

Pulse Oximeter 2 Wireless Monitor

Pulmonary/Cardiovascular Health



















www.activ8rlives.com







We are a healthcare company. Our mission is to empower you to take care of your health and that of your family by self-care through self-monitoring.

From tracking levels of physical activity, weight, food intake, cardiovascular and lung function, to a new generation of at-home testing for long-term lung disease, we provide the devices and web-based tools to help you be active, eat well and stay healthy. Learn more at www.activ8rlives.com



Your Activ8rlives Pulse Oximeter2 Monitor

Please read this manual carefully before you use your new device so that you do not injure yourself or others, or cause damage to your new device through improper use.

Intended Use for Activ8rlives Pulse Oximeter2 Monitor

The Activ8rlives Pulse Oximeter2 is a device that can measure your blood oxygen saturation, heart rate and perfusion index when connect to the Activ8rlives⁴ Health+Wellness Apps (free), Asthma[†]me and Active[†]me REMOTE (subscription) Apps.

This device is intended for measuring the blood oxygen saturation, heart rate and perfusion index on the finger tip and is intended for use by adults only and for use indoors. The solution is not intended for primary or self-diagnosis or as a substitute for medical care, and it is not intended to provide real-time data.

1 If in any doubt about your health, please consult your medical team first and follow their advice closely

Health and Safety Notices



MEDICAL ALERT: Seek medical advice before undertaking a strenuous exercise programme. Seek advice from your Doctor about any long-term condition. This device should not be used to make a primary diagnosis.



WARNINGS: The Activ8rlives Pulse Oximeter2 is NOT waterproof. Do not submerge it in water.



Do not expose your eyes to the light-emitting component of the Activ8rlives Pulse Oximeter2, as this $\stackrel{\frown}{\square}$ could cause harm to your eyes.



Do not use the device in an environment with any inflammable gases, inflammable anaesthetic or other /N inflammable substances.



Do not use the device in an MRI or CT environment or near high-frequency knives.



Do not operate the device when it is damp with overflow or water vapour condensation. Avoid moving $\stackrel{\frown}{\mathbb{N}}$ the device from excessively-cold environment to a high-temperature moist environment.



The device may have affected accuracy when the user suffers from hypotension, severe vascular 4 atrophy, severe anaemia, low oxygen, or if the user is in cardiac arrest or in a shock state.

This device is not a toy. It is not calibrated for new born babies or children.

Fingernail polish, fake fingernails and tattoos on the finger may cause incorrect readings.



Do not wash it in water. Use a soft dry, microfiber cloth for cleaning. Don't use harsh cleaning products as these will cause damage to your Activ8rlives Pulse Oximeter2. Don't allow sharp objects to scratch the screen of the OLED Display as this may damage it.

Do not allow your Activ8rlives Pulse Oximeter2 to be subjected to excessive forces, shocks, dust, temperature changes or humidity over the range specified. Harsh physical treatment may stop your Activ8rlives Pulse Oximeter2 from working properly.

Don't expose your Activ8rlives Pulse Oximeter2 to direct sunlight for long periods of time.



Don't remove the back cover and tamper with the internal components. If you do, you will invalidate riangle your warranty and may cause irreparable damage. Other than the replacement of the batteries, there are no user serviceable parts.

Take precautions when handling all battery types and dispose of batteries correctly. Remove the batteries if you are planning to store the device for a long period of time. We hope you use your device for many years of course, but long periods of storage with the batteries in place may damage the device and will cause the batteries to discharge. Only use the battery type recommended in this manual. Do not touch the exposed electronic circuits, as there is a danger of electric shock. Do not attempt to recharge the AAA Alkaline batteries supplied.



When disposing of this product, ensure that it is collected separately for special treatment and not as normal household waste.

The measurement functions built into the Activ8rlives Pulse Oximeter2 are not meant to substitute professional measurement or industrial precision devices. Values produced by the unit should be considered as reasonable representation only.



The technical specifications for this product and the contents of the User Manual are subject to change without notice by the manufacturer.



If you experience any serious incident that occurs in relation to this device, please report this to Aseptika Limited (Activ8rlives) and the competent authority of the Country in which you are based.

