INCREDIBLE DEVICES

EMS MAXX™
BODY TRIM & TONE

This manual outlines Operating Procedures, Safety Precautions and Maintenance for the **EMS MAXX Body Trim & Tone**™, ensuring effective treatments, consistent performance, and long-term reliability in professional aesthetic environments.

INCREDIBLE Devices
SHE-MSP006

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Chapter 1
Introduction - General Information

1.1 – Description of the Device

The **EMS MAXX Body Trim & Tone™** system consists of a main unit and one or more applicators. It features a high-visibility, high-resolution colour touchscreen interface that simplifies operation and provides clear, step-by-step guidance throughout the treatment process. The screen includes a free-sliding operation and can be adjusted up to 45 degrees for optimal viewing. Therapy settings can be quickly adjusted via the touchscreen and control buttons. During treatment, the screen displays real-time information such as remaining therapy time and key parameters. Treatment can be easily performed over clothing.

The **EMS MAXX Body Trim & Tone™** and its accessories are supplied non-sterile and are intended for external, non-invasive application only.

1.1.1 – Pulse Quality Monitor

Pulse parameters are being continuously monitored during therapy. In the event of any mismatch with expected values, the therapy is stopped to protect the device. Unwanted changes in pulse parameters may typically be caused by the presence of major metallic or ferromagnetic objects in the application field.

The Pulse Quality Monitor is not designed to ensure the safety of the operator or the patient. It is essential to strictly adhere to all operational and safety guidelines outlined in this manual. Failure to do so may result in device malfunction or serious injury.

1.2 – Contraindications

- Fever
- Pregnancy
- Drug pumps
- Metal implants
- Malignant tumor
- Electronic implants
- Cardiac pacemakers
- Pulmonary insufficiency
- Sensitivity or allergy to latex
- Application in the head area
- Application in the heart area
- Injured or otherwise impaired muscles
- Implanted defibrillators, implanted neurostimulators

1.3 – Possible Side Effects

The side effects may include, but are not limited to:

- Muscular pain
- Temporary muscle spasm
- Intramuscular fat decreases
- Temporary joint or tendon pain
- Local erythema or skin redness

1.4 – Intended Use

EMS MAXX Body Trim & Tone™ is intended to be used for:

- Improvement of abdominal tone, strengthening of the abdominal muscles, and development of a firmer abdomen.
- Strengthening, toning and firming of buttocks & thighs.

1.5 – Operating Environment

The device is exclusively for professional indoor use. The device is designed for indoor use only. Do not operate it in environments with explosion risks, water exposure, excessive dust, high humidity, or elevated oxygen levels.

1.6 – Patient Profile

Patients who seek improvement of their abdomen, buttocks and thighs and who do not show any signs of the conditions defined in the CONTRAINDICATIONS.
The device is intended for adults only.

1.7 – Prescription-Only Device

Prescription Use Only.

- The law restricts this device to be sold by or on the order of a physician.
- The device should only be used under the continued supervision of a physician or licensed practitioner.

3D Medical Technologies Inc. makes no representations regarding local laws or regulations that might apply to the use and operation of this medical device.

Chapter 2
Used Symbols and Markings


Warning


Caution

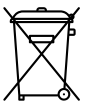

Type BF Applied Part


Warning! Magnetic Field


Follow Instructions for Use


No Access for Persons with Pacemakers


No Pushing


Electronic / Electrical Recycling

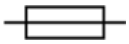

Name and Address of the Manufacturer


Date of Manufacturer


Class II Equipment


Dangerous Voltage

 Marking a Connector Sensitive to Electrostatic Discharge

 Fuse

SN Serial Number

LOT Batch Code

REF Catalogue Number

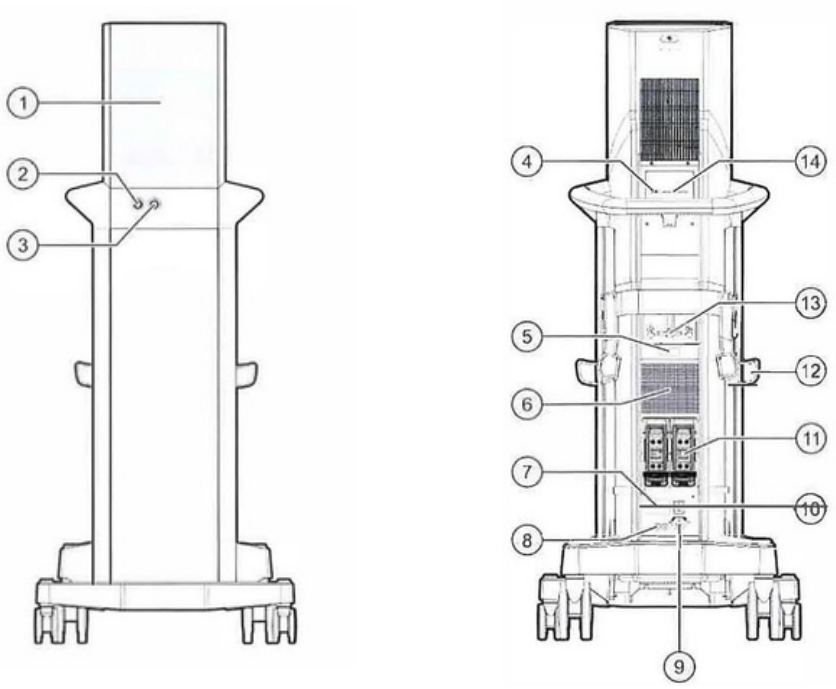
Rx ONLY Caution: Law restricts this device to be sold by or on the order of a physician.

 Standby (On/Off)

 Stop (Stop Therapy)

Chapter 3
Device and Accessories

3.1 – Front and Rear Panel of the Main Unit



① Touch Screen

② Button (Switch device from/to standby mode)

③ Button (Stop therapy)

④ USB port located in the grip space of the device. The port is for use only in accordance with IEC 60950-1; it is intended ONLY for technical servicing purposes, e.g. loading firmware; it is not intended for therapeutic use.

