What is the medical internet of things?

Essential elements of understanding

Fall 2023 – Anesthesia Patient Safety Foundation

Presented by Anura Fernando

Meet your presenter

Anura S. Fernando

Anura Fernando is the global head of medical device security at UL Solutions. He has twenty-five years of experience at UL Solutions with safety critical software and control systems certification and safety research across multiple application domains. He has contributed to research and industry publications in Predictive Modeling and Risk analysis, cybersecurity, Systems of Systems, Health IT, and medical device safety and security. Anura has participated in project collaboration with numerous Fortune 500 companies and has contributed to the development of several domestic and international consensus standards for software, security, and functional safety. His current focus looks at the intersection of cybersecurity and safe medical device interoperability.

To begin, we need to understand the term “Cyber”

Before there was *cyber*-anything, there was the field of cybernetics. Pioneered in the late 1940s by a group of specialists in fields ranging from biology to engineering to social sciences, cybernetics was concerned with the study of communication and control systems in living beings and machines. The interest in how systems work is reflected in the etymology of *cybernetic*, which comes from the Greek word kubernētēs (κυβερνᾶν), ‘steersman’, from *kubernan* ‘to steer’.

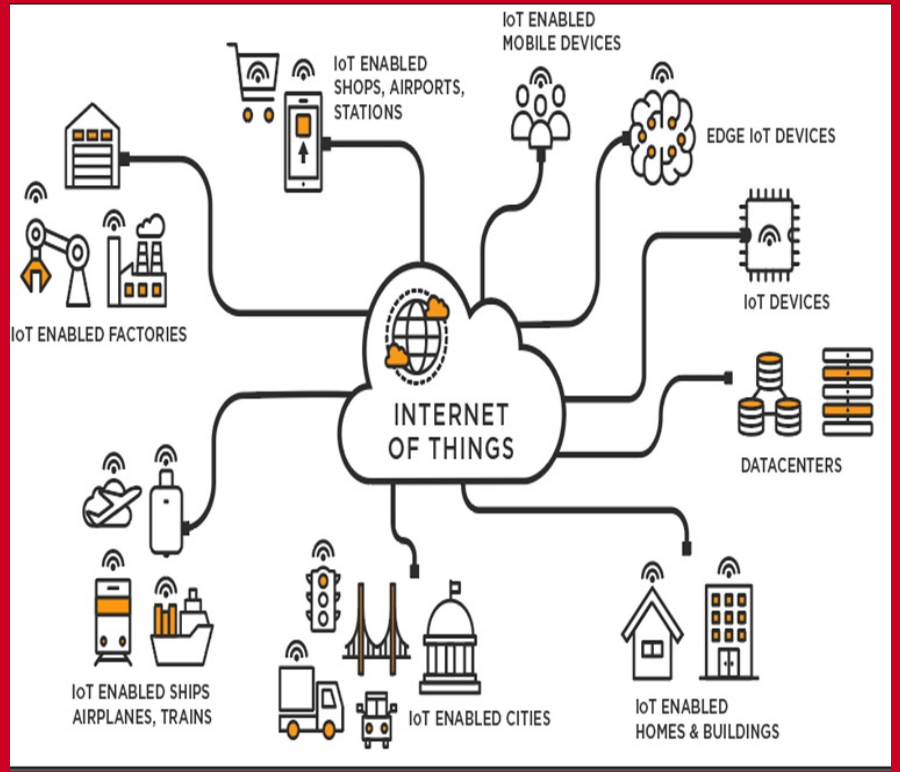
- Oxford University Press

Dionysus and the Steersman

Today, the term “steering” may refer to a very different looking activity.

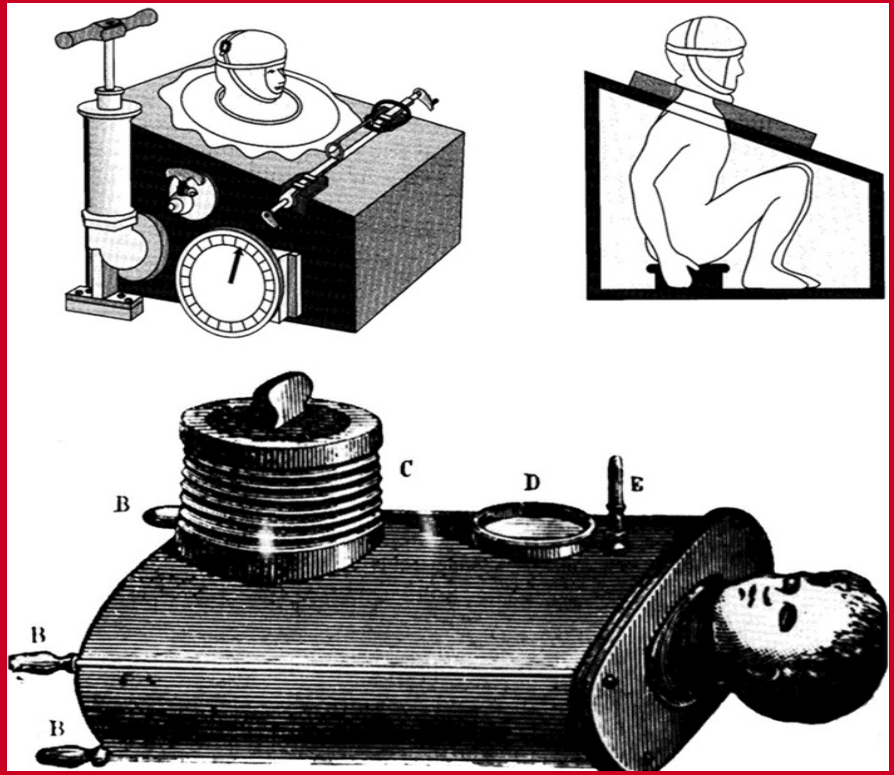
With all of the “things” that are now connected together, it is important to “steer” carefully when navigating the information superhighway.

This can help us build cyber physical systems that are cyber secure, cyber safe, and cyber resilient.



We can now connect almost anything to the internet…new or old.

