CE
2265

User's Manual

Compressible Limb and Circulation Therapy System
Model POWER-Q1000 PREMIUM

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

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Table of Content

1. General Information

1.1 Specification

Technical Requirement of product	
Product Name	Compressible Limb and Circulation Therapy System
Model Name	POWER-Q1000 PREMIUM
Brand	None
Dimensions	260 x 200 x 125 (mm)
Rated Voltage	220V-240V~, 50/60Hz
Power Consumption	70VA
Weight(Main Body)	2.0 kg
Performance Requirement of product	
Adjustable Time	0~99 minutes
Pressure Range	0~240mmHg
Accuracy	±20%

1.2 Classification

Classification	
Type of protection against electric shock	Class II
Type of applied part	Type BF applied part
Degree of protection against ingress of water	IP21
Mode of operation	Non-continuous use (on time: 30 min, off time: 10 min) Note: Devices for non-continuous operation can be destroyed during continuous operation.
Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	

1.3 Intended patient population

a) General: Patients who need to prevent or treat Primary lymphedema, Edema following trauma and sport injuries, Post-immobilization edema, Venous insufficiencies or lymphedema.

b) Gender: No limited

c) Age: 18 years old or greater

d) Weight: 40 kg or greater

e) Health condition: contraindication of user manual

f) Race: Multiple

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

a) Part of the body: Leg, Arm, and Waist

b) Type of tissue: It doesn't come in contact with the skin because there should be cloths on the body before wearing the cuffs.

1.5 Intended User

[Intended user group: Medical professionals]

a) Education:
  – at least 14 years of education and have a doctor/nurse/physical therapist
b) Knowledge:
  – minimum:
    – read and understand how to operate the device
    – can distinguish: leg, arm, and waist
    – understands hygiene
c) Language understanding:
  – understand user manual which is described in the relevant language
d) Experience:
  – minimum:: no special experience needed

[Intended user group: lay persons]

a) Education:
  – at least 10 years intensive reading experience (school)
b) Knowledge:
  – minimum:
    – read and understand how to operate the device
    – can distinguish: leg, arm, and waist
    – understands hygiene
c) Language understanding:
  – understand user manual which is described in the relevant language
d) Experience:
  – minimum:: no special experience needed

1.6 User environment

a) Environment
  – General: Home environment, Indoor
  – Environmental conditions: Refer to ‘7 Maintenance of this IFU’.
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 the cuff and air hose	Connecting the cuff and air hose to main unit for operation
	Disconnecting the cuff and air hose from main unit after use
Putting on/Taking off the cuff	Putting on the cuff for operation
	Taking off the cuff after use
Switching on/off the power	Switching on the power for operation
	Switching off the power after use

Controlling the setting	Setting the mode (A1, A2, B, C, D1, D2, D3, D4, and E), the interval (0, 5, 10, 15, 20, 25, and 30 sec) the pressure time (5, 7, 9, 11, 13, 15, 17, 19, and 21 sec), the time (0~99 min), and the pressure (0~240mmHg: A1, A2, B, D1, D2, D3, and D4, 0~130mmHg: C and E) including the reset function and the save function by controlling the panel of main unit.
Reading the LCD	Reading the operation status on LCD display
Operating/Stopping the device	Operating or Stopping the device by Start/Stop button.
Cleaning	Cleaning the main unit and components
Moving	Moving the main unit and components for operation
Storing	Storing the main unit and components when not in use.

1.8 Intended Purpose

The device is intended for use by medical professionals and lay persons to prevent and treat Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, and Lymphedema.

1.9 Indications:

- Primary lymphedema
- Edema following trauma and sport injuries
- Post-immobilization edema
- Venous insufficiencies
- Lymphedema

1.10 Clinical Benefit

Limb circumference and limb volume of patients with lymphedema decrease after pneumatic compression therapy according to clinical evaluation based on clinical literatures of similar devices.

2. Safety Information (Limitation)

Please read all instructions before using this product for the first time.

