



Activinsights Band

Instructions for Use

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1. Overview

About Activinsights Band

The Activinsights Band is a wrist-worn, event-based accelerometer and data logger. It is a wristwatch-like battery-operated activity recording device. It is a compact and lightweight device which is intended to be used for the acquisition of data related to limb movements during daily living and sleep.

The motion sensor (accelerometer) inside the Activinsights Band records the occurrence and degree of motion. The device's relative movement data is stored internally. The captured data can be further uploaded wirelessly with either the Activinsights Band PC Software or mobile Data Uploader app.using wireless connectivity.

The intended purpose of the device is to be worn on the wrist for the classification and characterisation of daily activities of living events with durations and timestamps. This manual provides instructions on how to set up, deploy, and upload data from the Activinsights Band.

The Band does not need re-charging and is waterproof so can be worn for swimming but is not suitable for use in a sauna.





2. Technical Specification

Size	23mm wide x 13mm deep
Weight	25g
Sensor Outputs	Behavioural event output inferred from acceleration (sit, stand, walk, sleep, etc.)
Connectivity	Wireless set-up on PC with download through PC, Android or iOS in field using wireless connectivity.
Data Format	Open COEL atom format with behaviour type, duration, intensity and characterisation
Data Storage	Privacy-by-design pseudonymous cloud data engine to COEL standard
Data Analytics	Standardised and customised reports available through the Activinsights data server client app and API
Battery Life	Upto 1 year with no charging needed
Data Capacity	Up to 3 weeks wear
Waterproof	Yes
Body Locations	Wrist
Approvals	CE Marked
Operating Temperature	5 - 40 Degrees Celcius
Warranty	1 year



Activinsights Band

3. Getting Started

a) System Requirements

In order to run the Activinsights Band PC software you must have the following Windows PC specification:

- PC with Intel Core i3 Processor, 2GB Memory
- Windows 10
- Bluetooth® LE
- Internet access

b) What's Included

- Activinsights Band
- Activinsights Band PC Software download link
- Configuration File (by email)

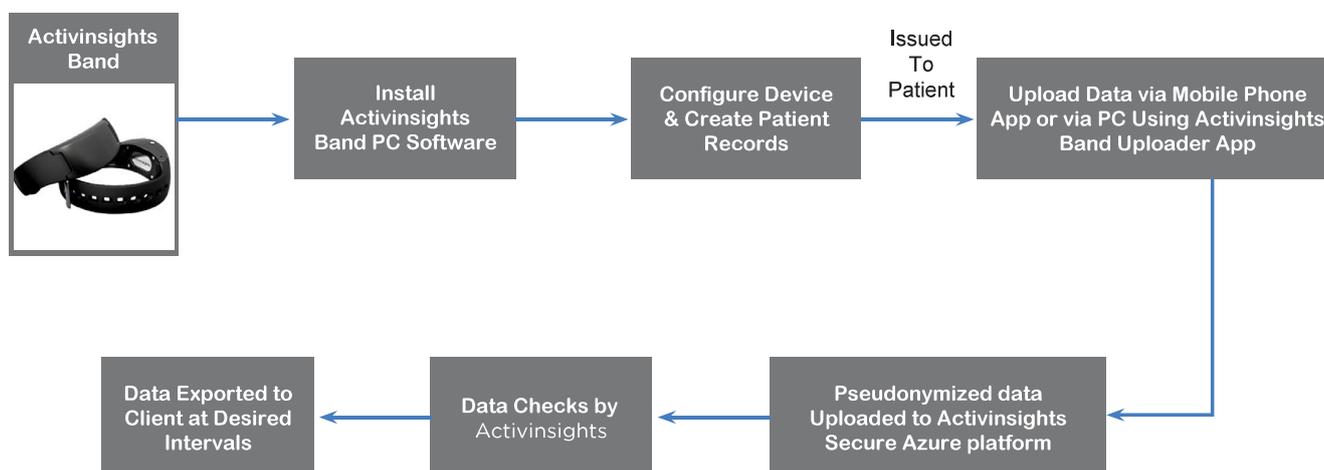


4. Modes Of Operation & Workflow Diagram

The Activinsights Band has the following modes of operation:

- Shipping Mode - The Band is supplied in Shipping Mode to conserve battery usage. Do not press the silver button on the Band before deployment as this will activate the Band starting use of the battery.
- Issue Mode - Using the Activinsights Band PC software, the Band is issued to allocate it to a patient. After being issued, the Band enters a low power usage state to conserve battery usage before the first use by the patient.
- Band and Mobile App Pairing - After the patient has uploaded the Band Uploader app to their mobile device, the Band is paired to the mobile device which activates the Band for data collection and uploading.
- Band Data Collection Mode - After the Band and Mobile app are paired, the Band starts collecting data.
- Band Uploading - The Band will upload data via the Band Uploader app on the mobile device by either manually by pressing the silver button or automatically following the time interval set up for the Band when it was issued. The Band can also be uploaded using a PC using the Activinsights Band PC Software.

Activinsights Band Workflow Diagram





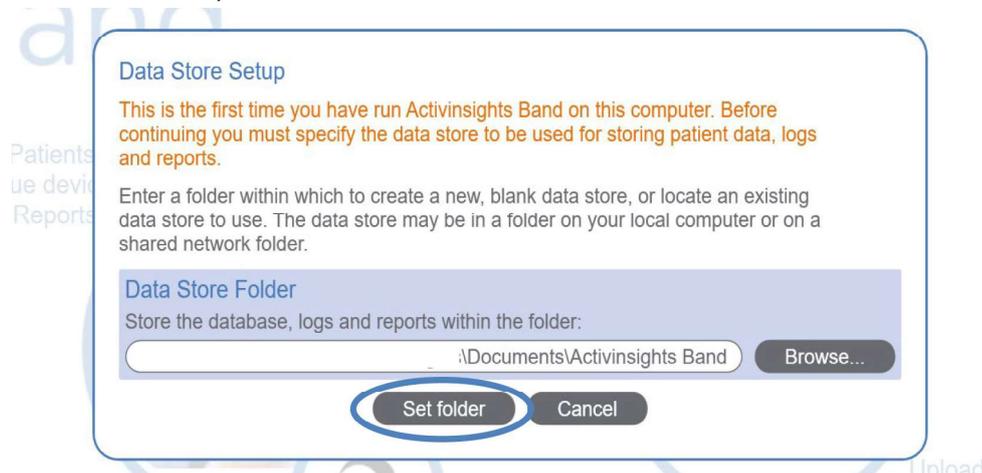
5. Installing & Using the Activinsights Band PC Software

a) Installing Activinsights Band PC Software

To start using a Band you will need to install the Activinsights Band PC software to your PC. This can be done as follows:

NOTE: You will need administration rights on your PC for first installation.

1. Download and save the Activinsights Band Set Up file from the link provided - (<https://dataservices.activinsights.net/download/ActivinsightsBandSetup-0.25.6978.exe>)
2. Double click the Activinsights Band Set Up icon & follow the step-by-step, pop-up instructions
3. Upon first set-up it will ask for a configuration file provided by Activinsights by email. If you have not received the configuration file, please contact info@activinsights.com
4. Set a location for Activinsights Band patient data to be stored.
 - It is recommended to install and save the 'Activinsights Band Setup file' to a location other than your Desktop. We recommend 'Documents'
 - Do not delete the additional folders that it creates
 - If you are sharing the database between different sites then you will need to ensure the 'Data Store Setup' it is saved to a shared file location
 - Once you have set up the first user you can set up additional users to use the same patient database (this may not be relevant in your case). As previously discussed, for data privacy and security, only the local database has capabilities to connect the directly identifying information with the patient.



