

Amplifying Your Athletes Healing Potential: Sustained Acoustic Medicine (sam®) 2020 Clinical Study Review

sam® is the only FDA approved multi-hour ultrasound device to deliver 20,000 joules of ultrasound and treat 5cm deep tissue targets. sam® is proud to be platinum partners of the Professional Football Athletic Trainers Society PFATS.

sam® technology and treatment overview: Sustained Acoustic Medicine (sam®) technology developed and manufactured by ZetrOZ Systems, LLC (Trumbull, CT) is the only treatment of its kind to reduce pain, increase local circulation and accelerate the healing cascade. sam® utilizes multi-hour ultrasound to generate deep diathermy and biomechanical modulation of cellular pathways in tissue. sam® is clinically proven to accelerate healing in over 30 Level 1-4 clinical trials. Additionally, recent meta-analysis of the literature demonstrates ultrasound delivered by sam® is safe, effective and a clinically cost-effective treatment option for patients.

The sam® device provides an ultrasound output of 3 MHz, 1.3 watts and 132mW/cm² intensity. Over the course of a 4 hour of treatment, the sam® device delivers 20,000 joules of energy into deep tissue. The sam® ultrasound lenses spread continuous ultrasound into the tissue and prevents focal regions or hotspots from occurring in musculoskeletal tissue. The divergent ultrasound field, and natural reflection and scattering in the tissue increase the treatment volume of each generator to be approximately 58 cm³ and over 5cm deep. sam® ultrasonic treatment is demonstrated to generate a human-tissue temperature rise *in vivo* of 4 degrees C. The temperature is controlled and regulated by the transducer-circuit interface which provides real-time echogenic feedback to the user. The generator design and ergonomics of the entire sam® device assist with proper use of the device by the patient.

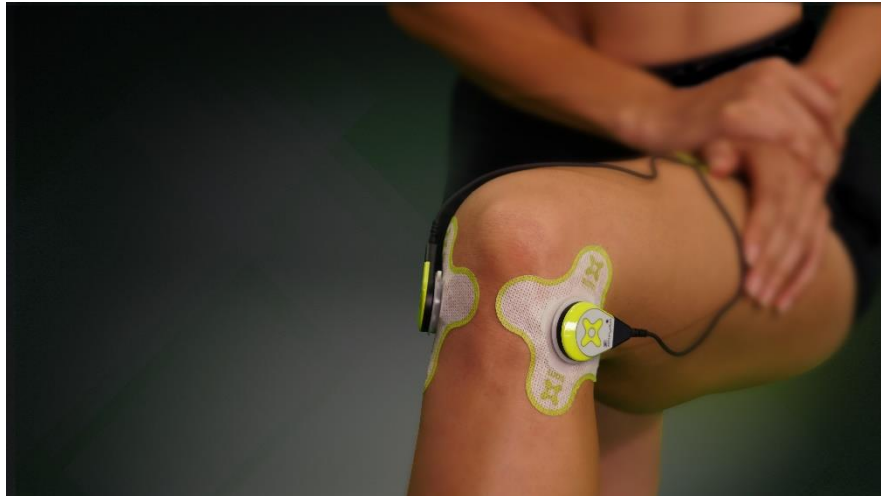
Overall, the science and design efforts by the company for the last 15-years have resulted in over 30 clinical publications, 46 separate IP filings around electronics, transducers,



The sam® Gel-Capture Patch now features product innovation being supported from the National Institutes of Health with 2.5% diclofenac for delivery of deep topical anti-inflammatory medication.

control-feedback, therapeutic treatment regimens and coupling devices to the human body, and a unique product portfolio that has delivered over 250k treatments.

New clinical studies published in 2020: It has been an amazing year for education and clinical research on sam®. sam® has added CME accredited courses, been featured in five textbooks, and participated in four new additional research publications now in press. The new research publications include 1. enhanced topical drug-delivery, 2. healing real-world athletes, 3. clinical multi-site randomized placebo-controlled study on neck/shoulder injury, and 4. health-economic analysis on sam® treatment.



The SAM 2.0 device is the latest medical device innovation from ZetroZ Systems. Now with expanded indications in 2020 by the Food and Drug Administration.