Call us 7-days-a-week, between 09:00—18:00

UK +44 (0)1480 352 821 or support@aseptika.com

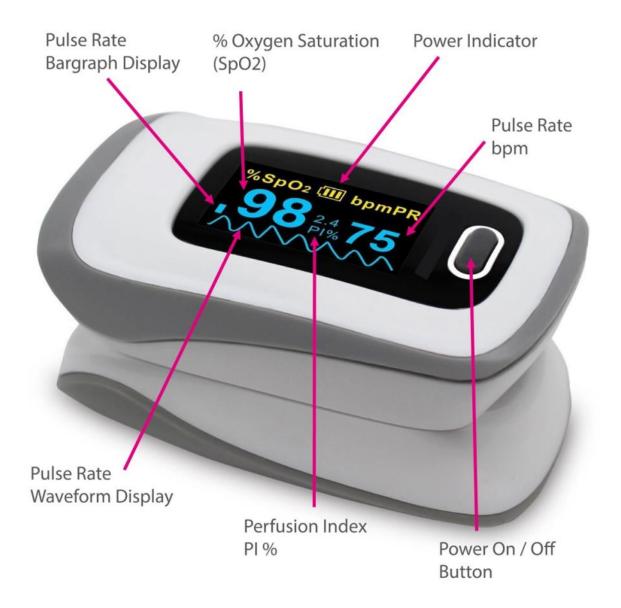


Your Activ8rlives Pulse Oximeter2

Your Activ8rlives Pulse Oximeter2 has several parts, the OLED Display, the On/Off Button, and the Battery Compartment. It is also supplied with a storage bag and User Manual.

The **OLED Display** has many parts: Oxygen saturation (or known as SpO₂ for short), Perfusion Index PI, Pulse Rate bpm, Battery symbol, Bluetooth 4.0 symbol, Pulse Rate Bar graph and the Pulse Rate Waveform Display or Plethysmogram or Plethysmograph.

Your Activ8rlives Pulse Oximeter2 also has a finger size adjustment, which can accommodate small and large circumference fingers to be measured. See page 11 for full instructions on the correct finger placement for optimal readings.P





Inserting Batteries in Activ8rlives Pulse Oximeter2

Your **Activ8rlives Pulse Oximeter2** uses two AAA 1.5V alkaline batteries, which are supplied. These are non-rechargeable batteries and no attempt should be made to recharge these.

Remove the back cover and add the 2 x AAA 1.5 V alkaline batteries in the direction indicated.

Replace the cover. The **OLED Display** should light up now when you press the **On/Off Button.**

If not used, it will power off after about 10 seconds to save battery power. A faulty operation would make it power off.

Remove the batteries if you are planning to store the device for a long period of time. We hope you use your device for many years of course, but long periods of storage with the batteries in place may damage the device and will cause the batteries to discharge.

Replace the set of batteries (2 x AAA) in the right direction when the battery symbol on the **OLED Display** shows an empty or the low battery symbol.





Note: Do not tamper or attempt to open the unit in which the electronic components are housed, your warranty will be invalidated. Substances contained within the battery may damage the environment or human health if handled and thus a risk of electric shock or burns. When disposing of this product and its batteries, ensure that it is collected separately for special treatment and not as normal household waste.



How Does the Activ8rlives Pulse Oximeter2 Work?

The Activ8rlives Pulse Oximeter2 is a non-invasive wireless method allowing the monitoring of the saturation of oxygen of the haemoglobin in your blood.

A sensor is placed on a thin part of your body, such as your fingertip. Light of two wavelengths is passed through the finger to a photodetector. The changing absorbance at each of the two wavelengths (red 660nm and infrared 905nm) is measured, allowing determination of the absorbances due to the pulsing arterial blood alone (the blood flowing from the heart and lungs), and excludes venous blood (the blood returning to the heart and lungs), skin, bone, muscle, fat, and fingernails.

A blood-oxygen monitor displays the percentage of arterial haemaglobin (Hb) in the oxyhaemoglobin (HbO₂) configuration. Acceptable normal ranges for patients without COPD with a hypoxic drive problem are from 95-99 percent (%), in those with a hypoxic drive problem would expect values between 88-94%. For a patient breathing room air at sea level, an estimate of arterial oxygen saturation levels (pO_2) can be made from the blood-oxygen monitor SpO_2 reading.

