

inmode

Operator Manual

InMode™ SYSTEM With BodyFX™ Handpiece

DO602777B







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Section 1 – Introduction

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.

System Overview

The InMode System with the BodyFX Handpiece 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 and adipose tissue.

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.

Conventions Used in the Manual

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



Note

Provides general information that is important to keep in mind.



WARNING: This information is extremely important!

Explanation of the Symbols used on the System

Symbol	Description
	Warning!
	Attention! Consult Accompanying Document
	CSA marking (212603 CSA master contract number)
	CE marking
	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 instructions for use
	Note

Section 2 – Safety

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

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

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



- **Read this chapter to be familiar with all its safety requirements and operating procedures prior to System operation.**
- **Skin massaging may cause bruising and skin damage if used improperly**
- **RF devices can cause injury if used improperly.**
- **High voltage is present inside the System.**
- **Always be aware of the possible dangers and take proper safeguards as described in the manual.**

The Patient

Well-trained staff is a key for assuring patient safety. A patient history should be completed prior to scheduling. Patients should be fully informed of the treatment protocol, the likely results and any risks associated with the treatment.

Patients should not be in contact with any metal or other alternate pathway to the ground while the system is in use. Metal jewelry should be removed if it is within the activation range of the Handpiece.

Treating Attendant

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

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.

Electrical and Mechanical Safety

- Keep all covers and panels of the System closed. Removing the covers creates a safety hazard.
- Keep hands away from the applicator during the System start-up.
- Perform maintenance procedures when the System is shut down and disconnected from the power.
- The System is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.
- Provide as much distance as possible between the system and other electronic equipment because the activated RF generator may cause interference between them.
- Move the System slowly and carefully. The System weighs approximately 30kg (66lb.) and may cause injury if proper care is not used when moving it.

Fire Hazards

- The conducted RF energy may raise the temperature of the material if misused. Do not use the System in the presence of explosive or flammable materials.
- Keep drapes and towels moist to prevent them from igniting and burning as a result of misuse. Use non-flammable prepping solutions.
- Do not use flammable substances when preparing the skin for treatment. Be especially careful with the use of oxygen.
- If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the System is used.

Safety Operational Use of the System

- The System incorporates the following safety features. All personnel operating the System should be familiar with these features.
- The power electronics cannot be activated unless the applicator has been connected to the System.
- An audible tone indicates energy activation.
- During activation, the System performs a self-test of the hardware.
- Hardware is tested periodically to ensure proper operation of electrical circuit.
- System starts at a low power setting.
- Vacuum level monitoring. RF is disabled when vacuum is below the predetermined level.

Active Accessory

- Examine the Handpiece and 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.
- Bad coupling of both electrodes with the skin result in a specific warning sound, a message on the screen, and disabling of RF.
- 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 personal.



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

Warnings



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

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

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

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

Always turn off and unplug the InMode System before cleaning.

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

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

Use the lowest output setting necessary to achieve the desired effect. Use the RF energy only for the minimum time necessary in order to lessen the possibility of unintended burn injury. The higher the RF energy and the longer the RF energy is applied, the greater the possibility of unintended thermal damage to tissue.

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

The operation of the InMode 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.

Device Labels

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

The following device labels are located on InMode device console:

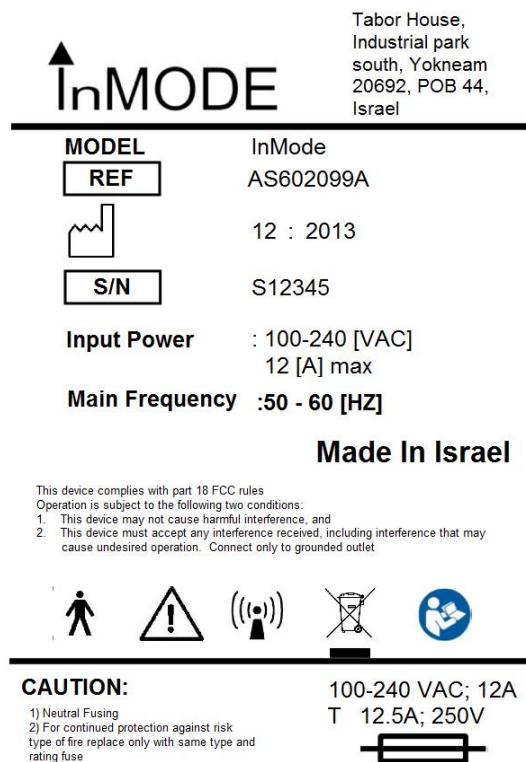


Figure 2.1 Manufacturer System Identification Label

CAUTION

Federal (US) law restricts this device to sale by on 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.

