



GoCheck Kids User Manual

GoCheck Kids Vision Screener V5 i7PFC - P/N 6003-001
Revision 01

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Welcome to GoCheck Kids!

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

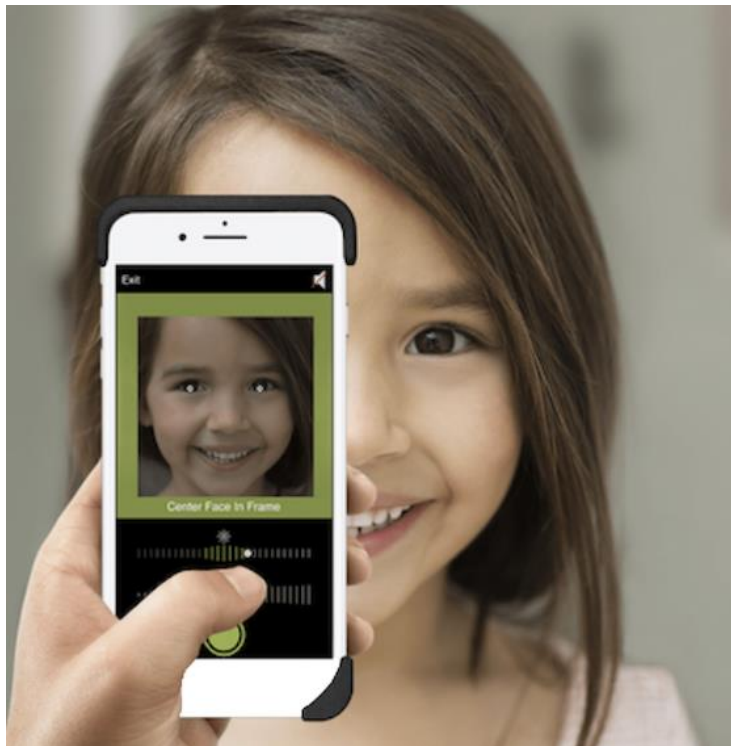
The GoCheck Kids vision screener is continuously undergoing improvement, and, as a result, this document is subject to change. It is not intended to be a complete guide and additional training may be required. For more information on how to use our product, please contact our customer support team at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

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Device Description



GoCheck Kids is a medical device comprised of hardware (flash concentrator case, smartphone with charger block and cable) and software (mobile medical application and web application – i.e., web portal) and an optional accessory (i.e., Attractor) and is intended to screen for vision impairment in children. This device is not a diagnostic tool, rather the vision screening data is used to help determine if a child may require further evaluation by a qualified eye care professional, and the results are presented to parents, teachers, and clinicians. The device is not intended as a substitute for a comprehensive vision evaluation by a qualified eye care professional.

- The GoCheck Kids device includes an ocular photoscreener intended to capture and record light reflex images to aid in vision assessment of children 12 months up to 72 months of age.
- The GoCheck Kids device includes a visual acuity screening tool, which tests each eye individually. It is intended to aid in the vision assessment of children 4 to 21 years of age.
- The GoCheck Kids device includes a web portal which provides access to the user for data management.

NOTE: The Attractor is an optional accessory attached to the GoCheck Kids parent device to support and augment the performance of the parent device. The Attractor indicates where the child should direct their gaze during photoscreening.

Intended Use

GoCheck Kids' intended use is screening as part of periodic visual system assessments in children (i.e., photoscreening and visual acuity tests).

GoCheck Kids is not a diagnostic tool, rather it is a vision screening tool used to help determine if a child may require further evaluation by a qualified eye care professional.

This intended use is accomplished through software applications and hardware components that make up the device.

Indications for Use

GoCheck Kids' indication for use is screening for amblyopia risk factors in children from age 12 months to 72 months (for photoscreening) and vision impairment in children from age 4 years to 21 years (for visual acuity tests).

Contraindications

The GoCheck Kids Vision Screener should not be utilized as a substitute for a comprehensive examination by a qualified eye care professional as this device is a screening tool, not a diagnostic tool.

The GoCheck Kids Vision Screener should NOT be used in clinical circumstances when a diagnostic test is indicated (i.e., child has a known or suspected vision disorder).

