OPTIMAS

# Operator Manual

## Optimas System

Version: DO608395A

INMODE

aesthetic solutions

Operator Manual: Optimas System with DiolazeXL, Vasculaze, Lumecca, Fractora and Forma Handpieces

DO608395A


Date: February 2019



InMode MD Ltd

Tabor House, Industrial Park South
Yokneam, 206926, POB 44, Israel

Tel.: +972-4-9096313
Fax: +972-4-9096310

# Table of Contents


**1 Section 1: Introduction ..... 1**

1.1 Before You Start ..... 1
1.2 System Overview ..... 1
1.3 Conventions Used in the Manual ..... 1
1.4 Explanation of the Symbols used on the System ..... 2

**2 Section 2: Safety ..... 3**

2.1 The Patient ..... 3
2.2 Treating Attendant ..... 3
2.3 Cautions ..... 4
2.4 Ocular Hazards ..... 4
2.5 Ocular Safety Considerations ..... 5
2.6 Electrical and Mechanical Safety ..... 6
2.7 Fire Hazards ..... 6
2.8 Safety Features of the System ..... 7
2.9 Safe use of the Active Accessories ..... 8
2.10 Warnings ..... 9
2.11 Device Labels ..... 10
2.12 Handpieces Labels ..... 13
2.13 Equipment Classification ..... 15

**3 Section 3: System Installation ..... 16**

3.1 Electrical Requirements ..... 16
3.2 Environmental Requirements ..... 16
3.3 Equipment List ..... 16
3.4 Unpacking ..... 17
3.5 Installation ..... 18
3.6 Filling Water ..... 18
3.7 Moving the System ..... 18
3.8 System Disposal ..... 19

**4 Section 4: Device Description ..... 20**

4.1 Rear Panel ..... 20
4.2 Front Panel and Operator Control Panel ..... 21
4.3 Software Screens ..... 22
4.4 Sound Indicator ..... 29
4.5 Cut-Off Temperature Control ..... 29
4.6 Handpieces ..... 30

**5 Section 5: System Operation ..... 34**

5.1 Device Start-Up ..... 34
5.2 System Shutdown ..... 35

6 Section 6: DiolazeXL Treatment Information ..... 36

6.1 Instructions for Use ..... 36
6.2 Contraindications ..... 36
6.3 Possible Adverse Effects ..... 37
6.4 Pre-treatment Recommendations ..... 38
6.5 Tip Cleaning Instructions Prior to Use ..... 38
6.6 Treatment Recommendations ..... 38
6.7 Treatment Schedule ..... 40
6.8 Post-treatment Recommendations ..... 40

7 Section 7: Vasculaze Treatment Information ..... 41

7.1 Indications for Use ..... 41
7.2 Contraindications ..... 41
7.3 Possible Adverse Effects ..... 42
7.4 Pre-treatment Recommendations ..... 42
7.5 Tip Cleaning Instructions Prior to Use ..... 43
7.6 Treatment Recommendations ..... 43
7.7 Treatment Schedule ..... 45
7.8 Post-treatment Recommendations ..... 45

8 Section 8: Lumecca Treatment Information ..... 46

8.1 Indications for Use ..... 46
8.2 Contraindications ..... 46
8.3 Possible Side Effects ..... 47
8.4 Pre-treatment Recommendations ..... 47
8.5 Tip Cleaning Instructions Prior to Use ..... 48
8.6 Test Spots ..... 48
8.7 Treatment Recommendations ..... 49
8.8 Post-treatment Recommendations ..... 50
8.9 Treatment Schedule ..... 50

9 Section 9: Fractora Treatment Information ..... 52

9.1 Fractional Skin Resurfacing ..... 52
9.2 Indications for Use ..... 52
9.3 Contraindications ..... 52
9.4 Possible Adverse Side Effects ..... 54
9.5 Pre-treatment Recommendations ..... 54
9.6 Tip Cleaning Instructions Prior to Use ..... 55
9.7 Test Spots ..... 55
9.8 Treatment Recommendations ..... 56
9.9 Treatment Schedule ..... 57
9.10 Post-treatment Recommendations ..... 57

10 Section 10: Forma Treatment Information ..... 59

10.1 Indications for Use ..... 59

10.2 Contraindications ..... 59
10.3 Possible Adverse Effects ..... 60
10.4 Handpiece Cleaning Instructions Prior to Use ..... 60
10.5 Pre-treatment Recommendations ..... 61
10.6 Treatment Recommendations ..... 61
10.7 Treatment Schedule ..... 64
10.8 Post-treatment Recommendations ..... 64

**11 Section 11: System Maintenance ..... 66**

11.1 Maintenance & Frequency ..... 66
11.2 Before and after each treatment ..... 66
11.3 Once a Week ..... 66
11.4 Once a Month ..... 66
11.5 Once a Year ..... 66
11.6 Filling Water for DiolazeXL, Vasculaze and Lumecca ..... 67
11.7 Draining Water for VASCULAZE, DIOLAZEXL and LUMECCA ..... 69
11.8 Draining the Laser/IPL Handpieces with the Water Draining Tool ..... 70
11.9 Replacing the Deionizer Cartridge ..... 71
11.10 Replacing the Capsule Filter ..... 72
11.11 Air Filter ..... 73

**12 Section 12: Troubleshooting ..... 75**

12.1 Description of Faults with All Handpieces ..... 75

**13 Section 13: System Specifications ..... 77**

13.1 Output Power Curves ..... 79
13.2 EMC Safety ..... 80

**14 Table from IEC60601-1-2, / 5.2.2.1 C&F ..... 85**

# 1 Section 1: Introduction

## 1.1 Before You Start

The manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique to be performed.

Federal (USA) law restricts sale of this device by or on the order of a physician.

Read this manual to become familiar with all safety requirements and operating procedures before attempting to operate the System.

## 1.2 System Overview

The InMode Platform with DiolazeXL, Vasculaze, Lumecca, Fractora and Forma Handpieces is marketed as the Optimas System which employs three different technologies for various aesthetic applications – Laser, Intense Pulsed Light (IPL), and Radio-frequency (RF).

The Optimas System operates while in contact with any of the following Handpieces: DiolazeXL (laser for hair removal), Vasculaze (laser for vascular lesions), Lumecca (IPL for skin rejuvenation), Fractora (RF for fractional resurfacing), and Forma (RF for facial wrinkle treatment). The System provides individual adjustment of treatment parameters to achieve maximum efficiency and safety for each patient.

## 1.3 Conventions Used in the Manual

The following conventions in the form of notes and warnings are used in this manual:

WARNING! This information is extremely important!

ATTENTION! Consult Accompanying Document.

NOTE! Provides general information that is important to keep in mind.

## 1.4 Explanation of the Symbols used on the System

| Symbol | Description |
|---|---|
|  | CSA marking<br>(212603 CSA master contract number) |
|  | Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner |
|  | Fuse |
|  | Type BF Equipment |
|  | Type B Equipment. |
|  | HF Isolated Patient Circuit |
|  | Follow the operating instructions |
|  | Federal (US) law restricts this device to sale by the order of a physician licensed by the law of the state in which he practiced to use or order the use of the device |
|  | Do not reuse/single use only. This symbol is used for disposable one-time-use products. |
|  | This equipment intentionally supplies non-ionizing RF energy |

***Table 1-1: Device Symbols***

# 2 Section 2: Safety

This chapter describes safety issues regarding the use and maintenance of the Optimas System, with a special emphasis on electrical and laser safety.

The System is designed for safe and reliable treatment when used in accordance with proper operation and maintenance procedures. Only trained, qualified practitioners can use the System. The operator and all other personnel operating or maintaining the System should be familiar with the safety information provided in this section.

The primary consideration should be to maximize safety for both the treating attendant and the patient.

Read this chapter to be familiar with all its safety requirements and operating procedures prior to system operation.

The laser, IPL or RF energy can cause injury if used improperly.

High voltage is present inside the System.

Always be aware of the possible dangers and take proper safeguards as described in the manual.

## 2.1 The Patient

- Well-trained staff is key for assuring patient safety. A patient history report should be completed prior to scheduling. Patients should be fully informed of the treatment details, the likely results and any risks associated with the treatment.
- Jewelry and metal accessories that are within the activation range of the Handpiece should be removed to avoid accidental laser/light reflection or RF conduction, as applicable.
- Protective eyewear must be used by the patient during DiolazeXL laser, Vasculaze laser or Lumecca IPL treatments

## 2.2 Treating Attendant

- Only authorized individuals with appropriate training and knowledge should operate, assist in the operation of, or provide maintenance to the Optimas System.
- Personnel should not operate the System until they have been fully educated in its use. Make sure that all treatment personnel are familiar with the System controls and know how to shut down the System instantly.

- There are no user-serviceable parts in the System, and all service and repair must be performed only by the factory or authorized field service technicians.
- Protective goggles must be used by all treatment attendants when using the DiolazeXL laser, Vasculaze laser or the Lumecca IPL Handpieces

## 2.3 Cautions

The following cautions should be heeded for safe System use:

- Do not touch the System's inner parts.
- Service is supplied by company authorized personal only.
- To avoid damage, do not allow the Handpiece to come in contact with hard materials.

## 2.4 Ocular Hazards

- The light emitted by the DiolazeXL laser Handpieces and Vasculaze laser Handpiece is capable of causing serious eye damage or blindness. The light emitted by the Lumecca handpieces is capable of causing eye irritation or damage.
- All persons potentially subject to exposure must wear protective goggles or eyewear whenever the main power is on, in accordance with national and international standards. The protective eyewear must have an optical density (OD) of 5 or greater at the DiolazeXL wavelength of 810nm, and at the Lumecca wavelength of 515-1200nm.
- For users outside the U.S., the appropriate standard may be EN 207, in which case the safety eyewear must have a protection class of L5. The protective eyewear must have an optical density (OD) of 5 or greater at the DiolazeXL laser wavelength of 730 - 1085nm (OD 5); 755nm (OD 7); 1064nm (OD >6); at the Vasculaze laser wavelength 1064nm (OD >6)) and at the Lumecca IPL wavelength of 515-1200 nm. For users outside the U.S., the protection values are for 1064nm, DIR LB6 + IR LB7, approved by PSP S CE.
- The laser and the IPL are to be operated only in an enclosed room with protective eyewear for all persons; direct eye exposure is not safe at any distance within the room. All windows in the laser room must be covered with opaque material, and measures should be taken to prevent unauthorized access to the room.
- For the laser, remote interlock is provided, which can be connected to the treatment room doors, disabling laser output if the door is opened during a procedure. In addition, compliance with ANSI Z1 36.3 and EN 60825-l requires that laser safety signs be posted at all entrances whenever the laser is in use.

Compliance with IEC60601-2-57 requires that warning label from IR exposure be posted at all entrances whenever the IPL is in use. Approved sign is provided with each System along with protective eyewear.

- Additional eyewear or safety signs may be obtained from the manufacturer.
- Never look directly into the laser aperture at the distal end of the Handpiece, even if you are wearing safety glasses. Serious eye injury or blindness could result.
- Avoid directing the laser beam anywhere other than the calibration port or intended treatment area. Stray laser light and reflection is always a potential hazard and may cause serious injury.
- Do not treat eyebrows, eyelashes, or other areas within the bony area surrounding the orbit.
- The light emitted by the laser or the IPL is capable of causing serious eye damage or blindness. For maximum safety, metal eye goggles must be worn by the patient for all facial treatments when laser is used.

## 2.5 Ocular Safety Considerations

- Identify the laser room clearly by posting approved safety signs in prominent locations.
- Cover all windows to prevent laser light from escaping the laser room.
- Restrict entry to the treatment room when the laser or IPL is in use. Allow access to those personnel both essential to the procedure and well trained in safety issues.
- Never direct the laser beam at anything other than the calibration port or the intended treatment site.
- Never look directly into the laser aperture at the distal end of the Handpiece.
- All persons in the treatment room must wear approved laser safety eyewear. This includes the operator, patient, nurses, and any other persons in the treatment room.
- Do not attempt to remove the plastic shell protective covers on the Handpiece which could allow exposure to high intensity laser light.

## 2.6 Electrical and Mechanical Safety

- Keep all covers and panels of the System closed. Removing the covers creates a safety hazard.
- Keep hands away from the applicator during the System start-up.
- Perform maintenance procedures when the System is shut down and disconnected from the power.
- The System is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.
- Move the System slowly and carefully. The System weighs approximately 32kg (70.5lb.) and may cause injury if proper care is not used when moving it.
- Provide as much distance as possible between the System, RF Handpiece and other electronic equipment as the activated RF generator may cause interference between them.

## 2.7 Fire Hazards

- The absorption of diode laser or IPL energy raises the temperature of the absorbing material. Do not use the System in the presence of explosive or flammable materials.
- Materials conducting RF energy may cause temperature rise of the absorbing material. Do not use the System in the presence of explosive or flammable materials conductive to RF.
- Do not use flammable substances when preparing the skin for treatment. Be especially careful with the use of oxygen.
- Keep drapes and towels moist to prevent them from igniting and burning. Use non-flammable prepping solutions.
- If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the System is used.

## 2.8 Safety Features of the System

The System incorporates the following safety features. All personnel operating the System should be familiar with these features.

- The System has unique password to avoid device operation by non-authorized personnel.
- The power electronics cannot be activated unless the applicator and Footswitch have been connected to the System. With IPL, connection of the applicator is sufficient.
- An audible tone indicates energy activation.
- During activation, the System performs a self-test of the hardware.
- Hardware is tested every 10ms to ensure proper operation of electrical circuit.
- Tissue impedance monitoring prevents accidental RF energy emission to the patient.
- Skin surface is monitored during the treatment of Forma Handpiece. RF energy delivery is terminated when skin temperature reaches the Cut-Off level.
- The System starts at a low setting.
- Temperature monitoring which disables system operation if the Handpiece sapphire temperature is outside the operating range for, DiolazeXL, Vasculaze and Lumecca Handpieces only.

The System with the DiolazeXL and Vasculaze Handpieces includes a comprehensive monitoring system that allows operation only when numerous safety conditions have been met. A fault must be corrected and the System reset before laser operation is re-enabled. The monitoring system includes the following:

- Remote interlock that allows laser emission only when electrical continuity is made across the contacts of the remote interlock connector located on the rear of the console. The System is shipped with a remote interlock jumper already connected, providing electrical continuity and allowing the laser to operate. To set up a remote interlock switch, such as on the treatment room door, please contact qualified personnel.
- The DiolazeXL and Vasculaze hand triggers allow laser emission only when the Footswitch is pressed.
- Laser Energy monitoring to verify that the laser output is within specific energy tolerances for every laser pulse. If abnormally low or high laser current (indicative of optical energy) is detected, a System fault is triggered and the user is notified.

- Temperature monitoring which disables System operation if the Handpiece sapphire temperature is outside the operating range.

- As a safety feature and in compliance with U.S. and international regulations, the DiolazeXL and Vasculaze Handpieces contain an electronic shutter to help prevent inadvertent laser emission. Located in the console, the shutter is an electronic switch that is independent of, and in addition to, the normal energy circuit for the laser ON.

