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: Marie-Diane Payeur
By e-mail to: Marie-Diane.Payeur@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 W6369-22-A070	**Amendment No. / Nº de la modification** 4
Date of Amendment / Date de la modification 25 March 2022	
Address Enquiries to / Adresser toutes questions à: Marie-Diane Payeur, D Svcs C 3-4-4 Marie-Diane.Payeur@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:

18 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 4 TO SOLICITATION NUMBER W6369-22-A070 IS RAISED TO:

1. Provide clarification and answers to questions from potential suppliers.

QUESTIONS AND ANSWERS:

Question 8	Based on our understanding, IEC60601-1-12 is a mandatory requirement for airworthiness approval. As noted in the tender, the requirement that the PFWU must meet IEC60601-1 series "including all applicable amendments and substandards", to the best of our interpretation of the regulatory requirements, must include the IEC60601-1-12 for airworthiness approval. Can you please clarify this?
Answer 8	As soon as a medical device obtains its Health Canada Medical Licence specifying the intended use for air and ground transport, it is deemed to have demonstrated safety and effectiveness for air and ground transport. Additional proofs of compliance such as mechanical, electromagnetic and environmental testing against applicable standards of military (MIL-STD), International Electrotechnical Commission (IEC), Canadian Standard Association (CSA) or Radio Technical Commission for Aeronautics (RTCA) are required in this tender but it's not mandatory to comply specifically with IEC60601-1-12. Apart from that, in Canada, 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. It's part of the regulation in many Canadian provinces where the PFWU will be used. Electrical Medical Devices must meet Canadian standard CAN/CSA-C22.2 NO. 60601-1 series including all applicable amendments and substandards and be certified by an SCC accredited certification body. As soon as the device obtains that certification and label, it is deemed to meet applicable electrical safety requirements for its intended use in Canada. Therefore mandatory requirement M1 remains unchanged
Question 9	If question eight is confirmed, this would mean the minimal ingress protection rating should be IP33. With IEC60601-1-11 being the current standard as noted, based on our understanding of this standard, it demands a minimum ingress protection rating of IP22. Both standards are higher than the IPX1 that the tender specifies. Can you please confirm which ingress standard the PFWU is required to meet?
Answer 9	IPX1 is a minimum requirement, based on the clinical needs and the historical use of this equipment. This does not conflict with conforming to applicable higher standards.
Question 10	Intermittent (bolus) flows generated via flow-accelerating devices/methods demand that the PFWU supports significantly higher delivery rate than 67ml per minute or 80ml per minute to warm the blood/fluid prior to administering it to the patient. The main reason for that is that these devices accelerate flow considerably. Further, since these devices produce intermittent (or pulsatile) flow, that is -- high flows followed by zero flows and so on until transfusion ends, the actual delivery rate that the PFWU needs to support is practically doubled. Typical flow rate range for these devices is a rate between 150-200ml/min. Based on the noted potential to use flow-accelerating devices/methods, can you please confirm that the PFWU should be able to effectively warm blood/fluid at the higher required rate, (for example ~175ml over 1 minute at 4C input) when used in tandem with the flow-accelerating devices/methods?
Answer 10	There is no additional requirement for a higher rate of flow with flow-accelerating devices.

ALL OTHER TERMS AND CONDITIONS REMAIN THE SAME.