THOMSON
Healthcare

User Manual
Manuel d'utilisation

Connected Armt Blood Pressure Monitor /
Tensiomètre bras connecté

THOMSON TLS808

FRANCAIS

DESCRIPTION DU PRODUIT ET RECOMMENDATIONS

Ce tensiomètre bras est un appareil électronique, conçu pour mesurer la pression artérielle et le nombre de pulsations cardiaques à la minute d'une personne adulte

- Pour obtenir des mesures fiables, prendre sa tension au même moment dans la journée de façon fréquente et régulière, et éviter de manger, se baigner, fumer, avoir une activité physique, ingérer de la caféine ou de l'alcool dans les 30 minutes précédent la mesure
- Rester assis et relaxez vous au moins 5 minutes avant la mesure.
- Positionner son tensiomètre à hauteur du coeur pour prendre la mesure.
- Pour effectuer des mesures régulières, l'intervalle de repos entre deux mesures ne doit pas être inférieur à 30 secondes.
- Consulter toujours votre médecin pour l'interprétation de vos mesures et suivre toujours ses prescriptions.
- Ce tensiomètre peut être utilisé avec l'application Thomson Healthcare téléchargeable sur Apple store et Play store, application compatible avec l'application Santé d'Apple.

CONSEILS POUR LA MESURE

Les mesures peuvent être faussées si elles sont réalisées dans les conditions suivantes:

- Avoir bu ou mangé moins d'une heure avant d'effectuer la mesure
- Immédiatemment après avoir bu un café, un thé ou fumé une cigarette
- Dans les 20 minutes qui suivent la prise d'un bain
- En parlant ou en bougeant
- Dans un environnement très froid

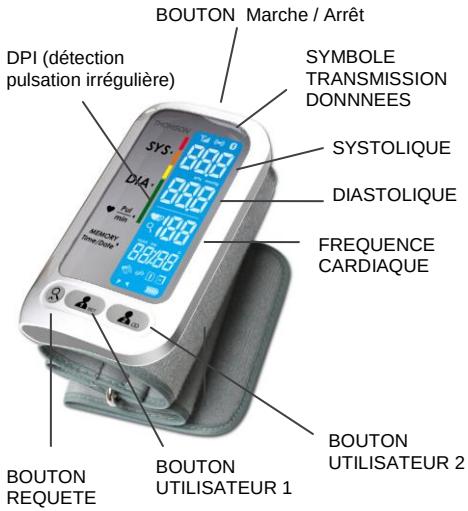
SECURITE

- Ce tensiomètre ne doit être utilisé que pour l'usage qui est prévu dans ce manuel d'utilisation.
- Consulter un médecin avant d'effectuer des mesures à votre domicile pour déterminer votre niveau de santé et de pression artérielle.
- Ne pas démarrer l'appareil si votre brassard n'est pas correctement fermé.
- Si votre brassard vous procure une quelconque gêne durant la mesure, éteindre votre appareil immédiatement en appuyant sur le bouton «USER »
- Enlever le velcro pour retirer le brassard si sa pression est supérieure à 300mmHg sans un rapide vidage automatique de l'air.
- Si vous rencontrez un problème de fonctionnement avec cet appareil, ne tentez pas de le réparer vous-même en le démontant.

ENTRETIEN

- Nettoyer l'appareil avec un linge légèrement humidifié par de l'eau puis essuyer le.
- Tenez le tensiomètre éloigné de l'eau et de toute source trop proche de chaleur, y compris l'exposition au soleil.
- Retirez les piles du tensiomètre si vous ne l'utilisez pas pendant une longue période.
- Eviter les vibrations et les chutes
- Ne pas essayer de nettoyer le brassard sous l'eau, ne jamais l'immerger

APERÇU



PREMIÈRE UTILISATION

- Utiliser l'adaptateur en le branchant à une prise secteur et en le connectant à la prise qui se trouve sur le dessus du tensiomètre afin de recharger la batterie Li-ion Polymère.
- Avant toute utilisation de l'appareil, assurez vous que le bouton marche/arrêt (ON/OFF) qui se trouve sur le dessus du tensiomètre est bien en position ON.
- Programmer la date, l'heure et l'unité de mesure

