

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



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.

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# Chapter 1

## Introduction and User Safety

### Welcome to Cue

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

### Intended Use

The Cue Health Monitoring System is an in vitro diagnostic medical device for use with test-specific Cue Cartridge(s) and the Cue Health Mobile Application (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 Testing with the Cue Health Monitoring System

Review the Quick Start Guide and this User Manual before you run a test using the Cue Health Monitoring System.

The Quick Start Guide will help you quickly set up your system and get ready to run a test. This User Manual gives you all the information you need to use your system 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 possible risk of injury or damage to your 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. Do not proceed if you do not fully understand the actions to take after seeing a Caution message.



## **Note**

A Note is used to give you more information to make the instructions clearer.

## 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 to be performed.

Procedure steps are numbered and should be performed in that order.

When there is a system response to the procedure step performed, it 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 as a result of pressing an icon or an action command in the Cue Health App
<b><i>Bold Italics</i></b>	Used to emphasize 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
<b>SN</b>	Serial Number
	Do not use if seal or packaging is broken or damaged
	Storage temperature range
	Humidity Storage range
<b>REF</b>	Catalog number

Symbol	Description
	Manufacturer
	Keep dry
	Electrical and Electronic Equipment Waste: Discard product at separate collection facility for recovery and recycling.
	Caution: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

## General Precautions

The Cue Health Monitoring System may not work correctly if there is damage to the package or the system parts.

- Do not use the Cue Health Monitoring System if the package seals are broken.
- Do not use Cue Health Monitoring System if any part is damaged.
- Do not run a test if the room temperature is outside of the testing conditions stated in the test-specific Cue Cartridge Instructions for Use. Testing in room temperatures that are too high or too low may cause an incorrect or invalid result.
- Do not use the Cue Health Monitoring System in 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 Health Monitoring System 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 Health Monitoring system or use any parts that did not come with the system, you may harm yourself and the system. You will also void your warranty.
- The Cartridge Reader should be placed on a stable, flat, and level surface while running a test. Do not move or tilt the Reader while a test is in progress.
- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA.
- This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
- 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.

- 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.
- This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:
  - (1) This device may not cause interference; and
  - (2) This device must accept any interference, including interference that may cause undesired operation of the device.
- Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:
  - (1) l'appareil ne doit pas produire de brouillage;
  - (2) l'appareil doit accepter tout brouillage radioélectrique

subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

- CAN ICES-3 (B)/NMB-3(B)

## Chapter 2

# Cue Health Monitoring System Overview and Features

The Cue Health Monitoring System include three parts. These parts include the Cue Cartridge Reader, the Cue Power Adapter, and the Cue Charging Cable. The Cue Wireless Charging Base is available as an optional part (accessory). The Cue Health Monitoring System is used with test-specific Cue Cartridges and sample collection devices (Cue Sample Wand). The Cue Cartridge 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 Cartridge Reader	The Cue Cartridge Reader communicates with the Cue Health App and the test-specific Cue Cartridges to run a test on a sample.	 A light gray, rectangular device with a slightly recessed front panel, representing the Cue Cartridge Reader.
Cue Power Adapter	The Cue Power Adapter plugs into standard wall power. The Cue Charging Cable plugs into the Cue Power Adapter.	 A white, rectangular power adapter with a standard two-prong electrical plug on one side and a USB port on the other, representing the Cue Power Adapter.
Cue Charging Cable	The Cue Charging Cable connects the Power Adapter to the Cartridge Reader.	 A coiled, grey and black charging cable with a USB connector on one end and a power connector on the other, representing the Cue Charging Cable.

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

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

- One (1) Cue Cartridge 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 Cartridge Pack**

The table on the next page describes Cue Test Cartridge Packs. Cue Test Cartridge Packs are available for different tests including a test for SARS-CoV-2 virus (COVID-19). Cue Test Cartridge Packs are sold separately and must be used before the Use By date printed on the cartridge pack label.

Component	Description	Image
Cue Test Cartridge Pack	<p>A Cue Test Cartridge Pack comes with a Cue test cartridge, 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 cartridge to run a test on the sample.</p>	 <p>Cue COVID-19 Test Cartridge</p>  <p>Cue Sample Wand</p>

## **Compatible Mobile Smart Devices**

The Cue Health Monitoring System can be used with mobile smart devices. 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 the Cue Health Monitoring System. 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, the test on the Cue Health Monitoring System will still run to completion. The result will not be displayed until the mobile smart device is charged. Bring the charged mobile smart device close to the Cue Cartridge Reader and open the Cue Health App to see the test result.

