



Activ8rlives⁴ Health
+Wellness App



Asthma⁺meTM



Active⁺me
REMOTE



www.activ8rlives.com

The Aseptika family of medical devices connects wirelessly and uploads data to **Activ8rlives⁴ Health+Wellness**, **Asthma⁺me** or **Active⁺me REMOTE** Apps. Work with: Bluetooth Smart Ready device (typically Bluetooth 4.0+), iOS 12+ and Android 10+. Apple Health App compatible.



Data Privacy and Security

Our Apps, which include **Activ8rlives⁴ Health+Wellness**, **Asthma⁺me** and **Active⁺me REMOTE Apps** and services are provided by Aseptika Ltd. Our services are developed and operated with a set of key principles which ensure the security and privacy of you and the family members that you care for using the functionality it provides under the legal basis of UK GDPR Article 6(1)(a), where Aseptika is the Data Controller.

1. We never access the data that you generate unless you have provided consent for us to do so. Usually this is so we can provide you with technical support or as part of a research project or clinical service to which you have previously provided your informed consent.
2. All data transmitted to and from our Apps (**Active⁺me REMOTE**, **Asthma⁺me** and **Activ8rlives⁴ Health+Wellness Apps**) and the Activ8rlives Cloud service, is encrypted to appropriate standards for your security.
3. Many other health Apps generate revenues by selling your anonymised data to advertisers. We have not and will never do this with your data. We do not generate revenue by selling advertising space to third parties who use anonymised personal data to target advertisements for specific products to you. For this reason, some of our services are a subscription or are prescribed. This protects you and the data you collect.
4. We do not share, sell or give your data with any third parties, other than trusted health and social care systems and only if this is with your informed consent.
5. Export to trusted health and social care systems, with your informed consent, can be enabled so that a specific care service may be provided to you. This will only be enabled with your informed consent and following the completion of an appropriate identification process. When you consent to share your data with trusted health and social care systems, Aseptika becomes the Data Processor on the legal basis of UK GDPR Article 6(1)(e). The operator of the trusted health and social care system becomes the Data Controller on the legal basis of UK GDPR Article 9(2)(h).

Regulated Medical Devices

Our Apps, which include **Activ8rlives⁴ Health+Wellness**, **Asthma⁺me** and **Active⁺me REMOTE Apps**, comply with the UK MDR 2002 in Great Britain (SI 2002 No 618, as amended).

The Aseptika Apps are compliant with Class I medical device under the EU MDR 2017/745.



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



Activ8rlives⁴ Health +Wellness App

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

The Self-Care mobile application and cloud services, is intended to deliver a comprehensive home self-care platform (remote monitoring from connected medical and non-medical devices, track medication use, peer-to-peer support, food diary, adventures, record other events such as cardiac or respiratory symptoms or exacerbations, for effective health self-management. The user can also share their data via sharing functions.

Activ8rlives⁴ Health+Wellness App is a stand-alone software product, which can be installed on Apple and Android platforms from their respective App stores. It can be accessed also via the Activ8rlives web portal. **Activ8rlives⁴ Health+Wellness App** is a free service. The lifetime of the medical device is a maximum of 2 years before an update is required to be downloaded by the lay user.

Included in the **Activ8rlives⁴ Health+Wellness App** (UDI-DI 5060293170946 and Part # P111) is:

- Wireless connectivity to the **Activ8rlives branded** self-monitoring devices: Connect PUFFClicker2 smart inhaler tracker for pressurised metered dose inhalers (pMDI), PUFFClicker3 smart inhaler tracker for dry powder inhalers (DPI), Peak Flow/FEV₁ monitor, Spirometer @Home, Pulse Oximeters, Blood Pressure Monitors, BuddyBand2 Activity Tracker, Body Analyser Smart Scales to monitor key physiological signs.
- Medication: Record medication prescribed and taken, track doses and use of batches of the prescription (e.g. antibiotics, steroids, antihistamines, beta blocker, ACE inhibitors, statins etc).
- Charts and Reports: Generate custom charts to identify trends. Create pre-configured report as a PDF which can be printed or emailed to a patient's Doctor.
- Behaviour Change: Encouraging adherence to their Care Plan and medication routine can be a challenge for all. **Activ8rlives⁴ Health+Wellness App** includes a configurable rewards capability to work towards, earning points for every action completed each day to motivate and encourage behaviour change.
- Adventures: Different adventure walking routes, that can be used individually or as a Group.
- Support Groups: Provide encouragement and tips to help you on your health and wellness journey.
- Food Diary: Can enter photographs of your meals or add ingredients, whole meals or carb counting for diabetics.

