Process for Development of Space Flight Biomedical and Health Hardware According to the Requirements Needs of Users in Medical Device and Diagnostic Industry

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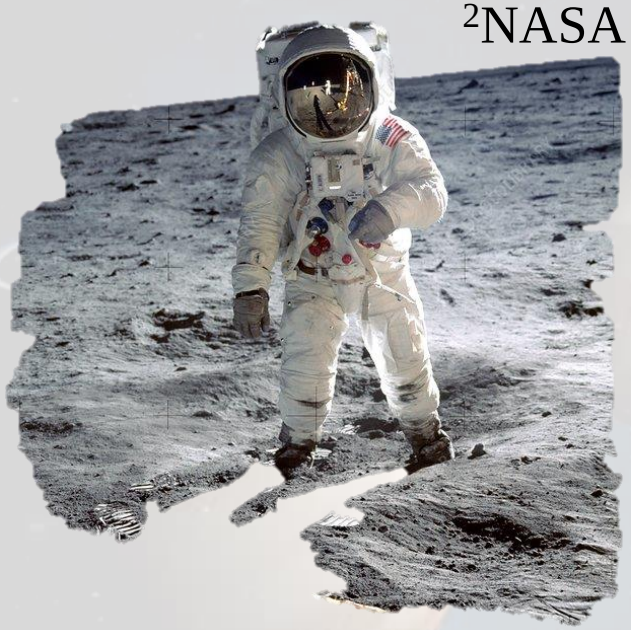

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Disclosure Information

90th Annual Scientific Meeting

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I have no financial relationships to disclose.

I will not discuss off-label use and/or investigational use in my presentation

Medical Device

It is intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease

MDDI Classification of Hardware: (FDA Water Fall)

- Class I: Have a low to moderate risk to the patient and/or user
- Class II: Have a moderate to high risk to the patient and/or user
- Class III: Have a high risk to the patient and/or user

Hardware Categories: (Class 1 or 1-E)

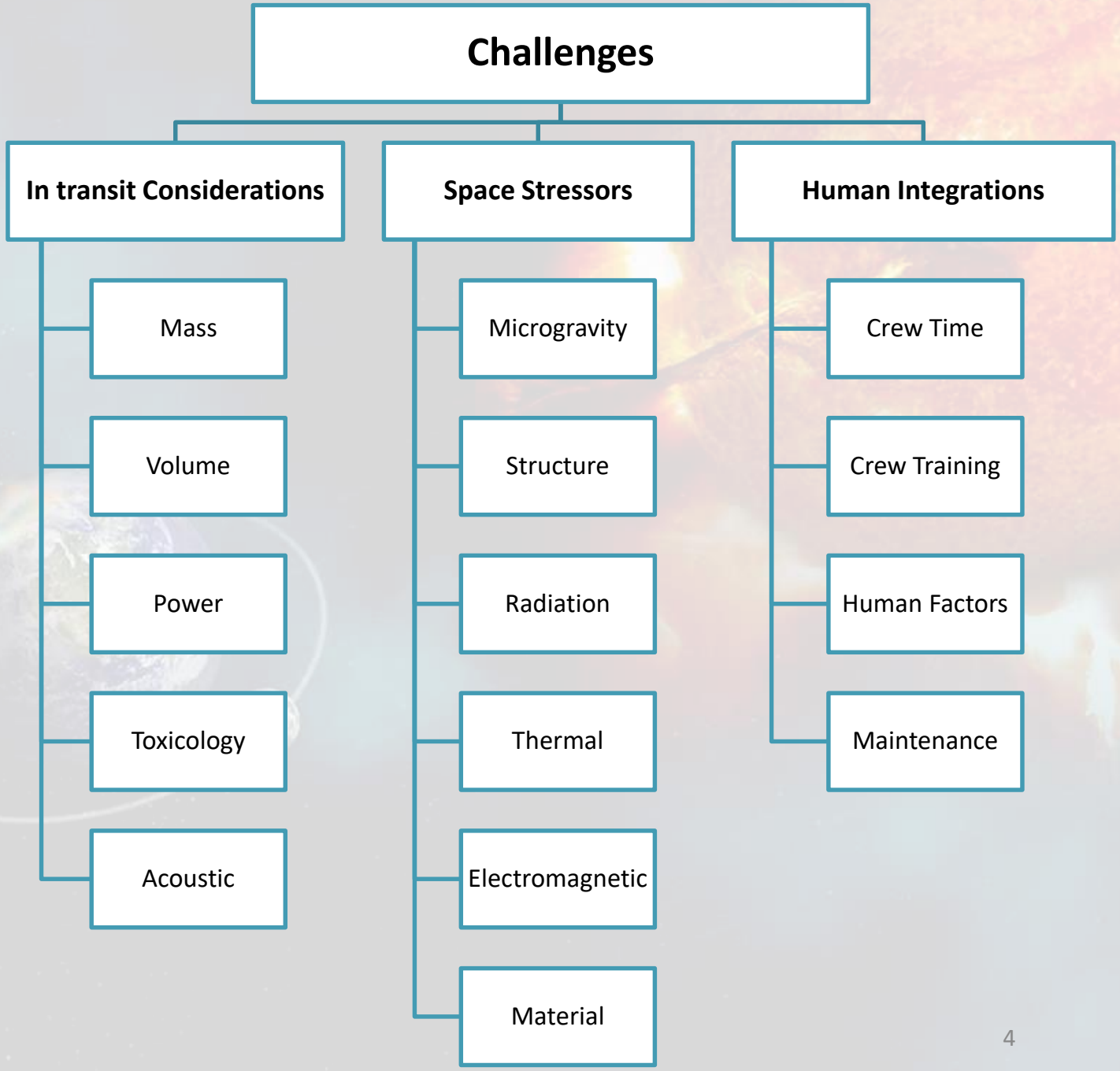
1. Information Technology
2. Custom Developed
3. General Use: Modified commercial product, referred to as MOTS
4. COTS : Off the shelf device ready to fly

