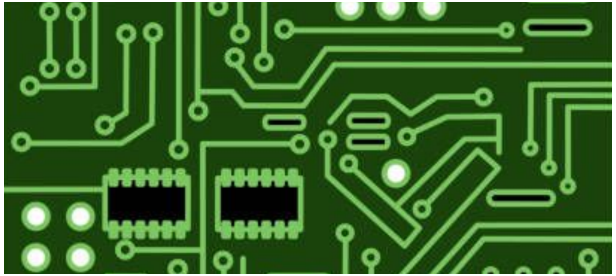
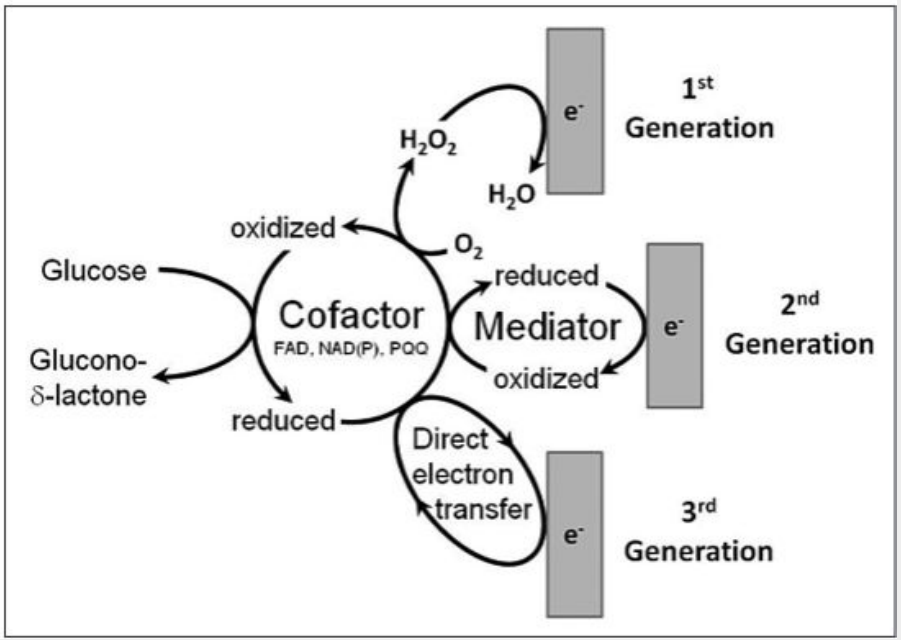


SweeTech

Glucometer Development Plan

Kayla Powell, Paulina Bargallo, Theertha Vannemreddy

How do glucometers work?



- Electrochemical reactions occur on biosensor
- Glucose oxidase (GOx) is most common enzyme
- Primary reaction is aerobic oxidation of glucose with GOx/FAD
  - O_2 electron acceptor
  - Concentration determined via O_2 consumption or H_2O_2 generation
  - Challenges: O_2 mass transfer limitations and high overpotentials
- Redox-mediated electron transfer introduced to improve efficiency, accuracy
- Advancements in nanotechnology allow for direct electron transfer to support continuous glucose level monitoring

AimStrip® Plus Glucose Meter and Strips

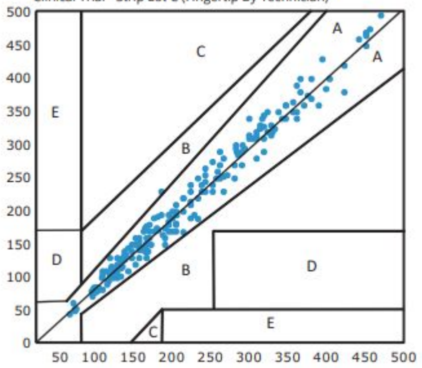
- Reliable, Accurate Results in 10 Seconds
- Only 1µL Blood Sample Required from Fingertip or Forearm Testing
- Single Code Chip for the Life of the Meter
- Memory Allows up to 300 Records with Date and Time
- English & Español Instructions