⑤ Production label (with serial number)

⑥ Ventilation grid

⑦ Type label

⑧ Two fuses

⑨ Mains cable connector

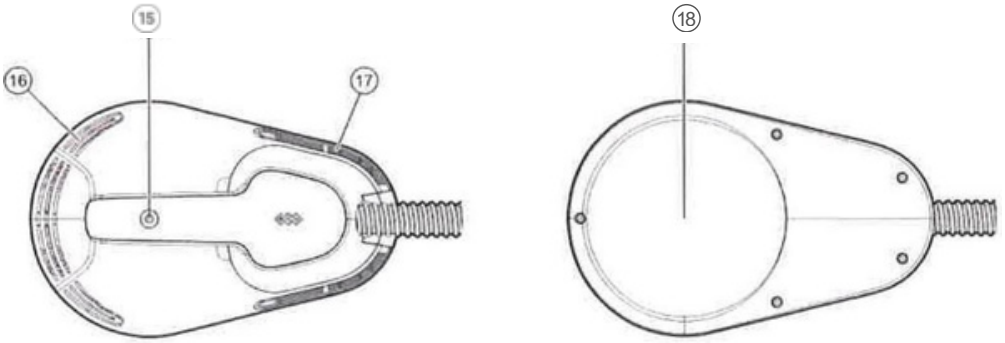
⑩ Mains power switch

⑪ Applicator connectors (A, B, C & D channels)

⑫ Applicator holder

⑬ Cable holder

3.2 – Applicator

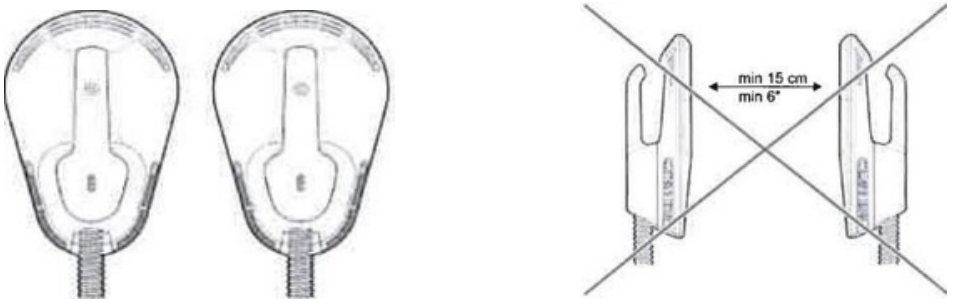


The applicator consists of a handle with a marked spot showing the coil center (15), air vents (16, 17) and therapy application area on the bottom side (18). The applicator may be in contact with the patient's skin. The warmest part (up to 109°F / 43 °C) of the device with potential contact is the applicator hose. The applicators should be in defined positions. See the applicators' position below.

The applicators must always be fixed by the fixation belt and must not be held in hand during therapy. The applicator cable must always be fixed in the cable holder during the therapy.

3.2.1 – Applicators' Position

When all applicators are in use, do not position them less than 6" (15 cm) facing or overlapping each other, as shown in the picture below.



When only a single applicator is in use, do not place it within a 6" (15 cm) proximity of any other applicator.

Incorrect position of applicators can cause high voltage risk to the operator, and the device can be damaged.

3.3 – List of Accessories

This device is not designed for use with any accessories or medical equipment other than those stated in this manual.

Available Accessories

- EMS MAXX Body Trim & Tone™ Applicator(s)
- Operators Manual
- Power Cord
- Mains Fuses
- Display Cover
- Fixation Belt

Chapter 4
Device Installation

Always inspect the packaging for damage. **If the packaging is damaged, do not proceed with assembly and set-up and return the device to the distributor.** Keep the original packaging to ensure safe future transport of the device.


Always inspect the packaging for damage. **If the packaging is damaged, do not proceed with assembly and set-up and return the device to the distributor.** Keep the original packaging to ensure safe future transport of the device.

Unpack the device and place it on a stable horizontal surface suitable for its weight.


Always place the device out of direct sunlight. The device gets warm during operation, so it must not be positioned near direct heat sources. The device is cooled by forced-air circulation. The cooling vents are located on the rear panel of the device and the applicator(s) and must not be covered. Do not place any heat-producing devices or any containers with water or other liquids on the device. Do not place the device close to appliances emitting strong electric, electromagnetic or magnetic fields or X-rays; otherwise, the device could be undesirably influenced.

For any questions, contact an authorized 3D Medical Technologies Inc. service center.

4.1 – Installation of the Applicator(S)

Installation Procedure:

1. Insert applicator(s) into the applicator holder(s).
2. Connect the applicator(s) to the main unit. Use safety locks to fix the connector(s).
3. Place the applicator(s) cable(s) into the cable holder.
4. Calibrate the applicator(s) (follow instructions in Chapter 6.4.5)

Chapter 5
Safety Precautions and Warnings

Read the User Manual carefully and become familiar with all its safety requirements, operating procedures and maintenance instructions before using the device. Use the device and its accessories only in accordance with the User Manual.

Therapy is strictly prohibited for persons with electronic implants.

Ensure that persons with pacemakers or defibrillators are not present in the vicinity of the device while the device is in Operation.

Do not deliver therapy to patients with metal implants.

Do not apply therapy over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

Do not apply therapy over the neck and/or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur, and the contraction may be strong enough to close the airway or cause difficulty breathing.

Do not apply therapy transcerebrally.

Do not apply over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.

Do not apply over, or in proximity to, cancerous lesions.

Avoid simultaneous application of applicators onto agonist and antagonist muscles.

Caution should be used with patients with: suspected or diagnosed heart problems; suspected or diagnosed epilepsy; a tendency to hemorrhage following acute trauma or fracture; following recent surgical procedures when muscle contraction may disrupt the healing process; over the menstruating or pregnant uterus, and over areas of the skin which lack normal sensation.

