Medical System Design and Risk Assessment

January 2024

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Exploration Medical Capability
NASA Human Research Program

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Advance medical system design and risk-informed decision-making for exploration beyond low Earth orbit to promote human health and performance in space.
Examples of medical kits for human spaceflight
Motivation

• How will the provision of medical care evolve for exploration missions?

• How can ExMC help to facilitate communication among spaceflight programs, engineers, scientists, and clinicians?

• Identified need to:
  – Employ systems engineering principles (just like how other vehicle systems are designed)
  – Assist in the development of evidence-based medical system requirements and their rationales
  – Enable traces between requirements, medical capabilities, medical conditions, and medical resources.
  – Advance and refine the medical system architecture for future mission planning.
  – Present information in an easily accessible format that is understandable across disciplines.
Integrating medical into a broader crew health and performance system

Habitat System

Crew Health and Performance

Crew Health and Wellness

Medical

Environmental Health

Crew Performance

Crew Health and Performance Data

Structures

Avionics & Software

Guidance, Navigation and Control

Comm & Tracking

Power

etc.

Ground System

MedOps

Crew as Caregiver

Crew as Explorer or Patient
Medical vs. non-medical risks to a mission

- Total Risk
- Non-Medical Risk
- Medical Risk

Ideal Mission Risk
Should we take an Automated External Defibrillator (AED) to Mars?

Yes?  No?
What if you had to choose?

AED  VS.  Ultrasound device
IMPACT is a new quantitative, evidence-based medical system risk and tradespace analysis tool for exploration missions.

IMPACT = Informing Mission Planning via Analysis of Complex Tradespaces.

- Tool will complete SAR in March 2024
- Presentation conveys the types of questions and data that you can expect from IMPACT
- NASA is looking for commercial partner use cases
Medical System Planning Needs

CHART TO HELP DETERMINE RISK OF BEAR ATTACK:

NO RISK OF BEAR ATTACK

ALSO NO RISK OF BEAR ATTACK

REALLY VERY HIGH RISK OF BEAR ATTACK

*And it is required by NASA STD-3001
What is Probabilistic Risk Analysis/Assessment?

• Risk analysis for complex engineered system with many variables and complex interactions

• Three basic questions
  – What can go wrong?
  – How frequently?
  – What are the consequences?

• Probabilistic
  – Evidence-based but intentionally incorporate randomness
  – Use historical data to inform possibility of events that have not yet occurred
Integrated Medical Model (IMM)

- Existing risk analysis tool
- Evidence and capabilities baselined to ISS
- 100 medical conditions

Limitations
- Considers only microgravity
- Not specifically designed for trade space analysis
- Heavy computational resources
- Last comprehensive update of evidence base was in 2017
Informing Mission Planning via Analysis of Complex Tradespaces

What is IMPACT?

- New Evidence Base
- New resource warehouse
- Expanded condition list
- Built-in tradespace capability
- Faster computational engine
Step 1 - IMPACT Medical Condition Selection

