VOTIVA

Operator Manual

Votiva System

Version: D0607094B

INMODE
aesthetic solutions

Operator Manual: Votiva System

D0607094B

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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.

- Read this manual to become familiar with all safety requirements and operating procedures before attempting to operate the System.
- RF electrosurgical devices can cause injury if used improperly, as high voltage is present inside 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 InModeRF Platform with Fractora and FormaV Handpieces is marketed as the Votiva System which employs Radio-frequency (RF) technologies for various aesthetic applications.

The Votiva System with FormaV Handpiece is a genital device for therapeutic use, an electrically operated device intended and labeled for therapeutic use in the treatment of sexual disfunction or as an adjunct to Kegel's exercise (tightening of the muscles of the pelvic floor to increase muscle tone). It is also intended for treatment of selected medical conditions such as relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.

The Votiva System with Fractora Handpiece is used in dermatologic procedures requiring ablation and resurfacing of the skin. It is also intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels, use of the applicator is limited to Skin Types I-IV.

The System provides individual adjustment of RF power to achieve maximum efficiency, safety and comfort for each patient. The System provides enhanced safety while minimizing possible side effects by monitoring RF parameters.

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.

Provides general information that is important to keep in mind.

1.4 Explanation of the Symbols used on the System

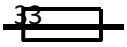
Symbol	Description
	CSA marking (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	HF Isolated Patient Circuit
	This equipment intentionally supplies non-ionizing RF energy
	Follow operating instructions
	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

Table 1-1: Device Symbols

2 Section 2: Safety

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

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

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

The 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 safe-guards as described in the manual.

2.1 The Patient

Well-trained staffs assure patient safety. A patient history should be completed prior to scheduling. Patients should be fully informed of the treatment protocol, the likely results and any risks associated with the treatment.

Patients will not be in contact with any metal or other alternate pathway to ground while system in use.

Metal jewelry should be removed if it is within the activation range of the active electrode or if there is risk of digit compromise or a foreign body lodging in the airway.

2.2 Treating Attendant

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

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.
- Provide as much distance as possible between the system and other electronic equipment as the activated RF generator may cause interference between them.
- Move the System slowly and carefully. The System weighs approximately 20kg (44lb.) and may cause injury if proper care is not used when moving it.

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.
- 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.

- System has a password to avoid device operation by non-authorized personnel.
- The power electronics cannot be activated unless the applicator and footswitch has 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 10msec to ensure proper operation of electrical circuit.
- System starts at a low power setting.
- Skin surface temperature monitoring.

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

Do not connect a wet accessory to the System.

Do not immerse the applicator under water at any time.

2.8 Warnings

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

Only handpieces manufactured or approved by InMode MD Ltd. should be used with 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 power cord to a properly grounded receptacle. Do not use power plug adapters.

Always turn off and unplug the System 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!

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

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 of skin.

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 [N_2O] 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 System in the same room with any of these substances or gases, prevent their accumulation or pooling within the area where System procedures are performed.

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

2.9 Device Labels

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

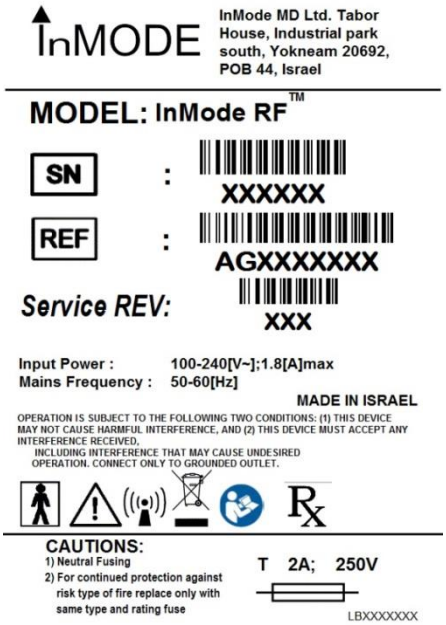


Figure 2-1: System Certification and Identification Label

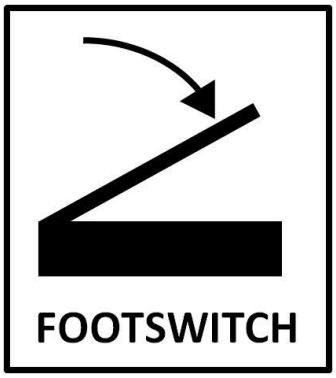


Figure 2-2: Footswitch Label

2.10 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:

Manufacturer identification labeling is placed on the hand pieces

Figure 2-3: The Plus90 (FormaV) Handpiece Label

Figure 2-4: The Fractora Handpiece Label

2.11 Equipment Classification

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

- Electric shock protection: Class I, Defibrillation-proof Type BF
- 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 Votiva system with the Handpieces is classified as class II device by CDRH.

3 Section 3: System Installation

3.1 Electrical Requirements

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

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

Proper grounding is essential for safe operation.

