EMPOWER**RF**

IN-SERVICE INSTRUCTIONS

EMPOWER RF

FORMAV, VTONE, MORPHEUS8V, TONE

INMODE – REVISION AUGUST 2022

INMODE

Contents

1 Preparing for service

1.1 Topics

- Training and safety measures for proper operation of the device:
  - Review of RF/EMS tissue interaction and Empower technology
  - Review of anatomy and physiology of female urogenital conditions
  - Patient assessment and consultation
  - Treatment protocols
  - Pre- and post- treatment care
  - Demonstration and hands-on training

Note:

The QRG's and Operator Manual include introductions to technology and applications, treatment protocols and safety instructions.

Do not attempt to use the device before reading the complete Operator Manual, and In-service training is completed.

Disclaimer: In-service training is offered by InMode through professionals in the aesthetic industry and is provided solely for educational purposes of device operation and safety. In-service training does not constitute any form of certification of competency. Practitioners should always consult additional sources of information including the appropriate laws governing their specialty and their supervising physician before making clinical decisions of any kind.

1.2 List of Supplies

- Please prepare for the in-service training day by having the following supplies on-hand at the facility:
  - Speculum and light source
  - Clear Ultrasound Gel
  - Rubbing Alcohol 70%
  - Wooden tongue depressors
  - Long cotton swabs with four-by-four gauze

- Wet wipes – non-alcoholic
- Soft tissues and paper towels
- Gauze
- Patient drapes or towels
- Gloves
- Healing ointment such as Aquaphor or Vaniply
- GYN table with foot peddle or appropriate pelvic support for proper visualization
- Topical anesthetic
- Acyclovir or Valacyclovir for prophylaxis (per physician discretion)
- Patient charts with intake forms: medical history, informed consent, treatment record sheet
- Panty Liners
- Disposable razors
- Treatment tips

1.3 In-Service Time Schedule

- Please note that trainees should be available for a full day of training depending on the number of volunteer patients.
  - Allow 1 hours for theoretical background and system description
  - Allow 1-2 hours for hands-on treatments
  - Allow 30-45 minutes per patient for treatment demonstration and parameters' choice discussion

1.4 Patient Selection for In-service Day

- It is recommended that you schedule 2-3 volunteer female patients for the "live" training session. Volunteer patients can include staff, family and friends, or patients who have a clear understanding that they will receive treatment during a training session. It is advisable to use a specific consent form designed for this purpose.

- Ensure that the volunteer patient does not have any contraindications to treatment and that the patient has an up-to-date normal PAP test and gynecological exam. Patients should be free of hair in any zone that is to be treated. Patients should not be actively menstruating or about to start their cycle. Obtain as much of the medical history before the treatment day, and if you are unsure if a patient is an appropriate candidate, contact your Empower clinical specialist.

- Patient selection for the training day should consist of patients with mild to moderate (not severe) symptoms or laxity.

- Provider must be able to:

1. Perform digital vaginal exam
2. Review full list of contraindications
3. Ensure that the patient has had an up-to-date gynecologic exam and PAP test

Degrees of Uterine Prolapse – uterine prolapse is described in stages, indicating how far it has descended. Other pelvic organs (such as bladder or bowel) may be prolapsed into the vagina. It is not recommended to treat patients with a degree greater than Stage I prolapse. The four categories of uterine prolapse are:

- Stage I – the uterus is in the upper half of the vagina
- Stage II – the uterus has descended nearly to the opening of the vagina
- Stage III – the uterus protrudes out of the vagina
- Stage IV – the uterus is completely out of the vagina

1.5 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.
  - Vaginal or pelvic surgery within the past 12 months.
  - Current or history of skin cancer and genital area 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, current urinary tract infection or pelvic infection, uterine prolapse, cystocele, rectocele.
- 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.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

1.6 Precautions (Tone/vTone)

- 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

Note

- In case of uncertainty regarding potential side effects, have the patient consult his/her physician and bring a written consent for treatment.
- Test Spots: a small area should be treated and assessed after a minimum of 10-15 minutes (for light skin I-III) and two to ten days later (for dark skin IV-VI) to determine if the patient will tolerate the treatment without developing adverse events.

