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AIRSSENTIAL

LifeLine[®] Alpha

Blood Pressure Monitor



Instruction Manual

This manual contains important information for the use of the LifeLine[®] Alpha Blood Pressure Monitor.

Read the manual carefully before using the monitor to understand its operational procedure and safety precautions.

If you do not understand any part of these instructions, contact the Airssential Customer Care Centre on (02) 9708 5560.

Keep this manual in a safe place for future reference.

CE 0197

Model: AI-ALPHA

www.airssential.com.au

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Introduction

The LifeLine® Alpha Blood Pressure Monitor is a fully automatic, upper arm digital blood pressure measuring device. This monitor is extremely easy to use, providing fast and reliable measurement of systolic and diastolic blood pressure and the pulse rate.

This device has been subjected to strict clinical testing and evaluated for accuracy to ensure the stipulations of the EU-Guidelines 93/42/EEC for Medical Products Class IIa have been fulfilled.

Features of this monitor include:

- Cuff placement and fitting indication
- Arm movement detection
- WHO Hypertension Risk Classification system.
- High accuracy measurement algorithm
- Arrhythmia detection
- Ability to monitor 2 independent users, each with storage for 120 measurements
- Averaging of last 3 measurement values

The measurement algorithm of the LifeLine® Alpha Blood-Pressure Monitor is proven clinically accurate and validated to within the following limits prescribed by the American National Standard Institute (ANSI criteria), for Electronic or Automated Sphygmomanometers¹:

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

Statement of Intended Use

This monitor is suitable for use by most adults for self-monitoring of blood pressure. This instrument should 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.



ATTENTION!

Important Information about Self-Measurement

- Replacement of original parts with generic components may result in measurement errors. Blood pressure cuffs or bladders should only be replaced with original Airssential branded parts.
- During measurements, ensure the cuff's tubing is not kinked to avoid possible injury or measurement errors.
- Frequent measurement can cause patient injury due to continued blood flow restriction. Avoid repeating measurements excessively.
- Do not apply and inflate the blood pressure cuff:
 - over a wound as this may exacerbate the injury.
 - on a limb where intravascular therapy or an arteriovenous (A-V) shunt is present, as the temporary interference with blood flow may result in a patient injury.
 - on the arm being on the same side of the body as a mastectomy
- Cuff inflation can cause temporary loss of function of simultaneously used monitoring equipment if applied on the same limb.
- 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 heartbeat irregularity, evaluate measurements made with this instrument in consultation with your doctor.

Note: Self-measurement of blood pressure means control, not self-diagnosis or treatment. Always discuss unusual measurements with your doctor.

Never use the results of your measurements to independently alter your prescribed doses of medication.

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.) that can cause temporary impairment of measuring accuracy.

Blood Pressure Measurement

How Does Blood Pressure Arise?

Blood pressure is determined in the brain's circulatory centre and adapted to suit daily situations via feedback from the nervous system.

Both the volume of blood pumped by the heart and the amount of resistance to blood flow encountered in the arteries determine blood pressure. The more blood pumped by the heart and the narrower the arteries, the higher blood pressure rises.

Blood pressure magnitude changes with the heart's activity, of circulating blood around the body in a regular rhythm. When the heart contracts blood is ejected from the heart and into the body. At this stage, the blood pressure is at its maximum value and called the systolic blood pressure (SBP). At the completion of the contraction, the heart begins a rest period known as Diastole. The blood pressure is now at its lowest value and known as the diastolic blood pressure (DBP). The recording of blood pressure values is presented as the SYS/DIA millimeters of mercury (mmHg).

To prevent cardiovascular diseases, blood-pressure must lie within a normal range. Classification categories for different blood pressure values are presented in Table 1.

Classification Category	Systolic Pressure (mmHg)	Diastolic Pressure (mmHg)	Measures	Risk Category Indicator Colour
Hypotension	Lower than 100	Lower than 60	See your doctor	
Optimum	Optimum	60 to 80	Self-check	Green
Optimum	100 to 120	60 to 80	Self-check	Green
Normal	120 to 129	80 to 84	Self-check	Yellow
High to Normal	130 to 139	85 to 89	Consult your doctor	Yellow
Slight Hypertension	140 to 159	90 to 99	Seek medical advice	Red
Moderate Hypertension	160 to 179	100 to 109	Seek medical advice	Red
Strong 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 Organization.

