

The GoCheck Kids logo, featuring a stylized green starburst icon to the left of the text "GoCheck Kids" in a blue, sans-serif font.

GoCheck Kids[®]

GoCheck MultiScreener User Manual

GoCheck i7P MultiScreener and GoCheck i15P MultiScreener
P/N 9000-008 Revision G

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Welcome to GoCheck!

This manual provides important information regarding the use of the GoCheck MultiScreener and should be read before using the application and device. This manual serves to provide you with general operating instructions.

The GoCheck MultiScreener is continuously undergoing improvement, and, as a result, this document is subject to change. It is not intended to be a complete guide, and additional training may be required. For more information on how to use our product, please contact our customer support team at 866-633-9243 or visit the Learn Site at learn.gocheckkids.com.

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Device Description



GoCheck i15P MultiScreener and GoCheck Audiometric Headphones, optional Attractor accessory not shown

The GoCheck MultiScreener is a medical device comprised of hardware (flash concentrator, smartphone with charger block and cable), software (mobile medical applications and web application) and accessories (i.e., Attractor, Audiometric Headphones). The GoCheck MultiScreener is intended to provide Healthcare Professionals tools for preventive health assessments, including screening tests for vision and hearing. This device is not a diagnostic tool, rather the screening data is used to help determine if an individual may require further evaluation and thereby should not be used as a substitute for a comprehensive vision or hearing evaluation by a qualified HealthCare Professional.

The GoCheck MultiScreener includes:

- An ocular photoscreener (i.e., photorefractor and ophthalmic camera) intended to capture and record light reflex images to aid in vision assessment of children 12 months up to 72 months of age.
- A visual acuity screening tool which tests each eye individually. It is intended to aid in the vision assessment of individuals 4 years of age and older.
- A web portal which provides access to the user for data management.
- A hearing screening tool (i.e., pure tone audiometry screening) which tests for potential hearing loss in individuals 4 years of age and older.

Accessories:

- The Attractor is an accessory attached to the GoCheck MultiScreener parent device to augment the performance of the parent device. The Attractor indicates where the child should direct their gaze during photoscreening.
- The Audiometric Headphones are an accessory that supports the performance of the GoCheck MultiScreener by enabling the device to perform according to its intended use as an audiometer.

Note: You will get access to only the GoCheck apps and accessories you have ordered.

Intended Use

The intended use of the GoCheck MultiScreener is to provide Healthcare Professionals tools for preventive health assessments including photoscreening, visual acuity, and audiometric testing. The GoCheck MultiScreener may also include software functions used in the clinical workflow that are considered non-devices or low-risk devices whereby the FDA exercises enforcement discretion or does not require 510k clearance (e.g., scheduling app, medical dictionaries, some clinical decision support – CDS software).

Note: CDS is described as a variety of tools including, but not limited to: computerized alerts and reminders for providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information.

Indications for Use

The GoCheck MultiScreener's indication for use is screening for amblyopia risk factors and ocular misalignment in children from age 12 months to 72 months (for photoscreening) and screening for vision impairment and hearing loss in individuals 4 years of age and older.

Contraindications

- The GoCheck MultiScreener should NOT be utilized as a substitute for a comprehensive examination by a qualified HealthCare Professional as this device is a screening tool, not a diagnostic tool.
- The GoCheck MultiScreener should NOT be used in clinical circumstances when a diagnostic test is indicated (i.e., child has a known or suspected vision impairment or hearing loss).

Device Setup

ATTENTION: Do not disconnect the device from its flash concentrator case or the device will not function properly.

ATTENTION: GoCheck Kids software is not standalone and must be used on validated hardware.



WARNING: The GoCheck MultiScreener is iPhone-based. MagSafe compatible iPhone models and accessories contain magnets as well as components and/or radios that emit electromagnetic fields. These magnets and electromagnetic fields might cause interference to cardiac pacemakers, implanted defibrillators (ICDs) and other implants. To avoid any potential interactions with these medical devices, keep your MagSafe compatible iPhone models and MagSafe accessories a safe distance away from your device (more than 15 cm, but consult with your physician and your device manufacturer for specific guidelines). The i15P MultiScreener model is MagSafe.

Creating User Credentials to Log In

On a laptop or computer, find the email titled “GoCheck Kids Invitation” in your inbox and click the link. Your user credentials will include an email and a password. Your email will be the email you were invited with. Create a strong password according to the instructions on the site. You will use the same user credentials on all GoCheck Kids logins, including the vision and hearing apps and the web portal. If your practice requires multi-factor authentication, you will be prompted to set up your authentication at this time.

Now that your user credentials have been set up, you can log in on the device. Connect to WiFi through the settings app. Tap the GoCheck Kids Vision or GCK Hearing app icon, and log in.

Required: WiFi Connectivity

The device requires a stable and secure WiFi connection to properly function. Please work with your IT department or manager to ensure proper connectivity. Your device will need to be connected to WiFi to upload screening results wirelessly after each screening is performed. For ongoing device performance and security, your device will need to be connected to WiFi to receive app updates. If the device is being stored, it should be powered up and connected to WiFi at least once every 90 days to maintain app updates, otherwise, it may be disconnected from the mobile device management system.

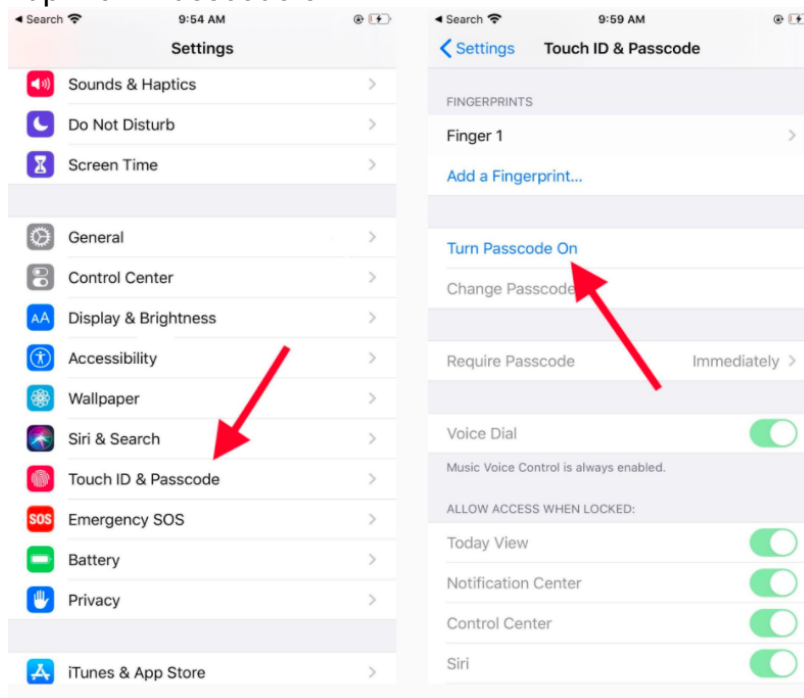
Passcode Protection

GoCheck Kids requires all devices to be passcode protected. To access the GoCheck apps, you must have a passcode turned on.

The passcode is specific to the device, but user credentials are specific to each user. If you are sharing the device with your colleagues, each of you will login to the device using the same passcode and then log into the app with your own unique user credentials.

To turn a passcode on:

- Go to the settings app on your device
- Tap “Touch ID & Passcode”
- Tap “Turn Passcode On”



Optional Accessory: Attractor Setup

The attractor is an optional accessory for your device that can aid in the photoscreening process.

For the i7 MultiScreener Attractor:



To set up this accessory, place the attractor on the back of the GoCheck screening device.

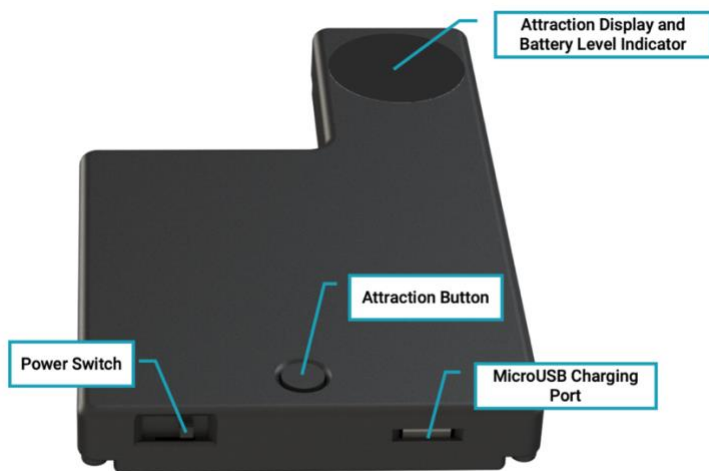
Make sure the registration posts of the attractor line up with the registration holes of the vision screening device.



Using the supplied Allen key, tighten the screw until the attractor is properly secured.
Be sure not to overtighten the screw.



For the i15P MultiScreener Attractor:



To set up this accessory, place the attractor on the back of the GoCheck screening device. The attraction display should be affixed in the below orientation to not obscure the camera. The attractor uses a magnet to stay in place.



Device Maintenance

Calibration and Preventive Maintenance

The GoCheck MultiScreener does not require calibration, verification of equipment's accuracy, or preventive maintenance performed by a technician. However, in order to ensure optimal device performance, the remainder of this "Device Maintenance" section documented below should be followed.

Note: It is recommended that the GoCheck Audiometric Headphones accessory should be re-calibrated on an annual basis. Re-calibration is included in your GoCheck Kids subscription to hearing screening capabilities.

Software Updates

The GoCheck MultiScreener Device is managed by a Mobile Device Management Solution. The Device iOS and software applications will receive updates which will automatically install as needed. To receive updates, please ensure that the device is connected to WiFi so it can communicate and sync accordingly. If your device has not had an active internet connection for an extended period, the Mobile Device Management Solution may inactivate the device. Please contact Customer Support team at 866-633-9243 after extended disconnection.

Cleaning the Device

Using a 70% isopropyl alcohol wipe, gently wipe the exterior surfaces of the GoCheck MultiScreener. Avoid getting moisture in any openings and gently dry the device with a lint free cloth after applying the alcohol. Use only 70% alcohol wipes as other cleaning agents may harm the device. Clean the device regularly or as needed.

Charging the Device

The GoCheck MultiScreener uses an iPhone charging cable which is provided with the unit- the i7P MultiScreener model uses a lightning cable and the i15P model uses a USB-C cable.

When the device is not in use, it should be plugged into the charging cable and powered off.

CAUTION: DO NOT REMOVE THIS PHONE FROM ITS CASE. This screening device WILL NOT FUNCTION PROPERLY if separated from its case.

If your charging cable needs to be replaced, please contact our Customer Support team at 866-633-9243.

Storing the Device

Store your device in a cool, moisture-free environment where the temperature is between -4° to 113° F. Don't leave your device in direct sunlight for extended periods of

time, as the device may overheat. Do your best to keep the device within its operating temperatures of 32° to 95° F.

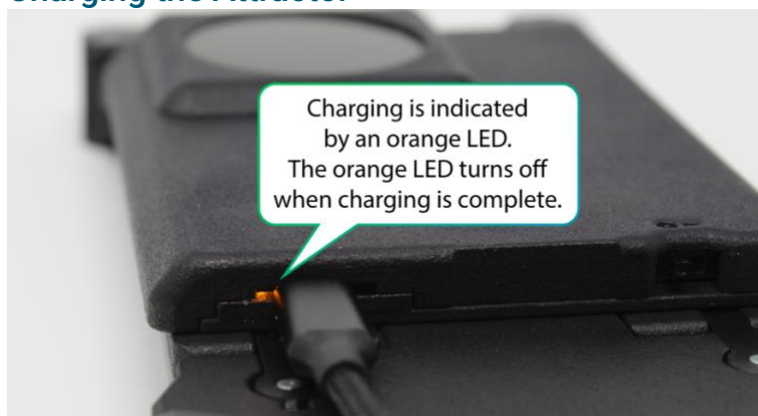
Store the device half-charged when you store it long term to best preserve battery life. Power down the device to avoid additional battery use.

Depending on how long you store your device, it may be in a low-battery state when you remove it from long-term storage. After it's removed from storage, it may require 20 minutes of charging with the original power adapter before you can use it.

If the device is being stored, it should be powered up and connected to WiFi at least once every 90 days to maintain app updates, otherwise, it may be disconnected from the mobile device management system.

Vision Screening Optional Accessory: Attractor Maintenance

Charging the Attractor



Use the micro-USB charge port with the provided micro-USB cable and USB charger. The Attractor will charge whether the power switch is On or Off.

Charging is indicated by an orange LED light next to the micro-USB port. The orange light turns off when charging is complete. The average time to full charge for the attractor is 5-6 hours.

Cleaning the Attractor

Using a 70% isopropyl alcohol wipe, gently wipe the exterior surfaces of the GoCheck Attractor. Avoid getting moisture in any openings and gently dry the device with a lint free cloth after applying the alcohol. Use only 70% alcohol wipes as other cleaning agents may harm the device. Clean the device regularly or as needed.

Hearing Screening Accessory: Headphones Maintenance

Calibration and Preventive Maintenance

The GoCheck Audiometric Headphones accessory will require annual re-calibration. You can see the calibration due date on the UDI number of the headphones. The last line, in bold, is the calibration due date in a YYYYMMDD format. In the example below, it is “20250805” or August 5th, 2025.



Please contact Customer Support at 866-633-9243 to receive a return label to ship your headphones to GoCheck for re-calibration.

Cleaning the Headphones

Between patients, it is recommended that you utilize disposable ear cushion covers made of acoustically transparent material.

Ear cushions may also be periodically cleaned with a soft cloth dampened (almost dry after wringing out any excess liquid) with mild soap and water. Harsh chemicals (e.g., Alcohol-based cleaners, bleach, and acetone) should be avoided to prevent damage to ear cushions (e.g., cracking).