The monitored signal fluctuates in time with the heart beat because the arterial blood vessels expand and contract with each heart beat. By examining only the varying part of the absorption spectrum (essentially subtracting minimum absorption from peak absorption), a monitor can ignore other tissues or nail polish (though black nail polish or false fingernails tend to distort readings) and discern only the absorption caused by arterial blood. Detecting a pulse is therefore essential to the operation of the Activ8rlives Pulse Oximeter2 and it will not function if there isn't one. See Page 13 for instructions on obtaining an accurate and consistent readings.

Your Activ8rlives Pulse Oximeter2 will give you two important pieces of information: your oxygen saturation levels (SpO₂) and your pulse rate in beats per minute (bpm).

1 If in doubt about your health, please consult your medical team first and follow their advice closely.



Let's get started with the Set-up and Connect to the Activ8rlives⁴ Health+Wellness App

The Activ8rlives Pulse Oximeter2 Monitor is programmed by and uploads information directly to and from your Activ8rlives account each time your Bluetooth connected Smartphone or Tablet is connected to it (not included).

This guide will show you how to:

- Install the Activ8rlives⁴ Health+Wellness App (or Asthma[†]me and Active[†]me REMOTE Recovery Apps) to your iOS or Android Smartphone or Tablet.
- How to operate, use and take care of your Activ8rlives Pulse Oximeter2 and connect to your Smartphone or Tablet; and
- How to take routine readings and upload directly to your Activ8rlives account.

If you follow these directions sequentially, it will take you about 5-10 minutes to learn how to measure your saturated blood oxygen, perfusion index and heartrate and connect to the Activ8rlives⁴ Health+Wellness App.

Intended Use for Activ8rlives⁴ Health+Wellness App:

The Activ8rlives⁴ Health+Wellness App is an application software for mobile device intended for use in the home to assist people to receive and review information from connected medical and non-medical devices, track medication use, for effective health self-management. The user also can share the data via sharing functions.

Activ8rlives⁴ Health+Wellness App is a Class I medical device designed for use with persons 5-80+ years-old, and 5-12 years-old with adult supervision, who have a health condition for which the App can be used at home for their self-care.

Health and Safety Notices:

Activ8rlives⁴ Health+Wellness App is 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** and follow the instructions carefully. If you continue to have symptoms, consult your medical team.

Do not rely on Activ8rlives⁴ Health+Wellness App the to diagnose or treat any long-term health condition.

Only recommended for children 5 years of age and over and only under adult supervision.

Do not rely solely on the Reminder capabilities of the Activ8rlives⁴ Health+Wellness App to take your prescribed medication as directed by your medical team.





Installing the Activ8rlives⁴ Health+Wellness App on Your Smartphone or

Tablet (Bluetooth 4.0 Enabled Devices are required to use the **Pulse Oximeter2**)

Download the Activ8rlives⁴ Health+Wellness App from the App Store appropriate to your device. Search for Activ8rlives in the search bar of your App Store or scan the QR code below and it will take you to the appropriate App Store for your device.











Apple devices running iOS 12+ that are Bluetooth Smart Ready (typically Bluetooth 4.0+).

Android devices running Android 10+ that are Bluetooth Smart Ready (typically Bluetooth 4.0+).

IMPORTANT NOTE: Please adjust the screen lock function on your Smartphone or Tablet to be <u>longer</u> than 2 minutes to allow the <u>Activ8rlives</u> Pulse Oximeter2 time to sync with your device.

Short times of less than 2 minutes cause frequent loss of connectivity.



Help Videos in App, follow this?

