Development and implementation of aseptic operations for the MOMA-mass spectrometer

SPIE 2018, Systems Contamination: Prediction, Control, and Performance

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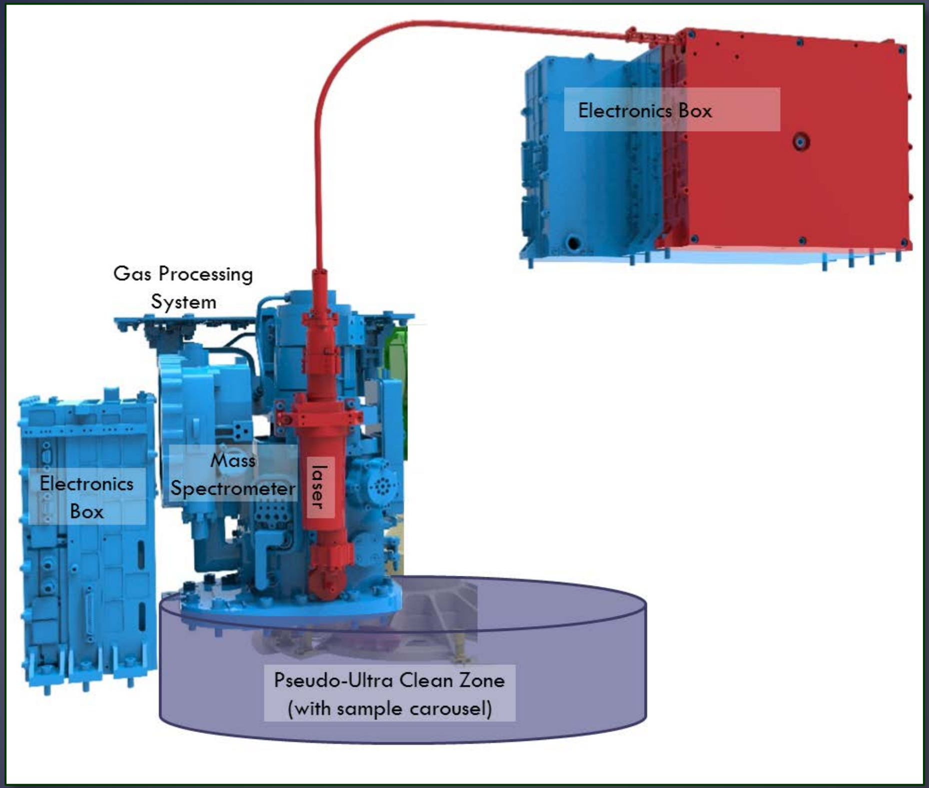
Exomars 2020 &
Mars Organic Molecule Analyzer (MOMA):

- Exomars 2020- an ESA lander and rover:
  - Scheduled Launch Date: July 2020
  - **Life detection mission**
  - Samples will be collected up to 2m below the surface by a drill
- Mars Organic Molecule Analyzer (MOMA) is an instrument suite on rover
  - **Mass Spectrometer (MS) – NASA/GSFC**
  - Sample Ovens – MPS
  - Gas Chromatograph (GC) – LISA and LATMOS
  - Laser Desorption (LD) - LZH

The ExoMars rover. *Credit: ESA*

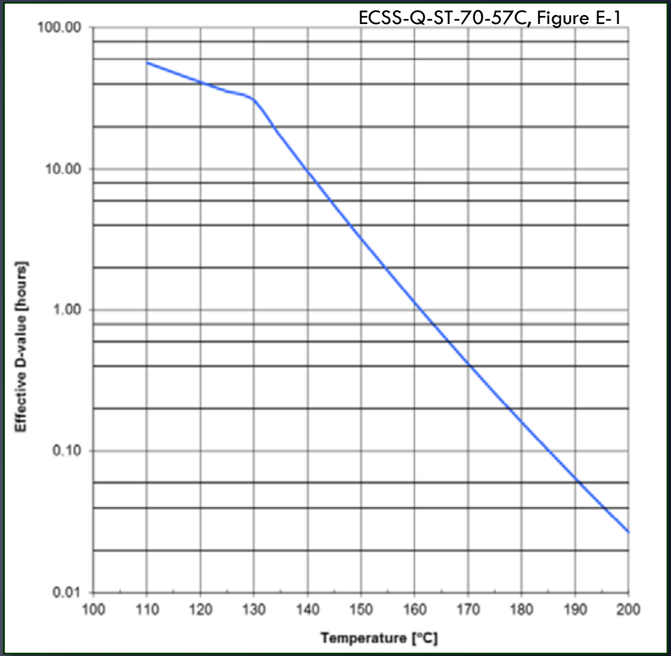
Verifying MOMA-MS Bioburden Requirements

