EVOLVE X

Operator Manual

Evolve System

with Tite, Transform and Tone

Version: DO610502A

INMODE

Operator Manual: EvolveX System with Tite Transform Tone Applicator

DO610502A

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Table of Contents

1 Section 1: Introduction 1

1.1 Before You Start 1
1.2 System Overview 1
1.3 Conventions Used in the Manual 2
1.4 Explanation of the Symbols used on the System 2

2 Section 2: Safety 4

2.1 The Patient 4
2.2 Treating Attendant 4
2.3 Cautions 5
2.4 Electrical and Mechanical Safety 5
2.5 Fire Hazards 5
2.6 Safety Features of the System 6
2.7 Safe Use of the Active Accessories 6
2.8 Device and Applicators Labels 8
2.9 Equipment Classification 10

3 Section 3: System Installation 11

3.1 Electrical Requirements 11
3.2 Environmental Requirements 11
3.3 Equipment List 11
3.4 Unpacking 12
3.5 Installation 13
3.6 Moving the System 13
3.7 System Disposal 14

4 Section 4: Device Description 15

4.1 Rear Panel 15
4.2 Front Panel and Operator Control Panel 16
4.3 Software Screens 17
4.4 Sound Indicator 22
4.5 Cut-Off Temperature Control 22
4.6 Applicator 23
4.7 Patient Call Button (Treatment Deactivation Switch) 24
4.8 Belt Set 25

5 Section 5: System Operation 25

5.1 Device Start-Up 25
5.2 System Shutdown 25

6 Section 6: Transform Treatment Information 27

6.1 Indications for Use 27
6.2 Contraindications 27
6.3 Precautions 30
6.4 Possible Adverse Effects 31
6.5 Applicator Cleaning Instructions Prior to Use 31
6.6 Pre-Treatment Recommendations 32
6.7 Treatment Recommendations 33
6.8 Treatment Schedule 34
6.9 Post Treatment Recommendations 35

7 Section 7: Tone Treatment Information 36

7.1 Indications for Use 36
7.2 Contraindications 36
7.3 Precautions 37
7.4 Possible Adverse Effects 38
7.5 Applicator Cleaning Instructions Prior to Use 38
7.6 Pre-Treatment Recommendations 39
7.7 Treatment Recommendations 40
7.8 Post-Treatment Recommendations 40
7.9 Treatment Schedule 40

8 Section 8: Tite Treatment Information 42

8.1 Indications for Use 42
8.2 Contraindications 42
8.3 Possible Adverse Effects 43
8.4 Applicator Cleaning Prior to Use 43
8.5 Pre-Treatment Recommendations 44
8.6 Treatment Recommendations 45
8.7 Treatment Schedule 46
8.8 Post-treatment Recommendations 46

9 Section 9: System Maintenance 47

9.1 Maintenance & Frequency 47
9.2 Before and after each treatment 47
9.3 Once a Week 47
9.4 Once a Year 47

10 Section 10: Troubleshooting 48

10.1 Description of Faults with All Applicators 48

11 Section 11: System Specifications 50

11.1 Output Power Curves 51
11.2 EMC Safety 52

1 Section 1: Introduction

1.1 Before You Start

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

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

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

1.2 System Overview

The EmBody Platform is marketed as the EvolveX System and supports Tite, Transform and Tone technology.

The EvolveX System with the Tite and Transform in RF mode Applicators is a hands-free medical aesthetic device 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.

RF energy does not cause any thermal damage to the treated skin. The System provides individual adjustment of RF power to achieve maximum efficiency, safety and comfort for each patient. The System provides enhanced safety while minimizing possible side effects by constantly monitoring RF parameters.

The EvolveX System with Tone and Transform in EMS mode Applicator is used in EMS mode for:

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

And in TENS mode for:

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

- Post-traumatic acute pain

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

1.3 Conventions Used in the Manual

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

WARNING! This information is extremely important!

ATTENTION! Consult Accompanying Document.

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

1.4 Explanation of the Symbols used on the System

Symbol	Description
	CSA marking (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	Type B Equipment.
	HF Isolated Patient Circuit
	Follow the operating instructions

Symbol	Description
	Federal (US) law restricts this device to sale by the order of a physician licensed by the law of the state in which he practiced to use or order the use of the device
	Non-Ionizing Radiation
	Serial Number
	Reference part number
	Symbol for date of manufacture. This symbol is accompanied by a date
	Symbol for manufacturer. This symbol is accompanied by the name and address of the manufacturer
	Symbol for do not reuse/single use only. This symbol is used for disposable one-time-use products

Table 1-1: Device Symbols

2 Section 2: Safety

This chapter describes safety issues regarding the use and maintenance of the EvolveX 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.

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

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

 RF energy and Electrical Pulses energy can cause injury if used improperly.

 High voltage is present inside the system.

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

2.1 The Patient

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

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

2.2 Treating Attendant

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

Personnel should not operate the System until they have been fully educated in its use. Make sure that all treatment personnel are familiar with the System controls and know how to shut down the System instantly.

There are no user-serviceable parts in the System, and all service and repair must be performed only by the factory or authorized field service technicians.

2.3 Cautions

The following cautions should be heeded for safe System use:

- Do not touch the System's inner parts.
- Service is supplied by company authorized personal only.
- To avoid damage, do not allow the Applicator to come in contact with hard materials.

2.4 Electrical and Mechanical Safety

- Keep all covers and panels of the system closed. Removing the covers creates a safety hazard.
- Keep hands away from the Applicator during the System start-up.
- Perform maintenance procedures when the system is shut down and disconnected from the power.
- The system is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.
- Move the system slowly and carefully. The System weighs approximately 33kg (72lb.) and may cause injury if proper care is not used when moving it.
- Provide as much distance as possible between the system, RF Applicator and other electronic equipment as the activated RF generator may cause interference between them.

2.5 Fire Hazards

- Materials conducting RF energy cause a temperature rise of the absorbing material. Do not use the System in the presence of explosive or flammable materials conductive to RF.
- Do not use the system in the presence of explosive or flammable materials.
- Materials conducting RF energy cause an increase in temperature of the absorbing material.
- 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.

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.
- An audible tone indicates energy activation.
- Special audible tone will be activated in case of bad coupling of one of the applicators.
- Patient call button allows to pause the treatment in case of discomfort
- During activation, the system performs a self-test of the hardware.
- Hardware is tested every few msec. to ensure proper operation of electrical circuits.
- Skin surface is monitored during the RF treatment. RF energy delivery is terminated when skin temperature accidentally reaches the Cut-Off level.
- System starts at a low setting.

2.7 Safe Use of the Active Accessories

- Examine the connection of the Applicator 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 Applicator cords around metal objects. It may induce current that could lead to electrical shocks, fire or injury to the patient or personnel.
- When using the RF applicators, ensure that all electrodes are in full contact with the skin. Bad coupling of electrodes with the skin results in a specific warning sound, a message on the screen, and disabling RF.

 Do not connect a wet accessory to the System.

 Do not immerse the Applicator under water at any time.

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

 Only Applicators manufactured or approved by InMode Ltd. should be used with EvolveX System.

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

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

 Always turn off and unplug the device before cleaning.

