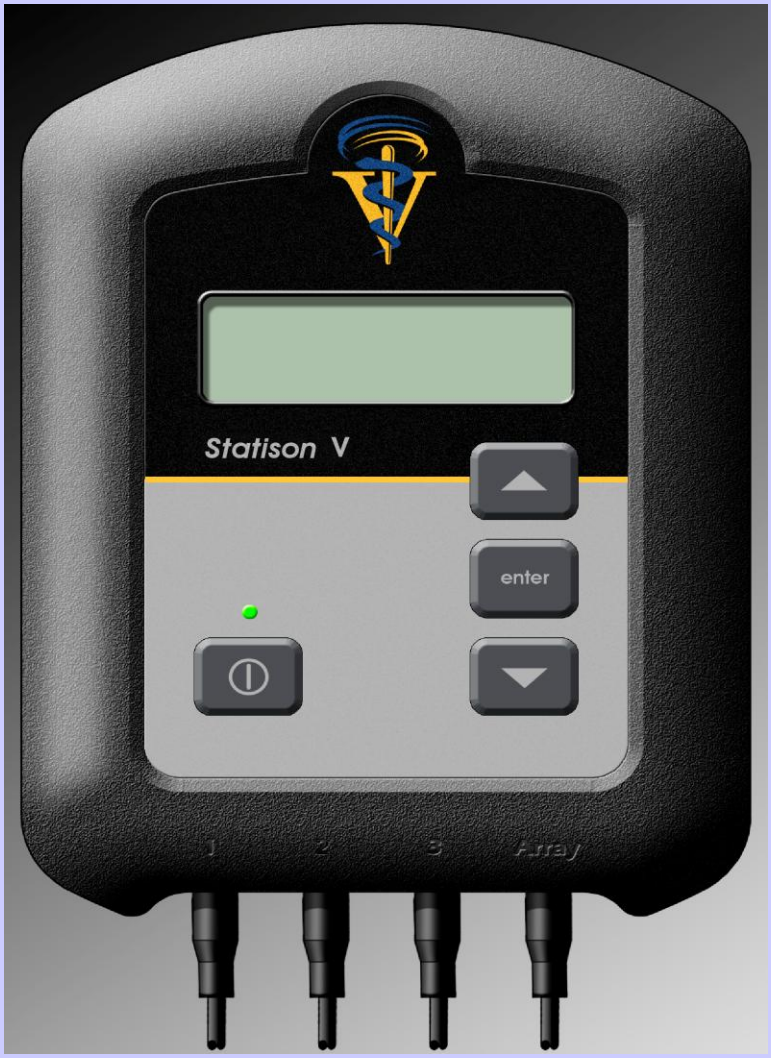
STATISON MEDICAL

Advancing the standard of care™

Statison V
Operations Manual



Statison V

Statison V is a veterinary medical device which has not yet been FDA approved for human use.

This device is for veterinary use only.

Introduction:

Your veterinarian has prescribed the use of Statison Medical's therapeutic ultrasound device, the **Statison V**. This device employs low-intensity ultrasonic pulses which have been clinically proven to heal fractures 38% faster, heal delayed union and nonunion fractures more than 86% of the time, as well as dramatically accelerate and improve the healing of diverse injuries to tendons, ligaments, cartilage and nerves. These low-intensity ultrasonic pulses have also been shown to stimulate the maturation and differentiation of stem cells*.

Questions regarding your animal's injury and the progression of healing should be directed to your veterinarian.

Please contact Statison Medical regarding any questions or problems with the use or operation of your **Statison V** device that cannot be resolved after consulting this manual. You may contact Statison Medical at:

(800) 806-8756

techsupport@statison.com

or by mail at: 1843 Stone House Rd.
Arcadia, CA 91006

*See references

Please be sure to read this entire manual before using the Statison V device.

Any use of this device other than for the veterinary condition for which it was prescribed invalidates our warranty and discharges Statison Medical from all liability.

Indications For Use:

The **Statison V** is indicated for the non-invasive treatment of fresh as well as delayed union and nonunion fractures and injuries to tendon, ligament, cartilage, muscle and other soft tissues. Low-intensity pulsed ultrasound (LIPUS) has been clinically proven to accelerate and improve healing in a wide variety of tissue types with diverse injuries*. Use of the **Statison V** with stem cell therapy may result in improved healing by stimulating the maturation and differentiation of the implanted stem cells*.

Traditional medical and/or surgical therapy of fractures and injuries to soft tissue structures should always precede the use of this device. Stability of the injury site via surgical intervention, casting (hard or soft), and bandaging is required to achieve the best results of **Statison V** therapy. LIPUS has been demonstrated to be safe and effective in the presence of surgical implants (screws) and fracture stability is always indicated prior to the use of this device.

Contraindications And Warnings:

There are no established contraindications to the use of this device or LIPUS in general.

The use of this device, as well as all ultrasonic devices, in the area of the skull and vertebra, as well as the reproductive organs should be avoided.

Warnings:

The safety and effectiveness of this device and LIPUS in general have not been established in the following conditions:

- Use on fractures of the vertebra and skull
- Use on or near the growth plates of skeletally immature animals
- Use on the reproductive organs

* See references

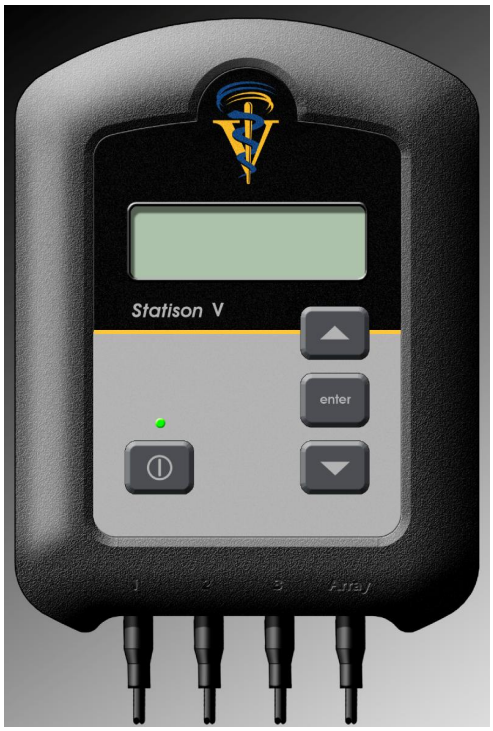
As with all electrical devices, cell phones and other emitting sources such as radios, x-ray machines, etc. may cause interference with the proper operation of the **Statison V** device. Please avoid using cell phones, radios, x-ray machines, etc. in close proximity of this device while it is operating.

Recent research has demonstrated a dose-dependant response of injuries to LIPUS. For this reason, the **Statison V** comes with a pre-set default treatment time of 40 minutes. This treatment time has been established by our clinical trials as well as in peer-reviewed, scientific papers. This 40 minute default treatment time is twice the 20 minute treatment time which has repeatedly proven LIPUS to be effective in accelerating fracture and soft tissue healing.

Statison Medical recommends the use of our **Statison V** for one (1), forty (40) minute treatment daily for a minimum of sixty days (60). Treatment for more than 40 minutes and/or more than once per day should be perfectly safe and may improve effectiveness - although these extended treatment times and use session combinations have not yet been clinically proven.

Medications adversely effecting bone and cartilage metabolism such as steroid and non-steroidal anti-inflammatories, calcium channel blockers, diphosphonate therapy, etc. may have a negative influence on the effectiveness of this device. Treatment with such medications should be under the guidance of your attending veterinarian and must be considered prior to the use of the **Statison V**.

Human and animal studies to date do not suggest any long-term adverse effects from the use of LIPUS or devices employing such waveforms.



Statison V Description:

The **Statison V** device is a non-invasive therapy to accelerate and improve the healing of fresh, delayed union and nonunion fractures, as well as tendon, ligament, cartilage, muscle and other soft tissue injuries. The **Statison V** may also accelerate and improve the healing of tissues treated with stem cell therapy by stimulating the maturation and differentiation of the stem cells.

The **Statison V** is the world's first and only veterinary therapeutic ultrasound device that is applied to the patient in a stationary fashion. This stationary application allows the device to be applied by the owner/caregiver of the animal rather than requiring the service of a skilled technician or veterinarian. You administer the **Statison V** therapy once daily for 40 minutes, or as prescribed by your veterinarian, until your veterinarian determines that the injury being treated has healed sufficiently to discontinue the therapy. Statison Medical suggests a **minimum treatment period of 60 days -- once daily treatments of 40 minutes** each during this period should produce a significant acceleration and improvement of healing. Fracture instability will necessitate a longer treatment period.

This device transmits a low-intensity pulsed ultrasound signal to the site of injury through coupling gel. The **Statison V** is the only therapeutic ultrasound device in the world to utilize **variable wave technology***. This unique energy delivery system allows us to utilize multiple waveforms (multi-variant waveforms*) to stimulate the healing processes. Scientific studies have demonstrated that different ultrasonic waveforms are capable of accelerating and improving the healing of injuries to a wide variety of tissues such as bone, tendon, ligament, cartilage, muscle, etc. It has also been demonstrated that injuries respond differently to different waveforms based upon tissue type and how old (chronic) the injury is. Rather than utilize just one of the ultrasonic waveforms that science has proven to be effective at accelerating and improving healing, our **variable wave technology** enables the **Statison V** to utilize numerous healing waveforms during each therapeutic session with the touch of a single button.

Ultrasound waves are high frequency sonic pressure waves. Conventional therapeutic ultrasound waves are powerful enough to cause tissue heating. This occurs as energy from the ultrasonic wave is transferred to the tissue being treated. These thermally inductive (heating) waveforms have intensities in the 1,000 – 3,000 mW per square centimeter range and are most often utilized in a continuous fashion. The **Statison V** cycles through pre-programmed waveforms that vary in a number of characteristics. All of the waveforms utilized are of a pulsed nature and have intensities in the 30 – 80 mW per square centimeter range. This intensity (power) range is comparable to that used in diagnostic ultrasound and is approximately 1% to 8% of the intensities used in conventional therapeutic ultrasound devices. Due to the low intensity of the ultrasound utilized and its delivery in a pulsed fashion, our animal patients feel little or no sensation during therapy. The intensities utilized will **not** cause any significant tissue heating during therapy allowing for the unique stationary application of our ultrasonic device.

How it Works:

The Statison V causes no sensation or tissue heating during use. There is no analgesia following treatment with the Statison V.

Active research continues to elucidate the mechanisms by which LIPUS has such a dramatic effect upon the rate and quality of healing. Currently it is believed that stable cavitation and micro-streaming cause the up-regulation of numerous cellular processes. By increasing cell and nuclear membrane pore formation, as well as increasing cytoplasmic streaming, mRNA production and protein synthesis are enhanced. A distinct increase in growth factor concentrations has also been documented in tissues undergoing LIPUS treatment. These cellular and environmental changes lead to angiogenesis and neovascularization. A reverse piezoelectric effect has also been documented during micro-movement of the fracture edges. The electrical currents generated signal for the influx of inflammatory and other cells necessary for healing. All of this results in an improvement in the quality and acceleration in the rate of healing.

Technical Specifications:

• Ultrasound Frequency	1.5 megahertz (MHz)
• Modulated signal pulse width	Variable: 100 usec - 2 msec
• Repetition rate	Variable: 166 - 1,000 Hz
• Effective radiating area	3.88 square cm
• Temporal average power	Variable 117 - 310 milliwatts (mW)
• Peak power	1.52 Watts
• Spatial Avg.-Temporal Avg. power	Variable 30 - 80 mW per square cm
• Average SATA power	44 mW per square cm
• Beam non-uniformity ratio (BNR)	4.0 maximum

Traditional therapeutic ultrasound machines deliver only one fixed and non-varying waveform during any treatment session. The waveform characteristics can often be varied by the operator, but once the device is in operation, the single waveform entered by the operator is delivered until the treatment is completed. The **Statison V** employs **variable wave technology*** which creates our **multi-variant waveform*** output. This variability of waveform intensity and pulse characteristics allows the **Statison V** to deliver a wide variety of ultrasonic waveforms that scientific studies have proven accelerate and improve healing.

*Patent Pending

Statison V System Components:

The **Statison V** device is composed of a **main control unit** with connection sites for up to three single transducers and one 5-transducer array. The single transducers may be employed with only one transducer or up to all three being connected and utilized at the same time (to treat multiple areas simultaneously). You may **NOT** operate the array at the same time as the single transducers. Please choose to operate **EITHER** the array or 1-3 of the single transducers. **DO NOT** connect both the array and any of the single transducers to the main control unit at the same time. An error message will be displayed if both types of transducers are connected at the same time and the device will not operate.

The connections for the single transducers are different from the connection on the array.

The cables used to connect the single transducers to the main control unit will **NOT** work with the array. Please be sure to use the proper cable for the transducer type you are connecting. The cables used to connect the single transducers to the main control unit will have three (3) holes in the connecting end. In comparison, the array connecting cable will have six (6) holes in its connecting end.

Included with the main control unit are three **(3) single transducers with connecting cables**, **one 5-transducer array with connecting cable, wraps** to apply the single transducers, one **surcingle,** one protective **satchel** used to hang the main control unit from the surcingle or stall wall during therapy, one **battery charger,** and **two (2) Statison gel bottles** containing high viscosity coupling gel. The entire system comes in a hard case and includes a soft case for easier transport. **Plastic transducer mounts** are also included to be utilized with the single transducers and their attaching wraps.

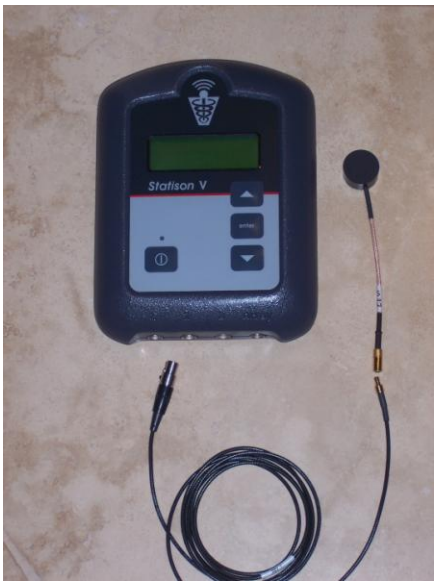
These mounts are employed to better ensure continuous positive contact of the transducer with the patient's injury site.