Figure 2.2 USA Federal Restriction Notice

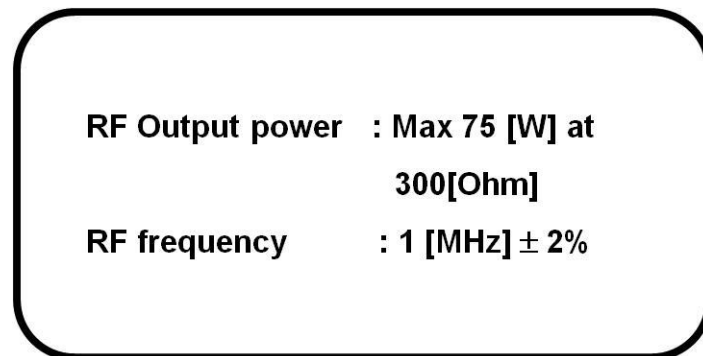


Figure 2.3 System RF output label

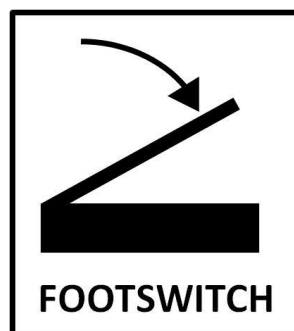


Figure 2.4 Footswitch Label.

Handpiece labels

Manufacturer identification labeling is placed on the InMode BodyFX Handpiece:



Figure 2.4 The InMode BodyFX Handpiece Label

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.

System is classified as an IIb device defined by the Medical Device Directive (93/42/EEC) for CE marking.

Section 3 - System Installation

Electrical Requirements

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



- **For continued protection against fire, replace the fuse only with one of the same type and rating.**
- **Proper grounding is essential for safe operation.**

Environmental Requirements

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

Equipment List

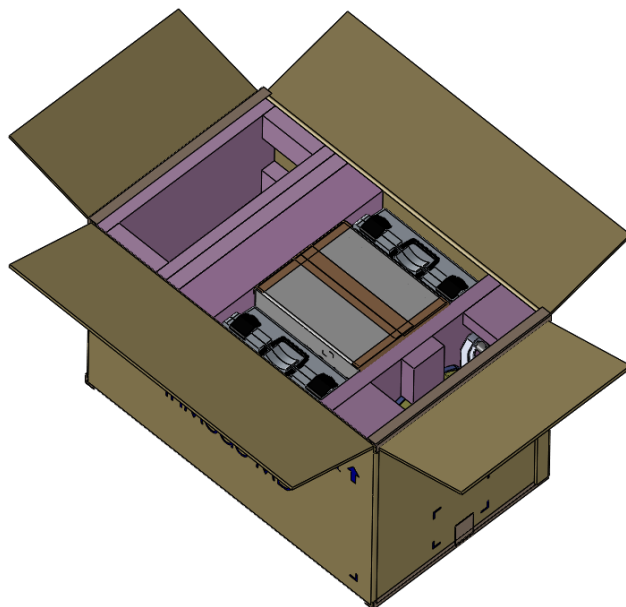
The System includes the following:

- System platform
- BodyFX Handpiece
- BodyFX Handpiece cradle
- Foot switch
- Operator manual
- Power cord

