

Purchase Order Terms & Conditions (UTC-0M) For Medical Equipment & Devices

1. COMPLETE AGREEMENT

This Purchase Order, together with all documents, drawings and specifications referred to in this Purchase Order and the Contact Schedule attached to these Purchase Order Terms and Conditions shall, when accepted by the Supplier, constitute the entire contract between the Supplier and Purchaser, and shall not be altered, amended or supplemented without the Purchaser's prior written approval. If there is a Master Agreement between the parties that this Purchase Order is issued under, in the event of any conflict or inconsistency between these Purchase Order Terms and Conditions and the Master Agreement, the terms and conditions of the Master Agreement shall govern. The Purchaser shall not be bound by any terms or conditions in any of the Supplier's forms or documents. Either the Supplier's written acceptance of this Purchase Order, or the shipment of any article, or the commencement of any work pursuant to this Purchase Order shall constitute unqualified acceptance and no contrary or additional terms or conditions shall apply. The Purchaser may insist upon strict compliance with these terms and conditions despite any previous custom, practice or course of dealing to the contrary.

2. PURCHASER

The Purchaser under this Purchase Order shall be University Health Network. The Purchaser is identified in the Purchase Order as the party at the applicable ship to address. The Purchaser shall be entitled to all the benefits of Supplier representations, warranties, covenants, and indemnities. Purchaser contact information and addresses shall be

listed in the Contact Schedule. The Supplier shall select and use the appropriate site-specific contact information as applicable.

3. CHANGES, TERMINATION

The Purchaser reserves the right to make any changes to this Purchase Order including, without limitation, changes in drawings and specifications, additions or deletions from the quantities, or termination of all or part of the Purchase Order. If any such change causes any increase or decrease in the cost of, or the time required for, the performance of any part of this Purchase Order, an equitable adjustment shall be made in the price or delivery date or both, and this Purchase Order shall be modified in writing accordingly. Any claim for an adjustment shall be asserted by the Supplier within thirty (30) days of the notification of change from the Purchaser.

4. PRICES, PAYMENTS

Unless otherwise expressly stated in the Purchase Order, all prices specified shall be fixed, and in the currency indicated on the Purchase Order and shall include all charges and expenses of the Supplier, as well as freight and insurance to destination including packing, boxing, cartage and any and all applicable import and other taxes, fees and duties of federal, provincial and local governments. Any applicable HST taxes shall be shown separately. The time specified for payment of invoices, or for accepting any payment of discounts offered, shall run only from the date invoices satisfactory to the Purchaser are furnished to the Purchaser or satisfactory receipt of the goods by the Purchaser, whichever shall be the latter.

5. DELIVERY

The Supplier shall deliver the Equipment, which includes any products or goods that are being purchased pursuant to this Purchase Order

("Equipment"), to the destination(s) specified in the Purchase Order to the attention of the Medical Engineering or Biomedical Engineering department of the Purchaser ("Medical Engineering") as specified in the Contact Schedule, or such other destination as the Purchaser may inform the Supplier in writing from time to time. Large volume shipments, larger than one (1) standard drop skid, must be made through special arrangements with Medical Engineering of the Purchaser. Equipment must be received by the Purchaser a minimum of five (5) days prior to first scheduled use of the Equipment to allow sufficient time for incoming inspection and documentation. The Supplier must notify the Medical Engineering department of the Purchaser of delivery particulars in advance of delivery as required by the Purchaser, and without limiting the particulars required, shall provide the following: delivery date, mode of shipment, name of shipping/courier company, courier tracking or identification number and special instructions regarding handling, uncrating, and assembly. Prior to the delivery date(s) specified, if any, the Supplier shall send the information to the Purchaser as listed on the Contact Schedule.

