ULTRAFORMER® MPT

OPERATION MANUAL

Ver. 1.0

CLASSYS

Technology for better life

ULTRAFORMER MPT (Model Name: UF4-M400)

The ULTRAFORMER MPT 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 user manual describes the operation of the ULTRAFORMER MPT 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.

Table of Contents

1. Introduction to Manual

1-1. Purpose

This manual provides a description of the ULTRAFORMER MPT system components, displays, operational instructions and other related information vital to the functions of the system.

Classys Inc. provides this manual in English by default. If the customer requires a translated manual in another language, we will proceed with the request to the appropriate country distributor.

WARNING: Do not operate the ULTRAFORMER MPT 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. Indications for Use

The ULTRAFORMER MPT is a non-invasive therapeutic device for skin lifting and tightening.

2-2. Contraindications

The ULTRAFORMER MPT is not recommended for patients with the following:

- Open wounds or lesions on the treatment area
- Severe or cystic acne in the area of treatment
- Metal stents / electrical implants in the treatment area
- Bio-absorbable mechanical implants
- Skin infections of any type
- Hemorrhagic disorders or dysfunctions
- Pregnancy or when breastfeeding

2-3. Precautions

Do not use the equipment without prior training and qualifications to operate the ULTRAFORMER MPT. Consult with experts or use a diagnostic device to check the depth to decide whether treatment is appropriate.

- Anticoagulant therapy
- Skin conditions caused by autoimmune diseases, skin cancer, and Herpes Simplex
- Diabetes or epilepsy
- Severe skin disease
- Decortication, heart disease, hypersensitiveness, hypertrophic scar
- Hypersensitiveness or hypertrophic scars
- Hemostatic dysfunction
- Avoid applying treatment on the thyroid gland, thyroid cartilage, and trachea

- Avoid applying treatment directly on the breast tissue and major vessels

Immediately stop treatment if the following occurs:

- The surface of the skin burns
- If the outer surface layer of skin rises by swelling

The following may occur post treatment:

- Temporary pain or discomfort
- Burns and scabbing
- Neurological symptoms

2-4. Potential Side Effects

This equipment is a non-invasive focused ultrasound therapeutic device, which is to be applied to the skin. This device has no serious adverse events or major side effects occurring during clinical research. The following occurred during clinical trials:

- Erythema (Redness): The treated area may exhibit erythema after treatment and typically resolves within a few hours of treatment.
- Edema (Swelling): The treated area may exhibit mild edema following treatment and typically resolves within a week.
- Pain: Momentary discomfort may be experienced during the procedure. If patients experience post procedure discomfort, this typically resolves within 2 days.
- Bruising: Mild bruising caused by damage to soft tissue blood vessels may occur occasionally and typically resolves within 48-72 hours of treatment.
- Scarring: If incorrect treatment techniques are used, scarring formations may occur.
- Nerve effects:
  - Transient local muscle weakness may result after treatment due to inflammation of a motor nerve.
  - Transient numbness may result after treatment due to inflammation of a sensory nerve.

- Transient pain, paresthesia and/or tingling maybe experienced.
- No permanent injuries to facial nerves have been reported.

2-5. Complaints and Adverse Events

No serious or adverse observations were made from the use of the preceding equivalent devices in reference to the clinical study.

3. System Overview

3-1. System Description

The ULTRAFORMER MPT is a non-invasive equipment. It is typically computer-controlled and is capable of producing localized heat within tissues or organs. Energy delivered to the patient is via an externally-mounted cartridge.

The life cycle of ULTRAFORMER MPT is 5 years.

3-2. System Components and Features

The ULTRAFORMER MPT consists of the following primary components as shown in the *Figure 3.1*: The Main Body with the integrated 10.4-inch touchscreen, Hand-piece cable, AC Power cable and interchangeable Cartridges.

Figure 3.1 Main components of the ULTRAFORMER MPT

No.	Item	No.	Item	No.	Item
1	Main Body	2	ULTRA F Hand-piece	3	ULTRA BOOSTER Hand-piece
4	ULTRAFORMER MPT 1.5	5	ULTRAFORMER MPT 3.0	6	ULTRAFORMER MPT 2.0
7	ULTRAFORMER MPT 4.5	8	ULTRAFORMER MPT 6.0	9	ULTRAFORMER MPT 9.0
10	ULTRAFORMER MPT 13	11	DERMA BOOSTER 1.5	12	CELL UP BOOSTER 3.0
13	LINE UP BOOSTER 4.5	14	AC Power Cable	15	Foot switch

3-2-1. Main Body

The Main Body is the information center for the ULTRAFORMER MPT. It houses the Graphic User Interface (GUI) that allows the user to interact with the device. This screen sets and displays the operating conditions including equipment activation status, treatment parameters, and system messages. *Figure 3.2* illustrates the physical features of the Main Body.

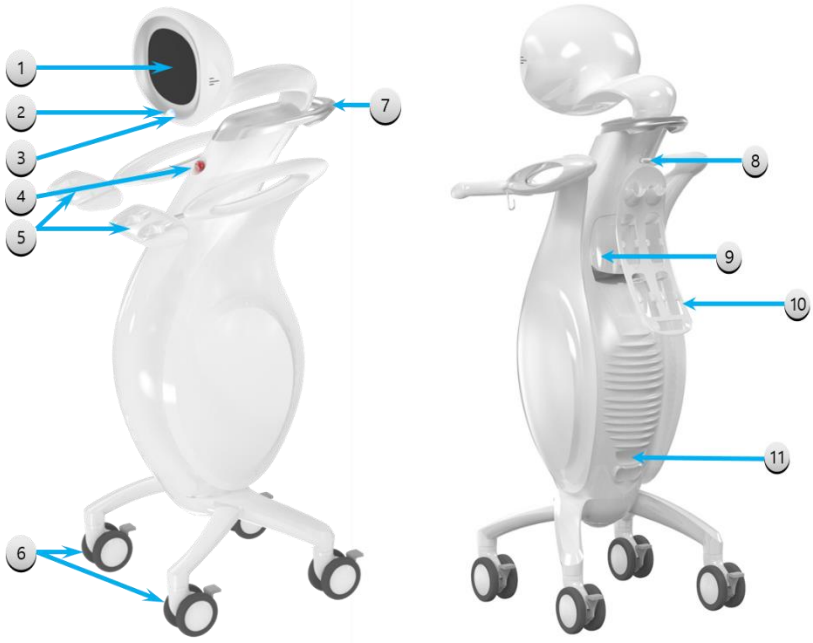


Figure 3.2 Main Body front view (left) and rear view (right)

