

VERSION 1.0

## TONE DEVICE

PRODUCT MANUAL





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# READ BEFORE USING THE TONE DEVICE

Tone Device Terms of Use

Revised: 19 February, 2022

#### Introduction

0892427 BC Ltd. D/B/A Ketogenic Girl, a British Columbia limited company ("Ketogenic Girl", "we", "our," or "us") would like to introduce you ("you", "your," or "User") to the Tone Device ("Tone"). The use of Tone shall be referred to herein as the "Services." It is important that you read these terms and conditions ("Terms"). You may use the Services only in accordance with these Terms. If you do not agree with these Terms, do not use Tone and contact Ketogenic Girl or the vendor who supplied your device immediately about returning Tone for a refund. Customers are eligible for a refund within 14 days of purchasing the Tone Device if it is sealed in its original packaging. Due to hygienic reasons, if the seal has been broken, it is not eligible.



#### K E T O G E N I C G I R I

Tone is a General Wellness Device. It is Not an Approved Medical Device.

Tone is a general wellness product intended to provide metabolic reading and tracking. It is not a medical device and has not been approved by the U.S. Food and Drug Administration or any other regulatory body. Tone does not diagnose, treat, cure, or prevent any disease, or otherwise assist in these activities. By using Tone, you agree and acknowledge that the use of the Services is at your own risk. Ketogenic Girl Does Not Provide Health-Related Advice. Consult a Physician Before Use. Ketogenic Girl does not provide any professional health-related advice or any medical diagnoses. For this reason, any information acquired from the use of the Services is not intended to be, and should not be deemed as, medical or other health-related professional advice, diagnosis or treatment. Furthermore, it is not intended as a substitute for medical or professional advice, diagnosis, or treatment. Prior to using Tone, you must consult with your physician to confirm that Tone is appropriate for you. Failure to do so is a violation of these Terms.

## Use by Minors Prohibited

The Services were designed to be used only by healthy individuals who are over the age of 16. No person under the age of 16 years old should use any of the Services.



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#### Disclaimer of Warranties

Ketogenic Girl does not warrant or make any representations regarding the use or the results of the Services. You agree and acknowledge that the use of the Services is at your own risk. Ketogenic Girl does not warrant or make any representations regarding the results of Tone or the accuracy of your data. The Services are provided on an "as is," "with all faults" basis without any warranties or conditions of any kind, express or implied, including but not limited to implied warranties of use, merchantability, or fitness for a particular purpose or function. To the fullest extent of the law, Ketogenic Girl disclaims and makes no representations or warranties as to the accuracy, availability, effectiveness, quality, usefulness, reliability, truthfulness, suitability, or completeness of the Services.

## Limitation of Liability and Indemnification

Use of the Services is at your own risk. Ketogenic Girl does not endorse or assume any responsibility for any decision made or action taken in reliance on the Services, nor any loss, injury, harm, or damage arising from the Services. By using Tone, you agree that Ketogenic Girl, including its officers, directors, shareholders, employees, subcontractors, and agents (collectively, the "Relevant Parties") shall not be responsible for or liable to you for any claim, loss, or damage arising from your use of the Services or any reliance on any information or suggestion provided thereby. No action may be brought for any breach of these terms more than eighteen (18) months after the cause of action has arisen, unless the relevant

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jurisdiction prohibits such limitations of claims, in which case it shall not apply. These disclaimers, exclusions and limitations apply to all claims for damages, whether sounding in breach of contract, negligence, tort, warranty, strict liability, or otherwise. In no event shall the cumulative liability of Ketogenic Girl or any of the Relevant Parties to you exceed the amount you (or in the case of a gift, the amount the giver) paid for the Services (if any). You agree to defend, indemnify, and hold the Ketogenic Girl and the Relevant Parties harmless from and against any claims, actions or demands, liabilities and settlements including without limitation, reasonable legal and accounting fees, resulting from, or alleged to result from, your violation of these Terms.

