User's Manual

Compressible Limb and Circulation Therapy System POWER-Q2200





Document No.: UM-Q20B0 (Oct.15,2018_Rev.3)

1. General Information

1.1 Specification

Technical Requirement of product		
Product Name	Compressible Limb and Circulation Therapy System	
Model Name	POWER-Q2200	
Dimensions	290(L) X 260(W) X 172(H) (mm)	
Rated Voltage	220V~240V~, 50/60Hz	
Power Consumption	60VA	
Time (Selectable)	15 min, 30 minutes (Maximum)	
Maximum Pressure	200mmHg±20%	
Weight(Main Body)	3.1 kg	

1.2 Classification

Classification		
Type of protection against electric shock	Class II	
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	Non-continuous operation (on time: 30 min, off time: 10 min)	

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 Waist
- 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 waist
- 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
Controlling the panel	Setting the mode (A, B, C, and D), pressure (20 to 200mmHg), working time (15min and 30min) and interval time (0, 5, 10, and 30 sec) by controlling the panel of main unit.
Reading the panel	Reading the status during setting the panel.
Operating the device	Pressing the start/stop button to operate the device when the device is standby status.
Stopping the device	Pressing the start/stop 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.

Indications

***	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	1060hPa 700hPa	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)
CE 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				

0	Skin irritation of contacted part (cuffs) was evaluated by biocompatibility testing according to ISO 10993. But, we didn't evaluate about long time exposure more than 24 hours, we recommend to use within 24 hours.
	Be sure to check the patient allergy history about nylon material which is used for cuff. If the patient has the allergy, please consult a physician.

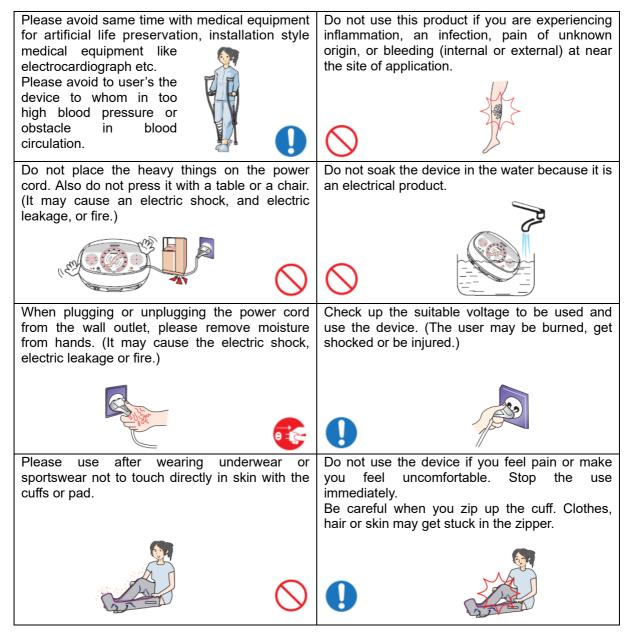
Contraindication

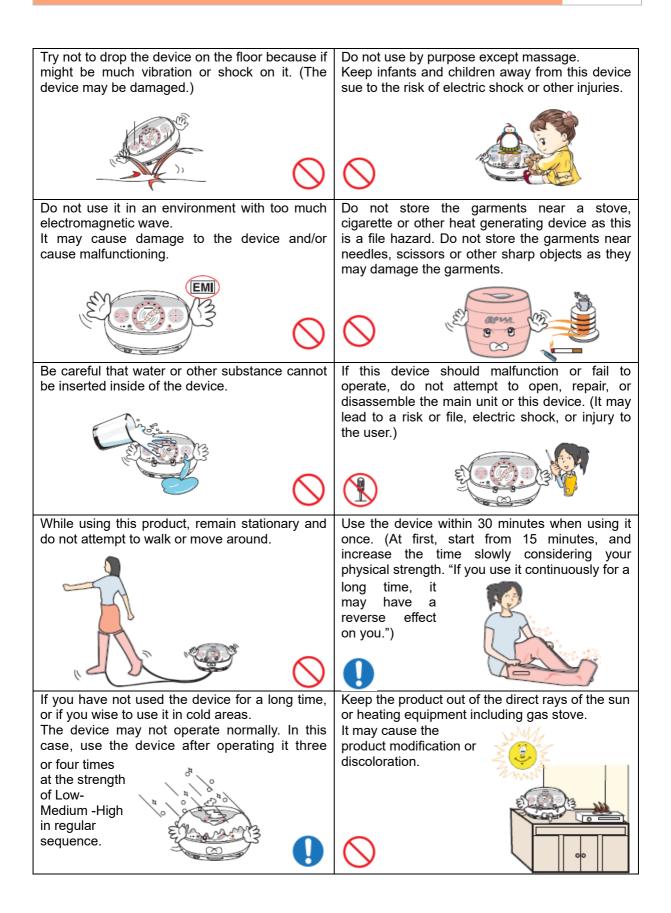
Do not use the device as follows;

