

ALL INDIA INSTITUTE OF MEDICAL SCIENCES  
ANSARI NAGAR, NEW DELHI-29  
STORES SECTION (DO)

Ref. No. 46/Stores(DO)/Pead/PAC/2019-20/FSC-II Dated-04/02/2020

**Sub:-** Purchase of "Automated Peritoneal Dialysis (APD) Cyclor – 01 No." for the Department of Pediatrics at AIIMS, New Delhi-110029, on proprietary basis Inviting comments thereon.

\*\*\*\*\*

The Institute is in the process to purchase "Automated Peritoneal Dialysis (APD) Cyclor – 01 No.at AIIMS, New Delhi from M/s. Baxter Healthcare SA, Singapore through M/s. Sterling Life Systems. The PAC Certifications by M/s. Baxter Healthcare SA, Singapore through as well as the user department are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within 15 day from the date of issue/uploading of the notification giving reference No. 46/Stores(DO)/Pead/PAC/2019-20/FSC. The comments should be received in office of Stores Officer (FSC), Store Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before 22/02/2020 upto 12.30 p.m. failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

  
SR. STORES OFFICER (DO)


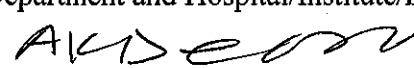
Encl: Related documents enclosed.

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES**  
**ANSARI NAGAR, NEW DELHI - 110029**


**Proprietary Article Certificate (PAC) (Machinery & Equipment)**

- (i) The indented goods are manufacture by **Baxter Healthcare Corporation**
- (ii) Item Name: **Baxter Homechoice Claria APD Cyclor**
- (iii) Model No: **5C6M10 - HOMECHOICE CLARIA APD CYCLERDUAL POWER**
- (iv) Vital technical Performance Parameters required which makes the requirement proprietary<sup>##</sup>: **Technical specifications are attached. Please note that a locally made product, also termed cyclor, is available but it is (i) not automated, (ii) does not have a class II device construction, (iii) does not have USFDA or CE certification, (iv) relies on gravity, drainage and (v) does not allow for prescription to be set for prolonged periods, or for information to be retrieved from machine.**
- (v) No other make or model is acceptable for the following reason:  
**Please note reply to (iv), above. This is a compact portable, closed unit that automatically cycles peritoneal dialysis fluid inside and outside the patient's body with a preset modifiable prescription for total therapy duration as well as length and volume of individual cycles. The cyclor device minimizes patient handling, thus reducing nursing need as well as the risk of infections by touch contamination. There are no similar locally procured and assembled equipment, suitable for use in children, that have these options.**

It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfil the vital requirements of end user.

  
 Signature of TSEC  
 With Name, Designation, Department and Hospital/Institute/DGHS  
  
 30/12/14


<sup>##</sup>Note: TSEC should clearly mention the vital functional parameters requirements which end user essentially require and are manufactured by only one manufacturer mentioned in Serial No. (i).


  
 डॉ. अशोक कु. देवराणी  
 Dr. Ashok K. Decorari, MD, FAMS  
 आचार्य एवं विभागाध्यक्ष / Professor & Head  
 बालरोग चिकित्सा विभाग / Department of Pediatrics  
 आर.आ.सं., नई दिल्ली / A.I.I.M.S., New Delhi-110029

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ANSARI NAGAR, NEW DELHI - 110029

