Inner Ball Roller Massage Machine - Official Clinical Overview & Technical Datasheet

INNER BALL ROLLER MASSAGE MACHINE

OFFICIAL CLINICAL OVERVIEW & TECHNICAL DATASHEET

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EXECUTIVE SUMMARY

The Inner Ball Roller Massage Machine represents a paradigm shift in deep tissue rehabilitation and aesthetic body contouring adjunct therapy. Unlike traditional vibration or percussive devices, this platform utilizes a proprietary internal ball-bearing roller mechanism housed within a medical-grade, ergonomic applicator. The rotating sphere delivers uniform, radial pressure waves that penetrate the subcutaneous adipose tissue and superficial muscular aponeurotic system (SMAS) without causing epidermal shear stress. This document details the clinical architecture, regulatory compliance, technical specifications, and evidence-based treatment protocols for OEM procurement and Med Spa integration.

CLINICAL ARCHITECTURE & DESIGN

1. INTERNAL MECHANISM TOPOLOGY

- Core Component: Chrome-alloy precision ground sphere (Ø 45mm) mounted on a dual-race bearing assembly.

- Actuation: High-torque, low-noise brushless DC motor (max 3,500 RPM) coupled via a flexible damping coupler.

- Radial Force Output: Adjustable between 15 N and 85 N (measured at the contact diaphragm).

- Vibration Isolation: The inner ball is isolated from the outer housing by a thermoplastic elastomer (TPE) suspension frame, ensuring operator hand fatigue is minimized during prolonged sessions (up to 60 minutes continuous use).

2. EPIDERMAL PROTECTION & PATIENT COMFORT

- Contact Interface: Single-use, hypoallergenic polyethylene film barrier recommended, or autoclavable silicone cover.

- Rolling Diaphragm: A low-friction medical-grade TPU membrane transfers the ball's radial motion while preventing pinching.

- Thermal Management: Passive air circulation channels within the handpiece maintain surface temperature below 37°C (98.6°F) during maximum duty cycle operation.

KEY INDICATIONS & CAPABILITIES

The device is indicated for temporary improvement in local circulation, reduction of appearance of cellulite (edematous fibrosclerotic panniculopathy), and relief of minor muscle aches and spasms when applied by trained personnel. Primary capabilities include:

- Deep tissue mobilization without painful tapping.

- Uniform pressure distribution over bony prominences.

- Adjunctive lymphatic drainage support (when used with directional rolling protocols).

COMPLIANCE & STANDARDS

- Medical Device Class: IIa (EU MDR 2017/745) / II (FDA 21 CFR 890.5150) – Transcutaneous electrical nerve stimulator equivalent category for massage devices.

- Safety Standards: IEC 60601-1 (General safety), IEC 60601-1-2 (EMC), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Irritation & skin sensitization).

- Quality System: Manufactured under ISO 13485:2016 certified facility.

TECHNICAL SPECIFICATIONS

Parameter	**Specification**
Device Dimensions (Console)	380 mm (L) x 260 mm (W) x 180 mm (H)
Console Weight	4.8 kg (10.6 lbs)
Handpiece Weight	420 g (0.93 lbs) including cable
Input Power	100-240 VAC, 50/60 Hz, 1.5 A
Max Power Consumption	120 VA
Motor Type	Brushless DC, Hall-effect feedback
Inner Ball Material	Medical grade 316L stainless steel, mirror polished
Ball Diameter	45 mm +/- 0.5 mm
Radial Force Range	15 – 85 N (continuous adjustment)
Rotational Speed Range	60 – 350 RPM +/- 5%

Operating Modes	Constant rotation, Oscillating (45 ° arc), Pulsed (0.5 Hz – 3 Hz)
Max Duty Cycle	60 minutes on / 30 minutes off (at 85N, 350 RPM)
Acoustic Noise	< 55 dBA at 1 m (normal operation)
Ambient Operation Range	+10 ° C to +30 ° C, 30% – 75% RH non-condensing
Storage Temperature	-10°C to +50°C
Ingress Protection	IP20 (console), IP22 (handpiece connector)

CLINICAL PROTOCOLS

- Pre-Treatment: Visual skin inspection; no open wounds, acute inflammation, or deep vein thrombosis.

- Treatment Duration: 15 – 30 minutes per target area (e.g., posterior thighs, lumbar region, deltoids).

- Pressure Settings: Start at 25 N for naïve patients; advance to 60 N for deep myofascial release.

- Rolling Speed: 1.5 to 3.0 cycles per second (90 – 180 RPM).

- Contraindications: Pregnancy over abdominal region, recent surgery,

implanted electronic devices (pacemakers), malignancy near treatment zone, anticoagulant therapy with INR > 3.0.

- Post-Treatment: Mild erythema is expected and resolves within 30-60 minutes. Recommend hydration.

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