CONTOURA

Operator Manual

Contoura System

Version: DO608402A

INMODE

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DO608402A

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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 InModeRF Platform with BodyFX, MiniFX and Plus Handpieces is marketed as the Contoura System which employs Radio-frequency (RF) technologies for various aesthetic applications.

The Contoura System with the BodyFX/MiniFX and Plus Handpieces is a medical aesthetic device combining mechanical vacuum skin massaging and non-thermal RF energy for the treatment of selected medical conditions such as relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

RF energy does not cause any thermal damage to the treated skin. The System provides individual adjustment of vacuum pulse parameters and non-thermal RF power to achieve maximum efficiency, safety and comfort for each patient.

The System provides enhanced safety while minimizing possible side effects by monitoring RF parameters.

1.3 Conventions Used in the Manual

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

WARNING! This information is extremely important!

ATTENTION! Consult Accompanying Document.

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

1.4 Explanation of the Symbols used on the System

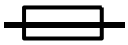
Symbol	Description
	CSA marking (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	Type B Equipment.
	HF Isolated Patient Circuit
	Follow the operating instructions
	Federal (US) law restricts this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

Table 01-1: Device Symbols

Section 2: Safety

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

The system is designed for safe and reliable treatment when used in accordance with proper operation and maintenance procedures. Only trained, qualified practitioners can use the system 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.

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

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 Contoura 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 12kg (26.5 lb.) and may cause injury if proper care is not used when moving it.
- Provide as much distance as possible between the System, RF Handpiece and other electronic equipment as the activated RF generator may cause interference between them.

2.5 Fire Hazards

- Materials conducting RF energy may cause temperature rise of the absorbing material. Do not use the System in the presence of explosive or flammable materials conductive to RF.
- Do not use flammable substances when preparing the skin for treatment. Be especially careful with the use of oxygen.
- Keep drapes and towels moist to prevent them from igniting and burning. Use nonflammable prepping solutions.

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

2.6 Safety Features of the System

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

- The System has unique password to avoid device operation by non-authorized personnel.
- The power electronics cannot be activated unless the applicator and Footswitch have been connected to the System.
- An audible tone indicates energy activation.
- During activation, the System performs a self-test of the hardware.
- Hardware is tested every 10ms to ensure proper operation of electrical circuit.
- Tissue impedance monitoring prevents accidental energy emission to the patient.
- Skin surface is monitored during the treatment. RF energy delivery is terminated when skin temperature accidentally reaches the Cut-Off level.
- Vacuum level monitoring. RF is disabled when vacuum is below the predetermined level.
- The System starts at a low setting.

2.7 Safe use of the Active Accessories

- Examine the connection of the Handpiece through the connector to the System before using. Ensure that the accessory functions as intended. Improper connection may result in arcs and sparks, accessory malfunction, or unintended treatment effects.
- Do not wrap the Handpiece cords around metal objects. It may induce current that could lead to electrical shocks, fire or injury to the patient or personnel.
- When using the RF applicators, ensure that both electrodes are in full contact with the skin.
- Bad coupling of both electrodes with the skin results in a specific warning sound, a message on the screen, and disabling of RF

Do not connect a wet accessory to the System.

Do not immerse the applicator under water at any time.

2.8 Warnings

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

Only Handpieces manufactured or approved by InMode Ltd. should be used with Contoura 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 Cotoura System in the same room with any of these substances or gases, prevent their accumulation or pooling within the area where Contoura procedures are performed.

The operation of the Contoura 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.

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 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 device and handpieces:

Figure 2-1: System Identification Label

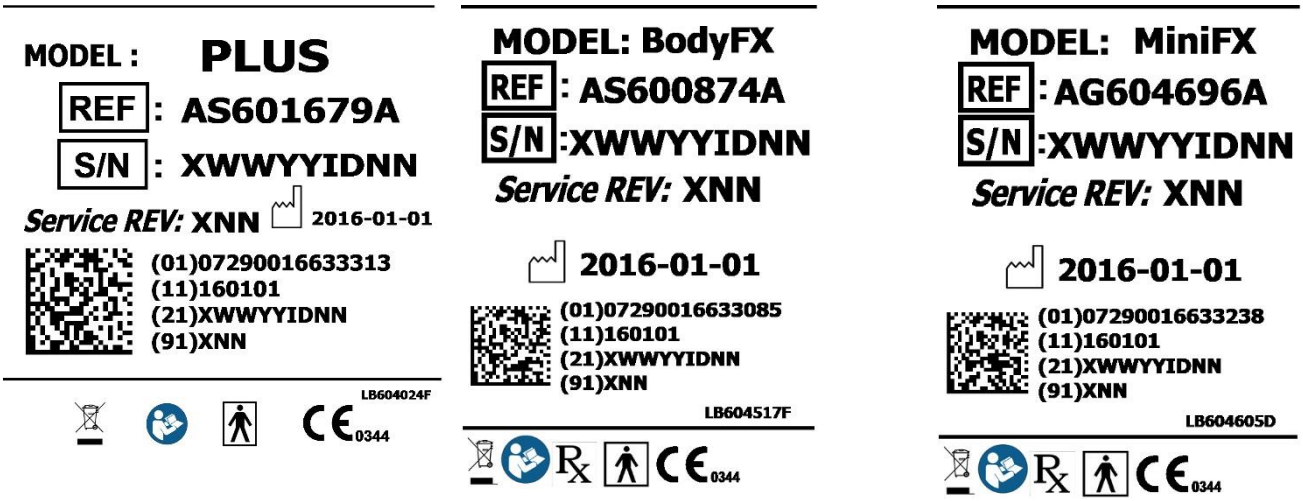


Figure 2-2: All Handpiece Identification Label

2.10 Equipment Classification

- The following is a list of the different equipment used and their classifications.
- Electric shock protection: Class I, Defibrillation-proof Type BF.
- Protection against ingress of liquids: Ordinary equipment.
- Not suitable for use in presence of flammable substance.
- Power receptacle must include protective earth and must be checked before connecting the System.
- The Contoura Systems is classified as Class II device defined by the Medical Device Directive (93/42/EEC).

Section 3: System Installation

3.1 Electrical Requirements

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

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

Proper grounding is essential for safe operation.

3.2 Environmental Requirements

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

3.3 Equipment List

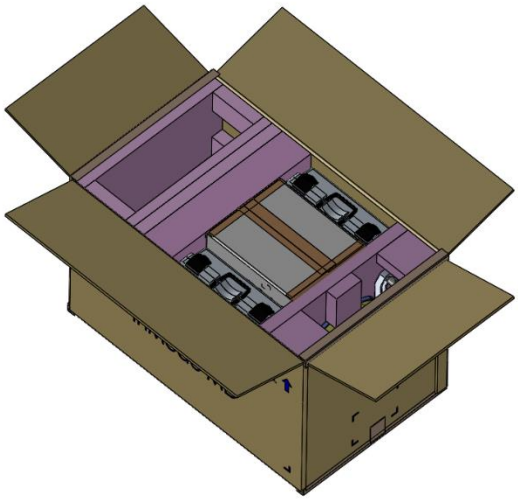
The System includes the following:

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

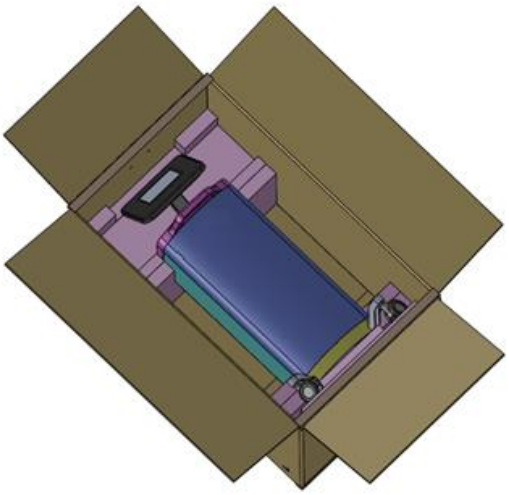
3.4 Unpacking

In order to unpack the device:

1. Remove the paper strip and open the box.



2. Remove accessories and foams around the device.



3. Take device out of the box using top and bottom handles.

3.5 Installation

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

1. Check the System and all its components for damage.

2. Connect cradle to the device.
3. Connect Handpiece to the connector and place into the cradle.
4. Connect the Footswitch.
5. Connect the power cord to the System inlet.
6. Plug the System Power Cord into an appropriate electrical outlet.

3.6 Moving the System

1. Turn the System off.
2. Disconnect the Power Cord.
3. Disconnect the Handpieces.
4. Disconnect the Footswitch.
5. Release the wheel brakes.
6. Slowly push or pull the System using the handle.

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

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

Always use the handles when moving the System.

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

3.7 System Disposal

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

Section 4: Device Description

4.1 Rear Panel

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

4.2 Front Panel and Operator Control Panel

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

Figure 4-1: Progress Screen

On the front panel there is a black On/Off switch on the left, and handpiece connector on the right.

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 Handpiece is not connected to its connector on the front panel.

