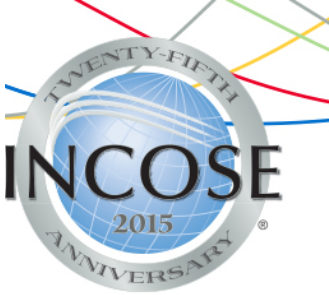
25th anniversary
annual INCOSE
international symposium
Seattle, WA
July 13 - 16, 2015

# From Asking Forgiveness to Saying "You're Welcome!" - *Introducing Requirements Engineering to Medical Device Development*

Casey Medina, CSEP
Kristina Fuerst, ASEP

# Top 10 Reasons Engineers Give for Not Writing Requirements




6. “Requirements? That’s somebody else’s problem.”

7. “We can’t know what they are until we actually build the system.”

8. “Why?  We’ve already designed it.”

9. “Requirements aren’t fun.”

10. “It takes too much time.”

# Top 10 Reasons Engineers Give for Not Writing Requirements

1. "But if I write them, I have to test them."
2. "Does anyone even look at the requirements?"
3. "Requirements stifle innovation!"
4. "Marketing is just going to change their minds anyway."
5. "Our customers don't know what they want, we know what they want."

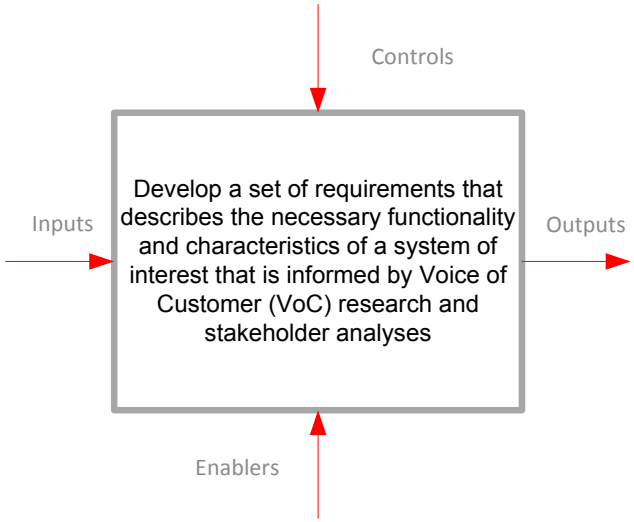
# We Started Here…

- Minimize user intervention.  Intuitive operation
- Minimize residuals
- Use existing approved material
- Easy to use
- Clamps ergonomic minimize
- Fitness

# Defining the Process

- Cultural resistance to adoption of requirements engineering process
- Regulations and standards governing requirements engineering in specific industries
- Availability of stakeholders

- Stakeholder needs
- Environmental constraints and characteristics
- System Concept, Operational Concept or Process idea for satisfying unmet needs
- Business Case



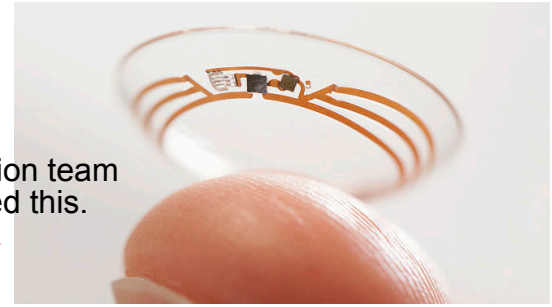

- Stakeholder Requirements Specification
- System Functional Model
- System Requirements Specification
- Logical Architecture
- Risk Analyses
- Lower-Level Requirements Specifications
- Requirements Analysis Report(s)
- Traceability Matrix

- Ethnographic and Anthropologic methodologies to obtain Stakeholder information and VoC data.
- Stakeholders
- Environments of Use

Without a proper understanding of the system's context, each individual on the team may have a different view of the implementation strategy for the finished system.

Systems team expected this.

GlucoWatch G2 Biographer



Innovation team expected this.

Google's "smart" contact lenses

Sales team expected this.

