FILE NO.A0300C



#### **Phoenix Medtech GmbH**

Koenigsberger Strasse 11, 64839. Muenster Hessen, Germany.

#### **UK Responsible Person**

SHARE INFO LTD 3rd Floor, Office C, Townend House, Park Street, Walsall, West Midlands, WS1 1NS,UK.

Revision:A/2

Effective Date: 2024.12.20



Shenzhen OSTO Medical Technology Co.,Ltd ADD:2104,zhongxin Longsheng Square. Baolong Street, Longgang District, 518116 Shenzhen City,Guangdong Province, China





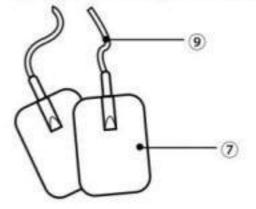
Thanks for your purchasing our electronic muscle stimulator Before using, please read the user manual carefully, especially the caution part, so that you can operate it correctly, and user manual should be well kept for your reference at any time.

# Content

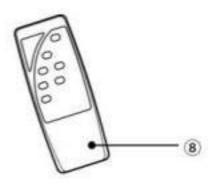
Parts identification	1
Functions	2
Usage of Electrode Gel Pads	2
Operation	3
Warnings	4
Storage /Maintenance	7
Specifications	7
Caution for Electrode Gel Pads (cleaning)	8
Trouble shooting	8
Description of Modes	9
Diagram of the Reflexive Zones of the Feet	12
Guarantee Card	

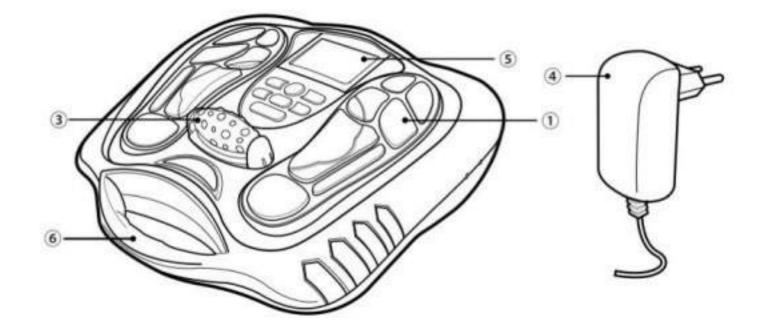
### Parts identification

- ① Electrode Silicon Area for Feet (Stimulate your foot muscles)
- 2 User manual (Users can be guided to security prompts)
- ③ Sole massage roller (Massage the soles of the feet)
- Adapter (Power the machine)
- (5) LCD Screen (Ease of use)
- 6 Handle (Easy lift)
- T Electrode pads (Body muscle stimulation)
- 8 Remote controller (Control machine)
- 9 Electrode wire (Action of wire)









# Function and intended application of the equipment

The principle of our electronic muscle stimulator is the low frequency current stimulate ache spots of the human body, cause muscle contraction or relaxation. When muscle relaxation, a large number of blood to enter in. When muscle contraction, the blood which contain metabolites to be sent out. This kind of actions will recycle which can help to accelerate the blood circulation and alleviate pain, swelling, fatigue, pain and other symptoms.

The expected purpose of our electronic muscle stimulator is to alleviate or reduce human muscle pain, swelling, fatigue ache and promote the blood circulation.

- Adopted to better ABS materials and design in according to man-machine engineering science. The item looks very modern, fashion and delicate
- 99 kinds electromagnetic wave intensity with continuous adjustment, will meet your required ideal result in proper sequence
- 3. 25 minutes automatical time set
- There are 25 kinds massage modes for sole and body, each impulse massage mode will improve the different symptoms, and eliminate fatigue
- 5. All functions can be operated by remote controller and be easy to use.

# Usage of Electrode Gel Pads

- 1. The size of pads is 5.5x8.5cm
- 2. Connect the output wire to the Electrode Gel Pads
- 3. Then connect output wire to the electrical muscle stimulator
- 4. Remove the protecting film from the adhesive pads
- 5. Attach the Electrode Gel Pads to the skin steadily
- Press the Switch button for 3 seconds to turn on the unit and adjust the stimulating mode and output intensity as your wish. (The display will show the mode and the level as you selected)
- Keep the adhesive gel pads clean, and never put them under high temperature and direct sunshine.
- If the electrode get pads are insufficiently adhesive or dirty, wipe with a wet cloth or change new ones. Don't clean the electrode gel pads with any chemical.
- 9. The effects of pads will be drops after many times usage. Pls change new pads if the pads never used in a year.