4.3 Software Screens

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

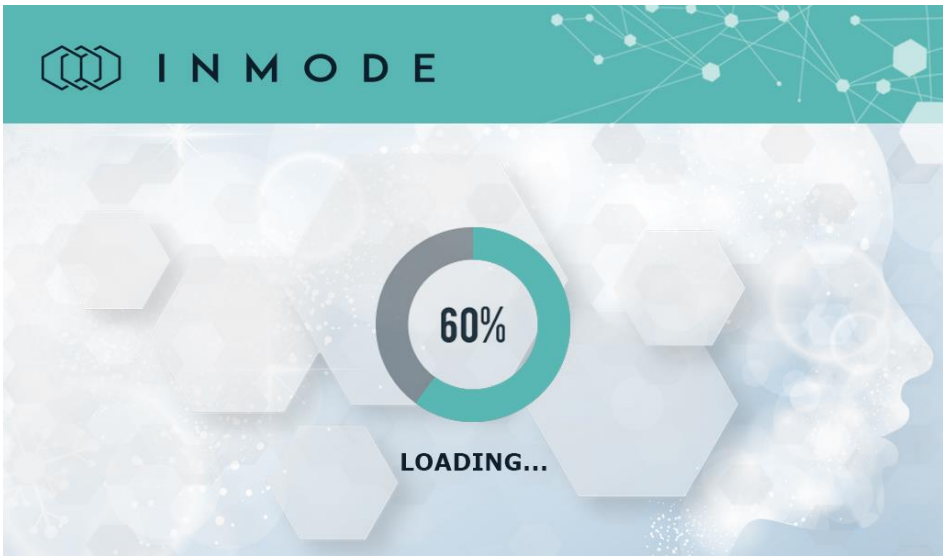


Figure 4-2: Progress Screen

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

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

Figure 4-3: Login Screen

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

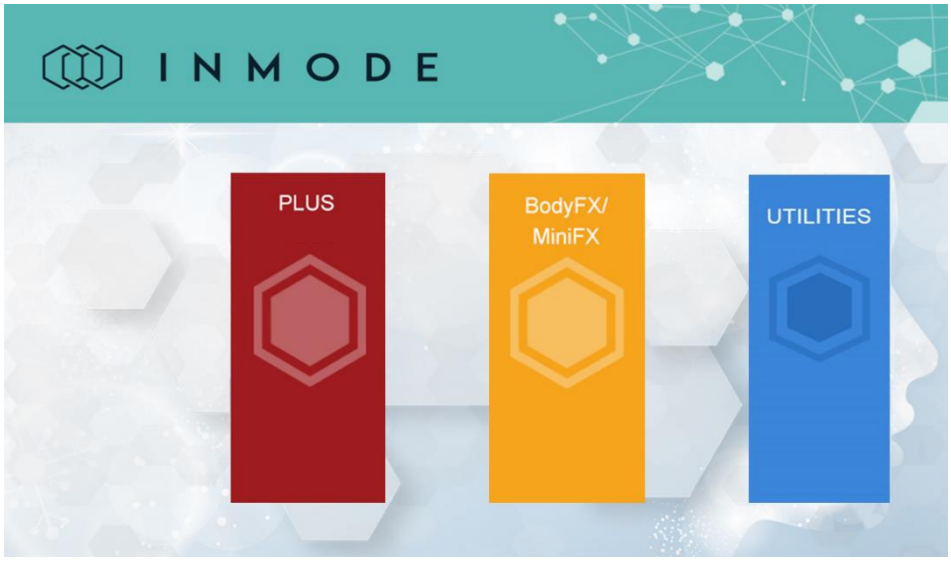


Figure 4-4: Menu Screen

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

Figure 4-5: 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.

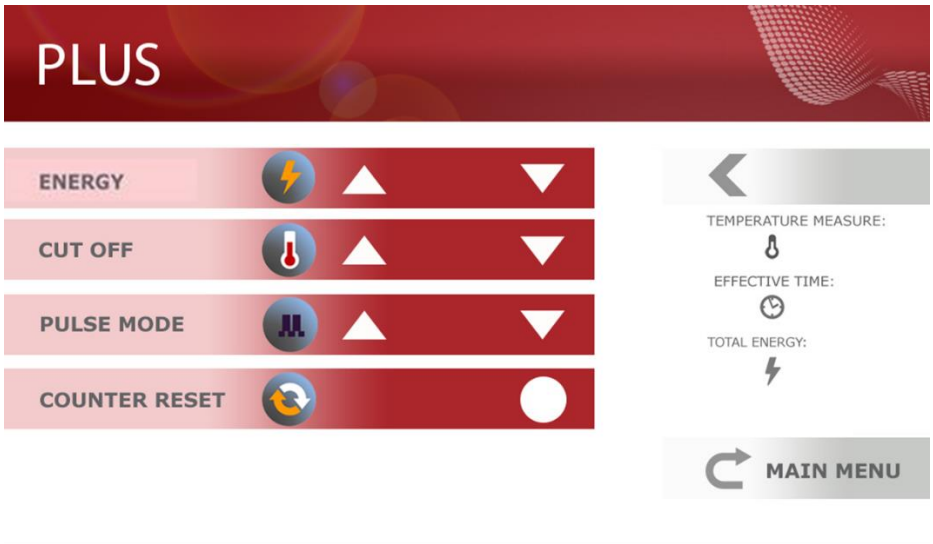


Figure 4-6: Plus Treatment Screen

Selection Frame	The frame selects parameters that can be changed by function keys.
Energy	Delivered energy is changed from level 20 to 62 energy levels and the System starts up at the minimal energy setting.
Cut-Off	Cut-off temperature settings are changed in the range of 35-43ºC. When measured skin surface temperature reaches the pre-set limit the RF energy is cut off.
Pulse Mode	Allows selecting between single RF pulses of 30sec in the Single Mode and continuous RF in Repeat Mode, as long as the foot switch is pressed.
Repetition	Select between single pulse delivery at Footswitch pressing and autorepeat mode with predetermined pulse repletion rate
Counter Reset	The Counter 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^{o}C below the cut-off temperature.
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 4-7: BodyFX/MiniFX Treatment Screen

The BodyFx/MiniFx Treatment Screen contains:

Screen Name	The Screen name BodyFX or MiniFX is determined by the connected Handpiece.
Selection Frame	The frame selects the parameters that can be changed by the function keys.
Power	RF power is changed within the limits allowed for the connected Handpiece. Power level settings are changed from 10 to 50W for BodyFX and from 10 to 25W for MiniFX. The System starts up at minimal power level setting.
Cut-Off	This indicator shows the Cut-Off temperature, which is adjustable from 35 to 43oC. This indicates measured temperature at which the RF delivery is stopped.
Pulse	This indicator shows the time period during which vacuum is applied and RF energy is delivered, which is adjustable from 2 to 7sec for BodyFX and from 1-5sec for MiniFX.
Counter Reset	The treatment time can be reset.
Temperature Control	This indicator shows on line the skin surface temperature, with a maximal Temperature of 43oC.
Vacuum Level	This indicator shows on line the negative pressure applied by the vacuum.
Total Time	This indicator shows the total time of RF delivery.
Main Menu	Return to the Main Menu to select another Applicator and change the Applicator if needed
System Mode	The System has three treatment modes. Standby, Ready and Active.

