

Indexing Metadata/Description

- › **Device/equipment:** Therapeutic Ultrasound
- › **Synonyms:** Ultrasonic therapy; ultrasonic diathermy; ultrasound, therapeutic
- › **Area(s) of specialty:** Acute care, hand therapy, neurological rehabilitation, orthopedic rehabilitation, pediatric rehabilitation, sports rehabilitation, women's health, geriatric rehabilitation
- › **Description/use:** A therapeutic modality that uses acoustic energy rather than electromagnetic energy to produce physiological effects.^(1,2) It should be differentiated from diagnostic ultrasound, which is used for imaging internal structures
 - Ultrasound waves have a frequency greater than 20,000 Hz (.02 MHz), which is higher than the audible range of the human ear. The frequency range for therapeutic ultrasound is between 0.75 and 3 MHz⁽¹⁾
 - Ultrasound is applied using a transducer, or "soundhead," that contains a piezoelectric crystal that converts electrical energy to acoustic energy⁽¹⁾
 - Thermal and nonthermal physiological effects can be produced by vibrations of the molecules of the biologic medium through which the waves travel⁽¹⁾
 - Ultrasound is primarily used for elevating tissue temperature.⁽¹⁾ It is considered a deep heating modality (as compared to other heating modalities such as hot packs or whirlpools) because of its ability to heat to a depth of 5 cm⁽¹⁾
 - Depth of tissue penetration is determined by the frequency, not the intensity, of ultrasound. In general, higher frequencies (e.g., 3 MHz) are absorbed more in superficial tissues. Lower frequencies (e.g., 1 MHz) penetrate to deeper target tissues
 - In addition to the production of heat caused by friction between the vibrating molecules, therapeutic ultrasound is also hypothesized to have mechanical effects due to production of small magnitude movements of fluids and ions⁽²⁾
 - Ultrasound is widely used in rehabilitation, primarily for improving connective tissue extensibility and pain relief in musculoskeletal injuries, and for promoting tissue healing and remodeling⁽²⁾
 - Physical therapists (PTs) use therapeutic ultrasound more than any other electrophysiological modality.⁽³⁾ The level of clinical benefit from therapeutic ultrasound remains uncertain,⁽³⁾ and depends on the application. Risk of harm is considered low when used properly, making ultrasound for physical therapy a treatment of modest efficacy but low risk⁽⁴⁾
- › **HCPCS codes**
 - X3900 Single modality to one area – initial 30 minutes
 - X3902 Single modality to one area – each additional 15 minutes
 - X3908 Treatment including a combination of any modalities and procedures (one or more areas) – initial 30 minutes
 - X3910 Treatment including a combination of any modalities and procedures (one or more areas) – each additional 15 minutes
 - CPT codes
 - 97035 Ultrasound – 15 Minutes

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–971390 Phonophoresis

- › **Reimbursement:** Varies by carrier. Some carriers might cover only when linked with specific diagnosis codes, and some might have limitations regarding maximum benefits per year. Documentation showing objective loss of mobility or function and estimated duration and goals of treatment might be required

Indications for device/equipment

- › There is a wide range of therapeutic applications of ultrasound,⁽⁵⁾ and new applications are constantly being investigated.⁽⁶⁾ Applications making use of the modality's ability to heat have been used by PTs for years to warm soft tissue⁽⁴⁾
- › More recently developed applications include using its ability to heat to cause tissue destruction, as in the case of regional heating for cancer therapy, or focused thermal lesions for tissue ablation⁽⁴⁾
- › Mechanical effects of ultrasound might be used for destruction of kidney stones (lithotripsy) and to assist thrombolysis.⁽⁴⁾ Other experimental applications include treatment of tendon injuries using lithotripter-like devices, stimulation of bone repair by low-intensity ultrasound, ultrasound-induced hemostasis, and targeted transdermal delivery of drugs by ultrasound (e.g., phonophoresis)
- › It has also been suggested for treatment of hypothermia⁽⁷⁾
- › Therapeutic ultrasound might accelerate and increase re-angiogenesis as demonstrated in a 2014 study using animal models⁽⁴¹⁾
- › Indications for its use in physical therapy include:⁽¹⁾
 - Acute and postacute musculoskeletal conditions (ultrasound with nonthermal effects)
 - Soft tissue healing and repair
 - Scar tissue
 - Joint contracture
 - Chronic inflammation
 - Increase extensibility of collagen
 - Reduction of muscle spasm
 - Pain modulation
 - Increase blood flow
 - Increase protein synthesis
 - Tissue regeneration (e.g., wound healing)
 - Bone healing
 - Repair of nonunion fractures
 - Inflammation associated with myositis ossificans
 - Plantar warts
 - Myofascial trigger points

