





Stasis Insulin Pump

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Gantt Chart



	Week									
	1	2	3	4	5	6	7	8	9	10
Topic Research	●	●	●	●	●					
Topic Ideation	●	●								
Opportunity Statement		●								
Ideation Sketches			●	●	●	●				
Manufacturing Ideation				●	●	●	●			
CAD Modeling					●	●	●			
Midterm Presentation					●					
Prototype Fabrication						●	●	●		
Process Book							●	●	●	●
Poster								●	●	●
Final Presentation									●	

Opportunity Statement

Increase access to wearable
medical technology



Opportunity Statement

Defining “access”

Cost- High prices can deter people from buying necessary medical supplies

Wearability- If a wearable is too obtrusive or can't withstand high impact activities, potential users perceive that the device doesn't fit their lifestyle

Aesthetic- Similarly, people may go without a helpful device simply because of an appearance that is either ugly or clearly medical

Learning Curve- A device that gives off the perception of being too advanced can intimidate potential users into going without it



Exploring the Opportunity

Among the most common wearable medical devices are **insulin pumps**. Insulin pumps are miniature IVs that deliver small, constant doses of fast-acting insulin to Type 1 diabetics. Pumps provide an alternative to syringe injections , and are not only more convenient ways to deliver insulin, but have also been proven to significantly improve patients' diabetes management.

Studying what keeps diabetics from switching from injections to the pump despite clear benefits will provide insights into designing more accessible devices. Principles used designing an insulin pump may translate over to devices like heart monitors and body sensors.

Current Market



Minimed Paradigm

Minimed models have a history of over 30 years on the market and set the standard for all other insulin pumps. They boast connection to extensive online data analysis and the Medtronic brand is known for their customer service.



Animas Vibe

The Vibe incorporates several features that allow for customization beyond insulin management. It comes ready to display data from a Continuous Glucose Monitor, which has shown to offer tighter management of blood glucose levels.



Tandem t:slim

Although not by much, the t:slim is the smallest wired pump on the market. It is also the only pump to integrate a full-color touchscreen display and a rechargeable battery that lasts seven days at a time.



Insulet Omnipod

Unlike the other pumps mentioned, the Omnipod dispenses insulin directly from the infusion site, meaning there is no tubing involved. It is controlled by a remote PDA that is also combined with a blood glucose reader.

Surveys

Surveys were submitted to anonymous Type 1 diabetics.

One set went out to pump users to get feedback on their experience with their pump. The second set went out those who use manual injections to find out what was keeping them from switching to the pump.

Questions for Pump Users and Summarized Answers

- How long were you on injections before switching to the pump? Which insulin did you use?
- Time before switching ranged from 6 months to 20 years. Most participants used a long-acting insulin supplemented by short-acting insulin for meals, a system closely resembling pump usage.
- Why did you switch to the pump? What worries did you have about switching? What were you excited about?
- Participants switched to the pump for better diabetes control and were by far most excited about not having to inject themselves, which also brought greater “freedom to eat” without having to plan shots around their meals. Worries included misusing the pump, tubing getting in the way, and becoming careless from the pump making things too convenient.

- How would you describe your switch to the pump? Has your diabetes been easier or harder to manage? How have you been feeling since you've switched compared to before?
 - Generally, participants found the transition smoother than they expected and have since found managing their diabetes easier and have seen better blood glucose levels.
- What brand and model of pump do you have? Have you changed brands? If so, why?
- An overwhelming majority of participants used either a Minimed or the Animas Ping, a model which preceded the Vibe and didn't include the Continuous Glucose Monitor.
- What were your priorities when choosing a pump? Did you have to make any compromises when selecting your pump? If so, which ones and why?
- Most participants' pump was recommended or chosen by their doctor. Others mentioned being drawn to their pump by one feature: tubeless, remote control, etc. Some had to go without a tubeless pump since they are often not covered by insurance.
- Does your pump attach directly to you or via separate site and wiring? Why did you choose this kind of pump? Where do you wear your pump?
- Having a separate site and wiring was most common, mostly because participants were worried about direct-attachment pumps being too bulky. The most common sites were on the stomach and lower back.
- What do you love about your pump? What do you hate?
- Participants like the convenience and better control provided by the pump, but they disliked the bulkiness, being aware they were constantly wearing something, and changing sites.

Surveys

- **Do you trust your pump? Why or why not?**
- Almost all participants trust their pumps, even if they have experienced malfunctions in the past.
- **What is your most memorable experience with your pump (good or bad)?**
- Good experiences involved more freedom and better blood glucose levels while bad experiences involved becoming sick after a pump malfunction or improper use.
- **Additional comments:**
- Participants wanted to see a more aesthetically pleasing pump that resembled more contemporary technology (touchscreens were brought up on multiple occasions) instead of resembling pagers.

Insights

- People can easily see the better control pumps provide.
- The most attractive aspect of the pump is the freedom it provides. The more freedom additional features provide, the better.
- Wireless pumps are harder for people to get because of spotty insurance coverage.
- Pump-wearers trust their pump because they have to, even if they maybe shouldn't.
- Outdated aesthetics are a prominent downside in people's minds, even though conversation was not steered towards them.

Questions for Injection Users and Summarized Answers

- How long have you been receiving insulin via injection?
 - Answers ranged from four years to forty-seven.
- Which insulin(s) do you use? Why?
 - Most participants used a combination of long and short-acting insulins.
- Do you use syringes or an insulin pen? Why?
 - Although insulin pens, which are user-friendly reusable syringes with disposable needles, offer greater convenience, only participants with insurance had access to them. Most participants identified pens as the preferable option.
- Where on your body do you inject insulin? Have you stopped injecting in certain areas? Why?
 - The stomach was an almost unanimous injection site. Other sites were more subject to not having enough fat for a painless injection.
- Do you calculate and draw out your insulin? If not, why not, and who does this for you?
 - All participants did they procedures themselves.
- Do you give yourself injections? If not, why not, and who does this for you?
 - Again, all users did this themselves.
- Have you considered switching to an insulin pump? If so, what reasons do you have for not switching?
 - Answers were evenly split between insurance not covering it, perceiving the pump as too complicated, and not wanting to constantly wear a device.