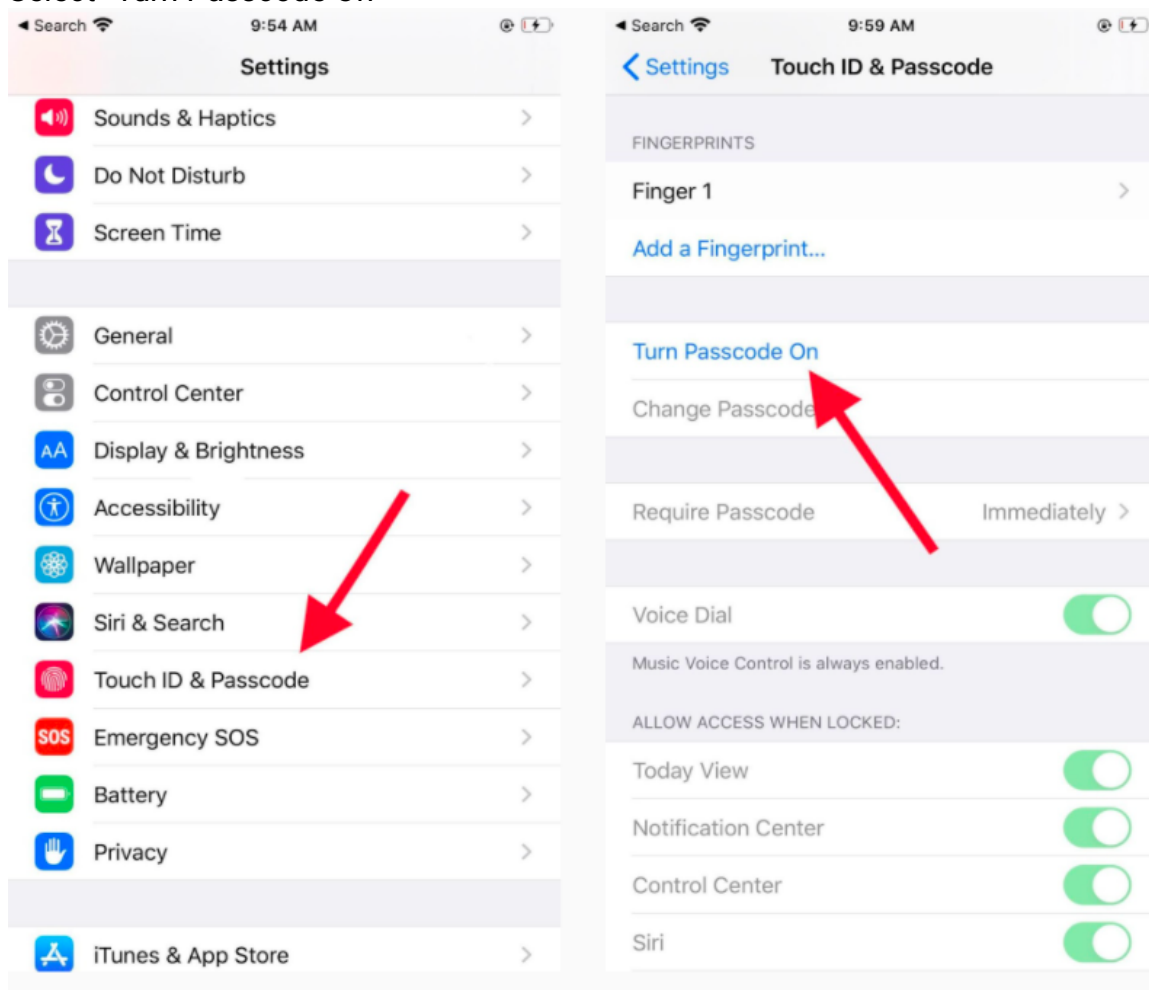
Device Setup

Connect to WiFi through the settings app. Find the email “GoCheck Kids Invitation” in your inbox and click the link. Tap the GoCheck Kids app icon, and login.

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

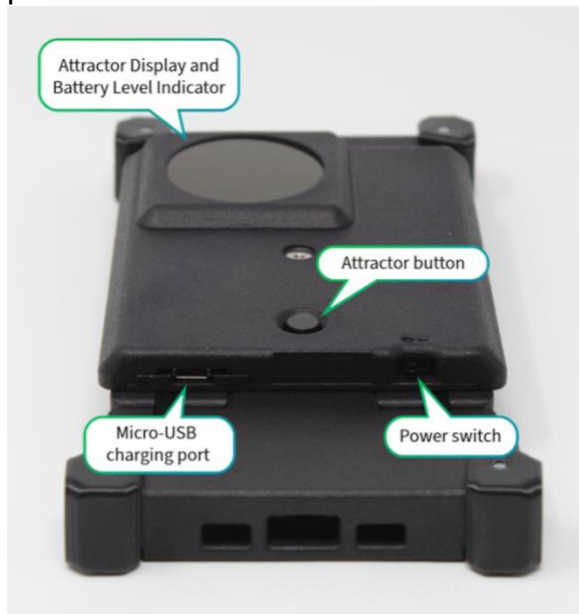
GoCheck Kids requires all devices to be passcode protected. To access the app, you must have your passcode turned on. The passcode is specific to the device, but user credentials are specific to each user. If you are sharing the device with your colleagues, you will login to the device using the same passcode and then log into the app with your own unique user credentials.

