For Immediate Release:

Syntermed awarded 510(k) clearance for Calcium Scoring and Strain Analysis

(preview)

Syntermed, Inc received 510K clearance from the Food and Drug Administration (FDA) for Emory Cardiac Toolbox™ (ECTb™), a software used in nuclear cardiology for analysis of SPECT and PET myocardial perfusion studies. ECTb is now cleared for the analysis of calcium scoring and heart strain analysis.

June 15, 2023 – Atlanta, GA - Syntermed, Inc. was recently awarded updated 510(k) clearance from the Food and Drug Administration for the Emory Cardiac Toolbox™ (ECTb™) used by nuclear cardiology labs doing SPECT and PET myocardial perfusion scans. ECTb is now FDA-cleared with a 510K indication for the analysis of calcium scoring and strain analysis.

Coronary Artery Calcium Scoring (CACS)

(CACS) calculates the volume and Agatston score of selected lesions based on the native resolution of the input image. The presence and magnitude of coronary calcium have been established as a marker of increased likelihood of CAD. Computerized Tomography (CT) has continued to be increasingly used clinically for the evaluation of calcium in the coronary arteries. ECTb now includes a tool to determine coronary calcium from a CT scan (CACS). David Cooke, Syntermed Director of Clinical Applications adds “the addition of Coronary Artery Calcium Scoring to ECTb provides improved workflow and additional quantitative and prognostic information when working up a patient”

Global Longitudinal Strain (GLS)

Myocardial perfusion imaging (MPI), including positron emission tomography (PET) and single photon emission computerized tomography (SPECT), is widely used in the assessment of ischemic heart disease, determination of myocardial viability, and evaluation of cardiac device-related infections. While Left ventricular ejection fraction (LVEF) is a well-established measure of global LV function that is associated with long-term outcomes, cardiac diseases affect individuals differently and may not conform to arbitrary EF cutoffs. Therefore, the ability to further categorize a patient’s LVEF is needed, particularly in those with EF 35-50%. Prior releases of ECTb have included an automated approach to track the LV myocardium throughout the cardiac cycle

to measure LV dyssynchrony using electrocardiogram-gated (ECG-gated). With this updated 510(k) clearance, ECTb will now expand on this approach to include tracking methodology to measure radial, circumferential, and longitudinal strain at rest and during pharmacologic stress which has been shown by echo to be a superior predictor of all-cause cardiac mortality compared to LVEF in patients with coronary artery disease. Furthermore, GLS has been shown to be a robust measure for identifying early LV myocardial dysfunction, especially in patients undergoing chemotherapy.

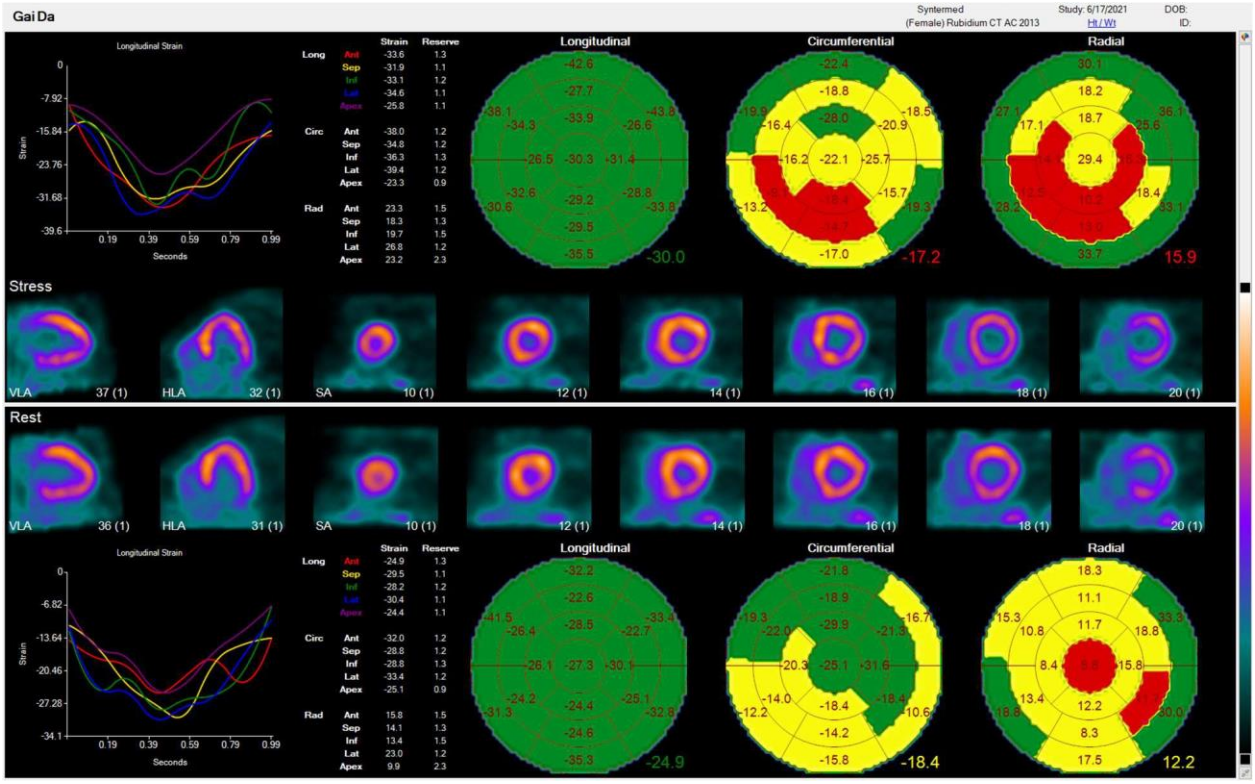

Figure Legend: Strain module in the Emory Cardiac Toolbox™ (Lower portion of screen) showing Global Strain Analysis.

"At Syntermed, we are dedicated to delivering intelligent imaging solutions which allow clinicians to deliver improved and more efficient healthcare worldwide. Our technology supports the current wave in medicine for intelligent solutions that provide decision support, and the new features for calcium scoring and strain analysis provide important additional information for analysis of SPECT and PET imaging studies" says Ken Van Train, Syntermed President.

About Syntermed, Inc.

Syntermed, Inc., an Atlanta-based imaging and informatics software company, is a global leader in providing Cardiac, NeuroRadiology, and Oncology solutions. Signature products include Emory Toolbox™ AI, NeuroQ™, and Syntermed Live™. Emory Toolbox™ AI incorporates an FDA 510K cleared AI platform for quantifying and reporting MPI SPECT/PET studies. NeuroQ™ is one of the

most widely utilized software solutions for quantifying brain PET-FDG, Amyloid, SPECT, DaTscan and Epilepsy studies. Syntermed Live™, which currently hosts almost 1M studies, is a cloud-based and HIPAA compliant platform used by nuclear medicine physicians to get round-the-clock secure, remote access to their studies and reports no matter where they are. All Syntermed solutions are 510K cleared, ISO Certified and carry the CE Mark and are compatible with virtually any nuclear medicine workstation or PC/MAC that supports Microsoft® Windows® operating system.

For more information, contact digitalmedia@syntermed.com or call 888-263-4446 ext.3.