

# Operating instruction

## Bio Wave Generator 77



We take up only and tighten, which in conformity with our oscillating frequency is.

Therefore the truth is honest with you, and loves.

Care love and harmony.

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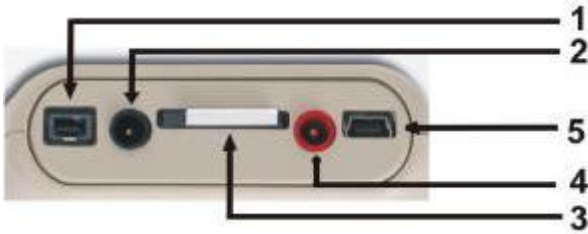
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Frequency generator for the therapy of acute and chronic pain by transkutane, electrical nerve stimulation.

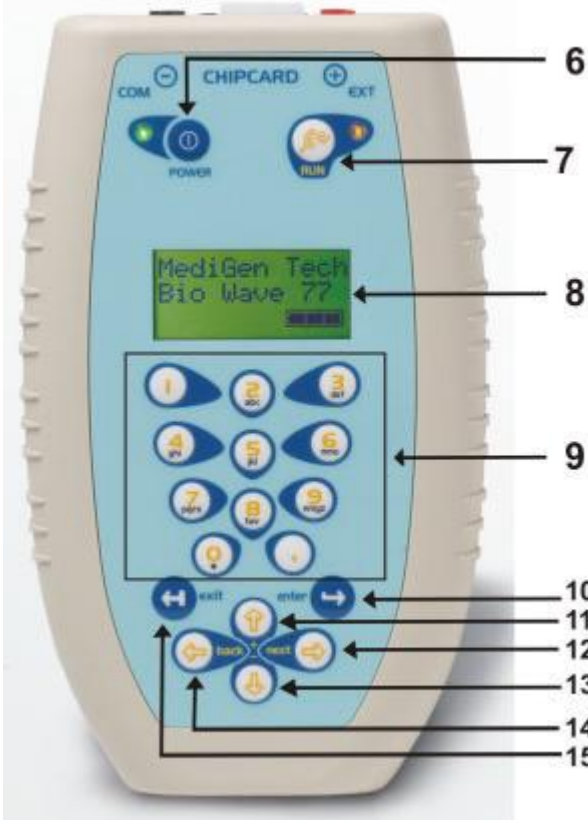
## Supporting pain treatment:

- ⤴ Headache (migraine)
- ⤴ Back pain - cross pain – Ischias
- ⤴ Joint pain by degenerative (inflammatory) joint illnesses like e.g. Arthritis, arthritis, final stage Lyme Borreliose
- ⤴ Pain during that blowing and birth
- ⤴ Post office-operational pain
- ⤴ after injury (post office trauma tables) pain like e.g. rib fracture, developed
- ⤴ Nerve pain (e.g. Diabeti peripheral neuropathy)
- ⤴ Phantom pain after amputation
- ⤴ vascular caused blood circulation disturbances (Claudicatio Intermittens)
- ⤴ Pain with interferences like e.g. shoulder Arthographie, Uterusspiegelung, not invasive fragmentation of nephritic stones by means of shock wave technology
- ⤴ Complaints of the movement apparatus
- ⤴ Rheumatism tables complaints

## 2 Marking and control elements



- 1 Com Port:** Interface for internal test purposes
- 2 Out - :** Cable exit minus pole; Connection red cable
- 3 Chip Card Drive assembly**
- 4 Out + :** Cable exit plus pole; black cable
- 5 Ext. Port:** Interface for external accessory equipment



- 6 Power-Lamp:**, enterprise indicates
- 7 Run-Lamp:** Frequency actively
- 8 LED display:** Display with battery announcement
- 9 Key field 0 9 with letter function and comma**
- 10 Enter key:** to confirming inputs, and/or to the selection
- 11 + key:** Stop from parameters, e.g. increase of the intensity
- 12 next-grope:** Selection of the different frequencies, expirations of frequency
- 13 - Key:** Stop of parameters, e.g. a reducing of the intensity
- 14 back-grope:** Selection of the different frequencies, expirations of frequency
- 15 exit - grope:** Return in the program



Equipment knowing sign

Belt fastens

Battery box



Battery box cover



Equipment knowing sign

## 2.1 Equipment knowing sign:

|                |  |
|----------------|--|
| Manufacturer:  | Medi - Gen Technology Ltd.                           |
| MEZ3AA0001     | Serial number  |
| Barcode:       | according to serial number                           |
| Typ: BW 77     | exact type designation                               |
| <b>CE 1275</b> | Certified Europe<br>+ Number of the designated place |



Application part of the type BF



Note: Operating instruction consider!



Safety class system II symbol



Separate collection of electrical and electronics devices  
Into the domestic refuse do not throw!

### 3 Name and address of the manufacturer

Medi -Gen Technology Ltd.