Note

For Tone Applicator only: Not recommended for transthoracic use.

1.7 Possible Side 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 skin redness (erythema)
- Damage to natural skin texture (crust, blister, burn)
- Change of pigmentation (hypo- or hyper-pigmentation
- Bruising
- Vaginal discharge during or after treatment (extreme vaginal atrophy)
- Infection

- When using Tone applicator minor, short term muscle spasm/pain may occur.

1.8 Who Should be Present?

- Everybody who will be involved in the treatment, including administrative staff members who have the first phone interaction with the patients.
- The responsible doctor/nurse should attend the training, devoting the whole time to training. It is recommended that the clinic owner be present, as there may be a turnover of employed staff members.

1.9 Pre-Treatment Preparations

- The patient should have an up-to-date normal PAP test (within last 12 months) and recent normal vaginal exam to ensure that there are no active infections
- Physician prescribed Acyclovir or Valacyclovir for prophylaxis prior to treatment
- Review all indications
- Review all contraindications
- Complete the medical history and physical prior to treatment
- Sign the informed consent prior to the procedure
- Hair should be shaved in the treatment area 2-4 days prior to the procedure. The hair should not be waxed or chemically removed.
- Perform a vaginal exam immediately prior to the procedure to visualize the area that is going to be treated
- The patient should use the restroom to urinate immediately prior to treatment.
- Clean the treatment area with Chlorhexidine or 70% rubbing alcohol. Ensure that the treatment area is clean and dry from all residue prior to beginning the procedure.
- Advise the patient to avoid anticoagulants such as aspirin throughout the treatment regimen, if medical condition permits and pertinent to physician approval. Anticoagulants increase the possibility of bruising.
- Any topical Lidocaine application or Lidocaine injection should only be administered with a physician order and under a medical director's supervision.

1.10 Post Treatment Guidelines

- After each treatment session, the physician should advise the patient on proper care.
    - Emollient cream or healing ointment would be applied to the Morpheus8V external treatment area. Vaniply, Vaseline, antibiotic ointment or Aquaphor may be used.
    - The patient should use the restroom to urinate immediately after treatment.
    - Antibiotics may be prescribed if infection is suspected. Patient is to contact the physician if there is any indication of infection, excessive swelling, redness, undue pain, or any other unusual or untoward symptom.
    - Tiny scabs may appear after 1-3 days and stay for several days following the treatment. The scabs should not be touched or scratched even if they itch and should be allowed to flake off naturally.

- Blisters may be treated with a prescribed antibiotic ointment or burn treatment cream as per physician's discretion.
- During the first 2 days following FormaV/vTone treatment, any mechanical or thermal damage to the area must be avoided.
- During the first 2-7 days following Morpheus8V treatment, any mechanical or thermal damage to the area must be avoided.
- In case of vaginal discharge, a panty liner may be worn for the first day after treatment.

2 Sample Patient Intake Forms

PERSONAL INFORMATION			
NAME		HOME PHONE	
ADDRESS		WORK / MOBILE PHONE	
CITY		PROVINCE / STATE	
ZIP CODE		DATE OF BIRTH	
REFERRED BY		GENDER	

GYNECOLOGICAL HISTORY			
LAST PAP:		PAP RESULTS:	
LAST MENSTRUAL PERIOD			
HISTORY OF ABNORMAL PAP SMEARS?	YES / NO	INDICATIONS FOR TREATMENT	

