

GALVAN DE 20

made in Germany

Operational manual for

DC- therapy - apparatus

With pulsating current (PC) und constant current (CC)
for

tap water- and medicament -iontophoresis, current-,
hyperhidrosis - therapy and for pain relief



manufacturer: AAM GmbH, Tiefentalstrasse 2, 78 098 Triberg-Nussbach
Tel: (49) 7722 / 86 66 22 Fax: (49) 7722 / 86 66 93
e-mail: dold@aam-med.com Homepage: www.aam-med.com

DE20, Vers. 03, 2010-03-29

Preface

The manual should be read thoroughly before operating this device. If there should still be any questions, please contact me.

The apparatus should be used once a day over a period of 2-3 months, even if your medical condition should get better. A lasting abatement can only be achieved when using the device over a longer period of time.

A therapy with this Galvan-apparatus can also be a good way to add on to other therapies which have been applied before.

General Description

Basic equipment: 1 combined PC- (pulsating current) and CC- (constant current) therapy apparatus, 2 electrode cables, 1 electrode duplet 135 x 100 mm with sponge pockets, 1 user manual

Special accessories: Plastic tubs for 2- cabin - bath (tap water iontophoresis), electrodes with sponge pockets in multiple sizes

Field of application:

Electrical currents stimulate the nerves. The currents are not harmful but comfortable and, according to previous medical findings, free of side effects. The intensity of the current can be adjusted smoothly.

Due to the direct and indirect effects of the current, the success of therapy can be achieved for following discomforts:

- | | |
|------------------------------------|------------------------|
| * Gout | * Arthrosis |
| * Myalgia | * Bronchitis |
| * Neuralgia | * Polyarthritis |
| * Muscle rheumatism | * Hyperhidrosis |
| * Disturbed blood flow | * Sleeplessness |
| * Disturbed cell metabolism | * Headaches |

Contraindications:

You should not use this device if you have electronic or metallic impants, malign tumors, thrombosis, renal insufficiency or if you are pregnant.

If you are concerned about the usage of this apparatus you should seek medical advice.

Examples of use can be found in the appendix. You do not need technical know-how to use this apparatus correctly.

Manufacturer liability:

The manufacturer is only liable for failures, which can be ascribed to improper production or allowances which were not adhered to. The manufacturer is not liable for application errors and errors in treatment.

According to §5 of the Medical Devices Directive, version of 07.August 2002, the manufacturer is AAM GmbH, Tiefentalstrasse 2, 78 098 Triberg-Nuss- bach.

Warranty

The warranty period for manufacturing errors is 24 months. The electrodes, sponge pockets, cables and batteries (consumable supply) are not included in the warranty.

Warning:

When using the apparatus next to (less than ca. 1m) a short wave or micro-wave device, fluctuations of the output value can occur.

Portable and mobile high-frequency devices (e.g. mobile phone) can affect the apparatus.

Using accessories, which are not approved by the manufacturer can cause damage and can lead to an increased emission of electromagnetic waves or to a reduced inference resistancy of the apparatus.

An effective current density on the electrodes exceeding 2 mA/cm² requires a great deal of attention. It is important that the electrodes are applied correctly, so that the sponge-covered electrode is in full contact with the skin. If only applied partially the current density can cause skin irritations.

The provided electrode cables are used to connect the electrodes to the apparatus.

Maintenance:

The apparatus is free of maintenance.

Only the manufacturer or companies authorised by the manufacturer are allowed to carry out repairs.

Classification " BF "

This electric-powered therapy apparatus operates on batteries and therefore is free of earthing. According to DIN EN 60601-1 it is a device of type BF.

Care instructions:

1. The apparatus and the electrodes can be cleaned and disinfected with all detergents normally used in medical practices. The apparatus should not be submerged in any form of liquids, furthermore no detergents which might cause corrosion should be applied to the apparatus.
2. After having used the apparatus the electrodes and the sponges are to be cleaned and disinfected in luke warm water. The sponges can also be washed in the washingmachine, along with your hot wash.
3. When disconnecting the cables from the apparatus, make sure to pull the plug gently. The cables should not be bent too much and knots in the cables should be avoided.
4. Should you not be using the apparatus over a longer period of time, please remove the batteries from the apparatus and store them separately. Used batteries are to be disposed in the hazardous waste.

Disposal:

In the case of disposal, the apparatus should be sent back to the manufacturer.

MPC

The apparatus complies with the electric protection class II and the medical protection class II a in accordance with MDD 93/42 EWG.

