canvas Dx™

by cognoa

*Rx only*

# Caregiver App User Guide

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# Canvas Dx Overview

Canvas Dx is an FDA-authorized prescription device that supports clinicians considering the diagnosis of Autism Spectrum Disorder (hereafter referred to as 'autism') in children 18 months through 72 months of age who are at risk for developmental delay. The child's caregiver uses a smartphone application ("App") to answer a questionnaire about the child and make video recordings of their natural behavior, while the clinician fills out a medical questionnaire online.

The Canvas Dx algorithm uses the collected information to produce an output (see Table 1). The clinician receives the Canvas Dx output and uses it, in conjunction with their clinical judgment, to help determine whether or not autism is present.

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# Canvas Dx: Device Output

Table 1: Canvas Dx Device Output

| Positive for autism |
| --- |
| The child has autism if the clinician confirms their clinical presentation is consistent with and meets diagnostic criteria. |
| **Negative for autism** |
| The child does NOT have autism if the clinician confirms the clinical presentation is consistent with ruling out autism and does NOT meet diagnostic criteria for autism. A negative result does not necessarily mean that the child will not develop autism in the future and continued monitoring or evaluation for non-autism conditions may be warranted. |
| **Indeterminate** |
| The available information does not allow the algorithm to render a reliable result. This does not mean that the child either has or does not have autism. Depending on the child's clinical presentation, the clinician may choose to diagnose or rule out autism, or conduct additional evaluations before making a definitive diagnosis. |

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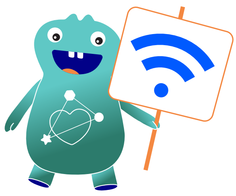
# Quick Guide: Instructions for Use

## Getting Started

You will receive a text and email message as soon as your child's clinician prescribes Canvas Dx. The message will give you instructions on how to get started. It will include a unique access code you will use to create an account.

Download the Canvas Dx App from the App Store for iOS or Google Play Store for Android.

Launch the App by selecting the Canvas Dx icon.



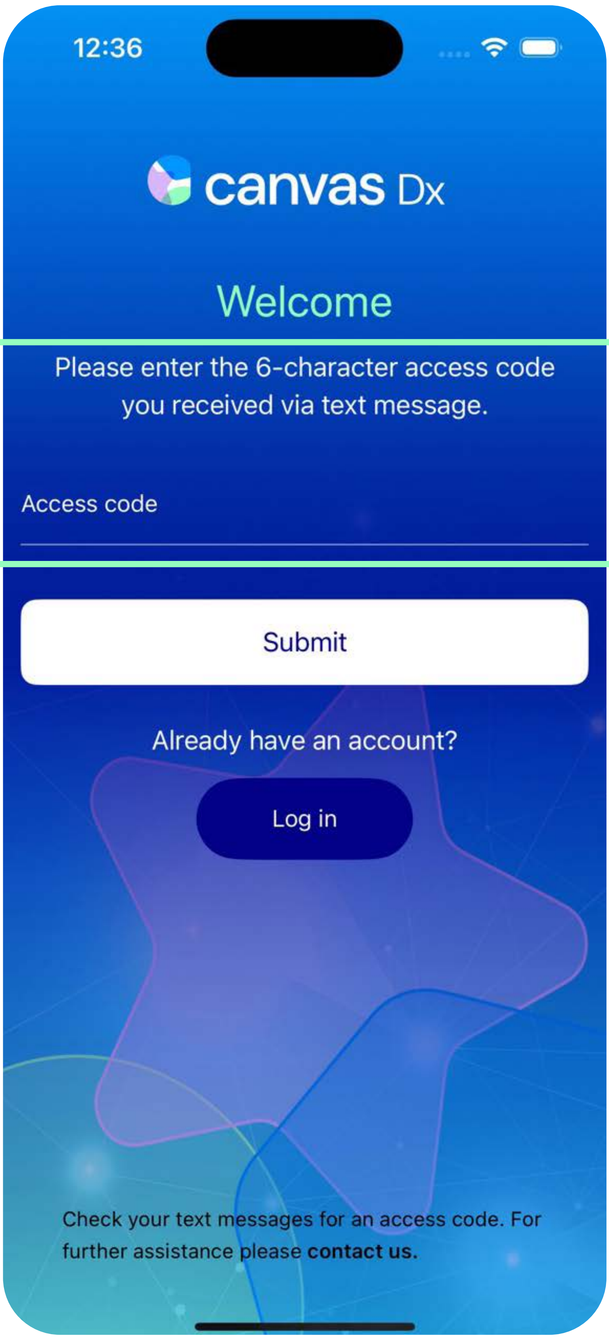
*Be sure your phone is connected to the internet. The app works best over Wi-Fi.*

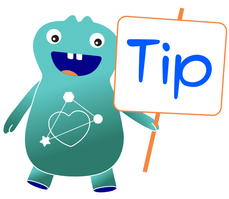
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# Account Set-up

Enter the **6-character access code** that was sent to you (see Figure 1).

