

# Using Nanocoatings: Opportunities & Challenges for Medical Devices

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# Topics to be covered

- Introduction
- What is nanocoating technology?
  - Super Hydrophobicity
  - Atomic Layer Deposition
  - Multi-Layer Barrier Films
- Who are the key players?
- What are the benefits?
- What are the risks?
- Summary

# What is a medical device?

*More diverse group than medical electronics!*

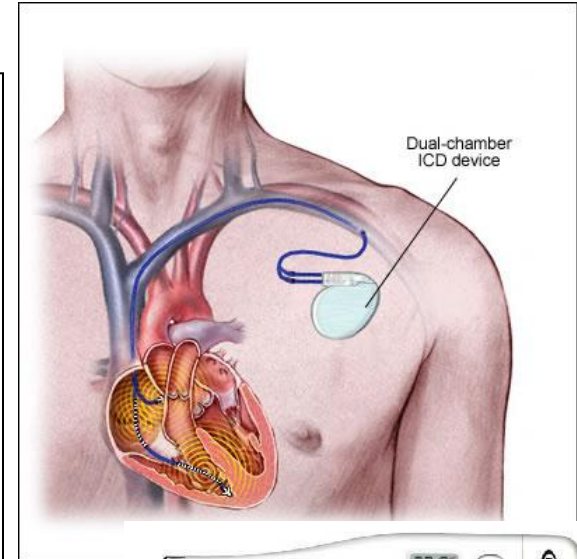


# Medical Device Definition

- Surprisingly, no good, uniform definition of a medical device.
- Increasing overlap in technologies combining medical devices with biologics or drugs.
- Example: *Drug-coated stents*.
  - How the device is regulated depends upon the primary function of the product. Since the stent is performing the primary function of holding a blood vessel open, it is regulated in the US as a medical device. If the primary function was to deliver medication, it would be regulated as a drug. This is an extremely complex area of regulation!



# Medical Electronics – Still very diverse!



# What are medical electronics?

- Is it a realistic category?
  - Some implanted in the body; some outside
  - Some portable; some fixed
  - Some complex; some simple
  - Some control; some monitor; some medicate
- All connected by the perception that one's life may be dependent upon this product
  - Creates a powerful emotional attachment/effect
  - Assuring reliability becomes critical

# Why are medical coatings used?

- Enhance performance of the device
  - Extend useful life
  - Cleaning, disinfection, and sterilization protocols degrade product
- Protect the device
  - Human body is a hostile environment
- Protect the patient
  - Body responds to intrusions
    - Defense mechanisms treat foreign objects as threats
  - Reduce scar tissue and infection opportunities
  - Encourage/enhance healing

# Medical Coating Challenges

- Biocompatibility
- Coating adhesion
- Uniform coverage over challenging shapes
- Strength
- Durability



# State of Coatings in Implanted Medical Devices

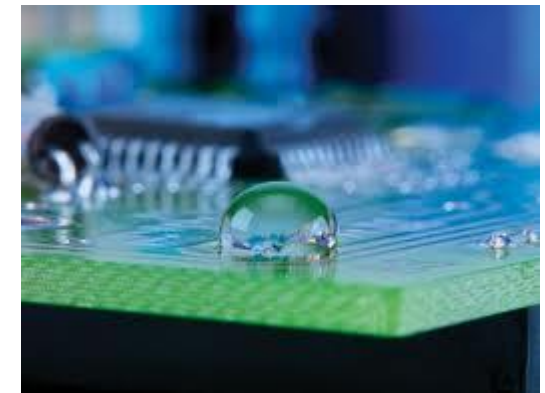
- Parylene-N and -C are currently approved by FDA as a USP class VI polymer, which allows them to be used in biomedical devices
  - Parylene-C has higher thermal stability and chemical/moisture resistance than Parylene N
    - Commonly chosen as an encapsulation material for biomedical devices
    - Applications have included stents, pacemakers, neural probes, and solder joints encapsulation
    - CVD Parylene can form a conformal and pinhole free coating; however, Parylene films do not have strong adhesion to inorganic surfaces such as silicon.
      - Reference” Characterization of Parylene-C film as an encapsulation material for neural interface devices”

# Medical Device Coating Needs

- Nonfouling (protein adsorption-resistant) thin-layer polymeric coatings offer more paths to reduce inflammatory responses
  - Surface coatings that completely eliminate protein adsorption over the lifetime of a device have not been found
- Design requirements for implanted materials and devices vary considerably
  - Depends on the application and site of implantation
- Polymeric surface coatings for implantables ideally conform to the following:
  - Use nontoxic materials
  - Prevent biofouling
  - Can be deposited on a variety of materials and architectures
  - Mechanical, chemical, and electrical stability to withstand surface deposition, sterilization methods, implantation procedures, and in vivo environment

# Nanocoating Introduction

- Explosion in new coating technologies over the past 24 months
- Drivers
  - Moisture proofing
  - Oxygen barrier (hermeticity)
  - Tin whiskers

