Fractional RF Microneedling Machine - Official Clinical Overview & Technical Datasheet

DEVICE IDENTIFICATION AND INTENDED USE

The Fractional RF Microneedling Machine is a Class IIa medical aesthetic device engineered for percutaneous collagen induction and fractional radiofrequency dermal remodeling. The system combines insulated or non-insulated gold-plated microneedle arrays with bipolar RF energy delivery to treat rhytides, acne scars, surgical scars, striae distensae, enlarged facial pores, and mild-to-moderate skin laxity. Intended for professional use exclusively in dermatology clinics, plastic surgery centers, and licensed medical spas.

INTERNAL HARDWARE TOPOLOGY

The platform integrates a digitally controlled RF generator (1MHz to 2MHz range), a high-torque motorized handpiece drive, and a closed-loop impedance feedback module. A dual-layer PCB architecture separates high-voltage RF generation from user-interface logic, reducing electromagnetic interference. The power supply unit delivers stabilized 48V DC to the RF amplifier stage, while a dedicated 12V rail supports touchscreen and cooling subsystems. A peristaltic pump (optional) facilitates topical anesthetic or serum infusion during needling. The handpiece contains a removable 5x5 or 6x6 microneedle cartridge, each needle individually insulated except for the tip (0.3mm to 2.0mm depth penetration). Needle deployment speed is servo-controlled at 15mm/s to 25mm/s for consistent tissue entry.

EPIDERMAL PROTECTION MECHANISMS

The device employs a two-layer epidermal safety architecture. First, real-time skin impedance monitoring (0 to 1500 Ohms) detects contact loss or tissue charring, cutting RF emission within 10ms. Second, an onboard temperature sensor (0 to 50°C ±0.5°C accuracy) at the handpiece tip tracks surface warming, triggering an automatic standby mode above 42°C. Optional contact cooling via Peltier elements (pre-cooling to 5°C) reduces patient pain perception during needling. A mechanical safety interlock prevents RF activation unless the cartridge is fully seated and skin contact is confirmed via three independent

pressure sensors.

TREATMENT ADVANTAGES

- Fractional RF delivery spares healthy epidermal bridges, accelerating healing to 24-48 hours.
- Insulated needles confine RF energy to dermal papillae and reticular dermis, eliminating epidermal charring.
- Adjustable needle depth (0.5mm to 3.5mm) and RF power (2W to 25W, pulsed or continuous) enable treatment of Fitzpatrick skin types I-VI.
- Minimal post-treatment hyperpigmentation risk compared to fractional ablative lasers.
- No mandatory topical anesthetic for low-fluence protocols (5-10W, 0.5-1.5mm depth).
- Combination capability: topical serum infusion, PRP, or growth factors applied immediately post-needling.

SPECIFICATION MATRIX

Parameter	**Specification**
RF Frequency	1.0 MHz ± 5%
Maximum RF Power	25W (bipolar, continuous/pulsed)

Needle Count per Cartridge	25 (5x5) or 36 (6x6)
Needle Material	Gold-plated stainless steel, insulated shaft
Needle Penetration Depth	0.5mm to 3.5mm (0.1mm steps)
Duty Cycle	10% to 100% in 10% increments
Pulse Duration	30ms to 500ms (adjustable)
Impedance Monitoring	Real-time, 0-1500 Ohm range
Cooling System	Peltier + water-circulation (internal)
User Interface	10.1-inch capacitive touchscreen, Android OS
Dimensions (W x D x H)	380mm x 420mm x 1050mm (console)
Weight	28 kg (console only)
Power Supply	100-240V AC, 50/60Hz, 400VA

REGULATORY COMPLIANCE AND STANDARDS

The device is manufactured under ISO 13485:2016 certified quality management systems. It holds CE marking (MDR 2017/745, Class IIa), and complies with IEC 60601-1 (basic safety), IEC 60601-1-2 (EMC), IEC 60601-2-2 (HF surgical equipment), and IEC 60601-2-57 (therapeutic RF equipment). FDA 510(k) clearance (Kxxxxxx) is active for sale in the United States. Biological

safety of needle cartridges conforms to ISO 10993-1 (cytotoxicity, sensitization, irritation). The device is classified as a Class II medical device in Canada, Australia (TGA), and Brazil (ANVISA). Annual electrical safety testing to IEC 62353 is recommended.