PROPRIETARY/SPECIFIC BRAND GOOD CERTIFICATE

|   |  |
|---|--|
| 1. Item/Type/Model no. required alongwith specification   | Baxter Homechoice Claria APD Cycler  |
| 2. Is the item a spare part/attachment or accessory for an existing equipment   | Essential equipment (not spare part or attachment)   |
| 3. Name of the manufacturers/supplier of the item proposed by the indenter.   | Baxter Healthcare Corporation  |
| 4. Are they sole manufacture/sole distributors of the item  | In India, this is the only fully automated cycler available for use in children.   |
| 5. Is there any other item with similar/equivalent specification available in the market to meet the job requirement envisaged. If the answer is yes, why the same can't be procured. Demanding officer should bring out comparative functional advantages and cost effectiveness of the recommended item from these offered by other | A locally made product, also termed cycler, is available but it is (i) not automated, (ii) does not have a class II device construction, (iii) does not have USFDA or CE certification, (iv) relies on gravity, drainage and (v) does not allow for prescription to be set for prolonged periods, or for information to be retrieved from machine.   |
| 6. What were the efforts made to locate alternative source of supply or use other substitutes.  | This is a compact portable, closed unit that automatically cycles peritoneal dialysis fluid inside and outside the patient's body with a preset modifiable prescription for total therapy duration as well as length and volume of individual cycles. The cycler device minimizes patient handling, thus reducing nursing need as well as the risk of infections by touch contamination. There are no similar locally procured and assembled equipment, suitable for use in children, that have these options. |
| 7. Why open/limited tender can't be resorted to for locating alternative source   | This is a proprietary based item, only manufactured by M/S Baxter Healthcare Corporation. Having used automated peritoneal dialysis for more than 15-years, we consider it unlikely that any other vendor will bid for the product if an open or limited tender is floated.  |
| 8. Are the proprietary item certify that the rates are reasonable or not  | Yes. The item is being provided at reasonable cost. The unit was procured by AIIMS Jodhpur from the same company recently, and the order copy is enclosed.   |
| 9. Any other justification for procuring item from single source.   | As in 6 above  |

  
Signature of indenter  
(Demanding officer)  
Dr. Arvind Bagga  
Senior Professor  
आर्यभट्ट विज्ञान विभाग/Department of Pediatrics  
अ.न.आ.स., नई दिल्ली/A.I.I.M.S. New Delhi-110029

  
(Counter signed)  
Dr. Ashok K. Deora, MD, FAMS  
(Head of the Department)  
आर्यभट्ट विज्ञान विभाग/Department of Pediatrics  
अ.न.आ.स., नई दिल्ली/A.I.I.M.S. New Delhi-110029

I certify that the item at Sr. no. 1 above is required to be procured on single tender basis as the source of the supply is definitely known/ the specified brand proposed was advantage in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

**DEPARTMENT OF PEDIATRICS**  
**ALL INDIA INSTITUTE OF MEDICAL SCIENCES**

|  |  |
|--|--|
| Item Name  | Automated Peritoneal Dialysis (APD) Cycler |
| Quantity   | 3 (Three), along with software             |
| Cost   | Rs. 18,00,000                              |
| Warranty/Guarantee: Five years comprehensive warranty with all spare parts and labor charges and comprehensive annual maintenance contract for next five years |  |

**TECHNICAL SPECIFICATIONS**

1. Should allow peritoneal dialysis (PD) therapy in all of the following modes: (a) intermittent or cyclic (CCPD/IPD); b) High dose CCPD; (c) Tidal; and (d) High dose tidal
2. Should have automatic calculation of number of cycles and dwell time
3. Should use disposable cassette assembly for therapy
4. Should have an inbuilt fluid warmer to warm fluid to 35-37 degrees centigrade
5. The total programmable volume should range from <200 ml to >50 liters, and the dwell volume should range from <75 ml to >2000 ml
6. Should be able to measure fluid flow and volume without the use of weighing scales
7. Therapy time should range from <15 minutes to >36 hours
8. Should have standard and low fill modes to allow the following:
  - a) Low fill mode with fill volume <75 to up to 1000ml
  - b) Standard mode with fill volume between 100 ml to 3000 ml
  - c) Last fill at the above volumes in the respective modes
9. Should allow connecting to patient with weight ranging from <2 kg to >90 kg
10. The disposable set for use with the system should have cassette or its equivalent and tubing lines pre-loaded on an organizer for simplified set up
11. The system should automatically calculate the number of cycles and dwell time per cycle once the patient enters the total therapy time, total volume and fill volume
12. The unit should automatically (by self) activate system error alarms in order to maximize patient safety and automatically (by self) correct errors continuously
13. The system should perform self-check before starting the treatment
14. The system should have built-in event, therapy and alarm logs for simplified trouble-shooting
15. The system should have a built-in nurses menu and service menu