Address BavariaLeiten 3

D 83556 Griesstätt

Tel. 0049/ (0) 700 /633 44 361 (12 ct/min)

Fax. 0049/ (0) 700/633 44 362 (12 ct/min)

Internet: www.medi-gen.de

With technical questions: hotline@medi-gen.de

### 4 Scope of supply

**Note: The German Federal Armed Forces 77darf only with original - accessories in enterprise to be taken.**

| Number | Unit  | Designation                      | Article No. |
|--------|-------|----------------------------------|-------------|
| 1      | Piece | Bio Wave Generator 77            | 1030        |
| 1      | Piece | Cables red tear firmly           | 2003        |
| 1      | Piece | Cables black tear firmly         | 2004        |
| 2      | Piece | Bracelet with yellow sponge      | 2013        |
| 2      | Piece | High-grade steel hand electrodes | 2030        |
| 2      | Piece | Sticking electrodes 45x35 mm     | 2070        |
| 1      | Piece | Battery alkali 9V block          | 2051        |
| 1      | Piece | Suit-case                        | 991151      |
| 1      | Piece | Operating instruction            |             |

### 5 Other accessories

Hand electrodes, high-grade steel, Art. No. 2030

Sticking electrodes, 53 x 96 mm, Art. No. 2071

8,4 V NiMH Akkus

Chip Cards

(to the use of accessories see. Point 7,2)



## 6 Start-up

### 6.1 Preparation of the German Federal Armed Forces 21:

1. Open the battery box cover on the back of the equipment.
2. Use the battery provided. Likewise loadable 8.4 V Ni-MH Akkus can be used.
3. Close the battery box cover again.

Pay attention with inserting to the correct polarity the battery, since it comes

**Die kleine rechte**

**Lasche ist +**

otherwise to the fast unloading of the battery.

4. Clean your palms of hand cream or Lotions with water and soap thoroughly forwards Start-up of the bio Wave 21. Otherwise it comes to getting the bracelets dirty and reduction of the current flow



5. Connect the cables of the German Federal Armed Forces 21LCD with the coloured corresponding exit hubs at the equipment.

6. Subsequently, you connect the cables in each case with the bracelets.

***Note: the yellow sponge of the bracelets must be well dampened before application with tap water.***

### 6.2 Switch the German Federal Armed Forces 77 on:

Press the power key to power lamp shine

Greeting text and version number appear on the display

- after approximately 5 sec. moves on the display automatically on the program window

### 6.3 Select an expiration of frequency:

1. before turning the German Federal Armed Forces 77 on if no chip Card was put in, then the sequence appears in the program window  
„3 x 7 min, with ever 20 min break “
2. before turning if chip was put in a Card on, then the sequence appears „chip Card in the program window “

### 6.4 Listing of the expirations of sequence:

1. **Chip Card Program**
2. ...
3. **TENS 1 ...**
4. **TENS 2 ...**
5. **TENS 3 ...**
6. **Attitudes**

select through pressures that  $\uparrow/\downarrow$  keys the desired expiration of sequence out.

Confirm the selected expiration of frequency by pressures „of the Enter“- key

The window of expiration of frequency appears in the display

By long pressing „of the Enter“- key change they back in „sequence select“ windows.

**Note: We recommend generally a therapy of elimination ways combined with rising therapy times of the German Federal Armed Forces 77!**

## 6.5 Start/stop of the frequency delivery:

after selection of the appropriate expiration of sequence you start the frequency delivery by short pressing „the run“- key. It sounds a long audio signal. „The run“- lamp lights up.

during the frequency delivery you can stop the active frequency by short pressing „the run“- key. (Clock continuous), an audio signal sounds, which „run“- lamp expires.

if the frequency delivery is again started not at the latest after 5 min, then scolded yourself the equipment automatically out.

**Note:**            **„short pressing“- 1 second**  
                          **„long pressing“- 3 second**

## 6.6 Contact control

Contact control is accomplished automatically at the beginning of each expiration of sequence, and/or as soon as „the run is pressed “- key. The measured value lies between 0 and 200.

It appears one of the following announcements:



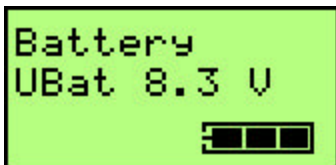
If the measured contact value under 5 lies, the announcement does not appear „a contact “, „the run “in the display - lamp flashes and the equipment delivers continuously an audio signal.

**Note: the frequency delivery is interrupted!**

Confirm contact control through to pressures „of the enter key “, in order to continue in the expiration of sequence, e.g. to test purposes. Sufficient contact is available jumps „contact “- windows after 3 sec. back into „the window of expiration of sequence “

**Note: „Run key “only after creation of the damp bracelets activate, there otherwise „no contact “!**

## 6.7 Fairs of the battery voltage:



If you press „the power “- key briefly, then the battery voltage in the inserted battery in volts appears.

After 5 sec. the announcement changes announcement again selected last automatically into - the window. The current battery voltage is represented to announcement in the display with 3 bars during the entire enterprise of the bio Wave 21 by the battery -. The battery - announcement decreases/goes back with the progressive emptying of the battery up to a bar and „the power “lamp flashes additionally before the battery is empty.

