

DAVITA®

Instruction Manual

Electrical Stimulation Instruments



DIGITAL FIT *Mini Wireless*

DIGITAL FIT

DIGITAL FIT PRO

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Chapter 1 – SAFETY INSTRUCTIONS

1.1 - Caution

Please read the safety instructions carefully before using the instrument the first time. Before switching on the instrument or applying it on a patient, proceed for a correct use as follows:

- (1) check visually if there is any sign of damage;
- (2) follow carefully all instructions given on the instrument;
- (3) remove any vessels containing liquids from the instrument; the instrument is not protected against penetration of liquids (IP 20);
- (4) check availability of all accessories required for the application of electrical stimulation (electrodes, output cable etc.).

1.2 - Contraindications

Electrical Stimulation must not be used in the following cases:

- (1) on patients with cardiac pacemaker, coronary heart disease or arrhythmia
- (2) at the front of the neck because of possible laryngospasm (convulsary contraction of the larynx with cramping of the vocal cord);
- (3) on the side of the neck because of the sensitive glomus carotis;
- (4) in the stomach area and in the sacrolumbal area during pregnancy;
- (5) in areas with injured skin, on mucous membranes, in cases of changed local sensitivity, during infectious processes, inflammations, phlebitis and thrombophlebitis;
- (6) on patients with implanted electronical devices (e.g. cardiac pacemakers) directly under the stimulated area;
- (7) near to metallic fixators and internal implantations (protheses, osteosynthesis material, spirals, screws, platings), especially when using single phase current (diadynamic, faradic, direct current for Iontophorese und Galvanotherapy);
- (8) near tumors and in the stomach and lumbar area in case of lithiasis (hepatolith or nephrolithiasis);
- (9) in areas with dermatitis, tactile hypoesthesia, allergies to substances used during the treatment, thermal anesthesia when using Iontophorese.
- (10) Keep out of reach of children.

1.3 - Precautionary Measures

In the following cases we recommend to consult a doctor and to use the electrical stimulation under his supervision:

1. When using the neuromuscular stimulation for alleviation of pain on patients with pain syndrome, to diagnose a disease, particularly in those cases when the symptoms do not recede within a few days after application of the pain therapy;
2. Application of the electrodes in the face;
3. In the vicinity of metallic fixators and internal implantations (prothesis, osteosynthesis material, spirals, screws, platings);
4. Patients suffering from Parkinson's disease because of possible changes in the sensory perception;
5. In case of suspected or certain pregnancy, stimulation may be only applied to peripheral areas such as legs and arms;
6. Applying the electrodes in areas with injured tendons and muscles;
7. Patients with spastic paralysis;

Observe the following when applying electrodes

1. Never to be placed on eyeballs.
2. Not to be placed on sensitive areas, such as the chest centre, the area of the groin or in the armpit or other sensible areas.
3. The heart muscle must never be interposed between the positive and negative pole, i.e. never place an electrode in the vicinity of the heart on the thorax front while there is an electrode on the back.

1.4 - Special Information

1. It is not advisable to use the electrical stimulation instrument after a large meal as the digestive process can be prolonged due to increased blood flow to another area.
2. In case of tachycardia or extrasystole symptoms during the treatment or if the stimulation is not tolerated, the treatment should be stopped in order to regain the normal state.
3. After a session a slight reddening of the spot to which the electrode was applied might occur or a few capillary vessels might break.
In this case we recommend a gentler program or the use of a lower intensity of stimulation.

Chapter 2 - OPERATION

Operation is simple and secure.

Three buttons suffice to operate the electrical stimulation instruments Digital Fit Mini Wireless and Digital Fit and six buttons for the Digital Fit Pro.

Operating the Digital Fit Mini Wireless

- Insert the 3 Volt battery into the instrument.
- The electrode with the press-stud fastener „Easy Snap“ is directly connected to the instrument and placed on the skin area to be treated.
- With the ON-button, the instrument is switched on and the current's intensity is increased.
- The programs are selected with the MODE-button.
- The OFF-button reduces the intensity and the instrument is switched off.



