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No. F-8(02069)RMSC/EPM/M-2/2024-25/NIB-844/ 444 Date 28/x/24

Clarification/Corrigendum/Addendum

Subject:- NIB No. F-8(02069)RMSC/EPM/M-2/2024-25/NIB-844/365Dated: 24.09.2024 for item (i) Bublle CPAP Consumable, (ii) (PICU/PHDU) HFNC Consumable Kit & (iii) (PICU/PHDU) Ventilator Consumable Kit

In Reference to subject cited above and NIB-844 The following Corrigendum/Addendum is issued for inclusion in bid document as below:-

1. REVISED TECHNICAL SPECIFICATION OF BUBBLE CPAP CONSUMABLES

1. The following consumables are required for the bubble CPAP system kit:
   a. CPAP circuit with auto-fill humidifier chamber with bubble CPAP generator (bubble jar)
   b. Nasal interface (of different sizes): nasal prongs**with depth marking**or nasal masks
   c. Cap/bonnet/hat (different sizes)
   d. Nasal tubing (different size) only if required to connect nasal interface to nasal prongs or nasal masks CPAP circuit
   e. Sterile standard oxygen tubings of at least 150 cm to connect the air-oxygen blender outlet to the humidifier chamber without the need of any other external connectors
2. All the items should be available in an individual pre-sterile packing including nasal interface and cap.
3. The different sizes of nasal interface, cap and nasal tubing (if required) should also be available as separate sterile packing.
4. All the above items should be disposable in nature.
5. All the entire CPAP system (except oxygen tubings) should be European CE or USA FDA certified.
6. **Offered product should have valid CDSCO License. Related document shall be submitted along with technical bid.**

A. CPAP circuit with auto-fill humidification chamber with bubble CPAP generator (bubble jar)

1. CPAP circuit

a. Should be corrugated hose
b. The length of the inspiratory, expiratory limbs of the CPAP circuit and size of the ports should be of standard size for neonatal use
c. Inspiratory limb should contain spiral heater wire for uniform heating
d. Should have airway and chamber temperature probe port
e. Should be compatible with available interfaces
f. Connector if required should be within the CPAP circuit for fixing the tubings with CPAP interface/nasal tubings
g. Circuits should be made of non-toxic additive free materials and devoid of DEHP
h. Safety feature in form of limiting the delivered pressure in the event of an occlusion should be present

2. Auto fill Humidification Chamber

a. There should be a disposable auto fill neonatal humidification chamber
b. The humidifier chamber should contain markings for the appropriate/ maximum/minimum water level

3. **Bubble CPAP generator (Bubble jar)**
   a. Adjustable pressure probe with PEEP settings 3-10 cmH20.
   b. Delivers intended pressure constantly and accurately (+ 1 cm)
   c. The gradations on PEEP setting probe should be easily visible from a distance of 4 feet
   d. PEEP setting probe should be easy to fix, and is designed to avoid slippage of PEEP rod
   e. Should contain maximum and minimum water level indication
   f. Has detachable overflow container
   g. Should not be made of PVC/DEHP

B. Nasal prongs
   a. It should be short (6 -15 mm length) binasal prongs
   b. Made up of soft silicone material
   c. Should be safe to use to minimize skin breakdown
   d. Should be anatomically curved**with depth marking**
   e. Should snugly fit in the nares to provide an effective seal for delivering pressure effectively
   f. Should put minimum pressure on nares and septum to prevent nasal trauma
   g. Should be compatible to use with the nasal tubings or has connectors to connect with CPAP circuit tubings directly
   h. Should be available in different sizes to provide optimal fit for neonates with birth weight between 700-4000 grams OR 25-42 weeks of gestation
   i. Should include guide to determine the appropriate size of nasal prongs
   j. Preferable to have colour coding of different sizes of prongs to make it more user friendly
   k. Should be European CE or US FDA approved

C. Nasal mask
   a. It should be made up of soft silicone material
   b. Should be anatomically shaped for better fitting
   c. Should be safe to use to minimize skin breakdown
   d. Should snugly fit the nose to provide an effective seal for delivering pressure effectively
   e. Should put minimum pressure on skin to provide comfort and prevent nasal trauma
   f. Should be compatible to use with the nasal tubings or has connectors to connect with CPAP circuit tubings directly
   g. Should be available in different sizes to provide optimal fit for neonates with birth weight between 700-4000 grams OR 25-42 weeks of gestation
   h. Should include guide to determine the appropriate size of nasal masks
   i. Should be European CE or US FDA approved

