



# A Clash of IP Cultures: Consumer Electronics and Medical Device Convergence

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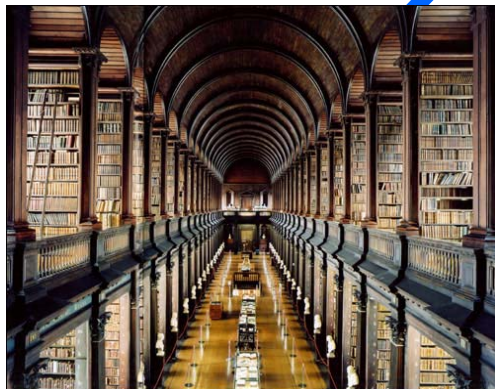
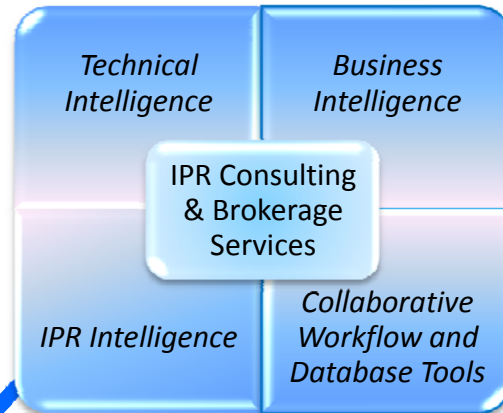


# Agenda

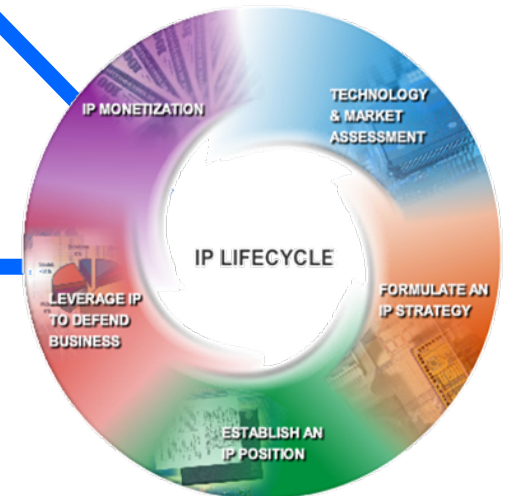
- Chronic Health Care Management
- Consumer versus Medical Development
- Convergence
- IP Issues
- Conclusion
- Questions

# UBM TechInsights

## A flexible value delivery system



**Largest technical and IP body of knowledge in the industry**



**The most comprehensive offering of any service-provider**

# Chronic Disease Impact

- Chronic diseases were estimated to account for 35 million of a total of 58 million deaths (60%) from all causes in 2005.
- Chronic diseases account for twice as many deaths as all communicable diseases, maternal and perinatal conditions, and nutritional deficiencies combined.
- An aging population means that the incidence of chronic disease will continue to increase as well.

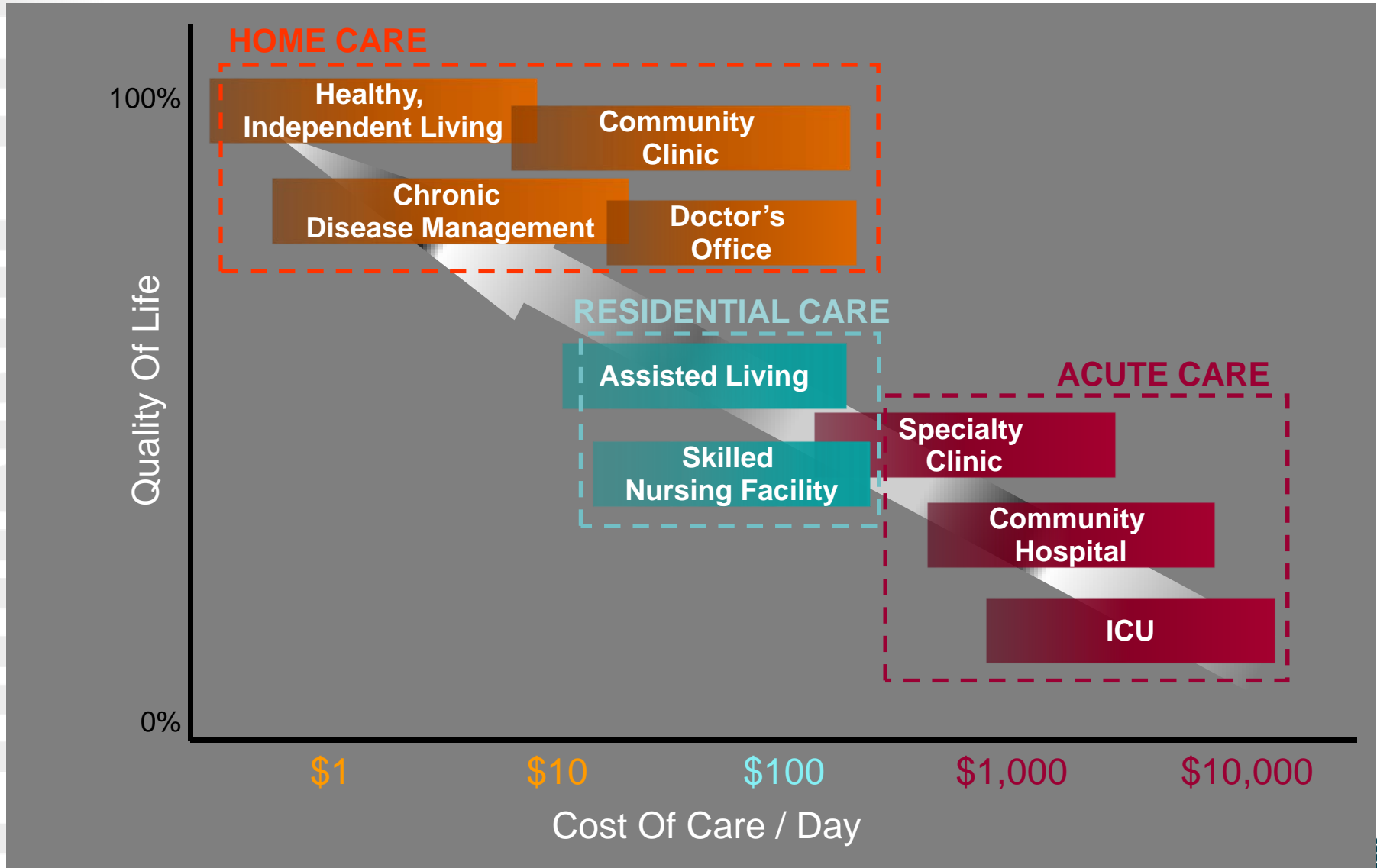
Source: World Health Organization: "Global Surveillance, Prevention and Control of Chronic Respiratory Diseases"

