ULTRAFORMER® III

Operation Manual

ver1.0

CLASSYS
Technology for better life

2017.04.26

ULTRAFORMER III (Model name is UF3-M300)

The “ULTRAFORMER III” is intended for use only by properly trained physicians and properly trained persons under the supervision of such a trained physician (Henceforth “the User”).

Prior to operating the system, the user must thoroughly read and understand this manual. Improper use of the system may cause personal injury and/or damage to the system that may invalidate the warranty agreement.

Note: This user manual describes the operation of the “ULTRAFORMER III” only. It is not a substitute for the required clinical training on the procedure that utilizes the system.

Table of Contents

1 Introduction to Manual

1-1. Purpose

This User's Manual provides a description of the System components, its controls and displays, instructions for its operation, and other equipment information important to the user.

Warning: Do not operate the "ULTRAFORMER III" before reading this manual thoroughly and being trained on the clinical procedure by an authorized Classys Inc. representative.
This manual is not a substitute for clinical treatment guidelines and training provided by the Company.

1-2. Conventions

Cautions alert the user to precautionary steps necessary to properly operate the system. Failure to observe these cautions may void the warranty.

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

All procedures are broken down by numbered steps. Steps must be completed in the sequence they are presented.

Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.

2 Medical Safety

2-1. Indications for Use

The “ULTRAFORMER III” is indicated for:
Use as a non-invasive dermatological therapeutic device for patients who have ptosis, psoriasis or usual cutaneous diseases using the principle of coagulation and necrosis and wound healing effect in the hyperthermia layer of body.

2-2. Contraindications

The “ULTRAFORMER III” is contraindicated for use in patients with open facial wounds or lesions and severe or cystic acne on the face and/or neck and metal stents/implants in the face and neck area and mechanical implants and implantable electrical devices and an active systemic or local skin disease that may alter wound healing.

2-3. Precaution

When not in use by trained personnel, the “ULTRAFORMER III” User Key should be removed from the system to help prevent unauthorized use. Keep the “ULTRAFORMER III” User Key in a designated place accessible only to authorized and trained personnel.

The “ULTRAFORMER III” has not been evaluated for use over various materials. Therefore, treatment is not recommended directly over those areas with any of the following:

- Mechanical implants
- Dermal fillers
- Implanted electrical devices
- Metal stents in the face and neck area

Treatment energy is not recommended for use directly on an existing keloid.

The “ULTRAFORMER III” has not been evaluated for use in patients on an anticoagulant treatment plan.

The “ULTRAFORMER III” has not been evaluated for use in the following patient populations:

- Pregnant or breast feeding women
- Children
- Decortication, heart disease, hypersensitiveness, keloid, hypertrophic scar
- Those with the following disease states
  - A hemorrhagic disorder or haemostatic dysfunction
  - An active or local skin disease that may alter wound healing
  - Herpes simplex
  - Autoimmune Disease
  - Diabetes
  - Epilepsy
  - Bell’s Palsy

2-4. Patient Safety

"ULTRAFORMER III" should not be used on a patient's eyes or in a location or technique where ultrasound energy can reach the eye.
Patients must wear protection goggles.

Use this system only if you are trained and qualified to do so.

If any problems occur during system operation, take immediate action(s):
Lift the Cartridge off the patient's skin, and turn off the key switch whit anti-clock wise.

2-5. Potential Side Effects

Side effects reported in the clinical evaluation of the "ULTRAFORMER III" were mild and transient in nature. These were limited to:

- **Erythema (redness):** The treated area may exhibit erythema immediately following treatment. This typically resolves within a few hours of treatment.
- **Edema (swelling):** The treated area may exhibit mild edema following treatment. This typically resolves within a few days of treatment.
- **Pain:** Momentary discomfort may be experienced during the procedure while energy is being deposited.
- **Bruising:** Mild bruising, which is caused by damage to soft tissue blood vessels may occur occasionally and typically resolves within a few days of treatment.
- **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.
No permanent injuries to facial nerves have been reported.

- **Scarring:** The possibility for scar formation (which will respond to medical care) may exist if incorrect treatment technique is used.

2-6. Complaints and Adverse Events

No serious adverse events were observed at the "ULTRAFORMER III".

Classys Inc. follows MDR (Medical Device Reporting) rules for handling complaints and adverse events. Should an adverse event be suspected or reported, contact Classys Inc. at the number on the cover page of this document: for those outside the Rep. of Korea, contact your local Classys Inc. representative.

3 System Overview

3-1. System Description

“ULTRAFORMER III” is an assembly of devices designed to produce and control the delivery of high heat (i.e., temperatures greater than 43° Celsius) to the body using ultrasonic energy for the intracorporeal treatment of ptosis, psoriasis or usual cutaneous diseases.

It is typically computer-controlled and is capable of producing or localized heating within tissues or organs. Energy delivered to the patient is an externally-mounted transducer. It is safe and effective device for the dermatologic disease.

It is better to use the general-purpose Ultrasound imaging system to visualize the skin and sub-dermal regions of interest in before treatment. It allows the user to assure proper skin contact in order to deliver the energy at desired depths.

The therapy feature directs acoustic waves to the treatment area. This acoustic energy heats tissue as a result of frictional losses during energy absorption, producing discrete points of heat.

ULTRAFORMER III’s Lifecycle is 5 years.

