

All India Institute of Medical Sciences

Jodhpur

Admn/Prop/52/2019-AIIMS.JDH

Dated: - 24<sup>th</sup> October 2019

Subject: Purchase of Optical Coharence Tomograph for the department of Cardiology at AIIMS,

Jodhpur on proprietary basis - **Inviting comments thereon.** 

The Institute is in the purchase of Optical Coharence Tomograph for the department of

Cardiology at AIIMS, Jodhpur from M/s Abbott Medical, 4 Robbins Road, Westford, MA 01886,

USA on proprietary basis. The proposal submitted by M/s Abbott Medical, USA and PAC

certification by user are attached.

The above document are being uploaded for open information to submit subjection,

comments, if any from any manufacturer regarding proprietary nature of the equipment within

21days of issue giving reference Admn/Prop/50/2019-AIIMS.JDH. The comments should be

received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 15th

November 2019 upto 03:00 PM failing which it will be presumed that any other vendor is having no

comment to offer and case will be decided on merits.

Yours faithfully,

**Administrative Officer** 

**Enclosed: Related documents enclosed.** 



## All India Institute of Medical Sciences Jodhpur



Abbott Medical

4 Robbins Road

Westford, MA 01886 USA

Main 976 577 3400

### TO WHOM IT MAY CONCERN

Subject: Proprietary Article Certificate for OPTIS Mobile System

We, St. Jude Medical, USA who are proven and reputable manufacturer of the medical device i.e. "OPTIS Mobile System" manufactured solely by Abbott Medical, 4 Robbins Road, Westford, MA 01886 USA do hereby confirm that the below mentioned device is proprietary product of St. Jude Medical. (Now its Abbott Medical)

Sincerely,

Mae C. Nies

Regulatory Affairs Specialist

St. Jude Medical

JENNIFER MARIE JACOBSON Notary Public-Minnesota telien Explora Jan 31, 3023



# All India Institute of Medical Sciences

Integrated Optical Coherence Tomography (OCT) and Fractional Flow Reserve (FFR) System with real time online 3D and Angio Co-registration (ACR) imaging features.

- The system should have an imaging engine that is based on the fiber optic technology.
- It should utilize catheter that emit near infrared light to produce high resolution real time images.
- Should have integrated system with Fractional Flow Reserve (FFR) Measurement capability with wireless FFR setup.
- Should have Angio Co-registration to visualize the linkage between OCT image and angiography with workflow that provides guidance on how to co-register an angio image with the OCT pullback.
- 5. Should be capable to do Angio Co-Registration (ACR) in multiple labs.
- 6. The System should have feature of MSO (Metallic Stent Optimization) Software.
- FFR and OCT should be immediately available during percutaneous coronary intervention (PCI)
- 8. Should have Real-time, automated image analysis for PCI planning and evaluation.
- 9. Should have Automatic lumen boundary detection on every frame.
- Should have Lumen Profile Display with immediate identification of MLA, lumen diameter, percentage area or diameter stenosis and user selected proximal and distal reference frames.
- 11. Should have Real-time 3D image reconstruction of lumen and vessel.
- Should have two monitors (17" and 19") plus remote video output feature for multiple sightlines.
- The system should have an integrated Drive-motor and Optical Controller (DOC).
- 14. Should have FD-OCT Imaging engine.
- 15. Should have a latest generation processor (i7 or above) computer with minimum 21inch monitor, a wireless keyboard, and a wireless mouse with latest antivirus software.
- 16. Should have CPU with high end DAS card for faster 3-D data acquisition speed
- 17. Should have Large hard drive (1 TB) for ample data storage.
- 18. CD/DVD RW dual player DVD RAM drive for faster image management.
- 19. Should have Cardiology Application Software Package.
- 20. DICOM compatibility.
- 21. Should have PER MDS2 security feature.
- 22. Should have Tableside controller to give better control to the operator.
- 23. Should provide Operator's Manual (English).
- Prices of all accessories like pullback device, catheter, guidewire etc. to be quoted separately for future purchase.
- Prices of the accessories should freeze for at least three years from the time of installation.
- The same machine must have been installed in India earlier and its satisfactory working certificate has to be attached.
- Manufacturing company has to give undertaking regarding maintenance of the system and availability of accessories and spare parts for next ten years.
- Latest authorization certificate in original should be attached with the quotation, failing
  which their tender application will be rejected. Photocopy/Xerox copy of authorization
  certificate will not be accepted.

 The machine should come with required UPS and should be compatible with standard Indian electrical sockets.



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#### 30. Accessories

- Color printer (01 No.)
- CD/DVD writer built-in
- OCT Catheters 10 nos.
- Reusable pullback device (2 Nos.)

#### Re-construction of lumen and vessel:

- 1. Immediate and accurate lumen boundary detection and Lumen Profile Display.
- 2. Stent planning workflow with automated minimum lumen area and percent stenosis
- Automatic lumen detection on every frame.
- 4. Profile of mean diameter or lumen area across pullback.
- Automatic marking of MLA frame.
- User-defined proximal and distal reference frames.
- 7. Automated display of reference frame area and diameters, distance between references, %AS and %DS.
- 8. Automated measurements mode for calculations for stent sizing.
- Seamless integration of FFR and OCT with guided workflows for exceptional ease-
- 10. Should allow user for easy orientation on Angiography.
- 11. Allow to acquire and review images in L-Mode (lateral view).
- 12. Overlay color maps to optimize contrast resolution.
- Enlarge a defined area of interest (zoom).
   Make measurement and calculations of % Diameter stenosis.
- Add text annotations.
- 16. Play back and edit images with a full range of playback and editing capabilities.
- 17. Export still images and movies in raw OCT format or in standard AVI, TIFF, JPEG, BMP, or DICOM formats.
- Import OCT format images and review and edit them with full OCT.
- 19. Review and edit capability.
- 20. Perform basic file management functions.

## The imaging Parameters of the system should be:

- 1. Pullback length: 54 mm & 75 mm
- 2. Frame rate: at least 180 frames/sec
- 3. Frame density: 5- and 10-frames/mm
- Nominal pullback speed: 18mm/sec 36mm/sec
- 5. Number of lines per frame: 500 or more
- 6. Scan diameter: 10 mm
- Axial resolution: 15 μm or less