INMODE

MORPHEUS8

Applicator

Operator Manual

DO608080F

INMODE

aesthetic solutions

CE 2797

Morpheus8 Applicators

Operator Manual

DO608080F

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INMODE

Table of Contents

Section 1 - Introduction

Before You Start

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

Federal (USA) law restricts sale of this device to, 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.

System Overview

The InMode Platform or InMode RF platform with Morpheus8 Applicator employs bi-polar Radio-frequency (RF) technology for facial acne treatment.

The device provides individual adjustment of treatment parameters to achieve maximum efficiency and safety for each patient and applications.

Conventions Used in the Manual

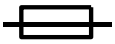
The following conventions in the form of notes and warnings are used in this manual:

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

WARNING: This information is extremely important.

ATTENTION! Consult Accompanying Document.

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
	HF Isolated Patient Circuit
	Type BF Equipment
	Follow 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

Section 2 - Safety

This chapter describes safety issues regarding the use and maintenance of the Morpheus8 Handpieces, 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.**

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.

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 Handpieces.

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.

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 personnel only.
- To avoid damage, do not allow the Handpiece to come in contact with hard materials.
-  only. Federal law (US) restricts this Device to sale by or on the order of a physician (applicable for USA only).
-  Do not connect a wet accessory to the Device.

Electrical and Mechanical Safety

- Keep all covers and panels of the system closed. Removing the covers creates a safety hazard.
- Keep hands away from the applicator during the System start-up.
- Perform maintenance procedures when the system is shut down and disconnected from the power.
- The system is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.
- Move the system slowly and carefully. The System weighs approximately 32kg (70.5lb.) and may cause injury if proper care is not used when moving it.

- Provide as much distance as possible between the system, RF Handpiece and other electronic equipment as the activated RF generator may cause interference between them.

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.
- Keep drapes and towels moist to prevent them from igniting and burning. Use nonflammable prepping solutions.
- Do not use the system in the presence of explosive or flammable materials.
- 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.

Safety Features of the System

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

- 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.
- System starts at a low setting.

Safe Use of the Active Accessories

- Examine the connection of the Handpiece through the connector to the system before using. 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.
- When using the RF applicators, ensure that both electrodes are in full contact with the skin. Bad coupling of electrodes with the skin results in a specific warning sound, a message on the screen, and disabling of RF.

- **Do not connect a wet accessory to the System.**
- **Do not immerse the applicator under water at any time.**

Warnings

This equipment is for use only by trained personnel.
Only Handpieces manufactured or approved by InMode Ltd. should be used with InMode System with Morpheus8 Handpieces.
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 energy is applied, the greater the possibility of unintended thermal damage.
Failure of the equipment could result in an unintended increase of output power.
The cables of the Handpiece should be positioned in such a way that contact with the PATIENT or other leads is avoided.
Fire / Explosion Hazard - The following substances will contribute to increased fire and explosion hazards in the operating room: • **Flammable substances (such as alcohol based skin prepping agents and tinctures).** • **Naturally-occurring flammable gases which may accumulate in body cavities such as the bowel.** • **Oxygen enriched atmospheres.** • **Oxidizing agents (such as nitrous oxide [N2O] atmospheres).**

- **Endogenous gases.**

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

The operation of the InMode System with Morpheus8 Handpieces 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.

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.