Hard surfaces of the headphones, for example, the headphone band, may be cleaned with an acceptable disinfectant (e.g., Audiologist's Choice® AudioWipes).

Storing the Headphones

Store your headphones in a cool, moisture-free environment. Keep the headphones away from liquids or electronic components that are not used in the operation of the headphones.



WARNING: The headphones accessory generates stronger permanent magnetic fields that could cause interference to cardiac pacemakers, implanted defibrillators (ICDs) and other implants. Always maintain a distance of at least 3.94" (10 cm) between the product component containing the magnet (the earmuffs) and the cardiac pacemaker, implanted defibrillator, or other implant.

Information Security

ATTENTION: Patient screening data and results are ePHI and should be handled according to your workplace PHI policies.

Each user should have a unique username and password for the GoCheck Kids system. Users should not share usernames and passwords.

If you are going to leave your device or computer unattended, log out of the GoCheck Kids web portal or lock the device screen.

Practice administrators are encouraged to enable Multi-Factor Authentication on the web portal for increased security. Please reach out to Customer Support to do so. It is recommended to connect to a secure wireless network. It is not recommended to connect to the GoCheck Kids web portal from an unsecured internet connection. When accessing the web portal, it is recommended to use a VPN if your workplace has one.

Data is temporarily stored on the device when the device is not connected to a wireless network. If the device is not connected to a wireless network during screening, please connect the device to a wireless network after screening is completed so that data can be uploaded wirelessly.

Install software updates to the mobile app(s) and the iOS operating system when prompted.

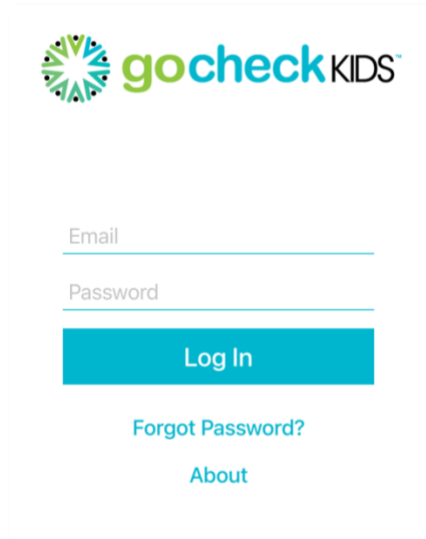
Double-check that any emails you receive come from an address that ends in “@gocheckkids.com”. GoCheck Kids will NEVER ask for your login credentials via email. When communicating with GoCheck Kids, do not include PHI in the email.

Follow your workplace recommendations for antivirus software for any workstations you use to access the web portal.

Using the Mobile App for Photoscreening

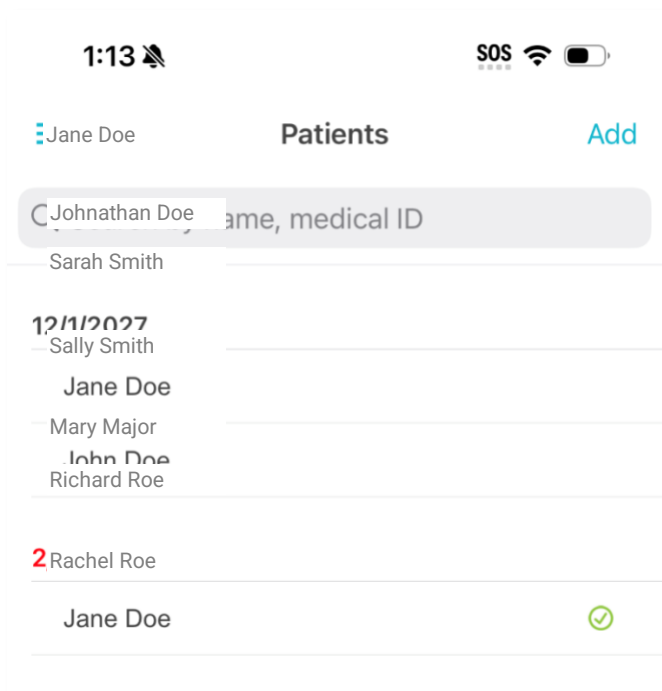
Logging into the GoCheck Kids Vision App

Select the GoCheck Kids Vision app on the home screen. Enter your username and password for the application.



If your practice enables text-based multi-factor authentication, you may be prompted to enter your phone number.

You will be directed to the patient queue. This is where you can select patients already scheduled and search for patients. If the patient has not yet been added, select "add" in the top right corner.

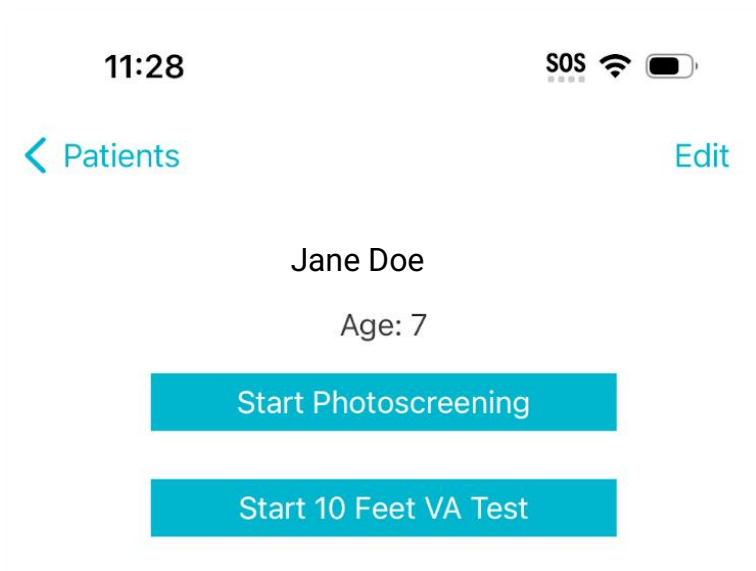


Adding a Patient

There are three required fields to add a patient: First Name, Last Name, and Date of Birth. All other information is optional. Add the patient's information and select "done" in the top right corner.

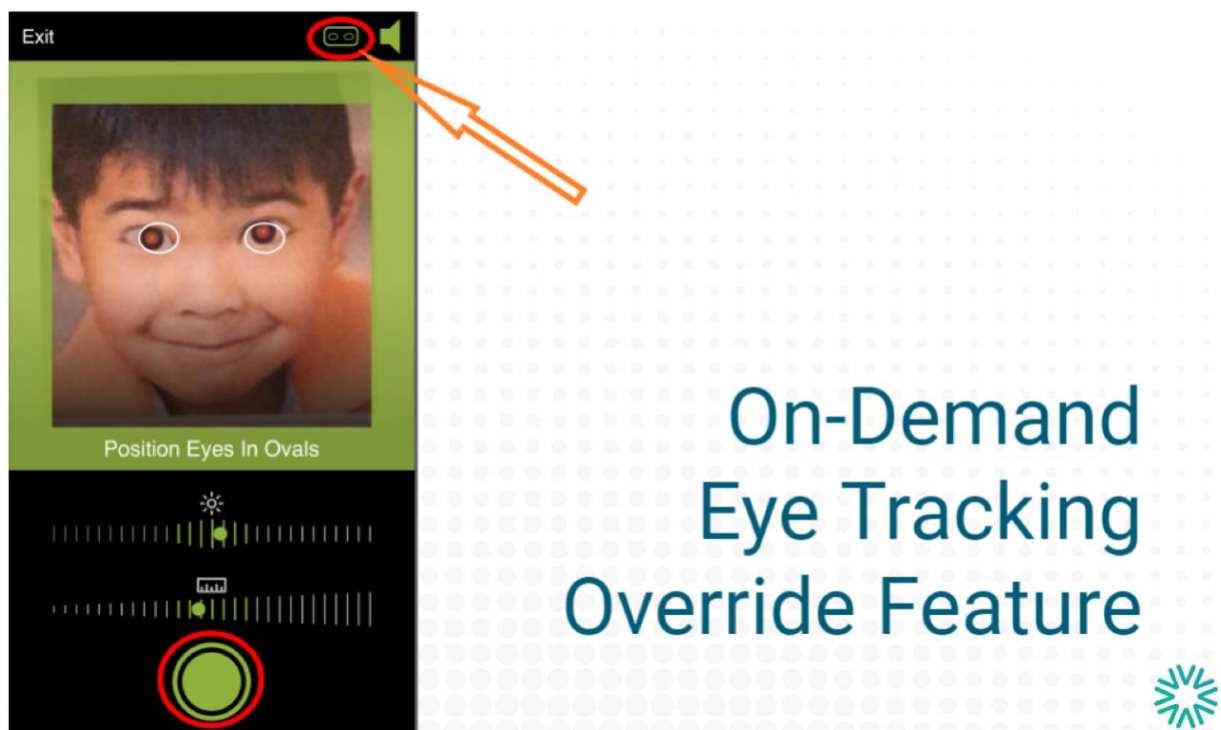
Performing a Photoscreening Test

To begin a photoscreening test, navigate to the patient's record and select "Start Photoscreening".



The child must be looking directly at the camera, the room must be dimly lit, and the test distance must be 40 inches if you are using the i7 MultiScreener model, or 44 inches for the i15P MultiScreener model (shown above). At this point, a green box will appear around the patient's face. Press the green button to take a picture. If you are using 2-photo mode, you will be prompted to take a second photo in landscape mode after taking your first photo in portrait mode.

Important: The room should be dimly lit for your photoscreening session. If there is too much light in the room, it may be difficult to capture an image without extraneous reflections on the cornea. The dim lighting also ensures proper pupil size for photoscreening measurements. For best results, **turn off the overhead lighting and use the door to control the light in the room.** Ensure a distance of 40 or 44 inches between the patient and the photoscreener.



If you would like to override the built-in eye tracking, you can toggle on the On-demand Eye Tracking Override. This is available with the goggles icon. You will see a pair of ovals to position the eyes in manually.

GoCheck Kids Vision App Icons Legend:

	Result - No Risk Factors Identified
	Result - Not Gradeable
	Result - Risk Factor Identified
	Toggle Sound On/Off
	Brightness
	Distance

The brightness and distance indicators are used to help you position the device for effective photoscreening and ensure proper room lighting. When both brightness and distance are acceptable, a green border will appear, and you can take a photo. The speaker button allows you to toggle sound effects on and off. Finally, the results icons provide information about your photoscreening session results.

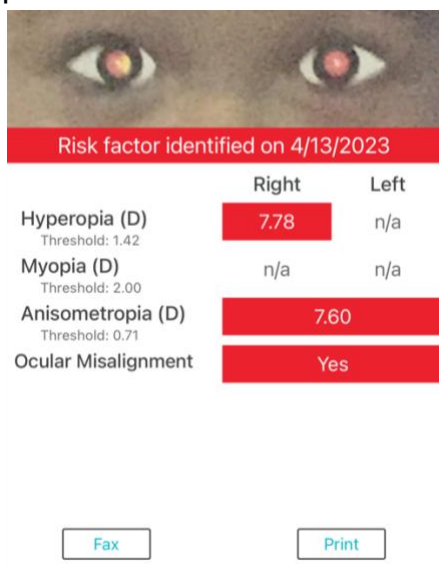
The photoscreening app will show you a result after you take the photo. There are 3 results: Risk Factor Identified, No Risk Factors Identified, and Not Gradable.

If you get a Not Gradable result, please try retaking the photo. You may need to adjust the lighting conditions or distance.

Accessing Photoscreening Results

The result report is then immediately available in the app and uploaded to the web portal. See the “Using the GoCheck Kids Web Portal” section of this manual for more details on reporting capabilities in the web portal.

If risk factors are identified, the child should be referred to a qualified eye care professional.



Risk factor identified on 4/13/2023

	Right	Left
Hyperopia (D) Threshold: 1.42	7.78	n/a
Myopia (D) Threshold: 2.00	n/a	n/a
Anisometropia (D) Threshold: 0.71	7.60	
Ocular Misalignment	Yes	

[Fax](#) [Print](#)

If your company has an EHR integration with GoCheck Kids, talk to your EHR integration specialist about exporting results to your EHR system.

You can fax your screening results. Click the Fax button on the results screen. There will be a confirmation pop-up box that will say "Fax Requested" indicating that the fax has been successfully processed.

If your practice has an AirPrint-enabled printer, you can print the patient's screening results. The printer needs to be discoverable wirelessly through Wifi and paired with the GoCheck Kids device. Click the "Print" button to export your results to the printer.

Vision Screening Optional Accessory: Attractor Use

The attractor is an optional accessory for the GoCheck Kids photoscreening system. The Attractor indicates where the child should direct their gaze during photoscreening.

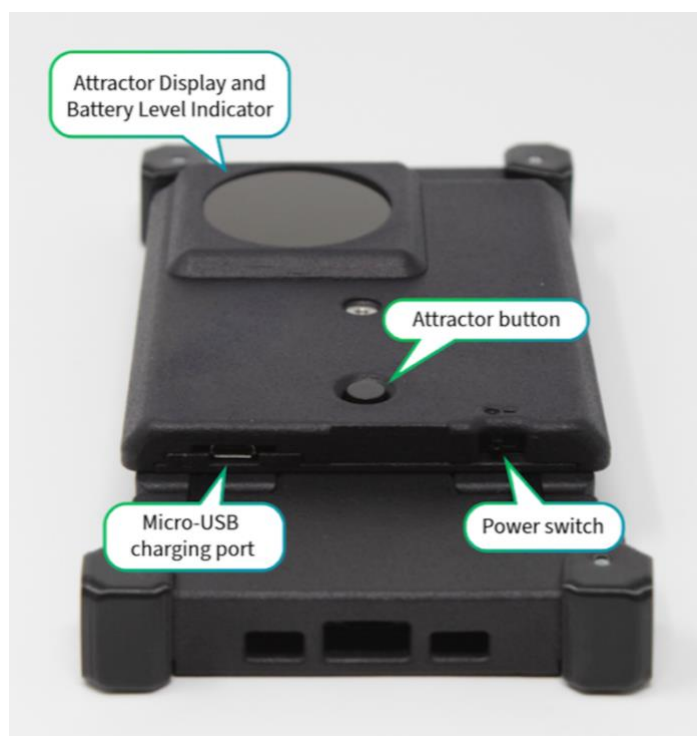
CAUTION: The attractor accessory emits a blinking light pattern with a low frequency. According to expert consensus of the Epilepsy Foundation of America Working Group, this has minimal risk of triggering photosensitive seizures. However, individuals with photosensitive conditions may still wish to limit exposure.

