Wearable Electronic Medical Devices: What Fails & Why?

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Dock Brown, dbrown@dfrsolutions.com
Cheryl Tulkoff, ctulkoff@dfrsolutions.com
DfR Solutions

Abstract

- What are the requirements of wearable electronic medical devices? They must be non-restrictive, portable, always accessible, easily controllable, and have both localized communication and possibly wireless communications capabilities.

- Wearable medical electronics falls into the categorization of “Next Generation Technologies”, technologies the supply chain or the user will implement because they are cheaper, faster, and stronger. One of the most common drivers for failure is inappropriate adoption of these new technologies. Since most designers have little or no influence over the packaging technologies chosen for implementation, awareness of the pitfalls and what actions need to be taken to assure that the new technologies are reliable is critical. With these new medical electronics, there are several issues that need to be addressed from a reliability perspective to assure these applications are both safe and reliable.

- Some of the challenges that will be discussed included failures due to new device packaging, environmental conditions like sweat, UV & temperature exposure, tumble & drop, bending and torque, and the inevitable water immersion. The implications of RF ID and battery life are also explored.

What is a medical device?

More diverse group than medical electronics!

What is a medical device?

Surprise!

. . . last year 23andMe apparently ignored the agency, that prompted the FDA to reiterate its longstanding policy that providing what looks like disease diagnoses ***made 23andMe's service a medical device.***

Forbes magazine, 20 June 2014 (italic emphasis added)

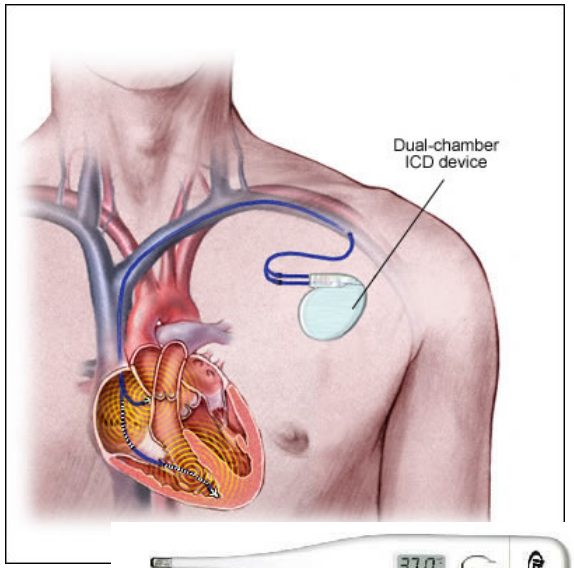
Medical Device Definition

- 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!

FDA proposes looser regulation of some clinical & consumer digital health devices……

- Affected devices are largely clinical, including things like anesthesiology, cardiovascular, and dental devices.
- Number of consumer mobile and digital health products are exempted
  - Thermometers, stethoscopes, talking first aid kits, hearing aids, fertility diagnostic devices & exercise equipment
- “The FDA believes devices . . . are sufficiently well understood and do not present risks that require premarket 21 notification (510(k)) review to assure their safety and effectiveness”

Medical Electronics – Still very diverse!



KAREN MIRZOYAN/ARMENIANOW.COM

What are medical electronics?

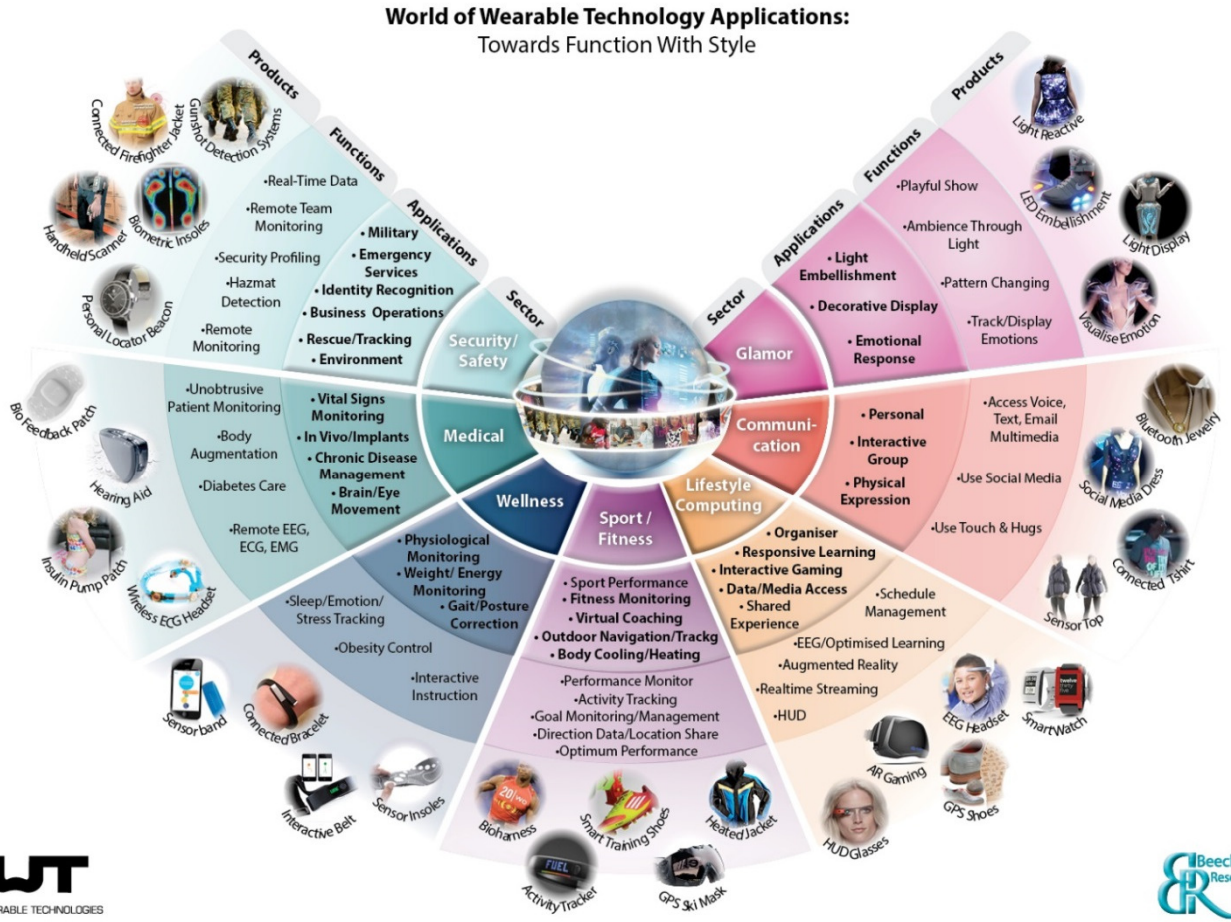
- Is it a realistic category?
  - Some implanted in the body; some outside
  - Some portable; some fixed
  - Some complex; some simple
  - Some control; some monitor; some medicate
- All connected by the perception that one's life may be dependent upon this product
  - Creates a powerful emotional attachment/effect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

What are Wearable Electronics?

- Wikipedia: "…miniature electronic devices that are worn by the bearer under, with or on top of clothing."
  - That's It?!

- Alternative Definition
  - Technology attached to the human body or clothing that allows the wearer to monitor, engage with, and control devices, themselves, or their social network

What are Wearable Electronics (cont.)



Beauty and Wearable Tech: Miss Idaho Proudly Displays Her Insulin Pump

- 29.1 million people in the US with diabetes
- 350,000 of those individuals are using wearable insulin pumps
- Growing trend of wearable tech extending beyond consumer devices to include medical devices.

What is Reliability?

- Reliability is the measure of a product's ability to:
  - …perform the specified function
  - …at the customer (with their use environment)
  - …over the desired lifetime

- To ensure reliability, we have to think about:
  - What is the product supposed to do?
  - Where is going to be used?
  - How long should it last?

