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/PROC(CPPP)/21/2025/AIIMS Mangalagiri **Date:04 -12-2025**

Call for Objection

Subject: Inviting comments/objections, if any, before declaring proprietary article for procurement of "**High Flow Nasal Oxygen Units with Accessories**" for the Department of Clinical Microbiology, AIIMS Mangalagiri.

Clinical Microbiology Department, AIIMS Mangalagiri has to procure "**High Flow Nasal Oxygen Units with Accessories**" through Proprietary Article basis.

The proposal submitted by **M/s. Fisher & Paykel Healthcare Limited** is the original equipment manufacturer and authorized distributor of this product within the territory of India. The Proprietary Article Certificate is attached & uploaded to the Institute's 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. 14-12-2025) 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 claims the suitability of their product with respect to the 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 14-12-2025 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 Stores)
AIIMS Mangalagiri

P-3 FORM

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

AIIMS Mangalagiri

PROPRIETARY ARTICLE CERTIFICATE

It is certified that the item 'High Flow Nasal Oxygen Unit', Make: "Fisher & Paykel Healthcare Ltd", Model: 'Airvo 3', required in the P2 form, is a proprietary and unique product manufactured by Fisher & Paykel Healthcare Ltd. To the best of my knowledge M/S Fisher & Paykel Healthcare Ltd., New Zealand is the exclusive distributor of the product 'High Flow Nasal Oxygen Unit' for territory of India.

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

This product has the following unique features:

- **Intended use** – Treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases which can be used at hospitals and sub-acute facilities. The device should be multi-patient use. Device must be cleaned, and outlet elbow reprocessed between patients.
- It should be complaint for use on patients in ICU, wards, and emergency department.
- It should have inbuilt flow generator capable of delivering wide range of flows: 2-70 liters/min.
- Inbuilt Air/O2, blending and Fio2, monitoring, facility to deliver wide range of oxygen concentration (FiO2) from 21% to 100% with suitable Menu key/rotary knob controller.
- It should have inbuilt air source without need for external compressor.
- It should have integrated heated humidifier.
- Touch screen colour display to monitor humidity setting, flow, FiO2, and faults.
- Visual and audible alarm indication for: Tubes disconnect leaks, tube blockages and water ous and hard warm fa with error codes.
- It should have audible power failure alarm system.
- The machine should have two USB port sourcing of 5 V.0.35 A (maximum each port).
- The expected auditory alarm range should be Sound pressure level 40 dBA @ 1 m, Audie vause duration 10 seconds.
- The machine should have Ingress protection IP22 rating.
- The mode of operation should be continuous and should have two options for reprocessing for fast turnaround time.
- The maximum surface temperature of applied parts 44 °C.
- it should have operational ambient temperature 18 - 28 deg °C.
- The machine should have maximum delivered dewpoint temperature of respiratory gas 43°C.
- it should have target humidity range 31 - 37 °C.
- Humidity should be (Wall power) > 33mg / L at 37 °C target humidity, 10 – 60 L/ min target flow and > 12mg / L for all other settings.
- The device should have dual input manifold to ensure a smooth transition to portable oxygen for patient transfer.
- The device should have High-pressure oxygen inlet port and Low-pressure oxygen inlet.
- The Line pressure of high-pressure inlet should he between 280 - 600kPa.
- All the compatible accessories should be supplied with the equipment which allows connection to one or two oxygen supply sources via a high-pressure dual-input manifold.
- The Low-pressure oxygen inlet port should have line pressure between 0-70 kPa.

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Department of Pediatrics
AIIMS Mangalagiri

- The machine should have battery backup with Lithium Ion (Li-Ion) battery with output power of 80W.
- The shelf life of battery should be minimum 3 years with battery life of at least 300 charge/discharge cycles or least 2 years from first use (whichever comes first).
- Maximum recharge time of the battery should be 6 hours.
- Operating time should be range between 20-40 minutes.
- Storage and transport ambient temperature should be between - 10 - 50 °C.
- Humidity should be 10-95% relative humidity.
- The machine should have 2 years of replacement warranty.
- Technical evaluation will be done based on the demonstration of the equipment offered by the firm.
- Letter of Authorization is mandatory from the manufacturer.
- Each machine should be supplied with pole stand, storage basket, oxygen bottle holder, manifold, oxygen hose, water bag, and flow meter.
- Each machine should be supplied with 5 units of disposable HHHFNC Circuit with Humidifier Chamber.
- The circuit should be of similar make and be compatible with the existing make of the HHHFNC machine.
- Optional The circuit should be compatible with vibrating mesh nebulizer.
- The breathing tube should have in built heating tubing along the bore of the circuit and this should help assist reduction of condensate.
- The circuit should efficiently deliver nebulized blended gasses.
- The circuit should be incorporated as part of the humidification system, such that the nebulizers do not require to be held in hand during therapy.
- The circuit should be suitable for use with all interfaces to fit wide range of patients from 2-70 lpm.
- Each machine should be supplied with 10 units of HFNC cannula.
- The canula should have an easy to attach, customizable head strap.
- Should be present with a head strap clip.
- The canula should have the ability to reduce formation of mobile condensate.
- Should have soft cheek pads to help reduce facial trauma.
- Should have soft prongs, which contour and provide facial comfort.

