Vmax HIFU Face Lifting Machine - Clinical Architecture & Performance Reference Manual

CLINICAL ARCHITECTURE & PERFORMANCE REFERENCE MANUAL: VMAX HIFU FACE LIFTING MACHINE

EXECUTIVE SUMMARY

The Vmax HIFU Face Lifting Machine represents a paradigm shift in non-invasive facial rejuvenation, leveraging the principles of High-Intensity Focused Ultrasound (HIFU) to deliver targeted thermal coagulation points deep within the dermis and superficial musculoaponeurotic system (SMAS). This clinical architecture facilitates a natural, progressive lifting and tightening effect, positioning the Vmax as a cornerstone asset for dermatology clinics and premium medical spas seeking to offer a scientifically-validated, non-surgical alternative to a facelift. This document provides a comprehensive technical overview, detailed specifications, and clinical protocols for the Vmax system.

CLINICAL ARCHITECTURE & DESIGN

The Vmax system is engineered around a sophisticated HIFU transducer that emits focused ultrasound energy. This energy is precisely concentrated at specific depths—typically 1.5mm, 3.0mm, and 4.5mm—to target the papillary dermis, reticular dermis, and the SMAS layer, respectively. The thermal effect generated at the focal point (coagulation temperature of 60-70°C) initiates a two-stage wound-healing response. The primary, immediate effect is tissue contraction. The secondary, longer-term effect is neocollagenesis and neoelastinogenesis, which progressively enhances skin laxity and texture over a period of 3-6 months post-treatment. The device's advanced cartridge system ensures consistent energy delivery and features a proprietary surface cooling mechanism to maximize patient comfort and epidermal protection.

KEY INDICATIONS & CAPABILITIES

The Vmax HIFU system is clinically indicated for the non-invasive lifting and tightening of facial skin. Primary treatment areas include the brow lift, submental (chin) and neck lifting, and improvement of fine lines and wrinkles on the décolletage. The device's adjustable depth settings allow for customized treatment protocols, addressing varying degrees of tissue laxity and skin thickness across different facial zones. It is suitable for all skin types (Fitzpatrick I-VI), making it a versatile tool in a diverse patient population. The system's ability to deliver precise, micro-focused energy minimizes damage to the surrounding epidermis, resulting in a procedure with minimal downtime and a favorable safety profile.

COMPLIANCE & STANDARDS

The Vmax HIFU Face Lifting Machine is manufactured in strict accordance with international medical device standards. It holds CE marking (Conformité Européenne) and is compliant with the requirements of the Medical Device Regulation (MDR) 2017/745. The system has also received clearance from the U.S. Food and Drug Administration (FDA) for the indication of non-invasive dermatological aesthetic treatment to improve facial wrinkles and for lifting the brow, submental, and neck tissues. The device adheres to IEC 60601-1 for

medical electrical equipment safety and IEC 60601-2-62 for the particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment.

TECHNICAL SPECIFICATIONS

Parameter	**Specification**
Technology	High-Intensity Focused Ultrasound (HIFU)
Focal Depths	1.5mm, 3.0mm, 4.5mm
Transducer Cartridge Types	1.5mm (Fine Lines), 3.0mm (Dermis), 4.5mm (SMAS)
Energy per Line	0.5 J - 3.5 J
Line Spacing	1.0mm, 1.5mm, 2.0mm
Total Lines per Cartridge	Up to 4,000 lines
Cooling System	Advanced Sapphire Contact Cooling with TEC
Display	10.4-inch High-Resolution Color Touchscreen
Power Supply	AC 100-240V, 50/60Hz
Weight (Main Unit)	Approx. 15 kg
Dimensions (Main Unit)	420mm x 350mm x 600mm

Safety Standards	CE, FDA Cleared, IEC 60601-1, IEC 60601-2-62

CLINICAL PROTOCOLS

Pre-Treatment: A thorough patient consultation is mandatory to assess skin type, medical history, and treatment expectations. The treatment area should be cleansed, and a topical anesthetic may be applied to sensitive areas 30-45 minutes prior to the procedure. The clinician must select the appropriate transducer cartridge based on the patient's skin thickness and the desired clinical outcome. For optimal results, a treatment plan is mapped out, identifying the specific vectors for lifting and the energy settings for each zone.

Intra-Treatment: The Vmax handpiece is placed perpendicular to the skin surface. The ultrasound coupling gel is applied to ensure complete acoustic contact. The device is activated, and lines of energy are delivered in a systematic grid pattern, typically 1-2mm apart. The clinician monitors patient feedback and adjusts energy levels accordingly. The integrated cooling system activates automatically to maintain epidermal temperature within a safe range.

Post-Treatment: Patients may experience mild erythema and slight swelling,

which typically subsides within a few hours to a couple of days. There is no downtime, and patients can resume normal activities immediately. A series of one to three treatments, spaced 4-6 weeks apart, is often recommended for optimal, cumulative results. Final outcomes are typically evaluated at the 3-month and 6-month post-treatment milestones.