GIMA

PROFESSIONAL MEDICAL PRODUCTS

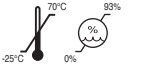
SFIGMOMANOMETRO DIGITALE AUTOMATICO DA BRACCIO

AUTOMATIC UPPER ARM BLOOD PRESSURE MONITOR

AUTOTENSIOMÈTRE BRACHIAL DE LA PRESSION ARTÉRIELLE

MONITOR AUTOMÁTICO DE BRAZO DE PRESIÓN SANGUÍNEA

IP22



REF **32924**

CE 0476

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M32924-M-Rev.5-02.22

Table of Contents

MEDICAL DISCLAIMER

This manual and product are not meant as a substitute for advice provided by your doctor. You are not to use the information contained herein, or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your healthcare provider.

INTENDED USE

This device uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate. The measurement position is at human being's arm. All values can be read out in one LCD panel. The device is designed for home use and recommended for use by adults aged 18 years and older with upper arm circumference ranging from 9 ~13" (approx. 23 ~ 33 cm).

ABOUT BLOOD PRESSURE

1. What is blood pressure?

Blood pressure is the measurement of the force of blood pushing against the walls of the arteries. Arterial blood pressure is constantly fluctuating during the course of the cardiac cycle. The highest pressure in the cycle is called the systolic blood pressure, and represents the pressure in the artery when the heart is beating. The lowest pressure is the diastolic blood pressure, and represents the pressure in the artery when the heart is at rest. Both the systolic and the diastolic pressure are necessary for a physician to evaluate the status of a patient's blood pressure.

Many factors such as physical activity, anxiety or the time of day, can influence your blood pressure. Blood pressure is typically low in the mornings and increases from the afternoon to the evening. It is on average lower in the summer and higher in the winter.

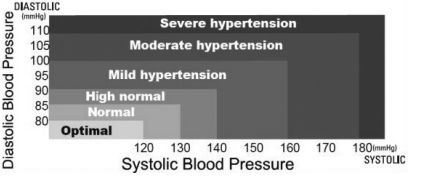
2. Why is it useful to measure blood pressure at home?

Having one's blood pressure measured by a doctor in a hospital or a clinic, is often associated with a phenomenon called "White Coat Hypertension" where the patient becomes nervous or anxious, thus raising his blood pressure. There are also numerous other factors that might cause your blood pressure to be raised at a specific time of day. This is why medical practitioners recommend home monitoring as it is important to get readings of blood pressure during different times of the day to really get an idea of your real blood pressure.

Medical practitioners generally recommend the "Rule of 3", where you are encouraged to take your blood pressure three times in a row (at 3-5 minutes interval), three times a day for three days. After three days you can average all the results and this will give you an accurate idea of what your blood pressure really is.

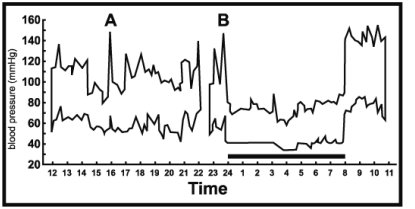
A. WHO blood pressure classifications:

Standards for assessment of high or low blood pressure without regard to age, have been established by the World Health Organization (WHO), as shown in the chart.
However this chart is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements.
Please consult with your physician for proper diagnosis.



B. Variations in blood pressure:

Individual blood pressures vary greatly both on a daily and a seasonal basis.
These variations are even more pronounced in hyper tense patients.
Normally the blood pressure rises while at work and is at its lowest during sleeping period.



(hyper tense: means a person who has high blood pressure symptom.)
The graph below illustrated the variations in blood pressure over a whole day with measurement taken every five minutes.
The thick line represents sleep. The rise in blood pressure at 4 PM (A in the graph) and 12 PM (B in the graph) correspond to an attack of pain.