Reliability Model – Conceptual Product Space

Product Use Conditions & Life Expectations

Environment Stress

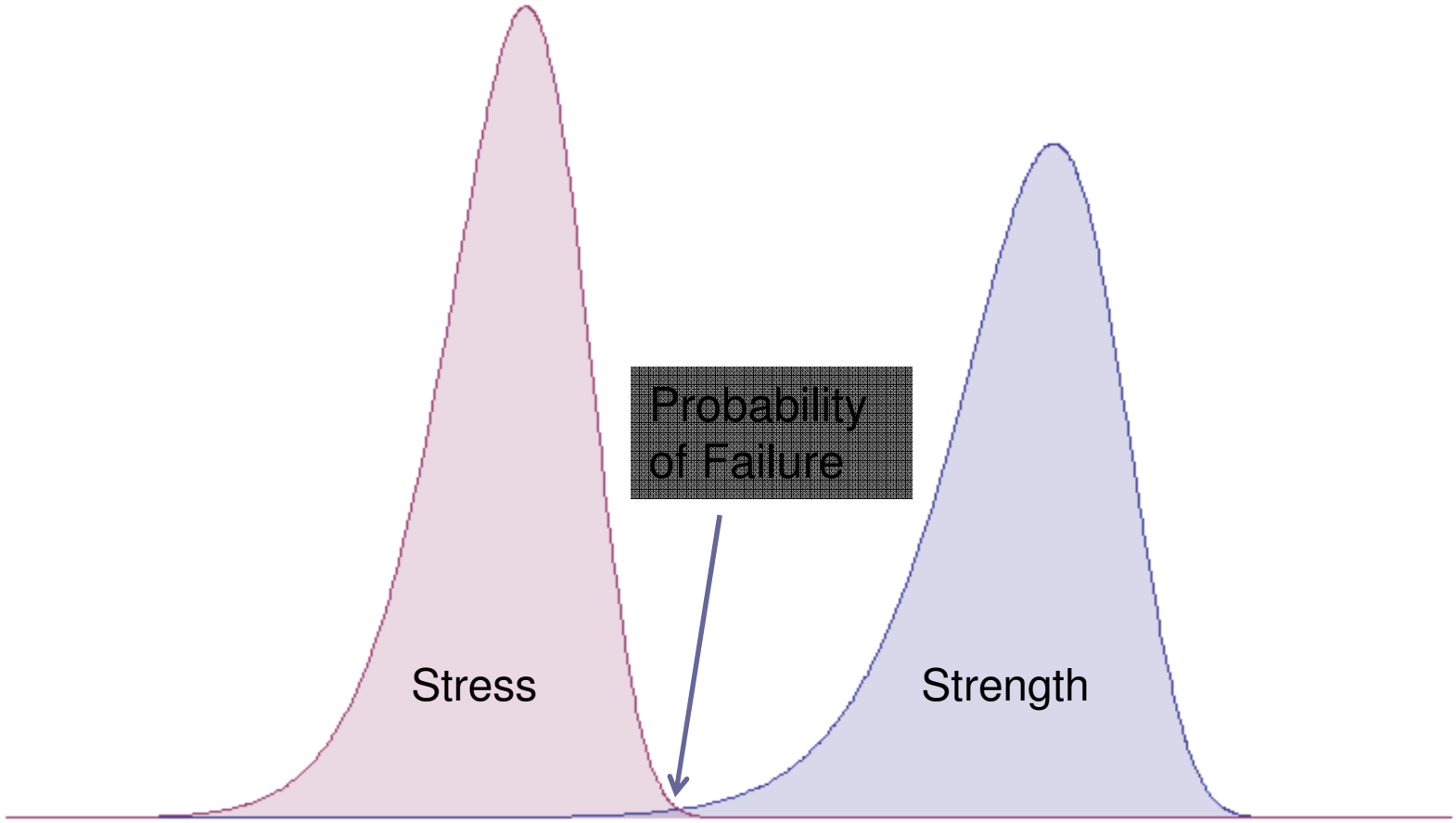
							Satellites		Military Aircraft
						Auto Safety		Commercial Aircraft	
				Outdoor Signage	Utility Monitoring	Chemical & Petroleum Production	DHS Monitoring		
				Servers, Routers, Switches, Storage	Auto Entertainment	Telecom Cell Towers			
	Cell Phones	Laptops	Video Games		Microwaves		Washers		
Toys		iPods	Desktop PCs		Televisions	Medical Imaging	Dryers		

Product Lifetime

MEPTEC THE NEXT GENERATION

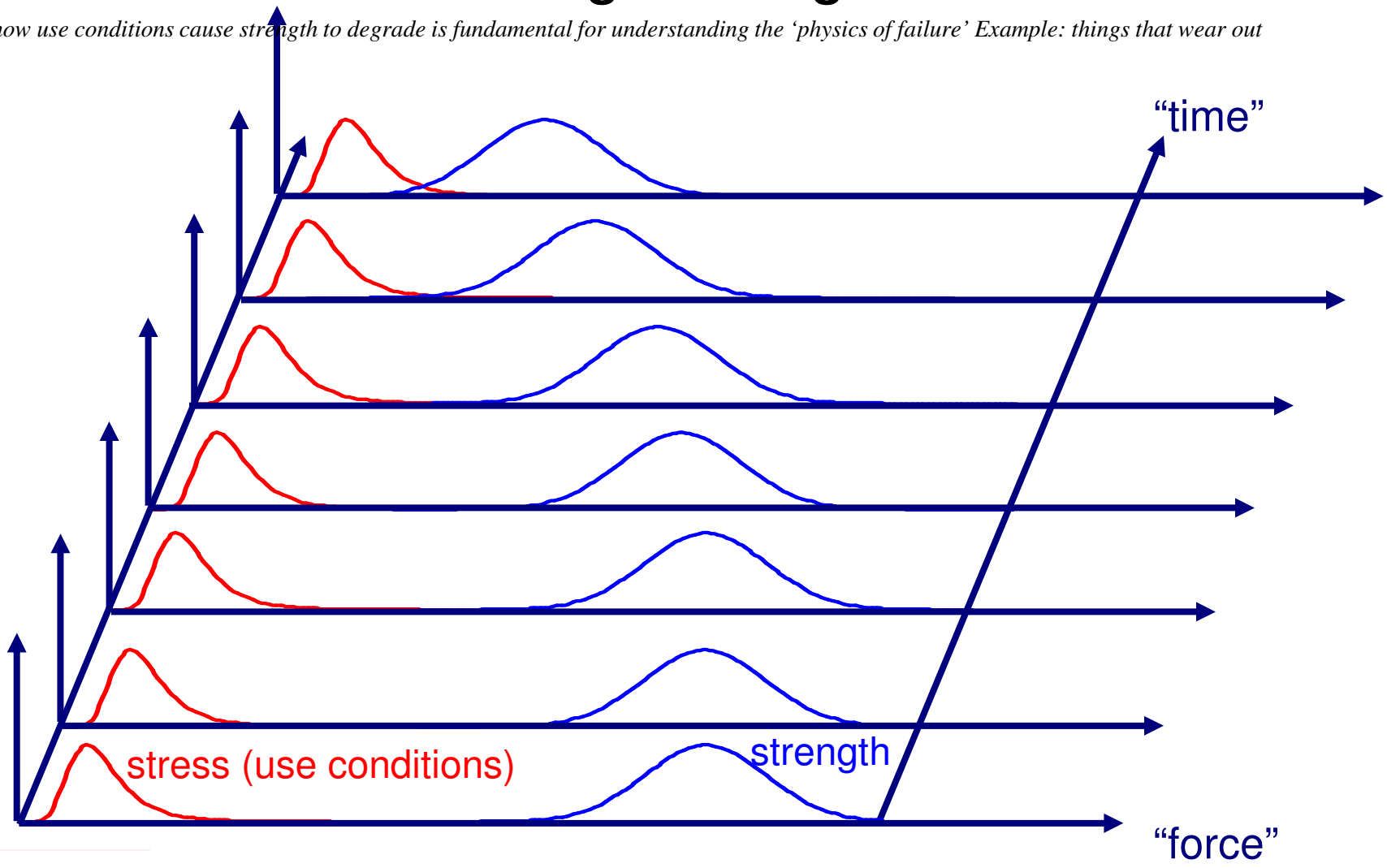
iNEMI International Electronics Manufacturing Initiative

When do Use Conditions Cause Issues?