Surveys

- How do you think switching from injections to a pump would make living with diabetes easier? How would it make it harder?
- Participants felt they may see better blood glucose levels and more convenience by switching, but were worried about ripping out sites and having poorly-tuned settings.
- What is your most memorable experience regarding insulin injections (good or bad)?
- Most participants recounted their pride after their first injection.
- Additional comments:
- No additionall data was provided.

Insights

- Pride is taken in indepence. A good design should retain this feeling.
- Diabetics avoid swtching to pumps for reasons consistant with the opportunity statement.
- Insurance (or lack of) is a major reason for people going without better medical supplies.
- Even diabetics who do not want to wear a pump realize its benefits.

Gathered insights were then crafted into a persona.



Veronica, 17 years old

Type I Diabetic for 8 years
Pump wearer for 7 years

Likes not having multiple injections everyday and has seen tighter BG control with the pump

Dislikes dealing with the pump during lacrosse games, looking like she is wearing a beeper, broken clips

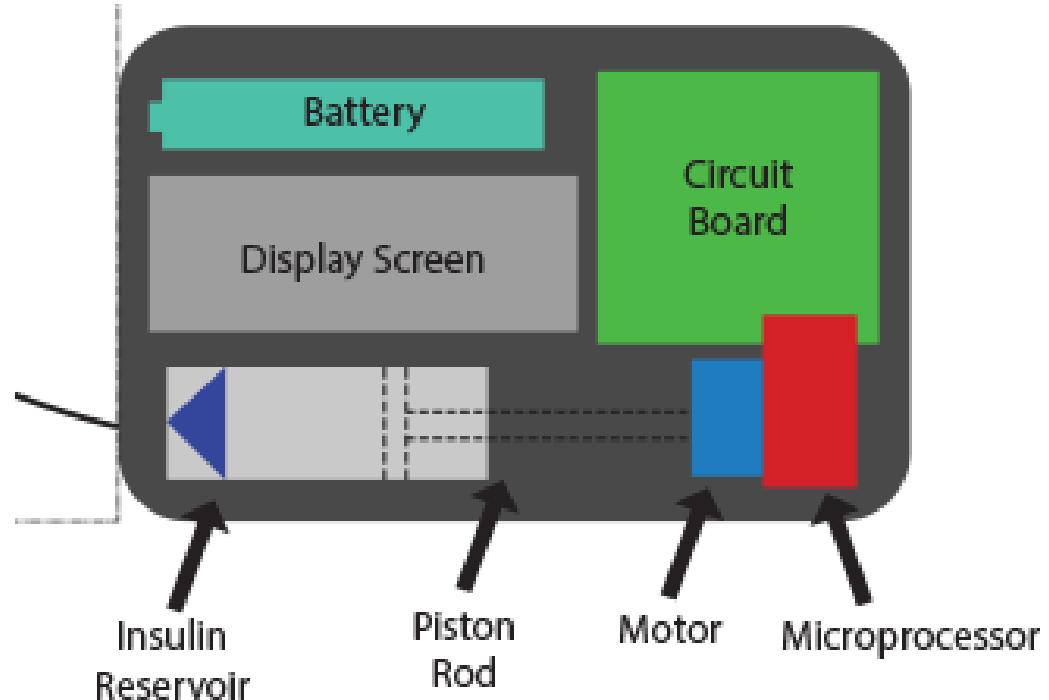
Although Type I Diabetes is often diagnosed in adolescence, diabetics are all ages and demographics. Thus, designs would not have to be based around a certain kind of user, but would have to be more universal, which comes with its own challenges.

Technical Research

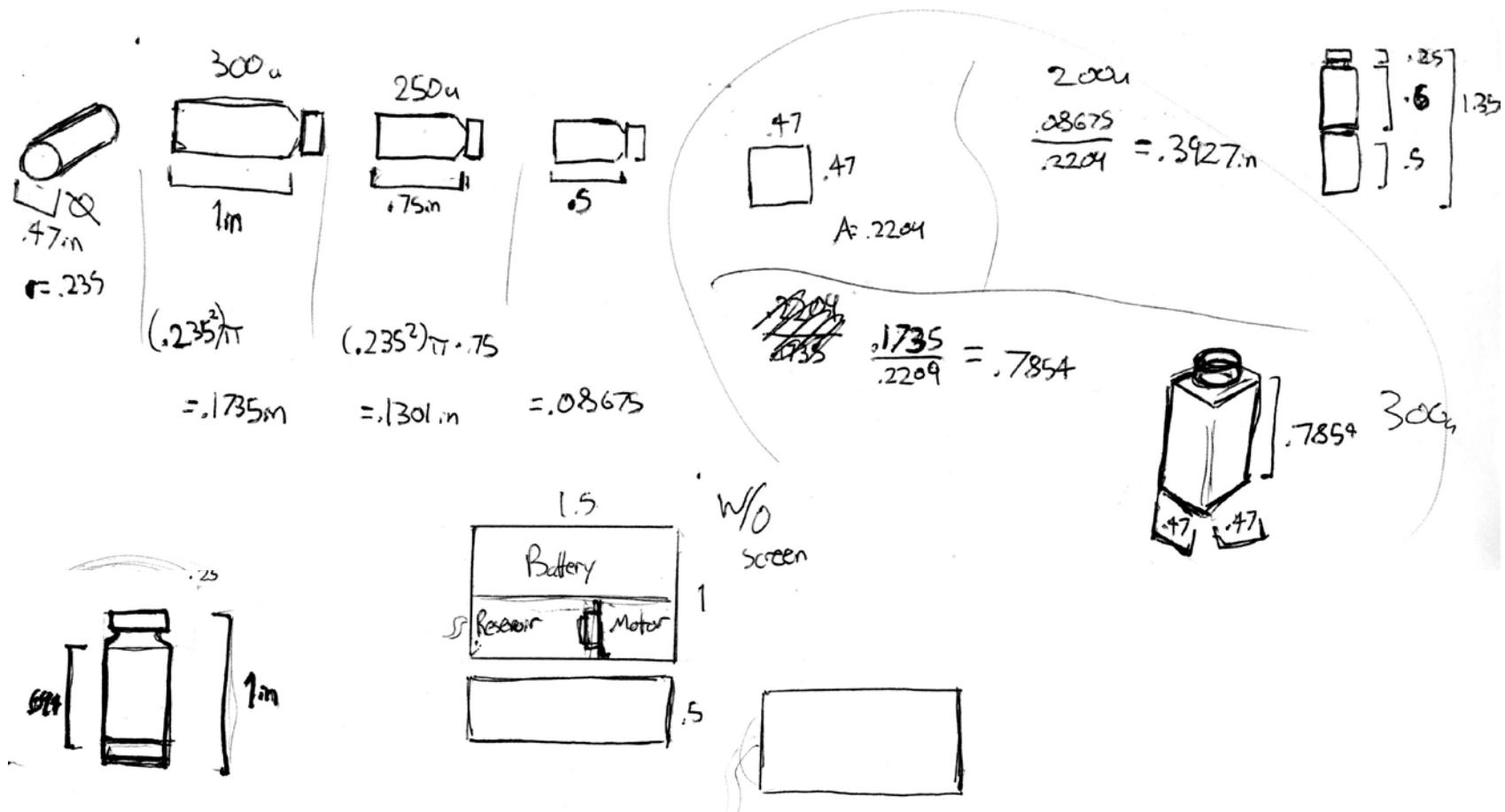
Opportunities of lowering cost and increasing wearability can be tackled by making a smaller, more compact pump.