1. Appuyer sur le bouton „user 1" pendant 3 s jusqu'à ce que l'heure situé sur l'afficheur du tensiomètre clignote.
2. Appuyez ensuite sur le bouton de gauche „mode" pour régler l'heure, chaque appui faisant avancer celle ci de façon séquentielle
3. Afin de mémoriser l'heure choisie, appuyez à nouveau sur „user 1", ce qui déclenche également le mode de définition des minutes, qui se mettent à clignoter sur l'afficheur du tensiomètre.
4. Repeter l'étape 2 pour régler les minutes, appuyez sur „user 1" pour confirmer les minutes.
5. Répeter les étapes 2 et 3 pour ajuster le mois,les jours, l'année.
6. Répeter les étapes 2 et 3 pour confirmer l'unité de mesure.

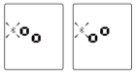
- Aprés la sélection et la mémorisation de l'unité de mesure, le LCD affichera „dOnE et l'appareil s'éteindra. Il est alors prêt à prendre des mesures.

APPAIREZ VOTRE TENSIOMÈTRE

1. Activez le Bluetooth de votre smartphone/tablette et ouvrez l'application Thomson Healthcare. Assurez vous que ces deux éléments fonctionnent lorsque l'appairage est en cours.
2. Démarrer l'application Thomson Healthcare sur votre smartphone/tablette

pour lancer l'appareillage avec le tensiomètre. Pour plus d'informations sur l'utilisation de l'application, rendez-vous sur www.thomson-hc.eu

3. Lorsque le tensiomètre est éteint, maintenez le bouton „user 2" (en bas à droite sur le tensiomètre) pendant 2 sec pour lancer l'appairage. Les symboles ci dessous apparaissent sur l'écran LCD de façon simultanées, ce qui indique que l'appairage est en cours.



Sur l'écran LCD, il apparaitra ensuite un des symboles suivant si:

L'appairage a fonctionné

L'appairage a échoué

Le tensiomètre s'éteint ensuite automatiquement.

POUR PRENDRE UNE MESURE

1- Retirez tous vos accessoires (collier, bracelet, etc.) de votre biceps gauche. Si votre médecin vous a diagnostiqué une circulation faible dans le bras gauche, utilisez votre bras droit.

2- Enroulez ou relevez votre manche afin d'exposer la peau à même le brassard.

3- Placez le bracelet gonflant à votre biceps à environ 2-3cm du coude, avec votre paume vers le haut.

4- Fixer le bracelet autour de votre biceps, en ne laissant pas d'espace entre le bracelet et la peau. Si le bracelet est trop lâche, la mesure ne sera pas précise.

5- Reposez vous 5 minutes avant de prendre la mesure.

6- Attendez au moins 3 minutes entre chaque mesure

7- Pour une comparaison significative, essayez de reproduire les mêmes conditions de mesure. Par exemple, prendre la mesure à peu près à la même heure, au même biceps ou avec l'assistance d'un médecin.

PRISE DE MESURE

Une fois le brassard enfilé autour du biceps, appuyez sur un des deux boutons „user" en fonction de l'utilisateur sélectionné.

Le processus de prise de mesure se fera automatiquement.

Cet appareil procèdera automatiquement à la transmission des données vers votre smartphone/tablette à l'issue des mesures. Le symbole „transmission" situé en haut de l'écran LCD clignote.

MÉMORISATION DES ENREGISTREMENTS

Appuyez sur la touche „Query" pour accéder à la mémoire puis sélectionner l'utilisateur dont vous souhaitez retrover les mesures stockées (User 1 ou User 2).
Appuyez à nouveau sur le bouton „query" pour visualiser l'une après l'autre l'ensemble des mesures. Le tensiomètre peut stocker jusqu'à 60 mesures pour chaque utilsateur.