**Figure 1: Access Code screen**



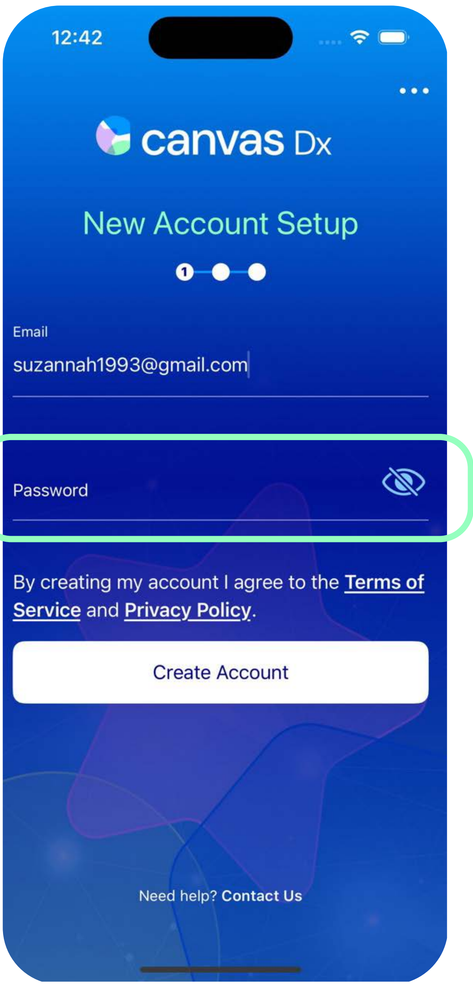

*Be sure your mobile device operating system is updated to the latest version.*

## Set-up your account by creating and entering a password (see Figure 2a & 2b).

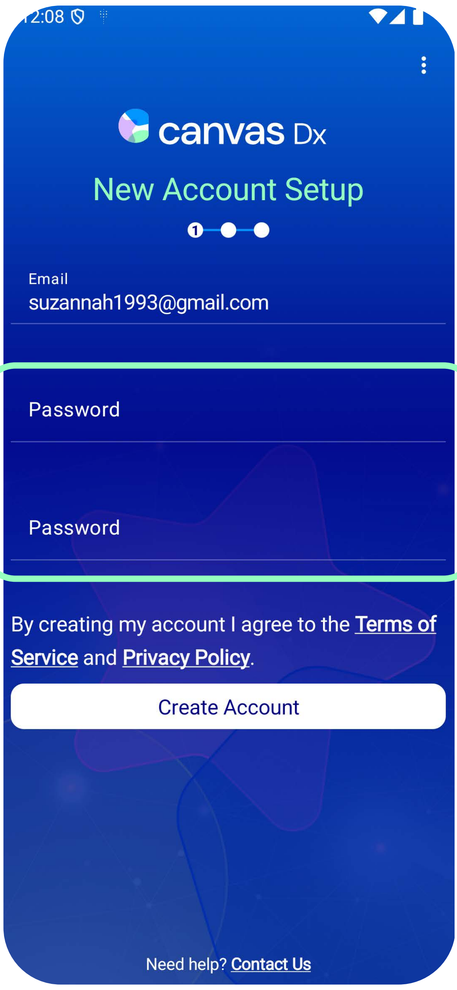
*Use at least 8 upper & lower case characters and 1 or more numbers. If you would like to use biometrics to login next time, you can activate this option by toggling on the biometrics switch. If you have not yet enabled biometrics on your phone, you will be prompted to go to settings to enable it.*

