

**TITLE:** Preliminary Protocol for Intense Therapeutic Ultrasound for the Treatment of Chronic Plantar Fasciitis

**PROTOCOL NO.:** WIRB® Protocol #20160753

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## Background

Chronic Plantar fasciitis (CPF) is a common cause of plantar heel pain that is a result of a degenerative process of the plantar fascia and its surrounding perifascial structures [1]. It is the most common cause of heel pain, affecting 10% of the U.S. population, and one of the most common foot and ankle problems [2]. One study showed that individuals with this disease scored significantly lower in general health-related quality of life in addition to foot specific quality of life (pain and function) [3]. In addition to a decreased quality of life, significant financial costs arise for these individuals: it is estimated that annual cost of treating this disease in the United States is 192-376 million dollars [4].

The plantar fascia, or plantar aponeurosis, originates on the posterior tuberosity of the calcaneus and inserts into the proximal phalanges of the toes. It acts like a cable, which tightens with flexion of the metatarsophalangeal joints, the "windlass" mechanism, thereby restoring the arch during mid-stance, stiffening the medial column of foot for pushoff and transferring the force of the gastrocnemius muscle contracture to the ground [5]. Although the exact etiology of CPF is unclear, the predominance of evidence indicates that it is the combination of age and overuse which lead to degenerative changes within the fascia that result in the symptoms associated with this disease [1]. The most common presentation for patients with plantar fasciitis include pain with the first few steps in the morning, pain at the beginning of the activity that resolves with continued activity, pain and stiffness with prolonged standing, and pain at the end of the day [6].

The diagnosis of CPF is made clinically based on history and physical exam [6]. Confirmation with diagnostic imaging may be necessary when the symptoms are atypical or are refractory to treatment. MRI is a useful diagnostic tool to evaluate for plantar fascia thickening and edema in and around the fascia, both of which are consistent with the diagnosis of CPF. In addition, many physicians use MRI to exclude other causes of plantar heel pain [7]. Ultrasound can also be used to quantify the thickness of the plantar fascia. Multiple studies have shown that patients with CPF have increased thickness of the fascia compared to asymptomatic individuals [8-12]. Mean thickness in these studies for subjects with CPF range from 4.8-6.5 mm as opposed to 2.3-4.0 mm for subjects without the disease [8-13]. One of the studies showed that the thickness was increased in medial, central and lateral bands of plantar fascia uniformly along with 68% of patients with CPF reporting central band tenderness as opposed to 26% having lateral band tenderness [12]. In addition to the evidence of inflammation [9], the presence of a hyperechoic lesion in the plantar fascia was noted in 68% [10] to 84% [8] of patients with

CPF. Diagnostic ultrasound has also been used to quantify the effectiveness of treatments such as extra-corporeal shock wave therapy, NSAIDs and Botox injections for subjects with CPF [11, 13].

More than twenty different treatments have been used for plantar fasciitis [14]. The combination of rest, ice, stretching and NSAIDs are used as initial management in most patients and have been shown to effectively treat symptoms in 90% of patients in less than 12 months [6]. However, 10% of patients fail conservative management and continue to have symptoms beyond 12 months (termed refractory plantar fasciitis or RPF) [1, 15, 16]. Surgery consisting of partial plantar fascia release or gastrocnemius recession is often considered in these patients. However, the outcomes of surgery are not uniformly positive with 50% of patients having residual symptoms. Moreover, evidence supporting surgical treatment of RPF is weak as there are no randomized controlled trials comparing its efficacy to other treatments. Thus, for many patients the risks of surgery such as arch instability, prolonged wound healing, and longer rehabilitation times simply outweigh the benefits [1]. ITU may be a non-invasive treatment that can be used as an adjunct to speed healing in patients with CPF and as an alternative to surgery in those with RPF.

### ***Intense Therapeutic Ultrasound (ITU)***

Various types of ultrasound have been used to treat soft tissue injuries since the 1930s [17]. Intense therapeutic ultrasound (ITU) is a recently developed ultrasound based therapy in which sound waves are concentrated to produce selective thermal coagulative change over a small area while leaving the remaining regions unaffected [18]. ITU has been used clinically for treating the facial skin for the past decade and it has recently received FDA approvals for non-surgical brow and submental tissue lifting. Over 1,000,000 patients worldwide have been treated using this technology. Clinical studies have shown that 85% of subjects receiving this treatment on facial skin tissue showed an improvement in facial lifting with no significant pain, erythema, inflammation or scarring [19, 20]. Histologically, it has been shown that ITU induces the production of dermal collagen with thickening of the dermis and straightening of the elastic fibers in the reticular dermis [18]. On-going research in our laboratory has shown that ITU can improve healing of damaged Achilles tendon in a rabbit model [21]. Preliminary results showed an increase in markers for wound healing (e.g. VEGFa, TNF  $\alpha$ , IL-1  $\beta$ , and TGF  $\beta$  1) and a decrease in markers for scar tissue formation (e.g. COL1a1, COL1a2, and COL2a1) in injured rabbit tendon treated with ITU compared to injured, untreated rabbit tendon. These results have led us to want to explore the possibility using ITU to treat patients with CPF.

Sept 2014 – present, ITU treatment for Plantar Fasciosis is currently being studied at the University of Arizona (University of Arizona - IRB approval #: 1404296558). To date we have completed 28 subjects with no adverse effects noted. Preliminary results were published August, 2015<sup>[27]</sup>.

### ***Purpose of Study***

The purpose of this study is to assess the effectiveness of ITU in the treatment of CPF by assessing pain, function, and change in perifascial lesions treated with ITU in addition to standard of care. The primary outcome measures will be clinical grading for plantar fasciitis/osis grading and subject reported questionnaires where pain, function and level of activity will be compared before, during and at 24 weeks after the first of 2 treatments. In addition diagnostic ultrasound images will assess the change of any perifascial hypoechoic lesions. Finally, the safety and tolerability of ITU will be monitored through the course of the study. It is hypothesized that patients receiving ITU in addition to standard of care will have a more rapid resolution of their pain, faster return to activities, and a decrease in perifascial lesions.

### ***Materials and Methods***

The **primary objective** of this study is to evaluate the efficacy of combining intense therapeutic ultrasound (ITU) with standard care, including post-treatment therapy, exercises and boot immobilization for the treatment

of chronic plantar fasciitis/osis. A **secondary objective is to** evaluate the tolerability and safety of intense therapeutic ultrasound in the treatment of plantar fasciitis.

These objectives will be accomplished through the following specific aims:

**Aim # 1:** Compare subject reported outcomes of pain, function and level of activity for all subjects before and after treatment. Follow the subjects for 24 weeks by clinic visits and phone surveys.

**Aim # 2:** Compare the changes in perifascial lesion volume for all subjects before and after treatment by diagnostic ultrasound imaging. Follow the subjects for 12 weeks by clinic visits.

