EVOKE

Operator Manual

EVOKE System

Version: DO608239B

INMODE

Operator Manual: Evoke System

DO608239B

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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 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 EmFace Platform with Chin and Cheek Applicators is marketed as the Evoke System which employs Radio-frequency (RF) technologies for various aesthetic applications.

The Evoke System with the Cheek and Chin Applicators is a hands-free medical aesthetic device using RF energy for the treatment of selected medical conditions such as relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.

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.

1.3 Conventions Used in the Manual

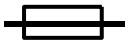
The following conventions in the form of notes and warnings are used in this manual:

WARNING! This information is extremely important!

ATTENTION! Consult Accompanying Document.

Provides general information that is important to keep in mind.

1.4 Explanation of the Symbols used on the System

Symbol	Description
	CSA marking (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	Type B Equipment.
	HF Isolated Patient Circuit
	Follow the operating instructions
	Federal (US) law restricts this device to sale by the order of a physician licensed by the law of the state in which he practiced to use or order the use of the device
	Non-Ionizing Radiation
	Serial Number
	Reference part number

Symbol	Description
	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 Evoke 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 safety requirements and operating procedures prior to System operation.

The RF energy can cause injury if used improperly.

High voltage is present inside the System.

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

2.1 The Patient

Well-trained staff is a key for assuring patient safety. A patient history 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 Evoke 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 20kg (44lb.) and may cause injury if proper care is not used when moving it.
- Provide as much distance as possible between the system, RF Applicator and other electronic equipment as the activated RF generator may cause interference between them.

2.5 Fire Hazards

- Materials conducting RF energy may cause temperature rise of the absorbing material. Do not use the System in the presence of explosive or flammable materials conductive to RF.
- Materials conducting RF energy cause an increase in temperature of the absorbing material.
- Do not use explosive and flammable substances when using the System or 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.
- Software is loaded from the flash memory and the following tests are performed:
  - Software checksum
  - Applicator ID check for each applicator
  - “Look up” calibration table check
  - Communication check
  - Temperature sensors check for each applicator
- During activation, the system performs a self-test of the hardware.
- Critical Hardware is tested every 1msec. to ensure proper operation of electrical circuits.
- Skin surface temperature is monitored during the treatment. RF energy delivery is terminated when skin temperature 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 both 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 trained personnel.

Only Applicators manufactured or approved by InMode Ltd. should be used with Evoke 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 RF energy and heating associated with the System can provide an ignition source. Observe fire precautions at all times. When using Evoke in the same room with any of these substances or gases, prevent their accumulation or pooling within the area where Evoke procedures are performed.

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

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

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 Evoke device console and the Applicator:

Figure 2-1: Device Identification Label

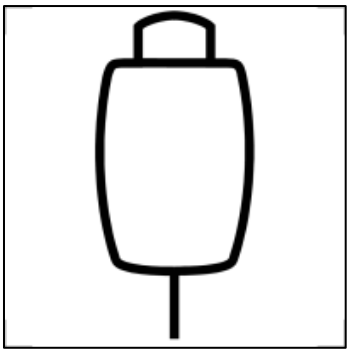


Figure 2-2: Hand-held Switch Label

Applicators Labels

Manufacturer identification labels are placed on the Cheek and Chin Applicators.

Figure 2-3: Cheek and Chin Applicators Identification Labels

Figure 2-4: Cheek and Chin Belt Set 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 a IIb device defined by the Medical Device Directive (93/42/EEC).

3 Section 3: System Installation

3.1 Electrical Requirements

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

For continued protection against fire, replace the fuse only with one of the same types 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

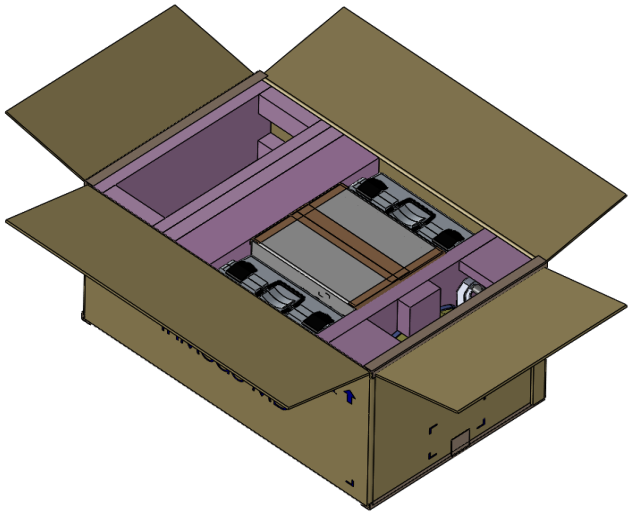
The System includes the following:

- System platform
- Adjustable Straps Belt Set (Cheek- two Nape belts and Chin overhead belt)
- Cheek Applicator
- Chin Applicator
- Treatment Deactivation button (Hand-held switch)
- Operator manual
- Power cord.