## Governing Law

The laws of British Columbia, Canada will govern this Agreement, without giving effect to any principles of conflicts of laws. User hereby irrevocably and unconditionally consents to submit to the jurisdiction of British Columbia for any litigation arising out of or relating to use of Services (and agrees not to commence any litigation relating thereto except in such courts), waives any objection to the laying of venue of any such litigation in British Columbia courts and agrees not to plead or claim in any British Columbia court that such litigation brought therein has been brought in an inconvenient forum. In the event that the laws of a jurisdiction other than British Columbia are determined applicable by a court of competent jurisdiction and such jurisdiction does not allow an exclusion or limitation of liability for consequential or incidental

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damages, such liability is limited to the fullest extent permitted by law. If any provision of these Terms is found to be unlawful, void, or for any reason unenforceable, then that provision will be deemed severable from these Terms and will not affect the validity and enforceability of any remaining provision. These Terms contain the entire terms and conditions governing the use of Tone and supersedes any and all prior written or other arrangements or understandings. Terms may be altered or modified by Ketogenic Girl from time to time in writing. Notices to you may be made via email or regular mail. The Services may also provide notices of changes to these Terms or other matters, by displaying such notices or by providing links to such notices without limitation, you agree that a printed version of these Terms and of any notice given in electronic form shall be admissible in judicial or administrative proceedings based upon or relating to these Terms to the same extent and subject to the same conditions as other business documents and records originally generated and maintained in printed form.



TONE RESULTS	
0 KET	No Ketones
1-9 KET	Light Fat Burning
10+ KET	Fat Burning Zone

The Tone Device measures acetone in part parts per million (PPM). To make it easier to relate to blood ketone measurements, we have created KET units.

For example:

- A reading of **0 KET** signifies that no ketones were detected on the breath.
- Readings of between 1 to 9 KET signify that the person is likely in a light state of
  ketosis or fat burning due to either a caloric deficit, which has been shown in
  research to produce breath acetone, or carbohydrate restriction such as on a
  ketogenic diet, inducing light ketosis.
- Readings of above 10 KET signify that the person is likely in the fat burning zone or a full state of ketosis, and may be predominantly burning fat for fuel, induced either by a caloric deficit or from carbohydrate restriction on a ketogenic diet.
   Please note that although higher levels of acetone and higher numbers likely indicate deeper ketosis, they do not necessarily imply that fat burning is greater than it may be at lower ranges. It is very possible to burn fat without ketosis; ketosis however is an indicator that lipids (fats) are being oxidized (burned) for fuel needs.

## PRECAUTIONS

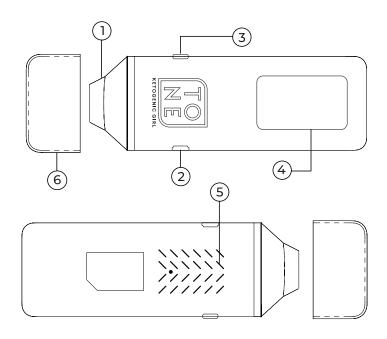
Thank you for purchasing the Tone Device breath acetone meter by Ketogenic Girl.

This manual provides important information to ensure proper and correct use of the Tone Device. Before using this device, please read this User's Manual thoroughly.

- 1. Use this device ONLY for its intended purpose, as described in this manual.
- 2. Do NOT use any accessories which are not approved by the manufacturer.
- 3. Do NOT use the device if it is damaged or malfunctioning.
- 4. Do NOT use the Tone Device when drinking alcohol or using mouthwash that contains alcohol. Doing so will inflate the reading numbers. The body may still be metabolizing alcohol for up to 36 hours following a drink of alcohol. Repeated exposure to alcohol may damage the sensor.
- 5. Do NOT use the equipment in places where aerosol sprays are used, or where oxygen is being administered.



## DEVICE COMPONENTS



- 1. Mouthpiece
- 2. Charging Port
- 3. Multifunction Button

- 4. LED screen
- 5. Ventilation
- 6. Cap

## PREPARATION BEFORE USE

Please check to make sure that all parts and components are included in the package. If any part is missing, please contact us immediately upon receiving and opening the package.

Contents of the package:

- 1. Tone Device
- 2. User Manual
- 3. Charging Cable



## **CLEANING & MAINTENANCE**

- To avoid damaging the device or its surface, do not use aggressive or abrasive cleansers such as benzene, thinners, or petrol to clean it.
- To clean the device, wipe the mouthpiece regularly with a clean damp paper towel or cloth carefully. Protective mouthpiece covers may be purchased separately for additional users.
- Avoid dropping or hitting the Tone Device, as it may become damaged and malfunction.
- Do not try to repair, rebuild, or dismantle any parts of the device.
- Do not clean the device with any alcohol based cleaners or solvents as it may damage the sensor.



# IMPORTANT TIPS ON USING THE TONE DEVICE

The breath acetone meter needs to be calibrated before your first use. To do this, turn on the Tone Device, wait for the 20-second countdown to be completed, and turn it off. Repeat the same procedure 1-2 times (without blowing) before you proceed to your first test. Please blow immediately after the countdown has been completed, and blow until the beep sound has stopped. The Tone Device will then start analyzing your breath. Please note that if there is no beep sound, it means that the Tone Device has not detected any ketones in your breath.