MEDICAL HISTORY			
PACEMAKER / DEFIBRILLATOR		ACTIVE SKIN INFECTION (E.G. PSORIASIS, ECZEMA)	
METAL IMPLANTS		SKIN DISORDERS/CONDITIONS (E.G. KELOIDS, ABNORMAL WOUND HEALING, VITILIGO)	
CURRENT OR HISTORY OF SKIN CANCER/ OTHER CANCER / PRE-MALIGNANT MOLES/SUSPICIOUS LESIONS		HISTORY OF BLEEDING DISORDERS	
SEVERE CONCURRENT MEDICAL CONDITIONS (E.G. CARDIAC DISORDERS)		ENDOCRINE DISORDERS (E.G. DIABETES, PCOS)	
PREGNANCY AND NURSING		LASER RESURFACING / DEEP CHEMICAL PEELING, LAST 3 MONTHS	
IMPAIRED IMMUNE SYSTEM		DISEASES STIMULATED BY HEAT (E.G. HERPES SIMPLEX)	
INTRA-DERMAL OR SUPERFICIAL SUB-DERMAL INJECTIONS/FILLERS/GRAFTS		TATTOO OR PERMANENT MAKEUP	
TANNED SKIN			
SURGICAL PROCEDURES			
CURRENT MEDICATIONS			
LIST ANY ALLERGIES			
DETAIL ANY MEDICAL CONDITION			
OTHER CONSIDERATIONS			

2.1 EMPOWER Sample Informed Consent Forms

BELOW ARE **SAMPLES** OF INFORMED CONSENT FORM AND TREATMENT FORMS FOR REGULAR PATIENTS OR FOR VOLUNTEER PATIENTS FOR TRAINING. INMODE PROVIDES THESE FORMS FOR DEMONSTRATION ONLY AND DOES NOT ACCEPT ANY LIABILITY FOR THEIR CONTENTS. IT IS ESSENTIAL THAT EACH CLINIC CUSTOMIZE THE CONSENT FORMS ACCORDING TO TREATMENT PROCEDURE, LOCAL SPECIFIC REGULATORY REQUIREMENTS AND LANGUAGE.

Sample Informed Consent for VTONE

Patient name: _____

Treatment Sites: _____

I duly authorize _____ to perform the VTONE treatment.

I understand that the VTONE is an EMS (Electrical Muscle Stimulation) device used for intra vaginal treatment providing electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women. It has been explained to me that although EMS treatments has been very effective there is no guarantee that I will benefit from this treatment. I understand the most common side effects and complications from this treatment are the following:

1. **Pain:** you may experience pain during or after the procedure. If you feel significant discomfort after the treatment, you may use over the counter pain medications after the procedure.
2. **Swelling:** there may be swelling in the treatment areas after the treatment which can last up to one week in duration.
3. **Skin irritation and burns:** you may experience a burn which can be mild, moderate or severe to different degrees in the treatment area. Minor burns generally heal without difficulty but more severe burns, though rate, can lead to scarring, sensory or pigmentary changes.
4. **Scarring:** the risk of this complication is minimal but it can occur whenever the surface of the skin is disrupted. Strict adherence to all post-operative instructions will minimize the possibility of this occurring.
5. **Allergic reactions:** it is possible to experience an allergic reaction to an anesthetic, topical cream or oral medication.
6. **Herpes Eruption:** it is possible, even with antiviral prophylaxis, to experience a herpes eruption if you are an HSV carrier. Inform your doctor immediately if you experience pain, skin eruptions or blistering post-treatment so that the proper treatment can be initiated.
7. **Infection:** this treatment has the potential to cause skin damage, so infection is possible. Infection is unlikely, but can be life-threatening if it does occur and is left untreated; signs and symptoms of infection are: redness, fever, pain, pus and swelling. Should infection occur, you should contact you doctor for immediate evaluation and treatment.

It is important that you tell your doctor if you experience any of these side effects.

I understand that clinical results may vary depending on individual factors, including but limited to medical history, skin type, patient compliance with pre/post treatment instructions, and individual response to treatment.

I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications, and I understand that no guarantee can be give as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to procced is based solely on my expressed desire to do so.

I confirm that I have informed the staff regarding any current or past medical condition, disease or medication taken. I confirm that I have had an up-to-date normal PAP test and that I have communicated these results.