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

Intended Use

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

Intended Population

The **Activ8rlives⁴ Health+Wellness App** is intended for use by lay user between 6 - 80+ year-olds, with adult supervision for under 13-years.

Contraindications

Activ8rlives⁴ Health+Wellness App is not intended to monitor vital physiological parameters where variation could result in immediate danger.

Not intended for diagnosis or treatment of any condition.

Not for use with children 5 years or younger.

Responsible adult supervision of children 6-12 years of age.

Not a substitute for expert clinical advice.

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

Not an alternative to your clinically prescribed Care Plan.



Warnings

Long-term health conditions (LTHC) can be life-threatening.

Always take your medication and follow your Care Plan as prescribed.

If you experience any symptoms of shortness of breath that does not get better after using your Reliever inhaler; trouble walking and talking because of shortness of breath; blue lips or fingernails; severe wheezing; or a peak flow reading of less than 50% of your personal best, chest pain or discomfort; heart palpitations; rapid or irregular heartbeats; unexplained wheezing; shortness of breath; fainting or near fainting; light headedness or dizziness; refer to your Care Plan and follow the instructions carefully. If you continue to have symptoms, consult your medical team.

Disclaimers

It remains your responsibility at all times to seek expert clinical advice in the event of an emergency or worsening symptoms. The functionality of the **Activ8rlives⁴ Health+Wellness App** should never be used as an alternative to medical advice from your doctor or other healthcare provider.

If you experience any serious incident that occurs in relation to the **Activ8rlives⁴ Health+Wellness App**, please report this to Aseptika Limited (Activ8rlives) and the competent authority of the Member State or Country in which you are based.



The **Asthma+me App** is a Class I medical device mobile application/system intended to deliver a home self-monitoring solution to assist children and young people (6-18-years) with asthma that is moderate to severe or difficult to control. Users receive and review information from connected medical and non-medical devices, which is shared with an appropriate adult and healthcare professional to enable effective health management and remote monitoring. This allows the User, device, appropriate adult and healthcare professional to track medication use and record asthma events, such as asthma attacks.

The **Asthma+me App** is a stand-alone software product, which can be installed on Apple and Android platforms from their respective App stores. The **Asthma+me App** is a subscription service with a monthly charge. The lifetime of the medical device is a maximum of 2 years before an update is required to be downloaded by the lay user.

Included in the **Asthma+me App** (UDI-DI 5060293170939 and Part # P104) is:

- Comprehensive Supported Self-Management solution for children and young people's with Asthma.
- Clinician-approved education syllabus on Asthma management: series of 50+ simple lessons delivered daily, provided training and instruction for the children and young people and family. Included at the end of each lesson is a simple quiz to confirm understanding.
- Wireless connectivity to self-monitoring devices: Connect PUFFClicker2 smart inhaler tracker for pressurised metered dose inhaler (pMDI), Peak Flow/FEV₁ monitor and Spirometer @Home and medication counted via the PUFFClicker to monitor physiological signs.
- Medication: Record the medication prescribed for each family member and track doses of inhaler use and use of batches of the prescription (e.g. inhaler in the bag, at home, at school, in the car etc.). Include non-inhaler medications such as antibiotics, steroids, antihistamines etc., which are manually added to the **Asthma+me App**. The PUFFClicker3 inhaler tracker works with both pMDI and dry powder inhalers (DPI) and sends the data in almost real time to the Cloud Server and does not require a smartphone for use.
- Reports: Generate custom charts to identify trends. Create pre-configured report as a PDF which can be printed, emailed or exported to clinical centres using **Asthma+me App**.
- Charts: View and understand your data with colour coded charts.
- Motivation: Encouraging children and young people to adhere to their Personalised Asthma Action Plan (PAAP) or Care Plan and medication routine can be a challenge for all family members or carers. **Asthma+me App** includes a configurable rewards capability for the children and young people's to work towards, earning points for every action completed each day to motivate and encourage behaviour change and medication adherence.
- PAAP or Care Plan: **Asthma+me App** brings together all of your children and young people's information in one, easy-to-read and printable or emailable PAAP or Care Plan. Everyone with asthma should have a written PAAP or Care Plan. Print and give to schools, friends, family, carer, GP and Hospitals to give clear instructions in the event of an asthma attack.
- Surveys, manual data entry and weather: A daily and weekly survey for the children and young people captures a lot of symptom information, which forms part of the weekly report, where clinical centres provide this service. FeNO data and other data can be manually entered into the **Asthma+me App**, along with weather and pollution feeds for the children and young people's local area.
- Remote Virtual Appointments: Using MS Teams or other online platform to maintain a schedule of remote support, if required, and ability to conduct remote Outpatient clinics by the Clinician/nurse that can be attended.

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

Intended Use

The **Asthma⁺me App** is a medical device mobile application/system intended to deliver a home self-monitoring solution to assist children and young people (6-18-years) with asthma that is moderate to severe or difficult to control.

Users receive and review information from connected medical and non-medical devices, which is shared with an appropriate adult and healthcare professional to enable effective health management and remote monitoring.

This allows the User, device, appropriate adult and healthcare professional to track medication use and record asthma events, such as asthma attacks.

Intended Population

The **Asthma⁺me App** has been designed for children and young people (CYP 6-18-years) that have asthma that is moderate to severe or difficult to control, with children 6-12 years under adult supervision by the lay user parent/carer.

The professional users are Clinician experts in their field of medicine, Physiotherapists and Exercise Trainers.

Contraindications

The **Asthma⁺me App** is not intended to monitor vital physiological parameters where variation could result in immediate danger.

Not intended for diagnosis or treatment of asthma.

Not for use by children under 13 years-old without supervision of a responsible adult.

Not for use with children 5 years or younger.

Not a substitute for expert clinical advice.

You should not rely solely on the Reminder capabilities of the **Asthma⁺me App** to take your prescribed medication as directed by your medical team.



Warnings

Asthma can be a life-threatening condition.

Always take the medication as prescribed.

If you experience any asthma-related symptoms of shortness of breath that does not get better after using your Reliever inhaler; trouble walking or talking because of shortness of breath; blue lips or fingernails; severe wheezing; or a peak flow reading of less than 50% of your personal best, refer to your Care Plan or PAAP and follow the instructions carefully. If you continue to have symptoms consult with your medical team.

Disclaimers

It remains your responsibility at all times to seek expert clinical advice in the event of an emergency or worsening of symptoms. The functionality and content within the **Asthma⁺me App** should never be used as an alternative to medical advice from your doctor or other healthcare provider.

If you experience any serious incident that occurs in relation to the **Asthma⁺me App**, please report this to Aseptika Limited and the competent authority of the Member State or Country in which you are based.



Active+me REMOTE App is a Class I medical device mobile application and cloud services intended to deliver a comprehensive home recovery system (live exercise classes, exercise videos, step counting, remote monitoring from connected medical and non-medical devices, track medication use, education, peer-to-peer support, dietary advice, record other events such as cardiac or respiratory symptoms or exacerbations) for effective health self-management. The user can also share their data via sharing functions. **Active+me REMOTE App** has been designed for use with adults that have had a cardiac or respiratory exacerbation or procedure or promoting physical activity and healthy weight management.

