

DESIGN AND DEVELOPMENT PROCESS FOR MEDICAL HARDWARE AND HEALTHCARE MONITORING DEVICES FOR SPACEFLIGHT

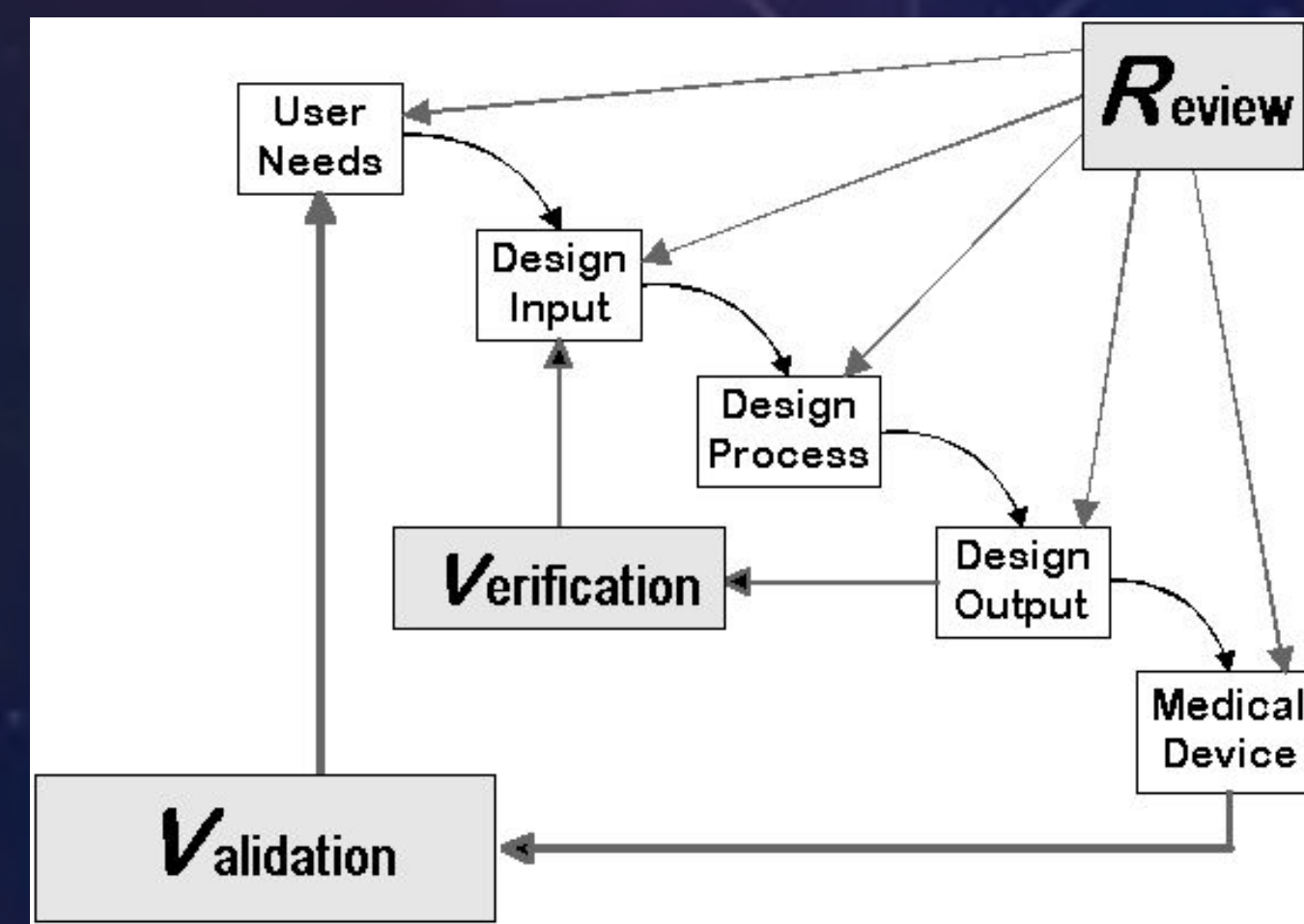
K. Seyedmadani¹, L. S. Gavalas², K. A. Tucker²

1. Aerospace Engineering Sciences, University of Colorado, Boulder, USA (kimia.seyedmadani@colorado.edu)
2. Human Health and Performance Directorate, NASA Johnson Space Center, Houston, TX, USA

