BODYTITE

Operator Manual

BodyTite

InMode RF

Version: DO607095B

INMODE

aesthetic solutions

Operator Manual: BodyTite™ System DO607095B

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Contents

1 Section 1: Introduction

This chapter provides a system overview and conventions used in this manual.

1.1 Before You Start

- The manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique to be performed.
- Federal (USA) law restricts sale of this device to, or on the order of a physician.
- Read this manual to become familiar with all safety requirements and operating procedures before attempting to operate the System.

1.2 System Overview

The BodyTite™ device is based on the InMode RF™ platform. BodyTite employs radiofrequency (RF) energy for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. The System operates when the Handpiece is connected.

- The System provides individual adjustment of treatment parameters to achieve maximum efficiency and safety for the specific treatment.
- The System provides enhanced safety while minimizing possible side effects by monitoring RF parameters and tissue temperature.

1.3 Conventions used in the Manual

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

WARNING! This information is extremely important!

ATTENTION! Consult Accompanying Document.

Provides general information that is important to keep in mind.

1.4 Explanation of the Symbols Used on the System

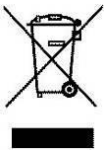
Symbol	Description
	CSA marking (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	HF Isolated Patient Circuit
	This equipment intentionally supplies non-ionizing RF energy
	Follow operating instructions

Table 1-1: Device Symbols

2 Section 2: Safety

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

The System is designed for safe and reliable treatment when used in accordance with proper operation and maintenance procedures. Only trained, qualified practitioners can use the System. The operator and all other personnel operating or maintaining the System should be familiar with the safety information provided in this Section.

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

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

The RF energy can cause injury if used improperly.

High voltage is present inside the System.

Always be aware of the possible dangers and take proper safe-guards as described in the manual.

2.1 The Patient

- Well-trained staff is a key for assuring patient safety. A patient history 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.
- Metal jewelry and metal accessories that are within the activation range of the Handpiece should be removed to avoid accidental RF conduction. The metal item(s) will be removed prior to use of the equipment.
- Patients will not be in contact with any metal or other alternate pathway to ground whilst the System is in use.

2.2 Treating Attendant

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

2.5 Fire Hazards

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

2.6 Safety Features of the System

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

- System has unique password to avoid device operation by non-authorized personnel.
- The RF energy 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.
- System starts at a low setting.
- Internal and skin surface temperature and impedance are constantly monitored.

2.7 Safe Use of the Active Accessories

- Examine the connection of the Handpiece through the connector to the System before using. Improper connection may result in arcs and sparks, accessory malfunction, or unintended treatment effects.
- Do not wrap the Handpiece cords around metal objects. It may induce current that could lead to electrical shock, fire or injury to the patient or personnel.
- Ensure that return electrode is in full contact with the skin. Bad coupling of the return electrode with the skin results in a specific warning sound, a message on the screen, and disabling of RF.
- Handpieces are for single use only. Do not try to reuse the handpiece. Re-use of the handpiece may create loss of integrity of handpiece components that may affect the performance and make the device non-functional.


Do not connect a wet accessory to the System.


Do not immerse the applicator under water at any time.


The Handpiece is gamma-sterilized for a single use only and CANNOT be autoclaved or re-sterilized by any other technology.

2.8 Warnings


This equipment is for use only by trained, licensed physicians.


Only Handpieces manufactured or approved by InMode MD Ltd. should be used with the BodyTite 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.

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

When BodyTite and physiological monitoring EQUIPMENT are used simultaneously on the same patient; any monitoring electrodes should be placed as far as possible from the handpiece electrodes. Needle monitoring electrodes are not recommended.

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

The operation of BodyTite 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.

Do not use BodyTite on patients with pacemakers or internal defibrillators.

