JORDAN ARMED FORCES

The DIRCETROATE OF ROYAL MEDICAL SERVICES

THE INSTITUE OF BIOMEDICAL TECHNOLOGY

Ophthalmology Department

Item:	Nystagmus Spectacles	Qty: (01)

IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:

The unit must meet or exceed the requirements listed in the table below.

Product Details	
Name of Manufacturer	
Model/ catalogue number	
Country of Origin for the offered model	
Country where the manufacturer is based	
Delivery time	
Full warranty period	

No.	Minimum Requirements	Compliance (Y/N) , Notes	Brochure Page No
1	**Frenzle glasses with binocular magnifier**		
2	**Lens type: medical-grade, distortion-free, prevents visual fixation.**		
3	**LED illumination.**		
4	**Power source :Rechargeable battery or AA/AAA**		
5	**Lightweight and Anti-Fog.**		
6	**Simultaneous both eyes**		
7	**Included Accessories: Carry case, Cleaning cloth, charger/ batteries.**		

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Item 2	Digital Hess-Harms Test System	Qty. (1)

IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:

The unit must meet or exceed the requirements listed in the table below.

Product Details	
Name of Manufacturer	
Model/ catalogue number	
Country of Origin for the offered model	
Country where the manufacturer is based	
Delivery time	
Full warranty period	

	Minimum Requirements	Compliance (Y/N) ; Notes	Brochure Page No.
1	**Advanced digital system for assessing extraocular muscles (EOM) and eye movement functionality.**		
2	**System Components :** **a- High-resolution digital display (LED or LCD), typically 55–65 inches.** **b- Laptop (at least requirments: windows10/11, SSD Hard disc 1TB, Core i5 GAN 11, 8 GB RAM, GPU 4GB) locally accepted.** **c- with software for test execution and data analysis.** **d- Dissociative viewing tools (e.g., red-blue glasses or equivalent) for isolating eye vision.** **e- Input interface: mouse or controller for interactive testing** **f- Color Printer (locally accepted).**		

	Minimum Requirements	Compliance (Y/N) , Notes	*Brochure Page No.*
3	**Software capabilities include:** **a- Digital Hess Test implementation** **b- Digital Harms Test implementation** **c- Ocular motility chart generation** **d- Diplopia charting** **e -Prism diopter deviation measurement and torsion analysis.**		
4	**Offers must include a certified operator training program at a reputable center abroad recognized by the manufacturer for one operator.**		

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Item 6	Handheld EMG/STIM Device	Qty: (1)

IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:

The unit must meet or exceed the requirements listed in the table below.

Product Details	
Name of Manufacturer	
Model/ catalogue number	
Country of Origin for the offered model	
Country where the manufacturer is based	
Delivery time	
Full warranty period	

#	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No
1	**The device shall be a handheld, portable EMG (Electromyography) and electrical stimulation unit for botulinum toxin guided injection .**		
2	**Must be lightweight, Rechargeable battery powered, and suitable for clinical use.**		
3	**Èlectromyography (EMG) Specifications :** **• Channels: dual channel.** **• Input Type: Surface electrodes, needle EMG** **• audio and visual EMG indication**		
4	**Electrical Stimulation (STIM) Specifications :** **• Stimulation Type: Monophasic and Biphasic.** **• Modes: Continuous, burst, EMG triggered.** **• Safety: Automatic cutoff on poor electrode contact**		

	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
5	**Supplied with :** ● Where applicable, a start-up kit of accessories and consumable items must be provided with system on a free-of-charge basis. ● Bio-ject Injectable Disposable Hypodermic Needle Electrodes. qty. (2 box) (Priced separately) ● Surface electrodes, lead wires, STIM electrodes. (Priced separately) ● Charging cable or adapter. ● Carrying case. ● all standard accessories		

Item 4	Synoptophore	Qty (1)

IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:

The unit must meet or exceed the requirements listed in the table below.

