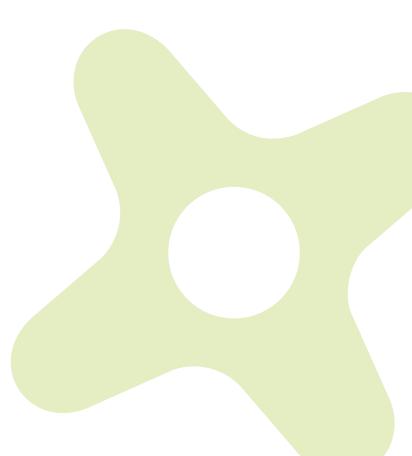
Sam[®] Program Guide







Sustained Acoustic Medicine is proven to 'supercharge' the body's natural healing process.



Clinically proven, wearable, safe, self-applied, in-home multi-hour low intensity ultrasound treatment.





Mechanism of Action

It amplifies our body's healing process by:

- Increasing collagen laydown and blood flow
- Building new capillaries
- Cytokine enzyme and cellular waste removal
- Increase oxygenated hemoglobin in tissue

What is sam[®]?

sam[®] is the only FDA cleared wearable ultrasound device for remote and in-home treatments that is clinically proven to "significantly" reduce pain and accelerate the rate of soft tissue healing by up to 50% because of the nutrient transfer and tissue healing.

How does it work?

Essentially, sam[®] "supercharges" the body's naturally healing cascade. sam treats the source of pain by accelerating collagen lay-down which helps to re-align and repair any adhesion(tear), in the muscles, tendons, and/or ligaments.

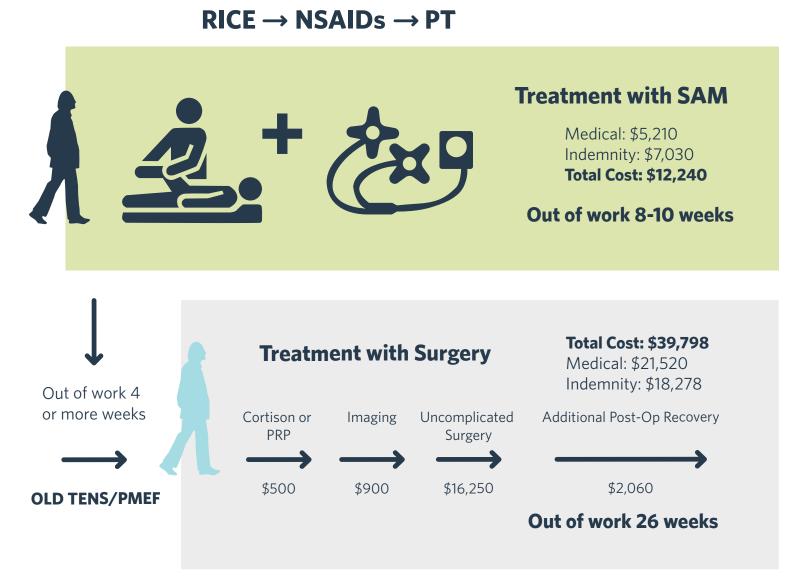


SAM Cost Benefits

- Average cost per injury \$39,000 National Safety Counsel
- Soft tissue injuries from repetitive motions, heavy lifting,

working overhead, etc. +50% of claims





+\$27,000 Savings

sam[®] Pro 2.0

The most advanced wearable and durable sustained acoustic medicine device to naturally accelerate soft tissue repair and reduce chronic pain.

Highlighted New Features for sam[®] Pro 2.0

- Power Controller: The 2.0 device features up to 4x faster rapid capability over existing sam[®] devices along with improved ergonomics and button-strength. The militarymedical-grade housing is coated with a molded label, and each system is uniquely serialized with laser engraving. Additional features include data-capture and treatment history monitoring upgrades*.
- Applicators: Design innovation leading to improved ultrasound delivery performance is the hallmark of sam® Pro 2.0. Thermally conductive transfer layers, thermoplastic design and smart treatment monitoring improve ultrasound delivery performance. Rugged in mold label housings with key-lock feature between applicator and y-adapter provide easy and secure wire connections.
- **Coupling Patches:** New custom stretch and hypoallergenic patches feature *3M Science Applied to Life*[™] technology. In addition to improved wear performance, 2.0 patches are easier to use and less messy with the patented gel-capture seals.



