AIRSSENTIAL

LifeLine® Kärdio

Blood Pressure Monitor

Automatic Upper Arm Style

Instruction Manual

This manual contains important information for the correct and safe use of the LifeLine® Kärdio Blood pressure Monitor. Before using, please read through this instruction manual carefully.

Keep this manual in a safe place for future reference. If you do not understand any portion of these instructions, contact the Airssential Customer Care Centre on (02) 9708 5560.

For further questions on Blood pressure and its measurement, please contact your doctor.

Model: AI-K118A

Contents

Introduction

Congratulations on your purchase. The LifeLine® Kärdio Blood Pressure Monitor AI-K118A is a fully automatic, digital blood pressure measuring device for use on the upper arm. This monitor enables fast and reliable measurement of systolic and diastolic blood pressure and the pulse rate.

This device offers clinically tested measurement protocols and very high accuracy. The monitor has been designed to be patient-friendly to use. The device has numerous features including:

- Cuff placement and fitting indicator
- Arm movement indicator
- WHO Traffic light hypertension classification.
- Adjustable time and date display
- Sophisticated measurement algorithm including Atrial Fibrillation (AFIB) and Irregular Heartbeat detection technology (IHB)
- Backlit screen with high visibility readout
- 2 user x 120 data memory
- AC and DC power options provided

The measurement algorithm of the LifeLine® Kärdio Blood Pressure Monitor is clinically proven accurate and validated to within the following limits prescribed by the American National Standard Institute (ANSI criteria), for Electronic or Automated Sphygmomanometers[1]:

- blood pressure: within +/- 3 mm Hg or 2% of reading
- pulse rate: within +/- 5% of reading

Statement of Intended Use

This device uses the oscillometric method to automatically measure systolic and diastolic blood pressure together with the heart rate and is suitable for use by the majority of adults for self-monitoring of blood pressure. This instrument may not be used for any purpose not described in this manual.

This device is unsuitable for use on neonates, pre-eclamptic, pregnant or unconscious persons. Consult your doctor before using a digital blood pressure monitor if you have suffered a stroke, circulatory disorders, diabetes, liver disease, severe hypertension, arrhythmia or kidney problems as these conditions can influence blood pressure measurements.

WARNING

Important Information about Self-Measurement

- Replacement of original parts with generic components may result in measurement errors. Blood pressure cuffs should only be replaced by compatible LifeLine cuffs.
- During measurements, ensure the cuff's tubing is not kinked to avoid a possible patient injury or measurement inaccuracy.
- Very frequent measurements can cause patient injury due to continued blood flow restriction.
- Do not apply and inflate the blood pressure cuff:
  - over a wound as this may exacerbate the injury.
  - on any limb where intravascular therapy or an arteriovenous (A-V) shunt is present, as the temporary interference with blood flow and may result in patient injury.
  - on the arm on the side of a mastectomy
- Cuff inflation can temporarily cause loss of function of simultaneously used monitoring equipment when applied on the same limb.
- Ensure operation of this device does not cause prolonged restriction of the patient's blood circulation.
- This device is not intended to be used in near proximity of high frequency (HF) surgical equipment.
- The pulse display on this device is unsuitable for checking the frequency of heart pacemakers.
- In cases of cardiac irregularity (Arrhythmia), measurements made with this instrument should be evaluated in consultation with your doctor.
- Self-measurement of blood pressure means control, not diagnosis or treatment. Unusual values must always be discussed with your doctor. **Never use the results of your measurements to independently alter the doses of medication prescribed by your doctor.**

Electromagnetic Interference

The device is a Microcomputer and contains sensitive electronic components. Therefore, avoid strong electrical or electromagnetic fields in the close vicinity of the device (e.g. mobile telephones, microwave ovens, etc.) to avoid temporary impairment of measuring accuracy.

Blood Pressure Measurement

How does Blood Pressure Arise?

Blood pressure is determined in a part of the brain, referred to as the circulatory centre which adapts blood pressure to the respective situation via feedback from the nervous system.

Blood pressure is subsequently adjusted by the circulatory centre by altering the heart rate (Pulse), its strength and the diameter of circulatory blood vessels by fine muscles in the blood vessel walls.