### Figure 2: Account set-up screen

#### Figure 2a: iOS



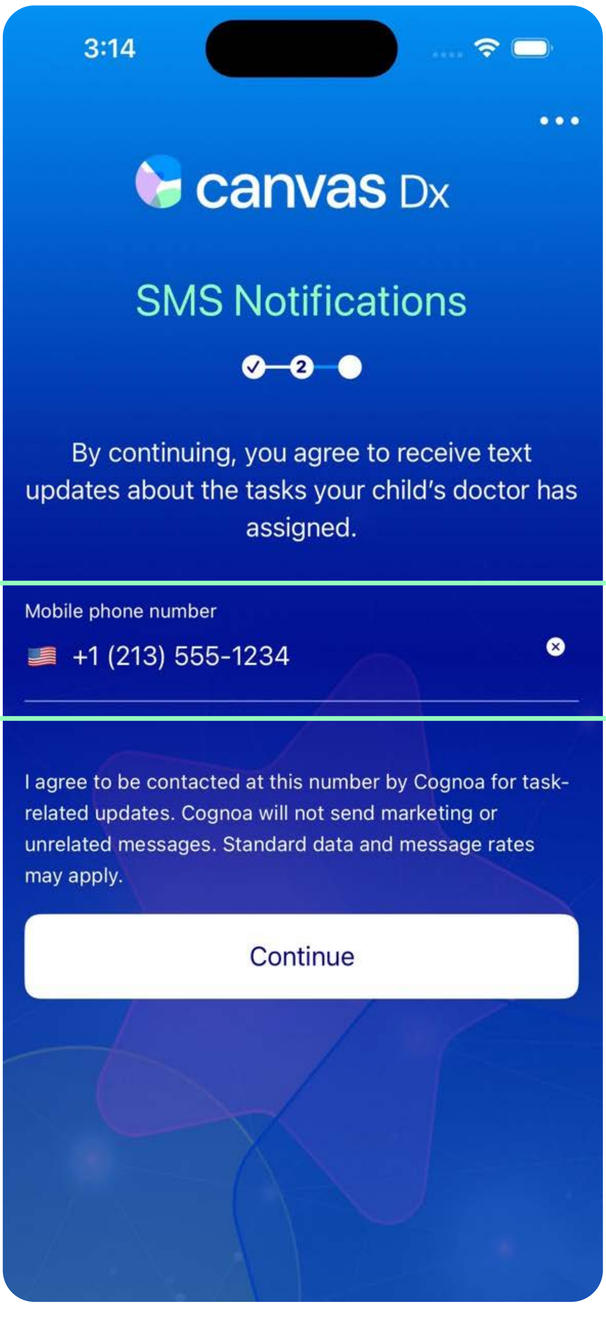

#### Figure 2a: Android



By continuing, you are opting in to SMS notifications (see Figure 3).

*You will only receive text updates related to the tasks your child's doctor has assigned. Opting in will not enroll you in any marketing messages.*

**Figure 3: SMS Notifications screen**




## You are now logged in.

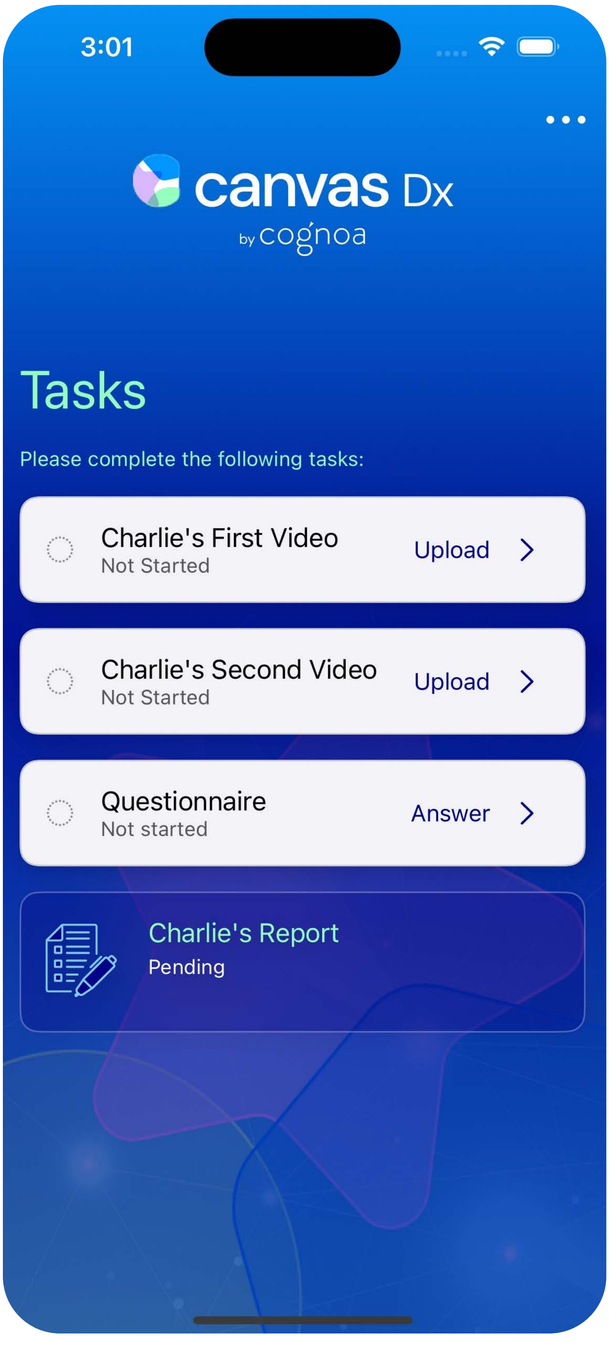
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# In-App Tasks

Watch the 50 second overview video about Canvas Dx. This video gives you information about what to expect from Canvas Dx.

