ENVISION

by INMODE

Operator Manual

Envision

Version: DO611646A

INMODE

Operator Manual DO611646A: Envision

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1 Section 1: Introduction

1.1. Before You Start

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

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

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

The System must be serviced only by InMode Ltd. qualified personnel).

1.2. System Overview

The InMode Platform with Forma-I, Morpheus8 and Lumecca Applicators (marketed as Envision technology) employs two different technologies for various aesthetic applications – Intense Pulsed Light (IPL), and Radiofrequency (RF). The System operates while in contact with any of the following Handpieces: Forma-I Handpieces employs bi-polar Radiofrequency (RF) technology for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation; Lumecca IPL for treatment of superficial vascular and pigmented lesions; and Morpheus8 for electro-coagulation. The device provides individual adjustment of treatment parameters to achieve maximum efficiency and safety for each patient and applications.

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 (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	HF Isolated patient Circuit
	This equipment intentionally supplies non-ionizing RF energy
	Follow the operating instructions
	Serial Number
	Reference part number
	Symbol for "BATCH CODE". This symbol shall be accompanied by the manufacturer's batch code.
	Do not reuse/single use only. This symbol is used for disposable one-time-use products.
	Sterilized by Radiation
	Symbol for "USE BY". This symbol shall be accompanied by a date to indicate that the device should not be used after the end of the year, month or day shown.

	Symbol for “DO NOT USE IF PACKAGE IS DAMAGED
	Symbol for date of manufacture. This symbol is accompanied by a date
	Symbol for manufacturer. This symbol is accompanied by the name and address of the manufacturer
	Federal (USA) law restricts this device to sale by or on the order of a physician

Figure 1-1: Device Symbols

2 Section 2: Safety

This chapter describes safety issues regarding the use and maintenance of the Envision™ System with the Forma-I, Morpheus8 and Lumecca™ IPL Handpieces, with a special emphasis on electrical, and optical safety, as applicable.

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 treating attendant and patient.

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

The 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 light reflection or RF conduction, as applicable.

Protective eyewear must be used by patient during 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 Envision 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 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 Lumecca IPL Handpiece 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 >6) at the Lumecca IPL wavelength of 515-1200 nm. For users outside the U.S., the protection values are for 730-1085, DIR LB5. All approved by PSP S CE.

The IPL is 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 room must be covered with opaque material, and measures should be taken to prevent unauthorized access to the room.

Compliance with IEC 60601-2-57 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.

Do not treat eyebrows, eyelashes, eyelids or other areas within the bony area surrounding the orbit. The light emitted by the IPL is capable of causing serious eye damage or blindness. For maximum safety, eye goggles must be worn by the patient for all facial treatments when IPL is used.

2.5. Ocular Safety Considerations

- Identify the room clearly by posting approved safety signs in prominent locations.
- Cover all windows to prevent IPL light from escaping the room.
- Restrict entry to the treatment room when the IPL is in use. Allow access to those personnel both essential to the procedure and well trained in safety issues.
- Never look directly into the distal end of the Handpiece.

- All persons in the treatment room must wear approved optical 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 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 (70lb.) and may cause injury if proper care is not used when moving it.
- For RF Handpieces provide as much distance as possible between the system and other electronic equipment as the activated RF generator may cause interference between them.

2.7. Fire Hazards

- The absorption of 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 causes temperature rise of the absorbing material. Do not use the System in the presence of explosive or flammable materials conductive to RF.
- Keep drapes and towels moist to prevent them from igniting and burning. Use non-flammable prepping solutions.
- Do not use flammable substances when preparing the skin for treatment. Be especially careful with the use of oxygen.
- 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 a unique password to avoid device operation by non-authorized personnel.

- The power electronics cannot be fully 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.
- The hardware is tested every 10ms to ensure proper operation of electrical circuit.
- The System starts at a low power setting.
- Temperature monitoring disables the System operation if the Handpiece sapphire temperature is outside the operating range for Lumecca Handpieces.
- The power electronics cannot be fully activated unless the RF Handpieces and Footswitch have been connected to the System. With IPL Handpieces, the connection of the Applicator is sufficient.

For the RF applications:

- There is skin temperature monitoring for Forma-I.

2.9. Safe Use of the Active Accessories

- Examine the connection of the Handpiece through the Connector 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 personal.
- Don’t direct the 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 all electrodes are in full contact with the skin.

2.10. Warnings


Do not connect a wet accessory to the System.


Do not immerse the Applicator under water at any time.


This equipment is for use only by trained, licensed personnel.


Only Handpieces manufactured or approved by InMode Ltd. should be used with InMode 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 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 optical or RF energy is applied, the greater the possibility of unintended thermal damage of skin.

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

The cables of the Handpieces 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 InMode in the same room with any of these substances or gases, prevent their accumulation or pooling within the area where InMode procedures are performed.

The operation of the InMode System may adversely influence the operation of other electronic equipment.

To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

2.11. Device Labels

As required by national and international regulatory agencies, appropriate warning and information labels have been attached to specific locations on the instrument as identified below. The following device labels are located on the InMode device console:

Figure 2-1: InMode System Identification Label

Figure 2-2: IPL Warning Label

Figure 2-3: IPL Emission Warning Label

Figure 2-4: Emergency Stop Label on the emergency Red Button

Figure 2-5: Footswitch Label for All Applicators (but IPL)

2.12. Handpiece Labels

The Handpieces certification 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:

