

Fractional Laser Machine - Official Clinical Overview & Technical Datasheet

EXECUTIVE SUMMARY

The Fractional Laser Machine represents a paradigm shift in dermatological and aesthetic medicine, combining the proven principles of fractional photothermolysis with advanced engineering to deliver superior clinical outcomes. This device is engineered for precision, safety, and versatility, offering practitioners a comprehensive solution for skin resurfacing, scar revision, and rejuvenation. Its innovative design prioritizes both patient comfort and operator efficiency, making it a cornerstone asset for any forward-thinking medical practice.



CLINICAL ARCHITECTURE & DESIGN

The core of the system is a high-performance laser engine that delivers a controlled array of microscopic treatment zones (MTZs). This fractional approach leaves the surrounding tissue intact, promoting rapid healing and reducing downtime compared to traditional ablative lasers. The device integrates a sophisticated scanning mechanism to ensure consistent and uniform energy distribution across the treatment area. Its modular handpiece design facilitates different spot sizes and densities, allowing for customized treatments that address a wide range of indications from fine lines and wrinkles to deep surgical scars. The system's software interface provides intuitive control over key parameters, enabling precise adjustments to match individual patient needs and skin types.

KEY INDICATIONS & CAPABILITIES

This device is clinically indicated for a variety of aesthetic and therapeutic applications, including:

- Facial and non-facial rhytides.
- Atrophic and hypertrophic scars, including acne scars.
- Pigmented lesions and dyschromias.
- Melasma and other forms of hyperpigmentation.
- Skin texture and tone improvement.
- Stretch marks (striae distensae).

Its versatility is further enhanced by a range of available handpieces and tips, accommodating both superficial and deep tissue treatments. The system's ability to adjust the pulse energy, density, and coverage enables a truly personalized approach to patient care.

COMPLIANCE & STANDARDS

The Fractional Laser Machine is manufactured in accordance with the highest international quality and safety standards. It complies with:

- ISO 13485:2016 (Medical Devices - Quality Management Systems).
- IEC 60601-1 (Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance).
- IEC 60825-1 (Safety of Laser Products - Part 1: Equipment Classification and Requirements).
- FDA 21 CFR Part 1040 (Performance Standards for Light-Emitting Products).
- CE Marking (Conformité Européenne) as per the Medical Devices Regulation (MDR) 2017/745.

TECHNICAL SPECIFICATIONS

Parameter	Specification
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Laser Type / Wavelength	Fractional Er:YAG (2940nm) or Fractional CO2 (10600nm)
Spot Size (Variable)	0.1mm - 1.0mm (Dynamic Adjustment)
Maximum Pulse Energy	Up to 50 mJ (per MTZ)
Cooling System	Integrated Active Sapphire + TEC + Water Circulation

CLINICAL PROTOCOLS

Standard operating procedures are designed to maximize safety and efficacy. Prior to any treatment, a comprehensive patient consultation is mandatory to assess skin type, medical history, and treatment goals. A patch test is recommended for first-time patients or those with a history of photosensitivity. The treatment area must be cleansed, and a topical anesthetic may be applied at the clinician's discretion to enhance patient comfort.

During the procedure, the operator selects the appropriate handpiece and adjusts the system parameters based on the established protocol for the specific indication. The device is applied to the skin in a series of passes, ensuring complete and uniform coverage. Post-treatment, a soothing ointment

or dressing is applied to the area, and patients are given detailed instructions for aftercare to promote optimal healing. A series of treatments, typically spaced 4-6 weeks apart, is often recommended to achieve the best results.

