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

Ref. No. 01/Stores(DO)/Pead.Surg/PAC/2021-22/FSC-I

Dated- 27/04/2021

Sub:- Purchase of "Monitor for Regional Oximetry – 20 Units. for the Department of Pediatric Surgery, at AIIMS, New Delhi-110029, on proprietary basis Inviting comments thereon.

表表方大方案

The Institute is in the process to purchase "Monitor for Regional Oximetry – 20 Units." for the department of Pediatric Surgery at AlIMS, New Delhi from M/s. Masimo Medical Technilogies, USA through M/s. Gaur Surgicals, New Delhi The PAC Certifications by M/s. Masimo Medical Technilogies, 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. 01/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 15/05/2021 upto12.30 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 - 110 029

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

1. The indented goods are Manufactured by M/s

:Masimo Medical Technologies

2. Item Name : Monitor For Brain Function Monitoring, Regional Oximetry, Oxygen reserve Index, Continuous Haemoglobin, Fluid Responsiveness Monitoring.

3. Model No.

: ROOT WITH RADICAL -7

4. Vital Technical Performance Parameters : Monitor Measure Brain function monitoring, Regional Oximetery, Oxygen Reserve Index, Continuous Haemoglobin, Fluid Responsiveness.

5. No other make or model is acceptable for : Proprietary product of M/S Masimo Medical **Technologies** 

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.

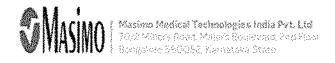
Stand/Professor with Name Designation Department (19) Pesh Janas and Mary And Red / Alles, New Demotion and Hospital/Institute/DGHS

#Note 1: TSEC should clearly mention the vital functional parameters requirements which end user essentially require sand are manufactured by only one manufacturer mentioned in

/ Denartment of Pediatric Surgery

Yorabudh Goel





May 31, 2018

#### TO WHOM IT MAY CONCERN

This is to certify that the following technologies, and parameters are unique to pulse-oximeters and Co-oximeters 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 TM (SETTM): Proprietary technology protected by patents, trademark, and trade secrets, that allow the measurement of oxygen saturation in the blood, in spite of motion (Otherwise know as 'read through motion') and low perfusion up to 0.02 Perfusion Index (PI)
- 2. Rainbow SETTM or Rainbow Technology: Proprietary technology protected by patents, trademark, and trade secrets, that allow the non-invasive and continuous measurement of the following parameters:
  - î. Hemoglobin (SpHb)
  - ii. Carboxyhaemoglobin (SpCO)
- iii. Methaemoglobin (SpMet)
- ìv. Pleth Variability Index (PVI)
- Acoustic Respiration Rate (RRa) ٧.

The combination of these measurements in one device is unique to Masimo, and is available as required in Masimo's Radical & Pulse Oximeter, Rad9, Rad97, and Rad 97 with NIBP

those who have licensed the technology from Masimo, produces, or can offer SETTM, Rainbow Anjan Kumas Ohua SETTM, Road through Motion, or Road through Law Partition 1999 technologies and capabilities.

For and on Behalf of Masimo Corporation

Brarat D. Monteiro

Country Manager - India & The Sub-continent

Dr. Vishesh Jain सह-आवर्ति / Àfsociale Professor शिष् ग्रन्थ विभाग / Department of Pediatric Surgery

आवार्य एवं किमानाच्यव / Professor & Head

-- Ineoth of Pediatric Surgery



og Folling.

Technical Specification for Regional Oximetry Line: 32 Lac

Coly cast: 320la

- 1. Monitor for Non invasive Monitoring of brain Function with 4ch EEG Regional Oximetry, Oxygen reserve Index, Continuous Haemoglobin, Fluid Responsiveness, Perfusion Index, Pluse Oximetry and Pulse rate in patients undergoing surgery.
- 2. Brain function monitoring with following features
  - a) Should provide 4 channel real time EEG simultaneously for continuous assessment of both sides of brain
  - b) Should have continuous numerical display of patient state index (PSI) a processed EEG parameter to help clinician access patient response to anesthesia and depth of anesthesia.
  - c) Should display easy to interpret Density Spectral array representing EEG Power and Bi Hemispheric activity including asymmetry.
  - d) Should also have continuous numerical Display of Suppression Ratio, Artifacts, Spectral edge frequency (Right & Left).
  - e) Should provide customizable Trend and views
  - f) Should have streamlined design easy and quick to apply sensor with plastic disk.
- 3. Regional Oximetry monitoring with following features
  - a) Should use Near Infrared Spectroscopy and reflectance Pulse oximetry for accurate monitoring to tissue axygen saturation in brain.
  - b) Should provide differential analysis of regional to arterial oxygen saturation for reference .SPO2
  - c) Should have numerical Display of Regional oximetry (rSO2), O3 (Forehead Arterial Oxygen saturation), Spo2, .base ( diff between current rSO2 and user defined baseline), AUC Index ( to quantify depth and duration of patient stay below Rso2 alarm limit), Spo2
  - d) Should provide graphical Trend display for regional Oximetry
- 4. Oxygen reserve Index monitoring with following features
  - A) Should provide non-invasive continuous monitoring of oxygen reserve index (ORI) in patient receiving supplemental oxygen to ensure safety of patients
  - B) Should have trend display for ORI and have alarm facility to notify clinicians of changes in patients oxygen index
- 5. Continuous Non Invasive Haemoglobin with following features
  - a) Should be able to measure continuous Non-invasive Haemoglobin, Spo2, Pulse rate, Perfusion Index, Pleth variability and Oxygen Reserve Index through same single finger sensor

