

INSERVICE INSTRUCTIONS



MORPHEUS8

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FRACTORA

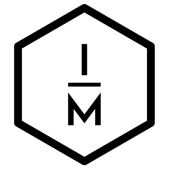
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RESURFACING



INMODE – REVISION AUGUST 2018



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Preparing for in

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service

## 1.1Topics

Training and safety measures for proper operation of the device:

* Review of QRG’s and clinical applications
* Patient assessment and consultation
* Treatment protocol
* Pre- and post-treatment care
* Hands-on training

**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.

## 1.2List of Supplies Fractora/Morpheus8

* 12-ply gauze
* Alcohol 70%, other medical disinfectants
* Germicidal or disinfectant solution (not containing chlorides or acetone)
* Soft tissues, paper towels and baby wipes
* Patient drapes or towels
* Hair cap/band
* Disposable Gloves
* Disposable razors and small scissors
* Cooling measures, such as cold compresses or Zimmer
* Emollient Cream (such as Aquaphor)
* Sunscreen with at least SPF 30
* Topical anesthetics (in case only Fractora is preformed)
* Patient charts with intake forms: medical history, informed consent, treatment record sheet
* Camera for photo documentation
* White eyeliner pencils for marking treatment areas
* Degreasing cleanser
* Treatment tips

## 1.3In-Service Time Schedule

* Allow time for theoretical background and system description.
* Schedule patients with a variety of lesions, body areas and skin types. ▪ Allow at least 45 minutes per patient for treatment demonstration and parameters choice discussion.
* Have the patient arrive early and allow 45-60 minutes for numbing of topical anesthetic.

## 1.4Patient Selection for In-service Day

It is recommended that you schedule volunteer 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 easier to have one patient for a few applications. It is advisable to use a specific consent form designed for this purpose (sample consent forms attached). Patient selection for training day should include patients that are not of very dark skin types or tanned. In-service day is intended to train new users to the system using the safest most effective settings on the most appropriate patients for an optimal learning experience.

Ensure that the volunteer patient does not have any contraindications to treatment with the InMode system. Obtain as much of the medical history as possible before the treatment day and review pre-treatment instructions with the patient before the in-service day. If you are unsure that a patient is an appropriate candidate, contact your InMode clinical specialist.

**For Fractional treatment**, for in-service training only select patients with skin type I-

III with naso-labial folds, fine lines and wrinkles on the face and neck and mild acne

scars. Body areas may also be treated for wrinkles, laxity and scarring. Should you desire to treat other skin types or indications discuss further with trainer.

## 1.5Contraindications

* Pacemaker or internal defibrillator, or other metallic or electronic implant anywhere in the body. The Hand piece 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 or silicon, unless deep enough in the periosteal plane.
* Intra-dermal or superficial sub-dermal areas injected with

Botox®/HA/collagen/fat injections or other augmentation methods with biomaterial, before the product has been dissipated (up to 6 months), except Botox after binding to the facial muscles (3-7 days). It is possible to treat sooner over injectable products placed in the deep, periosteal plane, as soon as the area has healed (1-3 weeks).

* Current or history of skin cancer, or any other type of cancer, or pre-malignant moles.
* Pregnancy and nursing.
* Severe concurrent conditions, such as cardiac disorders or sensory disturbances. ▪ 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 regime.
* Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
* Any active skin condition in the treatment area, such as sores, psoriasis, eczema, and rash.
* History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
* History of bleeding coagulopathies or use of anticoagulants in the last 10 days ▪ Any facial surgery performed within a year prior to treatment.
* Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, if face is treated.
* 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 Isotretinoin (Accutane®) within 6 months prior to treatment.
* 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.
* Treating over tattoo or permanent makeup to be kept.
* Treating over the lips.
* Skin type VI and dark VI patients treat with caution.
* Treating over hair bearing surfaces.
* Irritable skin like excessively tanned skin from sun, tanning beds or tanning creams and sprays within the last two weeks.
* As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient.

## 1.6Possible Side Effects

Use of the system, whether it be proper or improper, could result in possible side effects. Although these effects are rare and expected to be transient, any adverse reaction should be immediately reported to the physician. Side effects may include any of those conditions listed below. Side effects may appear either at the time of treatment or shortly after.

The side effects may include:

* Discomfort
* Excessive skin redness (erythema) and/or swelling (edema)
* Damage to natural skin texture (crust, blister, burn)
* Change of pigmentation (hyper- or hypo-pigmentation)
* Scarring
* Infection

1.7Who 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/PA 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.

## 1.8Pre-Treatment Preparations

* Advise the patient to avoid skin irritation or intentional skin tanning. Sun-screen is advisable when outdoors during daylight hours.
* The patient should discontinue any irritant topical agents for 2-3 days prior to treatment.
* The patient should arrive for treatment with clean skin. There should be no lotion, make-up, perfume, powder or bath/shower oil present on the skin in the area to be treated.
* The patient is prepared: photos, informed consent, marking of areas, etc.
* Cavicide wipes or similar product can be an alternative to Alcohol 70% to clean the Fractora tips and Handpiece before and after the procedure. The Fractora and Morpheus8 tip cannot be fully submerged in the liquid to avoid electrical shorts.

