

Pulse Oximeter 3 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 Oximeter3

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 Oximeter3

The Activ8rlives Pulse Oximeter3 is a device that can measure your blood oxygen saturation, heart rate and indication of pulse intensity when connect to the Asthma⁺me, Active⁺me REMOTE (subscription) and Activ8rlives⁴ Health+Wellness (free) Apps.

These devices are intended for measuring the blood oxygen saturation or functional arterial oxygen saturation (SpO_2) and pulse rate 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 or continuous data for long periods of time.

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

Need Help Setting-Up?
View Help Videos within App
Call us 7-days-a-week, between 09:00—18:00
UK +44 (0)1480 352 821

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 Oximeter3 is NOT waterproof. Do not submerge it in water.

Do not expose your eyes to the light-emitting component of the Activ8rlives Pulse Oximeter3, as this could cause harm to your eyes.

Do not use the device in an environment with any inflammable gases, inflammable anaesthetic mixture with air, oxygen or hydrogen, or other inflammable substances.

Do not use the device in an MRI or CT environment, near high-frequency knives or other high voltage cables, x-rays or ultrasound equipment.

Do not operate the device when it is damp with overflow or water vapour condensation. Avoid moving the device from excessively-cold environment to a high-temperature moist environment.

The device may provide inaccurate readings if the user suffers from hypotension, severe vascular 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 small 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. Do not use harsh cleaning products as these will cause damage to your Activ8rlives Pulse Oximeter3. Don't allow sharp objects to scratch the OLED screen as this may damage it.

Do not allow your Activ8rlives Pulse Oximeter3 to be subjected to excessive forces, vibration, shocks, dust, temperature changes, humidity or temperature over the range specified, corrosive substance or explosive materials. Harsh physical treatment may stop your Activ8rlives Pulse Oximeter3 from working properly.

Do not expose your Activ8rlives Pulse Oximeter3 to direct sunlight for long periods of time.

The Activ8rlives Pulse Oximeter3 does not have an alarm function, so do not use it in an environment where an alarm feature is required.

Do nt remove the back cover and tamper with the internal components. If you do, you will invalidate your warranty and may cause irreparable damage. Other than the replacement of the batteries, there are no user serviceable parts.

Ensure the Activ8rlives Pulse Oximeter3 has batteries with sufficient capacity, otherwise the user might experience inaccurate readings.

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, 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 Oximeter3 are not meant to substitute professional measurement or industrial precision devices. Values produced by the unit 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.



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.



Your Activ8rlives Pulse Oximeter3

Your Activ8rlives Pulse Oximeter3 has several parts, the OLED Display, the On/Off Button and the Battery Compartment. It is also supplied with 2 AAA Batteries, Lanyard and User Manual.

The **OLED Display** has many parts: Oxygen saturation (known as SpO_2 for short), Indication of Pulse Intensity (IPI), Pulse Rate bpm, Battery symbol and the Pulse Rate Waveform Display or Plethysmogram or Plethysmograph (displayed on 2 out of 6 possible screen orientations, see Page 17 for more details).

Your Activ8rlives Pulse Oximeter3 also has a finger size adjustment, which can accommodate small and large circumference fingers to be measured. See page 17 for full instructions on the correct finger placement for optimal readings.





How Does the Activ8rlives Pulse Oximeter3 Work?

The Activ8rlives Pulse Oximeter3 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 it to determine 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 haemoglobin (Hb) in the oxyhaemoglobin (HbO₂). Acceptable normal range from 95-99 percent (%). In those with a respiratory condition, they 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 Oximeter3 and it will not function if there isn't one.

Your Activ8rlives Pulse Oximeter3 will give you two important pieces of information: your oxygen saturation levels (SpO₂) and your pulse rate in beats per minute (bpm).

NOTE: To obtain an accurate and consistent reading you must:

- warm your hands, by rubbing them together before you start for at least 1 minute and get the blood moving;
- 2. calm your heart rate and breathing; and
- keep still throughout.