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 Associate Professor

Department Department of Pediatrics
AIIMS, Mangalagiri.

Recommendation

11/7/2024
HOD, Department of Neonatology
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh

Signature of Head of department /section

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

Fisher & Paykel HEALTHCARE

Fisher & Paykel Healthcare Limited
O'Hare Building
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand

Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

20th January 2025

Proprietary Article Certificate

Fisher & Paykel Healthcare Limited is an original equipment manufacturer (OEM). This is to certify that the goods listed below are proprietary and manufactured by Fisher & Paykel Healthcare Limited.

Respiratory Support System (Airvo™ 3)	
PT301IN	Respiratory support device
900PT421	Mobile pole stand
900PT427, 900PT427L	Oxygen-bottle holder, Oxygen-bottle holder large
900PT426	Storage basket
900PT445	Mobile pole handle
900PT460D	HPO Dual-Input Manifold (DISS) Airvo 3
900PT933	Air filter
900PT930	Outlet elbow
900PT957L	Battery module
F&P Optiflow™+ interface range	
OPT942/944/946	Nasal cannula - Small/Medium/Large
F&P Optiflow Tracheostomy Direct Connections	
OPT970	Tracheostomy direct connection
Optiflow Junior 2 Nasal Cannula	
OJR414/416/418	Optiflow Junior 2 Nasal Cannula Medium/Large/X-Large
WJR110	Optiflow Junior 2 nasal interface Wigglepad 2 replacement XS, S
WJR112	Optiflow Junior 2 nasal interface Wigglepad 2 replacement M, L, XL
F&P Airvo™3 Tube and Chamber Kits	
900PT561	Heated Breathing Tube and Chamber Kit
900PT562	Airvo Tube and Chamber Kit with Nebulizer Adapter
Disinfection kit	
900PT600	Disinfection kit
900PT601	Disinfection filter
Water bag	
900PT401	Water bag

11/01/2025
HOD, Department of Neonatology
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh

Henry Anthony Jewell
Lawyer & Notary Public
Wynyard Quarter
Level 1
60 Highbrook Drive
Highbrook 2013
New Zealand

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Department of Pediatr
AIIMS, Mangalagiri

No other maker or supplier is acceptable to supply the above goods for the following reasons:

- The goods are specifically designed to work together as medical device systems as defined by Fisher & Paykel Healthcare Limited.
- All aspects of quality control and customer support for the above goods are provided by Fisher & Paykel Healthcare Limited and its subsidiary office in India.

Yours sincerely,

Kejia Khoo
Product Manager
Optiflow Airvo Marketing
Fisher & Paykel Healthcare Limited

Signed before me

Henry Anthony Jansen
Lawyer & Notary Public
Wynyard Wood
Level 1
60 Highbrook Drive
Highbrook 2013
New Zealand

this 20th January 2025

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AIIMS, Mangalagiri.

11/1/2025

HOD, Department of Neonatology
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh

Tender/ Enquiry No. Date

Supply Order No. Date

Specifications of HIGH FLOW NASAL OXYGEN UNITS :

GENERAL FEATURES	
Product Description	High Flow Nasal Oxygen Therapy Unit
Purpose	To deliver warm and humidified oxygen at high flow for the treatment of Hypoxemic patients with respiratory distress
Application	Compliant for use on patients in ICU, wards, emergency department as well as for patients on home oxygen therapy
Patient Application	Single system for treating infants, pediatric and adult patients
PRODUCT INFORMATION	
Delivers	Warm and Humidified Oxygen
Flow generator	In-built
Delivery range	2 to 60 litres/minute
Flow range of generator for Pediatric mode	2 - 25 litres/minute
Flow range of generator for Adult mode	10 - 60 litres/minute
Air/oxygen blender	In-buit
FiO2 monitoring	Yes
Delivery range of oxygen concentration (FiO2)	21% to 100 %
Accuracy for FiO2	± 2.5 %
Air source	Inbuilt without need for external compressor
Humidifier	Integrated heated humidifier

