


Date of issue:	2022/12/12
Product name:	RAFI-TONE
REF	CeC_002_I
	CeC_002_A
	Clin-e-cal Ltd, Room 7, Harefield House, Alderley Road, Wilmslow, SK9 1RA; info@clin-e-cal.com
EC REP	Easy Medical Device vComm Guldenberg 1 bus 2-4,2000 Antwerpen, Belgium

About



RAFI TONE is an app designed to help make spacer use more fun.

RAFI TONE is a software app that helps a child accept having their inhaler medication. It is to be used only with a pressurised Metered Dose Inhaler (pMDI), a spacer device and the Clement Clarke International ‘whistle-tone mask’.

The RAFI TONE app was conceived at the University of Manchester by Professor Tariq Aslam (father of a child needing to use a spacer) and Dr Clare Murray (an expert in childhood breathing disorders).

Its development has been tested with children at the Royal Manchester Children’s Hospital, UK, who have all helped it to evolve.

A special mention to Rafi Aslam, for whom the app was first created and who has helped develop and test the system since then.

RAFI TONE is an accessory to a medical device.



Instructions

Intended Purpose

- RAFI TONE is a software app that helps a child accept having their inhaler medication.
- It is to be used only with a Pressurised Metered Dose Inhaler (pMDI), a spacer device and the Clement Clarke International ‘whistle-mask’.

Intended User

- RAFI TONE is intended for use patients/carers (typically patients under 5 yrs of age) using pMDI inhalers and a spacer device.

Patient Population:

- Children who have respiratory conditions taking prescribed medication using a pressurised metered dose inhaler (pMDI).

Precautions

- The Inhaler Tracker feature should not be used to make medical decisions.
- Use only with the whistle mask from Clement Clarke International and follow instructions for use.
- RAFI TONE is intended to encourage children to take inhaler medication effectively.
- No clinical benefit is claimed by use of the app.
- RAFI TONE should always be used under adult supervision.
- RAFI TONE may not function properly where there is a high level of background noise.
- In case of any incident involving the use of RAFI TONE please contact: info@clin-e-cal.com

And your national competent authority.

or visit: www.clin-e-cal.com

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

Set-up

- When you have obtained the whistle mask and spacer device assemble it as detailed in the product details.
- Open app from your mobile device.

Using for the first time and periodically thereafter

- Perform a microphone check. On very first launch the microphone check screen will appear automatically; thereafter periodically go to the settings screen select 'microphone: Perform Check'
- The app will instruct you to use the whistle mask without administering medication.
- If the whistle is detected the microphone icon will turn green indicating that whistle detection is working. Press the button to continue to the home screen. You are ready to start.
- If whistle detection fails, then see FAQ section for guidance or visit support website shown.

Using the game

- From the home screen select 'Play Game'
- Explain to your child that if they hold the mask to their face and breathe in deeply a whistle will sound which help Rafi the Robot defeat the baddies.
- When you are happy that your child's breathing is adequate administer the medication as prescribed.
- If you think the technique is adequate but your child is finding it difficult to achieve an whistle, sensitivity can be adjusted.
- To adjust sensitivity, return to the home screen and select 'settings' (⚙️). Select desired sensitivity.
- The app will default back to 'expert' sensitivity when it is has been fully exited.
- It is important that you continue to encourage your child to breathe slowly and deeply and aim to use expert sensitivity as soon as possible.
- On 'Beginner' and 'Intermediate' sensitivity settings the game may be activated more easily by sounds other than the whistle mask.

Inhaler Tracker

- RAFI TONE incorporates a useful Inhaler Tracker feature which allows you to log use of medication.
- To view the Inhaler Tracker, select 'Inhaler Tracker' from the home screen.
- When the game is played the app will automatically insert a green circle into the calendar at the corresponding date/time.
- **Please note that the time of the game play indicated in the tracker, relates to the time set in the device which may not necessarily correspond to your location. Please check the device settings if the times do not correspond.**
- It is possible to add notes to the event e.g. how many puffs were given.
- To do this, highlight the relevant box and press the (📝) icon in the control tab, a notes box will appear on screen. When the note is complete press the (✓) to confirm or (🗑️) to delete the note. You will return to the calendar screen.
- If notes have been added the (📝) icon will appear in the time box. To view the notes highlight the box and tap (📝) in the control panel.

Manual recording

- It is also possible to manually record administration to record any medication that may be taken without the use of the game.
- To do this, highlight the relevant date/time box and press the plus icon (+) in the control tab.

Exporting the Inhaler Tracker Record

- The inhaler Tracker record may be exported via email if required.
- To do this press the (📧) icon in the control tab.
- Select the format that you wish to use.
- If 'via email' is selected an email will automatically launch and it can be sent to a recipient of your choice.

- If 'via copy/paste' is selected, the data will be added to the clipboard and may be pasted in a location of your choice (e.g. notes app).

FAQs

There is no green light on the mic check screen

- Check you have given permission for the app to access your microphone. This can usually be found under the device settings.
- Ensure the device's microphone is not obscured and that you are in close proximity to the device and its microphone.
- If this does not work, please try shutting the app down completely (not just exiting from the app) and reopening it.








My child is struggling to make an effective whistle noise

- A clear whistle is an indication that an adequate flow of breath into the lungs is achieved. Some children may find this difficult particularly when it is first introduced. In order that the child is not discouraged RAFI TONE has settings which vary the sensitivity. This can be changed via the menu button. When the app is re-opened the app will automatically default to the expert setting.

The cartoon sometimes moves when we do not hear a whistle

- RAFI TONE works by listening for a specific noise and whilst it has high specificity for this sound, there are occasions when background noises mimic the frequency of the whistle and hence the cartoon may move forward. This may occur more frequently at 'Beginner' and 'Intermediate' settings. The app should be used in a quiet environment away from other distractions. We also recommend that you do not rely on the movements of the app for counting the breaths – if you are counting the breaths use the whistle sound as a guide.

Symbols

	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