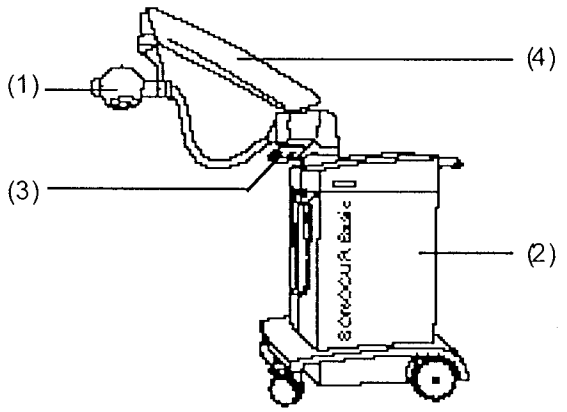
## *Product description:*

The Siemens SONOCUR Basic system (see figure below) is a mobile ESWT unit, which consists of the following main system components:




(1) Shock head (or pressure wave generator) with coupling bellows;

(2) transportable trolley with charging unit and water conditioning system;

(3) control console; and

(4) articulating arm to position the shock head.

The SONOCUR Basic system features a finely adjustable electromagnetic shock wave generator. The shock head, or pressure wave generator, is suspended by an articulating arm which allows flexible movement of the tube in three different planes. The flexible movement enables precise positioning of the shock tube for the pain therapy application. The focus of the therapeutic shock wave can be adjusted for variable penetration depths (0-50mm).

From the control console, the following parameters can be selected and/or displayed:

- number of impulses per treatment
- number of impulses currently applied during session
- energy level indication (the shock wave energy can be selected between densities ranging from 0.04 mJ/mm² to 0.5 mJ/mm² in eight energy levels)
- warning and error messages

## *Intended Use – Indications:*

The Siemens SONOCUR Basic is a non-surgical alternative for the treatment of chronic lateral epicondylitis (commonly referred to as tennis elbow) for patients with symptoms of chronic lateral epicondylitis for 6 months or more and a history of unsuccessful conservative treatments.

## *Contraindications:*

There are no known contraindications to ESWT with the SONOCUR Basic for treatment of chronic lateral epicondylitis.

## *Warnings:*

The following warnings pertain to the use of the SONOCUR Basic for treatment of chronic lateral epicondylitis (tennis elbow).

- Operators of the SONOCUR Basic 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.
- ESWT with the SONOCUR Basic should be prescribed by and performed under the supervision of a physician trained and experienced in the care of patients with lateral epicondylitis.
- 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.
- If patients experience severe pain/discomfort at the application site during treatment, the system operator should decrease the penetration depth of the therapeutic shock wave focus (0-50mm) by increasing the water level in the coupling bellows.
- If patients experience a vaso-vagal reaction during treatment, the patient should be reclined to a supine position until symptoms disappear.
- Patients currently undergoing systemic anticoagulation therapy (example—coumadin, heparin) should consult their physicians regarding temporary discontinuation of such medications before ESWT to prevent potential ecchymosis/bruising.
- Patients on daily aspirin therapy should temporarily discontinue aspirin intake 1 week before ESWT therapy.

## *Precautions:*

The following precautions pertain to the use of the SONOCUR Basic for treatment of chronic lateral epicondylitis (tennis elbow).

- Electromagnetic compatibility (EMC):

  If electromagnetic interference between the extracorporeal shock wave system and nearby electronic equipment is suspected (as evidenced by erratic behavior with either device), it is recommended that their distance be increased until proper operation resumes. If it is necessary to operate an electronic device in close proximity to the ESWT system during treatment, the device and the ESWT system should be tested for proper simultaneous operation prior to clinical use.

- Never remove any of the cabinet covers to the system's electronics. The high voltage power supply circuits utilized by extracorporeal shock wave systems use voltages that are capable of causing serious injury or death from electric shock.

- If the device malfunctions during treatment or the treatment is discontinued, the therapeutic effects may not be as noticeable.

