

# Operating Manual

## Bio Wave Generator 21 LCD



We only gain and attract those things  
which are in unity with our own resonance

Therefore, be honest with yourself,  
cherish the truth,  
and sustain love and harmony

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In your own interest, please read this operating manual completely before use and follow any warnings and messages in this manual and on the unit.

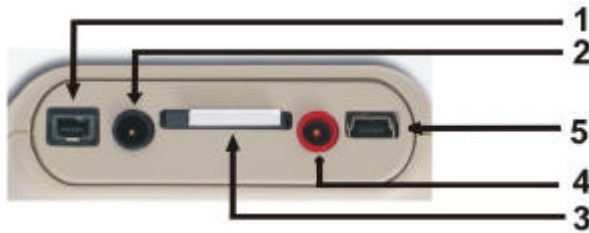
# 1 Therapeutic Applications and Indications

Frequency generator for use in the therapy of acute and chronic pain with Transcutaneous Electrical Nerve Stimulation

## **Alleviates pain from the following conditions:**

- ⤴ Headaches (migraines)
- ⤴ Back pain – lower back pain – sciatica
- ⤴ Joint pain caused by osteoarthritis (degenerative joint disease), arthritis, and the final stages of Lyme disease, or borreliosis.
- ⤴ Pain control during labour and birth
- ⤴ Postoperative pain relief
- ⤴ Injury induced (post traumatic) pain, e.g. fractured rib
- ⤴ Alleviate neuropathic pain (pain due to nerve damage), e.g. Diabetic peripheral neuropathy
- ⤴ Phantom limb pain after amputation
- ⤴ Vascular related circulatory disorder (intermittent claudication)
- ⤴ Pain following treatments like frozen shoulder (adhesive capsulitis), hysteroscopy, non invasive fragmentation of kidney stones using shock wave therapy
- ⤴ Musculoskeletal system disorders
- ⤴ Rheumatic disorders