Product Details	
Name of Manufacturer	
Model/ catalogue number	
Country of Origin for the offered model	
Country where the manufacturer is based	
Delivery time	
Full warranty period	

	Minimum Requirements	Compliance (Y/N)	Notes	Brochure Page No.
A	**The device shall be used for controlled and independent visual stimulation of each eye to evaluate ocular alignment, binocular vision, and sensory fusion.**			
B	**The offered Synoptophore shall meet or exceed the following minimum requirements:**			
1	**Two independently adjustable optical arms.**			
2	**Precise angular scales for accurate measurement.**			
3	**Capability to measure horizontal, vertical, and torsional deviations.**			
4	**Fine horizontal and vertical angle adjustment.**			
5	**Integrated illumination system with adjustable brightness.**			
6	**Set of interchangeable standard test slides for diagnostic and therapeutic purposes.**			
7	**Ergonomic patient support including chin rest and forehead rest.**			
8	**Stable and vibration-resistant base construction.**			

	Minimum Requirements	Compliance (Y/N), Notes	*Brochure Page No.*
9	Manual or motorized operation.		
C	Motorized table		
D	Ophthalmic patient chair with following specs.(third party accepted) : 1- Heavy duty construction with stable base that resists tipping over when the patient orientation is altered. 2- Upholstery in durable material that is easy to clean and resistant to common hospital disinfectant solutions. 3- Electrically powered up/down with manual manoeuvres for backrest tilt. 4- Control for movements through footswitch. 5- All accessories and options and color choices must be listed and priced separately.		
E	The bidder shall supply the device complete with all standard accessories, required for diagnostic and therapeutic use in ophthalmology departments.		

SPECIAL TERMS

- *Offers not complying with any of the special terms or the technical specifications shall be considered non-conforming with tender requirements.*
- *Any vendor providing FORGED documents shall be disqualified from the current tender and banned from participating in any future RMS tenders.*
- *Wherever term "based" is mentioned it refers to the country where the manufacturing company is founded & established.*

1. *All equipment must be the most recently released model/version which is equal to or higher than the range of the specifications of the required system (low, mid or high) and equal to or higher than the level of technology and required options mentioned in the technical specifications.*
2. *Required certificates (must be submitted with the technical offer):*
   - 2.1 *FDA clearance (510K) for equipment of USA based companies.*
   - 2.2 *Medical Device Regulation (MDR 2017/745) or In Vitro Diagnostic Regulation (IVDR 2017/746) certificate for equipment of EU (European Union) based companies.*
   - 2.3 *UKCA certificate for Equipment of Great Britain based companies (England, Scotland, Northern Ireland, and Wales).*
   - 2.4 *ARTG (Australian Register of Therapeutic Goods) certification or approval for Australian and New Zealand based companies.*
   - 2.5 *Establishment License with the relevant Device License issued by the Therapeutic Products Directorate for Equipment of Canadian based companies.*
   - 2.6 *PMDA (Pharmaceuticals and Medical Devices Agency) certification or approval for equipment of Japanese based companies.*
   - 2.7 *Swissmedic (Swiss agency for therapeutic products) certification or approval for equipment of Swiss based companies.*
   - 2.8 *Norwegian Medicines Agency certification or approval for equipment of Norwegian based companies.*
   - 2.9 *Only for class I medical equipment manufactured by companies based in one of the countries mentioned above, submission of either one of the certificates mentioned above or a declaration of conformity certificate from the manufacturer confirming that the equipment fully complies with the applicable regulations in at least one of these countries.*

2.10 *For X-ray equipment, MRI, and nuclear medicine systems (regardless where the manufacturing companies are based) the following are required:*

2.10.a) At least two of the certificates mentioned above, one of which must be FDA clearance (510K).

2.10.b) A list of installation basis of the same offered model and/ or previous models in reputable national and/or international healthcare institutes with at least three years of operation, list should include: Name of hospital, Model installed, Quantity, and date of installation.

The purchasing committee has the right to officially contact any of these hospitals and disqualify any offer where the feedback is negative in operation, after sales service or local agent performance

2.11 *For all other equipment mentioned in (2.10) and where the manufacturing companies are based in other origins than the mentioned in terms (2.1 - 2.8) the following is required <u>in addition to (2.10.a),</u> only for class I medical equipment submission of certificates mentioned in 2.9 shall be accepted:*

Evaluation certificate from the Royal Medical Services for the same offered model with at least 80% passing grade (If applicable based or/and needed on purchasing committee perspective).

If the evaluation is not applicable (based on purchasing committee perspective) bidder should submit a list of installation basis as mentioned in term (2.10.b).

2.12 *The vendor is responsible to ensure through official documents that classified medical devices are manufactured in conformity with applicable quality system standards (ISO, IEC); (the international quality systems standard for medical device manufacturing ISO 13485) or ISO9001.*

2.13 *With each offer, bidders must provide a formally endorsed document issued by the manufacturer stating that the bidder is the sole certified agent for the offered item.*

2.14 *In all of the above cases (except 2.13) certificates must be formally endorsed by JFDA.*

2.15 *Any vendor not submitting all required certificates will be eliminated.*

3. *Official website of the manufacturer must be provided. The website must clearly demonstrate the history profile and manufacturing features of the company including the same offered model and its brochure.*

In case of inconsistency between the information on the website with the provided information of the local agent regarding any offered product, the committee has the right to eliminate that product from the awarding process.

