OVERVIEW OF EXPLORATION MEDICAL CAPABILITY SYSTEMS ENGINEERING LEVEL 4 REQUIREMENTS FOR MEDICAL LEVEL-OF-CARE IV IN SPACE LUNAR ORBIT HABITAT

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ABSTRACT

This paper presents how the Exploration Medical Capability Element of the National Aeronautics and Space Administration's Human Research Program using Model-Based System Engineering is defining Level 4 Foundational Requirements to provide Medical Level-of-Care IV in a space Habitat during exploration missions.

OVERVIEW

The National Aeronautics and Space Administration's (NASA) Exploration Medical Capability (ExMC) Element of the Human Research Program is using a Model-Based System Engineering (MBSE) approach to define requirements to the Habitat System for the performance of medical activities in space missions.

The ExMC is developing this work founded on a vision for NASA of the Crew Health and Performance (CHP) System in space exploration missions. This vision comprises of system goals, stakeholder needs and mission activities as identified by ExMC subject matter experts and clinicians. The ExMC developed documents of medical clinical capabilities and concept of operations (ConOps), which together with NASA and International Space Station (ISS) standards and documents, provide the foundation of the Habitat CHP Systems and the capability to develop technical requirements, system architectures, interfaces, and verification and validation criteria [1].

As shown in Figure 1, formal MBSE modeling facilitates the communication of properties and behaviors of complex domains supporting the development of system requirements, design, analysis, verification and validation activities throughout the project life cycle, allowing one model as a single source for all project actions and decisions. Technical requirements specify the necessary functions and features of the system to perform medical activities while system design defines how those needs will be met. Requirements specified at every system level provide the system architecture foundation within the MBSE lifecycle. Here requirements are specified as Level 4 for the CHP Habitat system, denoted with a unique identifier and name, and a "shall" statement with a rationale justifying the requirement.

REQUIREMENTS

The CHP Habitat Medical System and the CHP Habitat Data Systems with 102 and 28 Level 4 Requirements have been delivered and approved by the HRP Control Board, respectively. The HRP ExMC Systems Requirements team developed these requirements in collaboration with the review and vetting process of the HRP ExMC Systems Engineering team and clinicians at Ames Research Center (ARC) and Johnson Space Center (JSC). These requirements represent the first component

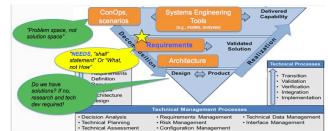


Figure 1. View of Requirements in the System Engineering Lifecycle. (Ref: Based on DoD graphics [2] and NASA NPR 7123.1C [3]).

	: Habitat CHP System	
: Wellness Support Domain	: Task Performance Support Domain	: Medical Domain
: Physiological Health Management	: Task Management	: Pharmacy Management
: Nutrition Management	: Crew Interfaces	: Clinical Care
: Behavioral Health Management	; Training	: Imaging
: Circadian & Sleep Management	· Hanning	: Laboratory Management
: Environmental Protection Domain	: Data Domain	: Testbed & Research Domain
: Microbial Environment Protection	: Data Storage	: Research
micro-g/Acceleration Environment Protection	: Descriptive Analytics	: Testbed
: Internal Atmosphere Protection		
: Trash & Waste Management	: Advanced Analytics	: Maintenance & Repair Domain
: Radiation Environment Protection	: Data Sources Interfaces	: Maintenance
: Acoustic Environment Protection		: Repair
: Toxicological Environment Protection	: Data User Interfaces	
: Extravehicular Activity Support Domain	: Human Domain	
: Extravehicular Activity Crew Health Support	: Crew as Crewmember	
	: Crew as Patient	
: Extravehicular Activity Performance Support	: Crew as Caregiver	

Figure 2. Context Architectural View of the CHP System [5].

of the CHP system in the Habitat for space missions (see Figure 2), and provide a system engineering foundation to support medical system delivery for exploration system maturation.

Presently, the requirements have been reviewed and distributed together with additional requirements comprising CHP and Non-CHP Habitat systems. The medical system needs are beyond the purview of the CHP Habitat Medical System as defined in the Concept of Operations [4,5] in terms of interfaces and activities performed by other systems and needs to provide In-Flight Level-of-Care IV in the Habitat as defined in NASA Standard [6-8] for prevention, diagnostic and treatment of medical conditions in space.