- Releasing the DiolazeXL and Vasculaze Handpiece's trigger will stop laser emission. In the event of an emergency, the laser can be shut down immediately by pushing the emergency stop button located on the console. To restore operation, rotate the button in the clockwise direction until it pops out again. Then follow the standard startup sequence. Since the emergency stop switch is not intended for routine use, please follow the procedure in the System Operation Section for normal shutdown.

**For the RF applications:**

There is a skin temperature monitoring for Forma Handpiece.

## 2.9 Safe use of the Active Accessories

- Examine the connection of the Handpiece through the connectors to the System before using. Ensure that the accessory functions as intended. Improper connection may result in arcs and sparks, accessory malfunction, or unintended treatment effects.

- Do not wrap the Handpiece cords around metal objects. It may induce current that could lead to electrical shocks, fire or injury to the patient or personnel.

- Don't direct the laser or IPL towards the window, other treatment attendants or on patient areas that are not intended to be treated.

- When using the RF applicators, ensure that both electrodes are in full contact with the skin. Bad coupling of electrodes with the skin results in a specific warning sound, a message on the screen, and disabling of RF.

Do not connect a wet accessory to the System.

Do not immerse the applicator under water at any time.

## 2.10 Warnings

This equipment is for use only by qualified medical professionals trained in the particular technique to be performed.

Only handpieces manufactured or approved by InMode MD Ltd. should be used with Optimas System.

Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.

Connect the System power cord to a properly grounded receptacle. Do not use power plug adapters.

Always turn off and unplug the device before cleaning.

The patient and treatment attendants must use protective eyewear during the use of laser and IPL.

The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth. The use of antistatic sheeting is recommended for this purpose. Treatment bed or chair should not be electric.

Use the lowest output setting necessary to achieve the desired treatment effect. The higher RF or laser/IPL energy is applied, the greater the possibility of unintended thermal damage.

Failure of the equipment could result in an unintended increase of output power.

The cables of the Handpiece should be positioned in such a way that contact with the PATIENT or other leads is avoided.

Fire / Explosion Hazard - The following substances will contribute to increased fire and explosion hazards in the operating room:

- Flammable substances (such as alcohol-based skin prepping agents and tinctures).
- Naturally occurring flammable gases which may accumulate in body cavities such as the bowel.
- Oxygen enriched atmospheres.

– Oxidizing agents (such as nitrous oxide [N2O] atmospheres).

– Endogenous gases.

The optical or RF energy and heating associated with the System can provide an ignition source. Observe fire precautions at all times. When using Optimas in the same room with any of these substances or gases, prevent their accumulation or pooling within the area where Optimas procedures are performed.

The operation of the Optimas may adversely influence the operation of other electronic EQUIPMENT.

To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.

## 2.11 Device Labels

As required by national and international regulatory agencies, appropriate warning and information labels have been attached in specific locations on the instrument as identified below.

The following device labels are located on the Optimas device console and the handpiece:


***Figure 2-1: System Certification and Identification Label***

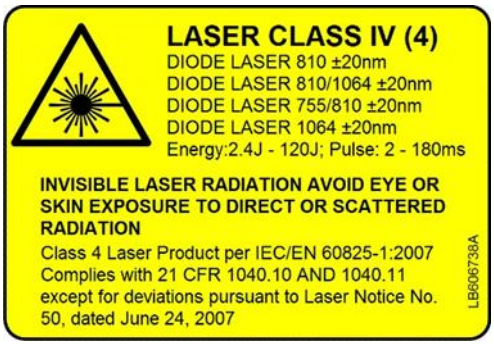



***Figure 2-2: Laser Emission Warning Label***

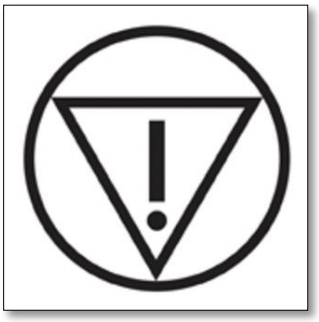


***Figure 2-3: Emergency STOP Label on Emergency Red Button***

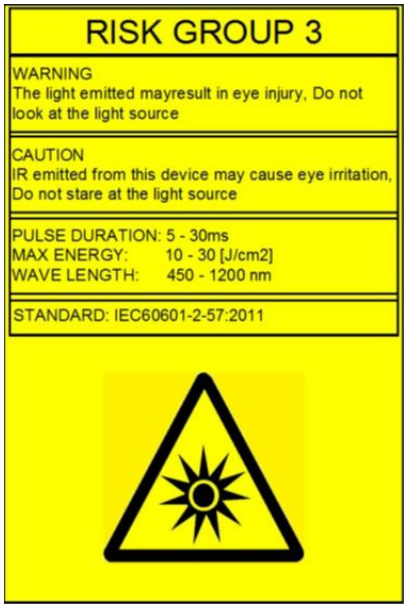



***Figure 2-4: IPL Warning Label***


***Figure 2-5: IPL Emissions Warning Label***

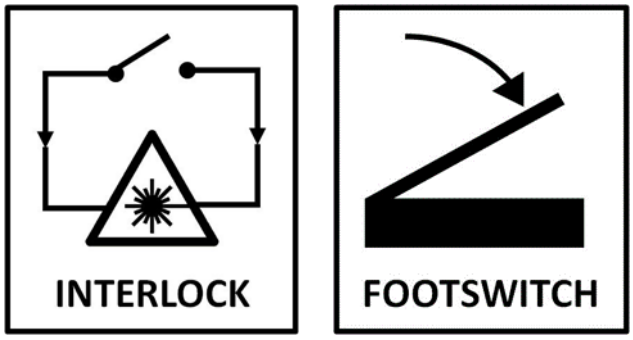



***Figure 2-6: Interlock and Footswitch Label***


***Figure 2-7: USA Federal Restriction Label***

## 2.12 Handpieces Labels

The Handpiece certifications and identification labels are attached to connectors on the Handpieces. It states that the product conforms to the performance standards, and indicates the manufacturer's name, date of manufacturing, model and serial number of the handpiece. The following labels are located on the Handpieces: Manufacturer identification labeling is placed on the Hand pieces:

- Laser aperture label placed on the Handpiece connector.
- Manufacturer identification labeling placed on the Handpiece connector.


***Figure 2-8: Lumecca Handpieces Label for IPL Aperture***


***Figure 2-9: DiolazeXL and Vasculaze Handpieces Label for Laser Aperture***

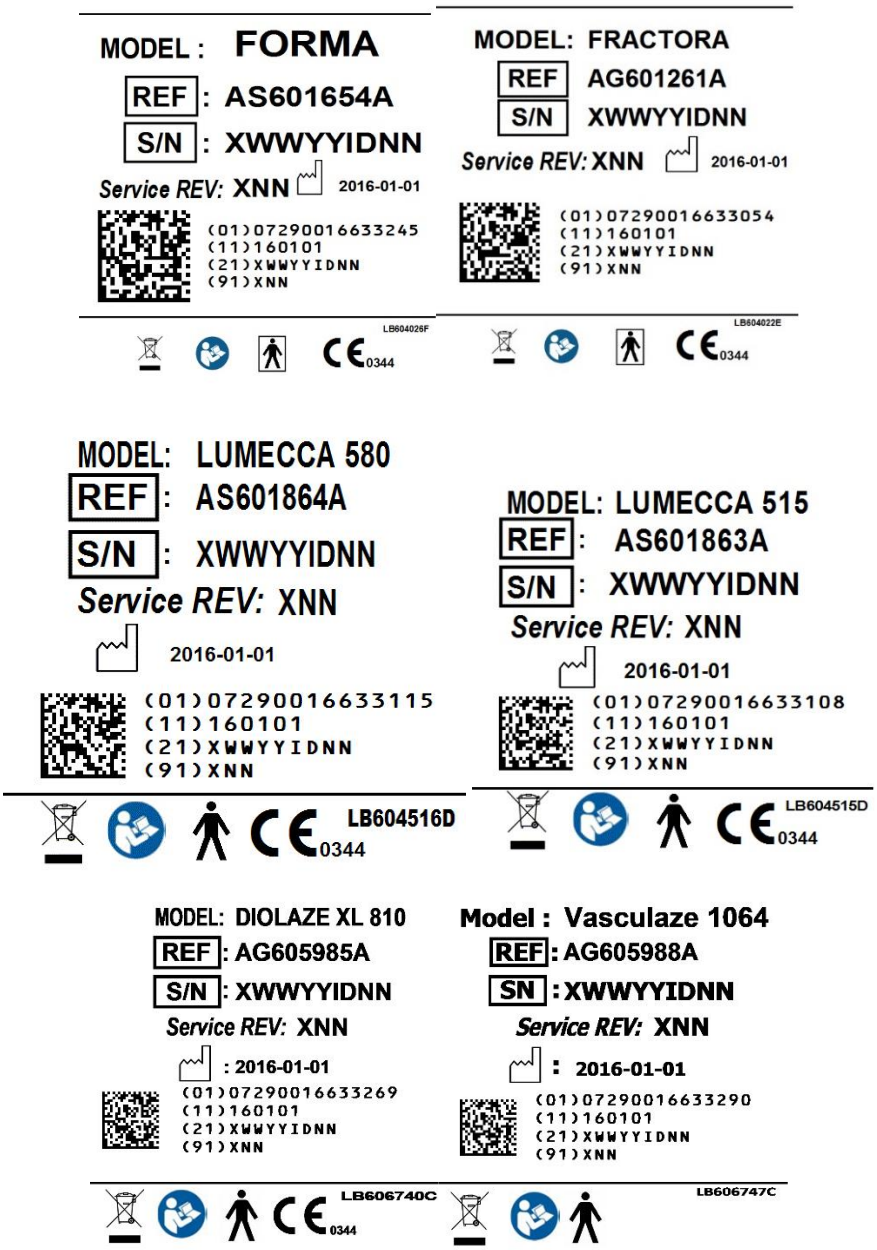



*Figure 2-10: All Handpiece Identification Labels*


*Figure 2-11: DiolazeXL 810 Handpiece Connector Label*

## 2.13 Equipment Classification

The following is a list of the different equipment used and their classifications.

- Electric shock protection: Class I, Defibrillation-proof Type B for the optical Handpieces - DiolazeXL, Vasculaze and Lumecca, and Type BF for the RF Handpieces – Fractora and Forma.
- Protection against ingress of liquids: Ordinary equipment.
- Not suitable for use in presence of flammable substance.
- Power receptacle must include protective earth and must be checked before connecting the System.

The Optimas System with d DiolazeXL and Vasculaze Handpieces complies with 21 CFR, Chapter L Subchapter J, as administered by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA). CE-labeled devices comply with all appropriate performance standards as specified in Annex III of the Medical Device Directive MDD 93/42/EEC. The Optimas System with DiolazeXL and Vasculaze Handpieces is classified as a Class IV laser by the CDRH and as a Class 4 laser by the European Standard EN 60825-l.

The Optimas System with Lumecca IPL Handpieces is classified as IIb device defined by the Medical Device Directive (93/42/EEC) for CE marking. The Optimas System with RF Handpieces - Fractora and Forma is classified as IIb device defined by the Medical Device Directive (93/42/EEC) for CE marking.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

# 3 Section 3: System Installation

## 3.1 Electrical Requirements

- The System will require a separate line supply of single phase (100Vac; 15A) or (115Vac; 15A) or (230Vac; 15A) or (240Vac; 15A) 50-60Hz. Zmax = 0.03Ω.
- Power receptacles must be within 15 feet of the System site.
- The System should not share a power line with other equipment.
- Power receptacle must include protective earth and must be checked before connecting the System.

For continued protection against fire, replace the fuse only with one of the same type and rating.

Proper grounding is essential for safe operation.

## 3.2 Environmental Requirements

- Corrosive materials can damage electronic parts; therefore, the System should operate in a non-corrosive atmosphere.
- For optimal operation of the System, maintain room temperature between 20º-27ºC (68º-79ºF) and relative humidity of less than 80%.

## 3.3 Equipment List

The System includes the following:

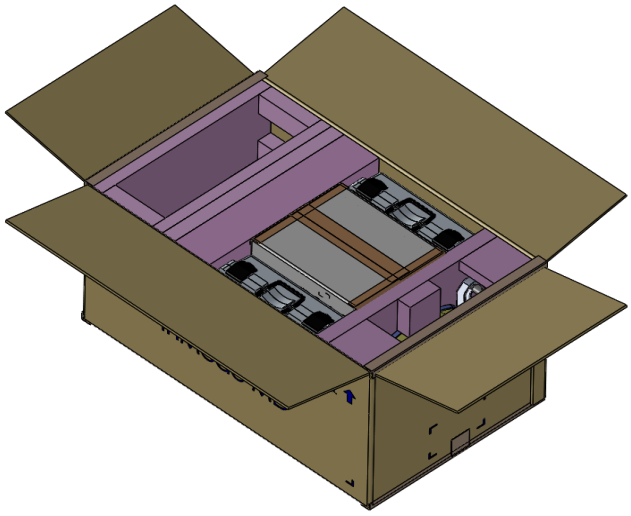
- System platform
- Handpieces
- Handpieces cradles
- Footswitch
- Operator manual
- Power cord

- User protective goggles
- Patient eyewear
- “Laser Danger” door sign

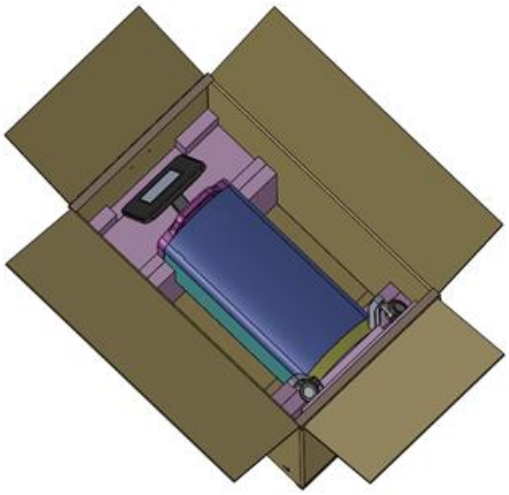
## 3.4 Unpacking

In order to unpack the device:

1. Remove the paper strip and open the box



2. Remove accessories and foams around the device.



3. Take the device out of the box using top and bottom handles.

## 3.5 Installation

The System is designed for installation in a clinic environment. To install the System, perform the following tasks:

- Check the System and all its components for damage.
- Add water. Use the Maintenance Screen.
- Connect cradle to the device (Fig. 3.1).
- Connect Handpiece to the connector and place into the cradle.
- Connect the Footswitch.
- Connect the power cord to the System inlet.
- Plug the System Power Cord into an appropriate electrical outlet.

