canvas Dx

Rx only

Caregiver App - User Guide

What is Canvas Dx™

Product Description

Canvas Dx is a prescription diagnostic aid to healthcare professionals (HCP) considering the diagnosis of Autism Spectrum Disorder (ASD) in patients 18 months through 72 months of age at risk for developmental delay. The patient's caregiver uses a smartphone application ("App") to fill out a caregiver questionnaire and to make video recordings of behavior at home, and then the physician fills out a medical questionnaire online. The results are made available to the physician.

Canvas Dx ("Device") uses an algorithm that collects information about the patient to determine whether the patient has Autism. Information is required from the caregiver, video analyst(s), and HCP. The caregiver will use the App to provide answers to questions and upload two videos of the patient's natural play, communication, and social behavior at home.

Once all information has been collected, Canvas Dx will provide its result to the HCP who will then use the output of the Canvas Dx to aid in the diagnosis of the patient (See Table 1).

Canvas Dx Device Output	**Output Meaning**
Positive for autism	The patient has autism Spectrum Disorder if the healthcare professional confirms the clinical presentation of the patient is consistent with and meets diagnostic criteria for autism.
Negative for autism	The patient does NOT have autism if the healthcare professional confirms the clinical presentation of the patient is consistent with ruling out autism and does NOT meet diagnostic criteria for autism. A negative result does not necessarily mean that the patient will not develop autism in the future and continued monitoring or evaluation for non-autism conditions may be warranted.
Indeterminate for autism	The available information does not allow the algorithm to render a reliable result. This does not mean that the patient either has or does not have autism.

Table 1. Outputs of Algorithm

Indications for Use

Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder (ASD) for patients ages 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider.

The device is not intended for use as a stand-alone diagnostic device but as an adjunct to the diagnostic process.

The device is for prescription use only (Rx only).

Contraindications

There are no contraindications to using Canvas Dx.

Precautions, Warnings

The Device is intended for use by healthcare professionals trained and qualified to interpret the results of a behavioral assessment examination and to diagnose autism.

The Device is intended for use in conjunction with patient history, clinical observations, and other clinical evidence the HCP determines are necessary before making clinical decisions. For instance, additional standardized testing may be sought to confirm the Device output, especially when the Device result is not Positive or Negative for autism.

Canvas Dx is intended for patients with caregivers who have functional English capability (8th grade reading level or above) and have access to a compatible smartphone with an internet connection in the home environment.

The Device may give unreliable results if used in patients with other conditions that would have excluded them from the clinical study. Among those conditions are the following:

- Suspected auditory or visual hallucinations or with prior diagnosis of childhood onset schizophrenia
- Known deafness or blindness
- Known physical impairment affecting their ability to use their hands
- Major dysmorphic features or prenatal exposure to teratogens such as fetal alcohol syndrome
- History or diagnosis of genetic conditions (such as Rett syndrome or Fragile X)
- Microcephaly
- History or prior diagnosis of epilepsy or seizures

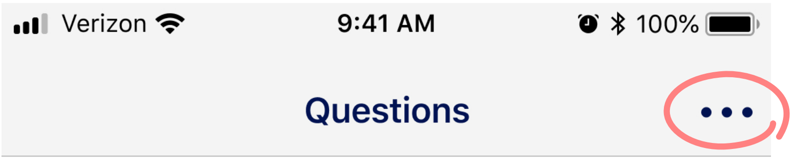
- History of or suspected neglect
- History of brain defect injury or insult requiring interventions such as surgery or chronic medication

The Device evaluation should be completed within 60 days of the time it is prescribed because neurodevelopmental milestones change rapidly in the indicated age group.

Instructions for Use

This user guide will instruct you on how to use the Canvas Dx App.

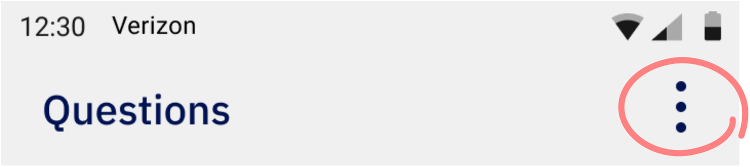
To access this user guide in the App, select the menu icon ⋮ in the top right in the navigation bar.



Verizon 9:41 AM 100%

Questions

iOS



12:30 Verizon

Questions

Android

•••

Figure 1. Access the User Guide

Minimum Technical Requirements

Mobile Device Operating System	iOS 15 or 16 Android 12 or 13 (excluding Android Go)
Mobile Device Storage	600 MB free
Mobile Device Camera	Back facing
Network	Wi-Fi access

The Canvas Dx caregiver app is compatible with the most recent and previous version of iOS and Android operating systems. Please be sure your mobile device is running an Operating System (OS) version matching those above. If not, please take time to update to the most recent version. The App was running on iOS 12 and 13, as well as Android 9 and 10 operating systems during clinical studies.

Be sure your phone is connected to the internet. App works best over Wi-Fi.

Cybersecurity

For your mobile device, the measures below are recommended to manage cybersecurity-related risks when using the Device:

Set a passcode or pin code on your mobile device to reduce the risk of unauthorized access. Review the security settings of your mobile device.

