User Manual

FOR MODEL # LRM36

Comfort Zone

LATERAL ROTATING MATTRESS

Alternating Pressure with Low Air Loss

MADE IN CHINA

INDEX

Class I Medical Device
according to Directive 93/42/EEC
and further modifications

MODEL # & DESCRIPTION

LRM36 (36” WIDE)

COMFORT ZONE LATERAL ROTATING MATTRESS -
ALTERNATING PRESSURE AND LOW AIR LOSS SYSTEM MATTRESS WITH PUMP

INTRODUCTION

Thank you for purchasing the MedaCure Comfort Zone Lateral Rotating Mattress System.
This user’s manual provides suggestions on how to correctly use the product and gives valuable advice regarding your safety. Please read through the manual carefully before using the product.
Should you have any questions, please contact your dealer for advice and assistance.

INTENDED USE

The Comfort Zone Mattress is designed for bed sore and wound care therapy treatment and prevention, which may occur during an extended hospital stay and nursing home /long term care environment.

- **CAUTION!**
- • Do not use the product for any purpose not indicated in this manual.
- • Only qualified personnel trained in the treatment and prevention of bedsores should operate this device.
- • MedaCure Inc. declines all liability for any consequences resulting from incorrect use of this product and from unauthorized alteration to the frame of the product.
- • The manufacturer reserves the right to change the information contained in this document without prior notice

STANDARDS

The system has been tested and successfully approved to the following standards: EN 60601-1
EN 60601-1-2

GENERAL WARNINGS

Keep this manual in a safe place and refer to the manual before use and under proper medical supervision. Improper operation of this system may cause damage to the product and possible injury to the user.

1. Do not use this product or any available optional equipment without first completely reading and understanding this instruction manual. If you are unable to understand the warnings, cautions or instructions, please contact a healthcare professional, dealer or authorized technician before attempting to use this equipment, otherwise injury or damage may occur.
2. Consult with physician or therapist to determine the correct adjustment and the correct use of this device.
3. Keep the packed kit away from heat sources.
4. SERVICE LIFE - the device use limit is defined by the wear of the parts.
5. Do not allow children to play with or operate the pump or mattress.

SYMBOLS


Caution

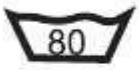

Medical Devices Directive 93/42/EEC


Electrical Protection Type B


Class II Equipment(Double Insulated)


Do not iron


compatible with any dry cleaning methods



No more than 80 degree wash


Do not bleach


Tumble dry with low heat


The marking of electrical and electronics devices according to Directive 2002/96/EC.
The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage.
Please follow Local Ordinances or Regulations for disposal.

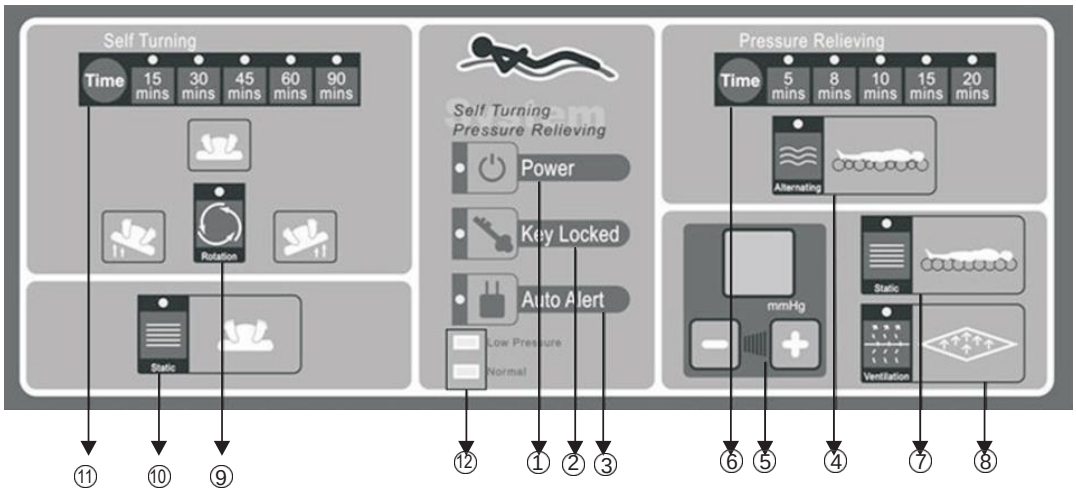

Date of manufacture


Refer to manual before use

GENERAL DESCRIPTION

Mattress and Pump

Controls and Features



Main Control Panel

① Power Switch

When the LED is lit the power is on

② Key Locked

Press and hold for 3 seconds to lock all functions except "Power", "Key Locked" and "Auto Alert".
Please note: for patients safety all functions are automatically locked after 5 mins.
To disable press and hold the button for 3 seconds.

