EMPOWER RF

by INMODE

Operator Manual

Empower RF

Version: DO610215A

INMODE

Operator Manual: Empower RF System

DO610215A

InMode Ltd

Tavor House, POB 533, Industrial Park South,

Yokneam, 2069206, Israel

For information call: +972-4-9096313

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Section 1: Introduction

1.1 Before You Start

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

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

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

1.2 System Overview

The InMode RF Pro Platform with FormaV, Morpheus8V, vTone, Tone, Morpheus8/Morpheus8 Body and Aviva Applicators (marketed as Empower RF) employs bi-polar Radio-frequency (RF) technology and Electrical Muscle Stimulation (EMS) technology for various aesthetic and medical applications.

The Empower RF System with FormaV applicator is 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 Empower RF System with the vTone applicator is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress urge and mixed urinary incontinence in women.

The Empower RF System with the Morpheus8V/Morpheus8/Morpheus8 Body applicators is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis

The Empower RF System with the Tone applicator is intended for use is used in EMS mode for: prevention or retardation of disuse atrophy, maintaining or increasing range of motion, muscle re-education, relaxation of muscle spasms, increasing local blood circulation, immediate postsurgical stimulation of calf muscles to prevent venous thrombosis. And in TENS mode for: symptomatic relief and management of chronic, intractable pain, post-surgical acute pain, post-traumatic acute pain.

The Empower RF System with the Aviva Handpiece employs radiofrequency (RF) energy for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

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

1.3 Conventions Used in the Manual

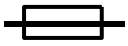
The following conventions in the form of notes and warnings are used in this manual:

WARNING! This information is extremely important!

ATTENTION! Consult Accompanying Document.

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

1.4 Explanation of the Symbols used on the System

Symbol	Description
	CSA marking (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	Type B Equipment.
	HF Isolated Patient Circuit
	Follow the operating instructions
	Federal (US) law restricts this device to sale by the order of a physician licensed by the law of the state in which he practiced to use or order the use of the device

Symbol	Description
	Do not reuse/single use only. This symbol is used for disposable one-time-use products.
	This equipment intentionally supplies non-ionizing RF energy
	Sterilized by Radiation

Table 01-1: Device Symbols

Section 2: Safety

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

The applicator 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 and the applicator. The operator and all other personnel operating or maintaining the system should be familiar with the safety information provided in this section.

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

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

RF energy can cause injury if used improperly.

High voltage is present inside the System.

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

2.1 The Patient

- Well-trained staff is key for assuring patient safety. A patient history report should be completed prior to scheduling. Patients should be fully informed of the treatment details, the likely results and any risks associated with the treatment.
- Jewelry and metal accessories that are within the activation range of the Handpiece should be removed to avoid accidental RF conduction.

2.2 Treating Attendant

Only authorized individuals with appropriate training and knowledge should operate, assist in the operation of, or provide maintenance to the Empower 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.
- 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.
- 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.
- Power Interruption – in case of unexpected power reset the system will shut down and restart to the password screen, no output Energy.

2.5 Fire Hazards

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

2.6 Safety Features of the System

- The System incorporates the following safety features. All personnel operating the System should be familiar with these features.
- The System has unique password to avoid device operation by non-authorized personnel.
- The power electronics cannot be activated unless the applicator and Footswitch have been connected to the System.
- An audible tone indicates energy activation.
- During activation, the System performs a self-test of the hardware.
- Hardware is tested every 10ms to ensure proper operation of electrical circuit.
- The System starts at a low setting.

2.7 Safe use of the Active Accessories

- Examine the connection of the Handpiece through the connectors to the System before using. Ensure that the accessory functions as intended. Improper connection may result in arcs and sparks, accessory malfunction, or unintended treatment effects.
- Do not wrap the Handpiece cords around metal objects. It may induce current that could lead to electrical shocks, fire or injury to the patient or personnel.

Do not connect a wet accessory to the System.

Do not immerse the applicator under water at any time.

2.8 Warnings

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

Only Handpiece manufactured or approved by InMode Ltd. should be used with Empower System.

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

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

Always turn off and unplug the device before cleaning.

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

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

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

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

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

- Flammable substances (such as alcohol-based skin prepping agents and tinctures).
- Naturally occurring flammable gases which may accumulate in body cavities such as the bowel.
- Oxygen enriched atmospheres.
- Oxidizing agents (such as nitrous oxide [N2O] atmospheres).
- Endogenous gases.

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

The operation of the Empower System may adversely influence the operation of other electronic EQUIPMENT.

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

Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), neither from electrodes placed on the chest and the upper back or crossing over the heart.

Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the EMS System output and may result in device damage.

Do not apply the EMS electrodes near the thorax to avoid risk of cardiac fibrillation.

2.9 Device and Handpiece Labels

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

The following device labels are located on Empower RF System console and on Handpiece body:

Figure 2-1: Empower RF Rear Panel with Labels

Figure 2-2: Device Identification Label

Figure 2-3: Footswitch Label (to be placed on system console)

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

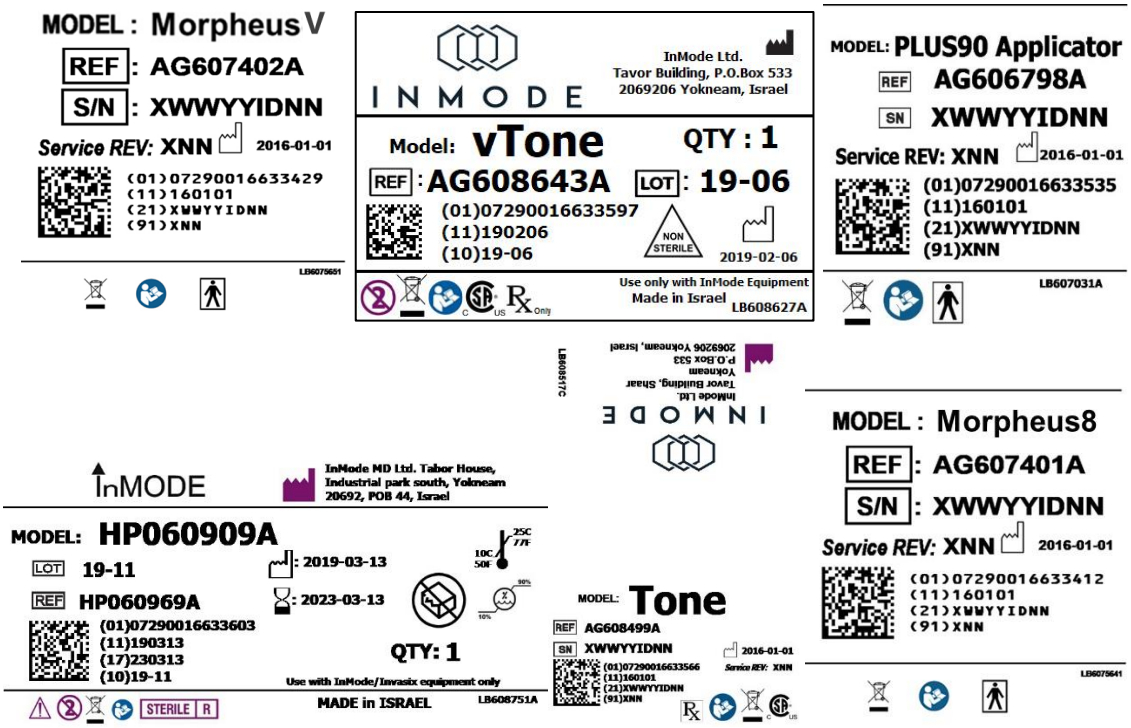
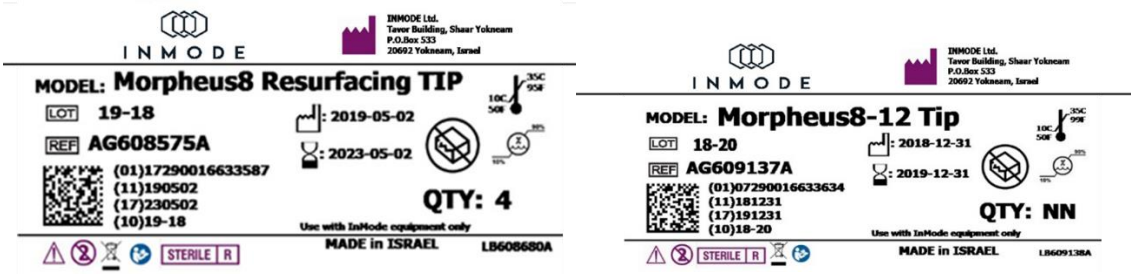


Figure 2-4: Handpieces Identification Labels



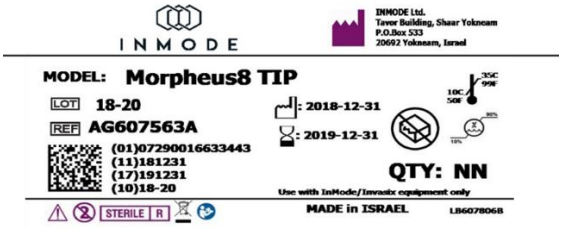


Figure 2-5: Morpheus8 Tip Identification Label

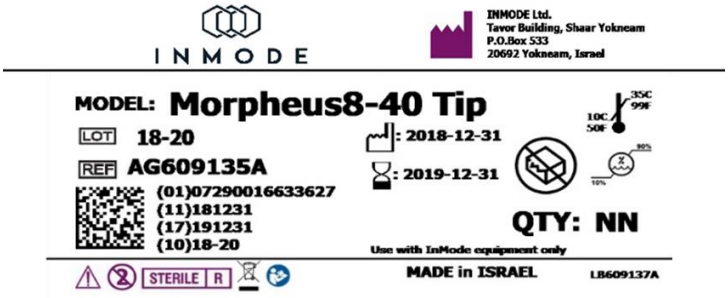


Figure 2-6: Morpheus8 Body Tip Identification Label

2.10 Equipment Classification

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

- Electric shock protection: Class I, Type BF for the RF Handpiece.
- Protection against ingress of liquids: Ordinary equipment.
- Not suitable for use in presence of flammable substance.
- Power receptacle must include protective earth and must be checked before connecting the System.
- The Empower System with the Morpheus8V/Morpheus8/Morpheus8 Body/vTone/FormaV/Tone/Aviva Handpieces is classified as Class II device defined by the FDA CDRH and complies with 21 CFR subparts E.