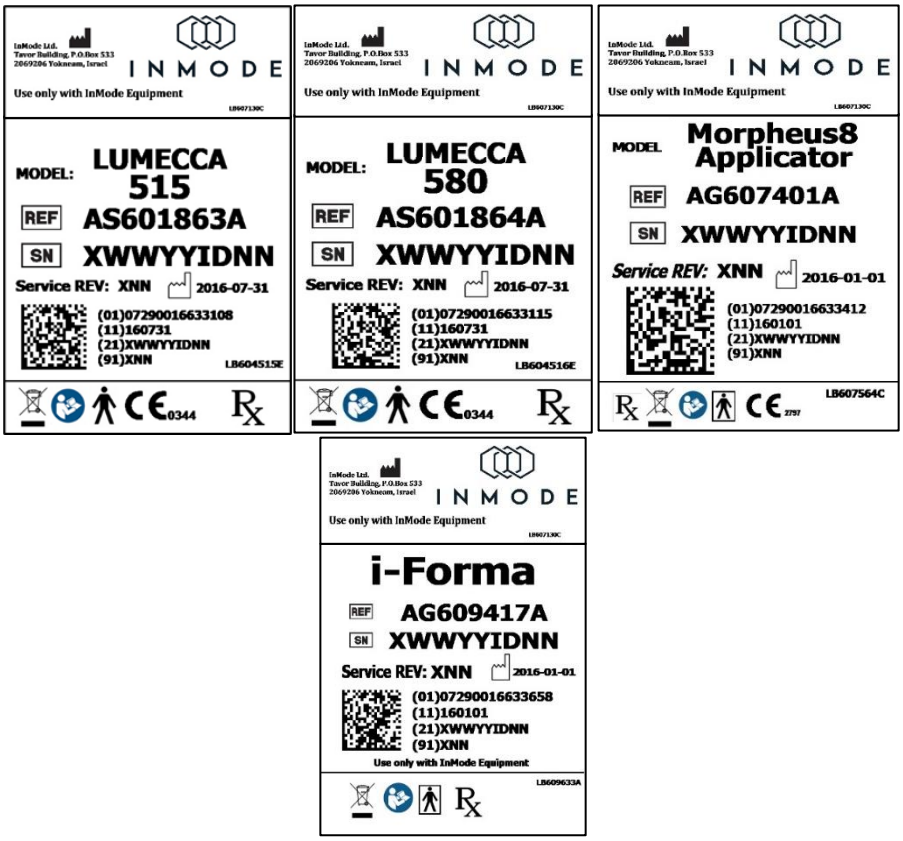


Figure 2-6: All Handpieces Identification Label

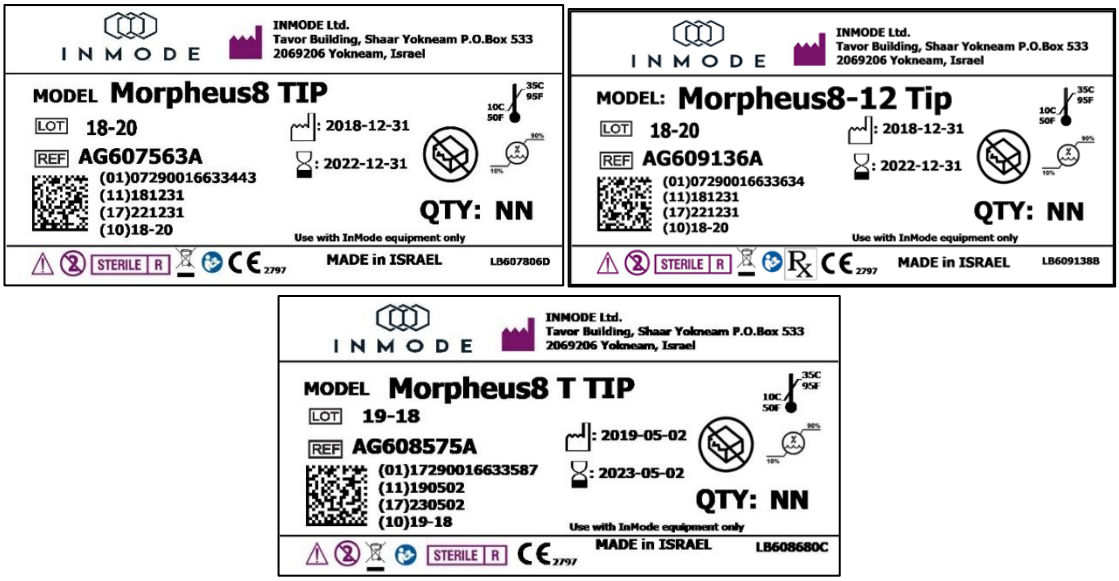


Figure 2-8: Morpheus8 Tip Identification Label

Figure 2-9: Lumecca Handpiece Label for IPL Aperture

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 Handpiece – Lumecca, and Type BF for the RF Handpieces Forma-I, Morpheus8.
- 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 InMode System with IPL Handpiece is classified as IIb device defined by the Medical Device Directive (93/42/EEC) for CE marking.

- The InMode System with IPL Handpieces is classified as a Class II in accordance with the 21 CFR 860 USA regulations.
- The InMode System Forma-I, Morpheus8 Handpieces is classified as IIb device defined by the Medical Device Directive (93/42/EEC) for CE marking.
- The InMode System with Forma-I, Morpheus8 is classified as Class II in accordance with the 21 CFR 860 USA regulations.

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 with all Handpieces includes the following:

- System platform
- Handpieces
- Handpiece cradles
- Footswitch
- Operator manual
- Power Cord

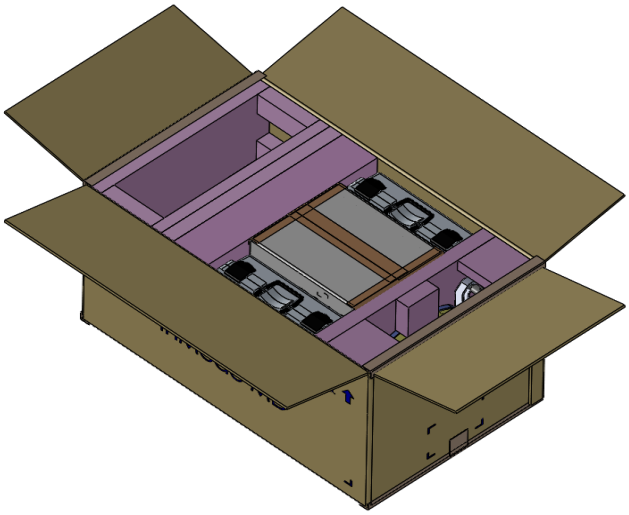
For optical Handpieces:

- User protective goggles.
- Patient eyewear.
- IPL “Danger” door signs, as applicable.

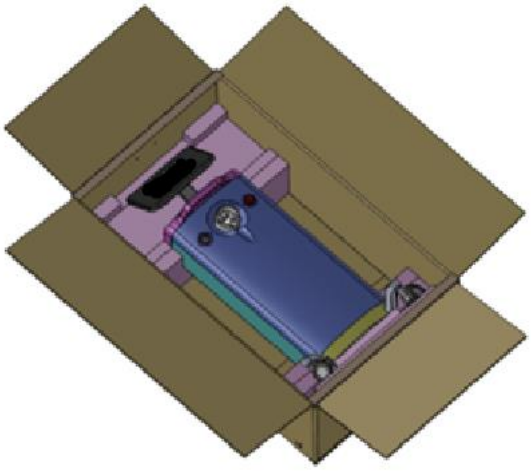
3.4. Unpacking

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 the Cradle to the device.
- Connect the Handpiece to the Connector on Front or Rear Panel (Fig 4.1 or 4.2) and place in the Cradle.
- Connect the Footswitch.
- Connect the Power Cord to the System inlet.
- Plug the System Power Cord into an appropriate electrical outlet.

3.6. Filling Water

The InMode System 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 System Maintenance.

3.7. Moving the System

- Turn the System off.
- Disconnect the Power Cord.
- Disconnect and remove the Handpieces.
- Disconnect the Footswitch.
- Release the Wheel Brakes.
- Slowly push or pull the System using the Handle.
- When moving to another facility, disconnect harness support, lift the System to the vehicle and lay it carefully on its side.
- For shipment with Lumecca, drain the water from the System and the Handpieces, as described in Section 12- 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** 100-240V~, 15A, 50-60Hz.
	**Fuse Holder** Rating is T 6.3A, 250V. Replace fuses if needed, only with fuses having exactly the same rating.
	**Software Flash Memory Plug** 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** The 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 Connectors	Located on the upper right side of the Rear Panel and connects to one of RF Handpieces (Forma -I – upper Connector) or to Morpheus8 – lower Connector) through two types of Connectors (Figure 4.1).
Additional Features	Interlock Connector

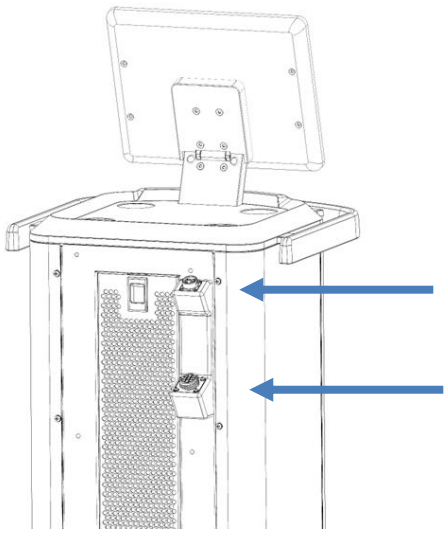


Figure 4-1: Two RF Connectors on the Rear Panel (Arrows)Front Panel and Operator Control Panel

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

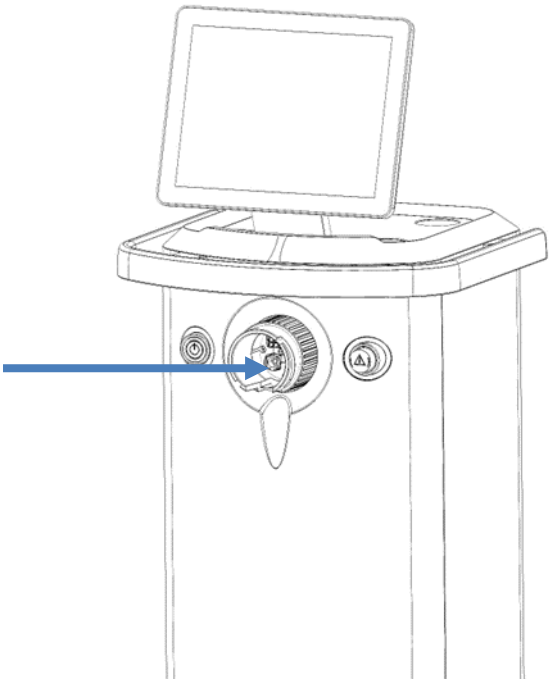


Figure 4-2: Front Panel and Operator Control Panel with Optical Handpieces Connector (Arrow)

Power On-Off Switch	The Power Switch turns the System on and off. The Switch is located on the Front Panel.
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. 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 only the relevant screen.