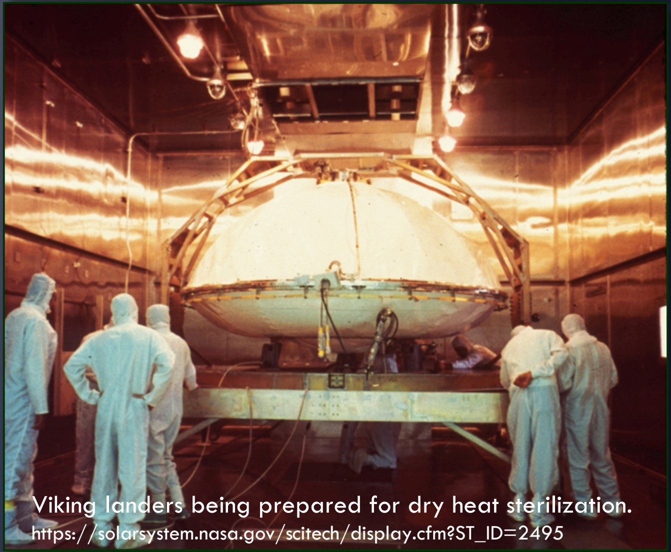


- Sample path: **<0.03 spores/m^2**
  - Accessible areas: Bioassay to 300 spores/m^2 at final access before 4 order of magnitude bioburden reduction with Dry Heat Microbial Reduction (DHMR)
  - Inaccessible areas: Bioassay surfaces with similar handling, calculate bioburden reduction credit from (DHMR)
- Surfaces not in contact with sample path: **300-1000 spores/m^2**
  - Internal volumes of electronics boxes: Inspect and bioassay before final assembly
  - Exterior surfaces: Inspect and bioassay before shipment and delivery to ESA.

DHMR: Dry Heat Microbial Reduction

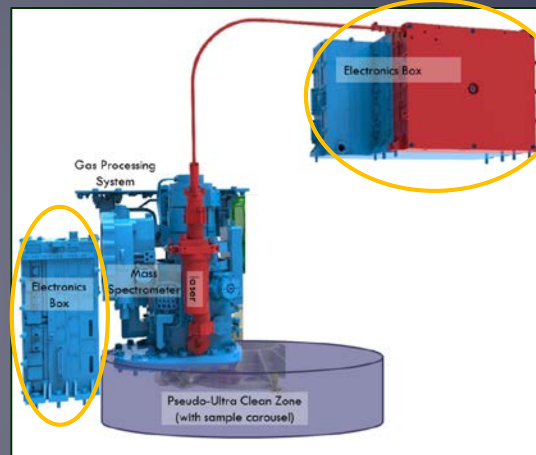
- Standard approved method of bioburden reduction on flight hardware
  - Exposing hardware to temperatures of at least 110°C with controlled humidity
  - 4 orders of magnitude decrease in viable bioburden
  - Higher temperatures= shorter bake, but many components are not compatible with high temperatures
- Viking: DHMR entire lander
- Today, subcomponents are usually treated
- Alternates to DHMR have to be analyzed, proven, and approved by PPO

