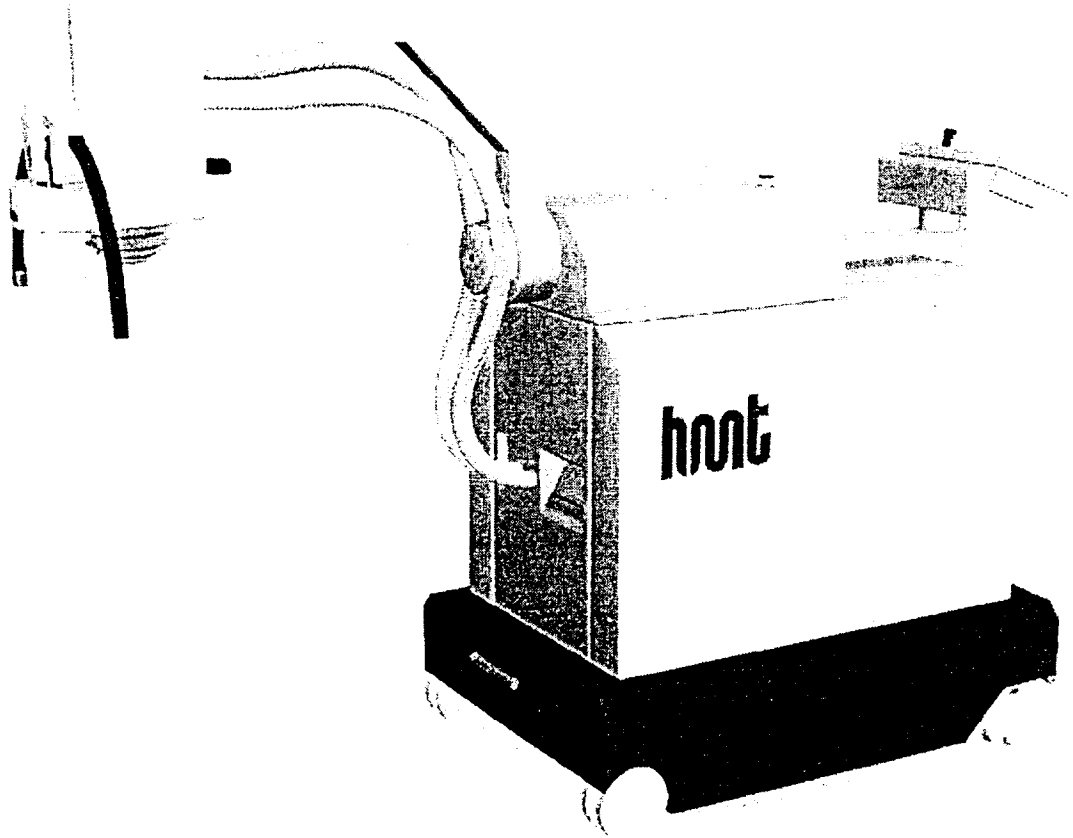


Operating Manual

OssaTron[®]

OSA 120



NOTE

Federal law restricts this device to sale on or by the order of a physician

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Documents for the installation's operator

Operating Manual OSA 120
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Date	Version	Changes
10/27/00	3.0	Complete revision because of new therapy head; new HMT-parts No.
02/28/01	3.1	Elimination of external enable plug (Ä0297)
09/21/01	3.2	change of tolerance limits for the electrical conductivity
10/03/02	3.3	Description of water change update
12/18/02	4.0	Addition of new indication for chronic lateral epicondylitis.

Manufacturer's responsibility

HMT is responsible for the safe operation, reliability, and performance of the OssaTron under the following conditions:

- Installation, adjustment, maintenance, and modification of the device are to be carried out by the employees of HMT or persons authorized by HMT.
- The electrical installation in the relevant room complies with national standards of the respective countries that the OssaTron is marketed.
- The device is operated according to the operating manual.