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 Installation

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

- Check the System and all its components for damage.
- Connect cradle to the device.
- Connect Handpiece to the connector and place into the cradle.
- Connect the Footswitch.
- Connect the power cord to the System inlet.
- Plug the System Power Cord into an appropriate electrical outlet.

3.4 Moving the System

- Turn the System off.
- Disconnect the Power Cord.
- Disconnect the Handpiece.
- Disconnect the Footswitch.
- Release the Wheel Brakes.
- Slowly push or pull the System using the handle.

When moving the System to another facility, lift the System to the vehicle and lay it carefully on its side.

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

Always use the handles when moving the System.

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

3.5 System Disposal

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

Section 4: Device Description

4.1 Rear Panel

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

Table 4-1: Rear Panel Symbols

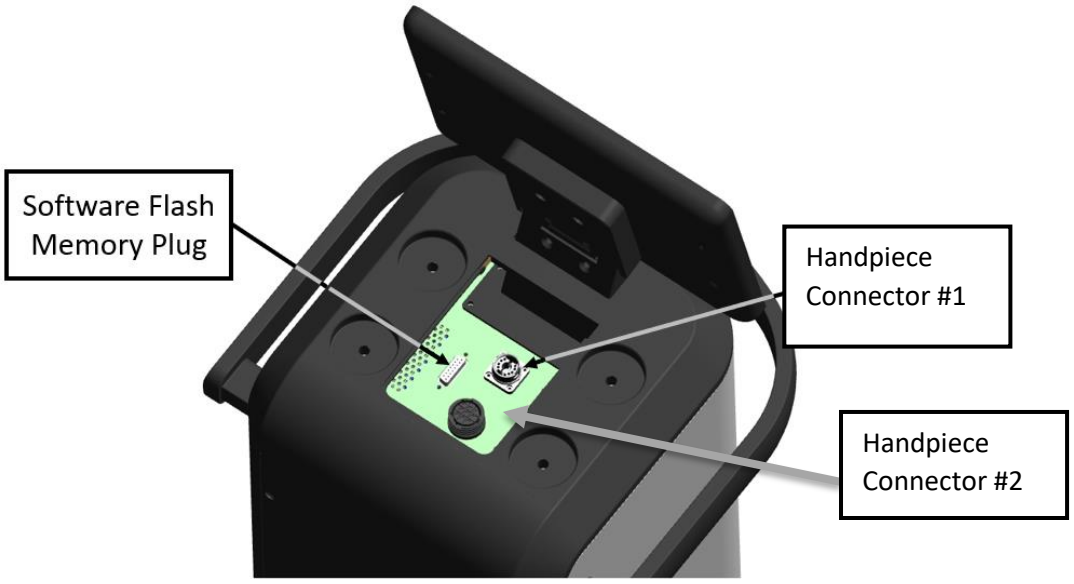


Figure 0-1: Handpiece Connectors on Top Panel

The Device has a connector panel, located on the top of the console. There are two connection ports – Handpiece Connector #1 and Handpiece Connector #2(See Figure 4-1), responsible to connect between the console and the applicators.

Power On-Off switch

Power switch turns system on and off – on top of front panel.

Handpiece connector

RF power cannot be activated if Handpiece is not connected to the connector – on top panel.

LCD screen with touch panel

LCD screen shows information about machine status, treatment parameter. Touch screen allows to user change treatment parameters and device mode.

Front Panel and Operator Control Panel

The Operator Control Panel is located on the upper front side of the System and consists of an On-Off switch and a Touch Screen (Figure 4.2).

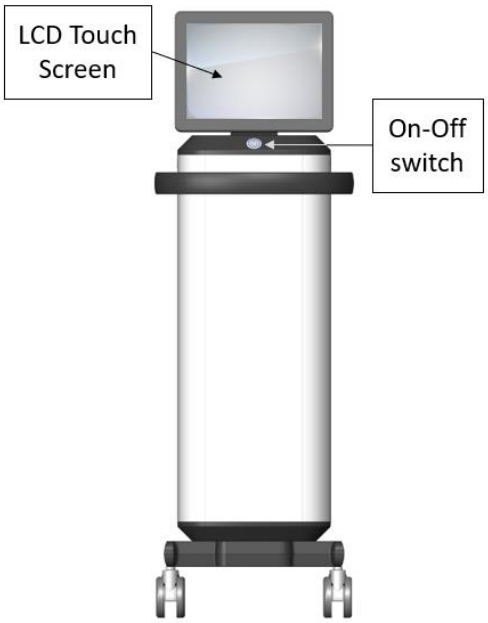


Figure 4-2: Schematic Front View of System

Power On-Off switch	Power switch turns power electronics On and Off.
LCD Screen	LCD Screen shows information about system mode and treatment parameters. The panel allows changing treatment parameters and system mode.

Power electronics is not activated if the Handpiece is not connected to its connector on the front panel.

4.2 Software Screens

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

Figure 4-3: Progress Screen

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

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

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

Figure 4-4: Login Screen

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

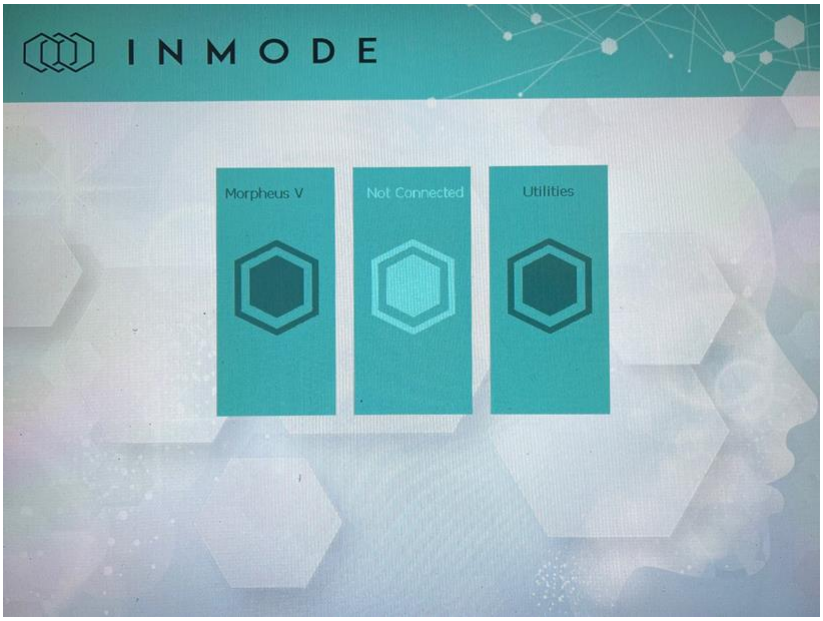


Figure 4-5: Menu Screen

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

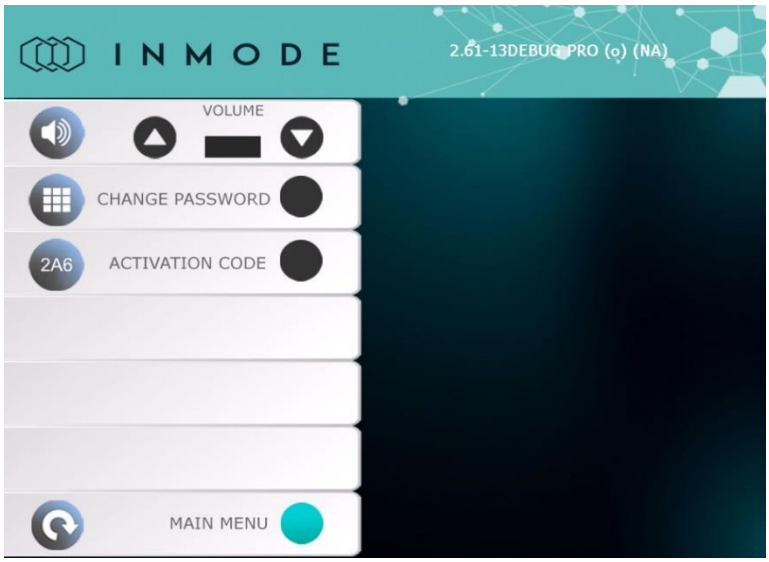


Figure 4-6: Utilities Screen

The Utility Screen contains:

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

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

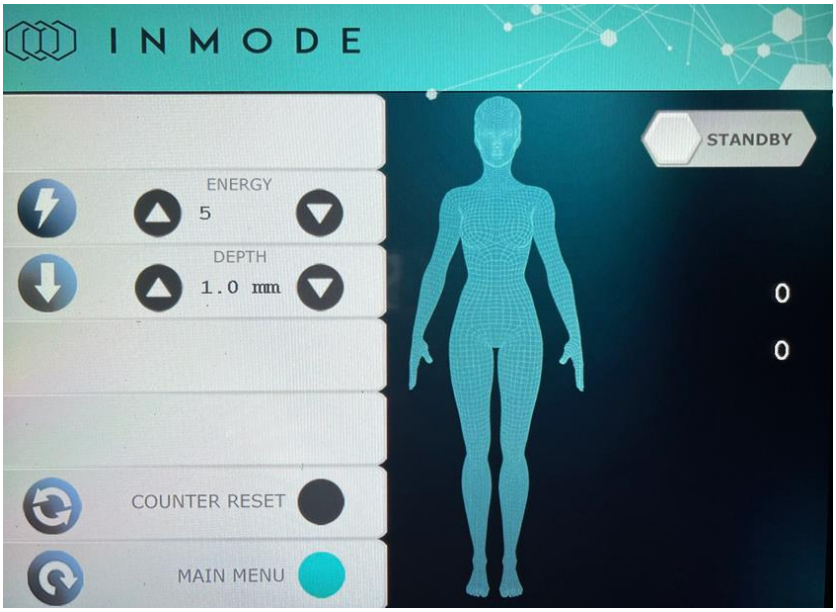


Figure 4-7: Morpheus8V Treatment Screen

Depth	Allows selecting the pins length and penetration depth. The tips may penetrate to a depth of 1 - 3mm.
Energy	Delivered energy is changed from level 5 to 60 energy levels and the System starts up at the minimal energy setting. For 1mm Depth energy range is 5 to 30
Counter Reset	Counter can be reset number of pulses per zone.
Pulse Counter	Shows number of pulses delivered on one zone and total number of pulses from the beginning of the treatment.
System Mode	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.
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