The safety and effectiveness of the SONOCUR Basic has not been established for:

- Pregnant women;
- Patients younger than 18 years of age;
- Patients with a coagulation abnormality, thrombopathy, infection, tumor, cervical compression syndrome, cervical or upper extremity arthritis, local arthrosis, neurologic abnormality, or radial nerve entrapment;
- Patients who have had previous surgery for lateral epicondylitis;
- Patients who suffer from severe systemic diseases that may lead to sensory changes or neuropathic pain. For example, this may include diseases such as gout, diabetes mellitus, rheumatoid arthritis;
- Patients with cardiac pacemaker;
- Patients who received physical or occupational therapy less than four (4) weeks prior to ESWT;
- Patients who received a local steroid injection less than six (6) weeks prior to ESWT; and
- Patients with tennis elbow affecting both arms or who have had previous surgery for this condition.

## *Adverse Events:*

Adverse events observed during a clinical study of 114 patients that were associated with extracorporeal shock wave therapy (ESWT) include those listed below, categorized by frequency:

Adverse events reported in >20% of patients:

- pain at, or surrounding the treatment site

Adverse events reported in <20% of patients

- nausea
- myalgia
- joint disorder
- pallor
- dizziness
- hypertonia
- hypesthesia
- paresthesia
- tremor
- vasodilation
- application site reaction
- sweating

The number and frequency of each reported event is summarized in Table 1 below:

**Table 1: Device Related Adverse Events at 12 Week Follow-up**

| | Active | | | Placebo | | |
|---|---|---|---|---|---|---|
| | Number of Patients [1] | Number of Occurrences | % of Patients [2] | Number of Patients [1] | Number of Occurrences | % of Patients [2] |
| Pain | 28 | 60 | 50% | 13 | 32 | 22.4 |
| Nausea | 10 | 10 | 17.9% | 0 | 0 | 0% |
| Application Site Reaction | 6 | 8 | 10.7% | 5 | 5 | 8.6% |
| Sweating | 5 | 5 | 8.9% | 0 | 0 | 0% |
| Dizziness | 4 | 4 | 7.1% | 0 | 0 | 0% |
| Hypertonia | 3 | 5 | 5.4% | 3 | 3 | 5.2% |
| Hypesthesia | 3 | 5 | 5.4% | 1 | 2 | 1.7% |
| Paresthesia | 3 | 4 | 5.4% | 8 | 12 | 13.8% |
| Joint Stiffness | 2 | 2 | 3.6% | 0 | 0 | 0% |
| Myalgia | 2 | 2 | 3.6% | 0 | 0 | 0% |
| Tremor | 2 | 2 | 3.6% | 0 | 0 | 0% |
| Vasodilation | 2 | 2 | 3.6% | 0 | 0 | 0% |
| Pallor | 1 | 1 | 1.8% | 0 | 0 | 0% |
| Accidental Injury | 0 | 0 | 0% | 2 | 3 | 3.4% |
| Headache | 0 | 0 | 0% | 2 | 7 | 3.4% |
| Peripheral Edema | 0 | 0 | 0% | 1 | 1 | 1.7% |
| Twitching | 0 | 0 | 0% | 1 | 1 | 1.7% |
| Sinusitis | 0 | 0 | 0% | 1 | 2 | 1.7% |

1. Number of patients experiencing at least one adverse event
2. Based on the total number of patients in each treatment group: active treatment group=56 patients, placebo group=58 patients

During the study, three patients exhibited EKG changes that were determined by the investigators and cardiologists not to be treatment related.

**Potential Adverse Events:**

Potential adverse events not seen during the study include:

- Neuropathy
- Tendon rupture
- Local hematoma
- Misdirection of energy

## *Clinical Study:*

***Study Design:***

The Siemens Sonocur Basic multi-center pivotal trial was a randomized, double-blind (patients and evaluators), placebo-controlled, parallel treatment study. A total of 114 patients were enrolled in the study at 3 investigational sites.