Regulatory Statement for the United States

CAUTION

Federal law restricts this device to sale on or by the order of a physician.

OSSATRON OSA 120

US Distributor

HealthTronics Surgical Services, Inc.
1841 West Oak Parkway, Marietta, GA 30062

Important instructions concerning operator safety and protection of the device are emphasized below:

WARNING

This heading is used when the patient's or the user's safety could be endangered if instructions concerning suitable use, operating instructions, prescribed operating procedures are not carefully followed.

PRECAUTION

This heading is used when damage to the device can be caused if instructions concerning suitable use, operating instructions, and/or prescribed operating procedures are not carefully followed.

NOTE

This heading indicates technical requirements that the user of the device must pay special attention to.

Electromagnetic compatibility (EMC)

In accordance with its intended use, this electronic apparatus complies with the law governing EMC, which defines the permitted emission levels from electronic equipment and its required immunity against electromagnetic fields.

Nevertheless, it is not possible to exclude with absolute certainty the possibility that radio signals from high frequency transmitters, e.g. mobile phones or similar mobile radio equipment, which conform to the EMC regulations, may influence the proper functioning of electro-medical apparatus if such equipment is operated in close proximity and with relatively high transmitting power.



Therefore, operating of such radio equipment in the immediate vicinity of electronically controlled medical apparatus should be avoided to eliminate any risk of interference.

Explanation:

Electronic apparatus that satisfy the EMC requirements are designed so that under normal conditions there is no risk of malfunction caused by electromagnetic interference. However, in case of radio signals from high frequency transmitters with relatively high transmitting power, the risk of electromagnetic incompatibility when operated in close proximity to electronic apparatus cannot be totally ruled out.

In usual circumstances, unintended functions of the apparatus could be initiated, possibly giving rise to undesirable risk for the patient or user.

For this reason, all kinds of transmission with mobile radio equipment should be avoided. This also applies when the apparatus is in "standby" mode. Mobile phones must be switched off in designated problem zones.



WARNING

High voltage

The device is charged with dangerously high voltages once it is connected to the power supply.

The device may only be serviced by trained and authorized service technicians.

The device must be completely disconnected from the power supply before cleaning and disinfecting the installation, or during servicing, maintenance, and repairs.

The device can be secured against unauthorized operation by removing the key from the main switch.

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1 Clinical Application

1.1 Indication for Use

1.1.1 Chronic Proximal Plantar Fasciitis

The OssaTron is indicated for use for performing extracorporeal shock wave (ESW) treatment in patients with chronic proximal plantar fasciitis that has failed to respond to conservative treatment.

Chronic proximal plantar fasciitis is defined as heel pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity that has persisted for six months or more.

1.1.2 Chronic Lateral Epicondylitis

The OssaTron is indicated for use for performing extracorporeal shock wave (ESW) treatment in patients with chronic lateral epicondylitis (tennis elbow) that have failed to respond to conservative treatment.

Chronic Lateral Epicondylitis is defined as lateral epicondylitis that has persisted for 6 months or more with a history of unsuccessful conservative treatment.

1.2 Contraindications

There are no known contraindications to ESW treatment with the OssaTron for treatment of chronic proximal plantar fasciitis and/or treatment of chronic lateral epicondylitis (tennis elbow).

1.3 Warnings

ESW treatment with the OssaTron should be performed by a physician trained and experienced in the care of patients with foot and ankle and/or upper extremity disorders who has completed a training course in the use of the OssaTron for proximal plantar fasciitis and/or chronic lateral epicondylitis.

Patients with bleeding disorders or taking medications that may prolong clotting time may be at risk for bleeding following OssaTron ESW treatment.

Anesthesia should be administered prior to the ESW procedure. ESW treatment with the OssaTron is painful.

The OssaTron must be carefully positioned by the physician throughout treatment to avoid vascular and nerve structures. Shock waves directed to large blood vessels or to major nerves may cause damage to these structures. Misdirected ESW may result in nerve or blood vessel injury.

