

o.sadh



IDUS 421: COMMERCIAL PRACTICES

Fall 2021 | Process Book

A special thanks to our...

EXPERT PANEL

Donald Lombardi, Chair

Served as Chief Intellectual Property Officer, Harvard Boston Children's Hospital

Founder and President Emeritus, Institute for Pediatric Innovation

Founder and VP Clinical Partnerships, Vascular Safeguard, LLC

Industry Resource Strategist/Mentor, SCAD

Arun Agarwal, B Tech – Electronics - Tech Biomedical Engineering

Founder at JANITRI Innovations, Bangalore Urban, Karnataka, India Social innovator, Biotechnology Industry Research Assistance Council

Fellow and Regional Leader The Kairos Society

Robyn Churchill, CNM, MSN, FACNM.

Maternal Health Team Lead, US AID

Clinical Director, Sexual, Reproductive, Maternal, & Newborn Health, Clinton Health Access Initiative

Clinical Midwifery Consultant, Global Health Media PROJECT

Anoop Rao MD, MS

Clinical Assistant Professor, Pediatrics (Neonatology)

Lucile Packard Children's Hospital

Clinical Neonatologist, Clinical Informaticist, > 5 years of Industry experience with a primary research focus on health tech innovation, medical devices (wearable sensors, non-invasive sensing), global health (affordable, low-cost medical device development)

Ben Mackowiak, MD

Neonatologist, Memorial Health

Associate Program Director, Memorial Health

Pediatrics

Stefanie Robinson-Program Manager Maternal, Newborn, and Child Health Discovery and Tools team Bill and Melinda Gates Foundation

Supports a portfolio of device product development to enhance obstetric technologies.

A background in life sciences and healthcare, including fourteen years at Seattle Children's Research Institute.

Focused on supporting product development of AI-enabled obstetric diagnostic tools to reduce adverse birth outcomes.

Hilary Gammill, MD

Obstetrics and Gynecology

Deputy Director, Maternal Health & Discovery, Bill & Melinda Gates Foundation

Affiliate Associate Professor, Maternal-Fetal Medicine, University of Washington

Caeley Harihara

Associate Strategy, Maternal, Newborn, and Child Health Discovery and Tools team Bill and Melinda Gates Foundation

Background in Electrical Engineering and management consulting

Focus on the Antenatal Risk Stratification Portfolio

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M Phil – Maternal and Child Health

Ph.D. Candidate-University of Technology Sydney-Australia

Council of International Neonatal Nurses Country Representative-Zambia

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William Rhine, MD, MS

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Linda Sacks, MD – Neonatology

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Physician's Lifetime Achievement Awardee, Georgia Medical Society

Diane Youmans, RN

M.S in Parent-Child Nursing

Neonatal clinical nurse specialist

Neonatal Outreach Coordinator, Memorial University Medical Center

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Martha Ndhlovu, RN-Midwife

M CUR in Registered Nursing, Nursing Administration, Clinical Nursing, and Nursing Research

Program Manager, Clinton Health Access Initiative, University of the Western Cape, Zambia

Technical Advisor, Maternal and Child Health Integrated Program, Jhpiego



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The Team

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PREGNANCY JOURNEY MAP

ARTIFICIAL INTELLIGENCE

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TARGET PERIOD & USER

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DEVELOP

FINAL SOLUTION

ORTHOGRAPHIC VIEWS

EXPLODED VIEWS

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CONCLUSION

PHASE ONE

DISCOVER

We Were Asked To...

Create an integrated digital backbone with AI-enabled decision-making support to guide pregnancy care in secondary regional care centers.

Design specific tools for risk assessment, monitoring, and decision-making in antenatal and intrapartum care.

The Goal:

A better understanding of the ideal pregnancy journey and common complications in various LMICs, analyze and assess devices currently on the market, and familiarize ourselves with artificial intelligence.

Research Topics

When diving into the initial research we really wanted to cover our bases. Our team split up into groups and compiled all of our research for each of these areas so we could best understand the scope of the project.

Ideal Pregnancy Journey*

Pregnancy Complications

LMIC Locations

Artificial Intelligence

Noninvasive Monitoring

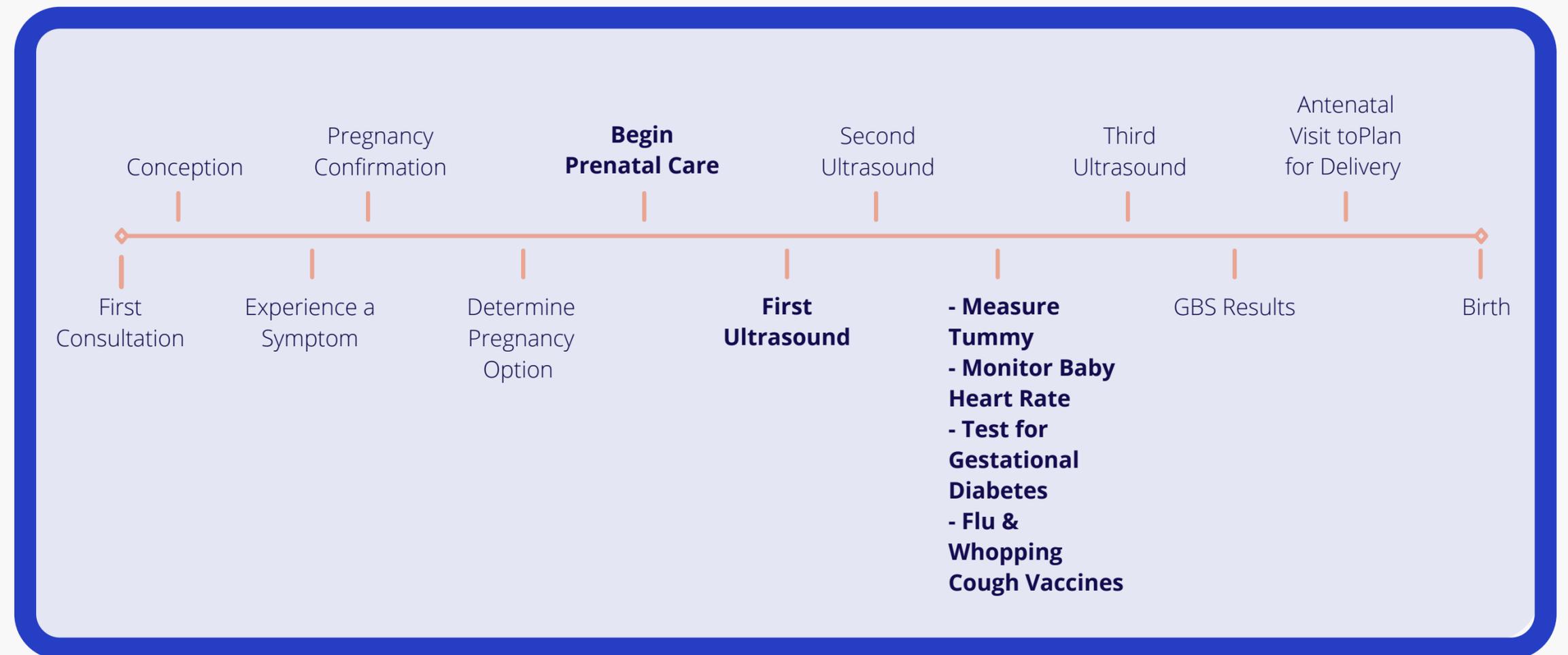
Sensors & Ultrasound*

*This is an ideal from the western physician-driven point of view

The **Ideal** Pregnancy Journey

By mapping out the ideal pregnancy journey, we were able to determine the most crucial points throughout a pregnancy that can impact the delivery, as well as the overall health of the mother and baby.

During this phase, we also learned that the earlier an expecting mother comes in for the first ultrasound, the lesser chance there is for complications.



Common Pregnancy Complications

Hypertension, Pre-Eclampsia & Eclampsia - Blood Pressure

Hypertension in pregnancy can cause serious complications for both mother and child and a more serious problem is encountered when pre-eclampsia develops. Pre-eclampsia is defined as new hypertension and substantial proteinuria after 20 weeks of gestation.

Pre-eclampsia can be accompanied by reduced blood flow through the placenta so that the baby receives less oxygen and nutrients. This can cause low birth weight, and other crucial issues for the baby.

A few women develop a condition called eclampsia, which results in seizures that occur during a woman's pregnancy or shortly after giving birth.

Hence, it is essential that blood pressure is monitored frequently and accurately during pregnancy.

Gestational Diabetes - Glucose

Gestational diabetes is a type of diabetes that can develop during pregnancy in women who don't already have diabetes. Managing gestational diabetes will help make sure you have a healthy pregnancy and baby.

Gestational diabetes can cause problems for your baby, like premature birth and stillbirth. Gestational diabetes can disappear after you have your baby; but 50% of women develop diabetes later in life.

Gestational diabetes typically doesn't have any symptoms, that is why it is important to be tested.

It is essential that treatment involves daily blood sugar monitoring, so the mother's blood sugar does not get too high.

Common Pregnancy Complications

Anemia - Hemoglobin

When you have anemia, your blood doesn't have enough healthy red blood cells to carry oxygen to your tissues and your baby. Anemia can leave you feeling tired and weak. If it is severe and goes untreated, it can increase your risk of serious complications like preterm delivery.

Severe or untreated iron-deficiency anemia during pregnancy can increase your risk of having: preterm or low-birth-weight baby, a blood transfusion, Postpartum Depression, a baby with anemia, and a child with developmental delays.

If you have lower than normal levels of hemoglobin or hematocrit, you may have iron-deficiency anemia.

This is why it is important to take a Hemoglobin test. It measures the amount of hemoglobin -- an iron-rich protein in red blood cells that carries oxygen from the lungs to tissues in the body.

Infection - Temperature

Women who are planning a pregnancy should consider taking steps to protect themselves from fever and infection during early pregnancy to help prevent birth defects.

In a study conducted by the CDC, Women who reported having a fever and did not consume the recommended 400 mcg of folic acid each day had the highest risk of having a baby with a neural tube defect.

Neural tube defects are serious birth defects of the brain and spine. It is common for Neural tube defects to occur during the first month of pregnancy.

