



User Guide

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Sincrolab

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Sincrolab



MANUFACTURER

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Indications for use

SEA OF HEROES: NEW WORLD is a digital therapy indicated for improving cognitive functions in children aged 8 to 12 diagnosed with combined-type ADHD.

Expected clinical benefits for the patient: SEA OF HEROES: NEW WORLD showed improvements in neuropsychological (cognitive) functions of attention, inhibitory control, working memory, and cognitive flexibility, as well as in clinical symptoms of ADHD related to attention and behavior and overall executive functioning.

Digital therapy with SEA OF HEROES: NEW WORLD should be directed by a healthcare professional and should be considered for use as part of a therapeutic program that addresses the symptoms of the disorder as a whole.

SIDE EFFECTS

No serious adverse effects occurred. Of the 41 patients participating in the SEA OF HEROES: NEW WORLD clinical trial, only one experienced an adverse event related to headache (0.18%). This event led to discontinuation of device use, and the adverse effect was reported to be transient and not lasting or irreversible after discontinuation.

CAUTION

If the patient experiences frustration, emotional reaction, dizziness, nausea, headache, eye fatigue, or joint pain while playing Sea of Heroes: New World, stop treatment. If the problem persists, contact the patient's healthcare professional. If the patient experiences a seizure, stop treatment and contact the healthcare professional.

LIMITATIONS AND/OR CONTRAINDICATIONS

Sea of Heroes: New World is not suitable for patients with photosensitive epilepsy, color blindness, color vision deficiency, or physical limitations that restrict the use of a mobile device. Furthermore, it is not suitable for patients with functional illiteracy in reading and calculation skills. Parents should consult with the patient's healthcare professional if they have any questions or concerns.

WARNINGS

The application should be used exclusively by the patient. Use of the application by anyone other than the patient will limit the results of treatment. It is recommended that the application be used in an environment free from distractions and noise. When a treatment session is complete, the patient should ensure that the Sea of Heroes: New World application is closed on their device.

If the patient experiences serious damage that puts their life at risk due to the use of Sea of Heroes: New World, they should immediately contact the manufacturer and/or notify the competent authority of the Member State in which the patient is established (in Spain, the competent authority is the Spanish Medicines Agency).

Malfunction of the Sea of Heroes: New World product cannot affect patient safety.

Product description

SEA OF HEROES: NEW WORLD is a digital, non-pharmacological treatment administered through a serious game that has been shown to improve cognitive functions in children aged 8 to 12 with combined ADHD.

The treatment programmed into the game was designed to challenge the patient's control of the three main cognitive domains (attention, memory, and executive functions) during treatment sessions, which require concentration and flexibility to manage multiple tasks at the same time.

The SEA OF HEROES: NEW WORLD treatment consists of an application that can be used on mobile devices: mobile phone and/or tablet. (See section "Compatible devices")



SEA OF HEROES: NEW WORLD includes 14 games that the patient must play throughout the treatment. The recommended guideline is three 15-minute sessions per week, with a total of 12 sessions per month for three months. The first treatment session consists of a selection from among the 14 games, which will change throughout the treatment to address different cognitive functions. The results obtained in each treatment session are transmitted to an Adaptive Cognitive Management System (ACMS) which, using artificial intelligence algorithms, automatically adjusts the selection of games and their levels to continue the treatment.

SEA OF HEROES: NEW WORLD has been evaluated in 41 children with combined ADHD in a clinical study, where SEA OF HEROES: NEW WORLD was used for a 12-week treatment period (3 sessions per week for 15 minutes each session) and improvements were observed in the cognitive functions of attention, inhibitory control, working memory, and cognitive flexibility, as well as in the symptoms and impairments of combined ADHD related to attention, behavior, and overall executive functioning.

User manual for parents and caregivers

RECOMMENDATIONS BEFORE STARTING TREATMENT

It is recommended that you keep your mobile device password protected to reduce the risk of unauthorized access.

Ensure that your mobile device is fully charged before use and that the device's audio system is working properly and set to an appropriate level. Ensure that app notifications are enabled to receive alerts about new treatments and app updates.

HOW TO START TREATMENT

The SEA OF HEROES: NEW WORLD treatment consists of 14 games that a patient must play throughout the treatment. The recommended treatment is three 15-minute sessions per week, with a total of 12 sessions per month for three months.

It is recommended that each session be completed without interruption. Ensure that the patient has the necessary uninterrupted time to complete each treatment session. Minimize distractions for the patient during each treatment with SEA OF HEROES: NEW WORLD. For example, consider taking them to a room or using headphones and turning off other mobile devices and televisions.

Find a comfortable place where the patient can use SEA OF HEROES: NEW WORLD, ideally sitting upright in a well-lit room with minimal glare on the device.