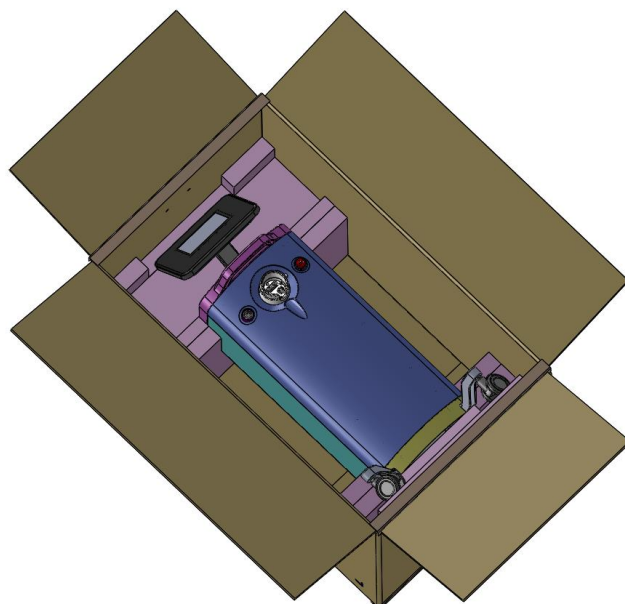
Unpackaging

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.

Installation

To install the System perform the following tasks:

- Check the System and all its components for damage.
- Add water. Use the Maintenance Screen.
- Connect Footswitch to the footswitch connector.
- Connect the Power Cord to the System inlet.
- Plug the System Power Cord into an appropriate electrical outlet.
- Connect Cradle to the System (Fig. 3.1).
- Connect Handpiece to top right inlet at rear panel (Fig 4.1).
- Place Handpiece into the cradle.

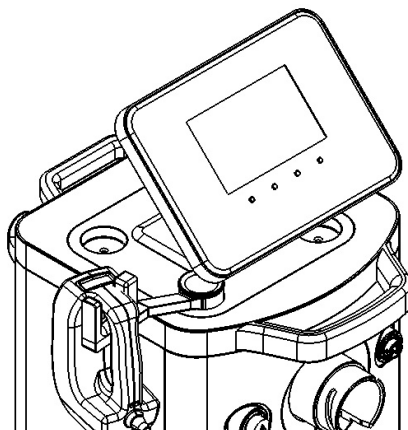


Figure 3.1 Cradle connections to the device

Moving the System

To move the System:

- Turn the System off.
- Disconnect the Power Cord.
- Disconnect the Handpieces.
- Disconnect the Footswitch.
- Release the wheel brakes.
- Slowly push or pull the System using the handle.



- **Never lift, pull or push the System using the operating panel.**
- **Always use handles moving or lifting the System.**

Disposal of System

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

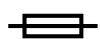
Section 4 - Description of Device

Rear Panel



Power cord inlet

100-240V~, 2A, 50-60Hz.



Fuse holder

Rating is T 2A, 250V SB. Replace fuse 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 non-thermal RF energy if the system is in Ready mode. Place the foot switch on the floor near the treatment area.

RF Handpiece Connector

Located on the upper right side of the rear panel and connects to the Handpiece.

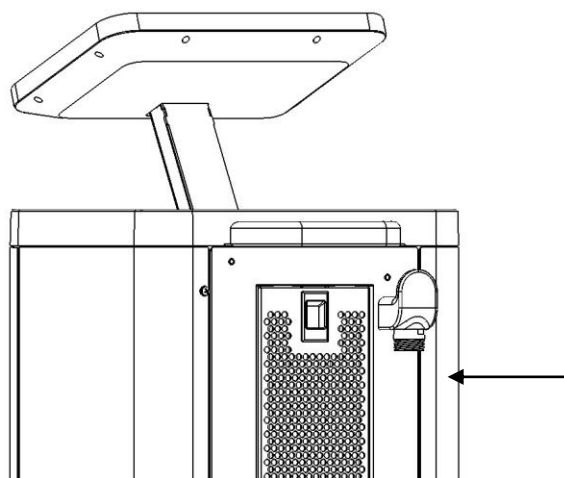


Figure 4.1 RF connector on rear panel (arrow)

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 and four buttons.