Medtronic CGM System

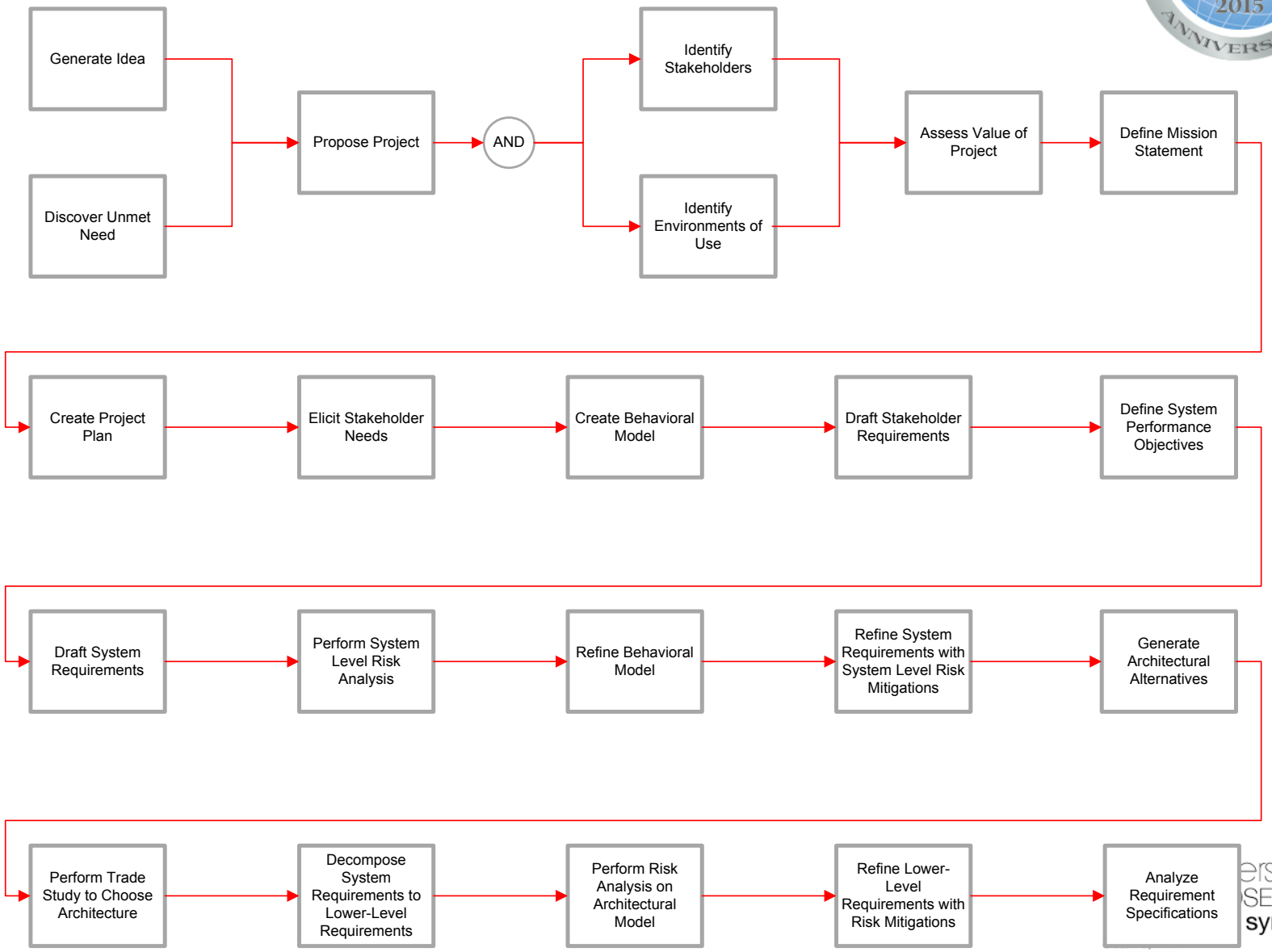
Customer expected this.

OneTouch® Ultra®2

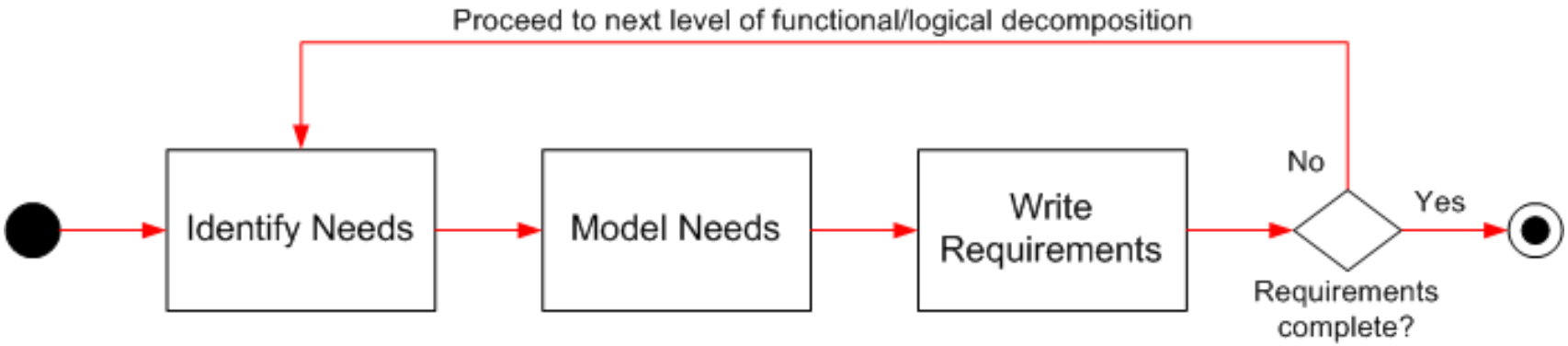

Regulatory team expected this.