• Determine medical conditions that are in scope or out of scope for system design (i.e. which conditions to plan around)
• 119 medical conditions of greatest likelihood and consequence for lunar missions
• Nothing specific about that number – determined by schedule/resources
<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal Wall Hernia</td>
<td>Barotrauma (Ear/Sinus Block)</td>
<td>Burn - Mild, Thermal</td>
<td>Dental Luxation/Avulsion (Tooth Loss)</td>
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<tr>
<td>Abnormal Uterine Bleeding</td>
<td>Benzodiazepine or Opioid Overdose</td>
<td>Burn - Moderate To Severe, Thermal</td>
<td>EVA Related Hand Injury</td>
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<tr>
<td>Acute Coronary Syndrome</td>
<td>BHP - Adjustment Disorder</td>
<td>Cerebrovascular Accident</td>
<td>Dislocation - Finger</td>
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<tr>
<td>Acute Radiation Syndrome</td>
<td>BHP - Anxiety</td>
<td>Cerumen Impaction</td>
<td>EVA Related Paresthesia</td>
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<tr>
<td>Allergic Reaction (Mild To Moderate)</td>
<td>BHP - Depression</td>
<td>Choking/Obstructed Airway</td>
<td>Diverticulitis, Acute</td>
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<td>Altitude Sickness</td>
<td>BHP - Grief Reaction</td>
<td>Cholelithiasis/Biliary Colic, Acute</td>
<td>EVA Related Shoulder Injury</td>
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<td>BHP - Psychosis Secondary To Depression</td>
<td>Dental Abscess</td>
<td>Dust Exposure - Lunar</td>
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<tr>
<td>Appendicitis</td>
<td>BHP - Sleep Disturbance</td>
<td>Dental Crown Loss</td>
<td>EVA Related Suit Contact Injury</td>
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<tr>
<td>Arthritis, Acute</td>
<td>Burn - Chemical Eye</td>
<td>Dental Filling Loss</td>
<td>Fracture - Cervical Spine</td>
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<tr>
<td>Condition</td>
<td>Gravity Well - Entry</td>
<td>Nephrolithiasis</td>
<td>Respiratory Failure</td>
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<tr>
<td>------------------------------------------------</td>
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<tr>
<td>Motion Sickness</td>
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<tr>
<td>Gravity Well – Neurovestibular Disturbance</td>
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<tr>
<td>Gravity Well - Orthostatic Intolerance</td>
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<tr>
<td>Headache</td>
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<tr>
<td>Headache - Co2 Induced</td>
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<tr>
<td>Hearing Loss</td>
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<tr>
<td>Hearing Loss - Noise-Related</td>
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<tr>
<td>Hemorrhoids</td>
<td></td>
<td></td>
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<tr>
<td>Herpes Zoster Reactivation (Shingles)</td>
<td></td>
<td></td>
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<tr>
<td>Mouth Ulcer</td>
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</tbody>
</table>

**Condition List:**

- Gravity Well - Entry
- Nephrolithiasis
- Respiratory Failure
- Small Bowel Obstruction
- Spaceflight Associated Neuro-Ocular Syndrome (SANS)
- Toxic Inhalation Exposure
- Gravity Well – Neurovestibular Disturbance
- Neuropathy - Central, Impingement Related
- Respiratory Tract Infection - Lower
- Space Adaptation - Back Pain
- Sprain/Strain - Back
- Toxic Inhalation Exposure - Combustion Products
- Gravity Well - Orthostatic Intolerance
- Otitis Externa
- Respiratory Tract Infection - Upper
- Space Adaptation - Constipation
- Sprain/Strain - Lower Extremity
- Trauma - Abdominal Injury (Blunt)
- Headache
- Otitis Media
- Seizures
- Space Adaptation - Epistaxis
- Sprain/Strain - Neck
- Trauma - Chest Injury (Blunt)
- Headache - Co2 Induced
- Pancreatitis, Acute
- Sepsis
- Space Adaptation - Headache
- Sprain/Strain - Upper Extremity
- Trauma - Minor Head
- Hearing Loss
- Pregnancy, First Trimester
- Shock - Cardiogenic
- Space Adaptation - Insomnia
- Streptococcal Pharyngitis
- Trauma - Severe Head
- Hearing Loss - Noise-Related
- Pregnancy, Risk For
- Skin Abrasion
- Space Adaptation - Nasal Congestion
- Sudden Cardiac Arrest
- Traumatic Hypovolemic Shock
- Hemorrhoids
- Prostatitis, Acute
- Skin Infection - Bacterial
- Space Adaptation - Space Motion Sickness
- Tendinopathy/Enthesopathy/ Bursitis/Over-Use Injuries - Lower Extremity
- Urinary Tract Infection
- Herpes Zoster Reactivation (Shingles)
- Rash, Spaceflight Associated
- Skin Infection - Viral/Fungal
- Space Adaptation - Urinary Retention
- Tendinopathy/Enthesopathy/ Bursitis/Over-Use Injuries - Upper Extremity
- Vaginal Yeast Infection
- Mouth Ulcer
- Reactive Airway
- Skin Laceration
- Space Adaptation - Urinary Incontinence
- Toxic Dermal Exposure
- Venous Thromboembolism
Step 2 – Medical Condition Data