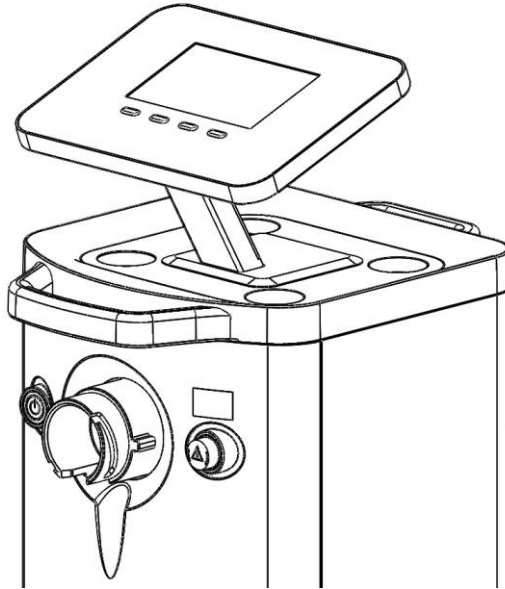


Figure 4.2 Front Panel and Operator Control Panel

- **Power On-Off switch** Power switch turns power electronics off.
- **Emergency Stop** Stops the power instantly in emergency conditions.
- **Button**
- **LCD screen** LCD screen shows information about system mode and treatment parameter
The panel allows changing treatment parameters and system mode.

Software Screens

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



Figure 4.3 Splash Screen

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

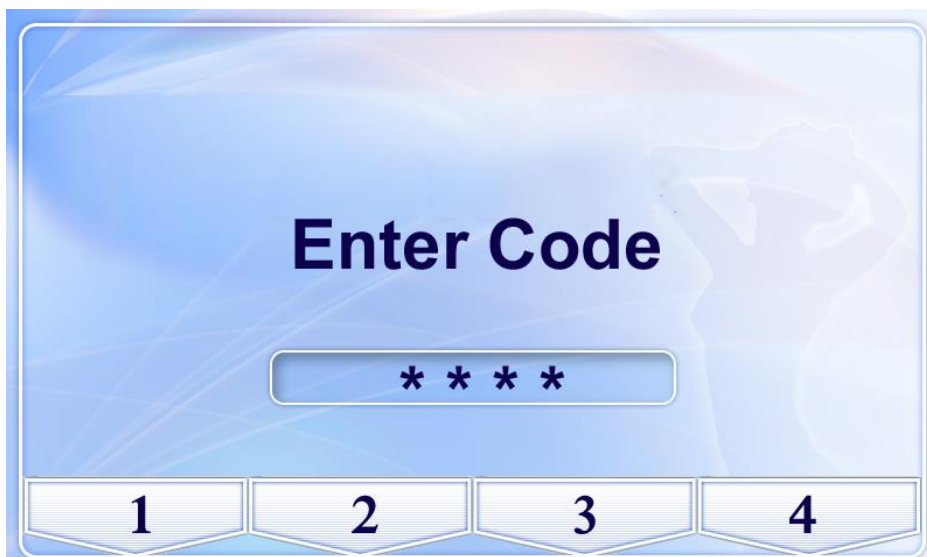


Figure 4.4 Login Screen

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

Menu Screen allows selection of connected Handpiece or entering Maintenance Screen.



Figure 4.6 Maintenance Screen

Maintenance Screen allows to drain water from the device prior to shipment and to fill water during installation

Choose the BodyFX application from the menu screen by pressing the green key at bottom right, and the Treatment Screen will appear.



Figure 4.7 Treatment Screen

- RF Power** RF power is changed within the limits allowed for the connected Handpiece. Power level settings are changed from 10 to 50W and the System starts up at minimal power level setting.
- Cut-Off Temperature** This indicator shows the Cut-Off temperature, which is adjustable from 35°C up to 43°C. This indicates measured temperature at which the RF delivery is stopped.
- Pulse Width** This indicator shows the time period during which vacuum is applied and warming RF energy is delivered, which is adjustable from 2 to 7sec.
- Measured Temperature and Vacuum** This indicator shows on line the skin surface temperature and the current negative pressure applied, with a maximal Temperature of 43°C And -500mBar maximal Vacuum level.
- Selection Frame** The frame selects parameters that can be changed by functional keys.

System Mode	<p>The System has three treatment modes.</p> <p>Standby mode allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode.</p> <p>In Ready mode, the system is waiting for a signal from the footswitch to activate the energy. Any attempt to change the treatment settings switches the system to Standby mode.</p> <p>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.</p>
Total Energy	<p>This indicator shows the total energy delivered from the beginning of the treatment.</p>
Volume	<p>This function allows the user to adjust system volume.</p>
Selection Frame	<p>The frame selects parameters that can be changed by functional keys.</p>
System Mode	<p>The System has three treatment modes.</p> <p>Standby mode allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode.</p> <p>In Ready mode, the system is waiting for a signal from the footswitch to activate the energy. Any attempt to change the treatment settings switches the system to Standby mode.</p> <p>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.</p>

Functional Keys



Shift

This sign indicates the functional key allowing the user to select the treatment parameters.