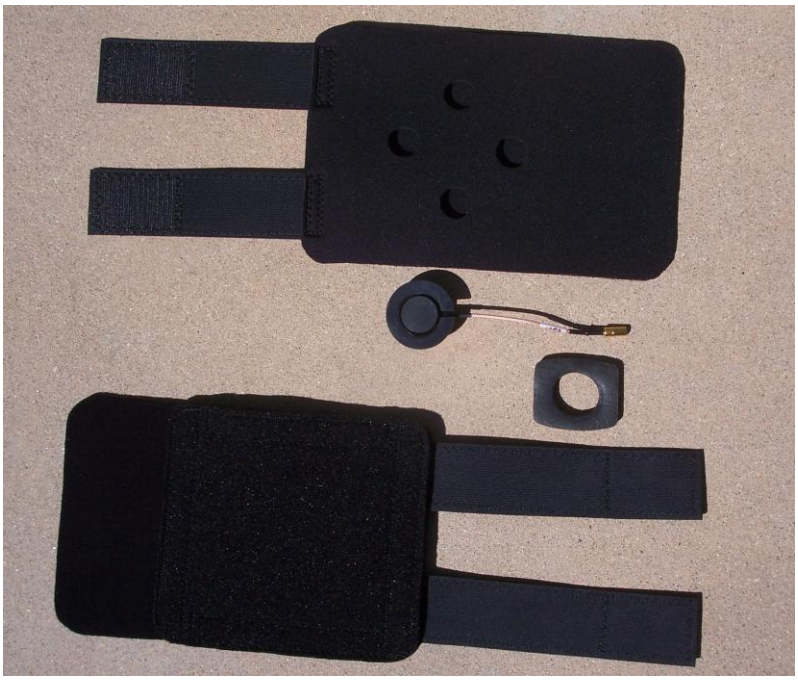
The **main control unit** is powered by a rechargeable NiMH battery pack. When first received from the factory, the battery pack will contain a partial charge. **The battery should be fully discharged prior to re-charging.** While operating properly, the main control unit will have a **green light** over the power button and the display will show the **waveform group** currently being delivered.

Any disruption in proper operation will result in the device operating light changing from a green to **red light** and an **error message** will be displayed detailing the problem.

Error Messages such as low battery, no transducer connected, etc. will be displayed when any such malfunction is detected. A list of error messages is included in Appendix 1.

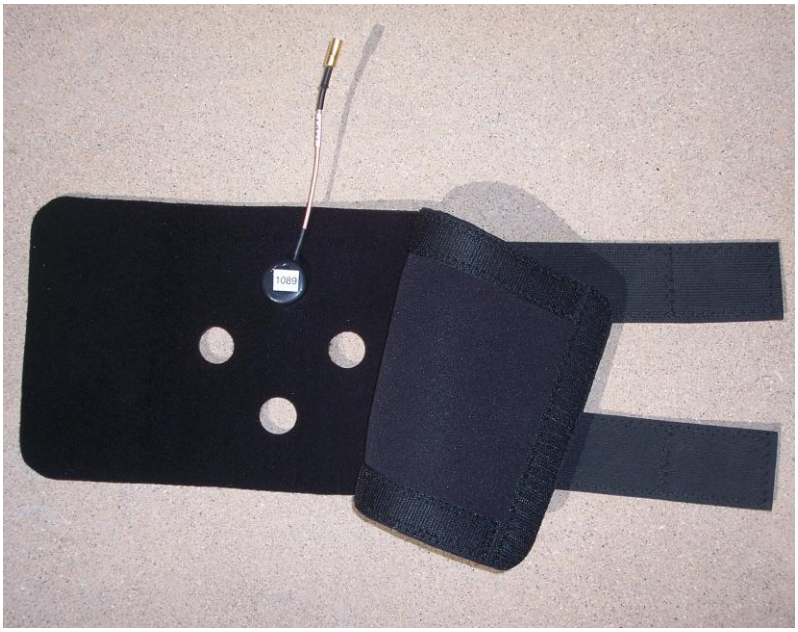
<u>PLEASE NOTE:</u> The device MUST be attached to the patient with ample conducting gel covering the transducer-patient contact surface BEFORE the device is activated (powered on). All patient injury sites should be clipped prior to device usage to ensure proper transducer-patient contact. The patient treatment site and all device contact surfaces should be cleaned after each use.

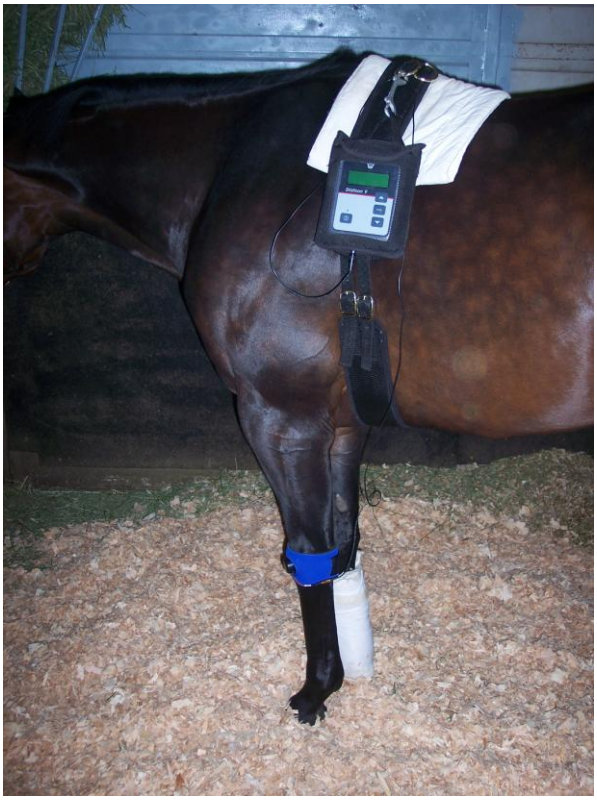




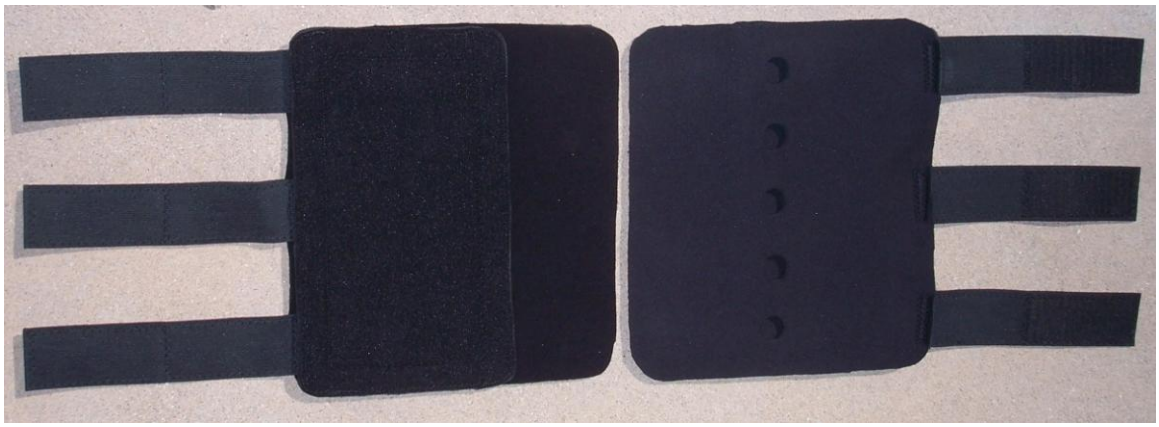
Three single transducer wraps are provided. These are designed for use in various locations such as the shin, knee, ankle and hock. The four hole design allows for the use of multiple transducers when desired - such as when treating both sesamoids or multiple locations on a metacarpus (shin).

As seen below, the transducer assembly is guided through the hole (connecting cable first) and seated on the neoprene. The Velcro cover holds the transducer in place and yet allows access for cleaning and variable transducer arrangements for treatment.





The Statison V control module may be attached to the patient or stall wall, etc. The patient should be adequately restrained (tied, held or closely monitored) for the entire therapy session to avoid damaging the Statison V device.



The array wrap holds five transducers for treatment of large areas such as tendons, shins, splint bones and suspensory ligaments.

Lifespan:

The Statison V contains a rechargeable battery pack. When received from the manufacturer, the battery pack will have a partial charge. You should use the Statison V until the battery is completely run down **PRIOR** to initial re-charging. A full charge will enable ten to fifteen treatments of forty minutes each (depending on the number of transducers utilized).

The Statison V has a lifespan of 1,500 hours of use which translates into 2,250 treatment sessions of forty minutes each. When the lifespan has elapsed, the Statison V and all transducers must be returned to Statison Medical for factory re-conditioning. If the device is under warranty or covered by our extended maintenance agreement during this time, a new or factory re-conditioned device will be available at a substantially reduced cost.

User Compliance:

User compliance may be monitored by use of the patient log contained in the Statison V. By pressing and holding the **Up and Down Arrow Keys** together anytime during the startup screen, until the progress bar completes, will display the Usage Log detailing hours used, lifespan hours remaining and partial and full treatment counts. Pressing any key at this point will display the main menu screen.

Error Messages:

Low Battery

Disconnect singles to enable array

Transducer Error – no transducer connected

Instructions For Use:

1. For best results, be sure the treatment area is clipped and cleaned prior to use.

2. Tie or hold the horse in a safe location and in such a fashion that the horse is not able to bite or get tangled in the transducer cables.

3. Attach the surcingle to the horse. We recommend placing some form of padding between the surcingle and the withers to ensure comfort (a folded towel or bandaging quilt work very well).

4. Place the main control unit into the protective satchel and attach the satchel to the surcingle on the same side of the horse as the injury being treated. To treat injuries on hind limbs, the satchel may be attached to the top of the surcingle with the transducer cable draped along the horse's back. A Velcro tail wrap may be employed to attach the cable to the tail head to prevent it from slipping down the side of the horse.

5. Alternatively, the protective satchel containing the main control unit may be attached to the stall wall or webbing or may be hand-held throughout the treatment cycle.

6. Connect the proper transducer cable to the transducer(s) or array being utilized and connect these to the main control unit in the proper areas. The single transducer cables have three (3) holes in their connecting end while the array cable has six (6) holes. The cables should connect easily to the main control unit. Never force any cable into a connection slot as this may damage the main control unit and render the **Statison V** non-operational.

7. Apply **Statison V** conducting gel to the transducer surface and attach the transducer securely to the treatment area. Neoprene wraps are included to facilitate transducer attachment, but any method of safely attaching the transducer while ensuring positive contact between the transducer and the treatment area is acceptable. If the horse paws or paces excessively, polo wraps or bandages below the transducer-wrap assembly may help in preventing accidental slipping of the transducer off of the treatment area.

8. Simply press the power button to activate the device once the **Statison V** is in place with the transducer securely attached to the treatment area.

9. The initial display screen will show the default treatment time, as well as a countdown bar, for approximately seven (7) seconds. During this time, you may choose to alter the treatment time to as little as twenty (20) minutes or to as long as sixty (60) minutes. Simply press the up or down arrow keys to alter the treatment time setting. The **Statison V** contains smart technology that will learn your new setting and use this as your new personalized default treatment time. The next time the device is utilized, this new time will be displayed as the default treatment time setting.

10. If you do not wish to change the default treatment time, you may press the enter button to initiate treatment. Once the power button is pressed, treatment will begin automatically after the seven second time adjustment phase has counted down.

11. The **Statison V** will now cycle through the pre-programmed waveforms until the treatment time setting has been achieved. At completion, the device will automatically shut down to conserve battery power.

12. A complete battery charge will allow approximately seventeen (17) treatments of forty (40) minutes each with a single transducer or approximately ten (10) treatments of forty (40) minutes each with three (3) transducers or the array before re-charging is necessary.

13. Low battery, single transducer(s) and the transducer array connected at the same time, no transducer connected, and other malfunctions will result in the operating light above the power button turning **RED.** During normal operation, this light should always be **GREEN.** Error messages will be displayed on the control unit for approximately ten (10) seconds and then the device will shut down to conserve battery power. The error message will be displayed again on power-up with instructions on how to continue treatment cycles.

14. The patient, and all equipment surfaces contacting the patient, should be cleaned after each use. No additional medications should be applied to the patient treatment area without express instructions from your veterinarian. Due to the low-intensity nature of the **Statison V**, concurrent treatment with most common topical medications may be perfectly safe. These combination therapies have not been tested and therefore are not recommended by Statison Medical.

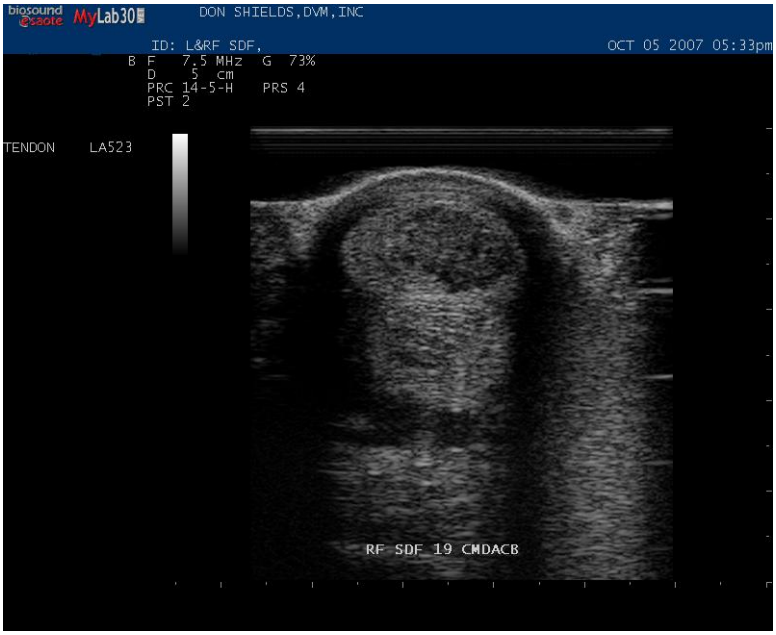
15. Always monitor the patient treatment site for any signs of irritation or allergic reaction. No skin irritation, blistering or allergic reactions have been noted in over two years of field testing.

