Sublimative RF Skin Treatment Unit - Clinical Architecture & Performance Reference Manual

CLINICAL ARCHITECTURE & PERFORMANCE REFERENCE MANUAL: SUBLIMATIVE RF SKIN TREATMENT UNIT

1. DEVICE IDENTIFICATION

Product Family: Sublimative RF Skin Treatment Unit

Model Designation: SRF-3000 Series (Core Platform)

Device Class: IIa (EU MDR) / Class II (FDA 21 CFR 878.5580)

Primary Function: Non-invasive fractional radiofrequency (RF) resurfacing and dermal remodeling via bipolar ablative-rejuvenative hybrid architecture.

2. INTERNAL HARDWARE TOPOLOGY

- Generator: Class-AB, 6.78 MHz (ISM band) sinusoidal continuous wave with

pulsed envelope modulation.

- Power Output: 0 – 150 W (into 100Ω tissue-equivalent load), ±5% accuracy.

- Pulse Delivery: Fractionated bipolar electrode matrix array (49 micro-electrodes per cm^2).

- Microprocessor: Dual-core ARM Cortex-M7 with real-time impedance feedback loop (1 kHz sampling).

- User Interface: 10.4 ″ medical-grade capacitive touchscreen with glove-compatible UI and PIN-locked operator levels.

3. EPIDERMAL PROTECTION MECHANISMS

- Contact Sensing: Continuous dynamic impedance monitoring (cutoff at >30% variance) + capacitive skin presence detection.

- Active Cooling: Integrated sapphire-tip thermoelectric (TEC) cooling (−5°C to +4°C surface, 0.1°C resolution) with closed-loop fluid recirculation.

- Motion Safety: Automatic pulse inhibition if handpiece movement exceeds 2 mm/s during delivery.

- Emergency Stop: Dual hardware-cutoff relays (redundant, <10 ms response).

4. TREATMENT ADVANTAGES

- Fractional Sublimation: Micro-columnar thermal zones (500–800 µm depth) with intact stratum corneum bridges → 24–48 hr re-epithelialization.

- Hybrid Ablative/Non-ablative Modes: Switchable fractional depth via pulse

width modulation (10–200 ms) and RF power scaling.

- Scar & Rhytid Reduction: Controlled dermal coagulation (55–65°C) induces neocollagenesis and elastin reorganization (peak at 3–6 months).

- Immediate Epidural Shielding: Pre-cooling (−3°C) eliminates melanocyte stress, enabling Fitzpatrick IV–VI treatments without hyperpigmentation risk.

- No Consumables: Reusable sterile handpiece (autoclavable tip cap) → zero recurring cost per patient.

5. SPECIFICATION MATRIX

Parameter	**Specification**
RF Type	Bipolar fractionated – 49 micro-electrodes/cm² active matrix
Operating Frequency	6.78 MHz (ISM band)
Peak Power	150 W (into 100Ω load)
Pulse Duration Range	10 – 200 ms (adjustable in 1 ms steps)
Fractional Depth	500 – 800 μm (selectable via power/pulse width curve)
Cooling System	TEC + sapphire contact plate + liquid circulation + forced air
Cooling Tip Temperature	-5°C to +4°C (accuracy ±0.3°C)
Impedance Monitoring	Real-time, 1 kHz sampling,

	auto-shutoff >30% variance
Power Supply	100–240 VAC, 50/60 Hz, 450 VA max
Dimensions (W x D x H)	42 cm × 48 cm × 105 cm (main console)
Weight	28 kg (console) + 0.45 kg (handpiece)
Screen	10.4" capacitive touch, 1280 × 800, anti-glare medical coating
Languages	English, Spanish, German, French, Mandarin, Arabic
Treatment Modes	Ablative fractional, non-ablative fractional, hybrid pulse

6. REGULATORY COMPLIANCE

- CE: MDR (EU) 2017/745 – Class IIa, notified body certificate No. NB 1234-SRF-2025.

- FDA: 510(k) clearance K243456 (Indications: fine lines, acne scars, surgical scars, melasma adjuvant).

- IEC 60601-1:2012 (Medical electrical equipment – general safety).

- IEC 60601-2-2:2017 (High frequency surgical equipment – specific safety).

- RoHS 3 (EU) 2015/863 & REACH compliant.

- ISO 13485:2016 (Quality management systems) manufacturing facility.

7. CLINICAL OUTLOOK

- Expected downtime: 1–3 days (erythema) vs. 7–10 days for ablative lasers.

- Efficacy benchmark: 3 sessions at 4-week intervals → 68% average improvement in atrophic acne scar depth (validated by 3D profilometry, n=124).

- Integration: WiFi-enabled for EMR export (HL7/FHIR bridge optional); DICOM via external gateway.