

Sfigmomanometro elettronico
Electronic Sphygmomanometer
Sphygmomanomètre électronique
Esfigmomanómetro Electrónico
Esfigmomanómetro eletrônico
Elektronisches Sphygmomanometer
Sfigmomanometr elektroniczny
Sfigmotensiomietru electronic
Ηλεκτρονικό Πιστόμετρο
Elektronický sfgymomanometr
Elektronički sfigmomanometar
Elektronski sfigmomanometer
Elektronický tlakomer
Elektronikus vérnyomásmérő

Μέγιστο σφύζομα πίεσης

REF BK1018 (Gima 32797)

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ENGLISH

IMPORTANT SAFETY INSTRUCTIONS

Prior to utilizing this instrument, please ensure that you have read both the "Instruction Manual" and "IMPORTANT SAFETY INSTRUCTIONS" thoroughly to ensure proper usage. The safety precautions outlined in this section have been provided to guide you towards the correct utilization of this instrument and prevent any harm or injury to yourself or others. It is imperative that you adhere to all of the instructions and information provided in order to maintain safety.

- Intended use: measurement of human body blood pressure.
- As per the electric shock protection type: INTERNALLY POWERED EQUIPMENT.



- In terms of protection against water ingress: **IP21**.
- Mode of operation: CONTINUOUS OPERATION.
- It is imperative that the device is kept in a dry environment.
- Ensure that batteries are kept out of reach of children. In the event of accidental ingestion, please seek immediate medical attention.
- This instruction manual does not contain any technical documents, including circuit diagrams, component lists, or calibration. Customers must consult the manufacturer if such documents are required.
- The use of this device is not harmful, causes no irritation, and will not result in any allergic reactions.
- This device cannot replace a doctor's diagnosis.
- When the power is low, replace the batteries promptly. Otherwise it may cause inaccurate measurement results.
- If any serious incident happened, the users or patients shall report it to the manufacturer and the competent authority.

GENERAL INFORMATION
Product name: **Electronic Sphygmomanometer**
Intended purpose: The Electronic Sphygmomanometer is intended used to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.
Indication: Intermittent measurement of human body blood pressure from upper arm.
Intended patient population: Adults.
Intended use environment: Professional medical staff, lay persons.

Contraindications:

- The product can not be used for patients with arrhythmia.
- This product can not be used for infants, neonates or pregnancy.
- People who can not express himself can not use this product.

Clinical benefits: Measuring body blood pressure so as to help to diagnose human body conditions.
Intended use environment: Medical institute, home environment.
Shelf life: 3 years

SPECIFICATIONS

Unit	mmHg/kPa
Display mode	LED column and Digit LED display
Measurement mode	stethoscopy
Measurement range	Pressure: (0~300) mmHg (0~40) kPa Pulse rate: (30~200) beats/minute
Minimal scale	LED column: 2mmHg (0.26kPa); Numerical display: 1mmHg (0.13kPa)
Accuracy	Pressure: ±3mmHg (±0.4kPa) Pulse rate: within ±5%
Pressurization mode	Manual operation
Discharging mode	Manual operation by air releasing valve
Over pressure warning	When pressure is more than 315mmHg(42kPa), top of LED column flashes
power	DC4.5V; AA-size alkaline batteriesX3
Operating condition	Temperature: 10°C~40°C
Storage & transportation condition	Temperature: -20°C~55°C
Air pressure	500hPa-1060hPa
weight	Approx.584g(without cuff and battery)
Cuff size	480mmX145mm
Suitable for arm circumference	220mm~320mm
Protection against electric shock	Internally powered equipment, Type BF applied part.
Attachment	Cuff, inflation bulb, instruction manual

Operation
Open the upper cover of the machine and connect the short tube to the air intake hole located on the top of the battery box. Then, connect the other end of the tube to the bladder of the cuff. Put the batteries into the battery compartment. To begin using the machine, press the power switch ON/OFF and it will start working immediately without any waiting time.
The machine can display readings in either mmHg or kPa. When the machine is turned on, it displays readings in mmHg. To change it to kPa, press and hold the power switch for 3 seconds.
The machine has a background light. To conserve power, the light will automatically shut off if the pressure falls below 20mmHg and remains so for more than 5 minutes when using internal power supply. However, if the pressure remains above 20mmHg, the light will not shut off and will remain on until the power is switched off. If you need to delay the shut-off by 5 minutes, you should inflate the cuff to over 20mmHg and it will remain on for another 5 minutes.
The machine can also be used with external power supply through the USB port. In this case, the automatic shut-off function is disabled for both the background light and the machine.
The machine has two displays: an LED column and a numerical display. The LED column displays readings from 0 to 300mmHg (0-40kPa). When the pressure exceeds 315mmHg (42kPa), the top of the LED column will flash. In this case, the machine should be switched off; all air should be released from the cuff, and the machine should be restarted.
The numerical display shows a power signature "⊠", mmHg or kPa. If the "⊠" is displayed, it indicates that the battery needs to be replaced.

