

REQUEST FOR INFORMATION (RFI)

Category of items: Medical Equipment for Cervical Cancer

Date of the RFI: 29 August 2021

Closing Date for receipt of RFI: 05 September 2021, 1500 Hours Bangladesh Standard time

Reference: RFI/BGD/2021/001

Address: procurement.bangladesh@unfpa.org

Description of requirements:

UNFPA is inviting Request for Information (RFIs) from eligible suppliers in respect to the provision of a full range of Medical Equipment for Cervical Cancer. The list of the items are:

No.	Short Description of Product
1.	Mobile Colposcope
2.	Optic Colposcope with monitor and screen
3.	Optic Colposcope (without monitor)
4.	Thermo Coagulator
5.	Handheld Thermo Coagulator
6.	Electrosurgical Equipment

The details specification is attached as Annex 1

Potential Suppliers

This RFI is addressed to (a) manufacturers of Medical Equipment for Cervical Cancer and (b) traders with experience in the sourcing and supply of Medical Equipment for Cervical Cancer.

UNFPA is particularly interested in identifying competitive sources of supply that can offer the complete range of products listed above.

Only suppliers with a Quality Management System in conformity with at least one of the following standards are invited to express interest:

- (a) ISO 9001/ISO 9002
- (b) ISO 9001:2000
- (c) ISO 13485 / ISO 13488
- (d) EN 46001 / EN 46002
- (e) Japan QS standard for medical devices # 1128
- (f) United States QS (21 CFR part 820)

Procedure for submission of RFI:

Interested suppliers are encouraged to **complete the attached form** and return it to UNFPA by e-mail to procurement.bangladesh@unfpa.org on or before the indicated deadline.

Note:

- (a) Please share **estimated** FOB price in USD (\$) for the items. UNFPA is seeking to identify suppliers interested in participating in a future bid.
- (b) **No queries shall be entertained by UNFPA on the conformity of the suppliers' products** at this stage.
- (c) **This RFI does not constitute a solicitation.** UNFPA reserves the right to change or cancel the requirement at any time during the RFI and/or solicitation process. UNFPA also reserves the right to require compliance with additional conditions as and when issuing the final solicitation document. Submitting a reply to an RFI does not automatically guarantee receipt of the solicitation when issued.

GUIDELINES FOR ELECTRONIC SUBMISSION

1. Supplier's shall make clear reference to the specific RFI in the subject field as instructed, otherwise proposals may be rejected. Clearly specify: [RFI_Medical Equipment For Cervical Cancer_2021](#), [company name](#) specify in the subject field.
2. Responses received at the procurement.bangladesh@unfpa.org mailbox are kept undisclosed and shall not be opened before the scheduled opening date.
3. E-mail submission shall not exceed **20 MB**. An auto-generated response will respond to emails received by the procurement.bangladesh@unfpa.org email box.

Annex-1: Request for Information Form for Medical Equipment for Cervical Cancer

Item No.	UNFPA proposed specifications	If Supplier is capable to deliver (Yes/No)	Estimated FOB price in USD	Manufacturer name & Country of Origin	Estimate delivery lead time in days
1	Product Name: Mobile Colposcope				
	Product Description: Digital device for examinations of the tissues of the vagina and cervix. Small, light, portable, internet connected colposcope, with legged stand. Digital smart phone-like screen capable of taking picture and video of cervix without touch. With wire-grid polarizer for glare reduction. The digital screen should allow adjustment of picture size, focusing light and magnification of the cervix. It must be capable of uploading the biometric and digital pictures of cervix to the secured, encrypted, HIPAA-compliant web browser for confirmation of diagnosis, quality assurance, treatment, and referral guidance, using minimal bandwidth internet. Also, it must allow video streaming of the examination in real-time between the point-of-care and a remote expert.				
	Technical specifications: Illumination: LED, approx. 6000k - 3.6V/3W. Filter: Digital green filter. Display: Super AMOLED HD, approx. 5.2". Working Distance: approx. between 250mm-400 mm. Image magnification: at least 16x between optical and digital (4.0X optical / 16X with digital zoom). Resolution: approx. 13 MP. Video: Full HD, approx. 1920x1080. Connectivity: Wi-Fi and Bluetooth. Power: Micro USB charger 5V DC. Battery: Rechargeable. Capable of holding charge for more than 24 hours.				
	Supplied with: 1 x Legged stand (Tripod stand need). 1 x Transport case. 1 x Battery charger and cables. 1 x Instructions for use. 1 x Spare battery				
	Accessories/ spare parts/consumables: Spare battery (1x, as mentioned above)				
	Instructions for use: Instructions for use or user manual must be provided in 3 languages (English, French and Spanish). It should describe the operation instructions for the equipment, and it should include installation, maintenance and cleaning, storage conditions, safe disposal, operation, training, etc.				