PRECAUTIONS

* Do not use this manual and product as a substitute for advice, diagnosing or treating a health problem or prescribing any medication by your doctor. If you have a medical problem, promptly consult your healthcare provider.
* Read the Instruction Manual thoroughly before measuring and keep it at hand for your reference at any time.
* This device uses the oscillometric method to measure systolic and diastolic blood pressure as well as your heart rate. It's recommended for use by people over the age of 18 and not to be used on infant or children.
* The device is designed for home use and not suitable for clinical use.

- Do not take a measurement in a low (less than 41°F/5°C) and high (more than 104°F/40°C) temperature, nor in a place outside humidity ranges (15% ~ 93% R.H.), and atmospheric pressure ranges (700 ~ 1060 hPa) or you may get inaccurate readings.
- Wait 30 ~ 45 minutes before measurement if you've just consumed caffeinated beverages or smoked cigarettes.
- Rest at least 5 ~ 10 minutes before taking a measurement.
- To allow your blood vessels to return to the condition prior to taking the measurement, please wait at least 3 ~ 5 minutes in between measurements. You may need to adjust the wait time according to your personal physiological situation.
- We recommend you using the same arm (preferably the left arm) and measuring around the same time each day.
- Sit down comfortably and place your elbow on the table with your feet flat on the floor. Please do not cross your legs during measurements.
- Keep the device at heart level. Relax your hand with the palm facing up.
- Perform measurements in a quiet and relaxed environment at room temperature.

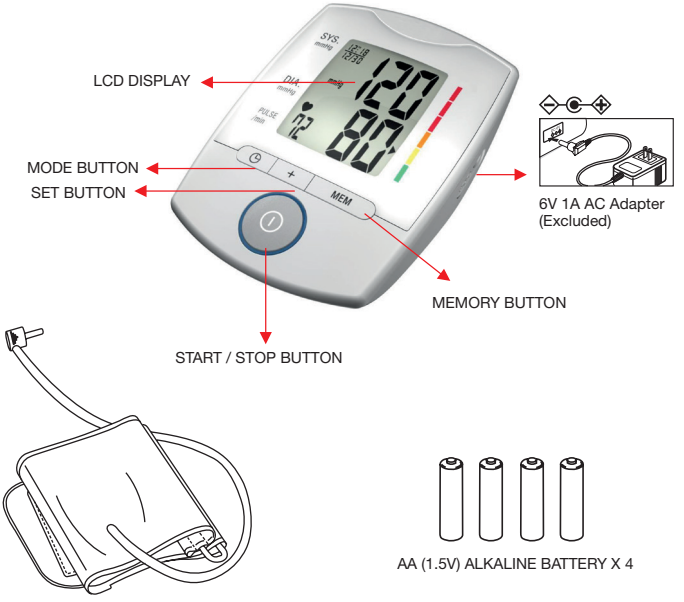
- Do not move or shake the device during a measurement. Please keep quite and do not talk at the same time.
- Keep in mind that blood pressure naturally varies from time to time throughout the day and is affected by lots of different factors such as stress, eating, smoking, alcohol consumption, medication, and physical activity, etc.
  Normally the blood pressure rises while at work and is at its lowest during sleeping period.
- Blood pressure measurements should be interpreted by a physician or a trained health professional who is familiar with your medical history. Using the unit and recording the results regularly for your physician to interpret, you will keep your physician informed of the continuing changes in your blood pressure.
- If you have one of the circulatory problems as arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension, peripheral circulation.., please consult your healthcare professional before using the device.
- This product is not suitable for people with arrhythmias and pregnant women.
- Blood pressure measurements taken with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultation method and are within the accuracy limits prescribed by the Standard of EN 1060-4.

Attention!