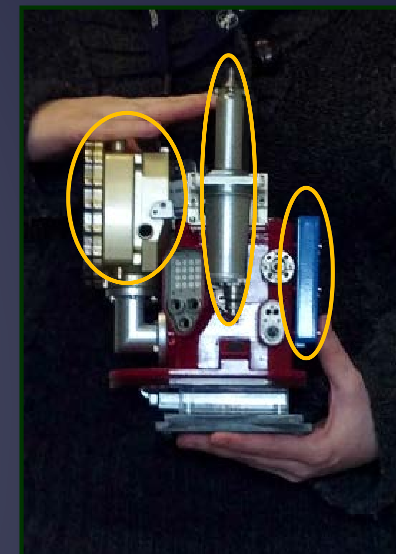



Viking landers being prepared for dry heat sterilization.
https://solarsystem.nasa.gov/scitech/display.cfm?ST_ID=2495

DHMR impact on Integration and Test (I&T) plans

- PP ideal I&T process, no need to expose sample path after DHMR:



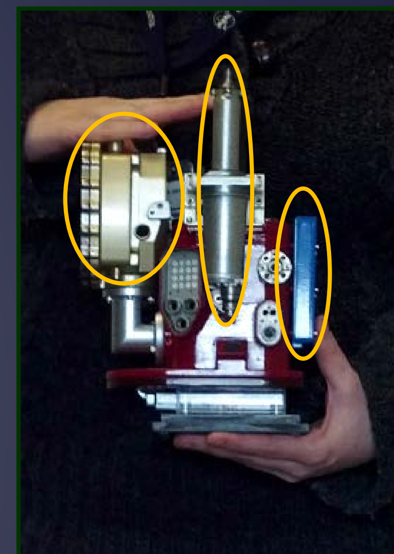


Integration → EMI-EMC → Vibe/ Shock → Thermal vacuum → DHMR → Final functional test → Ship to Italy

Laser, Detector Electronics (DET), and Radio Frequency electronics (RF) not compatible with DHMR, but need to be integrated for vibe/shock & thermal vacuum testing

DHMR impact on Integration and Test (I&T) plans

- DHMR before vibe/shock testing, necessitates aseptic activities for moving the MS to and from the vibration fixture.



Move MS to vibe fixture

Move MS back to pUCZ

Integration → EMI-EMC → Vibe/ Shock → Thermal vacuum → DHMR → Final functional test → Ship to Italy