Select **Continue** to be taken to your **Tasks Dashboard** (see Figure 4).

**Figure 4: Tasks Dashboard screen**



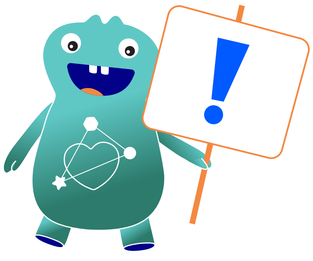
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# Answer Questions

The **Tasks Dashboard** lists all your tasks. You can complete these tasks in any order. A green check mark will appear next to each task once it is complete.

You will be asked to answer a few short multiple choice questions about the child's behavior and development. You must answer every question before you can submit the questionnaire.

If you are unsure what a question means, select the symbol for more information. After you have completed all of the questions, you will be asked to confirm if you are ready to submit your responses.



***WARNING:***

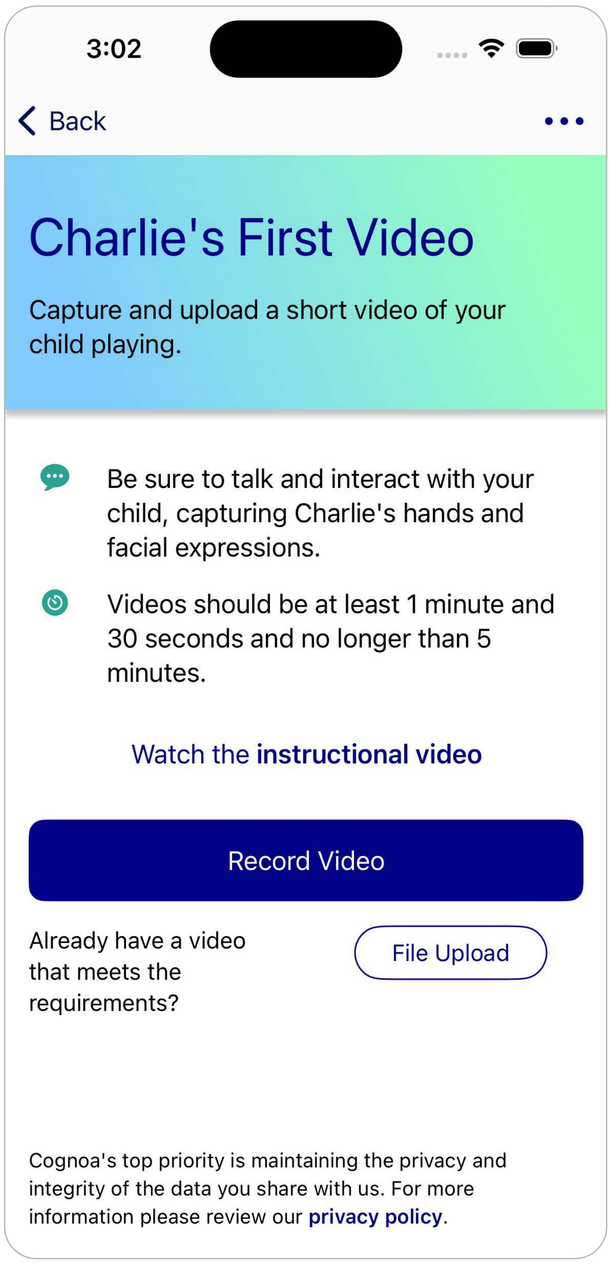
*You will not be able to change any responses after you submit.*

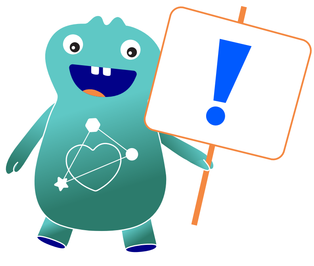
# Record Videos

Record and upload two short videos of your child playing and interacting. You will be shown a short video explaining how to record your child. **Each video should be between 1 minute & 30 seconds and 5 minutes in length.** Interact and talk to the child as much as possible while recording. It is also very important that the videos clearly show the child's face and hands. See the **Video Tips** section below for more information.

