Innovative Infusion Pump Technologies

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IEEE Long Island Chapter

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Background

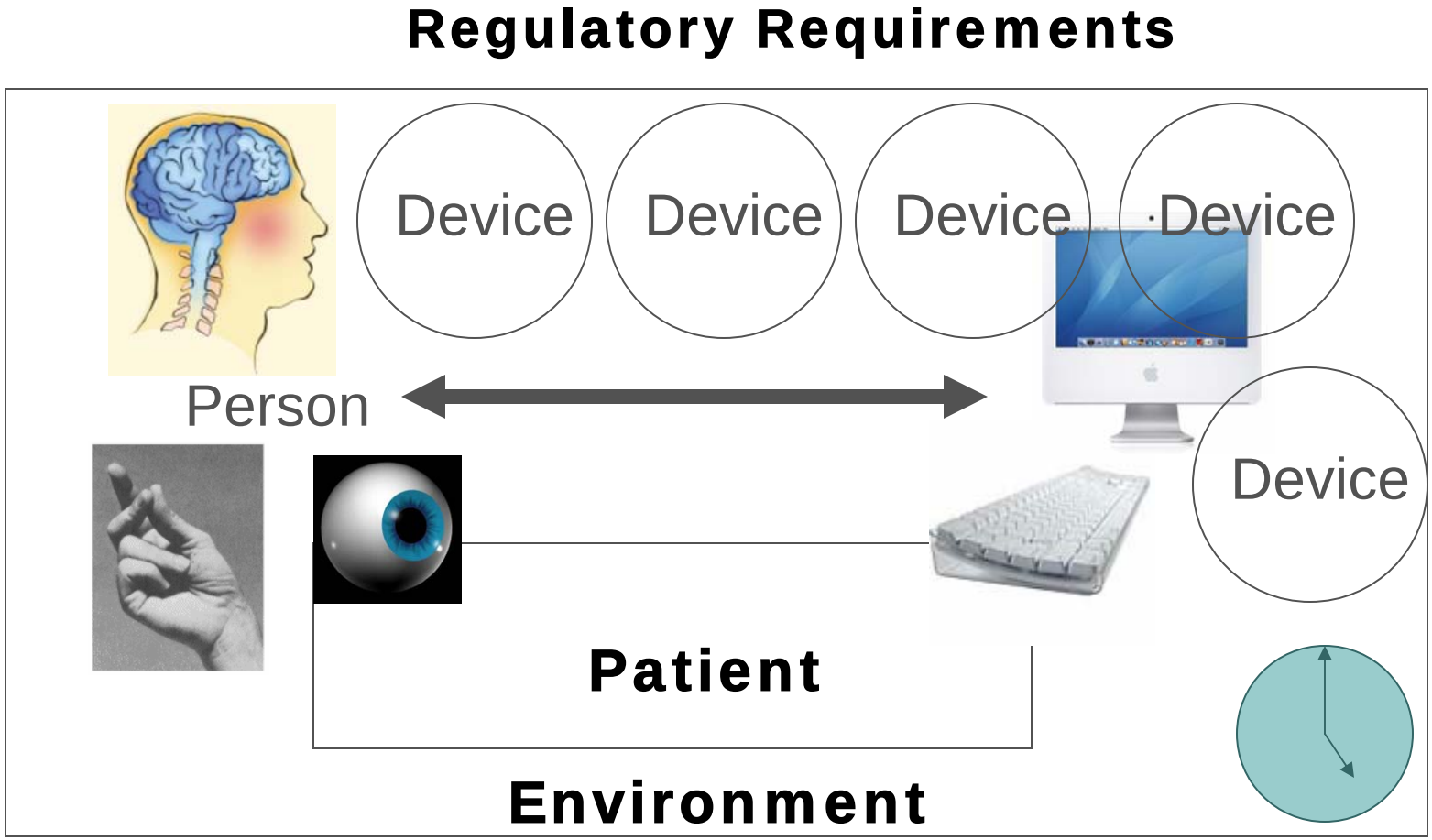
- Currently a Director of Clinical Engineering at ARAMARK Healthcare. Most recently served as the Director of Clinical Engineering at The Mount Sinai Medical Center, New York, NY
- Previously served as the Director of Technology Management at William Beaumont Hospital in Royal Oak, MI.
- Past President of ACCE (American College of Clinical Engineering)
- Board Member, AAMI-ACCE-HIMSS Strategic CE & IT Community
- Holds a B.S. in Electrical Engineering from the University of Cape Town in South Africa, a M.S. in Biomedical Engineering from the University of Connecticut and an MBA from Walsh College in MI.