# Operation

Before using it, please check whether the equipment is in its original state: MODE intensity level display, SOLE intensity level display and time display show ZERO, MODE display show 1.

Operation of the EUIPMENT above amplitude or value, otherwise may cause inaccurate results.

- 1. put your feet on the unit
- Press the switch button about 3 seconds to turn on the unit, then the LCD screen will light up in Blune
- Then you can adjust the mode by pressing "MODE△"&"MODE▽"to select different modes, Maximum is the 25th mode
- Please increase intensity by pushing the button of "SOLE △""BODY △"Or decrease intensity by pushing the button of "SOLE ♥""BODY ♥"
- You can adjust the modes at anytime, but once mode resetting, the intensity will be returned to "0". For avoiding user's shock from the new mode, the user should reset the intensity
- To terminate the massage period, user can turn off the unit anytime by expressing the Switch button about 3 seconds.

Tips: Please adjust the intensity gradually from lower to stronger .

ON/OFF: press the button about 3 seconds to switch on or off the unit

Sole △: increase the output intensity of foot sole

Mode∆: choose one mode from 25 pre-moded massage modes~upward

Body∆: increase the output intensity of electrode pads

Sole ∇: decrease the output intensity of foot sole

Mode ∇: choose one mode from 25 pre-moded massage modes~downward

Body ∇: decrease the output intensity of electrode pads

#### How to operate the remote control?

- Open the battery cover behind of the remote control.
- 2.Put the two 7# (AAA) batteries into battery cassette in correct polarities.
- Close the battery cover.

## ⚠ Notes:

- Please note that the the original recognized accessories, detachable parts and material which are approved by standard.
- 2. It is no needs to check & replace the original power source frequently.
- Usually, this device is affected by high frequency electromagnetism and microwave radiation machine, pls be far away from these machines beyond 500mm when using



### **Prohibitions**

For the following patients, they only can use this instrument after consulting doctors, otherwise it may lead to accident or physical discomfort:

- 1) Extremely debilitating, critical illness patients should not use:
- 2) With the tumor, cancer, hyperthyroidism, tuberculosis active period, suppurative inflammation;
- 3) The aged who has heart disease and more than 65 years old;
- 4) The patients who are nervous, in fear of and sensitive to electronic muscle stimulators, please
- 5) People who has severe diabetes, high fever, skin allergy, traumatic bleeding and fracture during treated period, please don't use it;
- High blood pressure patients;
- 7) Abnormal skin or skin consciousness obstacle;
- 8) Psychopath;
- Undergoing treatment, or who feel abnormal;
- 10) A PATIENT with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained.

### Caution

Lifetime of the device is 5 years. It depends on electronic appliance ageing. Once the product cannot work properly, please contact us or local dealers.

Suited to the crowd: It is mainly used over the age of 16, and required energetic and full of intelligence.

- -The product must be used with legally marketed EMS stimulating device.
- -Do not put the electrodes in water, fluids or any other substance.
- -Do not insert lead wires into a main power supply.
- -Do not apply the product to wound or damaged skin because it may disrupt the healing process.
- -Do not use the electrodes on open wounds, rashes, swollen, red, infected or inflamed areas or skin eruptions (eg. phlebitis, thrombophlebitis, varicose veins); On top of, or in proximity to cancerous lesions.
- -Do not use the electrodes over areas of skin that lack normal sensation.
- -Do not use the Electrodes on the skin near the heart, head, face, mouth, private parts or areas that has skin disease.
- -Do not apply stimulation over the front area of your neck or to your mouth because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing or adverse effects on heart rhythm or blood pressure.
- Discontinue use if skin irritation occurs on or around the application site.
- -The electrodes are intended for single person use.
- -Do not let children or persons incapable of expressing their thoughts or intentions use the electrodes.
- -If you experience any skin irritation or redness after using this product, do not continue stimulation in that area of the skin for a period of time until skin return to normal.
- -Keep out of the reach of children.

