INSTRUCTIONS FOR USE

ECG LOW EJECTION FRACTION TOOL (ELEFT)
March 15, 2023

ANUMANA

Intended Use
ECG Low Ejection Fraction Tool (ELEFT) is a machine learning algorithm 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 in digital format 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.

ELEFT 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 returns a binary (positive/negative) result indicating whether the presence of low LVEF (ejection fraction less than or equal to 40%) has been detected. The ELEFT 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. Please email Anumana at productsupport@anumana.net to request access to the software program housing the ELEFT algorithm.

Report
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

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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%.