trister

Automatic Upper Arm Blood Pressure Monitor

Model: **TS 350BP**



Thank you for buying the Trister TS 350BP Auto Upper Arm Blood Pressure Monitor. The unit has been constructed using reliable circuitry and durable materials. Used properly, this unit will provide years of satisfactory use.

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 inch - 13 inch (approx. 23 cm - 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?

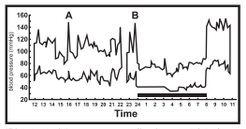
Having one's blood pressure measured by a doctor in a hospital or a clinic, is often associated with a phenomenon called "White Coat Hypertension" where the patient becomes nervous or anxious, thus raising his blood pressure. There are also numerous other factors that might cause your blood pressure 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 minute 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 AM (B in the graph) correspond to an attack of pain.



(Direct arterial pressure recording in unrestricted man
Beven, Honour & Stott: Clin. Sci. 36:329, 1969)

Precautions

* Read the Instruction Manual thoroughly before measuring and keep it at hand for your reference at any time.
* The device is designed for home use and not suitable for clinical use.
* This monitor is not intended for use in the MR environment.
* The applied part is cuff. The cuff needs to be wrapped around the upper arm (refer EN 60601-1 3.1 version 7.9.2.5 standard).
* The patient can operate this device by themselves and need not require the assistance of a physician or an operator (refer EN 60601-1 3.1 version 7.9.2.1 standard).

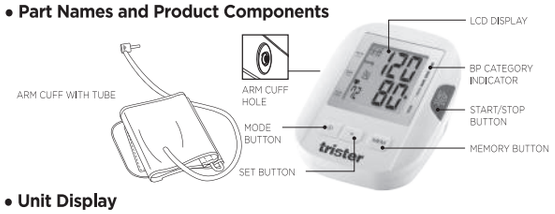
- Do not take a measurement in a low (less than 41 °F/ 5 °C) and high (more than 104 °F/ 40 °C) temperature, nor in a place outside humidity ranges (15 % - 93 % R.H.), and atmospheric pressure ranges (700 - 1060 hPa), or you may get inaccurate readings.
- Wait 30 - 45 minutes before measurement if you've 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.
- Perform measurements in a quiet and relaxed environment at room temperature.
- Do not move or shake the device during a measurement. Please keep quiet and do not talk during measurements.
- This product is not suitable for:
  - Pregnant women
  - People with arrhythmias
  - Undergoing intravenous injection on any limb
  - Currently in a dialysis treatment
  - In pre-eclampsia condition
- For those who have had mastectomy surgery (especially whose' lymph nodes removed), it's recommend take a measurement on the unaffected side.
- When used among medical electronic equipments on the same limb, pressurization of the cuff may cause temporarily malfunction to other devices.
- 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 device
- 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!**

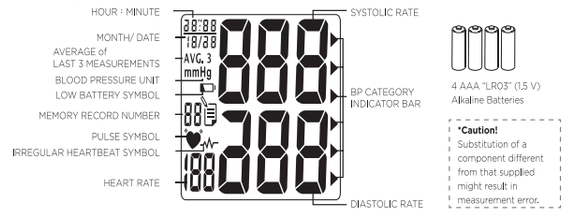
1. Do not use the device on infants, children, or those who cannot express their own intention. To avoid accidental strangulation, keep this product away from children and do not drape tube around neck.
2. The medical device should not used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary. The medical device should be observed to verify normal operation in the configuration in which it will be used.
3. Consider the electromagnetic compatibility of the device (ex. power disturbance, radio frequency interference etc.) Please use it indoor only.
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



• Unit Display



4 AAA "LR03" (1.5 V) Alkaline Batteries

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

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.
Measurement Number Symbol	This symbol goes along with figures according to the order of reading stored in the memory.
BP Category Indicator	The arrowhead points out the specific BP Category that your measurement reading fits in.
Average of Last 3 Measurements AVG. 3	Memory Average: Display average of last 3 readings

