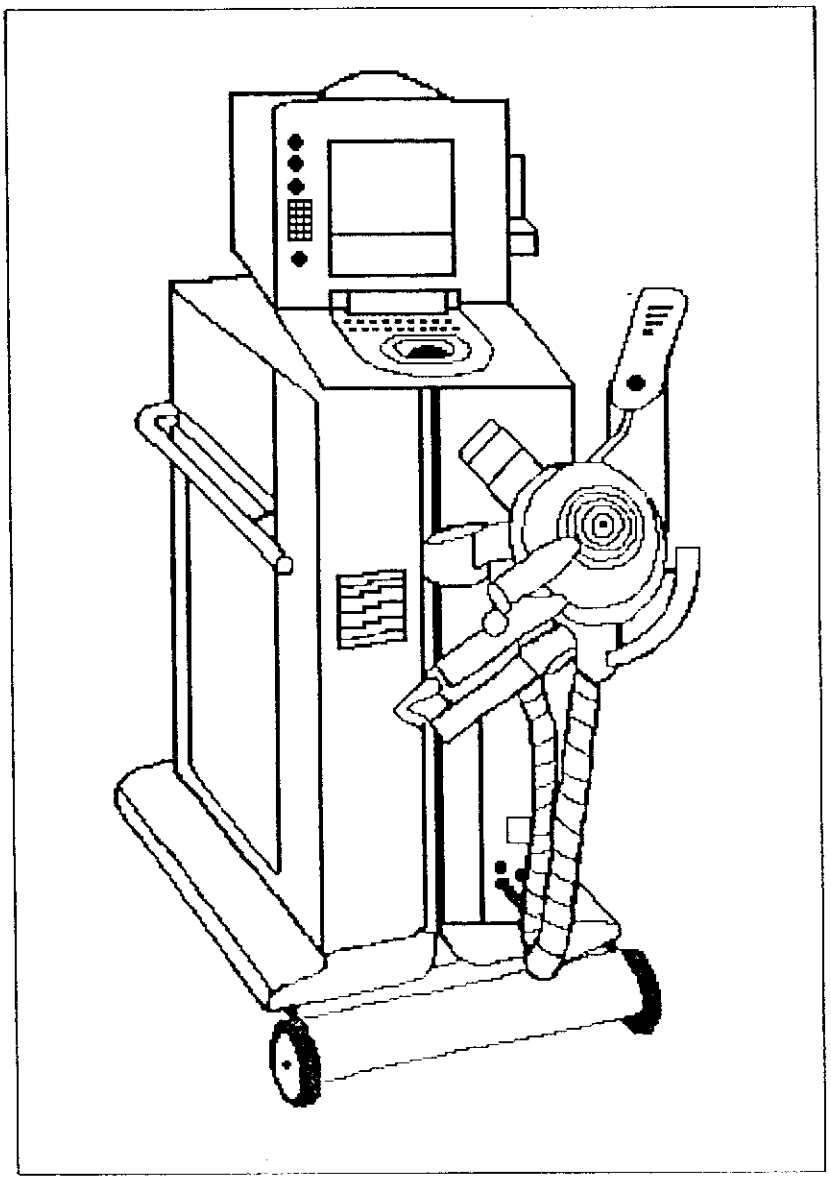
Dornier *MedTech*

Dornier *Epos Ultra*
Operating Manual



WARNING: This device must be operated by personnel trained in Extracorporeal Shock Wave Therapy.

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

20156

Operating Manual for Dornier Epos™ Ultra

Manufacturer
Dornier Medizintechnik GmbH
Argelsrieder Feld 7
D-82234 Wessling Germany

US Distributor
Dornier MedTech, Inc.
1155 Roberts Blvd.
Kennesaw, GA 30144, U.S.A.

