Legend Pro

Dare to imagine

Legend Pro™
USER MANUAL

Pollogen a company of Lumenis
Proprietary Information
Version 7 September 2019

Part Number 11600510U ver.7

Pollogen a company of Lumenis reserves the right to make changes without notice to its products or specifications to improve performance, reliability, or manufacturability.

All information supplied by Lumenis Ltd. is believed to be accurate and reliable. However, Lumenis Ltd. assumes no responsibility for its use. No license is hereby granted by its implication or otherwise under any patent or patent rights of Lumenis Ltd.

This document, in part or entirety, is not to be produced, reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of Lumenis Ltd.

Lumenis Ltd. has patents and pending patent applications, trademarks, copyrights, and/or other intellectual property rights covering the subject matter in this document.
Providing of this document does not give any license to these patents, trademarks, copyrights, and/or other intellectual property rights unless otherwise expressly provided in any written agreement from Lumenis Ltd.

All data is subject to change without prior notification.

Pollogen Ltd., 6 Kaufman St., PO Box 50320, Tel Aviv 6801298 Israel

Obelis S.A, Boulevard Général Wahis 53 1030 Brussels, BELGIUM
Tel: 32 (0) 2 732 5954, Fax: 32 (0) 2 732 6003, GSM 32 47545 4660,
e-mail: mail@obelis.net

Contact Information

Customer satisfaction is a Pollogen priority. To help us in providing you with the best possible product and support, please send us your comments and suggestions. Contact us at the details below:

Pollogen Ltd.
6 Kaufman St., Gibor House
PO Box 50320
Tel Aviv, Israel 6801298

Telephone: **+972 3 510 4110**
Facsimile: **+972 3 510 4112**
Web Site: **www.pollogen.com**

Email: **info@pollogen.com**

Contents

Figures:

Tables:

1. INTRODUCTION TO THE SYSTEM

The Legend Pro™ system intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm ™ Energy (Applicator VO). It is also intended for use in dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides when using TriPollar® RF Energy (Applicators 1-3)
Intended settings for the device: Clinics & Hospitals.
Intended users: Healthcare professionals (Doctors or Nurses)

Legend Pro™ consists of seven main parts: Main Unit, Applicator VO for VoluDerm™ and TriFractional™ treatments, Applicators 1-3 for TriPollar® treatments, Foot Switch and Patient-Controlled Manual Switch. The operator can adjust all system parameters from the user interface on the Main Unit.

2. SAFETY INSTRUCTIONS

2.1 Precautionary definitions

The precautionary instructions found in this section and throughout this manual indicated by specific symbols. Understand these symbols and their definitions before operating this equipment.

The definitions of these symbols are as follows:

	(Warning)	with a "**WARNING**" indicator explains possible safety infractions that may cause serious injury and equipment damage.
	(Caution)	with a **"CAUTION"** indicator explains possible safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.

Table 1: Precautionary Symbols and Definitions

The System is designed for safe and reliable treatment when used in accordance with proper operation and maintenance procedures. The operator and all other personnel operating or maintaining the System should be familiar with the safety information provided in this chapter.

2.2 Cautions 

- Read this chapter to become familiar with all the safety requirements and operating procedures prior to System operation.
- In order to protect the Legend Pro™ System from use by unqualified personnel, turn the system off while the system is not in use and lock it in a secure room.
- Do not disconnect any of the system components or accessories while the system is switched on.
- Keep the Applicators clean. See cleaning instructions in section 13 of this user manual.
- Do not allow the Applicator to come in contact with hard objects that can damage it.
- Always keep the System's wheel breaks locked to avoid uncontrolled movement. When movement is necessary, unlock the breaks before doing so. Always move the System slowly and carefully. The System may cause injury if proper care is not taken when moving it.

- Only move the system by using its handle. Pushing or pulling the system without using its handle can turn the system over and may result in damage to the system.
- Switch off the system when moving the unit.
- Before connecting the power supply cord, make sure that the ON/OFF switch is in the OFF position (“0”).
- Check all connections before plugging in the System’s power supply cord.
- Pay attention to the screen quality, to ensure that it is acceptable during the first few seconds of the system check (touch screen becomes active). At this time, the Applicator's LED flashes (first green then orange) as part of the System’s self-check. In case of display failure, stop system operation.
- In case of uncertainty regarding potential side effects, have the patients consult their physician and bring consent for treatment.
- Restart the system in the event that a wrong or incomplete program upload occurred while uploading the program version using the USB memory stick.
- Make sure that the counter on the display is stopped when the foot switch is released.
- Patients should remove all jewelry prior to treatment.
- Do not use Legend Pro™ System in close proximity to a short-wave or microwave therapy equipment.
- Before every treatment, verify that the applicator is intact.
- Make sure to replace the applicator if it falls before, during or after a treatment.
- Always use tips which were approved and supplied by Lumenis or its legal representatives.
- When treating with TriPollar® programs, patients should remove all jewelry prior to treatment

2.3 Warnings

- Before attempting to operate the Legend Pro™ System, be sure to read this manual to become familiar with all safety requirements and operating procedures.
- No modification of this equipment is allowed!
- When treating facial area, never treat the area below the eyebrow & never treat over the eye lids & eyes themselves. Never treat over the lips. Do not treat genitals, the chest, breasts or underarms.
- Do not connect a patient to High Frequency surgical equipment during treatment.
- Treatment should not be applied over swollen, infected, inflamed areas or skin eruptions.
- Verify that fan is functioning when operating the System. In case of fan failure do not operate the device, call your Lumenis representative for service.
- Do not operate the unit in the presence of electromagnetic interference. Electromagnetic interference may be caused by electro surgery, diathermy, magnetic resonance imaging or other type of equipment.
- Portable and mobile are RF communication equipment & may affect the operation of this device.
- Using power that is higher than needed can cause over-treatment of the skin.
- When treating with TriPollar® programs, do not treat using mineral oils.
- When treating with TriPollar® programs, do not heat the skin over 43°C (109.4°F).
- Treatment should not be applied over, or in proximity to, cancerous lesions.
- When treating with TriPollar® programs, to avoid the risk of potential burns, applicator must always be in constant movement while in contact with the skin. Never stop applicator movement while in contact with the patient.
- There may be risks associated with bipolar RF energy delivery to the skin that are yet unknown. Any procedure perforating the skin can cause discomfort, pain, bleeding, infection, swelling, edema, scar formation, permanent marking, and pigment alteration. Therefore, potential risks which could result from RF and electrode insertion include discomfort during and after the procedure, pain, infection, scarring, swelling or edema, and permanent discoloration.
- Do not allow patients to contact metal surfaces.
- The Applicator should be used at least 1 cm away from a cochlear implant.
- Check device for any damage prior to use.
- Do not activate the applicator when it is not in contact with the patient’s skin.
- Discontinue use immediately in case of excessive heat or burning sensation.

- Do not treat the area near the thorax which may increase the risk of cardiac fibrillation.
- Never treat over the eye socket, the chest, breasts or underarms.
- Never treat over the thyroid area.
- Patient should not come into contact with earthed metal parts or parts with appreciable capacitance to earth.
- Regularly inspect the accessories for possible damage; in particular, electrode cables and HF energized devices.

2.4 VO and disposable related warnings:

- Never direct the Applicator's tip at anything other than the treatment site.
- Reuse of single-use disposable tips creates a potential risk of self or cross-contamination and infection which may each lead to significant medical complications. Do not treat another patient with the same tip.
- Do not allow the Applicator to come in contact with hard materials that could damage the tip.
- Place the tip perpendicular to the skin with full contact, applying slight pressure.
- Ensure that the Applicator's tip is free of debris and thoroughly dry.
- No lotion, gel, oil or glycerin is used when treating with the VO Applicator. Verify clean & dry skin.
- Always discard the tip at the end of patient's treatment as biological hazardous waste.
- Do not use a tip if its expiry date is overdue.
- Do not use a tip if its package is compromised. Verify package integrity before use.
- Always check the integrity of the tip. Verify that all the electrodes are present. If any pins are missing, do not use the tip.
- Ensure that the tip is clean during treatment. Accumulated debris or non-dry skin may cause pain and skin damage.
- During treatment inspect the tip's integrity and cleanliness once every 10 to 15 pulses. This is especially important when using high parameters, which may cause increased buildup of debris. If the tip is not clean it must be replaced.
- After VO treatment, no other treatment should be performed until the treated area has completely healed.
- To protect from unwanted contact of the electrode pins, make sure to secure the tip using its protective cover when not in use.

2.5 Electrical and Mechanical Safety warnings:

- High voltage is present inside the Legend Pro™ System. Always take proper precautions as described in this manual, while making sure to constantly be aware of the possible dangers.
- Only qualified personnel that have been trained by Lumenis® are allowed to supply service to this equipment.
- Do not touch the inner parts of the system; service is supplied only by company's authorized personnel.
- To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth and must be used with the cable supplied. (cable10A, 250V, 1.8m length). The system is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.
- Keep all covers and panels of the System securely closed at all times when in use. Removal of the covers or panels can create a safety hazard.
- Perform maintenance procedures when the System is shut down and disconnected from power outlets.
- Always keep the System's wheel breaks locked to avoid uncontrolled movement. When movement is necessary, unlock the breaks before doing so. Always move the System slowly and carefully. The System may cause injury if proper care is not taken when moving it.

- ⚠ The System is grounded through the grounding conductor inside the power cable. This protective grounding is essential for safe operation.
- ⚠ Verify fan operation when operating the device and stop device operation when fan is not operating.
- ⚠ Verify that once the Foot Switch is released, the treatment will stop and the counter on touch screen will stop as well

2.6 Fire Hazards 

- ⚠ Do not use the System in the presence of explosive or highly flammable materials like alcohol, methanol, acetone, etc. (The suggested use of the Glycerin for TriPollar® treatments is in no way an explosive or highly flammable material and is approved for usage).
- ⚠ Do not have flammable substances in the treatment room when preparing the skin for treatment.
- ⚠ If alcohol is used for cleaning, it must be allowed to dry thoroughly before the System is used. The container of alcohol must be moved away from the System.

3. Safety Features:

The System is designed for safe and reliable treatment when used in accordance with proper operation and maintenance procedures. The operator and all other personnel operating or maintaining the System should be familiar with the safety information provided in this chapter.

- All Applicators must be connected to the system and locked prior to activation.
- To start the treatment, the Foot Switch must be pressed down by the operator. Output is emitted only after pressing the Foot Switch.
- No RF signal is delivered to the VO Applicator unless a treatment Tip is connected to the Applicator.
- The VO Tip electrode matrix in contact with tissue is pre-sterilized and designed for single use to avoid cross contamination.
- Patient-Controlled Manual Switch of sensation automatically terminates application of RF energy when pressed.
- The system automatically identifies the type of tip connected.
- An independent electronic circuit stops the operation of the system in case of a software error.
- After each press and release of the Foot Switch, the LED indicator guide ring turns Green. LED Indicator guide ring will turn Orange when the Foot Switch is pressed and treatment pulse power is transmitted to the electrodes. After treatment termination, the LED indicator guide ring will turn green and ONLY then, the operator can release the foot switch.

4. INDICATIONS

The Legend Pro™ system is intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm ™ (Applicator VO).
It is also indicated for the non-invasive treatment of mild to moderate facial wrinkles and rhytides when using TriPollar® RF energy (Applicators 1-3).

