GIMA

PROFESSIONAL MEDICAL PRODUCTS

SFIGMOMANOMETRO DIGITALE SENZA MERCURIO SU CARRELLO

DIGITAL SPHYGMOMANOMETER WITHOUT MERCURY ON CART

TENSIOMÈTRE NUMÉRIQUE SANS MERCURE AVEC PIED À ROULETTES

DIGITALES, QUECKSILBERFREIES BLUTDRUCKMESSGERÄT MIT STÄNDER

ESFIGMOMANÓMETRO DIGITAL SIN MERCURIO SOBRE CARRO

ESFIGMOMANÔMETRO DIGITAL SEM MERCÚRIO SOBRE RODAS

ΨΗΦΙΑΚΟ ΠΙΕΣΟΜΕΤΡΟ ΧΩΡΙΣ ΥΔΡΑΡΓΥΡΟ ΣΕ ΚΑΡΟΤΣΑΚΙ

جهاز رقمي لقياس الضغط الدموي بدون زئبق على عجلة

CE 0476

REF 32801

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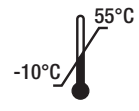
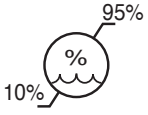
IP21





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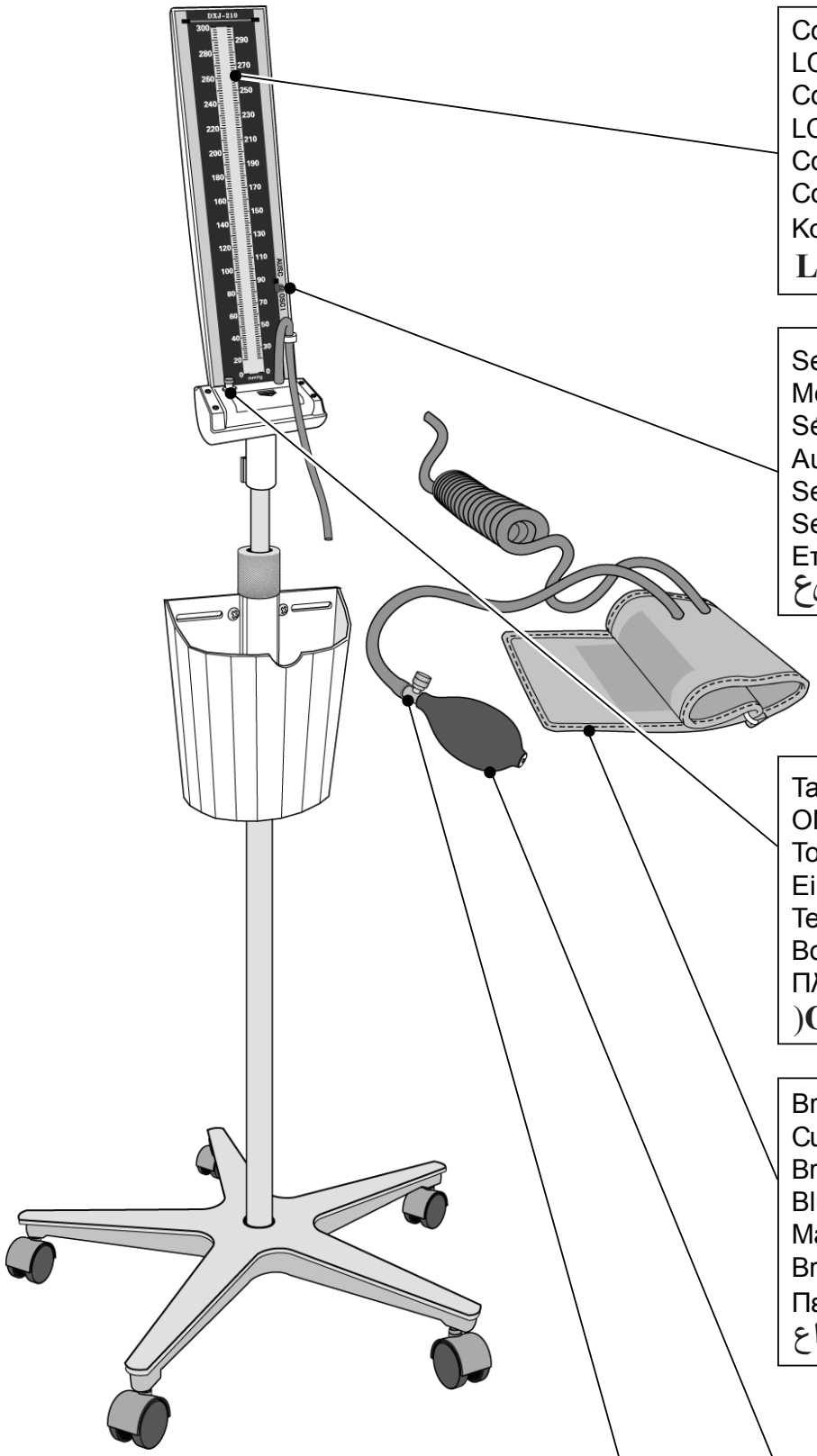


