



All India Institute of Medical Sciences, Bhubaneswar
At - Sijua (Patrapada), Post - Dumuduma, Bhubaneswar (Odisha) - 751 019

To be uploaded in Website: www.aiimsbhubaneswar.edu.in (Tender) & CPPP

Reference No: AIIMS/BBSR/HS/236/20-21

Dated: 19/01/2022

Subject: Procurement of Disposable Flow Sensor for Hamilton C3 Ventilators installed in various departments at AIIMS, Bhubaneswar on Proprietary basis - **Inviting Comments thereon.**

The Various Departments of AIIMS, Bhubaneswar has requested for procurement of Disposable Flow Sensor for Ventilators (Make: Hamilton; Model: C3) on Proprietary basis from **M/s HAMILTON MEDICAL** through their Authorized Channel Partner i.e. **M/s JK MEDICAL SYSTEM, Bhubaneswar.**

The Notice is being uploaded for general information of prospective manufacturer/Authorized Distributor/Dealers to submit their objection/proposal/comments, if any, on proprietorship of the item.

In case the product of any manufacturer/Authorized distributor/Dealer conforms to the enclosed specifications, they may submit their proposal for the supply of the same along with the brochures, point by point compliance of the enclosed specifications along with all documentary evidence. One quotation of the product may also be submitted.

The objections/comments/proposal should be sent in sealed cover to the **Office of Sr. Procurement Cum Stores Officer, AIIMS, Bhubaneswar (Odisha) – 751019** or through e-mail to spo@aiimsbhubaneswar.edu.in, aso.dkmahana@aiimsbhubaneswar.edu.in and stokee_lovneet@aiimsbhubaneswar.edu.in, so as to reach on or before **date: 04-02-2022** failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The ref. no. – **AIIMS/BBSR/HS/236/20-21** dt: **19-01-2022**, due on dated: **04-02-2022** should be superscripted on sealed envelope.

Enclosure:

1. Proprietary Article Certificate from Indenting Officer.
2. Manufacturer's Proprietary Certificate dated 11-10-2021
3. Brochure & Literature of required Product
4. Manufacturer's Authorization letter dated 11-10-2021
5. Price Quotation No. JKM/161/21-22 Dated 12-10-2021

Copy to:

- | | | |
|--------------------------------|---|------------------------------|
| 1. Medical Superintendent | : | for kind information please |
| 2. Indenting Officer | : | for kind information please |
| 3. Accounts Officer | : | for kind information please |
| 4. IT Cell, AIIMS, Bhubaneswar | : | for hoisting in the website. |


Sr. Procurement-cum-Stores Officer


Sr. Procurement-cum-Stores Officer

AIIMS, BHUBANESWAR

Proprietary Article Certificate
Valid for the Current Financial Year

File No. and Date Reference :		AIIMS/BBSR/HS/236/20-21	
1	Description of article	Flow Sensors for C3 Ventilator (Make: Hamilton) (a) Disposable, and (b) Reusable	
2	Forecast of quantity /annual requirement	Disposable Flow Sensors- 748 Nos.	
3	Approximate estimated value for above quantity	Rs. 14,24,192/- (Rupees Fourteen Lakh Twenty-Four Thousand One Hundred and Ninety Two Only)	
4	Maker's name and address	HAMILTON MEDICAL	
5	Name(s) of authorized dealers/ stockists		
6	I approve the above purchase on PAC basis and certify that : - Note- Tick to retain only one out of (b), C-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it - without which PAC certificate will be invalid.		
6 (a)	This is the only firm who is manufacturing / stocking this item. AND	Yes	
6 (b)	A Similar article is not manufactured / sold by any other firm, which could be used in lieu OR	X	
6 (c-1)	No other make/brand will be suitable for following tangible reasons (like OEM/ Warranty, spares.) : OR	X	
6 (c)	No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources): <u>Hamilton C3 Ventilator is a closed system and only Hamilton's Flow Sensor would be compatible</u>	✓	
7	Reference of concurrence of finance wing to the proposal :		
History of PAC Purchase of this item for past three years may be given below : <u>Not Applicable</u>			
Name of the Supplier: <u>Not Applicable</u>			
Order/ Tender Reference & Date	Quantity Ordered	Basic Rate on Order (Rs.)	Adverse Performance Reported if Any
-	-	-	-
-	-	-	-
-	-	-	-

Signature of Approving Authority.....

Date..... Designation of Officer.....