Durable carrying case with component, charger and accessory space

Made and designed in the U.S.A by ZetrOZ Systems, LLC. Trumbull, CT 06611 USA/PCT Patents 9,492,687; 9,480,863; 9,199,096; D746,994; D732,673; D732,672; D730,883. Additional patents pending. All rights reserved © 2018



Active-wear neoprene arm band

*For commercial accounts only. Discuss upgrade features with your sam® account representative



Specification Sheet sam[®] Pro 2.0 is a class II medical device



• Power controller with belt clip

sam[®]Pro

- Dual applicators with Y-adapter
- Rapid 2-amp USB charger
- Arm-band

sal

- 2-0z. Tube of Ultrasound Gel
- User manual and quick start guide
- 1-year full system warranty

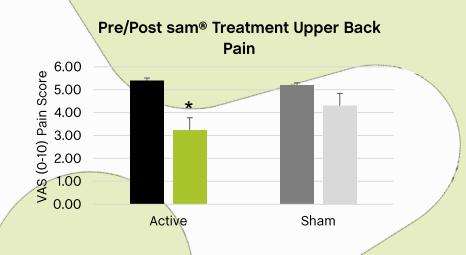


sam[®] Pro 2.0

Clinical evidence supports the use of sam[®] on a daily basis for the treatment of back pain from strain and disk herniation, joint pain from cartilage damage and arthritis, and tendon pain from overuse and injury.

New Highlighted Clinical and Scientific Evidence sam[®] Pro 2.0

- Upper and Lower Back Pain: In a 33-patient, 4-week randomized sham controlled study (RCT) on chronic upper back pain, active sam® provided a significant reduction in pain on the visual analogue scale (VAS). Pain was reduced by 2.15-points VAS (*40.0%) versus sham group 0.88-points VAS (17.4%) (p<0.05). The global rate of change score was also significantly better for the active treatment group (+2.84-points) versus (+0.46-points) for the sham group (p<0.01).
- In another recently completed 65-patient, 8-week RCT, sam[®] reduced pain by 2.08-points VAS (30.4%).



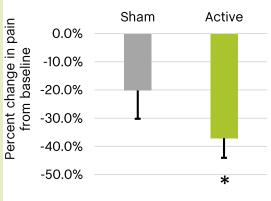
Osteoarthritis Joint Pain: In a 90-patient, 6-week, RCT on knee osteoarthritis pain sam® significantly reduced joint pain by 2.03-points VAS (*37.1%) versus sham treatment 1.02-points VAS (20.2%) (p<0.05). Additionally, the Western Ontario McMaster Osteoarthritis Questionnaire (WOMAC) score was significantly improved for all measures of pain, function and stiffness in the active treatment group. Active sam® treatment showed a 505point WOMAC improvement versus a 266-point WOMAC for sham (p<0.01).

sam[®] research is funded by the following United States government agencies: National Institutes of Health, US Department of Defense, National Science Foundation, National Air and Space Agency, and private funding from foundations and industry partners. All rights reserved © 2018. Clinical Evidence Summary and Treatment Guide Update