Item No.	UNFPA proposed specifications	If Supplier is capable to deliver (Yes/No)	Estimated FOB price in USD	Manufacturer name & Country of Origin	Estimate delivery lead time in days
	Packaging & Labelling: Unit presentation 1 (one) device per box w/accessories Symbols used according to ISO 15223 (Manufacturer's product code or reference number, Manufacturer identification, Address of the manufacturing site, Storage Conditions, etc.).				
	Warranty: The equipment must be new, not used. At least 24 months from the date of commissioning.				
	Regulation & conformity requirements FDA 510k Premarket registration (class II) or CE certificate (for class IIa, with Notified body number).				
	Safety & product Standards: Bidder shall furnish the documentary evidence to demonstrate that the good it offers meet the international safety & regulatory standards providing a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards: <ul style="list-style-type: none"> ISO 13485:2016 Medical devices - Quality management systems ISO 14971:2012 Medical devices - Application of risk management to medical devices ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - 				
	Part 1: General requirements <ul style="list-style-type: none"> HIPAA compliant - Health Insurance Portability and Accountability Act. IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices 				
	Environmental requirements: Rohs compliance				
	Special requirement for product no. 1 <ol style="list-style-type: none"> User manual should be explained in English language. If motion sensor is not available foot switch or hand switch can be added. Device Capacity should be at least 128GB Anti-blur camera with stabilizer Screen with motion sensor Encrypted data transfer facility to PC/laptop to server and viewing app 				
2	Product Name: Optic colposcope with monitor and screen				

Item No.	UNFPA proposed specifications	If Supplier is capable to deliver (Yes/No)	Estimated FOB price in USD	Manufacturer name & Country of Origin	Estimate delivery lead time in days
	<p>Product Description: Medical device for examinations of the tissues of the vagina and cervix. Colposcope with Video Camera, Monitor, Printer & Media Workstation Software including PC. Binocular colposcope with a cold light source, swing-in green filter and, incorporating a video camera. Mounted on a mobile floor stand and connected to stand with an adjustable arm, which allows the colposcope head to be placed more precisely and without interfering with the operator's comfort. Inclined binocular head, which can also be used as straight binocular tube. 5 Steps magnifications changer, depending on the combination of objectives and oculars. With manual fine focusing and adapter for laser systems.</p> <p>Technical specifications: Illumination: Coaxial illumination with lamp of cold light source (Halogen, LED or Xenon), fiber optic cable. Filter: Green filter. Working Distance with objectives: 250 mm or 300 mm. Magnification Changer: 5 steps, approx. between 0.4x, 0.6x, 1x, 1.6x, 2.5x or more. Total magnifications: approx. between 3x up to 21x. Visual Field: approx. 60mm - 8.5mm in 5 steps or more Fine Focusing: manual, Focusing objectives: f=250mm and f= 300mm Binocular Tubes: f = 125 mm 45° straight or inclined Adapted HD video camera, 14MP or higher CMOS sensor, HD quality with HDMI output approx. 1920(H)x1080(V) USB video, Image recording system with software for video documentation, PC, Printer, all compatible. Suspension Arm: approx. L= 630mm or more Power: 220VAC-230VAC, 50Hz</p> <p>Supplied with: 1x Dust Cover. 1x Objectives. 1x Online UPS, 2KVA or more. 2x Fiber optical cable 1x Laser adapter. 1x PC with softwares for use with colposcope image. 1x 21" or above color LED Monitor with mounting set. 1x Laser Printer. 1x Table for PC and Printer. 1x Multi Plug High Quality, 1 x Instructions for use.</p> <p>Accessories/ spare parts/consumables: Provide with alternative quotation of spare parts: Spare Lamps - 20 pcs.</p>				

