# **User's Manual**

# Compressible Limb and Circulation Therapy System Model: POWER RECOVERY





Wonjin Mulsan Co., Ltd. www.wonjininc.net

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## **1. General Information**

## **1.1 Specification**

Technical Requirement of product			
Product Name	Compressible Limb and Circulation Therapy System		
Model Name	POWER RECOVERY		
Dimensions	141(W) X 245(W) X 114(H) (mm)		
Power Supply	100V~240V~, 50/60Hz, 1.0A		
Power Consumption	50W		
Time (Selectable)	15 minutes ~ 2 hours		
Maximum Pressure	150mmHg±20%		
Battery Charging Time	About 4 hours		
Battery Use Time	About 2 hours		
Weight(Main Body)	2 kg		

#### **1.2 Classification**

Classification	
Type of protection against electric shock	Class II and Internally powered equipment
Degree of protection against electric shock	Type BF applied part 🗼
Degree of protection against ingress of water	IP21
Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable
Mode of operation	Continuous operation

#### 1.3 Intended patient population

- a) Age: 18 years old or greater
- b) Weight: 40 kg or greater
- c) Health: limitation to the people mentioned in contraindication of user manual
- d) Nationality: multiple
- e) PATIENT state:
  - PATIENT is USER: alert, mentally competent (The patient is an intended operator.)
  - PATIENT is not USER: not relevant, unless PATIENT is agitated

#### 1.4 Part of the body or type of tissue applied to or interacted with

- a) Part of the body: Leg, Arm, and Hip
- b) Type of tissue: Skin

#### 1.5 Intended User

- a) Education:
  - at least 18 years old at least 10 years intensive reading experience (school)
  - no maximum

- b) Knowledge:
  - minimum:
    - read and understand how to operate the device
    - can distinguish: leg, arm, and hip
    - understands hygiene
  - no maximum
- c) Language understanding:
  - understand user manual which is described in English
- d) Experience:
  - minimum:
    - laypersons
    - other: no special experience needed
  - no maximum
- e) Permissible impairments:
  - mild reading vision impairment or vision corrected to log MAR 0.2 (6/10 or 20/32)
  - impaired by 40% resulting in 60% of normal hearing at 500Hz to 2kHz

## 1.6 User environment

- a) Environment
  - General: Home environment, Indoor
  - Physical: Refer to environmental conditions of 6. Maintenance.
- b) Frequency of use
  - It is recommended to use up to 30 min / 1 time and 3 times / 1 day.
- c) Mobility
  - Transportable equipment

## 1.7 Frequently used functions

User Interface	Frequently Used functions		
Connecting/Disconnecting	Connecting the cuff and air hose to main unit for operation		
the cuff and air hose	Disconnecting the cuff and air hose from main unit after use		
Putting on/Taking off	Putting on the cuff for operation		
the cuff	Taking off the cuff after use		
Switching on/off the	Switching on the power for operation		
power	Switching off the power after use		
Setting operational mode	Setting cuff mode (Leg, Arm, and Hip), operation mode (Sequential, Wave, Recovery, Addition, and Massage), pressure intensity (Level 1 (60mHg) ~ Level 10 (150mmHg)), operation time (15 min ~ 2 hours), and rest time (0, 5, 10, 30 sec).		
Reading operational status	Reading operational status displayed on LCD during operation.		
Operating the device	Pressing the play button to operate the device when the device is standby status.		

Stopping the device	Pressing the pause button to stop the device when the device is working status.
Cleaning	Cleaning the main unit and accessories
Moving	Moving the main unit and accessories for operation
Storing	Storing the main unit and accessories when not in use.

#### 1.8 Intended Use

This device is intended for use by medical professionals and patents at home, in treating many conditions, such as:

- ① Primary lymphedema
- ② Edema following trauma and sport injuries
- ③ Post-immobilization edema
- ④ Venous insufficiencies
- (5) Lymphedema

The device is a pneumatic pressure treatment system that inflates sleeves (cuffs) to help blood circulation and prevent blood clots or clogs.

#### 2. Precautions

- This is for user safety and prevention against the property damage.
  - Please read it carefully prior to using the product.

