

File No.GEM/TP/Haemodialysis Machine/2019 (Version 3.0)										Draft T/P AFTER CCM	
Level 1 Category: Medical Equipment and Accessories and Supplies -UNSPS Code 42000000											
Level 2 Category: Dialysis equipment and supplies - UNSPS Code 42160000											
Level 3 Category: Extracorporeal hemodialysis equipment and supplies -UNSPS Code 42161600											
Level 4 Category: Haemodialysis Machine -UNSPS Code 42161632										GEM Version 3.0	
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES				UNIT	CATEGORY OF FIELD	REMARKS	
GENERAL FEATURES											
1	Product name	--	ENUMERABLE	Haemodialysis or Dialysis machine					--	MANDATORY	
2	Clinical purpose	--	ENUMERABLE	Purification of blood of a person by removing excess water and waste products from the blood using artificial kidney with the help of a dialysis machine out side the patient's body whose kidneys are dysfunctional, damaged or missing					--	MANDATORY	
3	Patient category	--	ENUMERABLE	Pediatrics and adults					--	MANDATORY	
CONSTRUCTION, OPERATION AND FUNCTIONAL FEATURES											
1	Material of the body	--	ENUMERABLE	Polypropylene (PP)	Aluminium and FRP				--	GOLDEN PARAMETER	
2	The Machine should be of latest technology with microprocessor controlled	--	ENUMERABLE	Yes					--	MANDATORY	
3	Machine should have Acetate & Bicarbonate dialysis facility	--	ENUMERABLE	Yes					--	MANDATORY	
4	Machine should have two bacterial filters (Pyrogen filters) one at water inlet and one before water going to dialyzer	--	ENUMERABLE	Yes					--	MANDATORY	
5	Machine should have Sequential/Isolation Ultra filtration facility	--	ENUMERABLE	Yes					--	MANDATORY	
6	It should have Arterial , Venous & Transmembrane pressure monitoring facility	--	ENUMERABLE	Yes					--	MANDATORY	
7	Arterial Pressure Monitoring	--	ENUMERABLE	-300mmHg to +300mmHg					--	MANDATORY	
8	Venous Pressure Monitoring	--	ENUMERABLE	-60mmHg to +500mmHg					--	MANDATORY	
9	Transmembrane Pressure Monitoring	--	ENUMERABLE	-60mmHg to +500mmHg					--	MANDATORY	
10	Treatment parameters should be displayed by trend curve and digital both in a user friendly manner	--	ENUMERABLE	Yes					--	MANDATORY	
11	Arterial Blood pump flow rate (ml/min)	--	ENUMERABLE	10 to 600	15 to 600	20 to 500	20 to 600	50 to 500	ml/min	GOLDEN PARAMETER	
12	Blood tubing pump segment should be operator changeable for use of different type of blood tubing sets	--	ENUMERABLE	Yes					--	MANDATORY	
13	Blood Tubing Pump segment range 4mm to 10mm approx	--	ENUMERABLE	Yes					--	MANDATORY	
14	Variable dialysate flow (ml/mt) with increasing facility step up by 20 ml	--	ENUMERABLE	200 to 800	300 to 800	300 to 700	100 to 800		ml/min	GOLDEN PARAMETER	
15	Dialysate Temperature (degree C)	--	ENUMERABLE	32 to 39	34 to 39				deg C	MANDATORY, FILTER	
16	Machine should have Single Needle dialysis facility	--	ENUMERABLE	With single blood pump	With double blood pump				--	GOLDEN PARAMETER	
17	Machine should have volumetric Ultrafiltration system	--	ENUMERABLE	Yes					--	MANDATORY	
18	Machine should have inbuilt on-line Dialysate fluid filter system for ultrapure Dialysate delivery	--	ENUMERABLE	Yes					--	MANDATORY	
19	Machine should have In-line Bicarbonate mixing and solution preparation facility with sterile dry powder cartridge during dialysis	--	ENUMERABLE	Yes					--	MANDATORY	
20	Machine should have Air bubble detector facility with level adjustment facility for Venous Chamber	--	ENUMERABLE	Yes					--	MANDATORY	
21	Machine should have Optical Sensor to check the presence of blood/saline in the extracorporeal blood circuit system	--	ENUMERABLE	Yes					--	MANDATORY	
22	Should have Na, Bicarbonate and UF profiling	--	ENUMERABLE	Yes					--	MANDATORY	
23	Should have drain facility	--	ENUMERABLE	Yes					--	MANDATORY	
24	Machine should have Heparin Infusion Pump with rate 0 to 10ml/min and Bolus infusion up to 5ml/min approx	--	ENUMERABLE	Yes					--	MANDATORY	