4. *The local agent shall provide a comprehensive and up-to-date company profile as part of the tender submission. The company profile must include, at minimum: a clear overview of the company's background and core business, valid commercial registration documents, authorized distributorship certificates for the offered products, organizational structure, details of technical support and after-sales service capabilities, and evidence of previous experience in supplying similar medical equipment. Failure to submit a complete and clear company profile shall result in the rejection of the tender offer*

5. *Offered items should be from reputable well known manufacturers and excellent experience in the field. In any case the purchasing committee has the right to request <u>any</u> of the following:*
   a) *Evaluation certificate from the Royal Medical Services for the same offered model or previous models as mentioned in term (2.11).*
   b) *A list of installation basis of the same offered model and/ or previous models as mentioned in term (2.10.b).*
   c) *A sample of the same offered model at any time during the purchasing process, the sample unit shall be delivered within three weeks from the date of a written notification; any vendor rejects to deliver a sample unit will be eliminated. Evaluation duration will be determined by the purchasing committee.*
   <u>Any offered item fail in the evaluation/assessment process will be rejected</u>
   d) *Free sale certificate issued and stamped by any governmental entity in one of the countries mentioned in (2.1-2.8).*

6. *Vendors must specify the origin of the offered items and accessories in the technical offer.*

7. *Bidders must submit their reservations/queries regarding tender specifications and/or special terms within the first half of the tender closing period starting from the tender announcement date. Reservations/queries submitted after the end of this period shall be rejected.*

8. *Goods are to be brand new; manufacturing date of the delivered products should not exceed 18 months from the date of the final award.*

9. *Delivery period should be mentioned clearly; the purchasing committee has the right to reject any offer with delivery time exceeding 4 months.*

10. *Warranty:*
    a- *Offers must include a full warranty for a period of a minimum of 24 months from the date of installation or 30 months from the date of receiving the items at the agreed location mentioned in the final order (whichever comes first).*
    The supplier must furnish DRMS with a financial warranty (either cheque or bank warranty) equals to 5% of the total value of the awarded items issued from an operating bank in Jordan.

Warranty must include corrective & preventive maintenance activities as per manufacturer recommendations including:

- *Required spare parts (free of charge)*
- *Labour*
- *Hardware*
- *Software*
- *Rechargeable batteries*

At the end of the warranty period, the supplier commits to implement final inspection of the submitted goods and submit the reports signed by the site chief engineer stating that the equipment is working properly as well as all preventive maintenance reports during the warranty period.

Warranty & installation are excluded for items mentioned in Attachment no.1 the purchasing committee has the right to exclude any other item not listed in the attachment and does not required installation and warranty.

b- *In the case where a delay in installation has occurred as a result of the supplier's dereliction and has exceeded a period of one month from the date of receiving the items, the approved warranty period will automatically be considered as 24 months from the date of installation.*

c- *If at any time during the warranty period the item becomes inoperative due to a technical fault, warranty will be extended according to downtime period.*

d- *If the downtime period exceeds 30 consecutive days the supplier must replace the item with a new identical functioning one (within the same delivery period mentioned in the final offer). In case the item was replaced by a new one, the warranty period mentioned in 10.a) above will start from the installation and commissioning date of the new item.*

e- *Local agent/ supplier is committed to transport and install any awarded item during the warranty period on free of charge basis to any location inside the country whenever required by Royal Medical Services, this should not include pre-installation requirements in the new site.*

11. *All offered items (main unit) should be fully designed, manufactured, and labelled by their real original manufacturer in which all related testing, research, development and approvals went through.*

    Any relabelled products for the main unit (white-label manufacturing, OEM, or repackaging) are rejected.

12. *One set of operation manual(s) and one set of service manual(s) including schematics and a spare-part list must be delivered with each unit, CD/DVD is acceptable. For large tenders, a certain agreed percentage of manuals per item may be agreed upon.*

13. *Where applicable, pre-installation shall be the sole responsibility of the supplier. Pre-installation shall include removal of old system(s), any civil work, electrical work or site modification(s) necessary to accommodate the new system(s) according to manufacturers' specifications and safety standards in addition to the work required for bringing back the site to the same working conditions as before installing the new system(s).*

14. *Power requirements: where applicable either single phase 220V, 50Hz or 3-phase 380V. Systems with external transformers are considered conforming only if clearly stated in the technical specifications.*

15. *Technical offers must include clear original technical brochures/catalogues for all offered items.*

16. *Offers must include fully detailed technical offers and compliance sheets as a soft copy (either Microsoft office or Microsoft excel format) in addition to a hard copy, mentioning the exact model/catalogue number and country of origin of the offered item(s), full technical description/specifications and any accessories or options included in the offer.*

    Offer must clearly indicate the origin of the offered item and the country where the manufacturer of the offered items is based.