Figure 2.4 Morpheus8 Handpiece label

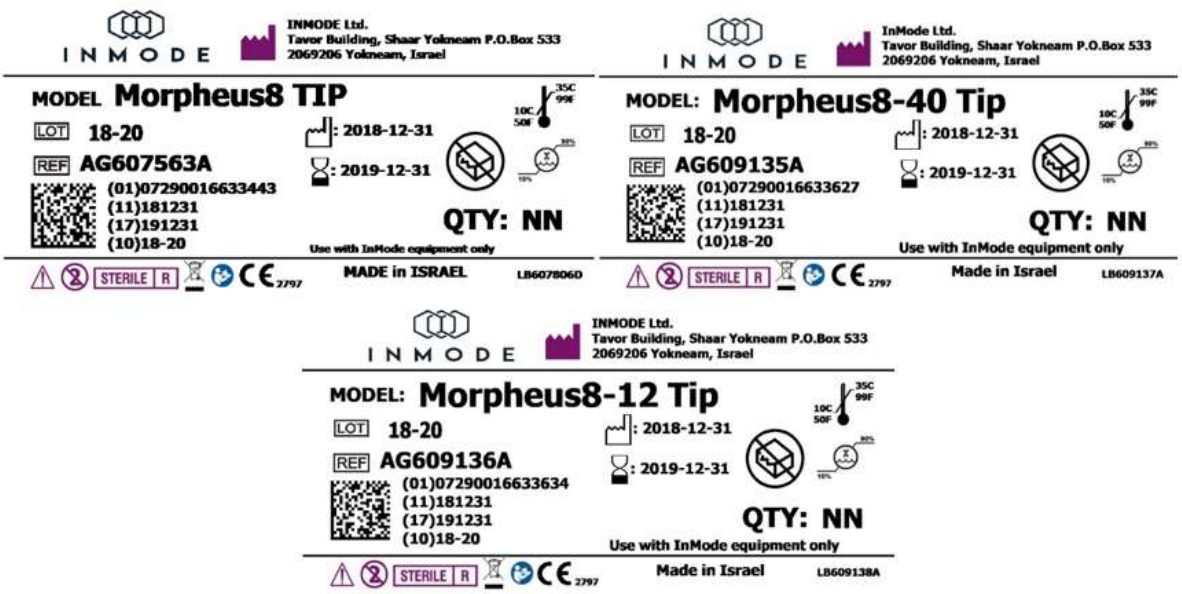


Figure 2.5 Morpheus8 24 Pin Tip (Upper Left), 40 Pin Tip (Upper right), 12 Pin Tip (Lower centre) labels

Equipment Classification

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

- Electric shock protection: Class I, Type BF for the RF Handpieces
- 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 or InMode RF systems with the Morpheus8 Handpiece is classified as Class IIb according to (MDD 93/42/EEC, Annex IX, Rule 9).

The Morpheus8 disposable tip (sterile) is classified as Class IIa according to (MDD 93/42/EEC, Annex IX, Rule 5)

The software contained in the medical device is Class C.

Section 3 - System Installation

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.**

Environmental Requirements

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

Installation

The System is designed for installation in a clinic environment. To install the System and 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.

Moving the System

To move 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, 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 or lifting the System.**
- **Upon unpacking check the System for mechanical damage** (e.g., cracks in the cable insulation).

Disposal of System

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.

Section 4 - Device Description

Rear Panel

Power cord inlet

100-240V~, 15A, 50-60Hz.

Fuse holder

Rating is T 12.5A, 250V. Replace fuse if it is needed only with fuses having exactly the same rating.

Software flash memory plug

The software plug is a flash memory that comes with the machine software. The software plug should be screwed into the connectors. To tighten and/or loosen the screws use fingertips only. Do not use screwdriver as it can damage the connectors.

Foot switch connector

Foot switch is connected to the inlet. Foot switch enables activation of Laser energy by the hand trigger if the System is in Ready mode. Place the foot switch on the floor near the treatment area.

Front Panel

RF Handpiece Connectors - Located on the upper front panel.

Software Screens

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

Figure 4.1 Splash Screen

After entering the individual code in 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

Menu screen allows selection of connected Handpiece or entering Utilities Screen

Figure 4.4 Utilities Screen

Utilities screen contains:

Volume	Volume. This function allows the user to adjust System volume.
Change Password	Change password by entering old password- (1, 2, 3, 4) and enter another 4-digit numerical password.
Calibration	NA
Main Menu	Return to Main Menu to select the Handpiece.

Figure 4.5 Morpheus8 Treatment Screen

Tip	Allows selecting the Tip.

Depth	Allows selecting the pins length and penetration depth according to dermis thickness in treated area to provide effective sub-dermal treatment.
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 auto repeat mode with predetermined pulse repletion rate
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.
Main Menu	Return to Main Menu to select another applicator and change the applicator if needed.
System Mode	The System has three treatment modes: Standby, Ready, and Active. 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.

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.

Sound Indicator

Periodic beeping signal is emitted when RF energy is delivered.

Warning sound tone indicates Bad Coupling.

Handpiece

Morpheus8 Handpiece (Figure 4.6) comprise motor with actuator pushing needle electrodes out to pre-determined depth up to 2.5mm. The tip (Figure 4.7) is connected or disconnected to or from the Handpiece.