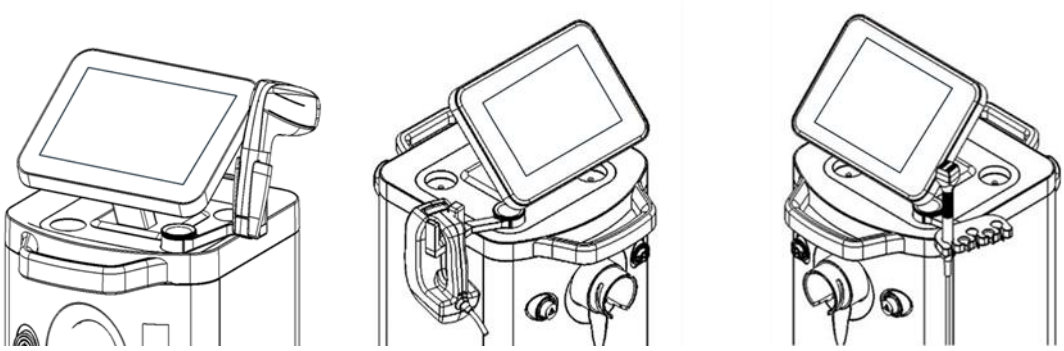


***Figure 3-1: Cradle Connections to the Device***

## 3.6 Filling Water

Optimas System and DiolazeXL, Vasculaze and Lumecca Handpieces are shipped without water. Distilled water must be used and failure to do so will void the service warranty. For detailed instructions refer to Section 10 – System Maintenance.

## 3.7 Moving the System

- Turn the System off.
- Disconnect the Power Cord.
- Disconnect the Handpieces.
- Disconnect the Footswitch.

- Release the Wheel Brakes.
- Slowly push or pull the System using the handle.
- When moving the System to another facility, lift the System to the vehicle and lay it carefully on its side.
- For shipment with DiolazeXL, Vasculaze and Lumecca, drain the water from the System and the Handpieces, as described in Section 9 - System Maintenance.


Never lift, pull or push the System using the operating panel.


Always use the handles when moving the System.


Upon unpacking, check the System for mechanical damage (e.g., cracks in the cable insulation).


Never leave the System or/and handpieces with water in, exposed to freezing temperatures (< 4°C).

## 3.8 System Disposal

To comply with European Commission Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and other country and state regulations, please DO NOT dispose of this equipment in any location other than designated locations.

# 4 Section 4: Device Description

## 4.1 Rear Panel

| | |
|---|---|
|  | **Power Cord Inlet**<br>100-240V~, 15A, 50-60Hz. |
|  | **Fuse Holder**<br>Rating is T 12A, 250V. Replace fuses if needed, only with fuses having exactly the same rating. |
|  | **Software Flash Memory Plug**<br>The software plug is a flash memory with the machine software. The software plug should be screwed to the connectors. To tighten and/or loosen the screws use fingertips only. Do not use screwdriver as it can damage the connectors. |
|  | **Footswitch Connector**<br>Footswitch is connected to the inlet. Footswitch activates RF energy if the System is in Ready mode. Place the Footswitch on the floor near the treatment area. |
| **RF Handpiece Connector** | The Handpiece connector is located on the upper right side of the rear panel and connects to one of the RF Handpieces (Fractora and Forma). |

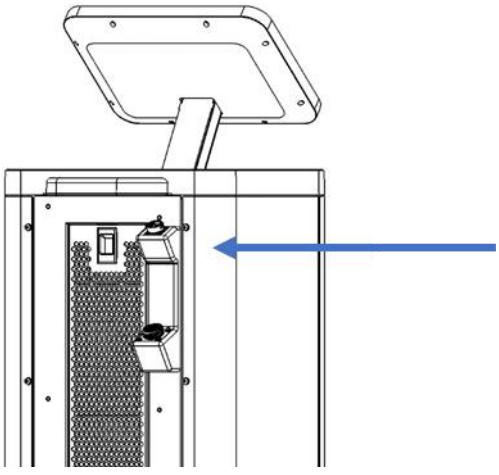


***Figure 4-1: RF Connector on the Rear Panel (Arrow)***

## 4.2 Front Panel and Operator Control Panel

The Operator Control Panel is located on the upper side of the System. The Operator Control Panel consists of an LCD touch screen.

On the front panel, there is a grey On/Off switch on your left, a red Emergency Stop Button on the right, and a Handpiece connector (arrow) in the center for either DiolazeXL, Vasculaze or Lumecca.

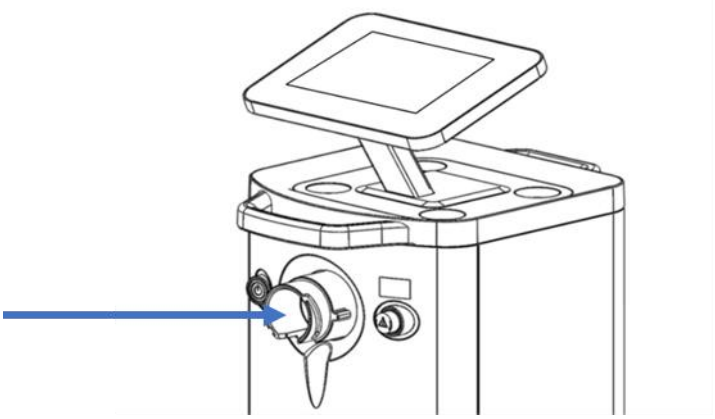


***Figure 4-2: Front Panel and Operator Control Panel with Optical Handpiece connector (Arrow)***

| | |
|---|---|
| **Power On-Off Switch** | Power switch turns System On and Off. |
| **Optical Handpiece Connector** | Located in the center of the front panel and connects to one of the optical Handpieces. |
| **Emergency Stop Button** | Stops the power instantly in emergency conditions. |
| **LCD Screen** | ▪ The LCD screen shows information about the System mode and treatment parameters.<br>▪ The panel allows changing treatment parameters and System mode. |

Power electronics is not activated if no Handpiece is connected to its connector on the front or the rear panel. The System recognizes the connected Handpiece and enables opening the relevant screen, except for Fractora and Forma that the user has to ascertain the match between the Handpiece connected on the rear panel and the screen.

## 4.3 Software Screens

The Progress screen appears after the On-Off switch is turned on.

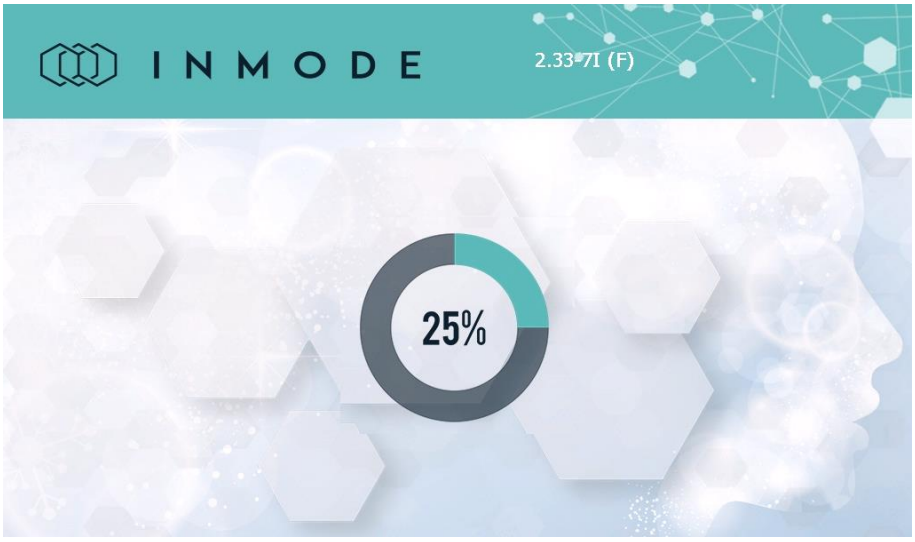



***Figure 4-3: Progress Screen***

*The SW version number will be displayed according to the software version.

After entering the individual code on the Login Screen, non-authorized use of the device is prevented.

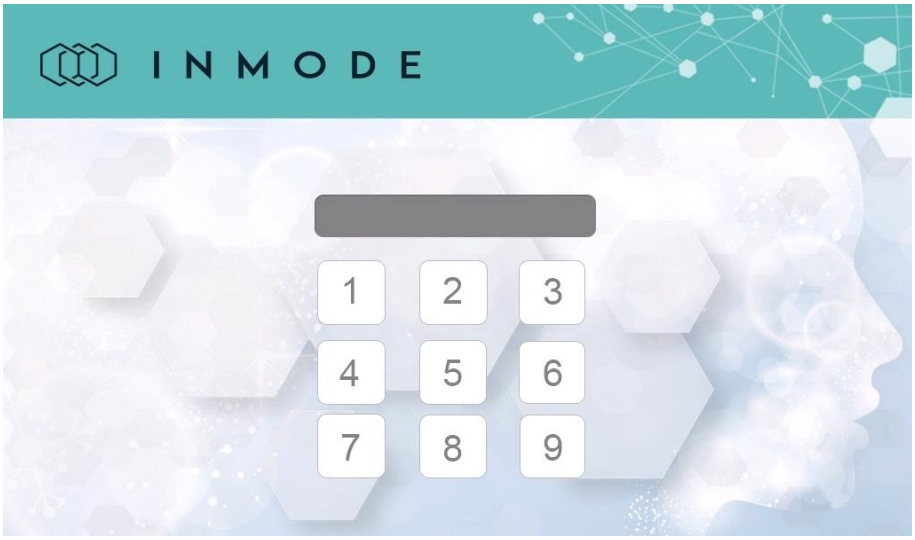



***Figure 4-4: Login Screen***

Software is loaded from the plug and self-test of the System modules is performed. After the end of the self-test the Menu Screen appears.


***Figure 4-5: Menu Screen***

The Menu Screen allows the selection of the connected Handpiece, or entry to the Utilities Screen.


***Figure 4-6: Utilities Screen***

The Utility Screen contains:

| | |
|---|---|
| **Volume** | This function allows the user to adjust the System volume. |
| **Drain / Fill Water** | Drain water from the DiolazeXL, Vasculaze and Lumecca Handpieces and System prior to shipment and fill water during installation. |
| **Change Password** | Change the password by entering the old password and then entering another 4-digit password. |
| **Calibration** | External validation module for optical Handpieces – DiolazeXL, Vasculaze and Lumecca. |
| **Main Menu** | Return to the Main Menu to select an applicator. |

After returning to the Menu Screen and choosing the application on the Menu Screen, the corresponding Treatment Screen appears.

When choosing the DIODE icon on the Menu Screen, the System recognizes the connected DiolazeXL Handpiece.

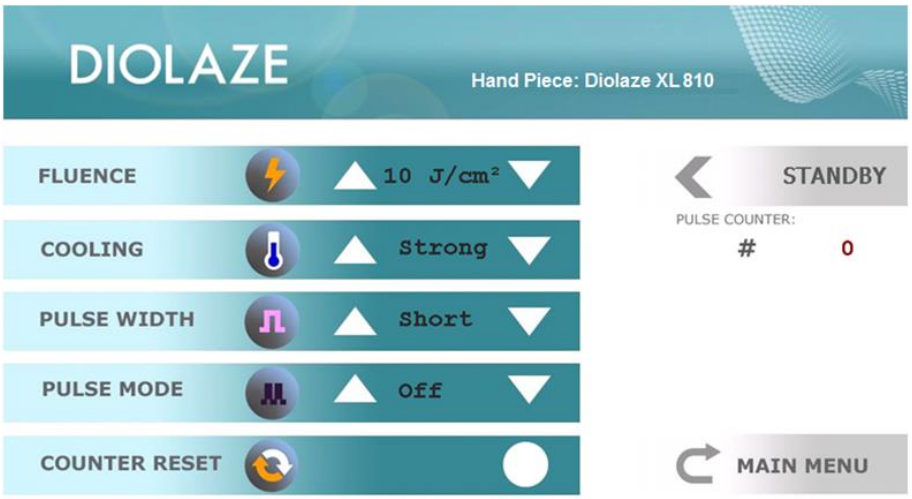



***Figure 4-7: DiolazeXL Treatment Screen***

The DiolazeXL Treatment Screen contains:

| | |
|---|---|
| **Selection Frame** | The frame selects parameters that can be changed by the function keys. |
| **Fluence** | Fluence (light energy density) is changed within the limits from 5 to 40J/cm² for DiolazeXL and the System starts up at the minimal setting. |

| | |
|---|---|
| **Cooling** | Normal and Strong cooling, 12 and 7°C, respectively, can be selected for DiolazeXL. |
| **Pulse Width** | Short or Long pulse can be selected for DiolazeXL. |
| **Pulse Mode**<br>**Note:**<br>**pps = Pulse Per Second** | Off (Single) 5-40J/cm2<br>1pps 5-40J/cm2<br>2pps 5-25J/cm2<br>Glide 5-10J/cm2 |
| **Counter Reset** | The Pulse Counter can be reset. |
| **Pulse Counter** | Shows the number of pulses delivered from the beginning of the treatment. |
| **System Mode** | The System has four treatment modes:<br>**Standby mode -** allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode.<br>**Armed mode -** when the Footswitch is pressed, before the hand trigger.<br>**Ready mode -** when the System is waiting for a signal from the trigger switch to activate the energy. Any attempt to change the treatment settings switches the System to Standby mode.<br>**Active mode -** when the laser is pulsed by pressing the hand trigger. |
| **Main Menu** | Return to the Main Menu to select another applicator and change the applicator if needed. |

When choosing the DIODE icon on the Menu Screen, the System recognizes the connected Vasculaze Handpiece.