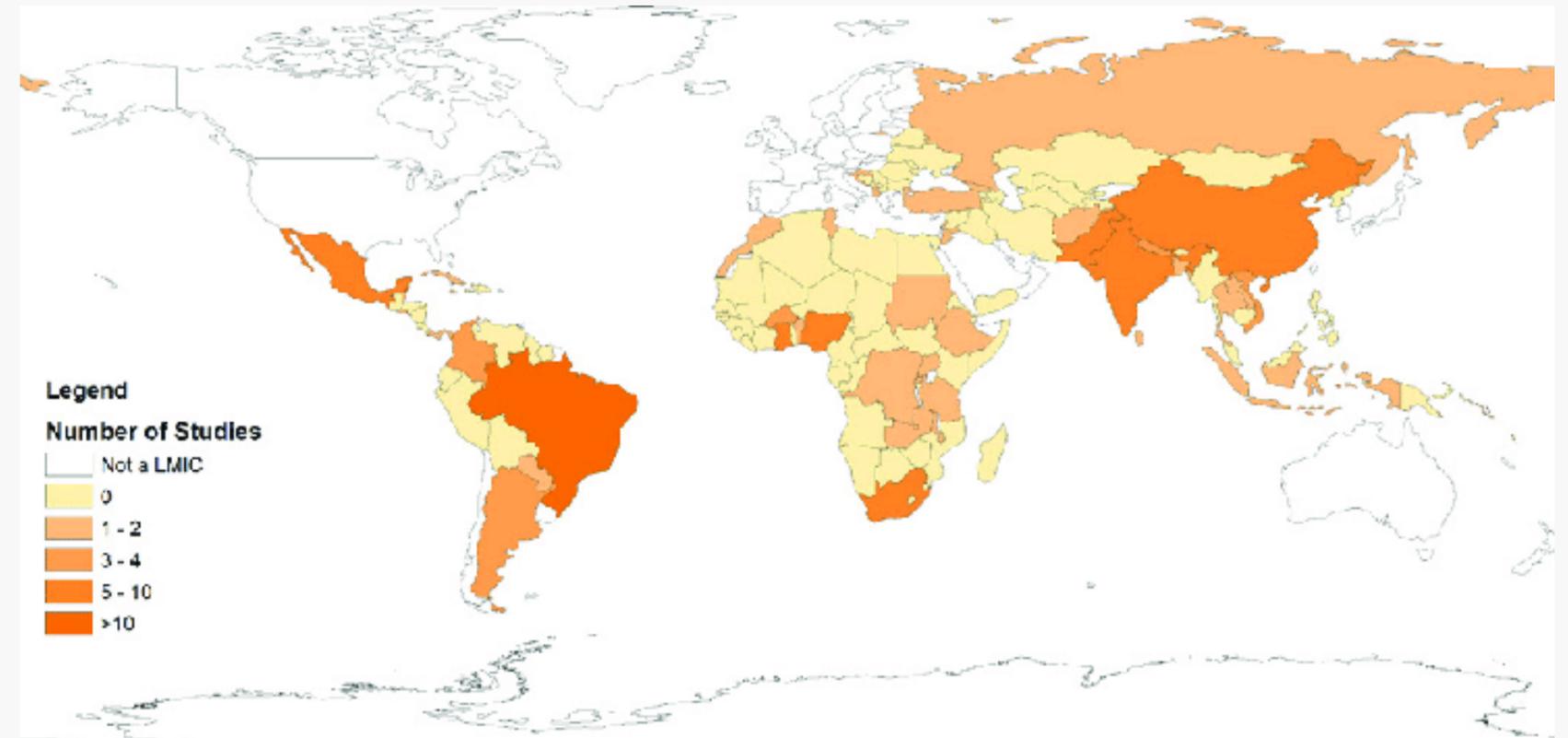
A fever is a normal response to infections, but sometimes it can mean more than just an infection. A reliable thermometer or way to take body temperature is essential in every pregnancy.

Low and Middle Incomes Countries

Determining the ideal location for the initial implementation of our final solution.

In our initial research, we looked into multiple countries on various continents such as Jordan, Rwanda, Ethiopia, India, Ghana, and Uganda.

However, in the end, we determined the best country would be India. Specifically, we are looking to implement this in **Karnataka, India**.



Why Karnataka?

High Infant Mortality Rate

- In 2018, the infant mortality rate for Karnataka was 23 deaths per 1000 live births.
- The fertility rate is 1.7 live births per women.

Minimal Antenatal Care

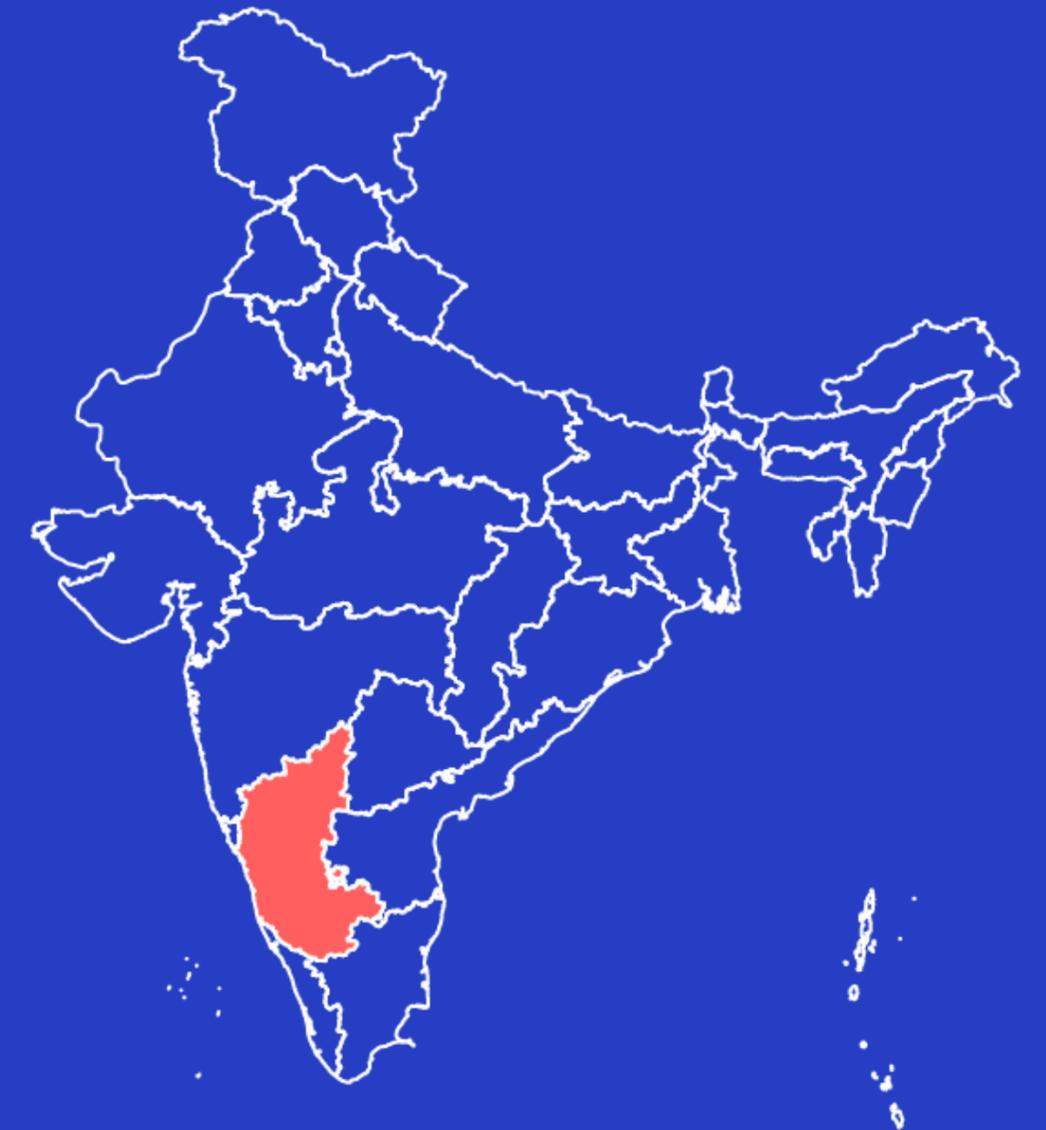
- Critical in resource-poor settings is the opportunity that antenatal care providers have in transmitting information to pregnant women and their families.
- The fertility transition is well advanced in this part of India but maternal health is still very poor.

Reign

- Karnataka has a rural profile typical of South India.
- A higher than average population of 68.4 million as of 2021.
- Literacy levels in the state are just a little higher than the national average of 52 percent.

Resources & Power

- Hydroelectric plants generate enough power to supply local and neighboring states.
- Additional energy is provided by thermal & wind-powered plants.
- Access to the Internet.
- 68.60% of the households in Karnataka have smartphones.



We also looked into...

Types of Artificial Intelligence

Reactive Machines

This is the oldest existing form of AI. No memory-based functionality, cannot use previously gained experiences. Used for automatic responses in limited or combination inputs

Limited Memory Machines

The Majority of chatbots use this now. Capable of learning from historical data to make decisions. Learning experience= increased accuracy/efficiency.

Artificial Narrow Intelligence

This form represents all existing AI. Can only perform a specific task autonomously using human like capabilities. It contains a narrow range of competencies because it only does what programmed to do.

Deep Brain Neural Networks

AI learns to optimize outcomes by repeating passes of data. Through processing information multiple times it uses machine learning to improve the outcome each time.

AI Scan

Pattern recognition software adapted into many different purposes for different industries. Described as an artisanal alternative to Deep Brain learning because for each individual recognition task it requires the software to be fine tuned for that task.

Artificial Intelligence

Key Takeaways

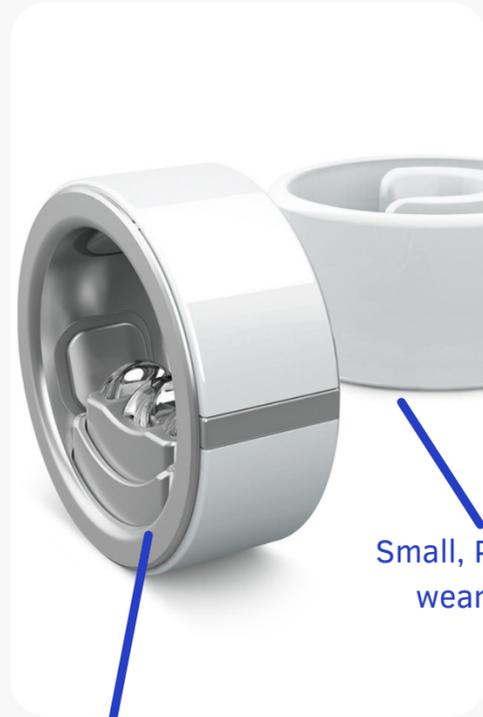
Patient data- AI is particularly good at combing data and finding patterns in vast numbers.

AI is currently being used for decision-making in data-based disciplines: radiology, pathology, ophthalmology.

AI is woking in data mining for large amounts of genetic, clinical, social, and lifestyle data for more precise precision medicine.

Then we took a look at what's currently on the market for...

Noninvasive, Continuous Monitoring



Small, Portable wearable.

Enables continuous monitoring of the pulse and of oxygen saturation in the blood.

If vitals are critical, the alarm function is activated.



Data can be transferred wirelessly to a network to share with doctors or store digitally.

Can quickly identify the patient's status based on the early warning scoring.



The ergonomically designed wearable modules allow for full monitoring of the vital signs once the patient is mobile. More modules can be easily added as well.

Is capable to continuously and medically precise measure cardiac functions, body temperature, activity levels, stress monitoring, ETC.