GlucoTrack

# The Process

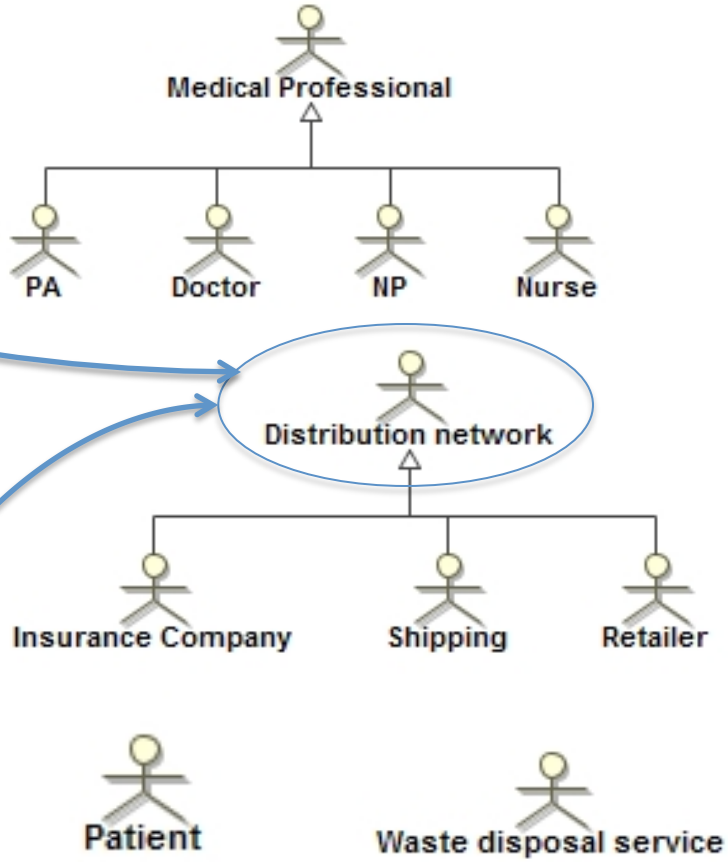

Generate Idea
Discover Unmet Need
Propose Project
AND
Identify Stakeholders
Identify Environments of Use
Assess Value of Project
Define Mission Statement
Create Project Plan
Elicit Stakeholder Needs
Create Behavioral Model
Draft Stakeholder Requirements
Define System Performance Objectives
Draft System Requirements
Perform System Level Risk Analysis
Refine Behavioral Model
Refine System Requirements with System Level Risk Mitigations
Generate Architectural Alternatives
Perform Trade Study to Choose Architecture
Decompose System Requirements to Lower-Level Requirements
Perform Risk Analysis on Architectural Model
Refine Lower-Level Requirements with Risk Mitigations
Analyze Requirement Specifications

# Philosophy


Proceed to next level of functional/logical decomposition
Identify Needs
Model Needs
Write Requirements
No
Yes
Requirements complete?

# ID Stakeholders and Observe Their Behaviors

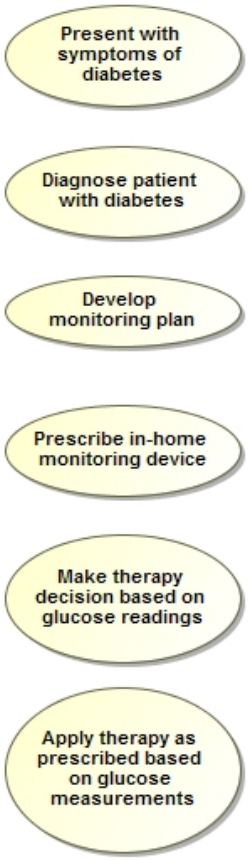
| | | | | |
|---|---|---|---|---|
| Patient acquires in-home glucose monitoring (g/m) device | instructions for using monitor | | | |
| | Patient uses g/m device per prescribed monitoring plan | -glucose readings<br>- request for supplies | | |
| | modified monitoring plan | Doctor makes therapy decision based on glucose readings | - therapy decision<br>- therapy prescriptions | renewal of monitoring prescriptions |
| | new established glucose level in patient | | Patient applies therapy as prescribed based on disease state | |
| | | | | Patient replenishes supplies |