Make sure that there is no lateral displacement of the cross point to the marked area on the patient skin during coupling. Displacement could result in misdirection of the shockwave and injury to adjacent nerves or blood vessels. Reduce the risk of hearing impairment due to sound of ESW by providing hearing protection for all persons in the treatment room, including the patient.

If the patient moves after correct positioning, carry out locating check and re-perform positioning if necessary. Failure to maintain correct positioning could result in misdirection of the shockwave and injury to adjacent nerves or blood vessels.

When moving the device, there is a danger of collision with the patient and objects in the room. For the safety of the patient, user, and other people, the user must be careful to:

- avoid collisions or harm to patients when moving the device for initial positioning; and
- avoid collisions with people and to avoid contact with patients when adjusting motor-driven components on the device.

When the device is not in operation, the key should be removed to prevent unauthorized use of the OssaTron.

1.4 Precautions

The safety and effectiveness of the OssaTron has not been established for patients with the following conditions:

- Tarsal tunnel syndrome, or other nerve entrapment disorders, ulnar neuritis
- Diabetic neuropathy
- Fracture of the foot, ankle or treatment arm
- Significant peripheral vascular disease, such as arteriosclerosis
- Skeletally immature patients
- Pregnancy
- Severe osteoarthritis
- Rheumatoid arthritis
- Osteoporosis
- Metabolic disorders
- Malignancies
- Paget's disease
- Osteomyelitis
- Systemic infection

1.5 Adverse Events

1.5.1 Chronic Proximal Plantar Fasciitis

The analyses to determine device safety included findings for all 302 subjects treated, which included 228 primary ESW procedures, 45 repeat ESW procedures, and 130 placebo procedures.

The most commonly reported complications were post-treatment pain and mild neurological symptoms (numbness, tingling) in the treated foot. Comparing findings for all subjects, post-treatment pain was reported following 4/273 active ESW treatments (1.5%) and 4/130 placebo treatments (3.1%). Localized numbness or tingling at the treatment site was reported following 6/273 active ESW treatments (2.2%), and 1/130 (0.08%) placebo treatments.

Two late procedure-related complications occurred, including an exacerbation of heel pain at 6 months following active treatment, and localized tingling at the site of the ankle block injection at 12 weeks post active treatment. Both of these late complications resolved spontaneously without intervention.

The adverse events data in the following table have been grouped according to the following classifications:

Device: A single instance of intra-operative device failure in an active treatment subject was assigned this classification.

Local: Complications including erythema, bruising, edema, or other localized reactions to the study procedure were grouped under this classification.

Neuro: This classification includes any post-treatment numbness or tingling of the treated foot or ankle.

Other: All complications and adverse events that are not related to the study procedure have been assigned the classification, "Other".

Pain: Complaints of post-treatment foot or ankle pain more intense or otherwise differing from the pain experienced pretreatment are assigned this classification.

Tear: Midsubstance ruptures of the plantar fascia.

Tendonitis: Pain due to Achilles or posterior tibial tendonitis is assigned this classification. The development of tendonitis is considered unrelated to the study procedure.