③ Auto Alert / Mute

Press “Auto Alert” to mute the "low pressure and "power failure" audible alarm.
The LED will illuminate when in "Auto Alert" mode.

⑫ Low Pressure/Normal

When the pressure is low the "Low Pressure" LED will illuminate in RED.
When the presure is normal the "Normal" LED will illuminate in GREEN.

Alternating Pressure Function

④ *Alternating*

When the LED is lit the mattress is operating in “Alternating” mode

⑤ *Pressure Adjustment*

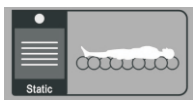
Incrementally adjusts overall pressure within the patient's therapeutic range from 30mmHg - 60mmHg.

⑥ *Cycle Time(Alternating)*

Adjust the "Alternating" cycle time for 5, 8, 10,15 and 20 minutes

⑦ *Static (Alternating)*

When the LED is lit the mattress is in “Static” mode
The mattress remains static and the cells do not alternate



⑧ *Ventilation*

When the LED is lit the “Ventilation” or Low Air Loss function is operating.

Self Turning or Lateral Rotation Function

⑨ Rotation

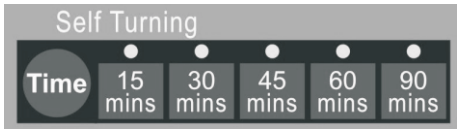
When the LED is lit the “Rotation” function is on.
1 Full Cycle equals Right turn and Left turn.

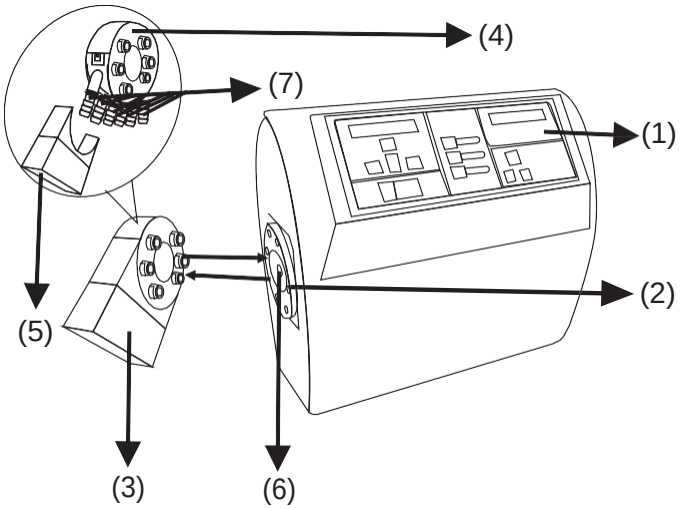
⑩ Static (Self Turning)

When the LED is lit the mattress is in “Static” mode.
The mattress remains static and the cells do not alternate.

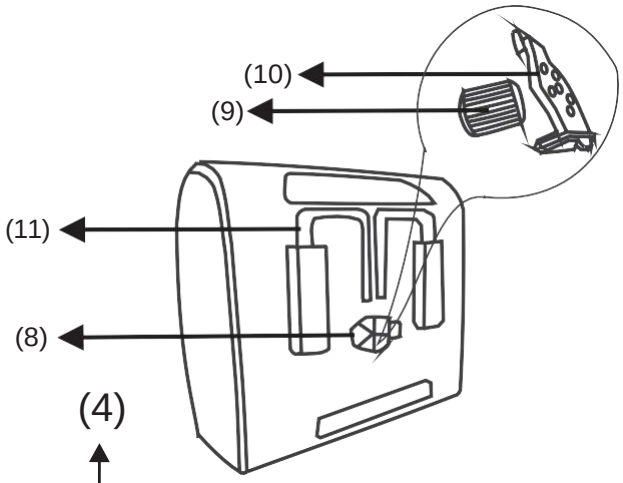
⑪ Cycle Time (Self Turning / Rotation)

Adjust the "Self Turning" / Rotation cycle time for 15, 30, 45, 60 and 90 minutes