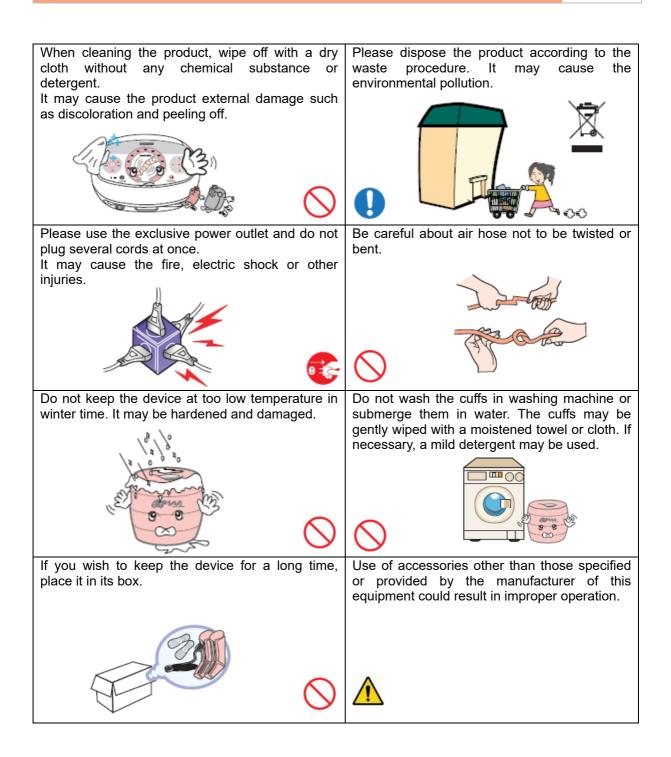
- A person with medical electronic implant device (artificial heart)
- A person who is in pulmonary edema, heart disease, vein cancer, high blood pressure, and high fever.
- A person who have skin disease such as skin burn, dermatitis, bedsore, purulent disease, malignant tumor and etc.
- A person who 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





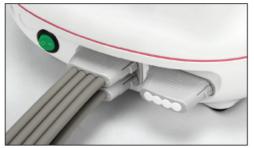


3. Device Description

3.1 Characteristics of this product

This machine has two air outlets (A & B) and two cuffs will be inserted and used into each air outlet at the same time.

If you can use only a cuff, you have to block the other air outlet with air blocked plug.

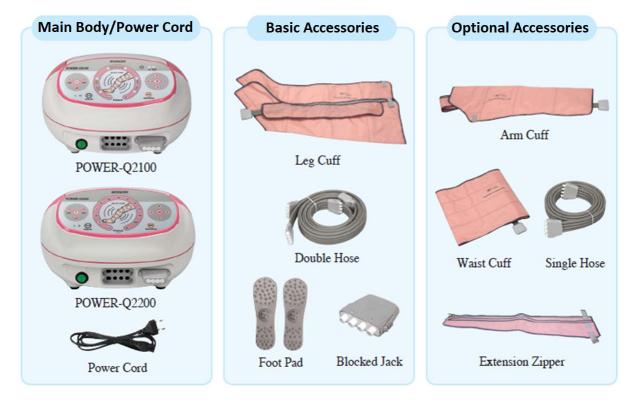


(Fig 1. Two hoses connection)



(Fig 2. One hose connection)

3.2 Composition



* Remark

- 1 It has 3 kinds of cuff.
 - Leg cuffs (Right, Left), Waist cuff (pad), Arm cuff
- ② These cuffs are consisted in a machine as an optional goods according to user's purchase order or as a whole set (all of them).
- ③ Extension zipper is necessary for bigger user
 Applied part: Leg cuffs, Arm cuff, Waist cuff.



No.	Name	Description
1	Name plate, Control button	Function command word is shown on the name plate. Press the command word (Press, T (Time), Interval, Select care, M (Mode), Start/Stop) to be selected.
2	Power switch	Input power turns ON/OFF.
3	Air outlet	Compressed air is coming out from the main body and flowing into the cuff through the Hose.
4	INLET	Connected Input power cord
5	Plugged space for blocked jack	If you do not use blocked jack, plugged into the blocked jack here.