Up

This sign indicates the functional key allowing the user to increase the selected treatment parameter.



Down

This sign indicates the functional key allowing the user to decrease the selected treatment parameter.



Mode

This sign indicates the functional key allowing the user to change the System Mode.

Sound Indicator

Periodic beeping signal is emitted when RF energy is delivered.

Warning sound tone indicates Bad Coupling.

Cut-Off Temperature Control

An upper limit of temperature of 41°C is constantly maintained, and when reached, RF delivery is automatically stopped. Temperature is monitored by a temperature sensor in the Handpiece. This is a safety feature which is maintained in addition to the external temperature measurements during treatment.

Handpiece

Handpiece comprises a vacuum chamber, RF electrodes, 8-character screen, handle, cable and connector.

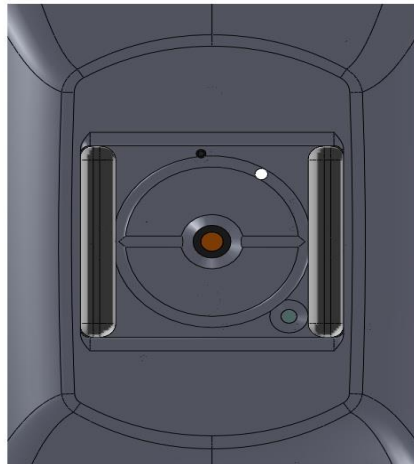


Figure 4.5 BodyFX Handpiece

Handle	Handpiece handle is made from plastic and has ergonomic design for easy treatment.
Vacuum Chamber	Applied to the skin surface for massaging.
RF Electrodes	Located in the vacuum chamber and delivers RF energy to mildly warm massaging tissue.
Screen	Shows measured skin temperature.
Cable	Has a length of 250cm (100’’).
Connector	Connector is located in the rear panel.
Temperature Sensor	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 Handpiece electrodes for cleanliness and possible mechanical damage.

Device Start-Up

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

System Shutdown

To shut down the system turn the power-switch off.

In case of an emergency, the system may be switched off instantly by pressing the red Emergency Stop Button on the right side of the System's front panel.

Section 6 - Treatment Information

Indications for Use

InMode System with the BodyFX Handpiece is intended for the treatment of the following medical conditions using non thermal RF combined with massage:

- Relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.
- Temporary reduction in the appearance of cellulite.
- Temporary improvement of circumferential reduction and body contouring.

Contraindications

Contraindications in the use of the System include:

- 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 periosteal plane.
- Current or history of cancer, or current condition of any other type of cancer, or pre-malignant 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.
- Any surgery in treated area within 3 months prior to treatment.
- 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.

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, burn), change of pigmentation (hyper- and hypo-pigmentation), scarring, 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.

Handpiece Cleaning Instruction Prior to Use



Warning!

These cleaning instructions are for Clinical Use only.

The following processes are validated for the InMode BodyFX Handpiece 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. Clean the Handpiece thoroughly with alcohol absorbed pad 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.

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.

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

- Clean the Handpiece with alcohol 70% or other disinfectant. Use alcohol-soaked cotton buds to clean inside the Handpiece cavity.

Treatment Recommendations

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

Treatment Approach	RF Power	Pulse Width [Sec]	Measured Skin Temperature [°C]
Sensitive skin e.g..arm, inner thigh	30-40	2	38-40
Normal skin e.g. abdomen, flanks	35-45	3	40-41
Resistant skin e.g. buttocks, outer thigh	40-50	4	41-43



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. Divide treatment area to zones of about the size of 4-8 finger prints of the vacuum chamber (large hand palm) and mark them.
7. Assume full contact of Handpiece with skin with a slight pressure to enable vacuum.
8. Use your free hand to flatten and stretch treatment area.
9. Press the foot switch and initiate the RF energy and suction, and massage the skin for preset pulse duration.
10. Move to adjacent site with no overlap from previous site and apply another pulse.
11. Apply multiple passes to the treated zone during ~5min. When skin temperature is 41°C, compensate with 1-2 more minutes of treatment.
12. 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.
13. After 5min move to the next zone, usually left or right side, and perform the same steps.
14. 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.
15. After treating the zone, move to the next area.