Electromagnetic compatibility

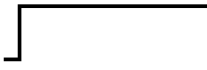
The apparatus is certified according to regulations of EN 60601-1-2:2001 and EN 60601-2-10:200. Tables of the guidelines of the manufacturer's declaration can be looked up in the internet at www.aam-med.com.

Equipment: DE 20


Technical details:

Measurement: 172 x 116 x 41 mm
Weight: 270 g
Nominal voltage: 6,0 V

Constant current (CC)

Current: constant current 
Amperage: 0 - 20 mA continuously adjustable
from 1 to max. 2000 ohm load resistance
Output voltage: maximum 40 V irrespective of measuring resistance

Pulsating Current (PC)

Current: pulsating current 
Amperage: 0 - 30 mA continuously adjustable
from 1 to max. 2000 ohm load resistance
Output voltage: maximum 60 V irrespective of measuring resistance

Accessories:

Electrode duplet with sponge pockets	135 x 100 mm	1 duplet	Order-no: Z 1000
Electrode cable		2 cables	Order-no: Z 0066
User manual		1	Order-no: B 0020

Special accessories:

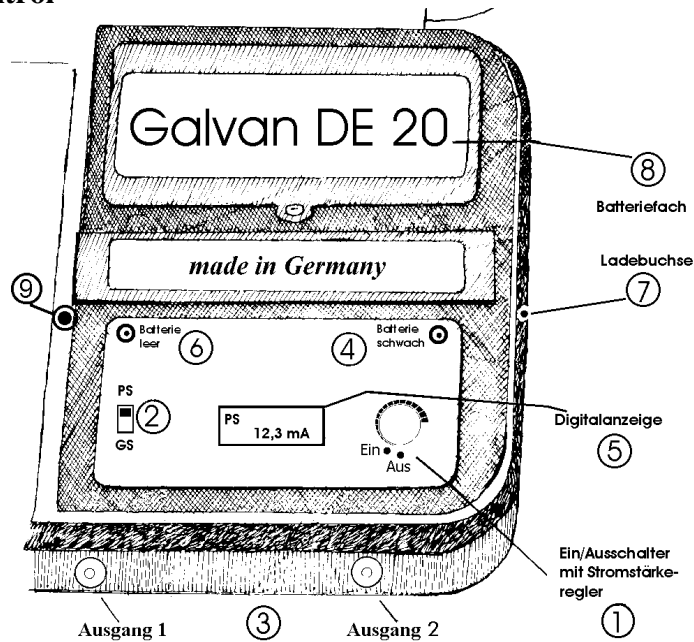
Accumulator (Baby)	1,2 V	4 Pieces	Order-no: A 0012
Charger		1	Order-no: A 0011
Electrodes with sponge pockets	90 x 50 mm		Order-no: Z 1001
Electrodes with sponge pockets	60 x 40 mm		Order-no: Z 1002

Maximum current density of electrodes when in full contact with skin:

135 x 100 mm	0,15 mA
90 x 50 mm	0,45 mA
60 x 40 mm	0,83 mA

Starting up the apparatus Galvan DE 20

1. On/Off switch with current controller
2. Diverter for type of current
3. Outlet sockets
4. LED, weak battery
5. Digital display
6. LED, flat battery
7. Charging socket
8. Compartment for batteries
9. Code-control



DC- current therapies can be conducted as follows:

1. Place each electrode separately into two nonelectroconductive tubs (e.g. plastic) filled with luke warm water. Place hands or feet into tubs.

If, after having placed hands or feet into the tubs, the milliamperemeter does not exceed 0,0mA the cutaneous electrical resistance is too high and the electrical conductivity of the water too low. In this case, add one teaspoon of common salt to each tub of water and stir thoroughly. Always use large electrodes when applying therapy to hands.

The measurement of the cutaneous electrical resistance or rather electrical conductivity of the water was integrated in order to keep the stress ratio at a minimum.

or

2. Apply sponge-covered electrodes directly to body parts which you wish to be treated. Before applying electrodes wet the sponges thoroughly. Water should not be dripping from the sponges.

Make sure you apply the electrodes correctly (surface of sponge-covered electrodes should have full contact to skin) in order to avoid punctual contact to skin only.

If the cutaneous electrical resistance is too high or the electrical conductivity of the water too low, fill up a tub with water and add a teaspoon of common salt. Wet the axillary sponges in the water.

