

## Non-invasive face lift machine - Official Clinical Overview & Datasheet

### EXECUTIVE SUMMARY

This document presents the clinical and technical profile of a next-generation Non-invasive Face Lift Machine, engineered for medical spas, dermatology clinics, and plastic surgery centers seeking a high-efficacy, zero-downtime alternative to surgical rhytidectomy. The device combines multi-source radiofrequency (RF) and focused magnetic energy to achieve deep dermal coagulation, neocollagenesis, and elastin remodeling without epidermal disruption. Its primary value proposition includes painless treatments (no topical anesthetic required), consistent clinical outcomes after 3-5 sessions, and a rapid ROI driven by high patient throughput and minimal consumables.

Designed for operators ranging from nurse injectors to board-certified dermatologists, the platform supports both lifting and skin tightening indications across all Fitzpatrick skin types (I-VI). By eliminating the risks associated with injectables (nodules, vascular occlusion) and surgical lifts (scarring, prolonged recovery), this device fills a critical gap in the non-surgical rejuvenation market. Clinical studies demonstrate average skin stiffness reduction of 48% and a 2-3 point improvement on the Merz scale for jawline definition after six months.



## CLINICAL ARCHITECTURE & DESIGN

The hardware architecture employs a fully digital-generation RF generator (1.0 MHz and 3.0 MHz dual-band) paired with a pulse-modulated magnetic field coil, delivering power up to 300W peak. All active components are sourced from ISO 13485-certified suppliers: German-made high-Q capacitors, Japanese ultra-low-loss ferrite cores, and a Swiss micro-precision temperature sensor array. The treatment handpiece integrates a dynamic contact cooling plate (sapphire tip, -2°C to +4°C adjustable) with continuous impedance monitoring to prevent hot spots. A four-stage thermal management system is incorporated: closed-loop water circulation (medical-grade pump, flow rate 1.8 L/min), dual TEC (thermoelectric cooler) modules, passive aluminum heat sink, and forced air evacuation. This design enables sustained power output without duty cycle limitations, crucial for treating larger areas such as the full lower face and

submentum in under 20 minutes.

#### KEY INDICATIONS & CAPABILITIES

- Multilayer Tissue Coagulation: Synchronous RF (1.0 MHz for deep SMAS-like layer heating up to 18mm, 3.0 MHz for mid-dermal tightening at 4-6mm) plus magnetic stimulation for lymphatic drainage and fibroblast activation.
- Smart Impedance-Adaptive Energy Delivery: 1,000 Hz closed-loop feedback adjusts power in real-time (sub-millisecond response) to maintain target tissue temperature of 52-58°C regardless of local conductivity variations (bone, fat, fluid).
- Touchscreen-Controlled Preset Protocols: Library of 12 clinical protocols (e.g., "Jawline Define," "Neck Harmonization," "Perioral Lift") with adjustable fluence, pulse width (10-400ms), and rep rate (0.5-4 Hz). Includes a visual skin impedance map overlay.
- Painless & No-Downtime Safety Envelope: Epidermal temperature maintained <42°C via real-time infrared sensor (accuracy  $\pm 0.3^\circ\text{C}$ ) linked to an automatic power-off interlock if contact is broken or skin temperature exceeds 44°C.
- Versatile Applicator Options: Three handpieces: (1) Standard 3.0 cm<sup>2</sup> for forehead & cheeks, (2) Tight-curve 1.5 cm<sup>2</sup> for periorbital & perioral, (3) Large 6.0 cm<sup>2</sup> for submentum & jowls.

#### COMPLIANCE & STANDARDS

The device holds Medical CE certification under EU MDR 2017/745 (Class IIb), with notified body oversight. It is FDA 510(k) cleared for non-invasive dermatological and aesthetic use for facial rhytides and skin laxity (Kxxxxxx). Manufacturing follows ISO 13485:2016, and the system complies with IEC 60601-1 (medical electrical equipment safety), IEC 60601-2-2 (RF therapy specific), and IEC 60601-1-11 (home healthcare environment, for clinic-use version). Additionally, electromagnetic compatibility (EMC) meets EN 55011 and CISPR 11 Group 1 Class A standards.

#### TECHNICAL SPECIFICATIONS

Listed below are the core engineering parameters for the Non-invasive Face Lift Machine. Values reflect nominal performance under standard clinical conditions (ambient 23°C, 50% RH).

Parameter	Specification
Technology Combination	Monopolar + Bipolar RF (1.0 / 3.0 MHz) + Pulsed Magnetic Field (0.5-10 Hz)
Max Output Power	300W (RF), 120mT (magnetic)
Treatment Depth	Adjustable 4 mm - 18 mm (RF) +

	magnetic up to 40mm
Spot Size / Applicator	1.5, 3.0, 6.0 cm <sup>2</sup> detachable tips
Cooling System	TEC + Sapphire contact cooling + Closed-loop water (1.8 L/min)
Skin Temperature Monitoring	Dual IR sensors (100 ms response), accuracy $\pm 0.3^{\circ}\text{C}$
Impedance Range	10 - 1000 Ohm, adaptive power scaling
User Interface	10.4-inch capacitive touchscreen, Android OS, Wi-Fi for updates
Dimensions (W x D x H)	420 x 510 x 960 mm (cart-mounted version)
Weight	38 kg (main unit) + 12 kg (water tank)
Power Supply	AC 100-240V, 50/60 Hz, max 1,500 VA
Safety Certifications	Medical CE (MDR), FDA 510(k), ISO 13485, IEC 60601 series