Agenda

- Overview - Infusion Technologies
- Types of Technologies and their Applications in Healthcare
- Evaluations & Human Factors Engineering
- Safety
- Wireless Applications
- Case Study

Overview – Infusion Technologies

Healthcare Environment



Today's Environment

- Increased acuity
- Fatigue
- Staffing levels
- Demographics
- Environmental factors
- Innovation: new medical technologies

Description

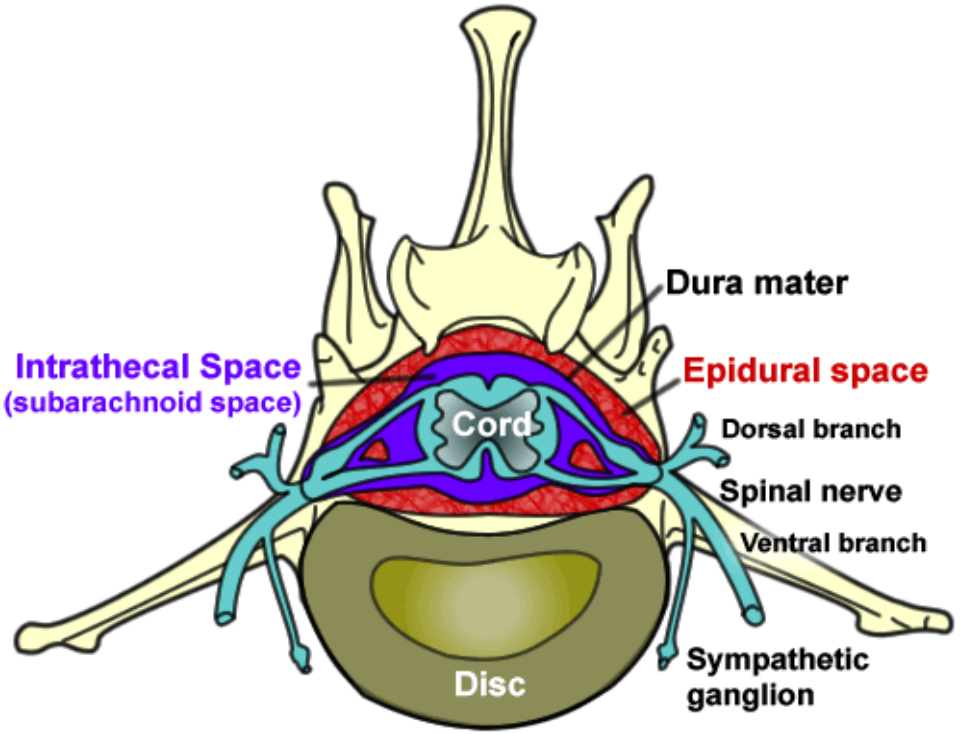
- Deliver fluids, including nutrients and medications, into a patient's body in a controlled manner.
- Used worldwide in healthcare facilities and home.
- Contribute to improvements in patient care, allowing for a greater level of control, accuracy, and precision in drug delivery, and thereby reducing medication errors.
- Referred to as "smart pumps"

Types of Infusion Technologies

- Large volume pumps
- Syringe pumps
- Patient analgesic pumps (PCA)
- Insulin pumps
- Enteral pumps
- Implantable pumps

Routes of Infusion

- Intravenous (IV)
- Subcutaneous
- Arterial
- Intrathecal
  - Directly into the CSF that surrounds the spinal cord
- Epidural
- Enteral



