



AN IN-SITU LABORATORY ANALYSIS CAPABILITY FOR EXPLORATION SPACEFLIGHT

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Disclosure Information

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I have the following financial relationships to disclose:

- Associate Professor, Center for Space Medicine and Department of Emergency Medicine, Baylor College of Medicine
- Element Scientist, Exploration Medical Capability, NASA Human Research Program

I will not discuss off-label use and/or investigational use in my presentation

The Need:



- NASA has identified **point-of-care medical diagnostic technology** as a critical need for future human space exploration **to enable diagnosis, monitoring, and treatment** of spaceflight medical conditions.
- An in-situ lab analysis capability will enable astronauts on deep space missions to **store, process, and analyze samples in flight** for both clinical and human research purposes.
 - Current ISS medical operations generally relies on the ability to return biological samples back to Earth for analysis using standard terrestrial lab analysis equipment.
- For Artemis missions, **there is limited to no opportunity for return mass** of samples for research purposes. Providing a capability for real-time medical research analysis could enable efficiencies in research studies, maximizing the benefit of scientific opportunities.

Key Capabilities of an In-Situ Lab Analysis Technology



Analyte Diagnostics

- Ability to analyze biological samples (blood, urine, sweat, etc.) – examples of targeted analytes:

Basic Metabolic Panel	Blood Gasses	Hematology	Cardiac	Liver & Renal	Urinalysis	Other
Glucose Calcium Sodium Potassium Bicarbonate (CO ₂) Chloride BUN Creatinine	PaO ₂ PaCO ₂ SaO ₂ HCO ₃ pH	WBC Count RBC Count HCT Hgb Neutrophils Abs. Neutrophils Lymphocytes Monocytes Eosinophils PLT	Troponin I CK BNP	ALP AST ALT Total Bilirubin Dif. Bilirubin	Specific Gravity pH Leukocytes Nitrites Proteins Glucose Ketones Bilirubin	Lactate CRP TSH, T3/T4 Lipase Magnesium PT/PTT

Software Integration

- Ability to store and integrate medical data into the overall Medical System (e.g. Electronic Health Records)

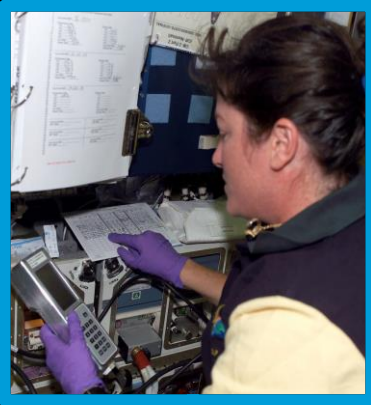
Minimally Invasive

- Minimized utilization of crew time & resources are desired (e.g. capillary stick vs. venous blood draw)
- Containment of biological waste & chemical reagent toxicity

Small Mass/Volume

- Not only size of the device, but reusability and minimization of consumables

ISS Technology Demonstrations



Portable Clinical Blood Analyzer Device:
**Abbott i-STAT & Cartridges demonstrated by Astronaut Laurel Clark during STS-107*



rHEALTH ONE:
Crew-4 Astronaut, Samantha Cristoforetti (ESA), using rHEALTH on ISS during the May 2022 technology demonstration.

2000s

2020

2021

2022

2023+



HemoCue:
ISS Inc-64 Astronaut Kate Rubins with the HemoCue® device during January 2021 operations, marking the first-ever real-time hematology performed in space!

**Enabling Progressively
Earth-Independent
Medical Operations**

HemoCue Demonstration



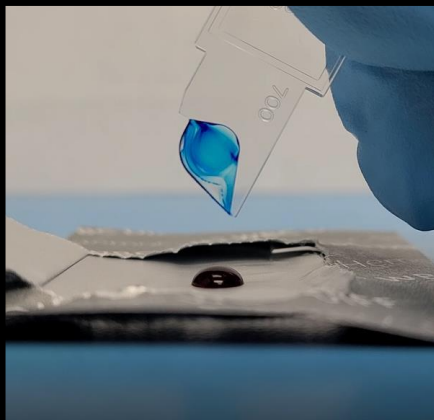
HemoCue® WBC Diff Analyzer



HemoCue® swabs
Shelf life: 1 year



Microcuvettes Shelf life: 1 year



Cuvette Filling Technique



Control Solutions
Shelf life:
~3.5 months
Cold stowage:
2°C-8°C
BSL 2M

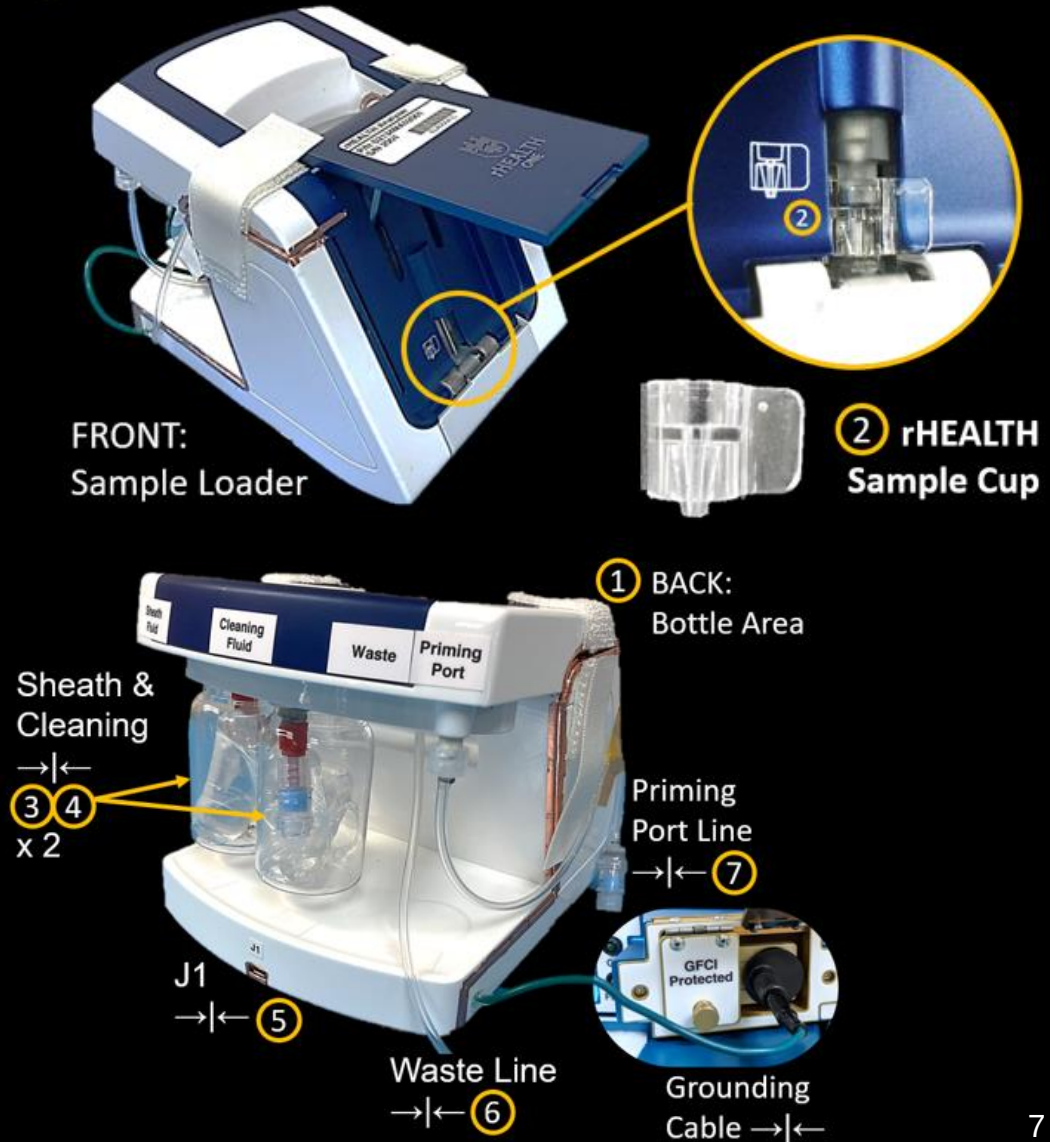
- The HemoCue device is a Commercial off-the-shelf (COTS) device capable of **analyzing total & differential WBC counts**.
 - Neutrophils, Lymphocytes, Monocytes, Eosinophils, and Basophils
- Uses an optical camera to count WBC's that have been stained with a reagent in the microcuvettes inserted into the device (Red blood cells are lysed). Microcuvettes are disposed of after use.
- **ISS Demonstration was a success (after some procedure modification)**, and included a real-time hematology demonstration in space using a finger-stick method.

rHEALTH ONE Demonstration



- rHEALTH ONE is a **miniature sheath-based flow cytometer** with fixed calibration that combines micro-fluidics and laser optics to analyze 5-10uL sample.
- In order to operate in micro-gravity, modifications were made to the COTS device to utilize a water bag design and self-sealing luer lock fittings to help prevent air bubbles which could disrupt the flow and sample collection.
- During ISS Operations, 4 control samples were tested in-flight & verified post-flight to confirm successful data collection and device performance.

① rHEALTH Analyzer



rHEALTH ONE on ISS



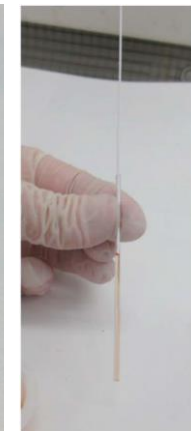
Ultra-compact Urinary Calcium Measurement Device



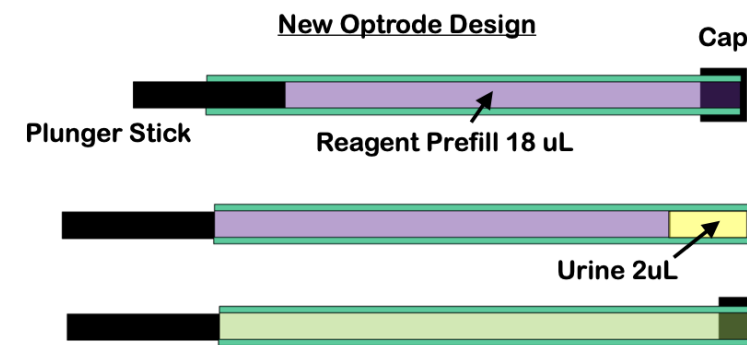
- NASA is currently funding the development of a point-of-care device to measure urine calcium concentration for proactive monitoring of kidney stone risk and bone mass changes in-flight.
- This small, compact, light-weight device uses an optrode & fluorometer to analyze an 20uL sample.
- Collection of a sample can use sequential first morning void urine testing rather than 24 hour urine collection to further simplify the testing process, operational use, & minimize crew time.
- Upcoming plans include human urine testing of 100 subjects for validation against a standard terrestrial urine chemistry analyzer



Fluorometer



Optrode



Future Plans - Market Survey & Trade Study



- **NASA has conducted market surveys & trade studies to identify technologies used for clinical lab analysis of biological samples, specifically blood & urine.**
 - The most recent market survey performed in 2019 was scoped more appropriately for the ISS operational solution space and was not fully optimized for exploration beyond low-earth orbit.

ID Number ==>>		10	17	16	30	13	12	25
Figures of Merit	Units	Absolute Quantity						
a. Device Volume	[mm^3]	1.30E+06	1.22E+06	1.01E+07	2.37E+07	3.15E+07	3.06E+07	5.07E+07
b. Device Mass	[g]	650	859	5100	6500	10944	8981	19000
c. Sample Size	[μL]	75	92	100	18	17	9.8	18
d. Power (Battery Operated?)	[yes=1 , no=0]	1	1	1	0	0	0	0
e. Quantity of required analytes	[count]	4	5	6	5	6	5	6
f. Quantity of desired analytes	[count]	9	5	4	4	1	1	0

- **Over the next 6 months, NASA will conduct a market survey & trade study for point-of-care lab analysis devices, with a specific focus on exploration-class missions**
 - Search will gather additional figures of merit related to use of consumables, shelf-life, data integration, & ease of use that were not previously evaluated
 - Search will also include lower Technology Readiness Level (TRL) devices and prototypes like those developed under previous SBIRs or grants



DISCUSSION



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