Interpreting Blood Pressure Values

High blood pressure (hypertension) is a common condition in which the long-term force of blood against the artery walls is high enough so that it increases the risk of serious diseases. Constant hypertension endangers health due to the progressive damage caused to the body's blood vessels. To ascertain at what range of blood pressure values hypertension occurs, review Table 1.

If systolic blood-pressure values lie between 140mmHg and 160mmHg and/or diastolic blood-pressure values lie between 90mmHg and 100mmHg, please consult your doctor. Measured diastolic blood-pressure values above 120mmHg require immediate medical treatment.

Low blood pressure (hypotension) occurs when systolic values are under 100 mmHg and/or diastolic values are under 60 mmHg. Please consult your doctor for further advice.

Regular self-monitoring of blood pressure, even for blood pressure values in the normal range, is recommended to allow early detection of changes in blood pressure and allow time to address any medical issue appropriately.

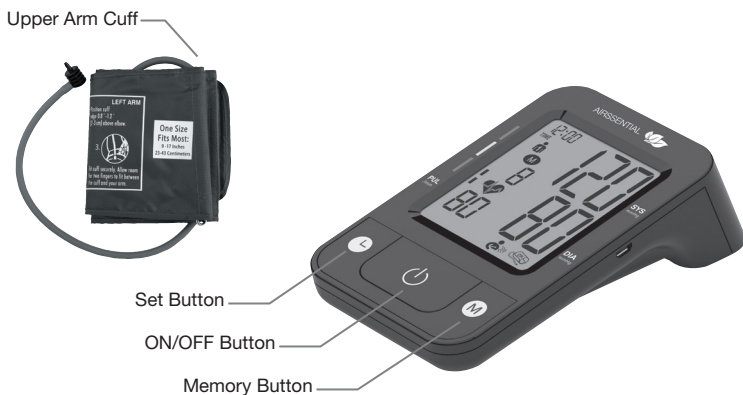
If you are undergoing medical treatment to control your blood pressure, keep a record of your blood pressure by performing regular self-measurements at specific times of the day using a set protocol to minimise the effect of different variables that will influence your measurements. Show these values to your doctor when visiting.

Notes:

- **This monitor is equipped with a Risk Category Indicator that classifies measurements into options based on the World Health Organisation's (WHO) blood pressure risk classifications. At the completion of each measurement, an arrow on the LCD display will automatically position the result into the correct segment of the coloured Risk Category, to confirm your present risk. See Table. 1.**
- **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 systolic and diastolic blood pressures fall into non-corresponding categories, the higher category determines the hypertensive risk. For example, a systolic pressure of 181 and a diastolic pressure of 99 is classified into the severe hypertension category.**

Preparing the Blood-Pressure Monitor for Use

LifeLine® Alpha Blood Pressure Monitor Parts



LifeLine® Alpha Screen Layout and Symbols

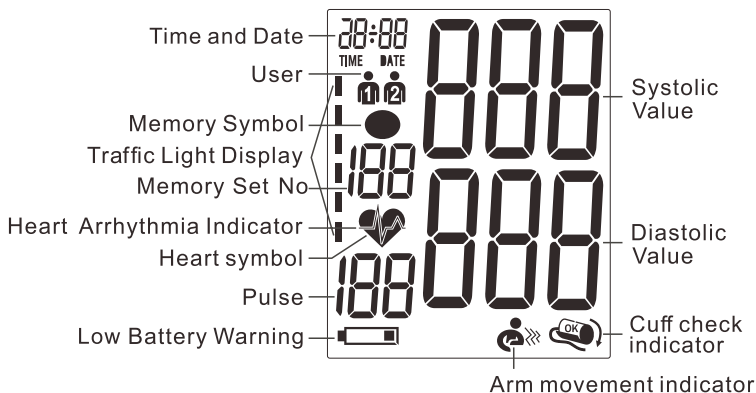


FIGURE 2. Identification of monitor screen icons

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® Alpha Monitor
- Standard Arm Cuff (22 - 42 cm)
- Instruction Manual
- Storage Case
- 4 AAA Alkaline Batteries 1.5V

Report anything missing or damaged to the point of purchase.

Installing Batteries

- a) Insert four AAA-size (1.5V) alkaline batteries into the monitor's battery compartment. Ensure that each battery's polarity is properly observed.
- b) When the battery warning () icon appears on screen, the batteries still retain 20% of their charge but will need replacing shortly.
- c) When the empty battery () icon appears on screen, the batteries are flat. The monitor becomes non-operational until the batteries are replaced.