**Aim # 3:** Evaluate the tolerability and safety of ITU for the treatment of the chronic plantar fasciitis.

### ***Selection of Subjects***

The study population will consist of up to 30 subjects recruited from the associated UCLA outpatient clinics. The selection of suitable subjects will be made according to the inclusion and exclusion criteria described below.

#### ***Inclusion Criteria***

Male and female adults (18 to 70 years) with plantar heel pain and point tenderness near the medial calcaneal insertion of the plantar fascia for at least three months without improvement will be considered for inclusion into the study.

Subjects must be willing and able to follow post treatment regimen including immobilization boot for 2 - 4 weeks after each treatment, and massage therapy.

#### ***Exclusion Criteria***

Subjects with diabetes or other circulatory issues that might impede healing, bilateral plantar heel pain, current systemic or local infection (within the last 30 days), previous foot surgeries, other previously diagnosed foot/ankle pathologies (inflammatory arthritis, gout, neurologic disorders, connective tissue disorders, bone spurs and fragments and malignancy), unwilling or unable to complete post regimen, and pregnancy will be excluded. Also excluded are subjects with thick calluses on their heel, making ultrasound imaging and treatment of the plantar fascia difficult.

### ***Interventions***

Standard of care treatment will include massage 5 minutes daily as defined by PI and the use of an immobilization boot along with an orthotic insert for 2 to 4 weeks after the each treatment. The decision to continue or discontinue the boot will be made during the follow-up phone call 2 weeks after each treatment. The caller will discuss (Appendix 1-F) the subject's progress and come to a decision on continuing or stopping the use of the boot. When it is determined that a subject can stop using the boot, they will continue to use the orthotic insert in firm soled shoe that does not flex or bend – Tennis shoe, platform, wedge, Birkenstock or FitFlop™ sandal. At that point the subject can resume light activities: Walking on a flat, hard surface (no hiking trails), bicycling and light exercises. Subject will massage region twice a day for 2 ½ minutes per each time, total 5 minutes/day.

During Visit 2 (4 weeks after the first treatment), subjects will receive a second treatment if heel pain is not 90% resolved. The use of the boot and orthotic will resume as defined after the first treatment. If a week 4 visit is not possible we will allow a 2<sup>nd</sup> treatment at week 6, if such treatment is deemed necessary. If a 2<sup>nd</sup> treatment is moved to week 6, subsequent follow-up dates will be adjusted accordingly. ITU treatments will be performed using a GEN III system (Guided Therapy Systems, Mesa, AZ, Appendix 4). Trained study personnel will conduct the treatments. The treatment session will last 15 – 20 minutes. During this time the subjects will be required to lay prone on an exam table with their feet hanging over the end of the table. An average energy up to 5 joules / thermal zone will be administered to the plantar fascia in a linear pattern (Figure 1) with up to 360 thermal zones. Each thermal zone will be less than 1 mm<sup>3</sup> in volume, centred at 10 - 15 mm depth, and approximately 1-3 mm apart.

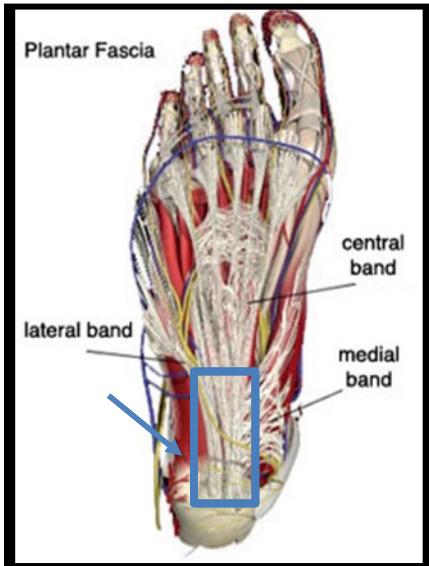


Figure 1: The treatment site located around the insertion of the plantar fascia onto the posterior process of the calcaneus

#### Treatment pattern transverse across the Plantar Fascia:

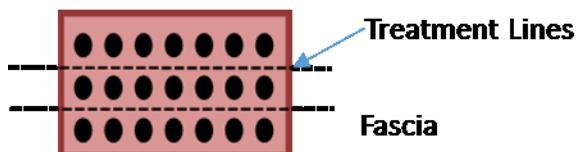


Figure 2. Treatment Zones

#### Outcome measures

Subjects will complete subject reported outcome instruments, and will undergo a focused physical examination and diagnostic ultrasound at 0, 4, 8, 12 weeks. At 2, and 24 weeks a phone survey will be administered by the Clinical Coordinator using the same subject report outcome questionnaires. Adverse events, if any, and treatment tolerability will be recorded at each visit and 2-3 days after each treatment.

#### Aim 1: Subject reported outcomes and structured physical exam

The principal aim of this study is to demonstrate the efficacy of treatment and time course of response to treatment and post treatment regimens using validated subject reported outcome measures assessing pain, function and level of activity and structured physical examination. Subjects will complete validated subject reported outcome questionnaires assessing pain, function and level of activity prior to initiating treatment and at 4, 8, 12, and 24 ( 24 week surveys will be completed by a phone interview) weeks after starting treatment. Subjects will also be contacted 2-3 days following each treatment to assess treatment tolerability and to document and address adverse effects (if any). They will also be contacted by phone 2 weeks after

treatment(s) to assess progress and determine if the boot can be discontinued.

**Pain** will be assessed using the of the foot function index pain subscale (FFI-P) and the subject reported outcome measures (SROM). These two instruments have been used to assess pain in previous studies of plantar fascia treatments. [22, 23]

**Function** will be assessed using two validated PRO instruments the PROMIS PF CAT and the FAAM. The PROMIS PFCAT is a subject relevant outcome measure that uses computer adaptive survey questions to assess the subject's pain and function in relation to daily activities [24]. The FAAM has been shown to be a reliable, responsive, and valid measure of physical function for individuals with a broad range of musculoskeletal disorders of the lower leg, foot, and ankle [25].

**Level of Activity** will be assessed using the activity subscale of FAAM. This subscale scores quantitatively the level of difficulty subjects face when they perform basic activities of daily living. It has shown to be an accurate and reliable predictor of the activity level while performing day-to-day activities [25]

**Structured physical examination** will consist of assessment of hindfoot and midfoot alignment, inspection for swelling, palpation of the calcaneus and entire plantar fascia, range of motion of the ankle with the knee flexed and with the knee extended, and calcaneal squeeze test. Pertinent positive findings on exam include: valgus hindfoot, midfoot planus, tenderness to palpation at the insertion of the plantar fascia onto the calcaneus, ankle dorsiflexion less than 10 degrees with the knee extended or greater than 10 degree augmentation in ankle dorsiflexion with the knee flexed. Pertinent negative findings include: lack of swelling at the ankle and midfoot, no tenderness at the Achilles insertion, the retrocalcaneal bursae, along the arch, posterior to the medial malleolus, or at Baxters point, and positive calcaneal squeeze test.