Guidelines for use of device/equipment

- › A basic therapeutic ultrasound unit consists of a console, a coaxial cable, and a transducer
 - The console generally includes an on/off switch, a treatment timer, an intensity control (in watts/cm²) that can be incrementally adjusted, and a frequency control that allows selection from at least 2 choices (typically 1 MHz and 3 MHz). Controls for pulsed ultrasound options might also be included⁽²⁾
 - Transducers are available in various sizes. The portion of the surface of the transducer that actually produces the sound wave, the “effective radiating area” (ERA), depends on the surface area of the crystal within it, and is always smaller than the transducer surface.⁽¹⁾ Significant variability in the ERA and output power of ultrasound transducers has been reported. It should not be assumed that a large transducer surface radiates ultrasound output from its entire surface⁽¹⁾
 - The appropriate size of the area to be treated is 2-3 times the size of the ERA⁽¹⁾
- › The purpose of the procedure should be explained to the patient and the patient should be told what to expect
- › Ask the patient for feedback during the treatment and make adjustments accordingly. During the procedure the patient might experience a comfortable heat; if the heat becomes too much, the patient should alert the therapist⁽⁸⁾
- › The soundhead must be moved continuously over the treatment site
- › A coupling medium such as ultrasound gel is used to transmit the sound waves

- Results of an experimental study conducted in Brazil comparing coupling agents indicates that water and gel have the best acoustic features for transmitting ultrasound waves⁽⁹⁾
 - The transmission, attenuation, reflection coefficient, and acoustic impedance of gel, mineral oil, white petroleum, and degassed water were measured
 - Water and gel had the highest transmission coefficients, the lowest reflection, and attenuation coefficients and acoustic impedances close to that of the skin
- Topical agents suspended in aqueous gel are more effective in transmitting ultrasound energy, while cream-based agents are less effective, particularly at 1MHz frequency⁽³²⁾
 - Based on a U.S. laboratory study comparing acoustic transmission allowed by various preparations at 1 MHz and 3 MHz
 - Many agents that are commonly used for their sensory effect, such as topical analgesic creams, might block ultrasound transmission⁽³²⁾
 - Agents that decrease ultrasound transmission might result in poor phonophoresis and decrease the therapeutic effects of ultrasound⁽³²⁾
- One of the most common topical analgesics used as a coupling agent, Biofreeze, does not increase intramuscular tissue temperature faster than using 100% ultrasound gel⁽³³⁾
 - Based on a U.S. laboratory study comparing a Biofreeze mixture of one part Biofreeze and three parts ultrasound gel and 100% ultrasound gel on 12 healthy college-aged students
 - Biofreeze is a menthol (4%) based topical analgesic gel used as a coupling agent to create a cooling sensation
 - A single-needle microprobe was initially inserted into the subjects' triceps surae muscle, the coupling agent was then applied to the treatment, and tissue temperatures were recorded for 5 minutes prior to the application of continuous ultrasound in order to establish a baseline tissue temperature
 - Following baseline intervention, a continuous 3-MHzultrasound treatment at 1.0 W/cm² was applied to the area for 10 minutes
 - Participants recorded their perception of heat on a VAS before and after treatment
 - 1 weeklater, participants returned to receive the opposite ultrasound coupling medium. Initial determination of coupling medium was based on random selection
 - Results indicated no statistical difference between the Biofreeze mixture and 100% ultrasound gel for mean intramuscular tissue temperature and rate of heating. However, the Biofreeze mixture produced a greater sensation of heat compared to the 100% ultrasound gel
- › For irregularly shaped body parts (e.g., fingers), the part might be submerged in water (indirect coupling)
 - With the advent of smaller transducers, indirect coupling is less necessary for irregularly shaped body parts than it was formerly
 - Indirect coupling might still be preferred when pressure from moving the transducer on the skin causes pain
 - Studies found that tissue temperature increases were 40-60% lower using the underwater technique, suggesting that treatment intensity must be set higher to achieve the same tissue temperature effects⁽²⁾
 - Commercially available disposable aqueous gel pads might be used as an alternative indirect coupling method. They have been reported to be effective but expensive.⁽²⁾ Sterile hydrogel sheets might be used for application to wound areas
- › Frequency is selected based on the treatment goals. Depth of tissue penetration is determined by frequency
 - If the target area is superficial (e.g., ankle ligament), 3 MHz is appropriate
 - The depth of penetration at 3 MHz is about 1-2 cm
 - If the area is deeper (e.g., soleus or piriformis), 1 MHz (or less if available) should be selected
 - The 3 MHz frequency ultrasound is absorbed more superficially and is also absorbed faster than 1 MHz ultrasound⁽¹⁾
- › There are no definitive rules on selection of intensity.⁽¹⁾ Increasing the intensity (dosage in W per cm²) increases the likelihood of biophysical effects and increases their magnitude⁽⁴⁾
 - An intensity of 3 W/cm² has been adopted as the upper limit for safety standards for the effective intensity produced by ultrasound machines, based on animal studies
 - High-intensity machines are used for tissue ablation in the treatment of cancer and hyperplasia
 - It is recommended that the lowest intensity therapeutic ultrasound at the highest frequency that will reach the specified tissue be used⁽¹⁾
- › Treatment time is approximately 5 to 10 minutes depending on the patient's comfort level and heat tolerance

- › The selection of pulsed ultrasound rather than continuous ultrasound is thought to favor nonthermal effects, although nonthermal effects might also be obtained with continuous ultrasound
- › Results of a survey study conducted in the United States indicate that PTs who are orthopedic certified specialists and report using ultrasound frequently in their practice are more likely to use continuous ultrasound when the goal is to increase tissue extensibility, decrease pain, or remodel scar tissue. A pulsed mode was more frequently chosen when the goal was to decrease soft tissue swelling or decrease soft tissue inflammation⁽¹⁰⁾
 - 207 responses to a 77-question survey were received and analyzed
 - Respondents indicated that they would use 3 MHz for treating superficial tissues and 1 MHz for deep tissues regardless of the therapeutic goal
 - No determination was made as to whether the respondents' judgments were based on clinical outcomes they had observed in their patients, by interpretation of current literature, or by personal comfort with the established use of this modality
- › The soundhead should be cleaned with alcohol after each use