The Canvas Dx App is password protected to reduce the risk of unauthorized access. Use a unique password that is at least 8 characters long. For security reasons, please do not share your password with anyone.

The mobile device should be in automatic lock mode after a period of inactivity.

Please log out of the Canvas Dx App before you let someone else use your mobile device. The Canvas Dx App will log you out automatically after 1 minute of inactivity.

Avoid using untrusted Wi-Fi networks.

Keep your mobile device operating system (OS) and Canvas Dx App updated to the latest version. Software updates and patches will be provided as needed to assure the continued safety and effectiveness of Canvas Dx.

Mobile device should not be jailbroken to maintain device manufacturer restrictions.

Getting Started

Download the Canvas Dx App from the App Store for iOS or Google Play Store for Android. Be sure your mobile device operating system (OS) and Canvas Dx App are updated to the latest version.

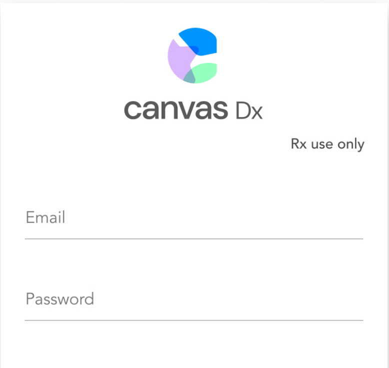
Launch the App by selecting the Canvas Dx icon.

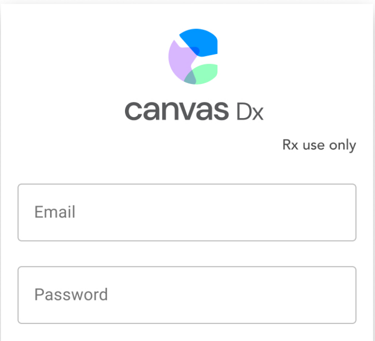
Once the prescription for the Device has been filled, you will be able to access the App to complete the caregiver questionnaire and upload the requested videos.

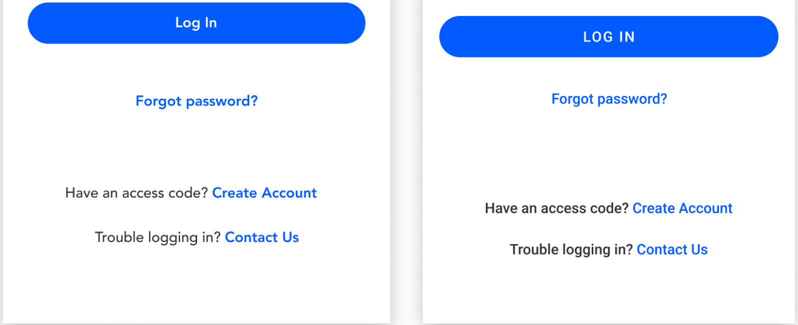
Enter the Access code you receive for Canvas Dx. Next, set and confirm a password. Choose a password that is at least 8 characters.

If you forgot your password, select the "**Forgot password?**" link on the login screen.

If you have problems logging in, select the "**Contact Us**" link on the login screen (See Figure 2).







Have an access code? Create Account

Trouble logging in? Contact Us

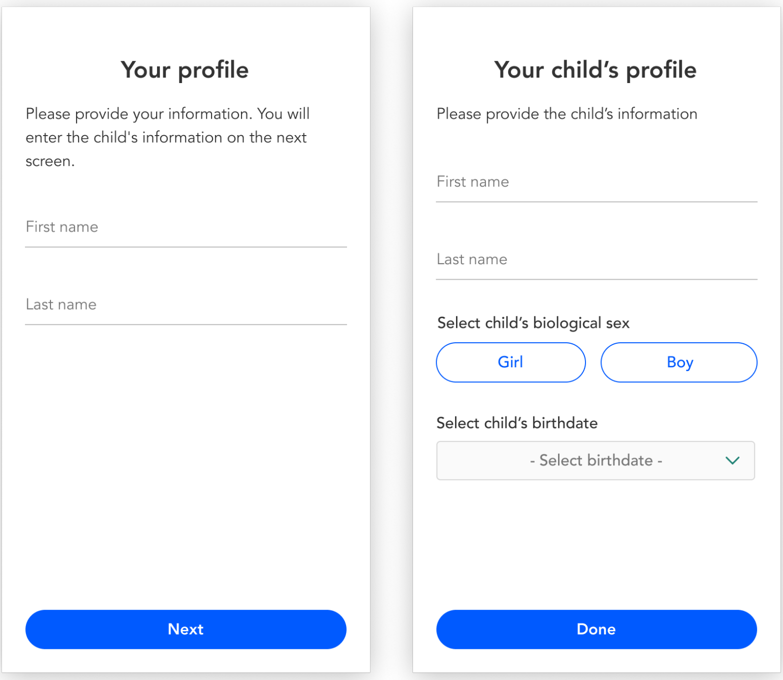
Have an access code? Create Account

Trouble logging in? Contact Us

iOS Android

Figure 2. App Login Screen

You may be asked to enter your first and last name as well as the child's information (See Figure 3).