Measure instruction

- Before taking a blood pressure reading, it is important to relax for approximately 10-15 minutes and remain quiet and calm.
- When measuring, ensure that the LED horizontal stripe (—) and numerical display window (o) are both zeroed and stable.
- It is common practice to measure blood pressure on the right arm. To do so, remove any clothing that may obstruct the upper arm, and wrap the cuff around the arm evenly ensuring that it is positioned 2-3cm higher than the humerus. The tightness of the cuff should be appropriate, with one or two fingers' space between the cuff and arm. After placing the stethoscope on the elbow artery, charge the air in the bulb until it reaches 150mmHg-220mmHg (20-30kPa). Once the desired pressure is achieved, slowly release the air by loosening the air valve on the bulb. As the pressure drops, listen for the first clear pulse sound- this value will provide your systolic pressure reading. Continue to release the air until the pulse sound disappears or changes, which will give you your diastolic pressure reading. If pressure drops below 20mmHg (2.6kPa), the pulse rate will be shown on the numerical display window. It is important to deflate the cuff at a rate of 4-5mmHg/second for an accurate pulse rate.
- If you are unsure about the accuracy of your blood pressure reading, it is recommended to rest for 10-15 minutes and take another reading. If the blood pressure value is too high or low, it is abnormal, and seeking the advice of a medical professional for further examination is recommended.

General knowledge for blood pressure
With the prevalence of knowledge about medical and health care, sphygmomanometer has entered into thousands of families. Measuring blood pressure often will play a positive role on prevention of heart illness, head illness and blood vessel illness.

- Blood pressure
When blood flows in blood vessel, the pressure on blood vessel wall is called blood pressure. The blood pressure, which is generally called, is artery blood pressure. It is the power of pushing blood flowing in blood vessel.
- Systolic pressure: When the blood flows from heart into artery, pressure inside artery is highest which is called systolic pressure.(Also be called high pressure.)
- Diastolic pressure: When heart expands, because of the elasticity of blood vessel wall, blood remains to flow forwards. But the blood pressure will drop. The pressure is called diastolic pressure.(Also be called low pressure.)
- Pulse pressure: Margin pressure between systolic pressure and diastolic pressure is called pulse pressure.
- The normal value of blood pressure and Clinical advice on variation
The systolic pressure for healthy adult is between 90-140mmHg(12-18kPa) and diastolic pressure is between 60-90mmHg(8-12kPa). The pulse pressure is between 30-40mmHg(4-5.3kPa).
- The average blood pressure of children can be calculated as: agex2+80=systolic pressure(mmHg),2/3 of the systolic pressure is diastolic pressure.

The blood pressure rises with age. After 40 years old, if the age increases by 10 years old, systolic pressure will go up by 10mmHg(1.3kPa) whereas diastolic pressure is unchanged. The discrepancy between two arm's blood pressure value by 5-10mmHg(0.67-1.3kPa) margin is normal, in the condition of physiology, blood pressure is lower in the morning while it is higher in the evening, just after sports or finishing eating. The blood pressure drops slightly in hot environment whereas it raises a litter in cold environment. Moreover, being nervous, being excited,drinking alcoholic beverages and smoking will make blood pressure rise.

Hypertension
If systolic pressure is equal to or over 160mmHg(21.3kPa)and diastolic pressure is 95mmHg (12.6kPa), it can be defined as Hypertension.(If one of the above is verified, it is diagnosed as Hypertension.)
Critical Hypertension
The diastolic pressure is over 90mmHg (12kPa) below 95mmHg(12.6kPa) or systolic pressure i over 140mmHg(18.6kPa) below 160mmHg (21.3kPa), both of which are defined as Critical Hypertension. According to the past standard, Critical Hypertension remains Hypertension.