Notes:

- **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 the batteries, the date and time functions will need to be reset.**
- **Battery replacement will not delete measurement data stored in the memories.**

User Selection

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

- a) Before a measurement, ensure the user number for the intended individual is selected (i.e., User 1 or User 2).
- b) Press and hold the TIME button until the user icon (either  or ) blinks. This indicates the user can now be changed. Press the MEMORY  button to change the User and then confirm the change, by pressing the ON / OFF  button.

Setting the Time and Date

This blood-pressure monitor incorporates an integrated clock with date display that allows storage of blood-pressure measurements with data values and exact time details.

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

1. Press the TIME  button until the user icon blinks. Press the TIME button again to display the year. Next press the MEMORY button to increase the year value as necessary. Confirm the change by pressing the TIME button.
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 next two characters (days) now blink. Press the MEMORY button to alter the days. Press the TIME button to confirm the entry.
4. The display now changes 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 set the minutes. Press the TIME button to confirm the entry. The settings are now confirmed, and the clock starts.

Each press of the button (TIME or 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 any exertion directly prior a measurement, as all these factors will influence your result. It is important that before a measurement, you sit comfortably in a quiet room and relax for several minutes.

Notes:

- Always measure blood pressure on the same arm (normally the left arm).
- Throughout the day blood-pressure fluctuates in all individuals based on necessity, environmental, biochemical, and psychological factors.

Hence to obtain measurements suitable for comparison they need to be made under the same conditions i.e., taken daily at the same time and following the same routine regarding eating, smoking, pre-measurement relaxation, exercise, environmental conditions, and the ingestion of medication.

- If, after observing all same conditions, measurements regularly fluctuate by more than 15mmHg, and/or you feel recurring irregular heartbeats, please consult your doctor.

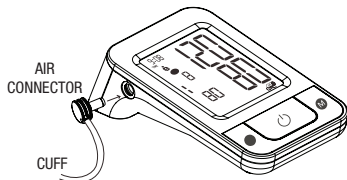


FIGURE 3: Connecting the blood pressure cuff to the air-outlet

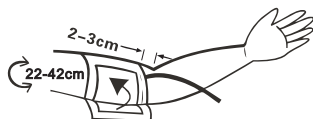


FIGURE 4: Proper Connection of the cuff and arm

Applying the Cuff

Insert the cuff's spigot connector into air outlet on the monitor's side. See Figure 3. Ensure the spigot is fully inserted into the outlet to avoid air leakage.

- Insert your arm through the cuff. Position the edge of the cuff about 2~3cm above the elbow. Position the air tubing so that it is on the inside of the arm as it returns to the monitor. See Figure 4.

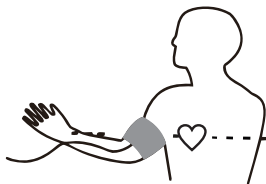


FIGURE 5: Securing the Velcro cuff to the arm

- b) Secure the cuff with the Velcro fastener so it is comfortable but not too tight. There should be about two fingers of space left in between the cuff and the arm.
- c) Lay your arm on a table, with the palm turned upwards so as the cuff is level with the heart. See Figure 5. If further height, to be at heart level, is required place a folded towel beneath the arm. Ensure the cuff and towel do not touch. Ensure legs are uncrossed, both feet are flat on the floor with your back and arm supported.

Sources of Measurement Error

- Any effort to support the arm during measurement can increase blood-pressure. Ensure the arm is in a relaxed position and do not tense the arm muscles during 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 before inflation. A loose cuff causes errors or false measurement values.
- When measurements are repeated excessively, blood accumulates in the arm, and may 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.

Measuring Procedure

Once the cuff has been correctly positioned, the measurement can begin:

- a) Press the ON/OFF button, and the cuff begins to inflate, with the increasing cuff-pressure continually displaying on the monitor's LCD screen. 
- b) Cuff fitting detection: the cuff icon  will appear and blink during the measurement procedure if the cuff is fitted too loosely.

The  icon will appear during measurement if the cuff is correctly fitted.