3.2 Environmental Requirements

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

3.3 Equipment List

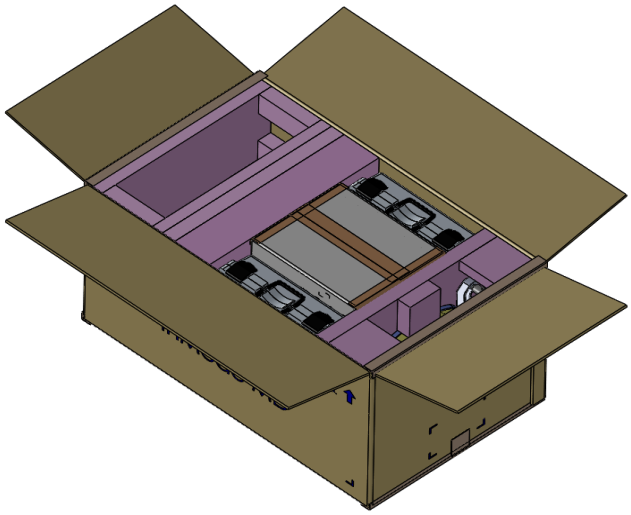
The System includes the following:

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

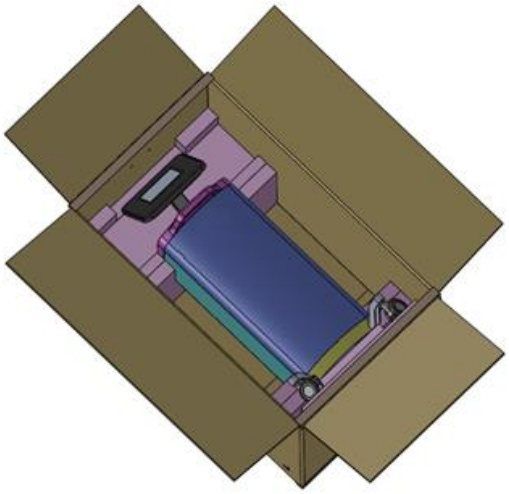
3.4 Unpacking

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

To install the System, perform the following tasks:

- Check the System and all its components for damage.
- Connect the Cradle to the System.
- Connect the Handpiece to the connector.
- Place the Handpiece into the cradle.
- Connect the Footswitch to the footswitch connector.
- Connect the Power Cord to the System inlet.
- Plug the System Power Cord into an appropriate electrical outlet.

3.6 Moving the System

- Turn the System off.
- Disconnect the Power Cord.
- Disconnect the Handpieces.
- Disconnect the Footswitch.
- Release the Wheel Brakes.
- Slowly push or pull the System using the handle.
- When moving the system to another facility, lift the System to the vehicle and lay it carefully on its side.

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).

3.7 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~, 1A, 50-60Hz.

Fuse Holder

Rating is T 2A, 250V. Replace fuses if it is needed only with fuses having exactly the same rating.

Software Flash Memory Plug

Software plug is a flash memory with the machine software. The software plug should be screwed to 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.

RF Handpiece Connector

Located on the upper right side of the front panel.

4.2 Front Panel and Operator Control Panel

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

Figure 4-1: Handpiece Connectors on Front Panel

Power On-Off Switch

Power switch turns system On and Off.

LCD Screen

LCD screen shows information about system mode and treatment parameters.

The panel allows changing treatment parameters and system mode.

4.3 Software Screens

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

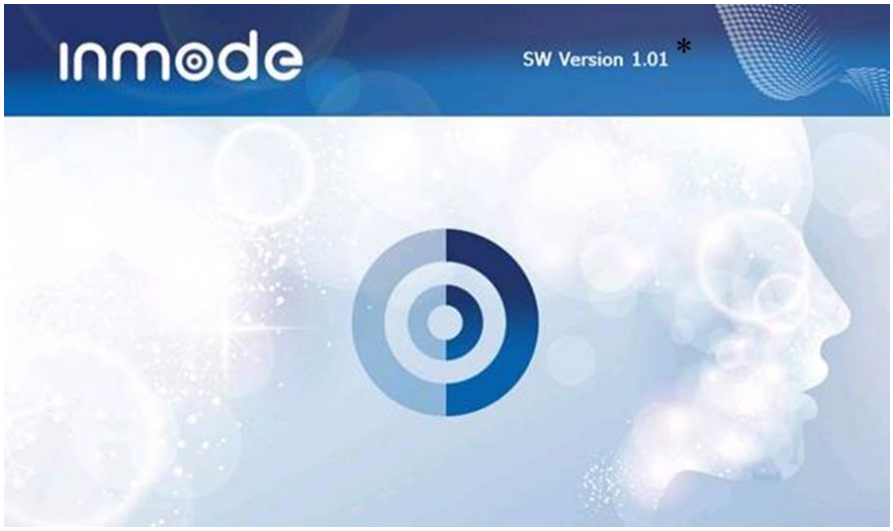


Figure 4-2: Splash Screen

*The 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.