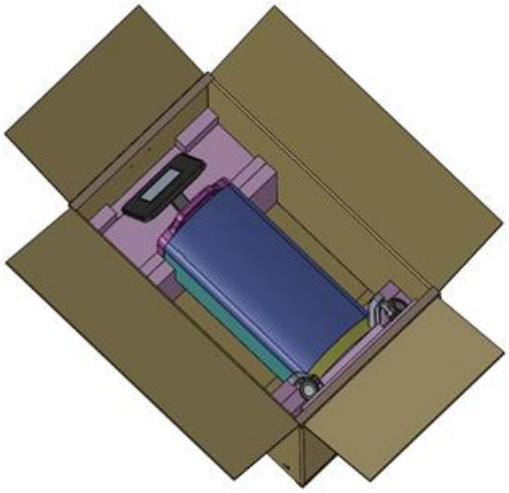
3.4 Unpacking

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.
- Connect Applicator to the connector/s.

- Connect the Hand-held switch (Treatment Deactivation button)
- Connect the power cord to the System inlet.
- Plug the System power cord into an appropriate electrical outlet.

3.6 Moving the System

To move the System:

- Turn the System off.
- Disconnect the Power Cord.
- Disconnect and remove the Applicators.
- Disconnect the Hand-held switch
- 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.
	**Hand-held switch Connector** The Hand-held switch is connected to the inlet. Hand-held switch pauses the RF energy while the System is in Active mode. Place the Hand-held switch near the treatment area.
RF Applicator Connector	Located at the top back side of the system

Figure 4-1: Evoke System Rear View

Figure 4-2: Applicator's connectors

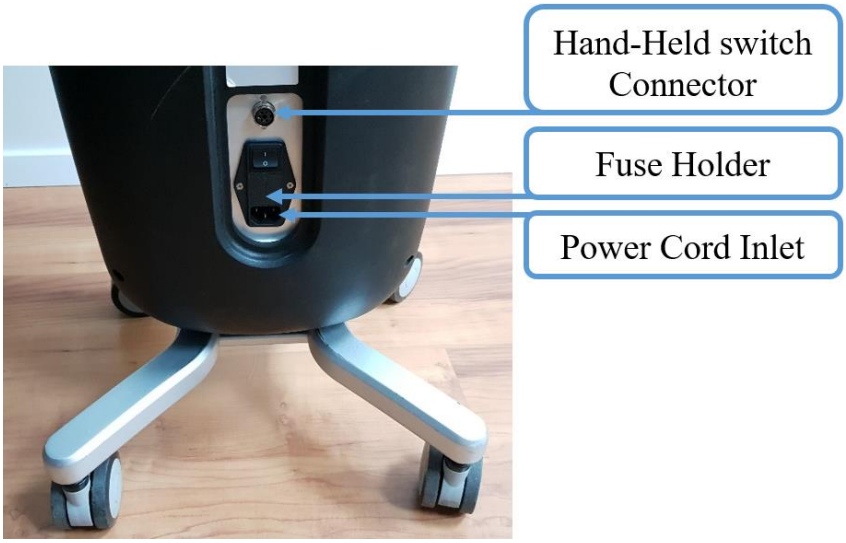


Figure 4-3: Lower rear Evoke connectors

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	Switch on/off the system
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 4-4: Evoke System Front View

4.3 Software Screens

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

Figure 4-5: Splash Screen

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

Figure 4-6: 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.

