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HƯỚNG DẪN SỬ DỤNG TIẾNG ANH TRANG THIẾT BỊ Y TẾ

Xác nhận bằng chữ kí số của cơ sở

VOLNEWMER

INSTRUCTIONS FOR USE (IFU)

Ver. 1.0

VOLNEWMER

The VOLNEWMER is intended for use only by properly trained physicians and properly trained persons under the supervision of such a trained physician.

Users must thoroughly read and understand this manual prior to operating the device. Improper use of the system may cause injury to parties and/or may cause damage to the system that may void the warranty agreement.

Note 1. This operation manual describes the operation of the VOLNEWMER only. It is not a substitute for the required clinical training to use the system.

Note 2. Classys Inc. provides this manual in English by default. Classys Inc. also translates the manuals into the language of each country sold in Europe only.

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1.About This IFU (Instructions for Use)

1-1. Use of the IFU

The VOLNEWMER is designed to meet international safety and performance standards. Personnel operating the device must have a thorough understanding of its proper operation.

This IFU has been prepared to aid medical and technical personnel to understand and operate the device. Do not operate the device before reading this IFU and gaining a clear understanding of device operation.

The information provided in this IFU is not intended to replace the professional training on the clinical use of the device.



Caution: Do not operate the VOLNEWMER prior to reading this manual thoroughly and being trained by an authorized Classys Inc. representative.

This manual is not a substitute for clinical treatment guidelines and training provided by the company or its distributors.

1-2. Conventions



Caution: This signal alerts the user to precautionary steps necessary to effectively operate the system. Failure to observe these cautions may void the warranty.



Warning: Warnings alert the user to information that is of the highest importance and vital to the safety of the patient and user.

Numbered sections are presented in steps and must be completed in sequence.

Bulleted lists indicate general information about a particular function or procedure. It does not imply a sequential procedure.

2. Safety Information

2-1. Indication for Use

The VOLNEWMER delivers monopolar radiofrequency(RF) energy for selective coagulation of tissue while conductively cooling the epidermis.

The VOLNEWMER is specifically indicated for non-invasive **periorbital** wrinkles and rhytids treatment.

2-2. Patient Safety

Patient selection must be performed by a physician.

- Regardless of gender
- Aged 35 to 60 years
- Patient with skin laxity(saggy, wrinkled skin) on the face and body

2-3. Contraindications

The VOLNEWMER is not recommended for patients with the following:

- Patients who receive an artificial pacemaker, implantable defibrillator(AICD), or other implantable electrical devices are prohibited from using them as they may adversely affect high frequencies or current.
- Patients with diabetes or epilepsy, connective tissue-disease, radiation therapy or chemotherapy.
- Patients injected with permanent fillers and facial implants
- Patients with open wound or with infection on treatment area
- Patients who are allergic to local anesthetics, antibiotics, or other medications
- Patients who cannot or do not follow the instructions for post treatment care
- Pregnant or breast feeding women, children
- Patients with severe or follicular acne in the treatment area
- Patients with systemic or localized skin diseases that may affect the wound healing process
- Around the patient's eyes or eyes where high frequencies can be in direct contact
- Patients with uncontrolled diabetes complications and other serious complications
- Patients with cancer or malignant disease
- Patients blood disorders and taking aspirin or blood disorders
- Patients with acute disease and hypertension

- Patients with herpes simplex or epilepsy

✘ For other conditions refer to your local doctor or practitioner for consultation

2-4. Precautions

Do not use the equipment without prior training and qualifications to operate the VOLNEWMER.

For the following conditions of patients, consult with experts to decide whether treatment is appropriate.

- Herpes simplex
- Autoimmune diseases and disorders
- A patient with a keloid constitution
- Patients injected with Botox or filler within the last 4 weeks
- Patients who have had a fat or skin graft at the treatment site within the last 6 months
- Patients with photosensitivity disease or those taking drugs that cause photosensitivity
- Those who continuously use steroid drugs or take anti-immunotherapy
- Patients with permanent makeup and tattoos
- Those with poor skin condition: Excessive damage from sunlight, severe elastic fibrosis, fibroblast response and poor elastin production
- In case of chronic use of nonsteroidal anti-inflammatory drugs(NSAIDs) or corticosteroids
- In case of poor overall physical and mental health
- Seniors 65 years or older
- In case of eye treatment
: You should not be a patient who has recently undergone corneal surgery
- Those with blood coagulation disorder-related diseases such as hemostasis or thrombosis.
- People with cardiovascular disease or other physical diseases
- Those with dermatological lesions or sensory abnormalities in the treatment area
- Those who have experienced peeling or liposuction on the treatment area

2-5. Potential Side Effects

The most frequently reported side effects during the treatment is mild to moderate pain. In general, discomfort is temporary during the treatment and is limited to the treatment site. The most frequently reported side effects are:

(1) Burn, Blister, Scabs, Scars

This process can generate heat, leading to burns and subsequent blistering and crusting in the upper layers of the skin. There is a slight chance of scarring. The use of topical steroid or antibiotic preparations may be helpful. In the rare cases of burns that result in scarring, the scar will likely be very small and will readily respond to laser treatment.

(2) Surface Irregularities

Surface irregularities(occurring locally) have various types such as “small pits” on the skin surface, “wrinkles”, “swelling”, honeycomb appearance, or “oil loss” (occupies a large surface area).

Surface irregularities usually do not become apparent immediately after treatment, but appear later (1 month or more after treatment). In most cases, Classys recommends monitoring surface irregularities for a six-month post-onset period.

(3) Sensory change

The sensory change is described as "numbness", "tingling" or "temporary paralysis". The sensory change usually resolves within a short time, but in rare cases it may take up to several weeks. This adverse event is rare and, as seen with invasive facelifts, disappears over time without any intervention.

(4) Masses / Nodules

It can be reported that "Masses" or "Nodules" occur under the skin, especially in the neck area. In general, it disappears within 1 or 2 weeks without leaving any sequelae.

(5) Pigment(Color) Changes (Focal)

Hyperpigmentation generally fades over time (within a few months).

(6) Bruising

Rarely, bruising may occur and usually goes away within a few days. Bruising is more typically associated with the injection of the anesthetic agent used.

(7) Erythema/Whitening

Erythema/bleaching may occur in mild forms and usually disappears within a few hours. However, in some rare cases, longer duration of erythema has been reported (up to several weeks). Bleaching usually disappears within twenty-four (24) hours.

(8) Swelling (Edema)

Edema may occur and usually disappears within 5 days, but may last up to several weeks. Applying a cold compress or gel immediately after treatment may help reduce the occurrence of this condition.

(9) Urticaria (Itching)

Occasional mild to moderate transient itching at the treatment site has been reported. Applying over-the-counter topical preparations can help relieve symptoms.

(10) Mild/ Moderate Pain During Treatment(Common and Expected)

In general, discomfort during the procedure is temporary and limited to the treatment area. Patients rarely report temporary pain in the treatment area lasting up to several months.

(11) Herpes Simplex Virus

In rare cases, Herpes simplex rash may occur in the treatment area previously infected with the virus. Reactivation of HSV is thought to occur in the perioral and genital skin region after various stimulations.

2-6. Complaints and Adverse Events

The VOLNEWMER is extremely safe when used properly.

No serious adverse events have been reported in clinical trials or commercial use. All adverse events are confined to the treatment area.

Regulatory requirements mandate that certain adverse events be reported to the relevant regulatory authorities. Classys Inc. follows MDR (Medical Device Reporting) rules for handling complaints and adverse events. Should an adverse event be suspected or reported, please contact Classys Inc.

3. System Overview

3-1. System Description

The VOLNEWMER is a non-invasive equipment that delivers monopolar RF(Radio-Frequency) energy in the form of an electrical current for treatment of periorbital wrinkles and rhytides including upper and lower eyelids. It consists of 2 hand-pieces, a control unit, Touch LCD monitor, power supply unit for irradiation and for setting parameters after the main power and power button are turned on. RF energy is irradiated through the hand-piece depending on irradiation energy, which is set in advance by the user.

The tip of the VOLNEWMER is not disposable and should be cleaned before use.(See Chapter 7-1 for details). The 4 types of treatment tips are designed to effectively treat large and small area for each type.

After connecting the AC Power Cable to the AC INLET of the Power Unit, and turning on the power switch and operation switch, DC power is applied to the device and the Password Input Screen is displayed on the LCD. After attaching the Return Pad to the appropriate part of the patient and separating the Handpiece to be used from the cradle, press the trigger button, touch the electrode Tip to the patient's treatment area(skin), and press it vertically to perform tuning. After setting the parameter value on the LCD screen that appears after the tuning is completed, and pressing the trigger button, touch the electrode Tip to the patient's treatment area (skin) and press the Handpiece vertically with sufficient pressure to output RF energy from the electrode Tip.

The life cycle of VOLNEWMER is 5 years.

3-2. System Components and Features

The VOLNEWMER is comprised of:

- Main Body including Touch Screen (10.1 inches)
- Arm Stand A(Left), B(Right)
- Tips (I Tip, F Tip, V Tip, S Tip)
- Return Pad and Return Pad Cable
- Essential Accessories: Coupling Gel, Footswitch
- AC Power Cable



Figure 3.1 Main components of "VOLNEWMER"

No	Component	No	Component	No	Component
1	Main Body	2	Arm Stand A (Left)	3	Arm Stand B (Right)
4	S Tip	5	V Tip	6	F Tip
7	I Tip	8	Return pad cable	9	Return pad
10	VOLNEMWER Coupling Gel	11	AC Power Cable	12	Foot Switch (2 type)
13	Cooling water Injection/ Discharge Jig				

3-2-1. Main Body

The Main Body of VOLNEWMER is the hub and information center of the device. The user can interact with the device through the touch screen of the Main Body. Photographs of the Main Body of VOLNEWMER are shown in Figure 3.2 below.

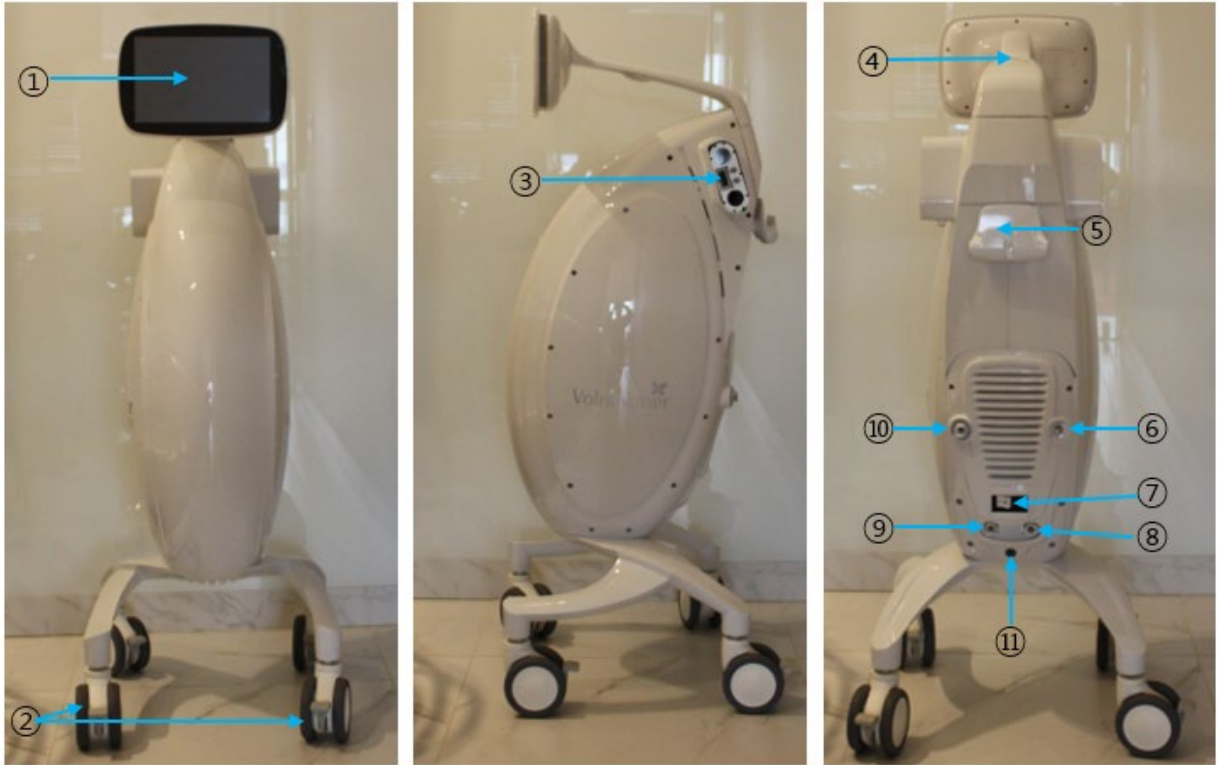


Figure 3.2 Main body front(left) veiw and side view, rear view(right)

No	Component	Description
1	LCD Touch Screen(10.1 inch)	The touch screen, which houses the Graphic User Interface(GUI), allows the user to interact with the device. The user can set and view the operating conditions including equipment activation status, treatment parameters, and system messages.
2	Locking Caster	Device Moving wheels (Lockable)
3	Connector of Arm Stand	Connector connecting the Arm Stand to the Main Body.
4	Power Button	A switch that turns ON/OFF the entire system operation.
5	Return Pad Holder	Holder for the Return Pad
6	Return Pad Cable Connector	Connector connecting the Return Pad Cable to Main body

7	Power Inlet	Connector connecting the AC Power Cable to the Main Body. An ON/OFF power switch is located next to the connector.
8	Water Level Regulator	Regulates the water level when injecting cooling water into the device.
9	Water Outlet(DRAIN)	Connector for connecting the drain pipe to the Main Body. Used when emptying the device of cooling water.
10	Water Inlet	Connector for connecting the water injection pipe to the Main Body. Used when filling the device with cooling water.
11	Foot switch connector	Connector connecting the Footswitch to the Main Body.

3-2-2. Arm Stand and Handpiece

The Arm Stand can be connected to the Main Body. The Handpiece is connected to the Arm Stand through a flexible cable. The Handpiece has a “Output Button”. A photograph of the Arm Stand and Handpiece of Volnewmer™ is shown in Figure 3.3 below.

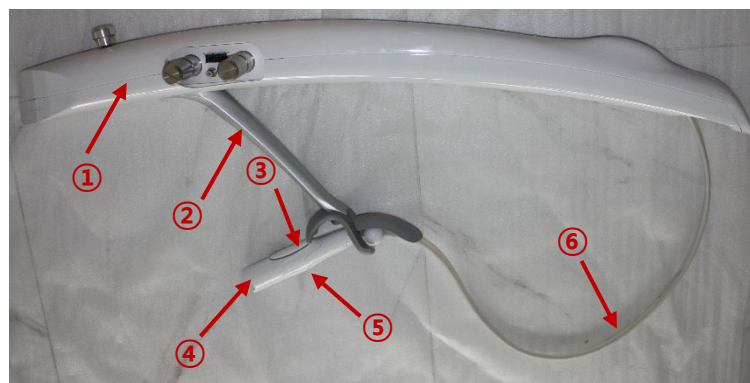


Figure 3.3 Arm Stand with handpiece

No	Component	Description
1	Arm Stand	Connection the hand-piece and Main body Connect
2	Handpiece Holder	Holder for Hand-piece
3	Output Button	Pressing the Output Button changes the system mode from “READY” to “SAFETY ON” in preparation for RF delivery.

