

# Indications for Precautions and other Safety Information

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## I. Intended Purpose

AngioPlus Core(  $\mu$  FR) is an analysis software designed for adult patients with stable and unstable angina pectoris or post acute myocardial infarction. By exporting the obtained DICOM format angiography data, then select the vascular region of interest and analyzes the region, AngioPlus Core outputs quantitative  $\mu$  FR values and anatomical parameters. AngioPlus Core (  $\mu$  FR) analysis is intended to aid the functional evaluation of coronary artery disease. The results of AngioPlus Core(  $\mu$  FR) are intended to be used by qualified cardiologists inconjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the cardiologists 's professional evaluation. For use only by qualified cardiologists or trained technicians for cardiac analysis.

## II. Indications

- Patients with stable and unstable angina pectoris or post-AMI;
- The diameter stenosis was  $\geq 30\%$  and  $\leq 90\%$  in coronary artery by visual assessment;
- Coronary bifurcation lesions: main branch and side branch lesions with Medina classification as 1,1,0、0,1,1、1,0,0、0,1,0、0,0,1 , and main branch lesions with Medina classification as 1,1,1、1,0,1.

## III. Contra-indications













None.











## IV. Precautions

The safety and effectiveness of the  $\mu$  FR measurement has not been evaluated for patients with the following conditions:



The luminal reduction was caused by myocardial bridge.

	Ostial lesions <3 mm from the aorta.
	Side branch lesions with Medina classification as 1,0,1、 1,1,1.
	Low quality angiography that cannot detect the boundary of blood vessels or poor filling of contrast media.
	Severe vessel overlap or tortuosity at the stenotic segments.
	Visual inspection of the reference lumen diameter of the lesion segment < 2mm.
	AngioPlus Core must be used by cardiologists or trained technicians who are qualified to perform cardiac analysis.
	The results of AngioPlus Core( $\mu$ FR) are intended to be used by qualified cardiologists in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the cardiologists 's professional evaluation. When the diagnosis result of AngioPlus Core is significantly different from the patient's clinical history, symptoms and other diagnostic test results, the doctor can reject the diagnosis result of AngioPlus Core. The results of clinical studies show that the diagnostic concordance between $\mu$ FR and FFR is 92.6%
	Users must have sufficient proficiency in the English language, and must be certified by Pulse Medical before using AngioPlus Core in a clinical environment in order to obtain reliable analysis results.
	Color blindness is not recommended to use this software.
	After you purchase our company's products, the pulse medical will provide users with user training online or offline.
	Other programs or third-party software products installed by users should not affect the normal operation of AngioPlus Core. The resulting security issues shall be the responsibility of the user.
	Only open the port for DICOM transmission on the operating system, and disable other unrelated ports to prevent viruses from invading through the network port.

	<p>It is necessary to choose a contrast image with short reduction, less overlap, and full contrast agent.</p>
	<p>Virtual stent: Visualize the length, diameter, and pressure gradient decrease values of any target vascular segment. Please refer to Chapter 4.2.6 for specific operation methods. Do not make clinical decisions directly based on automatically generated virtual stents.</p>
	<p>Before using the product, make sure that the Windows defender is on.</p>
	<p>Install anti-virus software and update the virus database in time, and add PStation.exe to the white list of anti-virus software.</p>
	<p>User Access Control : When the software starts, you need to enter a username and password to log in</p> <p>User Name: The user name used to log in to the software;          Password: The password for the user to log in.</p> <p>The user level is divided into two levels, ordinary users and administrators. The administrator account can configure DICOM communication and manage users (modify/delete/add regular accounts).</p>
	<p>It is suggested that patients use nitroglycerin to avoid vasospasm.</p>
	<p>Open up to 5 sequences simultaneously for analysis.</p>
	<p>The variation coefficient of the calibration factor is greater than 8%, the result may be inaccurate, please choose a longer or straighter catheter segment. Whether to re-mark the catheter?</p> <p>The catheter calibration factor differs from the isocentric calibration factor by more than 10%, measurement may be inaccurate.</p>
	<p>The region of interest selected for the second and first angiography is consistent.</p>
	<p>When completing an AngioPlus Core analysis, save the results and exit the software promptly to avoid misuse by unauthorized personnel.</p>

## V. Warnings

None

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