Make Sure the Medical Device You Choose Is Designed for You

This checklist is designed for health care professionals and patients to use when choosing a medical device that is best for the patient. It is intended to be modified by health professionals to focus on particular devices for certain target populations (e.g., arthritics, diabetics, heart patients).

1. Do you have limitations that can affect your use of the device?

- ❑ Could your health (stress, tired, medication effects, disease) affect the way you use the device?
- ❑ Do you have the physical size and strength (hand strength, lifting ability, and endurance) to use the device?
- ❑ Will you be able to see the display, hear the alarm, and feel the controls (knobs, buttons, switches, and keypads)?
- ❑ Do you have the coordination (manual dexterity, balance) to adjust the controls?
- ❑ Will you be able to understand and use the device?
- ❑ Do you need to remember complex instructions to use the device?

2. Is the device right for the environment where you plan to use it?

- ❑ Does the device have safety features to prevent it from harming your children or pets, and to prevent them from harming the device?
- ❑ Will you be able to hear the device's alarm in a noisy environment?
- ❑ Will the light levels (low or bright) in your environment affect your ability to use the device?
- ❑ Are you using other devices at the same time?
- ❑ Will sources of electromagnetic interference (e.g., Ham radio, AM FM TV broadcast antenna, electrical machinery, hand-held transmitters) affect the device?
- ❑ What things about your home will affect your use of the device (e.g., high heat and humidity, very dry air in the winter, too few electrical outlets, narrow doorways, wood stove heating)?
- ❑ What happens if you put the device in an inappropriate environment?

3. Are there device characteristics that can affect its use?

- ❑ Is the device simple to set up, operate, clean, maintain, and dispose of; and what happens if you don't do these things properly?
- ❑ What replacement parts or batteries are required, how frequently are they needed, how expensive are they, and are there special instructions for safely disposing of the device or its parts?
- ❑ What reading or training is required of you?
- ❑ Are there things about this device that are different from other similar devices you have operated?

Identifying and Understanding Medical Device Use Errors

Users sometimes experience difficulties using medical devices – and usually these difficulties are a result of a poorly designed system. This sometimes leads to hazardous situations that can cause patient or caregiver harm. Identifying and understanding errors that occur while using medical devices should be undertaken within the context of a complete understanding of the device-use system. Essential components of this understanding include:

- Device users - patients, family members, physicians, nurse, professional caregivers
- Typical and atypical device use,
- Device characteristics,
- Characteristics of the environments in which the device will be used, and
- The interaction between users, devices, and the environments in which the device is used.

These questions can act as a guide when identifying and understanding errors resulting from the use of medical devices:

- Have problems occurred with the use of other similar products? Why?
- Is device use consistent with user's expectations or intuition about device operation?
- Does the user understand device operation?
- Does the device require unexpected tasks or procedures to be performed?
- What are the critical steps in setting-up and operating the device? Can they be performed adequately by the users?
- How might the user set the device up incorrectly and what effects could this have?
- Does the user operate the device differently than the instructions indicate? What affect could this have?
- Does the device adversely affect established processes or procedures?
- Is the user or environment likely to be different than that originally intended? What affect could this have?
- Does device use requires physical, perceptual, or cognitive abilities that exceed those of the user? How might the user's abilities affect their use of the device?
- Can safety-critical tasks be performed incorrectly and what effects would this have?
- Have all users been trained on the device? Can users operate the device safely and effectively if they don't have it?
- Are storage and maintenance recommendations followed? What happens if they are not?
- Do any aspects of device use seem complex? Can the operator become "confused" when using the device?
- Can the user hear and see all of the auditory and visual warnings?
- Are device accessories expired, damaged, missing, or otherwise different than recommended?
- Has everyday handling of the device adversely affected it?
- Does the device "fail safe" or give the user sufficient indication of the failure?