Please do not take a deep breath before blowing. Instead, just blow into the Tone Device while breathing normally. Most of the acetone is at the bottom of your lungs, so increasing air intake may result in decreased acetone detection.

Please always wait 5 minutes before performing a second or third test. Otherwise, the residuals from the last test may influence the next reading. Please note that after each test, the air in your lungs gets diluted from the increased intake of air inhaled after testing. For this reason, it is optimal to wait 30 minutes between testing to maximize accuracy of the results.

If another person wants to use the Tone Device, they should also wait for 5 minutes

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after the last test was performed in order to obtain accurate readings.

Please note that everything you consume, including water, influences the ketone levels in your breath. For that reason, in order to accurately analyze and compare your test readings, we strongly recommend testing your ketone levels under the same conditions every day right after waking up and before consuming anything.

Please note that there is a time delay before your ketone levels drop after having consumed food, which is why you might still be getting high readings after eating.

The time delay is different for each individual, and will also depend on how long you have been adapted to burning fat. Please refer to the figure on page 26 to see the temporal lag.

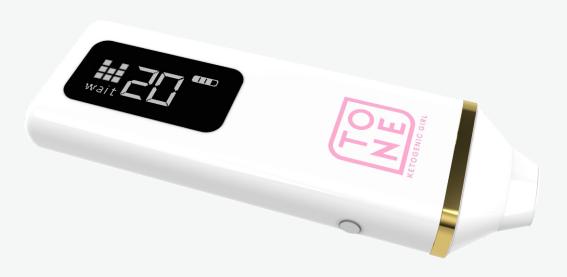
Consuming carbohydrates can influence the readings on the Tone and generate a false positive, as intestinal bacteria can produce methane during digestion. Foods that are high in raffinose, a sugar found in foods such as asparagus, Brussels sprouts, broccoli, radishes, celery, carrots, and cabbage, are also rich in soluble fiber, which does not fully break down until reaching the small intestine and may generate methane. The sensor on the Tone is sensitive to methane as well as acetone and alcohol. If you habitually consume meals with carbs or follow a high carb diet, it is best to only test in the morning before eating or drinking. Protein and fat do not produce methane when digested so if you consume a low carb or keto diet or practice intermittent fasting, it is less of a concern, however the readings will always be most accurate in a fasted state.

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The Tone Device is highly sensitive and is designed to detect even very small traces of ketones. This is why the results may be affected by external conditions, such as temperature, humidity, and chemicals in the environment such as disinfectants or cleaning agents in sterile environments such as hospitals or clinics, for example. If the readings on the Tone seem abnormally high and you are in such a setting it would be best to avoid testing in this setting or right after coming home from such a setting. Additionally, the results may be unstable if the device has not been used for a long time. Alcohol in drinks, food or mouthwashes as well as other mouth rinses and tooth brushing can inflate the numbers on the Tone. It is best to avoid testing while drinking alcohol, and waiting at least 3-4 hours to test after imbibing alcohol or any oral rinses.

Each test reading will be slightly different. There are many variables that might affect the results including the amount of air that you have inhaled and breathed out, variations in the force with which you breathe out air, and how long it took you to breathe out. Other factors that influence readings are the food and beverages that you have consumed, your activity levels (including exercise), whether you have been fasting, and so on. Nevertheless, the results from the same period of time of a given user should be similar.

By using the feedback from the Tone Device, you may test different macros, caloric intakes, exercise routines, and more to evaluate which approaches generate the best feedback and results for you, and adapt your lifestyle to reflect those most aligned with your optimal wellness.



## HOW TO USE THE TONE DEVICE

To use the Tone Device to detect ketones in your breath, follow these steps:

- Warm-up and calibration:
   Press the power button and hold for about 2 seconds. The display of the Tone
   Device will turn on.
- The "WAIT" symbol will be displayed and a countdown from 20 to 0 will begin.
   This indicates that the device is in Warm-up mode and is calibrating.
- When the device is ready, it will say "BLOW."
  Place your mouth on the mouthpiece and blow into the device until the end of the beep. Do not take a deep breath before blowing. If there are no ketones detected on the breath, there will not be a beep sound.
- · The ketone level of your breath will be displayed on the screen.

NOTE: If the warm-up wasn't successful, the device will reset automatically and will start warming up again until it is ready for use. On rare occasions, this may happen 1-2 times until the device is ready.