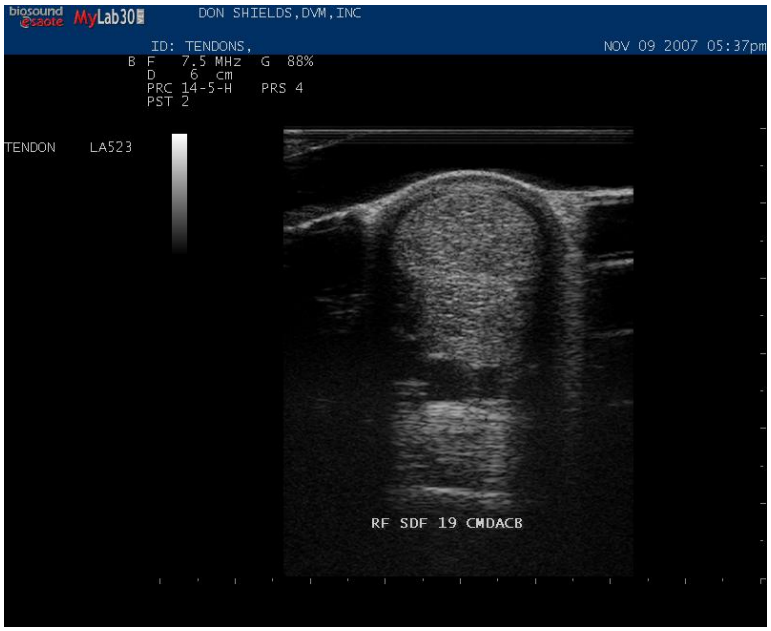
16. **Please Note:** the **Statison V** transducer must be attached to the patient in an orientation such that the sound waves emitted are able to impact the injured tissue or fracture line. While this sounds obvious, one should keep in mind that fracture lines and injury planes do not always occur in a straight, linear fashion. The thickness of the tissue and orientation of the injury plane will determine the most effective placement of the transducer(s). For example, fractures of the third metacarpal bone (canon bone) may benefit most from placement of three of the single transducers – one located on the dorsal surface and the others located on the axial and abaxial surfaces. This orientation of transducers allows the ultrasound waves to impact the fracture line from all directions. The therapeutic sound waves will not penetrate the hoof wall, solid boney surfaces nor propagate through air.

The **Statison V** was engineered and manufactured at Paragon Medsystems, an FDA approved, ISO certified human medical device engineering firm in San Diego, California.

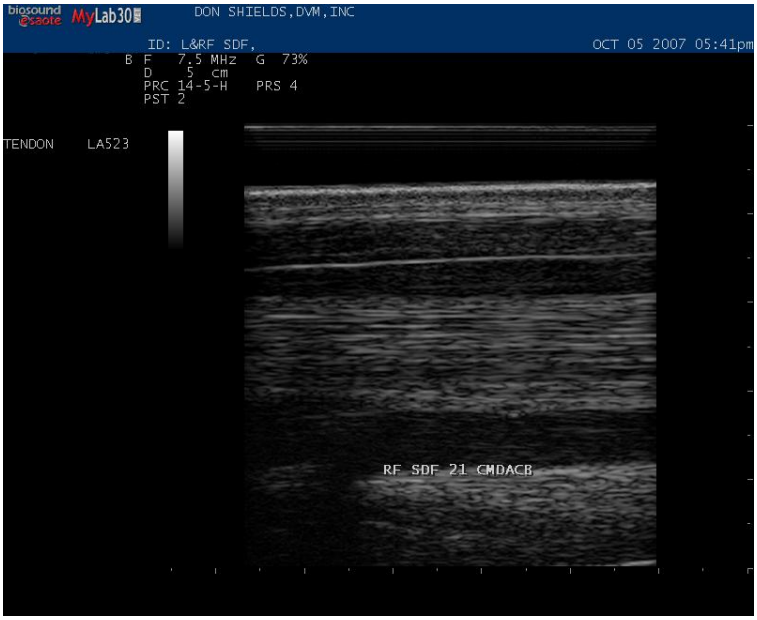
Case Examples

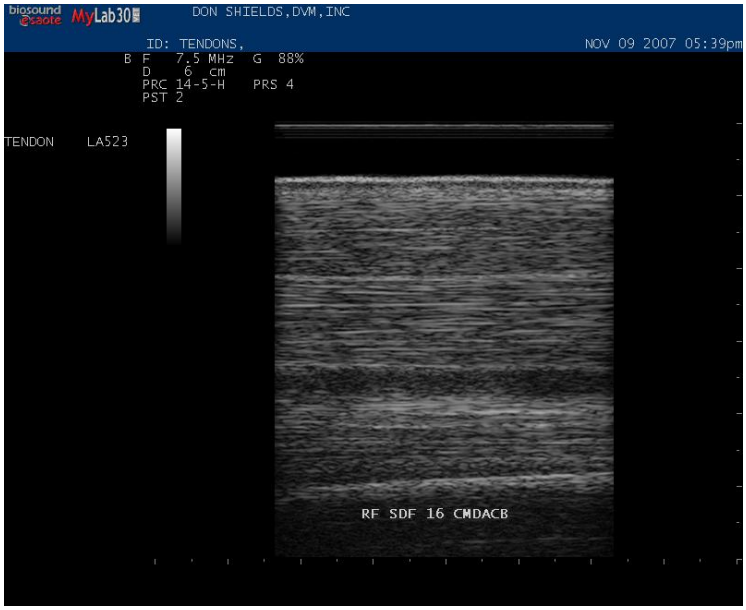
The following are a few examples of the results that have been achieved with **Statison V** (LIPUS) therapy. The dates when these digital radiographs and ultrasound scans were performed have been left visible.



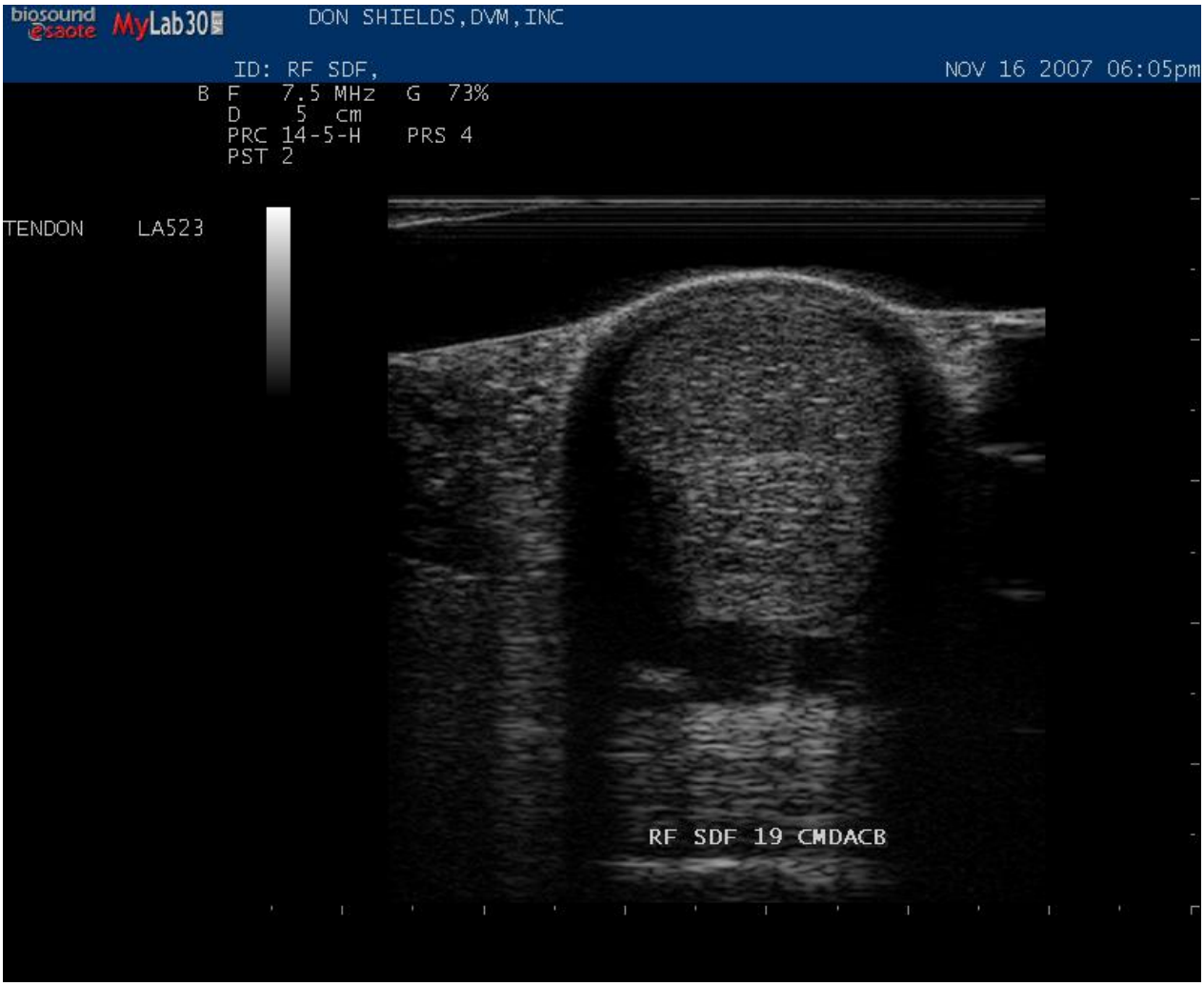


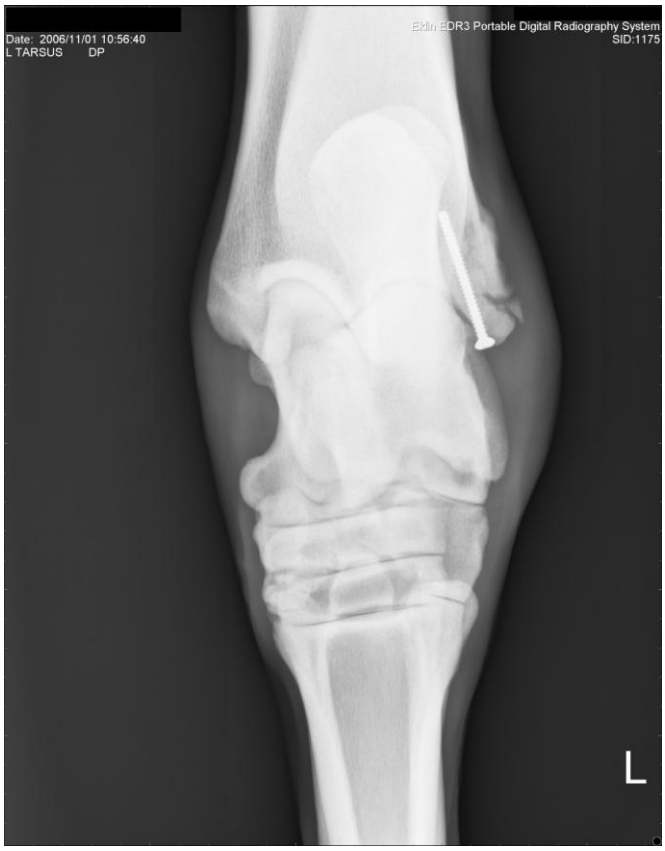
These scans represent the healing achieved with about one month of Statison V therapy applied via our 5-transducer array.

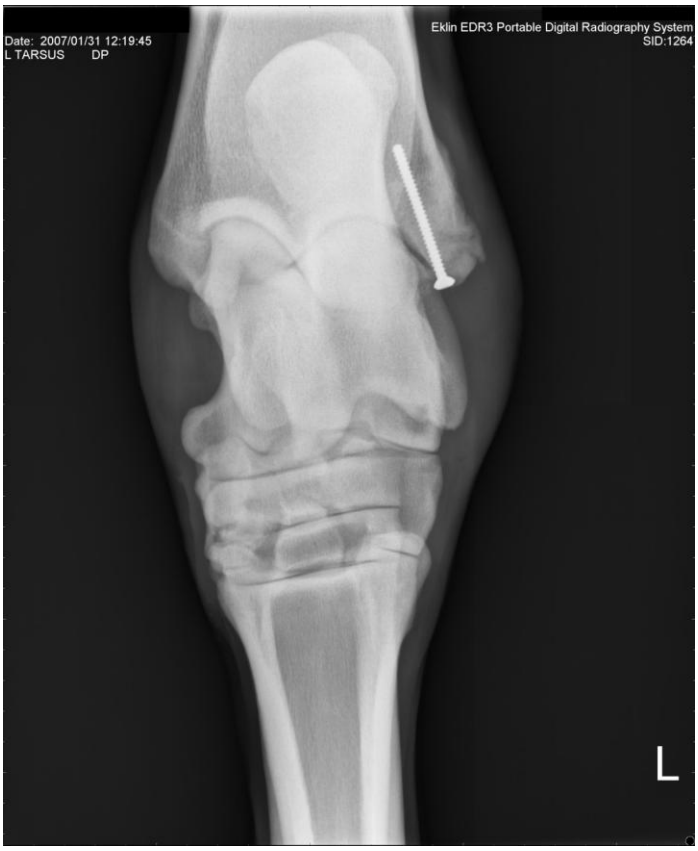




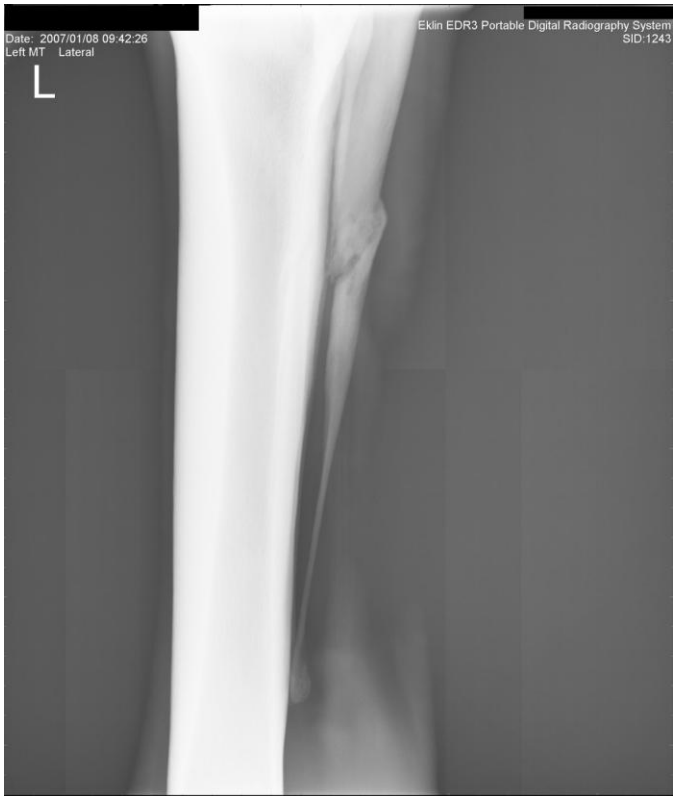
For those of you who may have noticed, the machine settings on the pre-treatment and follow-up scans above were not identical. I took another picture with exactly the same settings to show that the healing is real.



