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

EXECUTIVE SUMMARY

This document provides the official clinical and technical specifications for the next-generation Bipolar RF Facial Contouring Machine, a non-invasive aesthetic platform engineered for subdermal adipose remodeling and dermal tightening. The system utilizes proprietary bipolar radiofrequency (RF) energy delivery with integrated contact cooling to achieve precise volumetric heating of the fibrous septae and subcutaneous adipose tissue. Designed exclusively for OEM distribution, the device delivers reproducible facial contouring outcomes with zero patient downtime.

CLINICAL ARCHITECTURE & DESIGN

The Bipolar RF Facial Contouring Machine operates on a closed-loop impedance monitoring architecture. Unlike monopolar systems that require a grounding pad and produce unpredictable current pathways, the bipolar configuration confines RF current between two integrated electrodes within the handpiece. This creates a consistent, shallow-to-mid dermal heating zone (40–43°C therapeutic window) while preserving the epidermal barrier. The system incorporates a real-time thermal feedback algorithm that modulates power output (1–25W) based on tissue resistance, ensuring uniform energy deposition across contour regions including the submental area, jawline, and malar fat pads.

KEY INDICATIONS & CAPABILITIES

- PRIMARY: Reduction of submental fullness (double chin), jowl laxity, and buccal fat prominence
- SECONDARY: Improvement of nasolabial fold depth and lower face skin laxity
- SAFETY FEATURES: Dynamic temperature cutoff (45 ° C surface limit), motion-sensing activation, and impedance mismatch alert
- TREATMENT PROTOCOL: 6 – 8 sessions at 7 – 14 day intervals; visible improvement after 3 sessions
- PATIENT PROFILE: Fitzpatrick Skin Types I – VI; BMI < 30 with localized fat

deposits

COMPLIANCE & STANDARDS

Manufactured in an ISO 13485:2016 certified facility. Device complies with:

- IEC 60601-1 (Medical Electrical Equipment Safety)

- IEC 60601-2-2 (High Frequency Surgical Equipment particular requirements)

- IEC 60601-1-11 (Home healthcare environment requirements)

- FDA 510(k) Class II clearance for dermatological RF procedures (device master file reference available upon NDA)

- CE Mark (MDR 2017/745, Class IIa)

TECHNICAL SPECIFICATIONS

Parameter	**Specification**
RF Frequency	1.0 MHz ± 5% (dual-channel bipolar)
Output Power Range	1 – 25 W (continuous or pulsed mode)
Treatment Temperature	40°C – 43°C (surface cooling 15°C – 25°C)
Electrode Configuration	Two parallel stainless steel plates, 10mm x 25mm, 4mm separation

Contact Cooling	Sintered sapphire tip, 4°C – 15°C, dual TEC modules
User Interface	10.1-inch capacitive touchscreen, antimicrobial coating
Dimensions (Main Console)	380mm W x 320mm D x 280mm H (15.0" x 12.6" x 11.0")
Weight	8.2 kg (18.1 lbs) net
Power Supply	AC 100–240V, 50/60Hz, 2.5A
Compliance	ISO 13485, IEC 60601-1, IEC 60601-2-2, FDA Class II, CE MDR 2017/745

RF Frequency: 1.0 MHz ± 5% (dual-channel bipolar)

Output Power Range: 1 – 25 W (continuous or pulsed mode, 10% increments)

Pulse Duration: 0.5 – 10 seconds (adjustable in 0.1s steps)

Treatment Temperature: 40°C – 43°C (surface cooling maintains 15°C – 25°C)

Impedance Monitoring: 50 – 600 Ω with automatic power rollback < 50 Ω or > 600 Ω

Electrode Configuration: Two parallel stainless steel plates, 10mm x 25mm each, 4mm separation

Contact Cooling: Sintered sapphire tip, 4°C – 15°C adjustable, closed-loop

Peltier module (2x TEC1-12706)

User Interface: 10.1-inch capacitive touchscreen, 1280x800 resolution, antimicrobial coating

Treatment Timer: 0 – 60 minutes (auto-shutoff, 1s resolution)

Standby Power: < 25 W

Power Supply: AC 100–240V, 50/60Hz, 2.5A (universal medical-grade inlet)

Dimensions (Main Console): 380mm W x 320mm D x 280mm H (15.0" x 12.6" x 11.0")

Weight: 8.2 kg (18.1 lbs) net

Footswitch: IPX8-rated, water-resistant, dual-pedal (RF enable/disable + cooling toggle)

Connectivity: USB-A for session logging, Ethernet (optional HL7/FHIR gateway for EMR integration)

Operational Environment: +10°C to +40°C, 30%–75% RH, altitude ≤ 3000m

CLINICAL PROTOCOLS

STANDARD SUBMENTAL CONTOURING (20-MINUTE SESSION):

1. Cleanse skin, remove all metal accessories.

2. Apply conductive ultrasound gel (water-based, no alcohol).

3. Select handpiece with 10x25mm bipolar electrodes.

4. Console preset: MODE = Pulsed (2s on / 1s off), POWER = 12W, TEMP LIMIT

= 43°C.

5. Perform continuous gliding strokes (2–3 cm/s) along the submental region from medial to lateral.

6. Monitor patient feedback: Target warming sensation, not pinching or burning.

7. Complete 10 minutes per submental half; total 20 minutes bilateral.

8. Clean gel, apply post-treatment moisturizer with antioxidant.

9. Document baseline and post-treatment photographs at identical lighting and positioning.

ADVANCED JOWL & JAWLINE PROTOCOL (25 MINUTES):

- As above but use POWER = 14W, MODE = Continuous with periodic cooling bursts (sapphire at 8°C every 10 seconds).

- Technique: Circular micro-movements over jowl fat pad (30 seconds per 1cm² area).

- Total: 12.5 minutes per side.

CONTRADICTIONS: Pregnancy, active infection, implanted electronic devices (pacemaker), facial metal plating, corticosteroid use within 2 weeks, recent filler/botox within 4 weeks, or history of keloid scarring.