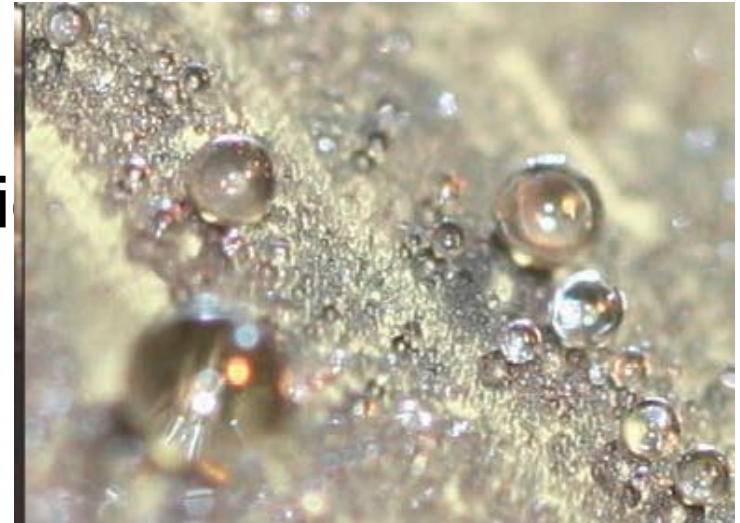


# Nanocoating Technology

- Super Hydrophobicity
- Atomic Layer Deposition
- Multi-Layer Barrier Films

# Super Hydrophobicity

- Definition: Wetting angle far greater than the 90 degrees typically defined as hydrophobic
  - Can create barriers far more resistant to humidity and condensation than standard conformal coatings
- How to get there?
  - Deposit materials with existing high surface tension (e.g., Teflon)
  - Replicate the surface of the Lotus Leaf



# Nano Deposition of High Surface Tension Materials

- Three companies currently focused on the electronics market



- The key technology for each company is the process, not necessarily the materials

# Nanocoating Companies

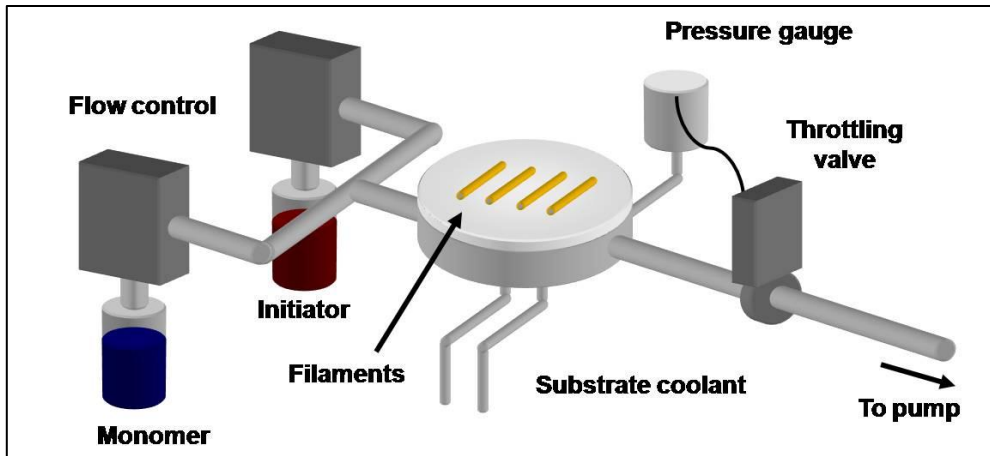
- GVD: Founded in 2001. Spinoff from MIT
  - Key technology is initiated chemical vapor deposition (iCVD) and PTFE and Silicone
  
- P2I: Founded in 2004. Spin off from UK MOD Laboratory and Durham University
  - Key technology is pulsed plasma and halogenated polymer coatings (specifically, fluorocarbon)
  
- Semblant: Founded in 2009. Spin off from Ipex Capital
  - Key technology is plasma deposition and halogenated hydrocarbon

# Process Technology

- Hydrophobicity tends to be driven by number and length of the fluorocarbon groups and the concentration of these groups on the surface
  
- The key points to each technology are similar
  - All assisted chemical vapor deposition (CVD) processes
  - Room Temperature Deposition Process
  - Low Vacuum Requirements
  - Variety of Potential Coating Materials (with primary focus on fluorocarbons)
  