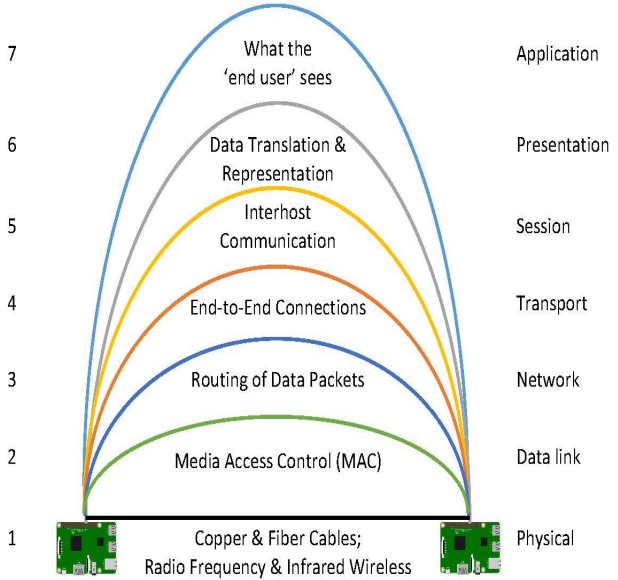
When these “things” help promote healthcare, this gives us the “medical Internet of Things”



The mIoT is more than just “medical things”

It’s a complex technology stack that has many layers intended to enable reliable, safe, secure, and effective communications.

What makes the “medical” aspect unique is the imperative of **patient safety** where harm and healing may need to be carefully balanced.



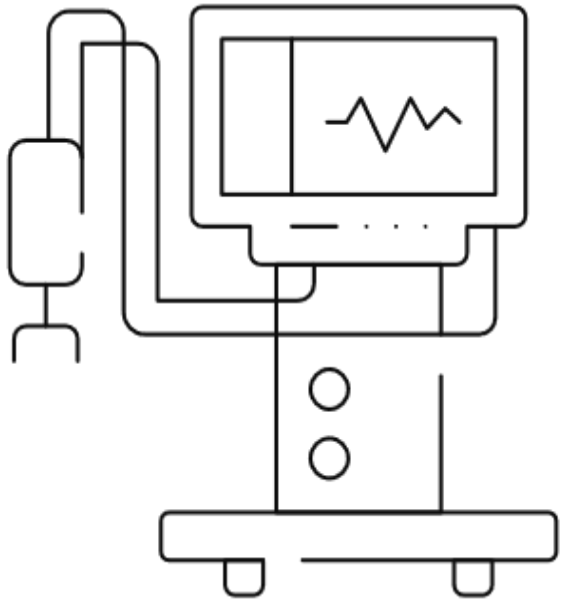
There are trade-offs and risks to consider at every step.

What are the clinical use cases for the application of this technology?

What's more important to patient safety, speed or accuracy?

TCP	UDP
Reliable	Unreliable
Connection-oriented	Connectionless
Segment retransmission and flow control through windowing	No windowing or retransmission
Segment sequencing	No sequencing
Acknowledge segments	No acknowledgement

Highly simplified example of a software controlled ventilator



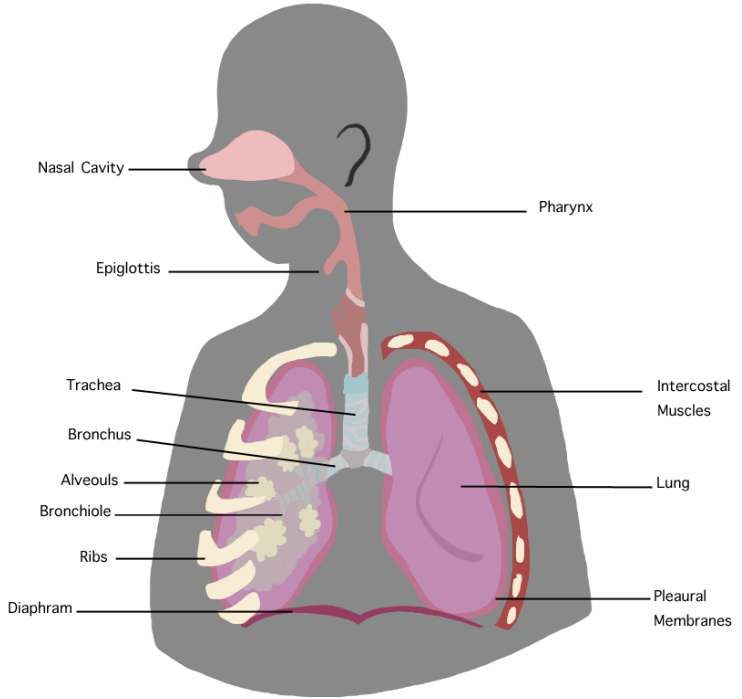
DISCLAIMER

The examples provided in this presentation are for educational purposes only.

They are highly oversimplified in order to demonstrate foundational concepts of Safety Science, which includes security, and they should not be the sole basis for the development or evaluation of medical devices or other products intended for real-world use.

What problem are we solving?

Why an IoT ventilator?

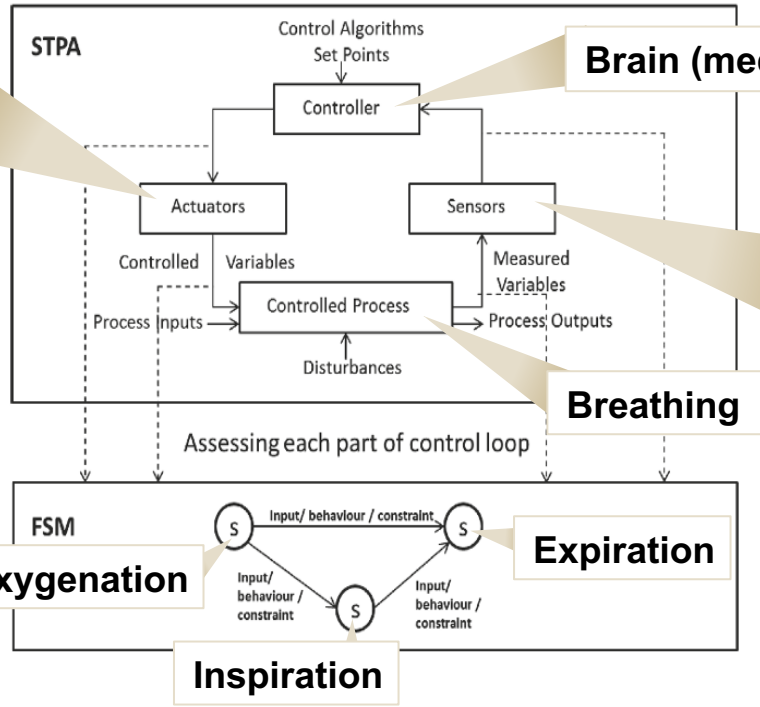


What exactly do we need to build?