4	Tip connector	Connector for connecting the Tip to Hand-piece
5	Hand-piece	<ul style="list-style-type: none"> • The Handpiece conducts the RF signal to the Tip. • The Handpiece also provides user-selectable vibration in the vertical dimension for mechanical manipulation of tissue.
6	Handpiece cable	<p>Cable for connecting Armstand and Hand-piece</p> <p>The cable conducts the RF signal to the Handpiece</p>

3-2-3. Tip (Consumables)

- The Tip contacts the surface of the patient’s skin and deliver the RF energy through the skin.
- The Tip can be connected to the Handpiece.
- When the activation switch (i.e., the Output Button or the Footswitch) is pressed, and when the Tip is pressed against the treatment area (skin), radiofrequency energy is irradiated from the Tip.
- The Tip conductively cools the epidermis during treatment. Cooling water from the Chiller Assay is supplied to the cooling plate of the Tip via the water pump and the Handpiece. The cooling water then flows back into the Chiller Assay and has a repetitive circulation structure where it is continuously cooled. Figure 3.4 shows the tip.

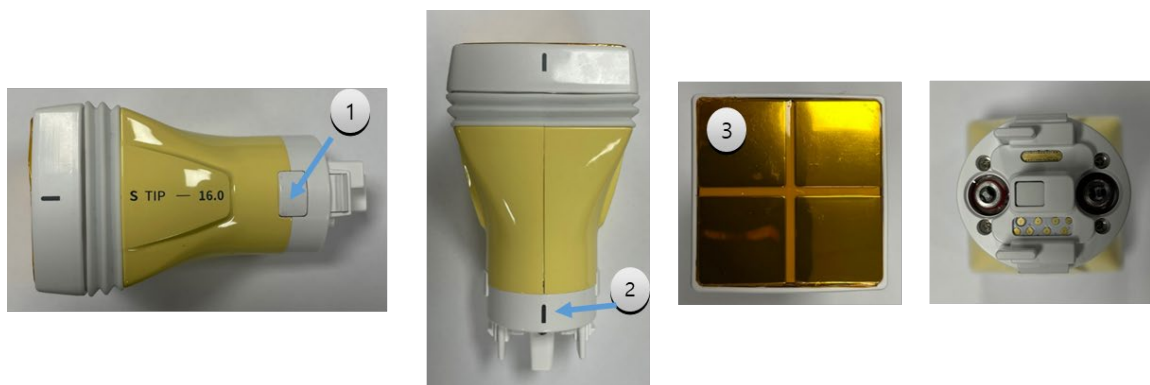






Figure 3.4 Tip detached from Handpiece

No	Component	Description
1	Tip Release Button	Press the button to detach the Tip from the Handpiece.
2	Tip Connector	Part that connects to the Handpiece.
3	Surface of Tip	Electrode irradiating radiofrequency energy. This component has direct patient skin contact.

This following is specification table including pictures of 4 tips

No	Tip Name	Specification	Pictures	No	Tip Name	Specification	Pictures
1	S Tip	Area: 16cm ²		2	V Tip	Area 4cm ²	
3	F Tip	Area 3cm ²		4	I Tip	Area 0.25cm ²	

3-2-4. Return Pad

The Return Pad is a single-use, disposable electrocautery grounding pad. The Return Pad is placed on the patient's skin to provide a return path for the applied RF current. The Return Pad consists of a flexible, thin-layered electrical conductor in aluminum, covered by an adhesive polymer gel layer.



Figure 3.5 Return Pad and Return Pad Cable

3-2-5. Coupling Gel

A non-sterile coupling gel that contributes to consistent electrical contact between the skin and the electrode (Tip) and reduces friction. The Coupling Gel should be used as a high frequency transmission gel to facilitate the transmission of high frequency energy. Use only the Coupling Gel provided by the manufacturer. Other lubricants or lotions,

especially mineral oil, may damage the Tip or Handpiece.



Figure 3.6 Coupling Gel

3-2-6. Foot Switch

The Footswitch has the same function as the Shoot Button of the Handpiece. When the Footswitch is pressed, or when the Output Button of the Handpiece is pressed, and when the Tip is pressed against the treatment area (skin), radiofrequency energy is irradiated from the Tip.



Figure 3.7 Foot Switch

No	Component	Description
1	Foot Switch	Pressing the Footswitch changes the system mode from "READY" to "SAFETY ON" in preparation for RF delivery.
2	Foot Switch Connector	Connector connecting the foot switch to the body

3-2-7. AC Power Cable: It is used to supply AC mains power the VOLNEWMER



3-2-8. Cooling water Injection/ Discharge Jig: It is used to inject or discharge the cooling water inside the VOLNEWMER.



3-3. Precautions for use

3-3-1. Warnings

1. For the safe use of VOLNEWMER, it must be used by a qualified doctor who has been trained, and any use other than the intended use is prohibited.
2. Users should thoroughly read and understand this operation manual prior to operating the device.
3. To prevent electric shock or injury, do not use near flammable anesthetics, flammable gases, flammable solutions, flammable or oxidizing agents. Always follow fire precautions.
4. Flammable materials used as cleaning, sterilization or solvents should be completely evaporated before using the equipment or applying RF energy.
5. Do not use the product near life support systems. The emission of high-frequency electromagnetic waves can interfere with the operation of electronic devices.
6. When the system and the living body monitoring device are used together, place all monitoring electrodes such as electrocardiogram (ECG, EKG) as far as possible from the treatment area. It is recommended to use a monitoring system with built-in high frequency current limiter.
7. Do not use this device in an oxygen-rich atmosphere or in an environment with nitrogen dioxide (N₂O).
8. Interference generated by the system can adversely affect the operation of other electronic devices.

9. The output can increase unintentionally due to a system failure.
10. The VOLNEWMER should only be connected to a power supply with a protective earth.
Do not use extension cables or adapter plugs.
11. Do not attempt to modify or repair devices (equipment and accessories).
12. Use only components and accessories provided by the manufacturer.

(Treatment tip, return pad, coupling gel etc)
13. All components and accessories should be inspected regularly for damage prior to use.
14. The return pad is a disposable product. If reused, contact failure, burns, or system performance may deteriorate.
15. Do not use the return pad on patients sensitive to acrylate.
16. Avoid getting alcohol in your eyes. If irritation occurs, wash your eyes with water for 5 minutes.
17. Remove all substances (local anesthetics, cosmetics, lotions, oils, deodorants, etc.) from the skin surface of the treatment site. During the procedure, there should be no material between the treatment tip surface and the patient's skin except for the coupling solution.
18. Remove all jewelry such as necklaces, arms, watches and earrings/piercings from the patient.
19. Before the procedure, remove the beard completely.
20. During the procedure, be careful not to allow the patient to come into contact with the grounded metal part (eg, the surgical table support).
21. Place the return pad properly before the procedure so that it can contact the patient.
22. Do not place the match plate on your shoulders, neck, head, arms or legs.
23. Be careful when there is a feeling of heat on the return pad. The patient should not

feel heat from the return pad during the procedure. If the patient feels heat or electrical stimulation on the return pad, stop the procedure and check the location and cable connection. Do not perform the procedure until the condition is corrected.

24. Avoid skin-to-skin contact. It is recommended to insert dry gauze between adjacent body parts (e.g. between the patient's arm and body).
25. Be careful when selecting a procedure level. The risk of side effects may be associated with a higher level for treatment.
26. Please note that there is a potential risk from neuromuscular irritation when using the equipment.
27. When using the device, ensure that the user does not touch the patient and the device at the same time. Users should be careful as the output power may increase unexpectedly in the event of a device malfunction.

3-3-2. Cautions

1. Read the safety considerations in the user manual before using “VOLNEWMER”.
2. This equipment should be used by a medical professional who has been properly trained in its use.
3. Electric parts of system may have power left even after the main power is turned off, so that unauthorized persons cannot inspect or disassemble the interior. Disassembly of the device by unauthorized persons is excluded from the warranty of the device guaranteed by the manufacturer.
4. When using an electrosurgical device, if flammable substances (gas, alcohol, etc.) are present due to electrical sparks and heat, it may become a source of ignition.
5. Since side effects related to the procedure beyond the intended use have not been evaluated, procedures that is not the intended use are prohibited.
6. Be careful when performing the procedure on the skin immediately above that has undergone metal dental treatment. In particular, when treating a large-surface treatment area, it is advisable to consider the insertion of a dry, water-soluble

cotton between the treatment area and the inner cheek to prevent heating of the metal material due to high frequency. If this occurs, it can lead to skin burns, toothache or damage to the dental treatment.

7. When opening the “VOLNEMWER” component, be careful not to injure the operator or damage or damage the equipment by a sharp tool.
8. Handpiece connectors must be clean and dry. The tip should not be used when the connector comes into contact with liquid, refer to the tip maintenance section.
9. Do not twist, roll or bend the handpiece cable unnecessarily or excessively.
10. If you drop the main body and handpiece, tip of this system on the floor or receive a severe impact, it may be permanently damaged. Take special care. In this case, the warranty does not apply. Do not use damaged handpieces.
11. Do not clean the handpiece or maintain or repair the device while the device is powered on.
12. When replacing the handpiece tip, for safety, turn off the system power by pressing the POWER button and then replace the tip.
13. In order to prevent serious damage to the connector or disconnection of the foot switch when moving the appliance, the foot switch must be removed from the system and moved safely.
14. Before use, check the surrounding environment so that liquid does not penetrate through the foot switch during treatment.
15. Be especially careful when moving the equipment as it may cause serious damage to the device.
16. If the device is not used for a long time, check if the main power switch is in the OFF position. Also, if the system is not used for a long period of time, remove the main power cord from the wall outlet and the main power socket of the system
17. When a malfunction occurs in the device If there is no qualified person, affix a fault indication on the device and contact Classsys Co., Ltd. or an agency.

3-3-3. Electromagnetic Compatibility and Immunity

The RF emission of the "VOLNEWMER" meets the requirements of the safety standard for medical equipment. Therefore, it causes almost no interference.

Its energy requirement is mainly commercial. However, a hospital installation is required except for near active HF surgical equipment and the RF shielded room for a system of magnetic resonance imaging, where the intensity of EM precautions is high.



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



Warning: Use of accessories other than those specified may result in increased emissions or decreased immunity of this system.









Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) from any part of the VOLNEWMER, including cables specified by Classys Inc. Otherwise, degradation of the performance of VOLNEWMER could result.



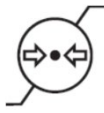




3-3-4. Environment








- Main (AC) power quality should be that of typical commercial or hospital environments.
- Flooring should be wood, concrete or ceramic tile. If covered with synthetic material, the relative humidity should be at least 30% to ensure that strong static electricity is not generated.
- Service personnel trained by an authorized Classys Inc. provide regular service during the life cycle of equipment to check the environment in terms of EM disturbance and to maintain the safe use of the device.


3-4. Safety Symbols

Be sure to read and follow the safety symbols marked on the product when using them.

Symbol	Symbol Title and Designation	Symbol Title (Reference Number)	Explanatory Text
	IEC 60601-1 Edition 3.1 2012-08 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Type B Applied Part (IEC 60417-5840)	Indicates part/accessory of the medical device that comes into direct physical contact with the patient, and which neither has a patient connection (point through which current can flow), nor is suitable for direct cardiac application
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Catalogue number (5.1.6 of ISO 15223-1)	Indicates the manufacturer's catalog number so that the medical device can be identified.
	IEC 60601-1 Edition 3.1 2012-08 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Alternating current (IEC 60417-5032)	Indicating on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Serial Number (5.1.7 of ISO15223-1)	Indicates the manufacturer's serial number so that a specific medical device can be identified
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Date of Manufacture (5.1.3 of ISO 15223-1)	Indicates the date when the medical device was manufactured
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Manufacturer (5.1.1 of ISO 15223-1)	Indicates the medical device manufacturer

Symbol	Symbol Title and Designation	Symbol Title (Reference Number)	Explanatory Text
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Temperature limit(5.3.7 of ISO 15223-1)	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Humidity limitation (5.3.8 of ISO 15223-1)	Indicates the humidity limits to which the medical device can be safely exposed.
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Atmospheric pressure limitation (5.3.9 of ISO 15223-1)	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	IEC 60601-1 Edition 3.1 2012-08 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Caution(5.4.4 of IEC 60601-1)	Indicates the need for the user to consult the instructions for use for important cautionary information
	IEC 60601-1 Edition 3.1 2012-08 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	General warning sign (ISO 7010-W001)	Indicates to signify a general warning
	IEC 60601-1 Edition 3.1 2012-08 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Follow instructions for use (ISO 7000- 1641)	Indicates the need for the user to consult the instructions for use
	IEC 60601-1 Edition 3.1 2012-08 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	No pushing (ISO 7010-P017)	Serves as a visual indication to prohibit pushing against an object

Symbol	Symbol Title and Designation	Symbol Title (Reference Number)	Explanatory Text
	IEC 60601-1 Edition 3.1 2012-08 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	No sitting (ISO 7010-P018)	Serves as a visual indication to prohibit sitting on a surface
	IEC 60601-1 Edition 3.1 2012-08 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	No stepping on surface (ISO 7010-P019)	Serves as a visual indication to prohibit stepping onto a surface
	DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)	WEEE Symbol	Indicating separate collection for EEE- Waste
	IEC 60601-1 Edition 3.1 2012-08 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Protective Earth (IEC 60417-5019)	Identifies any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Keep dry (5.3.4 of ISO 15223-1)	Indicates a medical device that needs to be protected from moisture
	ISO 7000 Sixth edition 2019-07 - Graphical symbols for use on equipment-Registered symbols	Use no hook (0622 of ISO7000)	Indicates that hooks shall not be used for handling the transport package
	Graphical symbols for use on equipment - registered symbols	This way up (ISO 7000-0623)	Indicating the correct upright position of the transport package

Symbol	Symbol Title and Designation	Symbol Title (Reference Number)	Explanatory Text
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Fragile, handle with care (5.3.1 of ISO15223-1)	Indicates a medical device that can be broken or damaged if not handled carefully

4. Setting Up for First-Time Use

4-1. Unpacking

The VOLNEWMER is packaged as a unit, and the box includes the Main Body, Arm Stand A, Arm Stand B, Tip, Return Pad Cable, Return Pad, Coupling Gel, AC Power Cable, and Footswitch.

4-2. Physical Environment

4-2-1. System Main Body

The device dimensions are shown in Figure 4.1. To maintain optional efficiency, sufficient space should be allocated in accordance with the indicated installation space shown in Figure 4.1. It is a general expected that external temperatures of the device will rise when the device is used continuously and should be accounted for. System weight and dimensions are additionally listed in “Specifications” (Refer to Section 8) of this IFU.

The device should be not placed to make it difficult for operating the disconnecting device.



Figure 4.1. The required storage area for the VOLNEWMER

4-3. Preparation before use

4-3-1. Connect the Arm stand

Connect arm stands A and B correctly according to the following instructions..

- 1) Make sure the power cable is disconnected.
- 2) Connect arm stands A and B to the arm stand connectors on the left and right sides of the body, respectively.

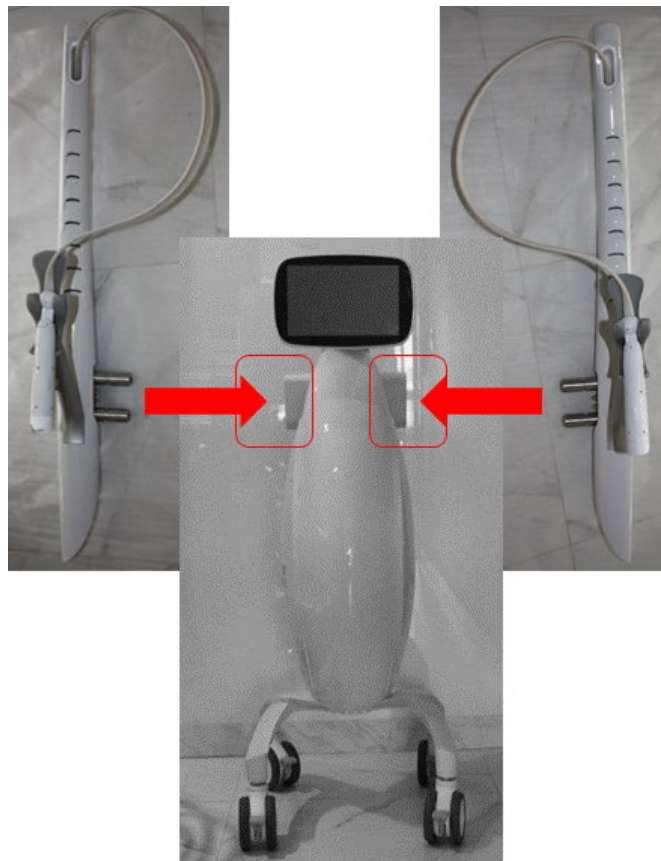


Figure 4.2 Connect Arm Stand A(Left) and Arm Stand B(Right) to the Main Body

4-3-2. Connect the Return Pad and Return Pad Cable

Remove the disposable packaging and connect the return pad to the return pad cable as shown in the picture below.

