

For Use Under an Emergency Use Authorization (EUA) Only  
For *in vitro* diagnostic use



cue

Cue<sup>®</sup> Health  
Monitoring System  
User Manual

# Cue® Health Monitoring System

## User Manual

### **Basic Information**

Please read this User Manual carefully. Contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at (833) CUE-TEST · (833) 283-8378 if you have any questions or comments.

### **Cue Health Inc.**

San Diego, CA 92121

[www.cuehealth.com](http://www.cuehealth.com)

# Table of Contents

<b>Chapter 1 - Introduction and User Safety .....</b>	<b>7</b>
Welcome to Cue .....	7
Intended Use .....	7
Before Using a Cue Reader and Cue Test .....	8
Safety Definitions .....	9
Practices Used in This User Manual .....	11
Symbols and Descriptions.....	12
General Precautions.....	14
<b>Chapter 2 - Cue Health Monitoring System</b>	
<b>Overview and Features.....</b>	<b>20</b>
Cue Health Monitoring System Components.....	21
Cue Health Monitoring System Package Contents .....	23
Cue Test Components .....	24
Compatible Mobile Smart Devices .....	26
Cue Health App .....	26

# Table of Contents

## Chapter 3 - Setting Up Your Cue Health

<b>Monitoring System (Reader)</b> .....	<b>28</b>
Identifying Parts of Your Cue Reader .....	28
Your Cue Health App Dashboard .....	31
Cue Reader Indicator Lights.....	32
Downloading and Installing the Cue Health App .....	34
Creating Your Cue Account and User Profile .....	36
Setting Up the Cue Reader .....	39
Account Login .....	43

## Chapter 4 - Running a Test on the Cue

<b>Reader</b> .....	<b>44</b>
Reasons for Incorrect or Invalid Results.....	46
Initiate Test.....	47

## Chapter 5 - Managing Your Cue Health Monitoring

<b>System (Reader)</b> .....	<b>49</b>
Charging your Cue Reader.....	49
Account Settings .....	51

# Table of Contents

Pairing Additional Cue Readers to Your Mobile Smart Device .....	52
Connecting the Cue Reader to the Cue Health App ....	53
Checking the MAC Address of a Connected Cue Reader .....	54
Disconnecting the Cue Reader from the Cue Health App .....	55
Unpairing the Cue Reader from Your Mobile Smart Device .....	56
Managing User Account and Profiles.....	57
Forgot Your Password?.....	58
Printing Your Test Results.....	58
Accessing Product Documentation .....	60
<b>Chapter 6 - Cleaning and Disinfecting .....</b>	<b>61</b>
Cleaning and Disinfecting .....	61

# Table of Contents

<b>Chapter 7 - Troubleshooting .....</b>	<b>63</b>
Error Messages and Recommended Actions .....	64
When to Use the Manual Reset Button .....	66
<b>Chapter 8 - Technical Information and Specifications .....</b>	<b>67</b>
How the Cue Health Monitoring System Works.....	67
Technical Specifications .....	68
Compliance with International Standards .....	70
Disposing of Your Cue Health Monitoring System and Components .....	70
<b>Chapter 9 - Warranty and Supplies .....</b>	<b>71</b>
Manufacturer's One Year Warranty .....	71
Supplies and Accessories .....	71

# Chapter 1

## Introduction and User Safety

### **Welcome to Cue**


The Cue Health Monitoring System (Reader) is a fast and easy-to-use system for performing Cue diagnostic medical tests. Your results are delivered and saved to mobile smart device in minutes. This User Manual will guide you through the proper setup and use of your Cue Reader. Read this manual thoroughly to help you understand the system and its many features.

### **Intended Use**

The Cue Reader is an in vitro diagnostic medical device for use with Cue tests and the Cue Health App installed on a mobile smart device. Go to [www.cuehealth.com](http://www.cuehealth.com) for a list of compatible devices.

## **Before Using a Cue Reader and Cue Test**

Review the Quick Start Guide and this User Manual before you run a test using the Cue Reader. The Quick Start Guide will help you quickly set up your Cue Reader and get ready to run a test. This User Manual gives you all the information you need to use your Cue Reader correctly and safely.