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 BodyTite device console and the handpieces:

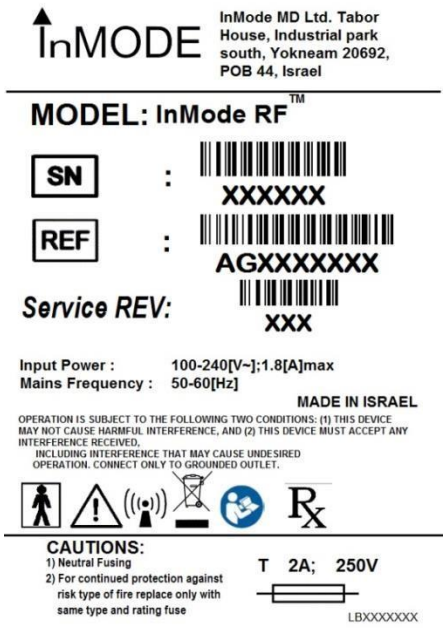


Figure 2-1:System Certification and Identification Label

Figure 2-2: 2 Footswitch label for all applications

Figure 2-3: BodyTite Handpiece Labels

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.
- System is classified as a IIb device defined by the Medical Device Directive (93/42/EEC).

3 Section 3: System Installation

3.1 Electrical Requirements

- The System will require a separate line supply of single phase (100Vac; 15A) or (115Vac; 15A) or (230Vac; 15A) or (240Vac; 15A) 50-60Hz.
- 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 on-ly with one of the same type and rating.

Proper grounding is essential for safe operation.

3.2 Environmental Requirements

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

3.3 Equipment List

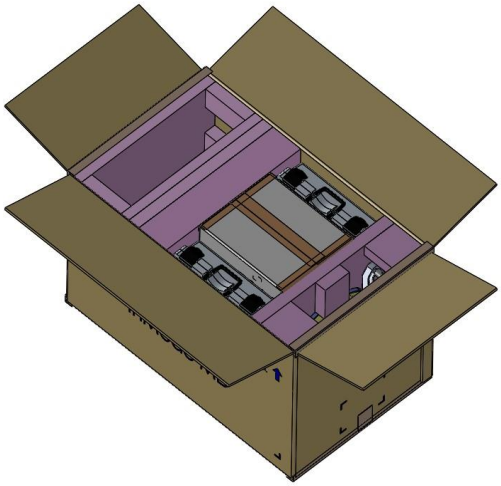
The System includes the following:

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

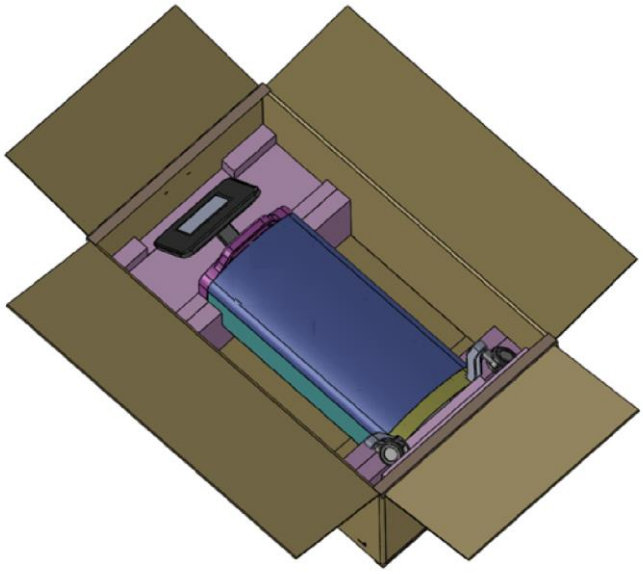
3.4 Unpacking

In order to unpack the device:

1. Remove the paper strip and open the box.



2. Remove accessories and foams around the device.



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

3.5 Installation

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 the Footswitch.
- Connect the power cord to the System inlet.
- Plug the System power cord into an appropriate electrical outlet.

3.6 Moving the System:

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

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

Always use the handles when moving the System.

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

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

Always use the handles when moving the System.

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

3.7 System Disposal

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

4 Section 4: Device Description

4.1 Rear Panel

Power cord inlet

100-240V~, 1A, 50-60Hz.