Source: Harding GFA, Wilkins AJ, Erba G, Barkley GL, Fisher RS. Photic- and pattern-induced seizures: Expert consensus of the Epilepsy Foundation of America Working Group. *Epilepsia*. 2005;46(9):1423-1425. doi:10.1111/j.1528-1167.2005.31305.x

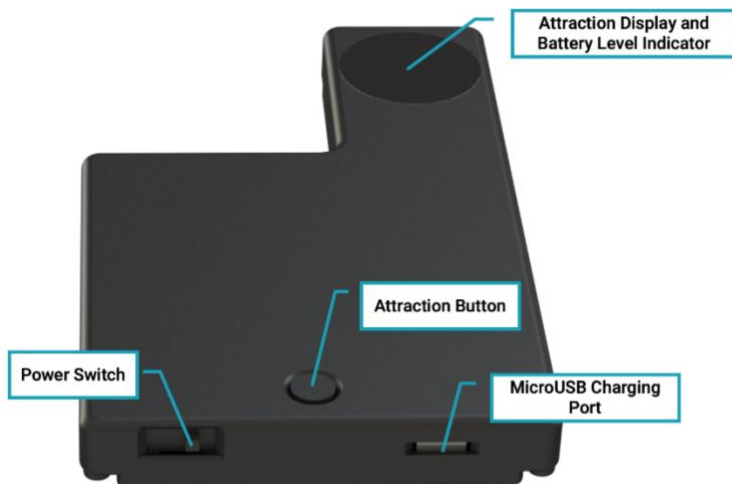
Getting Started

Start the attractor light before beginning your photoscreening session.

ATTENTION: Do not add any additional lights, stickers, or decorations to attract the child's attention as this may affect your screening results.



i7P MultiScreener Attractor



i15P MultiScreener Attractor

Photoscreening while using the Attractor

To perform a photoscreening session while using the Attractor, you will need to power on the attractor and turn on the attractor display before you take the photo.

Powering on the Attractor

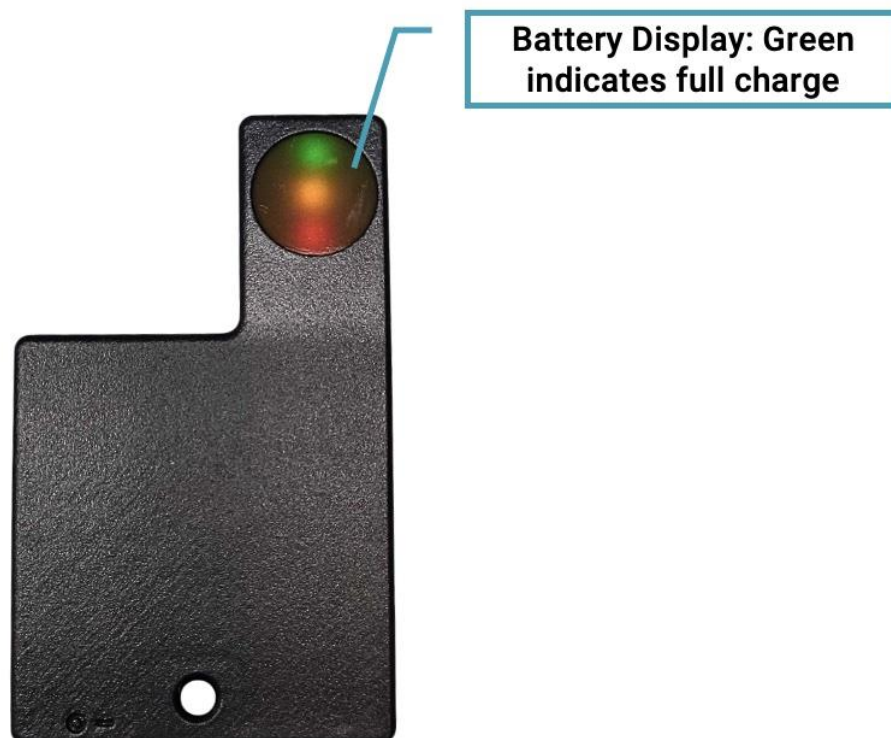
Switch the Attractor ON by sliding the power button to the right.
Press and release the Attractor button to start the attractor light.
Press and release the Attractor button again to turn OFF the attractor.
The attractor display will automatically stop after 4 minutes.



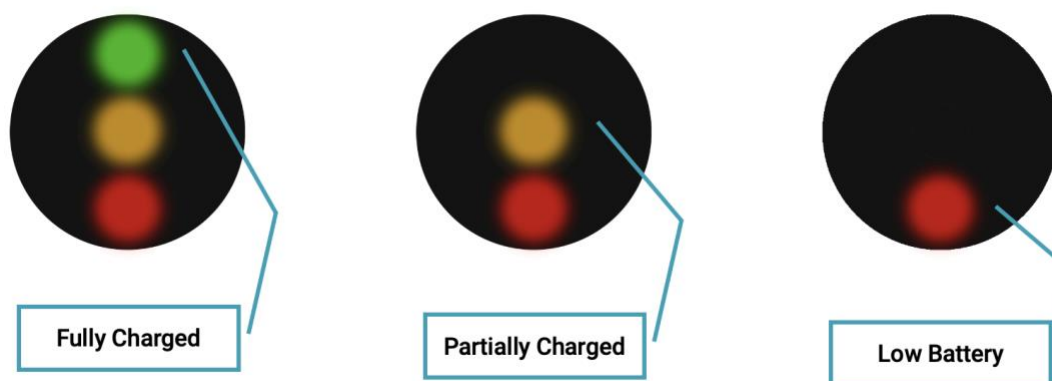
For the i7P MultiScreener Attractor, the battery level is briefly displayed when the power switch is turned on.

The battery level is also displayed briefly after the Attractor button is pressed and released to turn off the attractor. Charge when only one yellow dot and one red dot is shown. When the power is turned on, the typical battery life is 40-50 hours depending on how often it is used.

For the i15P MultiScreener Attractor, the battery level is briefly displayed in 3 circumstances:



1. The battery level will display when the power switch is turned on.
2. The battery level will display after the attractor display is turned off with the attraction button.
3. The battery level will display if the attraction button is pressed and held, when the attractor power is on.

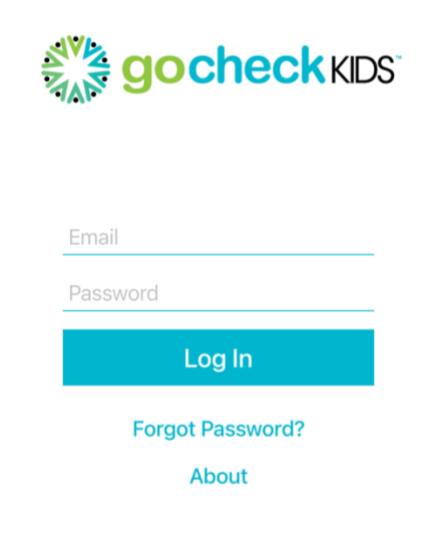


There are 3 battery levels: fully charged, partially charged, and low battery, indicated by the presence of green, yellow, and red lights- see image above. It is recommended to charge the attractor when you see a yellow “partially charged” indicator.

Using the GoCheck Kids Vision App for Visual Acuity

Logging into the GoCheck Kids Vision App

Select the GoCheck Kids Vision App on the home screen. Enter your username and password for the application.



The image shows the login screen of the GoCheck Kids Vision App. At the top is the GoCheck Kids logo, which consists of a colorful starburst icon followed by the text "gocheck KIDS". Below the logo are two input fields: "Email" and "Password". Below these fields is a blue "Log In" button. At the bottom of the screen are two links: "Forgot Password?" and "About".

If your practice enables text-based multi-factor authentication, you may be prompted to enter your phone number.

You will be directed to the patient queue. This is where you can select patients already scheduled and search for patients. If the patient has not yet been added, select “add” in the top right corner.

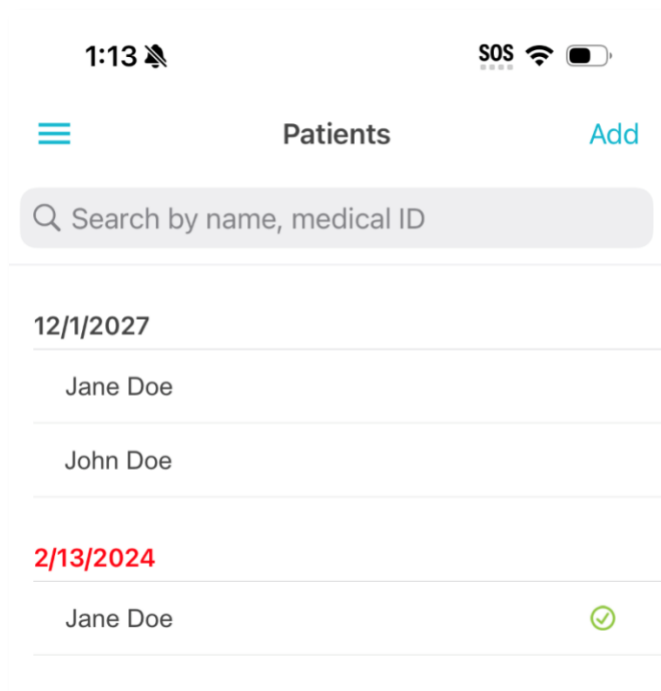
Johnathan Doe

Sarah Smith

Sally Smith

Mary Major

Richard Roe

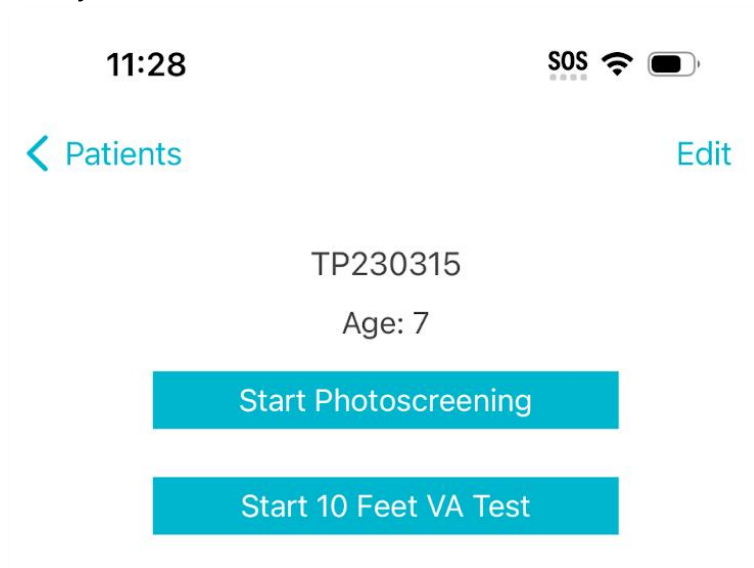


Adding a Patient

There are three required fields to add a patient: First Name, Last Name, and Date of Birth. All other information is optional. Add the patient's information and select "done" in the top right corner.

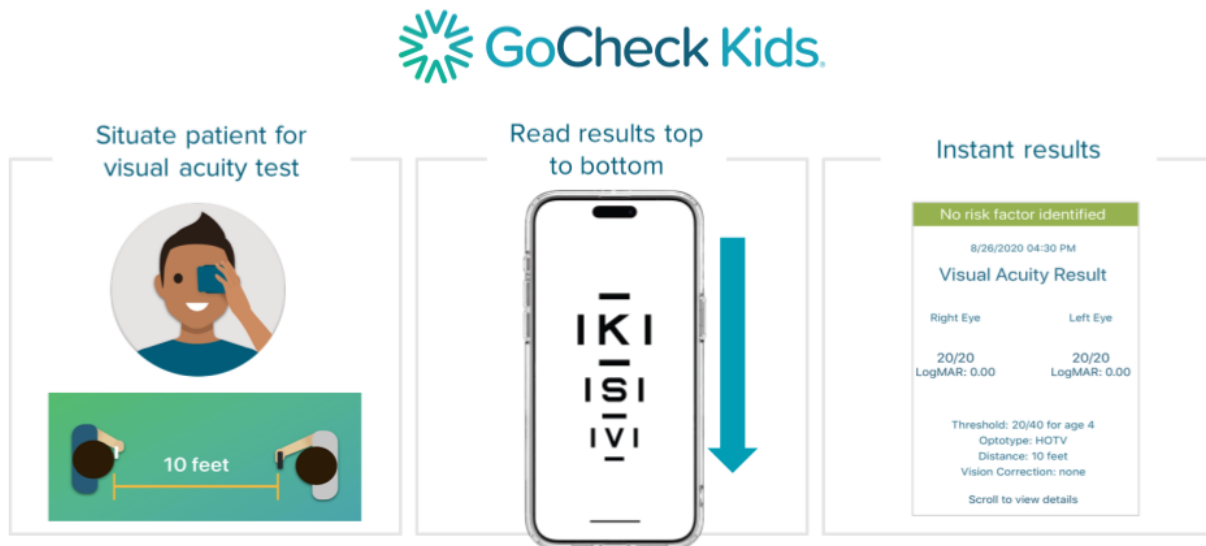
Performing a Visual Acuity Test

To begin a Visual Acuity test, navigate to the patient's record and select "Start Visual Acuity Test".