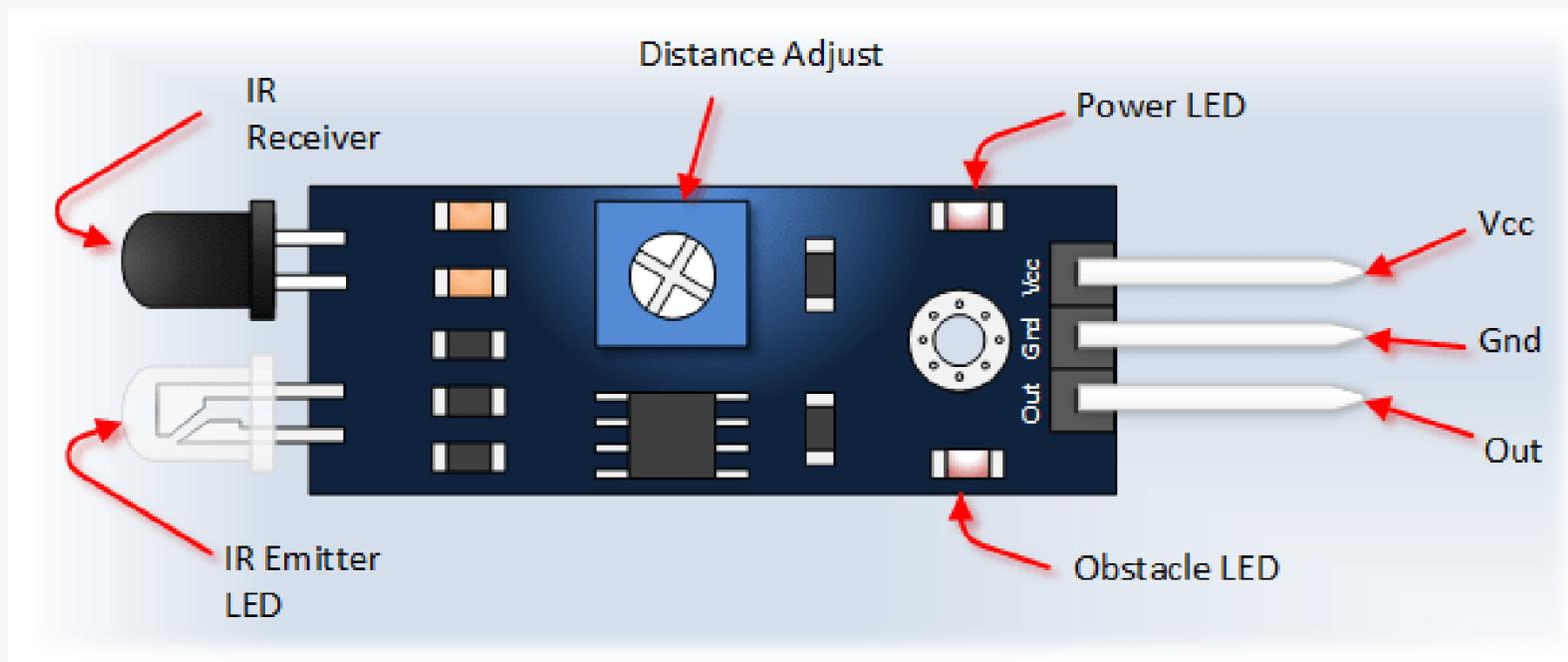
Wirelessly connects and syncs to an installed application.

Then we dove into...

Sensors

How do Active Infrared Sensors Work?

Active infrared sensors work with radar technology and they both emit and receive infrared radiation. This radiation hits the objects nearby and bounces back to the receiver of the device.



How do Light Sensors Work?

The light sensor is a passive device that converts the light energy into an electrical signal output. Light energy (photons) is able to convert into electronic signal (electrons).

From this research, we learned that Infrared-sensors are used in medicine to detect the temperature of the skin. The temperature distribution over the human skin surface gives insight into many physiological problems concerned with thermoregulation and metabolism. From this, we knew that infrared sensors were something we wanted to look at more in-depth as a feature to implement into our final design.

And finally, we analyzed the use of...

Ultrasound



While we understood the relevance of using ultrasound in our final solution, we also knew that we really had to consider all aspects of what we were implementing and why.

We ultimately decided to remove the use of ultrasound in our initial design due to various socio-cultural and research findings proving it to be that it is inappropriate for use given the level of training the caregivers, it is not needed to determine gestational age and, finally, the powerful point about female infanticide/ feticide.

Market Research

Key Takeaways

Through analyzing what is currently available and learning how it works, we were able to gain a better understanding of what our solution needed to feature and how it could function. Without an idea of the lookor feel we knew that ...

1

Create a real-time noninvasive monitoring system without the use of ultrasound.

2

Ensure that the motoring system has to be resistant to environmental factors.

3

Create a system that aids in determining whether to refer a patient to a higher level of care?

From our research

we moved on to...

PHASE TWO

DEFINE

Getting into specifics...

In phase two, we determined the exact period of pregnancy we wanted to target, our target user, the specific functions features of our final solution, and got to ideating.

The Goal:

Throughout this phase of the project, we were determined to finalize the parameters of our final solution and finally got to designing.

Antenatal Care

Graduate Nurses

Target PERIOD:

Antenatal care maintains the physical health and peace of mind of the expectant mother, thereby maximizing the chances for a normal pregnancy and a normal baby. Antenatal care prepares the prospective parents for pregnancy, labor, and delivery which is why it makes it so critical.

Target USER:

In our target location, it is common for women to deliver their babies at home with the assistance of a graduate nurse. This could be due to a variety of different reasons, such as physician shortages in public healthcare, inaccessibility to sufficient facilities, the inability to travel, etc. An all inclusive kit that is user friendly could act as a great aid in the performance of these graduate nurses.

Our Proposed Concept:

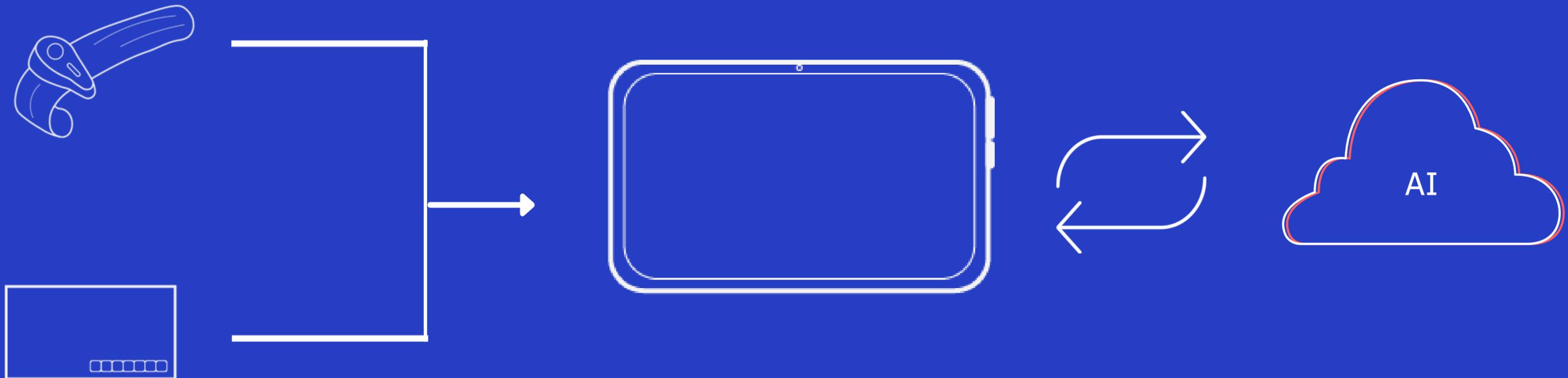
Antenatal Kit

The goal of the kit is to help the graduate nurse in determining 5 key elements: determine gestational age, measure glucose levels, monitor blood oxygen levels, take blood pressure readings, and testing for a variety of infections. The wearable device measures blood pressure and blood oxygen, and the color constant is for gestational age testing, glucose levels, and test infections. Ultimately this will provide an easy-to-understand data analysis, done by the AI, that explains simple steps on what graduated nurses can do next to help their patients.

01 Wearable Device
+ Color Constant

02 Android Tablet & App

03 AI Component



Proposed Technology

- Measure **glucose levels** through a urine test.
- Determine **gestational age** through a human chorionic gonadotropin (HCG) saliva test.
- Measure **blood oxygen** levels through the wearable device.
- Take **BP readings** with the monitor on the wrist.
- Measure possible **infection** through urine testing.
- Uses a **color constant**.

INFECTION

How it Works:

- 01 Patient urinates into collection cup or nurse administers saliva swab
- 02 Strip reacts and changes colors according to a gradient scale
- 03 Tablet takes photo of strips on top of the color constant background
- 04 AI analyzes image
- 05 App reports results

BLOOD PRESSURE

How it Works:

- 01 Patient activates reading with button
- 02 Patient elevates the arm
- 03 Armband inflates
- 04 Blood pressure is read
- 05 AI reads and analyzes data
- 06 App displays readings

GLUCOSE LEVELS

How it Works:

- 01 Patient urinates into collection cup
- 02 Strip soaks in urine and changes colors according to a gradient scale
- 03 Tablet takes photo of strip on top of the color constant background
- 04 AI analyzes image determines glucose levels
- 05 App reports results

BLOOD OXYGEN

How it Works:

- 01 Patient activates reading with button
- 02 Device releases red & infrared LED light
- 03 Sensor reads absorbed light
- 04 AI calculates blood oxygen percentage
- 05 App displays readings

GESTATIONAL AGE

How it Works:

- 01 Patient urinates into collection cup
- 02 Strip soaks in urine and changes colors according to a gradient scale
- 03 Tablet takes photo of strip on top of the color constant background
- 04 AI analyzes image determines gestational age
- 05 App reports results

How it Works:

The color constant allows you to gather an accurate reading of the urine strip sample test that will measure the HCG, gestational age, and the possibility of infection. The color constant ensures that no matter what environment or lighting the user is in, each image will be color corrected by the AI to be accurately analyzed. All of the strip tests can be conducted through one urine sample.



How does it CHARGE?

When considering the power source, we knew we wanted something reliable, powerful, rechargeable, and self-sustaining. In the end, we had three power sources, a power distributor, and the ability to charge the tablet and wearable while they're in the case.

Rechargeable Lithium-Ion Batteries

When deciding on the kit's battery, we went with rechargeable lithium-ion batteries for their safety, long life, fast charge time, and temperature tolerance.

Solar power: Built into top of the case

Aside from being a great source of sustainable energy, there has also been a recent push for increased solar power use in India, with their recent 'solar revolution'.

Tablet case charges from inside

Using wireless connection points from inside the kit's case, the tablet will sit snugly, safely inside, and get recharged for the next patient.

Next we dove into...

Determining Materials

WHY?

Wearable & Miscellaneous components

Polycarbonate (PC)
This material was chosen because it is easy to machine, preferred in the medical field due to its strength, it does not react negatively with the skin and it is fairly inexpensive.

Diaphragm on wearable

Neoprene/Nylon
This material was chosen because it is a standard material that is widely recognizable, that has durability as a wearable. Nylon is also made from man made fibers so it makes it completely hypoallergenic.

Wearable Band support

High-density polyethylene (HDPE)
This material was chosen because it is the most environmentally stable of all plastics, and it can be easily welded. It will not splinter, rot or retain harmful bacteria, and is extremely resistant to cleaning agents.

