

HIFU Machine - Official Clinical Overview & Datasheet

EXECUTIVE SUMMARY

This High-Intensity Focused Ultrasound (HIFU) system represents a non-invasive, non-thermal-coagulation platform clinically positioned for dermal regeneration, submental lifting, and superficial muscular aponeurotic system (SMAS) layer tightening. It is specifically architected for medical spas, dermatology clinics, and plastic surgery centers seeking a high-efficiency alternative to surgical facelifts. The primary value proposition centers on painless collagen remodeling with zero patient downtime, delivering immediate tissue contraction followed by sustained neocollagenesis over 3–6 months. The system offers a favorable ROI through rapid per-procedure throughput, long consumable life, and broad patient applicability across Fitzpatrick skin types.

By leveraging precision-focused ultrasound energy, the device bypasses epidermal injury while generating precise thermal zones of 60°C–70°C at depths of 1.5mm, 3.0mm, and 4.5mm. This triggers a wound-healing cascade without surface trauma, differentiating it from laser and RF technologies. The platform integrates real-time impedance monitoring, automatic energy calibration, and a multi-depth transducer cartridge system, allowing physicians to customize treatment vectors for the face, neck, décolleté, and body. Clinical evidence demonstrates brow elevation, jawline redefinition, and submental skin

tightening with a single 45–60 minute session, achieving patient satisfaction rates exceeding 90% in reviewed cohort studies.



CLINICAL ARCHITECTURE & DESIGN

The hardware architecture is built around a high-frequency ceramic piezoelectric transducer array with precision-machined acoustic lenses. Each transducer cartridge is individually calibrated at 1MHz, 3MHz, or 7MHz to achieve focused depths of 4.5mm (SMAS layer), 3.0mm (deep dermis), and 1.5mm (superficial dermis). The system incorporates a 32-bit ARM-based real-time control core that synchronizes energy delivery with an integrated five-mode safety watchdog: contact force sensing, skin impedance analysis, motion validation, tip temperature monitoring, and burst energy limiting.

Premium components include hermetically sealed, oil-filled acoustic coupling cartridges that eliminate degassing and provide 1000+ clinical shots before replacement. The active cooling mechanism features a dual-stage peltier thermoelectric cooler combined with a sapphire-tipped acoustic window, maintaining epidermal surface temperature at 15°C–18°C during treatment. A low-noise, magnetically coupled impeller pump circulates pharmaceutical-grade deionized water through the handpiece at 180 mL/min, ensuring consistent transducer thermal stability across extended duty cycles. The main chassis is constructed from medical-grade ABS with antimicrobial additive protection, fanless heat dissipation via aluminum fin array, and a 15.6-inch capacitive touchscreen with surgical-grade anti-glare coating.

KEY INDICATIONS & CAPABILITIES

- SMAS Lifting & Dermal Contouring: Deployable depths of 1.5mm, 3.0mm, and 4.5mm enable precision targeting from superficial periorbital wrinkles to deep platysmal bands. Delivers 0.2–1.5J per micro-beam with adjustable line spacing (1-5mm) and 10Hz burst mode for rapid coverage.
- Non-Invasive Body Sculpting (Off-Label Supported): The 7MHz/1.5mm and 13MHz superficial modes allow collagen remodeling in thin-skinned areas (periorbital, décolletage), while extended cartridges support small-area body treatments including pre-axillary rolls and infra-umbilical laxity.
- Real-Time Smart UI & Imaging Integration: The 12-inch clinical interface

includes a treatment protocol library with 18 pre-set algorithms for age, skin laxity grade (Fitzpatrick Laxity Scale I-IV), and anatomical zone. Supports DICOM bridge connectivity for PACS integration and live overlay of external ultrasound imaging (optional probe).

- Epidermal Protection & Pain Management: Closed-loop TEC cooling coupled with a sapphire contact plate achieves -2°C surface equilibrium within 2 seconds. Three analgesic modes: pre-chill (10s standby), simultaneous cooling during shot, and post-shot cryo-recovery. Zero topical anesthetic required in 84% of trial patients.

- Smart Shot Verification & Reporting: Each trigger requires minimum 5N of perpendicular contact force and $\leq 0.1\text{mm}$ motion to fire. Automated shot counter, energy log, and per-cartridge usage tracker generate encrypted treatment reports for medical records and liability compliance.

COMPLIANCE & STANDARDS

This HIFU system is designed and manufactured under ISO 13485:2016 certified quality management systems. It holds Medical CE Certification (Class IIa) under MDD 93/42/EEC and MDR (EU) 2017/745 for active therapeutic ultrasound devices. The platform has received FDA 510(k) clearance for non-invasive dermatological and aesthetic treatments for lifting and tightening (K191234-class reference). Additional certifications include IEC 60601-1 (medical electrical

equipment safety), IEC 60601-2-62 (specific requirements for high-intensity therapeutic ultrasound), and IEC 60601-1-11 (household/clinic use environments). The system complies with China NMPA Class II standards, UKCA marking for Great Britain, and is RoHS 3 Directive (2015/863) compliant for hazardous substance restrictions. Each unit undergoes 48-hour burn-in testing and acoustic power verification using a radiation force balance traceable to NIST standards.

TECHNICAL SPECIFICATIONS

All performance parameters validated under standard operating conditions (21° C ambient, 50% RH). System calibration intervals are 12 months or 100,000 therapeutic shots, whichever occurs first.

Parameter	Specification
Operating Frequency	1.0 MHz / 3.0 MHz / 7.0 MHz ±5% (swappable cartridges)
Focal Depths	1.5 mm / 3.0 mm / 4.5 mm (selectable per cartridge)
Focal Spot Size	0.8 mm (lateral) x 8 mm (vertical) - elliptical
Pulse Energy per Shot	0.2 J to 1.5 J (1.0J default for lifting)

	protocols)
Repetition Rate	0.5 Hz - 10 Hz (burst mode available)
Maximum Acoustic Output	$I_{sppa} \leq 1900 \text{ W/cm}^2$, $I_{spta} \leq 720 \text{ mW/cm}^2$
Cooling System	TEC + sapphire tip + water circulation (180 mL/min) + forced air
Epidermal Temperature	Controlled at 15°C–18°C (active), -2°C tip contact plate
Display	15.6 inch capacitive touchscreen, 1920x1080, anti-glare
Handpiece Connection	Rotating bayonet with RFID cartridge reader
Dimensions (Main Unit)	420 mm (W) x 350 mm (D) x 580 mm (H)
Weight (Main Unit)	18.5 kg (40.8 lbs)
Electrical Requirements	100-240 VAC, 50/60 Hz, 350 VA max
Operating Environment	+10°C to +30°C, 30% to 75% RH non-condensing
Standards Compliance	CE (MDR), FDA 510(k), ISO 13485, NMPA, IEC 60601 series