Contraindications/Precautions to device/equipment

› **Contraindications** ⁽¹⁾

- Acute and postacute conditions (ultrasound with thermal effects)
- Areas of decreased temperature sensation
- Areas of decreased circulation, vascular insufficiency – excessive heat buildup can potentially damage tissues
- Thrombophlebitis – there is a possibility of dislodging a clot and producing an embolus
- Over eyes, reproductive organs
- Pelvis immediately following menses
- Pregnancy
- Pacemaker – ultrasound can potentially interfere with normal function of some pacemakers
- Malignancy
- Epiphyseal areas in young children
- Total joint replacements in cases where methyl methacrylate cement was used
 - This cement absorbs heat rapidly and might become overheated, causing damage to surrounding tissue
 - The metal implants are not the issue as ultrasound might be safely used over metal since its high thermal conductivity means that heat is removed rapidly from the area
- Infection

› **Precautions**

- Current malignant tumors are a contraindication. Precaution should be taken before using ultrasound in patients with a previous history of malignant tumor because it is possible that small tumors remain without the patient's knowledge. Check with physician or oncologist⁽¹⁾
- When treating areas around the heart, there is the potential to cause changes in ECG activity⁽¹⁾
- Decreased communication or cognition
- Due to the focused beam of therapeutic ultrasound, the energy can be delivered to a well-delineated area. Ultrasound is not appropriate over large surface areas such as the low back. It is an inefficient way to heat paraspinal muscles because of the small area of the transducer and the moderate capabilities of the muscle to absorb ultrasound. Continuous shortwave diathermy is a much better way to heat deep large areas⁽²⁾
- Ultrasound equipment has been reported to be inaccurate in terms of power output and timing function in studies conducted in Australia, the United States, and Brazil.^(5,11,12,13) In one study,⁽¹¹⁾ 44% of 45 machines tested failed either calibration or electrical safety inspection. This has implications for patient safety
 - Equipment accuracy is required to ensure that patients receive correct therapeutic dosages
 - Older machines have been found more likely to be inaccurate^(11,13)
- Results of a study conducted in Australia indicate that therapeutic ultrasound equipment is a potential vector for nosocomial infections⁽¹⁴⁾
 - The degree of contamination on therapeutic ultrasound transducer heads and in ultrasound gel was investigated in a prospective cross-sectional design study
 - Microbiological cultures were obtained from 44 transducer heads and 43 gels in a variety of physiotherapy practice settings

- Reevaluation of the transducer heads after cleansing with a 70% alcohol wipe was subsequently performed
- Twenty-seven percent of transducer heads and 28% of gels were contaminated. Transducer heads were contaminated mostly with organisms found in normal skin and environmental flora. Gels were heavily contaminated with opportunistic and potentially pathogenic organisms
- Cleaning with 70% alcohol effectively reduced the level of contamination on the transducer head
- Further research is needed to determine how to reduce the risk of infection from ultrasound gels
- Authors from a 2014 study in the U.S. also showed ultrasound units potentially serving as a reservoir for bacteria ⁽³⁷⁾
 - US heads, gel bottle tips and gel were sampled from 9 outpatient clinics throughout Tennessee
 - Tips of the gel bottles had the highest contamination (52.7% positive for non-specific bacteria, 3.6% positive for MRSA)
 - US heads had non-specific bacterial contamination (35.5% positive, no MRSA)
 - Gel has 14.5% contamination, no MRSA
 - Disinfecting US heads after use showed removal of 90.9% of contamination
 - These studies demonstrated the need for better cleaning, storage and usage of US equipment
- › A review of general rehabilitation sources found that sources varied with regard to number of contraindications, references, and rationales cited for contraindications for superficial heat and therapeutic ultrasound⁽¹⁵⁾
 - 20 ultrasound sources identified between 9 and 36 contraindications/precautions
 - Agreement among sources was generally high, with lower agreement noted for pregnancy, metal implants, edema, skin integrity, and cognitive/communicative concerns
 - Many sources failed to agree on the level of concern (i.e., whether an issue was a contraindication, precaution, relative contraindication, or not a concern)
 - Consensus panels using a standardized classification system might be beneficial to develop more uniform contraindication categories

