

Package Insert / Instructions for Use



WARNING

- The Tiger Tech COVID Plus™ Monitor is NOT a diagnostic device, and must not be used to diagnose or exclude SARS-CoV-2 infection.
- Use of the Tiger Tech COVID Plus™ Monitor in an asymptomatic population is intended to be part of an infection control plan that includes uses of a thermometer. A “red light” indicator from the Tiger Tech COVID Plus Monitor does not necessarily indicate current SARS-CoV-2 infection. Instead, it is only an indication – like a fever – that a person is demonstrating biomarkers of certain conditions, such as hypercoagulation, that may be associated with SARS-CoV-2 infection. As such, this device is only for use as a preventative screening tool.

PRECAUTION

- An individual’s underlying hypercoagulable state (such as disseminated intravascular coagulation, sepsis, or cancer) or hyper-inflammatory condition (such as severe allergic reactions) may interfere with the COVID-19 related performance of the Tiger Tech COVID Plus™ Monitor and could lead to an incorrect screening result.
- Use of the Tiger Tech COVID Plus™ Monitor is authorized only for use by trained personnel to help prevent exposure to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where a temperature check is being conducted in accordance with Centers for Disease Control and Prevention (CDC) and local institutional infection prevention and control guidelines.¹

EMERGENCY USE INFORMATION

- The Tiger Tech COVID Plus™ Monitor has neither been cleared nor approved by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) for emergency use by trained personnel to help prevent exposure to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with CDC and local institutional infection prevention and control guidelines.

¹ A temperature check is commonly performed to screen for SARS-CoV-2 infection. For example, it is considered by CDC to be an optional strategy for reducing the spread of COVID-19 in workplaces (https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html#anchor_1609683211941) and community locations (<https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/symptom-screening.html>). The Tiger Tech COVID Plus Monitor is authorized to be used only as a secondary screening device in settings where temperature check is being conducted for screening for potential SARS-CoV-2 infection risk.

- The emergency use of the Tiger Tech COVID Plus Monitor is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, 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.

Device description:

The Tiger Tech COVID Plus™ Monitor is an armband with two embedded photoplethysmography (PPG) sensors and a processor. During use, the armband is wrapped around the recipient's bare left arm above the elbow. The PPG sensors acquire direct pulsatile biosignals over a period of 3-5 minutes from the outer left bicep. The processor interprets the signals obtained by the sensors. First, a series of morphological features ("biomarkers") are extracted from the pulsatile signals, which have been correlated with certain conditions, including the hypercoagulable state (a condition where a person's blood clots more easily than normal), that may be associated with SARS-CoV-2 infection. These features are fed into a probabilistic machine learning model that has been trained to make predictions on whether the individual is showing certain signals, such as hypercoagulation in blood. The model requires roughly two minutes of motionless (i.e., artifact-free) data to provide the screening result.

Intended use:

The Tiger Tech COVID Plus™ Monitor is intended to be used by trained personnel to help prevent exposure to and spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with Centers for Disease Control and Prevention (CDC) and local institutional infection prevention and control guidelines.

Operation steps:

1. Use the Tiger Tech COVID Plus™ Monitor only after an individual is confirmed to not have a fever (100.4 °F or 38 °C or higher) using a thermometer.
2. Wrap the Tiger Tech COVID Plus™ Monitor armband around the bare left arm above the elbow. Sensor should be placed facing the outer part of the bicep, as shown below.
3. Sensor should be flush to the skin. Loosen strap if it causes discomfort.
4. Tiger Tech COVID Plus™ Monitor must be placed on the recipient before the device is turned on. There is a switch on top of the device. Slide the switch into the "on" position. The LED light will sequentially flash several colors before the measurement starts, indicating the device is turned "on."
5. The recipient must sit still for 3-5 minutes. Motion will increase the length of time for the measurement. A blinking purple light will indicate that the recipient is moving or that the sensor placement is poor and should be re-adjusted. A blinking white light during the measurement indicates a quality signal.