3-2. System Components and Features

The “ULTRAFORMER III” is consisted of primary components as shown in the Figure 3.1: the main body unit with integrated touchscreen, the hand-piece with cable, and interchangeable Cartridges (see Figure 3.1).

No.	Item	No.	Item	No.	Item
1	Main body	2	Hand-piece(2ea)	3	AC Power cable
4	User Key	5	L4-4.5 Cartridge	6	L7-3.0 Cartridge
7	L7-1.5 Cartridge	8	MF6 Cartridge	9	MF9 Cartridge

Figure 3.1 Main components of the “ULTRAFORMER III”

3-2-1. Main body

The Main Body is the information center for the “ULTRAFORMER III”. It houses the touchscreen monitor and Graphical 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, system messages and prompts. Figure 3.2 illustrates the physical features of the Main body, such as the connector ports and power controls.

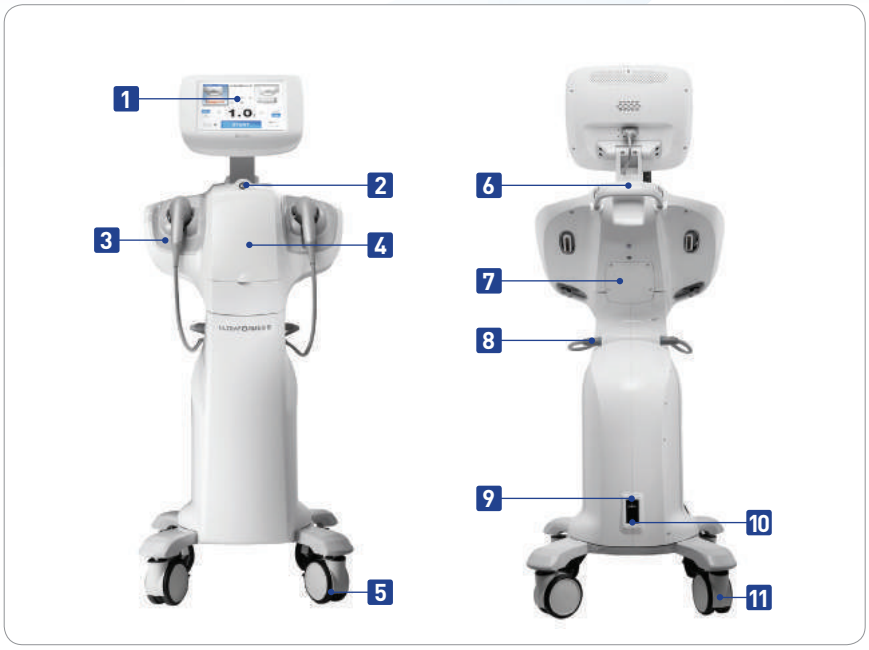


Figure 3.2 Main body front view (left) and rear view (right).

No.	Item	Description
1	10.4inch LCD Touch Screen	GUI
2	ON/OFF Key Switch	Turn ON/OFF Key Switch
3	Hand-piece Holder	Hand-piece holder
4	Cartridge storage	Cartridge storage
5	Locking Caster	Moving wheel (Locking)
6	Knob	Moving holder
7	Rear Cover	Cover of the connection area of screw
8	Hand-piece Connector Receptacle	Socket for plugging in Hand-piece cable
9	Main Power Switch	Supplies power to system. Leave ON (with Fuse(T10AL250V))
10	Power Cord Receptacle	Power Cable connection
11	Caster	Moving wheel

Table 3.1 Main body connector ports and controls (See Figure 3.2)

On the side of the main body is a Hand-piece connector receptacle that interfaces with the Hand-piece cable. Below the monitor, on the front panel is an ON/OFF Key switch.

"When not in use by trained personnel, the "ULTRAFORMER III" User Key of key switch should be removed from the system to help prevent unauthorized use. Keep the "ULTRAFORMER III" User Key of key switch in a designated place accessible only to authorized and trained personnel

The rear of the main body has an AC power receptacle and the main power switch. The main power switch should be up in the powered position. In such a configuration, the main body may be turned ON via the front panel ON/OFF key switch and can be turned OFF via either the front panel ON/OFF key switch.

3-2-2. Hand-piece

The Hand-piece is a handle with an integrated receptacle for insertion of a cartridge on one end and an electrical cable for attachment to the control system on the other end. The Hand-piece has button: deliver therapy (TREAT). Figure 3.3 provides two views of the Hand-piece, including one showing it connected to an Treat cartridge. Table 3.2 is a description of the various components and features illustrated in Figure 3.3.

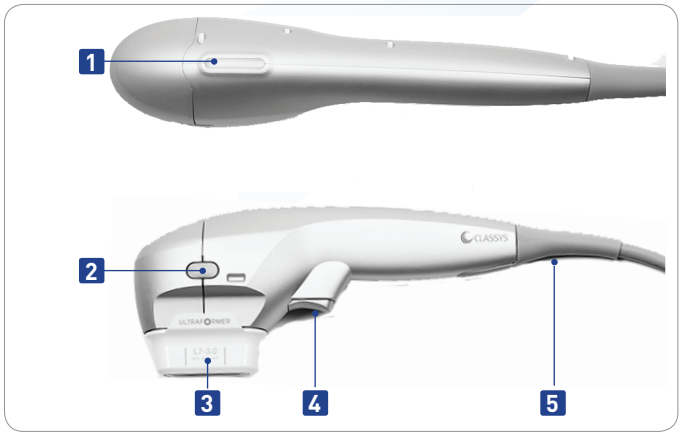


Figure 3.3 Hand-piece with cartridge inserted, top and side views.

