

## EMS Body Sculpting Machine - Official Clinical Overview & Technical Datasheet

### EXECUTIVE SUMMARY

The EMS Body Sculpting Machine represents a paradigm shift in non-invasive aesthetic medicine, merging High-Intensity Focused Electromagnetic (HIFEM) technology with advanced muscle stimulation protocols to deliver clinically validated body contouring outcomes. This device is engineered to induce supramaximal muscle contractions—unattainable through voluntary exercise—triggering profound adaptations in muscle architecture and localized lipolysis. Designed for integration into high-performance medical spas and dermatology clinics, the platform offers a sophisticated, multi-modal approach to simultaneously build muscle and reduce fat, addressing the growing consumer demand for comprehensive body sculpting solutions without the downtime associated with surgical interventions. The system's architecture prioritizes patient safety, comfort, and clinical efficacy through robust engineering and intelligent treatment protocols.



## CLINICAL ARCHITECTURE & DESIGN

The platform's clinical efficacy is rooted in its patented HIFEM technology, which generates a powerful, focused electromagnetic field that penetrates soft tissue to depolarize motor neurons, triggering intense, involuntary muscle contractions. Unlike voluntary muscle activation, which is limited by central nervous system inhibition, HIFEM technology forces muscles to contract at supramaximal intensities, leading to a cascade of physiological events: deep remodeling of muscle tissue, myofibrillar growth (muscle hypertrophy), and the production of new collagen chains (muscle hyperplasia). This extreme metabolic demand also drives a significant increase in local lipolysis, as the body breaks down triglycerides to fuel the heightened energy expenditure, resulting in a measurable reduction in subcutaneous fat thickness. The treatment architecture is designed to create a synergistic effect: while

electromagnetic energy drives muscle development, the concurrent application of targeted radiofrequency (RF) energy in advanced models preheats muscle tissue and induces apoptosis in adipocytes, achieving a dual-action effect of fat reduction and muscle enhancement in a single 30-minute session.

#### KEY INDICATIONS & CAPABILITIES

The EMS Body Sculpting Machine is indicated for the non-invasive strengthening, toning, and firming of muscles, as well as the reduction of localized adipose tissue. Its versatility allows for targeted treatment across multiple anatomical regions, including the abdomen, buttocks, thighs, arms, and flanks. The device is clinically proven to: increase muscle mass and density, improve muscle tone and definition, reduce subcutaneous fat and waist circumference, and enhance overall body contour. The system supports 2 to 4 simultaneous applicators, dramatically reducing total treatment time and enabling the coverage of larger or multiple areas in a single session. The 12.1-inch intelligent touchscreen interface provides intuitive control, offering both pre-set and customizable programs to tailor each treatment based on individual patient anatomy and desired outcomes. The system integrates a comprehensive patient safety framework, including a safety switch (EMO) and continuous temperature monitoring to ensure treatments remain within optimal and safe parameters.

## COMPLIANCE & STANDARDS

This device is engineered and manufactured in full compliance with the most stringent international medical device standards. It holds a Class 2 device classification with a U.S. FDA 510(k) clearance and complies with the essential requirements of the European Medical Device Regulation, bearing the CE mark. The system adheres to rigorous electrical safety standards as per IEC 60601-1, IEC 60601-1-2 (electromagnetic compatibility), and IEC 60601-2-10 (specific requirements for nerve and muscle stimulators). All patient-contact materials are certified for biocompatibility, meeting the requirements of ISO 10993-5 (cytotoxicity), ISO 10993-10 (skin sensitization), and ISO 10993-23 (irritation) standards. The device is manufactured in an ISO 13485-certified facility, ensuring the highest standards of quality management and production consistency.

## TECHNICAL SPECIFICATIONS

The following specifications detail the core technical parameters of the EMS Body Sculpting Machine, providing key performance indicators for clinical integration.

Parameter	Specification
Technology	High-Intensity Focused Electromagnetic (HIFEM) + Optional RF
Electromagnetic Intensity	Up to 7 Tesla
Pulse Frequency	1 - 150 Hz (Bidirectional Wave)
Pulse Width	300 $\mu$ s $\pm$ 10%
Output Power (System)	2600W - 5000W (Peak)
Input Voltage	AC 100-240V, 50/60Hz
Screen	10.4 - 15.6 inch Touchscreen
Cooling System	Advanced Air / TEC / Water / Wind
Treatment Handles	Up to 4 Applicators (Flat & Curved)
Contraindications	Pacemakers, Implanted Electronics, Pregnancy
Classification	FDA Class II (Product Code NGX)

## CLINICAL PROTOCOLS

A standard treatment protocol typically consists of four 30-minute sessions scheduled twice a week over a two-week period. This regimen is designed to maximize muscle adaptation and fat metabolism. Each session allows for

multi-area treatment using up to four handles, effectively doubling the efficiency compared to traditional two-handle systems. The device offers distinct operational modes—Sport, Gentle, and Professional—to accommodate varying patient tolerances and clinical objectives. Clinical evidence suggests that optimal results, including increased muscle thickness (averaging up to 16% to 25%) and reduced subcutaneous fat (averaging up to 30%), are observed at 1- to 3-month follow-ups. Patient satisfaction remains high, with the treatment offering a painless, non-invasive alternative to surgical body contouring, requiring zero downtime and yielding progressively improving results over six months.