Fuse holder

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

Software flash memory plug

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

Foot switch connector

Foot switch is connected to the inlet. Foot switch activates RF energy if the system is in Ready mode. Place the foot switch on the floor near the treatment area.

Table 4-1: Rear Panel Symbols

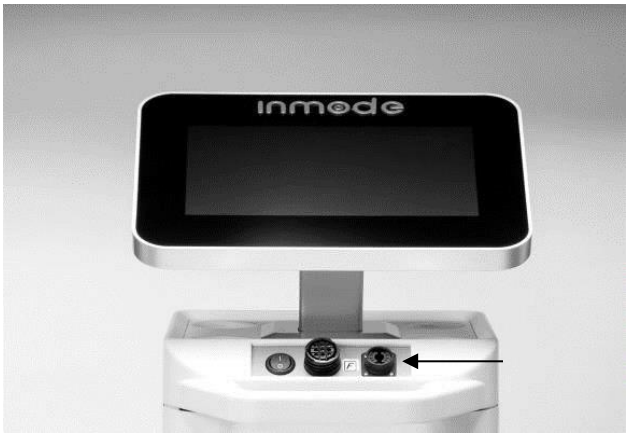


Figure 4-1: Handpiece Connector (Arrow) on Front Panel

4.2 Front Panel and Operator Control Panel

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

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

4.3 Software Screens

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

Figure 4-2: 2 Splash Screen

*The Software version number is displayed on the top of the screen and depends on the product version.

After entering the individual code in the Login Screen, the system allows access to the Treatment Screen.

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

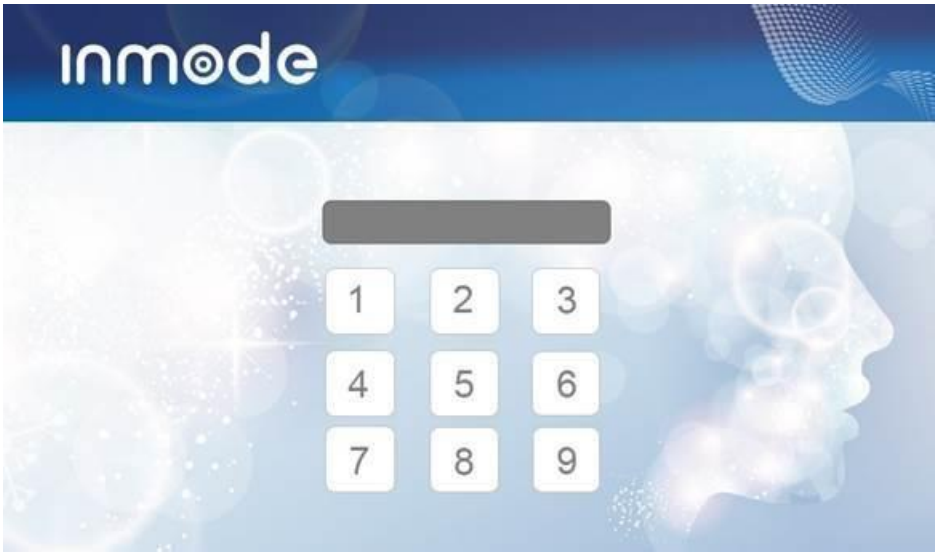


Figure 4-3: Login Screen

Prior to entering the Treatment Screen, a self-test of the system module is performed. After the end of the self-test, the Treatment Screen appears.

