Headquarters Air Combat Command

Field Intravenous Fluid Reconstitution (FIVR)

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Medical Modernization Division
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UNCLASSIFIED

Overview

- **Purpose: Discuss the operational capabilities of the FIVR device.**

- **Objective: Provide a summary of current integrated system design of the FIVR project.**

History of Field IV Systems Lessons Learned

- **Resuscitative Fluids Production and Reconstitution System (REFLUPS)**
- **Sterile Water For Injection device**

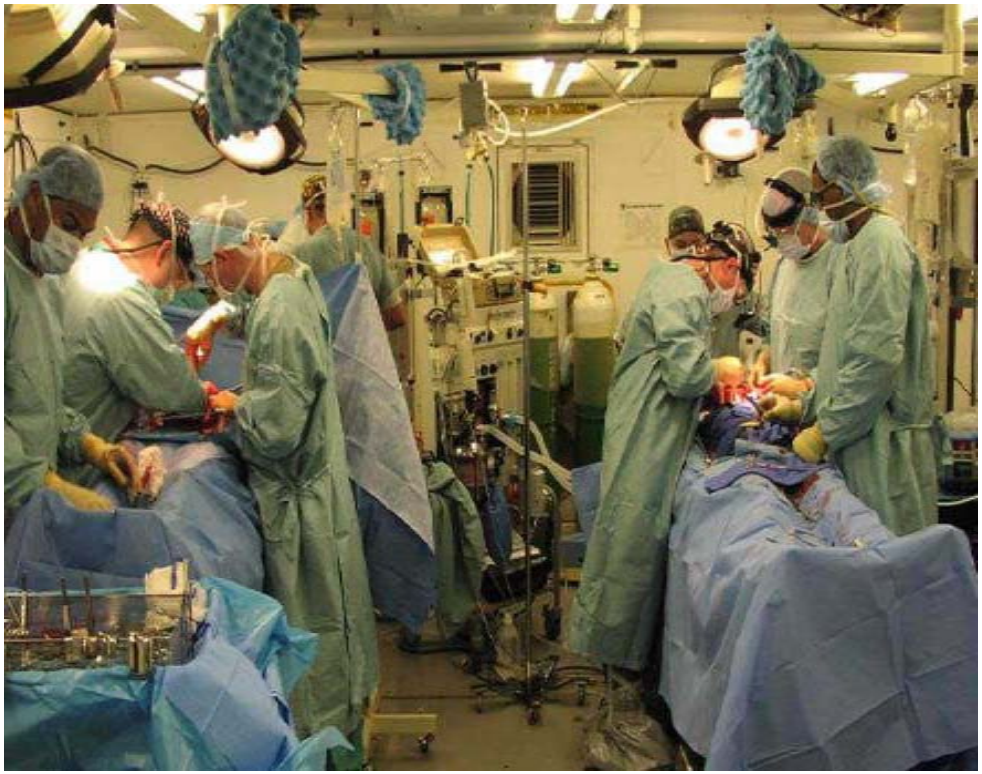
- **Lessons learned: Heat sterilization, automation, shelf life, and FDA approval**

Capability Gap

- **IV solutions are critical lifesaving drugs that are limited and nonrenewable**
- **Prepackaged IVs are 99.9% water, often transported from CONUS using valuable airlift**
- **Producing IVs at the deployed location**
  - **Increases logistical independence**
  - **Frees valuable airlift resources**
  - **Reduces forward foot print (weight and volume)**
  - **Makes deployed medical systems more expeditionary (EMEDS)**

Required Capability

- **To generate sterile water for topical use and intravenous (IV) fluids used in treatment of critical casualties**
  - **Used in forward resuscitative and field hospitalization facilities**
  - **Enhances expeditionary capability of medical first responders & initial/intermediate deployed medical treatment facilities**
- **Joint Future Capabilities: Focused Logistics & Protection**
- **Tier 1 Joint Capability Areas: Joint Protection, Joint Logistics, and Force Support.**
- **Tier 2 Joint Capability Areas: Force Health Protection; WMD Threat; Humanitarian Assistance; and Civil-Military Operations**
- **AF CONOPS: Agile Combat Support (ACS)**



Key Performance Parameters

CCJO Key Characteristics	Para #	KPP	Development Threshold	Development Objective	Rationale/ Analytical References
Expeditionary	6.1.2.1	Meets U.S. safety and efficacy standards	FDA approved with restrictions	FDA approved	DOD mandated standard of quality for medical materiel
Expeditionary	6.1.2.2	Produce IV fluids in the field	Pretreated source water complying with EPA standards derived from, STANAG 2136 water	Using any water source	Available water sources in the field environment

Force Protection/Survivability and Net Ready KPPs are Not Applicable

Key System Attributes

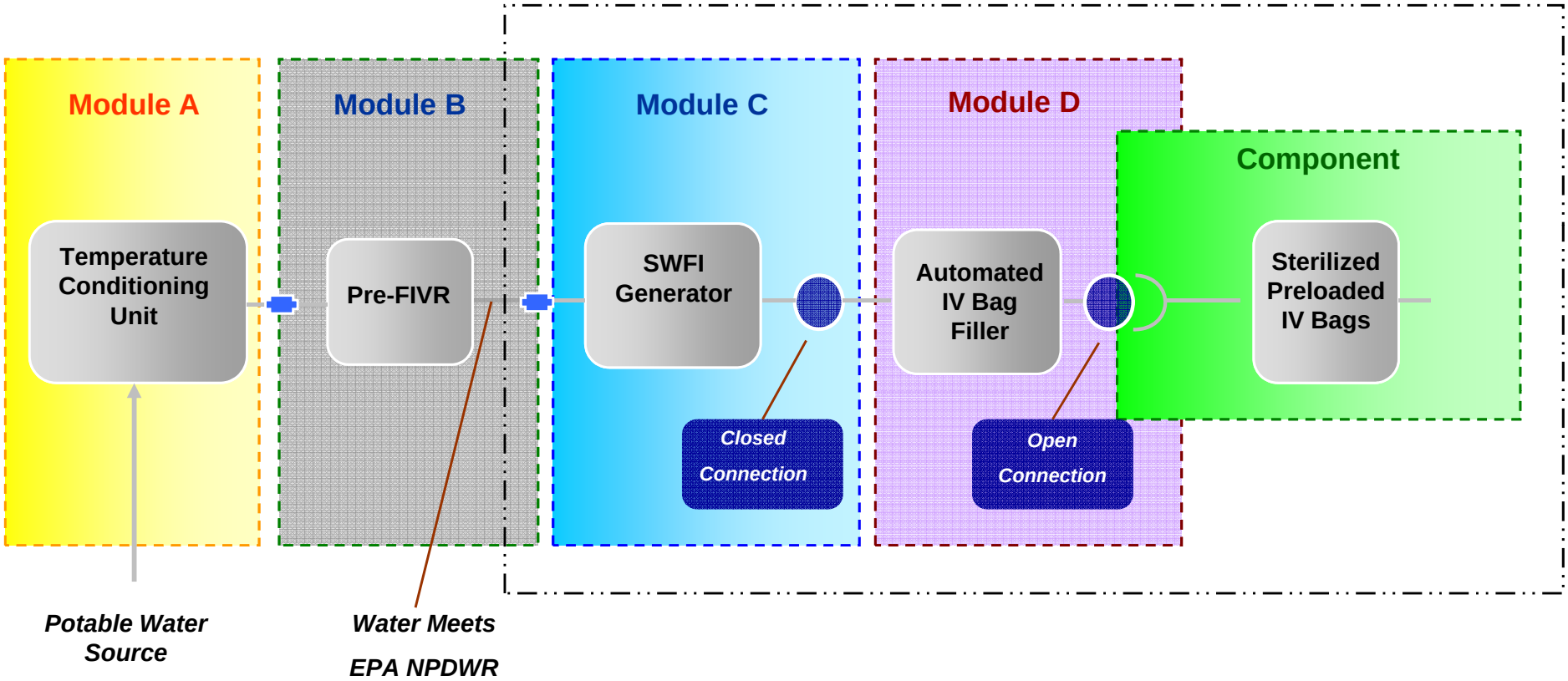
KSA	Development Threshold	Development Objective	Rationale/ Analytical References
Produce IV fluids	Sterile water for injection, Normal Saline, Ringers Lactate, D5W in Normal Saline	T=O	These fluids are essential to patient resuscitation procedures
Production Rates	10 liters/hour	20 liters/hour	Meet level II MTF needs
Waste Effluent	20%	5%	Waste effluent must be minimized in EMEDS
Prefilled bags (w/o SWFI added)	12 months	18 months	Product must be sustainable in WRM
Fluid Storage Life	1 month	6 months	4 Weeks supports minimum MTF needs
Size	20 Cubic Feet	6 Cubic Feet	Transportable on 463L pallets
Weight	120lbs (per modular component)	50lbs (per modular component)	Man portable
Power Requirements	6 KW	2 KW	Maximum power requirements

Intended Use
Make IV Solutions in the Field

Artist Rendition of Conceptual EDM Design

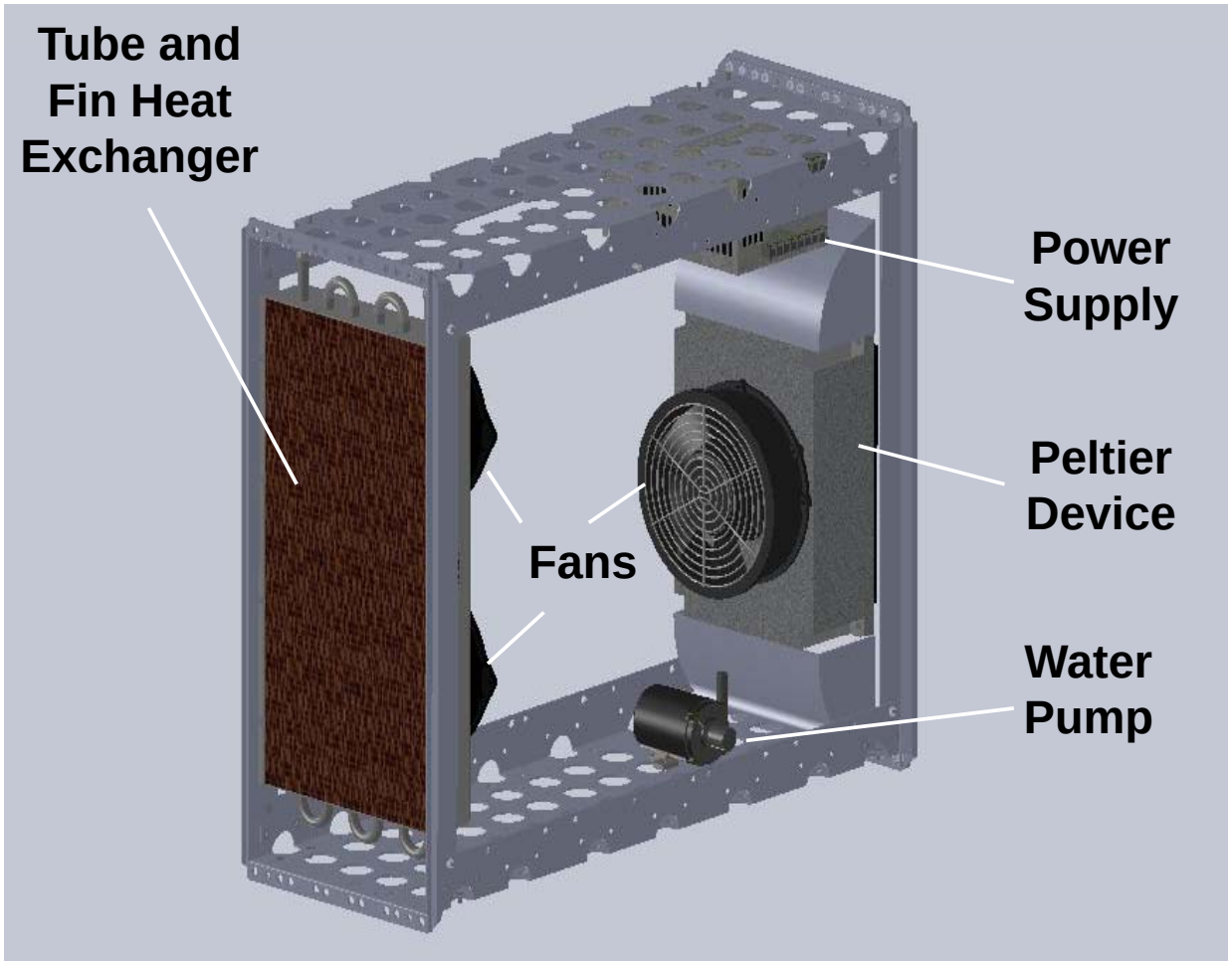
Provide FDA approved IV solutions in support of the full spectrum of deployed scenarios including wartime operations, deterrence and contingency operations, peacetime engagement, crisis response and humanitarian relief operations by trained military personnel.

FIVR – Modular Design



Temperature Control Unit Module

- Reduce potable feed water from max 140°F to 85°F
- Increase potable feed water from min 33°F to 65°F



- Cooling Capacity
  - 100W – 300W
- Weight
  - 11.9lb
- Dimensions
  - 10” X 7” X 6”
- Power
  - Power: 88W
  - Fan: 20W

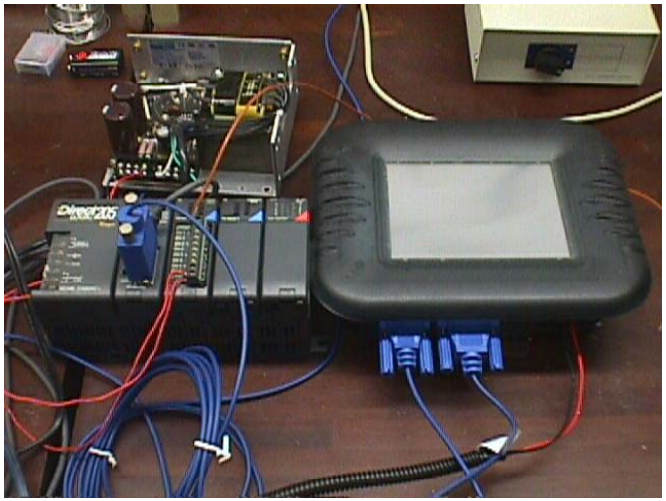
FIVR Water Preconditioner "Pre-FIVR"

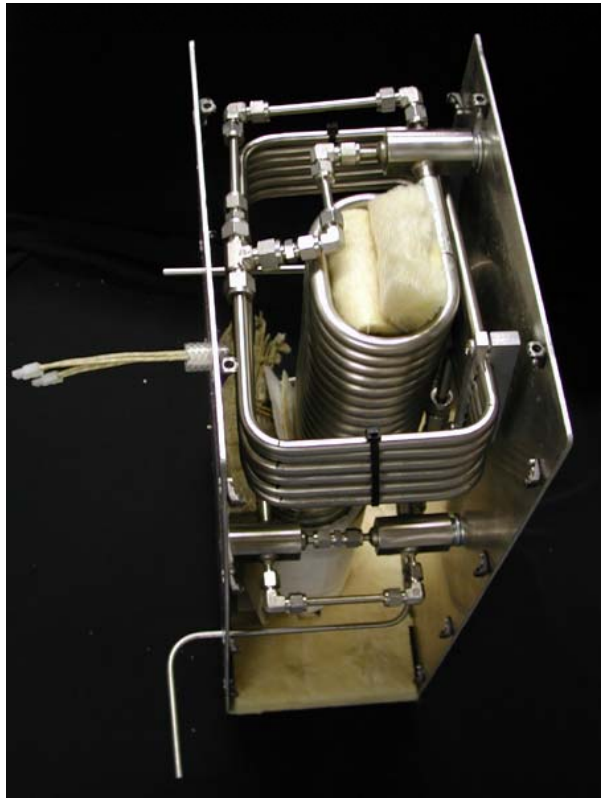
- **The Pre-conditioned component takes potable water and conditions it to Environmental Protection Agency (EPA) National Primary Drinking Water Standards**

  - **The U.S. Army Center for Health Promotion and Preventive Medicine conducted a worldwide analysis of water quality based on water test data to identify likely contaminants to potable water**
  - **US Army TARDEC, Water Treatment and Handling Team designed the test parameters, test plan, and oversaw the tests.**
  - **Commercial Off the Shelf (COTS) Reverse Osmosis Systems potable water challenge testing by the National Sanitation Foundation (NSF) International**

Sterile Water for Injection (SWFI) Generator

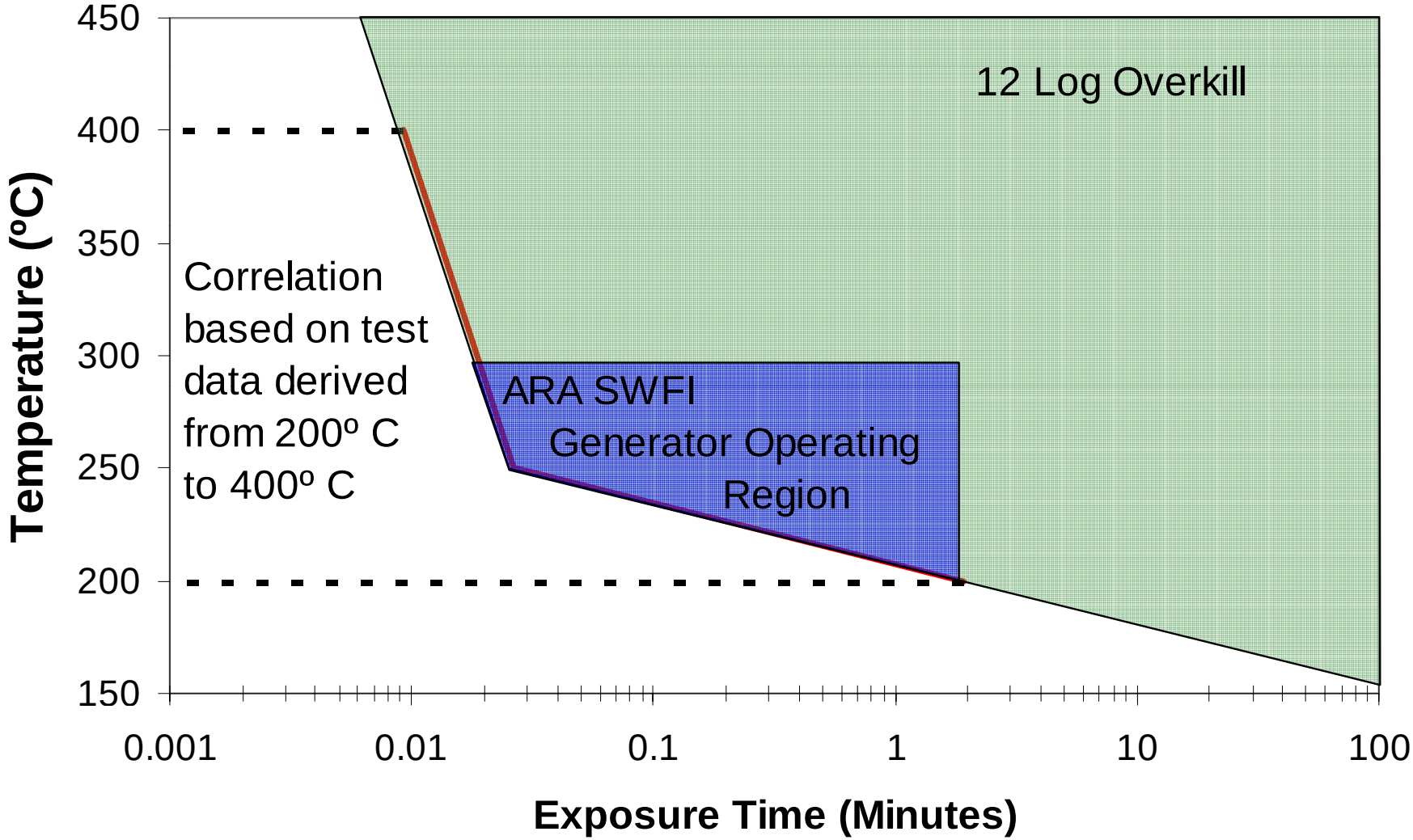
- Filtration (carbon filter/RO/IE Resin)
- Heat sterilization (hydrothermal)
- Quality Control





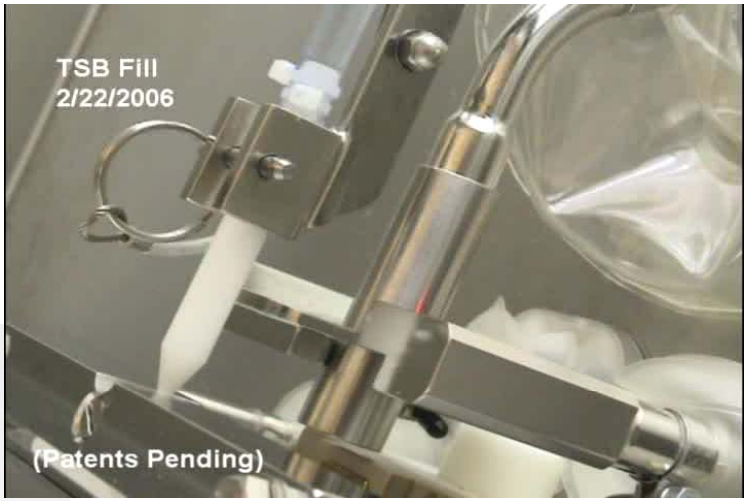
Sterile Water for Injection (SWFI) Generator

- **Design Basis for Sterilization and Depyrogenation of Water**



Components For Automation

PDC ASEPTIC FILLING SYSTEMS



Aseptic Fill

Bar Code Reader

Hot Stamp Printer

Overpouch Machine

Bag Design

- FDA compliance
- Material Selection & Testing
- Device Design Selection & Testing
- Material Compatibility
- Extractable / Leachable Investigation
- Printing Compliance / Leaching Ink
- MVTR & OTR / Influences Shelf Life
- cGMP Commercial Manufacturability
- Drug Loading / Equipment Investigation
- Leak Analysis / Barrier Integrity / Migration & Ingress
- Design with Push Port

IV Bags Preloaded With USP Powder

Half Saline

Normal Saline

D5NS

Lactated Ringers

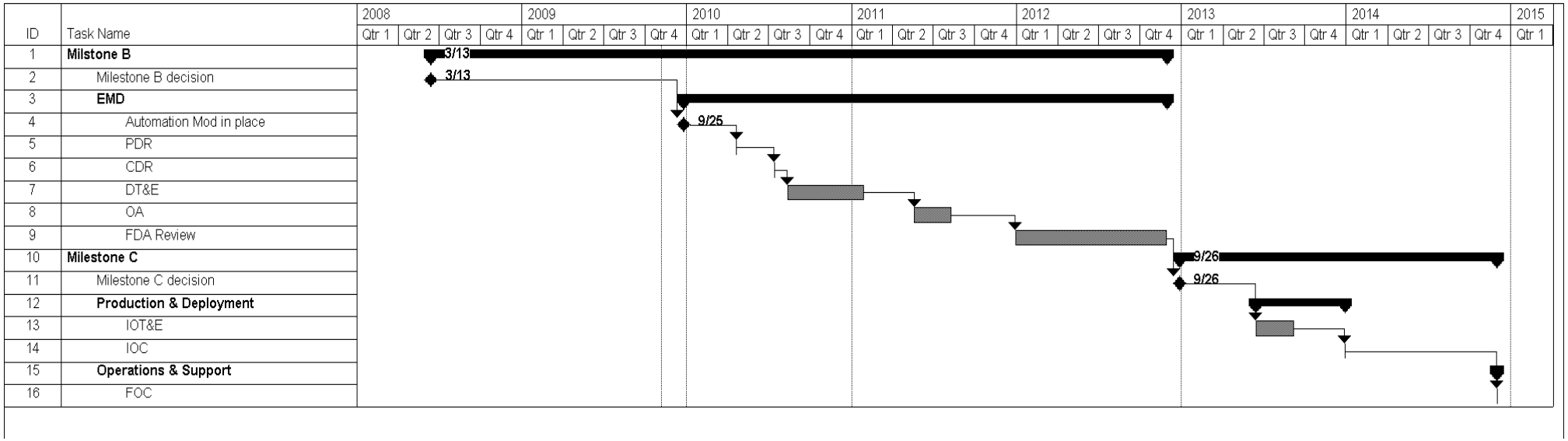
Packaging Weight and Size Savings

- **12-1 liter preloaded bags with foil overwrap and vacuum packed**
- **Shipping weight: 2.34 Lbs**

- **14-1 liter conventional IV Bags**
- **Shipping weight : 33 Lbs**

Road Ahead

- **Final Configuration**
- **Food And Drug Administration Approval Strategy**
- **Test and Evaluation**



FIVR

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