# Chronic Disease Attributes

- Chronic disease epidemics take decades to become fully established with many beginning in childhood.
- Because of their slow evolution and chronic nature, chronic diseases present opportunities for prevention.
- Many different chronic diseases may occur in the same patient (e.g. chronic respiratory diseases, cardiovascular disease and cancer).
- The treatment of chronic diseases demands a long-term and systematic approach as an integral part of the activities of health services.

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# The Shift in Healthcare

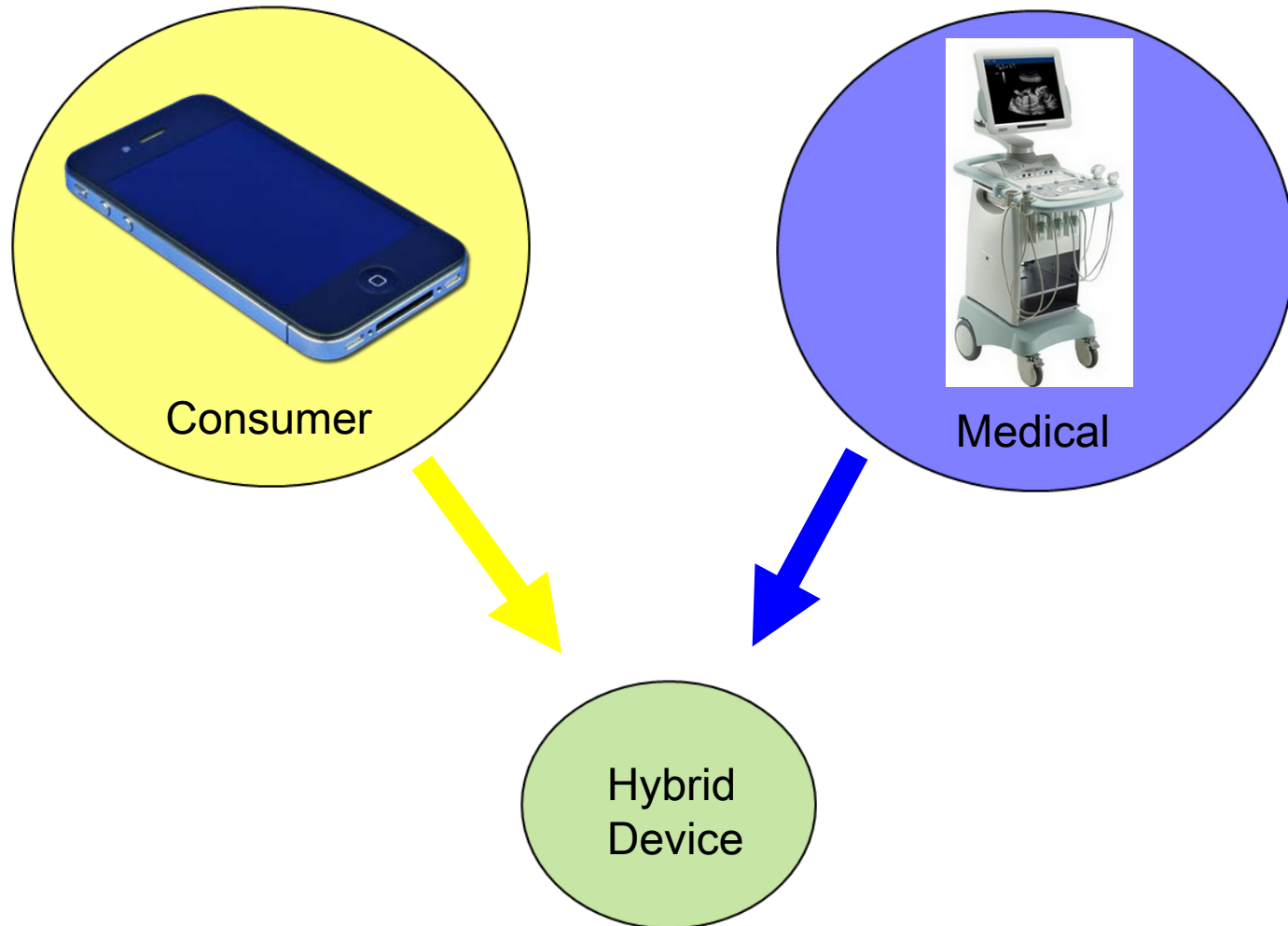


# Chronic Disease Management

- Home Health Care Drivers
  - Improved Efficiency
  - Lower Health Care Cost
  - Improved Patient Results
- Home Health Medical Equipment Needs
  - Small and Portable
  - Easy to Use
  - Low Cost
  - Connected



# Medical & Consumer Convergence



# The 3 Stages of Convergence

1. Wired or Wireless Connection
2. Physically Joined Together
3. Integrated

# The 3 Stages of Convergence

CoPilot GPS for Laptop



Navman GPS Sleeve



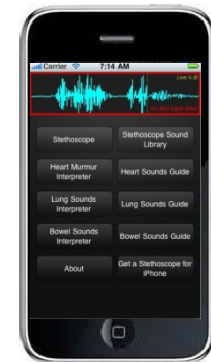
iPhone with GPS



Withings Blood Pressure Monitor



AliveCor EKG Sleeve



iStethoscope Expert

# Consumer Versus Medical Devices

<b>Attribute</b>	<b>Consumer Devices</b>	<b>Medical Devices</b>
Time to Market	Rapid (Less than one year)	Slow (3 - 5 Years)
Product Longevity	Short (Two years)	Long (7 - 15 Years)
Hardware	Latest and Greatest	Available and Stable
Software	Open Source	Differentiator
User Interface	Simple	Specialized
Price	Low	High (Less tied to hardware)
Reliability	Moderate	Vital
Regulatory	UL, FCC	UL, FCC, FDA, ISO 13485, etc.
Information Security	Moderate	High (HIPAA)
Volume	Millions - 100's of Millions	Thousands to a Million
Efficacy	Limited	Clinical Trials
Interoperability	Common	Limited
Intellectual Property	Aggressive	Incremental Innovation

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# Patents and Medical Innovation