Examination

- › **Contraindications/precautions to examination:** Depend on the underlying condition
- › **History**
 - **History of present illness/injury for which the device is needed**
 - Mechanism of injury or etiology of illness:** Describe history of patient’s condition, including onset, progression, complications, and treatment
 - Course of treatment**
 - **Medical management:** Describe hospitalizations, surgeries, immobilization, and weight-bearing status, as relevant to the condition and body part being treated with ultrasound
 - **Medications for current illness/injury:** Determine what medications clinician has prescribed; are they being taken? Are they effective?
 - **Diagnostic tests completed:** Depend on underlying condition
 - **Home remedies/alternative therapies:** Document any use of home remedies (e.g., ice or heating pack) or alternative therapies (e.g., acupuncture), what they are used for, and whether or not they help
 - **Previous therapy:** Document whether patient has had occupational or physical therapy for this or other conditions and what specific treatments were helpful or not helpful. Has the patient been treated with ultrasound in the past?
 - Aggravating/easing factors** (and length of time each item is performed before the symptoms come on or are eased): Inquire about factors related to this condition
 - Body chart:** Use body chart to document location and nature of symptoms
 - Nature of symptoms:** Document nature of symptoms (e.g., constant vs. intermittent, sharp, dull, aching, burning, numbness, tingling)
 - Rating of symptoms:** Use a visual analog scale (VAS) or 0-10 scale to assess symptoms at their best, at worst, and at the moment (specifically address if pain is present now and how much)
 - Pattern of symptoms:** Document changes in symptoms throughout the day and night, if any (A.M., mid-day, P.M., night); also document changes in symptoms due to weather or other external variables
 - Sleep disturbance:** Document number of wakings/night
 - Other symptoms:** Document other symptoms patient might be experiencing that could exacerbate the condition and/or symptoms that could be indicative of a need to refer to physician (e.g., dizziness, bowel/bladder/sexual dysfunction, saddle anesthesia)
 - Respiratory status:** Any history of respiratory compromise or use of supplemental oxygen?

- **Barriers to learning**
 - Are there any barriers to learning? Yes__ No__
 - If Yes, describe _____
- **Medical history**
 - **Past medical history**
 - **Previous history of same/similar diagnosis:** Document history of same or similar diagnosis
 - **Comorbid diagnoses:** Ask patient about other problems, including diabetes, cancer, heart disease, complications of pregnancy, psychiatric disorders, orthopedic disorders, cognitive disorders, etc.
 - **Medications previously prescribed:** Obtain a comprehensive list of medications prescribed and/or being taken (including over-the-counter drugs)
 - **Other symptoms:** Ask patient about other symptoms he or she might be experiencing
- **Social/occupational history**
 - **Patient’s goals:** Document what the patient hopes to accomplish with therapy and in general
 - **Vocation/avocation and associated repetitive behaviors, if any:** Is the patient employed? What is the nature of his or her work? Does the patient participate in recreational or competitive sports?
 - **Functional limitations/assistance with ADLs/adaptive equipment:** (include limitations with self-care, home management, work, community leisure) Document pre-existing functional limitations or equipment already in place
 - **Living environment:** stairs, number of floors in home, with whom patient lives, caregivers, etc. Identify if there are barriers to independence in the home; any modifications necessary?
- › **Relevant tests and measures: (While tests and measures are listed in alphabetical order, sequencing should be appropriate to patient medical condition, functional status, and setting)**
 - **Anthropometric characteristics:** Document patient’s height, weight, and body mass index (BMI). Assess edema/swelling using circumferential or volumetric measurements as indicated
 - **Arousal, attention, cognition (including memory, problem solving):** Assess orientation to name, place, time, and situation; attention; short- and long-term memory; and problem solving as indicated. Is the patient able to inform the provider about sensations being experienced?
 - **Assistive and adaptive devices:** Describe any assistive and adaptive devices that patient uses
 - **Balance:** Assess sitting and standing static and dynamic balance using a standardized test such as the Berg Balance Scale or Pediatric Balance Scale where indicated
 - **Cardiorespiratory function and endurance:** Monitor blood pressure, heart rate, respiratory rate, and oxygen saturation as indicated. Use 6-minute walk for distance test (6MWT) to assess endurance
 - **Circulation:** Check upper and lower extremity pulses for signs of diminished circulation
 - **Functional mobility:** Assess functional mobility using a standardized test such as the Rivermead Mobility Index, FIM, or WeeFIM as indicated by patient’s condition
 - **Gait/locomotion:** Assess gait as indicated. Are ambulatory assistive devices used?
 - **Joint integrity and mobility:** Assess as indicated by symptoms and reason for referral
 - **Motor function (motor control/tone/learning)**
 - Modified Ashworth Scale might be used to assess tone
 - Assess for presence of obligatory synergies, compensatory movement strategies, and selective voluntary muscle activation as indicated
 - Assess coordination of upper and lower extremities
 - **Muscle strength:** Assess muscle strength of upper and lower extremities using manual muscle testing (MMT) where tone and coordination are not affected. Assess functional strength of trunk
 - **Observation/inspection/palpation (including skin assessment):** Assess for skin irritation or breakdown. Palpate for muscle spasm and trigger points as indicated. Inspect skin before and after each treatment
 - **Posture:** Assess sitting and standing posture as indicated
 - **Range of motion:** Assess upper and lower extremity ROM and flexibility depending on reason for referral. Assess trunk and neck ROM as indicated
 - **Reflex testing:** Assess deep tendon reflexes bilaterally as indicated
 - **Self-care/activities of daily living (objective testing):** Barthel Index might be used to assess ADLs
 - **Sensory testing:** Assess light touch, temperature, pin-prick as indicated
 - **Special tests**
 - Short Form (36) Health Survey (SF-36): Quality of life measure – might be used as indicated depending on condition