Protective Case

Polypropylene copolymer (PPC)
This material was chosen because it has a high impact strength, and it also very durable. More resistant materials will better protect the internals of the case.

Initial Sketches



Initial Sketches

- Liys Corner**
- 1) All Reliability
 - 2) Power (Devels Power Crisis)
 - 3) Cost (Keep Low)
 - 4) don't necessarily know location of graduate (not rely on connectivity)
 - 5) getting strips to the people (have a study)
 - 6) storage of data (healthcare data)
 - 7) Wearable size -> need to fit all people (Design)
 - 8) can LED go on through arm band (hemoglobin) puling
- Cons**
- 1) how much power? Devel
 - 2) implementation/training
- Sharp**

PHONE / NO PHONE
LESS VALUE

NO APP DOWNLOAD
POT LESS DEVICES

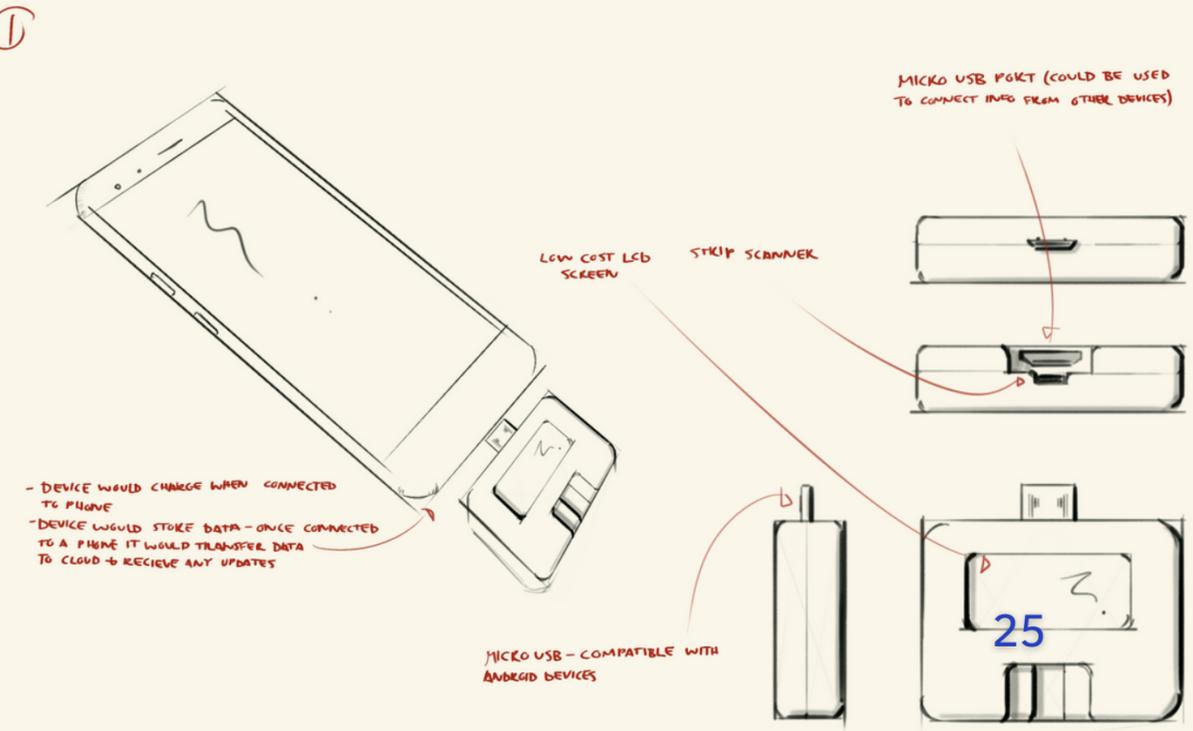
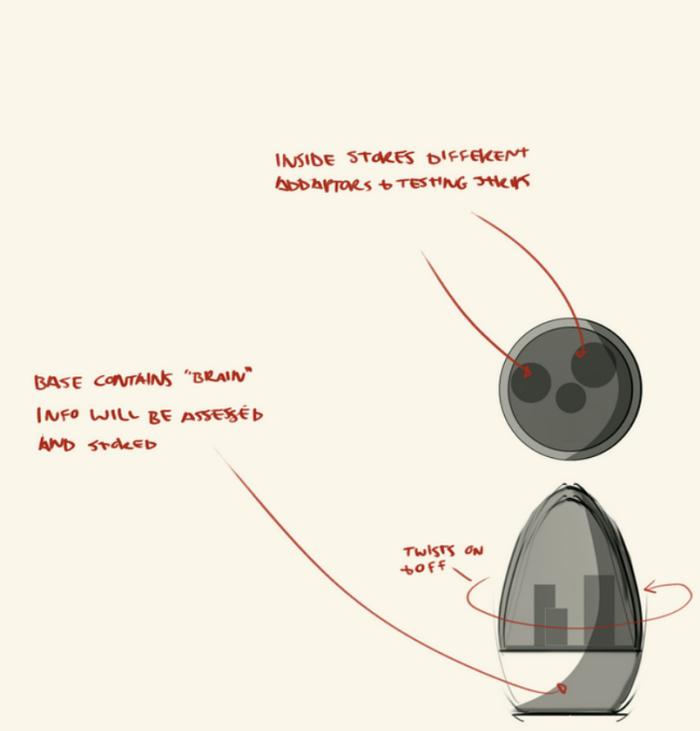
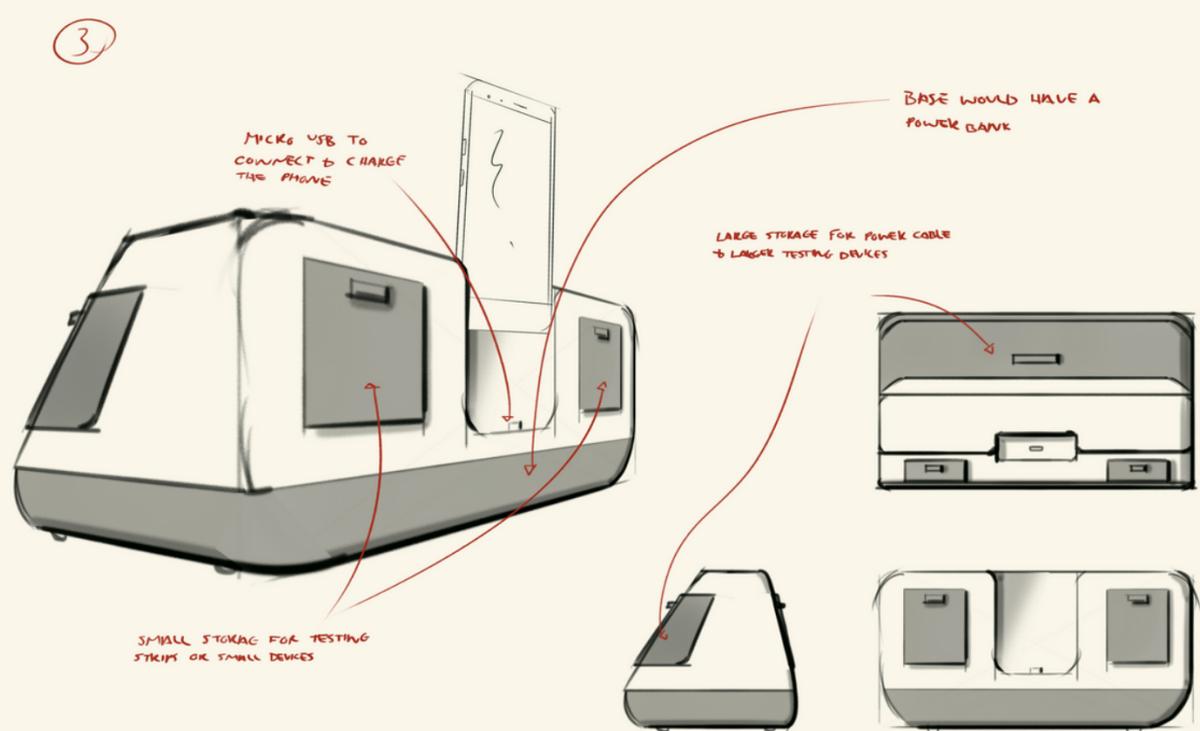
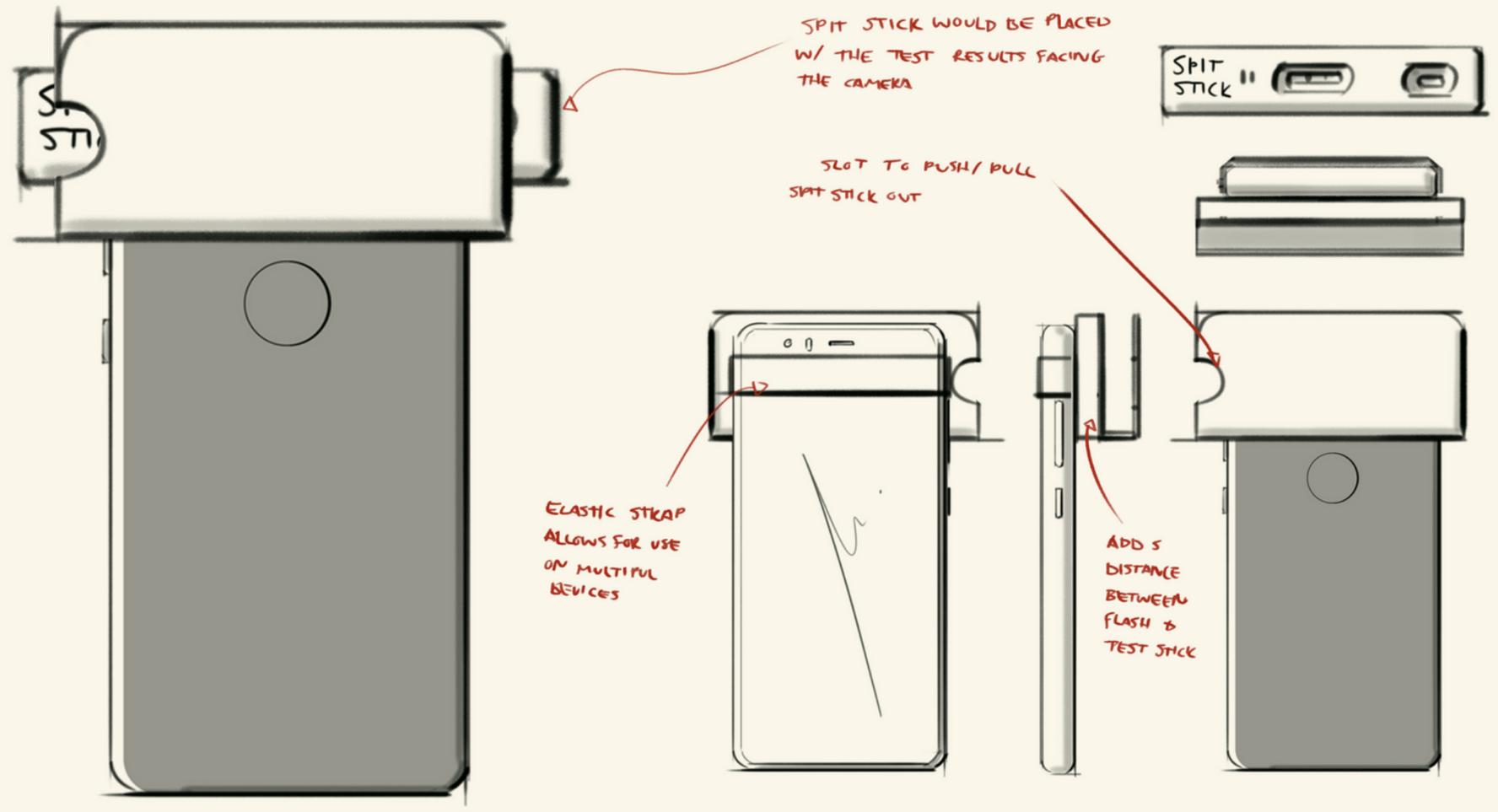
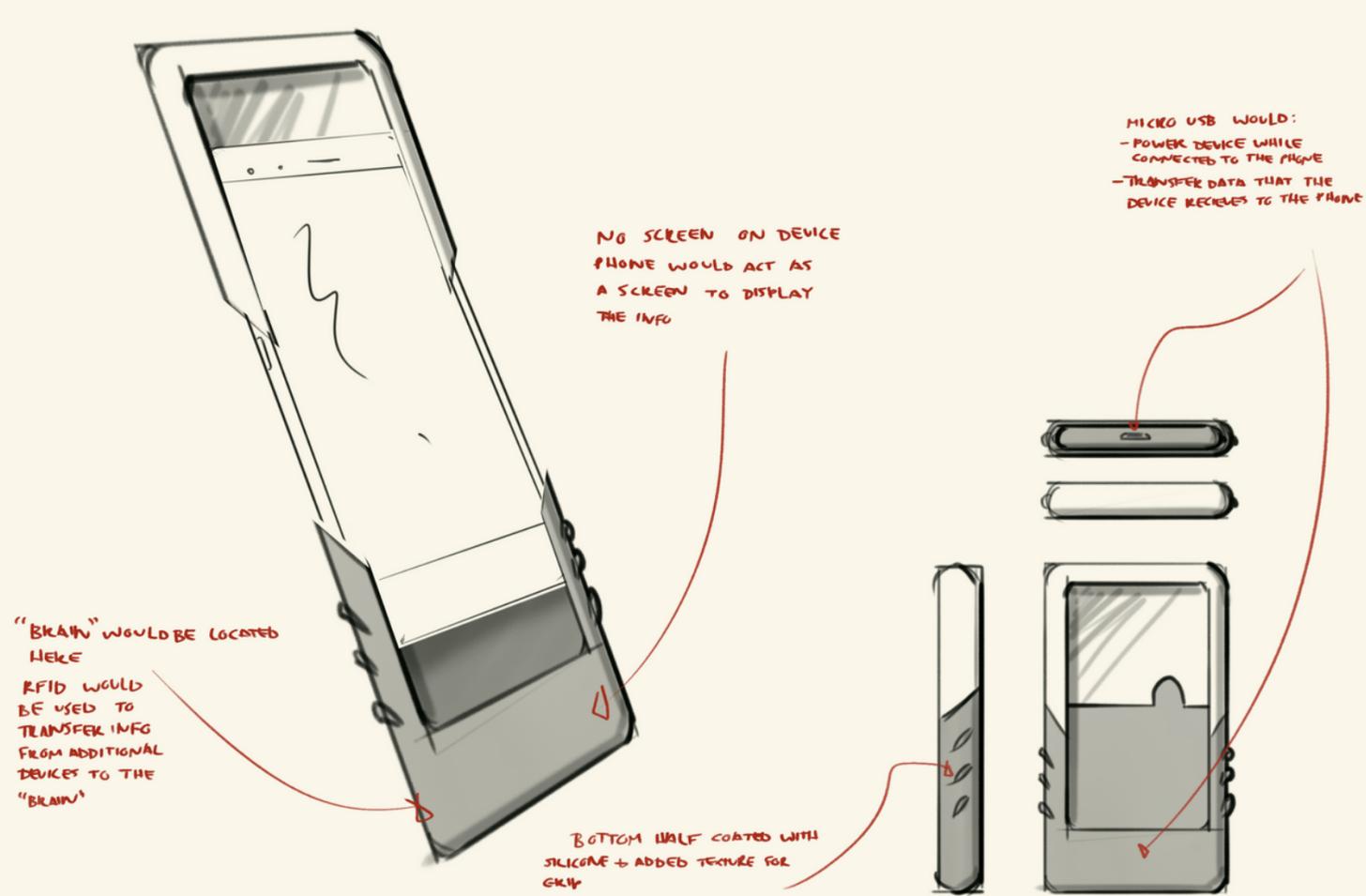
LED LIGHT
FIT LARGE SPEN

