A Voice of the Customer Process for Medical Device Development

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What's in it for us?

➢ Until the world is run by robots (latest estimate: 2017)…

➢ Humans interact with **any** technology at some level.

➢ VOC gives us a way to understand the users behind the technologies we develop… before we develop them.
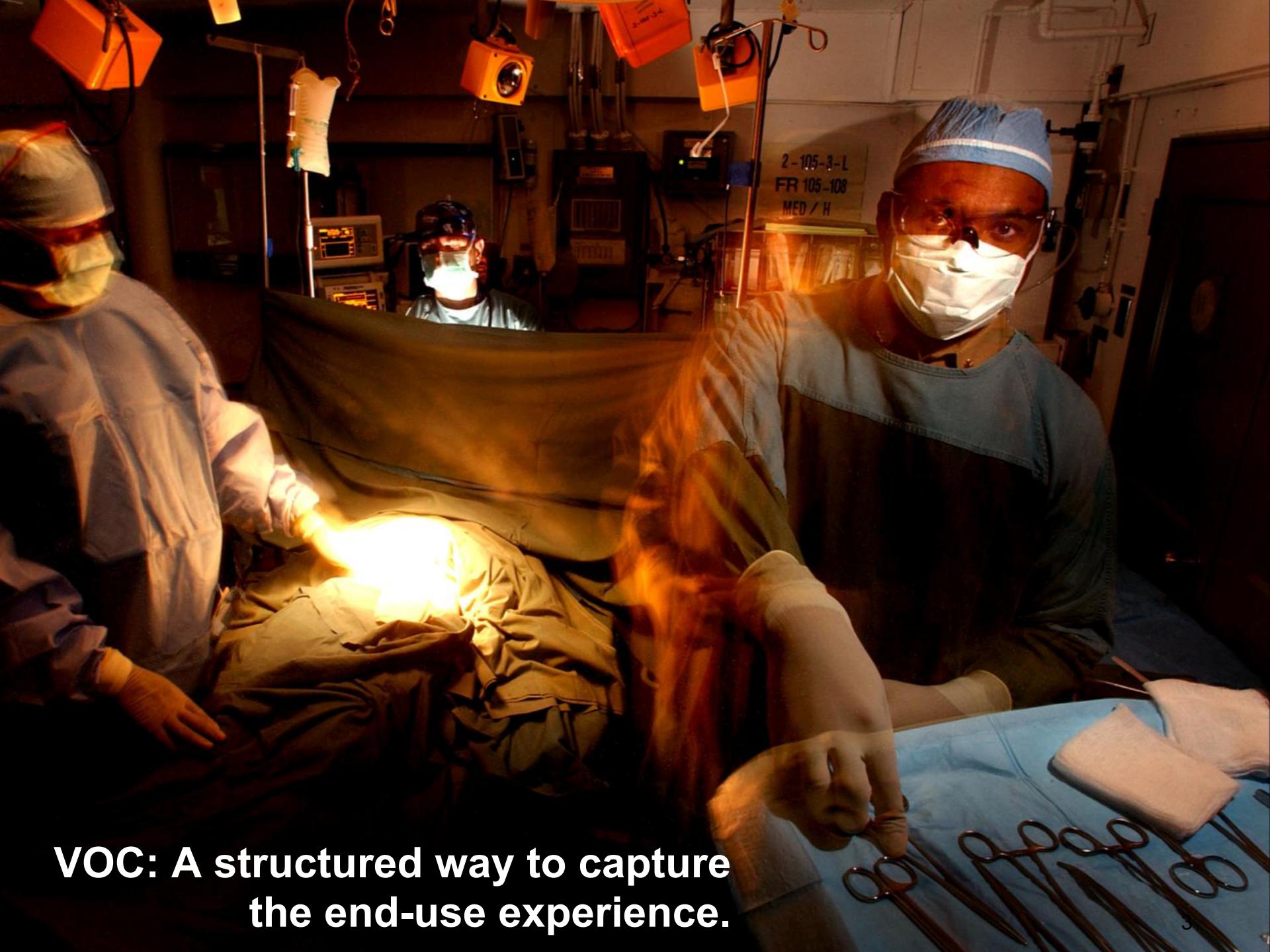
VOC: A structured way to capture the end-use experience.