Long-term effects of chronic magnetic stimulation are unknown.

Always keep verbal contact with the patient during therapy. Never leave the patient unattended.

Before starting therapy, always check the device and its accessories (such as cable, applicators, connectors, touch screen) for mechanical, functional or other damage. In case of a defect or deviation from normal function, stop using the device immediately and contact a **3D Medical Technologies Inc** authorized service center. Do not use the device if any defects are present.

During therapy and device calibration, do not place any ferromagnetic or metallic materials, data carriers (credit or debit cards, USB flash drives etc.), electronic devices (mobile phones, tablets, watches, PCs etc.), and other devices' applicators and accessories in the vicinity less than 3 feet (1 m) of the applicator(s). Do not leave the applicator in the applicator holder when active. The applicator holder is metallic.

Incorrect position of applicators can cause high voltage risk to the Operator and the device can be damaged. See **Chapter 4.2.1.** for **applicator positions.**

Always fix the applicator(s) by fixation belts. Do not hold applicators in your hand during therapy. Always fix the applicator(s) cable(s) in the cable holder during therapy.

Do not connect any cables or devices to the USB ports. These are for service purposes only! Only devices approved by the manufacturer can be connected to these ports.

Modifications to the device and its accessories are prohibited. Do not try to open or remove the device's protective covers or disassemble the device for any reason. There is a danger of electric shock and serious injury. All servicing must be carried out by an authorized 3D Medical Technologies Inc. service center; otherwise, 3D Medical Technologies Inc. bears no responsibility for further Operation of the device.

Never use the accessories' ports or other ports to plug in anything else but what the ports have been designed for. There is a serious risk of electric shock and serious damage to the device! The device is equipped with a protective system against connecting accessories other than those supplied by the manufacturer. The device does not function with accessories from different manufacturers.

Do not place the applicator(s) close to any part of the device during therapy.

Protect the device against unauthorized use.

The applicator(s) can only be plugged in and unplugged when the device is turned off.

To unplug applicator(s), release safety locks and pull out the connector(s). Never pull the applicator(s) cable(s). Never disconnect the applicator(s) during therapy.

Use of accessories other than those specified in this manual may result in increased electromagnetic emissions or a decreased resistance of the device. This does not apply to any parts provided by 3D Medical Technologies Inc. as part of an authorized service.

The device should not be used adjacent to or stacked with other equipment.

Do not push the device.

Before starting therapy, make sure all parameters set match your requirements. Review therapy contraindications.

The mains to which the device will be connected must be installed and revised according to the current standards for electrical installations in healthcare facilities. Make sure the voltage parameters of the power supply grid and device requirements match.

Transport, store and operate the device in the environment defined in Chapter 10. Do not operate the device if there is any danger of explosion or water intrusion into the device. The device cannot be in contact with flammable anesthetics or oxidizing gases (O2, N2O, etc.). The device is not intended for exterior use!

Do not place the device near other devices that produce strong electromagnetic fields (such as diathermy, X-ray, cell phones, and radiofrequency) in order to prevent mutual functionality influence. If this happens, move the device further away from the source of interference or contact an authorized 3D Medical Technologies Inc. service center.

Do not place the device in direct sunlight or near heat sources. It might lead to an excessive temperature increase and a possible risk for the patient and the device. The device heats up during operation and, therefore, must not be located near direct heat sources. The device is cooled by forced air circulation. The cooling vents are located on the rear panel of the main unit and the applicators' sides. The vents must not be covered. When placing the device, leave at least 4 inches of free space behind the rear panel.

Do not place any objects that produce heat or objects containing water or other liquids on the device.

After moving the device from a cold to a warm environment, wait until the temperature equalizes before connecting to the main power point (for at least 2 hours).

Applicators' and cables' surfaces might be hot when in operation or during the cooling process after therapy. Never turn the device off before the cooling process is finished.

The device displays messages concerning deviations or defects of the device and its accessories. If you are not sure what a message means, stop using the device and contact a 3D Medical Technologies Inc. authorized service center.

Keep the device out of reach of children.

During transport, always disconnect applicators from the device.

The device must only be operated in a professional healthcare facility.

The device has applied parts of the BF (Body Floating) type — i.e. parts which come into direct physical contact with the patient during normal device use.

The output voltage values of ports marked with this symbol can exceed safe values.

Dissipate static electricity by touching a grounded metal object before connecting or handling the device connected to the USB port.

Chapter 6
Basic Device Operation

6.1 – Applicator Exchange

You must calibrate the applicator after every installation or exchange.

The applicator can only be unplugged when the device is turned off. Never turn the device on when the applicator is disconnected

6.2 – Device Startup / Shutdown

1. Plug the main unit to the mains using the power cord. Plug the main unit directly into the mains; do not use extension cords with multiple sockets or multi-socket adaptors.
2. Switch the mains switch on the rear panel to the “I” position.
3. Press the On/Off button on the front panel.
4. Turn the device off by pressing the On/Off button. Thermal energy may be accumulated in the applicator at the end of the therapy; the automatic cooling process of the applicators has to be completed before the device shuts off. To interrupt the cooling process, press the Cancel button. The unit turns off automatically alter the cooling process is completed (when ambient and applicators’ temperatures are equal).

Always let the automatic cooling process finish before turning the device off. Not respecting the required cooling time could cause the device damage and the Operator or a patient injury.

6.3 – Navigation Controls

6.3.1 – Setting the Therapy by Controls

Preset therapy can be modified by controls placed on the therapy screen.

The following items and functions are displayed on the therapy screen:

1. Pattern Controls
2. Channels Selector
3. Start/Pause Therapy
4. Stop Therapy
5. Setting Up Therapy Parameters
6. Energy Adjustments

6.3.2 – Pattern Controls

Sport Mode	Suitable for first-time treatments.
Gentle Mode	Ideal for massaging to relax and soothe muscles.
Professional Mode	Suitable for muscle building.

