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CYNOGLOW

CYNOSURE®
BEAUTIFUL ENERGY

Treatment Guide



IMPORTANT! This document does not replace the PicoSure Pro and Potenza Operator's Manuals or Clinical Reference Guides. Refer to the PicoSure Pro and Potenza Operator's Manuals and Clinical Reference Guides for complete product information, including warnings, cautions, and other information.

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CYNOGLOW is a customizable treatment plan utilizing the most advanced picosecond laser, PicoSure Pro, and radiofrequency microneedling technology, Potenza, that targets the superficial and deep layers of the skin. Utilizing these two technologies allows practitioners to address some of the most common skin concerns amongst patients such as benign pigmented lesions, acne scars, wrinkles, and dermatologic procedures for electrocoagulation and hemostasis.

This comprehensive treatment allows practitioners the ability to create a customized treatment plan to cater to a patient's unique skin concerns.

Careful consideration of parameters must be taken for higher Fitzpatrick skin types (FP IV-VI). Elevated erythema places higher Fitzpatrick skin types at greater risk of post-inflammatory hyperpigmentation (PIH). The tables provided within this document are recommended starting settings. For application of additional optics with PicoSure Pro and/or treatment tips with Potenza, including more comprehensive treatment parameters, practitioners should adhere to the guidelines found within the Clinical Reference Guide of the appropriate device. Practitioners must always use their clinical judgement and conduct a patient assessment, including appropriate test spots, to determine the treatment plan appropriate to meet the individual needs of each patient.

The use of the B.E. Replenishing Face & Neck Mask may be used post Cynoglow treatment for the purpose of:

- Immediately reduces heat sensation in the skin
- Acts as a protective layer over compromised skin
- Soothes and calms skin for enhanced treatment results

Not all patients are candidates for this treatment. Review the full list of contraindications and cautionary criteria prior to beginning treatment. Topical anesthetic may be used and is at the practitioner's discretion. Thoroughly remove the topical anesthetic and cleanse the skin before starting treatment. Care should be taken to observe the desired clinical endpoint when determining appropriate treatment sequence.

Practitioners are advised to refer to the Operator's Manual and Clinical Reference Guide of both PicoSure Pro and Potenza to review appropriate settings, guidelines, and full recommendations per use of the device prior to beginning treatment. This document is not intended to replace or substitute the information found within the Operator's Manual or Clinical Reference Guides.

POTENZA™ Potenza is a trademark of Jeisys Medical, Inc.**Indications for use:**

The Potenza radiofrequency system is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Contraindications

Do not use this product on patients listed below.

- Patients with a pacemaker.
- Patients who have previously had a gold-thread skin-rejuvenation treatment.
- Patients with keloid formation propensity.
- Patients with skin infections.

Cautionary Criteria

Review these criteria when considering treating patients who:

- Have a cut, wound, or infected skin on the area to be treated (but skin eruptions may be treated).
- Are pregnant and/or breastfeeding (aesthetic application).
- Have a metal implant that interferes with the transmission of energy to the electrical field.
- Have any embedded electronic devices that give or receive a signal; the device should be turned off or removed prior to treatment. Always consult with the health care practitioner before turning off a patient's electronic device.
- Have Implantable Cardiac Defibrillators (ICD) or Cardiac Resynchronization Therapy (CRT) devices: treatment may interfere with the functionality of the device and/or damage the electronic implant.
- Have an embedded Implantable Cardioverter Defibrillator (ICD); the patient's cardiologist must be consulted prior to treatment.
- Have electronic implants without first consulting a qualified professional (e.g., cardiologist or the manufacturer of the electronic implant).
- Are allergic to adhesives such as glues on medical tape: they should be alerted that a rash may occur on the neutral electronic monitoring pad (NEM or neutral pad) site, and an over-the-counter preparation may be used to treat the area.
- Are allergic to gold.
- Have an unrealistic expectation of the results: this is not plastic surgery, and all patients should be fully informed of the treatment's expected results.
- Have nerve insensitivity to heat in the treatment area or in the neutral pad placement area.