How does it fit into the larger SE framework?
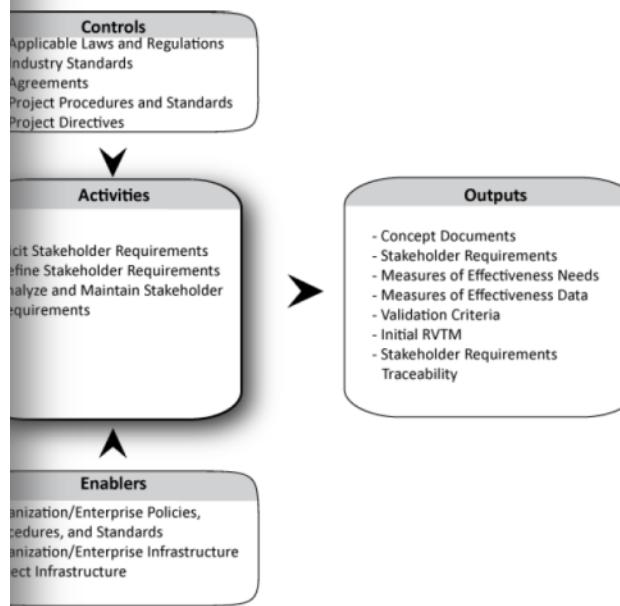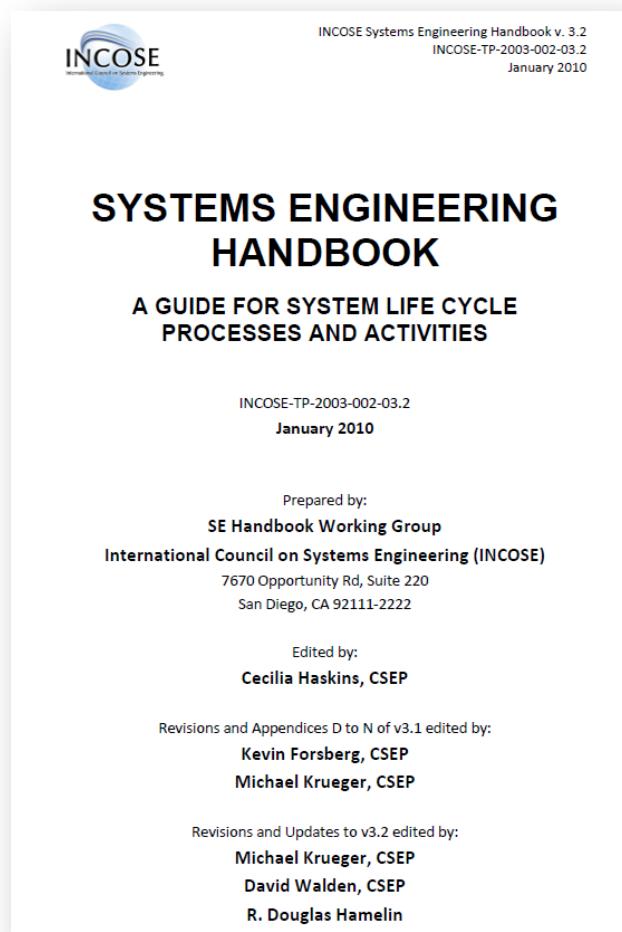
Additional Benefits for Medical Device Development

➢ Safety Risk Management
  – Use Error
  – Foreseeable Misuse
➢ Requirements Development
➢ Software Validation
➢ System Validation

VOC Process: Overview
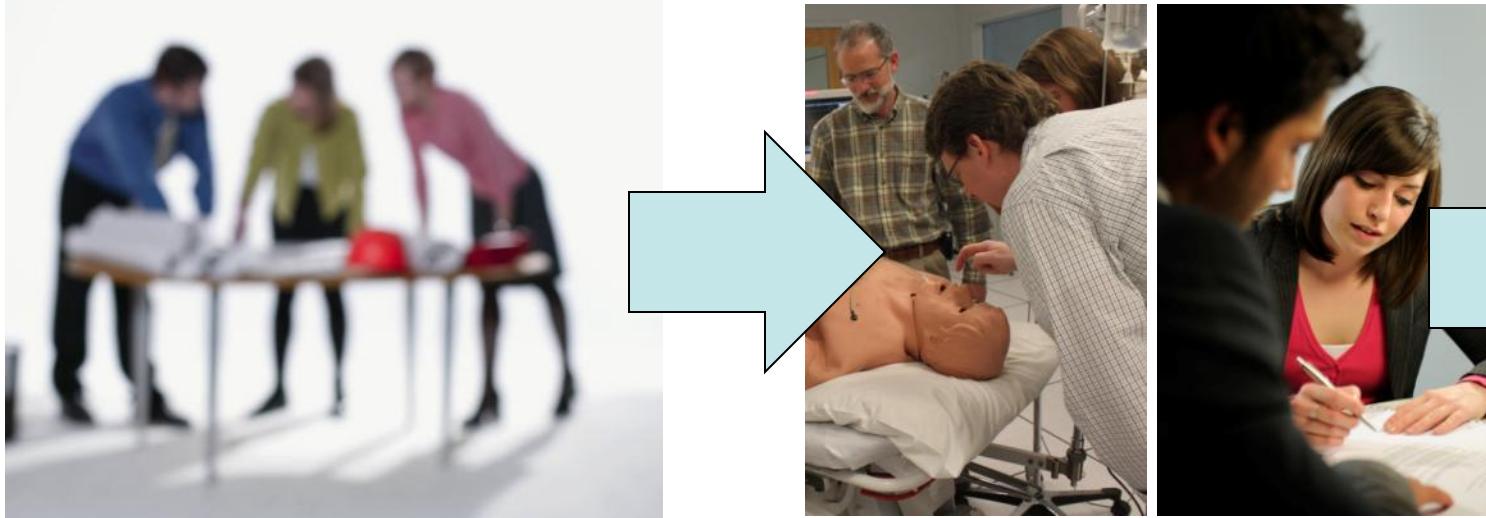
VOC Process: Preparation