- Patent Attributes
  - Practical use
  - Element of novelty
  - Inventive step
  - Patentable under law
- FDA Regulatory Process
  - Confirm the classification of your device.
  - Identify predicate devices already cleared for sale in the US.
  - Determine whether any standards and/or guidance documents apply.
  - Prepare and submit the 510(k) application to the FDA.

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- **Bottom Line: *Regulatory approval is easiest when stating how much your device is like a previous one.***

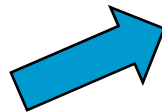
# Challenges of Convergence

- Even companies that are well-versed in IPR and patent protection may not be prepared for the challenges of expanding into the consumer market.
  - The typical drug-coated stent, for example, may have dozens of patents attached to it.
  - A sophisticated blood glucose monitor, on the other hand, could have thousands (GUI, software, battery, memory, power management system, integrated circuits (ICs) and any wireless or Internet connectivity).

# Ultrasound



Past



Current



Mobisante

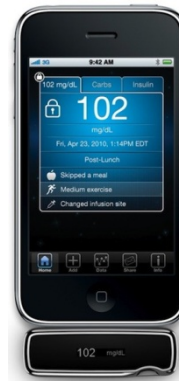


Future

# Other Examples of Medical Device Smartphone Convergence



Withings Blood Pressure Monitor



Sanofi Aventis iBGStar Blood Glucose Monitor



Airstrip Patient Monitoring



Wavesense Agamatrix Blood Glucose Monitor



Littman 3M Bluetooth Stethoscope

# Conclusions

- Management of chronic diseases is driving a fundamental change in health care.
- The convergence between consumer electronics and medical devices is changing both worlds.
- The challenge is to understand the complexities of managing and asserting intellectual property rights (IPR) in what is perhaps the most price-sensitive, fast-moving and competitive market in the world – consumer electronics.

# Questions?

For further information contact:

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