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

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

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

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

The operation of the EvolveX may adversely influence the operation of other electronic equipment.

The RF treatment mode and EMS/TENS mode should not be used sequentially.

To avoid the risk of electric shock, this equipment must only be connected to a main supply with protective earth.

For Tone/Transform Applicator only: Not recommended for transthoracic use.

2.8 Device and Applicators Labels

As required by national and international regulatory agencies, appropriate warning and information labels have been attached to specific locations on the instrument as identified below. The following device labels are located on the EvolveX device console and the Applicator:

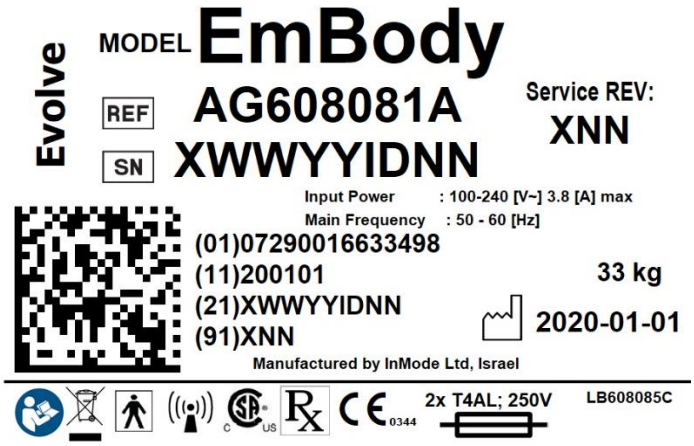


Figure 2-1: System Certification and Identification Label

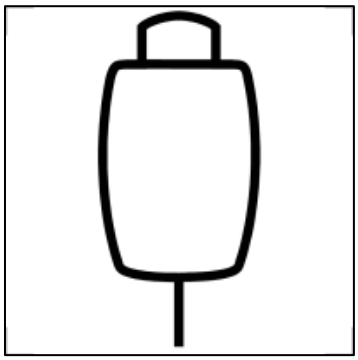


Figure 2-2: Patient Call Button

Figure 2-3: Belt Label

Applicator Labels

Manufacturer identification labels are placed on the Tite and Transform Applicators.

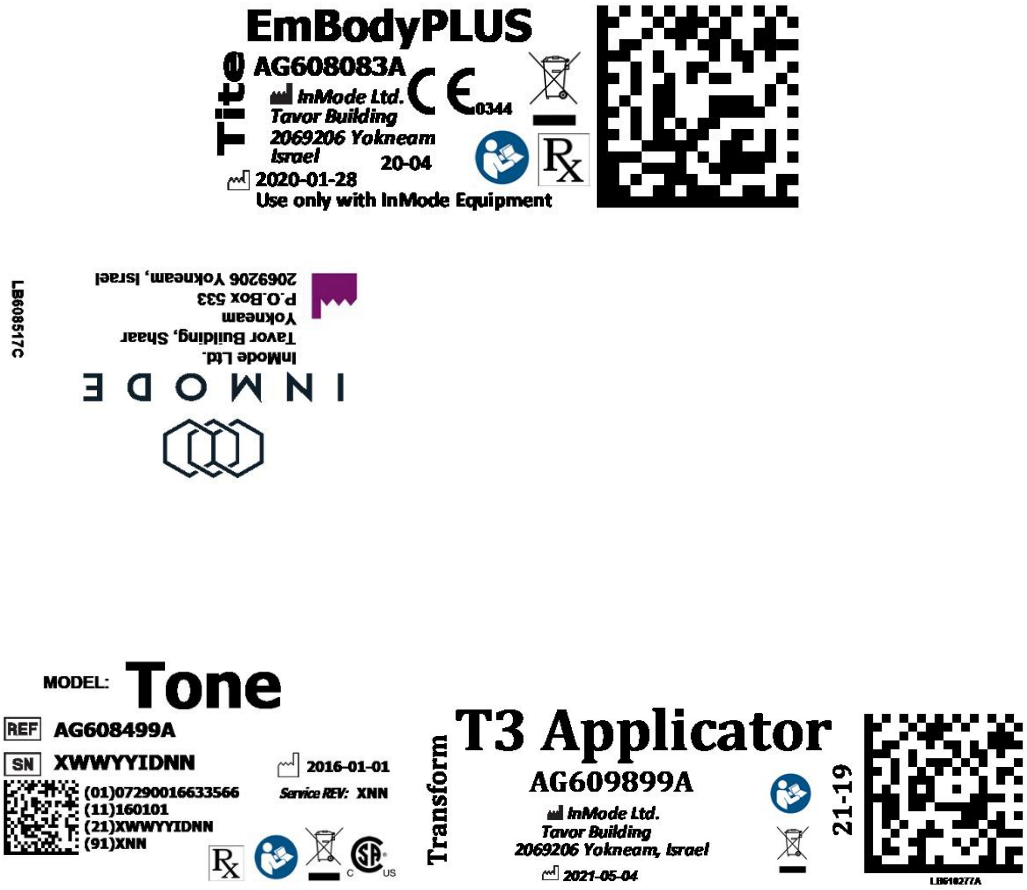


Figure 2-4: Tite, Transform and Tone Applicators Identification Labels

2.9 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 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. Zmax = 0.03Ω.
- Power receptacles must be within 15 feet of the System site.
- The System should not share a power line with other equipment.
- Power receptacle must include protective earth and must be checked before connecting the system.

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

 Proper grounding is essential for safe operation.

3.2 Environmental Requirements

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

3.3 Equipment List

The System includes the following:

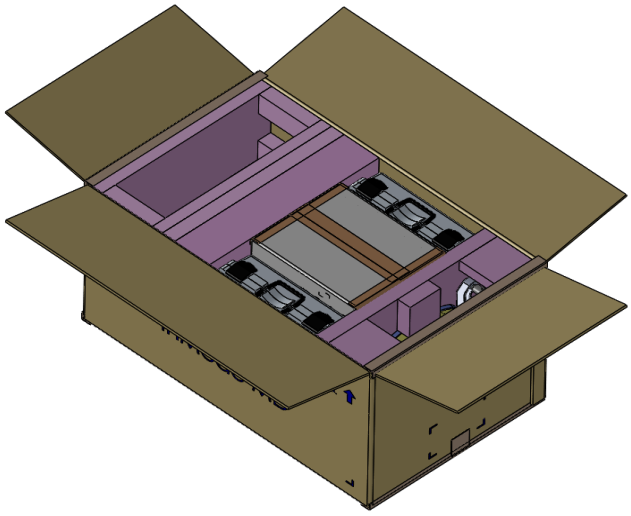
- System platform
- Harness support
- Harness
- Belts Set
- 8 Tite Applicators
- 6 Transform Applicators
- 4 Tone Applicators

- Treatment Deactivation Switch (Patient Call Button)
- Operator manual
- Power cord.