Twelve (+12) Clinical Studies Support sam[®] Pro 2.0 Treatment

Osteoarthritis Pain Reduction

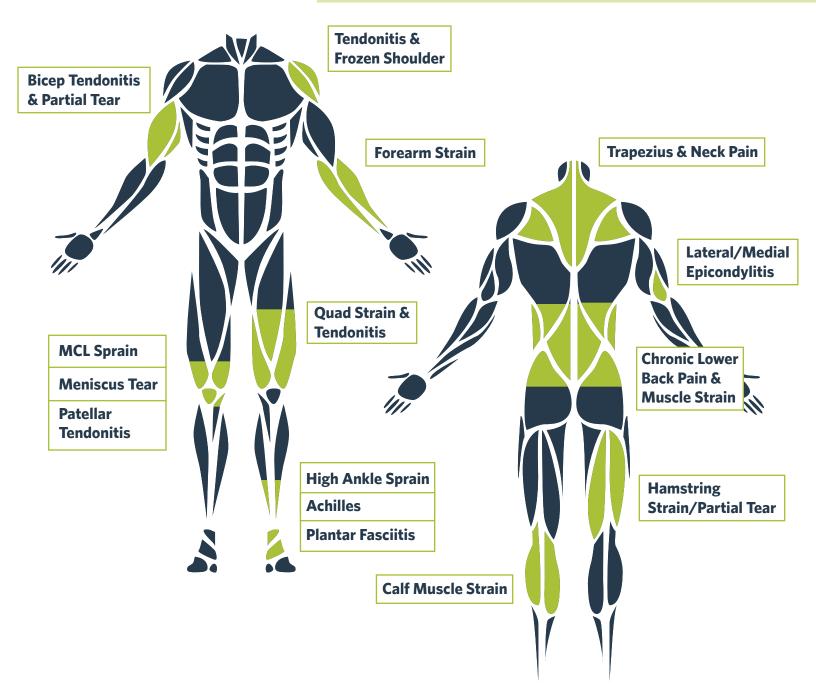


Health

Canada



SAM PRO 2.0: Potential Appropriate Clinical Conditions



Treatment Time: Up to 4-hours/day
 Rental Length: 36 Days

FDA Indication for Home Use and Self Administration 510K - #K191568, Class 2 Medical Device

X sam®

Application Placements



Treatment Time: Up to 4-hours/day



COMPARISON CHART



	sam [®] Ultrasound	Electrical & Magnetic Stim	Bracing Solutions	Joint Injection Biologics & HA
	Prescription Use Only /FDA Cleared	Over The Counter /No Prescription Required	Over The Counter /No Prescription Required	Prescription Use Only /FDA Cleared
Reduces Cause of Pain (not pain blocking)		X	X	
Accelerates Natural Healing		X	X	
Provides Deep Heat		X	X	X
Delivers Mechanical Compression		X	X	X
Increases Deep Circulation		X	X	X
Increases Oxygen & Nutrient Delivery		X	X	X
Provides Daily Multi-Hour Therapy			X	
Wearable & Portable				X



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Present vs Past

X sam®

	Pro 2.0 (New)	Sport (Old)
510K + Class 2 Medical Device	K191568, Yes	K103978, No
Upgraded Generation II sam 2.0 vs. Gen I	sam 2.0 (Gen II)	samSport (Gen I)
FDA Indication for "Home Use"	Yes	No
FDA Cleared for Self-Administration	Yes	No
Software/Firmware (Logs "on time")	Yes	No
Splash Resistant (remote use)	Yes	No
Direct Shipment to Home or Office	Yes	No
Quick Charge Battery Feature (90 min)	Yes	No
Hypoallergenic Patches, All Non-Latex	Yes	No
Robust Housing	Yes	No
Advanced Applicator System Monitoring	Yes	No
Improved sam-safe Dosage Monitoring	Yes	No
Ergonomically Designed	Yes	No
Higher Quality Controls	Yes	No
Cleared for "Increasing Local Circulation"	Yes	Yes
Thermal Effect (Heating of 4c or more)	Yes	Yes
Acoustic Streaming Benefits (healing)	Yes	Yes
Nutrient Transfer by way of AS	Yes	Yes
Output Channels	Тwo	Two
Origin of Manufacturing	USA	USA
Depth of Penetration	Deep Field 5cm/2.5"	Deep Field 5cm/2.5"
Dose	18,720 Joules	18,720 Joules
Operating Modes	TWO - 0.65W and/or 1.3W	TWO - 0.65W and/or 1.3W

WRS

112 South Main Street, Suite A | Ann Arbor, MI 48104

SAM[®] Order Checklist

SUSTAINED ACOUSTIC MEDICINE (ACUTE NON-OP & CHRONIC PAIN)

Obtain 3 signed forms upon Clinician commitment (2 Prescriptions & 1 Letter of Medical Necessity)

Patient Demographic with ICD-10 Code & Date of Injury (If applicable, please provide State DME request form)

Workers' Comp Insurance: Carrier, Adjuster Contact Info, Claim #

Clinical Note: Most current consultative note available Why is the Clinician ordering SAM? (Include 'failed' conservative treatment options)

Consultative Note (sample)

Prescribing the FDA cleared sam PRO 2.0 Long Duration Ultrasound Device for relief of pain, to promote soft tissue healing, increase circulation of the affected area and accelerate recovery.