Delivery shall not be complete and title shall not pass to the Purchaser, until the Equipment has been received which complies with the terms and conditions of this Purchase Order. All risk of damage or loss until completion of delivery shall be on the Supplier. Acceptance of Equipment shall not bind the Purchaser to accept future shipments. Where a delivery date or schedule is specified in this Purchase Order, timely delivery to the destination is of the essence, and the Supplier shall be responsible to ensure that such delivery is made and shall advise the Purchaser immediately of any anticipated delays and the reasons therefor. The Supplier is responsible, at its expense, within two (2) days of delivery of the Equipment, for the disposal off-site of the crating and packaging of the Equipment when requested by the Purchaser. The Supplier shall contact the Purchaser within two (2) days of delivery of the Equipment if disposal off-site is not possible and

disposal on-site shall be made through the approval of the Purchaser at the Supplier's expense.

6. SHIPMENT

The Supplier shall suitably pack, mark and ship in adequate protective packaging, and in accordance with any instructions from the Purchaser and the requirements of common carriers, in a manner to secure the lowest transportation cost, appropriate for the Equipment being purchased, and no additional charge shall be made by the Supplier therefor unless otherwise stated in this Purchase Order. The Supplier shall be liable for any difference in freight/transportation charges or damage to the Equipment resulting directly or indirectly from any failure by the Supplier to comply with this section.

7. INSPECTION

The Purchaser shall have the right to inspect and test the Equipment at any time during manufacture or prior to shipment and to final inspection within a reasonable time after arrival at the ultimate destination. The Supplier must specify, in writing, any installation and/or special test tools and/or components and/or kit requirements for the proper use and maintenance of the Equipment. The Medical Engineering department of the Purchaser shall be notified of such requirements before the Equipment is shipped. The Purchaser's personnel and/or authorized representative shall be allowed reasonable access to the Supplier's plant(s), and to those of the Supplier's suppliers, for the purposes of inspection and observation of progress towards completion of order.

8. ACCEPTANCE TESTING

There shall be an acceptance period of thirty (30) days ("Acceptance Testing Period") following clinical installation of the Equipment

including all accessories and documentation (“Clinical Installation”). Clinical Installation shall be deemed to be completed at the time that Equipment, accessories and documentation are received in full. Equipment shall not be deemed to be accepted until after installation, configuration, calibration, and acceptance/performance testing and clinical training as set out in Section 13 have been completed and the Equipment has operated for the Acceptance Testing Period all to the Purchaser’s satisfaction. Payment may be withheld until the Purchaser is satisfied that the Equipment is functioning properly and meets the Purchaser’s requirements. The Purchaser shall be notified promptly should there be any concerns or problems. If any problems remain unresolved at the end of the Acceptance Testing Period, the Purchaser reserves the right to return the Equipment or have it removed for a full refund of money paid against this Purchase Order or to extend the Acceptance Testing Period at the sole discretion of the Purchaser.

9. REJECTED EQUIPMENT

The Supplier shall be responsible for removal or replacement of any rejected Equipment, as set out in Section 8 or otherwise, at its own expense. Equipment rejected by the Purchaser shall be at the Supplier’s risk for damage or loss. The payment for the Equipment shall in no way impair the Purchaser’s right to reject certain Equipment or to avail itself of any other remedies to which the Purchaser may be entitled.

10. OWNERSHIP

Ownership of any documents, including specifications or drawings, supplied by the Purchaser, or produced by the Supplier upon request of the Purchaser, shall rest with the Purchaser at all times.

11. WARRANTY, GUARANTEE, COMPLIANCE

The Supplier warrants that the Equipment and/or work shall conform to the description and applicable specifications, drawings, samples or other description furnished or specified by the Purchaser, shall be of good merchantable quality, of good material and workmanship, free from defect and fit and sufficient for the purposes intended, for the period of time set out in this Purchase Order, and failing a specific term, the period of three (3) years from the date of Clinical Installation (“Warranty Period”). Clinical Installation of the Equipment shall be deemed to be completed at the time the Equipment, accessories and documentation are received in full and Medical Engineering has authorized the use of the Equipment. During the Warranty Period, defective Equipment and or parts shall be replaced at the Supplier’s expense as well as all labour charges for the Warranty Period. The Supplier also warrants that the Equipment and/or work shall be new, unless stated in the Purchase Order, shall comply with all federal, provincial and local laws, regulations and orders applicable to the manufacture, sale, packaging, storage, labeling and delivery of the Equipment and to the performance of the work, that the Supplier has absolute title, and that the use of the Equipment by the Purchaser shall not infringe on any other entities’ rights. The warranties shall apply notwithstanding any inspection, testing, acceptance of, or payment for the Equipment.