It is best for the patient to adjust the field of view and avoid using the device too close to their eyes. It is recommended to turn on the blue light filter on the device if it is administered at night, but it is also recommended not to play just before bedtime to avoid the risk of a possible reduction in sleep quality.

HOW TO GET STARTED WITH SEA OF HEROES: NEW WORLD

Try incorporating SEA OF HEROES: NEW WORLD into your family's routine and make it a habit. You can use the game's reminders or any other tools to manage your family's schedule.

Encourage the patient to give their full attention and effort to each treatment with SEA OF HEROES: NEW WORLD to help ensure the best treatment results.

Talk regularly with the patient about their treatment experience and let them know that SEA OF HEROES: NEW WORLD is designed to be challenging to play.

During the treatment session, make sure the patient knows that it is okay to pause treatment for a few minutes if necessary, for example, to avoid fatigue or eye strain.

To ensure the effectiveness of the treatment, it is recommended that the proposed treatment session be completed on the same day. Each treatment session includes all the islands that appear on the screen when the application is launched. The patient will receive notifications on their device to run the treatment sessions on the pre-set days.

If the patient does not finish the assigned treatment session on the same day, they will continue with the same session the following day.

Download and launch

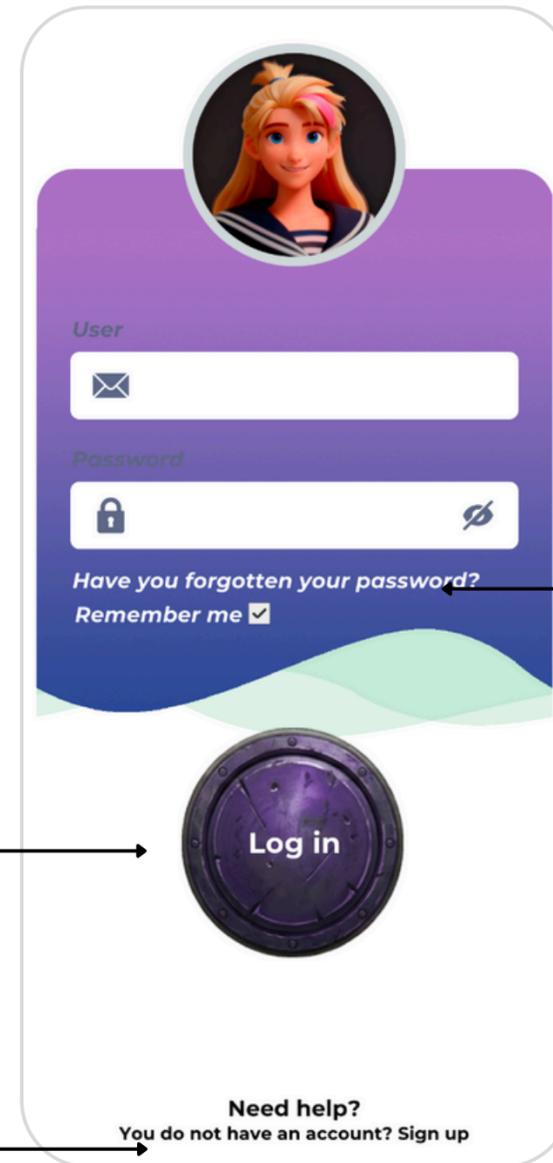
To begin treatment, search for and download “Sea of Heroes: New World” from your mobile device's app store, whether iOS or Android. Check with your therapist to ensure that your treatment device supports Sincrolab technology. Some device versions may be incompatible. Once the download is complete, find and tap the app icon on your mobile device. The app icon in stores looks similar to this:



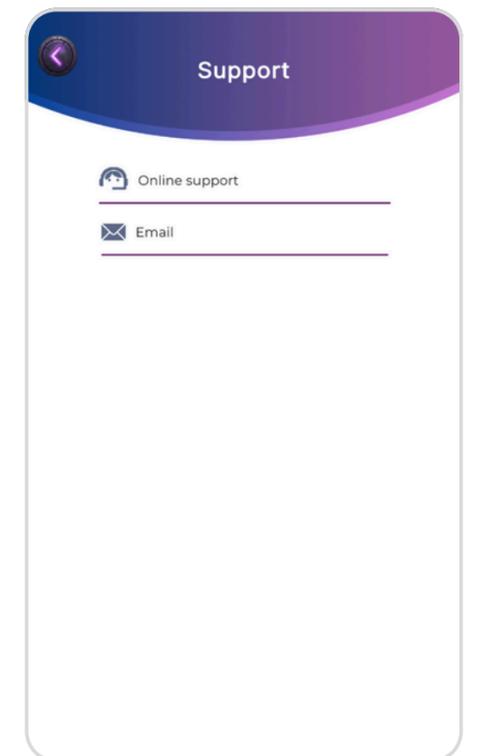
Follow the instructions on the screen to log in with the email address and password you previously created with your healthcare professional. When finished, select **“Log in.”**

If your session starts, the application is correctly installed. If not, select **“Need help?”** on the home screen. To get help from Sincrolab Support before logging in, select **“Need help?”** on the home page. By entering your email address, you can send a message to Sincrolab Support online and receive a response within 48 hours.