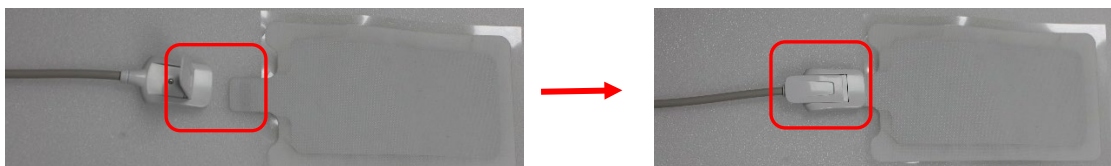


Figure 4.3 Connect the Return Pad Cable and Return Pad

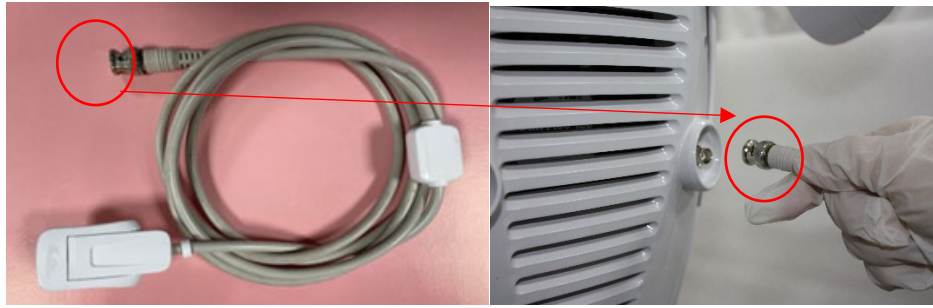


Figure 4.4 Connect the Return Pad Cable to the Return Pad Cable connector of the Main Body

4-3-3. Connect foot switch

Connect the foot switch cable to the corresponding connector on the main body.



Figure 4.5 Connect the Return Pad Cable to the Return Pad

4-3-4. Tip connection

Connect the Tip to be used to the Hand-piece as shown below.

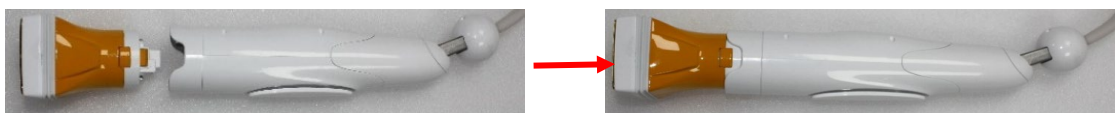


Figure 4.6 Connect the Tip to be Used to the Hand-piece

4-3-5. Inject Cooling Water

Inject distilled water during initial installation and when water error occurs. Before injecting distilled water, turn off the power and check if the power cable is removed.

1. Prepare a distilled water injection/ discharge jig
2. WATER IN(inlet) and VENT(outlet) are located on the back of the Main body.
3. When connecting or disconnecting the distilled water injection/discharge jig, press

the coupling part button in the direction of the arrow.

4. Connect the distilled water injection jig to WATER IN and the distilled water discharge jig to VENT.
5. Pour until distilled water is discharged from the VENT at the bottom of the device. Stop injecting when distilled water flows out, and remove the jig when no more water comes out.
6. When removing distilled water from the device, install the discharge jig on the drain and drain the distilled water.



※Cooling water specifications

> Type: DI Water or Distilled Water

> Temperature: Room temperature

4-3-6. Connect AC power cord to rear of device.

4-3-7. Turn ON the power button in rear of monitor.

4-3-8. Enter the password

To operate the VOLNEWMER, enter the password in the password input field of the monitor.

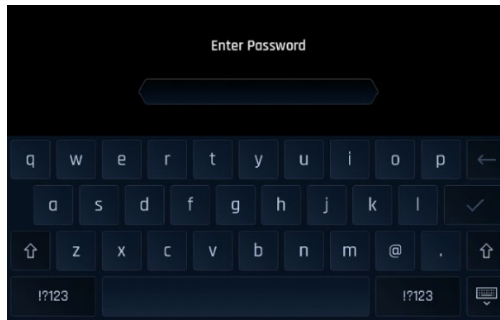


Figure 4.7 Password Input Screen When Booting

If the password has been entered normally, a loading screen will be displayed.



Figure 4.8 Loading Screen

4-4. License and Software management

4-4-1. License management

To use VOLNEWMER, it should be register a license by using the ID assigned to one device by the manufacturer, Classys Inc.

You can register manually through the managing license button on the set-up screen or automatically through a network connection.

4-4-2. The screen of license registration (manual)

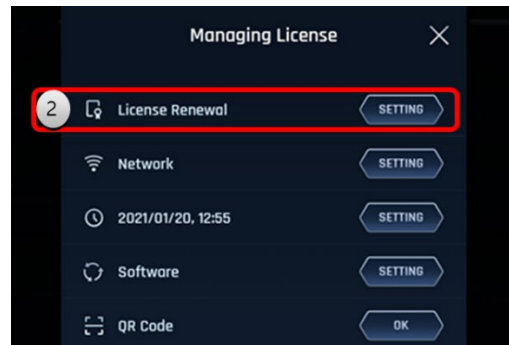
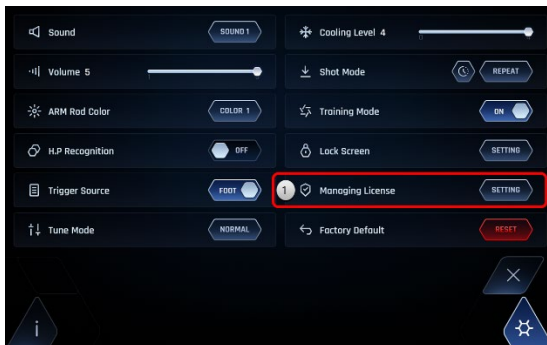


Figure 4.9 Set up

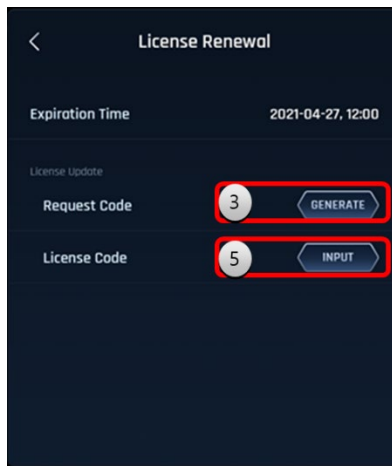


Figure 4.10 Managing License screen

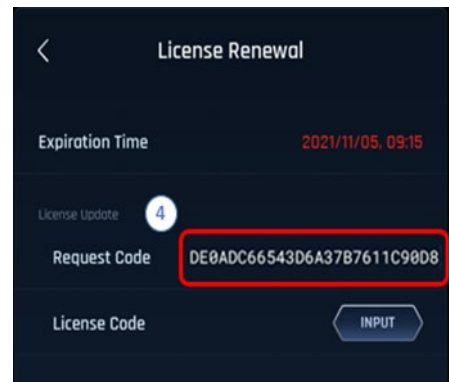
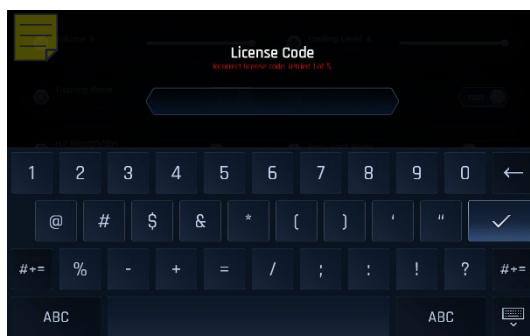
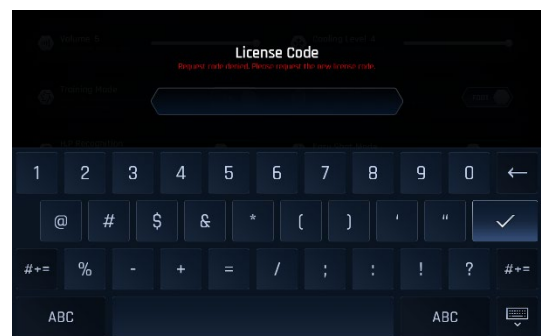


Figure 4.11 License renewal screen

- 1) Touch the Manage License button on the screen, it moves on to the screen of license management.
- 2) Touch the License Renewal button on the screen, it moves on to the screen of license renewal.
- 3) Touch the license request code, touch the button for requesting the license code.
- 4) Classys examines the request code after confirm that it is a genuine device, and then delivers the license code to the user.
- 5) Enter the license code received from the manufacturer.



a) Error in entering license code 1 time



b) Error in entering license code 5 times in continuous – license request code needs to be re-processed

Figure 4.12 License code input screen

4-4-3. The screen of license registration (automatic)

(1) Network connection

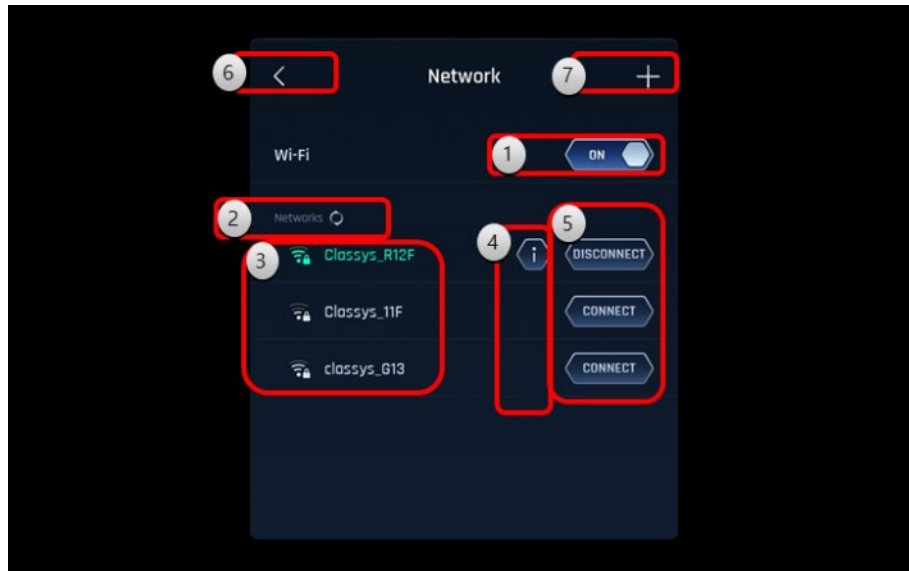


Figure 4.13 Network

- 1) Turn on the WIFI on the set up screen to connect to the network.
- 2) Touch the refreshified button for the newest list of WIFI.
- 3) The Wi-Fi list is arranged in order of the strongest connection signal, and you can see the available Wi-Fi network list, receiving strenght and the security icon. Select a network to connect to among these.
- 4) In the Wi-Fi list, a "i" icon will be displayed next to the the connected network.
 - If the user needs to enter a password for network connection, the password IME window is generated and can be entered the password.
 - When the user selects the "i" icon, user can see the detailed information of the connected Wi-Fi as shown below.

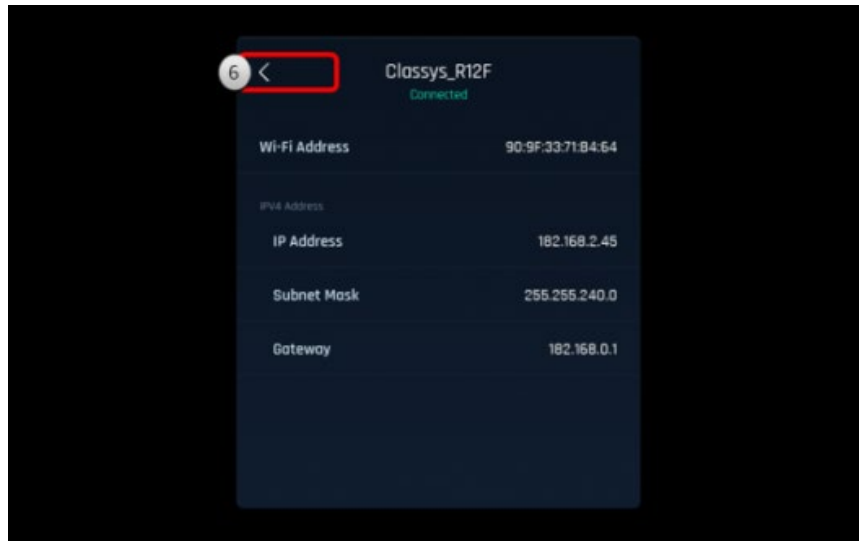


Figure 4.14 Selected Network

- > User can see that the device is connected to the network by displaying it on the screen.
- > The Wi-Fi address of the connected network is displayed.
- > Information about connected Internet protocols (IP address, subnet mask, router) is displayed.

5) A button has been created so that you can connect to the network and disconnect again.

6) Return to the previous screen and register the license.

7) Touch the button when user need to manually connect to the network.

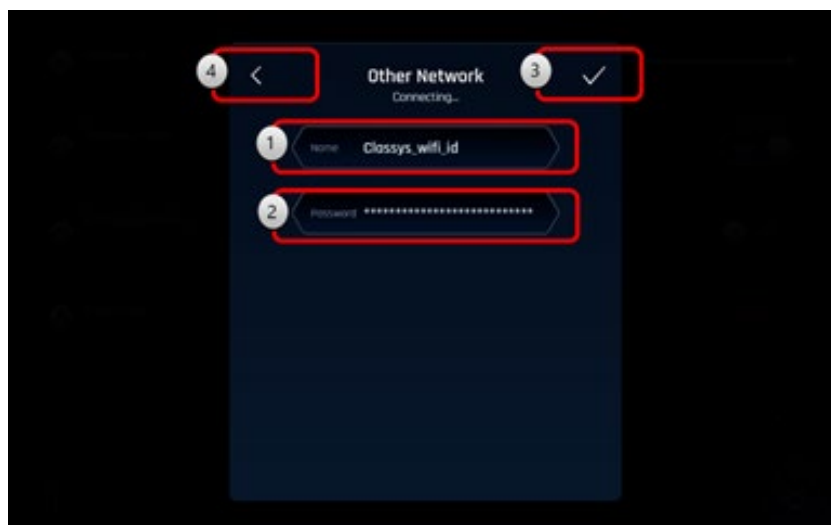


Figure 4.15 Other Network

- > Enter the AP name to connect the network in the box.
- > Enter the password for the AP to connect the network in the box.
- > Button to connect to the entered AP information.
- > Return to the previous screen and register the license.

(2) License registration

When the device is waiting for a wireless connection, turn on Wi-Fi in the surrounding environment (if not turned on) and the user must manually connect the system to the network.

The system registers a license by connecting to a wireless network, and the method is as follows.