The foregoing is in addition to any warranty or service guarantee given by the Supplier to the Purchaser or implied by law.

12. RIGHT TO RETURN AFTER ACCEPTANCE

The Purchaser reserves the right to return the Equipment, should it fail more than three (3) times during the Warranty Period, for a full refund or request a new replacement of the same type of Equipment to be

delivered, with a full warranty (including parts and labor) at no cost to the Purchaser. Failures that result from user negligence or unfamiliarity with the system shall not constitute Equipment failure in this regard.

13. SERVICE, CLINICAL & STERILIZATION TRAINING

The Supplier shall provide the following training for at least two (2) individuals specified by the Purchaser:

- a. Service Training which shall include technical training. At the option of the Purchaser, the Service Training shall take place within ninety (90) days of the delivery of the Equipment or after the expiry of the Warranty Period unless otherwise agreed to. At the request of the Purchaser, the Service Training shall take place at the Supplier's site in accordance with the cost provisions set out below in this section;
- b. Clinical Training on the Equipment regarding operation of the Equipment; and Sterilization Training for the cleaning, disinfecting and sterilizing of Equipment that is not intended to be single use or any single-use Equipment received unsterile which requires sterilization prior to use. All training shall be provided directly by the Supplier's staff. There shall be no third-party training unless otherwise agreed to in writing. After the Service, Clinical, and Sterilization Training on the Equipment has been completed, the Purchaser reserves the right to request additional follow-up training for a period of twelve (12) months commencing after the completion of the Clinical Installation or after the delivery of the Equipment if there is no Clinical Installation. The Purchaser shall have the right to videotape all such training sessions, provided, however, that such taped sessions shall be used solely by the Purchaser to train its staff. The cost of all the training, excluding travel and accommodation for the Purchaser's staff to attend training course(s) at the

Supplier's facilities if necessary, shall be borne by the Supplier. The payment of any training travel and accommodation costs shall be mutually agreed to by the parties. The Purchaser reserves the right to have different types of training provided to different individuals.

14. CLEANING DISINFECTING AND STERILIZATION

For any Equipment that is not intended to be single use, or any single-use Equipment received unsterile which requires sterilization prior to use, prior to the delivery of the Equipment, the Supplier shall submit to the Manager/Director of the Regional Processing Centre/Central Processing/Sterile Processing department of the Purchaser:

- i. a letter from a senior official of a quality, safety, regulatory or compliance department process parameters for the specific Equipment and/or a Scientific Validation Report that deals with the efficacy of the cleaning, disinfecting and sterilization of the Equipment, as applicable;
- ii. reprocessing instructions: step-by-step instructions on the cleaning, disinfection, maintenance, sterilization, reprocessing, disassembly and reassembly of the specific Equipment;
- iii. for Equipment sets containing multiple instruments: a picture of the Equipment set contents and a catalogued list of the individual pieces of the Equipment sets; and
- iv. for containerized Equipment sets: a letter and/or a Scientific Validation Report stating Equipment consisting of multiple instruments can be sterilized as a set in the container provided and a catalogued list of the individual pieces of the containerized Equipment sets.