PLEASE SUBMIT ALL SAM ORDERS TO:

F: (734) 316-6798

E: samadmin@wrspecialists.com

For questions relating to sam please call us directly at 734-215-2401



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	Cold Compression Therapy (F	Please check)		SCIM ustained Acoustic Med	dicine (Please check)	
	e: ess (*cannot be a P.O. Box):	City		Date of Birt	th: Zip	
Home Phone	2:	,	Cell Phone:		Σīp	
Insurance Ca	e: arrier:		Phone Numb	er:		
Employer Na	ame: ry: ICD-10: _	City	Employer Phon	State ne Number:	· · ·	
Adjustor Na	gery: Diagr me: ger Name:	Phone:		Email:		
How to Submit:						
	For CCT: F: (888) 829-0065 P: (734) 929-2160 E: admin@wrspecialist	s.com	For SAM: F: (734) 31 P: (734) 21 E: samadm	15-2401	ecialists.com	

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Prescription SAM© (Sustained Acoustic Medicine)



REQUESTED VENDOR: WRS

Do Not Substitute (DAW)

SAM PRO 2.0 *FDA Indication for Home Use*

510K - #K191568, Class 2 Medical Device

(The ONLY wearable ultrasound device cleared by the FDA for home use and self-administration)

Patient Name:			Date of Birth:	SS#:
Patient Address:		City:	State:	Zip:
Type of Injury:		Date of Injury:	ICD-10 Code:	
Email:	_ Employer:		Patient Pho	one #:
Insurance:	Address: _		Clai	m #:
Adjuster's Name:		Phone:	Fax	x:
Symptoms:				
Limitations:				
Pain Level: No Pain 🗌	Mild Pain 🗌	Moderate Pain [Severe Pain	Worst Pain Possible 🗌
Range of Motion:	Active	Passi	ve	Resistive
Initial Rental Days:	Extension	n Rental Days:		

Prescribed Therapy Settings: 1 Treatment per day; up to 4 Hours per day.

Prescriber Letter of Medical Necessity

I am prescribing the sam[®] wearable multi-hour low Intensity ultrasound device (with treatment up to 4-hours per day). The device can be used while doing most activities (at home or at work), including recommended rehabilitation exercise protocols. sam[®] is clinically proven to accelerate healing of musculoskeletal injuries, thereby enhancing tissue recovery, and reducing pain (all without the use of opioids or other prescription pain medications).

sam[®] utilizes proprietary technology that employs high frequency ultrasonic waves that penetrate the tissue and directly treat the pain source. These ultrasonic waves increase collagen lay-down, enhance circulation, increase tissue hemoglobin oxygenation, and optimize the removal of cytokine enzymes and other cellular waste products. sam[®] is not conventional therapeutic ultrasound which is applied by a technician for only 5-10 minutes and neither accelerates healing nor reduces chronic pain.

I consider the sam® device medically necessary for this patient, since I believe it will help enhance healing, help alleviate pain, decrease narcotic consumption, optimize overall recovery, and accelerate safe return to work and activities of daily living. More information can be found at https:// samrecover.com/clinical-evidence/.

PRESCRIBER'S INFORMATION			
Prescriber Signature:			Date:
Prescriber Print Name:			
Prescriber Address:	City:	State:	Zip:
Phone:	NPI:	License #:	

Submit this form, along with relevant medical history and treatment notes (MRI/Diagnostic Test & Op Report preferred), via Email to: samadmin@wrspecialists.com or Fax: 734-316-6798.