1. Do not use the device on infants, children, or those who cannot express their own intention.
2. The device is equipped with sensitive electronic components. While measuring, avoid strong electrical or electromagnetic fields, e.g. mobile phones, microwave ovens, etc; or it may lead to temporary reading error or inaccuracy.
3. To avoid accidental strangulation, keep this product away from children and do not drape tube around neck.
4. Over high frequency measurements may result in blood flow interference, which is likely to cause uncomfortable sensations, such as partial subcutaneous hemorrhage, or temporary numbness to your arm. In general, these symptoms should not last long. However, if you do not recover in time, please seek your medical practitioners for help.

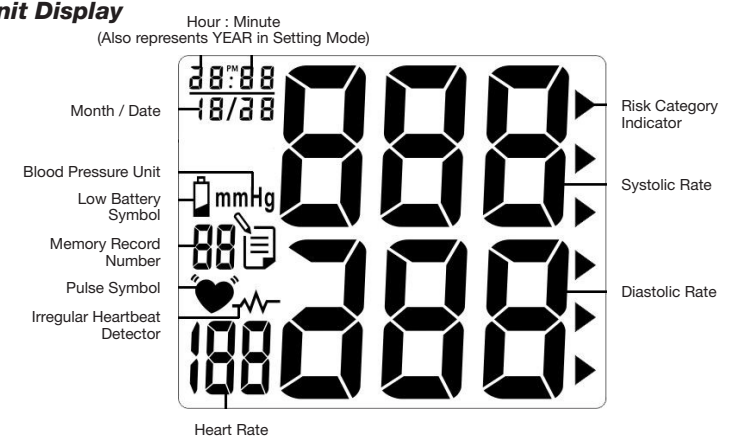
DEVICE OVERVIEW

Part names and product components



***Caution!**
Substitution of a component different from that supplied might result in measurement error.

Unit Display



SYMBOL DEFINITIONS

SYMBOLS	DEFINITIONS
Low Battery Symbol	This symbol appears when the battery power is excessively low or the polarity reverses. → We suggest you replace all batteries with new ones, and make sure the +/- polarities are properly positioned.
Pulse Symbol	Once pulse is detected, the symbol flashes with each pulse beat. → Our suggestion: Please do not talk or move during measurements.
Irregular Heartbeat Detector	This symbol appears for 1 minute when the user was talking, moving, shaking, or an irregular heart beat was detected during measurements. → Our suggestion: Please do not talk or move during measurements. Repeat the measurement after resting for at least 5 minutes, and restart your measurement while sitting down comfortably and quietly.
▶ BP Category Indicator	The arrowhead points out the specific BP Category that your measurement reading fits in.
Memory Record Symbol	Figures beside this symbol represent the order of memory stored.

FEATURES

Irregular Heartbeat Detector

The symbol  will appear on screen indicating a certain heartbeat irregularity was detected during measurement.
The heartbeat rhythm that is more than or less than 25% from the average rhythm is usually defined as an irregular heartbeat rhythm.
Talking, moving, shaking or an irregular pulse during the measurement can result in the appearance of this symbol.
Usually this is not a cause for concern, however if the symbol appears often, we recommend you seek medical advice.
And please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

***Note!**

- The pulse display is not suitable for checking the frequency of heart pacemakers. If a certain pulse irregularity is detected during measurement often, we recommend you seek medical advice
- As a safeguard, we recommend that if you have arrhythmias such as atrial or ventricular premature beats and atrial fibrillation or any other special conditions you should check with your physician before using your device.
- The IHB function is not designed for use by people with arrhythmias nor for diagnosing or treating an arrhythmic problem. In order to filter the unstable status of user and avoid affecting the detection of heart rate from any movement, shaking or talking in the beginning of measurement, the method of averaging heart beat intervals of subject device is calculated with the three proper heart beat pulses detected in the beginning of measurement and that is different from a strict mathematical averaging of all recorded intervals.
- At least 3 beats with at least 25% difference from the average heart beat interval will generate the IHB icon on the screen.