Muscular system

Skeletal system

Peripheral Nervous System



Brain (medulla oblongata)

Chemoreceptors

Proprioceptors

Peripheral Nervous System

Breathing

Expiration

Oxygenation

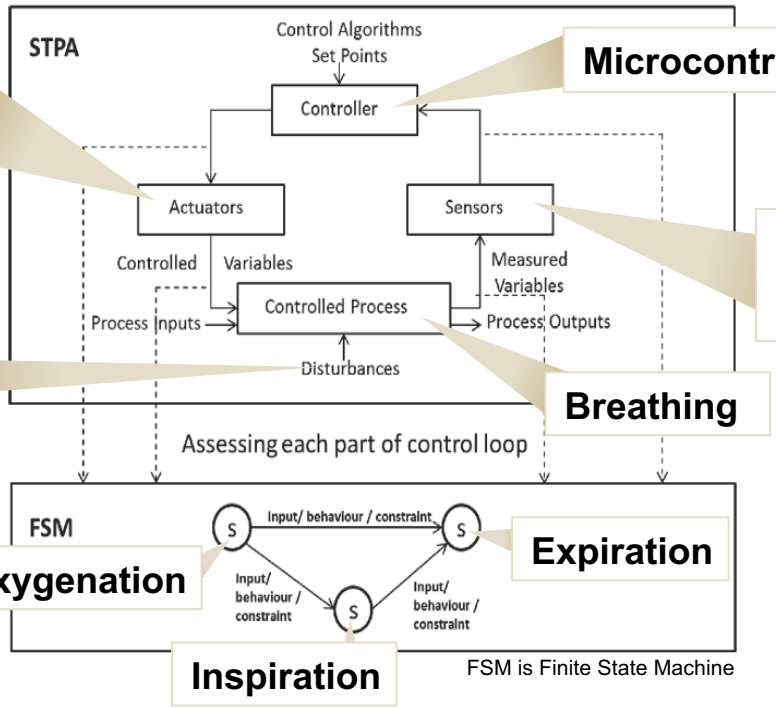
Inspiration

Integrating State Machine Analysis with System-Theoretic Process Analysis; Abdulkhaleq and Wagoner

How do we go about building this?

Electromechanical pump

0 to 5-volt signal



Microcontroller / SW

Servo feedback

Digital I/O

Breathing

Expiration

Oxygenation

Inspiration

FSM is Finite State Machine

Disturbances may be used to define tests

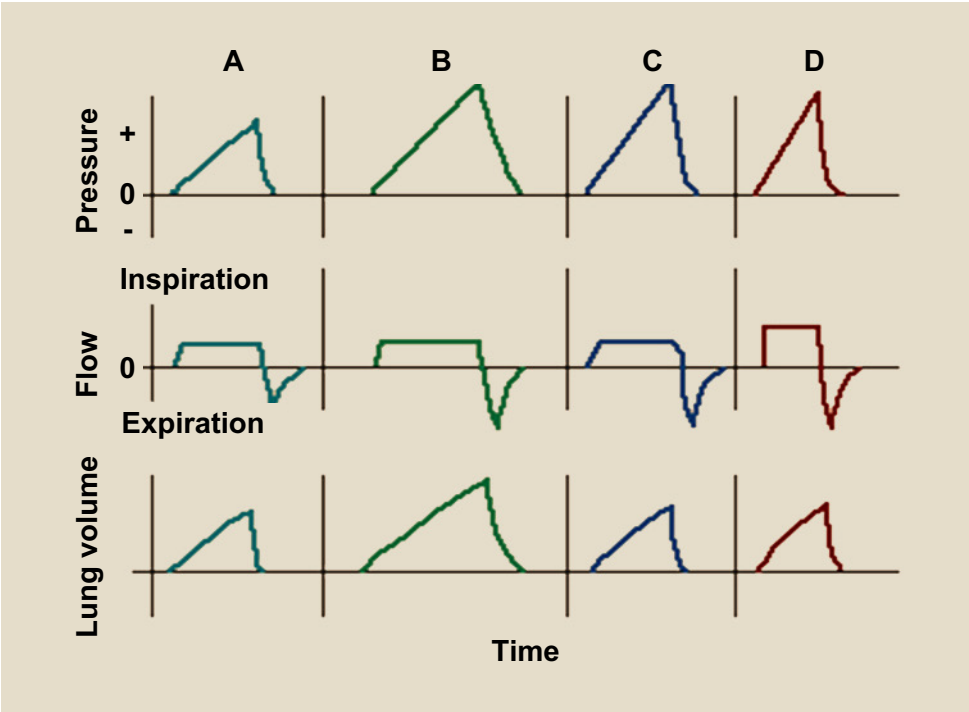
Control structures can help define pass / fail criteria for tests

Integrating State Machine Analysis with System-Theoretic Process Analysis; Abdulkhaleq and Wagoner

What are some important performance parameters?