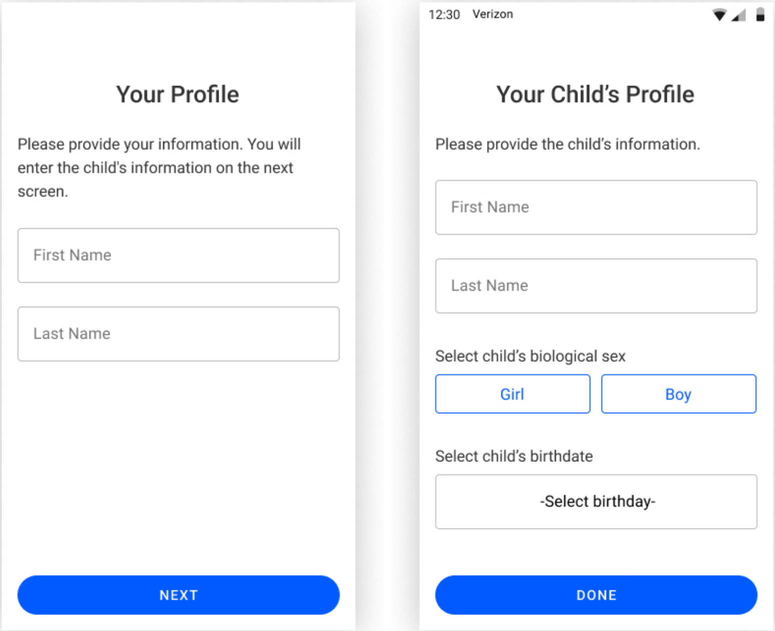
Please provide your information. You will enter the child's information on the next screen.

Please provide the child's information

Select child's biological sex

Select child's birthdate

iOS



Please provide your information. You will enter the child's information on the next screen.

Please provide the child's information.

Select child's biological sex

Select child's birthdate

Android

Figure 3. Profile Screens

Language

The Canvas Dx App will use the preferred language set in your phone's settings. If the preferred language is not supported by Canvas Dx, the default language used by Canvas Dx will be English. Go to your device settings to change the language used by Canvas Dx.

For the iOS User Guide: https://support.apple.com/guide/iphone/change-the-language-and-region-iphce20717a3/ios

For the Android User Guide: https://support.google.com/android/answer/12395118?hl=en

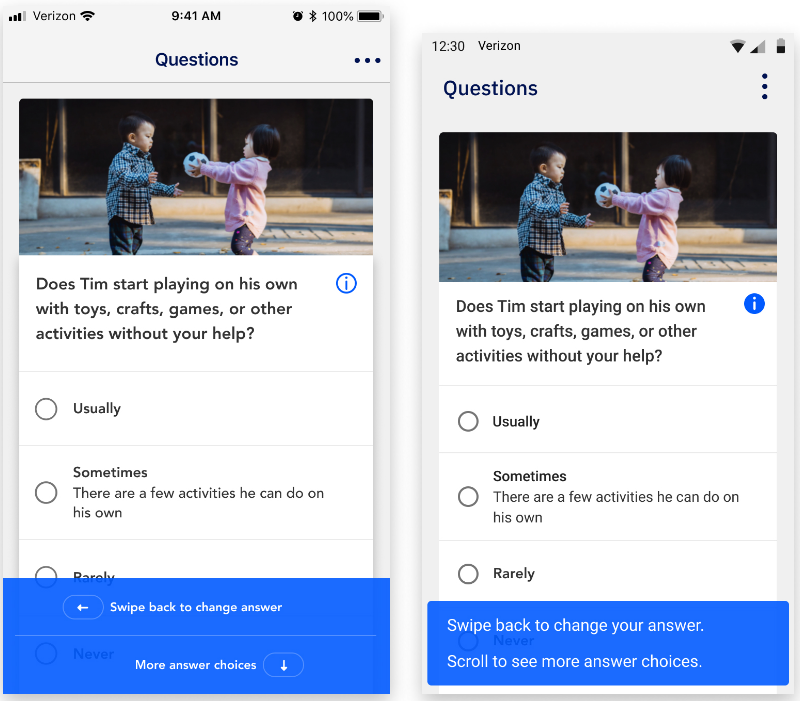
Answer the Autism Assessment

Questions

After logging in, you will see the autism assessment questions along with their answer choices. If you would like additional clarification, you may select the ⓘ icon. There is an ⓘ icon for each question.

For each question that is presented, select the response that is most appropriate for the child.

You will be notified if there are additional answer choices for a question that are off-screen. Before completing the assessment, you may swipe back to change your answer to any previous question. To return to the current unanswered question, swipe forward (See Figure 4).



Does Tim start playing on his own with toys, crafts, games, or other activities without your help? ⓘ

○ Usually

○ Sometimes
There are a few activities he can do on his own

○ Rarely

○ Never

← Swipe back to change answer

More answer choices ↓

Swipe back to change your answer.

Scroll to see more answer choices.