No.	Item	Description
1	LED indicator	 Red: Ultrasound energy is launching Blue: Cartridge is connected Green: “START ” mode
2	Latch	Locks cartridge into Hand-piece
3	Cartridge	Treat cartridge (applied part)
4	TREAT Push button	Engages TREATING state
5	Strain Relief / Cable	Connects Hand-piece to Main body

Table 3.2 Hand-piece and Cartridge Description

3-2-3. Cartridge

Figure 3.4 is an illustration of a treat cartridge. The cartridge can treat a region of tissue up to 25mm long. Treatment occurs along a line less than or equal to the cartridge's active length, which is indicated by guides on the sides of the cartridge, as described in Table 3.3. An additional guide at the front tip of the cartridge represents the center of the treatment line. In therapy mode, bursts of sound energy create a linear sequence of individual, discrete, cartridge type, expiration date, and other information.

Figure 3.4 Treat Cartridge, separated from Hand-piece (see Table 3.3)

No.	Item	Description
1	Labeling	Other information
2	Treat guides	Markers denoting cartridge type and maximum treatment line length and center of treatment line (center of cartridge)

Table 3.3 Cartridge Description

The types of cartridges reflect variations in frequencies and treatment depths as shown in Table 3.4

Cartridge Type	Treat Frequency	Treat Depth	Power
L4-4.5	4MHz	4.5mm	0.1 – 1.5 J
L7-3.0	7MHz	3.0mm	0.1 – 1.5 J
L7-1.5	7MHz	1.5mm	0.1 – 0.5 J
MF6	2MHz	6.0mm	0.1 – 3.0 J
MF9	2MHz	9.0mm	0.1 – 3.0 J

Table 3.4 Cartridge Types

3-2-4. Essential Accessories

Ultrasound gel to facilitate transmission of the acoustic energy is also required but is not provided as part of the system.

Other essential components provided for operation of the “ULTRAFORMER III” are the power cord that connects the “ULTRAFORMER III” to an AC power outlet, and the Power Key of switch

Operator must use the Ultrasound transmission gel that is certified CE or any other biocompatibility that have been proved by International Standard.

4 System Safety

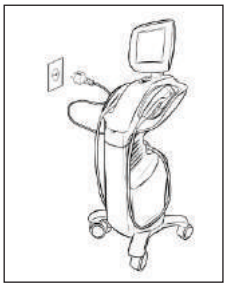
The following precaution and warnings must be reviewed and observed:

4-1. Electrical and Fire Safety

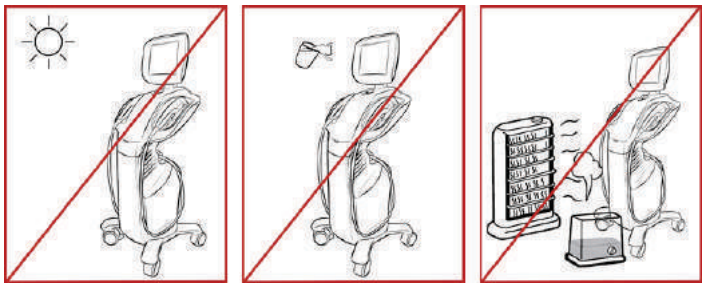
Warning

To avoid risk of electric shock, always inspect the cartridge, Hand-piece and cable before use. Do not use a damaged cable or a cartridge that has been damaged or is leaking fluid.

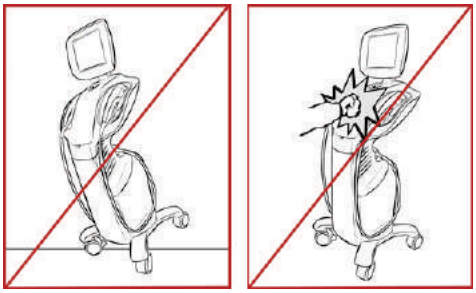
Power supply must be 100 – 240V~ to operate the system safely.



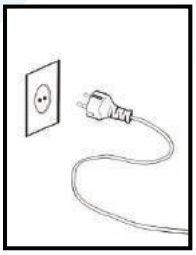
The “ULTRAFORMER III” is intended for indoor, dry location use. Avoid liquid spills and splashes. Do not place the system in the condition of direct sun light, high humidity and nearby heater.



Do not lean over the system obliquely. And do not give to external shocks to the system.



The “ULTRAFORMER III” comes with a three-conductor AC power cord and plug. Use a properly grounded outlet and always plug the “ULTRAFORMER III” directly into the outlet. Never remove the ground conductor or compromise the ground conductor via any AC adapter plugs or extension cords.

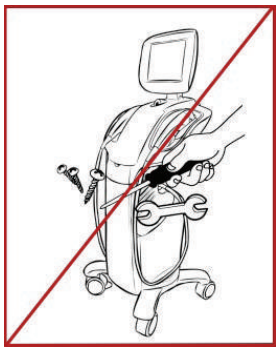


Disconnect the power cord from the outlet by pulling on the plug not the cord.

Do not touch the power cord with wet hand.

Turn off the AC power switch and disconnect the AC power supply before cleaning the main body.