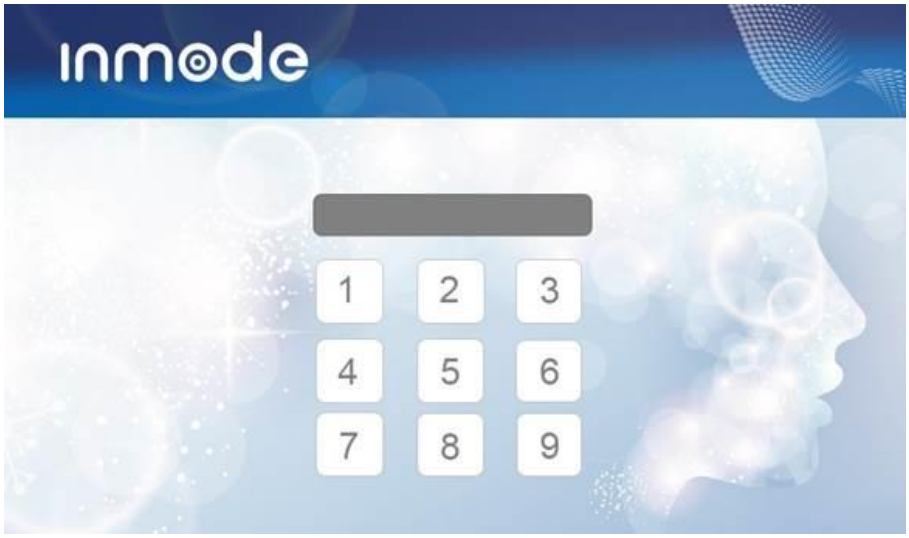


Figure 4-3: Login Screen

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 4-4: Menu Screen

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

The Utility Screen contains:

Volume	Volume. This function allows the user to adjust the system volume.
Drain / Fill Water	Not applicable.

Change Password	Change password by entering the old password and then entering another 4-digit password.
Calibration	Not applicable.
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.

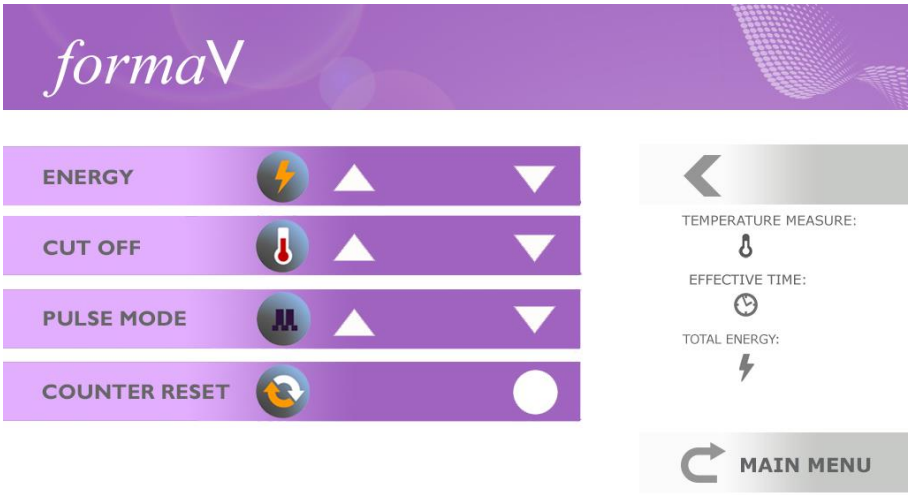


Figure 4-5: FormaV Treatment Screen

The FormaV Treatment Screen contains:

Selection Frame	The frame selects parameters that can be changed by the functional keys.
Energy	Delivered energy is changed from level 20 to 40 and the System starts up at the minimal energy setting.
Cut Off	Cut-off temperature settings are changed in the range of 35-43°C. When the measured skin surface temperature reaches the preset limit, the RF energy is cut off.
Pulse Mode	Allows selecting between single RF pulses of 30sec in the Single Mode and continuous RF in Repeat Mode, when the foot switch is pressed.
Counter Reset	Effective Time along with Energy can be reset.
Temperature Measure	This indicator shows the skin surface temperature, as measured by an integral temperature sensor.
Effective Time	This function shows the treatment time, starting from time-point of 2°C below the cut-off temperature.

Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

Figure 4-6: Fractora Treatment Screen

The Fractora Treatment Screen contains:

Selection Frame	The frame selects parameters that can be changed by the functional keys.
Tip Type	Allows selecting between different tip types of Fractora.
Energy	System starts up at the minimal energy setting.
Pulse Mode	Allows choosing between single pulse and pulse trains ranging from 0.5 to 2 pulses per second (pps).
Counter Reset	The Counter can be reset.
Pulse Counter	Shows number of pulses delivered on one zone and 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.