5. CONTRAINDICATIONS

Patients having the following conditions should not be treated:

- Pacemaker, defibrillator, or any implanted electronic device
- Metal implants in the treatment area
- Pregnancy or nursing
- Severe concurrent illness or condition such as cancer, lupus, uncontrolled diabetes, uncontrolled seizure disorders
- Concurrent or chronic skin disorders or lesions in the treatment area
- Severe bleeding or vascular disorders
- Under 18 years of age
- Patients who cannot feel heat to give proper treatment feedback (nerve damage, etc.)
- Those who form keloids or heal poorly
- Do not treat over tattoos or permanent make-up
- Those who have been on Accutane (Isotretinion) within the last six months

Relative contraindications (treatable at the physician's discretion)

- History of Herpes or similar conditions that can be triggered by heat should be treated prophylactically with the appropriate medication
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g. ibuprofen containing agents). Best practice would allow one week before and after treatment without use
- Excessively tanned skin from sun, tanning beds, or spray tans etc.
- Be sure that any other procedures such as surgery, laser treatments, chemical peels, injections, implants etc., are completely healed before treatment. Botox should be allowed to calm down at least 2-3 weeks before treatment, fillers 6 weeks plus, and more invasive procedures longer

5.1 PRECAUTIONS

Special caution should be taken in the following cases:

- Patients taking medications, herbal preparations, food supplements or vitamins that might cause fragile skin or impaired skin healing such as prolonged steroid regime, tetracyclines, or St. John's Wort
- Patient having any medical condition that might impair skin healing
- Patients having predisposition to allergic reactions

The following precautions are relevant only when using VO applicator:

- Treatment of male patients in hair bearing areas may affect hair follicles and result in some loss of hair. Avoid the beard or other hairy areas if the patient does not wish to potentially experience hair growth reduction
- The electrodes have sharp tips and can cause injury. Do not exceed the recommended number of insertions to prevent electrode tip damage. The recommended maximum number of insertions is 800 per tip. The RF energy can cause damage or burn the epidermis if the electrodes are inserted incorrectly and/or the device is not positioned correctly against the skin. After each deployment, ensure that the electrodes are fully inserted into the skin before initiating the treatment

6. POSSIBLE SIDE EFFECTS

Improper use of the System could result in possible side effects. Although these effects are rare and expected to be temporary, any adverse reaction should be reported to your physician immediately. Side effects may appear either at the time of treatment or shortly after.
Side effects may include any of the conditions listed below:

- Prolonged or significant pain
- Damage to natural skin texture (blister, burn)
- Excessive skin redness (erythema)
- Excessive swelling (edema)
- Fragile skin
- Bruising
- Excessive itching
- Change of pigmentation (hyper-pigmentation or hypo-pigmentation)
- Scarring
- Transient skin break-out such as acne and pimples

Caution: Relevant for treatment with VO Applicator, when treating skin types IV - VI or Asian skin, a bleaching regimen may be considered (pre or post treatment, according to physician discretion) to avoid any potential changes of pigmentation.

7. SYSTEM DESCRIPTION

This chapter provides a detailed description of the Legend Pro™ system, including its main components, controls, and technical specifications. Please review this chapter carefully to familiarize yourself with the controls, ports and connectors used during treatment.

7.1 System Components and Controls

The Legend Pro™ system consists of the following main components:

- Main Unit (System Console)
- Applicator VO intended for VoluDerm ™ and TriFractional treatments
- Applicator No.1 intended for TriPollar® treatment of large facial areas equipped with LED screen (see Applicator 1 and 2 indicator LED screen)
- Applicator No.2 intended for TriPollar® treatment medium size facial areas and face equipped with LED screen (see Applicator 1 and 2 indicator LED screen)
- Applicator No.3 intended for TriPollar® treatment of very small facial areas
- Foot Switch

- Patient-Controlled Manual Switch
- Non-Contact Infrared Thermometer

7.1.1 Main Unit (System Console)

The Main Unit controls the operation of the entire system (Figure 1). It contains the following parts:

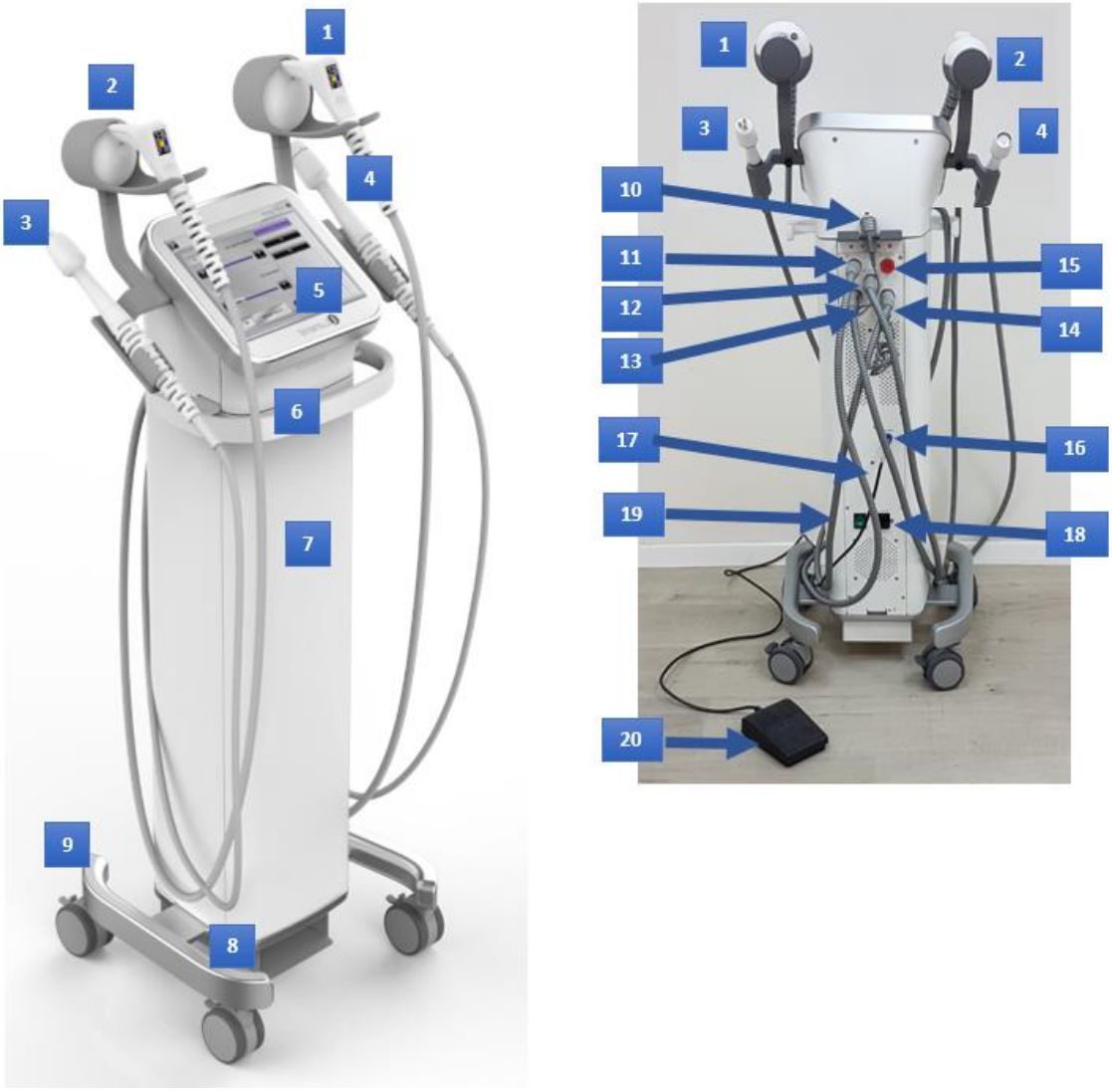


Figure 1: Legend Pro™ Main System Components (Left – front view, Right – back view)

Index:

1	Applicator 1	6	Device Handle	11	Applicator VO connector	16	Foot Switch connector
2	Applicator 2	7	Device Console	12	Applicator 3 connector	17	Device Nameplate label
3	Applicator 3	8	Device Base	13	Applicator 1 connector	18	Power Inlet
4	Applicator VO	9	Wheel with Brake	14	Applicator 2 connector	19	ON/OFF Switch
5	User Interface	10	Patient-Controlled Manual Switch	15	Applicator AFO connector	20	Foot Switch

Connector AFO is a connector for future operation and is not currently used.

7.1.2 Control Panel:

The Control Panel serves as the user interface and is located on the top of the Main Unit.
The Control Panel is a touch screen.

Figure 2: User Interface – Control panel

Function Keys

Select applicator:

				
VoluDerm ™ Technology Applicator VO	TriPollar® Technology	TriPollar® Applicator 1	TriPollar® Applicator 2	TriPollar® Applicator 3

Once selected, key will be color highlighted. Dim key cannot be selected

					
Increase	Decrease	Selected Decrease	Dim Decrease (Cannot be selected)	Exit	Press Foot Switch
					
Return	Setting Screen	Selected Help	Home screen	TriPollar® Applicator 1 selected	Applicator VO selected

User Interface Options

The MENU enables the following operations:

- **Select Treatment Technology** – VoluDerm ™ (VO) or TriPollar®.
- **Select the Treatment Applicator** – VoluDerm ™ (VO) applicator is selected once the technology is selected. TriPollar® - Applicator No. 1, 2 or 3.
- **Select treatment program** –
    - VoluDerm ™ treatment programs: Low, Medium, and High.
    - TriPollar® Energy treatment programs: Course App1-A & App1-B (For applicator 1), Course App2-A & App2-B (For applicator 2) & Course App3-A & App3-B (For applicator 3).
- **Select Treatment Parameters** –
    - VoluDerm ™: exposure and power setting
    - TriFractional: pulse width
    - TriPollar® Energy: time (0-40 minutes) and power setting (power levels range from 5 to 95 (5% to 95% of the maximum output power of Applicators 1&2 and 5% to 30% of applicator 3

7.1.3 Back Panel

The Back Panel includes the ON/OFF switch,
Controlled Manual Switch connector
Applicator VO connector,
Applicator 1 connector,
Applicator 2 connector,
Applicator 3 connector,
AFO connector,
device S/N label,
Foot Switch connector,
Memory stick inlet and power inlet with fuses.

Figure 3:Back Panel

7.1.4 Applicator VO - intended for the VoluDerm ™ and TriFractional™ treatments

The VO applicator is connected to the main unit using a cable comprised of electrical wires and a connector. It also consists of a plastic body with a disposable tip.
When not in use, the applicator should be stored in its cradle.

Figure 4: VO applicator

Applicator VO single use disposable tips

a) Single use gen36 – an array of 6x6 ultra-thin electrodes, 0.6mm long.

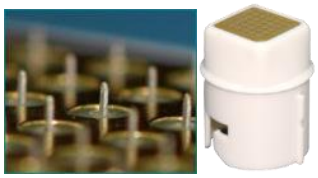


Figure 5:gen36 tip

b) Single use gen12 – an array of 6x2 ultra-thin electrodes, 0.6mm long.

Figure 6:gen12 tip

c) Single use gen36L – an array of 6x6 ultra-thin electrodes, 1mm long.

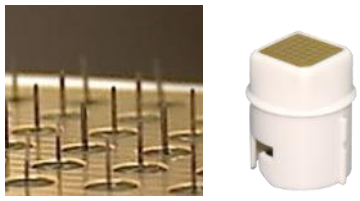


Figure 7: gen36L tip

d) Single use gen100 – an array of 10x10 ultra-thin electrodes, 0.6 mm long.

Figure 8: gen100 tip

e) Single use H 7X7 – an array of 7X7 micro pins, 0.2 mm long.

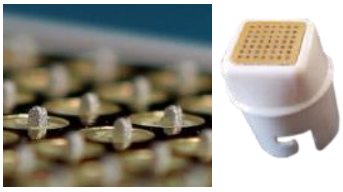


Figure 9: H7X7 tip

The Tips are supplied in packages of 5 units. The packaging of each Tip stamped with its lot number and expiration date.

7.1.5 Applicator No. 1:

Applicator No. 1(Figure 10: Applicator No.1) is connected to the main unit by a cable containing electrical wiring and a connector, also consisting of a plastic body with an integrated electronic system, 6 electrodes, IR sensor temperature, LCD screen and indication light guide ring. When not in use, the applicator should be stored in its holder.

Figure 10: Applicator No.1

7.1.6 Applicator No. 2:

Applicator No.2Figure 11: Applicator No.28) is connected to the main unit by a cable containing electrical wiring and a connector, also consisting of a plastic body with integrated electronic system, 3 electrodes IR sensor temperature, LCD screen and indication light guide ring. When not in use, the applicator should be stored in its holder.

Figure 11: Applicator No.2

7.1.7 Applicator 1 and 2 indicator LED screen

Applicators no.1 and 2 are equipped with IR sensors measuring the skin temperature. During treatment mode when the foot switch is pressed the measured temperature is indicated both on the LED screen located on the applicator and in the GUI. The temperature will display from 36° C. A visual bar indicating temperature level from low to high is visible within user interface together with numerical indication.
The built-in IR temperature sensor is being used only to verify that the recommended temperature (endpoint) of the treated area is being achieved and maintained.
The integrated IR temperature sensor should be used as an indicator only and cannot replace an external thermometer. The external Thermometer should be used during the entire procedure.