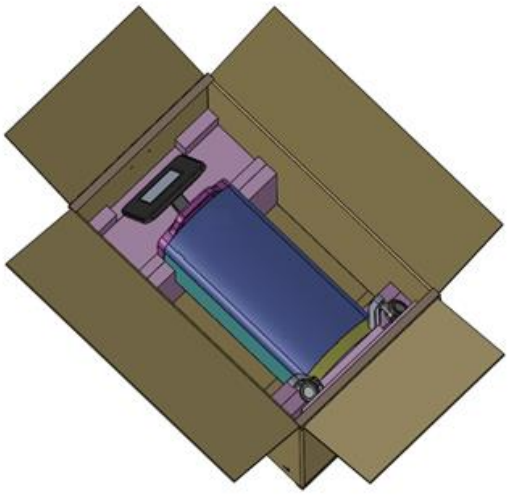
3.4 Unpacking

In order to unpack the device:

1. Remove the paper strip and open the box



2. Remove accessories and foams around the device.



3. Take 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.
- Set harness support (see Figure 3.1) and secure with clamping knobs.
- Connect cables of harness to connectors with corresponding numbers
- Pass harness through the harness support.
- Connect Applicators to cables.
- Connect the Patient Call Button.
- Connect the power cord to the System inlet.
- Plug the System power cord into an appropriate electrical outlet.

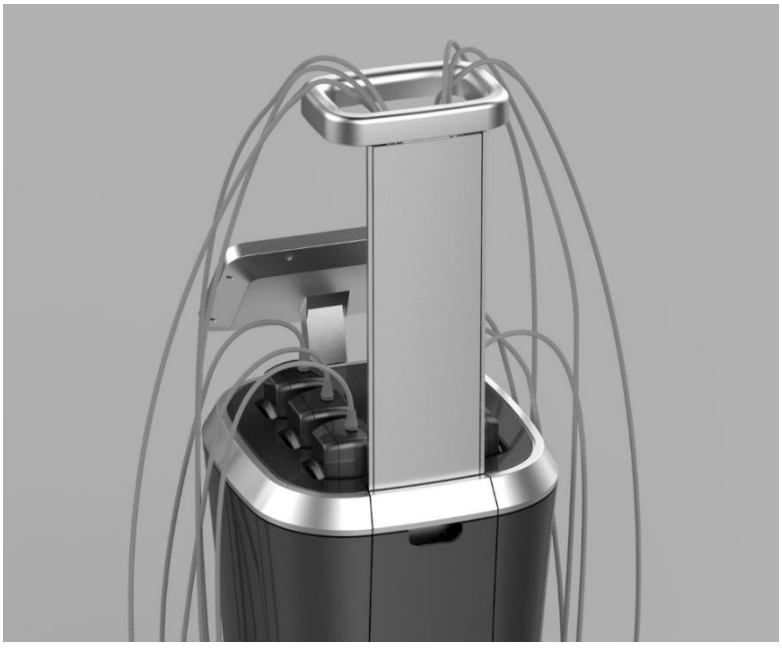


Figure 3-1: Harness Support Assembly

3.6 Moving the System

To move the System:

- Turn the System off.
- Disconnect the Power Cord.

- Disconnect and remove the Applicators.
- Disconnect the Patient Call Button.
- Release the wheel brakes.
- Slowly push or pull the System using the handle.
- When moving to another facility, disconnect harness support, lift the System to the vehicle and lay it carefully on its side.

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

Always use the handles when moving the System.

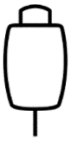
Upon unpacking, check the System for mechanical damage (e.g., cracks in the cable insulation).

3.7 System Disposal

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

4 Section 4: Device Description

4.1 Rear Panel

	**Power Cord Inlet** 100-240V~, 15A, 50-60Hz.
	**Fuse Holder** Rating is T 6.3A, 250V. Replace fuses if needed, only with fuses having exactly the same rating.
	**Software Flash Memory Plug** The software plug is a flash memory with the machine software. The software plug should be screwed to the connectors. To tighten and/or loosen the screws use fingertips only. Do not use screwdriver as it can damage the connectors.
	**Patient call button Connector** The Patient call button is connected to the inlet. Patient call button pauses the RF energy while the System is in Active mode. Place the Patient call button near the treatment area. Located behind the door on the Rear Panel.

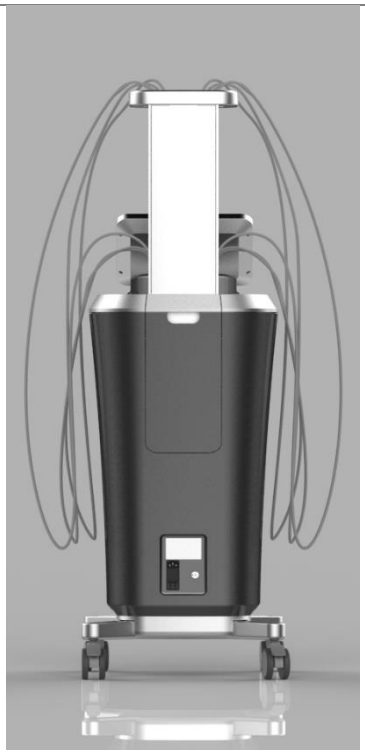


Figure 4-1: Rear View

4.2 Front Panel and Operator Control Panel

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

Power On-Off Switch	Power switch turns System On and Off. The blue switch is located on the Front Panel.
LCD Screen	▪ The LCD screen shows information about the System mode and treatment parameters. ▪ The panel allows changing treatment parameters and System mode.

RF power for the specific Applicator is not activated, if the Applicator is not connected to its connector on the Rear Panel.

Figure 4-2: Front View

4.3 Software Screens

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

Figure 4-3: Splash Screen

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

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

Figure 4-4: Login Screen

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

Figure 4-5: Menu Screen

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

Figure 4-6: Utility Screen

The Utility Screen contains:

Volume	This function allows the user to adjust the System volume.
Change Password	Change the password by entering the old password and then entering another 4-digit password.
Main Menu	Return to the Main Menu to select the Applicator.

