S/No. 4

APPENDIX-1D (i)

SL NO	NAME OF THE EQUIPMENT	IS IT AVAILABLE IN PET.IF YES MENTION THE SERIAL NO PET	QRS AVAILABLE OR NOT
1	CRYOCERVICAL CAUTERY COMPLETE WITH GAS CYLINDER	YES(S.NO 370)	YES

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)

Recommended / Not Recommended

Appendix-1D (iii)

1. QRs/SPECIFICATIONS & TRIAL DIRECTIVES OF "HYSTEROSCUPE FOR DIAGNOSTIC AND THERAPEUTICPURPOSE WITH ACCESSORIES (HYSTEROSCUPE TELESCOPE)"

INSTRUMENTS WITH SPECIFCATION	Procedure suggested for trail for board of Officers	Resulted expected/ desired
Hysteroscopy: **1. HIGH-DEFINITION MEDICAL GRADE MONITOR-for hysteroscopy :** Wide Screen Monitors Having the following features: A. HDTV Display in 16:10/16:9 HDTV format. B. LCD/LED Crystal display. C. 26" High Resolution HD video Medical grade monitor D. Resolution: 1920 x 1080 Pixels E. SDI/HD-SDI, Composite, S-Video RGB, DVI-D, VGA input, S-VHS-2 nos, should also have same video output F. All required cables and connectors, which should be specified G. TFT Screen stand/ fixtures for connecting to pendant system/Ceiling Light Arm H. Dust-proof and Drip water protected **2. CAMERA CONTROL UNIT AND CAMERA HEAD-for hysteroscopy:** High definition three chip Endoscopic camera system should have following features: a) Digital full HD technology (truly HD), should be upgradable to 3-D technology (future compatible). System should have inbuilt recording (video/picture) full HD with image enhancement mode and should be controlled from camera head. b) Progressive Scan	Board should check physically during demonstration OEM should submit an undertaking and documents in this regard	As per specification

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG (med)
Recommended/Not Recommended

Appendix-1D (iv)

INSTRUMENTS WITH SPECIFCATION	Procedure suggested for trail for board of Officers	Resulted expected/ desired
c) Camera control unit with three chip HD camera head having HD CCD chip of same aspect ratio of 16:9 and camera control unit should be able to produce following video output: DVI-D-2 nos, SDI-1 no, Composite Video d) Three chip camera head should produce at head itself pure digital signal with high definition video (1920*1080PI) with aspect ratio of CCD chip and video format of 16:9 or 16:10 e) System should have integrated Optical Zoom (12-28mm, 2 Z) to enhance image size and focus lens/rings to make it fully soak-able and waterproof f) System should be able to optimise all the settings and should be ready as soon as connected to camera control unit. g) Three chip Camera control in it should be compatible with all the three chip camera head and the company should provide standby facility within 48 hours of breakdown. h) Should be compatible for remote controlled operation of various features i) Camera should be suitable for both laparoscope, hysteroscope & resectoscope j) Should have Integrated gain, shutter, Enhancement, white balance with brightness control. k) All camera functions to be controlled from camera head buttons and through key board at camera control unit to make it controllable from both sterile and non-sterile zone 3. **Technical Specification** • Image Sensor CCD Chip • Pixels 1920 X 1080 • AGC Microprocessor controlled		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)
Recommended / Not Recommended

Appendix-1D (v)

INSTRUMENTS WITH SPECIFCATION	Procedure suggested for trail for board of Officers	Resulted expected/ desired
4. LED LIGHT SOURCE with fibre optic cable-for hysteroscopy: a) LED - 175 light source equivalent to Xenon 300 Watt. b) Manual and automatic adjustment of light intensity should be possible from camera head. c) Lamp life 30,000 hrs or more with at least two spare bulb d) Display of lamp life/Bulb usage meter warning light e) Long (250 cm or more) fluid and fibre-optic light cable of diameter 4.8-5 mm f. Light Weight g. Certified for National International safety standard normal **f)** Should be able to produce colour temperature of 6000k. **5. HYSTEROPUMP/HYSTEROMAT:** a) Irrigation system for use in hysteroscopy b) Irrigation function is performed by electric pump c) Maximum parameters for hysteroscopy are automatically set d) Precise pre-setting of volume and pressure of suction and irrigation parameters via touch keys e) Adjacent display scales for set values and actual value to ensure safe monitoring. f) To be used with pressure regulated from 35 to 150mm of Hg or more, and flow rate regulated from 0-500ml/min. Power supply 100-240 VAC, 50/60 Hz, Mains cord g) Connecting cable 100 cm, one pedal foot switch/Touch screen. h) Hysteroscopic tubing set i) Irrigation tube **j)** Bottle 1 L or more, sterilisable with bottle stand and bottle stand holder k) Silicon Tubing Set for suction, sterilisable. **l)** Hysteromat should be from same manufacturer as of Hysteroscope		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ATs(med)
Recommended / Not Recommended

