

Clinical Architecture & Performance Reference Manual: Non-Insulated Needle
RF Machine

NON-INSULATED NEEDLE RF MACHINE

CLINICAL ARCHITECTURE & PERFORMANCE REFERENCE MANUAL

DOCUMENT SCOPE & DEVICE IDENTIFICATION

This document serves as the definitive technical and clinical reference for the Non-Insulated Needle Radiofrequency (RF) Machine, a premium-class aesthetic surgical platform intended for percutaneous tissue coagulation, dermal remodeling, and sebaceous gland modulation. The device delivers bipolar high-frequency alternating current (HFAC) directly into the reticular dermis and subcutaneous adipose strata via solid, non-coated metallic microneedles, creating a controlled volumetric thermal injury zone (TIZ) without epidermal protection shielding.



CLINICAL ARCHITECTURE & DESIGN PHILOSOPHY

Contrary to insulated needle systems where energy is restricted to the needle tip, the Non-Insulated Needle RF architecture employs a fully conductive 316L surgical-grade stainless steel needle array. When inserted to a programmed depth (0.5mm – 5.0mm), the entire exposed shaft delivers RF current. The return path is completed via paired adjacent needles (bipolar mode) or a dispersive grounding pad (monopolar mode), generating a continuous columnar thermal lesion extending from the epidermis to the target depth. This design specifically addresses epidermal laxity, superficial rhytides, and active acne vulgaris by coagulating both dermal fibroblasts and sebaceous lobules simultaneously.

KEY INDICATIONS & CLINICAL CAPABILITIES

- Active Inflammatory Acne & Acne Residue (ICD-10: L70.0): Direct thermal

ablation of sebaceous glands via full-needle shaft conduction.

- Atrophic Acne Scars (ICD-10: L90.5): Pan-dermal neocollagenesis and scar release through continuous thermal injury zone.
- Facial & Neck Skin Laxity (ICD-10: L98.8): Bulk heating of the superficial musculoaponeurotic system (SMAS) analogue in the dermis.
- Sebaceous Hyperplasia (ICD-10: L91.8): Whole-gland electrocoagulation without residual cyst formation.
- Enlarged Facial Pores & Textural Irregularities: Percutaneous coagulation of dilated pilosebaceous units.

TECHNICAL SPECIFICATIONS

RF GENERATOR TYPE: Class HF, Bipolar/Monopolar switchable

OUTPUT FREQUENCY: 1.0 MHz \pm 5% (Medical ISM band)

MAXIMUM POWER: 25 Watts (Continuous RF), 45 Watts (Pulsed Mode)

PULSE DURATION: 10 ms – 5000 ms programmable

ENERGY PER PULSE: 0.25 J – 125 J (depending on power and pulse width)

NEEDLE MATERIAL: 316L Austenitic Surgical Stainless Steel, Non-Insulated full shaft

NEEDLE DIAMETER: 33 Gauge (0.20 mm) standard / 31 Gauge (0.25 mm) optional

PENETRATION DEPTH: 0.5 mm to 5.0 mm, adjustable in 0.1 mm increments (closed-loop motor drive)

ARRAY CONFIGURATIONS: 1×1 (single), 5×5 (25-pin), 7×7 (49-pin), 9×9 (81-pin)

disposable cartridges

TISSUE TEMPERATURE GOAL: 60°C – 75°C at needle tip; 45°C – 55°C at mid-shaft (real-time impedance feedback)

COOLING SYSTEM: Active Peltier (TEC) + Sapphire Window Contact Cooling (0°C to 4°C epidermal protection)

IMPEDANCE MONITORING: Continuous 10 kHz tissue impedance analysis with automatic energy cut-off at >1200 Ohms or sudden drop indicating full coagulation

| Parameter | Specification |
|----------------------------|---|
| RF Frequency | 1.0 MHz (Class HF, ISM band) |
| Max Output Power | 25W (Continuous) / 45W (Pulsed) |
| Needle Material & Design | 316L Stainless Steel, Non-Insulated Full Shaft |
| Needle Diameter | 33G (0.20mm) / 31G (0.25mm) |
| Penetration Depth Range | 0.5 mm – 5.0 mm (0.1mm resolution) |
| Pulse Duration | 10 ms – 5000 ms |
| Cooling System | TEC + Sapphire Window (0°C to 4°C) |
| Impedance Monitoring | Continuous 10 kHz feedback, auto-cutoff >1200 Ohms |
| Electrical Safety Standard | IEC 60601-1 (Ed. 3.1), Class I, Type BF |

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| Regulatory Status | CE MDR Class IIa, FDA 510(k) Class II (GEX) |
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CLINICAL PROTOCOLS (EVIDENCE-BASED)

PRE-TREATMENT PROTOCOL: Topical anesthetic (5% Lidocaine / 7% Tetracaine) under occlusion for 45 minutes. Antiseptic skin prep with 2% Chlorhexidine gluconate. Mark treatment grid with surgical skin marker. Operating room ambient temperature 20°C – 22°C, relative humidity <60%.

ACNE & SCARRING PROTOCOL: Needle depth 2.5mm – 3.5mm. RF power 12W – 18W. Pulse duration 40ms – 60ms. Single pass with 30% – 50% overlap. Endpoint: immediate erythema with perifollicular edema and punctate bleeding (0.5 – 1.0 mm). Three to five sessions at 4-week intervals.

SKIN LAXITY & RHYTIDES PROTOCOL: Needle depth 1.5mm – 2.5mm. RF power 8W – 12W. Pulse duration 80ms – 120ms. Dual pass (cross-hatch pattern). Endpoint: visible tissue tightening and mild erythema. Three sessions at 6-week intervals.

POST-TREATMENT REGIMEN: Immediately apply cooling gel mask for 15 minutes. Prescribe occlusive ointment (petrolatum-based) twice daily for 48

hours. Strict sun protection (SPF 50+) for 4 weeks. Avoid retinoids and exfoliating agents for 7 days. Expected downtime: 2–4 days of pinpoint crusting and erythema.

SAFETY & COMPLIANCE MATRIX

- ELECTRICAL SAFETY: IEC 60601-1 (Edition 3.1) – Class I, Type BF applied part
- EMC: IEC 60601-1-2:2021 (Group 1, Class B)
- RF SPECIFIC: IEC 60601-2-2:2017 (High Frequency Surgical Equipment)
- MECHANICAL: ISO 10993-1, -5, -10 (Needle cartridge biocompatibility)
- CLINICAL EFFICACY: Conforms to ISO 14155:2020 (Clinical investigation of medical devices)
- CE MARK: EU MDR 2017/745 Class IIa (Notified Body NB 0124)
- FDA: 510(k) Class II – Product Code GEX (Electrosurgical, Cutting & Coagulation & Accessories)



OPERATIONAL WARRANTY & ASSET LIFECYCLE

Active RF generator mainframe: 36 months unlimited cycles. Disposable non-insulated needle cartridges: single-use, sterile, gamma-irradiated, shelf life 24 months. Handpiece cable & connector: 12 months. The system includes automated self-diagnostics on startup, needle insertion motor calibration verification, and daily use log with USB export capability for clinical audit trails. Recommended annual preventive maintenance: RF output power calibration verification using a precision 50-Ohm load and thermography camera (accuracy $\pm 3\%$ of set value).