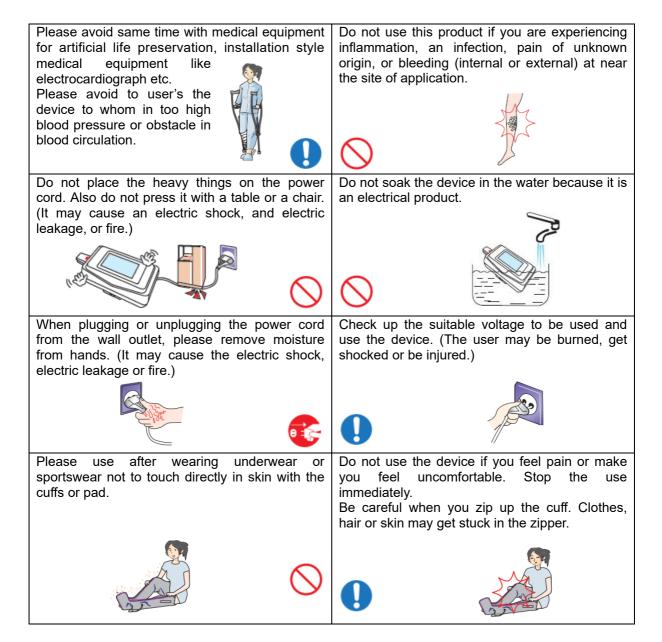
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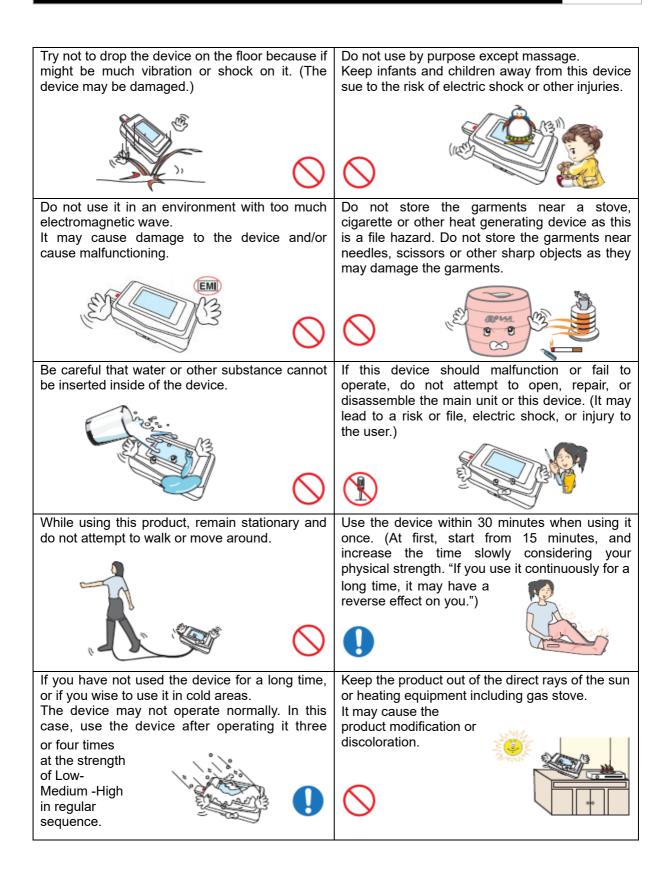
***	Manufacturer	SN	Serial Number	$\triangle$	Caution
~~	Date of Manufacture		Follow the instructions for use		Operating Instruction
-25°C	Temperature Limit	90% (3) 15%	Humidity Limitation		Atmospheric pressure limitation
	Sitting prohibited	$\bigcirc$	General prohibition sign	÷	Keep dry
	Stepping prohibited		This means not to take the device apart	×	Type BF applied part
EC REP	Authorized representative in the European community		This means to unplug the power cord		2 Level Insulation (Class II)
<b>CE</b> 1984	Complied with MDD 93/42/EEC		General mandatory action sign		General warning sign
X	Please do not throw any electrical equipment (including hose marked with this symbol in your bin)				
IP21	Protected from touch by fingers or objects greater than 12.5 mm Protected from vertically falling water drops				

