National Defence | Défense nationale

National Defence Headquarters
Ottawa, Ontario
K1A 0K2

Quartier général de la Défense nationale
Ottawa (Ontario)
K1A 0K2

SOLICITATION AMENDMENT / MODIFICATION DE L'INVITATION

RETURN BIDS TO / RETOURNER LES SOUMISSIONS À:

Director Services Contracting 3 (D Svcs C 3)
Attention: Lana Ibrahim
By e-mail to: Lana.Ibrahim@forces.gc.ca

The referenced document is hereby revised; unless otherwise indicated, all other terms and conditions of the Solicitation remain the same.

Ce document est par la présente révisé; sauf indication contraire, les modalités de l'invitation demeurent les mêmes

Title / Titre

Portable Fluid Warming Units

Solicitation No. / Nº de l'invitation	**Amendment No. / Nº de la modification**
W6369-22-A070	1

Date of Amendment / Date de la modification
11 March 2022

Address Enquiries to / Adresser toutes questions à:

Lana Ibrahim, D Svcs C 3-4-2
Lana.Ibrahim@forces.gc.ca

Telephone No. / Nº de téléphone	**FAX No. / Nº de fax**

Destination

National Defence Headquarters
Central Medical Equipment Depot
105 Montgomery Road, Building BB-104A
Petawawa, Ontario K8H 2X3

Instructions: Municipal taxes are not applicable. Unless otherwise specified herein all prices quoted must include all applicable Canadian customs duties, GST/HST, excise taxes and are to be delivered Delivery Duty Paid including all delivery charges to destination(s) as indicated. The amount of the Goods and Services Tax/Harmonized Sales Tax is to be shown as a separate item.

Instructions : Les taxes municipales ne s'appliquent pas. Sauf indication contraire, les prix indiqués doivent comprendre les droits de douane canadiens, la TPS/TVH et la taxe d'accise. Les biens doivent être livrés « rendu droits acquittés », tous frais de livraison compris, à la ou aux destinations indiquées. Le montant de la taxe sur les produits et services/taxe de vente harmonisée doit être indiqué séparément.

Solicitation Closes / L'invitation prend fin:

At / à:

02:00 PM Eastern Daylight Time (EDT)

On / le:

04 April 2022

Delivery Required / Livraison exigée	**Delivery Offered / Livraison proposée**

Vendor Name and Address / Raison sociale et adresse du fournisseur

Name and title of person authorized to sign on behalf of vendor (type or print) / Nom et titre de la personne autorisée à signer au nom du fournisseur (caractère d'imprimerie)

Name – Nom _____ Title – Titre _____

Signature _____ Date _____

Canada

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AMENDMENT 1 TO SOLICITATION NUMBER W6369-22-A070 IS RAISED TO:

1. Provide clarification and answer to questions from potential suppliers;
2. Update closing time to reflect the Eastern Daylight Time (EDT); and
3. Update Appendix 1 to Annex A.

QUESTIONS AND ANSWERS:

Question 1	Mandatory requirement M1 states that "The PFWU must comply with Canadian Standards CAN/CSA C22.2 60601-1 series, including all applicable amendments and substandards". Further, APPENDIX 1 TO ANNEX A -- 1. TECHNICAL REQUIREMENTS -- section 1.14 states that the equipment will be used in prehospital settings ("The PFWU must be approved for both air and ground transport"). In today's regulatory framework for EMS equipment / prehospital settings, these 2 requirements imply that the warmer MUST BE CERTIFIED against IEC60601-1-12 and IEC60601-1-2 4th edition standards. Please confirm our understanding of the regulatory requirements.
Answer 1	Electrical products must meet Canadian national codes and standards and be certified by an SCC accredited certification body or inspected by an SCC accredited inspection body. Therefore, the PFWU must comply with Canadian Standards CAN/CSA C22.2 60601-1 series, including all applicable amendments and substandards. Standard IEC60601-1-12 does not appear in Health Canada's list of Recognized Standards for Medical Devices: List of Recognized Standards for Medical Devices - Canada.ca. Therefore it is not mandatory for this tender. The PFWU must be approved for both air and ground transport. Approval can be proven in different ways. Mandatory requirement M1 and Article 1.14 of Appendix 1 to Annex A remain unchanged.
Question 2	Assuming that our understanding of the standards is correct (see [1] above), then the Ingress Protection rating specified in APPENDIX 1 TO ANNEX A -- 1. TECHNICAL REQUIREMENTS -- section 1.16 is in conflict with the mandatory regulatory requirements ("The PFWU must be water resistant with an enclosure IP rate of at least IPX1"). The IEC60601-1-12 demands a minimum IP33 rating for EMS equipment. Please confirm that the minimal IP rating that is demanded is in accordance with the IEC60601-1-12. If this is not the case, please confirm that the product will not be used outside the hospital (which would contradict section 1.14)
Answer 2	Standard IEC60601-1-12 does not appear in Health Canada's list of Recognized Standards for Medical Devices: List of Recognized Standards for Medical Devices - Canada.ca. Therefore it is not mandatory for this tender. The PFWU must be water resistant with an enclosure IP rate of at least IPX1. Article 1.16 of Appendix 1 to Annex A remains unchanged.
Question 3	The tender requests the ability to warm fluids from 20C to 38C +/-2C. At the same time, the tender also expresses the need to warm blood (APPENDIX 1 TO ANNEX A -- 1. TECHNICAL REQUIREMENTS -- section 1.1: "The PFWU must warm infused blood and fluid products including crystalloids, colloids and blood). This represents a

