

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

Ref. No. 21/Stores(DO)/Pead.Surg./PAC/2019-20/FSC Dated-28/10/2019

Sub:- Purchase of "Patient Monitoring System with safety net for HDU 20 Bed." for the Department of Pediatric Surgery at AIIMS, New Delhi-110029, on proprietary basis inviting comments thereon.

The Institute is in the process to purchase "Patient Monitoring System with safety net for HDU 20 Bed. at AIIMS, New Delhi from M/s. Masimo, USA through M/s. Gaur Surgical, New Delhi. The PAC Certifications by M/s. Masimo, USA 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. 21/Stores(DO)/Pead.Surg./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 14/11/2019 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.


(11)


**ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI - 110 029**

Proprietary Article Certificate (PAC) (Machinery & Equipment)


1. The indented goods are : Masimo, USA
Manufactured by M/s
2. Item Name : Patient Monitoring System with Safety Net
for HDU 20 Bed
3. Model No. : Patient Safety Remote Monitoring and
Notification System
4. Vital Technical Performance Parameters : Rainbow Technology allows non invasive
Required which makes the requirement continuous measurement of SpHb, SpCO,
Proprietary## SpNet&PVI through one device
5. No other make or model is acceptable for : Only Single Manufacturer
The following reasons


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

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##Note 1: 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. 1.

 डॉ. प्रबुद्ध गोयल/Dr. Prabudh Goel
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डॉ. एम. बाजपेई/Dr. M. BAJPAI
आचार्य एवं विभागाध्यक्ष/Professor & Head
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Signature of TSEC

with Name, Designation, Department
and Hospital/Institute/DGHS

 डॉ. अंजन कुमार धुआ/Dr. Anjan Kumar Dhua
सहायक आचार्य/Assistant Professor
शिशु शल्य विभाग/Department of Pediatric Surgery
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Unit Price = 1.67 Cr
Qty = one

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Technical Specifications for Patient monitoring System with Safety Net for HDU 20 Bed

1. The system should provide Remote monitoring of patients in High dependency unit/wards and provide notification in case of any change in condition of patient.
2. The system should monitor the patients by the bedside and relay the data to a central monitoring station from where the patients can be monitored.
3. The notification system should be capable of sending alarm notifications to care givers and should have auto escalation features for providing fool proof redundancies.
4. Auto escalation should be programmable as per the care area need
5. It should be suitable for all types of patients; Pediatric, Infant, and /or Neonate
6. Patient monitor should provide continuous, simultaneous measurements and displays of the following parameter:

- 1) SpO₂
- 2) Pulse rate
- 3) Perfusion Index
- 4) Pleth variability Index

7. Should have the facility to measure these parameters for spot check and at fixed time intervals
8. Should be able to measure SpO₂, Pulse Rate, Perfusion Index, Continuous Noninvasive Hemoglobin, Pleth viability through same single finger probe
9. Beside monitor Should have selectable SpO₂ averaging Modes- 2, 4, 8, 10, 12, 14 or 16 seconds & Sensitivity - APOD, Normal and Max
10. Central Monitoring Station should be color touch screen at least 21" size
11. Central station should have choice for Selecting multiple domains and monitor up to 40 patients at a glance in one single screen
12. Central monitoring display should have Choice of icon and/or Numeric views to quickly investigate patient alarms
13. Should have facility of comprehensive Review of trend data with Window selection of 10 minutes to 96 hours display on the central monitoring station
14. Should have Alarm notification system with multiple options including proprietary paging system and enterprise paging system

15. System should be complete with paging transmitter and pagers (at least 10 nos.) with provisions for auto escalation

16. System Should allow for 3rd party messaging with gateways that comply to TCP/IP, GSM, GPRS, Ethernet or HL7

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17. Individual Patient monitor should have rotational color touch screen with automatic, change to horizontal or vertical view
18. Patient monitor should have facility to customize display to see parameter, waveforms or trend patient monitor should have function with facility to select one or two parameters and move ,expand or collapse parameter trend for real time analysis
19. Individual monitor should have inbuilt battery backup of at least four hours
20. Display & measurement range, resolution and accuracy of bedside monitor should be as follows