- Go to your device settings.
- Select “Touch ID & Passcode”
- Select “Turn Passcode On”



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

Software Updates

The GoCheck Kids (GCK) Device is managed by a Mobile Device Management Solution. The Device iOS and GCK App Software 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.

Cleaning the Device

The GoCheck Kids device (smartphone screen and case) can be cleaned with isopropyl alcohol and a soft cloth. The device should be cleaned regularly or as needed.

Charging the Device

GoCheck Kids uses a standard iPhone 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.

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

Storing the Device

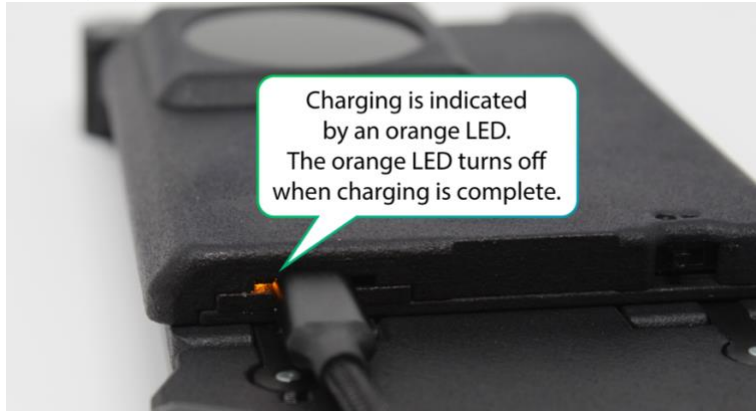
Store your device in a cool, moisture-free environment where the temperature is between -4° to 113° F. Don't leave your device in direct sunlight for extended periods of time, as the device may overheat. Do your best to keep the device within its operating temperatures of 32° to 95° F.

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.

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 is 5-6 hours.

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 portal or power off the device to lock the 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. Please connect the device to a wireless network after screening is completed so that data can be uploaded wirelessly.

Install software updates to the GoCheck Kids app 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 GCK App for Photoscreening

Logging into the GCK App

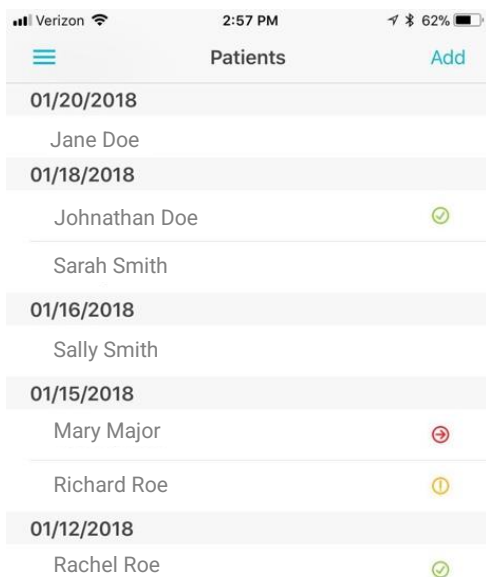
Select the GoCheck Kids App on the home screen. Enter your username and password for the application.

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.



Date	Patient Name	Status
01/20/2018	Jane Doe	
01/18/2018	Johnathan Doe	✓
	Sarah Smith	
01/16/2018	Sally Smith	
01/15/2018	Mary Major	✗
	Richard Roe	⚠
01/12/2018	Rachel 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.

