

3.2 Medical Requirements Overview

TABLE 3.2: MEDICAL REQUIREMENTS OVERVIEW

MEDB# and Title:	MEDB 4.1 Cycle Ergometer Test/Aerobic Functional Capacity
Sponsor:	Medical Operations
Discipline:	Bone, Muscle & Exercise
Category:	Medical Requirements (MR)
References:	International Space Station Medical Operations Requirements Document (ISS MORD), SSP 50260 Medical Evaluation Documents (MED) Volume B Section 4.1
Purpose/Objectives:	To provide assessment of astronaut cardiovascular health and aerobic fitness at specified intervals pre-, in- and postflight to guide individual physical training and to determine individual responses to training and countermeasures. The assessments also provide group data for analyzing countermeasures and rehabilitative programs.
Measurement Parameters:	Aerobic capacity (VO ₂ max), heart rate, ECG, blood pressure, work load and perception of effort.
Deliverables:	Assessment of aerobic fitness
Flight Duration:	≥ 30 days
Number of Flights:	Every Expedition
Number and Type of Crew Members Required:	All primary and back-up ISS crewmembers. Back-up crew will only complete all pre-flight testing in case of a crew change-out. The second pre-flight test time schedule will be L-60 to L-30 (during crewmembers last rotation to U.S. prior to flight). Participation of IP crew members in these specific test protocols performed by US personnel will be negotiated between the US and respective IP's Medical Operations representatives.
Other Flight Characteristics:	None

3.3 Preflight Training

TABLE 3.3: PREFLIGHT TRAINING

<p>Preflight Training Activity</p>	<p>Description:</p> <p><u>Medical Equipment Computer Overview (MEC OV):</u> The Medical Equipment Computer (MEC) Overview lesson introduces crewmembers to MEC tasks, functions, and software. Similarities and differences between the MEC and the International Space Station (ISS) Portable Computer System (PCS) and Station Support Computers (SSC) are discussed. MEC applications and navigation requirements related to each Crew Health Care System (CHeCS) subsystem are demonstrated. This lesson prepares crewmembers for the CHeCS operations lessons, which utilize the MEC for data storage, data transmission, and retrieval of reference data.</p> <p><u>Countermeasures Systems 1 (CMS Ops 1) :</u> This lesson introduces crewmembers to some of the Countermeasures Systems (CMS) hardware. This includes the Cycle Ergometer with Vibration Isolation System (CEVIS), Heart Rate Monitor (HRM) and Advanced Resistive Exercise Device (ARED).. There is also a review of the Medical Equipment Computer (MEC), which will cover PC Card operations and CMS applications on the MEC. The lesson will concentrate on the purpose and operation of the CMS hardware and will incorporate procedure use throughout.</p> <p><u>Countermeasures Systems Periodic Fitness Evaluation (PFE) Operations (CMS PFE Ops):</u> This lesson covers the Periodic Fitness Evaluation (PFE) procedure that is performed every 30 days in orbit. Crewmembers are expected to work through the procedures necessary that will integrate using the Cycle Ergometer Vibration Isolation System (CEVIS), the Medical Equipment Computer (MEC), and the Blood Pressure/Electrocardiograph (BP/ECG). Some review of the CEVIS and HRM operations are also included in the lesson.</p> <p><u>Integrated Physical Fitness Assessment Training:</u> This lesson provides further training on the test hardware and familiarizes the crewmembers with the testing protocol. This training is the responsibility of the Exercise Physiology Laboratory (EXL) and Astronaut Strength, Conditioning and Rehabilitation (ASCR) group.</p> <p>Crewmembers will be trained on the Russian ergometer (veloergometer) in Star City at approximately L-12 months, Russia by Russian trainers.</p>			
	<p>Schedule:</p>	<p>Duration:</p>	<p>Schedule:</p>	<p>Personnel Required:</p>
		<p>1 hr</p>	L-1 year MEC OV	Trainers/Crew
		<p>1.5 hrs</p>	L-1 year CMS Ops 1	Trainers/Crew
		<p>1.5 hrs</p>	L-150 CMS PFE Ops	Trainers/CrewCMO/Flight Surgeon
	<p>60 min</p>	L-180 Integrated Physical Fitness Assessment Training	Trainers/CMO Trainers/CMO/ASCR/EXL	