Deintegrate laser/ electronics

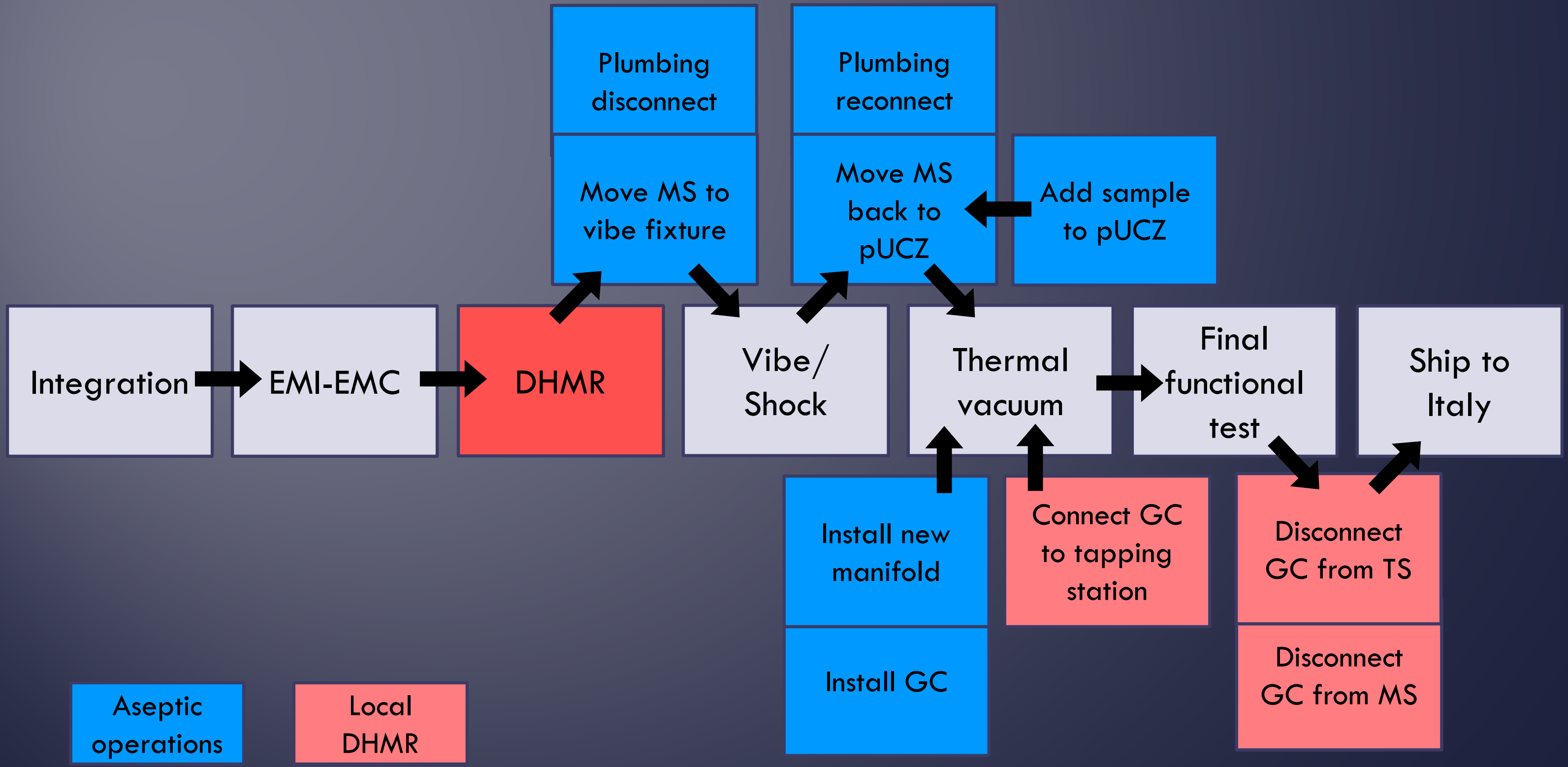
Reintegrate laser/ electronics

Aseptic operations

Laser, Detector Electronics (DET), and Radio Frequency electronics (RF) not compatible with DHMR, but need to be integrated for vibe/shock & thermal vacuum testing

DHMR impact on Integration and Test (I&T) plans

- Addition post-DHMR sample path breaks in plumbing and pUCZ access were added as I&T progressed, resulting in 7 aseptic activities, and 3 activities with localized DHMR.



Risk analysis before aseptic activities

- Existing requirements (NASA-HDBK-6022 and ESA ECSS-Q-ST-70-58C) define that activities on sterilized hardware must take place in an aseptic ISO 5 environment
- To ensure that ≤0.03 spores/m2 is maintained after DHMR, an acceptable exposure time was calculated based on exposed area and probability of viable microorganism fallout.
- Probability was calculated using the surface area of the sample path, fall out rates of an ISO class 5 environment, and room monitoring data from active air sampling for microorganisms

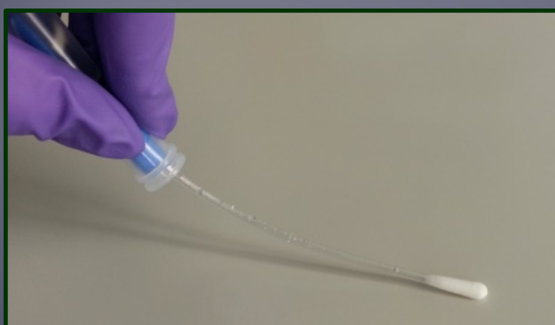
	Surface area (m^2)	Acceptable Probability (CFU)	Time (min)
Example	2	0.06	0.02
Base of MS	0.0212	6E-4	3
Plumbing	1.4e-5	4E-7	2000
Manifold 1	1e-4	3E-6	200