Figure 4-7: FractoraV Treatment Screen

The FractoraV Treatment Screen contains:

Selection Frame	The frame selects parameters that can be changed by the functional keys.
Applicator	24 pin tip is compatible with deep fractional coagulation and ablation of tissue.
Energy	Delivered energy is changed from level 20 to 40 energy levels and the System starts up at the minimal energy setting.
Pulse Mode	Allows selecting automatic pulsing with pre-set pulse repetition rate or single pulse mode.
Counter Reset	The Pulse Counter can be reset.
Pulse Counter	This function shows number of pulses applied.
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 footswitch 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

4.4 Sound Indicator

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

4.5 Cut-Off Temperature Control

The cut-off temperature is constantly maintained for the FormaV Handpiece. When the measured temperature approaches the Cut-off Temperature, the tone beeps double in speed. It becomes faster when the Cut-off Temperature is reached and RF is instantly inactivated. As soon as the temperature drops below the Cut-off temperature, RF starts again, thus maintaining the desired temperature with safety and when reached, RF delivery is automatically stopped. Temperature is monitored by a temperature sensor in the Handpiece and serves as a safety feature.

4.6 Handpieces

The FormaV Handpiece (Figure 4.8) comprises: disposable tip with electrodes and imbedded integral temperature sensor, handle, cable and connector.

Tip	The Tip is a disposable part of the Handpiece, comprising RF electrodes.
Handle	The Handle is made of metal and has ergonomic design for easy treatment with high visibility of the treated area.
Cable	The Cable has a length of 250cm (100’’).
Connector	The Connector is connected to the front panel of the system.

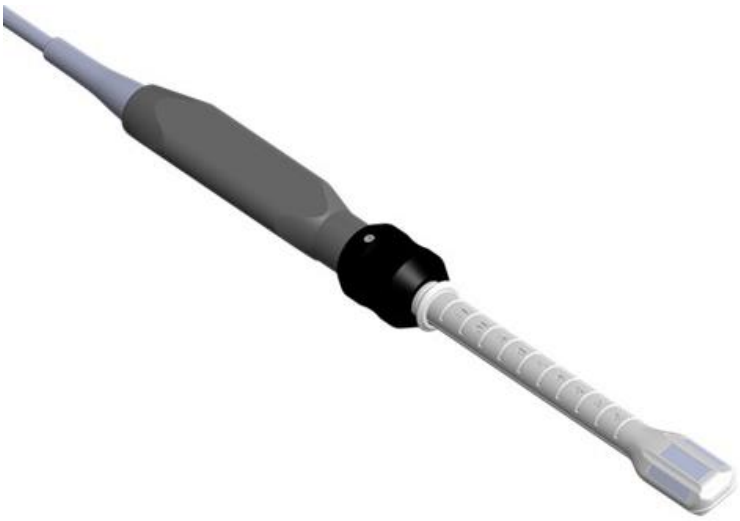


Figure 4-8: FormaV Handpiece

The Fractora Handpieces comprise: disposable tip with electrodes, handle, cable and connector. Fractora hand piece can be used in Fractora treatment for fractional skin resurfacing with 60-pin tip and 24-pin tip. In FractoraV mode the hand piece is operated with 24-pin tip only.

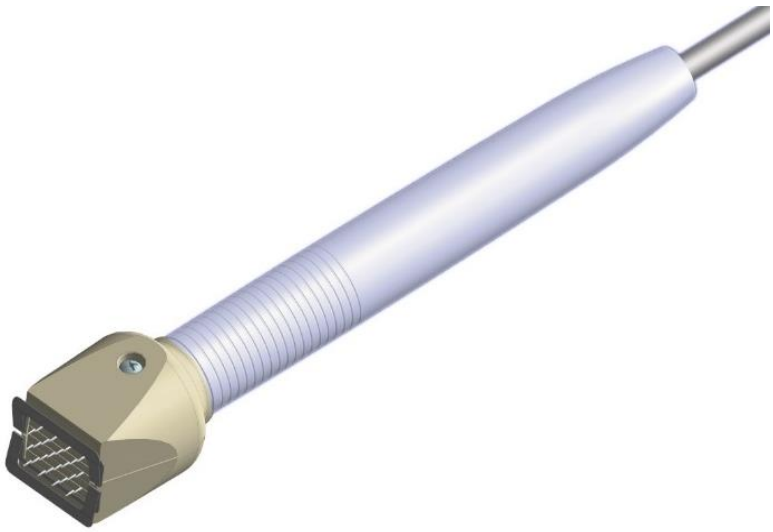


Figure 4-9:Fractora Handpiece

Handle	The Handle is made of metal and has ergonomic design for easy treatment with high visibility of the treated area.
Cable	The Cable has a length of 250cm (100'').
Connector	The Connector is connected to the front panel of the system.
Tip	Handpiece tips have 2 sizes of pin arrays (Figure 4.10). 60 pins are 600µ long, and 24 pins are 2500µ long. With FractoraV only 24 pin tips can be used. With Fractora all types of tips can be used.

Figure 4-10: FractoraTips: Left 60 pin; Right 24-pin (coated/noncoated)

5 Section 5: System Operation

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

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

5.1 Device Start-Up

1. Connect the Handpiece to the Handpiece connector socket on the System.
2. Turn on Main Power switch at the rear panel.
3. Press the On-Off button on the control panel to turn the device on. The System loads the software and enters the login Screen.
4. Enter unique password to get access to the device. If password is correct the system enters Menu Screen.
5. The System performs self-test of hardware. If any problem is detected during the test an error message will appear (See Troubleshooting Section in this manual). If the test is passed correctly, then the system automatically enters Menu Screen.
6. Select a handpiece from the Menu Screen and System will enter the Treatment Screen.
7. Verify on the screen that Software version is properly displayed and connected Handpiece type is recognized correctly.
8. Select treatment parameters using Up and Down keys.
9. Select Ready mode to confirm the selected parameters. The System is ready for pulsing.
10. Press footswitch to start the treatment.

