



Upper-arm Cuff 22 - 42cm

(8¾-16½")

Instructions for Use



5060293171035



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Manchester, M14 5TP, United Kingdom

ASL TF-020 MAN_IFU016 Blood Pressure3
Connected Monitor (V2.0)

Last Updated: 13.02.2022



♥ General Description

Thank you for selecting the Activ8rlives Blood Pressure3 Connected Monitor. The monitor measures blood pressure (Systolic/Diastolic), heart beat (bpm) and includes irregular heartbeat detection (IHD).

Readings taken by this model are equivalent to those obtained by a trained observer using the cuff and stethoscope method. The Instructions for Use contains important safety and care information and provides step-by-step instructions for using the device.

Read the Instructions for Use thoroughly before using the device.

♥ Indications for Use

The Activ8rlives Blood Pressure3 Connected Monitor is digital and is intended for use in measuring blood pressure and heartbeat rate for adults, with an upper-arm circumference ranging from 22 - 42cm (8¾-16½"). It is intended for indoor use by adults only.

♥ Contraindications

The device is not suitable for you if you think you are or maybe pregnant.

The device is not suitable for use by patients with implanted electrical devices, such as cardiac pacemakers or defibrillators.

♥ Safety Information

	Read before Use		Type BF applied parts
	Manufacturer		Electrical waste products should not be disposed of with household waste. Check with your local authority or retailer for recycling advice.
	Manufacture Date		
	Serial Number		
	Direct Current		Authorised Representative in European Community
	Complies with Medical Device Directive 93/42/EEC, amended 2007/47/EEC.		
	Follow instructions to prevent damage to device or harm to you.		Recycle

♥ Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the atmospheric pressure. Then it starts inflating the upper-arm cuff. The unit detects pressure oscillations generated by beat-to-beat pulse in the upper-arm, which is used to determine the systolic and diastolic pressure, and also pulse rate.

♥ This device is recommended by the British & Irish Hypertension Society (BIHS) for Home Use.

WARNING

The Activ8rives Blood Pressure3 Connected Monitor is intended for home use indoors by an adults. It is not intended or certified for use by medical professionals with patients during procedures, treatment or transport. The solution is not intended for self-diagnosis or as a substitute for medical care, and it is not intended for continuous use.

Contraindications: You should NOT use this device if you:

- are pregnant;
- have implanted electronic devices of any kind;
- have premature ventricular beats, atrial fibrillation or peripheral arterial disease;
- undergoing intravascular therapy or arteriovenous shunt;
- had a mastectomy;
- are allergic to polyester, nylon or plastic.

MEDICAL ALERT: High or low Blood Pressure can be a life-threatening condition. Do not start or end medical treatments based on information obtained from this device. Only make changes on the instruction of your Doctor. If you are taking medication, consult your Medical Team as to the best time for you to take measurements. Never change your medication regime other than under the instruction of your Doctor. If you continue to have symptoms, consult your Medical Team. Do not rely on the Activ8rives Blood Pressure3 Connected Monitor to diagnose blood pressure and irregular heartbeat conditions. This device is not suitable for continuous monitoring (ambulatory) during medical emergencies, operations, treatments or in transporting patients.

If you experience discomfort during measurement, such as pain in the arm or any other complaint, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm to prevent injury.

WARNING

If the cuff pressure reaches 40kPa (300mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reach 40kPa (300mmHg), detach the cuff from the upper-arm and press the START/STOP button to stop inflation.

After the cuff has been inflated for a long period, blood flow in the arm and fingers will be restricted. Detach the cuff from your arm to prevent injury. Rest for 5-minutes before attempting another reading. This device is intended for non-invasive measuring and monitoring of arterial blood pressure on the upper-arm only.

