



## Cell Culture Module (CCM)

June 2009

# The Company

- Tissue Genesis, Inc.
  - Honolulu, Hawaii
- Regenerative medicine company
  - Point-of-care solutions to recover and deliver adult stems cells in one hour
  - Translational R&D and enabling technologies
- 28 employees
  - 4 PhDs, 3 MDs, 4 Engineers, 5 Bioengineers
- Maintain core competency in cell culture and perfusion technology, including support of the Cell Culture Module (CCM) hardware system

# TGI CIS

(Cell Isolation System)



TGI Quality System: KEMA Certified  
ISO 9001:2000 (Dec. 2008)  
ISO 13485:2003 (Dec. 2008)



# TGI Cell Isolation System

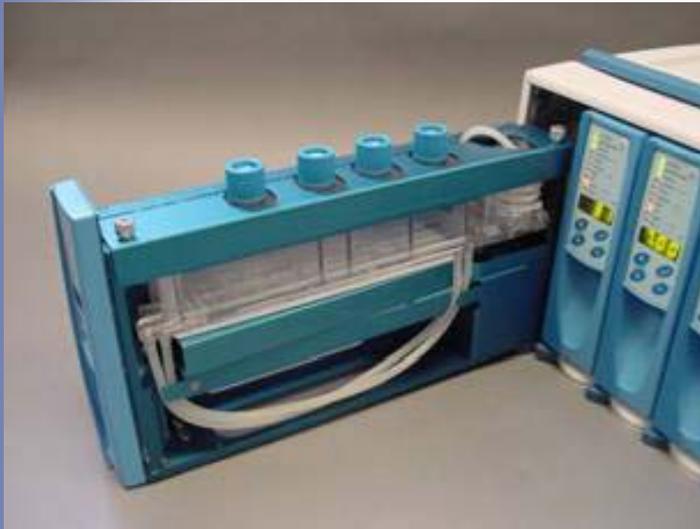


# TGI CIS

## GMP Manufactured



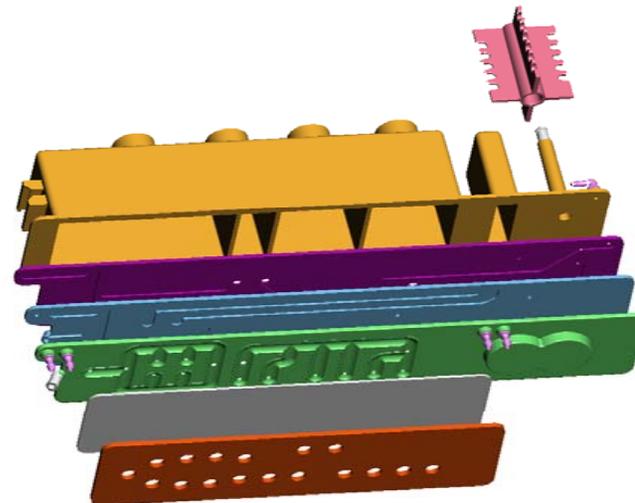
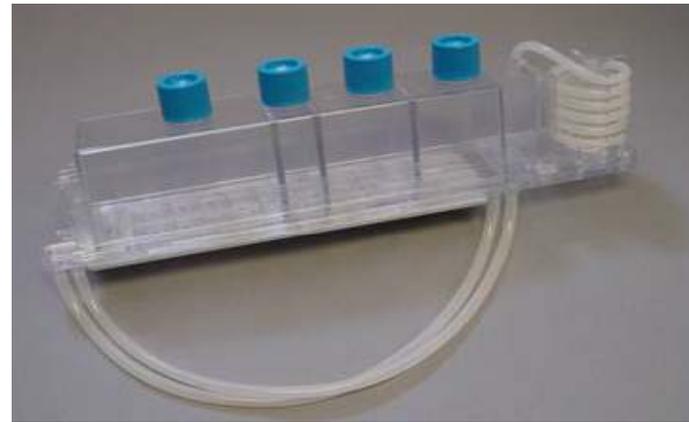
# BOS – Docking Station