Assessment/Plan of Care

› **Contraindications/precautions**

- **Patients with a diagnosis for which ultrasound is used might be at risk for falls; follow facility protocols for fall prevention and post fall prevention instructions at bedside, if inpatient. Ensure that patient and family/caregivers are aware of the potential for falls and educated about fall prevention strategies. Discharge criteria should include independence with fall prevention strategies**

› **Diagnosis/need for device/equipment:** Patients with various neuromuscular or musculoskeletal conditions might benefit from ultrasound to reduce pain and muscle spasm, improve tissue extensibility, and improve function. This form of heat application can provide deeper heating than many other forms and might be of benefit when target tissues are not superficial

› **Prognosis:** Depends on the nature of the underlying condition

- If the condition is severe or chronic, such as a frozen shoulder, intensive rehabilitation will be needed in addition to ultrasound⁽⁸⁾

› **Referral to other disciplines:** Referrals might include to pain management specialist, orthopedic surgeon, rheumatologist, and/or occupational therapist (OT) as indicated by condition and symptoms

› **Other considerations**

- There is controversy about the biophysical effects of therapeutic ultrasound
 - A 2001 review (republished in 2010) reported that frequently cited biophysical effects of ultrasound either do not occur in vivo under therapeutic conditions or have not been proven to have an effect under these conditions⁽¹⁶⁾
 - Biophysical effects are commonly divided into thermal and nonthermal effects, although in most circumstances both effects are present and neither can be completely eliminated
 - Nonthermal effects from pulsing the ultrasound have been hypothesized to include cavitation (defined as the formation of gas bubbles in tissues) and microstreaming (formation of eddies adjacent to an oscillating source)
 - These effects have been hypothesized to affect cell membrane permeability, which might account for improved tissue repair
 - Pulsed ultrasound has also been hypothesized to promote circulation independently of any thermal effects
 - Thermal effects depend on the intensity used
 - There is sufficient evidence that ultrasound can cause an increase in tissue temperature. The effects of a rise in tissue temperature on circulation are unclear in vivo, and depend on the amount of conduction into surrounding tissue and dissipation by blood perfusion. Changes in blood flow might be confined to the skin
 - Authors of a 2014 study suggest that tissue inhomogeneity caused phase aberration of the US beam. With increasing change in tissue, the acoustic field increased while peak temperature decreased. The change in tissue was set to mimic variations in abdominal muscle tissue⁽³⁹⁾
 - Increased cellular activity due to heating might occur. There is insufficient evidence to connect increased cellular activity with accelerated healing
- The mechanism of ultrasound's effect on pain might involve nociceptor modulation. Researchers who conducted a study in Taiwan of the effects of therapeutic ultrasound on inflamed ankles in Wistar rats demonstrated that c-Fos expression was suppressed after ultrasound⁽¹⁷⁾
 - c-Fos is a protein whose expression is used as a measure of spinal nociceptive neuronal activity
 - c-Fos expression in monoarthritic rats treated with ultrasound was suppressed compared to sham-treated rats
 - Nociceptive modulation by ultrasound was greater on early inflammatory pain than late inflammatory pain
- Researchers looked at the effectiveness of different ultrasound dosage on pain and grip strength in patients with lateral epicondylitis⁽⁴⁰⁾
 - The three different dosages included:
 - For all groups: Frequency: 1 Mhz, 7 minute duration, for 7 days
 - Group A: Continuous, Intensity: 1.5W/cm²
 - Group B: Pulsed 1:4, Intensity: 1.0W/cm²
 - Group C: Pulsed 1:1, Intensity: 0.8W/cm²
 - Results suggest a significant increase in grip strength in all groups after the application of ultrasound. Continuous mode showed a better effect compared to the other dosages
- It has been hypothesized that therapeutic ultrasound during the immobilization process might prevent changes that cause muscle contractures⁽¹⁸⁾

- Researchers who conducted a study in Japan demonstrated that ultrasound treatment prevented decreased joint mobility and collagen fibril movement in the endomysium of immobilized rat soleus muscle
- Rat soleus muscles immobilized for 4 weeks resulted in decreased dorsiflexion of the ankle joint and an increase in the circumferential direction in collagen fibrils in the endomysium, indicative of a reduction of extensibility of the endomysium
- Continuous ultrasound at 1 MHz frequency and 1 W/cm² intensity for 15 minutes daily inhibited these changes