**Note: With the use of Akkus the residual voltage sinks faster than independent in the case of batteries in the last third of the quality of the Akkus or the max. loading capacity!**

## 6.8 Adjust the intensity:

The intensity is adjustable from 0 V to 15 V in 0,2 V steps

The standard attitude amounts to 4 V.

By short pressing „of the Intensity „- key  $\uparrow/\downarrow$  the standard attitude in 0,2 V steps can be increased and/or lowered.

By long pressing: 1 V of steps (high-speed function)

**Note: Adjust the strength in such a way that it is pleasant for you. Turn back with burning or itching the intensity or the therapy break off! Use alternatively hand or sticking electrodes.**

## 6.9 Navigation during the frequency delivery:

If you want a frequency in the expiration of sequence to jump over or repeat, then you press „the program “- key  $\uparrow/\downarrow$  until the desired frequency in the display appears.

- A short whistler sounded, see point 6.5

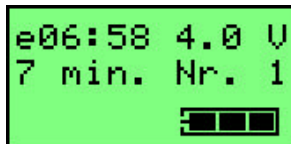
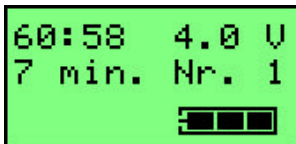
**Note:**

**The selection is also possible before you „the run “- key press, thus before the frequency is played.**

## 6.10 Changes between single and total time:

By long pressing „the run “- key changes the time indicator between the individual time of the frequency and total time of the expiration of sequence.

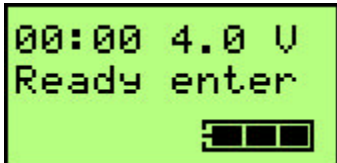
The individual time of the frequency is characterized by „an e “before the time indicator.



## 6.11 End terminating the expiration of sequence:

At the end of the expiration of sequence the announcement stands „for finished “.

Please confirm this announcement through to pressures „of the Enter “- key. The announcement changes then into „the Seq selects “windows.



If you want to terminate an expiration of frequency prematurely, press „the Enter “- key long (see Pkt.6.3) or to press it „the run “- key briefly (see point 6,5).

## 6.12 Switch off the bio Wave 77:

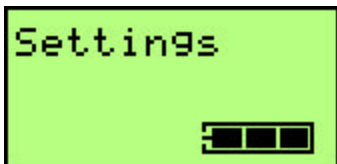
Around the bio Wave 77 to switch off hold you please „on “- key is enough pressed.

3 short audio signals and the announcement follow „power off “appear. The equipment scolded yourself thereafter off.

***Note: clean and dry these carefully under flowing water after use of the bracelets, before you keep these again into the suit-case. Damp bracelets in the suit-case can damage the bio Wave 21.***

## 7 Speaking and software attitudes, serial number

After switching on on (see point 6,2) to select you the point of program “attitudes “by 2-maliges pressures „bake “- key.



By pressures „of the Enter “- key is represented the current software version of the equipment. By pressures „of the NEXT “- they change key for the announcement of the serial number.

Repeated pressing it „program ? “- key leads to the language window. Pre-setting: German

To leaving the menu option „the exit “- key briefly press.

## 7.1 Use of hand electrodes:

Dampened sponge coverings for hand electrodes over the hand electrodes pull. (free from chlorine kitchen role also dampened possible)

Bio Wave generator 21 with the cables (red and black) connect.

Connect in each case 1 cable with the pushbutton at a hand electrode.

Bio Wave 77 switch on

Start desired expiration of sequence (see Pkt 6.4)

Take ever 1 hand electrode into a hand

Hold according to the duration of treatment.

Bio Wave generator 21 switch off (see point 6.9)

Sponge coverings remove

**Note: for further use hand electrodes and sponge coverings off/wash and drying store!**

## 7.2 Use of chip Cards:

- Chip Card put in, afterwards bio Wave 77 switch on (see Pkt 6.2)

to directional marker pay attention!



The equipment indicates now automatically the contents of the chip to Card.

See Pkt 6,4 to starting the expiration of frequency

See Pkt 6,7 to selecting individual frequency on the chip Card

At the end chip of the Card Auflaufs by short pressing „of the Enter“- key confirm

**7.3 Note: the chip can be taken out by short pressing in direction of arrow. (Feather/spring mechanism). Do not pull out please!**

## 7.4 Use of sticking electrodes:

Cables (red and black) with that coloured same sockets of the Biowave 77 connect.

- Connect in each case 1 cable with the pushbutton at a sticking electrode.

- To the desired place attach ever 1 sticking electrode into one (not on hair or mucous membranes as well as open places)
- Bio Wave 77 switch on, program sequence start
- Replace sticking electrodes at the end of application

Bio Wave 77 ausschalten.

- To the cleaning of the surfaces of the electrodes as well as the body places on those it to be used to recommend we excluding alcohol. This must have completely evaporated before application.

Keeping: The sticking electrodes in the packing at a temperature between 5°C and 35°C and a relative humidity from 20% to 80% on the protective plastic film keep.

