



Instructions for Use VV 3001 MED

OxyCare
Made in Germany by VibraCare





# Scope of delivery/parts

Power supply unit/charger MPM-X50-12



VibraVest instructions for use



Adapter cable for mains operation Article No. 499040



Carrier case





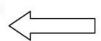
Rechargeable battery JGPB-1202500-NC







Hand-held controller





## Dear customer,

Thank you for choosing this product and the trust you have placed in us with your purchase. To ensure you are able to fully utilise all the advantages offered by our product, we have compiled all the information you will require for optimum use in these operating instructions. To ensure the safe use of the device, please pay particular attention to all the points identified by ((symbol)).

The instructions for use also contain important information on SAFETY and TECHNICAL DATA. You should therefore carefully read the instructions before using the device for the first time and keep these instructions in a safe place for future reference.

As a result of your efforts, you will be rewarded with a long service life and trouble-free operation of our product.

We hope you are pleased with our product.

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### **Explanation of symbols**

#### Test and identification symbols - VibraVest



TÜV symbol – tested medical product

**C€** 0197

Conformity symbol, medical product



Body floating (not earthed)



Direct voltage = DC



Alternating voltage = AC

### Test and identification symbols - Magic Power MPM-X50-12 power supply unit/charger



Not for outdoor use



TÜV Rheinland approval in accordance with EN60601-1 and IEC 60601-1



Communané Européenne (European Community). Directives governing electrical and electronic devices.



FCC is the USA test symbol for electromagnetic compatibility. It is issued by the Federal Communications Commission



USA test symbol (Recognised Component Mark), tested for Canadian and USA markets

#### Test and identification symbols - Sunny JGPB-1202500-NC battery pack



Recycling symbol



Electronic scrap - do not dispose of in household waste





Communané Européenne (European Community). Directives governing

electrical and electronic devices.



Attention! Read operating instructions before use!



Do not short-circuit!



Do not throw into fire!



Do not throw into water!

### Technical data

Nominal voltage: 12 V DC

Nominal power consumption: approx. 30 W

Power supply unit/charger: Model: MPM-X50-12

INPUT: 100-240 V AC / 50/60 Hz OUTPUT: 12 V DC / 4.17 A

Manufacturer: Magic Power Technology Co., Ltd.

Lithium polymer battery pack: JGBP-1202500-NC

OUTPUT: 12 V/2.5 Ah

Manufacturer: Sunny Computer Technology Co., Ltd.

Manufacturer: METEK GmbH

Stammweg 8

37327 Leinefelde-Worbis

Germany

Distributor: VibraCare GmbH

Holzweide 6 28307 Bremen Germany

Sizes: S (small) corresponds to the European size S

M (medium) corresponds to the European size M L (large) corresponds to the European size XL



#### **User information**

- In the interest of hygiene please use the VibraVest over clothing.
   Important: Not intended for use on more than one patient.
- Make sure that the VibraVest fits snugly with even body contact.
- There is no need to worry if you are disturbed while using your VibraVest. Your vest will interrupt
  all set functions after a programmed time and assume a safe standby state.
- In the case of contra-indications, it is advisable to consult your doctor before permanently
  wearing the oscillating/vibrating vest persons with electronic implants, pregnant women and
  nursing mothers as well as in all cases of acute illness, including
  - o fractures or pain in the upper part of the body
  - o recent surgical procedures on or acute injuries to the spinal column

### Purpose/method/application

Oscillating massage vest for the upper body to relieve internal stress, tenseness, promote circulation and blood flow through associated tissue, harmonise body and soul and to stimulate the lymphatic system.

Method: Oscillating massage (vibration)

Application: For back pain, tenseness and movement deficiency in upper body



## Starting the VibraVest in battery mode



<u>Attention</u>: The battery must be charged before start-up, see "User Information – Rechargeable Battery"

<u>Important</u>: The yellow INPUT jack on the battery is used solely for charging the battery.

### User information - rechargeable battery

- Only use the supplied rechargeable battery, type JGPB 1202500-NC to ensure safe and reliable operation of the product in battery mode. Only use the supplied charger MPM-X50-12 to charge the battery.
- The battery must be charged before using the vest for the first time. To charge the battery, connect it to the supplied charger/power supply unit (yellow mark on cable to yellow input jack, first open input jack with slide switch). The charging time is approx. 3 4 hours. The LED light on the battery turns green when the maximum charge is reached (avoid overcharging).
- When fully charged, the battery has the capacity for 3 4 applications of the vest at maximum intensity (the battery must be charged when the LED light turns red).
- When the battery has reached its maximum charge, disconnect it from the charger and connect it to the VibraVest. For this purpose, open the output jack on the battery.
- It is not recommended to start a new cycle if the LED light on the battery is red, as it cannot be guaranteed that there will be sufficient power to complete the cycle.

