Policy Name:	Policy Number:
PURCHASING MEDICAL DEVICES	**2506**
	Effective Date: **AUGUST 4, 2021**
Approved By: Executive Team	Date Revised: August 4, 2021
Reason for Revision: Click on item below and select item from list. **CONTENT- Enter BELOW Reason for change Ex: Combined Policy ## and ##.** New policy	Next Date for Review: August 4, 2024
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Policy

OBJECTIVES

- To outline a process for the purchase of medical devices for use at The Salvation Army Agape Hospice.

PRINCIPLES

- To support provision of quality health care by ensuring equipment purchased meets Health Canada Licensing Requirements and is safe and user friendly.
- To ensure new equipment is compatible with existing medical equipment.

APPLICABILITY

This policy applies to any end-user who is authorizing the purchase of new medical equipment.

POLICY ELEMENTS

1. If the reusable medical device is new or updated, uses new technology, introduces additional component, or requires changes in reprocessing, the **end-user** (defined as requester, purchaser, or decision maker authorizing the purchase):

1.1 Collects the necessary documentation and information to evaluate the purchase.
1.2 Requests manufacturer's instructions for use and licensing information from the vendor.
1.3 Confirms with the vendor that the device meets Health Canada licensing requirements.
1.3.1 For further detail about Health Canada licensing requirements refer to: Health Canada 2020 Guidance Documents for Medical Devices

2. Manufacturers are responsible to supply:
- Details about the device design and intended use;
- Directions for use;

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- Information on single-use components;
- Recommendations for checking device integrity when applicable e.g., sheath testing, sharpness of cutting edges, etc.

3. The end-user confirms the purchase supports provision of quality healthcare and necessary resources are in place by considering the following:
- Are there minimum technical requirements?
- Will the proposed equipment meet the requirements for IT Connectivity?
- Are there installation limitations or requirements, e.g., dimensions, weight, electrical and other utilities, environmental control? If yes, consult with maintenance/ED.
- Are facility modifications required? If yes, consult with maintenance/ED.
- Will the proposed equipment be used in conjunction with other equipment in the facility? If so, is the equipment compatible?
- Do employees know how to use the device or is additional training required?

4. The end-user confirms resources are in place to meet cleaning, disinfection, service, and maintenance requirements, for example:
- Who will be responsible for cleaning and disinfecting the device?
- How will the device be transported:
- What are the storage requirements?
- Are enough devices being purchased?
- Are all required components/consumables factored into the purchase?
- Who will be performing preventative and routine maintenance and are there associated costs to be factored into the purchase?

5. Before purchase, the end-user must confirm the device or reprocessing equipment is suitable and safe for the intended use.

6. Replacement of existing devices or equipment does not usually require evaluation unless the device or manufacturer's instructions have changed significantly, e.g., updated/revised to include additional components or require changes in reprocessing methods.

DEFINITIONS

End-user: means the requester, purchaser, decision maker authorizing the purchase.

REFERENCES

AHS Purchasing Medical Devices – Pre-purchase Criteria for End-Users
Health Canada 2020 Guidance Documents for Medical Devices