25	Heparin infusion pump delivery range (ml/min)	--	ENUMERABLE	0 to 10	0 to 20				ml/min	MANDATORY,FILTER	
26	Heparin infusion pump bolus infusion range (ml/min)	--	ENUMERABLE	0 to 5	0.5 to 5	0.1 to 9.9			ml/min	MANDATORY,FILTER	
27	Machine should have blood leak sensor	--	ENUMERABLE	Yes					--	MANDATORY	
28	Alarm will be activated for blood loss rate not greater than 0.5ml/min at maximum dialysate flow of 800ml/min	--	ENUMERABLE	Yes					--	MANDATORY	
29	Machine should be able to accept different concentrate formulation, different dialyzers and blood tubing set	--	ENUMERABLE	Yes					--	MANDATORY	
30	Ultrafiltration rate (Lts/Hr)	Must Declare	MEASURABLE	0 to 4					Ltr/Hr	MANDATORY	
31	Machine should have variable conductivity setting between 13 to 15	--	ENUMERABLE	Yes					--	MANDATORY	
32	Machine should have facility for priming and rinsing of dialyzer and blood lines	--	ENUMERABLE	Yes					--	MANDATORY	
33	Machine should have automatic priming/reinfusion facility	--	ENUMERABLE	Yes					--	MANDATORY	
34	Machine should have Hot Rinsing and Hot Chemical Disinfection facility (Temp. above 80 deg. Celsius) with recirculation system	--	ENUMERABLE	Yes					--	MANDATORY	
35	it should have various Chemo Thermal cleansing and disinfection programs	--	ENUMERABLE	Yes					--	MANDATORY	
36	Machine should have Ultrafiltration and Sodium Profiling facility	--	ENUMERABLE	Yes					--	MANDATORY	
37	Built-in heat exchanger	--	ENUMERABLE	Yes					--	MANDATORY	
38	Machine should have built-in automatic pulse rate and blood pressure(NIBP) monitoring unit	--	BOOLEAN	Yes	No				--	GOLDEN PARAMETER	
39	Built-in online NIBP recording facility	--	BOOLEAN	Yes	No				--	GOLDEN PARAMETER	
40	Online clearance kt/V facility	--	ENUMERABLE	Yes					--	MANDATORY	
41	Machine should be upgradable to future software development and can be linked for Data Management System	--	BOOLEAN	Yes	No				--	GOLDEN PARAMETER	
42	All important data should be preset so that machine can be used anytime without feeding data every time	--	ENUMERABLE	Yes					--	MANDATORY	
43	Should have automatic self test facility	--	ENUMERABLE	Yes					--	MANDATORY	
44	Automatic diagnosis of malfunctioning with on line ability to show the faults with trouble	--	ENUMERABLE	Yes					--	MANDATORY	
45	Audio visual alarms on limit violation of conductivity,blood leak, air leak, transmembrane pressure alarms,, Dialysis temperature alarm,dialysis can empty alarm, end of disinfection alarm,bypass alarm and blood pump stop alarm, alarm for reverse Ultrafiltration etc	--	ENUMERABLE	Yes					--	MANDATORY	
STANDARD ACCESSORIES											
1	Bacterial filters (Sets)	--	NUMERIC	2	4				No	GOLDEN PARAMETER	
ELECTRICAL FEATURES											
1	Should have auto ON/OFF Facility	--	ENUMERABLE	Yes					--	MANDATORY	
2	LED indicator on front panel for status of machine	--	ENUMERABLE	Yes					--	MANDATORY	
3	Power supply (with Indian plug)	--	ENUMERABLE	220+/-10% V, 50Hz, AC Single phase					--	MANDATORY	
4	Machine should have Automatic battery backup for complete Extracorporeal blood system during power failure	--	ENUMERABLE	Yes					--	MANDATORY	
5	UPS of suitable rating with voltage regulation and spike protection for 60 minutes back up.	--	ENUMERABLE	Yes					--	MANDATORY	

USER INTERFACE											
1	Colour TFT display operated by touch buttons or touch screen	--	ENUMERABLE	Yes					--	MANDATORY	
2	Colour panel display size (inch)	Must declare	MEASURABLE	10 to 15					--	GOLDEN	
3	Data protection while power goes off	--	ENUMERABLE	Yes					--	MANDATORY	
4	Memory for storage of records	--	ENUMERABLE	Yes					--	MANDATORY	
5	USB and Ethernet for file sharing	--	BOOLEAN	Yes	No				--	GOLDEN PARAMETER	
PACKING MODE											
1	The product is packed individually in a box with all its accessories in such a way that there will be no transit damage	--	ENUMERABLE	Yes					--	MANDATORY	
CERTIFICATIONS & REPORTS											
1	Availability of test report/quality assurance report from parent manufacturer	--	ENUMERABLE	YES					--	MANDATORY	
2	Product certification	--	ENUMERABLE	EU-CE	US-FDA				--	MANDATORY,FILTER	Multiselect
3	Certificate No	Must Declare	TEXT						--	MANDATORY	AKBNV
4	Certificate Date	Must Declare	TEXT						--	MANDATORY	AKBNV
5	Certificate issuing authority	Must Declare	TEXT						--	MANDATORY	AKBNV
6	Four digit number of notified body If product is EU-CE certified	Must declare, write '0' if not applicable	NUMERIC						--	MANDATORY	
7	Certification, performance and safety standards specific to the device	--	ENUMERABLE	IEC 60601-2-16	ISO 14971:2007	IS:13450(Part 1)			--	MANDATORY,FILTER	Multiselect
8	Submission of all the certifications and test reports to the buyer along with supplies on demand	--	ENUMERABLE	Yes					--	MANDATORY	
INSTALLATION & TRAINING											
1	Supplier to perform installation, safety and operation checks before handover	--	ENUMERABLE	Yes					--	MANDATORY	
2	Training of users in operation and basic maintenance shall be provided	--	ENUMERABLE	Yes					--	MANDATORY	
WARRANTY & MAINTENANCE											
1	Onsite Warranty (Yrs)	--	NUMERIC	5					Years	MANDATORY	
2	User technical and maintenance manual detailing complete maintaining schedule with routine maintenance should be provided	--	ENUMERABLE	Yes					--	MANDATORY	
3	Contact details of manufacturer, supplier and local service agent to be provided	--	ENUMERABLE	Yes					--	MANDATORY	

(A. KESAVA RAO)
AD, GEM-SPV

(MANJU SHARMA)
DY.CEO

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