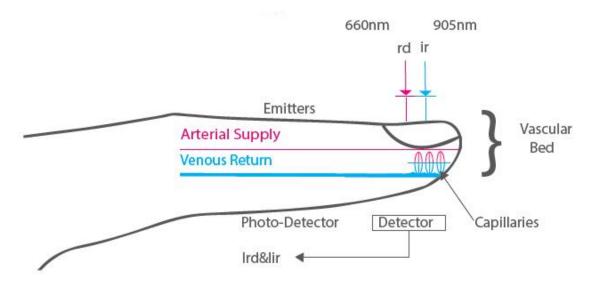
If in doubt about your health, please consult your medical team first and follow their advice closely.



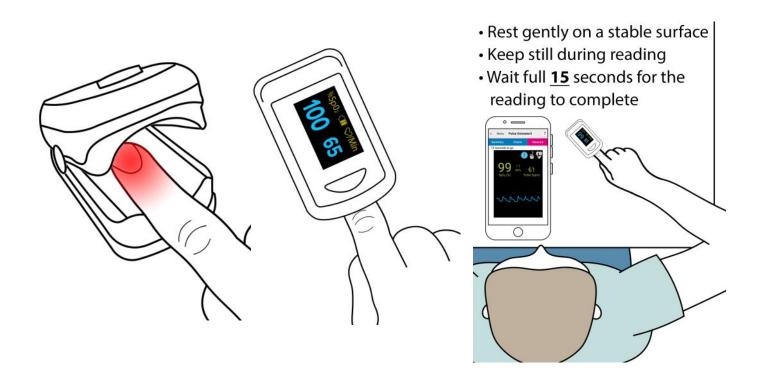
Indication of Pulse Intensity

The Activ8rlives Pulse Oximeter3 also measures the Indication of Pulse Intensity (IPI). This is the strength of the pulsatile or pulse blood flow.

The Activ8rlives Pulse Oximeter3 optimal pulse oximetry monitoring and accuracy is dependent on the selection of a monitoring site (e.g. fingertip) characterised by good perfusion or a higher Indication of Pulse Intensity with oxygenated blood. Once the Plethysmograph (pulse rate waveform) has become stable and the IPI is medium to high, then it is time to take your reading. Keeping still, calming your heart rate and breathing, and having warmer hands helps get a more accurate pulse oximeter reading. Sometimes you will need to select a different finger that may give a higher IPI and a more accurate reading.



Getting the Best Reading





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

The Activ8rlives Pulse Oximeter3 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 Activ8rlives Health+Wellness App (or Asthma me, Active me **REMOTE)** Apps to your iOS or Android Smartphone or Tablet.



How to operate, use and take care of your Activ8rlives Pulse Oximeter3 and connect to your Smartphone or Tablet.



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 Activ8rlives Health+Wellness App.

Intended Use for Activ8rlives⁴ Health+Wellness App:

The Activ8rlives 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. Activ8rlives 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:

Activ8rlives 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 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 Oximeter3**)

Download the Activ8rlives 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 Oximeter3 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