Do not remove the covers on the main body or Hand-piece; the main body contains hazardous voltages. The “ULTRAFORMER III” contains no user-serviceable components. If the system requires service, contact Classys Inc..
No modification of this equipment is allowed.



The “ULTRAFORMER III” should not be used near flammable gases or anesthetics. Fire or explosion can result. The “ULTRAFORMER III” is not AP or APG rated.

Avoid restricting ventilation under and behind the main body. Maintain an open space of at least 20cm around the main body. If ventilation holes are obstructed, the system could overheat.

The Cartridge and 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.

To avoid a burn hazard, remove the cartridge from the patient before performing HF electrosurgical procedure.

Warning

Please follow the direction below if the system does not turn on.
- Ensure the main power switch and key switch is in the ON position.
- If the problem still occurred, unplug the power cord.
- Pull the fuse holder below the main power switch.
- Replace the fuse (T10AL250V).
- If the problem still occurred, please contact the Classys Inc. support.

Caution

Failure to observe these precautions may void the warranty.
The Hand-piece connectors must be kept clean and dry. Do not use the cartridge if the connectors have been immersed in liquid. See the instructions for cleaning the cartridge.

Every effort has been made to make the cartridges as rugged as possible; however, they may be permanently damaged if dropped onto a hard surface or if the membrane is punctured. Cartridges damaged in this manner are not covered by the warranty.

The “ULTRAFORMER III” has no user-serviceable components except the fuse. Do not attempt to open the main body enclosure or cartridges. Contact Classys Inc. if service is required.

When not in use by trained personnel, the “ULTRAFORMER III” User Key should be removed from the system to help prevent unauthorized use. Keep the “ULTRAFORMER III” User Key in a designated place accessible only to authorized and trained personnel.

4-3. Electromagnetic Compatibility and Immunity

The electromagnetic of “ULTRAFORMER III” emissions are very low and are not likely to cause interference in nearby electronic equipment.

The “ULTRAFORMER III” is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Mains (AC) power quality should be that of a typical commercial or hospital environments.

Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% to avoid excessive static electricity.

Warning

The “ULTRAFORMER III” should not be situated adjacent to, or stacked with, other electronic equipment. If the system must be in installed in close proximity to other equipment, both the “ULTRAFORMER III” and the nearby equipment should be observed to verify normal operation in that configuration.

Warning

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

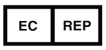
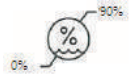
Caution

The “ULTRAFORMER III” has been designed to meet the standards of IEC60601-1-2 for electromagnetic compatibility; however some computer equipment unintentionally emits strong interfering RF signals. Portable RF communication devices may also affect “ULTRAFORMER III”.

4-4. Disposal

Depleted cartridges should be disposed of in accordance with federal, state, and local regulations. For expired cartridges (past expiration date), please contact your local Classys Inc. representative.

4-5. Safety Symbols

No.	Symbol	Meaning
1		CE marking indicating manufacturer’s declaration of compliance with appropriate EU product directives
2		Type B Applied Part
3		Alternate Current
4		Serial Number
5		Date of Manufacture
6		Manufacturer
7		Authorized Representative in The European Community
8		Storage Range
9		Relative Humidity
10		Atmospheric Pressure Limits
11		Caution
12		General warning, caution, risk of danger
13		Mind instruction for use

14		Pushing prohibited
15		Sitting prohibited
16		Stepping prohibited
17		Crossed out wheeled bin
18	STOP	Emergency Switch
19		Protective Earth
20		Dangerous Voltage

5 Setting Up for First-Time Use

5-1. Unpacking

The main body, Hand-piece and cartridges are shipped together in one container.

5-2. Physical Environment

5-2-1. System Base

The entire area for the device is shown in Figure 5.1. To maintain optional efficiency, space should be allocated in accordance with the indicated installation space as Figure 5.1. System weight and dimensions are listed in 9. Specifications.

Figure 5.1 The entire area for the "ULTRAFORMER III"

5-2-2. Electromagnetic Environment

The System is not likely to cause interference in nearby electronic equipment; however, other electronic equipment should not be stacked or placed immediately adjacent to the System.

Flooring should be wood, concrete or ceramic tile. If covered with synthetic material, the relative humidity should be at least 30%.

Warning

The “ULTRAFORMER III” should not be situated adjacent to, or stacked with, other electronic equipment. If the system must be installed in close proximity to other equipment, both the “ULTRAFORMER III” and the nearby equipment should be observed to verify normal operation in that configuration.

Caution

The “ULTRAFORMER III” has been designed to meet the standards of IEC60601-1-2 for electromagnetic compatibility; however, some computer equipment unintentionally emits strong interfering RF signals. Portable RF communication devices may also affect the “ULTRAFORMER III”.

5-3. Electrical Requirements

The “ULTRAFORMER III” has an international power supply and may be used with 100-240 V~, 50/60 Hz power systems. See Section 4-1. Electrical and Fire Safety for additional information.

5-4. Connecting Components

5-4-1. Connecting the Hand-piece

The Hand-piece connector receptacle is located on the left and right side of the main body as shown in Figure 5.2. To attach the Hand-piece connector, align it with the white line facing up and push it into the receptacle. It will latch when seated properly.

Figure 5.2 Hand-piece Connector Receptacle and Hand-piece

5-4-2. 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 indicated from its protective pouch. To connect the cartridge, slide the cartridge into the Hand-piece as shown in Figure 5.3. When the cartridge is fully seated you will hear a tone indicating that it has been correctly inserted.

