

MORPHEUS8

OPERATOR MANUAL



Morpheus8 Applicator

Version: DO607530A



INMODE

aesthetic solutions

Operator Manual: Morpheus8 Applicator
DO607530A

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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 Morpheus8 Handpiece employs bi-polar Radio-frequency (RF) technology for fractional resurfacing for various aesthetic applications. The Morpheus8 Handpiece used with Inmode platforms. 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



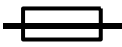







Symbol	Description
	CSA marking (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	Type B Equipment.
	HF Isolated Patient Circuit
	Follow the operating instructions
	Federal (US) law restricts this 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 Morpheus8 Handpiece, 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 treating attendant and patient.



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



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 RF conduction.

2.2 Treating Attendant

- Only authorized individuals with appropriate training and knowledge should operate, assist in the operation of, or provide maintenance to the device with Morpheus8 Handpiece.
- 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.

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 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 15kg (33 lb.) 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.

2.5 Fire Hazards

- 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 nonflammable prepping solutions.
- If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the System is used.

2.6 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. 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.
- The System starts at a low setting.

2.7 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.



Do not connect a wet accessory to the System.



Do not immerse the applicator under water at any time.

2.8 Warnings



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



Only handpiece manufactured or approved by InMode MD Ltd. should be used with InMode System with Morpheus8 Handpiece.



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 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 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 RF energy and heating associated with the System can provide an ignition source. Observe fire precautions at all times. When using InMode System with Morpheus8 Handpiece in the same room with any of these substances or gases, prevent their accumulation or pooling within the area where Morpheus8 procedures are performed.



The operation of the InMode System with Morpheus8 Handpiece 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.

2.9 Handpiece 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 InMode System with Morpheus8 Handpiece device console and the handpiece:

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 Handpiece: Manufacturer identification labeling is placed on the Handpiece:



Figure 2-1: All Handpiece Identification Labels

2.10 Equipment Classification

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

- Electric shock protection: Class I, Type BF for the RF Handpiece.
- 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 Systems with the Morpheus8 Hand pieces is classified as Class II device defined by the FDA CDRH and complies with 21 CFR subparts E.

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. $Z_{max} = 0.03\Omega$.
- 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 20°-27°C (68°-79°F) and relative humidity of less than 80%.

3.3 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.
- Connect cradle to the device.
- 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.

3.4 Moving the System

- Turn the System off.
- Disconnect the Power Cord.
- Disconnect the Handpiece.
- 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.



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).

3.5 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 12A, 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
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.

4.2 Software Screens

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

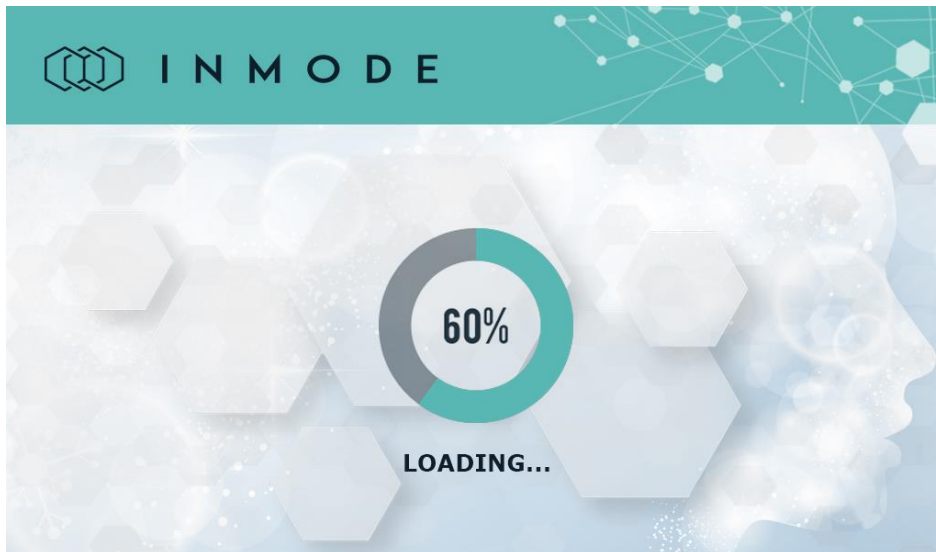


Figure 4-1: Progress Screen

*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 4-2: 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 4-3: Menu Screen