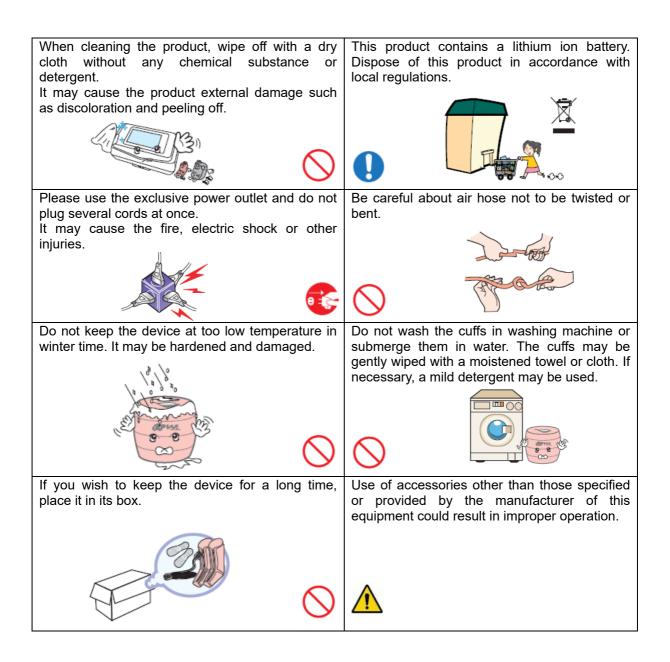
#### Contraindication

Do not use the device as follows;

- A person with medical electronic implant device (artificial heart)
- A person who is in pulmonary edema, heart disease, vein cancer, high blood pressure, and high fever.
- A person who have skin disease such as skin burn, dermatitis, bedsore, purulent disease, malignant tumor and etc.
- A person who took skin surgery (skin graft) on the part of use.
- A person who has blood vessel disease such as serious artery hardening or other angina, cardiac infarction and etc.
- Cases the suspected blood clot presence
- A person who has extreme malformation or a person who inserted pin on using part (artificial joint, beads, metal, silicon and so on)
- Right after the operation as varicose veins
- Recovering patients since after the surgery, pregnant woman, children
- In the case of increasing of pain after using this machine

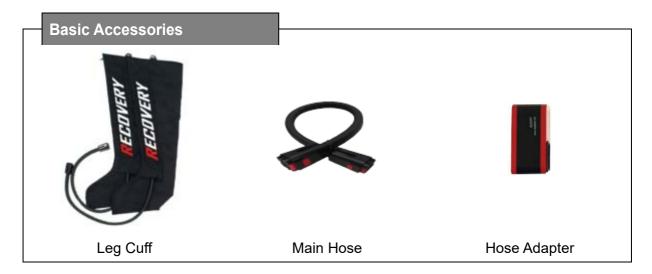






## 3. Device Description







#### \* Remark

- Applied part: Leg cuff, Arm cuff, Hip cuff.



## 4. Preparation before use

- 1) Select proper cuff to use. (Leg cuff, Arm cuff, Hip cuff)
- 2) In case you use two cuffs.
  - Connect one terminal of main hose to air outlet of main body. Press main hose into main body until you hear an audible 'click'.



② Connect another terminal of main hose in the direction which there is one outlet in hose adapter. Press main hose into hose adapter until you hear an audible 'click'.



③ Connect two terminals of cuff hoses in the direction which there are two outlets in hose adapter. Press cuff hoses into hose adapter until you hear an audible 'click'.





- ④ In this case, there are the following combinations.
  - a. Two leg cuffs
  - b. Two arm cuffs
  - c. One hip cuff with two cuff hoses
  - d. One leg cuff + One arm cuff

3) In case you use only one cuff, such as one leg cuff or one arm cuff, directly connect cuff hose to air outlet of main body. In this case, main hose and hose adapter are not required.

4) If cuff connection is completed, wear the cuff.



Use of cuff of hose other than those specified or provided by the manufacturer of this equipment could result in improper operation.

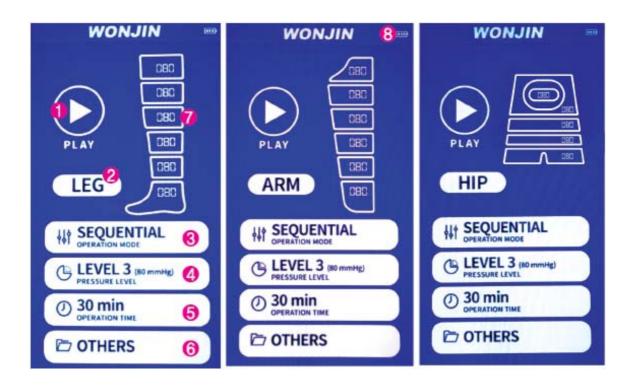
## 5. How to use

1) Connect AC-DC adapter into an electrical outlet and then into the main body.