Figure 5.3 Connecting a Cartridge

To disconnect the cartridge, press the latch at the both sides of the Hand-piece and slide the cartridge straight out of the Hand-piece.

Warning Check the water leaks from the cartridge, before cartridges installed in the Hand-piece.

Caution Do not apply force/displacement to latching cantilever without a cartridges installed in the Hand-piece.
Check the water leaks from the cartridge, before cartridges installed in the Hand-piece.

When the cartridge is inserted, the main body automatically detects it and updates the graphical user interface.

5-4-3. Connecting Accessories

The “ULTRAFORMER III” User Key should be inserted into the Key switch and turn the clock wise to “ON” otherwise the system cannot turn on.

6-1. Overview of System Functions

6-1-1. Operating Graphical User Interface (GUI)

The Settings function allows you to change general system settings and to recall parameters setting value of save existing.

An overview of this screen is seen in Figure 6.1.

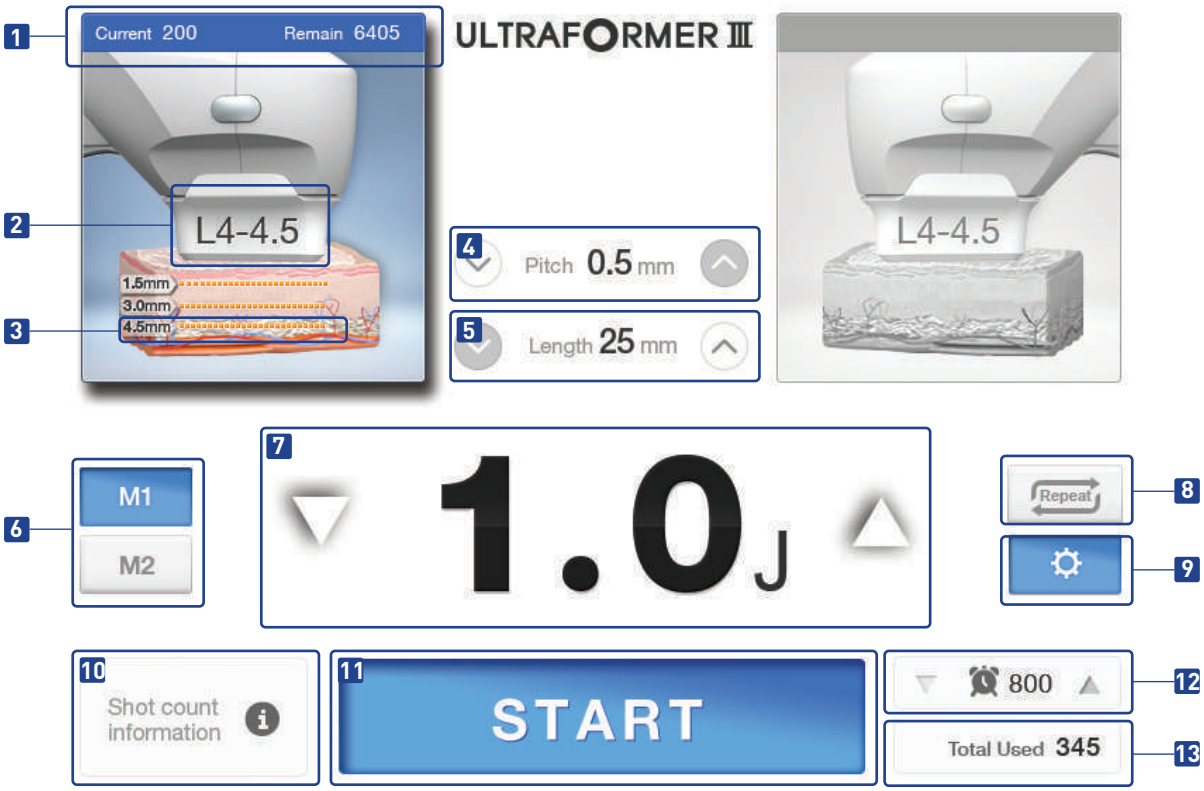
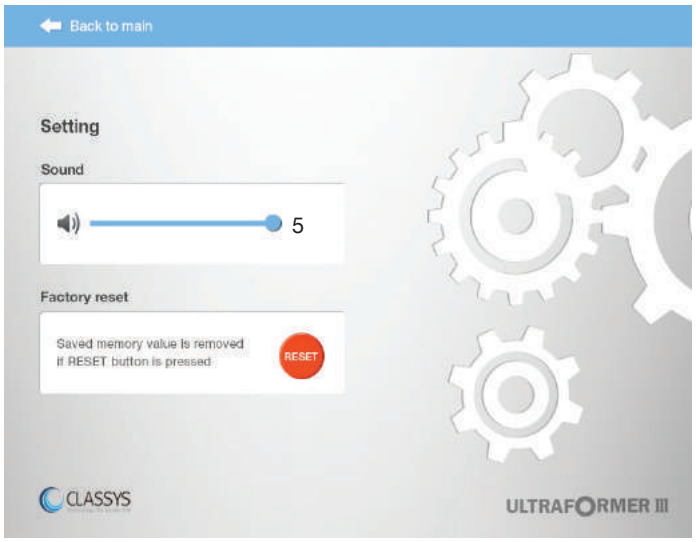
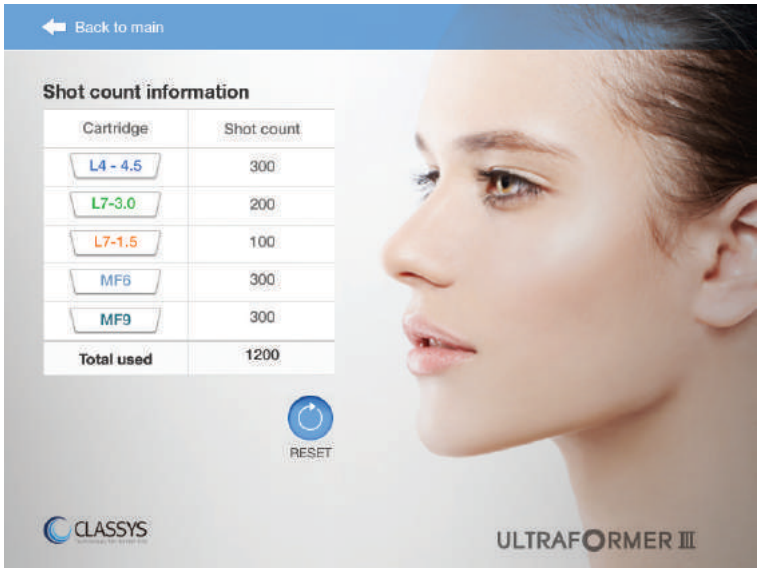