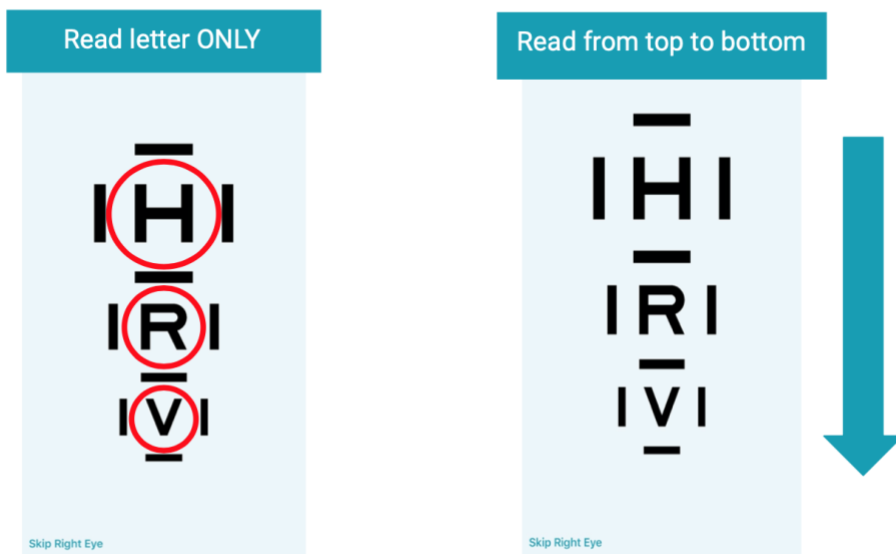
For this test, you will need a tester to hold the device, a patch or folded washcloth to cover the patient's eye, and a tape measure.

Measure 10 feet between the phone and the patient. Follow the instructions in the app to continue. Give the occluder (for example: patch/folded washcloth) to the patient. To begin the test, turn the device screen to the patient.

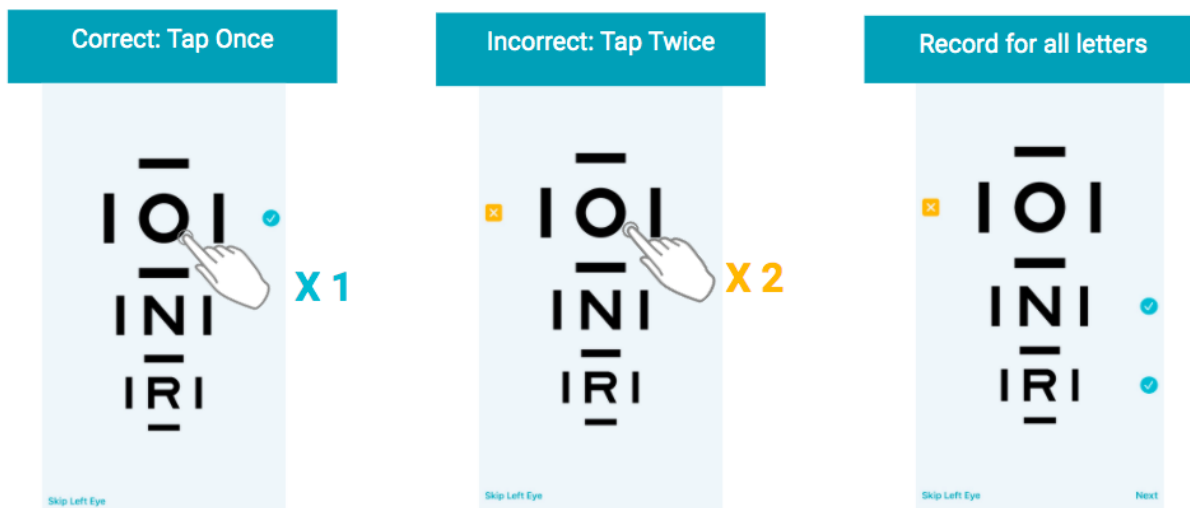


Ask the patient to read the letters inside the crowding bars from top to bottom. Make sure to remember the patient's responses.

Ask patient to:



To record results, tap once on a letter that the patient read correctly and twice on a letter that the patient read incorrectly. Record results for all letters and select 'Next' to advance.



Accessing Visual Acuity Results

The result report is then immediately available in the app and uploaded to the web portal.

No risk factor identified on 4/13/2023

	Right	Left
Visual Acuity	20/20	20/20
Threshold: 20/32		

Rerun Visit
Print

If risk factors are identified, the child should be referred to a qualified eye care professional.

If your company has an EHR integration with GoCheck Kids, talk to your EHR integration specialist about exporting results to your EHR system.

You can fax your screening results. Click the Fax button on the results screen. There will be a confirmation pop-up box that will say "Fax Requested" indicating that the fax has been successfully processed.

If your practice has an AirPrint-enabled printer, you can print the patient's screening results. The printer needs to be discoverable wirelessly through Wifi and paired with the GoCheck MultiScreener device. Click the "Print" button to export your results to the printer.

Using the GCK Hearing App for Hearing Screening



How GoCheck Pure Tone Screening Works

Pure tone screening is conducted on both ears. All tones listed on a protocol are played on the left ear first, before moving to the right ear.

Pure tones played during a screening start from the lowest frequency (or pitch) to the highest frequency. Each pure tone is randomized to play between 1-4 seconds after tapping “Play”.



Each screening consists of two phases, the Test Phase and the Retest Phase.

Between the two phases, each tone will be played up to 4 times.

During the Test Phase, when a tone is played:

- If the patient fails to respond to the tone once, the tone will be played again
- If the patient fails to respond to the tone twice, the tone will be marked for retest

The Retest Phase occurs if any tones were marked for retest during the initial test phase

- If the patient fails to respond to the tone once, the tone will be played again
- If the patient fails to respond to the tone twice, the tone will be marked as failed.

Screening Protocols

A pure tone screening protocol dictates the pure tones and their associated frequencies and intensity that will be played during a screening.

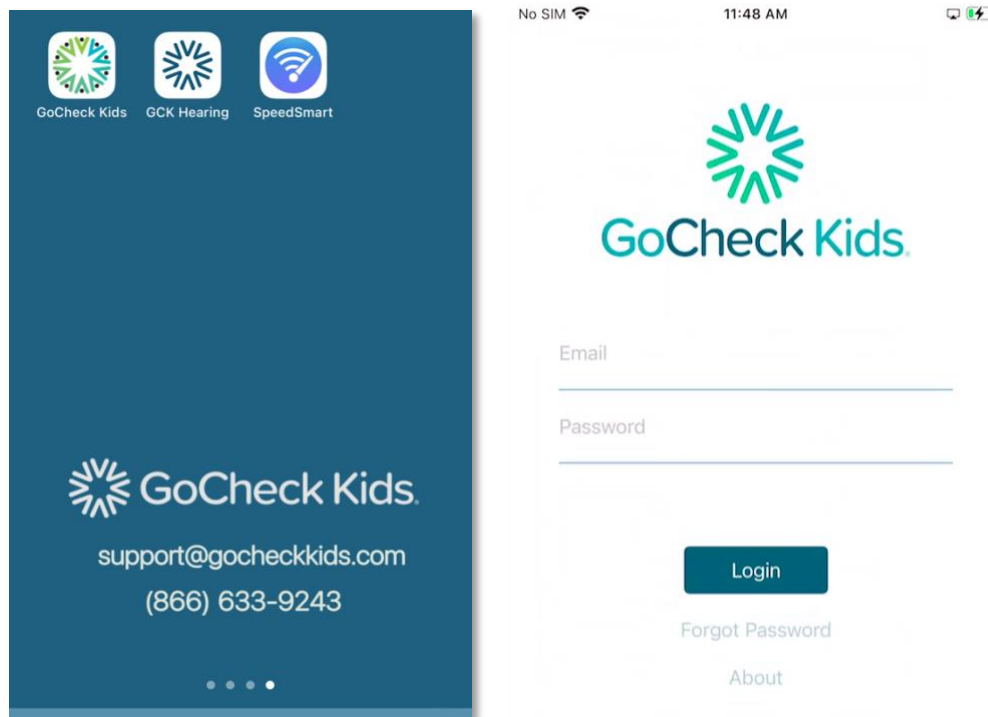
By default, users will have access to two screening protocols that follow AAP recommendations:

- Screening Protocol for Ages 4-10
- Screening Protocol for Ages 11-21

Pure tone screening protocols can be customized on the GoCheck Kids web portal, for more information see page 41 of this manual.

Logging into the GCK Hearing App

On the GoCheck MultiScreener Device, find the “GCK Hearing” mobile application. Enter your GoCheck username and password for the application.



You will be directed to the patient queue. This is where you can select patients who are already scheduled and search for patients.

If the patient has not yet been added to the queue, select “add” in the top right corner. By default, patients are shown by visit date order. You can search for patients by name or by patient ID.

MENU

Patients

ADD

Q Find patient by name or ID

09/03/2024

JANE DOE

SCREEN

09/03/2024

JOHN DOE

SCREEN

09/01/2024

ALICE SMITH

SCREEN

Adding a Patient

There are three required fields to add a patient: First Name, Last Name, and Date of Birth. All other information is optional. Add the patient's information and tap "submit".

CANCEL

Add a Patient

First Name*

First Name

Last Name*

Last Name

Date of Birth*

MM/DD/YYYY

Medical ID

Medical ID

Ethnicity

Unspecified

Gender

Male

Female

N/A

Location

NewUI Location

Provider

Unselected

SUBMIT

Linking Headphones



WARNING: The headphones accessory generates stronger permanent magnetic fields that could cause interference to cardiac pacemakers, implanted defibrillators (ICDs) and other implants. Always maintain a distance of at least 3.94" (10 cm) between the product component containing the magnet (the earmuffs) and the cardiac pacemaker, implanted defibrillator, or other implant.

Before a screening can begin, the device needs to be linked to a pair of GoCheck Audiometric Headphones. The device will need to be linked with headphones every 24 hours. The app will prompt you to link the headphones as needed. You will not be able to start a screening session until the headphones are linked.



There are two ways to link headphones: Automatic Scan of a QR code, or Manual Entry of the serial number of the headphones.

Select the linking type:

Tap "Automatic Scan" to link by scanning the headset's serial number
Tap "Manual Entry" to link by entering the headset's serial number

AUTOMATIC SCAN

MANUAL ENTRY

The QR code is located on a label inside the headphones and in the headphones case.




The 10-character serial number of the headphones is located inside the headphones band, below the QR code. Additionally, the serial number can be found on the UDI Label in the headphones band.



To find the serial number on the UDI label, look for the first two bold lines, in the above example "2AC9B5F6C&".

BACK

Link By Serial Number



Serial Number of headset can be found in the headset case

Enter the Serial Number below then press 'Submit'

SUBMIT

Note: Linking your headphones is not a Bluetooth or wireless connection. You will still need to plug the headphones into the device.

Performing a Hearing Screening

To ensure best results, please minimize background noise and other distractions for hearing screening. Additionally, ensure the patient does not have obstructions to the ear canal or outer ear that would interfere with screening (e.g. hair accessories, glasses, earrings).

Before you begin your screening, explain to your patient how the screening will be performed. Use simple, age-appropriate language. For example, “We are going to test your hearing. First, I am going to put a pair of headphones over your ears. Then, you will hear beeping sounds which may be loud or quiet. When you hear one of these sounds, raise your hand. Lower your hand when you no longer hear the sound.”

GoCheck recommends the use of acoustically transparent, disposable covers over the ear cushions. If you are using covers, place the covers over the headphone cushions before use. Place the headphones on the patient. The headphones should be centered over the patient’s ears, with no objects (e.g. hair accessories, glasses, earrings) obstructing the headphones. You may need to adjust the headphone band for optimal placement.

You can begin a hearing screening session from the patient queue or the patient record. To begin a hearing screening session in the patient queue, navigate to the patient and tap “Screen” on the right.

MENU

Patients

ADD

Find patient by name or ID

09/03/2024

JANE DOE

SCREEN

JOHN DOE

SCREEN

To begin a screening session from the patient record, tap “Conduct Pure Tone Screening”

DEMOGRAPHIC

First Name: Jane
 Last Name: Doe
 Date Of Birth: 01/20/2017
 Medical ID: JD200117
 Ethnicity: *Unspecified*
 Gender: Female

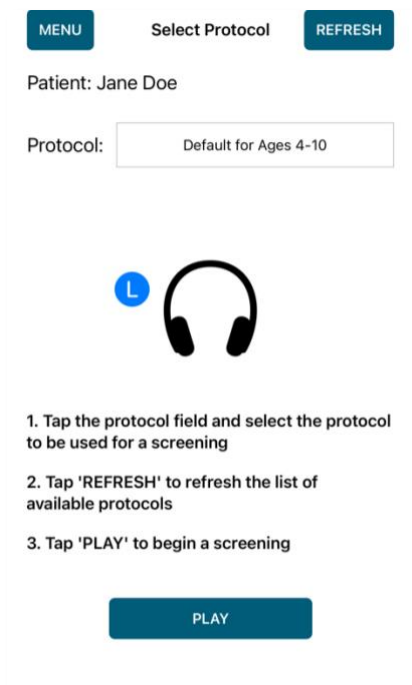
CONDUCT PURE TONE SCREENING

LATEST VISIT

Visit Date	Pure Tone (PT)
08/23/2024	<input checked="" type="radio"/> NO RISK FACTOR

VIEW OTHER VISITS

When you begin a hearing screening, you’ll start by choosing a protocol. If you are not using custom protocols, choose the protocol that is age appropriate:



The screenshot shows a mobile application interface for a hearing screening tool. At the top, there are three buttons: 'MENU' (dark blue), 'Select Protocol' (white), and 'REFRESH' (dark blue). Below these, the patient's name 'Jane Doe' is displayed. A 'Protocol:' label is followed by a dropdown menu currently showing 'Default for Ages 4-10'. In the center, there is a large icon of a pair of headphones with a blue circle containing a white 'L' next to it, indicating left ear testing. Below the icon, there are three numbered instructions: 1. Tap the protocol field and select the protocol to be used for a screening; 2. Tap 'REFRESH' to refresh the list of available protocols; 3. Tap 'PLAY' to begin a screening. At the bottom, there is a large dark blue 'PLAY' button.

