Commercialization of Emerging Medical Sensors for Disruptive Healthcare Applications

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Emerging Technology Commercialization

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Inspiration - Design - Commercialization

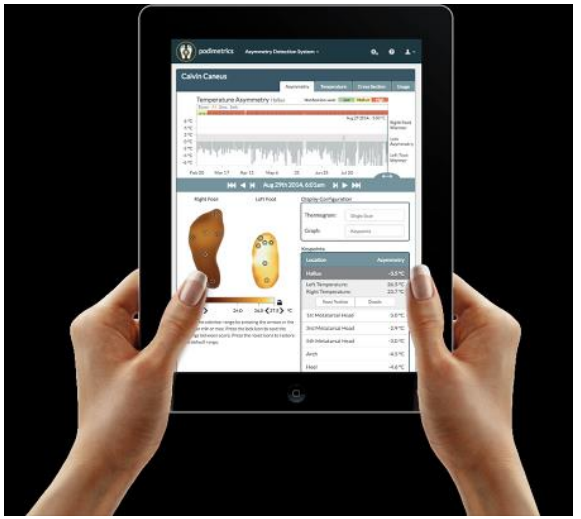
Sensors, MEMS / Nano, Electromechanical Products, Conservation

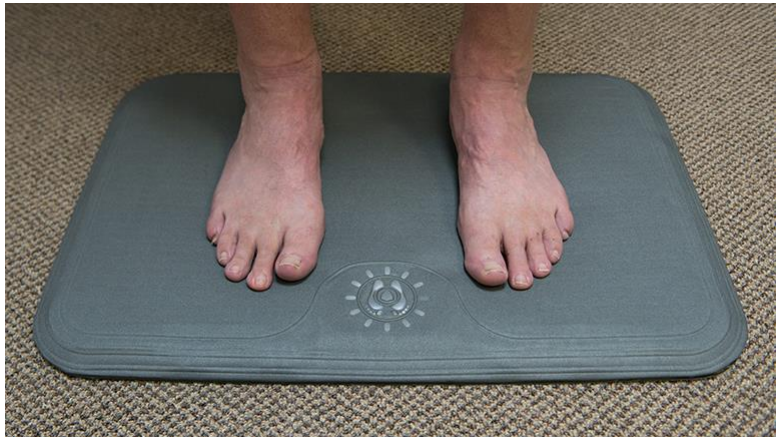
Background

- The medical industry is ripe for disruption from sensors that enable healthcare professionals to provide more effective, more affordable diagnosis and treatment
- Design for commercialization is necessary to reach the market and to achieve performance, scale and cost targets as quickly as possible
- This webinar segment will evaluate commercialization readiness of two medical sensors currently in development or the early stages of commercialization
- Factors considered will include:
  - Need
  - Overall impact
  - Time to market
  - FDA approval
  - Continuous vs intermittent monitoring
  - Design for manufacture and quality
  - Software integration
  - Performance
  - Cost
  - Core technology building block - derivatives for business growth
  - Marketing strategy

Podimetrics - RTM System

- Remote Temperature Monitoring System
- A system that monitors temperature differences between multiple locations on the same foot and between feet to detect a future diabetic foot ulcer before it occurs.
- Actionable information is provided via a smart device to patients and doctors