#### Statistical analysis

Data will be assessed for variance homogeneity and normality. FFI-P scores, PFCAT, FAAM scores before and after intervention will be compared using a paired t-test. Perifascial lesion volume is measured before and at each post treatment clinical visit using diagnostic ultrasound imaging, and paired t-tests will be utilized for comparison. For determination of statistical significance, a cutoff value of  $\alpha=0.05$  has been selected prior to start of data analysis.

#### Aim 2: Assessment of Perifascial Hypoechoic Lesions

Diagnostic ultrasound imaging will be performed with an FDA 510(k) cleared ultrasound scanner (Spark® System, Ardent Sound, Inc. – Mesa, AZ, see Appendix 5) using a coupling gel (Polysonic® Parker Laboratories, Inc., Fairfield, NJ, see Appendix 6) by a trained sonographer or physician. The subject will positioned prone on an exam table with the feet over the edge of the table. The plantar fascia of the affected and contralateral feet will be imaged. The thickness and depth of the fascia as well as the size and location of any hypoechoic lesion(s), when present, will be recorded using both long and short axis imaging. Change in the volume of hypoechoic plantar fascial lesions relative to the baseline measurement will be calculated.

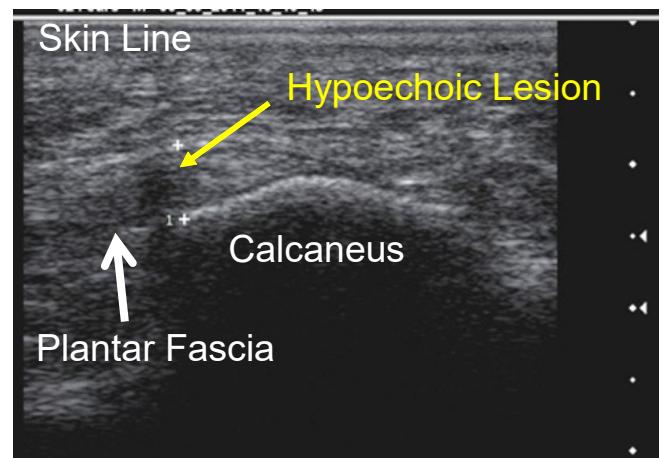
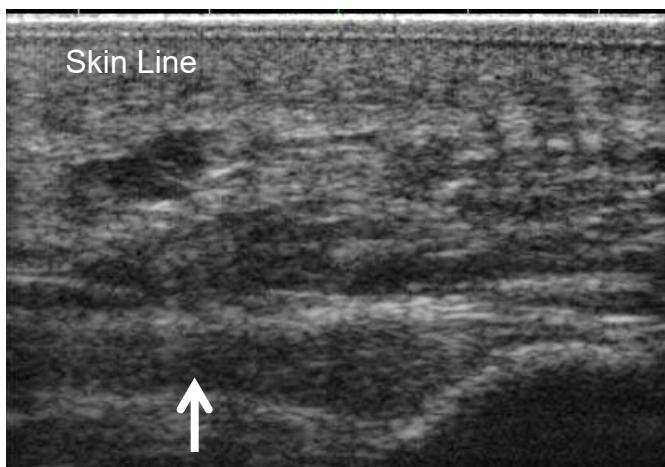


Figure 4: representative long and short axis ultrasound images

### **Aim 3: Assessment of safety and tolerability**

Subject self-assessments of treatment tolerability will be conducted immediately after, two –three days after (phone survey) and two weeks after (phone survey) treatment using a10-point visual analog scale (VAS, see Appendix 1). The subject will be asked to report their current level of pain and the maximum level of pain experienced over the last few days. The VAS is the standard for assessing pain for both clinical and research purposes [26]. All phone surveys will be completed by the Clinical Coordinator. Any adverse effects will be noted and addressed during these phone calls.

Recording of adverse events will take place at all clinic visits and follow-up phone calls (see adverse event reporting form Appendix 3). Adverse events and serious adverse events will be monitored throughout the study.

**Timeline**

Procedures	Visit 0	Visit 1	Visit 1 Follow-up Phone Interview Treatment Tolerability	Treatment 1 Follow-up Phone Call: Boot Decision	Visit 2	Visit 2 Follow-up Phone Interview Treatment Tolerability	Treatment 2 Follow-up Phone Call: Boot Decision	Visit 3	Visit 4	Phone Interview Subject's Progress Survey 2	Responsibility
	Baseline -14 - 0 Days	Week 0	Week 0 (+ 2 or 3 days)	Week 2	Week 4	Week 4 (+ 2 or 3 days)	Week 6	Week 8	Week 12	Week 24	
IC, eligibility paperwork, exam for inclusion criteria	X										PI/Clinical Coordinator (CC)
Ultrasound Imaging		X			X			X	X		GTS or PI
ITU Treatment		X			X (If required)						GTS or PI
TBD Clinical grading for Plantar Fasciitis severity	X	X			X			X	X		PI (cc documentation)
Subject Survey – Pain Scale and Ankle Mobility Scale		X			X			X	X	X Phone Interview	Subject (cc documentation)
Boot and Instructions		X		X			X If 2nd Treatment is Performed				PI (cc documentation)
Shoe, Insert and Instructions		X		X			X If 2nd Treatment is Performed				PI/CC
Follow-up call Treatment Tolerability			X			X If 2nd Treatment is Performed					PI/CC
Telephone Interview & Determine if Boot is continued (Week 2 and 6 only)				X			X If 2nd Treatment is Performed				PI/CC

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## Appendix 1: Patient reported outcome measures

### Appendix 1-A: PROMIS LE CAT

#### PFA1\_IADL

Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports? \_\_\_\_\_

5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

#### PFA10\_Lower

Are you able to stand for one hour? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 = Unable to do

Are you able to do chores such as vacuuming or yard work? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 = Unable to do

#### PFA12\_Lower

Are you able to push open a heavy door? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 = Unable to do

#### PFA13\_IADL

Are you able to exercise for an hour? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 = Unable to do

#### PFA14\_Lower

Are you able to carry a heavy object (over 10 pounds)? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 = Unable to do

#### PFA15\_Lower

Are you able to stand up from an armless straight chair? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 = Unable to do

#### PFA19\_Lower

Are you able to run or jog for two miles? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 = Unable to do

#### PFA21\_Lower

Are you able to go up and down stairs at a normal pace? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 = Unable to do

Are you able to go for a walk of at least 15 minutes? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 = Unable to do

**Appendix 1-A: PROMIS LE CAT, Continued****PFA25\_IADL**

Are you able to do yard work like raking leaves, weeding, or pushing a lawn mower? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFA29\_Central**