Colonna LCD
LCD column
Colonne LCD
LCD-Säule
Columna LCD
Coluna LCD
Κολόνα LCD
عامود LCD

Selettore modalità
Mode selector
Sélecteur de mode
Auswahl des Betriebsmodus
Selector de modalidad
Seletor de modalidade
Επιλογή λειτουργίας
محدد الوضع

Tasto di accensione/spegnimento
ON/OFF button
Touche marche/arrêt
Ein-/Ausschalttaste
Tecla de encendido/apagado
Botão ligar/desligar
Πλήκτρο έναρξης/σβησίματος
زر تشغيل/ إطفاء (ON/OFF)

Bracciale
Cuff
Brassard
Blutdruckmanschette
Manguito
Braçadeira
Περιβραχιόνιο
لفاف ذراع

Valvola di sfiato
Air release valve
Robinet de décompression
Luftablassventil
Válvula de desfogue
Válvula resfolegadoura
Βαλβίδα εξαερισμού
صمام تنفيس

Pompetta
Pump
Poire
Pumpe
Bombita
Bomba
Αντλία
صمام تنفيس

TECHNICAL FEATURES

The electronic sphygmomanometer without mercury is a control instrument for the measurement of blood pressure. Made out of ABS plastic and with an ergonomic design it assures precise measurements.
The reading of the values is made easier thanks to the double display (graduated and digital scale).
An LCD column replaces the mercury column thus avoiding possible leaks of mercury into the environment that could be dangerous for people also.
Display method: high definition LCD / digital display
Measurement range: 0-300mmHg (0-40kPa)
Precision: +/-3mmHg (+/-0.4IKpa)
Power supply: two “AA” alkaline batteries
Environmental conditions of use: 5-40° C, 30-85% RH
Environmental conditions for storage: -10 +55°C. 10-95% RH
Dimensions: Body: 360x96x66 mm
Cuff: from 22 to 33 cm

PRESCRIPTIONS

Do not use the equipment in case it is damaged. Apply to your retailer.
Avoid precarious repairs. Repairs shall be carried out with original spare parts only, which shall be installed according to the intended use.

Since the product is made of corrosion-proof materials suitable for the enviromental conditions foreseen for its normal use, does not require special care, however it is necessary to store it in a closed place making sure that is protected from dust and dirt to assure its hygenic conditions. Moreover, it is recommended to store the product in a place which can be reached easily by the personnel in case of necessity.

USE

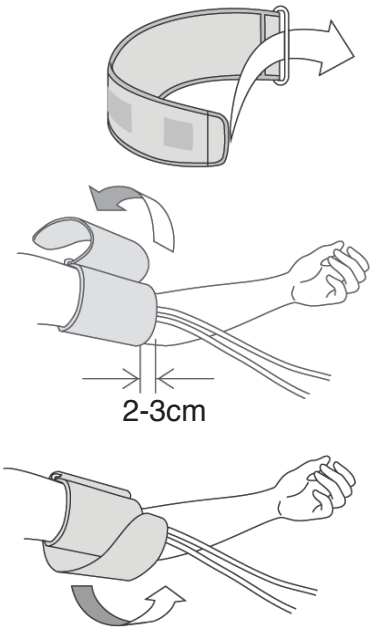
Always follow the indications of your doctor as concerns modalities and frequency of measurements.
Do not position the cuff on parts of the body other than the arm and do not use if not properly fastened.

Before the measurement

Perform measurement in a comfortable environment. Very hot or very cold temperatures could affect the measurement.
If drinks containing caffeine, such as coffee or cola, have been taken wait approx. 30-45 minutes. Do not smoke right before the measurement. Lay down and relax for approx. 10 minutes before starting the measurement.