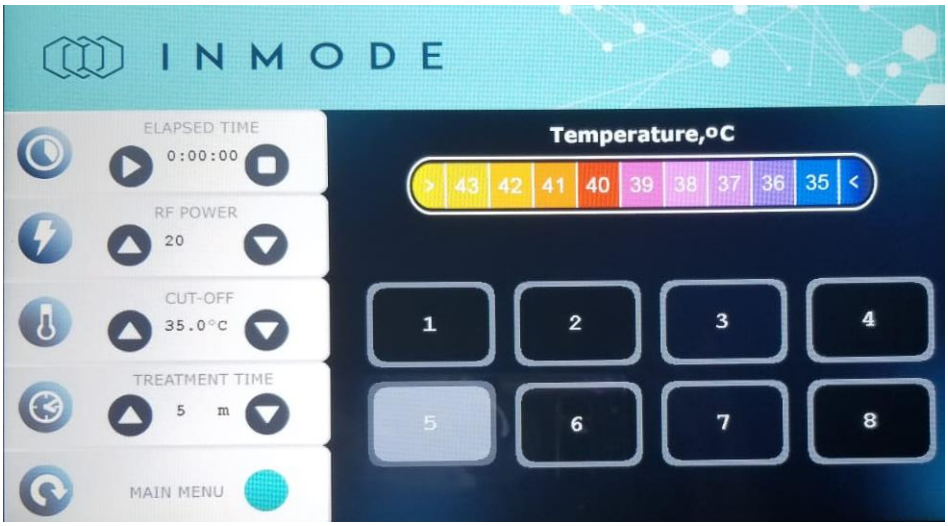


Figure 4-7: Tite Treatment Screen

Elapsed Time	This indicator shows elapsed time from the beginning of treatment activation.
Start / Pause	This button activates the treatment. After pressing the 'Start' button, the system is in 'Active' mode. The icon will then change to 'Pause' and clicking on it will pause the treatment ('Pause' mode). The 'Elapsed Time' counter will not reset while pausing the treatment. Any attempt to change the settings during treatment, switches the system to Pause mode.
Stop	This button Stops the treatment and switches the system to Standby mode. The 'Elapsed Time' counter resets.
RF Power	RF power is changed within the limits allowed for the connected Applicator. Power level settings are changed from 20 to 60 energy levels. The System starts up at minimal power level setting.
Cut-Off Temperature	This indicator shows the cut-off temperature, which is adjustable from 35 to 43°C. This indicates measured temperature at which the RF delivery is stopped.
Treatment Time	This indicator shows time when RF energy is applied sequentially to the Applicators.
Temperature Scale	Color temperature scale.
Applicators Status Indicators (1-8)	These indicators show online the measured skin surface temperature for each of the connected Applicators. The color of the buttons is in accordance with the temperature scale above. The grey color indicates that Applicator is not connected or not recognized.

Main Menu	Return to the Main Menu to select the Applicator.

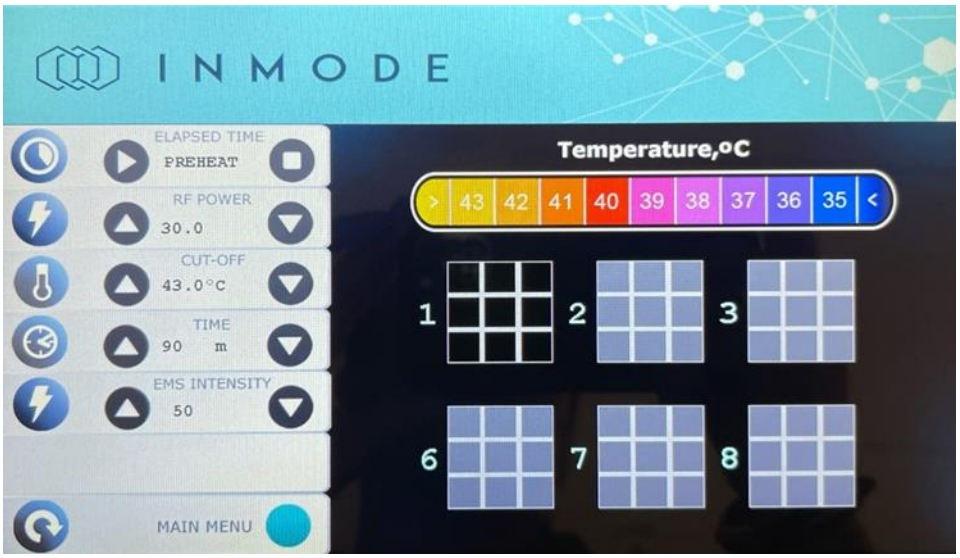


Figure 4-8: Transform Treatment Screen

Elapsed Time	This indicator shows elapsed time from the beginning of treatment activation.
Preheat	The device is automatically set to start with PREHEAT sequence: the system will deliver the lowest energy level to preheat the unit and to bring skin and electrodes to the same temperature
Start / Pause	This button activates the treatment. After pressing the 'Start' button, the system is in 'Active' mode. The icon will then change to 'Pause' and clicking on it will pause the treatment ('Pause' mode). The 'Elapsed Time' counter will not reset while pausing the treatment. Any attempt to change the settings during treatment, switches the system to Pause mode.
Stop	This button Stops the treatment and switches the system to Standby mode. The 'Elapsed Time' counter resets.
RF Power	RF power is changed within the limits allowed for the connected Applicator. Power level settings are changed from 20 to 50 energy levels. The System starts up at minimal power level setting.
Cut-Off Temperature	This indicator shows the cut-off temperature, which is adjustable from 35 to 43°C. This indicates measured temperature at which the RF delivery is stopped.
Treatment Time	This indicator shows time when RF energy is applied sequentially to the Applicators.

Intensity	Intensity is changed within the limits allowed for the connected Applicator. Intensity level settings are changed from 1 to 50 energy levels. The System starts up at minimal intensity level setting.
Temperature Scale	Color temperature scale.

Applicators Status Indicators (1-6)	These indicators show online the measured skin surface temperature for each of the connected Applicators. The color of the buttons is in accordance with the temperature scale above. The grey color indicates that Applicator is not connected or not recognized.
Main Menu	Return to the Main Menu to select the Applicator.

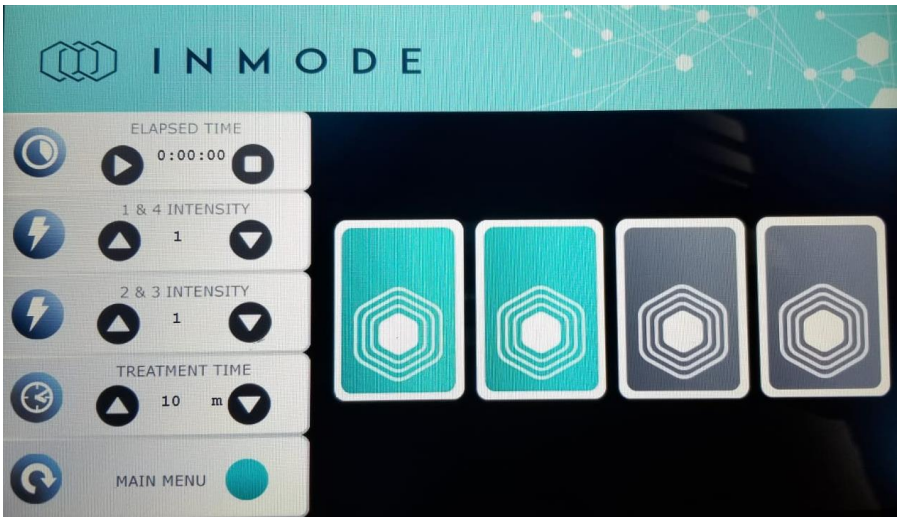


Figure 4-9: Tone Treatment Screen

Elapsed Time	This indicator shows elapsed time from the beginning of treatment activation.
Start / Pause	This button activates the treatment. After pressing the 'Start' button, the system is in 'Active' mode. The icon will then change to 'Pause' and clicking on it will pause the treatment ('Pause' mode). The 'Elapsed Time' counter will not reset while pausing the treatment. Any attempt to change the settings during treatment, switches the system to Pause mode.
Stop	This button Stops the treatment and switches the system to Standby mode. The 'Elapsed Time' counter resets.
Intensity	Intensity is changed within the limits allowed for the connected Applicator. Intensity level settings are changed from 1 to 50 energy levels and can be adjusted separately per pair of

	applicators 1&4 and 2&3. The System starts up at minimal intensity level setting.
Treatment Time	This indicator shows time when energy is applied sequentially to the Applicators.
Applicators Status Indicators (1-4)	These indicators show online status for each of the connected Applicators. The grey color indicates that Applicator is not connected or not recognized.
Main Menu	Return to the Main Menu to select the Applicator.