Five Rights of Medication

The Right Patient

The Right Time

The Right Medication

The Right Dose

The Right Route

Types of Technologies and their Applications in Healthcare

Large Volume Pumps

- IV, epidural routes : Primary/secondary sets
- Multipurpose pumps
  - Medication, anesthesia, chemo, etc.
- Accuracy: +/- 5%
- High flow rates: 0.1- 999 mL/hr
- Safety Features

http://www.alarismed.com

Syringe Pumps

- IV, enteral: different syringe sizes
- Accuracy: +/- 2-3%
- Typical flow rates: 0.01 – 10 ml/hr
- Auto ID of syringe size
- Safety features

http://www.alarismed.com

PCA Pump

- IV, subq, epidural delivery
- 20-500 cc syringes/bags
- Used for narcotics
- High flow rates: 0.1- 999 mL/hr
- Locked source, security code
- Patient controlled bolus delivery
- Safety features

http://www.alarismed.com
http://www.baxter.com

Insulin Pumps

- Subcutaneous
- Accuracy: +/- 5%
- Reservoir, pumping mechanism, infusion rate controller, catheter
- Reservoir: 3 ml of solution

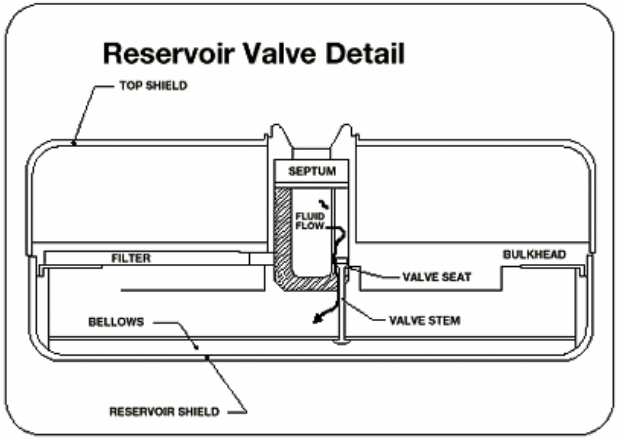
http://www.minimed.com

Enteral Pumps

- Routes:
  - Enteral (digestive tract)
  - Tubing sets
- Milk/Formula delivery
- Accuracy: +/- 10%
- Flow rate: 1-300 ml/hr
- Audible alarms

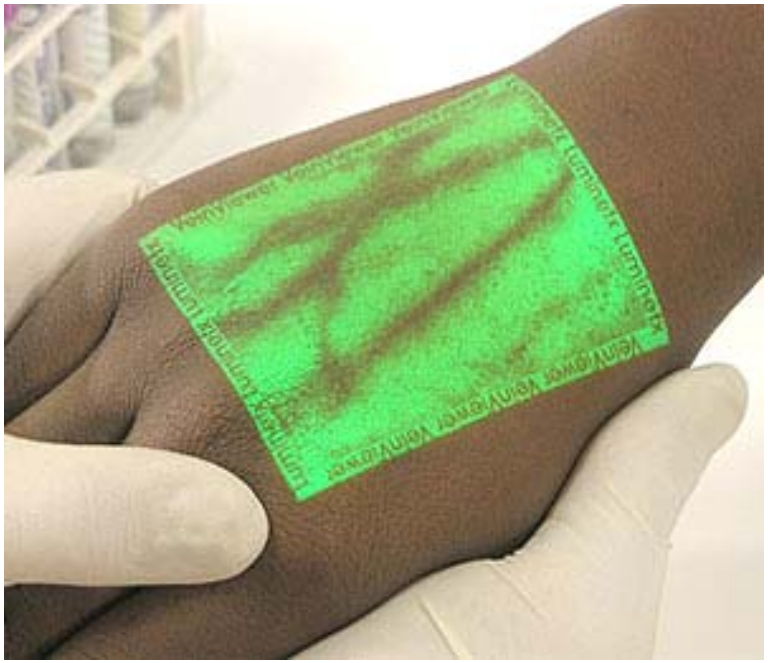
Implantable Pump

- Intra-thecal: Pain pumps
- Volume of reservoir: 10 ml and 18 ml
- Pump, catheter, programmer
- Kits: catheter access and refill
- Programmable & Reprogrammed via RF
- Battery powered



Education

Vein Finders



http://accuvein.com/iv-insertion/
www.photonics.com

System Integration

- Integration with Electronic Medical Record Systems (EMR)
  - Streamlined reporting and caregiver workflow
  - Reduced transcription errors
  - Increased data accuracy and completeness

System Integration cont.