Do **NOT**:

- kink the air hose during use;
- apply the cuff over a wound;
- inflate the cuff on the same arm where other monitoring equipment is also being used;
- service, maintain or use with the power adapter whilst the monitoring equipment is in use;
- take too frequent and consecutive measurements, allow 5-minutes between measurements;
- use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide;
- use in strong electromagnetic fields, radiated interference signals or electrical fast transient/burst signals;
- allow the device to experience excessive forces, shocks, dust, lint, direct sunlight, temperature and humidity over the range specified;
- place heavy objects on it;
- allow small children or pets to play with this device as this may cause injury, or in extreme cases, may be fatal;
- use any abrasive or volatile cleaners;
- remove the casing to the device or tamper with the internal components. If you do you will invalidate your warranty and may cause irreparable damage. There are no user serviceable parts.

WARNING

When disposing of this device, ensure that it is collected separately, it should not be disposed of in normal household waste.

Please use this device as specified in this Instructions for Use (Manual) or the results may be inaccurate, may cause damage to the device or harm to yourself.

Observe the storage and operating conditions described in the Instructions for Use.

The power adapter is specific to this device, do not use any other adapter.

Please use the device under environmental conditions outlined in the Instructions for Use. The service life of the cuff may vary by the frequency of washing, skin condition and storage state. The typical service life can be up to 10,000 inflations.

The measurement functions built into the Activ8rlives Blood Pressure3 Connected Monitor are not meant to substitute professional measurement or industrial precision devices. Values produced by the device should be considered as reasonable representation only. The reading should be used in conjunction with clinical signs and symptoms, as well as a clinical diagnosis.

If you experience any serious incident that occurs in relation to this device, please report this to Aseptika Limited (Activ8rlives) and the Competent Authorities of the country in which you reside.

The technical specifications for this device and the contents of the Instructions for Use are subject to change without notice by the manufacturer.

♥ List of Compatible Devices

Works with: Bluetooth Smart Ready device
(typically Bluetooth 4.0+).

- Apple devices running iOS 12+.
- Android devices running 10+.

♥ Apps

The Activ8rlives Blood Pressure3 Connected Monitor uploads data to the following Class I Medical Device Apps for smartphones:



Activ8rlives⁴
Health+Wellness
Free



Active'me
REMOTE
Subscription

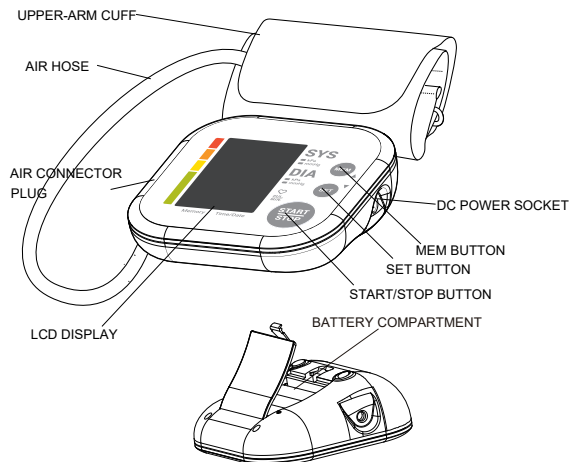
These Apps are not intended to monitor vital physiological parameters where variation could result in immediate danger.

Long-term health conditions (LTHC) can be life-threatening. Always take medication as prescribed. If you experience any LTHC-related symptoms, refer to your Care Plan provided by your medical team and follow the instructions carefully. If you continue to have symptoms, consult your medical team.

Do not rely on these Apps to diagnose or treat any long-term health condition. Do not rely solely on the Reminder capabilities of the Apps to take your prescribed medication as directed by your medical team.

♥ Monitor Components

MODEL: TMB-1491-BS



♥ List

Blood Pressure3 Monitor



4× AAA batteries



Upper-arm Cuff (22cm-42cm)



Instructions for Use



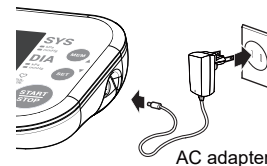
♥ Choice of Power Supply

Battery powered mode:

6V DC 4× AAA batteries

AC adapter powered mode: 6V  1A
(Optional not included).

Note: Only use recommended AC adapter model. Unplug adapter to stop using power.