The AimStrip® Plus Blood Glucose Test Strips is stored in a sealed vial with desiccant. Each test strip contains the following chemicals:

Glucose Oxidase	**CAS Number:** 9001-37-0	**Concentration:** <25IU
Mediator	**CAS Number:** 13746-66-2	**Concentration:** <30µg

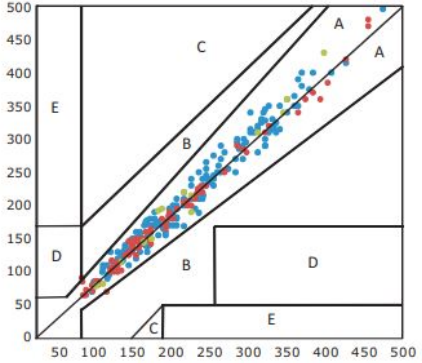
Accurate Fingertip Testing

Error Grid Analysis
Clinical Trial - Strip Lot C (Fingertip By Technician)



Patients can Perform a test as well as a trained technician

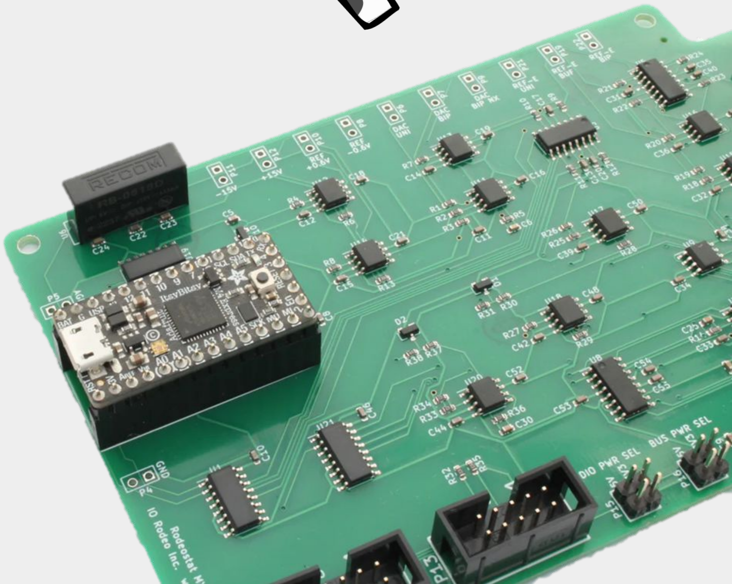
Error Grid Analysis
Clinical Trial - Strip Lot A, B, C (Fingertip)



https://www.germainelabs.com/wp-content/uploads/2020/08/AimStrip-Plus-BG-Flyer-02-19.pdf