Before you start, take off all accessories made of metal (e.g. jewelry). Connect the 2 mm connector of the red and black cables to the electrodes and insert electrodes into sponge pockets. Either place electrodes (in sponge pockets) separately in water tubs or apply electrodes (in wet sponge pocket) directly to body part. The electrodes (black silicon part) should not touch the skin. Now plug cables into respective plug socket of the apparatus (3). When the red cable is plugged into the red socket and the black cable plugged into the black socket, there is a “plus” (+) on the electrode with the red cable and a “minus” (-) on the black cable.

Before switching on the apparatus, use the respective switch to choose a type of current; PC for pulsating current or CC for constant current. **The type of current, PC or CC, can only be selected when the apparatus is turned off.**

You or your doctor will decide which type of current is best for you.

Apparently constant current is more effective but most patients feel more comfortable when using pulsating current.

In order to switch on the apparatus, turn the switch (1) to the left. A text will appear on the display for 5 seconds “AAM GmbH DE 20 V2.0”; this indicates that the apparatus is switched on. Now check if the type of current is correct. The first line of the display shows if the apparatus is set to “CC” constant current or “PC” pulsating current.

As soon as the electric circuit is closed the milliamperage meter will jump to the “0,4 – 0,7 mA” setting. This measurement indicates that the electric circuit is closed correctly. It will stand still until the amperage regulator is turned up or rather it will slowly rise until it has reached the previously chosen amperage.

When turning the button (1) clockwise, the amperage will be increased. The second line of the display (5) will show how much electricity flows.

Switching off the apparatus

The current flow will be disconnected automatically after 20 minutes. The text “treatment over” will appear on the display. To switch off the apparatus turn the button (1) back until it is engaged again. You will hear a click.

Changing polarity (4)

Change the polarity each time you start the therapy, unless otherwise recommended by your doctor. The pole reversal can be carried out when plugging the red cable into the black socket and the black cable into the red socket.

Maximum Amperage/Strength of current

The voltage of the constant current (CC) is limited to 40 V, the voltage of the pulsating current (PS) is limited to 60 V. Due to this, the maximum amperage cannot be reached when the electrical resistance of the skin is larger than 2000 ohm. In this case the word “max” will appear in the first line of the digital display. You should try decreasing the electrical resistance of your skin by wetting the sponges again or by taking a warm shower so that your skin is imbued. Another possibility would be measuring the inherent resistance of the electrodes with the help of an ohmmeter. After a certain time the electrodes lose their conductivity and need to be exchanged by new ones.

Combined treatment of hands and feet

Hands and feet can be treated simultaneously. Place your feet and your hands in a tub. If you wish to adjust the amperage, simply use one of your hands (already placed in tub) and turn the button (1) until you have reached the desired amperage. After having adjusted the amperage, place your hand back into the tub. This way all four extremities will be treated at the same time. We have had several patients who confirmed that this way of the treatment is as successful as the others.

Treatment of the hands

When doing the treatment for the first time you should ask another person to assist you with adjusting the amperage. When conducting the second treatment, simply turn on the apparatus using the turning knob and adjust the am-

perage according to the position you used during the first treatment. Place both of your hands in the tub filled with water. The current flow will be activated as soon as the electric circuit is closed. This will be the case when both of your hands are placed in the tub. The amperage will increase by 3 V per second until the desired/adjusted amperage is reached.

You can take your hands out of the tub at any time to readjust the amperage. Please note that you should only increase the amperage by one point at once.

Axillary treatment

The easiest way to attach the axillary electrodes is to put on a close-fitting t-shirt and to place the electrodes with the sponges underneath the t-shirt. The sponges need to be wetted thoroughly.

Iontophoresis treatment (Infiltration of medicals)

When choosing this treatment, please follow the instructions given in the directions for use which comes with the actual medicine. The directions of use will tell you which electrode you will have to apply the medical on to. When minus (-) apply supplement to the electrode with the black cable, when plus (+) apply the supplement to the electrode with the red cable. Connect the cables according to the coloration to the correct plugs of the apparatus. If there is no direction of use given, apply supplement to both electrodes and switch the polarity after you have reached half time of your treatment. The amperage has to be adjusted very smoothly and should not exceed 5mA or 0,1 mA/cm² on the surface of the electrode.

The directions for use must indicate that the supplement is applicable for the iontophoresis treatment.

Power supply:

The apparatus has a built in battery compartment (8) for four batteries (Baby – cell type LR 14) or rather accumulators (Baby – cell type C).

