Murphy’s Law Meets a Medical Device

What can possibly go wrong?
Relax, Mr. Miller. It's just a standard prostate exam.
Prostate Disease

Every man has a 1 in 6 lifetime risk of getting prostate cancer.
Of $1.75B spent on prostate biopsies each year in the US, more than $1.4B is completely unnecessary.

Some say prostate volume is the most important risk factor in diagnosing and monitoring prostate disease.
The Solution

Measure prostate volume *early* in the diagnostic process at low cost.

Knowing volume early allows the urologist to avoid most of the costs of unnecessary biopsies, providing potential savings of more than $2B in the US and additional billions globally.
Measuring Prostate Volume Challenging!

• Designing it
  • Is Wps correlated with Volume?
  • Human Anatomy

• Making it
  • Engineering Materials (*Hello Mr. Murphy*)
    • Works in vivo
  • Doctors forefingers and differing DRE techniques
Mr. Murphy’s Perversity

• Balloon inflation
  • Shape
  • Materials
    • Latex ➔ Polyisoprene ➔ Silicone
  • Surface (in and out)
  • Unexpected Deflation
  • Slippage on rectal wall

• Manufacturing
  • 3D Printing
  • Air path
  • Optics
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Evolution - Controller
Evolution - Controller

v.3.2 → v.4.3
Evolution - Controller

v.3.2 → v.4.3 → v.5.1
Evolution - Controller
Evolution - Controller

Connectors
Evolution - Controller
Evolution - Controller

2/2/2017
MedicaMetrix
Evolution - Controller

Relief valve and air pathway
Evolution - Encoder
Evolution - Encoder
Evolution - Encoder

Fingertip Optical Encoder

Measurement roller wheel

Balloon
Evolution - Encoder

"One Size Fits All"

Fingertip Optical Encoder

Measurement roller wheel

Balloon

Ambidextrous

Fits up to Size 9

2/2/2017 MedicaMetrix
Technology

• Based on technology from servomotors
Technology

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- First glove designs had a stationary grid and a moving encoder
Technology

• Based on technology from servomotors
• First glove designs had a stationary grid and a moving encoder
• Encoder has reversed this -- moving grid and a stationary encoder
  • Back to the servomotor design
Gremlins be Gone!

We’re in Production

ISO 13485 certified