 ***It is important that you follow the instructions in this User Manual. If you do not use the system correctly, you may get an incorrect or invalid result, the system may cancel your test, or you may damage the system. Do not use the system if you cannot follow the instructions.***

If you have any questions, please contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at (833) CUE-TEST · (833) 283-8378.



## **Safety Definitions**

This User Manual includes three types of important messages. They are Warnings, Cautions, and Notes. It is important that you pay close attention to these messages to make sure you use the Cue Health Monitoring System correctly and safely.



### **Warning**

A Warning message tells you what you need to do to prevent injury or damage to health.

Follow the instructions given when you see a Warning message. Do not proceed if you do not fully understand the actions to take after seeing a Warning message.



## **Caution**


A Caution message tells you what you need to do to prevent damage to your Cue Health Monitoring System (Reader). Do not proceed if you do not fully understand the actions to take after seeing a Caution message.



## **Note**

A Note gives you more information to help you understand the instructions.

## Practices Used in This User Manual

Procedure steps in this User Manual are easy to find. They begin with a  symbol, followed by a short description of the action you should take.







Procedure steps are numbered and should be completed in the order given.





A system response to a completed procedure step appears in italics below the procedure step.

Words in:	Description
<b>Bold</b>	Names of menus and buttons
<i>Italics</i>	System response that occurs after the user presses an icon or completes a step that appears in the Cue Health App
<b><i>Bold Italics</i></b>	Important information

## Symbols and Descriptions

The table below describes the symbols used on the Cue Health Monitoring System packaging and on the system parts.

Symbol	Description
	Consult User Manual
	Serial Number
	Do not use if seal or packaging is broken or damaged
	Storage temperature range
	Humidity storage range
	Catalog number

Symbol	Description
	Manufacturer
	Keep dry
	Electrical and Electronic Equipment Waste: Discard product at separate collection facility for recovery and recycling.
	Caution: User should consult the test's Instructions for Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be printed on the medical device itself.

## General Precautions

The Cue Health Monitoring System (Reader) may not work correctly if the package or the system parts are damaged.

- Do not use the Cue Reader if the package seals are broken.
- Do not use the Cue Reader if any part is damaged.
- Do not run a test if the room temperature is outside of the testing conditions stated in the Cue test Instructions for Use. Testing in room temperatures that are too high or too low may cause an incorrect or invalid result.
- Do not run a Cue diagnostic test at altitudes higher than 8530 feet (2600 meters). Testing at altitudes that are too high may cause an incorrect or invalid result.
- Do not leave the Cue Reader in temperatures below 39°F (4°C) or above 100°F (38°C).
- If you make changes to any of the parts of your Cue Reader or use any components that did not come with the Reader, you may harm yourself or the device. You will also void your warranty.
- Place your Cue Reader on a stable, flat, and level surface while running a test. Do not move or tilt the Reader while

a test is in progress.

- Do not bend or damage the Cue Charging Cable or Cue Power Adaptor (plug), or pull the cable excessively when disconnecting it from the Reader or the plug. Do not use a damaged power cable, plug, or loose electrical sockets. These actions could cause electric shock or fire.
- The Cue Reader includes a built-in, rechargeable lithium-ion polymer battery. Avoid exposing your Reader to very cold or very hot temperatures, or to high external pressure, and do not place or store your Reader near or in heaters, microwave ovens, or stoves. The battery could overheat and cause a fire.
- Do not use your Reader near flammable liquids, and never dispose of the Reader in a fire. The Reader could explode or cause a fire.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the

instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received,



including interference that may cause undesired operation.

- Electronic wireless devices or networks that are in use nearby, such as a cordless or cell phone (excluding your mobile device that is paired to the Reader) or a garage door opener, could prevent or delay communications between your Cue Reader and your mobile smart device and interfere with your Cue test.
- Do not use your Cue Reader or the Cue Health App where the use of cell phones or other electronic devices is restricted or prohibited, such as in aircraft or in hospitals. Your Cue devices must not cause harmful interference.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.