• Data Sources
  – Spaceflight
  – Analog
  – Modeling (e.g. ISS fire model)
  – Terrestrial Data

• Incidence

• Best Case/Worst Case Definitions and probabilities

• Clinical Phase Durations
  – Diagnosis
  – Treatment
  – End State
Step 2 – Risk Metrics

How does each intervention affect:

**Loss of Crew Life (events/mission)**
- Likelihood of a crewmember's death during the mission

**Medical Evacuation (events/mission)**
- Vehicle capabilities insufficient forcing consideration of evacuation to higher level of care

**Task Time Affected (crewmember-days)**
- Crew time affected by medical condition
Step 2 - Capability Resource Tables (CRTs)

- CRTs detail the capabilities/resources needed for prevention, diagnosis, stabilization, and management of each condition
- Adapted from evidence-based practice guidelines by space medicine SMEs
- Condition -> Capabilities -> Resources -> Mass/Volume
  - Capability - cognitive/procedural skillset or action (e.g., deliver IV antibiotics)
  - Resource - a piece of equipment, pharmaceutical, or skillset (e.g., 20g IV, interpret physical exam)
- 600+ capabilities and 800+ discrete resources in IMPACT
Step 3 - Probabilistic Risk Analysis

• Mission-specific inputs
  – Mission Duration
  – Mission Destination (with segment-specific conditions; e.g., Space Adaptation Syndrome)
  – Crew Characteristics (number, sex, pre-existing medical conditions)
  – EVA number and frequency

• Simulate 100k-300k missions
Step 3 - Probabilistic Risk Analysis

Medical Event Incidence

Best-case Scenario

- Best-case resources available?
  - Yes: Treated Case: Decrement medical resources
  - No: Untreated Case: Decrement medical resources

Worst-case Scenario

- Worst-case resources available?
  - Yes: Treated case: Decrement medical resources
  - No: Untreated Worst-Case: Decrement medical resources

Calculate End States:

- Loss of Crew Life (LOCL)
- Medical Evacuation
- Task Time Affected
- Resource Utilization

Outputs can adjust with changes in mass/volume

100,000 simulations
Step 4- Tradespace Optimization (The Backpack Problem)

- Optimization problem
- Maximize value subject to constraints
- Question: what combination of blocks yields the most money but does not exceed the weight limit?
Medical system:
- Mass
- Volume

Capabilities/Resources

Risk Metrics
- Loss of Crew Life
- Medical Evacuation
- Task time affected
ARTEMIS PREPARES FOR MARS

- International habitat delivered to Gateway, in-situ resource utilization (ISRU) demonstrations on the surface and LTV to expand exploration range
- Artemis IV: First lunar surface expedition through Gateway. External robotic system added to Gateway
- Sustainable operations with reusable landing system and enhanced lunar communications, refueling, and viewing capabilities on Gateway
- Airlock arrives at Gateway; surface habitat and pressurized rover delivered to expand exploration range and crew size
- Enhanced habitation capability delivered to Gateway for Mars dress rehearsals

SUSTAINABLE LUNAR ORBIT STAGING CAPABILITY AND SURFACE EXPLORATION

- Multiple science and cargo payloads
- U.S. government, industry, and international partnership opportunities
- Technology and operations demonstrations for Mars

All contents represent notional planning and are for discussion purposes only
Crew Members

• Representative of NASA astronaut population
  – Met Med A (selection) standards
• 2 Male Crew members
• 2 Female Crew members
• No pre-existing medical conditions
  – No prior surgeries
  – No prior dental work
  – Not on long term medication
Loss of Crew Life

Risk of Loss of Crew Life

Mass (kg)

Loss of Crew Life (Events/Mission)

Curve
Medical Set
Medical Evacuation

Risk of Medical Evacuation

- **Medical Evacuation**
- **Mass, kg**

The graph shows the risk of medical evacuation as a function of mass. The risk decreases significantly for lower masses, with a plateau at higher masses.
Most Frequent Conditions