6.3.3 – Channel Selector

Press the channel selector to select active channel(s). Select between channel A, channel B or select both channels A and B.

Channel A and B Selected

Channel C Selected

Channels D selected

6.3.4 – Therapy Chart

The therapy chart indicates intensity settings during treatment.

6.3.5 – Setting Therapy Time

Therapy time can be set up to 60 minutes using the time slider control.
This function is available only before therapy is started.

6.3.6 – Setting Intensity

Intensity can be set using the intensity slider control on the touch screen. This function is available only when therapy has started.

The maximum intensity setting may be limited when higher frequencies or a longer therapy time are set.

6.3.6 – Indications and Warnings

The following symbols may appear on the screen to inform the user about the therapy and the state of the device:

Metal Alarm — This indicates the presence of metal near the handle. Please inspect the area and remove any nearby metal objects before proceeding.t

Handle Disconnected Alarm — This indicates that the handle is either not connected or not securely attached. Please ensure the handle is properly connected before powering on the device.

6.4 – Unit Settings

Press the unit setting button on the touch screen to browse through the following menus of function settings and information screens:

Set the following parameters:

- Sound
- Brightness
- Date & Time
- Unit
- Applicators

6.4.1 – Sound

Use this option to change sound volume.

6.4.2 – Brightness

Use this option to change display brightness.

6.4.3 – Date & Time

Use this function to set the time and date.

6.4.4 – Unit

In the unit submenu, view information and/or change settings for the following parameters:

- Software
- Hardware
- Network Settings
- Keys
- Last Events
- Operation Mode
- Service Functions
- Service

6.4.4.1 – Software

Displays software packages and version number.

6.4.4.2 – Hardware

Displays device hardware and serial numbers.

6.4.4.3 – Network Settings

Displays information about network setup and its parameters.

6.4.4.4 – Keys

Displays connection key required to work with the device (for servicing purposes only).

6.4.4.5 – Last events

Displays list of the device's last events.

6.4.4.6 – Operation Mode

Use this function to switch between the device's Sport Mode, Gentle Mode & Professional Mode. Each mode opens further possibilities for setting therapy parameters.

Each protocol consists of three sections.

Energy Settings	You can adjust energy from 0-100% by pressing **"-"** or **"+"**.
Time Settings	You can adjust working time from 0-60 minutes (Min) by pressing **"-"** or **"+"**. The system default value is 30 Minutes.
Start / Stop Settings	Press **"Start"** and the treatment head starts working. Press **"STOP"** and the treatment head stops working.
Strength Level	You can choose strength levels from I to III in *Sport Mode*. 
	You can choose strength levels from I to IV in *Gentle Mode*.
Frequency / Sub-Frequency Settings	You can adjust these settings in the **Professional Mode** ONLY.

6.4.4.7 – Service Functions

This item is intended for servicing the device, including:

- Restore default settings
- Factory reset
- Export logs
- Enter unlock code

6.4.4.8 – Servicing

Use this function to access servicing mode. It can only be used by an authorized service center.

6.5 – Applicators

After installing or replacing an applicator, it is essential to calibrate it to ensure optimal therapy performance and proper function of the Pulse Quality Monitor.

Before starting the calibration process, ensure the applicator is cooled down and removed from the applicator holder. Additionally, all metallic or ferromagnetic objects must be removed from the applicator area, with a minimum distance of 3 feet (1 meter) from the applicator.

Chapter 7
Therapy

Suggested therapy time is 30 minutes per session, with sessions separated by at least 2 days.

7.1 – Preparing the Therapy

Prior to the treatment, the patient should remove all jewelry and electronic devices. For easy application it is recommended to remove clothes from the treated area and to position the patient lying down on the bed.

7.2 – Placing the Applicator

Position the applicator(s) on the treatment area, ensuring the connecting cable(s) face the patient's feet. Secure the applicator(s) with the fixation belt provided. The belt should be tightened over the center of the coil(s) beneath the applicator handle(s) to reduce any movement during therapy. Ensure that the bottom of the applicator(s) is in full contact with the treatment area.

Avoid placing the applicator(s) over bones or joints, as this may lead to discomfort during treatment.

7.3 – Setting the Therapy by a Preset

Select a preset in the navigation controls LIST by touching the button of the desired protocol on the screen.

After the selected preset is loaded the device displays the Therapy screen. Select the applicator(s) to be used for the treatment by pressing the channel selector on the screen.

The treatment time can be adjusted using the time slider control on the Therapy screen. This function is available only before start of the therapy. The default duration of a treatment is 30 minutes.

Therapy time cannot be modified when therapy has started.

7.4 – Therapy Start

Press the start button on the touch screen and fill in the basic patient demographic information fields. Press the start button on the bottom of the screen again to start therapy.

Adjust the stimulation intensity until comfortable motor response of the treated area is achieved. The stimulation intensity has to be adjusted according to the patient's feedback.

7.5 – Course of Therapy

During therapy the screen shows sliders with the main therapy parameters. The remaining time is highlighted to provide an instant overview of the course of the ongoing therapy.

Presence of an electromagnetic field during the ongoing therapy is indicated on the device by a non-zero intensity value on the intensity slider on the screen.

The intensity can be modified during therapy using the intensity slider control on the touch screen. Adjust the intensity according to patient's condition and feedback.

The maximum intensity may be limited when higher frequencies or a longer therapy time are set.

During therapy, check the applicator(s) regularly and make sure they stay positioned over the treated area throughout. Do not turn off or unplug the device during therapy or the cooling process.

7.6 – Therapy Interruption - End

Terminate the therapy at any point by pressing the stop button on the touch screen or the stop button on the front panel.

If patient reports uncomfortable pain at the site of application during therapy, stop therapy immediately.

When the therapy time expires, therapy is stopped automatically. Remove the fixation belt and the applicator(s) from the patient. The fixation belt is reusable; do not discard.