Operating the Digital Fit

- Insert the 9 Volt battery into the instrument.
- The two output cables are inserted at the top of the instrument. Each cable is then connected with two electrodes and placed on the skin area to be treated.
- With the ON-button, the instrument is switched on and the intensity is increased.
- The programs are selected with the program-button.
- The OFF-button reduces the intensity and switches off the instrument.



Operating the Digital Fit Pro

- Insert the three 1,5 Volt batteries into the instrument.
- The two output cables are inserted at the top of the instrument. To each cable two electrodes are connected and placed on the skin areas to be treated.
- Each channel of the Digital Fit Pro has one ON- and one OFF-button.
- Using the ON-buttons, the left or the right channel of the instrument is switched on and the intensity is increased.
- The programs are selected with the SELECT-button.
- The OFF-buttons serve to reduce the intensity of the instrument's left or right channels and for switching off.



Programming the Digital Fit Pro

Besides the 9 preset programs, the Digital Fit Pro offers the possibility of programming 9 additional programs.

Proceed as follows:

- Switch on the instrument with one of the ON-buttons.
- Press the SELECT-button until the display shows 01, this is the first programmable program to be used.
- Press the ENTER-button until Timer appears on the display and then set the desired application time from 0 – 120 minutes using the left or the right ON-button.
- Press again the ENTER-button until Rate appears on the display. With one of the ON-buttons you can then set the required pulse rate from 0 – 120 Hz.
- Press the ENTER-button until ON TIME (operating cycle) and OFF TIME (non-working cycle) begin to flash on the display. Now, with the left ON-button you set the length of the operating cycle in seconds and with the right ON-button the length of the non-working cycle is set. The cycles can be set in steps from 0 – 30 seconds each.
- By pressing the ENTER-button now, the settings for the other cycles can be made. A total of 12 cycles can be set. For each cycle the pulse rate and on-time (operating cycle) as well as off-time (non-working cycle) have to be set, as described above.
- Having completed the programming, a double acoustic signal confirms that the entered data has been stored.
- If you do not want to programme all 12 cycles, programming can be finished whenever you want by entering the pulse rate 0 in one cycle.
- If programming is interrupted by more than one minute, the instrument switches off automatically.

2.1 - Application areas of the Electrodes

The electrodes of the Digital Fit Mini Wireless, the Digital Fit and the Digital Fit Pro can be placed everywhere on the body and, particularly on muscles. Kindly refer to chapter 9 and the appropriate photos.

Attention: Do not use electrical stimulation on very sensitive body areas, such as face, the front and back of the neck, in the armpits, on the chest and on the lower abdominal area and the external genitalia.

2.2 - Switching on and Selection of the Program

After applying the electrodes on the area to be treated, the instrument can be switched on. Press the ON-button and select the desired program with the MODE-, or PROGRAM-, or SELECT-button. It is always possible to switch to another program during the stimulation. The stimulation intensity is then, however, reduced to stage 1 and you have to raise it again.

2.3 - Setting the Intensity

In order to start the stimulation, the current strength can be increased by pressing the ON-button until the desired stimulation level is reached. After a few minutes, depending on the sensibility or response of the area treated, a weaker or stronger stimulation of the area may be perceived. In case of a constant stimulation, the intensity can be increased or lowered accordingly. For the purpose of tightening or strengthening the muscles, we recommend to increase the intensity gradually during the whole program.

2.4 - Timer

The TIMER of the Digital Fit has a fixed setting, i.e. each program runs 30 minutes. After 30 minutes, the instrument switches off automatically. In case of the Digital Fit Pro the duration of the application can be set individually using the freely programmable programs.

2.5 - Switching off the Instrument

The Digital Fit can be switched off at any time with the OFF-button.

Chapter 3 - PROGRAMS

All programs of the three units make various electrical stimulation applications possible and allow changing the form of treatment during an application.

3.1 - Use of Programs

The following electrical stimulation instruments can be used daily. When using one instrument daily, different muscles or body parts can be treated one after the other.