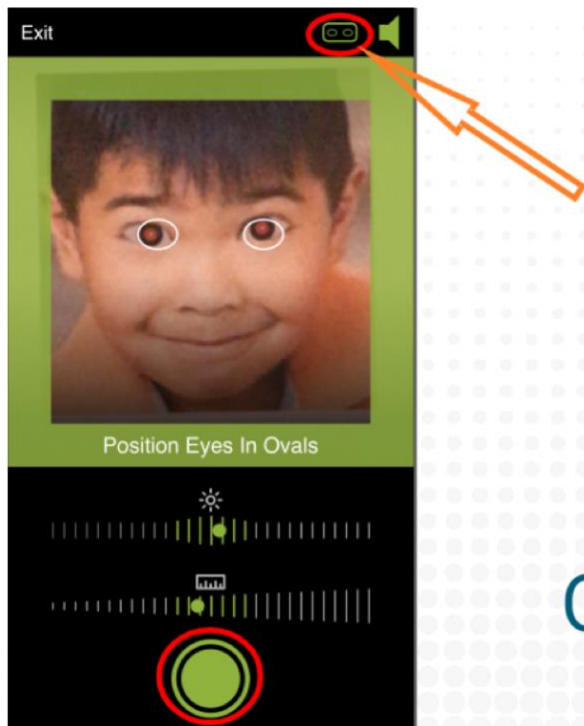
Performing a Photoscreening Test

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.





On-Demand Eye Tracking Override Feature



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 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.



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.

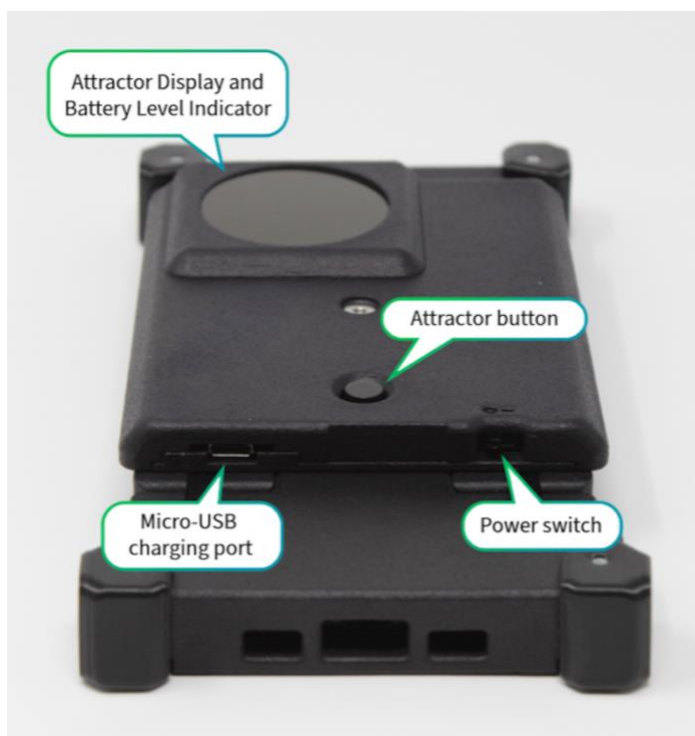
If your practice has an AirPrint-enabled printer, you can print the patient’s screening results. The printer needs to be discoverable wirelessly through Wifi and paired with the GoCheck Kids device. Click the “Print” button to export your results to the printer.

Optional Accessory: Attractor

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 GCK App for Visual Acuity

Logging into the GCK App

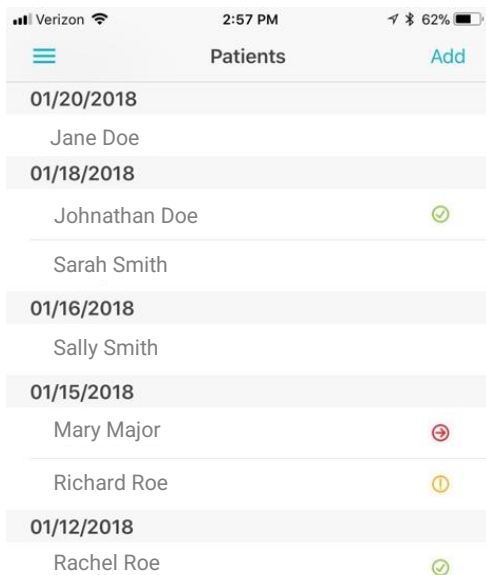
Select the GoCheck Kids App on the home screen. Enter your username and password for the application.

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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.