### Observe battery warning information

- Carefully remove the vest from the cardboard box and then take out of the polythene bag. Set the buckles to maximum size.
- Put on the vest and fasten all 5 buckles. Firmly pull the straps so that that the vest fits snugly on the body.
- Insert the supplied battery in its pocket in the vest (right-hand side) and connect it to the connection cable in the vest.
  - Attention: For this purpose open the battery slide switch, plug cable into blue OUTPUT jack in ON position.
- The flashing LED light on the hand-held controller indicates that the vest is ready for use. All functions are now available.
- Now select your programme DRAINAGE, VIBRATION or PERCUSSION. The vest will start to work about 1.5 seconds after selecting the programme.
- You can now choose the PROGRAMME and INTENSITY functions.







### Battery warning information

- Batteries must never be thrown into a fire or incinerated.
- The cells must not be immersed in liquids such as water, sea water or beverages. Contact with liquids must be avoided.
- Individual cells and batteries are not toys and must therefore be kept away from children. Keep batteries/cells out of the reach of small children. Keep batteries away from babies and toddlers.
- Batteries must not be placed in a microwave or subjected to pressure. They may combust resulting in smoke and fire.
- Battery packs must not be subjected to mechanical impact.
- Never dismantle a battery pack as this may cause internal short-circuits, resulting in gas emissions, fire and explosion or other problems.
- The electrolytes and electrolyte vapours contained in lithium polymer batteries are harmful to humans. Avoid direct contact with electrolytes. If, however, electrolyte comes in contact with the skin, eyes or other parts of the body, immediately flush or rinse with plenty of fresh water and seek medical assistance.
- To avoid total discharge always switch off the vest after use.
- · Always charge batteries in good time. Avoid overcharging.
- Store batteries on a non-combustible, heat resistance and non-conductive surface.
- Li-Po batteries that are totally discharged are defective and must no longer be used.
- Do not expose the battery pack to direct sunlight.
- The maximum permissible ambient temperature of the battery pack is 50 ℃.

## Starting in mains mode (with power supply unit) MPM-X50-12

- Connect the supplied adapter lead to the connection cable in the vest and the connection cable
  of the power supply unit (yellow lead to power supply unit cable, blue lead to connection cable in
  vest).
- Plug the mains power cable of the power supply unit into the socket.
- The flashing LED light on the hand-held controller indicates that the vest is ready for use. All functions are now available.
- Now select your programme DRAINAGE, VIBRATION or PERCUSSION. The vest will start to work about 1.5 seconds after selecting the programme.
- You can now choose the PROGRAMME and INTENSITY functions.

### Technology and design

- The VibraVest is packed with sophisticated features such as state-of-the-art technology and outstanding functionality. The attention to minute detail is reflected in superior quality.
- The safety aspect was of paramount importance in the design of the product. Consequently, the vest is equipped with following safety features:
  - > The motors of the vibration units are operated with safe, extra-low voltage
  - Protective fuse in the event of defective or malfunctioning motors
  - Timer operation
  - Battery operation
- A microprocessor control, with which input commands are assigned to the respective function via the membrane keypad, is at the core of the VibraVest.



#### **Buttons and functions**



After starting the programmes, the motors run through a "soft start" function (approx. 10 seconds) up to the set intensity level.

Programmes P1, P2 and P3 always start with SOFT intensity.

Note: The intensity automatically switches to SOFT when changing the programmes P1, P2 and P3. You can then freely select the intensity levels.

If the programme is not changed, the vest will switch off automatically after approx. 8 minutes. After each programme change, the new programme continues to run for approx. 8 minutes.

You can stop the application at any time by pressing the STOP button.



Note: The control will switch to standby about 7 minutes after the programme has switched off and all LED lights on the hand-held controller will go out.

All functions are available again after pressing any button.