- I. Display and Measurement Range (Adult/infant/paed)

- Plath Variability Index -0-100%
- Oxygen Saturation (SpO₂)- 0 – 100%
- Pulse Rate (PR)- 25-240bpm
- Perfusion Index (PI) -0.02-20%

II. Resolution (Adult /infant /paed)

- a) Oxygen Saturation (SpO₂)-0-100%
- b) Pulse Rate (PR) – 1 bpm

III. Measurement range and Accuracy (Adult /infant /paed)

- a) Saturation Range : 70% to 100%

-Accuracy in no Motion -2% Accuracy in Motion- 3% Accuracy in Low Perfusion- 2%

- b) Pulse Rate Range :25 -240 bpm

- Accuracy in no motion -3 bpm accuracy in motion -5 bpm

Perfusion -3bpm

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Accuracy in Low
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21. The system should be US FDA and CE approved product

22. The manufacture should have ISO certification for quality standards

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23. Should comply with following standards

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DR. ANITA SEN

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एन.सी.एस (बाय प्रत्य (मिलिटरी)) / AACH (Presid. Surgery)
सर्वत्र विशेषज्ञ राज राज प्रत्य मिलिटरी
a) Safe
Dr. Specialist Paediatric Surgery & Nephrology
बाल शल्य चिकित्सा विशेषज्ञ / Paediatric Surgeon
बाल शल्य चिकित्सा विशेषज्ञ / Paediatric Surgeon
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JAG & Salsar Hospital, New Delhi-2

a) Safety Standards : ANSI/AAMI

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आचार्य / Professor



डॉ. प्रबुद्ध गोयल / Dr. Prabhush Goel
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Dr. P. A. ... Professor



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Dr. Sandeep Aggarwal / Dr. Sandeep Aggarwal
Professor / Professor

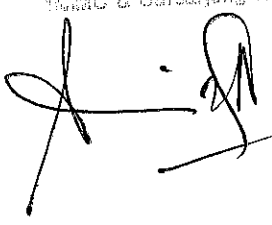
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- b) Pulse Oximeter Standards : ISO 80601-2-61
- c) Alarm Standards : IEC 60601 -1-8 Class B
- d) EMC Standards : EN60601 -1-1-2 ,Class B
- e) Degree of Protection : Type BF, DefibProof


- 24. The system should have the capability of connectivity/ Integration with hospital hl7 Admit, discharge and transfer (ADT) system for patient data management. Should also have provision for bedside patient association via ADT.
- 25. Should have option for integration into electronic medical record system using HL7 for automated documentation of patient data.
- 26. The system should support both wired and wireless installation.
- 27. The vendor should quote price for sensors valid for at least three years.
- 28. The system should be supplied complete with
 - a) Central monitoring station minimum 21' touch screen and required hardware, server etc.
 - b) Bedside patient monitors with facility to measure and display- SpO2, pulse rate, perfusion index continuous noninvasive hemoglobin, pleth variability index – 20 Nos.
 - c) Patient finger sensor - 20 Nos.
 - d) Patient Cable -20Nos.
 - e) NIBP Cuff – 20 Nos.
- 29. The System should have 5 year Comprehensive warranty and should quote price for CMC for 5 years after completion of warranty period.
- 30. Should have installation of quoted System in any reputed Govt. Hospital or Institution.