CONS

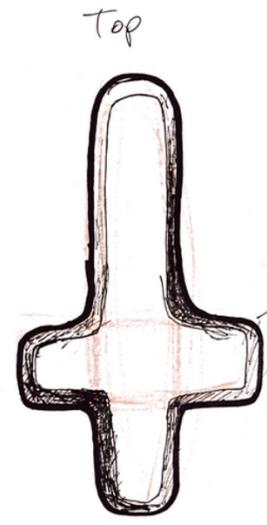
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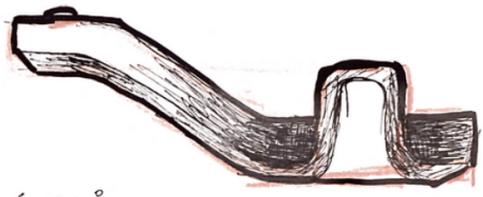
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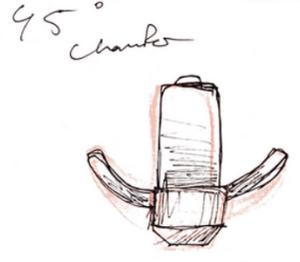
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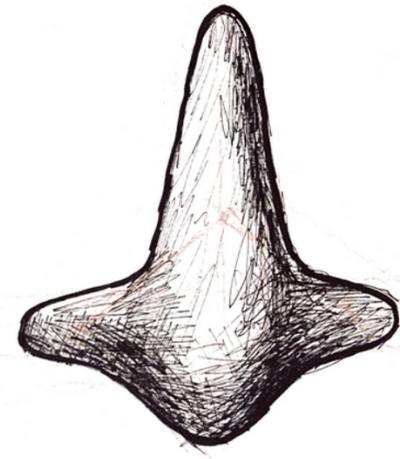
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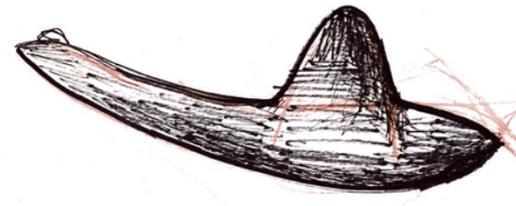
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Top



Side



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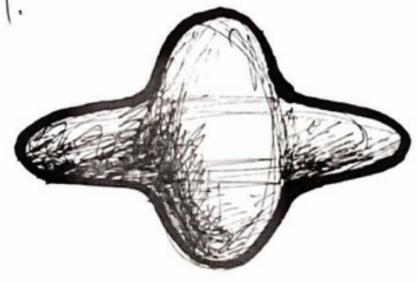


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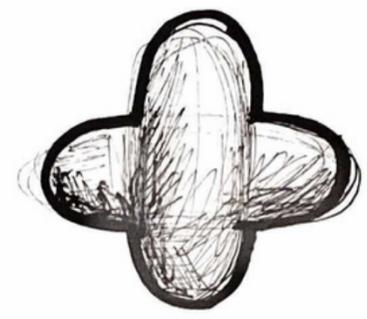