15. MANUALS & BULLETINS

The following manuals/materials must be provided at no charge and shipped with the Equipment, unless otherwise specified in the Purchase Order:

- a. Two (2) complete sets of operator/user manuals, including software manuals as applicable and any other printed or electronic media available for user education (e.g. videos, CD-ROMS); and
- b. Two (2) complete sets of service manuals including but not limited to, electrical/mechanical/pneumatic schematics manuals, parts lists, pricing lists or schedules, software manuals, troubleshooting guides as applicable, The Supplier shall forward to the Medical Engineering department of the Purchaser, any service bulletins, clinical user bulletins, or similar type of or related bulletin including, but not limited to, on-line technical resources that relate to the Equipment, as long as the Equipment is still being used or the Purchaser still requires the Equipment, at no additional cost to the Purchaser.

16. SERVICE SUPPORT / REPLACEMENT PARTS

The Supplier shall:

- a. ensure that full service support and parts must be available for a period of seven (7) years following the last date of production of the Equipment and related accessories;
- b. ensure that parts required to make the Equipment operational are delivered to the Purchaser within twenty- four (24) hours after a request has been made by the Purchaser for additional parts;

- c. provide full access to telephone technical support and on-line technical support, at no charge, as long as the Equipment remains in use by the Purchaser; and
- d. subject to (a) above, provide the Purchaser with a one (1) year written notification of the Equipment parts that are no longer being made available

17. RESPONSE TIME TO MALFUNCTIONS

At any time when the Purchaser is using the Equipment, the Supplier's response to malfunctions shall be two (2) hours by telephone and twelve (12) hours on-site if the malfunction cannot be resolved over the telephone. In the event that a malfunction cannot be resolved within twenty-four (24) hours of the initial telephone call, a loaner system or component of equal or superior performance, satisfactory to the Purchaser, shall be provided immediately or made available within forty-eight (48) hours of the initial telephone call at no charge to the Purchaser. During the Warranty Period, there shall be no charge for the services referred to in this section.

18. SERVICE RECORDS

The Supplier will submit to the Medical Engineering department of the Purchaser a detailed service report for any service work performed on the Equipment. The service report shall include the problem(s) identified, parts serviced or replaced, materials used, any costs associated with this service and appropriate technical values prior to and post repair calibration or certification. The labour and parts costs shall be itemized separately. The Supplier will notify the Medical Engineering department of the Purchaser of any service visits made on-site.

19. UPGRADES

Software, firmware or hardware changes to the Equipment which are corrective in nature and are initiated due to errors or as a result of any action taken pursuant to Section 25, Medical Alerts and Safety Notifications, shall be delivered and installed at no charge, as long as the Equipment is still being used or the Purchaser still requires the Equipment. Software, firmware or hardware changes, which solely enhance existing features, shall also be provided at no charge. The Supplier shall notify the Medical Engineering department of the Purchaser in writing of any software, firmware or hardware changes or enhancements as soon as they become available

20. ELECTRICAL EQUIPMENT

All electrical Equipment purchased pursuant to this Purchase Order shall be authorized or approved in accordance with the Ontario Electrical Safety Code, current as at the date of Purchase, by a Certification Organization, accredited with the Standards Council of Canada Act (Canada), and shall bear the Certification Organization's mark which identifies equipment certified for use in Canada. Certification shall be to the standard that is appropriate for the intended use of the Equipment at the Purchaser's facilities.

21. LICENSES

All Equipment, which includes any products or goods that are being purchased pursuant to this Purchase Order, that is defined as a Device under *Food and Drugs Act (Canada)* and as a *Medical Device under the Food and Drugs Act (Canada), Medical Devices Regulations* shall be licensed with Health Canada, Therapeutic Products Directorate, Medical Devices Bureau, unless it is exempted under the *Food and Drugs Act (Canada), Medical Devices Regulations*. The Supplier shall have a Medical Device Establishment License under the *Food and Drugs*

Act (Canada), Medical Devices Regulations unless it is exempted under the *Food and Drugs Act (Canada), Medical Devices Regulations*. At the time of purchase, the Supplier shall provide satisfactory evidence as applicable:

- a. that the Equipment is validly licensed with Health Canada, Therapeutic Products Directorate, Medical Devices Bureau;
- b. that the Supplier has a valid Medical Device Establishment License with Health Canada, Health Products and Food Branch Inspectorate; or
- c. that there is an exemption for either the Medical Device License or the Medical Device Establishment License.

