

ICE-PAC

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SCDOCBOX

 ICE-PAC is a joint working group between ASTM:

Device in the Integrated the Clinical Environment Standard (ICE) and IHE PCD in order to analyze existing standards (IEEE 11073 and ASTM F29.21)

to explore standards gaps and profile roadmap gaps.

- To produce requirements for across the different standards at a systems level
- Identify hazards where clinical practice meets engineering systems



Methodology

Clinicians

Clinical Engineers

Design Engineers

Clinical Scenario

Clinical Workflow

Workflow Analysis

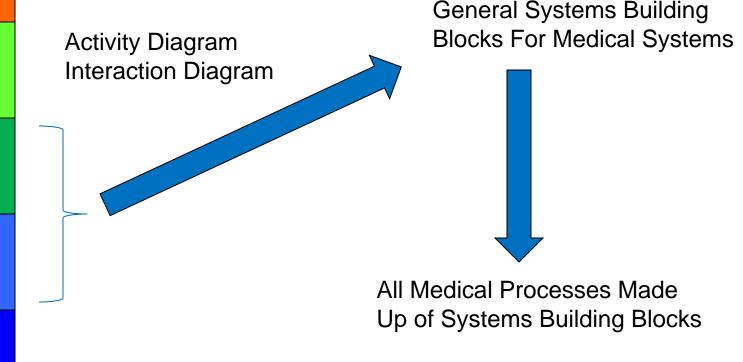
Risk Analysis

State Diagram

Technical
Solution and
Clinical

Clinical Scenarios
Clinical Concept of Operations

Graphical Workflow





Requirements

Clinicians

Clinical Engineers

Design Engineers

Clinical Scenario

Clinical Workflow

Workflow Analysis

Risk Analysis

State Diagram

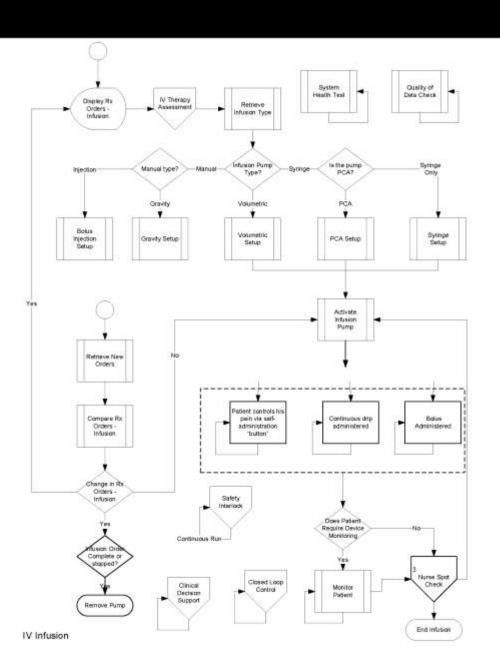
Technical
Solution and
Clinical
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- Gathering Requirements from Clinical System
- Providing Traceability of System Requirements
- Provide Systems Level Risk Analysis
- Provides Traceability to Mitigating Risk
- Designing for the System, not modifying the system causing unintended consequences
- General Building Blocks and Interactions between the blocks are key to Safety
- If General Building Blocks make up Specific Systems then Systems are safe



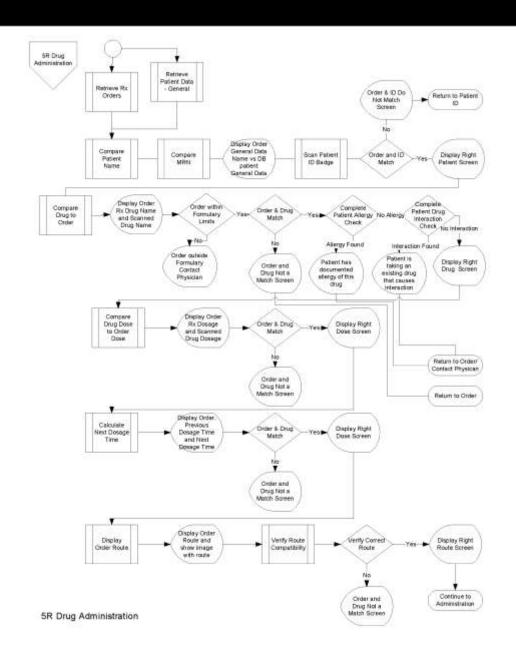
General Overview
Workflow of
All Infusion Therapies

Each Box is has at least one additional drilled down page

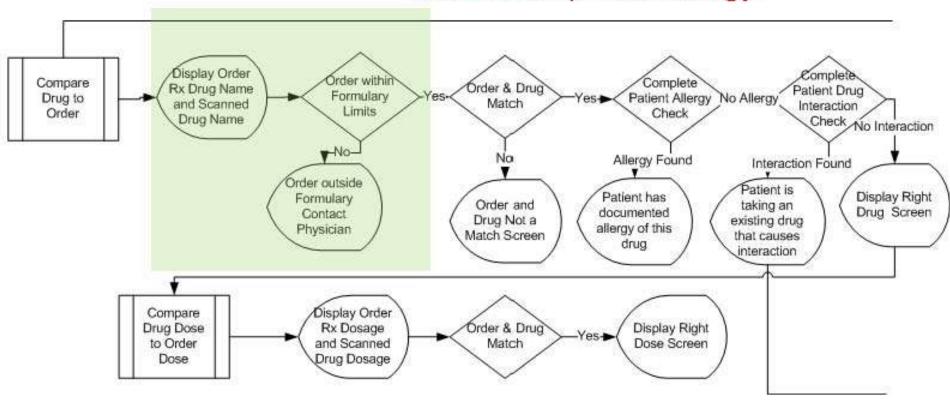




Example of the 5R's of Infusion Delivery



Smart Pump Technology





Workflow if patient is on 6 Infusion Pumps which is not uncommon in the ICU Retrieve New Orders

Compare Ro. Orders - Infusion

Charge in Re. Orders - Infusion



Current Findings

- Contextual Data is required for intelligent systems. This includes:
 - Device characteristics
 - accuracy,
 - Precision
 - Source/source characteristics
 - Quality of Data
 - communication quality
 - Data quality
 - Patient History