Documents for the installation's operator

Operating Manual Epos™ Ultra

Issue of operating manual

Date: FINAL DRAFT _____ Replaces: Edition _____

Release date:

Dornier MedTech, Inc. Part No.: 20156

Manufacturer's responsibility

DMT is responsible for the safe operation, reliability, and performance of the Epos™ Ultra under the following conditions:

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

Regulatory Statement for the United States

CAUTION

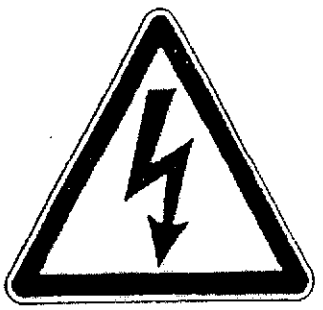
Federal law restricts this device to sale on or by the order of a physician.

Dornier Epos™ Ultra

US Distributor
Dornier MedTech, Inc.
1155 Roberts Blvd.
Kennesaw, GA 30144

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 rep=moving the key from the main switch.

WARNINGs and CAUTIONs are listed at the beginning of each subsection that includes steps that may endanger a person or may damage equipment. Combined with complete training in using the Epos™ Ultra, WARNINGs and CAUTIONs alert the user to potential hazards of ignoring or following instructions improperly.

See definitions for WARNING and CAUTION and NOTE, below:

WARNING	**A warning indicates that a person may be endangered if instructions or procedures are followed incorrectly or ignored.**
CAUTION	A caution indicates that equipment may be damaged if instructions or procedures are followed incorrectly or ignored.

NOTE A note provides further information for the reader.

Table of Contents

Section / Title		Page
1	**Clinical Application**	**1.1**
1.1	Indications	1.1
1.2	Contraindications	1.1
1.3	Warnings	1.1
1.4	Precautions	1.1
1.5	Adverse Events	1.2
1.6	Clinical Study	1.2
1.7	Summary of Clinical Study	1.3
1.8	Product Complaints and Contact Information	1.6
2	**Description**	**2.1**
2.1	Technical Description	2.1
2.2	Device protection and safety	2.1
2.3	Major Components of Epos™ Ultra	2.3
2.4	Operating Components	2.3
3	**Technical Data**	**3.1**
3.1	Dimensions/Weight	3.1
3.2	Acoustic Specifications	3.1
3.3	Noise Emission	3.1
3.4	Ultrasound Module	3.1
4	**Epos™ Ultra Activation**	**4.1**
4.1	Prepare Epos™ Ultra for Activation	4.1
4.2	Connect the Cables	4.1
4.3	Attach the Locating Arm to the Therapy Head	4.2
4.4	Switch the Epos™ Ultra ON	4.3
4.5	Switch the Ultrasound Unit ON	4.4
4.6	Evaluate Imaging Activation	4.4
5	**Locating and Positions**	**5.1**
5.1	Initial Positions	5.1
5.2	Position the Patient for ESWT	5.3
5.3	Visualize with Ultrasound Imaging	5.4
6	**Operating the Epos™ Ultra**	**6.1**
6.1	Pretreatment	6.1

6.2 Visualize with Ultrasound Imaging 6.2
6.3 Deliver ESWT 6.2
6.4 Evaluate ESWT 6.4
6.5 Conclude ESWT 6.5
6.6 Ending the Treatment 6.5
6.7 Switching off the Epos™ Ultra 6.6

7 Requirements for Transportation 7.1
7.1 Configure the *Epos* for TRANSPORT 7.1
7.2 Inspect and Deliver the Epos™ Ultra to the Storage Area 7.1

8 Troubleshooting 8.1
8.1 Handle Messages from the Hand Control on the Epos™ Ultra DISPLAY 8.1
8.2 Handle Messages from the Hand Control on the TRIGGER DISPLAY 8.3
8.3 On the INTENSITY Display 8.3
8.4 On the COUPLING Display 8.3

9 Care and Maintenance 9.1
9.1 General 9.1
9.2 Perform Required Maintenance 9.1
9.3 Recommended disinfection of Epos™ Ultra 9.2

10 Appendices 10.1

1 Clinical Application

1.1 Indications

The Dornier Epos™ Ultra is a non-surgical alternative for the treatment of chronic plantar fasciitis for patients with symptoms of plantar fasciitis for 6 months or more and a history of unsuccessful conservative therapy. Plantar fasciitis is defined as the traction degeneration of the plantar fascial band at its origin on the medial tubercle of the calcaneus.