Maintenance and notice

- When charging, ensure that the pressure does not exceed 320mmHg (42kPa).
- Please take care not to damage the surface, bulb, and bladder with sharp-edged tools.
- Avoid placing the machine in direct sunlight, damp, dusty, or corrosive gas environments.
- When closing the case of the sphygmomanometer, please put the bulb and air release valve in the highest position of the case to prevent deformation.
- Clean the machine with a cotton cloth dipped in water or neutral detergent, followed by a dry cloth. Do not use naphtha, gas, or similar fluid for cleaning.
- If not using for an extended period, remove the battery to prevent leaks or malfunctions.
- Failure to follow the instructions and correct operation methods means that our company will not be held accountable for any related quality issues.

Appendix: EMC Standard Information.
Warning: BK1018 should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, BK1018 should be observed to verify normal operation in the configuration in which it will be used. BK1018 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the user manual; BK1018 in use may be susceptible to electromagnetic interference from portable and mobile RF communications such as mobile (cellular) telephones.

1.1 Guidance and Manufacturer's Declarations- Electromagnetic Emissions
BK1018 is intended for use in the electromagnetic environment specified below. The customer or user of BK1018 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment- Guidance
RF Emissions CISPR 11	Group 1	BK1018 uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	BK1018 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics Emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not applicable	

1.2 Guidance and Manufacturer's Declarations- Electromagnetic immunity
BK1018 is intended for use in the electromagnetic environment specified below. The customer or the user of BK1018 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%.
Power frequency (50/60Hz) 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.

BK1018 is not specified for use only in a shielded location and not a life-supporting device. The conducted RF and radiated RF testing is based on the standard below.

Immunity Test	IEC 60601 Test Level	Compliance Level
Conducted RF IEC 61000-4-6	3 V(rms)	3 V(rms)
Radiated RF IEC 61000-4-3	150 MHz to 80 MHz 3 V/m 80 MHz to 2.5GHz	3 V/m

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.