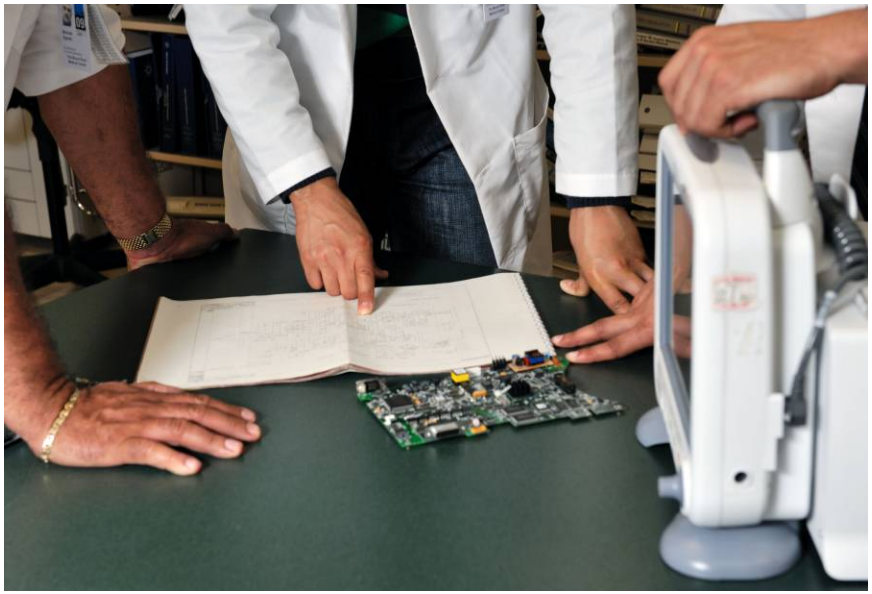
- Integration with communication devices
  - Alarm management
  - Programming/settings

Evaluations
and
Human Factors Engineering

Pictures courtesy of Mount Sinai

Evaluation Process

- Needs assessment
- Technology assessment
  - Presentations/demo
  - Benchtesting
  - Simulations
  - Clinical trials
- Procurement
- Implementation

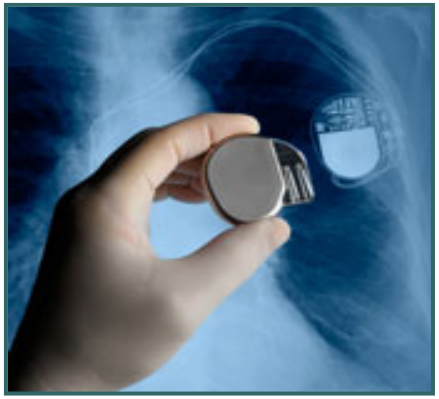


Human Factors Engineering

Human Factors Engineering (HFE) is the science and the methods used to make devices easier, more effective and safer to use. When applied to medical devices, HFE helps improve human performance and reduce the risks associated with use.

Why Apply HFE?

- Increased safety, effectiveness and quality
- Improved ease of use, system performance, reliability, and user satisfaction
- Reduced operational errors, operator stress, training requirements, user fatigue, and product liability
- Compliance with the regulatory agencies
- Streamlined interconnectivity and integration with other medical technologies
- Improved adoption of technology



Evaluation Requirements

- **Layout** – visible, legible, sufficient, flexible
- **Operation** – simple, within user's capabilities, minimized reliance on memory
- **Procedures** – logical, intuitive
- **Warnings, Labels and Alarms** – informative, easy to reverse an error
- **Text and Graphics** – clear, easy to interpret
- **Forcing Functions** – physical inability to complete an operation when not intended
- **Environment** – lighting, noise, temperature, humidity

Pictures courtesy of Mount Sinai

Presentations/Demo

Benchtesting

- Each vendor was asked to provide a pump, service manuals, all accessories
- Technical session

Pictures courtesy of Mount Sinai

Simulations

Pictures courtesy of Mount Sinai

Simulations cont.

Pictures courtesy of Mount Sinai

Simulations cont.