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: FormaV Treatment Information

6.1 Instructions for Use

The Votiva System with FormaV Handpiece is a genital device for therapeutic use, an electrically operated device intended and labeled for therapeutic use in the treatment of sexual disfunction or as an adjunct to Kegel's exercise (tightening of the muscles of the pelvic floor to increase muscle tone). It is also intended for treatment of selected medical conditions such as relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.

Consult with accompanying clinical documentations such as In-Service Instructions and Quick Reference Guide (QRG) for the most updated clinical recommendations.

6.2 Contraindications

Contraindications in the use of the System include:

- Active electrical implant/device in any region of the body, including pacemaker or internal defibrillator
- Permanent implant in the treated area such as metal plates, screws or silicon, metal piercing or other.
- Vaginal or pelvic surgery within the past 12 months.
- Current or history of skin cancer and genital area 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.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies or use of anticoagulants except for low-dose aspirin.
- 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.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV or use of immunosuppressive medications.
- Pregnancy and nursing.

- Poorly controlled endocrine disorders, such as Diabetes, or thyroid dysfunction and hormonal virilization.
- Isotretinoin (Accutane) within last 6 months.
- Any active condition in the treatment area, such as sores, Psoriasis, eczema, and rash, open lacerations, abrasions or lesions, infection in the area to be treated, current urinary tract infection or pelvic infection, uterine prolapse, cystocele, rectocele.
- Any surgical procedure in the treatment area within the last 12 months or before complete healing.
- 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 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.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

6.3 Possible Adverse Effects

Certain side effects may be experienced during treatment or shortly afterwards which may or may not be a result of improper use of the system. Although these side effects are rare and temporary, they should be reported immediately to a physician for proper treatment. These are the side effects that may appear in the treatment area:

- Pain
- Excessive redness (erythema)
- Damage to natural tissue texture (crust, blister, burn, bruising, minor bleeding)
- Change of pigmentation (hypo- or hyper-pigmentation)
- Swelling (edema)
- Scarring
- Treatment area infection

6.4 Handpiece Cleaning Instructions Prior to Use

These cleaning instructions are for CLINICAL USE only.

The following processes are validated for the Handpieces 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 or surface disinfectant such as Cavicide™ wipes or similar products.

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.

FormaV tips are single use only.

6.5 Pre-Treatment Recommendations

- The patient should have an up-to-date normal PAP test (within last 12 months) and recent normal vaginal exam to ensure that there are no active infections
- Review all indications
- Review all contraindications
- Complete the medical history and physical prior to treatment
- Sign the informed consent prior to the procedure
- Hair should be shaved in the treatment area 2-4 days prior to the procedure. The hair should not be waxed or chemically removed.
- Perform an exam immediately prior to the procedure to visualize the area that is going to be treated
- The patient should use the restroom to urinate immediately prior to treatment.

- Advise the patient to avoid anticoagulants such as aspirin throughout the treatment regimen if medical condition permits and pertinent to physician approval. Anticoagulants increase the possibility of bruising.

6.6 Treatment Recommendations

1. Follow **Device Start-Up** from Section 5.
2. Use energy level of 20-30 and set cut off temperature as high as tolerated, starting at 40°C.
3. Basic Parameters Consideration:
   - Plenty of ultrasound gel to be applied
   - Gel to be applied directly to all 3 electrodes on FormaV tip.
   - Pre-warm the gel by covering the tip electrodes completely and applying RF for a few seconds.
   - Inserting gel manually into the vaginal canal may be helpful in cases of moderate to severe atrophy.
   - Temperature cut-off as high as tolerable. In general, higher cutoff temperature yields best results.
   - Power level to be set according to patient tolerance.
   - Position the probe at the end of the canal without RF to determine the penetration depth for repeated insertion. Reaching the cervix is felt by both the patient and the operator.

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

4. Make sure that the hand piece for the treatment (FormaV) corresponds to the interface.
5. Assume full contact of Handpiece with tissue with a slight pressure.
6. Press the footswitch and initiate the RF energy.
7. Move the Handpiece back and forth and in circular movements with gentle pressure over the treated area to reach uniform heating. Movement should be constant and its amplitude should be at least double of Handpiece spot size to avoid hot spots.
8. Continue to treat the area of 10-20 cm2 in this fashion. Always start with a low setting level to check the patient's tolerance to the treatment parameters.
   - Increase the settings gradually.
9. Apply multiple passes to maintain the desired temperature during 10-30min per zone.

10. Movement speed, RF energy, and cut-off temperature can be adjusted in this order during the treatment for the best comfort of the patient.