The LED lights P1, P2 or P3 on the hand-held controller light up to indicate the currently active programme. The LED lights 1-5 show which massage zones are currently

The \*OFF\* LED light indicates

Constant flashing = VibraVest ready for operation

Continuous light

Selected massage programme active

### **Body zones**







Zone 1

Zone 2



### Test regulations for commercial/clinical use

## Technical inspection every 12 months

Check power consumption at following setting:

VIBRATION programme

Set intensity level to INTENSE: Target value: 30 – 35 watt

Max. permissible measured value/actual value: 35 watt



#### Safety information

The device is certified with the standard EN 60601 and corresponds to the Medical Devices Directive 93/42EEC:

The manufacturer, however, shall accept no liability whatsoever for any damage and/or consequential damage resulting from non-compliance with the following safety information:

- Repairs to electrical devices may only be carried out by authorised electricians or service dealers. Repairs not carried out professionally can place the user at considerable risk.
- The manufacturer shall not be liable for any damage as the result of the product being used for anything other than its intended purpose, operated incorrectly or not repaired professionally.
- The product may only be used with the power supply unit MPM-X50-12/rechargeable battery JGPB-120500-NC.
- The battery may only be charged with the supplied power supply unit/charger according to the
  instructions. The use of any other power supply units and chargers can lead to fire and electric
  shock. Overcharging must be avoided.
- Pay attention to the mains voltage ratings on the power supply unit. The device is designed for use with a mains voltage of 100-240 V AC, 1.5 A, 50-60 Hz. The ambient temperature range of the power supply unit/charger is 0 ℃ 50 ℃.
- The power plug of the power supply unit must always be disconnected from the socket in the event of malfunctions during operation, before cleaning/ upkeep procedures and after use.
- Never disconnect the power plug from the socket by pulling the cable or with wet hands.
- The power cable must never be pulled over sharp edges or trapped.
- Only the supplied power cables are to be used. If damaged, only replace by the same power cable that is available from the manufacturer.
- The use of any other power cable or charger can lead to fire or electric shock.
- Children and disabled persons must not use the vest without supervision.
- Do not use the product in damp environments such as in the bathroom or at a swimming pool.
- Do not puncture with sharp objects such as needles.
- The connection cables must never be used for the purpose of carrying the product.
- Depending on the amount of use, the outer material and cables of the product should be checked for damage from time to time.





## Guarantee of the battery pack

Every battery undergoes several tests and inspections during the manufacturing process. We are committed to ensuring the highest quality standards. The guarantee stipulates that we will repair free of charge proven material defects during the guarantee period. We reserve the right to replace the battery pack when a repair is not economically feasible. The receipt or bill that was issued on purchasing the product shall serve as proof for the start and expiration of this guarantee. Repairs shall not extend the warranty period. Incorrect use or operation, e.g. incorrect charging or excessively high discharge rates shall invalidate any guarantee claims. The same applies to defects caused by excessive loads or total discharge. Broader guarantee claims, e.g. in the event of consequential damage, are ruled out. The liability for damage that is caused by the battery pack or its use is also ruled out.

Guarantee claims must meet the following prerequisites:

- Enclose the purchase receipt/invoice with the return item.
- The battery pack must have been operated in accordance with these instructions for use.
- The battery pack must have been operated only at the voltage and current ratings specified in the technical data.
- · Include a detailed description of the fault or defect.



#### **Environmental protection**



This symbol on products and/or accompanying documents signifies that, at the end of their service life, electrical and electronic products must be disposed of separately from the household waste. To ensure these products are recycled effectively, deposit them at municipal collection points for recyclable materials where they will be accepted free of charge.

Correct disposal of products will help to protect the environment and avoid harmful effects for human beings and the environment that could arise from incorrect handling of devices at the end of their service life. You can obtain more detailed information at your nearest collection point for recyclable materials from your local authority.

Recycling instead of waste disposal: Devices, accessories and packaging should be recycled (only for electronic components)

#### Switching off

- Press the STOP button. All functions are interrupted and the flashing LED light indicates standby mode.
- Now disconnect the power plug or battery from the socket.

#### Cleaning and care

Never immerse the device in water. Use a moist cloth with a neutral detergent to clean the vest (make sure you do not soak the outer material). Do not rub too hard on the external labelling. The vest is not washable due to the integrated electronics.

#### Notes on disinfection, possible type of disinfection: wipe disinfection

#### Disinfectant: Dismozon pur supplied by Bode:

 You will find safety information, technical datasheets, mixing ratios corresponding to application profiles under www.bode-chemie.de

#### Standard application, wipe disinfection:

- Mixing ratio: 1 sachet (30 g) to 2 l of water makes a 1.5% solution

#### Disinfection time:

- Time to take effect is 30 minutes after wiping once, max. disinfection temperature: 40 ℃

### Care information

Disinfection resistant up to max. 40 °C

Disinfectant: Dismozon pur supplied by Bode

Mixing ratio: 1 sachet (30 g) to 2 l of water makes a 1.5% solution

Do not wash



Do not bleach



Do not tumble dry

X

Do not iron



Do not wet clean



# Troubleshooting

A problem may not necessarily be caused by the product. You can save time and money if you rectify simple problems yourself. The following information is designed to help you.