***Figure 4-8: Vasculaze Treatment Screen***

The Vasculaze Treatment Screen contains:

| | |
|---|---|
| **Selection Frame** | The frame selects parameters that can be changed by the function keys. |
| **Fluence** | Fluence (laser energy density) is changed within the limits from 100 to 300J/cm², and the System starts up at the minimal setting. |
| **Cooling** | Select between Strong and Normal cooling of lightguide. |
| **Pulse Mode** | Select between Off (Single pulse) or 1pps (Pulse Per Second). |
| **Pulse Width** | Short or Long pulse can be selected. |
| **Counter Reset** | The Pulse Counter can be reset. |
| **Pulse Counter** | Shows the number of pulses delivered from the beginning of the treatment. |
| **System Mode** | The System has four treatment modes:<br>**Standby mode-** allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode.<br>**Armed mode -** when the Footswitch is pressed, before the hand trigger.<br>**Ready mode -** when the System is waiting for a signal from the trigger switch to activate the energy. Any attempt to change the treatment settings switches the System to Standby mode.<br>**Active mode -** when the laser is pulsed by pressing the hand trigger. |
| **Main Menu** | Return to the Main Menu to select another applicator and change the applicator if needed. |


***Figure 4-9: Lumecca 580 Treatment Screen (same screen for 515)***

The Lumecca 580 or 515nmTreatment Screen contains:

| | |
|---|---|
| **Selection Frame** | The frame selects parameters that can be changed by the function keys. |
| **Fluence** | Fluence (light energy density) is changed within the limits from 5 to 30J/cm² for Lumecca and the System starts up at the minimal setting. |
| **Cooling** | Normal and Strong cooling can be selected for Lumecca. |
| **Pulse Width** | Short or Long pulse can be selected. |
| **Pulse Mode** | Repeat mode in Normal or Fast repetition rate or in Off as a single pulse mode. |
| **Counter Reset** | The Pulse Counter can be reset. |
| **Pulse Counter** | Shows the number of pulses delivered from the beginning of the treatment. |
| **System Mode** | The System has three treatment modes, Standby, Ready, and Active.<br>**Standby mode -** allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode.<br>**Ready mode -** the System is waiting for a signal from the Footswitch to activate the energy. Any attempt to change the treatment settings switches the System to Standby mode.<br>**Active mode** - when the signal from the Footswitch is indicated, the System switches to Active mode. Any attempt to change the treatment settings switches the System to Standby mode |
| **Main Menu** | Return to the Main Menu to select another applicator and change the applicator if needed. |


***Figure 4-10: Fractora Treatment Screen***

The Fractora Treatment Screen contains:

| | |
|---|---|
| **Selection Frame** | The frame selects parameters that can be changed by the function keys. |
| **Tip Type** | Allows selecting between different tip types of Fractora. |
| **Energy** | Delivered energy is changed from level 5 to 62 energy levels and the System starts up at the minimal energy setting. |
| **Pulse Mode** | Allows choosing between single pulse and pulse trains ranging from 0.5 to 2 pulses per second (pps). |
| **Counter Reset** | The Counter can be reset. |
| **Pulse Counter** | Shows number of pulses delivered on one zone and the total number of pulses from the beginning of the treatment. |
| **System Mode** | The System has three treatment modes: Standby, Ready, and Active.<br>**Standby mode-** allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode.<br>**Ready mode -** the System is waiting for a signal from the foot switch to activate the energy. Any attempt to change the treatment settings switches the System to Standby mode.<br>**Active Mode** - when the signal from the Footswitch is indicated, the System switches to Active mode. Any attempt to change the treatment settings switches the System to Standby mode. |
| **Main Menu** | Return to the Main Menu to select another applicator and change the applicator if needed. |


***Figure 4-11: Forma Treatment Screen***

The Forma Treatment Screen contains:

| | |
|---|---|
| **Selection Frame** | The frame selects parameters that can be changed by the function keys. |
| **Energy** | Delivered energy is changed from level 20 to 62 energy levels and the System starts up at the minimal power setting. |
| **Cut Off** | Cut-off temperature settings are changed in the range of 35-43°C. When measured skin surface temperature reaches the pre-set limit the RF energy is cut off. |
| **Pulse Mode** | Allows selecting between single RF pulses of 30sec in the Single Mode, and continuous RF in Repeat Mode, when the Footswitch is pressed. |
| **Counter Reset** | The Counter can be reset. |
| **Temperature Measure** | This indicator shows the skin surface temperature, as measured by an integral temperature sensor. |
| **Effective Time** | This function shows the treatment time, starting from time-point of 2°C below the cut-off temperature. |
| **System Mode** | The System has three treatment modes, Standby, Ready, and Active.<br>**Standby mode-** allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode.<br>**Ready mode-** the System is waiting for a signal from the Footswitch to activate the energy. Any attempt to change the treatment settings switches the System to Standby mode.<br>**Active mode -** when the signal from the Footswitch is indicated, the System switches to Active mode. Any attempt to change the treatment settings switches the System to Standby mode. |
| **Main Menu** | Return to the Main Menu to select another applicator and change the applicator if needed. |

## 4.4 Sound Indicator

- A periodic beeping signal is emitted when RF energy is delivered.
- A warning sound tone indicates Bad Coupling.

## 4.5 Cut-Off Temperature Control

The cut-off temperature up to an upper limit of temperature of 43°C is constantly maintained for the Forma Handpiece. When the measured temperature approaches the Cut-off Temperature, the tone beeps double in speed. It becomes faster when the Cut-off Temperature is reached and RF is instantly inactivated. As soon as the temperature drops below the Cut-off temperature, RF starts again, thus maintaining

the desired temperature with safety and when reached, RF delivery is automatically stopped. Temperature is monitored by a temperature sensor in the Handpiece and serves as a safety feature.

## 4.6 Handpieces

The DiolazeXL Handpiece comprises applicator, cable and connector.

***Figure 4-12: DiolazeXL Handpiece***

| | |
|---|---|
| **Applicator** | Comprises DiolazeXL diode laser of 810nm diode bar. There is a cooled sapphire output window (11X27.5mm), and electronic shutter (Figure 4-12). |
| **Cable** | Has a length of 170cm. |
| **Connector** | The Connector is connected to the System. |

The Vasculaze Handpiece comprises applicator, cable and connector.

***Figure 4-13: Vasculaze Handpiece***

| | |
|---|---|
| **Applicator** | The Vasculaze laser comprises a cooled sapphire output window (3x4mm) and electronic shutter (Figure 4-13). |
| **Cable** | The Cable has a length of 170cm. |
| **Connector** | The Connector is connected to the System. |

Each of the Lumecca Handpieces (515 and 580) comprises an applicator, cable and connector


***Figure 4-14: Lumecca Handpiece***

| | |
|---|---|
| **Applicator** | Comprises flash lamp and reflector emitting optical energy through the pre-cooled light guide (30x10mm) (Figure 4-14). |
| **Cable** | The Cable has a length of 170cm. |
| **Connector** | The Connector is connected to the System. |

The Fractora Handpiece comprises applicator, cable and connector (Figure 4-15). Single use tip is connected to the groove in the handle before each use (Figure 4-16). The tip is connected or disconnected by pull or push movement.

***Figure 4-15: Fractora Handpiece***

| | |
|---|---|
| **Handle** | The Handpiece handle is made of metal and has ergonomic design for easy treatment with high visibility of the treated area (Figure 4-15) |
| **Cable** | The Cable has a length of 280cm (110’’). |
| **Connector** | The Connector is connected to the rear panel of the System. |
| **Tips** | The Handpiece tips have 2 sizes of pin arrays (Figure 4.14). 60 pins are 600µ long, and 24 pins are 2500µ long. |

***Figure 4-16: Fractora Tips: Left 60 pin; Right 24 pin (coated/noncoated)***

The Forma Handpiece comprises applicator, cable, connector and an integral temperature sensor (Figure 4-17).

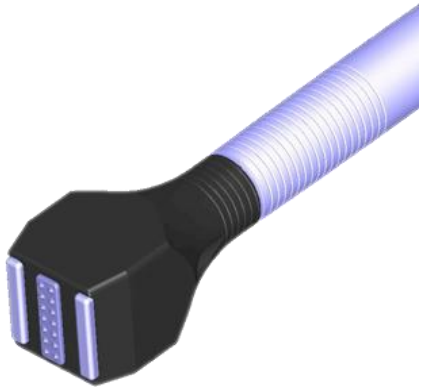


***Figure 4-17: Forma Handpiece***

| | |
|---|---|
| **Tip** | The Tip is a part of the Handpiece, comprising RF electrodes and a temperature sensor. |
| **Handle** | The Handpiece handle is made of metal and has an ergonomic design for easy treatment, with high visibility of the treated area. |
| **Cable** | The Cable has a length of 280cm (110’’). |
| **Connector** | The Connector is connected to the rear panel of the System. |

# 5 Section 5: System Operation

This section of the manual explains how to start the device, operate it, and turn it off.

Prior to using or connecting the Handpiece, inspect the System and Handpiece for possible mechanical damage.

## 5.1 Device Start-Up

1. Connect the handpiece to the handpiece connector socket on the System.
2. Turn on Main Power switch at the rear panel.
3. Press the On-Off button on the control panel to turn the device on. The System loads the software and enters the Login Screen.
4. Enter unique password to get access to the device. If password is correct the System enters Menu Screen.
5. The System loads the software and enters a self-test mode. If any problem is detected during the test the error message will appear (See Troubleshooting Section in this manual). If the test is passed correctly then the System automatically enters the Menu Screen.
6. Select the application from the Menu Screen and System will enter the Treatment Screen.
7. Verify on the screen that the Software version is properly displayed and the connected Handpiece type is recognized correctly.
8. Apply the Handpiece to the treated area, ensuring a full contact.
9. Select the treatment parameters using Up and Down keys.
10. Press the Standby icon that will change to Ready.
11. To start treatment, press the Footswitch for RF applicators, press the Hand-Trigger button for IPL applicators, and press the Footswitch followed by the Hand-Trigger press for laser applicators.

The following information relates to the lasers only –DiolazeXL and Vasculaze.

4. When Cooling Down is completed, within 1 minute, the icon will change to Ready.
5. If the laser is not activated within 3min, the System will go back to Standby mode.
6. Apply handpiece to the treated area, ensuring a full contact with pressure.

7. Press Standby icon that will change to Ready.
8. Press the Footswitch and then press trigger button on the Handpiece to start the treatment for DiolazeXL and Vasculaze; After pressing the foot-switch the icon will change to Armed.
9. After pressing the Hand Trigger the icon will change to Active Trigger and the laser can be emitted to start the treatment.
10. Lasing is apparent by blue light running around the window in the handpiece and by an audio signal.
11. During treatment, when the laser window is heating up, the System will go into Cooling Down mode. Wait until the icon will change to Standby mode.

## 5.2 System Shutdown

- To shut down the System turn the On-Off switch off.
- Turn the Main Power switch off at the end of the day.
- In case of an emergency, the System may be switched off instantly by pressing the red Emergency Stop Button on the right side of the System's front panel.

# 6 Section 6: DiolazeXL Treatment Information

DiolazeXL hair removal treatment is based on principles of selective photothermolisys. The light penetrates into the skin and is selectively absorbed by melanin of the hair shaft. The absorbed energy is converted into heat, coagulating the hair follicle. Multiple treatments are required for best results. White hairs are resistant to the treatment due to scares pigmentation in the hair shaft. DiolazeXL 810nm is a universal hair removal for all skin types.

## 6.1 Instructions for Use

The Optimas System with the DiolazeXL 810nm Handpiece is intended for hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime.

## 6.2 Contraindications

- Hair removal by lasers or intense pulse light sources can cause increased hair growth in some individuals. Based upon currently available data, the highest risk groups for this response are females of Mediterranean, Middle Eastern, and South Asian heritage treated on the face and neck.
- Current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Pregnancy and nursing.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes, thyroid dysfunction, polycystic ovary and hormonal virilization.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.

- Known skin photosensitivity or using drugs increasing skin photosensitivity.
- Diseases that may be stimulated by light, such as epilepsy, lupus and urticaria.
- Certain delay is recommended if other recent treatments like light, laser or RF were performed on the same area.
- Fresh tan from sun, sunbeds or chemicals.
- Lasers can cause increased hair growth in some individuals with the highest risk groups for being females of Mediterranean, Middle Eastern, and South Asian heritage treated on the face and neck.
- Vitiligo.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

 Do not treat the upper eyelids and the lips!

 Do not treat over tattoo and permanent makeup!

## 6.3 Possible Adverse Effects

Possible adverse effects include but are not limited by: discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, and burn), change of pigmentation (hyper- and hypo-pigmentation), in-growing hairs and scarring.

Peri-follicular erythema and edema lasting for a few days after the treatment is a desirable typical treatment end point.

The patient must understand the importance of pre-treatment and post-treatment instructions and that failure to comply with these instructions may increase the probability of complications.

Hair removal by lasers can cause temporal increased hair growth in some individuals. Based upon currently available data, the highest risk groups for this response are females of Mediterranean, Middle Eastern, and South Asian heritage treated on the face and neck

## 6.4 Pre-treatment Recommendations

During the patient's first visit the treating attendant should:

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- Advise the patient to avoid skin irritation or skin tanning. Sunscreen is advisable during outdoor activity at daylight hours.
- The patient should discontinue any irritant topical agents for 2-3 days prior the treatment.
- Stop anticoagulants 7-10 days prior to treatment, if medically permitted.
- Photograph the patient.
- Mark the treatment area.
- Clean the s parts that come in contact with the skin with 70% alcohol.

Treatment area should be shaved prior the treatment. Hairs may absorb light and leave burn marks on the skin.

## 6.5 Tip Cleaning Instructions Prior to Use

- Clean the light guide with 70% alcohol absorbed pad for at least 30 sec.
- Leave it for complete drying.

## 6.6 Treatment Recommendations

1. Follow the **Device Start-Up** procedure from Section 5.
2. Ensure that the skin is clean.
3. Apply a thin layer of water-based clear gel to the treated area.

Prior to using water-based gel, ensure that the container of ultrasound gel has not passed the expiration date

4. Make a test-spot with to see epidermal end-points of perifollicular erythema/edema. Use Strong Cooling while treating for better comfort and safety. Perform the test spot in the area to be treated in a non-conspicuous site and wait to check the response.

5. Test and wait at least 15-30min and increase or decrease by 2J/cm² for skin types I-IV. Wait 2-3 days and increase or decrease by 1-2J/cm² for skin types V-VI.

6. Set treatment parameters.

7. Always start with a low settings level to check patient tolerance. Test, watch epidermal response, and increase or decrease settings gradually. Darker skin is safer to treat with Long pulse width. Lighter hair requires higher fluence to reach the results. Stronger cooling allows better epidermis protection but may compromise results on very superficial hair e.g. upper lip or Asian skin in general. Reduce fluence on thin skin and in bone proximity along with a thicker layer of gel. Consider primarily safety for selection of parameters.

8. Apply to the treated area ensuring a contact with pressure, depress foot switch and press trigger button to deliver DiolazeXL laser pulse.

9. Move to adjacent site with small overlap and apply next pulses to cover all treatment area. Pulse Mode may vary from Off (single pulse) or 1, 2 pulses per second (pps) and Glide (5pps), restricted by certain fluence, as described in Device Description in Section 4.

10. In a continuous mode, coordinate handpiece movement with the repetition rate. Move handpiece to adjacent area only after the energy is delivered and machine has indicated that the pulse is completed.

11. In a single mode (Pulse Mode at Off) - move Handpiece to adjacent spot and apply next pulse to cover all treatment area.

12. If end-points are not obvious, or if gaps are apparent, perform another pass, preferably in a different direction, when general erythema subsides. Occasionally, a third pass on selected sites is applied on light skin. Ensure that there is a delay of a few minutes between passes (after the whole area is treated) before applying additional pass.

## 6.7 Treatment Schedule

The number of treatments is typically varied from 4-10 sessions every 4-8 weeks on the face and every 6-12 weeks on the body.

- Lighter and deeper hair is more resistant and requires more treatment sessions.
- Hair re-growth should be observed prior the treatment.
- Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.

## 6.8 Post-treatment Recommendations

Following each treatment session, the physician should advise the patient on proper care.

- Sun block should be used for 3 weeks following the treatment.
- Moisturizer may be applied after each treatment.
- Make-up may be applied immediately after facial treatment.
- During the first 2 days following treatment, care should be taken to prevent trauma to the treated area: avoid hot baths, massage, etc. The skin should be kept clean to avoid contamination or infection, any mechanical or thermal damage to the area must be avoided.

# 7 Section 7: Vasculaze Treatment Information

Vasculaze is a diode laser at 1064nm wavelength that is intended to treat predominantly blue reticular leg veins at a diameter of 1-4mm and depth of up to 5mm, including perforating veins. Due to the low absorption of 1064nm in hemoglobin, 500-600nm lasers or IPL are a better choice to treat red telangiectasia less than 1mm in diameter.

## 7.1 Indications for Use

The InMode System with the Vasculaze Handpiece is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasias, rosacea, venous lake, leg veins, spider veins, and poikiloderma of Civatte.