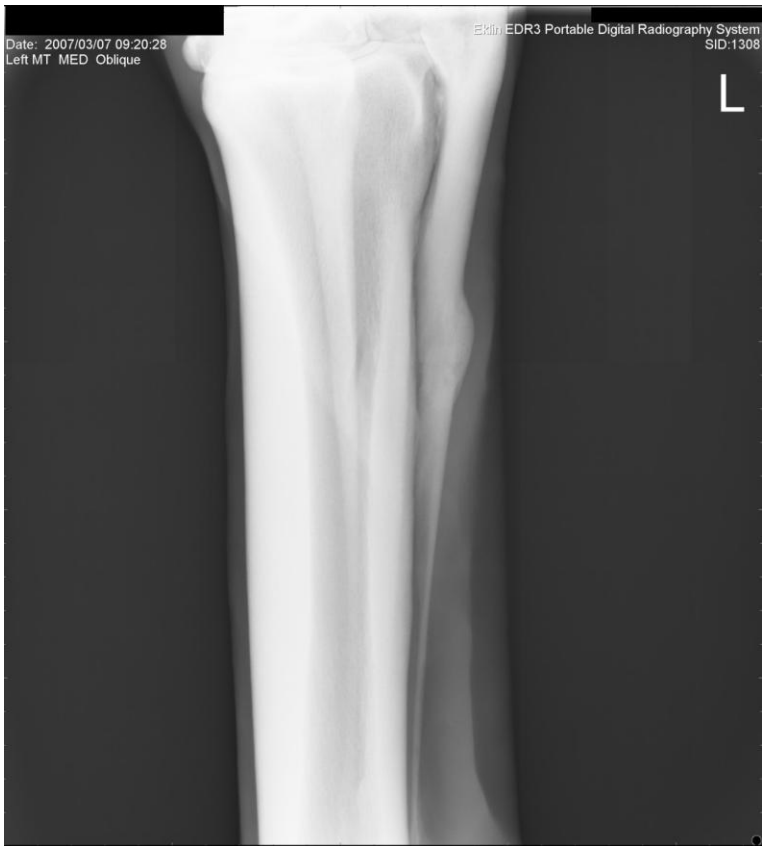


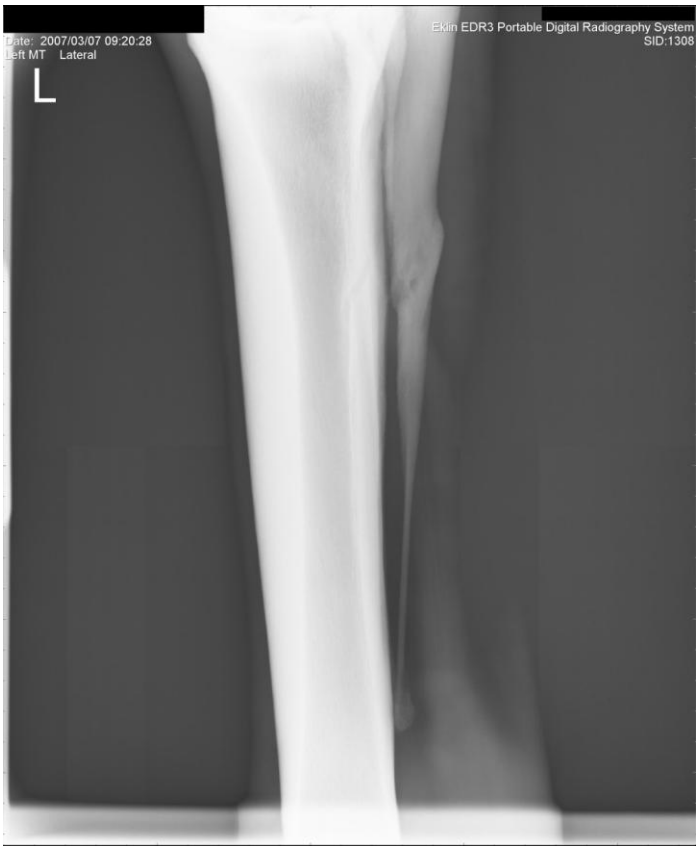


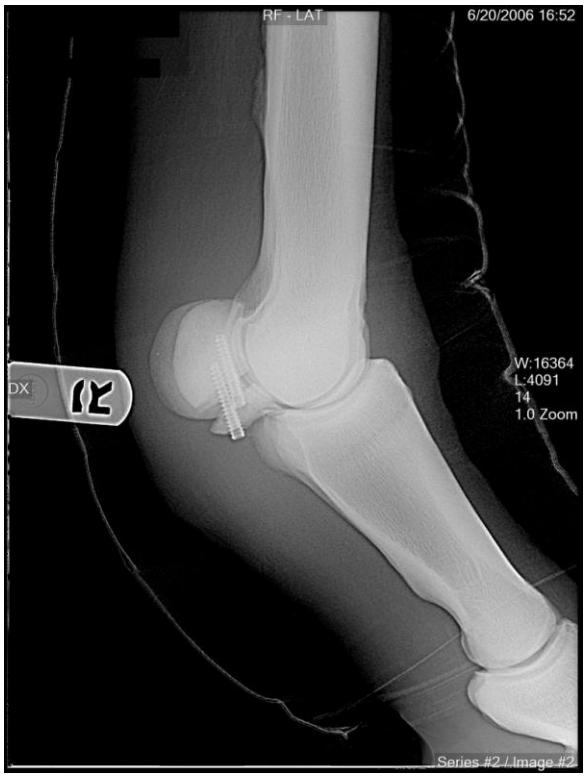
The radiograph taken 11/01/06 was taken two months post-surgery and demonstrates delayed healing. Statison therapy (LIPUS) was applied for three months and a follow-up radiograph obtained on 1/31/07.

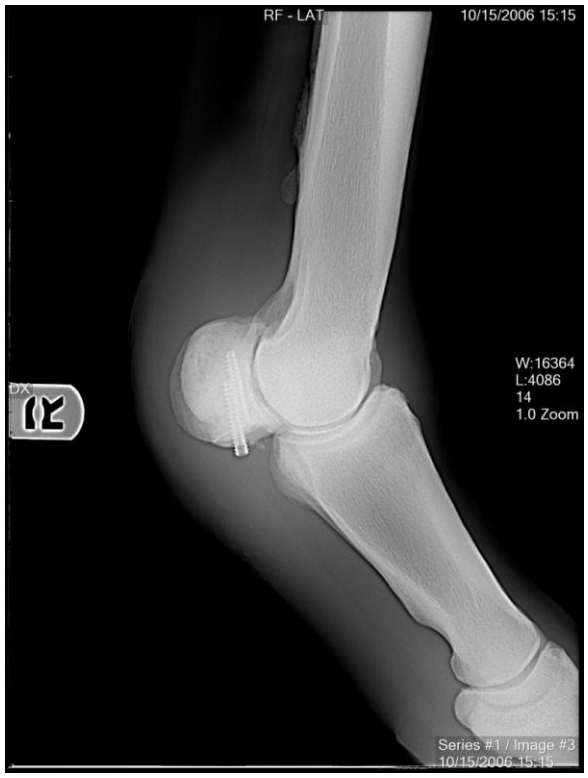


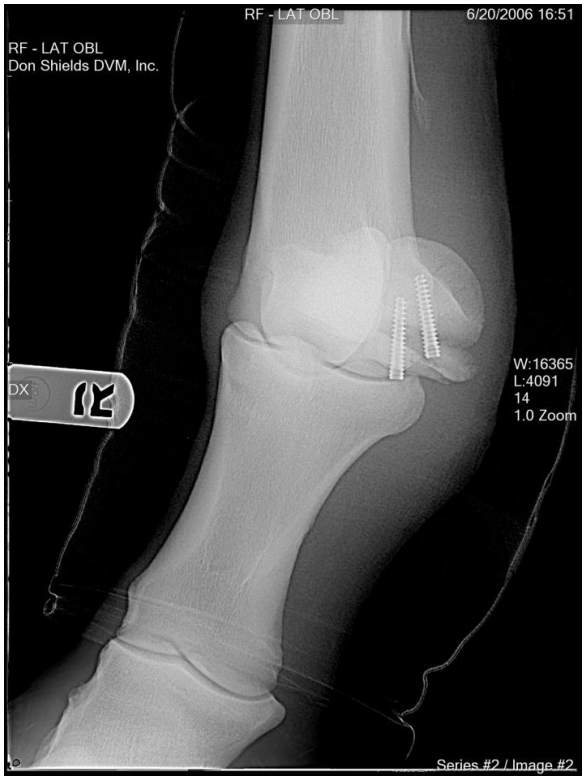
The original radiograph taken 1/8/07 represents three months of healing with no therapy and may now be considered a delayed union/non-union fracture. Statison (LIPUS) therapy was instituted for two months and follow-up radiographs obtained. Treatment was applied from the lateral aspect only. Even more complete healing may have been achieved if the transducer had been placed on the medial surface of the fracture as well.