The level of arterial blood pressure changes with heart activity. When blood is expelled from the heart and into the body, the blood pressure value is at its maximum and denoted as the systolic blood pressure (SBP). After the ejection of blood is completed the heart begins a rest period known as Diastole where blood pressure is at its lowest value and denoted as the diastolic blood pressure (DBP). Blood pressure values must lie within a normal range to prevent cardiovascular diseases.

Normal Blood Pressure Values

Blood pressure is too high, if at rest, the diastolic pressure is above 90mmHg and/or the systolic blood pressure is over 160 mmHg. Please consult with your doctor as continuing high values endanger human health due to the progressive damage caused to the blood vessels in the body.

If the systolic blood pressure values lie between 140mmHg and 160mmHg and/or the diastolic blood pressure values lie between 90mmHg and 100mmHg, please consult your doctor.

With blood pressure values are too low, i.e. systolic values under 100 mmHg and/or diastolic values under 60 mmHg, consult your doctor. Even with normal blood pressure values, regular self-monitoring of blood pressure is recommended to allow early detection of changes in blood pressure values and provide time to address all medical issues appropriately.

If you are undergoing medical treatment to control your blood pressure, keep a record of your blood pressure by performing regular self-measurements at specific times of the day. Show these values to your doctor.

Table 1 classifies blood pressure risk by measured values according to the recommendations of the World Health Organisation (WHO):

Classification Category	Systolic Pressure (mmHg)	Diastolic Pressure (mmHg)	Measures	Risk Category Indicator Colour
Hypotension	Lower than 100	Lower than 60	See your doctor	
Optimum	100 to 120	60 to 80	Self-check	Green
Normal	120 to 130	80 to 85	Self-check	Yellow
High Normal	130 to 140	85 to 90	Consult your doctor	Yellow
Mild Hypertension	140 to 160	90 to 100	Seek medical advice	Red
Moderate Hypertension	160 to 180	100 to 110	Seek medical advice	Red
Severe Hypertension	Higher than 180	Higher than 110	Seek urgent medical advice	Red

TABLE 1: Blood pressure value and risk classification according to the recommendations of the World Health Organisation.

Further Information

- If your values are normal under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from “labile hypertension”. Consult your doctor if you suspect this may be an issue.
- If the systolic and diastolic blood pressures fall into non-corresponding categories, the higher category determines the hypertensive risk. For example, a systolic pressure of 185 and a diastolic pressure of 95 is classified into the severe hypertension category.
- The monitor is equipped with a Risk Category Indicator that classifies measurements into options based on the WHO blood pressure risk classifications. See Table. 1.
- At the completion of the measurement, an arrow on the LCD display will automatically position the result into the correct segment of the coloured Risk Category Indicator, to confirm your present risk.
- Measured diastolic blood pressure values above 120mmHg require immediate medical treatment.

Preparing the Blood Pressure Monitor for Use

LifeLine® Kärdio Blood Pressure Monitor Parts

FIGURE 1. Identification of monitor button functions.

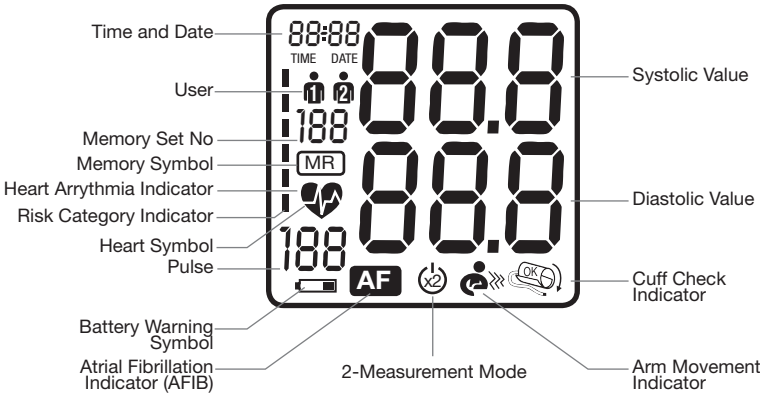


FIGURE 2. Identification of monitor screen icons.

