Intended Use

ECG Low Ejection Fraction Tool (ELEFT) is a software intended to be used by healthcare professionals (HCP) to provide an assessment of Left Ventricular Ejection Fraction (LVEF) for use as a diagnostic aid to screen for potential cardiac complications associated with Coronavirus Disease 2019 (COVID-19) or underlying cardiac conditions that may affect clinical management of COVID-19. ELEFT analyzes a standard 12 lead ECG to detect the presence of LVEF ≤ 40%. It is intended for use on patients over the age of 18 diagnosed with or suspected of having COVID-19.

The software should not replace an echocardiogram in cases where an echocardiogram is indicated. 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.

The software is only intended for use by healthcare professionals.

Description

ELEFT is a machine learning algorithm that analyzes a 12 lead electrocardiogram (ECG) to detect the presence of low LVEF.

The ELEFT algorithm is designed to be accessed using a cloud-based software application programming interface (API) that allows a health system to upload 12 lead ECG data for analysis. The process can be completed using the Electronic Medical Record of the health system. The software returns a binary (positive/negative) result indicating whether the presence of low LVEF (ejection fraction less than or equal to 40%) has been detected.

Report

The user interface and display of results is likely to depend on your particular health system. Please check with your health IT professional for details on how to access the results from the ELEFT algorithm. Below are the two possible results from the software, which would typically be provided along with the 12 lead ECG strip.

Low EF Screen Positive - High probability of low ejection fraction based on the ECG.
Low EF Screen Negative - Low probability of low ejection fraction based on the ECG

Clinical Performance

The results for a particular patient should be interpreted in light of other clinical information, such as the patient's history and symptoms. Additionally, it is helpful to consider the performance of the device when interpreting results.

ELEFT was validated using a retrospective dataset of 52,870 patients who had 12 lead ECG and echocardiogram performed within a 2 week window.

The observed sensitivity and specificity were:

Sensitivity = 83.3% (95% CI = (82.3 - 84.2))
Specificity = 84.9% (95% CI = (84.6 - 85.2))

Additionally, the PPV and NPV were 40.8% and 97.6% in this dataset in which the prevalence of

EF ≤ 40% was 11.1%.