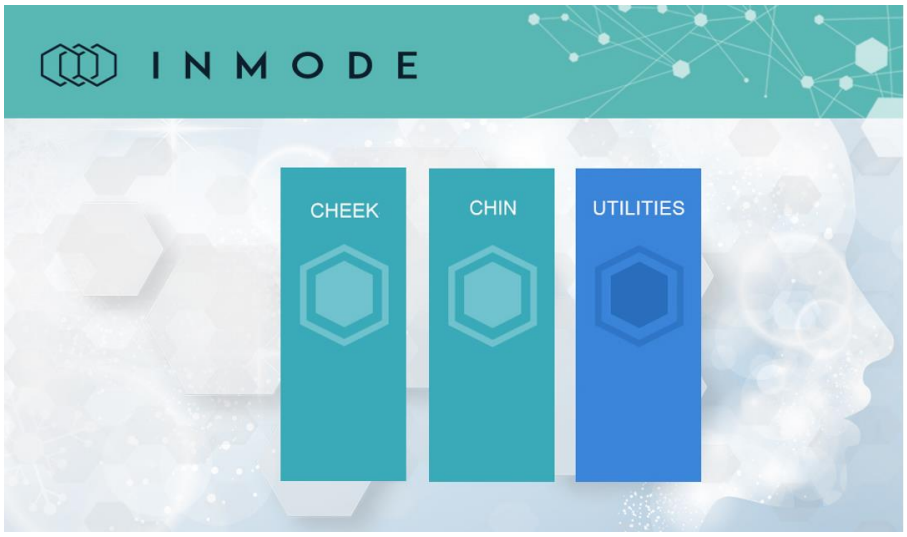


Figure 4-7: Menu Screen

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

Figure 4-8: 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.
SW Version	SW version is presented on the upper side of the screen.

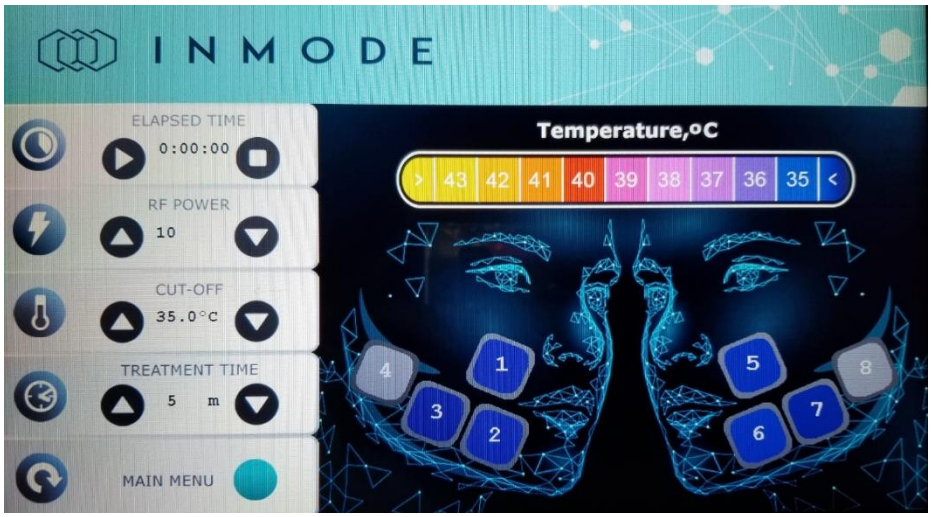


Figure 4-9: Cheek Treatment Screen

The Cheek Treatment Screen contains:

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 10 to 30. 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 RF Units.
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.