***Note: Multiple use with the same person possible with attention of the prescribed keeping and cleaning.***

## 7.5 Enter own frequencies:

1.1 Switch the BioWave 77 on. For this press the “power key”. The “Program Sequence”-Screen appears. You will hear a short signal.

```
choose Seq.  
7-20-7-20-7  
[ ][ ][ ]
```

1.2 Press the “Back”-Button until you see “Input Frequency”.

```
input  
Frequency →  
[ ][ ][ ]
```

1.3 Press “enter”. The “Frequency-Input window” appears “. A frequency can be entered directly over the number field. Save the frequency with “Enter”.

```
Freq. 4.0V  
100.00 Hz  
[ ][ ][ ]
```

(Optionally: to testing the frequency press the “Run”- Key).

```
Offset:  
Pos. Offset  
[ ][ ][ ]
```

1.4 Press “enter”. It appears the „Offset-Window“. By pressing „+/-“ the offset can be adjusted.

1.5 Press “enter”. It appears the „Time-input window“. The standard time is 3 minutes. The time can be individually changed over the numberfield or over the +/- keys.

```
input Time  
03:00 mm:ss  
[ ][ ][ ]
```

1.6 Press “enter”. It appears the Window “Accept Frequency”.

```
accept  
Frequency →  
[ ][ ][ ]
```

1.7 Press „Enter“ and the frequency will be saved in the internal Memory.

```
03:00 4.0V  
free (1)  
[ ][ ][ ]
```



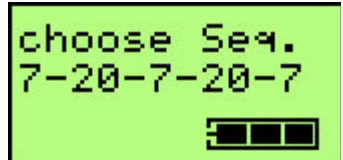
1.8 The „**Frequency Sequence Window**” shows the number of stored frequencies in the brackets. I.e. in our example 1 frequency is stored. The total time in our example is 3 minutes.

1.9 By pressures „**of the run key**” the program runs off. The time counts backwards. A short depressing the key is important! (because of dual function)

***Note: When switching the Biowave off the memory including the saved Frequencies will be deleted!***

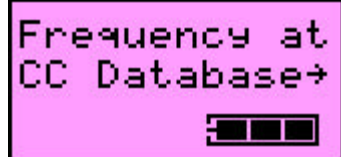
## 7.6 Load Frequencies from ChipCards:

**2.1** Insert the “**Database-Chipcard**”. Switch The Biowave on. The “Program Sequence” window appears. A short signal sounds.



```
choose Seq.  
7-20-7-20-7  
[ ][ ][ ]
```

**2.2** Press the „**NEXT** or **Back**”-Key until “**CC Frequency at CC Database**“ appears.



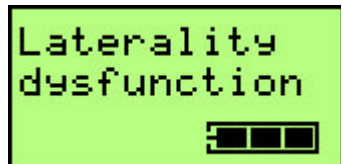
```
Frequency at  
CC Database →  
[ ][ ][ ]
```

**2.3** Press „**Enter**“. The first frequency of the Database Chipcard appears.  
(Optionally: You can run this frequency by Pressing the “**RUN**”-Key.



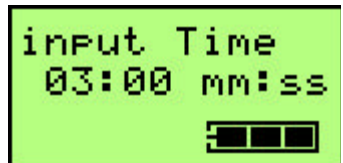
```
Brain  
frequency  
[ ][ ][ ]
```

**2.4** With the „**NEXT**” or “**Back**”-Key you can go to the next or last Frequency. To select or change the frequency press “**ENTER**”.




```
Laterality  
dysfunction  
[ ][ ][ ]
```

**2.5** The „**Time-Input Window**” appears. The standard time amounts 3 minutes. The time can be changed with the **+/-** Keys.



```
input Time  
03:00 mm:ss  
[ ][ ][ ]
```

**2.6** Press „**Enter**”.  
The window „**accept frequency**“ appears.



```
accept  
Frequency →  
[ ][ ][ ]
```

**2.7** Press „**Enter**” and the frequency will be saved in the internal Memory.

**2.8** The „**Frequency Sequence Window**” shows the number of stored frequencies in the brackets. I.e. in our example 1 frequency is stored.

The total time in our example is 3 minutes.

(Optionally: The entered frequencies can be started by clicking the „**Back/Next**” Key.)



**2.9** After pressing „**RUN**” the program (all frequencies) starts. The time counts backwards. (Optionally: The entered frequencies can be started by clicking the „**Back/Next**” Key.).

## **8 Chip Card administration:**

They find the point chip Card administration in the main menu.

This point contains two functions:

***Note! Only possible with master chip Cards!***

### **8.1 Several frequencies enter:**

**A condition: It must be entered already a frequency**

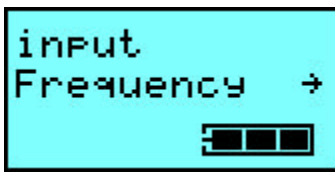
**3.1** They are in „**the window of expiration of frequency** “. The number in brackets indicates the number of frequencies already stored. „**enter key** “press.



With „**bake/next-grope** “can between the window „**own frequency be entered**“ and the window „**the CC frequency data base** “be changed.

You can decide whether you would like a frequency freely to enter or of the data base ChipCard select.