## 7.2 Contraindications

- Saphenous insufficiency.
- Current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Pregnancy and nursing.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes, thyroid dysfunction, and hormonal virilization.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- Known skin photosensitivity or using drugs increasing skin photosensitivity.
- Diseases that may be stimulated by light, such as epilepsy, lupus and urticaria.

- Certain delay is recommended if other recent treatments like light, laser or RF were performed on the same area.
- Fresh tan from sun, sunbeds or chemicals.
- Vitiligo.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

 Do not treat the upper eyelids and the lips!

 Do not treat over tattoo and permanent makeup!

 Severe varicosity will not benefit from the Vasculaze treatment.

## 7.3 Possible Adverse Effects

Possible adverse effects include but are not limited by: discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, and burn), change of pigmentation (hyper- and hypo-pigmentation), and scarring.

Erythema and edema along the vessels, lasting for up to 3 weeks after the treatment is a desirable typical treatment end point.

The patient must understand the importance of pre-treatment and post-treatment instructions and that failure to comply with these instructions may increase the probability of complications.

## 7.4 Pre-treatment Recommendations

During the patient’s first visit the treating attendant should:

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- Advise the patient to avoid skin irritation or skin tanning.

- Sunscreen is advisable during outdoor activity at daylight hours.
- The patient should discontinue any irritant topical agents for 2-3 days prior the treatment.
- Stop anticoagulants 7-10 days prior to treatment, if medically permitted.
- Mark the treatment area along the vessels with a white marker.
- Clean the sapphire that comes in contact with the skin with 70% alcohol.

The treatment area should be shaved prior to the treatment. Hairs may absorb light and leave burn marks on the skin.

## 7.5 Tip Cleaning Instructions Prior to Use

Clean the output window with 70% alcohol absorbed pad for at least 30sec and leave it for complete drying.

## 7.6 Treatment Recommendations

1. Follow the **Device Start-Up** procedure from Section 5 - System Operation.
2. Ensure that the skin is clean.
3. Apply a thin layer of water-based gel to the treated area.

Prior to using water-based gel, ensure that the container of ultrasound gel has not passed the expiration date

4. Make a test-spot with Normal/Strong Cooling to see epidermal end-points of erythema/edema along vessels. If lesion is deep enough, change to Strong Cooling while treating for better comfort and safety. Perform the test spot in the area to be treated in a non-conspicuous site and wait to check the response.
5. Test and wait a few minutes and increase or decrease by 2-5J/cm2 for skin types I-IV. Wait longer and increase or decrease by 1-2J/cm2 for skin types V-VI.
6. Set treatment parameters.
7. Always start with a low settings level to check patient tolerance. Test, watch epidermal response, and increase or decrease settings gradually. Darker skin is safer to treat with Long pulse width. Larger veins that are typically deeper require higher fluence to be eliminated.

Stronger cooling allows better epidermis protection but may compromise results on very superficial vessels. Reduce fluence on thin skin and in bone proximity along with a thicker layer of gel.

8. Apply to the treated area ensuring a contact with minimal pressure, depress foot switch and press hand-trigger button to deliver Vasculaze diode laser pulse.

9. Move along the blood vessel with gaps up to 1cm until the full length is covered. Pulse Mode may vary from Off (single pulse) or 1pps, depending on speed of operator's hand movement and convenience.

10. If end-points of erythema and/or edema along the vessel are not obvious, perform another pass. Occasionally, a third pass on selected sites is applied on light skin. Ensure that there is a delay of a few minutes between passes (after the whole area is treated) before applying additional pass.

When the site of perforating vertical feeder veins is not apparent, attempt at joint points few vessels.

## 7.7 Treatment Schedule

The number of treatments is typically varied from 1-3 sessions every 4-8 weeks. Larger veins that are typically deeper require more sessions and longer time should elapse between the treatment sessions.

Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.

## 7.8 Post-treatment Recommendations

Following each treatment session, the physician should advise the patient on proper care.

- Sun block should be used for 3 weeks following the treatment.
- Moisturizer may be applied after each treatment.

# 8 Section 8: Lumecca Treatment Information

IPL Lumecca treatment is based on principles of selective photothermolysis. The light penetrates into the skin and is selectively absorbed by lesion chromophore (melanin or hemoglobin) having darker color than surrounding tissue. Absorbed energy is converted into heat, coagulating the lesion which fades during a few weeks following the treatment. Fine textural lesions like macro-pores, and fine lines may improve along with the pigmented and vascular lesions in the skin photo-rejuvenation process. Multiple treatment sessions may be required for best results.

## 8.1 Indications for Use

The Lumecca Handpieces are intended for treatment of superficial vascular and pigmented lesions on skin type I to IV

## 8.2 Contraindications

- Current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Pregnancy and nursing.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- Certain delay is recommended if other recent treatments such as light, laser or RF were performed on treated area.
- Known skin photosensitivity or using drugs increasing skin photosensitivity.

- Diseases that may be stimulated by light, such as epilepsy, lupus and urticaria.
- Vitiligo.
- Skin type V and VI and excessively tanned skin from sun, tanning beds or tanning creams and sprays within the last two weeks.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

Do not treat the upper eyelids or the lips!

Do not treat over tattoo and permanent makeup and treat away from the tattoo at least the width of the treatment tip!

Permanent hair reduction may occur in treated area.

Don’t treat over area with high density of hair follicles. Absorption of light by hair follicles may cause skin adverse reaction.

## 8.3 Possible Side Effects

Possible adverse effects include but are not limited by: discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, and burn), change of pigmentation (hyper- and hypo-pigmentation), and scarring.

Erythema, lasting not longer than 24h is a typical skin reaction to the Lumecca treatment.

The patient must understand the importance of pre-treatment and post-treatment instructions and that failure to comply with these instructions may increase the probability of complications.

## 8.4 Pre-treatment Recommendations

During the patient’s first visit the treating attendant should:

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.

- Instruct the patient about the safety warnings.
- Advise the patient to avoid skin tanning for 3-4 weeks prior to the treatment and use at least 30 SPF sunblock during outdoor activity at daylight hours.
- The patient should discontinue any irritant topical agents for 2-3 days prior the treatment.
- Stop anticoagulants 7-10 days prior to treatment, if medically permitted.
- Photograph the patient.
- Mark the treatment area.
- Clean the handpieces parts that come in contact with the skin with 70% alcohol.

The patient may shave the area to be treated. Long and dark hair may absorb light and leave burn marks on the skin.

## 8.5 Tip Cleaning Instructions Prior to Use

- Clean the light guide with 70% alcohol absorbed pad for at least 30 sec.
- Leave it to dry completely.

## 8.6 Test Spots

A small test spot should be performed in a non-conspicuous area of the treatment site, prior to the first complete session. Test spot is performed to establish the following requirements:

- Confirm the patient's suitability for treatment:
  - For skin type I – IV wait 10-15 minutes before assessing the skin response.
  - Do not treat skin type V-VI.

## 8.7 Treatment Recommendations

1. Follow **Device Start-Up** Procedure from System Operation section.
2. Ensure that skin is clean.
3. Apply thin to thick layer of water-based gel to the treated area, mostly face.

Prior to using water-based gel, ensure that the container of ultrasound gel has not passed the expiration date.

4. Basic treatment considerations:
   - Treatment target is mainly face, or body, but not leg veins.
   - Treatment targets are epidermal and junctional pigments, but not dermal nevi and blood vessels 1-2mm deep and <0.5mm diameter (red and purple), but not deeper and larger (blue and black).
   - Set treatment parameters. Reduce ~20% fluence on thin sensitive skin like neck or bony area like forehead. Further reduce fluence on thin sensitive skin over bone like chest and hand dorsum and on off-face, body areas, as well as on off-face areas, such as arms and legs.
   - Use higher Fluence settings for vascular lesions than for pigmented lesions.
   - Use higher Fluence settings for lighter pigments than for darker.
   - Use higher Fluence settings for larger and deeper veins than for smaller and superficial ones.
   - The Strong Cooling should protect the skin surface.
   - Normal Cooling may be used after testing on very superficial and small capillaries on light skin to avoid vessel constriction.
   - Use a short pulse width for pigments on skin types I-II, occasionally III. Can also start in Long Pulse then make additional pass in Short Pulse.
   - Use a long pulse to prevent purpura or bruising in dense vascular areas such as cheeks and chin.
   - Do not treat moles or suspicious lesions. If unsure, consult a dermatologist or do not treat.
   - Treatment of facial melasma is controversial as it is a condition controlled by hormones and may often reoccur. Furthermore, the response is unpredictable, presenting no response, lesion lightening, or even lesion darkening.
   - In hair-bearing area there is a risk of hair loss, temporary or permanent.

5. Always start with a low settings level to check patient tolerance to the treatment parameters, test and then gradually increase energy fluence to reach the results without compromising safety.

6. Apply hand piece to the treated area ensuring a full contact with slight pressure (less pressure over superficial blood capillaries) and press trigger button to deliver light pulse.

7. Perform a test spot in the area to be treated in a non-conspicuous site and wait a few minutes to check the response. Wait a longer time on darker skin.

8. In a single mode (AutoRepeat Off), move Handpiece by stamping to adjacent area without overlap and apply next pulse to cover all treatment area.

9. In a continuous mode, coordinate handpiece movement with the repetition rate. Move handpiece to adjacent area only after the energy is delivered and machine has indicated that the pulse is completed.

10. After the first pass if end-points are not obvious, perform another pass, after 10-15 minutes, longer for darker skin type IV, or when general erythema subsides, preferably in a different light guide direction.

11. End-points are:

    – Greying and/or darkening of pigments.

    – Darkening of blood vessels.

    – Erythema and/or edema around lesions.

    – Tighter skin-look.

Lumecca is a very powerful applicator. Take care with the treatment parameters!

## 8.8 Post-treatment Recommendations

After each treatment session, the physician should advise the patient on proper care.

- Sun block should be used for 3 weeks following the treatment.
- Moisturizer may be applied after each treatment.
- Make-up may be applied immediately after the treatment.

## 8.9 Treatment Schedule

The number of treatments typically varies from 2-5 sessions every 3-4 weeks. Pigmented lesions usually require less sessions than vascular lesions.

Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.

# 9 Section 9: Fractora Treatment Information

## 9.1 Fractional Skin Resurfacing

The Fractora Handpiece is designed for delivering RF energy to the skin surface in a fractional manner with the energy applied to <10% of the total coverage area. The energy is delivered to the skin through bipolar arrays of pins and results in localized heating and ablation of the skin that is in direct contact with the pins. Ablation of the skin promotes skin resurfacing while untreated skin between the pins promotes faster healing of the tissue. There is also the contribution of non-ablative, non-coagulating dermal matrix heating that occurs in the skin that is not subject to fractional ablation.

## 9.2 Indications for Use

Fractora Handpiece with 60 pin tip is designed for use in dermatological procedures requiring ablation and resurfacing of the skin.

Fractora Handpiece with 24 pin tip is intended for use in Dermatologic and General Surgical procedures for Electrocoagulation and Hemostasis. At higher energy levels greater than 62, use of the applicator is limited to Skin Types I-IV.

## 9.3 Contraindications

- Pacemaker or internal defibrillator, or other metallic or electronic implant anywhere in the body. The Handpiece should be used at least 1cm away from cochlear implants in the ear.
- Permanent implant in the treated area such as metal plates, screws and metal piercing or silicon, unless deep enough in the periosteal plane.
- Intra-dermal or superficial sub-dermal areas injected with Botox®/HA/collagen/fat injections or other augmentation methods with bio-material, before the product has been dissipated (up to 6 months), except Botox after binding to the facial muscles (3-7 days). It is possible to treat sooner over injectable products placed in the deep, periosteal plane, as soon as the area has healed (1-3 weeks).
- Current or history of skin cancer, or any other type of cancer, or pre-malignant moles.
- Pregnancy and nursing.
- Severe concurrent conditions, such as cardiac disorders or sensory disturbances.

- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Any active skin condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies.
- Any facial surgery performed within a year prior to treatment.
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, if face is treated.
- Having received treatment with light, laser, RF, or other devices in the treated area within 2-3 weeks for non-ablative procedures, and 6-12 weeks for ablative fractional laser resurfacing (according to treatment severity) prior to treatment, except special recommendations.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session, as per the practitioner’s discretion.
- Treating over tattoo or permanent makeup.
- Treating over the lips.
- Treating over eyebrows or other hair bearing surfaces.
- Treat patients with skin types VI and dark VI with caution.
- Excessively tanned skin from sun, tanning beds or tanning creams and sprays within the last two weeks.
- As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient.

## 9.4 Possible Adverse Side Effects

Possible adverse effects include but are not limited by: discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, and burn), change of pigmentation (hyper- and hypo-pigmentation), and scarring.

Erythema lasting not longer than 24h and edema for 1-3 weeks is a typical skin reaction to the Fractora treatment.

Crusting from the ablated dots will exfoliate naturally after 1-3 weeks.

Occasionally, there is a potential low-level stimulation of branches of the facial nerve and there will be some involuntary contraction of the underlying facial muscle. This is transient and is not harmful, as the Fractora effect diminishes at the deeper level where parts of the facial nerve lie above the muscles.

The patient must understand the importance of pre-treatment and post-treatment instructions and that failure to comply with these instructions may increase the probability of complications.

## 9.5 Pre-treatment Recommendations

During the patient's first visit the treating attendant should:

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Determine accurately the patients Fitzpatrick skin type.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- Advise the patient to avoid skin irritation or intentional skin tanning. Sunscreen is advisable when outdoors during daylight hours
- Asian patients and those with skin types IV-VI should be treated gradually by bleaching products 6 weeks prior treatment and stop at least 48 hours prior Fractora treatment to minimize risk of post inflammatory hyper-pigmentation.
- Prophylactic antiviral therapy should be prescribed for patients with history of cold sores (Herpes Simplex) when treating around the mouth.
- Stop anticoagulants 7-10 days prior to treatment, if medically permitted.

- Clean the treatment area.
- Apply anesthesia:
  - Many patients can tolerate the treatment with no anesthesia at low energy levels of 5-20 energy levels and sometimes more. Topical anesthetic can be applied as needed prior to treatment.
  - Topical for 30-45 min – limited to energy as tolerated by the patient and may reach 40-62 energy levels, depending on the percent numbing ingredients and patient sensitivity.
  - A few patients require nerve block for higher energy, limited to central face.
  - Tumescent or IV sedation is applied usually when Fractora follows an invasive procedure.
- Cooling methods, such as air cooling, sterile ice-packs, or sterile latex gloves filled with ice, help patient comfort during and after treatment.

The patient should shave the area to be treated. Long and dense hairs prevent electrode contact with the skin's surface.

## 9.6 Tip Cleaning Instructions Prior to Use

- Clean the tip with 70% alcohol absorbed pad for at least 30sec.
- Leave it for complete drying.
- Before each use of the Fractora Handpiece and tip, they must be checked for integrity and proper cleaning and drying.

The Fractora tip is single use only!

## 9.7 Test Spots

A small test spot should be performed in a non-conspicuous area of the treatment site, prior to the first complete session. Test spot is performed to establish the following requirements:

- Confirm the patient's suitability for treatment:
  - For skin types I – III wait 10-15 minutes before assessing the skin response.
  - For skin types V-VI wait 2-3 days if energy level <30 is used and 7-10 days if energy level >30 is used.

