Date- 7th September, 2019

Clarification to queries raised by Bidders for Medical Equipment of ALS Ambulance, Tender Document No. 004 dated, August 14, 2019.

Philips:

Sr.No	Page No	RFP Clause	Sub Clause	Medical Equipment Item	Tender Text	Query	Reply to query
1	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Unit should be lightweight compact and portable (not exceeding 6 kg)	Unit should be lightweight compact and portable (not exceeding 6-7 kg)	Weight not exceeding 8 Kgs
2	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Should have facility for printing ECG and critical events.	Should have facility for printing and monitoring 12 lead ECG and critical events. It should be upgradable to transmit 12 lead ECG from a remote site to control room.	No Change
3	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Should be US FDA and European CE certified.	Should be US FDA / European CE certified.	No Change
4	20	Section 5: Technical Specification- Medical Equipment		Defibrillator		Point to be incorporated: a. It should have screen size of minimum 8 inches colored TFT with capability to display 4 waveforms. B. Unit should have automated self-test facility with ready for use indicator. It should also have paddle contact indicators to ensure best contact with patient while giving shock. C. Charging time to 200 joules should be less than 6 seconds	Minimum Screen Size of 8 inches

AEON Medical:

Sr.No	Page No	RFP Clause	Sub Clause	Medical Equipment Item	Tender Text	Query	Reply to query
1	19	Section 5: Technical Specification- Medical Equipment		Ventilator	Ventilator: Robust (drop and water resist)	Request specifying the applicable standards like EN-60068-2-64:2008 (Random vibration), EN-60068-2-6:2008 (Sinusoidal Vibration) & EN-60068-2-27:2009 (Shocks) or EN-1789 or ISO-60601-1-12 in lieu of this, so that ambiguity and discretion are avoided at the time of evaluation.	The ventilator should have EN1789 and ISO 60601-1-2 standards for ambulance use
2	19	Section 5: Technical Specification- Medical Equipment		Ventilator	suitable for adults, children and infant up to 7 kg.	Since the weight of 7 kg. for infants would clinically translate to around 50 ml. of tidal volume, request specifying the directly settable tidal volume range to avoid ambiguity and discretion in evaluation stage.	No Change
3	19	Section 5: Technical Specification- Medical Equipment		Ventilator	Modes of ventilation:	Considering the application requirement as well as the latest guidelines, we would request you to consider including a) "CPR mode with manual / auto metronome", b) Pressure controlled ventilation with non-invasive mode as mandatory requirements.	No Change
4	19	Section 5: Technical Specification- Medical Equipment		Ventilator	iii. Optional PEEP facility	Kindly confirm that the PEEP should be integrated PEEP and not detachable PEEP on the expiratory valve.	Integrated PEEP is made mandatory facility
5	19	Section 5: Technical Specification- Medical Equipment		Ventilator	a. Inspiratory time: 0.5 - 2 Sec b. Expiratory time 0.6 -6 Sec.	Request specifying a) If separate control for inspiratory and expiratory time would be mandatory or control of respiratory rate and I:E ratio would be enough to permit compliance? b) Respiratory rate (considering the minimum tidal volume requirement as above request specifying the matching)	No Change