Appendix-1D (vi)

INSTRUMENTS WITH SPECIFCATION	Procedure suggested for trail for board of Officers	Resulted expected/ desired
6. HYSTEROSCOPE TELESCOPES STANDARD: a) Operating and Compact-Hysteroscope, Forward-Oblique Telescope 30 degree, enlarged view, diameter 4.0 mm, length 30 cm, autoclavable, fibre optic light transmission incorporated with angle light guide adaptor. **b)** Forward-Oblique Telescope 30 degree, enlarged view, diameter 4.0 mm, length 30 cm, autoclavable, fibre optic light transmission incorporated. **7. Diagnostic Hysteroscope Sheath:** with obturator 5mm diameter for the above 4 mm Hysteroscope telescopes (item 6), with luer lock adapter. **8. Operative Hysteroscope Sheath:** with obturator, continuous irrigation outer and inner sheath for the above 4 mm hysteroscope telescope (item 6) with channel for semi-rigid 5/8 fr size instruments. Should have facility for self-closing sealing system for precise irrigation. **ACCESSORIES:** a) Hysteroscopy flexible / semi rigid instruments which should be adaptable to above sheath (item C), 5/8 fr. Diameter. Foreign body grasping forceps. b) Scissors-Scissors semi rigid, blunt tips, 5 Fr., length 33-36cm, single action jaws c) Scissors semi rigid, pointed jaws,5 Fr., length 33-36cm, single action jaws, semi-rigid. d) Biopsy and grasping forceps – Biopsy – and Grasping Forceps semi rigid, 5 Fr., length 33-36cm, double action jaws. e) Punch forceps – Punch through cutting semi rigid 5Fr, length 33-36 . **f)** Tenaculum grasping forceps, semi rigid, size 5Fr, length 33-36cm.		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG (med)

Recommended / Not Recommended

Appendix-1D (vii)

INSTRUMENTS WITH SPECIFCATION	Procedure suggested for trail for board of Officers	Resulted expected/ desired
g) Needle electrode and ball electrode-Unipolar – high frequency cords. h) Bipolar vaporising electrode . i) Myoma fixation screw. j) Palpation probe. **k)** Polypectomy loop. **RESECTOSCOPE FOR TCRE BI-POLAR SET:** a) Forward-Oblique Telescope 12°, enlarged view, diameter 4 mm, length 30 cm, autoclavable, fibre-optic light transmission incorporated, with angle light guide adaptor. b) BIPOLAR WORKING ELEMENT SET – BIPOLAR Working element to be used with 26FR Resectoscope sheath: Motion by means of a spring. The thumb support is movable. Return of the loop is controlled by thumb and in rest position the electrode should rest inside the operating sheath, to be used with 4 mm hysteroscopy telescope. Should work in saline c) BIPOLAR CUTTING LOOP –BIPOLAR cutting loop 24 Fr should work in saline d) BIPOLAR CUTTING LOOP SMALL – Cutting Loop 24Fr, bipolar, small should work in saline e) BIPOLAR ELECTRODE POINTED –Coagulating electrode 24Fr, bipolar, pointed should work in saline f) BIPOLAR ELECTRODE BALL END – Coagulating Electrode 24Fr, bipolar, ball end should work in saline g) BIPOLAR LOOP STRAIGHT – cutting Loop 24Fr, bipolar, straight should work in saline		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)