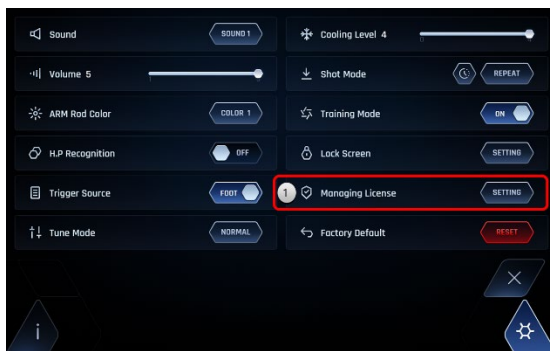


Figure 4.16 Set up screen

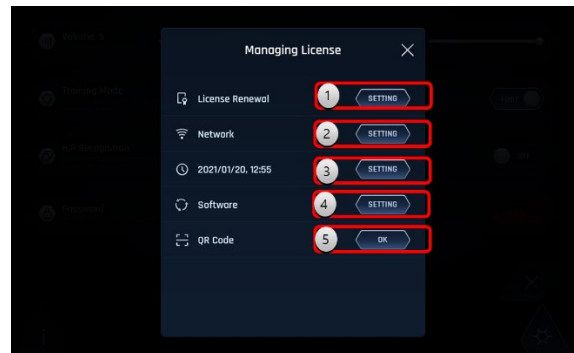


Figure 4.17 Managing License screen

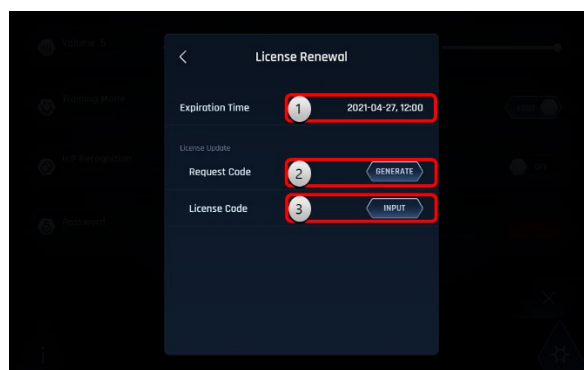


Figure 4.18 License Renewal screen

- 1) On the screen, touch the Managing License button to move to the Managing License screen.

2) Select “Managing License” on the Setup screen.

> License (Managing License) screen: Users can move to ① License Renewal, ② Wi-Fi network information, ③ date/time management, ④ program update, and ⑤ activation QR code screen.

3) Select button ① (“License Renewal”) to start Setting on the Managing License screen.

4-4-4. Time/ Date setting

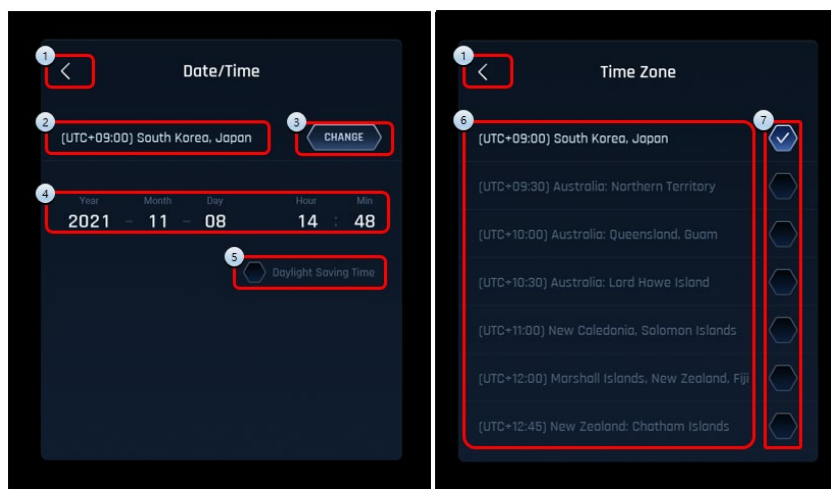


Figure 4.19 Date/Time and Time Zone

1) Return to the previous setting screen.

2) Display the region information currently set out.

3) Press the button to change the setting to the desired region

4) The current date/time is displayed on the screen.

5) ON/ OFF the summer time: When touching the corresponding function for countries applying “Summer time”, it is displayed by adding 1 hour to the existing time on the screen.

6) When the time zone needs to be reset, press the button ③ (“CHANGE”), a list of local information is displayed and can be set by moving up and down with a touch scroll on the screen.

- Select the applicable country or region on the list.

7) When setting the corresponding area, press the button.

4-5. Available wireless LAN specifications

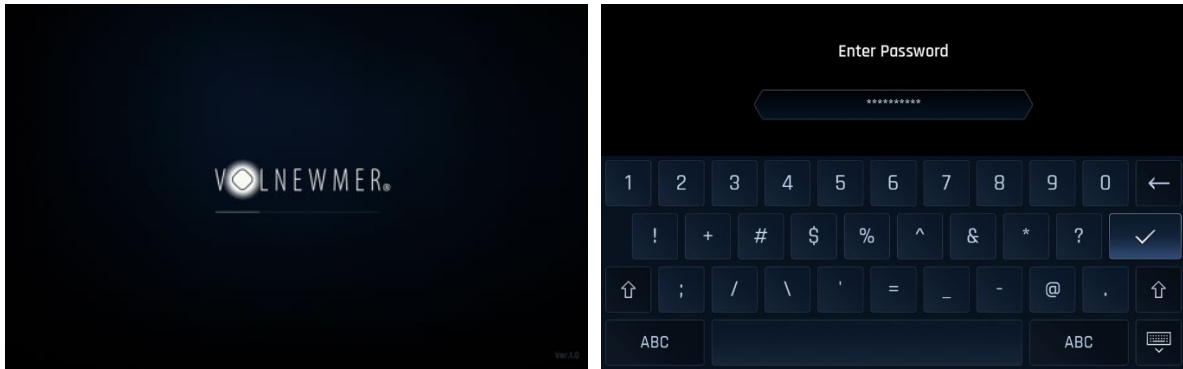
- 1) Wireless standard : IEEE 802.11n/b/g
- 2) Wireless RF : 2.4GHz

5. System Operation

5-1. Overview of System Function

5-1-1. Operating Graphical User Interface (GUI)

An overview of this screen is seen in *Figure 5.2* below.



<Loading screen>

< Password enter screen when booting >

Figure 5.1 Loading and Passwrod Enter Screen

5-1-2. Handpiece Selection Screen

A output of the Hand-piece Selection Screen is provided in *Figure 5.1* below.

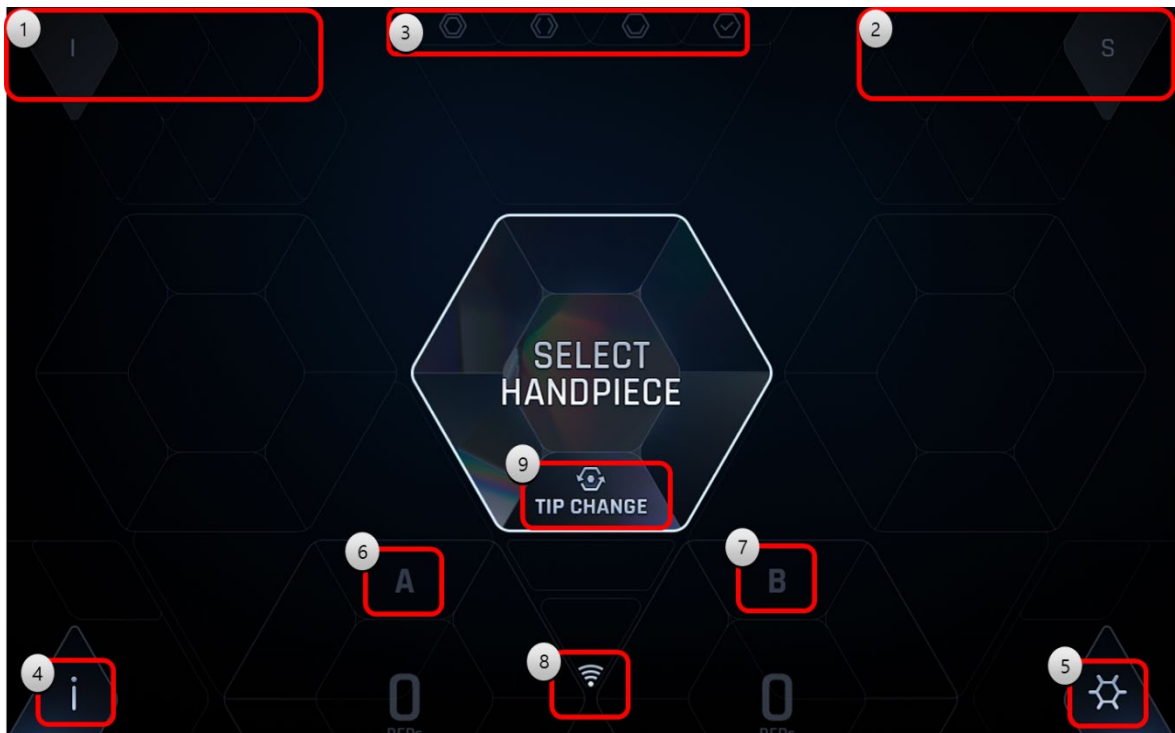

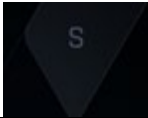




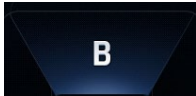


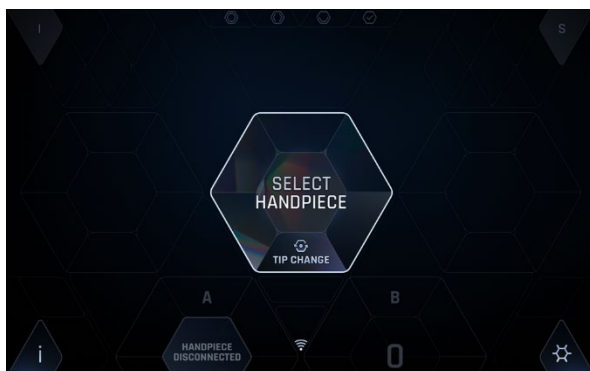


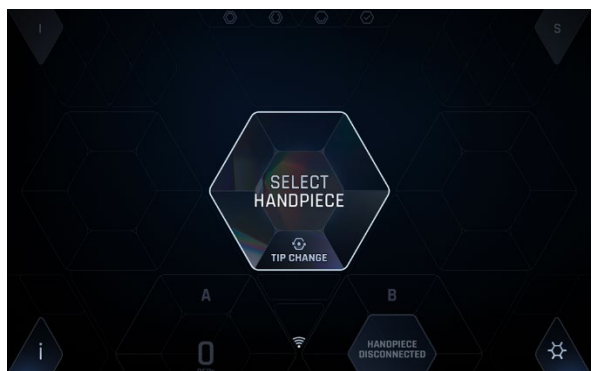
Figure 5.2 Handpiece Selection Screen

No	SIGN	Description
1		Information on the electrode tip connected to the handpiece A
2		Information on the electrode tip connected to the handpiece B
3		Treatment information: Refer to 5-1-3
4		Go to the Information Screen.
5		Go to the Setup Screen. Refer to Section "4.3.5 Setup Screen" below.
6		When the Handpiece automatic recognition mode (HP Recognition) is OFF, Handpiece "A" is selected when touched.
7		When the Handpiece automatic recognition mode (HP Recognition) is OFF, Handpiece "B" is selected when touched.
8		Display WiFi connection status
9		When tip change is needed, press the button and replace the tip..



Handpiece A cannot be selected because handpiece A is not connected




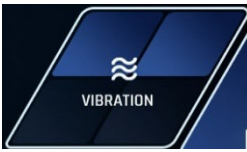






(can be performed with handpiece B)



Handpiece B cannot be selected because handpiece B is not connected

(can be performed with handpiece A)

Figure 5.3 Handpiece Selection Screen

3		Decrease the power level by 0.5
4		Current treatment power level (in increments of 0.5)
5		Increase the power level by 0.5
<p>Vibration intensity. By touching the button, the vibration intensity can be changed from level 0 to 3.</p>		
6	 	<p>① Displays the current vibration setting value and the configurable value.</p> <p>② Button to close the vibration setting screen.</p>
<p>However, the vibration function is only supported for the F Tip, V Tip, and S Tip. The vibration function is not supported for the I Tip.</p>		
7		Q Cooling is automatically activated when a Tip is connected to the Handpiece.
8		<p>-Select the memory by short press key</p> <p>-Save the memory by long press key</p> <p>-It saves the information for shot alarm, Q cooling, power level, vibration intensity.</p>
9		"A" indicates that Handpiece "A" has been selected.
10		Number of shots irradiated so far.
11		<p>Alarm ON/OFF.</p> <p>With the alarm ON, an alarm occurs when the number of shots is 400.</p>

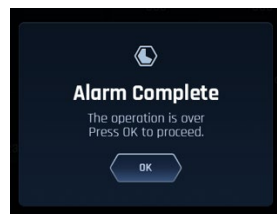
After pressing the button for setting the shot alarm, when the setting is complete, the screen is displayed as shown below.

- ① Display the currently shot alarm value that the users set on the screen.
- ② Button to decrease the setting value [Unit: 1]
- ③ Button to increase the setting value [Unit: 1]
- ④ Button to increase the setting value [Unit: as many as the number indicated on the button]
- ⑤ Button to reset value : set to '0'.
- ⑥ Button to close the shot alarm setting screen.


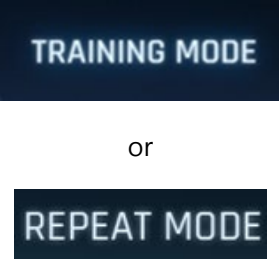




Shot alarm completion screen when the number of shot alarm settings has been reached during treatment

- ① If user presses the 'OK' button on the screen, it moves to the main screen.



12		When tip change is needed, press the button and replace the tip.
13		Power(J) irradiated from the current shot to the present
14		Average power(J/cm ²) irradiated per one shot
15		WI-FI connection status information
16		If you touch the "B" button, it moves you to the READY screen of Handpiece "B".

17		The procedure was completed normally.
18		Training mode for training purposes without actual shots. (ON/OFF available in Setup)
19		Shot alarm setting value decrease control button (unit: 1 shot)
20		Shot alarm setting value increase control button (unit: 1 shot)

5-1-4. Method of Tunning and Treatment

After connecting the Tip to the Handpiece, the tuning function must be performed before the treatment.