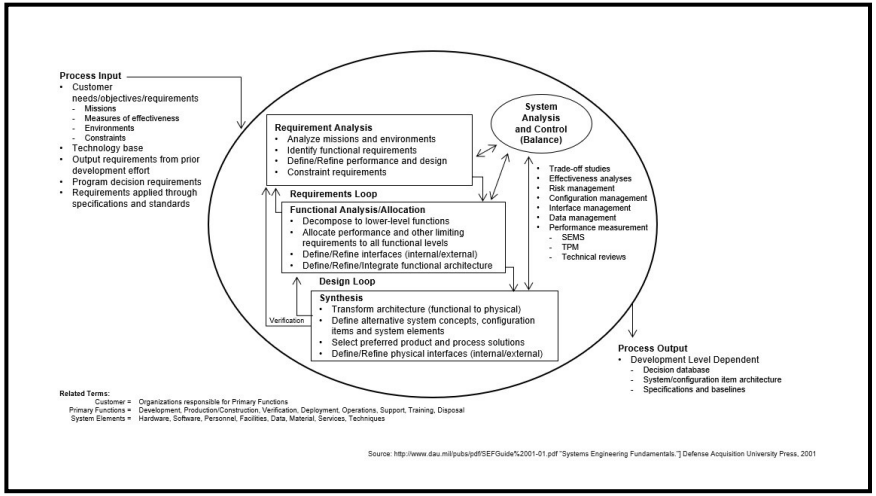
Waveforms for volume-cycle ventilator

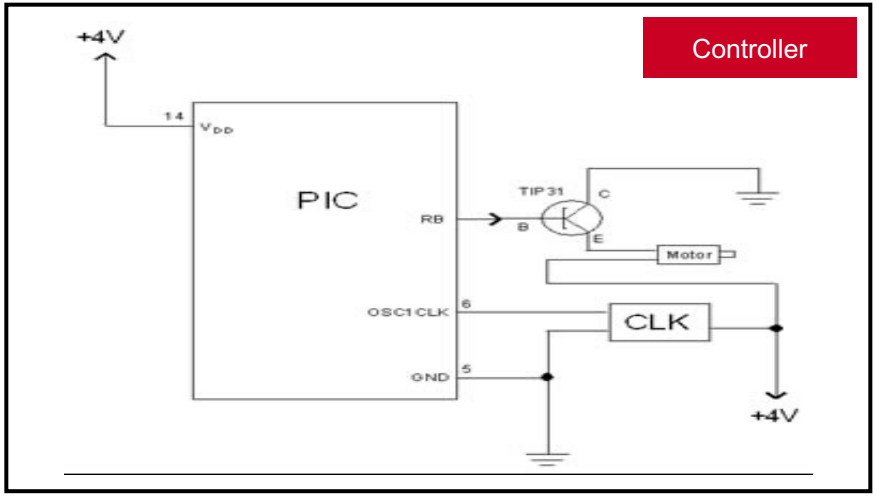
Pressure, flow, and volume waveforms for a volume-cycle ventilator using a constant flow generator (square wave) at baseline (A), and with increased delivered tidal volume (B), reduced lung compliance (C), and enhanced respirator flow rate (D). An increase in peak airway pressure occurs in the last three settings.



Adapted from Spearman, CB, Egan, DF, Egan, J, Fundamentals of respirator therapy, 4th ed, Mosby, st Louis, 1982.

We need a good plan to help get us started

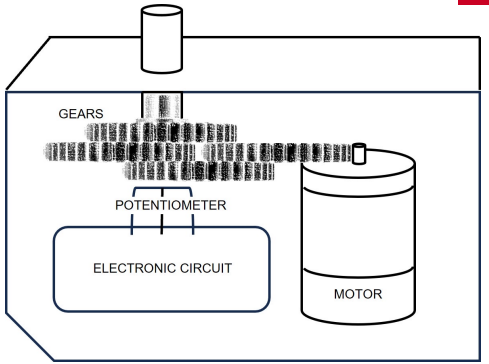




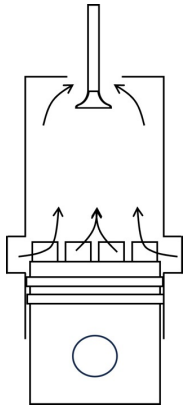
Then we need to start selecting the technologies we want to use.

We need a way to move the air

Motor



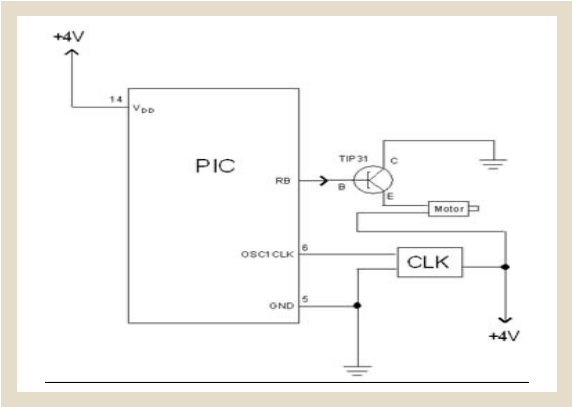
Pump

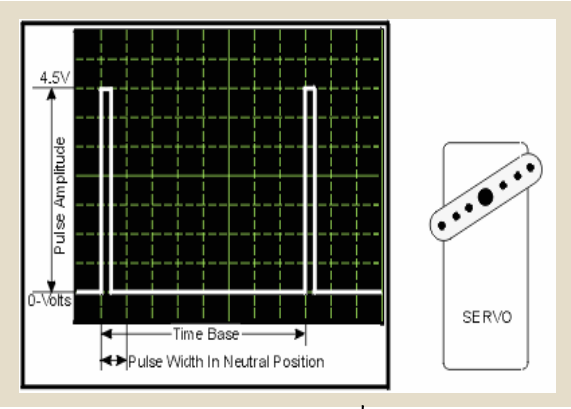


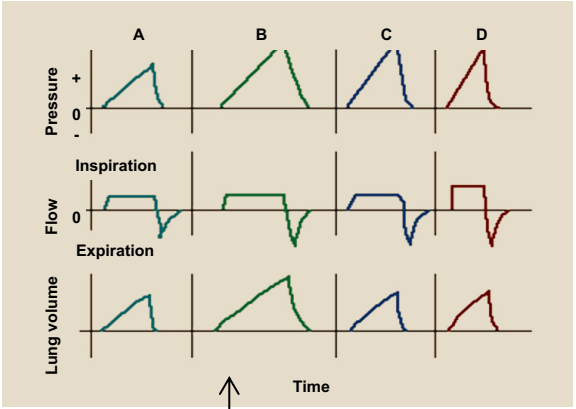
We also need feedback about the motion control and displacement of air.