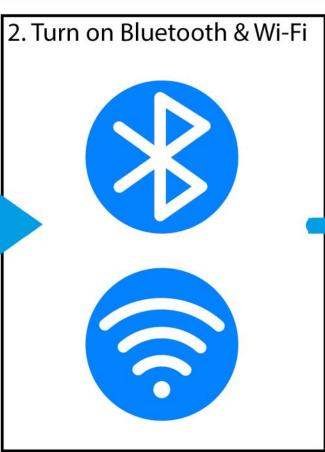
YouTube http://bit.ly/Activ8rlives

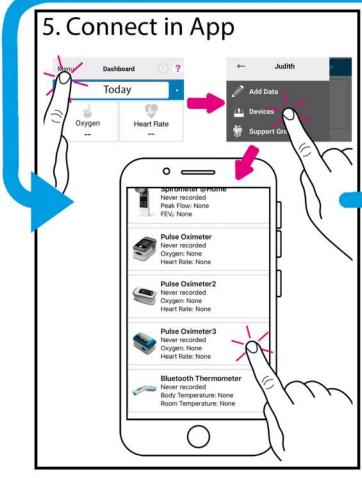
Still Need Help

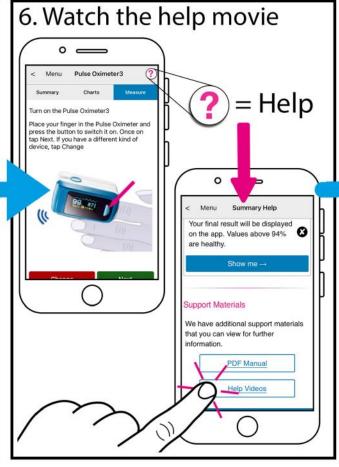
We are here to help you 7-days-a-week, so please call us to help you set-up your device on UK 01480 352821.