## /!\ Contraindications

- 1) It is prohibited to use without doctor's suggestion for the patient with an implanted electronic device (for example a cardiac pacemaker)
- 2) please note the patient who connect with h.f. surgical equipment may affect the stimulator, so please follow the doctor's suggestion

- 3) Do not operate it in close proximity (e.g. 1 m) to a shortwave or microwave therapy equipment, which may produce instability in the stimulator output
- 4) please note the following people should follow the doctor's suggestion if use: tumor; chronic disease of serious disease; serious heart disease, the insane; pregnant woman
- 5) Please don't let the electrode pads touch with metal substance, such as strap, watch, necklace and etc when the machine is working
- 6) please ensure your skin neat and clean before use electrode pads
- 7) Please do not use the machine under wet condition, such as bathroom
- 8) please do not sit or stand on apparatus, and do not cast & fall it
- 9) please stop to use it immediately if you fell any discomfort and nausea when using
- 10) Do not apply electrodes near the thorax, which may increase the risk of cardiac fibrillation

### Explanation of figures, symbols, warning statements and abbreviations on the equipment

1	LOT	(Symbol for "BATCH CODE. This symbol should be with Production Banks, and next to graph, batch code and lot number and batch number etc.)  Examples: Lot ABC123		
2	<u>~</u>	(Symbol for "DATE OF MANUAFCTURE. This symbol should be next to number.)  Production date of medical equipment( use mark in front of the production date)		
3	<u>^</u>	Symbol for "ATTENTION,CONSULT ACCOMPANYING DOCUMENTS" .		
4	€ 2862	After the adoption of the CE certification, CE mark is as following drawings. Its vertical height shall not be less than 5mm, clearly visible, clear, durable, the CE conformity assessment procedures are made by a Notified Body the Notified Body registration number should be the side of CE mark(Usually in the bottom right). The diameter of the CE marking should be not less than the 5MM semicircle of the two makes up, the XXXX at the lower right corner is the Notified Body identification number, such as the ITS-0473. All medical products sold in the EU market must identify the "CE". Affix the CE mark indicates that:  A. The equipment to meet the basic requirements of the MDR;  B. The equipment within the EU can be legally sold in the market;  C. The device has passed a the conformity assessment procedures.  The CE marks affixed to the medical devices have two types. That is, CE mark without Notified Body identification number and CE Mark with		

5	***	The Symbol for the Manufacturer (the "manufacturer" tag), the tag should contain the company name and address of the manufacturer.  Product manufacturers, EC represent the name and address of importers and/or distributors;
6	EC REP	Phoenix Medtech GmbH Koenigsberger Strasse 11, 64839, Muenster Hessen, Germany
7	X	The waste products should be handled legally.
8	<b>★</b>	BF devices
9	THIS SIDE UP	Upside
10	FRAGILE	Fragile
11	KEEP DRY	Keep dry
12		Stacking
13	SN	Devices serial number
14	IP21	Protected from touch by fingers and objects greater than 12 millimeters and protected from water spray less than 15 degrees from vertical.
15	MD	Indicates the item is a medical device

# Storage / Maintenance

- Use wet cloth or neutral cleanser to wipe the machine, and don't use volatile liquid to clean the machine, such as benzene, thinner or gasoline
- 2. keep it away from magnetic field and reach of children
- 3. keep the machine far away from moisture, high temperature, direct sunlight or sprinkling water
- If the electrode pads are insufficiently adhesive or dirty, please wipe with a wet colth or change new ones. Don't clean the electrode pads with any chemical
- please do not mantle, repair or rebuild the machine in private, or manufacturer will not guarantee to repair it and the after-sale services
- 6. if not use it for a long time, please remove the batteries from remote controller

## **Environmental protection**

Please make a rubbish classification after use, such as electrode pads, carton box and so on.

## **Specifications**

Model number: AST-300C

This equipment belongs to Type BF of Class II .



#### Shenzhen OSTO Medical Technology Company Limited

ADD: 2104, Unit4, Building2, Zhongxin Longsheng Square, Baolong Street, Longgang District, 518116 Shenzhen City, Guangdong Province, China ( € 2862

Phoenix Medtech GmbH
Koenigsberger Strasse 11,
64839, Muenster Hessen,
Germany

Rated: 5 V dc, 1000 mA

Powered by adaptor: HSMA05B-050100

Rated Voltage: 100-240V

Rated input: 0.1 A

Output waveform: Square wave

Pulse repetition frequencies: 10-100HZ Maximum amplitude of output voltage: 72V Software version No:MC0188F-REV-V1.0 Rated frequency: 50-60Hz Rated output: 5v 1000mA Pulse duration: 115 μS

Effect of load impedance:  $1K\Omega$ 

Operation condition:

10-40 C

30% RH ~ 75%RH

860 hPa to 1060 hPa

Store and transport condition:

0 - 40 C ≤80% RH

860 hPa to 1060 hPa

# 

Never stick two adhesive pads to each other.

