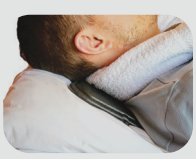
replexa+

Thermal Shortwave Diathermy Compared to Transcutaneous Electric Nerve Stimulation (TENS) in the Treatment of Chronic Pain

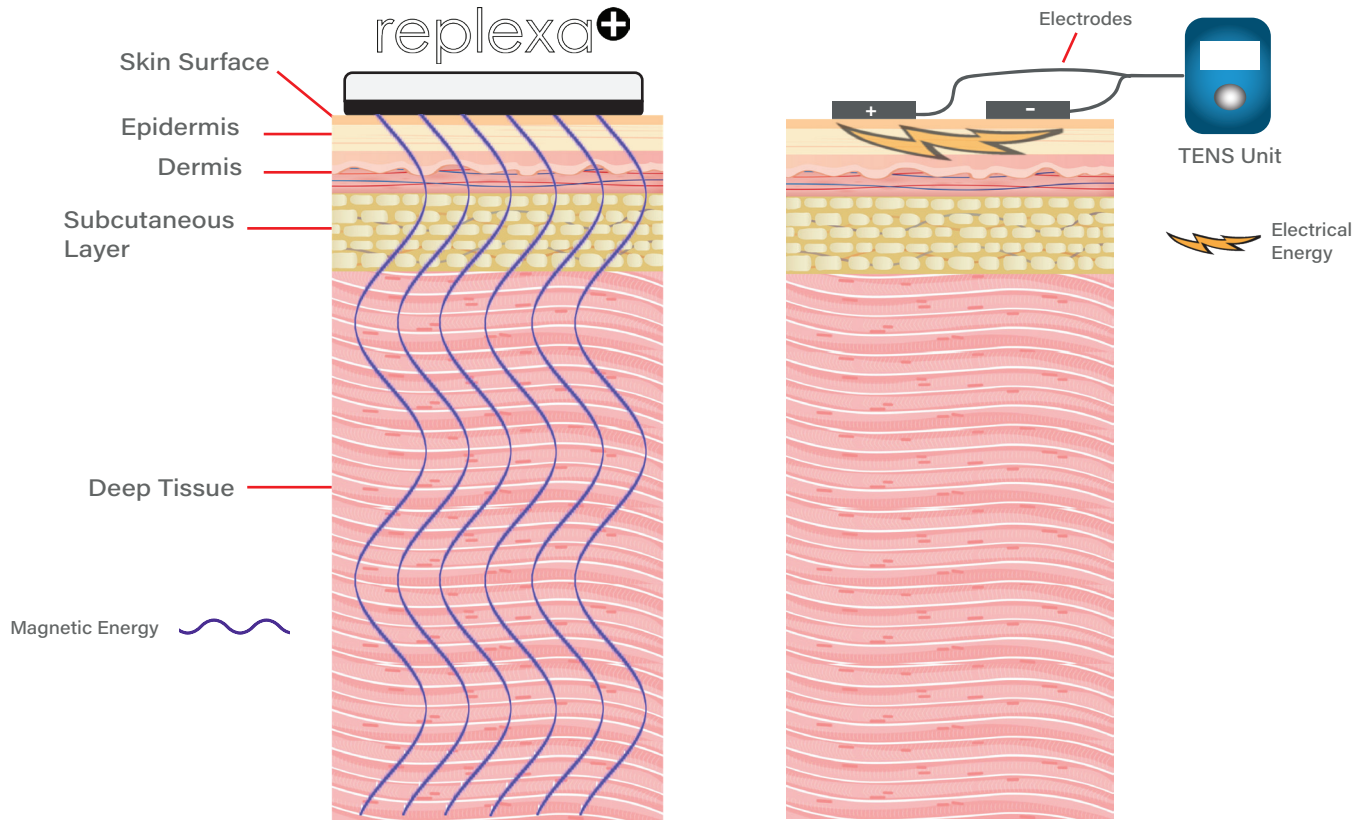
Manufactured by PROMEDTEK

Pain prevalence in the veteran population is over 3 times higher than the nonveteran population.[1] With many options available, it may be difficult to determine which modality is the most effective based on the patient's condition.

Replexa+ is an easy-to-use, one-touch device prescribed for chronic pain relief in patients who have not achieved their desired outcomes with other modalities.