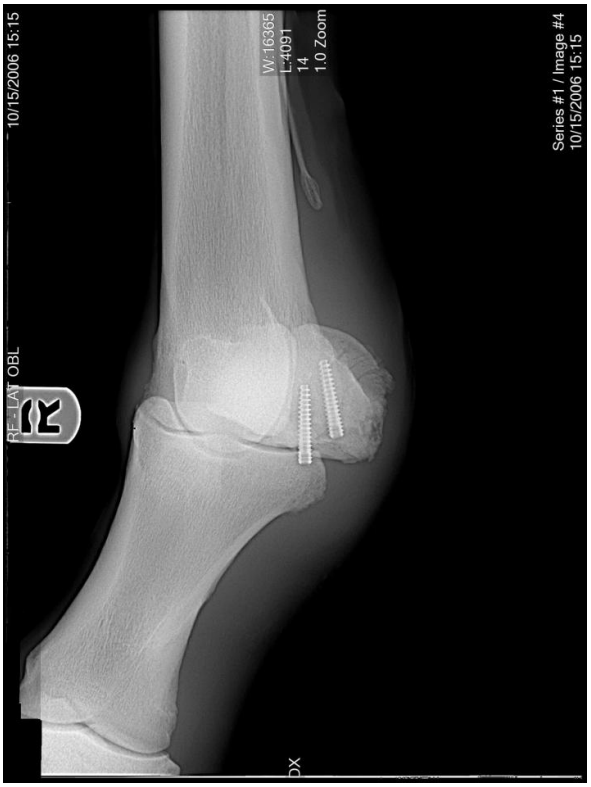






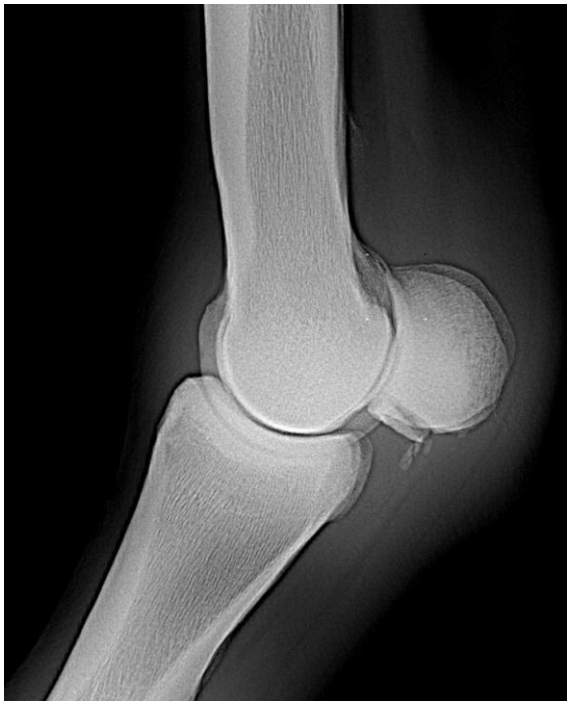


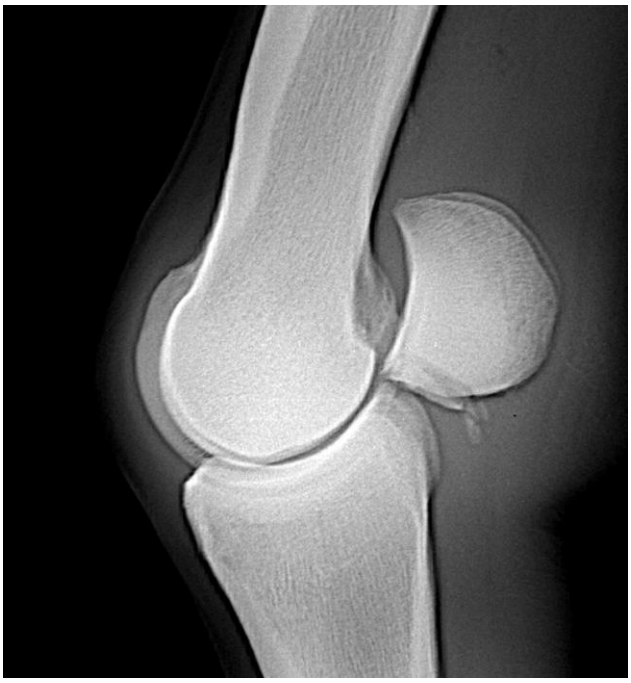




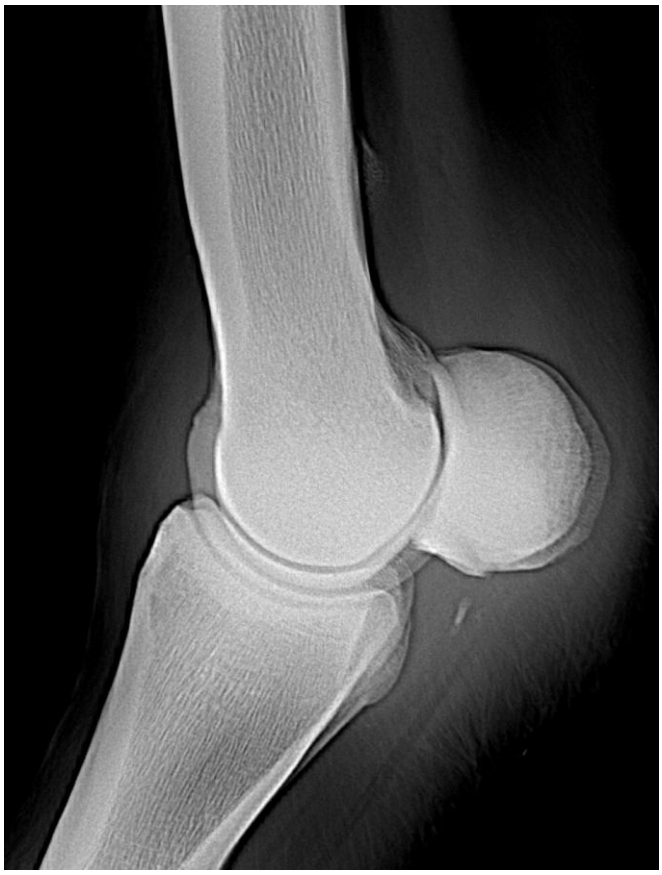
The implants in this base sesamoid fracture provided rotational stability, but no compression of the fracture site. In less than four months, the fracture gap was filled with bone. The only therapy utilized was low-intensity pulsed ultrasound (Statison therapy) applied once daily. No shockwave, stem cell, growth factor or other advanced therapies were utilized.

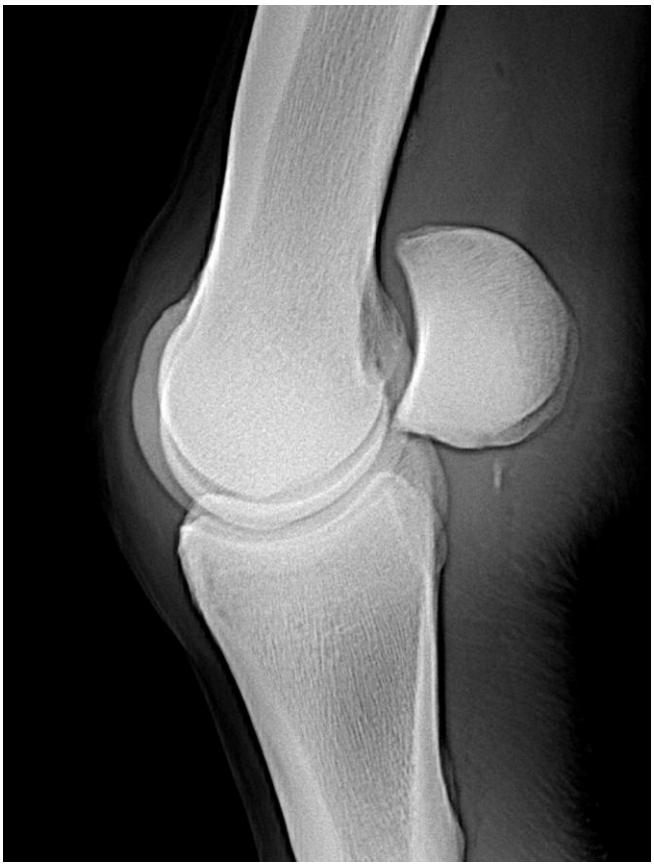
The following case demonstrates healing of a base sesamoid fracture when surgical intervention was not provided. The first radiographs are after four months of rest. The fracture is clearly visible and was virtually unchanged from the initial radiographs.



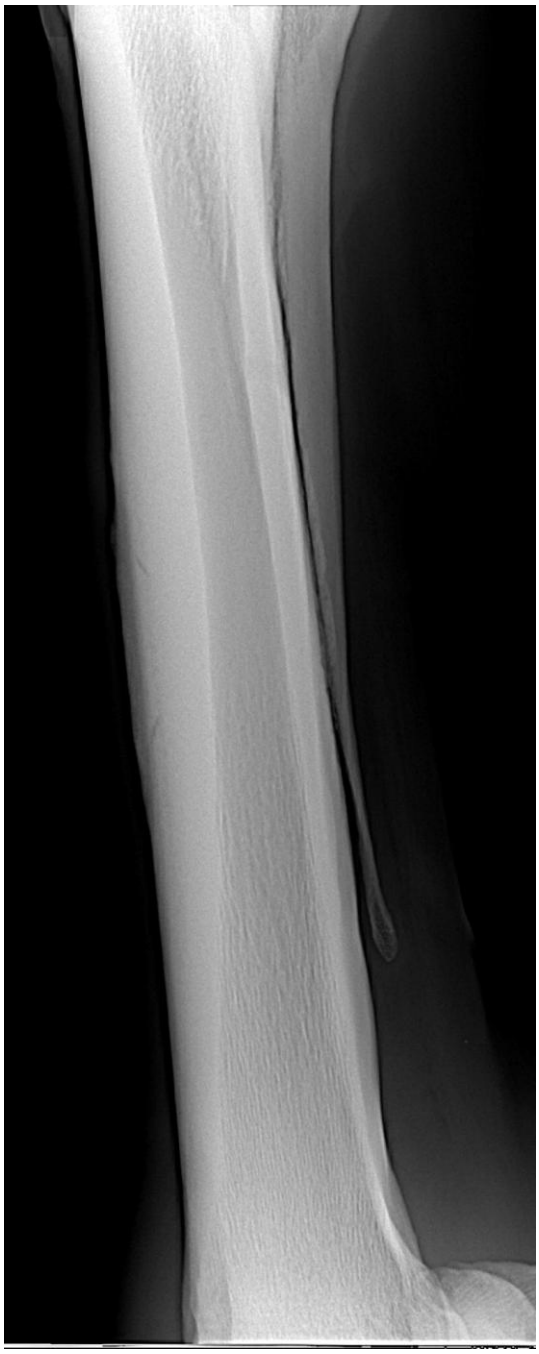


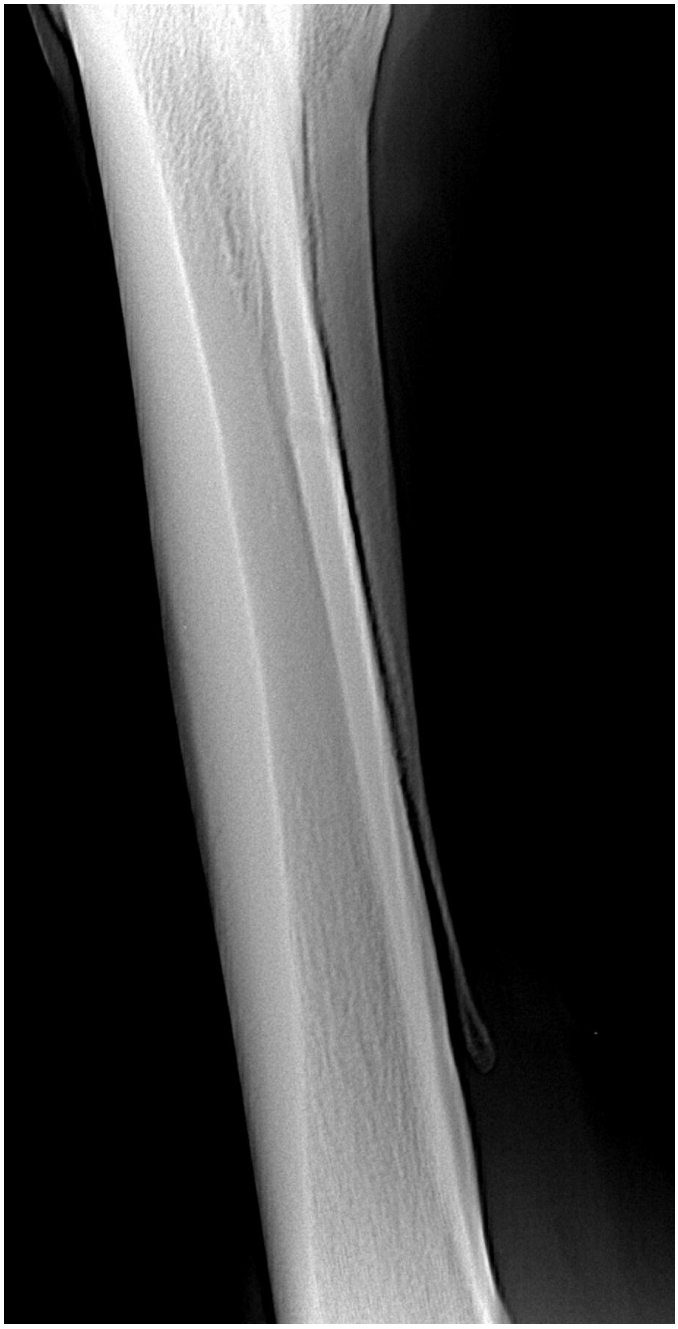
The second set of radiographs is one year later, but during this time, the horse was actively training and racing at Santa Anita racetrack.





The last case is a fracture of the third metacarpus (shin) in a racing thoroughbred. The radiographs are only three months apart. This horse remained at the racetrack in light training (walking at first) during the entire treatment and healing stages of this fracture. The horse ran roughly four months after the fracture was diagnosed and won his second start three weeks later (an allowance race). Normally, a horse with a fracture like this would be turned out for four to six months. Training would then resume for another three months before the horse would be ready to race. We basically cut this time in half and with glowing results!





Appendix 1

Device controls and error messages:

- Pressing the Power button turns the unit on and an audible beep is generated.

- When the main menu screen is displayed, a progress bar will count down, and if allowed to complete, the treatment will begin automatically.

- When the main menu screen is displayed, the Up and Down keys allow the treatment time in minutes to be set. Pressing an Up or Down key to select a new time will reset the countdown progress bar to the beginning allowing the user to 'take his or her time' to configure the desired treatment time.

- Pressing the Enter key while the main menu progress bar is counting down will cause treatment to begin.

- Before the treatment begins the unit will check for connected transducers. If none are connected an error will occur and a message will be displayed prompting the user to connect a transducer. Once a transducer is connected, treatment will begin automatically.

- If an error has occurred during the previous treatment or if the user had cancelled the previous treatment, a screen will display the details of the error at this time. Pressing any key at this point will display the main menu screen.

- Pressing the Up and Down keys together anytime during the startup screen and held until the progress bar completes will display the Usage Log detailing hours used, hours remaining and partial and full treatment counts. Pressing any key at this point will display the main menu screen.

- Treatments lasting shorter than 3 minutes are not counted towards unit usage time lifespan, allowing the unit to be demoed without affecting the lifespan of the unit.

- Treatments lasting longer than 3 minutes are counted towards unit usage time.

- Treatments lasting longer than 10 minutes but shorter than the treatment time configured by the user due to being cancelled or an error condition will be logged as 'Partial Treatments' in the usage log.

- Treatments successfully completed will count as ‘Full Treatments’ in the Usage Log.

- Pressing the Power button during treatment will display a message indicating that the unit will shutdown in 5 seconds. If the Power button is not pressed within 5 seconds (approx.) the unit will power down. Usage time for this incomplete treatment will be logged (according to the parameters detailed above) and a message will be displayed upon the next startup indicating the previous treatment did not complete.

- If an additional transducer is connected during treatment an error will occur.

- If a single transducer and the array are connected at the same time, an error will occur accompanied by the message, “Disconnect single to enable array”.

- If the battery power is low a “***BATT LOW” message will be displayed on the screen and treatment will continue for as long as there is sufficient power to run the unit.

- All errors are accompanied by an audible beep and the LED will turn RED. Otherwise, when the unit is powered on the LED will remain GREEN.

Appendix 2

References:

LIPUS References: BONE

Claes L, Willie B, The enhancement of bone regeneration by ultrasound. *Prog Biophys Mol Biol*. (2007) Jan-Apr;93(1-3):384-98. Epub 2006 Aug 10. Review.