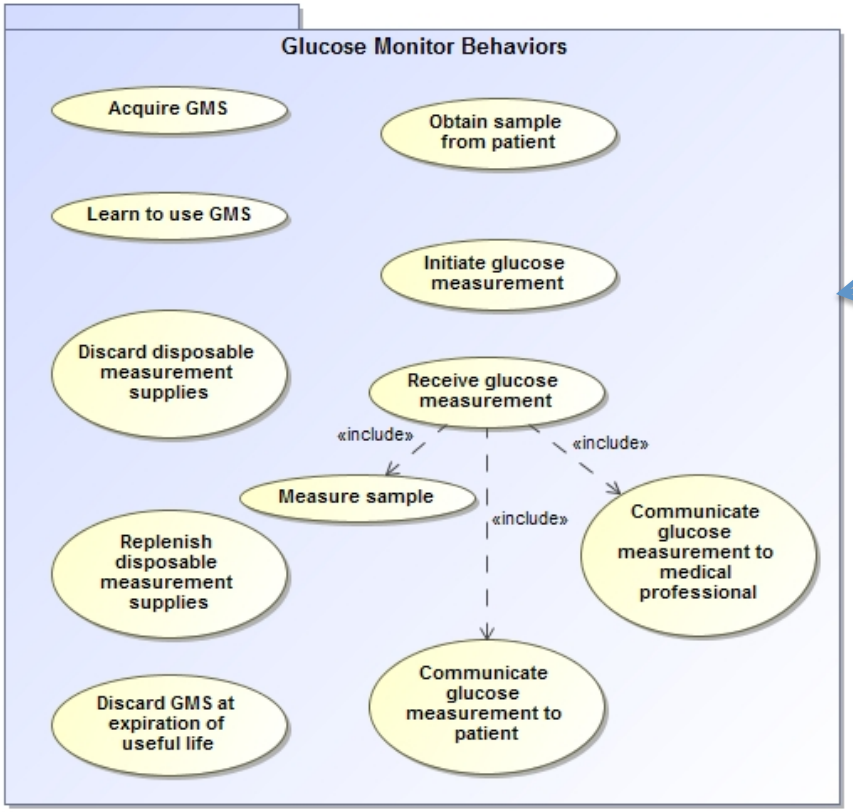


# Define System Mission

**Mission Statement:**

The GMS *receives* a **sample of patient fluid from the user**, *measures and reports* the glucose concentration of the sample to the user, and *transmits* the measurement to a remote data repository.