- c) If arm movement is detected during measurement, which may influence the accuracy of the reading, the  icon will appear to alert the user. If the movement was only minor, the measurement will be continued. If the movement was significant, the message **Err2** displays on screen and the measurement procedure is re-started.
- d) After reaching the inflation pressure the pump stops and a steady deflation of the cuff begins. The falling cuff-pressure is displayed on screen throughout the measurement process. When the monitor detects the pulse, the heart symbol in the display begins to blink with each heartbeat. See Figure 6.
- e) When the measurement concludes, the systolic and diastolic blood-pressure values together with the pulse rate are displayed. For example, in Figure 7 Systolic pressure is 126, Diastolic Pressure is 85, and the Pulse is 78.



FIGURE 6

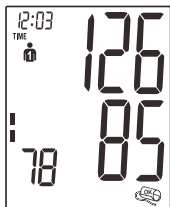


FIGURE 7

Discontinuing a Measurement

If it is necessary to interrupt a measurement, for any reason, press the power button  and the monitor will immediately stop the measurement and release the pressure in the cuff.

Memory – Storage and Recall of Measurements

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

Notes:

- The first time the MEMORY button is pressed the average value of the last 3 measurements displays. See Figure 8. The user is alerted to the fact this is an averaged value by the “A” which appears on screen.
- Each subsequent press of the MEMORY button shows the actual data from the last reading chronologically from M120 to M1. See Figure 9 below.

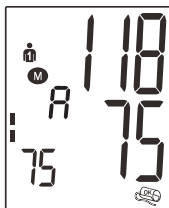
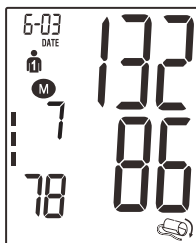
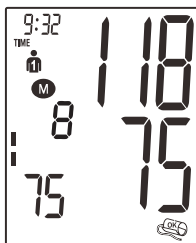
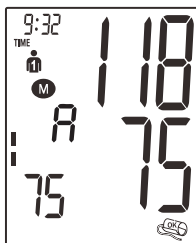


FIGURE 8:
Average of last 3
measurements



First press of Memory button shows the average value of the last 3 measurements.

Second press of Memory button shows the actual data from the last reading.

Third press of Memory button shows the actual data from the second last reading.

FIGURE 9

Memory– Deletion of Measurements

Before deleting the data from the memory, be sure there is no further need to refer to it in the future. Keeping a written record is prudent and may provide additional information for your doctor's visit.

To delete all the data stored in memory, with the monitor off, press the MEMORY button until the «CL» symbol is displayed and blinks on the screen. and then release the button. To permanently clear the memory, press the MEMORY button again while «CL» symbol is flashing. See Figure 10.

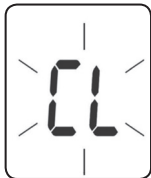


FIGURE 10:
Permanently
clearing the memory

Irregular Heartbeat (IHB) Detector

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 (arrhythmias) occur when the heart beats either too fast, too slowly or irregularly.

The  symbol appearing on the screen at the end of the measurement indicates that pulse irregularities were detected during your measurement. In most cases, this is not a cause for concern. However, if the symbol appears at the completion of your measurement on a regular basis (e.g., several times a week with measurements taken daily) we advise you to tell your doctor. Please show your doctor the following explanation:

Information for the doctor regarding the 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 evaluated and has been subjected to strict clinical testing and evaluated for accuracy to ensure the stipulations of the EU-Guidelines 93/42/EEC for Medical Products Class IIa have been fulfilled.

The arrhythmia symbol is displayed at the completion of a reading if pulse irregularities were detected during the measurement.

If the symbol appears regularly (e.g., several times per week on measurements performed daily) we recommended the patient to seek medical advice.

The instrument does not replace a cardiac examination but serves to detect pulse irregularities at an early stage.

Error Messages and Possible Malfunctions

If an error occurs during a measurement, the measurement will cease and the corresponding error code will display. See Table 2.

Error No.	Possible Cause(s)
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	Cuff pressure is over 290 mmHg

Possible Malfunctions and Their Rectification

If problems occur during use, refer to Table 3 and apply the corresponding action to rectify the issue. If the problem persists contact the Airssential Customer Service Centre on (02) 9708 5560 for further advice or service

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 (too high).	1. Check the positioning of the cuff. 2. Measure the blood-pressure again in a quiet environment.
Every measurement produces a different value although the instrument functions normally and the values displayed are normal	1. Please read the following information and the points listed under «Common sources of error». Repeat the measurement. Please note: Blood pressure fluctuates continually so successive measurements will show some variability.
Blood pressure measured differs from those values measured by the doctor.	1. Record daily measurements and consult your doctor. Please note: 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: Malfunctions and their rectification

Care, Maintenance, Recalibration and Disposal

Care

This monitor contains sensitive components and must be treated carefully. Observe the storage and operating conditions described in the “Technical Specifications” section. Read the additional safety instructions in the individual sections of this manual. Specifically:

- Protect the monitor from water and moisture, temperature extremes, impact (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.