Handolin L, Partio EK, Arnala I, Pajarinen J, Pätiälä H, Rokkanen P. The effect of low-intensity pulsed ultrasound on bone healing in SR-PLLA rod fixed experimental distal femur osteotomy in rat. *J Mater Sci Mater Med.* (2007) Jun;18(6):1239-45. Epub 2007 Feb 3

Jingushi S, Mizuno K, Matsushita T, Itoman M, Low-intensity pulsed ultrasound treatment for postoperative delayed union or nonunion of long bone fractures. *J Orthop Sci.* (2007) Jan;12(1):35-41 Epub 2007 Jan 31

Li J, Waugh LJ, Hui SL, Burr DB, Warden SJ, Low-intensity pulsed ultrasound and nonsteroidal anti-inflammatory drugs have opposing effects during stress fracture repair. *J Orthop Res.* (2007) Jun 25; [Epub ahead of print]

Miłowska K, [Ultrasound--mechanisms of action and application in sonodynamic therapy]. *Postepy Hig Med Dosw (Online).* (2007) Jun 1;61:338-49

O'Brien WD Jr, Ultrasound-biophysics mechanisms. *Prog Biophys Mol Biol.* (2007) Jan-Apr;93(1-3):212-55. Epub 2006 Aug 8

Rutten S, Nolte PA, Guit GL, Bouman DE, Albers GH, Use of low-intensity pulsed ultrasound for posttraumatic nonunions of the tibia: a review of patients treated in the Netherlands. *J Trauma*. (2007) Apr;62(4):902-8

Takayama T, Low-intensity pulsed ultrasound stimulates osteogenic differentiation in ROS 17/2.8 cells. *Life Sci.* (2007) Feb 13;80(10):965-71

Chan CW, et al., Dose-dependent effect of low-intensity pulsed ultrasound on callus formation during rapid distraction osteogenesis. *J Orthop Res.* (2006) Nov;24(11): 2072-9

Chan CW, Qin L, Lee KM, et al., Low intensity pulsed ultrasound accelerated bone remodeling during consolidation stage of distraction osteogenesis. *J Orthop Res.* (2006), 14, pp. 263-270

Erdogan O, et al., Effects of low-intensity pulsed ultrasound on healing of mandibular fractures: an experimental study in rabbits. *J Oral Maxillofac Surg*. (2006) Feb;64 (2): 180-188

Gleizal A, Li S, Pialat JB, Beziat JL, Transcriptional expression of calvarial bone after treatment with low-intensity ultrasound: an in vitro study. *Ultrasound Med Biol.* (2006) Oct;32(10):1569-74

Jones CP, Coughlin MJ, Shurnas PS, Prospective CT scan evaluation of hindfoot nonunions treated with revision surgery and low-intensity ultrasound stimulation. *Foot Ankle Int.* 2006 Apr;27(4):229-35

Lirani-Galvao AP, Jorgetti V, da Silva OL, Comparative study of how low-level laser therapy and low-intensity pulsed ultrasound affect bone repair in rats. *Photomed Laser Surg*. (2006) Dec;24(6):735-40

Luthje P, Nurmi-Luthje I, Non-union of the clavicle and delayed union of the proximal fifth metatarsal treated with low-intensity pulsed ultrasound in two soccer players. *J Sports Med Phys Fitness*. (2006) Sep;46(3):476-80

Malizos KN, et al., Low-intensity pulsed ultrasound for bone healing: an overview. *Injury*. (2006) Apr;37 Suppl 1:S56-62. Epub 2006 Apr 3. Review.

Malizos KN, et al., Transosseous application of low-intensity ultrasound for the enhancement and monitoring of fracture healing process in a sheep osteotomy model. *Bone.* (2006) Apr;38(4):530-9. Epub 2005 Dec 20

Warden SJ, Fuchs RK, Kessler CK, Avin KG, Cardinal RE, Stewart RL, Ultrasound produced by a conventional therapeutic ultrasound unit accelerates fracture repair. *Phys Ther*. (2006) Aug;86(8):1118-27

Claes L, Rüter A, Mayr E, Low-intensity ultrasound enhances maturation of callus after segmental transport. *Clin Orthop Relat Res.* (2005) Jan;(430):189-94

Dudda M, Pommer A, Muhr G, Esenwein SA, [Application of low intensity, pulsed ultrasound on distraction osteogenesis of the humerus. Case report] *Unfallchirurg.* (2005) Jan;108(1):69-74

El-Mowafi H, Mohsen M., The effect of low-intensity pulsed ultrasound on callus maturation in tibial distraction osteogenesis. *Int Orthop*. (2005) 29 pp. 121-124

Gebauer D, Correll J, Pulsed low-intensity ultrasound: a new salvage procedure for delayed unions and nonunions after leg lengthening in children. *J Pediatr Orthop*. (2005) Nov-Dec;25(6):750-4

Gebauer D, Mayr E, Orthner E, Rayby JP, Low-intensity pulsed ultrasound: effects on nonunions. *Ultrasound Med Biol*. (2005) Oct;31(10):1391-402

Gold SM, Wasserman R, Preliminary results of tibial bone transports with pulsed low intensity ultrasound (Exogen). *J Orthop Trauma*. (2005) Jan;19(1):10-6

Harle J, Mayia F, Olsen I, Salih V, Effects of ultrasound on transforming growth factor-beta genes in bone cells. *Eur Cell Mater*. (2005) Dec 5;10:70-6; discussion 76

Mukai S, Ito H, Nakagawa Y, Akiyama H, Miyamoto M, Nakamura T, Transforming growth factor-beta1 mediates the effects of low-intensity pulsed ultrasound in chondrocytes. *Ultrasound Med Biol*. (2005) Dec;31(12):1713-21.

Parvizi J, Vegari D, Pulsed low-intensity ultrasound for fracture healing. *Foot Ankle Clin*. (2005) Dec;10(4):595-608, vii.

Stein H, Lerner A, How does pulsed low-intensity ultrasound enhance fracture healing? *Orthopedics*. (2005) Oct;28(10):1161-3. Review.

Dalecki D, Mechanical bioeffects of ultrasound. *Annu Rev Biomed Eng*. (2004);6:229-48

Esenwein SA, Dudda M, et al., [Efficiency of low-intensity pulsed ultrasound on distraction osteogenesis in case of delayed callotasis -- clinical results] *Zentralbl Chir*. (2004) Oct;129(5):413-20

Fini M, et al., Current trends in the enhancement of biomaterial osteointegration: biophysical stimulation. *Int J Artif Organs*. (2004) Aug;27(8):681-90. Review.

Fujioka H, et al., Ultrasound treatment of nonunion of the hook of the hamate in sports activities. *Knee Surg Sports Traumatol Arthrosc*. (2004) Mar;12(2):162-4. Epub 2003 Sep 20

Giannini S, et al., Low-intensity pulsed ultrasound in the treatment of traumatic hand fracture in an elite athlete. *Am J Phys Med Rehabil*. (2004) Dec;83(12):921-5

Hantes ME, Mavrodontidis AN, Zalavras CG, Karantanas AH, Karachalios T, Malizos KN, Low-intensity transosseous ultrasound accelerates osteotomy healing in a sheep fracture model. *J Bone Joint Surg Am*. (2004) Oct;86-A(10):2275-82

Lerner A, Stein H, Soudry M, Compound high-energy limb fractures with delayed union: our experience with adjuvant ultrasound stimulation (exogen). *Ultrasonics*. (2004) Apr;42(1-9):915-7

Leung KS, et al., Low intensity pulsed ultrasound stimulates osteogenic activity of human periosteal cells. *Clin Orthop Relat Res*. (2004) Jan;(418):253-9

Leung KS, Lee WS, Tsui HF, et al., Complex tibial fracture outcomes following treatment with low-intensity pulsed ultrasound.
Ultrasound Med Biol 30 (2004), pp. 389-395

Pigozzi F, et al., Low-intensity pulsed ultrasound in the conservative treatment of pseudoarthrosis. *J Sports Med Phys Fitness*. (2004) Jun;44(2):173-8

Sakurakichi K, et al., Effects of timing of low-intensity pulsed ultrasound on distraction osteogenesis. *J Orthop Res*. (2004) Mar;22(2):395-403

Tsumaki N, et al., Low-intensity pulsed ultrasound accelerates maturation of callus in patients treated with opening-wedge high tibial osteotomy by hemicallotasis. *J Bone Joint Surg Am.* (2004) Nov;86-A(11):2399-405

Anglen, J, The clinical use of bone stimulators. *J South Orthop Assoc*. (2003) 12(2): 46-54.

Mohtadi N, Low-intensity pulsed ultrasound therapy for fracture healing: a meta-analysis. *Clin J Sport Med*. (2003) Mar;13(2):127

Naruse K, et al., Distinct anabolic response of osteoblast to low-intensity pulsed ultrasound. *J Bone Miner Res*. (2003) Feb;18(2):360-9

Okada K, et al., Congenital pseudoarthrosis of the tibia treated with low-intensity pulsed ultrasound stimulation (LIPUS). *Ultrasound Med Biol*. (2003) Jul;29(7):1061-4

Rawool, N. M., B. B. Goldberg, et al., Power Doppler assessment of vascular changes during fracture treatment with low-intensity ultrasound. *J Ultrasound Med.* (2003) 22(2): 145-53.

Warden SJ, A new direction for ultrasound therapy in sports medicine. *Sports Med.* (2003);33(2):95-107

Aynaci O, et al., The effect of ultrasound on the healing of muscle-pediculated bone graft in spinal fusion. *Spine.* (2002) Jul 15;27(14):1531-5.

Busse JW, Bhandari M, Kulkarni AV and Tunks E, The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: A meta-analysis, *CMAJ* 166 (2002), pp. 437–441

Chang, W. H., J. S. Sun, et al., Study of thermal effects of ultrasound stimulation on fracture healing. *Bioelectromagnetics.* (2002) 23(4): 256-63

El-Bialy TH, Royston TJ, Magin RL, Evans CA, Zaki Ael M and Frizzell LA, The effect of pulsed ultrasound on mandibular distraction, *Ann Biomed Eng* (2002) 30 pp. 1251–1261

Frankel VH, Mizuho K, Management of non-union with pulsed low-intensity ultrasound therapy--international results. *Surg Technol Int.* (2002) Sep;10:195-200. Review.

Gebauer GP, Lin SS, Beam HA, Vieira P and Parsons JR, Low-intensity pulsed ultrasound increases the fracture callus strength in diabetic BB Wistar rats but does not affect cellular proliferation, *J Orthop Res* (2002) 20 pp. 587–592

Handolin L, et al., The effects of low-intensity pulsed ultrasound on bioabsorbable self-reinforced poly L-lactide screws. *Biomaterials.* (2002) Jul;23(13):2733-6

Heybeli N, et al., Diagnostic ultrasound treatment increases the bone fracture-healing rate in an internally fixed rat femoral osteotomy model. *J Ultrasound Med*. (2002) Dec;21(12):1327-33

Machen MS, et al., The effect of low intensity pulsed ultrasound on regenerate bone in a less-than-rigid biomechanical environment. *Biomed Mater Eng.* (2002);12(3):239-47

Mayr E, et al., [Is low intensity ultrasound effective in treatment of disorders of fracture healing?] *Unfallchirurg.* (2002) Feb;105(2):108-15

Tis JE, et al., The effect of low intensity pulsed ultrasound applied to rabbit tibiae during the consolidation phase of distraction osteogenesis. *J Orthop Res*. (2002) Jul;20(4): 793-800

Azuma Y, et al., Low-intensity pulsed ultrasound accelerates rat femoral fracture healing by acting on the various cellular reactions in the fracture callus. *J Bone Miner Res*. (2001) Apr;16(4):671-80

Cook SD, Salkeld SL, Patron LP, Ryaby JP and Whitecloud TS, Low-intensity pulsed ultrasound improves spinal fusion, *Spine J* (2001) 1 pp. 246–254

Harle J, et al., Effects of ultrasound on the growth and function of bone and periodontal ligament cells in vitro. *Ultrasound Med Biol.* (2001) Apr;27(4):579-86

Harle J, et al., Effects of therapeutic ultrasound on osteoblast gene expression. *J Mater Sci Mater Med.* (2001) Oct-Dec;12(10-12):1001-4

Mayr E, Laule A, Suger G, et al., Radiographic results of callus distraction aided by pulsed low-intensity ultrasound. *J Orthop Trauma* (2001) 15(6) pp. 407-414

Nolte PA, et al., Low-intensity ultrasound stimulates endochondral ossification in vitro. *J Orthop Res.* (2001) Mar;19(2):301-7

Nolte PA, van der Krans A, Patka P, Janssen IM, Rayby JP, Albers GH, Low-intensity pulsed ultrasound in the treatment of nonunions. *J Trauma* (2001) Oct;51(4):693-702; discussion 702-3

Rubin C, Bolander M, Ryaby JP and Hadjiargyrou M, The use of low-intensity ultrasound to accelerate the healing of fractures, *J Bone Joint Surg Am* (2001) 83 pp. 259–270

Sun J, Hong R, Chang W, Chen L and Lin F, In vitro effects of low-intensity ultrasound stimulation on the bone cells, *J Biomed Mater Res*. (2001) 57 pp. 449–456

Takikawa S, et al., Low-intensity pulsed ultrasound initiates bone healing in rat nonunion fracture model. *J Ultrasound Med.* (2001) Mar; 20(3):197-205

Warden SJ, Favaloro JM, et al., Low-intensity pulsed ultrasound stimulates a bone-forming response in UMR-106 cells. *Biochem Biophys Res Commun.* (2001) Aug 24;286(3):443-50

Yang KH and Park SJ, Stimulation of fracture healing in a canine ulna full-defect model by low-intensity pulsed ultrasound, *Yonsei Med J*. (2001) 42 pp. 503–508

Fujioka H, et al., Treatment of ununited fracture of the hook of hamate by low-intensity pulsed ultrasound: a case report. *J Hand Surg [Am]*. (2000) Jan;25(1):77-9

Mayr E, Frankel V, Ruter A, Ultrasound--an alternative healing method for nonunions? *Arch Orthop Trauma Surg.* (2000), 120(1-2):1-8

Shimazaki A, Inui K, Azuma Y, et al., Low-intensity pulsed ultrasound accelerates bone maturation in distraction osteogenesis in rabbits. *J Bone Joint Surg Br*. (2000) 82 pp. 1077-1082

Warden SJ, et al., Acceleration of fresh fracture repair using the sonic accelerated fracture healing system (SAFHS): a review. *Calcif Tissue Int.* (2000) Feb;66(2):157-63

Sun JS, Tsuang YH, Lin FH, et al., Bone defect healing enhanced by ultrasound stimulation: an in vitro tissue culture model. *J Biomed Materials Res*. (1999) 46(2) pp. 253-261

Hadjiargyrou M, McLeod K, Ryaby JP, Rubin C, Enhancement of fracture healing by low intensity ultrasound. *Clin Orthop Relat Res.* (1998) Oct;(355 Suppl):S216-29

Cook SD, Ryaby JP, McCabe J, Frey JJ, Heckman JD and Kristiansen TK, Acceleration of tibia and distal radius fracture healing in patients who smoke, *Clin Orthop.* (1997), pp. 198–207

Kristiansen TK, Ryaby JP, McCabe J, Frey JJ and Roe LR, Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound: A multicenter, prospective, randomized, double-blind, placebo-controlled study, *J Bone Joint Surg Am.* (1997) 79 pp. 961–973