5-1-4-1. Method of Tunning

The tuning function measures the impedance of the treatment site (skin) before the procedure to check if the device is operating normally. Screenshots of the tuning screen are provided in Figure 5.3

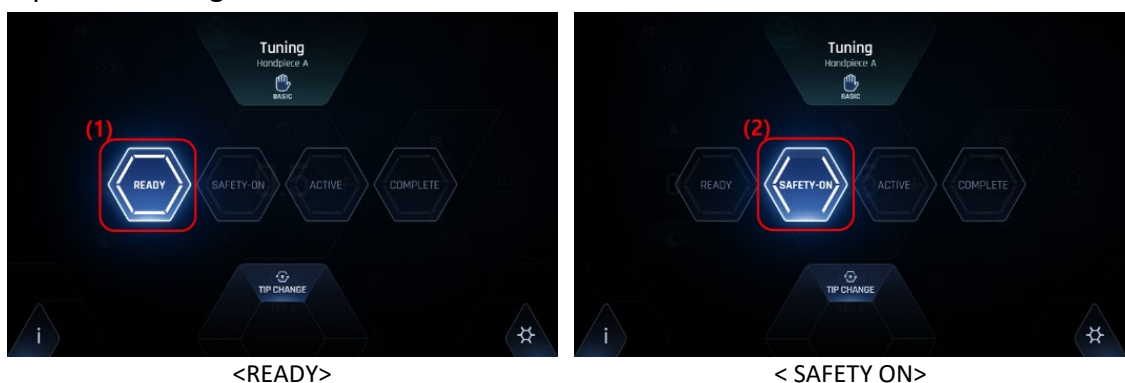
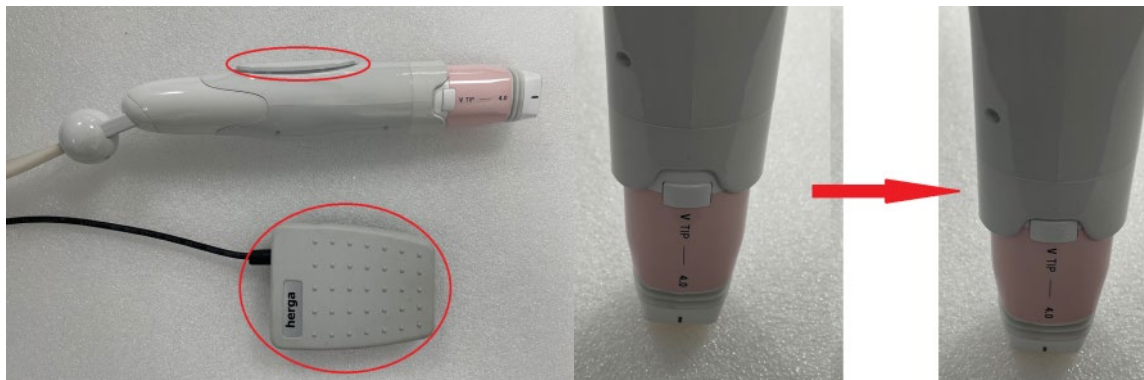




Figure 5.5 Screenshots of Tuning Step-By-Step

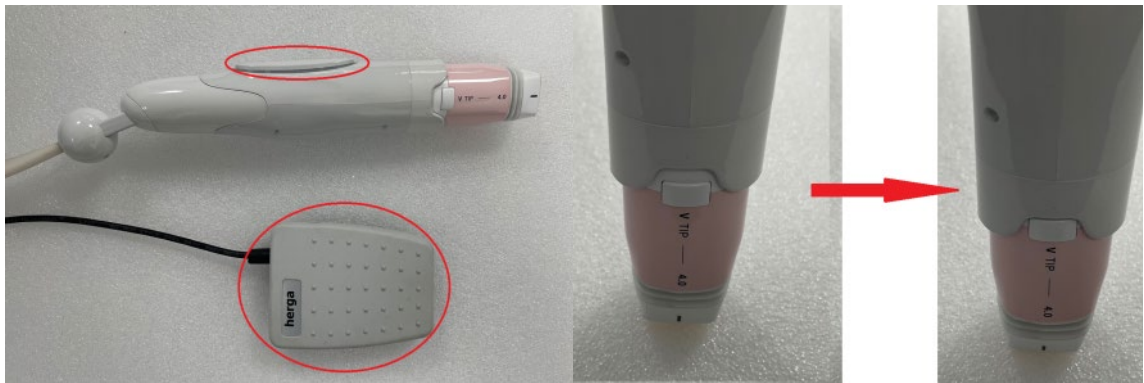
- ① READY: The Ready state indicates that the Tip is connected.
- ② SAFETY ON: When the Shot Button or Footswitch is pressed, 'SAFETY ON' is display.
- ③ ACTIVE : When the Tip of the Handpiece is pressed against the treatment site (skin), the impedance is measured, and the status is displayed as "ACTIVE".
- ④ COMPLETE : "COMPLETE" is displayed when the tuning has been completed normally.



SAFETY ON: Press shot button or foot switch

ACTIVE: Press the electrode tip of the Hand-piece against the treatment site(skin)

Figure 5.6 Tip including Hand-piece when SAFETY ON and ACTIVE activated



SAFETY ON: Press output button or foot switch

ACTIVE: Press the electrode tip of the Hand-piece against the treatment site(skin)

Figure 5.8 Tip including Hand-piece when SAFETY ON and ACTIVE activated

5-1-5. Information

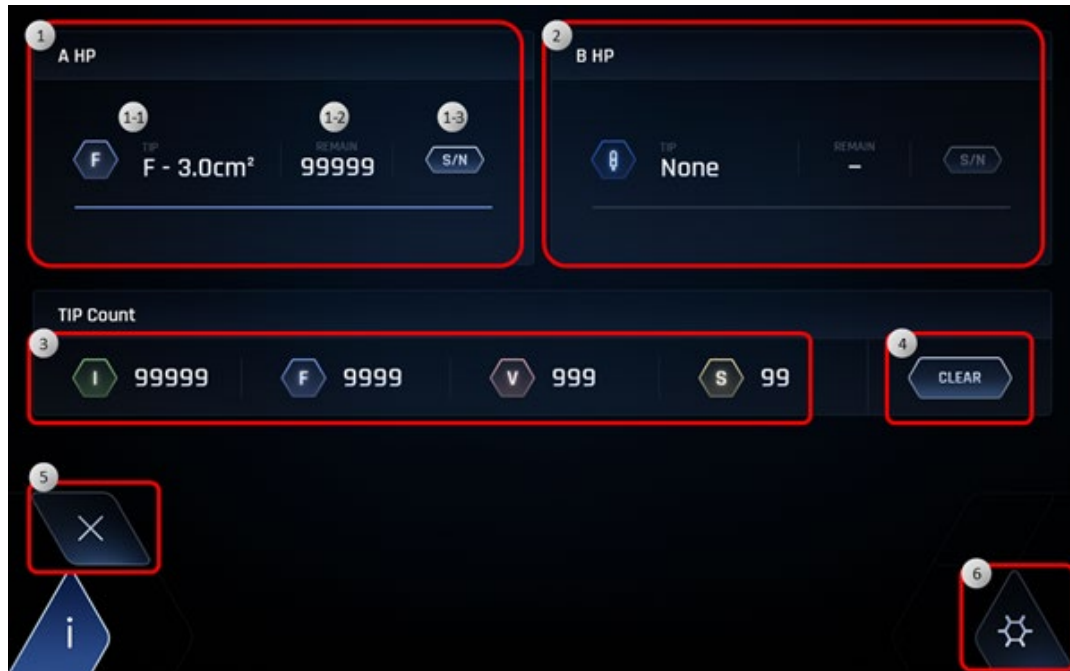
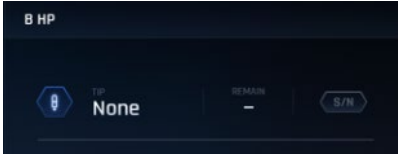
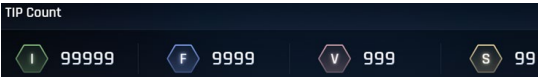
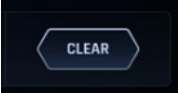




Figure 5.9 Information Screen

No	SIGN	Description
1		Displays information of a tip connected to the A-Handpiece
1-1		Tip ID and the remain shot number - Normal Status: S, V, F, I Type - Not connected Status - Error Status
1-2		the remain shot number
1-3		Button to display the serial number of Tip

No	SIGN	Description
2		Displays information of a tip connected to the B-Handpiece
3		The number of treatments for each type of electrode tip
4		Reset for accumulated shot count
5		Return the previous main screen
6		Setup screen button

5-1-6. Setup Screen



Figure 5.10 Setup Screen

No	SIGN	Description
1		Select the type of sound during treatment: 2 types
2		Select volume: 1 to 5 levels
3		Select the color and pattern type of ARM Rod - COLOR 1: Default colors and patterns - COLOR 2: Only the color and pattern of the selected armstand are displayed - COLOR 3: All armstand colors and patterns are displayed
4		Handpiece automatic recognition mode ON/OFF selection. - ON: Automatically recognizes the handpiece lifted from the arm stand - OFF: User needs to select the handpiece in the initial screen GUI
5		Select Trigger source(Output button(i.e., Hand-piece) or Footswtich)
6		Select the ON/OFF whether to tune mode : Normal /Auto



7 Select from 0 to 4 levels of cooling level

SHOT Mode

1) Basic mode : One shot can be irradiated when contacting the treatment site after pressing the shot button(or foot switch). (To irradiate the next shot, user needs to release and press the shot button again)

2) Easy mode : One shot can be irradiated by pressing and releasing the tip while pressing the shot button(or foot switch).

3) Repeat mode : When the shot button is pressed, energy is irradiated until the finger is released.



(Setting range: 0.4 seconds to 3.0 seconds). "REPEAT MODE" is displayed on the main screen.



- ① Electrode tip
- ② Irradiation interval decrease button (unit: 0.1 sec)
- ③ Set irradiation interval
- ④ Irradiation interval increase button (unit: 0.1 sec)
- ⑤ Button to finish the screen of Shot Interval setting

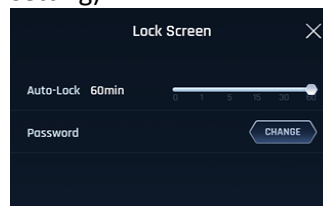


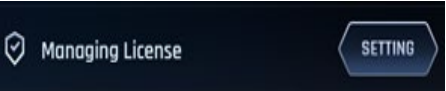





9 ON/OFF for training mode ("TRAINING MODE" is displayed on the main screen.)

: Not irradiated the energy

: Falshing marking during treatment

Lock screen change button (lock time, password setting)



11		License Management: License Management and Updates (License Renewal, Network, Time, Software Update)	
12		Reset of factory(Reset for all information)	
13		Button of moving the information screen	
14			Move the screen of set up
			Return to the previous main screen

5-1-7. Lock Screen setting

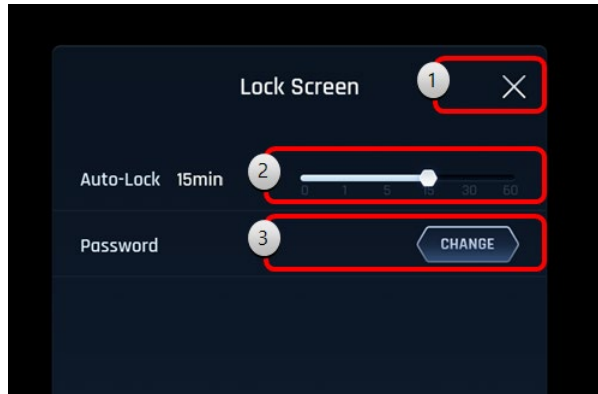





Figure 5.11 Lock Screen

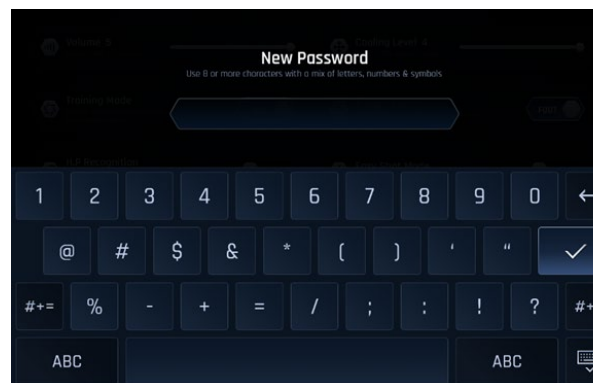
No	SIGN	Description
1		Button to close the screen of Lock screen setting
2		Set the screen auto-lock time - If the product is not used for a set period of time, the screen is automatically locked for security purposes. - Time setting(Unit: min): OFF(0), 1, 5, 15, 30, 60 - Enter the password to unlock the screen automatically
3		Button to change password - Change the password for lock screen

- Change the password

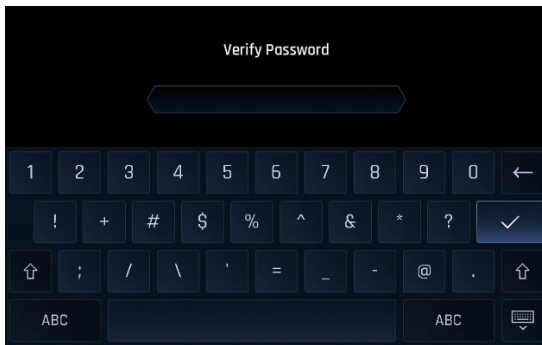
: Use 8 or more characters with a mix of letters, numbers & symbols



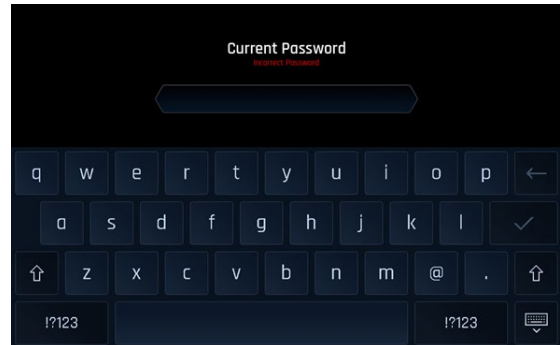
1) Enter current password



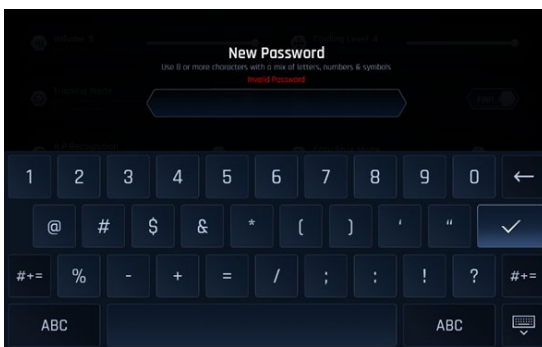
2) Enter new password



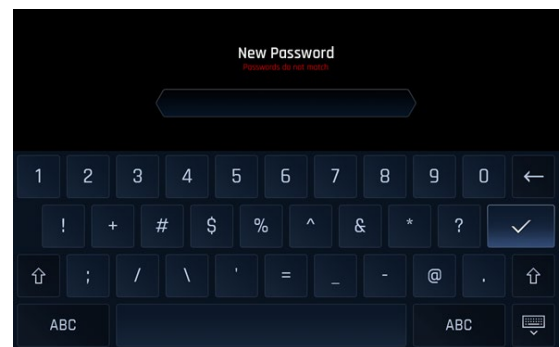
3) Re-enter new password



4) Incorrect the current password



5) New password is not valid



6) New password does not match

Figure 5.12 Change Screen of Password change

5-1-8. License management

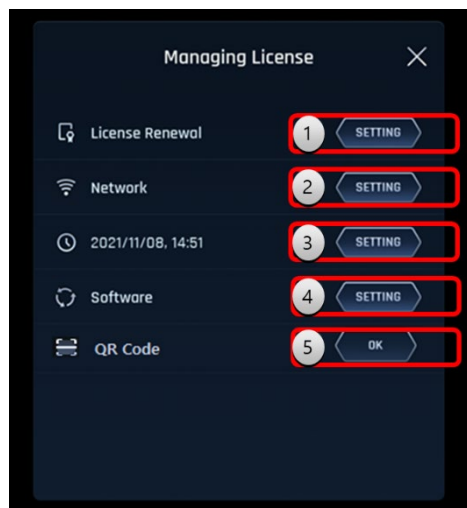





Figure 5.13 License Management Screen

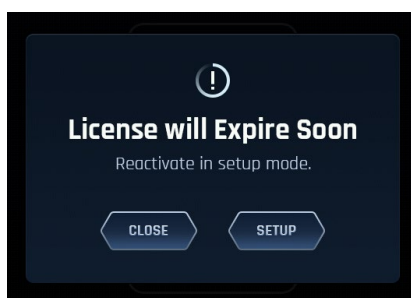
No	SIGN	Description
----	------	-------------

1		Button to go to the License Renewal screen
2		Set WIFI network information
3		Buttons to move to the time zone setting screen (date, time)
4		Button to move to display the software information and update settings screen
5		Button to move to the screen to check the QR Code

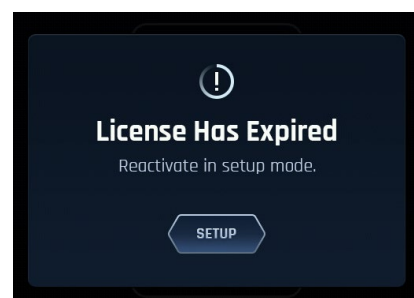
5-1-9. License Renewal

(1) Warning of pop-up in license expiration

To use VOLNEWMER, it should be registered a license by Classys, and when the renewal of license is close to expiration, the pop-up window is generated as follows.