Chapter 8
Troubleshooting

The device is designed with operator and patient safety in mind. During each start-up, the device carries out self-diagnostics of the internal circuits and functions. If there is any unacceptable deviation, the device therapy tab is blocked. If the problem persists after device restart (turn the device off and on using the main switch), follow the instructions on the screen and/or call an authorized 3D Medical Technologies Inc service center.

The following table serves as a guideline to solve some common problems that may occur during the operation of the device.

Problem	Possible Reason & Solution
The device does not start.	Check the power cord and the power cord connector. Switch the main switch to the ON position (“I”).
The therapy tab is not available after device start.	The device did not pass self-diagnostics. Check that the applicators are correctly connected and restart the unit. If the problem persists, follow the on-screen instructions or call a **3D Medical Technologies Inc.** service center.
Pulse Quality Monitor stopped the therapy.	Remove all metal objects from the proximity of applicators. Calibrate the applicators. Problems can persist if the environment where the device is operated is strongly electromagnetically polluted.
Therapy stopped unexpectedly due to the applicator or main unit overheating.	Ensure that all air vents of the applicators are free. Ensure that the recommended parameters of the therapy and device operating conditions are not exceeded.
The device does not turn off immediately after the button is pressed.	Applicator cooling is still in process. The device will turn off automatically when the cooling process ends.

Error during applicator calibration.	Check that the applicators are correctly connected. Remove the calibrated applicator from its holder. Remove all metallic or ferromagnetic objects in proximity to the applicator. Restart the device and repeat calibration.
Applicators were disconnected from the main unit while in operation.	Switch the device off and reconnect the applicators.
Applicators were connected to the main unit while in operation.	Restart the device.
Therapy cannot start, and the temperature symbol on the screen is shining.	The applicators or the main unit are overheated. Wait until the temperature symbol stops shining and starts again.
Therapy cannot start, and the temperature and device's heat symbols on the screen do not shine. A warning message about exceeding the allowed temperature appears.	The device can be overheated if the maximum recommended therapy parameters or operating conditions are not respected, or if another internal problem has occurred. Switch the unit off and let it cool down for at least 30 minutes. If the problem persists after the device restart, follow the instructions and call your **3D Medical Technologies Inc.** service center.
It is not possible to reach the same intensity values in consecutive therapies.	Maximum intensity values may differ in consecutive therapies due to changes in ambient temperature and accumulated heat in the applicator(s).

Chapter 9
Maintenance

Presence of an electromagnetic field during the ongoing therapy is indicated on the device by a non-zero intensity value on the intensity slider on the screen.

Do not repair the device. All servicing must be carried out by an authorized **3D Medical Technologies Inc.** service center. Only original parts can be used for repair; otherwise, **3D Medical Technologies Inc.** bears no responsibility for further Operation of the device.

Before contacting your authorized **3D Medical Technologies Inc.** service center, please have the device model number, serial number, and a detailed description of the issue you have encountered ready.

The applicators have a limited service lifetime. After expiration, the applicators must be replaced before further Operation of the device. To replace the applicators, **call** your **3D Medical Technologies Inc.** supplier or your service center.

9.1 – Fuse Replacement

Device fuses are located in the black fuse housing on the rear panel of the main unit. Ensure that the type and rating of the new and the replaced fuses match.

1. Turn off the device and disconnect the unit from the mains.
2. Remove the fuse housing by using a screwdriver.
3. Remove the burnt fuse.
4. Insert the new fuse. Make sure the fuse is properly seated within the fuse housing.
5. Connect the power cable to the unit and to the mains.
6. Turn on the device.

9.2 – Cleaning the Device Surface

The device has to be **always turned off** by means of the mains switch **when cleaning.** The mains power switch has to be in OFF (“0”) position.

To clean the device, use a soft cloth slightly moistened with water. Never use agents containing alcohol, chlorine, ammonia, acetone, benzine or thinners. Clean the touch screen gently by using a dry soft cloth. The cloth may be slightly moistened with a commercially available screen cleaner. Never apply the cleaner directly on the screen! Never use abrasive materials, otherwise the surface of the device or accessories could get damaged.

9.3 – Cleaning of Accessories That Come into Contact with the Patient

Always turn the device off before disinfecting applicators. Disinfectant must not reach the air vents.

Clean the applicators and the fixation belts after each use with disinfectants approved for use in medical environments. Do not use agents containing chlorine or those with a high alcohol content (more than 20 %). Use a soft cloth slightly moistened with disinfectant.

After disinfection, the accessories must be rinsed with a soft cloth slightly moistened with clean water to prevent an undesired allergic reaction!

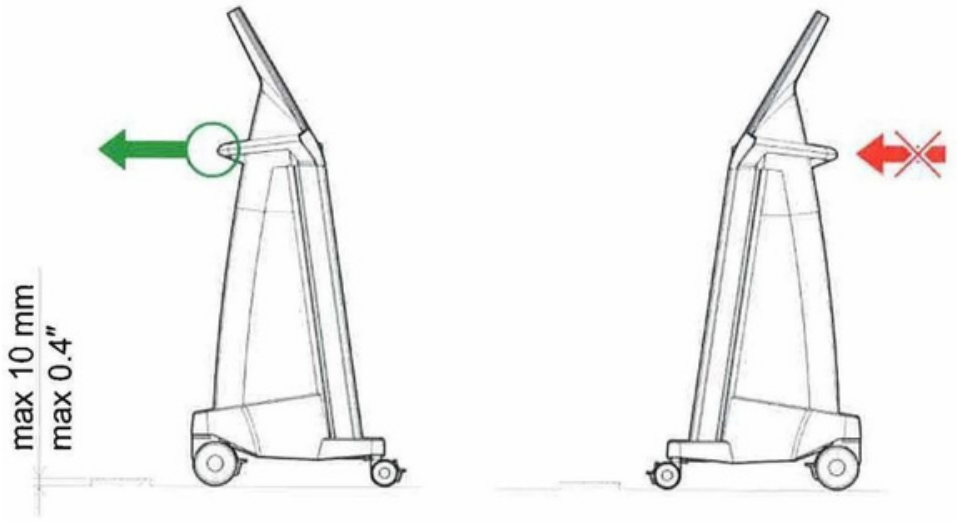
This device and its accessories are non-sterile and are intended for non-invasive use. They must be cleaned and disinfected between uses. Sterilization is not required and not permitted.