- You can choose to record a video from within the App or use an existing video (see Figure 5).
- After reviewing each video, you must select the **Submit** button. If you would like to cancel, select the **Retake** or **Reselect** button to record or select a new video.

## Figure 5: Video Instructions screen



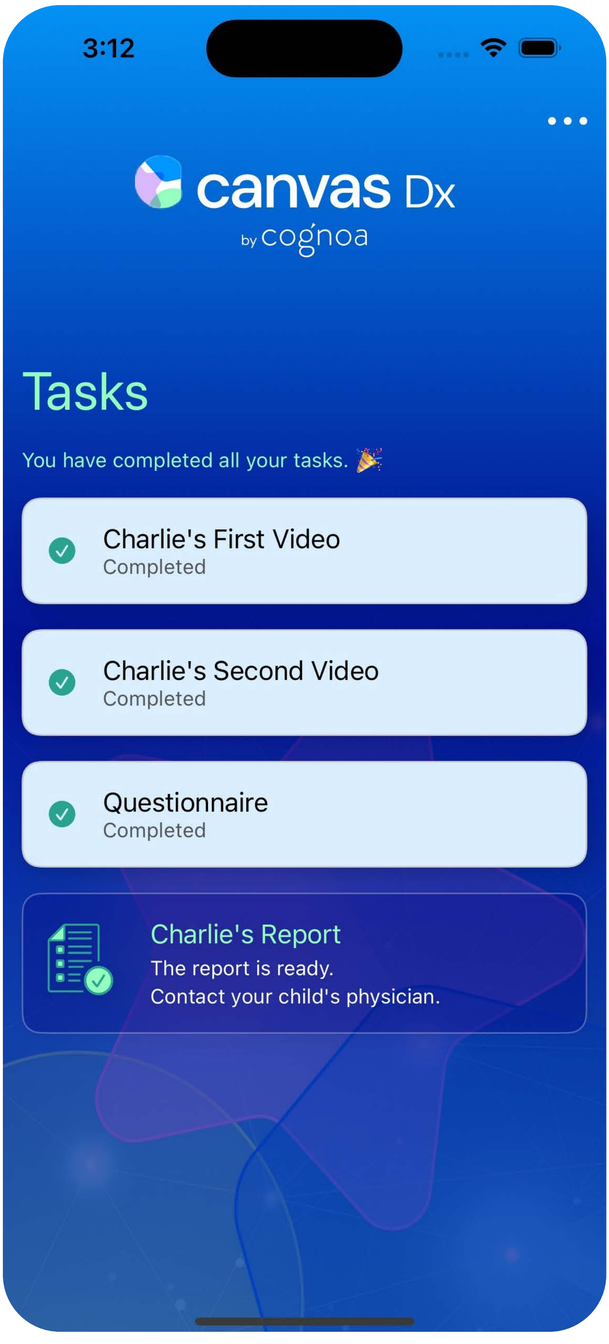
***WARNING:***

*After you submit, your video is final and cannot be changed.*

# Next Steps

Once both you and your child's doctor have completed all required Canvas Dx tasks, the report status will change from **Pending** to **Ready** (see Figure 6). Please contact your child's doctor to view and discuss the doctor's report and recommendations.

**Figure 6: Tasks Dashboard, Report Ready screen**



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# Detailed 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 behavior and development.

- Two ***different*** videos of the child are required
- Each video should be at least 1 minute & 30 seconds and no longer than 5 minutes
- You may be in the video with the child if you choose to be, but even if you are not, please make sure to talk and interact with them so we can see how they respond
- Please do not have the TV on or allow your child to play with electronics while recording
- If you include other children in the video, please make sure you clearly identify which child you want us to assess

*See examples of video recording best practices below.*

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# Video Tips

Record 2 *different* videos of the child

**Video Length**

Minimum: 1 minute & 30 seconds

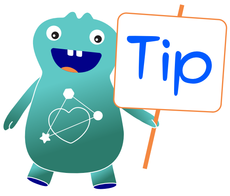
Maximum: no longer than 5 minutes



example: 1st video

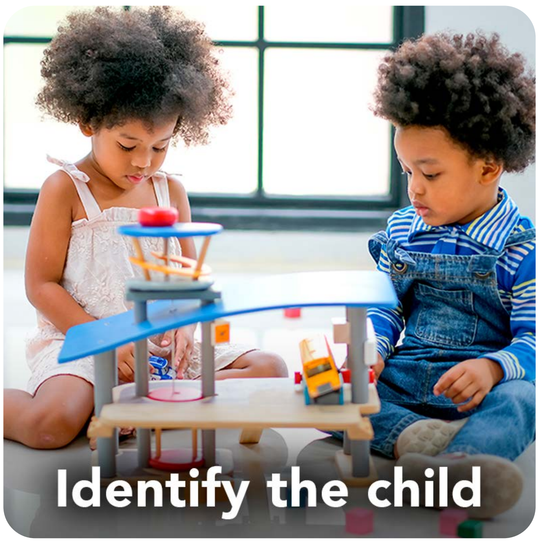


example: 2nd video




## Multiple children

*If there are other children in the video, clearly identify the child to be assessed*