Monitoring battery capacity

As soon as the battery voltage drops below 4,9 Volt the yellow LED (4) will light up. The display will alternatively show the message “battery low”, the type of current and the miliampere. You will be able to conduct max. 2 more treatments. When the battery voltage drops under 4,7 volt the red LED (6) will light up. The display will show the message “batteries empty”. You will

have to either charge the accumulators or replace them for dry batteries before you can continue your treatment.

Charging of accumulators (7):

Located on the right side of the apparatus is a charging socket (7). Only the charging device delivered by our company should be connected, since it is synchronized with the built in accumulators. **When the DC plug of the charging device is plugged into the charging socket the treatment cannot be conducted.** The DC plug of the charging device disconnects the electrical circuit of the power supply.

Before using the apparatus again the DC plug from the charging device must be unplugged from the charging socket.

If there is no possibility of recharging the accumulators (e.g. when you are in a country where the power supply is 110 V) you can also use dry batteries (baby cell, typ LR14) to ensure the power supply of the apparatus.

In any case it is prohibited to use accumulators and batteries at the same time.

When replacing empty batteries, all four batteries are to be replaced. We recommend using alkaline batteries.

The duration of recharging of the accumulators is ca. 14 hours.

Code status

The code status indicates the number of treatments you have already conducted. In order to read the code status off the digital display you need to insert a pointy device e.g. pencil (max. 4 mm diameter) into the hole on the left side of the nameplate to switch on the code status. A four letter-figure combination will appear on the display. If you wish to know how many treatments you have conducted so far you can call us. With the help of this letter-figure combination we will be able to inform you on the number of treatments already conducted.

This code status was integrated into the apparatus so that, at the end of the rental period, it can be assessed if the apparatus was used frequently enough and if an extension of the rental period is therapeutically reasonable.

In the past several of patients who hardly or even didn't use the apparatus at all were prescribed an extension of their rental period. This sort of deficiency

should be corrected. The treatment meter was coded so that patients who don't use the apparatus effectively can not give false information when providing us with the code status.

Application programmes:

Even if the goal of the therapy has been reached already it is advisable to continue the treatment frequently. It is easier to avoid health problems when conducting frequent therapies than to start the treatment each time they appear again.

Please inform us if you cannot find any application example in this operating manual, which fits your health problem. We would be glad to help/assist you on the basis of specialised literature.

Potential application errors:

If you should perceive the current to be biting or unequally strong you should wet the electrodes again or by adjusting the electrodes more precisely onto the area of your body which you wish to treat.

Overly high adjusted amperage can lead to skin irritations, it does not lead to a more successful treatment. This is considered to be an error in treatment. You should be able to feel the current, but it must NOT be uncomfortable.

You will perceive every treatment differently. This is why the miliampere gauge should only be referred to a benchmark. You should adjust the amperage according to your comfort.

If cases of skin irritations should come up, stop the Galvan treatment and seek advice from your doctor. The doctor will then decide how the treatment can be continued.

When turning off the apparatus it can come to electrostatic discharge. These can be unpleasant but they are totally harmless. This effect was only observed when the floor, on which the patient stood, was electroconductive e.g. carpet with plastif fibre. These electrostatic discharges have nothing to do with the wellknown electric fence effect.(effect of pasture fence)

Starting apparatus (short discription)

- 1. Type of current:** with this switch (2) you choose the type of current CC or PC
- 2. On/ Off switch:** When turning this button (1) to the left until it has reached „0“ the apparatus will be turned on. In order to switch the apparatus off you need to turn the switch all the way back until it has reached its starting point. You will hear a click.
- 3. Digital display (5):** The digital display shows you the type of current and the milliampere. Furthermore, it indicates if the battery voltage is low in this case you need to recharge the accumulators.
- 4. Amperage controller (1):** After you have applied the electrodes, plugged in the cable plug into the output sockets (3) and have switched on the devices, slowly turn the amperage controller (1) clockwise until you have adjusted the amperage so that you can feel the current which is comfortable for you. When turning the amperage controller back into the other direction (contractlockwise) the amperage will be decreased.
- 5. Commutator:** The pole change of the current flow can be carried out by replugging/changing the cables. The red cable needs to be plugged into the black socket. The black cable into the red socket.
- 6. Light-emitting diode LED(5):** When the light-emitting diode (LED) lights up, it indicates that the accumulators are weak. You will be able to conduct 2 more treatments before having to recharge the accumulators.
- 7. Light emitting diode LED(6):** As soon as this LED lights up in red it indicates that the accumulators are flat. You will have to recharge the accumulators before being able to use the apparatus again.
- 8. Charge socket:** The charging device will be connected to this socket. The DC-plug of the charging device which is plugged into the charging socket disconnects the electronic circuit from the power supply.
- 9. Battery compartment:** This apparatus operates on 4 batteries or rather accumulators. Accumulators/batteries of type “baby” are to be used.
- 10. Code-status:** The number of completed treatments will be saved and can be displayed when pressing this pushbutton and turning on the apparatus.