LETTER OF MEDICAL NECESSITY

SUSTAINED ACOUSTIC MEDICINE

Re Patient: Claim #: Insurance Carrier: DOB:

I am requesting approval for use of sam® (Sustained Acoustic Medicine) System for my patient ______. The sam® System is the first and only FDA cleared wearable multi-hour low intensity ultrasound device. It employs a technology that is clinically proven to accelerate healing of musculoskeletal injuries, thereby enhancing tissue recovery, and reducing pain (all without the use of opioids or other prescription pain medications). The device can be worn for up to 4-hours per day.

sam[®] utilizes proprietary technology that employs high frequency ultrasonic waves that penetrate 5 cm into the tissue and directly treat the pain source. These ultrasonic waves increase collagen lay-down, enhance circulation, increase tissue hemoglobin oxygenation, and optimize the removal of cytokine enzymes and other cellular waste products. sam[®] is not conventional therapeutic ultrasound which is applied by a technician for only 5-10 minutes and neither accelerates healing nor reduces chronic pain.

The sam® device is the only FDA cleared treatment modality that that has been shown in multiple level 1 clinical trials, sponsored by the NIH (National Institutes of Health), the DOD (Department of Defense) and NSBRI, the research arm of the NASA (National Aeronautics and Space Administration), to both reduce chronic pain (without prescription pain medication) and accelerate recovery of injured tissue (muscle, tendon, ligament).

In summary, the sam[®] device uses sustained acoustic medicine, a form of continuous high-frequency ultrasound. The device is wearable and can be applied by the patient, eliminating the need for multiple office visits. The patient can use the device while doing most activities, including recommended rehabilitation exercise protocols.

I consider the sam[®] device medically necessary for this patient, since I believe it will help enhance healing, help alleviate pain, decrease narcotic consumption, optimize their overall recovery, and accelerate their safe return to work and activities of daily living.

This device is being provided by WRS, as I support their compliance driven service model and preauthorization process. If you have any questions about this prescription or require further information, please contact my office directly.

PRESCRIBER'S INFORMATION	
Prescriber Signature:	Date:
Printed Name:	_ NPI:

X sam[®]

Peer Reviewed Prospective Clinical Trials and Outcomes on SAM Treatment (arranged by date)