Patients with chronic tennis elbow were examined and randomized to one of two treatment groups (active, placebo). Each patient was scheduled to receive three treatments: once a week for a three-week period. For all completed treatments, a maximum of 2100 impulses per treatment session was delivered for a total energy delivery of 9.27J for all three sessions. The procedure for the active and placebo treatments was performed identically except that for patients receiving the placebo treatment, a sound-reflecting pad was placed between the treatment site and the shock wave head. No local anesthetic injection or analgesic was allowed during treatment.

During the study, assessments of pain level and functional activity were performed. At each visit, the pain intensity was evaluated using the Thomsen provocation test (resisted wrist extension). The patient was asked to record the level of pain that he/she was experiencing on a visual analog scale (VAS), which was a 100mm scale with 0 for no pain and 100 for intolerable pain. In addition, functional improvement was also examined using an Upper Extremity Functional Scale, or UEFS, test. For this test, patients in the study were asked to score their ability to perform specific daily chores (such as opening jars/doors, washing dishes) on a scale from 1 to 10, with a score of 1 meaning that the patient had no problem at all and a score of 10 meaning that the patient could not perform the activity. Additional measures of efficacy were examined including the patient's overall impression, grip strength, activity evaluation (ability to perform activities that were limited by his/her tennis elbow condition), and pain medication consumption. Safety assessments included an assessment of adverse events, physical examination, X-rays, vital signs, 12-lead EKG, clinical labs, and proportion of patients who couldn't tolerate treatment.

Patients were scheduled for follow-up evaluations, occurring at 1-, 4-, 8-, 12-weeks, 6-months, and 12-months post-treatment. The primary analysis of the safety and efficacy data was performed after all patients were enrolled, treated, and completed their 12-week follow-up requirements.

***Inclusion/ Exclusion Criteria:***

The *inclusion criteria* included:

- history of lateral epicondylitis for at least 6-months;
- pain that is unresponsive to two of three conventional therapy programs (local steroid injections, physical/occupational therapy (PT/OT), non-steroidal anti-inflammatories (NSAIDs));
- pain by palpation of the lateral epicondyle;
- baseline pain that was ≥ 40 during resisted wrist extension ("Thomsen provocation test") on a 100mm visual analog scale (VAS); and
- signed informed consent.

The *exclusion criteria* included:

- < 18 years of age;
- received local injections within 6 weeks, physical/ occupational therapies within 4 weeks, or non-steroidal anti-inflammatories within 1 week prior to randomization;
- received systemic therapeutic anticoagulants;
- active bilateral epicondylitis;
- history *and/or* physical findings of cervical compression syndrome, cervical or upper extremity arthritis, local arthrosis or neurologic abnormality, rheumatoid disease, or radial nerve entrapment;
- arthrosis of the elbow, as confirmed by X-ray diagnosis (AP, lateral views)
- previous surgery for lateral epicondylitis;
- participated in a Workman's Compensation Program or planned to apply for the Program;
- thrombopathy, infection, tumor, or other severe systemic diseases;
- pregnancy;
- participated in a study with any experimental therapy within the last 30 days.

***Efficacy and Safety Endpoints:***

- *The primary efficacy endpoint* was at least a 50% reduction from baseline to Week 12 post-treatment in the pain visual analog scale (VAS) during resisted wrist extension. The VAS is a 100-mm straight line with 0 for no pain and 100 for intolerable pain.

- *The secondary efficacy endpoint* was an improvement from baseline to Week 12 post-treatment in the patient's mean upper extremity function score. Function was assessed using the Upper Extremity Function Scale (UEFS) (Pransky et al.). The UEFS assesses limitations on 8 activities on a scale of 1-10 (1=no problem, 10=major problem/can't do).