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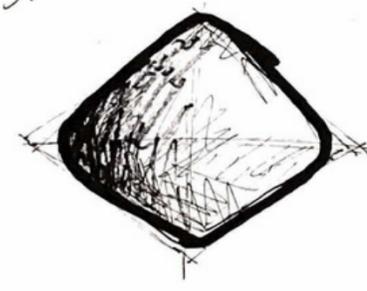
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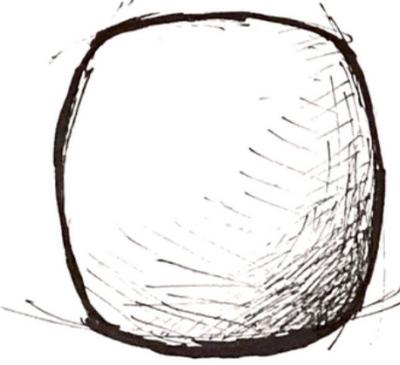
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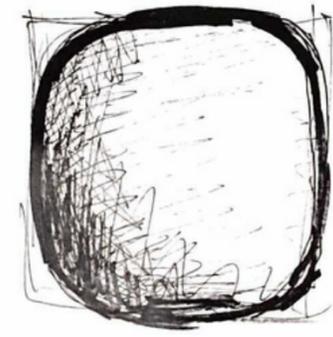
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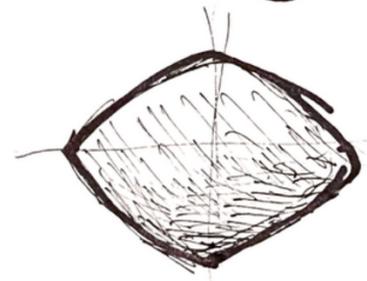
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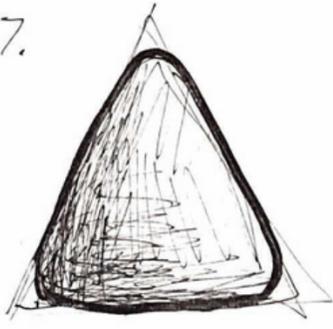
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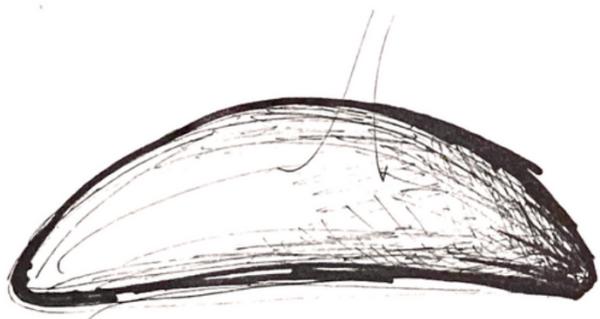
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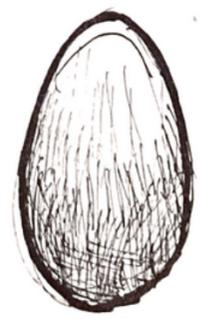
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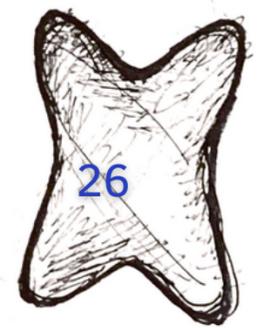
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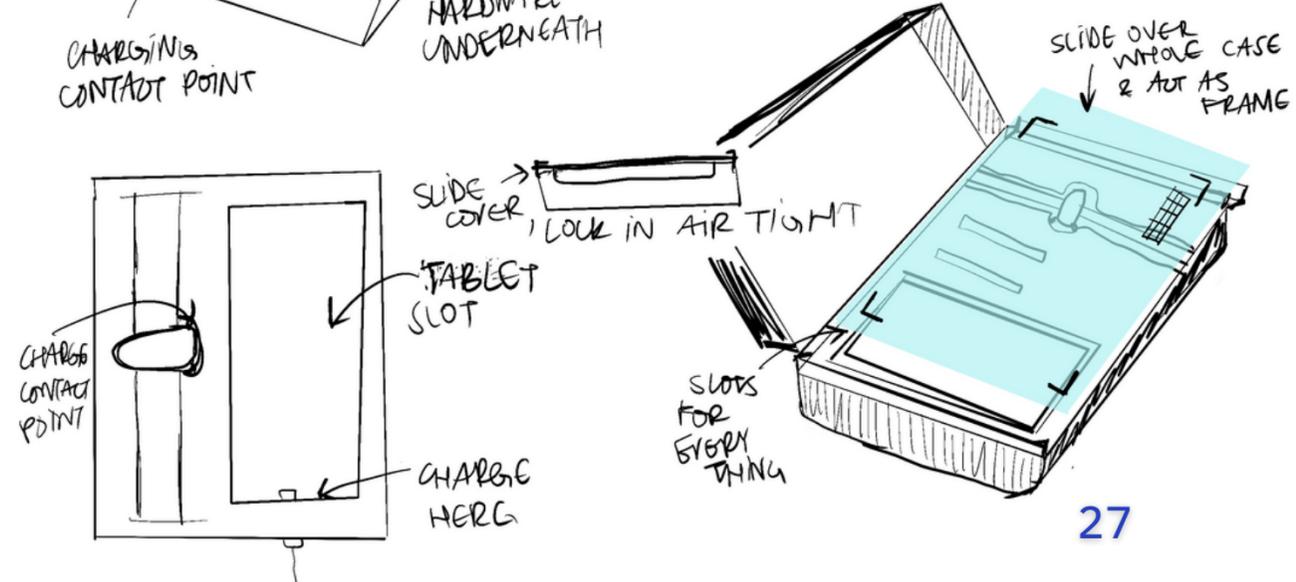
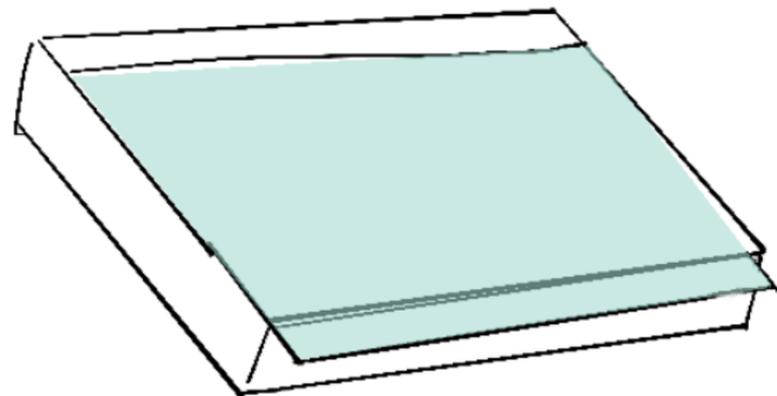
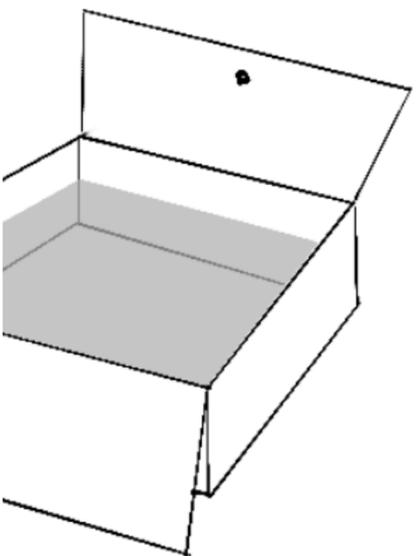
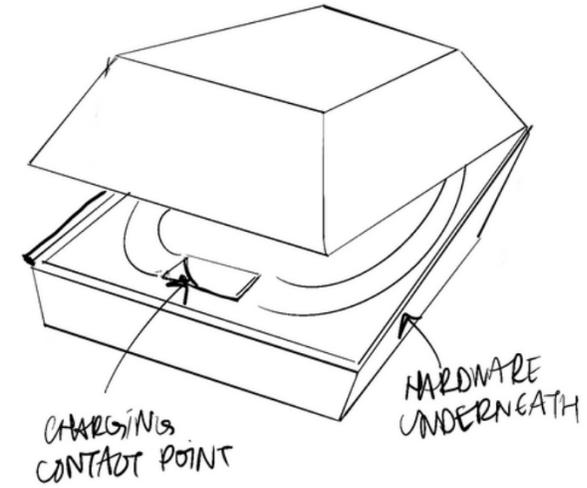
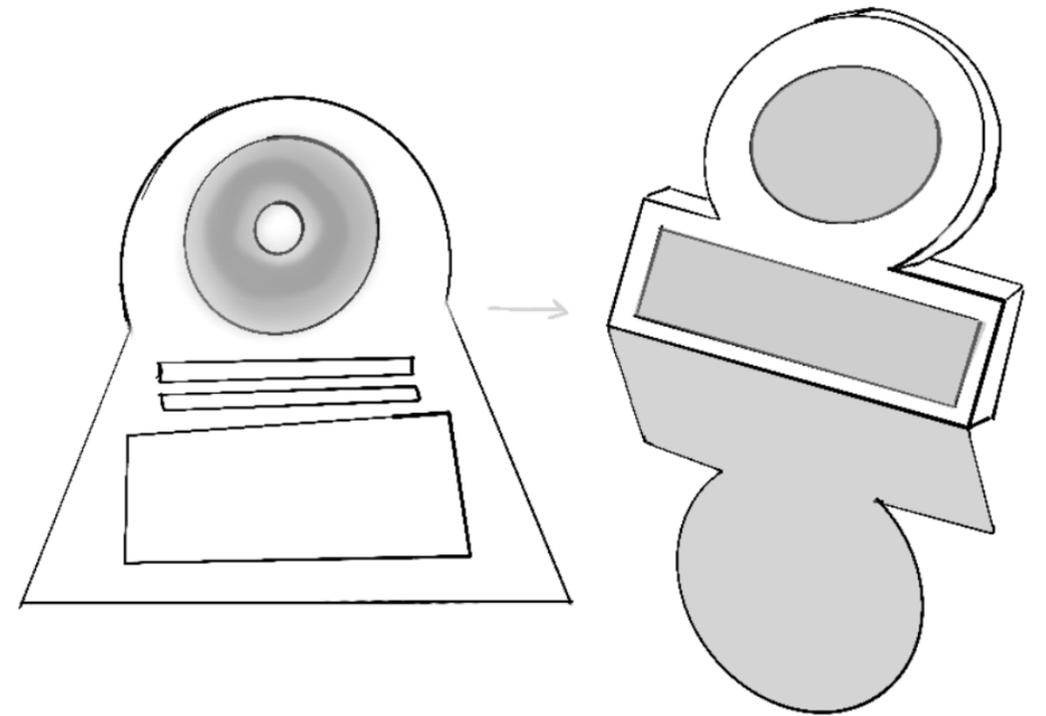
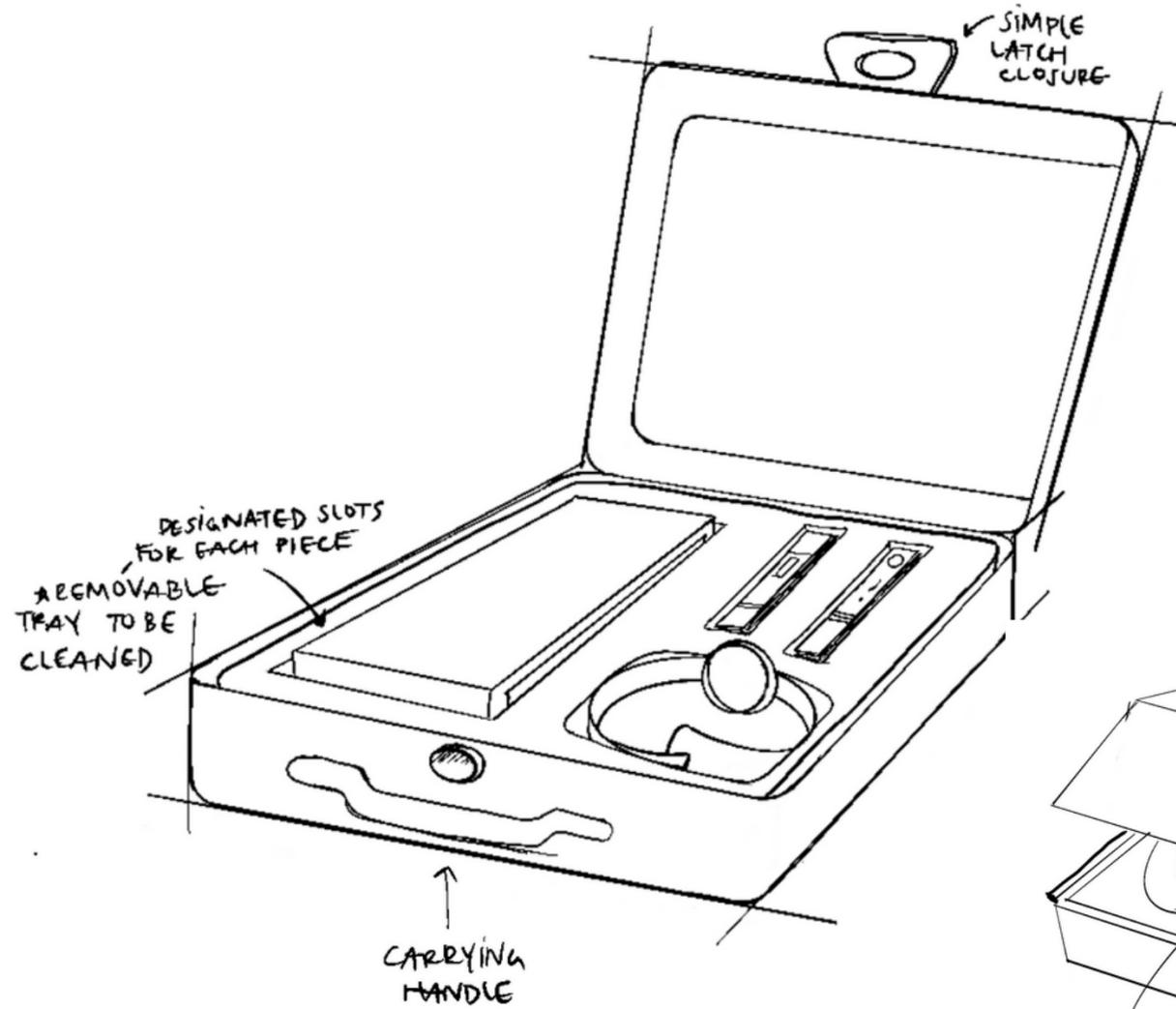
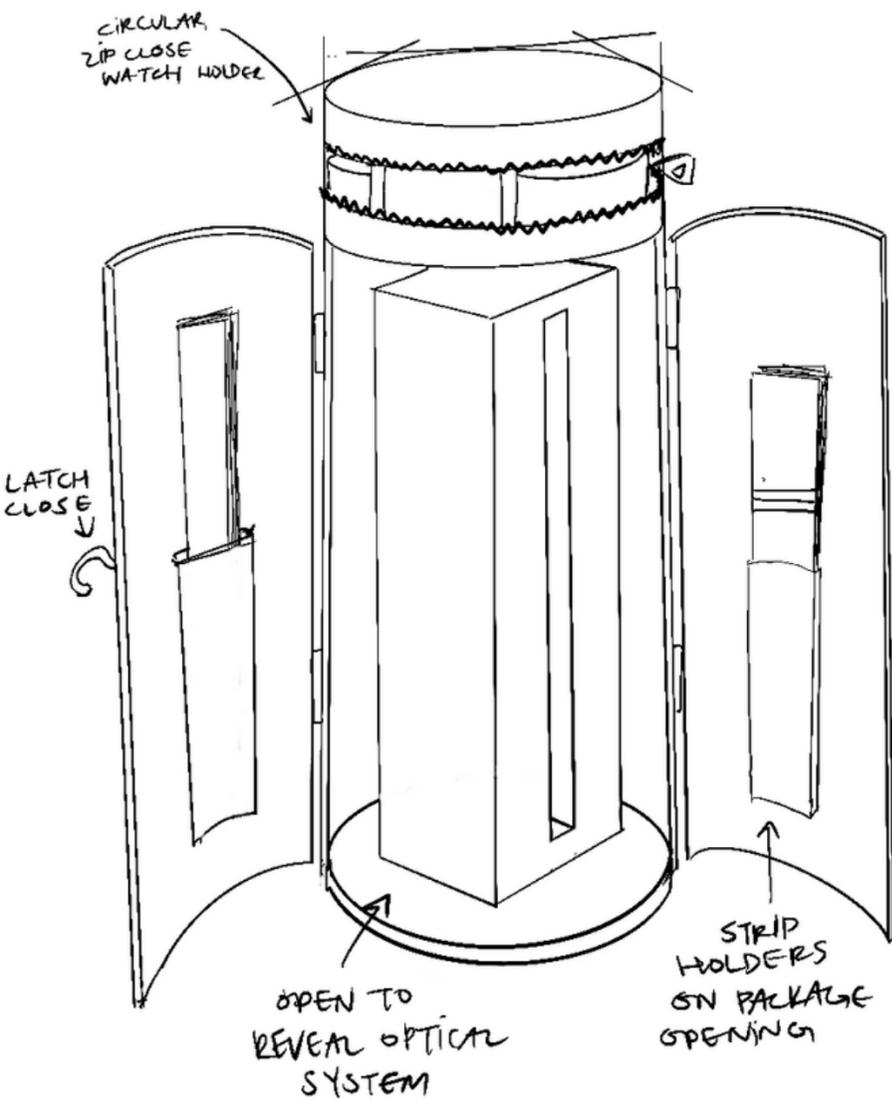