Reher P, et al., The stimulation of bone formation in vitro by therapeutic ultrasound. *Ultrasound Med Biol.* (1997);23(8):1251-8

Yang KH, Parvizi J, Wang SJ, et al., Exposure to low-intensity ultrasound increases aggrecan gene expression in a rat femur fracture model. *J Orthop Res*. (1996) 14 pp. 802-809

Heckman JD, Ryaby JP, McCabe J, et al., Acceleration of tibial fracture-healing by non-invasive, low-intensity pulsed ultrasound. *J Bone Joint Surg Am.* (1994) 76 pp. 26-34

Wang SJ, Lewallen DG and Bolander M, Low intensity ultrasound treatment increases strength in a rat femoral fracture model, *J Orthop Res.* (1994) 12 pp. 40–47

Tsai CL, Chang WH, Liu TK, Preliminary studies of duration and intensity of ultrasonic treatments on fracture repair. *Chin J Physiol.* (1992);35(1):21-6

Tsai CL, Chang WH, Liu TK, Song GM, Ultrasonic effect on fracture repair and prostaglandin E2 production. *Chin J Physiol.* (1992);35(1):27-34

Tsai CL, Chang WH, Liu TK, Song GM, Ultrasound can affect bone healing both locally and systemically. *Chin J Physiol.* (1991);34(2):213-22

Pilla AA, Mont MA, Nasser PR, et al., Non-invasive low-intensity pulsed ultrasound accelerates bone healing in the rabbit. *J Orthop Trauma.* (1990) 4 pp. 246-253

Duarte LR, The stimulation of bone growth by ultrasound, *Arch Orthop Trauma Surg.* (1983) 101 pp. 153–159

LIPUS References: Soft Tissue

Byuong-Hyun Min, et al., Low Intensity Ultrasound as a Supporter of Cartilage Regeneration and Its Engineering. *Biotechnology and Bioprocess Engineering* (2007), 12: 22-31

Lee HJ, Choi BH, Min BH, Park SR, Low-intensity ultrasound inhibits apoptosis and enhances viability of human mesenchymal stem cells in three-dimensional alginate culture during chondrogenic differentiation. *Tissue Eng.* (2007) May;13(5):1049-57

Miłowska K, [Ultrasound--mechanisms of action and application in sonodynamic therapy] *Postepy Hig Med Dosw (Online).* (2007) Jun 1;61:338-49

Noriega S., et al., Intermittent Applications of Continuous Ultrasound on the Viability, Proliferation, Morphology, and Matrix Production of Chondrocytes in 3D Matrices. *Tissue Eng*. (2007) Mar;13(3):611-8

O'Brien WD Jr., Ultrasound-biophysics mechanisms. *Prog Biophys Mol Biol.* (2007) Jan-Apr;93(1-3):212-55. Epub 2006 Aug 8

Walsh WR, Stephens P, Vizesi F, Bruce W, Huckle J, Yu Y, Effects of low-intensity pulsed ultrasound on tendon-bone healing in an intra-articular sheep knee model. *Arthroscopy*. (2007) Feb;23(2):197-204

Choi BH, Woo JI, Min BH, Park SR, Low-intensity ultrasound stimulates the viability and matrix gene expression of human articular chondrocytes in alginate bead culture. *J Biomed Mater Res A.* (2006) Dec 15;79(4):858-64

Ikeda K, et al., Effects of low-intensity pulsed ultrasound on the differentiation of C2C12 cells. *Life Sci.* (2006) Oct 12;79(20):1936-43. Epub 2006 Jun 23

Iwashina T, et al., Low-intensity pulsed ultrasound stimulates cell proliferation and proteoglycan production in rabbit intervertebral disc cells cultured in alginate. *Biomaterials.* (2006) Jan;27(3):354-61

Lee HJ, et al., Low-intensity ultrasound stimulation enhances chondrogenic differentiation in alginate culture of mesenchymal stem cells. *Artif Organs.* (2006) Sep;30(9):707-15

Leung MC, Ng GY, Yipp KK, Therapeutic ultrasound enhances medial collateral ligament repair in rats. *Ultrasound Med Biol*. (2006) Mar;32(3):449-52

Lu H, et al., Low-intensity pulsed ultrasound accelerates bone-tendon junction healing: a partial patellectomy model in rabbits. *Am J Sports Med.* (2006) Aug;34(8):1287-96

Qin L, et al., Low intensity pulsed ultrasound increases the matrix hardness of the healing tissues at bone-tendon insertion-a partial patellectomy model in rabbits. *Clin Biomech* (Bristol, Avon). (2006) May;21(4):387-94

Qin L, et al., Low-intensity pulsed ultrasound accelerates osteogenesis at bone-tendon healing junction. *Ultrasound Med Biol.* (2006) Dec;32(12):1905-11

Schumann D, et al., Treatment of human mesenchymal stem cells with pulsed low intensity ultrasound enhances the chondrogenic phenotype in vitro. *Biorheology*. (2006) 43(3-4):431-43.

Yeung CK, Guo X, Ng YF, Pulsed ultrasound treatment accelerates the repair of Achilles tendon rupture in rats. *J Orthop Res.* (2006) Feb;24(2):193-201

Warden S.J., et al., Low-intensity pulsed ultrasound accelerates and a nonsteroidal anti-inflammatory drug delays knee ligament healing. *Am J Sports Med.* (2006) Jul;34(7): 1094-102

Chang CJ, Hsu SH, Lin FT, Chang H, Chang CS, Low-intensity-ultrasound-accelerated nerve regeneration using cell-seeded poly(D,L-lactic acid-co-glycolic acid) conduits: an in vivo and in vitro study. *J Biomed Mater Res B Appl Biomater.* (2005) Oct;75(1):99-107

Iwabuchi S, et al., In vitro evaluation of low-intensity pulsed ultrasound in herniated disc resorption. *Biomaterials*. (2005) Dec;26(34):7104-14

Jia XL, et al., Effects of low-intensity pulsed ultrasound in repairing injured articular cartilage. *Chin J Traumatol*. (2005) Jun;8(3):175-8

Miyamoto K, et al., Exposure to pulsed low intensity ultrasound stimulates extracellular matrix metabolism of bovine intervertebral disc cells cultured in alginate beads. *Spine.* (2005) Nov 1;30(21):2398-405

Mukai S, et al., Transforming growth factor-beta1 mediates the effects of low-intensity pulsed ultrasound in chondrocytes. *Ultrasound Med Biol.* (2005) Dec;31(12):1713-21

Sena K, et al., Early gene response to low-intensity pulsed ultrasound in rat osteoblastic cells. *Ultrasound Med Biol*. (2005) May;31(5):703-8

Sparrow KJ, et al., The effects of low-intensity ultrasound on medial collateral ligament healing in the rabbit model. *Am J Sports Med*. (2005) Jul;33(7):1048-56

Dalecki D, Mechanical bioeffects of ultrasound. *Annu Rev Biomed Eng.* (2004);6:229-48

Korstjens CM, et al., Stimulation of bone cell differentiation by low-intensity ultrasound--a histomorphometric in vitro study. *J Orthop Res.* (2004) May;22(3):495-500

Saito M, Soshi S, Tanaka T, Fujii K, Intensity-related differences in collagen post-translational modification in MC3T3-E1 osteoblasts after exposure to low- and high-intensity pulsed ultrasound. *Bone.* (2004) Sep;35(3):644-55

Saito M, Fujii K, Tanaka T, Soshi S, Effect of low- and high-intensity pulsed ultrasound on collagen post-translational modifications in MC3T3-E1 osteoblasts. *Calcif Tissue Int.* (2004) Nov;75(5):384-95. Epub 2004 Jul 13

Zhou S, et al., Molecular mechanisms of low intensity pulsed ultrasound in human skin fibroblasts. *J Biol Chem.* (2004) Dec 24;279(52):54463-9

Vicenti FA, et al., Effects of low-intensity pulsed ultrasound on wound healing in corneas of dogs following keratoplasty. *Vet Ophthalmol*. (2003) Sep;6(3):255-63

Zhang ZJ, Huckle J, Francomano CA, Spencer RG, The effects of pulsed low-intensity ultrasound on chondrocyte viability, proliferation, gene expression and matrix production. *Ultrasound Med Biol.* (2003) Nov;29(11):1645-51

Crisci AR, Ferreira AL, Low-intensity pulsed ultrasound accelerates the regeneration of the sciatic nerve after neurotomy in rats. *Ultrasound Med Biol*. (2002) Oct;28(10): 1335-41

Johns LD, Nonthermal Effects of Therapeutic Ultrasound: The Frequency Resonance Hypothesis. *J Athl Train.* (2002) Jul;37(3):293-299

Nishikori T, et al., Effects of low-intensity pulsed ultrasound on proliferation and chondroitin sulfate synthesis of cultured chondrocytes embedded in Atelocollagen gel. *J Biomed Mater Res.* (2002) Feb;59(2):201-6.

Takakura Y. and Matsui N., Low-intensity pulsed ultrasound enhances early healing of medial collateral ligament injuries in rats, *J Ultrasound Med*. (2002) 21 pp. 283–288

Zhang ZJ, et al., The influence of pulsed low-intensity ultrasound on matrix production of chondrocytes at different stages of differentiation: an explant study. *Ultrasound Med Biol.* (2002) Nov-Dec;28(11-12):1547-53

Cook SD, et al., Improved cartilage repair after treatment with low-intensity pulsed ultrasound. *Clin Orthop Relat Res*. (2001) Oct;(391 Suppl):S231-43

Naruse K, et al., Anabolic response of mouse bone-marrow-derived stromal cell clone ST2 cells to low-intensity pulsed ultrasound. *Biochem Biophys Res Commun.* (2000) Feb 5;268(1):216-20

Doan N., Reher P., Meghji S. and Harris M., In vitro effects of therapeutic ultrasound on cell proliferation, protein synthesis, and cytokine production by human fibroblasts, osteoblasts, and monocytes, *J Oral Maxillofac Surg*. (1999) 57 pp. 409–419

Kokubu T, et al., Low intensity pulsed ultrasound exposure increases prostaglandin E2 production via the induction of cyclooxygenase-2 mRNA in mouse osteoblasts. *Biochem Biophys Res Commun.* (1999) Mar 16;256(2):284-7

Parvizi J, Wu CC, Lewallen DG, et al., Low-intensity ultrasound stimulates proteoglycan synthesis rat chondrocytes by increasing aggrecan gene expression. J Orthop Res. (1999) 17: 488-494

Wiltink A, et al., Effect of therapeutic ultrasound on endochondral ossification. *Ultrasound Med Biol.* (1995);21(1):121-7

Rogers G.J., Milthorpe B.K., Muratore A. and Schindhelm K., Measurement of the mechanical properties of the ovine anterior cruciate ligament bone–ligament–bone complex: A basis for prosthetic evaluation, *Biomaterials*. (1990) 11 pp. 89–96

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Statison Terms And Conditions Of Sale
Unless otherwise expressly agreed in writing, all transactions by Statison Medical are subject to the following terms and conditions.

Payment. Statison Medical's prices for our products are set forth on our order form or otherwise as published from time to time, or made available by sales representatives, or may be published on Statison Medical's internet website. Prices are exclusive of all taxes and duties of any kind, all of which you must pay. We reserve the right to change payment terms at any time or revoke any credit previously extended. Overdue payments are subject to finance charges of eighteen percent (18%) per annum or the maximum interest rate allowed by law. All payments and interest are payable in U.S. Dollars. If at any time you have not paid all amounts due, other than amounts disputed in good faith, then without prejudice to any other rights, we may suspend our performance under the Agreement, including our warranty service.

Delivery; Returns. Delivery date is the date that products are ready for pickup by you or a carrier for delivery to you, as such, title to and risk of loss of products passes to you on the delivery date. Some or all of our products are subject to a restocking fee of fifteen percent (15%).

Limited Warranty:

Who Is Covered: The benefit of this limited warranty extends to you only if you are the end-user of new products purchased by you, from us or from our authorized distributors. Our limited warranty is not applicable to any person or entity, other than you.

What Is Covered/Duration: We warrant our products to conform to our published specifications, when given normal and proper usage, for one (1) year after delivery to you. We do not warrant uninterrupted or error-free operation of our products. We do not warrant expendable parts such as the wraps, cables and gel.

Our Limited Warranty: During the applicable limited warranty period we will, at no additional charge, and at our sole option either repair a nonconforming product with new parts or serviceable used parts that are equivalent or superior to new parts in performance, and will return such to you, transportation and insurance prepaid. Our warranty on replacement parts and product repairs extends for thirty days (30) or the remainder of the applicable warranty period, whichever is longer. Our exclusive liability and your sole remedy for breach of any limited warranty shall be repair or replacement of a nonconforming product that does not meet our limited warranty. If after reasonable efforts we are unable to repair or replace a nonconforming product, your only remedy and our exclusive liability is a refund of the purchase price.

Warranty support is available during normal business hours at our service locations, except holidays. You must make any claim within the applicable warranty period. In case of malfunction, you must first contact Statison Medical customer service by either telephone, (800) 806-8756, or email: techsupport@statison.com. Our service personnel will try to help you correct the malfunction yourself. If this is not successful, we will supply you with further instructions. We have no obligation to provide on-site service. If it is necessary to return the product, you must do so, transportation and insurance prepaid, to our designated facility for examination. We must issue a return authorization number before any return can be made. If the product is non-conforming, we will return the repaired/replaced product to you, transportation and insurance prepaid, in accordance with our limited warranty, as stated above.

If we determine that the reported problem is not covered by our warranty, we will attempt to repair/replace the product at your cost, at our then standard rates for such work, or return it as you instruct and at your expense. All exchanged parts and products become our property.

Your Obligations: You must take reasonable care of the products, maintain them in a clean and appropriate environment and carry out the routine maintenance recommended by us in the applicable owner's manual, instructions or other documentation or otherwise communicated to you from time to time. You must provide reasonable supporting data to help identify reported problems.

Exclusions For Improper Use, Accidental Or Animal Damage, Etc: We do not warrant the performance of our products if you use them other than in strict accordance with our product instructions. Our warranty does not cover damage resulting from any causes external to our products, such as negligence or improper use or handling and/or damages caused by the animal patient or other animals; environmental damages such as exposure to water and/or excessive heat; casualty; external electrical fault; failure to follow packing or shipping instructions; use of unauthorized products in conjunction with our products; or repairs or modifications made by anyone other than us or our authorized service providers. We will repair normal wear-and-tear damage only to the extent required for proper functioning of equipment; cosmetic damage is not covered.