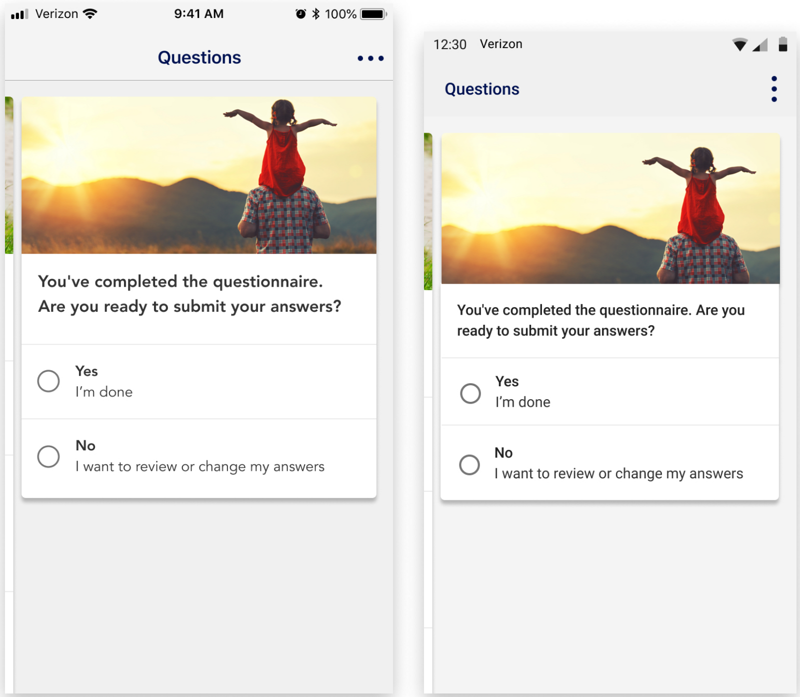
iOS

Android

Figure 4. Additional Answer Choices Message.
Option to Change Answers.

After you have completed all of the questions, you will be asked to confirm if you are ready to submit your responses (See Figure 5).

WARNING: You will not be able to change any responses after you submit.



You've completed the questionnaire. Are you ready to submit your answers?

○ Yes
I'm done

○ No
I want to review or change my answers

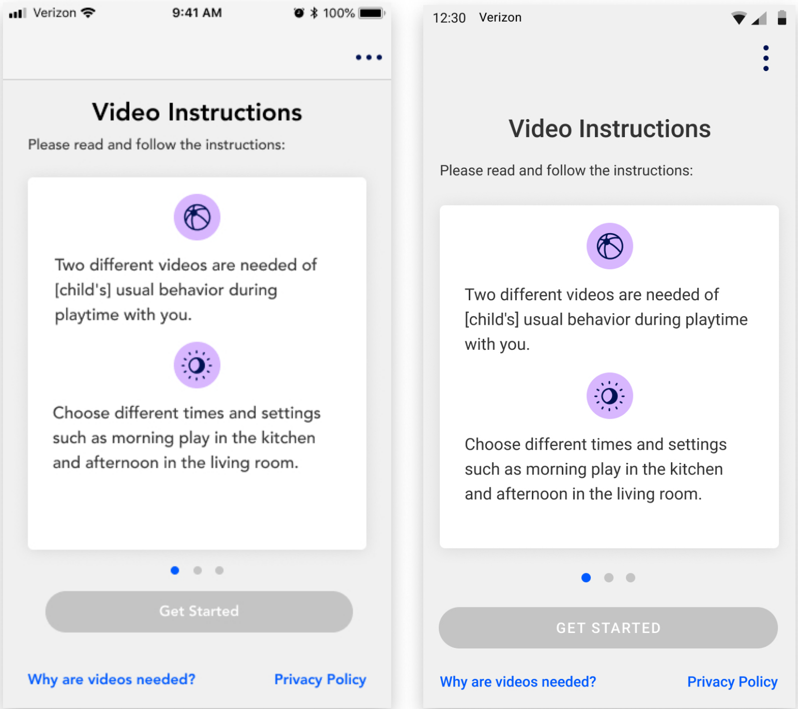
iOS

Android

Figure 5. Final Question

Submit Videos

After completing the autism assessment questions, you will be required to submit two (2) videos of the child's natural play at home with toys and other people. A link to Cognoa's Privacy Policy can be found in this section (See Figure 6).



Video Instructions

Please read and follow the instructions:

Two different videos are needed of [child's] usual behavior during playtime with you.

Choose different times and settings such as morning play in the kitchen and afternoon in the living room.

Video Instructions

Please read and follow the instructions:

Two different videos are needed of [child's] usual behavior during playtime with you.

Choose different times and settings such as morning play in the kitchen and afternoon in the living room.

