Admn/Prop/31/2017-AIIMS.JDH Dated: - 18th December 2017.

Subject: Purchase of Pediatric Simulator for the Department of Pediatrics at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Pediatric Simulator for the Department of Pediatrics at AIIMS, Jodhpur from M/s CAE Healthcare, 6300 Edgelake Drive, Sarasiota, FL 34240, USA on proprietary basis. The proposal submitted by M/s Hospimedica International Ltd and PAC certification by user are attached.

The above documents are being uploaded for open information to submit subjection, comments, if any from any manufacturer regarding proprietary nature of the equipment giving reference Admn/Prop/31/2017-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 08th January 2018 upto 03:00 PM 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,

Administrative Officer

Enclosed: Related documents enclosed.

CAE Healthcare

CAE Healthcare
6300 Edgelake Drive,
Sarasota, FL 34240
USA

Tel: +941-377-5562
caehealthcare.com

Dated : 10th May 2017

PROPRIETARY CERTIFICATE

Dear Sir,

This document serves to certify that Patient Simulation System Model PediaSim ECS, manufactured by CAE HealthCare [erstwhile known as Medical Education Technologies, Inc., (METI) U.SA.] has facility for bi-lateral pneumothorax, pediatric advance life support training with reactive eyes, facility for Simulation of Critical Event and Scenarios, facility for clinical intervention and administration of drugs resulting in appropriate and automatic responses according to underlying Physiology of the patient for Teaching and Training of Medical Professionals such as Doctors, Paramedical & Nursing Staff, is a proprietary and unique product.

This is also certified that the said product with given specifications is not manufactured by any other manufacturer in the world.

We confirm that M/s Hospimedica International Ltd. is our distributor in India and their personnel are fully trained towards carrying out Installation, Commissioning and Servicing for our products.

Should you have any question or need further clarification, please feel free to contact the undersigned at your convenience.

Sincerely,
For CAE HEALTHCARE

AUTHORIZED SIGNATORY

CAE Healthcare

CAE Healthcare
6300 Edgelake Drive,
Sarasota, FL 34240
USA

Tel: +941-377-5562
caehealthcare.com

EXCLUSIVE DISTRIBUTION CERTIFICATE

Dated : 2016 Aug 30

Dear Sir,

This is to certify that
M/S HOSPIMEDICA INTERNATIONAL LTD.
Leelawanti House, 58/10, Ashok Nagar,
New Delhi – 110018,
INDIA
is our distributor in India and are responsible for following :

- Quote, Negotiate & Conclude Business in India on our behalf.
- Demonstrate & Install Equipments.
- Provide after sales service, during & after the warranty period.

No Company / Individual / Firm, other than M/S HOSPIMEDICA INTERNATIONAL LTD. is authorized to Market / Quote for our products in India.

We also certify that in case of change of agency we shall inform the user about the change and shall make necessary arrangement to provide necessary after sales service.

This authorization is valid till 2019 March, 31.

M/S CAE HEALTHCARE, U.S.A.

Jennifer Jula
AUTHORIZED SIGNATORY

DECLARATION OF CONFORMITY

(In accordance with EN 45014)

We,

Medical Education Technologies Inc.
6000 Fruitville Road
Sarasota, Florida 34232 USA

declare under our sole responsibility that the product,

Type of Equipment: Human Patient Simulator Manikin
Model Number: ECS-X (AC Input)

to which this declaration relates is in conformity with the following standards or other normative documents:

EMC: EN 55011:1998 / A1:1999 Group 1 Class A
EN 61326:1997 / A1:1998
EN 61000-4-2:1995
EN 61000-4-3:2002 / A1:2002
EN 61000-4-4:1995 / A1:2001 / A2:2001
EN 61000-4-5:1995
EN 61000-4-6:1996
EN 61000-4-11:1994
EN 61000-3-2:2000
EN 61000-3-3:1995 / A1:2001

following the provision of the EMC Directive 89/336/EEC.

Sarasota, Florida 34232 USA

Signature and Date

Carlos E. Moreno

Typed Name and Title

DIRECTOR OF ENGINEERING

European Contact:

CAE Healthcare

DECLARATION OF CONFORMITY

(In accordance with EN 45014)

We,

Medical Education Technologies Inc.
6000 Fruitville Road
Sarasota, Florida 34232 USA

declare under our sole responsibility that the product,

Type of Equipment: Human Patient Simulator Manikin
Model Number: ECS-X (DC Input)

to which this declaration relates is in conformity with the following standards or other normative documents:

EMC: EN 55011:1998 / A1:1999 Group 1 Class A
EN 61326:1997 / A1:1998
EN 61000-4-2:1995
EN 61000-4-3:2002 / A1:2002
EN 61000-4-4:1995 / A1:2001 / A2:2001
EN 61000-4-5:1995
EN 61000-4-6:1996

following the provision of the EMC Directive 89/336/EEC

Sarasota, Florida 34232 USA

Signature and Date

Carlos E. Moreno
DIRECTOR OF ENGINEERING
Typed Name and Title

European Contact:

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Technical Specifications.