Never immerse the monitor or cuff in any liquids including water.

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

Recalibration

Sensitive measuring devices must be checked for accuracy. A periodical inspection of the monitor is recommended every 2 years. Contact the Airssential Customer Care Centre for more information or to arrange this service. This service is not covered by warranty.

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.

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.

The device has been subjected to strict clinical testing, by which the computer program used to measure blood-pressure values was evaluated for accuracy by cardiologists to ensure the stipulations of the EU-Guidelines 93/42/EEC for Medical Products Class IIa have been fulfilled.

This device complies with the following European reference standards for non-invasive pressure monitors:

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



Symbols Used in This Manual



Read the Instructions before use



Waste electrical products should not be disposed of with household waste.



Inapplicable for babies less than 3 years of age



Cuff Connector



To avoid inaccurate results caused by electromagnetic interference



Type BF Applied Part



Attention! Important information read carefully.



Keep Dry



CE 0197 is a notified body certification of medical quality used by the European community, analogous to TGA certification in Australia.

IP22

Water Ingress Protection Rating.

Warranty and Service

The LifeLine® Alpha 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 two 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 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. An authorised dealer must perform all repairs to ensure product safety and accuracy is not compromised.

To obtain warranty service return this Blood Pressure Monitor, together with proof of purchase, and a payment 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

Model	AI-ALPHA
Measurement Procedure	Oscillometric, corresponding to the Korotkoff method: Phase I: systolic, Phase V: diastolic
Display	Digital display
Measuring range	SYS/DIA: 30 to 280 mmHg (in 1 mmHg increment)
Static accuracy	Pulse: 40 to 199 beat/minute
Measuring resolution	SYS/DIA: ± 3 mmHg / Pulse: $\pm 5\%$ of reading 1mmHg
Inflation	Automatic inflation by an internal pump
Memory function	2 x 120 memories for 2 users (SYS, DIA, Pulse)
Decompression	Constant exhaust valve system
Power source	4- size "AAA" Alkaline Batteries
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	155 × 90 × 46 mm
Weight	384g $\pm$ 5g (including batteries and cuff)
Cuff pressure display range	0~290mmHg
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 "AAA" batteries, instruction manual, storage case and warranty card.

Specifications are subject to change without notice.

Appendix 1: Manufacturer's Declaration

The LifeLine® Alpha Monitor is intended for use in the electromagnetic environment specified below. Monitor users should assure that it is used in such an environment.

Electromagnetic Emissions: (IEC60601-1-2)

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	This monitor 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	This 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 domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker IEC 61000-3-3	Not applicable	

Electromagnetic Immunity: (IEC60601-1-2)

This device is intended for use in electromagnetic environments as listed below and should only be used in such environments:

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.

...continued over

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) for 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 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	Not applicable	Not applicable
Note: UT is the a.c. mains voltage prior to application of the test level.			

Recommended Separation Distances

Recommended separation distance between portable and mobile RF communications equipment and the monitor.

The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of this monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 $d = 1.2 \times p^{1/2}$	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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

Electromagnetic Immunity: (IEC60601-1-2)

This device is intended for use in electromagnetic environments as listed below and should only be used in such environments:

Immunity Test	IEC60601-1-2 Test Level	IEC60601-1-2 Test Level	Electromagnetic Environment - Guidance
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 this monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommend separation distance 3V $d = 1.2 \times P^{1/2}$ 80MHz to 800 MHz $d = 1.2 \times P^{1/2}$ 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). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey 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: 

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 monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this monitor.

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

Blood Pressure Diary

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DATE 	TIME 	MEAL ☐ BEFORE ☐ AFTER
SYSTOLIC/DIASTOLIC		PULSE 

DATE 	TIME 	MEAL ☐ BEFORE ☐ AFTER
SYSTOLIC/DIASTOLIC		PULSE 

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