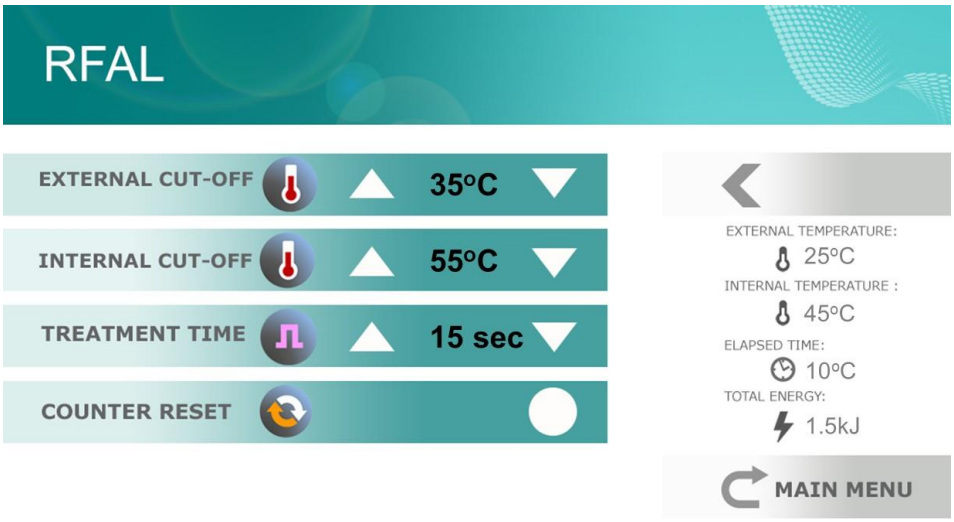


Figure 4-4: Treatment Screen

Item	Function
Selection Frame	▪ The frame selects parameters that can be changed.
External Cut-Off	▪ This indicator shows the skin Cut-Off temperature, which is adjustable between 35-42°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.
Internal Cut-Off	▪ This indicator shows the internal Cut-Off temperature, which is adjustable between 50-70°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.
External Temp. **Internal Temp.**	▪ This indicator shows measured external temperature. ▪ This indicator shows measured internal temperature.
Treatment Time	▪ This indicates the time that Cut-Off temperature is maintained. It varies from 15-120 sec with increments of 5 sec.
Elapsed Time	▪ This indicator shows elapsed treatment time.
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.

4.3.1 Sound Indicator

- Periodic beeping signal is emitted when RF energy is delivered.
- Warning sound tone indicates Bad Coupling.
- 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.

4.3.2 External Cut-Off Temperature Control

The selected Cut-Off temperature in the range of 35-42°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).

4.3.3 Internal Cut-Off Temperature Control

The selected Cut-Off temperature in the range of 50-70°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).

4.3.4 Treatment Time Control

The treatment time is selected in the range of 15-120sec and indicates time that Cut-Off temperature is maintained.

4.4 Handpieces

Handpiece comprises internal active electrode, external return electrode, both with temperature sensor, handle, cable and connector.

There are three types of handpieces, both with external and internal electrodes.

4. Handpiece HP101306A has an external electrode diameter of 13.5mm and internal electrode of 1.2mm diameter and 10cm long. Maximal RF power 20W
5. Handpiece HP172206A has an external electrode diameter of 13.5mm and internal electrode of 2.2mm diameter and 17cm long. Maximal RF power 20W
6. Handpiece HP172246A has an external electrode diameter of 22mm and internal electrode of 2.2mm diameter and 17cm long. Maximal RF power 40W