4. Preparation before use

4.1 Connection of power cord



The device is delivered factory-set for the proper ac line voltage of the country to which it is shipped. The ac line voltage appears on the label affixed to the bottom of the device.

The device is equipped with a power cord – one end for connection at the right side of the device, the other end for connection at the wall outlet, suited to the labeled power rating.

	As the power cord is disconnecting part, it can be separated from the power supply.
	Use of power cord 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

4.2 Connection of cuffs and hose



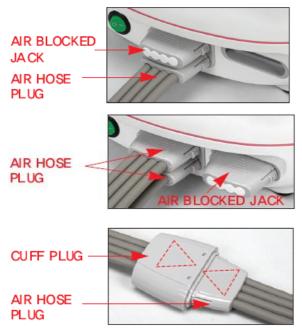


(Connection between main body and cuff)

(Air hose connection to main body)

- ① Select proper cuff or pad to use. (Leg cuff, Waist pad, Arm cuff)
- ② Connect hose to the cuff or pad and insert an air plug into the air outlet.
- ③ Wear a cuff or a pad to use if hose and plug is connected properly.
 - Use leg cuffs in condition of unfolded leg.
 - The waist pad could be used through abdomen and hip.
 - Put the Arm cuff and stick a cuff using fixed band in a part of the shoulder and chest. You may feel a pain wrapping the region of chest.
- ④ Connect hose (plug) to the main body.

Connection method between Main body and Hose plug



When user use an air hose,

Air hose plug will be inserted to the air outlet of the main body and the other is inserted using air blocked jack

When user use two air hose,

Two air hose plug will be inserted to the air outlet of the main body and air blocked jack will be inserted to the storage location.

When user connect air hose plug to main body or cuff,

User should check the mark on the plug case and connect them.

- Mark on plug case should be placed in the top side when user insert air plug to the main body.
- Mark on plug case should be placed in the same side when user insert air plug to the cuff.

※ A hose has two plugs.

One side plug of the air hose will be inserted to the main body and the other side plug will be inserted to the cuff.

% If an air outlet of the main body will be connected to the air hose plug,

The other side air outlet should be blocked using air blocked jack to prevent air leakage.

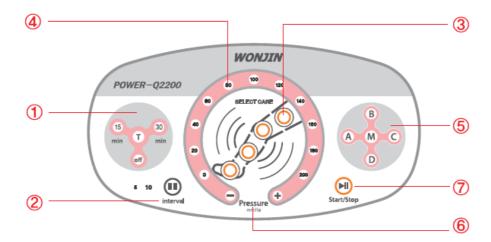


Use of hose other than those specified or provided by the manufacturer of this equipment could result in improper operation.

5. How to use

5.1 Name of each part

POWER-Q2200

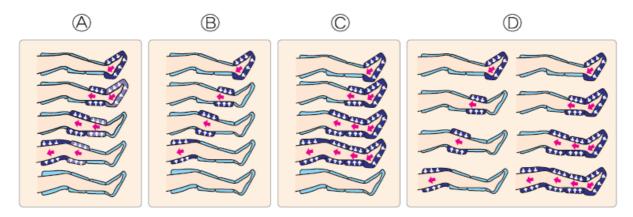


No.	Name	Description
1	Time	Select a working time of device. (15 min, 30 min)
2	Interval time	Select a interval time for rest during each cycle. (A/B MODE: 0, 5, 10, 30 sec, C/D mode: 30 sec fixed)
3	Pressure selectable for each room	Each room will be skipped if you turn off the LED of each room you don't want to use.
4	Pressure	Applied pressure will be shown on the name plate and adjusted select button (+ or -). - Pressure : 20 ~ 200 mmHg - Tolerance : 20%
5	Mode	Select a working mode to use
6	Pressure select button	Pressure value will be selected to press select button (+ or -)
7	Start/Stop	Device is worked by Start/stop button

5.2 Explanation of Operation mode

Working mode

- This device has 4 types compression mode program (A, B, C, D).
- User can select proper mode according to patient's condition.
- AC input is connected to main body and power is turns on, initial working mode is (A) mode

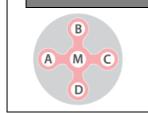


- Mode (A): Compressed air in cuff is moving from foot to Thigh in sequential.
 After pressure time is finished, extra 3 seconds hold the compressed air in each room. (Hold time of 3 seconds will gives a overlap effect.)
- Mode (B): Compressed air in cuff is moving from foot to Thigh in sequential.
- Mode ①: Compressed air in cuff is moving from foot to Thigh in sequential.