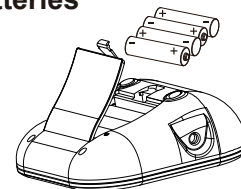


⚠ CAUTION

To protect your device and obtain consistent readings, please use the correct batteries and authorised power adapter, which complies with CE safety standards.

♥ Installing and Replacing Batteries

- Open the battery cover.
- Install batteries by matching the correct polarity, as shown.
- Replace battery cover.



Replace batteries when:

- The  shows.
- The display is dim.
- The display does not light up.

⚠ CAUTION

- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose of batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not being used for some time.
- Batteries are harmful to environment, dispose of correctly for your region.
- Remove old batteries from device and follow your local recycling guidelines.



♥ Tips Before Your Reading

Tip 1: Try to take your blood pressure at the same time each day. It will vary throughout the day. Doing this in the morning as part of your daily routine is a good time, or whenever your medical team recommends you perform a reading.

Tip 2: Sit down and relax for 5 minutes before each measurement. This is important to get consistent readings. It is often easier to do this at home when there is less stress.

Tip 3: Sit in a chair, with feet flat on the floor, legs uncrossed. Rest your arms on a table located in front of you so that the device is level with your heart.

Tip 4: Remove clothing on the upper-arm so that the cuff can be placed on bare skin.

Tip 5: When placing the device on your upper-arm, ensure that the cuff is secured within the OK region and the air hose runs down the inside of your arm.

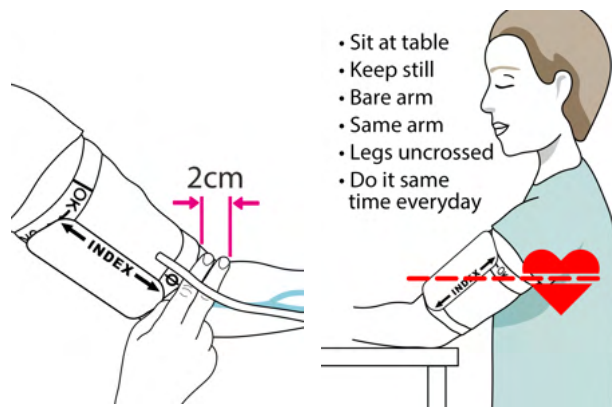
Tip 6: The bottom of the cuff should be 1-2 cm (about 1 or 2 fingers) above the bend in your arm.

Tip 7: The device has a small to large-sized circumference cuff. Ensure that the cuff is secured firmly together at the Velcro patches to stop the cuff slipping up or down on the upper-arm for a consistent reading.

Tip 8: Keep still for the duration of measurement. Moving, talking, eating, drinking or any other activity will produce errors.

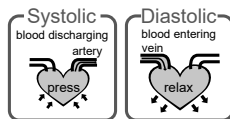
Tip 9: Use the same arm each time. Ideally the left arm (if you are right-handed) or vice versa.

Tip 10: Completely deflate the cuff and wait 5 minutes between readings if you decide to take another measurement. Remember that the cuff applies pressure and this restricts blood flow into your lower-arm.



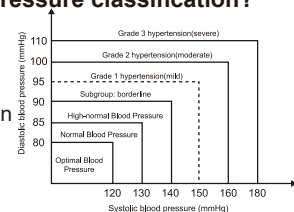
♥ What are systolic pressure and diastolic pressure?

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



♥ What is the standard blood pressure classification?

Blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in the table to the right. The British & Irish Hypertension Society (BIHS) recommends this device for Home Use.



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

♥ Irregular Heartbeat Detector (IHB)

During each measurement, the monitor records all pulse intervals and calculates the average. If there are two or more pulse intervals, the difference between each interval and average is more than the average value of $\pm 25\%$, or if there are 4 or more pulse intervals, the difference between each interval and the average is more than the average value of $\pm 15\%$, the irregular heartbeat symbol appears on the LCD.

If the IHB symbol displays on the LCD after your reading, it is usually NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice.