9.4 – Transport and Storage

Store the device packaging. Transport the unit and the applicators in the original packaging to ensure their maximum protection. Unplug the power supply cable and all accessory cables. Avoid strong shocks. The device should only be stored and transported under the defined conditions.

9.4.1 – Transport of Device

Before moving the device, unplug the power supply cable and all accessories. Unblock all wheels of the device. Pull the device using the device holder; never push the device. See the picture below for the device permitted transport position.



9.5 – User Data Management

The device incorporates a usage data management system for the purpose of running diagnostics and improving usability and performance of the system. Data collected does not contain any patient identification information.

The device is connected to the Internet through a USB dongle. **In case of any device misbehavior unplug the USB dongle.**

Chapter 10
Treatment Parameters

10.1 – How to Calculate Body Fat Percentage

You must calibrate the applicator after every installation or exchange.

Gender	Body Fat Percentage Formula
Female	Parameter a = Waist Circumference (cm) × 0.74 Parameter b = Body Weight (kg) × 0.082 + 34.89 Total Body Fat Weight (kg) = a-b Body Fat Percentage = (Total Body Fat Weight ÷ Body Weight) × 100%
Male	Parameter a = Waist Circumference (cm) × 0.74 Parameter b = Body Weight (kg) × 0.082 + 44.74 Total Body Fat Weight (kg) = a-b Body Fat Percentage = (Total Body Fat Weight ÷ Body Weight) × 100%

10.2 – Standard of Body Fat Percentage

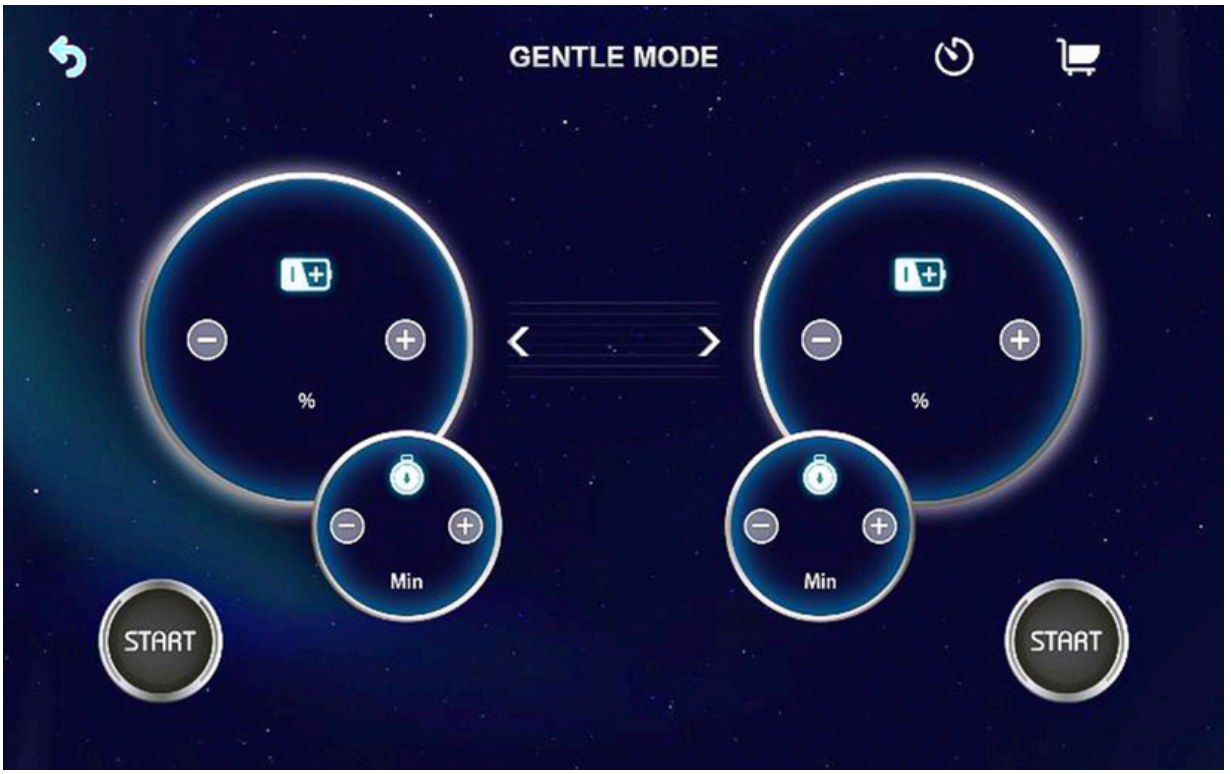
Body Figure	Body Fat Percentage (Male)	Body Fat Percentage (Female)
Underweight	5-10%	5-20%
Healthy Weight	11-21%	21-34%
Overweight	22-26%	35-39%
Obese	27-45%	40-45%