Already have an account setup? Skip straight to step 4

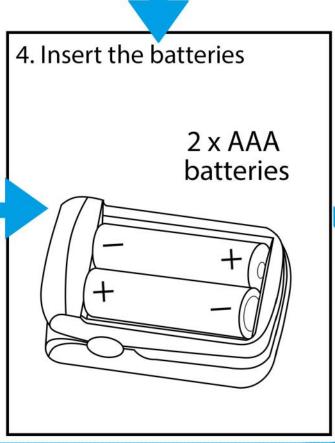


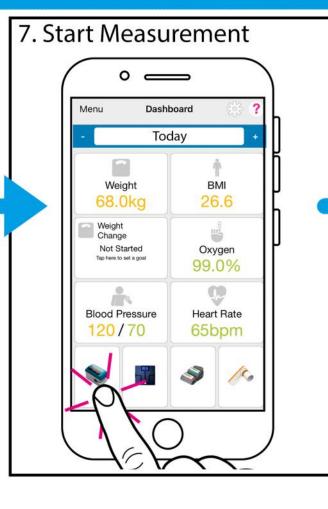


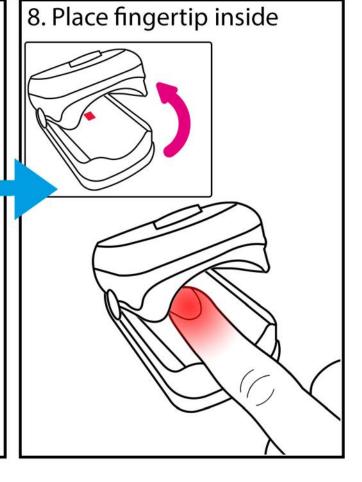


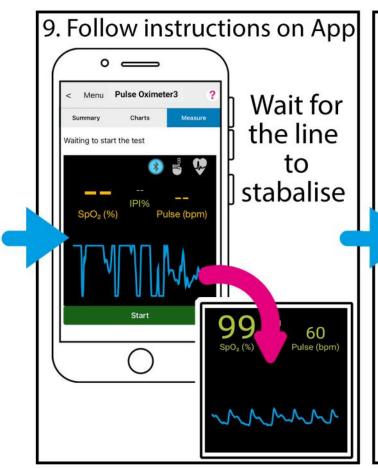


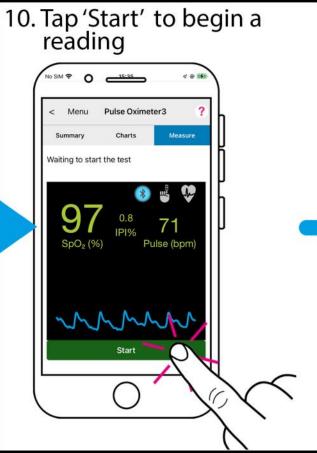


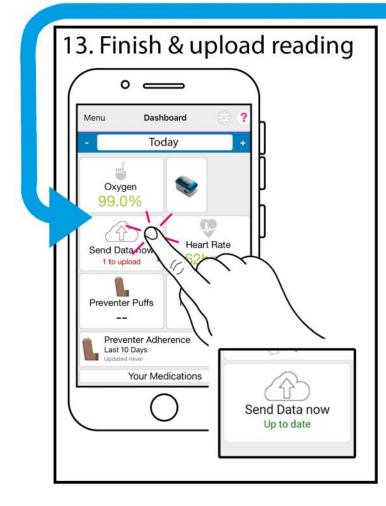


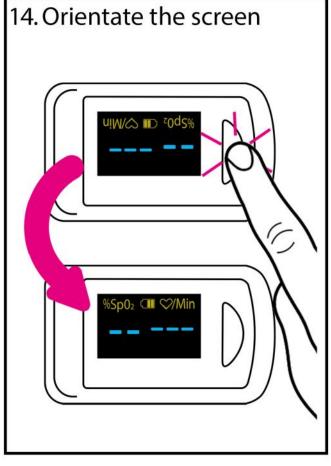


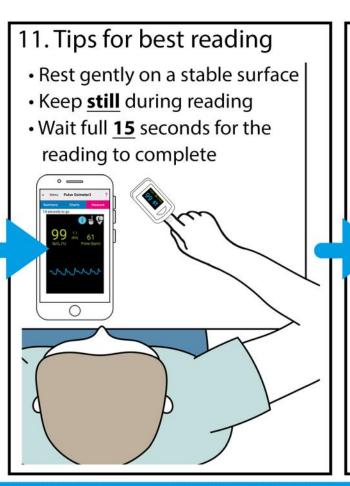


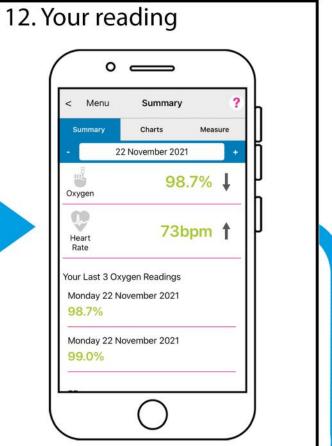


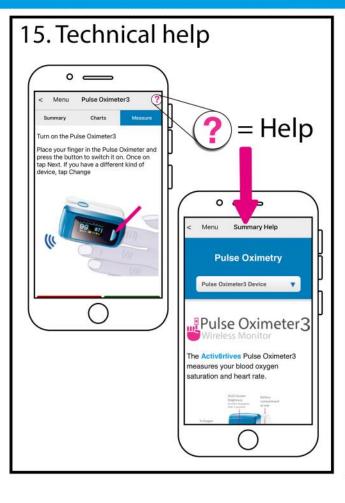






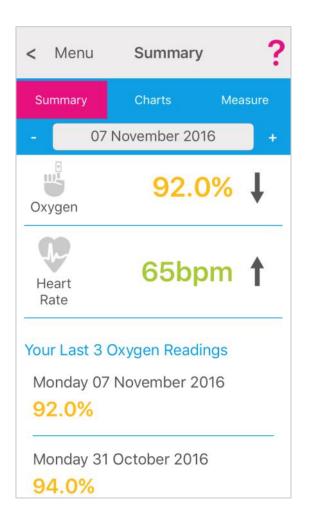












Viewing Data on Smartphone or Tablet

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



Refer to the Blood Oxygen Chart on Page 10 to see where your reading is placed in the population table.