4.4 Sound Indicator

- Periodic beeping signal is emitted, when energy is delivered.
- A warning sound tone indicates Bad Coupling.

4.5 Cut-Off Temperature Control

The cut-off temperature up to an upper limit of temperature of 43°C is constantly maintained. When the measured temperature approaches the Cut-off Temperature, the tone beeps double in speed. It becomes faster when the Cut-off Temperature is reached and RF is instantly inactivated. As soon as the temperature drops below the Cut-off temperature, RF starts again, thus maintaining the desired temperature with safety and when reached, RF delivery is automatically stopped. Temperature is monitored by a temperature sensor in the Applicator and serves as a safety feature.

4.6 Applicator

Each Tite Applicator unit comprises an Applicator, Cable, Connector and an Integral Temperature Sensor.

Figure 4-10: Tite Applicator

The Tite Applicator unit contains:

Electrodes	Three electrodes located on the side of applicator applied to the skin.
Connector	Connects applicator to the harness
Temperature Sensor	Located in the central electrode for skin temperature monitoring

Each Transform Applicator unit comprises Electrodes, Cable, Connector and an Integral Temperature Sensor.

Figure 4-11: Transform Applicator Unit

The Transform Applicator unit contains:

Electrodes	Nine electrodes located on the side of applicator applied to the skin.
Connector	Connects applicator to the harness
Temperature Sensors	Each electrode has embedded temperature sensor.

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

Figure 4-12: Tone Applicator Unit

The Tone Applicator unit contains:

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

4.7 Patient Call Button (Treatment Deactivation Switch)

The Patient Call Button interrupts the treatment process and switches the system to PAUSE state until the operator re-enables it.

The patient can use the Patient call button to pause the treatment if the discomfort becomes excessive.

Figure 4-13: Patient call button

4.8 Belt Set

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

The EvolveX System is equipped with an adjustable belt set. The belts enable an easy and comfortable setting of the EvolveX Applicators onto the patient skin.

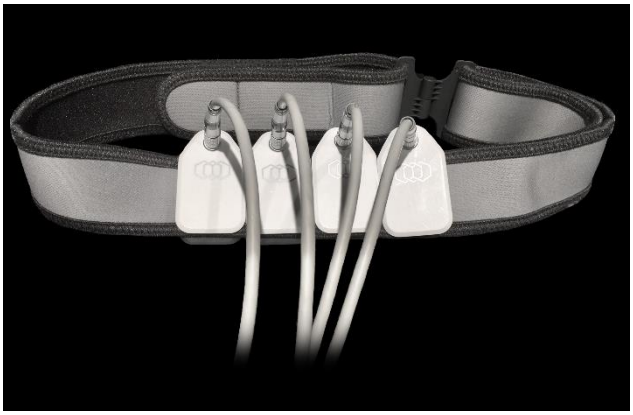


Figure 4-14: Tite Applicator Units with Belt Set

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 Applicator, inspect the System and Applicator for possible mechanical damage.

5.1 Device Start-Up

1. Connect the Applicators to the harness.
2. Turn on the Main Power switch on 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 a unique password to get access to the device. If password is correct the system enters the 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 the Troubleshooting section in this manual). If the test is passed correctly, then the System automatically enters the Menu Screen.
6. Select Application from the Menu Screen and the System will enter the Treatment Screen.
7. Verify on the screen that the software version is properly displayed, and that the connected Applicator type is recognized correctly.
8. Select the treatment parameters using up and down arrow keys.
9. Press the Start Button to activate the treatment.

5.2 System Shutdown

- To shut down the System, turn the On-Off switch located at the front to Off (Figure 5.2).
- Turn the Main Power switch located at the backside of the System to Off at the end of the day (Figure 5.1).

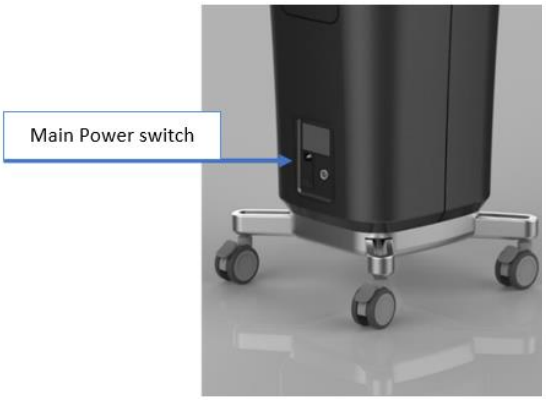


Figure 5-1: On Off Main Power Switch at the Rear (Arrow)

Figure 5-2: On Off Switch at the Front (Arrow)

6 Section 6: Transform Treatment Information

6.1 Indications for Use

The EvolveX System with the Transform Applicator units employs RF technology and EMS-TENS technology for the treatment of selected medical conditions.

The Transform Applicator in RF mode is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The Transform Applicator in EMS mode is intended for:

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

The Transform Applicator in TENS mode is intended for:

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

6.2 Contraindications

Contraindications in the use of the EvolveX System in RF mode 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 periostal plane.
- Current or history of skin cancer, or current condition of any other type of cancer, or premalignant moles.
- Severe concurrent conditions, such as cardiac disorders, epilepsy, uncontrolled hypertension, and liver or kidney diseases.
- Pregnancy and nursing.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies or use of anticoagulants in the last 10 days, according to physician's discretion.
- Any surgery in treated area within 6 months prior to treatment.
- Intra-dermal or superficial sub-dermal areas that have been injected with HA/collagen/fat injections or other augmentation methods with bio-material during last 6 months.
- Having received treatment with light, laser, RF, or other devices in the treated area within 3 months, or before complete healing.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- Intra-dermal or superficial sub-dermal areas that have been injected with HA/collagen/fat injections or other augmentation methods with bio-material during last 6 months.
- Having received treatment with light, laser, RF, or other devices in the treated area within 3 months, or before complete healing.
- As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient.

Contraindications in the use of the EvolveX System in EMS-TENS mode include:

- Active electrical implant/device in any region of the body, including pacemaker or internal defibrillator.
- Permanent implant in the treated area such as metal plates, screws or silicon, metal piercing or other.
- 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.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as Diabetes, or thyroid dysfunction and hormonal virilization.
- Any active condition in the treatment area, such as sores, Psoriasis, eczema, and rash, open lacerations, abrasions or lesions, infection in the area to be treated.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies or use of anticoagulants except for low-dose aspirin.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV or use of immunosuppressive medications.
- Any surgical procedure in the treatment area within the last 12 months or before complete healing.
- (Accutane) within last 6 months.
- Having received treatment with light, laser, RF, or other devices in the treated area within 2-3 weeks for non-ablative procedures, and 6-12

weeks for ablative fractional laser resurfacing (according to treatment severity) prior to treatment, except special recommendations.

- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session, as per the practitioner's discretion.
- Application of the device near the thorax may increase risk of cardiac fibrillation.
- Avoid application of device over the head, eyes, across the mouth and front of neck.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

6.3 Precautions

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following: a. When there is a tendency to hemorrhage following acute trauma or fracture; b. Following recent surgical procedures when muscle contraction may disrupt the healing process; c. Over the menstruating or pregnant uterus; and d. Over areas of the skin lacking normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electric conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Powered muscle stimulators should be kept out of the reach of children.
- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer

6.4 Possible Adverse Effects

Certain side effects may be experienced during treatment or shortly afterwards which may or may not be a result of improper use of the system. Although these side effects are rare and temporary, they should be reported immediately to a physician for proper treatment. These are the side effects that may appear in the treatment area:

- Pain
- Excessive redness (erythema)
- Swelling (edema)
- Muscles spasm
- Treatment area infection
- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.
- Skin burns
- Pigmentation change
- Scar

6.5 Applicator Cleaning Instructions Prior to Use

 These cleaning instructions are for clinical use only.

The following processes validated for the Transform Applicators when used in accordance with the instructions provided for cleaning products and/or processes.

Any deviation from said instructions or the cleaning agents listed below may affect the performance or durability of the product, and it's prohibited. Review those instructions for additional warnings and cautions.

We recommend the usage of the following cleaning agent that was tested in our company for material compatibility as 70% alcohol solution.

Cleaning Procedure

- Thoroughly clean the applicator with 70% alcohol absorbed pad for at least 30 sec and repeat as necessary.
- Leave it for complete drying.

Pre-use Check

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

- Check to ensure proper cleaning and drying of the Applicator.
- Visually inspect the applicators for residual soil. Repeat the Cleaning Procedure in the event that residual soil is visible. Inspect all components of the applicator for visible damage.
- Do not use the applicator/s in case of unacceptable deterioration was observed such as corrosion, discoloration, pitting, or cracked seals.

6.6 Pre-Treatment Recommendations

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

- Review all indications
- Review all contraindications and precautions and exclude from treatment anyone with the listed contraindications
- Complete the medical history and physical prior to treatment
- 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.
- Sign the informed consent prior to the procedure.
- Clean the Hand piece with alcohol 70% or other disinfectant. Use alcohol-soaked cotton buds to clean inside the Hand piece cavity.
- Clean the treatment area, remove creams/lotions and makeup, and dry the skin.
- Photograph the patient.
- Mark the treatment zones

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

Perform a test immediately prior to the procedure to visualize the area that is going to be treated

6.7 Treatment Recommendations

The treatment recommendations for the EvolveX System with the Transform Applicator in RF mode are as follows:

1. Ensure that skin is clean and dry.
2. Follow Device Start-Up from Section 5.1.
3. Set treatment parameters.
4. Start at the lower value and increase gradually, according to patient and skin tolerance. Patients who can tolerate higher values, may reach the cut-off temperature faster.

Reduce the RF power/EMS intensity with any discomfort or excessive skin response!

If not relieved, stop the treatment!

5. Any combination of treatment parameters should be according to skin response and patient tolerance. Combination of high RF power with short treatment time or vice versa may suit some patients better.
6. Usually, treatment parameters are higher for thicker skin with a lot of fat, like abdomen and are lower for thin sensitive skin like arm, but response is individual.
7. Arms skin, on top of being thinner and more sensitive is also a small area and therefore treatment should not exceed 20min. Always start with low settings and observe the skin's reaction and patient comfort before increasing the energy. However, high cut-off temperature is essential for treatment efficacy, and has to be increased gradually for better tolerance.
8. Apply water-based ultrasound gel to the skin below each of the Applicator units or directly to the Applicator electrodes.
9. Prior to using the ultrasound gel, ensure that the gel container has not passed the expiration date.
10. Up to 6 Applicator units can be applied to the treatment area. A conductive gel is applied to attach the units to the treatment area. Tight Applicator units to the body using the belt tightening mechanism to achieve good coupling between electrodes and the patient’s body.
11. Activate the treatment by pressing the "On" icon.

Slight erythema and edema are a typical immediate response. However, when there is an excessive skin response (erythema and edema) or strong discomfort level, stop the treatment.

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

The treatment recommendations for the EvolveX System with the Transform Applicator in EMS-TENS mode are as follows:

1. Ensure that skin is clean and dry.
2. Follow Device Start-Up from Section 5.1.
3. Always start with a low setting level to check the patient's tolerance to the treatment parameters. Increase the settings gradually to see muscle contraction.
4. Thin layer of conductive gel should be applied to the treated area or directly to the Applicator electrodes.

Prior to using the conductive gel, ensure that the gel container has not passed the expiration date.

5. Power level to be set according to patient tolerance, starting at 5 intensity level and increasing gradually.
6. Apply applicators to the treated area and tight with the belt to ensure good coupling.
7. Set treatment time and press the "On" icon to start the treatment.

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

6.8 Treatment Schedule

- The number of treatment sessions in RF mode depends on the individual patient and is typically 6 weekly sessions but can be as short as 3 at longer treatment durations. One session every ~3months, or as needed, may maintain treatment results.
- The number of treatment sessions in EMS/TENS mode is 4-10 sessions, once or twice a week but can vary according to patient response.
- Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.

6.9 Post Treatment Recommendations

- Skin cooling is NOT recommended.
- The patient should avoid very hot water for 2 days after the treatment.
- The patient should avoid scrubbing, pinching and etc. of the treated area.
- Moisturizer and makeup may be applied to the skin surface immediately post treatment.
- The Applicators should be cleaned from the gel and disinfected by 70% alcohol or surface disinfectant such as Cavicide™ wipes or similar products.
- 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.

7 Section 7: Tone Treatment Information

7.1 Indications for Use

The EvolveX System with Tone Applicator is used in EMS mode for:

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

And in TENS mode for:

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

7.2 Contraindications

Contraindications in the use of the System include:

- Active electrical implant/device in any region of the body, including pacemaker or internal defibrillator
- Permanent implant in the treated area such as metal plates, screws or silicon, metal piercing or other.
- 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.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.

- History of bleeding coagulopathies or use of anticoagulants except for low-dose aspirin.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV or use of immunosuppressive medications.
- Pregnancy and nursing.
- Poorly controlled endocrine disorders, such as Diabetes, or thyroid dysfunction and hormonal virilization.
- Isotretinoin (Accutane) within last 6 months.
- Any active condition in the treatment area, such as sores, Psoriasis, eczema, and rash, open lacerations, abrasions or lesions, infection in the area to be treated.
- Any surgical procedure in the treatment area within the last 12 months or before complete healing.
- Having received treatment with light, laser, RF, or other devices in the treated area within 2-3 weeks for non-ablative procedures, and 6-12 weeks for ablative fractional laser resurfacing (according to treatment severity) prior to treatment, except special recommendations.
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session, as per the practitioner's discretion.
- Application of the device near the thorax may increase risk of cardiac fibrillation
- Avoid application of device over the head, eyes, across the mouth and front of neck
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

7.3 Precautions

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.

- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following: a. When there is a tendency to hemorrhage following acute trauma or fracture; b. Following recent surgical procedures when muscle contraction may disrupt the healing process; c. Over the menstruating or pregnant uterus; and d. Over areas of the skin lacking normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Powered muscle stimulators should be kept out of the reach of children.
- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

7.4 Possible Adverse Effects

Certain side effects may be experienced during treatment or shortly afterwards which may or may not be a result of improper use of the system. Although these side effects are rare and temporary, they should be reported immediately to a physician for proper treatment. These are the side effects that may appear in the treatment area:

- Pain
- Excessive redness (erythema)
- Swelling (edema)
- Muscles spasm
- Treatment area infection

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

7.5 Applicator Cleaning Instructions Prior to Use

These cleaning instructions are for clinical use only.