SEA OF HEROES: NEW WORLD will send automatic notifications, previously activated, to the device on treatment days.



If you cannot remember your password, select **“Forgot your password?”** and you will receive an email to update/change it. Alternatively, speak to your healthcare professional.



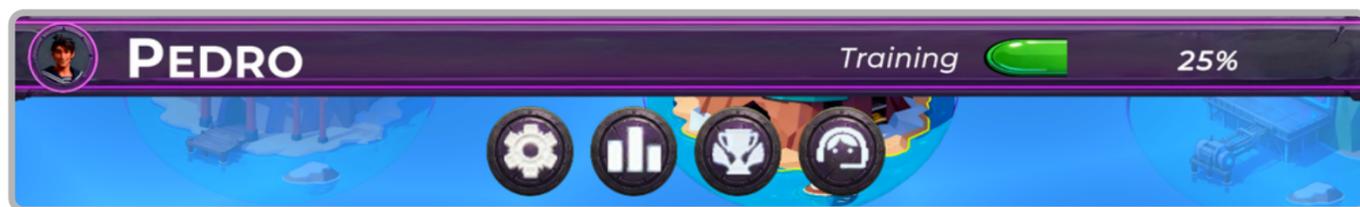
Login

When you select “Log in,” the map will appear with the islands selected in the treatment session to be worked on.



The island in the center of the map represents the “Home” island. When you select it, four icons appear (from left to right):

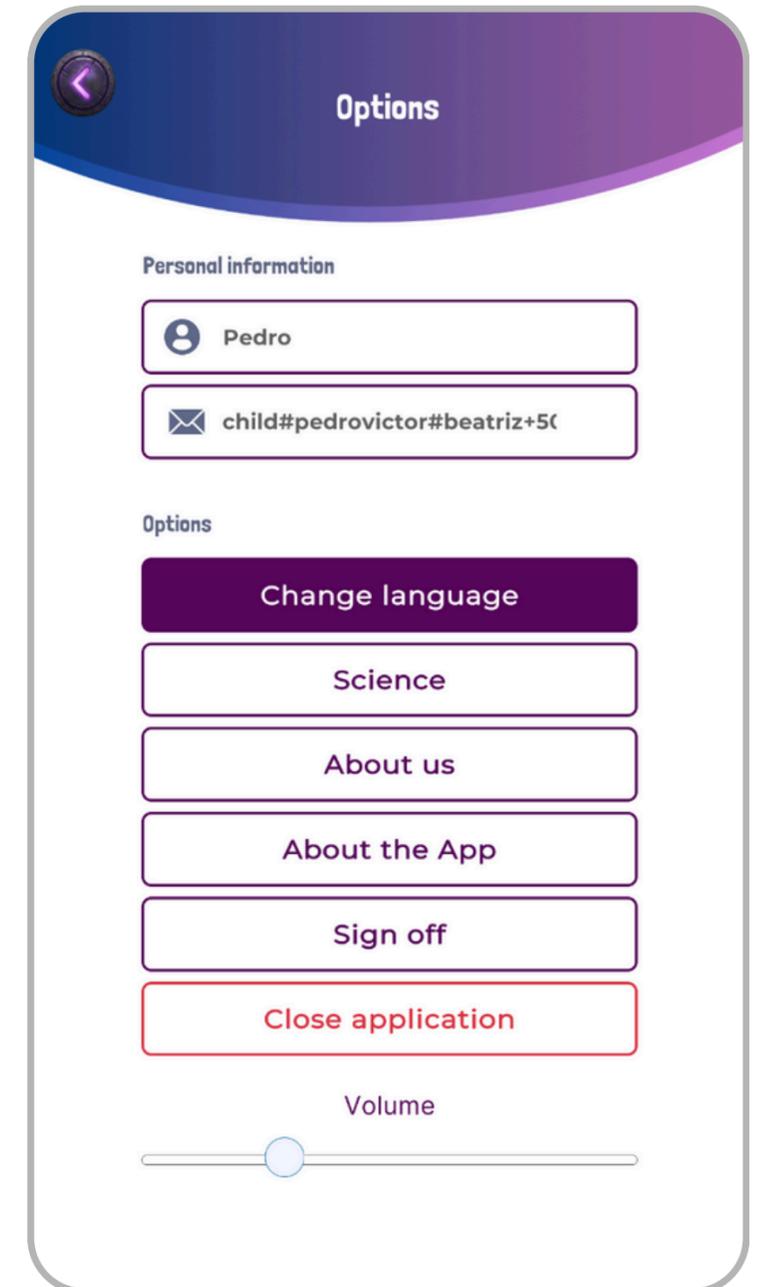
- Settings - Options
- Ranking
- Achievements
- Support



