

Indications for Precautions and other Safety Information

Update date: 2024/1/30

I. Intended Purpose

AngioPlus Core(u 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 u FR values and anatomical

parameters. Angio Plus Core (u FR) analysis is intended to aid the functional evaluation of

coronary artery disease. The results of AngioPlus Core(u 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;

 \triangleright The diameter stenosis was \geqslant 30% and \leqslant 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.

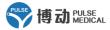
IV. Precautions

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

with the following conditions:

Ŵ

The luminal reduction was caused by myocardial bridge.



\triangle	Ostial lesions <3 mm from the aorta.
\triangle	Side branch lesions with Medina classification as 1,0,1、1,1,1.
\triangle	Low quality angiography that cannot detect the boundary of blood vessels or poor filling of contrast media.
\triangle	Severe vessel overlap or tortuosity at the stenotic segments.
\triangle	Visual inspection of the reference lumen diameter of the lesion segment $<$ 2mm.
\triangle	AngioPlus Core must be used by cardiologists or trained technicians who are qualified to perform cardiac analysis.
	The results of AngioPlus Core(μ FR) are intended to be used by qualified
<u> </u>	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 µ FR and FFR is 92.6%
	Users must have sufficient proficiency in the English language, and must be
\triangle	certified by Pulse Medical before using AngioPlus Core in a clinical
	environment in order to obtain reliable analysis results.
\triangle	Color blindness is not recommended to use this software.
\triangle	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
\triangle	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
\triangle	disable other unrelated ports to prevent viruses from invading through the
	network port.

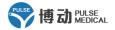


\triangle	It is necessary to choose a contrast image with short reduction, less
	overlap, and full contrast agent.
\triangle	Virtual stent: Visualize the length, diameter, and pressure gradient
	decrease values of any target vascular segment. Please refer to Chapter
	4.2.6 for specific operation methods. Do not make clinical decisions
	directly based on automatically generated virtual stents.
\triangle	Before using the product, make sure that the Windows defender is on.
\wedge	Install anti-virus software and update the virus database in time, and add
\(\frac{7:\}{\}\)	PStation.exe to the white list of anti-virus software.
	User Access Control: When the software starts, you need to enter a username and password to log in
	User Name: The user name used to log in to the software;
\triangle	Password: The password for the user to log in.
	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).
\triangle	It is suggested that patients use nitroglycerin to avoid vasospasm.
\triangle	Open up to 5 sequences simultaneously for analysis.
	The variation coefficient of the calibration factor is greater than 8%, the
	result may be inaccurate, please choose a longer or straighter catheter
\triangle	segment. Whether to re-mark the catheter?
	The catheter calibration factor differs from the isocentric calibration factor
	by more than 10%, measurement may be inaccurate.
\triangle	The region of interest selected for the second and first angiography is
	consistent.
\wedge	When completing an AngioPlus Core analysis, save the results and exit
<u> </u>	the software promptly to avoid misuse by unauthorized personnel.

V. Warnings

None

Shanghai Pulse Medical Technology,Inc.



A6, Building 1, No.900 Yishan Road.

Xuhui District, Shanghai, 200233, China

Revised January 2024

@2023 Shanghai Pulse Medical Technology, Inc.