	This device is equipped with a rechargeable lithium ion battery. The battery automatically charges when the AC-DC adapter is connected to an electrical outlet and main body.
	Use of AC-DC adapter other than those specified or provided by the manufacturer of this equipment could result in improper operation.
	The time required for the ME EQUIPMENT to warm from the minimum storage temperature between uses until the ME EQUIPMENT is ready for its INTENDED USE when the ambient temperature is 20 °C: one hour
0	The time required for the ME EQUIPMENT to cool from the maximum storage temperature between uses until the ME EQUIPMENT is ready for its INTENDED
	USE when the ambient temperature is 20°C: one hour

2) Press power switch to turn on the power.

3) How to operate the program



0	PLAY PAUSE	Play/Pause Button	That Play icon is displayed means that the device is not operating now. That PAUSE icon is displayed means that the device is operating now.		
2	LEG ARM HIP	Cuff Selection Button	There are three cuff modes. (Leg, Arm, and Hip) If you select one among Leg, Arm, and Hip, Le picture, Shoulder/Arm picture, or hip picture w be displayed.		
	SEQUENTIAL		<b>SEQUENTIAL</b> is the mode that the air pressure sequentially moves from foot (1 <sup>st</sup> chamber) to thigh (6 <sup>th</sup> chamber).		
8	WAVE	Operation	<b>WAVE</b> is the mode that the air pressure sequentially moves from foot (1 <sup>st</sup> chamber) to thigh (6 <sup>th</sup> chamber), and If the next chamber inflates, the previous chamber deflates in 3 seconds. (Overlapped for 3 seconds)		
	RECOVERY	Mode Selection Button	<b>RECOVERY</b> is the mode that the air pressure sequentially moves from foot (1 <sup>st</sup> chamber) to thigh (6 <sup>th</sup> chamber). If the operation of 4 <sup>th</sup> chamber is completed, 1 <sup>st</sup> chamber deflates and 5 <sup>th</sup> chamber inflates. If the operation of 5 <sup>th</sup> chamber is completed, 2 <sup>nd</sup> chamber deflates and 6 <sup>th</sup> chamber inflates. If the operation of 6 <sup>th</sup> chamber is completed, 3 <sup>rd</sup> chamber deflates. Each of 4 <sup>th</sup> /5 <sup>th</sup> /6 <sup>th</sup> chambers sequentially deflates in 10 seconds.		

	ADDITION		pressure chamber chamber chamber	sequentially ) to thigh (6 doesn't deflate is completed is completed,	that the mode that the air moves from foot (1 <sup>st</sup> 5 <sup>th</sup> chamber), and each e until the operation of 6 <sup>th</sup> . If the operation of 6 <sup>th</sup> all of chambers deflate at
	MASSAGE			<b>GE</b> is the coml ERY, and ADDI	pination of SEQUENTIAL, TION modes.
4	(LEVEL 1(60mmHg))	Pressure Intensity Selection Button	tensity You can select pressure intensity from LEVEL 1 (60mmHg) to LEVEL 10 (150 mmHg).		
6	15min	Operation Time			
	OTHERS	Rest Time	You can adjust rest time at Interval of 0/5/10/30 sec. Rest time is fixed at 30 sec at ADDITION and MASSAGE modes.		
		Memory		SAVE	You can save operation mode up to seven modes.
0			User 1~7	CHOICE	You can operate the selected USER mode by clicking PLAY.
6				PRIOROTY	If the power is turned off and on, the selected USER mode is displayed, and operated by clicking PLAY.
		Reset	Data in memory are deleted and all of functions are returned to factory release mode. Factory release mode: LEG / RECOVERY / LEVEL 3 (80 mmHg) / 30 min		
		Brightness	You can adjust screen brightness with MIN ~ MAX.		
0		You can adjust pressure intensity of each chamber by clicking the chamber picture. If you press and hold the chamber for 3 seconds, the chamber can be selected or be skipped.			
8		Full charging status of battery / Charging status			

