: 0.0mm ~ 5.0mm / Interval: 0.2mm)
3	Syringe Volume(cc) & Type	Select desired volume of syringe for operator's medical needs. The volume changes as the user presses the touch screen. (Range: 1cc, 2cc, 3cc, 5cc / Default: 1cc)
4	Treatment Mode	Two types of treatment mode is programed. Press the tab to change between 'INTERMITTENT' & 'CONTINUOUS'
5	Standby/Ready	STANDBY/ READY Only applicable through injector. No Standby/Ready button in the main screen.

7. Operating Instructions

7.2. System Operations

7.2.6. Injector Button & LCD



No	Item	Description
1	Backward Button	Move back position holder Keep pressing the button for 2 seconds then it automatically moves back. Press the button once more to stop the movement.
2	Forward Button	Move position holder forward
3	Standby/Ready	<ul style="list-style-type: none">StandbyReady Keep pressing the button for 2 seconds then it automatically moves back to the place where the position holder and syringe holder match.



NOTE

Auto reference positioning function

- 1) At the time the position holder reaches at the place near to 1cc, you may press “Back” button for over 2 seconds then it automatically moves back to the place where 1cc syringe mounted.
- 2) Press button once more then the movement stops.
- 3) 2cc, 3cc, 5cc syringe can be also automatically positioned themselves.

8. Maintenance

8.1. About Maintenance

This chapter contains maintenance instructions for the Vital Injector2.

Routine maintenance may be performed by clinic staff unless otherwise specified. Any maintenance procedure not mentioned in this chapter must be performed only by Eunsung Global personnel.

The system is designed to operate reliably without any need for operator maintenance. However, the outer surfaces of the system should be kept clean for hygienic reasons and the cartridge window should be cleaned between sessions to enable effective treatment.

8.2. Cleaning

To get the best possible performance, treat the equipment carefully by adhering to the following guidelines:
Always turn off the system before cleaning

8.2.1. Filter cotton ball part

Frequently check and replace a filter to maintain the machine.



8.2.2. Injection vacuum hall

Remove injector needle after each treatment and clear the vacuum hole with alcohol swab.



8.2.3. Injector

- Turn off the device and clean the outer plastic casing with dry towel. Prevent the needle connector from sticking dirty substances.

8.2.4. Console

- The outer surface of the system may be wiped clean with a soft wet cloth followed with dry microfiber towel.

8.2.5. LCD Screen

- The LCD screen preferably should be cleaned with a dedicated LCD cleaning solution along with microfiber cloth. This can be obtained from any office supply store.
- If dirt or any kind of debris are strongly attached to it, do not try to wipe it hard to remove it multiple times of soft stroke will do.



WARNING

Always turn the system off and unplug the power cable before performing maintenance procedures.



CAUTION

During the maintenance, user must turn off the power and disconnect the power plug. If the power is turned on, during the cleaning, it may cause to equipment failure.

8. Maintenance

8.3. System Error Messages

The user may encounter errors while operating the system. When an error occurs an error message appears on the display with a brief text message. All error messages are listed in the following along with corrective action if applicable.

The following does not attempt to list all possible system failures. Any error not listed should be referred to your local representative of Eunsung Global.

Message Displayed	Description
<p>CAUTION ! Returning to the reference position ? No : Left Yes: Right</p>	<p>The message appears when user press the STADNBY/READY button at the injector for more than 2 seconds. Then user would decide whether to go back to 'factory setting' or not.</p> <p>Forward button (at the right): Proceed on to 'factory setting' Backward button (at the left): Stick to the 'current setting'</p>
<p>CAUTION ! The reset completed. Please start the positioning.</p>	<p>The message appears when the 'factory setting' is completed and the system goes back to the default. The message disappears when pressing the 'backward button' once.</p>
<p>Warning ! This syringe is empty. Please move back the holder.</p>	<p>The message appears when drug inside the syringe is all consumed up. The user may move back the position of syringe then remove of it.</p>
<p>CAUTION ! The holder reached at the end.</p>	<p>The message appears when the position holder reaches at the end of injector. No more room to move backwards. Stop moving the position holder.</p>