## IMPORTANT

When taking the device out of the packaging for the first time, or if you haven't used it for a long period of time, impurities (such as fine particles and dust) may have accumulated on the surface of the ketone sensor. In that case, a longer warm-up is necessary. To do this, turn on the device, wait for the 20-second countdown to be completed, and turn it off. Repeat the same procedure 1-2 times (without blowing) before you proceed to test.

#### TEST:

- The "BLOW" symbol will be displayed on the screen once the warm-up has been successfully completed. A countdown will start indicating that the device is ready to be used. Breathe into the device for about 5 seconds until the beep stops. If there is no beep sound, it means that the Tone Device has not detected any ketones in your breath.
- The next screen indicates that the device is analyzing your breath.



## UNDERSTANDING RESULTS

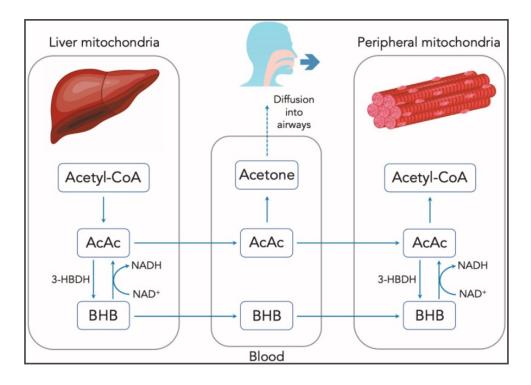
Once the testing and analysis phase has been successfully completed, the results will show on the screen. They will give you feedback on the ketone levels in your breath and whether or not you are burning fat for fuel. To get into a fat burning state in the body, you need an environment where glucose (blood sugar) is not elevated, the hormone insulin is suppressed, and the hormone glucagon is elevated.

When you eat carbohydrates (carbs), your body uses the sugar (glucose) from them for energy. After you eat, the hormone insulin moves glucose out of your bloodstream and into your cells. When you eat very few carbs, your body will not be able to use glucose for fuel and subsequently, it will burn fat instead. Consuming fewer carbs enables the body to access body fat stored in fat cells. The liver synthesizes ketones when the body is in a fat burning state (the body is using fat for fuel).



Ketone bodies are present in three main forms, which can be measured in the blood (BHB), in urine transiently (aceto-acetate), and finally in the breath (acetone).

Acetone is the main ketone when fat is your primary source of fuel, you make extra ketones, which are released into the breath. The Tone Device detects these breath ketones.



Original table source: III, Donald & Ratto, Timothy & Ratto, Matt & Mccarter, James. (2020). Characterization of a high-resolution breath acetone meter for ketosis monitoring. PeerJ. 8. e9969. 10.7717/peerj.9969.

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Ketone bodies are often higher in ketogenic diets whereby carbohydrates are restricted and both body fat and dietary fat are the main sources of fuel. However, any diet that increases fat metabolism will show elevated ketone bodies which we can measure with the Tone Device. This is referred to as "light fat burning" (light ketosis) or the "fat burning zone" (optimal or deep ketosis) on the Tone Device.

Acetoacetate spontaneously converts to acetone and we breathe it out which is why we can measure levels using a breath ketone sensor. Blood and breath levels will not usually be identical; however, the breath ketones may theoretically provide a better indicator of ketone utilization than the blood measurements when it comes to determining if fat is being burned for fuel. This includes both dietary fat and body fat. Typically, to achieve a quantifiable amount of fat burning for body fat loss, a caloric deficit must be in place.

This table illustrates the correlation of breath ketones (acetone) and blood BHB (ketones). Breath and blood ketones are not the same ketone. Acetone spontaneously converts from acetoacetate. Therefore the measurements have a correlation however they will not usually be exactly the same. Acetone also has a 7-8 hours temporal lag behind BHB, which can be seen in the figure on page 26.

Blood ketones (BHB) and breath ketones (acetone) are different forms of ketones expressed in different ways and in different pathways and organs (I.e. blood

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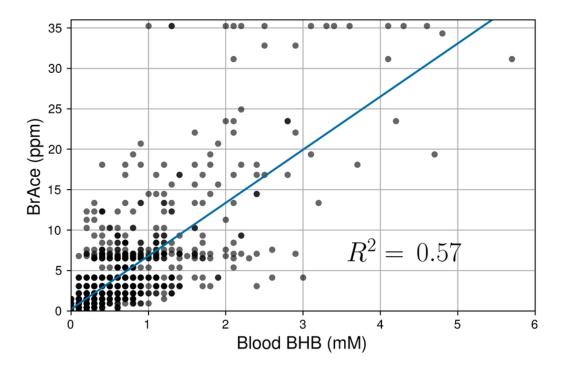
circulation for BHB vs lungs for acetone). As such, they do not have an exact correlation coefficient of 1; it is R2=57. They are also measured in different units (mmol vs ppm).