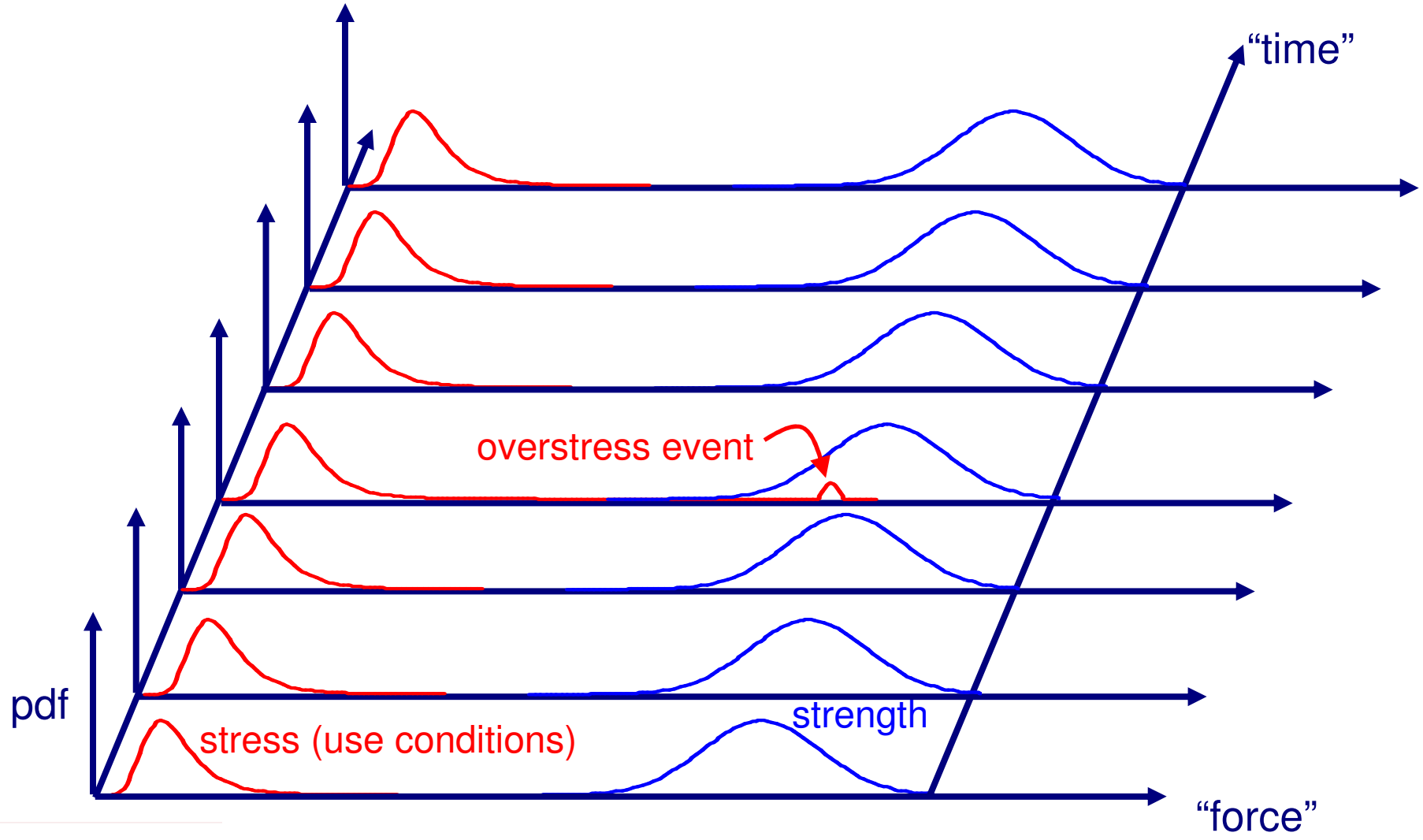


Use Conditions Cause Strength to Degrade Over Time

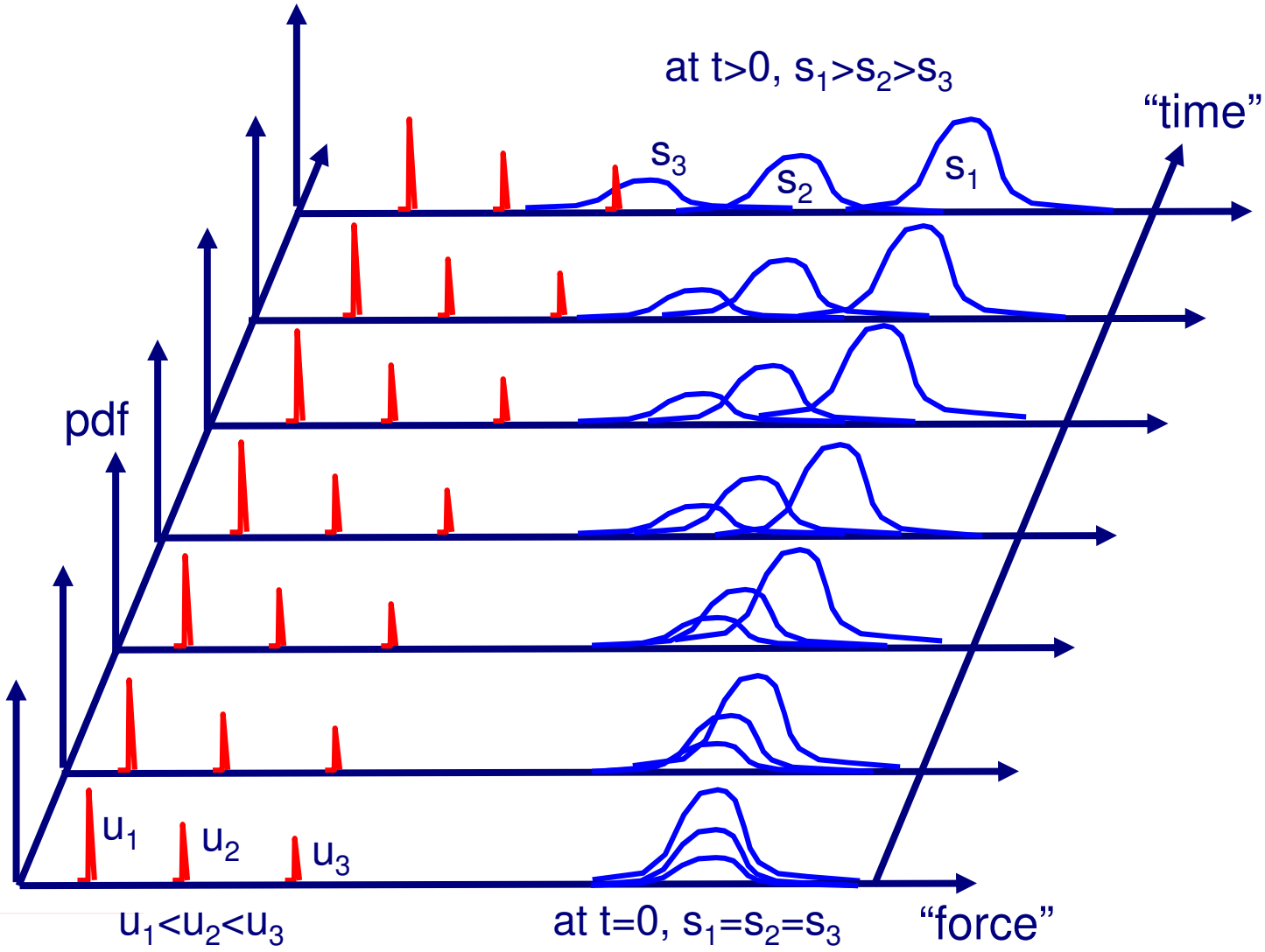
Knowing how use conditions cause strength to degrade is fundamental for understanding the 'physics of failure' Example: things that wear out



Failure due to sudden overstress (e.g. shock)

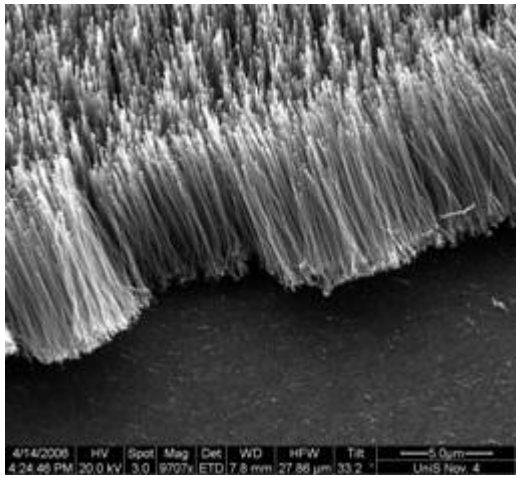


Wear-out phenomena (e.g. fatigue)



Wearable Electronics Use Next Generation Technology

- What is 'Next Generation' Technology?
  - Materials or designs currently being used, but not widely adopted (especially among hi reliability manufacturers)
- Carbon nanotubes are not 'Next Generation'
  - Not used in electronic applications
- Ball grid array (BGA) is not 'Next Generation'
  - Widely adopted



Carbon Nanotube Array for Tissue Regen. & Wound Repair

Next Generation Technology (cont.)