7.1.8 Applicator No. 3:

Applicator no.3 is connected to the main unit by a cable containing electrical wiring and a connector, also consisting of a plastic body with integrated electronic system, 3 electrodes and

Figure 12: Applicator No. 3

indication light guide ring. When not in use, the applicator should be stored in its holder. Applicator no.3 is not equipped with IR temperature sensors; therefore, during treatment the operator should use the supplied external Thermometer during the entire procedure.

The integrated IR temperature sensor should be used as an indicator only and **cannot replace an external thermometer**.
External Thermometer should be used during the entire procedure
The built-in IR temperature sensor is being used only to verify that the recommended temperature (endpoint) of the treated area is being achieved and maintained

On each TriPollar® applicator, after press and release of the Foot Switch, the "Ready" indicator light turns on when the system and selected applicator are ready for operation. The indicator light guide ring turns Green when the chosen Applicator is "Ready" for use and the indicator light guide ring will turn Orange when the Foot Switch is pressed and RF power is transmitted to the electrodes.

7.1.9 Foot Switch

Figure 13: Foot Switch

The Foot Switch is used for system activation upon press. The Foot Switch is supplied with cable and connector.

7.1.10 Patient controlled manual switch:

Figure 14 : Patient controlled manual switch

The Patient-Controlled Manual Switch is used as a patient control in case of discomfort. It consists of a plastic body with button, Velcro strip and cable with connector.

7.1.11 Non-Contact Infrared Thermometer:

Figure 15: Non-Contact Infrared Thermometer

The Infrared thermometer (Figure 15: Non-Contact Infrared Thermometer), measures the surface temperature of the skin. An optical component of the unit collects energy and focuses it onto a detector. Then an electronic component translates the information into a temperature reading which is displayed on the thermometer.

The laser is used for aiming purpose only.

Please note that calibration is required yearly and is within your responsibilities.

Lumenis does not calibrate or follow up thermometer calibration.

8. Technical Specifications

Parameter	Value/Data
Input voltage	100-240 Volt, 50-60Hz, max 2.2A
Mode of operation	VoluDerm™, TriFractional™, TriPollar™
Maximum output power RF	50 Watts @ 200 Ohm
Maximum output voltage	100±10 Vrms
Output frequency RF	1MHz
Output power control RF	Pulse width modulation (PWM)
Weight	~66 Kgs
Dimensions	L1.5 xW1.5 x H3.6 Inch
Environmental Conditions for Operation	
Temperature	15°C to +30°C (59°F to 86°F)
Relative humidity	Up to 80%; non-condensing
Atmospheric pressure	70-106 kPa
Maximum Altitude	2000 meters
Environmental Conditions for Transportation & Storage	
Temperature	-20°C to +55°C (-4°F to 131°F)
Relative humidity	80%; non-condensing
Atmospheric pressure	50-106 kPa
Maximum Altitude	2000 meters

Table 2: Technical Specifications

IEC 60601-1 Classification – Class I

9. Symbols & Labels

This section describes the symbols used throughout this user manual (Table 1: Precautionary Symbols and Definitions) and the labels affixed to the Legend Pro™ System. It is recommended that users review the meaning of these labels for everyday usage, and in case, any details are needed for service purpose.
The table below briefly reviews a number of internationally recognized symbols that found on the Legend Pro™ main unit.

9.1 Symbols Used in this User Manual:

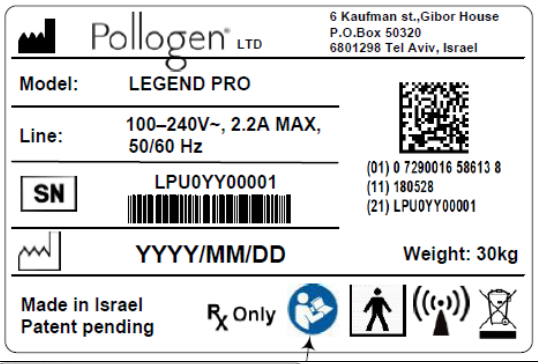
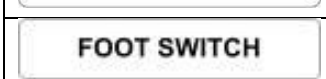
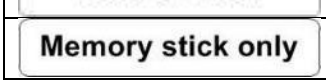
No.	Symbol	Description
1		CAUTION – READ THE INSTRUCTIONS BEFORE OPERATING THE SYSTEM
2		PROTECTIVE EARTH (GROUND)
3		TYPE BF APPLIED PART (Degree and type of protection against electric shock)
4		ATTENTION, CONSULT ACCOMPANYING DOCUMENTS
5		SERIAL NUMBER
6	**Model**	SYSTEM MODEL
7		DISCARD PRODUCT AFTER ESPIRATION DATE
8		PRODUCT WAS STERILIZED BY ETHYLENE OXIDE PROCESS
9		WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE) COMPLIANCE SYMBOL
10		SINGLE USE ONLY

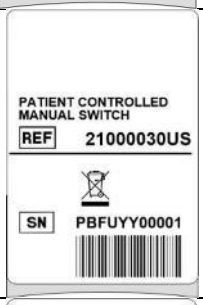
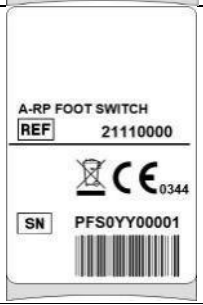
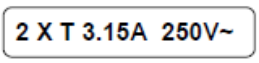
11		MANUFACTURER
12		DATE OF MANUFACTURING
13		PRESCRIPTION USE STATEMENT: CAUTION: FEDERAL LAW (US) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
14		NON-IONIZING ELECTROMAGNETIC RADIATION

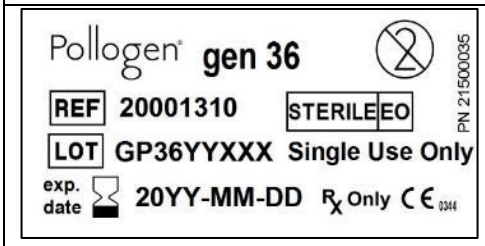
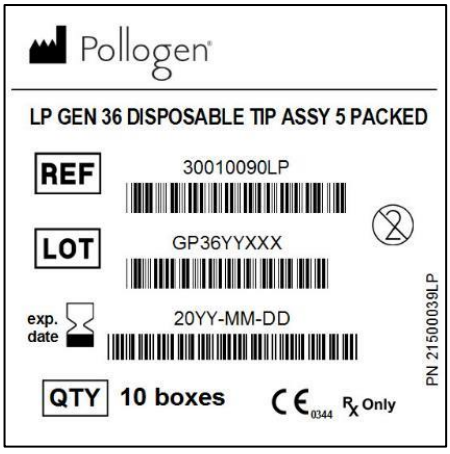
Table 3: Symbols used throughout this User Manual

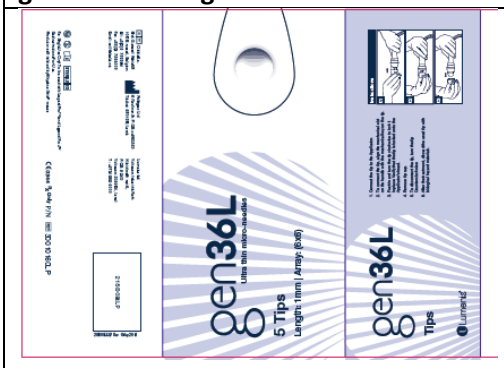
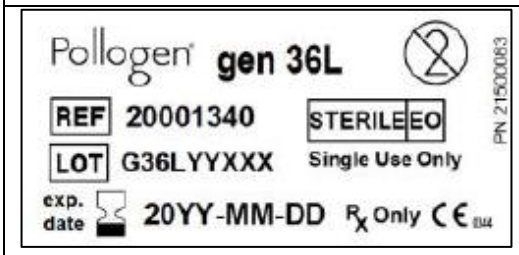
9.2 Labels affixed to the System and its accessories

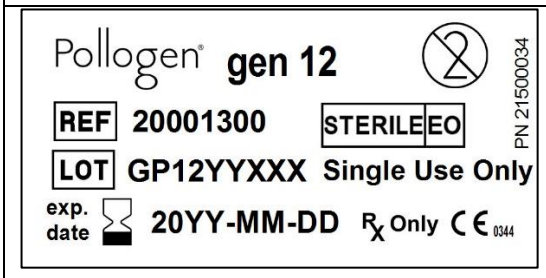
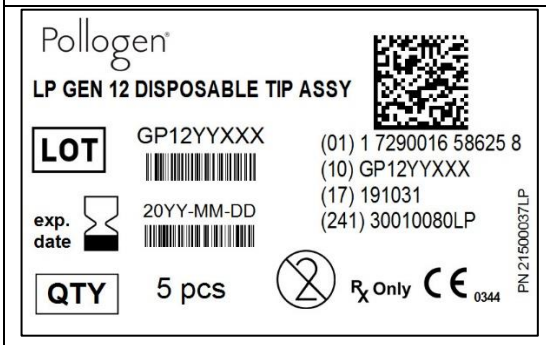
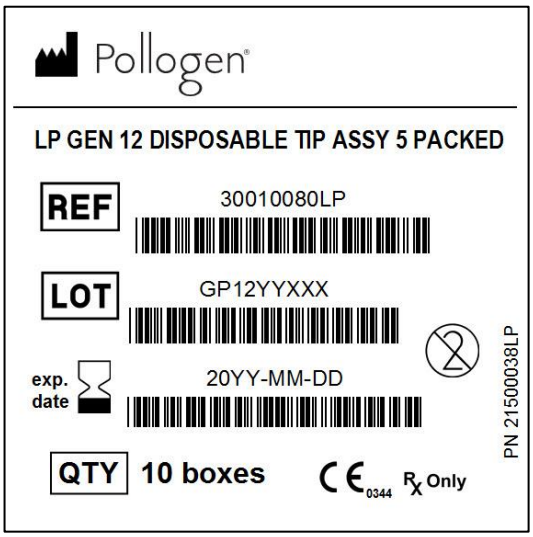
The labels shown in the following table are affixed to the back of the Main Unit as well as accessories. These include serial numbers of system parts and a few usage warnings.

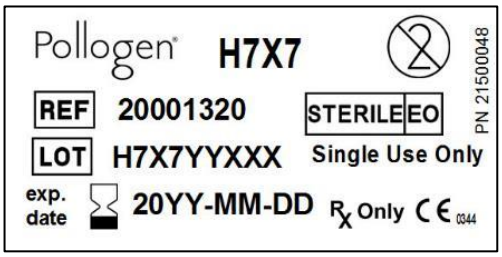
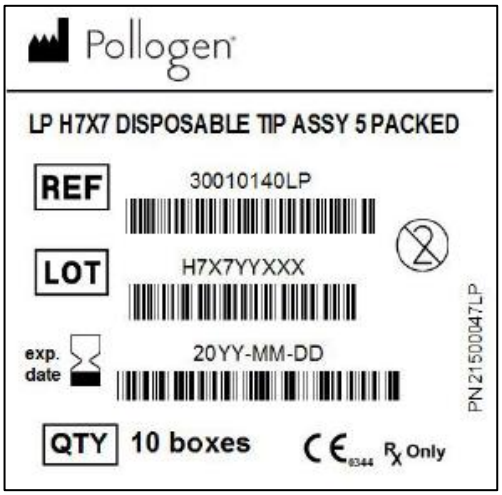
	Device serial number label.
	Label on Applicator VO connector.
	Label on Applicator 1 connector.
	Label on Applicator 2 connector.
	Label on Applicator 3 connector.
	Label on Applicator AFO connector.
	Label on Patient-Controlled Manual Switch connector.
	Label on Foot Switch connector.
	Label on Memory stick connector.

