



Running Contract Details	
Equipment Name	Portable Dialysis machine with SLED
Running Contract Valid Till	11-04-2020
Tender Ref No	KMSCL/EP/T248/1020/2017
Tendered Quantity	5
Supplier Name	M/s Grahams Pharmaceuticals
GST No	32ADCPL0649K1ZP
Installation & Delivery Period	6 Week(s)
Up-time / PM vist	95% & 4 Visits per year
Warranty period	3 Years

Supplier`s Details		
Address	Contact Details	
Chakkaraparambu Road Kottankavu Junction Vennala P.O Kanayannur- 682028	Contact Person	Mr. Lijo Baby
	Phone	0484- 2807376, 2808376
	Mobile No	9447721376
	Email	grahamspharmaceuticals@yahoo.com

Item-wise Price Details				
#	Item Details	Unit Rate (Incl.all taxes & charges)	Service Charges (Through KMSCL)	Grand Total
1	Portable Dialysis machine with SLED <i>Model & Make : 5008 Online Plus / Fresenius Medical Care</i>	1467200 Incl.GST :12%	108206	1575406
		1467200	108206	1575406

Annual / Comprehensive Maintenance Charges (Exl.Tax)							
Rate	4 th Year	5 th Year	6 th Year	7 th Year	8 th Year	9 th Year	10 th Year
Portable Dialysis machine with SLED							
Labour	30,208.00	31,624.00	33,304.00	34,969.00	36,716.00	38,552.00	40,480.00
Comprehensive	90,624.00	90,624.00	99,686.00	99,686.00	1,09,655.00	1,09,655.00	1,09,655.00

Other terms & conditions

1. The supplier shall execute an agreement with the purchaser as per tender conditions (agreement format is given in the tender

document).

2. The supplier shall submit performance security amounting to 5% of the value of the supply order.
3. The labour & comprehensive charges of equipment after the completion of warranty period is finalized by KMSCL as mentioned above.
4. Since discount rate is not applicable for equipment under Running Contract of KMSCL, purchase/supply order can be issued directly to supplier at the given rate with tax & other charges (exclusive of KMSCL service charges).
5. If purchase/supply order is issued directly to the supplier, KMSCL service charge need not be paid. But the copy of the said order may be forwarded to KMSCL for information.

Technical Specification

Equipment :Portable Dialysis machine with SLED

1. The machine should be capable of doing all the following renal replacement treatment as mentioned below
 - a. Haemodialysis (Normal HD)
 - b. Online Hemodiafiltration
 - c. Online Hemofiltration
 - d. SLED (sustained low efficiency Dialysis)
 - e. Sustained low-efficiency daily diafiltration SLEDDF
 - f. Extended daily dialfiltration EDD-f
 - g. Prolonged daily intermittent renal replacement therapy (PDIRRT)
 - h. Go-slow dialysis
 - i. Hybrid renal replacement modalities
2. The machine should have two roller pumps. One is for blood pump; other is substitution pump for generating replacement fluid which is used during online Hemodiafiltration and online Hemofiltration therapies.
3. Blood pump – blood flow range should be (effective) 30 to 600 ml/min, accuracy $\pm 10\%$
4. Effective blood flow rate should be calculated and displayed on the front panel in a real time basis during dialysis automatically
5. It shall be easy and safe to thread with bloodline diameter from 2 mm up to 10 mm
6. Automatic set up and priming is preferred
7. An emergency hand crank shall be provided for returning blood to patient when electrical power is lost. Direction of rotation shall be limited or visually indicated
8. Single needle system 2 blood pumps, internal pressure/pressure control with variable stroke volume(max 50 ml)
9. Dialysate flow:
 - a. Dialysis fluid flow range should be selectable from 0-1000 ml/min (steps of 100 ml/min)
10. Dialysate flow should be on adequacy favoured basis

11. Auto flow (selectable) automatic adaption of the dialysate flow to the effective blood flow (factors adjustable)

12. Dialysate consumption basis (It should be on selectable mode on needed basis)

II. Substitute Flow

1. Substitution fluid should be generated by machine itself from the hydraulic by filtering the dialysate through 2 endotoxin filters in series

2. Auto sub: where the machine can select optimum substitute flow according to the treatment condition. Auto sub substitution method should ideally match to effective blood flow

3. Substitution fluid should be generated by machine itself from the hydraulic compartment and delivered by substitution pump

4. Online Hemofiltration/online Hemodiafiltration substitution flow rate should be 25 -600 ml/min & accuracy $\pm 10\%$

5. The machine should contain online priming. Online bolus and online reinfusion facility during online modality is on.

6. Heparin pump should have infusion rate:0.5 ml-10 ml/hr. Bolus function:1.0 up to 20.0 ml. Syringe size : 30 ml. Accuracy $\pm 5\%$

7. Ultra filtration pump should be present in the hydraulic compartment

8. UF rate 0-4000ml/h (in steps of 10 ml), pump volume accuracy $\pm 1\%$, parameters displayed: UF goal, UF time, UF rate, UF volume

9. Dialysis and substitution fluid temperature range must be 34-39° C

10. Machine should have non-invasive arterial pressure dome to measure arterial pressure

III. Treatment Alarm Monitoring Systems

1. Arterial pressure monitoring limits should be display range -300 mmHg to + 300 mm Hg, Accuracy ± 7 mmHg, resolution 5 mmHg

2. Venous pressure monitoring limits should be display range -100 mmHg to +500 mmHg, Accuracy ± 7 mmHg, resolution 5 mmHg

3. Trans membrane pressure monitoring limits should be display range -100 mmHg to + 400 mmHg resolution 5 mmHg

IV. Treatment Menu Alarms

1. Machine should give the alarm with draft display and also possible causes for alarms, It also have Help Option to resolve the alarms.