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	<p>Instructions for use: Instructions for use or user manual must be provided in 3 languages (English, French and Spanish). It should describe the operation instructions for the equipment, and it should include installation, maintenance and cleaning, storage conditions, safe disposal, operation, training, etc.</p> <p>Packaging & Labelling: Unit presentation 1 (one) device per box w/accessories Symbols used according to ISO 15223 (Manufacturer's product code or reference number, Manufacturer identification, Address of the manufacturing site, Storage Conditions, etc.).</p> <p>Warranty: The equipment must be new, not used. At least 24 months from the date of commissioning.</p> <p>Regulation & conformity requirements FDA 510k Premarket registration (class II) or CE certificate (for class IIa, with Notified body number).</p> <p>Safety & product Standards: Bidder shall furnish the documentary evidence to demonstrate that the good it offers meet the international safety & regulatory standards providing a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> ISO 13485:2016 Medical devices - Quality management systems ISO 14971:2012 Medical devices - Application of risk management to medical devices ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices <p>Environmental requirements: Rohs compliance</p> <p>Special requirement for product no.2 1. It should be supplied with one fiber optical cable</p>				
3	<p>Product Name: Optic colposcope (without monitor)</p>				

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	<p>Product Description: Medical device for examinations of the tissues of the vagina and cervix. Optical binocular colposcope with a cold light source and swing-in green filter. Mounted on a mobile floor stand and connected to stand with an adjustable arm, which allows the colposcope head to be placed more precisely and without interfering with the operator's comfort. Inclined binocular head, which can also be used as straight binocular tube. 5 Steps magnifications changer, depending on the combination of objectives and oculars. With manual fine focusing and adapter for laser systems.</p> <p>Technical specifications: Illumination: Coaxial illumination with lamp of cold light source (Halogen, LED or Xenon), fiber optic cable. Filter: Green filter. Working Distance with objectives: 250 mm or 300 mm. Magnification Changer: 5 steps, approx. between 0.4x, 0.6x, 1x, 1.6x, 2.5x or more. Total magnifications: approx. between 3x up to 21x. Visual Field: approx. 60mm - 8.5mm in 5 steps or more Fine Focusing: manual, Focusing objectives: f=250mm and f= 300mm Binocular Tubes: f = 125 mm 45° straight or inclined Suspension Arm: approx. L= 630mm or more Power: 220VAC-230VAC, 50Hz</p> <p>Supplied with: 1x Dust Cover. 1x Objectives. 1x Online UPS, 2KVA or more. 2x Fiber optical cable 1x Laser adapter. 1 x Instructions for use.</p> <p>Accessories/ spare parts/consumables: Provide with alternative quotation of spare parts: Spare Lamps - 20 pcs.</p> <p>Instructions for use: Instructions for use or user manual must be provided in 3 languages (English, French and Spanish). It should describe the operation instructions for the equipment, and it should include installation, maintenance and cleaning, storage conditions, safe disposal, operation, training, etc.</p> <p>Packaging & Labelling: Unit presentation 1 (one) device per box w/accessories Symbols used according to ISO 15223 (Manufacturer's product code or reference number, Manufacturer identification, Address of the manufacturing site, Storage Conditions, etc.).</p>				

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	<p>Warranty: The equipment must be new, not used. At least 24 months from the date of commissioning.</p> <p>Regulation & conformity requirements FDA 510k Premarket registration (class II) or CE certificate (for class IIa, with Notified body number).</p> <p>Safety & product Standards: Bidder shall furnish the documentary evidence to demonstrate that the good it offers meet the international safety & regulatory standards providing a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> ISO 13485:2016 Medical devices - Quality management systems ISO 14971:2012 Medical devices - Application of risk management to medical devices ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices <p>Environmental requirements: Rohs compliance</p> <p>Special requirement on product no.3</p> <ol style="list-style-type: none"> Supplied with one fiber optical cable It should be accompanied by a manual with monitor or teaching aid for training purposes 				
4	<p>Product Name: Thermo Coagulator</p>				