No.	Item	Description
1	10.4” LCD Touch Screen	Graphic User Interface (GUI)
2	Key Button	Turn ON/OFF button
3	Insertion of Wireless LAN card	Entrance to insert LAN card for using wireless LAN
4	Emergency Switch	Operating Stop Switch when emergency
5	Hand-piece Holder	Hand-piece holder
6	Locking Caster	Moving wheel (Locking)
7	Knob	Handle for stability when moving
8	Monitor disconnect Switch	Used to remove the top monitor
9	Hand-piece Connector Cover	Cover of socket for plugging in Hand-piece cable
10	Cartridge holder (Back side)	The cartridges can be mounted with the cover where the connector connecting the body.
11	Main Power Switch	AC power ON/OFF Switch

3-2-2. Hand-piece

One end of the Hand-piece is a connection output to attach the Cartridge. The other end of the Hand-piece is connected to the insertion on the side of the Main Body. The Hand-piece images are shown below in *Figure 3.3*. The Hand-piece trigger button is utilized to apply the ultrasound shot.

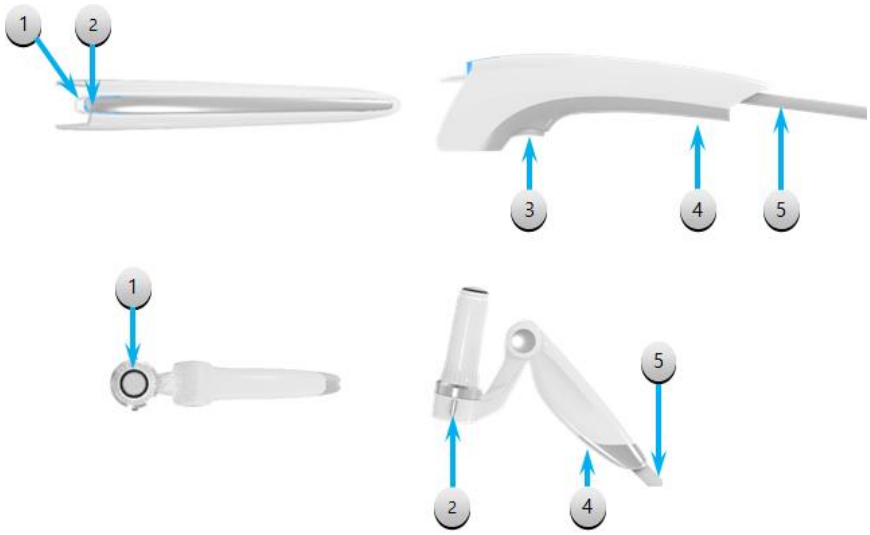


Figure 3.3 Hand-piece without cartridge inserted, top and side views

No.	Item	Description
1	LED indicator	Red LED displayed when ultrasound energy is applied. Green LED displayed when Cartridge connected to Hand-piece and ready to apply shot. Blue LED displayed when the Hand-piece is connected and recognized by the device. Blue LED blinks when the Hand-piece and device connection is not efficient.
2	Cartridge Disconnect Switch	Laches on either side for disconnecting on the Hand-piece
3	Ultrasound Output Switch	Hand-piece trigger to apply shot
4	Firmware connect cover	Connect cover when firmware of Hand-piece changed
5	Hand-piece cable	Cable for connecting Main Body and Hand-piece

3-2-3. Cartridge

Figure 3.4 is an illustration of the Cartridge. Both sides of the Cartridge marks maximum treatment range. The front side indicates the center point for treatment. The Cartridge marks the type and depth.

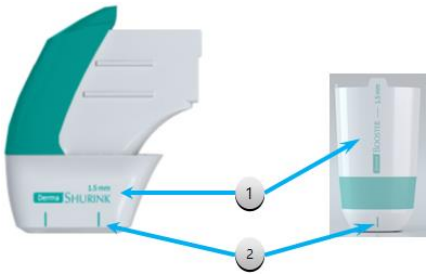


Figure 3.4 Treat Cartridge, separated from Hand-piece

No	Item	Description
1	Labeling	Mark the Cartridge type
2	Treat guides	Mark the Cartridge maximum length, treatment center point

The types of Cartridges vary in frequencies and treatment depths as shown in *Table 3.1*.

No.	Cartridge Type	Function	Remark
1	ULTRAFORMER MPT 1.5	Frequency: 7MHz, Depth: 1.5mm, Max. Power: 0.5J	Optional
2	ULTRAFORMER MPT 3.0	Frequency: 7MHz, Depth: 3.0mm, Max. Power: 1.0J	
3	ULTRAFORMER MPT 2.0	Frequency: 5.5MHz, Depth: 2.0mm, Max. Power: 0.4J	
4	ULTRAF	ULTRAFORMER MPT 4.5	Frequency: 4MHz, Depth: 4.5mm, Max. Power: 1.0J
5		ULTRAFORMER MPT 6.0	Frequency: 2MHz, Depth: 6.0mm, Max. Power: 1.5J
6		ULTRAFORMER MPT 9.0	Frequency: 2MHz, Depth: 9.0mm, Max. Power: 2.0J
7		ULTRAFORMER MPT 13.0	Frequency: 2MHz, Depth: 13mm, Max. Power: 2.0J

8	ULTRA BOOSTER	DERMA BOOSTER 1.5	Frequency: 7MHz, Depth: 1.5mm, Max. Power: 0.5J
9		CELL UP BOOSTER 3.0	Frequency: 7MHz, Depth: 3.0mm, Max. Power: 1.0J
10		LINE UP BOOSTER 4.5	Frequency: 4MHz, Depth: 4.5mm, Max. Power: 1.0J

Table 3.1 Cartridge Types

3-2-4. Essential Accessories

The essential accessory is an ultrasound transmission gel. Ultrasound transmission gel must be used at all times when treating.

