

# Pelvic Floor Muscle Stimulation Cushion - Official Clinical Overview & Technical Datasheet

## PRODUCT IDENTIFICATION & EXECUTIVE SUMMARY

Pelvic Floor Muscle Stimulation Cushion (Model PFE-2000) is a non-invasive, prescription-use electrostimulation device designed for the correction of pelvic floor muscle dysfunction. The system combines ergonomic seating architecture with proprietary bipolar pulsed current delivery to restore neuromuscular control, improve muscular endurance, and alleviate symptoms associated with stress urinary incontinence (SUI), mixed incontinence, and mild-to-moderate pelvic organ prolapse (POP).



## CLINICAL ARCHITECTURE & DESIGN

The device integrates a contoured medical-grade silicone cushion housing 8 independent bipolar electrode zones. Each zone is controlled via an isolated multichannel stimulation engine, enabling targeted recruitment of the pubococcygeus, iliococcygeus, and puborectalis muscle groups without intravaginal or intrarectal probes. The closed-loop impedance monitoring system dynamically adjusts current density to maintain therapeutic intensity while ensuring patient comfort and safety.

Key clinical design attributes include:

- Non-invasive transcutaneous stimulation via perineal and gluteal contact surfaces.
- Synchronized bilateral waveform delivery to prevent asymmetrical muscle fatigue.
- Automatic skin-electrode contact validation prior to treatment initiation.

## INDICATIONS & CAPABILITIES

FDA-cleared indications (Class II, 510(k) K213456):

- Stress, urgency, and mixed urinary incontinence in females.
- Pelvic floor muscle weakness (Grade 2 or less on Oxford Grading Scale).
- Post-partum pelvic floor rehabilitation ( $\geq 6$  weeks vaginal delivery,  $\geq 8$  weeks cesarean).

- Overactive bladder (OAB) with documented detrusor overactivity.

Contraindications: Active pelvic malignancy, implanted electronic devices (pacemaker, defibrillator, neurostimulator), pregnancy, undiagnosed pelvic bleeding, or active urinary tract infection.

#### TECHNICAL SPECIFICATIONS

Stimulation waveform: Symmetrical biphasic rectangular pulse, zero net charge.

Pulse frequency: 5 Hz – 100 Hz (adjustable in 1 Hz increments). Pulse width:

200 – 400  $\mu$ s. Output current range: 0 – 100 mA (peak). Number of channels: 8

independent. Electrode pad configuration: 16 reusable conductive silicone pads

(40x40 mm each). Treatment duration presets: 15, 20, 30 minutes.

<b>Parameter</b>	<b>Specification</b>
Stimulation Channels	8 independent, bipolar
Output Current Range	0 – 100 mA (peak, into 500 Ohm load)
Pulse Frequency	5 Hz – 100 Hz, step 1 Hz
Pulse Width	200 $\mu$ s – 400 $\mu$ s, step 10 $\mu$ s
Waveform	Symmetrical biphasic, net charge zero
Max. Compliance Voltage	150 V
Power Supply	100-240 V AC, 50/60 Hz, 60 VA

	(Medical-grade external PSU)
Cushion Dimensions / Weight	420 mm x 380 mm x 55 mm / 2.4 kg
Electrode Contact Material	Medical-grade conductive silicone, ISO 10993 compliant
Operating Conditions	+10 ° C to +30 ° C, 30% to 75% RH non-condensing

#### COMPLIANCE, STANDARDS & SAFETY SYSTEMS

- Regulatory: FDA 510(k) cleared, CE-MDR Class IIa (Certificate No. CE 123456), UKCA, TGA (Australia).
- Electrical safety: IEC 60601-1, IEC 60601-2-10 (nerve and muscle stimulator collateral standard).
- Electromagnetic compatibility: IEC 60601-1-2 (Edition 4.1).
- Biocompatibility: ISO 10993-5 (cytotoxicity), ISO 10993-10 (irritation & skin sensitization).
- Built-in safety: Patient-isolated outputs, automatic shutdown on electrode lift-off, individual channel current limiting (max 120 mA hardware clamp).



## RECOMMENDED CLINICAL PROTOCOLS & MAINTENANCE

Initial evaluation: Perform modified Oxford Grading and 1-hour pad test.

Baseline EMG assessment optional.

Standard treatment protocol: Three sessions per week for 8 weeks (total 24 sessions). Ramp-up phase (Week 1): 20-40 mA, 50 Hz, 250  $\mu$ s, 15 min. Conditioning phase (Weeks 2-6): 50-80 mA, 35 Hz, 300  $\mu$ s, 20 min. Maintenance phase (Weeks 7-8): 40-60 mA, 20 Hz, 250  $\mu$ s, 20 min, transitioning to home use schedule (2x/week).

Preventive maintenance: Clean conductive silicone pads after each session with non-alcoholic electrode wipe. Replace pads every 30 uses or when surface resistance exceeds 5 kOhms. Annual factory calibration verification.

Document version: 2.3. Expiry of technical data: 5 years from publication. This datasheet is an integral part of the operator manual (PFE-2000-OM-EN).