When used with the “Cue COVID-19 Test” or the “Cue COVID-19 Test for Home and Over The Counter (OTC) Use” EUA products

- This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens; and

- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

When used with the “Cue Mpox (Monkeypox) Molecular Test” EUA product

- This product has been authorized only for the detection of nucleic acid from monkeypox virus (or other non-variola orthopoxviruses), not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C §360bbb-3(b)

(1), unless the declaration is terminated or authorization is revoked sooner.

## Chapter 2


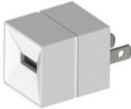

# Cue Health Monitoring System Overview and Features

The Cue Health Monitoring System (Reader) comes as three parts. These parts are the Cue Reader, the Cue Power Adapter, and the Cue Charging Cable.

The Cue Reader is used with test-specific Cue cartridges and sample collection devices (Cue Sample Wand). The Cue Reader connects to the Cue Health App installed on your mobile smart device. The mobile smart device is the primary display for the test system.

## **Cue Health Monitoring System Components**

Each Cue Health Monitoring System part (component) is described in the table on the next page.

Component	Description	Image
Cue Reader (C0201)	The Cue Reader communicates with the Cue Health App and a Cue Test Cartridge to run a test on a sample.	
Cue Power Adapter (C0011)	The Cue Power Adapter plugs into standard wall power. The Cue Charging Cable plugs into the Cue Power Adapter.	
Cue Charging Cable (C0020 or C0021)	The Cue Charging Cable connects the Power Adapter to the Reader.	

## **Cue Health Monitoring System Package Contents**

Make sure that your package contains the following parts (components):




- One (1) Cue Reader
- One (1) Cue Power Adapter
- One (1) Cue Charging Cable
- User Manual
- Quick Start Guide

Contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at (833) CUE-TEST · (833) 283-8378 if you do not have all of these parts. Also, contact Cue Health Customer Support if a part is damaged.

## **Cue Test Components**

The table on the next page describes the parts (components) of Cue tests, for example, the Cue COVID-19 Test, which detects SARS-CoV-2 virus, or the Cue Mpox (Monkeypox) Molecular Test, which detects monkeypox virus (or other non-variola orthopoxviruses). Cue tests are sold separately and can be purchased in multiple packs. Tests can be used only once, and they must be used before the Use By date printed on the packaging.



Component	Description	Image
<p>Cue Test Cartridge Pack</p>	<p>A Cue Test Cartridge Pack comes with a Cue test cartridge (Cue COVID-19 Test or Cue COVID-19 Test for Home and Over The Counter (OTC) Use or Cue Mpox (Monkeypox) Molecular Test), a Cue Sample Wand for collecting a sample, and Instructions for Use. The Instructions for Use tell you how to use the Cue Cartridge Reader, the Cue Health App, and the Cue test cartridge to run a test on the sample.</p>	 <p>Cue COVID-19 Test Cartridge</p>  <p>Cue Mpox (Monkeypox) Molecular Test Cartridge</p>  <p>Cue Sample Wand</p>

## **Compatible Mobile Smart Devices**

The Cue Health Monitoring System must be used with a mobile smart device downloaded with the Cue Health App. Go to [www.cuehealth.com](http://www.cuehealth.com) for a list of compatible devices.

## **Cue Health App**

The Cue Health App is required to run a Cue test on the Cue Reader. Download the Cue Health App from the Apple® App Store® or Google Play™ Store.

The Cue Health App displays test results from the Cue Health Monitoring System. The Cue Health App must be open to see test results.

If the mobile smart device loses power while the Cue test is running, the Cue Reader will still complete the test. The result will not be displayed until the mobile smart device is charged or connected to power, however. Bring the charged mobile smart device close to the Cue Reader and open the Cue Health App to see the test result.