22. LATEX

The Supplier shall provide the following information with respect to the Equipment, at the time of delivery or before if requested, whether:

- a. the Equipment contains any latex;
- b. the packaging of the Equipment contains any latex; and
- c. the Equipment indicates on the smallest unit packaging if there is latex in the Equipment or if it is latex-free. The Purchaser requests the right to ask for additional information with respect to latex.

23. CUSTOMS

All commercial customs documents, including but not limited to commercial invoices, Canada Customs Invoices, and bills of lading, as applicable, shall be fully and satisfactorily completed in accordance with Canada Border Services Agency (“CBSA”) requirements. The Supplier shall obtain from the Purchaser and show on the relevant commercial documents all that are accessible of the following: the Purchase Order Number or the department name of the Purchaser purchasing the Equipment. Equipment eligible for duty free entry into

Canada according to NAFTA shall be accompanied by a fully completed NAFTA Certificate of Origin or Statement of Origin, stamped or printed. Penalties assessed by CBSA due to incomplete, inaccurate or missing information on a commercial customs document shall be the responsibility of the Supplier, shall be charged to and paid by the Supplier or shall be deducted from any payment owing to the Supplier.

24. INDEMNIFICATION

The Supplier shall be responsible for and shall save harmless and indemnify the Purchaser, the Purchaser's employees, subcontractors, agents, officers and directors from and against all losses, costs, damages, suits, claims and demands of every nature whatsoever arising out of or by reason of the Equipment delivered or work performed pursuant to this Purchase Order, performance or purported performance of the terms and conditions of this Purchase Order by the Supplier or the Supplier's employees, subcontractors, agents, officers and directors, including without limitation those made or sustained in respect of property damage, personal injury (including death) and infringement of any intellectual property right, including but not limited to copyright, trademark, patent or trade secret.

25. MEDICAL ALERTS AND SAFETY NOTIFICATIONS

- a. In the event that a medical alert, recall, safety notification, advisory or warning is issued or communicated, applicable to the Evaluation Period, by the Supplier or manufacturer of the Equipment or a recognized reporting agency involving any of the Equipment delivered to any of the addresses set out in the Contact Schedule or such other designated destination or posted on the Health Canada Web site, the Supplier shall:

- i. communicate the medical alert, recall safety notification, advisory or warning by registered mail and by facsimile to the appropriate location(s) as listed on the Contact Schedule;
 - ii. follow any Health Canada protocols and requirements; and
 - iii. take all steps necessary to remedy the situation at no cost to the Purchaser.
- b. The supplier shall also:
- i. inform the Purchaser of any possible design defect or malfunction condition occurring anywhere in the world with the Equipment, or equipment similar to the Equipment supplied under this Purchase Order, at its earliest possible opportunity, but in no event, more than five (5) days after the Supplier becomes aware of the existence of such a defect or malfunctioning condition; and
 - ii. communicate the situation set out in Section 25 (b)(i) to the Purchaser in the same manner as set out in Section 25 above.

26. CONFIDENTIALITY

All information which the Supplier receives or acquires from the Purchaser either in writing, orally or through observation of the Purchaser's operation, or in the course of the Supplier's fulfilling its obligations hereunder, shall be held by the Supplier in confidence at all times and the Supplier shall not use the information unless required by this Purchase Order. Accordingly, the Supplier shall ensure that all recipients of the said information, including the Supplier's own employees, subcontractors, agents, officers and directors assume obligations identical in principle with those which the Supplier assumes under this section.

27. FIPPA

The Supplier and the Purchaser acknowledge and agree that as of January 1, 2012, the Freedom of Information and Protection of Privacy Act (Ontario) (“FIPPA”) applies to and governs certain information. The Purchaser will maintain the confidentiality of this information in accordance with the provisions of FIPPA. However, the Supplier acknowledges and agrees that FIPPA may also require the disclosure of such information to third parties.