Unpacking Your Blood Pressure Monitor

Remove the monitor from the carrying case and check that all the contents are included and undamaged. The contents included with the monitor are:

- LifeLine® Kärdio Monitor
- Instruction Manual
- AC Power Adaptor
- Standard Arm Cuff (22 - 42 cm)
- Storage Case
- 4 AA Alkaline Batteries

Report anything missing or damaged to the point of purchase.

Installing Batteries

a) Insert four AA-size (1.5V) alkaline batteries into the monitor's battery compartment. Ensure that each battery's polarity is properly located.

b) When the battery warning ( ) icon appears on screen, the batteries still retain 20% of their original power but will need replacing.

c) When the empty battery warning ( ) icon appears on screen, the batteries must be replaced. The monitor will remain non-operational until this occurs.

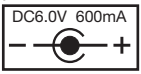
Note

- Remove the batteries from the device if it is not to be used for an extended period. Leaking batteries can damage the monitor.
- Batteries are hazardous waste. Please ensure their proper disposal.
- Keep batteries away from children to avoid swallowing.
- After replacing batteries, reset the date and time functions.
- Battery replacement will not delete data stored in the memories.

Using the AC Adapter

This monitor may be operated with the AC adapter provided with the device. which complies with safety standards EN60601-1 and EN60601-1-2.

The recommended voltage and current specifications for the adaptor are:
Input: 100 ~ 240V, AC, 50 ~ 60 Hz
Output: 6V, DC, 600mA



Do not use an adaptor with alternate specifications as it will not activate the device and may damage your monitor. Batteries are not required when operating the monitor with the included AC adapter.

User Selection

This monitor allows for the independent monitoring and recording of blood pressure readings for 2 individuals in 2 different memory zones.

- To select the user or memory zone, ensure the monitor is off. Press and hold the TIME button until the user icon begins to blink. Press the MEMORY button to change the User and then confirm the selection by pressing the START / STOP button. The monitor will then switch off and remain at this selected User.

Setting the Time and Date

Once new batteries are installed, the clock shows TIME “12:00” and “DATE” 1-01. The current time and date can then be entered as follows.

1. When the unit is off, press and hold the TIME button until the user icon begins to blink. Press the TIME button again to display the year. Press the MEMORY button to increase the year. Press the TIME button to confirm the year.

2. The display now switches to the Date. The first character (month) will blink. Press the MEMORY button to increase the month. Press the TIME button to confirm the entry.

3. The last two characters (days) will now blink. Press the MEMORY button to increase the day of the month. Press the TIME button to confirm the entry.

4. The display now switches to set the time. The first character (Hour) will blink. Enter the hour by pressing the MEMORY button. Press the TIME button to confirm the entry.

5. The last two characters (Minutes) now blink. Press the MEMORY button to increase the minutes. Press the TIME button to confirm the minutes.

6. A set of vertical “0” images now appears indicating mmHg units (the preferred unit for measuring blood pressure in Australia). Press the TIME button to confirm this selection. If two sets of “0.0” images appear you have selected kPa units. Change the units by pressing the MEMORY button and then confirm the correct selection with the TIME button.

7. The settings are now confirmed and the clock starts.

Further Information

Each press of the button (TIME, MEMORY) is one input (e.g. switching from hours to minute mode or altering the value by +1). Switching to the desired value is faster if the respective button is kept depressed.

The Measurement Procedure

Before Starting

Avoid eating, smoking and all forms of exertion or exercise directly before taking a measurement, as all these factors will influence the result. It is important that prior to beginning a measurement, that you sit comfortably in a quiet room and relax for several minutes.

- Always measure on the same arm (normally the left arm).
- Try and take measurements regularly at the same time of day, since blood pressure changes during the day.

Note: To obtain meaningful measurements for comparison, a set time to do readings should be chosen to minimise the influence exerted by the body's circadian rhythm over blood pressure.