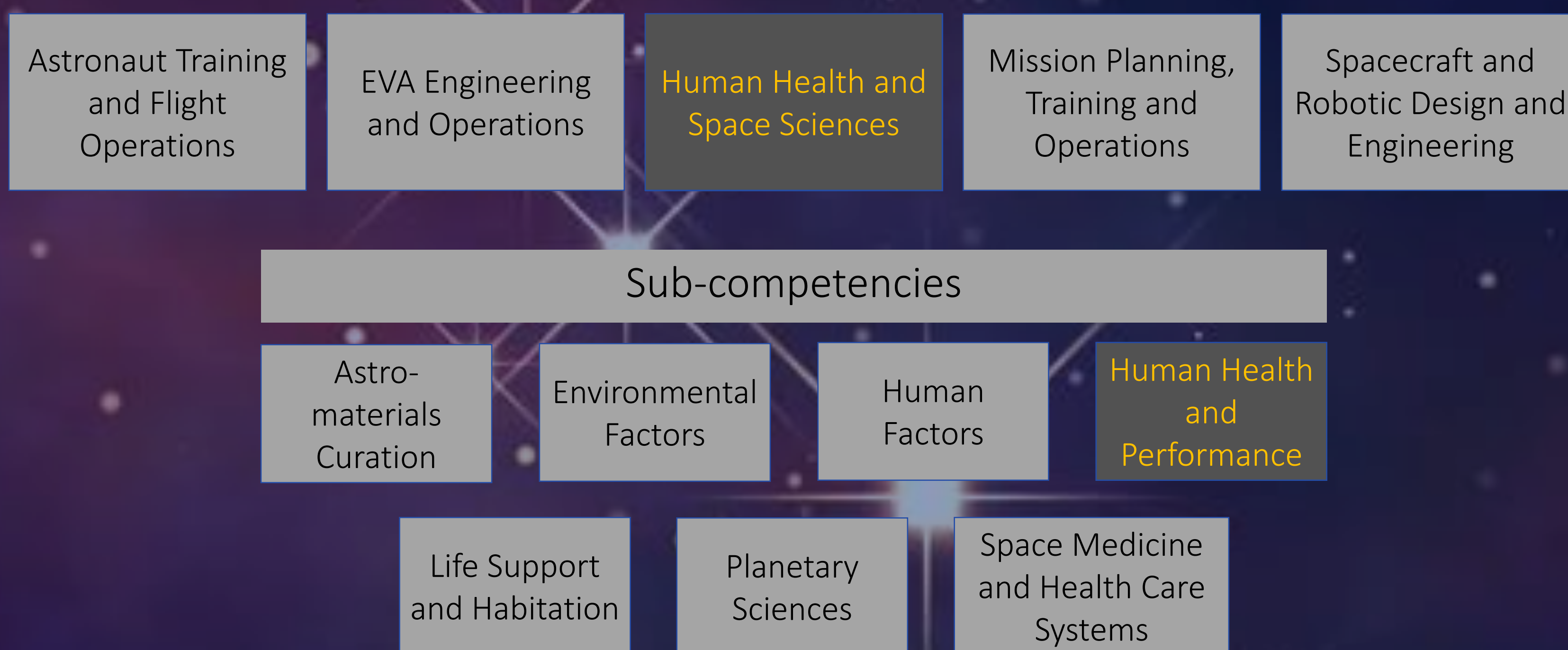
Medical Devices and Diagnostics

- Intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease.