Present analysis of the functional and non-functional requirements derived from the CHP ConOps includes systems and scenarios, and clinical capabilities for in-flight prevention, diagnoses and treatment of medical conditions. This work has developed a new set of requirements addressing the Habitat CHP domain including the Medical System and interface activities with the Data, Wellness Support, Task Performance Support, Environmental Monitoring, and Research & Testbed systems, and other domains of the Habitat including interface activities with the Maintenance, Waste Management, Extra-Vehicular Activity and Structures systems.

Requirement Development based on Functional Decomposition and Concept of Operations

The development of functional requirements based on Functional decomposition [9] and ConOps documents is described below. For example, Figure 3 shows "Analyze health data" as an attribute of the Habitat CHP Medical System and the binding context "Synthesize health data" of the medical requirement developed to address this need.

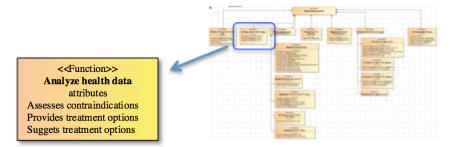


Figure 3. Functional Decomposition source [1].

Functional Decomposition: *Analyze health data* ID: *Hab-MedSysy-0007* Name: *Synthesize health data* Text: *The Habitat Medical System shall synthesize health status data*. Rationale: *The Habitat Medical System will combine health data from the medical system, the patient, the relevant physical and environmental data from the vehicle, and the information and data from the ground medical system to establish crew health status.*

Requirement Development based on Clinical Capabilities and Concept of Operations

The clinical information delivered by the ExMC clinicians contains 258 clinical capabilities to address prevention, diagnosis, and treatment of medical conditions in each in-flight planned activity as well as accepted medical conditions in each in-flight unplanned activity to be conducted in the Habitat [10]. These clinical capabilities address a large number of activities classified in 20 clinical categories as shown in Table 1 below.

Table 1. Clinical Categories

Administer and Manage Medications Assess and Monitor Vital Signs Configure Environment for Care Dietary Control / Nutrition Monitoring Document Care Evacuation In-Flight Prevention

Interview Patient Knowledge Augmentation KSA Medical System Support Monitor & Assess Environment Monitor and Control Sleep and Fatigue Perform Imaging

Perform Laboratory Analysis Perform Physical Exam and Conduct Screening exams/tests Perform Procedures Perform waveform monitoring Personal Protection Support Behavioral Health While Planned Clinical Capabilities are based on NASA documents including NASA-STD-3001 standard [6,7] and interpretation of the standard [8], unplanned capabilities are based on NASA's historical documents including the medical operations requirements documents (MORD) [11,12] and accepted medical conditions including stakeholders rank order [13], and likelihood of occurrence [14].

An example of the development of functional requirements based on Clinical Capability is shown below. Table 2 shows a brief list of Planned Clinical Activities under two Clinical Categories: "Perform imaging" and "Perform procedure."

Table 2. Two example Clinical Categories with their associated Capabilities

Perform Imaging	Perform Procedures
Image - airway	Airway - Abdominal Thrust/Chest Compression
Image - bone	Airway - Airway Adjuncts
Image - ear	Airway - Endotracheal Intubation
Image - eye	Airway - Foreign Body Removal
Image - GI tract - upper/lower	Airway - Suction
Image - integument	Airway - Supraglottic Intubation
Image - internal organs	Anesthesia - Local
Image - intracavity	Anesthesia - Moderate Sedation
Image - muscle	Anesthesia - Regional
Image - soft tissue	Breathing - Automated Ventilation
Image - urinary tract	Breathing - Chest Tube
Image - vasculature	Breathing - Continuous Positive Airway Pressure (CPAP)
Imaging - still/ video photography, external	Breathing - Hyperbaric Therapy

The information associated with these activities provides the foundation of the Level 4 Systems Engineering Requirements on "Perform imaging" and "Perform airway procedure" which are shown below with their unique ID, Name, Text and Rationale.