Figure 4.6 Morpheus8 Handpiece

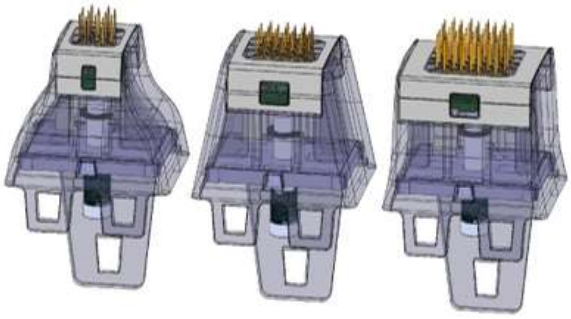


Figure 4.7 Handpiece Tips: 12 Pins Tip (Left), Morpheus8-24 Pins Tip (Center), Morpheus8-40 Pins Tip (Right)

Handle	Handpiece handle is made of plastic and has ergonomic design for easy treatment with high visibility of the treated area.
Cable	Has a length of 250cm.
Connector	It is connected to the front panel of the system.
Tip	See below table for Tip specifications.

Figure 4.8 Morpheus8 Tip Needle Structure

Note the insulation that leaves only the 0.5mm tip exposed

The table below summarizes the specifications of the various Morpheus8 tips:

Tip Name	Pins number	Depth mm	Energy Levels	Cycle Mode	Fixed Mode
Morpheus8 - 40	40	2-2.5	5-60	Yes	NA
Morpheus8 - 24	24	0.5-2.5	5-60 (up to 1mm-5-30)	Yes	NA
Morpheus8 - 12	12	1-2.5	5-30	Yes	NA

Prior to using or connecting the Handpiece, inspect the Device and Handpiece for possible mechanical damage (e.g., cracks in the cable insulation).

Device Start-Up

1. Connect the Handpiece to the Handpiece connector socket on the System.
2. Turn on Main Power switch at the rear panel.
3. Press the On-Off button on the control panel to turn the device on. The System loads the software and enters the Login Screen.
4. Enter unique password to get access to the device. If password is correct the system enters Menu Screen.
5. The system loads the software and enters a self-test mode. If any problem is detected during the test the error message will appear (See Troubleshooting Section in this manual). If the test is passed correctly then the system automatically enters the Menu Screen.
6. Select application from the Menu Screen and System will enter the Treatment Screen.

7. Verify on the screen that the Software version is properly displayed and the connected Handpiece type is recognized correctly.
8. Select treatment parameters using Up and Down keys.
9. Enter READY mode
10. After pressing the footswitch treatment starts.
11. RF emission is accompanied by an audio signal.

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.

Section 5 –Treatment Information

Sub-dermal Fractional Treatment

The Morpheus8 Handpiece is designed to deliver 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 facial acne.

Indications for Use

The InMode System with the Morpheus8 Applicator is intended for use in dermatological procedures for skin ablation and resurfacing for facial acne treatments

Contraindications

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

- Pregnancy and nursing.
- Severe concurrent conditions, such as cardiac disorders or sensory disturbances.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Any active skin condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies 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.

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 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.

Pre-Treatment Recommendations

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

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- Advise the patient to avoid skin irritation or intentional skin tanning. Sunscreen is advisable when outdoors during daylight hours.
- Prophylactic antiviral therapy should be prescribed for patients with history of cold sores (Herpes Simplex) when treating in the previously infected areas.
- Stop anticoagulants 7-10 days prior to treatment, if medically permitted.

- Clean the treatment area.
- Apply anesthesia: 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 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.

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

The operator shall inspect the Handpieces 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 Handpieces do not retract out of the skin, detach the disposable tip from the Handpiece and release the spring mechanism manually.

The operator shall wear latex gloves (single use only)

Instructions Prior to Use

Applicator Cleaning Instructions Prior to Use

These cleaning instructions are for clinical use only.

Any deviation from said instructions or the cleaning agents listed below may affect the performance or durability of the product, and it's 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

Clean the Morpheus8 Applicator handle thoroughly with alcohol absorbed pad and repeat as necessary. Leave it for complete drying. Avoid direct contact with the tip connection area.

The Morpheus8 treatment tips are supplied sterile and no pre-treatment cleaning is necessary.

Pre-Use Check:

Before each use thoroughly inspect the Handpiece that must pass the following:

1. Visually inspect the tip for cleanliness.
2. Inspect all components of the Handpiece for visible damage.

Morpheus8 tips are for single use only!