- Madzia, Alex, et al. "Sustained Acoustic Medicine Combined with A Diclofenac Ultrasound Coupling Patch for the Rapid Symptomatic Relief of Knee Osteoarthritis: Multi-Site Clinical Efficacy Study." The open orthopaedics journal 14 (2020): 176.
 - o https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7784557/
 - Measurable Outcomes/Results (Pain & Function): Patients with moderate to severe knee arthritis pain have a significant 2-3 point pain reduction (50-70%) from baseline, and significant 350-510 point improvement in joint function.
- Petterson, Stephanie, et al. "Low-intensity continuous ultrasound for the symptomatic treatment of upper shoulder and neck pain: A randomized, double-blind placebo-controlled clinical trial." *Journal of Pain Research* 13 (2020): 1277.
 - o https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7287226/
 - Measurable Outcomes/Results (Pain and Health Improvement): Patients with myofascial pain observed a significant 2.6 point pain reduction and 2.8 point improvement in health quality outcome with treatment.
- Draper, David O., et al. "Effect of low-intensity long-duration ultrasound on the symptomatic relief of knee osteoarthritis: a randomized, placebocontrolled double-blind study." Journal of orthopaedic surgery and research 13.1 (2018): 1-9.
 - o https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6192104/
 - Measurable Outcomes/Results (Pain and Function): Patients with moderate to severe knee arthritis pain observed a significant 2 point pain reduction and a significant 505 point improvement in joint function with SAM treatment.
- Langer, Matthew D., et al. "The Effect of Low Intensity Wearable Ultrasound on Blood Lactate and Muscle Performance after High Intensity Resistance Exercise." Journal of Exercise Physiology Online 20.4 (2017).
 - o https://www.asep.org/asep/JEPonlineAUGUST2017_Mattern.pdf
 - Measurable Outcomes/Results (Function and Lactate Removal): Participants demonstrated that SAM treatment significantly reduced blood lactate levels and significantly improved muscle performance and recovery.
- Best, Thomas M., et al. "Sustained acoustic medicine: wearable, long duration ultrasonic therapy for the treatment of tendinopathy." The Physician and sports medicine 43.4 (2015): 366-374.
 - o https://pubmed.ncbi.nlm.nih.gov/26468991/
 - Measurable Outcomes/Results (Pain, Function and Strength). Patients demonstrated a significant 3.9 point reduction in pain, a significant 2.83kg improvement in strength and function with SAM treatment of tendinopathy.
- Rigby, Justin H., et al. "Intramuscular heating characteristics of multihour low-intensity therapeutic ultrasound." Journal of athletic training 50.11 (2015): 1158-1164.
 - o https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732395/
 - Measurable Outcomes/Results (Diathermy): SAM treatment provides a mild IM temperature increase of 1°C for the first 10 minutes into the treatment, and a more vigorous temperature increase of 4°C 80 minutes into the treatment and sustained thereafter. SAM provides tissue heating equivalent to traditional ultrasound but can be sustained for multiple hours.
- Langer, Matthew D., et al. "Pilot clinical studies of long duration, low intensity therapeutic ultrasound for osteoarthritis." 2014 40th Annual Northeast Bioengineering Conference (NEBEC). IEEE, 2014.
 - o https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361017/
 - Measurable Outcomes/Result (Pain Reduction): Patients treated with SAM showed a significant 52% reduction in pain between 2-4 points, and a significant 20% increase in daily activity.
- Taggart, Rebecca, Matthew D. Langer, and George K. Lewis. "Human Factors Engineering and testing for a wearable, long duration ultrasound system self-applied by an end user." 2014 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE, 2014.
 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361019/
 - Measurable Outcomes/Result (Usability and Function): Nearly all patients were able to successfully operate the SAM device (95%) and thought the device was easy to use (93%). Additionally, 90% of users had a positive experience overall, and 87% of users would use the SAM device again.
- Lewis, George, et al. "Wearable long duration ultrasound therapy pilot study in rotator cuff tendinopathy." Proceedings of Meetings on Acoustics ICA2013. Vol. 19. No. 1. Acoustical Society of America, 2013.
 - o https://asa.scitation.org/doi/pdf/10.1121/1.4800272
 - Measurable Outcomes/Results (Pain and Health Improvement). Patients showed a significant 30% reduction in shoulder pain and a significant 52% improvement in health quality from SAM treatment.
- Lewis Jr, George K., et al. "Design and evaluation of a wearable self-applied therapeutic ultrasound device for chronic myofascial pain." Ultrasound in medicine & biology 39.8 (2013): 1429-1439.
 - o https://pubmed.ncbi.nlm.nih.gov/23743101/
 - Measurable Outcomes/Results (Pain and Health Improvement): Patients showed a significant 1.94x reduction in pain and a significant 1.58x improvement in health quality with the use of SAM treatment for myofascial pain.



Peer Reviewed Health Economic and Metanalysis Studies (arranged by date)



- Best, Thomas, et al. "Sustained acoustic medicine as a non-surgical and non-opioid knee osteoarthritis treatment option: a health economic costeffectiveness analysis for symptom management." Journal of orthopaedic surgery and research 15.1 (2020): 1-10.
 - o https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7574225/
 - Measurable Outcomes/Results (Pain, Function and Cost-Effectiveness): Patients treated with SAM have superior pain reduction and improvement in function compared with physical therapy alone. Incremental cost-effectiveness demonstrated that most of the time (84%) SAM treatment resulted in improved functional effectiveness at a slightly higher cost without the need for injections, therapeutics or surgery.

Peer Reviewed Real-World Outcomes Studies (arranged by date)

- Draper, David, et al. "Efficacy of Sustained Acoustic Medicine as an Add-on to Traditional Therapy in Treating Sport-related Injuries." Global journal of orthopedics research 2.4 (2020).
 - o https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7544191/
 - Measurable Outcomes/Results (Pain and Return to Activity): Patients treated has a significant 3 point reduction in pain, and 55% of patients were able to heal the injury and return back to work after conservative treatment had failed.
- Draper, David "Effect of Sustained Acoustic Medicine on Bruising Following A Bicycle Crash." Archives of orthopedics and rheumatology 3.2 (2020): 15.
 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7802766/
 - o Measurable Outcomes/Result (Pain and Healing): Reduced patient pain, healing soft tissue and bruises with treatment.