8. Maintenance

8.4. Troubleshooting

Trouble	Possible Cause	Solution
Power Problems	Power cable is not connected properly	<ul style="list-style-type: none">▪ Check whether the power is on▪ Check whether the power cable is connected
	Monitor freeze	<ul style="list-style-type: none">▪ Check after rebooting (Turn off the device and wait for 10 seconds then turn on the device)
	The monitor's power problem	<ul style="list-style-type: none">▪ Check the connection status of the injector connector
Operating Problem	System error message	<ul style="list-style-type: none">▪ Verify progress in the correct syringe setting - If this is the case, change to normal setting immediately
	Device stops	<ul style="list-style-type: none">▪ Verify progress in the correct syringe setting - If this is the case, change to normal setting immediately

9. Warranty

9.1. About Warranty

Eunsung Global implements Product Limited Warranty as follows based on reconciliation standard of consumers dispute by merchandise. (Notified by Fair Trade Commissions)

This section of the manual provides information regarding customer support, such as warranty & warranty Claims.

9.2. 6 months Limited Warranty

- 1) You may claim the warranty if the device gets malfunctioned within 6 months from the date of the purchase.
- 2) Eunsung Global has the sole responsibility to determine the cause of merchandise defect.
- 3) One year limited warranty only includes main console. (injectors and other accessories such as consumables are not included.)

9.3. Limitation & Exclusion

This limited warranty does not cover and Eunsung Global is not responsible for:

- The merchandise is being damaged caused by misuse, abuse, accidents, fire, theft, disappearance, misplacement, fluctuation and power surges, connection to improper voltage or incorrect electrical line voltage, malware, reckless, willful or intentional conduct
- Damages caused by a product or part that has been disconnected, modified, arbitrary repaired, altered without the permission or supervision of trained personnel from Eunsung Global.
- Damages caused by usage that is not in accordance with instruction of operator's manual, failure to follow the operator's manual or failure to perform cleaning or preventative maintenance.
- Damage caused by a product or components that has been modified to alter functionality or capability without the written permission of Eunsung Global.
- The merchandise that has no serial number.
- For all accessories, except for main console.
- Merchandise defect ascribed to natural disaster.
- Normal wear & tear.



NOTE

- Improper use or adjustment of this system may invalidate the service warranty agreement. Please contact your local representative of Eunsung Global before attempting to troubleshoot this system in any manner other than specified in this manual.
- Before returning merchandise, obtain prior approval from Eunsung Global.
- Fail to follow the detailed instruction will void the warranty. Also please read the following exclusion-conditions carefully before making any claim.

10. Specification

Needle Information	31 G, 5Pin Multi Needle Type
Needle Penetration Control	0.0 ~ 5.0 mm (Interval 0.2mm)
Syringe Type	1cc, 2cc, 3cc, 5cc
Operation Mode	Intermittent, Continuous
Voltage & Frequency	AC 110 ~ 240V, 50~60 Hz
Dimension (WxDxH mm)	Injector : 293 x 49 x 168 Body : 333 x 298 x 130
Panel	Injector LCD : 1.7 Inch Body LCD : 5.0 Inch, Touch Screen
Weight	4.7 Kg (Body + Injector)

11. Customer Support

Sales Representatives

Manufacturer



Eunsung Global Corp.

#1102~1105, 53, Gasan digital 2-ro, Geumcheon-gu, Seoul, 153-706, Korea

Tel: +82-2-514-9713(Rep) Fax: +82-2-514-9716

e-mail: es@esglobal.co.kr/www.esglobal.co.kr

Tel. 02-514-9713 / Fax. 02-514-9716

E-mail: es@esglobal.co.kr / Website: www.esglobal.co.kr