1.2 Contraindications

There are no known contraindications to ESWT with the Epos™ Ultra for treatment of chronic plantar fasciitis.

1.3 Warnings

The following warnings pertain to the use of the Epos™ Ultra to treat plantar fasciitis:

- Operators of the Epos™ Ultra should be aware of the proper use of the device in delivering the correct number of shocks and in localizing the proper area to be treated.
- The Epos™ Ultra must be carefully positioned and treatment should be performed by a physician trained and experienced in the care of patients with foot and ankle disorders who have completed a training course in the operation of the Epos Ultra.
- Reduce the risk of hearing impairment due to the sound of ESWT by providing hearing protection for all persons in the treatment room, including the patient.
- If the patient moves after correct positioning, re-perform localization if necessary. Failure to maintain correct positioning could result in misdirection of the shockwave and injury to adjacent nerves or blood vessels.
- When the device is not in operation, turn the power switch to the OFF position and unplug the device from the wall socket.
- Anesthesia should be administered prior to the ESWT procedure. Treatment with the Epos ™ Ultra is painful. Patients who are unable to tolerate local or regional anesthetic should not be treated with this device or should consider alternative therapies.
- Electromagnetic compatibility (EMC):

  In accordance with its intended use, this electronic apparatus was tested in accordance with IEC 60601-1-2 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 may influence the proper functioning of electromedical 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.

1.4 Precautions

The following precautions pertain to the use of the Epos™ Ultra to treat plantar fasciitis. The safety and effectiveness has not been established for patients with the following:

- Under 18 years of age
- Previous treatment with non-steroidal anti-inflammatory drugs or other conservative therapies within two (2) weeks of treatment or who have had a corticosteroid injection within one (1) month of treatment.
- Previous surgery for plantar fasciitis.

- A history or documented evidence of autoimmune disease, bleeding disorder or hemophilia, peripheral vascular disease, Type I or Type II diabetes mellitus, systemic inflammatory disease such as rheumatoid arthritis, ankylosing spondylitis, Reiter's Syndrome, etc., and/or generalized tumor(s) or tumor in the area to be treated.
- Abnormal capillary refill as assessed by compression of the nail bed of the great toe of the affected foot
- Nonpalpable posterior tibial AND dorsalis pedis pulses, a history or documented evidence of loss of ankle/foot sensation, reflex sympathetic dystrophy, and/or clubfoot
- Calcaneal stress fracture as evidenced by positive squeeze test
- Infections in the treatment area
- Pregnant
- Coagulation abnormalities; including patients currently receiving anticoagulants within 7 days of treatment and patients taking aspirin for prophylactic treatment of thrombus formation within 7 days of treatment as they may be at risk for bleeding following treatment with the Dornier Epos™ Ultra
- Prior diagnosis of peripheral neuropathy
- Cardiac pacemakers, a history of active coronary disease evidenced by unstable angina and uncompensated congestive heart failure
- Previous treatment with shock wave therapy (re-treatment)

The following precaution pertains to the use of the Epos™ Ultra:

- Thoroughly air the room before operating the Epos™ Ultra. Do not operate the Epos™ Ultra with flammable anesthetics or in a room recently washed with flammable cleaning/disinfecting agents. Cleaners can produce explosive vapors. Check labels or original containers of all cleaners and disinfectants for warnings about vapors.