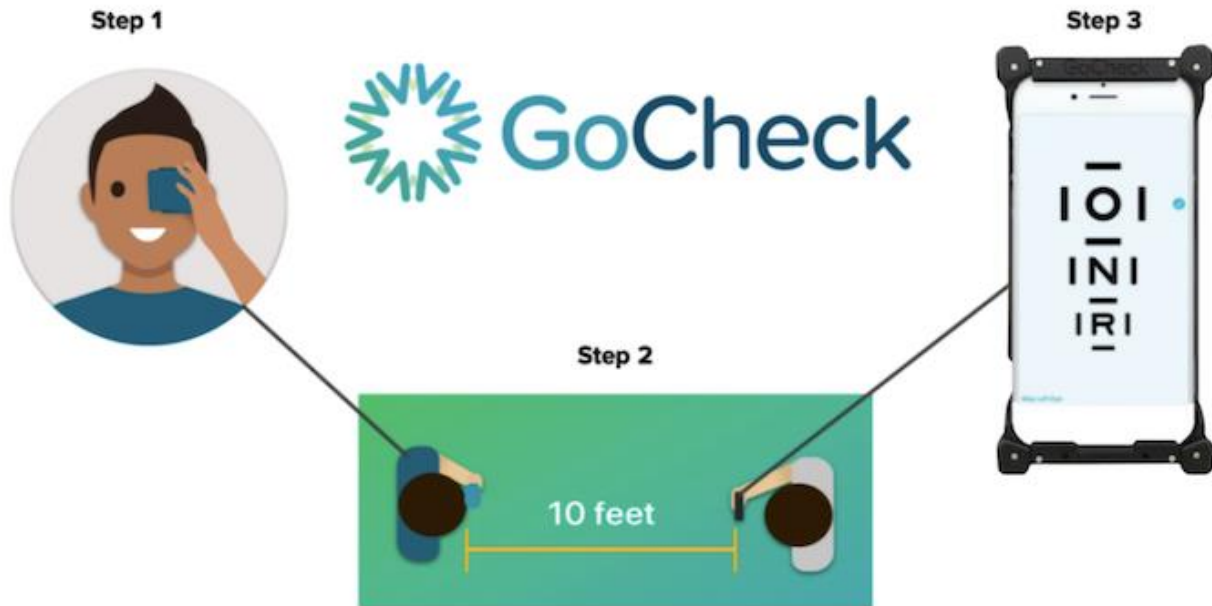
Performing a Visual Acuity Test

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



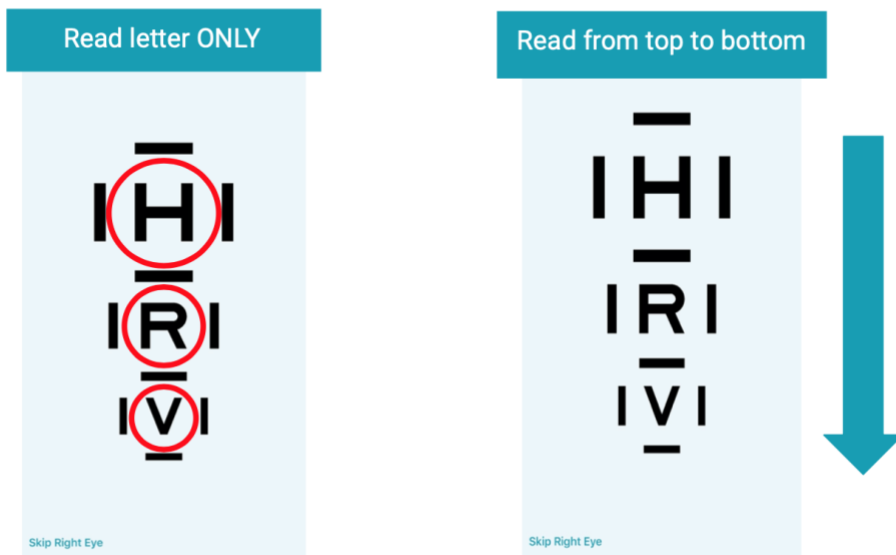
For this test, you will need a tester to hold the device, a patch or folded washcloth to cover the patient's eye, and a tape measure.

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.