## 2 Markings and Controls



**1 Com Port:** Interface used for internal test purposes only

**2 Out - :** Negative terminal for connecting the black cable

**3 Chip Card Drive**

**4 Out + :** Positive terminal for connecting the red cable

**5 Ext. Port:** External accessory port

**6 Power Lamp:** Green light shows when on.

**7 Run Lamp:** Yellow light when active.

**8 LCD display:** 2-line display with battery level indicator.

**9 Intensity Up:** For increasing the intensity.

<I-↑>

**10 Program Up:** For selecting higher program.

<P-↑>

**11 Program Down:** For selecting lower program.

<P-↓>

**12 Intensity Down:** For reducing the intensity

<I-↓>

**13 Enter:** Use this button to confirm selection

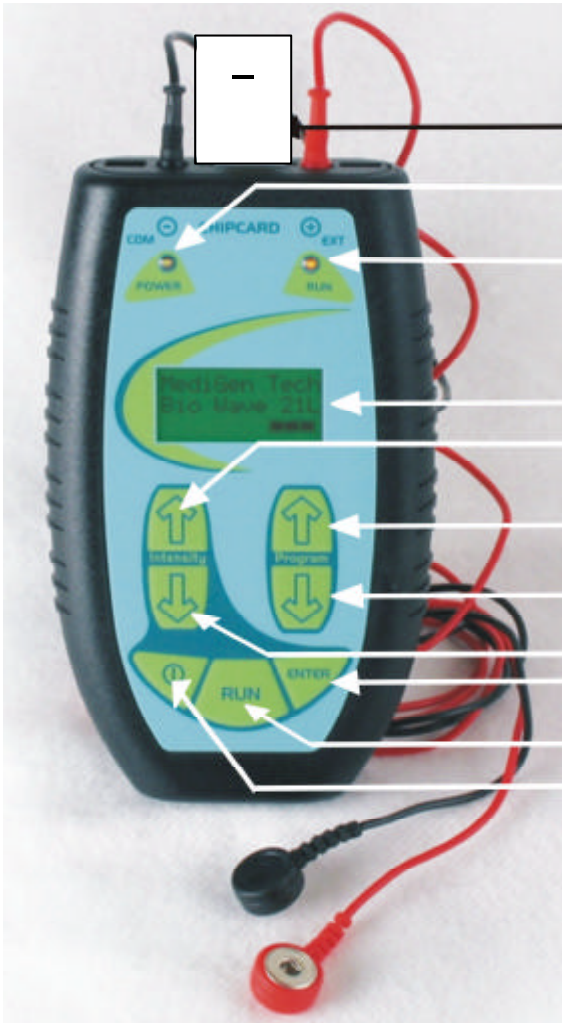
<Enter>

**14 Run:** Starts the therapy.

<Run>

**15 Power:** On/Off switch.

<Power>





Identification plate

Belt clip

Battery compartment



Battery lid



Identification plate

## 2.1 Identification Plate

Medi-Gen Technology Ltd.

Manufacturer

Barcode

Barcode for serial number

MEZ2AD0001 (for example)

Serial number

Type: BW21LCD

Device Type Code



European Certification (CE) code  
+ Notified body identity code



Applied Part: Type BF. Type BF is for devices that have conductive contact with the patient.



Important: Follow the operating instructions!



Appliance is a class II device. This means that it is double insulated and does not need to be grounded.



Do not dispose of this device in your domestic refuse. Use an authorized disposal centre for electronic waste.

### 3 Manufacturer's Name and Address

Medi-Gen Technology Ltd. & Co. KG

Leiten 3

D 83556 Griesstätt  
Germany

Tel. +49 (0) 700 777 999 11 (12 cent/min. within Germany)

Fax. +49 (0) 700 633 44 362 (12 cent/min. within Germany)

Internet: [www.medi-gen.de](http://www.medi-gen.de)

Technical support: [hotline@medi-gen.de](mailto:hotline@medi-gen.de)

### 4 Scope of Delivery

**Note: The Bio Wave 21 LCD may only be used with original - accessories.**

Quantity	Unit	Designation	Article No.
1	Piece	Bio Wave Generator 21 LCD	11110
1	Piece	Red cable	31110
1	Piece	Black cable	31120
2	Piece	Armbands with yellow sponge	32110
2	Piece	Adhesive electrodes 45x35 mm	32310
1	Piece	9V alkaline block battery	37110
1	Piece	Carrying case	
1	Piece	TENS Application brochure	
1	Piece	Operating Manual	

### 5 Other Accessories

High-grade steel hand electrodes Art. No. 32210

Adhesive electrodes, 53 x 96 mm, Art. No. 32320

8.4 V NiMH rechargeable battery

Chip Cards

(See section 7.1-3 for details on use of accessories)



## 6 Preparing for Use

### 6.1 Preparing the Bio Wave 21 LCD

1. Open the battery lid, on the rear of the unit.
2. Insert the battery provided.  
Alternatively, an 8.4 V Ni-MH rechargeable battery can be used.  
Be careful to insert the battery correctly with the smaller positive connector on the right as otherwise the battery could discharge quickly.
3. Attach the battery lid again.
4. Thoroughly clean your hands, with soap and water, to remove any hand creams or lotions before using the unit. This avoids soiling the armbands, etc. which can reduce their electrical efficiency.
5. Connect the cables of the BW 21 LCD with the colour coded connectors.
6. Finally, attach the button clip connectors to the armbands.

The smaller slot  
on the right is +



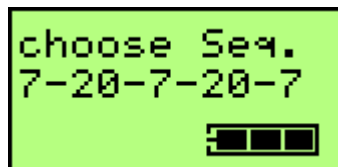
**Important:** Wet the yellow sponge armbands with tap water before use.

### 6.2 Switching on the Bio Wave 21 LCD

- Press the <Power> key briefly, the power lamp lights up.
- The device name and version number appears on the display
- After about 5 seconds, the program display is shown automatically.

### 6.3 Select a Frequency Program

1. If no *Chip Card* was inserted, before turning on the unit, the standard program “7-20-7-20-7” appears (3x7 min. with 20 min. breaks in-between).
2. If a pre-programmed *Chip Card* has been inserted, before turning on the unit, the *Chip Card*'s program is displayed in the program window.



## 6.4 Program Directory

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

- Use the <P-↑> or <P-↓> keys to select the desired program
- Confirm by pressing the <Enter> key
- The frequency application window appears
- Press the <Power> key briefly to return to the program directory.