We need to move the air in the right way

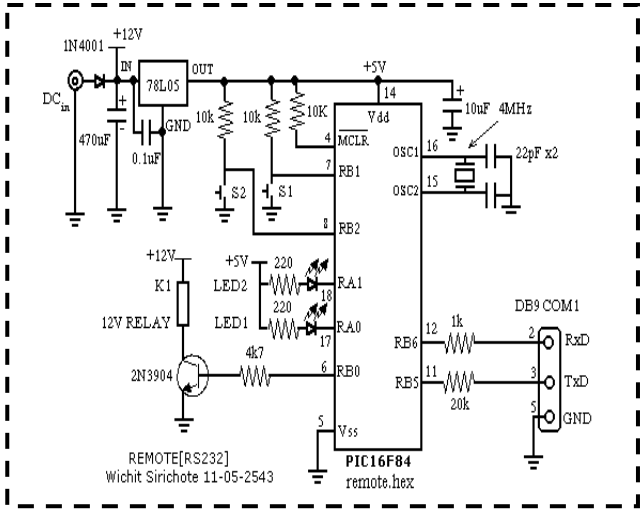
The intellectual property (IP) around motion control can be a significant corporate asset





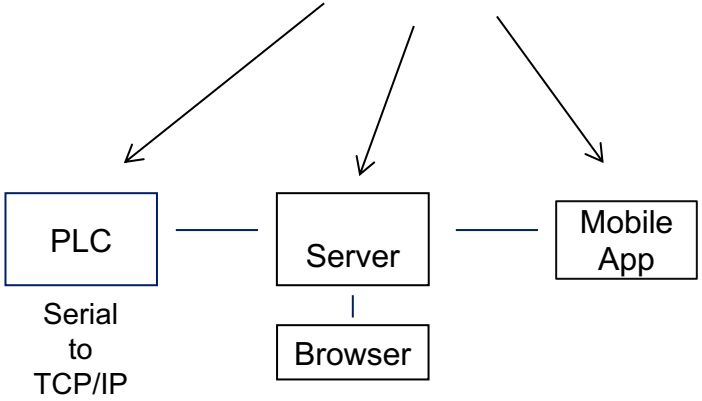


Can we adjust those parameters remotely?

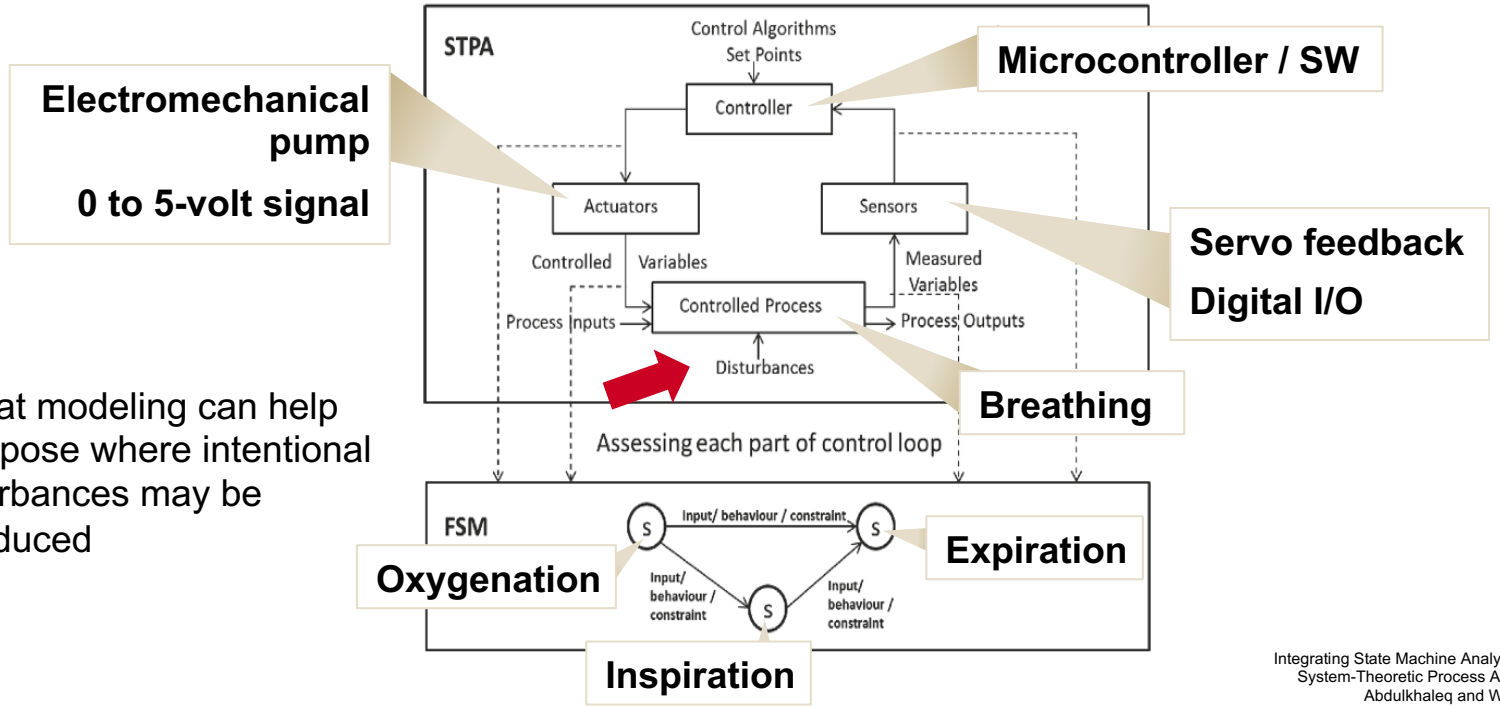


http://www.kswichit.com/easyserver0.9/easyserver0.9.htm

Use Cases:
- Local control HMI on PLC
- Remote control via browser
- Native app on mobile device



What could go wrong?