	Standby mode allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode. In **Ready mode**, the System is waiting for a signal from the foot switch to activate the energy. Any attempt to change the treatment settings switches the System to Standby mode. When the signal from the footswitch is indicated, the System switches to **Active mode**. Any attempt to change the treatment settings switches the System to Standby mode.

4.4 Sound Indicator

- A periodic tone indicates that RF is delivered.
- A warning sound tone indicates Bad Coupling.

4.5 Cut-Off Temperature Control

The cut-off temperature up to an upper limit of temperature of 43°C is constantly maintained for Plus, and BodyFX/MiniFX handpieces. 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. The temperature is monitored by a temperature sensor in the Handpiece and serves as a safety feature.

4.6 Handpieces

Plus Handpiece comprises Applicator, Cable, Connector and an integral Temperature Sensor

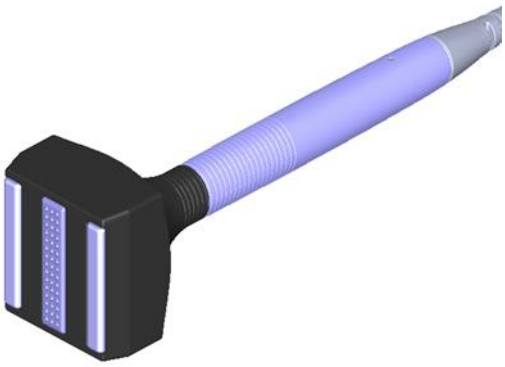


Figure 4-8: Plus Handpiece

Tip	Is a part of the Handpiece, comprising RF Electrodes and a Temperature Sensor.
Handle	Is made of metal and has ergonomic design for easy treatment with high visibility of the treated area
Cable	Has a length of 250cm (100’’).
Connector	It is connected to the rear panel of the System.

The BodyFX/MiniFX Handpiece comprises Vacuum Chamber, 2 RF Electrodes, Temperature Sensor, 8-character Screen, Handle, Cable and Connector.

Figure 4-9: BodyFX Handpiece

Figure 4-10: MiniFX Handpiece

Handle	The Handpiece Handle is made from plastic and has ergonomic design for easy treatment with high visibility of the treated area
Vacuum Chamber	Applied to the skin surface and shape the skin for optimal heating.
RF Electrodes	Located in the Vacuum Chamber and delivers RF energy to the treated tissue.
Screen	Shows the measured temperature.
Cable	Has a length of 250cm (100’’).
Connector	The Connector is located on the Rear Panel.
Temperature Screen	Located in the Vacuum Chamber for skin temperature measurement.

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 Handpieces 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 for RF applicators.
11. Apply Handpiece to the treated area, ensuring a full contact with pressure.

5.2 System Shutdown

- To shut down the System, turn the On-Off Switch located at the front to Off.
- Turn the Main Power Switch to Off at the end of the day.

Section 6: Plus Treatment Information

6.1 Indications for Use

The Plus hand Handpiece is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

6.2 Contraindications

- Pacemaker or internal defibrillator, or any other metallic or electronic implant anywhere in the body. The Handpiece should be used at least 1cm away from cochlear implants in the ear.
- Permanent implant in the treated area such as metal plates and screws, silicone implants or an injected chemical substance, unless deep enough in the periosteal plane.
- Intra-dermal or superficial sub-dermal areas that have been injected with HA/collagen/fat injections or other augmentation methods with bio-material during last 6 months.
- Current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances, epilepsy, uncontrolled hypertension, and liver or kidney diseases.
- Pregnancy and nursing.
- Impaired immune System due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.

- History of bleeding coagulopathies.
- Having received treatment with light, laser, RF, or other devices in the treated area within 3 months, or before complete healing.
- Any surgical procedure in the treatment area within the last 3 months or before complete healing.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient unsafe for the patient.

6.3 Possible Adverse Side Effects

Possible side effects include but are not limited by: discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, burn), change of pigmentation (hyper- and hypo-pigmentation), scarring.

Erythema and edema lasting not longer than 24h is typical skin reaction to the treatment.

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

6.4 Handpiece Cleaning Instructions Prior to Use

These cleaning instructions are for clinical use only.

The following processes are validated for the Plus 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.
2. Leave it for complete drying.

Pre-Use Check:

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

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

6.5 Pre-treatment Recommendations

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

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

- 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.
- Clean the face, remove crèmes and makeup, and dry the skin.
- Photograph the patient.
- Mark the treatment area.
- Clean the Handpieces parts that come in contact with the skin with 70% alcohol.