3-3. Precautions for use

3-3-1. Warnings

- To prevent unauthorized use of the ULTRAFORMER MPT, store in a controlled environment only accessible by authorized and trained personnel.
- For safety reasons, perform a test shot with the cartridge prior to performing a procedure.
- To avoid risk of electric shock, always inspect Cartridge, Hand-piece cable before use.
- Do not use a cable or Cartridge that has been damaged or is leaking fluid.
- When the Cartridge is damaged or torn, do not use and replace the Cartridge to operate the System.
- Power supply must be 100-240V~, 50/60Hz to operate the system safely.
- The ULTRAFORMER MPT is intended for indoor, dry location use. Avoid liquid spills and splashes.
- Do not place the System in vicinity of direct sun light, high humidity or nearby heating devices.
- Gel used for treatment should not be left on the Hand-piece or Cartridge.
- To avoid system damage, do not tilt the equipment and avoid collision with other electrical devices.

- The ULTRAFORMER MPT comes with a three-conductor AC power cable and plug. Use a properly grounded outlet and always plug the ULTRAFORMER MPT directly into the outlet.

  Never remove the ground conductor via any AC adaptor plugs or extension cables.
- Disconnect the AC Power cable from the outlet by pulling on the plug not the cord.
- Do not touch the AC Power cable with wet hands.
- Turn off the AC Power switch and disconnect the AC Power cable from the outlet prior to cleaning the Main Body.

- Do not remove the covers on the Main Body or Hand-piece. The ULTRAFORMER MPT contains no user serviceable components. If the System requires service, contact local distributors or Classys Inc.
- No modification of this equipment is allowed.
- The ULTRAFORMER MPT should not be used near flammable gases or anesthetics. Fire or explosions may occur. The ULTRAFORMER MPT is not AP or APG rated.
- Avoid restricting ventilation under or behind the Main Body of the system. Maintain an open space of at least 50cm around the Main Body. If ventilation holes are obstructed, the System may overheat.
- The Hand-piece is rated as a Type B patient applied part. It may provide a connection between the patient and protective earth. This may present a hazard if the patient becomes connected to other equipment with excessive electrical current leakage.
- Use the Cartridge provided by Classys Inc. only. Operating with any other Cartridges may cause patient injury or malfunction of the device.
- Do not suddenly remove the Hand-piece from the Main Body. It may malfunction or cause damage if separated by force.
- Please refer to section “3-3-3” for warnings of Electromagnetic Compatibility and Immunity”.

3-3-2. Cautions ⚠

- Do not turn on and activate the device without applying ultrasound transmission gel to the Cartridge. This could cause damage to the Cartridge.
- Do not apply the Cartridge to the skin without use of ultrasound transmission gel.
- Before proceeding with treatment, check if the Cartridge is properly attached.
- The Hand-piece connectors must be kept clean and dry. Do not use the Cartridge if the connectors have been immersed in liquid. Refer to sub-section 7.1 of this manual.
- The Hand-piece has been designed to be robust, however it may be damaged if dropped onto a hard surface or if the membrane is punctured. If physical damage is incurred it will not be covered by warranty.
- Operators are advised to check the remaining shots of the Cartridge prior to treatment, in order for the user to replace the Cartridge before depletion of the Cartridge. If additional Cartridges are required, contact local distributors or Classys Inc.
- Used cartridges should be disposed of in accordance with local regulations.
- Please refer to section “3-3-3” for cautions of Electromagnetic Compatibility and Immunity”.

Please follow the directions below if the system does not turn on:

- Ensure the Main Power and key switch is in the ON position.
- If the problem persists, unplug the Power cable.
- Pull the fuse holder below the Main Power switch.
- Replace the fuse (T10AH250V).
- If the problem persists, please contact the local distributors or Classys Inc.

3-3-3. Electromagnetic Compatibility and Immunity

The RF emission of the "ULTRAFORMER MPT" 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 “ULTRAFORMER MPT” adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation. If such use is necessary, “ULTRAFORMER MPT” 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 ULTRAFORMER MPT, including cables specified by Classys Inc. Otherwise, degradation of the performance of ULTRAFORMER MPT could result.

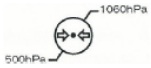
Caution: The EMISSIONS characteristics of ULTRAFORMER MPT make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

Caution: The “ULTRAFORMER MPT” has been designed to meet the standards of IEC60601-1-2 for electromagnetic compatibility; however, output can be lost or degraded due to EM disturbances.

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

No.	Symbol	Meaning
1		Type B applied Part
2		Alternate Current
3		Serial Number
4		Date of Manufacture
5		Manufacturer
6		Storage Temperature
7		Relative Humidity
8		Atmospheric Pressure Limits
9		Caution
10		General Warning, Caution, Risk of Danger
11		Mind instruction for use
12		Pushing prohibited
13		Sitting prohibited
14		Stepping prohibited
15		Crossed-out Wheelie bin
16		Protective Earth

4. Setting Up for First-Time Use

4-1. Unpacking

The Main Body, Hand-piece and Cartridges are shipped in one container.

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 User Manual.

Figure 4.1. The required storage area for the ULTRAFORMER MPT

4-2-2. Electromagnetic Environment

The system is unlikely to cause interference to nearby electronic equipment; however, other electronic equipment must not be stacked or placed immediately adjacent to the System. The floor should be wood, concrete or ceramic. If floors are covered with synthetic material, the relative humidity must be at least 30%

4-3. Connection to Components

4-3-1. Connecting the Hand-piece

The Hand-piece connector is located on the rear of the Main. Connect the Hand-piece connector to the Main Body. If connected correctly, a clicking sound will occur.

4-3-2. Identifying and Connecting Cartridges

Cartridges are identified by the label on the side of the Cartridge which includes the name of the Cartridge, treatment frequency and treatment depth.

Remove the Cartridge from its protective pouch. To connect the Cartridge, slide the cartridge into the Hand-piece as shown in *Figure 4.2*. If connected correctly, a clicking sound will occur.

Figure 4.2 Connecting the Cartridge

Figure 4.3 Disconnecting the Cartridge

To disconnect the Cartridge, press the latch on up sides of the Hand-piece and slide the cartridge straight out of the hand-piece. When the cartridge is inserted, the Main Body automatically recognizes and updates the Graphical User Interface.