**Note:** *We highly recommend you combine a detoxification therapy with increased therapy times on the Bio Wave 21 LCD!*

## 6.5 Starting and stopping the frequency program

- Once you have selected the appropriate program, you can start it by briefly pressing the <Run> key. A short beep will be heard and the run lamp illuminates.
- While the program is running, you can pause the current frequency by briefly pressing the <Run> key again. The run light switches off and a short beep can be heard (timer is stopped).
- To restart, simply press the <Run> key again. If you do not restart the program within 5 minutes, the unit will automatically switch itself off.

**Note:**            “Brief press”            = 1 second  
                      “Long press”            = 3 seconds

## 6.6 Contact Testing

A contact test is performed automatically at the beginning of each program and/or as soon as the <Run> key has been pressed. The value measured is in the range 0 - 200.

If the contact (with the patient) is not sufficient, one of the following appears:



If the measured contact value is below 5, "no Contact" is displayed, the run light flashes and a beep can be heard every second flash.

**Note: the frequency program has been interrupted!**

In order to override the contact test and continue the program (e.g. for test purposes) - simply press the <Enter> key.

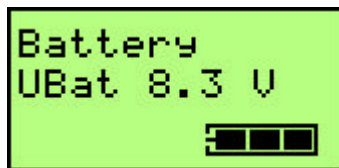
Once proper contact has been established for 3 seconds, the program starts automatically.

**Important:** Only press the <Run> key after attaching wet armbands and connecting them with the red and black cables. Otherwise the unit will display "no Contact"!

## 6.7 Measuring the battery voltage

Provided the unit has already been switched on and you are in the main menu, select one of the programs (e.g. TENS 1) and press <Enter>

A long press of the <Enter> key will now show the current battery voltage.



After 5 seconds, the previous display is shown again.

You can press <Power> briefly to return to the main menu.

The battery level is also shown continuously in the form of 3 bars on the battery level indicator. As the battery discharges, the level drops to just one bar and the power lamp will flash when the battery needs to be replaced.

**Note:** When using rechargeable batteries, the remaining voltage sinks faster than with primary alkaline batteries once only one bar is shown, independent of the quality of the rechargeable batteries or their maximum charge capacity!

## 6.8 Adjusting the Intensity

The intensity is adjustable from 0 to 15 Volts in 0.2 Volt steps where the default value is 4 Volts.

The intensity can be changed by briefly pressing the <I-↑> (increase) or <I-↓> (decrease) keys, which will adjust the intensity in 0.2 Volt steps.

By pressing the respective keys longer, the intensity will be adjusted in 1 Volt steps instead (high-speed function).

**Note:** Adjust the intensity such that the therapy remains comfortable. If you start to feel an unpleasant burning or itching sensation, the intensity is too high and you need to reduce it or stop the therapy (press <Run> to stop). You can also try using the hand or adhesive electrodes.

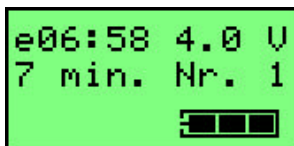
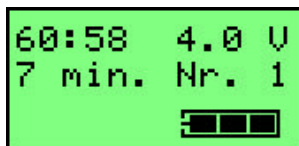
## 6.9 Navigating through the frequencies

- If you wish to skip forewords or backwards through the program sequence (list of frequencies to be applied), simply press the <P-↑> (backwards) or <P-↓> (forwards) keys respectively until the desired frequency is displayed.
- This can be done either before you start the program or during the program (after starting with the <Run> key).
- A short beep can be heard (see 6.5 for details).

## 6.10 Displaying individual or total remaining time

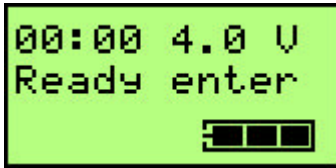
While the program is running, the remaining therapy time (e.g. 60:58) is displayed at the top left of the screen by default. This counts down until the therapy time is complete. If you would prefer to see the remaining time for each individual frequency, press and hold the <Run> key for 3 seconds.

An “e” is displayed in front of the timer to display the remaining time for each frequency (e.g. e06:58).



## 6.11 End / Terminating the Frequency Program

At the end of the program, the countdown timer shows “00:00” and “Ready enter” is displayed on the second line.