# DO:




*Interact, play, and talk with the child*

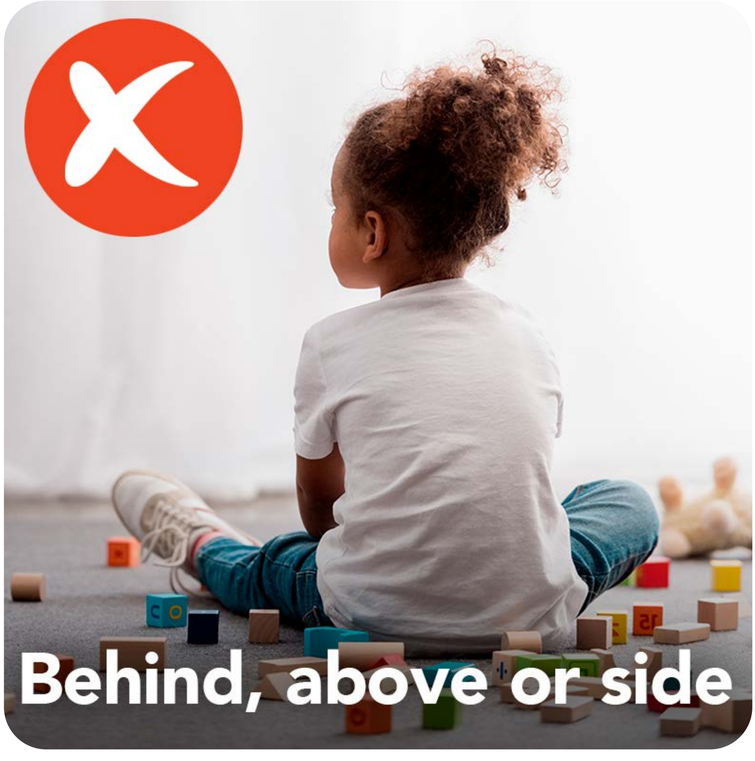



*Record with a clear view of the child's hands and facial expressions*

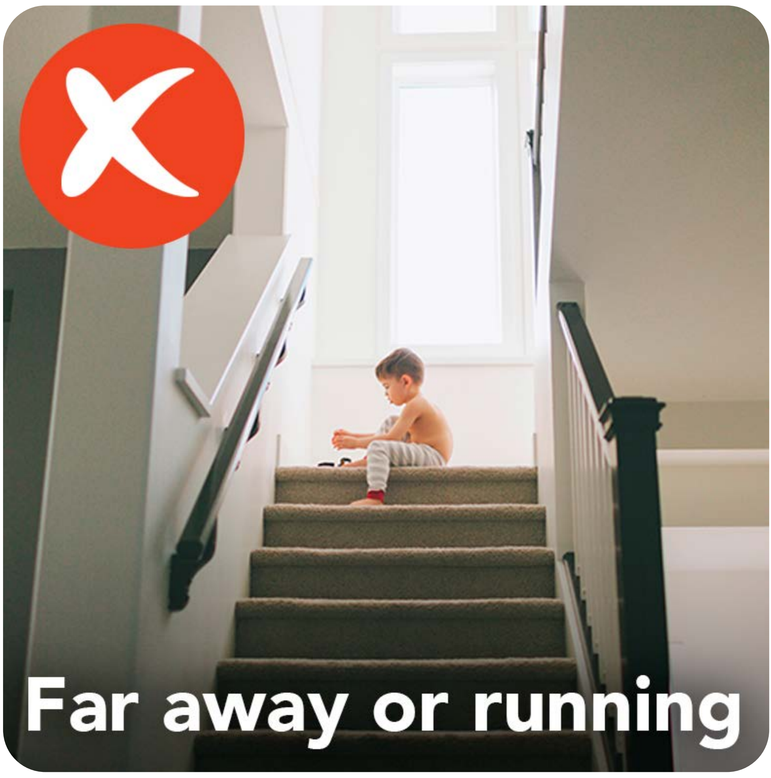
# Don’t:




*Don’t submit a video with little or no interaction from your child*



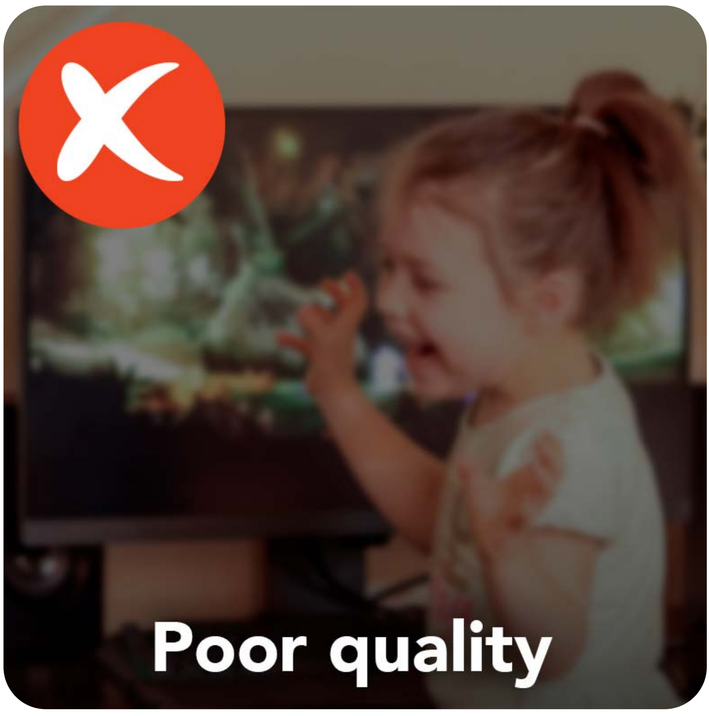

*Don’t record the child from above, behind, or the side*




*Don’t submit a video with your child too far away or running around*




*Don’t let the child play with electronics while recording*




*Don't submit poor quality recording: avoid background noise (e.g., TV), poor lighting (too bright or too dark), blur, shaking, and obstructed views*

If, for any reason, the video is not of sufficient quality for the analysts to score, we will reach out to you to request additional videos and provide guidance on what to do differently.

***Watch these helpful tips for recording video***

*Click or scan QR code below*

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# Services Menu

The services menu can be accessed on the top right hand corner of the screen (see Figure 7a & 7b). Use the services menu to access the following resources or actions:

- User Guide
- Terms of Service
- Privacy Policy
- Contact Us
- About this App
- Change Language
- Log Out

## Services Menu screen

Figure 7a: iOS

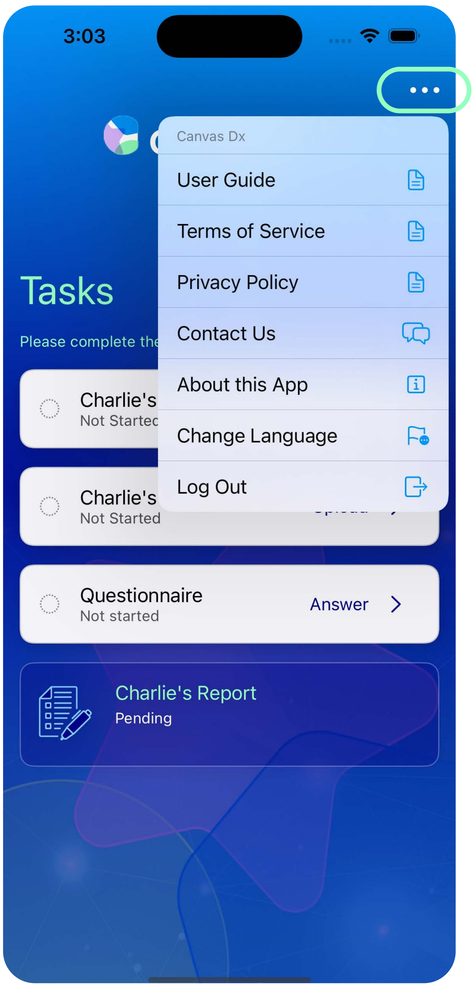
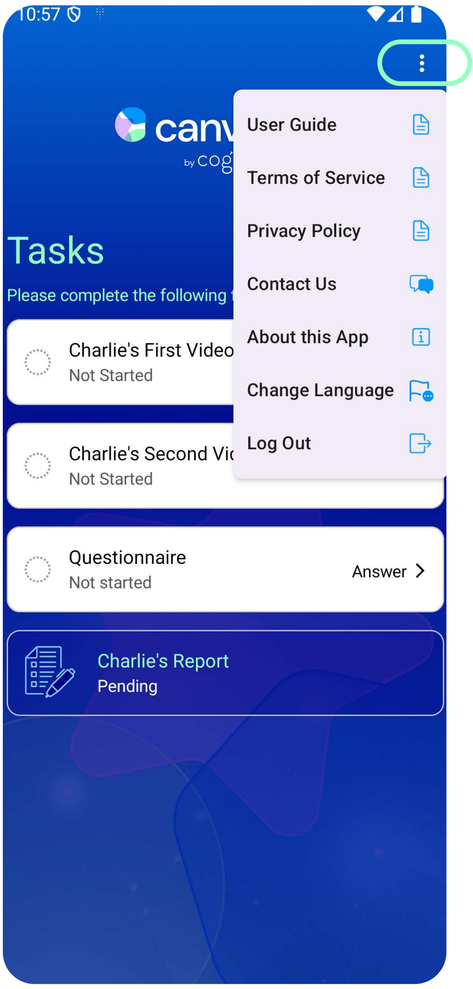