6	19	Section 5: Technical Specification- Medical Equipment		Ventilator	7. Equipment should be complete with carry bag, patient circuit, pressure regulator for the oxygen cylinder and relief valve.	Request a) Specifying that the pressure regulator be of same standard (European CE / USFDA) as the ventilator. b) Clarifying if the pressure regulator should have additional setting for oxygen dosaging?	All the Accessories and tubings should be USFDA/CE approved except carry bag
7	19	Section 5: Technical Specification- Medical Equipment		Ventilator	8. Should have airway pressure monitor	Although the word monitor is self-explanatory in the context of application but to avoid ambiguity and discretion at the time of evaluation, request clarifying that the airway pressure monitoring should be a electronic display and not a mere pressure gauge.	The system should have airway pressure monitoring on the display
8	19	Section 5: Technical Specification- Medical Equipment		Ventilator	9. Should have a disconnect alarm. (Visual and audible)	Kindly clarify because there are multiple clinical and technical alarms as under a) Low airway pressure, b) Tidal volume not reached, c) Low expired tidal volume, d) Patient leakage, e) System leakage, f) Apnea	The system should have both visual and audible alram for Low pressure,leakage,tube disconnection,Apnea etc
9	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump	Syringe Pump Certification	Request inclusion of product standard European CE / USFDA to the specifications.	Product standard European CE / USFDA to the specifications.
10	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump	11. Separate control for inspiratory and expiratory times and flow rate	Please clarify, as this is a part of the specification of the Syringe pump.	Deleted
11	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Defibrillator / Monitor with facility to monitor ECG, NIBP, SPO2	Request, including transcutaneous pacing and cpr feedback as a mandatory requirement for this essential life saving device in an ALS ambulance?	No change
12	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	1. Unit should be lightweight compact and portable (not exceeding 6 kg)	Though an ideal weight considering the application requirement for an essential life support device like this and request not to increase the weight to accommodate bulky hospital grade devices. But request clarifying that the specified weight is the weight of the device including batteries. But excluding all the detachable accessories.	Weight not exceeding 8 Kgs

13	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	a. Should have facility for charging from both 12V DC and 220V AC with battery backup of more than 4 hours	Kindly confirm if both the power supplies should be part of scope of supply or only the 12V DC power supply should be part of scope of supply but the device must have provision to be used with 230V AC power supply using the AC power adapter.	Yes should have both
14	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	b. Should be supplied with	Kindly confirm, if the following should be included to the scope of supply a) Any NIBP Accessories, b) Ambulance Mount, c) Accessories Bag, d) Printer paper	Yes
15	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	d. Optional item to be quoted invasive blood pressure monitoring module complete with reusable transducer.	Kindly confirm a) if one each venous and arterial measurement would be offered or two each measurement provision should be offered? b) If the device should have the option of telemetry to transmit real time data from the ambulance to the server?	No Change
16	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	6. Should be US FDA and European CE certified	Request a) Changing it to “US FDA or European CE certified”, in line with the specification for the transport ventilator, b) Inclusion of transport grade standards like: EN-60068-2-64:2008 (Random vibration), EN-60068-2-6:2008 (Sinusoidal Vibration) & EN-60068-2-27:2009 (Shocks) or EN-1789 or ISO-60601-1-12 in lieu of this, so that ambiguity and discretion are avoided at the time of evaluation, c) Clarifying if the device should be air worthy and if yes, request specifying RTCA certification.	No Change

Rabindra Surgicals:

Sr. No	Page No	RFP Clause	Sub Clause	Medical Equipment Item	Tender Text	Query	Reply to query
1	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Defib: Unit should be lightweight compact and portable (not exceeding 6 kg)	Unit should be lightweight compact and portable (not exceeding 6-7 kg)	Weight not exceeding 8 Kgs
2	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Should have facility for printing ECG and critical events.	Should have facility for monitoring and printing 12 lead ECG and critical events.	No Change
3	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Should be US FDA and European CE certified.	Should be US FDA / European CE certified.	No Change
4	20	Section 5: Technical Specification- Medical Equipment		Defibrillator		To Incorporate: It should have screen size of minimum 8 inches colored, TFT with capability to display 4 waveforms. To incorporate Unit should have automated self test facility with ready for use indicator. It should also have paddle contact indicators, to ensure best contact with patient while giving shock, Charging time to 200 joules should be less than 6 seconds	Minimum Screen Size of 8 inches
5	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump	Syringe Pump: Selectable occlusion pressure trigger level from 100mm hg to 1100mm hg to allow use over a range of applications	Change to 3 Pre set level	No Change

6	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump	AC mains (100 - 240V) and battery (lead acid) powered RS 232 serial link for remote monitoring and control of infusion.	Remove this point	Deleted
7	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump	Separate control for inspiratory and expiratory times and flow rate	Remove this point	Deleted