28. PUBLICITY

The Supplier shall not, in any of its advertising or otherwise, indicate that it has supplied or may in the future supply goods to the Purchaser or use the Purchaser’s name for the purpose of advertising or solicitation of business without the prior written consent of the Purchaser.

29. NON-WAIVER

Failure of the Purchaser to insist upon strict performance of any of the terms and conditions, or to exercise any rights or remedies provided in this Purchase Order or by law, or to properly notify the Supplier in the event of breach, or the acceptance of or payment for any Equipment or approval of design, shall not release the Supplier of any warranties or obligations of this Purchase Order.

30. INSURANCE

The Supplier shall maintain insurance covering public liability, bodily injury and property damage, product and completed operations liability and contractual liability in amounts satisfactory to and with a company approved by the Purchaser. Such policy shall contain a cross-liability clause; an endorsement adding the Purchaser as an additional

insured; and an endorsement stating that the policies shall not be cancelled, allowed to expire or materially changed without thirty (30) days prior written notice to the Purchaser. Upon request, the Supplier shall provide a certificate of liability insurance setting out the insurance coverage referred to in this section.

31. GOVERNING LAW

This Purchase Order shall be construed under and governed by the laws of the Province of Ontario, Canada, except that the United Nations Conventions on Contracts for the International Sale of Goods shall not apply.

32. ASSIGNMENT

The Supplier shall not assign, subcontract or otherwise transfer this Purchase Order, in whole or in part, by operation of law or otherwise, without the express written consent of the Purchaser. The Supplier agrees that the Purchaser may assign, subcontract and transfer its rights and remedies under this Purchase Order, in whole or in part.

33. SURVIVAL

In addition to the length of survival of any provision which may be explicitly stated in this Purchase Order, all of the indemnifications and confidentiality obligations, made by the Supplier and set out in this Purchase Order, shall survive the expiry or termination of this Purchase Order, as shall all other provisions of this Purchase Order which, by their nature, might reasonably be expected to survive.

34. COMPLIANCE WITH ACCESSIBILITY STANDARDS

The goods and/or services provided hereunder shall comply with applicable accessibility standards under the Accessibility for Ontarians with Disabilities Act, 2005 and its regulations. If requested by the

Purchaser, acting reasonably, the Supplier shall provide evidence of the policies, procedures and training practices that it has implemented to comply with the foregoing. The Supplier shall comply, and shall ensure that its personnel read and comply, with all Purchaser policies in respect of the *Accessibility for Ontarians with Disabilities Act, 2005* and its regulations, as may be applicable to the goods and/or services.

35. AODA COMPLIANCE PROCEDURE

- a. The Purchaser will manage complaints efficiently, fairly, effectively, and uniformly. In the event that an AODA complaint is registered in respect of any aspect of the competitive procurement process, the complainant shall submit the complaint in writing by mail, fax or email to the Purchaser, including the following:
 - i. specific identification of the AODA accessibility requirement that is alleged to have been breached;
 - ii. specific description of each act alleged to have breached the AODA requirement;
 - iii. precise statement of the relevant facts;
 - iv. identification of the issues to be resolved;
 - v. complainant's arguments and supporting documentation and
 - vi. complainant's requested remedy.
- b. Once a written complaint has been submitted to the Purchaser (to the contact identified in the procurement document or contract), receipt will be acknowledged within five (5) business days. If the information regarding the complaint is incomplete, the Purchaser will contact the complainant within ten (10) business days. Anonymous complaints will not be processed through this protocol.

Contact Schedule

DELIVERY (SECTION 5) , INSPECTION (SECTION 7) , MANUALS AND BULLETINS (SECTION 15), SERVICE RECORDS (SECTION 18) , AND UPGRADES (SECTION 19):

The Supplier shall select and use the appropriate site-specific information as applicable.

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