Pictures courtesy of Mount Sinai

Simulation Center

Clinical Trials

Safety

Safety with Infusion Pumps

http://content.wellspan.org/breakingnews/default.aspx?pageid=9023

Safety with Infusion Pumps cont.

- 56,000 reported **adverse events** associated with infusion devices over the past five years.

- From 2005 through 2009, 87 infusion pump **recalls** were conducted by firms to address identified safety problems

www.fda.gov
www.hitspehere.com

Safety with Infusion Pumps cont.

- 100,000 **medical device** reports per year received by the FDA
  - More than 1/3 involve use errors
  - Use error often linked to design flaws

- 44% of medical device recalls due to **design problems**

Common Problems

- Software glitches such as failures of safety alarms.
- Confusing instructions leading to dosing errors.
- Mechanical or electrical failures, such as battery failures, sparks or pump fires.

Note: Unlike pills, a 10- or 100-fold error can easily go unnoticed during IV delivery

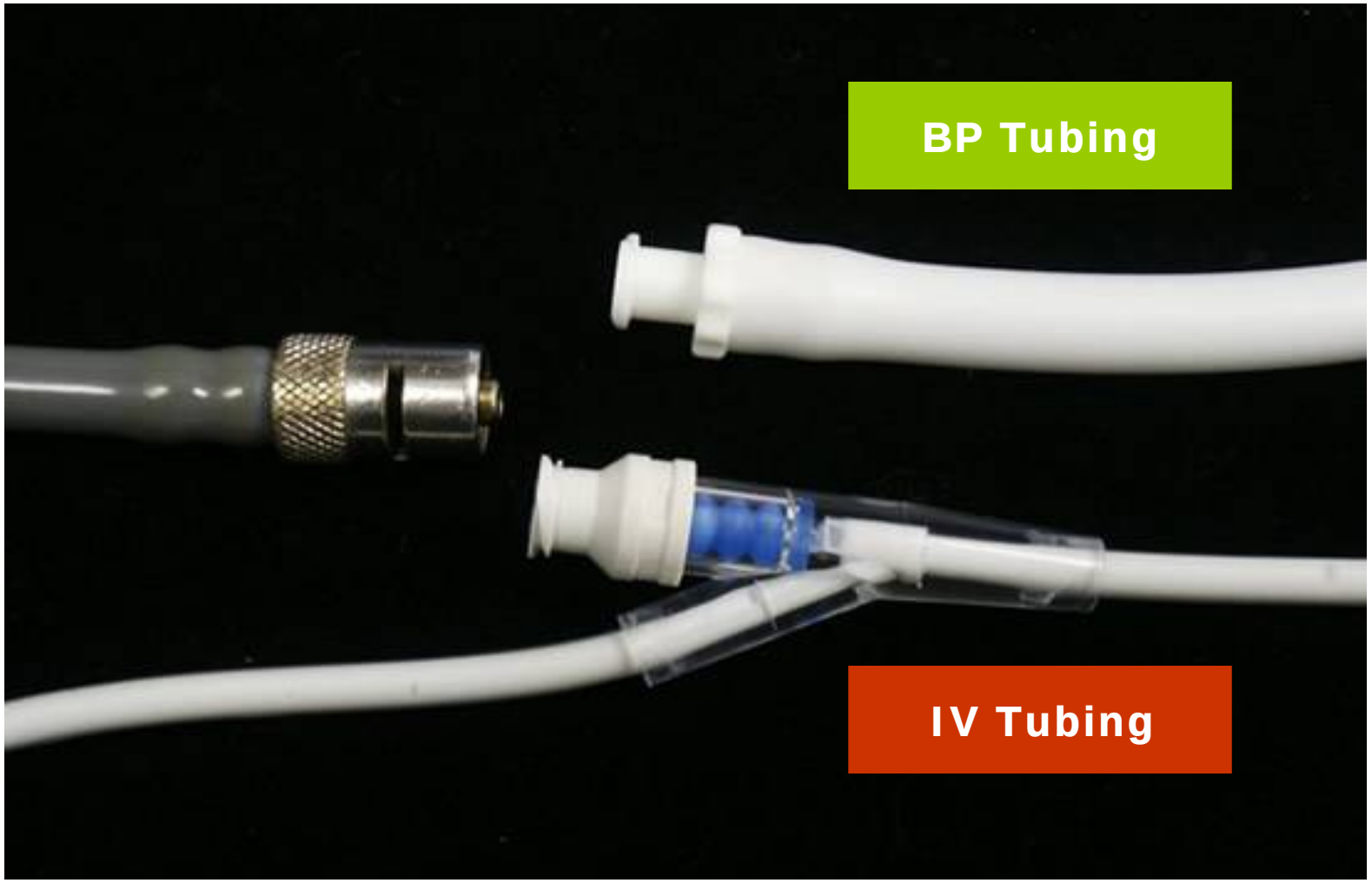