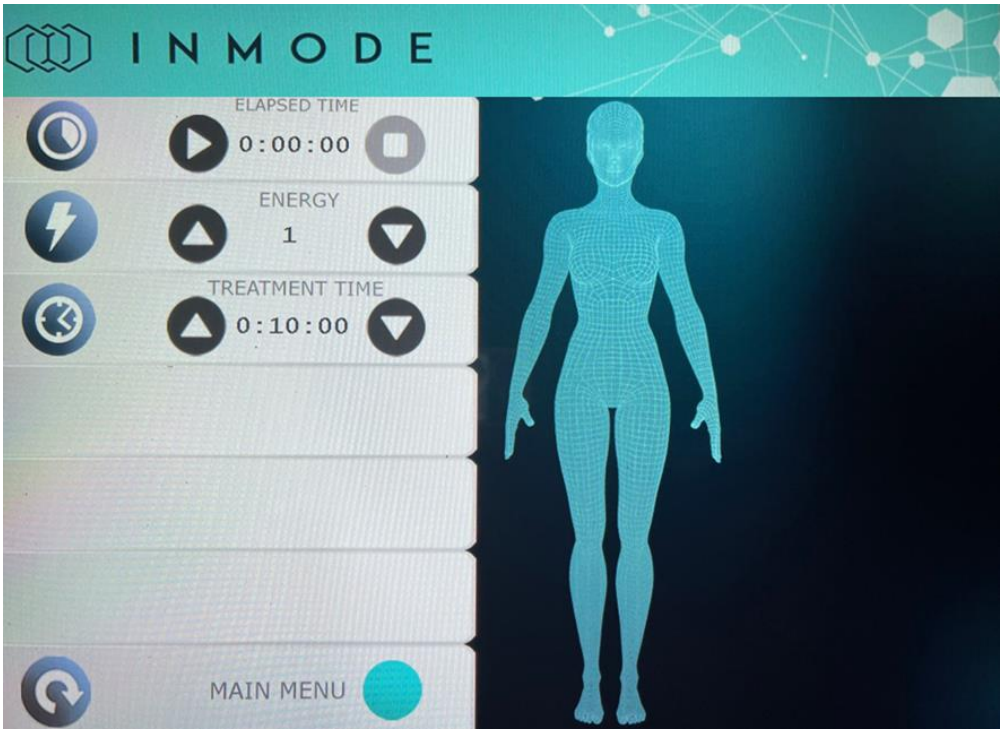


Figure 4-8: vTone Treatment Screen

Elapsed Time	This indicator shows elapsed time from the beginning of treatment activation.
Start / Pause	This button activates the treatment. After pressing the 'Start' button, the system is in 'Active' mode. The icon will then change to 'Pause' and clicking on it will pause the treatment ('Pause' mode). The 'Elapsed Time' counter will not reset while pausing the treatment. Any attempt to change the settings during treatment, switches the system to Pause mode.
Energy	Allows selecting intensity level of EMS pulses from 1 to 50 intensity levels.
Treatment time	Allows selecting the treatment time in minutes.
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

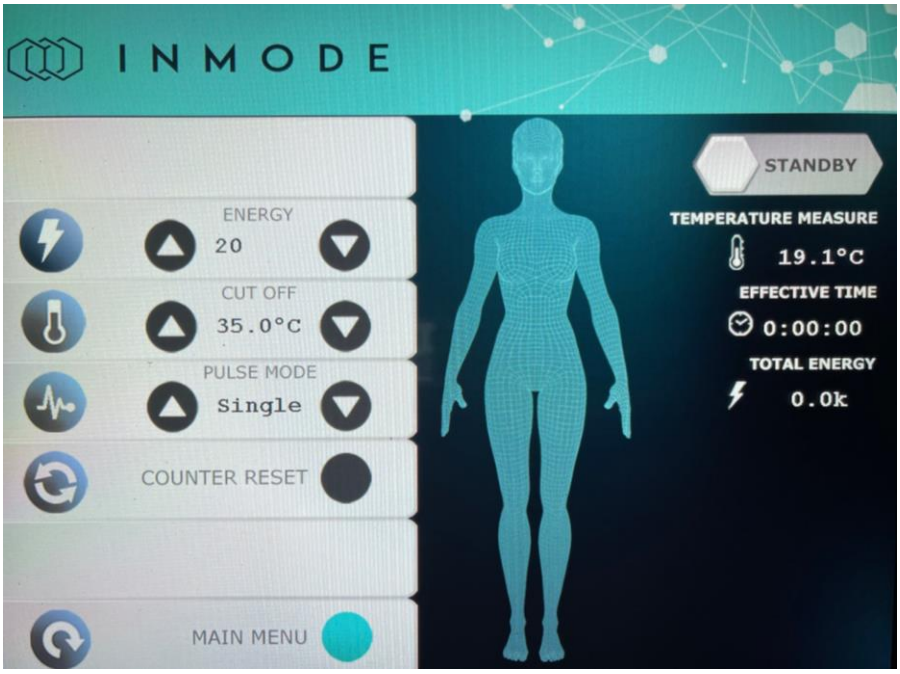


Figure 4-9: FormaV Treatment Screen

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.
Total Energy	Indicates total energy used during the session.
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

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

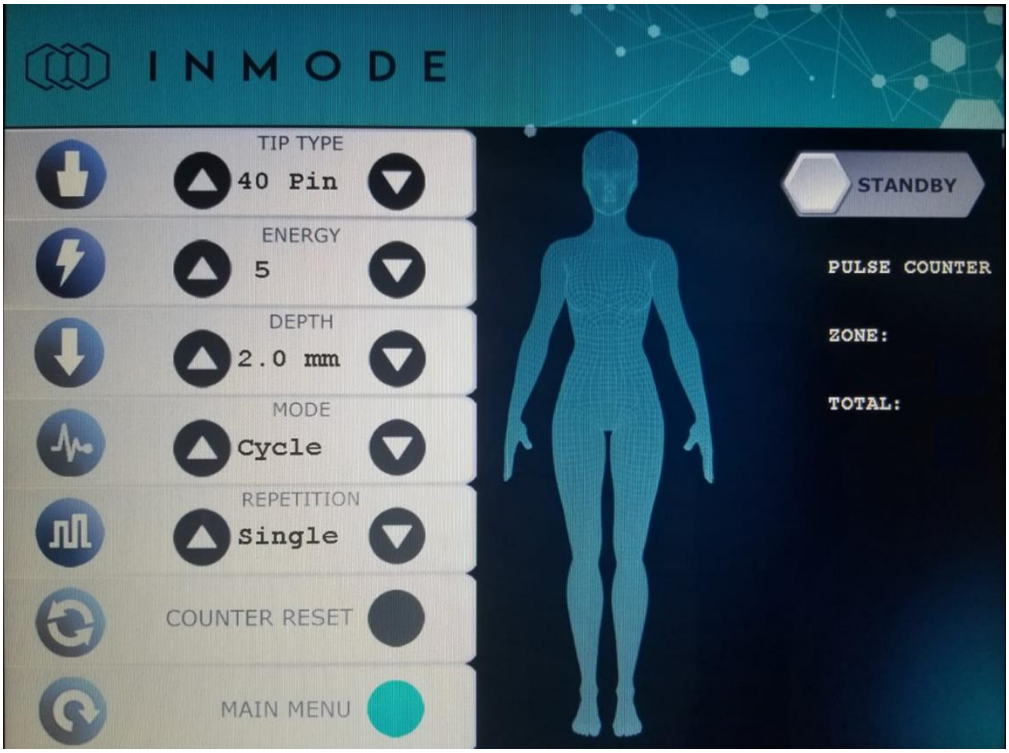


Figure 4-10: Morpheus8 Treatment Screen

Tip	Allows selecting the Tip. Available Tips are: • Morpheus8 Applicator: Resurfacing (Resrf.) tip, 12 Pin tip, 24 Pin tip • Morpheus8 Body Applicator: 40 Pin tip.

Depth	Allows selecting the pins length and penetration depth according to dermis thickness in treated area to provide effective sub-dermal treatment. Available depths are: for 40 pins tip 2, 3, 4, 5, 6 and 7mm. The 12 and 24 pins tips may penetrate to a depth of 1 - 4mm. When connecting the Resurfacing tip, depth control is disabled, and the pin length is constant (0.5mm).
Energy	Delivered energy is changed from level 5 to 60 energy levels and the System starts up at the minimal energy setting. For 1mm Depth and Resurfacing Tip energy range is 5 to 30
Mode	Selects between Cycle mode when needle goes out and in at each pulse and Fixed mode when needles go out at foot switch pressing and stay protruded until Footswitch is released. In Fixed mode RF pulses are applied automatically with predetermined pulse repetition rate.
Repetition	Select between single pulse delivery at Footswitch pressing and autorepeat mode with predetermined pulse repletion rate
Counter Reset	Counter can be reset number of pulses per zone.
Pulse Counter	Shows number of pulses delivered on one zone and total number of pulses from the beginning of the treatment.
System Mode	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.
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