I consent to the taking of photographs and authorize their anonymous use for the purpose of medical audit, education and promotion.

I agree to waive, release, discharge, and covenant not to sue Invasix, Inc. d/b/a InMode ("InMode") and its employees, agents, and representatives, from any liability, loss, cost, damage, expense, claim or lawsuit whatsoever for any and all injury, loss, illness, harm, cost, expense, or damage related to the treatment, including any negligent acts or conduct by InMode and its agents, employees, and/or representatives (collectively, "Claims").

I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

Patient Signature _____ Date _____

Witness Signature _____ Date _____

Sample Informed Consent for MORPHEUS8V/MORPHEUS8

BELOW IS A **SAMPLE** INFORMED CONSENT FORM FOR REGULAR PATIENTS OR FOR VOLUNTEER PATIENTS FOR TRAINING. INMODE PROVIDES THESE FORMS FOR DEMONSTRATION ONLY AND DOES NOT ACCEPT ANY LIABILITY FOR THEIR CONTENTS. IT IS ESSENTIAL THAT EACH CLINIC CUSTOMIZE CONSENT FORMS ACCORDING TO TREATMENT PROCEDURE, LOCAL SPECIFIC REQUIREMENTS AND LANGUAGE.

Patient name: _____Treatment Sites:

_____

I duly authorize _____ to perform the MORPHEUS8V treatment.

I understand that the MORPHEUS technology utilizes fractional radiofrequency (RF) to induce ablation, thus improving the appearance of the treated tissue, stimulates collagen generation and replenishment. It has been explained to me that although RF treatments has been very effective there is no guarantee that I will benefit from this treatment. I understand the most common side effects and complications from this treatment are the following:

1. **Pain:** you may experience pain during or after the procedure. If you feel significant discomfort after the treatment, you may use over the counter pain medications after the procedure.
2. **Swelling:** there may be swelling in the treatment areas after the treatment which can last up to one week in duration.
3. **Skin irritation and burns:** you may experience a burn which can be mild, moderate or severe to different degrees in the treatment area. Minor burns generally heal without difficulty but more severe burns, though rate, can lead to scarring, sensory or pigmentary changes.
4. **Scarring:** the risk of this complication is minimal but it can occur whenever the surface of the skin is disrupted. Strict adherence to all post-operative instructions will minimize the possibility of this occurring.
5. **Allergic reactions:** it is possible to experience an allergic reaction to an anesthetic, topical cream or oral medication.
6. **Herpes Eruption:** it is possible, even with antiviral prophylaxis, to experience a herpes eruption if you are an HSV carrier. Inform your doctor immediately if you experience pain, skin eruptions or blistering post-treatment so that the proper treatment can be initiated.
7. **Infection:** this treatment has the potential to cause skin damage, so infection is possible. Infection is unlikely, but can be life-threatening if it does occur and is left untreated; signs and symptoms of infection are: redness, fever, pain, pus and swelling. Should infection occur, you should contact you doctor for immediate evaluation and treatment.
8. When using Morpheus8, there is a potential low-level stimulation of branches of facial nerve, and involuntary contraction of the underlying muscle may occur. This is transient and is not harmful, as the Morpheus8 effect diminishes at the deeper level where parts of the nerve lie above the muscles. These effects have been fully explained to me. _____ (patient's initials).

It is important that you tell your doctor if you experience any of these side effects.

I understand that clinical results may vary depending on individual factors, including but limited to medical history, skin type, patient compliance with pre/post treatment instructions, and individual response to treatment.

I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications, and I understand that no guarantee can be give as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to procced is based solely on my expressed desire to do so.

I confirm that I have informed the staff regarding any current or past medical condition, disease or medication taken. I confirm that I have had an up-to-date normal PAP test and that I have communicated these results.

I consent to the taking of photographs and authorize their anonymous use for the purpose of medical audit, education and promotion.