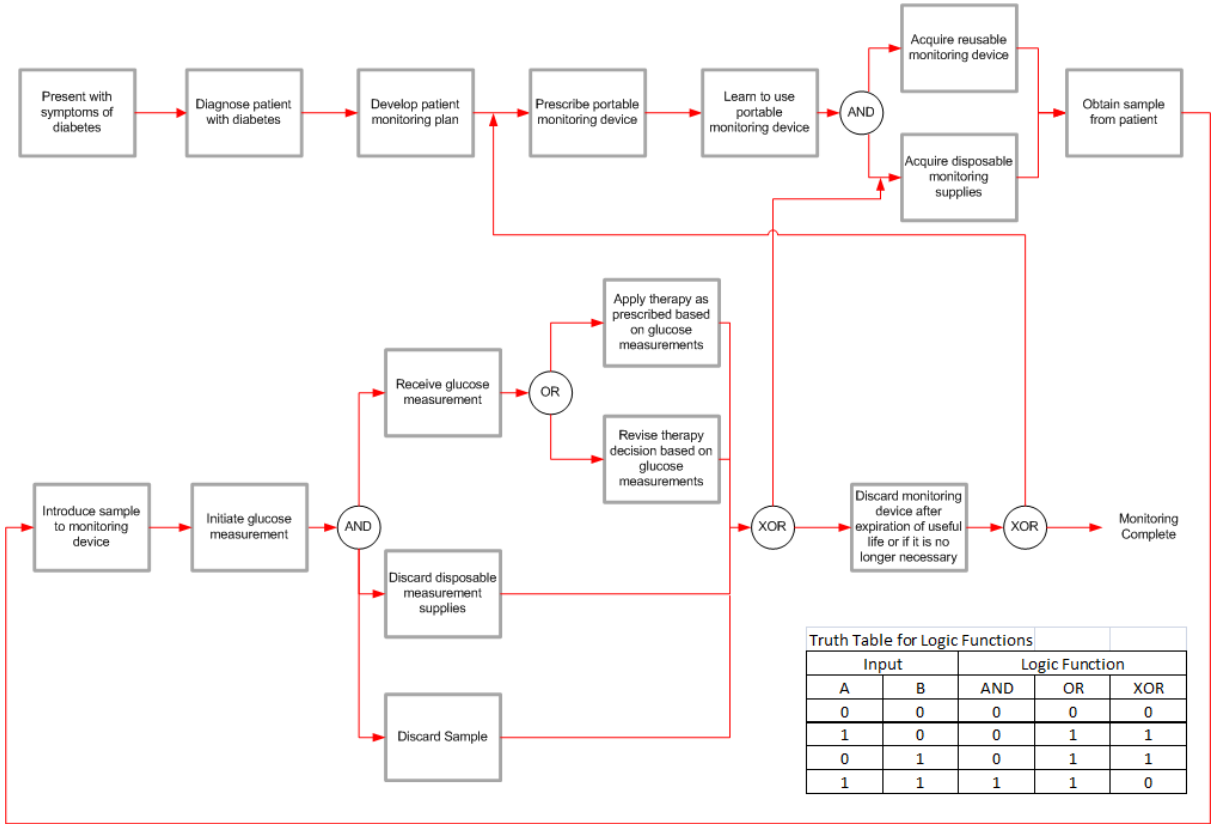




| | | |
|---|---|---|
| Patient uses g/m device per prescribed monitoring plan | -glucose readings<br>- request for supplies | |
| modified monitoring plan | Doctor makes therapy decision based on glucose readings | - therapy decision<br>- therapy prescriptions |
| new established glucose level in patient | | Patient applies therapy as prescribed based on disease state |

# Identify Stakeholders' Needs

| | Use Cases | |
|---|---|---|
| **Stakeholder** | Acquire G/M | Obtain glucose measurement per monitoring plan |
| Healthcare Institution | - Needs G/M to be cost-effective in large quantities<br>- Needs G/M to be reliable and durable<br>- Needs G/M to consume minimal storage space | |
| Medical Professional | | - Needs glucose readings to be accurate |
| Nurse | | - Needs G/M to be able to take measurements in rapid succession |
| Patient | - Needs G/M to be affordable or covered by insurance<br>- Needs to be able to obtain G/M through local sources, e.g. retail stores with pharmacies, or receive via shipping company | - Needs to be able to distinguish between the G/M and other monitoring devices<br>- Needs to be able to lift and maneuver the G/M with one hand<br>- Needs to feel confident that he/she is using the G/M correctly<br>- Needs the G/M and supplies clearly identified to ensure he/she does not make a mistake when using it<br>- Needs to be able to use the G/M by him/herself<br>- Needs measurement to occur as quickly as possible to avoid disruption to daily activities<br>- Would like measurement process to generate little physical pain as possible<br>- Needs to be able to use the G/M if he/she cannot see the interfaces |

# Process Breakdown




Truth Table for Logic Functions

| Input | | Logic Function | | |
|---|---|---|---|---|
| A | B | AND | OR | XOR |
| 0 | 0 | 0 | 0 | 0 |
| 1 | 0 | 0 | 1 | 1 |
| 0 | 1 | 0 | 1 | 1 |
| 1 | 1 | 1 | 1 | 0 |

- Patient fluid sample
- Patient unique identification
- Patient glucose nominal range
- Location of patient data file

- Patient mobility
- Patient comfort with technology
- Required frequency of measurement
- Availability of support services if patient is unable to use monitor
- Availability of system to acquirer
- FDA governance
- Country-specific regulations
- Method of disposal available to user
- Shipping environment
- Use environment
- Storage environments