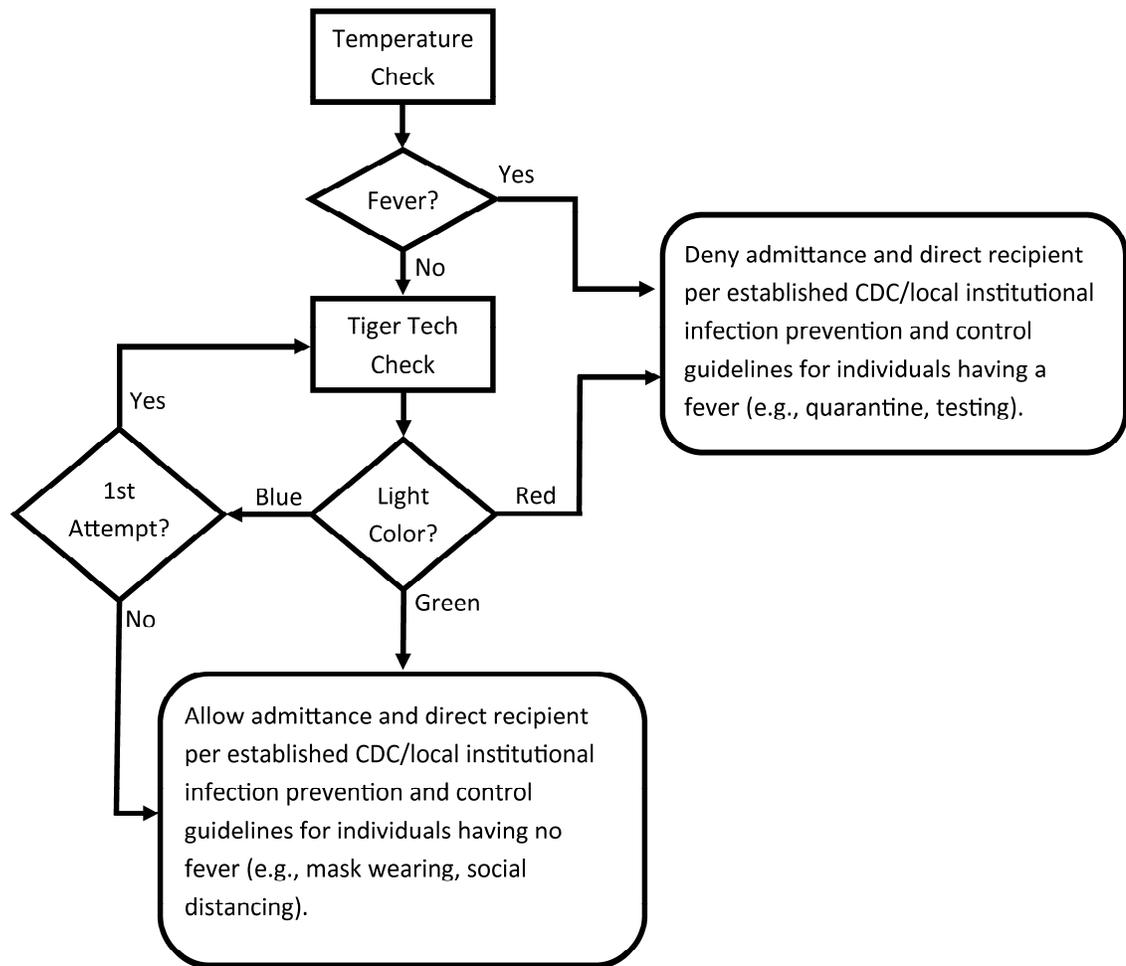
6. At the end of the measurement, the LED light will glow solid green, red, or blue.
 - a. A green light indicates that the recipient is not demonstrating biomarkers of certain conditions, such as hypercoagulation in blood. Direct the recipient according to the decision tree shown below.
 - b. A red light indicates that the recipient is demonstrating biomarkers of certain conditions, such as hypercoagulation in blood. Direct the recipient according to the decision tree shown below.
 - c. A blue light indicates that the test is inconclusive due to indeterminate features. The user should reset the device by turning the board off, remove the device from the recipient, wait 5 minutes, and try again. If the device is unable to render a red or green light after one additional attempt, no additional attempt is needed; direct the recipient according to the decision tree shown below.
7. Turn the board off to reset the device.
8. Sanitize the device after each use using at least 70% alcohol wipes.



Key for Lights	
Light	Meaning
Blinking white light	Quality signal being acquired
Blinking purple light	Quality signal not being acquired (adjustment needed)
Blinking red light	Battery low
Solid green light	Biomarkers not demonstrated
Solid red light	Biomarkers demonstrated
Solid blue light	Inconclusive (repeat testing needed)

Decision tree:

After obtaining the results from the Tiger Tech COVID Plus™ Monitor, follow the decision tree below to direct the recipient:



Replacing the battery:

The Tiger Tech COVID Plus™ Monitor is powered by a single rechargeable 9V battery. A blinking red light indicates that the battery is low and should be replaced.

Device storage and use environment:

The Tiger Tech device is designed to work best in ambient temperatures between 32°F and 95°F (0°C and 35°C) and be stored in temperatures between -4°F and 113°F (-20°C and 45°C).