Contraindication	Indicates a situation in which the device should not be use.
Warning	Indicates a situation which, if not avoided, could result in death or serious injury.
Caution	Indicates a situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

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

Warning

- Do not use this device on patients under 18 years of age, under 40kg or in patients who fall under the contraindications in this user manual.
- Do not use this device simultaneously with life support device or electrocardiograph.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Do not use this product if you are experiencing inflammation, an infection, pain of unknown origin, or bleeding (internal or external) at near the site of application.
- Do not place the heavy things on the power cord. Also do not press the cord with a table or a chair. (It may cause an electric shock, and electric leakage, or fire.)
- Do not soak the device in the water because it is an electrical product.
- When plugging or unplugging the power cord from the wall socket, please remove moisture from hands. (It may cause the electric shock, electric leakage or fire.)
- Check up the suitable voltage to use the device. Otherwise, the user may be burned, get shocked or be injured.
- Please use after wearing underwear or sportswear not to touch directly in skin with the cuffs.
- Do not use the device if you feel pain or make you feel uncomfortable. Stop the use immediately. Be careful when you zip up the cuff. Clothes, hair or skin may get stuck in the zipper.
- Try not to drop the device on the floor because if might be much vibration or shock on it. (The device may be damaged.)
- Do not use this device except the intended purpose. Keep infants and children away from this device due to the risk of electric shock or other injuries.

Caution

- Portable and mobile RF communication equipment can affect medical equipment. Therefore, keep the portable and mobile RF communication equipment 30 cm from the medical equipment.
- Do not store the garments near a stove, cigarette or other heat generating device as this is a fire hazard. Do not store the garments near needles, scissors or other sharp objects as they may damage the garments.
- Be careful that water or other substance cannot be inserted inside of the device.
- If this device should malfunction or fail to operate, do not attempt to open, repair, or disassemble the main unit or this device. (It may lead to a risk of fire, electric shock or injury to the user.)
- While using this product, remain stationary and do not attempt to walk or move around.
- It is recommended to use up to 30 min / 1 time and 3 times / 1 day. At first, during period of 15 minutes. If you use it continuously for a long time, it may have a reverse effect on you.
- If you have not used the device for a long time, or if you have used it in cold areas, the device may not operate normally. In this case, use the device after operating it three or four times at the strength of Low-Medium -High in regular sequence.
- Keep the product out of the direct rays of the sun or heating equipment including gas stove. It may cause the product modification or discoloration.
- 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.
- Please use the exclusive power socket and do not plug several cords at once. It may cause the fire, electric shock or other injuries.
- Please dispose Electrical & Electronic Equipment in accordance with WEEE Directive 2012/19/EU.
- Be careful about air hose not to be twisted or bent.
- Transport and store the device in accordance with Transport/Storage environment in '7 Maintenance' of this IFU.
- Do not wash the cuff in washing machine or submerge them in water. The cuff may be gently wiped with a moistened towel or cloth. If necessary, a mild detergent may be used.
- If you wish to keep the device not used for a long time, place it in its box.
- Use of components other than those specified or provided by the manufacturer is prohibited.
- It is recommended that the device be inspected every 2 years and after maintenance and repair to ensure proper functioning and accuracy.

NOTE:

■ If you experience pain or discomfort during or after using the device, or if there is onset of skin irritation during or after using the device, discontinue use and consult your physician.

■ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

[Symbols]

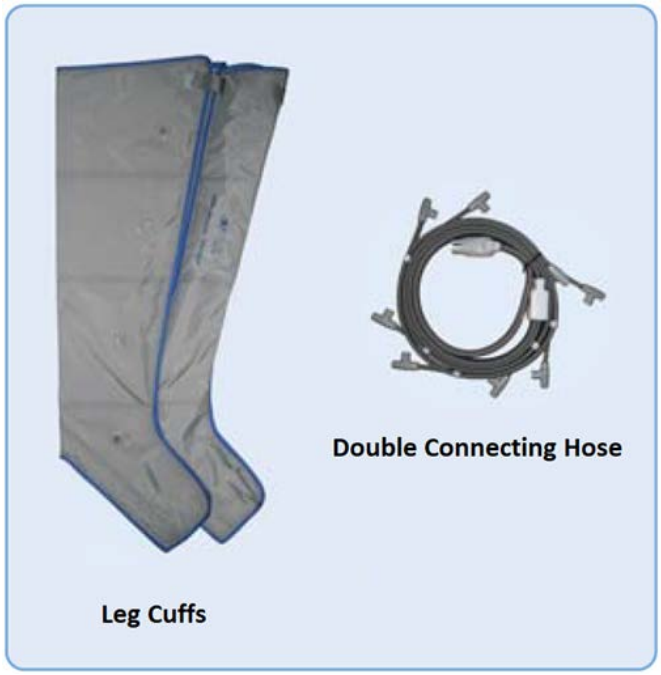
SN	Serial Number	#	Model Number	UDI	Unique Device Identifier
	Manufacturer		Date of Manufacture		Caution
	General prohibition sign		Refer to instruction manual		Class II equipment
	Type BF applied part	CE 2265	Complied with MDR 2017/745	EC REP	Authorized representative in the EU /EC
	Temperature limit		Keep dry		Atmospheric pressure limitation
	Humidity Limitation		This way up		Fragile, handle with care
6	Max stacking limit	MD	Medical Device		Importer
	General warning sign		Electrical and Electronic Equipment Waste-Discard it separately from other objects		
IP21	Protected from touch by fingers or objects greater than 12.5 mm Protected from vertically falling water drops				