VOC Process: Interview and Observe
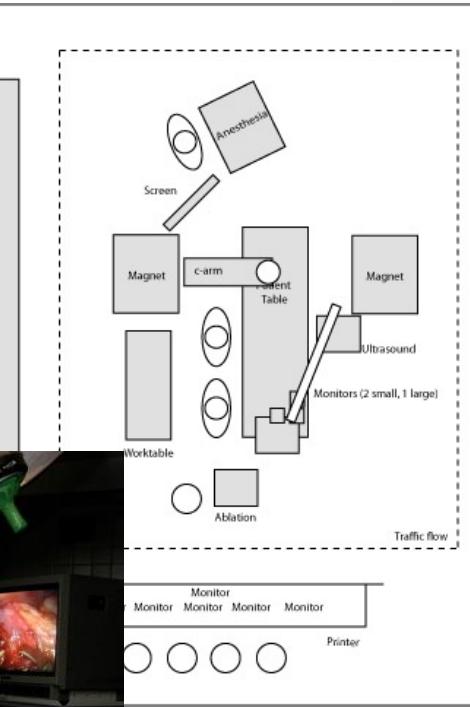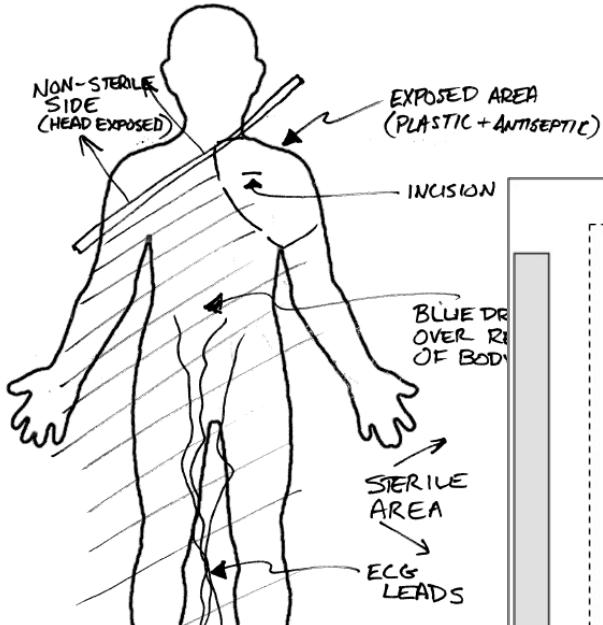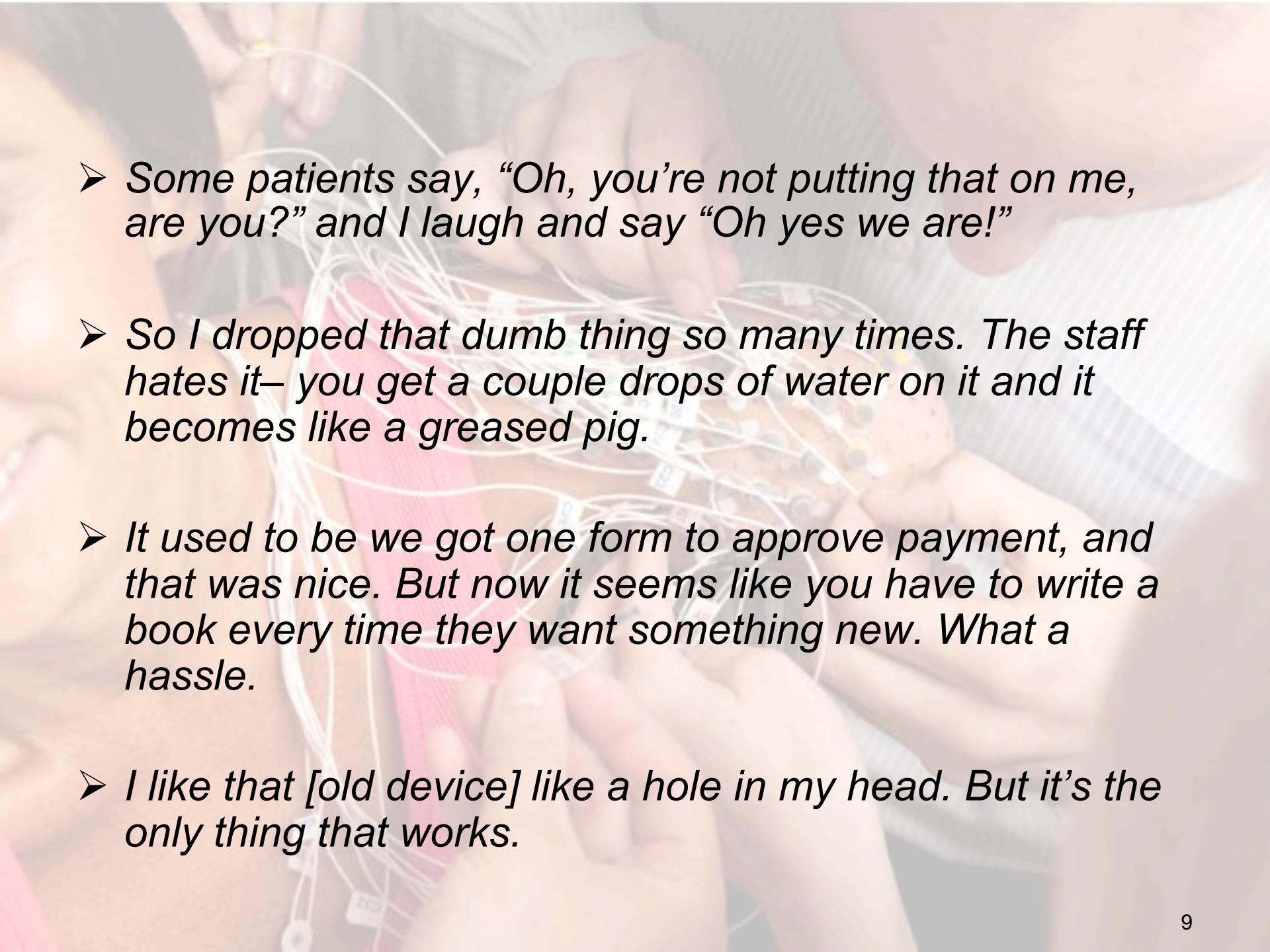
- *Some patients say, "Oh, you're not putting that on me, are you?" and I laugh and say "Oh yes we are!"*