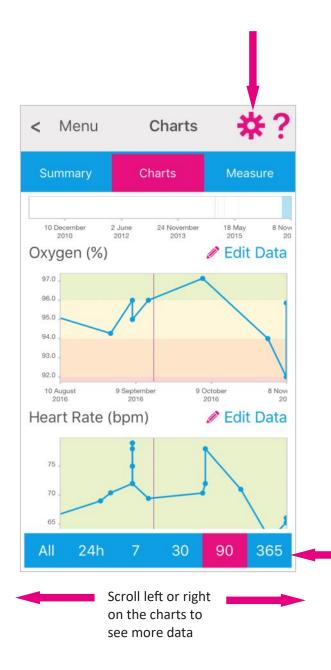
Colour coding of parameters within normal **Green**, alert **Amber** and out of parameter readings **Red** are easily seen on the **Summary** and **Charts**.

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.

Note: If your **Activ8rlives Pulse Oximeter3** is **NOT** connected to your Smartphone or Tablet via Bluetooth, the data will **NOT** be stored on the **Activ8rlives Pulse Oximeter3**.





Data Charts

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

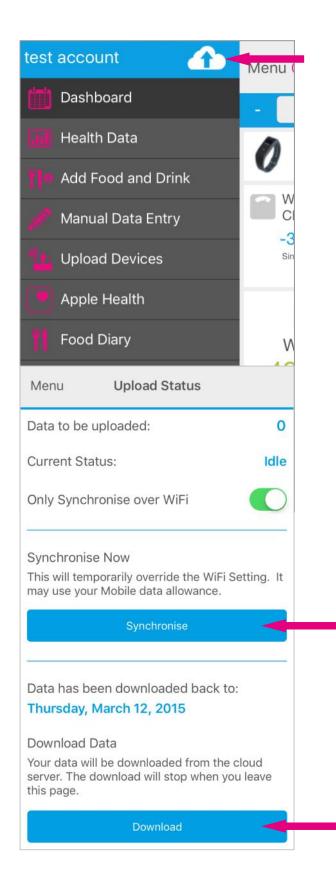
To change how these **Charts** display your data you can select and deselect via the **Settings Cog**.

Also change the **timeframe** from the bottom blue selector to display the number of days of data you wish to display.

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.





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 AWS (London, UK). No data ever leaves the UK and we work to the NHS Data Security and Protection Toolkit and Cyber Essentials Plus standards.

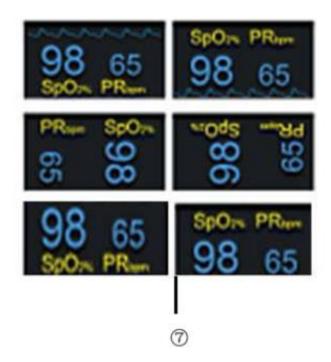




OLED & Brightness Settings for Activ8rlives Pulse Oximeter3



- SpO₂ Plethysmogram
- 2 SpO₂ reading
- 3 Pulse rate reading
- 4 Indication of battery capacity
- ⑤ Indication of pulse intensity
- 6 Indication of screen brightness
- 7 Display modes



To change the **OLED Display orientation** touch the **On/Off Button** once to rotate the screen 90° and keep rotating by touching the **On/Off Button** until you get to the desired orientation of the **OLED Display**.

To change **Brightness of screen**, touch for a longer press on the **On/Off Button** to increase the brightness from 1 to 5, with 5 being the brightest. After approximately 2 seconds the Screen Brightness number disappears from the screen once the screen brightness is adjusted to its new level.

SpO₂ and Heart Rate Values at Rest

These values have been created from population tables of the normal distribution of oxygen saturation and Heart Rate values within the general population. The colour coding by traffic light colours are a good indicator if the reading is **Normal or Fair - Green zone**, **Poor or Concern - Amber zone** or **Alert - Red zone**.