› **Treatment summary**

- PTs most commonly use therapeutic ultrasound for its muscular effects, connective tissue effects, effects on joint pain, hemodynamic effects, and effects on inflammation and tissue repair
- Authors of a 2014 Cochrane review examining the effectiveness of therapeutic ultrasound in the management of chronic nonspecific LBP concluded that there is no high quality evidence to support the use of US for improving quality of life or decreasing pain⁽³⁸⁾
 - There is some evidence that US has a limited effect in the short-term. However, it is unlikely that this benefit is clinically meaningful
 - Seven randomized controlled trials with a total 362 patients with chronic LBP were included
 - All studies were in secondary care settings; most included US and therapeutic exercise at various intensities for 6-18 treatment sessions
 - There was moderate quality evidence that US improves back specific function in the short term
 - There was low quality evidence that US plus exercise was not better than exercise alone for short term pain reduction
 - There was low quality evidence that spinal manipulation reduces pain and functional disability more than US in short/medium term
 - There is low quality evidence that there is no obvious benefit on any outcome measure between electrical stimulation and US
 - Overall, there are not many high quality RCTs; available trials are small. Future large scale trials with good methodology will have an important impact on truly estimating effect of US
- Researchers who conducted a 2013 Cochrane review examining therapeutic ultrasound for carpal tunnel syndrome concluded that there is poor quality evidence from limited data to suggest that therapeutic ultrasound might be more effective than placebo for short- or long-term symptom improvement⁽³¹⁾
 - Eleven randomized controlled studies with 414 participants were included in the review. The ultrasound interventions varied in intensity, frequency, and duration across the studies
 - Two trials compared therapeutic ultrasound with placebo (“sham” ultrasound at 0 W/cm² intensity)
 - Two trials compared one ultrasound regimen with another
 - One compared different frequencies, and the other compared different intensities
 - Two trials compared ultrasound with another nonsurgical intervention
 - One compared it to treatment with low-level laser therapy and one compared it with local steroid injection
 - Six trials compared ultrasound as part of a multicomponent intervention with another nonsurgical intervention
 - Multicomponent interventions included ultrasound plus dexamethasone iontophoresis, nerve and tendon gliding exercises, activity modification, NSAIDs, and/or night splints, and were compared to multicomponent interventions without ultrasound
 - There is insufficient evidence to support one type of therapeutic ultrasound regimen over another
 - There is insufficient evidence to support the use of therapeutic ultrasound as a treatment with greater efficacy compared to other nonsurgical interventions for carpal tunnel syndrome, including splinting, exercise, and oral medications
- Researchers who conducted a 2010 update of a Cochrane review of therapeutic ultrasound for treatment of osteoarthritis (OA) of the hip or knee concluded that therapeutic ultrasound might be beneficial for patients with OA of the knee but not the hip⁽¹⁹⁾
 - The previous Cochrane review on this topic had concluded that therapeutic ultrasound had no benefit over sham ultrasound for pain relief or functional status for either of these conditions
 - Compared to the previous review, 4 additional trials, all investigating treatment of knee OA, were included. A total of 341 patients with knee OA were involved
 - There was an effect in favor of ultrasound therapy in pain scores and function scores
 - The magnitude of the effects on pain and function remain uncertain, due to the low quality of the evidence and the high degree of heterogeneity among the trials

- Researchers who conducted a 2010 Cochrane review update examining the use of therapeutic ultrasound for acute ankle sprains concluded that ultrasound therapy does not seem to enhance recovery or help reduce ankle swelling or pain⁽²⁰⁾
 - 6 trials that tested use of ultrasound in clinical practice were included
 - A total of 606 participants with acute ankle sprains were involved
 - Studies varied in reporting the use of continuous or pulsed ultrasound, initial treatment following injury, number and spacing of ultrasound treatments, and final assessment (2-4weeks)
 - Five of the 6 trials compared ultrasound to sham ultrasound (machine was turned off). Three trials compared ultrasound with 3 other treatments
 - Results indicated 2-4 weeks following the initial injury, most participants would recover regardless of the use of therapeutic ultrasound
 - Most acute ankle sprains heal quickly. Any contribution to recovery from ultrasound treatment is probably too small to be important
- Researchers who conducted a 2013 Cochrane review examining the use of therapeutic ultrasound for treating patellofemoral pain syndrome (PFPS) concluded that ultrasound therapy has yet to demonstrate a clinically significant effect on pain relief for people with PFPS⁽³⁴⁾
 - Researchers stated that their conclusions were limited due to poor research methodology and that more well-designed research is needed in order to determine the effectiveness of therapeutic ultrasound on pain relief for PFPS
 - A search of published articles to December 2000 resulted in 8 that were potentially relevant; there was only 1 randomized controlled trial (53 participants)
 - The 1 randomized controlled trial compared ultrasound to ice massage for pain relief. Subjects reported greater pain relief with ultrasound compared to ice massage; however, it was not clinically significant
- Researchers who conducted a 2001 systematic review of the effectiveness of therapeutic ultrasound concluded that there was little evidence that active therapeutic ultrasound is more effective than placebo ultrasound for treating people with pain or musculoskeletal injuries or for promoting soft tissue healing⁽²¹⁾
 - 10 randomized controlled trials were accepted for analysis
 - Results of 2 of the 10 studies suggested that therapeutic ultrasound was more effective than placebo for treatment of specific clinical problems (carpal tunnel syndrome, calcific tendinitis of the shoulder)
 - Results of 8 of the 10 studies indicated that ultrasound was not more effective than placebo
 - Few studies had adequate methodology. Treatment of a wide range of conditions was studied, and dosages varied considerably
- Therapeutic ultrasound in addition to standard exercise training was determined to not provide any additional benefit in improving pain and function in patients with knee OA based on a double-blind, randomized controlled trial conducted in Turkey in 2014⁽³⁵⁾
 - A total of 60 patients diagnosed with knee osteoarthritis according to the American College of Rheumatology guidelines were randomized to 1 of 3 groups: continuous ultrasound at 1MHz and 1W/cm², pulsed ultrasound at 1MHz and 1W/cm² on 1:4 pulse ratio, or sham ultrasound
 - All patients received treatment 5 times a week for 2 weeks in addition to a home exercise program (lower extremity strengthening and stretching exercises) they were instructed to perform at least 3 times a week
 - Primary outcomes measures were the Western Ontario and McMaster Universities Osteoarthritis Index-pain, stiffness, function, visual analog scale-pain at rest, visual analog scale-pain on movement, visual analog scale-disease severity, and 20-m walking time
 - All 3 groups showed significant improvement in all parameters after 2 weeks of treatment intervention and at the 6-month follow-up; however, there was no significant difference between groups
- Authors of a 2014 questionnaire study conducted in Ontario, Canada, indicate that many physiotherapists using therapeutic ultrasound thought it to be effective in reducing knee pain in patients with osteoarthritis⁽³⁶⁾
 - 123 respondents, all members of the Ontario Physiotherapy Association, completed the electronic survey
 - 81% reported at least some use of ultrasound; 45% reported using ultrasound sometimes or often in the management of patients with OA of the knee
 - 89% reported the main goal for using ultrasound was to reduce pain in the surrounding soft tissue and/or knee joint
 - 46% supported the belief that ultrasound is likely to be beneficial for patients with knee osteoarthritis
 - 85% expressed the desire for more randomized controlled trials to study the effectiveness of ultrasound on knee pain in patients with OA

