High-Intensity Focused Ultrasound (HIFU) Body Contouring Machine - Official Clinical Overview & Technical Datasheet

DEVICE IDENTIFICATION

Product Designation: High-Intensity Focused Ultrasound (HIFU) Body Contouring System

Model Series: HBC-2000 (Class IIa Medical Device)

Intended Use: Non-invasive thermal ablation of subcutaneous adipose tissue for circumferential reduction of the abdomen, flanks, thighs, and upper arms. Also indicated for the improvement of skin laxity via neocollagenesis in the superficial muscular aponeurotic system (SMAS) layer.

OEM Manufacturer: [Your OEM Brand Name] – A Top-Tier Medical Aesthetic Device OEM.

INTERNAL HARDWARE TOPOLOGY

The HBC-2000 employs a linear-array ceramic piezoelectric transducer capable of generating acoustic energy at a focal depth of 4.5mm, 3.0mm, and 1.5mm. The core engine consists of a Class-D RF amplifier coupled with a real-time impedance matching network to ensure energy transfer efficiency above 95%. The system utilizes a 7-axis articulated armature with electromagnetic counterbalance to eliminate operator fatigue during prolonged circumferential treatments.

Key Subsystems:

- Transducer Driver: Programmable burst mode controller (1-10Hz PRF).
- Power Supply: Resonant LLC converter (200W continuous, 450W peak).
- Thermal Management: Parallel-plate liquid cooling loop (Delta T < 2°C after 60 cycles).

EPIDERMAL PROTECTION MECHANISMS

The device implements a multi-stage safety architecture to prevent superficial burns. The handpiece integrates a real-time thermistor array (accuracy ±0.5°C) and a capacitive contact monitoring system that disables energy emission if acoustic coupling gel integrity is compromised. A closed-loop feedback system

automatically reduces fluence by 20% if skin surface temperature exceeds 40°C.

Parameter	**Specification**
Focal Depth (Selectable)	4.5mm (SMAS) / 3.0mm (Deep Dermis) / 1.5mm (Superficial Dermis)
Acoustic Energy per Line	0.2 J/mm² to 0.8 J/mm² (variable step 0.05 J/mm²)
Transducer Lifetime	> 100,000 shots (or 3 years from date of manufacture)
Cooling Interface	Active Sintered Sapphire + Forced Air Convection (Skin temperature maintained at 15°C ± 2°C)
Safety Interlocks	Capacitive Contact Sensor (requires Z < 50 kOhm), Thermal Cutoff (42°C ± 0.5°C)

TREATMENT ADVANTAGES

- Dual-Layer Targeting: Simultaneous or sequential treatment of the SMAS layer (4.5mm) and dermal layer (3.0mm/1.5mm).

- Zero Downtime: Non-invasive mechanism preserving epidermal integrity.

- Rapid Protocol: Average full abdominal treatment under 45 minutes.

- Patient Comfort: Dynamic pulse train technology reduces peak acoustic pressure, minimizing sharp sensations.

SPECIFICATION MATRIX

Transducer Frequency: 4MHz (4.5mm), 7MHz (3.0mm), 10MHz (1.5mm)

Focal Length: 4.5mm / 3.0mm / 1.5mm (selectable)

Fluence per Line: 0.2 J/mm² to 0.8 J/mm²

Acoustic Power: Max 32W (single pulse)

Pulse Repetition Rate: 1 Hz, 2 Hz, 3 Hz, 5 Hz, 10 Hz

Line Spacing: 1.0mm, 1.5mm, 2.0mm (user-configurable)

Line Length per Shot: 25mm

Display: 15.6-inch Capacitive Touchscreen, 1920x1080

Dimensions (WxDxH): 450mm x 550mm x 1200mm

Weight: 38 kg (net)

Power Supply: AC 100-240V, 50/60Hz, 800VA

REGULATORY COMPLIANCE

- Medical Electrical Equipment: IEC 60601-1 (Edition 3.2), IEC 60601-2-62 (High

Intensity Therapeutic Ultrasound).

- Electromagnetic Compatibility: IEC 60601-1-2:2020 (Group 1, Class A).

- Biocompatibility: Handpiece materials certified per ISO 10993-5 & -10.

- Laser Safety (as accessory): IEC 60825-1 (for alignment beam: Class 2M, 650nm, <1mW).

- Quality Management System: ISO 13485:2016 certified manufacturer.

The HBC-2000 is CE MDR (EU 2017/745) compliant and registered with the US FDA as a Class II device (510(k) clearance pending per regional requirements).