4-3-3. Device connection setup

Ensure the AC power cable connected from the back of the System is plugged into the wall socket. For electrical safety, connect the external ground terminal of the device to a separate ground terminal.

5. System Operation

5-1. Overview of System Functions

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

An overview of this screen is seen in *Figure 5.1* below.

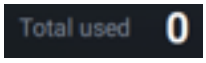
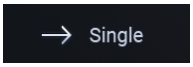
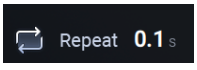
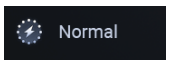
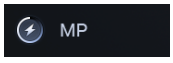
Figure 5.1 Initial screen

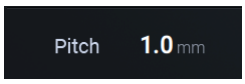
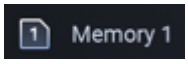
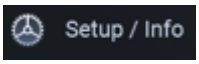
5-1-2. Operating Graphical User Interface

When you select the Hand-piece, display screen is as shown *Figure 5.2.*

< ULTRA F > < ULTRA BOOSTER >

Figure 5.2 Setting screen

No	SIGN	Description
1		Cartridge temperature display (normal / warning / error) Wi-Fi signal strength(high/normal/ low/ disconnecting) When the Error icon is touched in the screen, the popup window came on. (not connected to the server/not connected to the AP server/ not connected to the internet/failed to license registration)
		When problem occurs for the rear fan of device
		 When the error occurs for the SMPS  When  and  occur at the same time  When it's estimated that there's something wrong with the output of HIFU
2		Remain shot of Cartridge
3		Display the installed Cartridge information.
4		Used shot of Cartridge
5		Display of available trigger sources. -Hand / Foot / Foot switch disconnected -Trigger pressed
6		Increase the output Adjustable between 0.1~2.0J (depending on the Cartridge energy) in increments of 0.1J. Decrease the output
7		Treatment total shot of face Cartridge after system power on
8		Beeping sound reminds user that the total shot counter of face Cartridge has been reached. Continuous shots may be applied to a maximum of 9999.
9		Single application mode
		Repeat application mode After one shot, pause for a set time and then output the next shot. (Pause time is 0.1~1 second)
10		Irradiation while moving by a set pitch during ultrasonic output
		When outputting ultrasound, irradiate at once without stopping

11		Increase the length. Adjustable between 5~25mm in increments of 5mm. Decrease the length.
12		Increase the pitch. Adjustable between 1.0~2.0mm in increments of 0.1mm. Decrease the pitch
13		Save the setting parameters to either M1, 2 or 3. Save setting by holding the button down for 2-3 seconds. Able to rewrite over existing saved parameters.
14		Setup button and Cartridge information button
15		Displays “READY” when in use, displays “STANDBY” when not in use”
16		Display the currently used slot (Hand-piece change button when automatic recognition function “OFF” in Setup

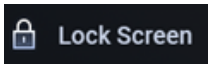
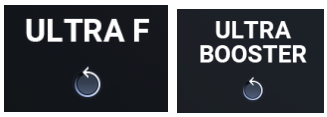
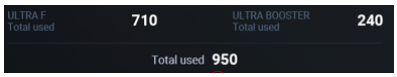
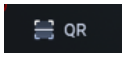
5-1-3. Setup / Info GUI (Graphical User Interface)

When you select “Setup/Info” the display composition is shown as *Figure 5.3.*

< SETUP > < INFO >

Figure 5.3 Setup / Info GUI

No	SIGN	Description
1		Setting volume (0 ~ 5)
2		Display of available trigger sources. (Hand or Foot/ Only hand-piece button / Only Foot switch)
3		Hand-piece automatic recognition function ON / OFF

4		Animation function ON / OFF
5		Setting license, network, date
6		Lock screen setting and Password setting -Setting the screen protection and usage restriction if user do not use it for a certain period of time. -Password setting (The user need to know the existing password to change it)
7		Reset factory (Reset the memory and shot information)
8		Go to the main screen
9		Hand-piece type indication and shot clear button
10		Information of previously used Cartridges Information of previous shot count from Cartridges
11		Total number of shots used by hand-piece type
12		QR code for device information

5-2. Activating the System

5-2-1. Ensure the AC Power cable on the back of the System is plugged into the wall socket.

For the safety of patients, operators and electrical safety, connect the external ground terminal of the device to a separate ground terminal in the room.

5-2-2. Ensure the Main Power Switch is in the ON position.

5-2-3. Press the power button to turn the System ON.

5-3. Treatment Steps

5-3-1. Set the parameters (Energy, Pitch, Length) manually for treatment by adjusting the buttons on the GUI.

5-3-2. Ultrasound transmission gel should use previously registered sterile or non-sterile medical gels by health authority.

5-3-3. Ensure the treatment area has been cleansed thoroughly.

5-3-4. Apply a thin layer of ultrasound transmission gel to the Cartridge. Use aqueous ultrasound transmission gel only, as other lubricants or lotions may damage the Cartridges or Hand-piece.

5-3-5. Select the “STANDBY” button on the GUI. Once selected it will change to “READY”.

5-3-6. Apply a thin layer of ultrasound transmission gel to the patient’s skin. Place the Cartridge window on the patient’s skin and pull the trigger to emit ultrasound energy.

5-3-7. To deliver the next treatment line within the same treatment region, align the Cartridge 2-3mm to adjacent tissue within the treatment area and pull the trigger to emit ultrasound energy.

5-3-8. After 5 treatment lines are delivered, conduct a visual check of the Cartridge window to assess if the gel needs to be reapplied.

5-3-9. Continue in this pattern until the recommended number of treatment lines for the region has been delivered. A beeping sound will occur when the correct number of treatment lines is delivered.

5-3-10. When treatment is complete on the target region, press the “READY” button.

5-3-11. Place the Hand-piece on the Hand-piece holder.

5-4. Shutting Down the System

5-4-1. Turn off the device by pushing the power button located on the Main Body.

5-4-2. The Main Power Switch on the rear of the Main Body should be OFF. The System may be switched OFF when moving the equipment between rooms or for storage or cleaning purposes.