**3.2** The window appears  
„**own Frq. enter** “.

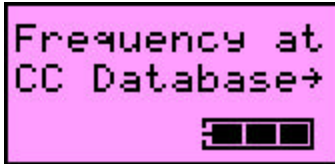


OR

„next-  
key“



„back-  
key“



3.3 The window appears

„CC frequency data base “

## 8.2 Save own Frequencies to a Master ChipCard:

(only with Upgrade possible)

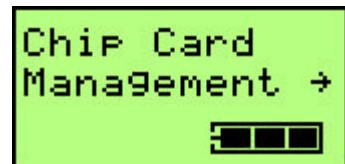
**4.1 Please go to the „Program Sequence”-window.** In parentheses the number of stored frequencies is indicated. In our example 1 frequency is stored. The total time amounts 3 minutes.



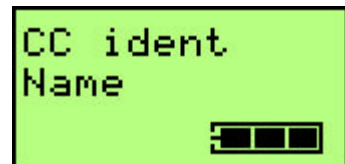
**4.2 Press „Exit”.** The window appears „Make Sequence”.



**4.3 Press „Exit”.** The window „Chip Card Management” appears.



**4.4 Press „Enter”.** The window „CC ident ame” appears. Now put the empty MasterChipcard in.



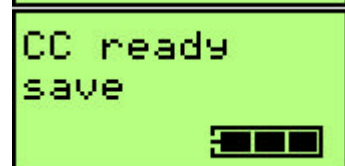
**4.5 Press „Enter”.** It appears the window „Chip Card save”.



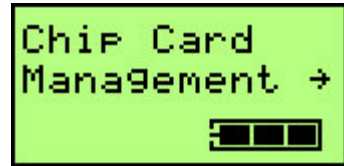
**4.6 Press “Enter”** to save the frequencies. The window appears „wait save”.



A short “BEEP” sounds – the frequencies are saved.



- 4.7 Press „Enter“. The window appears „Chip Card Management“ appears (a component of the main menu).



## 5 Load Programmed Master Chipcards

- 5.1 Insert the programmed Master Chipcard into the Biowave 77.

- 5.2 Select through “NEXT/BACK” Keys “ChipCard Management” Window in the main menu.

- 5.3 Press „Enter“

- 5.4 Press „NEXT“ and press “Enter” again.

The window appears: “ChipCard Load”

- 5.3. Press again “Enter” and the Biowave loads the frequencies from the MasterChipcard into the unit

- 5.4 After completion of this procedure a beep sounds and in the display the following message is indicated: „CC completely load“.

Now you can run, edit or change the loaded frequencies in the Biowave and save them again.

For that you go to the mainmenu “Edit Sequence/frequency”.

## 9 Warnings and/or safety references

In order to avoid endangerments by electrifying, the housing may neither be removed nor the back be opened.

Consider in the own interest all warning referring to the equipment.

Use the equipment never in close proximity to water e.g. Bath tub, wash basin etc. or at places with increased air humidity, e.g. Steam sauna.

The penetration of liquids is to be avoided in each case.

Do not bring the equipment into the proximity of heat sources like e.g. to heating elements, furnaces etc.

Protect the equipment against extreme variations in temperature, since otherwise the LED can become defective.

While do not telephone to application with the mobile phone!

Minimum distance to a switched on mobile phone: 2 m

References on special precautionary measures during the current supply:

No power pack may be attached!

Enterprise exclusive with 9 V manifold or 8.4 V nickel metal hydride accumulator.

***Note: with neglect, as well as use of not original - accessories expire the warranty and liability claim!***

***Outgoing cables as well as accessories never into the plug socket put!***

## 10 combination their devices/avoidance of risks



NOTE! Use does not permit with cardiac pacemakers!

Does not permit with electromagnetic perturbative fields or in close proximity to microwaves.

No simultaneous application with other electrical devices.

Bracelets hand electrode/sticking electrodes not on open wounds, allergies or eczema, not directly on mucous membranes put or in body openings would not bring in. (Strongly exists ranges before application shave.)

Drink during and after the application of the German Federal Armed Forces 21 sufficiently mineral-poor, carbonic acid-poor water. (1 - 2 litre )

With an application of more than 2 hours daily a therapist should be consulted. With an application of max. 8 weeks a break should be inserted of at least 2 weeks. The equipment continuously do not use.

When heavy, chronic illnesses the application of the German Federal Armed Forces 77 is not replacement for a controlled medical therapy by a physician or a welfare practical man.

Children and persons with reduced read abilities and view and reduced mental abilities may use the equipment only under supervision.



## **11 Hygiene and cleaning regulations:**

### **11.1 For bracelets hand electrodes:**

Our recommendation: with pure water or moderate soap solution after each using. Subsequently, dry leave.

With a rental business of the German Federal Armed Forces 77 each user should use its own bracelets for hygiene reasons.

### **11.2 For the bio Wave 77 :**

With a damp cloth.

Please do not use alcoholic solutions or solvents for the cleaning!