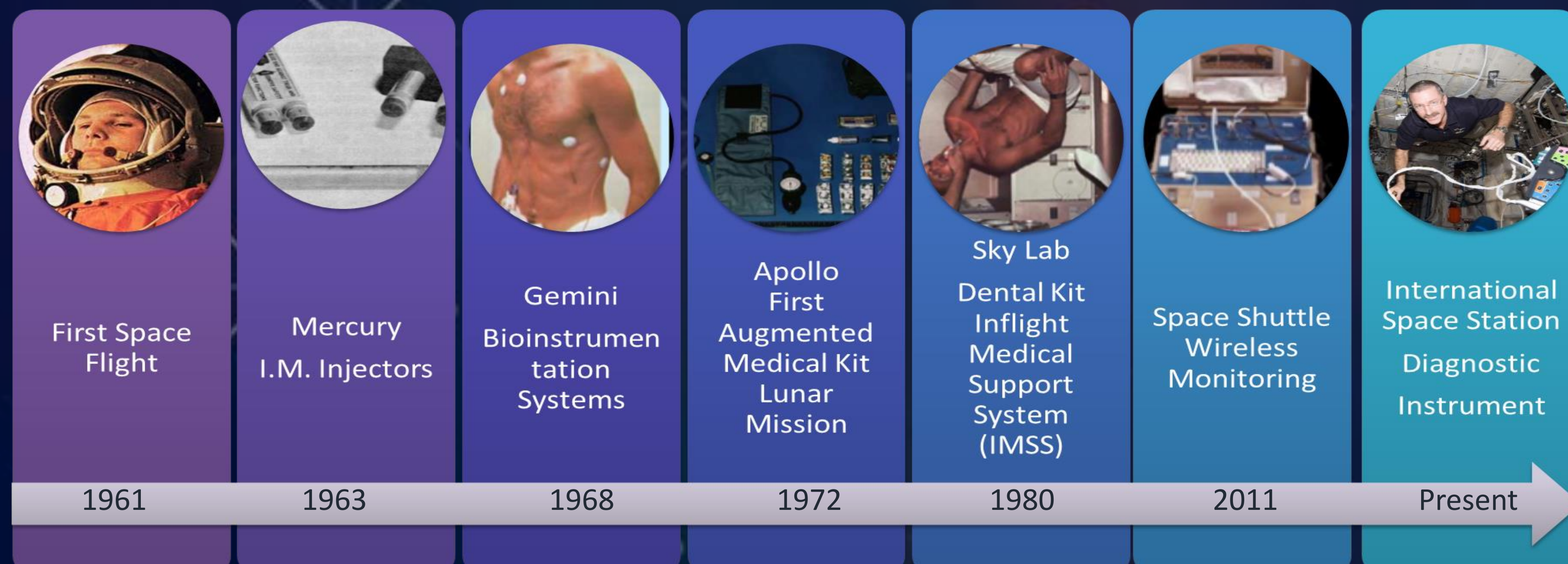
Class I- Class II and Class III
NASA- Class 1 and Class 1E



Core Competencies



Develop necessary hardware and software for medical research projects on the International Space Station – HRP Element: Research Operation Integration (ROI)
Provide support across the entire hardware life cycle to ensure crew health and safety, and manage technical requirements, budget, and schedule