Threat modeling can help to expose where intentional disturbances may be introduced

Integrating State Machine Analysis with System-Theoretic Process Analysis; Abdulkhaleq and Wagoner

Hazard analysis is one way to think through this

Energy/Substance ... or data

Harm
- Person (injury/health)
- Property (fire)
- Environment

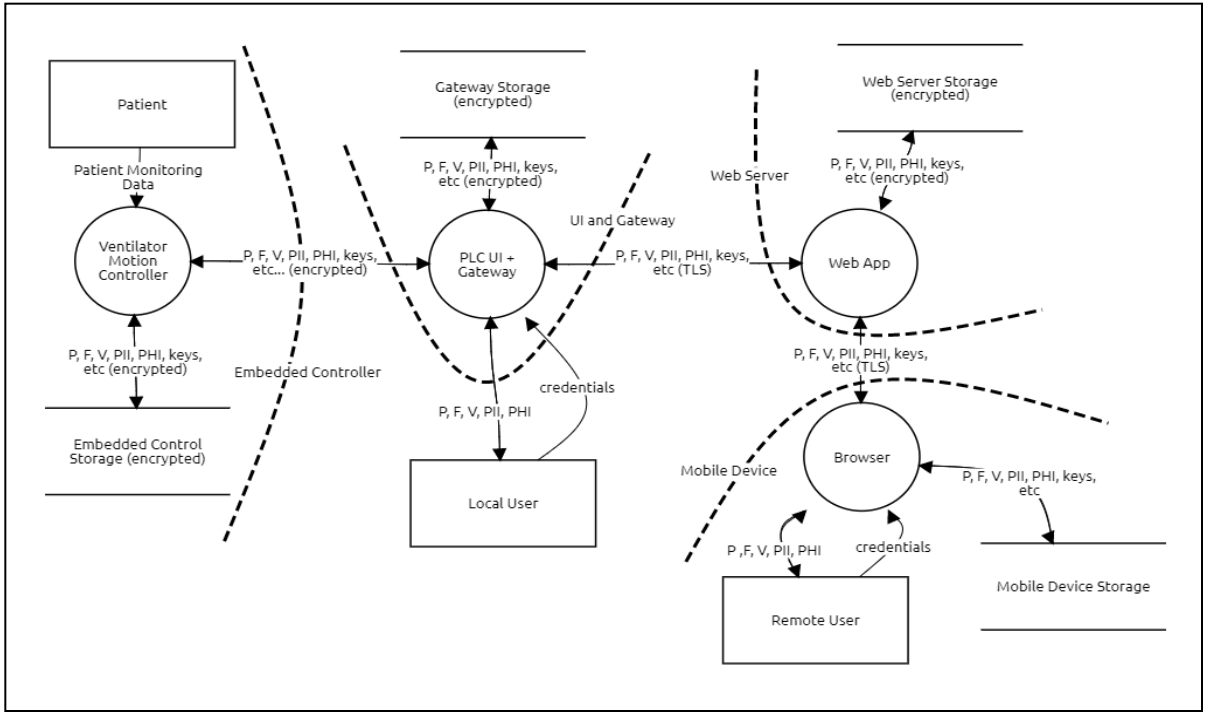
Eliminate

Guard

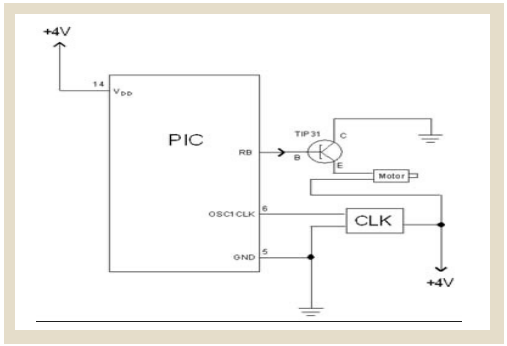
Warn

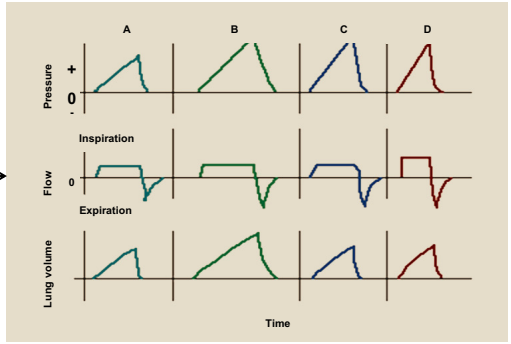
Reduce susceptibility

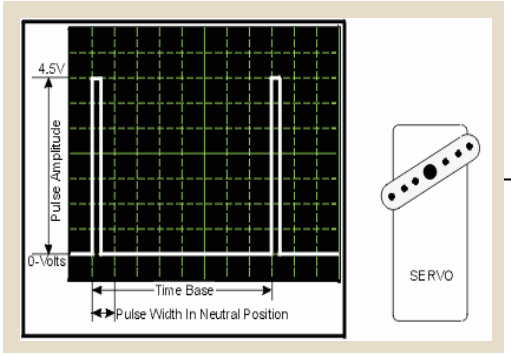
Threat modeling can help define information flows

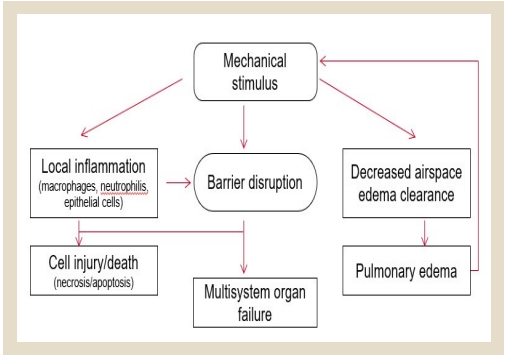


Ventilator Induced Lung Injuries (VILI)