- Differentiation is how they breakdown the monomer before deposition



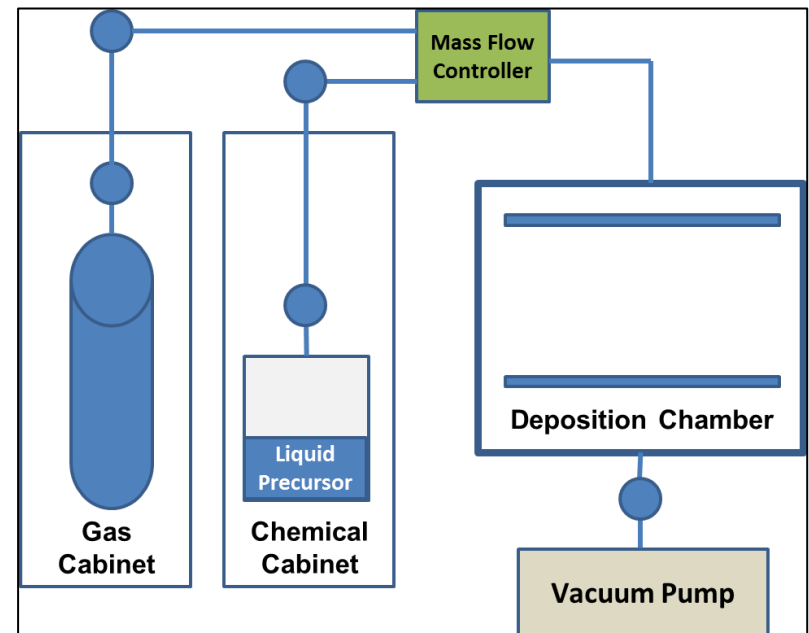
# Process Differentiation



<http://web.mit.edu/gleason-lab/research.htm>

- Plasma-Enhanced CVD (PECVD) uses plasma to breakdown the monomer

- iCVD uses a chemical initiator to breakdown the monomer

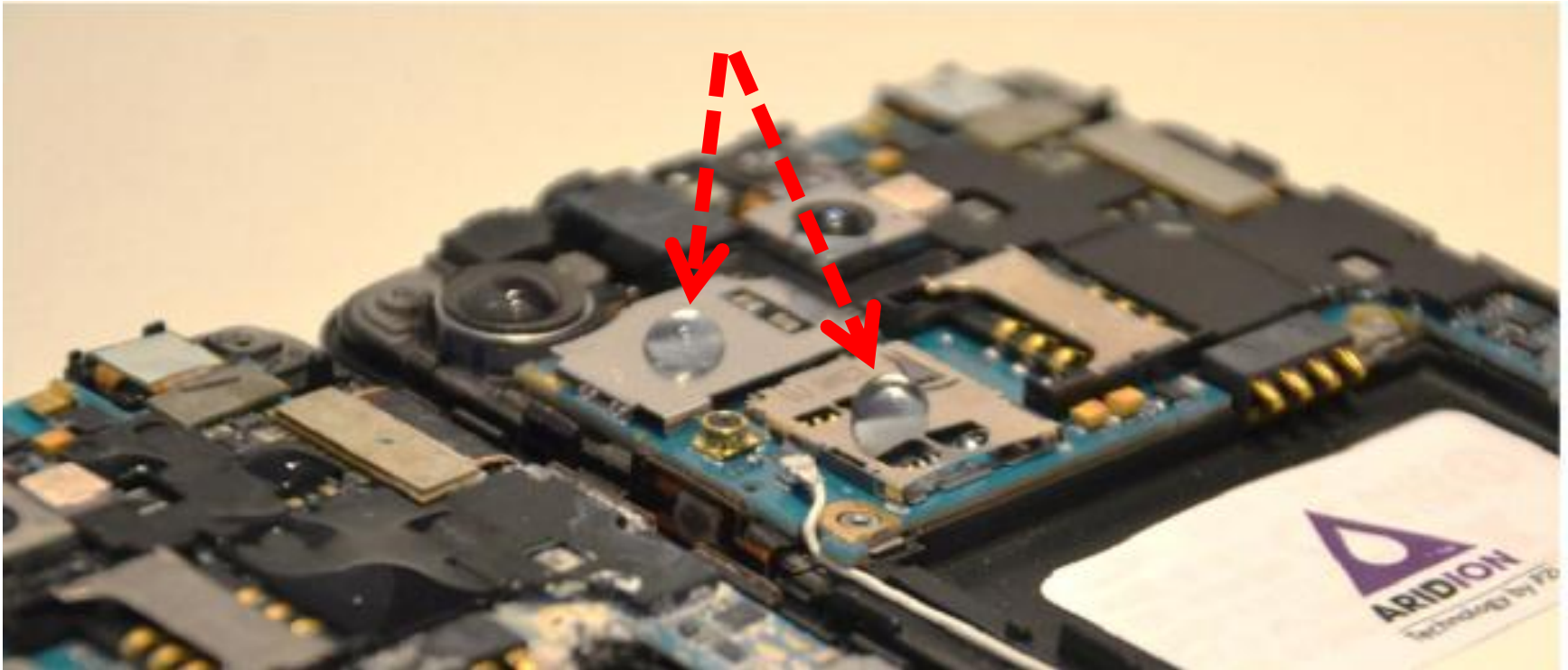


Courtesy of Semblant Ltd.