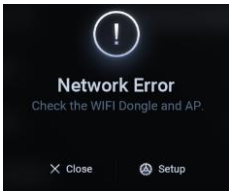
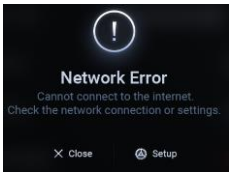
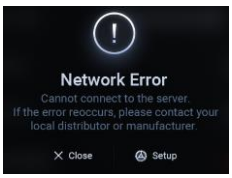
5-4-3. Follow maintenance and storage instructions shown in Section 7 of this manual.

6. System Messages

The ULTRAFORMER MPT 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.	Error Message	Description	Corrective Action
E-01		Disconnected Hand-piece	1. Ensure that the Hand-piece is properly mounted in the Main body. 2. Turn the system “OFF” 3. Remove and reinsert the Hand-piece 4. Turn the system restart. 5. If the problem persists please contact Classys Inc. support.
W-02		Calibration Fail	1. Ensure that the Cartridge is properly mounted in the Hand-piece. 2. Remove and reinsert the Cartridge. 3. Turn the system “OFF” and restart. 4. If the problem persists please contact Classys Inc. support.
No Cartridge		Connection failure (Cartridge)	
W-03		Motor Stall	
W-04		Motor Moving error	

No.	Error Message	Description	Corrective Action
			
E-05		Electronic Control error	1. Turn the system “OFF” and restart. 2. If the problem persists please contact Classys Inc. support.
E-06		Fan error	
E-07		Not Connected	
W-08		Cartridge temperature error -Cartridge temperature is high -Cartridge temperature is low	1. Change the cartridge or Pause the procedure until the temperature inside the cartridge decreases. 2. Change the cartridge or Pause the procedure until the temperature inside the cartridge increases. 3. If the problem persists please contact Classys Inc. support.
W-09		Fire switch pressed	1. Pull the trigger switch only if the system status is on “ready”. 2. If the problem persists please contact Classys Inc. support.

No.	Error Message	Description	Corrective Action
W-10		Footswitch disconnected	1. Ensure that the Footswitch is properly mounted in the Main body. 2. Turn the system “OFF” 3. Remove and reinsert the Footswitch 4. Turn the system restart. 5. If the problem persists please contact Classys Inc. support.
E-11		Error the internal base board	Restart the system. If the error reoccur, please contact your local distributor or manufacturer.
E-12		Security rock of cartridge	Cartridge not recognized, please replace the Cartridge.
W-11		Network Error (WIFI dongle) Check the WIFI Dongle and AP.	Unplug the Wi-Fi dongle and plug it back in. If it’s still the same, use another Wi-Fi dongle to check
W-12		Network Error (Internet) Cannot connect to the internet. Check the network connection or settings. (Network error),	Check WLAN operation in network environment where Wi-Fi is connected.
W-13		Network Error(Network) Network connection is unstable. Check the network settings.	Check the network settings and contact customer service if there is no problem
W-14		Network Error(Server) Cannot connect to the server. If the error reoccurs, please contact your local distributor or manufacturer.	

7. Cleaning and Storage

7-1. Cleaning the Main Body, Hand-piece and Cartridge

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

Step	Main body	Hand-piece	Cartridge
Common	1. Turn off the system 2. Unplug the system from the electrical outlet 3. Tester should wear gloves and masks. 4. Do not reuse materials used for reprocessing.		
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 Clean each visible contaminant from the Cartridge with a new Cotton Cloth. ② If contaminants have not been removed from the skin contact surface of the cartridge, manually shake the skin contact surface of the cartridge in clean water for 1 minute and dry the moisture completely with a new cotton cloth. ③ Clean Before and after treatment
	2. Disinfection ① Wipe for more than a minute with a new cotton pad soaked enough in all parts with isopropyl alcohol (70%). ② Dry naturally so that all isopropyl alcohol is evaporated on the surface of the device. ③ Inspect the cartridge for damage such as cracks, corrosion, discoloration, or water leakage. If damage is evident, discontinue use and contact the manufacturer. ④ Perform the disinfection once before treatment after moving to the treatment room		2. Disinfection ① Wipe for more than a minute with a new cotton pad soaked enough in all parts with isopropyl alcohol (70%). ② Dry naturally so that all isopropyl alcohol is evaporated on the surface of the device. ③ Perform the disinfection once before and after each procedure
After device use	1. Cleaning ① Clean the visible contaminants on the main body and hand-piece surfaces with new Cotton cloth. ② Wash every 10 to 15 days for long-term		1. Cleaning ① Clean each visible contaminant on the Cartridge surface with a new cotton cloth.

Step	Main body	Hand-piece	Cartridge
	storage.		② If contaminants are not removed from the skin contact surface of the cartridge, manually shake the skin contact surface in clean water for 1 minute and dry it completely with a new cotton cloth. ③ Wash every 10 to 15 days for long-term storage.

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

To achieve a longer lifetime and use of the ULTRAFORMER MPT, treat the equipment carefully by adhering to the following guidelines:

- Inspect the Hand-piece and Cartridges regularly for any issues.
- Turn the device off before changing Cartridges to ensure proper identification of Cartridges and to prolong the life of the System.
- Do not drop the Hand-piece or Cartridges on the floor or other hard surfaces. This may cause permanent damage.
- Do not twist or pull the hand-piece cables. This could cause damage to internal wires and connections.
- Use aqueous ultrasound transmission gel only. Other lubricants or lotions, particularly mineral oil, may damage Cartridges or the Hand-piece.
- Do not use acoustic standoff pads or any objects between the Cartridge and the patient.
- Apply ultrasound transmission gel only to the window of the Cartridge and wipe it from the Cartridge after completing a session of treatment. Avoid the gel from contact with the Hand-piece or the Main Body.
- Cartridges should be cleaned between procedures. Refer to the cleaning procedure information allocated in subsection 7-1.

7-3. Movement, Storage and Disposal

7-3-1. Movement

- Handle the ULTRAFORMER MPT 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

Avoid direct sunlight and/or excessive moisture, wind and dust. Also keep away from the heater. Never let the gel remain in the connection between the hand-piece and cartridge. Store the cartridge in the packaging or in the cartridge holder in the main body.

