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

Ref. No. 14/Stores(DO)/Pead.Surg/PAC/2021-22/FSC

Dated-09/12/2021

Sub:- Purchase of "Patient Safety Remote Monitoring and Notification system (Central Monitoring Station) for 45 Bed – 03 Unit. for the Department of Pediatric Surgery, at AlIMS, New Delhi-110029, on proprietary basis Inviting comments thereon.

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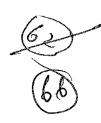
The Institute is in the process to purchase "Patient Safety Remote Monitoring and Notification system (Central Monitoring Station) for 45 Bed – 03 Unit. at AIIMS, New Delhi from M/s. Masimo, USA through M/s. Gaur Surgicals, New Delhi. The PAC Certifications by M/s. Masimo, USA as well as the user department 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. 14/Stores(DO)/Pead.Surg/PAC/2021-22/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 30/12/2021 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.



BARRY CHARLS

Director Professor pit. of Pediatric Surgery Li.M.C. & K.S.C. Hospital New Deibi-110001

#### **ALL INDIA INSTITUTE OF MEDICAL SCIENCES**

#### ANSARI NAGAR, NEW DELHI- 110029

## Proprietary Article certificate (PAC)( Machinery & Equipment)

1. The Indented goods are Manufactured by M/S: Masimo Corporation U.S.A

2. Item Name: Safety Net Remote Monitoring and notification system

Model No: Safety Net Remote Monitoring and notification system with Rad 97

4. Vital Technical Performance Parameter which makes the requirement Proprietary:

Requirement of SpO2, Pulse rate, Perfusion index, PVI, Continuous Hemoglobin, NIBP in a single monitor which can measure all the parameters Non Invasively. All devices should be connected with central monitor which can store the data and can show the trend of every data with events . System should be capable of generation different types of report to analyse the fluctuation in vital sign parameters . Nursing staff should have a device where they can get the notification and that notification should be having the feature of auto escalation.

- 5. No Other make or model is acceptable or the following reasons:
  - A. Masimo parameters sensitive is 97%.
  - B. Specificity of all parameters is 95 %.
  - C. Can work in Motion.
  - D. Can work in low perfusion up to 0.02.
  - E. Noninvasive PVI which can tell the hydration level of a body.
  - F. Non invasive continuous hemoglobin to administer right amount of blood and to detect the chances of Internal bleeding.
  - G. Every nurse will get the the notification through pagers apart from the notification on central screen.
  - H. each notification will be auto escalated if not attended because of any reason.
  - l. System can generate various reports based on the vital signs .
  - J. Each de saturation event is record-able for better daignosis and analysing the

PROF. OR Pediatric ABVIME can be linked with EMR system consultant Hospital 1,0001

डॉ! एमं. बाजपेई / Dr. M. BAJPAI आचार्य एवं विभागाध्यक्ष / Professor & Head शिशु शल्य विभाग/Deptt. o. Pearstoc Garger अ.भा.आ.रा., नई दिल्ली / A.I.I.Se C

र्याचेव / Dr. Devendra K. Yadav सह-आचार्य/Associate Professor शिशु शल्य विभाग / Department of Pediatric Surgery अ.भा.आ.सं., नई दिल्ली / A.I.I.M.S., New Delhi-110029

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#### Technical Specifications for Patient safety Remote monitoring and Notification system for 45 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: Adult , 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)Pleath variability Index 5) Non Invasive Blood pressure monitoring 6)Non-invasive continuous Haemoglobin(SpHb) 7)Respiration Rate(RRp)

- 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, Pleathviability through same single finger probe
- 9. Bedside 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 10nos ) with provisions for auto escalation

16, System Should allow 3rd party messaging with gateways that comply to TAP 1.6/1.8 over Ethernet

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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 ortrend 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 beside monitor should be as follows:-
- a). The model should be a desktop model with weight less than 2 kg.
- b). It should have reliable signal detection even in low perfusion states with perfusion indicator (Signal extraction technology-SET).
- c). The reading should be resistant to motion artifacts (with certificate).
- d). Oxygen saturation
- 1. Range: 1-100%
- 2. Accuracy: ±3% (70-100%)
- 3. Averaging time should be user selectable and should be minimum 2 second and maximum 16 sec
- e). Pulse rate measurement
- 1. Waveforms: Plethysmographic form
- 2. Range: 40-230 beats per minute
- 3. Accuracy: ±3-5 bpm
- 4. Should work up to perfusion index of 0.02
- f). Non-invasive blood pressure (NIBP)

1. NIBP range in mmHg: 20-400

2. Cuff size:

Neonatal, Paediatric

3. Number of cuff's provided

g).Plath Variability Index range -0-100%

h).Perfusion Index (PI) -0.02420%

i).Non Invasiye sontinuous Haemoglobin (SpHb):-

तथान / Department of Ped.

Director Professor of Pediatric Surgery

CHESTAL TE RECORD ALLIM.S., No.