Are you able to pull heavy objects (10 pounds) towards yourself? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFA3\_Central**

Does your health now limit you in bending, kneeling, or stooping? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**PFA30\_Lower**

Are you able to step up and down curbs? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFA31\_Lower**

Are you able to get up off the floor from lying on your back without help? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFA32\_Lower**

Are you able to stand with your knees straight? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

Are you able to exercise hard for half an hour? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFA37\_Central**

Are you able to stand for short periods of time? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFA39\_Lower**

Are you able to run at a fast pace for two miles? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFA4\_IADL**

Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or  
 moving heavy furniture? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**Appendix 1-A: PROMIS LE CAT, Continued****PFA41\_Lower**

Are you able to squat and get up? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
Unable to do**PFA42\_Lower**

Are you able to carry a laundry basket up a flight of stairs? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
Unable to do**PFA45\_IADL**

Are you able to get out of bed into a chair? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
Unable to do

Are you able to bend or twist your back? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
Unable to do**PFA5\_IADL**

Does your health now limit you in lifting or carrying groceries? \_\_\_\_\_

5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**PFA51\_IADL**

Are you able to sit on the edge of a bed? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
Unable to do**PFA53\_IADL**

Are you able to run errands and shop? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
Unable to do**PFA56\_IADL**

Are you able to get in and out of a car? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
Unable to do**PFA6\_IADL**

Does your health now limit you in bathing or dressing yourself? \_\_\_\_\_

5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**PFA7\_Lower**How much do physical health problems now limit your usual physical activities (such as walking or climbing  
stairs)? \_\_\_\_\_

5 = Not at all 4 = Very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

Are you able to move a chair from one room to another? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =

Unable to do

### ***Appendix 1-A: PROMIS LE CAT, Continued***

#### **PFA9\_Lower**

Are you able to bend down and pick up clothing from the floor? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

#### **PFB1\_IADL**

Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or  
 carrying in groceries? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

#### **PFB10\_Lower**

Are you able to climb up five steps? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

#### **PFB11\_IADL**

Are you able to wash dishes, pots, and utensils by hand while standing at a sink? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

#### **PFB12\_IADL**

Are you able to make a bed, including spreading and tucking in bed sheets? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

#### **PFB13\_IADL**

Are you able to carry a shopping bag or briefcase? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

Are you able to take a tub bath? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

#### **PFB24\_Lower**

Are you able to run a short distance, such as to catch a bus? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

#### **PFB3\_IADL**

Does your health now limit you in putting a trash bag outside? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

#### **PFB32\_Lower**

Are you able to stand unsupported for 10 minutes? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

## Appendix 1-A: PROMIS LE CAT, Continued

PFB40\_Lower

**Appendix 1-A: PROMIS LE CAT, Continued**

Are you able to stand up on tiptoes? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

PFB42\_Lower

Are you able to stand unsupported for 30 minutes? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

PFB43\_IADL \_\_\_\_\_

Does your health now limit you in taking care of your personal needs (dress, comb hair, toilet, eat, bathe)?  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

Does your health now limit you in doing moderate activities, such as moving a table, pushing a vacuum cleaner,  
 bowling, or playing golf? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

PFB48\_IADL

Does your health now limit you in taking a shower? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

PFB49\_Lower

Does your health now limit you in going for a short walk (less than 15 minutes)? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

PFB5\_Lower

Does your health now limit you in hiking a couple of miles on uneven surfaces, including hills? \_\_\_\_\_  
 5 = Not at all 4 = Very little 3 = Somewhat 2 = Quite a bit 1 = Cannot do

PFB50\_IADL

How much difficulty do you have doing your daily physical activities, because of your health?  
 5 = No difficulty at all [SEP] 4 = A little bit of difficulty [SEP] 3 = Some difficulty [SEP] 2 = A lot of difficulty [SEP] 1 = Can't  
 do because of health

PFB51\_IADL \_\_\_\_\_

Does your health now limit you in participating in active sports such as swimming, tennis, or basketball?  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

PFB54\_IADL \_\_\_\_\_

Does your health now limit you in going OUTSIDE the home, for example to shop or visit a doctor's office?  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

Does your health now limit you in doing strenuous activities such as backpacking, skiing, playing tennis,  
 bicycling or jogging? \_\_\_\_\_

5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**Appendix 1-A: PROMIS LE CAT, Continued****PFB8\_IADL**

Are you able to carry two bags filled with groceries 100 yards? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFB9\_Lower**

Are you able to jump up and down? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC10\_Lower**

Does your health now limit you in climbing several flights of stairs? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**PFC12\_IADL**

Does your health now limit you in doing two hours of physical labor? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**PFC13\_Lower**

Are you able to run 100 yards? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC20\_Lower**

Does your health now limit you in walking one hundred yards? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**Are you able to walk up and down two steps? \_\_\_\_\_**

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC32\_Lower**

Are you able to climb up 5 flights of stairs? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC33\_Lower**

Are you able to run ten miles? \_\_\_\_\_  
 5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC34\_Lower**

Does your health now limit you in walking several hundred yards? \_\_\_\_\_  
 5 = Not at all [SEP] 4 = Very little [SEP] 3 = Sometimes 2 = Quite a lot 1 = Cannot do

**PFC35\_IADL**

Does your health now limit you in doing eight hours of physical labor? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**Appendix 1-A: PROMIS LE CAT, Continued****PFC36\_Lower**

Does your health now limit you in walking more than a mile? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

**PFC37\_Lower**

Does your health now limit you in climbing one flight of stairs? \_\_\_\_\_  
 5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

Are you able to walk at a normal speed? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC39\_Lower**

Are you able to stand without losing your balance for several minutes? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC40\_Lower**

Are you able to kneel on the floor? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC41\_Lower**

Are you able to sit down in and stand up from a low, soft couch? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC45\_Lower**

Are you able to get on and off the toilet? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC46\_Lower**

Are you able to transfer from a bed to a chair and back? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC47\_Central**

Are you able to be out of bed most of the day? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

Are you able to water a house plant? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

**PFC52\_Axial**

Are you able to turn from side to side in bed? \_\_\_\_\_

5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
 Unable to do

### ***Appendix 1-A: PROMIS LE CAT, Continued***

#### **PFC53\_IADL**

Are you able to get in and out of bed? \_\_\_\_\_  
5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 1 =  
Unable to do

#### **PFC54\_IADL**

Does your health now limit you in getting in and out of the bathtub? \_\_\_\_\_  
5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

#### **PFC56\_Lower**

Does your health now limit you in walking about the house? \_\_\_\_\_  
5 = Not at all 4 = very little 3 = Somewhat 2 = Quite a lot 1 = Cannot do

## Appendix 1-B: Foot and Ankle Ability Measure

### Foot and Ankle Ability Measure (FAAM)

Please answer **every question** with the **one response** that most closely describes your condition within the past week. If the activity question is limited by something other than your foot or ankle mark N/A (not applicable).