SUPRESSION DES ENREGISTREMENTS

Pour supprimer un enregistrement de mesure, appuyez sur la touche „query" durant 3 secondes. Lorsque le message „dEL ALL" apparait sur l'écran LCD, appuyez à nouveau sur le bouton „Query".

RÉSOLUTION DES PROBLÈMES

L'écran s'obscurci ou ne s'allume pas: Vérifiez que les piles ne sont pas déchargées ou sont correctement installées. Si les piles sont vides, remplacez les 2 piles en même temps par de nouvelles piles.

La transmission de données a échoué: Assurez vous que la fonction Bluetooth de votre téléphone est allumée et que le téléphone soit à bonne distance du tensiomètre.

E1 : Le gonflement est lent ou le brassard n'est pas correctement positionné
Positionnez à nouveau le brassard puis procédez à une nouvelle mesure

E2 : Le brassard est trop serré
Desserrez le brassard puis reprenez la mesure

E3 : La pression du brassard est excessive
Positionnez à nouveau le brassard puis procédez à une nouvelle mesure

E5 /E6 : Une erreur système est survenue
Procédez à une nouvelle mesure. Si le problème persiste, contactez le détaillant ou notre service client afin d'obtenir de l'aide

E10 / E11 : L'appareil à détecté un mouvement lors de la mesure
Les mouvements peuvent influer sur la mesure. Relaxez-vous puis recommencez la mesure

E20 : Le pouls n'a pas été détecté lors de la prise de mesure
Desserrez le vêtement sur votre bras puis recommencez la mesure

E21 : Mesure incorrecte
Relaxez-vous un instant et recommencez la mesure

Ce tensiomètre est conforme aux normes de fabrication :

EN/ISO 14971:2007, EN 15223:2012, EN 1014:2008, EN 60601-1-11:2010, EN 1060-1:1995+A2:2009, EN 1060-3:1997+A2:2009, EN 1060-4:2004, EN 60601-1-2:2007/ac/2010? En 62304/2006:AC:2008, EN 60601-1-6:2010.

Représentant européen: MDSS – Medical Device Safety Service GmbH Schiffgraben 41, 30175 Hanover, Germany.

Fabriquant: Guangdong Transtek Medical Electronics Co.,Ltd.,

Importateur: Thomson HC – STAB –XTOM, Parc Lumière, 46 avenue des Frères Lumière, 78190 Trappes – France

Cet appareil est garanti 24 mois à partir de la date d'achat pour les vices de fabrication et sous condition d'utilisation normale

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ENGLISH

PRODUCT DESCRIPTION AND RECOMMENDATION

This arm blood pressure monitor is an electronic device intended to make human blood pressure and pulse rate at arm of adult population.

- In order to get reliable measurements, keep taking and recording blood pressure measurement at the same time every day and avoid eating, bathing, smoking, exercising, ingest caffeine or alcohol at least 30 minutes prior to take measurement.
- Be seated and relax for at least 5 minutes before measuring
- Make sure the cuff is at heart level for taking measurement
- To make repeated measurements, the rest interval between measurements shall not be less than 3 minutes.
- Consult your physicians for interpretation of blood pressure measurement and follow their direction.
- This blood pressure monitor could be used with Thomson healthcare app downloadable on Apple Store and Play Store. The app is also suitable with Apple Health Kit.

TIPS FOR MEASUREMENT

It can cause inaccuracy if the measurement is taken in the following circumstances:

- Within 1 hour after dinner or drinking
- Immediate measurement after tea, coffee, smoking
- Within 20 minutes after taking a bath
- When talking or moving your fingers
- In a very cold environment
- When you want to discharge urine