Event	Active Treatment Group (n=130)	Nonrandomized Group (n=42)	Placebo Treatment Group (n=130)	
	Total ESW Procedures (n=159) ¹	Total ESW Procedures (n=53) ²	ESW Procedures (n=61) ³	Placebo Procedures (n=130)
Procedure Related:				
Device	1 (1%)	0 (0%)	0 (0%)	0 (0%)
Local	1 (1%)	1 (2%)	0 (0%)	0 (0%)
Neuro	5 (3%)	1 (2%)	0 (0%)	1 (1%)
Pain	1 (1%)	2 (4%)	1 (2%)	4 (3%)
Tear	2 (1%)	0 (0%)	0 (0%)	0 (0%)
Subtotal:	10 (6%)	4 (8%)	1 (2%)	5 (4%)
Not Procedure Related:				
Other	7 (5%)	1 (2%)	1 (2%)	6 (5%)
Tendonitis	1 (1%)	0 (0%)	0 (0%)	2 (2%)
Subtotal:	8 (5%)	1 (1%)	1 (2%)	8 (6%)
Total:	18 (11%)	5 (9%)	2 (3%)	13 (10%)
Total Events:				
Active Treatment	25/273 (9%)			
Placebo Treatment				13/130 (10%)
¹ Total ESW procedures include 130 primary procedures and 29 repeat treatments in 29 subjects who failed to meet success criteria at 12 weeks ² Total ESW procedures include 40 primary procedures and 11 repeat treatments in 10 subjects who failed to meet success criteria at 12 weeks ³ A total of 61 placebo treatment patients underwent primary ESW treatment after failing to meet success criteria at 12 weeks post placebo treatment				

1.5.2 Chronic Lateral Epicondylitis

A total 98 complications or adverse events were reported for the 225 treated subjects participating in this study. These 225 subjects received 273 active ESW treatments and 90 placebo treatments. No unanticipated adverse events or serious adverse events have occurred to date in any subject participating in this investigation.

The most commonly reported procedure or device related complications occurred during or shortly after the study procedure and included localized swelling, bruising or petechiae at the treatment site (n=19) and reactions to anesthetic agents (n=9). It is noted that all of the reactions to anesthetic agents occurred at a single site, and may have been related to the method of administering a regional block.

The adverse events data in the following table have been grouped according to the following classifications:

Device: A single instance of interoperative device failure in an active treatment subject was assigned this classification.

Local: Complications including erythema, bruising, edema, or other localized reactions to the study procedure were grouped under this classification.

Neuro: This classification includes any post-treatment numbness or tingling of the treated elbow.

Other: All complications and adverse events that are not related to the study procedure have been assigned the classification, "Other".

Pain: Complaints of post-treatment elbow pain more intense or otherwise differing from the pain experienced pretreatment are assigned this classification.

Event	Active Treatment Group (n= 93)	Nonrandomized Group (n= 42)	Placebo Treatment Group (n= 90)	
	Total ESW Procedures (n= 131) ¹	Total ESW Procedures (n= 56) ²	ESW Procedures (n= 86) ³	Placebo Procedures (n= 90)
Procedure related				
Anesthesia	3 (2%)	1 (2%)	2 (2%)	3 (3%)
Local	8 (6%)	7 (13%)	1 (1%)	3 (3%)
Neuro	2 (2%)	0 (0%)	1 (1%)	0 (0%)
Pain	5 (4%)	0 (0%)	1 (1%)	0 (0%)
Subtotal	18 (14%)	8 (14%)	5 (6%)	6 (7%)
Not Procedure related				
Other	28 (21%)	4 (7%)	15 (17%)	14 (16%)
Tear	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Subtotal	28 (21%)	4 (7%)	15 (17%)	14 (16%)
TOTAL	46 (35%)	12 (21%)	20 (23%)	20 (22%)
Total events:	78/273 (29%)			
Active treatment				
Placebo treatment				20/90 (22%)
¹ Total ESW procedures include 93 primary procedures and 38 repeat treatments in 38 subjects who failed to meet success criteria at 8 weeks ² Total ESW procedures include 42 primary procedures and 14 repeat treatments in 13 subjects who failed to meet success criteria at 8 weeks ³ A total of 86 placebo treatment patients underwent primary ESW treatment after failing to meet success criteria at 8 weeks post placebo treatment				

The potential adverse effects of ESW treatment with the OssaTron include:

- Pain during the ESW treatment;
- Localized numbness, tingling or decreased sensation in the foot or at the site of shock wave delivery;
- Local subcutaneous hematoma, bruising, or petechial bleeding in the foot/elbow or at the treatment site;
- Misdirection of ESW energy to a major nerve or blood vessel, resulting in injury;
- Anesthesia complications, including allergic reactions to local or regional anesthetic agents; and
- Rupture of plantar fascia.