# Benefits (especially compared to Parylene)

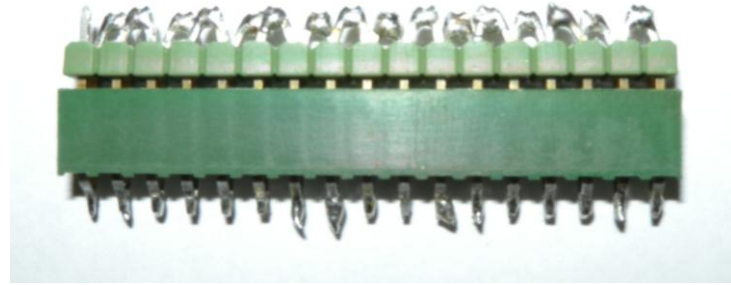
- These are truly nanocoatings
  - Minimum Parylene thickness tends to be above one micron (necessary to be pinhole free)
  - These coatings can be pinhole free at 100 nm or lower
  
- Nanocoating allows for
  - Optical Transparency
  - RF Transparency
  - Reworkability
  - Elimination of masking

# Optically Transparent



Courtesy of P2i

# Benefits: No Masking

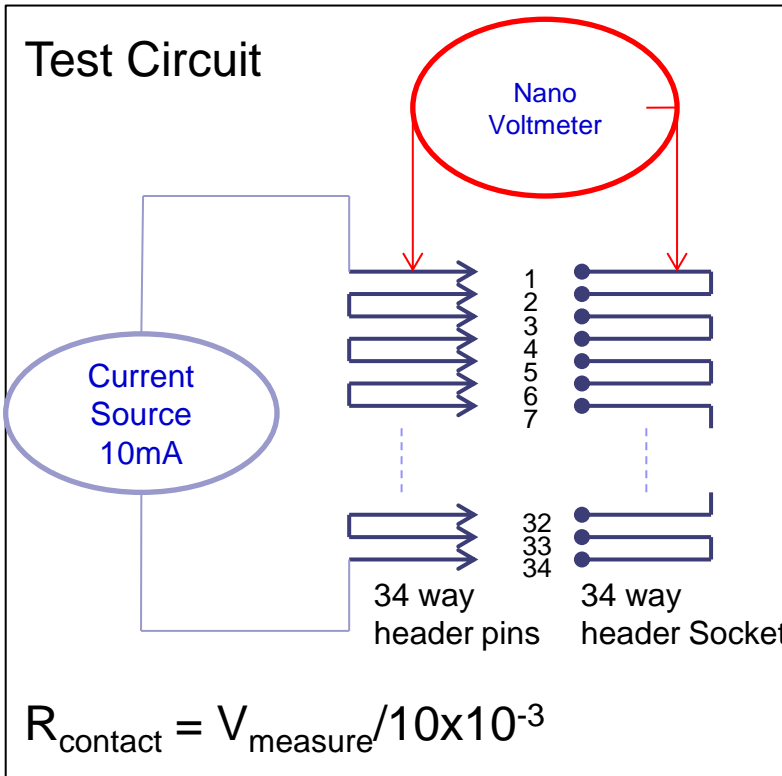


## LLCR Measurements

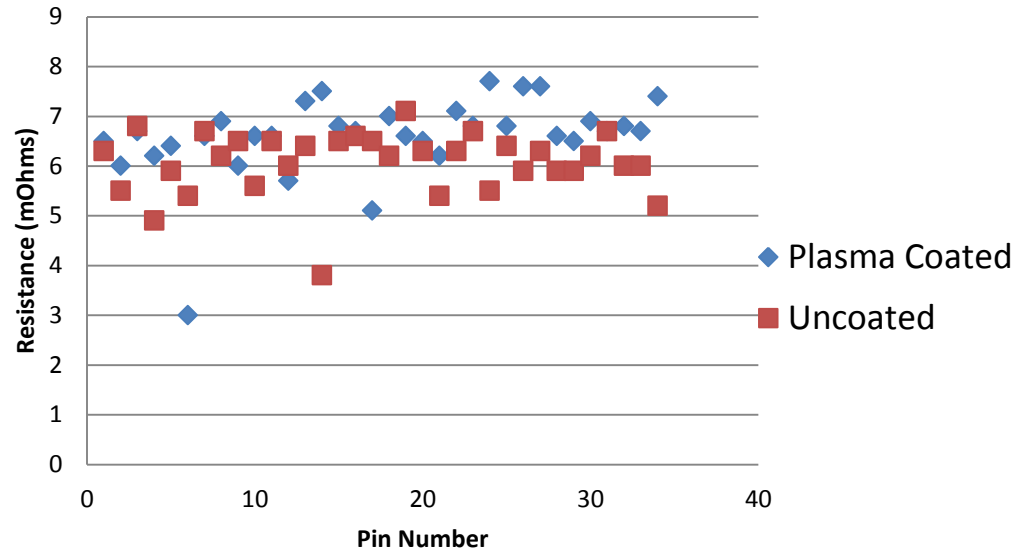
Current (A) 0.01  
 V comp (V) 0.1

Connector Male 34way Pin Header Au over nickel contact (TE Connectivity 1-215307-7)

Connector Female 34way Socket Header Au over nickel contact (TE Connectivity 1-826632-7)



## Low Level Contact Resistance



Courtesy of Semblant Ltd.