Of the parts the pump contains, technology can reduce the size of almost everything except the insulin reservoir and the piston rod, the size of which is dependent on the reservoir size.

The key to reducing the pump's size would be finding the most efficient size and form for the reservoir.



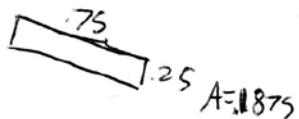
Countless calculations were done to find the best size and shape for the reservoir. To compete with other pumps, it would have to hold 250-300 units of insulin. Having more than that would encourage prolonging the lifespan of an infusion site, which could lead to infection



Technical Research



$$A = .225$$



$$A = .1875$$

$$\begin{array}{r} 300u \quad .1735 \\ \hline 250u \quad .225 \\ \hline .5783 \\ 200u \quad .3856 \end{array}$$

$\frac{300u}{250u} \cdot \frac{.1735}{.225} = .7711$

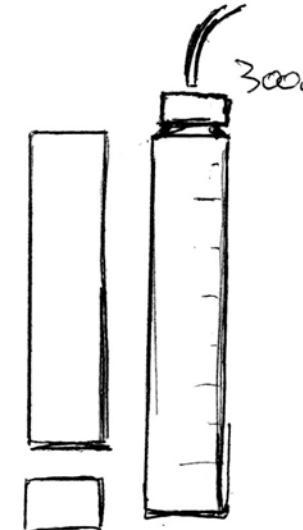
$$\begin{array}{r} 300u \quad .1735 \\ \hline 250u \quad .1575 \\ \hline .694 \\ 200u \quad .4623 \end{array}$$

$\frac{300u}{250u} \cdot \frac{.1735}{.1575} = .9253$



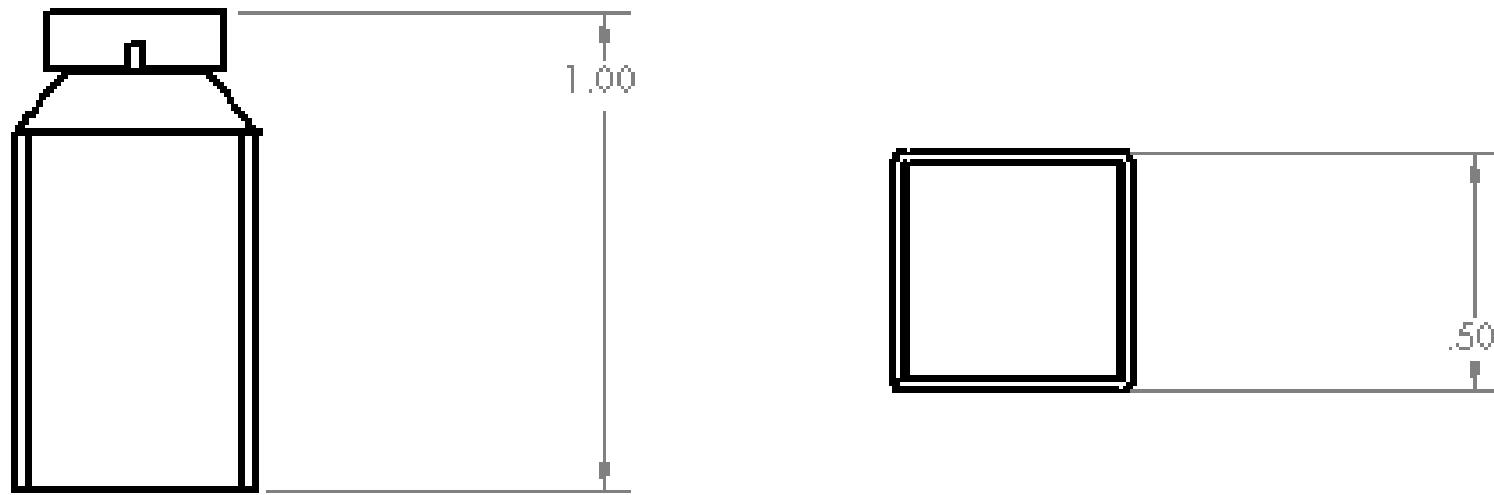
$$A = .0937$$

$$300u \cdot \frac{.1735}{.0937} = 1.8517$$



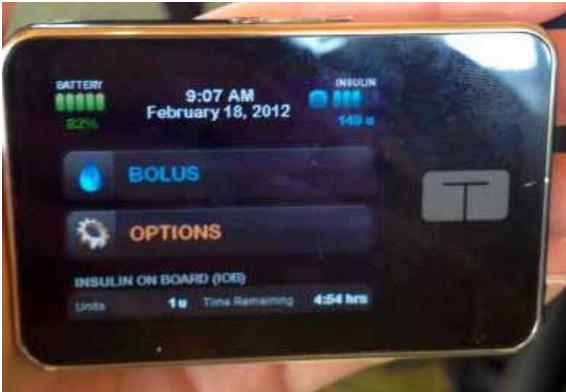
Having too thin of a reservoir would call for a thinner plunger to push insulin out, compromising its sturdiness and ability to do so.

