FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the ELEFT During the COVID-19 Pandemic **March 15, 2023**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the ECG Low Ejection Fraction Tool (ELEFT). This software device is for diagnosing low Left Ventricular Ejection Fraction (LVEF), for use by healthcare professionals (HCP) to provide an assessment of LVEF for use as a diagnostic aid to screen for potential cardiac complication 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. The ELEFT algorithm defines low LVEF as less than or equal to 40%.

LVEF is the measurement of how much blood is pumped out of the left ventricle of the heart (the main pumping chamber) at the end of each heartbeat. It is typically expressed as a percentage of volume from each heartbeat. LVEF is a standard measure of cardiac efficiency and is used in the evaluation of patients. While LVEF is commonly and most accurately assessed using echocardiography, such imaging studies are not always available or indicated.

All patients who are tested with this device during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of the ELEFT During the COVID-19 Pandemic

ELEFT is not meant to be used by laypeople (e.g., patients), and is not meant to provide a standalone diagnosis of low LVEF. A prediction of LVEF less than or equal to 40% by the ELEFT should be confirmed with additional testing (i.e., echocardiogram, physical exam, etc.) to confirm the result before undertaking any treatment. 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.

What do I need to know about COVID-19 treatment?
Current information on COVID-19 infection for HCPs, including case definitions and information about clinical signs and symptoms and/or epidemiological criteria, is available on the CDC website listed at the end of this Fact Sheet.
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

There is rapidly growing evidence that patients with cardiac comorbidities are at substantially increased risk for complications from COVID-19, and that COVID-19 may actually exacerbate existing or introduce new cardiac comorbidities. Some reports show that even in patients without a history of cardiovascular disease, cardiac involvement may occur with COVID-19, without respiratory tract signs and symptoms of infection.

Screening for cardiac conditions, particularly low LVEF which may herald the onset of heart failure and require medical interventions, is therefore an important part of managing COVID-19 patients. While echocardiography is the standard for diagnosis, screening tools that are quick and accurate for detecting cardiac dysfunction are becoming increasingly important. This is especially true for patients for whom an echocardiogram would otherwise not be indicated.

What is the ELEFT device?
ELEFT is a machine learning algorithm that interprets a 12 lead electrocardiogram (ECG). The tool analyzes 10 seconds of ECG, and provides a yes/no prediction of likelihood of low LVEF. The algorithm is embedded in a software program which allows the algorithm to have access to the ECG traces and which displays the output of the algorithm.

ELEFT is authorized to screen patients over the age of 18 diagnosed with or suspected of having COVID-19. ELEFT should be used as an aid to determine if a patient that otherwise may not receive an echocardiogram should receive an echocardiogram. It should not be used in place of an echocardiogram if otherwise indicated. It should be emphasized that the only cardiac abnormality that ELEFT may detect is low LVEF (< 40%). A normal ELEFT does not exclude other cardiac abnormalities (for example, valve disease, segmental wall motion abnormalities, right ventricular

dysfunction, pericardial effusion/tamponade, pulmonary hypertension). If those are suspected, ELEFT does not help decide if an echocardiogram is needed.

ELEFT does not make a diagnosis, but rather provides one more input into the healthcare provider's decision making. For patients with 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.

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

Known and potential benefits of the ELEFT include:

- During the initial triage and intake process for COVID-19 patients, ELEFT provides an initial indication of the presence of low LVEF, such that medical management of the patient could take their decreased cardiac function into account.

The ELEFT has been designed to minimize the risk of misuse with guidelines provided in its *Instructions for Use*. However, should misuse occur, they may present the following risks to patients:

- Results provided by ELEFT may be falsely positive or falsely negative; that is, it may fail to identify patients who have low LVEF and/or mistakenly identify a patient as having a low LVEF when he or she does not.

Overall, it is reasonable to conclude that the benefits of ELEFT use outweigh the risks.

What is an EUA?

The United States Food and Drug Administration (FDA) has made the ELEFT available under an Emergency Use Authorization (EUA).
The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

The ELEFT made available under this EUA has not undergone the same type of review as an FDA-approved or cleared device. However, in the absence of an FDA-approved or cleared alternative and based on the totality of scientific evidence, it is reasonable to believe that the ELEFT may be effective for use by HCPs to provide an assessment of LVEF for use as diagnostic aid to screen for potential cardiac complication 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.

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

How can I learn more?

CDC websites:
General: https://www.cdc.gov/COVID19
Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html

FDA websites:
General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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