Additional measures of efficacy were examined including the patient's overall impression (measured on 100mm VAS), grip strength testing (measured using a standard dynamometer), activity evaluation (ability to perform activities that were limited by his/her tennis elbow condition- measured similar to UEFS), and pain medication consumption. The patients grip strength was measured. Safety assessments included an assessment of adverse events, physical examination, X-rays, vital signs, 12-lead EKG, clinical labs, and proportion of patients who couldn't tolerate treatment.

***Study Population:***

Of the 114 patients enrolled in the study and included in the intent-to-treat (ITT) cohort, 56 patients were assigned to the active treatment group and 58 patients were assigned to the placebo group. Two (3.6%) active treatment group patients could not tolerate treatment and discontinued from the study prior to completing all three scheduled treatments. A third active treatment group patient was discontinued due to a low platelet count, which was found to be a pre-existing condition prior to study participation. Of the 58 placebo patients, 3 (5.2%) patients discontinued prior to the 12- week follow-up period to seek alternative therapy.

Patient demographics and treatment history are summarized in Table 2, below. The mean age for the active treatment group was 47 years (ranging from 35-71 years), and the mean age for the placebo group was 47 years (ranging from 35-60 years). There were 27 male (48.2%) and 29 female (51.8%) patients in the active treatment group and 27 male (46.6%) and 31 female (53.4%) patients in the placebo group. The mean height was 171 cm and the mean weight was 77kg. Physical exam and medical histories at baseline were also similar between the treatment groups.

**Table 2: Patient Demographics and Treatment History**

| Characteristic | Active Treatment Patients (N=56) | Placebo Treatment Patients (N=58) |
|---|---|---|
| Age (years) | | |
| Mean | 47 | 47.3 |
| Range | 35-71 | 35-60 |
| Gender | | |
| Male | 27 (48.2%) | 27 (46.6%) |
| Female | 29 (51.8%) | 31 (53.4%) |
| Height (cm) | | |
| Mean | 170.9 | 171.8 |
| Range | 152.4-188.0 | 149.9-190.5 |
| Weight (kg) | | |
| Mean | 75.9 | 78.9 |
| Range | 50.9-120.0 | 53.0-120.2 |
| Affected Arm | | |
| Right | 35 (62.5%) | 41 (70.7%) |
| Left | 21 (37.5%) | 17 (29.3 %) |
| Prior Therapies* | | |
| All three | 41 (73.2%) | 43 (74.1%) |
| Steroid Injections & PT/OT | 4 (7.1%) | 6 (10.3%) |
| Steroid Injections & NSAIDs | 6 (10.7%) | 5 (8.6%) |
| PT/OT & NSAIDs | 5 (8.9%) | 4 (6.9%) |
| Symptom Duration (months)** | | |
| Mean | 21.3 | 20.8 |
| Range | 6.0-178.0 | 6.0-176.0 |

* PT/OT= physical and occupational therapy, NSAIDs= non-steroidal anti-inflammatories

** from date of initial diagnosis by a physician to enrollment into the study

Each treatment group (active, placebo) had lateral epicondylitis for an average of 21 months (12-month median) prior to randomization. In total, seventy-six (66.7%) patients had their right arm affected and 38 (33.3%) patients had their left arm affected. Mcre than 70% of the patients in each treatment group had all three types of therapies (injections, PT/OT, NSAIDs) prior to enrollment, and 54 (93.1%) placebo patients and 51 (91.1%) active treatment patients had steroid injections.

***Efficacy and Safety Results:***

*Efficacy Results:*

For the ITT population (refer to Table 3, below), the placebo and active treatment groups had comparable pain scores at the baseline evaluation. The average pain score for patients who received the active treatment was 74 at baseline and 37.6 at 12 weeks. The average score for the placebo patients was 75.6 at baseline and 51.3 at 12 weeks.

