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No. F-8( ) RMSC/EPM/M-3/21-22/NIB-661/1701 Dated: 22/02/2022

CLARIFICATION/CORRIGENDUM/ADDENDUM

Sub:- Revised Amended Technical Specifications of the rate contract for High Flow Nasal Cannula System (HFNC) for under NIB No. F-8() RMSC/EPM/M-3/NIB-661/2021-22/1571 dated 07.1.22

In Reference to subject cited above and NIB-661, the various representations received from the firms and issues raised by the Bidders are examined by the competent Authorities and technical committee. The following Clarification/Corrigendum/Addendum is issued for inclusion in Bid document & Technical Specification of items as below:-

Revised Technical Specifications of the High Flow Nasal Cannula System (HFNC)

1. It should be complaint for use on patients in ICU,wards,Emergency department oxygen therapy .
2. It should be single system for treating Infant and paediatric patients .
3. Device should have integrated flow generator to deliver flows from 2 to 60 litres.
4. Inbuilt or Integrated Air/ Oxygen blending and Fio2 monitoring with facility to deliver wide range of oxygen concentrations from 21 to 100% .
5. It should have Integrated or Inbuilt Compressor /Air source.
6. Oxygen sensor should not require in field calibration
7. Visual and audible alarm indication for Tube disconnects leaks, tube blockages and Water out and Hardware Fault with Error Codes. Audible power failure alarm.
8. Device should have thermal disinfection mode to minimize contamination, (If required in Quoted model).
9. Heated tube for sterilization of device should be provided, (If required in Quoted model).
10. Device should be capable to be installed on Mounting Tray and Pole with Castor & IV Hook .
11. Complete Device or core components like blender, humidifier, should be USFDA/European CE Certified (With four digit notified body number)/IEC 60601/ISO 13485. Compressor /Air source manufacturer should be ISO-13485 certified.
12. Device should have Oxygen Inlet Tube and Air Filter.
13. Device should be supplied with Patient Breathing Circuits/Tube – 2 pcs (Each) for Infant and paediatric patients .
14. The circuit should have integrated temperature sensor with no need of external probes, cables or Adapter.
15. The Circuit should be supplied with a humidifier chamber for water.
16. The Circuit should have heating fine wire inside the circuit to gently and accurately deliver warm and humidified gases.
17. Device should be supplied Nasal Cannula interface for proper fitting : 02 Pcs – Each for Infant and paediatric patients .
18. Rate of one heated wire patient breathing tube and the rate of one nasal cannula of Infant , peadiatric & adult should be offered separately. (Should be USFDA/European CE Certified).
19. Device should have two years of warranty from manufacturer.
20. Device should have universal connection compatibility for certified (USFDA/European CE) HFNC Circuit / tubes/ other consumable kit.

Note:- Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-V, Schedule of Supply, and Point no. 3) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

22/2/22

Executive Director (EPM)
RMSCL, Jaipur