11. FormaV hand piece can be used for skin treatment.

12. Slight erythema and edema is a typical immediate response. However, when there is excessive tissue reaction, stop treatment. 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 stop the treatment.

6.7 Treatment Schedule

- The number of treatment sessions depends on the individual patient and is typically 2-3 sessions, every 2-4 weeks but can vary according to patient response.
- Treatment time internally and externally up to 30 minutes may reduce the number of sessions to 1-2 but depends on skin response and patient tolerance.
- Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.

6.8 Post Treatment Recommendations

- The Patient should avoid very hot water for 2 days after the treatment.
- The Patient should avoid mechanical contact with the treated area for 2 days.
- 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 of the gel and disinfected by 70% alcohol or surface disinfectant such as Cavicide™ wipes or similar products.
- The tip should be disposed.

7 Section 7: Fractora/FractoraV Treatment Information

7.1 Fractional Skin Resurfacing

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

Consult with accompanying clinical documentations such as In-Service Instructions and Quick Reference Guide (QRG) for the most updated clinical recommendations.

7.2 Indications for Use

The Fractora Handpiece is designed for use in dermatological procedures requiring ablation and resurfacing of the skin.

The Fractora with 24-pin tip is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62, use of the applicator is limited to skin types I-IV.

7.3 Contraindications

Contraindications in the use of the System include:

- Active electrical implant/device in any region of the body including pacemaker or internal defibrillator. 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, metal piercing or silicon, mesh or other.
- 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 current condition of any other type of cancer, or pre-malignant lesions.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances, epilepsy, uncontrolled hypertension, and liver or kidney diseases.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies or use of anticoagulants.
- 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.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV or use of immunosuppressive medications.
- Pregnancy and nursing.
- Poorly controlled endocrine disorders, such as Diabetes, or thyroid dysfunction and hormonal virilization.
- Isotretinoin (Accutane) within last 6 months.
- Any active condition in the treatment area, such as sores, Psoriasis, eczema, and rash, open lacerations, abrasions or lesions, infection in the area to be treated.
- Any surgical procedure in the treatment area within the last 12 months or before complete healing.
- 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 non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session, as per the practitioner’s discretion.
- Treating over tattoo or permanent makeup.
- Treating over the lips.
- Treating over eyebrows or other hair bearing surfaces.
- Skin type VI and dark V patients treat with caution. Do not treat skin type VI and dark V patients with 60 pin tip.
- Excessively tanned skin within the last two weeks.

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

7.4 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, bleeding and burn), change of pigmentation (hyper- and hypo-pigmentation), and scarring.
- Erythema lasting not longer than 24h and edema for 1-3 weeks is a typical skin reaction to the Fractora treatment.
- Crusting from the ablated dots will exfoliate naturally after 1-3 weeks.
- Occasionally, at energy level above 30, there is a potential low-level stimulation of branches of the facial nerve and there will be some involuntary contraction of the underlying facial muscle. This is transient and is not harmful, as the Fractora effect diminishes at the deeper level where parts of the facial nerve lie above the muscles.
- The patient must understand the importance of pre-treatment and post-treatment instructions and that failure to comply with these instructions may increase the probability of complications.

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.
- When face is treated Asian patients and skin type IV-VI should be treated gradually by bleaching products 6 weeks prior to treatment and stop at least 48 hours prior Fractora treatment to minimize risk of post inflammatory hyper-pigmentation.

- Prophylactic antiviral therapy should be prescribed for patients with history of cold sores (Herpes Simplex).
- Stop anticoagulants 7-10 days prior to treatment, if medically permitted.
- Clean the treatment area.
- Apply anesthesia:
  - Many patients can tolerate the treatment with no anesthesia at low energy levels of 5-20 energy levels and sometimes more.
  - Topical for 30-45 min – limited to energy as tolerated by the patient and may reach 40-62 energy levels, depending on the percent numbing ingredients and patient sensitivity.
  - A few patients require nerve block for higher energy, limited to central face.
  - Tumescent or IV sedation is applied usually when FRractora follows an invasive procedure.
- Cooling methods, such as air cooling, sterile ice-packs, or sterile latex gloves filled with ice, help patient comfort during and after treatment.

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

7.6 Tip Cleaning Instructions Prior to Use

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

The Fractora tip is single use only!

7.7 Sterilization

Each disposable handpiece can be sterilized before use. Use steam autoclave sterilization only. The handpiece should be autoclaved at 250 degrees F (121 deg C) with 15 psi for 30min or more with 30 minutes of dry time.

Autoclave temperatures should not exceed 279 deg F (137 deg C) handles; insulation or other non-metallic parts may be damaged.

* Do not sterilize with hot air

Make sure that hand piece is dry before use. Use of tips or handpiece when wet can result in inadequate impedance of the energy, arcing and burning.

7.8 Test Spots

A small test spot should be performed in a non-conspicuous area of the treatment site, prior to the first complete session. Low energy level, <25 is recommended for testing. 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 at energy level 15 or lower.
  - 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.
- Tolerance of patient to the treatment: low energy levels of 10-25 may be tolerated after topical anesthesia application. Energy levels of 25-40 may require nerve block or tumescent and high energy levels of 40-62 may call for tumescent or IV sedation.