*[Signature]*

*[Signature]*

*[Signature]*

*[Signature]*

16. The system should have protective system to prevent overflow
17. The system should have a program lock
18. The system should allow for last fill with same or different strength of dextrose-containing solution
19. The system should have accurate volume delivery with accuracy of at least  $\pm 2\%$  and  $\pm 10\text{mL}$
20. The unit should be operable at 220-240V with appropriate Indian plugs
21. The unit should consume less than 600VA power
22. The equipment should be compact, weighing less than 15 kg and with size less than 20 cm x 50 cm x 40 cm
23. The system should be able to detect air bubbles exceeding 3 ml
24. The system should have battery back-up for program of up to at least 1 hour
25. The system should comply with US FDA or European CE standards
26. The system should comply with electrical safety clause of IEC 60601-1-11 (Clause 8.3.1)
27. The system should be a class II double-insulated device that does not rely on an earth ground conductor for protection against electric shock
28. The system should be compliant with the latest EU environmental standards for Restriction of Hazardous Substances (RoHS) in electronic equipments
29. The system should have a digital display in large font using an organic light emitting diode (OLED)
30. The system should have a USB type B port
31. The system should have memory to allow storage of more than 60 days of therapy on device
32. The system should come with warranty in form of five years of comprehensive maintenance contract and additional five years of annual maintenance contract
33. The company should have been in market for at least 5 years
34. All spare parts, including electronic, mechanical and plastic parts and software, required as such or due to wear and tear, should be included in the warranty period of five years and in Comprehensive AMC period of next five years.
35. The prices of all disposables for use with the machine, including pediatric and standard (adult) size disposable tubings and cassettes, and 5L bags with drainage bags, should be quoted and fixed for a period of five years
36. Each system should be supplied with 50 sets of disposable pediatric tubings and cassettes.

*Handwritten signatures:*  
1. *Shree G*  
2. *Shree*  
3. *HL*  
4. *Rupesh*

37. The parent company has the sole responsibility of warranty and CMC even if the company's distributor is quoting to supply the machine.

38. Company personnel shall have the following responsibilities:

- Elective visit once a month, day as decided by the department
- Preventive machine maintenance four times in a year
- Response time for acknowledgment of complaint: Within 30 minutes
- Response time for physical presence within one working day
- Machine uptime 355 days in a year
- Machine downtime 48 hours, with a penalty of Rs. 5000/- every day after downtime
- Training to the pediatric dialysis unit staff and fellows who use the machine and retraining of two personnel every year for five years

39. Documents to be enclosed:

- Service manual in English
- Product Catalog and User manual in English
- Compliance Report: To be submitted in a tabulated and point wise manner, clearly mentioning the page number of original catalog of data sheet
- Essential and additional equipment list: To be provided, including those required for providing calibration and routine preventive maintenance support, as per manufacturer documentation
- Spare parts and accessories: List of important spare parts and accessories provided with the machine, part numbers and cost
- Local components: A clearly defined list of components/parts of machine or its accessories that are to be provided by Indian counterpart/agent, that are not being provided with the machine. The costs of these components and their replacement frequency should be clearly stated
- Institution supply list: A complete list of the institutions where the machine has been supplied in last five years, along with the name, mobile and office contact details of the person handling the machine
- Details about company website where machine details and brochure are available
- Log book with instructions for regular maintenance and its checklist
- Job description: Clearly defined job description of the hospital staff and company service engineer
- User certificate and satisfactory performance report of the equipment in last five years from users in any central or state government hospital
- Letter of accreditation from the manufacturer of the machine stating that the machine to be supplied is new, the model is being manufactured as on tender date, the spare parts will be available for the next ten years from the date of delivery, and that service will be maintained even if the distributor changes

*Aditya*

*Harsh*

*[Signature]*

*Rupendra*

- Documentary evidence of local service facility with registered office in India: The service provider should have necessary equipment recommended by the manufacturer to carry out preventive maintenance service (PMS) as per guideline in the dialysis machine manual
40. Accessories, spare parts and consumables to be supplied with the equipment; all with at least one year between supply and expiry:
- Any consumables and equipment needed for installation and standardization of machine
  - Any equipment required for calibration and routine preventive maintenance support, as per manufacturer documentation in service/technical manual
  - UPS of suitable rating with voltage regulation for 30 minutes back up

Specifications finalized and approved on 14 October 2019.

