Republic of the Philippines
Department of Health
CARAGA REGIONAL HOSPITAL

TECHNICAL SPECIFICATION

PROCUREMENT OF INFUSION PUMP FOR PEDIA
IB NO. 2023 - 04 - 24 (15)

1	INFUSION PUMP FOR NICU	15 UNITS @ PHP 100,000.00	TOTAL: PHP 1,500,000. 00
2	INFUSION PUMP FOR PICU	20 UNITS @ PHP 100,000.00	TOTAL: PHP 2,000,000. 00
		Total Approved Budget for the Contract	PHP 3,500,000.00

Specification and Terms of Reference Below are applicable to both NICU and PICU Infusion Pump.

	PURPOSE OF USE		
		Clinical or other purpose	It is a medical device that delivers fluids, such as nutrients and medications, into a patient's body in controlled amounts
		Clinical department/ward	NICU / PICU
		Overview of functional requirements	The solution to be administered must be deliverd with greater accuracy than can be provided through a manually adjusted gravity administration set. Alarms indicates if any error situations occur
	TECHNICAL CHARACTERISTICS		
			Touch screen LCD TFT (thin film transistor)
			Peristalsic pump method

		Detailed requirements	Should have a flow rate accuracy of +/- 5% and drip rate accuracy of +/- 2%
			Motor-driven door and anti-leakage clip design
			VTBI: 0.01-9999 ml
			Flow rate range: 0.01 -1200 ml/h
			KVO Rate: 0.01-5.00 ml/h adjustable
			The increment is 0.01 ml / h
			Should have an audible and visual alarm for occlusion pressure, air alarm, door open, drop sensor, empty, low battery, and infusion complete
		Displayed parameters	Should have a 7 segments display or LCD display with backlight and graphical display of infusion, display or information: Flow rate, volume limit, accumulated volume, power indicator light air, occlusion, empty, drug library
		User adjustable settings	Should be compatible with most of the IV set (macroset/microset/blood set)
			Should be operated with any blood components
			Drip / drop rate
	PHYSICAL/CHEMICAL CHARACTERISTICS		
		Components	ABS plastic
			Less than 3kg
		Mobility, portability(if relevant)	Can be integrated into docking station or stackable

			Portable
	UTILITY REQUIREMENTS		
		Electrical, water and/or gas supply (if relevant)	Should have a minimum 5-7 hours battery back up at highest delivery rate.
			Charging: Less than 6 hours
			AC Power Supply: 220-230 V / 50-60 Hz. With option for external DC power supply (13-15 Volts) when used to transport patient via ambulance
			Type of shock protection: Class I
			Type of CF, defibrillation - proof
	ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
		Accessories (if relevant)	IV Pole, pole clamp and power adapters
	ENVIRONMENTAL REQUIREMENTS		
		Context-dependent requirements	Operating conditions: 10°C-30°C
			Storage conditions: 20°c - 55°c
			Atmospheric Pressure: 700 - 1060 hPa
			Class II, Type CF, and drip proof classification
	TRAINING, INSTALLATION AND UTILIZATION		
		Pre-installation requirements (if relevant)	Assembly and installation should be carried out by a qualified technician
		Requirements for commissioning	Calibration Certificate

		Training of user/s (if relevant)	Training of end-users and biomed staff
		User care (if relevant)	Capable of Cleaning with alcohol and any hospital disinfectants
			Cleaning Instruction
		Place of installation	Pedia Department
	WARRANTY AND MAINTENANCE		
		Warranty	2 years Parts and labor
		Maintenance tasks	Advance maintenance and calibration tasks required shall be documented
		Type of service contract	Free servicing during warranty period.
		Spare parts availability post-warranty	Spare parts and price list for maintenance and repairs in future after guarantee / warranty period should be attached
		Software / Hardware upgrade availability	Built-in
	DOCUMENTATION		
		Documentation requirements	Operating and Services Manuals (In English), Calibration Certificate
			List of important spare parts and accessories, with their part numbers and cost
			Contact details of manufacturer, supplier and local service agent to be provided
	DECOMMISSIONING		
		Estimated Life Span	5 years
	SAFETY AND STANDARDS		

		Regulatory Approval / Certification	Should be FDA, CE or UL approved product.
		Internationally Standards	IEC 60601-1:2005 + A1: 2012 (E) Medical electrical equipment - Part 1-1: General requirements for basic safety and essential performance
			IEC 60601-1-2:2014 Medical Electrical equpment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
			IEC 60601-1-8 Medical Electrical equipment- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
			Compliance to ISO 13485-Quality Management System
			IEC 60601-2-24 Medical Electrical Equipment - Part 2-24 : Particular requirements for the safety of infusion pumps and controllers
		Other Requirements	All machines must be manufactured by a known and reputable company with Certificate of Good Manufacturing Practice (GMP), TUV or ISO or its equivalent for equipment only.
		COMPLETION OF DELIVERY AND INSTALLATION	ITEM SHALL BE DELIVERED WITHIN 45 CALENDAR DAYS FROM RECEIPT OF NOTICE TO PROCEED, INCLUDING ITS INSTALLATION
		TERM OF PAYMENT	Payment shall be processed right after complete delivery, commissioning and compliance with all necessary documents in according to audit rules and regulations.

		Validity of the Contract / Contract Termination	Without prejudice to the provision of applicable laws, rules and guidelines, the Contract shall be automatically terminated under the following conditions:
			a. When the total quantity specified in the Contract has been exhausted and not exceed to a period of one (1) year; or
			b. For any justifiable reason ground where the contract will not redound to the benefit of the government or there is violation of the contract.
		Repeat Order	1. No Repeat Order for an item in contract being awarded shall be allowed until after the procuring entity has exhausted the estimated quantity for the same item specified therein or after the contract has expired, whichever comes first, and subject to the conditions provided in Section 51 of RA 9184 and its IRR. For this purpose, the Repeat Order shall be availed of only within six (6) months from the date of the last of final Delivery Order Contract for a specific item where the estimated quantity has been exhausted, or the expiration of the contract.
			2. In case Repeat Order is allowed and resorted to, the twenty-five (25%) maximum allowable quantity shall be based on the aggregate quantity of actual items ordered and delivered.
		General Conditions	All other rules governing contract implementation and termination under RA 9184 and its IRR, and relevant procurement policies shall be applicable.