High Intensity Focused Ultrasound HIFU SMAS Targeting Study - Official Clinical Overview & Technical Datasheet

HIGH INTENSITY FOCUSED ULTRASOUND (HIFU) SMAS TARGETING STUDY

OFFICIAL CLINICAL OVERVIEW & TECHNICAL DATASHEET

EXECUTIVE SUMMARY

The High-Intensity Focused Ultrasound (HIFU) platform represents a paradigm shift in non-invasive aesthetic medicine, offering a clinically validated solution for skin tightening and lifting by precisely targeting the Superficial Musculoaponeurotic System (SMAS)—the same anatomical layer addressed in surgical facelifts. This document provides a comprehensive technical and clinical overview of the HIFU system, detailing its mechanism of action, targeting precision, technical specifications, and clinical application protocols. By delivering focused ultrasound energy to generate thermal coagulation points at predetermined depths without epidermal damage, the HIFU device initiates immediate collagen contraction and stimulates sustained neocollagenesis, resulting in progressive lifting and contouring outcomes over 3 to 6 months . This whitepaper serves as an authoritative reference for clinical product managers, dermatologists, and medical spa operators seeking to integrate this high-ROI, zero-consumable technology into their practice.

CLINICAL ARCHITECTURE & DESIGN

MECHANISM OF ACTION: BEYOND SELECTIVE PHOTOTHERMOLYSIS

Unlike laser and intense pulsed light (IPL) devices that operate on the principle of selective photothermolysis by targeting chromophores such as melanin or hemoglobin, the HIFU system employs focused ultrasound energy to bypass the epidermis entirely . The mechanism of action is thermal coagulative necrosis: a focused ultrasound beam converges at precise depths within the tissue, rapidly raising the temperature at the focal point to 60-70°C in microseconds . This creates microscopic Thermal Coagulation Zones (TCZs) that trigger a dual biological response:

1. Immediate Tissue Contraction: The application of heat causes

instantaneous denaturation and contraction of existing collagen fibers, providing an immediate tightening effect.

2. Sustained Neocollagenesis: The localized micro-injury activates the body's wound healing cascade, stimulating fibroblasts to produce new collagen (predominantly Type I and III) and elastin over a period of 3 to 6 months, leading to progressive lifting and skin quality improvement .

TARGETING THE SMAS: THE SURGICAL PLANE

The defining clinical advantage of the HIFU system is its ability to precisely target the SMAS layer. The SMAS is a continuous fibrous network of collagen and elastin that envelops the facial muscles and is the primary structural support for the face. During a surgical facelift, this layer is physically plicated and lifted. The HIFU device replicates this effect non-invasively by delivering focused energy to depths of 4.5 mm, creating thermal injury zones specifically within the SMAS, which induces contraction and lifting of the foundational tissue . This capacity to reach the SMAS differentiates HIFU from monopolar radiofrequency (RF) devices, which generally provide volumetric heating but lack the depth precision to consistently target this specific structural layer, and from lasers, which are largely limited to dermal effects .

KEY INDICATIONS & CAPABILITIES

VERSATILE DEPTH PENETRATION

The system is equipped with interchangeable transducer cartridges designed to treat various tissue depths and anatomical regions. By utilizing multiple focal depths within a single treatment session, a comprehensive, multi-layered approach to tissue remodeling is achieved, enhancing clinical outcomes across the full face and body .

FOCAL DEPTH TARGETS:

- 1.5 mm: Superficial Dermis. Designed for fine lines, textural irregularities, and superficial skin resurfacing.
- 2.0 mm: Deep Dermis. Emerging as a key depth for upper-face rejuvenation, particularly for eyebrow lifting and periorbital tissue contraction .
- 3.0 mm: Deep Dermis/Subcutis Junction. Targets the foundational dermal layer for collagen remodeling and treatment of deeper rhytids.
- 4.5 mm: SMAS Layer. The primary depth for achieving significant lifting of the lower face, jowls, and submental region, replicating the surgical facelift plane .
- 6.0 mm - 13.0 mm: Subcutaneous Fat and Deep SMAS. Designed for body contouring applications, including reduction of submental fat (double chin), abdominal laxity, and buttock lifting. A 6mm deep transducer has also

demonstrated efficacy in treating the temporal fat pad for midface rejuvenation without damaging hair follicles .

INDICATIONS FOR USE

The HIFU platform is indicated for non-invasive dermatological and aesthetic procedures. Suitable candidates include all Fitzpatrick skin types (I-VI) due to the ultrasound energy's independence from melanin absorption, making it a safe option for darker skin tones where laser-based therapies carry a higher risk of dyspigmentation .

PRIMARY TREATMENT AREAS

FACIAL & CERVICAL REJUVENATION

- Eyebrow Lifting (Ptosis Correction): Utilizes 3.0 mm and 4.5 mm transducers to target the SMAS and deep dermis superior to the orbital rim .
- Submental Tightening (Double Chin): Employs 6.0 mm transducers to achieve fat reduction and dermal contraction in the submental region .
- Jawline and Jowl Lifting: Treats the lower face with 3.0 mm and 4.5 mm transducers to improve jawline definition and reduce jowl prominence .
- Nasolabial Folds and Marionette Lines: 3.0 mm focal depth is effective for

softening the appearance of these deep folds .