Item No.	UNFPA proposed specifications	If Supplier is capable to deliver (Yes/No)	Estimated FOB price in USD	Manufacturer name & Country of Origin	Estimate delivery lead time in days
	<p>Product Description: Medical Device for surgical treatment of women cervix cancer by thermic coagulation. This method is an ablation treatment of cervical lesions by boiling of pathological tissue. The procedure is a relative low temperature 60-120°C procedure. Its faster applications prevent pain scores and bleeding events. The device must be easy to clean and disinfect or being autoclavable according to manufacturer's instructions.</p> <p>Technical specifications: Power: 220VAC-230VAC, 50Hz Power Input: 66 VA Range of Temperature Setting: 60-120° C Regulation of Temperature: Continuous with minimum tolerance of 1°C. Probes made of stainless steel with protection system to avoid vagina and birth canal over-heating or tissue damage. Audible and visible alarms when device is emitting. Different interchangeable probes sizes and shapes Dimensions: W x h x d = 270x120x190mm (approx.) Weight: 3.6 Kg approx.</p> <p>Supplied with: 1 x Therapy handle. 2 x Instrument silicone cable 1 x Power Cord. Electrical socket according to local standard 6 x Therapy Probes (different end tips: flat, conical, cylindrical, rounded, etc) 1 x Instructions for use.</p> <p>Accessories/ spare parts/consumables: Provide with alternative quotation of spare parts; 1 x Therapy Probes set (all measures)</p> <p>Instructions for use: Instructions for use or user manual must be provided in 3 languages (English, French and Spanish). It should describe the operation instructions for the equipment and it should include installation, maintenance and cleaning, storage conditions, safe disposal, operation, training, etc.</p> <p>Packaging & Labelling: Unit presentation 1 (one) device per box w/accessories Symbols used according to ISO 15223 (Manufacturer's product code or reference number, Manufacturer identification, Address of the manufacturing site, Storage Conditions, etc.).</p> <p>Warranty: The equipment must be new, not used. At least 24 months from the date of commissioning.</p> <p>Regulation & conformity requirements FDA 510k Premarket registration (class II) or CE certificate (for class IIa, with Notified body number).</p>				

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5	<p>Product Name: Handheld Thermo Coagulator</p> <p>Product Description: Light portable, hand-held and mobile medical device for surgical treatment of women cervix cancer by thermic coagulation. This method is an ablation treatment of cervical lesions by boiling of pathological tissue. The procedure is a relative low temperature 60-120°C procedure. Its faster applications prevent pain scores and bleeding events. The device must be easy to clean and disinfect or being autoclavable according to manufacturer's instructions.</p> <p>Technical specifications: Power charger: 220VAC-230VAC, 50Hz Internal batteries pack: Battery pack autonomy at least 50 treatments (in 72hs approx). Audible and visible alarm of low battery status. Range of Temperature: 60-120° C. Regulation of Temperature: Steeples. Timer setting: It allows setting of treatment time from 1 second to 60 seconds. Probes made of stainless steel with protection system to avoid vagina or birth canal over-heating or damage. Audible and visible alarms when device is emitting. Auto shut-off system with alarm sound (beeping) and lights indicating withdraw. Different interchangeable probes sizes and shapes</p> <p>Supplied with: 1 x Therapy handle 1 x Instrument silicone cable 1 x Power Cord and battery charger. Electrical socket according to local standard 6 x Therapy Probes (different end tips: flat, conical, cylindrical, rounded, etc) Two available probes are-flat, nipple head) 1 x Batteries power-bank 1 x Instructions for use.</p> <p>Accessories/ spare parts/consumables: To be quoted separately: 1 x Therapy Probes Set (all measures) 1 x Batteries power-bank</p> <p>Instructions for use: Instructions for use or user manual must be provided in 3 languages (English, French and Spanish). It should describe the operation instructions for the equipment and it should include installation, maintenance and cleaning, storage conditions, safe disposal, operation, training, etc.</p> <p>Packaging & Labelling: Unit presentation 1 (one) device per box w/accessories Symbols used according to ISO 15223 (Manufacturer's product code or reference number, Manufacturer identification, Address of the manufacturing site, Storage Conditions, etc.).</p> <p>Warranty: The equipment must be new, not used. At least 24 months from the date of commissioning.</p>				