Settings - Options

Selecting the settings button will display your personal details (username and email address) and several options to choose from:

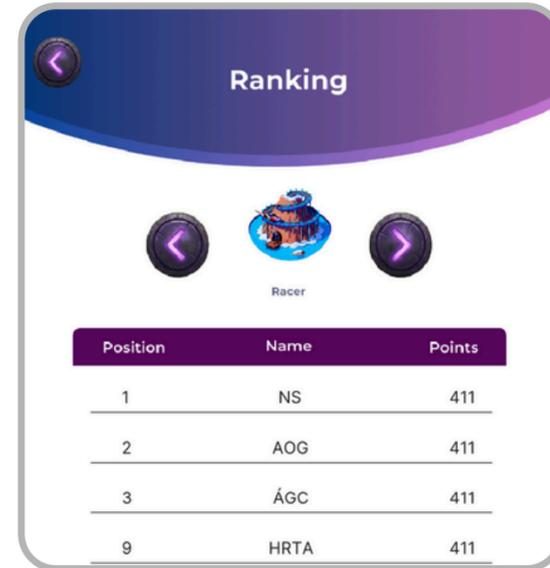
- **Change language:** you can select the most appropriate language from Spanish, English, Portuguese (from Portugal), Portuguese (from Brazil). Once you have made your choice, select “Select language”.
- **Science:** you can read about studies that have demonstrated the validity of SEA OF HEROES: NEW WORLD.
- **About us:** you can read about Sincrolab and its team.
- **Log out:** this will give you the option to log out of your user account. If you log out, you will need to enter your email address and password to log back in. We recommend that you do not log out during treatment sessions.



Login

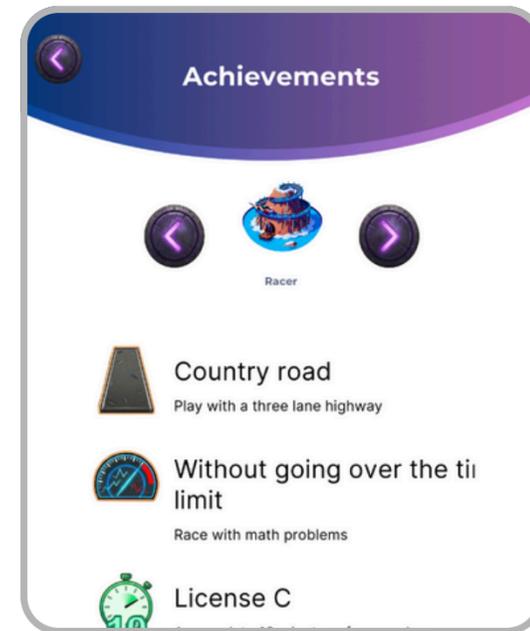
RANKING

Select the ranking button to see the points accumulated in each game and the ranking in relation to other players.



ACHIEVEMENTS

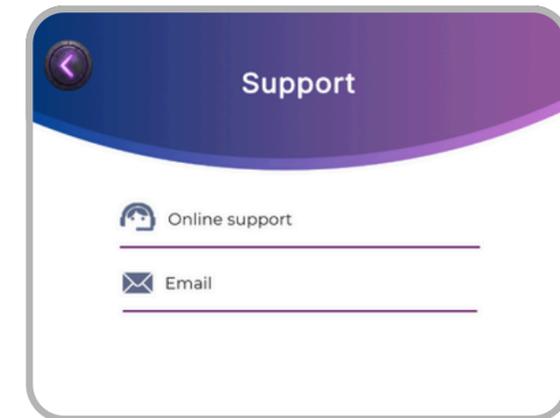
Select the achievements button to find out the achievements obtained in each game.