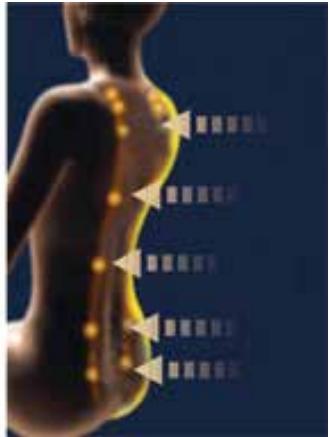
Likewise, having too wide of a reservoir would mean that insulin would be pushed into the tubing at too high a pressure and could lead to pain and injury.



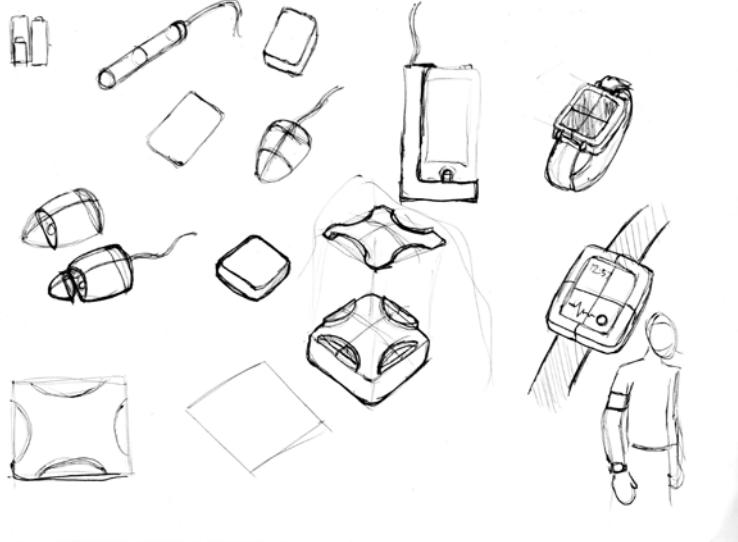
A square base provided an efficient compromise.

Form Inspiration





Concept Ideation

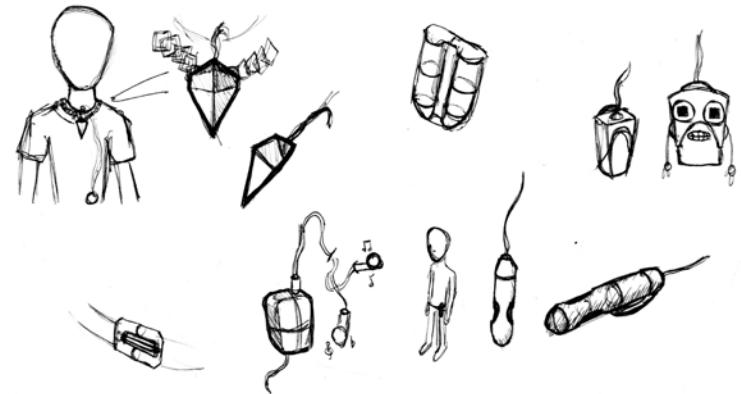
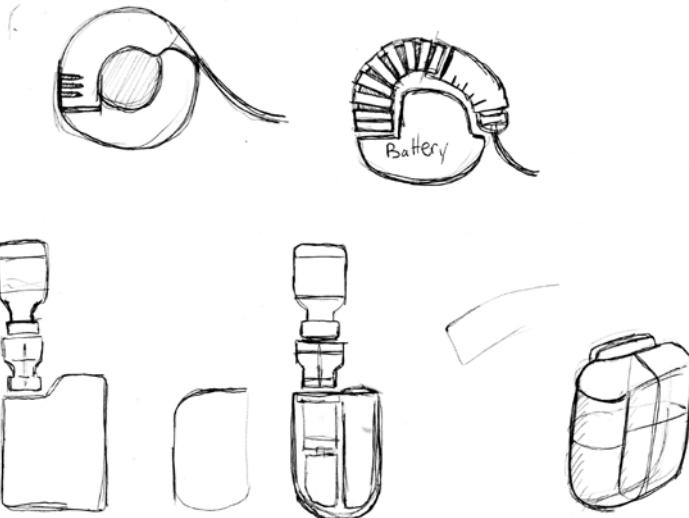


Different methods of site attachment were considered. Ultimately, the focus of the project narrowed down to the pump body itself.

Initial concepts explored several forms and different kinds of devices. They were less concerned about plausible size and more so on establishing an innovative form. At this stage, more organic forms were proving more interesting.

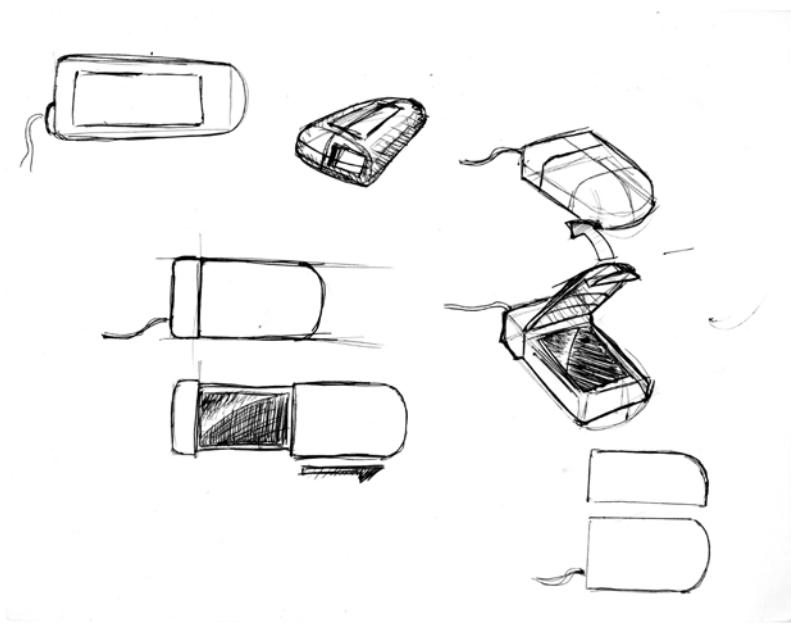


Early on, wireless forms were explored more. However, they were abandoned after considering the need for an external form of controlling them.



