

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



cue

Cue Health Monitoring  
System (Reader)  
[Get Started Here](#)



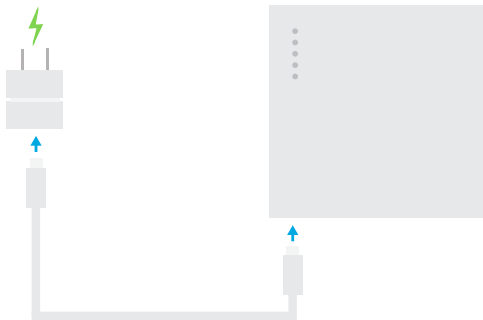
Cue Health



---

## Set Up Your Cue<sup>®</sup> Account

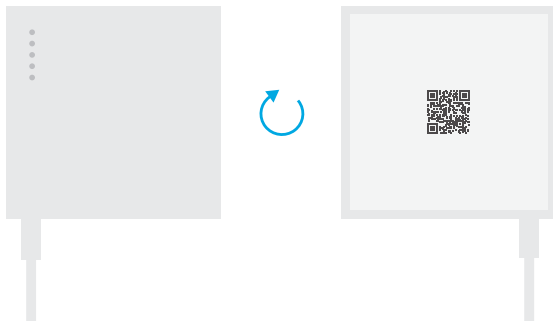
Download the Cue Health App from the Apple App<sup>®</sup> Store<sup>®</sup> or Google Play Store<sup>™</sup> to your mobile smart device. Go to [www.cuehealth.com](http://www.cuehealth.com) for a list of compatible devices. Follow the on-screen instructions to create your account and pair your Cue Health Monitoring System (Reader) to your mobile smart device.



---

## Connect Reader to power

When prompted on the Cue Health App, connect your Reader directly to power using the supplied Cue Power Adapter and USB Charging Cable.

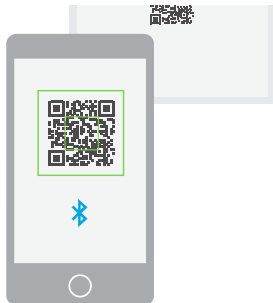


---

## Find Reader QR code

Rotate your Reader upside-down so the bottom of the Reader is facing up and the QR code is visible to you.

The QR code is located on the bottom of the Reader.

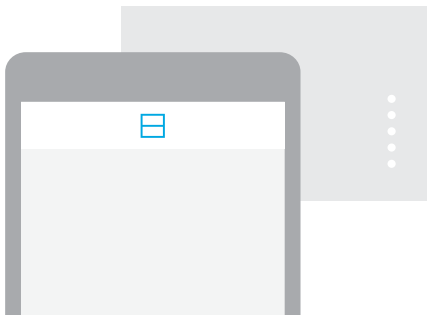


---

## Pair Reader to mobile device

When prompted on the Cue Health App, adjust the camera so the QR code is visible on-screen and inside of the capture outline.

When the QR code is recognized, the Reader is paired securely to the mobile smart device.



---

## Cue Reader is ready to use

To begin using the Reader to run tests, open the Cue Health App and follow the on-screen instructions.

---

# Welcome to Cue®

## Welcome

This guide will help you get started using the Cue Health Monitoring System (Reader) and the Cue Health App.

## Get Started

See opposite page for instructions on downloading the Cue Health App, creating your Cue Account, and setting up your Cue Reader.

## Questions

Dial (833) CUE-TEST · (833) 283-8378 · [www.cuehealth.com](http://www.cuehealth.com)

Cue and the Cue logo are registered trademarks of Cue Health Inc.

Apple and App Store are registered trademarks of Apple Inc.

Google Play is a trademark of Google LLC.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Cue is under license. Other trademarks and trade names are those of their respective owners.

This product has not been FDA cleared or approved; but has been authorized for emergency use by FDA under an EUA. This product has been authorized only for the detection of nucleic acid from SARS-COV-2 virus, 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 product has not been FDA cleared or approved; but has been authorized for emergency use by FDA under an EUA. This product has been authorized only for the detection of nucleic acid from monkeypox virus, 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 infection with the monkeypox virus, including in vitro diagnostics that detect and 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.

---

# About the Cue Health Monitoring System (Reader)

## **Cue Reader**

Your Reader pairs with the mobile smart device, accepts Cue test-specific Cartridges, and runs tests.