Sources of Measurement Error

- Any effort to support the arm during measurement can increase blood pressure. Ensure you are in a relaxed position and do not tense any of the muscles in the arm during the measurement. Use a cushion to support the arm if necessary.
- The performance of automated sphygmomanometers can be affected by extremes of temperature, humidity, and altitude.
- Avoid compression or restriction of the blood pressure cuff's connection tubing during measurement.
- Ensure the blood pressure cuff is correctly fitted to the arm. A loose cuff causes errors or false measurement values.
- When measurements are excessively repeated, blood accumulates in the arm, which can lead to false results. Blood pressure measurements should only be repeated once and thereafter a 5-minute pause should be taken to allow proper resumption of the circulation.
- Do not use the monitor near strong electromagnetic fields such as mobile telephones, microwaves, etc.

Applying the Cuff

Insert the cuff's air connector into air outlet on the side of the monitor as shown in Figure 3. Ensure the air connector is fitted properly fitted to avoid leakage.

a) Check the distance between the edge of the cuff and the elbow is approx. 2~3cm. See figure 4.

b) Secure the cuff with the Velcro fastener so it is comfortable but not too tight. About one to two fingers of space should remain between the cuff and the arm.

c) Lay the arm on a table, with the palm upwards. The cuff should be about level with the heart (see figure 5). If further height is required to be at heart level place a folded towel beneath the arm. Ensure, that the cuff and towel do not interfere with each other. Sit in this position quietly for 2 minutes, before beginning the measurement.

d) Ensure legs are uncrossed, both feet are flat on the floor, your back and arm are supported.

FIGURE 3: Connecting the blood pressure cuff to the air-outlet

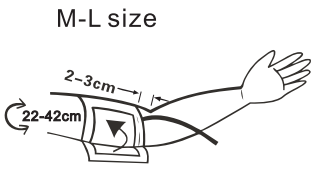


FIGURE 4: Proper Connection of the cuff and arm

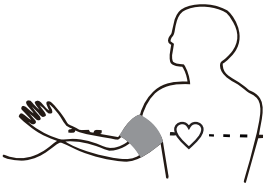
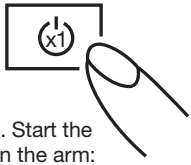


FIGURE 5: Securing the Velcro cuff to the arm

Measuring Procedure

1. Measuring in **Standard Mode** (1 Measurement Mode)

Note: Standard mode measurement provides standard arrhythmia detection but not Atrial Fibrillation detection technology.



In standard mode, only 1 measurement is taken in succession. Start the measurement as follows after the cuff has been positioned on the arm:

a) Press the x1 button, and the pump begins to inflate the cuff.

Cuff placement and fitting indicator: the icon will appear and blink during the measurement if the cuff is fitted too loosely. The OK icon will appear during measurement if the cuff is correctly fitted.

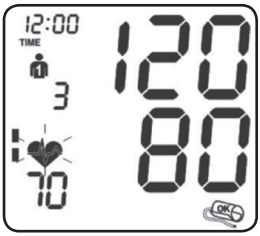
b) If arm movement is detected during measurement: the icon appears to alert the user that movement was detected which may influence accuracy. If the movement was minor, the measurement will be continued. If the movement is serious, the message Err2 is displayed on the screen and the measurement procedure should be re-started.

c) After reaching the inflation pressure the pump stops and the slow deflation of the cuff begins. Cuff-pressure is displayed on screen throughout the measurement. When the monitor detects the pulse, the heart symbol in the display begins to blink.

d) When the measurement concludes, the measured systolic and diastolic blood-pressure values together with the pulse rate are displayed.

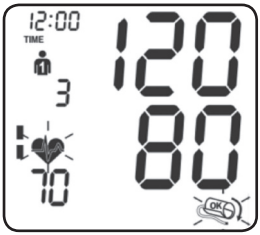
Examples of Measurement Readings

Example 1: Systolic 120, Diastolic 80, Pulse 70. Irregular heartbeat detected with the IHB icon appearing. The cuff is correctly fitted.



EXAMPLE 1

Example 2: Systolic 120, Diastolic 80, Pulse 70. Irregular heartbeat detected with the IHB icon appearing, The cuff is fitted too loosely.



