

ADDENDUM TO TENDER INVITATION NO  
KDU/PRO/CAP/154/2022  
PURCHASE OF HEMODIALYSIS MACHINES FOR  
DIALYSIS UNIT AT UHKDU

1. It is here by informed that the tender will be opening on 06<sup>th</sup> September 2023 due to update of the specifications discussed during the pre-bid meeting, and the specifications are attached as annex 'A' to this addendum.
2. Forwarded for your information and necessary action please.

## (HD) TECHNICAL SPECIFICATION FOR SUPPLY OF HAEMODIALYSIS MACHINES 02 NOS

## Technical Specifications:

Description: Technical specifications of supply, installation, commission, training and maintenance of 3D mapping system with accessories

1.00	Purchaser's Requirement	2	3		4	5
			Bidder's Offer <sup>1</sup>			
Srl No	Purchaser's Requirement	Priority <sup>2</sup>	Conformity		Proof <sup>4</sup>	Remarks <sup>3</sup>
			Yes	No		
01	The unit shall operate on 230±10%, 50 Hz power supply and there shall have in built battery for back up for emergency power failure for at least 15 minutes. Power cable should be with 13A replaceable fuse with square 3 pin plug top.	C				
02	The unit shall have ability to perform Acetate & Bicarbonate Dialysis & Isolated Ultrafiltration, a. Bicarbonate shall be supplied in the mean of liquid and powder cartridges	C				
03	Machine shall be able to perform HD (Haemodialysis)	C				
04	The unit shall be capable for profiling of Sodium & Ultra filtration and capable of Adjusting bicarbonate levels and Sodium levels.	C				
05	The unit shall have capability of performing both standard and single needle techniques.					
06	It shall have a facility to perform HD for LOW WEIGHT & LOW VOLUME PATIENTS (If low blood volume Blood line/consumables are available mention in the offer) a. It shall have accurate ultra filtration principal shall be volumetric system	C				
07	Facilities for both Chemical & Thermal (at least 80°C - 90°C) disinfection methods shall be available.					
08	Blood pump shall have adaptable pumping rate of 20-500ml/min of standard AV blood line	C				
09	It shall have the ability to adjust blood pump segment & pump Rotor as per the segment (2mm-10mm)	C				
10	The ultra filtration rate shall be 0-4000ml/Hr & UF volume up to 10L/Hr	C				
11	It shall consist of built in syringe type Heparin pump with minimum two syringe	C				
12	Heparin Delivery rate shall be adjustable up to 10ml/hr	C				
13	Concentrate pump raw material must be indicated					
14	Dialysate fluid shall be of the Temperature range 32°C - 37°C	C				

15	It shall have dialysate flow rates <b>300 to 700ml/min</b>						
16	All standard safety features like audio visual alarms on limit violation of Conductivity, blood leak, air leak, transmembrane pressure alarms, dialysatetemperature alarm, dialysate empty alarm, end of disinfection alarm, bypass alarm, blood pump stop alarm etc. shall be available.	C					
17	Blood detect sensor should be available in Blood module. (to detect with in 20 sec and blood pump stop until user confirm.	C					
18	Automated self-testing & rinsing facilities shall be available	C					
19	Treatment parameters shall be displayed via an easily readable interface by the machine at the time of operation.	C					
20	It shall have facilities for quality control tool to measure KTV at end of treatment.	C					
21	Clear display of flow path for blood, bypass, dialyser and ultra filtration shall be available	C					
22	It shall have the ability to monitor pulse rate & NIBP with graphic & tabulated trends	C					
23	IV Pole, dialyser holder, bicarbonate cartridge & blood pump crank shall be available with the unit.	C					
24	It should have AV blood lines. If it is machine specific not universal, indicate the prices for 3 years with the quotations for evaluations.	C					
25	<b>HIS</b> connectivity must be provided with the unit and be able to communicate with hospital HIS system. HL7 format	C					
<b>GENERAL REQUIREMENTS FOR THE MACHINE</b>							
26	International Quality Certificates and standards such as (ISO, CE and FDA) and valid CDDA registration certificate for the model offered should be attached with the tender documents	C					
27	Bidder shall specify availability of online clearance facility, dialysate filter to prepare ultrapure dialysate and probe disinfection facility during disinfection. If these are optional they should quote separately	C					
28	All the consumable items price need to be indicate separately in USD.	C					
29	A user list of current installations in Sri Lanka and overseas shall be provided						
30	Overseas Technical Training: Bidders shall quote for an overseas training programme of not less than 7 days on an all inclusive basis for 01 Biomedical engineer/Technician (Technical training). Training programme should be arranged on an identical system in a training centre at OEM premises within 06 months after QCI	C					