Clinical Capability Category: Perform imaging ID: Hab-MedSysy-0025 Name: *Perform imaging* Text: *The Habitat Medical System shall support caregivers performing imaging.* Rationale: *The Habitat medical system needs to provide capabilities (e.g., tools, technology, skills, medications) to perform imaging of the body (integument, vasculature, bone, ear, eye, internal organs etc.). Imaging capability is essential for all phases of medical care (prevention, diagnosis, treatment) and includes external and internal imaging of the body. Specific imaging modalities and target anatomical areas are specified at Level 5.* Clinical Capability Category: Perform procedure ID: Hab-MedSysy-0030 Name: *Perform airway procedures* Text: *The Habitat Medical System shall enable caregivers to perform airway procedures.* Rationale: *The Habitat Medical System requires capabilities (e.g., tools, technology, skills, medications) to perform procedures that support the maintenance of an open airway (abdominal thrusts, supraglottic*

intubation, suction, etc.). These procedures are needed to support the treatment of unexpected medical conditions such as choking, severe allergic reactions, and sudden cardiac arrest. Types of airway procedures are specified at Level 5.

Habitat Medical System Requirements

The development of the Habitat Medical Systems Requirements represents the foundational research work developed with the participation of the ExMC element team consisting of systems engineers and subject matter experts geographically dispersed across different NASA Centers.

The analysis of the functional and non-functional needs in the Habitat to provide in-flight prevention, diagnosis and treatment of medical conditions led to a new set of 270 In-Flight Habitat Medical System Level 4 Engineering

Requirements for space missions. These requirements are distributed in different systems of the Habitat according to the scope of influence and responsibility of each system as defined or implied by the ConOps documents. The distribution of these requirements is shown in Figure 4.

Habitat System				
Habitat CHP System				
Medical Domain Pharmacy Management Clinical Care Imaging Laboratory Management 75 Functional Requirements + 34 Non-Functional Requirements 	Data Domain Data Sources Interfaces Data Storage Descriptive Analytics Advanced Analytics Data User Interfaces 52 Requirements	Environmental Monitoring Domain Microgravity/ Acceleration Environment Protection Radiation Environment Protection Microbial Environment Protection Internal Atmosphere Protection Toxicological Environment Protection Acoustic Environment Protection 14 Requirements		
Wellness Support Domain o Physiological Health Management o Nutrition Management o Behavioral Support o Sleep Management 34 Requirements	Research and Testbed Domain • • Research • • Testbed 26 Requirements 26 Requirements Maintenance Domain 9 Requirements 1000000000000000000000000000000000000	Task Performance Support Domain o Training Task Management o Task Management 21 Requirements 21 Requirements 21 Requirement Extravehicular Activity Support Domain 1 Requirement 1 Requirement		
Other Habitat Systems: Structures Domain 1 Requirement 3 Requirements				

Figure 4. Distribution of Habitat Medical Systems Level 4 Engineering Requirements. Requirement groupings are shown as bulleted text and the number of requirements for each System are provided. (Ref.: Based on Model [1]).

A brief sample of the requirements is shown in Figure 5 as a condensed view showing ID, Name, Text, and Rationale of the corresponding broader version developed. This figure only shows 4 of the 72 functional requirements of the Habitat Medical System, while similar information is available for each one of the 270 requirements.

Assess and Monitor Vital Signs				
ID	Name	Text	Rationale	
L4-Hab-MedSys-0019	Interpret vital signs	The Habitat Medical System shall interpret vital signs.	This capability enables interpretation of vital sign data and supports collaborative decision making with the ground system. This capability ensures caregivers have the necessary information to interpret crewmembers vital sign, and other physiologic metrics, including waveforms for the purposes of diagnosis and treatment. Specific data to be interpreted as needed by the caregiver are specified at Level 5.	
L4-Hab-MedSys-0020	Collect vital signs	The Habitat Medical System shall collect vital signs.	Vital sign collection is needed during examinations for most planned activities and the diagnosis and treatmen of conditions. Collecting crewmembers vital signs and other physiological metrics, including waveforms for the purposes of diagnosis and treatment, provides medical information that will be stored in the habit data system. Specific vital signs are specified at Level 5.	
L4-Hab-MedSys-0021	Monitor vital signs	The Habitat Medical System shall monitor vital signs.	Vital sign monitoring is needed during planned physical exams, as well to support the diagnosis and treatment of medical conditions. This capability ensures that caregivers have the necessary equipment and support to monitor crewmembers vital signs and other physiologic metrics including waveforms. Specific data to be monitored are defined at Level 5.	
L4-Hab-MedSys-0022	Record vital signs	The Habitat Medical System shall record vital signs.	Recording vital signs (e.g., ECG waveforms) and other physiological metrics (e.g., measures of blood pressure, body mass and temperature) for the purposes of diagnosis and treatment- provides medical information that will be stored in the habit data system. Specific data to be recorded are defined at Level 5.	