5. Once completed there will be an additional, new icon on the desktop called 'Activinsights Band'.

NOTE: If you are part of an institution with a highly protective Firewall you may want to inform your IT department of the installation and request that the three services below should be whitelisted for both the download and operation of the Activinsights Band PC software:

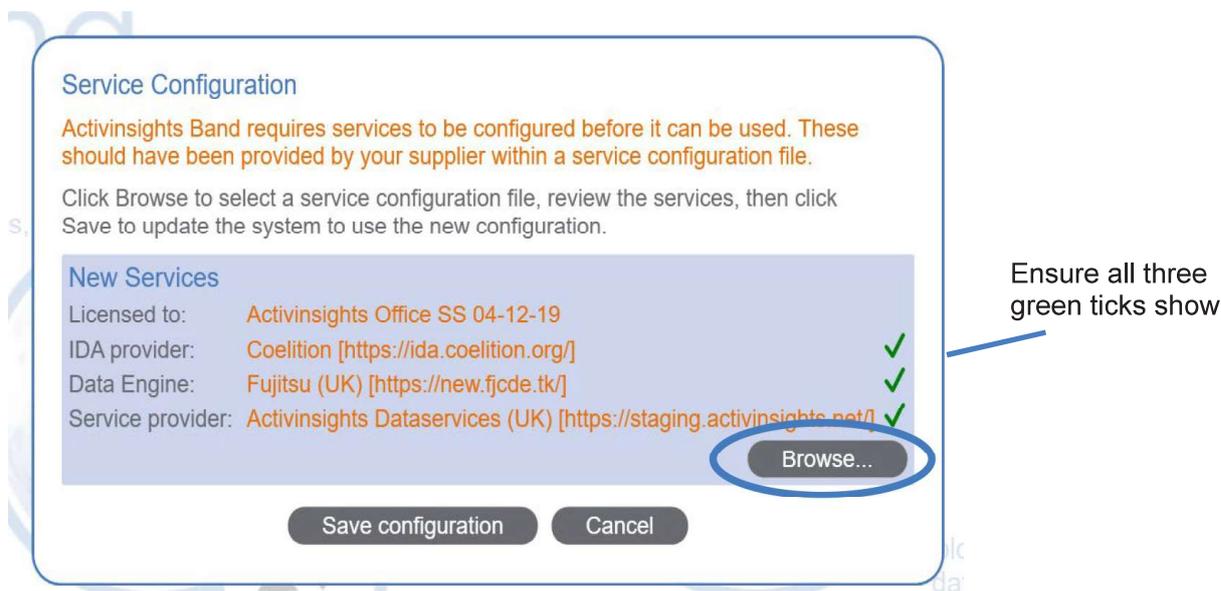
- <https://dataservices.activinsights.net/>
- <https://new.fjcde.tk/>
- <https://ida.coelition.org/>



b) Configuration file set up

Once the data store setup has been completed, follow the steps below to complete the configuration file setup:

1. After clicking OK, the Service Configuration box will appear.
2. Click 'Browse' select the configuration file (.cfg) provided to you via email. This is so only your local PC can match the personal data with the pseudonymised behavioural data.
3. Once the config file is uploaded, the screen will look like the image below and then click 'Save configuration'.
4. It is important that all three green ticks are shown as in the image below.



c) Devices settings

The device settings need to be configured on the Activinsights Band PC software before issuing a Band to a patient:



- Automatically upload atoms every: Set this to the time interval required from the options in the drop down box. If "Never" is selected, uploads will not happen automatically and it will be necessary for the silver button on the Band to be pressed to initiate an upload. Please note, shorter time interval between uploads will lead to increased battery usage and shorter life of the Band in field.
- Automatically upload atoms when atom count reaches: Set this to an atom count that triggers an automatic upload. Please note, if a count of zero is selected, automatic uploads will not be triggered based on the atom count.

6. Patient & Device Setup

a) Setting up a new patient

1. Open the Activinsights Band PC software
2. Select 'Patients, Issue devices, Reports'



3. Select 'New patient'

The screenshot displays the "New patient" registration form within the software. The form is titled "New patient:" and includes the following fields: "Last name" (with a red error message "A last name is required"), "First name", "Gender" (set to "Female"), "Date of birth" (format: dd/MM/yyyy), "Patient ID", "Height" (with input for meters and feet/inches), and "Weight" (with input for kilograms and pounds). At the bottom, there is a "Register" button and a radio button for patient consent, with the text: "The patient has been made aware of the privacy notice available [here](#) and has provided consent for personal data to be used for the analysis of lifestyle." Navigation links for "Devices", "Settings", and "Home" are visible at the bottom right.