- Why is knowing about 'Next Generation' Technologies important?

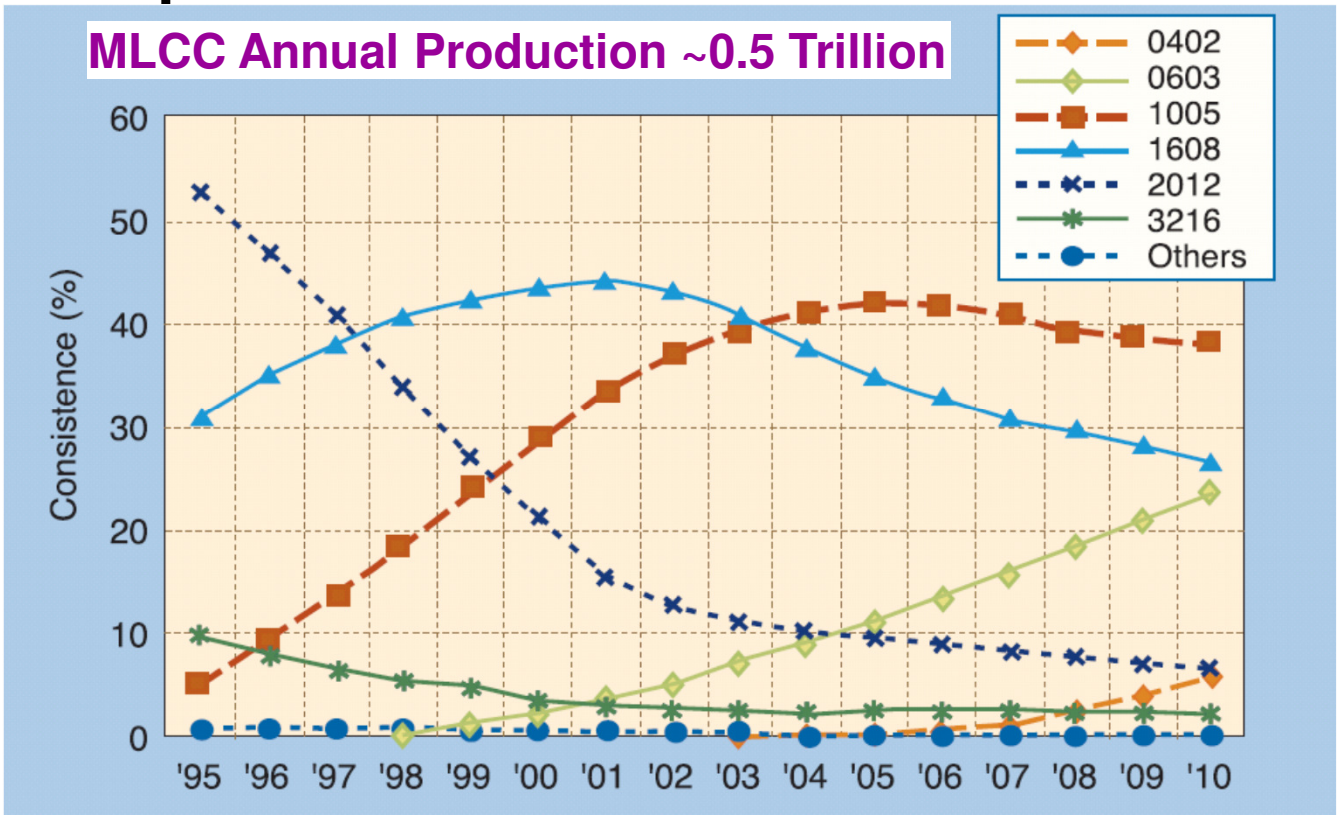
- These are the technologies that you or your supply chain will use to improve your product
  - Cheaper, Faster, Stronger, 'Environmentally-Friendly', etc.
- However…

NextGen Technologies: The Reality

- Market studies and mobile phone markets can skew reality of market adoption
  - Annual sales of >100 million may be due to one or two customers
- Mobile phone requirements may not match the needs of wearable electronics
- Market studies exclusively focused on volume
  - More relevant may be number of customers
- Example: 0201 capacitors

“The Smaller the Better”: 0201 Ceramic Capacitors

Metric	English
0402	01005
0603	0201
1005	0402
1608	0603
2012	0805
3216	1206



- Based on volume, 0201 capacitors were 25% of the multilayer ceramic capacitor (MLCC) market in 2010

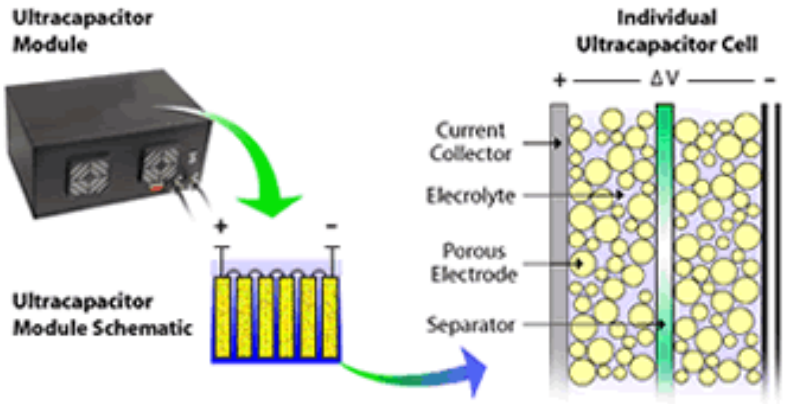
0201 Ceramic Capacitors: The Reality

- Actual high usage applications
  - Ultra small modules (primarily hearing aids) / high frequency
- Major users were limited to ~ 8 to 10 high volume companies
  - Very benign environments and very limited lifetimes
- Attempts to integrate 0201 capacitor technology into more demanding applications, such as medical implants, resulted in quality issues, unexpected degradation, and major warranty returns

Examples of Next Gen Technologies in Wearables

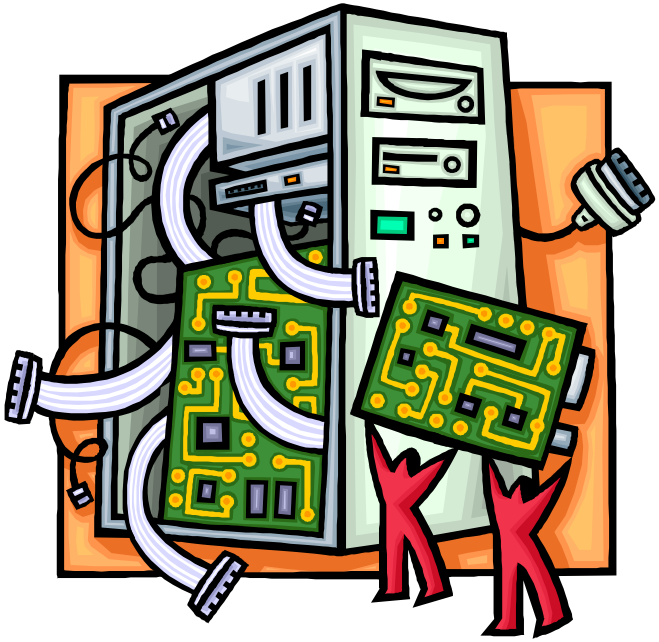
- Embedded components

- Ultra-small components (i.e., 01005 capacitors)
- New substrate materials
  - Polyethersulfone, polyethylene terephthalate (PET), polyethylene napthalate (PEN)
  - Polyimide is <u>not</u> a next gen technology
- Printed connections
  - Silver inks, copper inks, nanosolders, conductive polymers
- Organic displays
- Power Via Supercapacitors



Reliability and Next Gen Technologies

- One of the most common drivers for failure is inappropriate adoption of new technologies
  - The path from consumer (high volume, short lifetime) to high reliability is not always clear
- Obtaining relevant information can be difficult
  - Information is often segmented
  - Focus on opportunity, not risks
- Sources are either marketing mush or confusing, scientific studies
  - Where is the practical advice?