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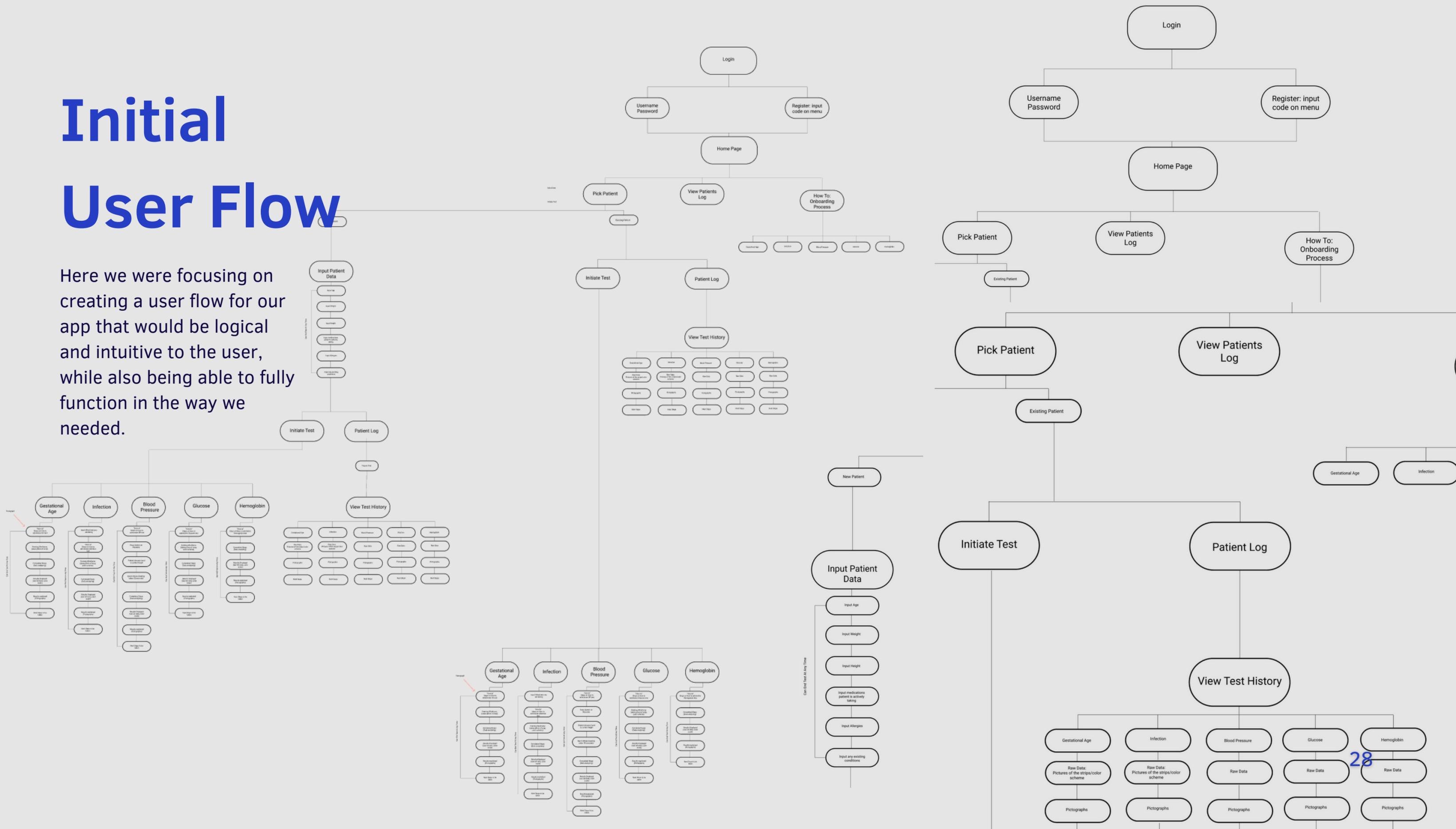
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Initial User Flow

Here we were focusing on creating a user flow for our app that would be logical and intuitive to the user, while also being able to fully function in the way we needed.



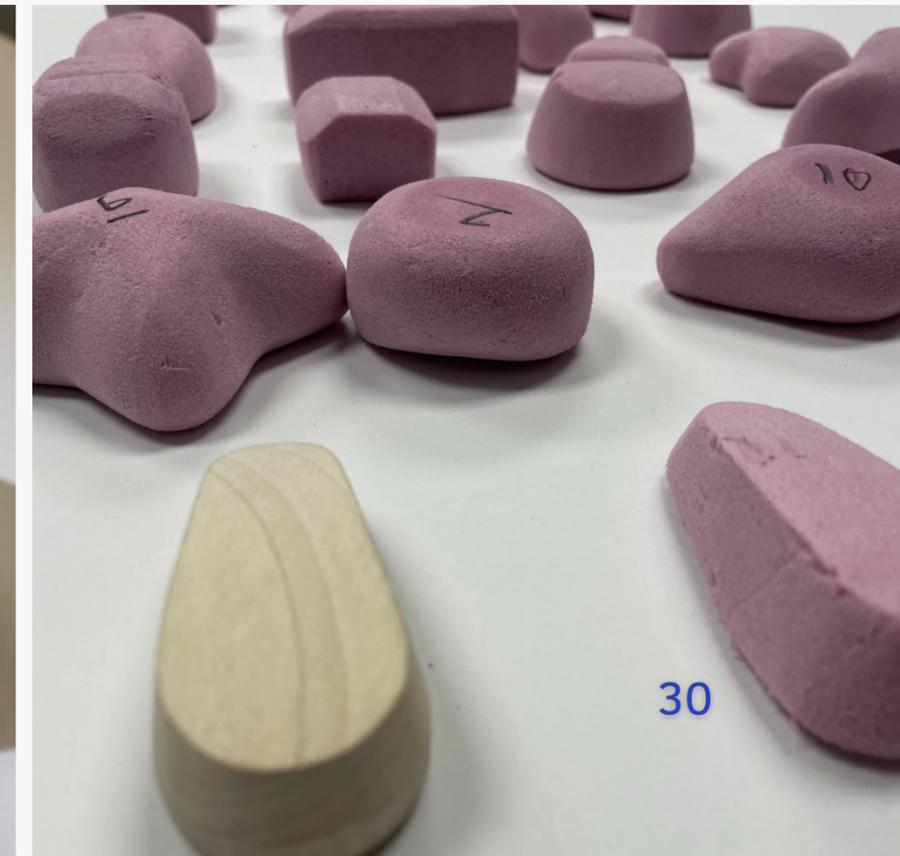


Models & Prototypes



Form Ideation Models

Pictured are our initial foam model prototypes. There were 27 handmade models that were initially tested in class for things such as comfortability, the size on the wrist, and the form. We decided to go forward with the wood prototype pictured in the bottom right photo due to its unique sleek form. It felt pleasant on the wrist, the scale was appropriate in relation to an average wrist, and it seemed less intimidating than the existing wearable devices on the market today .

