

AKL-T01

Instructions for Use

5012 Revision E

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Investigational Medical Device Software

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Caution

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use

Game-based Digital Therapy May Cause:

Dizziness, Nausea, Headache, Emotional Reaction, Aggression,
or Decreased Frustration Tolerance

Software developed by:

Akili Interactive Labs, Inc.

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AKL-T01 may not be appropriate for patients with photosensitive epilepsy, color blindness, or physical limitations that restrict use of a mobile device. Consult with your healthcare provider or study doctor before use.

If using a personal mobile device, follow 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.

Getting Started

If you are using this on a personal mobile device, we recommend that you **password protect** your mobile device to reduce the risk of unauthorized access.

Follow all instructions provided by your study coordinator for the operation of this investigational software.

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

Daily treatments with AKL-T01 last approximately 25 minutes, and it is recommended that they are completed without interruption. Try to ensure **25 minutes of uninterrupted time** to complete each daily treatment.

Minimize distractions during each AKL-T01 session. We recommend playing in a quiet room or using headphones, turning off other mobile devices and televisions, and, if using a personal mobile device, **turning off device reminders and notifications**.

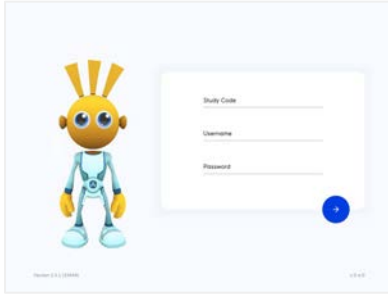
Find a comfortable place where you can use AKL-T01 daily, ideally **seated in an upright position** in a **well-lit room with minimal glare on the device**.

Adjust the field of view and avoid using the device too close to your eyes. It is recommended to turn on the blue light filter on the device if administered during nighttime, but also recommended not to play right before bedtime to avoid risk of potential reduction in sleep quality.

Give the treatment your **full attention and effort** to help ensure best treatment results. By design, AKL-T01 is **challenging** (and sometimes frustrating) to play.

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

Operating Instructions



LAUNCH & LOGIN

Tap the AKL-T01 application icon on the mobile device to start.

Log in using the login credentials provided by your study coordinator.



MANIPULATING THE DEVICE

AKL-T01 features 3 primary actions: 1) **Steering**, 2) **Tapping**, and 3) **Steering and Tapping** at the same time (Multitasking).

To **Steer**, tilt the mobile device left and right. Hold the mobile device with both hands to help with the steering and tapping.

To **Tap** on a target, touch the right half of the mobile device screen using your thumb. This touch can be anywhere on the right side of the screen – it does not have to be directly on the flying target or the "target" button.



In addition to the primary actions above, you will be able to unlock **Boosts** through the course of play. Equipped **Boosts** can be activated by tapping the left side of the screen and have a variety of effects in the racing experience.

Daily Treatment



When using AKL-T01, the goal is to successfully **Steer** your character through a course while driving over power zones, avoiding obstacles, or both, and **Tap** the right side of the screen to collect only the correct targets when they appear.



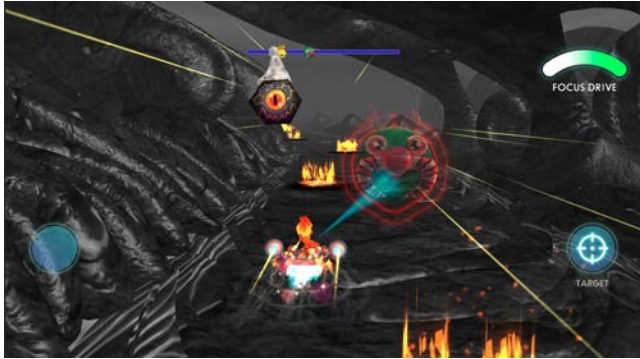
Each course completed from start to finish is an individual **Mission**. A daily treatment with AKL-T01 requires you to complete 6 to 8 game missions each day. There are many separate **Worlds** to unlock and explore as you progress through treatment.



AKL-T01 will display reminders if treatment is not played for 24 hours and when the treatment is soon to expire. Follow the study- specific treatment schedule provided by your study doctor.

Unlike an action video game, there is no way to "win" AKL-T01. The game continuously challenges you by adjusting the gameplay to maintain a consistent level of difficulty relative to how well you are playing the game. As long as you play consistently and trying your best, you are engaging with the game as intended.

