

# Consumable Configuration

Cartridge Outer Box  
Holds 3 cartridge  
pouches



Instructions For Use (IFU)  
1 in each cartridge outer box



Cartridge Pouch  
(Contains Tray,  
Cartridge, Sample  
Wand Pouch, &  
Sample Wand )



Tray  
(holds cartridge & sample wand)



Cartridge



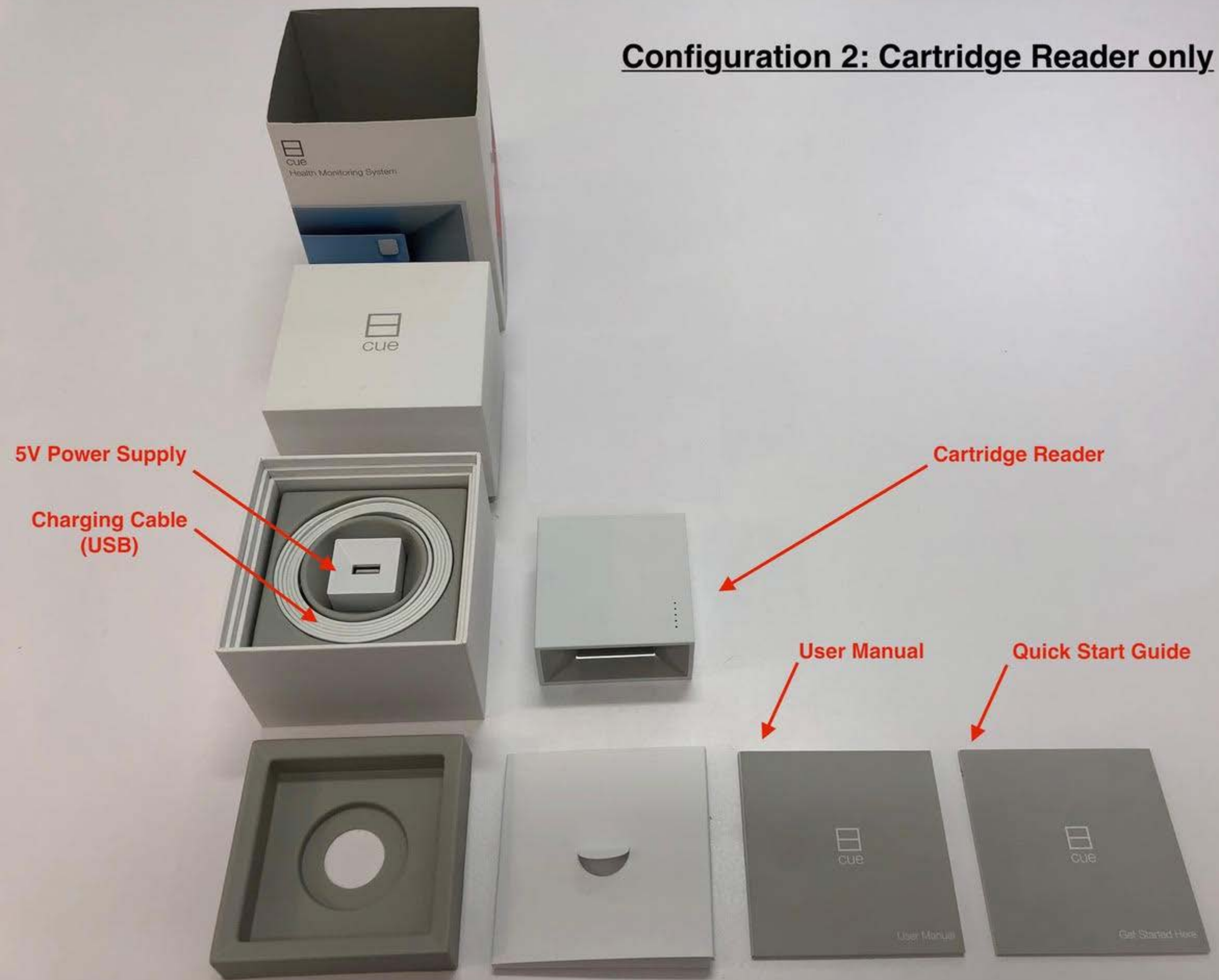
Sample Wand Pouch  
(holds sample wand,  
can be sterilized)