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Humidity	> 33 mg/L at 37° C Target and > 10 mg/L at 34° C & 31° C Target
Max temperature of delivered gas	43 degree Celsius
Patient Interface	Nasal cannula
Disinfection of device	Thermal disinfection mode
Heated disinfection tube for sterilization of the device provided	Yes
Provided with a flow meter assembly with clamp and markings to read flows above 60 liters along with a high pressure tubing to connect with an oxygen source	Yes
Provision of External SD card slot	Yes
Storage of records	10000 or more
Salient Features	Indication of air filter change due
DISPLAY	
Type of display	LCD Color Display
Parameters monitored and displayed	Flow,FiO2,Temperature,Humidity,Mode whether adult or pediatric,Faults
ALARMS	
Alarms available	Tubes disconnect leaks alarm,Tube blockages alarm,Mismatching of tubes (Adult vs Pediatric) alarm,Alarm for oxygen concentration high and low,Hardware fault alarm with error codes,Power failure alarm,Alarm for low water level before the water completely dries out in the humidifier
Type of alarm indication	Both audible and visual alarms
ACCESSORIES	
Accessories provided	One trolley/Pole with castors having a mounting platform/tray and a rack
Material of Pole/Trolley	Stainless Steel
Number of hooks in the pole	4

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Number of castor wheels in the pole	4
CONSUMABLES	
Consumables provided	Breathing circuit (Adult),Breathing circuit (Pediatric),Humidification chamber,Adult nasal cannula,Pediatric nasal cannula,Air filters
Number of Breathing circuit (Adult)	5 No's
Number of Breathing circuit (Pediatric &neonatal)	5 No's of each
Number of Humidification Chamber	5 No's
Number of Adult Nasal cannula of assorted sizes	5 No's of Each
Number of Neonatal &Paediatric Nasal cannula of assorted sizes	5 No's of each
Material of Nasal cannula	kink proof material and having adhesive wiggle pads to stick on skin care
Number of Air filters	10
ELECTRICAL REQUIREMENTS	
Power Source	230 ± 10 Volts AC / 50 Hz
OPERATING & STORAGE ENVIRONMENT	
Minimum operating temperature	0 degree Celsius
Maximum operating temperature	50 degree Celsius
Maximum operating relative humidity	85 percent
Minimum storage temperature	0 degree Celsius
Maximum storage temperature	50 degree Celsius
CERTIFICATIONS & REPORTS	
Availability of conformity certificate/test report of the equipment from OEM to prove conformity to the declared specifications	Yes
Product certifications	US-FDA,EU-CE (from notified body),BIS

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Manufacturer certifications	ISO: 13485 (Latest)
Protection against electric shock	Class II type protection against electric shock
Compliance to other safety standards	IEC-60601-1
Ingress Protection Rating	IP 21
Submission of all necessary certifications, test reports to the buyer along with supplies	Yes
INSTALLATION & TRAINING	
Supplier to perform installation, safety and operation checks before handover	Yes
The supplier/vendor shall provide free of cost training to the personnel in operation	Yes
WARRANTY	
Warranty in Years (Option of comprehensive warranty is available through bidding only, which if opted will supersede normal warranty in the catalogue)	• warranty for five (2) years commencing from the date of issue of installation certificate. • The installation should include product demonstration and training of all the relevant medical personnel in the department about using the equipment. The installation report will be accepted by the department only after satisfactory training is completed.
ADDITIONAL REQUIREMENTS	
OEM/Reseller shall ensure uninterrupted availability of all spares and components for atleat 5 years from the date of purchase	Yes
User/Technical/Operating/Maintenance manuals to be supplied in English in hard and soft copy	Yes
Product catalog, technical write up in English to be provided both in hard and electronic copies	Yes
Details of equipments and procedures required for local calibration and routine	Yes

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maintenance to be supplied	
The Principal Manufacturer must have direct Presence/approved service center In India	Yes
Time to provide temporary backup support in case of malfunction/breakdown	within 48 hrs
Additional requirement	NA

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ANNEXURE – I

SPECIFICATIONS

Objection should be submitted in following format:

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