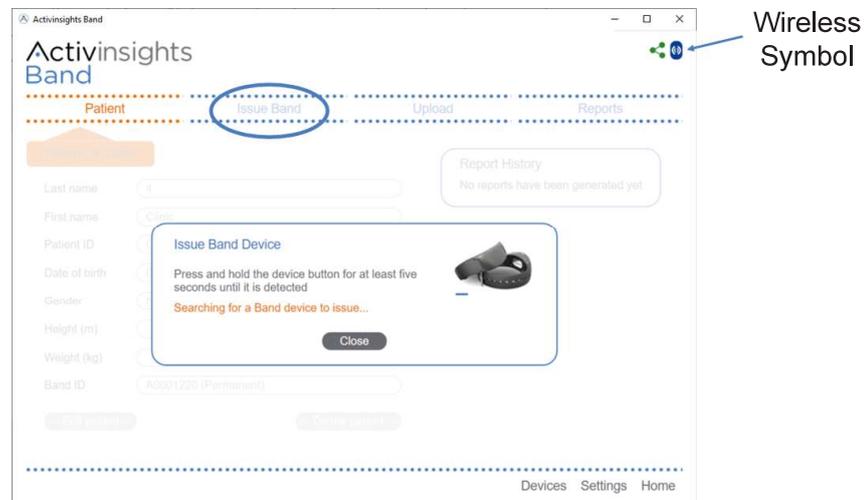
4. Complete fields on patient details
5. Click on the radio button to confirm patient consent and then click on 'Register'

IMPORTANT: The patient must give consent before registering. Note that no directly identifying personal data will leave the healthcare professional's PC.



b) Issuing a Band to a Patient

1. Click 'Issue Band'.



2. Hold the silver button on the side of the Band for 5 seconds (on first use you need to press the silver button twice).
3. The Wireless symbol will turn from blue to grey whilst searching for the device to connect. It will then change to green when it is ready and you will receive a pop-up message.
4. For first-time use select 'Erase data without uploading'.
5. Then choose 'Temporary' or 'Permanent' issue. This is dependent on whether you plan to use the same device on multiple participants, or just one participant for the life of the Band. If you are unsure it is best to select 'temporary issue'.

Temporary issue

The device will collect data until it is uploaded. It will not continue collecting data after that point until it is reallocated and data collection. This is used for for a one-off snapshot.

NOTE: Choosing temporary issue means the device must be reconfigured each time.

Permanent issue

The device will continue to collect data after each upload. If you need to deallocate a permanent issue device, click 'Devices' - double click on the relevant serial number of the device (the serial number can be found on the silver backplate of the device) and click 'deallocate'.

c) Issuing to the patient

This device can now be cleaned and given to the patient. Please refer to page 15 for cleaning instructions.

If the device is being shipped to the patient, please ensure the Band is packaged, ideally in the original packaging, so the silver button cannot be pressed in transit.



7. Device Management

1. Open the Activinsights Band PC Software
2. Select 'Devices'
3. Double click on a device to open up a dialog box to view device details and options to deallocate or view patient details relating to the device.

The screenshot shows the Activinsights Band PC Software interface. On the left, a 'Device List' table displays various devices with columns for Device ID, Status, Last Seen, Battery, Age, and Firmware. The device A0001239 is highlighted. On the right, a 'Device A0001239 Properties' dialog box is open, showing details such as Current status (Allocated (Permanent)), Last extract/upload, Last battery level (4.2), Last seen (27/05/2022 10:45), Days since last seen (299), First seen (27/05/2022 10:45), Age (days) (299), Total atoms extracted (0), and Firmware version (322). Buttons for Sleep, Deallocate, View patient, and Close are visible at the bottom of the dialog box.