3. Device Description

3.1 Main Body

3.2 Components

[Basic Components]



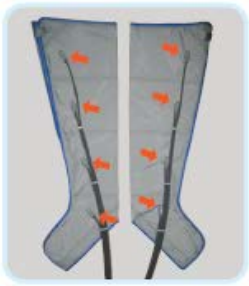
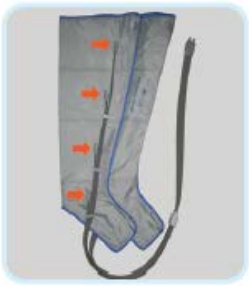
[Optional Components]

※ **Applied parts**: Leg Cuff, Arm Cuff, Waist Cuff, Extension Zipper, Half-Leg Cuff, and Half Pants

4. Preparation before use

① Select proper cuff to use.

② Connect hose with below picture.

③ Put cuff to use if conjunction was ended.



- Use leg cuffs when unfolded leg.
- The waist cuff could be used through abdomen and hip, you can pain when wrapping the region of chest.
- Put the shoulder cuff to wrap the shoulder with fixed band.

④ Connect hose to the main body.

⚠	The cuff should be placed on the patient's gown or clothing through which pressure can be transmitted.
⚠	Use of hose 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
⚠	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
⚠	As the mains plug is disconnecting part, it can be separated from the power supply.

Extension zipper connection method

- Extension zipper is an optional item that increases the size of leg cuff
- Connect the extension zippers between leg cuff zippers as shown in the figure below.

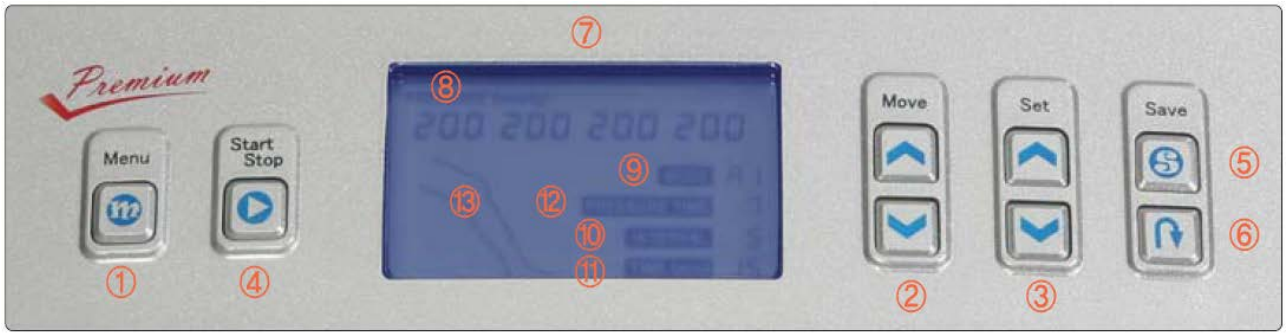
Extension Zipper (R/L)