Features

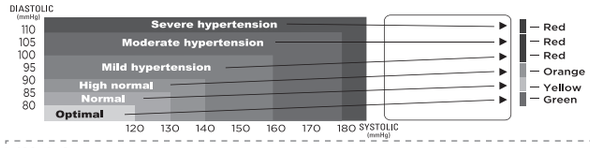
• BP Category Indicator

This device is equipped with BP 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 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.
Optimal		<120	<80	Green	(patients aged > 75 years offered annual health check)

. 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 BP 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.

• Irregular Heartbeat Detector

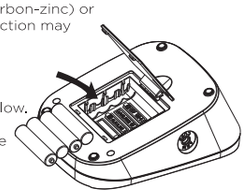
The symbol ♥ will appear on screen indicating a certain heartbeat irregularity was detected during measurement.
The heartbeat rhythm that is more than or less than 25% from the average rhythm is usually defined as an irregular heartbeat rhythm.
Talking, moving, shaking or an irregular pulse during the 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.

Installing Batteries

When LOW BATTERY SYMBOL appears on the display, or no reaction toward operation, please change batteries.
Replace all worn-out batteries with new ones and do not mix new and used batteries. Do not mix alkaline, standard (carbon-zinc) or rechargeable (cadmium) batteries either. Such action may shorten the battery life or cause the device to malfunction.
Slide the battery cover and insert 4 AAA (1.5 V, LR03) alkaline batteries into the battery compartment as shown on the figure below. Make sure the polarities "+" and "–" ends are coinciding with similar markings engraved on the battery housing.



***Attention!**

- Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please discard worn-out batteries to the recycling site according to local regulations.
- Keep the battery away from children in case they choke on 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.
- Replacing batteries clear all stored memory.
- After replacing the batteries, reset date and time.
- 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.
- Accuracy: In case it is needed to have the device checked for calibration, please consult the distributor.

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.
- 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 comfortably, put your feet flat on the floor and lay your forearm on the table, make sure your back and arm supported, legs uncrossed, 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.
- If you have any infectious skin disease or the device has been used by an
- infected person, please do not continue using the device.
- Before using the device, user should check the appearance of the cuff. If you notice blood or other dirt particles, please do not use this device. In case of any of the above mentioned circumstances, please dispose the device without reusing it.
- Do not use this device if your arm has any wound or injury, especially after surgery on the arm. It may cause infection at the surgical site. Please use the device after the wound has been healed.

Measurement Procedure

- **Switching on the monitor**
  Press START/STOP button to switch on the monitor.
- **Setting year, date and time**

A. To enter Setting Mode, press ⏲ button, then YEAR digit flashes. Use + button to select current year.
B. When above settings are done, press ⏲ button to adjust current MONTH. Press + button to select current MONTH.
C. Continue to set current DATE (varies from 1 to 31), HOUR (1, 2.....12PM, 1PM.....,12) and MINUTE (00,01.....,59) by following Step B.
D. Users can adjust YEAR-MONTH-DATE-HOUR-MINUTE in an orderly manner. Press ⏲ button to save the settings and switches to Standby Mode.



- **Taking a measurement**

A. Under Standby Mode, press + button to select User 1, 2, or 3.



B. With the cuff wrapped around your arm, press START/STOP button to confirm the chosen user and start measurement.

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



All display symbols appear on the screen for 1.5 seconds. 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 the initial inflation of the cuff, the pressure will slowly decrease and when a pulse is detected, PULSE SYMBOL ♥ will start flashing.

***Note!**
- This monitor will re-inflate automatically if the system detects that your body requires more pressure for measurement.
- If the cuff does not stop inflating, remove the cuff at once.
- To stop measurement, press START/STOP button to switch to Standby Mode.
- Standby Mode: Segments appeared, but not under BPM measuring.