10.3 – Applicator Modes

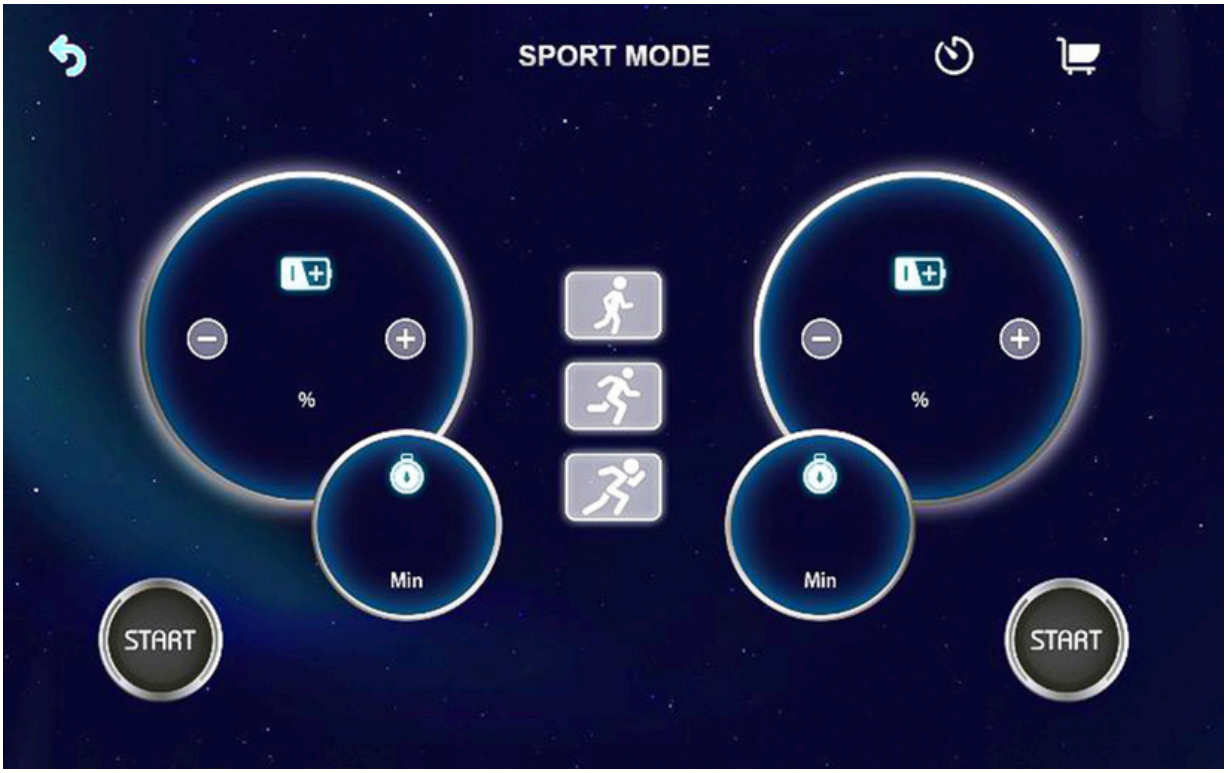
Professional Mode (For Gaining Muscles)				
Female				
Working Time		**30 min**		
Body Fat Percentage	**Underweight: 5 - 20%**	**Healthy Weight: 21 - 34%**	**Overweight: 35 - 39%**	**Obese: 40 - 45%**
Main Frequency (Hz)	1~10	5~10	5~10	1~5
Main Time (s)	1~3	1~2	1~2	1~2
Energy	30%-60%	40%-70%	40%-80%	50%-90%
SUB Frequency (Hz)	20-30	30-35	35-40	40-50
SUB Time (s)	3~8	1~4	1~3	1

10.3 – Applicator Modes

Professional Mode (For Gaining Muscles)				
Male				
Working Time		**30 min**		
Body Fat Percentage	**Underweight: 5 - 10%**	**Healthy Weight: 11- 21%**	**Overweight: 22 - 26%**	**Obese: 27 - 45%**
Main Frequency (Hz)	1~10	5~10	5~10	1~5
Main Time (s)	1~3	1~2	1~2	1~2
Energy	40%-60%	40%-70%	50%-80%	60%-90%
SUB Frequency (Hz)	20-30	30-35	35-40	45-50
SUB Time (s)	3~8	1~4	1~3	1



Gentle Mode (For Muscles Relaxing)				
Working Time		**30 min**		
		Body Figure	Energy (Female)	Energy (Male)
Strength Level	I	Underweight	30%-50%	40%-60%
	II	Healthy Weight	40%-60%	40%-70%
	III	Overweight	40%-70%	50%-80%
	IV	Obese	50%-80%	60%-90%
	Choose working modes according to patient's tolerance.			



Sport Mode (Easier and Convenient for Beginners)				
Working Time		**30 min**		
		Body Figure	Energy (Female)	Energy (Male)
Strength Level	I	Underweight	50%-70%	60%-80%
		Healthy Weight	60%-80%	70%-90%
	II	Overweight	50%-80%	60%-90%
	III	Obese	60%-90%	60%-100%
	Choose working modes according to patient's tolerance.			

10.4 – Parameters for Pelvic Floor Muscles Treatment

Professional Mode (For Pelvic Floor Muscles Treatment Cushion)				
Female				
Working Time		**30 - 40 min**		
Body Fat Percentage	**Underweight: 5 - 20%**	**Healthy Weight: 21 - 34%**	**Overweight: 35 - 39%**	**Obese: 40 - 45%**
Main Frequency (Hz)	3~10	5~10	5~10	1~5
Main Time (s)	1~3	1~2	1~2	1~2
Energy	20%-35%	30%-45%	35%-55%	45%-65%
SUB Frequency (Hz)	20-30	30-35	35-40	40-50
SUB Time (s)	3~8	1~4	1~3	1

Professional Mode (For Pelvic Floor Muscles Treatment Cushion)				
Male				
Working Time		**30 min**		
Body Fat Percentage	**Underweight: 5 - 20%**	**Healthy Weight: 21 - 34%**	**Overweight: 35 - 39%**	**Obese: 40 - 45%**
Main Frequency (Hz)	3~10	5~10	5~10	1~5
Main Time (s)	1~3	1~2	1~2	1~2
Energy	25%-40%	35%-50%	40%-60%	50%-70%
SUB Frequency (Hz)	20-30	30-35	35-40	45-50
SUB Time (s)	3~8	1~4	1~3	1

Note

(1) Body Fat Percentage is the average value of Total Body Fat Weight, while treatment is for some parts of the body, thus parameters shall be adjusted within patient's tolerance. Within patient's tolerance, larger parameters bring better treatment results.

