



GoCheck i7P MultiScreener- P/N 9000-008 Revision A



GoCheck MultiScreener User Manual

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Welcome to GoCheck!

This manual provides important information regarding the use of the GoCheck i7P MultiScreener and should be read before using the application and device. This manual serves to provide you with general operating instructions.

The GoCheck i7P 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 i7P 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

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.

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.

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"

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 Search 		• 🕩	< Search 🗢	9:59 AM	•
	Settings		Settings Te	ouch ID & Passco	ode
(1)	Sounds & Haptics	>	FINGERPRINTS		
C	Do Not Disturb	>	Finger 1		>
X	Screen Time	>	Add a Fingerpri	nt	
Ø	General	· >	Turn Passcode	On	
	Control Center	>	Change Passco		
AA	Display & Brightness	>			
(1)	Accessibility	>	Require Passco	de	Immediately >
*	Wallpaper	>		•	
	Siri & Search	>	Voice Dial		
	Touch ID & Passcode	>	Music Voice Contro	l is always enabled.	
SOS	Emergency SOS	>	ALLOW ACCESS W	HEN LOCKED:	
	Battery	>	Today View		
	Privacy	>	Notification Ce	nter	
			Control Center		
A	iTunes & App Store	>	Siri		



Optional Accessory: Attractor Setup

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



To set up this accessory, place the attractor on the back of the GoCheck Kids vision 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.**





Device Maintenance

Calibration and Preventive Maintenance

The GoCheck i7P 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: The GoCheck Audiometric Headphones accessory will require annual recalibration.

Software Updates

The GoCheck i7P 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 i7P 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 i7P MultiScreener uses an iPhone lightning charging cable which is provided with the unit.

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.



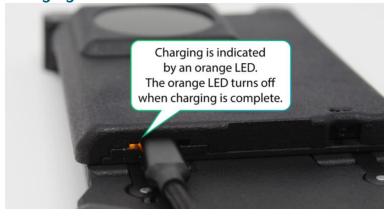
Storing the Device

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.

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.

Attention: If you have gone past the calibration date, a prompt will show up in the hearing mobile app and you will not be able to proceed to screening.

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 should enable 2-Factor Authentication on the web portal for increased security. 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.

To Log in to the app:

- Use your email address as username and password created during registration





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.

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≡	Patients	Add
01/20/2018		
Jane Doe		
01/18/2018		
Johnathan	Doe	\oslash
Sarah Smit	h	
01/16/2018		
Sally Smith		
01/15/2018		
Mary Major		\odot
Richard Ro	e	0
01/12/2018		
Rachel Roe		\oslash



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

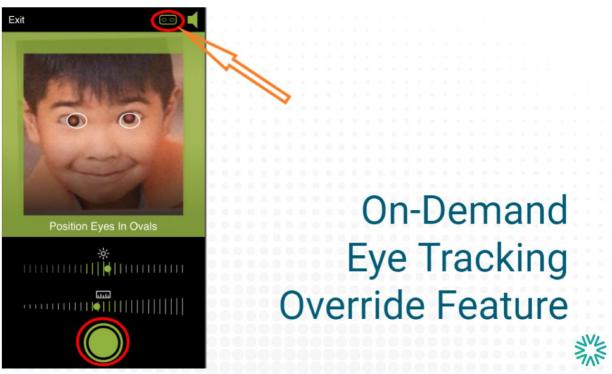
To begin a photoscreening test, navigate to the patient's record and select "Start Photoscreening".



The child must be looking directly at the camera, the room must be dimly lit, and the test distance must be 40 inches. At this point, a green box will appear around the patient's face. Press the green button to take a picture.

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 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 at the top right of your screen, with the goggles icon. You will see a pair of ovals to position the eyes in manually.

GoCheck Kids Vision App Icons Legend:

\odot	Result - No Risk Factors Identified
0	Result - Not Gradeable
Θ	Result - Risk Factor Identified
	Toggle Sound On/Off
<u> </u>	Brightness
لىلىلىا	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.