Figure 5. Sample of level 4 Habitat Medical System Requirements.

The Functional Requirements of the Habitat Medical System are further classified in categories and sub-categories shown in Table 3. This classification facilitates their comprehension and traceability to higher and lower level requirements and clinical capabilities.

Table 3. Habitat Medical System Level 4 Functional Requirements Categories

- Provide Appropriate Level of Care
- Environment Configuration for Medical Care
 - Configure Environment for Care
 - Habitat Medical System Inventory
- Knowledge-Based Support for Crew Performing Medical Tasks
 - Augment Crew Knowledge

- Medical Assessment and Monitoring • Analyze Health Data
- Habitat Medical Human System
 - Crew Crew as caregiver
 - *Crew as patient*
 - Crew as crewmember

Caregiver/Patient Interactions

- Interview Patient 0
- Perform Physical Exam and Conduct 0 Screening exams/tests
- Assess and Monitor Vital Signs 0
- Administer and Manage Medications 0
- Perform Imaging 0
- Perform Laboratory Analysis 0
- Perform Procedures 0
- 0 Personal Protection

Medical Assessment and Monitoring

- Dietary Control / Nutrition Monitoring 0
- Monitor and Assess Environment 0
- Monitor and Control Sleep and Fatigue 0
- Support Behavioral Health 0
- Support Musculoskeletal Health 0
- Support Physical Therapy 0
- Maintaining Current State of Medical System Document Care 0

These requirement categories provide further guidance considering the large number of requirements, clinical capabilities, and complexity of the information addressed. For example, just listing the Names and ID of the functional requirements of the Medical System leads to a large list, as shown below in Table 4. These requirements also include Text, Rationale, Comments, Traces, and other information not shown in this table due to its extent. This information is available in the ExMC MBSE Model.

Table 4. Habitat Medical System Level 4 Functional Categories and Requirement ID and Names