Number of Events Per Mission

- LUNAR DUST EXPOSURE - SURFACE EVA: 72.0
- LUNAR DUST EXPOSURE - EVA HABITAT: 54.0
- INSOMNIA: 14.9
- EVA-RELATED SUIT CONTACT INJURY: 13.0
- EVA-RELATED PARESTHESIA: 9.3
- HEADACHE: 7.7
- EAR/SINUS BAROTRAUMA: 7.5
- SPACEFLIGHT-ASSOC SKIN RASH: 7.4
- EYE IRRITATION/CORNEAL ABRASION/ULCER: 6.4
- SKIN ABRASION: 6.1
LOCL – Events Per Mission

Events per Mission

- EVA-RELATED DCS: 0.00145
- RESPIRATORY FAILURE: 0.00095
- PYELONEPHRITIS: 0.00064
- TRAUMA-RELATED HYPOVOLEMIC SHOCK: 0.00061
- ABNORMAL UTERINE BLEEDING: 0.00060
- EBULLISM: 0.00030
- SKIN/SOFT TISSUE INFECTION: 0.00025
- OBSTRUCTED AIRWAY: 0.00025
- TOXIC INHALATION OF COMBUSTION PRODUCTS: 0.00024
- DENTAL ABSCESS: 0.00018
History

Vitals, Primary Assessment (Circ, Airway, Breathing), Capnography

Physical Exams: Oropharyngeal, Cardiac, Pulmonary, Abdominal, Neuro, MSK, skin

Ground-based Communication

Venipuncture; intravenous and intraosseous access

Lab result interpretation

Ultrasound performance and interpretation
  – Abdominal, Pulmonary, Cardiac
TTA – Crewmember Days per Mission

<table>
<thead>
<tr>
<th>Condition</th>
<th>Days Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVA-RELATED SHOULDER INJURY</td>
<td>17.8</td>
</tr>
<tr>
<td>UE SPRAIN</td>
<td>9.4</td>
</tr>
<tr>
<td>LE SPRAIN</td>
<td>9.4</td>
</tr>
<tr>
<td>EAR/SINUS BAROTRAUMA</td>
<td>7.3</td>
</tr>
<tr>
<td>SPACEFLIGHT-ASSOC SKIN RASH</td>
<td>5.8</td>
</tr>
<tr>
<td>BACK SPRAIN</td>
<td>5.8</td>
</tr>
<tr>
<td>EVA-RELATED SUIT CONTACT INJURY</td>
<td>5.6</td>
</tr>
<tr>
<td>INSOMNIA</td>
<td>5.5</td>
</tr>
<tr>
<td>NECK SPRAIN</td>
<td>5.0</td>
</tr>
<tr>
<td>ACUTE DIARRHEA</td>
<td>4.5</td>
</tr>
</tbody>
</table>
## Introduction to the Med System Contents

<table>
<thead>
<tr>
<th>Resource Name</th>
<th>Resource Quantity</th>
<th>Total Resource Mass (kg)</th>
<th>Total Resource Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device - Lifepak 15 Device</td>
<td>1</td>
<td>9.100</td>
<td>29,400.000</td>
</tr>
<tr>
<td>Pharmaceutical - Intravenous - Pre-Filled Sodium</td>
<td>4</td>
<td>4.120</td>
<td>4,800.000</td>
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<tr>
<td>Chloride 0.9% Solution 1000mL</td>
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</tr>
<tr>
<td>Hygiene - Instrument Disinfectant</td>
<td>9</td>
<td>2.556</td>
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<tr>
<td>Pharmaceutical - Topical - Moisturizing Cream 5ml</td>
<td>24</td>
<td>1.683</td>
<td>3,384.000</td>
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<td>Wound Care - Bandage - 4 Inch Rolled Gauze</td>
<td>68</td>
<td>1.564</td>
<td>7,888.000</td>
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<tr>
<td>Device - Alpha Stim CES Device</td>
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<td>1.500</td>
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<td>Pharmaceutical - Topical - Diclofenac Sodium 1%</td>
<td>10</td>
<td>1.389</td>
<td>4,836.811</td>
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<tr>
<td>0.5 Inches</td>
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<tr>
<td>Pharmaceutical - Oral - Benzocaine And Menthol</td>
<td>594</td>
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<tr>
<td>Lozenge 15mg/3mg</td>
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<tr>
<td>Device - Lifepak 15 Device Power Supply</td>
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<td>1.300</td>
<td>3,802.000</td>
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<tr>
<td>Pharmaceutical - Topical - Mupirocin 0.25 inch</td>
<td>36</td>
<td>0.955</td>
<td>1,330.277</td>
</tr>
</tbody>
</table>
Overview of Resources by Mass in the Medical System

