

# Hospital and Practitioners Perspective

Working Group 10.4 Summer Meeting  
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# Operation Issues

- Confusing interfaces
  - Small number of inputs
    - Typically a few buttons
    - Functions often overloaded / modal
  - Incomplete displays
  - Non-integrated alarms
    - Encourage disabled alarms
    - Can lead to alarm storms
- Sparse error information
  - Incomplete error set
  - Much of information is centered in the patient

# Devices vs Systems

- Most devices are stand-alone
  - No interest in importing / exporting information
  - Marketed on basis of unique features / cost
- Systems beginning to emerge
  - Devices that need continued support
    - Complex configuration steps
    - Long-term maintenance and updates
    - Remote use
    - Examples: pacing products
  - Medical data systems
    - Collection and archiving of data from multiple devices
    - Introduce challenges in data normalization/integrity, confidentiality
    - Very limited support for key users
    - Not usable for real time control
    - New source of information for understanding clinical system behavior
- Many rely on modes

# System and IT Administration

- Existing Hospital Staffing
  - IT configuration and management
  - Device specification and procurement
- Missing Staff Functions
  - Overall clinical system design
  - Total system integration and test

# Who is Responsible?

- Device Manufacturer
  - Formal process for a limited portion of the functionality
  - No requirement to provide design data to operator
- Regulatory Agency
  - Specification of minimum requirements
  - Review of design documentation
- Purchaser
  - Not beholden to integrator or operator
  - Does not appear to be part of any quality feedback loop
- Integrator
  - Configuration of device for ultimate environment
  - Integration of device into ultimate environment
  - Initial testing of installed device
- Operator
  - Learning functions and functional interfaces
  - Correctly managing device operation
  - Questionable information for above functions
- Owner ?