♥ Why does blood pressure fluctuate throughout day?

Individual blood pressure varies throughout the day. It is also affected by the way you fasten your cuff and your measurement position, so always take your reading under the same conditions. If you take medications, your blood pressure will vary more. Wait at least 5 minutes between measurements.



Pay attention to:

Is the cuff fastened properly? Is the cuff too tight or too loose?
Is the cuff tied on the upper-arm without clothing?
Do you feel anxious?
Taking 2-3 deep breaths before measuring again for a better reading.

Advice: Rest for 5-minutes before taking another reading.

♥ Why do I get a different blood pressure at home compared to the hospital?

Blood pressure varies throughout the day due to weather, emotion, exercise etc.

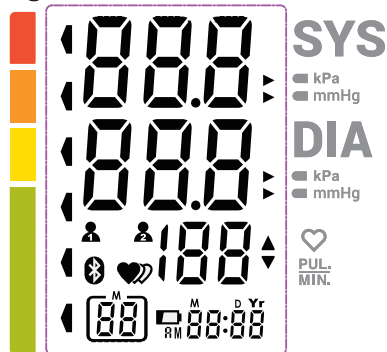
There is also the “white coat” effect, which means blood pressure usually increases in clinical settings.

♥ Is the result the same if I measure on either arm?

It is fine to use on either arm, but there will be slightly different results for you. We suggest you measure on the same arm every time.



♥ LCD display signal



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High blood pressure.
DIA	Diastolic blood pressure	Low blood pressure.
Pul/min	Pulse display	Pulse in beats per minute.
▼	Deflation symbol	The cuff is deflating.
M 88	Memory	Indicate it is in the memory mode and which group of memory it is.
kPa	kPa	Measurement Unit of the blood pressure.
mmHg	mmHg	Measurement Unit of the blood pressure.
Lo +	Low battery	Batteries are low and need to be replaced.
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
	Blood pressure level indicator	Indicate the blood pressure level.
M D Yr 88:88	Current Time	Year/Month/Day, Hour/Minute
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
	User 1/User G/User 2	Start measurement for User 1 / User 2
	Bluetooth icon	The bluetooth icon blinks when the bluetooth is working.

♥ Maintenance

To obtain the best performance from your device, follow the maintenance instructions below.



Store, use in dry place and avoid direct sun.



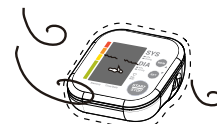
Avoid shaking and hard knocks.



Use damp cloth to remove dirt.



Do not submerge in water, clean with damp cloth.



Avoid dusty, humid and unstable temperature environments.



Do not wash the reusable cuff with water.

♥ Troubleshoot

Will not connect by Bluetooth! Check Bluetooth is switched on your smartphone or tablet. Disconnect other Bluetooth devices.

Check your smartphone supports Bluetooth Smart (4.0) on page 7.

App crashes! Close other apps and reboot your smartphone.

Something went wrong! Our Apps will tell you when something has gone wrong with your measurement, check Error Codes on page 16.

Blood pressure reading high! When first using you may find the cuff inflates high and possibly gives a higher than normal reading. After 8-10 uses the cuff relaxes and will not inflate as high and will give more consistent readings. Tips on page 10-11.

This section includes a list of error messages and frequently asked questions for problems you may encounter with the Activ8rives Blood Pressure3 Connected Monitor (P109).

Problem	Symptom	Check This	Remedy
No power	Display will not light up.	Batteries exhausted.	Replace with new batteries.
		Batteries inserted incorrectly.	Insert batteries correctly.
Low batteries	Display is dim or shows  +10	Batteries low.	Replace with new batteries.
Error message	E 1 shows	Data communication failed.	Ensure Bluetooth is turned on & App open, measure again.
	E 3 shows	Cuff not secure.	Readjust cuff & rest for 5-minutes & measure again.
	E10 or E11 shows	Monitor detects motion or talking.	Movement can affect measurement. Rest for 5-minutes & measure again.
	E20 shows	Measurement process does not detect pulse.	Loosen clothing on upper-arm & measure again.
	E21 shows	Measurement failed.	Rest for 5-minutes & measure again.
	EExx, shows on the display.	Calibration error occurred.	Measure again. If problem persists, contact customer support for further assistance. Refer to warranty for contact information and return instructions.
Warning message	"out" shows	Out of measurement range.	Rest for 5-minutes. Refasten cuff & measure again. If problem persists, contact your Doctor.