4.2. Software Screens

The Splash Screen appears after the On-Off switch is turned on.

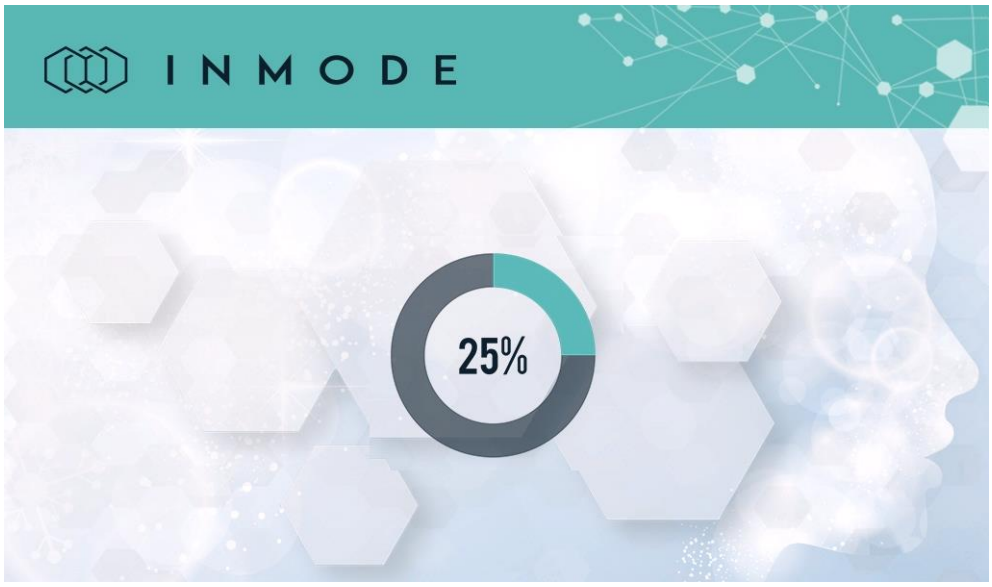


Figure 4-3: Splash Screen

*The Software version number is displayed on the top of the screen and depends on the product version.

After entering the individual code in the Login Screen, the system allows access to the Menu Screen.

Default Login code **1234** can be changed in the Utilities Screen. The acoustic Volume level can also be reduced in the Utilities Screen.

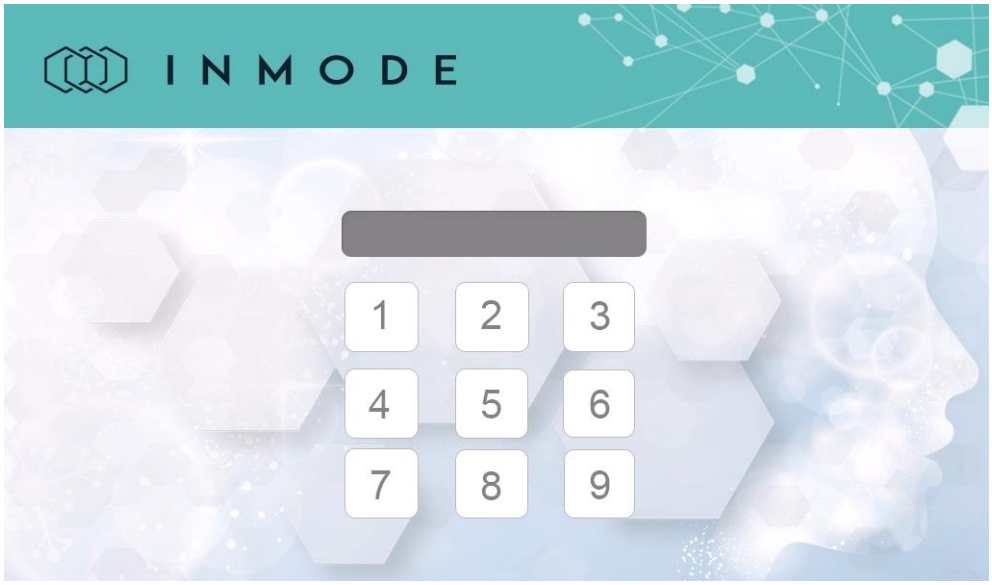


Figure 4-4: Login Screen

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.

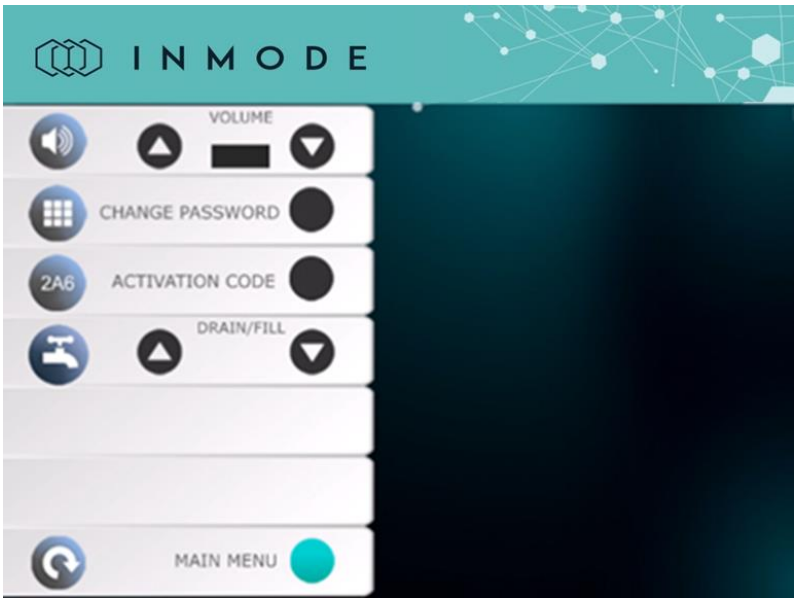


Figure 4-5: Utilities Screen

Figure 4-6: Menu Screen

The Menu Screen allows the selection between the connected Handpiece, or entry to the Utilities Screen. The Handpiece name will appear on the menu screen Only when it is connected (e.g., in figure 4-7, the Lumecca Handpiece is connected). The three icons represent the three available connectors.

The treatment selection icons utilize the system Handpiece as follows:

- One RF Connector is used for Forma-I Handpiece. The System automatically identifies the connected handpiece and presents the designated Treatment screen
- The other RF Connector is used for Morpheus8,
- The third connector is used for Optical Handpieces: Lumecca.