Treatment Schedule

The number of treatment sessions depends on the individual patient and typically varies between 6-8 sessions, once a week.

Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.

Post-Treatment Recommendations

- 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 7– System Maintenance

External Validation Module

Energy calibration is needed for the optical Handpieces only. It is needed to determine the relationship between electrical and optical parameters and verifies that the laser/IPL energy is within the required range. The procedure consists of measuring the output energy of the laser/IPL with an energy meter connected to the calibration port, as described in the instructions below. The microcontroller automatically sets the laser /IPL parameters over the operating range, determining the electrical parameters, and comparing the measured parameters, and compares the measured and expected pulse energies. Monthly validation is recommended.

To perform the calibration on maintenance screen by authorized technician once a year:

- Choose 30J/cm² and short pulse.
- Ensure that the Handpiece sapphire output window and energy meter window are clean and free of condensed water, for accurate energy calibration.
- Insert the sapphire output window of the Handpiece carefully into the calibration device. The window must be pointing downward the energy meter and the Handpiece fully seated in its place.
- Press the footswitch and Handpiece trigger.
- The measured energy should be between 96J and 144J. If measured energy is out of range, clean the Handpiece window and repeat the test. If after cleaning the energy is still out of range, call service.

Filling / Draining Water

1. Open the back cover and take out the bottle.
2. Remove bottle cork.
3. Fill/drain distilled water to/from the bottle.
4. Close the cork and insert the bottle, close the back cover.
5. Turn on the machine and plug the IPL Handpiece.
6. Enter the Maintenance Screen and choose Filling/Draining option (wait until the end of the process).
7. Repeat the steps until the bottle filled to the marked sign or until the water drained.

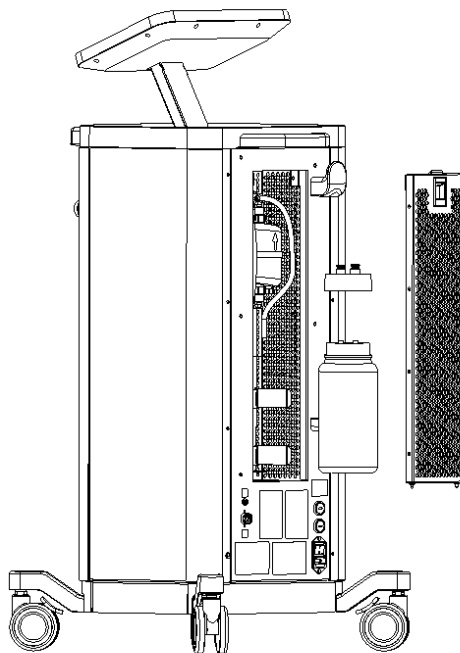


Figure 11.1 Filling water

Cleaning the Device

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 after removal of the residual gel, when applicable.

Section 8 – Troubleshooting

The InMode 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.

Description of Faults with All Handpieces

System did not turn on

- Check power cord connection
- Check that main switch on rear panel is on
- Check 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
- Replace Handpiece
- Call Technical Service if problem persists

Fault H8005 – System Memory Fault

- Call Technical Service if problem persists

Fault H8601 – Distributor Card Connection Fault

- Call Technical Service if problem persists

Fault H8609 – Water Temperature Fault

- Call Technical Service if problem persists

Fault H860B – Water Flow Fault

- Call Technical Service if problem persists

Laser Related Faults - H8003, H8006, H8007

- Call Technical Service if problem persists



IPL Related Faults – H8401, H8410, H8420, H8421, H8422, H8430, H8431

- Call Technical Service if problem persists

RF Related Faults – H8202, H8210, H8211, H8220-H8229, H8222A, H8222C, H8222D, H8222E

- Call Technical Service if problem persists

Section 9 - System Specifications

Input Power

Main Line Frequency (nominal)	50-60 Hz
Input Voltage (nominal)	100-240 VAC
Input Current (rms)	2A

Operating Parameters

Ambient Temperature Range	15° – 35° C [59° – 95° F]
Relative Humidity	30% to 80%, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa
Warm-up Time	If transported or stored at temperatures outside the operating temperature range, allow one hour for to reach room temperature before use.