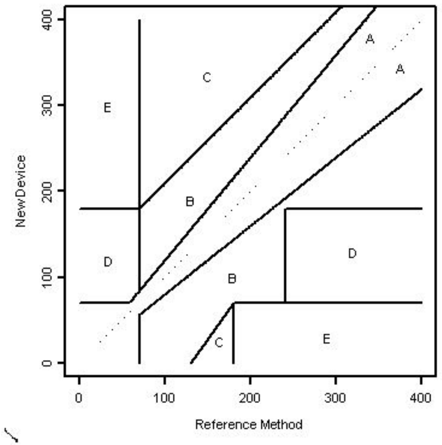
Our glucometer design

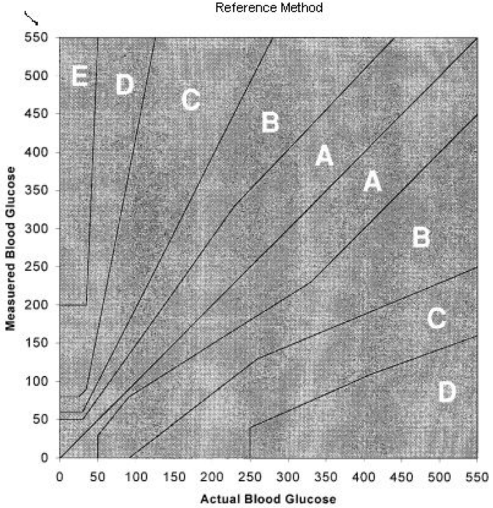
- **IO Rodeostat supported amperometry**
  - Digitally-controlled
  - Selective oxidation of mediator for calibration
- **Hardware selection**
  - Adafruit ItsyBitsy M4 MCU
    - Internal and serial flash memory
    - Supports python + USB debugging
    - 12-bit ADC and general in/output pins
  - Arduino GIGA Display Shield/R1 WiFi
    - High resolution and touch-screen function
    - SPI communication with board
    - Python support for integration
- **3D printing**
  - Biosensor connection
  - Sturdy design for practical use and secure integration of components