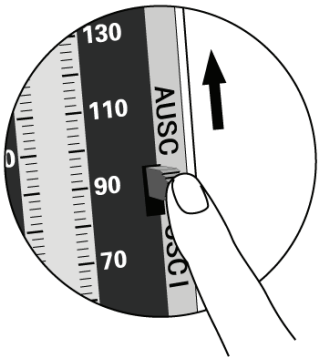
During the measurement

Sit down and stay still as much as possible during the measurement. Talking or moving may increase the value of the measurement. Do not cross legs and do not touch the cuff during the measurement.
To obtain proper results to compare, always measure the pressure on the same arm and possibly at the same time. We suggest measuring the blood pressure on the left arm.
To perform multiple measurements wait at least 10 minutes between each measurement.

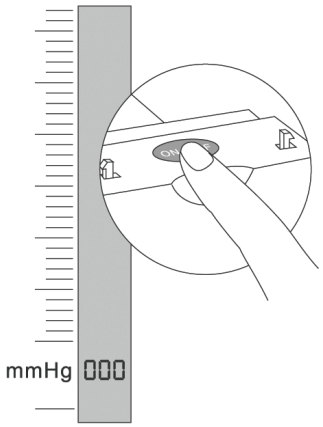


Fasten the cuff around the upper part of the arm. The cuff must be tightly fastened but not too tight. Remove anything that may block circulation (rolled-up sleeves or tight clothes). Make sure the cuff is at the same height of the heart.

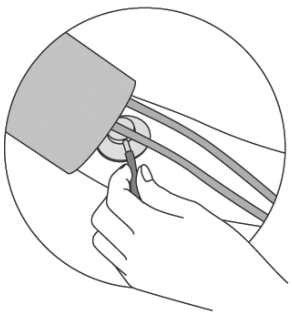
Auscultation Mode



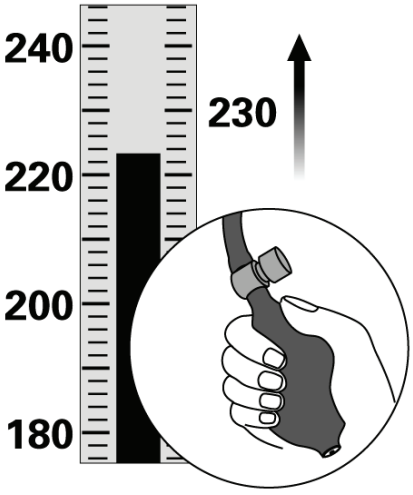
1. Set the mode selector to the high position (AUSC) to select the auscultation method of measurement.



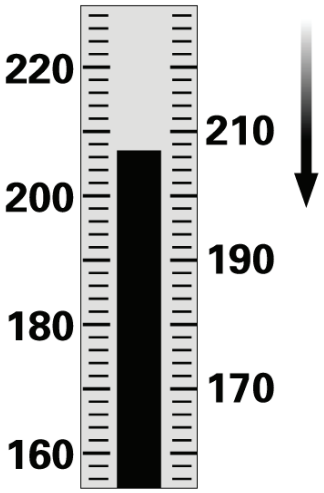
2. Press the ‘ON/OFF’ button. After the loading phase, ‘000’ will appear on the display and the LCD scale will be set to zero. The device has an auto-diagnosis function: if residual air is detected in the cuff, a flashing ‘P’ will appear. Once the residual air has been eliminated, ‘000’ will appear on the display.



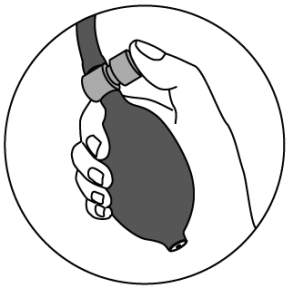
3. Insert the stethoscope’s bell into the cuff, positioning it over the brachial artery in the crook of the elbow.



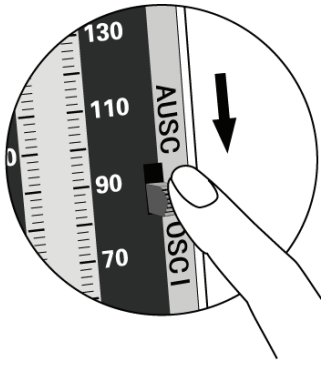
4. Close the air vent valve and start to inflate the cuff using the pump. When the indicator reaches a value higher than around 2.5~4.0 kPa (18.75~30 mmHg) compared to the normal systolic pressure, inflation can be stopped.