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

Start the attractor light before beginning your photoscreening session.



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.





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.



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.

To Log in to the app:

- Use your email address as username and password created during registration





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.

📶 Verizon 🗢	2:57 PM	∜ ≵ 62% ■)
=	Patients	Add
01/20/2018		
Jane Doe		
01/18/2018		
Johnathan	Doe	\oslash
Sarah Smit	h	
01/16/2018		
Sally Smith		
01/15/2018		
Mary Major		\odot
Richard Ro	e	O
01/12/2018		
Rachel Roe		\oslash



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

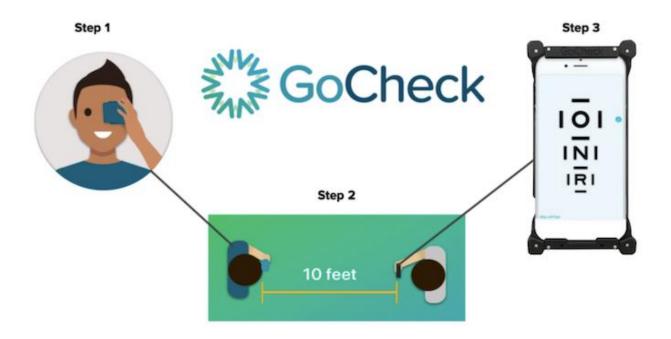
To begin a Visual Acuity test, navigate to the patient's record and select "Start Visual Acuity Test".



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.





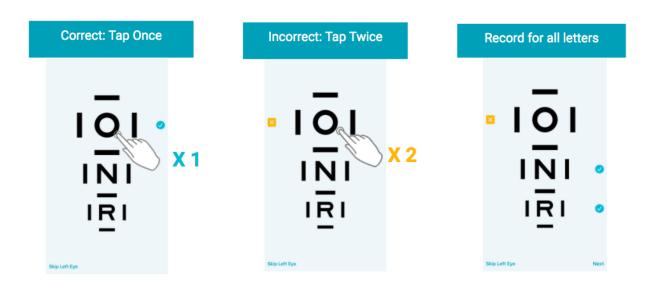
Ask the patient to read the letters inside the crowding bars from top to bottom. Make sure to remember the patient's responses.

Read from top to bottomImage: state of the state

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.

Ask patient to:





Accessing Visual Acuity Results

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

	Newly added	d (PHI hidden)	Done
Age 4			
	No risk fact	tor identified	
	8/26/202	0 04:30 PM	
	Visual Ac	uity Result	
	Right Eye	Left Eye	
	20/20 LogMAR: 0.00	20/20 LogMAR: 0.00	
	Optoty Distanc	0/40 for age 4 be: HOTV e: 10 feet rection: none	
	Scroll to v	view details	

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

Print

Fax



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.

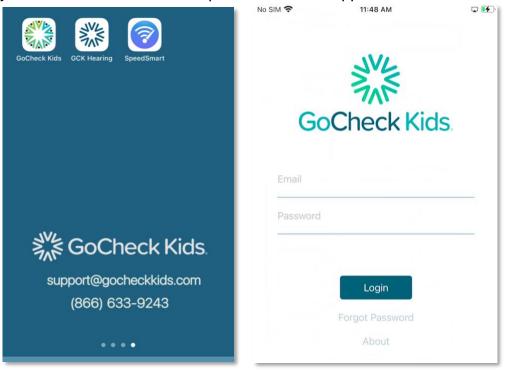
By default, users will have access to two screening protocols that follow AAP recommendations:

- 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.

