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F/No. P-24011/EC-VII/1/TD-QRs/MoD-II/2015/MHA/Prov-I

Bharat Sarkar/Government of India
GrihaMantralaya/Ministry of Home Affairs
PM Division/Prov.I Desk

26, Man Singh Road, Jaisalmer House
New Delhi, Dated .10.2016

DD/ADG

Dy No. 29911m

28/10/2016

IG (Prov.)

IG (Med.) To,

DsG: AR (through LOAR), BSF, CISF, CRPF, ITBP, SSB, NSG & BPR&D.

Subject: QRs and Trial Directive of 33 nos various types of Hospital Equipments for procurement under MoD Plan-II.

Sir,

The QRs and Trial Directives in respect various types of 33 nos hospital equipments (as per detail given below) have been revised and accepted by the Competent Authority as per Annexure in MHA.

Sl. No.	Equipment Name	Remarks
1.	100 mA X-Ray Machine.	Revision of existing QRs
2.	300mA X-Ray Machine.	-do-
3.	1000mA Digital Radiography System.	-do-
4.	CT - Angio Machine.	-do-
5.	High End/Premium Whole Body Dexa Scanner.	-do-
6.	Digital Mammography.	-do-
7.	1.5 Tesla Magnetic Resonance Imaging System.	-do-
8.	Colour Doppler	-do-
9.	IFT (combination with TENS and Muscle Stimulator)	Fresh QRs/ TDs
10.	Occupational Ultrasonic Therapy Machine (Combined) 1 MHz and 3 MHz	Revision of existing QRs
11.	Traction Table with cervical and Lumber Traction Unit (Automatic).	-do-
12.	Shortwave Diathermy.	-do-
13.	Semi Automatic Bio-Chemistry Analyzer	-do-
14.	Embalming Machine.	-do-
15.	C-Arm Compatible Electro Hydraulic Orthopedic Operation Table with Remote Control.	-do-
16.	Electric Operated Programme Automatic Turning Hi-LO ICU Bed.	Fresh QRs/ TDs
17.	High Definition Upper & Lower GI Scope & ERCP Scope.	-do-
18.	Infant Open Care System	Revision of existing QRs
19.	Resuscitation Kit	Fresh QRs/ TDs

Shruti
27/10/16

DIG (Prov.)
Encl (Prov.)

उप.महा (संभरण)
DIG (Prov.)
उप. कमाण्डेंट (संभरण)
Dy. Comdt. (Prov.)
सहायक निदेशक (संभरण/लेखा)
AD (Prov./Adm.)
कार्यालय

20.	Automatic External Defibrillator	-do-
21.	Digital ECG Holter Monitor.	Fresh QRs/TDs
22.	Human Dummy.	-do-
23.	Electrically Operated Air Mattress.	-do-
24.	AC for Cool Room.	-do-
25.	Alcohol Breath Analyzer.	-do-
26.	Mortuary Chambers.	-do-
27.	Trauma Kit.	-do-
28.	Haemodialysis Machine	-do-
29.	Spirometer (PFT)	-do-
30.	Assorted Pre-Fab Splints.	
31.	Aneasthesia Work Station	Revision of existing QRs
32.	Computerized Clinical Audiometer with free Field and with VRA Testing Facility.	Fresh QRs/ TDs
33.	Ophthalmic Surgical Microscope.	Revision of existing QRs

2. The CAPFs concerned will be accountable for correctness of the QRs/Trial Directives

3. Henceforth, all the CAPFs should procure the above item required by them strictly as per the laid down Technical Specifications/QRs.

Yours faithfully,

Rmo
20/10/16

(Ritesh Kumar)

Under Secretary to the Govt. of India

Tel: 23381278

Encl: As above

Copy forwarded for necessary action to :-

SO (IT), MHA : It is requested to host the QRs and Trial Directives (soft copy attached) on the MHA website (under the page of Organizational Set up- Police Modernization Division- Qualitative Requirement under Hospital Equipments.

DM
20/10/16

(V. Devadas)

Section Officer (Prov-I)

Copy to: DDG (Procurement), MHA.

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QRS / TECHNICAL SPECIFICATIONS FOR HAEMODIALYSIS

MACHINE

RENAL REPLACEMENT THERAPY

I. Operational Requirements

. Machine should have facility for Acetate, Bicarbonate, sequential dialysis (isolated UF) upgradable to future software developments.

. The blood pump should run even in the absence of water or dialysate flow.

