

# FACT SHEET FOR PATIENTS

## Coronavirus Disease 2019 (COVID-19)

Emergency Use of the ELEFT During the COVID-19 Pandemic

March 15, 2023

You are being given this Fact Sheet because you have a confirmed or suspected COVID-19 infection (the disease that is caused by the SARS-CoV-2 virus), and your doctor plans to use the ECG Low Ejection Fraction Tool (ELEFT) to assess whether your heart has decreased function.

This Fact Sheet contains information to help you understand the risks and benefits of your healthcare provider using ELEFT as an aid to screen your heart for a low Left Ventricular Ejection Fraction (LVEF). The ELEFT algorithm defines low LVEF as less than or equal to 40%. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

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**For the most up to date information on COVID-19, please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**

<https://www.cdc.gov/COVID19>

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### What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell. It has been observed that some patients with severe infections have decreased heart function. This can increase their risk of complications or even death.

### What is the ECG Low Ejection Fraction Tool (ELEFT)?

Ejection fraction (EF) is a measurement of your heart's ability to pump blood. The ELEFT is designed to identify (screen) patients who may have an EF of 40% or less, which is commonly associated with decreased heart function. In particular, ELEFT is a software tool that your

healthcare provider can use to assess your heart's LVEF.

ELEFT will use the information collected from a common assessment of the electrical activity of your heart, called an electrocardiogram (ECG or EKG), to make an assessment of your heart's LVEF. The ELEFT analyzes 10 seconds of your ECG and displays a yes/no prediction of likelihood of low LVEF to your healthcare provider.

### Why will ELEFT be used on me?

We know that a small percentage of patients with COVID-19 are suffering heart damage from their infection. Additionally, patients who already suffer from decreased heart functions may be at greater risk for complications from COVID-19. One way to identify those patients, who may not have any obvious signs or symptoms of this problem, is to screen them by using a test called an echocardiogram. Echocardiograms may not be available immediately or may not be appropriate for every patient. ELEFT is another tool that can detect a low EF, which may be associated with decreased heart function. ELEFT analyzes data from an electrocardiogram (ECG) or a recording of the electrical activity of the heart.

By using ELEFT to analyze your ECG, your doctor may be able to detect whether you have a decreased LVEF. Then your doctor can decide if any additional testing or treatment may be necessary.

### What are the known and potential risks and benefits of the ELEFT?

Some of the known and potential benefits include:

- Early detection of decreased heart function, especially if there was no other reason to order an echocardiogram. This allows your doctor to determine if additional testing may be needed and to start monitoring as quickly as possible.
- Early detection of normal heart function. This allows your doctor to focus on other body problems you may have because of COVID-19, and avoid unnecessary tests or delays in your care.

Because it is a software product, ELEFT is not used on or inside the body. Therefore, there is no risk of direct

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**How can I learn more?** The most up-to-date information on COVID-19 is available at the CDC General

Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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physical harm from the use of ELEFT. However, some of the known and potential risks include:

- “False negative” test: Even if you have a low LVEF, it is possible that your ELEFT result could be incorrectly negative. In clinical testing, about 15 out of every 100 negative results were incorrect.
- “False positive” test: Some patients receive a positive (abnormal) ELEFT result even though they do not have a low LVEF. In clinical testing about 17 out of every 100 positive results were incorrect.

### How is the ELEFT Used?

ELEFT is computer software used by your healthcare provider to analyze the ECG you had. Your doctor sees the results and then decides the next steps for treating you by using that information, along with other information about you.

### Limitations of the ELEFT

As with any test, ELEFT sometimes provides incorrect results. Additional testing should be performed if you are experiencing symptoms suggestive of a reduced heart function.

ELEFT is not meant to be used by laypeople (e.g., patients), and is not meant to provide a diagnosis of low LVEF. ELEFT should not replace an echocardiogram in cases where an echocardiogram is indicated. The software does not detect any possible cardiac abnormality besides reduced LVEF. It is not intended for monitoring of patients diagnosed with heart failure. The software is not intended as a sole means of diagnosis and is intended to be used when echocardiography is not yet available or is not indicated.

ELEFT does not make a diagnosis, but rather provides one more input into the healthcare provider’s decision making. If you have any signs or symptoms of heart failure or when there is a high level of suspicion for low LVEF, additional testing (i.e., an echocardiogram) should be performed to confirm the result before undertaking any treatment

### Is this ELEFT FDA-approved or cleared?

No. ELEFT is not approved or cleared by the United States (U.S.) FDA. Instead, FDA has made ELEFT

available under an emergency access mechanism called an Emergency Use Authorization (EUA).

### What is an EUA?

The EUA is supported by the Secretary of Health and Human Service’s declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic. The use of the ELEFT available under this EUA has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the ELEFT may be effective for use by HCPs to provide an assessment of LVEF for use as a diagnostic aid to screen for potential cardiac complications associated with COVID-19 or underlying cardiac conditions that may affect clinical management of COVID-19, in adult patients having or suspected of having COVID-19, and the known and potential benefits of ELEFT, for such use, outweigh the known and potential risks.

The EUA for the ELEFT is in effect for the duration of the COVID-19 declaration justifying emergency use of the product, unless terminated or revoked (after which the product may no longer be used).

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### How can I learn more?

#### CDC websites:

General: <https://www.cdc.gov/COVID19>

#### FDA websites:

General: [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

#### Manufacturer: Anumana, Inc.

1 Main Street, Suite 400 East Arcade, Cambridge, MA 02142

Phone: 1-800-395-2715

For Technical Assistance: E-Mail: [productsupport@anumana.net](mailto:productsupport@anumana.net)

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**How can I learn more?** The most up-to-date information on COVID-19 is available at the CDC General Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.