1.5 Adverse Events

The adverse events that occurred during the clinical study are listed under Table 2 of this section. The adverse events observed during treatment with the Dornier Epos™ Ultra include:

- Pain and/or discomfort during treatment;
- Pain or swelling for a brief period following treatment;
- Localized numbness, tingling or decreased sensation in the foot or at the site of shock wave delivery; and
- Local subcutaneous hematoma, minor bruising, or petechial bleeding in the foot or at the treatment site

Other potential adverse events include:

- Rupture of plantar fascia
- Possible bleeding and/or infection at the injection site
- Temporary or permanent nerve damage associated with the injection or shock wave treatment
- Misdirection of ESWT energy to a major nerve or blood vessel, resulting in injury; and
- Anesthesia complications, including allergic reactions to local or regional anesthetic agents.

1.6 Clinical Study

A multicenter, randomized, placebo controlled, prospective, double blind clinical study with two groups: a group receiving FSWT with the Epos™ Ultra and a control group receiving a sham treatment was conducted. A total of 150 patients, randomized in a 1:1 allocation ratio, were enrolled at six clinical sties. For the purpose of this study, plantar fasciitis was defined as symptoms of at least moderate 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 criteria described in the study protocol included such requirements as:

1.6.1 Inclusion Criteria

- Greater than 18 years old
- Symptoms present for greater than 6 months as assessed by patient history
- Participation in and compliance with a physician prescribed stretching program for plantar fasciitis within the last 6 months
- Pain with local pressure over the medial calcaneal tuberosity on passive dorsiflexion of the foot
- Visual Analog Scale (VAS) score of >5 for pain during the first few minutes of walking in the morning
- Single site of tenderness with local pressure over the medial calcaneal tuberosity on passive dorsiflexion of the foot
- History of 6 months of unsuccessful conservative treatment to include NSAIDS AND at least two of the following therapies (rest, stretching, heel cushions, heat, ice, ultrasound, massage, orthotics, heelcups, steroid injection, casting, taping, shoe modifications, nightsplinting)
- Willingness to forgo any other concomitant therapy (including rest, stretching, heel cushions, heat, ice, ultrasound, massage, orthotics, heelcups, steroid injections, casting, taping, shoe modifications, nightsplinting, or surgery) for the duration of the study
- Willingness to use adequate contraceptive measures to prevent pregnancy for 4 months after enrollment into study (for female patients of child bearing capacity)
- Roles and Maudsley Score of 3 or 4
- Signed informed consent

1.7 Summary of Clinical Study

Patients were evaluated for inclusion/exclusion criteria prior to receiving shock wave therapy. If enrolled, the patients were treated with 3800 +/- 10 shocks. All patients received an injection using a 23-25 gauge hypodermic needle, of 5ml 1% xylocaine into the medial calcaneal branch of the tibial nerve 15 – 20 minutes prior to therapy.

Once a sham patient was identified, a thin air cushion was placed on the therapy head to prevent shock waves from being delivered to the patient. The thin air cushion was put in place prior to the patient's arrival in the treatment room so that the patient was not aware of any differences with the device. Physicians, technicians or study coordinators who were aware of the patient's randomization and were in the room during treatment were not involved in any follow up evaluations. The treating physician was different from the physician who performed the follow up evaluations. The follow-up visits occurred at 3-5 days, 6 weeks, 3 months, 6 months, and 12 months after treatment. Patients were asked which treatment they believed they received as an assessment of masking. At 3 months, patients who were originally treated with sham treatment were offered an Active unmasked treatment in the open label extension study if they still met the inclusion criteria. This was done after the masked 3 month safety and effectiveness outcome assessments were collected.

Efficacy Endpoints

The primary efficacy endpoint was the difference between the active Epos™ Ultra treatment and the sham Epos™ Ultra treatment at 3 months post-treatment in the improvement from baseline in the VAS score for pain while walking for the first few minutes in the morning using a repeated measures analysis with covariates. In addition to evaluating the actual changes in pain score, the proportion of patients achieving at least 60% improvement in pain while walking for the first few minutes in the morning was compared between treatment groups at 3 months.