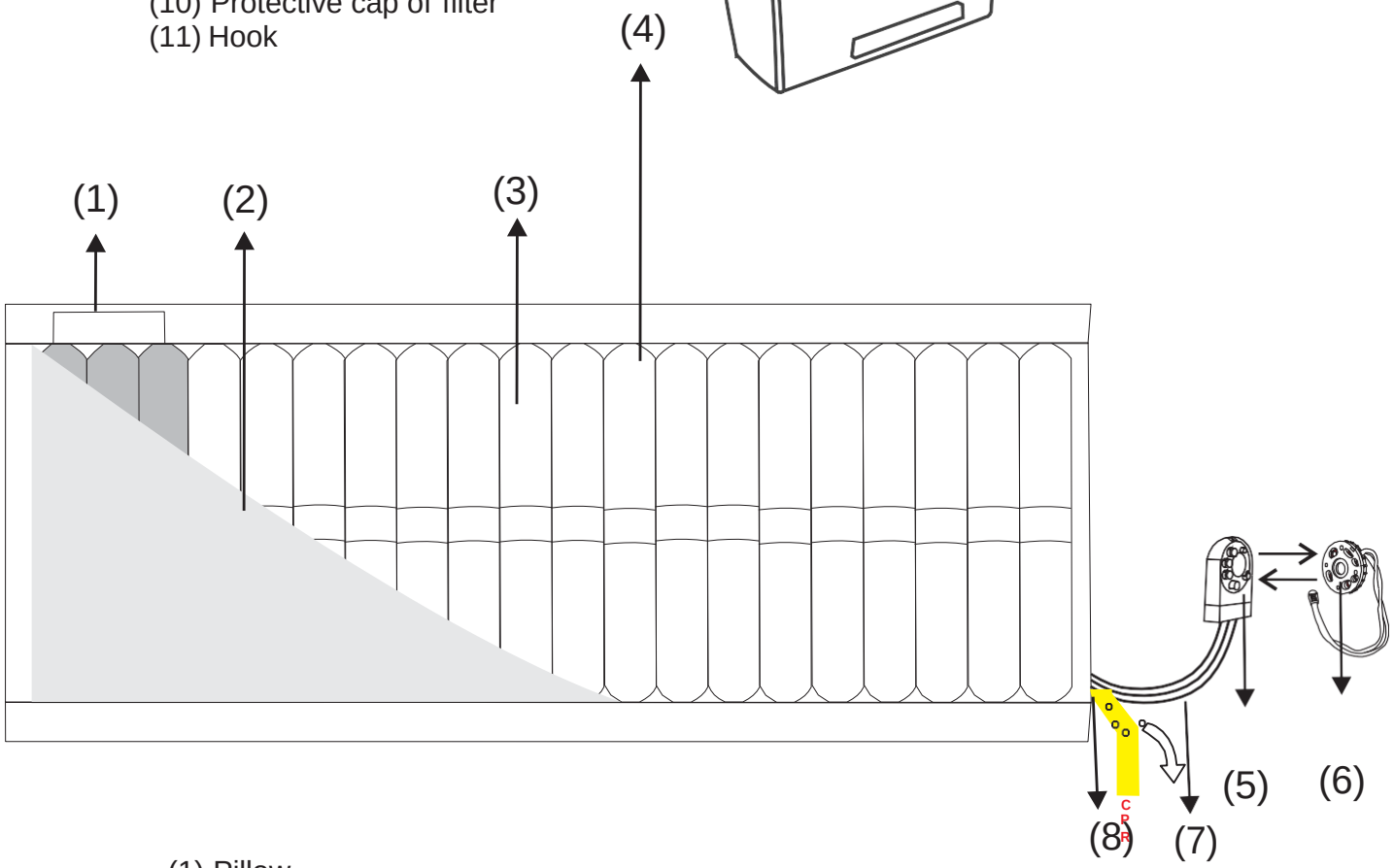




Front
(1) Control panel
(2) Female quick connector
(3) Male quick connector
(4) Main male quick connector
(5) Protective cap of connector
(6) Fuse
(7) Sealing ring



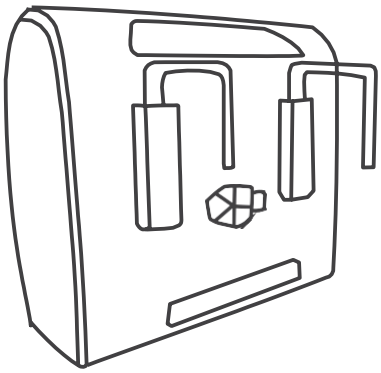
Back
(8) Filter
(9) Main filter
(10) Protective cap of filter
(11) Hook