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

6.6 Treatment Recommendations

1. Ensure that skin is clean and dry.
2. Follow the Device Start-Up procedure from Section 5.
3. Set the treatment parameters. Suggested body treatment parameters for Plus are shown in the table below:

Body Treatment Zone	RF Energy Level	Cut-Off Temperature [°C]	Gel
Resistant skin in normal size zone of ~15x15 cm e.g. abdomen, buttocks	35-45	As high as tolerable starting at 40°C	Thin layer 2-3mm
Resistant skin in small size zone e.g. navel area	30-40	As high as tolerable starting at 40°C	Thin layer 2-3mm
Sensitive skin in normal size zone of ~15x15 cm e.g. Inner thigh	30-35	As high as tolerable starting at 40°C	Thin layer 2-3mm
Sensitive skin in small size zone e.g. Arms, knees an	25-35	As high as tolerable starting at 40°C	Thick layer 3-4mm

4. Any combination of treatment parameters should be according to skin response and patient tolerance.

5. Air condition directed at the patient treated area may reduce the skin surface temperature in 1-2°C, and cut-off temperature should be reduced accordingly.

6. Always make a test-spot, starting with low settings and observe the skin's reaction and patient comfort before increasing the RF energy.

7. Treat body areas by zones with size of about 2 hand palms (~15x15cm), such as half of abdominal area, flank, outer thigh, inner thigh, buttocks. When treating smaller zones as upper arm, reduce energy setting to avoid patient discomfort.

8. Water-based gel should be applied to the treated zone, one at a time to couple the RF and to enable a smooth movement on the skin. Adjacent zone could also be covered with gel that can serve as a gel reservoir for replenishing gel in the treatment area with minimal delay.

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

9. Assume full contact of Handpiece with the skin with a slight pressure.

10. Use your free hand to flatten and stretch treatment area if needed for complete contact and smooth movement.

11. Press the footswitch and initiate the RF energy.

12. Move the Handpiece in circular movements or back and forth with gentle pressure over the full treated zone to reach uniform skin heating. Movement should be constant and its amplitude should be at least double of Handpiece spot size to avoid hot spots.

13. Continue to treat the area in this fashion. Always start with a low setting level to check the patient's tolerance to the treatment parameters and increase the settings gradually.

14. After reaching the cut-of temperature apply multiple passes to maintain the desired temperature during 5-7min/zone on the face and 10min/zone on the body. If cut-off temperature is <41^{o}C, maintain the temperature for >5 or >10min per zone.

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

16. After treating the zone, move to the next zone.

17. Slight erythema and edema are typical immediate response. However, when there is excessive skin response (erythema and edema), stop treatment and move to the next zone. For excessive heat sensation, you may increase the movement speed, reduce the RF power and lastly, reduce the cut-off temperature. If this does not help, move to the next zone.

The skin should be observed for excessive erythema or edema. If observed, stop the treatment and move to the next treatment zone.

6.7 Treatment Schedule

- The number of treatment sessions depends on the individual patient and is typically 6 weekly sessions, but can vary according to patient response.
- Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.
- One session every 1-3 months, or as needed, may maintain treatment results.

6.8 Post-treatment Recommendations

- Skin cooling is **not** recommended.
- Patient should avoid very hot water for 2 days after the treatment.
- Patient should avoid scrubbing, pinching and etc. of the treated area.
- Moisturizer and makeup may be applied to the skin surface immediately post treatment.
- After each treatment session, the patient should be advised to contact the physician if there is any indication of infection, excessive swelling, redness, pain, or any other unusual or untoward symptom.
- The Handpiece should be cleaned from the gel and disinfected by 70% alcohol.

Section 7: BodyFX/MiniFX Treatment Information

7.1 Indications for Use

The BodyFX/MiniFX Handpieces are intended for the treatment of the following medical conditions using RF combined with massage: Relief of minor muscle aches and pains, relief of muscle spasms, temporary improvement of blood circulation, temporary reduction in the appearance of cellulite

7.2 Contraindications

- Pacemaker or internal defibrillator, or any other metallic or electronic 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 peri-ostal plane.
- Intra-dermal or superficial sub-dermal areas that have been injected with HA/collagen/fat injections or other augmentation methods with bio-material during last 6 months.
- Current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Severe concurrent conditions, such as cardiac disorders, sensory disturbances, epilepsy, uncontrolled hypertension, and liver or kidney diseases.
- Pregnancy and nursing.
- Impaired immune System due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.

- History of bleeding coagulopathies.
- Any surgery in treated area within 3 months prior to treatment.
- 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.

7.3 Possible Adverse Effects

Possible side effects include but are not limited by: discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, and burn), change of pigmentation (hyper- and hypo-pigmentation), scarring, and vacuum bruising.

Erythema and edema lasting not longer than 24h is typical skin reaction to the treatment.

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

7.4 Handpiece Cleaning Instructions Prior to Use

These cleaning instructions are for clinical use only.

The following processes are validated for the BodyFX/MiniFX 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.

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.
2. Leave it for complete drying.

Pre-Use Check:

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

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

7.5 Pre-Treatment Recommendations

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

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- 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.
- Photograph the patient.
- Mark the treatment area.
- Clean the Handpiece with alcohol 70% or other disinfectant. Use alcohol-soaked cotton buds to clean inside the Handpiece cavity.

