



Company: REACT Holdings, LLC

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Overview:

In 2017, React Innovations acquired the assets of Magic Race/Neotonus which manufactured and distributed the Extracorporeal Magnetic Innervation (ExMI) therapy. The non-invasive technology can stimulate muscles, nerves and tendons up to 4 inches deep into the body. Patients are treated with their clothes on as the bio-electric magnetic therapy requires no skin contact in order to actuate the tissues. Videos of the technology in action can be found online at our websites.

The company manufactures tables, chairs and hand-held units utilizing its core technology. All products are manufactured in the USA utilizing ISO-13485 manufacturing standards. Pelvic Wave, LLC is a subsidiary of React Holdings, LLC focused on the Pelvic Floor / Incontinence therapy market.

ExMI therapy has two issued 510(k) issuances from the FDA. The device is classified as a Class II – Power Muscle Stimulator.

510(k) Summary - K973929

Indications for Use for Muscle Stimulation

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

510(k) Summary – K973096

Indication for Use for Pelvic Floor Therapy

- Provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles
- Restoration of neuromuscular control for the treatment of urinary incontinence in women.

ExMI Mechanism:

Pulses of steep gradient magnetic flux are produced by the therapy head (magnet). These fields penetrate the patient's perineum and initiate nerve impulses that ultimate innervate both the smooth and striated muscles, causing them to contract.

The time-varying magnetic fields create an electrical potential that causes ion flow (Eddy currents) within the targeted tissues. This ion flow results in the results ion resting motor neuron membrane potentials greater than the threshold potential necessary to start an action potential.

Once this action potential has been realized, the sodium (Na⁺) and potassium (K⁺) ions flow across the neuron membrane. This action propagates a nerve impulse to the motor end plate.

The musculature responds with contractions as a rate determined by the output pulse rate of the system. If the output pulse rate exceeds that of the muscles ability to contract and relax with each pulse, the result is a constant and steady contraction of the muscles.

The following references a total of 67 studies performed over 20+ years citing the Extracorporeal Magnetic Innervation (ExMI) therapy.

- 45 on pelvic floor and incontinence
- 13 on traditional rehabilitation
- 10 on animal and physiological studies

Pelvic Floor / Incontinence References:

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3. Ishikawa N, Suda S, Sasaki T et al Development of a non-invasive treatment system for urinary incontinence using a functional continuous magnetic stimulator. Med Biol Eng Comput 1998; 36: 704-710
4. Galloway NTM, El-Galley RES, Sand PK, Appell RA, Russell HW and Carlan SJ: Extracorporeal magnetic therapy for stress urinary incontinence. Urology 53(6): 1108-1111, 1999 (also AUA presentation Dallas 1999)
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6. Appell R, Bourcier AP and Torre F: In Pelvic Floor Dysfunction, Investigations and Conservative Treatment. Rome: Casa Editrice Scientifica Internazionale, Chapter 12, 1999
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13. Bavendam T, Braddon L, Carlan S, Sand P, Appell R and El-Galley R: Impact of Extracorporeal Magnetic Innervation (ExMI) on Quality of Life in the treatment of stress urinary incontinence Abstract AUA Presentation Atlanta 2000. Conclusion: validated QOL instrument demonstrates the effectiveness of ExMI as a treatment for stress urinary incontinence
14. Kennett KM and Bell D: A Prospective Study of the Effectiveness of Extracorporeal Magnetic Innervation (ExMI) for the Treatment of Stress Urinary Incontinence in Women. Presented at Annual Meeting of Society of Urology Nurses and Associates, Atlanta 2000
15. Gammonley J A Review of Extracorporeal Magnetic Innervation Therapy Outcomes in Older Females with Urinary Incontinence. National Multi-Specialty Conference on Urinary Incontinence, SUNA January 2000
16. Wolff WL Ouslander JG Experience with Extracorporeal Magnetic Innervation Therapy (ExMI) for Urinary Incontinence in an Assisted Living Facility. Abstract and Presentation The American Geriatric Society Annual Meeting, Nashville 2000
17. Moorthy P, Lim PHC and Queck P: Extracorporeal Magnetic Innervation (ExMI) of the pelvic floor: Therapeutic efficiency in Female stress urinary incontinence. 2nd Scientific Meeting of Asian Society for Female Urology Hong Kong Aug 2000. Conclusion: effective in strengthening pelvic floor muscles, which regulate continence. Confirms a safe painless and cost effective therapeutic method for stress incontinence
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20. Patel A, Rowe E and Laverick L: A prospective randomized placebo controlled double-blinded study of electromagnetic therapy in the treatment of Chronic Pelvic Pain Syndrome in Men

London UK (#20 men with pelvic pain). Presented IBS March 2001 Washington DC and EAU April 2001, Geneva, Switzerland

21. Gillig PJ, Kennett KM, Bell D and Fraundorfer MR: Extracorporeal magnetic stimulation (ExMI) versus sham treatment for female genuine stress incontinence. A randomized trial. Eur. Urology 39: abstract 287, 2001 (New Zealand #70 patients). Conclusion: Patients who failed pelvic floor muscle exercise did improve with ExMI
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27. Shobeiri SA, Chesson RR, Echols KT, Beech S and Hoyte L: Evaluation of Extracorporeal Magnetic Innervation (ExMI) for the treatment of Fecal Incontinence New Orleans LA (#19 with fecal incontinence) ICS Seoul, Korea 2001 # 324
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41. Perianan M, Chye H and Peter L: Efficiency of Extracorporeal magnetic Innervation (ExMI) in Urinary Incontinence: A symptomatic Assessment Presented ICS Congress 2002, Heidelberg Germany, Abstract # 435
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Traditional Rehabilitation Therapy in Humans:

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Animal and Physiological Studies:

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