Pop-up screen when the license expiration date is near



Pop-up screen when license expired

Figure 5.14 Pop-up Screen for License Expiration

※ The license expiration pop-up window is displayed on the screen while the user is using the device, the user can renew the license to use all functions of the VOLNEWMER product without restrictions.

- ① Press the SET UP button in the license expiration pop-up warning window, the screen is moved to the license renewal screen.

② The expiration date on this license is displayed on the screen of license renewal (automatic) and the warning sign is given to user such as following color.



Figure 5.15 License Renewal Screen

- License expires : Expiration Time 2021/11/05, 09:15 (Display in red)
- License expires soon. : Expiration Time 2021/11/09, 09:15 (Display in yellow)
- License valid : Expiration Time 2022/11/09, 09:15 (Display in white)
- License Unlimited : Expiration Time UNLIMITED (Display in UNLIMITED)

(2) The screen of license renewal (manual)

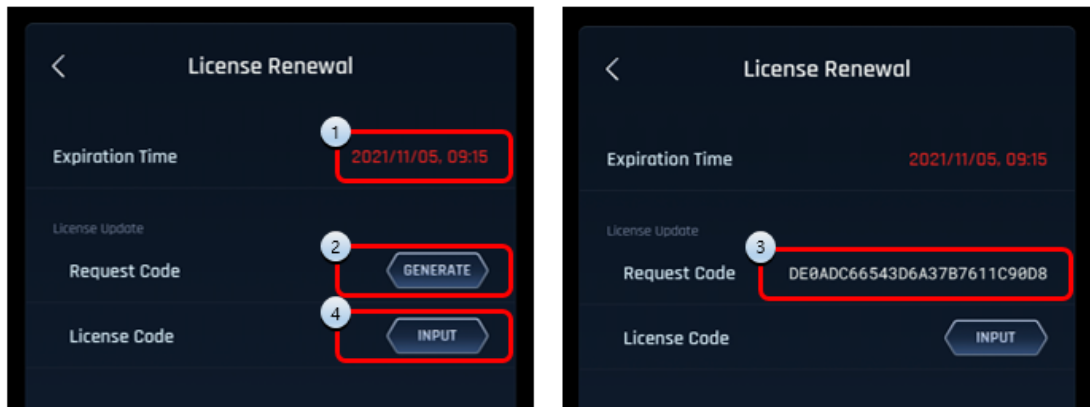
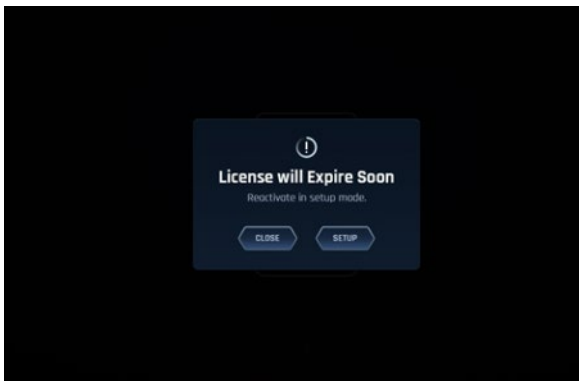


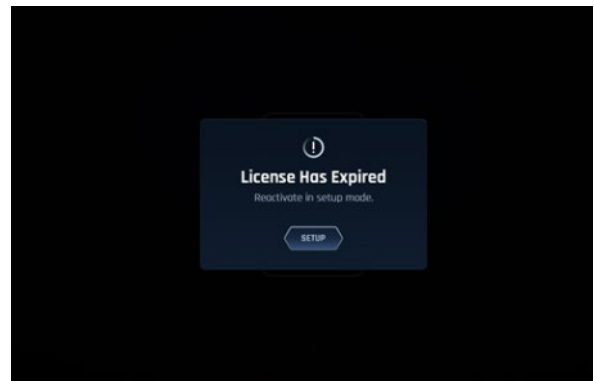
Figure 5.16 License Renewal Screen (Manual)

No	SIGN	Description
1		Display the expiration date of license
2		Button for generating request code for manual license renewal
3		The generated request code
4		Button for entering response code for manual license renewal

(3) Warning of pop-up in license expiration



Pop-up screen when the license expiration date is near

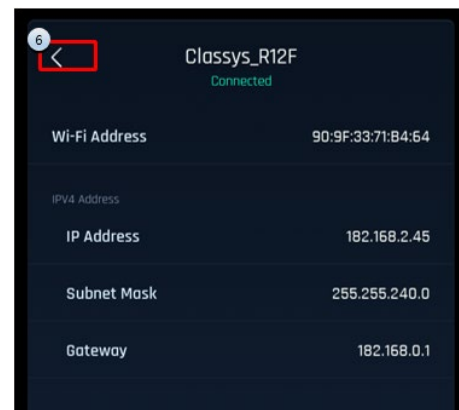


Pop-up screen when license expired

5-1-10. Network setting




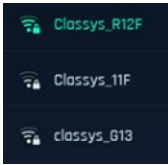

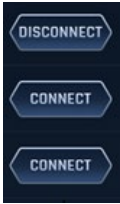


Network setting screen



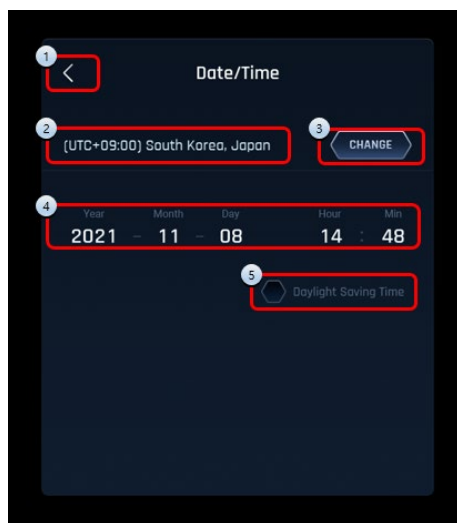
Connected AP Details

Figure 5.17 Network Setting Screen

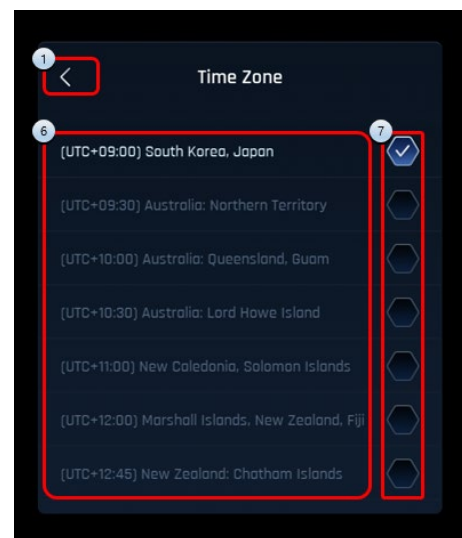
No	SIGN	Description
1		ON/ OFF the WIFI

2		Searching for AP on the network
3		Searched WIFI list
4		Details of connected AP address
5		- DISCONNECT: Disconnect of the AP address - CONNECT: Connection of the AP address
6		Button to return to the previous screen
7		Button to connect hidden network

5-1-11. Time/ Date setting





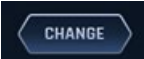
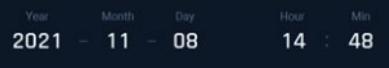

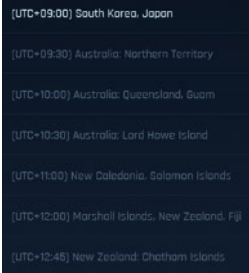

a) Date and time setting screen



b) Connected AP Details

Figure 5.18 Time/ Date Setting Screen

No	SIGN	Description
1		Button to return to the previous screen
2		Information of current time

3		Button to change the Time Zone
4		Display the currently date and time
5		ON/ OFF the summer time - Displayed by adding 1 hour to the existing time when activated
6		<p>Changeable time zone list</p> <ul style="list-style-type: none"> - ③ This is a list of time zones displayed when pressing the button of time zone. - User can scroll to the up or bottom of the time zone list on the screen by touch.
7		Time zone setting button

5-1-12. Software management

(1) Software management screen

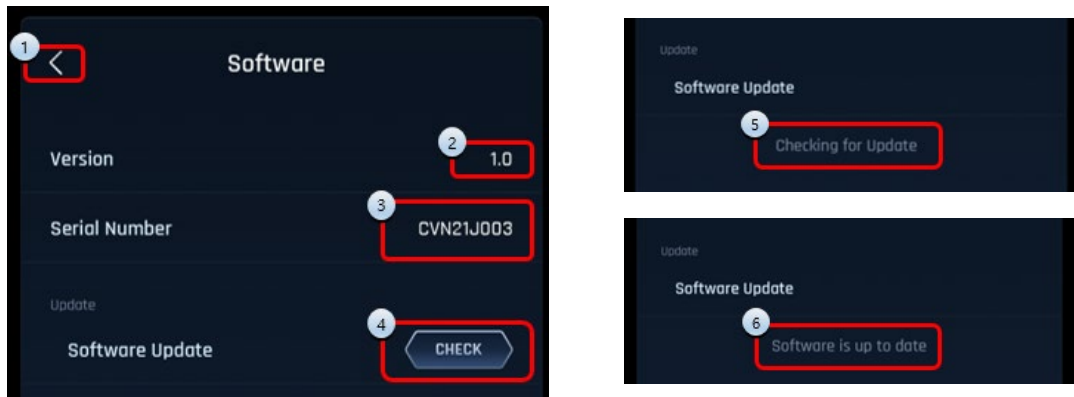
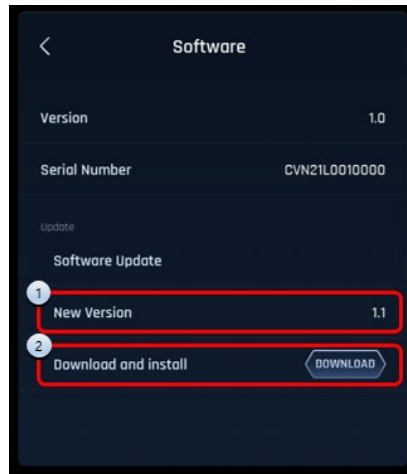


Figure 5.19 Software Management Screen

No	SIGN	Description
1		Return to the previous screen
2		Current software version
3		The information of device
4		A button to check for the latest version and update of the software
5		Checking for software updates - If there is a software update, move to the software update screen
6		Display the latest software version
	or 	Display the Server error while checking the software version

(2) Software update screen



1) Display the latest software version

2) When downloading and installing the latest software, touch the download button on the screen.

- Create a progress bar when downloading.: Display the current download status.



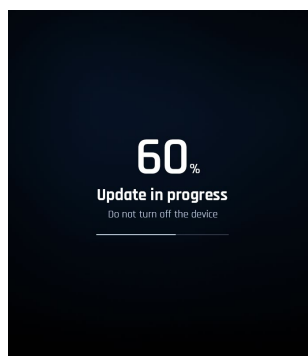
- If an error occurs while downloading, the following message will be displayed.



- Create the install button when download is completed: When the download is complete, an install button is created and the update file can be installed as shown below.



- After the software is downloaded and installed, the progress rate is displayed on the screen as shown below.



5-1-13. QR CODE

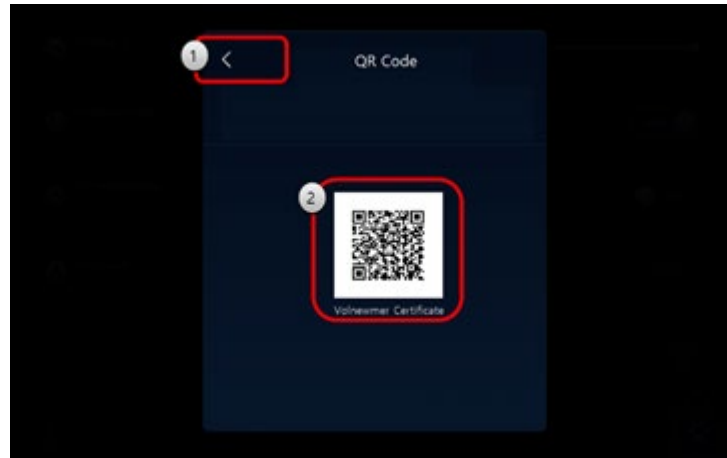




Figure 5.20 QR CODE Screen

No	SIGN	Description
1		Return to the previous screen
2		Display a QR code indicating that the connected device is genuine volnewmer

5-2. Treatment Steps

- 5-2-1. Attach closely the Return pad to the skin on the upper part of the waist or back.(Do not apply near the shoulder, neck or head). Return pad cable should be connected away from the treatment area.
- 5-2-2. Apply a sufficient amount of the coupling gel provided by the manufacturer before starting the procedure
- 5-2-3. The main screen of the selected hand-piece appears on the touch screen of the main body. Set the values to be treated.
- 5-2-4. Select the treatment site and attach the tip of the hand-piece to the treatment site.
- 5-2-5. When the user presses the shot button of handpiece or the foot switch, the state goes for “READY” to “ARMED” at the top of the touch screen
- 5-2-6. RF energy is irradiated when it detects that the tip has been in contact with the skin in the ‘ARMEN’ state.
- 5-2-7. If it is detected that the skin contact falls during energy irradiation, an error message is generated, and it appears as standby until the ARMED condition is satisfied.
- 5-2-8. If the energy is being irradiated normally, the “ACTIVE” icon is found on the top of the touch screen. The “ACTIVE” mode means that RF energy deliver to treatment site
- 5-2-9. When the energy transfer is complete, the “COMPLETE” icon is found at the top of the touch screen.
- 5-2-10. At the end of the procedure, place the handpiece with the tip attached on the handpiece holder and release the handpiece activation button(or foot switch)
- 5-2-11. The top icon on the main body touch screen returns to the “READY” mode.

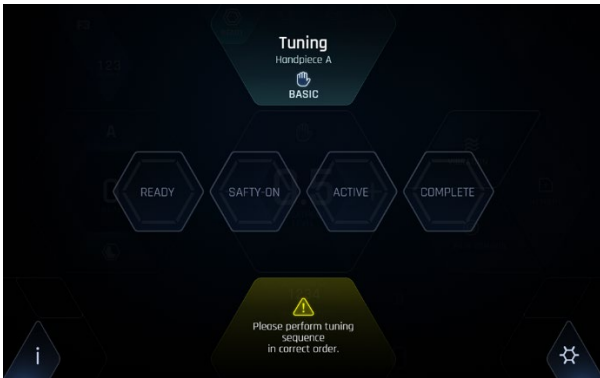
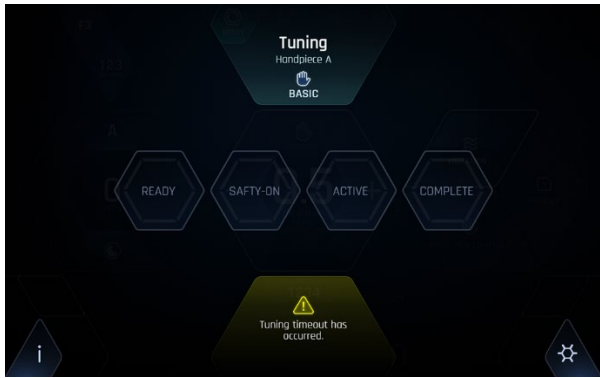
5-3. Shutting Down the System

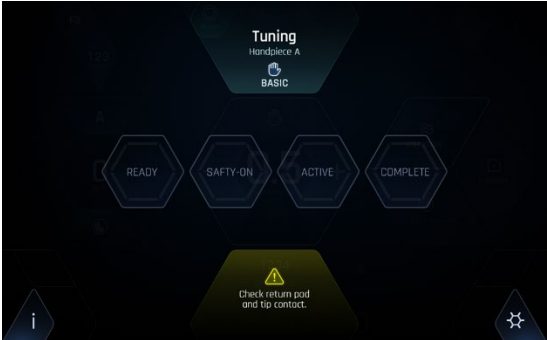
- 5-3-1. Keep tips in a designated location to prevent use by untrained personnel.
- 5-3-2. The Main Power Switch on the rear of the Main Body should be facing down in the ON position. The System may be switched OFF when moving the equipment between rooms or for storage or cleaning purposes..