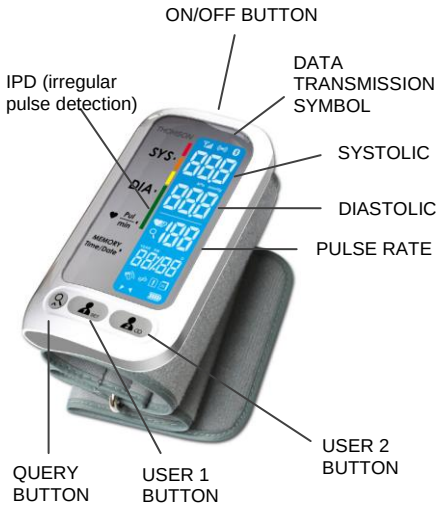
SECURITY

- This arm blood pressure monitor can be only used for which it has been designed as explained in the instruction booklet
- Consult your physician for health status and blood pressure range before taking measurement at home with this device
- Do not press the power button if the cuff has not been properly wrapped
- If the cuff causes you any discomfort during measurement, press the power button to turn off the device immediately
- Pull off the Velcro strap to detach the cuff if the cuff pressure exceeds 300mmHg without an automatic exhaust
- Do not modify or try to repair yourself this device

MAINTENANCE

- Clean your device with a soft dry cloth, lens with a cotton swab moistened with water then wipe it dry
- Do not store the device with direct sunlight and keep it away water
- Remove batteries from your device if you don't use for a long time

OVERVIEW



INITIAL START-UP

- Use the AC power adaptator by connecting to the blood pressure monitor to reload the Li-polymer battery.
- Before using the device, please make sure that the ON/OFF BUTTON is ON.
- Setting Date, Time and Measurement Unit
- Press the USER 1 BUTTON during 3 seconds until the hour on the left of the screen display starts to flash.
- Press the left button "mode" to set the hour. Each press is increasing the number of hour.
- To confirm the hour, press the USER 1 BUTTON then the numeral representing minute starts to blink.
- Repeat the previous steps to set the time.
- Repeat the previous steps to set the month, day, year.
- After confirming [YEAR], the LCD will display „dONE" and the monitor will shut off automatically

It's ready to take measurements.

PAIR-UP THE BPM WITH YOUR DEVICE

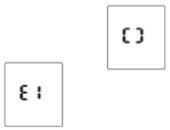
Turn on Bluetooth and the Thomson Healthcare app. Please make sure that both are working.

Launch the app to start the pair-up. For more informations about using the Thomson Healthcare app, please visit our website: www.thomson-hc.eu

When the monitor is OFF, press and hold the START button for 2 sec to start the pair-up. The following symbols appear on the display which means the pair-up is in progress.

Then, one of the two following symbols will appear :

If succeed
If fail



TO TAKE A MEASUREMENT

1- Remove all accessories (watch, bracelet, etc) from your left wrist. If your physician has diagnosed you with poor circulation in your left arm, use your right arm

2- Roll or push up your sleevse to expose the skin

3- Apply the cuff to your left wrist with your palm facing up

4- Position the edge of the cuff about 2-3 cm of the elbow with your palm up.

5- Fasten the arm cuff around your arm, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate

6- Resting for 5 minutes before measuring

7- Wait at least 3 minutes between measurements

8- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurement at approximately the same time, on the same arm, or as directed by a physician

START THE MEASUREMENT

Press START to turn ON the monitor then press your user button, it will complete the measurement process automatically.
This device will proceed to data transmission automatically after measurement. The Bluetooth symbol blinks.

RECALLING THE RECORDS

Press „QUERY" button to access to memory the select the user
Press "QUERY" again to visualize one by one all the measurements. The blood pressure monitor can store 60 measurements by user.

DELETING THE RECORDS

To delete a record, press the QUERY BUTTON during 3 seconds. When the message "dEL ALL" display on the screen, press QUERY BUTTON again.

