



**MANUFACTURER**

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These Instructions for Use were last  
updated in March 2024  
Part Number: 5015 Revision I

REF



**Endeavor OTC<sup>®</sup>**  
**INSTRUCTIONS FOR USE**  
**REVISION I**

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# Labels and Symbols



CAUTION: Pay special attention to the following details



Manufacturer



Reference Part Number



Lot Number



Consult Instructions for Use

## We're here to help.

**Ensuring your satisfaction with our products is our priority.**

For answers to common questions related to purchases, treatment recommendations, technical issues, or general information check out our [Frequently Asked Questions](#).

For anything else please email us at

[support@endeavorotc.com](mailto:support@endeavorotc.com)

EndeavorOTC, and the use thereof, may be covered by one or more patents. Please click [here](#) for more information.

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# Instructions For Use

## CAUTIONS

Please follow all of your mobile device manufacturer's instructions for the safe operation of your mobile device. For example, this may include appropriate volume settings, proper battery charging, not operating the device if damaged, and proper device disposal. Contact your mobile device manufacturer for any questions or concerns that pertain to your device.

If you experience frustration, emotional reaction, dizziness, nausea, headache, eye-strain, or joint pain while playing EndeavorOTC, pause the treatment. If the problem persists contact your health care provider. If you experiences a seizure stop the treatment and contact your health care provider.

EndeavorOTC is not a substitute for your medication.

## U.S. FDA ENFORCEMENT DISCRETION POLICY

EndeavorOTC is made available under the U.S. Food and Drug Administration's current Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. EndeavorOTC has not been cleared or authorized by the U.S. Food and Drug Administration for any indications. It is recommended that patients speak to their health care provider before starting EndeavorOTC treatment.

For additional resources relating to ADHD treatment, or if your ADHD symptoms and/or impairments are not improving, contact your health care provider. If you are experiencing a medical emergency, please dial 911.

## INDICATIONS FOR USE

EndeavorOTC is a digital therapeutic indicated to improve attention function, ADHD symptoms, and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD. EndeavorOTC utilizes the same proprietary technology underlying EndeavorRx, a prescription digital therapeutic indicated to improve attention function as measured by computer-based testing in children ages 8-17 with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue.

## SIDE EFFECTS

No serious adverse events have been reported in any of our clinical studies. Of 945 participants in trials supporting the technology behind EndeavorOTC and EndeavorRx (AKL-T01) receiving the intervention, 73 participants (7.2%) experienced treatment-related adverse events (probable, likely). Associated adverse events included decreased frustration tolerance (3.92%), headache (1.48%), nausea (0.63%), dizziness (0.42%), irritability (0.32%), and emotional reaction (0.21%). All adverse events were generally transient, and no subject reported lasting or irreversible effects after discontinuation.

NOTE: EndeavorOTC and EndeavorRx were previously known as AKL-T01 during the clinical investigations.

## NOTES

EndeavorOTC may not be appropriate for patients with photo-sensitive epilepsy, color blindness, or physical limitations that restrict use of a mobile device; patients should consult with their health care provider.

# Compatible Devices

## ANDROID DEVICE MINIMUM SPECIFICATIONS

Android™ OS version	10.0
Storage	32 GB of storage space
Memory	3 GB of RAM
Network Infrastructure	WiFi
Example Devices	<b>Samsung Galaxy S10™, Samsung Tab A8, and similar or later models.</b>

## iOS DEVICE MINIMUM SPECIFICATIONS

iOS™ version	15.0	iPadOS® version	15.0
Storage	16 GB of storage space		
Memory	2 GB of RAM		
Network Infrastructure	WiFi		
Example Devices	<b>iPad® Mini 5, iPhone® 11 and later models.</b>		

For more information on device compatibility, please visit the [EndeavorOTC.com FAQ](#). Refer to the section *Technical > “What devices are compatible with EndeavorOTC?”*

To easily determine if your device is compatible, download EndeavorOTC from your app store and open it. If you cannot find it in your app store, your device may not be compatible.