Figure 6.1 Screen in "START" state (See Table 6.1 for description)

No.	Sign	Description
1		Used & Remain shot of cartridge (Ex: 123 used shot, 9877 remain shot)
2		Displayed a installed cartridge information (Ex: 4MHz 4.5mm Cartridge)
3		Displayed Current setting(Depth, Pitch, Length) of each cartridge (Only display)
4		Sets the distance between thermal heat points (From 1.0 to 2.0mm, 0.1mm Step)
5		Sets the length of the treatment line (From 5 to 25mm, 5mm Step)
6		Bring the preset value “M1”, “M2” Save Parameter value(Press and hold for 3sec to save)
7		Sets acoustic energy level
8		One shot by one click of treat pushbutton Continuous shot during clicking a treat pushbutton
9		Configuration of volume control, factory default setting 

10		Shot count information 
11		System Status “STANDBY” or “START”
12		Setting the limitation shot (Beep sound occurs after over counter on it)
13		Total used shot (The same as Total shot of Shot count information)

6-2. Activating the Main Body

6-2-1. Ensure the power cord on the back of the system is plugged into wall socket. For the safety of patients, operators and electrical safety, you should connect the external ground terminal of the device to the separate ground terminal in the room.

6-2-2. Ensure the main power switch on the back of the main body is in the ON position.
This switch may be up side in the ON position even when the system is not in use.

Warning

While running, this switch should not be used to shut down the system.

6-2-3. Insert the “ULTRAFORMER III” User Key into the Key switch on the front of the main body.
The “ULTRAFORMER III” must be used only with the authorized “ULTRAFORMER III” User Key.

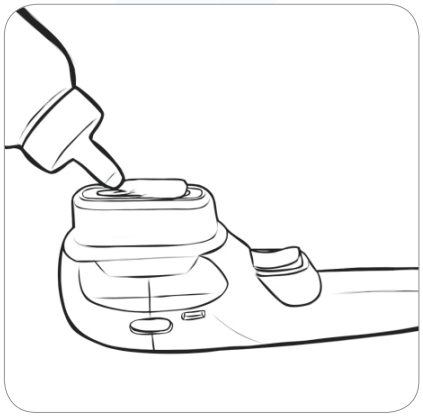
6-2-4. Turn the key switch clock wise.

6-3. Treatment Steps

6-3-1. Set the parameter while holding the Hand-piece.

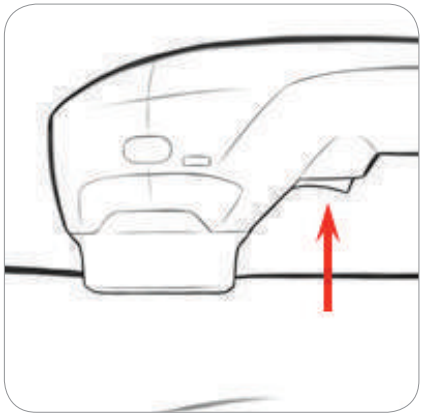
6-3-2. Ensure the face and neck have been cleansed thoroughly.

6-3-3. Carefully apply a thin layer of ultrasound transmission gel to the cartridge window. Too much or too little gel will result in poor skin contact. (Use aqueous ultrasound transmission gel only, as other lubricants or lotions can damage the cartridges and cables).



6-3-4. Press the “STANDBY” button.

6-3-5. Carefully apply a thin layer of ultrasound transmission gel to the patient’s skin. And place the cartridge treatment window flush with the patient’s skin and press the TREAT button.

