DEPARTMENT OF

Biomedical Engineering

UNIVERSITY OF WISCONSIN–MADISON

Ella

Glucose Alerting System Team

BME 200/300 Section 301-1

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Client: Olive Cerniglia, Callie Berg, Beth Martin

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Outline

- Problem Statement
- Introduction
- Product Design Specifications (PDS)
- Design Matrix #1 – Materials
- Design Matrix #2 – Batteries & Charging
- Design Matrix #3 – Connectivity
- Final Design
- Concluding Items
- Future Work Timeline
- References
- Question Time

Ella

Problem Statement

The overall goal of the Continuous Glucose Monitoring Bracelet is to make blood glucose status more clearly visible, understandable, and actionable for anyone supervising a young child with Type 1 Diabetes. Studies show that a diagnosis of diabetes can become just as stressful for parents to monitor and understand as it is for the kids. This prototype should help relieve some of this stress by eliciting a visible and actionable signal to parents, which will convey whether treatment is needed or not.

Ella

Background:

- Type 1 Diabetes is an autoimmune disease where the body's immune system mistakenly attacks and destroys the insulin-producing beta cells in the pancreas [1].
- Insulin is a hormone that regulates blood sugar levels
  - T1D affects 1.2 million children in the United States [2]
- Our clients are interested in a device compatible with a CGM that visibly alerts caregivers if a child with diabetes is hyperglycemic, hypoglycemic, or a dramatic change in blood sugar levels is anticipated

Competing Designs:

Figure 1:
GlowCose [3]

Figure 2:
Sugar Pixel [4]

Current Methods:

Figure 3:
Dexcom G7 CGM [5]

Lauren

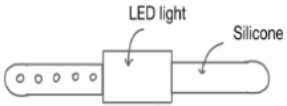
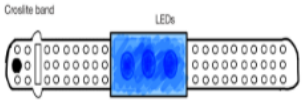
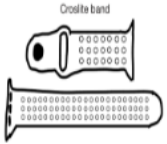
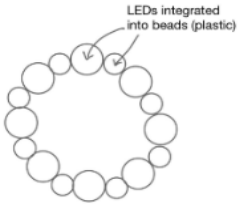
Product Design Specifications

Client Requirements:

- Displays glucose level status of child with T1D.
  - Signal will be clearly visible, understandable, and actionable.
- Comfortable to wear around wrist.
- Visual indication to signal when readings are unavailable or malfunctioning.
- Adjust to accommodate wrist sizes from 12.5-17.5 cm [6].
- Securable around wrist of child
- Compatible with a Dexcom G7.
- Rechargeable and replaceable.
- FDA Class II – Integrated CGM Category.
- IP54 for water resistance [7].
- ISO 15197 & ISO 175119 - 95% Glucose Test Strip Accuracy [8,9].

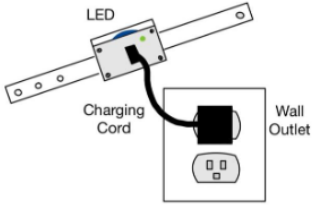
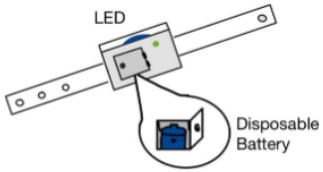
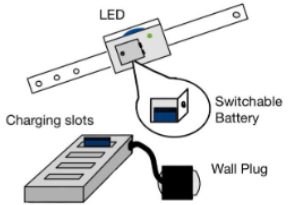
Audrey

Design Matrix - Materials

Designs / Criteria	Design 1: Silicone band with LED light		Design 2: Croslite band with LEDs		Design 3: LED light with plastic beaded bracelet	
	  		 			
Safety & Ergonomics (25)	5/5	25	4/5	20	3/5	15
Adjustability (20)	5/5	20	4/5	16	3/5	12
Durability (20)	5/5	20	3/5	12	2/5	8
Accuracy (15)	5/5	15	4/5	12	3/5	9
Water Resistant (10)	4/5	8	3/5	6	2/5	4
Cost (10)	4/5	8	5/5	10	2/5	4
Total (100)	96		76		52	

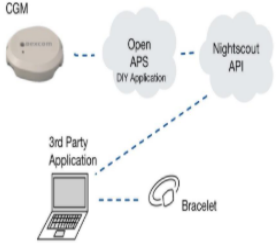
Kiera

Design Matrix – Battery and Charging

Designs / Criteria	Design 1: Lithium-Ion with Recharging Cord 		Design 2: Disposable Battery 		Design 3: Switching Battery with Wall Charger 	
Compatibility (20)	5/5	20	3/5	12	4/5	16
Safety (15)	3/5	9	4/5	12	5/5	15
Security (25)	5/5	25	2/5	10	3/5	15
Lifespan (20)	5/5	20	3/5	12	4/5	16
Cost (10)	3/5	6	1/5	2	4/5	8
Size & Weight (10)	4/5	8	2/5	4	3/5	6
Total (100)	88		52		76	

Claudia

Design Matrix - Connectivity

Designs / Criteria	Design 1: Dexcom Developer Program		Design 2: Nightscout API		Design 3: BLE Connection	
						