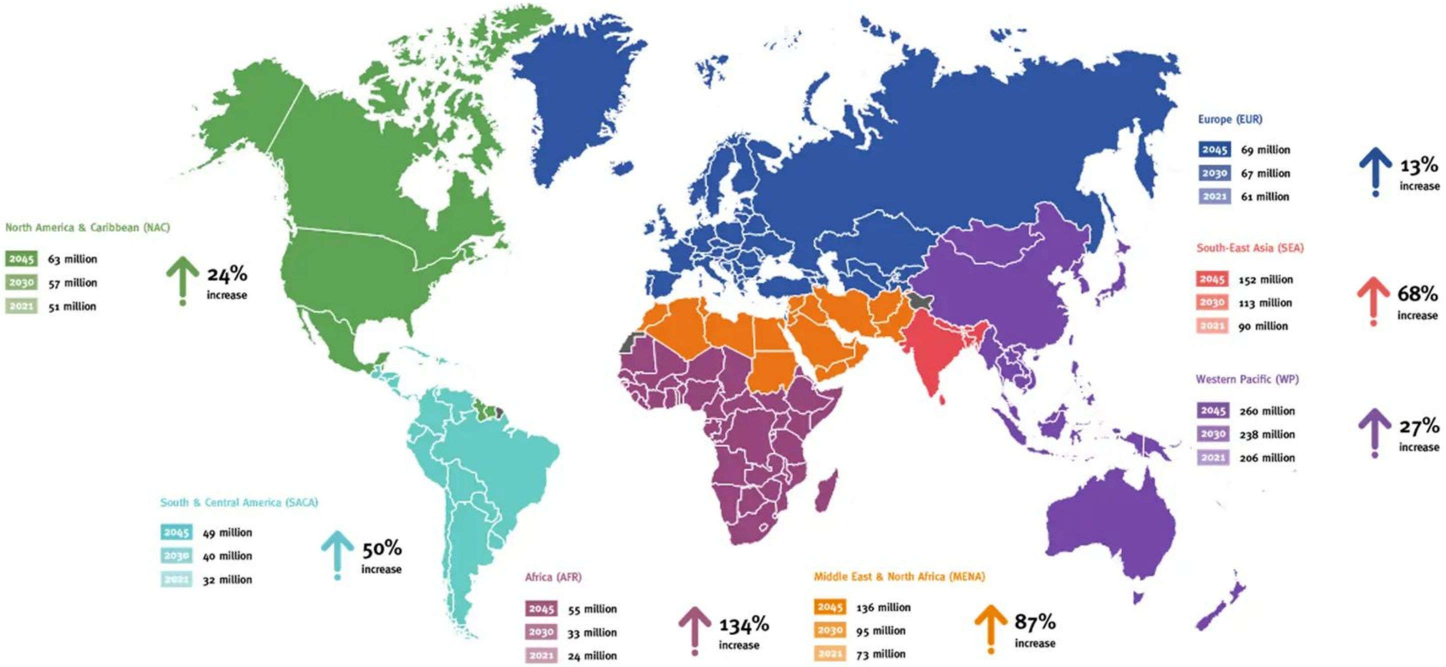
Accuracy standards

- **ISO 15197:2013** (user performance evaluation for 95% of samples)
  - <100 mg/dL: ± 15 mg/dL
  - ≥100 mg/dL: ± 15% error
- **Error grids (right)**
  - Clarke Error Grid (top)
  - Consensus Error Grid for Type II diabetes (bottom)
    - Advanced grid following the development of glucose monitoring devices
- **FDA/EU requirements**
- **WHO recommendations**
  - Testing range of 30-400 mg/dL
  - ISO compliance
  - 99% results fall within zones A/B of Consensus Error Grid
  - Technical and performance specifications are [detailed] for enzymatic with amperometric detection formats