The Cue Health App also stores test results and communicates with the internet and the secured cloud storage.

## Accessories Available Separately

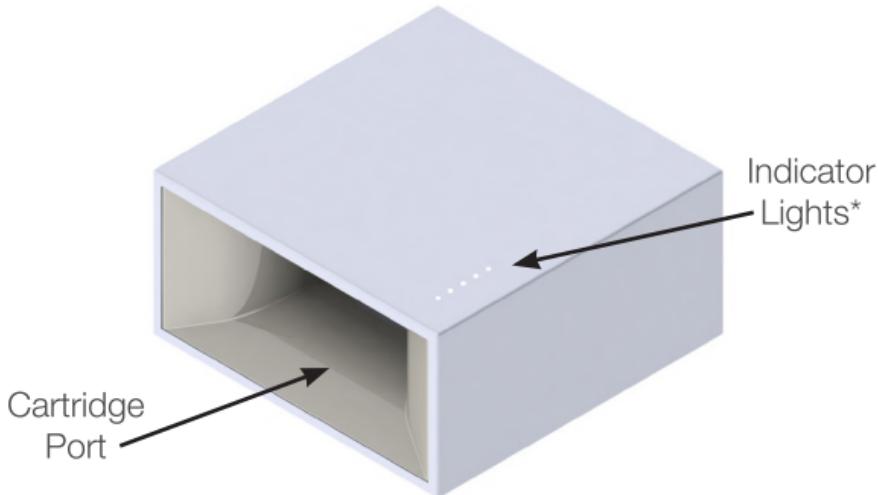
Component	Description	Image
Cue Wireless Charging Base	The Cue Cartridge Reader may be charged wirelessly using the Cue Wireless Charging Base. The Cue Cartridge Reader is secured by magnets when charging on top of the Cue Wireless Charging Base.	

# Chapter 3

## Setting Up Your Cue Health Monitoring System

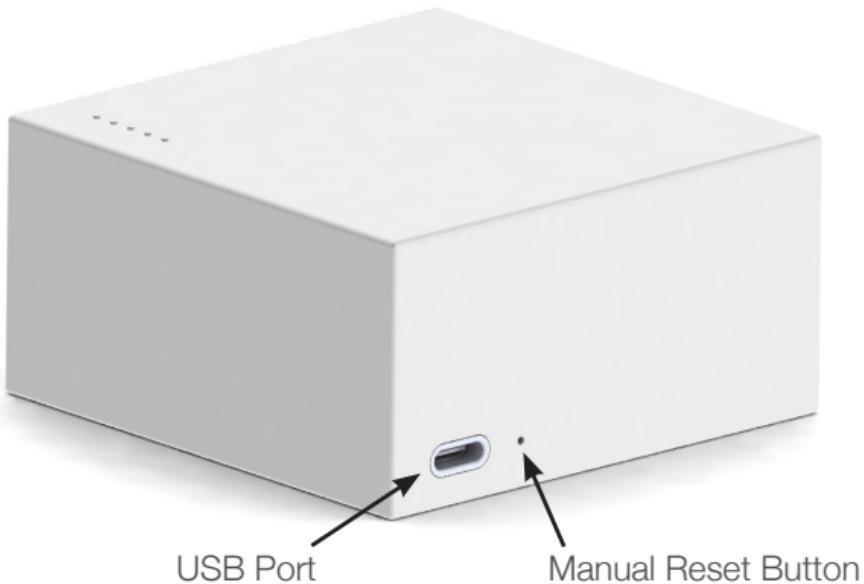
### Identifying Parts of Your Cue Cartridge Reader