How Have Wearable Consumer Electronics Failed?

- Sweat
  - It has been documented in blogs that Apple iPOD Nano's have shorted out due to sweat
- Strain relief
  - Wearable on clothing, attached by a cord to power device, failed prematurely due to a lack of strain relief
- Plasticizer
  - First-generation of Amazon Kindle wiring insulation cracked/crumbled due to the use of non-optimized plasticizer formulation
- Cyclic Fatigue
  - Initial video game controllers experienced fatigue of solder joints on components attached to the backside of the push buttons

How Have Wearable Consumer Electronics Failed?

- Fitbit Recalls Force Activity-Tracking Wristband Due to Risk of Skin Irritation
  - Complaints of itchy, irritated wrists
    - 1.7% of Force users reported cases of skin rashes after wearing the devices
  - Allergic contact dermatitis
    - Either the nickel that's in the stainless steel part of the device
    - Or adhesives or other materials used in the strap.

- Fitbit

LG G Watch Charging Point Injury

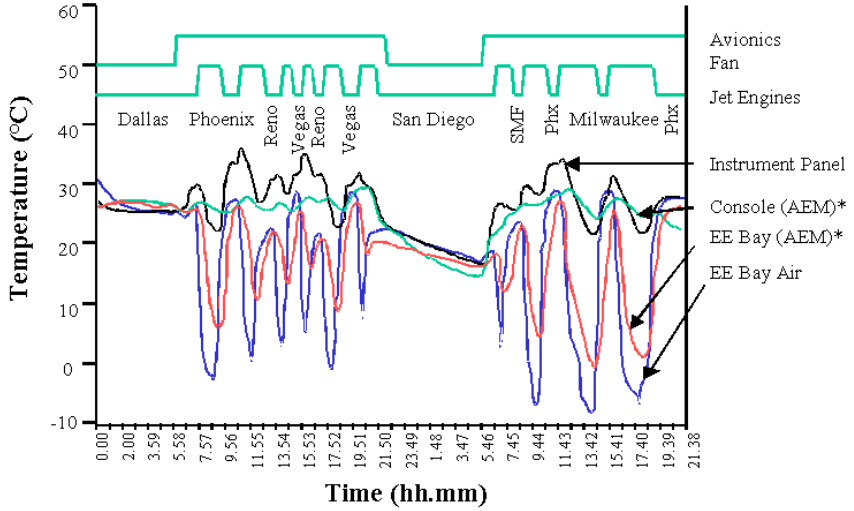
- Users report that due to hot summer & extra sweaty arms, copper charging contact points on the underside of the G Watch erode to the point that they will no longer charge.
- Eroded copper could also be causing damage to the wearer by rubbing the skin raw underneath.

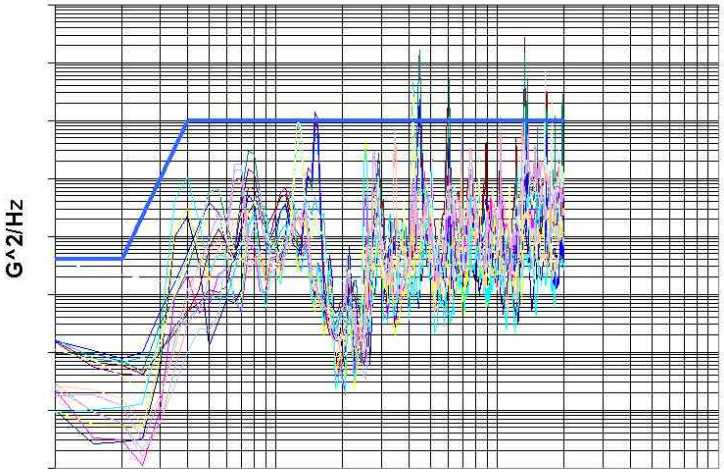
http://www.n3rdabl3.co.uk/2014/07/lg-g-watch-charging-points-cause-injury-users/

Identify and Quantify Failure Inducing Loads

- Temperature Cycling
  - Tmax, Tmin, dwell, ramp times
- Sustained Temperature
  - T and exposure time
- Humidity
  - Controlled, condensation
- Corrosion
  - Salt, corrosive gases (Cl2, etc.), UV
- Power cycling
  - Duty cycles, power dissipation
- Electrical Loads
  - Voltage, current, current density
  - Static and transient
  - Electrical Noise
- Mechanical Bending (Static and Cyclic)
  - Board-level strain
- Random Vibration
  - PSD, exposure time, kurtosis
- Harmonic Vibration
  - G and frequency
- Mechanical shock
  - G, wave form, # of events

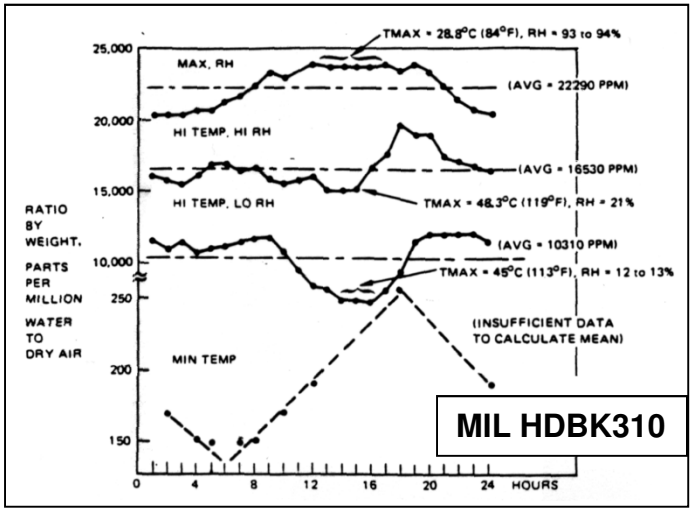
Reliability Improvement with Design of Experiment, Second Edition, By Lloyd Condra





Identify Environment: Standards

- Usually, the first approach is to use standards
- However, existing standards do not work well with wearable electronics
- More geared towards permanent installations