Figure 4-7: Menu screen when Lumecca Handpiece is connected

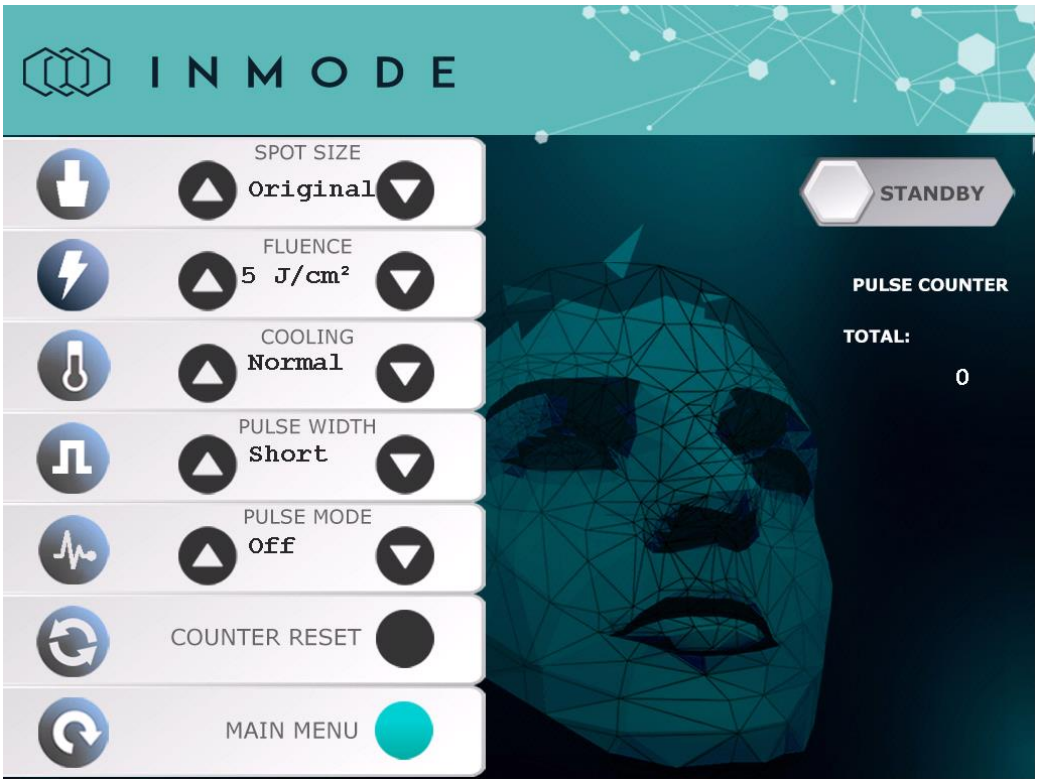


Figure 4-8: Lumecca 580 Treatment Screen (same screen for the 515)

The Lumecca 580 or 515nm Treatment Screen contains:

Spot size	Allows selecting the spot size. Available spot sizes are: **Original**, **Small** (Applicator with the Small Spot Size adaptor on). Small spot size shall be only used with 580 nm
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 can be selected.
Pulse Width	Short or Long can be selected.
Pulse Mode	Repeat mode in Normal or Fast repetition rate or in Off as a single pulse mode.
Counter Reset	The Counter can be reset. When utilizing the **Small** Spot Size adaptor, the system will transition into Standby Mode after every 30 pulses. To return the system to the Ready mode, a Pulse Counter reset will be required.
Pulse Counter	Shows the number of pulses delivered from the beginning of the treatment.
System Mode	**Standby mode** allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode.

	In **Ready mode**, 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.
Main Menu	Return to the Main Menu to select another Applicator and change the Applicator if needed.

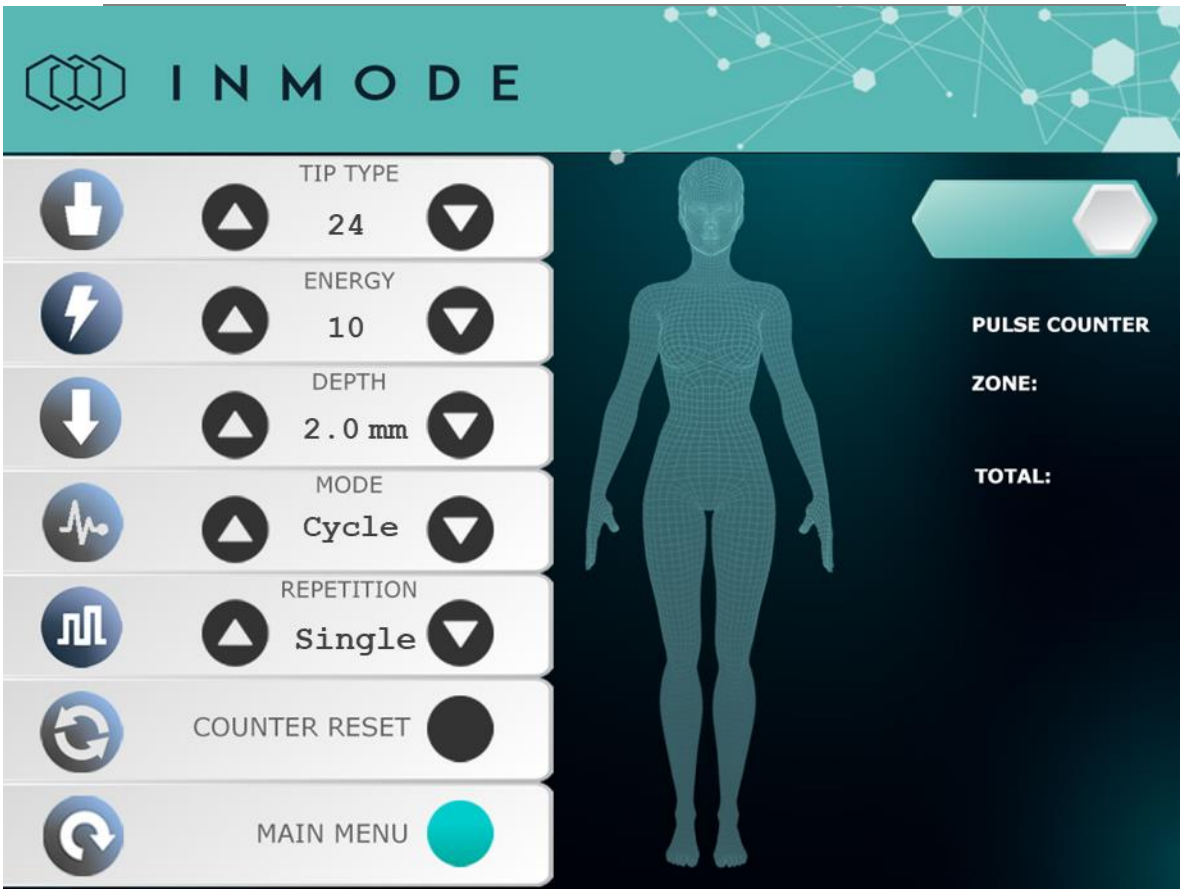


Figure 4-9: Morpheus8 Treatment Screen

The Morpheus8 Treatment Screen contains:

Tip	Allows selecting the Tip. Available Tips are: Resurfacing, 12 Pin, 24 Pin tip.
Depth	Allows selecting the pins length and penetration depth according to dermis thickness in treated area to provide effective sub-dermal treatment. Available depths for Morpheus8 are: For the Morpheus8 Prime (12 pins) Tip: 1 to 4mm (In increments of 1mm) For the Morpheus8 (24 pin) Tip 1 to 4mm (In increments of 1mm) When connecting the Morpheus8 Resurfacing Tip, depth control is disabled and the pin length is fixed (0.5mm).

Energy	Delivered energy for 12, 24 is changed from level 5 to 60 energy levels and for Resurfacing tip from 5-30 energy levels and the System starts up at the minimal energy setting.
Mode	Selects between Cycle mode when needle goes out and in at each pulse and Fixed mode which is solely used for Resurfacing tip.
Counter Reset	Counter can be reset.
Pulse Counter	Shows number of pulses delivered on one zone and total number of pulses from the beginning of the treatment.
System Mode	Standby mode allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode. In 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.
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