NEWS

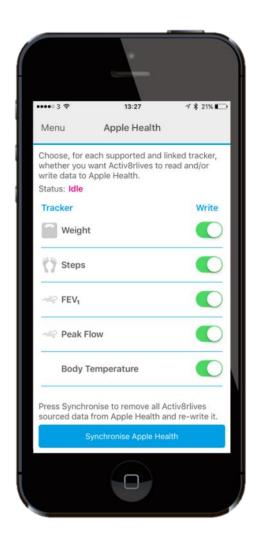
The National Early Warning Score (NEWS), like many existing Early Warning Score systems, is based on a simple scoring system in which a number is allocated to physiological measurements (**Vital Signs**) routinely measured in hospital and recorded on the patient clinical chart. The six simple physiological parameters form the basis of the scoring system:

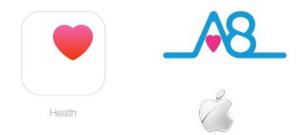
- 1. Respiratory rate;
- 2. Oxygen saturations;
- 3. Temperature;
- 4. Systolic blood pressure;
- 5. Heart rate; and
- 6. Level of consciousness.

A score is allocated to each of these **Vital Signs** as they are measured and added together, and the magnitude of the score reflects how extreme the parameter varies from the norm.

The Royal College of Physicians (RCP) advocates standardising the use of a NEWS system across the NHS in order to drive the 'step change' required in the assessment and response to acute illness.

| ALL VALUES AT REST | | | |
|---|-------------------------------|--|--|
| SpO ₂ | | | |
| 94-100% | Normal | NEWS = 0 | |
| 93-94% | Fair | NEWS = 1 | |
| 92-93% | Poor | NEWS = 2 | |
| | | | |
| 87-92 % | Alert | NEWS = 3 | |
| Heart Ra | Alert te (bpm) Alert | NEWS = 3 | |
| Heart Ra | te (bpm) | | |
| 87-92% Heart Ra 30-40 40-50 50-90 | te (bpm) Alert | NEWS = 3 NEWS = 1 | |
| Heart Ra 30-40 40-50 | te (bpm) Alert Poor Normal | NEWS = 3 NEWS = 1 | |
| Heart Ra 30-40 40-50 50-90 90-110 | te (bpm) Alert Poor Normal | NEWS = 3 NEWS = 1 NEWS = 0 NEWS = 1 | |





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.

Printing your Data

Printing your data can be achieved by going to the Web version www.activ8rlives.com and using the same Username and Password for your Activ8rlives account.

Select **Health Data** from the menu and then select **Print All** to print-out all data sets selected or copy the chart. These will be saved as a PDF file, as the example below, for easy printing or sending via email.





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.

Will Not Connect via Bluetooth?

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

If the Activ8rlives Pulse Oximeter3 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 blue On/Off Button on the Activ8rlives Pulse Oximeter3 to wake it up.

If your device is still not seeing the Activ8rlives Pulse

Oximeter3 you may need to go back to Upload Devices and the first screen, choose Change and the next screen you can choose between three Activ8rlives Pulse Oximeter models.

Lastly, try rebooting your Smartphone or Tablet and reopening the **Activ8rlives App**.

On/Off Button Does Not Respond

Ensure that you depress the **On/Off Button** completely to turn on the **Activ8rlives Pulse Oximeter3** to wake it up. Also the batteries may be depleted or incorrectly orientated in the battery department. Reinsert or replace the batteries.





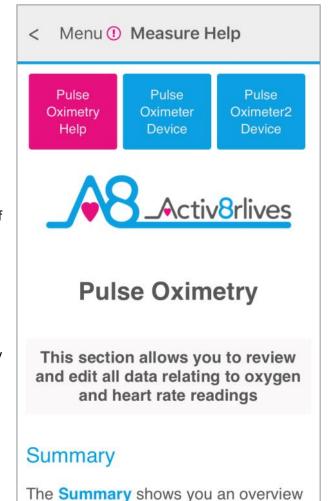
Trouble Shooting

Activ8rlives App Crashes

Close other Apps open on your Smartphone or Tablet, as these may be using too much memory to allow the Activ8rlives⁴
Health+Wellness App to function fully.