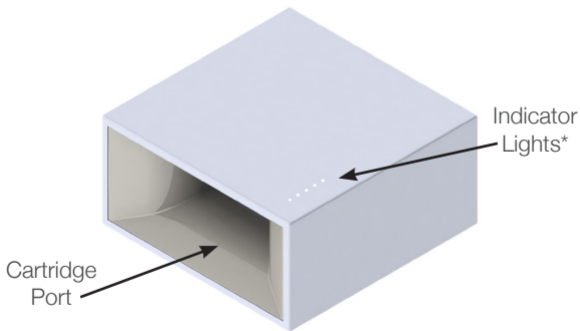
The Cue Health App securely stores test results and communicates results to authorized individuals.

## Chapter 3

# Setting Up Your Cue Health Monitoring System (Reader)

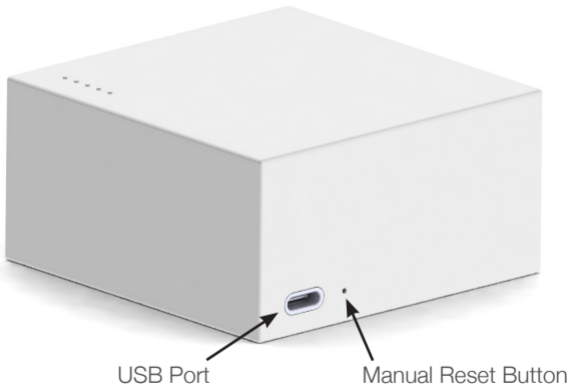
### Identifying Parts of Your Cue Reader

#### The Top and Front of Your Cue Reader



\*See “Cue Reader Indicator Lights” in Chapter 3 for information on the meaning of the indicator light patterns.

## The Back of Your Cue Reader



# The Bottom of Your Cue Reader



Cartridge Reader

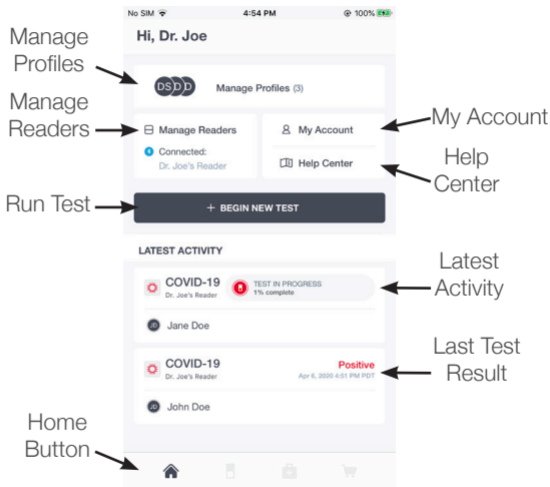
REF: C0201

S/N: 21802010000481

L9000207-2 Rev 1.0



# Your Cue Health App Dashboard



Press the Home Button  on the Cue Health App screen to see with your Cue Dashboard.

## Cue Reader Indicator Lights

### Status Indicators

You will see different light patterns on top of the Reader. The light patterns will tell you when the Reader is connected to the Cue Health App. The light patterns will also tell you when a cartridge is inserted, and when there is an error.



Lights Flash when connected



Lights Flash when the Cue Cartridge or the Cue Sample Wand is inserted



Error, see Cue Health App for details



## Prompts for Action

You will see these light patterns on top of the Reader after you insert a Cue Cartridge into the Cartridge Port.



Insert Sample Wand with collected specimen into the Cue Cartridge



Remove Cue Cartridge (with Sample Wand inside) from the Cue Reader

## Downloading and Installing the Cue Health App

You can download and install the Cue Health App to your mobile smart device from the Apple App Store or Google Play Store. The Cue Health App is downloaded and installed the same way as other apps on your mobile smart device. The Cue Health App is free of charge.



Cue Health

 Downloading the Cue Health App from the Apple App Store or Google Play Store requires internet connectivity.

 Download the Cue Health App:

1. Turn on your mobile smart device.
2. Confirm your mobile smart device has internet connectivity.

3. Launch the Apple App Store or Google Play Store app.
4. Search for the “Cue Health App” by Cue Health Inc. and tap on the Cue Health App icon.
5. Tap Install.
6. Enter your App password information as required.

