

Rcadia's COR Analyzer Family of Products Receives Second FDA Clearance

HAIFA, Israel, Sep 25, Rcadia Medical Imaging, Ltd., developer of novel computer-aided diagnostic software, has received a second U.S. Federal Food and Drug Administration (FDA) clearance to market its COR Analyzer family of products, which assists in triaging patients for coronary artery disease (CAD). The new approval includes segmentation of the coronary tree with no human intervention and automatic detection of pathologies in the main coronary arteries.

Coronary artery disease is a major underlying cause for acute chest pain in Emergency Department (ED) patients. Annually, more than 5 million US patients present in the ED with acute chest pain. CT Angiography (CTA) is being rapidly adopted to triage patients in EDs across the U.S. Rcadia's COR Analyzer quickly identifies coronary artery disease and helps exclude patients without coronary arterial disease with a high negative predictive value (NPV). Rcadia's COR Analyzer system uses proprietary image processing algorithms allowing a no human intervention analysis of Coronary CTA studies to characterize patients. While improving ED workflow, it can lead to a more rapid diagnosis, enabling appropriate treatments and avoiding unnecessary delays and invasive tests in patients who do not have coronary artery disease.

"The COR Analyzer is expected to assist the ED staff in reading Coronary CTA studies 24/7. Prioritizing patients with CAD, identifying and characterizing pathologies will save time and improve workflow in the ED as well as the radiology and cardiology departments," commented Shai Levanon, Rcadia CEO.

Coronary CTA studies are sent from the CT scanner to the COR Analyzer and analyzed without human intervention. The COR Analyzer is highly reliable in ruling out coronary artery disease. In analyzing over 350 CTA studies, generated by all four CT manufacturers, the Rcadia COR Analyzer successfully identified coronary artery disease and had a high NPV of over 97%.

"As a result of the COR Analyzer high negative predictive value we are currently finalizing testing of the product and strongly hope to start using it to triage cases that need to be read, alerting the reader which patients are most likely to have coronary arterial disease. Since COR Analyzer automatically marks pathologies; this in turn will make reading cases significantly faster even for the experienced radiologists." added Nathan Peled, MD, Head Department of Radiology at the Lady Davis Carmel Medical Center in Haifa.