Figure 4-5: Handpiece HP101306A

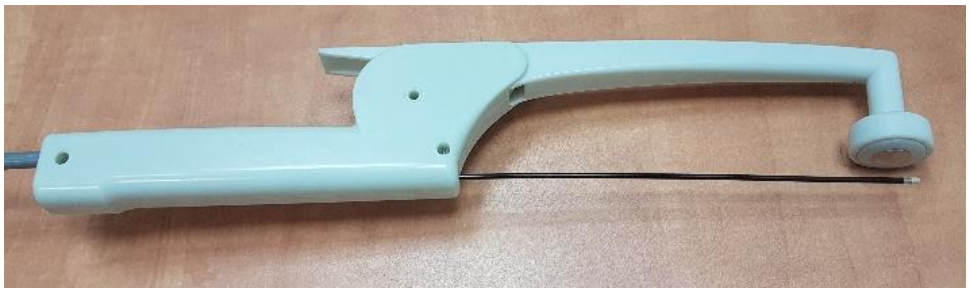


Figure 4-6: Handpiece HP172206A

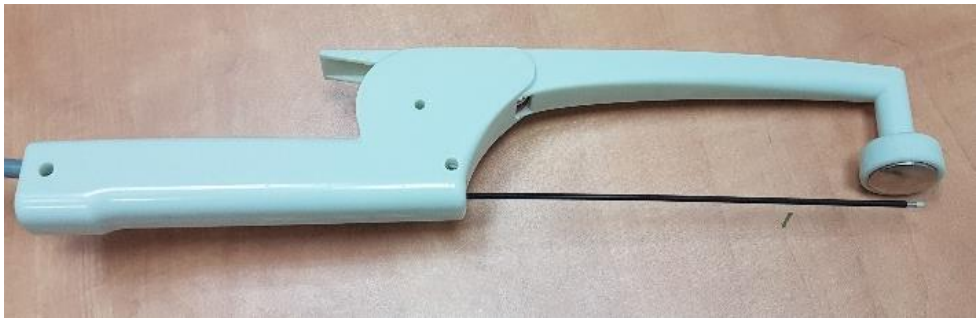


Figure 4-7: Handpiece HP172246A

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 blunt plastic tip which is not conductive. ▪ The internal electrode has an embedded temperature sensor to monitor the tissue temperature.
Return Electrode	▪ The handpiece has a large area return electrode with embedded temperature sensor to monitor the skin temperature.
Cable	▪ Has a length of 250cm (100”).
Connector	▪ It is connected to the front control panel of the system.

5 Section 5: System Operation

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

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

5.1 Device Start-Up

1. Connect the Handpiece to the Handpiece connector socket on the front panel.
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 treatment screen.
5. The system loads the software and enters a self-test mode. If any problem is detected during the test, an error message will appear (See Troubleshooting Section in this manual). If the test is passed correctly then the system automatically enters the Treatment Screen.
6. Select treatment parameters using touch screen.
7. Enter Ready mode to confirm the selected parameters. The System is ready for RF delivery.
8. Press footswitch to start procedure.

5.2 System Shutdown

To shut down the System turn the On-Off switch on the front panel off. Turn the Main Power switch off at the end of the day.

6 Section 6: Treatment Information

6.1 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 BodyTite. Updated treatment protocols and recommendations are presented in the Quick Reference Guide (QRG).

6.2 Indications for Use

The BodyTite system is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

6.3 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.

6.4 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 skin redness (erythema) and/or swelling (edema), ecchymosis, burns, damage to natural skin 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.

Make sure that Handpiece is dry and intact before use.

Do not use the Handpiece if it is damaged.

6.4.1 Gamma sterilized - Instruction Prior to Use

The Gamma sterilized Handpieces 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).

6.5 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.

6.6 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 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 skin surface
- Enter Ready mode, press the footswitch and apply the RF energy.
- Release the footswitch after treatment time is elapsed.
- Move to the next site or terminate the treatment.

6.7 Post-Treatment Recommendations

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

7 System Maintenance

7.1 Cleaning the Device

- Wipe the device, including the footswitch with a damp, soft cloth.
- Liquid disinfecting solution may be used.
- Avoid using flammable solutions.
- Do not immerse any part of the system.
- The Handpiece should be discarded after use.

8 Troubleshooting

The BodyTite System provides monitoring of all critical parameters to ensure safety of the patient and user. If any of the following faults are detected the System automatically disables RF output and goes to an Error Screen.

8.1 Description of Faults

Problem	Checks
System did not turn on	▪ Check power cord connection ▪ Check that main switch on rear panel is on ▪ Check fuses on back panel of the System ▪ Call Technical Service if problem persists
Software plug missing	▪ The software plug is not inserted
Checksum	▪ The software was not loaded properly from software plug ▪ Check plug connection and reboot the System ▪ Call Technical Service if problem persists
Fault H8002 - Handpiece is not connected	▪ Check connection of Handpiece ▪ Reboot the System ▪ Replace Handpiece ▪ Call Technical Service if problem persists
Fault H8005 – System Memory Fault	▪ Reboot the System ▪ Call Technical Service if problem persist
RF delivery problem	▪ No energy delivery after the footswitch is pressed. Check that system is in READY mode and the footswitch is connected. Reboot the system. Call Technical Service if this problem persists.

