Design and development of a non-invasive optical volume measurement system for sepsis management

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Stanford Biodesign Model

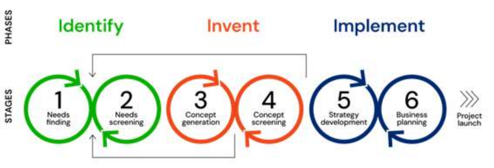

Figure 1: Stanford Biodesign Model which guided this project [1]

Background Research

Sepsis Fundamentals

- **Most expensive disease** for U.S. hospitals ($38.2 billion) [2]
- Inaccurate immune reaction to infection
- **Excessive blood clots, low blood pressure, organ failure, and death** [3]
- Around **2 million** adults develop sepsis **annually** in the U.S. [4]
- Incidence rates are significantly **higher in lower income areas** [5]
- **IV fluids** are **important aspects of sepsis treatment** [6]

Sepsis Management

Proper IV fluid (crystalloid, colloidal, and medicinal) administration is critical for sepsis patients, placing **heavy demands on medical staff**. To ease this burden, our project uses **LiDAR technology** to monitor IV volume without disrupting flow.

Existing Solutions

Examples of existing and emerging IV monitoring solutions include:

- Infusion pumps (elastomeric, volumetric, syringe) - 73% of hospitals in the U.S utilize infusion pumps [7]
- Optical measurements (IR alert, DripAssist, FIVAflow, ivWatch) [8,9]
- Capacitive sensors [10]
- Strain gauges

Existing infusion monitoring solutions **may not have continuous/remote monitoring**, and **cost ranges from $400 to several thousand** [9].

Impacts

Cultural: sepsis threatens **vulnerable individuals**, straining communities
Global: rural areas especially outside U.S. more vulnerable to sepsis
Social: assists **healthcare workload**, reduces stress, better continuous care
Economic: **accessible** device, scalable manufacturing

Design Requirements and Acceptance Criteria

Need statement: *A way to **reduce the time** spent on **active IV fluid monitoring** by health professionals to **improve the workflow** during sepsis management in **emergency settings.***

Acceptance Criteria	Required Metrics
Non-invasive	Does not interact with inside of bag
Accurate	≤ 10% volume error of 500 mL bag
Continuous Monitoring	Takes multiple measurements without additional input
Remote Monitoring	Data streamed to separate device in user interface (UI)
Prevents Interference	Identifies bag from environment
Lightweight	Below 5 lb
Inexpensive	Below $400
Proximity to IV bag	Can scan a bag 40 cm away or closer

Proof-of-Concept Prototypes

Functionalities: Conceptualization of the position of device and LiDAR scanners

Challenges:

- Arms create **too much bulk**
- Magnet-based **clamps too weak**

Figure 2: Conceptualized model

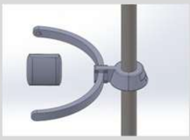

Figure 3: CAD assembly of the conceptual design

Engineering Prototype

Functionalities:
Manually **rotates LiDAR to scan object**.

Challenges:

- Current scanner **incompatible with Raspberry Pi 5**
- **Requires automated rotation**

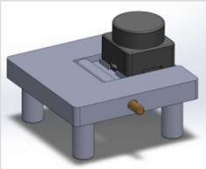

Figure 4: CAD assembly of engineering prototype.

Table 1: Required angles for a simulated LiDAR to scan a model bag (29.3 x 12 x 2.84 cm).

Distance from "bag"	Horizontal rotation angle	Vertical rotation angle
2 cm	169º	-
3 cm	150º	166.2º
4 cm	133.5º	158º
6 cm	105.3º	142º
9 cm	76.6º	123º
12 cm	59º	106º

Simulated in **Ansys Zemax OpticStudio**

Pre-Production Prototype

Functionalities:

- **LiDAR rotates horizontally** and scans object
- Converts **Spherical to Cartesian coordinates**
- **Hierarchical clustering** identifies bag
- **Volume measurement** achieved

Standards:

- ISO 13485, ISO 9001, ISO 19159, 21 CFR Part 820, ISO 5425, IEC 60601

Challenges:

- Needs to **verify the bag's position and size** before assuming symmetry
- **Needs two scanners**
- **Bulky**, with wires still exposed

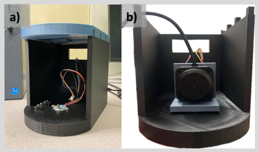

Figure 5: Engineering prototype with stepper motor and switches (a) and the mount with LiDAR scanner on top of the motor (b).

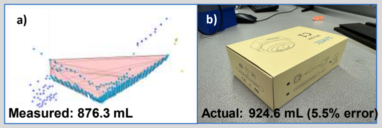

Figure 6: Example of hierarchical clustering (a) on a box (b). Volume estimated by multiplying convex hull volume by 2.

Production Prototype

Functionalities:

- Device **clamps on IV pole**
- **(1.84 lb / 0.835 kg)**
- **2 LiDAR scanners** mesh data
- Calculates volume w/ **convex hull**
- **Fan/heat sink** reduce overheating
- UI displays measurements sent over **Wi-Fi**

Challenges:

- Measurements from 30 cm
- Data point distortion from water scattering

Figure 7 (left): Final production prototype showing two scanners and clamping on IV pole (a). Display of volume calculation on UI (b).

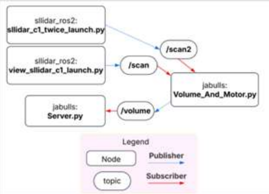

Figure 8: Flowchart of ROS2 architecture used in production prototype.

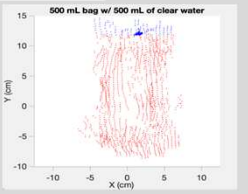

Figure 9: Example of hierarchical clustering identifying IV bag (red).

Testing

Optimal Distance Testing

Goals:

- Test accuracy at **various distances** from bag
- **30 cm was chosen** to perform measurements

Table 2: Measurements of a full 500-mL IV bag with water at different distances from the device. (n=30 for each volume)

Distance	25 cm	30 cm	35 cm
Avg Vol (mL)	670.8 ± 43.4	441.4 ± 17.1	437.5 ± 12.5
Error (%)	34.1 ± 8.7	11.7 ± 3.4	12.5 ± 2.4

Continuous Accuracy Testing

Goals:

- **Continuously monitor** volume change over time
- Analyze impact of **volume change** on accuracy

Table 3: Raw calculations of 3 volumes of water in 500-mL bag.

Volume	100 mL (n=30)	300 mL (n=30)	500 mL (n=50)
Avg Raw (mL)	119.7 ± 36.2	264.7 ± 32.6	464.8 ± 67.8
95% CI of Avg Raw (mL)	106.75-132.65	253.03-276.37	446.01-483.59
Avg Error (%)	29.6 ± 28.3	11.0 ± 6.5	10.3 ± 11.2
95% CI of Avg Error (%)	19.47-39.73	8.67-13.33	7.20-13.40

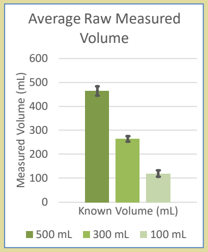

Figure 10: Comparing raw data averages (95% Confidence Intervals visualized as error bars).

Business Plan

Year:	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Revenue ($)	-	-	-	64,750	1,050,000	1,575,000	2,630,250
Manufacturing Cost ($)	-	-	-	52,000	780000	1080000	1653300
Gross margin ($)	-	-	-	12,750	270,000	495,000	976,950
Gross Margin (% of Sales)	-	-	-	20%	26%	31%	37%
Operating Expenses							
R&D Costs	424,600	265,000	847,500	450,000	289,900	215,700	220,800
% of Sales	-	-	-	695%	28%	14%	8%
SG&A Costs	-	75,500	143,000	167,200	314,500	345,900	364,100
% of Sales	-	-	-	258%	30%	22%	14%
SG&A Facility Costs	-	45,000	48,000	82,000	91,000	97,000	102,000
% of Sales				127%	9%	6%	4%
Total Operating Expenses	424,600	385,500	1,038,500	699,200	695,400	658,600	686,900
% of Sales	-	-	-	1080%	66%	42%	26%
Pre-Tax Operating Profit	(424,600)	(385,500)	(1,038,500)	(686,450)	(425,400)	(163,600)	290,050
Operating Margin	-	-	-	-	-40%	-24%	11%

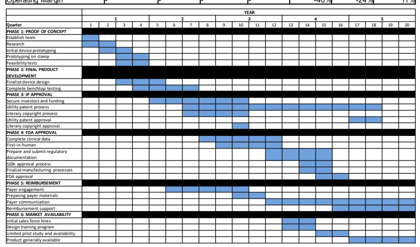

Figure 11: (Top) 7 Year Income Statement, **(Bottom)** 5 Year Operating Plan for Device

Conclusion

Acceptance Criteria	Actual Metric
Non-invasive	Scans bag's exterior
Accurate	7.20-13.40% error (500mL, 95% CI)
Continuous	Sets desired cycle number
Remote Monitoring	UI displays most recent calc.
Prevents Interference	Hierarchical clustering
Lightweight	1.84 lb (0.835 kg)
Inexpensive	$294.41
Proximity to IV bag	30 cm distance

Future Work

- Improve filtering to get results at closer distances.
- Integrate internal power.
- Update design for non-removable IV pole hooks.
- Begin clinical testing.

Contact

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