You can confirm the end of the program by pressing the <Enter> key. The main menu is now displayed again.

If you want to stop the program before it has ended, either press the <Enter> key longer or briefly press the <Run> key.

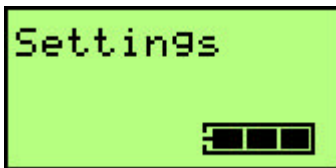
## 6.12 Switching off the Bio Wave 21 LCD

To switch off the Bio Wave 21 LCD, simply press and hold the <Power> key for at least 3 seconds until you hear 3 short beeps and “Power Off” is shown on the display. If the unit has been unused for 5 minutes, it will switch off by itself.

**Note:** After use, thoroughly clean the armbands, under running water, and dry them before storing them in the case next to the Bio Wave 21 LCD. Damp armbands stored with the Bio Wave 21 LCD can cause damage to the unit.

## 6.13 Language and Software settings, Serial Number

After switching on (see 6.2), select “Settings” by pressing the <P-↑> key twice.



Press the <Enter> key and the current software version will be displayed.

Press the <P-↓> key to show the Boot loader ID (e.g. V03)

Press the <P-↓> key again to show the serial number

Press the <P-↓> key again to show the current language (default is German).

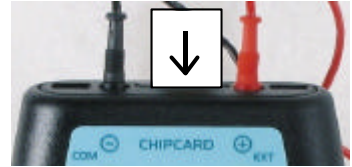
Press the <Power> key to leave the settings menu.

**Note:** Other languages (e.g. English) can be installed via a special Chip Card.

## 7 Use of External Accessories

### 7.1 Use of Chip Cards

- Insert the Chip Card, of your choice, into the reader at the top of the Bio Wave 21 LCD. **Make sure that the arrow is pointing down as shown in picture.**
- Switch on the unit (see 6.2)
- The unit will automatically display the contents of the *Chip Card*.
- See 6.4 for details of how to select and run the program
- See 6.9 for details of how to select and run an individual frequency from the Chip Card
- Do not remove the card while the program is running. When the program is complete, press <Enter> to end the program selection.



**Notes:** *The Chip Card can be removed after pushing it in slightly to release the catch and activate the spring mechanism. The card can then be removed easily. Do NOT try to pull the card out without releasing the catch first. Cards labelled “BW77” cannot be used in a BW21LCD. Do not use these cards in mobile phones or try to insert mobile phone SIM cards into the Bio Wave 21 LCD.*

### 7.2 Use of Hand Electrodes

- Cover the metal hand electrodes with wet sponge sleeves (Wet chlorine-free kitchen paper can also be used).
- Connect the red and black cables to the respective ports on the top of the Bio Wave 21 LCD unit.
- Connect each cable with the button connector on the metal hand electrode.
- Switch on the Bio Wave 21 LCD
- Start the selected frequency program (see 6.4-6.5)
- Hold a hand electrode in each hand and hold it until the treatment is complete.
- After treatment, switch off the Bio Wave 21 LCD (see 6.11)
- Put down the hand electrodes and remove the sponge covers

**Note:** *Before further use or storage, ensure the hand electrodes and sponge coverings have been properly washed and dried!*

## 7.3 Use of Adhesive Pad Electrodes

- Connect the red and black cables to the respective ports on the top of the Bio Wave 21 LCD unit.
- Connect each cable to the button connector of the adhesive pad electrodes
- We recommend using pure alcohol to clean the surface of the electrodes and the body where the adhesive pads are to be applied. Make sure the alcohol has completely evaporated before applying the pads to the body.
- Remove the protective film (keep these for later use) and attach the electrodes as recommended by your practitioner, avoiding hair, mucous membranes and open wounds.
- Switch on the Bio Wave 21 LCD
- Select and run the frequency program
- After treatment, carefully remove the adhesive pads from the body and attach them to the protective plastic film again.
- Switch off the Bio Wave 21 LCD

**Storage:** The adhesive electrodes should be attached to their plastic protective film when not in use. They should be stored in their packaging at a temperature in the range of 5-35°C (40–95°F) with a relative humidity of 20% to 80%.