**Total Mass**
Limit 50 kg

- Device: 18.20
- Pharmaceutical: 15.74
- Hygiene: 4.55
- Wound Care: 2.76
- Airway: 2.44
- Ultrasound: 1.29
- Medical Instrument: 3.30
- General Supplies: 0.96
- Splint: 0.64
- Bandage: 0.22
- Laboratory: 0.20
- Vascular Access: 0.19
- Cast: 0.04

**Total Volume**
Limit 150 L

- Hygiene: 9,084 ml
- Medical Instrument: 6,436 ml
- Splint: 5,054 ml
- Cast: 1,770 ml
- Vascular Access: 1,680 ml
- Ultrasound: 1,532 ml
- General Supplies: 1,176 ml
- Bandage: 822 ml
- Laboratory: 294 ml

- Pharmaceutical: 25,923 ml
- Wound Care: 21,724 ml
- Airway: 13,026 ml
IMPACT Future Updates

• Mission Segments – optimize resources across the missions and within given phases (e.g., Orion, Gateway)
• Perform trades on Knowledge, Skills, Abilities (KSA) of crew
• Refinement of medical evacuation risk
• Expanded medical condition list
• Weighting of resources (relative contribution to outcome)
• What features would you like to see?
Overall Conclusions

• We need a quantitative method to estimate medical risk for exploration missions
• IMPACT has sophisticated capabilities to define a medical system’s capabilities by trading off medical risk against system resources
• Progressive updates to increase fidelity
• NASA plans to start using IMPACT for medical risk modelling in 2024
  – Very interested in work with commercial providers – please talk to us!
Medical System Design Approach

• An interdisciplinary process of integrating clinical and systems engineering inputs to generate recommendations for medical system design

Medical Domain Activities

- NASA Std’s & Req’s
- Medical Conditions
- Medical System Capabilities
- Medical System Resources
- Medical System Requirements

Sys Eng Activities

- Mission Env Assumptions
- NASA Std’s & Req’s
- NASA Std’s
- Med System Context
- Concept of Operations
- Medical System Functions

Teams work closely together

KEY:
- Medical domain products
- Systems engineering products
- Human Research Program products
Why model-based systems engineering (MBSE)?

- Using a model-based systems engineering (MBSE) approach has been identified by the Office of the Chief Engineer as **best practice** for system design and is consistent with the use of digital architectures by Exploration Programs.

- MBSE enables users to **visualize** the medical system functions, conditions, capabilities, and resources and understand how they all trace to medical system recommended requirements.

- As a starting point **for any program to tailor a set of requirements** that best suit respective vehicle and mission needs, the MBSE medical system model is designed to be flexible and modifiable such that **changes can propagate throughout the model** without significant manual effort.

![Diagram showing changes and relationships between high level requirements, changes in architecture, removed resource, functions, capabilities, and conditions.]
Exploration Medical System Models

High-level system vision and scope

Functions + Capabilities = Requirements

Resulting Outputs including:
- Medical system architecture
- Medical system master equipment list
- Medical system resources
Medical System Foundation for Level of Care IV: Long-Duration Lunar Orbit and Lunar Surface

Version 1.0 (Current)

A Medical System Foundation is a system model that contains both Systems Engineering products and Clinical Data. It is meant to serve as a starting point for NASA programs that are developing mission- and vehicle-specific medical systems. New users of this web report are recommended to reference the accompanying context, process and history document while viewing the report: Medical System Foundation for Level of Care IV Long-Duration Lunar Orbit and Lunar Surface: Context, Process, and Project History.

The Medical System is a subsystem of the Crew Health and Performance (CHP) system; it interfaces with the other CHP subsystems and vehicle systems external to the CHP system. The Medical System Foundation model captures systems engineering and clinical content and the relationships that exist between and among them. The model includes a Concept of Operations (ConOps), a list of functions traceable to the ConOps content, requirements derived from the functions, a set of medical conditions that could occur in-flight, medical capabilities, and example resources that could be used to diagnose or treat these conditions.