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

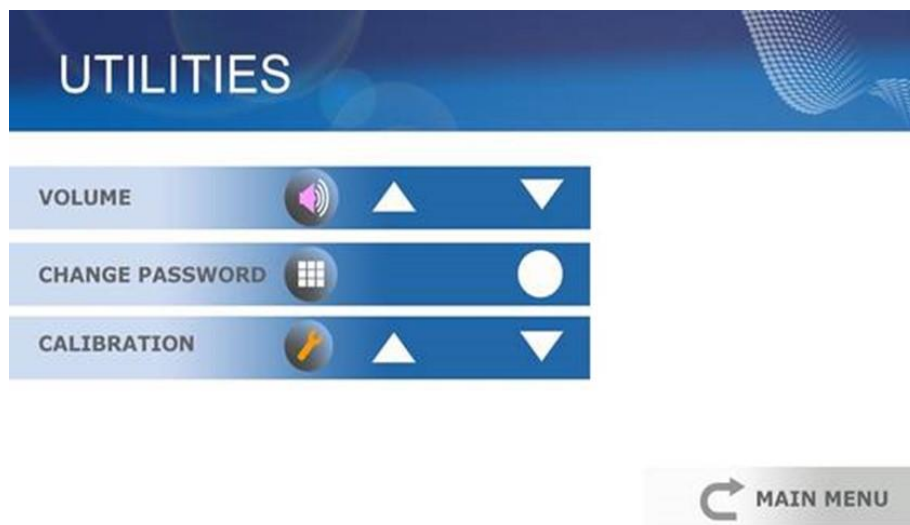


Figure 4-4: Utilities Screen

The Utility Screen contains:

Volume	This function allows the user to adjust the System volume.
Change Password	Change the password by entering the old password and then entering another 4-digit password.
Calibration	N/A
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.

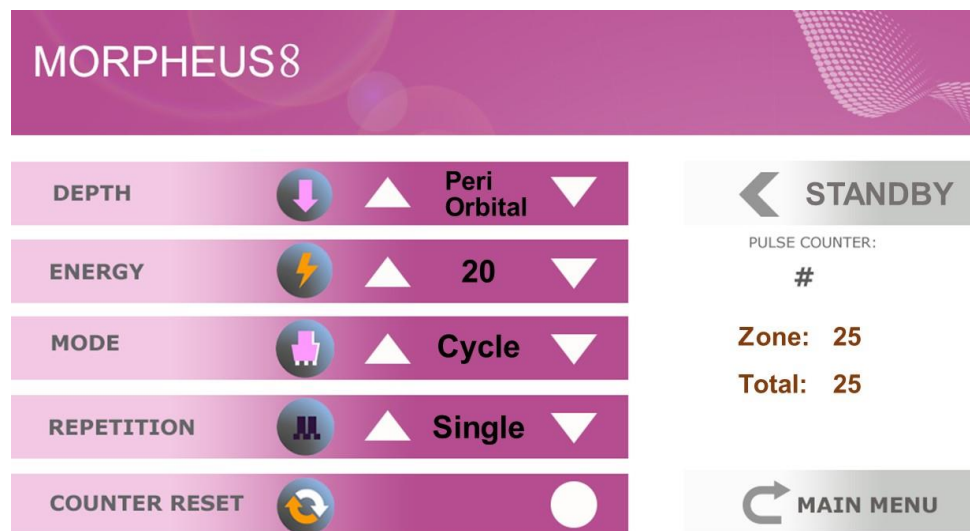


Figure 4-5: Morpheus Treatment Screen

Depth	Allows selecting the pins length and penetration depth according to dermis thickness in treated area to provide effective sub-dermal treatment . For Peri-orbital area – 2mm, Face – 3mm, Body – 4mm.
Energy	Delivered energy is changed from level 5 to 62 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 when needles goes out at foot switch pressing and stay protruded until footswitch is released. In Fixed mode RF pulses are applied automatically with predetermined pulse repetition rate.
Repetition	Select between single pulse delivery at footswitch pressing and autorepeat mode with predetermined pulse repetition rate
Counter Reset	Counter can be reset number of pulses per zone.

Pulse Counter	Shows number of pulses delivered on one zone and total number of pulses from the beginning of the treatment.
System Mode	<p>The System has three treatment modes: Standby, Ready, and Active.</p> <p>Standby mode allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode.</p> <p>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.</p> <p>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.</p>
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

4.3 Sound Indicator

Periodic beeping signal is emitted when RF energy is delivered.

4.4 Handpiece

Morpheus8 Hand piece (Figure 4.6) comprise motor with actuator pushing needle electrodes out to pre-determined depth up to 4mm. The tip (Figure 4.7) is connected or disconnected with the Hand piece.