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MENU Patients	ADD
Q Find patient by name or ID	
09/03/2024	
JANE DOE	SCREEN
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	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

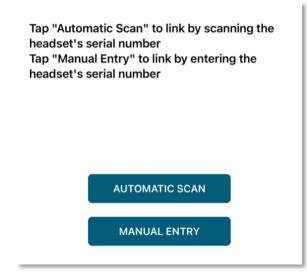
WARNING: The headphones accessory generates stronger permanent magnetic fields that could cause interference to cardiac pacemakers, implanted defibrillators (ICDs) and other implants. Always maintain a distance of at least 3.94" (10 cm) between the product component containing the magnet (the earmuffs)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





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

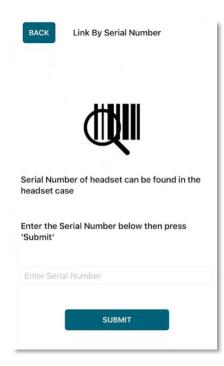


The 10-character serial number of the headphones is located inside the headphones band, below the QR code. Additionally, the serial number can be found on the UDI Label in the headphones band.



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

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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.

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MENU	Patients	ADD
Q 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: 01/2	20/2017		
Medical ID: JD200	0117		
Ethnicity: Unspecif	ied		
Gender: Female	J		
CONDUCT PURE TONE SCREENING			
LATEST VISIT			
Visit Date	Pure Tone (PT)		
08/23/2024	⊘ 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:



MENU	Select Protocol	REFRESH						
Patient: Jar	Patient: Jane Doe							
Protocol:	Default for Ages 4-10							
	•							
	otocol field and select or a screening	the protocol						
2. Tap 'REFR available pro	ESH' to refresh the list stocols	t of						
3. Tap 'PLAY	3. Tap 'PLAY' to begin a screening							
PLAY								

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

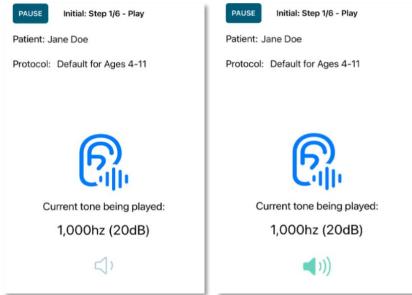
Test Phase

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.



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

PAUSE Initial: Step 1/2 - Capture	PAUSE Initial: Step 2/6 - Ready
Patient: Jane Doe	Patient: Jane Doe
Protocol: Mock Protocol	Protocol: Default for Ages 4-11
•?	
Did the patient hear the tone?	
	1. When ready, press PLAY to send the tone
	PLAY
NO YES	



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

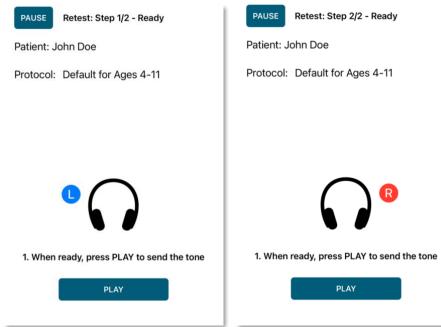
Tones that are marked not heard twice in a row will be flagged for the retest phase. The retest tones will play after the protocol tones have all played once, before the end of the screening.

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

Patient: John Doe Protocol: Default for Ages 4-11	PAUSE	Retest: Step 1/2 - Ready					
Image: Constraint of the constraint	Patient: J	lohn Doe					
Patient has failed one or more frequencies. A retest will now be performed. OKAY	Protocol:	Default for Ages 4-11					
Patient has failed one or more frequencies. A retest will now be performed. OKAY							
Patient has failed one or more frequencies. A retest will now be performed. OKAY		\bigcirc					
frequencies. A retest will now be performed.		Retest					
		equencies. A retest will now be					
PLAY		ΟΚΑΥ					
		PLAY					



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.

SULT DETA		Te	est	Det	test
Frequency (Hz)	Intensity (dB)	L	R	L	R
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

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.