# Risks?

- Voltage Breakdown
  - Levels tend to be lower compared to existing coatings (acrylic, urethane, silicone)
  - Can be an issue in terms of MIL and IPC specifications
  
- Optically Transparent
  - Inspection is challenging
  
- Cost
  - Likely more expensive than common wet coatings
  - However, major cell phone manufacturer claims significant ROI based on drop in warranty costs
  
- Throughput
  - Batch process. Coating times tend to be 10 to 30 minutes, depending upon desired thickness
  - However, being used in high volume manufacturing

# High Volume Manufacturing

- Nanocoating technology is being used by almost every major hearing aid manufacturer (8 million per year)



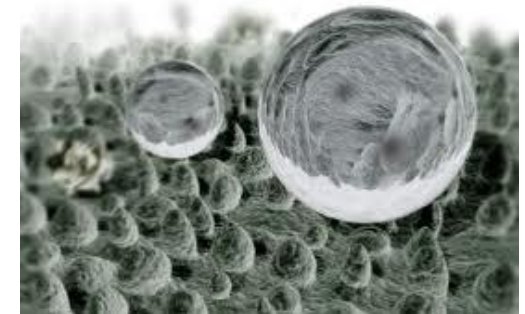
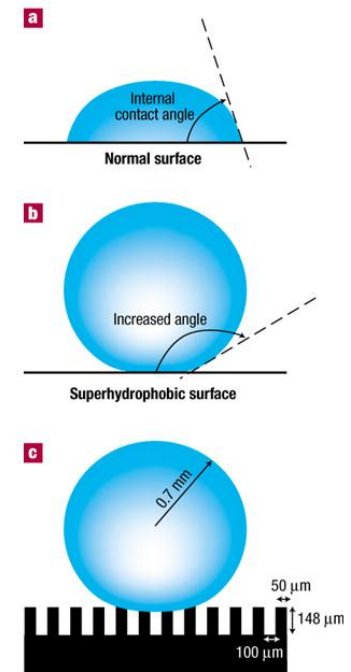
Courtesy of P2i

# Manufacturing

- P2i combats contamination and costly sample loss through coatings for medical devices & laboratory equipment
- Semblant developed Plasma Shield, a conformal coating to coat electronic components for internal medical devices and equipment
- GVD provides protective coatings for medical electronics, biocompatible coatings on implantable devices, & lubricious coatings for tubes and trocars.

# Where are Lotus Leaf Coatings?

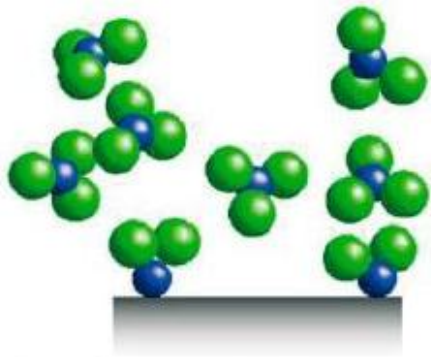
- High aspect surfaces create very high (>150°) wetting angles
- Rapid adoption in other industries
  - Paints, clothing, etc.
- Challenges with electronics
  - Different surfaces/chemistries can disrupt surface modification





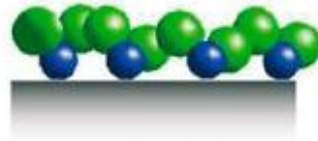
# Atomic Layer Deposition (ALD)

Deposit  
organometallic /  
hydroxyl compounds



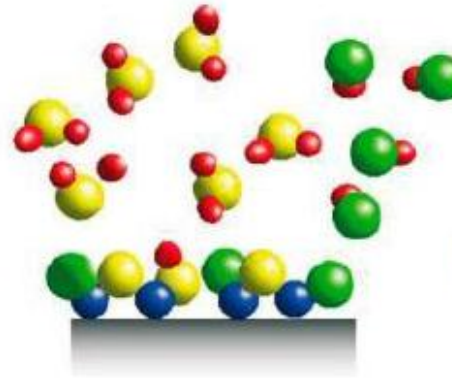
$\text{Al}(\text{CH}_3)_3(\text{g})$   
Pulse

Purge



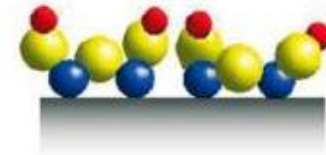
$\text{Al}(\text{CH}_3)_2(\text{s})$   
Purge

Treatment to react 1<sup>st</sup>  
precursor (2<sup>nd</sup>  
precursor or energy)



$\text{H}_2\text{O}(\text{g})$   
Pulse

Purge



$\text{Al}_2\text{O}_3(\text{s})$   
Purge

Repeat ALD cycle N times

- Developed in the 70s and 80s
- Sequential surface reactions
- Deposition rate of ~0.1 nm/cycle