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

7.6 Treatment Recommendations

1. Ensure that skin is clean and dry.
2. No gel allowed!
3. Follow **the Device Start-Up Procedure** from Section 5.
4. Set treatment parameters. Suggested parameters are shown in the table here:

Handpiece	Treatment Approach	RF Power [W]	Pulse Width [Sec]	Cut-Off Skin Temperature [ºC]
BodyFX	Sensitive skin	30-40	2	As high as tolerable Starting at 40°C
BodyFX	Normal skin	35-45	3	As high as tolerable Starting at 40°C
BodyFX	Resistant skin	40-50	4	As high as tolerable Starting at 40°C
MiniFX	Sensitive area	10	1-3	As high as tolerable Starting at 40°C
MiniFX	Normal area	15-20	1-3	As high as tolerable Starting at 40°C
MiniFX	Resistant area	20-25	1-3	As high as tolerable Starting at 40°C

Any combination of treatment parameters should be according to skin response and patient tolerance.

5. Always start with low settings and observe the skin's reaction and patient comfort before increasing the RF power, the temperature or pulse width.
6. Reduce the RF Power on thin fat areas and on small areas. When using MiniFX restrict RF Power to 10-20W, occasionally to 25W.
7. Reduce the Pulse Width if bruises appear and with MiniFX restrict Pulse width to 1-3 seconds.

8. Divide treatment area to zones of about the size of a large hand palm, 4-8 foot-prints of the vacuum chamber (full abdomen = 4 treatment zones), and about half for MiniFX. Mark the treatment area and zones. The smaller the zone and the thinner the fat, the lower the RF Power.
9. Assume a full contact of Handpiece with skin with a slight pressure to enable vacuum.
10. Use your free hand to flatten and stretch treatment area.
11. Press the Footswitch and initiate the RF energy and suction, and dwell on the site for preset pulse duration.
12. Move to adjacent site with no overlap from previous site and apply another pulse.
13. Apply multiple passes to the treated zone. When skin temperature is <41°C, compensate with 1-2 more minutes of treatment.
14. Excessive heat sensation after a few passes may call for a faster movement, reduced pulse width, reduced RF power level, and last, reduced cut-off temperature, in this sequence.
15. Move to the next zone, usually left or right side, and perform the same steps.
16. Some patients, who cannot tolerate the heat for full 10min, may have the treatment divided to 5+5min, allowing the skin to cool down. One zone is then treated for 5min and the other zone (left or right) is treated for 5 minutes. After treating the second zone for 5min return to the first zone and complete additional 5min. Repeat treatment of the second zone. Each zone is treated for a total time of 10min. In odd areas like navel area, pause for 5min between repeated treatments.
17. After treating the zone, move to the next zone.

7.7 Treatment Schedule

- The number of treatment sessions depends on the individual patient and typically varies between 6-8 sessions, once a week. Some patients may get satisfactory results after 4 sessions.
- The treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.
- One session every 3-6 months, or as needed, may maintain treatment results.

7.8 Post-Treatment Recommendations

- Erythema and occasionally purpura is a common response and will subside naturally within a few days.
- Patient should avoid very hot water for 2 days after the treatment.
- Patient should avoid scrubbing, pinching and etc. of the treated area.
- Moisturizer can be applied to the skin surface.
- 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.

Section 8: System Maintenance

8.1 Maintenance & Frequency

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

8.2 Before and after each treatment

Wipe the device with a damp soft cloth. The Handpiece elements that are in contact with the skin should be disinfected with 70% alcohol between patients, as described in detail for each handpiece in “Handpiece Cleaning Instruction Prior to Use”. For applications that require gel (Plus), remove the gel before cleaning.

8.3 Once a Week

Clean the System at least once a week. Turn the System off and wipe all surfaces. Be careful not to spill any liquids on the System.

8.4 Once a Year

By authorized service personnel only:

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

Section 9: Troubleshooting

The Contoura 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.

9.1 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 10: System Specifications

Input Power		
Main Line Frequency (nominal)	50-60Hz	
Input Voltage (nominal)	100-240VAC	
Input Current (rms)	2A	
Operating Parameters		
Ambient Temperature Range	15 – 30°C [59 – 86°F]	
Relative Humidity	30% to 80%, non-condensing	
Atmospheric Pressure	90 - 110kPa	
Warm-up Time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the device to reach room temperature before use.	
Transport and Storage		
Ambient Temperature Range	-20 – 65°C [-4 – 14°F]	
Relative Humidity	0% to 80%, non-condensing	
Atmospheric Pressure	50 to 110kPa	
Dimensions		
System	46cm W x 46cm D x 100cm H	[18.2'' W x 18.2'' D x 40'' H]
Handpiece Cable	280cm L	[100`` L]
Weight		
System	15.000kg	[33.069lb]
Plus Applicator	0.170Kg	[0.375 lb]
BodyFX Applicator	0.900Kg	[0.375 lb]
MiniFX Applicator	0.750Kg	[1.653 lb]
Plus Output Parameters		
RF Energy	20 – 62 energy levels	
Frequency	1MHz	
BodyFX Output Parameters		
RF Power	10 - 50 W	