Courtesy of Beaumont Hospitals

Misconnections

Factors that contribute to misconnections: disconnections, adapters, Luer fittings, look-alike

Courtesy of Beaumont Hospitals

BP Tubing to IV Catheter



http://www.uwhealth.org

Safety Features

- Medication safety mechanisms
  - Dose error reduction systems
  - Hard/soft limits
- TALLman lettering
  - doBUTamine vs. DOPamine
  - NovoLOG vs. NovoLIN

Pictures courtesy of Carefusion

Safety Features cont.

- Anti-flow mechanisms (IV free flow)
  - Important for narcotics, cardiac medication, etc.
- Alarm
  - Down and Up pressure sensor (occlusion)
  - Air-in-line detector
  - Low battery
- Data logs
  - Event logs
  - CQI logs

Safety Features cont.

- Warnings
  - Low reservoir
  - Infusion set not loaded properly
  - Key press required
  - Low battery

Safety Features cont.

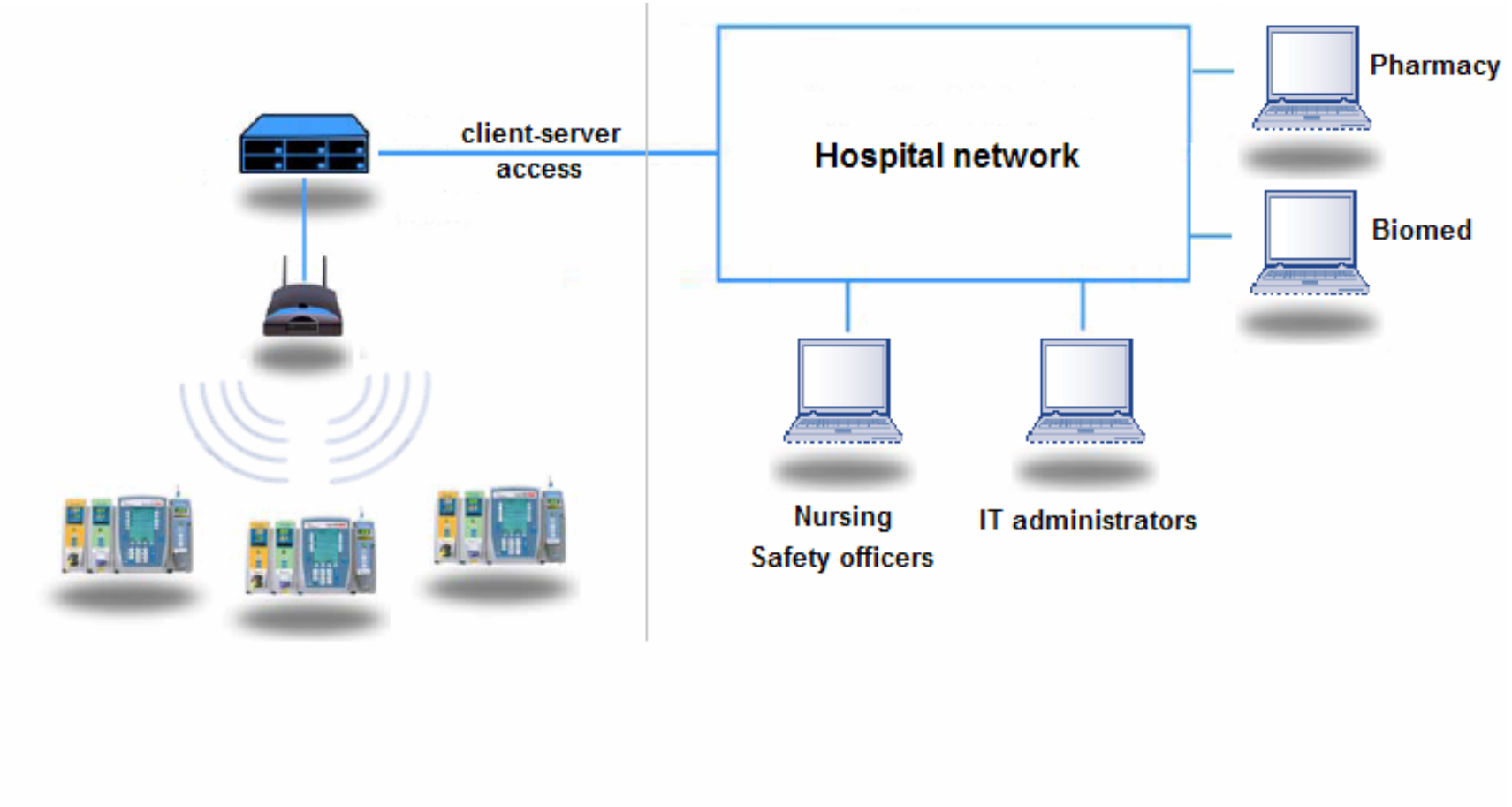
- Tubing sets
  - Standards harmonization
  - Change in clinical practices
  - Vendor support
  - Continued education