Power supply	Battery powered mode: 6V DC 4*AAA batteries. AC Adapter powered mode: 6V  1A (not included)
Display mode	Blue LCD with backlight V.A.60 × 40.5mm
Measurement mode	Oscillographic testing mode.
Measurement range	Cuff pressure: 0 - 299mmHg (0 - 39.9kPa) Measurement pressure: SYS: 60 - 230mmHg (8.0 - 30.7kPa) DIA: 40 - 130mmHg (5.3 - 17.3kPa) Pulse value: (40 - 199) beat/minute
Accuracy	Pressure: 5°C - 40°C within ± 0.4kPa (3mmHg) Pulse value: ± 5%
Normal working condition	Temperature range: +5°C - +40°C Relative humidity range: 15 - 90%, non-condensing, but not requiring water vapour partial pressure greater than 50hPa Atmospheric pressure range: 700 - 1060 hPa
Storage & transportation condition	Temperature: -20°C - +60°C Relative humidity range: ≤ 93%, non-condensing, at water vapour pressure up to 50hPa
Measurement circumference upper-arm	22 - 42 cm (8½" - 16½")
Net Weight	Approx. 182g (Excluding batteries)
External dimensions	Approx. 110 × 110 × 41mm
Accessories	4× AAA batteries, Instructions for Use.
Mode of operation	Continuous operation.
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 means the device is protected against solid foreign objects of 12.5mm and greater, and protect against falling water drops.
Device Classification	Battery Powered Mode: Internally Powered Medical Device Class IIa
Software Version	A01

♥ EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

Warning: Do not be near the active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment TMB-1490-BHJ including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.
2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not Applicable 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U _T ; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles; Single phase: at 0°. 0% U _T ; 250 / 300 cycle	0% U _T ; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles; Single phase: at 0°. 0% U _T ; 250 / 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz
NOTE U _T is the a.c. mains voltage prior to application of the test level.		

Table 3

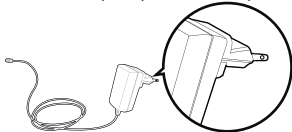
Guidance and manufacturer's declaration - electromagnetic immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM $\pm$ 5k Hz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							

♥ Complied Standards List

Risk management	EN ISO 14971:2012/ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016/ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
User manual	EN 1041:2008 + A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013/IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	EN 60601-1-2:2015/IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type IEC 80601-2-30:2018 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of intermittent automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008/IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2018 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitisation

♥ Authorised Component

Please use the Activ8rlives authorised adapter (Not included).



Adapter

Type: BLJ06L060100P-B

Input: 100~240V, 50~60Hz, 0.2A Max

Output: 6V $\overline{\overline{\sim}}$ 1A

♥ Contact Information

Manufactured by: Guangdong Transtek Medical Electronics Co., Ltd.

Company: Guangdong Transtek Medical Electronics Co., Ltd.

Address: Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China

Authorised European Representative:

Company: MDSS - Medical Device Safety Service GmbH

Address: Schiffgraben 41, 30175 Hannover, Germany

Authorised UK Responsible Person:

Company: MDSS-UK RP Ltd

Address: 6 Wilmslow Road, Rusholme, RP Manchester, M14 5TP, United Kingdom

♥ Need to contact Customer Support?

We take Customer Support seriously so we provide 7-days-a-week support for you, between 09:00-18:00.

You can contact us:



UK +44 (0)1480 352 821



support@aseptika.com



www.activ8rlives.com



Look for in-App Help where you see ?