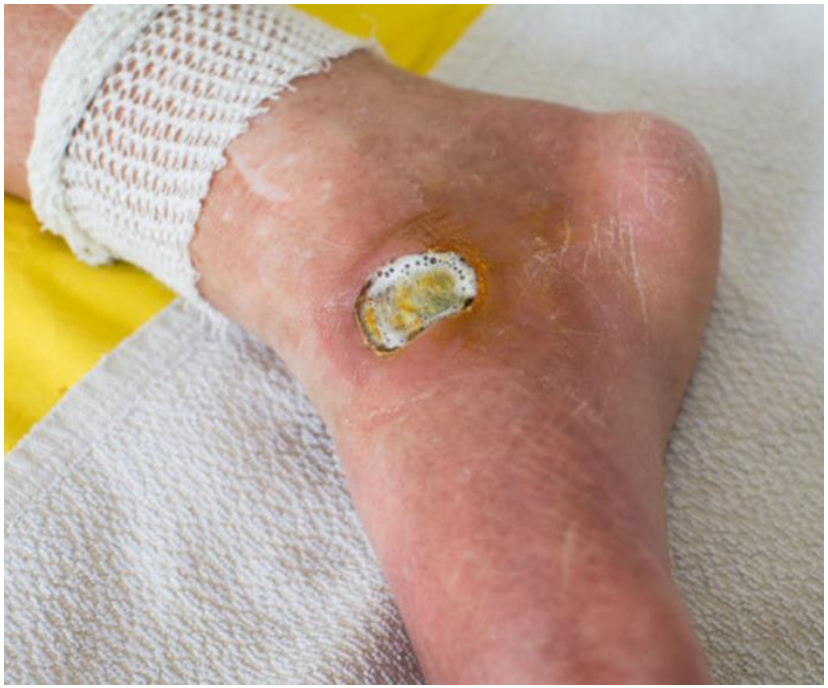




Photos courtesy of Podimetrics - https://www.podimetrics.com/

Podimetrics - RTM System

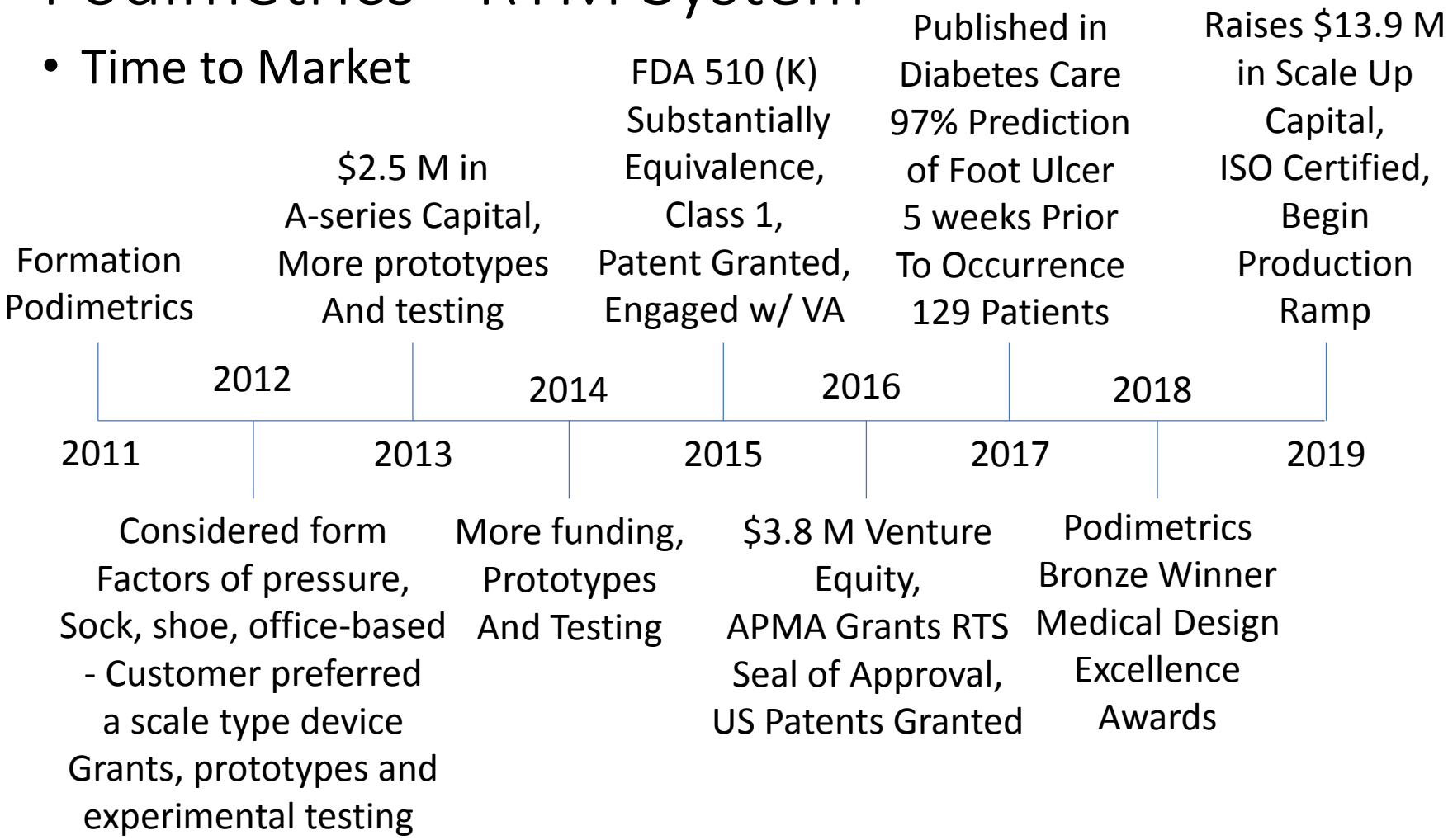
- Need for Remote Temperature Monitoring System
  - Diabetics are at risk of developing neuropathy (numbness in the extremities) resulting in uneven foot pressure distribution and ulcers
  - Foot ulcers effect 3.6 Million diabetics in the US alone (CDC)
    - https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5245a3.htm
  - Cost of treatment for a foot ulcer, the leading cause of below knee amputations, is $30,000 post initial two years or $10.9 billion annually in US alone for diabetic foot care management and treatment (NCBI)
    - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5761954/
  - Detection of foot ulcers requires daily foot inspection by patients and is not straight forward for a podiatrist with limited visits



