User Manual

FOR MODEL # CZ42 & CZ48 & CZ42-BIP & CZ48-BIP

10” REPLACEMENT CELL-ON-CELL MATTRESS

Comfort Zone

Bariatric Alternating Pressure with Low Air Loss

MedaCure

MADE IN CHINA

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

MODEL # & DESCRIPTION

CZ42 (42” WIDTH) & CZ48 (48” WIDTH) MATTRESS & PUMP – BARIATRIC WIDTH WITH 10” CELL-ON-CELL HEIGHT

INTRODUCTION

Thank you for purchasing the Comfort Zone Bariatric Mattress with Alternating Pressure and Low Air Loss by MedaCure. 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 60601-1-1-2

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


Do not bleach


Medical Devices Directive 93/42/EEC


Tumble dry with low heat


Electrical Protection Type B


The marking of electrical and electronics devices according to Directive 2002/96/EC. The device, accessories and the packaging must be disposed of correctly at the end of the usage. Please follow local ordinances or regulations for disposal.


Class II Equipment (Double Insulated)


Do not iron


Date of manufacture

Compatible with any dry cleaning method

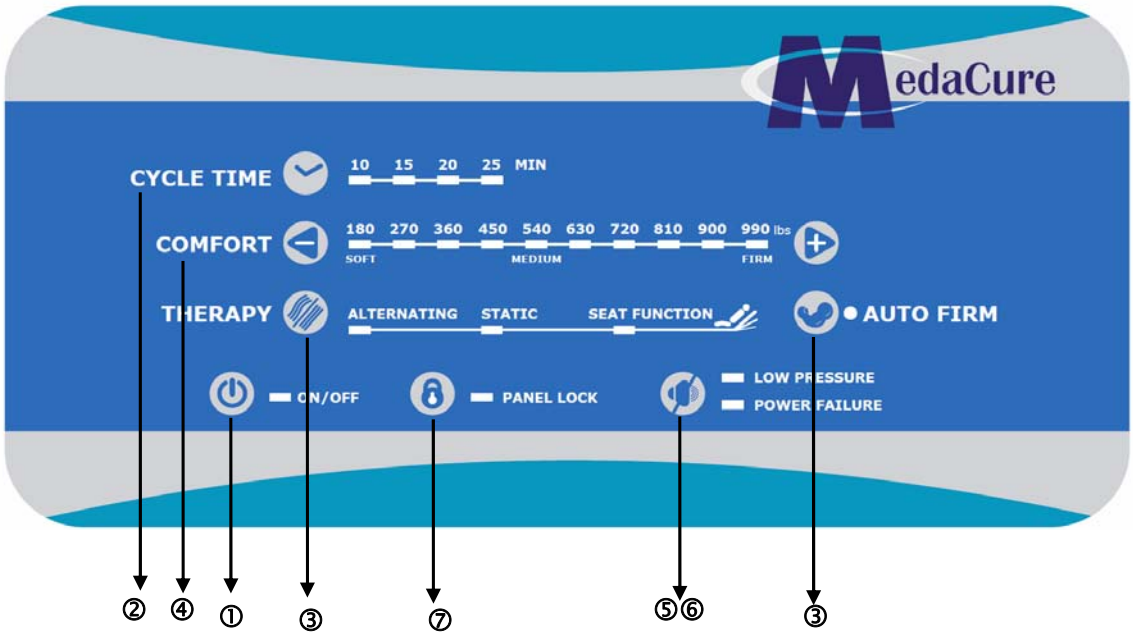
No more than 80 degree wash


Refer to manual before use

GENERAL DESCRIPTION

Pump and Mattress

Controls and Features



Main Control Panel

① POWER SWITCH 

When LED is illuminated the power is on.

② CYCLE TIME 

Adjust the cycle time from 10,15, 20 and 25 minutes for “Alternating” cell function.

③ THERAPY/AUTO FIRM 

a. AUTOFIRM: Quickly inflates mattress to maximum firmness.
b. ALTERNATING: Normal alternating function.
c. STATIC: Does not alternate & keeps mattress always inflating.
d. SEAT FUNCTION: If there is a situation of seat up.

④ COMFORT 

To increase or decrease airflow for a softer or firmer setting between 1 to 10 range.