My Patients Add A Patient Upload Patients	My Patient Listing							
My Practice	Daily Photoscreen Report	Monthly Photo	screen Summ	ary Photosc	reen Ut	ilization Report	Visual Acuity Report	0-
Add Member	Progress Snapshot	PS: 👩 To Dat	ite: 0				To Date: 0	(0%)
My Account My Protocols	Progress Snapanor	VA: To Date: 0	0				To Date: 0	(0%)
Learn GoCheck Kids		PT: To Date: 0)				To Date: 0	(0%)
Contact Us							-	
Contact Us	C Type 3 characters of Last Name F		name, last nam Medical ID		Ø		Search GoCheck Reviewed	VA
Contact Us	Last Name F	First Name I						VA 0
Contact Us	Last Name F	First Name I	Medical ID	Visit Date 🔺	Ø	PS Result		

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.

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.

×					0	Example Admin
My Patients Add A Patient Upload Patients My Practice Add Member	Practice: Example Practice Edit Practice Add Practice Member Add Prov	You are logged	In as Practice Admin			
My Account My Protocols		All Roles ~	All Users - Search	Reset Search		
Learn GoCheck Kids	Name	Roles	Location	Provider	Joined	Edit
Contact Us	Example Admin	Practice Admin	Example Practice -		9/3/2024	8
						1111
					1	Te

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



Practice Name: *	Example Practice	
Phone Number: *	555555555 1 Fax Number:	B
Login Timeout (Minutes):	240	
Password Expiration (Days):	365	

Inviting Practice Users

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

×	≡ ⊜gocheck k⊡s				•	
My Patients Add A Patient Upload Patients My Practice Add Member My Account	Practice: Example Practice Edit Practice Add Practice Member Add Provider Practice Members Invitations Providers	\$	You are logged in as Practice			
My Protocols	Search name, email or location 🚯 All F	Roles ~ All Users	~ Search Re	set Search	1	T. A.J.A.S
Learn GoCheck Kids	Name	Roles	Location	Provider	Joined	Edit
Contact Us	Example Admin	Practice Admin	Example Practice -		9/3/2024	
				1		

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

×	≡ § gocheck k⊡s	🔅 Example Admin
My Patients Add A Patient		You are logged in as Practice Admin
Upload Patients	Add Member to Example Practice	
My Practice	First Name: *	ixample (1)
Add Member	Last Name: *	fember lå
My Account My Protocols	Email Address: *	D.
Learn GoCheck Kids	Is Provider:	
Contact Us		Make practice administrator
	Send Email:	Now
	0	On Scheduled Date
		Invite Cancel



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.

×	⊜gochec l	KIDS								ф Б		nin
My Patients Add A Patient Upload Patients	My Patient Listin	g	PS:	×	1.44		C	0	You	are logged in a	Practice Ac	.lmin
My Practice	Daily Photoscreen Report	Monthly Photoscreen Sum	mary Photoscre	en Utilization Report	Visual Acuity Report							
Add Member My Account My Protocols Learn GoCheck Kids	Progress Snapshot	PS: To Date: 0 VA: To Date: 0 PT: To Date: 0			 → To Date: 0 (→ To Date: 0 (→ To Date: 0 (0%)						-
Contact Us	Type 3 characters of	the patient's first name, last n	ime, or Medical ID		Search				*///			
	Last Name F	irst Name Medical ID	Visit Date 🔺	DS Result	GoCheck Reviewed	VA	VA Result	PT	PT Result	Home VA	Action	
	Doe	Jane 123123123	09/04/2024	0 O Inconclusive		0	O Inconclusive	0 (O Inconclusive			0
	Doe J	Jane 123123123	09/04/2024	0 O Inconclusive		0	O Inconclusive	0	O Inconclusive		-	

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

Patient History < Back Jane Doe Medical ID: 123123123	Edit Patient Date of Birth: 09/04/2017		You are logged in as Practice A
Provider:	Location:		
Reschedule Visit 09/09/2024	All Choose Provider Save		
Screenings	And the other Designation of the Owner, where the other Designation of the Owner, where the Owner, where the O	Result	Manual Action
8/19/2024	Visual Acuity	O No Risk Factors	0
10/27/2021	Visual Acuity		0
10/25/2021	Visual Acuity	No Risk Factors	0
10/20/2021	Visual Acuity		0
			1



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.