1960 Nova Blood Pressure Monitor

2018 Nova Blood Pressure Monitor

Terrestrial vs. Extraterrestrial:

- Patient/Subject Population Differs
- End User
- Space, and Craft Stressors
- Physiological Adaption
- Systematic Adaptation



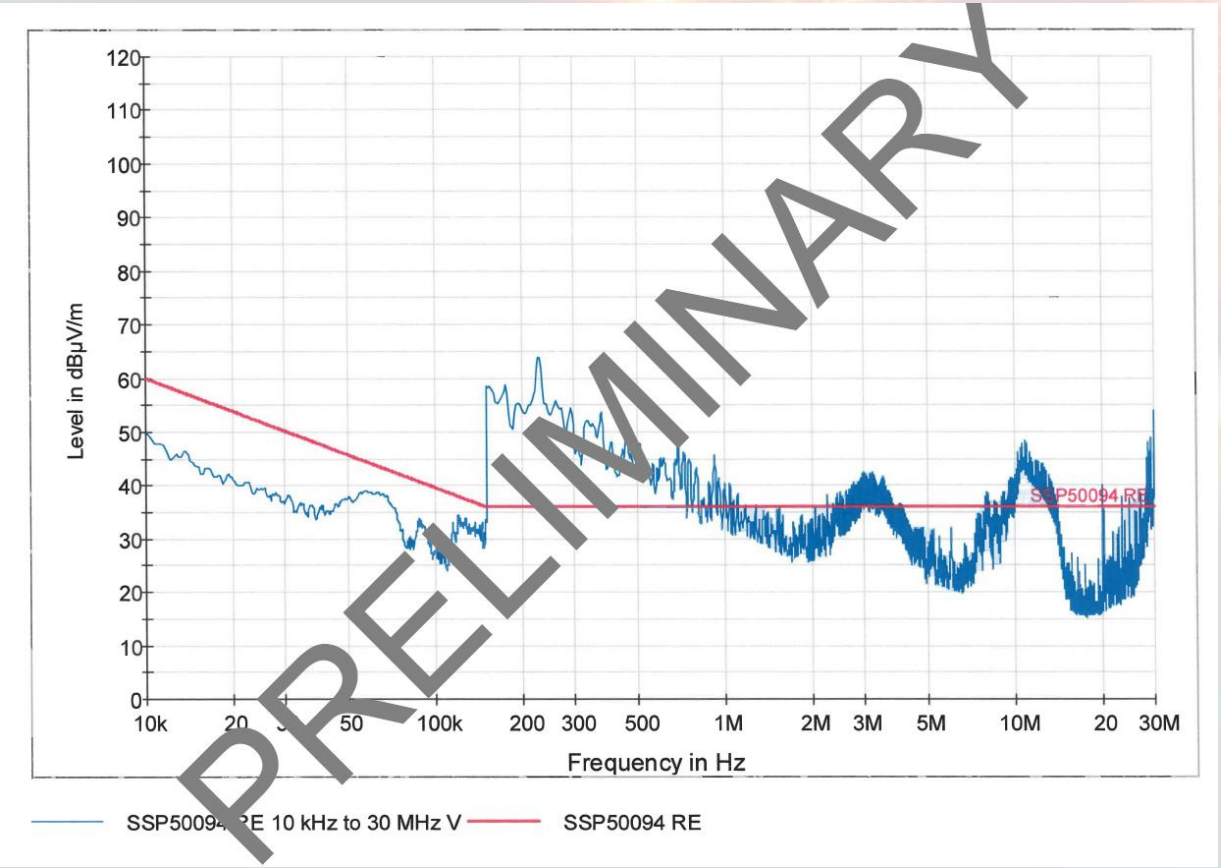
Challenges Driving Requirements

1. Material Compatibility [6]

- If the product is extremely small it is not a concern
- Plastics:
  - 3D printing: Ultem vs. PLA
  - Gels, Solvents: No alcohols
- Use conformal coating and treat capacitors as toxic, design to contain

2. Electromagnetic Compatibility

- Avoid magnets
- Requirements below 100 MHz
- Start intentional transmitter
- Standard Bluetooth



Challenges Driving Requirements

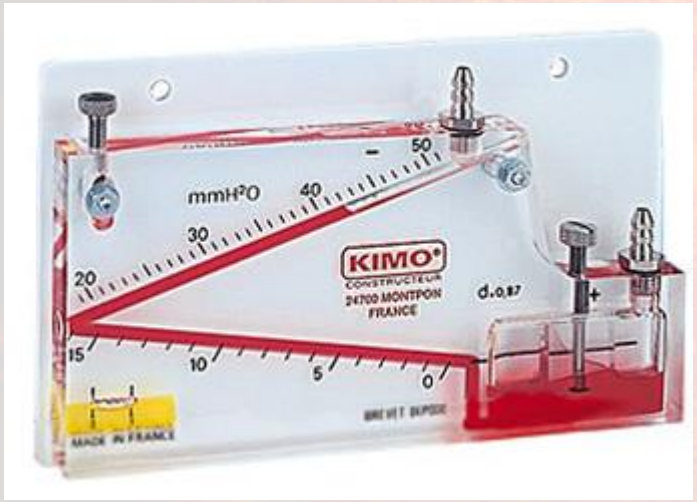
3. Batteries and Power Source

- Custom battery designs
- Even COTS solutions
- Button cells, alkaline have no circuit design constraint, all others do.
- Do not develop a custom piece of hardware that charges a Lithium cell, testing will destroy multiple units, not just the cell is damaged but the hardware as well

4. Acoustic

- NC 34 Standard
- 59 dBA, it is limited to 2 hours of operation per 24-hour period
- Acoustic Shielding required for all motors and fans

Challenges Driving Requirements



5. Weightlessness and Gravity Profile

- Fasteners and safety hazard
- Vacuum systems

6. Structure

- Loads on the system including Kick loads
- Fasteners and safety hazard
- Configurability and number of Parts

7. Thermal

- Convection Problem in microgravity – Heat rejection
- Safety Touch temperature

8. Containment: Liquids, Toxins, Capacitors etc

- Tox/ BSL level hazard dictates the number of redundant levels of containment
  Example Tox level 2 M blood handling require three level of containment

CHALLENGES DRIVING REQUIREMENTS

9. Servicing of hardware

- How easily can the hardware be repaired or subcomponents replaced (Orbital Replaceable Unit (ORU))
- Use of captive fasteners
- Number of unit required on Orbits
- What is the knowledge needed for repair
- Time require for maintenance
- Hardware or Software Compatibility

