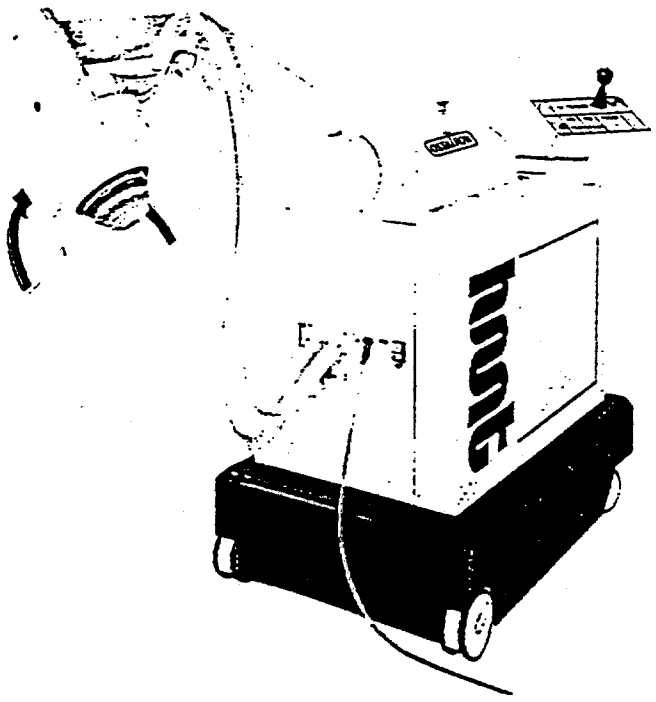
hmt

OSSATRON



Operating Manual OSA 120

NOTE

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

Manufacturer
HMT High Medical Technologies AG
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CH - 8574 Lengwil
Switzerland
Tel.: (++41 / 71) 6866 200
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US Distributor
HealthTronics, Inc.
1841 West Oak Parkway
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Mühlbachstr. 20
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Documents for the installation's operator
Operating Manual OSA 120

Issue of operating manual
Date: FINAL DRAFT 10/11/00 Replaces: Edition 11/11/99
release date:

HMT Parts No.: 01937a+01

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

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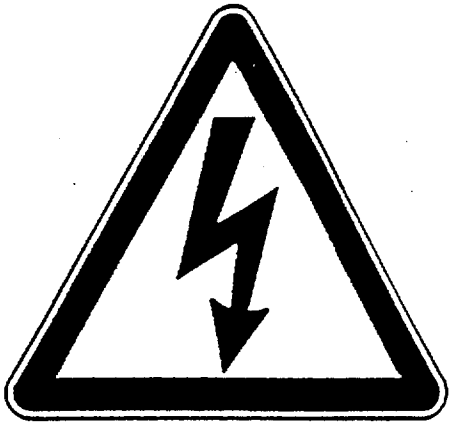
WARNING

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 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.

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.

CAUTION

This heading is used when damage to the device can be caused if instructions concerning suitable use, operating instructions, and 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 electromedical apparatus if such equipment is operated in close proximity and with reatively 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 satisfies 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.

1.0 Clinical Application

1.1 Indication for Use

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.

1.2 Contraindications

There are no known contraindications to ESW treatment with the OssaTron for treatment of chronic proximal plantar fasciitis.

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 disorders who has completed a training course in the use of the OssaTron for proximal plantar fasciitis.

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 crosspoint 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.

If the patient moves after correct positioning, carry out locating check and reperform positioning if necessary. Failure to maintain correct positioning 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.

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 others in the treatment room, 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
- Diabetic neuropathy
- Fracture of the foot or ankle
- 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

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 overall complication rate for any subject receiving an active ESW treatment was 12%, including both device- or procedure-related events and events unrelated to the study procedure.

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 treated subjects sustained midsubstance plantar fascia tears during the course of study participation.

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 intraoperative 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.

All Complications or Adverse Events
All Study Procedures

	Active Treatment Group (n=130)	Nonrandomized Group (n=42)	Placebo Treatment Group (n=130)		TOTAL (n=302)
Event	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	0	0	0	1
Local	1	1	0	0	2
Neuro	5	1	0	1	7
Pain	1	2	1	4	8
Tear	2	0	0	0	0
Subtotal	10	4	1	5	20
Not procedure related					
Other	7	1	1	6	15
Tendonitis	1	0	0	2	3
Subtotal	8	1	1	8	18
TOTAL	18	5	2	13	38
Total events:					38/403
Active treatment	25/273				
Placebo treatment				13/130	

[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

1.6 Potential Adverse Effects

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 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

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 $\geq$ 5.0 on a 10 cm. Visual Analog Scale (VAS);
- subject self-assessment of pain after the first five minutes of walking in the morning $\geq$ 5.0 cm on a 10 cm 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 18kV. 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.

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 treatment and 116 placebo, 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 below.

12 Week Response to Treatment
All Components of Success

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

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 Inc. If any HealthTronics

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

Patient Information

Extracorporeal Shock Wave (ESW) Treatment for Chronic Proximal Plantar Fasciitis with the HealthTronics OssaTron®

What is extracorporeal shock wave (ESW) treatment?

"Extracorporeal" means "outside the body". Shock waves are created by very strong acoustic (sound) energy. Your ESW treatment will be performed with a device called the OssaTron.

The OssaTron is a shock wave generator, very similar to the shock wave devices used to treat kidney stones without surgery. The shock waves are created by a spark plug that is enclosed in a soft plastic dome filled with water. During ESW treatment, this dome is placed closely against the heel so that the shock waves pass through the dome to the heel. ESW treatment has recently been found to be effective to treat chronic proximal plantar fasciitis, a condition that causes pain in the heel of the affected foot and is sometimes called "heel spurs".

