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Product name:	Clip-Tone Buddy
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	CeC_006_A
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About



CLIP-TONE BUDDY is a software app designed to work with the Clip-Tone E or Clip-Tone F guidance tools.

If you don't have a Clip-Tone please contact your doctor or nurse to see how you might be able to benefit from one.

CLIP-TONE BUDDY is an accessory to a medical device.

Instructions



Intended Purpose

- CLIP-TONE BUDDY is a software app designed to work with the Clip-Tone E or Clip-Tone F guidance tools.
- If you don't have a Clip-Tone please contact your doctor or nurse to see how you might be able to benefit from one.

Intended User

- CLIP-TONE BUDDY is designed for:
 - Inhaler users over the age of 13 who have been advised by a healthcare professional.
 - Healthcare professionals training patients to use pressurised meter dose inhalers (pMDIs).

Precautions



- Clip-Tone Buddy should be used only with the specified hardware.
- Use your inhaler only as prescribed and advised by a qualified healthcare professional.
- Background sounds may interfere with the app.
- No clinical decisions should be made based on the information in this app.
- In case of any incident involving the use of CLIP-TONE BUDDY please contact: info@clin-e-cal.com or visit www.clin-e-cal.com

Or your national competent authority.

- **If you have any concerns about your condition, please contact your healthcare professional.**
- If you do not have automatic updates, please check regularly for the availability of new versions of Clip-Tone Buddy.

How do I attach my Clip-Tone?

When you have obtained your Clip-Tone attach it to your inhaler as described in the accompanying leaflet.

Clip-Tone E – Ventolin or Flixotide

Clip-Tone E - Seretide

Clip-Tone F – Fostair, Clenil, Trimbaw

Check the Clip-Tone is fitted correctly.

Do not activate the inhaler to perform this check.

Check the Clip-Tone is fitted correctly by inhaling slowly through the inhaler; you should hear a gentle whistle sound as you inhale.

Using your inhaler with the app.

- When you are ready to use your inhaler tap the 'Use Your Inhaler' button on the Home screen.
- You will be taken to the activity screen with a floating balloon and progress bar.
- Follow the instructions on screen.
- When you use your inhaler you should hear the whistle and see the balloon rise on the screen.
- Once you hear the whistle press the button firmly and continue your inhalation for as long as you can.
- Use the progress bar on the screen to try and aim for at least 3-5 seconds.
- When complete hold your breath for as long as comfortable and remove the inhaler from your mouth.
- The app will provide you with an assessment of your inhaler technique.
- If a [!] symbol is displayed, it will provide some specific tips to help the next time you take your inhaler.

- If you need to take another dose, press the 'Use Inhaler Again?' button and repeat the steps.
- DO NOT take more doses than you have been prescribed even if your technique has aspects that need improvement.
- The feedback from the app should be used for information only and to facilitate discussions with your healthcare professional.
- The feedback should not be used to inform medication decisions.

Activity Tracker

To check your inhaler use record, exit to the Home screen and tap on the 'Activity Tracker' button.

The Activity Tracker provides four different views of your activities: Details, Days, Weeks and Months.

Days View

- In the Days view, you will see each individual inhaler activity displayed.
- For each activity, the vertical bar represents the inhalation duration. The taller the bar the longer the inhalation.
- If a button press was detected during inhalation, a mark will be visible on the vertical bar at the point it occurred.
- Across the top of the graph you will see a symbol indicating if the technique was good ([Thumbs up]) or whether some errors were detected ([!]).

Details View

- To access Details view, tap anywhere within the graph area whilst in Days view.
- Details for all activities recorded on that day will be displayed with feedback on whether the activity was good or how technique could be improved.

Weeks/Months View

- Tapping on the Weeks or Months view buttons allows you to see how many activities were recorded by week or month.
- Weeks and Months views give you an idea of whether you are taking your inhaler often enough.
- E.g. If you are advised to take two puffs twice daily you would expect to see around 28 activities each week.

Multiple Inhalers

- If you are using more than one inhaler type and have a Clip-Tone on both you may see different bars relating to different inhalers.
- Clip-Tone E is shown as a blue bar, Clip-Tone F as a pink bar.

What else do I need to know?

- When you first launch the app, we will ask you to share some basic information.

- This information, if shared, will help us develop the app and make improvements in the future.
- None of the information shared can identify you personally.

- See our privacy policy for more information.

FAQs

What is the app for?

The app is designed to give you visual feedback to help guide the use of your inhaler.

It also has a helpful tracker feature which keeps a record of your inhaler use. This can help when discussing your medication with your doctor or nurse.

I can't hear the whistle sound. Is it working?

The whistle is designed to be discreet.

You can check if the whistle is being picked up by the app by accessing the 'Use Your Inhaler' screen from the main menu.

If the whistle isn't being heard, check that you have allowed access to the microphone by looking in your device settings.

If you aren't able to hear the whistle and it isn't being detected by the app, check that the Clip-Tone is correctly fitted by following the instructions.

If you are still having problems, contact us for further support:

info@clin-e-cal.com

How does the app assess my inhaler technique?

The app is programmed to identify two main features of inhaler use:

- 1) Length of inhalation.
- 2) Co-ordination of inhalation with button press.

The Clip-Tone device is specifically designed to emit defined sounds when the optimal slow and steady flow of breath is used.

The app will respond to these sounds and determine the features of the inhaler use.

Pressing the inhaler button results in a soft whoosh like sound being generated which the app monitors for to determine if and when the inhaler was activated.

To achieve a thumbs up ([:: Thumbs up graphic ::]) assessment the inhalation will need to continue for at least 3 seconds and actuation (pressing of the inhaler) will need to be detected within the first second of inhalation.








If you did not achieve a thumbs up ([:: Thumbs up graphic :]), the app will provide tips on how to improve the technique.

The app is not detecting when I press my inhaler

Background noise can affect the app's ability to detect the soft whoosh sound when you press your inhaler.

Do what you can to keep background noise to a minimum when using the app.

Also make sure you are pressing the inhaler button firmly.

	Product code
	Manufacturer
	EU authorised representative
	This product complies with the essential requirements of the medical devices directive (93/42/EEC)
	This product complies with the essential requirements of the UK Medical Device Regulations (UK MDR 2002).
	Consult instructions
	Caution