Active+me REMOTE App is a stand-alone software product, which can be installed on Apple and Android platforms from their respective App stores. The **Active+me REMOTE App** is a subscription service with a monthly charge. The lifetime of the medical device is a maximum of 2 years before an update is required to be downloaded by the lay user.

Included in the **Active+me REMOTE App** (UDI-DI 5060293171004 and Part # P102) is:

- Clinician-approved education syllabus on Cardiac or Pulmonary disease management: series of 60+ simple lessons delivered daily, provided training and instruction for the patient and carer. Included at the end of each lesson is a simple quiz to confirm understanding.
- Wireless connectivity to our self-monitoring devices: Connect PUFFClicker2 smart inhaler trackers for pressurised metered dose inhalers (pMDI), PUFFClicker3 smart inhaler tracker for pMDI and dry powder inhalers (DPI), Peak Flow/FEV₁ monitor, Spirometer @Home, Pulse Oximeters, Blood Pressure Monitors, BuddyBand2 Activity Tracker, Body Analyser Smart Scales to monitor key physiological signs.
- Medication: Record the medication prescribed, track doses and use of batches of the prescription (e.g. antibiotics, steroids, antihistamines, beta blocker, ACE inhibitors, statins etc). The PUFFClicker3 inhaler tracker works with both pMDI and DPI and sends the data in almost real time to the Cloud Server and does not require a smartphone for use.
- Charts and Reports: Generate custom charts to identify trends. Create pre-configured report as a PDF which can be printed, emailed or exported to clinical centres using **Active+me REMOTE App**.
- Behaviour Change: Encouraging adherence to their Care Plan and medication routine can be a challenge for all. **Active+me REMOTE App** includes a configurable rewards capability to work towards, earning points for every action completed each day to motivate and encourage behaviour change.
- Care Plan: **Active+me REMOTE App** brings together all of your information in one, easy-to-read and printable or emailable Care Plan. Everyone with a long-term health condition should have a written care plan. Print and give to work, friends, family, carers, GP and Hospitals to give clear instructions in the event of an exacerbation, cardiovascular incident or worsening symptoms.
- Exercise: Includes live exercise classes via Microsoft Teams or other video platforms and embeds exercise videos within the **Active+me REMOTE App**.

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

Intended Use

Active⁺me REMOTE App is a Class I medical device mobile application and cloud services intended to deliver a comprehensive home recovery system (live exercise classes, exercise videos, step counting, remote monitoring from connected medical and non-medical devices, track medication use, education, peer-to-peer support, dietary advice, record other events such as cardiac or respiratory symptoms or exacerbations) for effective health self-management.

The user can also share their data via sharing functions. **Active⁺me REMOTE App** has been designed for use with adults that have had a cardiac or respiratory exacerbation or procedure and to promote physical activity and healthy weight management.

Intended Population

The user target group are lay person adults (patients) over the age of 18 years that have had a cardiac or pulmonary exacerbation or procedure and their use at home in their recovery and to promote physical activity and healthy weight management.

The professional users are Clinicians exert in their field of medicine, Physiotherapists and Exercise Trainers.

Contraindications

Active⁺me REMOTE App is not intended to monitor vital physiological parameters where variation could result in immediate danger.

Not intended for diagnosis or treatment of cardiac or pulmonary disease.

Not for use by those under 18-years-old.

Not a substitute for expert clinical advice.

You should not rely solely on the Reminder capabilities of the **Active⁺me REMOTE App** to take your prescribed medication as directed by your medical team.



Warnings

Cardiac or pulmonary events can be life-threatening.

Always take your medication and follow your Care Plan as prescribed.

If you experience any pulmonary-related symptoms of shortness of breath that does not get better after using your Reliever inhaler; trouble walking and talking because of shortness of breath; blue lips or fingernails; severe wheezing or a peak flow reading of less than 50% of your personal best, refer to your Care Plan and follow the instructions carefully. If you continue to have symptoms, consult your medical team.