Disclaimer Of Additional Warranties:

Limitation Of Liability. WE ARE NOT LIABLE FOR FAILURE TO PERFORM UNDER THIS AGREEMENT DUE TO CIRCUMSTANCES BEYOND OUR REASONABLE CONTROL. UNDER NO CIRCUMLSTANCES WILL WE OR OUR LICENSORS BE LIABLE TO YOU OR ANY OTHER PERSON FOR LOSS OF PROFIT OR USE, SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES, INCLUDING WITHOUT LIMITATION FOR LOSS OF GOODWILL, DATA, OR EQUIPMENT, OR FOR BUSINESS INTERRUPTION, ARISING OUT OF THE MANUFACTURE, SALE, SUPPLY OR USE OF OUR PRODUCTS OR SERVICES OR FAILURE OR DELAY IN DELIVERING SUCH PRODUCTS OR SERVICES, WHETHER BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE, EVEN IF WE WERE ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES. OUR ENTIRE LIABILITY FOR A PRODUCT OR SERVICE, WHETHER BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE, SHALL NOT EXCEED THE AMOUNT YOU PAID FOR SUCH PRODUCT OR SERVICE. SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES OR THE LIMITATION OF LIABILITY TO THE ACTUAL PRICE PAID FOR THE PRODUCT OR SERVICE, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO YOU. OUR LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS THAT VARY FROM JURISDICTION TO JURISDICTION.

Limited Warranty

LIMITED WARRANTY. Statison Medical ("Company"), warrants that (a) its Statison V device and components of the Statison V system ("Product") will perform substantially in accordance with the accompanying written materials for a period of one (1) year from the date of purchase and (b) that the Product will be free from defects in materials and workmanship under normal use and service for a period of one (1) year. In the event applicable law imposes any implied warranties, the implied warranty period is limited to ninety (90) days from the date of purchase. Some jurisdictions do not allow such limitations on duration of an implied warranty, so the above limitation may not apply to you.

CUSTOMER REMEDIES. Statison Medical's and its suppliers' entire liability and your exclusive remedy shall be, at the Statison Medical's option, either (a) return of the price paid for the Product, or

(b) repair or replacement of the Product that does not meet this Limited Warranty and which is returned to the Company with a copy of your receipt. This Limited Warranty is void if failure of the Product has resulted from accident, abuse, or misapplication. Any replacement Product will be warranted for the remainder of the original warranty period or thirty (30) days, whichever is longer.

NO OTHER WARRANTIES. **TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, THE COMPANY AND ITS SUPPLIERS DISCLAIM ALL OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, WITH REGARD TO THE PRODUCT AND ANY RELATED OR ACCOMPANYING WRITTEN MATERIALS. THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY HAVE OTHER RIGHTS WHICH VARY FROM JURISDICTION TO JURISDICTION.**

NO LIABILITY FOR DAMAGES. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL THE COMPANY OR ITS SUPPLIERS BE LIABLE FOR ANY DAMAGES WHATSOEVER (INCLUDING WITHOUT LIMITATION, SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES FOR PERSONAL INJURY, LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, OR ANY OTHER PECUNIARY LOSS) ARISING OUT OF THE USE OF OR INABILITY TO USE THIS PRODUCT, EVEN IF THE COMPANY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ANY CASE, THE COMPANY'S AND ITS SUPPLIERS' ENTIRE LIABILITY UNDER ANY PROVISION OF THIS AGREEMENT SHALL BE LIMITED TO THE AMOUNT ACTUALLY PAID BY YOU FOR THE PRODUCT. BECAUSE SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF LIABILITY FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES, THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THE PROVISIONS OF THIS AGREEMENT ALLOCATE THE RISKS BETWEEN COMPANY AND CUSTOMER. COMPANY'S PRICING REFLECTS THIS ALLOCATION OF RISK AND BUT FOR THIS ALLOCATION AND LIMITATION OF LIABILITY, COMPANY WOULD NOT HAVE ENTERED INTO THIS AGREEMENT.

These terms and conditions are the commercial terms of purchase of Products from Statison Medical, Inc. and its subsidiaries and affiliates ("Company") and apply to all purchases from Company by any purchaser with notice however gained ("Customer") including the use of Company's website. Company's offer to sell Products to Customer is expressly limited to and conditioned on Customer's acceptance of these terms and conditions. No additional or different terms or attempted exclusions or modifications by way of order summary, acceptance, confirmation, communication, course of performance or otherwise, shall be effective against Company in the absence of the express written consent of Company; any attempt by Customer to add, exclude or modify the terms is objected to and will be of no force or effect. The contract between Company and Customer, including these terms and conditions, which are incorporated in, and are a part of each purchase order, requisition, shipping instruction and other document, whether expressed in written form, by electronic data interchange or other tangible format, relating to Products purchased by Customer from Company, shall be referred to as the "Agreement."

1. **Delivery**. Statison Medical shall use its reasonable efforts to deliver the Equipment to Customer on the delivery date set forth in signed purchase order or this Agreement. Delivery shall be made F.O.B. at Statison Medical's offices in Arcadia, California. If the delivery is not made within 10 days of the scheduled delivery date, other than because of the fault of Customer or by *force majeure*, Customer may cancel its purchase of the Equipment. All transportation, shipping and handling charges shall be paid by Customer. Customer bears all risk of loss or damage to the Equipment after delivery to the transportation shipping point.

2. **Operation of the Equipment**. Customer shall be responsible for operation of the Equipment. Customer shall operate the Equipment in a reasonably competent manner and in compliance with the operations manual for the Equipment. Customer shall comply with all applicable rules, laws, and regulations in connection with operation of the Equipment.

3. **Infringement Indemnity**. Statison Medical will defend and indemnify Customer against a claim that the Equipment infringes a United States copyright or patent, provided that: (a) Customer notifies

Company in writing within 30 days of the claim; (b) Company has sole control of the defense and all related settlement negotiations; and (c) Customer provides Company with the assistance, information and authority necessary to perform Company's obligations under this Section. Reasonable out-of-pocket expenses incurred by Customer in providing such assistance will be reimbursed by Company. Company shall have no liability for any claim of infringement based on use of Equipment altered by Customer. In the event the Equipment is held or is believed by Company to infringe, Company shall have the option, at its expense, to (a) modify the Equipment to be non-infringing; (b) obtain for Customer a license to continue using the Equipment; or (c) refund the fees paid for the Equipment. This Section 3 states Company's entire liability and Customer's exclusive remedy for infringement, misappropriation or related claims.

4. Disclaimers and Warranty.

(a) Company warrants to the original purchaser of Equipment that for the Warranty Period (as defined below), the Equipment will be free from material defects in materials and workmanship. The foregoing warranty is subject to the proper installation, operation and maintenance of the Equipment in accordance with installation instructions and the operating manual supplied to Customer. Warranty claims must be made by Customer in writing within sixty (60) days of the manifestation of a problem. Company's sole obligation under the foregoing warranty is, at Company's option, to repair, replace or correct any such defect that was present at the time of delivery, or to remove the Equipment and to refund the purchase price to Customer.

(b) The "Warranty Period" begins on the date the Equipment is shipped and continues for twelve (12) months.

(c) Any repairs under this warranty must be conducted by an authorized Company service representative.

(d) Excluded from the warranty are problems due to accidents, misuse, misapplication, storage damage, negligence, or modification to the Equipment or its components.

(e) Company does not authorize any person or party to assume or create for it any other obligation or liability in connection with the Equipment except as set forth herein.

(f) THE INDEMNITY AND WARRANTY ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER INDEMNITIES OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

5. Finance Charge/Costs of Collection. Any amount not paid when due shall accrue a late charge at a rate of one and one-half percent (1.5%) per month (eighteen percent (18%) per year), or the maximum rate provided by law, whichever is less. If Customer is delinquent in paying any amount owed to Company by more than ten (10) days, then without limiting any other rights and remedies available to Company under the law, in equity, or under contract, Company may (i) suspend production, shipment and/or deliveries of any or all Products purchased by Customer, or (ii) by notice to Customer, treat such delinquency as a repudiation by Customer of the portion of the Agreement not then fully performed, whereupon Company may cancel all further deliveries and any amounts unpaid hereunder shall immediately become due and payable. Customer shall pay all collection costs incurred by Company including, but not limited to, collection agency fees, attorneys' fees and court costs. Customer hereby represents to Company that Customer is now solvent and agrees that each acceptance of delivery of the Products sold hereunder shall constitute reaffirmation of this representation at such time.

6. Force Majeure. Neither party shall be liable for any damages or delays caused by or in any manner arising from fires, floods, accidents, riots, acts of God, war, governmental interference or embargoes, strikes, labor difficulties, any shortage of labor, fuel, power, materials or supplies, transportation delays, delays in deliveries by Company's vendors or any other cause or causes (whether or not similar in nature to any of these hereinbefore specified) beyond such party's control.

7. Miscellaneous.

(a) Governing Law. This Agreement, and all matters arising out of or relating to this Agreement, shall be governed by and construed in accordance with the laws of the State of California (exclusive of conflict of laws principles whether of the State of California or any other jurisdictions), and shall be deemed to be executed in County of Los Angeles, State of California, and each party hereto irrevocably submits to the jurisdiction of the state and federal courts sitting in the County of Los Angeles, State of California, for the adjudication of any disputes arising hereunder.

(b) Attorneys' Fees. Any legal action or proceeding brought to enforce or interpret or

otherwise relating to any part of this Agreement and/or the rights or obligations of any of the parties involved in the Agreement shall be instituted solely in a state or federal court in the county of Los Angeles, California. Statison Medical and Customer agree to submit to the jurisdiction of, and agree that venue is proper in, these courts in any such legal action or proceeding. The prevailing party in such action shall be entitled to recover as an element of such party's costs, in addition to any damages to be awarded to it, reasonable attorneys' fees and expenses, and court costs.

(c) Severability. If any provision of this Agreement is invalid or unenforceable under any statute, regulation, ordinance, executive order or other rule of law, such provision will be deemed reformed or deleted, as the case may be, but only to the extent necessary to comply with such statute, regulation, ordinance, order or rule, and the remaining provisions of this Agreement will remain in full force and effect.

(d) All notices, including notices of address change, required to be sent hereunder shall be in writing and shall be deemed to have been given when mailed by first class mail or by fax to the address or fax listed herein – 1843 Stone House Road, Arcadia, CA 91006// fax (800) 806-8756.

(e) Prices for Equipment specified herein are exclusive of all city, state and federal taxes, including, without limitation, taxes on manufacture, sales, receipts, gross income, occupation, use and similar taxes. Customer agrees to pay such taxes directly or to reimburse Statison Medical for all such taxes, whether imposed on Customer required to be collected by Statison Medical, or imposed on Equipment or on Customer in connection with this sale. Wherever applicable, such tax or taxes shall be added to the invoice as a separate charge on invoiced separately. Customer agrees to pay all personal property taxes that may be levied against Equipment after the date of delivery.

(f) To secure payment and performance of all Customer's obligations hereunder, Statison Medical hereby retains title to Equipment and a security interest therein until payment in full and performance by Customer of all said obligations. When requested by Statison Medical, Customer shall duly acknowledge this Agreement, and execute, acknowledge and deliver to Customer, in Statison Medical's usual form, a supplement hereto, security agreement, financing statement and other appropriate instruments to constitute Equipment as the unencumbered security for the obligations of Customer hereunder, or to enable Statison Medical to comply with all applicable filing or recording laws.

(g) The waiver by either party of any default or breach of this Agreement shall not constitute a waiver of any other or subsequent default or breach. Except for actions for non-payment or breach of Statison Medical's proprietary rights, no action, regardless of form, arising out of or in connection with this Agreement may be brought by either party more than one year after the cause of action has accrued.

(h) Customer agrees to comply fully with all relevant export laws and regulations of the United States ("Export Laws") to assure that the Equipment is not (1) exported, directly or indirectly, in violation of Export Laws; or (2) intended to be used for any purposes prohibited by the Export Laws. Customer agrees that the Equipment will only be used or operated in the United States and other territories approved in writing by Statison Medical or in countries or territories where Statison Medical's products are legally available for purchase.

(i) Relationship of the Parties. Seller (Statison Medical) and Purchaser are independent contracting parties. Nothing in this Agreement shall be construed to create a partnership, joint venture or agency relationship between the parties. Nothing in this Agreement makes either party the agent or legal representative of the other party for any purpose whatsoever, nor grants either party any authority to assume or create any obligation on behalf of or in the name of the other party.

(j) Entire Agreement. This Agreement constitutes the complete agreement between the parties with respect to its subject matter and supersedes, terminates and otherwise voids any and all prior or contemporaneous agreements, understandings, representations, discussions, proposals, literature, and the like, written and/or oral between the parties with respect to all Statison Medical Products and services. There are no warranties, representations, or understandings of any kind or description whatsoever made by either party to the other, except such as are expressly set forth herein. This Agreement may not be modified or amended except in a writing signed by a duly authorized representative of

each party; no other act, document, usage or custom shall be deemed to amend or modify this Agreement. It is expressly agreed that the terms of this Agreement shall supersede the terms in any Customer purchase order or other ordering document, if any.

(k) In any proceeding brought to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to recover its attorneys' fees and costs incurred.

(l) This Agreement shall be construed as to its fair meaning and not strictly for or against either party.

(m) Statison Medical shall not be deemed to be in default of any provision of this Agreement, or for failures in performance, resulting from acts or events beyond its reasonable control. Such acts shall include but not be limited to acts of God, civil or military authority, civil disturbance, war, strikes, fires, other catastrophes, labor disputes, parts shortages, or other events beyond Statison Medical's reasonable control.

(n) No action, regardless of form, arising out of this Agreement may be brought by either party more than one year after the cause of action arose, or in the case of non-payment, more than two years from the date of last payment.

(o) This Agreement is not assignable, directly or indirectly, by Customer.

(p) This Agreement may be executed in counterparts and by fax.