Extension zipper connection

After extension zipper connection

5. How to use

Operating Screen



No.	Name	Description
1	Menu	It brings out the menu.
2	Move	It lets you choose around the options. (Mode, Pressure Time, Interval, Time, Pressure (mmHg))
3	SET	It lets you choose a value.
4	Start/Stop	It operates and stops the device.
5	Save	It saves the current state (press down on the button for 10 seconds).
6	Reset	It brings back to the initial state (press down on the button for seconds).
7	LCD Windows	It shows the current setting and operation state.
8	Pressure (mmHg)	It shows the set pressure (range: 0~240 mmHg) 0~240: (A (A1, A2), B, D (D1, D2, D3, D4)) Mode 0~130: C, E Mode
9	Mode	Mode Selection (A (A1, A2), B, C, D (D1, D2, D3, D4), E)
10	Interval	Interval Time Selection (0, 5, 10, 15, 20, 25, 30 sec)
11	Time (min)	Operation Time Selection (5~99 min)
12	Pressure Time	Pressure Time Selection (5, 7, 9, 11, 13, 15, 17, 19, 21 sec)
13	Leg Picture	It shows the operation state.

How to use

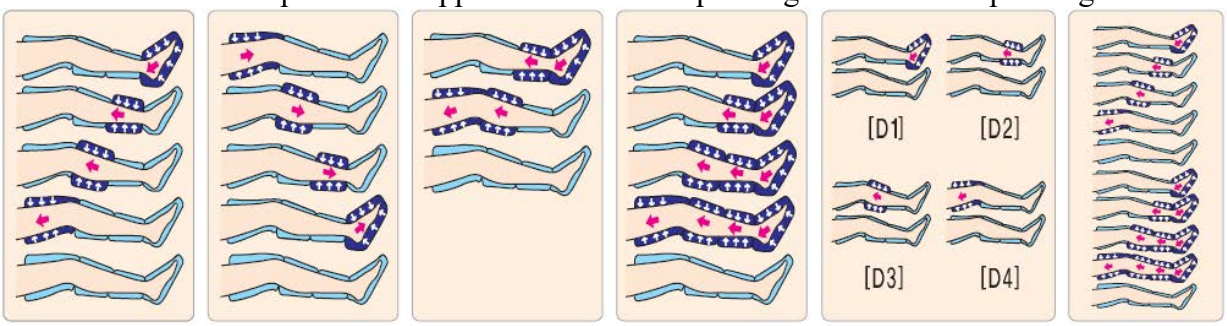
① Insert the power plug into the wall socket.
• Check up the suitable voltage to use the device.

② Turn on the Power.
• Pressure the power button.

③ Menu selection (if changed by the user)

a. If you want to use the basic setting, move to ④.
b. Press Menu to change to customer setting.
c. Move to Menu to be changed using the Move button.
Refer to the previous page.
d. Change the value using Set button. If you want to choose something else, repeat the steps c & d.
e. If you have set the setting, press Menu button to get out of the setting change.
f. If you want to use the current customer setting again later, press and hold the S button for 10 seconds to save. (If you press and hold the reset button for 10 seconds, it goes back to the basic setting). If you want to use the setting but don't want to save it, move down to g.
g. Move down ④.

-Order of pressure is applied to the cuff depending on the mode operating-



Exemption of the United States-A2

④ Operate the device by pressing the start/stop button.
-The device stops working automatically if the set time is ended.

6. When closing the use

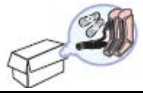
After one or two minutes of closing the use, the air will be discharged. Then, remove the cuff, and pull off the power plug out of the wall socket.

Remove the connector from the main body.

⚠ When you pull off the power plug or connector, pull off it holding the plug, not the cord.

Disconnect the hose connector from the cuffs.

If you wish to keep the device not used for a long time, place it in its box.