Please refer to the Web Portal section of this user manual for more information on creating custom protocols.

Test Phase

Make sure the patient is wearing the GoCheck headphones and is ready to respond for each tone, then press “Play”.

You will be able to see which tone is currently being played, and an icon which indicates which ear will be tested. Blue ear icons indicate left ear testing, red ear icons indicate right ear testing. icons. First, the left ear will be tested for all tones in the protocol. Next, the right ear will be tested for all tones.


The icon will turn green while the tone is being played. You can expect a patient to indicate they can hear the tone after the icon is green.

PAUSE

Initial: Step 1/8 - Play


Patient: John Doe

Protocol: Default for Ages 4-10



Current tone being played:

500hz (20dB)



You will be prompted to capture a response for the patient:

PAUSE

Initial: Step 1/8 - Capture

Patient: John Doe

Protocol: Default for Ages 4-10



Did the patient hear the tone?

NO


YES

PAUSE

Initial: Step 8/8 - Ready

Patient: John Doe

Protocol: Default for Ages 4-10



1. When ready, press PLAY to send the tone

PLAY

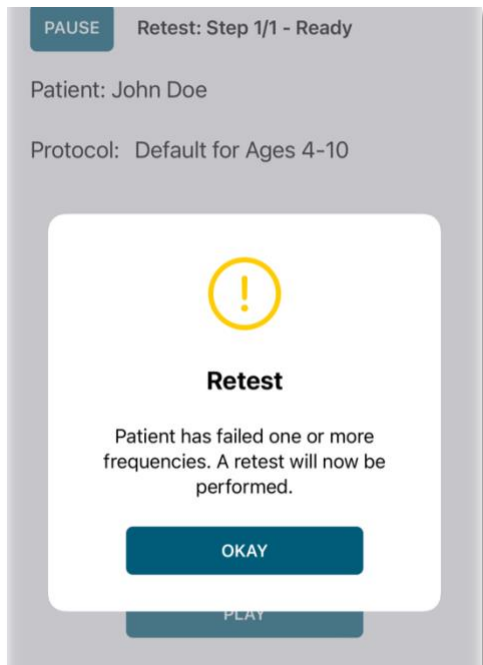
When you've captured the patient's response, press "Play" again to send the next tone. Each tone will repeat once, if it was marked not heard the first time it was played.



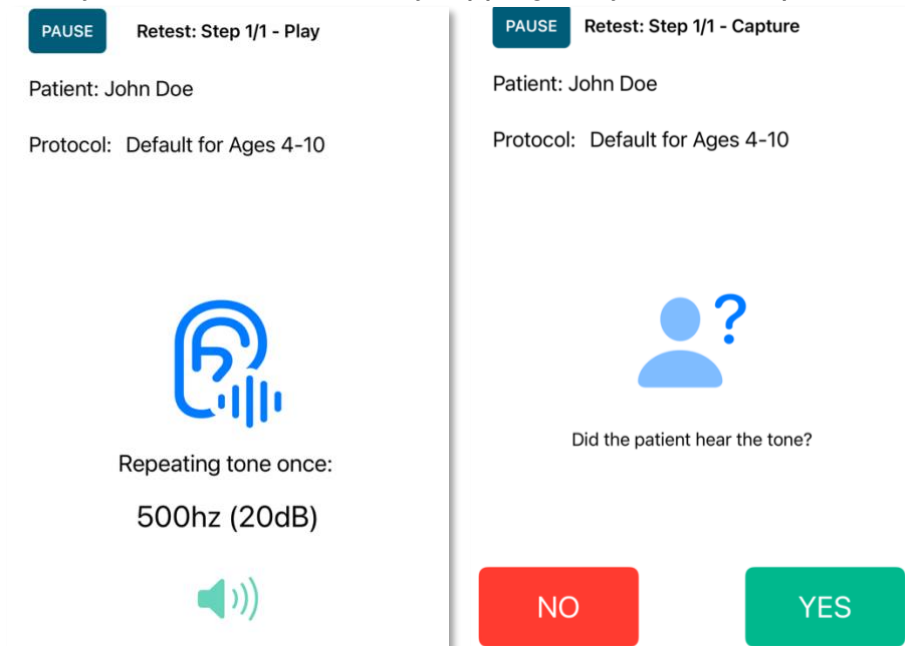
Retest Phase

Tones that are marked not heard twice in a row will be flagged for the retest phase. The retest tones will play after the protocol tones have all played once, before the end of the screening.

You will see a notification that a retest will be performed. Tap "Okay".



Next, you will send the tone by tapping “Play” when the patient is ready.



The tone will play twice for the retest, once for each ear. The blue “L” icon indicates left ear, the red “R” icon indicates right ear. Record the patient’s response each time. When the retest is complete, you will get the screening results.

Screening Results

When you complete a screening, results will be immediately available for review.

Patient Result
DONE

DEMOGRAPHIC
Full Name: John Doe
Visit Date: 12/31/2024
Screening Type: Pure Tone Screening

RESULT SUMMARY

NO RISK FACTOR

RESULT DETAILS

Frequency (Hz)	Intensity (dB)	Test		Retest	
		L	R	L	R
500 Hz	20 dB	✗	✓	✓	
1,000 Hz	20 dB	✓	✓		
2,000 Hz	20 dB	✓	✓		
4,000 Hz	20 dB	✓	✓		

If risk factors are identified, the child should be referred to a qualified hearing care professional.

You can fax your screening results. Click the Fax button on the results screen. There will be a confirmation pop-up box that will say “Fax Requested” indicating that the fax has been successfully processed.

If your practice has an AirPrint-enabled printer, you can print the patient’s screening results. The printer needs to be discoverable wirelessly through Wifi and paired with the GoCheck MultiScreener device. Click the “Print” button to export your results to the printer.

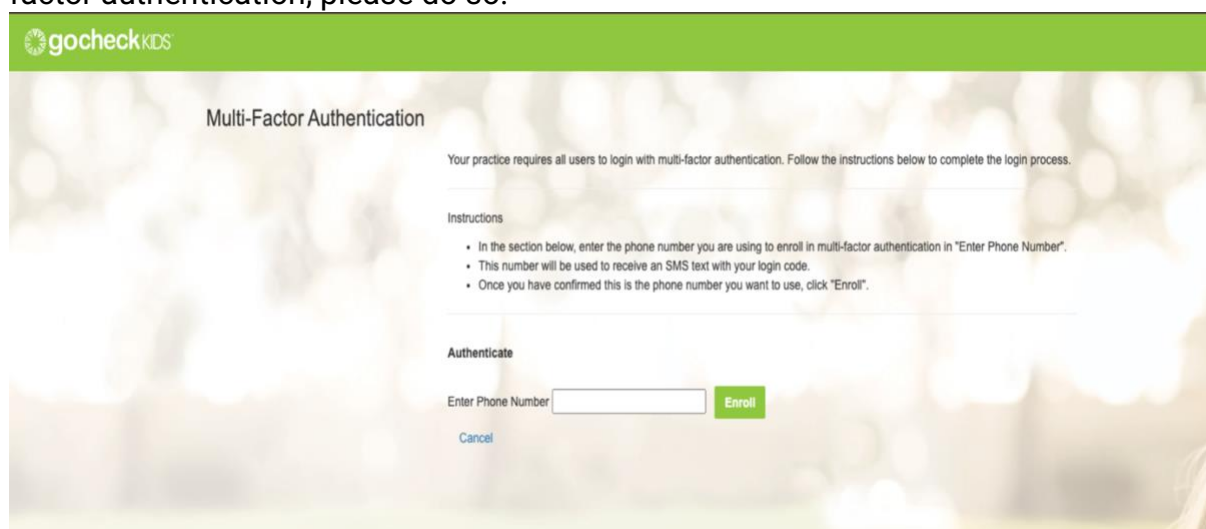
Using the GoCheck Kids Web Portal

Browsers supported for GoCheck web portal use

The web portal currently supports Chrome, Edge, Firefox and Safari. GoCheck does not recommend or support Internet Explorer for web portal use.

Logging in to the Portal

To access the GoCheck Kids Web Portal, go to portal.gocheckkids.com. Log into the portal with your GoCheck Kids username and password. If prompted to complete multi-factor authentication, please do so.

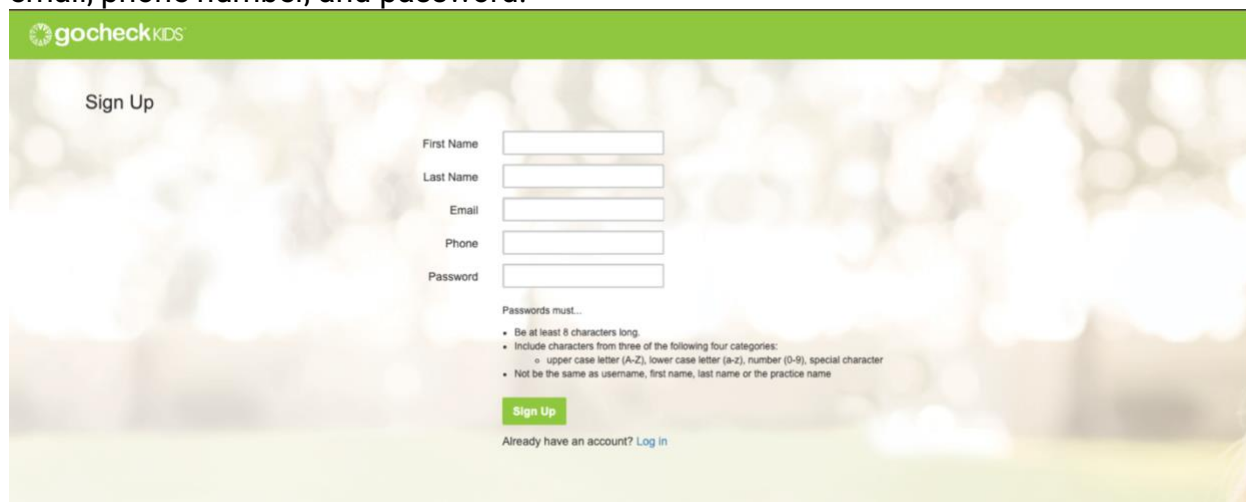


The screenshot shows the 'Multi-Factor Authentication' page. At the top is the 'gocheckKIDS' logo. Below it, the title 'Multi-Factor Authentication' is centered. A message states: 'Your practice requires all users to login with multi-factor authentication. Follow the instructions below to complete the login process.' Under the heading 'Instructions', there are three bullet points:

- In the section below, enter the phone number you are using to enroll in multi-factor authentication in "Enter Phone Number".
- This number will be used to receive an SMS text with your login code.
- Once you have confirmed this is the phone number you want to use, click "Enroll".

 Below the instructions is the 'Authenticate' section. It contains the label 'Enter Phone Number' followed by a text input field and a green 'Enroll' button. A blue 'Cancel' link is positioned below the input field.

You can set up your user account by clicking the link to register in your portal invitation email. The email will be titled "GoCheck Kids Invitation" and will include a custom link. The sign-up page for your account will prompt you to enter your first and last name, email, phone number, and password.



The screenshot shows the 'Sign Up' page. At the top is the 'gocheckKIDS' logo. Below it, the title 'Sign Up' is centered. The form contains five input fields: 'First Name', 'Last Name', 'Email', 'Phone', and 'Password'. Below the 'Password' field, there is a section titled 'Passwords must...' with three bullet points:

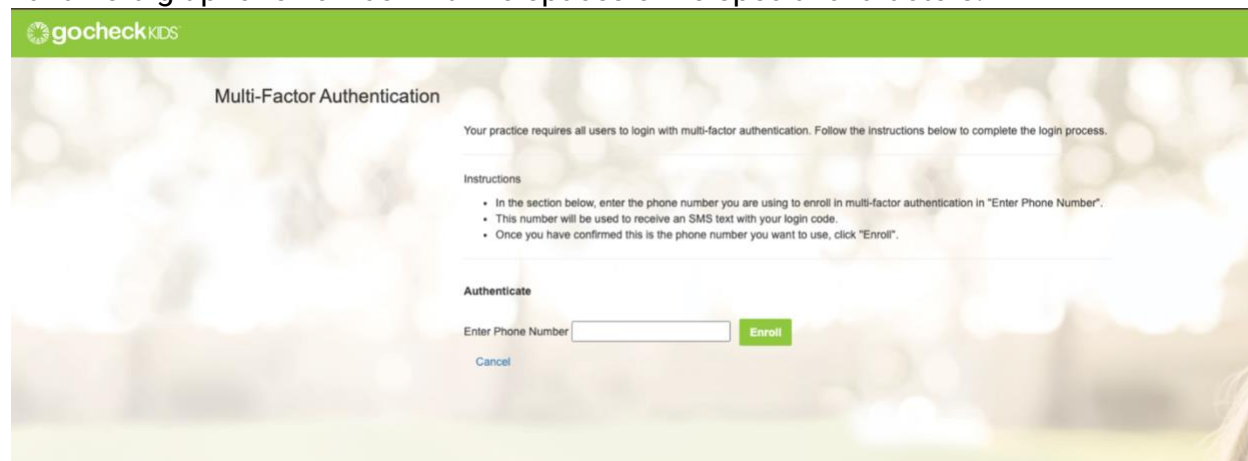
- Be at least 8 characters long.
- Include characters from three of the following four categories:
 - upper case letter (A-Z), lower case letter (a-z), number (0-9), special character
- Not be the same as username, first name, last name or the practice name

 Below these instructions is a green 'Sign Up' button. At the bottom, there is a link: 'Already have an account? [Log in](#)'.