Diabetic Foot Ulcers: Why You Should Never Ignore Them, Cleveland Clinic - Diabetes & Endocrinology, April 24, 2018, https://health.clevelandclinic.org/diabetic-foot-ulcers-why-you-should-never-ignore-them/

Podimetrics - RTM System

- Time to Market



Podimetrics - RTM System

- FDA Classification and Determination
  - Submitted a Section 510(k) premarket notification
  - FDA Determination: Substantially Equivalent
  - Class 1
  - General controls: Annual registration, listing of devices, good manufacturing practice with quality system, medical device reporting (medical device-related adverse events), labeling, and prohibitions against misbranding and adulteration

Podimetrics - RTM System

- Continuous vs Intermittent Monitoring
  - Once per day for 20 secs but proven effective
  - Cannot track changes throughout the day
  - Requires participation and consistency

Podimetrics - RTM System

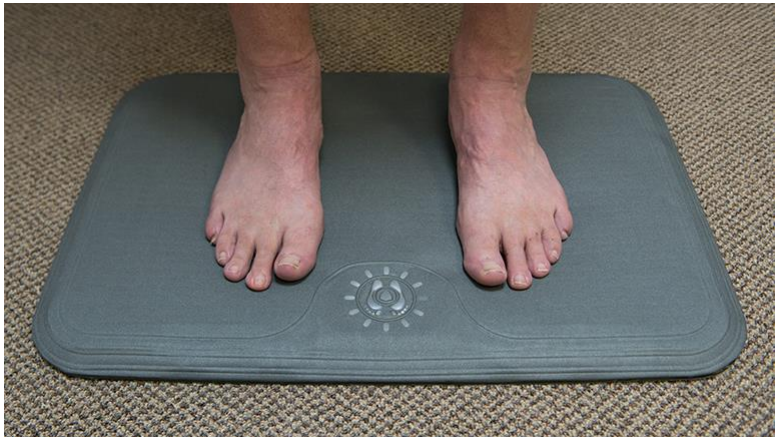
- Design for Manufacture and Quality
  - Manufacturing partner brought into game very late (8 years after start)
    - Production variation may effect performance beyond acceptable limits and could result in an expensive design change or yield loss
  - A quality system may have been developed prior to FDA determination of substantially equivalence but Podimetrics did not receive ISO certification until 2019
    - Control plan, FMEA, dimensional capability studies, manufacturing test methods, design and pilot validations
    - Is there a method to test and diagnose system without disassembly?
  - Some changes in product system after clinical studies
    - Every time a change is made you risk introducing a new variable that changes performance or can introduce a quality problem
    - Better to get to final production design as soon as possible