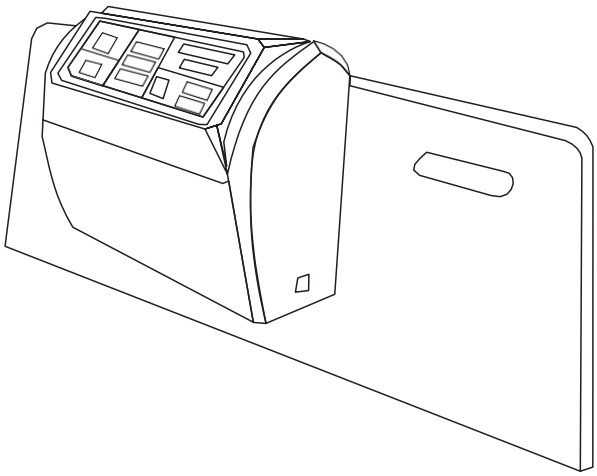


(1) Pillow
(2) Cover
(3) Fixing belt
(4) Low air loss
(5) Male quick connector
(6) Protective cap of connector
(7) Air tubing
(8) CPR

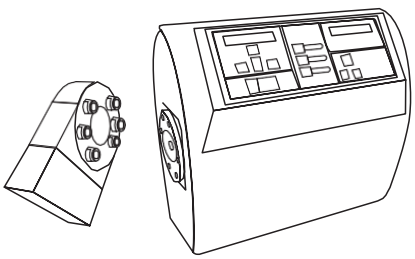
INSTALLATION

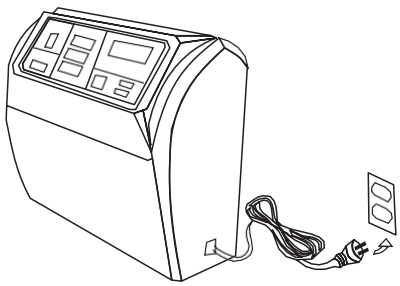
1. Comfort Zone is a replacement mattress. Place the mattress directly on the bed frame, with the air hose connectors positioned at the footboard.
2. Hang the pump over the foot board using the hooks on back of the pump, or place it on a flat surface.

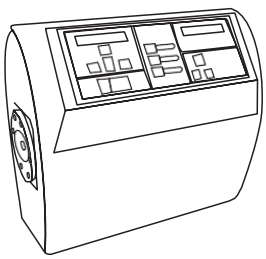




3. Connect air hose connectors from air mattress to the pump unit. Ensure the air hoses are not kinked or tucked under mattress.
4. Plug the power cord into the electrical outlet.
5. Turn the switch ON.







WARNING!
- Make sure the pump unit is suitable for the local power voltage.
- Do not position the equipment so it is difficult to disconnect the plug.

BEFORE USE

Check the correct assembly, paying particular attention to air hoses connector.

USER WARNINGS

1. Electric shock - Avoid electric shock
It is very dangerous to use electric products improperly or damaged ones. 1) Unplug the pump control unit if you will not use it for a long time.
2) Do not use the pump control unit near water or any other fluid.
3) Avoid having the cable, plug and main control unit being in contact with water or any other fluid.
4) Unplug the pump control unit if or when it is in contact with water or other fluid.
Do not open the control unit by yourself. This should only be done by an authorized technician.

2. Safe Place

1) Avoid damaging the plug or cables when moving the patient or bed.
2) Ensure that the cables are safe and tidy and not caught in the bed mechanism or resting on the floor.
3) Keep sharp objects or strong acid and alkali chemical agents away from the mattress.
4) Fuse will blow to protect the device when electric short circuit is caused by the current loading.

3. Cautions - Keep the system away from fire, avoid electric shock or any danger that will cause injury to the user.

1) Only use the system under the supervision of a nurse or caregiver that understands how to operate this device.
2) Do not use any parts that did not come with this unit or supplied by MedaCure or authorized dealer.
3) Ensure that the mattress, cover, cables and power outlet are not in contact with fire, heat or strong acid and alkali chemical agents.
4) Do not modify the pump and mattress without authorization of the manufacturer and do not insert objects into the control unit or mattress.
6) Please plug the control unit into the ground power supply.
7) Do not use the product in case of the following:
   1. the plug or the cable is damaged.
   2. the system sounds abnormal or vibrates intensely.
   3. the control unit fell on the floor and caused damaged to the housing
   4. the control unit fell into water or other fluid.