	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
1. Standing	<input type="checkbox"/>					
2. Walking on even ground	<input type="checkbox"/>					
3. Walking on even ground without shoes	<input type="checkbox"/>					
4. Walking up hills	<input type="checkbox"/>					
5. Walking Down Hills	<input type="checkbox"/>					
6. Going up stairs	<input type="checkbox"/>					
7. Going down stairs	<input type="checkbox"/>					
8. Walking on uneven ground	<input type="checkbox"/>					
9. Stepping up and down curbs	<input type="checkbox"/>					
10. Squatting	<input type="checkbox"/>					
11. Coming up on your toes	<input type="checkbox"/>					
12. Walking initially	<input type="checkbox"/>					
13. Walking 5 minutes or less	<input type="checkbox"/>					
14. Walking approximately 10 minutes	<input type="checkbox"/>					
15. Walking 15 minutes or greater	<input type="checkbox"/>					

Because of your foot and ankle how much difficulty do you have with:

16. Home responsibilities	<input type="checkbox"/>					
17. Activities of daily living	<input type="checkbox"/>					
18. Personal care	<input type="checkbox"/>					
19. Light to moderate work (Standing or walking)	<input type="checkbox"/>					
20. Heavy work (pushing/pulling, Climbing, carrying)	<input type="checkbox"/>					
21. Recreational activities	<input type="checkbox"/>					

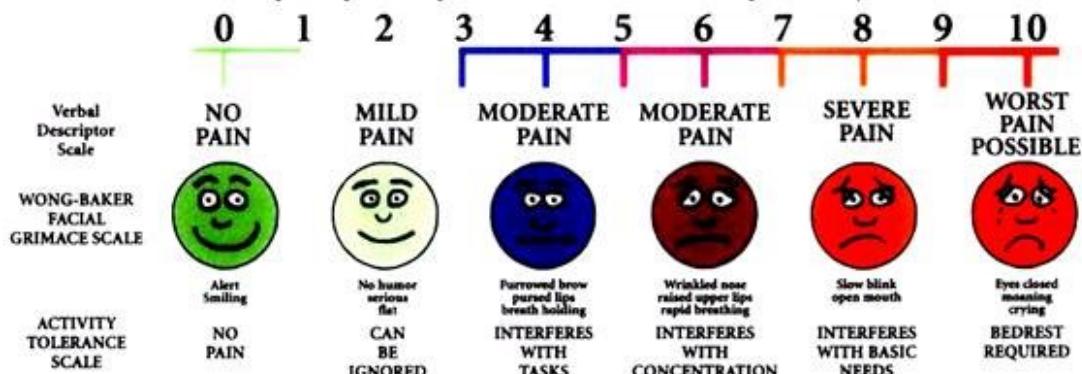
How would you rate your current level of function during your usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities? \_\_\_\_\_ %

### Appendix 1-C: Universal Pain Scale

## UNIVERSAL PAIN ASSESSMENT TOOL

This pain assessment tool is intended to help patient care providers assess pain according to individual patient needs.

Explain and use 0-10 Scale for patient self-assessment. Use the faces or behavioral observations to interpret expressed pain when patient cannot communicate his/her pain intensity.



## Appendix 1-D: Foot function index pain subscale (0 – 10)

How severe is your heel pain?

---

1. At its worst?	No pain	Worst pain imaginable
------------------	---------	-----------------------

---

2. After you get up in the morning with the first few steps?	No pain	Worst pain imaginable
--	---------	-----------------------

---

3. At the end of the day?	No pain	Worst pain imaginable
---------------------------	---------	-----------------------

---

4. When you walk barefoot?	No pain	Worst pain imaginable
----------------------------	---------	-----------------------

---

5. When you stand barefoot?	No pain	Worst pain imaginable
-----------------------------	---------	-----------------------

---

6. When you walk wearing shoes?	No pain	Worst pain imaginable
---------------------------------	---------	-----------------------

---

7. When you stand wearing shoes?	No pain	Worst pain imaginable
----------------------------------	---------	-----------------------

---

8. When walking with orthotics?	No pain	Worst pain imaginable
---------------------------------	---------	-----------------------

---

9. When standing with orthotics?	No pain	Worst pain imaginable
----------------------------------	---------	-----------------------

---

## ***Appendix 1-E: Subject reported outcome measures***

SROM 1.

Compared to your initial visit:

- I feel BETTER OFF than before treatment
- I feel THE SAME as before treatment
- I feel WORSE than before treatment

SROM 2.

Compared to your initial visit, describe your heel pain now:

- I have NO PAIN
- I have LESS PAIN than before the treatment regimen
- I have THE SAME PAIN as before the treatment regimen
- I have MORE PAIN than before the treatment regimen

SROM 3.

What percent improvement in heel pain have you experienced since starting the study?

- None
- 1 to 25%
- 26 to 50%
- 51 to 75%
- 76 to 99%
- 100%

SROM 4.

How do you rate your heel pain since the start of the study treatment?

- All better
- Much better
- Slightly better
- Unchanged
- Worse

SROM 5.

What percent improvement in overall daily function including work and/or recreational activities have you experienced since starting the study?

- None
- 1 to 25%
- 26 to 50%
- 51 to 75%
- 76 to 99%
- 100%

SROM 6.

Regarding the treatment that you received:

- I am TOTALLY SATISFIED with the treatment
- I am SATISFIED with MINOR RESERVATIONS with the treatment
- I am SATISFIED with MAJOR RESERVATIONS with the treatment
- I am DISSATISFIED with the treatment

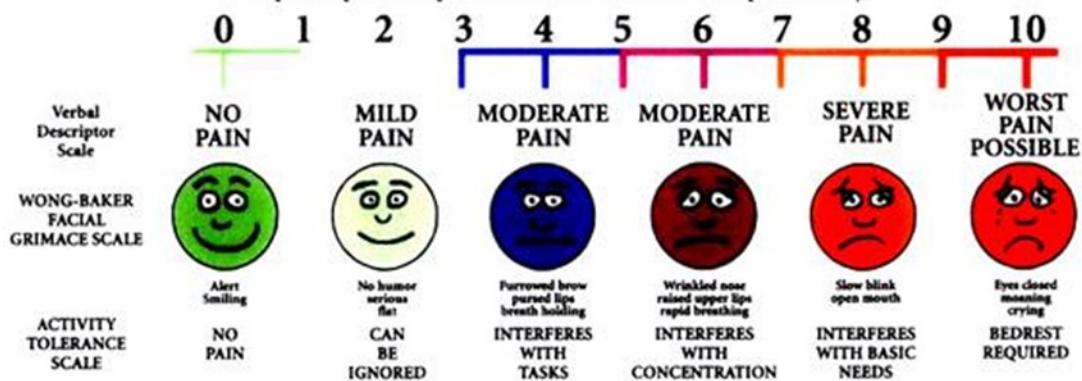
## Appendix 1-F: Boot Continuance Decision Checklist

2 Weeks after Treatment:      1      2  
Circle Appropriate Time

Ask the Subject about their overall pain from a Scale of 0 – 10.  
Mark the Universal Pain Assessment Tool below.