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

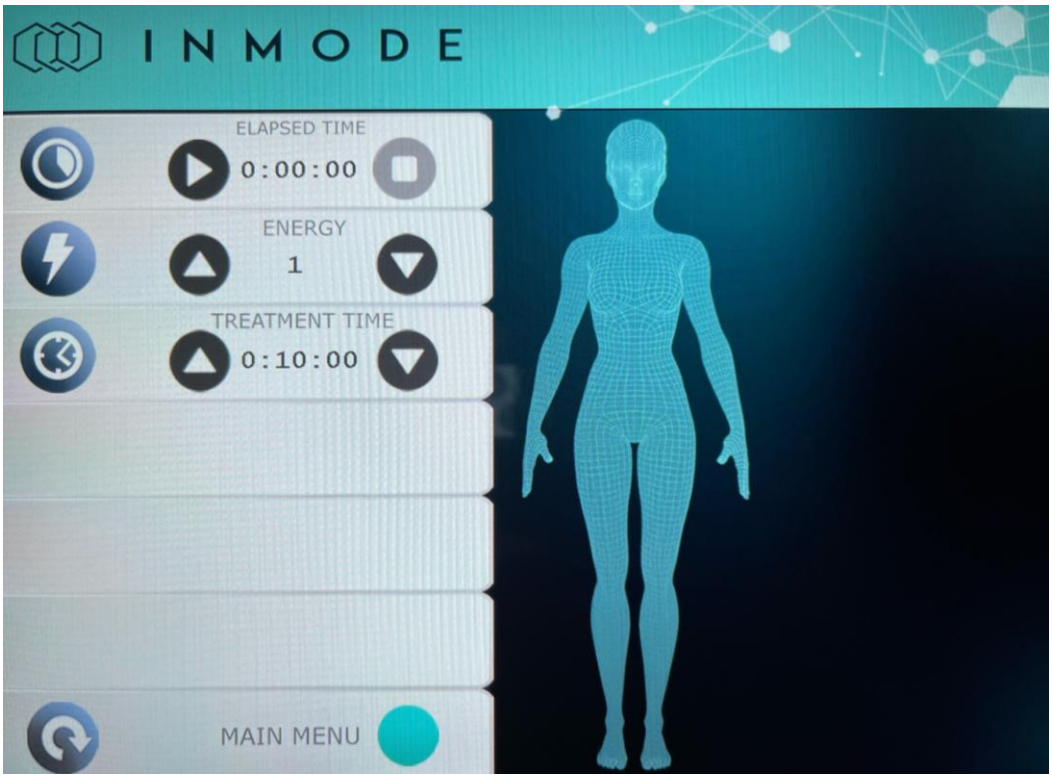


Figure 0-11: Tone Treatment Screen

Elapsed Time	This indicator shows elapsed time from the beginning of treatment activation.
Start / Pause	This button activates the treatment. After pressing the 'Start' button, the system is in 'Active' mode. The icon will then change to 'Pause' and clicking on it will pause the treatment ('Pause' mode). The 'Elapsed Time' counter will not reset while pausing the treatment. Any attempt to change the settings during treatment, switches the system to Pause mode.
Stop	This button Stops the treatment and switches the system to Standby mode. The 'Elapsed Time' counter resets.
Intensity	Intensity is changed within the limits allowed for the connected Applicator. Intensity level settings are changed from 1 to 50. The System starts up at minimal intensity level setting.
Treatment Time	This indicator shows time when energy is applied sequentially to the Applicators.
Main Menu	Return to the Main Menu to select the Applicator.

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

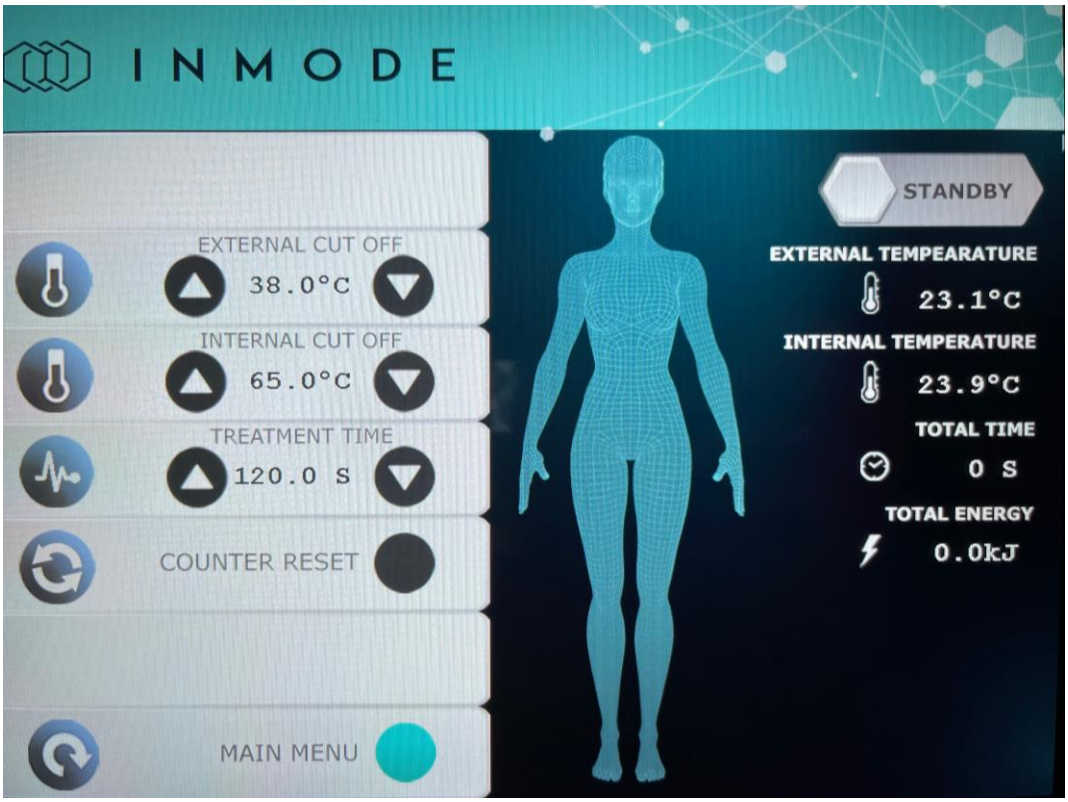


Figure 0-12: Aviva Treatment Screen

External Cut-Off	This indicator shows the treatment area surface Cut-Off temperature, which is adjustable between 35-40oC, with increments of 1°C in the tissue. The selected value indicates measured temperature which is maintained during the treatment according to the setting.
Internal Cut-Off	This indicator shows the internal Cut-Off temperature, which is adjustable between 50-65°C, with increments of 1°C in the tissue. The selected value indicates measured temperature which is maintained during the treatment according to the setting.
Treatment Time	This indicates the time that Cut-Off temperature is maintained. It varies from 15-120 sec with increments of 5 sec.
External Temp.	This indicator shows measured external temperature.
Internal Temp.	This indicator shows measured internal temperature.
Total Time	This indicator shows total time of RF delivery.
Total Energy	Indicates total energy used during the session.
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 unavailable in Standby mode.

	In Ready mode, the system waits for a signal from the footswitch to activate the energy. Any change to the treatment settings switches the system to Standby mode. Active mode is entered during RF energy delivery.
Main Menu	Return to the Main Menu to select the Applicator.

4.3 Sound Indicator

A periodic tone indicates that RF is delivered.

A warning sound tone indicates Bad Coupling.

4.4 Cut-Off Temperature Control

FormaV Handpiece:

- 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.

Aviva Handpiece:

- The selected Cut-Off temperature in the range of 35-40°C is constantly maintained and when reached, RF delivery is adjusted automatically to maintain required temperature. Temperature is monitored by temperature sensors in the Handpiece (in the external electrodes).
- For Aviva Handpiece the selected Cut-Off temperature in the range of 50-65°C is constantly maintained and when reached, RF delivery is adjusted automatically to maintain required temperature. Temperature is monitored by temperature sensors in the Handpiece (in the internal electrodes).
- The treatment time is selected in the range of 15-120 sec and indicates time that Cut-Off temperature is maintained.

4.5 Handpieces

Morpheus8V Handpieces (Figure 4-13) comprise motor with actuator pushing needle electrodes out to pre-determined depth up to 3 mm. The tip is connected or disconnected with the Handpiece.

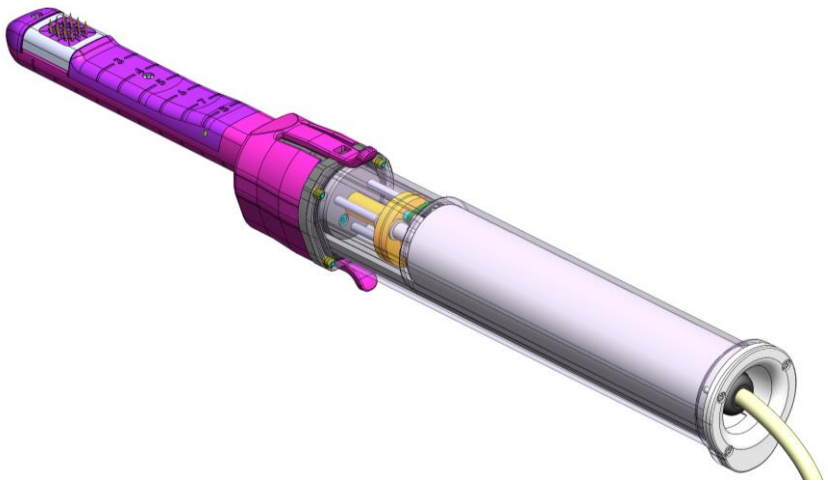


Figure 4-13: Morpheus8V Handpiece

Tip	The tips comprise 24 needles that are coated along with an insulating material except the distal 0.5mm edge (Figure 4-14). Note the insulation that leaves only the 0.5mm tip exposed.
Handle	The Handpiece handle is made of plastic and has an ergonomic design for easy treatment, with high visibility of the treated area.
Cable	The Cable has a length of 270cm.
Connector	The Connector is connected to the front panel of the System.

Figure 4-14: Morpheus8V tip needle structure

The insulation leaves only the 0.5mm tip exposed.

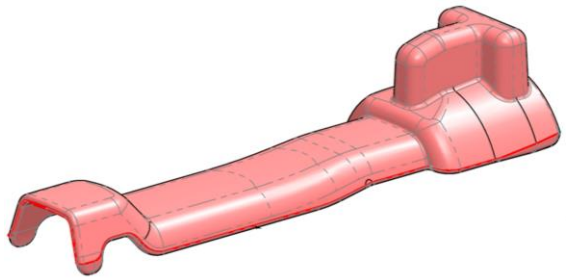
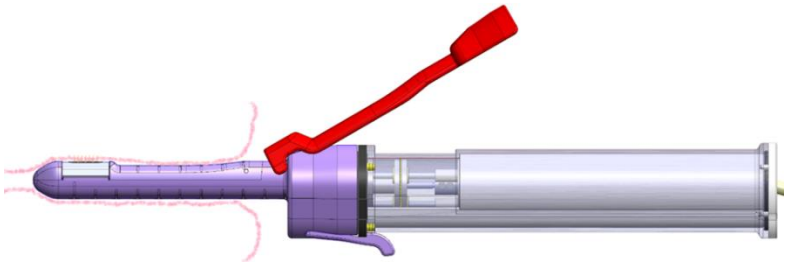


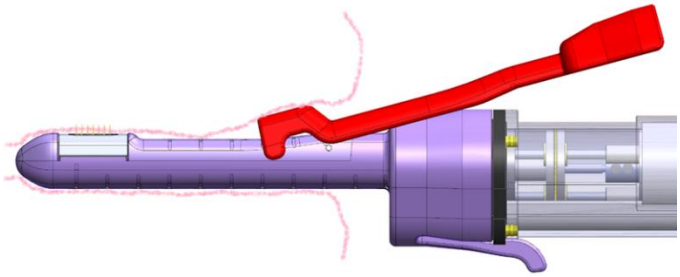
Figure 4-15: Morpheus8V Emergency Extraction Tool

In a highly unlikely event that the needles after being deployed into the tissue do not retract back into the applicator the Emergency Extraction Tool can be used. To use the tool:

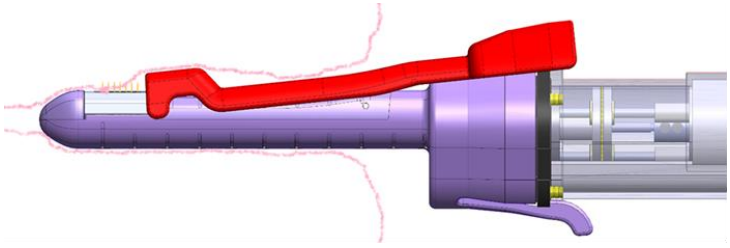
1. Place the Extraction tool at the 30° angle at the bottom of the disposable tip.



