भारत सरकार/Government of India
स्वास्थ्यऔर परिवारकल्याणमंत्रालय/ Ministry of Health and Family Welfare
प्रधानमंत्री स्वास्थ्य सुरक्षा योजना/PMSSY
अखिलभारतीयआयुर्विज्ञानसंस्थान/All India Institute of Medical Sciences
www.aiimsmangalagiri.edu.in मंगलगिरि , आंध्रप्रदेश/Mangalagiri, Andhra Pradesh

Ref: AIIMSM-ADMN/PROC(GEM)/315/2025-Procurement AIIMS MG **Date: 17-06-2026**

Call for Objection

Subject: Inviting comments/objection, if any before declaring proprietary article for procurement of **"Non – Invasive Cardiac Output Monitor with Accessories (Electrical Cardiometry) and I Sense for Pediatrics and Adults"** for the Department of **Pediatrics**, AIIMS Mangalagiri.

Pediatrics Department, AIIMS Mangalaigiri has to procure **"Non – Invasive Cardiac Output Monitor with Accessories (Electrical Cardiometry) and I Sense for Pediatrics and Adults"** through **Proprietary Article basis**.

The proposal submitted by **M/s. Reach Medical Systems Private Limited, 59-A-10-3, Plot No 34, Road No 1 K.P Nagar, Vijayawada, Andhra Pradesh-520008, India** are the exclusive distributor of the product for territory of India along with OEM Proprietary Article Certificate **(M/s.Osypka Medical GmbH, Albert- Einstein Strasse-3, 12489 Berlin Germany)** are attached & uploaded on Institute website.

The above documents are being uploaded for open information to submit objections, comments if any from any manufacturer/supplier before declaring proprietary article of the said equipment/items to be procured, within 10 days (i.e. **27-06-2026**) from the date of issuance/uploading of the notification.

The objection should be raised in the technical compliance sheet as enclosed in Annexure -I, if any Firm claiming suitability of their product with respect to specification mentioned.

The comments should be sent to the office of Procurement Cell, Room no: 2151, Logistic block at AIIMS Mangalagiri in a sealed envelope with above reference on or before **27-06-2026** up to 05:00 PM from the date of uploading on institutional website, failing which it will be presumed that any other manufacture/vendor is having no comment to offer and case will be decided on merits.

-sd-
AAO (Procurement cum Central Store)
AIIMS Mangalagiri

Cardiac Output Monitor

(Item No.142 GTE List dated 17th Feb 2025)

1. It should be a hand-held device, weighing less than 800grams to easily carry in different departments, during patient transport and in the ambulance (Air & Road) during emergency.
2. It should display minimum following parameters:
    a. Stroke volume/index
    b. Cardiac output/index
    c. Systemic vascular resistance/index
    d. Index of contractility
    e. SVV (Stroke Volume Variation)
    f. TFC (Thoracic Fluid Content)
    g. FTc (Flow Time Corrected)
    h. DO2
    i. It should give index in both BSA and in Weight for Neonatal patients .
3. Technology, clinical validations
    It should be a non- invasive cardiac output monitor
    a. It should be based on advanced electrical velocimetry or similar proven technology.
    b. It should have the facility to measure the beat-to-beat cardiac output .
    c. It should work in Pre- Term & Neonatal , Pediatric and adult patients
    d. Should submit three recently published clinical articles about applications on Neonatal , Paediatric Septic shock patients.
4. User-friendly and compatibility with other devices
    a. It should require only 4 externally applied sensors.
    b. Sensor placement should be on one side of the patient and can be applied fast.
    c. It should work with pacemaker and display the pacing signal.
    d. Sensor should work for 72 hours .
5. Display
    a. Display parameters must show the bar diagnostic screen with normal range and measured value for each parameter, trends, charts, waveform screens and PLR test.
    b. It should have a built in display of 3.5" screen
    c. Should be supplied with an extended touch screen size minimum 12"with windows , memory >100 GB, and custom made trolley.
6. Storage and back-up
    a. It should record continuous data , have internal data storage of at least 72 hours, and transmission to PC through serial cable .
    b. Technology should be compatible with HL7 data management
    c. It should have rechargeable battery backup of at least two hours.
7. Certifications and Warranty
    a. It should be approved by US FDA for use in Neonatal , Pediatric and Adult.
    b. In the indications for use in USFDA certificate , Neonatal , Pediatric and adults applications should be mentioned .
8. Others:
    a. Should have customs made sensors for Adults , Pediatric , Neonatal & Pre- Term.
    b. Unit should be supplied with 50 sets of Pediatric and 20 sets of Pre-term Neonatal sensors
    c. Price of the sensors should be mentioned separately for Adults ,Ppediatric and Neonatal for the rate contract with **validity for two years**.