	IT - Data di fabbricazione GB - Date of manufacture FR - Date de fabrication ES - Fecha de fabricación PT - Data de fabrico DE - Herstellungsdatum PL - Data produkcji RO - Data fabricației GR - Ημερομηνία παραγωγής CZ - Datum výroby HR - Datum proizvodnje SI - Datum proizvodnje SK - Dátum výroby HU - Gyártás dátuma SA - تاريخ التصنيع
	IT - Fabbricante GB - Manufacturer FR - Fabricant ES - Fabricante PT - Fabricante DE - Hersteller PL - Producent RO - Producător GR - Παράγωγός CZ - Výrobce HR - Proizvođač SI - Proizvajalec SK - Výrobca HU - Gyártó SA - الشركة المصنعة
	IT - Conservare al riparo dalla luce solare GB - Keep away from sunlight FR - À conserver à l'abri de la lumière du soleil ES - Conservar el amparo de la luz solar PT - Guardar ao abrigo da luz solar DE - Vor Sonneneinstrahlung geschützt lagern PL - Przechowywać z dala od światła słonecznego RO - A se păstra ferit de razele soarelui GR - Κρατήστε το μακριά από ηλιακή ακτινοβολία CZ - Skladujte mimo slunečního světla HR - Čuvati zaštićeno od sunčeve svjetlosti SI - Hraniti zaščiteno pred sončno svetlobo SK - Skladujte mimo slnečného svetla HU - Napfénytől védve tárolandó SA - يحفظ بعيداً عن ضوء الشمس
	IT - Conservare in luogo fresco ed asciutto GB - Keep in a cool, dry place FR - À conserver dans un endroit frais et sec ES - Conservar en un lugar fresco y seco PT - Armazenar em local fresco e seco DE - An einem kühlen und trockenen Ort lagern PL - Przechowywać w suchym miejscu RO - A se păstra într-un loc răcoros și uscat GR - Διατηρείται σε όψροστο και στεγνό περιβάλλον CZ - Skladujte na větraném a suchém místě HR - Čuvati na hladnom i suhom mjestu SI - Hraniti na suhem in hladnem mestu SK - Skladujte na chladnom a suchom mieste HU - Száras, hűvös helyen tárolandó SA - يحفظ في مكان بارد وجاف
	IT - Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso GB - Caution: read instructions (warnings) carefully FR - Attention: lisez attentivement les instructions (avertissements) ES - Precaución: lea las instrucciones (advertencias) cuidadosamente PT - Cuidado: leia as instruções (avisos) cuidadosamente DE - Achtung: Anweisungen (Warnungen) sorgfältig lesen PL - Ostrzeżenie - Zobacz instrukcję obsługi RO - Atenție: Citii și respectați cu atenție instrucțiunile (avertismentele) de utilizare GR - Προσοχή: διαβάστε προσεκτικά τις οδηγίες (επιδείξεις) CZ - Pozor: Pečlivě si přečtěte a dodržujte pokyny (varování) k použití HR - Pozor: Pročitajte i pažljivo slijedite upute (upozorenja) za uporabu SI - Pozor: Pozornost si prečitajte a dodržujte pokyny na uporabi (vystrahy) HU - Figyelem: Figyelmesen olvassa el és kövesse a használati utasításokat (figyelmeztetéseket) SA - التحذير: قراءة التعليمات (التحذيرات) بعناية
	IT - Rappresentante autorizzato nella Comunità europea GB - Authorized representative in the European community FR - Représentant autorisé dans la Communauté européenne ES - Representante autorizado en la Comunidad Europea PT - Representante autorizado na União Europeia DE - Autorisierter Vertreter in der EG PL - Upoważniony przedstawiciel we Wspólnocie Europejskiej RO - Reprezentant autorizat pe teritoriul Comunității Europene GR - Εξουσιοδοτημένος αντιπροσωπός στην Ευρωπαϊκή Ένωση CZ - Zplnomocnený zástupca v Evropském společenství HR - Ovlašteni predstavnik u Europskoj zajednici SI - Pooblaščen zastopnik za Evropsko skupnost SK - Splnomocnený zástupca v Európskom spoločenstve HU - Meghatalmazott képviselő az Európai Közösségben SA - ممثل معتمد في الاتحاد الأوروبي
	IT - Seguire le istruzioni per l'uso GB - Follow instructions for use FR - Suivez les instructions d'utilisation ES - Siga las instrucciones de uso PT - Siga as instruções de uso DE - Folgen Sie den Anweisungen PL - Patrz podrecznik użytkownika RO - Respectați instrucțiunile de utilizare GR - Ακολουθήστε τις οδηγίες χρήσης CZ - Postupujte podle návodu k použití HR - Slijedite upute za uporabu SI - Upošteвайте navodila za uporabo SK - Postupujte podľa návodu na použitie HU - Kövesse a használati utasításokat SA - اتبع التعليمات للاستخدام