- *So I dropped that dumb thing so many times. The staff hates it– you get a couple drops of water on it and it becomes like a greased pig.*

- *It used to be we got one form to approve payment, and that was nice. But now it seems like you have to write a book every time they want something new. What a hassle.*

- *I like that [old device] like a hole in my head. But it's the only thing that works.*

VOC Process: Voice to Need Translation

➢ <u>Voice</u>: "I'm never really sure of my glucose meter's results."

➢ <u>Key Items</u>: accuracy, repeatability, instill confidence.

➢ <u>Stakeholder Need</u>: The patient takes their blood glucose readings more accurately.

VOC Process: Stakeholder Validation

VOC Process: Other Stakeholder Needs

VOC Process: Transition to "Solution Space"
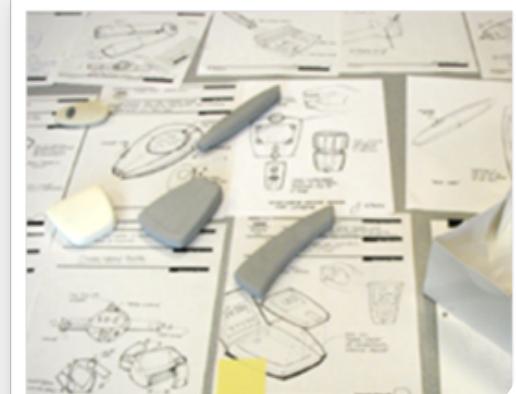
VOC Summary

➢ Structured process to understand stakeholder needs.

➢ Fits well into other front-end systems engineering activities.

➢ Its use in medical devices industry creates other tangible benefits downstream.

Battelle Medical Devices & Diagnostics

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*Innovation occurs at the intersection
of multiple disciplines.*

- Contract medical device research & product development company

- ISO13485 and ISO9001 registered Quality Management System

**1967-2009
217 total**

**2004,
2008**

2002