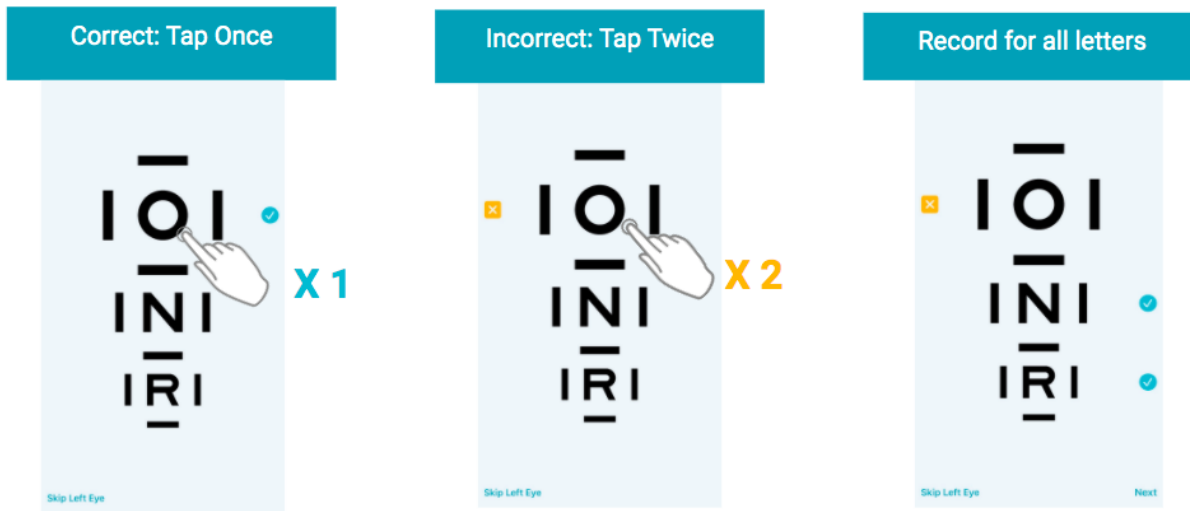


Ask the patient to read the letters inside the crowding bars from top to bottom. Make sure to remember the patient's responses.

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.

Newly added (PHI hidden) [Done](#)

Age 4

No risk factor identified

8/26/2020 04:30 PM

Visual Acuity Result

Right Eye	Left Eye
20/20 LogMAR: 0.00	20/20 LogMAR: 0.00

Threshold: 20/40 for age 4
 Optotype: HOTV
 Distance: 10 feet
 Vision Correction: none

[Scroll to view details](#)

[Fax](#)

[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.

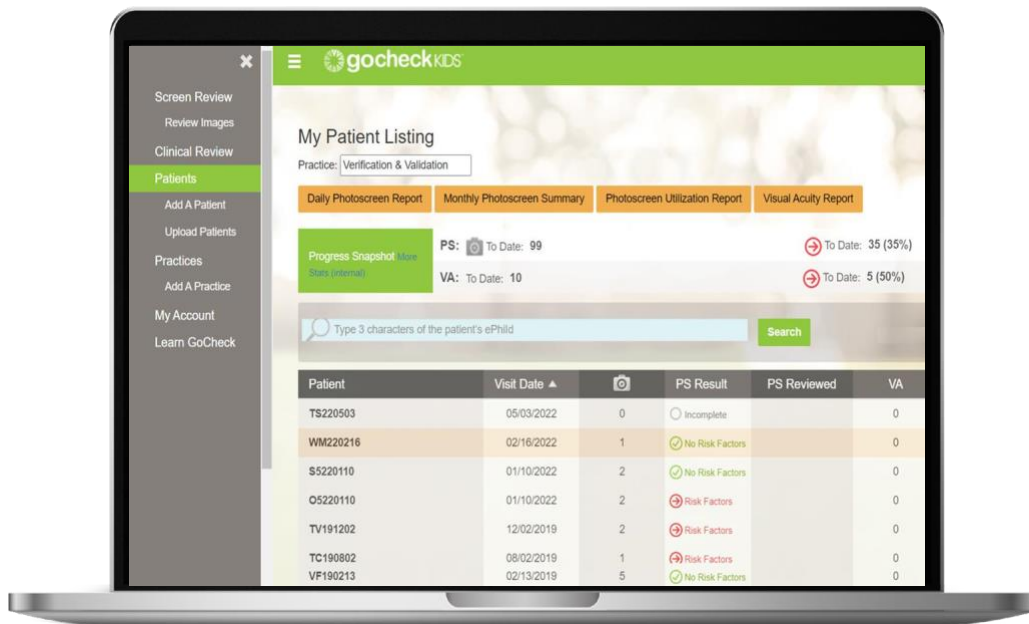
You can fax your screening results. Click the Fax button on the results screen. There will be a confirmation pop-up box that will say "Fax Requested" indicating that the fax has been successfully processed.

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 Kids device. Click the "Print" button to export your results to the printer.