10. Human Factors

- Usability for a wide range of sizes of humans
- Form and Function

11. Operations

- Number of crew required to run the system
- Crew time

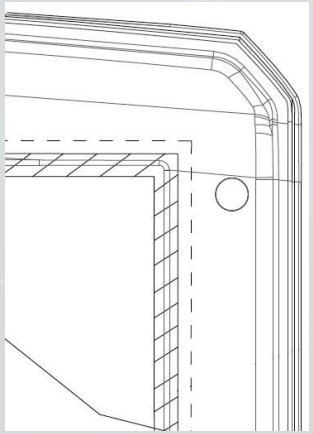
Case study – Ultrasound Imaging

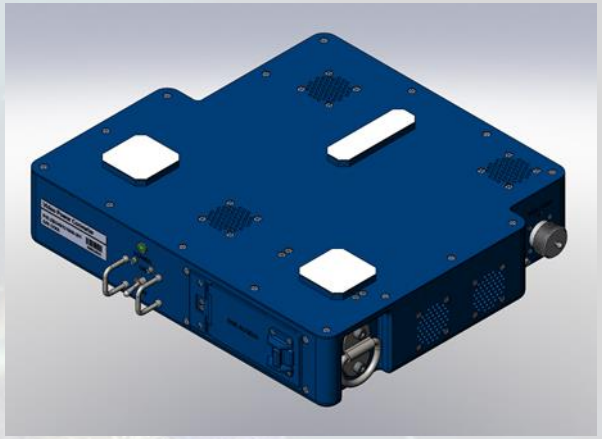
- Ultrasound imaging (sonography) uses high-frequency sound waves to view inside the body. Because ultrasound images are captured in real-time, they can also show movement of the body's internal organs as well as blood flowing through the blood vessels.
- Class II 510 K approved was purchased for used on board of station

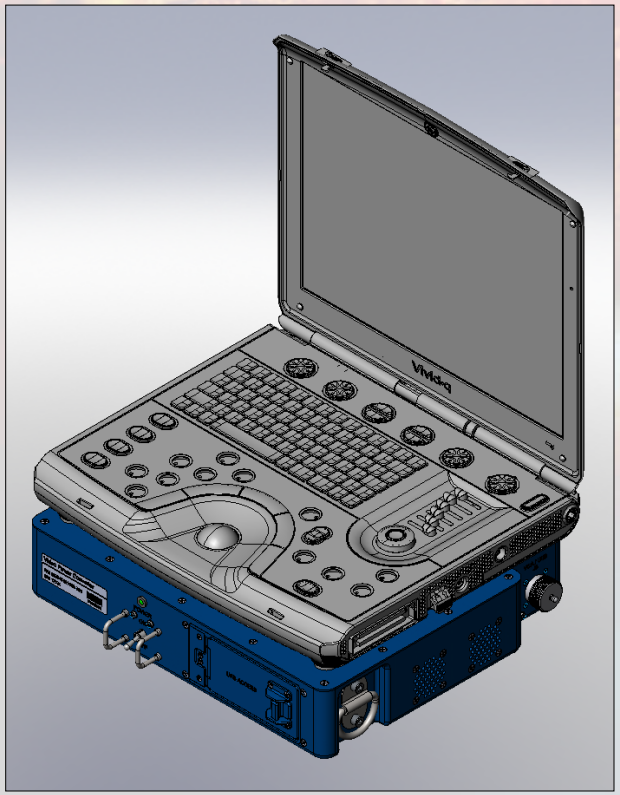
General Specification

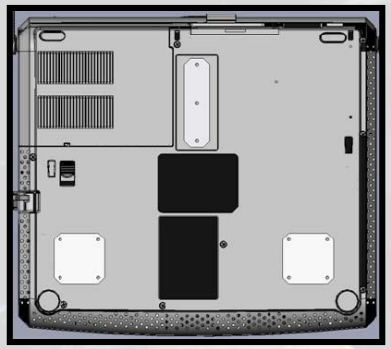
- Weight 5.2 Kg
- Dimension 15 X 3 X 14 in^3
- Power 130 VA , 100 VAC
- High resolution LCD
- 2D and 3-D Tissue
- Different application probes (Cardiac, Small organ,..etc)
- Multi scanning mode
- Video printer
- USB hard drive