⑤ LOW PRESSURE 

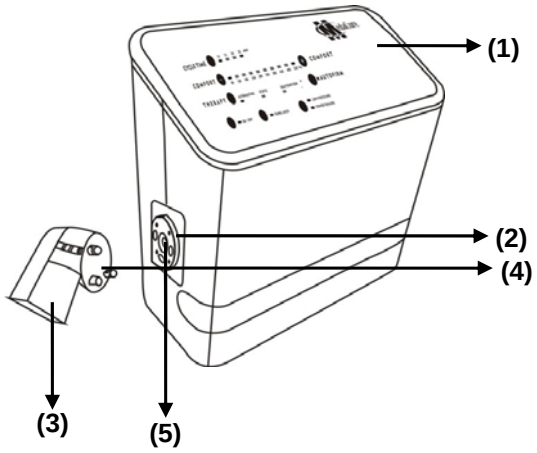
Low Pressure light will illuminate and alarm sounds when the pressure is below the preset level. Reset system.

⑥ POWER FAILURE 

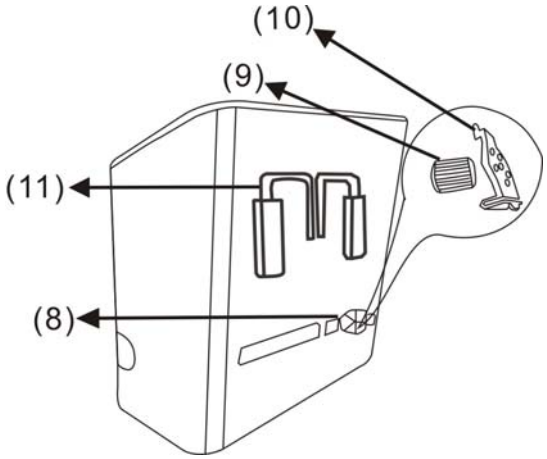
Mutes the audible alarm when LED turns off.

⑦ PANEL LOCK 

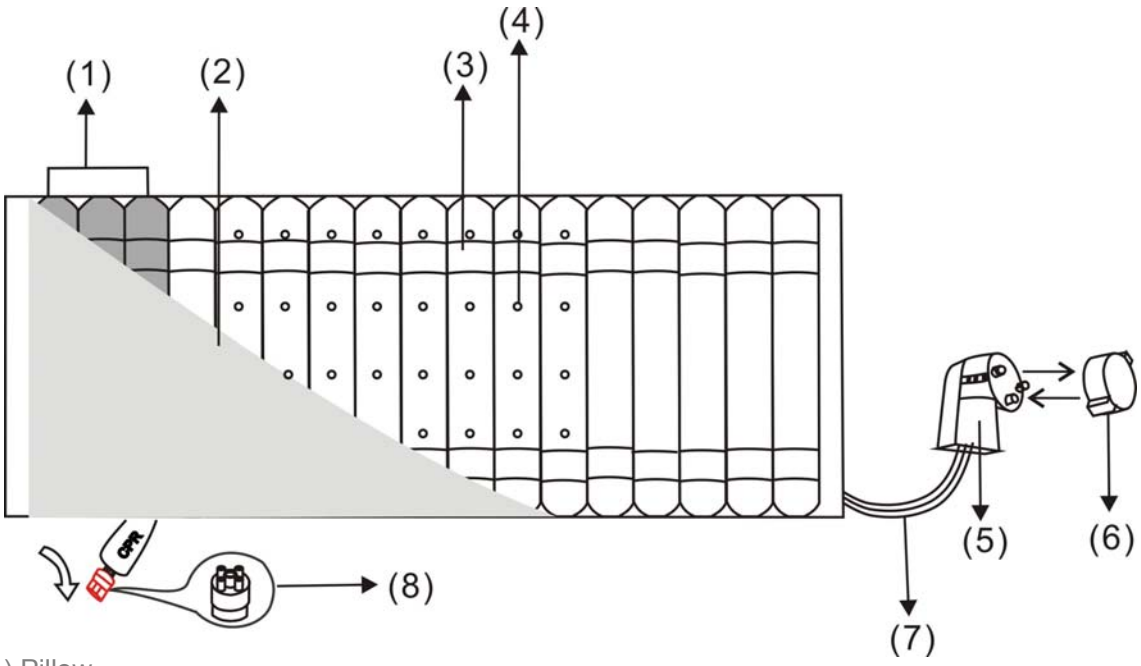
Locks all functions* automatically after 5 mins.
To disable, press and hold the button for 3 sec.
* Except “Power”, “Low Pressure” and “Alarm Off” function.