Your administrator may have already associated your phone number with your email. If so, you will not be prompted to enter your phone number to sign up.

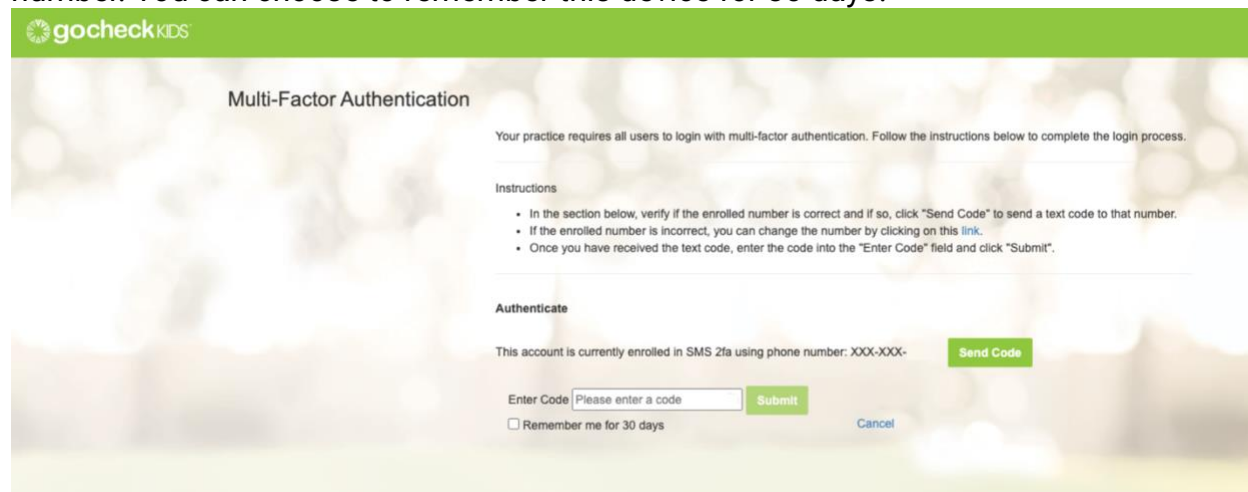
Multi-Factor Authentication Prompts

If your practice enables text-based multi-factor authentication after member accounts have been set up, you may be prompted to enter your phone number. Please enter a valid 10-digit phone number with no spaces or no special characters.



The screenshot shows the 'Multi-Factor Authentication' page on the gocheckKIDS portal. At the top, the gocheckKIDS logo is visible. The page title is 'Multi-Factor Authentication'. Below the title, a message states: 'Your practice requires all users to login with multi-factor authentication. Follow the instructions below to complete the login process.' Under the 'Instructions' section, there are three bullet points: 'In the section below, enter the phone number you are using to enroll in multi-factor authentication in "Enter Phone Number".', 'This number will be used to receive an SMS text with your login code.', and 'Once you have confirmed this is the phone number you want to use, click "Enroll".' The 'Authenticate' section contains a text input field labeled 'Enter Phone Number' and a green 'Enroll' button. A 'Cancel' link is located below the input field.

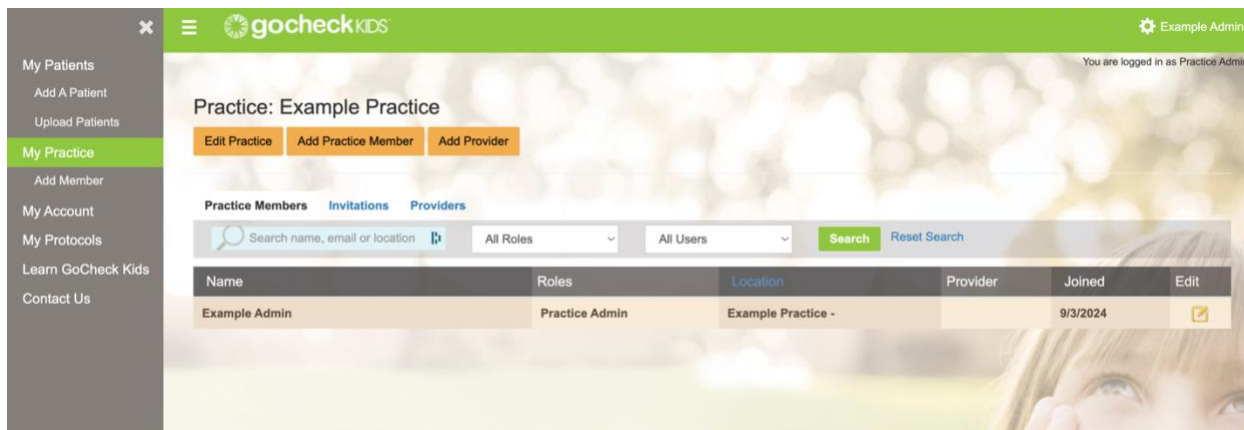
Once you are enrolled in multi-factor authentication, you will occasionally be prompted to authenticate your account with a 6-digit code in a text message sent to your phone number. You can choose to remember this device for 30 days.



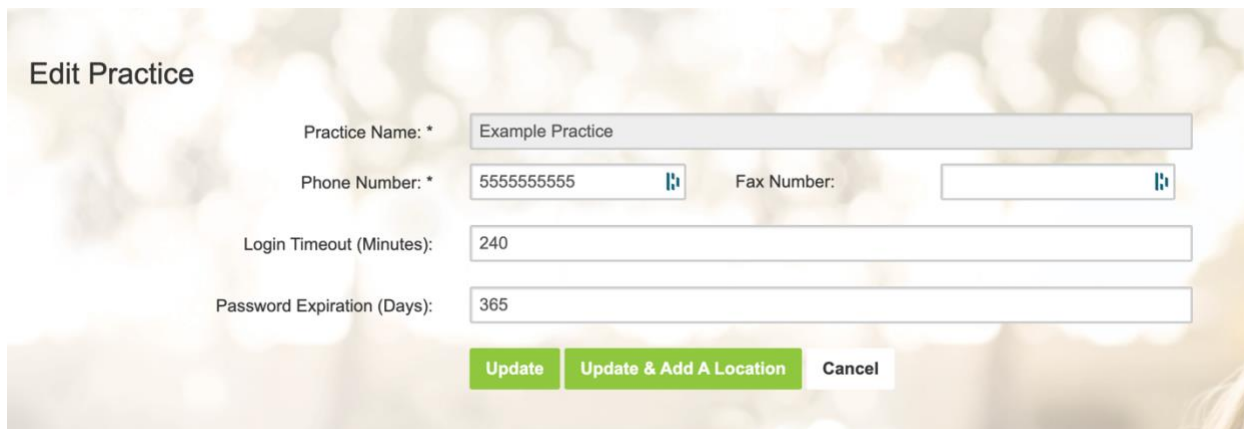
The screenshot shows the 'Multi-Factor Authentication' page on the gocheckKIDS portal, specifically the authentication step. The gocheckKIDS logo is at the top. The page title is 'Multi-Factor Authentication'. A message states: 'Your practice requires all users to login with multi-factor authentication. Follow the instructions below to complete the login process.' Under the 'Instructions' section, there are three bullet points: 'In the section below, verify if the enrolled number is correct and if so, click "Send Code" to send a text code to that number.', 'If the enrolled number is incorrect, you can change the number by clicking on this [link](#).', and 'Once you have received the text code, enter the code into the "Enter Code" field and click "Submit".' The 'Authenticate' section shows the message 'This account is currently enrolled in SMS 2fa using phone number: XXX-XXX-'. To the right of this message is a green 'Send Code' button. Below this, there is a text input field labeled 'Enter Code' with the placeholder text 'Please enter a code', a green 'Submit' button, and a checkbox labeled 'Remember me for 30 days'. A 'Cancel' link is located at the bottom right of the form.

Entering and Editing Practice Info

If you are the administrator for your practice, you will be able to enter and update the information for your practice on the portal.



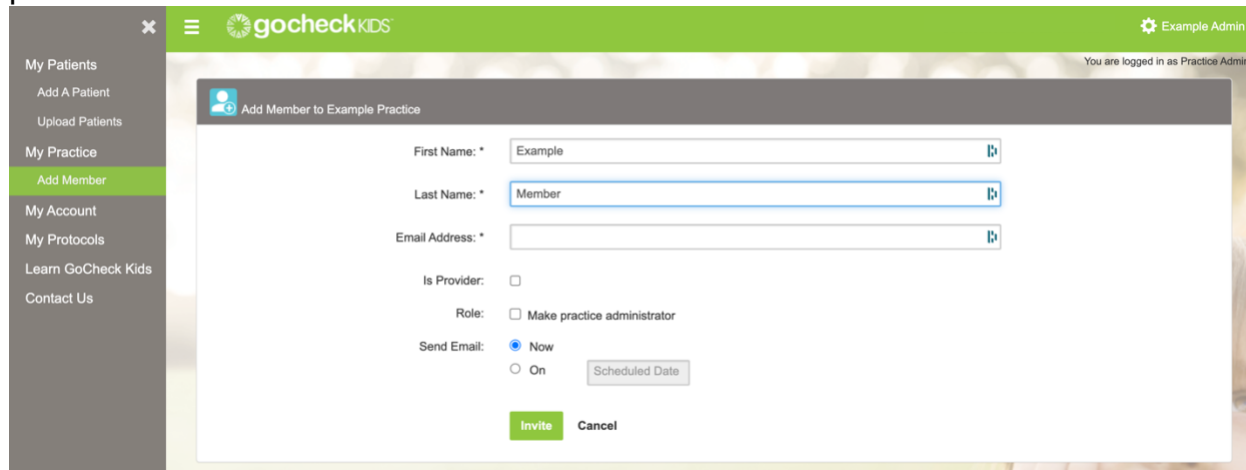
Click on the “Edit Practice” button to update the information for your practice.



Inviting Practice Users

You can add a user to your practice with the “Add Practice Member” button.

You will be able to enter your practice member’s first and last name, email, phone number, practice location, and role. This invitation will be sent as an email to your new practice member.



Setting Up Multi-Factor Authentication for Your Practice

On the GoCheck Kids platform, Multi-Factor Authentication can be enabled for the GoCheck Web Portal. GoCheck’s Multi-Factor Authentication uses a Text-Based Authentication (SMS) method.

Multi-Factor Authentication is enabled by the GoCheck Kids Support team and is controlled on the practice level. Once enabled, all users associated with that practice will be required to enroll and authenticate upon successful login to the GoCheck Web Portal.

Enabling Multi-Factor Authentication

To enable Multi-Factor authentication, submit a request to the GoCheck Kids Support team. The request should include the following information:

- The name of the practice in the GoCheck Kids platform.
- The date and time for when your practice wants to go-live with Multi-Factor authentication.

Contact information for GoCheck Kids Support:

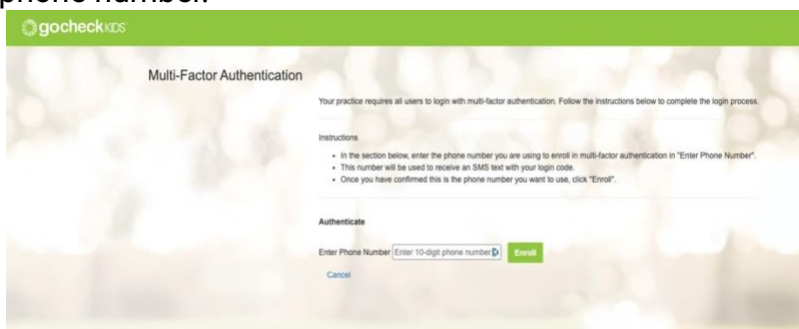
- Email: support@gocheckkids.com
- Phone Number: 1-866-633-9243

Enrollment & Verification

Once Multi-Factor Authentication is enabled for a practice, there are several ways to enroll users.

For existing user accounts:

1. Upon initial log in to the GoCheck Web Portal, the user will be asked to enroll a phone number.



The screenshot shows the 'Multi-Factor Authentication' page in the GoCheck Kids portal. It includes instructions for enrolling a phone number and a form to enter the phone number.

Multi-Factor Authentication

Your practice requires all users to login with multi-factor authentication. Follow the instructions below to complete the login process.

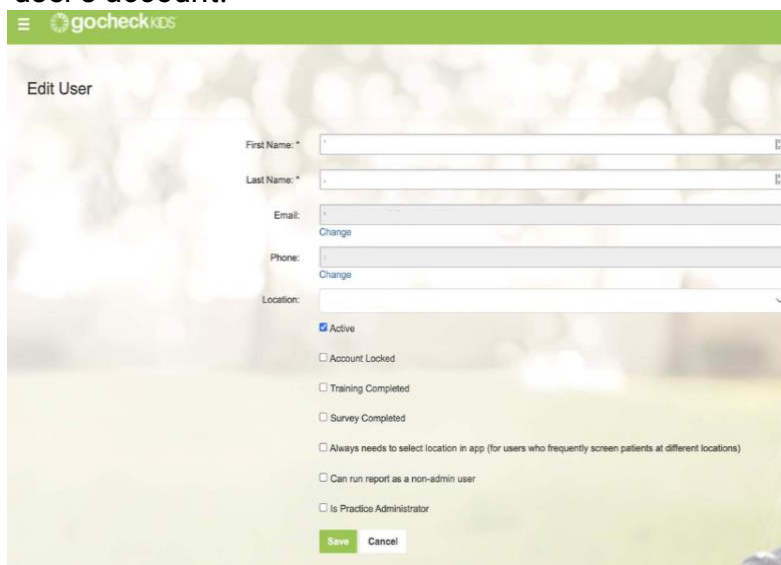
Instructions

- In the section below, enter the phone number you are using to enroll in multi-factor authentication in "Enter Phone Number".
- This number will be used to receive an SMS text with your login code.
- Once you have confirmed this is the phone number you want to use, click "Enroll".