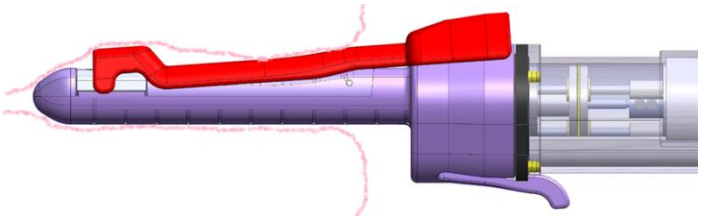
2. Start to slowly slide the extraction tool forward along the disposable tip while changing the angle of the tool to 15°. Ensure the emergency tool always has firm contact with the disposable tip.



3. As the extraction tool advances along the disposable tip, slowly change the angle to 6°. When the extraction tool is at a 6° angle and approximately 2/3 of the way along the disposable tip, the separation of the needles from the tissue has started.



4. When the extraction tool is completely inserted, the base of the extraction tool and the base of the disposable tip will be completely aligned. Once they are aligned, it means that the needles have been separated from the tissue and covered by the extraction tool for a safe extraction. It is now safe to remove the handpiece.



The vTone Applicator is connected to the applicator Cable with Connector to the Pulse Generator Adaptor (Figure 4.16). The Pulse Generator Adaptor is connected by a cable to Adaptor Connector which is connected to the system.

The vTone Applicator with the applicator Cable and Connector to the Pulse Generator Adaptor (Figure 4.16) is for single use only!

Figure 0-16: vTone Applicator components and

vTone single use components packed in their Tyvek packaging

Electrodes	Delivers electrical pulses to the treatment area
Applicator Cable with Connector	Connects the applicators to the electrical pulse generator adaptor
Pulse Generator Adaptor	Generates bi-phasic electrical pulses with controlled intensity and structure and transfers it to the applicator via vTone cable

Adaptor Connector	Connects the Pulse Generator Adaptor to the Console

The FormaV Handpiece (Figure 4.17) 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.

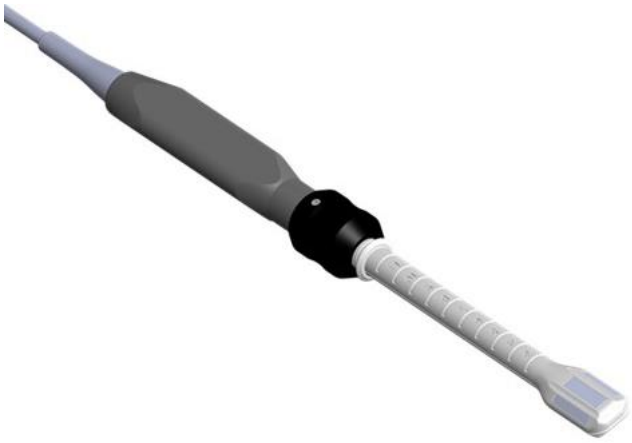


Figure 4-17: FormaV Handpiece

Morpheus8 Handpieces (Figure 4-18 and Figure 4-20) comprise motor with actuator pushing needle electrodes out to pre-determined depth up to 7mm. The tip (Figure 4-19 and Figure 4-21) is connected or disconnected with the Handpiece.

Figure 4-18: Morpheus8 Handpiece

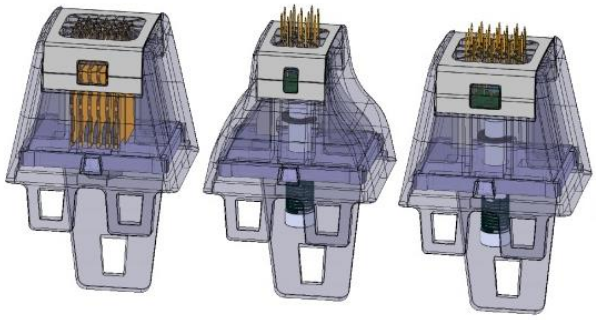


Figure 4-19: Morpheus8-Resurfacing Tip (Left), Morpheus8-12 Pins Tip (Center), Morpheus8-24 Pins Tip (Right)

Figure 4-20: Morpheus8 Body Handpiece

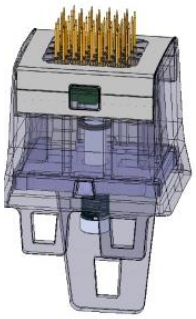


Figure 4-21: Morpheus8-40 Pins Tip (Body)

Tip	The tips comprise 24, 40 or 12 needles that are coated along with an insulating material except the distal 0.5mm edge (Figure 4-22). Note the insulation that leaves only the 0.5mm tip exposed. For the Resurfacing tip, depth control is disabled, and the pin length is constant (0.5mm).
Handle	The Handpiece handle is made of plastic and has an ergonomic design for easy treatment, with high visibility of the treated area.
Cable	The Cable has a length of 270cm.
Connector	The Connector is connected to the Handpiece Connector#2.

Figure 4-22: Morpheus8 tip needle structure

The insulation leaves only the 0.5mm tip exposed.

Each Tone Applicator unit comprises a 2 electrodes, and a Connector.

Figure 0-23: Tone Applicator Unit

The Tone Applicator unit contains:

Harness	The Cable has a length of 250cm (100’’) and connects two applicators to the platform.
Connector	The Connector is connected to the Handpiece Connector#2.
Electrodes	Two stainless steel electrodes are located on the each of Tone hand pieces.

Belt Set

The Belt Set is intended to be used on an individual patient during a single procedure and then discarded. The Belt Set is not intended to be reprocessed and used on another patient

The Aviva (HP060909A) Handpiece comprises internal active electrode, external return electrode, both with temperature sensor, handle, cable and connector.

Figure 0-24: HP060909A Handpiece

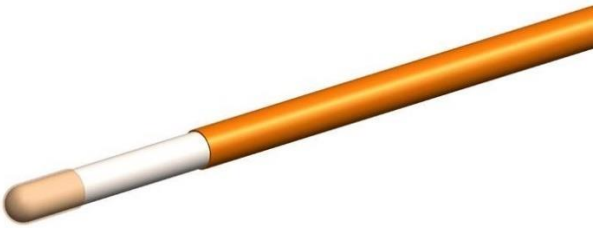


Figure 0-25: HP060909A Handpiece Tip

Internal Electrode	The Handpiece active internal electrode is an insulated metal tube with conductive area at the distal part, but not at the tip. For added safety, at the end of the electrode there is an isolated plastic tip which is not conductive. The internal electrode has an embedded temperature sensor to monitor the tissue temperature.
External Electrode	The handpiece has a large area external electrode with embedded temperature sensor to monitor the treatment area surface temperature.
Cable	Has a length of 250cm (100”).
Connector	It is connected to the front control panel of the system.

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 password to get access to the device. If password is correct the System enters Menu Screen.
5. The System loads the software and enters a self-test mode. If any problem is detected during the test the error message will appear (See Troubleshooting Section in this manual). If the test is passed correctly then the System automatically enters the Menu Screen.
6. Select the application from the Menu Screen and System will enter the Treatment Screen.
7. Verify on the screen that the Software version is properly displayed and the connected Handpiece type is recognized correctly.
8. Select the treatment parameters using Up and Down keys.
9. Press the Standby icon that will change to Ready.
10. To start treatment, press the Footswitch.

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.

Section 6: Morpheus8V Treatment Information

6.1 Fractional Treatment

The Morpheus8V Handpiece is designed for delivering RF energy to the tissue in a fractional manner with the energy applied to <5% of the total coverage area. The energy is delivered 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 tissue promotes remodeling while untreated tissue between the pins promotes faster healing of the tissue.

6.2 Indications for Use

The Morpheus8V applicator is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

6.3 Contraindications

- Pacemaker or internal defibrillator, or other metallic or electronic implant anywhere in the body. The 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 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 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 surgery performed within a year prior to treatment.
- Dermabrasion, resurfacing, or deep chemical peeling within the last three months.
- 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.
- Skin type V and dark VI patients treat with caution.
- Treating over hair bearing surfaces.
- Irritable skin like excessively tanned skin from sun, tanning beds or tanning creams and sprays within the last two weeks.
- As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient.

6.4 Possible Adverse Side Effects

Possible adverse effects include but are not limited by: discomfort or pain, excessive redness (erythema) and/or swelling (edema), damage to natural 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 reaction to the treatment.

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

6.5 Pre-treatment Recommendations

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

1. Complete or update the patient's medical and physical history.
2. Exclude from treatment anyone with the listed contraindications.
3. Determine why the patient is seeking treatment and what patient's expectations are.
4. Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
5. Instruct the patient about the safety warnings.
6. Prophylactic antiviral therapy should be prescribed for patients with history of cold sores (Herpes Simplex) when treating around the mouth.
7. Stop anticoagulants 7-10 days prior to treatment, if medically permitted.
8. Clean the treatment area.
9. Apply anesthesia:
   - Topical anesthetic can be applied as needed prior to treatment.
   - A few patients require anesthetic local injection for higher energy.

Cooling methods, such as air cooling, sterile ice-packs, or sterile latex gloves filled with ice, help patient comfort during and after treatment.

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

The Morpheus8V tip arrives gamma-sterilized and is single use only! These tips SHOULD NOT be autoclaved or re-sterilized by any other technology!