Podimetrics - RTM System

- Design for Manufacture and quality

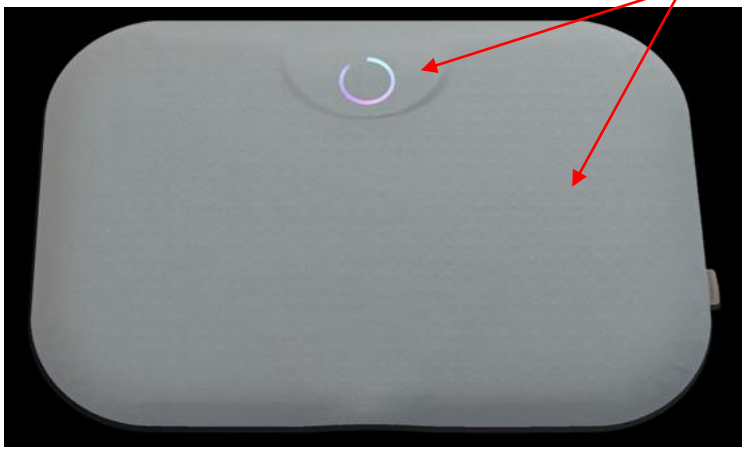
Chance for Quality issues

Prototype design



Medgadget: https://www.medgadget.com/2017/07/podimetrics-system-helps-prevent-diabetic-foot-ulcers-interview.html

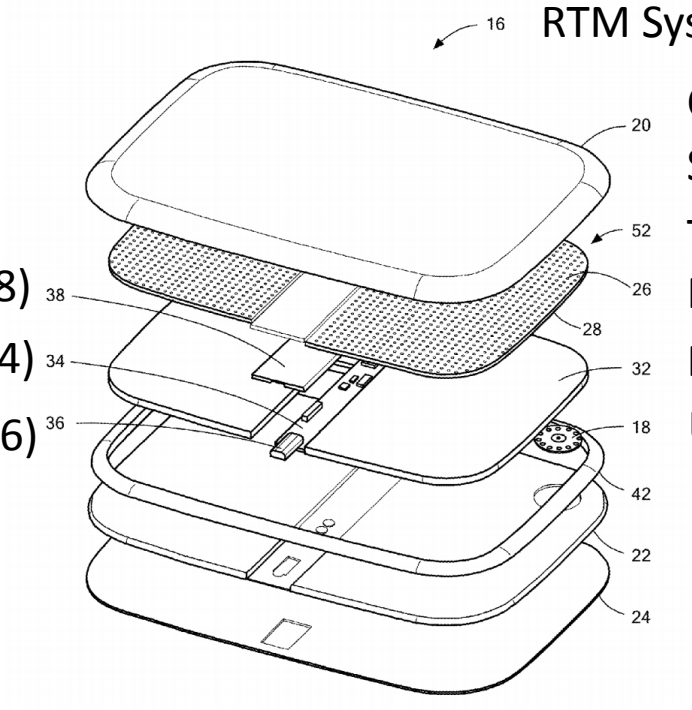
Production design



Photograph courtesy of Podimetrics

Podimetrics - RTM System

- Design for manufacture and quality
  - Can components be combined for added simplicity and reduced part count?