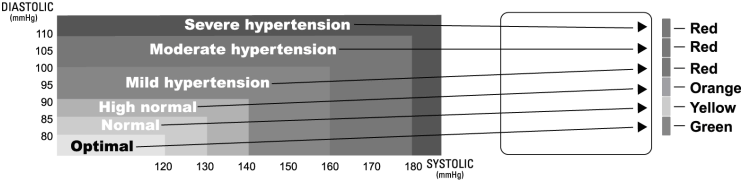
Risk Category Indicator

This device is equipped with Risk Category Indicator which classifies your blood pressure measurements into six stages (Optimal to Severe hypertension) as shown in below chart:

Stages of Blood Pressure Levels		Systolic (mmHg)	Diastolic (mmHg)	Color	Recommendations by SIGN n. 49: Hypertension in older people
Grade 3	Severe Hypertension	≥180	≥110	Red	Confirm immediately and repeat BP in one day and again within one week depending on clinical situation.
Grade 2	Moderate Hypertension	160 ~ 179	100 ~ 109	Red	Serial blood pressures repeated within one month.
Grade 1	Mild Hypertension	140 ~ 159	90 ~ 99	Red	Provide advice about lifestyle modification and confirm within two months.
High-Normal		130 ~ 139	85 ~ 89	Orange	Provide advice about lifestyle modification and recheck in one year.
Normal		120 ~ 129	80 ~ 84	Yellow	Recheck in 2 - 5 years. (patients aged > 75 years offered annual health check).
Optimal		< 120	< 80	Green	

Source: WHO 2003

After each measurement is completed, LCD display will show your position automatically on the six segments of the bar indicator which corresponds to Risk Category Indicator.



***Note!**

When a person's systolic and diastolic pressures fall into different categories, the higher category should apply.

e.g. systolic rate 181 & diastolic rate 99 → Red category (Severe Hypertension)

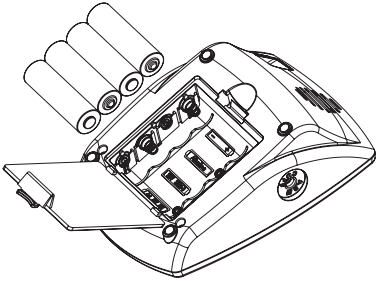
e.g. systolic rate 110 & diastolic rate 95 → Red category (Mild Hypertension)

***Note!**
The above table is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements.
Usually this is not a cause for concern; however we recommend you consult with your physician for proper diagnosis or seek medical advice according to our recommendation mentioned above. Please note that the device does not appropriate to diagnose hypertension, and it is only for user reference on blood pressure monitoring.

INSTALLING BATTERIES

When LOW BATTERY SYMBOL appears on the display, or nothing appears on the display when the power is switched on, please change the batteries.
Replace all the batteries with new ones and do not mix new and old batteries.
Do not mix alkaline, standard (carbon-zinc) or rechargeable (cadmium) batteries either.
It may shorten the battery life or cause the device to malfunction.

Remove the battery cover and insert 4 AA alkaline batteries into the battery compartment as shown.
Make sure the polarities "+" and "–" ends are properly positioned.



***Attention!**
- Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please take the used batteries to the recycling collection point according to your local regulations.
- Keep the battery away from small children in case they swallow it.
- To prolong the battery life and prevent damage caused by leakage, remove the batteries from the device if the device is not to be used for a long period.
- Memories (if any) will not be deleted during battery replacement.
- After replacing the batteries, reset the date and time.

USING THE AC/DC ADAPTER

This monitor is designed for operation with batteries or an AC/DC adapter.
Please use only a compatible AC/DC adapter with required voltage and current as indicated in this manual.