Assistant Professor
Department of Pediatrics
AIIMS, Mangalagiri
8/4/25

Professor & Head
Department of Pediatrics
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh.

5

P-3 FORM

(To be attached with P-2 form for properietary items)

AIIMS Mangalagiri

PROPRIETARY ARTICLE CERTIFICATE

It is certified that the item 'Non – Invasive Cardiac Output Monitor with accessories (Electrical Crdiometry)', Make: "Osypka Medical GmbH", Model: 'ICON', required in the P2 form, is a proprietary and unique product manufactured by Osypka Medical GmbH. To the best of my knowledge M/S Osypka Medical GmbH, Germany is the exclusive distributor of the product "Non – Invasive Cardiac Output Monitor with accessories (Electrical Crdiometry) '' for territory of India.

Similar items manufactured by other firms(s) shall not be suitable for our purpose for the follow.ng reasons:-

This product has the following unique features:

1. It should be a hand-held device, weighing less than 800grams to easily carry in different departments, during patient transport and in the ambulance (Air & Road) during emergency.
2. It should display minimum following parameters:
    a. **Stroke volume/index**
    b. **Cardiac output/index**
    c. **Systemic vascular resistance/index**
    d. **Index of contractility**
    e. **SVV (Stroke Volume Variation)**
    f. **TFC (Thoracic Fluid Content)**
    g. **FTc (Flow Time Corrected)**
    h. **DO2**
    i. **It should give index in both BSA and in Weight for Neonatal patients .**
3. Technology, clinical validations
    It should be a non- invasive cardiac output monitor
    a. It should be based on advanced electrical velocimetry or similar proven technology.
    b. It should have the facility to measure the beat-to-beat cardiac output .
    c. It should work in Pre- Term & Neonatal , Pediatric and adult patients
    d. Should submit three recently published clinical articles about applications on Neonatal , Paediatric Septic shock patients.
4. User-friendly and compatibility with other devices
    a. It should require only 4 externally applied sensors.
    b. Sensor placement should be on one side of the patient and can be applied fast.
    c. It should work with pacemaker and display the pacing signal.
    d. Sensor should work for 72 hours .
5. Display
    a. Display parameters must show the bar diagnostic screen with normal range and measured value for each parameter, trends, charts, waveform screens and PLR test.
    b. It should have a built in display of 3.5" screen
    c. Should be supplied with an extended touch screen size 12" and above with windows , memory >100 GB, and custom made trolley.
6. Storage and back-up
    a. It should record continuous data , have internal data storage of at least 72 hours, and transmission to PC through serial cable .
    b. Technology should be compatible with HL7 data management
    c. It should have rechargeable battery backup of at least two hours.
7. Certifications and Warranty
    a. It should be approved by US FDA for use in Neonatal , Pediatric and Adult.
    b. In the indications for use in USFDA certificate , Neonatal , Pediatric and adults applications should be mentioned .

Professor & Head
Department of Pediatrics
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh.

Assistant Professor
Department of Pediatric
AIIMS, Mangalagiri

8. Others:

a. Should have customs made sensors for Adults , Pediatric , Neonatal & Pre- Term.

b. Unit should be supplied with 50 sets of Pediatric and 20 sets of Pre-term Neonatal sensors

c. Price of the sensors should be mentioned separately for Adults ,Ppediatric and Neonatal for the rate contract with **validity for two years**.

The above features are beneficial for teaching and learning purposes. To the best of my knowledge these features are not available in any other product

Sign of indenter

Designation Asst. Professor

Department Pediatrics

Recommendation

Assistant Professor
Department of Pediatrics
AIIMS, Mangalagiri

Signature of Head of department/section

Professor & Head
Department of Pediatrics
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh.

N.B.: The indenter before recording the above certificate should satisfy himself that the article is genuinely of nature manufactured under patent laws.