Delay Time (25)	1/5	5	4/5	20	4/5	20
Feasibility (20)	3/5	12	4/5	16	2/5	8
Reliability (20)	5/5	20	3/5	12	2/5	8
Privacy (15)	4/5	12	3/5	9	4/5	12
Cost (10)	5/5	10	5/5	10	1/5	2
Replication (10)	2/5	4	4/5	8	1/5	2
Total (100)	63		75		52	

Isabel

Final Design

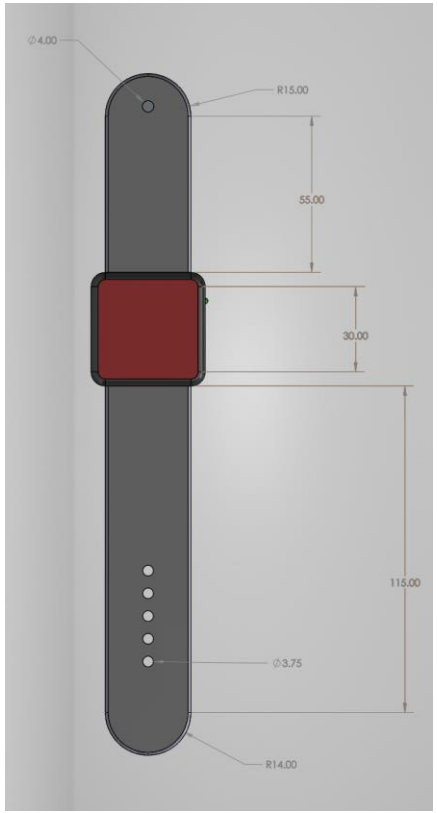


Figure 4: Top of Bracelet

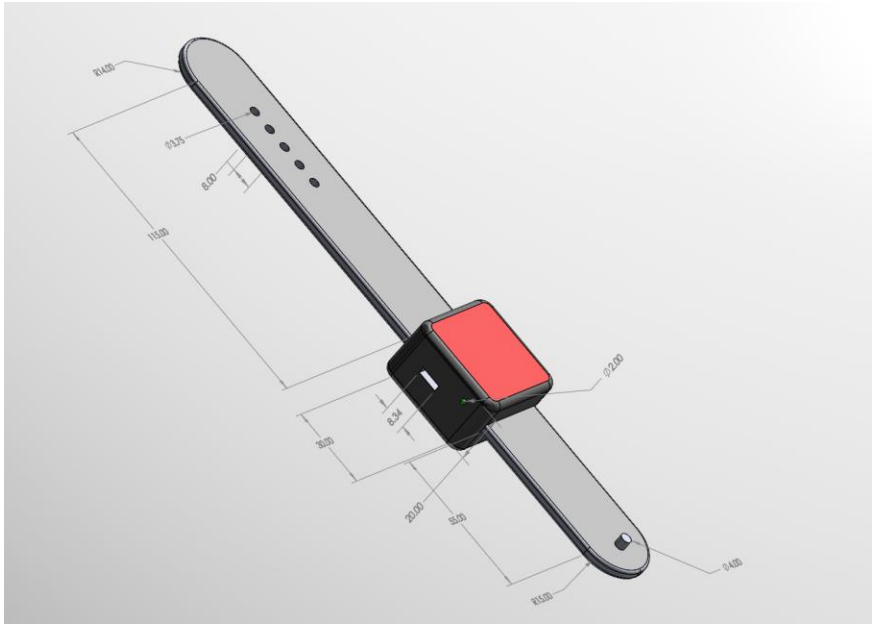


Figure 5: Side View of Bracelet

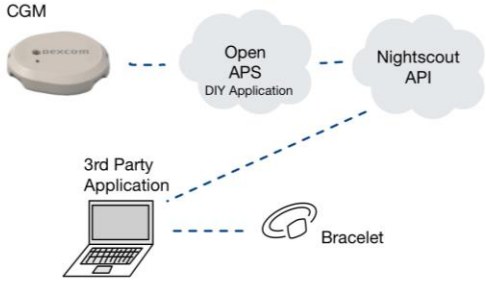


Figure 6: Nightscout Flow Diagram

- Lithium-Ion w/ USB-C Charging Port
- Nightscout API data retrieval

Isabel

Future Work Timeline

October

- Material Research & Ordering!
- Initial Prototyping

November

- Initial Prototype testing
- Modifications
- Focus on Connectivity
- Finalize Design

December

- Manufacture Final Prototype
- Final Presentations!

Isabel

Acknowledgements

- Olive Cerniglia
- Callie Berg
- Dr. Beth Martin
- UW-Madison School of Pharmacy
- Dr. John Puccinelli
- Isabelle Peters

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[7] S. K. Garg and H. K. Akturk, “A New Era in Continuous Glucose Monitoring: Food and Drug Administration Creates a New Category of Factory-Calibrated Nonadjunctive, Interoperable Class II Medical Devices,” *Diabetes Technology & Therapeutics*, vol. 20, no. 6, pp. 391–394, Jun. 2018, doi: https://doi.org/10.1089/dia.2018.0142.

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[9] [13] Guido Freckmann, A. Baumstark, and S. Pleus, “Do the New FDA Guidance Documents Help Improving Performance of Blood Glucose Monitoring Systems Compared With ISO 15197?,” *Journal of Diabetes Science and Technology*, vol. 11, no. 6, pp. 1240–1246, Jun. 2017, doi: https://doi.org/10.1177/1932296817713220.

Thank You!
Questions?

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