The applications to stimulate or relax certain parts of the body can be carried out at any time of the day. The programs can be used before or after physical work for warm up or for relaxation of the muscles mainly used. Additionally it is possible to substitute training by the application of one of the instruments when there is lack of time or training cannot be carried out for other reasons.

If you want to recover or relax, take a comfortable position (sitting, standing or lying) which helps to stimulate blood circulation. During the active muscle stimulation, however, you should be in a position in which the muscle to be treated is extended (e.g. extensor of the thigh – knee at 90 ° in a sitting position, stomach muscles lying, biceps – arm extended). It is also possible to carry out other activities during or after the program, such as exercises (bending, weights etc.).

3.2 - Programs of the Digital Fit Mini Wireless / Digital Fit

Each, the Digital Fit Mini Wireless and the Digital Fit have 10 preset programs.

NO.	PROGRAM	DESCRIPTION
P1	Acute pain	Program for treatment of acute pain
P2	Chronic pain	Program for treatment of chronic pain
P3	Aerobic	Program for aerobic endurance
P4	Strength endurance	Program for strength endurance
P5	TENS	Program for treatment of local pain
P6	Neck pain	Program for treatment of neck pain
P7	Back pain	Program for treatment of back pain
P8	Disuse atrophy	Program for treatment of disuse atrophy
P9	Reinforcement	Program for reinforcement
P0	Muscle training	Program for muscle training

3.3 - Program of the Digital Fit Pro

The Digital Fit Pro has 9 preset programs and 9 additional programs which can be programmed individually.

NO.	PROGRAM	DESCRIPTION
P1	Relaxation	Program to relax muscles and increase arterial flow
P2	Disuse atrophy	Program for treatment of disuse atrophy
P3	Reinforcement	Program for reinforcement
P4	Muscle training	Program for muscle training
P5	TENS	Program for treatment of local pain
P6	Acute pain	Program for treatment of acute pain
P7	Chronic pain	Program for treatment of chronic pain
P8	Strength endurance	Program for strenght endurance
P9	Aerobic	Program for aerobic endurance

The electrical stimulation unit Digital Fit Pro offers the possibility to program up to 9 programs individually.

The following parameters can be set individually:

Total application time (timer):	1 – 120 minutes
Pulse rate (rate):	0 Hz – 120 Hz
Length of contraction (on time):	1 – 30 seconds
Length of break (off time):	0 – 30 seconds

Here are 2 suggestions for customized programs:

- Conventional TENS*-Program: Timer (total length): 30 minutes, Rate (pulse rate): 85 Hz, on time (length of contraction) >0 sec., off time (length of break) = 0 sec., for cycle 1-12.
- Program for Muscle Build-up: Timer (total length): 30 minutes, Rate (pulse rate): 35 Hz, on time (length of contraction) 6 sec., off time (length of break) = 7 sec., for cycle (Phase) 1-12.

Chapter 4 - INSTRUCTIONS

- Type of Protection IP20 (pl. Refer to Chapter 5 „Specifications“). Keep the unit away from liquids as there is no appropriate protection.
- Do not use the unit in close proximity to mobile phones (a minimum distance of a few meters must be kept).
- Operation in close proximity (e.g. 1 m) to short wave or microwave therapy equipment may produce instability in the stimulator's output.
- Application of an electrical stimulator and a surgical HF unit is not allowed in order to exclude any danger to patient and equipment.
- The equipment does not produce electromagnetic fields.
- Therapists are advised not to touch patients and active parts at the same time.
- The instrument's technical properties are guaranteed for an environmental temperature between 5° C (= 41° F) and 40° C (= 104° F) and a humidity under 80 %. These conditions must be guaranteed for transport and storage.
- In case of functional disorders or defects, return the unit exclusively to the manufacturer.
- Do not use in the proximity of inflammable materials.
- There is the risk of infection when using the same electrodes on more than one patient.

- Always use exclusively the accessories included and listed in the manual.
- It is important to inform the patient of the sensations which might be perceived during the therapy so that cases of non- tolerance can be identified immediately and the session in progress can be stopped immediately (either by switching off the unit or removing the electrodes.)
- Keep out of reach of children.