SUPPORT

By selecting the support button, you will be redirected to the Support page and will be able to choose between two support options:

- **Online support:** you will send a message directly to Sincrolab online support and you will be assisted within 48 hours.
- **Email:** you will be redirected to your email to send an email to soporte@sincrolab.es



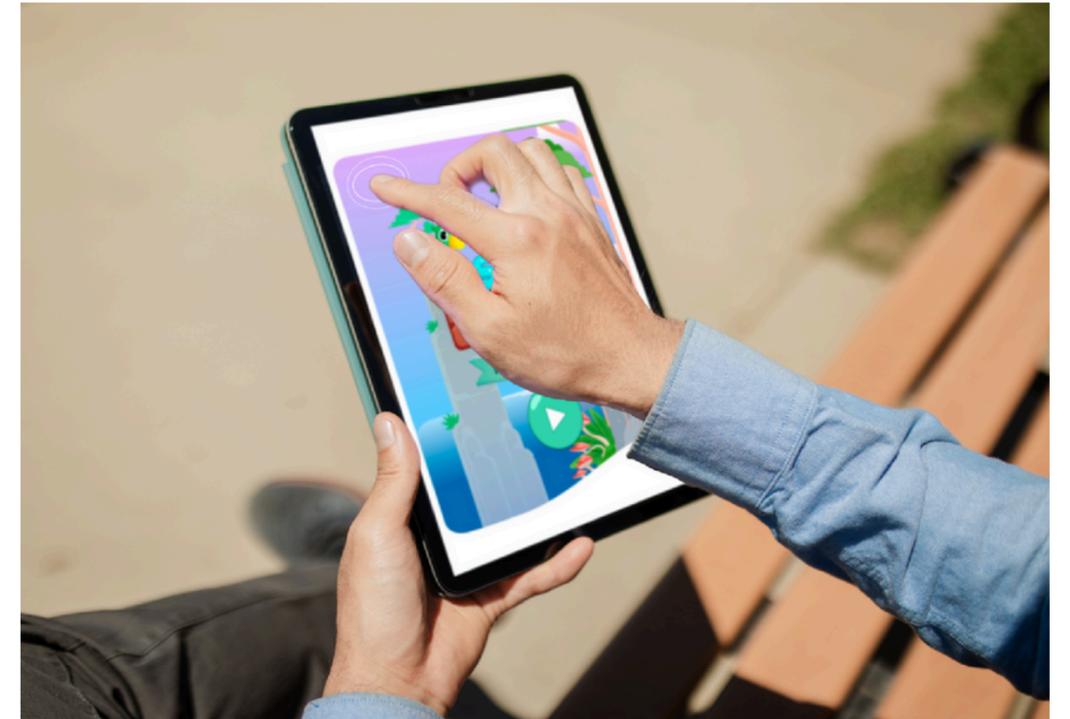
Device handling

To play, Sea of Heroes: New World has two main actions:

1) Tap; 2) Don't tap.

To press a target, the patient must touch the screen of the mobile device or tablet with their finger.

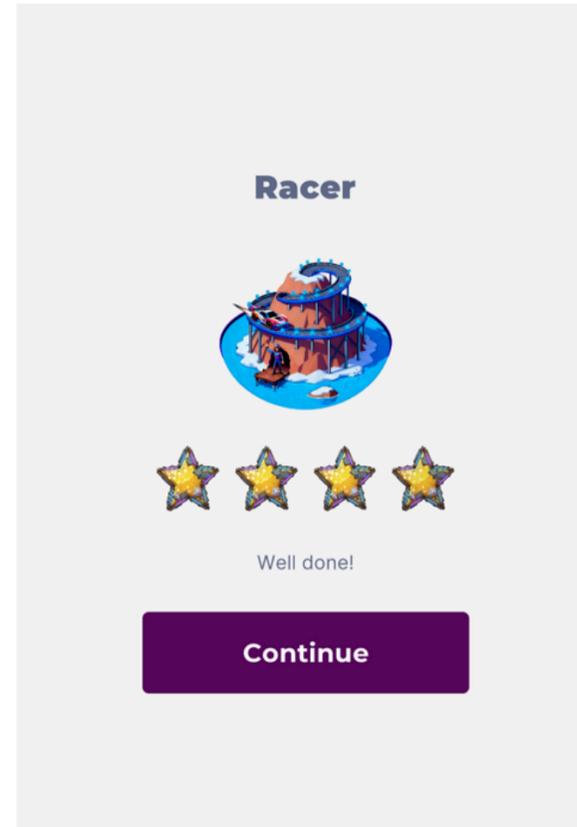
Encourage the patient to use both hands.