1. Laboratory Research: Local drug delivery of diclofenac and other NSAID's (Sonophoresis) with sam®. Matterson et al. 2020 *Journal of Therapeutic Delivery—University of Cincinnati*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7373207/>

- The results of this study showed that the application of sam® with diclofenac for 4 hours increases diclofenac delivery by 380% ($p < 0.01$) and penetration by 32% ($p < 0.01$) into tissue. The authors concluded that sustained acoustic medicine can be used as a transdermal drug-delivery technology for nonsteroidal anti-inflammatory drugs.

2. Clinical Real-World Case Study: sam® for Healing sports related injuries. Draper et al. 2020 *Journal of Orthopedic Research—Brigham Young University*. <https://irispublishers.com/gjor/pdf/GJOR.MS.ID.000545.pdf>

- The study examined 18 professional and amateur athletes with different injuries and observed their response to sam® treatment. All injuries previously followed traditional physical-therapy and found little to no

improvement. Before using sam, none of the athletes were able to return to sport.

- The results of this study showed that all athletes were satisfied with the usability and comfort of the sam® therapy and 93% reported the device was sufficiently discrete. After using sam®, 87% of athletes had improved function and 55% of athletes were able to return to sport. Additional outcomes indicate all athletes showed an average pain decrease of 3.33 ± 0.82 ($p < 0.05$) numerical rating scales, improvement in function, and quality of life. 87% of the athletes documented an improvement in function. The authors concluded that sam® improves athletes' healing outcomes and return to play.

3. Multi-Site Randomized Controlled Trial: sam® for treating chronic shoulder and neck injuries. Patterson et al. 2020 *Journal of Pain Research—Orthopaedic Foundation*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7287226/>

- The results of the study showed that sam® therapy provided a significant mean pain reduction from baseline of 2.61 points for active ($p < 0.001$), compared to 1.58 points decrease from baseline for placebo ($p = 0.087$), resulting in a 1.03 points significant decrease in the active group over placebo ($p = 0.003$). The total global improvement score was also significantly higher in the active sam® group at 2.84 points compared to the placebo group at 0.46 points ($p < 0.001$). The authors concluded that sam® can effectively be used to treat clinical pain related to upper trapezius myofascial pain.

4. Health Economic Research: sam® as a cost-effective treatment option of joint arthritis. Best et al. 2020 *Research Square, Journal of Orthopedics—University of Miami*. <https://assets.researchsquare.com/files/rs-64024/v1/914da195-cbaa-4025-9832-b084fd9d6565.pdf>

- The results of the study demonstrated that over 6 months, the cost and functional effectiveness of sam® for the management of arthritis was \$8,641 and 0.52 versus standard of care at: \$6,281 and 0.39, respectively. The incremental cost effectiveness demonstrated that most of the time (84%), sam® treatment resulted in improved functional effectiveness but at a slightly higher cost. The authors concluded that sam® treatment demonstrated improved pain and functional gains compared to standard of care, and sam® is a home-use cost-effective treatment for arthritis.

New technology offerings for PFATS members: Thanks to the incredible support from the National Institutes of Health, US Department of Defense and the PFATS community, sam® has continued to innovate and develop new medical technologies ranging for high-school athletes to military veterans. Some of our innovative product offerings include:

1. Sonophoresis Patches with 2.5% Diclofenac: Specially formulated multi-hour coupling sam® gel with analgesic and anti-inflammatory.
2. sam® 2.0 and Gel-Capture Patches: Military specification, rapid-charge capability, and improved durability/ergonomics.
3. sam® 2.0 Rapid Charging Stations: Medical-grade 20-unit rapid charging portal for wall or table mounting within the athletic training facility.



The sam® Product Family includes new accessories such as the 20-unit rapid charging cabinet to provide easier device care and field deployment.

Further learning and clinical education: We are fanatic about research, education and improving patient care. As such, we regularly update online training, clinical videos and have weekly in-services/webinars. If you would like to learn more about sam® technologies we can always be reached at 888-202-9831 or info@samrecover.com

Below are a few clinical educational tools available to PFATS members:

- sam® 2.0 New Features Overview Video:
<https://www.youtube.com/watch?v=4mi2kHIVUaE>
- sam® Mechanisms of Action Video
<https://www.youtube.com/watch?v=NpdYAibHV0g>
- sam® Online Clinical Training Portal:
[https://rise.articulate.com/share/a1hlap4ryFDU7k8RvqZjIEICYjMt2PcG#/#](https://rise.articulate.com/share/a1hlap4ryFDU7k8RvqZjIEICYjMt2PcG#/)
- sam® Clinical Education Live Presentation:
https://www.youtube.com/watch?v=g1FXe0N_L_c&t