Figure 4-6: Morpheus8 Handpiece

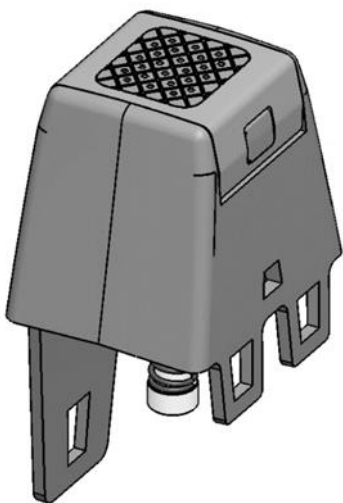


Figure 4-7: Morpheus8 Tip

Tip	The tips comprise 24 needles that are coated along with an insulating material except the distal 0.5mm edge (Figure 4.8). Note the insulation that leaves only the 0.5mm tip exposed.
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 4-8: Morpheus8 tip needle structure

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. Press the On-Off button on the control panel to turn the device on. The System loads the software and enters the Login Screen.
3. Enter password to get access to the device. If password is correct the System enters Menu Screen.
4. 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.
5. Select the application from the Menu Screen and System will enter the Treatment Screen.
6. Verify on the screen that the Software version is properly displayed and the connected Handpiece type is recognized correctly.
7. Select the treatment parameters using Up and Down keys.
8. Press the Standby icon that will change to Ready.
9. To start treatment, press the Footswitch for RF applicators.
10. Apply handpiece to the treated area, ensuring a full contact with pressure.

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.

6 Section 6: Morpheus8 Treatment Information

6.1 Sub-dermal Fractional Treatment

The Morpheus8 Handpiece are designed for delivering RF energy to the 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. Coagulation of the skin promotes tissue remodeling while untreated tissue between the pins promotes faster healing of the tissue. The Morpheus8 handpiece is versatile fractional technology to treat different body areas.

6.2 Indications for Use

The Morpheus8 applicators are intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

6.3 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 VI 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.

6.4 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 hypopigmentation), 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.

6.5 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 patient's 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 hyperpigmentation.
- 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.

- A few patients require nerve block for higher energy, limited to central face.
- 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.



The Morpheus8 tip is single use only!

6.6 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 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.

6.7 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. Always start with a low energy level, test patient comfort and observe the skin's response before increasing the energy.
8. On sensitive thin skin area apply lower parameters with more passes, rather than higher parameters in one pass. It is also applicable to new users for any area.
9. Dark skin (V-VI) treat with restricted 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.
10. Apply the Hand piece to the treated area ensuring a contact with pressure to minimize discomfort, and press footswitch to deliver RF energy
11. Move Hand piece to the adjacent area and activate RF again.
12. Move to adjacent areas with no overlapping of side-electrodes (30-50% overlap).
13. 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.
14. The endpoint is substantial erythema and edema, visible ablative craters, and burnt tissue smell often accompanied by tingling heat sensation.

6.8 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.

6.9 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.

7 Section 7: Troubleshooting

The InMode System with Morpheus8 Handpiece 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.

7.1 Description of Faults with All Handpiece

Problem	Description and Checks
System did not turn on	<ul style="list-style-type: none"> Check power cord connection. Check that On/Off switch on front panel is on. Check fuses on back panel of the System. Call Technical Service if problem persists.
System shuts down by itself	<ul style="list-style-type: none"> Check power cord connection. Check fuses on back panel of the System. Call Technical Service if problem persists.
Checksum	<ul style="list-style-type: none"> The software was not loaded properly from software plug. Check the plug connection and reboot the System. Call Technical Service if the problem persists.
Fault H8002 - Handpiece is not connected	<ul style="list-style-type: none"> Check the connection of the Handpiece. 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 H800E- System Incompatible Software Version	Call Technical Service if the problem persists.
Fault H800F- System Memory Fault	Call Technical Service if the problem persists.
Faults H8003, H8006, H8007 - RF Related Faults	Call Technical Service if the problem persists.

8 Section 8: System Specifications

Input Power		
Main Line Frequency (nominal)	50-60Hz	
Input Voltage (nominal)	100-240VAC	
Input Current (rms)	2A	
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	280cm L	[100’’ L]
Weight		
System	15.000kg	[33.069lb]
Morpheus8 Applicator	0.400kg	[0.243lb]
Morpheus8 Output Parameters		
Maximum Output Power	65[W]	
Frequency	1MHz	
Crest Factor (Rated Load)	1.4± 2%	