Frequency	1 MHz
Vacuum	Automatically controlled
MiniFX Output Parameters	
RF Power	10 - 25 W
Frequency	1 MHz
Vacuum	Automatically controlled

10.1 Output Power Curves

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

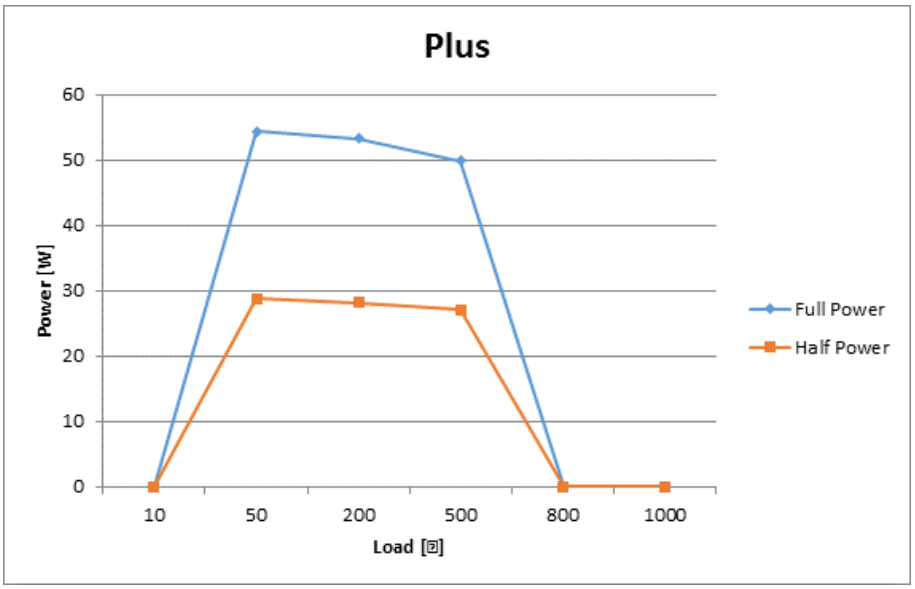


Figure 10-1: Plus Output Power versus Impedance

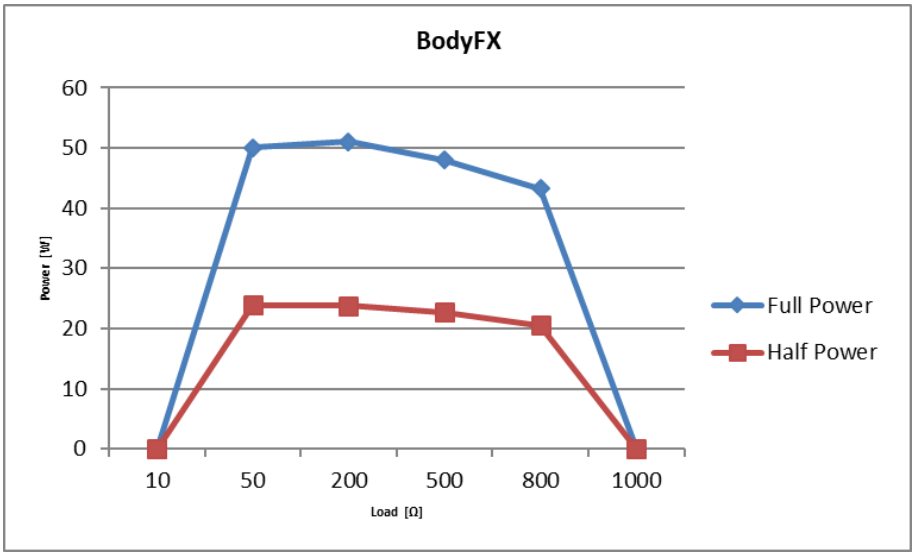


Figure 010-2: BodyFX Output Power versus Impedance

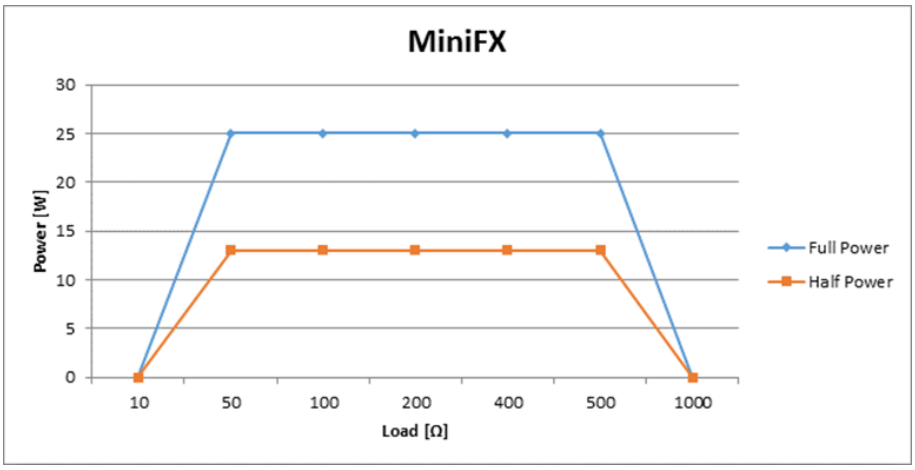


Figure 10-3: MiniFX Output Power versus Impedance

The following curves depict the Contora Peak Voltage vs. Power Settings.