	gap in the requirements, since blood is stored at 4C, not 20C. Therefore, we would like to get clarifications regarding the expected performance, particularly with blood. In similar tenders, and since blood is applied in trauma situations that often involve massive rapid transfusion, much higher delivery rates are requested, typically >150ml/min and up to 200ml/min. Please confirm the requested delivery rates and initial starting temperature for blood products are accurate. Also please confirm if any weight towards award is considered for improved capability specifications.
Answer 3	The PFWU must warm blood stored at 4C. Delivery rates required for blood can go up to 1 Liter per 15 minutes or higher rates in severe cases. The following requirement has been added to Appendix 1 to Annex A at Article 1.17: The PFWU must maintain an output temperature of equal to 38°C ±2°C for blood administered at input temperature equal to 4°C and flow rate of at least 67mL/min.
Question 4	In addition to [3] above, a growing number of customers are using rapid intermittent flow methods such as push-pull / hand pump / LifeFlow / syringe to accelerate the flow of blood and fluids to patients. This requires a very sophisticated warming algorithm, very efficient warming process, and a very resilient cassette / disposable unit. Please advise whether the system will be used by any of these methods, at what flow rates, and what pressure it should be able to take before structural failure.
Answer 4	The PFWU might be used by any of these methods depending on the context.
Question 5	In addition to [3] above, given pre-hospital use as per 1.14, ambient temperature could be lower than standard room (hospital) temperature of 20C. Therefore, please advise the worst-case ambient temperature in which the system is expected to operate and warm fluids/blood to target temperature (preferably, please indicate ambient temp and max flow rates required).
Answer 5	The coldest ambient temperature in which the system is expected to operate temporarily is -20°C. The following requirement has been added to Appendix 1 to Annex A at Article 1.18: The PFWU must be capable of operating at cold temperatures down to -20°C.
Question 6	The tender does not specify the operating conditions (e.g. operating temperature range, relative humidity range, altitude, storage temperature, etc.). Can we assume that the environmental conditions should be in accordance with the IEC60601-1-12? If not, please specify the operating condition
Answer 6	There are no additional requirements for operating conditions.
Question 7	According to item 4.1 of section 4 (The PFWU must comply with Canadian Standards CAN/CSA C22.2 60601-1 series, including all applicable amendments and sub-standards. A certificate of compliance and a proof of label delivered by an inspection body accredited by the Standards Council of Canada (www.scc.ca) must be included with the bid submission), please let me know if CE mark is acceptable as an alternative standard?
Answer 7	Electrical products must meet Canadian national codes and standards and be certified by an SCC accredited certification body or inspected by an SCC accredited inspection body. Therefore, the PFWU must comply with Canadian Standards CAN/CSA C22.2 60601-1 series, including all applicable amendments and substandards.

	CE mark is a label for European market and is not an acceptable alternative to Canadian Standards CAN/CSA C22.2 60601-1 series. Mandatory requirement M1 remains unchanged.

SOLICITATION NUMBER W6369-22-A070 IS HEREBY AMENDED AS FOLLOWS:

1.1 **DELETE** from Page 1, 02:00 PM Eastern Standard Time (EST)" and I**NSERT** "02:00 PM Eastern Daylight Time (EDT)"

1.2 **DELETE** Appendix 1 to Annex A, in its entirety and **INSERT** the following**:**

APPENDIX 1 TO ANNEX A

1. TECHNICAL REQUIREMENTS

1.1. The PFWU must warm infused blood and fluid products including crystalloids, colloids and blood.
1.2. The PFWU must maintain an output temperature of equal to 38 °C ±2 °C for fluid products administered at input temperature equal to 20 °C and flow rate of at least 80 ml per minute.
1.3. The PFWU maximum output temperature must be ≤ 43°C, to prevent injuries.
1.4. The PFWU must operate on a rechargeable battery.
1.5. The rechargeable battery must provide ≥ 4 liters or more of warmed fluid, at input temperature of equal to 20 °C, on a single charge.
1.6. The PFWU must have a sealed heating unit, or heating plate, with no wires or heating coils exposed
1.7. The PFWU disposable set fluid path must be aluminum-free
1.8. The PFWU must be designed to prevent air bubbles.
1.9. The PFWU must be designed to prevent backflow of fluid in the intravenous line.
1.10. The PFWU disposable fluid path set must have a standard connector compatible with standard IV lines.
1.11. The PFWU must have visual light indicators for system malfunction, battery status, fluids below set-point temperature.
1.12. The PFWU must be compact, no greater than 15 cm x 15 cm x 30 cm all components with disposable set included.
1.13. The PFWU must weigh less than 1.5 kg.
1.14. The PFWU must be approved for both air and ground transport.
1.15. The PFWU must have an auto-switching power supply able of accepting vehicle charge 12 volts and AC/DC 110 volts.
1.16. The PFWU must be water resistant with an enclosure IP rate of at least IPX1.
1.17 The PFWU must maintain an output temperature of equal to 38oC ±2oC for blood administered at input temperature equal to 4oC and flow rate of at least 67mL/min.
1.18 The PFWU must be capable of operating at cold temperatures down to -20oC.

2. ACCESSORIES

2.1. Each PFWU must be provided with the following accessories:

2.1.1. Five (5) disposable sets

2.1.2. An internal battery pack;

2.1.3. A carrying pouch, able of holding the warmer, minimum of two (2) disposable sets and battery;

2.1.4. A portable, external battery charger; and

2.1.5. Operating manual in a pdf format that must, at a minimum, include information on handling the device, error code explanation, troubleshooting, and recommended operator maintenance.

ALL OTHER TERMS AND CONDITIONS REMAIN THE SAME.