The tip must be discarded following a single use treatment

Connecting the tip:

1. Use disposable gloves
2. Carefully extract the tip from the sterile bag avoiding contact with tip head (the part that comes in contact with the patient's body)
3. Align the central pin (see figure 5.1) into the round opening on the HP.
4. Align the 2 bottom tabs (see figure 5.1) in their designated locations.
5. With slight pressure insert the top tab (see figure 5.1) until you hear the click, which ensures proper locking.

Disconnecting the tip:

1. Push the top tab upwards with your finger to unlock the tip.
2. Remove the tip
3. Discard used tip

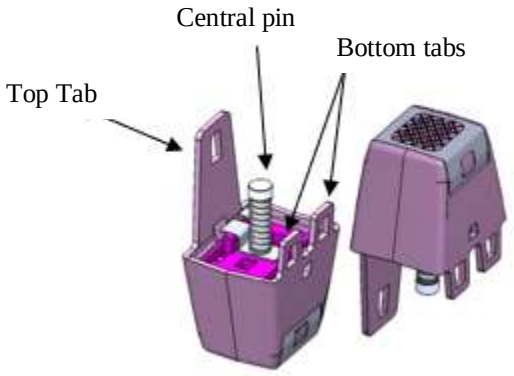


Figure 5.1 Morpheus8 Tip Structure

Test Spots

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

- Confirm the patient's suitability for treatment:
    - For skin type I – 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.

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 a sterile tip and connect it to the Handpiece.
4. Connect Handpiece to the system.
5. Follow Device Start-Up Procedure from System Operation section.
6. Set treatment parameters – treatment Depth, Energy, Mode and Repetition.
7. The thicker the skin, the longer the treatment Depth.
8. Always start with a low Energy level, test patient comfort and observe the skin's response before increasing the Energy.
9. 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.
10. 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.
11. Use Cycle mode in Repetition of Single or automatic rate as pre-determined.
12. Use Fixed mode when stacking is required in automatic Repetition rate as pre-determined.
13. Apply the Handpiece to the treated area ensuring a contact with pressure to minimize discomfort, and press footswitch to deliver RF energy
14. Move Handpiece to the adjacent area and activate RF again.
15. Move to adjacent areas with no overlapping of side-electrodes (30-50% total tip overlap).
16. 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.
17. The endpoint is substantial erythema and edema, visible ablative craters, and burnt tissue smell often accompanied by tingling heat sensation.

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. Treatments should not be repeated until complete healing is achieved. 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.

Post-Treatment Recommendations

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

- Cool the skin for 10-20 min.
- 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.
- 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).
- Patient should avoid very hot water for 2 days after the treatment.
- Patient should avoid scrubbing, pinching and etc. of the treated area.
- Moisturizer may be applied 24-72 hours after each treatment and then should be applied regularly throughout the course of the treatment. 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 type 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 the next scheduled treatment takes place.

Section 6 - Troubleshooting

The InMode System with Morpheus8 Handpieces 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.

Description of Faults with All Handpieces

System did not turn on

- Check power cord connection.
- Check that main switch on rear panel is on.
- 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

- Check power cord connection.
- Check fuses on back panel of the system.
- Check Emergency button not pressed.
- Call Technical Service if problem persists.

Checksum

- The software was not loaded properly from software plug.
- Check plug connection and reboot the System.
- Call Technical Service if problem persists.

Fault H8002 – Handpiece is not connected

- Check connection of Handpiece.

- Replace Handpiece.
- Call Technical Service if problem persists.

Fault H8005, H800F, H8010 – System Memory Fault

- Call Technical Service if problem persists.

Fault H800E- System Incompatible Software Version

- Call Technical Service if problem persists

Fault H800F- System Memory Fault

- Call Technical Service if problem persists.

Faults H8003, H8006, H8007 - RF generator Related Faults

- Call Technical Service if problem persists.