Authenticate

Enter Phone Number

2. A practice administrator for the practice can manually add a phone number to a user's account.



The screenshot shows the 'Edit User' page in the GoCheck Kids portal. It includes fields for user information and checkboxes for user status and permissions.

Edit User

First Name: *

Last Name: *

Email:

Phone:

Location:

☒ Active

☐ Account Locked

☐ Training Completed

☐ Survey Completed

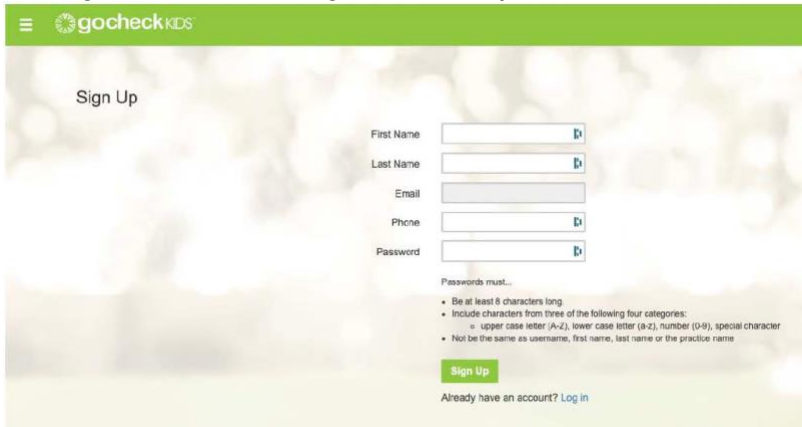
☐ Always needs to select location in app (for users who frequently screen patients at different locations)

☐ Can run report as a non-admin user

☐ Is Practice Administrator

For new user accounts:

1. During user account registration, a phone number can be added to the account.

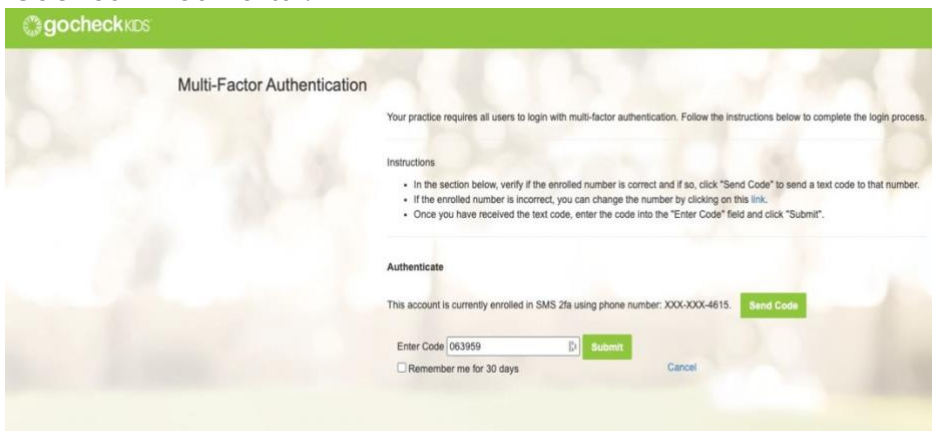


The image shows the 'Sign Up' page for GoCheck KIDS. The page has a green header with the GoCheck KIDS logo. The main content area has a light green background with a blurred image of children. The 'Sign Up' form includes fields for First Name, Last Name, Email, Phone, and Password. Below the Password field, there are instructions: 'Passwords must...' followed by a bulleted list:

- Be at least 8 characters long
- Include characters from three of the following four categories:
 - upper case letter (A-Z), lower case letter (a-z), number (0-9), special character
- Not be the same as username, first name, last name or the practice name

 Below the instructions is a green 'Sign Up' button and a link 'Already have an account? Log In'.

2. Upon successful enrollment, users will be required to authenticate using a verification code sent to the enrolled phone number when trying to log in to the GoCheck Web Portal.



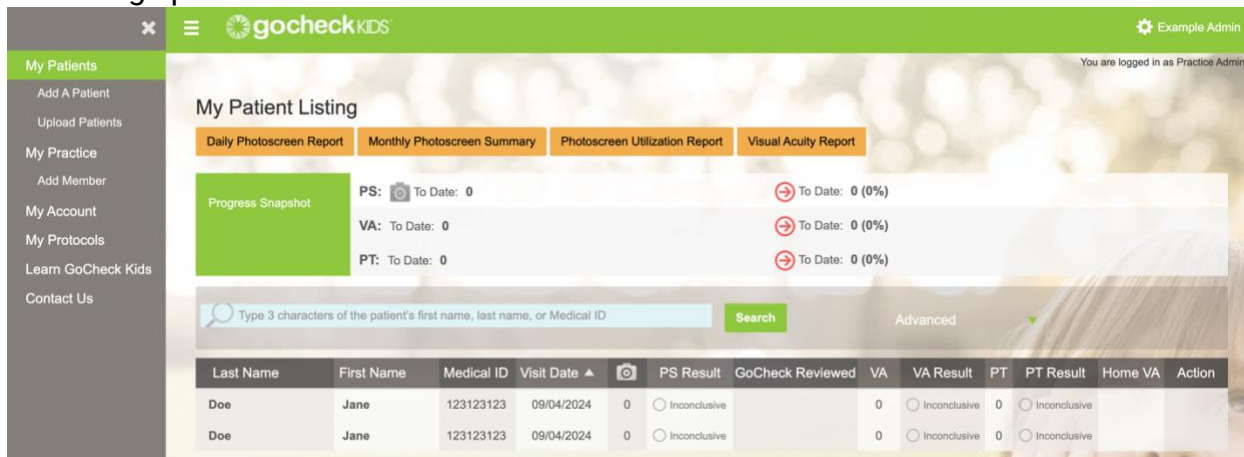
The image shows the 'Multi-Factor Authentication' page for GoCheck KIDS. The page has a green header with the GoCheck KIDS logo. The main content area has a light green background with a blurred image of children. The 'Multi-Factor Authentication' section includes the text: 'Your practice requires all users to login with multi-factor authentication. Follow the instructions below to complete the login process.' Below this is an 'Instructions' section with a bulleted list:

- In the section below, verify if the enrolled number is correct and if so, click "Send Code" to send a text code to that number.
- If the enrolled number is incorrect, you can change the number by clicking on this link.
- Once you have received the text code, enter the code into the "Enter Code" field and click "Submit".

 Below the instructions is an 'Authenticate' section. It includes the text: 'This account is currently enrolled in SMS 2fa using phone number: XXX-XXX-4615.' To the right of this text is a green 'Send Code' button. Below the text is an 'Enter Code' field with the value '063959' and a green 'Submit' button. To the left of the 'Submit' button is a checkbox labeled 'Remember me for 30 days'. To the right of the 'Submit' button is a 'Cancel' link.

Screening Metrics/ Reporting

You will be able to view photoscreening and visual acuity reporting for your practice in the portal. On the My Patients page, you will see a list of reports available at the top of the page. Click on the desired report to start the report generation process. Under the reports, you can also see a progress snapshot that shows the total number of screenings performed and the total number of risk factors identified to date.



My Patient Listing

Daily Photoscreen Report | Monthly Photoscreen Summary | Photoscreen Utilization Report | Visual Acuity Report

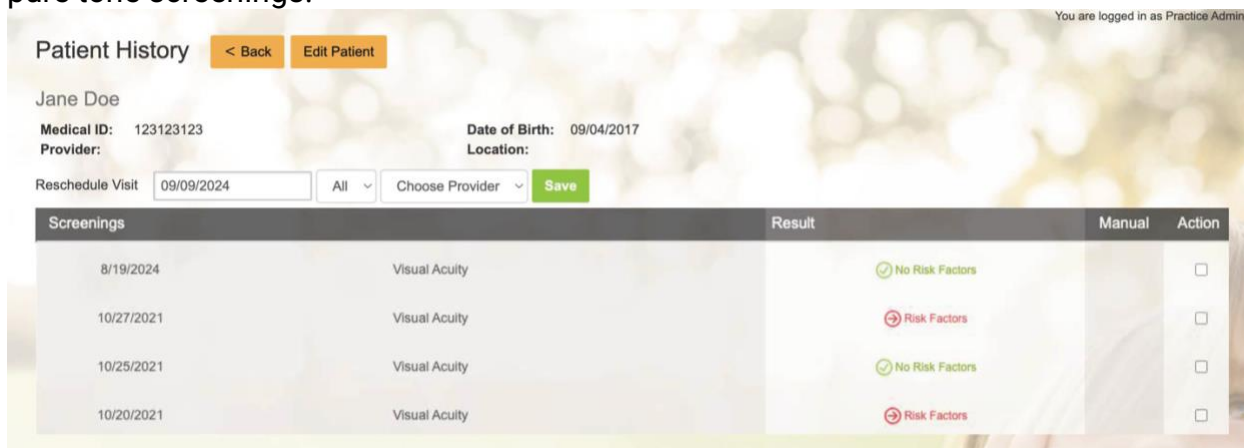
Progress Snapshot

PS: To Date: 0 To Date: 0 (0%)
 VA: To Date: 0 To Date: 0 (0%)
 PT: To Date: 0 To Date: 0 (0%)

Type 3 characters of the patient's first name, last name, or Medical ID **Search** Advanced

Last Name	First Name	Medical ID	Visit Date	PS Result	GoCheck Reviewed	VA	VA Result	PT	PT Result	Home VA	Action
Doe	Jane	123123123	09/04/2024	0 Inconclusive		0	Inconclusive	0	Inconclusive		
Doe	Jane	123123123	09/04/2024	0 Inconclusive		0	Inconclusive	0	Inconclusive		

PS Results are for photoscreening, VA Results are for visual acuity, PT Results are for pure tone screenings.



Patient History < Back Edit Patient

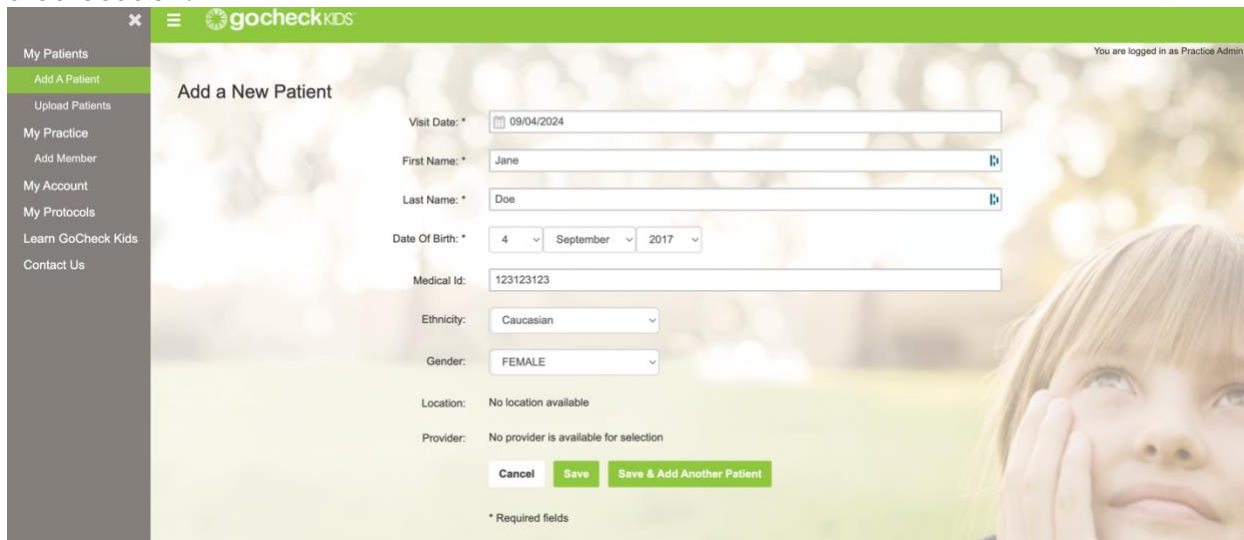
Jane Doe
 Medical ID: 123123123 Date of Birth: 09/04/2017
 Provider: Location:

Reschedule Visit 09/09/2024 All Choose Provider **Save**

Screenings	Result	Manual	Action
8/19/2024 Visual Acuity	No Risk Factors		<input type="checkbox"/>
10/27/2021 Visual Acuity	Risk Factors		<input type="checkbox"/>
10/25/2021 Visual Acuity	No Risk Factors		<input type="checkbox"/>
10/20/2021 Visual Acuity	Risk Factors		<input type="checkbox"/>

Updating a Patient Record

To change a patient's record, select the patient and hit "Edit" in the top right corner. You can edit the patient's information or change the practice location of the most recent test via this form. Note: changing the practice location will move the patient's test results to that location.