Figure 7b: Android



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# Minimum Technical Requirements

| | |
|---|---|
| **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.

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# Language Settings

The Canvas Dx Caregiver 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-thelanguage-and-region-iphce20717a3/ios

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

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# Troubleshooting

Email support@cognoa.com if you have technical difficulties or questions regarding Device usage. General troubleshooting tips are included in the table below.

| Issue | Potential Issue/s | How to Resolve |
|---|---|---|
| My doctor prescribed Canvas Dx but I did not receive an access code. | Your email and/ or text message about Canvas Dx may have gone to SPAM. | Check your SPAM folder. If you still cannot locate the email please contact us at **support@cognoa.com** |
| I want to use Canvas Dx but I don't have an access code. How can I get one? | Canvas Dx is a prescription only product. A doctor must prescribe it before an access code can be generated. | See our website for a list of prescribers by location and ask them if Canvas Dx is suitable for a child in your care. |
| I entered the access code that was sent to me but received the following error message: ***Incorrect access code. Please try again.*** | Access codes can only be used once. If you already used the access code once you will not be able to use it again. | Use the following option instead: ***Already have an account? Log in.*** |
| Login error: ***Oops! Please check your email and password and try again.*** | You have typed an incorrect email and/or password. | Confirm you typed your email correctly. If you cannot remember your password use the **Reset** option to update your password. |
| Error message: ***Network unavailable. Connect device to network service and try again.*** | Network unavailable. | Connect your device to Wi-Fi then attempt the task again. |
| Error uploading video/Failed to upload. | Loss of/spotty connectivity. Upload times out. | Ensure the device is connected to Wi-Fi and select **Re-load** to try again. |

# 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.

# Current Performance Metrics

The device provides a “Negative for autism” result with a 97% Negative Predictive Value (NPV). This means that for every 100 children who receive a Negative for autism result from Canvas Dx, 97 are negative for autism according to the blinded specialist review panel. †

Positive Predictive Value (PPV): Canvas Dx provides a “Positive for autism” result with 95% Positive Predictive Value (PPV). This means that for every 100 children who receive a Positive for autism result from Canvas Dx, 95 are Positive for autism according to the blinded specialist review panel. †

Canvas Dx returns a determinate (positive or negative for autism) result with a sensitivity of 95% and a specificity of 95%. †

† Clinical specialist review procedure: As part of its obligation to conduct continuous algorithmic performance monitoring, the device manufacturer tracks Canvas Dx performance against a panel of blinded independent, board-certified child and adolescent psychiatrists, child neurologists, developmental-behavioral pediatricians, or child psychologists with more than 5 years experience in diagnosing autism. A specialist, blinded to the device results and to the diagnostic call of the prescribing doctor, evaluates the device inputs and determines if autism and/or other neurodevelopmental conditions are present based on DSM-5 criteria. In cases where the specialist and the prescribing doctor’s diagnostic calls disagree, an additional specialist, also blinded, reviews the data, and the majority decision determines the clinical reference standard diagnosis.

† The most recent testing population included 148 unique patients (29.7% female, with a median age of 38 months and an ASD prevalence of 45.9%) from the intended use population, drawn from 48 unique sites across the US.

# Clinical Study Results

Canvas Dx 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 an "Indeterminate"result. During the study, 68% (290 patients) received an Indeterminate 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

- 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.
5000 Campus Drive, Newport Beach, CA 92660
Website: www.cognoa.com
Email: support@cognoa.com

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