## 1.9Post-Treatment Care

* Immediately after treatment, most patients will experience erythema (redness) for 1-3 days, however for more aggressive treatments this may last longer. Slight to moderate edema (swelling) and a mild to moderate sunburn sensation are also common post treatment and may last 1-3 days. Skin may crust and peel for 2-7 days depending on treatment settings.
* Before discharge a topical ointment may be applied to the face, no bandages or wraps are necessary.
* There are no restrictions on bathing except to treat the skin gently, avoid scrubbing or trauma to the treated area.
* Avoid sun exposure to reduce the chance of hyperpigmentation.
* The use of a zinc oxide sun block SPF 30+ at all times after 24-48 hours. ▪ Multiple treatments over a period of several months may be required to achieve the desired response.

Sample Patient Intake Forms

# Sample Patient Intake Forms



|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Personal Information** | | | |  | | | | |
| NAME |  | | | HOME PHONE | |  | | |
| ADDRESS |  | | | WORK / MOBILE PHONE | |  | | |
| CITY |  | | | PROVINCE / STATE | |  | | |
| ZIP CODE |  | | | DATE OF BIRTH | |  | | |
| REFERRED BY |  | | | GENDER | | MALE / FEMALE | | |
| **Skin Type Assessment** | | | |  | | | | |
| FITZPATRICK SKIN TYPE | | **I II III IV V VI** | |  | ETHNICITY |  | | |
| LAST EXPOSED TO UV | | (SUN OR TANNING BED) | |  | | | | |
| PASSIVE TAN? | | YES / NO | | SELF-TANNING LOTION? | | | YES / NO | |
| **Medical History** | | | |  | | | | |
| PACEMAKER / DEFIBRILLATOR | | |  | ACTIVE SKIN INFECTION (E.G. PSORIASIS, ECZEMA) | | | |  |
| METAL IMPLANTS | | |  | SKIN DISORDERS (E.G. KELOIDS, ABNORMAL WOUND HEALING) | | | |  |
| CURRENT OR HISTORY OF SKIN CANCER/ OTHER CANCER / PRE-MALIGNANT MOLES | | |  | HISTORY OF BLEEDING DISORDERS | | | |  |
| SEVERE CONCURRENT MEDICAL  CONDITIONS (E.G. CARDIAC DISORDERS) | | |  | USE OF MEDICATION / HERBS INDUCING PHOTOSENSITIVITY | | | |  |
| PREGNANCY AND NURSING | | |  | FACIAL LASER RESURFACING / DEEP CHEMICAL PEELING, LAST 3 MONTHS | | | |  |
| IMPAIRED IMMUNE SYSTEM | | |  | NEEDLE EPILATION, WAXING OR TWEEZING, LAST 6 WEEKS | | | |  |
| DISEASES STIMULATED BY LIGHT (E.G. LUPUS, PORPHYRIA, EPILEPSY) | | |  | TATTOO OR PERMANENT MAKEUP | | | |  |
| DISEASES STIMULATED BY HEAT (E.G. HERPES SIMPLEX) | | |  | TANNED SKIN | | | |  |
| ENDOCRINE DISORDERS (E.G. DIABETES, PCOS) | | |  | INJECTIONS/FILLERS | | | |  |
| SURGICAL PROCEDURES | | |  |  | | | |  |
| **List any medications taken** | | |  |  | | | | |
| **List any allergies** | | |  |  | | | | |
| **Detail any medical condition** | | |  |  | | | | |
| **Other considerations** | | |  |  | | | | |

Sample Informed Consent Forms

# 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 REQUIREMENTS AND LANGUAGE. **For Volunteer Patients, In-service Training FRACTORA / MORPHEUS8**

**PATIENT NAME \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**TREATMENT SITES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**I DULY AUTHORIZE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ TO PERFORM \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ TREATMENT.**

I understand that the device being used for Skin Rejuvenation, Fractional Skin Resurfacing, Skin Tightening, of which I am consenting to be a patient receiving \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ treatment (specify procedure).

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 posttreatment instructions, and individual response to treatment.

I understand that there is a possibility of short-term effects such as reddening, mild burning, temporary bruising and temporary discoloration of the skin, as well as the possibility of rare side effects such as 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 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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Treatment Forms



Treatment Forms

PATIENT NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

TREATMENT**: FRACTORA / MORPHEUS8**

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** | **Treatment Area/Lesions** | **Energy** | **Applicator** | **Tip Type** | **Total Pulses** | **N of Stacks** | **Notes (# passes, treatment time, Skin response, etc)** |
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