New Initiatives

- FDA will move to establish new requirements for infusion pump manufacturers, including a greater emphasis on design and testing.
- FDA will require additional information and testing as part of pre-market submissions.
- A draft guidance document from FDA recommends each infusion pump include a structured, evidence-based discussion of what manufacturers use to mitigate risk at each stage of the device's design cycle.

Wireless Applications

Wireless Applications



Courtesy of Carefusion

Wireless Applications

- Remote monitoring
- Maintenance
- Software upgrades & upgrades
- Customer support
- QI management

Courtesy of Carefusion

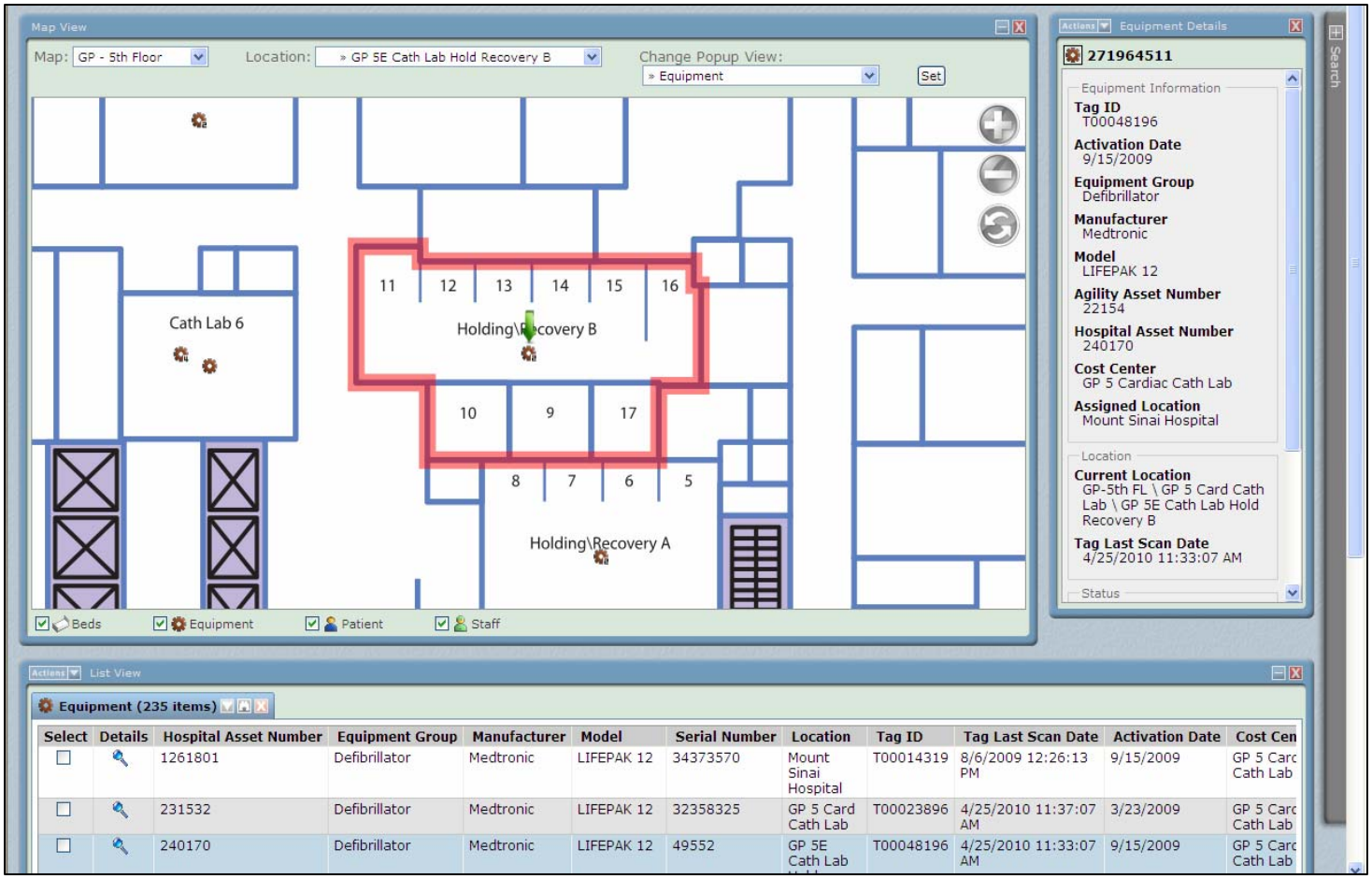
Barcode Scanning

- Provides bar code scanning for all infusions (bags and syringes)