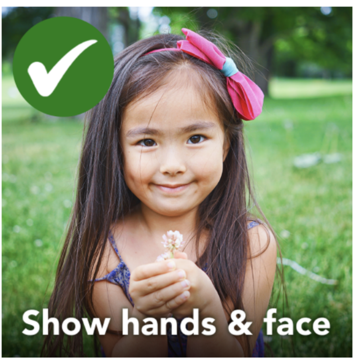
iOS Android

Figure 6. Video Instructions

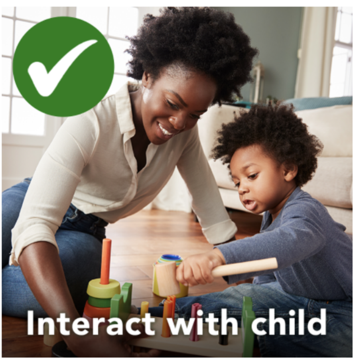
Videos allow Cognoa's childhood development experts to look at and understand the child's natural behavior. When paired with the questions you answered, videos provide a more accurate picture of the child's development. Therefore, it is important to provide videos that are representative of the child's typical day-to-day behavior. Avoid filming or using videos of the child during periods when they are sick, tired, hungry, starting a new medication or otherwise disrupted from their typical daily activities and general health.

Videos should be at least 1 minute 30 seconds and no longer than 5 minutes. You will be unable to upload and submit videos that are less than 1 minute 30 seconds long or longer than 5 minutes.

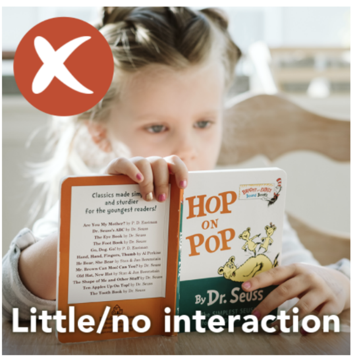
Tips for a good video:



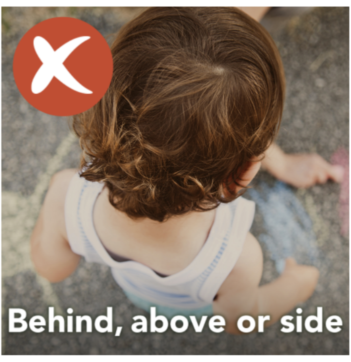
Do: Film with a clear view of your child's hands and facial expressions.



Do: Interact, play, and talk with the child.



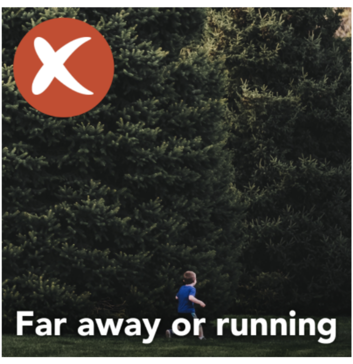
Don't: Submit a video



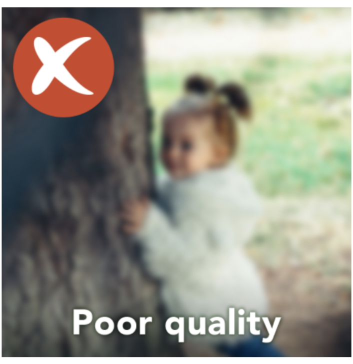
Don't: Film the child

with little or no interaction from your child.

from behind, above, or the side.



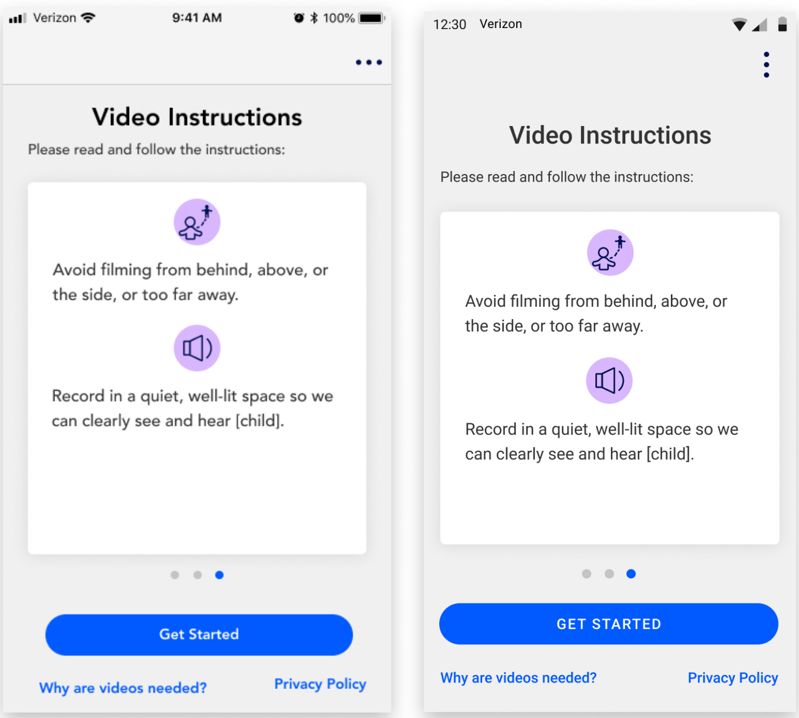
Don't: Submit a video with your child too far away or running around.



Don't: Submit poor recordings. Avoid background noise (e.g., TV), poor lighting (too bright or too dark), blur, shaking, and obstructed views.