I agree to waive, release, discharge, and covenant not to sue Invasix, Inc. d/b/a InMode ("InMode") and its employees, agents, and representatives, from any liability, loss, cost, damage, expense, claim or lawsuit whatsoever for any and all injury, loss, illness, harm, cost, expense, or damage related to the treatment, including any negligent acts or conduct by InMode and its agents, employees, and/or representatives (collectively, "Claims").I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

Patient Signature _____ Date _____

Witness Signature _____ Date _____

Sample Informed Consent for FormaV

BELOW IS A **SAMPLE** INFORMED CONSENT FORM FOR REGULAR PATIENTS OR FOR VOLUNTEER PATIENTS FOR TRAINING. INMODE PROVIDES THESE FORMS FOR DEMONSTRATION ONLY AND DOES NOT ACCEPT ANY LIABILITY FOR THEIR CONTENTS. IT IS ESSENTIAL THAT EACH CLINIC CUSTOMIZE CONSENT FORMS ACCORDING TO TREATMENT PROCEDURE, LOCAL SPECIFIC REQUIREMENTS AND LANGUAGE.

Patient name: _____

Treatment Sites: _____

I duly authorize _____ to perform the FormaV treatment.

I understand that the FormaV is an RF device used for remodeling of the tissue. It has been explained to me that although RF treatments has been very effective there is no guarantee that I will benefit from this treatment. I understand the most common side effects and complications from this treatment are the following:

1. **Pain:** you may experience pain during or after the procedure. If you feel significant discomfort after the treatment, you may use over the counter pain medications after the procedure.
2. **Swelling:** there may be swelling in the treatment areas after the treatment which can last up to one week in duration.
3. **Bruising:** you may experience temporary bruising in the treated area which will subside with healing.
4. **Ecchymosis & Purpura:** you may experience some temporary bruising or purple discoloration in the treatment area which will subside with healing.
5. **Blistering / Bullae:** you may experience some temporary blistering / bullae in the treatment area which will subside with healing.
6. **Burn:** you may experience a burn which can be mild, moderate or severe to different degrees in the treatment area. Minor burns generally heal without difficulty but more severe burns, though rate, can lead to scarring, sensory or pigmentary changes.
7. **Pigmentary changes:** you may experience lightening of the skin which may be temporary or permanent (hypopigmentation). You may experience temporary or permanent darkening of the skin (hyperpigmentation).
8. **Scarring:** the risk of this complication is minimal but it can occur whenever the surface of the skin is disrupted. Strict adherence to all post-operative instructions will minimize the possibility of this occurring.
9. **Allergic reactions:** it is possible to experience an allergic reaction to an anesthetic, topical cream or oral medication.
10. **Herpes Eruption:** it is possible, even with antiviral prophylaxis, to experience a herpes eruption if you are an HSV carrier. Inform your doctor immediately if you experience pain, skin eruptions or blistering post-treatment so that the proper treatment can be initiated.

11. **Infection:** this treatment has the potential to cause skin damage, so infection is possible. Infection is unlikely, but can be life-threatening if it does occur and is left untreated; signs and symptoms of infection are: redness, fever, pain, pus and swelling. Should infection occur, you should contact you doctor for immediate evaluation and treatment.

It is important that you tell your doctor if you experience any of these side effects.

I understand that clinical results may vary depending on individual factors, including but limited to medical history, skin type, patient compliance with pre/post treatment instructions, and individual response to treatment.

I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications, and I understand that no guarantee can be give as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to procced is based solely on my expressed desire to do so.

I confirm that I have informed the staff regarding any current or past medical condition, disease or medication taken. I confirm that I have had an up-to-date normal PAP test and that I have communicated these results.

I consent to the taking of photographs and authorize their anonymous use for the purpose of medical audit, education and promotion.

I agree to waive, release, discharge, and covenant not to sue Invasix, Inc. d/b/a InMode ("InMode") and its employees, agents, and representatives, from any liability, loss, cost, damage, expense, claim or lawsuit whatsoever for any and all injury, loss, illness, harm, cost, expense, or damage related to the treatment, including any negligent acts or conduct by InMode and its agents, employees, and/or representatives (collectively, "Claims").

