**Instruction Manual** 

2

6

8

Typical fluctuation within a day

(Measured every five minutes)

⚠ Caution

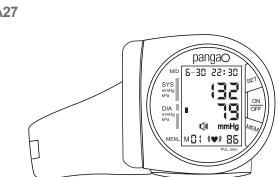
Shenzhen Pango Medical Electronics Co., Ltd Main Site: Building 2, No. 25 Fenghuang Road, Industrial Zone, Xikeng First Village, Henggang Street, Longgang District, Shenzhen, 518115 Guangdong, P. R. China. Additional site I: 2-4 Floor ,No.5 Shanzhuang Rd., Xikeng Village, Henggang Town, Longgang District, Shenzhen,

Tel:+86-755-33825988 Fax:+86-755-33825989

518115 Guangdong, P. R. China.

EC REP Lotus NL B.V. Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands, Tel: +31644168999

**MODEL: PG-800A27** 



**TABLE OF CONTENTS** INTRODUCTION..... 1

C E 2862 Date: 2023-04-13 Rev:A/2

INTRODUCTION

NOTES ON SAFETY......2 ABOUT BLOOD PRESSURE......6 PRECAUTIONS BEFORE USE......8 FEATURES OF THE PRODUCT......9 PARTS IDENTIFICATION......10 INSERT OR REPLACE BATTERIES.....11 TIME AND VOICE ON/OFF OF SYSTEM SETUP......12 UNIT CONVERSION mmHg/kPa DISPLAY......13 WHO BLOOD PRESSURE CLASSIFICATION DISPLAY......14 ATTACHING THE ARM CUFF.......15 HOW TO MEASURE BLOOD PRESSURE......16 TROUBLESHOOTING......20 

The **1** icon indicates something that is compulsory (what must always

Matters involving actual compulsory actions are indicated by text or

The Monitor uses the oscillometric method of blood pressure measurement. Measurement Automatic Electronic Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate, with an air wrist cuff buckled around one's wrist according to the instructions in the "ATTACHING THE WRIST CUFF." The expected life of the product is 5 years. The product complies with the electromagnetic compatibility requirement of IEC 60601-1-2 and safety standards of IEC 60601-1 and performance of

IEC 80601-2-30 as specified in Regulation (EU)2017/745. **NOTES ON SAFETY** 

The warning signs and sample icons shown here are listed for your safe and correct use of the unit, so as to prevent injuries or damages to the device. \* The icons and meanings are as follow.

Examples of signs The ⊘ icon indicates prohibitions (what you should not do). Matters involving actual prohibitions are indicated by text or pictures in or near ○. The left icon refers to "general prohibition".

Patient must follow doctor's instruction and should not perform

Self-diagnosis of measured results and treatment are dangerous. The device should not be used to judge illness, first aid and continuously

self-judgment and self-treatment by the measuring result,

pictures in or near • .The left icon refers to "general compulsion". The 3 icon indicates something can't be disassembled or "Don' disassemble" Matters involving actual compulsory actions are indicated by text or pictures in or near \sqrt{s}. The left icon refers to "general prohibition". ∠!\\ Caution

Type BF Applied part **IP Classification: IP20 Consult instruction** Please refer to the for use instructions for use

Indicates a medical device that needs to be protected from moisture.

MD Indicates medical device

Contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and accessories. 3

avoid any injury to patient.

Do not smoke

Reduce salt and fat intake

Maintain proper weight

that the device is MR-unsafe:

The following

symbol indicates

monitor measuring. This device can not be used for Patient transport and surgical care .It can be used in household or fixed places only. Please press "on/off" button to stop work when you feel uncomfortable with the wrist, or if the air is inflating abnormally without stop. This device should not be used by children under 18 years old or people who cannot express their will, otherwise it will cause harm. Do not use the unit for purpose other than measuring blood pressure. May cause accident or trouble. Please do not use mobile phone around the device. Please do not use the device around the magnetic field.