Controls

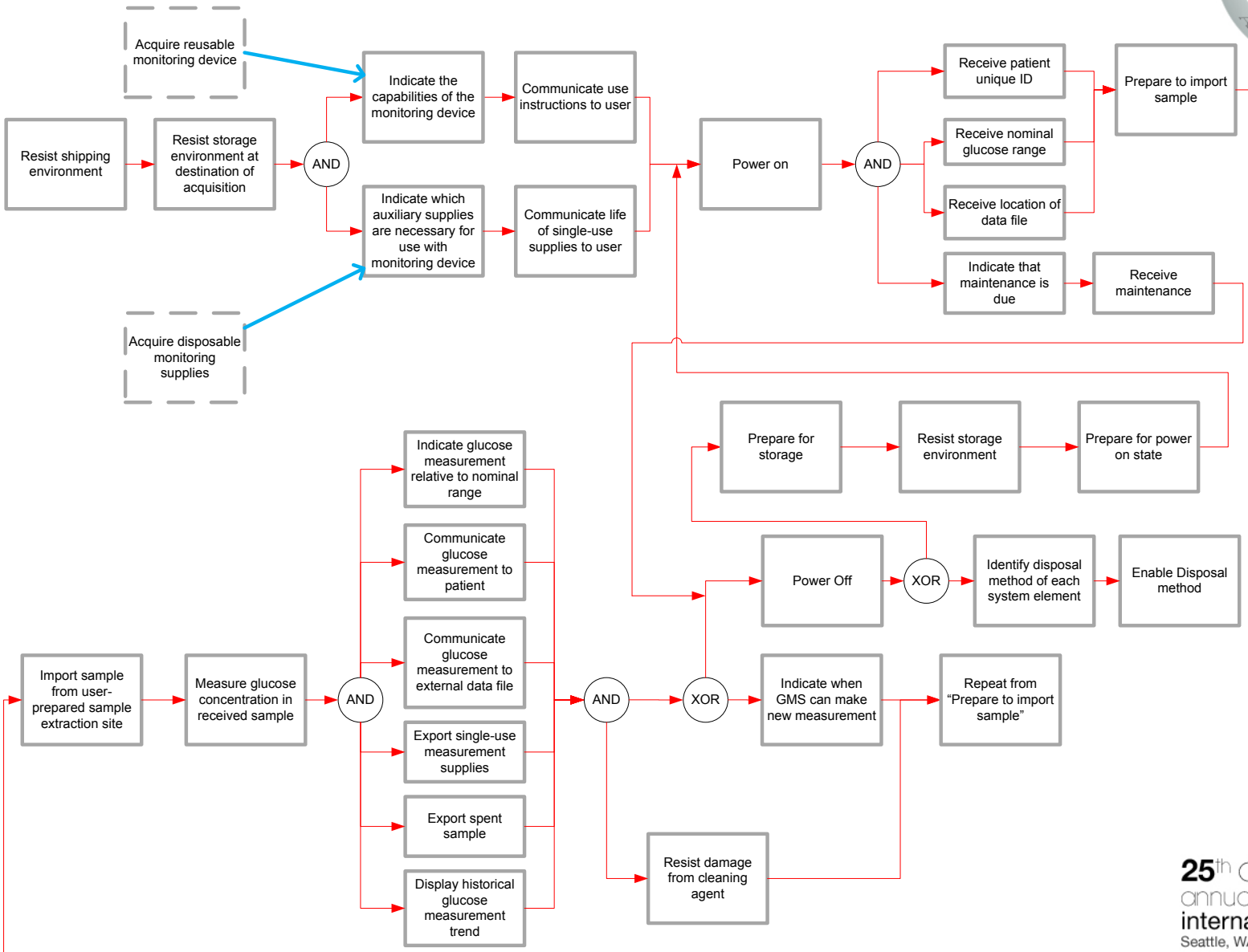
Inputs → Provide glucose measurements to the patient and a remote patient data file upon the patient's request. → Outputs

Enablers

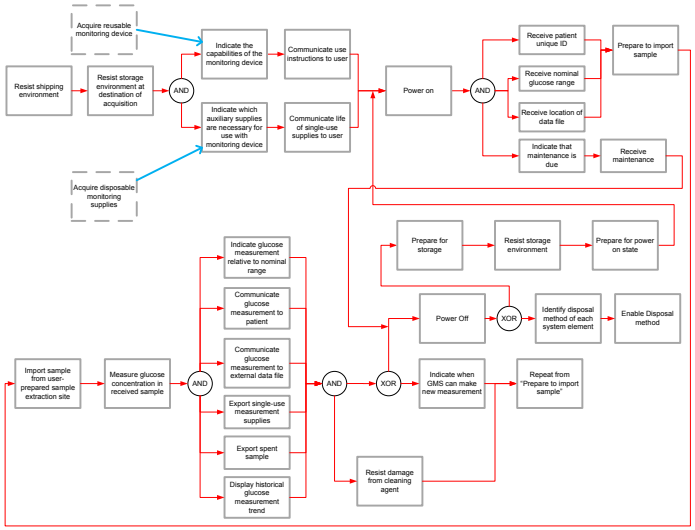
- Whole-blood glucose monitoring technology
- Instructions for operation of the monitor
- Glucose Monitor, including device and any single-use supplies
- Auxiliary supplies to assist with sample site preparation
- Existing patient data file