Provide Appropriate Level of Care Caregiver/Patient Interactions - Perform Physical Exam and L4-Hab-MedSys-0199 Provide first aid Conduct Screening exams/tests L4-Hab-MedSys-0200 Provide basic life support L4-Hab-MedSys-0017 Conduct screening exam L4-Hab-MedSys-0201 Provide advanced life support L4-Hab-MedSys-0018 Perform physical exam L4-Hab-MedSys-0202 Provide primary care Caregiver/Patient Interactions - Assess and Monitor Vital Signs L4-Hab-MedSvs-020L4 Provide dental care L4-Hab-MedSys-0019 Interpret vital signs L4-Hab-MedSys-0205 Provide preventive care L4-Hab-MedSys-0020 Collect vital signs L4-Hab-MedSys-0220 Adjust crew health management L4-Hab-MedSys-0021 Monitor vital signs Environment Configuration for Medical Care - Configure L4-Hab-MedSys-0022 Record vital signs Environment for Care Caregiver/Patient Interactions - Administer and Manage L4-Hab-MedSys-0002 Provide crew physical access to medical Medications inventory L4-Hab-MedSys-0024 Provide pharmacy L4-Hab-MedSys-0078 Prepare medical supplies for habitat Caregiver/Patient Interactions - Perform Imaging evacuation L4-Hab-MedSys-0025 Perform Imaging L4-Hab-MedSys-0083 Provide crew role-based privileges Caregiver/Patient Interactions - Perform Laboratory Analysis L4-Hab-MedSys-0084 Provide access to other habitat system L4-Hab-MedSys-0026 Perform Laboratory Analysis Caregiver/Patient Interactions - Perform Procedures resources L4-Hab-MedSys-0223 Share medical records L4-Hab-MedSys-0029 Perform wound care L4-Hab-MedSys-0030 Perform airway procedures L4-Hab-MedSys-0224 Access medical records L4-Hab-MedSys-0225 Access wellness records L4-Hab-MedSys-0031 Perform anesthesia procedures L4-Hab-MedSys-0032 Perform breathing procedures L4-Hab-MedSys-0231 Access task performance records Environment Configuration for Medical Care - Habitat Medical L4-Hab-MedSys-0033 Perform circulation procedures L4-Hab-MedSys-00L44 Perform dental procedures System Inventory L4-Hab-MedSys-0003 Prepare habitat for medical activities L4-Hab-MedSys-00L45 Perform eye procedures L4-Hab-MedSys-0028 Manage biological material L4-Hab-MedSys-00L46 Perform gastrointestinal procedures Knowledge-Based Support for Crew Performing Medical Tasks -L4-Hab-MedSys-00L47 Perform immobilization procedures Habitat Medical System - Augment Crew Knowledge L4-Hab-MedSys-00L48 Perform musculoskeletal procedures L4-Hab-MedSys-0006 Access knowledge augmentation L4-Hab-MedSys-0039 Perform ENT procedures L4-Hab-MedSys-0116 Update medical records L4-Hab-MedSys-0204 Perform genitourinary procedures Knowledge-Based Support for Crew Performing Medical Tasks -L4-Hab-MedSys-0211 Perform medical suctioning procedures Habitat Medical System - Analyze Health Data Caregiver/Patient Interactions - Personal Protection L4-Hab-MedSys-0007 Synthesize health data L4-Hab-MedSys-0041 Provide biohazard waste containment L4-Hab-MedSys-0042 Provide eye protection L4-Hab-MedSys-0219 Assess crew status L4-Hab-MedSys-0232 Interpret task performance data L4-Hab-MedSys-0044 Provide medical skin protection L4-Hab-MedSys-0046 Provide menstrual flow absorption Habitat Medical System - Crew - Crew as caregiver L4-Hab-MedSys-0095 Access medical decision support L4-Hab-MedSys-0047 Provide postmortem containment of body L4-Hab-MedSys-0097 Diagnose patient L4-Hab-MedSys-0049 Provide sharps containment L4-Hab-MedSys-0098 Treat patient Medical Assessment and Monitoring - Dietary Control / Nutrition L4-Hab-MedSys-0170 Interview patient Monitoring Habitat Medical System - Crew - Crew as patient L4-Hab-MedSys-0050 Adjust nutritional management L4-Hab-MedSys-0099 Activate medical support L4-Hab-MedSys-0226 Interpret crew nutritional health status Habitat Medical System - Crew - Crew as crewmember Medical Assessment and Monitoring - Monitor and Assess L4-Hab-MedSys-0107 Participate in private medical conferences Environment L4-Hab-MedSys-0051 Interpret habitat environment monitoring data **Caregiver/Patient Interactions - Interview Patient** L4-Hab-MedSys-0016 Collect medical data throughout caregiver and L4-Hab-MedSys-0229 Access environmental monitoring records L4-Hab-MedSys-0230 Adjust habitat environment patient interaction

Medical Assessment and Monitoring - Monitor and Control Sleep and Fatigue L4-Hab-MedSys-0052 Interpret crew sleep health status	L4-Hab-MedSys-0056 Adjust physiological health countermeasures L4-Hab-MedSys-0221 Monitor crew health L4-Hab-MedSys-0233 Adjust task management
L4-Hab-MedSys-0053 Interpret crew fatigue status	Medical Assessment and Monitoring - Support Physical Therapy
Medical Assessment and Monitoring - Support Behavioral Health	L4-Hab-MedSys-0218 Access physical therapy consultation
L4-Hab-MedSys-0054 Interpret behavioral health status	Maintaining Current State of Medical System - Document Care
L4-Hab-MedSys-0227 Adjust behavioral health countermeasures	L4-Hab-MedSys-0057 Record medical findings/results
Medical Assessment and Monitoring - Support Musculoskeletal	L4-Hab-MedSys-0058 Record occurrence of medical action
Health	L4-Hab-MedSys-0059 Record interpretations
L4-Hab-MedSys-0055 Interpret physiological health status	L4-Hab-MedSys-0222 Document crew health status

The Non-Functional Requirements of the Habitat Medical System address technical performance, design, reliability, and other -ilities needs of the system that complement the functional needs of the medical system. Although they do not address all the non-functional characteristics of the system [15], they do provide the most relevant requirements considered at this time and are shown below in Table 5.