- Provides patient, clinician and drug recognition at the point of care

Courtesy of Carefusion

Courtesy of Mount Sinai

RTLS* Tracking



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Location tag

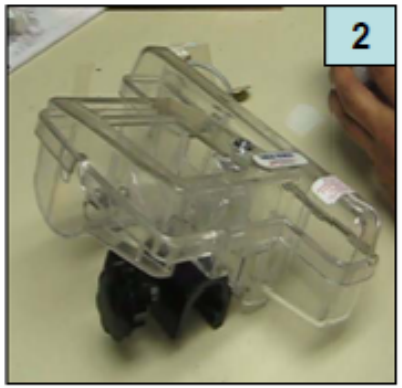
spider

star

* Real Time Locating System

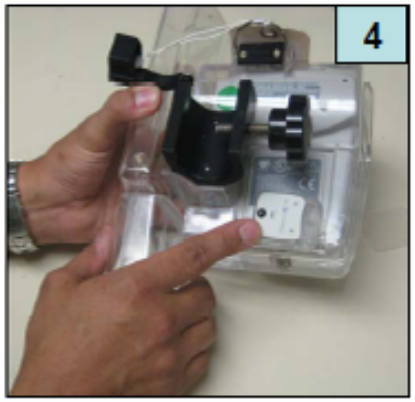
PCA Pump – RFID Tag

1. Rotate the RFID Tag over the battery door.



2. Have the lock box ready.

3. Insert the pump into the lock box. Close and lock the lock box.

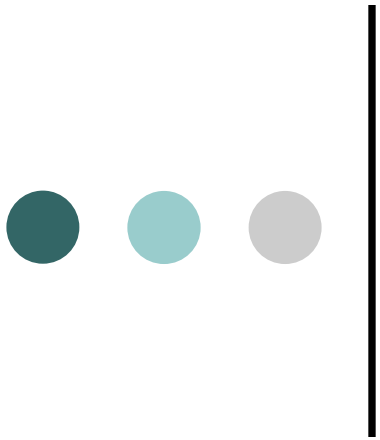


4. The pump and the lock box are ready for use.

Courtesy of Mount Sinai

References

- The Mount Sinai Medical Center, New York City
- William Beaumont Hospital, Royal Oak, MI
- FDA, www.fda.gov



Thank You!