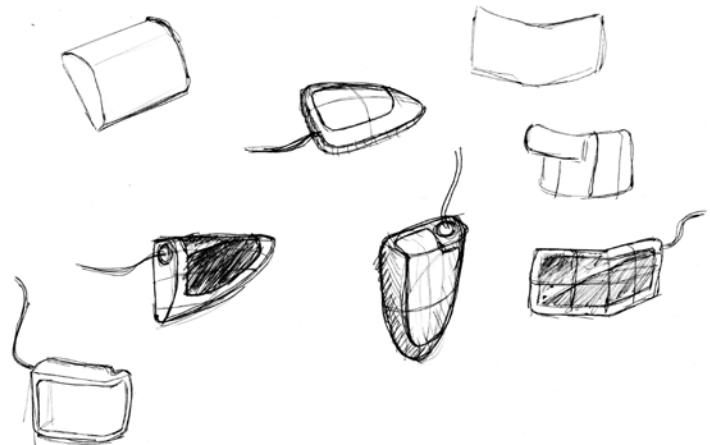
Disc-shaped forms were considered, as well. Given that all the necessary pieces have the same curvature, the actual pumping would not be a problem. The angle of the reservoir, though, would lead to complications in loading the insulin.

Refined Ideation

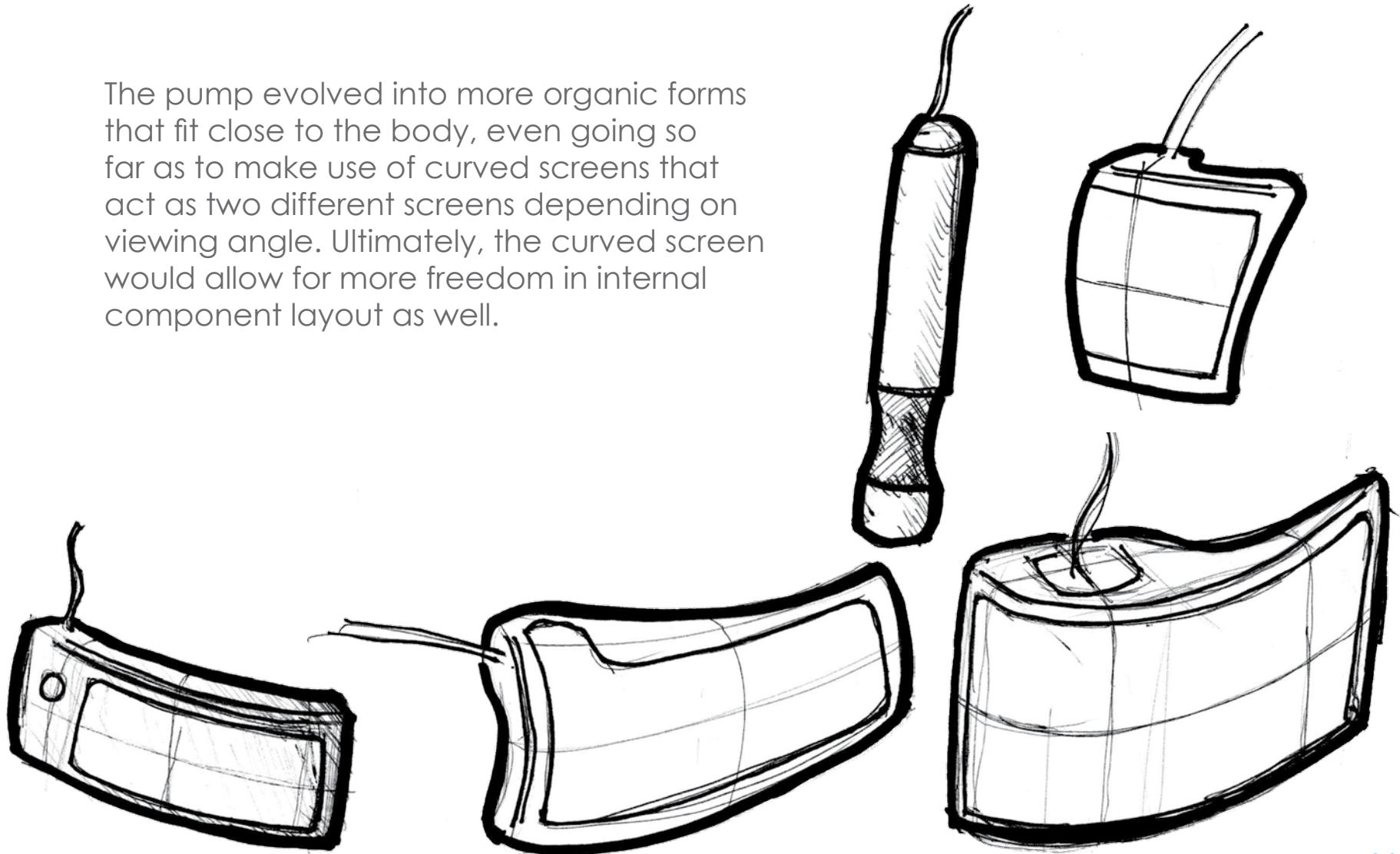


The pump began to shift towards a more traditional body form. As the development continues, the form became variants of ABS shells.

Earlier concepts played with hiding the screen, but if the screen was left exposed for an aesthetic more in-line with contemporary technology. With that aesthetic goal, the designs became more touchscreen-centric.