Ground Support Requirements Hardware/Software	Preflight Hardware:		Preflight Software:		Test Location:
	Russian Ergometer (Russian Training Only) ISS Ergometer (CEVIS) Medical Equipment Computer Metabolic Gas Analyzer Consumables BP/ECG (3 lead for Peak, 3 lead for Submax) Heart Rate Monitor (HRM) Rating of Perceived Exertion (RPE) Chart Advanced Resistive Exercise Device (ARED)		MEC Software For BP/ECG MEC Software For Metabolic Gas Analysis* MEC Software for HRM		U.S. and Russia
Training Facilities	Minimum Room Dimensions:	Number of Electrical Outlets:	Temperature Requirements:	Special Lighting:	
	Approximately 15 ft. x 15ft.	Two 120 VDC and one 110 VAC (USA) Five 220 (Russia)	20 -25°C	N/A	
	Hot or Cold Running Water:	Privacy Requirements:	Other:		
	Both	N/A	N/A		
Constraints/Special Requirements:	<ul style="list-style-type: none"> • No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing • Wear workout clothing (shorts, t-shirt, sneakers). • No large meals 2 hrs prior to test (A light meal is permitted up to 60 minutes before test) • Limit caffeine intake to 1cup (8oz) of regular coffee or equivalent 60 minutes before test. • No alcohol, or nicotine 8 hrs prior to test • Contraindications: previous musculoskeletal injury • No Neutral Buoyancy training 48 hours prior to test; prefer 72 hours. • 3-lead BP/ECG is required for maximal tests and pre-flight submaximal tests; only a HR monitor is required for pre-breathe submaximal tests • No physical testing or physical training will be conducted with the crewmembers within 72 hours of returning from overseas travel. • No physical testing or physical training will be conducted with the crewmembers within 48 hours of domestic travel unless approved by the Crew Surgeon. 				

	Test Termination Criteria: See page 7.
Launch Delay Requirements:	Crewmembers will be required to participate in refresher training sessions if launch is delayed by more than 3 months.
Notes:	

3.4 Preflight Activities

TABLE 3.4: PREFLIGHT ACTIVITIES

Preflight Activity	Description:	<p><u>Peak Cycle Exercise Test:</u> One upright maximal cycle ergometer test will be performed at L-270 to establish peak HR and VO₂ max. Blood pressure, workloads, and perception of effort also will be measured throughout the test. The values obtained from this test will be used to establish the work loads and HR termination criteria for the submaximal tests.</p> <p><u>Submaximal Cycle Exercise Test:</u> A submaximal exercise test protocol will be performed pre-flight to assess changes in fitness from the L-270 peak test. HR, ECG (3-lead), and VO₂ max will be measured during the test. See “Submaximal Cycle Exercise Test and Peak Cycle Exercise Test” Tables below.</p>				
	Schedule:	Duration:	Schedule:	Flexibility:	Blood Volume	Personnel Required:
	60 min 60 min	<u>Peak:</u> L-270* <u>Submax:</u> L-60 to L-30	+/- 3 weeks +/- 5 Days	N/A	Lab personnel/ Crewmember/Crew surgeon (peak only)	
Ground Support Requirements Hardware/Software	Preflight Hardware:		Preflight Software:		Test Location:	
	LODE Electronic Cycle Ergometer Metabolic Gas Analyzer* Metabolic Gas Analyzer Accessories Metabolic Gas Analyzer Consumables Heart Rate Monitor		Ergometer Software MGA Software*		U.S. and Russia	