Section 7 - System Specifications

Input Power		
Main Line Frequency	50 - 60 Hz	
(nominal)	100 - 240 VAC	
Input Voltage (nominal)	1.0A (for InMode RF System), 2.0A (for InMode System)	
Input Current (rms)		
Operating Parameters		
Ambient Temperature Range	15 – 30° C [59 – 86° F]	
Relative Humidity	30% to 80%, non-condensing	
Atmospheric Pressure	700kPa – 1060kPa	
Warm-up Time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the system to reach room temperature before use.	
Transport and Storage		
Ambient Temperature Range	-20 – 65° C [-4 – 149° F]	
Relative Humidity	0% - 80%, non-condensing	
Atmospheric Pressure	50 - 110 kPa	
Dimensions		
System	46 cm W x 46 cm D x 100 cm H	[18.2’’ W x 18.2’’ D x [40’’ H]
Handpiece cable	250 cm L	[100`` L]
Weight		
System	*15.000kg*	[33 lb]
Morpheus8 Applicator	*0.400 kg*	[1.268 lb]
Output Parameters		

Output Configuration	Isolated Output
Needle length	Up to 2.5mm
RF	
Maximum Output Power	65[W]
Output Frequency	1[MHz] ± 20%
Crest Factor (Rated Load)	1.4± 2%

Output Power Curves

The following curve depicts the Morpheus8 device output Power vs. range of Load Impedance.

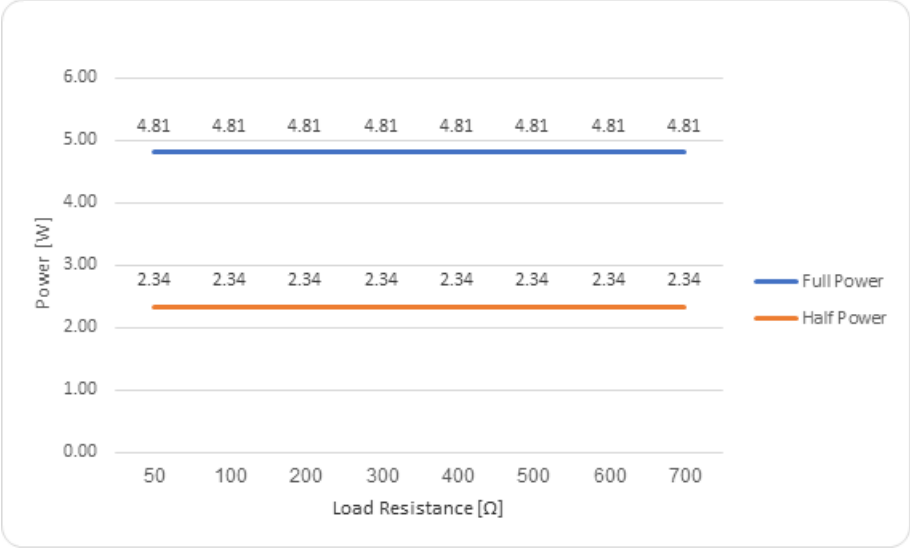


Figure 7.1: Morpheus8 Applicator output power versus impedance

EMC Safety for the InMode System with Morpheus8 Handpieces

The device has been tested and found to comply with the limits specified in IEC 60601-1-2 FDA recognized consensus standard. These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device generates RF energy and can radiate RF 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 Morpheus8 Handpieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8 Handpieces 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 Handpieces uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The InMode System with Morpheus8 Handpieces is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The InMode System with Morpheus8 Handpieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8 Handpieces 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 5 sec	>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 Handpieces requires continued operation during power mains interruptions, it is recommended that the InMode System with Morpheus8 Handpieces 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 Morpheus8 Handpieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8 Handpieces should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	[3] V [3] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the InMode System with Morpheus8 Handpieces, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3,5}{V_1}\right]\sqrt{P} = \left[\frac{3,5}{3}\right]\sqrt{65} = \mathbf{9.4}\ [\boldsymbol{m}]$ $80\ MHz\ to\ 800\ MHz$ $d = \left[\frac{7}{E_1}\right]\sqrt{P} = \left[\frac{7}{3}\right]\sqrt{65} = \mathbf{18.81}\ [\boldsymbol{m}]$ $80\ MHz\ to\ 2,5\ GHz$ Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the InMode System with Morpheus8 Handpieces is used exceeds the applicable RF compliance level above, the InMode System with Morpheus8 Handpieces should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the InMode System with Morpheus8 Handpieces.

[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 Morpheus8 Handpieces System

The InMode System with Morpheus8 Handpieces 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 Morpheus8 Handpieces can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the InMode System with Morpheus8 Handpieces 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.