Stops Monitoring

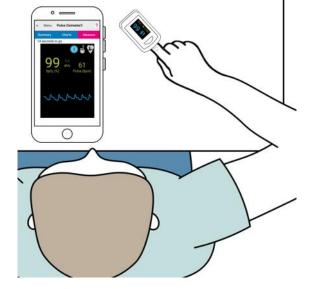
- You may be moving slightly during the reading period of 15 seconds and your pulse traceline will be lost temporarily until you stop moving. Remain still throughout the rest period and when the countdown disappears and then your Reading Today will show on the Activ8rlives⁴ Health+Wellness App.
- You 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 Oximeter3 time to sync with your device. Short times of less than 2 minutes cause frequent loss of connectivity and sometimes loss of new data.
- 3. 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% 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 or repositioning may help.
- 5. Your Indication of Pulse Intensity IPI may not be high enough for an accurate reading. Change finger or follow details on Page 7 for accurate consistent readings.
- Electromagnetic interference may be preventing the Activ8rlives Pulse Oximeter3 from tracking the pulse. Accurately, remove the source of interference.



- Rest gently on a stable surface
- · Keep still during reading

of the latest data that you have

 Wait full <u>15</u> seconds for the reading to complete



Pulse Oximeter 3 Wireless Monitor

| Туре | Description | |
|----------------------------------|--|--|
| Model | M70C | |
| Dimensions of main unit | 57mm (Length) x 33mm (Width) x 30mm (Height) | |
| Weight | 54g (including batteries) | |
| Communication interface | Bluetooth Smart (4.0) | |
| Sensor Specifications | | |
| Wavelength | Red light ~660nm Infrared ~905nm | |
| Total optical output power | LEDs less than 15mW | |
| Sensor LED light emissions | Fall within Class 1 level, according to IEC 60825-1:2001 | |
| SpO ₂ | | |
| Measuring range | 0-100% | |
| Resolution | 1% | |
| Accuracy | At 70-100%, ±2% At 0-69%, unspecified | |
| Data update period | <13 seconds | |
| Pulse Rate | | |
| Measuring Range | 25-250bpm | |
| Resolution | 1bpm | |
| Accuracy | ±1% or ±1bpm, whichever is greater | |
| Data update period | <13 seconds | |
| Power supply | 2 x 1.5V AAA alkaline batteries | |
| Type of electrical protection | Class II | |
| IP protection level | IPX1 | |
| Regulations applicable | Electrical Safety IEC 60601-1 Electromagnetic Compatibility IEC 60601-1-2 | |
| Electromagnetic Emissions | | |
| RF emissions CISPR 11 | Group 1, uses RF energy only for its internal function. RF emissions very low. | |
| RF emissions CISPR 11 | Class B, suitable for all establishments, including domestic use. | |
| Environmental Conditions | | |
| Storage and Transport conditions | Temperature: Min -20°C, Max +55°C Atmospheric Pressure: 500hPa-1060hPa Humidity: ≤93% RH | |
| Operating conditions | Temperature: Min +5°C, Max +40°C Atmospheric Pressure: 700hPa-1060hPa Humidity: ≤85% RH | |

Labelling and Symbols





This product is manufactured by **Guangdong Biolight Meditech Co., Ltd.,** No.2 Innovation First Road, Hi-tech Zone, Zhuhai, P. R. China.



Date of Manufacture.

Model

Pulse Oximeter Bluetooth 4.0 M70C.

LOT

Indicates the Lot number.

SN

Serial Number of device.

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 60601-1:1995 the product and its applied parts are type BF and thus protected against the risks of electrical leakage.

IPX1

In accordance with IEC 60529 the International Protection rating is IPX1, which relates to the degree of waterproofing this product complies with.

FCC ID

Indicates the FCC ID for this 2AC6R-M70C.



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



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.

EC REP

European Representative: Shanghai International Holding Corp. GmbH (Europe), Eiffestrasse 80, D-20537, Hamburg, Germany.

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 Instruction for Use.



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e: support@aseptika.com

w: www.activ8rlives.com

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ASL TF-016 MAN/IFU12 Pulse Oximeter3 (V3.0)

Last updated 30.10.2022