31	User Training: Comprehensive training of at least 2 weeks shall be provided to the users at each site Nurse/Medical officer by a clinical trainer. in addition staff Bio Medical eng. Dep. should be trained locally.	C					
32	Supplier shall have trained technical staff and necessary testing equipment such as conductivity meter, recommended by the manufacturer to carry out preventive/corrective maintenance as per guidelines provided in the service/maintenance manual	C					
	Original technical literature describing the equipment offered shall be provided with the offer	C					
	<b>Warranty, Services Agreements and Documentation</b>	C					
	i. Letter of guarantee that after sale services is available should be provided from the local agent.	C					
	ii. Tender shall provide manufacturer's authorization letter for sale from the same manufacturer.	C					
iii. A list of reference sites of the same model already installed should be attached	C						
iv. All sub items described in this schedule should be covered by a warranty for a period of not less than <b>24 calendar months</b> from the date of successful commissioning of the equipment including for any defect in manufacturing process, workmanship and all accessories and turnkey work. Such a warranty should also include servicing and at least 4 preventive maintenance per year during the period of validity	C						
v. A Labour-only service contract for a 03 year period and Comprehensive Maintenance Contract (CMC) for the whole equipment including installation material for another 5 years should be quoted as per schedule given below after 02 year warranty period. Further those prices should be quoted in USD. (A list of probable spare parts to be replaced & their unit price in USD should be provided along with the main offer)	C						
a. 1st & 2nd year : Warranty period	C						
b. 3rd to 5th year : Labour only contract	C						
c. 6th to 10 year : Comprehensive maintenance	C						
vi. The technology manuals having full details of installation, operations, service and maintenance in the English language must be made available in duplicate at the time of installation and commissioning.	C						
vii. Spares/ replaceable items/ consumables required for the system must be guaranteed for supply over a period of 10 years from the date of installation. The price list for such items over a period of 10 years from the date of installation should be made available.	C						
viii. If the equipment supplied needs any special type of power supply (eg UPS) cost of such items to be indicated separately but include in the total cost.							

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ix. A sample unit must be available for demonstration and performance evaluation at the request of the TEC	C					
x. Prospective suppliers must provide documentary evidence of their previous experience with similar units installed in Sri Lanka and overseas as well as evidence of the reliability of after-sales services provided.	C					
xi. The successful bidder shall also install and commission the equipment at University Hospital, KDU	C					
xii. Training should be provided to end users in respect of operation, handling and maintenance of equipment supplied.	C					
xiii. NIRA/CDDA Certificate must be available	C					

Make & Model:

Country of Manufacturer:

Relevant catalogues & technical information attached.

Information given under "Bidder's Offer" is true and correct.

Bidder's Name:

Signature:

Date:

1. Bidder shall fill in Col.4,5 & 6
2. Purchaser will mark C for critical requirements
3. If the bidder has marked no for conformity, bidder shall provide information in this column of his offer against the clause concerned in Col.2 (Purchaser's requirements). If the bidder has marked Yes, Bidder has the option of providing additional information to established that it conforms to the specification given
4. Bidder shall include proof to support the conformity of the specification e.g. document and the page number in the original user/service manual mentioning the specification