If you experience any cardiac-related symptoms of chest pain or discomfort; heart palpitations; rapid or irregular heartbeats; unexplained wheezing; shortness of breath; fainting or near fainting; light headedness or dizziness; refer to your Care Plan and follow the instructions carefully. If you continue to have symptoms, consult your medical team.

Disclaimers

It remains your responsibility at all times to seek expert clinical advice in the event of an emergency or worsening symptoms. The functionality of the **Active⁺me REMOTE App** should never be used as an alternative to medical advice from your doctor or other healthcare provider.

If you experience any serious incident that occurs in relation to the **Active⁺me REMOTE App**, please report this to Aseptika Limited and the competent authority of the Member State or Country in which you are based.

Let's get started with the Set-up and Connect to one of our Apps

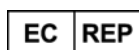
The **Aseptika branded medical devices** are programmed by and uploads information directly to and from your account each time your Bluetooth Smartphone or Tablet is connected to it (not included).

This guide will show you how to:

- Install the free **Activ8rlives⁴ Health+Wellness** or the paid subscription Apps **Asthma⁺me** and **Active⁺me REMOTE Apps** to your iOS or Android Smartphone or Tablet.






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European Healthcare & Device Solutions (Ireland) Ltd. (AER-EU), Stratton House, Bishopstown Road, Bishopstown, Cork, T12 Y9TC, Ireland.



Read instructions before use. <https://www.activ8rlives.com/mwdownloads/download/link/id/59>

Medical Device Name & Model	Manufacture Date	Version & LOT	UDI-PI
Activ8rlives ⁴ Health+Wellness App P111	2023-08	4.11.0 series A1197	 5060293170946202308A1197
Asthma ⁺ me App P104	2022-07	3.2.0 series A1118	 5060293170939202207A1118
Active ⁺ me REMOTE App P102	2024-02	1.10.0 series A1200	 5060293171004202402A1200





Installing our Apps on Your Smartphone or Tablet

Note: Bluetooth 4.0 Enabled Devices are required to use the **Activ8rlives** medical devices.

Download one of our **Apps** from the App Store appropriate to your device. Search for **Activ8rlives** in the search bar of your App Store that is appropriate for your smart device (iOS or Android) or scan the corresponding QR code below and it will take you to the appropriate App Store for your device.



Activ8rlives⁴ Health+Wellness App
(Free)



Asthma⁺me App
(Subscription)



Active⁺me REMOTE App
(Subscription)



Apple devices running iOS 12+.



Android devices running 10+.

NOTE: Please adjust the screen lock function on your Smartphone or Tablet to be longer than 2 minutes to allow the **Aseptika** branded medical device time to sync with your device.

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

Our Apps Developed Around Six Pillars of Self-Care

Our Apps are based around the six pillars of successful self-care, evidence-based from a meta-review of 270 studies of supporting self-management of asthma in adults (Hilary Pinnock, *et al.* 2017). The six pillars for patient self-care include: a care plan, management of triggers, medication adherence, technology for measuring physiological signs, education and behaviour change techniques where there is active involvement of the participants in reducing unscheduled healthcare visits and admissions.





Trouble Shooting

Help Menu?

Help can be found on nearly all pages of our **Apps** 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  also provides helpful hints, when found within each of the **Apps**.

Will Not Connect via Bluetooth?

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

If our **branded medical device** 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 **On/Off Button** on the **medical device** to wake it up.

If your device is still not seeing the our **branded medical device**, you may need to go back to **Upload Devices** and the first screen, choose **Change** and the next screen you can choose between several our **branded medical device** models.

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

On/Off Button Does Not Respond

Ensure that you depress the **On/Off Button** completely to turn on our **branded medical device** to wake it up. Also the batteries may be depleted or incorrectly orientated in the battery department. Reinsert or replace the batteries or charge the device where it has an integrated battery and then try to pair again with one of our **Apps**.

App Crashes

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



Help Videos in **App**, follow this **?**

Website www.Activ8lives.com

YouTube <http://bit.ly/Activ8lives>

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.



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