HOW TO USE

Patient Weight	Pressure
up to 110 lbs.	30 - 33 mmHg
110 – 145 lbs.	33 - 36 mmHg
145 – 175 lbs.	36 - 39 mmHg
175 – 210 lbs.	39 - 42 mmHg
210 – 240 lbs.	42 - 45 mmHg
240 – 275 lbs.	45 - 48 mmHg
275 – 310 lbs.	48 - 51 mmHg
310 - 350 lbs.	51 - 54 mmHg
350 - 400 lbs.	54 - 57 mmHg
400 - 450 lbs.	57 - 60 mmHg

NOTE
In case the pressure is constantly low, check for any holes on the interchangeable air cells or on the connection tubes. If necessary, contact your dealer to exchange the air cells or connection tubes/hoses.

If a rapid deflation is necessary, unplug the connection tube from the mattress.

STORAGE

1) Switch off power from main and unplug, separate the pump from the mattress and place the mattress flat.
2) Fold the mattress in two from mattress foot to head.
3) Allow time for air to escape from mattress to reduce storage space.
4) Close the protective cap cover on the quick connector.

MAINTENANCE

In case of repair, use only original spare parts and accessories.

CLEANING AND DISINFECTION

WARNING!
Unplug the pump before starting the cleaning procedure.

1. Clean the mattress with mild soap.
2. Do not immerse or soak pump unit.
3. After cleaning, dry the mattress without direct sunlight
4. Check that the connection tubes are not obstructed by dust or other object. Use a soft swab to clean the tubes if necessary.

NOTE Never use acids, alkalis or solvents such as acetone to clean the mattress

CONDITIONS OF DISPOSAL
General conditions of disposal

Dispose the device in the appropriate disposal areas for recycling.
At the end of its life, the products must not be disposed of along with other domestic waste.
Dispose this equipment by bringing it to a specific recycling point for electric and electronic equipment or others that provide this service.

SPARE PARTS/ACCESSORIES

For spare parts and accessories refer to main catalogue.

TROUBLESHOOTING

If your questions can't be answered with the information below, please contact your local agent directly. They might require a technician to take care of the problem.

No Lights on Pump Unit	Check that the control unit is connected to the mains power supply and that the unit is switched on. Check thr quick blow fuse on the control unit or mains plug fuse.
Low pressure alert	Check the main power to the control unit and that the plug is well connected. Check that mattress air supply connector is connected to the pump securely and correctly. Check that the CPR connector is connected securely and properly. Under the mattress cover check that all "T" & "L" connectors are connected to the air tubes. Check the connector tubes for kinks, crimps or damage.
Patient's body is sagging in the middle/ bottoming out	Increase the value of the comfort setting. Wait a couple of minutes so pressure can stabilize before making another change.
Control lock up or "freeze"	Turn the control unit off and unplug the pump. Wait a few minutes and plug the control unit back in. Turn on the control unit.

ELECTROMAGNETIC COMPATIBILITY DECLARATION

Guidance and manufacturer's declaration-electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The device 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 device 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	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

ELECTROMAGNETIC COMPATIBILITY DECLARATION

Guidance and manufacturer's declaration-electromagnetic immunity The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV differential mode ± 2kV differential	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% 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 device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The device power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

ELECTROMAGNETIC COMPATIBILITY DECLARATION

The Comfort Zone is intended for use in the electromagnetic environment specified below.

The customer or the user of the Comfort Zone should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Comfort Zone including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz 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 separation distance in meters (m). (a) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a 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 Comfort Zone is used exceeds the applicable RF compliance level above, the Comfort Zone should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Comfort Zone

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

ELECTROMAGNETIC COMPATIBILITY DECLARATION

Recommended separation distance between portable and mobile RF communications equipment and the Comfort Zone

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

Rated maximum Output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

TECHNICAL FEATURES

Pump Control Unit

FEATURE	PUMP
Power supply	120V/60Hz, 230V/50Hz
Power	18W
Fuse rating	500mA/250V
Pressure	30mmhg~60mmhg
Dimensions	11.4” (L) x 12.2” (W) x 6” (H)
Weight	8.6 lbs.
Environment temperature	Operation: +10° C /+40° C Storage: -15° C /+50° C Shipping: -15° C /+70° C
Environment humidity	Operation:10%-90% non-condensing Storage:10%-90% non-condensing Shipping:10%-90% non-condensing
Atmospheric Pressure	Operation: 700-1013,25 hPa

Mattress

FEATURE	MATTRESS
Dimensions	80” × 36” × 10”
Cell height(inflated)	8”
Air cell material	TPU
Cover material	PU
Elements number	21 cells
Max weight	450 lbs.
Weight	29 lbs.