Testing Facilities	Minimum Room Dimensions:	Number of Electrical Outlets:	Temperature Requirements:	Special Lighting:
	Approximately 15 ft. x 15ft.	Four 110V and one 220V (U.S.) Five 220V (Russia)	20 -25°C	NA
	Hot or Cold Running Water:	Privacy Requirements:	Other:	
	Running water is necessary. Prefer hot.	Access to room must be controlled during testing.	<p><u>Peak cycle exercise testing:</u> An Advanced Cardiac Life Support (ACLS)-certified physician must be present at time of testing. One Basic Life Support (BLS) and one ACLS certified operator must be present.</p> <p><u>Submaximal exercise testing:</u> An ACLS physician will be available within 15 minutes of notification while testing is being conducted. One BLS and one ACLS certified operator must be present</p> <p>A crash cart and IV pole should be in the immediate vicinity for both tests.</p>	

<p>Constraints/Special Requirements:</p>	<ul style="list-style-type: none"> • No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing • Wear workout clothing (shorts, t-shirt, sneakers). • No large meals 2 hrs prior to test. A light meal permitted up to 60 minutes before test. • Limit caffeine intake to one cup (8 oz) of regular coffee or equivalent 60 minutes before test. • No alcohol, or nicotine 8 hrs prior to test • Contraindications: previous musculoskeletal injury • No Neutral Buoyancy training 48 hours prior to test; prefer 72 hours. • A 3-lead ECG is required for peak and submaximal tests. A 12-lead ECG can be substituted upon crew surgeons request. • No physical testing or physical training will be conducted with the crewmembers within 72 hours of returning from overseas travel. • No physical testing or physical training will be conducted with the crewmembers within 48 hours of domestic travel unless approved by the Crew Surgeon. <p>Test Termination Criteria: See page 7. *L-270 testing must be scheduled before EVA Prebreathe Protocol training</p>
<p>Launch Delay Requirements:</p>	<p>L-30 or L-60 data collection will be repeated if launch is delayed by more than 3 months. If launch is delayed one year, L-270 peak cycle exercise test should be repeated.</p>
<p>Notes:</p>	<p>The crew surgeon can request a 12-lead ECG. A peak cycle exercise test performed within one year of the launch date may be substituted for the L-270 peak test upon crew surgeon approval. In the case that a crew members back-up L-30 (US launch) or L-60 (Russia launch) falls within a year of their prime flight launch date, the crew members may perform a peak test in place of the nominal peak submaximal exercise test to meet both the back-up and prime MedB4.1 requirement (contingent upon crew member approval). After the last test session, submaximal cycle exercise protocols must be posted to the Medical Operations secure server and then transferred to the PCMCIA card within 24 hours. PCMCIA card to have a late stowage access at L-21 days.</p>
<p>Data Delivery</p>	<p>Data/Report to Designated Recipients (Nominal/Contingency):</p> <p>Cycle exercise test data will be analyzed by the discipline experts and shared with the Astronaut Strength, Conditioning and Rehabilitation team (ASCR) for interpretation and recommendations. The data may be shared with the Flight Medicine Clinic when approved by the crewmember in advance. Preliminary MAT reports for all L-30 and L-60 submaximal cycle tests will be posted to the Medical Operations secure sever within 48 hours of test completion. A final report shall be posted to the Medical Operations secure server within 14 days following the final preflight test session. If the preliminary report requires no changes it shall serve as the final report. Cycle test data also will be shared with EVA experts to develop EVA pre-breathe reduction exercise protocols for pre-flight training</p>

Peak Cycle Exercise Test Protocol

Protocol A		Protocol B	
Work Rate (Watts)	Time (min)	Work Rate (Watts)	Time (min)
50	3	50	3
100	3	75	3
150	3	100	3
175	1	125	1
200	1	150	1
225	1	175	1
250	1	200	1
275	1	225	1
300	1	250	1
325	1	275	1
350	1	300	1
375	1	325	1