- Have severe laxity or sagging that causes redundant folds of tissue or hanging skin in the area to be treated: this treatment will be ineffective.
- Have used Accutane (isotretinoin) six to twelve months prior to treatment, as this can thin the skin and make it brittle.
- Have diabetes or diabetic complications.
- Are taking aspirin or are currently taking antiplatelets, thrombolytics, anti-inflammatories or anticoagulants.
- Have a history of bleeding coagulopathies.
- Are allergic to topical anesthetic.
- Studies have not been conducted on the use of the Potenza System on patients with any of the following conditions:
 - Pregnant and breast-feeding women
 - Autoimmune disease
 - Diabetes
 - Herpes simplex
 - Epilepsy
 - HIV
 - Hypertension
 - Dermatitis

Precautions

For all microneedling with fractional RF, treatment is cautioned for patients that meet the following criteria. A doctor's approval should be obtained before treating with the Potenza who:

- Are prone to fever blisters: they should receive a prophylactic antiviral medication regimen prior to treatment.
- Have lesions in the treatment area that have not been evaluated and diagnosed: they should be evaluated prior to the treatment day.
- Have malignant disease including skin malignancies. Precautions should be taken if a person has any other form of a malignant disease (cancer).
- Have used retinoids in the last seven days in the area to be treated: retinoids can create erythema and cause the skin to become heat sensitive.
- Have used any chemical peels in the last two to three months in the treatment area: patients should wait until any remaining erythema or side effects have resolved.
- Have tattoos, permanent makeup, and permanent brows in the treatment area: caution must be used. (The ink used in these applications is unregulated and may have metallic components.)

- Have an autoimmune disease.
- Avoid medications that alter the healing response or hemostasis for three to seven days.
 - Always check with the prescribing physician before stopping any medications.
- Have a history of healing problems.
- Have a neuropathic disorder, impaired skin sensation or diabetic neuropathy.
- Have an Implanted Cardioverter Defibrillator (ICD): the patient's cardiologist must be consulted prior to treatment.
- Have received fillers or neurotoxin injections: patients should wait two weeks before receiving a Potenza treatment.

PICOSURE® PRO

Indications for Use:

755nm Wavelength: The PicoSure Pro workstation is indicated for tattoo and benign pigmented lesions removal including but not limited to: Nevus of Ota, Hori macules (nevus of Hori), and Melasma. The PicoSure Pro workstation using the Platinum focus™ lens array is indicated for the treatment of acne scars and wrinkles in Skin Types I-IV. The device is not intended to treat Nevus of Ota pigmentation of eye, only pigmentation of the skin. It is at the practitioner's discretion to determine which treatment course is appropriate per the patient's needs.

Contraindications

Therapy using the PicoSure Pro laser is contraindicated for those patients who:

- Are hypersensitive to light in the near infrared wavelength region
- Take medication which is known to increase sensitivity to sunlight
- Have seizure disorders triggered by light
- Take or have taken oral isotretinoin, such as Accutane®, within the last six months
- Have an active localized or systemic infection, or an open wound in area being treated
- Have a significant systemic illness, such as lupus, or an illness localized in area being treated
- Have common acquired nevi that are predisposed to the development of malignant melanoma
- Have herpes simplex in the area being treated
- Are receiving or have received gold therapy
- Are pregnant or breast feeding (lactating)

Warnings/Precautions

Physician discretion is required to determine feasibility of treatment administration:

- Unprotected sun exposure within four weeks of treatment, including the use of tanning beds or tanning products, such as creams, lotions and sprays
- History of immunosuppression/immune deficiency or an auto-immune disorder
- Coagulation disorder or currently using anticoagulation medication, including heavy use of aspirin
- Medications that alter the wound-healing response or evidence of compromised wound healing
- If patient is known to have a history of keloid formation
- If patient has a history of skin cancer or suspicious lesions in the treatment area
- If a patient's tattoo is the result of an event in which gunpowder or combustible elements may be the foreign body creating the "tattoo"
- The safety of the 532-nm delivery system treatment on skin types IV or higher has not been assessed
- Protective metal eye shields must be used in the eyes and must be fully occlusive. It is important to use extreme caution when treating near the eyes

Adverse Effects

Adverse effects can include discomfort, redness, swelling, pinpoint bleeding, blistering, scabbing, crusting and bruising/petechiae, which are usually transient and resolve without intervention.

Possible adverse effects include pustules, skin burns, hypopigmentation, hyperpigmentation, scarring, infection, erosion, desquamation, and allergic reaction. Most of these are transient and resolve over time.

Treatment Recommendations for Potenza:

- Test spots should be performed prior to treatment to determine suitability
- Always apply the neutral pad to the patient when using fractional microneedle tips in Monopolar mode.
- Always use a new, sterilized, single-use, disposable tip.
- Apply anesthetic cream (follow Rx recommendations)
- Cleanse skin thoroughly prior to beginning treatment
- Before starting a full treatment, always perform two to three test spots at the selected sites.
- When treating facial tissue, be sure to decrease the depth of needle penetration for areas with thinner tissue, i.e., eye area or forehead.
- A minimum of 300-400 pulses is recommended for each pass when treating the face
- Proper Impedance reading during a treatment should be 600 ohms or less.