Front
(1) Control panel
(2) Female quick connector
(3) Male quick connector
(4) Main male quick connector
(5) Fuse



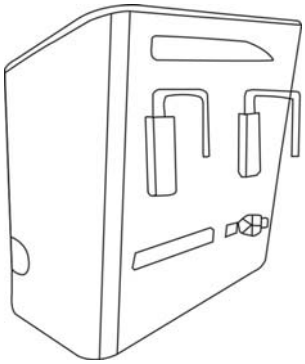
Back
(8) Filter
(9) Main filter
(10) Protective cap of filter
(11) Hook

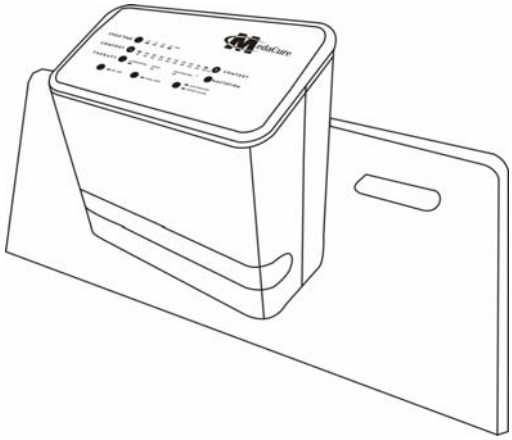


(1) Pillow
(2) Cover
(3) Fixing belt
(4) Low air loss holes
(5) Male quick connector
(6) Protective cap of connector
(7) Air tubing
(8) Patented Quick Inflation CPR
(to be used with the included Inflator)
& Emergency CPR Quick Deflator

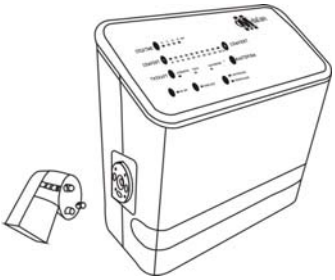
INSTALLATION

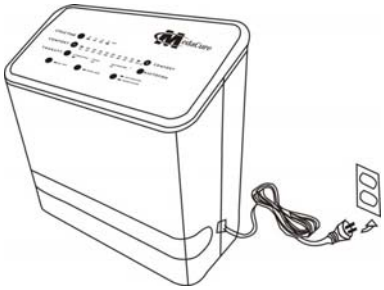
1.Comfort Zone is a replacement mattress. Place the mattress directly on the bed frame, with the air hose connectors positioned at the footboard.
2.Hang the pump onto the bed board (footboard side) using the hooks on back of the pump, or place it on a flat surface.

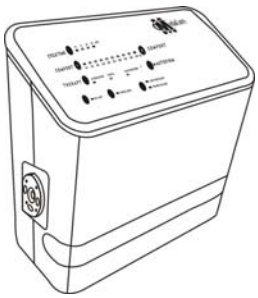




3.Connect air hose connectors from air mattress to the pump unit. Ensure the air hoses are not kinked or tucked under the mattress.
4.Plug the power cord into the electrical outlet.
5.Turn the power ON.







WARNING!

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

MATTRESS & COVER

The mattress is a 10” cell-on-cell type mattress which prevents bottoming out in case of a sudden power outage.
The mattress will temporarily retain air even when the pump is turned off or during a power outage.
Please note this only temporary.

The cover sheet protects the cells against unexpected contamination, and makes cleaning of the mattress easier.

BEFORE USE

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

USE 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

Position on the Pressure knob	Weight	Pressure
1	180 LBS	20~24mmHg
2	180~270 LBS	24~28mmHg
3	270~360 LBS	28~32mmHg
4	360~450 LBS	32~36mmHg
5	450~540 LBS	36~40mmHg
6	540~630 LBS	40~44mmHg
7	630~720 LBS	44~48mmHg
8	720~810 LBS	48~52mmHg
9	810~900 LBS	52~56mmHg
10	900~990 LBS	56~60mmHg

NOTE

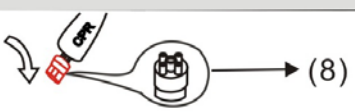
In case the pressure is constantly low, check for any holes on the interchangeable air cells or on the connection tubes. If necessary, contact your dealer to exchange the air cells or connection tubes/hoses.

HOW TO USE THE CPR DEFLATOR & INFLATOR

In case of emergency and/or if rapid deflation is necessary, rotate the CPR valve to deflate, as noted below:

CPR Deflator –
How to deflate the mattress using the CPR valve

1) Connect the CPR to the mattress - Connect the 3 prongs on the CPR Valve to the CPR hose on the mattress.
Leave the CPR Valve connected to hose in case of future use.