17. *Compliance sheets must be as per the tabular format of the technical specifications in the tender documents, listing the required specifications on one column and a <u>Yes or NO</u> response to each point in the adjacent column, with reference to page and line numbers in the relevant technical brochure. Offers not complying with this term shall be rejected.*

18. *Qualifications and after sales service: The technical bid should contain all the necessary documents (training certificates) to prove the capability of the bidders for supplying and installing a trouble free equipment meeting the quality standards and technical specifications of the manufacturer and the ability of the bidders for providing efficient after sales service conducted by authorized certified biomedical service engineers with minimum 2 years experience in the same field.*

19. *Accessories and consumables:*

    19.1 *Any accessories and consumable items necessary to operate the offered system must be clearly identified and priced separately.*

    <u>All offered accessories and consumables must be approved by the manufacturer.</u>

    19.2 *Technical offers must include a priced list for all accessories and consumables related to the required equipment as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) with prices fixed for a period of five years from the date of installation and commissioning with a maximum annual increase of 2%, <u>any essential item not listed will be considered free of charge.</u>*

19.3 *Accessories and consumables must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.*

19.4 *Where applicable, a start-up kit of accessories and consumable items must be provided with each system on a free-of-charge basis.*

20. *Spare Parts:*

20.1 *Technical offers must include a comprehensive and priced list of all spare parts related to the awarded equipment (including rechargeable batteries) as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) valid for a minimum period of five years with a maximum annual increase of 2%, commencing at the end date of the warranty period, any essential item not listed will be considered free of charge.*

20.2 *Spare parts must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.*

20.3 *Prices of spare parts should be reasonable and will be taken into consideration during the purchasing process; the purchasing committee has the right to eliminate any offered item with unreasonable high prices of spare parts.*

20.4 *Delivery period of required spare parts should not exceed 2 months from the date of the final order.*

21. *Spare parts, consumables and accessories availability must be guaranteed for a minimum period of ten years starting from the date of installation and commissioning.*

22. *Local agent is committed to sign a service contract with Royal Medical Services to perform all relevant maintenance for the awarded equipment (whenever required by DRMS within a period that does not exceed one year from the end date of the warranty period and if mentioned clearly in the specifications) without exceeding the original mentioned cost and as per mentioned terms within minimum required period.*

23. *Tender Awards:*

23.1 *For the final list of offers having a chance of winning the award, the awarding process shall be based on the accumulative value of both the offered item and its' running cost (Total Cost of Ownership) over a period of seven years from the date of installation and commissioning. Only offers with the lowest total cost of ownership over a period of seven years from the date of installation and commissioning shall qualify for the award.*

23.2 *Running cost includes the value of consumables, accessories needed to operate the system over the same period as well as the cost of any service contract (where applicable).*

24. *For PC/Laptop based systems:*

24.1 *Complete restoration medium (CD/DVD/etc.) of the operating system and the application software must be supplied.*

24.2 *Purchased licenses, software keys & dongles must be provided at any time during and after the warranty period on free of charge basis whenever required by DRMS for a minimum period of ten years starting from the date of installation and commissioning.*

24.3 *Where locally supplied computers, laptops & printers are offered, the offered model should be from well known manufacturer.*

25. *Pricing must include services of sale, shipment, transportation, delivery from port to site or to Main Medical Stores, installation, pre-installation (if needed), training, commissioning, warranty and bringing the equipment into service.*

26. *Custom clearance of goods shall be the responsibility of the Jordanian Armed Forces (JAF), however, suppliers shall bear all costs incurred by handling charges and any demurrage charges or extra expenses incurred by the port's corporation (including expenses caused by delay in presenting the necessary shipment documents for either clearing or transporting the goods to the required location mentioned in the final order, delivery note issuing charges, unloading charges, local shipping charges etc.). The supplier is also responsible for providing of all relevant shipping documents, together with the delivery order(s).*

27. *a. DRMS has the right to increase the awarded quantities by a percentage not exceeding 35% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.*

b. DRMS has the right to decrease the awarded quantities by a percentage not exceeding 50% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.