Website www.Activ8rlives.com

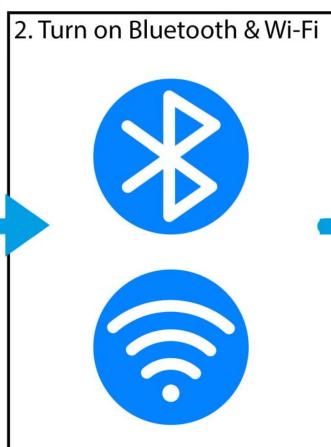
YouTube http://bit.ly/Activ8rlives

Still Need Help

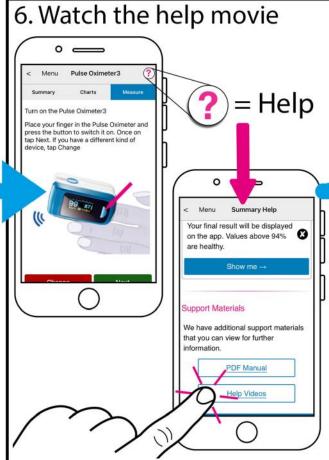
We are here to help you 7-days-a-week, so please call us to help you set-up your device on UK 01480 352821.

Already have an account setup? Skip straight to step 4

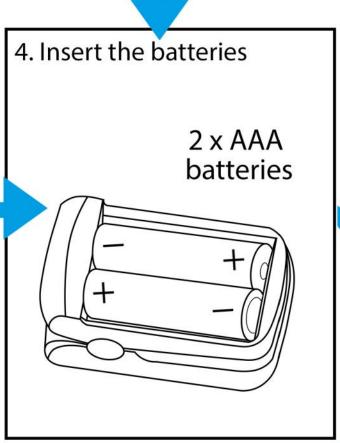


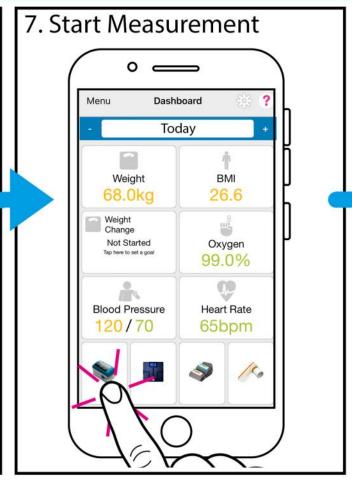


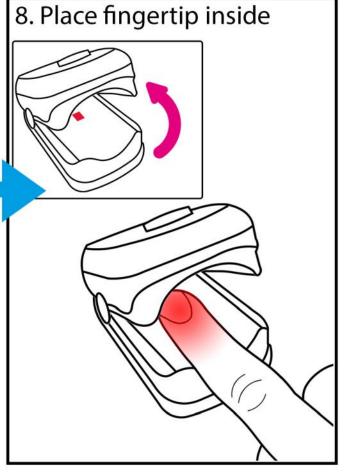




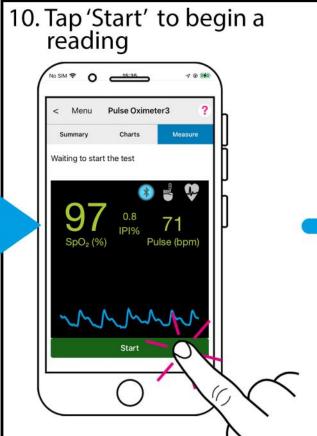


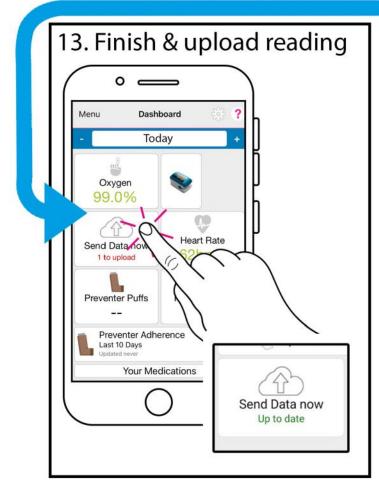


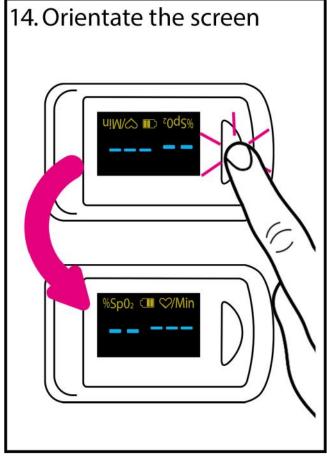


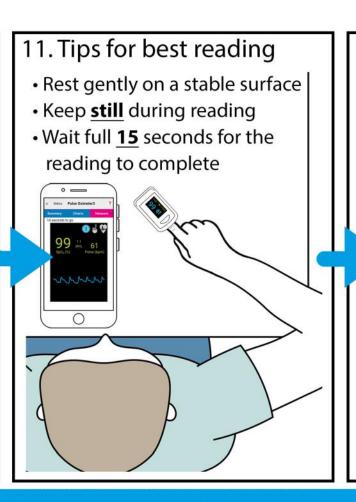










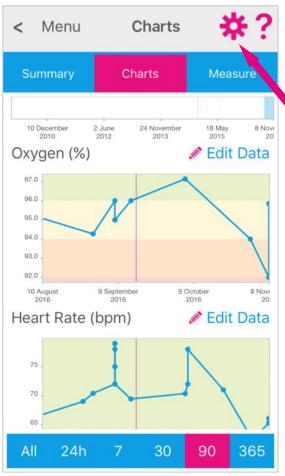








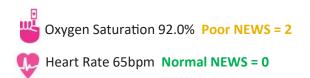






Viewing Data on Smartphone or Tablet

Detailed data can be viewed from the Activ8rlives⁴ **Health+Wellness App**. The example shown here gives:



With an accumulated NEWS of 2. Refer to the Blood Oxygen Chart on Page 10 to see where your reading is placed in the population table.

Colour coding of parameters within normal **Green**, alert **Amber** and out of parameter readings **Red** are easily seen on the **Summary** and **Charts**.

The **arrows** beside your current reading indicate in which direction your reading is going: i.e, rising, static or falling from your last reading.

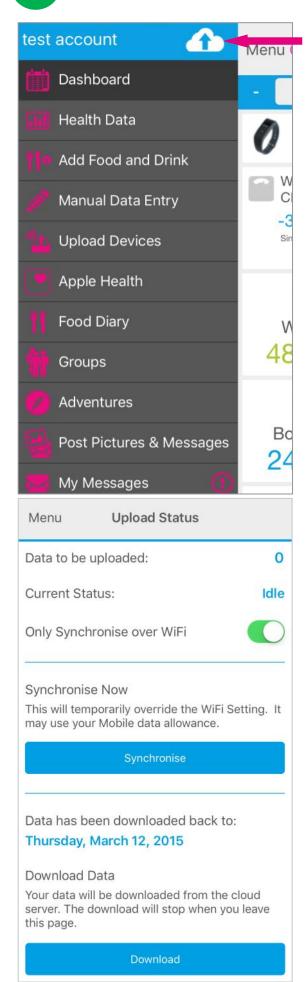
Your **last 3 readings** will be displayed below for your reference.

Detailed data **Charts** can be viewed from the **Activ8rlives**⁴ **Health+Wellness App** by selecting from the **Main Menu** > **Health Data** > **Charts**.

To change how these **Charts** display your data you can select and deselect via the **Settings Cog**. Also change the **timeframe** from the bottom blue selector. Within this section you can start to see trends of what affects your other health parameters, and you begin to learn good behaviours or detect declining health.

The data displayed in this **Chart** shows the individual's **Oxygen** Saturation and Pulse Rate over a period of 90 days. You can scroll through the **Chart** to the left and right to change the timeframe.

Note: If your **Activ8rlives Pulse Oximeter2** is **NOT** connected to your Smartphone or Tablet via Bluetooth, the data will **NOT** be stored on the **Activ8rlives Pulse Oximeter2**.





Sending Your Data to Cloud

If your Smartphone or Tablet is connected to the internet by WiFi, your data will upload to your online **Activ8rlives** account automatically.

If there is an arrow in the **Cloud** it indicates that you have data to upload to the **Cloud** Server. Touch the **Cloud** icon and it will automatically detect and synchronise if you are on WiFi.

Touch the **Synchronise** bar to upload via Cellular network to upload the data.

By touching the **Download** bar your data will download from the **Cloud** for you to view on the App.