- Establish and confirm treatment parameters: if the desired end-point of erythema and edema – in a tip-shaped pattern – has not been achieved within 10-15 minutes, increase the RF energy. If the response is excessive, decrease the parameters.

- Low energy levels of 10-25 may be tolerated after topical anesthesia application. Energy levels of 25-40 may require nerve block or tumescent and high energy levels of 40-62 may call for tumescent or IV sedation.

## 9.8 Treatment Recommendations

1. Apply the necessary means of anesthesia. If topical, make sure that it is cleaned off the face before treatment and the skin is dried with alcohol 70%.
2. Ensure that skin is clean and dried with alcohol 70%.
3. Take an alcohol cleaned and dry tip and connect it to the Handpiece in the groove.
4. Connect Handpiece to the System.
5. Follow Device Start-Up Procedure from System Operation section.
6. Set treatment parameters.
7. Basic treatment consideration:
   - All tips may be applied to skin type I-IV. Skin types IV-VI are better treated by 24 Coated pin tip.
   - 60 pin tip energy is limited to 30 and repetition rate of 1pps in auto pulse mode.
8. Always start with a low energy level, test and observe the skin's response before increasing the energy.
9. The deeper the lesion, the higher the energy. However, this consideration is limited according to patient tolerance, the anesthetic method used, and the affordable down time.
10. On sensitive thin skin area, such as lower eyelid, apply lower parameters with more passes, rather than higher parameters in one pass. It is also applicable to any facial area for new users. Use lower energy (~20%) for thin skin like neck or bony area like forehead. When working on thin skin over bone, such as hand dorsum or chest, further reduce energy (~20%).

11. Treat dark skin (V-VI) with the 24 coated pin tip, restrict energy, starting at energy level 15 or lower, adding 5 levels each visit (every 3-4 weeks) to a maximum of energy level 40 on soft tissue, and energy level 25 over bone, preferably following bleaching regimen.

12. Apply the Fractora Handpiece to the treated area ensuring a contact with pressure to minimize discomfort, and press the Footswitch to deliver RF energy

13. Move Handpiece to the adjacent area and press Footswitch again in the SINGLE mode or adjust the repetition rate to the speed you move the tip to adjacent site.

14. Move to adjacent areas with no overlapping of side-electrodes (30-50% overlap).

15. Occasionally, additional 1-2 passes may be applied to reinforce results on the full area or on selected spots. Gaps may be treated after the full area is done.

16. The endpoint is substantial erythema and edema, visible ablative craters, and burnt tissue smell often accompanied by tingling heat sensation.

## 9.9 Treatment Schedule

The number of treatment sessions depends on the individual patient and treatment aggressiveness and may vary from 1-5 sessions. Treatments are typically repeated every 3-6 weeks.

It is recommended to schedule follow-up session 2-3 days after the treatment to ensure safe healing process.

Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion. Generally, 3-5 sessions are needed for mild to moderate depth settings. It is not typical to perform more than five consecutive sessions however more sessions can be performed as per physician discretion. In some instances, 1-2 sessions may be sufficient.

## 9.10 Post-treatment Recommendations

After each treatment session, the physician should advise the patient on proper care.

- Cool the skin for 10-20 min.
- Emollient cream or occlusive dressing could be applied to the treatment area.
- Alternatively, prophylactic antibiotic treatment may be prescribed for 1-3 days post treatment. Patient is to contact the physician if there is any indication of infection, excessive swelling, redness, undue pain, or any other unusual or untoward symptom.

- Tiny scabs may appear after 1-3 days and stay for several days following the treatment. The scabs should not be touched or scratched even if they itch and should be allowed to flake off naturally.
- Blisters may be treated with a prescribed antibiotic ointment or burn treatment cream as per physician's discretion.
- During the first two days following treatment the skin should be kept clean to avoid contamination or infection; any mechanical or thermal damage to the area must be avoided.
- Prophylactic antiviral therapy should be continued for patients with history of cold sores (Herpes Simplex) when treating around the mouth.
- Moisturizer may be applied 24-72 hours after each treatment and then should be applied regularly throughout the course of the treatment. Make-up may be applied only 24-72 hours after each treatment session. Generally, 24 hours after treatment, patients may use regular soaps, but not scrub soaps or exfoliates.
- The patient should use a high-factor sunscreen (at least 30 SPF) and protect the treated area from over-exposure to sunlight for at least one month after the treatment, starting 24-72 hours post treatment. Excessive tanning of any sort (sun exposure, tanning beds, and artificial tanning lotions) is not allowed in the treated areas during the entire course of the treatment.
- For Asian patients and skin types IV and V, a prescription or compounded bleaching regimen may be prescribed by the physician for 6-12 weeks, 2-3 times a week following the healing of treatment area (typically 7 days) to minimize risk of post inflammatory hyper-pigmentation. It should be stopped 48-72 hours before another Fractora session.

# 10 Section 10: Forma Treatment Information

## 10.1 Indications for Use

The Forma Handpiece is intended for use in dermatologic procedures for noninvasive treatment of mild to moderate facial wrinkles and rhytids. Hand pieces is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

## 10.2 Contraindications

- Pacemaker or internal defibrillator, or any other metallic or electronic implant anywhere in the body. The Handpiece should be used at least 1cm away from cochlear implants in the ear.
- Permanent implant in the treated area such as metal plates, screws and metal piercing, silicone implants or an injected chemical substance, unless deep enough in the periosteal plane.
- Intra-dermal or superficial sub-dermal areas that have been injected with HA/collagen/fat injections or other augmentation methods with bio-material during last 6 months.
- Current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances, epilepsy, uncontrolled hypertension, and liver or kidney diseases.
- Pregnancy and nursing.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, autoimmune disorders or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.

- History of bleeding coagulopathies, or use of anticoagulants in the last 10 days, as per the practitioner discretion.
- Facial dermabrasion, laser resurfacing and deep chemical peeling within the last 3 months prior Forma treatment.
- Having received treatment with light, laser, RF, or other devices in the treated area within 3 months, or before complete healing.
- Any surgical procedure in the treatment area within the last 3 months or before complete healing.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient unsafe for the patient.

## 10.3 Possible Adverse Effects

Possible side effects include but are not limited to:

- Discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, burn), change of pigmentation (hyper- and hypo-pigmentation), scarring.
- Erythema and edema lasting not longer than 24h is typical skin reaction to the treatment.
- The patient must understand the importance of pre-treatment and post-treatment instructions and that failure to comply with these instructions may increase the probability of complications.

## 10.4 Handpiece Cleaning Instructions Prior to Use

These cleaning instructions are for clinical use only.

The following processes are validated for the Forma Handpiece when used in accordance with the instructions provided for cleaning products and/or processes. Any deviation from said instructions or the cleaning agents listed below may impact the performance or durability of the product and is prohibited. Review those instructions for additional warnings and cautions.

We recommend the usage of the following cleaning agent that was tested in our company for material compatibility as 70% alcohol solution.

**Cleaning Procedure:**

- Thoroughly clean the Handpiece with 70% alcohol absorbed pad for at least 30 sec and repeat as necessary.
- Leave it for complete drying.

**Pre-Use Check:**

Before each use of the Handpiece, the device must pass the following:

- Check to ensure proper cleaning and drying of the Handpiece.
- Inspect all components of the Handpiece for visible damage.

## 10.5 Pre-treatment Recommendations

During the patient's first visit the treating attendant should:

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- The patient should discontinue any irritant topical agents for 2-3 days prior to treatment and if medically permitted, anticoagulants should be stopped 1-2 weeks prior treatment.
- Clean the face, remove creams/lotions and makeup, and dry the skin.
- Photograph the patient.
- Mark the treatment area.
- Clean the handpiece's parts that come in contact with the skin with 70% alcohol.

Long and dense hairs may affect the treatment and may be shaved according to the physician's discretion.

## 10.6 Treatment Recommendations

1. Ensure that the skin is clean and dry.

2. Follow the **Device Start-Up** procedure from Section 5.
3. Set treatment parameters.
4. Any combination of treatment parameters should be according to skin response and patient tolerance.
5. Always start with low settings and observe the skin's reaction and patient comfort before increasing the RF energy.
6. Air condition directed at the patient treated area may reduce the skin surface temperature in 1-2$^{o}$C, and cut-off temperature should be reduced accordingly.
7. Divide facial and neck treatment area to zones as shown in figure below:
8. Neck may be 2 zones for under-chin or 4 zones with neck as well.
9. Users may prefer other ways to subdivide the face.
10. Body zone is ~12x12cm unless the area is smaller (~8x8cm).
11. Mark treatment zones prior to beginning treatment while patient is standing.

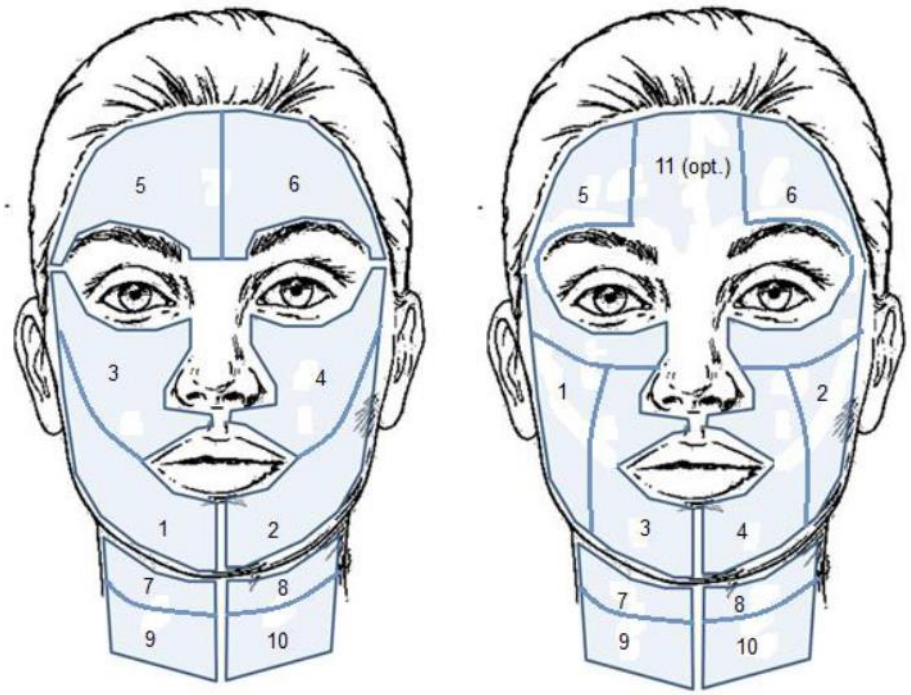



***Figure 10-1: Recommended Forma Facial and Neck Treatment Zones***

12. Apply 2-4mm clear ultrasound gel (not oil) to the treated zone and to adjacent zone that can serve as a warm gel reservoir for replenishing gel in the treatment zone with minimal delay.

⚠ Prior to using water-based gel, ensure that the container of ultrasound gel has not passed the expiration date.

13. RF is continuous in Repeat mode and stops every 30sec in Single mode. Always work in Repeat mode.

14. Assume full contact of Handpiece with the skin with a slight pressure.

15. Use your free hand to flatten and stretch treatment area if needed for complete contact and smooth movement.

16. Press the Footswitch and initiate the RF energy.

17. Move the Handpiece in circular movements or back and forth with gentle pressure over the full treated zone to reach uniform skin heating. Movement should be constant and its amplitude should be at least double of Handpiece spot size to avoid hot spots.

18. Continue to treat the area in this fashion. Always start with a low setting level to check the patient's tolerance to the treatment parameters and increase the settings gradually.

19. Apply multiple passes to maintain the desired temperature during ~5-7min on face and neck. If cut-off temperature is <41°C, maintain the temperature for additional 1-3min per zone.

20. After treating the zone, move to the next zone.
21. For excessive heat sensation, you may increase the movement speed, reduce the RF power and lastly, reduce the cut-off temperature for patient comfort. If this does not help, stop the treatment and move to the next zone.
22. When skin temperature reaches cut-off limit in ~2min, continue to treat for 15-30min/zone the longer, the better. If cut-off temperature is <41°C, maintain the temperature for additional 1-3min.
23. Repeat treatment for the other zones, following the same protocol.
24. Slight erythema and edema is a typical immediate response. However, when there is excessive skin response (erythema and edema), stop treatment and move to the next zone.

The skin should be observed for excessive erythema or edema. If observed, stop the treatment and move to the next treatment zone.

Asian skin is typically thicker and more fibrotic than Caucasian skin, hence occasionally higher energy, smaller zones, longer treatment and more sessions (all or part) may be required.

## 10.7 Treatment Schedule

- The number of treatments is typically 8 sessions, once weekly and may vary individually. Some patients may need 10 weekly sessions.
- Longer treatment time in each treatment may help reduce the number of sessions.
- Thicker skin that is more fibrotic may require more sessions.
- Single maintenance sessions may be needed every 1-3 months.

## 10.8 Post-treatment Recommendations

- Skin cooling is NOT recommended.
- The patient should avoid very hot water for 2 days after the treatment.
- The patient should avoid scrubbing, pinching and etc. of the treated area.
- Moisturizer and makeup may be applied to the skin surface immediately post treatment.

- After each treatment session, the patient should be advised to contact the physician if there is any indication of infection, excessive swelling, redness, pain, or any other unusual or untoward symptom.
- The Handpiece should be cleaned from the gel and disinfected by 70% alcohol.

# 11 Section 11: System Maintenance

## 11.1 Maintenance & Frequency

The following list suggests how often each of the maintenance procedures should be performed by the operator.

## 11.2 Before and after each treatment

Wipe the device with a damp soft cloth. The Handpiece elements that are in contact with the skin should be disinfected with 70% alcohol between patients, as described in detail for each handpiece in “Handpiece Cleaning Instruction Prior to Use”. For applications that require gel (DiolazeXL, Vasculaze, Lumecca and Forma), remove the gel before cleaning.

## 11.3 Once a Week

Clean the System at least once a week. Turn the System off and wipe all surfaces. Be careful not to spill any liquids on the System.

Clean the Dust Cover. In dusty environments or desert regions, it should be checked **daily**.

## 11.4 Once a Month

Replace the cooling water at least once a month. Follow the instruction of “Draining Water” and “Filling Water” below.

## 11.5 Once a Year

**By the operator:**

- Replace the Deionizer Cartridge and Capsule Filter at least once a year. Follow the “Replacing the Deionizer Cartridge” and Replacing the Capsule Filter” instructions below.
- Replacement Deionizer Cartridge and Capsule Filter can be purchased by your local service center.

**By authorized service personnel only:**

- System and Hand pieces full test and calibration is required to be done. Please make sure to contact your local service center to perform this process.

⚠ Failure to replace your filters can lead to serious malfunctions of the laser/IPL Handpieces!

## 11.6 Filling Water for DiolazeXL, Vasculaze and Lumecca

Optimas System, as well as, DiolazeXL, Vasculaze and Lumecca Handpieces are shipped without water. When filling water upon installation, distilled water must be used and failure to do so will void the service warranty.