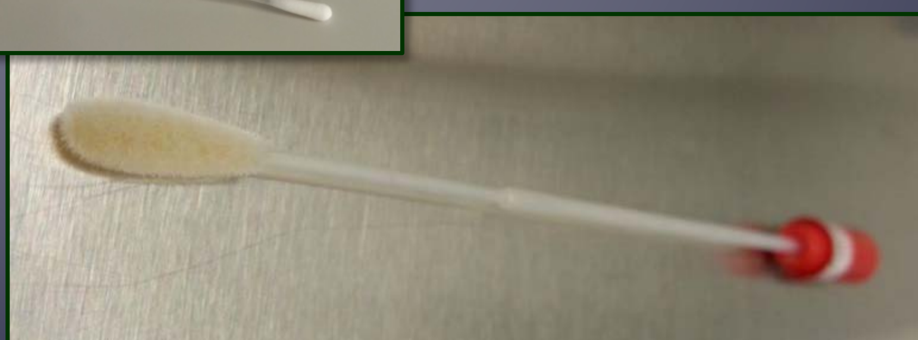
Preparation for aseptic operations

- Work area: 70% isopropanol and 7% hydrogen peroxide used to clean surfaces. When possible, sanitizing ultra-violet C lamps are also used.
- Hardware: Non sterile surfaces isolated with bag or drape (where feasible)
  - Non sterile exposed surface wiped with sterile 70% isopropanol
- All tools are cleaned and sterilized.
  - Tools that cannot be sterilized wrapped with sterile foil before being handled, and the sockets that interact directly with the hardware are sterile.

Verifying aseptic work space

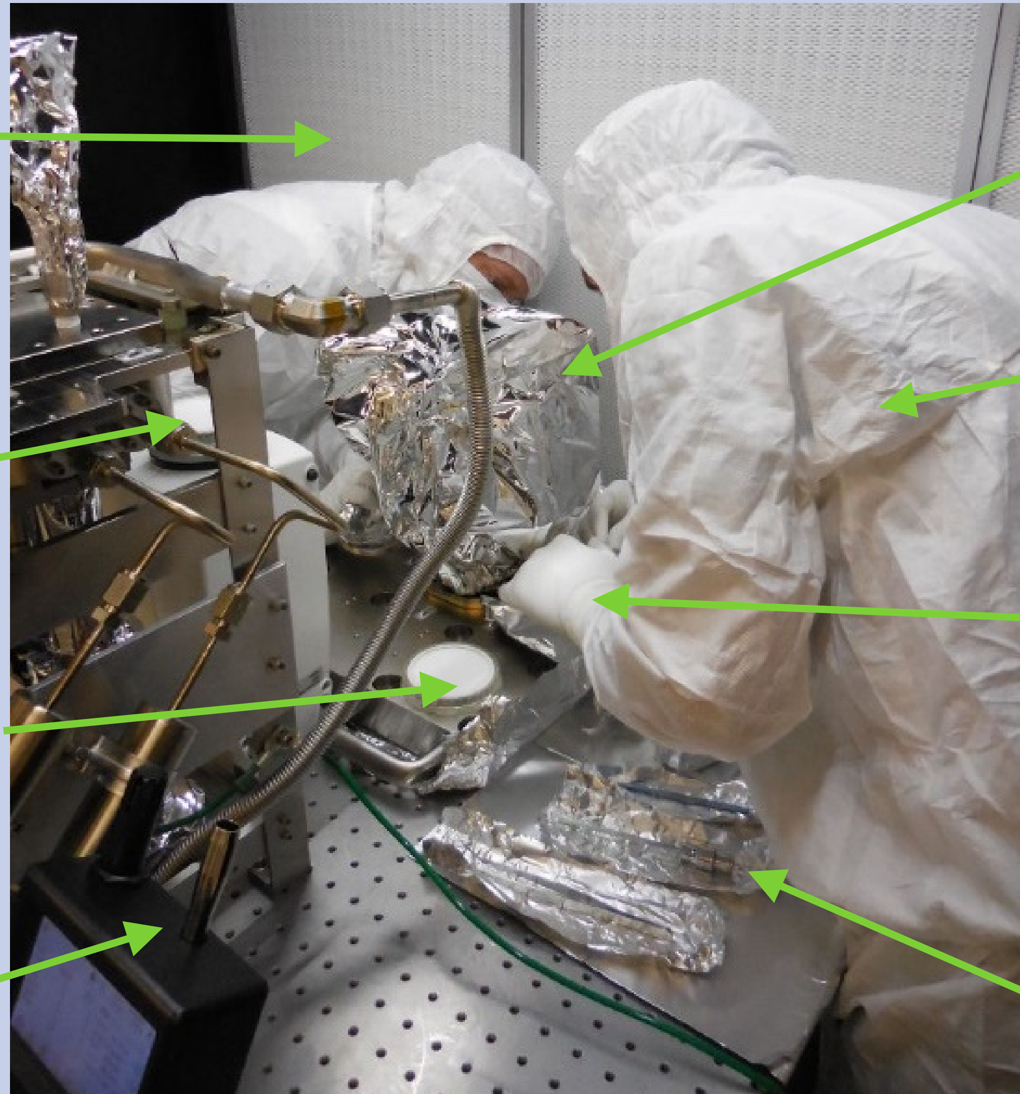
- 4 forms of cleanliness verification:
  - Air samples for bioburden (<1 CFU/m^2)
  - ATP (adenosine triphosphate) rapid bioassay Any high ATP readings require immediate re-cleaning before swab bioassays.
  - ESA swab bioassay (72h, <400 CFU/m2)
  - Particle counter monitoring (ISO 5)