J D Medicare

Sr. No	Page No	RFP Clause	Sub Clause	Medical Equipment Item	Tender Text	Query	Reply to query
1	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Unit should be lightweight compact and portable (not exceeding 6 kg)	Unit should be compact and portable (not exceeding 8 kg) As per the international standard a Sturdy Defibrillator design for Ambulances will always carry a weight of 8 kg or more will meet the desired specifications. Underlining the Monitor Size of 8 inches of more with the Defibrillator Monitor will give a better visibility to the care giver while transporting the patient even during the sunlight.	8 Kgs weight approved. 8 inch screen size
2	20	Section 5- Technical Specification- Medical Equipment		Defibrillator	Should be able to deliver shock from 2-200 joules through biphasic technology	Should be able to deliver shock from 2-360 joules through biphasic technology. So that if any critical patients are unable to resuscitate with 200 joules then the option of delivering shock with higher energy of 360 joules work to resuscitate the patient	No Change

Medicon

Sr. No	Page No	RFP Clause	Sub Clause	Medical Equipment Item	Tender Text	Query	Reply to query
1	19	Section 5- Technical Specification- Medical Equipment		Ventilator		Ventilator :Minimum Display size of 7 inch with touch screen provision- This is very much mandatory for the ease of operation while transportation	LCD display of minimum 4"
2	19	Section 5: Technical Specification- Medical Equipment		Ventilator		Inbuilt Etco2 provision for convenience of intubation on the go- Etco2 is very much mandatory in order to avoid erroneous \intubation of patient	No Change
3	19	Section 5: Technical Specification- Medical Equipment		Ventilator		Battery Backup of minimum 2 hrs- Minimum battery backup of 2 hours required considering transport ventilator	4 hours battery backup
4	19	Section 5: Technical Specification- Medical Equipment		Ventilator		CPAP mode is mandatory in any emergency ventilator especially for the patient where ET tubing is required.	No Change
5	19	Section 5: Technical Specification- Medical Equipment		Ventilator		SMIV mode both in pressure & volume control help the paramedical to ensure Synchronized mandatory ventilation to severe patients	No Change
6	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump		Support 5 ml syringe- 5 ml syringe size is more convenient consider paediatric & neonatal patients	2ml to 60ml

7	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump		Display size of Minimum 2.5 inch- An LCD display provide ease of view from distance and also varied view of angle	Approved Check Corrigendum.
8	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump		Versatile Clamp to fix the pump on horizontal as well as vertical fixtures- Considering the limited space in ambulance syringe pump should have provision to fix the same on either vertical or horizontal fixture (patient bed railing etc)	Necessary Clamp to be supplied with pump to fix in the ambulance
9	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump		Rate Mode(ml/hr), Time Mode, Body Weight Mode- These modes provided flexibility to the user considering the physical characteristics of the patient.	No Change

Sarvottam

Sr. No	Page No	RFP Clause	Sub Clause	Medical Equipment Item	Tender Text	Query	Reply to query
1	19	Section 5- Technical Specification- Medical Equipment		Ventilator	Ventilator: Should be light weight (less than 4kg), robust drop and water resist and user friendly and suitable for adults , children and infant upto 7kg	Should be light weight (less than 7kg), robust drop and water resist and user friendly and suitable for adults , children and infant patient.	No Change
2	19	Section 5- Technical Specification- Medical Equipment		Ventilator	Optional PEEP facility	This point should be upgraded as peep facility should be available as main feature which is mandatory for the patient in clinical point of view	Integrated PEEP is made mandatory facility
3	19	Section 5- Technical Specification- Medical Equipment		Ventilator	Power source: compressed air/oxygen dependence on battery or AC is not desirable	This point should be upgraded as power source dependence on battery or AC power is not desirable, Air Source: Compressed air/in built Air source generated, O2 source: should be come with low flow/high flow port	Any power source is acceptable
4	19	Section 5- Technical Specification- Medical Equipment		Ventilator	with above controls , one should be able to deliver respiratory ratio of upto 1:3	this point should be upgraded with above controls, one should be able to deliver respiratory ratio of up to 1:2 as this most common clinical setting	No Change
5	19	Section 5- Technical Specification- Medical Equipment		Ventilator	F102:100% oxygen and air mix, approx. 45%	F102: 100% oxygen and air mix, approx. 40% and blender for 21% oxygenation in case of o2 failure and no availability of o2.	No Change
6	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump	Syringe Pump: Separate control for inspiratory and expiratory times and flow rate	Separate control for inspiratory and expiratory times and flow rate. This point should be deleted as nowhere terminology for syringe pump inspiratory and expiratory time exists.	Deleted
7	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump		One more point should be added drug library most common use in syringe pump	The system should have drug library for atleast 50 emergency drugs

