

Level 1 Category: Medical Equipment and Accessories and Supplies -UNSPS Code 42000000

Level 2 Category:Patient care and treatment products and supplies - UNSPS Code 42140000

Level 3 Category: Obstetrical and gynecological equipment and supplies -UNSPS Code 42143100

Level 4 Category: CTG Machine (Cardio Tocography) -Fetal Monitor -UNSPS Code 42143120

DRAFT
T/P

GEM Version 3.0

S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES	UNIT	CATEGORY OF FIELD	REMARKS	
GENERAL FEATURES								
1	Product description	--	ENUMERABLE	CTG Machine (Cardio Tocography)-Fetal Monitor			MANDATORY	
2	Type	--	ENUMERABLE	Trolley mounted	Wall mountable		GOLDEN PARAMETER	Multiselect
3	Clinical purpose	--	ENUMERABLE	For recording and analyzing the Fetal Heart Rate (FHR) and contractions of uterus during antepartum and intrapartum period			MANDATORY	
PROCUCT & FUNCTIONAL REQUIREMENTS								
1	Advanced digital signal process	--	ENUMERABLE	Yes			MANDATORY	
2	Toco and Maternally sensed fetal movements are detected both manually and automatically	--	ENUMERABLE	Yes			MANDATORY	
3	Facility of twin monitoring	--	ENUMERABLE	Yes			MANDATORY	
4	Display of FHR upto twins FHR1, FHR2 and Toco	--	ENUMERABLE	Yes			MANDATORY	
5	Heart rate offset mode to visually distinguish between the heart rates of twins with ability to offset the secondary FHR by atleast 20bpm	--	ENUMERABLE	Yes			MANDATORY	
6	Capable to simultaneously provide integrated fetal heart rate (FHR) and Uterine activity	--	ENUMERABLE	Yes			MANDATORY	
7	Blinking correspondence to each beat	--	ENUMERABLE	Yes			MANDATORY	
8	In-built / Separate Acoustic Stimulator with a separate marker on the graph for acoustic stimulators	--	BOOLEAN	Yes	No		MANDATORY,FILTER	
9	Ultrasound transducer for measuring fetal heart rate with auto correlation	--	ENUMERABLE	Yes			MANDATORY	
10	Pulse Doppler transducer frequency (MHz)	--	ENUMERABLE	=< 1.5			MANDATORY	
11	Pulse Doppler with 7 to 9 elements/crystal design for better sensitivity	--	ENUMERABLE	6 to 9	10 to 12	13 to 15	GOLDEN PARAMETER	
12	Transducer should be waterproof	--	ENUMERABLE	Yes			MANDATORY	
13	Fetal Heart Rate measurements Range (BPM)	--	ENUMERABLE	30 to 240			GOLDEN PARAMETER	
14	FHR measurement tolerance (BPM)	--	ENUMERABLE	+/-1			MANDATORY	
15	Intensity of ultrasound transducer(mW/Sq.Cm)	Must declare, =<10	NUMERIC				MANDATORY,FILTER	
16	User adjustable audio visual alaram for fetal heart rate (FHR)	--	ENUMERABLE	Yes			MANDATORY	
17	High alarm range (bpm)	--	ENUMERABLE	160 to 180			MANDATORY	
18	Low alarm range (bpm)	--	ENUMERABLE	90 to 120			MANDATORY	
19	Auto timer for NST tracing	--	BOOLEAN	Yes	No		MANDATORY,FILTER	
20	External Toco transducer unit, sealed waterproof and designed with guard ring to reduce maternal respiration artifact	--	ENUMERABLE	Yes			MANDATORY	
21	Strain gauge sensor element for measuring uterine tone contraction	--	ENUMERABLE	Yes			MANDATORY	

