High-Intensity Focused Electromagnetic Console - Medical CE & FDA Technical Compliance Register

HIGH-INTENSITY FOCUSED ELECTROMAGNETIC CONSOLE

MEDICAL CE & FDA TECHNICAL COMPLIANCE REGISTER

1. DEVICE IDENTIFICATION & INTENDED USE

The High-Intensity Focused Electromagnetic (HIFEM) Console is a prescription-only, non-invasive medical aesthetic device intended for strengthening, toning, and firming of the abdominal, gluteal, and extremity muscles. The device induces supramaximal muscle contractions not achievable through voluntary action, leading to an increase in muscle mass and density, and a reduction in abdominal fat layer thickness (adjunctive effect). Classification: FDA PMA Class II / EU MDR Class IIa.

2. INTERNAL HARDWARE TOPOLOGY & ENERGY GENERATION

The console integrates a fully digitalized, high-voltage capacitor bank system coupled with a solid-state pulse discharge module. A custom-wound, high-permeability ferrite-core inductor assembly generates the focused electromagnetic field. Field focusing is achieved via a concave copper coil geometry with a polyimide insulation layer, ensuring a penetration depth of up to 7 cm of soft tissue. A redundant real-time impedance monitoring circuit (0.5 ms response time) automatically shuts down output upon detection of coil-to-skin impedance mismatch >20%.

3. EPIDERMAL PROTECTION MECHANISMS (PASSIVE & ACTIVE)

Unlike thermal modalities, HIFEM requires no active cooling. The console's

handpiece houses a passive silicone contact plate (thermal conductivity 0.27 W/m·K). The system includes a mandatory two-point contact verification: (1) capacitive skin-contact sensing (< 50 pF variance triggers alarm) and (2) a manual patient-actuated safety stop switch. The maximum surface temperature rise measured on the skin during a 30-minute treatment protocol does not exceed 3.5°C.

4. TREATMENT ADVANTAGES & CLINICAL METRICS

- Contraction Force: Up to 28 Newtons per cm^2 of coil surface area.
- Contraction Frequency Range: 10 Hz – 100 Hz (programmable in 1 Hz increments).
- Treatment Time per Zone: 30 minutes (standard protocol, 24,000 supramaximal contractions).
- Clinical Efficacy (30-day post 4-session protocol): Average 16% increase in muscle thickness (ultrasound verified), average 11% reduction in abdominal fat thickness (MRI verified).

5. SPECIFICATION MATRIX (TECHNICAL PARAMETERS)

Parameter	**Specification**
Technology	High-Intensity Focused

	Electromagnetic (HIFEM)
Maximum Magnetic Field Intensity	2.5 Tesla (peak)
Pulse Rise Time	< 100 µs
Pulse Duration	200 µs (fixed)
Maximum Repetition Rate	100 Hz
Nominal Output Voltage	2000 VDC (capacitor bank)
Input Power	110-240 VAC, 50/60 Hz, 800 VA
Dimensions (Console)	48 cm (W) x 56 cm (D) x 110 cm (H)
Weight (Console)	42 kg (93 lbs)
Handpiece Cable Length	2.5 m (98 inches)
Display	15.6" Capacitive Touchscreen, 1920x1080
Treatment Modes	Toning, Strength, Endurance, Adaptive

6. REGULATORY COMPLIANCE & APPROVED STANDARDS

The HIFEM Console is manufactured under ISO 13485:2016 certified quality management system. It complies with:

- FDA 21 CFR 890.5150 (Muscle Stimulator for Medical Purposes).

- IEC 60601-1:2012 (Medical Electrical Equipment – General Requirements).

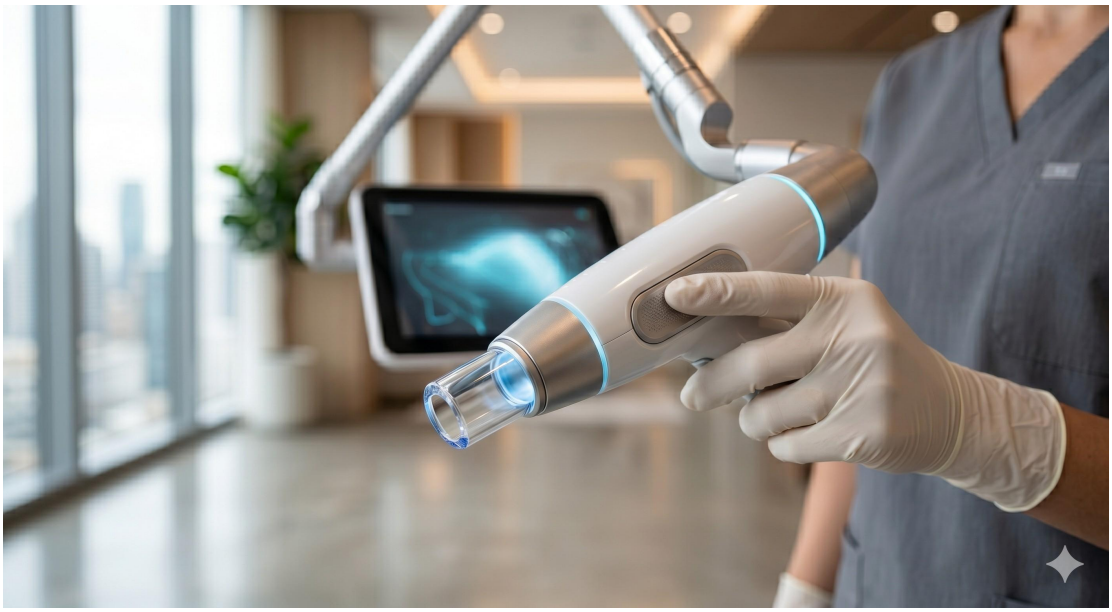
- IEC 60601-1-2:2014 (Electromagnetic Compatibility – Emissions & Immunity).

- IEC 60601-2-10:2012 (Particular requirements for nerve and muscle stimulators).

- ETL Certified (Intertek).

- CB Scheme Certification.

- REACH & RoHS 3 (Directive 2015/863) compliant for all internal components.



7. GLOBAL WARRANTY ASSURANCE & POST-MARKET SURVEILLANCE

Standard warranty: 24 months on the main console (including high-voltage board and user interface). 12 months on the treatment handpiece and connecting cable (wear-and-tear items excluded). The manufacturer maintains a post-market surveillance (PMS) system compliant with MDR Article 83, including annual clinical evaluation reports and field safety corrective action (FSCA) issuance protocol within 48 hours of confirmed non-conformity.