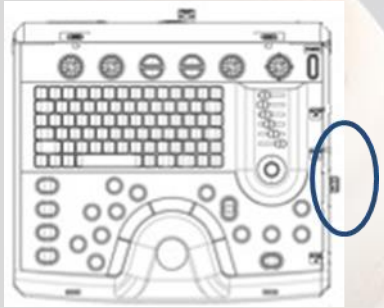
Ultrasound System update for flight

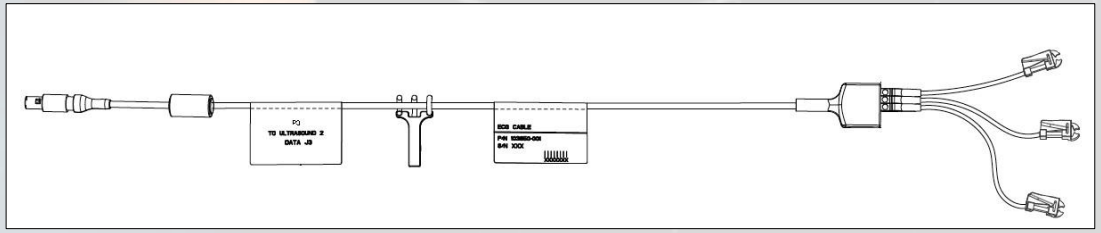






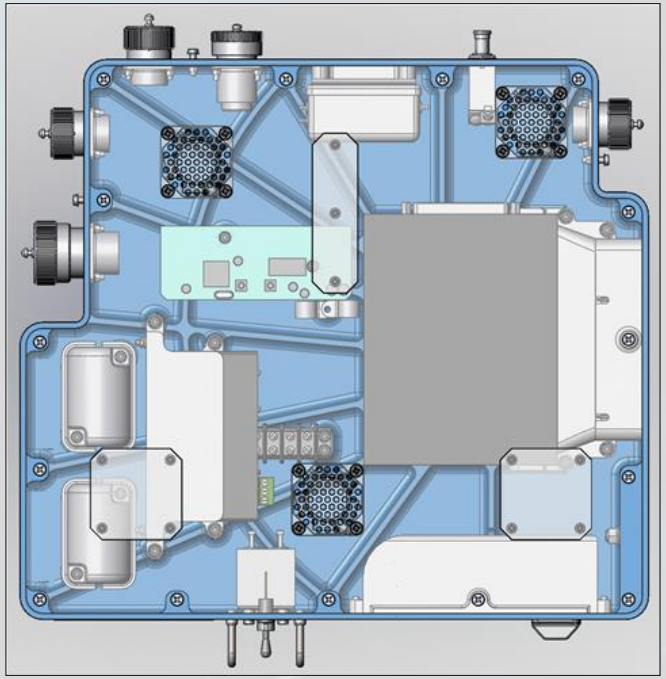






Video Power Convertor

KEY COMPONENTS	
Item	Part Description
1	DC Converter
2	Video Converter,
3	Video Transformer
4	USB Hub,
5	EMI Bullet Filters,
6	Input Breaker/Switch
7	Output Breaker,
8	Ultrasound 2 USB Drive,
9	DC Cooling Fans



Time of Development till Launch ….

Lesson Learned

Depends on the hardware category (Custom, MOTS or COTS) Result Very

1. Space stressors, in transit system and human in the loop main factors
2. Familiarity with standards before finalizing investigation protocols
3. Customize tools required more operation time (crew training)
4. COTS hardware often used are DoD commercialized venders
5. Most common hardware are MOTS
6. On average assessment and modification device takes 6 months to 2 years
   - Training time is not included
   - Cost also depends on the equipment and change required
   - All devices require safety review and this process is min 45 days
7. Do not forget the launch conditions
8. There are experts: HRP, ISSMP, ExMC and Contractors

Evolution of Medical Kit

First Space Flight

1961

Mercury

I.M. Injectors

1963

Gemini

Bioinstrumentation Systems

1968

Apollo First Augmented Medical Kit Lunar Mission

1972

Sky Lab

Dental Kit Inflight Medical Support System (IMSS)

1980

Space Shuttle Wireless Monitoring

2011

International Space Station

Diagnostic Instrument

Present

Recommendations

- Use of commercially acquired equipment and tools requires understanding of challenges and requirements (MIL STD 810-g vs. CFR 21 ss 820)
- Equipment that can serve multiple purposes
- Communicate often and early on: (Failing forward while we can)
  - Scientist, engineers and healthcare providers
  - Miscommunication impacts the future of science

Questions / Reference

References:

[1] Nicogossian, Huntoon and Pool. Space Medicine and Physiology, 2nd edition. Section 1, page 5

[2] Duncan J, Bogomolovb V, Castruccic F, Koiked, Y, Comtoise JM, Sargsyanf AE. Organization and management of the International Space Station (ISS) multilateral medical operations. Acta Astronautica. 2008;63:1137 .