The device is prohibited from being used during movement. Do not use the equipment in outdoor or shower rooms. Do not disassemble, repair, or remodel the main unit or the wrist cuff of the blood pressure monitor. Will cause the unit to function erroneously

-Not servicing and maintenance while the ME EQUIPMENT is in use. -The user can maintain the product, the maintenance method is described in the maintenance instructions of manual. -Stop using the equipment immediately, if it is in contact with water. **ABOUT BLOOD PRESSURE** 

-The PATIENT is an intended OPERATOR.

otherwise will cause extravasated blood. Do not measure your blood pressure over 6 times each day. Do not apply the cuff over a wound as this can cause further injury. Do not measure on the wrist which is on the side of a mastectomy, otherwise Observe the air pressure value from the LCD display. When measuring, it could not exceed 280 mmHg, otherwise Please press "on/off" button to stop Do not use force to bend the wrist cuff or the air tube. Do not knock or drop the main unit. Always use the specified accessories in the manual, the use of other parts not approved by the manufacturer may cause faults or injuries For service information, parts list etc., please contact the dealer. 5

Requests from Manufacturer

For any patient, do not measure more than 3 times continuously, it should be

at least above 5 minutes of interval rest between any two measurements,

Make sure there is no connection tubing kinking before start measuring to

1. What is blood pressure? Blood pressure is the force exerted by blood against the walls of the arteries. Systolic pressure occurs when the heart contracts. Diastolic pressure occurs when the heart expands. Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing in the morning while one is still at rest and before eating.

2. What is hypertension and how is it controlled?

hypertensive individuals, variations are

Normally, the blood pressure rises while at work or play and falls to its lowest

levels during sleep. So, do not be overly

Take measurements at the same time every

day using the procedure described in this manual, and know your normal blood pressure.

Many readings give a more comprehensive

3. WHO blood pressure classification display.

5. Automatically turns off (within 1 minute) to save power

values and measurement time.

concerned by the results of one

even more pronounced.

blood pressure history.

measurement.

Hypertension, an abnormally high arterial blood pressure, if left unattended, can cause many health problems including stroke and heart attack. Hypertension can be controlled by altering lifestyle, avoiding stress and with medication under a doctor's supervision. To prevent hypertension or keep it under control:

mmHg

3. Why measure blood pressure at home? Blood pressure measured at a clinic or doctor's office may cause apprehension and produce an elevated reading, 25 to 30 mmHg higher than that measured at home, Home measurement reduces the effects of outside influences on blood pressure readings, supplements the doctor's readings and provides a more accurate, complete blood pressure history. 4. WHO blood pressure classification Standards for assessment of high blood pressure, without regard to age, have Reference Material: Journal of Hypertension been established by the World Health 1999, Vol 17 No.2 Organization (WHO), and shown in mmHa Grade 3 hypertension (severe) chart below. Grade 2 hypertension (moderate)

95

High-normal

Exercise regularly

Have regular physical checkups

An individual's blood pressure varies greatly on a daily and seasonal basis. It may vary by 30 to 50 mmHg due to various conditions during the day. In

5. Blood pressure variations

diabetes, liver disease, hardening of the arteries, etc., there may be fluctuation in blood pressure values measured at the upper arm versus at the wrist.

devices or turn them off.

90 85 120 130 140 150 160 170 180 2. For people with irregular or unstable peripheral circulation problems due to 3. Measurements may be impaired if this device is used near televisions, microwave Be sure to note date and time when recording your blood pressure. Consult your doctor to interpret your blood pressure data. PRECAUTIONS BEFORE USE 1. If you are taking medication, consult with your doctor to determine the most appropriate time to measure your blood pressure. NEVER change a prescribed medication without first consulting with your doctor.

4. Easy to use, Press a button to automatically measure, record the measurement

PARTS IDENTIFICATION

Systolic Blood pres

LCD Display

4. Before using, should wash your hands. 5. Do not measure on the arm which simultaneously used monitoring ME Equipment, otherwise it could cause loss of function. 6. Consult your doctor if the unexpected readings are obtained, also please refer to "Trouble shooting" of the manual. 7. The reading is probably a little lower than measured in the hospital due to the steady mood at home. 8.Cuff pressure range 0-299mmHg

ovens, X-ray, mobile phone equipment or other devices with strong electrical fields.

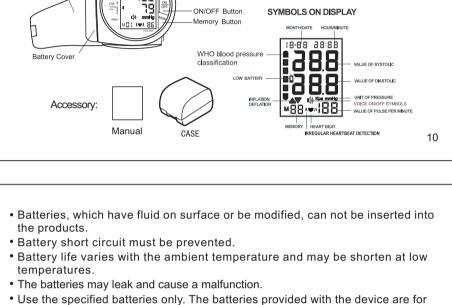
To prevent such interference, use the monitor at a sufficient distance from such

FEATURES OF THE PRODUC 1. Memory can store 90 measurements. 2. Large and clear LCD display 9

2. Insert new batteries into the battery compartment as shown, taking care that the

**INSERT OR REPLACE BATTERIES** 1. Remove the battery cover.

polarities(+) and (-)are correct.



the authorized collecting party subject to the regulation of each individual territory.