MEDACURE LIMITED WARRANTY

MEDACURE LIMITED WARRANTY

This warranty is extended only to the original purchaser who purchases this product when new and unused from MedaCure or a dealer. This warranty is not extended to any other person or entity and is not transferable or assignable to any subsequent purchaser or owner. Coverage under this warranty will end upon any such subsequent sale or other transfer of title to any other person.

This warranty gives you specific legal rights and you may also have other legal rights which vary from state to state.

MedaCure warrants the mattress and cover when purchased new and unused to be free from defects in materials and workmanship for a period of one (1) year from the date of purchase from MedaCure or a dealer, with a copy of the seller's invoice required for coverage under this warranty. MedaCure warrants the control unit when purchased new and unused to be free from defects in materials and workmanship for a period of one (1) year from the date of purchase from MedaCure or a dealer, with a copy of the seller's invoice required for coverage under this warranty. If within such warranty period any such product shall be proven to be defective, such product shall be repaired or replaced, at MedaCure's option. This warranty does not include any labor or shipping charges incurred in replacement part installation or repair of any such product. MedaCure's sole obligation and your exclusive remedy under this warranty shall be limited to such repair and/or replacement.

For warranty service, please contact the dealer from whom you purchased your MedaCure product or MedaCure customer service only if purchased from MedaCure direct. Provide model number, and the date of purchase, indicate nature of the defect and, if the product is serialized, indicate the serial number.

DO NOT return products to MedaCure without prior consent. Please obtain a return authorization number from MedaCure. C.O.D. shipments will be refused; return shipping charges must be prepaid. The defective unit or parts must be returned for warranty inspection using the serial number, when applicable, as identification within thirty days of return authorization date.

LIMITATIONS AND EXCLUSIONS: THE WARRANTY SHALL NOT APPLY TO PROBLEMS ARISING FROM NORMAL WEAR OR FAILURE TO ADHERE TO THE INSTRUCTION MANUAL THAT COMES WITH THE PRODUCT. IN ADDITION, THE FOREGOING WARRANTY SHALL NOT APPLY TO SERIAL NUMBERED PRODUCTS IF THE SERIAL NUMBER HAS BEEN REMOVED OR DEFACED; PRODUCTS SUBJECTED TO NEGLIGENCE, ACCIDENT, IMPROPER OPERATION, MAINTENANCE OR STORAGE; OR PRODUCTS MODIFIED WITHOUT MEDACURE'S EXPRESS WRITTEN CONSENT INCLUDING, BUT NOT LIMITED TO: MODIFICATION THROUGH THE USE OF UNAUTHORIZED PARTS OR ATTACHMENTS: PRODUCTS DAMAGED BY REASON OF REPAIRS MADE TO ANY COMPONENT WITHOUT THE SPECIFIC CONSENT OF MEDACURE; PRODUCTS DAMAGED BY CIRCUMSTANCES BEYOND MEDACURE'S CONTROL; PRODUCTS REPAIRED BY ANYONE OTHER THAN AN MEDACURE DEALER, SUCH EVALUATION SHALL BE SOLELY DETERMINED BY MEDACURE.

THE FOREGOING EXPRESS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND THE SOLE REMEDY FOR VIOLATIONS OF ANY WARRANTY WHATSOEVER, SHALL BE LIMITED TO REPAIR OR REPLACEMENT OF THE DEFECTIVE PRODUCT PURSUANT TO THE TERMS CONTAINED HEREIN. THE APPLICATION OF ANY IMPLIED WARRANTY WHATSOEVER SHALL NOT EXTEND BEYOND THE DURATION OF THE EXPRESS WARRANTY PROVIDED HEREIN. MEDACURE SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES WHATSOEVER.

THIS WARRANTY SHALL BE EXTENDED TO COMPLY WITH STATE/PROVINCIAL LAWS AND REQUIREMENTS