Please configure the mobile device with the device manufacturer's security suggestions.

# Product Description

EndeavorOTC is a digital, non-drug treatment delivered through an action video game that was shown to improve attention function in adults with ADHD.

EndeavorOTC treatment is used on a mobile device. See page 6 for [compatible devices](#).

EndeavorOTC is different from action video games that you might play. The treatment programmed into the experience was designed to challenge attentional control during gameplay, requiring focus and flexibility to manage multiple tasks at the same time.

The proprietary technology (AKL-T01) underlying EndeavorOTC and EndeavorRx has been supported by clinical studies. For a full synopsis of the clinical trials conducted with AKL-T01, refer to the [Evidence section on EndeavorOTC.com](#). Please note: EndeavorOTC and EndeavorRx were previously known as AKL-T01 during the clinical investigations.

# Getting Started with EndeavorOTC

## RECOMMENDATIONS BEFORE YOU START TREATMENT

It is recommended that the mobile device be stored **password protected** to reduce the risk of unauthorized access.

Be sure that the mobile **device is fully charged** before use and that the **device's audio system is functioning properly** and the **audio is set at an appropriate level**.

## GETTING STARTED WITH TREATMENT

For best results, we recommend using the treatment approximately 25 minutes a day, 5 days a week. Our adult ADHD clinical study showed that the best results come with this routine for 6 weeks, although many participants showed substantial improvements in attention and clinical functioning with less play time. To assist in understanding daily progress, the app displays a 25 minute countdown timer on the home screen that resets at the start of each treatment day. The 25 minutes only counts gameplay time, referred to as Mission Minutes, and does not include extra time you may spend in the app browsing non-mission areas like the Costume Store and the Collection.

Try to fit EndeavorOTC into your routine and make it a habit. You can make use of reminders in the app or any other tools you use for managing your schedule.

Minimize distractions during each treatment with EndeavorOTC. We recommend turning off device reminders and notifications, using EndeavorOTC in a quiet room with headphones, and turning off other mobile devices and televisions. Find a comfortable place where you can use EndeavorOTC daily, ideally seated in an upright position in a well-lit room with minimal glare on the device.

It is best if the user adjusts the field of view and avoids using the device too close to their eyes. It is recommended to turn on the blue light filter on the device if administered during nighttime, but also recommended not to use the app right before bedtime to avoid risk of potential reduction in sleep quality.

Understand that by design, EndeavorOTC will be **challenging** (and sometimes frustrating) to use. Try and give each treatment of EndeavorOTC your full attention and effort to help ensure the best treatment results.

During a treatment session **it is OK to occasionally take a break** from treatment for a few minutes if needed, for example to avoid excess eye strain or fatigue.

# Operating Instructions

## LAUNCH & LOGIN

Tap the application icon on the mobile device to start. If you already have an existing Akili account, tap the **"Log In"** button and log in with your existing Akili Account using your email address and password. At this point you will be granted access to treatment if you have an active subscription. If you do not have an active auto-renewing subscription you will be prompted to purchase one after login.

If you do not have an Akili account, tap the button on the initial screen to get started, create an Akili Account, and sign up for an auto-renewing subscription.

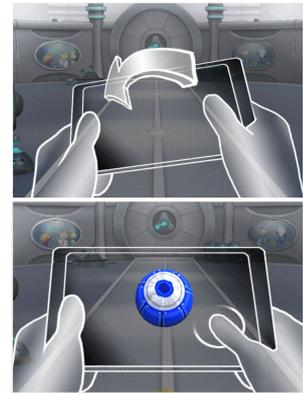
To open the EndeavorOTC product label, tap the "Product Label" link found in corner of the screen. Here you can find helpful information like the app version number and a link to the EndeavorOTC Instructions for Use.