RTM System (16)

Cover (20)

Sensor Matrix (52)

Temperature Sensors (26) and Printed circuit board (28)

Circuit Housing (38)

Mother board (34)

Flexible layer of foam (32)

Battery Pack (36)

User Interface Display (18)

Edge for aesthetics (42)

Rigid base (22)

Non-skid base (24)

Photograph courtesy of US Patent

Podimetrics - RTM System

- Software integration and user interface
  - RTM System automatically connects to cloud and Podimetrics does all the analysis for the patient
  - Patient alerted via text of issue requiring action
  - Patient sees analysis from smart device
  - 86% adherence rate 3 times a week in clinical studies (high) and 88% reported easy to use (again high)
  - User Interface can be improved for doctors and patients to focus on the critical area and immediately know if an issue is present
  - Can voice be used? Siri can help.
  - Individual can then view more detailed information can if desired

Photograph courtesy of Podimetrics

Podimetrics - RTM System

- Performance
  - Numerous awards and publications of their work
  - Diabetes Care: 97% prediction of foot ulcer 5 weeks prior to occurrence (extremely strong performance)
  - 86% adherence rate 3 times a week
  - VA recently released a national guidance document recommending Podimetrics for high-risk patients
  - Will this performance of RTM system hold with devices made in production environment with tolerance and equipment variability?
  - What happens with an ulcer is not located on the bottom of the foot?
- No cost information available currently
  - Given the severity of foot ulcers what will insurance pay to have this in every diabetic's home who is in at risk group? Are they selling to podiatrists and insurance companies?
  - What will consumers pay for this device? Can price be reduced for direct to consumer option?

Podimetrics - RTM System

- Use of a core technology building block for future derivatives and business growth
  - Can data collection hardware and wireless communication be used for an alternate medical devices
  - Can software and data analytics and user interface be modified slightly for another product
  - What other diseases can this core technology be used for?
    - Can a pressure sensor be added to provide better detection of Charcot's Foot and related swelling and unnatural pressure distribution?
    - Monitor recovery of foot injury and effectiveness of treatments with the same or alternative packaging?
- Marketing strategy
  - Senior sales executive hired in 2019 to broaden use among the veteran affairs clinics
  - Podiatrists don't know of this system's existence
  - Better approach is spending equivalent dollars on marketing as the technical

GBS Inc. – Saliva Glucose Biosensor

- First non-invasive, saliva-based glucose test for diabetes management

Place Saliva Glucose Biosensor in contact with saliva

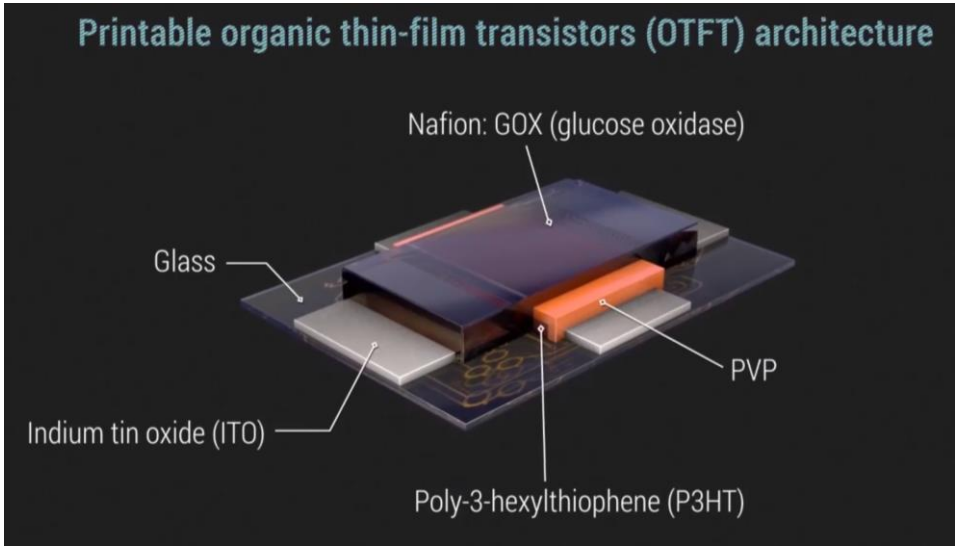
With biosensor nearby, the digital app displays glucose measurement