If there are no networks available the data will be uploaded at a later time by either WiFi or Cellular when you are within range. The data is not lost and you do not have to take the reading again.

When the data is stored in the **Activ8rlives** secure **Cloud**, this means that you can view your data (from today, yesterday, a week, a month or years ago) at any time via the Smartphone App or **Activ8rlives** website.

www.activ8rlives.com

Data Security

The storage of your data is hosted on our private **Cloud** Server operated by UKCloud (Farnborough, UK). No data ever leaves the UK and we work to the NHS Data Security and Protection Toolkit and Cyber Essentials Plus standards.





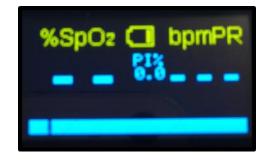
Manual Setting SpO₂ Alarm

The Activ8rlives Pulse Oximeter2 can be manually programmed to set-off an Alarm if your reading is above or below a certain SpO₂ level.

To programme the device:

- Press **On/Off Button** to bring the device to life and show the default screen.
- Press the **On/Off Button** for 1 second to move to **Interface 1**.
- Touch On/Off Button once to scroll * to Alarm (Alm)
 position.
- Press the On/Off Button for 1 second to scroll * to on for the
 Alm.
- Touch the On/Off Button and scroll * to Exit position.
- Press **On/Off Button** for 1 second to move to **Interface 2.**
- Touch the On/Off Button once to scroll * to SpO₂ Alm Hi and enter an upper limit depending on your lung function.
- Touch the On/Off Button once to scroll * to SpO₂ Alm Lo and
 enter a lower limit depending on your lung function.
- Touch the On/Off Button once to scroll * to Exit position and the device will return to the default screen ready for you to take a reading.

Note: Having the **Beep** turned on will decrease the battery life.



Default Interface



Interface 1



Interface 2



Manual Setting Pulse Rate Beep

The Activ8rlives Pulse Oximeter2 can be manually programmed to set-off a Beep to correspond with every Heart Beat. To programme the device:

- Press On/Off Button to bring the device to life and show the default screen.
- Press the **On/Off Button** for 1 second to move to **Interface 1**.
- Touch On/Off Button once to scroll [★] to Beep position.
- Press the On/Off Button for 1 second to scroll * to on for the Beep.
- Touch the On/Off Button and scroll [★] to Exit position
- Press On/Off Button for 1 second to move to Interface 2.
- Touch the On/Off Button once to scroll * to PR Alm Hi and enter an upper limit depending on your cardiovascular function.
- Touch the On/Off Button once to scroll * to PR Alm Lo and enter a lower limit depending on your cardiovascular function.
- Touch the On/Off Button once to scroll to Exit position and the device will return to the default screen ready for you to take a reading.



Default Interface



Interface 1



Interface 2

Setting OLED Display Brightness & Restore Factory Setting

The Activ8rlives Pulse Oximeter2 can be manually programmed to increase the Brightness of the OLED Display or Restore Factory Settings via Interface 1 screen, with the range from 1—5 being the brightest setting.



Viewing Your Data on Your PC or Mac Computer

Login via the **Activ8rlives** website, go to **www.activ8rlives.com** using the same **Username** and **Password** that you used for your App **Login**.

From your Activ8rlives account you can view your Health Data, select the Timeframe and scroll down to view.

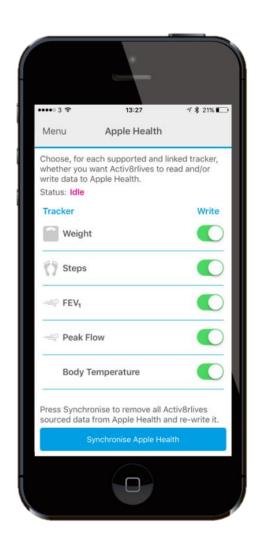
The Activ8rlives Data website hosts an enhanced Dashboard. You have the choice of using either the Simple, Advanced or Expert settings by selecting the buttons in the top right-hand corner to switch between increasingly complex Dashboard layouts.

