REQUIREMENT SPECIFICATIONS

TENDER NO. 20170502

TENDER FOR FOR THE SUPPLY, DELIVERY, INSTALLATION AND COMMISSIONING OF ONE HUNDRED AND FORTY-SEVEN (147) UNITS OF HAEMODIALYSIS MACHINES 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 one hundred and forty-seven (147) units of haemodialysis machines as described in these Requirement Specifications (the "**Goods**"), to its six (6) 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 the **147 units** of the Goods specified in paragraph 2.1. The breakdown number of haemodialysis machines (the "**Goods**") for the 6 dialysis centres and delivery schedule shall be as follows:

Sno	Name of Dialysis Centre	Quantity of Haemodialysis machine	Delivery Schedule (Estimated date and subject to confirmation)
1	West Coast Dialysis Centre	22	October 2017
2	Marsiling Dialysis Centre	25	December 2017
3	Integrated Renal Centre	46	February 2018
4	Teck Whye Dialysis Centre	20	February 2018
5	Bukit Panjang 1 Dialysis Centre	19	February 2018
6	Yishun 1 Dialysis Centre	15	February 2018
	Total number of machines	**147**	

4. Submission of tender bids

4.1 Each Tenderer should provide the price quote in the Price Schedule Part 1 to Part 3 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 number of Engineers dedicated to support NKF in the provision of technical services during the warranty period.

4.3 Under Price Schedule, Part 3, item 1, the Tenderers are required to provide the breakdown list of components for software, hardware and installation.

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.			
Additional Features Required	Blood pressure monitor			
	Endotoxin filter			
	Real time Kt/V measurement			
	Heparin Module			

Annex A2

Certification requirements: i. Does HSA registration required? Yes / No ii. Has the product been registered? Yes / No / Pending iii. If yes, the registration no. is_____ iv. The HSA classification is Class A / B / C / D
Vendor shall provide the following documents to support the certification of the product: • To provide copy of product licence with Health Science Authority • To provide copy of manufacturing licence with Health Science Authority • To provide copy of Certificate of Product Quality • 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 B

Additional requirements

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.

Requirements

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 enable the transmission of the machine readings to the RPOC System.		
• The communication protocol must be provided to NKF to enable the transfer of the dialysis machine readings to our 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.		
• The system must support the entry of Nurses notes (both intra dialysis and independent) 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 licenses for the RPOCS System must be perpetual i.e. once installed, it can be used continually even if the machines are replaced with the newer ones after their life span		
• The vendor must be able to provide local support		

Accepted By:

Authorised Signature: _____

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

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