*The application downloads. Once installed, the Cue Health App icon appears on your mobile smart device home screen.*




The Cue Health App needs to be installed on each mobile smart device that will be paired with the Cue Reader.



Cue Health App updates must be downloaded from the Apple App Store or Google Play Store when a new version is available.

## Creating Your Cue Account and User Profile

 *Your test results will be saved to your Cue Account and in a secured cloud storage.*

 To create your Cue Account and User Profile:

1. Launch the “**Cue Health App**” on your mobile smart device.

*The “Login” screen will be displayed by the Cue Health App.*

2. Tap on “**Create Account**”.
3. Input your email and create a password on the “Create Account” screen. Continue following the on-screen instructions. You must accept the End User License Agreement and Privacy Policy to continue.


*After you have created your account, the Cue Health App will display the “Profile Information” screen.*

4. At the “Profile Information” screen, input the requested information in each field.
5. Tap on “**SUBMIT**” and follow the on-screen instructions.

*After you have created your profile, the Cue Health App will display the “Permissions” screen.*

6. Follow the Cue Health App on-screen instructions to progress through the “Permissions” screens.

*After you have progressed through the “Permissions” screens, the Cue Health App will display the “Set Up the Cue Cartridge Reader” screen.*


 *Multiple user profiles can be created under one Cue Account. The primary Cue Account holder will have access to all user profiles and test results under the same Cue Account.*

## Setting Up the Cue Reader

 To set up your Cue Cartridge Reader:

*After you set up your user profile(s), the Cue Health App will display the “Set Up the Cartridge Reader” screen.*

1. Place the Cue Reader on a stable, flat, and level surface.
2. Connect the Cue Charging Cable to the Cue Power Adapter and plug the Power Adapter into wall power.
3. Follow the Cue Health App Instructions.

 ***Only the Cue-supplied Charging Cable and Power Adapter.***

4. Wake the Cue Reader by connecting it to the Cue Charging Cable.


*When the Cue Reader is connected to power, the lights on top of the Reader will illuminate one-by-one. The lights will then flash to show charge level. The Reader is now ready for pairing with a mobile smart device.*




Another way to wake the Cue Reader is by disconnecting and reconnecting the Cue Charging Cable.


5. In the “Set Up the Cartridge Reader” screen in the Cue Health App, tap on “**SCAN NOW**” to begin pairing the Reader to the mobile smart device.
6. Turn your Cue Reader upside-down so the bottom of the Cue Cartridge Reader is facing up. You will see the serial number and QR code.
7. Move the mobile smart device until you can see the QR code inside of the focus square on the camera screen.




 If the QR code does not scan quickly, make sure the Cartridge Reader is connected to power.

*When the QR code is recognized, the Cue Health App will display a message that says, “Reader Authorized Successfully”. This means that the Cue Reader is paired securely to the mobile smart device. The Cue Dashboard will then be displayed on the screen. Make sure to turn the Cartridge Reader over to top-side up after you have scanned the QR code. The side with the lights on top of the Reader is top-side up.*


 “Pairing” a Reader is scanning the QR Code found on the bottom of the Reader. When a “paired” Reader is within range of the BLUETOOTH® wireless technology of your smart mobile device, the Reader is “connected” to the Cue Health App on the smart mobile device.


 If the camera scan of the Reader QR code does not work, the Cue Health App will let you manually enter the Reader MAC address and Pin Number. The MAC address

and Pin are on the bottom of the Reader. See “Identifying Parts of Your Cue Cartridge Reader” in Chapter 3 for how to find the MAC address and Pin Number.

 One Cue Reader can pair with multiple mobile smart devices.

 One mobile smart device can pair with multiple Cue Readers.

 When you choose a paired Cue Reader to run a test, that Reader is connected to the Cue Health App. One Cue Reader can only connect with the Cue Health App on one mobile smart device at one time.

 Multiple Cue Readers can be connected to the Cue Health App on one mobile smart device at one time.

## Account Login

If you already have a Cue Account, you can log in directly. If you do not have a Cue Account, see “Creating Your Cue Account and User Profile” in Chapter 3 for instructions on how to set up a Cue Account.