8.1 Output Power Curves

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

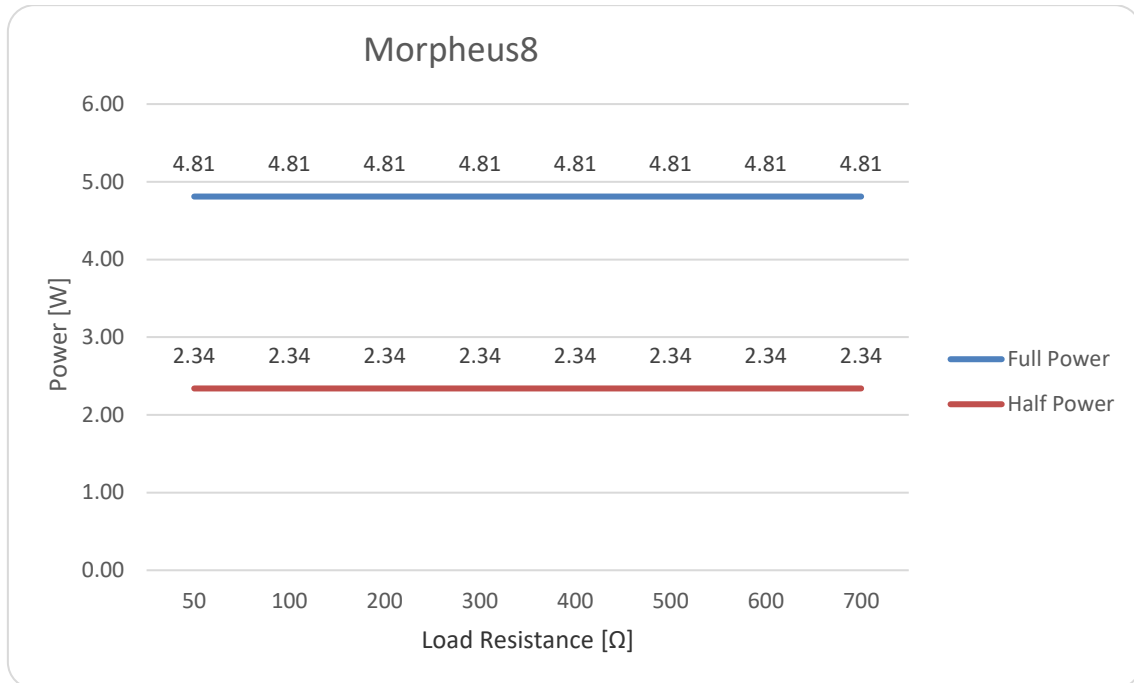


Figure 8-1: Morpheus Output Power versus Impedance

8.2 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 InMode System with Morpheus8Hand pieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8Hand pieces should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The InMode System with Morpheus8 Hand pieces 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	
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The InMode System with Morpheus8 Hand pieces 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.

Guidance and manufacturer's declaration – electromagnetic immunity			
The InMode System with Morpheus8Hand pieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8Hand pieces should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 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 ± 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 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5sec	>95 % dip for 10 ms 60 % dip for 100 ms 30 % dip for 500 ms 95 % dip for 5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the InMode System with Morpheus8 Hand pieces requires continued operation during power mains interruptions, it is recommended that the InMode System with Morpheus8Hand pieces 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 InMode System with Morpheus8Hand pieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8Hand pieces should assure that it is used in such an environment.			
IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>[3] V</p> <p>[3] V/m</p>	<p>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.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P} = \left[\frac{3,5}{3} \right] \sqrt{65} = \mathbf{9.4 [m]}$ <p>80 MHz to 800 MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P} = \left[\frac{7}{3} \right] \sqrt{65} = \mathbf{18.81 [m]}$ <p>80 MHz to 2,5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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 InMode System with Morpheus8Hand pieces is used exceeds the applicable RF compliance level above, the InMode System with Morpheus8Hand pieces should be observed to verify normal operation. If abnormal performance is observed, additional</p>			

measures may be necessary, such as re-orienting or relocating the InMode System with Morpheus8Hand pieces.

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 InMode System with Morpheus8Hand pieces System

The InMode System with Morpheus8Hand pieces System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the InMode System with Morpheus8Hand pieces can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the InMode System with Morpheus8Hand pieces 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.

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



THE STANDARDS INSTITUTION OF ISRAEL

Electronics & Telematics Laboratory

Test Report No.: 9712324195

Page 4 of 44 Pages

Title: Test on RF System**Name:** InMode**Model:** InMode with FRACTORA 3D and FRACTORA 3D 90 Handpieces

1. Summary of Test Results

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 Freq. range: 150 kHz - 30 MHz	sec. 6.1.1 / 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. 6.1.1 / 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	N/A
Voltage changes, Voltage fluctuations and Flicker test	sec. 6.1.3.2 & IEC 61000-3-11	AC mains	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 & 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 VRMS on 230 VAC mains , Handpiece & Footswitch 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: 100 % - 10 ms; 60%- 100 ms; 30% - 500 ms; 100% - 5sec	Complies

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