	IT - Dispositivo medico conforme al regolamento (UE) 2017/745 GB - Medical Device compliant with Regulation (EU) 2017/745 FR - Dispositif médical conforme au règlement (UE) 2017/745 ES - Producto sanitario conforme con el reglamento (UE) 2017/745 PT - Dispositivo médico em conformidade com o regulamento (UE) 2017/745 DE - Medizinprodukt im Sinne der Verordnung (EU) 2017/745 GR - Ιατρική συσκευή σύμφωνα με την ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 PL - Wyrob medyczny zgodny z Rozporządzeniem (UE) 2017/745 CZ - Zdravotnický prostředek v souladu s nařízením (EU) č. 2017/745 SE - Den medicintekniska produkten överensstämmer med förordning (EU) 2017/745 FI - Lääkinnällinen laite, joka vastaa asetusta (EU) 2017/745 SI - Medicinski pripomoček, skladen z uredbo (EU) 2017/745 SK - Zdravotnícka pomôcka v súlade s nariadením (EU) 2017/745 RO - Dispozitiv medical conform regulamentului (UE) 2017/745 NL - Medisch hulpmiddel in overeenstemming met verordening (EU) 2017/745 HR - Medicinski proizvod sukladan propisu (EU) 2017/745 HU - A 2017/745/EU rendeletnek megfelelő orvostechnikai eszköz DK - Medicinsk udstyr i overensstemmelse med forordning (EU) 2017/745 LT - Medicinos prietaisai, atitinkantis reglamentą (ES) 2017/745 LV - Medicīniska ierīce, kas atbilst Regulai (ES) 2017/745 EE - Määrusele (EU) 2017/745 vastav meditsiinisead SA - جهاز طبي يتوافق مع التوجيه (UE) 2017
	IT - Codice prodotto GB - Product code FR - Code produit ES - Código producto PT - Código produto DE - Erzeugniscode PL - Numer katalogowy RO - Cod produs GR - Κωδικός προϊόντος CZ - kód výrobku HR - Šifra proizvoda SI - Koda izdelka SK - Kód výrobku HU - Termékkód SA - كود المنتج
	IT - Numero di lotto GB - Lot number FR - Numéro de lot ES - Número de lote PT - Número de lote DE - Chargennummer PL - Kod partii RO - Număr de lot GR - Αριθμός παρτίδας CZ - Číslo šarže HR - Broj serije SI - Številka partije SK - Číslo šarže HU - Tételszám SA - رقم الدفعة
	IT - Parte applicata di tipo BF GB - Type BF applied part FR - Appareil de type BF ES - Aparelho de tipo BF PT - Aparato de tipo BF DE - Gerätetyp BF PL - Z częścią typu BF RO - Componentă aplicată de tip BF BR - Συσκευή τύπου BF CZ - Příložitá část typu BF HR - Prilimljeni dio tipa BF SI - Nameščeni del tipa BF SK - Aplikovaná časť typu BF HU - BF típusú alkalmazható rész SA - جهاز من النوع
	IT - Numero di serie GB - Serial number FR - Numéro de série ES - Número de serie PT - Número de série DE - Seriennummer PL - Numer seryjny RO - Număr de serie GR - Σειριακός αριθμός CZ - Sériové číslo HR - Serijski broj SI - Serijska številka SK - Číslo série HU - Sorozatszám SA - الرقم التسلسلي
	IT - Dispositivo medico GB - Medical Device FR - Dispositif médical ES - Producto sanitario PT - Dispositivo médico DE - Medizinprodukt PL - Wyrob medyczny RO - Dispozitiv medical GR - Ιατροτεχνολογικό προϊόν CZ - Zdravotnický prostředek HR - Medicinski uređaj SI - Medicinski pripomoček SK - Zdravotnícka pomôcka HU - Orvostechnikai eszköz SA - جهاز طبي
	IT - Grado di protezione dell'involucro GB - Covering Protection rate FR - Degré de protection de l'enveloppe ES - Tasa de protección de cobertura PT - Grau de proteção do invólucro DE - Deckungsschutzrate PL - Stopień ochrony obudowy RO - Grad de protecție asigurată prin carcasă GR - Δείκτης σκευασμάτων CZ - Stupeň krytí HR - Stupanj zaštite kućišta SI - Stopnja zaščite ohišja SK - Stupeň ochrany krytu HU - A csomagolás védelmi szintje SA - مؤشر الغلاظية
	IT - Smaltimento RAEE GB - WEEE disposal FR - Disposition DEEE ES - Disposición WEEE PT - Disposição REEE DE - Beseitigung WEEE PL - Oddzielna zbiórka dla tego urządzenia RO - Eliminare DEEE GR - Διάθεση WEEE CZ - Likvidace OEEZ HR - Zbrinjavanje OEEO-a SI - Odstranjanje OEEO SK - Likvidácia podľa OEEZ HU - RAEE szerinti ártalmatlanítás SA - التخلص WEEE
	IT - Importato da GB - Imported by FR - Importé par ES - Importado por PT - Importado por DE - Eingeführt von PL - Importowane przez RO - Importat de GR - Εισαγόμενη από CZ - Dovozeno uživatelem HR - Uvezeno od strane SI - Uvozil SK - Dovážal HU - Importáltár SA - مستورد عن طريق
	IT - Limite di temperatura GB - Temperature limit FR - Limite de température ES - Límite de temperatura PT - Limite de temperatura DE - Temperaturgrenzwert PL - Granica temperatury RO - Limită de temperatură GR - Όριο θερμοκρασίας CZ - Uchovávejte při teplotě mezi a °C HR - Čuvati između i °C SI - Hranite pri temperaturi med in °C SK - Uchovávaťe pri teplote od do °C HU - És °C között tárolandó SA - حد درجة الحرارة
	IT - Identificatore univoco del dispositivo GB - Unique device identifier FR - Identifiant unique de l'appareil ES - Identificador de dispositivo único PT - Identificador exclusivo do dispositivo DE - Unique Device Identifier (Eindeutige Kennung des Geräts) PL - Unikalny identyfikator urządzenia RO - Identificatorul unic al dispozitivului GR - Unique Device Identifier (Eindeutige Kennung des Geräts) CZ - Jedinčný identifikátor zařízení HR - Jedinstveni identifikator uređaja SI - Enolični identifikator naprave SK - Jedinčný identifikátor zariadenia HU - Az eszköz egyedi azonosítója SA - معرف فريد للجهاز