- After cleaning and bioassay, the **cleanroom is closed to all entry for 72 hours** until the results from swab bioassays are finalized.

Sample path exposure



ULPA wall

Active airborne bioburden sampling

Passive bioburden fallout witness

Continuous airborne particle monitoring

Sterile cinch bag

Sterile Garments

Sterile Gloves

Sterile Tools on sterile operating field

Minimize & document sample path exposure times

Operation	Date	Exposed sample path	Total Exposure time
P0/P5 plumbing connections	9/19/17	0.28 cm^2	1 minute
MS from pUCZ to Vibe Plate	9/29/17	106 cm^2	17 seconds
R6G Sample addition	10/23/17	106 cm^2	36 seconds
MS from Vibe Plate to pUCZ	10/27/17	106 cm^2	18 seconds
P0/P5 plumbing connections	10/27/17	0.28 cm^2	4 minutes 45 seconds
Manifold 1 Swap	12/21/17	1 cm^2	25 minutes*
GC installation	12/27/17	0.14 cm^2	1min 21 seconds

* Cumulative exposure time for 8 plumbing locations, resulting in 16 sites that were opened, capped, uncapped, and remated.

Risk analysis after aseptic activity

One colony detected in active air sampling during aseptic activity

DNA sequencing identified *Staphylococcus epidermidis*

Parameters	Expected	Measured	
Settling Rate (0.5 µm)	8.80E-05	8.80E-05	m/s
ISO Class	5	4	
Particles (0.3µm)#/m3	10176	1018	particles /m^3
Particles/cfu	1.76E+04	2.04E+02	particles/cfu
Active Sample Volume	0.2	0.2	m^3
Particles in sampled volume	2035	204	particles
Viable particles in sampled volume	0.116	1	viable particles
Exposure Time	30	17	Seconds
Critical Surface Area	0.0106	0.0106	m^2
Particles in settled volume	2.85E-1	1.61E-2	particles
Viable fallout	1.62E-5	7.91E-05	viable particles
Acceptable limit	6E-4	6E-4	viable particles

Summary: After DHMR, care must be taken to prevent recontamination of the sample path.

- Aseptic operations involves:
  - Cleaning ISO 5 work space with biocides
  - Verification of low bioburden
  - Sterile tools and garments
  - Careful attention to movements of operators to prevent contact transfer
  - Bioburden and particle monitoring during the activity
  - Limited exposure time of sample path
- Microbe detection during aseptic activity
  - Use fallout analysis to determine the probability of compromising 0.03 spores/m2 requirement
- Costs of aseptic activity
  - Time: ~1 week per activity
  - Logistical complexity
  - Increases overall risk to meeting PP requirements

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