SYMPTOM	CAUSE	REMEDY
"OFF" LED light does not flash when vest is ready for operation	Plug connection of the connection cable and the power supply unit/battery is not connected	Plug in correctly
	Power plug of power supply unit is not plugged into socket or battery is not connected/charged	Plug in power plug     Plug in/charge battery
	The integrated fuse tripped due to a fault in the electronic control	Needs to be repaired by an authorised electrician or service dealer
	Power supply unit/battery defective	See above
	Power supply fuse defective or automatic circuit breaker tripped	Change power supply fuse or reset automatic circuit breaker
	Power failure	•
	Standby mode	Press any button on the hand-held controller
Massage function has suddenly switched off	The programmed time set on the timer has elapsed Battery discharged	Restart     Charge battery or switch to mains mode
Functions cannot be set or are not indicated by the corresponding LED light	Fault in the electronic control	Needs to be repaired by an authorised electrician or service dealer
Vibration units inoperative	Motor blocked	See above



# Electromagnetic guidelines for clinical applications

### T201

The <b>VibraVest</b> is intended for use in the electromagnetic environment specified below.  The customer or user of the <b>VibraVest</b> should ensure that it is used in such an environment.			
Emitted interference measurement	Conformity	Electromagnetic environment - guidelines	
RF emissions as per CISPR 11	Class B	The <b>VibraVest</b> is suitable for use in all establishments, including domestic, and those directly connected to the public power supply network that supplies buildings used for domestic purposes.	
Harmonic component emissions as per IEC 61000-3-2	Class A		
Voltage fluctuations/flicker emissions as per IEC 61000-3- 2	Compliant		

# T202

The VibraVest is intended for use in the electromagnetic environment specified below.				
The customer or user of the <b>VibraVest</b> should ensure that it is used in such an environment.				
Interference immunity tests	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines	
Electrostatic discharge (ESD) as per IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
Fast electrical transients/bursts as per IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.	
Surge voltajes (surge) as per IEC 61000-4-5	±1 kV normal-mode voltage ±2 kV common mode voltage	±1 kV normal- mode voltage ±2 kV common mode voltage	Mains power quality should be that of a typical commercial or hospital environment.	
Voltage dips, short- term interruptions and fluctuations in supply voltage as per IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VibraVest requires continued operation during interruptions in the power supply, it is recommended that the VibraVest be powered from an uninterruptible power supply or a battery.	
Power frequency (50 Hz) magnetic field as per IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a location in a commercial or hospital environment.	
Note: UT is the mains AC voltage prior to application of the test level.				



#### T204

Interferen ce immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment - guidelines
			Portable and mobile RF communications equipment should be used no closer to any part of the VibraVest, including the cables, than the recommended distance calculated from the equation applicable to the transmit frequency.  Recommended distance:  d = 1.2 m P
Conducted RF interference as per IEC 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz	3 V <sub>rms</sub>	
Radiated RF interference as per IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 m P for 80 MHz to 800 MHz d = 2.3 m P for 800 MHz to 2.5 GHz  where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended distance in metres (m). The field strength of fixed RF transmitters, as determine by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup> . Interference may occur in the vicinity of equipment marked with the following symbol.

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

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

b. The field strength should be less than 3 V/m over the frequency range from 150 kHz to 80 MHz.

The field strength from fixed transmitters, such as base stations for radio telephones and mobile terrestrial radio equipment, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in terms of fixed RF transmitters an electromagnetic site survey should be considered. If the measured field strength in the location in which the **VibraVest** is used exceeds the applicable compliance level specified above, the **VibraVest** should be observed to verify normal operation. If abnormal performance features are observed, additional measures may be necessary, such as re-orienting or relocating the **VibraVest**.



#### T206

Recommended distances between portable and mobile RF telecommunications equipment and the **VibraVest**.

The **VibraVest** is intended for use in an electromagnetic environment, in which RF interference is controlled. The customer or user of the **VibraVest** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the **VibraVest** as recommended below – dependent on the maximum output power of the communications equipment.

Nominal transmitter output W	Distance dependent on transmit frequency m		
	150 kHz to 80 MHz d = 1.2 m P	80 MHz to 800 MHz d = 1.2 m P	800 MHz to 2.5 GHz d = 2.3 m P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The recommended distance d in metres (m) for transmitters with a maximum nominal output not specified in the table above can be calculated using the equation applicable to the transmitter frequency (in the specific column in the table), where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

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