Chapter 5 - SPECIFICATIONS

5.1 - Digital Fit Mini Wireless

5.1.1 - Technical Data

Number of channels:	1
Power supply:	battery, 3 Volt
Wave form:	dual phase rectangular wave
Intensity:	0 to 90 mA , settable in 15 steps of 6mA each
Pulse rate:	2 Hz to 86 Hz
Timer:	30 minutes

5.1.2 - Other Features

Dimensions:	53 x 30 x 10 mm
Weight:	30 g
Class II:	Type BF
Protection Type:	IP 20
Protection against anaesthetic, inflammable gases:	Does not belong to AP or APG Protection Class
Unit designed for:	temporary use

5.2 - Digital Fit

5.2.1 - Technical Data

Number of channels:	2 detachable
Power supply:	battery, 9 Volt
Wave form:	dual phase rectangular wave
Pulse width:	200 μ s
Intensity:	0 to 100 mA , settable into 16 steps

Pulse rate: 2 Hz – 86 Hz
Timer: 30 minutes or 1 – 99 minutes,
which are counted down to 0

5.2.2 - Other Features

Dimensions: 169 x 60 x 26 mm
Weight: 138 g
Class II: Type BF
Protection Type: IP 20
Protection against anaesthetic,
inflammable gases: Not belonging to AP or APG Protection Class
Unit designed for: temporary use

5.3 - Digital Fit Pro

5.3.1 - Technical Data

Number of channels: 2 channels, which can be controlled separately
Power supply: battery, 3 x 1,5 Volt
Wave form: dual phase rectangular wave
Pulse width: 250 µs
Intensity: 0 to 100 mA, settable in 15 steps
Pulse rate: 0 Hz – 120 Hz
Timer: 30 minutes or 1 – 120 minutes,
which can be counted down to 0

5.3.2 - Further Features

Dimensions: 150 x 60 x 21 mm
Weight: 156 g
Class II: Type BF
Protection type: IP 20
Protection against anaesthetic,
inflammable gases: Does not belong to AP or APG Protection Class
Unit designed for: temporary use

Manufactured in accordance with the following regulations:

EN 60601-1 (1998) - Elektromedizinische Geräte (Electro-medical Instruments):
Allgemeine Sicherheitsvorschriften (General Safety Regulations)

EN60601-2-10 (2001) - Elektromedizinische Geräte (Electro-medical Instruments):
Besondere Sicherheitsvorschriften für neuromuskuläre
Stimulatoren (Special Safety Regulations for neuromuscular Stimulators)

EN60601-1-2 (1998) - Sekundäre Vorschriften: (Secondary Regulations)
Elektromagnetische Verträglichkeit - Vorschriften und Tests
(Electromagnetic Compatibility – Regulations and Tests)

EN60601-1-1 (2002) - Sekundäre Vorschriften: (Secondary Regulations)
Sicherheitsvorschriften für elektromedizinische Systeme
(Safety Regulations for electro-medical systems)

Chapter 6 - SYMBOLS



INSTRUMENT of CLASS II



BF-INSTRUMENT



READ the ATTACHED DOCUMENTATION



THE DEVICE IS IN ACCORDANCE WITH THE EEC-GUIDELINE 93/42
FOR MEDICAL INSTRUMENTS AND CARRIES THE CE-SIGN NO. 0123.

Chapter 7 - MAINTENANCE

7.1 - Cleaning the Instrument

For cleaning we recommend to use a moist cloth. Never use any liquids as the protection type IP20 is not designed to cope with liquids.

7.2 - Battery

The battery supplied with the Digital Fit is for a daily operation of approx. 30 minutes and has a working life of a few months. If the instrument switches off by itself, the battery has to be replaced by a new one of the same type. Pay attention to the polarity in the battery case at the back of the instrument. Remove the battery if the instrument is not used for a longer period.