 To Log In:

1. Launch the “**Cue Health App**” on your mobile smart device.

*The “Login” screen will be displayed by the Cue Health App.*


2. Input your Email and Cue Account password.
3. Tap on “**LOGIN**”.


*The “Dashboard” screen will be displayed by the Cue Health App after login.*


## Chapter 4

### Running a Test on the Cue Reader

Carefully read this chapter. It is important that you read and follow the test-specific Instructions for Use available electronically in the Help Center of the Cue Health App, or at [www.cuehealth.com](http://www.cuehealth.com).

 ***If you do not follow all of the instructions you may get an incorrect or invalid result.***

 ***The Reader should be on a stable, flat, and level surface while running a test. Do not move or tilt the Reader while a test is in progress.***

 The Cue Health App will tell you if the Reader battery is too low to complete a test. Connect the Reader to power when needed.



If your mobile smart device loses power, the test on the Cartridge Reader will still run to completion. The test result will be saved. The mobile smart device must be charged to see the test result. Make sure your mobile smart device is close to the Reader after a test completes so you can view your result on the screen in the Cue Health App.

## **Reasons for Incorrect or Invalid Results**

Always follow the directions in this User Manual when you store, handle, and operate the Cue Health Monitoring System (Reader).

Some reasons for incorrect or invalid results are:

- Storing or operating the Cue Reader in temperatures that are too low or too high. See “Technical Specifications” in Chapter 8 for more details.
- Storing or operating the Cue Reader at altitudes that are too high. See “Technical Specifications” in Chapter 8 for more details.
- Dropping the Cue Reader.
- Using a damaged Cue Reader.

## Initiate Test

 To initiate a test:

1. Launch the **Cue Health App** on your mobile smart device.



Cue Health

*The “Login” screen is displayed by the Cue Health App after launch.*

2. Log into your Cue Account.

*The “Dashboard” screen is displayed by the Cue Health App after successful account login.*

3. On the “Dashboard” screen, tap on “**+ BEGIN NEW TEST**”.

4. Follow on-screen instructions to run a test.

*After the test is complete, the Reader will automatically go into standby mode.*

**ⓘ** *If two or more Readers are paired, you must identify the Reader you want to use by its MAC address. See “Checking the MAC Address of a Connected Cue Cartridge Reader” in Chapter 5 for more details.*



## Chapter 5

# Managing Your Cue Health Monitoring System (Reader)

### **Charging your Cue Reader**

Your Cue Reader has a built-in, rechargeable lithium-ion polymer battery. By charging your Reader's battery, you don't need a separate power source to take a Cue test.

 To charge your Cue Cartridge Reader:

1. Plug the Cue Power Adapter into wall power.
2. Connect the Cue Charging Cable to the USB port of the Cue Power Adapter.
3. Connect the other end of the Cue Charging Cable to the USB port of the Cue Reader to start charging.

*When you connect or disconnect the Cue Charging Cable, the lights on the Reader will light up one-by-one (sequentially) and then flash to tell you the charge level.*



Lights illuminate sequentially




Battery is 80% charged




Battery is 20% charged

\*Green indicates flashing light


## Account Settings

 To access your account settings:

1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**My Account**”.
3. Tap on “**Settings**”.
4. Within the “**Settings**” menu, you can:
  - Allow Notifications
  - Allow Location Services
  - Enable Camera Access
  - Auto - Reconnect
  - Change Password
  - Delete Account

## Pairing Additional Cue Readers to Your Mobile Smart Device


 To pair additional Cue Readers to your mobile smart device:


1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. Confirm that the BLUETOOTH wireless technology of your mobile smart device is enabled.
4. Tap on “+”.
5. Follow on-screen instructions to pair the additional Cue Reader.

*The Cue Reader is now paired to the mobile smart device.*


## Connecting the Cue Reader to the Cue Health App



 To connect a paired Cue Reader to the Cue Health App:

 A Cue Reader that is “Paired” to your mobile smart device can disconnect if the Reader is out of range of the BLUETOOTH wireless technology of the mobile smart device.