Keep the adhesive gel pads clean, and never put them under high temperature and direct sunshine.

For protection the gel pads, always put it on to the gel pad protector after use.

Don't touch the gel of the pads by your figure, or it reduce the gel and lose its function.. Don't clean the electrode pads with hot water or any chemical.

If the electrode pads become soiled, the adhesive power may decrease and the skin might become irritated. If this situation happens, should moisten the surface of the pads with water and wipe away the soiled portion, this will allow a pad restoration of the adhesive poser. But it will lose the adhesive power if there is too much water. The best way is to purchase another pads.

The electrode pads has been passed the Biocompatibility test (Test report is SDFY-2006-2623. The test report shows that it does not induce any irritation to skin.

# **Trouble Shooting**

Questions	Reason	Solvent  Connect the wire correctly.  Remove the protective membrane of the pads	
No stimulation	If connect the wire? If remove the protective membrane? of the pads?		
Weak stimulation	If the pads stick to the skin tightly? If the pads stick overlapped? If the pads are dirty? If the intensity is weak? If the stick place not goods?	Stick the pads tightly.  Detach the pads, and stick again.  Clean the pads.  Adjust the intensity to be stronger.  Change the stick place.	
The skin become red and stingged	Therapy time is too long? The pads too dry? The pads are sticked too tightly? The pads are dirty? The pads are damaged?	Therapy time always be 10-15minutes once. Clean with the wet cloth, then use again. Stick the pads tightly to the skin. Clean the pads. Change the pads.	
The power cut off during therapy	The pads fall off from the skin? The wire connect cut off? No battery? The therapy time over?	Turn off the power, stick the pads again. Turn off the power, connect the pads again. Change new battery. The power will turn off after 15minutes therapy	

# **Description of Modes**

MODE	PATTERN
1	Accupuncture Pushing
2	Accupuncture
3	Accupuncture Kneading
4	Accupuncture Tapping
5	Scrapping
6	Squeezing
7	Massage
8	Pushing Massage
9	Pushing Squeezing
10	Accupuncture Squeezing
11	Accupuncture Hammering
12	Kneading
13	Thumping
14	Scrapping Pressing
15	Cupping
16	Body Shaping
17	Hammering
18	Massage Tapping
19	Pushing
20	Rolling Pounding
21	Squeezing
22	Stroke
23	Acupuncturetherapy Massage
24	Shiatsu
25	Rolling Kneading