During water filling, air bubbles can form inside the hoses which may cause water flow issues. This instruction will help prevent this from occurring.

1. Open the back cover and take out the bottle.
2. Unscrew the water bottle cap (Figure 11.1).
3. Slowly pour distilled water into the bottle while water filter and tube are inside the bottle to prevent over pouring (Figure 11.2).

***Figure 11-1: Water Bottle Cap***

***Figure 11-2: Distilled Water Filling***

***Figure 11-3:Water Bottle in Bracket***

4. Fill the bottle up to the maximum level.
5. Close the bottle cap and insert the bottle at the back of the System (Figure 11.3).
6. Connect any DiolazeXL, Vasculaze or Lumecca 515 or 580 Handpiece.
7. Turn the System ON.
8. Select “Utilities” on the Main Menu (Figure 11.4).

9. Select “Water Drain/Fill” (Figure 11.5).

10. Pressing the UP arrow will activate the pump and count down from 600 seconds (10 minutes) to 0 seconds (Figure 11.6).


***Figure 11-4: Menu Screen***


***Figure 11-5: Utilities Screen***

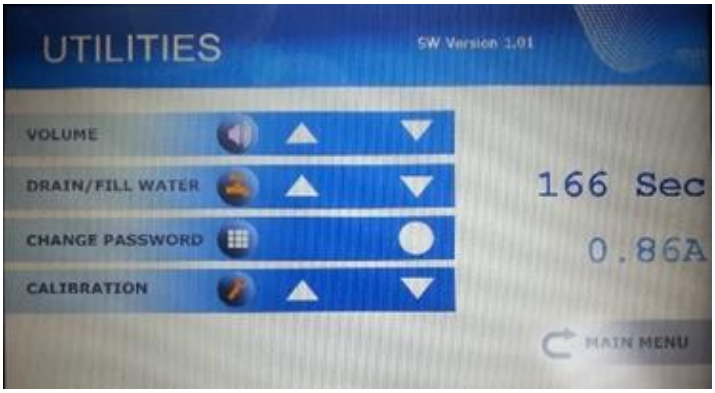



***Figure 11-6: Time Counter Water Pump Current Value***

11. After 300 seconds (while the pump is working), unscrew the plastic cap on the side of the Capsule Filter counterclockwise to release air. Afterwards, screw the cap clockwise to close it (Figure 11.7). Ensure that no water is leaking.

***Figure 11-7: Capsule Filter with Plastic Cap***

12. Pressing the Down arrow will stop the Water Pump.

13. Repeat steps 2 to 5 since the System and Handpiece will take some of the water.
14. Turn the System OFF.
15. Connect additional Handpieces.
16. Repeat Steps 6 to 12 for each Handpiece.
17. Ensure the water level is checked periodically.

## 11.7 Draining Water for VASCULAZE, DIOLAZEXL and LUMECCA

For shipping and storage, the Optimas Systems and optical Handpieces must be drained of water during freezing temperature. Failure to do so will void the service warranty. Frozen water in the System and Handpiece hoses can lead to damages

1. Open the back cover and take out the bottle.
2. Unscrew the water bottle cap and slowly remove it from the bottle (Figure 11.8).


***Figure 11-8: Water Bottle with Deionizer Cartridge***

***Figure 11-9: Water Bottle in Drain Position***

3. Empty the bottle.
4. Place the bottle inside the chamber with the black hose outside the bottle (Figure 11.9).
5. Connect the available optical Handpieces, one by one.
6. Turn the System ON.
7. Select “Utilities” on the Main Menu (Figure 11.4).
8. Select “Water Drain/Fill” (Figure 11.5).

9. Pressing the UP arrow will activate the pump and count down from 600 seconds down to 0 seconds (Figure 11.6).
10. Pressing the DOWN arrow will stop the water pump.
11. Repeat Steps 5 to 9 for draining any remaining optical Handpiece.
12. Observe the reservoir; when no more water is pouring out turn off the System.

## 11.8 Draining the Laser/IPL Handpieces with the Water Draining Tool

When only applicators are shipped or stored, follow applicators draining instructions below. It is possible to connect them to the System and perform the draining procedure, as above. It is also possible to use the InMode Water-draining tool (Figure 11.10).

***Figure 11-10: Water-Draining Tool***

The DiolazeXL, Vasculaze and Lumecca Handpieces may be damaged in cold (freezing) temperatures that occur during transportation or the local storage environment. In cold climates, especially during the winter, systems and handpieces may be damaged during transportation or storage when exposed to freezing temperature.

**To drain the Handpiece:**

1. Hold the water draining tool's connector and insert the Handpiece's connector with the label at a 90° counter-clockwise angle (Figure 11.11), and twist it 90° to the right, such that the label is straight.

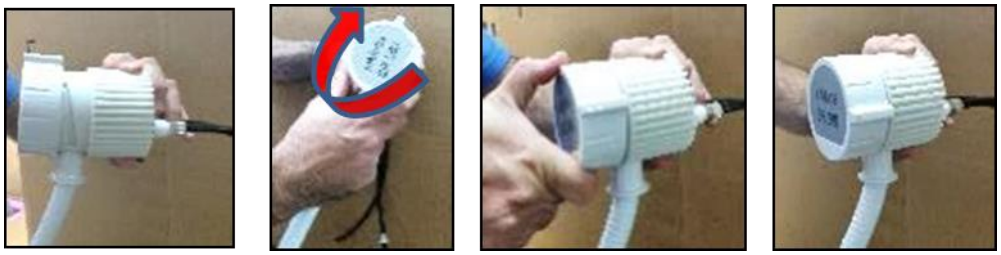


***Figure 11-11: Connecting the Handpiece to the Water Draining Tool***

2. Hold the Handpiece and draining tool over a sink and start pumping air through the Handpiece until no more water drains out.

3. Disconnect the Handpiece from the water draining tool.

Damage to the System or Handpieces by frozen water will not be covered under System's warranty.

Only InMode draining mechanical hand pumps (InMode P/N AT604837x) could be used to drain DiolazeXL, Vasculaze and Lumecca Handpieces.

To order the water drain tool contact our Service department.

## 11.9 Replacing the Deionizer Cartridge

For safety, and proper System performance, replace the cooling water with fresh distilled water only.

**To remove the Deionizer Cartridge:**

1. Drain the water from the System following “Draining Water” procedure.

2. Turn the System off.

3. Push the slide latch of the bottle door down and remove the door.

4. Holding the bottle cover with one hand, loosen the bottle by turning it clockwise.

5. Disconnect the Deionizer Cartridge from the water hoses by pressing the Release Button on the upper part of the Deionizer (Figure 11.8).

**To install a new Deionizer Cartridge:**

1. Connect the water hose into the Deionizer filter until is securely locked.
2. Remove the water bottle from the compartment, pour out the distilled water from the bottle according to “Draining Water” procedure and wash it with new fresh water.
3. Fill 1 liter of distilled water into the bottle and return it to its compartment. Perform “Filling Water” procedure as described above.

## 11.10 Replacing the Capsule Filter

For safety, and proper System performance, replace the cooling water with fresh distilled water only.

**To remove the Capsule Filter:**

1. Drain the water from the System following “Draining Water” procedure
2. Turn the System off.
3. Push the slide latch of the bottle door down and remove the door.
4. Holding the Capsule Filter with one hand, loosen the filter by pressing the upper black quick connector and pulling the filter out of the water hose (Figure 11-12 left).
5. Holding the Capsule Filter with one hand, loosen the filter by pressing the lower black quick connector and pulling the filter out of the water hose (Figure 11-12 right).

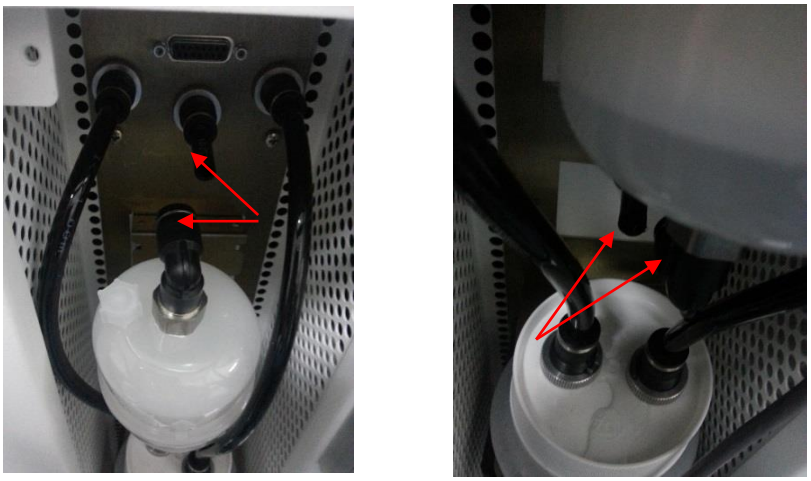


***Figure 11-12: Upper (Left) and Lower (Right) Filter Quick Connectors***

**To install a new Capsule Filter:**

1. Hold the Capsule Filter when the arrow on the filter body pointing upwards.
2. Push the lower system water hose into lower filter's quick black connector as much as possible (Figure 11.12 right).
3. Push the upper system water hose into upper filter's quick black connector as much as possible (Figure 11.12 left).
4. Remove the water bottle from the compartment, pour out the distilled water from the bottle according to "Draining Water" procedure and wash it with new fresh water.
5. Fill 1 liter of distilled water into the bottle and return it to its compartment. Perform "Filling Water" procedure as described above.

## 11.11 Air Filter

Systems marked by the Service Revisions listed in the table below are equipped with new air filters. The Filters are intended to reduce dust and debris entering and accumulating inside the System. Dust and debris may affect internal heat exchanges and the performance of other components.

| Platform Description | Part Number | Service Revision |
|---|---|---|
| InMode II | AG606666A | B04 |
| Optimas | AG606991A | B04 |
| Triton | AG606992A | A02 |

Dust filter are located on inside back over door (***Figure 11-13***).

***Figure 11-13: Back Cover Door with Dust Filter***

**Air Filter Maintenance**

- Dust Filter must be to be cleaned **once a week**. In dusty environments or desert regions, it should be checked **daily**.
- Replace the Dust Filter if damaged.

**Cleaning method**

- Remove back cover door and wash it under tap water until filter net is clean from a dust. Air pressure can used carefully if available.
- Shake and dry the back cover door before use.
- Return the back cover door when dry.

**Dust Filter ordering**

- In order to add a back cover with Dust Filter to existing Systems, order the parts as listed in the table.
- For Systems which already have a support for the back door, order a Mesh for Cabinet Back Cover (part number MM607749X).

| Platform | Item Description | Part Number |
|---|---|---|
| AG606666A InMode II | White Back Cover door with Dust filter | AS607830X |
| AG606991A Optimas<br>AG606992A Triton | Black back Cover door with Dust Filter | AS607831X |

# 12 Section 12: Troubleshooting

The Optimas System provides monitoring of all critical parameters to ensure safety of patient and user. If any of the following faults are detected by the System automatically goes to STAND BY mode.

## 12.1 Description of Faults with All Handpieces

| Problem | Description and Checks |
|---|---|
| **System did not turn on** | ▪ Check power cord connection.<br>▪ Check that main switch on rear panel is on.<br>▪ Check that On/Off switch on front panel is on.<br>▪ Check Emergency button not pressed.<br>▪ Check fuses on back panel of the System.<br>▪ Call Technical Service if problem persists. |
| **System shuts down by itself** | ▪ Check power cord connection.<br>▪ Check fuses on back panel of the System.<br>▪ Check Emergency button not pressed.<br>▪ Call Technical Service if problem persists. |
| **Checksum** | ▪ The software was not loaded properly from software plug.<br>▪ Check the plug connection and reboot the System.<br>▪ Call Technical Service if the problem persists. |
| **Fault H8002 - Handpiece is not connected** | ▪ Check the connection of the Handpiece.<br>▪ Replace the Handpiece.<br>▪ Call Technical Service if the problem persists. |
| **Fault H8005, H800F, H8010 – System Memory Fault** | Call Technical Service if the problem persists. |
| **Fault H8601 – Distributor Card Connection Fault** | Call Technical Service if the problem persists. |
| **Fault H8609 – Water Temperature Fault** | Call Technical Service if the problem persists. |

| Problem | Description and Checks |
|---|---|
| **Fault H800E- System Incompatible Software Version** | Call Technical Service if the problem persists. |
| **Fault H800E- System Incompatible Software Version** | Call Technical Service if the problem persists. |
| **Fault H800F- System Memory Fault** | Call Technical Service if the problem persists. |
| **Fault H8010- System Memory Fault** | Call Technical Service if the problem persists. |
| **Faults H83XX, H84XX, H82XX** | Call Technical Service if the problem persists. |
| **Faults H86XX Water Flow Fault** | ▪ Open cover on the back panel and check if water level is within defined limits.<br>▪ Call Technical Service if the problem persists. |
| **Faults H8003, H8006, H8007 - RF Related Faults** | Call Technical Service if the problem persists. |
| **Faults H8401, H8410, H8420, H8421, H8422, H8430, H8431, H8481 - IPL Related Faults** | Call Technical Service if the problem persists. |
| **Faults H8202, H8210, H8211, H8220-H8229, H8222 - Laser Related Faults** | Call Technical Service if the problem persists. |

# 13 Section 13: System Specifications

| | | |
|---|---|---|
| **Input Power** | | |
| Main Line Frequency (nominal) | 50-60Hz | |
| Input Voltage (nominal) | 100-240VAC | |
| Input Current (rms) | 12A | |
| **Operating Parameters** | | |
| Ambient Temperature Range | 15 – 30°C [59 – 86°F] | |
| Relative Humidity | 30% to 80%, non-condensing | |
| Atmospheric Pressure | 90 - 110kPa | |
| Warm-up Time | If transported or stored at temperatures outside the operating temperature range, allow one hour for the device to reach room temperature before use. | |
| **Transport and Storage** | | |
| Ambient Temperature Range | -20– 65°C [-4 – 14°F] | |
| Relative Humidity | 0% to 80%, non-condensing | |
| Atmospheric Pressure | 50 to 110kPa | |
| **Dimensions** | | |
| System | 46cm W x 46cm D x 100cm H | [18.2'' W x 18.2'' D x 40'' H] |
| Handpiece Cable | 170; 280cm L | [67; 110`` L] |
| **Weight** | | |
| System | 32.000kg | [70.548lb] |
| DiolazeXL Applicator | 0.450kg | [0.991lb] |
| Vasculaze Applicator | 0.420kg | [0.925lb] |
| Lumecca Applicator | 0.575kg | [1.268lb] |
| Fractora Applicator | 0.100kg | [0.220lb] |
| Forma Applicator | 0.110kg | [0.243lb] |

| | |
|---|---|
| **DiolazeXL Output Parameters** | |
| Wavelength | 810nm |
| Fluence | 5-40 J/cm² |
| Pulse width (duration) | Short/Long |
| Light guide cooling | Strong: 7°C, Normal: 12°C |
| Spot size | 11mm x 27.5mm |
| **Vasculaze Output Parameters** | |
| Wavelength | 1064nm |
| Fluence | 100-300J/cm² |
| Pulse width (duration) | Short/Long |
| Light guide cooling | Strong: 7°C, Normal: 12°C |
| Spot size | 3mm x 4mm |
| **Lumecca Output Parameters** | |
| Wavelength | 515 – 1200nm (SR 515)<br>580 – 1200nm (SR 580) |
| Fluence | 5 – 30J/cm² |
| Pulse width (duration) | Short/Long |
| Light guide cooling | Strong: 15°C, Normal: 22°C |
| Spot size | 10mm x 30mm |
| **Fractora Output Parameters** | |
| RF Energy | 5 – 62 energy levels |
| Frequency | 1MHz |
| **Forma Output Parameters** | |
| RF Energy | 20 – 62 energy levels |
| Frequency | 1MHz |

## 13.1 Output Power Curves

The curves that follow depict the changes for each RF mode at specific power settings.