22	Toco Transducer measurement range, (Units)	--	ENUMERABLE	0 to 100				unit	MANDATORY	
23	Resolution for transducer measurement, (Units)	--	ENUMERABLE	+/-1				unit	MANDATORY	
24	Recorder for Fetal Heart Rate and Uterine contractions	--	ENUMERABLE	Yes				--	MANDATORY	
25	Computerized trace interpretation should be provided for antepartum monitoring of high risk pregnancies	--	BOOLEAN	Yes	No			--	GOLDEN PARAMETER	
26	Digital display or waveform of Tabular/Graphical data of the patient containing the details viz. Patient Name, ID, date and time for minimum of 24 hours.	--	ENUMERABLE	Yes				--	MANDATORY	
27	Suitable trolley with castor wheels, cover and locking facility with provision for parking the transducer etc	--	ENUMERABLE	Yes	NA			--	GOLDEN PARAMETER	
28	Size (LxWxH) (mmxmmxmm)	Must declare	TEXT					mmxmmxmm	MANDATORY	
29	Weight (Kg)	Must declare, (not more than 8Kg)	NUMERIC					Kg	GOLDEN PARAMETER	
ELECTRICAL REQUIREMENTS										
1	Power supply	--	ENUMERABLE	220+/-10% V, 50/60 Hz, AC Single phase				--	MANDATORY	
2	Input power (Watts)	--	NUMERIC	40				watt	MANDATORY	
3	In-built rechargeable battery	--	ENUMERABLE	Yes				--	MANDATORY	
4	Type of battery	--	ENUMERABLE	Li-ion				--	MANDATORY	
5	Battery back up (hrs)	Must declare, 3=<N=<5	NUMERIC	3 to 5				hr	GOLDEN PARAMETER	
6	Auto power off when machine is not in use for more than a preset time (minutes)	Must declare	NUMERIC					minute	MANDATORY,FILTER	
USER INTERFACE										
1	Colour screen monitor type	--	ENUMERABLE	TFT	LCD	LED		--	GOLDEN PARAMETER	
2	Touch screen flat panel display, tiltable and foldable	--	BOOLEAN	Yes	No			--	GOLDEN PARAMETER	
3	Display monitor size (inch)	Must declare, 7=<N=<12	NUMERIC	7 to 12				inch	GOLDEN PARAMETER	
4	Built-in Printer to print patient data & Test Results	--	ENUMERABLE	Yes				--	GOLDEN PARAMETER	
5	Type of printer	--	ENUMERABLE	High resolution Thermal printer				--	MANDATORY	
6	Selectable Print speed for real time traces (Cm/minute)	--	NUMERIC	1	1,2,3			Cm/minute	MANDATORY	
7	Print media	--	ENUMERABLE	Z folded Thermo sensitive paper				--	MANDATORY	
8	Print media sheet size (mmxmm)	Must declare	ENUMERABLE					mmxmm	MANDATORY	
9	Patient data storage and trend graph for 48 to 72 hrs with fast printing facility of stored data	--	ENUMERABLE	Yes				--	MANDATORY	
10	Fast print speed for printing stored data (Cm/minute)	Must declare	NUMERIC					Cm/minute	MANDATORY,FILTER	
11	FHR Chart printing width (mm)	Must declare	NUMERIC					--	MANDATORY,FILTER	
12	Toco Chart printing width (mm)	Must declare	NUMERIC					--	MANDATORY,FILTER	
13	Memory for storage of records (hrs)	Must declare	NUMERIC					--	GOLDEN PARAMETER	
14	Machine should be compatible with wireless connection system for central monitoring	--	BOOLEAN	Yes	No			--	MANDATORY,FILTER	
15	Machine should be compatible with wired connection system for central monitoring	--	BOOLEAN	Yes	No			--	MANDATORY,FILTER	

LIST OF ACCESSORIES										
1	FHR probe (No)	--	NUMERIC	2	3	4		No	GOLDEN PARAMETER	
2	TOCO probe (No)	--	NUMERIC	1	2	3		No	GOLDEN PARAMETER	
3	Event Marker (No)	--	NUMERIC	1	2	3		No	GOLDEN PARAMETER	
4	Fetal Simulator (No)	--	NUMERIC	1	2	3		No	GOLDEN PARAMETER	
5	Probe belt (No)	--	NUMERIC	3	4	6		No	GOLDEN PARAMETER	
6	Ultrasound gel (No)	--	NUMERIC	10	50	100	250	No	GOLDEN PARAMETER	
7	Power Cable (No)	--	NUMERIC	1	2			No	GOLDEN PARAMETER	
8	Compatible size of z folded thermal sensitive continuous paper in packets of 150 sheets each (Number of Packets)	--	NUMERIC	20	50	100		packet	GOLDEN PARAMETER	
PACKING MODE										
1	The product is packed individually in a box with all its accessories in such a way that there will be no damage during transportation	--	ENUMERABLE	Yes				--	MANDATORY	
ENVIRONMENTAL CONSIDERATIONS										
1	Storage conditions	--	ENUMERABLE	Temperature -10 deg C to 40 deg C, RH not more than 85%				--	MANDATORY	
2	Work or usage environment	--	ENUMERABLE	Temperature 5 deg C to 40 deg C, RH not more than 85%				--	MANDATORY	
CERTIFICATIONS & REPORTS										
1	Submission of Test Report from Central Govt./NABL/ILAC accredited Lab to prove the conformity to declared specification at the time of supply	--	ENUMERABLE	YES				--	MANDATORY	
2	Product certification	--	ENUMERABLE	BIS	EU-CE	US-FDA		--	MANDATORY,FILTER	Multiselect
3	Certification, performance and safety standards specific to the device	Must Declare like IEC 60601-1:2012, IEC 6060-1-2:2014, ISO 14971:2007	TEXT					--	MANDATORY	
4	Submission of all the certifications and test reports to the buyer along with supplies on demand	--	ENUMERABLE	Yes				--	MANDATORY	
INSTALLATION & TRAINING										
1	Supplier to perform installation, safety and operation checks before handover	--	ENUMERABLE	Yes				--	MANDATORY	
2	Agreed for installation in case if machine requirement is for remote/field locations and to provide services onsite to end user	--	BOOLEAN	Yes	No			--	MANDATORY,FILTER	
3	Training of users in operation and basic maintenance shall be provided	--	ENUMERABLE	Yes				--	MANDATORY	
WARRANTY & MAINTENANCE										
1	Warranty (Yrs)	--	NUMERIC	3	4	5		Years	GOLDEN PARAMETER	
2	Provision of international warranty for 5 years	--	BOOLEAN	Yes	No			--	MANDATORY,FILTER	
3	User technical and maintenance manual detailing complete maintaining schedule with routine maintenance should be provided	--	ENUMERABLE	Yes				--	MANDATORY	
4	Contact details of manufacturer, supplier and local service agent to be provided	--	ENUMERABLE	Yes				--	MANDATORY	