Device	Status	Last Seen	Battery	Age	Firmware
A0001235	Allocated (Permanent)	22/05/2022 04:12	4.21	304	322
A0001236	Allocated (Permanent)	22/05/2022 04:18	4.21	304	322
A0001234	Unallocated	22/05/2022 04:21	4.14	304	322
A0001241	Unallocated	06/01/2023 08:24	3.74	304	322
A0001239	Allocated (Permanent)	27/05/2022 10:45	4.2	299	322
A0001240	Allocated (Permanent)	27/05/2022 10:50	4.26	299	322
A0001242	Allocated (Permanent)	10/06/2022 09:09	4.23	299	322
A0001243	Allocated (Permanent)	27/05/2022 10:57	4.25	299	322
A0001248	Allocated (Permanent)	27/05/2022 11:03	4.24	299	322

8. Data Uploading Using Activinsights Band PC Software

a) Uploading data from a Band

The steps below outline instructions for uploading data from a Band via the Activinsights Band PC software application:

1. Open the Activinsights Band PC Software
2. Select 'Upload data'
3. Press and hold the Band silver button for 5 seconds
4. A 'data upload' process pop-up bar will appear, showing that the atoms have successfully been uploaded.
5. The data has then been successfully uploaded, the device is ready to re-configure for further data collection or generate a lifestyle report immediately. Depending on Temporary or permanent issue.

The screenshot shows a 'Band Data Upload' dialog box. It displays the text 'Device A0000700 detected, containing 2 atoms' and 'Extracting A0000700...'. A progress bar is shown below the text, and an 'Abort' button is visible at the bottom. An image of the Activinsights Band is shown in the top right corner.

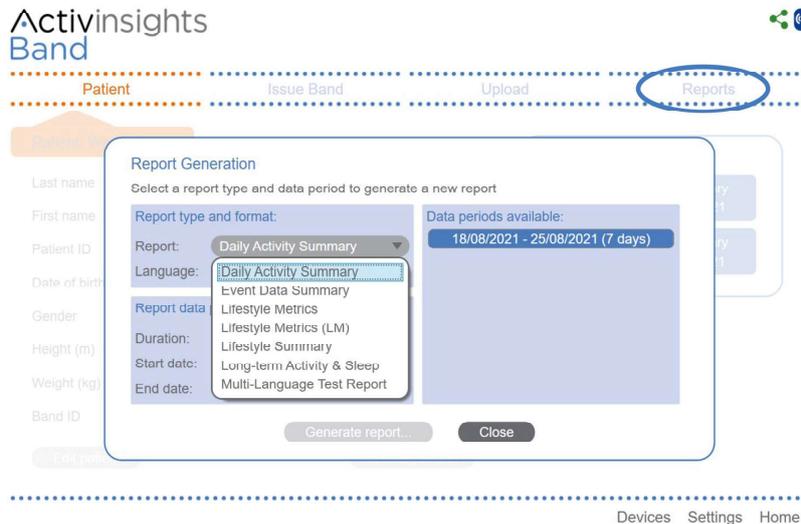
NOTE: Data must be uploaded a minimum of every 2 weeks via either the PC or mobile apps in field.

NOTE: Activinsights Band PC software is only required for extracting data from a Band in deployments where the Activinsights Band Uploader app is not used.



9. Reports From The Activinsights Band PC Software

1. From the Patient screen, click 'Reports'



2. Select the data collection period for which you'd like a report generating – it will automatically populate the most recent data collection period. This will populate the 'Report Data Period' which can be manually edited, if required.
3. Select the type of report you wish you generate:
 - i) Daily Activity Summary - A bar chart visualisation of the data collected.
 - ii) Event Data Summary - A time stamped .csv file of the data collected.
 - iii) Lifestyle Summary - A summary visualisation of the lifestyle data collected.
 - iv) Long-term Activity & Sleep - Pseudonymous plots of daily individual or group physical activity & sleep patterns over a period of up to 8 weeks.
4. Select language from the drop-down list. (Currently only English is provided).
5. Click 'Generate Report'.
6. A new PDF window of the lifestyle report will pop up. Please note that the lifestyle report visualises 1 week of wear time. The 'Report History' stores the lifestyle reports generated within the app and can be viewed for each patient to show all previous reports.

