Coronary Arterial Physiological Function Evaluation Software

Product Manual

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1 System introduction

[Product name] Coronary Arterial Physiological Function Evaluation Software

[Model specification] CoronaryScope

[Release version No.] V1

[Intended use] This product achieves accurate modeling and data mining based on coronary artery CT imaging, accurately assesses the fractional flow reserve (FFR) of suspected patients with coronary heart disease by means of simulation and is expected for functional evaluation of diseased vessels of coronary arteries in patients by qualified medical technicians. Coronary vessels shall also be subject to functional comprehensive evaluation clinically combined with the patient's clinical history, symptoms, other diagnostic results and the clinician's professional judgment.

[Intended patient population] Suspected patients with CAD and patients with CAD

[Intended user] This software only could be operated by the well-trained professional clinician.

[Contraindications]

1) Pregnant or lactating women or those planning to become pregnant
2) History of myocardial infarction within 30 days prior to CCTA examination.
3) Previous coronary CABG, placement of stent or pacemaker, ICD, prosthetic valve.
4) Hypertrophic obstructive cardiomyopathy or severe heart failure (NYHA $\geqslant$ III).
5) Body mass index > 35 kg/m^2.
6) Blood creatinine > 178 μmol/L.
7) Less than 18 years old or more than 80 years old.

[Precautions]

1) The software does not take the place of a doctor to make diagnosis;
2) The operator must be trained before using the software;

[Warning]

1) The software does not take the place of a doctor to make diagnosis; the calculation result is only for reference. The clinical diagnostic result must be comprehensively judged in combination with clinical history, symptom and other relevant diagnosis results.
2) The operator should have training prior to the use of the software.

3) Data collection must be compliant with the CTA data collection specification and made according to SCCT Guidance.

4) Conducting the CCTA check must be completed on CT equipment having 64-row detectors or above.

5) The following quality of CCTA imaging may result in calculation errors or incorrect results of the software.

a) Poor images and severe hierarchy of CT imaging may result in deformation of coronary artery tree models.

b) Artifacts related to metal, sport and respiration may result in deformation coronary artery tree model.

c) Delay of scanning may result in lightening vein, thus affecting modeling of the software.

d) Signal to noise ratio is too high, making image granularity rough.

e) Contrast agent is poor, causing the software has no way to extract the coronary artery tree.

f) Please follow the local laws and regulations to dispose the scrap safely.

[Software Languages]

Current: Chinese, English

Future: Other languages will be used to meet requirements of customers

[Production information]

The medical device is produced by Shenzhen Escope Technology Co., Ltd. (See Section 9). For the medical device, its incoming materials, process, and finished products have been inspected or validated, and no any additional ingredient is used.

2 Software functional requirements

1) The object processed by this product is coronary artery CT angiography images conforming to DICOM3.0 standard.

2) The product user shall have relevant professional knowledge and receive professional training.

3 Product maintenance

The Company provides product technical support and maintenance services:

1) When the program itself is wrong, the user can restart the program to operate again;

2) If the user cannot maintain it by himself/herself, he or she can contact the Company via the

contact information left in the software to report the problem, and the Company can provide remote assistance;

3) If the problem cannot be solved remotely, the Company will assign personnel to the user site for on-site maintenance.

4) After the release of the software, the Company will provide subsequent updates. In case of maintenance and upgrade services involving software defects, the Company will provides them free of charge. If there are maintenance upgrades involving functional changes, the Company may provide paid services according to user requirements.

5) In case of poor image quality or high degree coronary artery stenosis, vascular discontinuity, poor model quality and other problems are easy to occur during the coronary artery model generation, resulting in the failure or ineffectiveness of coronary artery FFR calculation. In this case, please contact our technical personnel for solutions.

6) Service life of 10 years.

4 Manufacturer information

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If you are encountered with any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State.

Please note that an appropriate training for any user is always prepared by Shenzhen Escope Technology Co., Ltd. before the user starts to use the software.