Submaximal Cycle Exercise Protocol

Elapsed Time (min)	Stage Time (min)	Stage
0-2	2	Seated Rest
2-7	5	25% VO _{2max}
7-12	5	50% VO _{2max}
12-17	5	75% VO _{2max}
17-22	5	25% VO _{2max}

Note: Protocol A is to be used for subjects weighing >65 kg. Some discretion may be used on the assignment of protocols. For example, Protocol A would also be appropriate for a 62 kg individual who regularly performs cycle exercise. Peak and submaximal cycle exercise test pedal speed =75rpm

Pre-flight Peak Cycle Exercise Test Termination Criteria

1. Onset of symptoms consistent with angina pectoris
2. Progressive drop of heart rate or systolic blood pressure during increasing exercise intensity accompanied by signs or symptoms
3. Serious dysrhythmias (e.g. , second or third degree AV Block, sustained ventricular tachycardia, increasing premature ventricular contractions, exercise induced left bundle branch block, atrial fibrillation, paroxysmal supraventricular tachycardia).
4. Exercise SBP > 250 mmHg, DBP>115
5. Pronounced ST segment changes from baseline that have not been observed in previous testing
6. Unusual or severe shortness of breath (inconsistent with level of effort)
7. Signs of poor perfusion, including pallor, cyanosis, or cold and clammy skin
8. Volitional fatigue

Pre-, and In-and Post-flight Submaximal Cycle Exercise Test Termination Criteria

1. Measured HR greater than HR at 90% of pre-flight VO2 max for a 2 minute measurement period
2. Onset of symptoms consistent with angina pectoris
3. Progressive drop of heart rate or systolic blood pressure during exercise accompanied by signs or symptoms
4. Exercise SBP > 250 mmHg, DBP>115
5. Unusual or severe shortness of breath (inconsistent with level of effort)
6. Signs of poor perfusion, including pallor, cyanosis, or cold and clammy skin
7. Serious dysrhythmias (e.g. , second or third degree AV Block, sustained ventricular tachycardia, increasing premature ventricular contractions, exercise induced left bundle branch block, atrial fibrillation, paroxysmal supraventricular tachycardia).
8. Volitional fatigue

3.5 In-Flight Activities

TABLE 3.5.1: IN-FLIGHT ACTIVITIES

In-Flight Activity	Description:	<u>Submaximal Cycle Exercise Test:</u> A submaximal cycle test will be performed on the inflight cycle ergometer on flight day 14 then every 30 days of the mission. The test is also required for ISS crewmembers performing EVAs in the EMU. Russian 3-lead ECG Gamma-1 Equipment or HRM can be used to measure heart rate per crew surgeon discretion.				
	Schedule:	Duration:	Schedule:	Flexibility:	Blood Volume:	Personnel Required:
	90 min 90 min		FD 14 then every 30 days 7 days prior to the EVA	+/- 2 days +/- 2 days	NA NA	ISS Crewmember ISS crewmembers who will perform EVAs in the EMU
Procedures:	NA					
Constraints / Special Requirements:	Wear workout clothing (shorts, t-shirts, sneakers). No max exercise 24 hrs prior to testing: no regular exercise 8 hrs prior to testing. Limit caffeine intake to 1 cup (8 oz) of regular coffee or equivalent 60 minutes before test. No large meals 2 hrs prior to test. A light meal is permitted up to 60 minutes before test. No alcohol, or nicotine 8 hrs prior to test Contraindications: previous musculoskeletal injury Test Termination Criteria: See page 7. Each crewmember will don a Heart Rate Monitor as defined by MRID MR019Land BP/ECG (3-lead).					
Photo / TV Requirements:	Obtain video of the first PFE for each crewmember. 10 min setup, 10 min stow per session.					
Cold Stowage Requirements:	NA					
Mission Extension Requirements:	As prescribed					
Landing Wave-Off Requirements:	NA					
Notes:	<ul style="list-style-type: none"> In the event that the cycle ergometer is inoperable the Russian ergometer and/or Treadmill may be considered for use as contingency devices. 					