# ALD (cont.)

- Designed for inorganic compounds

- Primarily simple oxides and nitrides

- Limited industrial acceptance

- Electroluminescence displays (obsolete)
- Basic research
- Glass strengthening
- Considered for next-gen silicon
- Interest from solar
- Moisture / oxygen barriers**

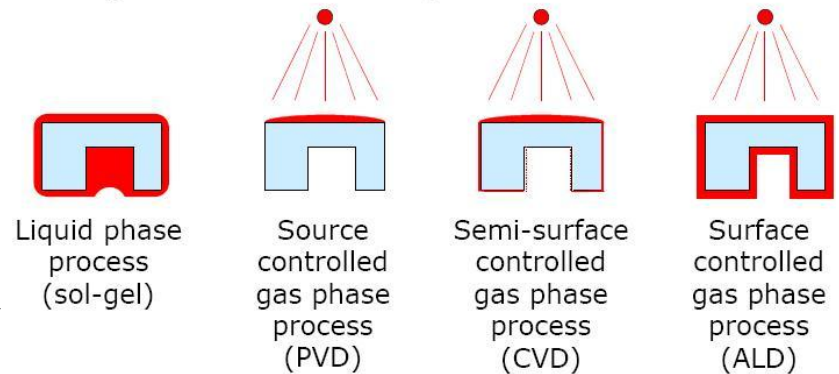


# ALD (cont.)

## ■ Advantages

- Deposition at low temps (80-150C)
- Not line of sight (conformal)
- Precise thickness control
- Large area
- Less stringent vacuum requirements (0.1 – 5 mbar)
- Multilayer and gradient capability (it can be tailored)

Coating thickness uniformity with different methods



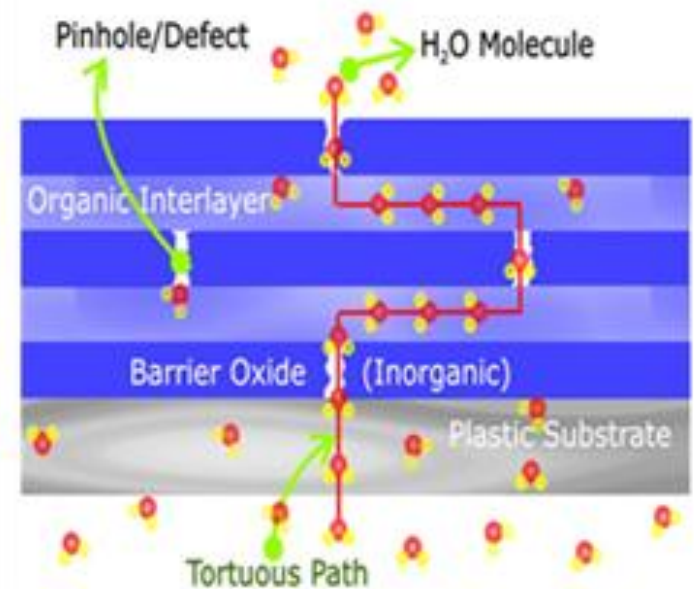
- Northrop Grumman / Lockheed Martin estimated cost reductions of 50% vs. traditional hermetic approaches

# Risks

- The process can be very slow  
(100nm thickness can take over an hour)
  
- Not reworkable
  
- There have been challenges in regards to compatibility of ALD with existing electronic materials and manufacturing process
  - Clean surfaces with similar coefficient of thermal expansion (CTE) work best
  - De-adhesion and cracking sometimes observed when applied to metals, polymers, and surfaces with flux residue (requires some tailoring)