28. *a. Bidder is not allowed to submit more than one offer for the same item whether that's solely or in coalition or partnership with other bidders.*

b. Bidder is allowed to include within their offer optional alternatives for the same offered item from the same manufacturer.

29. *The supplier must furnish DRMS with a guarantee stamped and legalized by the Notary Public equals to (115%) of the total value of the awarded equipment valid for twelve months from the date of final acceptance of the equipment by DRMS.*

30. *Training:*

30.1 *For items where abroad service training courses are required in technical specifications, offers must include a certified service training program for at least 3 working days at a reputable center abroad recognized by the manufacturer for at least one biomedical engineer or biomedical technician; all costs inclusive, air tickets, , boarding, commuting, accommodation (minimum 3 star hotel on full board basis) and any extra costs.*

30.2 *For items where abroad <u>user</u> training courses are required in technical specifications, offers must include a certified operator training program at a reputable center abroad recognized by the manufacturer for at least one operator; all costs inclusive, air tickets, boarding, commuting, accommodation (minimum 3 star hotel on full board basis) and any extra costs.*

30.3 *The period of the training courses must be according to the manufacturer's program excluding traveling days and must be stated clearly in the technical offer.*

30.4 *Training Programs must conform to the following standards:*

- *User training must comprise understanding and use of operation manual(s), correct and safe operation of the equipment, as well as user preventive maintenance and calibration.*
- *Service training must comprise: theory, understanding and use of service manual(s), calibration, preventive maintenance procedure, and practical troubleshooting and repair exercises, and must be conducted by professional instructors employed or authorized by the system manufacturer.*
- *Service training must be conducted on a system of identical make, model, and configuration to that purchased by DRMS, and designated by the manufacturer or the local agent for training purposes.*
- *Certificates must be endorsed and officially sealed by the system manufacturer, legally empowering trainees to engage in user and service activities according to operation and service manual(s).*
- *Where applicable, offers must include an on-site user and service training.*

31 .For offers submitted in Jordanian dinars ,Payment will be either by wire transfer or by cheque after final acceptance of goods .Any other way of payment will be rejected

Attachment 1

#	Equipment
1	Adjustable Auto Pipettes
2	Resuscitation Bag
3	Laryngoscope Set
4	Oxygen Flow meter wall type/ single
5	Regulator Suction with canister, wall vacuum outlet
6	Oxygen Regulator for Oxygen Cylinders
7	Pulse Oximeter, Finger type
8	Oxygen Cylinder
9	Doppler, portable
10	Diagnostic set, Portable
11	Direct Ophthalmoscope, Portable
12	Otoscope, Portable
13	Air Mattress System, homecare
14	Stethoscope
15	Aneroid Sphygmomanometer
16	Video Assisted Laryngoscope, portable
17	Scale, Manual
18	Wood's Light
19	Cough Pressure, Normal Saline
20	Rehabilitation Walking Parallel Bars, non-powered
21	Therapy Mat
22	Medical Ball All Size
23	Dumbbells Rack with complete set of dumbbells
24	Crutches
25	Shoulder wheel
26	Mobile Mirror
27	Cuff Weights
28	Walker, different sizes
29	Patient Elbow Stick
30	Rehabilitation Training Ladder
31	Rehabilitation Suspension Frame
32	Exercise Band All Size (Theraband)

33	*Lens trial set*
34	*Wheel Chair*
35	*Commode Chair*
36	*Bassinet (Baby Cot)*
37	*Resuscitation Cart (Crash Cart)*
38	*Medication Cart*
39	*Cart, Drawers*
40	*Examination Couch, Manual*
41	*Gynaecology Examination Table, Manual*
42	*Examination Table, Neonates, Manual*
43	*Intravenous Pole, Mobile Stand*
44	*DDA Cabinet*
45	*Stainless steel Multipurpose Trolley*
46	*Cabinet, Instrument, Operation Theatres*
47	*Dressing Cart*
48	*Stainless steel wire shelving unit*
49	*Paper Trolley*
50	*Stainless Steel Sink (Clean up counter)*
51	*Scopes Cabinet*
52	*Mayo Table*
53	*Table, Instrument*
54	*Stool, Adjustable, Doctor*
55	*Stool, Adjustable, Operation Theatres*
56	*Carts, linen/laundry, soiled, Double*
57	*Closed distribution trolley*
58	*Step Ladder, Conductive, Double*
59	*Step, Surgeon, Single*
60	*Kick Bucket*
61	*Mobile Stand for Oxygen Cylinder*
62	*Stainless Steel Wire Basket, 1 STU*
63	*Cart, Plaster*