Data Delivery	Data/Report to Designated Recipients (Nominal/Contingency):
	CEVIS, BP/ECG, Metabolic Gas Analyzer and HR monitor data will be received by ground support personnel (includes the Flight Surgeon), who will forward the data to the discipline experts for analysis. Test results will be shared with ASCR for interpretation and recommendations. The discipline experts will deliver test results and final recommendations to the crew surgeon via the secure Medical Operations server within 48 hours of receiving initial cycle exercise data.

In-Flight Activities, (cont.)

TABLE 3.5.2: IN-FLIGHT HARDWARE

Hardware/Software Name	P/N
Russian Ergometer (operational)	XM.2.893.048
Russian Ergometer (transport)	XM.2.893.048
ISS Ergometer	SEG46115811-301
CEVIS Accessory Bag	SEG46116009-301
Isolator Kit Assembly	SEG46116012-XXX
On-Orbit Mounting Frame	SEG46116010-301
IVIS Box, Blue	SED46110777-302
IVIS Box, Red	SED46110777-301

In-Flight Activities, (cont.)

TABLE 3.5.2: IN-FLIGHT HARDWARE

Hardware/Software Name	P/N
Medical Equipment Computer Kit 1	SEG46116031-XXX
PCMCIA Card	SEG46116005-XXX
Metabolic Gas Analyzer	TBD
Metabolic Gas Analyzer Accessories	TBD
Blood Pressure / Electrocardiograph Monitor (BP/ECG) Kit	SED46115812-XXX
BP/ECG Resupply Kit	SEG46115989-XXX
Metabolic Gas Analyzer Consumables	TBD

Hardware/Software Name	P/N
Heart Rate Monitor Kit	SED46115818-xxx
RPE Chart	TBD

3.6 Postflight Activities

TABLE 3.6: POSTFLIGHT ACTIVITIES

Postflight Activity	Description:	<u>Submaximal Cycle Exercise Test:</u> Crewmembers will perform the same submaximal cycle exercise test postflight as performed preflight. HR, BP, ECG (3-lead), and VO ₂ max will be measured during the test.				
	Schedule:	Duration:	Schedule:	Flexibility:	Blood Volume:	Personnel Required:
		60 min 60 min	R+4 R+29	+/- 1Days +/- 2 Days	NA	Lab personnel/ Crewmember
Ground Support Requirements Hardware/Software	Postflight Hardware:			Postflight Software:	Test Location:	
	Electronic Cycle Ergometer Metabolic Gas Analyzer Metabolic Gas Analyzer Accessories Metabolic Gas Analyzer Consumables RPE Chart	Heart Rate Monitor 3-Lead ECG Sphygmomanometer	Ergometer Software MGA Software	ISS crewmembers		
Testing Facilities	Minimum Room Dimensions:	Number of Electrical Outlets:	Temperature Requirements:	Special Lighting:		
	Approximately 15 ft. x 5ft.	Four 110V and one 220V (U.S.) Five 220V (Russia)	20 -25°C	NA		
	Hot or Cold Running Water:	Privacy Requirements:	Other:			
	Running water is necessary. Prefer hot.	Access to room must be controlled during testing.	<u>Submaximal exercise testing:</u> On R+4, and Advanced Cardiac Life Support (ACLS) certified physician must be present at the time of testing. One Basic Life Support (BLS) and one ACLS certified operator must be present. On R+29, a physician will be available within 15 minutes of notification while testing is being conducted. One BLS and one ACLS certified operator must be present. A crash cart and IV pole should be in the immediate vicinity for both tests.			
Constraints/Special Requirements:	Wear workout clothing (shorts, t-shirt, sneakers). No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing. No large meals 2 hrs prior to test. A light meal is permitted up to 60 minutes before test. Limit caffeine intake to 1 cup (8 oz) of regular coffee or equivalent 60 minutes before test. No alcohol, or nicotine 8 hrs prior to test Contraindications: previous musculoskeletal injury No physical testing or physical training will be conducted with the crewmembers within 72 hours of returning from overseas travel.					