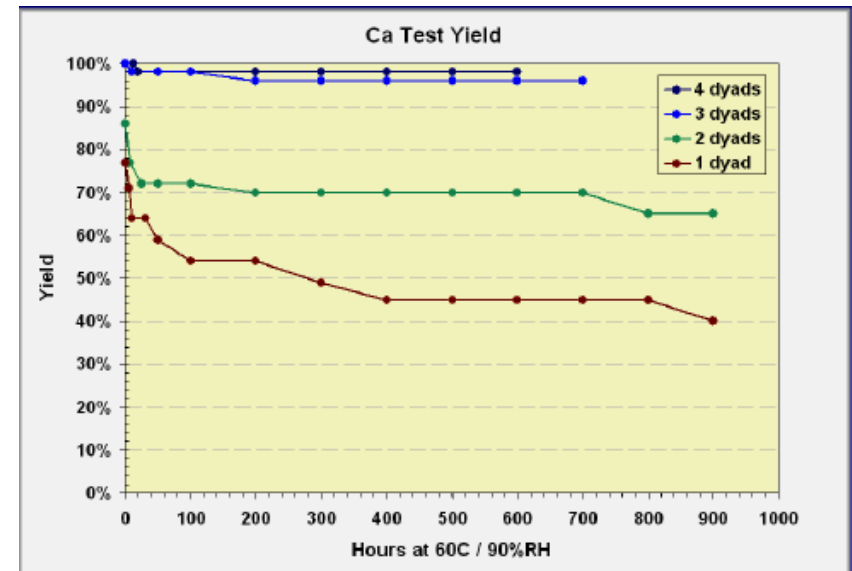
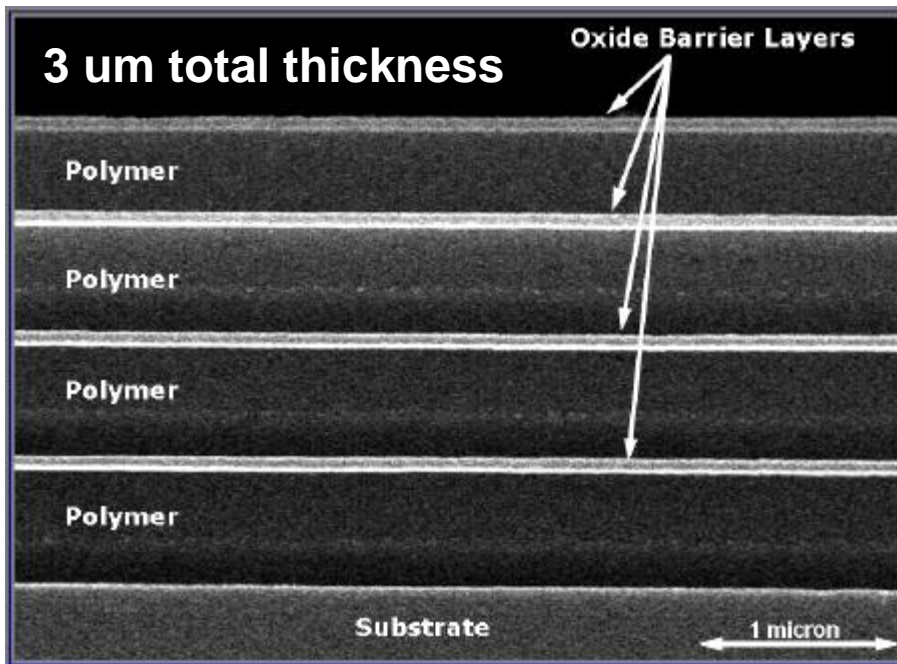
# Multi-Layer Barrier Films: What is the Technology?

- A Multi-Layer Barrier Stack to retard water vapor and oxygen diffusion
  - Patent history includes Osram, filed in 2001
  - Similar patents filed by Battelle Labs and commercialized by Vitex Systems in 1999 (Barix) (now Samsung America)
- Flexibility and transparency key attributes of the technology
  - Index matching of materials (primary driver is organic LEDs and thin film solar)



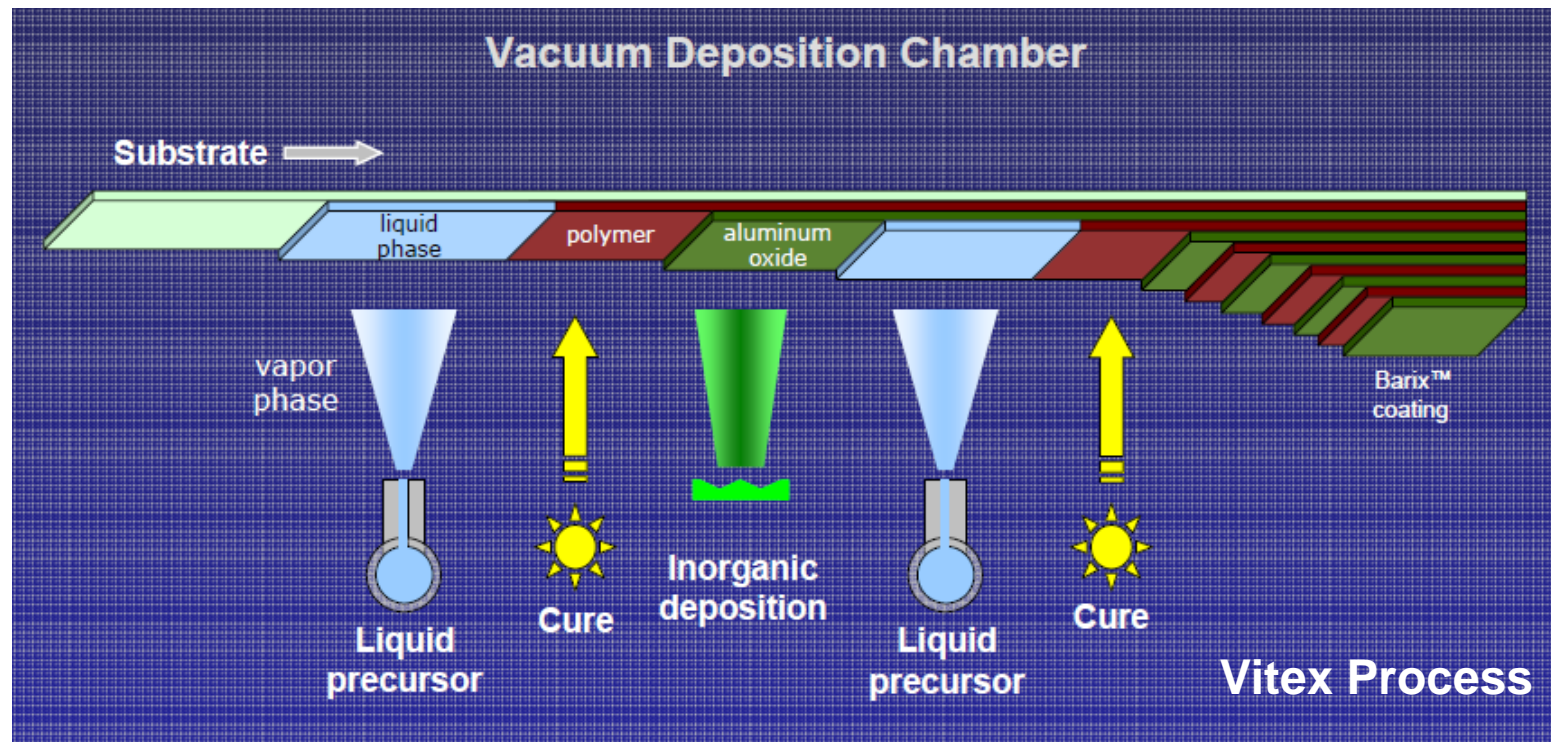
# Multi-Layer Barrier (cont.)