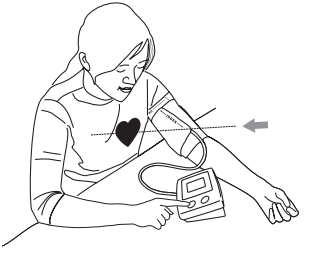
Note!
- No batteries are needed when operating with an AC/DC adapter.
- Please unload the batteries when operating with an AC/DC adapter for an extended period of time.
- Leaving the batteries in the compartment for a long time may cause leakage, which may lead to damage of the unit.
- Recommend Adapter specification, do not use otherwise:
  Model: SINPRO, HPU15-102 (optional)

Rating:
Input: 100 ~ 240V, AC, 47 ~ 63 Hz, 0.4 ~ 0.2 A
Output: 5.99V, DC, 2A,

Note!
When you use the blood pressure monitor with AC/DC adapter, do not position the device to make it difficult to disconnect the adapter plug.

APPLYING THE CUFF

- Press your brachial artery approximately 1 inch (2 ~ 3 cm) above the elbow on the inside of your left arm to determine where your strongest pulse is.
- Slide the end of arm cuff furthest from the tube through the metal ring to a loop. The smooth cloth should be on the inside of the cuff.
- Wrap the cuff on a bare arm or over thin clothing. Thick clothing or a rolled up sleeve will cause inaccurate blood pressure measurements.
- If the cuff is located correctly, the velcro will be on the outside of the cuff and metal ring will not touch your skin.
- Put left arm through the cuff loop.
  The bottom of the cuff should be approximately 1 inch (2 ~ 3 cm) above the inner elbow.
  The tube should lie over the brachial artery on the inner part of the arm.
- Pull the cuff so that the top and bottom edges are tightened around your arm.
- When the cuff is positioned properly, press the velcro firmly against the pile side of the cuff.
- Sit on a chair and lay your forearm on the table so that the cuff is at the same level as your heart.



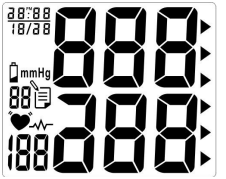
- Relax your arm and turn your arm upward.
- Make sure there are no kinks in the air tube.

***Note!**

- Fit the cuff snugly, leaving enough space for 1 inch (2 ~ 3 cm) between the inner elbow and the lower edge of the cuff, or the measurement may not be accurate.
- This monitor comes with one size of arm cuff: 9” ~ 13” (23 ~ 33 cm).
- In case the cuff kept pumping up non-stop, open the cuff at once.
- Do not wrap the cuff around any body part other than your arm.
- The device is not supposed to be used when your arm is wounded or injured.

MEASUREMENT PROCEDURE

Switch on the monitor



A. Press ⏻ button to switch on the monitor.
B. All segments appear on the screen.

Setting year, date and time

A. Press 🕒 button (“YEAR” flashes). Press + button to adjust YEAR value.
B. Press 🕒 button (“MONTH” flashes). Use + button to adjust MONTH (1, 2, 3,……, 12).
C. Adjust DATE (1, 2, 3,…, 31), HOUR (1, 2, 3,……..12PM,1PM,…, 12) and MINUTE (00,01,02,03,.....59) as described in Step A above.
When settings are done, press 🕒 button to confirm the entries.
The device is ready for use.

Taking a Measurement

A. Before measurement, press + button to select User 1, 2, or 3.

B. With the cuff wrapped around your arm, press ⏻ button to start measurement. All display units appear on the screen.

***Note!**
Do not inflate the cuff until it is wrapped around your arm.

After all symbols disappear, the display will show “00”. The monitor is “Ready to Measure” and will automatically inflate to the level that is right for you.

C. After inflation of the cuff, the pressure will slowly decrease.
When pulse is detected, PULSE SYMBOL ♥ flashes.

***N.B.!**
- If the cuff does not stop inflating, remove the cuff at once.
- To stop measurement, press ⏻ button.

D. LCD screen displays your systolic rate, diastolic rate, pulse, Risk Category Indicator Bar, and Irregular Heartbeat Detector symbol with date and time for 1 minute.