1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. From the list of “**DISCONNECTED**” Cue Readers, tap on the one you would like to connect to.  
*The indicator lights will flash when the Cue Reader is connected to the Cue Health App.*

## Checking the MAC Address of a Connected Cue Reader

 To check the MAC address of the connected Reader on the Cue Health App:



1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. From the list of “**CONNECTED**” Cue Readers, tap on the  next to the one you would like to check.

*The MAC address will be displayed on the “Reader Information” screen.*

4. Compare the MAC address printed on the bottom of the Cartridge Reader to the MAC address displayed on the “Reader Information” screen.



## Disconnecting the Cue Reader from the Cue Health App

 To Disconnect the Cue Health App from connected Cue Readers:

1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. From the list of “**CONNECTED**” Cue Readers, tap on the  next to the one you would like to disconnect.
4. Look at the MAC address on the bottom of the Reader. Confirm the MAC address on the screen matches the MAC address on the bottom of the Reader you want to disconnect.
5. Tap on “**DISCONNECT**”.  
*The Cue Reader is now disconnected from the Cue*

## Unpairing the Cue Reader from Your Mobile Smart Device


 To Unpair the Cue Reader from your mobile smart device:


1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. From the list of “**CONNECTED**” and “**DISCONNECTED**” Cue Readers, tap on the  next to the Reader you would like to unpair.
4. Tap on “**FORGET THIS READER**”.

*The Cue Reader is now unpaired from the mobile smart device.*




## Managing User Account and Profiles

 To manage your user account:

1. When logged into your Cue Account, access the Cue Dashboard by tapping on the home button  at the bottom of the screen.
2. Tap on **“My Account”** for more options.


 To manage profiles:

1. When logged into your Cue Account, access the Cue Dashboard by tapping on the home button  at the bottom of the screen.
2. Tap on **“Manage Profiles”**.
3. Tap on the profile of interest and tap on **“VIEW”** for more options.

*The “Test History” and “Medication History” of the*

*profile can be viewed on the screen.*


## **Forgot Your Password?**

 To retrieve your password:


1. Launch the **Cue Health App** on your mobile smart device.
2. Tap on “**Forgot Password?**”
3. Follow the on-screen instructions.


## **Printing Your Test Results**

 To print your test results:

1. When logged into your Cue Account, access the Cue Dashboard by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Profiles**”.
3. Tap on the profile of interest and tap on “**VIEW**”.

*The “Test History” and “Medication History” of the profile can be accessed on the screen.*


4. From the “**TEST HISTORY**” list, tap on the test result of interest.
5. Tap the button at the top right corner of the screen. Then tap on “**PRINT**” at the bottom of the results display screen and choose the printer icon . Then tap Print at the top right of the screen.

 Printing test results from the Cue Health App requires that a printer be connected to (or paired with) the mobile smart device.

 If you print results in public places, you could be sharing your personal information.

## Accessing Product Documentation

 To access product documentation:

1. When logged into your Cue Account, access the Cue Dashboard by tapping on the home button  at the bottom of the screen.
2. Tap on “**Help Center**” for options.


## Chapter 6

# Cleaning and Disinfecting


This section provides cleaning and disinfecting information for your Cue Health Monitoring System (Reader).


### **Cleaning and Disinfecting**


The Cue Reader should be cleaned and disinfected after each use. Wipe down with Clorox® Germicidal Wipes or equivalent (containing 0.55% sodium hypochlorite as the active ingredient).

 Do not spray any cleaning solution directly onto the Cue Reader or into the cartridge port.

 Do not put any part of the Cue Reader under water or any other liquid.

 Do not attempt to clean any internal parts.

 If part of your device becomes wet, wipe off all moisture and allow sufficient time for drying before use.

 Only Clorox Germicidal Wipes or equivalent should be used. Other products have not been tested and should not be used. Follow manufacturer's instruction for handling and storage of wipes.

# Chapter 7

## Troubleshooting

In this chapter, you will learn about symbols and error messages displayed by the Cue Health App.