The following processes validated for the Tone Applicators when used in accordance with the instructions provided for cleaning products and/or processes.

Any deviation from said instructions or the cleaning agents listed below may affect the performance or durability of the product, and it's prohibited. Review those instructions for additional warnings and cautions.

We recommend the usage of the following cleaning agent that was tested in our company for material compatibility as 70% alcohol solution.

Cleaning Procedure

- Clean the Applicator units thoroughly with alcohol absorbed pad (not soaked) and repeat as necessary. Do not submerge in fluids. Leave it for complete drying.

Pre-use Check

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

- Check to ensure proper cleaning and drying of the Applicator.
- Visually inspect the applicators for residual soil. Repeat the Cleaning Procedure in the event that residual soil is visible.
- Inspect all components of the Applicator for visible damage.

Do not use the applicator/s in case of unacceptable deterioration was observed such as corrosion, discoloration, pitting, or cracked seals.

7.6 Pre-Treatment Recommendations

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

- Review all indications
- Review all contraindications and precautions
- Complete the medical history and physical prior to treatment
- Sign the informed consent prior to the procedure.
- Perform a test immediately prior to the procedure to visualize the area that is going to be treated

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

7.7 Treatment Recommendations

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

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

5. Set treatment time and activate the treatment
6. Slight erythema and edema are a typical immediate response. However, when there is excessive tissue reaction, stop treatment. For excessive heat sensation, you may decrease the intensity of pulses

The patient can use the Patient Call Button to pause the treatment if the discomfort becomes excessive

7.8 Post-Treatment Recommendations

- After each treatment session, the patient should be advised to contact the physician if there is any indication of infection, excessive swelling, redness, pain, or any other unusual or untoward symptom.
- The applicators should be cleaned of the gel and disinfected by 70% alcohol or surface disinfectant such as Cavicide™ wipes or similar products.

7.9 Treatment Schedule

- The number of treatment sessions depends on the individual patient and is typically 3-4 sessions, every 1-2 weeks but can vary according to patient response.

- Treatment duration is 20 to 40 minutes according to patient tolerance and conditions.
- Treatment should be concluded when the results are satisfactory to the patient or according to the physician’s discretion.

8 Section 8: Tite Treatment Information

8.1 Indications for Use

The EvolveX System with the Tite Applicator units is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

8.2 Contraindications

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

- History of bleeding coagulopathies, or use of anticoagulants in the last 10 days.
- Laser resurfacing and deep chemical peeling within the last 3 months prior Tite treatment.
- Having received treatment with light, laser, RF, or other devices in the treated area within 3 months, or before complete healing.
- Any surgical procedure in the treatment area within the last 3 months or before complete healing.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

8.3 Possible Adverse Effects

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

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

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

8.4 Applicator Cleaning Prior to Use

These cleaning instructions are for clinical use only.

The following processes are validated for the Tite Applicator when used in accordance with the instructions provided for cleaning products and/or processes. Any deviation from said instructions or the cleaning agents listed below may affect the performance or durability of the product and 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

- Thoroughly clean the Applicator units with 70% alcohol absorbed pad for at least 30sec and repeat as necessary
- Leave it to dry completely.

Pre-Use Check

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

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

8.5 Pre-Treatment Recommendations

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

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- The patient should discontinue any irritant topical agents for 2-3 days prior to treatment and if medically permitted, anticoagulants should be stopped 1-2 weeks prior treatment.
- Clean the treatment area, remove creams/lotions and makeup, and dry the skin.
- Photograph the patient.
- Clean the parts of the Applicator those come in contact with the skin with 70% alcohol.

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

8.6 Treatment Recommendations

The caregiver shouldn't leave the patient unattended during treatment

The patient can use the Patient call button to pause the treatment if the discomfort becomes excessive

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

1. Follow **Device Start-Up** from Section 5.
2. Set treatment parameters. Suggested starting treatment parameters for Tite Applicator are shown in the table below:

RF Power Energy Level	Cut-Off Temperature [°C]	Treatment time [min]
Starting at 20, increase according to patient's comfort	As high as tolerable, Starting at 40°C	30-60, According to patient comfort

3. Any combination of treatment parameters should be according to skin response and patient tolerance.
4. Always start with low settings and observe the skin's reaction and patient comfort before increasing the RF energy.
5. Apply conductive gel to the skin, addition gel can be applied directly to the Tite units.

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

6. Set Tite units on the belt.
7. Apply the belt with the Tite units on treatment area while the patient is positioned in the same position as the treatment will be performed.
8. Ensure there is minimal movement after the Tite units are applied.
9. There should be a complete contact between the unit and the skin during the treatment session.

10. The belt should not be loose. Ensure the belt is taut around the treatment area. Secure the units with additional belt on the top if needed.

11. Up to 8 Applicator units can be applied to the treatment area. Tight Applicator units around the treatment area with a belt to assume good coupling between electrodes and skin.

12. Activate the treatment by entering Active mode.

13. Slight erythema and edema is a typical immediate response. However, when there is an excessive skin response (erythema and edema) or strong discomfort level, stop the treatment.

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

8.7 Treatment Schedule

The number of treatment sessions depends on the individual patient and is typically 6 weekly sessions but can be as short as 3 at longer treatment durations.

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

One session every ~3months, or as needed, may maintain treatment results.

8.8 Post-treatment Recommendations

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

9 Section 9: System Maintenance

9.1 Maintenance & Frequency

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

9.2 Before and after each treatment

Wipe the device with a damp soft cloth. The Applicator elements that are in contact with the skin should be disinfected with 70% alcohol between patients, as described in detail for the Applicator.

9.3 Once a Week

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

9.4 Once a Year

By authorized service personnel only:

- A full test and calibration are recommended. Please be sure to contact your local service center to perform this process.

10 Section 10: Troubleshooting

The EvolveX 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.

10.1 Description of Faults with All Applicators

Problem	Description and Checks
System did not turn on	▪ Check power cord connection. ▪ Check that main switch on Rear Panel is on. ▪ Check that On/Off switch on Front Panel is on. ▪ Check fuses on the Back Panel of the System. ▪ Call Technical Service if the problem persists.
System shuts down by itself	▪ Check power cord connection. ▪ Check fuses on the Back Panel of the System. ▪ Call Technical Service if problem persists.
Checksum	▪ The software was not loaded properly from software plug. ▪ Check the plug connection and reboot the System. ▪ Call Technical Service if the problem persists.
The connected Applicator is not recognized	▪ Check connection of the Applicator. ▪ Replace the Applicator. ▪ Call Technical Service if the problem persists.
Fault H8005, H800F, H8010 – System Memory Fault	Call Technical Service if the problem persists.
Fault H800E- System Incompatible Software Version	Call Technical Service if the problem persists.
Fault H800F- System Memory Fault	Call Technical Service if the problem persists.
Fault H8010- System Memory Fault	Call Technical Service if the problem persists.