But Compressed air doesn't leak in each room until working of 4th room will be terminated.

 \blacksquare Mode O: This mode is mixed mode B and mode C.

Set the MODE



When the power is turned ON, initial mode (A) is set automatically;

- To select the mode
- Press Mode Button
- Stop at the mode you want to use.
- LED light will be shown

_ 3	Set th	ne INTER	VAL (0, 5, 10, 30 seconds)	
5	10	interval	 Press Interval Button Stop at the point you want to use. A, B MODE : 0, 5, 10, 30 sec (selectable) C, D MODE : 30 sec (fixed) LED light will be shown LED light on the Interval button is 30 seconds. 	

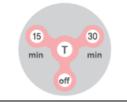
Set the PRESSURE



POWER-Q2200

- ① Press Pressure Button (+ or -)
- ② Stop at the pressure you want to use.
- ③ LED light will be shown

Set the TIME (15 min, 30 min)



① Press T Button

- 2 Stop at the time you want to use.
- ③ LED light will be shown

Set the PRESSURE of Each chamber

If user wants to skip any part (chamber), press the button on the each room to turn on/off.

Then, compression does not work at setting chamber.

- ① Look at the Leg drawing
- ② Button at each chamber will be shown.
- 3 If you don't want to use any chamber,

you just press the button and find a LED light.

- LED ON : working
- LED OFF : No working

5.3 Usage sequence

 Insert the power plug into the power outlet. Check up the suitable voltage to be used and use the device. 	Second Second
② Turn on the Power.- Press the ON button	
 If you want to use a setting value, you just press (start) button. If you want to change the setting value, You can select a setting value by using each functional button. After setting the value of function, you just press start button. 	Start/Stop
 ④ Regulate the Mode to be used. A mode is a initial setting mode from the factory. 	
 ⑤ Press the start/stop button to stop the device. If operating time is terminated, the operation is stopped automatically. 	Start/Stop

5.4 When closing the Use

 After operation is terminated, ① turn off the power switch ② pull out the power plug from the power outlet. 	
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 [pad].	
If you wish to keep the device for a long time, place it in its box	

6. Maintenance

^	No modification of this equipment is allowed
	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.
	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.
\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.
\bigcirc	Do not keep the device at too low temperature in winter time. [It may be hardened and damaged.]
	If you wish to keep the device 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	
	 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
	 O,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

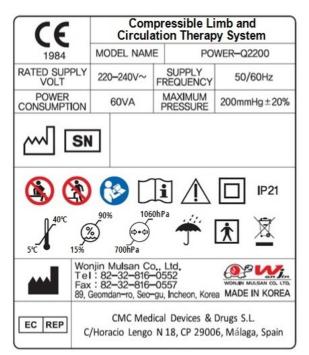
7. Temporary action taken during usage

Contents	Check-up		
	Check up if you have plugged it in.		
When it doesn't	Turn on the power switch.		
work	 Check up if there is any problem in the power Cord (Check up the voltage). 		
	Check up if you have set the timer select.		
When there is a	 Check up if there is any damage in the connecting hose and connector. 		
strange sound like air leakage	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	Check up if you have connected the connector with the device.		
not go into the cuffs and waist pad or when there is no pressure	 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 pad groove with a rhythmical sound. 		
When the wind continues to go into the cuffs and when the wind leakage sound is made	 Check up where the wind leakage is there in the cuffs. If there is no wind leakage, turn off the power, and then, turn on the power again and check up if it does work properly. (cuffs and each pad 		
When the pressure is too strong or discomfort to the patient	• Press the stop button to deflate the cuff, set the pressure to the reduced one, and perform the operation again.		

8. Label

8.1 ID Label

[POWER-Q2200]



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 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		
Harmonic emissions IEC 61000-3-2	Class A	 connected to the public low-voltage power supply netw 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	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	<5% U⊤ (>95%dip in U⊤) for 0.5 cycle 40% U⊤ (60%	<5% U _T (>95%dip in U _T) for 0.5 cycle 40% U _T (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_T) 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% $U_{\rm T}$ (30% dip in $U_{\rm T})$ 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 Recommended separation distance: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 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	 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, a 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	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-Q2100 POWER-Q2200
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.

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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