7.9 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 clean and dry tip and connect it to the Handpiece in the groove.
4. Follow Device Start-Up Procedure from System Operation section.
5. Set treatment parameters according to test spot and training materials.
6. Use significantly low energy for treatment over bony areas as forehead, jaw line and cheek bones. Avoid treatment area where full contact of side electrode cannot be insured.

   WARNING! - Failure to do so can result in possible burning and scarring.
7. 60 pin tip energy is limited to 30 and repetition rate of 1pps in auto pulse mode. Use it only for superficial indications.
8. Use 24-pin tip for deeper lesions treatment.
9. Always start with a low energy level, test and observe the skin's response before increasing the energy.

10. The deeper the lesion, the higher the energy. However, this consideration is limited according to patient tolerance and safety considerations, the anesthetic method used, and the affordable down time.

11. On sensitive thin skin area, such as lower eyelid, apply lower parameters with more passes, rather than higher parameters in one pass. It is also applicable to any facial area for new users. Use lower energy (~20%) for thin skin like neck or bony area like forehead. When working on thin skin over bone, such as hand dorsum or chest, further reduce energy (~20%).

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

13. Apply the Fractora Handpiece to the treated area ensuring a contact with firm pressure to ensure proper coupling of the electrodes and minimize discomfort, and press footswitch to deliver RF energy.

WARNING! - Failure to do so may result in arcing of energy, burning and scarring.

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

15. Move to adjacent areas overlapping the treatment tip 30-50%, with no overlapping of side-electrodes.

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.

7.10 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. In some instances, 1-2 sessions may be sufficient.

7.11 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 type IV and V, bleaching cream should be prescribed for 6-12 weeks, 2-3 times a week following the healing of treatment area (typically 7 days) to minimize risk of post inflammatory hyper-pigmentation. It should be stopped 48-72 hours before another Fractora session.

8 Section 8: System Maintenance

8.1 Maintenance & Frequency

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

8.2 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 or surface disinfectant such as Cavicide™ wipes or similar products between patients, as described in detail for each handpiece in “Handpiece Cleaning Instruction Prior to Use”. Remove the gel from the applicator before cleaning.

8.3 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.

8.4 Once a Year

By Authorized Service personnel only:

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

9 Section 9: Troubleshooting

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

9.1 Description of Faults

Problem	Description and Checks
System did not turn on	– Check power cord connection. – Check that main switch on rear panel is on. – Check fuses on back panel of the System. – Call Technical Service if the problem persists.
Software Plug Missing	– The software plug is not inserted.
Checksum	– The software was not loaded properly from software plug. – Check plug connection and reboot the System. – Call Technical Service if the problem persists.
Fault H8002 - Handpiece is not connected	– Check connection of Handpiece. – Replace Handpiece. – Call Technical Service if the problem persists.
Fault H8005 – System Memory Fault	– Call Technical Service if the problem persists.
Faults H8003, H8006, H8007 - RF Related Faults	– Call Technical Service if the problem persists.

10 Section 10: 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 - 110 kPa	
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– 65C [-4 – 14°F]	
Relative Humidity	0% to 80%, non-condensing	
Atmospheric Pressure	50 to 110 kPa	
Dimensions		
System	35cm W x 35cm D x 100cm H	[18.2'' W x 18.2'' D x 40'' H]
Handpiece cable	250 cm L	[100`` L]
Weight		
System	20.000 Kg	[44lbs.]
FormaV Applicator	0.22 Kg	[0.5 lbs.]
FractoraV Applicator	0.22 Kg	[0.5 lbs.]
Output Parameters		
Fractora RF Maximum Output Energy	62 [energy level]	
FormaV RF Maximum Output Energy	40 [energy level]	
RF Frequency	1[MHz] ± 2%	