OSYPKA MEDICAL

Osypka Medical GmbH

Albert-Einstein-Strasse 3
12489 Berlin · Germany

Telefon: +49 (30) 6392 8300
Telefax: +49 (30) 6392 8301
E-Mail: mail@osypkamed.com

Osypka Medical GmbH · Albert-Einstein-Strasse 3 · 12489 Berlin

Proprietary Article Certificate

Osypka Medical GmbH, with their corporate office/Manufacture at: Albert- Einstein-Straße,3, 12489 Berlin, Germany is the sole manufacture of **ICON®** the non-invasive Cardiac Output Monitor which uses Electrical Cardiometry (EC™) and the Algorithm Electrical Velocimetry (EV ™)

ICON® uses an unique and innovative technology called Electrical Cardiometry (EC™) , algorithms Electrical Velocimetry (EV ™) which is differ from conventional bio-impedance method for the determination of stroke volume (SV), cardiac output (CO), thoracic fluid content (TFC) and many other calculated hemodynamic parameters.

ICON® Electrical Cardiometry (EC™) / Electrical Velocimetry (EV ™) is US FDA approved for **Adults, Paediatrics, and Neonatal patients**. Hemodynamic reading will be available in within 2 minutes of connecting to the patient. **Electrical Cardiometry (EC™) and Electrical Velocimetry (EV ™) - Algorithm is a proprietary method trademarked by Osypka Medical GmbH.**

This technology has been tested, validated and used in many reference centre's worldwide. Electrical Cardiometry (EC™)/ Electrical Velocimetry (EV ™) is recommended by ample clinical research publications worldwide for its accuracy and speed. **ICON® is a Portable , Point Of Care , Hand Held unit with built in display, weight less than 800 grams for easy to carry from patient to patient in an emergency situation , Ambulances and for continues monitoring.**

To the best of our knowledge, there is no other manufacturer who is using Electrical Cardiometry (EC™) and the Electrical Velocimetry (EV ™) - Algorithm for obtaining SV-Stroke Volume , CO-Cardiac Output , CI – Cardiac Index , ICON -Contractility, Variation of the index of contractility , STR- Systolic Time Ratio , TFC – Thoracic Fluid Content , FTc – Flow Time Corrected , SVV – Stroke Volume Variation and other available parameters non-invasively in **Adult, Paediatric and Neonatal Patients** .

Thanking you
For **Osypka Medical GmbH**

Thilo Thumecke
Director – Operations

Osypka Medical GmbH
Albert- Einstein- Straße 3
12489 Berlin

June 19,2024
Stamp

Professor & Head
Department of Pediatrics
All India Institute of Medical Sc
Mangalagiri, Andhra Prade

Assistant Professor
Department of Pediatrics
AIIMS, Mangalagiri

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 08 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RECEIVED OCT 14 2008

Osypka Medical, Inc.
c/o Markus Osypka, PhD
President
7855 Ivanhoe Avenue, Suite 226
La Jolla, CA 92037

Re: K082242
Trade/Device Name: ICON Model C3
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: September 19, 2008
Received: September 22, 2008

Dear Dr. Osypka

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Assistant Professor
Department of Pediatrics
AIIMS, Mangalagiri

Professor & Head
Department of Pediatrics
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

Assistant Professor
Department of Pediatrics
AIIMS, Mangalagiri

Professor & Head
Department of Pediatrics
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh.

OSYPKA MEDICAL

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Osypka Medical GmbH · Albert-Einstein-Strasse 3 · 12489 Berlin

November 21,2025

Letter Of Authority

This is to confirm that, Reach Medical Systems Private Limited , 59-A -10-3, Plot No.34, Road No.1, K.P Nagar, Vijaywada , Andhra Pradesh -520008, India ., is our authorized distributor for All India Institute Of Medical Science , Magalagiri, Vijawada , Andhra Pradesh.

The distributor is responsible for sales, product promotion, installation ,demonstration, aftersales service , participation in tender , negotiation and entering into contract for products manufactured by Osypka Medical GmbH. Germany which includes the **ICON, Non- Invasive Cardiac output monitor** , Accessories and I Sensors.

Distributor will comply with warranty and CMC conditions as per the tender conditions from AIIMS , Mangalagiri , Vijayawada , Andhra Pradesh.

Yours faithfully,
For **Osypka Medical GmbH.,**

Thilo Thümecke,
Director Operations.

Osypka Medical GmbH
Albert-Einstein-Strasse 3
12489 Berlin

Stamp

ANNEXURE – I

SPECIFICATIONS

Objection should be submitted in following format:

S. no	Item specification as given	Specification offered by firm	Deviation if any	Remarks