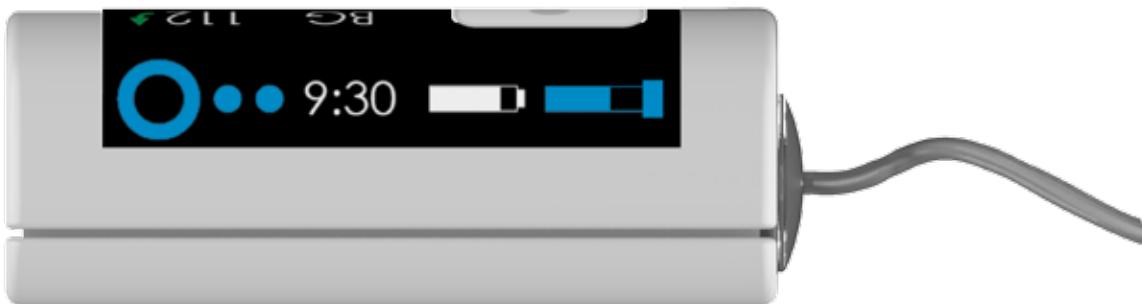
The pump evolved into more organic forms that fit close to the body, even going so far as to make use of curved screens that act as two different screens depending on viewing angle. Ultimately, the curved screen would allow for more freedom in internal component layout as well.



Final Concept



- Rounded touchscreen allows for two-sided display and innovative component arrangement
- Rechargeable battery via Mini USB Type A
- Compact and streamlined
- Holds 300 units of insulin

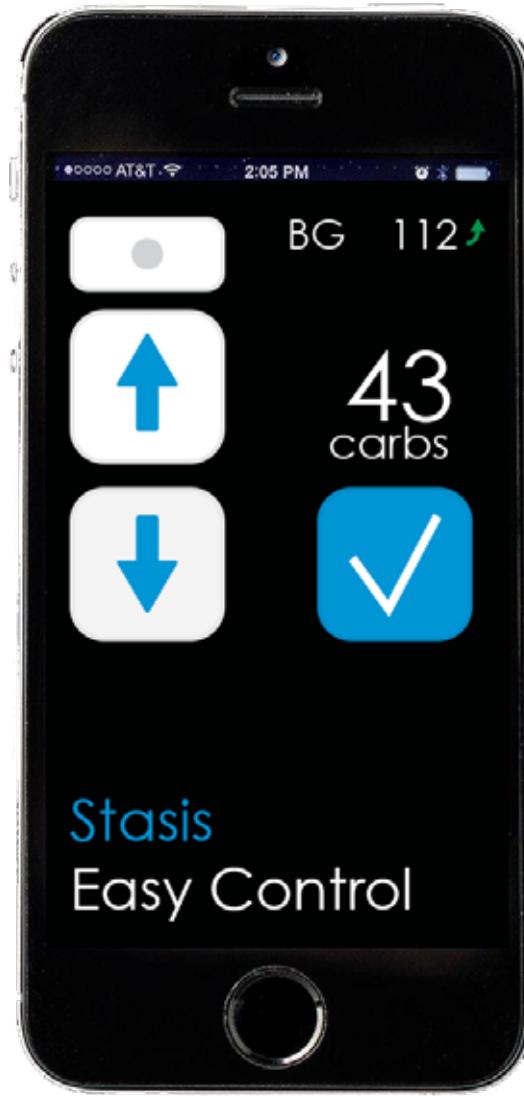




Left: Size comparison
with t:slim

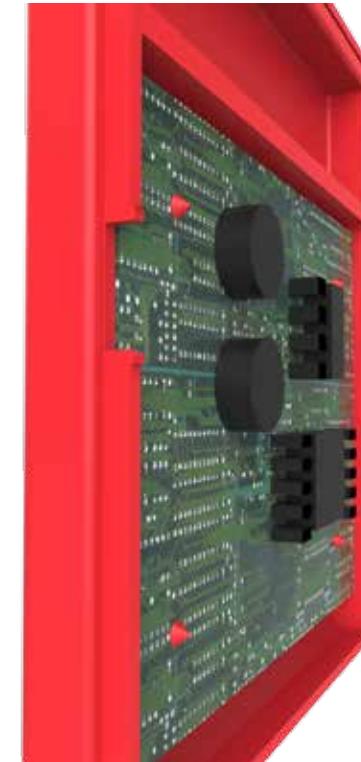
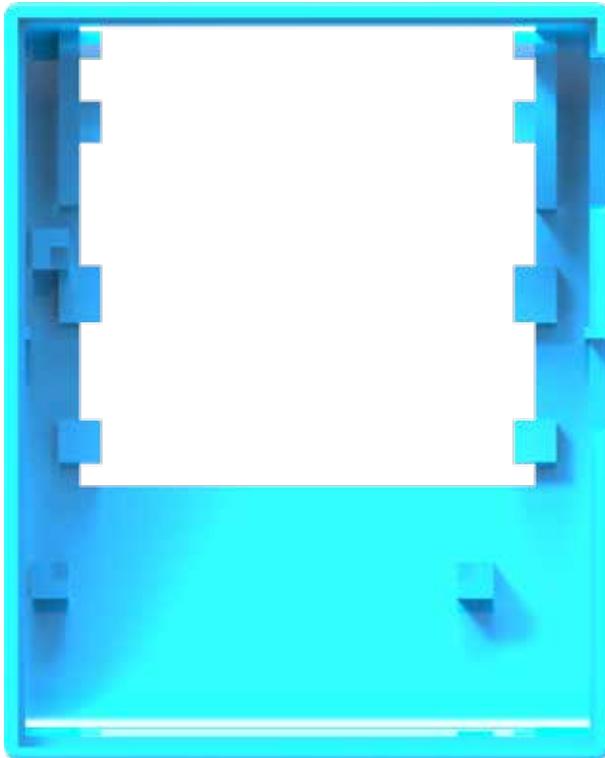