2) Pull down tab to open the valve as shown.

IMPORTANT:
Always keep this tab in the closed position when mattress is in use to prevent deflating.

3) Turn the CPR as show to open the valve for deflating.

4) Align the air holes as shown to deflate.

CPR Inflator –
How to quickly inflate the mattress using the CPR valve & Quick Inflate Pump

1) This mattress includes a Quick Inflate Pump and nozzle attachment.

2) Attach the nozzle to the pump as shown.

3) Align the air holes on the CPR.
Insert the Quick Inflate Pump into the CPR Valve.
Turn on the Pump.
The mattress will rapidly inflate in around 7 – 8 minutes

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 exposure.
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 please contact MedaCure or authorized dealer.

TROUBLESHOOTING

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

No lights on unit	Check control unit is connect to the mains power supply and that the unit is switched on. Check quick blow fuse on the control unit or mains plug fuse.
Low pressure alert	Check main power to the control unit and that the plug is switched. Check mattress air supply connector is connected to the pump unit correctly. Check CPR connector is connected properly. Under the mattress cover check 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 comfort level 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 on. 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

Guidance and manufacturer's declaration-electromagnetic immunity			
The CZ42 & CZ48 is intended for use in the electromagnetic environment specified below. The customer or the user of the CZ42 & CZ48 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 CZ42 & CZ4800 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d = 1,2 √*P* d = 1,2 √*P* 80MHz to 800 MHz d = 2,3 √*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 CZ42 & CZ48 is used exceeds the applicable RF compliance level above, the CZ42 & CZ48 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CZ42 & CZ48 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 CZ42 & CZ48

The CZ42 & CZ48 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of theCZ42 & CZ48 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CZ42 & CZ48 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
Power	12.0W
Fuse rating	1A/250V
Pressure	20mmhg~60mmhg
Dimensions	12 ½" (W) x 12" (L) x 6" (H)
Cycle	10/15/20/25mins
Weight	9 lbs.
Environment temperature	Operation:+10□/+40□ Storage:-15□/+50□ Shipping:-15□/+70□
Environment humidity	Operation:10%-90% non-condensing Storage:10%-90% non-condensing Shipping:10%-90% non-condensing
Atmospheric Pressure	Operation:700-1013,25hPa

Mattress

FEATURE	MATTRESS
Dimensions	80" (L) x 42" (W) x 10" (H) 80" (L) x 48" (W) x 10" (H)
Cell height(inflated)	10"
Air cell material	Nylon/TPU
Cover material	PU + Fiber Quilting
Elements number	20 cells
Max weight	1000 lbs.
Weight	25 lbs.

APPENDIX---

BUILT-IN AIR PERIMETER MATTRESS

MODEL # CZ42-BIP & CZ48-BIP

THESE MODELS COME WITH A BUILT-IN AIR PERIMETER
PLEASE CHECK THE BACK OF THE PUMP FOR CORRECT MODEL NUMBER.

The built in air perimeters are located on both the left & right side of the mattress. This prevents the patient's arms and legs from getting caught in between the air mattress and side rail. It also acts as an aid to prevent the patient from falling out of bed.

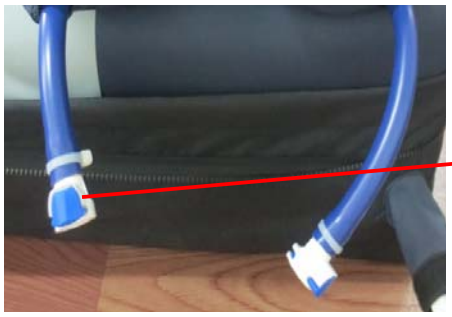
Please note however that the perimeter is not intended to be a guaranteed protection against falling. Patient must be under the constant watch of a caregiver to monitor the patient's movements.

When the patient needs to transfer out of bed, each side can be deflated individually to allow the patient easy access. To deflate the air perimeter, simply slide open the cover and disconnect the air tubes. Each side can be deflated independently and inflated again when you re-connect the air tube.

HOW TO INFLATE & DEFLATE THE SIDE AIR PERIMETERS:

Connect the tubes to inflate the perimeter
Disconnect to deflate the perimeter
Tubes are located at the head and foot of the mattress

Cover the tubes with the integrated cover when connected to protect the tubes



Press on the blue tab to disconnect the tubes

MADE IN CHINA