The secondary efficacy endpoints were the difference between groups in the improvement from baseline at 3 months post-treatment of the pain evaluation from the AOFAS Ankle-Hindfoot Scale Score, the Roles and Maudsley Score, the SF-12 health status questionnaire, pain measurement on palpation with a pressure threshold meter, and the ROM Assessment from the AOFAS Ankle-Hindfoot Scale Score. Safety was assessed as the number of adverse events and severity of complications that were related to extracorporeal shock wave therapy.

Study Methodology

At screening and follow up, data collection included: history and physical exam, pain measurement on palpation with pressure threshold meter, VAS pain score questionnaires, SF-12 health status questionnaire, AOFAS Ankle-Hindfoot Scoring System questionnaire, and Roles and Maudsley questionnaire. Patients were asked which treatment they believed they received as an assessment of masking.

Primary Endpoint

In the Active group, the mean pain score decreased from 7.7 ±1.4 at baseline to 3.4 ± 2.8 at 3 months post-treatment, a mean percent improvement of 56.5%. In the Sham group, the mean score decreased from 7.7 ± 1.5 at baseline to 4.1 ± 3.1 at 3 months post-treatment, a mean percent improvement of 46.6%. The change from baseline to 3 months in VAS pain due to treatment was statistically significant using a repeated measures analysis (p=0.0149), with covariate analysis and without imputing missing data (3 active and 1 sham) as summarized in Table 1.

The proportion of patients achieving at least 60% improvement in pain during the first few minutes of walking in the morning was compared between treatment groups at 3 months. Fifty-six percent (56.2%) of the Active group demonstrated 60% improvement from baseline in their VAS scores or greater reduction in their pain, compared to 45.2% of the patients in the Sham group. This was not statistically significant.

Table 1: VAS Scores for Active and Sham Patients from Baseline Through 3 months Post Treatment

		Baseline	3-5 days	6 weeks	3 months	Change from baseline
Active Tx Pts	N	76	74	72	73	--
	Mean	7.7	5.0	4.6	3.4	-4.4
	SD	1.4	2.8	3.1	2.7	2.8
Sham Tx Pts	N	74	74	71	73	--
	Mean	7.7	5.7	5.0	4.1	-3.6
	SD	1.5	2.8	3.0	3.1	3.1

The clinical data showed that on average, patients with a lower baseline VAS score, a shorter duration of symptoms, or a lower body mass index (BMI) had a higher improvement in VAS pain score.

Secondary Endpoint

The Roles and Maudsley pain score was used as a secondary endpoint. At 3 months post treatment, the distribution of patients in the four categories, excellent, good, fair, and poor, was found to be statistically significant between the treatment groups (p=0.03) with 61.6% pf Active patients having good to excellent results, compared to only 39.7% of Sham patients

The AOFAS Ankle-Hindfoot Scale and the SF12 Health Status Questionnaire, which did not show statistically significant change between active and sham patients, over time, were also used as secondary endpoints.

Safety Results

Adverse events were evaluated by type, nature, severity and intensity during treatment and at each follow up visit. No study subject experienced an unanticipated serious device related adverse event during the course of the study.

All of the complications were temporary in nature and all but one resolved spontaneously with minimal or no intervention. The most common complications were pain during treatment and pain 3-5 days post-treatment. Pain during treatment occurred in 72.4% Active patient group and 6.8% Sham patient group. Pain during treatment was recorded on a scale of 1-10 (mild-severe) with a mean score during treatment of 3.5 in the Active group and 0.2 in the Sham group. Pain post-treatment at 3-5 days was reported in 40.8% of Active patients (31/76) and 35.1% of Sham patients (26/74).