TROUBLE SHOOTING

The display is dim or is not lighting up
Check out if the batteries are exhausted or inserted correctly. If they are exhausted, replace the 2 batteries at the same time with new one.
Data communication has failed
Make sure that phone's Bluetooth is on or within the distance range
E1 : Inflation is slow or the cuff is not secure
Refasten the cuff and then measure again
E2 : The cuff is very tight
Refasten the cuff ans then measure again
E3 : The pressure of the cuff is excess
Refasten the cuff and then measure again
E5 /E6 : System error occurred
Retake the measurement. If the problem persist, contact the retailer or our customer service department for assistance
E10 / E11 : The monitor detected motion while measuring
Movement can affect the measurement. Relax for a moment and then measure again
E20 : The measurement process does not detect the pulse signal
Loosen the clothing on the arm and then measure again
E21 : Measure incorrectly

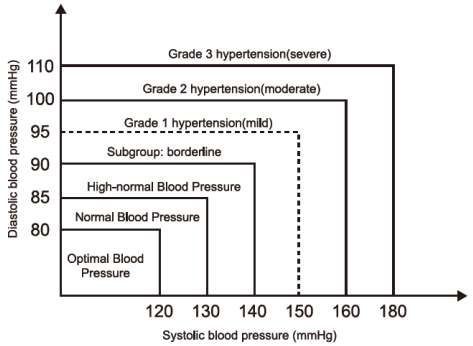
Relax for a moment ans then measure again

STANDARD BLOOD PRESSURE CLASSIFICATION

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:

CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Kindly note that only a physician could tell whether your blood pressure value has reached a dangerous point.



Blood Pressure (mm Hg) \ Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120-129	130-139	140-159	160-179	≥180
DIA	<80	80-84	85-89	90-99	100-109	≥110

IRREGULAR HEART BEAT DETECTOR

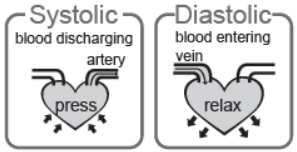
This Blood Pressure Monitor is equipped with an intelligent function of Irregular Heartbeat (IHB) Detector. During each measurement, this equipment records the heart beat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, this equipment will light up the IHB symbol on the screen when displaying the measuring result.

CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum alue in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies every in one day, it is also affected by the way you tie your cuff and the your measurement position, so please take the measurement at the same condition.
2. The varies of the pressure is greater if the person take medicine.
3. Waiting at least 3 minutes for another measurement

Why the blood pressure I get from the hospital is different from home?

The blood pressure is different even during 24 hour because of the weather, emotion, exercise etc, specially the “white coat” in hospital which makes the results are higher than the ones at home.
The attention need to pay when you measure your blood pressure at home:

- If the cuff is tie properly.
- If the cuff is too tight or too loose.
- If the cuff is tied on the upper arm.
- If you feel anxious pressured.

You had better take deep breath 2-3 times before beginning.

Advice: adjust yourself for 4-5 minutes until you calm down.

If the result is the same if measuring on the right arm?
It is ok for both arms, but there will be some different results for different arm, so suggest you measure the same arm every time.

COMPLIED EUROPEAN STANDARDS LIST

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	EN 60601-1: 2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC/EN 60601-1-11: 2010 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC/EN 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
Electromagnetic compatibility	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests
Performance requirements	EN 1060-1:1995+A2:2009 Non-invasive blood pressure Part 1: General requirements EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system
Clinical investigation	EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system interventional accuracy of the testing process
Usability	IEC/EN 60601-1-6: 2010 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC/EN 62366: 2007 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

EMC GUIDANCE

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	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.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	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. **Recommended separation distance** $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2,5 GHz where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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 re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.167\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.690	3.690	7.378
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, 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.			

COMPLIANCE

This blood pressure monitor is compliant with European certification:

EN/ISO 14971:2007, EN 15223:2012, EN 1014:2008, EN 60601-1-11:2010, EN 1060-1:1995+A2:2009, EN 1060-3:1997+A2:2009, EN 1060-4:2004, EN 60601-1-2:2007/ac/2010? En 62304/2006:AC:2008, EN 60601-1-6:2010.

- **European representative**: MDSS – Medical Device Safety Service GmbH Schiffgraben 41, 30175 Hanover, Germany.
- **Manufacturer**: Guangdong Transtek Medical Electronics Co.,Ltd.,
- **Importer** : Thomson HC – STAB –XTOM, Parc Lumière, 46 avenue des Frères Lumière, 78190 Trappes – France

WARRANTY

This device is guaranteed for 24 months from the date of purchase against manufacturer defect under normal use