II. Technical specifications

1. Should have facility for conventional and High Flux dialysis.
2. Machine should have two bacterial filters (pyrogen filters) one at water inlet and one at before water going to dialyser.
3. Battery back-up for at least 20-30 minutes to run complete machine with heater supply.
4. Should have Na, Bicarbonate and UF profiling.
5. Dialysate temperatures selectable between 35 degrees C to 39 deg. C.
6. Variable conductivity setting between 12 to 15 ms/cm.
7. Should have variable dialysate flow 300-800 ml/min.
8. Should have facility to show trends curve of all parameter for 15-20 minutes.
9. Heparin pump with syringe sizes up to 50ml with pump flow rate from 1-10 ml/hr(0.1 ml increments)
10. Ultrafiltration 0.1 to 2.5 litres/hr. The in and out fluid circuit must be separated so that there is no chance of contamination in the event of membrane rupture.
11. Treatment parameter should be displayed by graph and digitally both.
12. Should have integrated heat and chemical disinfection programme with day night week schedule.
13. Should have accurate feedback control conductivity mixing technique.
14. Should have drain facility.
15. Should have accurate UF control by flow by volume measurement technique.
16. Extra facilities like Blood Volume sensor, Bicarb select technique.
17. All important data should be presented so that machine can be used anytime without feeding data every time.
18. Should have automatic self-test facility.

19. Should have auto ON/OFF facility.
20. Should have touch button screen and large colour TFT screen.
21. Automatic diagnosis of malfunctioning with on line ability to show the faults with trouble (Technical service mode).
22. Machine can be connected to computer to feed all data and trouble shoot whenever any problem.
23. Blood pump from 20-500ml/min adaptable to A-V bloodlines.
24. Ability to monitor pulse rate and NIBP.
25. Audio visual alarms on limit violation of conductivity, blood leak, air leak, transmembrane pressure alarms, Dialysis pressure alarms, Dialysis temperature alarms, dialysis can empty alarm, end of disinfection alarm, bypass alarm and blood pump stop alarm.
26. Alarm for reverse ultrafiltration.
27. Built-in device for measurement and monitoring of effective urea clearance and dialysis dose (KT/V).

III .System as specified

.All consumables required for installation and standardization of system to be given free of cost.

IV Environmental factors

. The unit shall be capable of being stored continuously in ambient temperature of 0-50 deg C and relative humidity of 15-90%.

.The unit shall be capable of operating continuously in ambient temperature of 10-40deg C and relative humidity of 15-90%.

V. Power Supply

. Power input to be 220-240V AC, 50 Hz fitted with Indian plug.

. UPS of suitable rating with voltage regulation and spike protection for 30 minutes back up.

VI. Standards, safety and training.

US-FDA OR European CE approved product.

Manufacturer/supplier should have ISO certification for quality standards.

Shall comply with IEC 60601-2-16 safety requirements of medical electric part 2-particular requirements for the safety of Haemodialysis equipment.

Should carries warranty for 2 years.

Comprehensive training lab staff and support services till familiarity with the system.

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5 Am 6 Am 7 Am 8 Am

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. Should have local service facility. The service provider should have necessary equipments recommended by the manufacturers carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.

VII Documentation

- . User/Technical/Maintenance manuals to be supplied in English.
- . Certificate of calibration and inspection.
- . List of equipment available for providing calibration and routine preventive maintenance, support, as per technical manual.
- . List of important spare parts and accessories with their part number and costing.
- . Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist.

P.O
Dr M. Bhagat, DIG (MED)
FHQ BSF Hosp- I

M-I
Dr. O.A. Rizvi, CMO(SG)
FHQ BSF Hosp- I

M-II
Dr Pradeep Joshi, CMO(SG)
FHQ SSB Hosp

M-III
Dr. R.K. Singh, CMO(SG)
CH CRPF Jharoda Kalan

M-IV
Dr. Pankaj Kumar Jha, MO
Base Hosp ITBP, Tigri

Co-Opted Members

1. Dr. Arun Kumar, CMO(SG)

2. Dr. Sukhjinder Singh CMO(SG)

3. Dr. Babita Kumari, CMO(SG)

4. Dr. Manjit Singh, CMO

5. Dr. Jayawant K, CMO

6. Dr. Anupam Upadhyay, CMO

7. Dr. Himmat Singh CMO

8. Dr. Ajaz Ahmad, SMO

9. Dr. Simrat Chandi SMO

☒ TECHNICALLY APPROVED / NOT APPROVED

Done
29/6/15

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TRIAL DIRECTIVE FOR HAEMODIALYSIS MACHINE

S.NO	SPECIFICATION	PROCEDURE SUGGESTED FOR TRIAL FOR BOARD OF OFFICERS	RESULT EXPECTED / DESIRED	COMPLIED/ NOT COMPLIED
RENAL REPLACEMENT THERAPY				
1.	<u>Operational Requirements</u> . Machine should have facility for Acetate, Bicarbonate, sequential dialysis (isolated UF) upgradable to future software developments The blood pump should run even in the absence of water or dialysate flow.	Check physically or get demonstration	As per specification	
2.	<u>Technical specifications</u>	Check physically or get demonstration	As per specification	
	Should have facility for conventional and High Flux dialysis.	Check physically or get demonstration	As per specification	
	Machine should have two bacterial filters (pyrogen filters) one at water inlet and one at before water going to dialyser.	Check physically or get demonstration	As per specification	
	Battery back-up for at least 20-30 minutes to run complete	Check physically or get	As per	