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- 1. Haemoglobin range: 8-17 gm/dl
- 2. Haemoglobin Accuracy:- ± 1 gm./dl
- j). Display
- 1. Large and bright with contrast background
- 2. Oxygen saturation, pulse rate, perfusion index and Pleath variability index
- 3. Alarms and alarms limit
- 4. Battery charge status
- 5. Sensor off indicator
- k). Alarms
- 1. Type of alarm: Audio and visual
- 2. Alarm volume: Adjustable
- 3. High/low SPO2 alarms
- 4. High/low Pulse rate alarms
- 5. System alarms: Probe and system failure, Low battery
- I). Trends
- 1. Trend display up to 96 hours at 2 seconds sampling rate
- m). Power
- 1. 220/240VAc, 50/60 Hz
- 2. Rechargeable internal battery with backup of at least 6 hours

n). Probe compatibility - Should be compatible with both reusable and disposable probes.

<sup>Meuqis</sup> K. Asqs<sub>a</sub>

21. The system should be USFDA and CE approved product / ഉപവരന മുക്കി

22. The manufacture should have ISO certification for quality standards

23. Should comply with following standards

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Sig vice farm Department of Pediatric সংগ্ৰাপ্ত, শই বিজ্ঞী/A.LI.M.S., New Delhi

हुत. (प्रो.) अजिता होना Dr. (Prof.) Amita Sen or this mount control of the service Student

Dr. Devendra Kumar Yadav Additional Profession con Professor Department of Pediatrics ChiPethatric Surgery W. & K.S.C. Hospital Mem vi Dellaw Delhi-110001



a) Safety Standards : ANSI/AAMI ES 60601 -1 , CAN/CSA C22.2 No 60601 -1 IEC/EN 60601 -1

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. Bedside Device should be upgradable to Methaemoglobin (spMet) and Carboxyhemoglobin (spCo)
- 26. Should have option for integration into electronic medical record system using HL7 for automated documentation of patient data.
- 27. The system should support both wired and wireless installation.
- 28. The vendor should quote price for sensors valid for at least three years.
- 29. The system should be supplied complete with
  - a) Central monitoring station minimum 21' touchscreen and required hardware, server etc.
  - Bedside patient monitors with facility to measure and display- SpO2, pulse rate, perfusion index, Pleath variability index, SpHb(Non-invasive continuous Haemoglobin) ,RRp(Respiration Rate) – 45 Nos.
  - c) Reusable Patient sensor- 45 Nos.
  - d) B.P. Cuff 45 Nos.

Director Professor

Podiatric Surgery

Mew Delhi-110001

Mew Delhi





8th June 2021

### TO WHOM IT MAY CONCERN

This is to certify that the following technologies, and parameters are proprietary in Masimo's pulse-oximeters and Co-oximeters manufactured by Masimo Corporation, and are subject to intellectual property rights of Masimo Corporation:

- 1. **Signal Extraction Technology**<sup>TM</sup> (SET): Proprietary technology subject to intellectual property rights of Masimo that allows the measurement of oxygen saturation in the blood, even when there is motion (Otherwise known as 'measure through motion') and low perfusion up to 0.02 Perfusion Index (PI)
- 2. Rainbow SET or Rainbow Technology: Proprietary technology subject to intellectual property rights of Masimo that allows the non-invasive and continuous measurement of the following parameters:
  - Hemoglobin (SpHb)
  - Carboxyhemoglobin (SpCO)
  - Methemoglobin (SpMet)
  - Pleth Variability Index (PVI)
  - Acoustic Respiration Rate (RRa)
  - Oxygen Reserve Index
- 3. **Brian function monitoring technology:** Proprietary technology protected by patents, trademark, and trade secrets that allow the non-invasive and continuous measurement of the following parameters:
  - O3 Regional Oximetry
  - SedLine- Depth of sedation monitoring

The combination of these measurements in one device is unique to Masimo, and is available as required in Masimo's Patient Safety Net which may also include the ROOT platform.

Further, to the best of our knowledge, no other company or manufacturer in the market, other than those who have licensed the technology from Masimo, profluces, or can offer SET $^{TM}$  or Rainbow SET $^{TM}$  technologies and capabilities. विश्व विश्वोगङ्ग बाल एक शाल्य विश्व सा Yours faithfully, Sr. Specialist Paediatric Surgery 8, 1,00 गल्य चिकित्सा विभाग IDeal of Paer sincs वीएमएमशी एवं सफड़ VMMC & Safds <sub>iir Kant Acharya</sub> The British of the Market of the State of th विश्व शब्य विश्व Hig Contains Country Manager, India and the Sub Continent St. Specialist From The Sub Continent जात शत्य विक्रिसी विमाग and and and Hospital New Delyn शास्त्राम्सी एवं सक्तवस्त्रा अस्तित्रा Page 1 of 1



#### Masimo Medical Technologies India Pvt. Ltd Billor's Pladium, 1st Floor 19/3 Cunningham Road Bangalore, Karnataka, 560052, India



Date: 23-04-2021

#### 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 for Safety Remote Monitoring & Notification system for Pediatric Surgery Department.

We, Masimo who are proven and reputable manufacturers Of Safety Remote Monitoring & Notification system . 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 our 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.,