Recommended / Not Recommended

INSTRUMENTS WITH SPECIFCATION	Procedure suggested for trail for board of Officers	Resulted expected/ desired
h) RESECTOSCOPE SHEATH FOR BIPOLAR – Continuous Flow resectoscope Sheath 26 Fr., for Bi-Polar including connection tubes for in-and outflow, 2 LUER-lock adaptors, diameter 8mm, oblique beak, rotating inner tube, with ceramic insulation, for use with working element should work in saline i) OBTURATOR – Obturator, for use with the Resectoscope sheath j) FIBRE OPTIC CABLE – Fibre Optic Light Cable, diameter 3.5 mm, length minimum 300 cm. k) All Possible accessories of the equipments should be quoted. The specific accessory and its quantity will be decided on the basis of actual requirement. l) The codes and rates of all relevant individual accessories should be quoted separately with clear mention of period of validity of rates **Endoscopic trolley-for hysteroscopy:** (Should be from the same OEM providing hysteroscopy system). a) Made of stainless steel/Epoxy coated metal b) Portable on 4 antistatic dual castors, 2 with locking brakes c) Central monitor holder d. CO2 cylinder holdere. d) Required number of shelves for housing all the units of the set e) Adjustable arm for fixation to either side for fixing the TFT monitor f) One drawer unit with lock and key g) Cable Manage h) Power box with concealed wiring for providing electrical connections of proper rating to all the units. i) Modular in nature j) Should be able to add shelves and components later if required.		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)
Recommended / Not Recommended

Appendix-1D (ix)

INSTRUMENTS WITH SPECIFCATION	Procedure suggested for trail for board of Officers	Resulted expected/ desired
ELECTROCAUTERY COMPATIBLE WITH LAPAROSCOPE, HYSTEROSCOPE AND RESECTOSCOPE: a) Should have unipolar cutting and coagulation as well as bipolar cutting and coagulation modes and have the facility of blending cutting and coagulation in different ratios and degree – soft, standard and / or forced coagulation and spray coagulation. b) Arc controlled cutting with a pre selectable power of 200 watts in both unipolar and bipolar mode. c) Arc controlled coagulation with a pre selectable power of 120 watts in both unipolar and bipolar modes. d) Auto stop function with automatic power – off on completion of coagulation process. e) Automatic start function for bi-polar coagulation. Should be operable both in hand and foot mode and should have hand control switch on the handle of the electrode. Bipolar application with irrigation with sodium chloride f) Endoscopy mode with reduced voltage out put for use with fine endoscopic electrodes. (micro-function) g) Should be compatible with under water operative procedures h) It should have neutral electrode monitoring though a patient contact system. i) It should have automatic high frequency power cut off by autocoagulation stop and autostart facility j) The unit should have the facility of self-testing for trouble shooting k) Visual and acoustic signs of HF activation by different coloured indicators and different acoustic tones for cutting and coagulation l) Unit should have safety monitoring circuit in event of malfunction for output monitoring. Neutral electrode connection. Automatic self test and automatic power cut off in event of malfunction. Ground leakage current (LF/HF) HF application time		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG (med)
Recommended/ Not Recommended

Appendix-1D (x)

INSTRUMENTS WITH SPECIFCATION	Procedure suggested for trail for board of Officers	Resulted expected/ desired
m) Power supply 230VAC, 50/60 Hz n) The unit should be supplied with all standard accessories such as electrode, foot switch, Twin earth pad, bipolar forceps with Cord, Electrode Handle with switches, neutral plate, ball electrodes, Loop electrodes, variable output power for all types of currents o) Trolley should be provided for electrocautery. **p)** Cautery system should be upgradable for vessel sealing device **MISCELLANEOUS ITEMS:** 1)Sterilisation/Disinfection Tray: a. Disinfection/Sterilization tray with sieve, tray to lift size: 27"X5"X5" (LXBXD) b. Suitable autoclavable plastic tray double tray for sterilization and storage for hand instruments of minimum 20 hand instruments preferably from OEM 2)Formalin Chamber (Imported/Indian make): Formalin Chamber made of virgin Acrylic 4.5mm thickness; size: 26"X8"X8" (LXBXH) with three tray, for sterilising the Hysteroscope **ENVIRONMENTAL FACTORS**: 1) The unit shall be capable of being stored continuously in ambient temperature of 0-50 deg C and relative humidity of 15-90% 2) The unit shall be capable of operating continuously in ambient temperature of 10-40 deg C and relative humidity for 15-90% (H.) **POWER SUPPLY**: 1) Power input to be 220-240VAC, 50Hz fitted with Indian power-plug 2) UPS for all systems of adequate rating for power supply to the system for 60 minutes.		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)
Recommended / Not Recommended

Appendix-1D (xi)

INSTRUMENTS WITH SPECIFCATION	Procedure suggested for trail for board of Officers	Resulted expected/ desired
STANDARDS & SAFETY: 1) Should be USFDA or European CE approved product 2) Electrical safety conforms to standards for electrical safety IEC 60601-1 General requirements (or equivalent BIS Standard) 3) Shall meet internationally recognised standard for electro Magnetic compatibility (EMC) for electro medical equipment: IEC-60601 1-2:latest edition or Equivalent BIS) or should comply with 89/366/EEC/;EMC directive as amended Certified to be complaint with IEC 60601-2-2 Medical Electrical Equipment part 2-2: Particular requirements for the safety of equipment mentioned above-wherever applicable		