5-3-3. Follow maintenance and storage instructions shown in Section 7 of this manual.



6. System Message

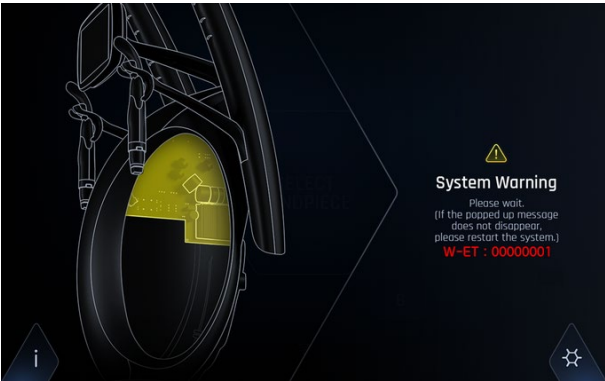
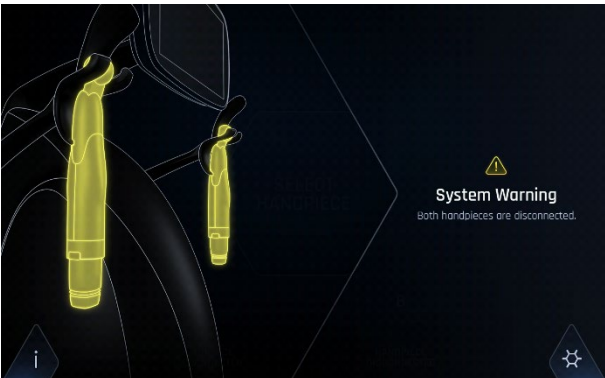
The VOLNEWMER is designed with internal checks to ensure that all aspects of the equipment are functioning appropriately. Please follow the instructions and refer to the information listed below when errors occur.

No	Message Displayed	Description	Corrective Action
1		<p>Warning 1 of Tunning Button press sequence error</p> <p>When you have to press the SHOT button after the ARMED button, but the order has been changed or only the shot button is pressed.</p>	<ol style="list-style-type: none"> 1. Return to the READY state by releasing both the ARMED button and the SHOT button.(If your foot is on the FOOT switch, take your foot off the foot switch) 2. Follow the procedure in the user manual and try again. 3. If the problem persists please contact Classys Inc. support.
2		<p>Warning 2 of Tunning The error that the shot is being irradiated for too long</p> <p>The tuning shot is forcibly stopped for safety when it is being irradiated for too long</p>	<ol style="list-style-type: none"> 1. Return to the READY state by releasing both the ARMED button and the SHOT button.(If your foot is on the FOOT switch, take your foot off the foot switch) 2. Follow the procedure in the user manual and try again. 3. If the problem persists please contact Classys Inc. support.

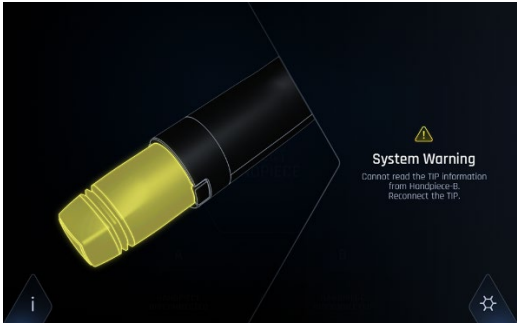


No	Message Displayed	Description	Corrective Action
3		<p>Warning 3 of Tuning Stop on error during shot irradiation</p> <p>-If the ARMED or SHOT button is released while irradiating the tuning shot -If the tip or return pad is not in close contact with the skin -Damage to the grounding harness assembly or if the assembly is bad -If the area where the treatment tip comes in contact is dry(lack of coupling gel)</p>	<ol style="list-style-type: none"> 1. During tuning, check whether the treatment tip is in vertical contact with the affected area and that the coupling gel is sufficiently applied. 2. Check that the return pad is in close contact with the affected part, and that the return pass harness assembly is well coupled to the body and the return pad. 3. Check that the return pad harness assembly is not damaged or bent. 4. Try again according to the procedure in the user manual. 5. If damage to the return pass harness assembly is confirmed or continuous error occurs, please contact Classys Inc. support.

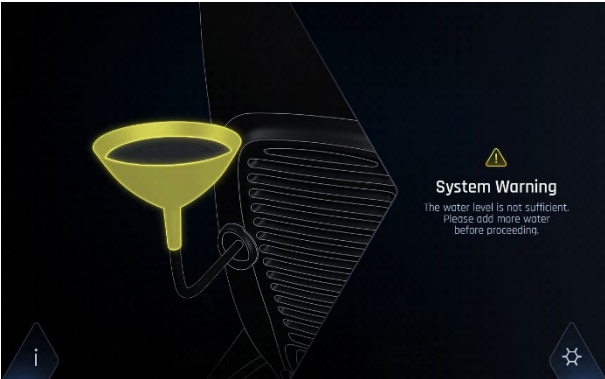
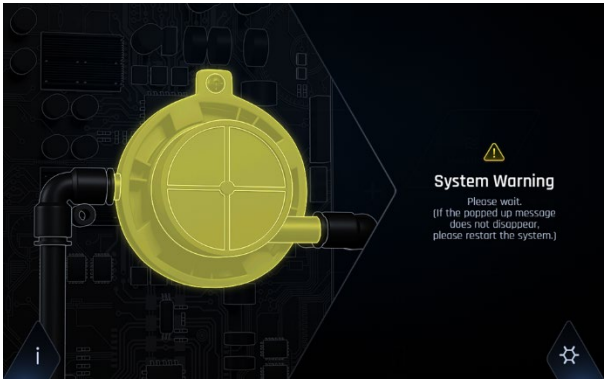
No	Message Displayed	Description	Corrective Action
4		<p>Warning 1 for Shot Button press sequence error</p> <p>When you have to press the SHOT button after the ARMED button, but the order has been changed or only the shot button is pressed.</p>	<ol style="list-style-type: none"> 1. Return to the READY state by releasing both the ARMED button and the SHOT button.(If your foot is on the FOOT switch, take your foot off the foot switch) 2. Follow the procedure in the user manual and try again. 3. If the problem persists please contact Classys Inc. support.
5		<p>Warning 2 for Shot The error that the shot is being irradiated for too long</p> <p>The tuning shot is forcibly stopped for safety when it is being irradiated for too long</p>	<ol style="list-style-type: none"> 1. Return to the READY state by releasing both the ARMED button and the SHOT button.(If your foot is on the FOOT switch, take your foot off the foot switch) 2. Follow the procedure in the user manual and try again. 3. If the problem persists please contact Classys Inc. support.


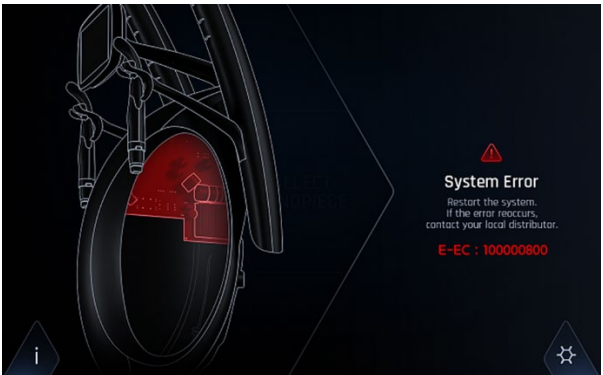
No	Message Displayed	Description	Corrective Action
6		<p>Warning 3 of Shot Stop on error during shot irradiation</p> <p>-If the ARMEND or SHOT button is released while irradiating the tuing shot -If the tip or return pad is not in close contact with the skin -Damage to the grounding harness assembly or if the assembly is bad -If the area where the treatment tip comes in contact is dry(lack of coupling gel)</p>	<ol style="list-style-type: none"> 1. During tuning, check whether the treatment tip is invertical contact with the affected area and that the coupling gel is sufficiently applied. 2. Check that the return pad is in close contact with the affected part, and that the return pass harness assembly is well coupled to the body and the return pad. 3. Check that the return pad harness assembly is not damaged or bent. 4. Try again according to the procedure in the user manual. 5. If damage to the return pass harness assembly is confirmed or continuous error occurs, please contact Classsys Inc. support.
7		<p>Warning 4 of Shot Return pad fell off</p> <p>-Warning screen when the return pad is not connected during shot irradiation.</p>	<ol style="list-style-type: none"> 1. Turn off the power 2. Check that the return pad is attached to the device or the patient. 3. Check the attachment and operate the device again. 4. If the problem persists please contact Classsys Inc. support.



No	Message Displayed	Description	Corrective Action
8		<p>Warning System temperature error</p> <p>- Screen displayed because the system temperature is not in the normal range</p>	<ol style="list-style-type: none"> 1. Turn the system “OFF” and restart. 2. If the problem persists please contact Classys Inc. support.
9		<p>Warning A/B handpiece not connected</p> <p>- When both A/B handpieces are not connected, so the operation is not possible.</p>	<ol style="list-style-type: none"> 1. Turn off the equipment and check the mounting status of arm stands A and B. If necessary, remove the arm stand from the body and reattach it. 2. Apply power and check for errors. 3. If the problem persists please contact Classys Inc. support.

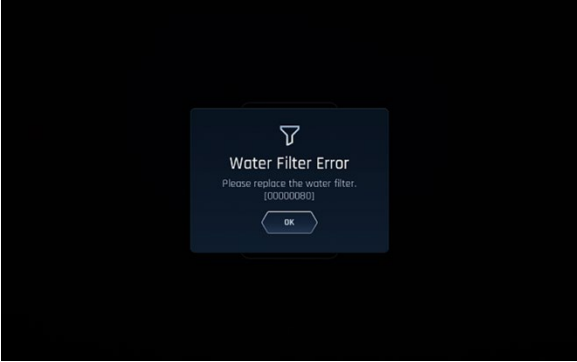
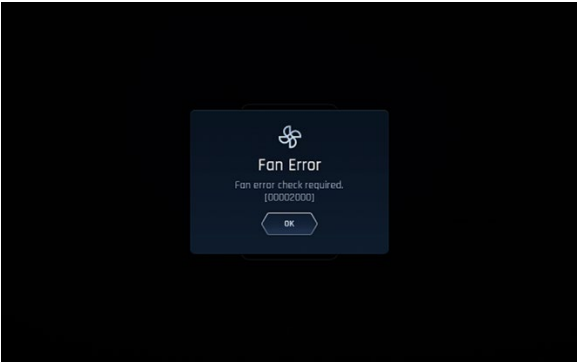
No	Message Displayed	Description	Corrective Action
10		<p>Warning Electrode tip connection error to handpiece</p> <p>- When the operation is not possible because the electrode tip is not properly connected to the handpiece. – Reconnect</p>	<ol style="list-style-type: none"> 1. Check that the electrode tip is properly mounted on the A or B handpiece. 2. Turn off the power of the equipment. 3. Remove the electrode tip from the A or B handpiece and refit it. 4. Power on the equipment and check for errors. 5. If the problem persists please contact Classys Inc. support.
11		<p>Warning Electrode tip recognition error on the handpiece</p> <p>- When an electrode tip is connected to the handpiece but cannot be recognized due to an ID error. – Expired electrode tip or malfunction</p>	<ol style="list-style-type: none"> 1. Check that the electrode tip is properly mounted on the A or B handpiece. 2. Turn off the power of the equipment. 3. Remove the electrode tip from the A or B handpiece and refit the new electrode tip. 4. Power on the equipment and check for errors. 5. If the problem persists please contact Classys Inc. support.



No	Message Displayed	Description	Corrective Action
			Classsys Inc. support.
12		<p>Warning The electrode tip has exhausted all count of shot : (When using a new electrode tip) all count of shot has been exhausted. Needs to be replaced with a new electrode tip.</p>	<ol style="list-style-type: none"> 1. Check that the electrode tip is properly mounted on the A or B handpiece. 2. Turn off the power of the equipment. 3. Remove the electrode tip from the A or B handpiece and refit it. 4. If the problem persists please contact Classsys Inc. support.
13		<p>Warning for foot switch error When foot switch does not connected (If Armed button source selecte the foot)</p>	<ol style="list-style-type: none"> 1. Turn off power and connect to the foot switch. 2. Turn on power and check the same error. 3. If the problem persists please contact Classsys Inc. support. 4. If the hand switch use, select the trigger source as HAND in setup screen.

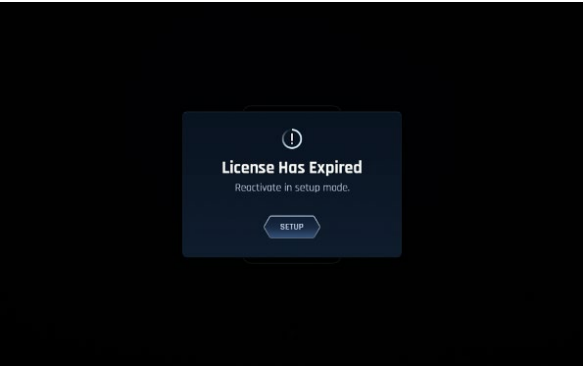

No	Message Displayed	Description	Corrective Action
14		<p>Warning for lack of the cooling water error</p> <p>-Lack of the cooling water</p>	<ol style="list-style-type: none"> 1. Turn off the power. 2. Connect the funnel to the water inlet and connect the drain hose to the water level control port. 3. Inject cooling water (D/I water or distilled water) into the water inlet. 4. Stop water infusion when water comes out of the drain hose. 5. Turn on the power and check for errors. <p>※ When a water error occurs, use about 150-200ml of 1cup of paper cup(Recommended to support every 1month)</p>
15		<p>Warning for flow sensor</p>	<ol style="list-style-type: none"> 1. Turn off the device and restart it. 2. If the problem persists please contact Classys Inc. support.

No	Message Displayed	Description	Corrective Action
16		<p>E-RC error System time error</p> <p>- System setup time error. Requires battery check and system time reset</p>	<ol style="list-style-type: none"> 1. Turn off the device and restart it. 2. If the problem persists please contact Classys Inc. support.
17		<p>E-SC error Timeout of baseboard standby</p> <p>-Stop the system due to timeout of waiting -Impossible treatment</p>	<ol style="list-style-type: none"> 1. Turn the system "OFF" and restart. 2. If the problem persists please contact Classys Inc. support.

No	Message Displayed	Description	Corrective Action
18		<p>E-NC error Failure of baseboard communication</p> <p>-When the baseboard and communication line are broken -The communication is not operated due to other problem occurs -Impossible treatment</p>	<ol style="list-style-type: none"> 1. Turn the system "OFF" and restart. 2. If the problem persists please contact Classys Inc. support.
19		<p>E-EC error Occurred the baseboard fault</p> <p>Impossible treatment due to baseboard problem</p>	<ol style="list-style-type: none"> 1. Turn the system "OFF" and restart. 2. If the problem persists please contact Classys Inc. support.

No	Message Displayed	Description	Corrective Action
20		Filter replacement warning pop-up	<ol style="list-style-type: none"> 1. Turn off the equipment. 2. Check and replace the water filter. 3. If the problem persists please contact Classys Inc. support.
21		Fan error warning pop-up	<ol style="list-style-type: none"> 1. After turning the equipment off, turn it on again. 2. If the problem persists please contact Classys Inc. support.

No	Message Displayed	Description	Corrective Action
22		<p>Password change pop-up - Password over 90 days</p>	
23		<p>Pop-up on boot when license is near expiry</p>	<ol style="list-style-type: none"> 1. The license of the equipment will expire within a certain period of time. Connect the network to renew the license. 2. If the problem persists please contact Classys Inc. support.