7. Maintenance

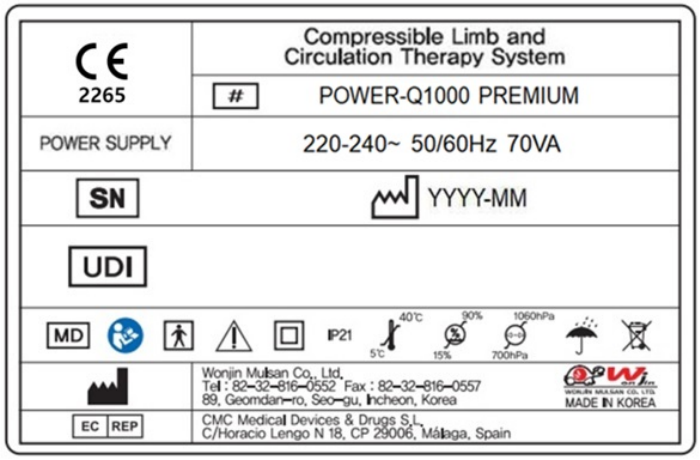
	No modification of this equipment is allowed.
	Do not modify this equipment without authorization of the manufacturer.
	If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
	We will make available on request circuit diagrams, 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.
	To check or replace the fuses, please contact the distributor or the manufacturer.
	All the cuffs are not to be repaired as consumption goods. Be always careful.
	Do not place the cuff near the sharp things such as furnaces, needles, scissors, etc.
	Keep the device in the dry place where there is no water or humidity
	Do not wash the cuffs in washing machine nor submerge them in water.
	Transport and store the device in accordance with Transport/Storage environment below.
	If you wish to keep the device not used for a long time, place it in its box.
	**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** **1 Operation** - a temperature range of +5°C to +40°C; - a relative humidity range of 15% to 90%, non-condensing and - an atmospheric pressure range of 700hPa to 1060hPa. - home use as well as professional, indoor use only **2 Transport/Storage** - a temperature range of -25°C to +70°C; - a relative humidity range of 15% to 90%, non-condensing and - an atmospheric pressure range of 700hPa to 1060hPa

8. Temporary action taken during usage

Contents	Check-up
When it doesn't work	• Check up if you have plugged it in. • Turn on the power switch. • Check up if there is any problem in the power Cord (Check up the voltage). • Check up if you have set the timer switch.
When there is a strange sound like air leakage	• Check up if there is any damage in the connecting hose and connector. • Check up if you have connected the connector with the device. • Check up if the connecting hose is pressed or bent.
When the air does not go into the cuffs or when there is no pressure	• Check up if you have connected the connector with the device. • Check up if any heavy stuff is placed on the connecting hose or the connecting hose is bent. • Check up if the connecting hose is properly connected with the cuff groove with a rhythmical sound.
When the air continues to go into the cuffs and when the air leakage sound is made	• Check up where there is air leakage in the cuffs. 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. (cuff is consumption goods.)
When the pressure is too strong or discomfort to the patient	• Reduce the pressure using pressure adjustment dial. • Turn off the power and remove air hose from main body to deflate cuff.

9. Label

9.1 ID Label



The ID labels are affixed on the rear of main unit and the side of the packaging box.

9.2 Importer Label

The importer label is affixed on the rear of the main unit.

9.3 Type BF Applied Part

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

10. Electromagnetic Compatibility

POWER-Q1000 PREMIUM has been tested according to EN 60601-1-2 standard and meets the requirements. Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use this device.
Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer' declaration –electromagnetic emissions		
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 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	Complies	

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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

	±1kV for input/ output lines	±1 kV for input/ output lines	
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	3 A/m	3 A/m	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 lines IEC6100-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	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 interruptions, it is recommended that the equipment be powered from an uninterruptible power supplied or a battery.

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**	**Compliance 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. **Recommended separation distance:** **$d=1.2\sqrt{P}$**
Radiated RF IEC61000-4-3	3V/m 80MHz to 2,5GHz	3V/m	

			d=1.2√P 80 MHz to 800 MHz **d=2.3√P 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 separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], 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: 

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.

[a] **:** 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.

[b] **:** 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 output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	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.

Disposal of Use Electrical & Electronic Equipment in accordance with WEEE Directive 2012/19/EU

Proper disposal of this product will help protect the environment. For further details on the disposal of this product, please contact local authorities, the provider of the domestic waste disposal service or the outlet where you have purchased it.

WARRANTY

Name of Product	Compressible Limb and Circulation Therapy System	**Applicable Model**	POWER-Q1000 PREMIUM
Date of Purchase		**Serial No.**	
Agent of Purchase		**Warranty Period**	2 Years
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)

※ 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.
※ 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 abided by the matters that require attention in this instruction manual (Please read the matters that require attention carefully.)

Other cases

※ In case of natural disasters (fire, damage from sea wind, flood damage, thunder, lightening, earthquake, etc.)

※ 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.
Address : 2F, 89, Geomdan-ro, Seo-gu, Incheon, Rep. of KOREA
A/S telephone : + 82-32-816-0552

EC REP

CMC Medical Devices & Drugs S.L.
C/Horacio Lengo N 18, CP 29006, Málaga, Spain

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