- Two different videos (including audio) of the child's usual behavior during playtime are required.
- You may be in the video with the child if you choose to be.
- Choose different times and settings such as morning playtime in the kitchen and afternoon playtime in the living room.
- Videos should be at least 1 minute 30 seconds and no longer than 5 minutes.
- Videos should show the front of the child for at least 30 seconds.
- Videos may be recorded either vertically or horizontally (portrait or landscape), but vertical format is preferred.
- Show a clear view of the child's hands and facial expressions.
- Talk, interact, and play with the child.
- Avoid filming from behind, above, or the side, or too far away.
- Record in a quiet, well-lit space so we can clearly see and hear the child.

Select Get Started to advance to the next screen (See Figure 7).



Video Instructions

Please read and follow the instructions:

Avoid filming from behind, above, or the side, or too far away.

Record in a quiet, well-lit space so we can clearly see and hear [child].

Video Instructions

Please read and follow the instructions:

Avoid filming from behind, above, or the side, or too far away.

Record in a quiet, well-lit space so we can clearly see and hear [child].

iOS

Android

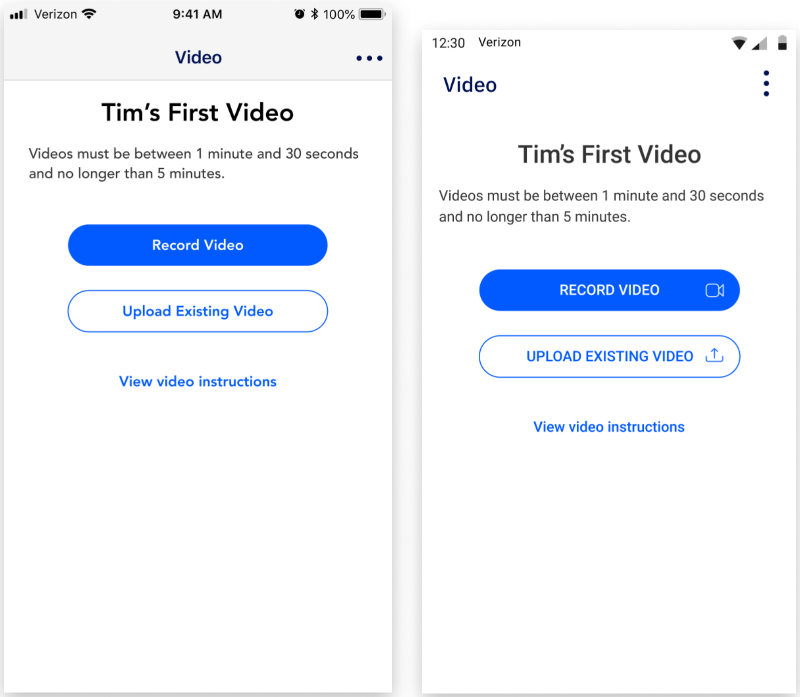
Figure 7. Get Started

It is important to ensure the following:

Videos are of the correct child. Review previously recorded videos or watch what you are recording on your device.

Whenever possible, the video should only include the child who is to be assessed. If there are multiple children, the analyst may not be able to confirm which child needs to be assessed. In these situations, you will be required to submit new videos.

You can either choose to record a video directly within the App or choose to use an existing video (See Figure 8).



Tim's First Video

Videos must be between 1 minute and 30 seconds and no longer than 5 minutes.

Tim's First Video

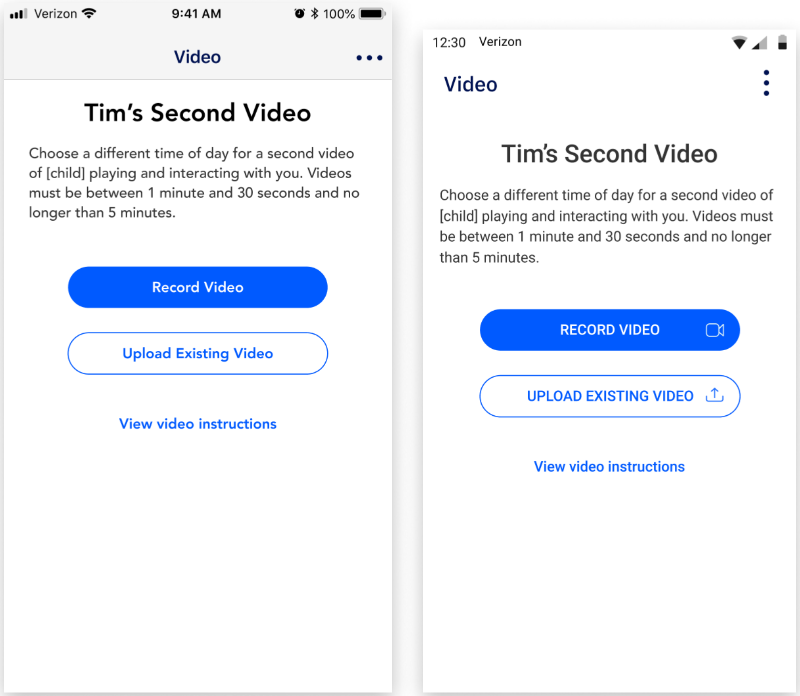
Videos must be between 1 minute and 30 seconds and no longer than 5 minutes.

iOS

Android

Figure 8. First Video

Figure 9 shows the screen to record the second video and/or choose a different video to upload.