Add a New Patient

Visit Date: * 09/04/2024

First Name: * Jane

Last Name: * Doe

Date Of Birth: * 4 September 2017

Medical ID: 123123123

Ethnicity: Caucasian

Gender: FEMALE

Location: No location available

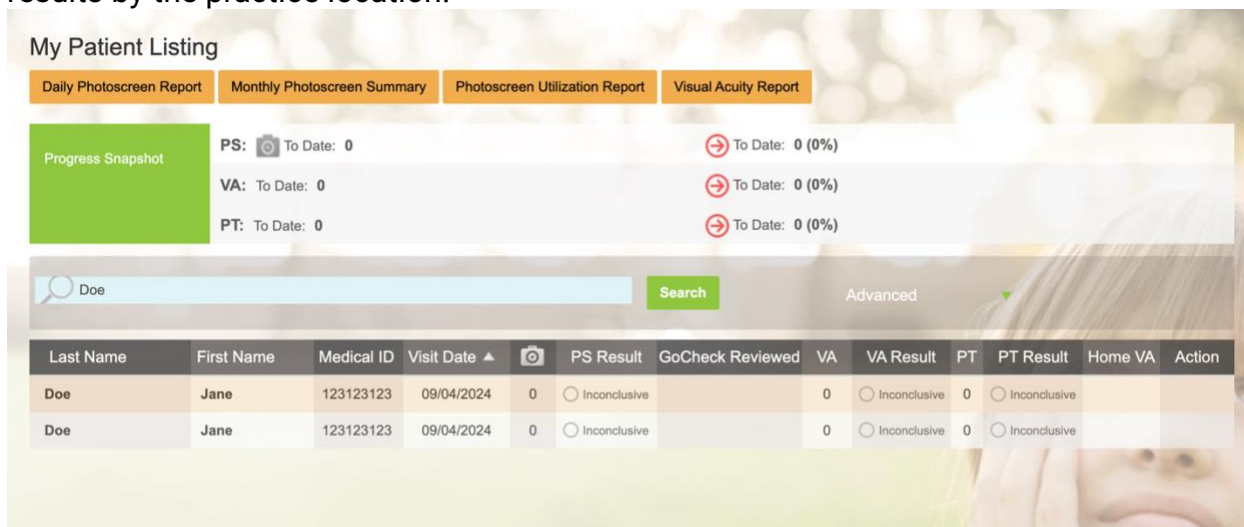
Provider: No provider is available for selection

Cancel Save Save & Add Another Patient

* Required fields

Viewing and Searching a Patient Record

From the "My Patients" page, you can search for a specific patient record. Type the patient's name or medical ID number to locate a patient record. You can narrow search results by the practice location.



My Patient Listing

Daily Photoscreen Report Monthly Photoscreen Summary Photoscreen Utilization Report Visual Acuity Report

Progress Snapshot PS: To Date: 0 VA: To Date: 0 PT: To Date: 0

Doe Search Advanced

Last Name	First Name	Medical ID	Visit Date	PS Result	GoCheck Reviewed	VA	VA Result	PT	PT Result	Home VA	Action
Doe	Jane	123123123	09/04/2024	0 Inconclusive		0	0 Inconclusive	0	0 Inconclusive		
Doe	Jane	123123123	09/04/2024	0 Inconclusive		0	0 Inconclusive	0	0 Inconclusive		

Adding a Pure Tone Protocol

You can edit or add pure tone protocols on the portal on the “My Protocols” page.



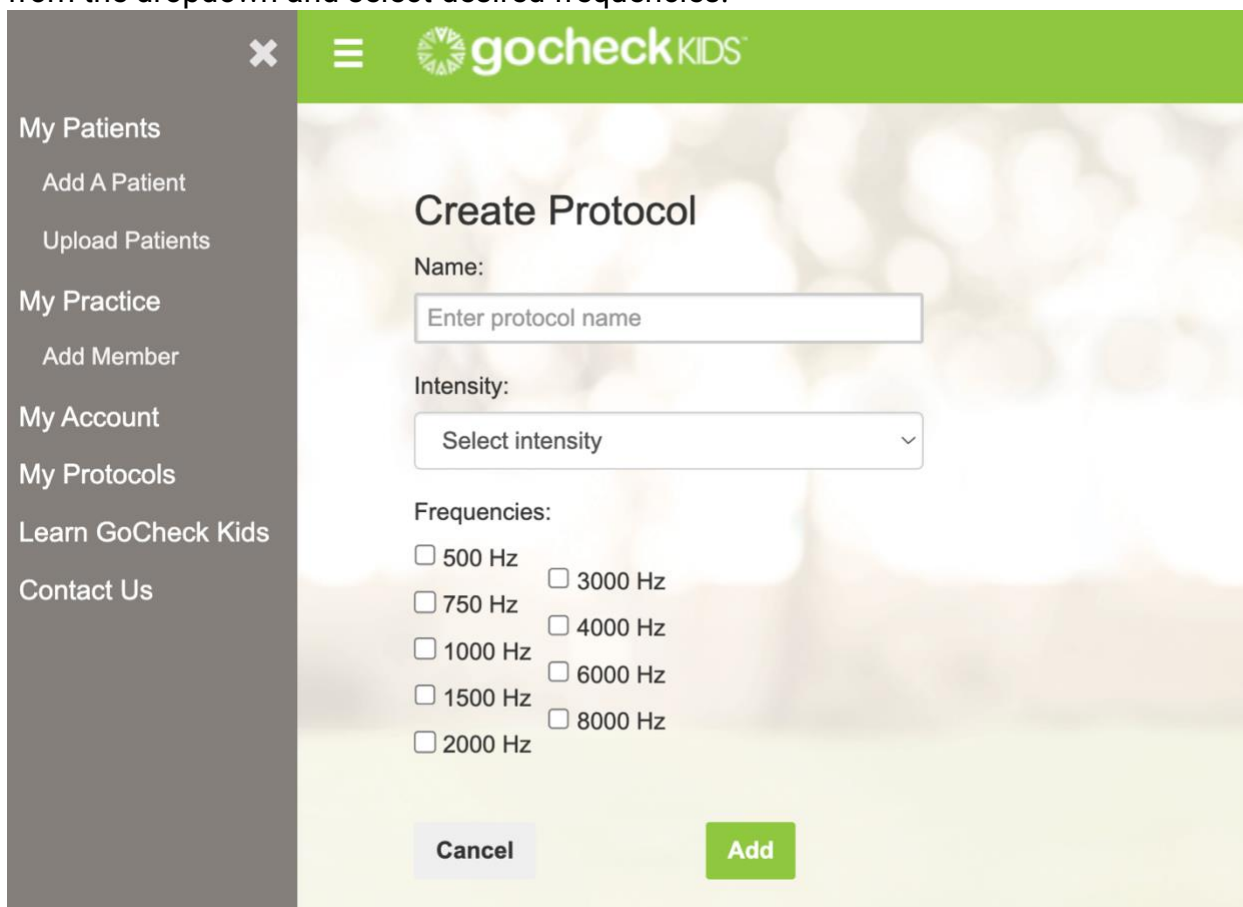
Pure Tone Protocols

Practice:

Current Clinic Selected:

Name	Frequencies	Intensity	Edit
Default for Ages 4-10	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz	20 dB	<input type="checkbox"/>
Default for Ages 11-21	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, 6000 Hz, 8000 Hz	20 dB	<input type="checkbox"/>

To add a custom pure tone screening protocol, click “Add Protocol”. Select an intensity from the dropdown and select desired frequencies.



Create Protocol

Name:

Intensity:

Frequencies:

☐ 500 Hz ☐ 3000 Hz

☐ 750 Hz ☐ 4000 Hz

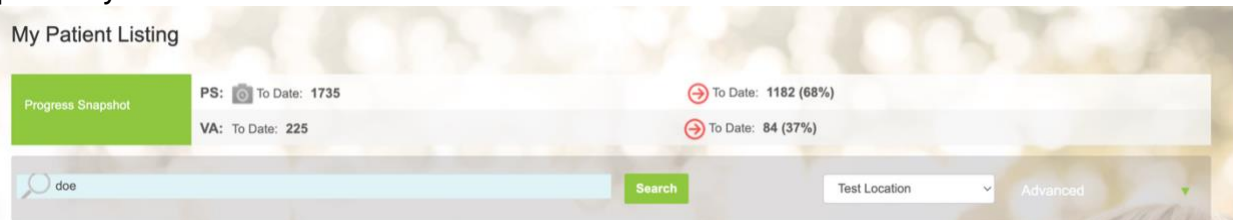
☐ 1000 Hz ☐ 6000 Hz

☐ 1500 Hz ☐ 8000 Hz

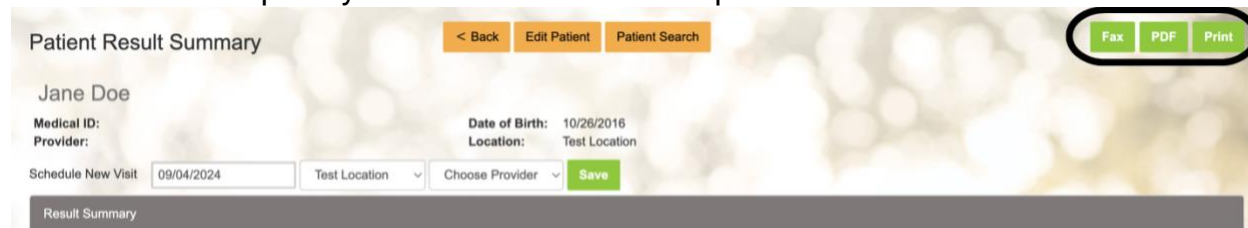
☐ 2000 Hz

Exporting Results- Viewing, Faxing, or Printing PDFs of Patient Results

To export a patient's results using the portal, click "My Patients" and search for the patient you would like results for.



Click on the patient to bring up the patient's record. Click on the screening you would like to export or print. You have three options in the upper right corner: Fax, PDF, and Print. Select the option you would like to use to export the results.



If your company has an EHR integration with GoCheck Kids, talk to your EHR integration specialist about exporting results to your EHR system.

You can fax your screening results. Click the Fax button on the results screen. There will be a confirmation pop-up box that will say "Fax Requested" indicating that the fax has been successfully processed.

If your practice has an AirPrint-enabled printer, you can print the patient's screening results. The printer needs to be discoverable wirelessly through Wifi and paired with the GoCheck MultiScreener device. Click the "Print" button to export your results to the printer.

You can export your screening results as a PDF from the web portal and it will be downloaded onto your computer.

Troubleshooting Common Problems/ FAQs

Photoscreening FAQs

[Why did I receive a Not Gradable photoscreening result?](#)

There are a few reasons why you may receive a Not Gradable result. There could be issues with image quality. For example, if the child is not looking directly at the camera or the photo is blurry from motion, you will get a Not Gradable result. Lighting may need to be adjusted, as overly bright lighting can interfere with screening results. If you do receive a Not Gradable result, you should try again and take another image.

[How can I adjust the lighting to perform photoscreening?](#)

Photoscreening should be performed in an environment with dim, ambient lighting to ensure effectiveness of the photoscreening. Please turn off overhead lights, hall lights and other sources of light (i.e. laptop or smartphone screen, lamp stand, tablets, windows, etc.). These light sources can cause extraneous reflections on the cornea. The dim lighting also ensures proper pupil size for photoscreening measurements. Use the door to control the amount of lighting in the room. If the room has blinds, you may need to adjust the blinds to filter more light.

Visual Acuity FAQs

[Can I remove the crowding bars around the letters?](#)

No, GoCheck Kids visual acuity incorporates crowding bars which are recommended best practice for testing young children. Crowding bars are the vertical and horizontal bars surrounding a letter in a visual acuity test.

[What optotypes are available for visual acuity?](#)

The GoCheck Kids visual acuity test uses recommended optotypes based on age: HOTV optotypes with crowding bars for children under 7 years and Sloan optotypes in a modified-ETDRS approach for children 7 years and up.

[Can visual acuity be performed at distances other than 10 feet?](#)

The GoCheck Kids visual acuity test is designed for use at 10 feet to test distance visual acuity. The test is not designed for other distances.

Hearing FAQs

[Are my login credentials the same in the hearing app as the vision app?](#)

Yes, you will use the same login credentials for both the vision app and the hearing app. You can be logged into both apps at the same time.

[What kind of test environment should I use for hearing screening?](#)

To ensure best results, please minimize background noise and other distractions for hearing screening.

Can I still use my device if my headphones are past due for calibration?

Yes, you can still perform hearing screenings even if your headphones are past due for calibration, however, GoCheck recommends keeping up with annual calibration which is included with your hearing screening subscription. You may see a reminder to send in your headphones for calibration.

Web Portal FAQs

Will I be able to see both hearing and vision results in the web portal?

Yes, both hearing and vision results will be visible.

Which browsers does the GoCheck web portal support?











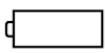

The web portal currently supports Chrome, Edge, Firefox and Safari. GoCheck does not recommend or support Internet Explorer for web portal use.


Support

For additional support, contact customer support at support@gocheckkids.com or call 866-633-9243.

Symbols Glossary

These symbols may be used in the GoCheck Kids product labeling.

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	21 CFR Part 801	Medical devices - Labeling	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.
	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1: 2021 Reference no. 5.1.3. (ISO 7000-2497)	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured
	ISO 15223-1:2021 Reference no. 5.4.3. (ISO 7000-1641)	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use iso_15223 Consult instructions for use iso_grs_7000_1641 Operator's manual; operating instructions
	ISO 15223-1: 2021 Reference no. 5.4.4. (ISO 7000-0434A)	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	iso_grs_7010_W001	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	General warning sign	To signify a general warning
	ISO15223-1: 2021 Reference no. 5.7.10	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Unique device identifier	Indicates a carrier that contains unique device identifier information
	ISO 15223-1: 2021 Reference no. 5.1.5. (ISO 7000-2492)	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified. Synonyms for "batch code" are "lot number", "lot code" and "batch number".
	ISO 15223-1: 2021 Reference no. 5.1.7. (ISO 7000-2498)	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	ISO 7000 Reference no. 0623	Graphical symbols for use on equipment - registered symbols	This way up	N/A
	IEC 60417 Reference no. ISO 7000-5001B	Graphic symbols for use on electrical equipment	Battery, general	On battery powered equipment
	N/A	N/A	SOC-2 Audit Badge	Service Organization Controls (SOC) 2 audit, a 3 rd party cybersecurity audit

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ANSI Z535	Safety Colors	Strong Magnetic Field	This product generates stronger permanent magnetic fields that could cause interference to cardiac pacemakers, implanted defibrillators (ICDs) and other implants. Always maintain a distance of at least 3.94" (10 cm) between the product component containing the magnet (the earmuffs) and the cardiac pacemaker, implanted defibrillator, or other implant.



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