### UNIVERSAL PAIN ASSESSMENT TOOL

This pain assessment tool is intended to help patient care providers assess pain according to individual patient needs. Explain and use 0-10 Scale for patient self-assessment. Use the faces or behavioral observations to interpret expressed pain when patient cannot communicate his/her pain intensity.



If the Subject's assessment of Universal Pain is 3 or less on the scale, the Subject can be advised that they may stop using the boot. They should continue to use the orthotic insert in firm soled shoe that does not flex or bend – Tennis shoe, platform, wedge, Birkenstock or FitFlop™ sandal. The Subject should be reminded that at that point they can resume light activities: Walking on a flat, hard surface (no hiking trails), bicycling and light exercises. Subject will massage region twice a day for 2 ½ minutes per each time, total 5 minutes/day.

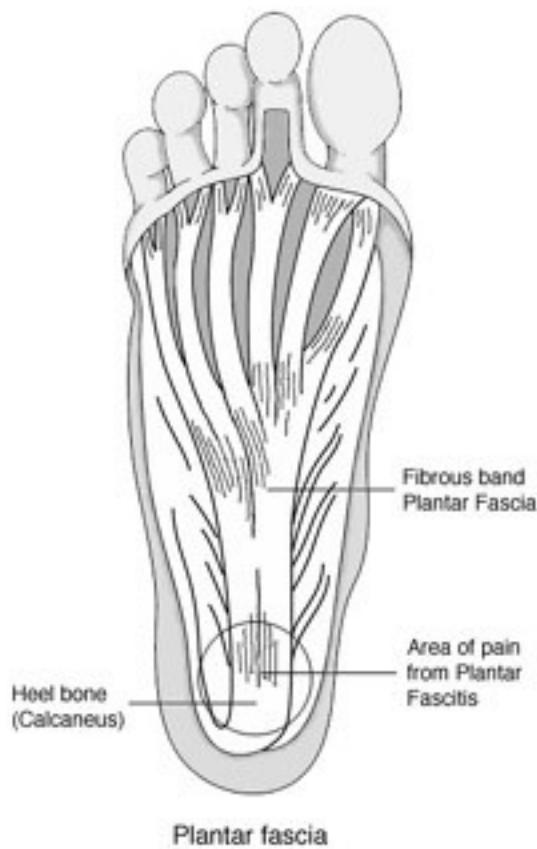
If the Subject's pain is 4 or more, they are to continue to wear the boot and orthotic insert provided by Dr. Baravarian until their next visit.

Circle the Subject's response.

Does the Subject agree to continue wearing the Boot:      Yes      No

Document this Page along with Patient's other responses.

## Appendix 2: Subject Instructional handout



### Plantar Fasciitis

You have been diagnosed with plantar fasciitis (fashee-EYE-tiss), an overuse injury that affects the sole of the foot. A diagnosis of plantar fasciitis means you have inflamed the tough, fibrous band of tissue (fascia) connecting your heel bone to the base of your toes.

You're more likely to get the condition if you're female, overweight or have a job that requires a lot of walking or standing on hard surfaces. You're also at risk if you walk or run for exercise, especially if you have tight calf muscles that limit how far you can flex your ankles. People with very flat feet or very high arches also are more prone to plantar fasciitis.

The condition typically starts gradually with mild pain at the heel bone often referred to as a stone bruise. You're more likely to feel it after (not during) exercise. The pain classically occurs right after getting up in the morning and after a period of sitting.

If you don't treat plantar fasciitis, it may become a chronic condition. You may not be able to keep up your level of activity, and you may develop symptoms of foot, knee, hip and back problems because plantar fasciitis can change the way you walk.

### Diagnostic Ultrasound and ITU Treatment

You will be asked to lie on your stomach with your feet hanging over a wedge shaped pillow. Acoustic coupling lotion will be applied to the bottom of your feet and allowed to soak in. A sonographer will complete a diagnostic ultrasound scan on both feet at each clinic visit for treatment guidance and follow-up evaluation. During the scan, the sonographer will define the treatment area. Additional acoustic coupling lotion will be applied and ITU treatment will be completed. The total diagnostic and treatment time is 15-20 minutes. The first 2 – 3 days after treatment, you may experience a feeling of fullness in your foot and minor discomfort while walking. This is normal and should subside within a few days.

### Immobilization Boot and Orthotic

You have been given an immobilization boot and orthotic. Use them together for up to 4 weeks after treatment as described below:

1. Dr. Baravarian's will provide instructions for wearing the Boot.
2. When the use of the boot is discontinued, wear the orthotic in supportive firm soled shoes that do not flex or bend—Tennis shoe, platform, wedge, Birkenstock or FitFlop™ sandal. Move the orthotic between shoes, and use it with every step you take.

### Massage

Dr. Baravarian will provide instructions for self-massage.