Pay attention to all symbols, messages, and indicator lights when you use the system. They give you important information to help you use the system correctly and safely.

If you have questions, contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at (833) CUE-TEST · (833) 283-8378.

## Error Messages and Recommended Actions

Certain messages displayed by the Cue Health App indicate an error. An error message requires your attention and action.

The following table lists the Error Message and the Recommended Action.

Error Message	Recommended Action
App displays “Tilt Warning”	Position the Cue Reader on top of a stable, flat, and level surface.
App displays “The battery on your cartridge reader is too low to run a test”	Connect the Cue Reader to power. Use the Cue Health Monitoring System components or accessories.



Error Message	Recommended Action
App displays “Testing Error” or “Cartridge Error”	Follow on-screen instructions.
App displays “Test Has Been Canceled”	Remove and dispose of the Cue Test Cartridge. Take a new sample using a new test-specific Cue Sample Wand and use a new test-specific Cue Test Cartridge to repeat the test. See the Cue Health App on-screen instructions for additional details.

## **When to Use the Manual Reset Button**

If the Reader is not responding as described in this User Manual you must reset the Reader. Press and hold the Manual Reset Button for one second using the end of a small wire, such as a paperclip. Do not hold the Manual Reset Button for more than 3 seconds.

 Pressing the Manual Reset Button for 10 seconds will bring the Reader back to the out-of-the box settings. Wake the Reader by connecting it to power.

# Chapter 8

## Technical Information and Specifications

This section provides technical information on your Cue Health Monitoring System.

### **How the Cue Health Monitoring System Works**

The Cue Health Monitoring System (Reader) detects test-specific targets using electrochemical biosensor technology.

## Technical Specifications

### Cue Reader Specifications

Dimensions	(2.9 in x 2.9 in x 1.5 in) (74 mm x 74 mm x 37 mm)
Weight	5.29 oz (150 g)
Power Supply	Input: 100-240V~, 50/60Hz, 0.2A Output: 5VDC, 1.5A, 7.5W  Battery 1 (one) pre-installed, non-serviceable, 1400mAh rechargeable lithium polymer battery, 3.85v (5V input voltage)
Display	Cue Health App on a mobile smart device screen
Operational Temperature	59°F (15°C) to 95°F (35°C)
Operational Humidity	10% to 100%

Operational Altitude	0 ft (0 m) to 8530 ft (2600 m)
Storage Temperature	39°F (4°C) to 100°F (38°C)
Storage Humidity	10% to 100%
Storage Altitude	< 8530 ft (2600 m)
FCC ID	2A3QA-001



For technical specifications of Cue diagnostic tests, refer to the test-specific Instructions for Use. All product documentation can be found at the Help Center on the Cue Health App or on the Cue website at [www.CueHealth.com/help-and-support/product-documentation/](http://www.CueHealth.com/help-and-support/product-documentation/).

## **Compliance with International Standards**

The Cue Health Monitoring System complies to the following standards:

- UL 61010-1. 3rd Edition.
- UL 61010-2-101. 2nd Edition.
- FCC Part 15B
- ICES-003
- IEC/EN 61326 Class B
- FCC Part 15.247
- UL 60950-1
- UL 62368-1

## **Disposing of Your Cue Health Monitoring System and Components**

Dispose of used products according to regulations applicable in your country. For information about the correct method of disposal, contact your local authorities.

# Chapter 9

## Warranty and Supplies

### **Manufacturer's One Year Warranty**

Cue Health Inc. warrants your new Cue Health Monitoring System will be free from defects in materials and workmanship for a period of one (1) year from the date of the original purchase. If during this time the Cue Health Monitoring System does not work properly because of a defect in materials or workmanship, Cue Health Inc. agrees to replace free of charge any and all parts proven to be defective and subject to warranty. This warranty only applies to the original purchaser of the Cue Health Monitoring System.

### **Supplies and Accessories**

Cue Health Monitoring System supplies and accessories are available by calling toll-free at (833) CUE-TEST • (833) 283-8378.





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