Blood BHB ketones and breath acetone ketones are produced at a ratio that differs for each person, depending on several factors including the redox potential of the mitochondria, the energy status of the liver and more.

For example, when someone is eating at maintenance or in a surplus, their BHB and acetone will be more at a 1:1 ratio. During a fast, acetone can be de-coupled from this ratio and be as much two or three times BHB. After around 48-72 hours we sometimes see blood and acetone ketones at a 1:1 again. When eating in a caloric deficit, BHB tends to be lower and acetone higher which is a reflection of the higher rate of fat oxidation occurring.

This is why we recommend testing every day first thing in the morning in a fasted state, or anytime of the day when still in the fasted window.

## Correlation of coincident BrAce and blood BHB measurements

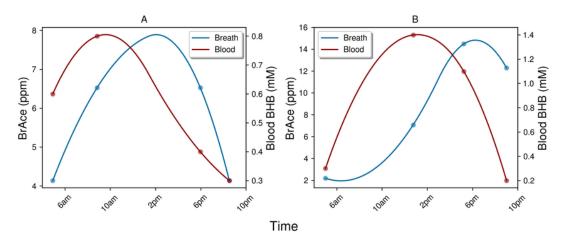


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Both example days (A and B) demonstrate a lag of approximately 7-8 hours between peak concentrations of blood BHB and BrAce. This time lag effectively decreases the point-to-point correlation coefficient.

## Examples of the temporal lag between blood BHB and BrAce.



Original table source: III, Donald & Ratto, Timothy & Ratto, Matt & Mccarter, James. (2020). Characterization of a high-resolution breath acetone meter for ketosis monitoring. PeerJ. 8. e9969. 10.7717/peerj.9969.

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The Tone Device measures acetone in part parts per million (PPM). To make it easier to relate to blood ketone measurements, we have created KET units.

### For example:

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  of ketosis or fat burning due to either a caloric deficit, which has been shown
  in research to produce breath acetone, or carbohydrate restriction such as on
  a ketogenic diet, inducing light ketosis.
- Readings of above 10 KET signify that the person is likely in the fat burning
  zone or a full state of ketosis, and may be predominantly burning fat for fuel,
  induced either by a caloric deficit or from carbohydrate restriction on a
  ketogenic diet.
- The Tone Device is a General Wellness Device and as such is not to be used as
  a medical device or to diagnose, treat, or cure any disease state. It is used to
  provide feedback in order to help users maintain a healthy weight, encourage
  healthy eating, or assist with weight loss goals.
- Making healthy lifestyle choices may play an important role in optimal health outcomes; such associations are described in peer-reviewed scientific publications.



## CHARGING, POWERING ON AND OFF, & RE-TESTING

## Charging

Plug the device into the charger when the battery is low. Once the battery is fully charged, the battery icon will stop flashing, indicating that it is fully charged. The screen will still show the word "charging" and the battery will only display 3/4 full but once it is disconnected from the charger and powered it will display a full battery. Do not charge it again until it requires a charge and the device has no power.



## Auto power off

The results will be displayed on the screen for about 10 seconds. After that, "Powering Off" will appear on the screen for 2 seconds and the Tone Device will turn itself off

## Turning the device on and off

To turn the device on or off in any mode, press the Multifunction button for 2 seconds.

## **Testing again**

After the test results are displayed, you can press the Multifunction button to enter testing mode again. You don't need to wait for the device to turn itself off to do this. For maximum accuracy, please wait 30 minutes before testing again. During a test, acetone in the lungs is breathed out. If a test is conducted again right after the first test, it will show a lower number because there is less acetone left over from the previous test. Testing multiple times, back-to-back, will lower the accuracy.



# ACCESSING THE TESTING RECORDS

To access the recent testing records (up to 64 readings are saved), follow these steps:

- While the device is calibrating in "WAIT" mode, double-click the Multifunction
  button to enter Memory mode. The previous test data will be displayed. Click
  the power button to cycle through previous results. Double-click the
  Multifunction button to exit Memory mode and return to Test mode. If the
  device is not operated for 10 seconds it will turn itself off.
- While in Records mode, press the Multifunction button to return to Test mode.
- If there is no activity within 10 seconds, the device will turn itself off.