1.7 Clinical Study

1.7.1 Chronic Proximal Plantar Fasciitis

A multicenter, randomized, double-blinded, placebo-controlled clinical study was conducted to determine the safety and effectiveness of ESW treatment with the OssaTron in patients with chronic proximal plantar fasciitis.

For purposes of this study, chronic proximal plantar fasciitis was defined as symptoms of moderate to severe pain in the affected heel at the origin of the plantar fascia on the medial calcaneal tuberosity that had persisted for at least six months prior to study enrollment. The inclusion/exclusion criteria described in the study protocol included such requirements as:

- failure to respond to at least three attempts at conservative treatment, including such treatments as:
 - Rest from excessive or abusive activity and the application of heat or cold
 - Physical conditioning exercises
 - Use of a shoe insert or heel cup
 - Physical therapy, including ultrasound therapy
 - Over-the-counter pain relievers, such as aspirin or Tylenol (acetaminophen)
 - Prescription pain relievers
 - Non-steroidal anti-inflammatory medications (NSAID's), such as Advil (ibuprofen) or Aleve (naproxen)
 - Steroid injections (cortisone)

- investigator assessment of pain at the origin of the plantar fascia on the medial calcaneal tuberosity ≥ 5.0 on a 10cm Visual Analog Scale (VAS);
- subject self-assessment of pain after the first five minutes of walking in the morning ≥ 5.0 on a 10cm VAS;
- female subjects must not be pregnant
- other causes for heel pain have been ruled out, such as vascular insufficiency or neuropathy of the lower extremities; and
- concomitant pathology has been ruled out, including severe osteoarthritis; rheumatoid arthritis, osteoporosis; metabolic disorders; malignancies; Paget's disease; and acute, subacute or chronic osteomyelitis or systemic infection; or fracture of the affected foot or ankle.

A minimum of two investigators participated in the study at each site so that one investigator could serve as the blinded evaluator for baseline and post treatment follow up visits. The study procedures were performed by the nonblinded investigator as follows: Each study subject received a local anesthetic or an ankle block prior to the study procedure. The affected leg was then draped from the view of the study subject. Each subject assigned to active treatment then underwent an ESW procedure with a total of 1500 shocks delivered at a power setting of 18 kV. The average active treatment time was 17 minutes. For subjects assigned to placebo treatment, a Styrofoam block was placed against the coupling membrane of the shock head to absorb the shock waves. A fluid-filled IV bag was then placed between the Styrofoam block and the subject's heel to mimic the feel of the coupling membrane, and 1500 shocks were then delivered at 18 kV.

The study was designed to compare the proportion of patients in the active treatment group who had a successful outcome to the proportion of control patients with a successful outcome. The effectiveness of OssaTron ESW treatment for chronic proximal plantar fasciitis was measured according to 4 parameters, and the success criteria for all 4 must have been met in order for a subject to be assigned a final status, "Success". These parameters are:

Investigator assessment of pain: minimum 50% improvement over baseline, and a VAS score ≤ 4.0

- Subject's self-assessment of pain: minimum 50% improvement over baseline and a VAS score ≤ 4.0
- Subject's self-assessment of activity: improvement of 1 point on a 5 point scale OR maintenance of a baseline a score of 0 or 1.
- Use of pain medications: no pain medications required for heel pain.