Dr. Tushar Subhakarshan Mishra
Professor & Head
Dept. of Trauma & Emergency
AIIMS, Bhubaneswar-751005
Signature of the Initiating Officers
Dr. Swagata Prapaty
Associate Professor
Dept. of Anaesthesiology
AIIMS, Bhubaneswar-751005
Dr. Spurin Bhunia
Additional Professor
Department of Pulmonary
Medicine & Critical Care
AIIMS, Bhubaneswar-751005

To whom it may concern

Bonaduz, 11 October 2021

Declaration Medical Device Parts

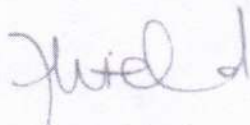
Dear Sir or Madam,

This is to certify that Hamilton Medical AG, Bonaduz, Switzerland is the legal manufacturer of the following products:

- Flow Sensor, single-use, adult/pediatric, P/N 281637

We are the sole manufacturer of the products mentioned above. We confirm the products are specially developed and approved for the safe use with our ventilator **HAMILTON-C3**.

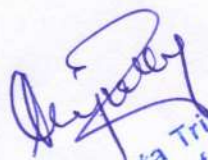
With kind regards



Johanna Wieland
Sales and Marketing Support
Hamilton Medical AG

**HAMILTON
MEDICAL**

Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz
+41 58 610 10 20 – info@hamilton-medical.com



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AIIMS, Bhubaneswar



Dr. Tushar Subhadarshan Mishra
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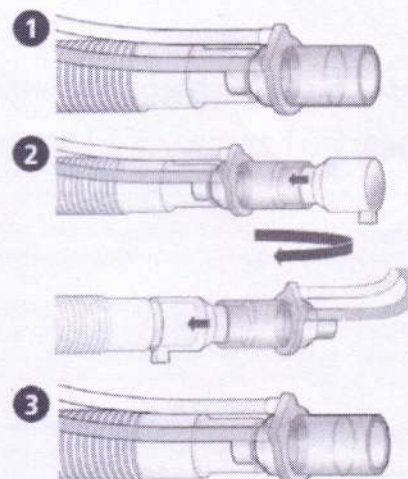
HAMILTON MEDICAL

Adult/pediatric flow sensor, single use
Flow-Sensor für Erwachsene/Pädiatrie, für den Einmalgebrauch
Capteur de débit adulte/enfant, usage unique
REF 281637 / REF 282049 / REF 282092 / REF 282051

Directions for use
Gebrauchsanweisung
Mode d'emploi
PN 624269/09 / 2018-01-31

	Consult the appropriate ventilator operator's manual for more detailed information. Detailliertere Informationen sind im Bedienungshandbuch zum Beatmungsgerät enthalten. Consulter le manuel de l'utilisateur du ventilateur approprié pour plus d'informations.		
CE0197	Conformity with Council Directive 93/42/EEC concerning medical devices. Entspricht den Anforderungen der EU-Richtlinie 93/42/EWG über Medizinprodukte. Conforme à la Directive du Conseil européen 93/42/CEE sur les dispositifs médicaux.		
	Applicable to adult/pediatric patient groups. Für die Patientengruppen „Erwachsene/Pädiatrie“. Applicable aux groupes de patients adulte/enfant.		
	Do not reuse. Nicht wiederverwenden. Ne pas réutiliser.		MR safe. MR-sicher. MR Safe.
	Quantity Menge Quantité		Do not use if package is damaged. Bei beschädigter Verpackung nicht verwenden. Ne pas utiliser si l'emballage est endommagé.

Calibration
Kalibration
Calibration



CE0197

Manufacturer/Hersteller/Fabricant
Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz
Telephone/Telefon/Téléphone: (+41) 58 610 00 20
email: info@hamilton-medical.ch
www.hamilton-medical.com
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Adult/pediatric flow sensor, single use (REF 281637 / REF 282049/ REF 282092/

REF 282051) Directions for use

NOTE:

- Hamilton Medical cannot be held responsible for the correct functioning of flow sensors that are cleaned by the user and reused on patients.
- Replace the flow sensor in accordance with hospital infection control procedures, or depending on patients secretion and nebulization of medication, if required.
- Follow internal hospital infection control procedures.
- Visually inspect the flow sensor body, tubings, and internal flap. Discard the flow sensor if there is any sign of damage.
- The flow sensor should be calibrated prior to patient use. If calibration fails, it may be repeated once. The flow sensor must be discarded if the flow calibration fails the second time.

Intended use

The Hamilton Medical flow sensor is a device to measure patient air flow with Hamilton Medical ventilators.