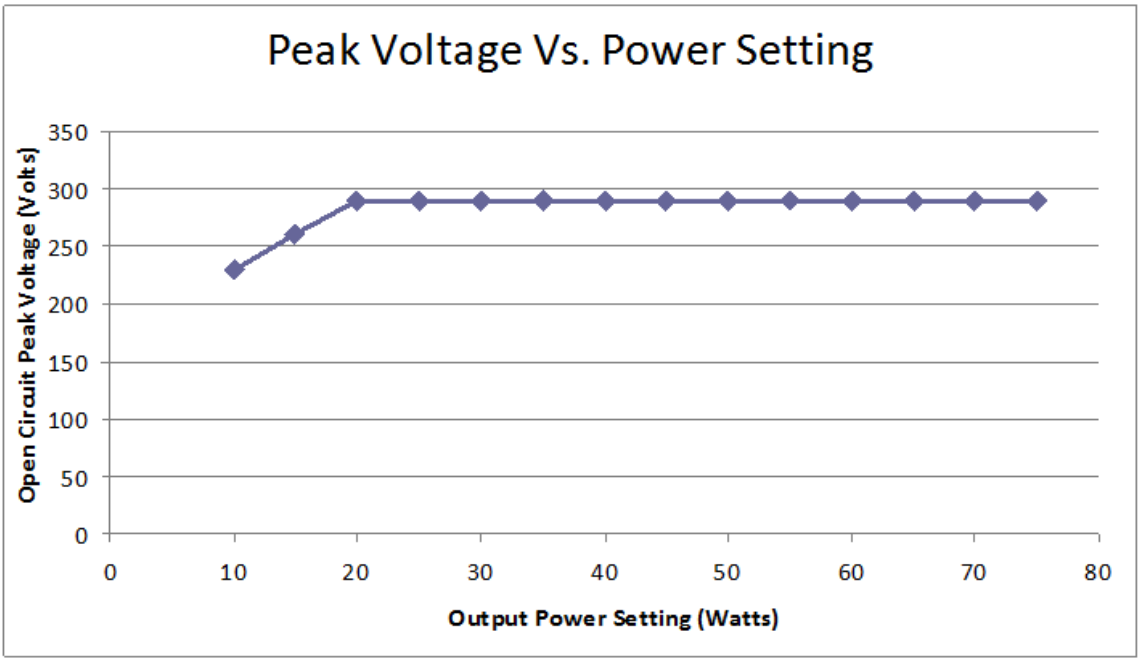


Figure 10-4: Output Power Versus Impedance

10.2 EMC Safety

The device has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device generates uses and can radiate radio frequency energy. If not installed and used in

accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that the interference to other devices, which can be determined by turning the device off and on, is caused by this instrument.

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

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect the device into an outlet on a circuit different from that which was previously used.
- Consult InMode service personnel for help.
- Interference to the device may be caused by portable and mobile RF communication equipment. In case of an interruption, beware of such a device in the vicinity.
- Use of the System with any accessory, transducer or cable other than those specified may result in increased EMISSIONS or decreased IMMUNITY than those specified.
- The System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Contoura System is intended for use in the electromagnetic environment specified below. The customer or the user of the Contoura System should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The Contoura System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The Contoura System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Complies</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The Contoura System is intended for use in the electromagnetic environment specified below. The customer or the user of the Contoura System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5sec	>95 % dip for 10 ms 60 % dip for 100 ms 30 % dip for 500 ms 95 % dip for 5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Contoura System requires continued operation during power mains interruptions, it is recommended that the Contoura System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE - U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

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

IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	[3] V [3] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P} = \left[\frac{3,5}{3}\right]\sqrt{65} = \mathbf{9.4}\ [\boldsymbol{m}]$ $80\ MHz\ to\ 800\ MHz$ $d = \left[\frac{7}{E_1}\right]\sqrt{P} = \left[\frac{7}{3}\right]\sqrt{65} = \mathbf{18.81}\ [\boldsymbol{m}]$ $80\ MHz\ to\ 2{,}5\ GHz$ Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

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

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

Recommended separation distances between portable and mobile RF communications equipment and the Contoura System

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

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

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

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

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

Table from IEC60601-1-2 Edition 4.0

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

Environment of intended uses:
- Professional Healthcare Facility Environment

Summary of Test Results:

Test	Standard	Class/ Severity level	Test result
Emission (IEC 60601-1-2 section 7.1 & 7.2 & IEC 60601-2-2)			
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class A	Complies
Conducted emission Freq. range:150 kHz - 30 MHz		Group 1 Class A 100/ 120/ 230 VAC	Complies
Harmonic current emission test	IEC 61000-3-2	AC mains	Exempted
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 8.9 & 8.10 IEC 60601-2-2)			
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, 1kHz	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 kV on 230 VAC mains, Pedal, Applicator Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1.0 kV DM/ 2.0kV CM on 230 VAC Tr/Th – 1.2/50 (8/20) μs	Complies
Immunity from conducted disturbances induced by RF fields	IEC 61000-4-6	3.0 & 6.0 V_{RMS} on 230 VAC mains, Pedal, Applicator 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	230 & 100 VAC mains; 0 % - 10 ms; 70% - 500 ms; 0% - 20 ms; 0% - 5sec	Complies