**12 Week Response to Treatment
All Components of Success
All Patients Eligible for 12 Week Follow-up**

Response			
Measure	Active OssaTron ESW Treatment (n=119)*	Placebo Treatment (n=116)**	p Value ¹
Investigator Assessment	62.2%	44%	0.005
Self Assessment, Pain in AM	60%	48%	0.080
Activity Level	71%	67%	0.486
Medication Use	70%	65%	0.406
Composite: All 4 Components	47%	30%	0.008
¹ Pearson X ² * Excludes one subject lost to follow up prior to 12 weeks ** Excludes three subjects lost to follow up prior to 12 weeks			

A total of 260 subjects were randomized into the study; 130 into the active treatment group and 130 into the placebo treatment group. Four subjects were lost to follow up before the 12-week follow up visit, one subject in the active treatment group and 3 subjects in the placebo group. Twenty-one subjects had not yet reached the 12-week post treatment interval at the time data analysis was performed. Therefore, an effectiveness analysis was performed on 235 subjects, 119 active treatments and 116 placebos, who had completed the 12 week follow up assessments.

In the active treatment group, 47% of the subjects met all 4 components of the composite score, compared to 30% of the placebo treatment group ($p=0.008$). The study results for the individual components are presented in the table above.

1.7.2 Chronic Lateral Epicondylitis

A multicenter, randomized, double-blinded, placebo-controlled clinical study was conducted to determine the safety and effectiveness of ESW treatment with the OssaTron in patients with chronic lateral epicondylitis (tennis elbow).

The inclusion/exclusion criteria described in the study protocol included such requirements as:

- failure to respond to at least three attempts at conservative treatment, including such treatments as:
 - rest from excessive or abusive activity and the application of heat or cold
 - physical conditioning exercises
 - physical therapy, including ultrasound therapy

- over-the-counter pain relievers, such as aspirin or Tylenol (acetaminophen)
- prescription pain relievers - non-steroidal anti-inflammatory medications (NSAID's), such as Advil (ibuprofen) or Aleve (naproxen).
- steroid injections (cortisone)
- investigator assessment of pain at the point of tenderness over the lateral epicondylitis ≥ 5.0 on a 10cm Visual Analog Scale (VAS);
- subject self-assessment of pain during activity is ≥ 5.0 on a 10cm VAS;
- female subjects must not be pregnant;
- other causes for elbow pain have been ruled out, such as vascular insufficiency or neuropathy of the upper extremities; and concomitant pathology has been ruled out, including severe osteoarthritis; rheumatoid arthritis, osteoporosis; metabolic disorders; malignancies; Paget's disease; and acute, subacute or chronic osteomyelitis or systemic infection.

**8 Week Response to Treatment
All Components of Success, All Patients Randomized**

Response			
Measure	Active OssaTron ESW Treatment (n=93)	Placebo Treatment (n=90)	p Value
Investigator Assessment	45 (48%)	26 (29%)	0.007
Self Assessment, Pain during activity	51 (55%)	37 (41%)	0.063
Medication Use	75 (81%)	63 (70%)	0.095
Composite: All 3 Components	33 (35%)	20 (22%)	0.043

The following table represents the demographics for the 183 randomized subjects who participated in the study.

Study Demographics of subjects enrolled in the chronic lateral epicondylitis clinical study

Characteristics	Active Treatment Patients (N=93)	Placebo Treatment Patients (N=90)
Age (years)		
Mean:	44	46
Range:	22-66	32-71
Gender		
Male:	46	41
Female:	47	49
Affected Arm		
Right:	64	69
Left:	29	21
Prior Therapies		
Cortisone Injections:	26	25
NSAID's:	15	12
Both:	52	53
Physical Therapy:	93	90
Symptom Duration (Days)		
Mean:	684.37	783.79
Range:	161-4920	126-8089

A minimum of two investigators participated in the study at each site so that one investigator could serve as the blinded evaluator for baseline and post treatment follow up visits. The study procedures were performed by the nonblinded investigator as follows: Each study subject received a local anesthetic or a Bier block prior to the study procedure. The affected arm was then draped from the view of the study subject. Each subject assigned to active treatment then underwent an ESW procedure with a total of 1500 shocks delivered at a power setting of 18 kV. The average active treatment time was 20.5 minutes.