Peer Reviewed Technology Assessments, Review Articles and Society Support (arranged by date)

- Draper, David O., and Thomas Best. "Critical survey and panel review of sustained acoustic medicine in the treatment of sports-related musculoskeletal injuries by professional sports athletic trainers." Current Orthopaedic Practice (2021).
 - o <u>https://journals.lww.com/c-orthopaedicpractice/Abstract/9000/Critical survey and panel review of sustained.98954.aspx</u>
 - Measurable Outcomes/Results (Consensus on USE): Healthcare providers reported an 87% satisfaction and increased confidence in the ability of SAM to accelerate the healing process. SAM is considered a recommended treatment and is helpful on multiple musculoskeletal injuries.
- Draper, David, and Rajiv M. Mallipudi. "Therapeutic ultrasound: myths and truths for non-portable in-clinic and portable home use ultrasound." MOJ sports medicine 4.4 (2020): 115.
 - o https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7802764/
 - Measurable Outcomes/Results (Technology Assessment): The benefits of SAM over other non-portable ultrasound devices is the capability of delivering daily ultrasound at home or in the office for up to 4 hours at a time. Traditional ultrasound is applied for 5–15 mins delivering between 2,000–5,000 Joules. The 4 hour sam ® treatment can produce nearly 4 times as much (18,000 joules) as traditional ultrasound. The portable SAM device can be used at home at any time of the day and during any activity; however, traditional ultrasound requires application by a therapist in the clinical facility.
- Daniels, Sarah, et al. "The effects of low-intensity therapeutic ultrasound on measurable outcomes: a critically appraised topic." Journal of sport rehabilitation 27.4 (2018): 390-395.
 - o https://journals.humankinetics.com/view/journals/jsr/27/4/article-p390.xml
 - Measurable Outcomes/Results (Literature Review): Studies show that SAM can deliver low-intensity acoustic energy over a prolonged period (hours), as well as medium-intensity treatments over a shorter period (minutes), achieving the same temperature increase and pain relief that come from traditional US units, in a more versatile and patient-friendly manner.
- Best, Thomas M., et al. "Low intensity ultrasound for promoting soft tissue healing: a systematic review of the literature and medical technology." Internal medicine review (Washington, DC: Online) 2.11 (2016).
 - o https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6128661/
 - Measurable Outcomes/Results (Literature Review): SAM has demonstrated ability to accelerate and improve soft-tissue healing outcomes of tendon, ligament, muscle and bone injuries.
- Langer, Matthew D., and George K. Lewis Jr. "Sustained acoustic medicine: a novel long duration approach to biomodulation utilizing low intensity therapeutic ultrasound." Micro-and Nanotechnology Sensors, Systems, and Applications VII. Vol. 9467. International Society for Optics and Photonics, 2015.
 - o https://pubmed.ncbi.nlm.nih.gov/30078928/
 - Measurable Outcomes/Results (Technology Assessment): Therapeutic ultrasound is an established technique for biomodulation used by
 physical therapists. Typically, it is used to deliver energy locally for the purpose of altering tissue plasticity and increasing local circulation.
 Ultrasound miniaturization in SAM allows for portable, wearable, self-applied ultrasound devices that sidestep these limitations. Additionally,
 research has shown that the timescale of acoustic stimulation matters, and directly affects the quality of result. This paper describes a novel,
 long duration approach to therapeutic ultrasound and reviews the current data available for a variety of musculoskeletal conditions.
- ZetrOZ Systems CE/FDA Literature Review for Mechanisms of Action, Company Document 2014.
 - o https://secureservercdn.net/45.40.148.147/72b.d14.myftpupload.com/wp-content/uploads/2018/11/Lewis-et-al-2015-White-Paper-Reviewof-Literature-on-sam.pdf
 - o Measurable Outcomes/Results (Technology Assessment): Review of therapeutic ultrasound treatment delivered by SAM.