- Neck Rejuvenation: Combination protocols using 1.5 mm, 3.0 mm, and sometimes 4.5 mm transducers can significantly improve horizontal neck lines and platysmal banding. Care must be taken to avoid the thyroid cartilage area .

BODY CONTOURING

- Abdominal Skin Laxity: Post-pregnancy or significant weight loss laxity can be addressed with 8.0 mm and 13.0 mm large-focus transducers .

- Buttock Lifting (Non-Surgical BBL): A protocol combining 3.0-4.5 mm transducers (for SMAS/dermis) and 6-9 mm transducers (for subcutaneous tissue) has demonstrated an 89% patient satisfaction rate in clinical studies for gluteal augmentation .

- Bra Line, Axillary Fat, and Thigh Tightening: Targeted treatment of localized adiposity and laxity using appropriate body transducers.

Parameter	**Clinical Specification**
Focal Depths (TCZ)	1.5mm (Dermis), 2.0mm, 3.0mm, 4.5mm (SMAS), 6.0mm - 13.0mm (Body)
Energy per Shot (Fluence)	0.5 J to 2.5 J (programmable in 0.1 J steps)

Acoustic Frequency	4 MHz to 10 MHz (variable per transducer depth)
Spot Size (Line Transducers)	6mm x 6mm to 13mm x 13mm
Cooling System	Active TEC + Sapphire Contact Cooling + Forced Air
Real-time Imaging	Optional 10 MHz Linear Array Ultrasound (B-Mode)
Treatment Speed (Face)	200-300 lines / 25-35 minutes active delivery
Compliance & Standards	Medical CE (MDR), FDA 510(k), ISO 13485, IEC 60601

CLINICAL PROTOCOLS

PRE-TREATMENT GUIDELINES

- Patient Assessment: A thorough consultation is mandatory to evaluate medical history, identify contraindications, and set realistic expectations. Topographic thickness of the skin and SMAS varies by region, age, and gender; a point of care ultrasound can help plan depth selection for optimal outcomes .
- Contraindications: Active infections, open wounds, severe or cystic acne,

pregnancy, implanted electronic devices (e.g., pacemakers), and metal implants in the treatment field are absolute contraindications. Caution should be exercised in patients with a history of keloid scarring or autoimmune diseases.

- Pain Management: A topical anesthetic (e.g., 23% lidocaine/7% tetracaine) is generally applied to the treatment area 30 to 45 minutes prior to the procedure to maximize patient comfort .

TREATMENT WORKFLOW

1. Skin Preparation: The treatment area is cleansed, and a coupling gel is applied to ensure optimal acoustic energy transmission between the transducer and the skin.
2. Transducer Selection: The clinician selects the appropriate transducer cartridge based on the treatment area, target depth, and patient anatomy.
3. Energy Delivery: The handpiece is placed firmly against the skin, and the energy is delivered in a predetermined grid or line pattern. The motorized handpiece ensures consistent shot spacing, minimizing operator variability .
4. Energy Parameters: The number of lines or shots, as well as the energy per shot (0.7 - 2.0 Joules), is adjusted based on the patient's skin thickness, tissue laxity, and tolerance . For instance, a full-face protocol typically involves 200-300 lines delivered over 25-35 minutes of active energy delivery .

POST-TREATMENT CARE

- Expected Side Effects: Mild to moderate transient erythema and edema are common and typically resolve within a few hours to a couple of days. Isolated instances of localized swelling or discomfort may occur but are self-limiting .

- Results Timeline: Patients can expect an immediate tightening sensation, with progressive lifting and contouring observed over the subsequent 3 to 6 months as neocollagenesis reaches its peak. Results typically last 12 to 18 months, after which maintenance treatments can be performed .

COMPLIANCE & STANDARDS

REGULATORY APPROVALS & CERTIFICATIONS

The HIFU medical device platform has been meticulously engineered and manufactured to adhere to the most stringent international regulatory and quality standards.

- Medical CE Certification: Fully compliant with the European Medical Device Regulation (MDR 2017/745), indicating conformity with health, safety, and environmental protection standards for products sold within the European Economic Area .
- FDA 510(k) Clearance: Cleared by the U.S. Food and Drug Administration for non-invasive dermatological use, substantiating its safety and efficacy for aesthetic skin tightening and lifting .
- ISO 13485:2016: Manufactured under a certified Quality Management System (QMS) specific to medical devices, ensuring consistent design, development, production, and delivery .
- IEC 60601 Series: Compliance with international standards for electrical safety and electromagnetic compatibility of medical electrical equipment.

SAFETY ASSURANCE

The system incorporates multiple fail-safes to ensure patient safety. Advanced models integrate real-time ultrasound imaging guidance (e.g., linear array 10MHz) to visualize tissue layers before firing, ensuring accurate energy

deposition to the SMAS without damaging adjacent nerves or vessels . Real-time impedance monitoring and automated energy calibration maintain consistent energy output across varying tissue densities, mitigating the risk of burns and injury. Active surface cooling (TEC + Sapphire) protects the epidermis from thermal damage, rendering the procedure safe and well-tolerated .