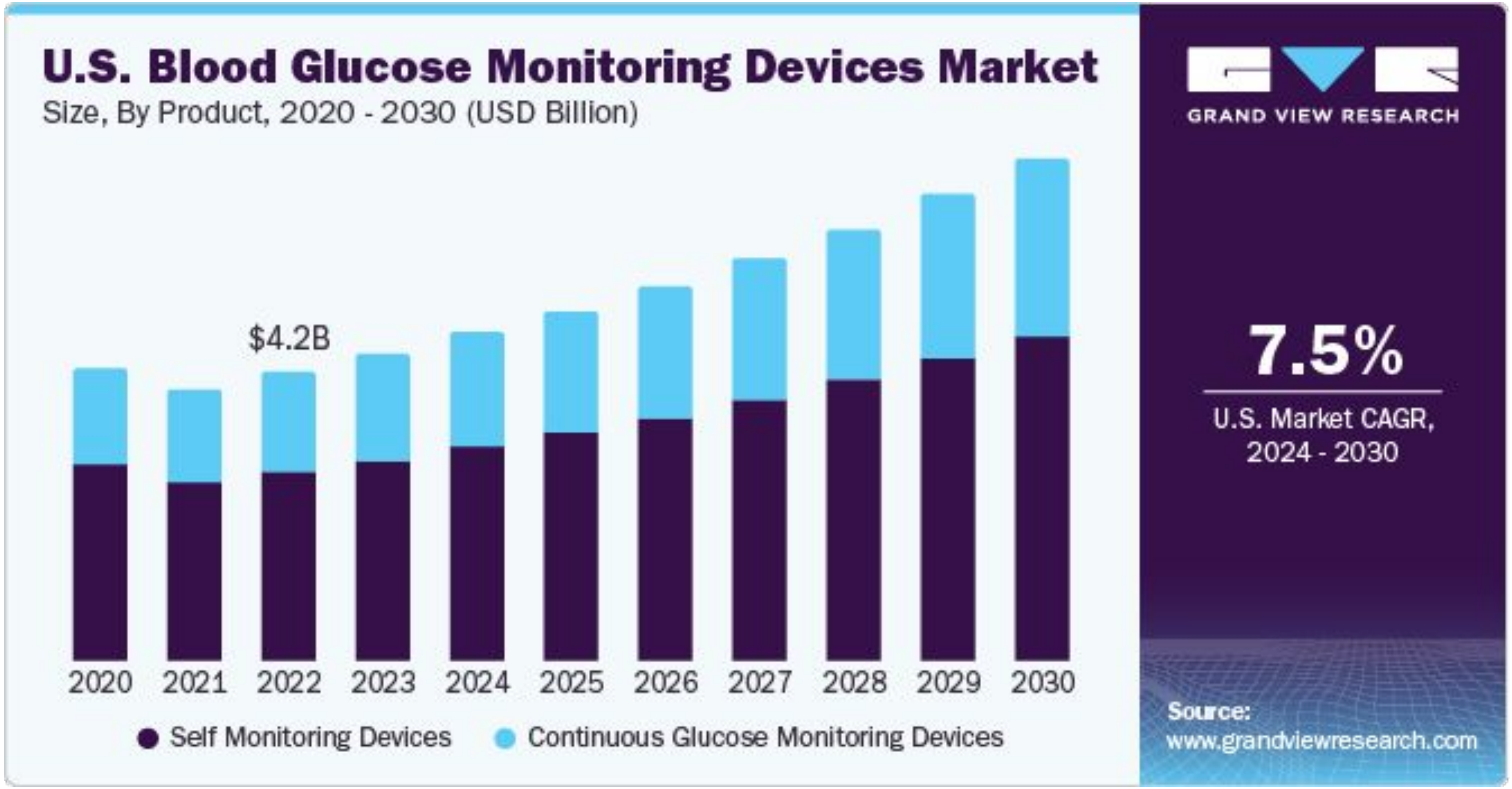




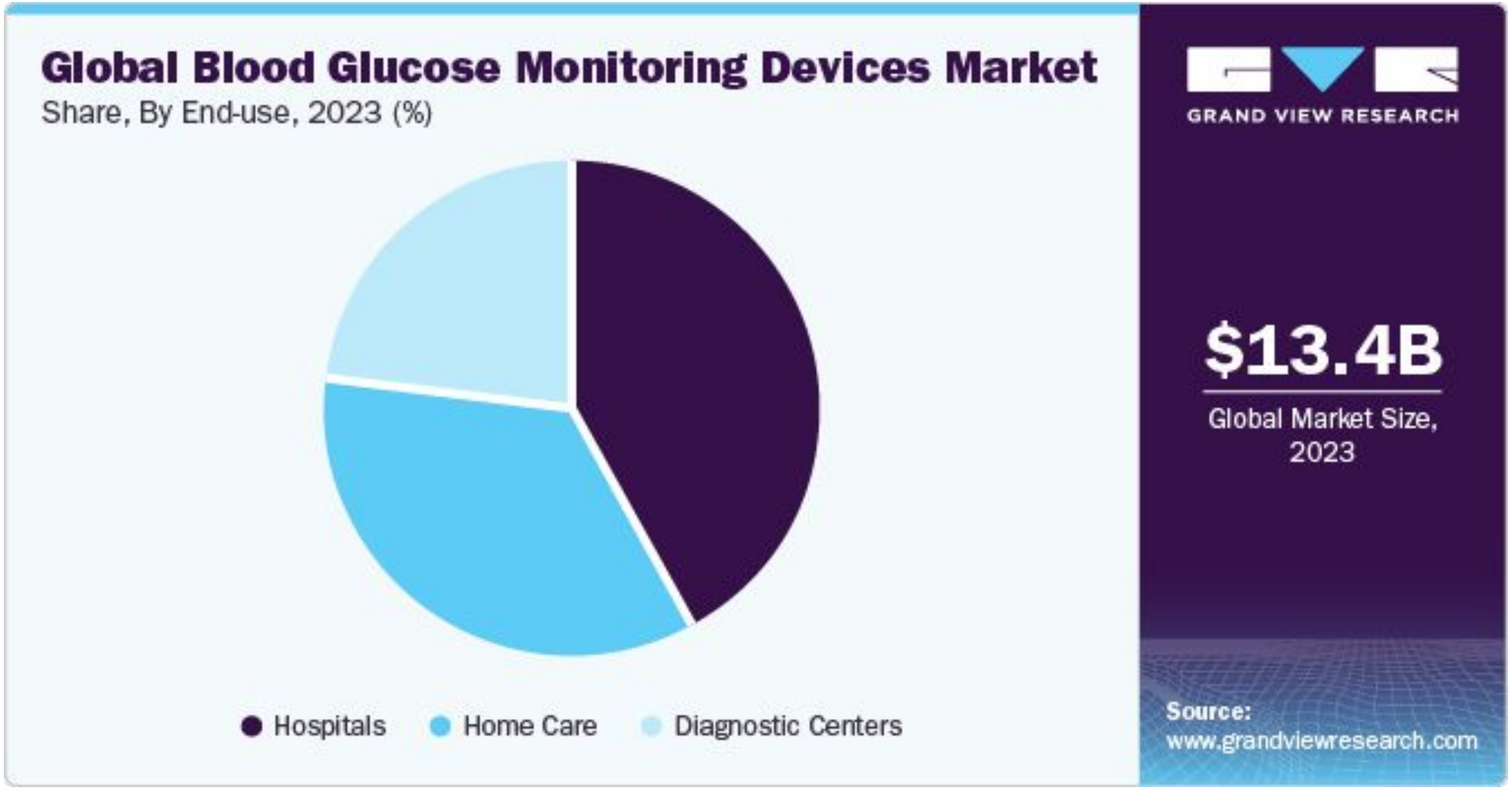
Diabetes and glucose monitoring market trends