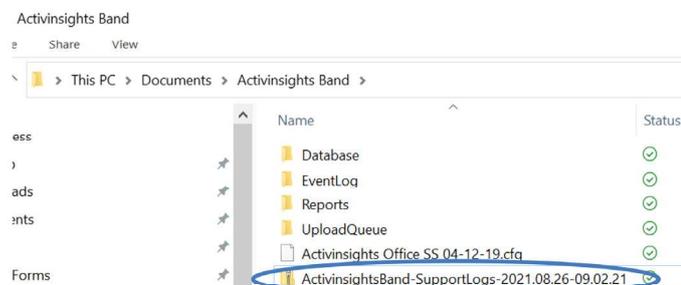
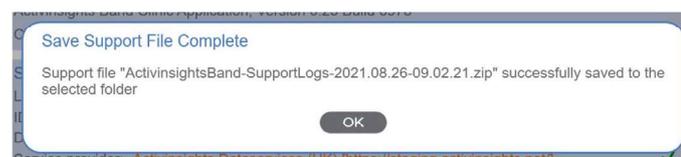
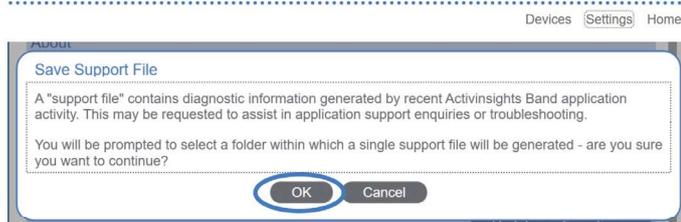
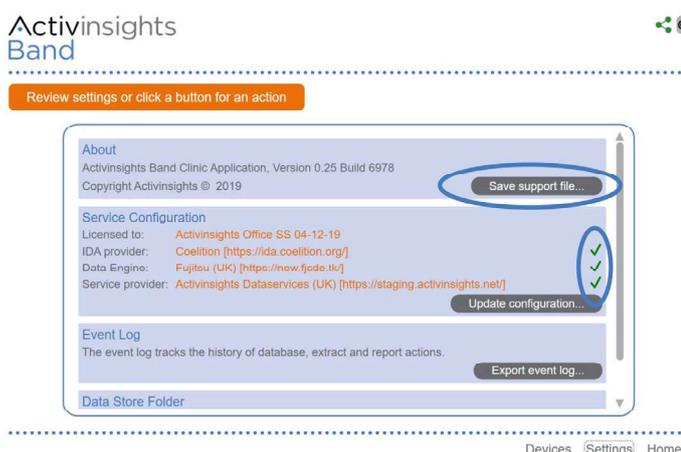




10. Settings & Support For The Activinsights Band PC Software

If there are any connection issues, please click 'Settings' where you will see the following information:

1. Under 'Service Configuration', three green ticks should be present at all times. This is also reflected in the three green dots in the top right hand corner of the window. If either are not there, click 'Save support file'
2. 'Save Support File' pop up box will appear, please click 'OK' and save the support file locally.
3. After 'OK' has been clicked, this notification will appear, confirming the Support File has saved to the folder location selected.
4. In this example, the location selected is the Activinsights Band folder and the Support log will save as a zip. file.
5. Email this file to Activinsights (info@activinsights.com)





11. Patient Options for Uploading Data

For patients to upload data from the Band, it is necessary for the patient to install and use the Activinsights Band Uploader app.

a) Uploading Using Mobile Devices With The Uploader App

The mobile applications for both iOS and Android are a means of transferring the data collected by the Band to the configuration file. To upload data, it is necessary to have a connection to the internet.

The app does not record any behavioural information or link patient data to the device.

iOS Apple

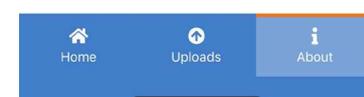
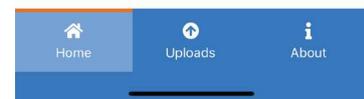
1. Search for Activinsights Band Uploader in store in the App Store and install app.
2. Once installed, open the app to connect your Band by pressing and holding the silver button on the side for approximately 5 seconds.
3. When it has connected, leave the app open on your device for uploads to continue. If it is closed accidentally, it will need to be reopened for the Band to upload data.
4. Use the tabs at the bottom of the app to select "Home", "Uploads" and "About" and following the on-screen information and instructions.