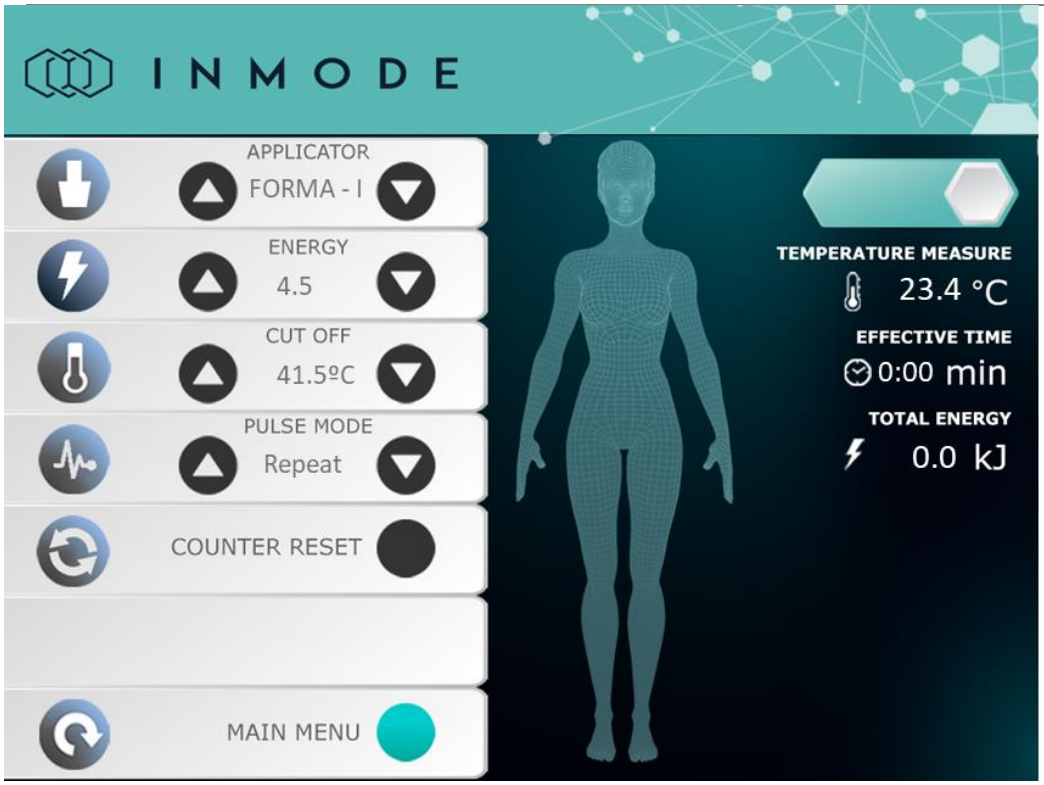


Figure 4-10: Forma-I Treatment Screen

Selection Frame	The frame selects parameters that can be changed by functional keys.
Applicator	Allows selecting Forma-I

Energy	Delivered energy is changed from level 1 to 9 energy levels and the System starts up at the minimal energy setting.
Cut-Off	Cut-off temperature settings are changed in the range of 35-43ºC. 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, as long as the foot switch is pressed
Counter Reset	Counter can be reset.
Temperature Measure	This indicator shows the skin surface temperature, as measured by an integral temperature sensor.
Treatment Time	This function shows the total time that RF is activated.
Effective Time	This function shows the treatment time, starting from time-point of 2°C below the cut-off temperature
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.
System Mode	Standby mode allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode. In 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.

4.3. Sound Indicator

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

4.4. Cut-Off Temperature Control

The cut-off temperature up to an upper limit of temperature of 43ºC is constantly maintained for Forma-I 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.

4.5. Handpieces

Figure 4-12: Forma-I Handpiece

Forma-I Handpiece (4-12) comprises applicator, cable, connector and an integral temperature sensor.

Tip	Is a part of Handpiece, comprising RF electrodes and temperature sensor.
Handle	Is made of metal and has ergonomic design for easy treatment with high visibility of the treated area.
Cable	Has a length of 200cm (80'').
Connector	The Connector is connected to the front/rear panel of the System.

Each of the Lumecca Handpieces (515 and 580) comprises an Applicator, Cable and Connector.

Figure 4-13: Lumecca Handpiece

Figure 4-14: Lumecca Handpiece with Lightguide Adaptor for smaller areas

Applicator	Comprises flash lamp and reflector emitting optical energy through the pre-cooled light guide (30x10mm) (Figure 4-13).
Lightguide Adaptor	Small Spot-size Applicator (8 mm diameter) (Figure 4-14)
Cable	Has a length of 170cm.
Connector	The Connector is connected to the System.

Morpheus8 Handpiece (Fig 4-15) comprise motor with actuator pushing needle electrodes out to pre-determined depth up to 4mm. The tip (Figure 4-16) is connected or disconnected with the Handpiece.

Figure 4-15: Morpheus8 Handpiece

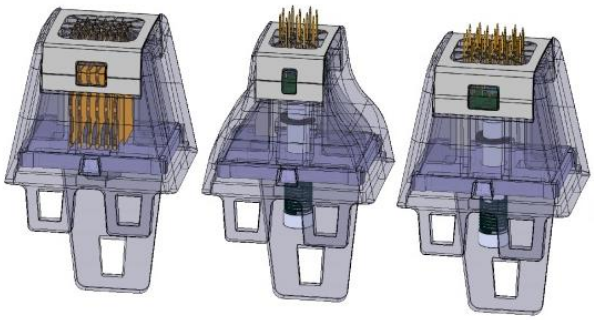


Figure 4-16: Morpheus8-Resurfacing Tip (Left), Morpheus8-12 Pins Tip (Center), Morpheus8-24 Pins Tip (Right)

Tip	The tips comprise 24, or 12 needles that are coated along with an insulating material except the distal 0.5mm edge (Figure 4-17). Note the insulation that leaves only the 0.5mm tip exposed. For the Resurfacing tip, depth control is disabled, and the pin length is constant (0.5mm).
Handle	The Handpiece handle is made of plastic and has an ergonomic design for easy treatment, with high visibility of the treated area.
Cable	The Cable has a length of 270cm.
Connector	The Connector is connected to the front panel of the System.

Figure 4-17: Morpheus8 tip needle structure

The insulation leaves only the 0.5mm tip exposed

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 the Main Power Switch on 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 Menu Screen.
4. Enter a unique password to get access to the device. If the password is correct, the System enters the 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 the Troubleshooting section in this manual). If the test is passed correctly, then the System automatically enters the Menu Screen.
6. Select Application from the Menu Screen and the System will enter the Treatment Screen.
7. Verify on the screen that the software version is properly displayed, and that the connected Handpiece type is recognized correctly.
8. Select the treatment parameters using Up and Down arrow keys.
9. Apply the Handpiece to the treated area, ensuring a full contact.
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.

5.2. System Shutdown

- To shut down the System, turn the On-Off Switch located at the front to Off.
- Turn the Main Power Switch to 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: Lumecca Treatment Information

IPL Lumecca treatment is based on principles of selective photothermolysis. The light penetrates 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.

6.1. Indications for Use

The InMode IPL Device wavelengths (515-1200nm and 580-1200nm) are indicated for use for the following treatments:

- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
- The treatment of benign cutaneous vascular lesions, including port wine stains, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, superficial leg veins and venous malformations.

6.2. 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 and the lips!


Do not treat over tattoo and permanent makeup!


Permanent hair reduction may occur in the treated area.


Do not treat over an area with a high density of hair. Absorption of light by hair follicles may cause an adverse skin reaction.

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), 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.

6.4. Pre-Treatment

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 for at least 2 weeks. Sunscreen is advisable during outdoor activity at daylight hours.
- 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 direct 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 mark 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

Follow Device Start-Up Procedure from System Operation section.

1. Ensure that skin is clean.
2. Apply 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.

3. 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.
4. Typical treatment parameters are shown in the table below:

Skin type	Lesions type	Handpiece	Fluence	Pulse width	Cooling
I-II	Pigmented lesions	515nm	8-12J/cm²	Short Long	Strong
	Vascular lesions	515nm	12-16J/cm²	Short Long	Strong
III-IV	Pigmented lesions	580nm	6-12J/cm²	Short Long	Strong
	Vascular lesions	580nm	10-16J/cm²	Long	Strong

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 the Handpiece to the treated. Use slight pressure and activate the Hand Trigger Button to deliver a light pulse.

7. Perform a test spot in the area to be treated on a non-conspicuous spot and wait 10-15 minutes to check the response.

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

9. In a continuous mode - slide the Handpiece to adjacent area without overlap and chose Auto Repeat Normal or Fast Mode according to the speed of your hand movement.

10. If end-points of darkening lesions and inflammation around them are not obvious after a few minutes, perform a second pass, preferably in a different direction.

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

6.7. 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 and make-up may be applied immediately after each treatment.

6.8. 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 at the discretion of the physician.

7 Section 7: Morpheus8 Treatment Information

7.1. Sub-dermal Fractional Treatment

The Morpheus8 Applicators are designed for delivering RF energy to the dermal and sub-subdermal tissue in a fractional manner with the energy applied to <5% of the total coverage area. The energy is delivered to the skin through bipolar arrays of coated needles and results in localized heating and coagulation of the tissue that is in direct contact with the needle tip. The Morpheus8 Applicator is a versatile fractional technology to treat different body areas.