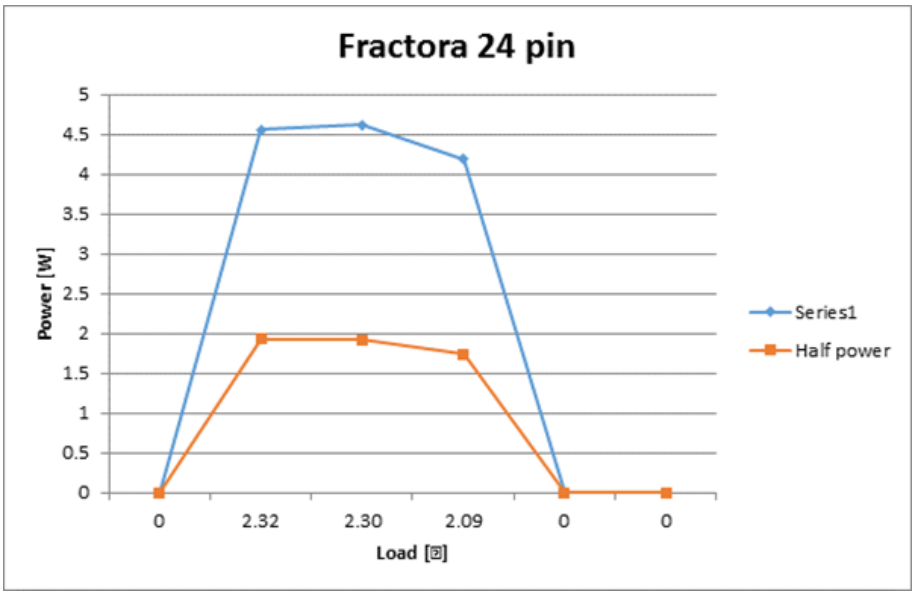



***Figure 13-1: Fractora 24 Pin Output Power versus Impedance***

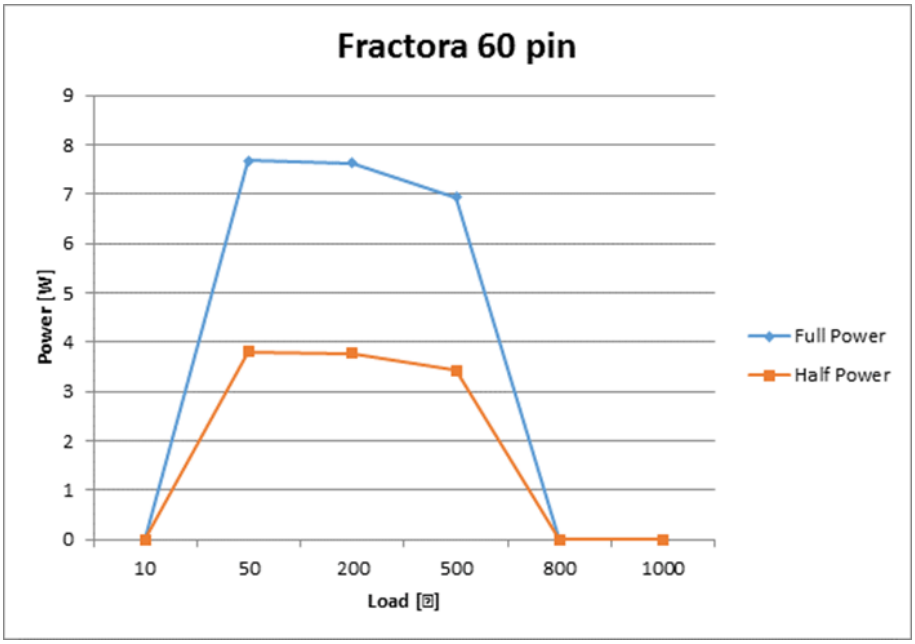



***Figure 13-2: Fractora 60 Pin Output Power versus Impedance***

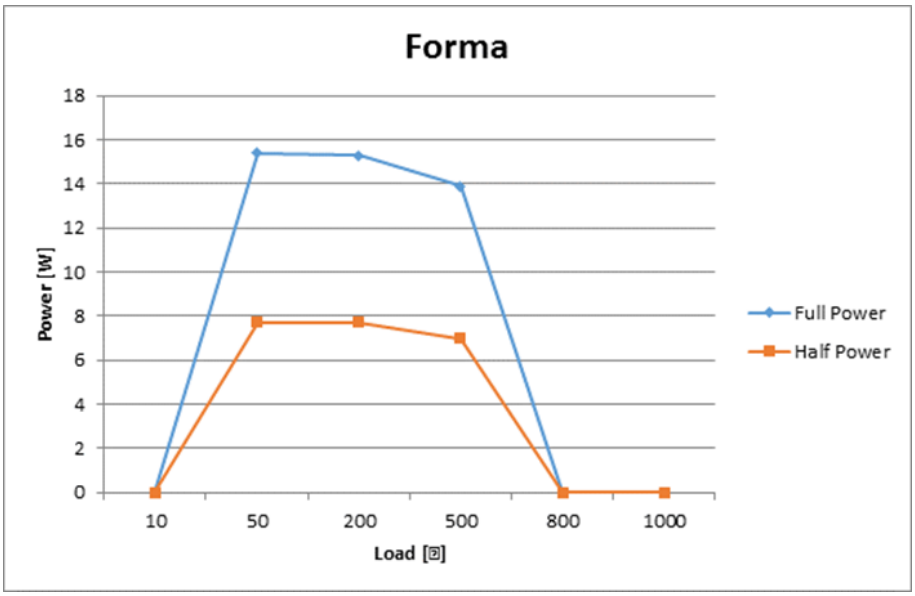



***Figure 13-3: Forma Output Power versus Impedance***

## 13.2 EMC Safety

The device has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device generates uses and can radiate radio frequency energy. If not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that the interference to other devices, which can be determined by turning the device off and on, is caused by this instrument.

The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect the device into an outlet on a circuit different from that which was previously used.
- Consult InMode service personnel for help.

Interference to the device may be caused by portable and mobile RF communication equipment. In case of an interruption, beware of such a device in the vicinity.

- Use of the System with any accessory, transducer or cable other than those specified may result in increased EMISSIONS or decreased IMMUNITY than those specified.

- The System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The Optimas System is intended for use in the electromagnetic environment specified below. The customer or the user of the Optimas should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF emissions CISPR 11 | Group 1 | The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | The System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Complies | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The System is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode<br>± 2 kV common mode | ± 1 kV differential mode ± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % $U_T$ (>95 % dip in $U_T$) for 0,5 cycle<br><br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br><br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><br><5 % $U_T$ (>95 % dip in $U_T$) for 5sec | >95 % dip for 10 ms<br><br>60 % dip for 100 ms<br><br>30 % dip for 500 ms<br><br>95 % dip for 5000 ms | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE - $U_T$ is the AC mains voltage prior to application of the test level. | | | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The System is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment. | | | |
| **IMMUNITY Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic environment – guidance** |
| Conducted RF IEC 61000-4-6<br><br>Radiated RF IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br><br>3 V/m<br>80 MHz to 2,5 GHz | [3] V<br><br>[3] V/m | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = \left[\frac{3,5}{V_1}\right]\sqrt{P} = \left[\frac{3,5}{3}\right]\sqrt{65} = \mathbf{9.4}\ [\boldsymbol{m}]$<br>$80\ MHz\ to\ 800\ MHz$<br>$d = \left[\frac{7}{E_1}\right]\sqrt{P} = \left[\frac{7}{3}\right]\sqrt{65} = \mathbf{18.81}\ [\boldsymbol{m}]$<br>$80\ MHz\ to\ 2{,}5\ GHz$<br>Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System. | | | |

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between**

**portable and mobile RF communications equipment and the System**

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

| Rated maximum output power of transmitter [W] | Separation distance according to frequency of transmitter [m] | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ | 80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ | 800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ |
| 0,01 | 0.117 | 0.117 | 0.233 |
| 0,1 | 0.369 | 0.369 | 0.738 |
| 1 | 1.167 | 1.167 | 2.333 |
| 10 | 3.689 | 3.689 | 7.379 |
| 100 | 11.667 | 11.667 | 23.333 |

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

# 14 Table from IEC60601-1-2, / 5.2.2.1 C&F

## 1. Summary of Test Results

**InMode with HR (DIOLAZE) Laser, SR (LUMECCA 515) IPL and SR (LUMECCA 580) IPL Applicators**

| Test | Standard | Class/ Severity level | Test result |
|---|---|---|---|
| **Documentation** (IEC 60601-1-2 sections 4 and 5) | | | |
| General requirements General requirements for EMC | section 4.1.1. | -- | Complies |
| External labels | section 5.1 | -- | Complies |
| Conformity of Users' Manual | section 5.2.1 | -- | Complies |
| Accuracy of Technical Description | section 5.2.2 | -- | Complies |
| **Emission** (IEC 60601-1-2 section 6.1) | | | |
| Conducted emission Freq. range:150 kHz - 30 MHz | sec. 6.1.1 & CISPR 11 | Group 1 Class A on 230, 120 & 100 VAC mains | Complies |
| Radiated emission Freq. range: 30 - 1000 MHz | sec. 6.1.1 & CISPR 11 | Group 1 Class A | Complies |
| Harmonic current emission test | sec. 6.1.3.1 & IEC 61000-3-2 | AC mains | Complies |
| Voltage changes, Voltage fluctuations and Flicker test | sec. 6.1.3.2 & IEC 61000-3-3 | AC mains | Complies |
| Voltage changes, Voltage fluctuations and Flicker test | IEC 61000-3-3-/ IEC 61000-3-11 | For InMode with Applicator LUMECCA: on AC mains (Z max = 0.17 Ω) | Complies |
| **Immunity** (IEC 60601-1-2 section 6.2) | | | |
| Immunity from Electrostatic discharge (ESD) | IEC 61000-4-2 | 6 kV contact discharges & 8 kV air discharges | Complies |
| Immunity from radiated electromagnetic fields | IEC 61000-4-3 | 3.0 V/m 80 MHz ÷ 2.5 GHz, 80% AM, 1 kHz | Complies |
| Immunity from Electrical Fast transient (EFT) | IEC 61000-4-4 | ± 2.0 kV on 230 & 100 VAC mains, Tr/Th – 5/50 ns, 5 kHz | Complies |
| Immunity from Surge | IEC 61000-4-5 | ±1.0 kV DM / ±2.0 kV CM on 230 & 100 VAC 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 $V_{RMS}$ on 230 VAC mains & Applicator & Pedal cables; 0.15÷ 80 MHz, 80% AM, 1 kHz | Complies |
| Immunity from power frequency magnetic field | IEC 61000-4-8 | 3 A/m, 50 Hz & 60 Hz | Complies |
| Immunity from Voltage interruptions | IEC 61000-4-11 | 230 & 100 VAC mains: > 95 % - 10 ms; 60%- 100 ms; 30% - 500 ms; >95% - 5sec | Complies |

**InMode with WMbody (BodyFX) RF, WMface (Forma / Fractora Firm) RF, MiniFx, PLUS (Fractora Plus) RF and FRACTORA (Fractora )RF**

| Test | Standard | Class/ Severity level | Test result |
|---|---|---|---|
| **Documentation** (IEC 60601-1-2 sections 4 and 5) | | | |
| General requirements for EMC | section 4.1.1. | -- | Complies |
| External labels | section 5.1 | -- | Complies |
| Conformity of Users' Manual | section 5.2.1 | -- | Complies |
| Accuracy of Technical Descri. | section 5.2.2 | -- | Complies |
| **Emission** (IEC 60601-1-2 section 6.1 and IEC 60601-2-2 section 202.6.1) | | | |
| Conducted emission<br>Freq. range:150 kHz - 30 MHz | sec. 6.1.1 /<br>202.6.1.1.1 &<br>CISPR 11 | Group 1 Class A<br>on 230, 120 & 100 VAC mains | Complies |
| Radiated emission<br>Freq. range: 30 - 1000 MHz | sec. 6.1.1 /<br>202.6.1.1.1 &<br>CISPR 11 | Group 1 Class A | Complies |
| Harmonic current emission test | IEC 61000-3-2 | For InMode with Applicator BodyFx:<br>AC mains | Complies |
| | IEC 61000-3-2 | For InMode with Applicator PLUS RF:<br>AC mains | N/A |
| Voltage changes, Voltage fluctuations and Flicker test | IEC 61000-3-3 | For Inmode with PLUS RF: AC mains | Complies |
| | IEC 61000-3-3-/<br>IEC 61000-3-11 | For InMode with Applicator BodyFx:<br>on AC mains (Z max = 0.12 Ω) | Complies |
| **Immunity** (IEC 60601-1-2 section 6.2 and IEC 60601-2-2 section 202.6.2) | | | |
| Immunity from Electrostatic discharge (ESD) | IEC 61000-4-2 | 6 kV contact discharges &<br>8 kV air discharges | Complies |
| Immunity from radiated electromagnetic fields | IEC 61000-4-3 | 3.0 V/m<br>80 MHz ÷ 2.5 GHz, 80% AM, 1 kHz | Complies |
| Immunity from Electrical Fast transient (EFT) | IEC 61000-4-4 | ± 2.0 kV on 230 & 100 VAC mains,<br>Tr/Th – 5/50 ns, 5 kHz | Complies |
| Immunity from Surge | IEC 61000-4-5 | ±1.0 kV DM / ±2.0 kV CM<br>on 230 & 100 VAC mains;<br>Tr/Th – 1.2/50 (8/20) µs | Complies |
| Immunity from conducted disturbances induced by radio-frequency fields | IEC 61000-4-6 | 3.0 VRMS on 230 VAC mains &<br>Applicator & Pedal cables;<br>0.15÷ 80 MHz, 80% AM, 1 kHz | Complies |
| Immunity from power frequency magnetic field | IEC 61000-4-8 | 3 A/m, 50 Hz & 60 Hz | Complies |
| Immunity from Voltage interruptions | IEC 61000-4-11 | 230 & 100 VAC mains: > 95 % - 10 ms;<br>60%- 100 ms; 30% - 500 ms; >95% - 5sec | Complies |

Electronics and
Telematics Laboratory
3 December 2015

Approved by: Eng. Yuri Rozenberg
Position: Head of EMC Branch

Written by: Rotenfeld Mariya
Position: Technical Writer

Tested by: Maxim Reizin
Position: Test Technician

Tested by: Piter Sapir
Position: Test Engineer