	Label on Applicator VO serial number label.
	Label on Applicator 1 serial number label.
	Label on Applicator 2 serial number label.
	Label on Applicator 3 serial number label.
	Patient controlled manual switch number label.
	Foot Switch serial number label.
	Fuse label.

gen 36 labeling:	
	gen 36 : 5 pack cover sleeve
	Label on gen 36 Disposable Tip for VO
	Label on 5 pack of gen 36 Disposable Tips for VO This label is placed on the 5 pack box and device packaging
	Label on 50 pack of gen 36 Disposable Tips for VO

gen 36L labeling:	
	gen 36L : 5 pack cover sleeve
	Label on gen 36L Disposable Tip for VO
	Label on 5 pack of gen 36L Disposable Tips for VO This label is placed on the 5 pack box and device packaging
	Label on 50 pack of gen 36L Disposable Tips for VO

gen 12 labeling:	
	**gen 12 : 5 pack cover sleeve**
	Label on gen 12 Disposable Tip for VO
	Label on 5 pack of gen 12 Disposable Tips for VO This label is placed on the 5 pack box and device packaging
	Label on 50 pack of gen 12 Disposable Tips for VO

H7X7 labeling:	
	H7X7 : 5 pack cover sleeve
	Label on H7X7 Disposable Tip for VO
	Label on 5 pack of H7X7 Disposable Tips for VO This label is placed on the 5 pack box and device packaging
	Label on 50 pack of H7X7 Disposable Tips for VO

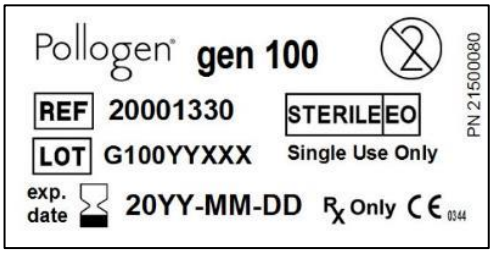
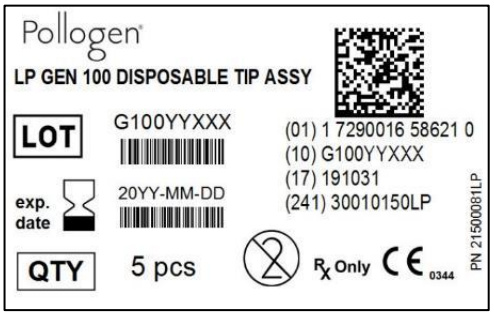
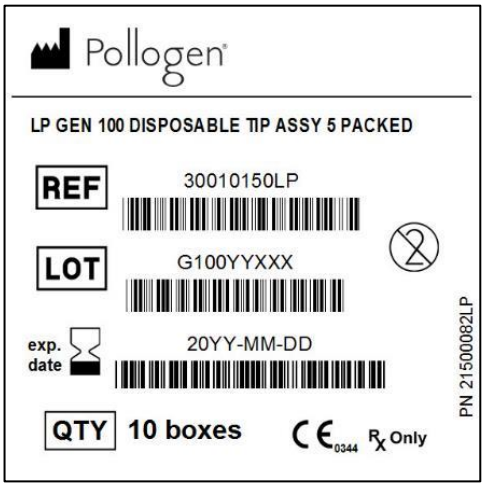
Gen100 labeling:	
	
	Label on gen 100 Disposable Tip for VO
	Label on 5 pack of gen 100 Disposable Tips for VO This label is placed on the 5 pack box and device packaging
	Label on 50 pack of gen 100 Disposable Tips for VO

Table 4: Labels affixed to the System and disposables

10. INITIAL SET UP

The System designed for simple installation. To install the system, follow the subsequent procedure:

10.1 Unpacking the System

Unpack the System and verify that the system is intact and that all its components are present. Recommended for future safe transport of the device, that the original box and internal packaging be saved.
Make sure to remove all covers and wrappings from all parts prior to the installation of the system.

The system is comprised of the following modules:

1. Main Unit
2. Applicator VO
3. Applicator 1
4. Applicator 2
5. Applicator 3
6. Foot Switch
7. Patient-Controlled Manual Switch
8. Non-Contact Infrared thermometer
9. 2 Applicators holders (Including 2 screws)
10. Power Cable
11. User Manual
12. Disposables – 1 Box– H7X7 TF Tips
13. Disposables – 1 Box– gen36 VO Tips
14. Disposables – 1 Box– gen36L VO Tips
15. Disposables – 1 Box– gen100 VO Tips
16. Disposables – 1 Box– gen12 VO Tips

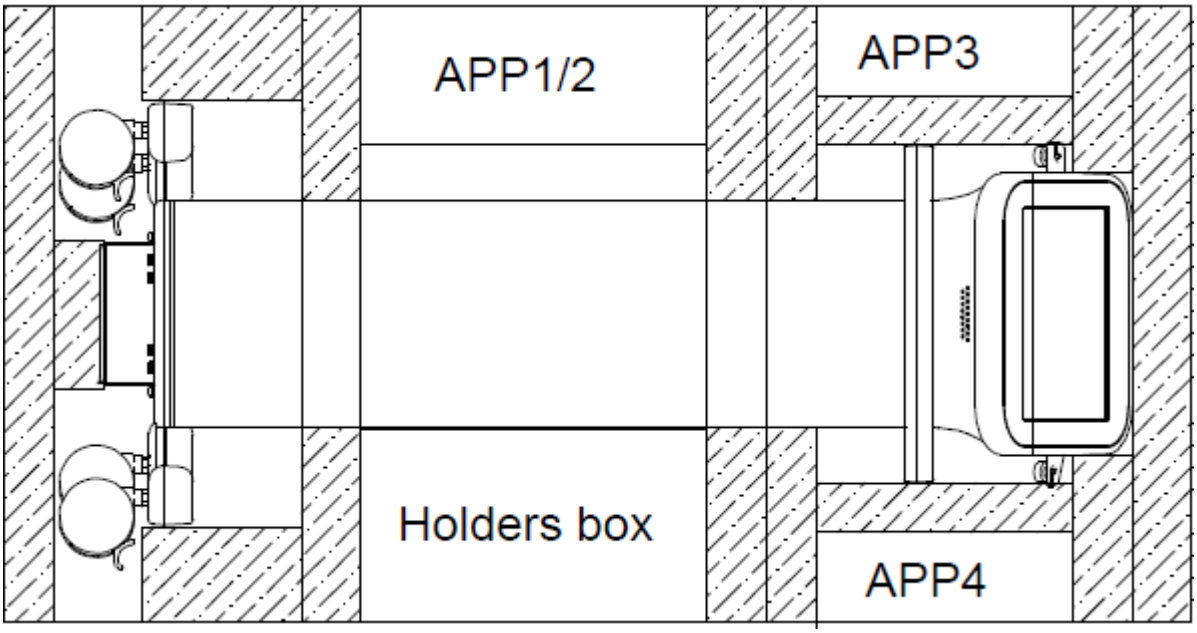


Figure 16: Unpacking the System

10.2 General overview and Installation Requirements

- Electrical Requirements

The System has a universal power inlet Single phase 100 - 240 VAC; 5A; 50-60Hz.
The system must be connected to a grounded power outlet (3-pin). Only supplied cable is to be used. (Cable 10A, 250V, 1.8m length)

- Environmental Requirements

Corrosive materials can damage electronic parts. Therefore, the System should only be operated in a non-corrosive atmosphere. For optimal operation of the System, maintain room temperature between 15^{o}-30^{o}C and keep relative humidity at less than 80% and maintain Atmospheric pressure of 70kPa to 106kPa.

- Moving the System

1. Place the Applicators into their cradles.
2. Turn the System off.
3. Disconnect the power cord, Foot Switch and Patient-Controlled Manual Switch.
4. Release the wheel brakes.
5. With one hand securing the Applicator, slowly pull the System using its handle.

C A U T I O N
ONLY MOVE THE SYSTEM BY USING ITS HANDLE. PUSHING OR PULLING THE SYSTEM WITHOUT USING ITS HANDLE MAY TURN THE SYSTEM OVER AND RESULT IN DAMAGE TO THE SYSTEM.

10.3 Preparation for Operation

10.3.1 Applicator and cable holder's assembly procedure:

- Take both applicators holders and screws out of the box

- Note the locations of the holders, and differentiate left (applicator no.2) and right (applicator no.1) holders

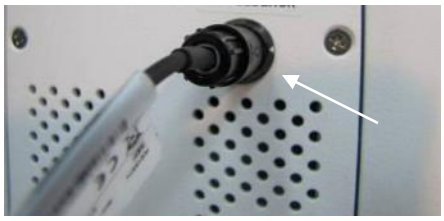
- Fit each holder and secure the position with the provide screw
- Make sure to tighten screws properly

- Place each applicator in its cradle, according to each applicator size and arrange its cable.

10.3.2 Foot Switch connection.

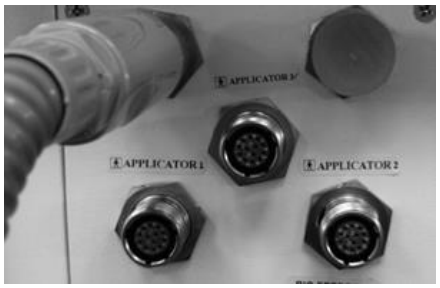
- Align the arrow on the connector with the arrow on its receptacle. (labeled accordingly)
- Push the connector into its receptacle until a click sound is heard
- Verify that connector is properly connected and locked

10.3.3 Patient-Controlled Manual Switch connection.



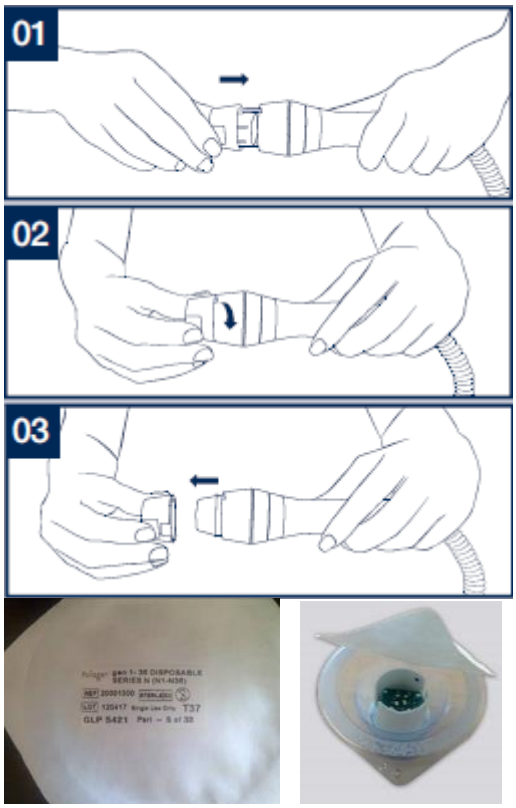
- Align the arrow marks on the connector with the arrow on its receptacle. (labeled accordingly)
- Push the connector into its receptacle until a click sound is heard
- Verify that connector is properly connected and locked

10.3.4 Connect VO Applicator



- Remove protective VO shipping cover from VO Applicator head.
- Place VO Applicator in its holder
- Push the connector into its receptacle and fasten the connector nut properly. Make sure the red marking on the receptacle is totally covered by the nut

10.3.5 Attach VO disposable tips



To connect the VO disposable tips, gen 36, gen36L, gen100, gen 12 or H7X7: do the following:

- Select a blister pack containing from one of the above mentioned tip boxes.
- Verify valid expiration date printed on the tip's blister pack. (gen 36 is provided as an example)
- Remove cover from the blister pack.
- Place on a flat surface
- Apply sterile gloves
- Connect the tip to the VO Applicator. See detailed instructions below
- To connect the tip, align the raised strip on the tip with the groove on the applicator and push them together
- Push in and turn the tip clockwise to lock it in place Verify that the tip is locked onto the applicator's head
- Remove tip cap
- To disconnect the tip, turn the tip counterclockwise
- After the treatment, discard the used tip with biological hazard materials

10.3.6 Connect and lock Applicator No. 1

Make sure it is properly attached and fastened securely.

10.3.7 Connect and lock Applicator No. 2.

Make sure it is properly attached and fastened securely.

10.3.8 Connect and lock Applicator No. 3.

Make sure it is properly attached and fastened securely.

10.3.9 Power supply cord connection

Reminder: Before connecting the power supply cable, make sure that the ON/OFF switch is in the OFF position (“0”), and the cable has a grounding wire (3-pin plug).

11. USER INTERFACE

11.1 Turning System On

Before turning the System on, verify that the System power supply cord connected to the System inlet on the back panel and to the power outlet. The System must be connected to grounded power outlet (3-pin) and must be used only with the cable supplied. (Cable 10A, 250V, 1.8m length).

Warnings:

- High voltage is present inside the system.
- Delivering excessive energy to the treatment area can damage the skin, resulting in burns.
- Lock the wheels during operation of the System (see Figure 1).
- Check all connections before plugging in the System's power supply cord.
- Verify that fan is functioning when operating the System. In case of fan failure do not operate the device, call your Lumenis representative for service.
- Do not operate the unit in the presence of electromagnetic interference. Electromagnetic interference may be caused by electro surgery, diathermy, magnetic resonance imaging or other type equipment.
- Portable and mobile are RF communication equipment & may affect operation of this device.