I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

Patient Signature _____ Date _____

Witness Signature _____ Date _____

TONE Sample Informed Consent Form

BELOW IS **SAMPLE** OF INFORMED CONSENT FORM FOR REGULAR PATIENTS OR FOR VOLUNTEER PATIENTS FOR TRAINING. INMODE PROVIDES THESE FORMS FOR DEMONSTRATION ONLY AND DOES NOT ACCEPT ANY LIABILITY FOR THEIR CONTENTS. IT IS ESSENTIAL THAT EACH CLINIC CUSTOMIZE THE CONSENT FORMS ACCORDING TO TREATMENT PROCEDURE, LOCAL SPECIFIC REGULATORY REQUIREMENTS AND LANGUAGE.

TONE SAMPLE INFORMED CONSENT

PATIENT NAME _____

TREATMENT SITES _____

I DULY AUTHORIZE _____ **TO PERFORM TONE TREATMENT.**

I understand that the device being used for muscle tone improvement of which I am consenting to be a patient receiving TONE treatment.

I understand that clinical results may vary depending on individual factors, including but not limited to medical history, skin type, patient compliance with pre- and post-treatment instructions, and individual response to treatment.

I understand that there is a possibility of short-term effects such as reddening, mild burning, pain, swelling, muscles spasm, and temporary discoloration of the skin, as well as the possibility of rare side effects such as treatment area infection, scarring and permanent discoloration. These effects have been fully explained to me _____ (patient's initials).

I understand that treatment with this system involves a series of treatments and the fee structure has been fully explained to me _____ (patient's initials).

I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications, and I understand that no guarantee can be given as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to proceed is based solely on my expressed desire to do so.

I confirm that I have informed the staff regarding any current or past medical condition, disease or medication taken.

I consent to the taking of photographs and authorize their anonymous use for the purposes of medical audit, education and promotion.

I agree to waive, release, discharge, and covenant not to sue Invasix, Inc. d/b/a InMode ("InMode") and its employees, agents, and representatives, from any liability, loss, cost, damage, expense, claim or lawsuit whatsoever for any and all injury, loss, illness, harm, cost, expense, or damage related to the treatment, including any negligent acts or conduct by InMode and its agents, employees, and/or representatives (collectively, "Claims").

I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

Patient Signature _____ Date _____

Witness Signature _____ Date _____

2.2 CONTRAINDICATIONS CHECKLIST:

- Surgery in the treatment within the last 12 months.
- Implants in the treatment area
- History of herpes. 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.
- UTI
- Current or history of skin cancer and genital area cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Significant illness such as diabetes, cardiac disease, autoimmune disease
- History of epidermal or dermal disorders involving collagen or microvasculature
- Active electrical implant in any region of the body
- Pregnancy and nursing
- Diseases of the immune system such as HIV, AIDS or immunosuppressive med
- Use of anticoagulants or history of bleeding disorders
- Any active condition in the treatment area, such as open lacerations, infection, abrasions or lesions, psoriasis, eczema or rashes
- History of skin disorders, keloids, abnormal would healing
- Tattoo in the treatment area
- History of Accutane use in the previous 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.
- Excessively tanned skin in the treatment area from sun, sun-beds or tanning creams

2.3 Sample Empower Treatment Record

PATIENT NAME: _____ DOB:_____

TREATMENT**:** **Morpheus8 / Morpheus8V**

Date	Treatment Indication	Tip	Energy Setting	Depth	Total RF Pulses	Notes (No. of passes, response, etc)

PATIENT NAME: _____

TREATMENT**:** **vTone/FormaV/Tone**

SKIN TYPE**:** **I** **II** **III** **IV** **V** **VI**

Date	Treatment Area/ Handpiece	Energy of Power/ Intensity	Cut-off Temp.	Time per Zone	Notes (Skin response, total energy, etc)