Google Play (Android)

1. Search for Activinsights Band Uploader in the Google Play Store and install app.
2. Once installed, open the app to connect your Band by pressing and holding the silver button on the side for approximately 5 seconds.
3. When it has connected, leave the app open on your device for uploads to continue. If it is closed accidentally, it will need to be reopened for the Band to upload data.
4. Use the tabs at the bottom of the app to select "Home", "Uploads" and "About" and following the on-screen information and instructions.

NOTE: The app may ask for permission to access your Bluetooth® and notifications on your mobile device.

This is required for the connection to the Band.





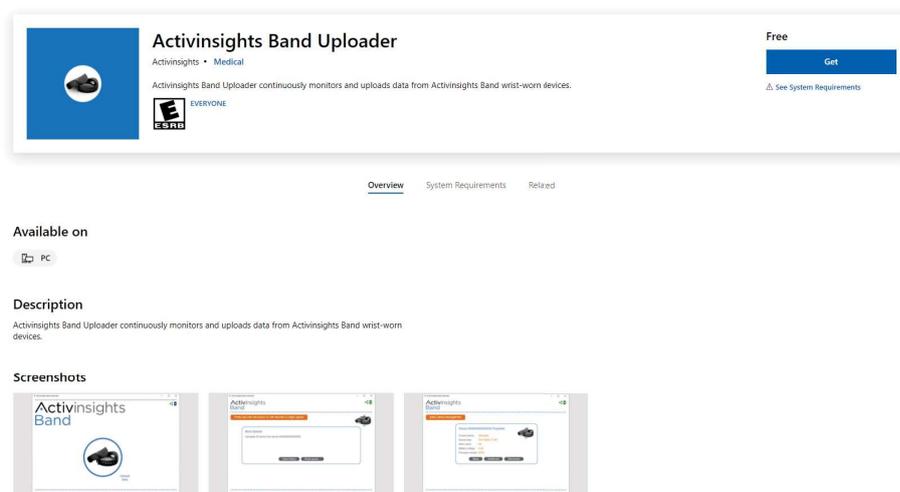
b) Uploading Using A PC Uploader App

NOTE: This PC app only acts as a hub to transfer data from the Band to the location set up by the configuration file. It does not set up the device or store any patient identifiable information on the PC.

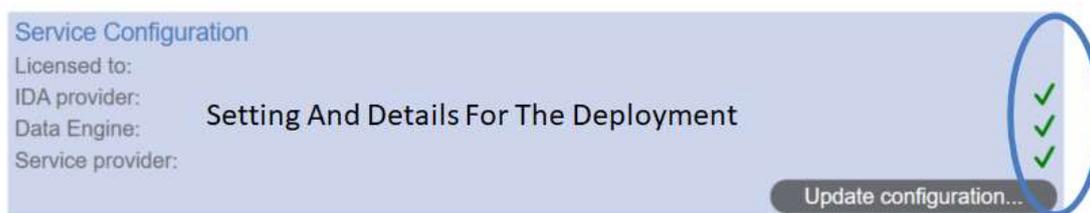
NOTE: The Activinsights Band Uploader app should not be installed if the Activinsights Band PC software is already installed on the computer to manage patients and issue Bands.

Microsoft

1. Search for Activinsights Band Uploader app in the Microsoft Store and install software (www.microsoft.com/store/productId/9N4GQTVK9PKF)



2. Once installed, open the app, and click Settings.
3. Then click Update configuration, click 'Browse' and select the configuration file (.cfg) provided via email. This is so only your local PC can match the personal data with the pseudonymised behavioural data.
4. Once the config file is uploaded, the screen will look like the image below and then click 'Save configuration'.
5. It is important that all three green ticks are shown as in the image below. Once the configuration file is uploaded, return to the home page, and click Upload data.