8	19	Section 5: Technical Specification- Medical Equipment		Syringe Pump		One more point should be added branded syringe directory availability for error less delivery of drug to patient	No Change
9	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Defib: Unit should have facility for Automatic external defibrillation and manual defibrillation	Point No2. Should be upgraded as automatic external defibrillation and manual defibrillation and there should be separate monitor for the measurement of Spo2 , NIBP, ECG, As it help in clinical application to user and It will avoid chaos.	No change
10	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Should have facility for charging from both 12v DC and 220v Ac with battery backup of more than 4hrs., should be supplied with i. reusable pulse oximeter probe (two), ECG Cable -12 lead (two), ECG cable - 3 lead (two)	Should have facility for charging from both 12v DC and 220v Ac with battery backup of more than 4hrs., should be supplied with i. reusable pulse oximeter probe (two), ECG Cable -12 lead (two), ECG cable - 3 lead (two) along with this defibrillator also required adult and paediatric reusable pad incorporated in same or separately for the shock delivery	Both are okay
11	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Optional item to be quoted invasive blood pressure monitoring module complete with reusable transducer	Point no 5(D) should be deleted as it is not required while transporting patient and machine has already NIV blood pressure monitoring. Moreover it is precise measurement process performed in IPD only.	NO change
12	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Should be US FDA and European CE certified	Should be US FDA / European CE certified. To bring better competition and pricing	No change

Styker

Sr.No	Page No	RFP Clause	Sub Clause	Medical Equipment Item	Tender Text	Query	Reply to query
1	20	Section 5: Technical Specification- Medical Equipment		Defibrillator	Unit should be lightweight compact and portable (not exceeding 6 kg)	Unit should be compact and portable (not exceeding 8 kg) As per the international standard a Sturdy Defibrillator design for Ambulances will always carry a weight of 8 kg or more will meet the desired specifications. Underlining the Monitor Size of 8 inches of more with the Defibrillator Monitor will give a better visibility to the care giver while transporting the patient even during the sunlight.	8 Kgs weight approved. 8 inch screen size
2	20	Section 5- Technical Specification- Medical Equipment		Defibrillator	Should be able to deliver shock from 2-200 joules through biphasic technology	It should be able to deliver shock from 2-360 Joules through biphasic technology. Even if any critical patients are unable to resuscitate with 200 Joules then having options of delivering shocks with higher energy of 360 Joules improves shock success. Study says that Impedance change between consecutive shocks is minimal and inconsistent. Therefore, to increase current of a subsequent shock requires an increase of the energy settings. Only current alone doesn't determine shock efficacy.	No Change

Drager

Sr. No	Page No	RFP Clause	Sub Clause	Medical Equipment Item	Tender Text	Query	Reply to query
1	19	Section 5- Technical Specification- Medical Equipment		Ventilator		1. You have not asked for any power backup for the ventilator, which is a very serious concern. Since the ventilator must have enough (At least 4 – 5 hours) battery backup for smooth transportation.	4hrs battery backup
2	19	Section 5- Technical Specification- Medical Equipment		Ventilator		2. You also have not mentioned the display type of the ventilator. Which also is a big gap of tender specs, since now a days almost all transport ventilator have LCD color display of ventilation parameter.	LCD display of minimum 4"
3	19	Section 5- Technical Specification- Medical Equipment		Ventilator		3. Last but not the least, US FDA certificate should be mandatory for all types of class 2 graded equipment, since those are directly related with patient's life. To get best ventilators of the market, you should make US FDA certificate as mandatory.	Product standard European CE / USFDA to the specifications.