Problem	Description and Checks
Faults H83XX, H84XX, H82XX	Call Technical Service if the problem persists.
Faults H8003, H8006, H8007 - RF Related Faults	Call Technical Service if the problem persists.

11 Section 11: System Specifications

Input Power		
Main Line Frequency (nominal)	50-60Hz	
Input Voltage (nominal)	100-240VAC	
Input Current (rms)	4A	
Operating Parameters		
Ambient Temperature Range	15 – 30°C [59 – 86°F]	
Relative Humidity	30% to 80%, non-condensing	
Atmospheric Pressure	90 - 110kPa	
Warm-up Time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the device to reach room temperature before use.	
Transport and Storage		
Ambient Temperature Range	-20– 65°C [-4 – 14°F]	
Relative Humidity	0% to 80%, non-condensing	
Atmospheric Pressure	50 to 110kPa	
Dimensions		
System	46cm W x 46cm D x 100cm H	[18.2'' W x 18.2'' D x 44'' H]
Applicator Cable	280cm L	[110`` L]
Weight		
System	33kg	[72.00lb]
Tite Applicator	0.17kg	[0.375lb]
Transform Applicator	0.90kg	[2.00lb]
Tone Applicator	0.29 Kg	[0.64 lbs.]
Tite Output Parameters		
RF Maximum Output Power	26W	
RF Frequency	1Mhz	
RF Pulse duration	2 Sec.	
Transform Output Parameters		

RF Maximum Output Power	50W
RF Frequency	1Mhz
Pulse Duration	2 Sec.
Intensity (output voltage) Waveform Pulse shape	Up to 50 intensity level (=54 Vpeak) Bi-phasic Rectangular
Pulse width	20-400 [µsec]
Frequency	3-200 [Hz]
Tone Output Parameters	
Intensity (output voltage)	Up to 50 energy level (=54 Vpeak)
Waveform	Bi-phasic
Pulse shape	Rectangular
Pulse width	20-400 [usec]
Frequency	3-200[Hz]

11.1 Output Power Curves

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

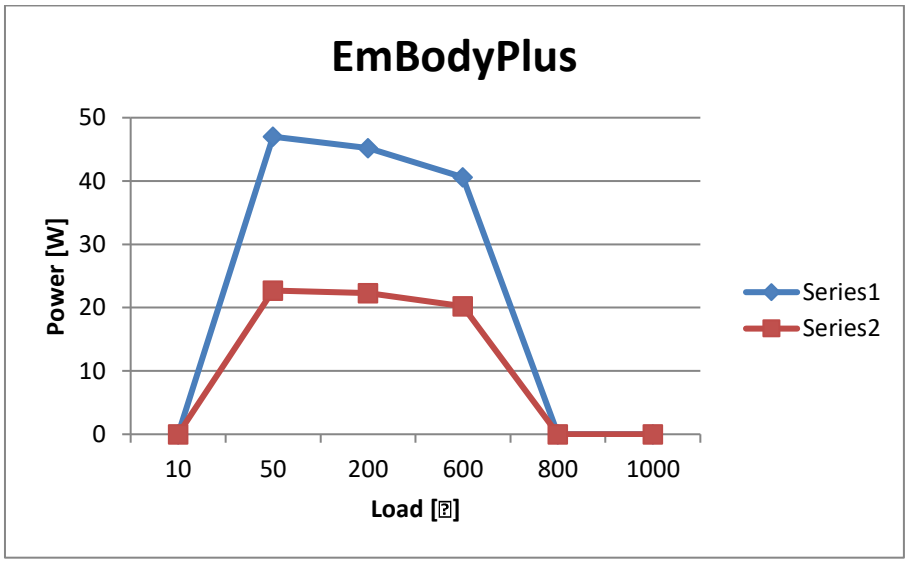


Figure 11-1: Tite Output Power versus Impedance

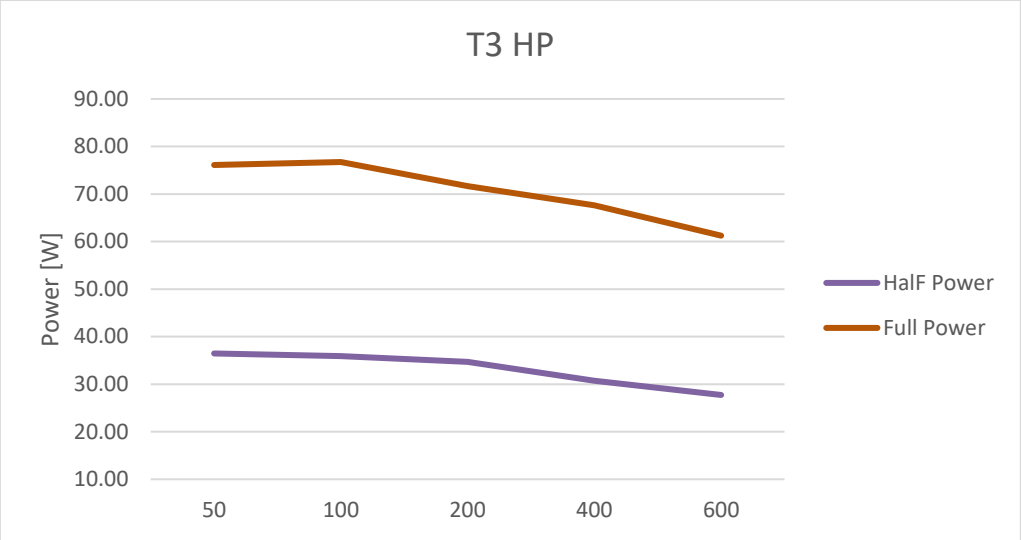


Figure 11-2: Transform Output Power versus Impedance

11.2 EMC Safety

The device has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2 Ed.4 (2014). These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device generates uses and can radiate radio frequency energy. If not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that the interference to other devices, which can be determined by turning the device off and on, is caused by this instrument.

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

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect the device into an outlet on a circuit different from that which was previously used.
- Consult InMode service personnel for help.

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

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

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

IEC 60601-1-2 Edition 4.0 (2014)
Environment of intended uses:
Professional Healthcare Facility Environment

Summary of Test Results

Test	Standard	Class/ Severity level	Test result
Emission (IEC 60601-1-2 section 7.1 & 7.2 & IEC 60601-2-2)			
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class A	Complies
Conducted emission Freq. range:150 kHz - 30 MHz		Group 1 Class A 100/ 120/ 230 VAC	Complies
Harmonic current emission test	IEC 61000-3-2	AC mains	Exempted
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 8.9 & 8.10 IEC 60601-2-2)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	3.0 V/m 80 MHz ÷ 2.7 GHz, 80% AM, 1kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2 kV on 230 VAC mains, Pedal, Applicator Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1.0 kV DM/ 2.0kV CM on 230 VAC Tr/Th – 1.2/50 (8/20) μs	Complies
Immunity from conducted disturbances induced by RF fields	IEC 61000-4-6	3.0 & 6.0 V_{RMS} on 230 VAC mains, Pedal, Applicator 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	230 & 100 VAC mains; 0 % - 10 ms; 70% - 500 ms; 0% - 20 ms; 0% - 5sec	Complies