What other treatments are available for treating chronic proximal plantar fasciitis?

Doctors know that many people who have heel pain get better with time, even with no treatment. Many other people get better after trying one or several conservative treatments, which include:

- 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)

In difficult cases of chronic proximal plantar fasciitis, open or arthroscopic surgery may be performed.

Who should consider having ESW treatment for proximal plantar fasciitis?

ESW treatment with the OssaTron is for patients who have had heel pain for at least 6 months and who have tried other methods for treating their heel pain. In the OssaTron clinical study, the treated patients had failed to respond to at least three attempts at conservative treatment: two prior courses of non-invasive treatment, including physical therapy and the use of an orthotic device; and one prior course of pharmacological treatment.

ESW treatment with the OssaTron is for patients who can tolerate anesthesia prior to the ESW procedure. ESW treatment with the OssaTron is painful.

ESW treatment with the OssaTron is for patients who can tolerate hearing protection to reduce the risk of hearing impairment due to the sound of the OssaTron.

Who should not have ESW treatment for proximal plantar fasciitis?

- **Anyone taking medications that may prolong or interfere with blood clotting should not have ESW treatment.**
- **Anyone with a history of bleeding problems should not have ESW treatment.**
- **Children should not have ESW treatment.**
- **Pregnant women should not have ESW treatment.**

Because the OssaTron has not been tested on people who have the following conditions, its effect, safety,

and effectiveness on someone who has one of the following conditions is unknown:

- **Tarsal tunnel syndrome, or other nerve entrapment disorders (damage or pressure on the nerves to the foot)**
- **Diabetic neuropathy (nerve damage due to diabetes)**
- **Fracture of the foot or ankle**
- **Significant peripheral vascular disease (problems with the circulation in the blood vessels in the legs)**
- **Severe osteoarthritis**
- **Rheumatoid arthritis**
- **Osteoporosis**
- **Metabolic disorders**
- **Malignancies**
- **Paget's disease**
- **Osteomyelitis**
- **Systemic infection**

Your doctor can provide you with additional information about these and other conditions, and how they might affect the decision to perform ESW treatment.

What are the side effects and complications that could happen?

- The ESW treatment may cause skin reddening or bruising of the treated foot, which usually clears within a few days.
- The ESW treatment may cause numbness or tingling in the treated foot
- The ESW procedure may cause the plantar fascia to tear
- The ESW treatment may not help heel pain in your case. You may have episodes of pain similar to the pain you had before treatment. The pain may continue for a few days to several weeks after treatment.

What will happen on the day of the ESW treatment?

Your doctor will probably ask you to come to the hospital or surgery center a few hours before the ESW treatment is scheduled. You should wear shorts or loose fitting clothing that can easily be rolled up to the knee of your affected leg. Otherwise, you may be asked to change from your own clothes into a hospital gown. The staff may take your temperature, pulse and blood pressure and ask you some

questions about your general health. They will also make sure you have signed a consent form for the ESW treatment.

The ESW treatment may cause some pain or discomfort, so an anesthetic is commonly given before the procedure. Usually, this will be a local anesthetic or a regional anesthetic called a heel block. You will be asked to rest comfortably on your back while your doctor holds your foot up to the OssaTron shock head as shown on the front of this pamphlet.

An ESW treatment for chronic proximal plantar fasciitis usually takes about 30 minutes. The ESW treatment is performed as an outpatient procedure; no overnight hospital stay is necessary.

What will happen after the ESW treatment?

Immediately after treatment, you will stay at the hospital or surgery center until the anesthetic wears off enough so it is safe for you to walk. Your doctor will probably ask you to restrict stressful activity involving the treated foot for 4 weeks after treatment. "Stressful activity" may include running or jogging, doing heavy housework or yard work, and participating in sports.

Some patients need a mild pain medication following ESW treatment. Although some patients in the clinical study felt immediate relief from pain after the ESW treatment, it is more common for it to take up to 6 weeks for pain relief to begin.

What are the expected results from ESW treatment?

In the OssaTron clinical study, patients with chronic proximal plantar fasciitis were graded "Success" or "Fail" according to 4 measurements. 1) The doctor graded the amount of pain with pressure on the heel; 2) the patient graded the amount of pain during walking first thing in the morning; 3) the patient graded the time and distance he or she could walk without pain and 4) the patient reported the amount of pain medication he or she needed for heel pain.

Percentage of Patients with Successful Outcome at 12 Weeks

Results at 12 Weeks		
Measurement	**OssaTron Treatment (n=130)**	**Placebo Treatment (n=130)**
Investigator Assessment	62.2%	44%
Self Assessment, Pain in AM	60%	48%
Activity Level	71%	67%
Medication Use	70%	65%
Composite: All 4 Components	47%	30%

Your doctor will ask you to return to the office for a follow up visit, probably at about 6 or 8 weeks after your OssaTron treatment. Please check with your doctor about this follow up visit.

I have more questions about ESW treatment for heel pain. How can I get more information?

Talk to your doctor if you have any questions.

In order to use the OssaTron to treat chronic proximal plantar fasciitis, your doctor had to complete a specialized training program. The training program not only allowed your doctor to learn how to perform the ESW treatment, but it also included information about shock wave energy in general, and information from the OssaTron clinical study. Therefore, your doctor is the best person to talk to if you have any questions or concerns about ESW treatment for chronic proximal plantar fasciitis with the OssaTron.

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