NOTE: Decrease energy setting (W) if severe edema is evident within minutes after energy delivery or if the needle array or imprint of the four corners of tip is noted on the tissue.

NOTE: If the patient develops hyper- or hypopigmentation post treatment, treatment should be discontinued, and the side effects should be treated.

POTENZA: Recommended Starting Settings/Test Spot Treatment Insulated I-25 Tip for Revitalization Through Soft-Tissue Coagulation									
FST	Pass	Target	Depth (mm)	Mode	Frequency	Power	Pulses & PW	Impact	mJ/Pulse
I-IV	Pass 1	Deeper Dermis	1.5-2.75	Bipolar	1 MHz	20 W	1 Pulse 40 ms	3 - 4	800
I-IV	Pass 2	Upper Dermis	0.75-1.0	Monopolar	1 MHz	20 W	1 Pulse 40 ms	3 - 4	800
V-VI	Single Pass Only	Deeper Dermis	1.5-2.75	Monopolar	1 MHz	15 W	1 Pulse 40 ms	3 - 4	600

NOTE: These parameters are suggested starting settings and may be adjusted based on the physician's discretion, the patient's skin condition (including its hydration and tissue thickness), and the location of the area being treated.

NOTE: Moderate to severe skin conditions may take a series of treatments to achieve an optimal outcome; results may be seen several weeks to months after the final treatment. It is at the practitioner's discretion to determine which treatment course is appropriate per the patient's needs. Observation for appropriate clinical endpoint must be maintained.

Treatment Recommendations for PicoSure Pro:

- For the PicoSure Pro device, appropriate eye protection for the wavelength being used must be worn by all individuals in the room during treatment to avoid eye injury.
- Test spots should be performed prior to treatment to determine suitability
- Adverse effects may be reduced by air cooling prior to treatment, and removal of all make up, lotions or creams from the area to be treated.
- Energy levels used during treatment should be based on the patient's skin type or type of pigmented lesions. Administering test spots prior to treating and starting treatment at the lowest suggested energy setting is recommended.
- The practitioner should determine the end of treatment by the complete success of treatment, non-compliance on the part of the patient, or adverse effects of the treatment.
- When treating the full face, divide treatment areas into quadrants. Then divide each quadrant into smaller areas, this allows laser energy to be distributed effectively and efficiently.
- Deliver passes using a "feathering" (painting) technique in a multidirectional pattern.
- Use a 10-25% overlap for mild to moderate conditions and up to a 50% overlap for severe acne scars, pigmentation, and wrinkles.

Clinical Endpoint

- Erythema typically resolves in less than an hour but in some cases may linger for 24 hours.
- Frosting usually fades in 30 minutes.
- Unwanted pigment will continue to darken and may turn 2–3 shades darker than original color and shed over time.
- Most unwanted pigment will significantly lighten or clear in 2–3 sessions.
- Hypopigmentation may occur when treating epidermal pigmented lesions. It is usually transient and resolves over a period of 4–6 months.
- Post-inflammatory hyperpigmentation and/or hypopigmentation may occur with any laser treatment. Typically, both resolve spontaneously without intervention in 6–12 months.
- Proper post-treatment care should be followed per the guidelines found within the CRG.

The following suggested parameters are the most commonly used. More conservative parameters reduce the likelihood of adverse effects for darker skin types. Suggested treatment parameters are based on information provided by practitioners using the PicoSure Pro laser, published articles and results of clinical studies. Each patient is unique and should be evaluated prior to treatment for skin type.

PicoSure Pro: Platinum Focus Lens Array, 755 nm (Fixed HP)			
NOTE: Overall skin area includes hands and chest area			
Skin Type	Spot Size (mm)	Fluence (J/cm²)	Number of Passes per Treatment Area
I-III	6	0.70	3–6
IV	8	0.40	3–6
V, VI*	10	0.25	2–6
*Evaluate test spots in 48–72 hours, use caution when treating Skin Type V and VI.			

NOTE: Observation for appropriate clinical endpoint must be maintained.



PICOSURE[®] PRO

755nm PICOSECOND LASER

POTENZA[™]

RF MICRONEEDLING

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