Requirement Specifications - Hemodiafiltration (HDF) Machine

Description of function : A Hemodiafiltration (HDF) machine is a medical device used to treat kidney failure by combining treatment methodologies such as Hemodialysis and Hemofiltration . An HDF machine uses a blood pump, dialyser and substitution fluid pump, along with safety monitors and a user interface to provide precise and safe treatment.

Description	Parameters	Specifications	Comply [Yes/ No]	Remarks
General parameters	Power Supply	230V (±10%)		
	Nominal Frequency	47 to 63 Hz		
	Current Consumption	Max 11A @ 230V AC		
	Inlet water pressure	1.5 to 6 bar max		
	Inlet Water temperature range	5°C to 30°C		
	Concentrate supplies	Canister / Cartridge / Bags / Acid Central Delivery System		
Safety Standards	General requirement for safety, class 1, type B.	EN 60601-1: (IEC 601-1)		
	Requirements for the safety of HDF machine	EN 60601-2-16: (IEC 601-2-16)		
	Electromagnetic compatibility	EN 60601-1-2: (IEC 601-1-2)		
	Certification	CE certification		
		HSA Approval [indicate certification number]		
Extracorporeal circuit	Arterial pressure range	- 300 mmHg to + 280 mmHg (wider range is acceptable)		
	Accuracy	±10mmHg		
	Venous pressure range	- 20 mmHg to + 390 mmHg (wider range is acceptable)		
	Accuracy	± 10mmHg		
	Transmembrane pressure	- 60 mmhg to +400 mmHg (wider range is acceptable)		
	Accuracy	±10 mmHg		
	Blood pump	Peristaltic pump/ Roller pump		
	Blood flow range	30 to 600 ml/min with 8mm tube size [wider range is acceptable]		
	Accuracy	±10%		
	Substitution (HDF) Pump	Peristaltic pump/ Roller pump		
	Substitution (HDF) Pump Flow Range	30 to 400 ml/min [wider range is acceptable]		
	Substitution (HDF) Pump Accuracy	±10%		
	Air bubble detector	Ultrasound method or alternative technique to monitor the entire operating phase		
	Alarm Indicator	Traffic light to indicate the status		
	Safety line clamp	Safety line clamp for Arterial & venous blood line		

Dialysate and Substitution Fluid system	Dialysis fluid flow range	0-300-500-700-800-1000 ml/min,selectable.		
	Dialysis fluid flow selection mode	Auto Flow, Eco Flow and Manual		
	Dialysis fluid temperature range	35°C to 39°C		
	Accuracy	± 0.5 °C		
	Mixing Ratio	1:34		
	Concentration of dialysate	12.8 to 15.3 mS/cm at 25°C [wider range is acceptable]		
	Accuracy	± 0.2 mS/cm		
	Electrolyte concentration adjustment	Prescribe Na+ and HCO3 adjustment		
	Substitution Fluid Mode	Manual & Auto		
	Substitution Fluid Flow Range	0-200 (ml/min)		
	Substitution Fluid Delivery Options	Pre Dilution, Post Dilution & Mixed Dilution		
	Priming, Rinsing , IV Bolus, Reinfusion	Online		
	Dialysate & Substitution fluid filter system	Minimum one endotoxin filter for dialysate and minimum two endotoxin filters for substitution fluid		
	Blood leak detector	Optical detector/ ultrasound, colour-specific or any alternative technique		
		Response threshold ≤ 0.5 ml/min @ HCT 0.25		
Ultrafiltration	UF rate	0 to 4000 ml/hr (higher range is acceptable) [ranges should be controllable]		
	Accuracy	± 3%		
Disinfection and Cleaning programs	Rinse [Rinsing of hydraulics with RO water].			
	Thermal Disinfection/Hot Rinse/ Integrated hot rinse [Disinfection of hydraulics with approx. 85°C hot water]			
	Chemical Disinfection - Hot/Heat Disinfection at Approx 85°C. [by using recommended chemicals for decalcification and disinfection]			
	Chemical Disinfection - Cold Disinfection (by using Bleach / Bio spot / any equivalent recommended chemicals)			
Battery	Battery must be able to provide backup for minimum 20 minutes to 30 minutes during power failure			
Additional Features Required	Blood pressure monitor			
	Real-time KT/V measurement			
	Profiles: Sodium and Bicarbonate			
	Profiles: Ultrafiltration			
	Heparin Pump Module with option for 10ml, 20ml & 30ml syringes			
	Network connectivity for patient data management (RPOC)			
	Patient Card reader for RPOC system [Indicate the list of compatible platform weighing scales]			
	Dry Concentrate - Bicarbonate			
	Disinfection History			
	Auto ON/OFF weekly program			
	HD and HDF treatment			

	Is there an option for single needle dialysis [indicate details and price]		
	Option for Blood Volume Monitoring [indicate the price]		
	Option for Blood Temperature Monitoring [indicate the price]		
	Option for Centralised Acid Concentrate Delivery System (CDS) / Upgradable		
Maintenance	Indicate the Service/breakdown calls response time during office hrs (Mon to Sat)		
	Indicate the Service/breakdown calls response time after officer hrs (Mon to Sat)		
	Indicate the Service/breakdown calls response time on Public holiday/ Sunday.		
	Indicate the Battery replacement Schedule [The cost of battery replacement must be included with warranty]		
	Indicate frequency of Preventive Maintenance [minimum yearly once is mandatory]		
	Indicate all preparatory consumables and items		
	Indicate lifespan of the machine		
User/Technical Training	User training must be provided with a competency check as and when required by NKF		
	A minimum of two sessions of technical training must be provided for NKF BMEs during the warranty period		
Additional Information	Indicate the number of hospital/ medical centre / Other kidney dialysis centre installed/supplied with the proposed HDF machine.		
	Indicate the number of hospital/ medical centre / Other kidney dialysis centre installed/supplied with other medical products by your company.		
Sustainability Initiatives	Please specify and provide a comprehensive list of all sustainability initiatives associated with the proposed HDF machines, including energy efficiency, water-saving features, remote monitoring, product life extension through software/firmware upgrades, reduction of plastic waste from consumables and packaging, recyclable packaging, consumable optimization, end-of-life equipment take-back and recycling programs, and sustainable manufacturing practices such as waste reduction, responsible sourcing, carbon footprint reduction, renewable energy usage, and water conservation initiatives. Please include details of any environmental certifications, sustainability programs, and measurable environmental benefits where applicable.		