10.1 Output Power Curves

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

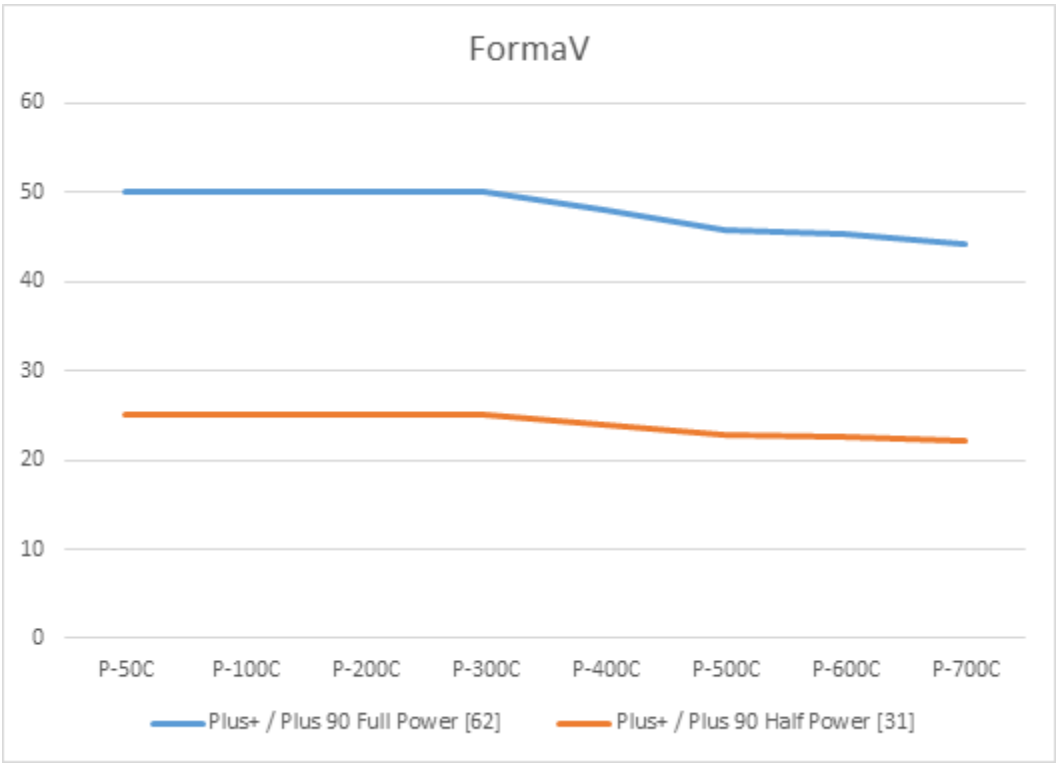


Figure 10-1: FormaV Output Power Versus Impedance

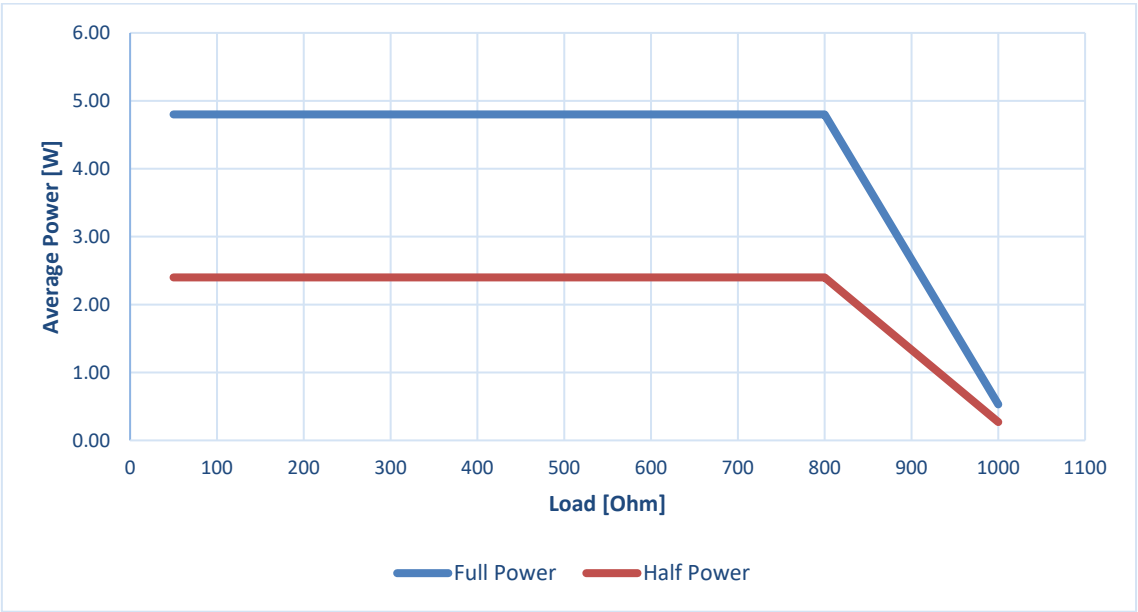


Figure 10-2: Fractora 24 Pin Tip Output Power Versus Impedance

10.2 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.

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The device 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The device 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.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Complies</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 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 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) 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 device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE - UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The System is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 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 device, 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 strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.

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

Recommended separation distances between

portable and mobile RF communications equipment and the System

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

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

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

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

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

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

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	IEC 61000-3-2	For InMode with Applicator BodyFx: AC mains	Complies
	IEC 61000-3-2	For InMode with Applicator PLUS RF: AC mains	N/A
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	For Inmode with PLUS RF: AC mains	Complies
	IEC 61000-3-3-/ IEC 61000-3-11	For InMode with Applicator BodyFx: on AC mains (Z max = 0.12 Ω)	Complies
Immunity (IEC 60601-1-2 section 6.2 and IEC 60601-2-2 section 202.6.2)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	6 kV contact discharges & 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 & Applicator & Pedal cables; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	3 A/m, 50 Hz & 60 Hz	Complies
Immunity from Voltage interruptions	IEC 61000-4-11	230 & 100 VAC mains: > 95 % - 10 ms; 60%- 100 ms; 30% - 500 ms; >95% - 5sec	Complies

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3 December 2015

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