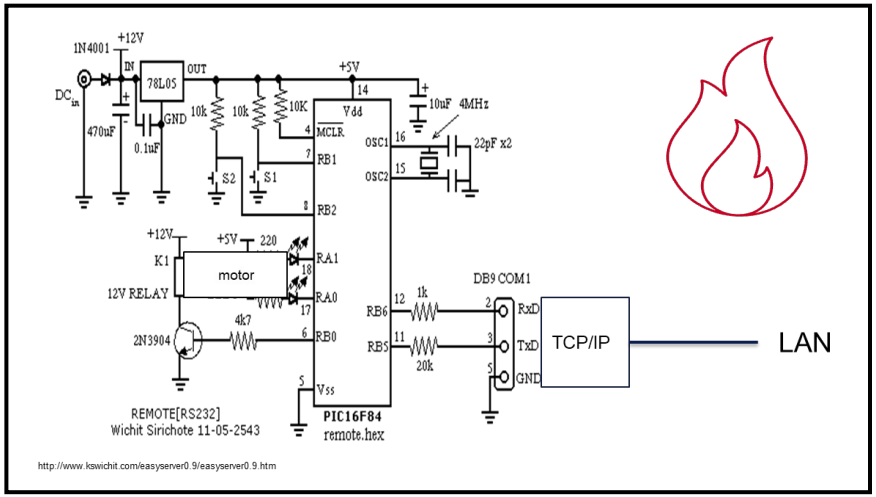


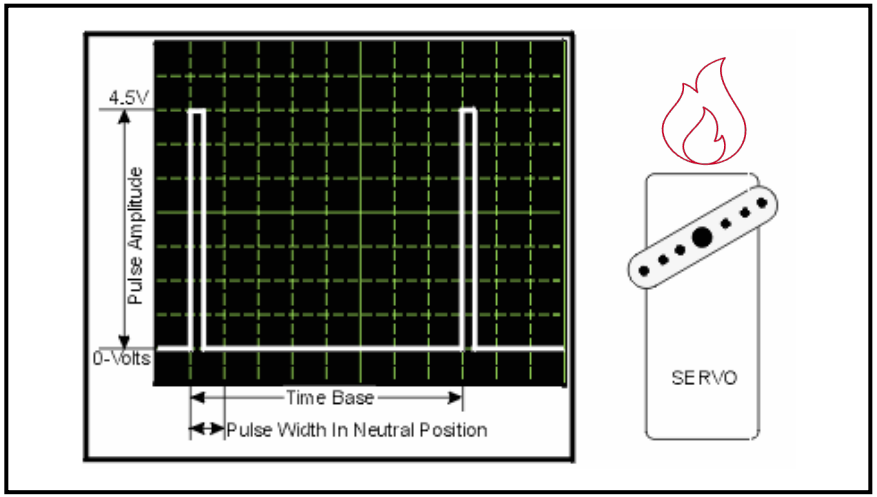






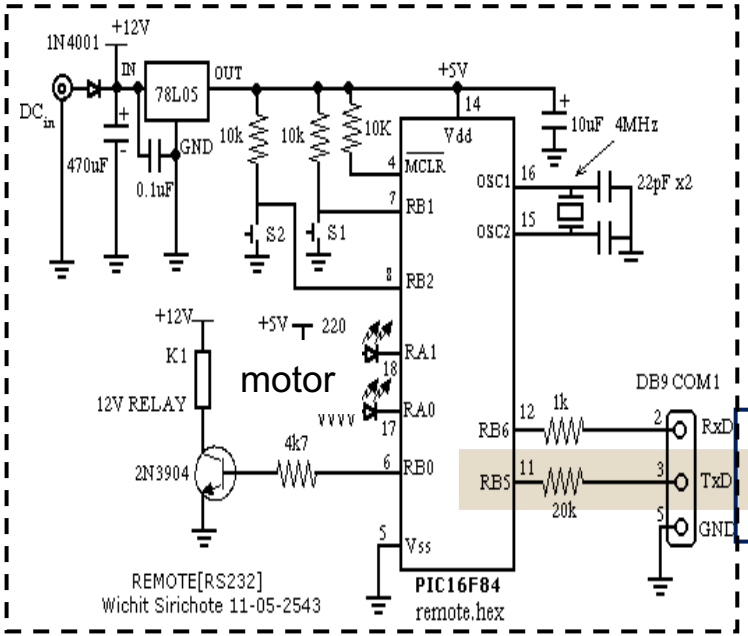
Basic safety impact: fire





Motor overdriven and overheating leads to fire

Security impact: stolen IP



http://www.kswichit.com/easyserver0.9/easyserver0.9.htm

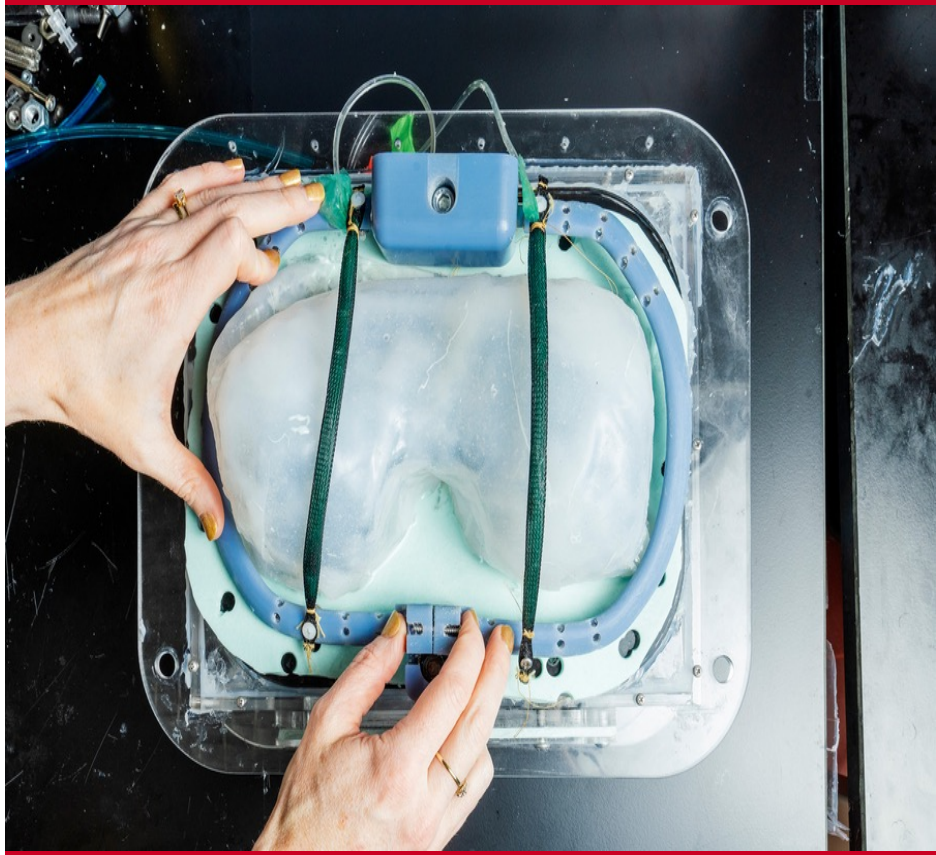
Exfiltration of intellectual property (e.g., algorithms)

TCP/IP

LAN

```
; FILE: PWM.asm
;           cpu equates (memory map)
            list      p=16f84
            radix     hex
portb       equ       0x06          ; port b equate
duty        equ       0x0c          ; length of duty cycle
temp        equ       0x0d          ; length of duty cycle
;-----------------------------------------------------------------
c           equ       0             ; status bit to check after subtraction
;-----------------------------------------------------------------
            org       0x000
            movlw     0x00          ; load W with 0x00 make port B output
            tris      portb         ; copy W tristate to port B outputs
            movlw     0x00          ; fill w with zeroes
            movwf     portb         ; set port b outputs to low
rstrt       movlw     d'0'
            movwf     portb
            movlw     d'157'        ; Duty cycle length
            movwf     duty
b0loop      movf      duty,w
            movwf     temp
            bsf       portb,0
pwma        nop
            nop
            nop
            nop
            nop
            nop
            nop
            nop
            nop
            nop
```

Today, researchers are even working on implantable ventilators.