EXAMPLE 2

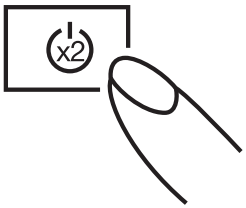
Example 3: Systolic 120, Diastolic 80, Pulse 70. Movement detected. The cuff is correctly fitted.

Measurement results are displayed until the device is turned off. If no button is pressed for 3 minutes, the device switches-off automatically.

EXAMPLE 3

2. Measuring **Atrial Fibrillation (AFIB) Mode** (2-measurement mode)

In AFIB mode, 2 measurements are automatically taken in succession and the result is then analysed and displayed. As blood pressure constantly fluctuates, a result determined in this manner is more reliable than one produced by a single measurement. To measure in AFIB mode:



a) Position the cuff to the arm and press the (x2) *Afib* button. The symbol (x2) appears on the screen and cuff inflation begins.

b) The lower, left section of the screen shows a 1 or 2 to indicate which of the measurements is currently being taken. See Figures 6A and 6B.

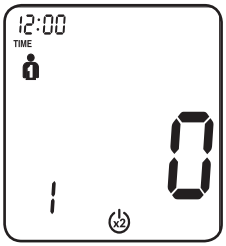


FIGURE 6A: 1st AFIB measurement

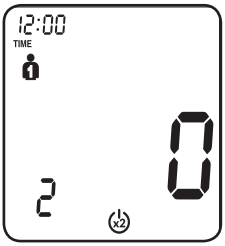


FIGURE 6B: 2nd AFIB measurement

c) When the first measurement is complete a 15 second break occurs. A countdown will begin to indicate the remaining time before the second measurement will start. Do not remove the cuff between measurements.

d) The blood pressure will display after both measurements are completed. Individual results are not displayed. If one of the individual measurements was questionable, a third one is automatically taken.

FIGURE 7

Measured result:
After reaching the inflation pressure the pump stops and the slow deflation of the cuff begins. Cuff-pressure is displayed on screen throughout the measurement. When the monitor detects the pulse, the heart symbol in the display begins to blink. See Figure 7.

Example 1:
The measured systolic and diastolic blood pressure values together with the pulse rate are now displayed on the screen and read:

Systolic 128, Diastolic 86, Pulse 68, irregular heartbeat detected with both IHB and AFIB **AF** icons appearing. Arm movement detected. The cuff is correctly fitted. See Figure 8.

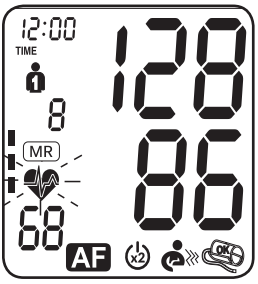


FIGURE 8: Example 1

Example 2:
Systolic 128, Diastolic 86, Pulse 68, irregular heart beat detected with IHB icon appearing, but no AFIB is detected. Arm movement detected, and the cuff is fitted correctly. See Figure 9

FIGURE 9: Example 2

Discontinuing a Measurement

If it is necessary to interrupt a measurement, for any reason, press either power button (x1) or (x2) and the monitor will immediately stop the measurement and release the pressure.

Memory – Storage and Recall of Measurements

The monitor will automatically store 120 measurements in each of the two memory zones. To access stored data, press the MEMORY button.

Note: The first display is the average value of the last 3 measurements. See Figure 10.

Each subsequent press of the MEMORY button displays the actual measurement data in chronological order from M120 to M1. See Figure 11.

The indicate "A" means an average value for the last 3 measurements

FIGURE 10:
The average value of last 3 measurements

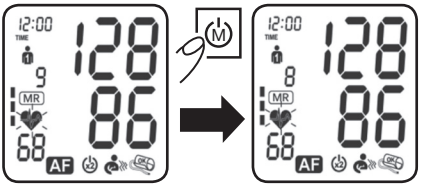


FIGURE 11: Each subsequent press of the MEMORY button displays the the next measurement data in chronological order

Memory– Deletion of Measurements

Before deleting the data stored in the memory, be sure there is no further need to refer to it in the future.

To delete all stored readings, be sure the monitor is off. Press the MEMORY button for 5 seconds. Release the button when the «CL» symbol is displayed. Pressing the MEMORY button again while the «CL» symbol is flashing will permanently clear the memory. See Figure 12.