Ventilator connection

Connect the small tubes of the flow sensor to the color-coded connectors on the ventilator panel.

Patient connection

Insert the flow sensor between the Y-piece of the patient circuit and the patient connection. The end of the flow sensor which should be towards the patient is marked with „Patient“. It is recommended that a short section of flexible tubing be used between the flow sensor and the actual patient connection.

Tubing clip

The clip is designed to secure the flow sensor's sensing tubing to the patient circuit. Always leave a loop of tubing from the clip to the flow sensor to accommodate the full range of patient movement.

Calibration

The flow sensor must be calibrated prior to patient use. To calibrate, follow the instructions in the appropriate ventilator operator's manual. Connect the supplied calibration connector for the calibration. After successful completion of the procedure, the flow sensor is ready for patient use. If calibration fails, it may be repeated once. The flow sensor must be discarded if the flow calibration fails the second time.

Cleaning and disinfection

The flow sensor is delivered clean, ready for clinical use.

Disposal

Flow sensor has to be handled as contaminated. Follow all local, state and federal regulations with respect to environmental protection when disposing of used sensors.

Environmental requirements and storage conditions

Operating: -20°C to 50°C (-4°F to 122°F), relative humidity 5%-95%, noncondensing. Storage: -20°C to 60°C (-4°F to 140°F).

CAUTION

- (USA only) Federal law restricts this device to sale by or on the order of a physician.
- Hamilton Medical single-use products may release material particles, microbiological substances and biomolecular structures if they are reprocessed and may endanger patients. The product properties are affected by both physical and chemical processes. A mechanical change to the material properties can lead to the release of an increased number of particles and changes to the surface structure that can cause cracks. Furthermore, a changed surface structure can lead to an aggregation of germs, spores, allergens, endotoxins and pyrogens.



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AIIMS Bhubaneswar

Dr. Tushar Subhadarshan Mishra
Professor & Head
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Flow-Sensor für Erwachsene/Pädiatrie, für den Einmalgebrauch (REF 281637 /

REF 282049/ REF 282092/ REF 282051) Gebrauchsanweisung

HINWEIS:

- Hamilton Medical haftet nicht für die korrekte Funktion von Flow-Sensoren, die vom Anwender gereinigt und bei Patienten wiederverwendet werden.
- Tauschen Sie den Flow-Sensor gemäß den krankenhausinternen Verfahren zur Infektionskontrolle oder bei Bedarf abhängig von den Atemwegssekreten und der Verneblung von Medikamenten aus.
- Beachten Sie die krankenhausinternen Verfahren zur Infektionskontrolle.
- Führen Sie eine Sichtkontrolle des Gehäuses, der Schläuche und der internen Klappe des Flow-Sensors durch. Entsorgen Sie den Flow-Sensor, wenn er Anzeichen von Schäden aufweist.
- Vor der Verwendung an einem Patienten sollte der Flow-Sensor kalibriert werden. Wenn die Kalibration fehlerhaft ist, darf sie einmal wiederholt werden. Der Flow-Sensor muss entsorgt werden, wenn die Kalibration des Flow-Sensors ein zweites Mal fehlschlägt.

Vorgesehener Verwendungszweck

Der Hamilton Medical Flow-Sensor ist eine Vorrichtung, mit der der Luftstrom von Patienten bei Beatmungsgeräten von Hamilton Medical gemessen wird.

Anschluss am Beatmungsgerät

Verbinden Sie die kleinen Schläuche des Flow-Sensors mit den farbkodierten Anschlüssen am Bedienfeld des Beatmungsgerätes.

Patientenanschluss

Setzen Sie den Flow-Sensor zwischen dem Y-Stück des Beatmungsschlauchsystems und dem Patientenanschluss ein. Das Ende des Flow-Sensors, das zum Patienten zeigt, ist mit „Patient“ markiert. Es wird empfohlen, zwischen dem Flow-Sensor und dem tatsächlichen Patientenanschluss ein kurzes Stück flexiblen Schlauch zu verwenden.

Schlauchclip

Der Clip dient dazu, die Schläuche des Sensorsystems des Flow-Sensors am Beatmungsschlauchsystem des Patienten zu fixieren. Zwischen Clip und Flow-Sensor sollten die Schläuche in einer Schlaufe gelegt werden,

sodass der Patient eine möglichst große Bewegungsfreiheit genießt.