Right: Controlling Stasis
via smartphone app



Stasis
Easy Control

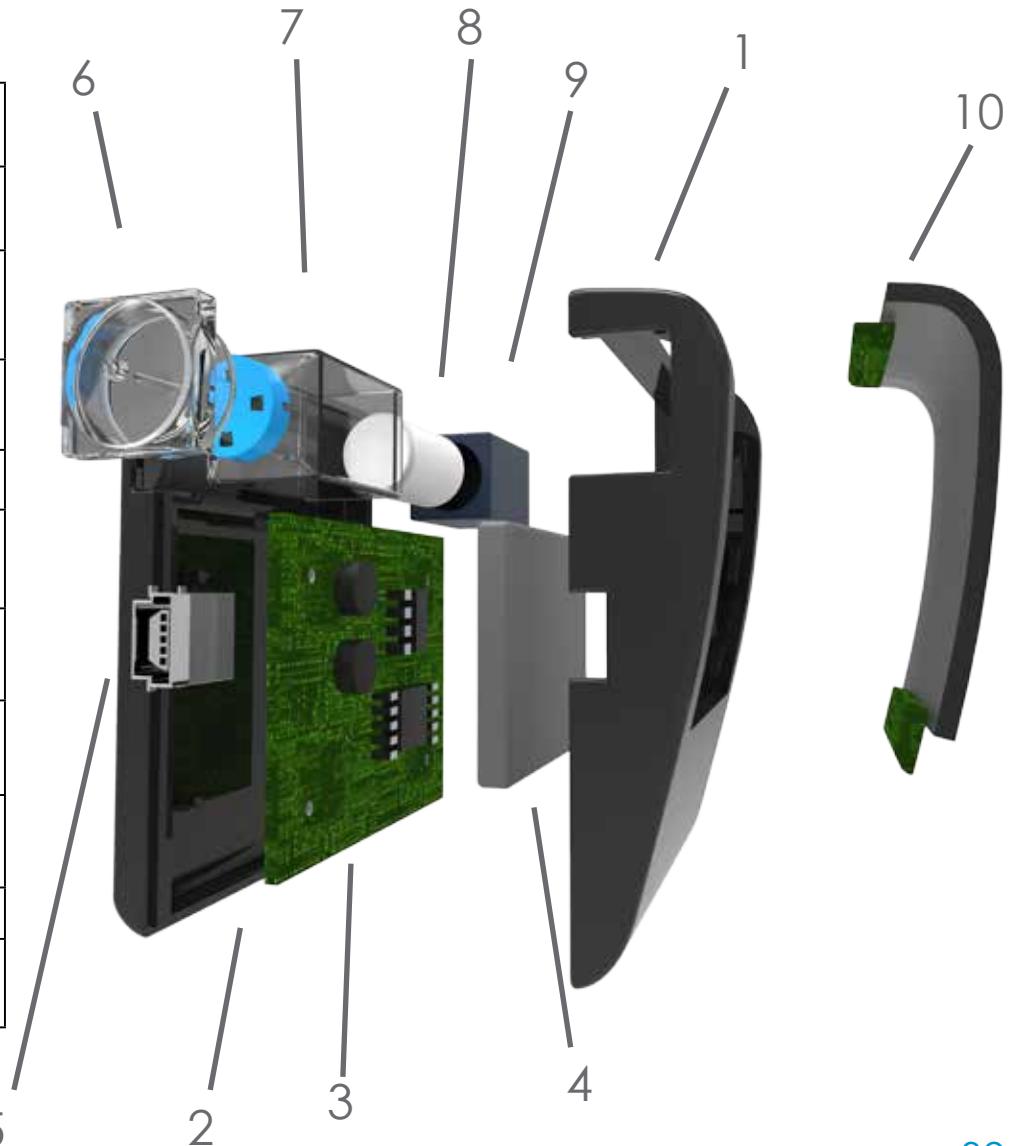
Manufacturing



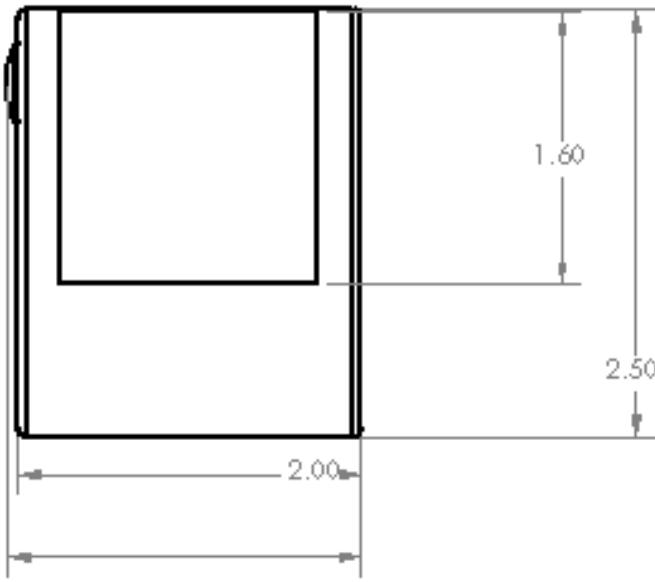
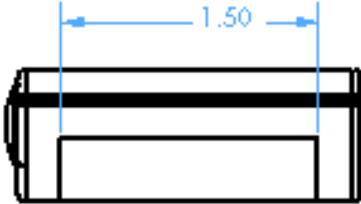
Plastic pieces are all designed to be injection molded and ultrasonic welded together. The circuit board is heat staked to the shell.