Tim's Second Video

Choose a different time of day for a second video of [child] playing and interacting with you. Videos must be between 1 minute and 30 seconds and no longer than 5 minutes.

Tim's Second Video

Choose a different time of day for a second video of [child] playing and interacting with you. Videos must be between 1 minute and 30 seconds and no longer than 5 minutes.

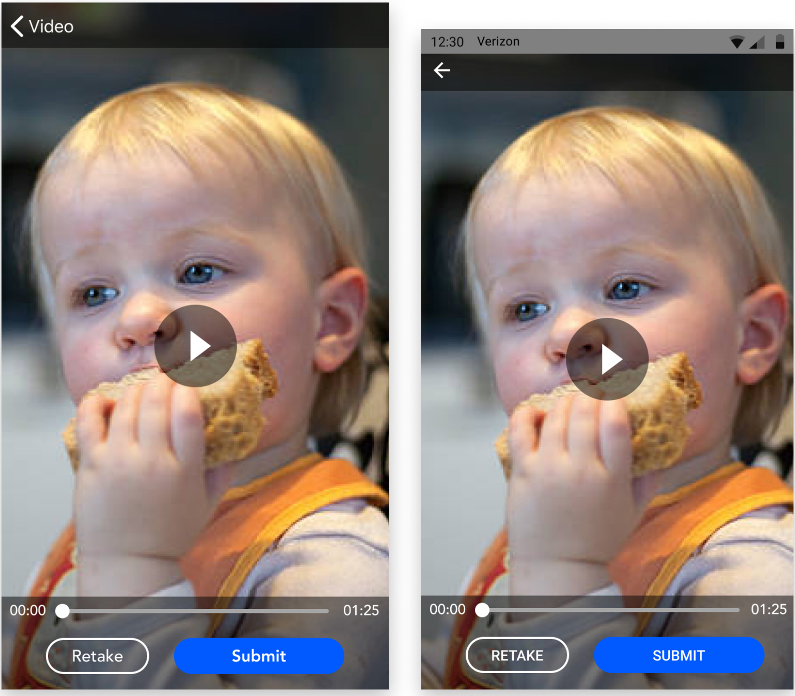
iOS

Android

Figure 9. Second Video

IMPORTANT:

After reviewing each video, you must select the "Submit" button (Figure 10). If you would like to cancel, select the Retake or Reselect button to record or select a new video.

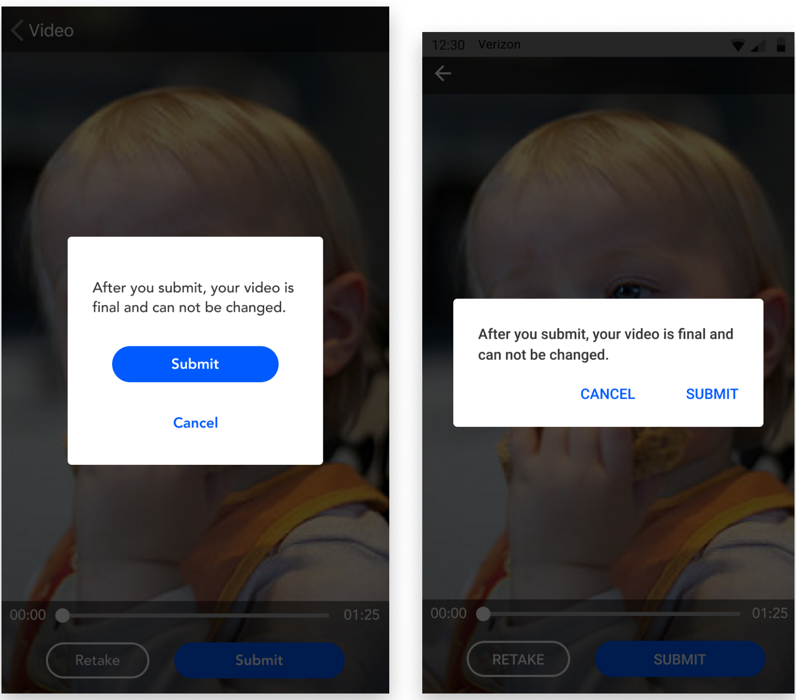


iOS

Android

Figure 10. Submit Video

After you submit, your video is final and cannot be changed (See Figure 11).


After you submit, your video is final and can not be changed.

After you submit, your video is final and can not be changed.

iOS

Android

Figure 11. Confirm Video Submission

IMPORTANT:

If the video(s) submitted are determined to be insufficient for analysis, you will receive a request to submit additional videos.

Once the videos have been submitted, your portion of the Canvas Dx is complete and you will be contacted about next steps.

Notifications

You will receive notifications letting you know what, if anything, is still needed for you to complete.