7.3 - Maintenance of the Gel-Electrodes

- For the electrodes' maintenance apply some water to the adhesive gel after each application. Let it dry for a few seconds before attaching the electrode to the silicone pad. Close the bag with the electrodes carefully to avoid desiccation. Keep at room temperature.
- Keep in mind that the working life of an electrode depends on correct maintenance as well as on the type of current used and its strength. A clean skin is of great importance. Electrodes which do not stick properly to the skin, must be reattached.
- Apply only to healthy skin. In case of allergies or skin irritation, stop treatment and consult a doctor. (A pair of electrodes should be used by one person only).

7.4 - Immediate Maintenance

An immediate maintenance to be carried out by DAVITA® or authorized trained staff is required in the following cases:

- mechanical strain, e.g. the instrument was dropped and, therefore, damaged;
- the instrument was overheated after leaving it near a source of heat;
- suspicion that water has entered the instrument;
- case or other instrument's parts are damaged, broken or missing;
- the unit does not seem to work properly.



For safety reasons we recommend to use exclusively the accessories supplied by the manufacturer (e.g. electrodes and cables).



Maintenance, functional test and checking whether the safety regulations for medical equipment EN60601-1 (with Secur-Tester) have been observed, must be carried out yearly. The instrument's working life is guaranteed by the manufacturer only on the condition that maintenance is carried out at regular intervals.

NOTE: We recommend to have controls carried out exclusively by DAVITA® or by authorized trained staff. The instrument to be serviced can be sent directly to the customer service of the manufacturer or to the dealer.

Customer service centre:

DAVITA® Medizinische Produkte GmbH & Co. KG
Telephone: +49 (0)1805 - 9 11270 • Telefax: +49 (0)1805 - 9 11275
E-Mail: mail@davita.de • www.davita.de

7.4.1 - Basic Equipment of the Instruments

7.4.1.1 - Digital Fit Mini Wireless

1 pce. self-adhesive electrode 11 x 6 cm with press-stud fastener "Easy Snaps"
1 pce. battery, 3 Volt
1 pce. Instruction manual

7.4.1.2 - Digital Fit

2 pces. output cable
4 pces. self-adhesive gel-electrodes 4 x 4 cm
1 pce. battery 9 Volt
1 pce. packing case
1 pce. Instruction manual

7.4.1.3 - Digital Fit Pro

2 pces. output cable
4 pces. self-adhesive gel-electrodes 4 x 4 cm
3 pces. 1,5 Volt batteries
1 pce. packing case
1 pce. Instruction manual

7.4.2 - Spare Parts and Accessories

Self-adhesive electrodes 4 x 4 cm with press-stud fastener „Easy Snaps“
for Digital Fit and Digital Fit Pro Art. No.: 31001
Self-adhesive electrodes 11 x 6 cm with press-stud fastener „Easy Snaps“
for Digital Fit Mini Wireless Art. No.: 31002

Chapter 8 – GUARANTEE

DAVITA® guarantees for this instrument for a period of 24 months after date of sale. Wear parts, such as batteries and gel-electrodes are excluded from the guarantee. The guarantee is valid for material defects and manufacturing faults and includes the provision of spare parts as well as labour. Guarantee expires if the instrument has been damaged, or used improperly or unauthorized intervention was carried out. Keep the purchase receipt as proof and submit it together with your claim for guarantee. DAVITA® will only fulfill the guarantee upon receipt of your purchase proof.

Chapter 9 – APPLICATIONS

Following are some examples for possible applications of the electrodes; The electrodes can also be applied to other spots/areas, except the spots/areas mentioned before (please refer to chapter 1.1).

Attention: Cables and electrodes of Digital Fit can be used either as positive or negative poles (only for conventional reasons the pole has been stated on the photos).

REFERENCE MOTOR POINTS



III. 1: Biceps



III. 2: Triceps



III. 3: Triceps (woman)



III. 4: Thoracic muscle



III. 5: Thoracic muscle (woman)



III. 6: Abdominal muscle

EXAMPLES FOR PAIN THERAPY



III. 7: Trapezioid muscle



III. 8: Dorsal muscle



III. 9: Extensor of thigh



III. 1: Cervical syndr.



III. 2: Lumbar syndr.



III. 3: Ankle sprain

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