# BOS

## Disposable Flowpath

- Reservoirs
  - Media (2)
  - Media Additive
  - Media/Sump
- Valving Matrix
  - Low Residual
- Sampling / Inject Port
- Gas Exchange
- Integrated 2-150 ml/min. pump
- 30 flow states



# Walter Reed Army Institute of Research (WRAIR)

- WRAIR is the flagship laboratory for the Army Medical Research and Development Command
- Designed and built the CCM hardware
  - Star Wars Program
- DoD Space Test Program
  - Flight integration and safety
- WRAIR/NASA/NIH-C series of cell culture experiments
- STS-131

# Flight History

<b>CCM</b>	<u>Designation</u>	<u>Mission</u>	<u>Date</u>
	STL 1	STS 45	Mar. 1992
	STL 2	STS 53	Dec. 1992
	STL 3	STS 56	Apr. 1993
	STL / NIH.C 1	STS 59	Apr. 1994
	STL / NIH.C 2	STS 66	Oct. 1994
	STL / NIH.C 3	STS 63	Feb. 1995
	STL / NIH.C 4	STS 69	Sep. 1995
	STL / NIH.C 5	STS 72	Jan. 1996
	STL / NIH.C 7	STS 77	May 1996
	CCM / NIH.C 6	STS 80	Nov. 1996
	CCM / 01	STS-86	Sept. 1997
	CCM / NIH.C 8	STS-95	Oct. 1998
	CCM-C / 02	STS-93	Jul. 1999
	CCM	STS-118	Aug. 2007

<b>STL-B</b>	<u>Designation</u>	<u>Mission</u>	<u>Date</u>
	STL	STS-59	Apr. 1994
	STL	STS-70	July 1995
	STL	STS-78	June 1996
	STL	STS-93	Jul. 1999

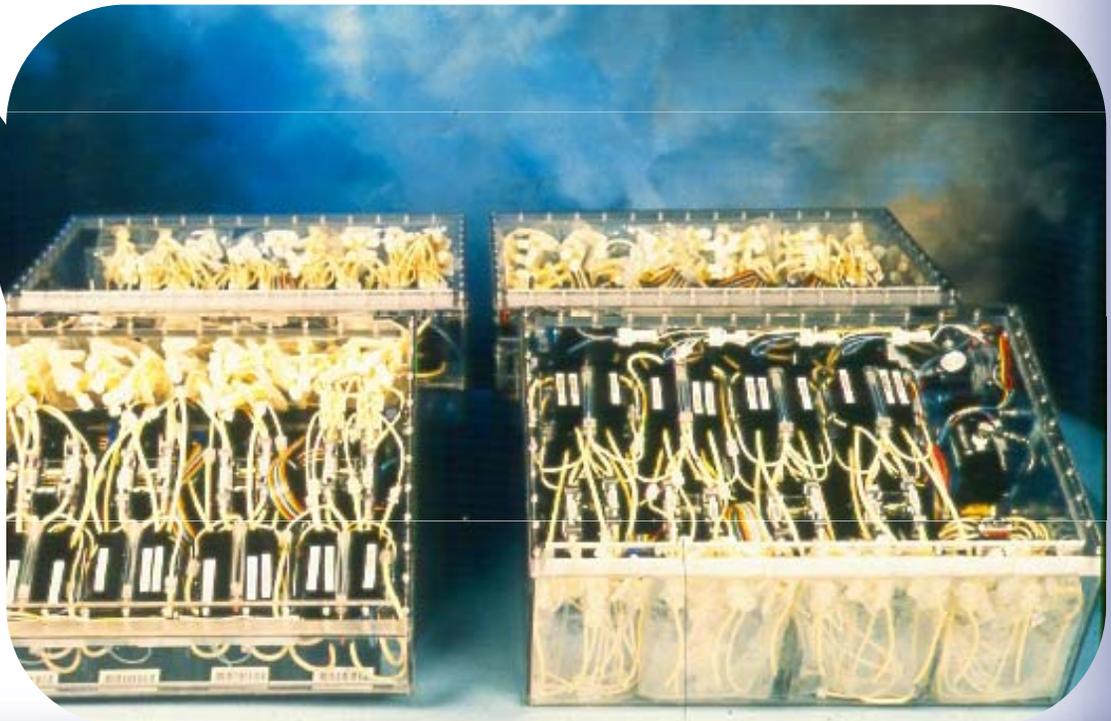
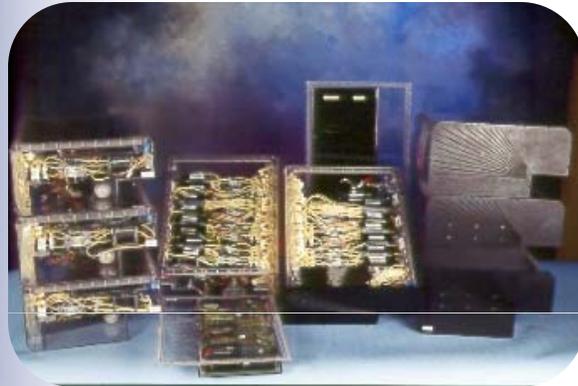