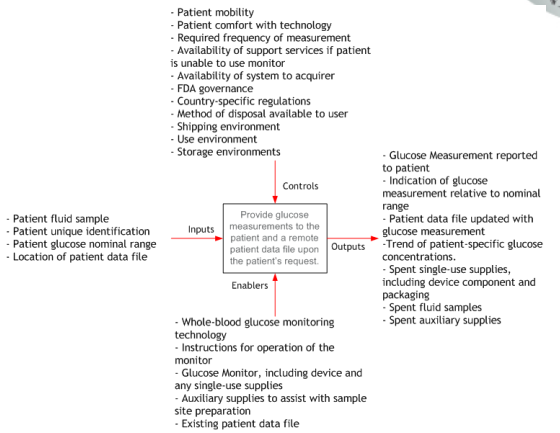
- Glucose Measurement reported to patient
- Indication of glucose measurement relative to nominal range
- Patient data file updated with glucose measurement
- Trend of patient-specific glucose concentrations.
- Spent single-use supplies, including device component and packaging
- Spent fluid samples
- Spent auxiliary supplies

# Process Breakdown

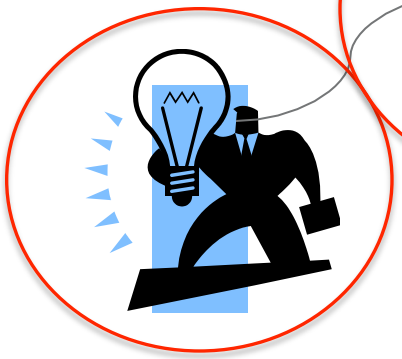


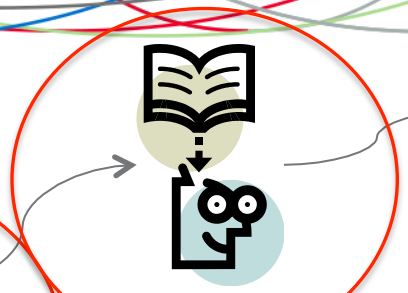
# Process Breakdown

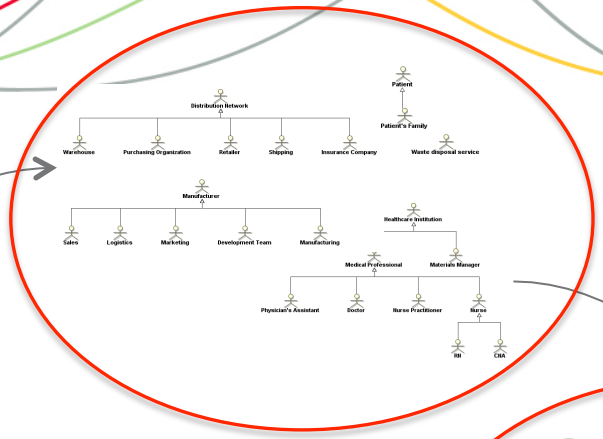


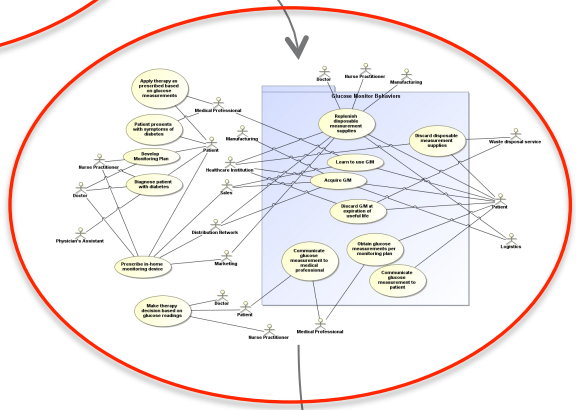



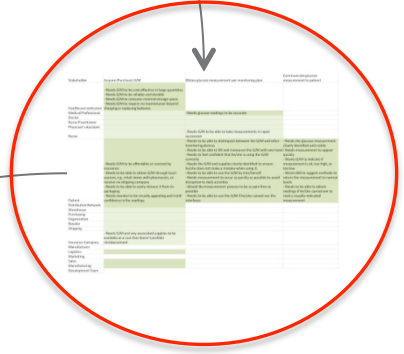

| Location of Stakeholder Need | Description | Stakeholder Requirement |
|---|---|---|
| Input | Patient fluid sample | The system shall receive a sample of patient fluid. |
| Output | Trend of patient-specific glucose concentrations | The system shall display a trend of historical, measured glucose concentrations of a single patient. |
| Control | Required measurement frequency | The system shall exhibit a maximum mean time between measurements of 2 minutes. |
| Enabler | Auxiliary supplies to assist with sample site preparation. | The system shall identify auxiliary supplies necessary for operation. |
| System FFBD | Measure glucose concentration in received sample | Upon receipt of the sample of patient fluid, the system shall measure the glucose concentration in the sample of patient fluid. |