***Note: put only completely dry devices or accessories into the suit-case for keeping for hygiene and safety reasons please!***

## 12 Data to the disposal:

Please dispose of the German Federal Armed Forces 77 according to the locally valid rules for the disposal of electronic devices and Batteries. That equipment into the garbage can do not throw, but dispose of in the containers planned for it.

## 13 FAQ which is if?

|  |   |
|--|---|
| Equipment beeps, „to run “-<br>light flashes, announcement:<br>„no contact “ | Intertwining examine bracelets sufficiently<br>wet make cables possibly defective -<br>exchange |
| Battery announcement in the<br>display flashes                               | Battery nearly empty - exchange   |
| Chip Card program not<br>selectable (despite put in chip)                    | Chip Card the wrong way round put in  |
| Equipment indicates „Watchdog<br>to error “                                  | Chip Card was taken during chip the Card<br>of access   |
| Equipment cannot be switched<br>on   | Battery empty - Exchange  |
| Equipment cannot be switched<br>off  | Battery take - manufacturers contact  |

## **14      Contraindications / side effects**

### **14.1     Heavy illnesses of the elimination organs**

When heavy illnesses the elimination organs (liver, kidney, intestine, lung, skin) it recommends to consult itself therapists. It can come in rare cases to reactions, if by application does not increase resulting Metabolism of products of the body so fast be ruled out can. Meaningfully initially a therapy of the elimination ways is combined with rising therapy times of the German Federal Armed Forces 77.

### **14.2     Skin reactions**

In use of skin creams etc. allergic reactions can by electrolysis to arise at the contact points (bracelets) isolate. If the intensity of the equipment is too highly adjusted, then it can come to unpleasant Kibble, itching or burning, which does not affect therapy success however.

Reduce in this case the intensity (see Pkt.2) off or to break you the therapy, until no unpleasant skin features are more present. As alternative to bracelets you can use high-grade steel hand electrodes or sticking electrodes around these reactions to avoid. (see Pkt.7)

Avoid application:

Changes of the surface of the sticking electrodes, (drained, damaged or curved adhesive surface)

Visible damage to the bracelets, hand electrodes or to the cable connections

incomplete contact between skin and electrodes.

### **14.3 Reciprocal effects**

Reciprocal effect with other drugs are not well-known.

With regular intake of medicines you ask please your physician or therapists to risks and side effects when using the German Federal Armed Forces 77.

When the occurrence complaints a therapist should be consulted immediately.

### **14.4 Use during the pregnancy:**

For the use during the pregnancy no investigations are present, we recommend a consulting of a therapist.

During relieving the equipment can be used to the pain reduction.


## **15 Declaration of guarantee:**

Guarantee period 2 years

Warranty starting from invoice date

Bracelets, cables and batteries are expendable material and from there excluded from the warranty. If an error is present on the part of the manufacturer, must be lodged a complaint within one week after receipt of the equipment.

## 16 Technical data:

|   |  |
|---|--|
| Average life span:  | min. 3 years   |
| Operating temperature:  | 0 °C to 50 °C  |
| Storage temperature:  | <br>-20°C to 70°C   |
| <i>akklimatisieren with extreme variations in temperature equipment please slowly</i> |  |
| Air humidity:   | 30% to 75 % rel. Air humidity  |
| Air humidity:   | 0 to 90 % rel. Air humidity  |
| Weight of the equipment:  | (inclusive. Battery) approx. 200 g<br>(inclusive. Bracelets and battery)<br>approx. 500 g  |
| Current supply:   | Battery 9 V E-block or<br>Ni-MH- Akku (8,4 V)  |
| Current supply in the enterprise:   | approx. 20 – 30 mA<br>(depending upon skin resistance)   |
| Power input in break:   | approx. 12 mA  |
| Life span battery:  | with 3*7 min (approx. 500 mA/h) Program<br>approx. 20 Applications<br>with continuous operation approx. 5 to 10 hr.<br>varied after battery type,<br>Skin type and Intensity |
| Output voltage:   | 1 V to 15 V<br>independently of the battery voltage  |
| Output signal form:   | symmetrical rectangle  |
| Offset:   | positive (Std. Clark),<br>positive Offset with + 0,25 V Residual voltage<br>no Offset (plus / minus)   |
| Output frequency:   | 33,33 kHz<br>(and/or frequency as per program)   |
| Frequency range:  | 1 Hz to 1 MHz  |
| Frequency accuracy:   | +/- 100 ppm  |
| Internal resistance:  | 1 k  |
| Max. output current in the case of short-circuit:                                     | < 10 mA  |

## Table 201 - Guidelines and manufacturer explanation electromagnetic sending

The BW77 is intended for the enterprise in one like environment indicated down. The customer or the user of the BW77 should guarantee that it is operated in a such environment.

| Breakdown sending measurements  | Agreement      | Electromagnetic environment manual  |
|---|----------------|---|
| HF - Sending after CISPR 11   | Group 1        | The BW77 uses HF-energy exclusive for its internal function. Therefore its HF sending is very small, and it is improbably that neighbouring electronic devices is disturbed.                                      |
| HF- Sending after CISPR 11  | Class B        | The BW77 is suitable for the use in other mechanisms than the apartment range and such, which are directly attached to a public supply network, also the building supplied, which is used for apartment purposes. |
| Sending from harmonics to International Electronical Commission 61000-3-2                     | Not applicably |   |
| Sending of voltage fluctuations/Flicker after International Electronical Commission 61000-3-3 | Not applicably |   |