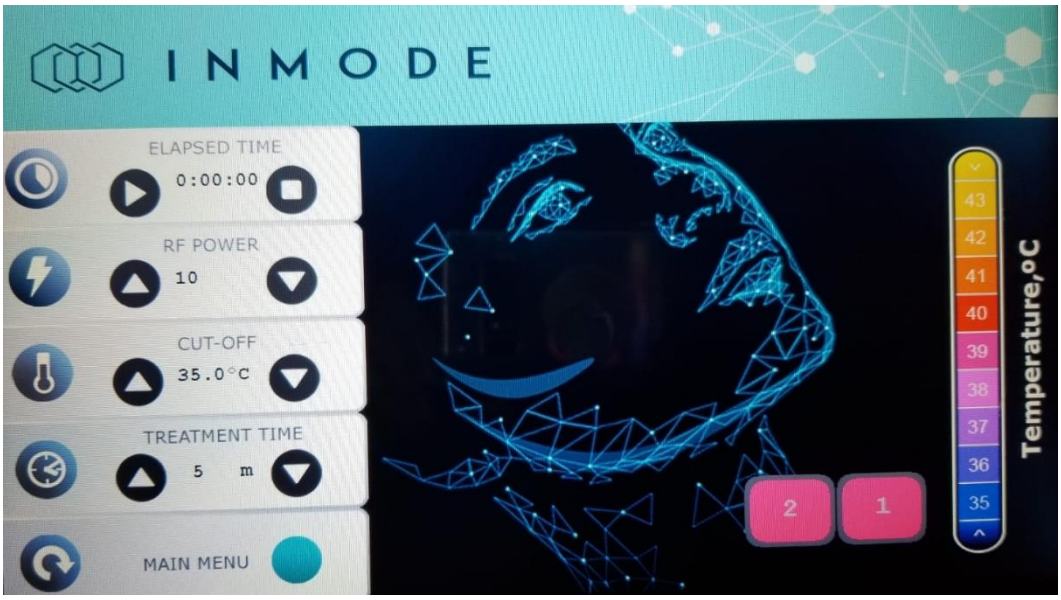


Figure 4-10: Chin Treatment Screen

The Chin Treatment Screen contains:

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 10 to 30. 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 RF Units.
Temperature Scale	Color temperature scale.

Applicators Status Indicators (1-2)	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.

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 Applicators

The Cheek Applicator comprises eight RF units with RF electrodes, and a temperature sensor in each unit. The four left units and the right four units are connected to the mask by magnets and may be detached for cleaning. When reassembling, it is crucial to keep the same sides.

Figure 4-10: Cheek Applicator Unit

The Cheek Applicator contains:

Housing	The Applicator housing is made of plastic and has ergonomic design for easy treatment with high visibility of the treated area.
RF Electrodes	Located on each of eight RF units.
Cable	Has a length of 180cm (71'').
Connector	Is located in the top Panel of the System.
Temperature Sensor	Embedded in in each RF units for skin temperature measurement.

The Chin Applicator comprises two RF units with RF electrodes, Cable, Connector and a temperature sensor located in the middle RF electrode of each unit.

Figure 4-11: Chin Applicator

The Chin Applicator contains:

RF unit	Part of the Applicator comprising RF electrodes and a temperature sensor.
Cable	Has a length of 180cm (71’’).
Connector	Is located in the top Panel of the system.
Temperature Sensor	Embedded in each RF unit for skin temperature measurement

4.7 Hand-held Switch (Treatment Deactivation Switch/ Patient Call Button)

The Hand-held switch interrupts the treatment process and switches the system to PAUSE state until the operator re-enables it.

The patient can use the Hand-held switch to pause the treatment if the discomfort becomes excessive.

Figure 4-12: Hand-held switch

4.8 Adjustable Straps Belts Sets

The Straps 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 Evoke System is equipped with an adjustable strap set. The straps enable an easy and comfortable setting of the applicator onto the patient skin.

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 Applicator to the Applicator Connector Sockets on the System.
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 connected Applicator type is recognized correctly.
8. Select the treatment parameters using up and down arrow keys.
9. Press the Status 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: Main Power Switch at the Rear (Arrow)

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

6 Section 6: Evoke Treatment Information

6.1 Indications for Use

The Evoke System with the Cheek and Chin Applicators is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

6.2 Contraindications

- Pacemaker or internal defibrillator, or any other active electrical 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. When treating over dental metal implants, it is possible to create a barrier by condensed cotton rolls or gauze and treat over it.
- 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 premalignant 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 as per the practitioner discretion.
- Facial dermabrasion, laser resurfacing and deep chemical peeling within the last 3 months prior 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 6 months or before complete healing.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient

6.3 Possible Adverse Effects

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

Erythema and edema lasting not longer than 24h is typical skin reaction to the treatment. Minor bruising can be seen during a few days for sensitive skin.

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

6.4 Applicator Cleaning Instructions Prior to Use

These cleaning instructions are for clinical use only.

The following processes validated for the Evoke 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 for material compatibility as 70% alcohol solution.

Cleaning Procedure

Clean the Applicator units thoroughly with alcohol absorbed pad 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.

Inspect all components of the Applicator for visible damage.

6.5 Pre-Treatment Recommendations

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

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

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

Caution should be taken when selecting patients, as this device is NOT to be used in areas where fat loss is of concern or is not desired.