To turn the system on, switch the ON/OFF control to the ON position on the back panel.
The button will turn green.

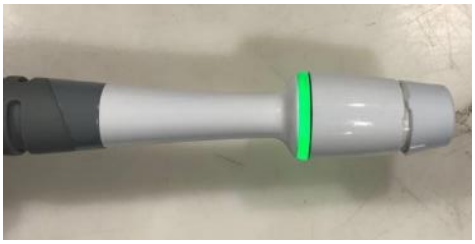
ON / OFF switch on the back panel

- **0** position pressed – OFF
- **1** position pressed - ON

Pay attention that the touch screen quality is OK during the first few seconds of the system check (touch screen will become black and then turn white). At this time, the Applicator LED will flash (first Green then Orange) as part of the System's self-check.

In the following cases, please consult your Lumenis Service representative:
- Residual black pixels while the screen turns white
- No applicator indications appear

As part of the System's self-check, and while the touch screen becomes black, the LED Indicator ring on the applicator flashes green and then orange.
Touch screen becomes black and then white as part of the screen quality check.
(Please refer to Applicator VO as an example)

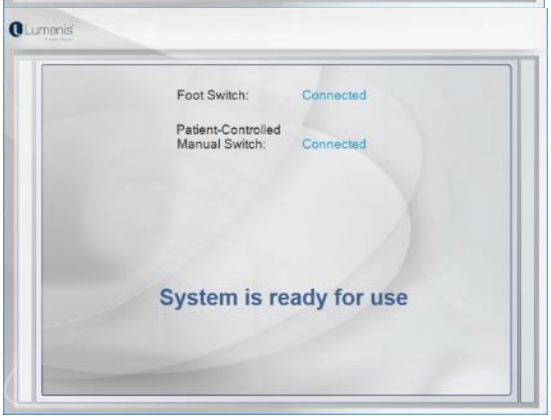


As part of the System's self-check, and while the touch screen becomes black, the LED Indicator ring on the applicator flashes green and then orange.
Touch screen becomes black and then white as part of the screen quality check)

After turning the system ON, the touch screen will show the following picture, for 10-15 sec. while the system starts.

Following the screen quality check, the System will move on to check proper connections. The connections status is displayed on the screen.
If self-test is successful, the System will request "Please press Patient-Controlled Manual Switch", after pressing the Patient-Controlled Manual Switch, a "System is ready for use" screen will flash for 2-3 seconds and the system will automatically proceed to the Setting screen for language selection.

During the connection checks of the system, the following warning messages may appear:



During preliminary System check, an alarm will sound if the Foot Switch is not connected and will be indicated in red on the screen. Once the Foot Switch is connected properly, the system will continue automatically after check is successful.

During preliminary System check, an alarm will sound if the Foot Switch is pressed. Once the Foot Switch is released, the System will continue automatically after check is successful.

During preliminary System check, an alarm will sound if the Patient-Controlled Manual Switch is not connected and is indicated in red on the screen. In case of disconnection, the System check will stop. Once the Patient-Controlled Manual Switch is connected properly, the System will continue automatically after check is successful.

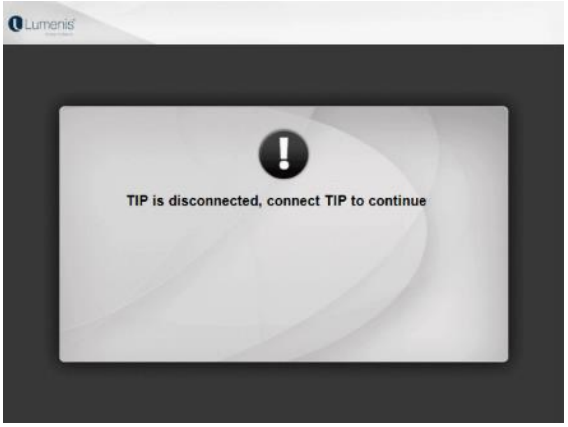
During the preliminary System check, if the Patient controlled manual switch is pressed, the System check will stop and will not move on to next screen until released. Once the Patient-Controlled Manual Switch is released, the System will continue automatically after check is successful.

Once the preliminary System check is complete, the System will automatically go to the Home screen.

Only when an applicator is properly connected it enables to enter a treatment mode

It is recommended to verify the functioning of touch screen keys before starting the treatment.

In case one of the tips is already connected while turning the system on, the 'Remove tip' screen will be shown. Please remove the tip from the applicator in order to continue to the home screen.



11.2 Selecting Treatment Application

Select Treatment Application by taping on the VoluDerm ™ or TriPollar® key in the Home Screen.

Once a key is selected, it is color highlighted.
The system does not enable to select an application if its applicators are not properly connected. Its image will appear dim on the screen.
You may select the TriPollar® Application if at least one of its applicators is properly connected.

11.3 TriPollar® Treatment Application

11.3.1 Select TriPollar® Treatment Applicator

Select the TriPollar® Application to reach Applicators 1-3.
Select the requested Applicator.

The system does not enable to select an application if its applicators are not properly connected. Its image will appear dim on the screen.
In the image to your right, you may select the TriPollar® Application No. 1 that is properly connected. Applicators 2-3 are not properly connected.

11.3.2 Select TriPollar® treatment course

(Applicator 1 Course A is used as an example in below screen)

TriPollar® application enables 2 treatment courses per each Applicator. Courses are distinguished by their configuration settings (default parameters and range of parameters values). In each course, changes can be made to the following parameters: RF Power (%) and Duration (Min).

To change each parameter, move the slider, right to increase or left to decrease, or press on the "+"or "-" button accordingly.

During the treatment, all keys will be dimmed/not active. To end a TriPollar® treatment course, select the "door" Exit symbol in the upper right corner of the treatment screen.

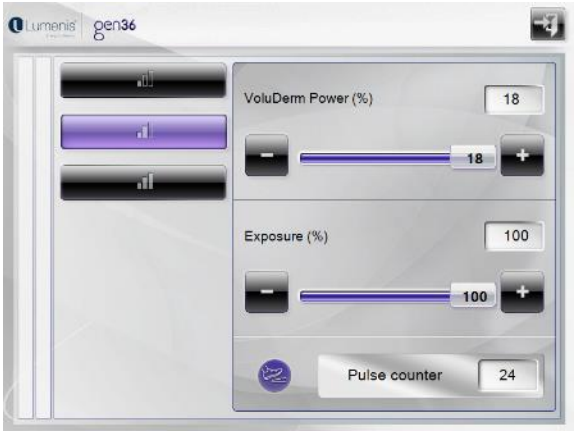
11.4 VoluDerm ™ Treatment Application

11.4.1 Select VO Treatment Applicator

Select the VoluDerm ™ (VO) Application on the home screen to start the VO treatment.

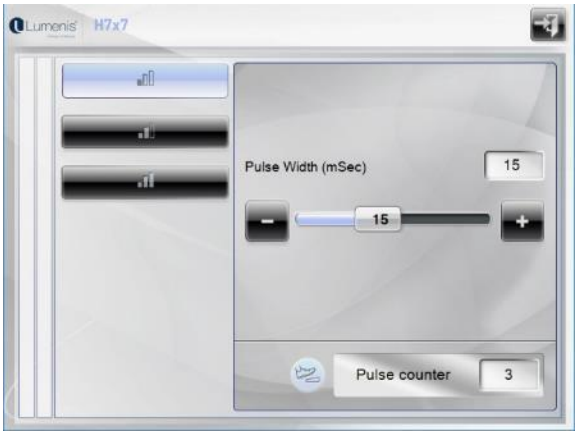
11.4.2 VoluDerm ™ treatment level

VoluDerm ™ application enables 3 treatment levels: Low, Medium, High. Programs are distinguished by their configuration settings (default parameters and range of parameters values). In each program, changes can be made to the following parameters: VoluDerm ™ power (%) and Exposure (%).
(Applicator VO with gen 36 is used as an example in below screens)
To change each parameter move the slider, right to increase or left to decrease, or press on the "+"or "-" button accordingly.



TriFractional H7X7
TriFractional operation mode enables 3 treatment levels: Low, Medium, and High.
Programs are distinguished by their configuration settings (default parameters and range of parameters values). In each program, adjustments can be made to the Pulse Width parameter.

To adjustment each parameter move the slider, right to increase or left to decrease, or press on the "+"or "-" button accordingly.



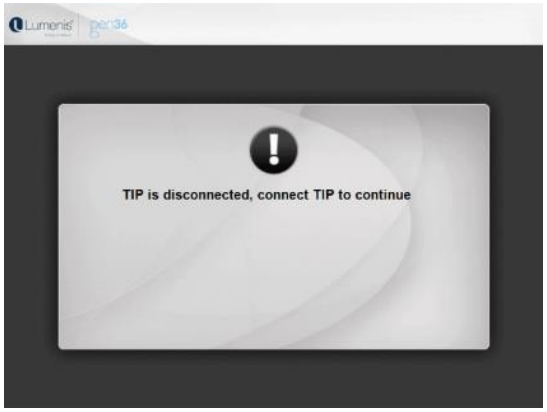
11.4.3 VO Applicator tips

If a treatment tip is not connected, a warning message is displayed.
The system does not enable starting a VoluDerm ™ treatment until a tip is connected. VoluDerm ™ power will not be emitted unless a tip is connected (For treatment tip connection instructions, please refer to “To connect the tip”).

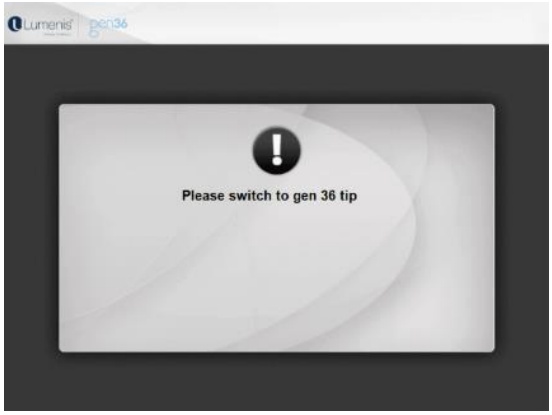
During the treatment, all buttons will be dimmed/not active.

During the treatment, if the tip is removed, a warning message is displayed.
The system does not enable to proceed with VoluDerm ™ treatment until a tip is re-connected.

- Once the tip is connected to the VO Applicator, verify the type of tip indicated on the screen before starting the treatment.
- The system shall automatically identify the type of tip attached to the VO applicator and select treatment parameters according to tip selected.



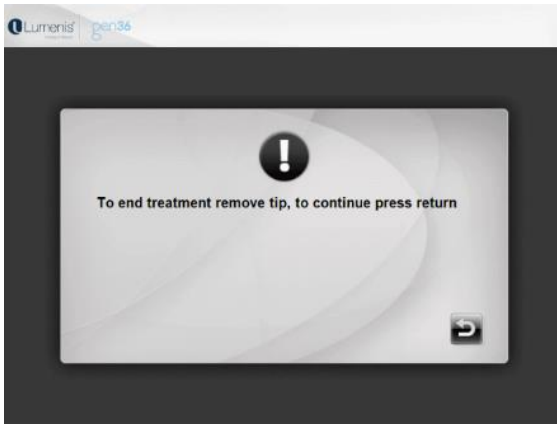
During the treatment, if the tip is removed, and another type of tip is connected, a warning message is displayed.
The system does not enable to proceed with VoluDerm ™ treatment until the same type of tip is connected.
This message will also be applicable for gen100, gen 12 and H7X7 tips and gen36L.



VO tip pulse limit is 800 pulses. When starting a new treatment using VO tip with more than 800 pulses, the system will show 'tip is used' screen.

In order to continue, please replace the tip with a new one.

To end a VoluDerm ™ treatment, select the “door” Exit symbol in the upper right corner of the treatment screen.
The following screen will appear.
You will be instructed “To end treatment remove the tip, to continue press return.”
After removing the tip, the system will return to the main screen.