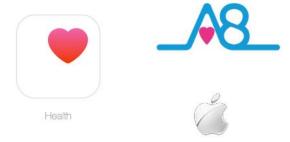


Printing your Data

Printing your data can be achieved by going to the Web version of your Activ8rlives account and touch the Print All tab or Copy Graph. These will be saved as a PDF file, as the example below, for easy printing or sending via email.







Apple Health App Integration

Included in the Activ8rlives⁴ Health+Wellness App is the ability to allow users to record data from Activ8rlives' growing range of consumer-focused health monitors and store these data in both the Activ8rlives Cloud servers and Apple's Health App via your iPhone.

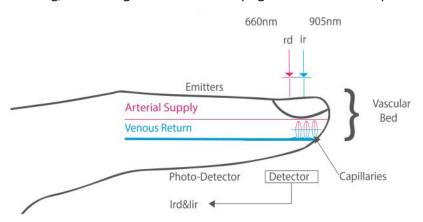
From the Menu of the Activ8rlives⁴ Health+Wellness App, select Apple Health and it will guide you through step-by-step the process of set-up of Apple Health within the Activ8rlives⁴ Health+Wellness App. You must enable all related types of data in the categories to sync to Apple Health then touch Synchronise Apple Health.

Note: Apple's Health App option does not appear on iPads or on older iPhones running versions below iOS 9.**Perfusion Index**

Perfusion Index

The Activ8rlives Pulse Oximeter2 also measures the Perfusion Index (PI). This is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. Perfusion Index thus represents a non-invasive measure of peripheral perfusion that can be continuously and non-invasively obtained from the Activ8rlives Pulse Oximeter2. To make informed patient management decisions, clinicians often need to be aware of changes in peripheral perfusion and circulatory status.

Optimal pulse oximetry monitoring accuracy is dependent on the selection of a monitoring site (e.g. fingertip, hand, toe, foot, forehead, ear) characterised by good perfusion with oxygenated blood. The Activ8rlives Pulse Oximeter2 now records the PI to ensure that a good reading is taken. Once the Plethysmograph (pulse rate waveform) has become stable it is then time to take your reading. See Page 19 for more details but keeping still, calming your heart rate and breathing, and having warmer hands helps get a more accurate pulse oximeter reading.



Trouble Shooting

Help Menu?

Help can be found on all pages of the Activ8rlives⁴

Health+Wellness App in the top right-hand corner. Touch? to expand the page and scroll down through the Help information, including viewing the Help Videos.

This symbol ① also provides helpful hints, when found in one of the Activ8rlives Apps.

Will Not Connect via Bluetooth?

Requires Bluetooth Smart Ready devices (typically Bluetooth 4.0+), iOS 12+ and Android 10+.

If the Activ8rlives Pulse Oximeter2 will not connect to Bluetooth, first check that your Smartphone or Tablet is connected to the Internet and has Bluetooth turned on. Then touch the grey On/Off Button on the Activ8rlives Pulse Oximeter2 to wake it up.

If your device is still not seeing the Activ8rlives Pulse

Oximeter2 you may need to go back to Upload Devices and the first screen, choose Change and the next screen you can choose between two Activ8rlives Pulse Oximeter models.

Lastly, try rebooting your Smartphone or Tablet and reopening the Activ8rlives⁴ Health+Wellness App.

Still Need Help

We are here to help you 7-days-a-week, so please call us to help you set-up your device on UK 01480 352821 between 09:00-18:00.





Trouble Shooting

Activ8rlives App Crashes

Close other Apps open on your Smartphone or Tablet, as these may be using too much memory to allow the **Activ8rlives App** to function fully.

Stops Monitoring

This may be caused by:

- You may be moving slightly during the reading period of 15 seconds and your pulse traceline will be lost temporarily until you stop moving. Remain still throughout the rest period and when the countdown disappears and then your Reading Today will show on the Activ8rlives⁴ Health+Wellness App.
- You may have to adjust the screen lock function
 (usually found in Settings) on your Smartphone or
 Tablet to be longer than 2 minutes to allow the
 Activ8rlives Pulse Oximeter2 time to sync with your
 device. Short times of less than 2 minutes cause
 frequent loss of connectivity and sometimes loss of
 new data.
- Remove nail polish, false nails or other coatings on fingernails that obstruct the light waves going through the finger.
- 4. If you find that your SpO₂ reading defaults to 97-97% but your normal SpO₂ reading is lower than this, follow the instructions on Page 10-13 to improve the accuracy and consistency of your reading. Sometimes swapping fingers may help.