## Appendix 3: Adverse Events Reporting Form

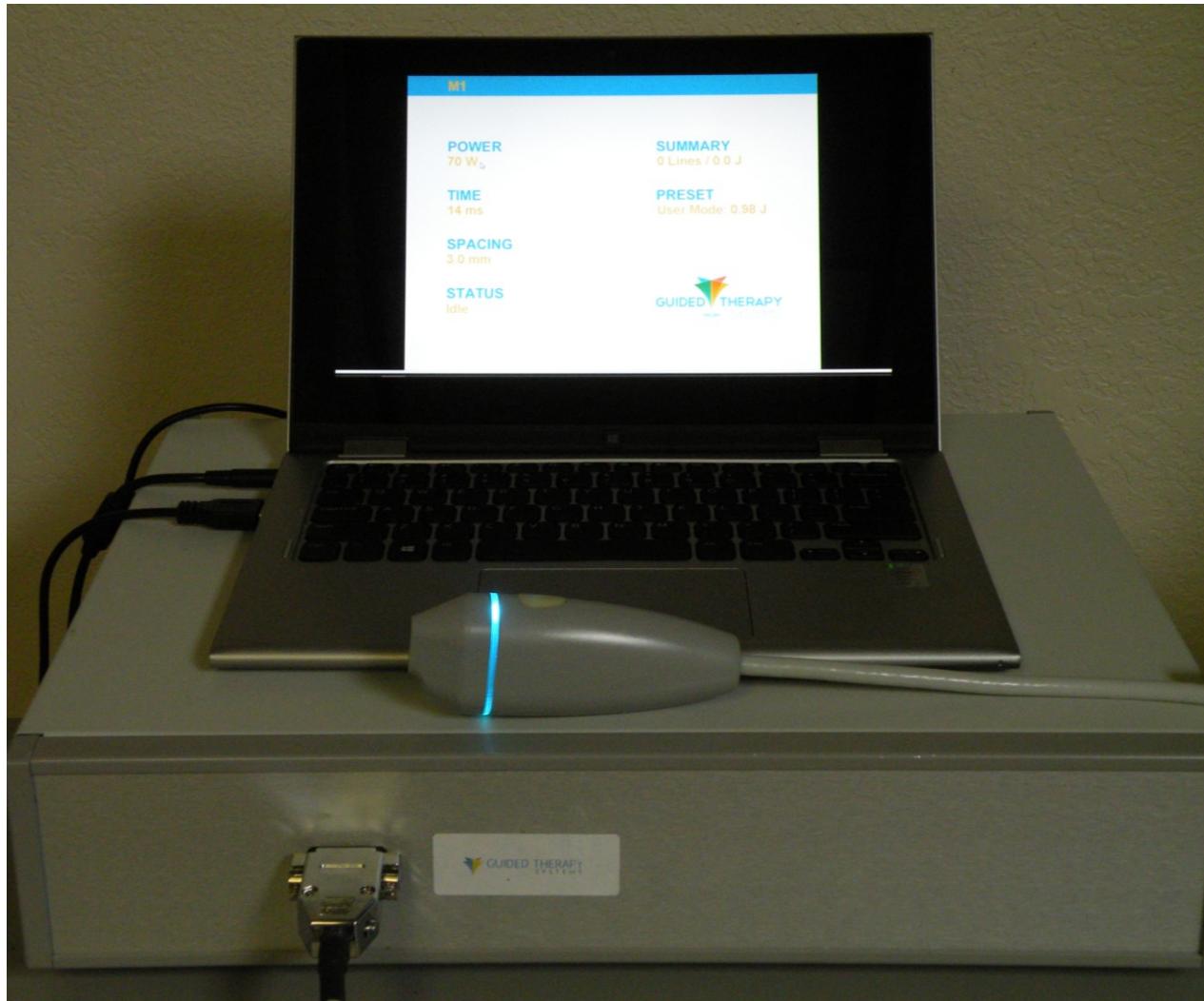
**ADVERSE EVENTS**
**Subject Number\_\_\_\_\_ Initials\_\_\_\_\_**

Event	Date started	Date ended	Ongoing/ Intermittent	Severity	Related to Study	Related to ITU	Action Taken	SAE ?	sig

**Severity:** 1. Mild, 2. Mod, 3. Severe      **Relationship:** 1. Probably    2. Possibly    3. Probably not related    4. Not related

**Action:** 1. None    2. Interrupt Study    3. DC study    4. dose Mod    5. Other Mod    6. Other

## Appendix 4: GEN III Therapy System



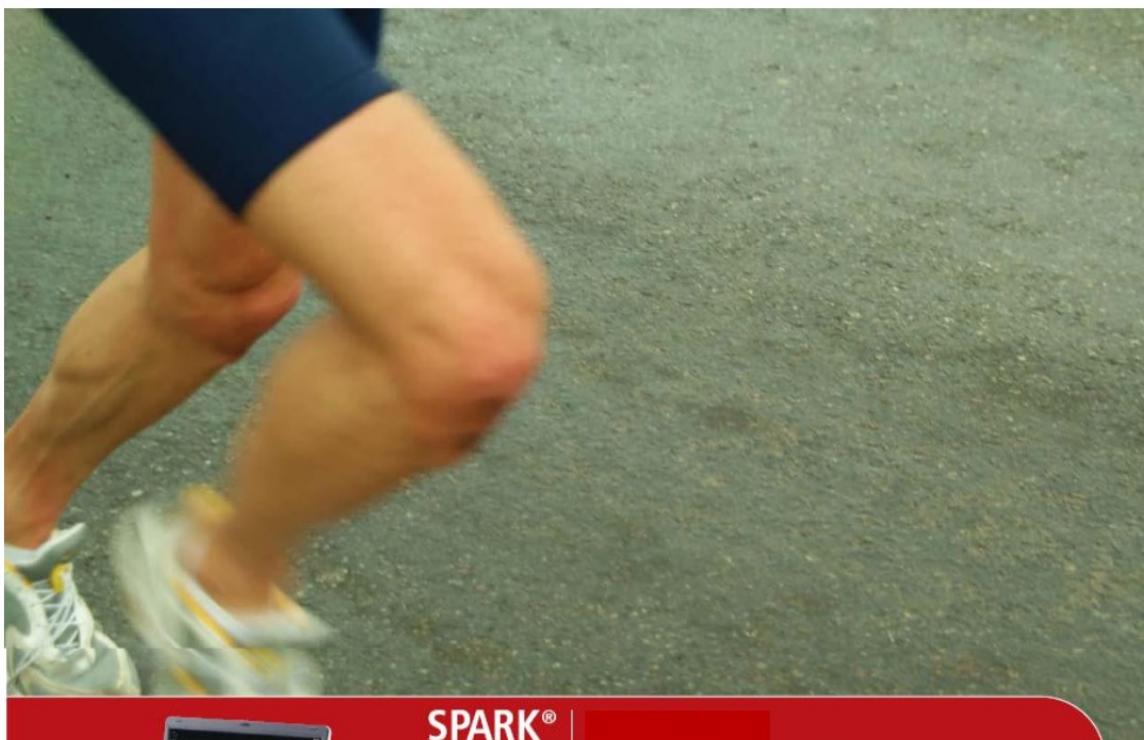
Clinical Prototype GEN III

Power: 3-50 Watts

Frequency: 4 – 10MHz

Energy/Zone: up to 5 Joules (tech. mode)

## Appendix 5: Diagnostic Ultrasound Imaging System



### SPARK® |

Point of Care Ultrasound for Superficial Applications  
such as Musculoskeletal, Skin, and Breast



*The affordable approach to ultra-high resolution  
and deep penetration of the superficial layer.*

#### CHALLENGE

How many times in your practice have you wished that there was a way for you to run a quick scan of something in a patient's superficial layer? How many times have you suspected that a patient had torn cartilage in their knee, a dislocation of a thumb or shoulder, or an early-stage growth on a breast or testicle? Instead of being able to confirm your suspicion on the spot, you were forced to delay diagnosis and treatment while the patient scheduled and underwent comprehensive imaging—often times to confirm what you already knew.

High quality ultrasound for superficial applications have to this point been unaffordable and impractical for Point of Care practices. Requiring large pieces of proprietary equipment and systems, these systems have been cost prohibitive. Until now.