**Note:** *Adhesive pad electrodes can be used multiple times, by the same person, if you follow these storage and cleaning instructions. For hygienic reasons, do not share adhesive pads with others. Ensure each person has their own set of pads.*

## 8 Warnings and Safety Instructions

In order to avoid any danger of electric shock, do not remove the casing or open the back of the unit.

In your own interest, please read this operating manual completely before use and follow any warnings and messages in this manual and on the unit.

Never use this equipment near water, e.g. bath, shower, sink, etc. or in areas of high humidity, e.g. Sauna.

Do not immerse the unit in any liquids or allow any liquids to enter the unit.

Do not use the equipment near heat sources like heaters, ovens, etc.

Protect the unit from extreme changes in temperature, dust and direct sunlight as this can damage the display.

During application, do not make any phone calls with a mobile phone and maintain a distance of at least 2 meters (7 feet) from any mobile phone that has been switched on.

### **Special precautions relating to the power supply:**

Do not use the device while connected to any mains power supply, transformer, charger, etc.

This unit may only be used with either a 9 V primary alkaline battery or with an 8.4 V NiMH rechargeable battery cell.

Keep batteries/rechargeable batteries out of reach of children.

Please observe the correct polarity, when inserting the battery into the unit.

Remove any batteries from the unit to prevent damage if you do not intend to use the unit for longer periods of time (e.g. when storing).

***Do NOT connect any cables or accessories, which are connected to this unit, with any mains power supply socket!***

***In the case of any damages which are caused due to failure to observe these operating instructions, the guarantee will expire and we will not assume any liability for resulting damages!***

***Nor do we assume liability for damage to property or personal injury, caused by improper use or failure to observe the safety instructions. The guarantee will expire in any such case!***



## **9 Use in Combination with other Devices / Avoiding Risks**



**WARNING!** Do not use with cardiac pacemakers!

Do not use this unit near electromagnetic fields or close to microwaves.

Do not operate other electrical devices while using this equipment.

Do not apply any armbands, hand electrodes or adhesive electrodes to any open wounds, allergies, eczema, mucous membranes or in any bodily orifices. Areas with heavy concentrations of hair should be shaved before application.

Drink sufficient (1-2 litres / 2-4 pints) low mineral, non or low carbonated water during application.

When applied for more that 2 hours/day, please consult a therapist.

After a maximum of 8 weeks application, a pause of at least 2 weeks is necessary. Do not use the unit continuously.

Use of the Bio Wave 21 LCD is not a replacement for controlled medical therapy from your doctor or nonmedical practitioner, especially for serious and chronic illnesses.

Children and/or persons with inhibited eyesight and reading abilities as well as those who are mentally handicapped may only use the equipment under supervision.

## **10 Hygiene and Cleaning Instructions**

### **10.1 For Armbands / Hand Electrodes**

We recommend cleaning with pure water or mild detergent after every use.

Dry thoroughly after cleaning and before storing in the case.

If the Bio Wave 21 LCD is loaned out to others, each user should have their own personal armbands for reasons of hygiene. Alternatively use the hand electrodes covered with moist chlorine-free kitchen paper which is thrown away after every use.

## 10.2 For the Bio Wave 21 LCD

Clean the product with a soft, clean, dry and lint-free cloth. If you wish to clean the product intensively, use a cloth slightly moistened with lukewarm water.

Never use solvent based cleansing agents, since this might damage the surface of the plastic housing and labels.

***Important: For hygiene and safety reasons, do not place the unit or its accessories in its case until they are completely dry!***

## 11 Disposal Instructions

Please dispose of the Bio Wave 21 LCD, and its accessories, according to the current legal regulations.

As an end user, you are legally obliged to dispose of exhausted (rechargeable) batteries properly. **It is not permitted to dispose of any used batteries in your domestic refuge.**

You can return such batteries free of charge to any authorized disposal station in your area including any stores where such batteries are sold.