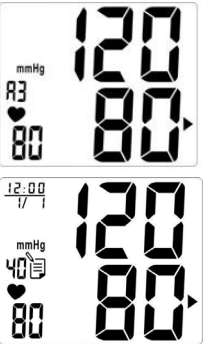
E. Without any operation for 1 minute, device automatically shuts off.

MEMORY FUNCTION

Storing data

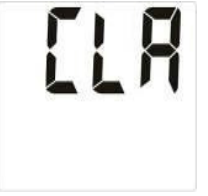
After each measurement, the systolic and diastolic pressure, heart rate with date and time will be automatically stored.
The monitor can store 120 memories total for 3 users, and automatically replace the oldest data with new one.

Recalling data



A. Press + button to select User 1, 2, or 3.
B. Press M button to enter Memory Mode. LCD displays average of last 3 measuring results first.
C. Press M button again, LCD displays the latest measuring result. Keep pressing M button, user can scroll through following measurements in sequence.
D. To stop reading memories, press ⏻ button, and switch to Standby Mode.

Erasing data



A. Press + button to select User 1, 2, or 3.
B. Press M button to enter Memory Mode.
C. Press and hold ⏲ and + buttons at the same time, the data will be erased automatically.
D. To confirm the data in the selected user has been erased, press M button and no data should appear.

Note: Once deleted, your data can NOT be restored.

STORAGE AND MAINTENANCE

General Use

- Do not in any way twist the cuff.
- Do not press ⏻ button if the cuff is not wrapped around your upper arm.
- Do not drop the product and avoid any strong impacts.

Maintenance

- Use a piece of cloth with water or mild cleansing agent to wipe the device and dry it immediately with a dry cloth.
- Do not use detergent or any strong chemicals to clean the device.
- Use only a dry cloth to wipe the cuff.
- Do not attempt to disassemble or change any parts of the monitor, including arm cuff, due to substitution of a component different from that supplied might result in measurement error.
- If any suggestion or service is requested, please consult your service station.

Disinfection

Use a piece of cloth with 75% alcohol to wipe the surface of the cuff for 10 seconds.

Storage

- If the device is not to be used for a long time, please remove the batteries from the device (leaking of battery acid can cause the device to malfunction).
- Always store the unit in the storage case after use.
- Do not place the device directly under sunlight, in high temperature, or in humid or dusty places.
- Do not store the device in extremely low (less than –13°F/–25°C) and high (more than 158°F/70°C) temperature, nor in a place its humidity exceeds 93% R.H.

TROUBLESHOOTING

SYMBOLS/SYMPTOMS	CONDITIONS/CAUSES	INDICATION/CORRECTION
No power-on by pressing ⏻ button.	Worn-out batteries.	Replace them with 4 new AA alkaline batteries.
	Battery polarities have been positioned incorrectly.	Re-insert the batteries in the correct positions.
EE Measuring Error Symbol appears when blood pressure value displayed is excessively low or high.	Cuff has been placed incorrectly.	Wrap the cuff properly so that it is positioned correctly.
	Did you talk or move during measurement?	Measure again. Keep arm steady during measurement.
	Shaking of the arm with the cuff on.	
Measuring Error Symbol. E1	Air circuit abnormality. Cuff tube may not be plugged into monitor correctly.	Check cuff connection. Measure again.
Measuring Error Symbol. E2	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.
Measuring Error Symbol. E3	Error determining measurement data.	Measure again.

Note: If “EP” appears on the display, just return the device to your local distributor or importer.