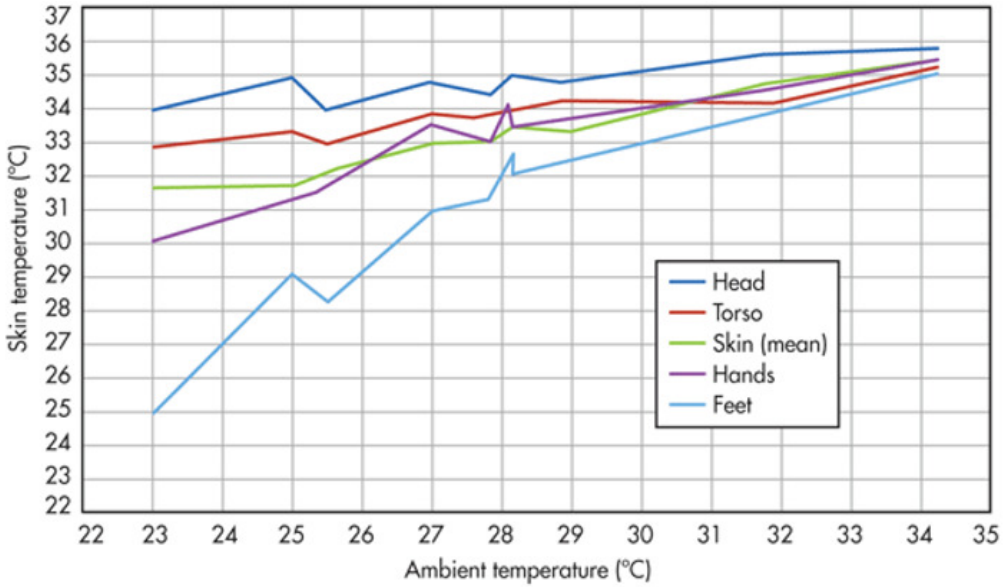


MIL HDBK310

USE CATEGORY	WORST-CASE USE ENVIRONMENT Tmin °C	Tmax °C	ΔT(1) °C	t_D hrs	Cycles/ year	Typical Years of Service	Approx. Accept. Failure Risk, %	ACCELERATED TESTING Tmin °C	Tmax °C	ΔT(2) °C	t_D min
1) CONSUMER	0	+60	35	12	365	1-3	1	+25	+100	75	15
2) COMPUTERS	+15	+60	20	2	1460	5	0.1	+25	+100	75	15
3) TELECOM	- 40	+85	35	12	365	7-20	0.01	0	+100	100	15
4) COMMERCIAL AIRCRAFT	-55	+95	20	12	365	20	0.001	0	+100	100	15
5) INDUSTRIAL & AUTOMOTIVE PASSENGER COMPARTMENT	-55	+95	20 &40 &60 &80	12 12 12 12	185 100 60 20	10	0.1	0	+100	100 & COLD(3)	15
6) MILITARY GROUND & SHIP	-55	+95	40 &60	12 12	100 265	10	0.1	0	+100	100 & COLD(3)	15
7) SPACE leo geo	-55	+95	3 to 100	1 12	8760 365	5-30	0.001	0	+100	100 & COLD(3)	15
8) MILITARY AVIONICS a b c	-55	+95	40 60 80 &20	2 2 2 1	365 365 365 365	10	0.01	0	+100	100 & COLD(3)	15
9) AUTOMOTIVE UNDER HOOD	-55	+125	60 &100 &140	1 1 2	1000 300 40	5	0.1	0	+100	100	15

IPC SM785

Field Environment: Body & Outdoor Temperatures



- Maximum temperatures likely not a significant concern
- Typically far below ratings

- However, very cold temperatures (below -20C) could be a challenge
- Especially in combination with a mechanical load

Temperature	Avg. U.S. CLIM Data	Avg. U.S. Weighted by Registration (Source: Confidential)	Phoenix (hrs/yr)	U.S. Worst Case (hrs/yr)
95F (35C)	0.375%	0.650%	11% (948)	13% (1,140)
105F (40.46C)	0.087%	0.050%	2.3% (198)	3.8% (331)
115F (46.11C)	0.008%	0.001%	0.02% (1.4)	0.1% (9)

Field Environment: Mechanical

- Vibration
  - Not typically affiliated with human body, but outliers can occur (especially with tools, transportation)
  - Examples: Jackhammer, reciprocating saw
  - Have induced failures in rigid medical devices

- Mechanical Shock
  - Drop loads can reach 1500g for mobile phone (some OEMs evaluate up to 10,000g)
  - Likely to be lower for lighter wearables, but could be repeated (i.e., affiliated with shoes)

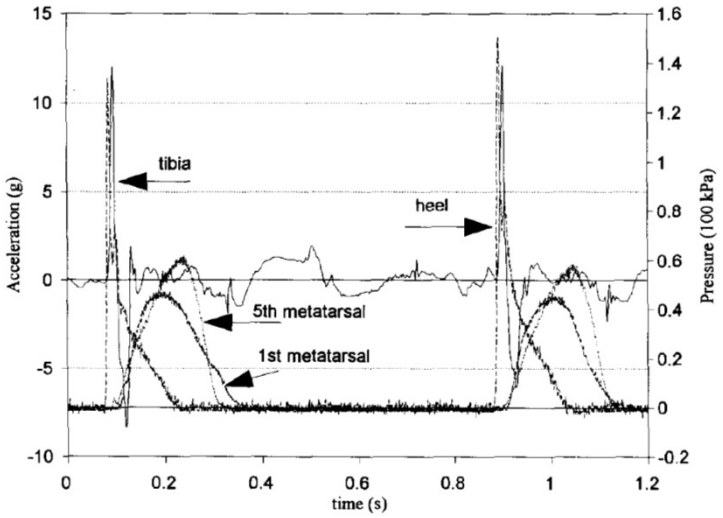
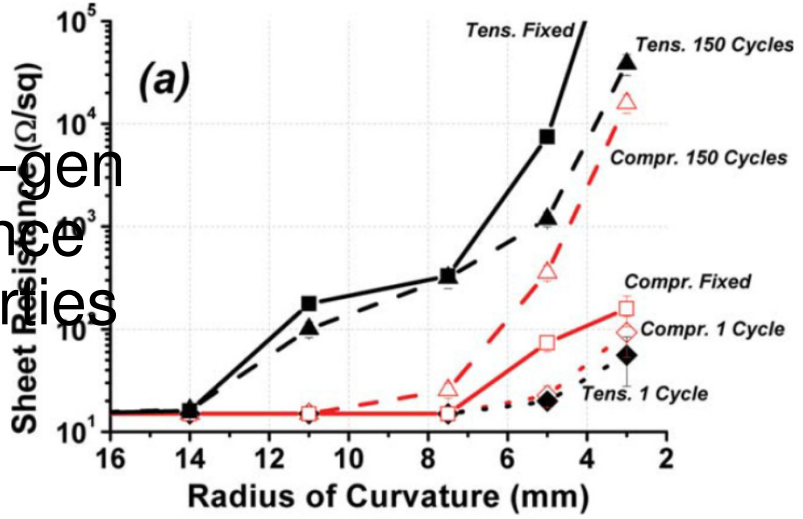


Fig. 7. Typical acceleration and pressure patterns recorded while subject was running.

Field Environment: Mechanical (cont.)

- Bending (Cyclic / Overstress)
  - Often considered one of the biggest risks in regards to wearables
  - Certain human movements that induce bending (flexing of the knee) can occur over 1,000/day

- Case Study
  - There is indication that next-gen substrate materials experience a change in electrical properties after exposure to bending
  - Can be exacerbated by elevated temperature



Other Challenging Environments for Wearables

- Washer / Dryer
- Cleaning fluids
- Mud / Dust / Water

Rain & Water Immersion Challenges

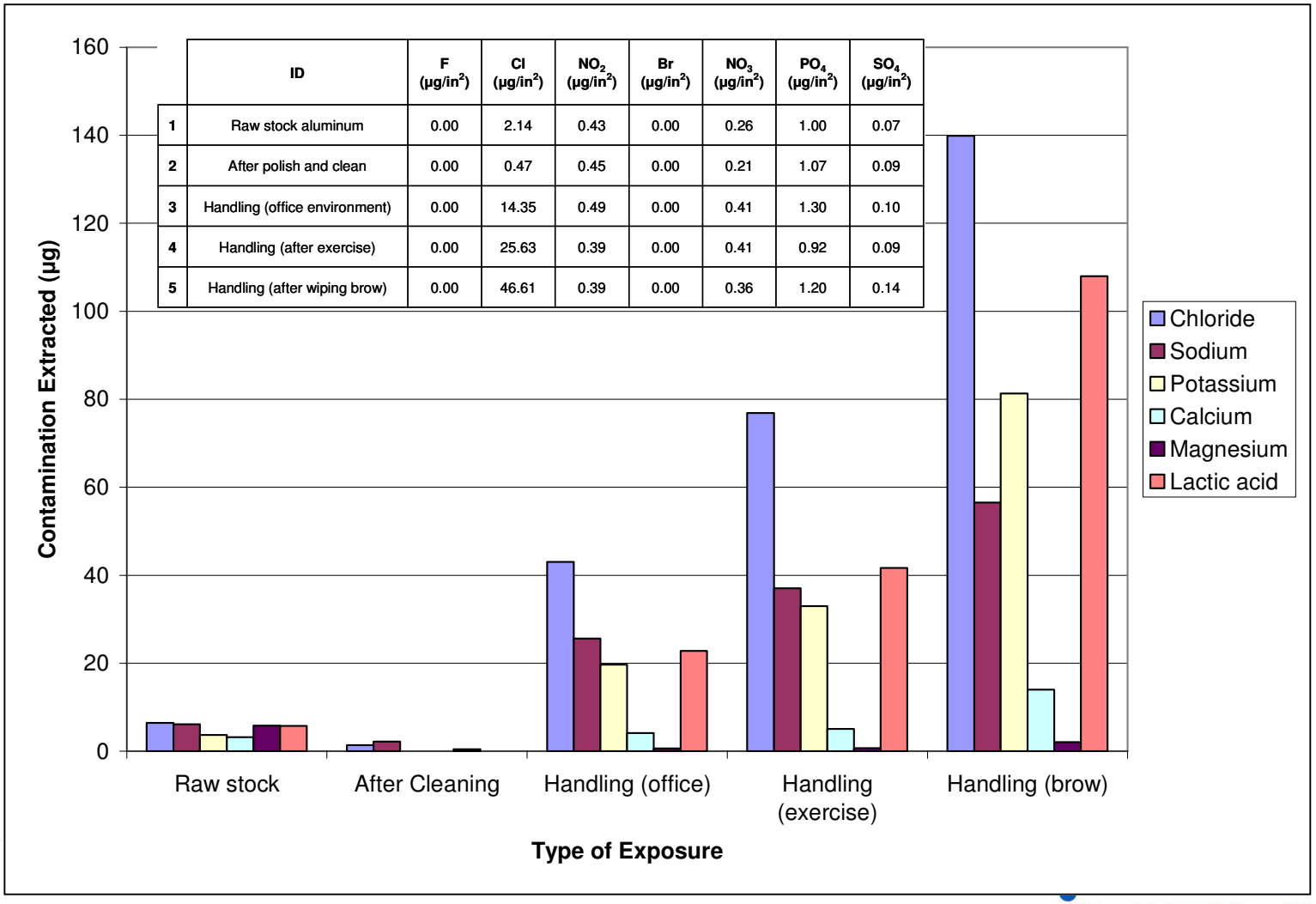
- Issue of exposure to water and rain must be addressed for wearable electronics to survive
- Some cell phone manufacturers coat the product with either a conformal coating or a superhydrophobic coating to protect the electronics