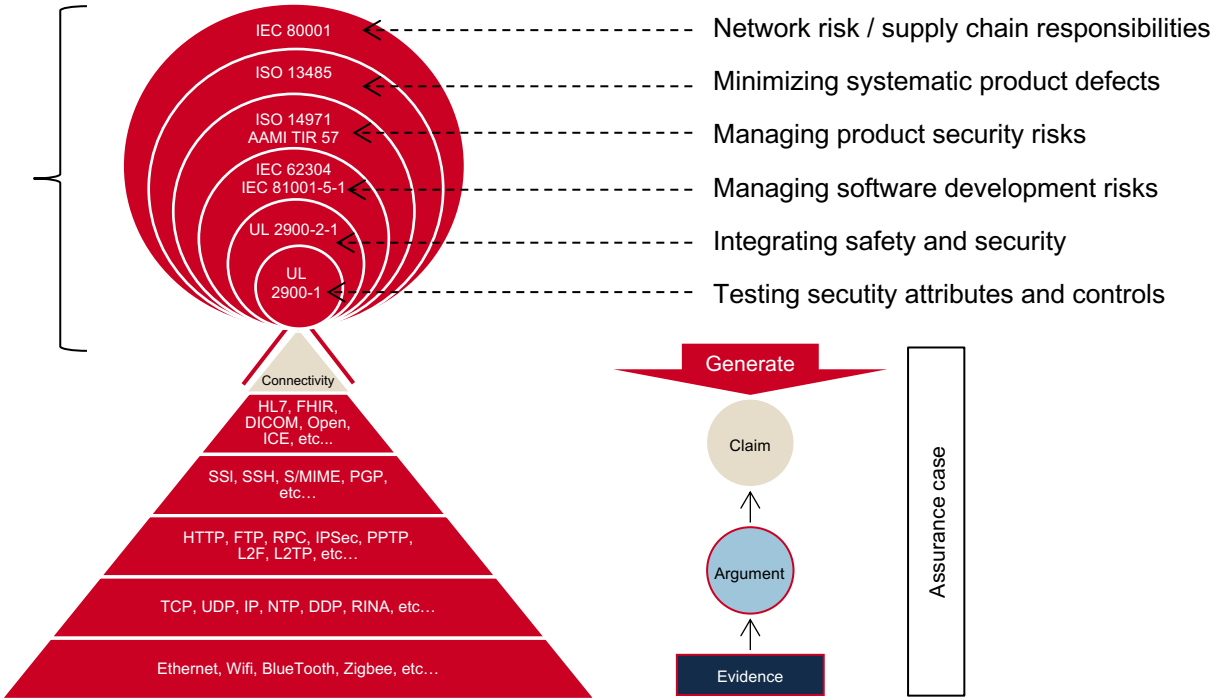


Standards can help improve patient safety and security

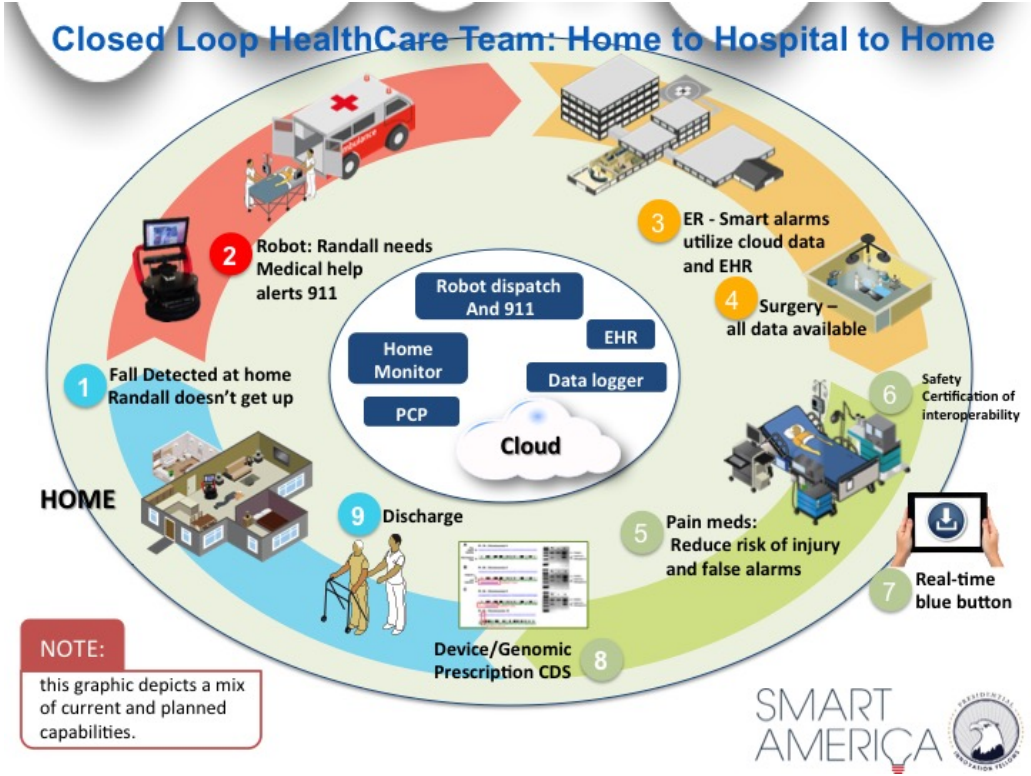
Total product lifecycle

- Concept of operations
- Requiremnets and architecture
- Detailed design
- Development
- Integration, test and verification
- System V&V
- Operation and maintenance
- Decommissioning / disposal

Accommodates variations in technical implementation standards



The future of wearables, robots, and the medical internet of everything is just steps away



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