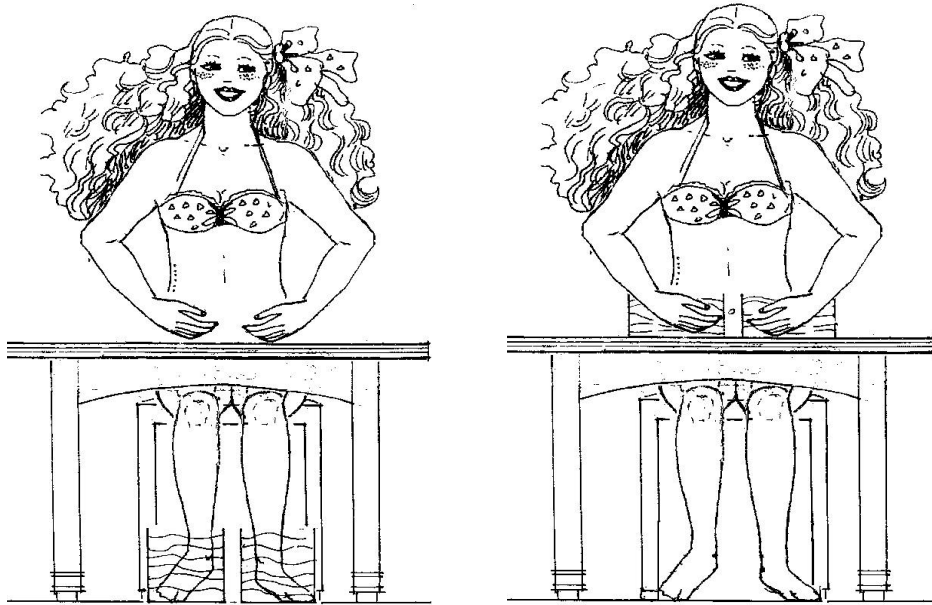
Double cell bath: hands or feet

When applying the constant current therapy: turn up the amperage until the current is noticeable, then turn it down again until not noticeable anymore.
When applying the pulsating current therapy: turn up the amperage until the current is slightly noticeable.

The display will show how much current is flowing.

Duration of treatment: approx. 20minutes **Treatment: daily**

Pole change: change the pole with every following treatment



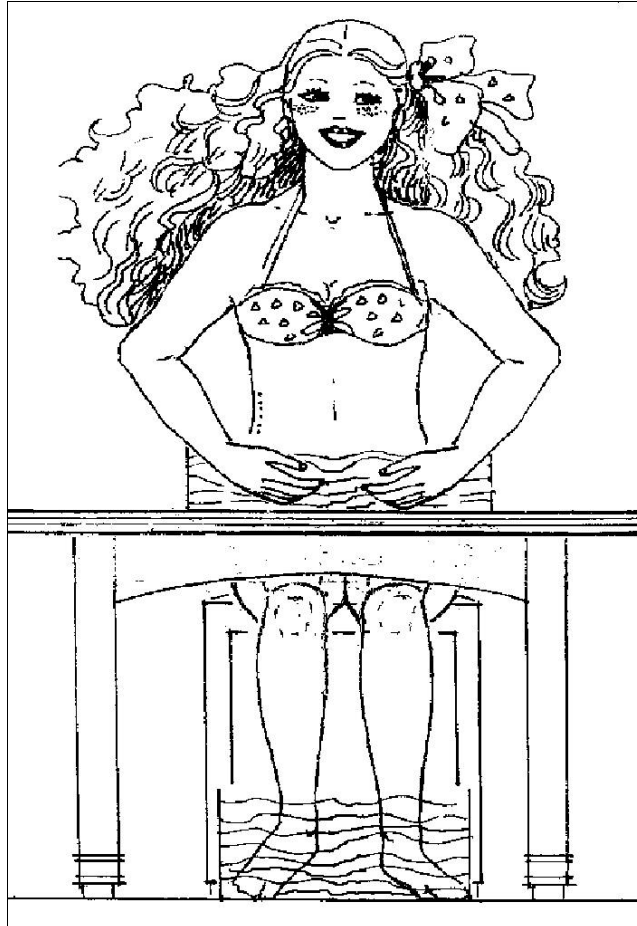
Double cell bath: hands and feet

When applying the constant current therapy: turn up the amperage until the current is noticeable, then turn it down again until not noticeable anymore.