Information about the Medical System Foundation

- Navigation Support
- Model Stakeholders and Contact Information
- Model Version
- Concept, Process, and Project History
- Glossary and Acronyms
- Applicable Documents
- Reference Documents

System Inputs

The guiding inputs of the Medical System Foundation Model include NASA standards, program-specific requirements related to medical care, and assumptions regarding mission operating environments and interfaces between the Medical System and other systems.

Concept of Operations and Functional Decomposition

The Medical System Foundation is a system engineering concept that consists of a Concept of Operations (ConOps) and System functions.

The ConOps includes stakeholder needs, system goals, mission constraints, operating environments, and representative scenarios that highlight potential needs the system must fulfill.

System functions and subfunctions are derived from the ConOps via a functional decomposition process. These functions serve as an input to the requirements development process.

Clinical Content

The Medical System Foundation clinical content includes medical conditions and derived clinical capabilities and associated resources needed to diagnose and treat those medical conditions. The clinical capabilities served as an input to the technical requirements derivation process. These contents as well as the traceable relationships between them live in this section.

Technical Requirements

The Medical System requirements represent the functional and non-functional system needs and are driven by the content documented in the ConOps (e.g., scenarios and functions), clinical capabilities, NASA standards and historical documents, and parent system requirements. Interface requirements were also developed, which represent medical needs that are allocated to other systems based on the proposed system architecture. The Medical System functions, non-functional, and interface requirements are defined within NASA as Level 4 and have links to their Level 2 and 3 parent requirements, NASA Standards and historical documents, and the clinical capabilities.
Function blocks represent key system features and were used to derive representative medical scenarios.
The conditions list was derived from the following sources:

- Lunar Extravehicular Activity (EVA) Incapacitation Condition List (No Link available)
- Artemis Phase I: Functional Medical Concept of Operations Condition List (No Link available)
- The EL Team Condition List (Not available outside of NASA)
- Evidence Library Pilot Project Rochester Epidemiology (REP) Study Condition List (Unpublished)
- Evidence Library Pilot Project Spaceflight Condition List (Not available outside of NASA)
- Evidence Library Pilot Project Toxic Exposures and Injuries Condition List (Not available outside of NASA)
- IMCL Historical Spaceflight Condition List (Unpublished)
- IMM-GEN 309. Rev.1: IMM Medical Conditions List (IMCL) (IMM Portal Access Required)
- JSC-55722_ Exploration Medical Condition List (EMCL) (Not available outside of NASA)
Clinical Capabilities

This section includes the following:

- Clinical capability tables
- Conditions ↔ Capabilities mappings
Medical Resources

This section includes the following:

- Medical resources lists
- Medical resources mappings
  - Resources $\rightarrow$ capabilities
  - Capabilities $\rightarrow$ resources
  - Resources $\rightarrow$ conditions

<table>
<thead>
<tr>
<th>#</th>
<th>Medical Resources</th>
<th>Volume per unit</th>
<th>Mass per unit</th>
<th>Average power consumption per unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Airway - Bag Valve Mask</td>
<td>6218.8908 cc</td>
<td>0.5806 kg</td>
<td>0.0 W</td>
</tr>
<tr>
<td>2</td>
<td>Airway - Device - Capnography Nasal Cannula</td>
<td>509.703239 cc</td>
<td>0.091172 kg</td>
<td>0.0 W</td>
</tr>
<tr>
<td>3</td>
<td>Airway - Device - Capnography Sensor</td>
<td>0.0 cc</td>
<td>0.0 kg</td>
<td>0.0 W</td>
</tr>
<tr>
<td>4</td>
<td>Airway - Device - Invasive Airway Tube Capnography Adaptor</td>
<td>199.3506 cc</td>
<td>0.031751 kg</td>
<td>0.0 W</td>
</tr>
</tbody>
</table>
Technical Requirements

Traces to:

- Medical System functional, non-functional, and interface requirements
- Medical system requirement relationships
Questions?

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