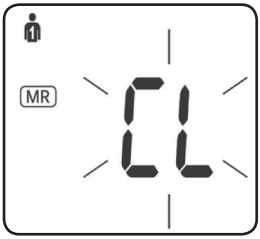


FIGURE 12: Permanently clearing the memory

Note: You cannot delete individual measurements.

Irregular Heartbeat Indicators and Atrial Fibrillation Detection

The heart contracts and relaxes in a regular rhythm governed by the sinoatrial node (SA Node), a group of cells located in the wall of the right atrium. Abnormal heartbeats or heart arrhythmia occurs when the heart beats too fast, too slowly or irregularly.

The appearance of the IHB (Irregular Heat Beat) icon is to advise that during the current blood pressure measurement an irregular heartbeat was detected. In such instances, the reading may deviate from your normal blood pressure. This is usually not a cause for concern but requires the measurement be repeated to obtain a more accurate result. If this icon regularly appears during measurements (e.g. several times weekly) please discuss this with your doctor for further advice, providing the following explanation for reference:

> *Doctor Information on frequent appearance of the Arrhythmia Indicator.*
>
> *This instrument is an oscillometric blood pressure monitor that also analyses pulse frequency during measurement. This instrument is clinically tested. The arrhythmia symbol is displayed after the measurement, if pulse irregularities occur during measurement. If the symbol appears frequently (e.g. several times per week on daily performed measurements) we recommend the patient to seek medical advice.*

Many blood pressure monitors allow measurements to proceed when irregular heartbeats occur but do not distinguish between benign arrhythmias and those which may be of greater concern to health

When blood pressure measurements are performed using the Kärdio Monitor, Atrial Fibrillation and Irregular Beat (AFIB) detection technology, once activated, can screen and distinguish between various irregular heartbeats. If an irregular heartbeat is detected, accessed by the software, to be of possible concern the AF icon will display. In this instance, repeat the measurement again in AFIB mode.

If the AF symbol appears after having performed the second measurement, wait for one hour and again perform a third AFIB measurement. If the AF symbol continues to appear this situation should be discussed with your doctor to determine if any further investigation should be considered.

If after the third measurement the AF symbol is no longer displayed then return to your regular monitoring procedure.

Note: The illumination of the AF icon does not provide any diagnosis. It is an alert to the patient and their doctor to consider if any further medical investigation may be required.

Illuminated heart arrhythmia icons do not replace a cardiac examination and only serve to facilitate an earlier investigation of heartbeat irregularities. Early medical intervention of cardiac arrhythmia, in some instances, can significantly improve patient health outcomes. This device may not detect abnormal heart rhythms in people with pacemakers or defibrillators.

Error Messages and Possible Malfunctions

Error No.	Possible Causes
ERR 1	No pulse has been detected.
ERR 2	Unnatural pressure impulses have influenced the measurement result. Reason: The arm was moved during the measurement (creating artifacts).
ERR 3	Cuff inflation is taking too long. The cuff is incorrectly fitted.
ERR 5	The measurement indicated an unacceptable difference between systolic and diastolic pressures. Repeat the reading following the directions carefully. Contact your doctor if you continue to get unusual readings.
ERR8	Pressure is over 290 mmHg

TABLE 2: Explanation of error code meanings.

Possible Malfunctions and their Remedy

Malfunction	Remedy
The display remains empty when the instrument is switched on although the batteries are in place.	1. Check batteries polarity is correctly located and if necessary insert correctly. 2. If the screen display is unusual, the batteries should be re-inserted or replaced.
The device frequently fails to measure blood pressure, or the values measured are too low or too high.	1. Check the positioning of the cuff. 2. Measure the blood pressure again in a quiet environment.
Blood pressure measured differs from those values measured by the doctor.	Record daily measurements and consult your doctor. Individuals visiting their doctor frequently experience anxiety which can result in a higher reading at the surgery than obtained at home under resting conditions.

TABLE 3: Possible malfunctions and their rectification.

Care, Maintenance, Recalibration and Disposal

Care

This instrument contains sensitive components and must be treated carefully.