When choose "Fractional" on Menu Screen, the connected Morpheus8V handpiece with tip is performing self -test. The pins go out and in, as the Treatment Screen opens. It is crucial to avoid touching the skin with the tip at this stage and leave the Handpiece in its cradle.

The operator shall wear surgical gloves (single use only)

6.6 Test Spots

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

6.7 Treatment Recommendations

1. Apply the necessary means of anesthesia. If topical, make sure that it is cleaned off the treatment area before treatment and the surface is dried with alcohol 70%.
2. Connect Handpiece to the System.
3. Follow Device Start-Up Procedure from System Operation section.
4. Set treatment parameters.
5. Always start with a low energy level, test patient comfort and observe the tissue's response before increasing the energy.
6. On sensitive, thin tissue apply lower parameters with more passes, rather than higher parameters in one pass. It is also applicable to new users for any area.
7. Reduce ~20% energy when working on thin skin/tissue. Further ~20% reduction on bony areas.
8. Apply the Handpiece with complete contact and firm pressure.
9. Move Handpiece to the adjacent area with 30-50% overlap and activate RF again.
10. Occasionally, additional 1-2 passes may be applied to reinforce results on the full area or on selected spots.
11. The endpoints are minimal to substantial erythema and edema often accompanied by tingling heat sensation. Minor pin-point bleeding can be observed.

6.8 Treatment Schedule

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

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

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

6.9 Post-treatment Recommendations

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

- Cool the treatment area 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 treatment area 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).
- 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.

Section 7: vTone Treatment Information

7.1 Intended Use

The vTone applicator is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women.

The System provides individual adjustment of Intensity level to achieve maximum efficiency, safety and comfort for each patient.

7.2 Contraindications

Contraindications in the use of the System include:

- Patients with cardiac demand pacemakers and internal defibrillators or any active electrical implant/device in any region of the body.
- 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 or before complete healing.
- 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 vaginal disorders, keloids, abnormal wound healing.
- 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.
- Use of Isotretinoin (Accutane) within last 6 months.

- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash, open lacerations, abrasions, lesions, or infection in the area to be treated, current urinary tract infection or pelvic infection, uterine prolapse, cystocele, or rectocele.
- 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.
- Patients who have vaginal metal piercing, or intrauterine contraceptive device (IUCD or ICD or coil or any other device made of metal). As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

7.3 Warnings

1. Long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions.
3. Stimulation should not be applied over, or in proximity to, cancerous lesions.

7.4 Precautions

1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
5. When there is a tendency to hemorrhage following acute trauma or fracture;
6. Following recent surgical procedures when muscle contraction may disrupt the healing process;
7. Over the menstruating or pregnant uterus; and
8. Over areas of the skin which lacks normal sensation.

9. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical-conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
10. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
11. Powered muscle stimulators should be kept out of reach of children.
12. Powered muscle stimulators should be used only with the leads of the electrodes recommended for use by the manufacturer.

7.5 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:

1. Skin irritation and burns beneath the electrodes
2. Pain
3. Excessive redness (erythema)
4. Damage to natural tissue texture (crust, blister, burn, bruising, minor bleeding)
5. Swelling (edema)
6. Scarring
7. Treatment area infection

7.6 Applicator Cleaning Instructions Prior to Use

vTone Applicator, including the Applicator cable with connector is a single use only!

These cleaning instructions are for CLINICAL USE only.

The following processes are validated for the applicators 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 Ethanol 70% solution.

Cleaning Procedure

1. Thoroughly clean the applicator 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 applicator, the device must pass the following:

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

7.7 Pre-Treatment Recommendations

1. 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.
2. Review all indications.
3. Review all contraindications.
4. Complete the medical history and physical prior to treatment.
5. Sign the informed consent prior to the procedure.
6. Perform a test immediately prior to the procedure to visualize the area that is going to be treated.
7. The patient should use the restroom to urinate immediately prior to treatment.
8. 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.

7.8 Treatment Recommendations

1. Follow **Device Start-Up** from Section 5.
2. Always start with a low setting level to check the patient's tolerance to the treatment parameters. Increase the settings gradually to have muscle contraction reported by the patient.
3. Basic Parameters Consideration:

- Plenty of water-based ultrasound gel to be applied.
- Gel to be applied directly to the electrodes of the applicator.
- Inserting gel manually into the vaginal canal may be helpful in cases of moderate to severe atrophy.
- Intensity level to be set according to patient tolerance.
- Position the probe with electrodes facing the lateral sides of the vaginal canal.

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

- Press start button on the screen to initiate the pulses.

7.9 Treatment Schedule

1. The number of treatment sessions depends on the individual patient and is typically up to 6 sessions, every 1-3 weeks but can vary according to patient response.
2. Treatment time is 20-90 minutes according to patient tolerance and conditions.
3. Longer treatment time may reduce number of sessions but depends on tissue response and patient tolerance.
4. Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.

7.10 Post Treatment Recommendations

1. The Patient should avoid sexual intercourse or the use of mechanical vibrator within the treated area for 2 days.
2. 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 single-use vTone Applicator should be disposed after use.

Section 8: FormaV Treatment Information

8.1 Intended Use

The Empower System with FormaV Handpiece 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.

8.2 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.

8.3 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

8.4 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.

Cleaning Procedure

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

Leave it for complete drying.

Pre-Use Check:

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

2. Check to ensure proper cleaning and drying of the Handpiece.

Inspect all components of the Handpiece for visible damage.

FormaV tips are single use only.

8.5 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.

8.6 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.
9. Increase the settings gradually.
10. Apply multiple passes to maintain the desired temperature during 10-30min per zone.

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

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.

8.7 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.

8.8 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.
- The tip should be disposed.

Section 9: Morpheus8/Morpheus8Body Treatment Information

9.1 Sub-dermal Fractional Treatment

The Morpheus8 Handpieces are designed for delivering RF energy to the subdermal tissue in a fractional manner with the energy applied to <5% of the total coverage area. The energy is delivered to the skin through bipolar arrays of coated needles and results in localized heating and coagulation of the tissue that is in direct contact with the needle tip. Coagulation of the skin promotes tissue remodeling while untreated tissue between the pins promotes faster healing of the tissue. The Morpheus8 Handpiece is versatile fractional technology to treat different body areas. Depth settings above 4 mm are used for the treatment areas with subcutaneous fat thickness of 1 cm or higher.

The Morpheus8 Handpiece with Resurfacing Tip can be used for superficial skin resurfacing.

9.2 Indications for Use

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

9.3 Contraindications

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

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

9.4 Possible Adverse Side Effects

- Possible adverse effects include but are not limited by: discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, and burn), change of pigmentation (hyper- and hypo-pigmentation), and scarring.
- Erythema lasting not longer than 24h and edema for 1-3 weeks is a typical skin reaction to the 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.

9.5 Pre-treatment Recommendations

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

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Determine accurately the patients Fitzpatrick skin type.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- Advise the patient to avoid skin irritation or intentional skin tanning. Sunscreen is advisable when outdoors during daylight hours
- Asian patients and those with skin types IV-VI should be treated gradually by bleaching products 6 weeks prior treatment and stop at least 48 hours prior Morpheus8 treatment to minimize risk of post inflammatory hyper-pigmentation.
- Prophylactic antiviral therapy should be prescribed for patients with history of cold sores (Herpes Simplex) when treating around the mouth.

- Stop anticoagulants 7-10 days prior to treatment, if medically permitted.
- Clean the treatment area.
- Apply anesthesia:
- Topical anesthetic can be applied as needed prior to treatment.
- A few patients require nerve block for higher energy, limited to central face.
- Cooling methods, such as air cooling, sterile ice-packs, or sterile latex gloves filled with ice, help patient comfort during and after treatment.

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

The Morpheus8 tip with 1-7 mm depth arrives gamma-sterilized and is single use only! These tips SHOULD NOT be autoclaved or re-sterilized by any other technology!

When choose "Fractional" on Menu Screen, the connected Morpheus8 handpiece with tip is performing self -test. The pins go out and in, as the Treatment Screen opens. It is crucial to avoid touching the skin with the tip at this stage and leave the Handpiece in its cradle.

The operator shall wear surgical gloves (single use only)

9.6 Test Spots

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

For skin types I – III wait 10-15 minutes before assessing the skin response.

For skin types V-VI wait 2-3 days.

- **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.

9.7 Treatment Recommendations

1. Apply the necessary means of anesthesia. If topical, make sure that it is cleaned off the treatment area before treatment and the surface is dried with alcohol 70%.
2. Connect Handpiece to the System.
3. Follow Device Start-Up Procedure from System Operation section.
4. Set treatment parameters.
5. Always start with a low energy level, test patient comfort and observe the tissue's response before increasing the energy.
6. On sensitive, thin skin/tissue apply lower parameters with more passes, rather than higher parameters in one pass. It is also applicable to new users for any area.
7. Reduce ~20% energy when working on thin skin/tissue like neck, or on bony areas. Further ~20% reduction on thin skin over bone, like upper chest and back of hands.
8. Apply the Handpiece perpendicular to the treated area, with complete contact and firm pressure. To improve coupling between the treatment area and the tip stretch very soft tissue or pinch on bony areas.
9. Move Handpiece to the adjacent area and activate RF again.
10. 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.
11. Resurfacing Tip with fixed pins allows superficial skin resurfacing. This can be used as an addition to sub-dermal adipose tissue fractional remodeling or as a stand-alone treatment. When using the Resurfacing Tip, choose Resurfacing Depth on the screen. Resurfacing Depth energy range is 5 to 30.
12. The endpoints are minimal to substantial erythema and edema often accompanied by tingling heat sensation. Minor pin-point bleeding can be observed.

9.8 Treatment Schedule

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

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

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

9.9 Post-treatment Recommendations

- After each treatment session, the physician should advise the patient on proper care.
- Cool the treatment area 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 treatment area should be kept clean to avoid contamination or infection; any mechanical or thermal damage to the area must be avoided.
- Prophylactic antiviral therapy should be continued for patients with history of cold sores (Herpes Simplex) when treating around the mouth.
- Moisturizer may be applied 24-72 hours after each treatment and then should be applied regularly throughout the course of the treatment. Make-up may be applied only 24-72 hours after each treatment session. Generally, 24 hours after treatment, patients may use regular soaps, but not scrub soaps or exfoliates.
- The patient should use a high-factor sunscreen (at least 30 SPF) and protect the treated area from over-exposure to sunlight for at least one month after the treatment, starting 24-72 hours post treatment. Excessive tanning of any sort (sun exposure, tanning beds, and artificial tanning lotions) is not allowed in the treated areas during the entire course of the treatment.