Treatment with Sea of Heroes: New World

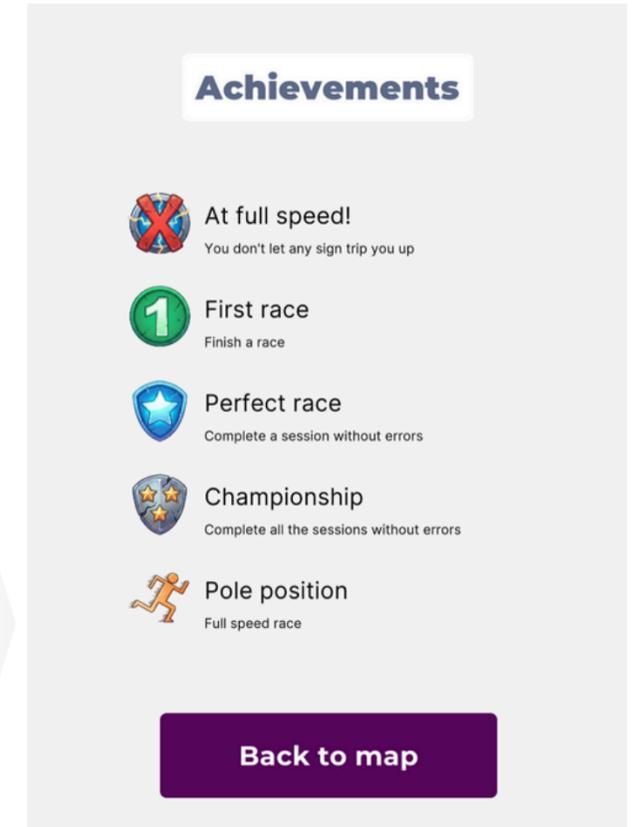


The objective of SEA OF HEROES: NEW WORLD is for the patient to successfully discover the islands that appear in each assigned treatment session. The number of islands that will appear depends on the time recommended by the healthcare professional and the patient's cognitive profile. You must select an island and follow the oral and written instructions provided by the application in order to train correctly. The patient will then play a trial game to practice the interactions required by the game.



Each time an island is completed, its image will fade and it will not be possible to select it again until the next treatment session in which it is assigned. Upon completing an island, the patient will receive a reward in the form of stars and a summary of their achievements.

The daily treatment session ends when all islands assigned for the session have been blurred and none remain to be discovered until the next day of treatment. This ensures that SEA OF HEROES: NEW WORLD is used consistently with the intended treatment program and prevents excessive use.



Unlike an action video game, there is no way to “win” SEA OF HEROES: NEW WORLD. The game's algorithm continues to challenge the patient at a specific and consistent level of difficulty throughout treatment sessions. The multitasking rules become more complex as treatment sessions progress based on the patient's performance. As long as the patient plays consistently as prescribed and tries their best, they are participating in treatment as intended.

Pause



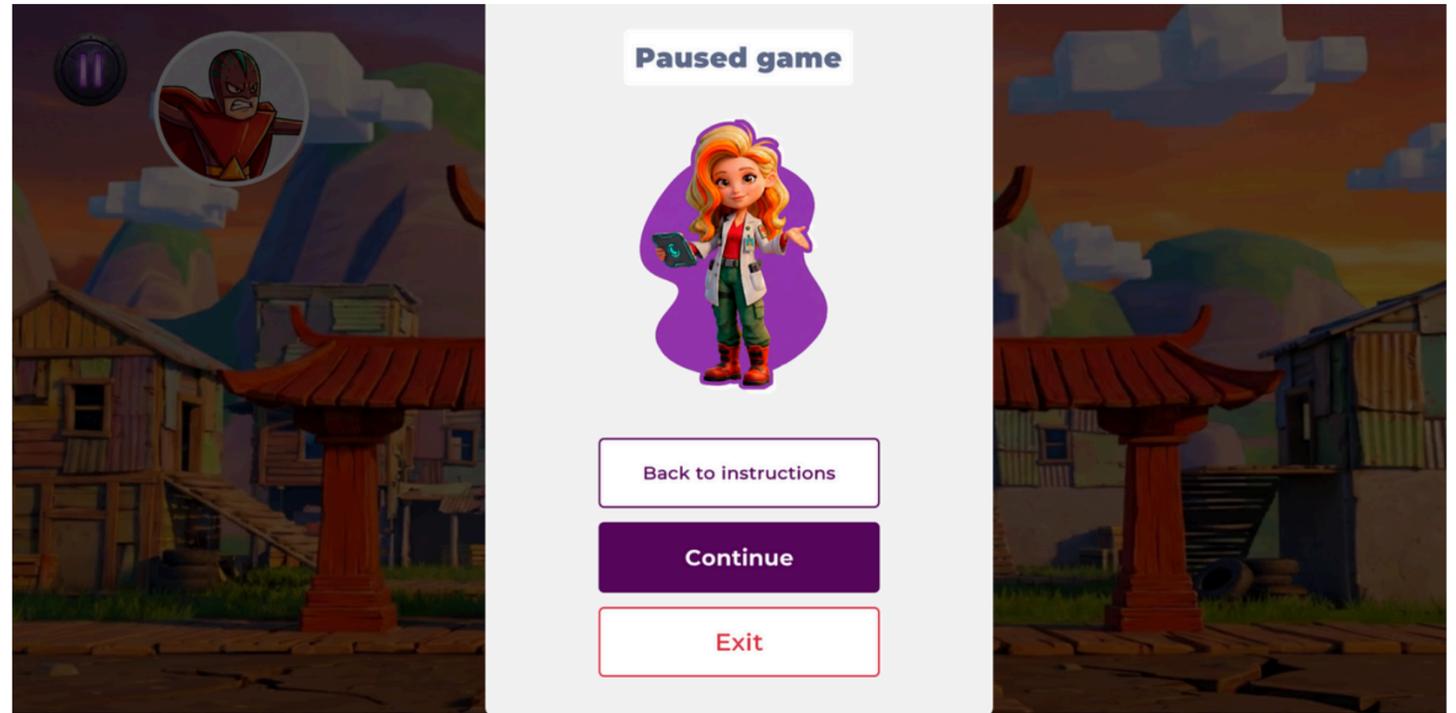
Each treatment session can be paused at any time by selecting the “Pause” button in the upper left corner of the screen.