6. Connect the Band by holding the silver button on the side for approximately 5 seconds.
7. Once connected, the wireless icon in the top right corner will turn green and the data will begin uploading to the config. file.

c) Troubleshooting

If you experience errors with the Activinsights App, click the 'About' tab and then 'Upload Support File'. This will send diagnostic information to Activinsights. No personal information will be shared.



12. Cleaning & Storage

a) Cleaning

To clean the Band, wipe with a cloth, or scrub with a soft bristle brush using warm soapy water or a mild detergent solution and allow to air dry. Alcohol wipes and mild sterilising solutions may also be used.

To disinfect the Band, use the Clinell Universal Wipe or equivalent product. Thoroughly cover and wipe the device so all surfaces are wetted. Ensure the device is allowed time to air dry completely before next use. Change the wipe if it becomes dry or soiled and dispose of it appropriately.

NOTE: Do not use hot water, scouring pads, abrasive cleaning agents or aggressive liquids (such as petroleum-based solvents, acetone or strong alkaline cleaners) on the Band.

b) Storing Band

Bands should be stored in the packaging provided, at temperatures between 5-40 Degrees Celsius to ensure optimal battery life.

Please note that the Band has a battery life of up to one year with unlimited data services during that time, so they can be stored until the next use. After a device reaches the end of its battery life, the device can be replaced with continued access to the data services (if appropriate).

13. Getting More Help

For more information about Frequently Asked Questions (FAQs), please visit our website: www.activinsights.com/expertise/activinsights-band/faqs.

For further information or assistance, please contact:

Activinsights Limited
Unit 11, Harvard Industrial Estate
Kimbolton
Cambridgeshire PE28 0NJ

Telephone: +44 (0)1480 862082
Email: info@activinsights.com
Website: www.activinsights.com

A company registered in England & Wales. Registered number: 06576069



14. Regulatory Standards



The Activinsights Band complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.



This product is compliant with the Directive 2014/30/EC and has been designed and manufactured to the following specifications EN61326-1:2013 (Emissions), CFR 47 Pt 15 B (Emissions) and EN61326-1:2013 (Immunity); the relevant Declaration of Conformity is available from Activinsights Ltd.

This product has been tested to BS EN 61000-6-1 :2007 and BS EN 61000-6-3 :2007 (Electromagnetic compatibility (EMC), Generic standards, Immunity for residential, commercial and light-industrial environments).

The product has wireless connectivity under FCC:T7V1740 and complies with the following standards:

- EN60950-1:2006+A11:2009+A1:2010+A12:2011+AC:2011+A2:2013 Safety/Health – wireless module
- EN62311:2008 Safety/Health – wireless module
- EN 301 489-1 V2.1.1:2017-02 EMC – wireless module
- EN 301 489-17 V3.1.1:2017-02 EMC – wireless module
- EN 300 328 V2.1.1:2016-11 Radio – wireless module



In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), this item must not be disposed of in the normal unsorted municipal waste stream. Instead, it is the user's responsibility to dispose of this product by returning it to a collection point designated for the recycling of electrical and electronic equipment waste or directly to ActivInsights Ltd. Separate collection of this waste helps to optimize the recovery and recycling of any reclaimable materials and also reduces the impact on human health and the environment. For more information concerning the correct disposal of this product, please contact your local authority or our issuing authority.

This product meets the minimum standards of the RoHS Directive 2002/95/EC.

The lithium polymer cell has met the acceptance criterion for the UN Recommendations on the Transport of Dangerous Goods relating to lithium batteries, reference Para 38.3 of Manual tests and Criteria document No. ST/SG/AC.10.11/Rev.4:2003.

Safe handling guidelines

- Do not use with children without supervision or further safety assessments.
- Do not disassemble the device. The battery in the device is not replaceable. If the device is damaged, dispose of it responsibly or return to Activinsights.
- If the device becomes warm to the touch whilst in use, remove and return to Activinsights.
- Clean the device with a soft moistened cloth. Do not use abrasive cleaners or solvents.
- Do not subject the device to excessive force, shock or extreme temperature changes.
- Do not put the device in a microwave, oven, dishwasher, or washing machine. Do not use an external heat source such as a hair dryer or heater to dry the device.
- At the end of the product life, please return it to your issuing authority.

Activinsights

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