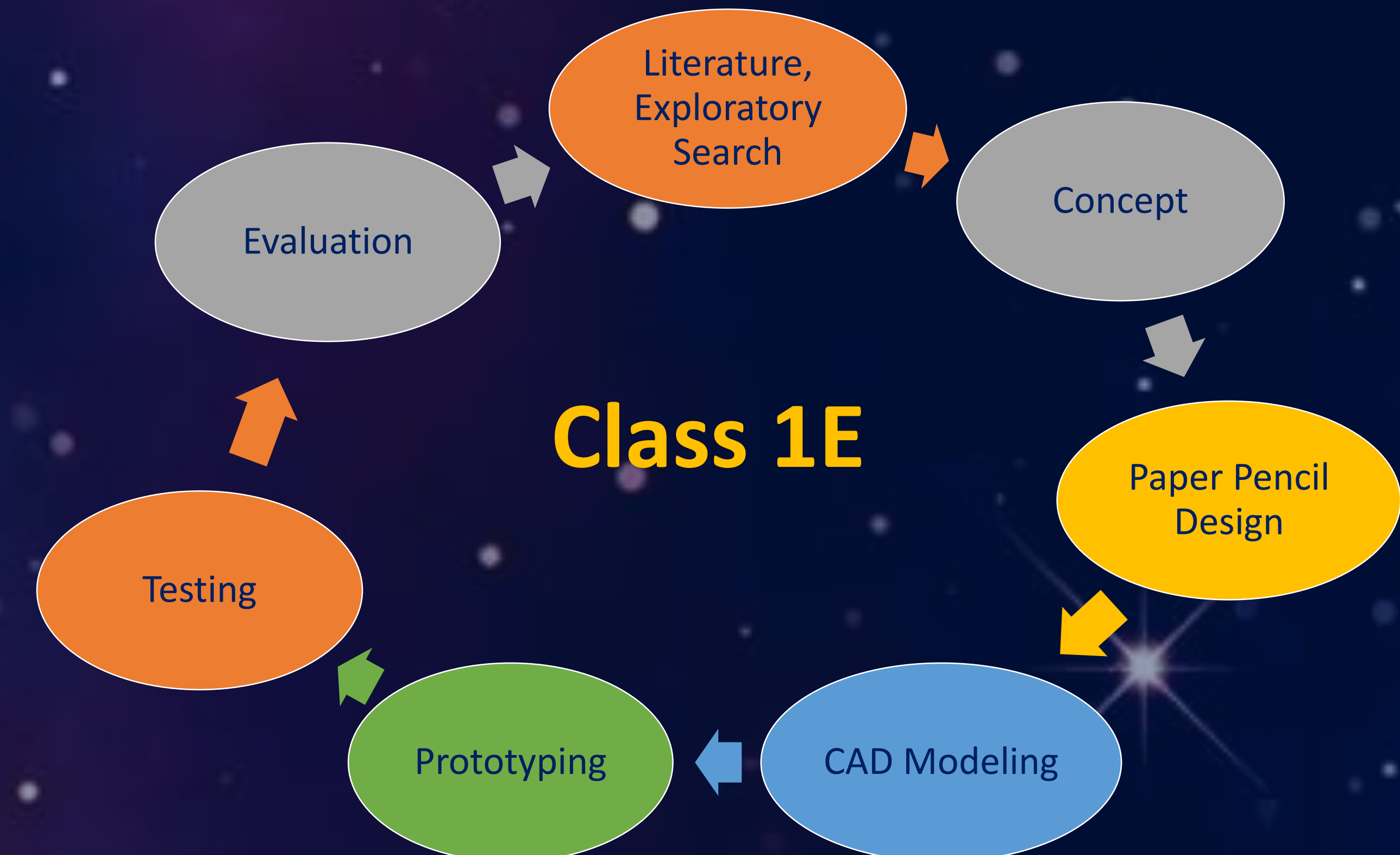


Terrestrial vs. Extraterrestrial Differences:

- Patient/Subject Population
- End User
- Space Environment and Spacecraft Stressors
- Physiological Adaption
- Systematic Adaptation