No	Message Displayed	Description	Corrective Action
24		<p>Pop-up on boot when license expires</p>	<ol style="list-style-type: none"> 1. Since the license of the device has expired and cannot be operated, connect the network to renew the license. 2. If the problem persists please contact Classys Inc. support.
25		<p>Tip Replacing mode</p>	<ol style="list-style-type: none"> 1) Operates the separation, installation, and replacement of the electrode tip. 2) Click the 'OK' button on the pop-up window to complete the electrode tip replacement operation.

7. Cleaning and Storage

7-1. Cleaning the System

System is Main body, Hand-piece and Tip. When cleaning system surfaces, apply the recommended cleaning method and solution. Be careful when cleaning the Hand-piece and Tip. Tips are packaged and shipped non-sterile and ready to use.

Allow the isopropyl alcohol solution to evaporate before using the system. Do not allow liquids to enter the body. Do not spray or pour liquids into the device.

Step	Main body	Hand-piece	Tip
Common	1. Turn off the system 2. Unplug the system from the electrical outlet 3. The user should wear gloves and masks. And wipe the gloved hands with 70% isopropyl alcohol, and thoroughly dries them. 4. Do not reuse materials used for reprocessing. 5. Using a mild, non-abrasive cleanger. The CLASSYS INC., recommends the cleaning agent information below -Cleaning agent information : Endozime AW Triple Plus with A.P.A (by Subtilisins) : Washing Liquid Concentration: 0.4% diluent(Endozime 4mL/ Water 1L)		
Before device use	1. Cleaning ① Clean the visible contaminants on the main body and hand-piece surfaces with new Cotton cloth. ② Once before treatment after moving to the treatment room		1. Cleaning ① Wet a diluted cleanger in new cloth(clean and soft cotton cloth) and wipe the TIP surface meticulously for 2 minutes. ② Use a new cloth to gently wipe the cleanger on the TIP surface for 1 minutes. ③ Hold the TIP with one hand shake off the cleanger at least 5 times with a clean cloth placed over the other hand. ④ Wipe the TIP surface for 2 minutes with purified water on a clean and soft cloth. ⑤ Gently wipe the water on the surface of the TIP for 1 minute using a clean, soft cloth, etc., and shake off the water as in step 4.

Step	Main body	Hand-piece	Tip
	<p>2. Disinfection</p> <p>① Wipe for more than a minute with a new cotton pad soaked enough in all parts with isopropyl alcohol (70%).</p> <p>② Dry naturally so that all isopropyl alcohol is evaporated on the surface of the device.</p> <p>③ Inspect the cartridge for damage such as cracks, corrosion, discoloration, or water leakage. If damage is evident, discontinue use and contact the manufacturer.</p> <p>④ Perform the disinfection once before treatment after moving to the treatment room</p>		<p>2. Disinfection</p> <p>① Wipe for more than a minute with a new cotton pad soaked enough in all parts with isopropyl alcohol (70%).</p> <p>② Dry naturally so that all isopropyl alcohol is evaporated on the surface of the device.</p> <p>③ Perform the disinfection once before and after each procedure</p>
After device use	<p>1. Cleaning</p> <p>① Clean the visible contaminants on the main body and hand-piece surfaces with new Cotton cloth.</p> <p>② Wash every 10 to 15 days for long-term storage.</p>		<p>1. Cleaning</p> <p>① Clean each visible contaminant on the TIP surface with a new cotton cloth.</p> <p>② If contaminants are not removed from the skin contact surface of the TIP, manually shake the skin contact surface in clean water at least 5 times and dry it completely with a new cotton cloth.</p> <p>③ Wash every 10 to 15 days for long-term storage.</p>



Warning: Be careful not to let isopropyl alcohol enter the drain hole due to careless handling of the isopropyl alcohol container. Excess amounts of isopropyl alcohol can cause soil, surface or groundwater contamination.

7-2. General Care of the System

In order to maintain optimal condition, the instructions below should be followed.

1. Check the handpiece and tip regularly for problems.
2. Make sure to power off the equipment before replacing the tip.
3. Do not drop the handpiece and tip onto the floor or hard objects. It can cause serious damage.

4. Do not twist or pull the handpiece cable. It may break the internal wire or cause damage to the connector.
5. Use the coupling gel provided by the manufacturer, and do not use other lubricants or lotions, especially mineral oils, as they may damage the tip or handpiece.
6. Before use, wipe the tip with 70% isopropyl alcohol and periodically inspect the tip surface for damage or wear. It must be cleaned between procedures.

7-3. Movement and Storage

7-3-1. Movement

- Handle the VOLNEWMER with caution at all times.
- Unlock the Main Body casters and using the knob, move the equipment to the desired site.

7-3-2. Storage

Please store the VOLNEWMER in an environment where the conditions are as follows:

- Temperature: 5°C - 60°C
- Relative Humidity: 0% - 90%
- Air Pressure: 500hpa - 1060hPa

7-3-3. Disposal

- Electric and electronic equipment must not be disposed of together with household waste.
- The user is obligated to dispose of a broken redundant electrical or electronic device at a dedicated collection location and put it in a special container.



The details are set forth based on the relevant national laws. The obligation is indicated on the product label or in the manual in the form of a crossed-out waste bin. By sorting waste for recycling, you help to protect the national environment.

8. Specification

No	Performance	Specification
1	Trade Name	VOLNEWMER
2	RF energy	6.78MHz ±1%
3	Impedance	75 ~ 400 Ω
4	Average output power	Max. 115 W
5	Energy type	Monopolar Radio Frequency(RF)
6	Touch screen	10.1 Inch LCD Touch Screen
7	Input Rating	220-240V, 50/60Hz
8	Type and degree of protection against electrical shock	Class I, Type BF
9	Electric Power consumption	1200 VA
10	Dimension	466 (W) X 567 (D) X 1527 (H) mm
11	Weight	56kg (including cooling water)
12	Tip specification	I Tip / F Tip / V Tip / S Tip
13	Environment	[Operating Environment] - Temperature: 10°C - 35°C - Relative Humidity: 0% - 90% - Air Pressure: 700hpa - 1060hPa
		[Shipping and Storage] - Temperature: 5°C - 60°C - Relative Humidity: 0% - 90% - Air Pressure: 500hpa - 1060hPa

Appendix A. Electromagnetic Emissions and Immunity

Manufacturer's declaration - electromagnetic emission

The VOLNEWMER is intended for use in the electromagnetic environment specified below. The customer or the user of VOLNEWMER should assure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The VOLNEWMER is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonics emission IEC 61000-3-2	A	
Voltage fluctuation IEC 61000-3-3	Complies	

Manufacturer's declaration - electromagnetic immunity

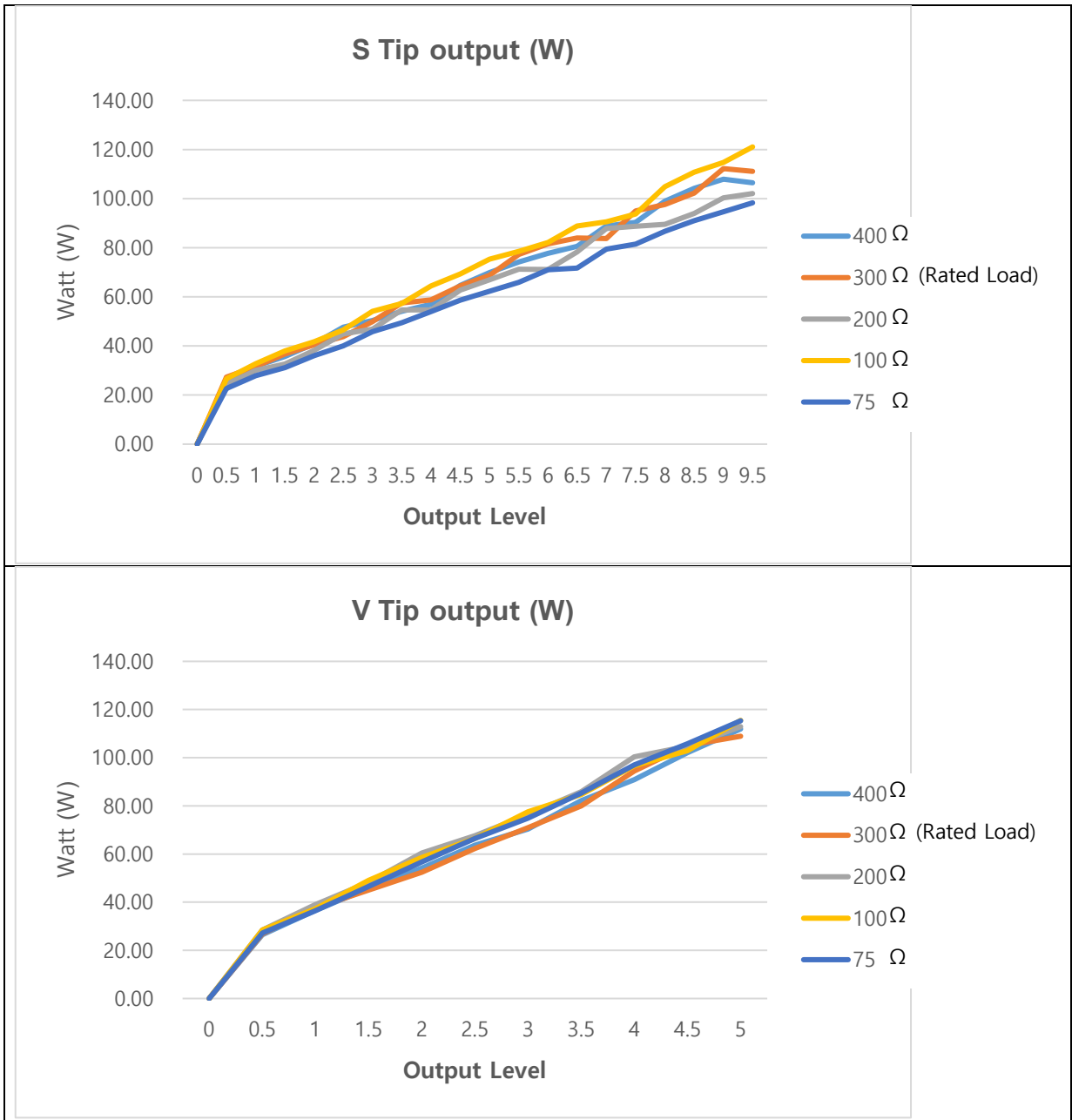
The VOLNEWMER is intended for use in the electromagnetic environment specified below. The User or Licensee of the VOLNEWMER should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic Environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV Contact 15 kV Air	8 kV Contact 15 kV 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	2kV for power supply lines 1kV for input/output lines	2kV for power supply lines 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

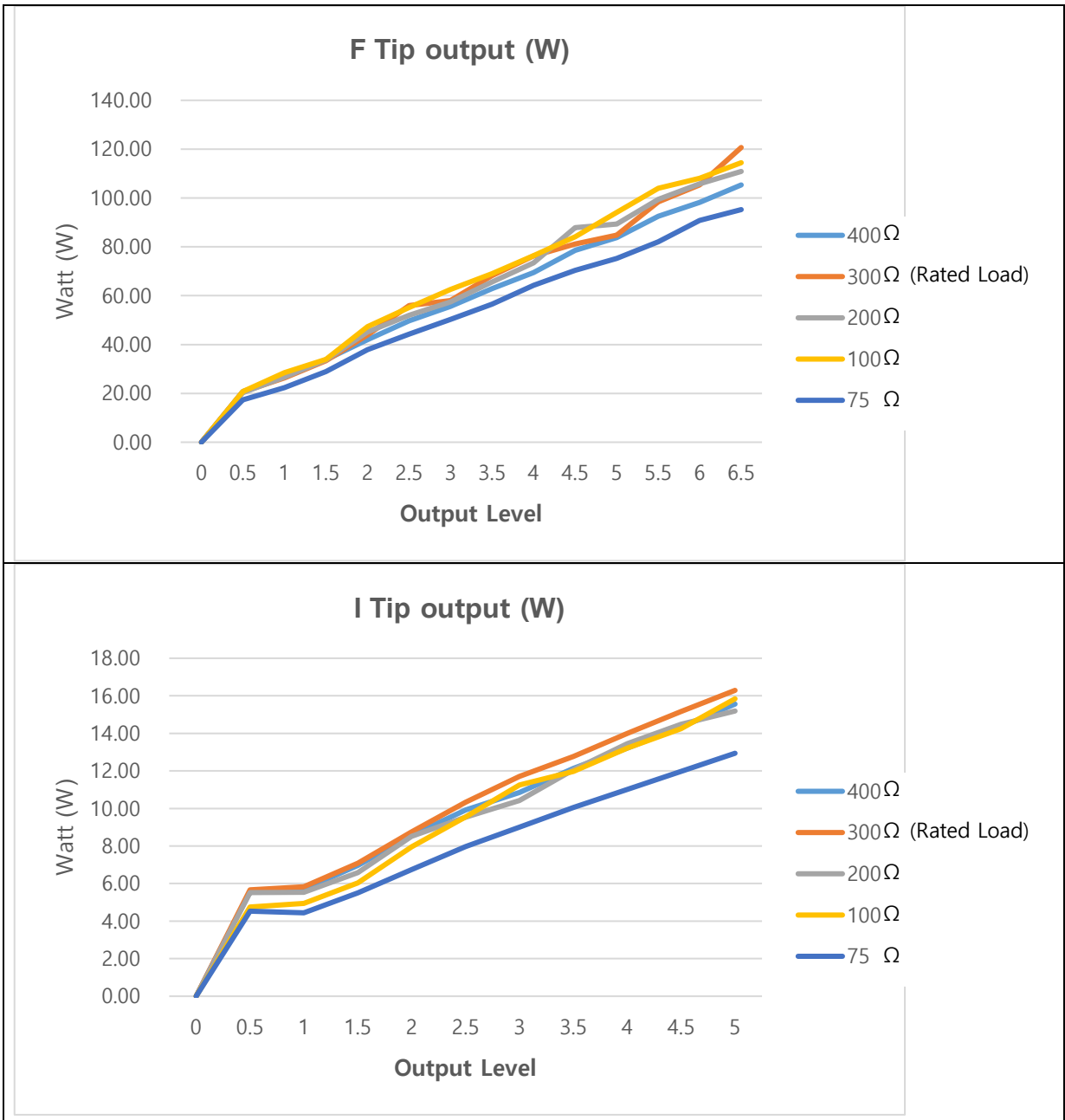
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV differential mode 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

The VOLNEWMER is intended for use in the electromagnetic environment specified below. The User or Licensee of the VOLNEWMER should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic Environment - guidance
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5cycle (at 0, 45, 90, 135, 180, 225, 270 and 315)	0% U_T (100% dip in U_T) for 0.5cycle (at 0, 45, 90, 135, 180, 225, 270 and 315)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VOLNEWMER requires continued operation during power mains interruptions, it is recommended that the VOLNEWMER be powered from an uninterruptible power supply or a battery
	0% U_T (100% dip in U_T) for 1cycle	0% U_T (100% dip in U_T) for 1cycle	
	70% U_T (30% dip in U_T) for 25 cycle (at 0)	70% U_T (30% dip in U_T) for 25 cycle (at 0)	
	0% U_T (100% dip in U_T) for 250 Cycle	0% U_T (100% dip in U_T) for 250 Cycle	

<p>Conducted RF IEC 61000-4-6</p>	<p>3 V 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz</p>	<p>3 V 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz</p>	<p>-</p>
<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80.0 MHz to 2.7 GHz</p>	<p>3 V/m 80.0 MHz to 2.7 GHz</p>	<p>Recommended separation distance $E = \frac{6}{d} \sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL IN V/m.</p>
<p>Note 1) U_T is the A.C. mains voltage prior to application of the test level.</p> <p>Note 2) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT.</p>			

Appendix B. Power Output Data





VOLNEWMER

Operation Manual (Ver. 1.0, Aug. 2023)



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