1. The simulator mannequin must be anatomically correct to replicate a real life sized paediatric patient with anatomical landmarks.
2. The simulator must have functional pupils that blink and can be adjusted for pupil dilation and restriction
3. The simulator must have automatic physiology response models that can objectively confirm airway management without the need for visual observation by an instructor
4. The simulator must have a hematology model for hemorrhage control showing the impact of progressive blood loss and compensation to the patient in real time
5. The simulator must have the capability to integrate a blood / secretions flow model for representation of trauma conditions to the patient
6. The simulator must have automatic physiological and pharmacological response models with responses to reflect the actual effects of the drug or multiple sets of drugs
7. The simulator and its accompanying components must be portable and easily stored when necessary.
8. The simulator must include a simulated patient monitor which has the capability to display the parameters below in addition to custom configurations
    - ECG I, II, III and V and heart rate
    - Arterial Blood Pressure
    - Pulmonary Artery Pressure
    - Pulmonary Capillary Wedge Pressure
    - Central Venous Pressure
    - Mean Arterial Pressure
    - Non Invasive Blood pressure
    - CO2 Capnography
    - SPO2
    - Heart rate
    - Thermolidution cardiac output and continuous cardiac output
    - Blood temperature
    - Body temperature

AIRWAY

1. Simulator must have a life like intubation head with a flexible tongue, epiglottis, aryepiglottic fold, cuneiform tubercle, corniculate tubercle ,laryngeal inlet, vocal cords , esophagus and simulated lungs for spontaneous breathing and realistic chest movement and compressions
2. Simulator must have tracheal access through the neck for cricothyrotomy ,tracheostomy
3. The simulator must have the following standard ALS airway skills:
    - Bag/ valve/mask ventilation
    - Oral intubation
    - Nasal intubation
    - Esophageal intubation
    - Combitube placement
    - LMA Placement
    - Retrograde intubation
    - Fiber optic intubation

- Light wand intubation
- Cricothyrotomy
- Oropharyngeal and nasopharyngeal airway placement

4. Exhaled CO 2 Flow to confirm placement of airway devices with in the trachea
5. Signs of spontaneous respiration to include:
   - Independent right and left chest movement
   - Exhalation of air from mouth
   - Exhaled CO2 Capability.
6. Simulator must have a respiratory rate that is physiologically modeled **and can** be manually controlled by an instructor.
7. The simulator must be able to accommodate the following airway features:
   - Pharyngeal obstruction
   - Multiple levels of swollen tongue
   - Laryngospasm
   - Left & right broncheal obstruction
   - Stomach decompression
   - Cannot intubate, can ventilate
   - Cannot intubate, cannot ventilate

CARDIOVASCULAR SYSTEM:

1. The simulated patient should generate heart sounds including a range of pathological ones which are synchronized to the QRS complex of the ECG and should be audible with a standard stethoscope over the left and right upper sternal border, left lower sternal border and apex.
2. The simulator must have an integrated IV training arm with replaceable skin and veins, IV insertion into peripheral veins of forearm, anticubital fossa and the dorsum of the hand, simulated blood flash back on cannulation, IV Bolus or infusion.
3. A 5 Lead ECG capability emitted from the appropriate positions on the patient's chest for display on a standard monitor
4. Palpable carotid, radial, brachial, femoral, popliteal and pedal pulses which are synchronous to the ECG.
5. Simulator pulses must be dependent on BP of the patient and must be independently Controlled on left & right side of the body
6. A standard blood pressure cuff and sphygmomanometer can be used to assess systolic blood pressure by palpation or by auscultating Korotkoff sounds.
7. The invasive hemodynamic monitoring package should provide the capability to measure and monitor the following:
   - Arterial blood pressure
   - Left ventricular pressure
   - Central venous pressure
   - Right atrial pressure
   - Right ventricular pressure
   - Pulmonary artery pressure
   - Pulmonary artery occlusion (wedge) pressure
   - Thermodilution cardiac output

TRAUMA FEATURES:

Simulator must have the ability to perform the following trauma functions:

- Bi-Lateral Pneumothroax needle decompression
- Bi-lateral chest tube placement
- Blinking eye with adjustable pupil size
- Bulging Fontanel

IV DRUG ADMINISTRATION:

1. Simulator must have an intensive drug library that includes ACLS drugs.
2. The simulators response to drugs administered must be automatically linked to physiology and will not rely on manual input.

CARDIAC FUNCTIONS:

1. The simulator package must include an ECG library that contains an extensive library of physiological modeled cardiac rhythm variations
2. The simulator must be able to accommodate the following:
   - Live defibrillation from an AED and a manual defibrillator
   - Cardiac monitoring with blood pressures and cardiac output
   - 5 Lead ECG Monitoring
   - External pacing with various pacing threshold
   - Produce chest compression artifacts on ECG
   - Show a displayed heart rate and ECG on a compatible simulated monitor

BLOOD PRESSURE:

1. The simulator must have a blood pressure that can be taken either automatically, by auscultation or palpated.
2. The simulator must include a blood pressure arm that has Korotkoff sounds, which can be used for auscultation and palpation of the blood pressure.
3. The blood pressure must be able to be displayed on a compatible simulated monitor.