Problem	Checks
Bad Coupling Indicator exists at all times during treatment	■ Check that there is a water based gel applied to the skin surface,and ensure that proper tumescent infiltration has been done. Reboot the system. ■ Replace the Handpiece if this problem continues. Call Technical Service if this problem persists
Low Temperature	■ Message is displayed on screen if the temperature does not rise during the treatment. ■ Reboot the system. Replace the Handpiece if this problem continues. Call Technical Service if this problem persists.

9 System Specifications

Category	Item	Detail	
Inut Power	Main Line Frequency (nominal) Input Voltage (nominal) Input Current (rms)	50 - 60Hz 100 - 240VAC 2A	
Operating Parameters	Ambient Temperature Range Relative Humidity Atmospheric Pressure Warm-up Time	15° – 35°C [59° – 95°F] 30% to 80%, non-condensing 90 - 110kPa If transported or stored at temperatures outside the operating temperature range, allow one hour for the system to reach room temperature before use.	
Transport and Storage	Ambient Temperature Range Relative Humidity Atmospheric Pressure	-20° – 65°C [35° – 131°F] 0% - 80%, non-condensing 50 - 110 kPa	
Dimensions	System Handpiece cable	35 cm W x 46cm D x 100cm H 250 cm L	[18.2'' W x 18.2'' D x 40'' H] [100" L]
Weight	System Handpiece	20Kg 0.2Kg	[44lb] [0.4lb]
Output Parameters	Maximal RF Power External Cut-Off Internal Cut-Off Treatment Time RF Frequency Tissue impedance	20 W for HP101306A and HP172206A 40 W for HP172246A 35-42°C 50-70°C 15-120sec 1MHz 50 -300Ohm	

9.1 BodyTite Output Power Curves

The following curves depict the BodyTite output Power vs. Range of Load Impedance.