11.5 Adjusting System’s Default (Preset) Parameters

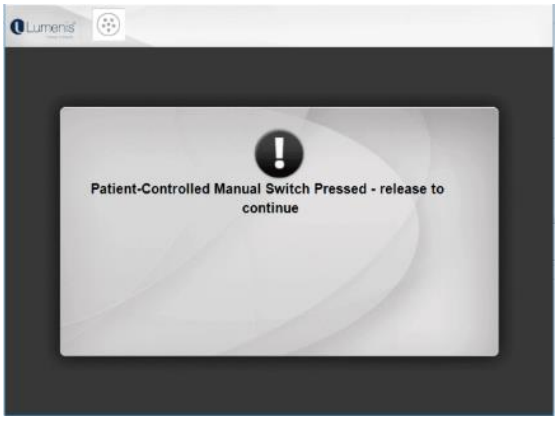
For safety reasons, each time you switch the System OFF, all parameters return to the default values.

- Default (Preset) parameters are displayed on the screen for each treatment program.
- Each one of the treatment parameters may be easily adjusted using the simple user interface.
- Select a parameter to be adjusted by sliding its slider, right to increase or left to decrease, or pressing on the “+“ or “-” button accordingly. After setting all parameters on the treatment screen, press foot switch for operation.

11.6 Operation

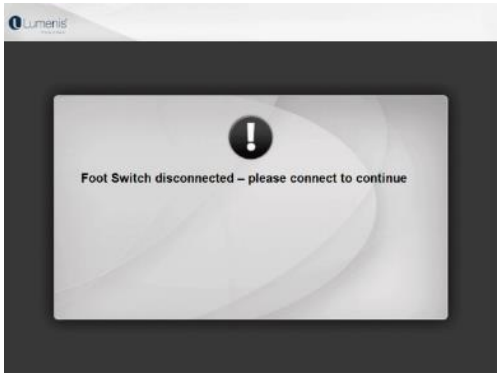
Treatment may be started any time after the treatment program has been selected.
Be aware that treatment pulse will be emitted when the footswitch has been pressed.
Release the foot switch ONLY after the BEEP sound, indicating that pulse emission is complete.

Patient-Controlled Manual Switch
System will immediately stop the treatment once Patient- Bio Feedback Control is pressed.



After the Patient-Controlled Manual Switch has been pressed the treatment may only be continued if the Patient controlled manual switch is released and the Foot Switch is also released and pressed again.

During treatment, the System is continuously checking proper connection of the selected Applicator, Foot Switch and Patient-Controlled Manual Switch. In case of a connection failure, the System will sound an alarm and display a warning message (see Footswitch connection error as an example).



When the Foot Switch is pressed, RF power is transmitted to the target area by a sequence of two pulses. The first RF pulse is pre-set. The second RF pulse is pre-programmed with default treatment parameters per each treatment level. Parameters may be modified according to skin condition and number of treatment.

11.7 Indications

11.7.1 Applicator Indication

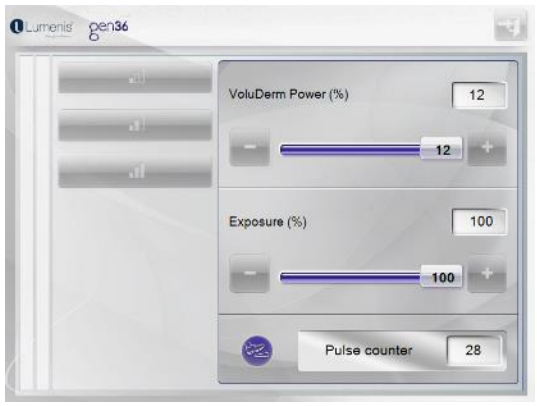
- After pressing and releasing of the Footswitch, the LED indicator ring on the selected applicator will turn green.

- When the Foot Switch is pressed, and Energy is transmitted to the electrodes, the LED indicator ring will turn orange.

10.7.2 Indication on Touch Screen

- During normal operation procedure the selected applicator and treatment parameters are displayed on the touch screen.

- When treatment begins and after the foot switch has been pressed, all keys become dim and will not enable changes until the end of the pulse emission.



11.8 Settings

11.8.1 Home screen

The basic screen from which you can select other screens is the home screen.

Press on the  key to reach the “Setting Screen”

11.8.2 Date/Time selection

It is recommended to define the date/time during installation of the system, as this will enable referring to treatment logs with date & time of treatment.
To define the date & time: Select the current date and time.
Press  to confirm

Press on  to exit the setting screen.

11.8.3 Technician mode

⚠ Only qualified personnel who have been trained by Lumenis are allowed to provide service for this equipment.

A qualified technician is provided with a technician password.
To activate this screen, enter the technician password in the “Password” bar.
All other information relevant for this screen will be detailed in the Service Manual.
For Touch Screen calibration press the “Touch screen calibration” and follow the instructions.

11.8.4 Program upload

The System is equipped with a USB port, located at the back panel of the device, see 6.1.3 Back Panel If a program update is required, the software can be downloaded using Lumenis memory stick ONLY. This is done by entering the “Setting Screen”.

1. Enter the “Setting Screen” by pressing the key.

2. Select the “Prog Update” key. The selected key will be highlighted blue.
3. The current program versions installed will be displayed on the screen.
4. Connect Lumenis SW USB flash disk to the USB port. The system will display a message: “For Program update connect Lumenis SW Memory Stick to USB port”
5. Program version is marked on the SW Memory Stick.
6. The “MCU Program” & "GUI program" keys will remain dim until a Lumenis SW Memory Stick is properly connected to the USB port.
7. When a Lumenis SW Memory Stick is properly connected to the USB port, the system will request you to press the “Program” key.
8. Press the “MCU Program” or "GUI program" according to the SW updated file provided in the memory stick.
9. System is now uploading the new software.
10. Once the program upload was successfully completed, the system will display a confirmation on the screen: “New program version installed”.
11. The system will display the new software version “Current program version”.
12. Verify that the current program version displayed on the screen matches the program version marked on the SW Memory Stick.
13. If the program is not successfully installed, the System will display the program update main screen. You will be requested to try to repeat the installation. If the device does not operate, please contact your service representative.

11.8.5 Data Log

The system enables a download of data logs.
Select the “data log” key.
To download the data, select the “Export to memory stick” key.
The “Export to memory stick” key will remain dim until a Memory Stick is properly connected to the USB port.
When a Memory Stick is properly connected to the USB port, the system will request to press the “Export to memory stick” key Press the “Export to memory stick” key
System is now downloading the data.

11.9 Turning the System OFF

To turn the system off, switch the ON/OFF control to the OFF position on the back panel. The green light will switch off. Disconnect power supply cord.


Before disconnecting the power supply cord, make sure that the ON/OFF switch is in the OFF position (“0”).

12. Legend Pro™ treatment

This section is a safe start guidelines for treatments with the Legend Pro™ System.
This is intended as a guide only and it is not a replacement for clinical training, certification or supervised experience. Please follow the instructions in this User Manual.

12.1 VoluDerm ™ Treatment using VO applicator

- Prior to the first treatment, a patch test should be done on a hidden area using Low, Medium and High settings to evaluate the patient's response to the treatment. Skin reaction should be monitored immediately and a few days after treatment. If there is an excessive and progressive skin reaction for all settings lasting more than 2-3 days, the patient shouldn't be treated
- Using higher parameters than needed can cause overtreatment and lead to undesired effects of the skin
- Patient safety can be ensured only when well-trained personnel operate the system
- Never treat a patient in areas that are not specified within the intended use

12.1.1 Pre-Treatment Preparation

During the first visit, the physician should assess the areas intended for treatment and take the following actions:

- Take a detailed patient medical and physical history including previous treatment methods
- Determine if the patient is suitable for treatment - do not treat patients with any of the contraindications outlined in this User Manual
- Determine why the patient is seeking treatment and what his/her expectations are
- Inform the patient about the course of treatment and possible side effects and discomfort
- Inform the patient about the safety warnings
- Inform the patient about post-treatment skin care. Advise the patient to avoid skin tanning or skin irritation and that sunscreen is required when outdoors during daylight hours
- Instruct the patient to remove all jewelry prior to treatment
- Instruct the patient to shave any hair in the treatment area
- No coupling medium such as glycerin, lotion, or gel should be used during the treatment
- Topical anesthetic may be applied on the treatment area prior to treatment. It is recommended to use EMLA. Use the anesthetic according to manufacturer guidelines. Pay attention to any contraindications for use of the anesthesia
- Use low parameters when treating over bone areas and delicate skin

12.1.2 Treatment Guidelines:

Caution:

- In case of uncertainty regarding potential side effects, have the patients consult their physician and bring consent for treatment.

- Verify that patient's tolerance to the treatment was tested and verified
- Treatment area should be thoroughly cleaned: free of makeup, soap, glycerin etc.
- Make sure a suitable new and sterile treatment tip is attached correctly to the Applicator
- Before the treatment, the physician should inspect the area to be treated and determine the

treatment details: treatment tip to be used, suitable treatment parameters and any other special treatment requirements.

- Five types of tips are available: gen 36 (6x6),gen36L (6x6), gen100 (10x10), gen 12 (6x2) and H7X7.
- Topical anesthetic may be applied on the treatment area prior to treatment. It is recommended to use EMLA. Use the anesthetic according to manufacturer guidelines. Pay attention to any contraindications for use
- Post anesthesia, anesthetic should be removed according to IFU of the selected product. Ensure that all anesthetic has been removed and that the skin is completely clean & dry before commencing treatment
- Before starting the treatment, always verify chosen parameters on the screen
- When placing the Applicator on the skin, make sure it is not transmitting power energy (foot switch is not pressed and LED indicator on the applicator is not orange)
- It is recommended to use Low power settings during initial phases of the first treatment. Assess the immediate response and if the immediate response is mild and well accepted by the patient, you can gradually increase the power level if needed.
- Using higher treatment parameters than needed can lead to undesired adverse effects
- Place the Applicator on the skin with slight pressure to ensure you have full contact. In areas with uneven skin surface it is recommended to stretch the treatment area (using your fingers) before placing the tip on it. Use less pressure over bones and delicate skin
- When moving the Applicator to the area of the next pulse, place the tip adjacent to the previous pulse. Overlapping may induce excessive reaction especially if occurs when using high parameters
- Avoid stacking pulses
- Specific treatment parameters are individual and should be adjusted (increased or decreased) according to patient feedback and skin tolerance. In the case of patients with sensitive skin, it is recommended to use Low power settings and elevate if needed at following treatments
- Areas over dental crowns, caps, braces or metal fillings may be sensitive to treatment and dental rolls or folded gauze may be used to cover them

Warnings:

- Never treat the area below the eyebrow, over the eye lids and eyeballs
- When working around the eye, always make sure to treat only over bone area
- Never treat over the lips
- During the treatment, skin should be clean and dry
- During the treatment, no coupling medium such as lotion, gel, oil or glycerin is allowed to be used
- Ensure that the Applicator's tip is free of debris and is thoroughly dry
- After treatment, no other treatment should be performed until the treated area has completely healed

12.1.3 Treatment Parameters

The following table displays the DEFAULT treatment parameters of the VO Applicator.
Range of parameters is detailed in brackets.

12.1.3.1 VO : Default Treatment parameters:

VoluDerm ™: Default Treatment parameters:

Tip	Treatment Mode	LOW (Min – Max)	MED (Min – Max)	HIGH (Min – Max)
Gen12	Energy	8 (5 – 10)	10 (5 – 10)	20 (10 – 20)
	Exposure	3 (1 – 3)	10 (1 – 10)	10 (1 – 10)
Gen36	Energy	10 (5 – 15)	20 (15 – 25)	30 (25 – 35)
	Exposure	15 (1 – 75)	25 (1 – 100)	25 (1 – 100)
Gen36L	Energy	10 (5 – 15)	20 (15 – 25)	30 (25 – 35)
	Exposure	15 (1 – 75)	25 (1 – 100)	25 (1 – 100)
Gen100	Energy	10 (5 – 15)	20 (15 – 25)	30 (25 – 35)
	Exposure	15 (1 – 75)	25 (1 – 100)	25 (1 – 100)

Table 5.1: VoluDerm ™ Treatment parameters

TF H7X7 Default Treatment parameters

MODE	Pulse width (ms)
LOW (Min – Max)	15 (5 – 30)
MED (Min – Max)	30 (5 – 55)
HIGH (Min – Max)	55 (5 – 75)

* Values in parenthesis represent the range within each level

VoluDerm ™ notes:

- You may adjust VoluDerm ™ Power & Exposure parameters within the indicated range
- To adjust the VoluDerm ™ output, start by adjusting the % Power. Change of % Exposure is only for advanced usage
- Mild vibration is felt during the initiation of VO pulse

Always wait for the BEEP sound before moving to the adjacent pulse. Do not move the Applicator until you hear a BEEP sound.