## 12 Troubleshooting

Beeping sound, Run-lamp flashing, Display shows: "no contact"	Check cables are properly connected and not damaged. Are both armband wet enough and attached to the patient?
Battery symbol on display is flashing	Battery is almost empty – exchange battery
Chip Card not recognised by unit after being inserted	Ensure Chip Card has been inserted correctly with arrow pointing into unit
"Watchdog Error" shown on display	Chip Card was removed from unit while it was still being used.
Unit cannot be switched on	Battery is empty – exchange battery
Unit cannot be switched off	Remove battery - contact manufacturer

## **13 Contraindications / Side Effects**

### **13.1 Serious illnesses of the Excretory System**

It is highly advisable, in the case of serious illnesses of the excretory organs (liver, kidney, intestines, lung, skin), to consult a therapist. In rare cases, negative reactions are possible where application results in an increase in waste products, from the metabolism, that cannot be excreted from the system fast enough.

It is suggested to first treat the excretory system followed by rising therapy times with the Bio Wave 21 LCD.

### **13.2 Skin Reactions**

If skin creams, etc. have been used, it is possible in rare cases that allergic reactions can occur where the armbands, etc. are attached due to electrolysis. It is advisable not to use any hand creams, etc. in combination with any electrotherapy.

If the intensity has been set too high, it can lead to an unpleasant tingling sensation, itching or burning, although such effects do not affect the effectiveness of the treatment itself.

Reduce the intensity of the therapy (see 6.8) or break off the therapy until the unpleasant skin reactions have subsided.

As an alternative to armbands, you can use the stainless-steel hand electrodes or the adhesive electrodes to avoid such reactions (see 7.2-3).

Avoid application when there are:

- Changes to the surface of the adhesive electrodes, (dried out, damaged or uneven adhesive surface)
- Visible damage to the armbands, hand electrodes or any of the cables
- Poor contact between the skin and electrodes.

### **13.3 Interactions with Medicines**

There are no known interaction effects with other medicines.

If you regularly take medicines, please consult with your doctor or therapist in regard to any possible risks and side effects when used in combinations with the Bio Wave 21 LCD.

If any have any symptoms, please consult a therapist, immediately.

### **13.4 Use during Pregnancy**

There is no data available regarding the use of the Bio Wave during pregnancy. We recommend consulting a therapist before use.

The equipment can be used during birth for pain reduction (TENS).

## **14 Guarantee Declaration**

This unit is guaranteed for a period of 2 years, valid from the date of the original invoice.

Armbands, cables and batteries are expendable materials and are therefore excluded from warranty. If any manufacturing defects have been found, complaints must be made within one week after receipt of the equipment.

## 15 Technical Data


Average life span:	min. 3 years
Operating temperature:	0 °C to 50 °C (32°F to 122°F)
Storage temperature:	 -20°C to 70°C (-4°F to 160°F)
<i>By extreme variations in temperature, please acclimatise the equipment slowly</i>	
Humidity:	30% to 75 % rel. humidity
Weight:	Approx. 200 g (incl. battery) Approx. 500 g (incl. armbands and battery)
Power supply:	9 V E-block alkaline primary battery or 8.4V Ni-MH E-block rechargeable battery
Current use under load:	Approx. 20 – 30 mA (according to skin resistance)
Current use in stand-by:	Approx. 12 mA
Battery life span:	
- 3x7 min program	Approx. 500 mA/h (about 20 applications)
- Continuous operation	approx. 5 to 10 hrs depending on battery, skin type and intensity used
Output voltage:	1 V to 15 V independent of battery voltage
Output signal form:	symmetrical square wave
Offset:	Positive (Standard acc. to Clark), Positive offset with + 0.25 V residual voltage No Offset (plus / minus)
Output frequency:	33.33 kHz (or frequency as programmed)
Frequency range:	1 Hz to 1 MHz
Frequency accuracy:	+/- 100 ppm
Internal resistance:	1 kΩ
Max. Output short-circuited:	< 10 mA

Table 201 – Guidance and manufacturer’s declaration – electromagnetic emissions

The BW21LCD is intended for use in the electromagnetic environment specified below. The customer or the user of the BW21LCD should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BW21LCD uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The BW21LCD is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Table 203 - RF immunity of life-support equipment or system - **not applicable for BW21LCD**

Table 205 - Recommended separation distances between life-support equipment or system and portable or mobile RF communications equipment - **not applicable for BW21LCD**

Table 207 - RF immunity of life-support equipment or system that is specified for use in shielded locations - **not applicable for BW21LCD**

Table 208 - RF immunity of non-life-support equipment or system that is specified for use in shielded locations - **not applicable for BW21LCD**

Table 202 - Guidance and manufacturer's declaration – electromagnetic immunity

The BW21LCD is intended for use in the electromagnetic environment specified below. The customer or the user of the BW21LCD should assure that it is used in such an environment.