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6	<p>Product Name: Electrosurgical Equipment</p> <p>Product Description: Medical Device intended for surgical cutting and for controlling bleeding by causing coagulation (hemostasis) at the surgical site. An electrosurgical unit applies HF current through the patient between a dispersive electrode and a high-density current probe for cutting tissues at the surgical site.</p> <p>Features should include:</p> <ul style="list-style-type: none"> - 3 independent displays for cutting; coagulation and bipolar modes. - Controlled by manual pencil probe and footswitch. - Automatic monitoring of patient-electrode contact is connected. - 10 or more program memory for different applications. - Self-errors check facility (error code display). - Visual and audible alarms for active emission, HF overpower, cables disconnection. - All modes must be written below display (not symbols only) with activation-indicator light. - Facility for using both disposable and reusable patient plate. <p>The device must be easy to clean and disinfect or being autoclavable according to manufacturer's instructions.</p> <p>Technical specification: Monopolar cut: Max. power 200 Watt Monopolar cut mode: pure/blend/haemostasis Monopolar coagulation: Max. power 100 Watt Monopolar blend mode: soft/forced/spray/hybrid Bipolar: Max. Power 50 Watt Operating frequency for all modes: 440 KHz or more Power supply: 220±5%, VAC 50 Hz Approx. dimensions (mm): 777 x 360 x 505 Approx. weight (kg): 28</p> <p>Supplied with:</p> <p>1 x Multi-switch double pedal Footswitch, cable length approx. 4.5m 1 x Patient plate, reusable, with cable length of cord approx. 4.5m 1 x Hand switching pencil, reusable, Length of silicone cord approx. 4.5m 1 x Cushing bipolar forceps, straight, insulated, Tip 0.7mm, length approx, 15.0cm</p>				

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	<p>Accessories/ spare parts/consumables: To be quoted separately: 100 x Patient plate without cord, disposable 2 x Cord for patient plate, reusable, length of cord approx. 4.5m 5 x Hand switching pencil, reusable, Length of silicone cord approx. 4.5m 10 x Ball Electrode, reusable, diameter 3.2mm length 5.33cm 2 x Needle Electrode, reusable, length 6.6 cm 50 x Loop electrode, 10mm (W) x 10mm (L) 100 x Loop electrode, 15mm (W) x 10mm (L) 50 x Loop electrode, 15mm (W) x 15mm (L) 5 x Non insulated smoke evacuator speculum (115mm X 30mm) 2 x Non insulated smoke evacuator speculum (130mm X 40mm) 2 x Nylon Coated Insulated speculum with smoke evacuator (115mm X 30mm) 1 x Nylon Coated Insulated speculum with smoke evacuator (130mm X 40mm) 1 x Tichlar Morgan biopsy forcep (3x7mm) 2 x Spare Fuses set (if replacing fuses is applicable)</p>				
	<p>Instructions for use: Instructions for use or user manual must be provided in 3 languages (English, French and Spanish). It should describe the operation instructions for the equipment and it should include installation, maintenance and cleaning, storage conditions, safe disposal, operation, training, etc.</p>				
	<p>Packaging & Labelling: Unit presentation 1 (one) device per box w/accessories Symbols used according to ISO 15223 (Manufacturer's product code or reference number, Manufacturer identification, Address of the manufacturing site, Storage Conditions, etc.).</p>				
	<p>Warranty: The equipment must be new, not used. At least 24 months from the date of commissioning.</p>				
	<p>Regulation & conformity requirements FDA 510k Premarket registration (class II) or CE certificate (for class IIa, with Notified body number).</p>				

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	<p>Safety & product Standards: Bidder shall furnish the documentary evidence to demonstrate that the good it offers meet the international safety & regulatory standards providing a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:</p> <ul style="list-style-type: none"> · ISO 13485:2016 Medical devices - Quality management systems · ISO 14971:2012 Medical devices - Application of risk management to medical devices · ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements · IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance · IEC 60601-1-1 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems · IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests · IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices · IEC 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories <p>Environmental requirements: Rohs compliance</p> <p>Special requirement for product no. 6 1. These speculums are not easily available at local market so the number of supplied speculums should be maximized.</p>				