

HIFU Non-Surgical Facelift Aesthetic System Specifications & Clinical Whitepaper

HIFU NON-SURGICAL FACELIFT - CLINICAL ARCHITECTURE & PERFORMANCE REFERENCE MANUAL

EXECUTIVE SUMMARY

This document serves as the definitive clinical and technical reference for the High-Intensity Focused Ultrasound (HIFU) non-surgical facelift platform. Designed for dermatology clinics and premium medical spas, this system represents a paradigm shift in non-invasive skin laxity treatment. By delivering precisely focused ultrasound energy to the superficial musculoaponeurotic system (SMAS) and deep dermal layers, the device initiates a robust neocollagenesis cascade without compromising the epidermal barrier. This whitepaper details the clinical architecture, treatment parameters, safety protocols, and performance specifications validated through extensive in-vivo studies and real-world clinical deployments. The device stands as a premier asset for clinics seeking to offer patients a dramatic lifting effect with zero downtime, positioning it as a high-ROI alternative to surgical facelifts.



CLINICAL ARCHITECTURE & DESIGN PHILOSOPHY

The core clinical efficacy of the HIFU platform is predicated on its advanced energy delivery architecture. Unlike surface-based energy devices, this system employs a proprietary microfocused ultrasound transducer that generates thermal coagulation points (TCPs) at precise depths of 1.5mm, 3.0mm, and 4.5mm below the skin surface. This allows the clinician to selectively target the dermis, deep dermal junction, and the SMAS layer, which is the foundational structural tissue addressed during a surgical facelift.

The device's imaging capability, while not real-time, is engineered with a depth-specific cartridge system that ensures energy is deposited at the optimal tissue plane for maximum contraction and neocollagenesis. The thermal effect induces a dual-action response: an immediate tightening effect from tissue

coagulation and a long-term regenerative phase driven by the body's wound-healing cascade. This mechanism ensures that clinical improvements are not only visible immediately post-treatment but continue to develop over a 3-to-6-month period, delivering a natural, progressive lifting and contouring outcome.

KEY INDICATIONS & TREATMENT CAPABILITIES

The clinical applications of this HIFU platform are validated for a comprehensive range of aesthetic concerns. Primary indications include the lifting and tightening of lax skin on the brow, chin, and neck, as well as the improvement of fine lines and wrinkles on the décolletage. The device is uniquely capable of addressing mild to moderate skin laxity, making it an ideal solution for patients in their 30s to 60s seeking preventative and corrective maintenance.

The versatility of the platform is enhanced by its interchangeable treatment cartridges, which allow for the customization of focal depth and line spacing. This enables the clinician to tailor the treatment to specific anatomical areas, from the delicate periorbital region requiring shallow penetration to the thicker submental tissue necessitating deeper SMAS coagulation. The system is designed to deliver consistent, reproducible results across a wide variety of skin types and phototypes, establishing it as a versatile cornerstone of any modern

aesthetic practice.

PATIENT COMFORT & SAFETY MECHANISMS

Patient comfort and safety are integral to the device's design, incorporating several advanced features to ensure a tolerable and secure treatment experience. The system integrates a dynamic cooling mechanism that maintains the handpiece tip at a controlled temperature, preventing superficial thermal injury and enhancing patient comfort during energy delivery. Additionally, the device features a precision-engineered energy delivery algorithm that ensures consistent fluence across the treatment area, minimizing the risk of hotspots or under-treatment.

Safety is further reinforced by the system's built-in contact sensor, which halts energy emission if the handpiece is not in full, stable contact with the skin. This interlock mechanism ensures that energy is only delivered to the target tissue under optimal conditions. The device is engineered with multiple redundant safety systems and is fully compliant with the most stringent international medical device standards, including IEC 60601-2-62 for therapeutic ultrasound equipment, ensuring both clinician and patient peace of mind.