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Recommendation of ADG(med)
Recommended / Not Recommended

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Presiding Officer

APPROVED / NOT APPROVED

DIRECTOR GENERAL
BORDER SECURITY FORCE

APPENDIX-2D (i)

SL NO	NAME OF THE EQUIPMENT	IS IT AVAILABLE IN PET.IF YES MENTION THE SERIAL NO PET	QRS AVAILABLE OR NOT
1	HYSTEROSCOPE FOR DIAGNOSTIC AND THERAPEUTIC PURPOSE WITH ACCESSORIES (HYSTEROSCPE TELESCOPE)	YES (S,NO 359)	NA
2	COLPOSCOPE FOR GYNAECOLOGICAL EXAMINATION	YES (S.NO 322)	NA

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)

Recommended/ Not Recommended

Appendix-2D (ii)

1. QRS/SPECIFICATIONS AND TRIAL DIRECTIVES OF "COLPOSCOPE (FOR GYNECOLOGICAL EXAMINATION)"

Sl. No.	SPECIFICATIONS	Procedure suggested fortrial for board of officers	Result expected/ Desired
A.	1. Should have > 100 TV Lines std. > 1200 TV Lines (Gamma ON). 2. Should have full HD – 1920 x 1080 resolutions. 3. Should have CCD sensor – (1/3 Type Exmore CMOS sensor). 4. Should have aspect 16:9 (HD). 5. The video colposcope must have magnification from min. 1 x to max. 45 x. 6. Facility to increase and decrease the light intensity. 7. Should have 20,00,000 no. of pixels. 8. Should have full HD component output : Y Pb Pr. 9. Magnification indicator should be on the video colposcope. 10. High MCD super bright white shadow less LED light for true color reproduction. 11. Auto focus range should be up to 30-40cm. 12. Facility for fast focusing, zooming, image freeze using thumb on the hand held unititself. 13. Acetic test timer and magnification indicator should be displayed on screen. 14. There must be Electronic Green Filter in the hand held unit without decrease inillumination. 15. Control panel should have feather touch and water proof buttons. 16. Facility for fast auto/manual focusing. 17. It should be equipped with Gamma Processor to enhance vascular structure. 18. Should be integrable to LAN and HIS. 19. Should be USFDA or European CE approved.	Board should check physically during demonstration. OEM should submit an undertaking and documents in this regard.	As per specification.

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)
Recommended/ Not Recommended

Appendix-2D (iii)

Sl. No.	SPECIFICATIONS	Procedure suggested fortrial for board of officers	Result expected/ Desired
B.	1. Upgradable software. 2. Should have facility to generate Cryo-Surgery report. 3. Should have facility to masking, marking and highlighting of any abnormalities. 4. Image capturing while recording/playing. 5. Final reports with one, two, three & four images with facility to adjust height & widthof images. 6. Referral linked images with findings for comparison. 7. Should be able to wow three visits of patient on search of patient ID with displayof all 3 visits simultaneously. 8. Facility to save & send the report through e-mail in pdf format. 9. Online support facility (through internet) for software. 10. Colposcopy software would run on window 8 / windows XP software. 11. Facility to make colposcopy images with the colposcopy report on hard copy. 12. Facility to store still images, cine loop or procedure on CD. 13. Software should be compatible with both desktop & laptop, no need of separatecapture card. 14. Should have REID revaluation chart in tabular form.	OEM should submit an undertaking and documents in this regard.	As per specification. Recommendation of ADG(med) Recommended/ Not Recommended
C.	**Company has to provide Desktop Computer with :** 1. CPU intel Core i5 2. RAM 4 GD 3. Hard Disk : 500GB 4. Window 8 Home basic or better 5. DVD Writer 6. Inkjet Printer 7. Computer should be fitted in imported fiber body workstation.	OEM should submit an undertaking and documents in this regard.	As per specification.
D.	**Company should provide : 24" Flat Screen High Definition Monitor :** 1. Should be high definition (HD) of 24" with side screen.		