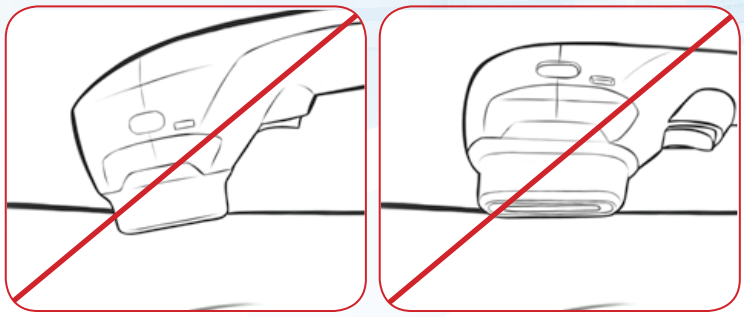


Caution

Do not in the air without applying ultrasound transmission gel on the cartridge (It may cause by a damage of the cartridge). And do not shot to skin without applying ultrasound transmission gel on the skin.

Before shot, check if the cartridge is attached on the skin properly.

Wrong position



Warning

If desired, therapy may be cancelled at any time by the cartridge can be simply lifted off the patient's skin quickly.

6-3-6. To deliver the next treatment line of energy within the same treatment region, advance the cartridge 2-3mm to adjacent tissue and press a TREAT button.

6-3-7. After 5 treatment lines are delivered do a visual check of the cartridge window to ascertain if gel needs to be reapplied such that a small bead of gel covers the window.

6-3-8. Continue in this fashion until the recommended number of treatment lines for the region has been delivered. When the correct number of treatment lines is delivered, beep sound occurs after over counter on it.

Warning

Stop the work for 5minutes if the operator use 1,000 shot of cartridge continuously.

6-3-9. When all targeted regions have been treated, press the "START" button.

6-3-10. Please the Hand-piece place on the Hand-piece holder as below picture.

6-3-11. If treatments are finished, turn off the key switch with anti-clock wise.

6-4. Shutting Down the System

6-4-1. Turn off the key switch with anti-clock wise and Remove the “ULTRAFORMER III” User Key to prevent unauthorized usage.

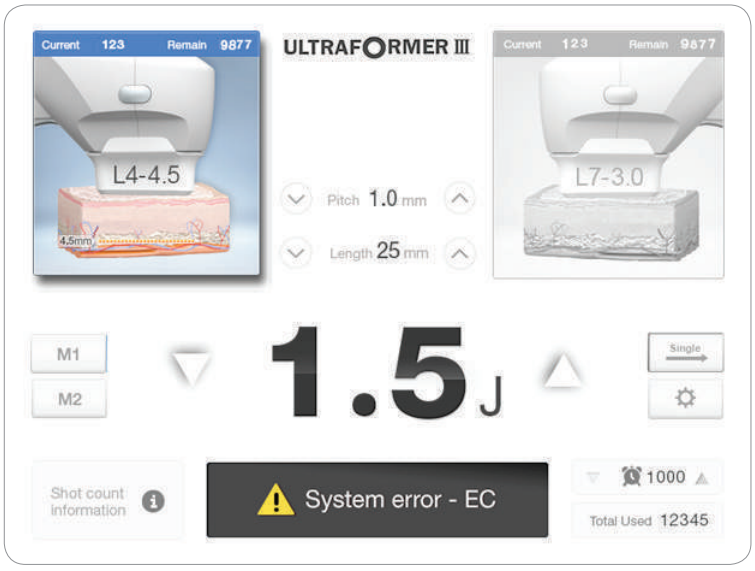
6-4-2. The main power switch on the rear of the main body should be down in the ON position; however, it may be switched OFF when moving the system between rooms or for storage or cleaning.

6-4-3. Follow cleaning and maintenance instructions in Section 8.

7 System Messages

The “ULTRAFORMER III” is designed with internal checks to ensure that all aspects of the device are functioning appropriately. Please follow the instructions refer to the information listed below.

Info Code	Message Displayed	Description
A	⚠ Check HP-ME ⚠ Check HP-CF	**Cartridge motions was occurred Malfunction.** 1. Ensure that the cartridge is properly mounted in the Hand-piece. 2. Remove and reinsert the cartridge. 3. If the problem persists please see the User’s Manual for further information or contact Classys Inc. Support.
B	⚠ Check HP-MS	**Motor of Hand-piece was occurred Malfunction.** 1. Inspect Hand-piece. 2. Ensure that the cartridge is properly mounted and latched in the Hand-piece. 3. If the problem persists please see the User’s Manual for further information or contact Classys Inc. Support.
C	⚠ System error - F1 ⚠ System error - F2	**Hardware (Cooling FAN) was halted due to an event detected in the Main body.** 1. System “OFF” and restart. 2. If the problem persists please contact Classys Inc. Support.
D	⚠ System error - EC	**Hardware (Power Driver) was halted due to an event detected in the Main body.** 1. System “OFF” and restart. 2. If the problem persists please contact Classys Inc. Support.



8-1. Cleaning the Cartridge and Hand-piece

Cartridges are packaged and shipped non-sterile and ready to use.
Because the cartridge will come in contact with the skin of a patient, the standard practice for cleaning and low level disinfection of cartridges between patients is to gently but thoroughly wipe the cartridge with a standard 90% isopropyl alcohol prep pad(See Figure 8.1). One may also use a standard 90% isopropyl alcohol prep pad to gently wipe the Hand-piece and cable. Neither the cartridges nor the Hand-piece should be submerged in liquid.

Figure 8.1 Cleaning of a cartridge

Place the cartridge back into its original packaging or cartridge storage of main body between uses. (See Figure 8.2)

Figure 8.2 Cartridges Storage

Warning

Use only this procedure for cleaning. Do not use acetone or other solvents as this can damage the cartridge.

