REQUIREMENT SPECIFICATIONS

TENDER NO. 20210601

TENDER FOR FOR THE SUPPLY, DELIVERY, INSTALLATION AND COMMISSIONING OF HAEMODIALYSIS AND HAEMODIA-FILTRATION MACHINE WITH RENAL POINT OF CARE SYSTEM TO NKF

1. Introduction

1.1 The National Kidney Foundation ("**NKF**) wishes to appoint a contractor (the "**Contractor**") for the supply, delivery, installation and commissioning of haemodialysis and haemodia-filtration machines as described in these Requirement Specifications (the "**Goods**"), of dialysis centres in Singapore.

2. Product Specification

2.1 The Goods must be registered with Health Science Authority and shall conform to the detail specifications in **Annex A1, A2 and B.**

3. Quantity Requirement and Delivery Schedule

3.1 Contractor shall supply a range of **50-200** units of haemodialysis machines with **an option** of a range of 1-20 units of Haemodia-filtration machines specified in paragraph 2.1.

4. Submission of tender bids

4.1 Each Tenderer should provide the price quote in the Price Schedule Part 1 to Part 6 for the number of Goods specified in paragraph 3.1 above.

4.2 Under Price Schedule, Part 1, item 1, the Tenderers are required to indicate the manufacturer's guideline on replacement of backup and internal battery set per machine.

4.3 Under Price Schedule, Part 1, item 1, the Tenderers are required to indicate the number of Engineers dedicated to support NKF in the provision of technical services during the warranty period and ensure preventive maintenance completed in scheduled month

4.4 Under Price Schedule, Part 5 and 6, item 1, the Tenderers are required to provide the breakdown list of components for software, hardware and installation.

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Annex A1

General specification of Haemodialysis machine				
Technical information	**Parameters**	**Specifications**	**Comply Yes/ No**	**Remarks**
General parameters	Power Supply	230V (±10%)		
	Nominal Frequency	47 - 63 Hz		
	Current Consumption	Max 9 A		
	Inlet water pressure	1.5 - 6 bar max		
	Water temperature range	5°C to 30°C		
	Concentrate supplies	Canister / Catridge / Bags		
Safety Standards	General requirement for safety, class 1, type B.	EN 60601-1: (IEC 601-1)		
	Requirements for safety of haemodialysis equipment	EN 60601-2-16: (IEC 601-2-16)		
	Electromagnetic compatibility	EN 60601-1-2: (IEC 601-1-2)		
		CE certification		
Extracorporeal circuit	Arterial pressure range	- 300 mmHg to + 280 mmHg (wider range is acceptable)		
	Accuracy	±10mmHg		
	Venous pressure range	-60 mmHg to + 520 mmHg (wider range is acceptable)		
	Accuracy	± 10mmHg		
	Transmembrane pressure	-60 mmhg to +520 mmHg (wider range is acceptable)		
	Accuracy	±10 mmHg		
	Blood pump	Peristaltic pump		
	Blood flow range	15 to 600 ml/min in 8mm size tube		
	Accuracy	±10%		
	Air bubble detector	Ultra sound method, monitor the entire operating phase		
	Alarm Indicator	Traffic light to indicate the status		
Dialysis Fluid system	Dialysis fluid flow range	0-300 - 500-700-800ml/min, selectable.		
	Dialysis fluid temperature	35°C to 39°C		
	Concentration of dialysate	12.8 to 15.7 mS/cm (25°C) (wider range is acceptable)		
	Accuracy	±0.2mS/cm		
	Blood leak detector	Optical detector, colour specific		
	Ultrafiltration			
	UF rate	0 to 4.00 l / hour (higher range is acceptable)		
	Accuracy	± 3%		
	Dialysate fluid filter system	Endotoxin filter		
Disinfection and Cleaning program	Rinse, Hot cleaning and Hot disinfection cycles are required. Use recommended chemicals at a temperature of min 84°C.			
General Feature Required	Battery able to backup 20 mins to 30 mins during power failure			
Additional Features Required	Blood pressure monitor			
	Endotoxin filter			
	Real time Kt/V measurement			

	Heparin Module		

Certification

a) Is HSA registration required? Yes / No
b) Has the product been registered? Yes / No / Pending
c) If yes, the registration no. is _____
d) The HSA classification is Class A / B / C / D

Vendor shall provide the following documents to support the certification of the product:

e) Product licence with Health Science Authority
f) Manufacturing licence with Health Science Authority
g) Certificate of Product Quality
h) Any other relevant licence necessary for the tender

Accepted By:

Authorised Signature: _____

Signatory's name: _____ Signatory's title: _____

Tenderer's name: _____ Tenderer's stamp: _____

Annex A2

General specification of Haemodia-filtration machine (HDF Machine)				
Technical information	**Parameters**	**Specifications**	**Comply Yes/ No**	**Remarks**
General parameters	Power Supply	230V (±10%)		
	Nominal Frequency	47 - 63 Hz		
	Current Consumption	Max 9 A		
	Inlet water pressure	1.5 - 6 bar max		
	Water temperature range	5°C to 30°C		
	Concentrate supplies	Canister / Catridge / Bags		
Safety Standards	General requirement for safety, class 1, type B.	EN 60601-1: (IEC 601-1)		
	Requirements for safety of haemodialysis equipment	EN 60601-2-16: (IEC 601-2-16)		
	Electromagnetic compatibility	EN 60601-1-2: (IEC 601-1-2)		
		CE certification		
Extracorporeal circuit	Arterial pressure range	- 300 mmHg to + 300 mmHg (wider range is acceptable)		
	Arterial pressure Accuracy	±10mmHg		
	Venous pressure range	-60 mmHg to + 520 mmHg (wider range is acceptable)		
	Venous pressure Accuracy	± 10mmHg		
	Transmembrane pressure	-60 mmhg to +520 mmHg (wider range is acceptable)		
	Transmembrane pressure Accuracy	±10 mmHg		
	Blood pump	Peristaltic pump		
	Blood flow range	15 to 600 ml/min		
	Blood Pump Accuracy	±10%		
	Substitution Pump (HDF Pump)	Peristaltic pump		
	Air bubble detector	Ultra sound method, monitor the entire operating phase		
	Alarm Indicator	Traffic light to indicate the status		
Dialysis Fluid system	Dialysis fluid flow range	0-300 - 500-700-800ml/min, selectable (Auto flow 100-1000ml/min)		
	Dialysis fluid temperature	35°C to 39°C		
	Concentration of dialysate	12.8 to 15.7 mS/cm (25°C) (wider range is acceptable)		
	Accuracy	±0.2mS/cm		
	Blood leak detector	Optical detector, colour specific, infrared light		
	Ultrafiltration			
	UF rate	0 to 4.00 l / hour (higher range is acceptable)		
	Accuracy	± 3%		
	Dialysate fluid filter system	Endotoxin filter – Dual filter		
Disinfection and Cleaning program	Rinse, Hot cleaning and Hot disinfection cycles are required. Use recommended chemicals at a temperature of min 84°C.			

Additional Features Required	Single Needle system (2 blood Pump)		
	Program: Auto On / Off		
	Mode: HD and HDF Treatment		
	Pre- Dilution and Post Dilution		
	Mixed Dilution (Option)		
	Blood Pressure monitor (BP)		
	Blood Volume monitor (BVM)		
	Blood Temperature monitoring (BTM)		
	Large Screen (LED)		
	Online HD and HDF Monitoring		
	Online Clearness Monitor (OCM)		
	Online Priming		
	Online Bolus		
	Online Reinfusion		
	Profiles: Sodium, Bicarbonate and Ultrafilter Filter		
	Inbuilt Patient Card reader for RPOC system		
	Dry Concentrate – Bibag		
	Disinfection - Citrosteril		
	Heparin Module – 10ml to 50ml		
	Battery backup minimum 20 mins		

Certification

a) Is HSA registration required? Yes / No
b) Has the product been registered? Yes / No / Pending
c) If yes, the registration no. is _____
d) The HSA classification is Class A / B / C / D

Vendor shall provide the following documents to support the certification of the product:

e) Product licence with Health Science Authority
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h) Any other relevant licence necessary for the tender

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Annex B

ADDITIONAL REQUIREMENT

The Objectives of the Renal Point-Of-Care (RPOC) System are as follows:

- To enable the capture of patient information during every dialysis treatment so as to provide a comprehensive medical record of all our patients inclusive of pre & post dialysis treatment parameters, medication ordered and prescribed, clinical notes, session alerts etc.
- To automate the download of clinical data from the dialysis machines during the treatment sessions at periodic intervals to our back-end main Clinical System.
- To provide online monitoring during the dialysis sessions with the necessary alerts and reminders.
- To provide online access of our patient information by our doctors and clinicians anytime anywhere so as to enable timely intervention of patient treatment.
- To enable bi-directional data exchange with external systems via XML.

Renal Point-Of-Care (RPOC) system requirements	Comply Yes/No	Remarks
• The dialysis machines must be equipped with the patient card reader and the ability to transmit dialysis machine readings and settings to and from NKF's selected RPOC System.		
• The communication protocol must be provided to NKF to enable the transfer of the dialysis machine readings and settings to and from NKF's selected RPOC System.		
• The system must be able to communicate with the weighing scales used by NKF to capture pre and post weight data.		
• The system must be configurable to allow NKF to customise its own checklists, pre and post dialysis assessments with data validation and mandatory field options.		
• The system must support the entry of Nurses notes (both during dialysis and independently) in the form of a clinical diary.		
• The system must allow NKF to maintain and manage its own master data.		
• The system must provide all the data captured during the dialysis process to NKF's Clinical System.		
• The system must be customisable to allow NKF's data to be updated to the RPOC System.		
• The reports produced by the RPOC system must be customisable to our requirements.		
• The RPOC system must be able to integrate with existing NKF Clinical System.		
• Include 5 concurrent licenses per DC plus 1 concurrent license for every 4 machines or part thereof. Eg. 20 machines must include 10 concurrent licenses.		
• The RPOC licence must be transferrable to the next purchase of the same brand of HD machine.		
• There must be 6 patient cards included for every machine purchased. Example: 20 machines must include 120 patient cards.		
• The Contractor must be able to provide local application and technical support.		
• Local application and technical support coverage must be as follows: - Monday to Saturday (including Public Holidays) 7am to 11pm - Response time within 4 hours (acknowledge and commence investigation) - Issues resolved within 72 hours		

Accepted By:

Authorised Signature: _____

Signatory's name: _____ Signatory's title: _____

Tenderer's name: _____ Tenderer's stamp: _____