6.6 Treatment Recommendations

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

RF Power	Cut-Off Skin Temperature [ºC]	Treatment time [min]
10-30	As high as tolerable, Starting at 40°C	15-45

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, cut-off temperature, treatment time, or more than one parameter. However, high cut-off temperature is essential for treatment efficacy, and has to be increased gradually for better tolerance.
5. Ensure that the skin is clean and dry.
6. Apply conductive gel to the skin below each of the Applicator units.
7. The system can support one applicator (either Cheek or Chin) at a time. A single use adjustable straps are used to attach Applicators to the treatment area. Tight each Applicator with the adjustable straps to ensure good coupling between cavity of each RF unit and skin.
8. Activate the treatment by entering Active mode.
9. Check that skin temperature starts rising after a few cycles.
10. If parameters are changed during the treatment, restart the treatment with adjusted Treatment Time.
11. The longer the treatment time, the better the results. Occasionally, this may decrease the number of sessions.
12. 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 caregiver shouldn’t leave the patient unattended during treatment

The patient can use the Hand-held switch to pause the treatment if the discomfort becomes excessive

6.7 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.
- Skin cooling is NOT recommended.
- The Applicator should be cleaned from the gel and disinfected by 70% alcohol.

Instruct the patient to:

- Avoid very hot water and direct heat exposure (tanning bed or sun) for 2 days post treatment.
- Avoid scrubbing and scratching the treated area.
- Moisturize the skin.
- Applicator belt to be discarded upon use.

6.8 Treatment Schedule

Typically, 3-6 treatments are required, once per week and may vary individually.

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

One session every 1-3 months, as needed, may maintain treatment results.

7 Section 7: System Maintenance

7.1 Maintenance & Frequency

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

7.2 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 each Applicator, remove the gel before cleaning the Applicators

7.3 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.

7.4 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.

8 Section 8: Troubleshooting

The Evoke 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.

8.1 Description of Faults

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.
Power Interruption	System will turn off, then when power gets back on, system will restart into standby mode, requesting user intervention

9 Section 9: System Specifications

Input Power		
Main Line Frequency (nominal)	50-60Hz	
Input Voltage (nominal)	100-240VAC	
Input Current (rms)	3.5A	
Operating Parameters		
Ambient Temperature Range	15 – 35°C [59 – 95°F]	
Relative Humidity	0% 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	40.7cm W x 40.9cm D x 102.5cm H	[16'' W x 16.1'' D x 40.3'' H]
Applicator Cable	180cm L	[71`` L]
Weight		
System	20.0kg	[44.00lb]
Chin Applicator	0.5kg	[1.1lb]
Cheek Applicator	0.90kg	[2.00lb]
Output Parameters		
RF Maximum Output Power	50W	
Frequency	1Mhz	
RF Pulse width	2 sec. for Cheek Applicator 2 sec. for Chin Applicator	

9.1 Output Power Curves

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

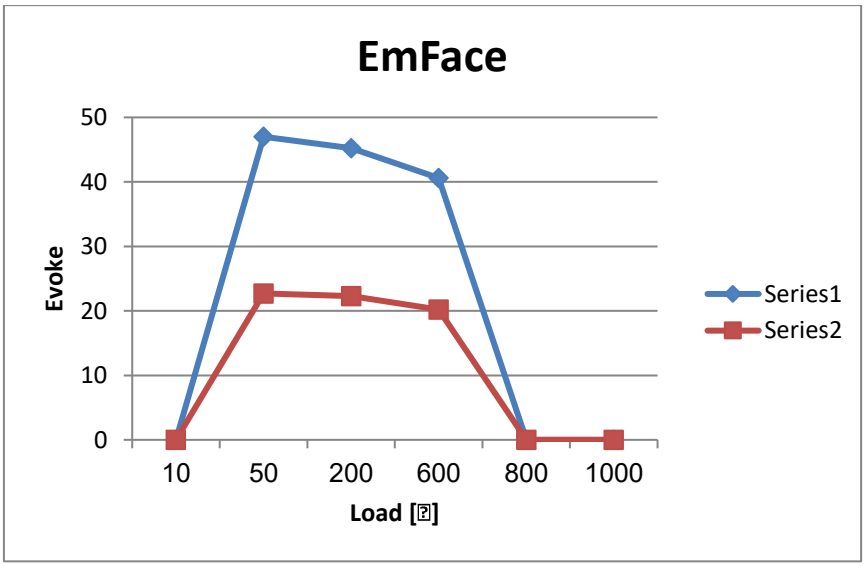


Figure 9-1: Evoke Output Power versus Impedance

10 EMC Compliance

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

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

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

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

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

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