Member-I | Member-II | Member-III | Member-IV | Member-V | Member-VI | Member-VII | Member-VIII | Member IX | Member-X | Member-X | Member-XI | Member-XII | P.O

Sl. No.	SPECIFICATIONS	Procedure suggested fortrial for board of officers	Result expected/ Desired
	2. Should have resolution of 1920 X 1200 (WUXGA) 3. Should be fully compatible with OR video control application. 4. Should have surgeon specific user selectable setting. 5. Should have low voltage DC power input, 24V. 6. Should have Class-I medical Device Certification. 7. Should have fastest response time (10-15 ms). 8. Should have PIP facility. 9. It should consist of Multi-Modality Image viewing inputs: HC-SDI, HD-RGBS/Y, Pb Pr, DVI V Composite : Syn-On-Green.	OEM should submit an undertaking and documents in this regard.	As per specification.

2. QRS/SPECIFICATIONS AND TRIAL DIRECTIVES OF "CRYO CAUTERY MACHINE WITH NITROGEN CYLINDER WITH REGULATOR"

Recommendation of ADG (med)
Recommended / Not Recommended

Sl. No.	SPECIFICATIONS	Procedure suggested for trial for board of officers	Result expected/ Desired
A.	1. Operating Pressure Range: 40-60 bar. 2. Coolant: N2O or CO2 in two cylinders (A Type). 3. Gas consumption for freezing: ca. 35g – 50 g/min. 4. Max. exhaust gas volume: 40-60 l/min. 5. The unit should have Manometer to monitor operating pressure. 6. A different indicator lamp to indicate freezing and defrosting phase. 7. Should have a connection pile for gas exhaust. 8. It should be mounted in a cart with cylinder case for easy mobilization. 9. Activation should be via footswitch. 10. Min. Freezing temperature should reach within 5 seconds. 11. It should be supplied with multiple different sized probe-tips to cater for cervical lesionof all 12. All cryo probes and accessories should be autoclavable. 13. Should be European CE or USFDA approved. 14. Minimal maintenance, flawless performance, available with knob to regulate pressure	Board should check physically during demonstration. OEM should submit an undertaking and documents in this regard.	As per specification.

Member-I | Member-II | Member-III | Member-IV | Member-V | Member-VI | Member-VII | Member-VIII | Member-IX | Member-X | Member-X | Member-XI | Member-XII | P.O.

Appendix-2D (v)

3. GAS/SPECIFICATIONS AND TRIAL DIRECTIVES OF "ETO STERILISER

Sl. No.	SPECIFICATIONS	Procedure suggested for trialfor board of officers	Result expected/ Desired
1	The ETO gas sterilizer should be fully automatic type for the sterilization of heat sensitive plastic items.	Board should check physically during demonstration. OEM should submit an undertaking and documents in this regard.	As per specification.
2	The dimension of the sterilizer should have at least 1500mm depth, 800mm width and 1600mm height.		
3	Technical data- a. Sterilization gas: Ethylene oxide 100% b. Sterilization method: Cold sterilization ofheat sensitive materials. c. Operating temperature range: 37-55 deg.Centigrade. d. Number of doors: One		
4	The sterilization chamber should be made up of suitable alloy which is resistance to corrosion and ETO gas.		
5.	This should be insulated against heat chamber emission.		
6	The construction of the chamber, door and all contact parts should be rust proof. It should be made up of stainless steel of 304/316 grade or rust proof anodized aluminum (HE 30).		
7	The inner surface should be smoothly finished to minimize gas deposits.		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)

Recommended / Not Recommended

Sl. No.	SPECIFICATIONS	Procedure suggested fortrial for board of officers	Result expected/ Desired
8	The sterilizer door should have a quick release locking arrangement. The door locking should be automatic. There should not be any handle at door to avoid tedious locking process. There should be provision for door push to lock the door and touch screen to unlock the door.		
9	There should have safety interlocking arrangement for the door so that the sterilization process does not start unless the door is properly locked in position and during the programmer run, it should not open unless the residual gas has completely eliminated from the chamber.		
10	The sterilizer should have suitable mechanism to separate and evacuate residual gas from chamber.		
11	The sterilizer should have following cycle programmers-		
	a. Sterilization cycle for heat sensitive objects that ensure temperature from 37^0C-55^0C with subsequent aeration for protection of the operating personnel. Aeration cycle / programmer to extract residual gas out of the sterilized objects after each sterilization cycle. b. Automatic chamber evacuation cycle with subsequent venting before releasing the door lock for opening, thereby prohibiting exposure of the operating personnel by gas dissolving from the chamber walls during shut down period.		