## MANIPULATING THE DEVICE

EndeavorOTC features 3 primary actions: 1) **Navigating**, 2) **Tapping**, and 3) **Navigating** and **Tapping** at the same time (multitasking).

To **Navigate**, tilt the mobile device left and right. Try to hold the mobile device with both hands to help with the navigation and tapping.

To **Tap** on a target, touch either the right or left half of the mobile device screen using your thumb. This touch can be anywhere on the right or left side of the screen – it does not have to be directly on the flying target nor the thumbpad icons.



# EndeavorOTC Daily Treatment



When using EndeavorOTC, the goal is to successfully **Navigate** the character through a course while driving over Power Zones or avoiding obstacles, and **Tap** the right or left sides of the screen to collect only the correct targets when they appear while ignoring all other targets. At the beginning of the **Mission**, you will be shown multiple targets and asked to collect only specific types of targets - for example, you may be shown red, green, and blue targets and will be asked to only tap the red targets.



Each course completed from start to finish is an individual **Mission**, and time spent within those Missions are known as **Mission Minutes**. The technology behind EndeavorOTC has been shown to benefit those who play up to 25 minutes a day. For this reason, we've included a 25 **Mission Minute** countdown in the treatment intended to help you maximize your time.

There are many separate **Worlds** to unlock and explore as you progresses through treatment.



Playing **EndeavorOTC** can fit into your daily routine. The more you play, the better your results.

Using the treatment at least 5 days a week for six weeks can improve your attention and other functions that make up your ability to focus. At six weeks, we recommend a short recovery period to evaluate your progress and prepare for the next dose, as the treatment is intentionally challenging. Then, resume treatment for another six weeks to further enhance your progress.

Unlike a video game, there is no way to "win" EndeavorOTC. The treatment continuously adjusts to maintain a consistent level of difficulty relative to how well you are managing each challenge. As long as you are using the product consistently and trying your best, you are engaging with the treatment as intended.

# Daily Mission Minutes



The technology behind EndeavorOTC has been shown to benefit those who use the treatment up to 25 minutes a day. For this reason, we've included a 25 **Mission Minute** countdown in the experience, intended to help you maximize your time. **Mission Minutes** can be tracked on the Main Hub screen. When **Mission Minutes** reach zero you will receive an in-app reward for your efforts and be reminded to take a break until the next day, consistent with the intended treatment.

During each **Mission**, you will **Navigate** your character through a course, moving through gates and/or avoiding obstacles, and **Tap** to collect targets when they appear. With successful tapping and navigating, you can collect **Guides** and earn rewards.

The hover pod's capture ray will automatically lock on when you get close to the **Guide**. If you remain locked on for a few seconds, you will capture the **Guide** and earn a **Gem**. **Gems** can be hard to get – and each one will be harder to get than the previous one.