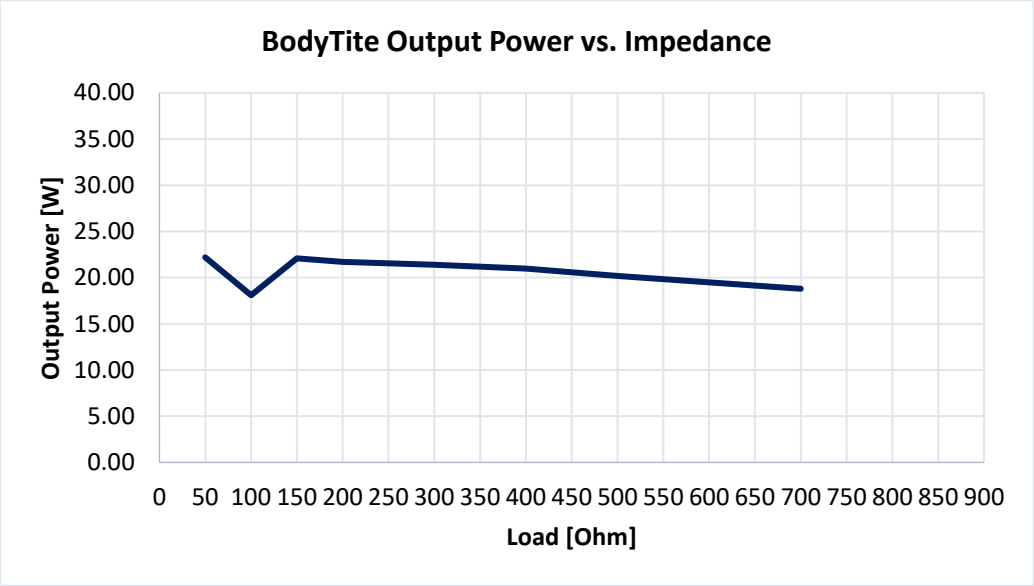


Figure 9-1: Output Power Versus Impedance

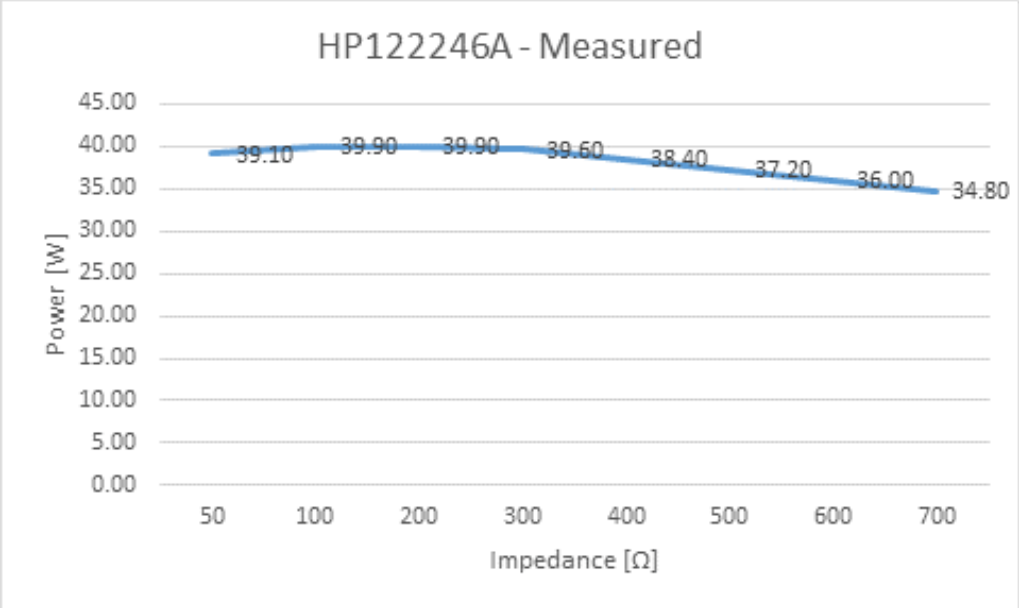


Figure 9-2: Output Power Versus Impedance

9.2 EMC Safety for the BodyTite Device

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 MD Ltd. 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.

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Test Report No.: 9612328399/1 **Page 4 of 42 Pages**
Title: Test on RF System
Name: InMode RF, **Model:** InMode RF with InMode RF Handpieces

1. Summary of Test Results

Test	Standard	Class/ Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements for EMC	section 4.1.1.	--	Complies
External labels	section 5.1	--	Complies
Conformity of Users' Manual	section 5.2.1	--	Complies
Accuracy of Technical Descri.	section 5.2.2	--	Complies
Emission (IEC 60601-1-2 section 6.1 and IEC 60601-2-2 section 202.6.1)			
Conducted emission Freq. range:150 kHz - 30 MHz	sec. 6.1.1 / 202.6.1.1.1 & CISPR 11	Group 1 Class A on 240, 120 & 100 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	sec. 6.1.1 / 202.6.1.1.1 & CISPR 11	Group 1 Class A	Complies
	IEC 61000-3-2	AC mains	N/A
Voltage changes, Voltage	IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 6.2 and IEC 60601-2-2 section 202.6.2)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	6 kV contact discharges & 8 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	3.0 V/m 80 MHz ÷ 2.5 GHz, 80% AM, 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on 240 & 100 VAC mains, Tr/Th – 5/50 ns, 5 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1.0 kV DM / ±2.0 kV CM on 240 & 100 VAC mains; Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0 V_{RMS} on 240 VAC mains & Applicator & Footswitch cables; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	3 A/m, 50 Hz & 60 Hz	Complies
Immunity from Voltage interruptions	IEC 61000-4-11	240 & 100 VAC mains: > 95 % - 10 ms; 60%- 100 ms; 30% - 500 ms; >95% - 5sec	Complies

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