Select the pause button to stop the treatment.

Leave and finish treatment

When a treatment session is complete, be sure to close the SEA OF HEROES: NEW WORLD app on your device. After you have completed the SEA OF HEROES: NEW WORLD treatment period recommended by your therapist, access to the treatment will be deactivated.

To remove/uninstall the application, follow the instructions provided by the manufacturer of your mobile device.



To return to treatment, select “continue.”

To reread/relisten to the instructions and play a practice game, select “Back to instructions.”

Security for mobile devices and tablets

DEVICE SAFETY RECOMMENDATIONS

The SEA OF HEROES: NEW WORLD software has been designed with the most advanced cybersecurity measures in mind. For your mobile device, the following measures are recommended to maximize overall cybersecurity:

- Mobile devices must be stored password/PIN protected to reduce the risk of unauthorized access.
- Mobile devices must be stored password/PIN protected to reduce the risk of unauthorized access.
- Avoid using untrusted WiFi networks.
- The operating system (OS) of mobile devices must be updated to the latest available version.
- Please contact the manufacturer of your mobile device if you have any questions or concerns regarding your device.



Application maintenance

The application must be updated to the latest version available. If you have automatic updates enabled, the application will update automatically. If you do not have automatic updates enabled, a message will appear allowing you to update it from the store.

Troubleshooting

Q. The SEA OF HEROES: NEW WORLD application does not start properly.

Ensure that your mobile device is connected to a Wi-Fi network or has mobile data. Ensure that your mobile device meets the minimum specifications listed in the compatible devices section. Ensure that there is sufficient free storage space on your device to download and use the app.

Q. My email address/password is not accepted by the SEA OF HEROES: NEW WORLD app.

- Please verify that you have entered the text correctly. Ensure that your mobile device is connected to a Wi-Fi network or has mobile data during login, account registration, or activation.

Q. The app does not show me the islands to play on.

- If you play close to midnight in your local time zone, the session may count toward the following day (for example, if you start playing at 11:50 p.m. and finish at 12:20 a.m.). This issue can be mitigated by completing the treatment session on the same calendar day.

Q. The application closes unexpectedly, stops responding, or does not open.

- Follow the instructions provided by your device manufacturer to force close the app (and then reopen it), restart your device, check for system updates, or reinstall the app, if necessary.

Compatible devices



The application can be downloaded to mobile devices with access to the Apple and/or Android stores.

The mobile device must be compatible with the stores where the app is available (Apple Store and Play Store).

For Android, the list of compatible devices is available at:

<https://support.google.com/googleplay/answer/1727131?hl=es-419>.

Huawei and Lenovo devices are not compatible with the application.

Tampered devices are incompatible with the application.

Check with your therapist to ensure that your treatment device supports Sincrolab technology. Some device versions may be incompatible.

MINIMUM IOS DEVICE REQUIREMENTS

iOS Versión	From iOS 12
Hardware <i>Storage</i>	16 GB - At least 1.5 GB free
Processor	Dual-core CPU, 1.8 GHz, 64-bit architecture
RAM	3 GB
Network Infrastructure	Wi-Fi or Mobile Data

MINIMUM ANDROID DEVICE REQUIREMENTS

Android Version	From Android 13
Hardware <i>Storage</i>	16 GB - At least 1.5 GB free
Processor	Dual-core CPU, 1.8 GHz, 64-bit architecture
RAM	3 GB
Network Infrastructure	Wi-Fi or Mobile Data

The platform uses secure and encrypted communications between the apps and the server. Specifically, it uses HTTPS encrypted connections. Access control is managed through authentication and authorization protocols, ensuring secure access to information. Therefore, it can connect to any Wi-Fi network or Mobile Data connection.