# CCM-C



# CCM

## Secondary Containment



# CCM

## Biology Requirements

- Nutrient Media
- Temperature Control
- Gas Exchange System
  - 20% Oxygen for metabolism
  - 5% CO<sub>2</sub> for pH control
- Substrate on which to Grow
- Sterility
- Biocompatibility

### Temperature Controls

37°C CCM-A

37°C CCM with  
4°C Cooling Chamber

# Bioreactor

- Sizes and Cell Capacity
  - 7 ml             $10^6 - 10^8$
  - 2.2 ml         $10^5 - 10^6$

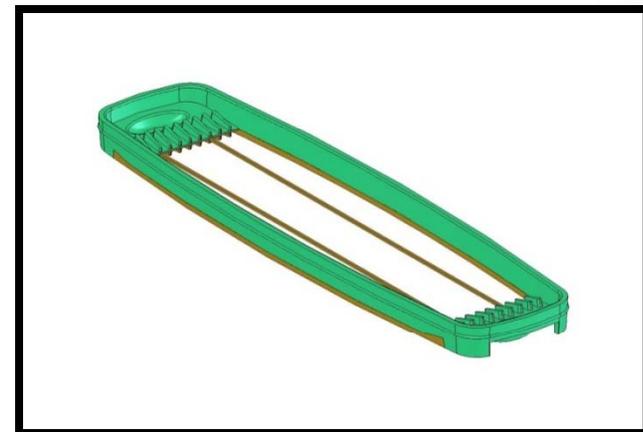
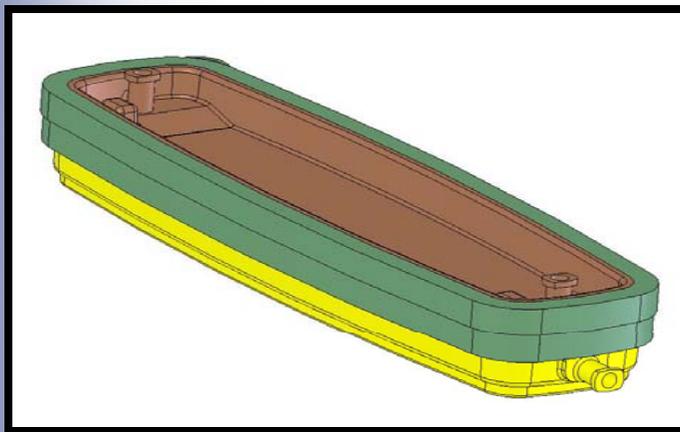


The cells are housed in hollow fiber bioreactors (cartridges) manufactured by Spectrum. The cells grow on and around a network of artificial capillaries which are perfused with an oxygen rich nutrient medium

# TGI

## Dual Function Chamber

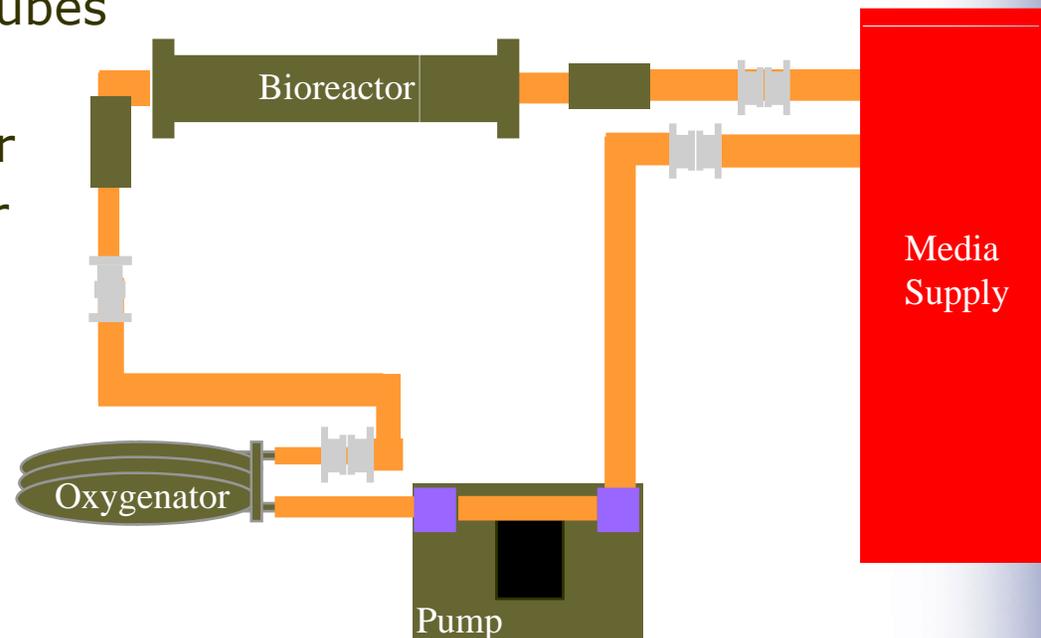
- Static and Perfusion Culture
  - Petri dish access
  - Gladware seal for perfusion
  - Easy open for biology processing
  - Multiple inserts with optimized flow distribution through the flatbed



# CCM

## Flowpath

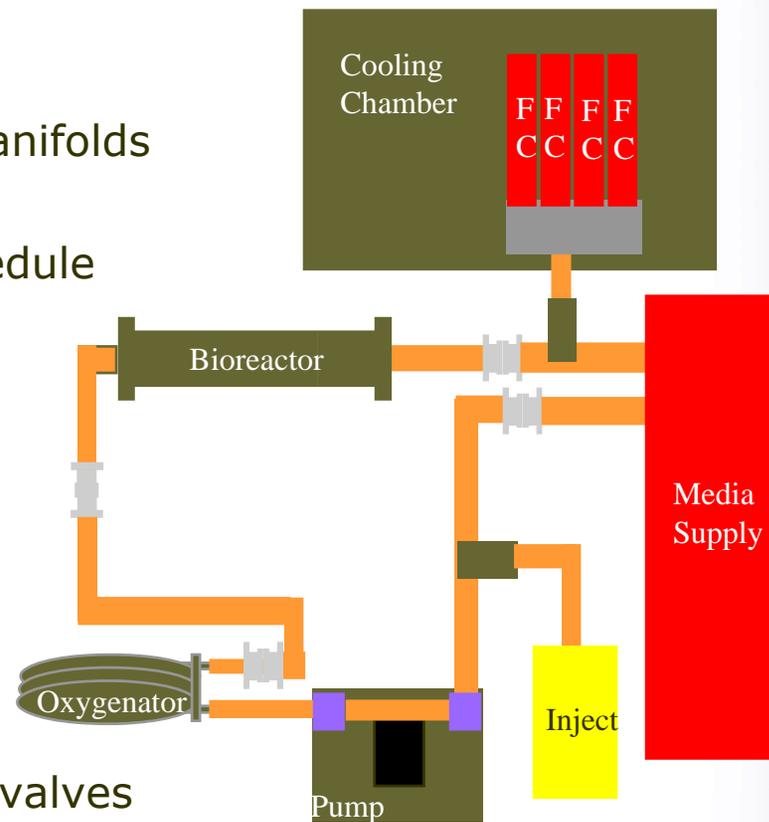
- Up to 24 individual flowpaths
- Media/FlowPath
  - Media Reservoir
  - Routing Tubes
  - Pump
  - Oxgenator
  - Bioreactor



# CCM

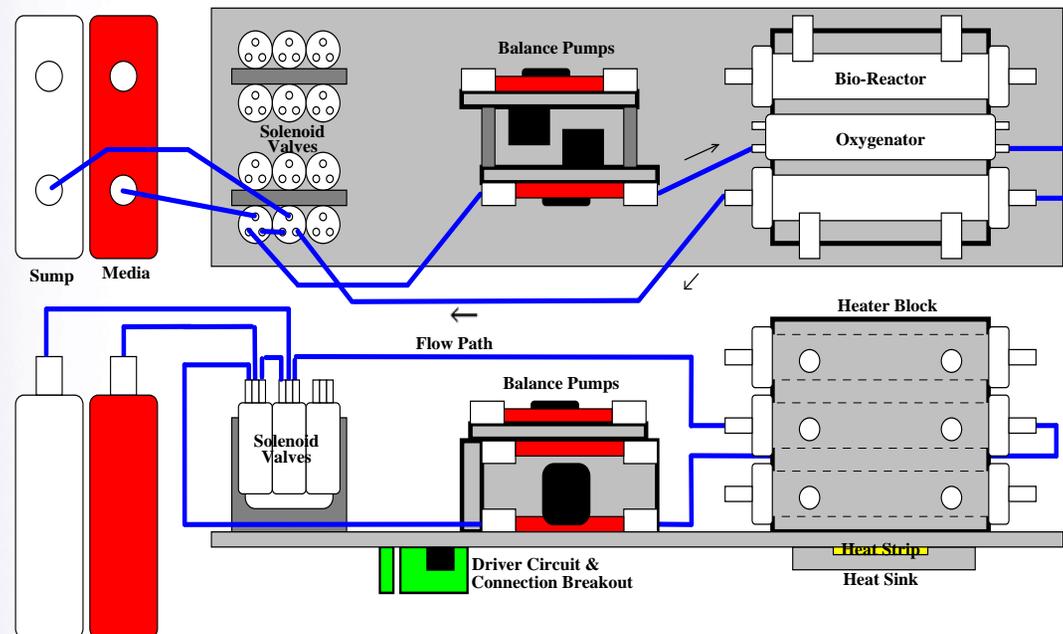
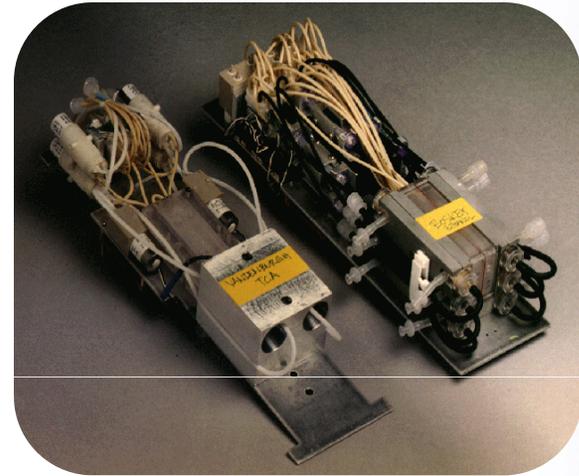
## Experiment Utility

- Fraction Collection
  - Components
    - Solenoid valve manifolds
    - Collection bags
    - Programmed schedule
- Fluid Injection
  - Fresh Media
  - Chemical Fixatives
  - Radioisotope Labeling
  - Components
    - Solenoid diverter valves
    - Fluid/Sump bags



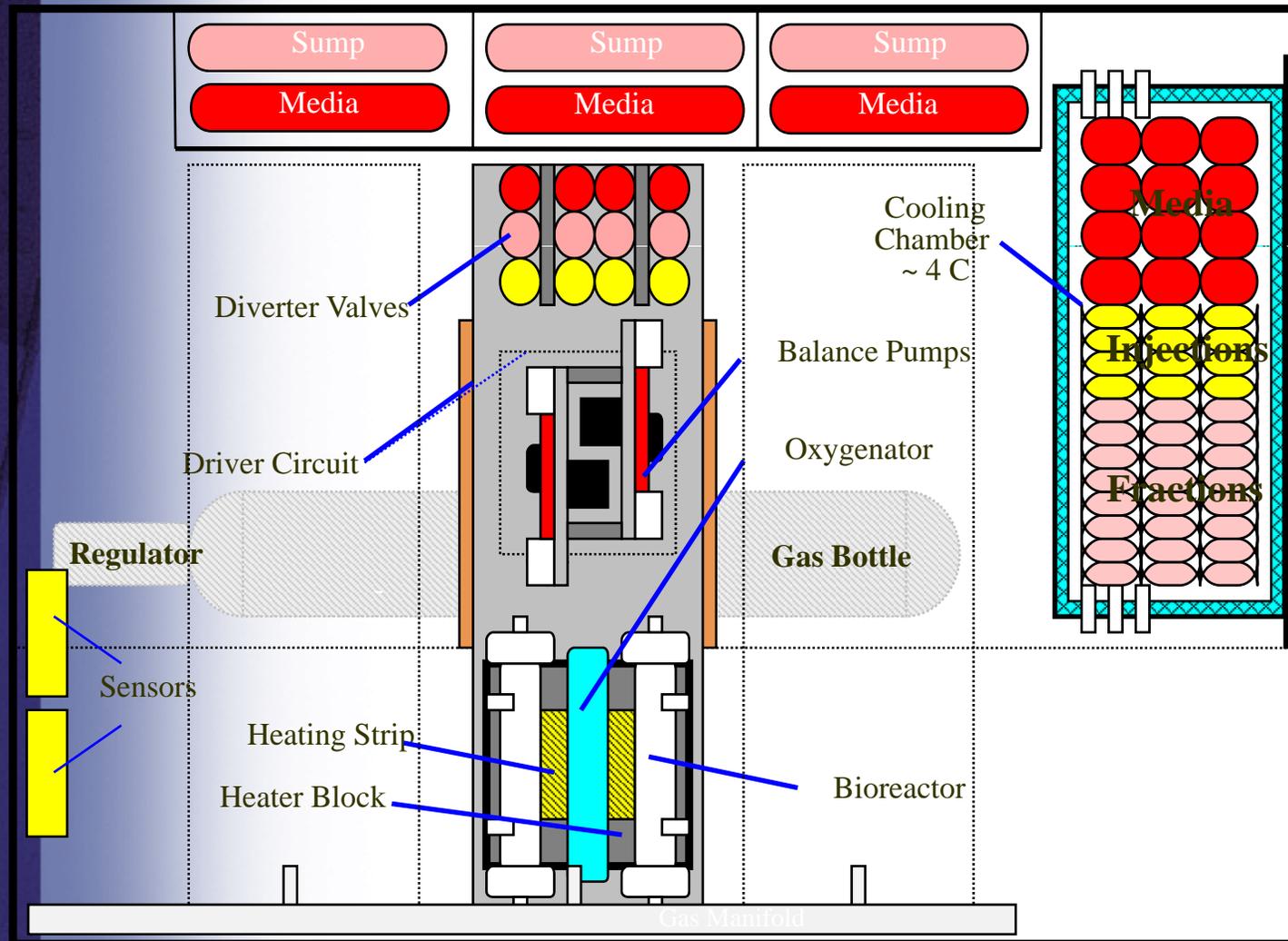
# The Rail

- Thermal Control
- Organization Level



# CCM-C

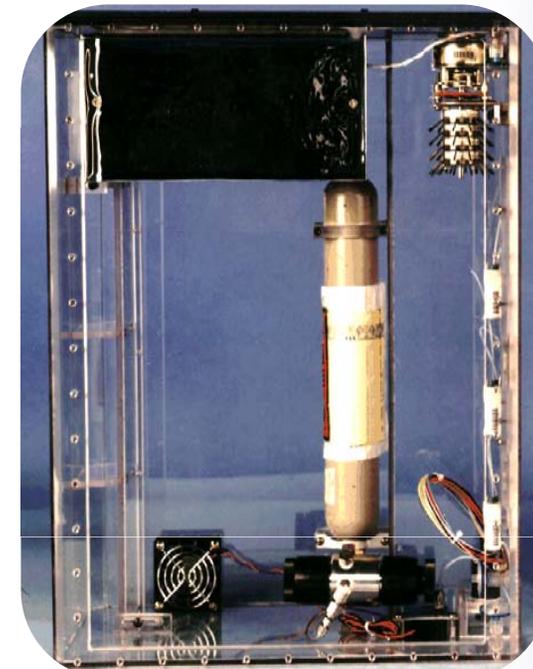
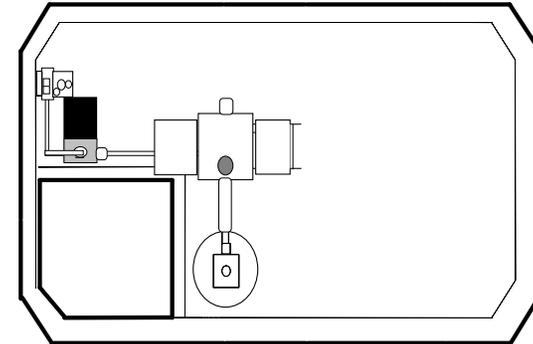
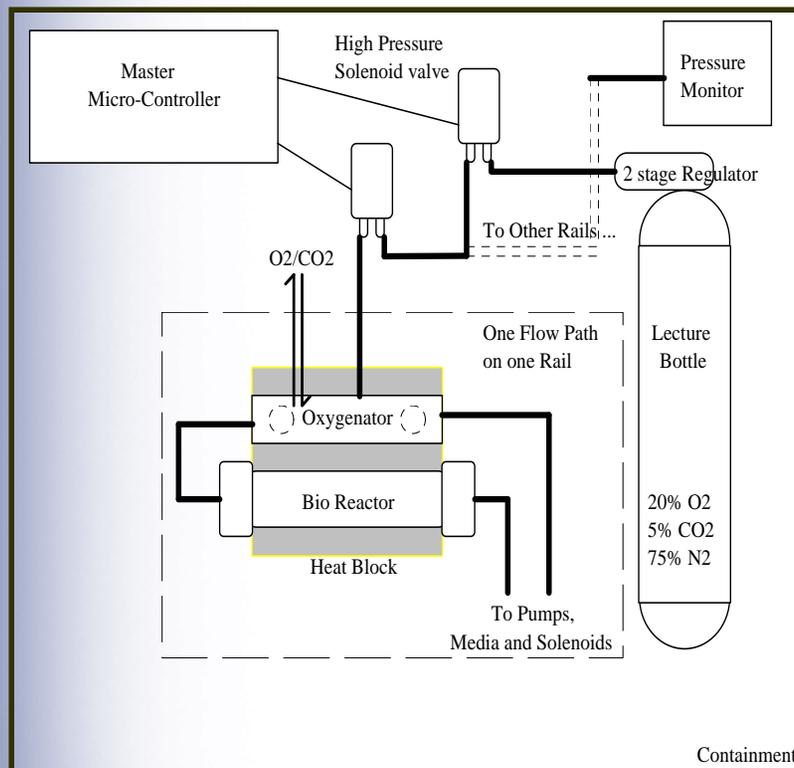
## System Layout



# The Rail

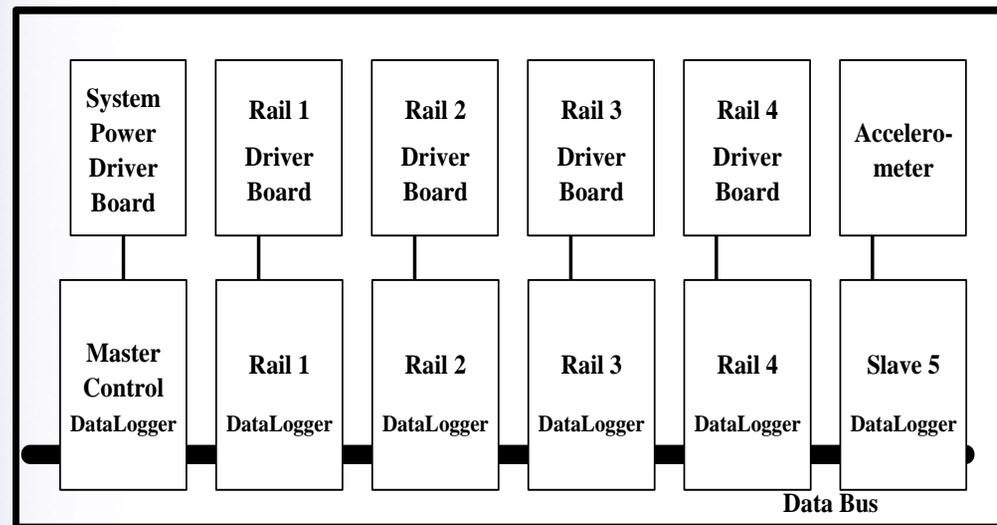
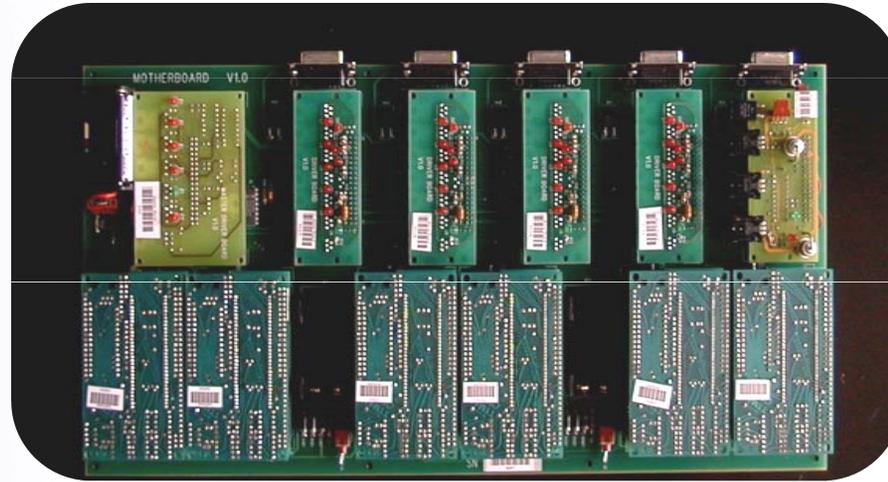
## Gas Delivery System

- Regulated Delivery
- Pressure Monitoring



# The Rail

## Electronics Compartment



# Integration & Safety

CCM Pre-Flight



## STS-95: CCM in the Middeck