2. Air detector should have ultrasound transmission measurement on blood line, additional capacitive level and optical monitoring

3. Blood leak detector should detect sensitivity? 0.5 ml blood/min (Hct=25%)

4. Flow rate 100 ml/min -1000 ml/min

5. The machine should have online KT/V monitoring

6. Accuracy clearance $K \pm 6\%$ should be on display during dialysis. Built-in device for online measurement and monitoring of effective urea clearance (K), dialysis dose (Kt/V) and plasma sodium (Na) automatically during treatment (M)

7. The measurement of effective urea clearance (K) dialysis dose (Kt/V) and plasma sodium (Na) shall be performed in non-invasive, real-time mode without additional disposable required during treatment (M)

8. Measuring accuracy

9. Clearance measurement accuracy: $\pm 5\%$ (standard deviation) (M)

10. Kt/V determination accuracy : $\pm 9\%$ (standard deviation) (M)

11. Machine should have built in non-invasive blood pressure monitoring with programmable measurement interval with display range systole: 30 mmHg -280 mmHg, Diastole:10 mmHg- 240 mmHg ,MAP : 20 mmHg-255 mmHg, Accuracy ± 3 mmHg. The machine should contain BPM cuff holder.
12. The machine should deliver ultrapure dialysate by using built in endotoxin filter. The machine should contain dialysis fluid filter system, lower patient inflammatory responses, essential component contributing to the quality of dialysis treatment worldwide
13. The machine should contain blood temperature monitoring, temperature measurement accuracy $\pm 0.2^\circ\text{C}$,body temperature control allowed change rate $\pm 0.5^\circ\text{C/h}$, recirculation measurement accuracy $\pm 2\%$
14. The machine should contain blood volume monitoring, relative blood volume (RBV) 1.7%, (absolute) Haematocrit (Hct) ± 2.9 Hct% (if plasma protein concentration range is 60 -85 g/l) Haemoglobin (Hb) ± 0.8 g/dl, temperature 0.1°C (33.5-40 $^\circ\text{C}$)
15. Dialysis fluid conductivity range 12.8 -15.7 mS/cm accuracy ± 0.1 mS/cm
16. Sodium concentration dialysis fluid mixing ration freely adjustable eg. 1+44, 1+34 ,adjustment range 125 to 151 mmol/l, depending on the concentrate used $\pm 10\%$ of the base value
17. Bicarbonate concentration dialysis fluid default mixing ration 1+27.6 (others possible), Adjustment range 24.0 -40.0 mmol/l (steps of 0.5 mmol/L)
18. The machine should be able to connect with centralized IT systems used for managing treatments, external connections alarm output : potential free alarm outlet (Alternating contact max.24 V/24 W), LAN (RJ 45) port for data exchange with IT systems

V. Disinfection and Cleaning Programmes

1. Rinse
2. Temperature/flow $37^\circ\text{C}/600\text{-}800\text{ml}/\text{min}$ (adjustable)
3. Hot rinse (recirculation)
4. Temperature/flow $85^\circ\text{C}/600\text{-}800\text{ml}/\text{min}$ (adjustable)
5. Cleaning (sodium Hydrochlorite recirculation)
6. Temperature/flow $37^\circ\text{C}/600\text{-}800\text{ml}/\text{min}$ (adjustable)
7. Heat disinfection (recirculation)
8. Temperature/flow $85^\circ\text{C}/600\text{-}800\text{ml}/\text{min}$ (adjustable)
9. Disinfection citrate based cleaning agent 340/plus (recirculation)
10. Temperature/flow $37^\circ\text{C}/600\text{-}800\text{ml}/\text{min}$ (adjustable)

VI. Electrical Data

1. Power supply 100 to 240 V AC $\pm 10\%$, 47 -63 Hz, current consumption approx.6A (at 230 V) at a water inlet temperature of 17°C , dialysate temperature 37°C dialysate flow:500 ml/min

VII. Electrical Safety

1. Type of protection against electric shock should be CE certified
2. High resolution TFT LCD with touch screen user interface

3. Monitor rotatable around the 3 axes
4. Display should contain status indicator traffic light (red, green & yellow)
5. Extracorporeal blood module should be protected by two doors and should contain leak sensor on safety basis
6. Should have UF/Na profiling – min, 6 profiles
7. Should have automatic functional self test: before the start of the dialysis

VIII. Dialysis Parameter Display

1. The equipment shall have digitally and graphical display for the parameters
 - a. Arterial pressure (M)
 - b. Venous pressure (M)
 - c. Blood flow rate (M)
 - d. Dialysate conductivity (M)
 - e. TMP (M)
 - f. UF volume (M)
 - g. UF rate (M)
 - h. Remaining treatment time (M)
 - i. Heparin infusion rate (M)
 - j. Alarm information in text format (M)

IX. Should have safety certificate from a competent authority CE issued by a notified body registered in the European commission / FDA (US)/ STQC CB Certificate/ STQC S Certificate or valid detailed electrical and functional safety test report from ERTL. Copy of the certificate/ test report shall be produced along with the technical bid