TF H7X7 Notes:

- You may adjust RF Exposure parameters within the indicated range
- Make sure the skin is completely dry and that there is full contact of all pins with the skin, ensure it by stretching the skin and applying mild pressure.

12.1.4 Treatment Procedure

- Selecting the appropriate program and tip (gen 12, gen 36, gen36L , gen100 or H7X7) is essential for a successful treatment
- The choice of treatment parameters depends on the treatment area, skin condition, patient skin type, and tolerance
- For each tip there are three levels: Low, Medium and High. It is recommended to always start with the

Low program and to increase gradually after inspecting the skin response to the treatment. Using high settings increases the treatment impact on both the epidermis and dermis

- When treating skin types IV -VI or Asian skin, use Low parameter settings

Prepare the treatment area:

- Clean the treatment area with soap and water and dry the skin completely after cleaning
- Wait until the skin is completely dry before continuing
- Apply the EMLA topical anesthetic on the treatment area, allow recommended exposure time of skin to the topical anesthetic according to the manufacturer guidelines. Remove it as indicated in the manufacturer guidelines and make sure the skin is clean and dry
- Turn the system on and set the appropriate treatment parameters as described. Always use Low setting on a new patient treatment
- Ensure that the tip is sealed within the blister and is intact. Open the sealed pack of the appropriate tip and connect the new and sterile tip to the Applicator (see instructions in section 7.3.5 of this UM). Ensure that the tip is secured in place
- Remove tip cap before use
- Check the integrity of the tips and pins. In case of any missing/loss parts, do not use the tip.
- When choosing the appropriate tip and treatment parameters, always consider the skin type and thickness, severity of treated condition, treatment area, bone proximity, etc.
- Provide the patient with the 'Patient controlled manual switch' with the push button in range of their thumb for easy access. Then explain that they can stop the treatment at any time by pressing the button in case of excessive discomfort
- Position the patient is a comfortable position according to the treatment type and location
- Decide on the treatment path and placement pattern of the tip to ensure optimal skin coverage of the treatment area. When working on large areas, it is recommended to work in a systematic sectional manner according to planned sections to enable an organized coverage
- It is recommended to start the first treatment of a patient with a patch test using Low setting. Inspect the treated test area immediately after a few pulses to assess the skin reaction. If the area does not demonstrate an abnormal reaction and if patient's tolerance allows, you can continue to other areas of treatment while gradually changing to higher setting parameters if desired. Always adjust the parameters (increase or decrease) according to the skin's reaction
- Place the Applicator perpendicular to the skin surface while applying mild pressure to ensure full contact. Low pressure is required especially over bony areas
- In areas where skin surface is uneven and there is a chance of partial contact, it is recommended to stretch the skin between your fingers and then position the tip on the stretched skin surface
- Once you have achieved full contact and the tip is positioned correctly, press the foot switch to activate the Power
- A Beep sounds will be heard when the pulse emission is complete, and the indicator light has turned from red to green
- Move the tip to the adjacent spot. Make sure you do not leave an untreated surface between pulses
- If you work on a large surface or if the patient perspires during the treatment, it is recommended to dry the next treatment areas with gauze and wait for complete drying of these areas
- When treating large area, after treating half of it, make sure that the untreated half is clean and completely dry before continuing treatment
- Monitor the patient's sensation verbally and regularly throughout the treatment
- Examine the skin during the treatment. Immediate responses of skin erythema (redness) and /or edema (swelling) usually develop. These signs are indications of the desired effect. The response usually appears a few minutes after pulsing and reaches its peak within 30 minutes to 1 hour. In darker skin types, erythema is not easily detected, and edema is more prominent
- Treatment consists of a single pass over the treatment area

- Summary of treatment sequence is as follows: The Applicator tip should be placed on the skin, a pulse emitted, and then Applicator is lifted and moved to an adjacent area. Emitted pulses usually create tip-shaped erythema and edema zones
- At the end of the treatment area, examine the skin and apply additional pulses if there are patches of untreated areas
- During treatment, inspect the tip for cleanliness once every 10 to 15 pulses. This is especially important when using high parameters, which may cause increased buildup of debris. If the tip is not clean it must be replaced
- After completing the treatment, exit the treatment screen by pressing the Exit "door" button. The following screen appears: "To end treatment remove tip". Remove the treatment tip and dispose of it appropriately
- Post treatment soothing agents such as emollient cream or topical medication may be applied to the treatment area, according to the physician discretion
- After each treatment, the Applicator should be cleaned according to section 10 of this User Manual
- In subsequent visits, the treatment program can be modified at the practitioner's discretion

12.1.5 Post Treatment Care

Post treatment, tiny scabs in the form of the tip's ultra-thin electrodes / micro-pins array will usually form within 24 hours to 3 days.

- Do not scratch the treated area or peel the scabs off the skin!
- The scabs usually remain for several day
- Scabs should be allowed to shed off naturally
- If Low treatment parameters were used, scabs may not appear or may appear and disappear fast

Refer to the following recommendations to determine your own suitable course of action for post-treatment care.

- In case of excessive edema, erythema, or discomfort, cool the area for at least 15 minutes until heat sensation fades (you may use cold, not frozen, packs)
- It is recommended that the patient returns two to three days post treatment to evaluate the treatment area and ensure that no adverse effects have occurred
- Typically, there will be a slight edema or slight erythema which may last for 2-3 days. If side effects persist excessively and beyond the indicated period, the patient should seek medical advice
- In case of blisters, ulcerated or infected skin, the patient should seek medical advice. Such symptoms can be treated with a prescribed antibiotic ointment or burn treatment cream as per physician's discretion
- Patient should avoid makeup and moisturizer for about 24 hours. Afterwards, the patient may use makeup, moisturizer, regular soap (not scrub soap or exfoliant) unless unwanted reaction occurs in the area
- For skin types IV – VI and Asian skin, bleaching agents may be prescribed following healing of the treatment area (a few days after crusting has completely disappeared), to minimize risk of post inflammatory hyperpigmentation. Bleaching treatment should be stopped 48-72 hours before another session. Bleaching treatment should be conducted as per physician discretion
- During the first two days after the treatment, extra care should be taken to keep the skin clean to avoid contamination or infection. Additionally, avoid hot baths, massage or any mechanical or thermal damage to the treated area
- Avoid exposure to sunlight or tanning rooms and cover the treated skin with a high factor sun screen. Tanning after treatment may cause change of pigmentation
- Treatment Protocol will be according to the physician's discretion and pending complete healing of

the treated area

- Suggested number of treatments may vary between individuals and between treatment areas
- Typical course of VoluDerm ™ treatment involves 4-5 treatments: 3 treatments spaced 1-2 weeks apart (depends on skin condition and healing rate) followed by additional 1-2 treatments spaced 2-3 weeks apart
- Before performing the next treatment, it is important to always verify that the treatment area has completely healed.
- Patient medical history should be updated before each session including sun exposure, new medications etc.
- A touch up treatment may be needed approximately every six months, according to individual need and response

12.2 TriPollar® Energy Treatments using Applicators 1, 2, 3

12.2.1 Pretreatment guidelines:

- Patient safety can be ensured only when well trained personnel operate the system
- A patient's medical history should be completed prior to scheduling a treatment
- Never treat a patient with any of the contraindications criteria listed (see section 4)
- Patients should be fully informed of the treatment protocols including inclusion and exclusion criteria, clear expectations/realistic results and if there are any risks associated with the treatment

12.2.2 During the treatment

- When placing the applicator on the skin, make sure it is not transmitting RF power (Foot switch is not pressed and Indication ring light on the applicator is green)
- Make sure to move the applicator at all times on skin surface, never stop moving the applicator on the skin (even when it is not transmitting RF power and the indicator light is green)
- Using power that is higher than needed or longer treatment sessions can cause over-treatment and lead to undesired over-heating of the skin
- The desired end point surface temperature for facial treatments should range between 40-42 °C (104-107.6°F). Never exceed 43°C (109.4°F) when treating the face
- When treating a patient for the first time, always begin treatment with COURSE A default settings for RF power
- Do not increase power level at once by more than 2 increments
- Exact treatment parameters are individual and should be adjusted (increased or decreased) according to patient feedback and skin tolerance
- Upon reaching the endpoint skin surface temperature, treatment should be continued for at least the recommended exposure time to maintain the generated heat
- In the case of patients with sensitive skin, it is recommended to gradually reduce power level.
- Maximum power level for Applicator 3 is restricted to 30
- During the treatment, make sure to monitor the surface temperature to ensure power settings are suitable
- Never increase surface skin temperature over 43°C (109.4 ° F)

NOTE: When treating facial area, never treat the area below the eyebrow & never treat over the eye lids & eyeballs.

12.2.3 Treatment Parameters

The following table shows the default treatment parameters based on physician's experience with the TriPollar® Applicators.

Treatment Course	Applicator	Default Power Level	Treatment duration (minutes)
Course A	1	18 (5-95)	8 (1-40)
Course B	1	22 (5-95)	8 (1-40)
Course A	2	15 (5-95)	24 (1-40)
Course B	2	27 (5-95)	24 (1-40)
Course A	3	6 (5-30)	10 (1-40)
Course B	3	15 (5-30)	10 (1-40)

Table 5: Treatment Parameters for TriPollar®

Treatment parameters vary between individuals, affected by speed of applicator movement and movement styles. It is important to begin systematically with default parameters when treating a patient for the first time.
Always start a new patient with Course A default parameters. You may use course B in further treatments.
The below table represents treatment values that are based on the range of RF power used for face treatment in clinical trials.

Applicator	Range of RF Power (%)
1	RF Power (%)14-32
2	RF Power (%)20-40
3	RF Power (%)8-25

Table 6: Typical treatment parameters for face treatment

NOTE:

- Always use default RF power settings when treating a patient for the first time
- It is important to define your treatment settings by following the treatment instructions in Section 9.2.3

12.2.4 TriPollar® treatment procedure

Pre-Treatment Preparation

During the first visit, the operator or an authorized staff member should assess the areas intended for treatment and take the following actions:

- Take a detailed patient medical and physical history including previous treatment methods
- Determine if the patient is suitable for treatment - do not treat patients with any of the contraindications outlined in this User Manual
- Determine why the patient is seeking treatment and what his/her expectations are
- Inform the patient as to the course of treatment and possible side effects
- Instruct the patient as to the safety warnings
- Instruct the patient to remove all jewelry prior to treatment

Once treatment area is selected and treatment plan has been discussed with the patient, it is recommended to take a picture of the treatment area for recording the pre-treatment condition in the patient's file.

Performing Treatment Procedure

- Clean the treatment area with soap and water
- Dry completely after cleaning
- Lubricate the treatment area thoroughly using medical grade and high purity Glycerin
- Turn the system on and set the appropriate treatment parameters as described in section 8.3. For the first treatment select COURSE A and begin treatment using default RF power setting.

- An alarm will sound when treatment time reaches half way through the pre-determined exposure time. This will enable you to choose the option of moving to the other facial side
- Provide the patient with the 'Patient-Controlled Manual Switch'; have them position the push button in range of their thumb for easy access. Then explain that they can stop the treatment at any time by pressing the button in case of discomfort
- Have the patient sit / lay in a comfortable position for treatment.
- Measure a baseline skin temperature.
- Position the clean Applicator onto the skin of the patient and move it, then press the Foot Switch for treatment to begin.
- Note the reading of temperature on the LCD screen or in the GUI for reference as a baseline temperature.
- It is recommended to start the treatment using Applicator 1 in order to pre-heat the cheek area, to continue treatment of full face using Applicator 2 and to finalize treatment using Applicator 3 on small delicate areas such as around the eyes and mouth.
- Apply the appropriate applicator with a mild pressure and repeating rubbing/massaging movements on the area. (Elliptical, circular, etc., depending on the area). When administrating the treatment, the applicator should be constantly moved on the skin.
- Monitor patient's skin temperature using the integrated temperature-reading bar located in the screen and in the LED screen of the applicator, for applicators 1 and 2.
- When using applicator no 3, periodically, every 3 minutes, throughout treatment by using a non-contact infrared thermometer. Using the non-contact IR thermometer:
    - Remove the cap; press the "house" button constantly.
    - 2 red IR circles will appear, move the thermometer closer or away from the skin in order to align the 2 red circles.
    - Once they are aligned, stop pressing the "house" bottom.
    - The red circles will flicker and when the stop you may take the reading from the thermometer's screen placed a few centimeters above the skin.