GENITOURINARY

1. The simulator must include both male and female genitalia which are interchangeable and anatomically correct
2. The genitalia must have the ability to be catheterized with the ability to produce urinary output.

NEUROLOGIC SYSTEM

Should model Cardiovascular and respiratory responses to sympathetic and parasympathetic activities

ADVANCED CARDIAC LIFE SUPPORT (ACLS) SYSTEM

1. **Airway Management and Ventilation:** Alveolar and arterial gas concentrations should appropriately reflect the efficacy of the employed ventilatory technique, such as mouth- to-mouth,bag-valve-mask, endotracheal intubation and transtracheal catheter ventilation. Administration of supplemental oxygen should extract automatic and appropriate patient clinical responses.
2. **Chest Compression: Should allow chest compression** In accordance with ACLS guidelines, effective chest compression of the patient's sternum should result in artificial circulation, cardiac output, central and peripheral blood pressures, palpable pulses and CO2 return and Pressure fluctuations should be visible on invasive catheter waveforms.
3. **Cardiac Arrhythmias:** The instructor should be able to select and maintain a desired arrhythmia and control the simulated patient's response to clinical interventions.
4. **Electrical Therapy:** Both conventional defibrillators and automatic external defibrillators (AEDs) can be applied to the simulator generating appropriate patient response in real-time.

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Capable of applying transcutaneous pacemakers

5. **Pharmacological Therapy:** All IV drugs required by the ACLS algorithms should be supported.

SOUNDS AND PHONATION:

The simulator must have the ability to produce the following sounds:
Speaking through the instructor microphone

- Heart sounds which are synchronized with the ECG
- Independent left and right sounds
- Bowel Sounds
- Heart, lung and bowel sounds auscultated with a stethoscope.
- Independent volume adjustment

PATIENT & SCENARIOS

- Should be delivered with pre-programmed patients. System should have patient editor software to edit/ modify preconfigured patient profiles or to create new patient profile.
- Should be delivered with pre-programmed scenarios. System should have scenario editor software to edit/ modify preconfigured scenarios or to create new scenario.
- At any point during a simulation session it should be possible to capture the current state of a patient which can be used as a new patient.
- Should be capable of running multiple patient **conditions** simultaneously **on one patient** to create multiple patient care conditions

  PALS Module
  Septic Shock
  Asthma Attack
  Asystole
  Bradycardia
  Ingestion
  Supraventricular and Ventricular Tachycardia
  Ventricular Fibrillation

Audio Video Recording System

- **Microphone**

  Sensitivity: – 25 dB
  Dynamic range: 82-90 dB
  Signal-to-noise ratio: not more than 70 dB
  Cameras: Two camera to be supplied
  Computer to be supplied with system for display and control

- **Server**

  Intel Core i5 4690T quad core CPU
  2x 1TB internal HD storage with RAID-1disc mirroring
  8 GB RAM
  2 Gigabit Ethernet ports (LAN, Simulator)
  4 gigabit PoE Ethernet ports, up to 15.4 W per port
  Wi-Fi (802.11n) access point for client access
  Wi-Fi 802.11n network interface for connecting to wireless simulator

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DVI/VGA/HDMI input for HD display capture with real time
H.264 encoding and OCR
XLR audio input with phantom power for high quality
Audio capture and real-time AAC encoding
Ability to capture and video output (display)
Size: portable
Wall mountable
External 100-240 V 200 W power supply

- **System features**

Scalable from 2 cameras to 200 + cameras
24/7 recording capability
Software detects start of simulation activity via simulator connection to a scenario, start of an evets log, addition of team member, start of annotations
Software automatically retrieve and stores all recorded video
Video recording and associate data are segmented in chapters for easy retrieve
Recorded simulation activity is saved forever or until the user decided to delete the file
Physiological data recorded in real time including waveform displays and trend charts
Annotate live or recorded video with auto-complete text based on post records
Pick a category that represents the annotation, assign the annotation to team member
Advanced search capabilities to find any specific simulation moment
Search by date, time, person, room, physiological data or annotation

- Cloud based backup services

EVENT LOG:

1. The simulator must include physiological, pharmacological event data that is logged and timed stamped.
2. The log must automatically calculate and log the following items:
   - Alveolar and blood gases
   - Cardiac Output
   - Heart rate
   - SPO2
   - Invasive blood pressure
   - Hematocrit and hemoglobin values
   - Temperatures
3. The event long must be able to be saved and printed.

CONTROL SYSTEM:

Control system should be comprised of

- Instructors wireless remote control capable driving all software programme
- Instructor wireless remote control must be expandable for future software up-gradation.

Demonstration should be offered if required.

The equipment should be USFDA or European CE approved.