Press Release

FAST study demonstrates high diagnostic accuracy of CAAS vFFR and received USA 510(k) market clearance.

Maastricht, May 22nd 2018 - **A highly innovative software, developed by Pie Medical Imaging** – PMI – B.V. (Esaote Group) will be presented at EuroPCR 2018, the world-leading course in interventional cardiovascular medicine, that will be held in Paris, Palais des Congrès (France) between 22 - 25 May 2018.

This software – **called CAAS vFFR (Cardiovascular Angiographic Analysis Systems for vessel Fractional Flow Reserve) – can calculate the pressure drop and vFFR value in the coronary artery non-invasively, which means that there is no need for a pressure wire and hyperemic agent.**

FFR is an established technique used in interventional cardiology to measure pressure differences across a coronary stenosis. Based on this, cardiologist may take a decision on whether a coronary stenosis has to be treated with angioplasty or not. This examination is done during a catheterization procedure with the support of costly pressure wire and hyperemic agent.

CAAS vFFR allows clinicians to use two standard angiograms taken during a standard catheterization procedure as input to get access to coronary physiology assessment. For percutaneous coronary interventions (PCI), within one easy workflow, **CAAS vFFR offers a unique combination of functional and anatomical lesion assessment (such as percentage stenosis) to support the interventional cardiologist in the clinical decision making process**.

FAST, a clinical study led by Ken Masdjedi, MD and Joost Daemen MD, PhD from Erasmus Medical Center, Rotterdam **shows that vFFR as calculated using CAAS vFFR has a high linear correlation to invasively measured FFR**.

"In the FAST study" said Joost Daemen MD, PhD, principal investigator *"we demonstrated that vFFR as calculated using CAAS vFFR has a high linear correlation to invasively measured FFR and high diagnostic accuracy to detect FFR ≤ 0.80. **vFFR is a promising, fast and easy to use tool to assess coronary physiology without the need for a costly pressure wire or hyperemic agent**."*

"*We are very proud of this technological and clinical achievement*" declared René Guillaume, PMI CEO "*which is the result of 30-year commitment and experience of our Company in the field of cardiovascular analysis software and of the successful collaboration with the most prestigious medical and scientific research centers*".

CAAS vFFR received USA 510(k) market clearance and is CE marked and PMDA cleared (Japan). For more product information on CAAS vFFR:
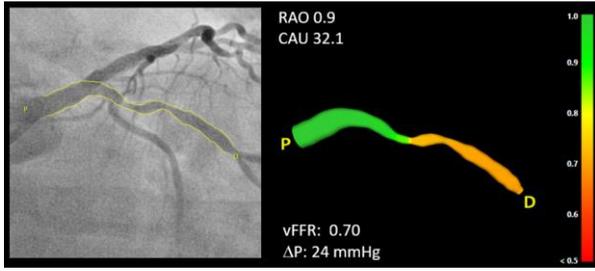https://www.piemedicalimaging.com/product/caas-workstation/vffr/

About PMI. PMI BV is a world leader in quantitative analysis of cardiovascular images, well known for its CAAS and 3mensio product lines. Based in Maastricht (The Netherlands), it hosts the global sales for the CAAS and 3mensio product lines. PMI and 3mensio Medical Imaging are part of the Esaote Group, leader in the biomedical equipment sector, in particular the areas of ultrasound, dedicated MRI and Medical IT. More information about PMI is available at www.piemedicalimaging.com

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3D representation of vessel with color scale indicating vFFR value