- Therapeutic ultrasound in addition to standard physical therapy was reported to be beneficial for pain, functional status, and quality of life in patients with hip OA based on a randomized controlled trial conducted in Turkey in 2010⁽²²⁾
 - A total of 45 patients with primary hip OA were randomized to 1 of 3 groups: standard physical therapy including hot pack and exercise, sham ultrasound in addition to standard physical therapy, or ultrasound and standard physical therapy
 - Ultrasound treatment was continuous 1 MHz frequency, at 1 W/cm² intensity over the lateral, anterior, and posterior area of the hip for 5 minutes at each field
 - Outcome measures were pain intensity by VAS, functional status by 15-meter walk test and WOMAC, and quality of life by the SF-36
 - Pain and functional outcome measures improved significantly in all the groups by the end of therapy, but these improvements were maintained 1- and 3-month follow-up only in the group that received ultrasound in addition to standard physical therapy. Physical subscores of the SF-36 were improved only in the patients receiving additional ultrasound therapy, and mental subscores on the SF-36 did not change for any group
- Researchers who conducted a retrospective study in Turkey found no effect of ultrasound on bone mineral density (BMD) in postmenopausal women⁽²³⁾
 - The mean BMD of 36 patients who had received therapeutic ultrasound was compared to the mean BMD of 38 patients who had never received any kind of physical treatment
- The effectiveness of conventional ultrasound to assist fracture healing has been shown in animal studies.⁽²⁴⁾ Many of the animal studies used specialized ultrasound units designed to deliver fixed parameters of low-intensity pulsed ultrasound. Current literature on use of conventional ultrasound units for fracture healing in humans is less conclusive.⁽²⁵⁾ More well-designed clinical trials are needed⁽²⁾
- Physiological effects of low-frequency ultrasound include metabolic enhancement, perfusion, wound cleansing, and acceleration of wound granulation. Both high-frequency and low-frequency therapeutic ultrasound have been reported to induce cell proliferation, protein synthesis, and the production of cytokines by fibroblasts, osteoblasts, and monocytes⁽²⁶⁾
 - Therapeutic ultrasound has been reported to have beneficial effects on leg ulcer healing, although reported studies had small sample sizes
 - There is need for studies comparing ultrasound debridement with other methods of debridement in diabetic and other lower extremity wounds⁽²⁶⁾
 - A meta-analysis of 4 studies that compared ultrasound with standard or sham treatment for venous leg ulcers showed that the number of ulcers healed was greater and the percentage of remaining ulcer area was smaller in the ultrasound treatment group than in the group not receiving ultrasound⁽³³⁾
 - Low-frequency (40kHz) noncontact ultrasound has been recently approved by the U.S. Food and Drug Administration (FDA) for treatment of wounds⁽³³⁾
 - The mechanical energy at this frequency is thought to have a debriding and cleansing action and a bactericidal effect through enhanced cavitation and streaming⁽³³⁾
- Results of a questionnaire study conducted in Australia indicate that many physiotherapists using therapeutic ultrasound thought it to be most effective in producing a placebo effect⁽³⁾
 - Ultrasound was perceived to be effective for treatment of chronic scar tissue, chronic muscle strains, acute tendinitis, and acute bursitis. It was perceived to be more effective when applied in conjunction with other physiotherapy techniques such as passive mobilization and stretching
- Phonophoresis is a technique that involves using ultrasound to enhance delivery of medication to tissues^(1,27)
 - Medications most commonly applied in this manner are anti-inflammatories (e.g., hydrocortisone, salicylates) and analgesics (e.g., lidocaine)
 - It is thought that thermal and nonthermal mechanisms increase the permeability of the stratum corneum, allowing medication to diffuse across the skin
 - Many medications are poor coupling agents. Mixing the topical agents with ultrasound gel often does not improve their transmission capabilities
 - Phonophoresis with lidocaine has been reported to be effective in treating trigger points⁽¹⁾
 - Pulsed ultrasound with topical lidocaine gel has been reported to induce greater analgesic effect than continuous ultrasound⁽²⁷⁾ Other physical therapy uses of ultrasound that have been reported to be effective include as an alternative

treatment to antibiotics in the management of acute bacterial rhinosinusitis⁽²⁸⁾ and for symptomatic postpartum breast engorgement relief⁽²⁹⁾