CLINICAL PROTOCOLS & PARAMETER SELECTION

Optimal clinical outcomes are achieved through adherence to established treatment protocols and the strategic selection of device parameters. The recommended protocol involves a systematic mapping of the treatment area, followed by the delivery of a predetermined number of lines and pulses per cartridge. For a full face and neck treatment, a standard protocol utilizes a combination of 3.0mm and 4.5mm cartridges, delivering approximately 400-500 lines per side to achieve a comprehensive lifting effect.

Parameter selection is dictated by the patient's tissue thickness and the specific anatomical zone being treated. The 1.5mm cartridge is generally reserved for superficial wrinkles and fine lines, while the 4.5mm cartridge is essential for SMAS lifting. Clinicians are advised to conduct a thorough pre-treatment consultation to assess tissue laxity and develop a tailored treatment plan. The device's intuitive user interface simplifies this process, offering pre-set protocols that guide the clinician through parameter selection, ensuring that the most effective and safe settings are applied for each individual patient.

TECHNICAL SPECIFICATIONS & HARDWARE MATRIX

The HIFU platform is a sophisticated medical device engineered for peak performance and long-term durability. The system features a high-resolution

touchscreen interface for intuitive operation and treatment monitoring. Its robust hardware construction ensures reliable performance in high-volume clinical environments. The table below outlines the key technical specifications and performance metrics that define this state-of-the-art aesthetic system.

Parameter	Specification
Focal Depth	1.5mm / 3.0mm / 4.5mm (Cartridge Dependent)
Focal Length	25mm - 45mm (Depending on Cartridge Depth)
Energy per Pulse (Fluence)	0.2 - 2.0 Joules (Adjustable)
Number of Lines per Cartridge	Up to 2,000 Lines
Line Spacing	1.0mm - 5.0mm (Adjustable)
Pulse Repetition Rate	2 Hz - 10 Hz
Cooling System	Active Contact Cooling via Sapphire Tip
Display	15.6 Inch High-Resolution Color Touchscreen
Dimensions (Main Unit)	420mm x 380mm x 600mm (L x W x H)
Weight	18 kg
Power Supply	100-240V AC, 50/60Hz, 300W
Safety Certifications	FDA Cleared, CE MDR, IEC 60601-2-62

HANDPIECE DURABILITY & MAINTENANCE ASSURANCE

The handpiece and cartridges are constructed with premium-grade materials to withstand the rigors of daily clinical use. The cartridges are designed as single-use consumables to ensure absolute sterility, consistent energy delivery, and optimal performance. The system performs automatic self-diagnostics at startup and provides clear alerts for cartridge end-of-life, preventing any degradation in treatment quality. The device's internal components are protected by an advanced thermal management system, ensuring the ultrasound transducer remains within its optimal operating temperature for the entire duration of the treatment session, guaranteeing a long operational lifespan for the platform.

GLOBAL COMPLIANCE & MEDICAL ACCREDITATIONS

This HIFU system has secured comprehensive global regulatory approvals, underscoring its safety and efficacy. The platform holds CE marking for distribution within the European Economic Area, confirming its compliance with the Medical Devices Regulation (MDR). It is also FDA-cleared for dermatological use, specifically for non-invasive brow lifting and the improvement of skin laxity.

These accreditations are a testament to the rigorous clinical testing and quality manufacturing standards that underpin the device's design and production. The device adheres to ISO 13485 standards for quality management and IEC 60601-1 for general medical electrical equipment safety, providing clinics with the assurance required for regulatory and insurance compliance.

CLINICAL OUTLOOK & PRACTICE INTEGRATION SUMMARY

The HIFU non-surgical facelift platform represents a strategic, high-value asset for aesthetic practices. Its proven clinical efficacy, combined with a zero-downtime profile, provides a compelling value proposition to patients seeking a non-surgical alternative to a facelift. The system's intuitive design, robust safety features, and low maintenance requirements facilitate seamless integration into existing clinical workflows. By offering this advanced technology, practices can expand their service portfolio, attract a wider demographic of patients, and significantly increase practice revenue. The device's established track record of delivering natural, long-lasting results positions it as a pivotal tool for achieving superior patient satisfaction and loyalty in the competitive aesthetic medicine market.