D. Cap/Bonnet/Hat
   a. Should be provided with disposable caps of different sizes to fit the head circumference (17-36 cm) snugly for securing the nasal prongs with the nasal tubings or CPAP circuit tubings
   b. The cap should be made up of high quality fabric/cotton
   c. Cap should be provided with adhesive material to secure the CPAP circuit tubings or has straps to secure and stabilize the nasal tubings
   d. Sizing guide should be available to determine the appropriate size of cap

E. Nasal Tubings (if required)
   a. Should be provided with disposable nasal tubings to connect nasal interface to CPAP circuit tubings

b. Made up of polypropylene or similar flexible material which is PVC/DEHP free
c. Should be available in different sizes with its size guide

F. Oxygen tubing

a. Standard oxygen tubings of at least 150 cm to connect the air-oxygen blender outlet to the humidifier chamber without the need of any other external connectors
b. Should be sterile and disposable in nature

Note:- 1. Bubble CPAP consumable should be universal & should be compatible to Bubble CPAP.

REVISED VENTILATOR CONSUMABLE KIT (CPAP CIRCUIT + AUTO FILL HUMIDIFICATION CHAMBER)

1. CPAP circuit

a. Should be corrugated hose
b. The length of the inspiratory, expiratory limbs of the CPAP circuit and size of the ports should be of standard size for neonatal use
c. Inspiratory limb should contain spiral heater wire for uniform heating
d. Should have airway and chamber temperature probe port
e. Should be compatible with available interfaces
f. Connector if required should be within the CPAP circuit for fixing the tubings with CPAP interface/nasal tubings
g. Circuits should be made of non-toxic additive free materials and devoid of DEHP
h. Safety feature in form of limiting the delivered pressure in the event of an occlusion should be present
i. Should be available in an individual pre-sterile packing.
j. Should be European CE or US FDA approved.
k. Offered product should have valid CDSCO License. Related document shall be submitted along with technical bid.

2. Auto fill Humidification Chamber

a. There should be a disposable auto fill neonatal humidification chamber
b. The humidifier chamber should contain markings for the appropriate/ maximum/minimum water level.
c. Should be available in an individual pre-sterile packing.
d. Should be European CE or US FDA approved.
e. Offered product should have valid CDSCO License. Related document shall be submitted along with technical bid.

3. This item can beis used in HFNC Machine &CPAP Machine.
4. Nasal interface (prong**with depth marking**/ mask for neonate) with Cap/Bonnet/Head Gear.

REVISED HFNC SYSTEM CONSUMABLE KIT

1. CPAP circuit

l. Should be corrugated hose
m. The length of the inspiratory, expiratory limbs of the CPAP circuit and size of the ports should be of standard size for neonatal use
n. Inspiratory limb should contain spiral heater wire for uniform heating
o. Should have airway and chamber temperature probe port
p. Should be compatible with available interfaces
q. Connector if required should be within the CPAP circuit for fixing the tubings with CPAP interface/nasal tubings
r. Circuits should be made of non-toxic additive free materials and devoid of DEHP
s. Safety feature in form of limiting the delivered pressure in the event of an occlusion should be present

t. Should be available in an individual pre-sterile packing.
u. Should be European CE or US FDA approved.
v. **Offered product should have valid CDSCO License. Related document shall be submitted along with technical bid.**

2. **Auto fill Humidification Chamber**
f. There should be a disposable auto fill neonatal humidification chamber
g. The humidifier chamber should contain markings for the appropriate/ maximum/minimum water level.
h. Should be available in an individual pre-sterile packing.
i. Should be European CE or US FDA approved.
j. This item can be is used in HFNC Machine and CPAP.
k. **Offered product should have valid CDSCO License. Related document shall be submitted along with technical bid.**

3. High flow nasal cannula for preterm/neonate/pediatric no.01 shall be supplied.

2. **Date extension of Bid:-**

Existing Dates			Extended Dates		
Last Date & Time of Online Downloading of Bidding Document	Last Date & Time of Online Submission of Bid	Date & Time of Online Opening of Technical Bid	Last Date & Time of Online Downloading of Bidding Document	Last Date & Time of Online Submission of Bid	Date & Time of Online Opening of Technical Bid
28.10.2024 6:00 PM	28.10.2024 6:00 PM	29.10.2024 03:00 PM	06.11.2024 6:00 PM	06.11.2024 6:00 PM	07.11.2024 03:00 PM

All other terms & conditions remains the same.

Executive Director (EPM)
RMSCL, Jaipur

Note:- Please note that all above amendments/corrigendum is technical specifications/bid conditions is the integral part of (Section-VIII) and the bid document. This corrigendum/addendum should be signed and annexed with bid document. All other terms & conditions remains the same.