Table 2 summarizes the adverse events related to ESWT at treatment through 3 month follow up. Other than pain during treatment, there were no differences in the nature or type of adverse events reported between the Active and Sham groups. There were no serious unanticipated adverse device effects to report related to

Table 2: Adverse Events Treatment Through 3 Months Follow Up

Adverse Event	Active Treatment Patients (n = 76)			Sham Treatment Patients (n = 74)			p-value
	Number of Patients[1]	Number of Occurrences	% of Patients	Number of Patients[1]	Number of Occurrences	% of Patients	---
Pain During Treatment[2]	55	55	73%	5	5	7%	<0.001
Pain Post Treatment[3]	28	31	37%	24	26	32%	1.0000
Edema	5	5	7%	6	7	8%	0.3655
Ecchymosis	5	5	7%	4	4	5%	1.0000
Petechiae	0	0	0%	1	1	1%	0.4933
Rash	1	1	1%	0	0	0%	1.0000
Hypesthesia	2	3	3%	6	6	8%	1.0000
Neuralgia	1	1	1%	0	0	0%	1.0000
Paresthesia	3	3	4%	3	4	4%	1.0000
Total Events	104			53			---

1. Number of patients experiencing at least one occurrence
2. Pain during shock wave application: statistical significance with p-value <0.0001 by Fischer's Exact Test
3. Pain experienced immediately after treatment through 3 month follow-up

All but one adverse event was reported by the investigator as not serious: one patient reported strong pain at the 3 month follow-up visit The event resolved without intervention before the patient was exited from the study.

All but one adverse event had resolved: one patient in the Active group reported paresthesia of the lateral distal part of the plantar surface at the 3-5 day follow-up visit. The ankle-foot sensation testing was abnormal for all four locations at the 3-5 day follow-up visit. The patient was prescribed ibuprofen, ice, and rest and was referred to a neurologist for further evaluation, with abnormal ankle/foot sensation testing at locations 1,2,3, but normal at location 4. The neurologist report noted irritation of the N. plantaris lateralis with no loss of muscle strength. This adverse event was reported as unresolved at the 3 month visit. The patient was seen at the 6 month follow-up visit and the adverse event was again reported as unresolved. The patient discontinued from the study before the 12 month follow-up.

Adverse events were evaluated through 12 months for Active and Sham patients. No adverse events were reported in the Active group after the 3 month follow-up visit. Adverse events for patients who originally received Sham treatment who elected Active unmasked treatment were also evaluated. The events, which are summarized in Table 3 below, were evaluated through 12 months after initiating Active unmasked treatment. Of the 73 Sham patients remaining at the 3 month follow-up visit, 51 elected to receive the unmasked Active treatment. Adverse events reported through 12 months for these patients are presented in Table 3 below.

Table 3: Adverse Events for Open Label Active Treatment of Patients Originally Randomized to Sham Treatment Through 12 Months Follow Up

Adverse event	X-over Tx (n = 51)		3-5 day		6 weeks		3 months		6 months		12 months	
	pts[1]	occur	pts[1]	occur	pts[1]	occur	pts[1]	occur	pts[1]	occur	pts[1]	occur
Pain during treatment	26	26	--	--	--	--	--	--	--	--	--	--
Pain post treatment	--	--	11	11	3	3	3	4	2	2	0	0
Edema	--	--	7	7	0	0	0	0	0	0	0	0
Ecchymosis	--	--	1	1	0	0	0	0	0	0	0	0
Petechiae	--	--	1	1	0	0	0	0	0	0	0	0
Paresthesia	--	--	1	1	1	1	0	0	0	0	0	0
Infection	--	--	0	0	0	0	1	1	0	0	0	0
Injection Site Hemorrhage	--	--	1	1	0	0	0	0	0	0	0	0

1. Patients experiencing at least one occurrence within each interval

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 by dissatisfaction in the quality, identification, durability, reliability, safety, effectives and/or performance of this product should notify the distributor, Dornier MedTech, Inc. If any Dornier 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:

Dornier MedTech, Inc.
1155 Roberts Blvd.
Kennesaw, Georgia 30144
Telephone: 1 800-367-6437
Fax: 1-770 514-6288, Attn: Regulatory Affairs