Table 5. Habitat Medical System Level 4 Non-Functional Requirement ID and Names

Accessibility Hab-MedSys-1063 Non-operating Environment Hab-MedSys-1064 Power Interfaces Hab-MedSys-1072 Lifecycle Accessibility Hab-MedSys-1065 Structural Interfaces Human Risk Hab-MedSys-1041 Loss of Crew Risk Hab-MedSys-1066 Fluid Interfaces Hab-MedSys-1042 Transfer Mission to Definitive Care Risk Hab-MedSys-1067 Data Interfaces Hab-MedSys-1073 Toxicity Minimization Hab-MedSys-1043 Quality Time Lost Risk Maintainability Reliability Hab-MedSys-1048 Preventive Maintenance Hab-MedSys-1053 Repair Time Hab-MedSys-1049 Corrective Maintenance Hab-MedSys-1054 Failure tolerance Hab-MedSys-1050 Lifecycle Modularity Hab-MedSys-1055 Failure Propagation Hab-MedSys-1051 Lifecycle Adaptability Hab-MedSys-1056 Operational Life Hab-MedSys-1057 Unintentional operation Hab-MedSys-1052 Lifecycle Replaceability Performance **Resource Allocation** Hab-MedSvs-1044 Time behavior Hab-MedSys-1068 Minimize Mass Hab-MedSys-1045 Minimize Resource utilization Hab-MedSys-1069 Minimize Power Hab-MedSys-1046 Provide Ground Awareness Hab-MedSys-1070 Minimize Volume Hab-MedSys-1047 Provide Interoperability Security Hab-MedSys-1071 Operational Time Hab-MedSys-1058 User Confidentiality Hab-MedSys-1074 Failure Notification Hab-MedSys-1059 System Integrity **Physical Constraints** Hab-MedSys-1060 Action Accountability Hab-MedSys-1062 Operational Habitat Environment Hab-MedSys-1061 System Authentication

TRACEABILITY

The traceability of the requirements as shown in Figure 6 ensures that the requirements address each one of the clinical activities and ConOps functions of the Habitat Medical System. The left graphic shows traces of clinical capabilities and functional requirements, while the right graphic shows traces of a Level 4 requirement and the associated Level 5 child requirements.

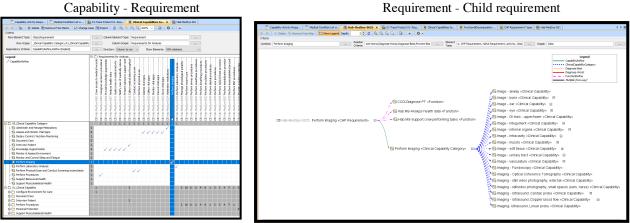


Figure 6. Requirements traceability [1].

CONCLUSIONS

The ExMC Systems Engineering Requirement Team developed 270 Level 4 Systems Engineering Foundational Requirements to provide In-Flight Level-Of-Care IV prevention, diagnosis and treatment of medical conditions in Space Lunar Orbit Habitat. These requirements address needs in the Habitat System as follows:

Habitat CHP Medical Domain

- 75 Functional Requirements of the Habitat CHP Medical System
- 34 Non-Functional Requirements of the Habitat CHP Medical System

Habitat CHP Domain

- 52 Functional Requirements of the Habitat CHP Data System
- 34 Functional Requirements of the Habitat CHP Wellness Support System
- 21 Functional Requirements of the Habitat CHP Task Performance Support System
- 14 Functional Requirements of the Habitat CHP Environmental Monitoring System
- 26 Functional Requirements of the Habitat CHP Research and Testbed System
- 9 Requirements of the Habitat Maintenance System
- 1 Requirements of the Habitat EVA System

Habitat Domain

- 3 Requirements of the Habitat Waste System
- o 1 Requirements of the Habitat Structures System

This requirement development is based on available information obtained from different resources:

- Concept of Operations for space missions with draft document narratives of system and sub-systems needs to maintain crew health and enable mission success, and complementary information from the functional decomposition of the system addressing the sub-systems of the space Habitat.
- Comprehensive list of Clinical Capabilities addressing in-flight planned and unplanned activities for space missions.
- Reviews from subject matter experts developed by the ExMC Systems Engineering and clinician team following the ExMC SE MBSE formal approach to deliver the system needs as Foundational Requirements as a basis to provide medical care for space Habitat missions.

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