Diabetes and glucose monitoring market trends



Diabetes and glucose monitoring market trends



Competitive evaluation

- **Key features of industry self-monitoring devices**
  - $20-100 per glucometer
  - Portable and compact
  - Some devices have continuous monitoring.
  - Most of cost is test strip (glucometers often included for free)
  - Waterproof

- **Features of SweeTech glucometer**
  - $240 potentiostat
  - $137 display components
  - Much more sophisticated potentiostat than is needed for glucometer function
  - Not commercially competitive; better for learning and research purposes
  - Not portable due to large size. Not compact
  - Does not have live monitoring features.

SWOT analysis

Strengths

- Easy to replicate at student level
- Accessible for lab experiments and easy to modify.

Weaknesses

- Not portable
- Not scalable
- Lacks clinical application and trials

Opportunities

- Simplify potentiostat for cost reduction and portability
- Use databases instead of only experimental results

Threats

- Live monitoring glucose meters
- FDA approved glucose meter

Project timeline and deliverables

TASK NAME	STATUS	ASSIGNED TO	START DATE	END DATE	DURATION in days	Need to submit:	COMMENTS	Schedule
Planning	In Progress	All	01/27	1/31	5	For presentation and in february		internal schedule
Introducing Theertha to the Project	Complete	Kayla, Paulina	01/27	01/27	1		Show what we did last semester to Threetha so she knows our base line	
3-D printing	Complete	All	01/27	01/30	4	group assignment, (print one item per group), individually CAD files and		
3-D CAD files test	Complete	All	01/27	01/30	4	Have files ready by lab meeting on Thursday	CAD and slicing done for nameplates, box with sliding lid and UNO Case.	class schedule
3-D printing (test)	Complete	All	01/27	02/06	11	Have files ready by lab meeting on Thursday		class schedule
Writing	Complete	All	02/03	02/07	5	Compling Preliminary Design Presentation on team GitHub page		class schedule
Electrochemistry reactions and analytical methods	Complete	Kayla	02/03	02/07	5			class schedule
Firmware development	Complete	Kayla	02/03	02/07	5			
Product standards research	Complete	Kayla	02/03	02/07	5			
Project scope: Minimum and maximum expectations	Complete	All	02/03	02/07	5			class schedule
Materials; costing and sourcing	Complete	Paulina	02/03	02/07	5			class schedule
Getting proposal into github	Complete	Paulina	02/03	02/07	5			
Design principles outlined	Complete	Theertha	02/03	02/07	5			class schedule
Market research	Complete	All	02/03	02/07	5			class schedule
Proposal editing	Complete	Kayla, Paulina	02/10	02/14	5			class schedule
Getting updated proposal into GitHub	Complete	Paulina	02/10	02/14	5			class schedule
Sending materials to Joe/Dr Huff	Complete	Paulina	02/11	02/14	4			class schedule
Testing rodeostat with Fe CV	Not Started	Kayla	02/20	03/07	16			class schedule
Circuit design research	Not Started	Theertha, Paulina	02/20	03/07	16			class schedule
Set up of display	In Progress	Paulina	02/20	03/06	15			
Assignment 2: Update Presentation	In Progress	All	02/23	02/27	5	Updating project presentation as requested by Professor Osuji		class schedule
SPRING BREAK	Not Started	All	03/11	03/17	7			class schedule