› See *Description, Indications of device/equipment, and Guidelines for use of device/equipment*, above

Problem	Goal	Intervention	Expected Progression	Home Program
Pain from soft tissue injury	Decrease pain Promote soft tissue healing and repair	<u>Application of therapeutic ultrasound</u> Should begin as soon as possible after injury ⁽¹⁾ Duration of treatment depends on the size of the area, the intensity used, the frequency, and the desired temperature increase ⁽¹⁾	Typically, acute conditions require more frequent treatments over a shorter period of time; chronic conditions require less frequent treatment over a longer period of time ⁽¹⁾	Instruct patient in appropriate home program for specific condition
Muscle spasm	Decrease muscle spasm	<u>Application of therapeutic ultrasound</u> Continuous moderate intensities are generally used to obtain thermal effects	Progression will depend on patient's response to treatment	N/A
Decreased ROM, decreased tissue extensibility	Increase ROM, tissue extensibility	<u>Application of therapeutic ultrasound</u> During the time period immediately after ultrasound application, heated tissues will undergo their greatest extensibility and elongation ("stretching window") ⁽¹⁾	Progression will depend on patient's response to treatment	Patient should be instructed in appropriate stretches and ROM exercises to perform at home
Chronic inflammation	Decrease inflammation Promote blood flow in chronic inflammatory conditions	<u>Application of therapeutic ultrasound:</u> Study results conflict as to whether ultrasound significantly enhances recovery in chronic inflammation ⁽¹⁾	Progression will depend on patient's response to treatment	N/A

Fracture	Promote bone healing	<p><u>Application of therapeutic ultrasound</u></p> <p>Treatment given during the first 2 weeks after injury might accelerate bony union</p> <p>Growing epiphyses should be avoided</p>	Acceleration of bone healing	N/A
Risk factors, including inaccurate calibration, potential for infection, and potential for thermal injuries	Minimize risks	<p><u>Risk reduction strategies</u></p> <p>Maintain and use equipment according to safety standards and manufacturer's specifications</p> <p>Clean soundhead between patients</p> <p>Only use with appropriate patients (e.g., not with patients who cannot accurately report sensation)</p>	N/A	N/A

Desired Outcomes/Outcome Measures

- › Desired outcomes
 - Decreased pain
 - VAS
 - Improved ROM/flexibility
 - Goniometric measurements of ROM and reassessment of flexibility
 - Decreased edema
 - Volumetric or circumferential measurements of edema
 - Decreased muscle spasm
 - Muscle length testing
 - Improved functional mobility
 - FIM
 - Rivermead Mobility Index
 - Barthel Index
 - SF-36
 - Improved efficacy of other treatments

Maintenance or Prevention

- › Ultrasound units should have routine maintenance checks to ensure that there is no line leakage and that calibration is accurate^(12,30)
- › Numerous surveys to test the performance of physiotherapy ultrasound equipment have been conducted. The vast majority of systems display errors in the indicated output settings of greater than 20%⁽⁵⁾
- › Case studies of equipment failure resulting in thermal injuries in patients have been reported⁽⁵⁾
- › Guidelines establishing the need for regular calibration of therapeutic ultrasound machines have been produced and practical instructions of how measurements should be carried out are available⁽⁵⁾
 - The measurements that are required for testing conventional low power therapeutic ultrasound systems in order to meet manufacturers' specifications are well established and devices for carrying them out are readily available⁽⁵⁾
- › Despite widespread availability of suitable test equipment, there continues to be an issue of poor calibration of physiotherapy equipment⁽⁵⁾
 - Length of time since machine calibration was associated with machine inaccuracy in a study conducted in Australia⁽¹³⁾
 - Results of a questionnaire study conducted in Brazil suggest that few physiotherapy professionals conduct maintenance of ultrasound machines to meet manufacturers' specifications. Specifications are available that define acceptable weekly and annual maintenance.⁽¹²⁾ Currently it is recommended that maintenance frequency be related to the amount of daily usage of the ultrasound machine⁽¹²⁾
 - It is recommended that professional undergraduate and graduate curriculums contain more education on equipment maintenance^(11,12)

Patient Education

- › FDA Web site, "Radiation-Emitting Products: Ultrasonic Therapy Product or Ultrasonic Diathermy,"
<http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/surgicalandtherapeutic/ucm115937.htm>

Coding Matrix

References are rated using the following codes, listed in order of strength:

M Published meta-analysis	RV Published review of the literature	PP Policies, procedures, protocols
SR Published systematic or integrative literature review	RU Published research utilization report	X Practice exemplars, stories, opinions
RCT Published research (randomized controlled trial)	QI Published quality improvement report	GI General or background information/texts/reports
R Published research (not randomized controlled trial)	L Legislation	U Unpublished research, reviews, poster presentations or other such materials
C Case histories, case studies	PGR Published government report	CP Conference proceedings, abstracts, presentation
G Published guidelines	PFR Published funded report	

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