D. When the measurement is finished, the systolic pressure, diastolic pressure, and heart rate with BP CATEGORY INDICATOR bar will be displayed for about 1 minute.
E. Device automatically shuts off if no operation over 1 minute.



Memory Function

• Storing data

After each measurement, the systolic and diastolic pressure, heart rate and BP Category Indicator bar with the time and date will be automatically stored. The monitor features 3 user memory capabilities. Each user holds the last 40 measurements, and automatically replacing the oldest data with new one.

• Recalling data



A. Press + button to select User 1, 2, or 3.
B. Press MEM button to enter Memory Mode.
If there is no data stored before, nothing (except month, date, and time) will appear on the display. If yes, the first reading will be the average of last 3 measurements.
C. Press MEM button to read the following measurements in sequence.
D. To stop reading the memories, press START/STOP button and switchto Standby Mode.

• Erasing data



A. Press + button to select User 1, 2, or 3.
B. Press MEM button to enter Memory Mode.
C. Press and hold ◷ and + buttons at the same time, all the data for the selected user will be erased automatically.

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 START/STOP 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.
- Disinfection - Use a piece of cloth with 75% alcohol to wipe the surface of the cuff for 30 seconds.
- Make sure the cuff is completely dry before using.
- 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 nearest service station.
- Do not implement the maintenance procedures for equipment during measurement.
- Only trained technicians are allowed to repair and dissemble the device including software upgrades, patches and maintenance.
- After cleaning / disinfection/ before use, please make sure that there are no blood stains or soil on the LCD, the device and cuff. If there is any blood stains or soil, please dispose the device without reuse.
- If it is used in a complex environment (such as a hospital) or after multiple people (non-family), please discard the old cuff and replace it with a new one.

***Note** !
- Water quality required for cleaning and disinfection: Tap water.

• 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. It is intended to be transported or stored in a carrying case between uses.
- Do not place the device directly under sunlight, in high temperature, or in humid or dusty places.

Troubleshooting

SYMBOLS/ SYMPTOMS	CONDITIONS/ CAUSES	INDICATION/ CORRECTION
Unit does not turn on when START/STOP button is pushed.	Worn-out batteries.	Replace them with four new AAA (1.5 V, LR03) 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.	
E1 Measuring Error Symbol	Air circuit abnormality. Cuff tube may not be plugged into monitor correctly.	Check cuff connection. Measure again.
E2 Measuring Error Symbol	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.
E3 Measuring Error Symbol	Can't determine blood pressure measurement data.	Wrap the cuff properly and keep steady. Measure again.
Note: If "EP" appears on the display, just return the device to your local distributor or importer.		

Limited Warranty

• Warranty For 5 Year from the manufacturing date

Please note that this warranty does not cover damage caused by misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; improper installation; unauthorized repairs or modifications; improper use of electrical/power supply; loss of power; dropped product; malfunction or damage of an operating part from failure to provide manufacturer's recommended maintenance; transportation damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of importers or distributors.

Specifications

Model Number	TS 350BP
Measurement Method	Oscillometric
Rated Range of Cuff Pressure	0-300 mmHg
Rated Range of Determination	40-280 mmHg
Measurement Range of Heart Rate	Pulse : 40 - 199 Beats / Minute
Accuracy	Pressure: 3 3 mmHg Pulse: 3 5 % Max.
Inflation	Automatic Inflation (Air Pump)
Deflation	Automatic Air Release Control Valve
Display	Liquid Crystal Display
Memory	120 Memory Total for 3 Users
Unit Dimensions	3.86 x 5.51 x 2.56 in (L x W x H) 98 x 140 x 65 mm (L x W x H)
Unit Weight	231 ±5g (8.15 oz ± 0.18 oz) (Cuff and batteries excluded)
Cuff Size	9 - 13 inch (23 - 33 cm)
Storage/ Transportation Environment	Temperature: -25 °C - 70 °C (-13 °F - 158 °F) Humidity: ≤ 93 % R.H.
Operation Environment	Temperature: 5 °C - 40 °C (41 °F - 104 °F) Humidity: 15 % - 93 % R.H. Atmospheric pressure: 700hPa - 1060hPa
Power Supply	DC 6 V, AAA "LR03" (1.5 V) Alkaline Battery x 4
Battery Life	Approx. 300 measurements
Product Life	5 Years (4 times per day)
Sleeping Mode	Without any operation for 1 minute, device automatically shuts off.
Accessories	4 AAA (LR03) Alkaline Batteries, Arm Cuff with Tube, Instruction Manual, Pouch