- Treatment endpoint is increasing the skin temperature to above 40°C (104^{0}F) and below 43°C (109.4^{0}F) and maintaining it for a minimum of 10 minutes. Elevated skin temperature should be maintained for at least the recommended exposure time.
- After 1 minute of treatment, if skin temperature does not increase by at least 4°C (39.2^{0}F), power should be increased by 2 units.
- After 1 more minute, if skin temperature does not increase by additional 4°C (39.2^{0}F), power should be increased again by 2 units.
- After 1 more minute, if temperature didn't reach 40°C (104°F), continue increasing power, according to the needed temp adjustment.
- Endpoint temperature of 40-42°C (104-107.6°F) is typically achieved after about 5 minutes of treatment, occasionally slightly more or less time is required, depending on individual skin response.
- During the treatment, mild skin erythema (redness) and /or edema (swelling) may develop. These signs are indications of the heating process.
- While maintaining endpoint temperature, power could be gently adjusted (increased or decreased) according to skin temperature and tolerance.
- After each TriPollar® treatment, the applicator should be cleaned according to section 10.2.

NOTE:

- Never stop applicator's movement on the skin
- When starting a treatment, make sure you are moving the applicator on the skin surface while initiating the RF power by pressing the foot switch

Do not use mineral oils instead of glycerin.

W A R N I N G
• NEVER TREAT OVER THE EYE SOCKET

Post Treatment Care

Refer to the following recommendations to determine your own suitable course of action for post treatment care.

- In case of excessive edema or erythema, cool the area well for at least 15 minutes until heat sensation fades.
- Typically, there will be a slight edema or slight erythema which may last for 1-2 days. If side effect persists beyond the above-indicated period, the patient should seek medical advice.

Treatment Protocol and Conclusion

Normally, treatment should be administrated once a week for at least 4-6 successive weeks.
Additional treatments are recommended every 4-8 weeks, according to individual needs. Treatment should be concluded when operator and patient are satisfied with the results.

- Do not use mineral oils instead of glycerin.

13. MAINTENANCE

13.1 Cleaning the System

Clean the System at least once a week. Turn the System off and wipe all surfaces with a soft, damp, non-abrasive cloth. Be careful not to spill any liquids on the system.

13.2 Cleaning the Applicators

After every treatment, clean the Applicators with special care to the area between electrodes, according to the following procedure:

1. Use a soft cloth, moistened with detergent solution 0.55% ortho-phthalaldehyde disinfectant for 5 minutes (such as Cydex OPA), to clean the Applicator until it is visually clean.
2. Use a new soft cloth, moistened with tap water for 15 seconds, to remove detergent residuals.
3. Use a dry soft cloth to dry the Applicator.
4. Use a soft cloth, moistened with medical grade 70% alcohol solution for 1 minute, to wipe the Applicator.
5. Spray the applicator with medical grade 70% alcohol solution, then wipe with a dry soft cloth. Be careful not to spill any liquids on or into the Applicator.
6. If dirt residues were not fully removed, repeat cleaning steps 1-5.

14. FUSE REPLACEMENT

When the device is not functioning, one of the reasons for it could be a burnt fuse.
In the package you can find two fuses for replacement. The fuses are placed inside a small drawer located inside the AC power Inlet at the back of the device.

In order to expose the fuses, press on the snap and take out the drawer.

Remove both fuses and place new ones instead.
Verify the type and ratings are:
Slow Burn 250V/3.15 A.
Insert drawer back into the AC inlet and confirm lock.

15. Troubleshooting

No.	Failure	Cause of Failure	Description	Action
1.	Device unexpectedly shut down	Mains Electrical power interruption	All indications and display are off	The device will turn back on automatically once power is resume
2.	A1 & A2 applicator LCD disrupted display	Electrical interruption	In case of interference with the applicator LCD display	Please view the data on the system's GUI display.
3.	Applicator does not emit an energy pulse to the treatment area	Foot Switch failure	No feedback on TOUCH SCREEN when Foot Switch is pressed	If System still does not operate properly, contact local Lumenis representative for service.
4.	Applicator does not emit an energy pulse to the treatment area	Patient controlled manual switch is pressed	Warning on the screen "Patient controlled manual switch IS PRESSED" Applicator does not heat the treatment area	Release Patient controlled manual switch , release Foot Switch and press Foot Switch. If System still does not operate properly, contact local Lumenis representative for service.
5.	Applicator does not emit an energy pulse to the treatment area	Applicator connection problem	Applicator key on the screen is dimmed No indication on the Applicator	Check that the relevant Applicator is properly connected with locking mechanism. Replace relevant Applicator If Applicator still does not operating properly, contact local Lumenis representative for service.
6.	Applicator does not heat the treatment area	Mix-up between Applicator connections	No indication on either Applicator. Applicator key on the screen is dimmed	Ensure that Applicator is connected to the correct connector (see Figure 3). If System still does not operate properly, contact local Lumenis representative for service.
7.	Applicator does not heat the treatment area	Patient controlled manual switch is not connected	Software warning "Patient controlled manual switch DISCONNECTED".	Connect Patient controlled manual switch (see Figure 3). If System still does not operate properly, contact local Lumenis representative for service.

8.	No text on the TOUCH SCREEN	Communi-cation problem	ON/OFF power switch is lit.	Switch OFF the system and then switch ON again. If there is still no display on TOUCH SCREEN, stop system operation and contact local Lumenis representative for service.
9.	No backlight on the TOUCH SCREEN	AC/DC Power supply failure	No backlight on the touch screen. ON/OFF power switch is lit. No indication on either Applicator.	Switch OFF the system and then switch ON again. If there is still no display on TOUCH SCREEN, stop system operation and contact local Lumenis representative for service.
10.	Display failure	Touch screen fault	Partial data displayed on the touch screen.	Switch OFF the system and then switch ON again. If there is still no display on TOUCH SCREEN, stop system operation and contact local Lumenis representative for service.
11.	System does not stop treatment when Foot Switch is released	Foot Switch failure	Screen display still operating when Foot Switch is released.	Switch OFF the system and then switch ON again to check Foot Switch. If System still does not operate properly, contact local Lumenis representative for service.
12.	No AC power supply to the unit	One of the inlet fuses is burned	No display on the touch screen. ON/OFF switch is not illuminated in ON position.	Ensure that there is voltage in power supply socket. If ON/OFF switch is still not illuminated in ON position – contact local Lumenis representative for service.
13.	System cannot be switched off	ON/OFF switch failure	System cannot be switched off.	Unplug the device. Contact local Lumenis representative for service.
14.	Unit Fan is not operating	Fan or fan connection failure.	Fan is not operating.	Contact local Lumenis representative for service.
15.	Touch screen does not operate as a control panel	Touch Screen failure.	Touch screen not operating.	Contact local Lumenis representative for service.

16.	Energy cannot be adjusted	Touch Screen failure	No feedback on touch screen when Slider or button are adjusted	Contact local Lumenis representative for service.
17.	Energy cannot be adjusted	Failure to enter treatment Mode.	Machine in Ready Mode	Press shortly on FS to enable Mode calibration
18.	No Energy output	PPB Failure	No Energy output	Contact local Lumenis representative for service.

16. WARRANTY TERMS

This product is subject to strict quality control performed by the manufacturer. For this reason, the distributor in your country guarantees proper function of your product for 12 months from date of actual purchase. If you use the device properly, follow all instructions outlined in the user manual, you can enjoy the product to your ultimate satisfaction.

This policy warrants the support that the distributor provides for the device, should it happen that failures attributable to manufacturing defects be found. In such case, you shall be entitled to make full use of the benefits of this warranty. This implies the reason and replacement of parts, free of charge (regarding both service and parts) at any Authorized Service Center. Within its validity term, you are entitled to make use of the warranty if necessary to have a fully enjoyable product, provided the above-indicated conditions are fully met. This warranty is valid for the device marketed by the distributor in your country.

The warranty is not valid when:

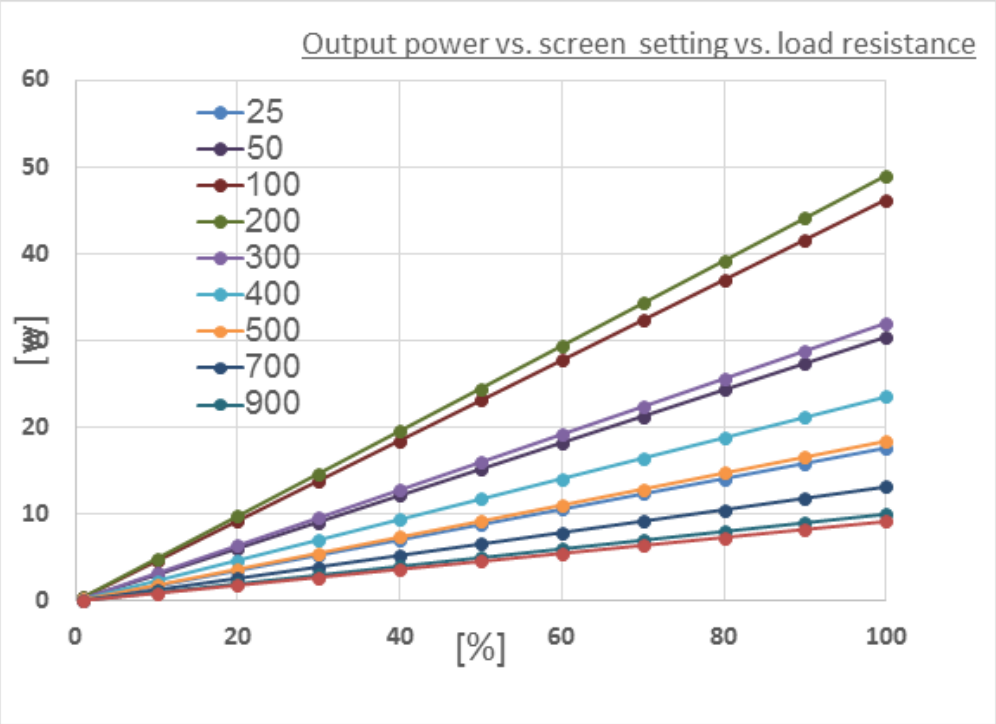
1. Amendments in the warranty policy, sales receipt or invoice, or the absence of any of these original documents.
2. Damage or deterioration of the device due to improper use or if the device has been modified or repaired by an unauthorized third party.
3. Damage of the product due to defects incurred during transportation, such as bumps, bangs or improper handling.
4. Damage due to humidity or any kind of liquids, foreign bodies inside the device or the use of unapproved, unadvised accessories with the device contradictory to the user manual.
5. When the device is not used in accordance with the respective user manual or with its supplied accessories.
6. Partial or total damage or loss of the device, due to natural disasters (such as earthquakes, floods, fire, lightening, etc.), force majeure or accident.
7. Damage to the device after being subject to high dust environments, humidity or application of excessive voltage from the power inlet.
8. If the product's serial number has been amended or erased.
9. To cosmetic damage, including but not limited to scratches and dents.

17. ELECTROMAGNETIC COMPATIBILITY TABLE SHOWN IN SECTION 5.2.2 IEC 60601-1-2 Ed. 4.0 (2014)

Summary of Test Results

Test	Standard	Class/ Severity level	Test result
Emission (IEC 60601-1-2 sec. 7, IEC 60601-2-2 sec. 202.6.1 & IEC 60601-2-10 sec. 202.6.1)			
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11	Group 1 Class B 230 &100 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class B	Complies
Harmonic current emission test	IEC 61000-3-2	AC mains	N/A
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 8, IEC 60601-2-2 sec. 202.6.2 & IEC 60601-2-10 sec. 202.6.2)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	3.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on AC mains; Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±2.0 CM / ±1.0 kV DM on AC mains; Tr/Th – 1.2/50 (8/20) μs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0; 6.0 V_{RMS} on AC mains, & Applicators cables; 0.15÷ 80 MHz, 80% AM 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	30 A/m @ 50 Hz & 60 Hz	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On AC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

18. DIAGRAM FOR THE RF OUTPUT THAT SHOW THE SUBJECT DEVICE POWER OUTPUT VS. OUTPUT CONTROL



Control setting of 10-100% of available maximum power presented

19. DIAGRAM FOR POWER OUTPUT AT FULL AND HALF FOR THE LOAD RANGE OF 25 - 1,000Ω