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	machine with heater supply.	demonstration	specification	
	Should have Na, Bicarbonate and UF profiling.	Check physically or get demonstration	As per specification	
PO	Dialysate temperatures selectable between 35 degrees C to 39 deg. C.	Check physically or get demonstration	As per specification	
I	Variable conductivity setting between 12 to 15 ms/cm.	Check physically or get demonstration	As per specification	
II	Should have variable dialysate flow 300-800 ml/min.	Check physically or get demonstration	As per specification	
III	Should have facility to show trends curve of all parameter for 15-20 minutes	Check physically or get demonstration	As per specification	
IV	Heparin pump with syringe sizes up to 50ml with pump flow rate from 1-10 ml/hr(0.1 ml increments)	Check physically or get demonstration	As per specification	
computer	Ultrafiltration 0.1 to 2.5 litres/hr. The in and out fluid circuit must be separated so that there is no chance of contamination in the event of membrane rupture.	Check physically or get demonstration	As per specification	
1. Hous	Treatment parameter should be displayed by graph and digitally both.	Check physically or get demonstration	As per specification	
2.	Should have integrated heat and chemical disinfection programme with day night week schedule.	Check physically or get demonstration	As per specification	
3.	Should have accurate feedback control conductivity mixing technique	Check physically or get demonstration	As per specification	

4. 5. 6. 7. 8. 9.

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Should have drain facility	Check physically or get demonstration	As per specification	
Should have accurate UF control by flow by volume measurement technique.	Check physically or get demonstration	As per specification	
Extra facilities like Blood Volume sensor, Bicarb select technique.	Check physically or get demonstration	As per specification	
All important data should be presented so that machine can be used anytime without feeding data every time	Check physically or get demonstration	As per specification	
Should have automatic self-test facility.	Check physically or get demonstration	As per specification	
Should have auto ON/OFF facility	Check physically or get demonstration	As per specification	
Should have touch button screen and large colour TFT screen.	Check physically or get demonstration	As per specification	
Automatic diagnosis of malfunctioning with on line ability to show the faults with trouble (Technical service mode).	Check physically or get demonstration	As per specification	
Machine can be connected to computer to feed all data and trouble shoot whenever any problem.	Check physically or get demonstration	As per specification	
Blood pump from 20-500ml/min adaptable to A-V bloodlines.	Check physically or get demonstration	As per specification	
Ability to monitor pulse rate and NIBP.	Check physically or get demonstration	As per specification	
Audio visual alarms on limit violation of conductivity, blood leak, air leak, trans membrane pressure alarms, Dialysis pressure alarms, Dialysis temperature alarms, dialysis can	Check physically or get demonstration	As per specification	

4. OK 5. OK 6. OK 7. OK 8. OK 9. OK

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	empty alarm, end of disinfection alarm, bypass alarm and blood pump stop alarm.			
	Alarm for reverse ultrafiltration.	Check physically or get demonstration	As per specification	
	Built-in device for measurement and monitoring of effective urea clearance and dialysis dose (KT/V).	Check physically or get demonstration	As per specification	
3	System as specified			
	.All consumables required for installation and standardization of system to be given free of cost.	Undertaking should be submitted	As per specification	
4	Environmental factors			
	The unit shall be capable of being stored continuously in ambient temperature of 0-50° C and relative humidity of 15-90%.	Undertaking should be submitted	As per specification	
	The unit shall be capable of operating continuously in ambient temperature of 10-40° C and relative humidity of 15-90%.	Undertaking should be submitted	As per specification	
5	POWER SUPPLY			
	Power input to be 220-240 V AC, 50 Hz fitted with Indian plug.	Undertaking should be submitted	As per specification	
	UPS of suitable rating with voltage regulation and spike	Undertaking should be	As per specification	

1. Access
 2. Co-apted
 3. Power
 4. System
 5. Environmental
 6. Undertaking
 7. Submitted
 8. As per
 9. Specification

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	submitted	specification	
6	protection for 30 minutes back up. <u>Standards, safety and training.</u>		
	. US-FDA OR European CE approved product. . Manufacturer/supplier should have ISO certification for quality standards. . Shall comply with IEC 60601-2-16 safety requirements of medical electric part 2-particular requirements for the safety of Haemodialysis equipment. . Should carries warranty for 2 years. . Comprehensive training lab staff and support services till familiarity with the system. . Should have local service facility. The service provider should have necessary equipment's recommended by the manufacturers carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.	Obtain OEM Certificate	As per specification
7	<u>Documentation</u> User/Technical/Maintenance manuals to be supplied in English. Certificate of calibration and inspection.	Check physically Obtain OEM certificate	As per specification

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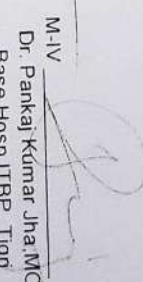
. List of equipment available for providing calibration and routine preventive maintenance, support, as per technical manual. . List of important spare parts and accessories with their part number and costing. . Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist.	Obtain undertaking from OEM / Firm Obtain list from OEM / Firm Check physically	As per specification	
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CH CRPF Jharoda Kalan

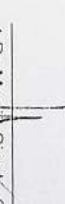
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TECHNICALLY APPROVED / NOT APPROVED

29/10/15
Addl. Director
CHCRPS, NSG & AR
MHA, Govt. of India