Sincrolab Support

Sincrolab Support is available for questions regarding the use of SEA OF HEROES: NEW WORLD, technical assistance, and requests for paper copies of this instruction manual.

Business hours: Monday through Friday from 9:00 a.m. to 6:00 p.m. (except national holidays)

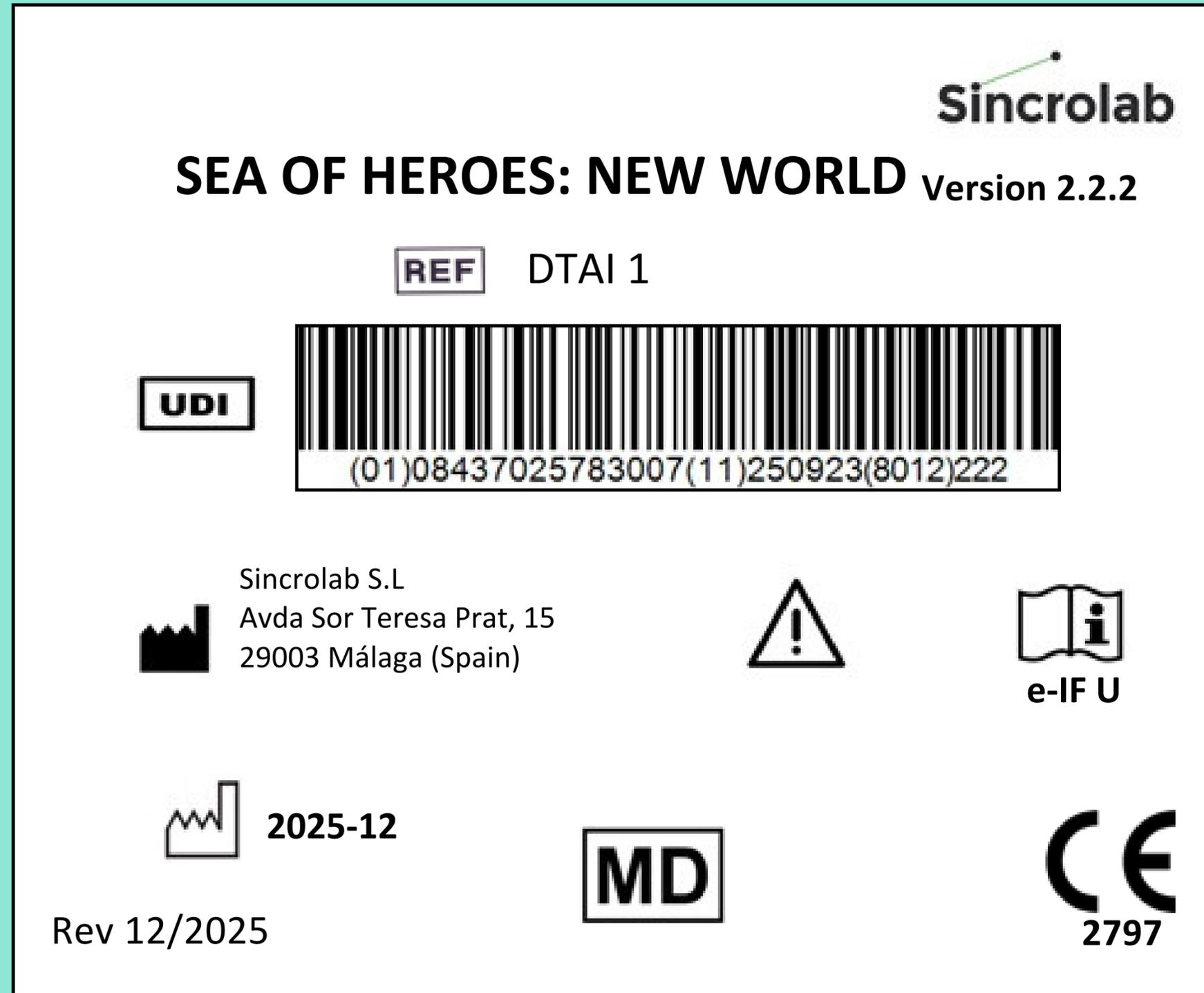
Website: www.sincrolab.es

Phone/Whatsapp: +34 622 216 481

The instructions for use are also available for download at <https://www.seaofheroes.com/static/usermanual/>



Label



Reference image: version, date, and UDI data will vary
depending on the update installed.

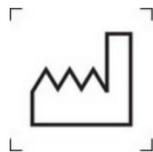
Symbols



CAUTION: Pay special attention to the following details



Manufacturer



Date of Manufacture



Catalog Number



e-IFU See the instructions for use on the website web <http://www.seaofheroes.com/static/usermanual/>



Unique Device Identifier



Medical Device



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