**Table 3: Summary of Patient Pain Assessments from Baseline to Week 12**

| Treatment Group | | Baseline | Week 1 | Week 4 | Week 8 | Week 12 |
|---|---|---|---|---|---|---|
| Active | N | 56 | 56 | 56 | 56 | 56 |
| | Mean | 73.98 | 55.55 | 49.09 | 40.77 | 37.59 |
| | SD | 15.79 | 25.18 | 26.79 | 28.67 | 28.68 |
| Placebo | N | 58 | 58 | 58 | 58 | 58 |
| | Mean | 75.57 | 63.97 | 60.57 | 54.81 | 51.33 |
| | SD | 16.00 | 23.19 | 25.48 | 25.12 | 29.65 |
| | | | | | | |

**N=number of patients**
**SD= standard deviation**

The primary efficacy endpoint was at least a 50% reduction from baseline to 12-weeks post-treatment in the pain visual analog scale (VAS) during resisted wrist extension. For the intent-to-treat cohort, the results show that the active treatment group had 34/56 (60.7%) of the patients and the placebo group had 17/58 (29.3%) of the patients achieving at least a 50% reduction in pain during provocation at Week 12 compared with baseline. There was a statistically significant (p=0.001) between group difference.

The secondary efficacy endpoint was an improvement from baseline to Week 12 post-treatment in the patient's mean upper extremity function scale (UEFS) score. For the ITT population (refer to Table 4, below), the placebo and active treatment groups had comparable mean upper extremity function scores (UEFS) at the baseline evaluation. The mean UEFS score for the active treatment group was 4.68 at baseline (SD=1.78) and the mean UEFS score for the placebo group was 4.63 (SD=1.8) at baseline. At Week 12, there was a statistically significant (p=0.01) difference between groups in the mean UEFS scores, compared with baseline.

**Table 4: Summary of UEFS Assessments from Baseline to Week 12**

| Treatment Group | | Baseline | Week 1 | Week 4 | Week 8 | Week 12 |
|---|---|---|---|---|---|---|
| Active | N | 56 | 53 | 51 | 52 | 53 |
| | Mean | 4.68 | 3.23 | 2.80 | 2.54 | 2.25 |
| | SD | 1.78 | 1.89 | 1.70 | 1.52 | 1.57 |
| Placebo | N | 58 | 57 | 57 | 55 | 54 |
| | Mean | 4.63 | 3.71 | 3.79 | 3.54 | 3.23 |
| | SD | 1.80 | 1.77 | 1.98 | 2.12 | 2.09 |
| | | | | | | |

**N=number of patients**
**SD= standard deviation**

The percent improvement in the average efficacy scores (pain, UEFS, patient's overall impression, activity level, and grip strength testing) at 12-weeks compared with baseline is summarized in Table 5, below.

**Table 5: Percent Improvement in Average Efficacy Scores at 12 Weeks, Compared with Baseline**

| | SONOCUR Basic | | | Placebo (Mock) | | |
|---|---|---|---|---|---|---|
| | average score at beginning of study | average score at 12 weeks | % improvement | average score at beginning of study | average score at 12 weeks | % improvement |
| Pain * | 74 | 37.6 | 49% | 75.6 | 51.3 | 32% |
| UEFS * | 4.7 | 2.3 | **51%** | 4.6 | 3.2 | **30%** |
| Activity Evaluation * | 7.7 | 3.5 | **55%** | 7.4 | 5 | **32%** |
| Overall Impression * | 70.3 | 32.8 | **53%** | 66 | 46.2 | **30%** |
| Grip Strength Testing | 71 | 87.1 | **23%** | 72.5 | 81.5 | **12%** |

* statistically significant ($p<0.05$) between group difference. p-value is calculated using one way ANOVA

*Safety Results:*

In general, the nature, severity, frequency, duration and resolution of adverse events were similar in the active and placebo group, with the exception of certain vasovagal responses (i.e. nausea, sweating, dizziness, hypesthesia) and reports of pain during treatment for the active group.

Table 1 (page 7: Adverse Events) summarizes the number and frequency of adverse events that were categorized as being possibly or probably related to the study treatment.

The following table (Table 6) shows the occurrence of adverse events for the active treatment group that were judged to be possibly or probably treatment related over the course of the 12-month study period.