#### SOLUTION

Spark® is a vital breakthrough in Point of Care imaging for superficial structures. Offering unprecedented sensitivity and ultra-high resolution not found on traditional units 10x or more its price point, Spark is revolutionizing ultrasound for front-line physicians with its performance, price, and value. Highly portable, adaptable, and upgradeable, Spark is powered by a standard PC or laptop and can rapidly integrate with your Patient Information System. Spark is a standardized interface peripheral device that connects to your PC via a standard USB connection; it's as easy to install as connecting a mouse (and almost as simple to use).



#### WE CALL IT "PLUG AND KNOW"

- 1 ..... Simply attach the Interface to your computer via a Standard USB (Universal Serial Bus) cable
- 2 ..... Automatically install the software Suite from a CD-ROM
- 3 ..... Immediately gain deeper insights into your patients' condition to improve and accelerate your decision making and/or treatment at the Point of Care



Wide interoperability via USB 2.0

#### Features and Benefits

##### Excellent Image Quality

- Superb Detail and Contrast Resolution
- Wide Bandwidth Architecture
- ArdentView Image Filters
- Capable of Imaging from 5.0MHz - 21MHz (transducer dependent)
- High Frame Rate: up to 139fps

##### Research

- Human: RF Out Capabilities
- Small Animal:
  - RF Out Capabilities
  - 1KHz M-Mode PRF

#### Clinical Utility

##### Superficial Structures

- High Frequency Linear: 5mm - 30mm
- 12MHz Linear Array: 15mm - 45mm

#### Technical Specifications

##### Physical Characteristics

- Height: 10.75 in (273 mm)
- Width: 4.75 in (121 mm)
- Length: 19.00 in (483 mm)
- Weight: 22 lbs (10 kg)

##### Transducer Options

- 5.0 - 8.0 MHz Convex Endo
- 9.0 - 14.0 MHz Linear Array
- 14.0 - 21.0 MHz Linear Array

##### Imaging Modes

- B-Mode
- B-M Mode
- M Mode
- Zoom (Pan)

##### Measurement Tools

- Distance
- Circumference
- Area
- Volume
- Beats/Minute (m-mode)

##### Image Storage & Cine

- Dicom Compatible
- Stores Images and Cine as Raw Data
- Export Images as bmp or jpg
- Export Cine as AVI
- Back-up Database to internal or external Hard Drive, CD, DVD or Network

**Power: 100-240 VAC  
50-60 Hz input**

##### Minimum Computer Requirements

Windows XP OS: USB 2.0 Port, 256 MB RAM, 1 GB Available Hard Drive Space

Windows7/ Vista OS: USB 2.0 Port, 500 MB RAM, >1 GHz Duo-Core Processor\*, 1 GB Available Hard Drive Space

\*assumes Windows7/ Vista Home OS.  
More Advanced Versions of Vista may require a faster processor and more RAM

#### CONTACT INFO

To learn more or purchase Spark, please contact Ardent Sound at 480-649-1806 or [sales@ardentsound.com](mailto:sales@ardentsound.com).



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33 S. Sycamore St. Mesa, AZ 85202-1150 USA

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Protected by US Patents: 6440071, 6049159, 6120452, 6213948 others pending

## Appendix 6: Coupling Gel

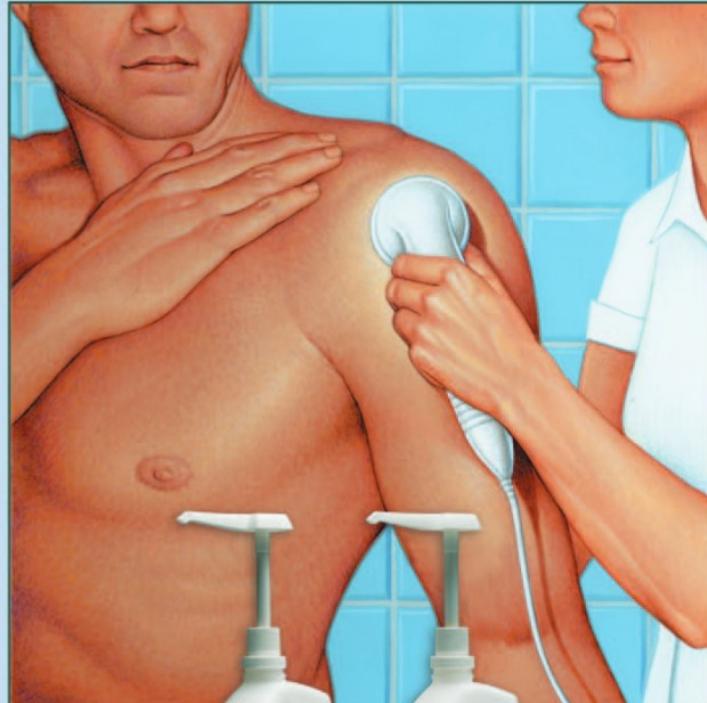
# The best cosmetic quality lotion for medical ultrasound

## Polysonic® Ultrasound Lotion

**W**hen tough injuries call for gentle treatment, POLYSONIC® Ultrasound Lotion combines the pleasing appeal of a fine cosmetic with superior soundwave transmission. It transmits ultrasonic waves more efficiently than most gels, and is acoustically correct for medical ultrasound procedures.

The rich, moisturizing formulation of POLYSONIC® Ultrasound Lotion is the ideal medium for therapeutic ultrasound when followed with massage. It's kind to your skin as well as to your patients... and won't damage your equipment.

Our multi-purpose lotion, **also available with aloe vera**, is recommended for all medical ultrasound procedures... Another world-class quality product from Parker, a company dedicated to quality.



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The sound choice in patient care.™

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## POLYSONIC® ULTRASOUND LOTION

Multi-purpose ultrasound lotion with superior coupling efficiency in a pleasing, cosmetic-quality base. Recommended for all ultrasound procedures when a lotion is preferred. Also available, Polysonic Ultrasound Lotion with Aloe Vera.

### FEATURES

- Rich, moisturizing formula
- Comfortable and pleasing to patient and ultrasound practitioner
- Acoustically correct for the broad range of frequencies used
- Will not damage equipment or stain clothing
- Hypoallergenic, bacteriostatic
- No formaldehyde

Product #	Package Size
21-08	250 ml (8.5 fl. oz.) dispenser, 12 per box
21-28	3.8 liter (1 US gallon) with dispenser, 4 per case (Dispenser pump not included)
21-50	POLYPAC® contains: 4 Polysonic gallons, 2 dispensers and 1 pump
20-08 with Aloe Vera	250 ml (8.5 fl. oz.) dispenser, 12 per box
20-28 with Aloe Vera	3.8 liter (1 U.S. gallon) with dispenser, 4 per case (Dispenser pump not included)
20-50 with Aloe Vera	POLYPAC® contains: 4 Polysonic with Aloe Vera gallons, 2 refillable dispensers and 1 pump



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