[3] Kaplan A, Baim D, Smith J, Feigal D, Simon M, Jeffrys D, et al. Medical Device and Development from Prototype to Regulatory Approval. Circulation . 2004;102(25):3068–72.

[4] Blue R, Bridge L, Chough N, et al Identification of Medical Training Methods for Exploration missions. National Aeronautics and Space Administration. 2014

[5] Antonsen E, Bayuse T, et al, Evidence Report Risk of Adverse Health Outcomes and Decrements in Performance due to In-Flight Medical Condition. National Aeronautics and Space Administration. 2017

[6] Tucker K and Gavalas L You Want to Fly What Kind of Hardware, Human Research Program Investigators Workshop, 2017

Backup slides

Medical Device: It is intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease

MDDI Classification based on FDA CFR 21 ss 820:

Class I:

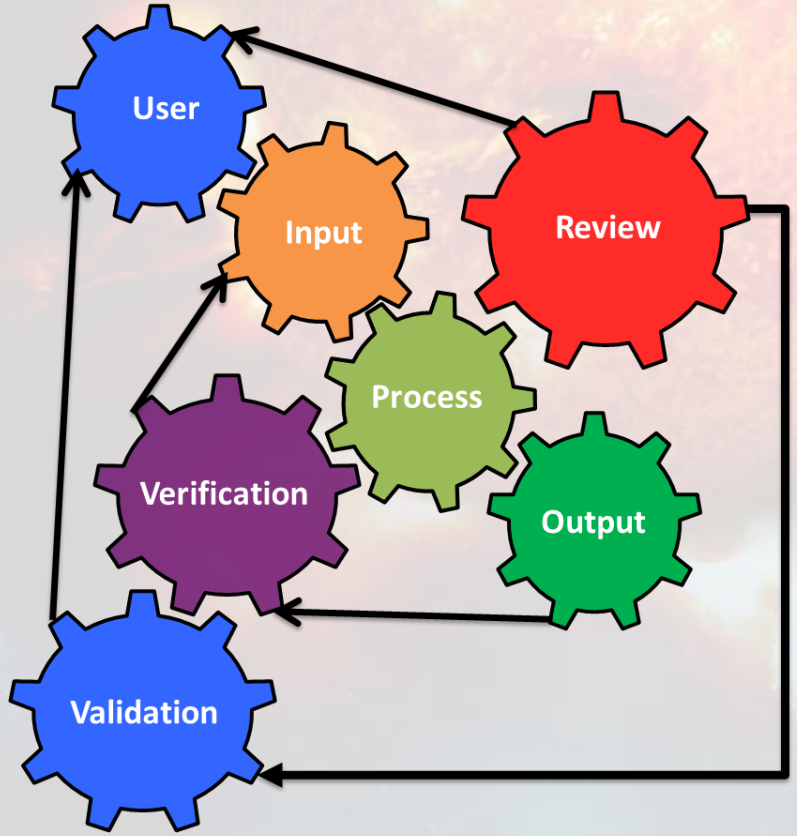
- Have a low to moderate risk to the patient and/or user
- 47% of medical devices fall under this category
- 95% of these are exempt from the regulatory process
- On average 3-7 years

Class II:

- Have a moderate to high risk to the patient and/or user
- 43% of medical devices fall under this category
- Examples of Class II devices include powered wheelchairs and some pregnancy test kits
- On average 5 to 15 years

Class III:

- Have a high risk to the patient and/or user
- 10% of medical devices regulated by the FDA.
- Examples of Class III devices include implantable pacemakers and breast implants
- On average 10+ years



FDA Waterfall Design Process

Medical Device Technology

1960 Nova Blood Pressure Monitor

2018 Nova Blood Pressure Monitor