	No physical testing or physical training will be conducted with the crewmembers within 48 hours of domestic travel unless approved by the Crew Surgeon. Test Termination Criteria: See page 7.
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Early Destow / Early Return:	NA
Notes:	NA
Data Delivery	Data/Report to Designated Recipients (Nominal/Contingency):
	Cycle exercise test data will be analyzed by the discipline experts and shared with the Astronaut Strength, Conditioning and Rehabilitation team (ASCR) for interpretation and recommendations. Preliminary MAT reports for all post-flight submaximal cycle tests will be delivered to the crew surgeon within 48 hours of test completion. A final report shall be delivered to the Crew surgeon via the Medical Operations secure server 14 days following the final preflight tests session for all MedB 4.1 cycle tests.

3.7 Summary Schedule

TABLE 3.7: SUMMARY SCHEDULE

ACTIVITY	DURATION	SCHEDULE	FLEXIBILITY	PERSONNEL REQUIRED	CONSTRAINTS
Preflight Training					
Medical Equipment Computer Overview (MEC OV) Countermeasures Systems 1 (CMS Ops 1)	1 hr 1 hr	L-1 year L-1 year	+/- 5 Days	Trainers/Crew Trainers/CMO	
Countermeasures Systems Periodic Fitness Evaluation (PFE) Operations (CMS PFE Ops)	1.5 hrs	L-150 days	+/- 5 Days	Trainers/CMO	
Integrated Physical Fitness Assessment Training	60 min	L-180 Days	+/- 5 Days	Trainers/Crew Trainers/CMO/ EXL personnel/ASCR	
Preflight					
Peak Cycle Exercise Test	60 min	L-270 Days	+/- 3 Weeks	Lab personnel/ Crewmember	See Note
Submaximal Cycle Exercise Test	60 min	L-60 to L-30 Days (during crewmembers last rotation to U.S. prior to flight)	+/- 5 Days	Lab personnel/ Crewmember	See Note
In-Flight					
Submaximal Cycle Exercise Test	90 min 90 min	FD 14 and every 30 days thereafter 7 days prior to the EVA	+/- 2 Days +/- 2 Days	ISS Crewmember ISS Crewmember	See Note ISS crewmembers who will perform EVAs in the EMU
Postflight					
Submaximal Cycle Exercise Test	60 min	R+4 Days R+29 Days	+/- 2 Days	Lab personnel/ Crewmember	See Note

Postflight Debrief					
No extra time	~R+30 d	As scheduled	N/A	ASCR/ Crewmember/Lab Personnel/Crew surgeon	Included as part of the Med Ops overall debrief.

Note:

48 hrs prior to test: No neutral buoyancy training; prefer 72 hrs from test.
 No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing.
 No large meals 2 hrs prior to test. A light meal is permitted up to 60 minutes before test.
 MR019L.
 Limit caffeine intake to 1 cup (8 oz) of regular coffee or equivalent
 60 minutes before test.
 No alcohol, or nicotine 8 hrs prior to test
 Wear workout clothing (shorts, t-shirt, sneakers).
 No physical testing or physical training will be conducted with the crewmembers within 72 hours of returning from overseas travel.
 No physical testing or physical training will be conducted with the crewmembers within 48 hours of domestic travel unless approved by the Crew Surgeon.

Contraindications: previous musculoskeletal injury

Test Termination Criteria: See page 7.

Each crewmember will don a Heart Rate Monitor as defined by MRID