Using the GoCheck Kids Web Portal

Logging in to the portal

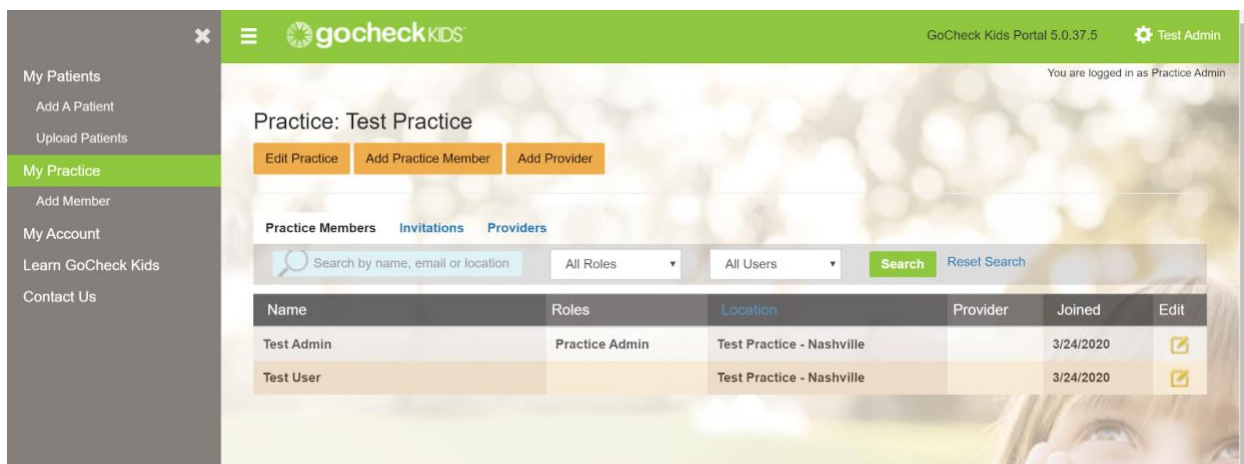
To access the GoCheck Kids Web Portal, go to portal.gocheckkids.com. Log into the portal with your GoCheck Kids username and password.



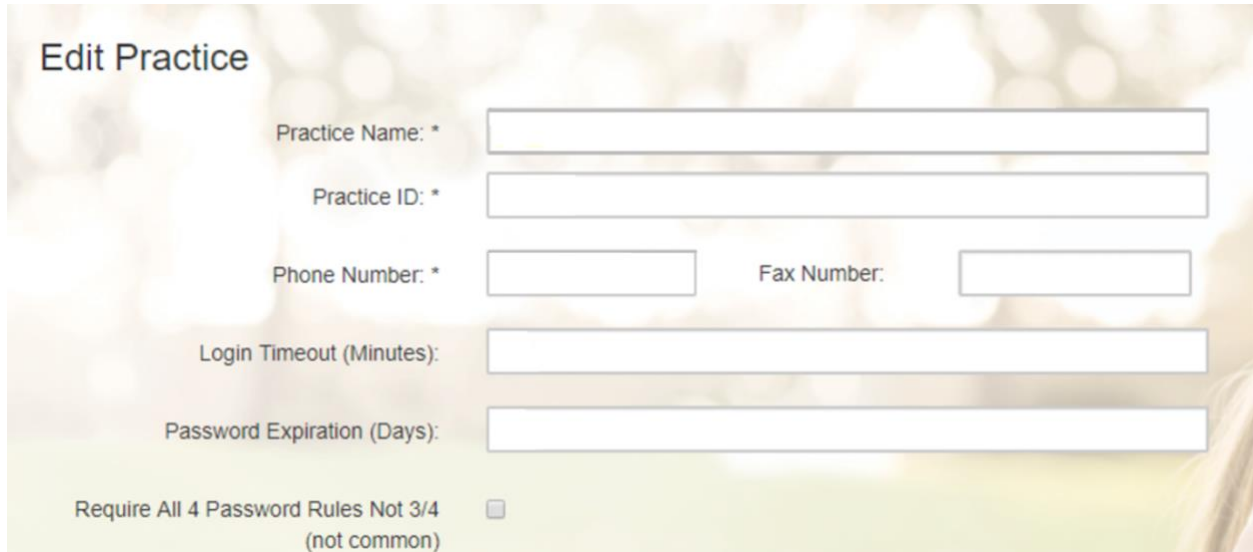
You can set up your user account by clicking the link to register in your portal invitation email. The email will be titled “GoCheck Kids Invitation” and will include a custom link.

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.