**Members of the specifications committee:**

1. Prof. Arvind Bagga, Department of Pediatrics:
2. Prof. Pankaj Hari, Department of Pediatrics:
3. Dr. Aditi Sinha, Department of Pediatrics:
4. Dr. R. K. Yadav, Department of Nephrology:
5. Dr. Jitender Sodhi, Department of Hospital Administration:

*[Handwritten signatures of Prof. Arvind Bagga, Prof. Pankaj Hari, Dr. Aditi Sinha, Dr. R. K. Yadav, and Dr. Jitender Sodhi]*

*[Handwritten signature of Dr. Ashok K. Deorari]*



डॉ. अशोक कु. देवरासी  
Dr. Ashok K. Deorari, MD, FAMS  
आचार्य एवं विभागाध्यक्ष / Professor & Head  
बालरोग चिकित्सा विभाग / Department of Pediatrics  
अ.भा.आ.सं., नई दिल्ली / A.I.I.M.S., New Delhi-110029

**Date Mar 27 '19**

**PROPRIETARY ARTICLE CERTIFICATE**

**TO WHOM IT MAY CONCERN**

**This is to certify that the following product is a proprietary product of Baxter:**

**5C6M10 - HOMECHOICE CLARIA APD CYCLERDUAL POWER**

**The above product is manufactured by:**

***Baxter Healthcare SA, Singapore Branch  
2 Woodland Industrial Park D Street 2  
Singapore 737778***

**Marketed in India by wholly owned subsidiary:  
*Baxter (India) Pvt. Ltd.  
5th Floor, Tower-A, Building No. 9,  
DLF Cyber City, DLF Phase III, Gurgaon-122002, Haryana***

**Sincerely,**

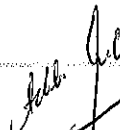
**For and on behalf of  
Baxter Healthcare SA, Singapore Branch**



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**James Tan  
Quality Director  
Baxter Woodlands**

**Baxter Healthcare SA  
Singapore Branch of Baxter Healthcare SA (Incorporated in Switzerland)  
2 Woodlands Industrial Park D Street 2 Singapore 737778  
T (65) 63685555 F (65) 69337781  
Regn No: T03FC6334K**





Dated: 28<sup>th</sup> December 2019

To,  
The Director,  
Through HOD Pediatrics.,  
All India Institute of Medical Sciences,  
New Delhi.

Ref No- For Claria With Share Source

Dear Sir,

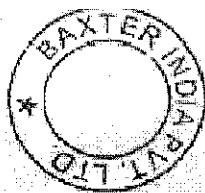
We, Baxter India Pvt. Ltd., who are proven and reputed manufacturers of "CLARIA WITH SHARESOURCE", hereby authorize M/s STERLING LIFE SYSTEMS, B-29, DSIDC Complex, 1<sup>st</sup> Floor, Kirti Nagar, New Delhi-110015 to submit a Bid, process the same further and entire into a contract with you against your requirement contained in the above referred TE documents for the above goods manufactured by us.

We further confirm that no supplier or firm or individual other than M/s Sterling Life Systems, is authorized to submit the Bid, process the same further and entire into a contract with you against your requirement contained of Claria With Share Source manufactured by us.

We also hereby extend our full warranty, CAMC as applicable as per clause no- 15 of the general conditions of contract, read with modification, if any, in the special condition of contract for the goods and services offered for supply by the above firm against "Claria With Share Source".

We also hereby confirm that we would be responsible for the satisfactory execution of the contract placed on the authorized agent and the spares for the equipment shall be available for at least 10 years from the date of supply of the equipment.

Thanking You  
Yours Sincerely



Vineet Kumar  
Sales Manager-North  
Baxter India Pvt.Ltd.  
Mobile: +91-9999321250