Troubleshooting

Contact Cognoa Support (information provided below) if you have any technical difficulties or questions regarding Device usage (See Table 2 and Table 3).

Email: support@cognoa.com
Phone: 1-866-4COGNOA

Problem	Solution
Unable to login or log out.	Try closing the App and re-opening to login or log out again. If the issue remains, contact Cognoa Support for further assistance.
Forgot password or need to reset password.	If you have forgotten your password, select the "Password Reset" link on the login screen, enter your email address and select the "Send Reset Password" link. An email will be sent to your email address with instructions on how to reset your password. If the issue remains, contact Cognoa Support for further assistance.
Do not understand autism assessment questions.	Contact Cognoa Support.
App is not working.	Be sure your mobile device operating system (OS) and the App are updated to the latest version. If the issue remains, contact Cognoa Support for further assistance.
Need a printed version of the User Guide.	Contact Cognoa Support for a printed copy of this guide.

Table 2. Troubleshooting – General Tips

Error Message	Potential Issue	How to Resolve
There is not enough available storage to download these items.	Not enough available memory/storage on the device.	Go to your phone's settings and follow the recommendations to manage storage on your device.
Oops! The access code is not valid.	Access code not found.	Contact Cognoa Support.
Email is already registered.	An account is already associated with the email address.	Contact Cognoa Support.
Must be a valid email address.	Email may not be entered correctly. Email entered may not be associated with an account.	Correct the email address. Contact Cognoa Support.
Password must be at least 8 characters.	Password does not meet the minimum requirements.	Select another password.
Cognoa experienced an internal error. Please contact us so that we can help.	Device system error.	Contact Cognoa Support.
Network unavailable. Connect device to network service and try again.	No network service.	Connect the device to Wi-Fi.
Session expired. Please login again.	You have been logged out.	Log back into the app.

Failed to save file for uploading. Try uploading your video again.	App was unable to save the video file to the device.	Try to upload the video again.
Please use a video with a duration of at least 1 minute 30 seconds.	Videos must be at least 1 minute 30 seconds long.	Record a new video, or select a video that is at least 1 30 seconds long.
Please use a video shorter than 5 minutes.	Videos must be shorter than 5 minutes.	Record a new video, or select a video that is shorter than 5 minutes.
Error uploading video. Please try uploading your video again. You can find your recorded video in the camera roll.	Loss of/spotty connectivity. Upload times out.	Ensure the device is connected to Wi-Fi and try to upload again.
There was an error recording the video. Please try again.	The camera view experienced an error while attempting to record. App was not given necessary permissions to record video.	Close and re-open App to try recording again. Go to device settings, Canvas Dx App and adjust permissions.
Not all permissions granted. Unable to proceed with video recording.	App was not given necessary permissions to record video.	Go to device settings, Canvas Dx App and adjust permissions.
Oops! Please check your email and password and try again.	On login screen, incorrect email and/or password.	Confirm you have the correct log-in information and try again.
Oops! Your request cannot be processed at this time. Please try again later.	System error.	Close the App and try again. If the issue persists, contact Cognoa Support.

Table 3. Troubleshooting – Error Messages

Clinical Study Results

The Cognoa ASD Diagnosis Aid was evaluated in a 425 patient, 14 site, clinical study. All study participants and assessors were blinded to the results of the Device. The results of the Device were compared to a reference diagnosis based on DSM-5 criteria, made by a specialist clinician and corroborated with independent review by a group of specialist clinicians.

The study population included female and male patients between the ages of 18 months through 72 months with a developmental concern.

The outcome measures of the study were:

- Positive Predictive Value (PPV): probability that a patient identified by the Device as Positive for ASD has ASD as determined by specialist clinicians, and
- Negative Predictive Value (NPV): probability that a patient identified by the Device as Negative for ASD does not have ASD as determined by specialist clinicians.

In the 32% of patients for which the Device provided a definitive answer, the Device demonstrated a:

- PPV of 81% (63/78 patients classified as Positive for ASD).
- NPV of 98% (56/57 patients classified as Negative for ASD).

When predictive ability is low, the Device returns a “No Result”. During the study, 68% (290 patients) received a No Result. Within this cohort, 20% were found to be positive for ASD, 71% had a non-ASD neurodevelopmental condition, and 9% were found to be neurotypical.

The study also measured the sensitivity (probability that a patient who specialist clinicians determine has ASD is identified by the Device as having ASD) and specificity (probability that a patient who truly does not have ASD is identified by the Device as not having ASD) of the Device.

At the conclusion of the study, the Device demonstrated a:

- sensitivity of 98%
- specificity of 79%

in patients for whom the Device rendered a diagnostic output.

Risks related to the study were minimal and no adverse events were reported during the study.

Name and Place of Business of Manufacturer

Cognoa, Inc.
2185 Park Blvd
Palo Alto, CA 94306
Website: https://www.cognoa.com
Email: support@cognoa.com
Phone: 1-866-4COGNOA

LBL-002 - Cognoa ASD Diagnosis Aid Instructions for Use, Rev. N
(2023-04-28)