Corrosion: Handling / Sweat

- Composition of dissolved salts in water
  - Can include other biological molecules.
- Main constituents, after the solvent (water),
  - Chloride, sodium, potassium, calcium, magnesium, lactate/lactic acid, and urea/ammonia.
- Chloride and sodium dominate.
  - To a lesser but highly variable extent, iron, copper, urocanate (and the parent molecule histidine), and other metals, proteins, and enzymes are also present.
- The main concern regarding sweat is as a source of chloride

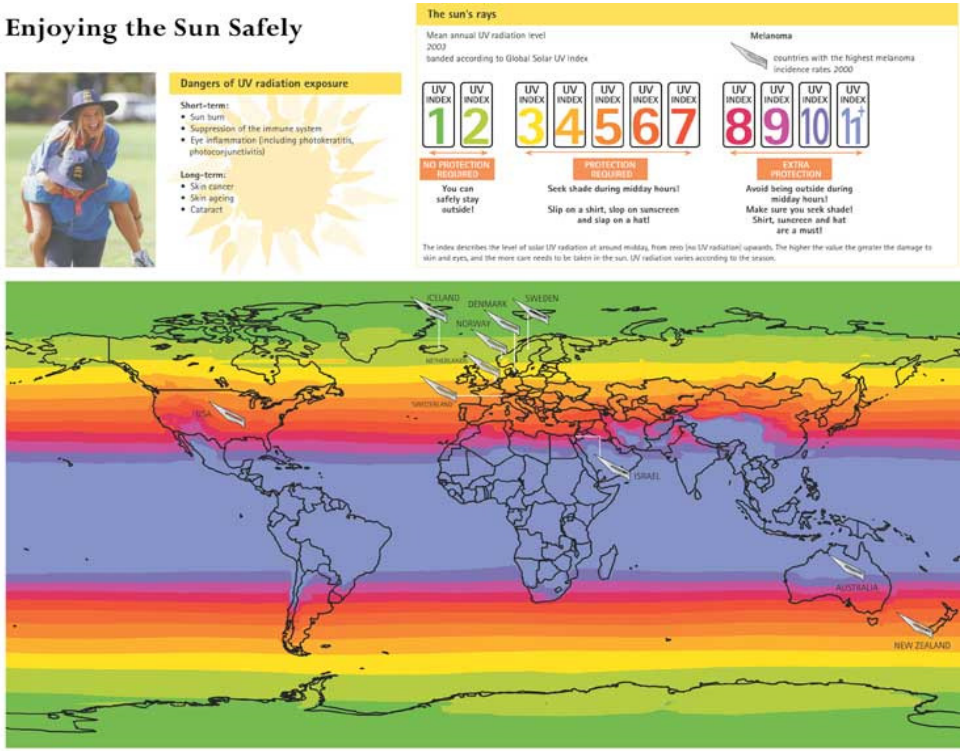
Handling / Sweat (cont.)

	ID	F ($\mu g/in^2$)	Cl ($\mu g/in^2$)	NO_2 ($\mu g/in^2$)	Br ($\mu g/in^2$)	NO_3 ($\mu g/in^2$)	PO_4 ($\mu g/in^2$)	SO_4 ($\mu g/in^2$)
1	Raw stock aluminum	0.00	2.14	0.43	0.00	0.26	1.00	0.07
2	After polish and clean	0.00	0.47	0.45	0.00	0.21	1.07	0.09
3	Handling (office environment)	0.00	14.35	0.49	0.00	0.41	1.30	0.10
4	Handling (after exercise)	0.00	25.63	0.39	0.00	0.41	0.92	0.09
5	Handling (after wiping brow)	0.00	46.61	0.39	0.00	0.36	1.20	0.14



UV Exposure

Annual UV Intensity – Global Picture



http://www.drb-mattech.co.uk/uv%20map.html

Annual UV Energy Calculations by City

City	Latitude	Average Total Energy at 340nm (W*hr/m^2/nm)	Average Annual Total Radiant Dose at 340nm (kJ/m^2/nm)
Singapore	1	426	1532
Paris, France	48	499	1796
Sao Paulo, Brazil	22	553	1991
Tokyo, Japan	35	570	2053
Guatemala	14	648	2334
Miami, FL	25	661	2380
New York NY	40	661	2381
Barcelona, Spain	41	662	2382
Brasilia, Brazil	15	662	2383
Melbourne, Australia	37	708	2549
Buenos Aires, Argentina	34	727	2618
Baghdad, Iraq	33	732	2634
Minneapolis, MN	44	735	2647
Townsville, Australia	19	743	2673
Madrid, Spain	40	748	2694
LA, CA	34	767	2761
Phoenix, AZ	33	869	3129

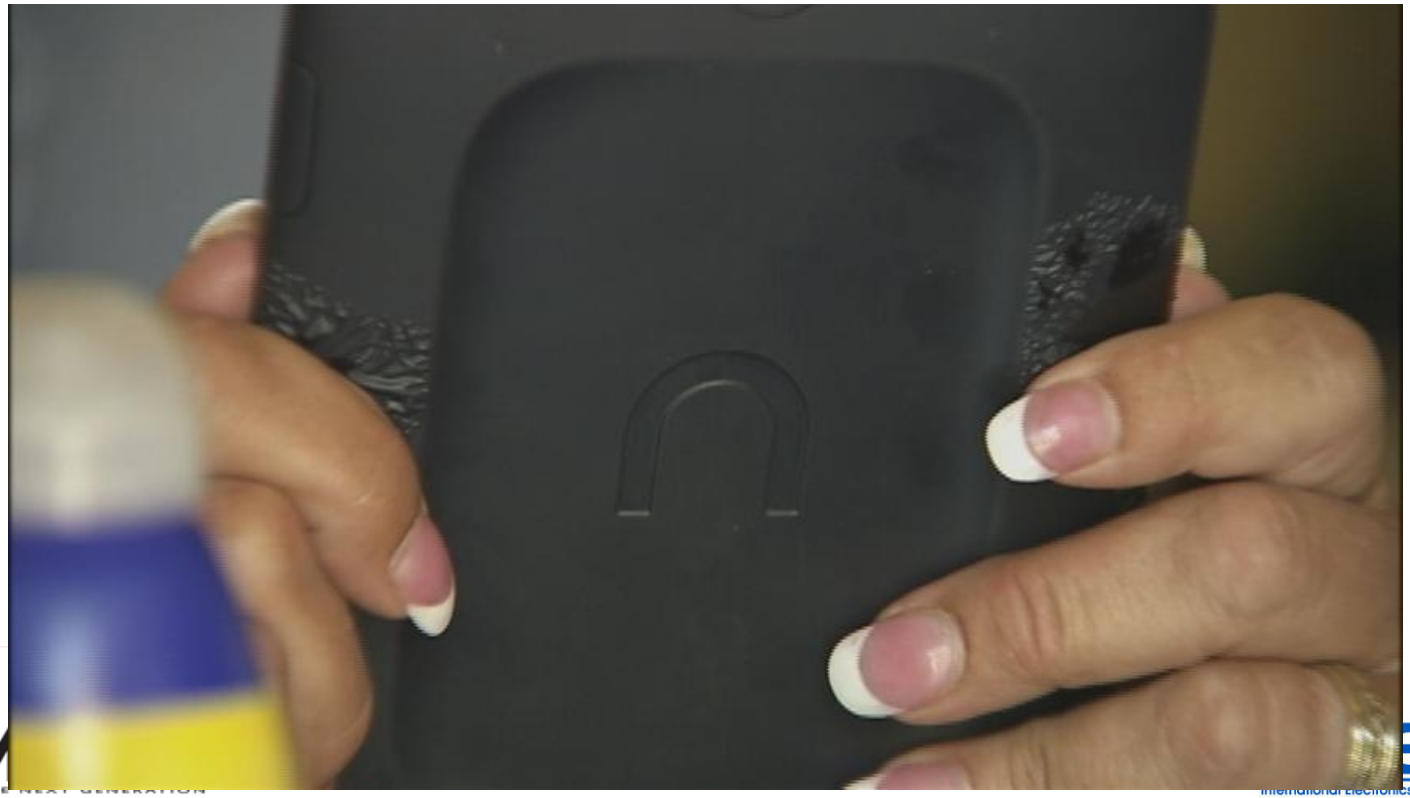
- Of Cities listed, Phoenix has highest avg annual exposure. Note: Model is isolated to UV. Humidity is not included.