7.2. Indications for Use

The Morpheus8 Applicators are intended for use in dermatological procedures for electrocoagulation and hemostasis.

7.3. Contraindications

- Pacemaker or internal defibrillator, or other metallic or electronic implant anywhere in the body. The Hand piece 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 or use of anticoagulants in the last 10 days
- 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 to be kept.
- Treating over the lips.
- Skin type V and dark VI patients treat with caution.
- Treating over hair bearing surfaces.
- Irritable skin like 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.

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

7.5. 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 Morpheus8 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:
  - Topical anesthetic can be applied as needed prior to treatment.
- 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.

The operator shall inspect the hand pieces functionality prior to use, by attaching the disposable tip, pressing the footswitch and observing the pins to come out and returning back.

In case of engine failure when the pins of the hand pieces do not retract out of the skin, detach the disposable tip from the hand piece and release the spring mechanism manually.

7.6. Handling Instructions Prior to Use

The Applicator should be thoroughly cleaned before and after use by applying 70% alcohol-absorbed pad for at least 30 sec.

Before each use thoroughly inspect the Applicator for visible damage and cleanliness.

Inspect all components of the Hand piece for visible damage.

The Morpheus8 tips arrive sterile and are for single use only!

7.7. 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.

7.8. 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 Applicator in the groove.
4. Connect Applicator to the System.
5. Follow Device Start-Up Procedure from System Operation section.
6. Select tip and set treatment parameters.
7. Make sure that the treatment settings correlate to the treated tissue depth.
8. Always start with a low energy level, test patient comfort and observe the skin's response before increasing the energy. Tips, depth and energy levels may vary according to physician discretion, based on patient response.
9. On sensitive thin skin area apply lower parameters.
10. Dark skin (V-VI) treat with restricted energy, starting at the minimal suggested energy level or lower, adding 5 levels each visit (every 3-4 weeks).
11. Apply the Applicator to the treated area ensuring a contact with pressure to minimize discomfort, and press footswitch to deliver RF energy.
12. Move Applicator to the adjacent area and activate RF again.
13. Move to adjacent areas with no overlapping of side-electrodes (30-50% overlap).

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

15. The below list summarizes the Treatment recommendations per each tip type:

Tip name	Treatment areas
Morpheus8 Prime (12 pin) Tip	Dermal and subdermal treatment of small areas difficult to maneuver
Morpheus8 Resurfacing Tip	Superficial (epidermal) treatment
Morpheus8 (24 pin) Tip	Dermal and subdermal treatment
Typical number of treatments is 1 to 6 and depends on used energy and treatment goal	
Typical down time is 1 to 6 days and depends on used energy and number of passes	

7.9. Treatment Schedule

The number of treatment sessions depends on the individual patient and treatment aggressiveness and may vary from 1-6 sessions, depending on used energy and treatment goal, as well as patient tolerance and skin response. Treatments are typically repeated every 3-6 weeks.

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

Typical down time is 1 to 6 days and depends on used energy.

Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion. Generally, 3-6 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.

7.10. 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 Morpheus8 session.

8 Section 8 : Forma-I Treatment Information

8.1. Indications for Use

The Envision system with the Forma-I Handpiece is intended for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation. FORMA-I is designed for treatment of smaller zones.

8.2. 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 and screws, 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, 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.
- 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.
- If face is treated, facial dermabrasion, laser resurfacing and deep chemical peeling within the last 3 months prior Forma-I treatment.

- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient unsafe for the patient.

8.3. Possible Adverse Side Effects

- Possible side 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, 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.

8.4. Handpiece Cleaning Instruction Prior to Use

The following processes are validated for the Envision System with Forma-I 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:

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

Pre-Use Check:

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

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

8.5. Pre-treatment Recommendations

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

1. Complete or update the patient’s medical and physical history
2. Exclude from treatment anyone with the listed contraindications.
3. Determine why the patient is seeking treatment and what his/her expectations are.

4. Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
5. Instruct the patient about the safety warnings.
6. 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.
7. Clean the face, remove crèmes and makeup, and dry the skin.
8. Photograph the patient.
9. Mark the treatment area.
10. Clean the handpieces 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 physician’s discretion.

Ensure that the patient's eyelids remain closed throughout the duration of the procedure.

8.6. Treatment Recommendations

1. Ensure that skin is clean and dry.
2. Connect Handpiece to the System.
3. Follow Device Start-Up Procedure from System Operation section.
4. Set treatment parameters.
5. Always start with a low energy level, test patient comfort and observe the tissue's response before increasing the energy.
6. Any combination of treatment parameters should be according to skin response and patient tolerance.
7. Air condition directed at the patient treated area may reduce the skin surface temperature in 1-2°C, and cut-off temperature should be reduced accordingly.
8. Always make a test-spot, starting with low settings and observe the skin's reaction and patient comfort before increasing the RF energy.
9. Divide treatment area to zones.
10. Water based gel should be applied to the treated zone, one at a time to couple the RF and to enable a smooth movement on the skin. Adjacent zone could also be covered with gel that can serve as a gel reservoir for replenishing gel in the treatment area with minimal delay.

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

11. Assume full contact of Handpiece with the skin with a slight pressure.
12. Use your free hand to flatten and stretch treatment area if needed for complete contact and smooth movement.
13. Press the footswitch and initiate the RF energy.
14. Move the Handpiece 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.

15. 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.
16. After reaching the cut-of temperature apply multiple passes to maintain the desired temperature during 10min/zone. If cut-off temperature is <41°C, maintain the temperature for >5 per zone.
17. Movement speed, RF energy, and cut-off temperature can be adjusted in this order during the treatment for the best comfort of the patient.
18. After treating the zone, move to the next zone.
19. Slight erythema and edema are a typical immediate response. However, when there is excessive skin response (erythema and edema), stop treatment and move to the next zone. For excessive heat sensation, you may increase the movement speed, reduce the RF power and lastly, reduce the cut-off temperature. If this does not help, move to the next zone

8.7. Treatment Schedule

The number of treatment sessions depends on the individual patient and is typically 6 weekly sessions, but can vary according to patient response.

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

One session every 1-3 months, or as needed, may maintain treatment results.

8.8. Post-treatment Recommendations

- After each treatment session, the physician should advise the patient on proper care.
- Skin cooling is NOT recommended.
- Patient should avoid very hot water for 2 days after the treatment.
- 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.

9 Section 9: System Maintenance

9.1. Maintenance & Frequency

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

9.2. 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 (Lumecca, Forma-I), remove the gel before cleaning

9.3. 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.

9.4. Once a Month

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

9.5. 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 IPL Handpieces!

9.6. Filling Water for Lumecca

InMode System with Lumecca handpieces are shipped without water. 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. Connect one of the Handpieces.
2. Open the back cover and take out the Bottle.
3. Unscrew the water Bottle Cap (Figure 9-1).
4. Slowly pour distilled water into the Bottle while the Water Filter and Tube are inside the Bottle to prevent over pouring (Figure: 9-2).

Figure 9-1: Water Bottle Cap

Figure: 9-2: Distilled Water Filling

Figure 9-3: Water Bottle in Bracket

5. Fill the Bottle up to the maximum level.
6. Close the bottle cap and insert the Bottle at the back of the System (Figure 9-3).
7. Connect any Handpiece to the System.
8. Turn the System On.
9. Select “Utilities” on the Main Menu (Figure 9-4).
10. Select “Water Drain/Fill” from the Utilities Screen (Figure 9-5).
11. Pressing the Up arrow will activate the Pump and count down from 600 seconds (10 minutes) to 0 seconds (Figure 9-6).