Technology Differentiators	Replexa+	TENS (e.g., H-Wave H4, BioWaveGO RX, Rebuilder 2407)
FDA Product Classification	IMJ: Shortwave Diathermy, For Use In Applying Therapeutic Deep Heat[2].	GZJ: Stimulator, Nerve, Transcutaneous, For Pain Relief[3].
Primary Use	Pain relief through application of therapeutic deep heat.	Pain management through nerve stimulation.
FDA 510(k) Indications of Use	Replexa+ can be used to treat selected medical conditions such as: 1. Relieving pain 2. Increasing blood flow 3. Increasing range of motion 4. Reducing muscle spasm	▪ Symptomatic relief of pain ▪ As an adjunctive treatment in the management of post-surgical and post-traumatic pain.
Technology	Replexa+ uses shortwave diathermy to deliver electromagnetic energy to the body to provide deep heating therapeutic effects to superficial and deep tissues.	TENS uses battery power, electrical stimulation to interfere with pain signals sent to the brain, by stimulating the nerve pathways. This "closes the gate" to the transmission of pain signals, thus reducing the perception of pain.
Treatment Limitations	Specifically designed for chronic pain patients or when other treatment modalities have failed. Addresses the underlying condition causing pain.	No evidence of sustained effect after treatment stops[4]. No noticeable difference in outcomes when compared to a placebo TENS device[4].
Application of Therapy	Replexa+ generates magnetic energy that can pass through fabric. Direct skin contact is not necessary.  	TENS devices require direct contact with the skin, as the electrodes must make firm contact to deliver electrical impulses. 

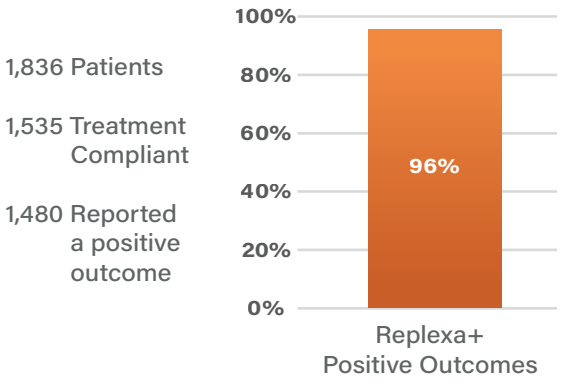
Depth of Penetration



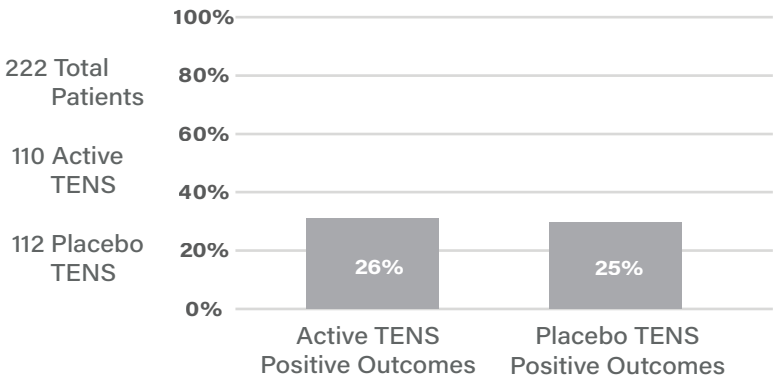
Outcome Differentiators

96% of compliant Replexa+ patients achieved a positive outcome.[5] Whereas, the European Journal of Pain study does not support the use of TENS in the treatment of patients with chronic pain.[6]

Replexa+ Retrospective Study Results[5]



Acitve TENS vs Placebo TENS Study Results[6]



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[1] Taylor, K.A. et al. (2023). Seventeen-Year National Pain Prevalence Trends Among U.S. Military Veterans. Johnson, Mark I., et al. [2] U.S. Food and Drug Administration. (2024 July 29). Product Classification: IMJ. Accessdata.fda.gov, https://www.accessdata.fda.gov. [3] U.S. Food and Drug Administration. (2024 July 29). Product Classification: GZJ. Accessdata.fda.gov, https://www.accessdata.fda.gov. [4] Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Pain in Adults. Cochrane Database of Systematic Reviews, no. 10, 2022, Article CD011890. Wiley, https://doi.org/10.1002/14651858.CD011890.pub3. [5] ProMedTek. (2022). A Retrospective Examiniation of Patient Results after Replexa+ Treatment. [6] Buchmuller, A. et al. (2011). Value of TENS for relief of chronic low backpain with or without radicular pain.