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



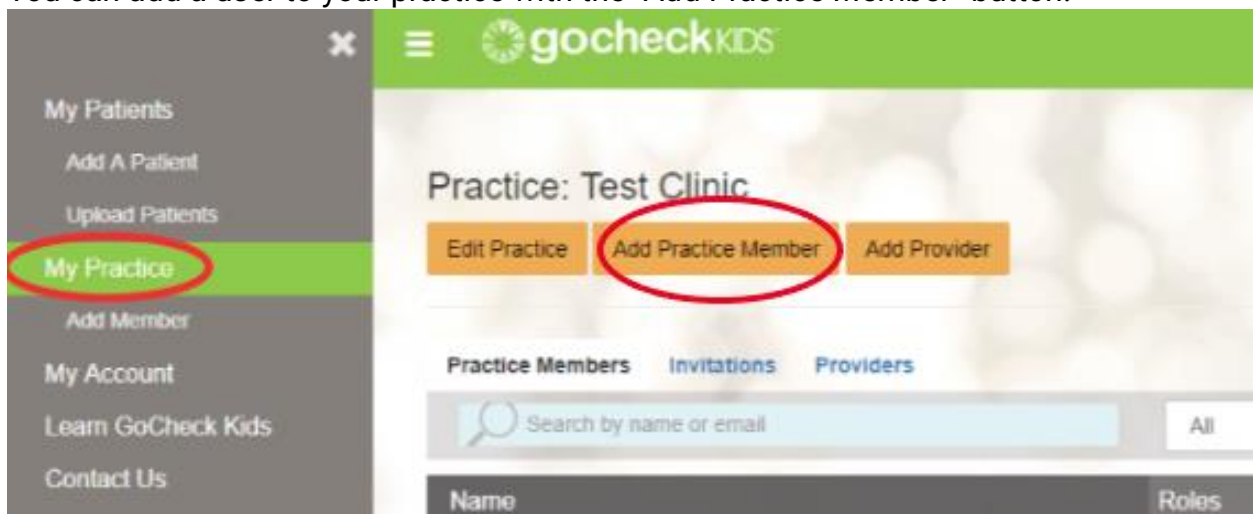
The screenshot shows the 'Edit Practice' form with the following fields:

- Practice Name: *
- Practice ID: *
- Phone Number: * and Fax Number: *
- Login Timeout (Minutes):
- Password Expiration (Days):


At the bottom, there is a checkbox labeled 'Require All 4 Password Rules Not 3/4 (not common)' which is currently unchecked.

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, practice location, and role. This invitation will be sent as an email to your new practice member.

 Add Member to Test Clinic

First Name: *

Last Name: *

Email Address: *

Location:



Is Provider:

Role: Make practice administrator

Send Email: Now On

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.

   GoCheck Kids Portal 5.1.22.8  Nicole PA



My Patients
Add A Patient
Upload Patients
My Practice
Add Member
My Account
Learn GoCheck Kids
Contact Us

You are logged in as Practice Admin

My Patient Listing

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

Progress Snapshot

PS:  To Date: 1726	 To Date: 1179 (68%)
VA: To Date: 214	 To Date: 84 (39%)

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.

The screenshot shows the 'Edit Patient' form in the GoCheck Kids Portal. The form is set against a background image of a young girl. The form fields are as follows:

- First Name: * Jane
- Last Name: * Doe
- Date Of Birth: * 24 April 2020
- Medical ID: [Empty field]
- Ethnicity: Unspecified
- Gender: Choose Gender
- Latest Location: Test Location
- Provider: [Empty dropdown]

At the bottom of the form are 'Cancel' and 'Save' buttons. A note below the form states '* 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.

The screenshot shows the 'My Patient Listing' page in the GoCheck Kids Portal. The page features a search bar and several report buttons:

- Search bar: Type 3 characters of the patient's first name, last name, or Medical ID
- Report buttons: Daily Photoscreen Report, Monthly Photoscreen Summary, Photoscreen Utilization Report, Visual Acuity Report
- Progress Snapshot: PS: To Date: 1726, VA: To Date: 214
- Summary statistics: To Date: 1179 (68%), To Date: 84 (39%)
- Search filters: Test Location, Advanced
- Table headers: Last Name, First Name, Medical ID, Visit Date, PS Result, GoCheck Reviewed, VA, VA Result, Home VA, Action

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 Kids device. Click the "Print" button to export your results to the printer.

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?











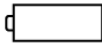

The GoCheck Kids visual acuity test is designed for use at 10 feet to test distance visual acuity. The test is not designed for other distances.

Support

For additional support, contact us 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



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STE 100
Santa Clarita CA 91355



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