ø) Bedside monitor should have selectable Spo2 averaging Modes – 2,4,8,10,12,14 or 16 € seconds & Sensitivity – APOD, Normal and Max

c) Should display continuous Haemoglobin trend to enable clinician take quick decision

- Monitor should have Multi touch Backlit TFT LCD Colour Display Atleast 10" size with Adjustant Brightness. Monitor should be high resolution (1280 x 800 Pixels )
- 7.4 Should also have an integrated hand held monitor. This monitor should be detachable and usable as a portable independent monitor with inbuilt battery backup for atleast four hours

Patient monitor should have rotational colour touch screen with automatic change to horizontal or vertical view

ALCA BALLIVO

9. Patient monitor should have facility to customize display to see parameter, waveforms or trends patient monitor should have trend function with facility to select one or two parameters an expand or collapse parameter trend for real time analysisain A A STAN ASSESSMENT PLOTES The state of the s

a Landogung Maranal. New



- 10. Should have facility store patient parametric data and display trend up to 96 hours at 2 seconds sampling rate
- 11. Should have user configurable display setting and alarms for patient parameters
- 12. Should have Audible and visual alarms for High/Low Haemoglobin (SpHb), High/Low Spo2, High/Low pulse Rate, High/Low PVI, High/Low Oxygen reserve Index, Probe off, cable disconnects and low battery

#### 13. Display and Measurement Range

- Total Haemoglobin (SpHb ) 0-25 g/DI
- Oxygen Reserve Index 0.00 1.00
- Oxygen Saturation (Spo2) 0- 100%
- Pulse Rate (PR) 25 240bpm
- Perfusion Index (PI) -0.02 205
- Pleth Variability Index 0- 100 %

#### 14. Accuracy

Total Haemoglobin: 8-17 g/DI

ACCRACY: +-1g/DI

Saturation range: 70 % to 100 %

Accuracy: +- 2%

Pulse Rate: 25-240bpm

Accuracy: +- 3bpm

Oxygen Reserve Index: 0.00 - 1.00 Accuracy: > 85 % sensitivity and > 80% specificity to a PaO2 value < 150 mm Hg

Trending Regional Oxygen Saturation (Rso2) ARMS - 3 %

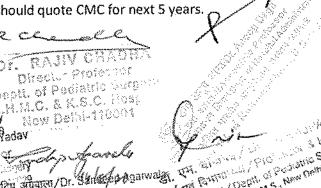
Absolute regional oxygen Saturation (Rso2) ARMS - 4 %

#### 15. Resolution

- Total Haemoglobin (SpHb) 0.1 G/DI
- Oxygen Saturation (SpO2) 1%
- Pulse Rate (PR) 1 bpm
- Perfusion Index (PI) 0.01 5
- 24 Bits at 250 samples per second- Depth of Sedation Monitoring
- 16. Monitor should meet international quality and safety standards and should be USFDA and European CE approved product
- 17. The vendor should quote price for sensors valid for atleast Five Years
- 18. The patient monitor should be supplied complete with
  - a) Sensor for continuous Haemoglobin, ORI, PVI, Spo2, PI 10 nos.
  - b) Sensor for regional Oximetry 10 nos
  - c) Sensor for Brain function monitoring 10 nos

19. Should be compatible for connectivity with patient safety Remote monitoring and Notification system

20. System should have warranty for 5 years and should quote CMC for next 5 years



Surgery Surgery Regarded To British Department of Pediatric Surgery To Reservations, New Debt 10000 to Reservations, Mr. Reservations, New Debt 10000 to Reservations, Mr. Reservations, New Debt 10000 to Reservations of Reservations, New Debt 10000 to Reservations of Reservations of Reservations.

तिम्यु शत्य विभाग/

MEMORIE, HE RESTALLMS. New Debi-1107



Masimo Medical Technologies India Pvt. Ltd

Billos's Padism, F'Floor 1973 Cummighan Read Bangslore, Kornataka, S60052, India



Date: 09-04-2021

## 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 Monitor for Regional Oximetery for Pediatric Surgery Department.

We, Masimo who are proven and reputable manufacturers Of Monitor for Regional Oximetery. 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,

Bruno Corda - Country Manager, India and the Sub Continent

W\_