SPECIFICATIONS

Model Number	32924
Measurement Method	Oscillometric
Measurement Range	Pressure: 0 ~ 300 mmHg Pulse: 40 ~ 199 Beats/Minute
Accuracy	Pressure: ± 3 mmHg Pulse: ± 5% Max.
Rated Range of Determination	40~280 mmHg
Inflation	Automatic Inflation (Air Pump)
Deflation	Automatic Air Release Control Valve
Display	Liquid Crystal Display
Memory	120 Memory Total for 3 Users
Unit Dimensions	5.51 x 4.09 x 1.97 inch (L x W x H) 140 x 104 x 50 mm (L x W x H)
Unit Weight	8.73 ± 0.35 oz (247.5 ± 10 g) (Cuff and Batteries Excluded)
Cuff Size	23 ~ 33 cm (9 ~ 13 inch)
Storage/ Transportation Environment	Temperature: -25°C ~ 70 C (-13°F ~ 158°F) Humidity: ≤ 93% R.H. Atmospheric pressure: 700 hPa ~ 1060 hPa
Operation Environment	Temperature: 5°C ~ 40°C (41°F ~ 104°F) Humidity: 15% ~ 93% R.H.
Power Supply	1. AA (1.5V) alkaline battery x 4 2. 6V 1A AC Adapter (Excluded)
Battery Life	Approx. 300 measurements
Power-saving Mode	Without any operation for 1 minute, device automatically shuts off
Accessories	4 AA Alkaline Batteries, Arm Cuff with Tube, Instruction Manual, Pouch
Product life	5 years (4 times per day)

***The contents of this manual and the specifications of the device covered by this manual are subject to change for improvement without notice.**

NOTE

This blood pressure monitor complies with the EC Directive and bears the CE mark This blood pressure monitor also complies with mainly following standards (included but not limited). CE 0476

Device information:

- Internally powered equipment.
- Not suitable for use in presence of flammable anesthetic mixture with air or with Oxygen or nitrous oxide.
- Continuous operation with short-time loading.

To avoid inaccurate results caused by electromagnetic interference between electrical and electronic equipments, do not use the device near a mobile phone or microwave oven. At least keep a maximum output power of 2 W yields and a distance 3.3m away from this equipment.

SYMBOLS

	Keep in a cool, dry place
	Keep away from sunlight
	Follow instructions for use
CE	Medical Device complies with Directive 93/42/EEC
REF	Product code
LOT	Lot number
SN	Serial number
	Manufacturer

	Temperature limit
	Date of manufacture
IP22	Covering Protection rate
	WEEE disposal
	Type BF applied part
	Humidity limitation
	Caution: read instructions (warnings) carefully

APPENDIX

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device 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's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT –GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	In the case of air discharge testing, the climatic conditions shall be within the following ranges: Ambient Temperature:15°C~35°C, Relative Humidity: 30%~60%.
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV 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 IEC 61000-4-5	AC Power port ±1 KV Line to Line	AC Power port ±1 KV Line to Line	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycle At 0°,45°, 90°, 135°, 180°, 225°, 270°and 315°. 0% U_T; 1 cycles 70% U_T; 25/30 cycles 0% U_T; 250/300 cycle	0% U_T; 0.5 cycle At 0°,45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycles 70% U_T; 25/30 cycles 0% U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Guidance and manufacturer's declaration – electromagnetic immunity
The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Conducted RF IEC 61000-4-6	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq.	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq.	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3 (Proximity fields from RF wireless communications equipment IEC 61000-4-3)	110 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	**Recommended separation distance** Considering to reduce the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = 6/d\ \sqrt{P}$ where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVELS in V/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: 

NOTA 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Test specifications for enclosure port immunity to RF wireless communications equipment.

Test frequency (MHz)	Modulation	IMMUNITY TEST LEVEL (V/m)
385	Pulse modulation 18 Hz	27
450	FM ± 5 kHz deviation 1kHz sine	28
710	Pulse modulation 217 Hz	9
745		
780		
810	Pulse modulation 18 Hz	28
870		
930		
1720	Pulse modulation 217 Hz	28
1845		
1970		
2450	Pulse modulation 217 Hz	28
5240	Pulse modulation 217 Hz	9
5500		
5785		
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m, the 1 m test distance is permitted by IEC 61000-4-3.		
a). The carrier shall be modulated using a 50% duty cycle square wave signal. b). AS an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.		

***Disposal**: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.