# Electrode pads therapy usage example

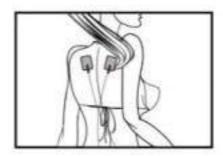
Shoulder, back

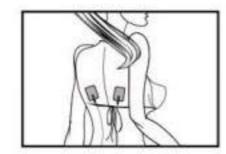
Symptom

Shoulder, back muscle ache, etc



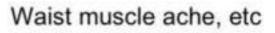
Cutlinc

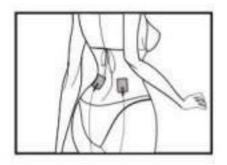




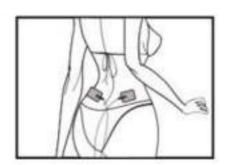
Waist

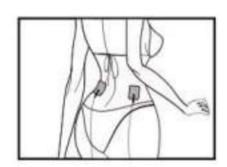
Symptom





Cutlinc



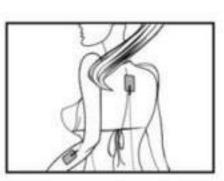


Arm

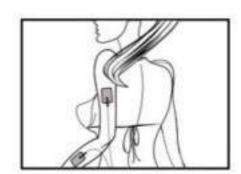
Symptom

Anm numb, muscle ache, etc







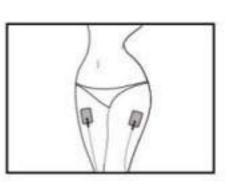


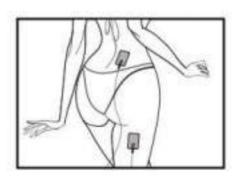
Leg

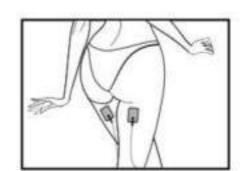
Symptom

Leg muscle ache, etc

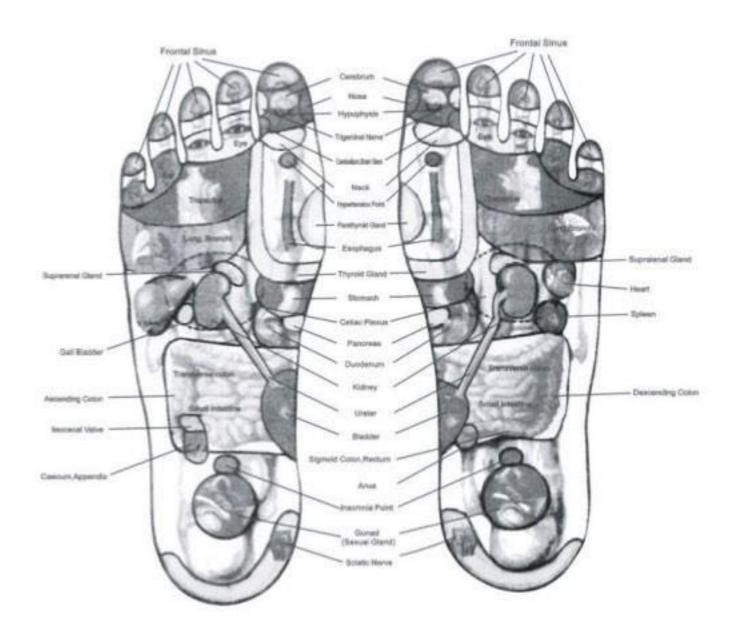
Cutlinc







# Diagram of the Reflexive Zones of the Feet



# Accompanying Documents:

#### Instructions for use

- AST-300C needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;
- 2. Portable and mobile RF communications equipment can affect AST-300C.

### **Technical description**

- Warning that the use of accessories, transducers and cables other than those specified with the exception of transducers and cables sold by the manufacturer of the AST-300C as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the AST-300C.
- 2. Warning that the AST-300C should not be used adjacent to or stacked with other equipment

3.

### Guidance and manufacturer's declaration - electromagnetic emissions

The AST-300C is intended for use in the electromagnetic environment specified below. The customer or the user of the AST-300C should assure that it is used in such an environment.

Emissions	Compliance	Electromagnetic environment guidance	
RF emissions CISPR 11	Group 1	The AST-300C 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 AST-300C is suitable for use in all establishments, including domestic establishments	
Harmonic emissions IEC 61000-3-2	Class A	and those directly connected to the public low-voltage power supply network that	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	<ul> <li>supplies buildings used for domestic purposes.</li> </ul>	

4.

### Guidance and manufacturer's declaration - electromagnetic immunity

The AST-300C is intended for use in the electromagnetic environment specified below. The customer or the user of the AST-300C should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environmentguidance
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	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) and neutral	±1 kV line(s) and neutral	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	± 2 kV line(s) to earth <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 5s	± 2 kV line(s) to earth <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 5s	Mains power quality should be that of a typical commercial or hospital environment. If a dips or an interruption of mains power occurs, the current of the AST-300C may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position the AST-300C image intensifier further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE UT is the a.c. mains voltage prior to application of the test level

5.

### Guidance and manufacturer's declaration - electromagnetic immunity

The AST-300C is intended for use in the electromagnetic environment specified below. The customer or the user of the AST-300C should assure 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the AST-300C, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance	
Radiated RF	3 V/m	3 V/m	d=1,2√P d=1,2√P 80 MHz to 800 MHz d=2,3√P 80 MHz to 2,5 GMHz	
IEC 61000-4-3 8	80 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 80 MHz and 800 MHz, 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 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 AST-300C is used exceeds the applicable RF compliance level above, the AST-300C should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AST-300C. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

6.

### Recommended separation distances between portable and mobile RF communications equipment and the AST-300C

The AST-300C is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AST-300C can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AST-300C as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d=1,2√P	80 MHz to 800 MHz d=1,2√P	800 MHz to 2.5 GHz d=2,3√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 metres (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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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 card

- we guarantee that the product is warranted against all defects for one year from the day of purchase without any charge for accessory or maintenance provided that the product is used correctly as instructed in the operation and instructions
- we charge for accessory cost only when the components are required to replace over 1 year and do not charge for maintenance
- please send the malfunction product to us or local dealers and we will pay immediate attention to it.

Valid for warranty 1 year after	the date of purchase
Purchase date:	
Consumer's Add:	
Consumer's Name:	
Consumer's Tel:	
Dealer Name:	
Dealer Add:	
Dealer Tel:	
Description:	