Figure 9-4: Menu Screen

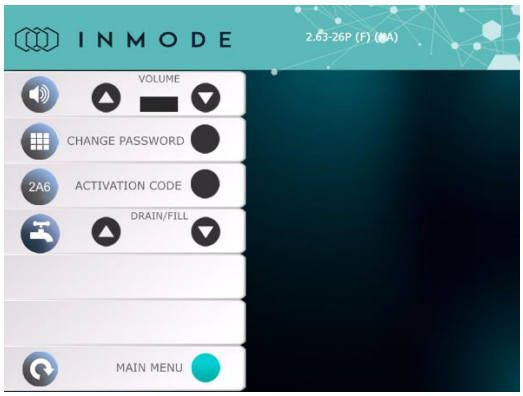


Figure 9-5: Utilities Screen

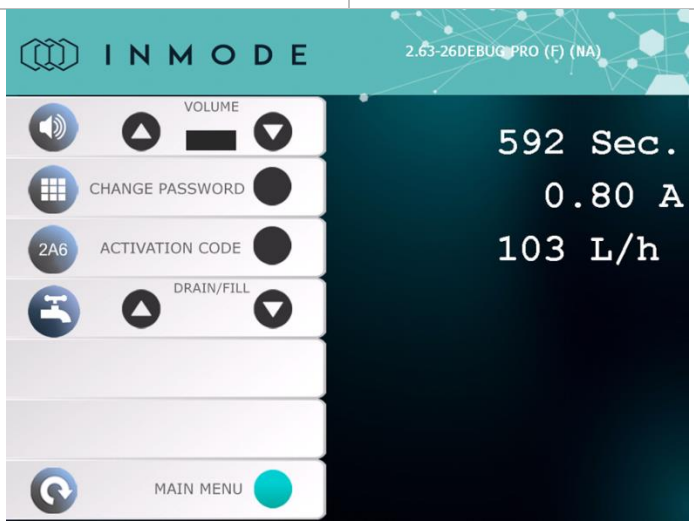


Figure 9-6: Time Counter Water Pump Current Value (right side of screen)

12. After 300 seconds (while the Pump is working), unscrew the plastic Cap on the side of the Capsule Filter counter clockwise to release air. Afterwards, screw the Cap clockwise to close it (Figure 9-7). Ensure that no water is leaking.

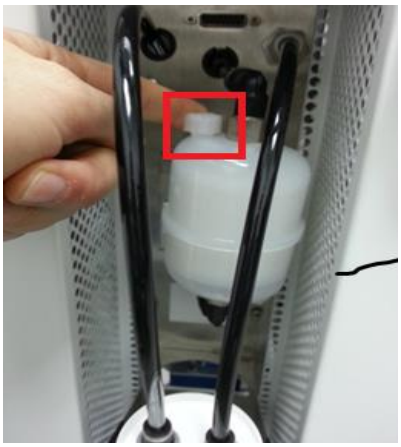


Figure 9-7: Capsule Filter with Plastic Cap

13. Pressing the Down arrow will stop the Water Pump.
14. Turn the System Off.
15. Repeat steps 2 to 5 since the System and Handpiece will take some of the water.
16. If additional Lumecca Handpieces are present, connect each Handpiece and repeat steps 6 to14. Ensure the water level is checked periodically.

9.7. Draining Water for Lumecca

For shipping and storage, the InMode systems and 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 9-8).

Figure 9-8: Water Bottle with Deionizer Cartridge

Figure 9-9: Water Bottle in Drain Position

3. Empty the Bottle.
4. Place the Bottle inside the Chamber with the black hose outside the Bottle (Figure 9-9).
5. Connect the Lumecca Handpiece.
6. Turn the System On.
7. Select “Utilities” on the Main Menu (Figure 9-4Figure 9-4).
8. Select “Water Drain/Fill” (Figure 9-5).
9. Pressing the Up arrow will activate the Pump and count down from 600 seconds (10 minutes) to 0 seconds (Figure 9-6).

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

11. Repeat Steps 5 to 9 for draining any remaining IPL Handpiece.

12. Observe the reservoir; when no more water is pouring out, turn off the System.

9.8. Draining the 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 9-10).

Figure 9-10: Water Draining Tool

The 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 handpiece 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 Connector with the label at a 90° counter clockwise angle (as shown ii Figure 9-11), and twist it 90° to the right, so that the label is straight.

Figure 9-11: Connecting the Handpiece to the Water Draining Tool

2. Hold the Handpiece and the 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 Lumecca Handpieces. To order the Water Draining Tool, contact our Service department.

9.9. 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 9-8).

To install a new Deionizer Cartridge:

4. Connect the Water Hose into the Deionizer Filter until is securely locked.

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.

Fill 1 liter of distilled water into the Bottle and return it to its compartment. Perform “Filling Water” procedure as described above.

9.10. 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 9-12 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 9-12 right).

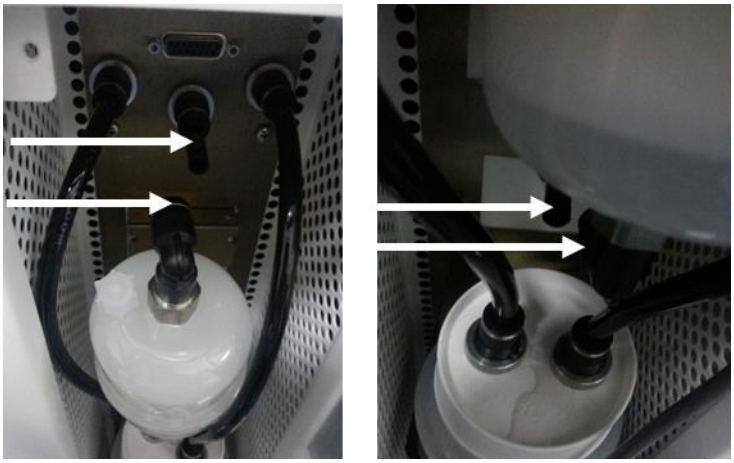


Figure 9-12: Upper (Left) and Lower (Right) Filter Quick Connectors

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 9-12 right).

3. Push the upper System Water Hose into upper Filter's Quick Black Connector as much as possible (Figure 9-12 left).

4. Remove the Water Bottle from the compartment, pour out the distilled water from the Bottle according to the "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.

9.11. 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.

Dust filter are located on inside back over door (Figure 9-13).

Figure 9-13: 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).

10 Section 10: Troubleshooting

The InMode System provides monitoring of all critical parameters to ensure safety of patient and user. If any of the following faults are detected system automatically goes to Stand By mode.

10.1. Description of Faults with All Handpieces

Problem	Description and Checks
The System did not turn on	▪ Check the Power Cord connection. ▪ Check that the Main Switch on Rear Panel is On. ▪ Check that the On/Off Switch on Front Panel is On. ▪ Check that the Emergency Button has not been pressed. ▪ Check the fuses on the Back Panel of the System. ▪ Call Technical Service if the problem persists.
The System shuts down by itself	▪ Check the Power Cord connection. ▪ Check the fuses on the Back Panel of the System. ▪ Check that the Emergency Button has not been pressed. ▪ Call Technical Service if the problem persists.
Checksum	▪ The software was not loaded properly from the Software Plug. ▪ Check the Plug connection and reboot the System. ▪ Call Technical Service if the problem persists.
Fault H8002 - Handpiece is not connected	▪ Check the Handpiece connection. ▪ Replace the Handpiece. ▪ Call Technical Service if the problem persists.
Fault H8005, H800F, H8010 – System Memory Fault	Call Technical Service if the problem persists.
Fault H8609 – Water Temperature Fault	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	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.