## When closing the Use

If the use is completed, ① Press the power switch to turn off the power, ② Disconnect AC DC edenter from an electrical cutlet and main	O
② Disconnect AC-DC adapter from an electrical outlet and main body.	
Disconnect main hose from the main body. -Press red button on main hose and pull off main hose.	
Disconnect main hose and cuff hoses from hose adapter.	
If you wish to keep the device for a long time, place it in its box	RECOVERY

## 6. Maintenance

^	No modification of this equipment is allowed.
<u>/!</u>	No modification of this equipment is allowed.
$\wedge$	Do not modify this equipment without authorization of the manufacturer.
Â	If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
Â	We will make available on request circuit diagrams, component part lists, descriptions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by us as repairable by SERVICE PERSONNEL.
0	All the cuffs are not to be repaired as consumption goods. Be always careful.
$\bigcirc$	Do not place the cuff near the sharp things such as furnaces, needles, scissors, etc.
$\bigcirc$	Keep the device in the dry place where there is no water or humidity
$\bigcirc$	Do not wash the cuffs in washing machine nor submerge them in water.
	Do not keep the device at too low temperature in winter time.
$\mathbf{S}$	[It may be hardened and damaged.]
0	If you wish to keep the device for a long time, place it in its carrier.
	Cleaning
	When cleaning the product, wipe off with a dry cloth without any chemical

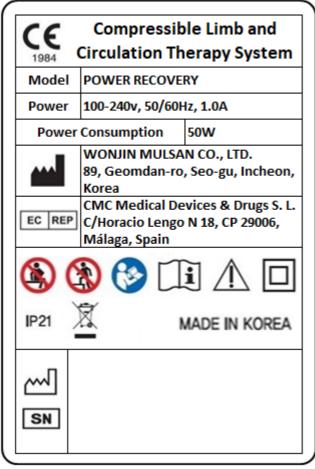
substance or detergent. It may cause the product external damage such as discoloration and peeling off. The cuffs may be gently wiped with a moistened towel or cloth. If necessary, a mild detergent may be used. **Environmental conditions** Q O,1 Operation - a temperature range of +5°C to +40°C; - a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50hPa; and - an atmospheric pressure range of 700hPa to 1060hPa. - home use as well as professional, indoor use only **○,2** Transport/Storage - -25 °C to + 5 °C , and - +5 °C to + 35°C at a relative humidity up to 90%, non-condensing; - >35°C to 70°C at a water vapour pressure up to 50hPa

## 7. Temporary action taken during usage

Contents	Check-up		
	• Check up if the power switch is turned on.		
When it doesn't work	<ul> <li>Check up if there is any problem in AC-DC adapter.</li> </ul>		
	<ul> <li>Check up if it is low battery. If yes, connect AC-DC adapter into main device to charge the battery.</li> </ul>		
When there is a strange sound like air leakage	<ul> <li>Check up if there is any damage in the connecting hose and hose adapter.</li> <li>Check up if you have connected the connector with the device.</li> </ul>		
	<ul> <li>Check up if the connecting hose is pressed or bent.</li> </ul>		
When the air does not go into the cuffs or when there is no pressure	<ul> <li>Check up if you have connected the connector with the device.</li> <li>Check up if any heavy stuff is placed on the connecting hose or the connecting hose is bent.</li> <li>Check up if the connecting hose is connected to main body</li> </ul>		
When the air continues	and hose adapter until you hear an audible 'click'.		
to go into the cuffs and when the air leakage sound is made	<ul> <li>Check up where there is air leakage in the cuff. If there is no air leakage, turn off the power, and then, turn on the power again and check up if it does work properly. (the cuffs are consumption goods.)</li> </ul>		
When the pressure is too strong or discomfort to the patient	• Press the PAUSE button to deflate the cuff, set the pressure to the reduced one, and perform the operation again.		

## 8. Label

## 8.1 ID Label



The ID label is affixed on main unit and inner box.

## 8.2 Type BF Applied Part



The type BF applied part label is affixed near air outlet of main unit.