(2) People who often play sports/exercise develop more stretched muscles. Thus, they can accept higher Energy and frequency. To prevent energy loss during treatment caused by thick fat layer, obese patients may need higher Energy. Parameters listed are only for reference, adjust parameters within patient's tolerance.

(3) Under the same Energy, patients with more muscles may feel more severe muscle vibration.

**Lower the Energy for treatment on muscular calves.*

Chapter 11
Technical Parameters

Operating Conditions	
Ambient Temperature	50 °F to 86 °F (+10 °C to +30 °C)
Relative Humidity	30 % to 75 % (non-condensing)
Atmospheric Pressure	800 hPa to 1060 hPa
Position	Vertical — on castors
Type of Operation	Continuous

Transport & Storage Conditions	
Ambient Temperature	14 °F to 131 °F (-10 °C to +55 °C)
Relative Humidity	10 % to 85 % (non-condensing)
Atmospheric Pressure	500 hPa to 1060 hPa
Position	Vertical / Horizontal in the packaging
Other Conditions	Transport & store only in the supplied packaging

11.1 – Shelf-Life

This device does not have a defined expiry date. The materials used in its manufacture are stable under normal storage conditions. The device may be used as long as it remains undamaged and within its original packaging integrity, as per the storage conditions/instructions.

Power Supply	
Maximum Input	4000 W (peak) 100 V to 240 V AC (mains impedance max. 0.20 (I)
Supply Voltage	It is recommended to supply the device from a separate power circuit. If the RCD is used, it shall also be separate and have a time delay.
Frequency	50 to 60 Hz
Protection Class	II (connection to protective earth for functional reasons only).
External Fuse	2x T10 AH / 250 V, 5x20 mm
Switch	On the front panel, marked by symbol **(5)**
Mains Power Switch	On the rear panel, positions **0** (off) and **I** (on)

Classification	
Applied Parts Type	BF / Single-Patient
Number of Channels	Four
Essential Performance According to IEC 60601-1	No essential performance

Design	
Weight	165 lb (75 kg) / 231 lb (105 kg) including packaging and accessories
Dimensions (W x H x D)	23 x 55 x 23 in (580 x 1380 x 580 mm)
Packaging Dimensions (W x H x D)	21 x 45 x 33 in (540 x 1150 x 840 mm)

Display	
Graphic Colour Touch Screen	15.6" / 39.6 cm, 1920 x 1080 pixels

Therapy	
Time Settings (±5 %)	0 to 60 minutes
Pulse Type	Sine, biphasic
Magnetic Field Pulse Width (±20 `1/O)	280µs
Settable Intensity Range (±20 %)	0.5-1.8 T (on the coil surface)
Intensity Settings Unit	Relative 0-100 % (therapy pulses not generated at 0 %)
Pulse Repetition Rate (Accuracy ±5 %)	1-150 Hz

Power Cord Specifications	
Rating	125 V, 15 A (250 V, 10 A)

11.2 – Electromagnetic Compatibility (EMC)

The **EMS MAXX Body Trim & Tone™** device should be used with caution in accordance with the **EMC** (Electromagnetic Compatibility) directive. **It must be installed following the EMC guidelines provided in this manual to prevent any adverse effects from mobile RF transceivers.**

Using accessories, transducers, or cables other than those specified, except for those sold by the manufacturer as spare parts for internal components, may increase radiation or decrease the device's durability.

11.3 – Guidance and Manufacturer's Declaration — Electromagnetic Emissions

The **EMS MAXX Body Trim & Tone™** device is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Group 1	EMS MAXX Body Trim & Tone™ device uses RF energy only for its internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Class B	EMS MAXX Body Trim & Tone™ device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonie Emissions IEC 61000-3-2.2019	Class B	**Warning:** The EMS MAXX Body Trim & Tone™ device is designed for use by medical professionals only. It may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the device or shielding the location.
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3.2013 + A1.2019	Complies	

11.4 – Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Device

EMS MAXX Body Trim & Tone™ device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **EMS MAXX Body Trim & Tone™** device, 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 = 1.17i112	80 MHz to 800 MHz d = 1.17-VP	800 MHz to 2.7 GHz d = 2.34\1P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

11.5 – Guidance and Manufacturer's Declaration — Electromagnetic Immunity

The **EMS MAXX Body Trim & Tone™** device is intended for use in the electromagnetic environment specified below. The user of the device 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 61000-4-2:2008	± 8 kV Contact ± 2,4,6,8,15 kV Air	± 8 kV Contact ± 2,4,6,8,15 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 61000-4-4:2012	± 2 kV for power supply lines +1kV for input/output lines	± 2 kV for power supply lines +1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2017	± 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 and Power			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Voltage Dips, Short Interruptions and Voltage Variations in Power Supply Input Lines IEC 61000-4-11:2017	<5 % UT (>95 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <5 % UT (>95 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25 cycles at 0° <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <5 % UT (>95 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25 cycles at 0° <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EMS MAXX Body Trim & Tone™ requires continued Operation during power mains interruptions; it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz)	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the AC mains voltage before application of the test level.

11.6 – Guidance and Manufacturer's Declaration - Electromagnetic Immunity

EMS MAXX Body Trim & Tone™ device is intended for use in the electromagnetic environment specified below. The user of the **3D Medical Technologies Inc.** device must ensure that the device is used in a safe and controlled environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6:2013	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the EMS MAXX Body Trim & Tone™ device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d 1.17e d = 1.17e 80 MHz to 800 MHz d = 2.34e 800 MHz to 2.7 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).
Radiated RF IEC 61000-4-3:2010	10 V/m 80 MHz to 2.7 GHz	10 V/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 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. Suppose the measured field strength in the location in which the **EMS MAXX Body Trim & Tone™** is used exceeds the applicable RF compliance level above. In that case, the device should be observed to verify normal Operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **EMS MAXX Body Trim & Tone™**.

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

Manufacturer

This product is manufactured by:

3D Medical Technologies Inc.

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