Date of issue: 4th March 2019

Product name: RAFI TONE Junior

Product Code(s): CeC_002a_I and CeC_002a_A

⚒ Manufacturer: Clin-e-cal Ltd, Room 7, Harefield House, Alderley Road, Wilmslow, SK9 1RA

Contact: info@clin-e-cal.com

About $C\epsilon$

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' or Flo-Tone whistle.

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 Junior 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' or Flo-Tone whistle.

Intended User

- RAFI TONE Junior is intended for use by patients/carers with patients typically 6-16 yrs of age using pMDI inhalers, a spacer device and the Clement Clarke International 'whistle mask' or Flo-Tone whistle.

Patient Population:

Clin-e-cal Ltd, Room 7, Harefield House, Alderley Road, Wilmslow, SK9 1RA

- Children (typically 6-16 years of age) 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 or Flo-Tone whistle from Clement Clarke International and follow its instructions for use.
- RAFI TONE Junior is intended to encourage children to take inhaler medication effectively.
- No clinical benefit is claimed by use of the app.
- RAFI TONE Junior should always be used under adult supervision.
- RAFI TONE Junior may not function properly where there is a high level of background noise.
- In case of any incident involving the use of RAFI TONE Junior please contact: info@clin-e-cal.com or visit www.clin-e-cal.com

- **If you have any concerns about your child's condition, please contact your healthcare professional.**

Set-up

- When you have obtained the whistle mask or Flo-Tone whistle and spacer device assemble it as detailed in its product details.
- Open the Rafi Tone app on 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 device without administering medication.
- If the whistle sound 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'
- The patient should breathe in deeply through the spacer/whistle device, a whistle will sound which the app responds to by progressing the game activity.
- When you are happy that breathing is adequate administer the medication as prescribed.
- If you think the inhalation technique is adequate but the game is not responding to the whistle, then the game sensitivity can be adjusted.
- To adjust game 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.

Clin-e-cal Ltd, Room 7, Harefield House, Alderley Road, Wilmslow, SK9 1RA

- It is important that the user continues 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 inhaler use 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.

Clin-e-cal Ltd, Room 7, Harefield House, Alderley Road, Wilmslow, SK9 1RA

- 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.

I am 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 game sometimes moves without the whistle sound being made

- 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 game 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.