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?