The display will show how much current is flowing.

Duration of treatment: approx. 20minutes **Treatment: daily**

Pole change: change the pole with every following treatment



Iontophoresis treatment (Infiltration of medicinals) for arthrosis in the knees

With the help of Iontophoresis Diclofenac medicaments can be channeled directly to the aching joint. The package insert will indicate if the supplement should be applied to the plus- or minus - electrode.

+ = red cable connected to red socket

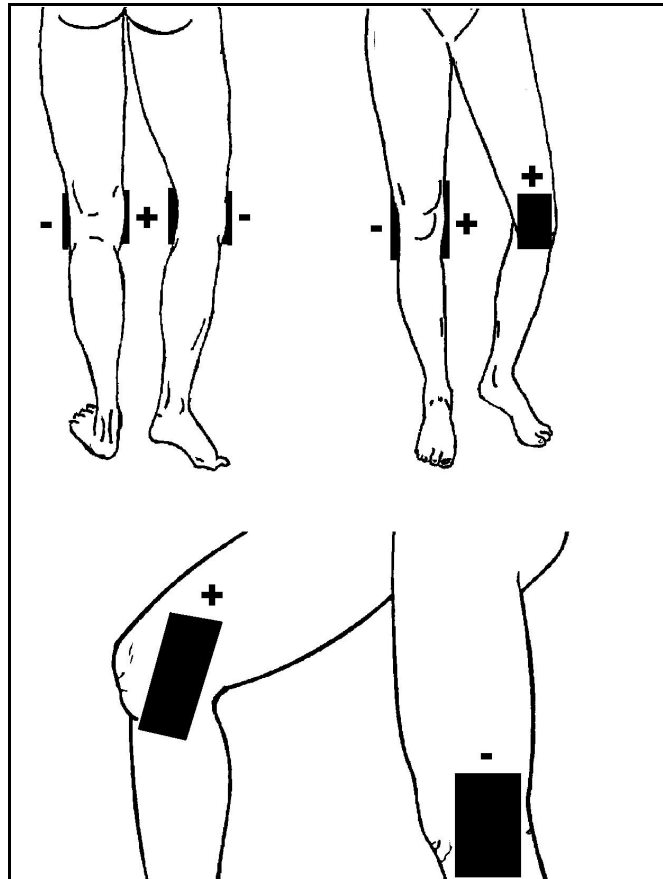
- = black cable connected to black socket

Note: only conduct pole change if indicated by pharmaceutical manufacturer.

Maximum amperage: 5 mA or 0,1 mA/cm² on the surface of the electrode.

Duration of treatment: approx. 20minutes

Treatment: daily



Osteoarthritis

Osteoarthritis is a of ailment of the joints, which results from several of factors such as degenerative wear out and chronic status of inflammation in one or several of joints at the same time. Osteoarthritis is a painful ailment which is also difficult to approach. It will always be bound to a long and agonizing way until relief sets in.

Arthritis can affect all joints.

The causes of arthritis are processes of aging and wear out. This leads to inflammable and severe deformations in the affected joints. Furthermore, it can be also caused by changes in the hormonal balance of the body. This kind of ailment often sets in during or after menopause and affects women rather than men.

Several of years ago it was experienced that the galvanic currents are an entirely harmless way of pain relief, free of side effects and applicable to several types of pain.

Daily galvanic current treatments increase the body energy and enhance the overall wellbeing.

Furthermore, this treatment stimulates the blood circulation which leads to a better blood flow in the affected tissue or joints.

The process of pain relief is as follows: additional movement of the affected joint leads to the sinews being stretched and the muscles strengthened. This on the other hand leads to a relief in pain.

Arthritis in finger joints-, hand- and elbow joints

Hand- double cell bath

**1-2 daily treatments
à 20 minutes**

Arthritis in toe-, foot-, knee- and hip joints

Foot- double cell bath

**1-2 daily treatments
à 20 minutes**

Polyarthritis (pain in all joints)

Hand–Foot–four cell bath

**1-2 daily treatments
à 20 minutes**

Electrode pair 1:

Left hand and right foot

Electrode pair 2:

Right hand and left foot