×			🔅 Elizabeth Ham
My Patients	hard to be a first to		You are logged in as Practice Admin
Add A Patient	Add a New Patient		
Upload Patients	Visit Date: *	09/04/2024	
My Practice			
Add Member	First Name: *	Jane	D
My Account My Protocols	Last Name: *	Doe	(b)
Learn GoCheck Kids	Date Of Birth: *	4 v September v 2017 v	The Aller
Contact Us			11/11/13/13
	Medical Id:	123123123	
	Ethnicity:	Caucasian	
	Gender:	FEMALE	
	Location:	No location available	The second second
	Provider:	No provider is available for selection	11.000
		Cancel Save & Add Another Patient	
		* Required fields	1111

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.

Daily Photoscreen Report	Monthly Ph	otoscreen Sumn	hary Photoso	reen Ut	ilization Report	Visual Acuity Report	1					
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%)					
Doe Last Name F	First Name	Medical ID	Visit Date 🔺	Ø	PS Result	Search GoCheck Reviewed		Advanced VA Result	PT	PT Result	Home VA	Action
	Jane	123123123	09/04/2024	0	O Inconclusive		0	O Inconclusive		-		
Doe	Jane	123123123	09/04/2024	0	O Inconclusive		0	O Inconclusive	0	O Inconclusive		



Adding a Pure Tone Protocol

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

y Practice	Name	Frequencies	Intensity	Edit
Add Member	Default for Ages 3-10	1000 Hz, 2000 Hz, 4000 Hz	20 dB	Ø
y Account	Default for Ages 11-21	1000 Hz, 2000 Hz, 4000 Hz, 6000 Hz, 8000 Hz	20 dB	2
/ Protocols	Default for Ages 3-10	1000 Hz, 2000 Hz, 4000 Hz	20 dB	Ø
arn GoCheck Kids	Default for Ages 11-21	1000 Hz, 2000 Hz, 4000 Hz, 6000 Hz, 8000 Hz	20 dB	0
intact Us			110	

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

×	Ξ	Gocheck KIDS [®]
My Patients	and the second	
Add A Patient		
Upload Patients		Create Protocol Name:
My Practice		Enter protocol name
Add Member		Intensity:
My Account		
My Protocols		Select intensity ~
Learn GoCheck Kids		Frequencies:
Contact Us		□ 3000 Hz □ 750 Hz
		□ 4000 Hz □ 1000 Hz
		□ 6000 Hz □ 1500 Hz
		□ 8000 Hz □ 2000 Hz
		Cancel Add



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.

My Patient Listin	ng					
Progress Snapshot	PS: 👩 To Date: 1735	→ To Date: 1182	(i) To Date: 1182 (68%)			
	VA: To Date: 225	To Date: 84 (3)	7%)			-
O doe		Search	Test Location	~		

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.

Patient Result Summary	< Back Edit F	Patient Search	Fax PDF
Jane Doe			
Medical ID: Provider:	Date of Birth: Location:	10/26/2016 Test Location	1

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?

You will be able to continue to perform vision screenings, but you cannot use your device to perform hearing screening until your headphones are re-calibrated.

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.

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
R _x Only			Prescription Use	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare
	21 CFR Part 801	Medical devices - Labeling Medical devices – Symbols to	Only	professional.
	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)	be used with information to be supplied by the manufacturer - Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer
\sim	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
Ĩ	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
\triangle	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
Â	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
UDI	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
LOT	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".
SN	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
<u> 11 </u>	ISO 7000 Reference no. 0623	Graphical symbols for use on equipment - registered symbols	This way up	N/A
٩	IEC 60417 Reference no. ISO 7000- 5001B	Graphic symbols for use on electrical equipment	Battery, general	On battery powered equipment
SOC 2	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.





Gobiquity, Inc. 25020 Avenue Stanford STE 100 Santa Clarita CA 91355



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