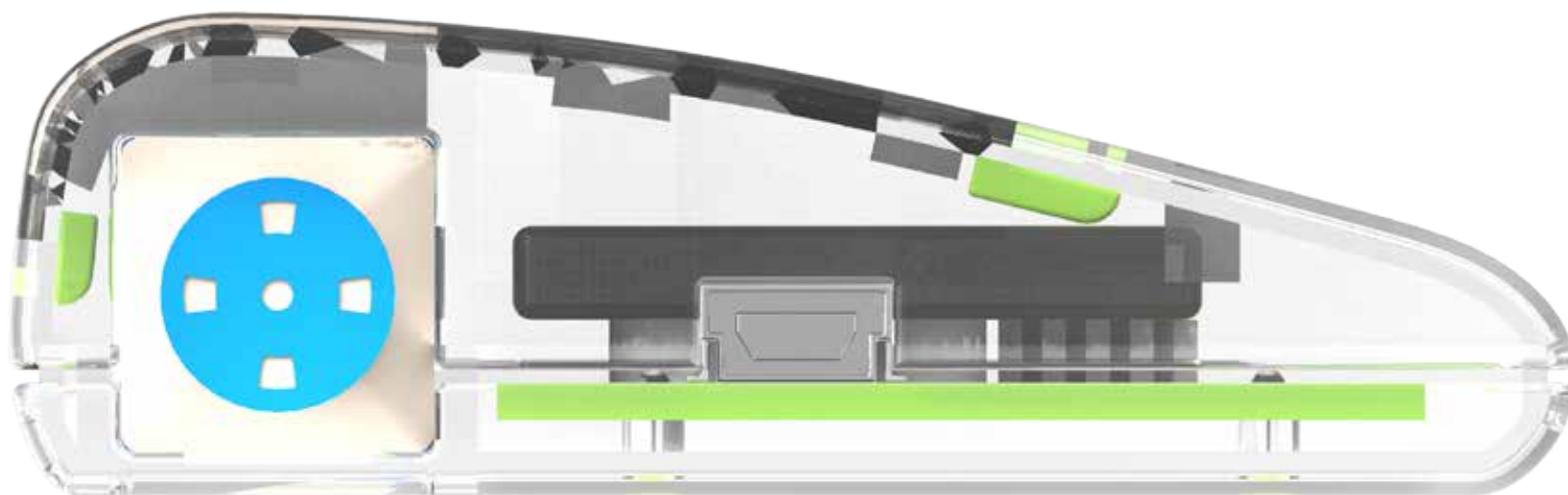
Bill of Materials

Item #	Part Name	Quantity	Material	Process
1	Top Shell	1	ABS	Injection Molding
2	Bottom Shell	1	ABS	Injection Molding
3	Circuit Board	1	Multiple	Heat Staking
4	Battery	1	Multiple	Soldering
5	Mini USB A Port	1	Multiple	Soldering
6	Reservoir Cap	1	ABS	Injection Molding
7	Reservoir	1	ABS	Injection Molding
8	Plunger	1	ABS	Injection Molding
9	Motor	1	Multiple	Soldering
10	Screen	1	Multiple	Adhesive Stips



CAD Modeling





Clearance Render

Accessories

Sport Reservoir



The Sport Reservoir is a pre-filled reservoir of medium-acting insulin. Before playing a high-contact sport, going swimming, etc, the wearer can quickly replace their reservoir with the Sport reservoir, pump its contents, and then disconnect from their pump for a few hours so the pump is not damaged. Athletes can still keep up their lifestyle and have the health and convenience benefits of the pump.

Unbreakable Clip



The Unbreakable Clip can confidently claim its title because it is designed to fall apart and come back together good as new. The joining of two sections via rare earth magnets ensures that any potentially clip-fatal scrapes are met with little resistance and easily fixed.

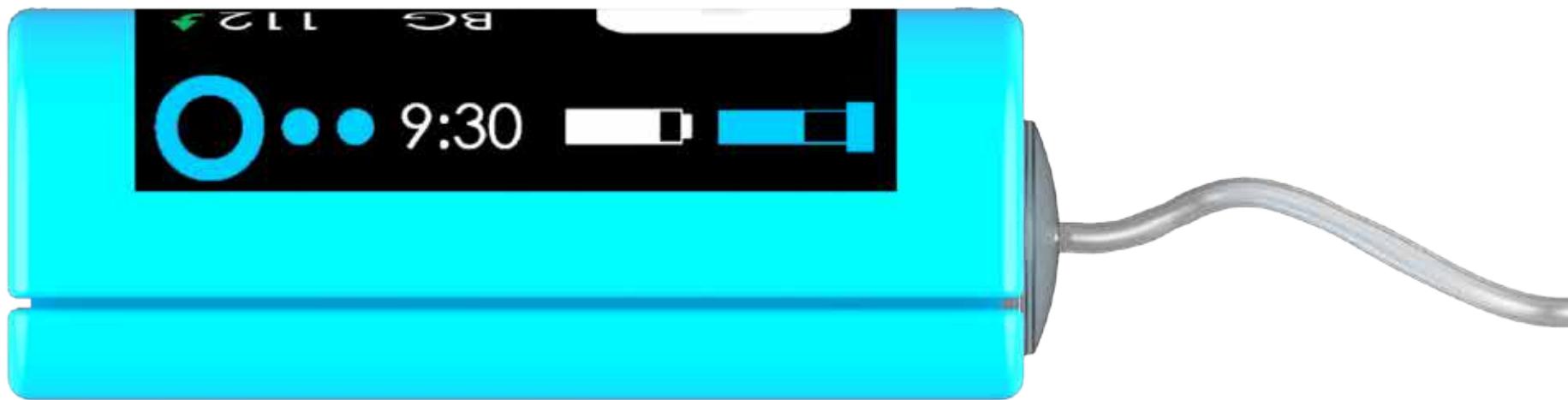


Summary



- Reduced material means reduced cost
- Compacted size and Unbreakable Clip increase wearability
- Aesthetic matches that of contemporary technology
- Phone app and familiar touchscreen interface erase a perceived learning curve

The **Stasis** Insulin Pump shows how design can increase access to medical technology.



Appendix

Tandemdiabetes.com

Medtronic.com

Integrateddiabetes.com

Diabetes.org

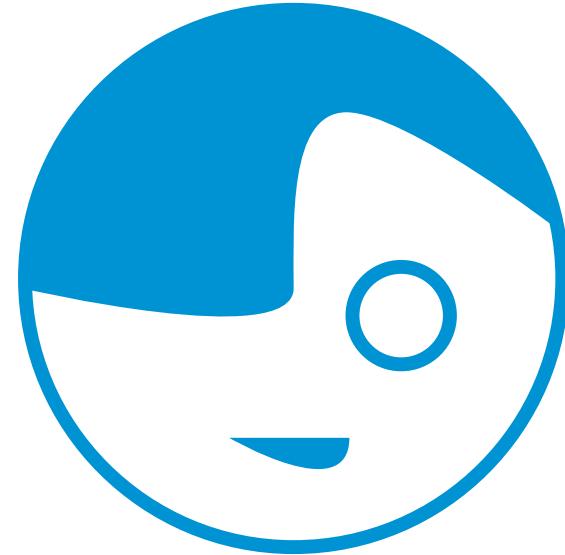
Diabetesforecast.org

Myomnipod.com

Thanks to:

Jason Farnan at Tandem Diabetes Care
SurveyMonkey participants

Stasis Insulin Pump



Nick Tourville
nicktourville.com