- Protect the monitor from water and moisture, temperature extremes, impact and dropping, dust or direct sunlight.
- The cuff contains a sensitive air-tight bladder. Handle this carefully to avoid any damage caused through twisting or buckling.
- Ensure that infants do not use the monitor unsupervised as some parts are small enough to be swallowed.

Maintenance

Clean the blood pressure monitor with a soft, dry cloth. Stains on the cuff can be carefully removed with a moist cloth and mild soap. During cleaning, avoid squeezing or twisting the cuff.

Do not expose any part of the monitor to chemical cleaners such as paint thinners, turpentine, methylated spirits, etc.

Disposal

Waste electrical products should not be disposed of with household waste. If this device is no longer required or it is no longer serviceable, dispose of the device and its accessories to a recycling collection point. Check with your local Council for recycling information.

The expected service life of this monitor, under normal use and conditions, is 5 years.

Device Certification

This monitor is a Class IIa Medical Device. In compliance with the European standard, this device bears the CE conformity mark according to Annex II of the Medical Devices Directive 93/42/ EEC. This device complies with the following reference and performance standards for arm blood pressure monitors with adaptors:

International reference and performance standards complied with include:

- IEC60601-1-6:2010+A1:2013
- IEC60601-1:2005+A1:2012
- IEC60601-1-2:2014
- IEC/EN60601-1-11:2015
- IEC80601-2-30:2009+A1:2013
- EN60601-1-6:2010+A1:2015
- EN60601-1:2006+A11:2011+A1:2013+A12:2014
- EN60601-1-2:2015
- EN80601-2-30:2010+A1:2015

Symbols Used in This Manual

Table 4 provides a summary of the meanings of symbols used in this manual.

	Waste electrical products should not be disposed of with household waste.		Attention consult accompanying documents
	Manufacturer		Read the Instructions before use
	Inapplicable for babies less than 3 years of age		Type B equipment
	Cuff Connector		AC/DC Adapter
CE 0197	TUV No.	**Ingress of Water**	IP22

TABLE 4: The meanings of symbols used in this manual.

Warranty and Service

The LifeLine Kärdio blood pressure Monitor is covered by a limited warranty offered by Airssential Health Care (“Airssential”), a division of Boian Surgical Pty Ltd., to the original purchaser of this product. Proof of purchase is required to substantiate warranty claims.

Airssential warrants that for a period of three years from the date of purchase, this product will be free from defects in material and workmanship. Airssential, at its option, will repair or replace this device or any component of the device found to be defective during the warranty period, provided the product has been used in accordance with the instructions provided. If the product is no longer available, replacement may be made with a similar product. Airssential shall not be liable for any incidental or consequential damages caused by the breach of any express or implied warranty.

This warranty excludes the repair or replacement of parts,including the cuff due to normal wear, recalibration, damage due to improper usage or accidental user damage. Freight costs associated with all warranty claims or service requests will be borne by the consumer.

Do not disassemble this device, as it cannot be serviced at home. Unauthorised disassembly of this device will void the warranty.

To obtain warranty service return this blood pressure Monitor, together with proof of purchase and a cheque or money order made out to “Boian Surgical” for $9.90 to cover return shipping and insurance, to Airssential Customer Care Service Centre, 122 Gow Street, Padstow NSW 2211. Please include your name, address and a contact telephone number with your request.

Technical Specifications

Measurement Procedure:	Oscillometric, corresponding to the Korotkoff method: Phase I: systolic, Phase V: diastolic
Display:	Digital display
Measuring range:	Pressure: 30 to 280 mmHg Pulse: 40 to 199 beat/minute
Static accuracy:	BP ± 3mmHg / Pulse: ± 5% of reading
Measuring resolution:	1mmHg
Inflation:	Automatic inflation by an internal pump
Memory function:	2 x 120 memories for 2 users
Decompression:	Constant exhaust valve system
Power source:	4 “AA” Alkaline Batteries
Rated voltage:	DC 6.0V 4.0W (direct current)
Operation temperature:	5~40°C / 41~104°F
Operating humidity:	15%~85%RH maximum
Storage temperature:	-10~55°C / 14~131°F
Storage humidity:	10%~95%RH maximum
Dimensions:	153× 110× 63 ±1.0 mm
Weight:	540 g±5g (including batteries and cuff)
Cuff pressure display range:	0~290mmHg / 0~38.7KPa
Electrical shock protection:	Internal power unit
Safety classifications:	Type B equipment
Mode of operation:	Continuous operation
Protection against ingress of water:	IP22
Accessories:	Cuff 22-42cm, 4 “AA” batteries, instruction manual and warranty card. AC power adaptor.