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

7-3-3. Disposal of old Electrical & Electronic Equipment (WEEE)

(Application in the European Union and other European countries with separate collection system.)

- 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.

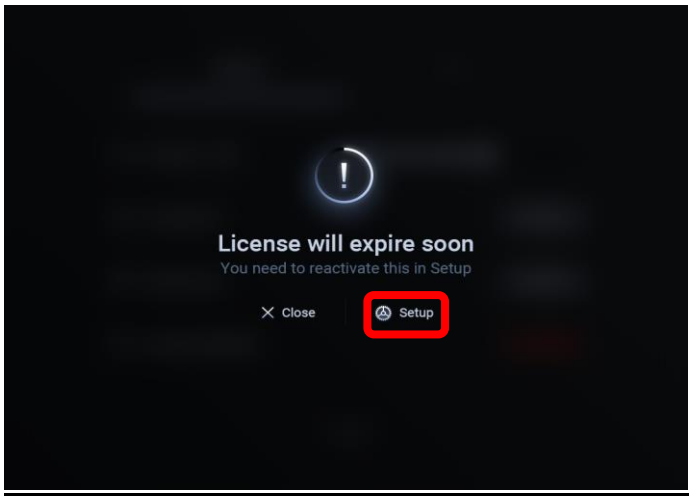
The details are set forth based on the relevant national laws. The obligation is indicated on the product label or in the manual in the form of a crossed-out waste bin. By sorting waste for recycling, you help to protect the national environment.

7-4. License and Software management

7-4-1. License management

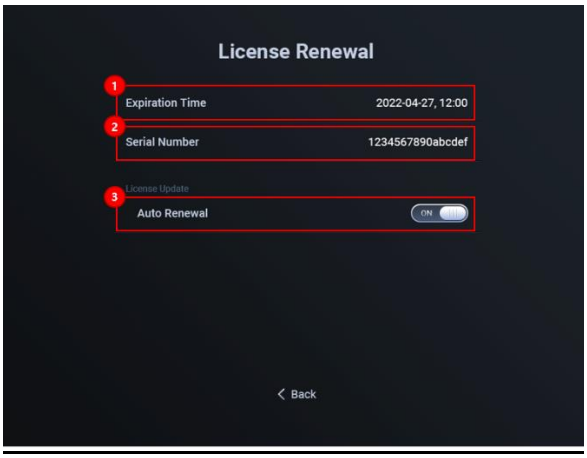
1) Warning of pop-up in license expiration

To use ULTRAFORMER MPT, 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.



2) The screen of license renewal (automatic)

<Set up>



<The screen of license renewal (automatic)>

① Touch the Manage License button on the screen, it moves on to the screen of license management.

② -1. 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.

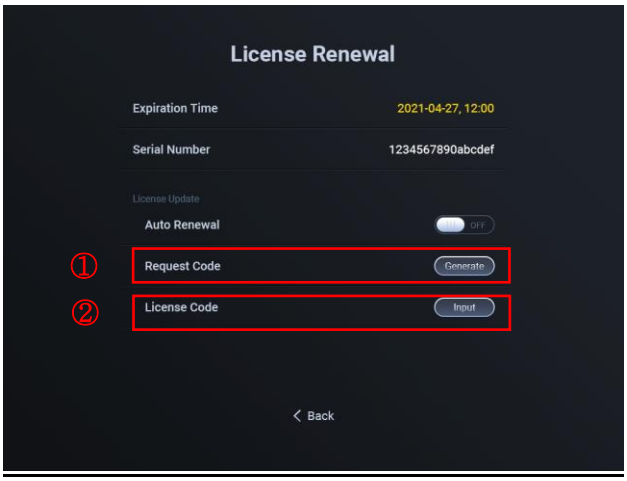
- License expires soon. : 2021-04-27, 12:00

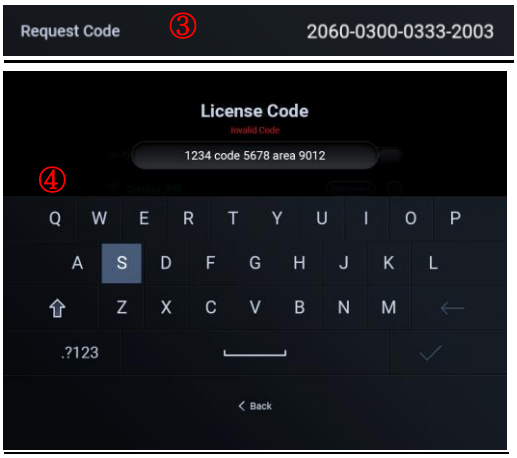
- License expires. : 2021-04-27, 12:00

③ -2. Display the equipment serial number

④ -3. ON/ OFF the renewal of license

3) The screen of license renewal (manual)





① To issue the license code, touch the button for requesting the license code.

② When entering the issued license code, touch the button on the screen.

③ It generates the code, the code is displayed as shown in Figure ③.

④ To insert the license code on the screen, an IME (input method editor) window should be generated and then user can input the license code as in Figure ④.

7-4-2. Software management

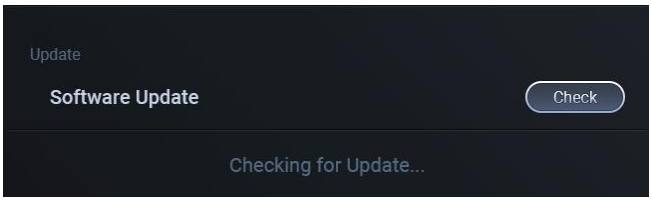
1) The screen of Software management

① The software version is displayed on the screen.

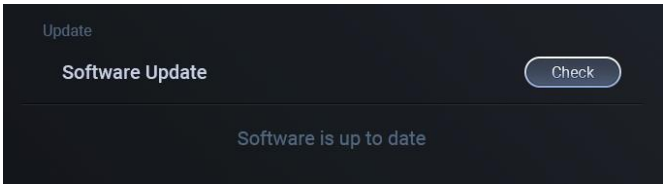
② It displays the serial number of this software.

③ Check the latest software and update it as follows.

- Searching for the latest updated of software



-If the current version of software is the latest version, it is displayed as shown below. If needed the latest update, go to the update screen.