- Oxide barrier layer protects against oxygen and moisture
  - Can be aluminum oxide, silicon oxide, or silicon nitride
- Polymer layer provides adhesion, smooth surface, decouples defects
  - Three to four layers required to survive 60C/90%RH for 500 hrs.
  - Requires permeation less than  $10^{-6}$  g/m<sup>2</sup>/day



# Multi-Layer Barrier Manufacturing Process

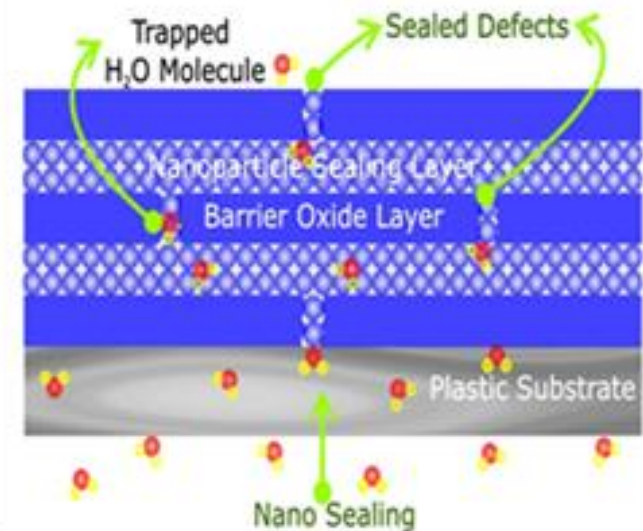
- Requires a low temp vacuum deposition process (PVD or CVD)
  - Concerns about cost and throughput (similar to parylene)



# Multi-Layer Barrier Advances

■ Recent advances use nanotechnology to eliminate defects

- Nanoparticles seal defects and react/retain oxygen and moisture
- Requires fewer layers to be effective
- Claims up to 2300 hours at 60C/90%RH





# Risks

- Multi-layer barrier is believed to be the only solution for OLEDs
  - However, commercialization has been limited
  - Developed over ten (10) years ago; still not in commercial production
  
- Only one or two manufacturers in this space
  
- Cost could be high (similar to parylene) and potential for low throughput (batch process)
  
- Rework is likely impossible

# Conclusion

- There is significant opportunity for field performance improvement and cost reduction through the use of nanocoatings
  
- Requires a knowledge of the materials and processes on the market
  - Benefits vs. Risks
  
- With any new technology, do not rely on standard qualification tests!
  - A physics-based test plan provides the most robust mitigation

# Instructor Biography



- Cheryl Tulkoff has over 22 years of experience in electronics manufacturing with an emphasis on failure analysis and reliability. She has worked throughout the electronics manufacturing life cycle beginning with semiconductor fabrication processes, into printed circuit board fabrication and assembly, through functional and reliability testing, and culminating in the analysis and evaluation of field returns. She has also managed no clean and RoHS-compliant conversion programs and has developed and managed comprehensive reliability programs.
- Cheryl earned her Bachelor of Mechanical Engineering degree from Georgia Tech. She is a published author, experienced public speaker and trainer and a Senior member of both ASQ and IEEE. She holds leadership positions in the IEEE Central Texas Chapter, IEEE WIE (Women In Engineering), and IEEE ASTR (Accelerated Stress Testing and Reliability) sections. She chaired the annual IEEE ASTR workshop for four years and is also an ASQ Certified Reliability Engineer.
- She has a strong passion for pre-college STEM (Science, Technology, Engineering, and Math) outreach and volunteers with several organizations that specialize in encouraging pre-college students to pursue careers in these fields.

# Contact Information

- Questions?
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