Pulse Oximetry Help

Pulse Oximeter Device Pulse Oximeter2 Device



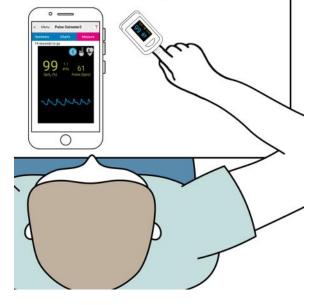
Pulse Oximetry

This section allows you to review and edit all data relating to oxygen and heart rate readings

Summary

The **Summary** shows you an overview of the latest data that you have

- Rest gently on a stable surface
- Keep still during reading
- Wait full <u>15</u> seconds for the reading to complete





Help Videos in App, follow this?

Website www.Activ8rlives.com

YouTube http://bit.ly/Activ8rlives

Pulse Oximeter 2 Wireless Monitor

Specifications	Description
Oxygen Saturation	
Range	35—100% (resolution 1%)
Measurement Precision	<u>+</u> 2 (70-100%)
Alert Range	50-100%
Alert Error	±1% of pre-set value
Accuracy	70—79% accuracy is <u>+</u> 2%, 80—100 accuracy is <u>+</u> 3
Perfusion Index	
Range	0-20%
Weak PI	Min 0.2%
Pulse Rate	
Display Range and Alert Range	25—250 bpm (resolution 1 bpm)
PR Accuracy	<u>+</u> 2 bpm
Alert Error	The greater of ±10% of pre-set value & ±5 bpm
Peak Wavelength Range	Red light 660nm <u>+</u> 3; infrared light 905nm <u>+</u> 5
Maximum optical output power	1.2mW for infrared light (905nm)
Alkaline	2 x AAA 1.5V batteries
Rated Voltage	DC 3.0V
Working Temperature	5°C—40°C (41°F—104°F)
Relative Humidity	15—80%, non-condensing
Atmospheric pressure	70—106 Kpa

Warranty

Activ8rlives (Aseptika Limited) guarantees this product for one (1) year after the date of purchase. The guarantee does not cover the batteries, packaging and damages of any kind due to misuse, such as: dropping or physical misuse caused by the user or water damage outside of the stipulated usage. Claimed products will be replaced when returned marked as **DAMAGED** together with the original proof-of-purchase. For any general enquiries or technical questions concerning the product or questions about the warranty, please contact Activ8rlives — details are on the back of this User Manual.



Labelling and Symbols



This product is manufactured by Shenzhen Jumper Medical Equipment Co., Ltd, Building D, No 71, Xintian Road, Fuyong Street, Baoan, Shenzhen, Guangdong Province, 518102, China.



Date of Manufacture.

Model

Digital Pulse Oximeter Monitor JPD-500F.

LOT

Indicates the lot number for this product 1712-02-00600.

SN

Device serial number.

Battery

2 x AAA Alkaline Batteries.



Medical Device.



This product is a certified Class IIa medical device and complies with the requirements of Directive 93/42/EEC, amended by 2007/47/EEC.



In accordance with IEC 60601-1 the product and its applied parts are type BF and thus protected against the risks of electrical leakage.

FCC ID

Indicates the lot number for this product 2ADYL-JPD500F.

IP22

In accordance with IEC 60529 the International Protection rating is IP22 which relates to the degree of waterproofing this product complies with.



This symbol is required by European directive 2002/96/EEC on waste electrical and electronic equipment (WEEE). At the end of its useful life this device must not be disposed of as normal domestic waste. Instead it must be delivered to a WEEE authorised collection centre. Due to the construction materials used for the device, disposal as normal waste could cause harm to the environment and/or health.



Read instructions before use. https://www.activ8rlives.com/support/manuals

EC REP

REP European Representative: Wellkang Ltd, Suite B, 29 Harley Street, London, W1G 9QR, UK.



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ASL TF-005 MAN/IFU04 PulseOximeter2 (V5.0)

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