3. Close the battery cover, Use only LR03, AAA batteries.

CAUTION • Insert the batteries as shown in the battery compartment. If not, the device will not work. • When 🗓 (LOW BATTERY mark) blinks in the display, replace all batteries with new ones. Do not mix old and new batteries. It may shorten the battery life, or cause the

device to malfunction. (LOW BATTERY mark) does not appear when the batteries run out. when replacing batteries 11

year

1. Fastening the wrist cuff

level as your heart.

15

in the figure at the right.

measure on a bare wrist. 2. How to take proper measurements

2) Fasten the wrist cuff tightly by using the Velcro Strip. For proper measurements, fasten the wrist cuff tightly and

For best accuracy in blood pressure measurement: • Sit comfortably at a table. Rest your wrist on the table.

Relax for about 5 to 10 minutes before measurement.

• Raise your hand so that the wrist cuff is at the same

• Remain still and keep quiet during measurement.

month

• Please ensure to distinguish positive polar "+" and negative polar "-" of batteries

Disposal of empty battery to

minute/Voice (on/off) until setting completed (" In" is the On, " IF" is the Off) Non-talking model does not have this function, or you may choose method No.2 to set the voice

date

\* 00

hour

**"**-\0\0

ΟÑ

minute

4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/

\* If you are not going to use the unit for a long period of time (approximately three months or more), remove the batteries. \* Replace worn batteries with their polarities in the correct direction.

Used batteries may leak and damage the main unit. Pleases observe the following

testing monitor performance and may have a shorter life.

TIME AND VOICE ON/OFF OF SYSTEM SETUP 1. Press "SET" key to Time display. 2. In the off state, Press and hold "SET" key until the year number displays and flashes on LCD to enter setting mode.

3. Press "MEM" key to adjust the year, then press "SET" key again to save your setting and enter the month setting mode.

nomal boot unit values are shown as blood pressure. Also select memory unit value changes.

Diastolic blood pressure

Reference material: iournal of

The units will be chosen by the above shows mmHg/kPa after decontrol, After the

Grade 3 hypertension (severe)

Grade 2 hypertension (moderate)

14

16

18

20

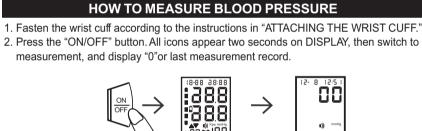
UNIT CONVERSION mmHg/kPa DISPLAY The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display units(mmHg factory to express). Press "ON / OFF" button for 10 seconds to display unit switching interface, then press "MEM" key to select mmHg / KPa, press "ON / OFF" button to exit. 13

ATTACHING THE WRIST CUFF

1) Wrap the wrist cuff around your wrist about (1-2)cm above your hand as shown

Grade 1 hypertension (mild) hypertension 1999. vol 17 No.2 High-normal Normal Optimal

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY



The mark(♥)will flash on LCD. When complete, the results will be displayed.

3. Start measurement, the cuff in the strap will automatically inflate.

58

• Do not measure left after physical exercise or a bath. • Measure your blood pressure at about the same time every day.

displayed regardless of period). Press "MEM" button, a memory reading out the latest measurements, "MEM" for the buttons(UP). "SET" button for the memory (DOWN) Power Measurement closure or after the end of the state .can press the "MEM" button read out the latest measurement of memory.

**READ MEMORY** 

Display: the latest 3 groups of memory average values (Memory values are

**DELETE MEMORY** 

Press " MEM " button to inquire memory average values " RUS "Average Value

∞0: 68 nol

display "П□" has been to delete all memory.

2.Do not fold the arm cuff too tightly.

Memory

Power supply:

Operating condition:

Storage condition:

Dimensions:

Classification

Wrist circumference

Weight:

E1:can't normally

Increase pressure

is used in such an environment.

Immunity test

Electrostatic

discharge

(ESD)IEC

61000-4-2

frequency

(50/60 Hz)

magnetic field

IEC 61000-4-8

Power

23

27

29

IEC 60601

test level

±8 kV contact

±2 kV, ±4 kV,

±8 kV, ±15KV

The state read out the memory press the (memory) button five seconds, the LCD

5. Store the device and the components in a clean and safe location. 6. The clean steps for the cuff is provided as following. Completely wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly. moistened with 75% Ethyl alcohol 3 times.