Table 203 - Guidelines and manufacturer explanation - electromagnetic noise immunity for life-supporting devices and systems - not applicable for BW77

Table 205 - Recommended protection distances between portable and mobile HF telecommunications devices and the BW21/BW77 for life-supporting devices or systems

**- not applicable for BW77**

**Table 207 - Guidelines and manufacturer explanation - electromagnetic noise immunity - for life-supporting devices and systems, which are intended exclusively for the enterprise at abgeschrimten locations - not applicable for the BW77**

**Table 208 - Guidelines us manufacturer explanation - electromagnetic noise immunity for devices and systems, which are not life-supporting and exclusively for the enterprise at protected locations are intended - not applicable for the BW77**

Table 202 - Guidelines and manufacturer explanation - electromagnetic noise immunity for the BW77

The BW77 is intended for the enterprise into de electromagnetic environment indicated down. The customer or user of the BW77 should guarantee that it is used in such an environment.


| Noise immunity examinations   | International Electronical Commission 60601 - Test level  | Agreement level  | Electromagnetic environment – guidelines   |
|---|---|--|--|
| Unloading of static electricity (ESD) after International Electronical Commission 61000-4-2                                       | +/- 6 kV Contact NT load<br><br>+/-8 kV contact NT load   | +/- 6 kV Contact NT load<br><br>+/- 8 kV Air unloading             | Floors should consist of wood or concrete or be provided with ceramic tiles. If the floor is provided with synthetic material, the relative humidity must amount to at least 30%.  |
| quick transient electrical variable disturbances Bursts after International Electronical Commission 61000-4-4                     | +/- 2 kV for mains<br><br>+/- 1 kV for initially and outlet lines   | Battery operation, not applicable                                  | The quality of supply voltage should correspond to the typical business or hospital environment.   |
| Impulse voltages (Surges) after International Electronical Commission 61000-4-5   | +/- 1 kV Against clock tension<br><br>+/- 2 kV Common mode tension  | +/- 1 kV Against clock tension<br><br>+/- 2 kV Common mode tension | The quality of supply voltage should correspond to the one typical business or hospital environment.   |
| Voltage drops, short time interruptions and fluctuations of supply voltage after International Electronical Commission 61000-4-11 | < 5 % $U_T$<br>(> 95 % Break-down that $U_T$ ) for ½ periode<br><br>40 % $U_T$<br>(60 % Break-down that $U_T$ ) for 5 periods<br><br>70 % $U_T$<br>(30 % break-down that $U_T$ ) for 25 periods<br><br>< 5 % $U_T$<br>(> 95 % break-down that $U_T$ ) for 5 s | Battery operation, not applicable                                  | The quality of supply voltage should correspond to the one typical business or hospital environment. If the user of the BW77 demands continued function also when the occurrence interruptions of the power supply, one recommends, to feed the BW77 from an no-break current supply or a battery. |
| Magnetic field with the supply frequency (50/60 cycles per second) after International Electronical Commission 61000-4-8          | 3 A/m   | Battery operation, not applicable                                  | Magnetic fields with the frequency should correspond to the typical values, how they are to be found in the business and hospital environment,.  |

Note:  $U_T$  is the net alternating voltage before the application of the test levels.

Table 204 - Guidelines and manufacturer explanation - electromagnetic noise immunity - for BW77, which is not LIFE-SUPPORTING

Guidelines and manufacturer explanation - electromagnetic noise immunity

The BW77 is intended for the enterprise in the electromagnetic environment indicated down. The customer or user of the German Federal Armed Forces 77 should guarantee that it is used in such an environment.

| Noise immunity examinations  | IEC 60601- Test level  | Agreement level           | Electromagnetically environment – guidelines   |
|--|--|---------------------------|--|
| <p>Led HF-variable disturbances after IEC 6100-4-6</p> <p>Radiated HF-variable disturbances after IEC 6100-4-3</p> | <p>3 Veff<br/>150 kHz to 80 MHz</p> <p>3 V/m<br/>80 MHz to 2,5 GHz</p> | <p>10 V</p> <p>10 V/m</p> | <p>Portable and mobile radios should be used in no smaller distance to the BW21LCD/BW77 including the lines than the recommended protection distance, which is computed after the equation applicable for the transmitter frequency.</p> <p>Recommended protection distance:</p> <p><math>d = 0,35 \sqrt{P}</math></p> <p><math>d = 0,35 \sqrt{P}</math> for 80MHz to 800 MHz</p> <p><math>d = 0,7 \sqrt{P}</math> for 800 MHz to 2,5 GHz</p> <p>with P as rated output of the transmitter in Watts (in accordance with W) the data of the transmitter manufacturer and D as recommended protection distance in meter (m).</p> <p>The field strength stationary Funksender should be smaller with all frequencies in accordance with an investigation before Orta than the agreement level.</p> <p>In the environment of devices, which carry the following symbol, disturbances are possible.</p>  |



NOTE 1: With 80 MHz and 800 MHz the higher frequency range is valid.