8-2. General Care of the System

To get the best possible performance, treat the equipment carefully by adhering to the following guidelines:

1. Inspect the Hand-piece and connectors regularly for any problems.

2. Turn off before changing cartridges to ensure proper identification of cartridges and to prolong the life of the system.

3. Do not drop the Hand-piece or cartridges on the floor or other hard surfaces. This can cause permanent damage.

4. Do not twist or pull the Hand-piece cables. This could cause damage to internal wires and connections.

5. Use aqueous ultrasound transmission gel only. Other lubricants or lotions, particularly mineral oil, could eventually damage cartridges or Hand-piece.
Do not use acoustic standoff pads or any objects between the cartridge and patient.

7. Apply ultrasound transmission gel only to the window of the cartridge and wipe it from the cartridge after completing a treatment. Avoid getting the gel on the Hand-piece or main body.

8. Cartridges should be cleaned between procedures. See cleaning procedure information immediately preceding this subsection.

Check the water leaks from the cartridge, before cartridges installed in the Hand-piece.

Specifications

No.	Performance	Specification
1	Item	Focused Ultrasound Therapeutic System
2	Classification	Class IIa
3	Model Name	UF3-M300
4	Intended Use	This device is non-invasive dermatological therapeutic device for patients who have ptosis, psoriasis or usual cutaneous diseases using the principle of micro coagulation and necrosis and wound healing effect in the hyperthermia layer of body.
5	Output power	0.1 ~ 3.0 J
6	Pitch	1 ~ 2mm
7	Length	5 ~ 25mm
8	GUI	10.4 Inch LCD touch screen
9	Input power, Frequency	100-240V~, 50/60Hz
10	Power consumption	500VA
11	Protection by electric shock	Class 1, Type B Applied part
12	Dimension	500(D) X 515(W) X 1310(H) mm
13	Weight	35kg
14	Cartridge	L4-4.5 : Frequency:4MHz, Depth:4.5mm, Max Power: 1.5J L7-3.0 : Frequency:7MHz, Depth:3.0mm, Max Power: 1.5J L7-1.5 : Frequency:7MHz, Depth:1.5mm, Max Power: 0.5J MF6 : Frequency:2MHz, Depth:6.0mm, Max Power: 3.0J MF9 : Frequency:2MHz, Depth:9.0mm, Max Power: 3.0J
15	Environmental	Operating Environment - Temperature: 10°C ~ 35°C - Relative Humidity: 0% ~ 90% - Air Pressure: 500hPa ~ 1060hPa Shipping and Storage, System without Cartridge - Temperature: 5°C ~ 60°C - Relative Humidity: 0% ~ 90% - Air Pressure: 500hPa ~ 1060hPa Shipping and Storage, Cartridges - Temperature: 15°C ~ 30°C - Relative Humidity: 0% ~ 90% - Air Pressure: 500hPa ~ 1060hPa

Electromagnetic Emissions and Immunity
Manufacturer's declaration - electromagnetic emission

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

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The "ULTRAFORMER III" 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 III" 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 III" is intended for use in the electromagnetic environment specified below.
The customer or the user of the "ULTRAFORMER III" 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	6 kV Contact 8 kV Air	6 kV Contact 8 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	3.0 A/m	3.0 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	<5% Uт (>95% dip in Uт) for 0.5cycle 40% Uт (60% dip in Uт) for 5 cycle 70% Uт (30% dip in Uт) for 25 cycle <5% Uт (<95% dip in Uт) for 5 s	<5% Uт (>95% dip in Uт) for 0.5cycle 40% Uт (60% dip in Uт) for 5 cycle 70% Uт (30% dip in Uт) for 25 cycle <5% Uт (<95% dip in Uт) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the “ULTRAFORMER III” requires continued operation during power mains interruptions, it is recommended that the “ULTRAFORMER III” be powered from an uninterruptible power supply or a battery
Note: Uт is the a.c. mains voltage prior to application of the test level.			

The “ULTRAFORMER III” is intended for use in the electromagnetic environment specified below. The customer or the user of the “ULTRAFORMER III” should assure that it is used in such an environment

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the ULTRAFORMER III, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$

Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5 GHz	3 V/m 80.0 MHz to 2.5 GHz	Recommended separation distance $d = [\frac{3,5}{E1}]\sqrt{P}$ 80 MHz to 800 MH $d = [\frac{7}{E1}]\sqrt{P}$ 800 MHz to 2,5 GH Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey, (a) Should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1) Uт is the A.C. mains voltage prior to application of the test level.

Note 2) At 80 MHz and 800 MHz, the higher frequency range applies.

Note 3) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a - 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.

b - Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V / m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the "ULTRAFORMER III".

The "ULTRAFORMER III" is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the ULTRAFORMER III can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the "ULTRAFORMER III" as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power (W) of transmitter	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Immunity and Compliance Level

Immunity test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms, 150 kHz to 80 MHz	3 Vrms, 150 kHz to 80 MHz	3 Vrms, 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m, 80 MHz to 2.5 GHz	3 V/m, 80 MHz to 2.5 GHz	3 V/m, 80 MHz to 2.5 GHz

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80 MHz	"ULTRAFORMER III" must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5 GHz	3 V/m 80.0 MHz to 2.5 GHz	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m.a Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a- 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 outside the shielded location in which the EUT is used exceeds 3V/m, the EUT should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as relocating the EUT or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

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ULTRAFORMER® III

CE 1984

OPERATION MANUAL

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