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

Note

CE 0197

This blood pressure monitor complies with the EC Directive (93/42/EEC) and bears the CE mark. This blood pressure monitor also complies with mainly following standards (included but not limited):

Safety standard:
EN 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EMC standard:
EN 60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard:
Electromagnetic disturbances - Requirements and tests.

Performance standards:
EN 1060-1 Non-invasive sphygmomanometers - Part 1: General requirements
EN 1060-3 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems.
EN 1060-4 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.
EN ISO 81060-1 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type. (partially applied)
IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Explanation of Symbols

Item	Explanation	Trister Information
CE	CE conformity marking	-
0197	Notified Body (NB) number	-
	Refer to instruction manual/ booklet	-
	TYPE BF Applied Part	-
	To avoid inaccurate results caused by electromagnetic interference	Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the device. Otherwise, degradation of the performance of this equipment could result.
	Waste of electrical and electronic equipment (WEEE)	-
	Manufacturer	Health & Life Co., Ltd 9F, No. 186, Jian Yi Road, Zhonghe District 23553, New Taipei City, Taiwan www.healthandlife.com.tw
	Date of Manufacture	YYYY-MM

Explanation of Symbols

Item	Explanation	Trister Information
EC REP	Authorized representative in the European Community	EC REP EMERGO EUROPE Prinsessegracht 20, 2514 AP The Hague, The Netherlands
SN	Serial number	SN YYMMXXXXXX
IP22	Ingress Protection Rating	First characteristic numeral- Degree of protection against access to hazardous parts and against solid foreign objects N1=2 (Protected against solid foreign objects of 12,5 mm Ø and greater) Second characteristic numeral- Degree of protection against ingress of water N2=2 (Protected against vertically falling water drops when ENCLOSURE tilted up to 15°)
1060 hPa / 700 hPa	Atmospheric pressure limitation	Atmospheric pressure: 700 hPa -1060 hPa
93 % / 15 %	Humidity limitation	R.H.: 15 % - 93 %
+40 °C (104 °F) / +5 °C (41 °F)	Temperature limit	Temperature: 5 °C - 40 °C (41 °F - 104 °F)
	Non-ionizing electromagnetic radiation	-

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

Manufacturer: HEALTH & LIFE CO., LTD.
9F, No. 186, Jian Yi Road, Zhonghe District, New Taipei City, Taiwan

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	
Harmonic emissions IEC 61000-3-2	Class A	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.
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 ± 15 kV air discharge	± 8 kV contact ± 15 kV air discharge	In the case of air discharge testing,theclimatic 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 power supply lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be a typical commercial or hospital environment.
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
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 a typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle At 0°,45°,90°,135°,180°, 225°,270°and 315°. 0 % UT; 1 cycles 70 % UT; 25/30 cycles 0 % UT; 250/300 cycle	0% UT; 0.5 cycle At 0°,45°,90°,135°,180°, 225°,270°and 315°. 0 % UT; 1 cycles 70 % UT; 25 cycles 0 % UT; 250 cycle	Mains power quality should be a typical commercial or hospital environment. If the user of the device requires continues operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Appendix

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.

• 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
Radiated RF IEC 61000-4-3 (Proximity fields from RF wireless communications equipment 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	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:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 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 3 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.

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