3. Clean the monitor with a soft dry cloth. Do not use any cleaning solution.

Remove the batteries if the unit will not be used for three months or longer. Always replace all the batteries with new ones at the same time.

to ensure proper function and performance.

\* See the Calibration Method for more details.

• This product is designed for use over an extended period of time; however, it is generally recommended that it be inspected and calibrated every two years

4.Do not submerge the device or any components in water

**CAUTION** 

**ERROR DISPLAY** 

Nothing is displayed When you push the

POWER button or

Battery icon flash

is used in such an environment

**Emissions** 

RF emissions

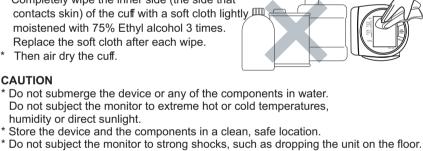
RF emissions

CISPR 11

CISPR 11

Harmonic

emissions



Measuring Method Oscillometric Measurement Digital LCD display Indication Pressure:(30~280)mmHg Measuring Range: Pulse:(40~199)Beat/min Static Pressure:  $\pm 3$ mmHg Pulse:  $\pm 5\%$ Accuracy:

2x1.5V Batteries(LR03or AAA)

+5°C~+40°C. 15%RH~93%RH Atmospheric pressure: 70kPa~106kPa

-20°C~+55°C. 0%RH~93%RH

Approx: 80(W)X73(H)X33(D)mm

Approx: 120g, excluding batteries

Atmospheric pressure:50kPa~106kPa

use alkaline battery, measure above 200 times.

Replace wrist cuff with new one

Electromagnetic environment-

quidance

Floors should be wood, concrete

or ceramic tile. If floors are covered

with synthetic material, the relative

humidity should be at least 30 %.

location in a typical commercial

Power frequency magnetic

fields should be at levels

characteristic of a typical

or hospital environment.

90 Memories

Type BF

(13.5~19.5)cm

Check your wrist cuff if any

air leakage

\* Specifications may be changed without notice in the event of improvement being made

SPECIFICATIONS

**CLEAN AND MAINTENANCE** 

1. Keep this device in the case provided with the device when you do not use it.

1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT. 2.Degree or protection against electric shock: TYPE BF APPLIED PART. 3. Mode of operation: CONTINUOUS OPERATION 4. Equipment not suitable for category AP&APG equipment use in presence. the system might not meet its performance specifications if stored or used outside the temperature and humidity as mentioned below: Operating conditions: +5°C~+40°C. 15%RH~93%RH 70kPa~106kPa Storage conditions: -20°C~+55°C. 0%RH~93%RH

**TROUBLE SHOOTING** 

**HOW TO CORRECT** 

Replace new batteries

Insert battery in the correct

Insert batteries

Electromagnetic environment-guidance

Pressure Monitor 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.

The PG-800A27 Series Electronic Blood

Pressure Monitor is used in home and it's

The PG-800A27 Series Electronic Blood

polarities

If you have trouble in using the unit please check the following points first.

POSSIBLE CAUSE

Battery worn out

placed wrongly

**Appendix 1 Guidance and Manufacturer Declaration Tables** 

Compliance

Group 1

Class B

N. A.

Guidance and manufacturer's declaration – electromagnetic emissions

The PG-800A27 Series Electronic Blood Pressure Monitor is intended for use in

the electromagnetic environment specified below. The customer or the user of the PG-800A27 Series Electronic Blood Pressure Monitor should assure that it

powered by DC 3V

No battery installation

The polarities of batteries

| E3 inflate pressure too high  | Pressure value of more than 299mmHg                      | Re-measurement or send back dealer for re-calibrate pressure                                      |  |
|---|--|---|--|
| E2E4:have shaking while measurement                                       | Hand or body shaking while measurement                   | keeping static and correct gesture to measure again   |  |
| Battery icon on   | Battery low power  | Replace battery and measure again   |  |
| The systolic pressure<br>Value or diastolic<br>Pressure value<br>too high | 1.The wrist cuff was held lower than your heart          |   |  |
|   | 2.The wrist cuff was not attached properly               | keeping correct position<br>and gesture to measure<br>again                                       |  |
|   | 3. You moved your body or spoke during measurement       |   |  |
| The systolic pressure<br>Value or diastolic<br>Pressure value<br>too low  | 1.The wrist cuff was held higher than your heart         |   |  |
|   | 2.you moved your body or<br>Spoke during measurement     |   |  |
|   |  |   |  |
|   |  |   |  |
| Guidance and manu   | facturer's declaration –                                 | electromagnetic immunity  |  |
| The PG-800A27 Series the electromagnetic er                               | s Electronic Blood Pressur<br>avironment specified belov | e Monitor is intended for use i<br>w. The customer or the user of<br>e Monitor should assure that |  |

