Bipolar RF Facial Contouring Machine - Official Clinical Overview & Technical Datasheet

EXECUTIVE SUMMARY

This document provides a comprehensive clinical and technical overview of the Bipolar Radiofrequency (RF) Facial Contouring Machine, a non-invasive aesthetic platform engineered for dermal remodeling, subdermal adipose reduction, and facial contour refinement. Operating on a closed-loop bipolar RF architecture, the system delivers controlled volumetric heating to the reticular dermis and superficial fat compartments while preserving epidermal integrity. Designed for medical spas, dermatology clinics, and plastic surgery centers, the device offers a predictable safety profile, minimal patient downtime, and reproducible clinical outcomes.

CLINICAL ARCHITECTURE & DESIGN

The Bipolar RF Facial Contouring Machine employs a true bipolar electrode configuration, wherein RF current flows between two closely spaced electrodes integrated within the same handpiece. This topology confines energy penetration to a defined tissue volume (3–6 mm depth), eliminating the need for a dispersive return pad. A real-time impedance matching algorithm dynamically adjusts power output to maintain consistent energy delivery across heterogeneous facial tissues (e.g., zygomatic fat pads, jowls, submental region). The system integrates a surface thermistor array (four-point contact) and an optional cryogen-free sapphire contact cooling module to maintain epidermal temperature below 40°C while allowing target tissue temperatures of 48–55°C for collagen denaturation and neocollagenesis.

KEY INDICATIONS & CAPABILITIES

- Reduction of mild to moderate submental fat (double chin)
- Improvement of jawline definition and marionette lines
- Laxity reduction in lower face and perioral region
- Diminishment of jowl prominence via thermal lipolysis
- Post-treatment skin tightening through Type I collagen remodeling (immediate crimp relaxation and delayed synthesis over 3–6 months)

- Non-surgical brow elevation (off-label with appropriate training)

COMPLIANCE & STANDARDS

The device is manufactured under ISO 13485:2016 certified quality management systems. It complies with:

- IEC 60601-1 (Medical electrical equipment — General requirements for basic safety and essential performance)
- IEC 60601-2-2 (Particular requirements for the basic safety and essential performance of high-frequency surgical equipment and high-frequency surgical accessories)
- IEC 60601-1-11 (Requirements for medical electrical equipment used in home healthcare environments — applicable to clinic variants)
- CE marking (Class IIa under Medical Device Regulation (EU) 2017/745) and FDA 510(k) clearance as a non-invasive dermal and subcutaneous heating device

TECHNICAL SPECIFICATIONS

Parameter	**Specification**
RF Technology	True Bipolar, 1.0 MHz / 2.5 MHz dual-frequency selectable

Maximum RF Power	120 W ±10% (continuous wave, 50Ω load)
Electrode Configuration	2 parallel bar electrodes, spacing: 1.5 mm / 2.5 mm / 4.0 mm (interchangeable tips)
Penetration Depth	Selectable: superficial mode ~3 mm, deep mode ~6 mm (adipose-dominant)
Cooling System	Contact sapphire window + forced air + closed-loop water circulation, 0–10° C selectable tip temperature
Temperature Monitoring	4× thermistor array, + thermopile IR sensor (accuracy ±0.5°C)
Impedance Range	10 – 1500 Ω , adaptive power adjustment (1 ms response)
Treatment Modes	Continuous RF, Pulsed RF (5–500 ms on/off), and Scan (automated multi-pass)
User Interface	10.1-inch capacitive touchscreen, preset protocols by Fitzpatrick skin type (I–VI)
Dimensions (Main Unit)	380 mm × 320 mm × 260 mm (W ×

	D × H)
Weight	8.4 kg (main console), handpiece: 210 g with cable
Electrical Input	100–240 V AC, 50/60 Hz, 250 VA
Operational Environment	+10 ° C to +30 ° C, 30% to 75% RH, non-condensing

CLINICAL PROTOCOLS

Pre-Treatment: Cleanse facial skin, remove all metallics and conductive makeup. Apply conductive gel or coupling fluid to treatment sites. Select appropriate handpiece (standard facial: 1.0 cm^2 electrode; precision: 0.5 cm^2 for periorbital/perioral zones).

Treatment Parameter Guidance (indicative starting values):

- Submental & jowls: 85–100 J/cm^3 volumetric energy density, 50–70 W power, 4–6 passes, electrode spacing 2 mm
- Cheeks & jawline: 70–85 J/cm^3, 40–60 W, 3–5 passes
- Perioral fine lines: 50–65 J/cm^3, 30–45 W, 2–3 passes

Endpoint: Mild erythema and perceived deep warmth without sharp pain.

Surface temperature maintained ≤42°C via cooling interrupt cycles.

Post-Treatment: Remove gel, apply soothing hyaluronic mask. Sunscreen SPF 30+ recommended. Visible results typically after 3–6 sessions (weekly intervals), with optimal contouring at 3 months.