**Table 6. Active Treatment Group: Adverse Events Through 12 Months of Follow-up**

| Adverse Events | Treatment Period | | | | Follow-up Period [1] | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Day of Treatment (*Treatments 1, 2, 3*) [N=56] | | Between Treatments 1-2 [N=56] | Between Treatments 2-3 [N=54] | <=1 Week [N=53] | >1-4 Weeks [N=51] | >4-8 Weeks [N=52] | >8-12 Weeks [N=53] | >12 Weeks-6 Months [N=48] | >6-12 Months [N=46] |
| | # of patients [2] | # of occurrences | # of patients [2] | # of patients [2] | # of patients [2] | # of patients [2] | # of patients [2] | # of patients [2] | # of patients [2] | # of patients [2] |
| Pain | 24 | 46 | 6 | 5 | 4 | 5 | 3 | 1 | 0 | 0 |
| Nausea | 10 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Application Site Reaction | 4 | 6 | 2 | 2 | 3 | 2 | 2 | 1 | 1 | * |
| Sweating | 5 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dizziness | 4 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypertonia | 2 | 3 | 1 | 0 | 2 | 1 | 1 | 1 | 0 | 0 |
| Hypesthesia | 3 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Paresthesia | 3 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Joint Stiffness | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | * |
| Myalgia | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tremor | 2 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vasodilation | 2 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pallor | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

[1] relative to the last treatment, using protocol defined windows. No new adverse events judged as being possibly or probably related to treatment were reported after the 6-month follow-up period.

[2] number of patients experiencing at least one occurrence within each time interval

* patient discontinued from study during the 6-month follow-up visit and subsequently had surgery for tennis elbow. No additional study data is available for this patient after the 6-month follow-up period.

At the time of the 12-week follow-up visit, all device related adverse events had resolved, except for one patient who had moderate elbow stiffness and mild swelling that was still ongoing at the time of the 6-month follow-up visit. This patient, who had an x-ray with normal findings at baseline and 12 weeks, was unresponsive to treatment and terminated study participation soon after the 6-month follow-up visit for surgery. There were no new device related adverse effects reported during the long-term (3-12month) follow-up period.

In addition to adverse events, lab values, physical exam results, X-rays, vital signs, and EKGs were assessed. No significant between group differences were observed.

## *Training:*

### The Physician

The physician prescribing ESWT with SONOCUR should be trained and experienced in the care of patients with tendinopathies and /or lateral epicondylitis. This includes conventional therapies for this indication, as well as knowledge of exclusion criteria and precautions as described in this manual. The physician should identify the region to be treated and supervise the treatment sessions performed by a trained operator.

### The Operator

The operator should be trained by an authorized* application specialist. The training includes:

- Study of the operating manual
- SONOCUR functionality of all keys and menu options
- SONOCUR transportation and storage
- System set-up and daily maintenance procedures
- System malfunctions, error codes and proceedings
- Patient seating and positioning of the patient's arm.
- Positioning of the shockwave head and treatment protocol
- Knowledge of potential adverse events (AE) and procedures if AE's occur.
- Cleaning and disinfecting of coupling bellows

The operator should perform at least two to four (2-4) procedures under the guidance of the application specialist. The name of the trainee and the trainer should be kept on file with the clinic along with the training date.

* The application specialist will be provided by the manufacturer or distributor.

# *System start-up*

Establish the line connection to the SONOCUR Basic

# *Switching on the therapy system*

Press this button to turn on the power switches on the front panel of the SONOCUR Basic.

Run the daily function and safety tests before beginning therapy.

## *Daily tests*

Before beginning therapy

As the user, you must make sure that all safety-related equipment is functioning properly and the system is ready for operation.

Check the function of the unit foot brakes

Inspect the articulating arm travel and counterbalance

Inspect all readings on control display

# *Switching off the therapy system*

Press this button to turn off power via the switch on the front panel of the SONOCUR Basic