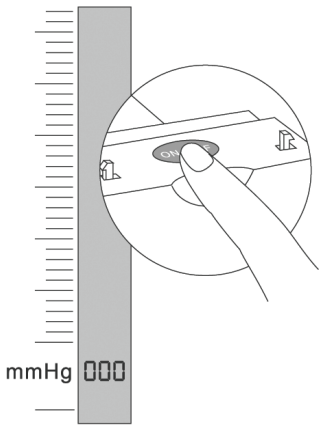
5. A the end of the inflation, the air vent valve will open automatically. Air is slowly released and the pressure decreases. The first pulsation detected by the stethoscope corresponds to the value of the 'systolic or maximum pressure' on the LCD column display. During decompression, the pulsations will continue and then decrease until they suddenly disappear or are so faint that they are imperceptible. The pressure shown when the pulsations disappear corresponds to the 'diastolic or minimum pressure'.



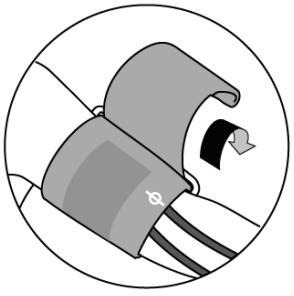
Oscillographic Mode



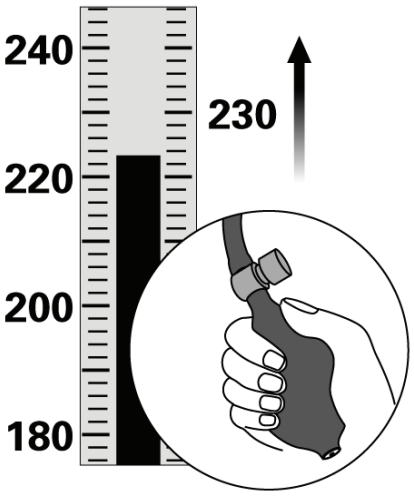
1. Set the mode selector to the low position (OSCI) to select the oscillographic method of measurement.



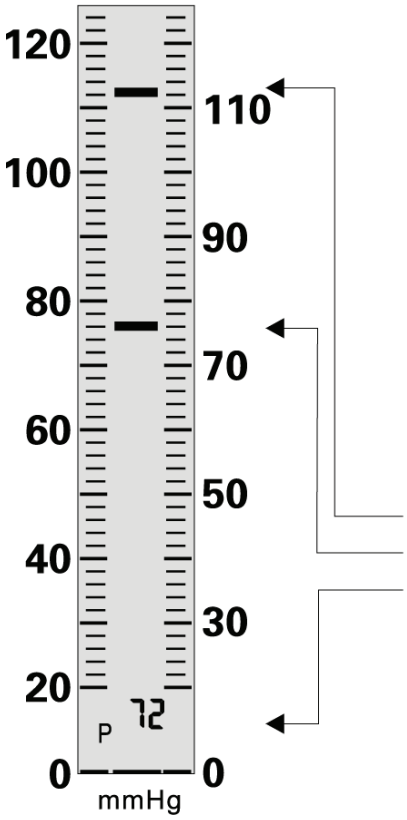
2. Press the 'ON/OFF' button. After the loading phase, '000' will appear on the display and the LCD scale will be set to zero. The device has an auto-diagnosis function: if residual air is detected in the cuff, a flashing 'P' will appear. Once the residual air has been eliminated, '000' will appear on the display.



3. Check that the symbol on the cuff is positioned in correspondence with the brachial artery, in the crook of the elbow.



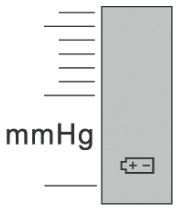
4. Close the air vent valve and start to inflate the cuff using the pump. When the indicator reaches a value higher than around 2.5~4.0 kPa (18.75~30 mmHg) compared to the normal systolic pressure, inflation can be stopped.



5. A the end of the inflation, the air vent valve will open automatically. Air is slowly released and the pressure decreases. The device will begin to measure the blood pressure and heart rate automatically.