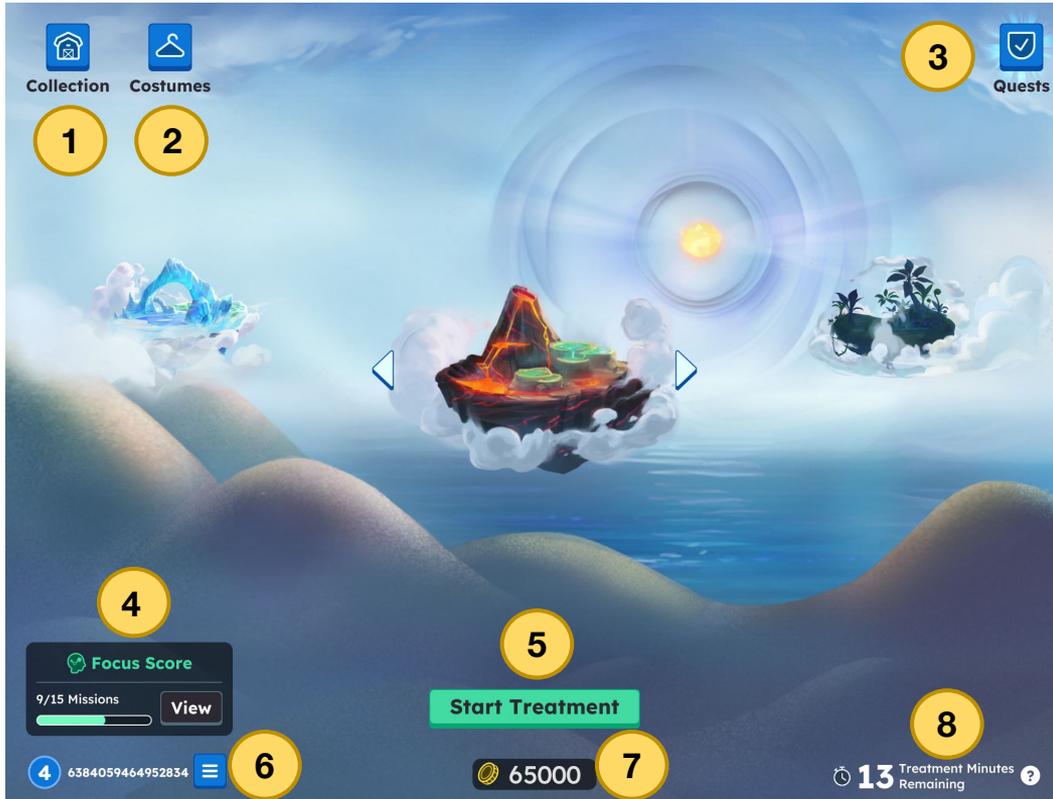
When the hover pod locks on to a **Guide** and captures it, EndeavorOTC has recognized that you have reached a new ability level in your play.

After collecting 15 **Gems** a new **World** will be unlocked.

EndeavorOTC was designed to, on average, take around 4 weeks to unlock all worlds, but actual speed of progression may vary across users. Independent of your progress, it is important that you engage regularly with the treatment.

Once all worlds are unlocked, you can revisit your favorite **World** to play and beat your previous scores. In addition, you can continue to complete **Quests**, unlock costumes, and view your **Collection**.

# The Main Hub Interface



- 1** **Collection:** As you progress you will collect different Guides. View them in the Collection area.
- 2** **Costumes:** Spend your earned Coins to unlock your desired costumes. As you progress you can choose the costume you like best, or collect them all!
- 3** **Quests:** View and complete available Quests to earn more rewards.
- 4** **FOCUS SCORE™:** View your Focus Score. A new one unlocks every 15 Missions, learn more [here](#).
- 5** **Start Treatment:** Begin your treatment by flying down into the selected planet and choosing the area you want to complete a Mission or Challenge in.
- 6** **User Info and Settings:** View your Level, return to the Dashboard, or replay the Tutorial. The Settings menu to adjust vibration, volume and sound levels is available here as well.
- 7** **Coin Count:** Amount of Coins collected available to spend on Costumes.
- 8** **Treatment Minutes:** Displays the amount of Treatment Minutes remaining out of the recommended 25 minutes for the day

# Treatment User Interface



## PAUSE AND RESUME MISSION

Each daily treatment can be paused at any time by tapping the upper-left corner of the screen. Tap **“Resume”** to continue the treatment. *Note: There are built-in rest periods between missions.*



## SETTINGS MENU

The Settings Menu is available on the Main Hub in the bottom left. It allows you to toggle Music and Sound Effects off and on, contact Customer Support, and access Licence, Terms of Use and Privacy information. Vibration can also be toggled off and on if your device supports it.



## EXIT AND END TREATMENT

When a daily session is completed, the EndeavorOTC application can be closed on your device. After your treatment subscription to EndeavorOTC expires, the treatment will become automatically disabled.

Please contact your health care provider to discuss your experience and the best treatment plan for you.