Recommendation of ADG (med)

Recommended / Not Recommended

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Appendix-2D (vii)

S. No.	SPECIFICATIONS	Procedure suggested fortrial for board of officers	Result expected/ Desired
12	There should be appropriate pollution control device for safe disposal of ethylene oxide like catalytic converter or equivalent technology / gas disposal management to be as per local pollution control norms, if any.		
13	The sterilizer should have chamber capacity of at least 240 liters.		
14	Should be suitable for 3 carriage basket for sterilization load.		
15	The ETO cartridge puncturing mechanism must be automatic and must not require any manual operation during sterilization process.		
16	The system should not require any pneumatic air supply or compressor.		
17	The entire system should be oil free.		
18	In case if the ETO cartridge does not puncture inside the ETO machine, then there should be an option for alarm and it should be displayed that "cartridge puncture failure".		
19	One complete sterilization cycle should contain all the phases and it should be finished within 8-10 hours. All time-based parameters must be mentioned in printing.		
20	The temperature, pressure and status (along with all alarms) of the cycle must display on HMI screen duringsterilization process.		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG (med)
Recommended/ Not Recommended

Sl. No.	SPECIFICATIONS	Procedure suggested fortrial for board of officers	Result expected/ Desired
21	It should have minimum of 10" color display touch screen for operation.		
22	During sterilization cycle, the chamber pressure must maintain negative pressure.		
23	There should be reminder for ETO cartridge and fill water (RO water) before the start of cycle.		
24	There should be a noise proof and vibration proofvacuum pump for the evacuation of air, gas and aerate the load. Vacuum level should be -850mbar.		
25	There must be alarm in case of vacuum / air break could not achieve in desire time and also for hightemperature.		
26	There should be provision to allow the operator/user to monitor and access sterilization cycle through a smartphone.		
27	The touch screen should have 21CFR part 11 features like audit trail, alarm longing and multiple password.		
28	The ETO sterilizer should have compliance to ISO 9001. (Certificate has to be produced by the equipmentmanufacturer)		
29	The ETO sterilizer should have compliance to ISO13485. (Certificate has to be produced by the equipment manufacturer)		

Recommendation of ADG(med)

Recommended / Not Recommended

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Appendix-2D (ix)

S. No.	SPECIFICATIONS	Procedure suggested fortrial for board of officers	Result expected/ Desired
30	The ETO sterilizer should have compliance to OSHA/NIOHA/OHSAS 45001 exposure monitoring.		
31	The ETO sterilizer should have compliance to ISO 14937. (Certificate has to be produced by themanufacturer)		
32	The vendor should provide 200 number of ETO cartridges along with the sterilizer.		
33	The vendor should disclose the list of consumables required for each cycle of sterilization process.		
34	The vendor should mention clearly the price of any accessories or consumable required to run a sterilization cycle. And the price should be valid during the warranty and CMC period.		
35	The vendor should mention clearly the price of any accessories or consumable required to run a sterilization cycle. And the price should be valid during the warranty and CMC period.		
36	The vendor has to undertake the supply, installation, testing and commissioning of the ETO sterilizer.		
37	The necessary civil, electrical and plumbing works if required for the installation of ETO machine has to be done by the vendor. The vendor may inspect the installation site prior to quoting the price.		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG (med)
Recommended / Not Recommended

Appendix-2D (x)

No.	SPECIFICATIONS	Procedure suggested fortrial for board of officers	Result expected/ Desired
38	All regulatory requirements (including the safe disposal of exhausted gas from the machine) for the safe installation of ETO sterilizer should be incorporated within the site. The EO gas aeration line should be installed with copper pipe.		
39	The equipment should have 05 (five) years of warranty		

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(Dr. Rakesh Tiwari)
CMO (SG)
(Anaesthesia),
ITBP **Member-VII**

(Dr. Shaifali Gupta)
Comdt /Spl. Gr.I
(Ophthalmology), ITBP,
Member-VIII

(Dr. Rajkamal Nimesh)
Comdt /Spl. Gr-I (Surgery),
ITBP,
Member-IX

(Dr. Gaitri Devi)
CDS (SG), (Dental),
SSB
Member-X

(Dr. Neeraj Kumar)
CMO, (Medicine),
ITBP
Member-XI

(Dr. Soumyesh Ghosh)
Comdt./Spl. Gr.I
(Pathology), ITBP
Member-XII

Recommendation of ADG (Med)
Recommended / ~~Not Recommended~~

(Dr. A C Bhardwajan)
DG (Med.), RH, ITBP, Gr. Noida
Presiding Officer

APPROVED / ~~NOT APPROVED~~

DIRECTOR GENERAL
BORDER SECURITY FORCE