Corrosion: UV Exposure

- Exposure to ultraviolet (UV) is typically not sufficient to induce degradation in electronic materials
- However, a combination of temperature, moisture, and UV can induce scission in polymeric chains
  - Exact combination, and specific portion of the UV spectrum, is not always well characterized
- It has been documented that stress corrosion cracking has been caused by sunscreen lotion

Material Interactions

- "Sunscreen melted my Nook"
  - A tiny warning on the can reads it can damage some fabrics materials or surfaces.
  - http://bcove.me/hh5yfn26



Ensuring Wearable Electronics Reliability

- DfR at Concept / Block-Diagram Stage
  - Specifications
- Part Selection
  - Derating and uprating
- Design for Manufacturability
  - Reliability is only as good as what you make
- Wearout Mechanisms and Physics of Failure
  - Predicting degradation in today's electronics

Specifications

- Two key specifications important to capture at concept/contract stage that influence reliability

Reliability expectations

Use environment

Reliability Goals

- Identify and document two metrics
  - Desired lifetime
  - Product performance
- Desired lifetime
  - **Defined as when the customer will be satisfied**
  - Should be actively used in development of part and product qualification
- Product performance
  - Returns during the warranty period
  - Survivability over lifetime at a set confidence level
  - MTBF or MTTF calculation should be primarily an administrative or marketing exercise (response to customer demands)

Desired Lifetime and Wearable Electronics

- What is the desired lifetime of wearable electronics?

- Rough equivalents: Clothes, shoes, watches, glasses, cell phones
  - Clothes: ??
  - Shoes: 3 months to 5 years (600 miles)
  - Watches: 3 to 20 years
  - Glasses: 2 to 5 years
  - Cell phones: 12 to 36 months

- With a new technology, there is an opportunity to influence expectations

Environment (Best Practice)

- Use standards when…
  - Certain aspects of your environment are common
  - No access to use environment
- Measure when…
  - Certain aspects of your environment are unique
  - Strong relationship with customer
- Do not mistake test specifications for the actual use environment
  - Common mistake with mechanical loads

Conclusion

- Wearable electronics are an exciting revolution in our engagement with ourselves and the world around us
- However, there are clear risks
  - Wearables use new technology that has not been fully characterized
  - They will be placed in environments that are not fully considered by the designer
- There will be unexpected failures, resulting in delays in product launch and potential advisory notices, if wearable manufacturers do not use industry best practices and physics of failure to qualify their technology

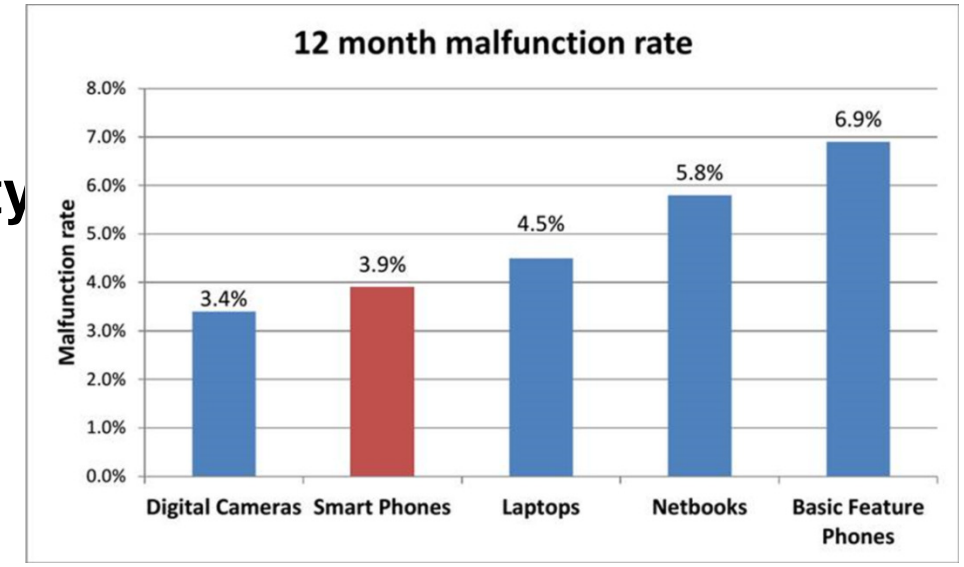
Presenter Biography

- Dock has over 40 years of experience in the electronics industry holding engineering positions in design, test, sustaining, software, process, manufacturing, quality, and reliability. He's also held management positions in quality, engineering, operations, materials technology, and program management.
- In his latest position as a Senior consultant for DfR Solutions, he enjoys focusing that diverse skill set onto client problems and opportunities .
- As a volunteer, he has worked with ASQ, IEEE, IPC, MRS, SMTA, and TMS. He's particularly proud of the students he's taught in refresher classes for Certified Quality Auditor and Certified Quality Engineer.
- He's also done volunteer work with secondary education co-ops, American Red Cross, Seattle Mountaineers, and Seattle Mountain Rescue.

Additional Material

Product Performance: Warranty Returns

- **Consumer Electronics**
  - 5-25%
- **Low Volume, Non Hi-Reliability**
  - 1 to 2%
- **Industrial Controls**
  - 500 to 2000 ppm (1st Year)
- **Automotive**
  - 1 to 5% (Electrical, 1st Year)
  - Can also be reported as problems per 100 vehicles



http://www.squaretrade.com/htm/pdf/cell_phone_comparison_study_nov_10.pdf

Product Performance: Survivability

- Some companies set reliability goals based on survivability
  - Often bounded by confidence levels
  - Example: 95% reliability with 90% confidence over 15 years
- Advantages
  - Helps set bounds on test time and sample size
  - Does not assume a failure rate behavior (decreasing, increasing, steady-state)

Wearable Tech Can't Tell Us What We Don't Already Know

- Healthcare providers have been slow on the uptake.
- Promise in sharing patient-generated health and wellness data with physicians
  - Few patients have the time, resources or know-how to collect data
  - Few physicians have the time, resources or know-how to sift through the data that patients collect.
- Emerging consumer health apps may help, but they're just as likely to confuse.

http://www.cio.com/article/2452759/health/wearable-techs-dilemma-too-much-data-not-enough-insight.html

Integrate Into the Healthcare System

- Collecting health metrics and accurate data is the first step towards building trust and credibility with physicians and care providers
- Wearable creators should focus on two details:
  - Establish a partnership with existing technologies and systems in hospitals and physician's offices
  - Focus on the design, privacy factors, battery life, & all-in-one-device offerings

http://digitalhealthpost.com/2014/07/09/focus-wearables-2-0/

What worries researchers about using wearables in clinical trials

- Context of data
- Compliance
- Everything's relative
- Lost data

http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/article/articleDetail.jsp?id=850114&pageID=3