



On-Demand, Portable Dialysate Generator

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Introduction

- Acute kidney injury (AKI) is a common complication of severe trauma, and it is critical for these patients to have rapid access to dialysis treatment to improve their likelihood of survival
- Future near-peer conflicts will render evacuation from theatre impossible or impractical (the standard of care in recent conflicts)
- Battlefield hospitals often do not have access to the large volumes of dialysate required for treatment (up to 100 L/patient per day)
- To avoid the high logistical cost of shipping aqueous solutions to battlefield locations and to ensure that access to dialysate is not interrupted during combat operations, it would be preferable to produce dialysate on-demand in the field using locally available water sources
- TDA is developing two light weight devices to produce dialysate on-demand using locally available potable or non-potable water sources
 - A non-powered device for austere, power-limited environments
 - An electrically powered, automated device with reduced energy consumption and size/weight compared to existing dialysate production equipment (funded by USAMRDC through an MTEC MPAI award)

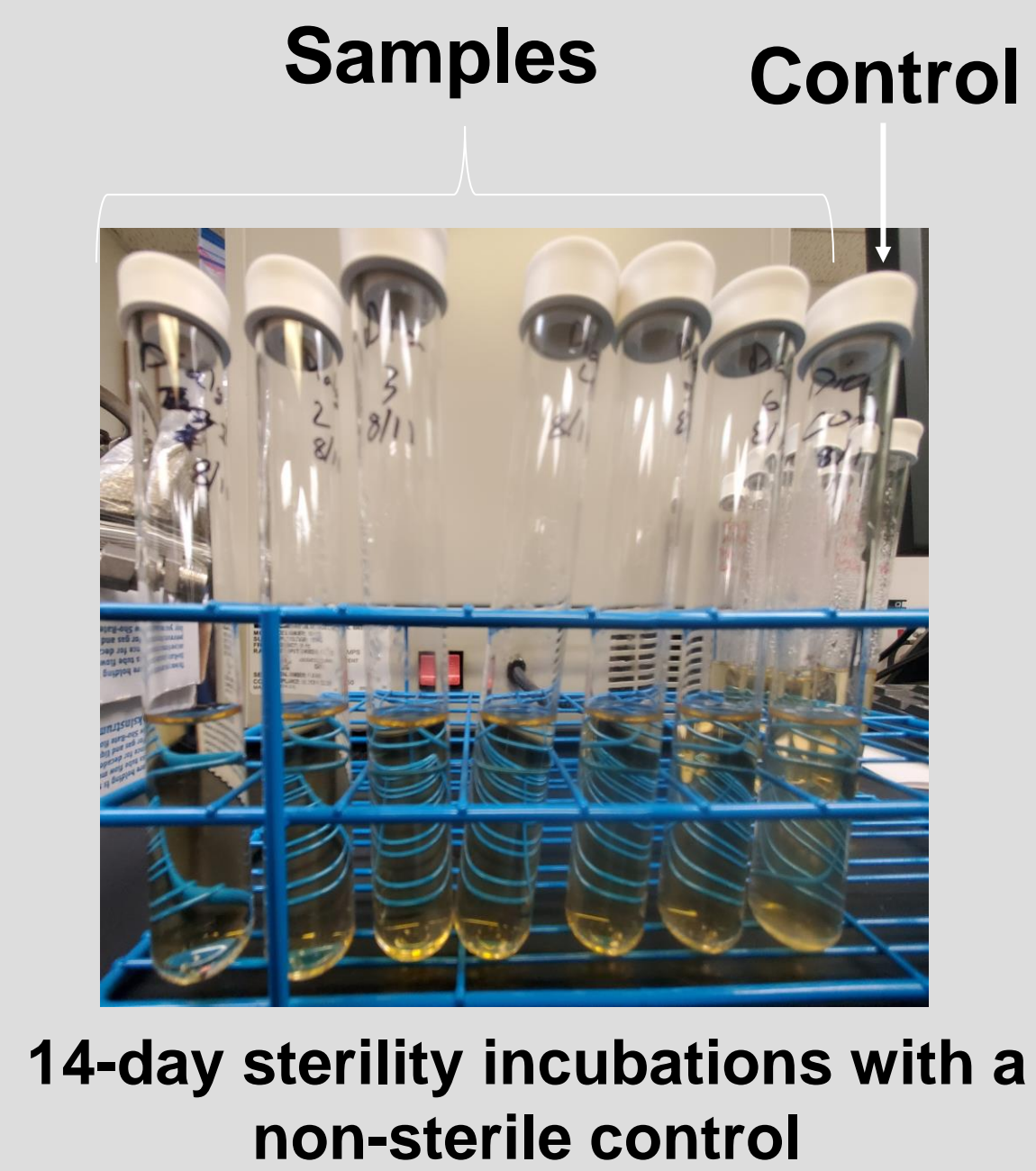
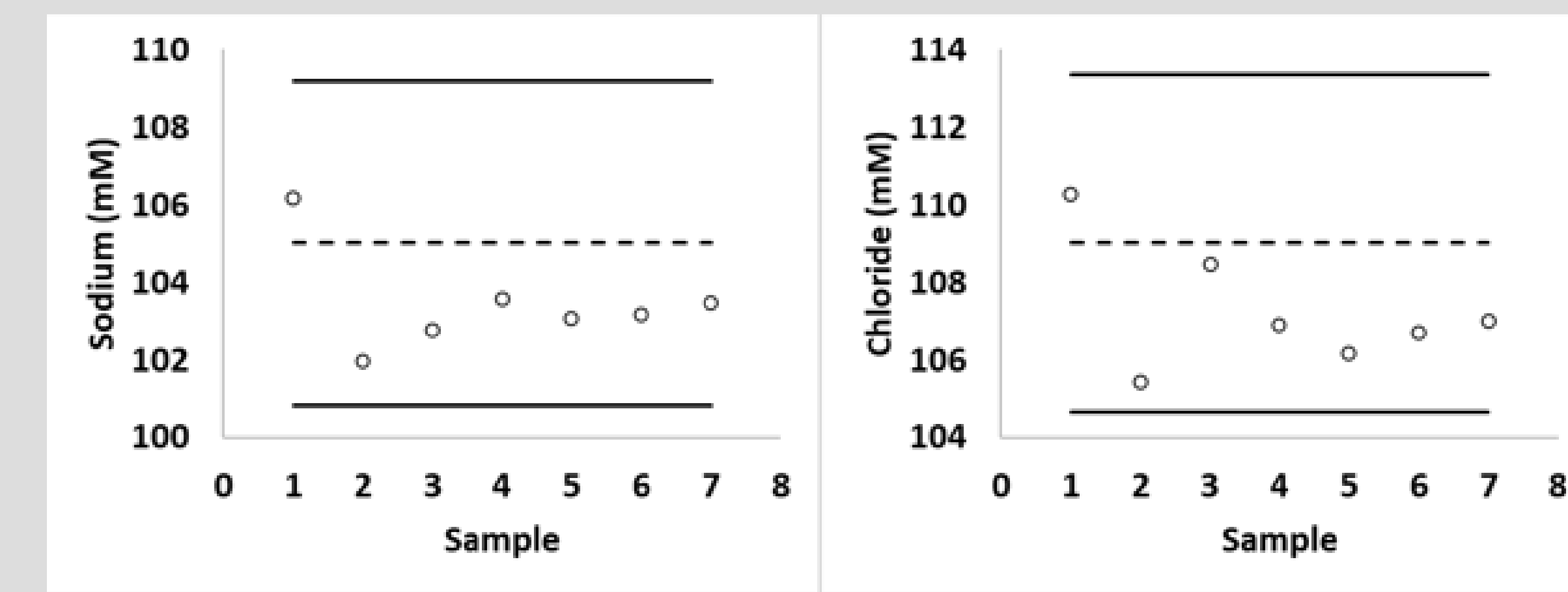
Methods and Materials



- Sheet metal housing with clearly labeled valves and ports
- 25:1 reduction in shipped liquid volume (40 mL of injection to make 1 L of dialysate)
- System is designed to work with both potable and non-potable water sources
- Produces 1 L of dialysate in < 10 minutes (144 L/day)
 - Depends on operating conditions such as feed water temperature and salinity

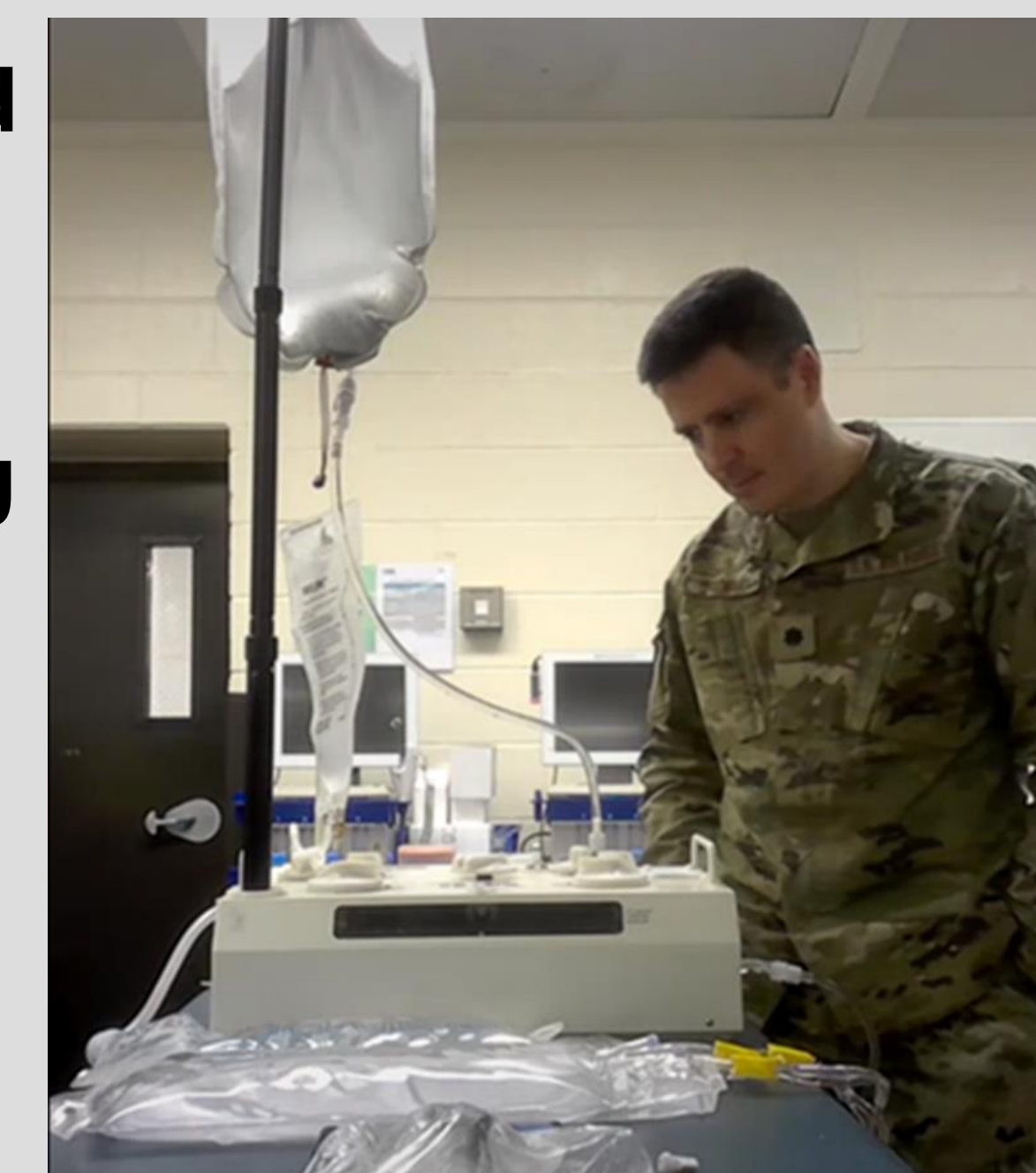
Results

- Ion testing shows that TDA's system can produce dialysate that meets the target ion composition
 - TDA is conservatively targeting a 4% margin of error around the target (dashed line)
 - For comparison, the USP acceptable margin for Multiple Electrolytes Injection (an injectable drug with much stricter standards) is 10%
- Demonstrated chlorine and chloramine removal using activated carbon in accordance with ANSI/AAMI RD62 standards
- Demonstrated production with local river water and with brackish water
- Demonstrated sterile production



Discussion

- Demonstrations have been performed with our collaborators at USU, Dr. Ian Stewart and Dr. David Burmeister
- End user feedback from USU will be incorporated into the design (e.g., updates to the labeling to make operation intuitive)
- Swine model studies are planned to begin at USU in Fall 2023 to compare dialysate produced on TDA's device with commercial Fresenius dialysate (RFP 402) in AKI models



Target Composition of TDA's Dialysate

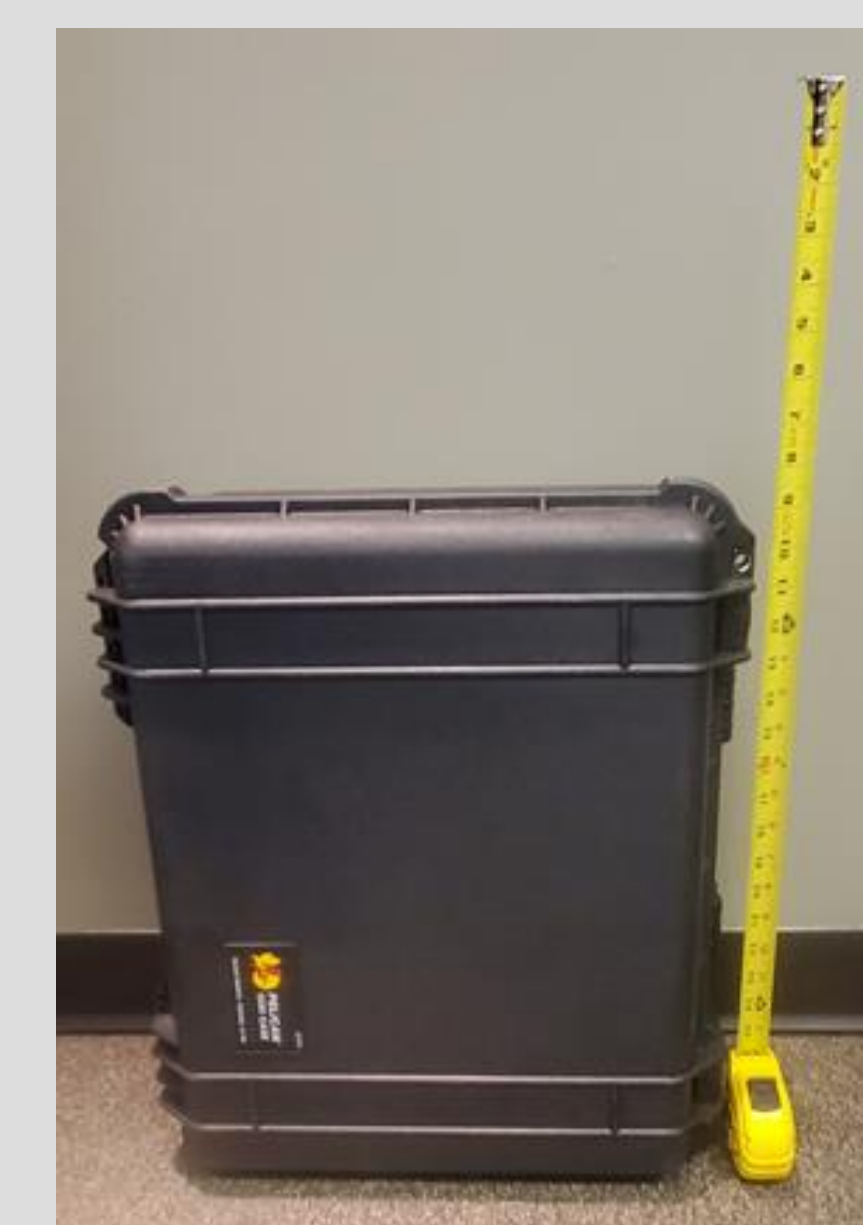
Compound	Dialysate Composition
Na ⁺ (mmol/L)	140
K ⁺ (mmol/L)	0
Ca ²⁺ (mmol/L)	1.5
Mg ²⁺ (mmol/L)	0.5
Cl ⁻ (mmol/L)	109
HCO ₃ ⁻ (mmol/L)	35
Acetate (mmol/L)	0
Glucose (g/L)	1

Dialysate will be produced into 5L bags (Liberty Cycler Drain Set) and sodium bicarbonate will be added via syringe shortly before use to avoid precipitation



Conclusion

- Portable devices for on-demand dialysate production will dramatically reduce the logistical burden of providing treatment for AKI
- TDA's system reduces the shipped volume of fluid by ~95%, massively reducing the logistical burden to provide dialysis care
- TDA has completed an initial cGMP prototype production run with our manufacturing partner, Fort Defiance Industries (FDI)
- TDA has submitted a pre-submission package to the FDA



TDA Research, Inc. Proprietary

About TDA

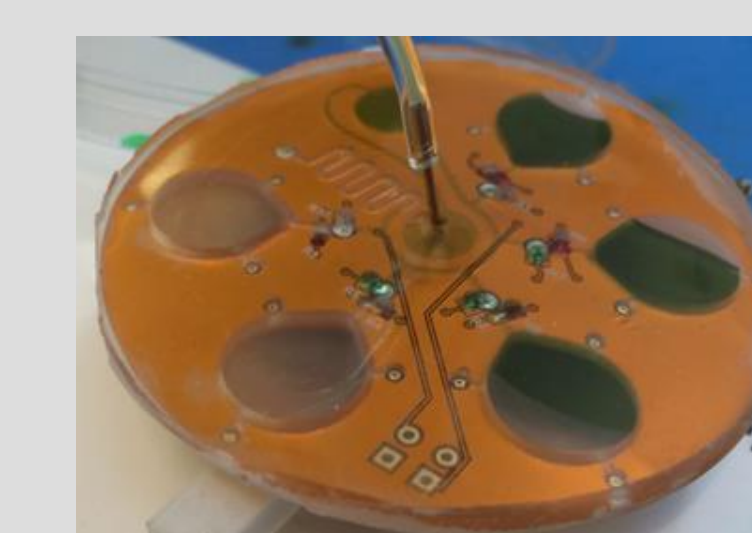
- In Business for over 30 years
 - Privately held
 - 130 employees, 30 Ph.D.'s in chemistry/engineering
 - Over \$30 million in annual revenue
- Facilities: Combined 78,000 sq. ft. near Denver, CO
- Core capabilities
 - Prototype development, Medical device design, Catalyst testing, Sorbents, Materials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



Bridge Hemodialysis Unit for Trauma Care



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)