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact  +/-8 kV air	+/- 6 kV contact  +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines  +/- 1 kV for input/output lines	Battery operation, not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode  +/- 2 kV common mode	+/- 1 kV differential mode  +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % $U_T$ (> 95 % dip in $U_T$ ) for 0.5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  < 5 % $U_T$ (> 95 % dip in $U_T$ ) for 5 sec	Battery operation, not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BW21LCD requires continued operation during power mains interruptions, it is recommended that the BW21LCD be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Battery operation, not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note:  $U_T$  is the a.c. mains voltage prior to application of the test level.

Table 204 – Guidance and manufacturer’s declaration – electromagnetic immunity – for BW21LCD that are not LIFE-SUPPORTING

Guidance and manufacturer’s declaration – electromagnetic immunity

The BW21LCD is intended for use in the electromagnetic environment specified below. The customer or the user of the BW21LCD should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V<sub>eff</sub> 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>10 V</p> <p>10 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the BW21LCD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 0.35 \sqrt{P}$ <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>where <math>p</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).<sup>b</sup></p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 



NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> - Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BW21LCD is used exceeds the applicable RF compliance level above, the BW21LCD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BW21LCD.

<sup>b</sup> - Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

### Table 206 - Recommended separation distances between portable and mobile RF communications equipment and the BW21LCD that are not LIFE-SUPPORTING

The BW21LCD is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BW21LCD can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BW21LCD as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of the transmitter	Separation distance according to frequency of transmitter		
	M		
	150 kHz to 80 MHz $d = 0.35 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
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 rated at a maximum output power not listed above the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## 15.1 EC Declaration of Conformity - Appendix II, Guideline 93/42/EWG

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

*Leiten 3*

*83556 Griesstaett*

*Germany*

declare under our sole responsibility that the product:

Type: **BW 21 LCD**

From Ser. No.: **MEZ2AD0001, JMZ2AD0001, MPZ2AD0001  
BWZ2AD0001, MWZ2AD0001**

Product class: **Ila (Appendix IX, rule 9)**

to which this declaration relates, is in conformity with the  
guideline 93/42/EWG for medical products.

The notified body is the LGA InterCERT CE 1275

Signed by the manufacturer

Peter Franke (Director)

**Griesstätt, 01. Februar 2007**

## 16 Dealer Information

Device code: **BW 21 LCD**

Serial number: \_\_\_\_\_

Sold to: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Telephone: \_\_\_\_\_

Date purchased: \_\_\_ / \_\_\_ / 20 \_\_\_ (DD / MM / 20YY)

Dealer Address:

## 17 Quick User Guide!

In your own interest, please read this operating manual completely before use and follow any warnings and messages in this manual and on the unit.

1. Insert battery
2. Wet the armbands and connect them to the cables
3. Attach the armbands to the body, e.g. to left wrist and right ankle
4. Connect the cables to the respective colour coded (red/black) sockets on top of the Bio Wave 21 LCD (see 6.1 for details)
5. Briefly press the <Power> button (see 6.2)
6. Device starts showing version information for 5 seconds.
7. Select the desired therapy program with the Program  $\uparrow/\downarrow$  keys (see 6.4)
8. Press the <Run> key to start the program (see 6.5)
9. Adjust the intensity with the Intensity  $\uparrow/\downarrow$  keys (see 6.8)
10. At the end of the treatment, press the <Power> key for 3 seconds to switch the unit off (see 6.12)
11. Disconnect the cables and armbands and wash the armbands under tap water and thoroughly dry them before storing in the case.

***Important: To preserve your hygiene and safety, always clean the armbands and completely dry them before returning them and the Bio Wave 21 LCD to the case. Each person using the device should have their own set of armbands!***

***Please read the Warnings and Safety instructions (section 8) and follow them precisely!***

***Please read the Hygiene and Cleaning Instructions for this equipment and its accessories (see section 10)!***