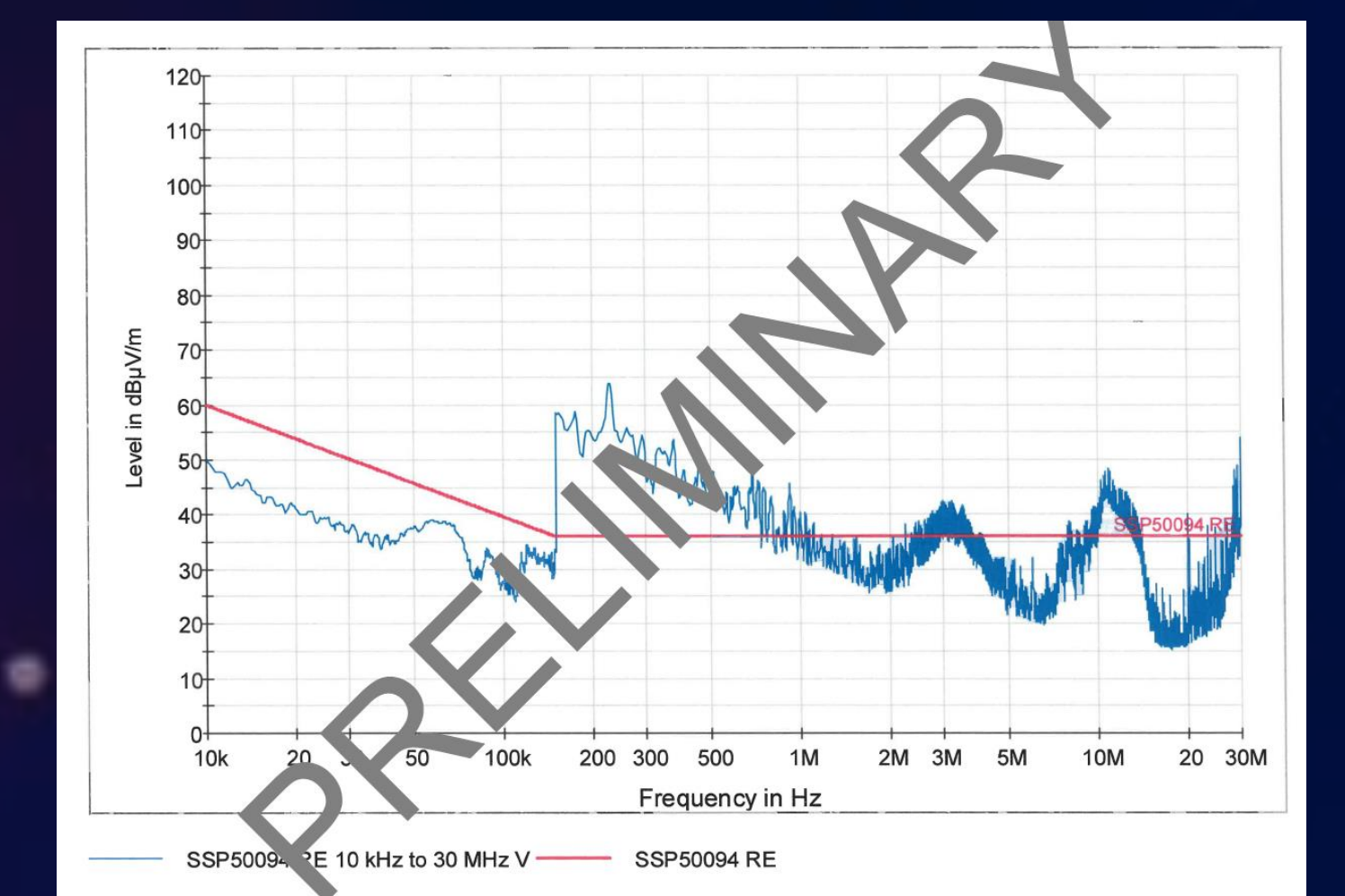


Medical Design



Challenges Driving Requirements

1. Materials Compatibility
2. Electromagnetic Compatibility
3. Batteries or Other Power Sources
4. Acoustics
5. Weightlessness and Gravity Profile
6. Structures
7. Thermal Environment
8. Hazard Containment : Liquids, Toxins, Capacitors etc

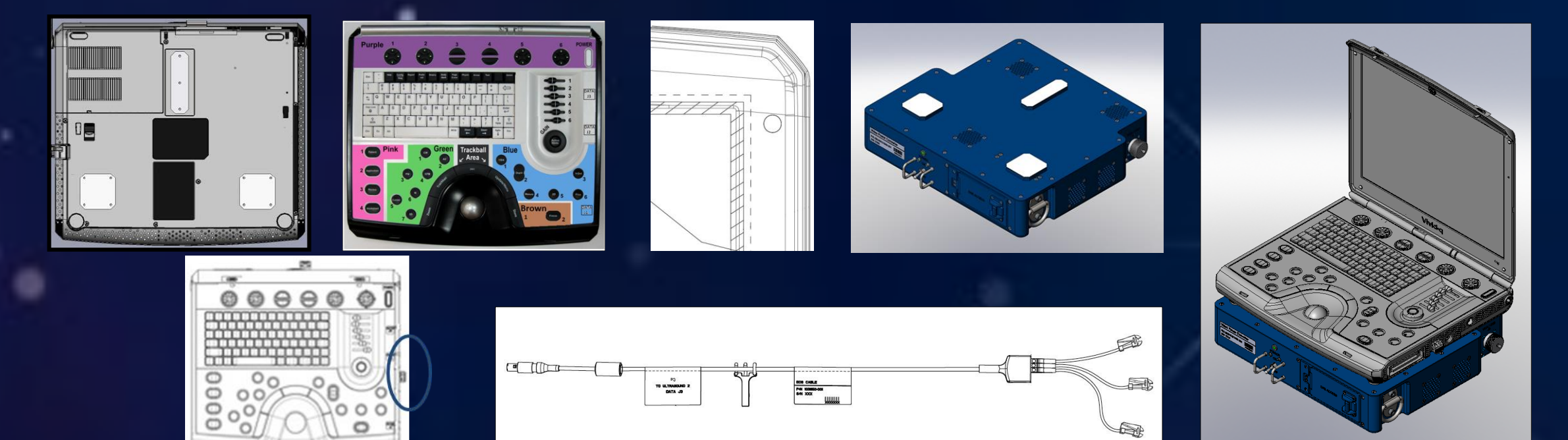


Case Study: Ultrasound Imaging

Ultrasound imaging (sonography) uses high-frequency sound waves to obtain views of the inside of 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.
A Class II, FDA 510 K approved unit was purchased for use on board Station



2 Year Development Cycle



Lessons Learned

1. Space stressors, in-transit vehicle and human in the loop are main considerations
2. Familiarity with applicable standards is necessary before finalizing investigation protocols
3. Customized tools require more operations time (crew training)
4. COTS hardware often used are DoD commercialized vendors
5. Most common hardware is MOTS

Acknowledgment: KBR and Leidos Contractors, Special Thanks to Timothy Haley, ROI group