SYS: 112 mmHg
DIA: 76 mmHg
PUL: 72 n/min

6. On the LCD column display 2 bars will appear. The bar on top is the 'systolic or maximum pressure' value, the bar at the bottom shows the 'diastolic pr minimum pressure'. The heart rate is shown on the number display, underneath the LCD column display.



* When the LCD display shows the symbol in the illustration it means the batteries are low and the sphygmomanometer cannot operate. Replace the "AA" alkaline batteries with two new ones.

After the measurement, completely open the valve to let the residual air out, remove the cuff, press the ON/OFF button to switch device off. (This device automatically switches off after five minutes).

Clean the cuff and place it in its case along with the tube which, to avoid damages, must not be tightly coiled up.

HOW TO STORE AND MAINTAIN THE DEVICE

Keep the product far from direct sunlight, humidity and rapid temperature changes.
Avoid crashes or falls.
Do not kept body detached from cuff and do not fix it in a place different from its stand. If you want to clean the device, use a soft dry cloth or a slightly damp cloth Do not use alcohol, benzene solvents or other aggressive chemical products to clean the device or cuff.
Before using the device, wash hands. Do not wash or wet the cuff or the pump.

Note: When the device is not used for a long period of time, remove the batteries because they could damage the device.

What is blood pressure?

Blood is sent to the arteries with the action of a pump called heart (contraction and dilation). The pressure of blood leaving the heart is called "blood pressure", Blood Pressure pulsate with each beat of the heart. The high blood pressure when the heart contracts are called "Systolic pressure" and the low blood pressure when the heart dilates is called "diastolic pressure", The threshold value for hypertension in adults is defined by the World Health Organization (WHO) as 140/90 mmHg.

Health and blood pressure!

When people reach middle age, the risk of hypertension markedly increase. With aging, the blood vessels age rapidly, Furthermore, because of the obesity and lack of exercise, cholesterols stick to blood vessels, causing them to lose elasticity, Therefore, watching daily blood pressure help to evaluate our health condition.

Why do we need to monitor blood pressure at home?

By recording the blood pressure values and the measuring conditions such as the measuring time or living state every day, you can know the fluctuation tendency of your blood pressure, which helps control your health. Furthermore, recording of daily blood pressure values is very helpful for your doctor to diagnose.

How to manage your Blood Pressure if it works unsuitable?

If correct measurement is impossible even after checking the above-mentioned points, consult at the store where you have purchased the unit or the nearest dealer without touching the internal mechanism.

In some very rare cases, there may be error due to the physical condition of the person. In such cases, please consult your doctor.

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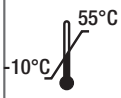
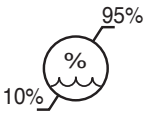
	Caution: read instructions (warnings) carefully		Follow instructions for use
	Keep in a cool, dry place		Keep away from sunlight
	Manufacturer		Date of manufacture
REF	Product code	LOT	Lot number
CE	Medical Device complies with Directive 93/42/EEC		WEEE disposal
	Type BF applied part	IP21	Covering Protection rate
	Store between -10 and 55°C		Moisture limitation 10% - 95%
	Direct Current		

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.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1

For all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration - electromagnetic emissions		
The arm type blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the arm type blood pressure monitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions EN 550 11	Group 1	The arm type blood pressure monitor uses RF energy only for its internal function. Therefor, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions EN 550 11	Class B	The arm type blood pressure monitor 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 6 domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Table 2

For all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The arm type blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the arm type blood pressure monitor 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%.
Electrostatic transient / burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	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 EN 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 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the arm type blood pressure monitor requires continued operation during power mains interruptions, it is recommended that the a rm type blood pressure monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/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.

Table 3

For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity

The arm type automatic blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the arm type blood pressure monitor should assure that it is used in such an environment

IMMUNITY test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the arm type blood pressure monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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 meters (m).[b] 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic 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 arm type blood pressure monitor is used exceeds the applicable RF compliance level above, the arm type blood pressure monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the arm type blood pressure monitor..
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the arm type blood pressure monitor

The arm type blood pressure monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the arm type blood pressure monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the arm type blood pressure monitor 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0,01	/	0,12	0,23
0,1	/	0,38	0,73
1	/	1,2	2,3
10	/	3,8	7,3
100	/	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.