---

# About the Cue Health Monitoring System (Reader)



Your Cue Reader communicates with the Cue Health App using a secure wireless connection to your mobile smart device with **BLUETOOTH®** wireless technology.

A Cue Reader can be used with multiple mobile smart devices, but only one smart device at a time can connect to a Reader to run a test and receive test results.

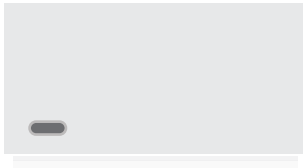


---

# Charging the Reader

## Charging with USB

Your Cue Reader can be quick-charged directly using a cable through the USB port located on the Reader. ....■



---

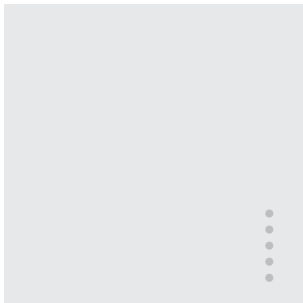
# Indicator Lights

## **Reader lights communicate status**

The Cue Reader features 5 LED indicator lights located on the top of the Cue Reader.

The lights provide quick feedback on the status of the Cue Reader together with the Cue Health App.

The lights display unique patterns to communicate charging status, battery level, prompts for testing actions, test status, and test errors.



---

## Battery Level

When the Reader is connected to power, the lights will sequentially illuminate then flash to indicate the battery charge level.



Lights illuminate sequentially



Battery is 80% charged



Battery is 20% charged

## Prompts for an Action

While running a test or after a test has completed, the indicator lights will sweep from top to bottom or in reverse



Insert Cue Sample Wand with collected specimen into the Cue Test Cartridge



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

## Alerts

When connecting to the Cue Reader or at the start of a test, the indicator lights will flash in different patterns



Lights flash when connected



Lights flash when the Cue Test Cartridge or the Cue Sample Wand is inserted



Error. See the Cue Health App for details

**Document Detail**

9/12/2023

1

**Type:** AIIN**Document No.:** AIIN9100158-4[1]**Title:** Artwork, Quick Start Guide, Cue Mpox (Monkeypox) Molecular Test**Document Owner:** MARIA.VESTAL Maria Vestal**Status:** CURRENT**Effective Date:** 26-May-2023**Expiration Date:** 26-May-2027**Revision Notes**

<u>Document Build</u>	<u>Access Activity</u>	<u>Accessed By</u>	<u>Accessed Date</u>
<u>No.</u>			
1	Check In	N.REAKSECKER	26-May-2023

**Note:**

Review

Build No.: 1

Closed Date: 5/26/2023 11:06:58PM

Review: CP Document Approval

Review Purpose: Document approval on CP

Review Note: SYSTEM AUTO CLOSE REVIEW

Level	Owner Role	Actor	Sign-off Date	Sign-off By
1	FN-Document Reviewer-RA Document Reviewer-Regulatory Affairs	MARIA.VESTAL Maria Vestal	26-May-2023 11:06 pm	MARIA.VESTAL
Note To Approver:				
Note From Approver:				
1	FN-Document Owner Document Owner Functional Role	RODERICK.CASTILLO Roderick Castillo	26-May-2023 10:29 pm	RODERICK.CASTILLO
Note To Approver:				
Note From Approver:				
1	FN-Document Reviewer-QA Document Reviewer-Quality Assurance	E.AMIRI Ellie Amiri	26-May-2023 11:05 pm	E.AMIRI
Note To Approver:				
Note From Approver:				
1	FN-Change Plan Initiator Change Initiator Functional Role	S.DAMBRAUSKAS Susan Dambrauskas	26-May-2023 10:37 pm	S.DAMBRAUSKAS
Note To Approver:				
Note From Approver:				
1	FN-Document Reviewer-ProductDevEng Document Reviewer-Product Development Engineering	JOE.PETRILLI Joseph Petrilli	26-May-2023 10:33 pm	JOE.PETRILLI
Note To Approver:				
Note From Approver:				
1	FN-Document Reviewer-Marketing FN-Document Reviewer-Marketing	K.PEERZADA Khalid Peerzada	26-May-2023 10:35 pm	K.PEERZADA
Note To Approver:				
Note From Approver:				