Kalibration

Der Flow-Sensor muss vor der Verwendung bei einem Patienten kalibriert werden. Befolgen Sie zum Kalibrieren die Anweisungen im entsprechenden Bedienungshandbuch zum Beatmungsgerät. Schließen Sie zum Kalibrieren den mitgelieferten Kalibrationsanschluss an. Nach erfolgreichem Abschluss des Verfahrens ist der Flow-Sensor bereit für den Einsatz am Patienten. Wenn die Kalibration fehlerhaft ist, darf sie einmal wiederholt werden. Der Flow-Sensor muss entsorgt werden, wenn die Kalibration des Flow-Sensors ein zweites Mal fehlschlägt.

Reinigung und Desinfektion

Der Flow-Sensor wird sauber und bereit für den klinischen Einsatz ausgeliefert.

Entsorgung

Der Flow-Sensor ist als kontaminiertes Produkt zu behandeln. Befolgen Sie bei der Entsorgung gebrauchter Sensoren alle gesetzlichen Bestimmungen hinsichtlich des Umweltschutzes.

Standortanforderungen und Lagerungsbedingungen

Betrieb: -15 bis 50 °C, relative Luftfeuchtigkeit 5 bis 95 %, nicht kondensierend. Lagerung: -20 bis 50 °C.

VORSICHT

Wenn Hamilton Medical Produkte für den Einmalgebrauch aufbereitet werden, können sie Stoffpartikel, mikrobiologische Substanzen und biomolekulare Strukturen freisetzen und möglicherweise Patienten gefährden. Die Produkteigenschaften werden sowohl von chemischen als auch von chemischen Prozessen beeinflusst. Eine mechanische Veränderung der Materialeigenschaften kann zur Freisetzung einer erhöhten Partikelzahl sowie zu Veränderungen der Oberflächenstruktur führen, die möglicherweise Risse zur Folge haben. Außerdem kann eine veränderte Oberflächenstruktur zu einer Ansammlung von Keimen, Sporen, Allergenen, Endotoxinen oder Pyrogenen führen.

Dr. Tushar Subhadarsan Mishra
Professor & Head
Dept. of Trauma & Emergency
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Capteur de débit adulte/enfant, usage unique (REF 281637 / REF 282049/ REF 282092/

REF 282051) Mode d'emploi

REMARQUE:

- Hamilton Medical décline toute responsabilité en ce qui concerne le bon fonctionnement des capteurs de débit nettoyés par l'utilisateur et réutilisés sur des patients.
- Remplacer le capteur de débit conformément aux procédures de contrôle des infections en vigueur dans l'hôpital ou en fonction des sécrétions du patient et de la nébulisation des médicaments, le cas échéant.
- Respecter les procédures de contrôle des infections en vigueur dans l'hôpital.
- Inspecter visuellement le corps du capteur, les tubulures et le clapet interne. Jeter le capteur de débit s'il semble endommagé.
- Le capteur de débit doit être calibré avant de l'utiliser sur un patient. Si la calibration échoue, répéter la procédure une deuxième fois. Le capteur de débit doit être mis au rebut si la calibration échoue la deuxième fois.

Usage prévu

Le capteur de débit Hamilton Medical est un dispositif qui permet de mesurer le débit d'air du patient avec des ventilateurs Hamilton Medical.

Connexion du ventilateur

Raccorder les petits tubes du capteur de débit aux connecteurs de code couleur sur le panneau du ventilateur.

Connexion patient

Insérer le capteur de débit entre la pièce en Y du circuit patient et la connexion patient. L'extrémité du capteur de débit qui doit être orientée vers le patient porte la mention « Patient ». Il est recommandé d'utiliser une petite partie de la tubulure flexible entre le capteur de débit et la connexion patient définie.

Clip tubulure

Le clip est conçu pour fixer les tubes de détection du capteur de débit au circuit patient. Toujours laisser une boucle de tubulure entre le clip et le capteur de débit pour ne pas entraver la liberté de mouvement du patient.

Calibration

Le capteur de débit doit être calibré avant de l'utiliser sur un patient. Pour le calibrer, suivre les instructions du manuel de l'utilisateur du ventilateur correspondant. Connecter le connecteur de calibration fourni pour la calibration. Une fois la procédure réussie, le capteur de débit est prêt à être utilisé sur le patient. Si la calibration échoue, répéter la procédure une deuxième fois. Le capteur de débit doit être mis au rebut si la calibration échoue la deuxième fois.

Nettoyage et désinfection

Le capteur de débit est livré propre et prêt à une utilisation clinique.

Mise au rebut

Le capteur de débit doit être manipulé comme un objet contaminé. Respecter la réglementation locale et nationale sur la protection de l'environnement lors de la mise au rebut des capteurs usagés.