- For Asian patients and skin types IV and V, a prescription or compounded bleaching regimen may be prescribed by the physician for 6-12 weeks, 2-3 times a week following the healing of treatment area (typically 7 days) to minimize risk of post inflammatory hyper-pigmentation. It should be stopped 48-72 hours before another Morpheus8 session.

Section 10: Tone Treatment Information

10.1 Indications for Use

Tone Applicator is used in EMS mode for:

- Prevention or retardation of disuse atrophy
- Maintaining or increasing range of motion
- Muscle re-education
- Relaxation of muscle spasms
- Increasing local blood circulation
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

And in TENS mode for:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-traumatic acute pain

10.2 Contraindications

- Pacemaker or internal defibrillator, or any other active electrical implant anywhere in the body.
- Permanent implant in the treated area such as metal plates and screws, silicone implants or an injected chemical substance, unless deep enough in the periostal plane.
- Current or history of skin cancer, or current condition of any other type of cancer, or premalignant moles.
- Severe concurrent conditions, such as cardiac disorders, epilepsy, uncontrolled hypertension, and liver or kidney diseases.
- Pregnancy and nursing.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.

- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies or use of anticoagulants in the last 10 days, according to physician's discretion.
- Any surgery in treated area within 6 months prior to treatment.
- Intra-dermal or superficial sub-dermal areas that have been injected with HA/collagen/fat injections or other augmentation methods with bio-material during last 6 months.
- Having received treatment with light, laser, RF, or other devices in the treated area within 3 months, or before complete healing.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient

10.3 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)
- Swelling (edema)
- Muscles spasm
- Treatment area infection

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

10.4 Applicator Cleaning Instructions Prior to Use

These cleaning instructions are for clinical use only.

The following processes validated for the Tone Applicators 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 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 Applicator units thoroughly with alcohol absorbed pad (not soaked) and repeat as necessary. Do not submerge in fluids. Leave it for complete drying.

Pre-use Check

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

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

10.5 Pre-Treatment Recommendations

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

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- The patient should discontinue any irritant topical agents for 2-3 days prior to treatment and if medically permitted, anticoagulants should be stopped 1-2 weeks prior treatment.

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

10.6 Treatment Recommendations

1. Follow **Device Start-Up** from Section 5.
2. Up to 4 Applicator units can be applied to the treatment area. Tight Applicator units around the treatment area with a belt to assume good coupling between applicators and skin.
3. Use intensity level to reach visible muscle contraction.
4. Basic Parameters Consideration:
   - Thin layer of ultrasound gel should be applied to the treated area
   - Power level to be set according to patient tolerance.

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

5. Set treatment time and activate the treatment

10.7 Post-Treatment Recommendations

 Slight erythema and edema are typical immediate response. However, when there is excessive tissue reaction, stop treatment. For excessive heat sensation, you may decrease the intensity.

- 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 Handpieces should be cleaned of the gel and disinfected by 70% alcohol.

10.8 Treatment Schedule

- The number of treatment sessions depends on the individual patient and is typically 3-4 sessions, every 1-2 weeks but can vary according to patient response.
- Treatment duration is 20 to 40 minutes according to patient tolerance and conditions.
- Treatment should be concluded when the results are satisfactory to the patient or according to the physician’s discretion.

Section 11: Aviva Treatment Information

11.1 Training Requirements

This manual is not intended to be a complete clinical guide to the use of the System. All users should be trained prior to operating the System with Aviva Handpiece.

11.2 Indications for Use

The System with Aviva Handpiece is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

11.3 Contraindications

- DO NOT USE in patients who have electronic implants such as cardiac pacemakers or internal defibrillators without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- The Handpiece should be used at least 1cm away from cochlear implants in the ear.
- Permanent implant in the treated area such as metal plates and screws, silicone implants or an injected chemical substance, unless deep enough in the periosteal plane.
- Current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances, epilepsy, uncontrolled hypertension, and liver or kidney diseases.
- Pregnancy and nursing.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.

- History of skin disorders, keloids, abnormal wound healing.
- History of bleeding coagulopathies.
- Any surgical procedure in the treatment area within the last 3 months or before complete healing.
- Any therapies or medications which may interfere with treatment.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

11.4 Possible Adverse Effects

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

Possible adverse effects include, but are not limited by: discomfort or pain, excessive tissue redness (erythema) and/or swelling (edema), ecchymosis, burns, damage to natural skin/tissue texture (crust, blister, and burn), change of pigmentation (hyper- and hypo-pigmentation), scarring, temporary injury to nerves (neuropraxia) where nerve branches are superficial, and very slight risk of infection.

11.5 Instruction Prior to Use

The Gamma sterilized Handpiece are sent sterile by gamma-rays in double sterilization bags. Therefore, the gamma sterilized handpieces **SHOULD NOT** be autoclaved, as the thermal fuse of the hand piece is destroyed and the handpieces are no longer functional.

There are a few signs to recognize the gamma-sterilized handpieces:

1. There is a white sticker on the large box, stating "Gamma Sterilized" and on it is a small red sticker. This sticker is not on the smaller individual boxes.
2. The hand pieces are packed in double sterilization bags inside a small cardboard box, two in each box.
3. There is a silver sticker on each large and small box carrying the sign “Sterile R” that stands for Sterilization by Radiation.
4. The color of the handpiece is green (unlike the white color of the autoclavable handpiece).
5. The internal electrode is covered by a transparent sleeve (unlike a white sleeve of the autoclavable handpiece).

 Make sure that Handpiece is dry and intact before use.

Do not use the Handpiece if it is damaged.

11.6 Pre-Treatment Recommendations

- Make sure that the Handpiece is intact and sterile.

There are a few signs to recognize the gamma-sterilized hand pieces as specified in items 1-5 above.

During the patient's first visit treating attendant should:

- Exclude from treatment anyone who may be affected by the listed contraindications.
- Instruct the patient about the safety warnings.
- Have the patient sign an informed consent form.
- Make sure that the hand-pieces are intact, sterile and dry.

11.7 Treatment Recommendations

- The device can be used in a certified operating room or in a clean procedure room in an office setting, using a sterile technique.
- Apply sterile water–based gel, such as ultrasound gel to the skin/tissue surface to ensure good contact of external electrode.
- Select treatment parameters.
- Insert cannula to the intended tissue and ensure good contact of return electrode with treatment area surface
- Enter Ready mode, press the footswitch and apply the RF energy.
- Release the footswitch after treatment time is elapsed or desired end point is reached.
- Move to the next site or terminate the treatment.

11.8 Post-Treatment Recommendations

- Post treatment recommendations should be provided by doctor.
- The Handpiece should be discarded

Section 12: Troubleshooting

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

12.1 Description of Faults with All Handpiece

Problem	Description and Checks
System did not turn on	▪ Check power cord connection. ▪ Check that On/Off switch on front panel is on. ▪ Check fuses on back panel of the System. ▪ Call Technical Service if problem persists.
System shuts down by itself	▪ Check power cord connection. ▪ Check fuses on back panel of the System. ▪ Call Technical Service if problem persists.
Checksum	▪ The software was not loaded properly from software plug. ▪ Check the plug connection and reboot the System. ▪ Call Technical Service if the problem persists.
Fault H8002 - Handpiece is not connected	▪ Check the connection of the Handpiece. ▪ Replace the Handpiece. ▪ Call Technical Service if the problem persists.
Fault H8005, H800F, H8010 – System Memory Fault	Call Technical Service if the problem persists.
Fault H800E- System Incompatible Software Version	Call Technical Service if the problem persists.
Fault H800F- System Memory Fault	Call Technical Service if the problem persists.
Faults H8003, H8006, H8007 - RF Related Faults	Call Technical Service if the problem persists.

Section 13: 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 – 35°C [59 – 95°F]	
Relative Humidity	30% to 80%, non-condensing	
Atmospheric Pressure	90 - 110kPa	
Warm-up Time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the device to reach room temperature before use.	
Transport and Storage		
Ambient Temperature Range	-20 – 65°C [-4 – 149°F]	
Relative Humidity	0% to 80%, non-condensing	
Atmospheric Pressure	50 to 110kPa	
Dimensions		
System	36.5 cm W x 39.3 cm D x 111.0 cm H	[14.4'' W x 15.5'' D x 43.7'' H]
Handpiece Cable	280cm L	[100`` L]
Weight		
System	15.000kg	[33.069lb]
FormaV Applicator	0.22 Kg	[0.5 lbs.]
vTone Applicator	0.11kg	[0.25lb]
Morpheus8V Applicator	0.400kg	[0.243lb]
Morpheus8 Applicator	0.400kg	[0.243lb]
Tone Applicator	0.29 Kg	[0.64 lbs.]
Aviva Handpiece	0.2 Kg	[0.4lb]
MorpheusV Output Parameters		
Maximum Output Power	65[W]	

Frequency	1MHz
Crest Factor (Rated Load)	1.4± 2%
vTone Output Parameters	
Intensity (output voltage)	Up to 50 intensity level (=54 V_{peak})
Waveform	Bi-phasic
Pulse shape	Rectangular
Pulse width	50-400 [µsec]
FormaV Output Parameters	
Maximum Output Power	40 [energy level]
Frequency	1MHz
Morpheus8 Output Parameters	
Maximum Output Power	65[W]
Frequency	1MHz
Crest Factor (Rated Load)	1.4± 2%
Tone Output Parameters	
Intensity (output voltage)	Up to 50 energy level (=54 Vpeak)
Waveform	Bi-phasic
Pulse shape	Rectangular
Pulse width	20-400 [usec]
Frequency	3-200[Hz]
Aviva Output Parameters	
Maximal RF Power	16 W
Internal Cut-Off	50-65°C
Treatment Time	15-120 sec
RF Frequency	1 MHz
Tissue impedance	50 -300 Ohm

