Sterile Water for Injection Generator

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Background

- Deployed medics must transport, maintain and be resupplied with liquid-based medications that are heavy, expensive to transport and may require refrigeration
- Many medicines and materials are available in freeze dried formulations that require sterile water for injection (SWFI) for reconstitution
- There is currently no portable device to produce SWFI on-demand in austere environments to ensure a consistent supply and to reduce logistical burden
- TDA is currently developing a SWFI generator to meet this objective
- The SWFI generator can be used for reconstituting freeze dried or lyophilized blood products (including plasma) and medications
- It also meets the standards for Sterile Water for Irrigation, used to clean wounds and surgical incisions to decrease the risk of infection

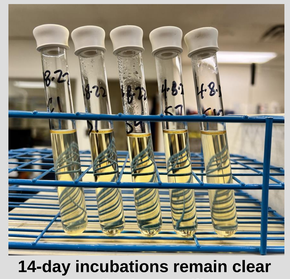
Property	USP Sterile Water for Injection	USP Sterile Water for Irrigation	3rd Party Verified Results after 20 L of Production
TOC	500 ppb	500 ppb	Pass
Conductivity	<5 µS/cm	<5 µS/cm	Pass
Sterility	No growth in 14 days	No growth in 14 days	Pass
Bacterial Endotoxins	<0.25 EU/mL	<0.25 EU/mL	Pass
Particulate Matter (10 µm)	<25 particles/mL	No requirements	Pass
Particulate Matter (25 µm)	<3 particles/mL	No requirements	Pass

Prototype

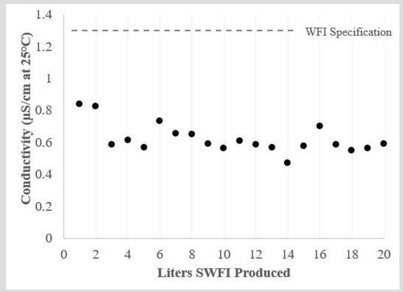
- Current design uses a powder coated aluminum housing for a light weight but very robust device
- A small screen built into the unit provides operator feedback and allows easy selection of operation mode and desired production volume
- Sorbent cartridges are easily replaced as a single unit

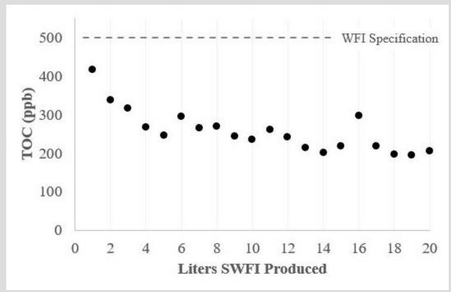
Results

- TDA's system produces water meeting the U.S. Pharmacopeia's SWFI criteria
- Testing has shown the system can produce over 30 L of SWFI without changing consumables
- System maintains sterility for extended periods of time (even in storage)



14-day incubations remain clear confirming sterility





5th generation SWFI generator trial results using tap water from TDA's Golden, CO facility

Discussion

Dimensions (W x D x H)/Cube
- 3.75" x 4.5" x 11.125" | 0.11 ft³

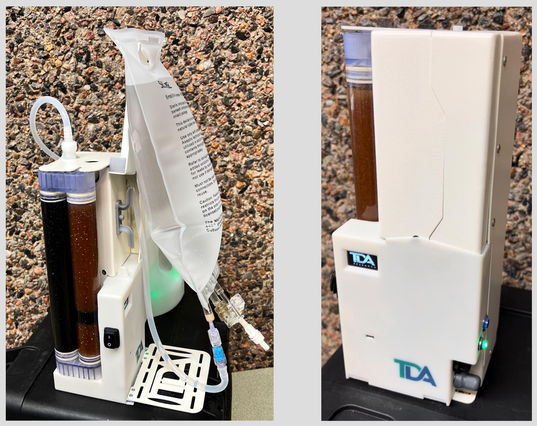
Weight
- 4.1 lb

Power Requirements
- At least 10 1L IV bags produced on a single charge (~70 minutes)
- Full charging time ~70 minutes

Lifetime and Fill Volumes
- Fills IV bags of SWFI, with multi-mode flow amounts (50, 100, 250, 500, and 1000 mL)
- System is rated to produce 1,000 L of SWFI before requiring service out of theater in a manufacturing facility.

Conclusion

- Portable sterile water generation capabilities can be used to reconstitute medications or blood products in austere locations. It can also be used in wound irrigation.
- TDA's SWFI Generator reduces both weight and volume by over 95% compared to shipping pre-filled bags of SWFI.
- TDA has submitted a pre-submission package to the FDA

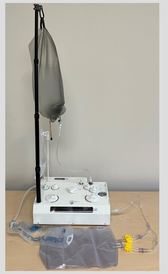


About TDA

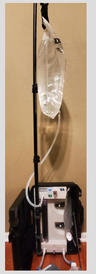
- In Business for over 30 years
  - Privately held
  - 130 employees, 30 Ph.D.'s in chemistry/engineering
  - Over $30 million in annual revenue
- Facilities: Combined 78,000 sq. ft. near Denver, CO
- Core capabilities
  - Prototype development, Medical device design and fabrication, Catalyst testing, Sorbents, Materials processing and testing, Process development
- Business Model
  - Identify opportunities with industry
  - Perform R&D
  - Secure intellectual property
  - Commercialize technology *via*
    - spin-offs
    - licensing
    - joint ventures
    - internal business units

RediSter Chemical Sterilant

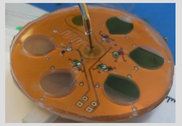
Oxi-Floc™ Non-Halogenated Water Disinfectant



On-Demand Dialysate Generator



Lactated Ringer's Solution Generator



Flexible Smart Sweat Sensor Patch for Real-Time Analysis

Medical Oxygen Generation System, referred to as the Expeditionary Portable Oxygen Generation System (EPOGS)