Manufacturer's Declaration

The monitor is intended for use in the electromagnetic environment specified below.

Electromagnetic Emissions: (IEC60601-1-2)

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	The BP118A AFIB uses RF energy only for internal functions. Therefore, this RF emission is extremely weak and there is little chance of it creating any kind of interference whatsoever with nearby electronic equipment.
RF emissions CISPR 11	Class B	The BP118A AFIB is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker IEC 61000-3-3	Not applicable	

Electromagnetic Immunity: (IEC60601-1-2)

Immunity Test	IEC60601-1-2 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 %.
Electric fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT 95% dip in UT for 0.5 cycle 40 % UT 60% dip in UT for 5 cycles 70 % UT (30% dip in UT) fo r 25 cycles <5 % UT 95% dip in UT for 5 sec.	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the upper arm style requires continued operation during power mains interruptions, it is recommended that the BP118A-AFIB be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
Note: UT is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 80% AM (2Hz) 3 Vrms 80 MHz to 2.5 GHz 80% AM (2Hz)	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the BP118A-AFIB, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommend separation distance 3V d = 1.2×p1/2 80Mhz to 800 MHz d = 2.3×p1/2MHz 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 recom¬mended separation distance in meters (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:

Immunity Test	IEC60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Note1: At 80 MHz and 800 MHz, the higher frequency range applies. Note2: 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 BP118A-AFIB is used exceeds the applicable RF compliance level above, the BP118A-AFIB should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BP118A-AFIB. b Over the frequency range 150 to 80MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances

Recommended separation distance between portable and mobile RF communications equipment and the BP118A-AFIB

The BP118A-AFIB is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BP118A-AFIB can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BP118A-AFIB 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 $d = 1.2 \times p^{1/2}$	80 MHz to 800 MHz $d = 1.2 \times p^{1/2}$	800 MHz to 2.5 GHz $d = 2.3 \times p^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

recommended separation distance d minimetres (m) can be determined 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: At 80MHz and 800MHz, the separation distance for the higher frequency range applies

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

Bibliography

1. National High Blood Pressure Education Program. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure. Bethesda (MD): National Heart, Lung, and Blood Institute (US); 2004 Aug. https://www.ncbi.nlm.nih.gov/books

2. Wiesel J, Abraham S, Messineo F. Screening for asymptomatic atrial fibrillation while monitoring the blood pressure at home: trial of regular versus irregular pulse for prevention of stroke (TRIPPS 2.0). Am J Cardiol 2013, 111:1598–1601.

3. Gandolfo C, Balestrino M, Bruno C, Finocchi C, Reale N: Validation of a simple method for atrial fibrillation screening in patients with stroke. Neurol Sci 2015; 36:1675-1678.

4. Kearley K, Selwood M, Van den Bruel A, Thompson M, Mant D, Hobbs FR et al.: Triage tests for identifying atrial fibrillation in primary care: a diagnostic accuracy study comparing single-lead ECG and modified BP monitors. BMJ Open 2014; 4:e004565.

5. Verberk WJ, Omboni S, Kollias A, Stergiou GS: Screening for atrial fibrillation with automated blood pressure measurement: Research evidence and practice recommendations. Int J Cardiol 2016; 203:465-473.

6. Camm AJ, Lip GY, De Caterina R, Savelieva I, Atar D, Hohnloser SH et al 2012 focused update of the ESC Guidelines for the management of atrial fibrillation: an update of the 2010 ESC Guidelines for the management of atrial fibrillation--developed with the special contribution of the European Heart Rhythm Association. Europace 2012; 14:1385-1413.

Blood Pressure Diary

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