Medical CE & FDA Technical Compliance Register: Desktop EMS Muscle Toning Unit

1. REGULATORY CLASSIFICATION & DEVICE IDENTIFICATION

The Desktop EMS Muscle Toning Unit (Model: EMS-2000) is classified as a Class IIa medical device under EU Medical Device Regulation (MDR) 2017/745 and a Class II device under FDA 21 CFR 890.5850 (Neuromuscular Stimulator). The system delivers non-invasive electrical muscle stimulation (EMS) for the purpose of muscle conditioning, toning, and rehabilitation in clinical and med-spa environments.

Indication for Use: Prescription and over-the-counter use for strengthening, toning, and firming of abdominal, gluteal, thigh, and arm musculature via transcutaneous electrical stimulation of motor nerves.

2. CLINICAL ARCHITECTURE & WAVEFORM DESIGN

The EMS-2000 utilizes a proprietary Symmetrical Biphasic Rectangular Waveform with active charge-balancing circuitry to prevent net DC current and eliminate the risk of electrochemical skin irritation. The hardware topology comprises a dual-channel isolated output stage, each independently controlled via a dedicated ARM Cortex-M4 safety processor. Pulse frequency ranges from 1 Hz to 120 Hz, with a pulse width adjustable between 150 µs and 450 µs. A ramp-up and ramp-down profile (0.5 – 3.0 seconds) is programmable to maximize patient adherence and comfort during supramaximal contractions.

3. KEY INDICATIONS & PERFORMANCE CAPABILITIES

- Muscle Endurance & Strength: 10 – 30 Hz (Type I fiber recruitment)

- Muscle Toning & Hypertrophy: 40 – 70 Hz (Type II fiber recruitment)

- Post-injury rehabilitation & spasticity reduction: 1 – 10 Hz

- Duty cycle: 5 sec on / 10 sec off (default), user-adjustable from 2 to 30 seconds on/off

- Maximum output current: 120 mA peak into 500 Ω load

- Channel count: 2 independent output channels (4 electrodes total)

Parameter	**Specification**
Waveform	Symmetrical Biphasic Rectangular, active charge balancing
Pulse Frequency Range	1 Hz – 120 Hz (step size 1 Hz)
Pulse Width Range	150 µs – 450 µs (step size 10 µs)
Maximum Output Current	120 mA peak into 500 Ω load
Number of Channels	2 (independently controlled)
Power Supply	100–240 V AC, 50/60 Hz, 24 V DC 3.0 A adapter
Unit Dimensions (W x D x H)	210 mm x 165 mm x 55 mm
Weight	0.95 kg (2.09 lbs)
Display	4.3-inch resistive touchscreen, 480 × 272 px
Safety Certifications	CE (MDR), FDA 510(k), IEC 60601 series, ISO 13485

4. COMPLIANCE & SAFETY STANDARDS

The Desktop EMS Muscle Toning Unit has been validated to meet the following international standards:

- IEC 60601-1:2012 (Medical electrical equipment – General requirements for basic safety and essential performance)
- IEC 60601-1-2:2014 (Electromagnetic compatibility – Emissions and immunity)
- IEC 60601-2-10:2012 (Particular requirements for nerve and muscle stimulators)
- FDA 510(k) Premarket Notification – Substantial equivalence to predicate devices
- ISO 13485:2016 certified manufacturing facility
- RoHS 3 (2015/863/EU) and REACH compliance

5. TREATMENT PROTOCOLS & CLINICAL WORKFLOW

Standard Protocol for Abdominal Toning (8 weeks):

- Frequency: 3 sessions per week, minimum 48 hours between sessions

- Session duration: 25 minutes (including 2 minute warm-up at 15 Hz)

- Electrode placement: 4 carbon-rubber electrodes (5cm x 5cm) positioned rectus abdominis and external obliques

- Intensity: Titrated to visible muscle contraction without pain (typically 40–80 mA)

- Duty cycle: 6 sec on / 8 sec off, 50 Hz with 0.5 sec ramp

Contraindications: Active implantable devices (e.g., pacemakers, ICDs), pregnancy, malignancy over treatment area, deep vein thrombosis, or epilepsy. Do not apply over carotid sinus, transcerebrally, or transcardially.