2) Screen of software update

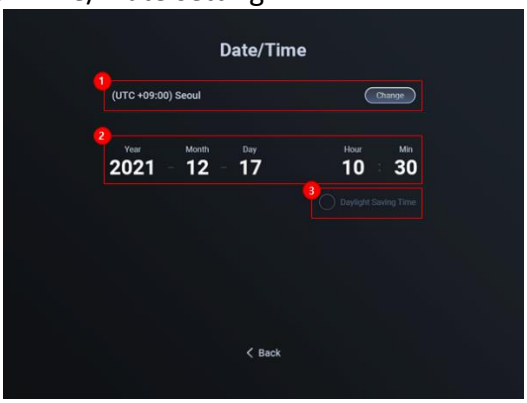
① Displays the latest version of software.

② Touch the “download” button when downloading and installing the latest version of software.

- Generate the progress bar during the download : When downloading the update of software, the user can check the current status.

- Generate an install button when the download is complete: When the download is completed, the user can touch the “install” button, and install the update file on the main

7-4-3. Time/ Date setting



① Move the setting the time zone

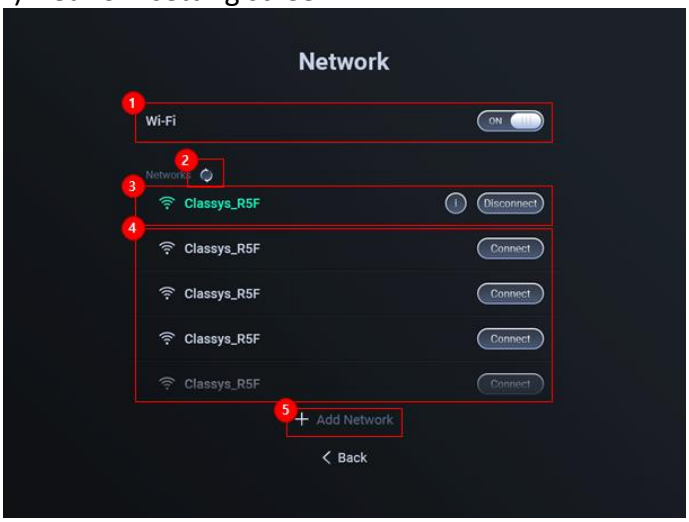
② Display the setting date/ time

③ ON/ OFF the summer time

- Displayed by adding 1 hour to the existing time when activated
- Show existing time when deactivated

7-4-4. Network setting

1) Network setting screen



① ON/ OFF the WIFI

② Refresh the WIFI list

③ Connected WIFI

- Place it at the top.
- Wi-Fi reception strength / security icon
- Disconnect button
- Detail information button

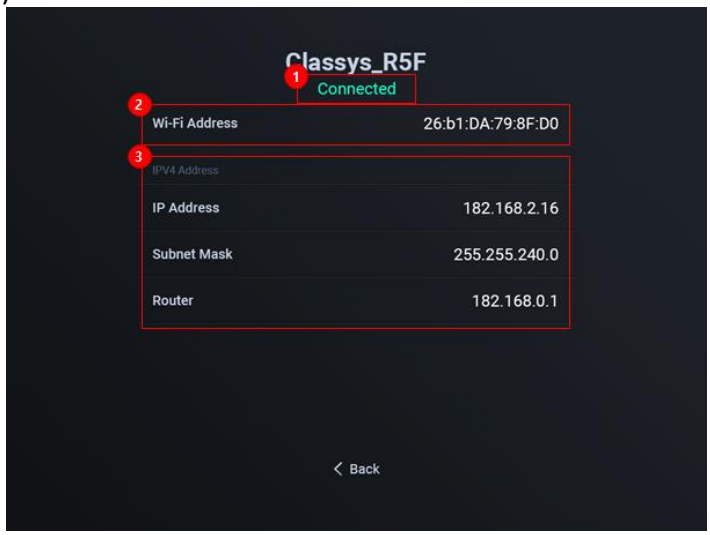
④ WIFI list

- Place the connection signal in the order of strong.
- Wi-Fi reception strength / security icon
- Connection button