Compliance

level

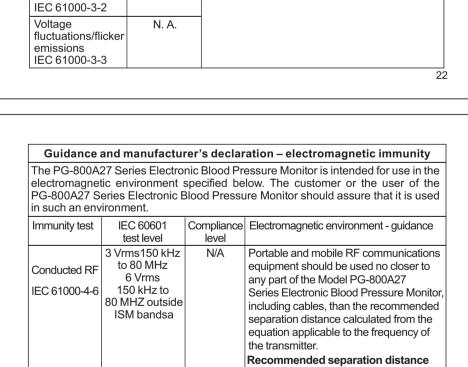
±8 kV contact

±2 kV, ±4 kV,

±8 kV, ±15 KV

30 A/m, 50/60Hz 30 A/m, 50/60Hz

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



| Radiated RF  | 10 V/m<br>80 MHz to 2.7 GHz | 10 V/m   | $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}  80 \text{MHz to } 800 \text{MHz}$  |
|--------------|-----------------------------|----------|--|
| EC 61000-4-3 | 80 NINZ to 2.7 GHZ          | 10 7/111 | $d = \left[\frac{7}{E_1}\right] \sqrt{P}  800 \text{MHz to } 2.7 \text{GHz}$   |
|              |                             |          | 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,<br>as determined by an electromagnetic site<br>survey, <sup>a</sup> should be less than the<br>compliance level in each frequency range <sup>b</sup> |
|              |                             |          | Interference may occur in the vicinity of equipment marked with the following symbol: (((•)))  |

c Field strengths from fixed transmitters, such as base stations for radio (cellular/

electromagnetic site survey should be considered. If the measured field strength

in the location in which the PG-800A27 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the PG-800A27 Series

Electronic Blood Pressure Monitor should be observed to verify normal operation.

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

MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges. 26

b The compliance levels in the ISM frequency bands between 150 kHz and 80

distance between portable and mobile RF communications equipment (transmitters) and the PG-800A27 Series Electronic Blood Pressure Monitor 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 | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz  $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ W 0.23 0.01 0.12 0.12

If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PG-800A27 Series Electronic Blood Pressure Monitor. d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. 0.73 0.38 0.38 0.1 Recommended separation distances between 1.2 1.2 2.3 1 portable and mobile RF communications equipment and the PG-800A27 Series 10 3.8 3.8 7.3 **Electronic Blood Pressure Monitor** 100 12 12 23

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. **CALIBRATION METHOD** 

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

1. Press and hold the "ON/OFF, MEM" button at the same time, load the battery, enter the static air pressure calibration mode after the LCD screen is fully displayed, and then release the button. 2. Press ON/OFF to close the internal air valve.

3. Connect the external standard barometric interface and the digital barometer

interface to the cuff interface.

⚠ Caution 1. ME devices can be used in exposed environments, including electromagnetic interference environment to ensure basic safety and basic performance unchanged. 2.In the event of any serious event related to this product, such as serious adverse

4. External input 50mmHg and 200mmHg standard static air pressure, and observe the

air pressure value displayed at the position of the LCD systolic pressure (SYS) and

the value of the digital pressure gauge should be in the range of +/-3mmHg.

event, significant alteration of the product resulting in change of intended use, etc., it will be reported to the manufacturer and the competent authorities of the user and/or the member states where the patient is located.

Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets the requirements of ISO 81060-2:2018. 102 30

Essential performance: Limits of the error of the manometer, ±3mmHg.Reproducibility of the blood pressure determination, ±3mmHq.

28

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 The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz: and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHZ, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and

The PG-800A27 Series Electronic Blood Pressure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PG-800A27 Series Electronic Blood Pressure

50,0 MHz to 54,0 MHz.

Monitor can help prevent electromagnetic interference by maintaining a minimum output of transmitter

Rated maximum