11 Section 11: 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	32.000 kg	[70.548 lb]
Lumecca Applicator	0.575 kg	[1.268 lb]
Morpheus8 Applicator	0.400 kg	[0.243lb]
Forma - I Applicator	0.35 kg	[0.77 lb]
Lumecca Output Parameters		
Wavelength	515 – 1200nm (515) 580 – 1200nm (580)	
Fluence	5 – 30 J/cm²	
Pulse width (duration)	Short/Long	

Light guide cooling	Strong - 15ºC, Normal - 22ºC
Spot size	10mm x 30mm
Repetition Rate	1Hz
Forma - I **Output Parameters**	
Maximal Output Power	12 W
Frequency	1MHz

11.1. RF Output RF Power Curves

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

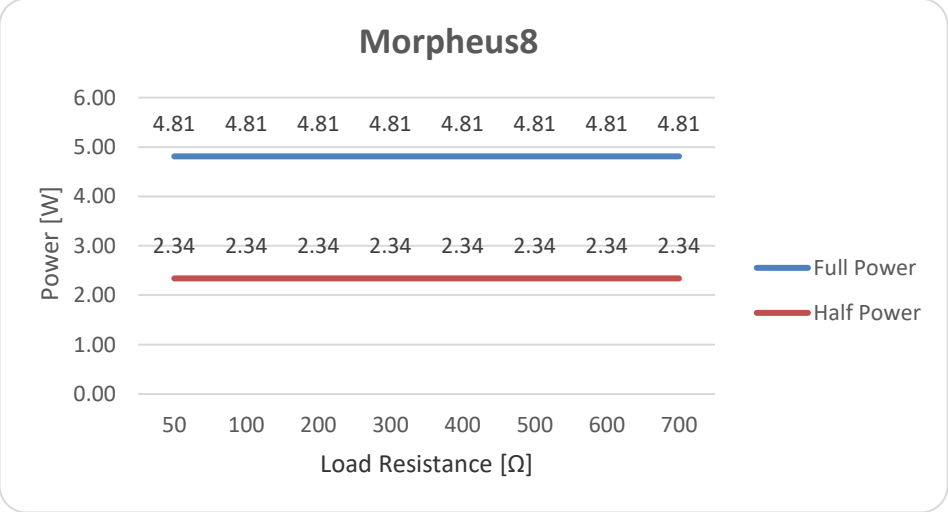


Figure 11-1: Morpheus8 Output Power versus Impedance

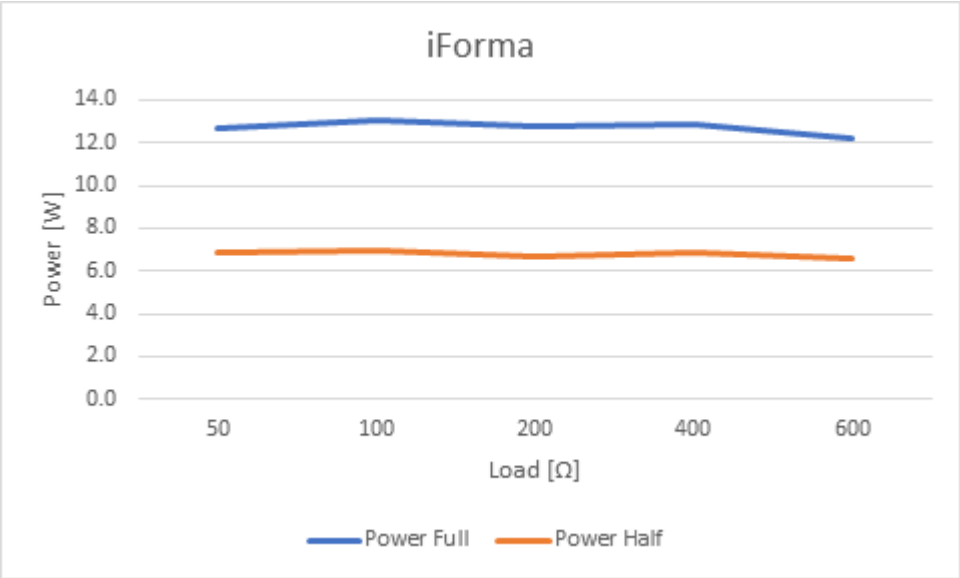


Figure 11-2: Forma - I Output Power versus Impedance

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

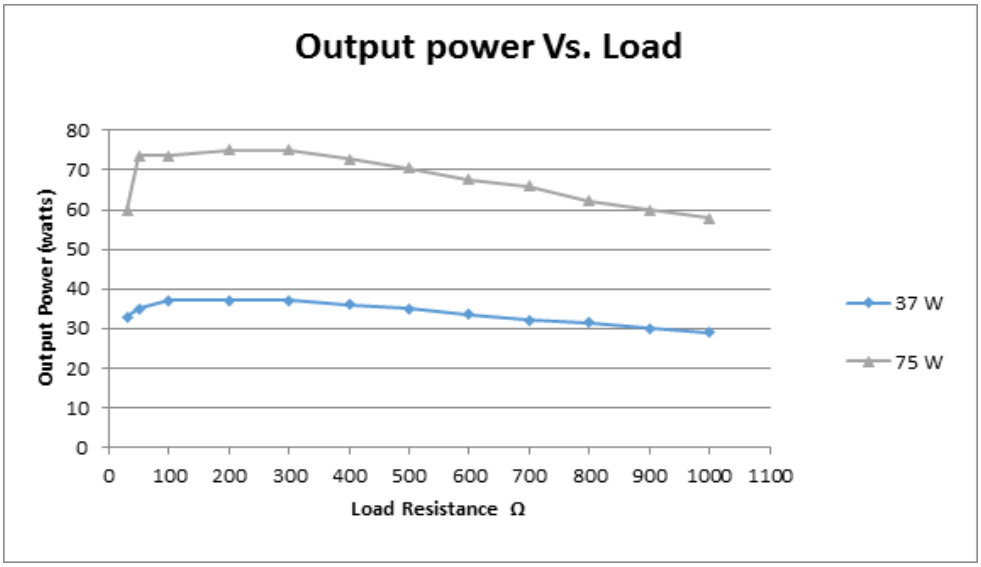


Figure 11-3: Output Power Versus Impedance

11.2. 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.

IEC 60601-1-2 Edition 4.0 (2014):

Environment of intended uses:
Professional Healthcare Facility Environment

Summary of Test Results:

InMode with HR (DIOLAZE), Diolaze XL 810, Diolaze 810/1064, Diolaze 755/810 Laser, Vlaze, LUMECCA 515, LUMECCA 580 (IPL), LUMECCA HR/SR (IPL) hand pieces

Test	Standard	Class/ Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements for EMC	section 4.1	--	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 7.1 & 7.2)			
Conducted emission Freq. range:150 kHz - 30 MHz	sec. 7.1 & CISPR 11	Group 1 Class A on 230, 120 & 100 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	sec. 7.1 & CISPR 11	Group 1 Class A	Complies
Harmonic current emission test	sec. 7.2.1 & IEC 61000-3-2	AC mains	Complies
Voltage changes, Voltage fluctuations and Flicker test	sec. 7.2.2 & IEC 61000-3-3-/ IEC 61000-3-11	For InMode with Hand Pieces Diolaze, Vlaze & LUMECCA: on AC mains (Z max = 0.03 Ω)	Complies
Voltage changes, Voltage fluctuations and Flicker test	sec. 7.2.2 & IEC 61000-3-3	For InMode with Hand Piece LUMECCA 515 (October 2021))	Complies
Immunity (IEC 60601-1-2 section 8.9 & 8.10)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	3.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on AC mains, Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1. kV DM / ±2.0 kV CM on AC mains; Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0 & 6.0 V_{RMS} on AC mains & 4 cables to hand pieces; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	30 A/m @ 50 Hz & 60Hz	Complies
Immunity from Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 & 100 VAC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

InMode with WMbody(BodyFX), MiniFX, WMface/Fractora Firm), PLUS(Fractora Plus), FRACTORA(Fractora), PLUS 90, FRF RF/ Fractora3D (Morpheus8) hand pieces

Test	Standard	Class/ Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements for EMC	section 4.1	--	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 sections 7.1 & 7.2; IEC 60601-2-2 section 202)			
Conducted emission Freq. range:150 kHz - 30 MHz	sec. 7.1 / 202.6.1.1.1 & CISPR 11	Group 1 Class A on 230, 120 & 100 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	sec. 7.1 / 202.6.1.1.1 & 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
Immunity (IEC 60601-1-2 sections 8.9 & 8.10; IEC 60601-2-2 section 202)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	3.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on AC mains, Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1. kV DM / ±2.0 kV CM on AC mains; Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0 & 6.0 V_{RMS} on AC mains & 4 cables to hand pieces; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 & 100 VAC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

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2 January 2022

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