For subjects assigned to placebo treatment, a Styrofoam block was placed against the coupling membrane of the shock head to absorb the shock waves. A fluid-filled IV bag was then placed between the Styrofoam block and the subject's elbow to mimic the feel of the coupling membrane, and 1500 shocks were then delivered at 18 kV.

The study was designed to compare the proportion of patients in the active treatment group who had a successful outcome to the proportion of control patients with a successful outcome. The effectiveness of OssaTron ESW treatment for chronic lateral epicondylitis was measured according to 3 parameters, and the success criteria for all 3 must have been met in order for a subject to be assigned a final status, "Success". These parameters are:

- Investigator assessment of pain: minimum 50% improvement over baseline, and a VAS score ≤ 4.0
- Subject's self-assessment of pain: minimum 50% improvement over baseline and a VAS score ≤ 4.0
- Use of pain medications: none or rare pain medications required for elbow pain. Rare: Subject has taken no more than three doses of medication during the week immediately prior to being seen.

A total of 183 subjects were randomized into the study; 93 into the active treatment group and 90 into the placebo treatment group. Eighteen subjects were lost to follow up before the 8-week follow up visit, 11 subjects in the active treatment group and 7 subjects in the placebo group.

In the active treatment group, 33 of 93 or 35% of the subjects met all 3 components of the composite score, compared to 20 of 90 or 22% of the placebo treatment group ($p=0.043$). The study results for the individual components are presented in the table above.

Eighty-two of the 93 active subjects and 83 of the 90 placebo subjects returned for the 8-week follow-up visit. Thirty-three of the 82 active subjects (40%) and 20 of the 83 placebo subjects (24%) meet the study success criteria with a p-value of 0.018.

The following table represents data collected for the three success/fail endpoints.

Investigator Assessment – Baseline Through 8 Weeks

		Baseline	4 Weeks	8 Weeks
Active	N:	93	84	82
	Mean (StD):	7.73 (1.38)	5.02 (2.73)	3.64 (2.52)
	Median:	7.6	5.3	3.35
	Range:	4.8-10	0-10	0-9.7
Placebo	N:	90	80	83
	Mean (StD):	7.81 (1.50)	5.48 (3.31)	5.17 (3.13)
	Median:	7.7	6.05	5.5
	Range:	5.0-10	0-10	0-10

1.8 Product Complaints and Contact Information

Any health care professional (e.g., customer or user of this system) who has any complaints or who has experienced any dissatisfaction in the quality, identification, durability, reliability, safety, effectiveness and/or performance of this product should notify the distributor, HealthTronics Surgical Services, Inc. If any HealthTronics Surgical Services product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. The distributor may be contacted at:

HealthTronics Surgical Services, Inc.
 1841 West Oak Parkway, Suite A
 Marietta, Georgia 30062
 Telephone: 1-800-464-3795
 Fax: 1-770-419-9490

Subject Self-Assessment – Baseline Through 8 Weeks

		Baseline	4 Weeks	8 Weeks
Active	N:	93	84	82
	Mean (StD):	7.37 (1.21)	4.53 (2.26)	3.53 (2.53)
	Median:	7.4	4.75	2.9
	Range:	4.6-10	0-9	0-8.4
Placebo	N:	90	80	83
	Mean (StD):	7.76 (1.31)	4.84 (2.51)	4.37 (2.58)
	Median:	7.95	4.35	4.2
	Range:	4.9-10	0-9.9	.02-9.7

Medication Requirements – Baseline Through 8 Weeks

	Baseline	Medication Requirements	4 Weeks	8 Weeks
Active	None: 37	None	49	58
	NSAID's: 46	Rare	14	13
	Other: 10	Occasional	8	2
		Frequent	5	2
		Chronic	8	7
Placebo	None: 34	None	48	57
	NSAID's: 52	Rare	7	4
	Other: 4	Occasional	10	9
		Frequent	10	8
		Chronic	5	5