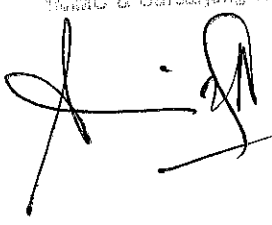
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
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TO WHOM IT MAY CONCERN

February 28, 2019

This is to certify that the following technologies, and parameters are unique to pulse-oximeters, Co-oximeters and Masimo's Patient SafetyNet™ system manufactured by Masimo Corporation, are protected by patents, trademarks and or trade secrets as appropriate, and are proprietary to Masimo Corporation:

1. Signal Extraction Technology (SET™): Proprietary technology protected by patents, trademark, and trade secrets, that allow the measurement of oxygen saturation in the blood, even when there is motion (Otherwise known as 'read through motion') and low perfusion up to 0.02 Perfusion Index (PI)

2. Rainbow SET™ or Rainbow Technology: Proprietary technology protected by patents, trademark, and trade secrets, that allow the non-invasive and continuous measurement of the following parameters:

- i. Hemoglobin (SpHb)
- ii. Carboxyhemoglobin (SpCO)
- iii. Methemoglobin (SpMet)
- iv. Pleth Variability Index (PVI)

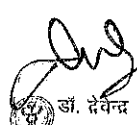
The combination of these measurements in one device is unique to Masimo, and is available as required in Masimo's devices such as Rad-97, Radical-7, and Root.

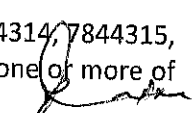
Further, Masimo's Patient SafetyNet™ system is uniquely positioned to provide supplemental remote monitoring of data from all the above bedside devices to display near real time information at a central monitoring station, automate data transfer to EMR and additionally send alarms and alerts to clinicians. The Patient SafetyNet includes the following proprietary features which include:

- Halo Index- A Cumulative Trending Assessment of Global Patient Status
- Replica - A mobile application for supplemental remote monitoring and clinician notification on a smart phone

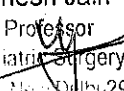
We hereby confirm that to the best of our knowledge no other manufacturer can offer the combination of above technologies for supplemental remote monitoring!

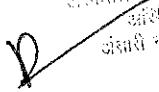
Masimo's Patient SafetyNet is Covered by one or more of the following U.S. Patents: 7844314, 7844315, 8274360, 8310336, 8892180, 9142117, 9211095, 9218454, international equivalents, or one or more of the patents referenced at www.masimo.com/patents. Other patents pending.


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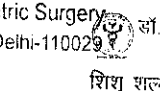

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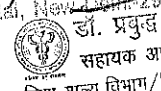

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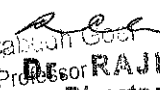
Bhart D Monteiro
Country Head-India & The Sub-Continent

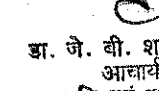

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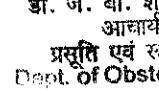

डॉ. राजीव चड्ढा / Dr. Rajiv Chadha
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Date -03-09-2019

SECTION – XII
MANUFACTURER'S AUTHORISATION FORM

The Director
All India Institute of Medical Sciences Ansari Nagar,
New Delhi-110029, India.

Dear Sir,

Ref: Your TE document No- Patient SafetyNet™ Remote Monitoring and Notification System for HDU on 20 Beds for Pediatric Surgery Department.

We, Masimo who are proven and reputable manufacturers Of Patient SafetyNet™ Remote Monitoring and Notification System for HDU on 20 Beds having factories at USA, hereby authorize **GAUR SURGICALS** having Reg. Office at **187, W. No. 3, Meherauli, New Delhi – 110030** to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also state that we are not participating directly in this bid for the following reason(s): Company has decided to quote the Tender through their Authorized dealer.

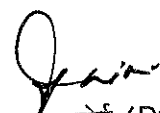
We further confirm that no supplier or firm or individual other than **Messrs. GAUR SURGICALS** having address at **-W.No. 3, Meherauli, New Delhi – 110030** is authorized to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us. We also hereby extend our full warranty, CAMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

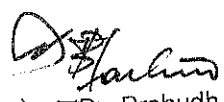
We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized agent and the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.

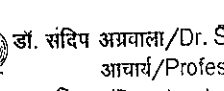
We also confirm that the price quoted by our agent shall not exceed the price which we would have quoted directly"


Yours faithfully,

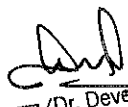
For Masimo Medical Technologies India Pvt Ltd.,



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