Transport and Storage

Ambient Temperature Range	-20° – 65° C [35° – 131° F]
Relative Humidity	0% to 80%, non-condensing
Atmospheric Pressure	500 hPa to 1060 hPa

Dimensions

System	36cm W x 36cm D x 100cm H	[14.2'' W x 14.2'' D x 40'' H]
Handpiece Cable	250 cm	[100``]

Weight

System	30 Kg	[66 lbs.]
Applicator	1 Kg	[2.2 lbs.]

Output Parameters

Maximum Output Power for	
BodyFX Handpiece	10-50 [W]
RF Output Frequency	1[MHz] ± 2%
Vacuum	Up to 500mBar

Output Power Curves

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

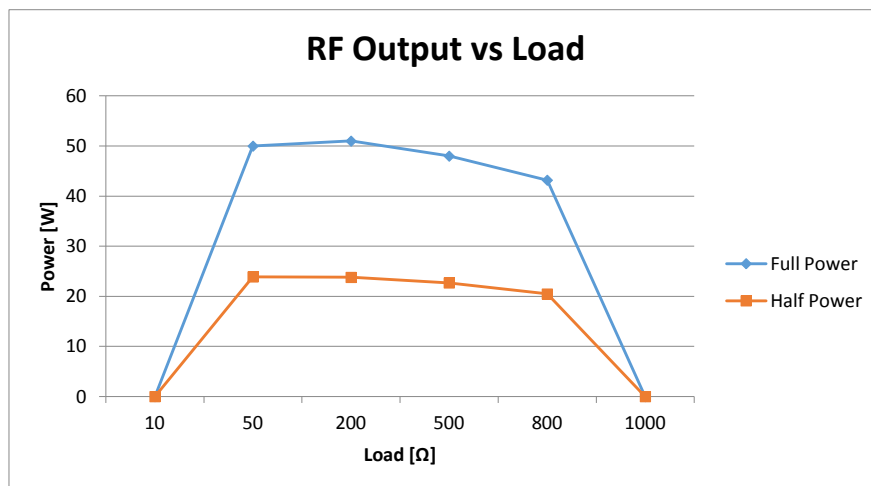


Figure 8.1 Output Power versus Impedance

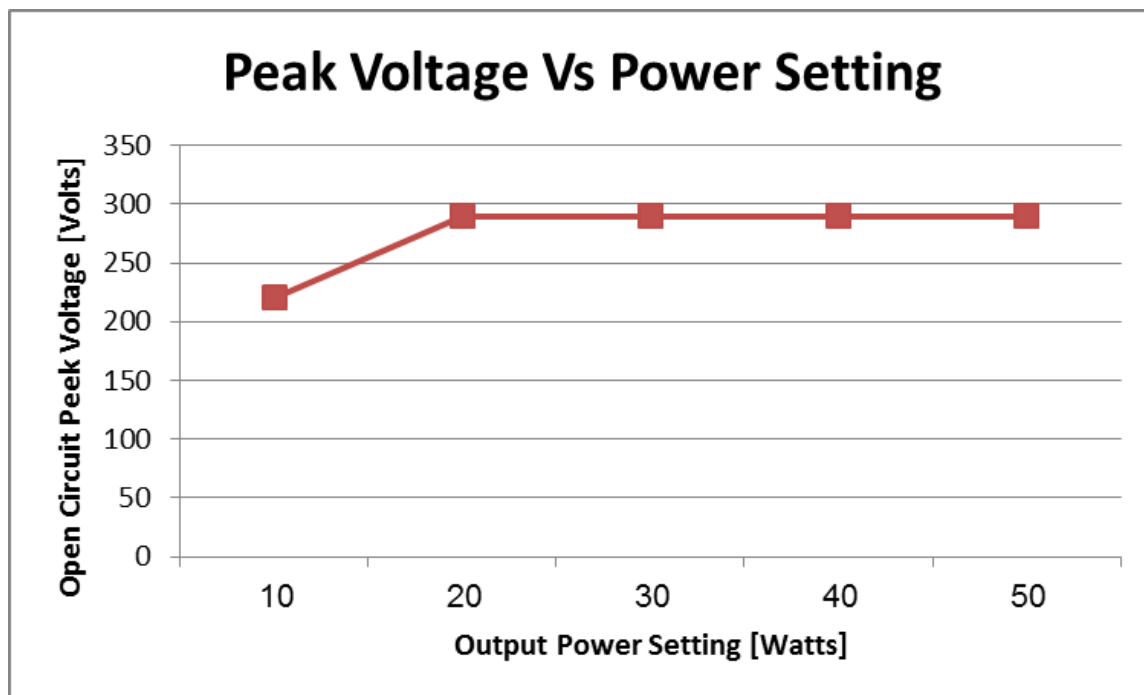


Figure 8.2 Peak Voltage Versus Power Setting

EMC Safety for the InMode 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 Invasix service personnel for help.

Interference to the device may be caused by portable and mobile RF communication equipment. In case of an interruption, beware of such a device in the vicinity.

- Use of the system with any accessory, transducer or cable other than those specified may result in increased EMISSIONS or decreased IMMUNITY than those specified.
- The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer’s declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The InMode uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The InMode is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer’s declaration – electromagnetic immunity


The InMode is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode 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	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	>95 % dip for 10 ms 60 % dip for 100 ms 30 % dip for 500 ms 95 % dip for 5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the InMode requires continued operation during power mains interruptions, it is recommended that the InMode be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE - U_T is the AC mains voltage prior to application of the test level.

Guidance and manufacturer’s declaration – electromagnetic immunity

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

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>[3] V</p> <p>[3] V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the InMode, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P} = \left[\frac{3,5}{3} \right] \sqrt{65} = 9.4 [m]$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} = \left[\frac{3,5}{3} \right] \sqrt{65} = 9.4 [m]$ <p>80 MHz to 800 MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P} = \left[\frac{7}{3} \right] \sqrt{65} = 18.81 [m]$ <p>80 MHz to 2,5 GHz</p> <p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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