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

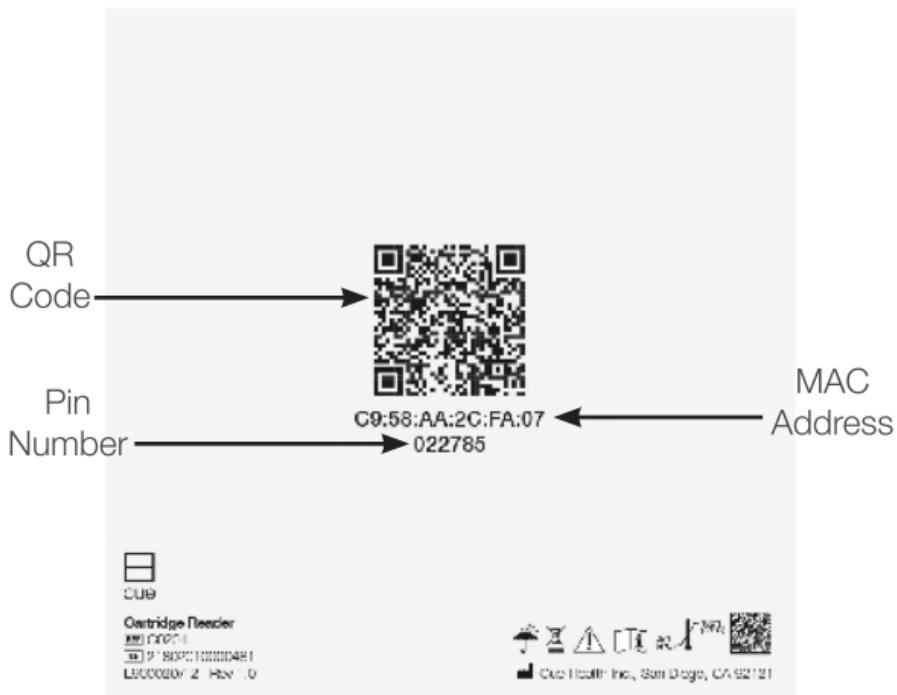


\*See “Cue Cartridge Reader Indicator Lights” in Chapter 3 for information on the meaning of the indicator light patterns.

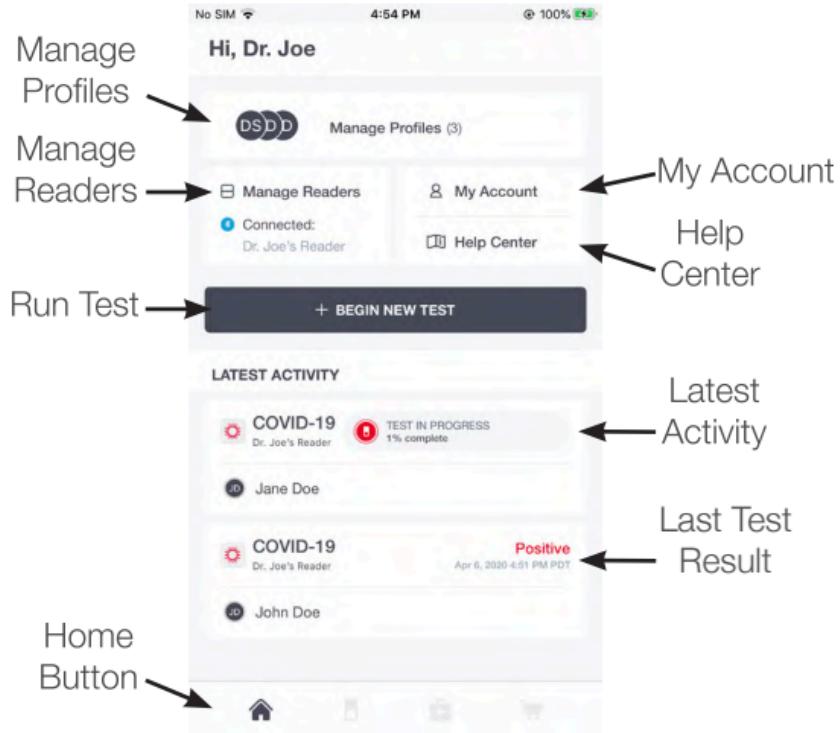
## The Back of Your Cue Cartridge Reader



## The Bottom of Your Cue Cartridge Reader



# Your Cue Health App Dashboard



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

## Cue Cartridge Reader Indicator Lights

### Status Indicators

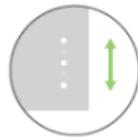
You will see different light patterns on top of the Reader. The light patterns will tell you when the Reader is connected to the Cue Health App. The light patterns will also tell you when a cartridge is inserted, and when there is an error.



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 an 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 Cartridge 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.

1. Launch the Apple App Store or Google Play Store app.
2. Search for the “Cue Health App” by Cue Health Inc. and tap on the Cue Health App icon.
3. Tap Install.
4. 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.
-  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.