Conditions environnementales et de stockage

Fonctionnement: -15 à 50 °C, humidité relative 5 à 95 %, sans condensation. Stockage: -20 à 60 °C.

PRÉCAUTION

Les produits Hamilton Medical à usage unique sont susceptibles de libérer des particules de matière, des substances microbiologiques et des structures biomoléculaires s'ils sont retraits et risquent de mettre en danger la vie des patients. Les propriétés du produit sont altérées par des processus physiques et chimiques. Un changement mécanique des propriétés matérielles peut provoquer la libération d'un nombre croissant de particules et des modifications de la structure de surface susceptibles de provoquer des fissures. En outre, une structure de surface altérée peut provoquer une aggrégation de germes, de spores, d'allergènes, d'endotoxines et de pyrogènes.

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Dr. Swagata Tripathy
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AIIMS, Bhubaneswar-751019

To
The Director
AIIMS
Bhubaneswar

Bonaduz, 11 October 2021

Letter of Authorization

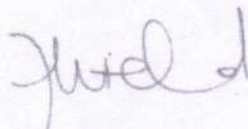
Dear Sir

this is to certify that "JK MEDICAL SYSTEM! PLOT NO.3000/5059, M.N.BUILDING,RAVI TALKIES ROAD, BHUBANESWAR-751002 ODISHA, India" is our authorized channel partner for sales of ventilators and accessories/spare parts and also to provide Services for Hamilton Medical range of products. The validity of this authorization shall be 1 year subject to the conditions hereunder:

1. Both Parties may terminate the present arrangement under observance of a notice period of one month.
2. Should "JK MEDICAL SYSTEMS" fail to provide Services in full, on time and to the required quality standard Hamilton Medical AG shall be entitled to terminate the present arrangement with two days' notice.

In the event of anyone else claiming to be an authorized representative or partner approaching your team, we request you to please ensure written confirmation is obtained from Hamilton Medical. Please do not allow unauthorized persons access to Hamilton Medical ventilators, as this will void warranty conditions.

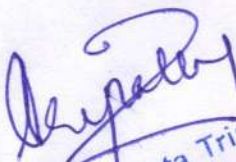
With kind regards



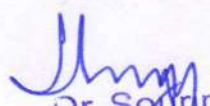
Johanna Wieland
Sales and Marketing Support
Hamilton Medical AG

**HAMILTON
MEDICAL**

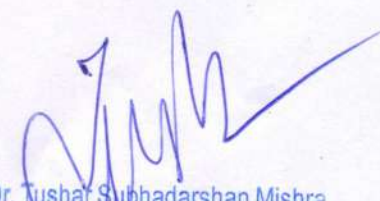
Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz
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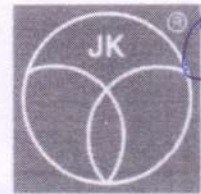
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Tel: 0674- 2341208, 2341210
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email: jkmedbbsr@gmail.com

GST No.21ATCPS3521P1ZL

J K Medical Systems

To Store & Purchase Officer All India Institute of Medical Sciences, Patrapada, Bhubaneswar- 751019.	QUOTATION NO : JKM/161/21-22 Dated : October 12, 2021.
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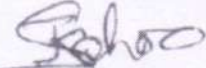
Sl.No.	Cat.No.	Product Description	Unit Price
01	281637	Flow Sensor Single Use Adult/Pediatric (Hamilton)	Rs. 1,700.00

Terms and Conditions:

1. TAX (GST) : @18% Extra as applicable.
2. Prices : F O R Destination.
3. Payments : At the earliest.
4. Delivery Period : Within 4-6 weeks after getting your confirmed order.
5. Validity : 60 days. (Extended upto 15/02/2022 vide e-mail dt. 15/01/2022)

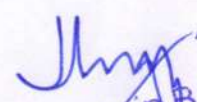
Thanking you.

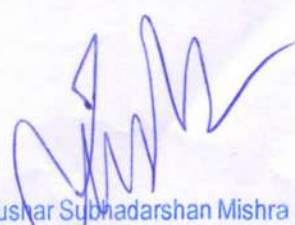
Sincerely Yours
For JK Medical Systems


Authorised Signatory




Dr. Swagata Tripathy
Associate Professor
Dept. of Anaesthesiology
AIIMS, Bhubaneswar-751019


Dr. Sourin Bhunia
Additional Professor
Department of Pulmonary
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Health Care
SERVICE