  : For security reasons, the password IME appears.
- Details button

⑤ Add the other network

2) WIFI information screen



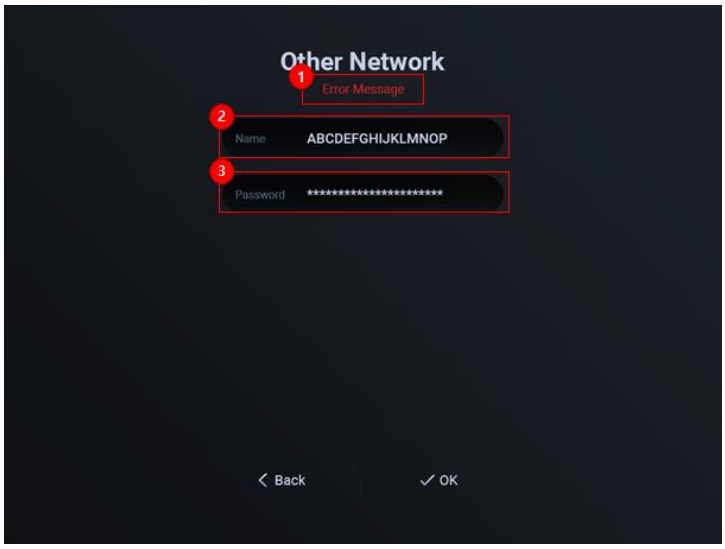
① Status the WIFI connection

② WIFI address

③ WIFI information display

-IP address, Subnet Mask, Router

3) Add the other network



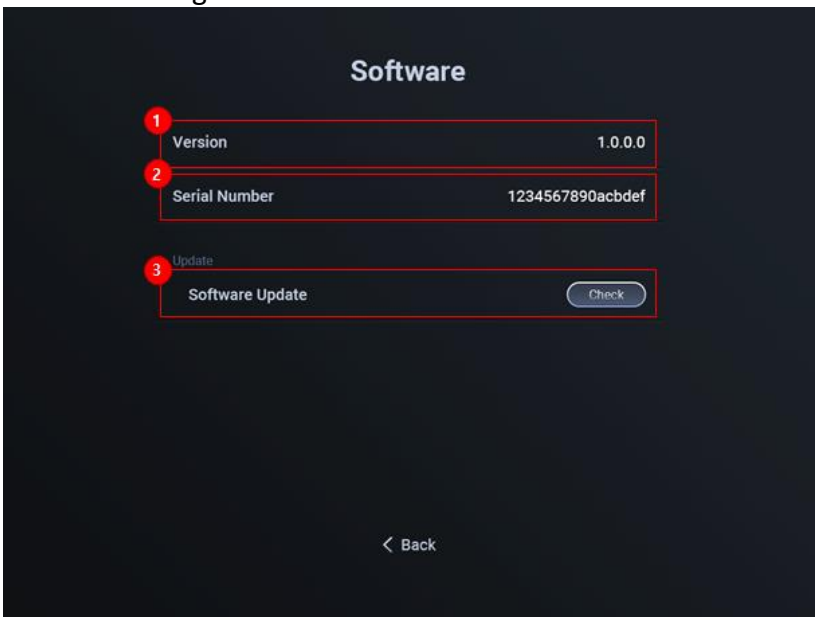
① Display the error marking

② Input the WIFI name: Input method editor(IME) appears when input is made.

③ Input the WIFI password: Input method editor(IME) appears when input is made.

7-4-5. Software management

1) Software management screen

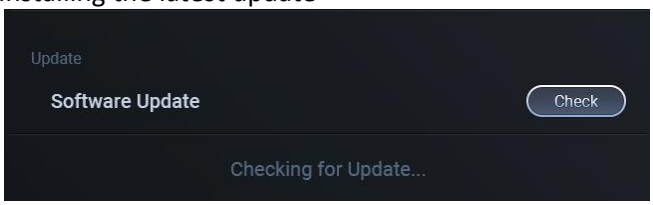


① Software version

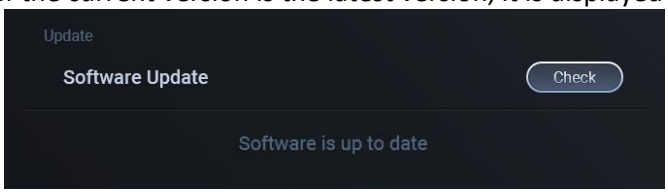
② Serial number

③ Check the software update

-Installing the latest update



-If the current version is the latest version, it is displayed as follows.



2) Software update screen

① Display the latest software version

② Download and install the latest software

-Create a program bar when downloading.

-Create the install button when download completed

7-4-6. Recommended Specification of WIFI LAN Dongle

1) Wireless standard: IEEE 802.11n/b/g

2) Power: USB Power
3) Interface: USB 2.0, Type-A
4) Wireless RF: 2.4GHz, 5GHz
5) Maximum size that can be installed: less than 50mm(W) x 20mm(H) x 8mm(D)
6) Usable CHIPSET LINUX Driver

Realtek	8188eu,8188fu,8192eu,8192su,8812au,8821cu,8822bu
Mediatek	mt7610,mt7612

7) Please purchase and use a wireless LAN using a supported chipset.
8) If it is difficult to confirm whether the model you want to purchase is applicable, please contact the service team.

8. Specifications

8-1. Specifications Table

No.	Item	Specification	
1	Product Name	Focused Ultrasound Therapeutic Equipment	
2	Brand /Model Name	ULTRAFORMER MPT, UF4-M400	
3	Output	0.1J – 2.0J	
4	Pitch	1mm - 2mm	
5	Length	5mm - 25mm	
6	Display	10.4 Inch LCD touch screen	
7	Electrical Requirement	100 - 240V~, 50/60Hz	
8	Electric power consumption	400VA	
9	Type and degree of protection against electrical shock	Class I, Type B	
10	Dimension	570(L) X 630(W) X 1330(H) mm	
11	Weight	37kg	
12	Cartridge (Optional)	ULTRA F	ULTRAFORMER MPT 1.5/ ULTRAFORMER MPT 2.0 ULTRAFORMER MPT 3.0 /ULTRAFORMER MPT 6.0 ULTRAFORMER MPT 9.0 /ULTRAFORMER MPT 13.0

		ULTRA BOOSTER	DERMA BOOSTER 1.5/ CELL UP BOOSTER 3.0 / LINE UP BOOSTER 4.5
13	Environmental	[Operating Environment] - Temperature: 10℃ - 35℃ - Relative Humidity: 0% - 90% - Air Pressure: 700hpa - 1060hPa	
		[Shipping and Storage] - Temperature: 5℃ - 60℃ - Relative Humidity: 0% - 90% - Air Pressure: 500hpa - 1060hPa	

Appendix A. Electromagnetic Emissions and Immunity

Manufacturer's declaration - electromagnetic emission

The ULTRAFORMER MPT is intended for use in the electromagnetic environment specified below. The customer or the user of ULTRAFORMER MPT should assure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ULTRAFORMER MPT uses RF energy only for its internal function. Therefore. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The ULTRAFORMER MPT 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.
Harmonics emission IEC 61000-3-2	A	
Voltage fluctuation IEC 61000-3-3	Complies	

Manufacturer's declaration - electromagnetic immunity

The ULTRAFORMER MPT is intended for use in the electromagnetic environment specified below. The User or Licensee of the ULTRAFORMER MPT 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 ULTRAFORMER MPT is intended for use in the electromagnetic environment specified below. The User or Licensee of the ULTRAFORMER MPT 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 1cycle 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 0.5cycle (at 0, 45, 90, 135, 180, 225, 270 and 315) 0% U_T (100% dip in U_T) for 1cycle 70% U_T (30% dip in U_T) for 25 cycle (at 0) 0% U_T (100% dip in U_T) for 250 Cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ULTRAFORMER MPT requires continued operation during power mains interruptions, it is recommended that the ULTRAFORMER MPT be powered from an uninterruptible power supply or a battery
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	-
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.7 GHz	3 V/m 80.0 MHz to 2.7 GHz	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.
Note 1) U_T is the A.C. mains voltage prior to application of the test level. 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.			

ULTRAFORMER® MPT

OPERATION MANUAL (Ver. 1.0, November. 2023)

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