NOTE 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic sizes is affected by absorptions and reflections of the buildings, articles and humans.

a: The field strength of stationary transmitters, like e.g. basis stations of radio telephones and mobile rural broadcasting devices, amateur radio act ions, TO and FM broadcast and television stations cannot be predetermined theoretically exactly. In order to determine the electromagnetic environment regarding the stationary transmitters, a study of the location should be considered. If the measured field strength at the location, at which the BW77 is used, which exceeds above agreement level, the BW77 should be observed, can additional measures necessarily be, like e.g. changed adjustment or another location of the BW77.

b: Over the frequency range from 150 kHz to 80 MHz the field strength should be smaller than 10 V/m.

Table 206 - Recommended protection distances between portable and mobile HF- Telecommunications devices and the BW77 those not LIFE-SUPPORTING are.

The BW77 is intended for the enterprise in an electromagnetic environment, in which the HF-variable disturbances are controlled. The customer or the user of the BW77 can help to avoid electromagnetic disturbances by the minimum distance between portable and mobile HF- Telecommunications devices (transmitters) and the BW77 - dependent of the power output of the communications equipment, how down indicated - keeping.

| Rated output of the transmitter<br><b>W</b> | Protection distance dependently of the transmitter frequency<br><b>M</b> |                                   |                                   |
|---|--|-----------------------------------|-----------------------------------|
|   | 150 kHz to 80 MHz<br>D = 0,35 v P  | 80 MHz to 800 MHz<br>d = 0,35 v P | 800 MHz to 2,5 GHz<br>d = 0,7 v P |
| 0,01  | 0,035  | 0,035                             | 0,07                              |
| 0,1   | 0,11   | 0,11                              | 0,22                              |
| 1   | 0,35   | 0,35                              | 0,7                               |
| 10  | 1,11   | 1,11                              | 2,21                              |
| 100   | 3,5  | 3,5                               | 7                                 |

For transmitters, whose maximum rated output is not indicated in above table, the recommended protection distance D can be determined belonged in meter (m) using the equation, to the respective column, whereby P the maximum rated output of the transmitter in Watt (W) in accordance with indication of the transmitter manufacturer is.

NOTE 1: With 80 MHz and 800 MHz the higher frequency range is valid.

NOTE 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic sizes is affected by the absorptions and reflections of the buildings, articles and humans.

## Konformitätserklärung nach Anhang II Richtlinie 93/42/EWG

*Declaration of Conformity according to Annex II Medical Device Directive 93/42/EWG*

*Déclaration de Conformité selon Annexe II de la Directive 93/42/EWG*

### **Medi-Gen Technology Ltd. & Co. KG**

Leiten 3

DE - 83556 Griesstätt

erklären in alleiniger Verantwortung, dass das Produkt „Stimulator (TENS):

*declare under our sole responsibility, that the product „Stimulator (TENS):*

*déclarons sous notre seule responsabilité, que le produit „Stimulator (TENS):*

**Typ: BW 77**

**Ab Ser. Nr.: MEZ3AD0001,**

**Produktklasse: IIa (Anhang IX, Regel 9)**

mit den Anforderungen der Richtlinie 93/42/EWG für Medizinprodukte übereinstimmt.

*fulfils the requirements of the Medical Directive 93/42/EWG for medical products.*

*satisfait aux exigences de la Directive 93/42/EWG et des normes.*

Die benannte Stelle ist die LGA InterCert CE 1275



(Geschäftsführer / Director)

Griesstätt, 01. Januar 2009

Ort und Datum der Ausstellung

*Place and Date*

*Lieu et date*

Name und Unterschrift des Befugten

*Name and Signature of authorized person*

*Nom et signature de la personne autorisée*

**Indication of dealer:**

Equipment designation: **BW 77**

Serial number:

bought to:

Dealer:



## 17 Operating instruction for hasty ones!

1. Battery insert
2. 2. Bracelets well dampen and with the cables connect
3. Cable with colored fitting sockets connect with BW 77 (see point 6.1)
4. „On key “briefly press (see point 6.2.1.)
5. Greeting text appears for approx. 5 seconds
6. 6. Desired expiration of frequency select through pressures „the programs  $\uparrow/\downarrow$  keys“ (see point 6.4)
7. „Run key“ press (see 6.5)
8. 8. Intensity through pressures „of the Intensity  $\uparrow/\downarrow$  keys“adjust (see point 6.8)
9. 9. At the end of the expiration of frequency by long pressing of the “on key “switch the equipment off (see Pkt.6.12)

***Note: put only completely dry devices or accessories into the suit-case for keeping for hygiene and safety reasons please!***

***The safety references of the operating instruction are to be considered absolutely!***

***Please consider the hygiene regulations for the equipment and accessories! (see point 9)***

Operating instruction BW 77 for Software-Version V010tb

Valid off: 06.05.2008