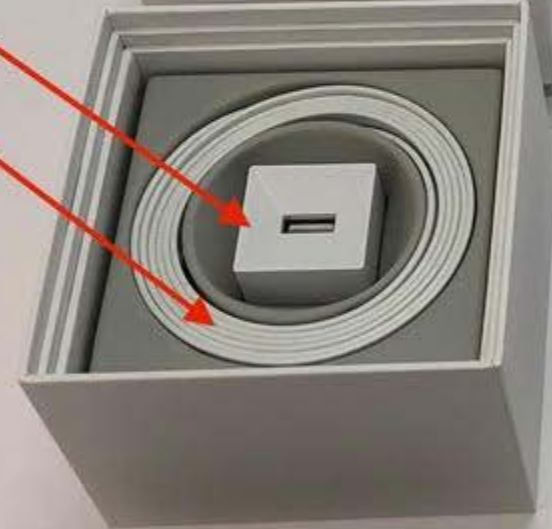
Sample  
Wand



## Configuration 2: Cartridge Reader only



# Configuration 1: Cartridge Reader + Charging Base



Charging Base



Cartridge Reader



User Manual

Quick Start Guide





## 1 Intended Use

The Cue™ Health Monitoring System with Cue Inflammation Monitoring Cartridge (Cue Inflammation) is a highly sensitive diagnostic test that measures C-reactive protein (CRP) in capillary whole blood from a fingerstick. The whole blood is collected using an FDA-cleared fingerstick device (lancet) and the Cue sample wand.

C-reactive protein (CRP) is a substance produced most often by the liver, but also by adipocytes (cells specialized for the storage of fat) and vascular smooth muscle cells in response to inflammation. Elevated CRP levels can indicate that there is inflammation caused by injury to muscles or bones, upper respiratory infections, or build-up of lipids on the walls of arteries of the heart which can mean a higher risk for heart attack. Chronic inflammation can be a marker for chronic inflammatory and autoimmune diseases, and be a precursor to more serious conditions such as cancer. CRP can be elevated in any inflammatory condition and is not specific to any one inflammatory condition. Generally, when CRP levels drop, inflammation is decreasing.

The Cue Inflammation test may be used by men and women 18 years of age and older with personal or family history of cardiac disease. These people may use the test for monitoring C-reactive-protein levels for personal risk of cardiovascular disease or future adverse cardiac events and to prompt appropriate lifestyle changes to reduce inflammation, risk of heart disease, and CRP levels. These lifestyle changes would include healthy diet, regular physical activity, and avoidance of tobacco smoke. The Cue Inflammation test results can be shared immediately with a healthcare provider and should be used along with consultation with this healthcare provider to discuss results and recommendations for any additional testing, treatment, or lifestyle adjustments.

The Cue Health Monitoring System with Cue Inflammation Monitoring Cartridge is used with the Cue Health Mobile Application.

This test is for over-the-counter use. It may be sold directly to the consumer without a prescription.

## 2 Summary and Explanation of the Test

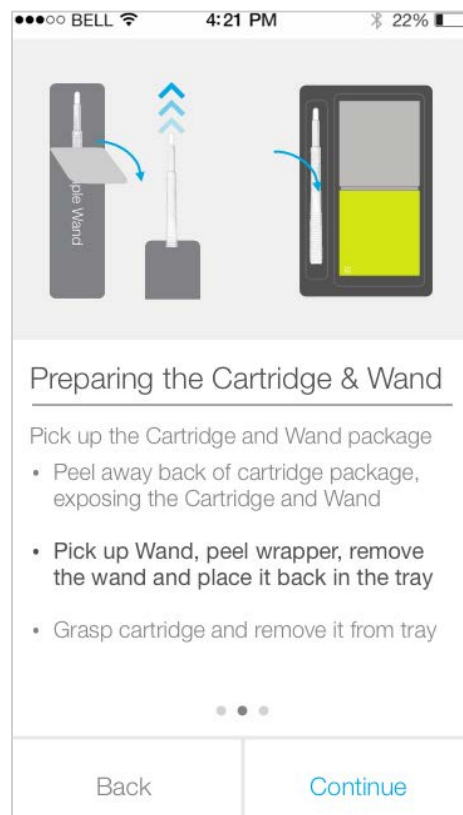
Inflammation is the body's response to stimulus like injury or chronic illness. Inflammation is a protective response that involves immune cells, blood vessels, and additional substances that enable the body's early defense (your immune system). Inflammation influences how quickly your injuries heal and the overall health of your cardiovascular system. Too much inflammation in some circumstances can have negative effects on your body, particularly on blood

### 7.3 Preparing the Cue cartridge and Cue sample wand

Screen 7.3-1



Screen 7.3-2



Screen 7.3-3

