

TECHNICAL SPECIFICATION FOR INTRA VASCULAR ULTRASOUND (IVUS)

1. System should be latest generation, easy-to-use, Smart High Definition (HD) IVUS imaging and physiology system; designed for peripheral vascular, structural heart and coronary procedures; operable directly from the sterile field with three modality support i.e., (1) Coronary, (2) Peripheral, (3) FFR (including DFR/IFR/RFR).
2. IVUS imaging should have dynamic review feature (blood flow, plaque morphology, dissections, and stent opposition).
3. Automated Lumen Assessment (ALA) function for Quick measurements. IVUS should give data for Lesion Significance, MLA, MLD & % Stenosis, Plaque Burden, Positive and negative Remodeling of Vessel, Plaque Tissue Type, Lesion Length, Necrotic/Calcified/Lipidic/Fibrotic Plaque, Dissections, Thrombus, Protrusion, Stent Expansion & Apposition, & Placement, Stent Strut Coverage, Thin Cap Fibroatheromas & In Stent Restenosis.
4. It should be a truly mobile system. It should be easy to move. Full integration options should be available.
5. Should determine FFR/DFR/IFR/RFR value with Optical sensor-based wire to assess Arterial Pressure through Cath Lab transducer system.
6. It should have 18" or more color full HD display screen.
7. It should have compatibility with Coronary (40 to 60 MHz High-Definition) single rotating or phased array mechanical transducer catheter, Peripheral (10 to 30 MHz) catheter.
8. FFR/DFR/IFR/RFR Pressure Guide wire should be one optical sensor pressure wire for entire procedure i.e. for FFR measurement and angioplasty procedure with better torque and push ability.
9. It should be provided with ready to use platform with all required cables and accessories to interface with all available Cath labs.
10. Operating system: minimum requirement window 7 and above. Archiving Options: internal hard disk with sufficient storage capacity and should have USB drive option for data export.
11. It should have automated/manual IVUS catheter pull back system. Fast Pullback - 7 different pullback speed (1mm/sec to 8mm/sec or more) for quick vessel imaging with High Quality Images with permanent pull back device option.
12. Sterile Field control for both sterile & non-sterile operator.
13. Multiple Image Screen Format should be available
14. Should be Indian regulatory body certified/CDSCO/BIS/ US FDA/European-CE approved product
15. Manufacturer/Supplier should have ISO certification for quality standards
16. At the time of supply the intravascular ultrasound system should be of latest generation.
17. Ten (10) IVUS Catheters should be provided with the machine.
18. Should have local service facility.
19. Comprehensive warranty for 5 years and CMC for next five years post warranty.
20. Availability of spares & consumables to be ensured for minimum 10 years period.