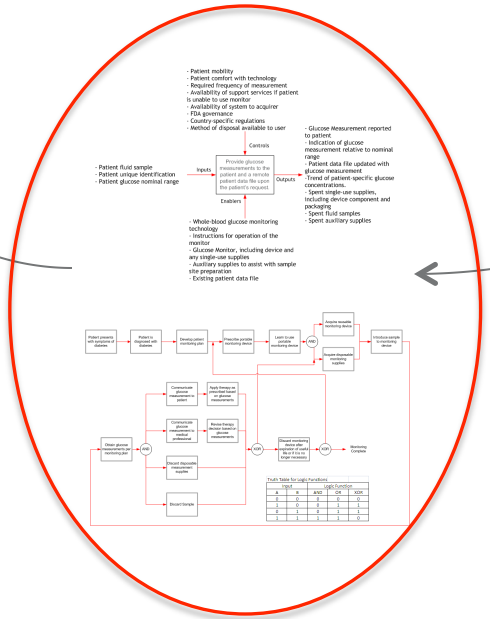


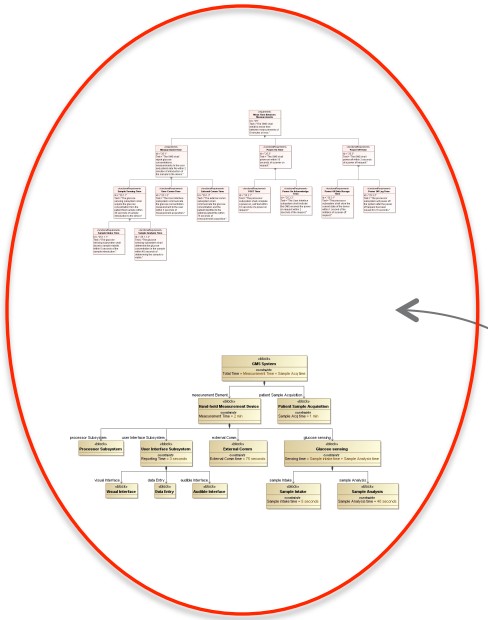







25th anniversary annual INCOSE international symposium
Seattle, WA
July 13 - 16, 2015

# Keep This In Mind

**Do:**

- Identify early adopters
- Use an early adopter to help teach and implement
- Coach and mentor with positive reinforcement
- Use accepted terms
- Encourage tough discussions
- Be patient

**Don't:**

- Teach a classroom full of "haters"
- Expect everyone will like the process
- Tell them "You're wrong!"
- Force systems engineering vernacular
- Sweep issues under the rug
- Expect perfection

# Successful Implementation

Teams are…

- Generating mission statements earlier
- "User" is not just the "operator"
- Identifying and describing interfaces
- Evolving the expectation that requirements are to be complete and written before development starts

# Successful Implementation

Teams understand…

- Purpose of complete requirements
- Purpose of tracing requirements
- Concept of  architecture
- System items interact to achieve necessary system function

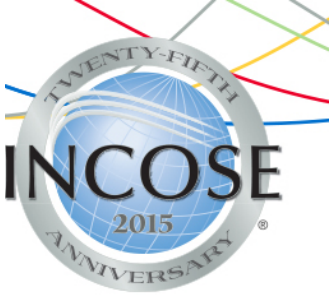
# Remember where we started:

- Minimize user intervention.  Intuitive operation
- Minimize residuals
- Use existing approved material
- Easy to use
- Clamps ergonomic minimize
- Fitness

# We Have Arrived Here!!!

- The system shall operate between ambient temperature conditions of 16ºC to 26ºC.
- The system shall transport byproducts of cellular respiration out of the cell culture environment.
- The subsystem shall enable the user to obtain a representative, minimum of one 0.6 mL sample of media, while maintaining the functionally-closed state.

# Top 10 Things Overheard After Implementation




6. "I can't believe *that* team didn't write requirements for their project first!"

7. "Now we're more confident we're building the right thing."

8. "It's much cheaper to write requirements first."

9. "Tribal knowledge is captured, I finally know what that old dude was thinking!"

10. "Our projects run better now, but I'll never admit it."

# Top 10 Things Overheard After Implementation

1. “I actually know what I need to verify; but I still don’t like that I have to.
2. “We’re catching problems much earlier in the process.”
3. “There’s a lot less scope creep now; I hate it when these guys are right.”
4. “It’s so much easier to plan the technical effort now!”
5. “We delivered a product our customers loved!”

Thank you!

# QUESTIONS?