13.1 Output Power Curves

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

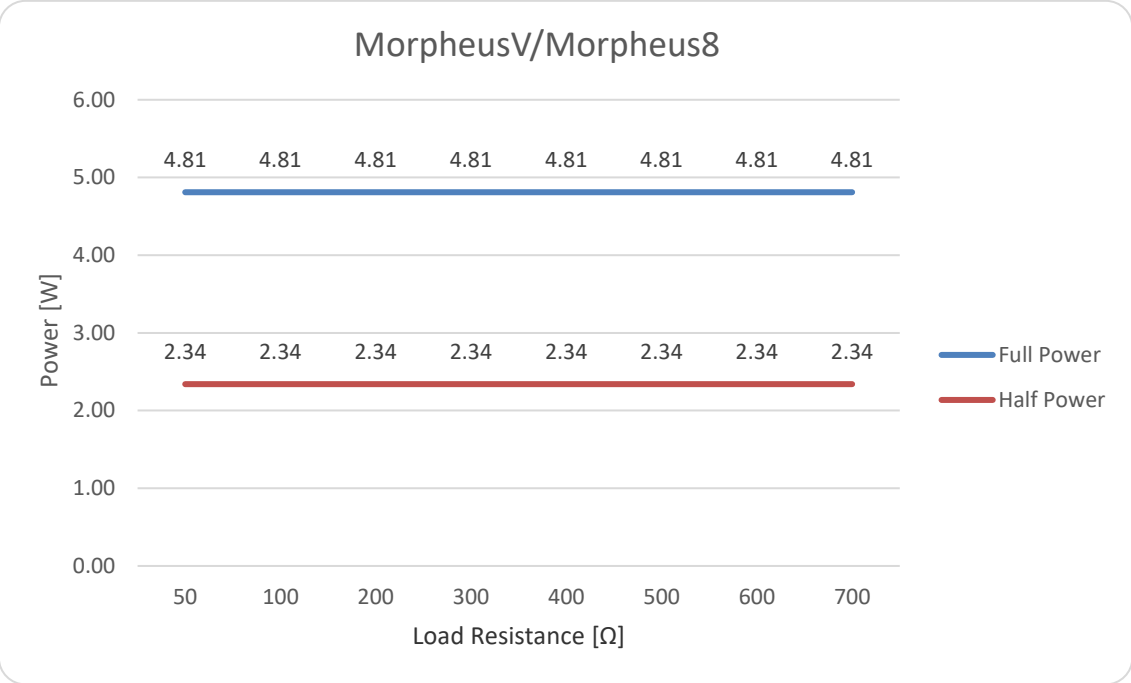


Figure 11-1: Morpheus8V/Morpheus8 Output Power versus Impedance

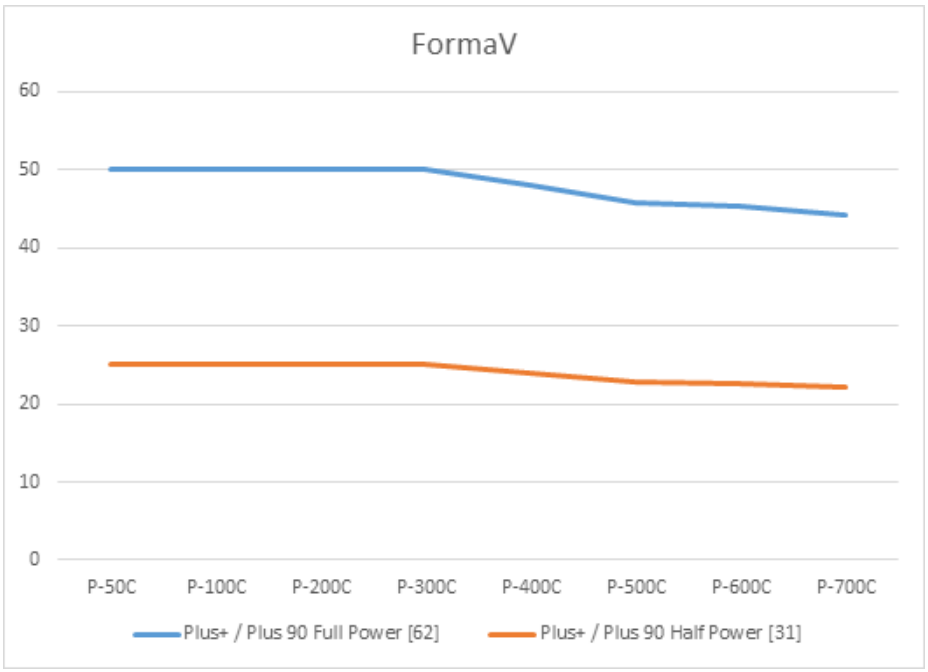


Figure 11-2: FormaV Output Power Versus Impedance

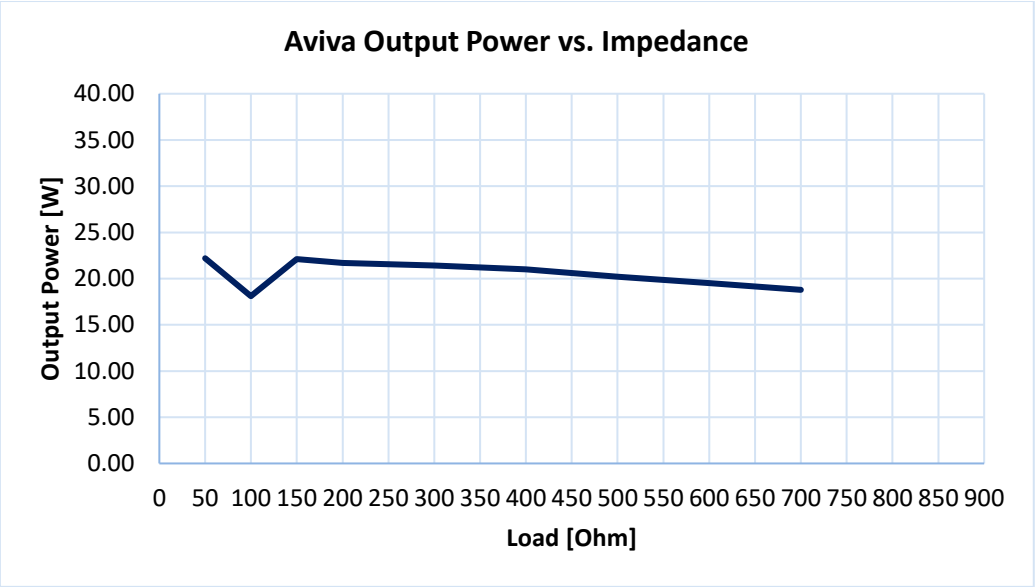


Figure 11-3: Aviva Output Power Versus Impedance

The following curves depict Peak Voltage vs. Power Settings.

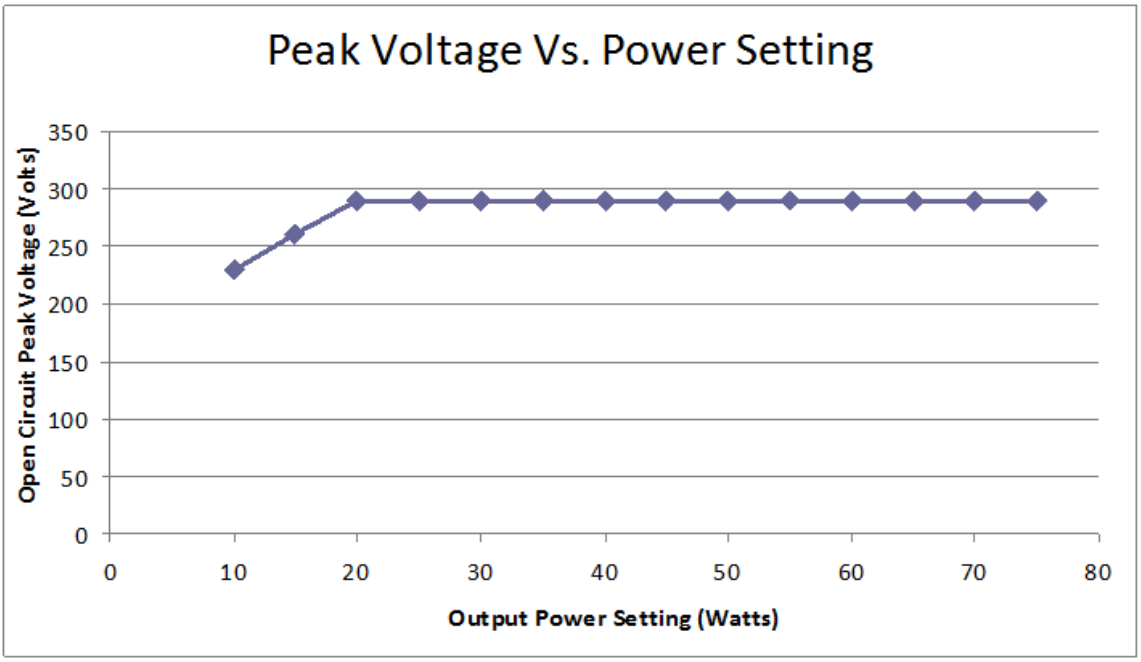


Figure 11-4: Output Power Versus Impedance

13.2 EMC Safety

The device has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device

generates uses and can radiate radio frequency energy. If not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that the interference to other devices, which can be determined by turning the device off and on, is caused by this instrument.

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

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect the device into an outlet on a circuit different from that which was previously used.
- Consult InMode service personnel for help.
- Interference to the device may be caused by portable and mobile RF communication equipment. In case of an interruption, beware of such a device in the vicinity.

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

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

Table from IEC60601-1-2

Summary of Test Results

Test	Standard	Class/ Severity level	Test result
Emission (IEC 60601-1-2 sec. 7 & IEC 60601-2-10 sec. 202.6.1)			
Conducted emission Freq. range:150 kHz - 30 MHz	sec. 7.1 & CISPR 11	Group 1 Class A on 230, 120 & 100 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	sec. 7.1 & CISPR 11	Group 1 Class A	Complies
Harmonic current emission test	sec. 7.2.1 & IEC 61000-3-2	AC mains	Exempt
Voltage changes, Voltage fluctuations and Flicker test	sec. 7.2.2 & IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 8 & IEC 60601-2-10 sec. 202.6.2)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	3.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on AC mains, Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1.0 kV DM / ±2.0 kV CM on AC mains; Tr/Th – 1.2/50 (8/20) μs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0 6.0 V_{RMS}, 6.0 V_{RMS} (ISM Band) on AC mains & HP cables; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	30 A/m @ 50 Hz & 60 Hz	Complies
Immunity from Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 & 100 VAC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies