



Trine University
Biomedical Engineering

Lymphedema Physical Therapy Device

Teresa M. Ashbrook¹, Paige L. Skaff¹, Caleb P. Koob¹, Isabel M. Bowers¹, John T. Patton Ph.D.¹

¹Bock Department of Biomedical Engineering, Trine University, Angola, Indiana 46703



Introduction and Motivation

- Lymphedema is a chronic condition characterized by swelling due to impaired lymphatic drainage [1]

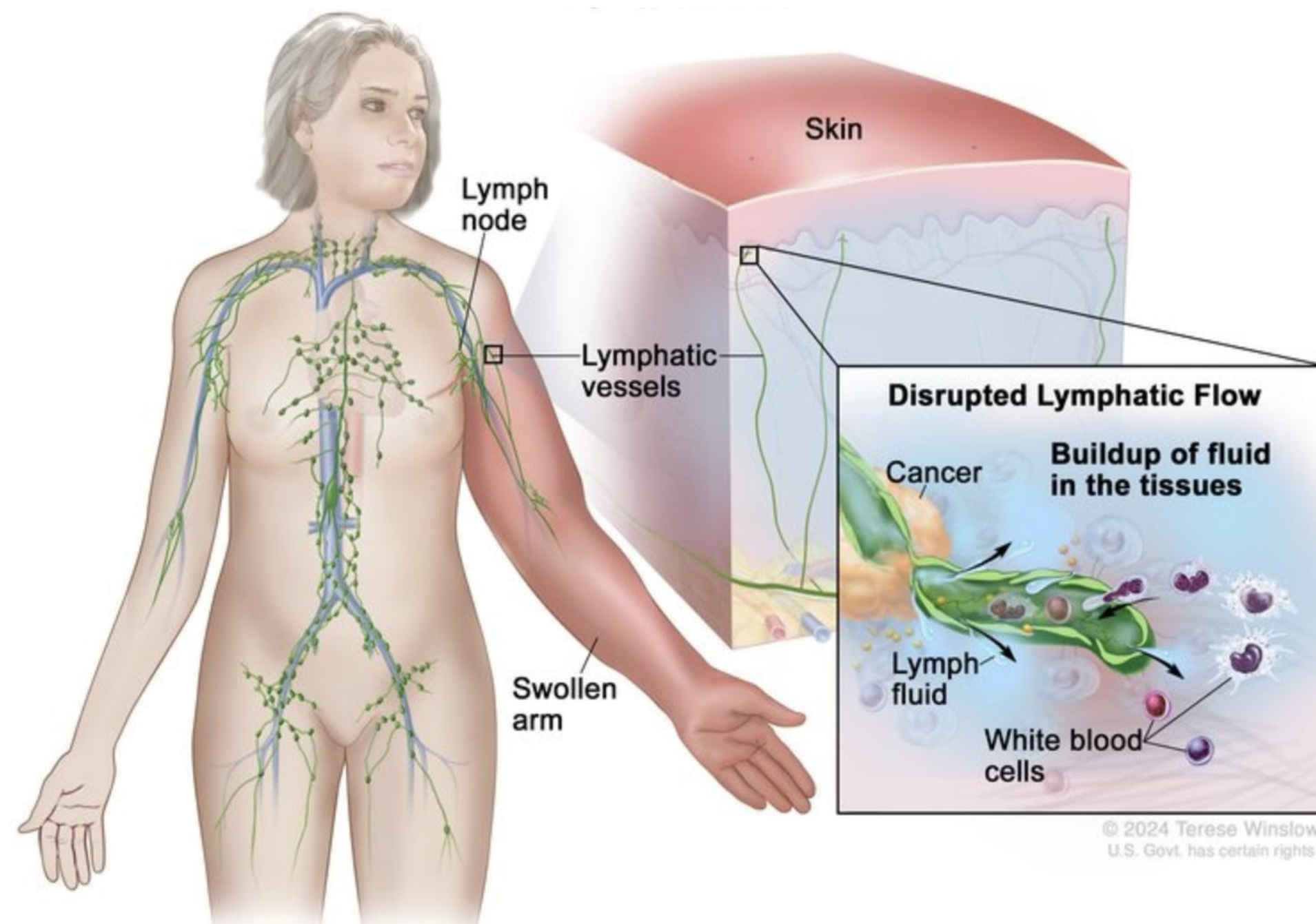


Figure 1. Diagram for the mechanism of lymphedema in the body[2]

- Affects roughly 10 million Americans because of cancer treatment, heart disease, and many other diseases [3]
- Accurate measurement of limb volume is essential for diagnosing and monitoring lymphedema
- Current manual methods of using a tape measure to measure circumference every 4 cm are time-consuming and prone to variability
- This project aims to design a durable, easy-to-clean segmented model with integrated measurement straps evenly spaced every 4 cm to automate the measurement

Device Design

Structure

- 3D printed thermoplastic polyurethane (TPU) 3x2x4 cm LEGO®-like pieces with 2.5 cm gap for straps on inner side
- Velcro on outer side for strap security
- Secondary processing is needed to remove build supports

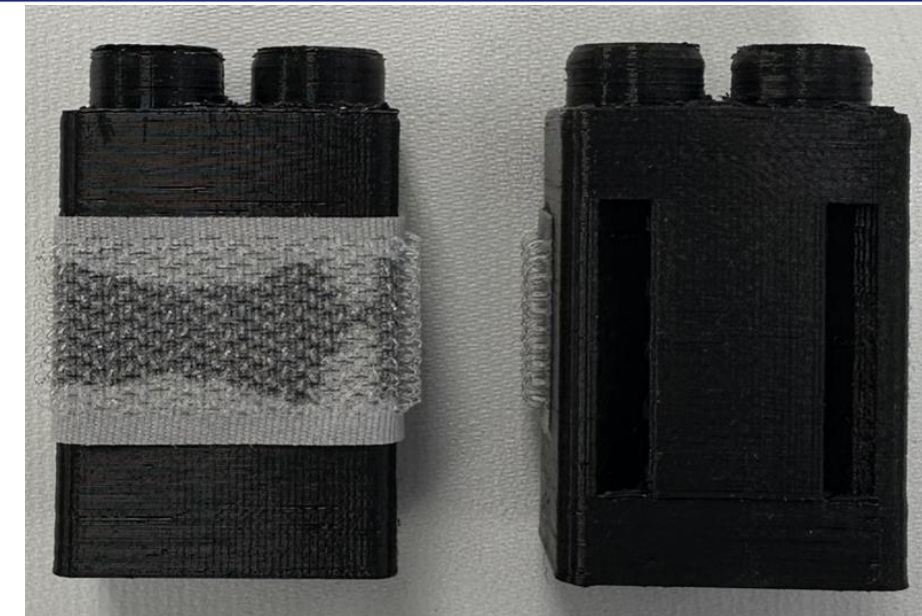


Figure 2. 3D printed TPU structured portion of Lymphametrics PT Device



Figure 3. Adjustable polypropylene strap for Lymphametrics PT Device



Figure 4. Full Lymphametrics PT Device Assembly

Straps

- Polypropylene (PP) straps with 1" D-rings and measuring tapes covered by 0.2 mm vinyl
- Six different strap length ranges
 - Smallest: 10-19 cm
 - Largest: 40+ cm

Assembly

- Straps feed through 2.5 cm gap in structured pieces spanning length of arm
- Number of necessary blocks given by:
 - Lymphametrics website
 - Dividing full arm length by 4

Website

- Built in JavaScript framework Vue.js to generate HTML (visible elements) and CSS (stylistic elements) code
- Enter patient arm length and calculate number of measurements
- Enter measurement for every 4 cm and calculate volume
- Displays total limb volume for each arm, percent difference in limb volume, and statement of likelihood of lymphedema

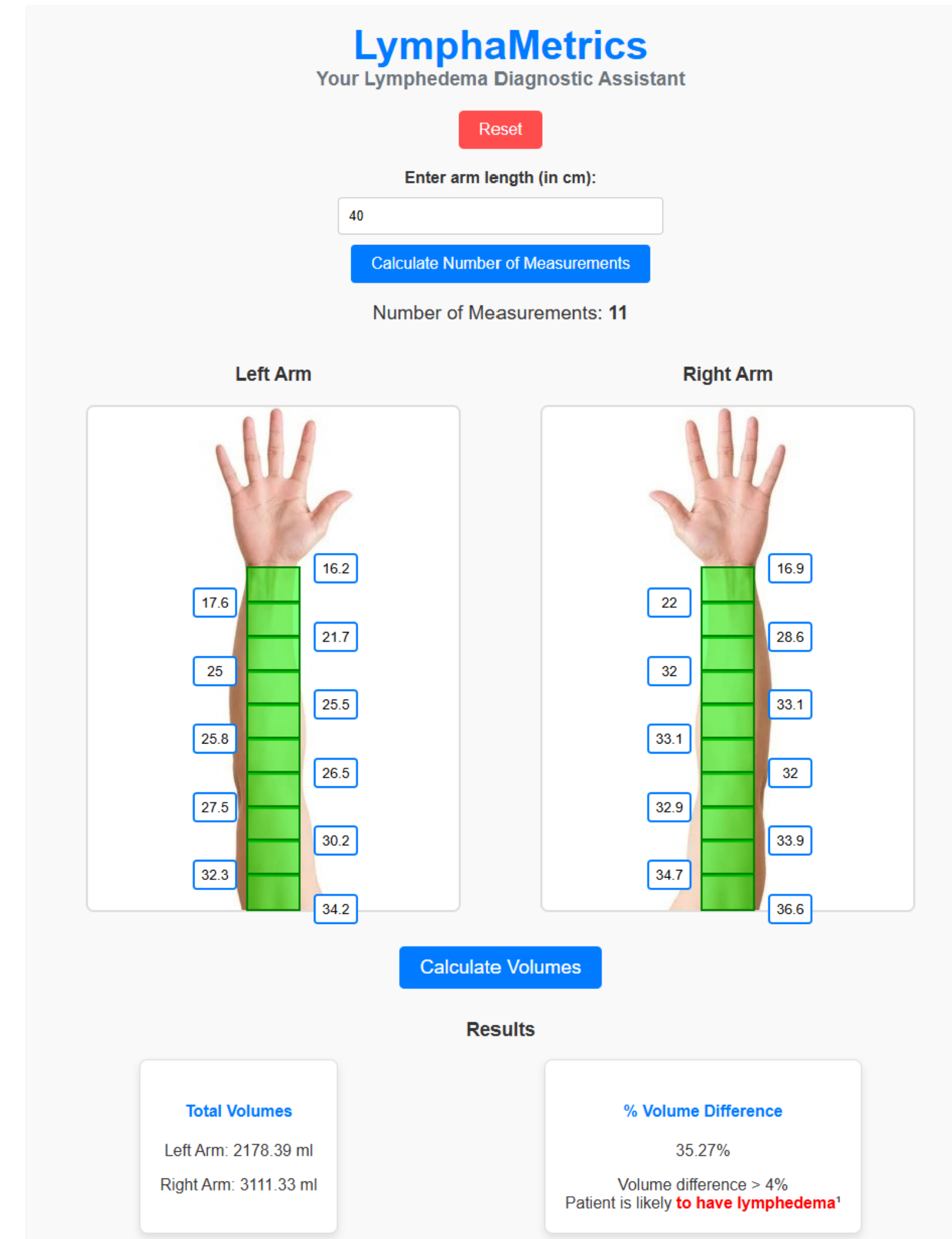


Figure 5. Snapshot of the website interface

Testing / Results

Sterilization Testing

- Conducted to ensure device could be effectively sterilized between patients
- Bacterial species staphylococcus epidermidis on agar and in tryptic soy broth (TSB)

Turbidity via plate reader:

- Acrylonitrile Butadiene Styrene (ABS) sample from other senior design group was used as a positive control
- All samples except PP and ABS without sterilization are similar to empty cells
- TPU is antimicrobial, leading to unexpected result for turbidity

	Empty	ABS	PP	TPU
Control	1 A 0.048	2 0.049	3 0.049	4 0.049
Sterilized	B 0.048	0.050	0.050	0.048
No Sterilization	C 0.048	0.384	0.287	0.049

Figure 6. Plate reader results for turbidity with three samples of each material, measurements in NTU

Testing / Results

Confluence via MATLAB:

- Agar plate sections:

1. PP: No bacteria, no sterilization
2. PP: Bacteria, no sterilization
3. PP: Bacteria and sterilization
4. TPU: No bacteria, no sterilization
5. TPU: Bacteria, no sterilization
6. TPU: Bacteria and sterilization

- 8.69% of agar plate covered by bacteria, 52.14% of section 2 is covered in bacteria, 0% in all other regions

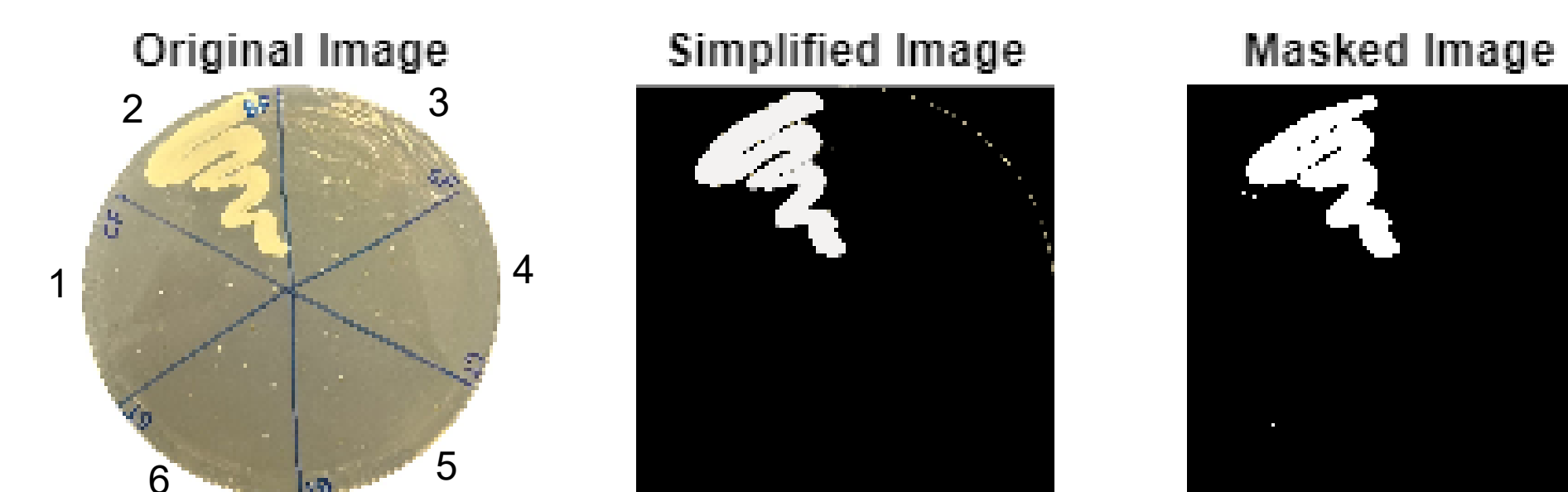


Figure 7. MATLAB analysis results for confluence of bacteria after sterilization testing.

Timing Test

- Conducted to see if using the device and Lymphametrics website is more time efficient than current method of a tape measure and pre-made lymphedema calculator in Excel
- Test conducted with 8 raters that had no prior experience measuring lymphedema and separate single trial by clinician
 - 8:36 (min:sec) for device compared to 10:20 for the current method

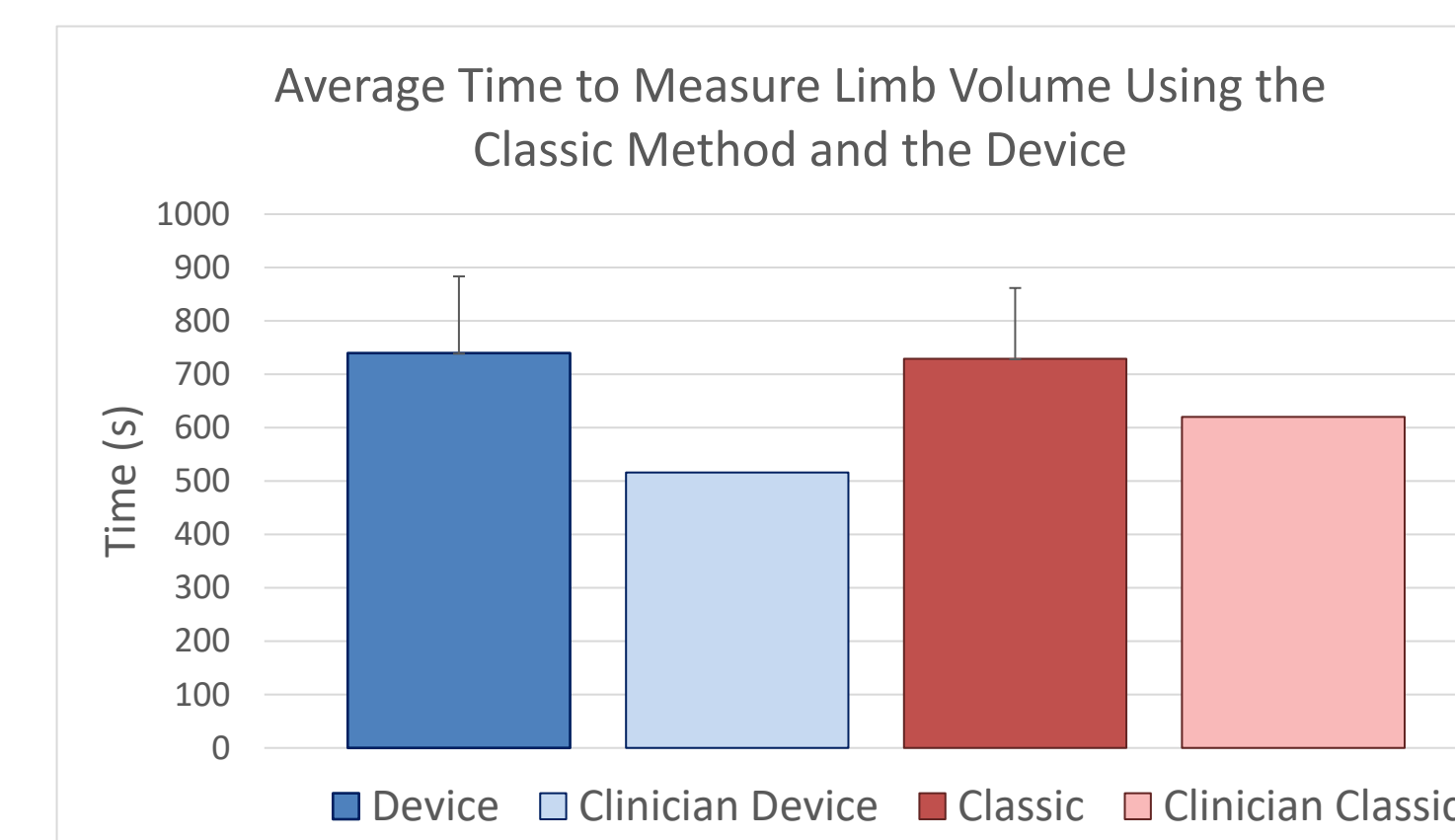


Figure 8. Comparison of the average time it takes to determine the limb volume of a patient

- No significant difference in limb volume measurement time between the two methods ($p = 0.881$) for non-clinician raters
- No statistical analysis was run for single data point from clinician
- Results may not be indicative of true timing efficiency due to availability of raters and patients

Intraclass Correlation (ICC) Testing

- Conducted to evaluate the consistency and reliability of the device
- Limb volume measurements taken using the device and classic measurement methods by three raters across multiple patients

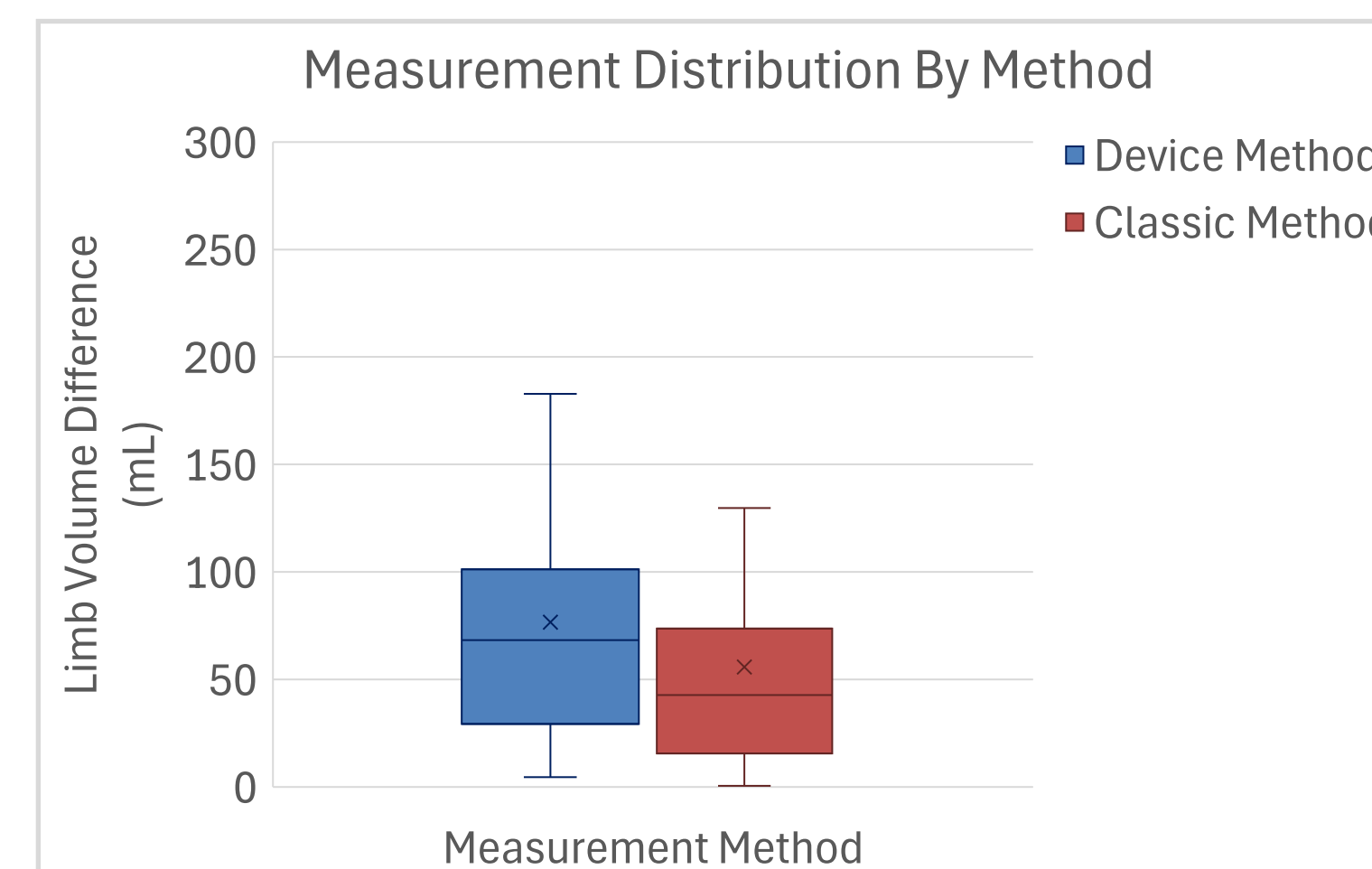


Figure 9. Distribution of limb volume difference measurements for both measurement methods

- No significant difference in measured limb volume between methods
- Results may not be indicative of true measurement reliability due to availability of raters and patients and inconsistent adherence to provided instructions

Testing / Results

Intraclass Correlation (ICC) Testing cont.

Table 1. Two-factor ANOVA with replication results.

TWO-FACTOR ANOVA WITH REPLICATION	
SOURCE OF VARIATION	p-value
METHOD	0.478
RATER	0.693
INTERACTION	0.091

- Percent limb volume difference is not dependent on which rater took the measurement or what method they used

Table 2. ICC values for inter-rater reliability for each method.

Inter-Rater Reliability – ICC(2,1)				
Method	ICC(2,1)	p-value	Interpretation	
Device	0.15	0.087	Poor reliability, not statistically significant	
Classic	0.24	0.199	Poor reliability, not statistically significant	

- The inter-rater ICC for the device and the classic method indicate poor reliability with no significant consistency between raters

Table 3. ICC values for intra-rater reliability for each rater and method.

Intra-Rater Reliability – ICC(3,1)				
Rater	Method	ICC(3,1)	p-value	Interpretation
R1	Device	0	0.952	Poor reliability
R2	Device	0	0.475	Poor reliability
R3	Device	0	0.821	Poor reliability
R1	Classic	0.16	0.284	Poor reliability
R2	Classic	0.02	0.406	Poor reliability
R3	Classic	0.18	0.269	Poor reliability

- The intra-rater ICC values were insignificant for both methods across all raters, indicating neither method was highly reliable in testing

Conclusions

- Device is segmented and can be easily assembled
- Device can be quickly sterilized and TPU is an antimicrobial material
- The website is a user-friendly interface for limb volume calculations
- Device parts can be replaced if damaged
- Device has a comparable ICC score to the classic method, and future clinical use of the device will confirm these results

Potential Device Modifications

- Adjust strap and block size for patient comfort and aesthetic
- Modify color to reduce stain visibility
- Adapt design, include alternate sizing to measure the leg

Literature Cited

- [1] National Cancer Institute, "Lymphedema and Cancer Treatment - Side Effects," *National Cancer Institute*, Apr. 29, 2015. <https://www.cancer.gov/about-cancer/treatment/side-effects/lymphedema>
- [2] "Lymphedema: Image Details - NCI Visuals Online," *Cancer.gov*, 2024. <https://visualsonline.cancer.gov/details.cfm?imageid=13268> (accessed Apr. 15, 2025).
- [3] "Lymphedema and Lymphatic Diseases Affect Millions and Concern Us All | Lymphatic Education & Research Network," Accessed: Nov. 13, 2024. [Online]. Available: <https://lymphaticnetwork.org/living-with-lymphedema/lymphedema-and-lymphatic-diseases-affect-millions-and-concern-us-all/>

Acknowledgements & Contacts

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