App provide real time comparison and flags attention when needed

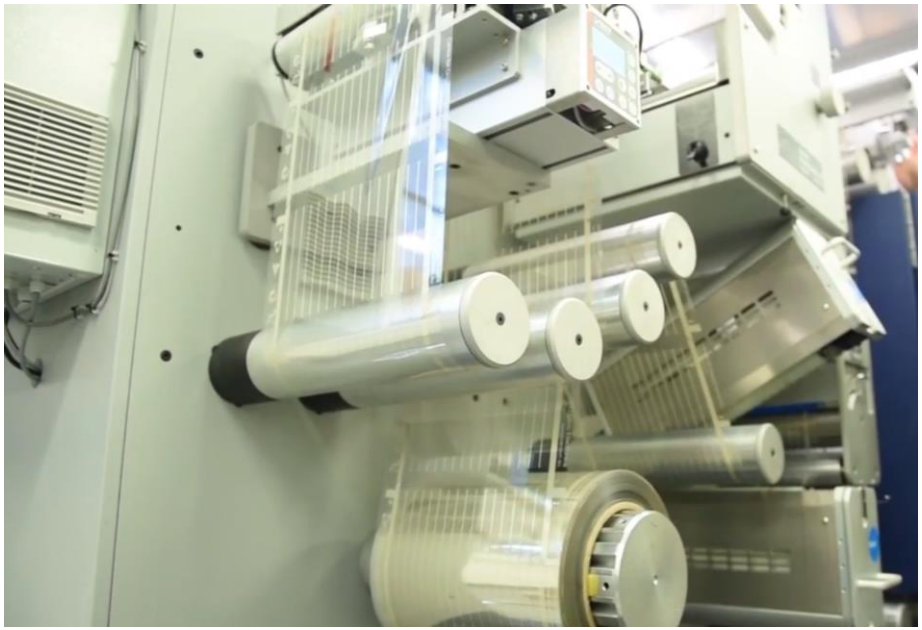
Photos courtesy of GBS Inc. - https://glucosebiosensor.com/saliva-glucose/

GBS Inc. – Saliva Glucose Biosensor

- Manufacturing (reel to reel printing) was at the forefront of this development in contrast to Podimetrics
  - Printable enzymatic glucose sensor based on organic thin film transistors are printed via inkjets
  - Strategy for scale manufacturing developed prior to clinical studies for regulatory approvals



Prototype



Scale Production

Photos courtesy of GBS Inc.

GBS Inc. – Saliva Glucose Biosensor

- Platform technology
  - Can be adapted to detect a variety of substances that identify a range of diseases
  - Looking for substances that identify cancer, heart disease and allergies
  - Technology can scale derivatives rapidly

- Company needs to be careful of project creep and defocus of resources, draining of capital and delayed timelines
  - 6 years in development and path to regulatory approval and full commercialization unclear

Conclusions

- A great technical product alone is not enough to successfully launch at scale, design for commercialization is a necessity
- Before you start have a clear plan of the timeline to market
  - The benchmark for FDA substantially equivalent medical devices is 3 – 5 years
  - Competitors will take advantage of your missteps and investors will get impatient
- Manufacturing and quality should be considered at the start and developed in parallel with the core technology
  - Performance and quality issues that arise in production are extremely expensive to fix and can terminate your product
- Software integration and user interface are vital to maximize ease of use and add value
- Building your market and brand needs equal resources to technology development
- Use these lessons to assess your own products from the very beginning to maximize your success rate