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

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

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

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

The InMode is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the InMode can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the InMode 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, / 5.2.2.1 c&f

Compliance with specification

Test	Standard	Class/ Severity level	Test result
Emission			
Radiated emission Frequencies range of 150 kHz – 30 MHz	FCC Part 18 Subpart C	--	Complies
Radiated emission Frequencies range 30 MHz – 1000 MHz		Limits Per FCC Part 15 Subpart B Class B	Complies
Conducted emission Freq. range:150 kHz - 30 MHz		Limits Per FCC Part 15 Subpart B: Class B at 115 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	IEC 60601-1-2 clause 36.201.1 & CISPR 11	Group 1 Class B	Complies
Conducted emission Freq. range:150 kHz - 30 MHz		Group 1 Class B / Class B 230 VAC & 100 VAC mains	Complies
Harmonic current emission test	IEC 60601-1-2 clause 36.201.3.1 & IEC 61000-3-2	AC mains	Exempt
Flicker test	IEC 60601-1-2 clause 36.201.3.2 & IEC 61000-3-3	AC mains	Complies
Immunity (per IEC 60601-1-2)			
Immunity from Electrostatic discharge (ESD)	clause 36.202.2 & IEC 61000-4-2	6 kV contact discharge 8 kV air discharge	Complies
Immunity from radiated electromagnetic fields	clause 36.202.3 & IEC 61000-4-3	3.0 V/m, 80 MHz + 2.5 GHz, 80% AM, 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	clause 36.202.4 & IEC 61000-4-4	± 2 kV, 230 VAC & 100 VAC mains; Tr/Th – 5/50 ns, 5 kHz	Complies
Immunity from Surge	clause 36.202.5 & IEC 61000-4-5	±2.0 kV CM /±1.0 kV DM 230 VAC & 100 VAC mains; Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by RF fields	clause 36.202.6 & IEC 61000-4-6	3.0 VRMS at 230 VAC mains, Footswitch and Handpiece, 0.15+ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	clause 36.202.8 & IEC 61000-4-8	3 A/m, 50 Hz & 60 Hz	Complies
Immunity from Voltage dips, short interruptions and voltage variations	clause 36.202.7 & IEC 61000-4-11	230 VAC & 100 VAC mains; >95% - 10 ms; 60% - 100ms; 30% - 500ms; >95% - 5sec	Complies

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