

# Painmaster™

## Therapeutic Results of a New Method of Stable Galvanization with Current of 10µA

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### Preface

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PAINMASTER provides a totally new physical treatment method for electrotherapy. Two self-adherent, active electrode patches, linked by a cable, self generate the necessary current of approximately 10µA required for a stable, constant galvanism. This current is about 1% of the commonly used factor of 1mA for electrotherapy. The treatment however lasts 100 times longer than usual. Crucial for galvanic treatment is the quantity of charge carriers Q (ions), which are being moved in the body tissues in the electrical field between the therapeutic electrodes as a measure of the degree of stimulation of electrically active body structures (Gillert), in accordance with the equation for the physiological galvanization effect:  $Q(\text{carrier}) = I(\text{current}) \times t(\text{time})$ . An equal quantity of ions are moved during the course of 24 to 48 hours treatment with PAINMASTER as with the more usual electrotherapy involving approximately an I(current) of 1mA for a t(time) of 15 to 20 minutes.

For this reason, as may be expected, the common indications for short term electrotherapy are also those for PAINMASTER.

Since there is no requirement for any electrical device, the patient can continue his/her day-to-day activities without any hindrance.

### Patients, Materials and Methods

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**STUDY 1.** A total number of 269 patients with different musculoskeletal complaints were studied. The PAINMASTER patches used were always fully functional. The following physicians were involved in the study:

1. Dr.med. Brand, Clinical Director, Painclinic spec in Migraine, Koenigstein, FRG
2. Dr.med. Doemer, Private Orthopedic Surgeon, Winterberg, FRG
3. Dr.med. Mueller-Reinhardt, Private General Physician, Medebach, FRG
4. Dipl.med. Bergner, Physician, Inventor of PAINMASTER, University of Ulm, FRG

**STUDY 2.** Dr. Doemer, a private orthopedic surgeon from Winterberg, Germany, additionally conducted a pilot double blind study with 12 patients. Painful muscular contractions in the cervical spine (1x), of the dorsal spine (1x) and the lumbar spine (10x) were treated.

**STUDY 3.** Skin compatibility with copper, aluminum and the PE (polyethylene) foam patch was also assessed.

## Results

**STUDY 1.** The results of all 269 patients in the open study are summarized and shown in table 1. In 136 (50.6%) a dramatic pain relief i.e. complete resolution of pain was achieved. In a further 50 (18.6%) a significant improvement was recorded.

In a total of 186 cases (69.1%), a significant improvement was recorded. 66 patients (24.5%) reported no improvement and 17 (6.3%) reported an increase in pain.

**Table 1**

Diagnosis	Degree of Effect					Total
	+	(+)	0	(-)	-	
Muscle spasms, lumbar spine	44	12	7	2	5	70
Muscle spasms, cervical spine	27	8	11	0	1	47
Muscle spasm, dorsal spine	12	8	7	0	1	28
Chronic nerve root irritation	9	3	6	0	0	18
Headache, cervical spine origin	13	5	8	0	3	29
Migraine	8	0	6	2	2	18
Prolapse	5	2	5	0	0	12
Morbus Scheuermann	1	1	1	0	0	3
Arthritis of knee joint	6	7	6	0	0	19
Arthritis of hip joint	3	1	3	0	0	7
Arthritis of the shoulder	4	2	4	0	0	10
Epicondylitis (tennis elbow)	3	1	2	0	0	6
Insertion tendinosis after bicep rupture	1	0	0	0	0	1
Rheumatoid arthritis, shoulder	0	0	0	0	1	1
<b>Total Results</b>	<b>136</b>	<b>50</b>	<b>66</b>	<b>4</b>	<b>13</b>	<b>269</b>

Legend: + Significant  
 (+) Good  
 0 None  
 (-) Low increase of pain  
 - High increase of pain

**STUDY 2.** During a randomized double blind study, TEST electrodes were used eight times and placebo electrodes were used four times. Seven times the TEST electrodes met with success while one patient reported no result. Two of the four patients using placebo electrodes stated positive results while two reported no results.