Missions



During each mission, you will **Steer** your character through a course, moving through gates and/or avoiding obstacles, and **Tap** to collect targets when they appear. With successful tapping and steering, you can catch **Mystic Creatures** and earn rewards.

The hover pod's capture ray will automatically lock on when you get close to the **Mystic Creature**. If you remain locked on for a few seconds, you will capture the creature and earn a **Mystic Gem**. Mystic 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 creature and captures it, AKL-T01 has recognized that you have reached a new ability level in your play.

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

AKL-T01 was designed to, on average, take around 4 weeks to unlock all worlds, but actual speed of progression may vary across individuals. Independent of your progress, it is important that you engage regularly with the treatment. Follow the study-specific schedule recommended by your study doctor.

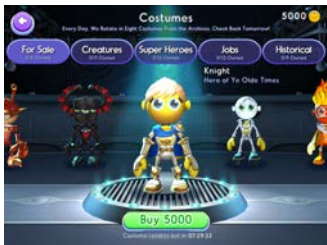
Once all worlds are unlocked, you can revisit your favorite world to play and beat previous scores. In addition, you can continue to complete Quests, unlock costumes, and upgrade your Space Farm.

Game User Interface



SUMMARY SCREEN

When you finish a mission, a summary screen will appear displaying the important goals, progress, and rewards achieved.



STORE

You can use the rewards you have earned to unlock desired costumes in the game store. As you progress you can choose costumes you like the best or collect them all!



GALAXY MAP

This 'main menu' provides a visual representation of overall progress through the many environments across the Galaxy of AKL-T01! From here, you can access the costume store, visit your **Space Farm**, view your quests, and choose an environment in your current 'world' to play next! In the bottom-center of this screen you can see how many missions you have left to play until your **Fuel Gauge** is empty.

Game User Interface (cont.)



FUEL GAUGE

The Fuel Gauge is an indicator of Missions remaining. After completing all missions, the Fuel Gauge will be empty and you will no longer be able to play until the next day. This makes sure AKL-T01 is used in a manner consistent with the intended treatment schedule and prevents overuse.



SPACE FARM

As you play, you will capture different kinds of **Mystic Creatures**. Captured creatures live in the **Space Farm** and each kind of creature gets its own special dwelling. These dwellings generate **Boosts** that you can use during gameplay. You can upgrade a **Mystic Creature's** dwelling by collecting more of that creature. Build better dwellings to get better **Boosts**!



BOOST EQUIP SCREEN

Prior to each **Pursuit Mission**, you will be able to equip a **Boost** to help during the race. There is a limit on how many boosts you can bring with you based on your **Player Level**, and you can only equip from your current inventory of **Boosts**. New **Boosts** are generated each day after the first mission!

Pausing and Exiting Treatment



PAUSE AND RESUME TREATMENT

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, so the use of this feature is not recommended during treatment for maximum engagement.



EXIT AND END TREATMENT

When a daily treatment is completed, the AKL-T01 application can be closed on your device.

The treatment will automatically become disabled after you complete a full treatment cycle specified in the study protocol.

AKL-T01 will display notifications when the treatment is soon to expire.

Mobile Device Security

DEVICE SECURITY RECOMMENDATIONS

AKL-T01 software incorporates state of the art security features in order to protect user data. If using an Akili-provided study device, then the device has already been preconfigured to maximize security. If using a personal mobile device, we recommend configuring your mobile device with the following settings to maximize security:

Configure the mobile device with a strong passcode, pincode, Face ID, or Touch ID. Configure the mobile device to automatically lock after a period of inactivity. Configure the mobile device with USB Restricted Mode enabled.

Configure the mobile device with two factor authentication enabled.

Configure the mobile device to show notifications only when the device is unlocked.

Only connect the device to secure wireless networks with a passcode and encryption.

Configure the mobile device backup with encryption enabled.

Keep the mobile device operating system and AKL-T01 application up to date with the latest available versions.

Do not jailbreak or root the device to maintain manufacturer security protections.

Compatible Devices

iOS DEVICE MINIMUM REQUIREMENTS

iOS version	13.0
Hardware	16 GB
Chip	1.3 Ghz dual-core with 64-bit architecture CPU
Memory size	2GB
Network Infrastructure	Wi-Fi

Some of the devices with the above minimum specifications are **iPad® Mini 4, iPhone® 7 & later models.**

NOTE: AKL-T01 is not currently available on Android OS.