## 9. Electromagnetic Compatibility

Guidance and manufacturer' declaration –electromagnetic em
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This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The equipment 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 equipment is suitable for use in all establishmer including domestic establishments and those direc connected to the public low-voltage power supply netwo
Harmonic emissions IEC 61000-3-2	Class A	that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guida	Guidance and manufacturer' declaration –electromagnetic immunity			
This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that is used in such an environment.				
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment- guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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	±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 IEC61000-4-5	±1 kV line(s) to lines ±2 kV line(s) to earth	±1 kV line(s) to lines ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.	
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	Hz) stic field		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.	
Voltage dips, short interruptions and voltage variations on power supply	<5% U⊤ (>95%dip in U⊤) for 0.5 cycle 40% U⊤ (60%	<5% U <sub>T</sub> (>95%dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains	

lines IEC6100-4-11	dip in U <sub>T</sub> ) for 5 cycles	in $U_T$ ) for 5 cycles	interruptions, it is recommended that the equipment be powered from an uninterruptible power supplied or a
	70% U⊤ (30% dip in U⊤) for 25 cycles	70% $U_T$ (30% dip in $U_T$ ) for 25 cycles	battery.
	<5% U⊤ (>95% dip in U⊤) for 5 sec	$<\!5\%$ $U_T$ (>95% dip in $U_T$ ) for 5 sec	

Guidance and manufacturer' declaration –electromagnetic immunity				
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that it is used in such an environment				
Immunity test	IEC60601 test level	Complia nce level	Electromagnetic environment-guidance	
Conductive RF IEC61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the equipment Including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter <b>Recommended separation distance:</b> $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz	
Radiated RF IEC61000-4-3	3V/m 80MHz to 2,5GHz	3V/m	<ul> <li>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 metres (m).</li> <li>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>.</li> <li>Interference may occur in the vicinity of equipment marked with the following symbol:</li> </ul>	

Note 1 At 80MHz and 800MHz 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.

- <sup>a</sup> : Field strengths from fixed transmitted, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in the location due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this equipment is used exceeds the applicable RF compliance level above, this equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this equipment.
- <sup>b</sup>: Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

# Recommended separation distances between portable and mobile communication equipment and this equipment

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

Rated maximum	Separation distance according to frequency of transmitter (m)				
output power of transmitter W	150kHz to 80MHz d=1.2√P	80MHz to 800MHz d=1.2√P	800MHz to 2.5GHz d=2.3√P		
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		
1.0	1.2	1.2	2.3		
10	3.8	3.8	7.3		
100	12	12	23		

For transmitter 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 of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1. At 80MHz and 800MHz 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.

## WARRANTY

Name of Products	Compressible Limb and Circulation Therapy System	Applicable Model	POWER RECOVERY
Date of Purchase		Serial No.	
Agent of Purchase		Warranty Period	Body : 1 Year Cuffs (Consumption Goods) : 3 Months (Work Place)

The life cycle of the device is 6 YEARS based on the motor pump which are the shortest life cycle part of the device.

#### About Our Service

This is a product that we, Wonjin Mulsan Co., Ltd. manufactured though its own strict quality management and inspection process.

#### Paid Services

Please be careful about the fact that the service fee will be charged even within the warranty period if the consumer requests the service due to his/her carelessness or if no defects are found in it.

In case of faults due to the consumer's mistake (When the faults occur due to consumer's carelessness or wrong repair)

- X When the fault occurs due to the wrong use for the electrical capacity.
- % When the fault occurs because the consumer has fallen down the device during the transfer after installation.
- % When the fault occur because the consumer has used the consumption and optional goods that we did not designated.
- % When the fault occurs because other companies' repairman has repaired the product concerned.
- X When the fault occurs because the consumer has used the product in the prohibited area(outdoors) or beyond the original use, because the consumer has disassembled, alternated and repaired at his/her discretion.
- % When the consumer has not Abide by the matters that require attention in this instruction manual (Please red the matters that require attention carefully.)

#### Other cases

- % In case of natural disasters(fire, damage from sea wind, flood damage, thunder, lightening, earthquake, etc.)
- X Where the consumption goods are used up or their warranty period has already lapsed.
  - Unprofessional operators or untrained operators need information service such as installation, maintain of the device
  - Report unexpected operation or event.
  - Circuit diagrams, component part lists, etc. are needed for service personal.

#### Manufacturer: Wonjin Mulsan Co., Ltd.

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