Type of Electrode	Total # Tested	Positive Effect	No Effect	% of Total Tested
TEST	8	7		58
TEST	8		1	8
Placebo	4	2		17
Placebo	4		2	17
<b>Total</b>	<b>12</b>	<b>9</b>	<b>3</b>	<b>100</b>

In 75% of all cases (i.e., 7 TEST electrode with positive effect and 2 Placebo electrodes with no effect), a correlation has been made between the functional status of the patch and the expected treatment result.

**STUDY 3.** Very few skin reactions were identified against the patches in this test study. Of 269 patients in this study, 32 instances of redness occurred. Two were a reaction to the copper; one was a reaction to the aluminum; twenty-nine were reactions to the dressing. The redness disappeared after a couple of hours (11.4%) In four of these cases (1.4%), the allergic reaction also caused a small blister (vesicles) on the skin. Two patients developed the small blisters below the adhesive area of the dressing; one patient developed the small blisters below the copper electrode; one patient developed the small blisters below both metal areas.

Type of Allergy	Small blister	Small blister and redness	Total
Allergy to copper	1	2	3
Allergy to Aluminum		1	1
Allergy to copper/aluminum	1		1
Allergy to dressing	2	29	31
<b>Total</b>	<b>4</b>	<b>32</b>	<b>36</b>

In a total of 36 cases (13.4% of patients in study), skin reactions have been identified. 31 cases (86% of reactions) were due to the dressing material, a material similar to that used in ECG electrode patches. In only five of the cases (1.86%), the reaction was to the copper or aluminum metals.

**Conclusion:** One may state this is an acceptable level with only minor allergic reactions observed.

## Discussion

The present treatment results are a summary of all documented previous treatments with PAINMASTER. Within the open multicentric pre-study, the 269 patients involved reported a positive treatment in 69.1% of the cases. Due to the simplicity of the method, a high acceptance was shown by the patient.

While a prolongation of therapy may improve results, more studies are needed to clarify this. In the few cases of pain increase during the therapy (6.3%), the cause is perhaps an overdose reaction. Due to the mild current, the patient was able to control the therapy time depending on the start of his/her reaction.

Within a randomized double blind study, one has to differentiate real versus imagined results due to the use of placebos. The results reported by Dr. Doemer (75% correlation between the functional status of PAINMASTER and the expected treatment results) show positive results as to the effectiveness of PAINMASTER.

## Summary

A new method is being recommended when electrical current therapy is indicated in cases such as painful muscular contractions, especially in the spinal area, arthritis and headache. This treatment consists of a stable constant galvanization with a current (I) of approximately 10uA, 1/100 of the commonly used current of 1mA. Due to the fact that therapy time (t) has been increased by a factor of 100 in accordance with the recognized equation  $Q \text{ (carrier)} = I \text{ (current)} \times t \text{ (time)}$ , one can expect a similar effect to the conventional electrotherapy methods. In **STUDY 1**, the multicentric pre-study of 269 patients, 69.1% show positive results.

In **STUDY 2**, the double blind study with twelve patients, 75% of patients showed expected results.

At the present time, a randomized double blind study of 200 patients is being conducted at the University of Heidelberg under the supervision of Prof. Dr. M. Zimmermann, president of "The German Liga for Study of Pain." The leader of the study is Mrs. Dr. Zoeller, a private anesthetist in Heidelberg.

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\* ORIGINALLY IN GERMAN WITH ENGLISH TRANSLATION

## Painmaster™ Principle

Painmaster™ electrodes consist of two self adhesive skin-contact electrodes, one of aluminum/copper and one of copper/aluminum configuration. When in contact with the electrolyte salt found in normal perspiration, the electrodes will generate a weak potential difference. The two electrodes are connected by a flexible connecting wire. Prior to use, the electrolyte gel within the electrodes is isolated and the cells are held inactive. A thin breakable membrane covering the electrolyte gel is broken when the electrode is applied to the skin by pressing on the electrode cap. The rupturing of the thin breakable membrane allows the gel to contact the gel contact layers of the electrode, completing the circuit and beginning the action of the natural galvanic battery. Self-adhesive plastic foam rings serve as insulators around the rims of the Painmaster's electrodes creating a sealed chamber for the electrolyte gel of the natural galvanic battery.

The Painmaster™ electrode produces a stable 10  $\mu$ A current for continuous treatment extending over several days. The same number of ions (charge) will be carried in the tissues in 24 hours as by conventional treatment at 1 mA for 15 minutes.