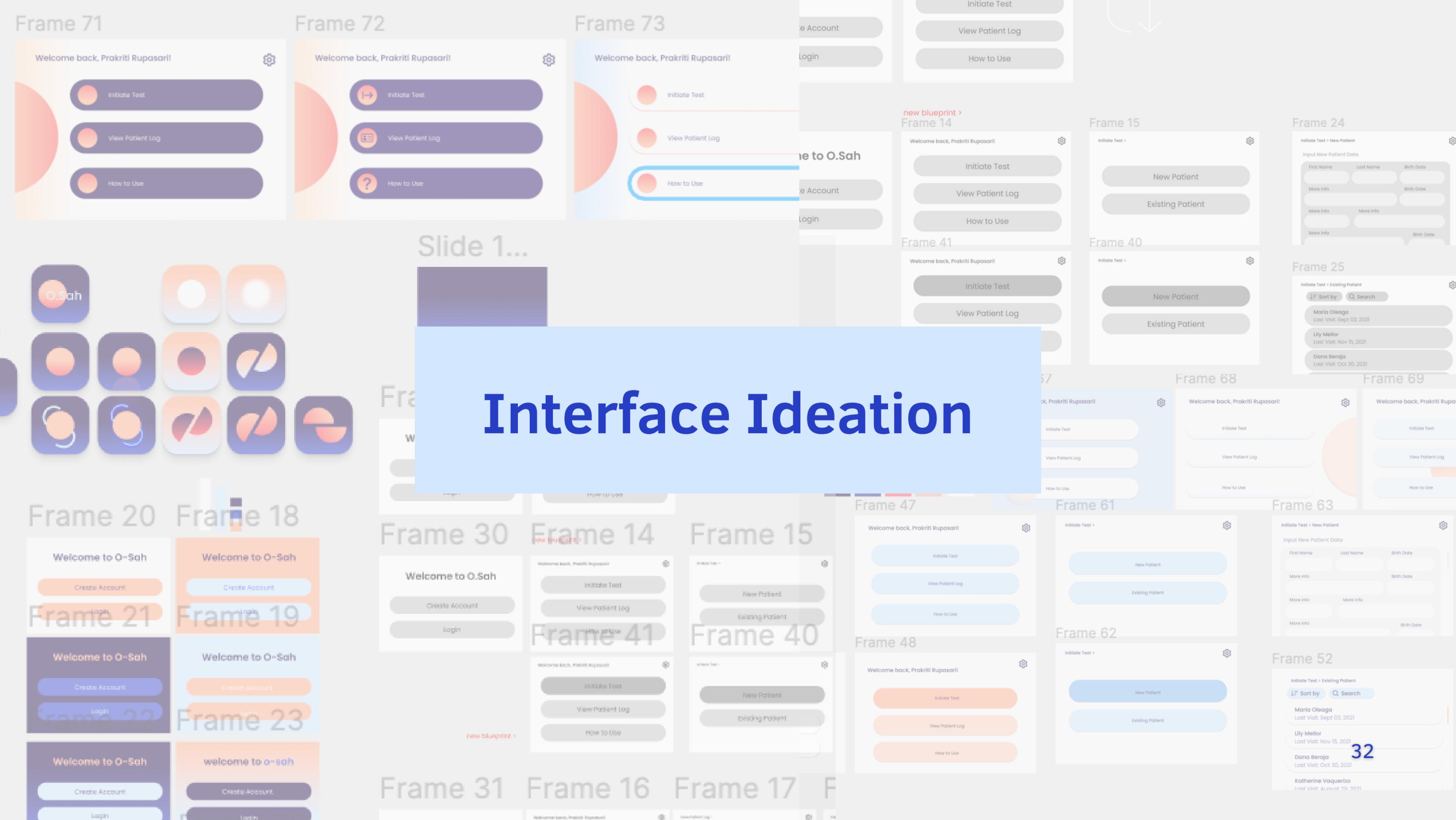




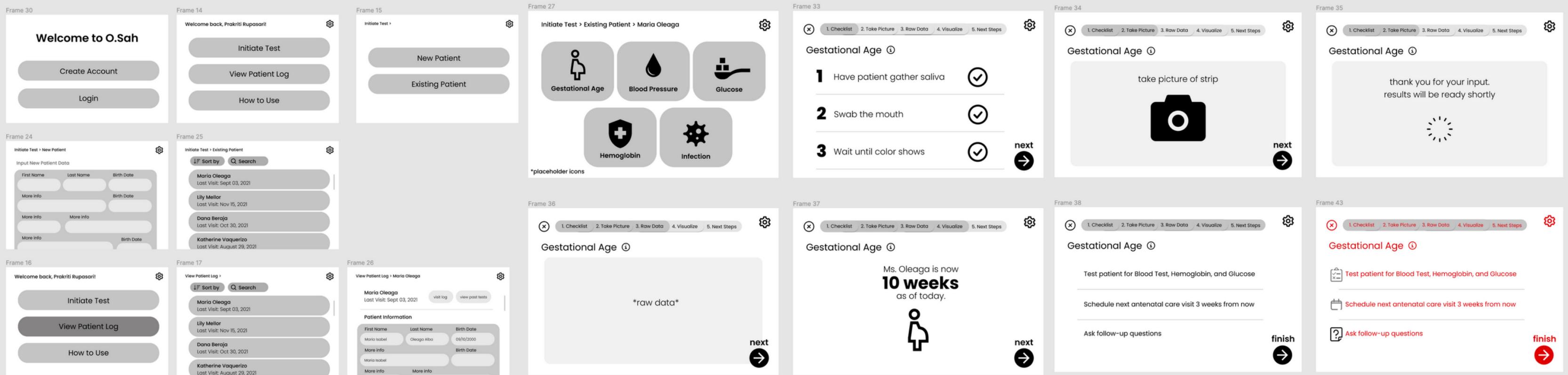
Case Prototypes

Pictured is our initial case prototype. Originally it measures at 4 inches in thickness when completely closed, it features 5 compartments on the left side that hold our wearable device, the HCG test strip box, a tube to protect the urine test strips, alcohol wipes, and a disposable urine cup. On the left side there is a compartment for the android tablet and underneath features a space for instructions on how to use the kit and solar-powered batteries that can charge the kit in a situation where there is no electricity.





Interface Ideation

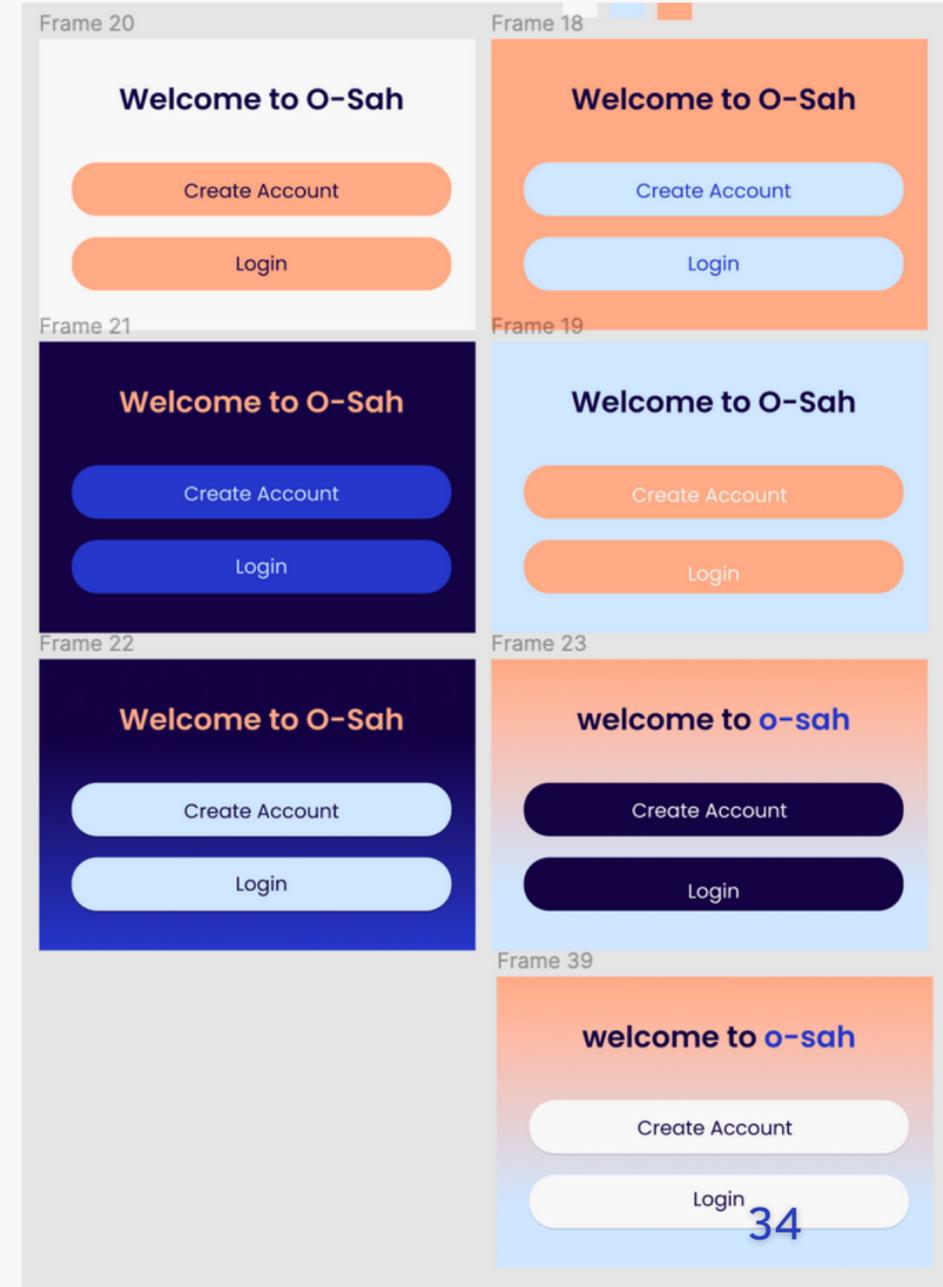
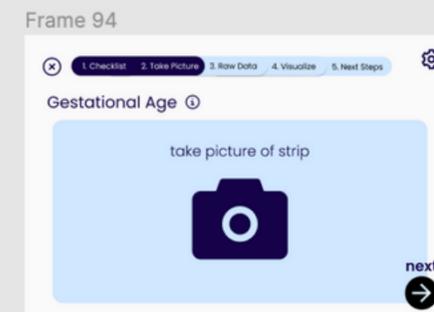
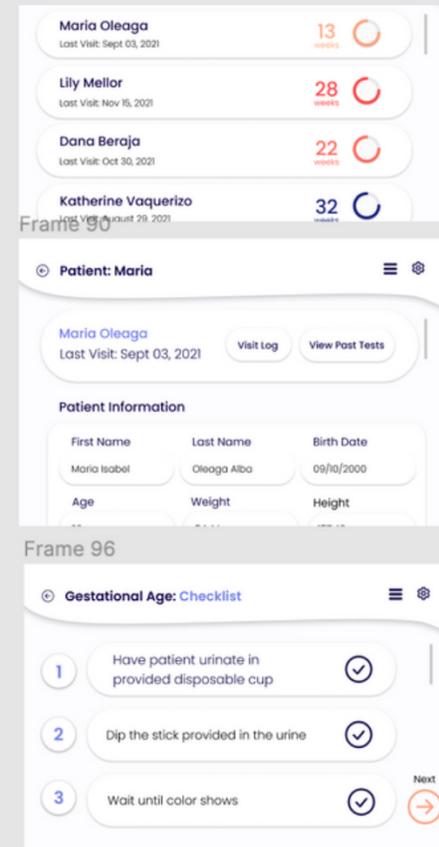
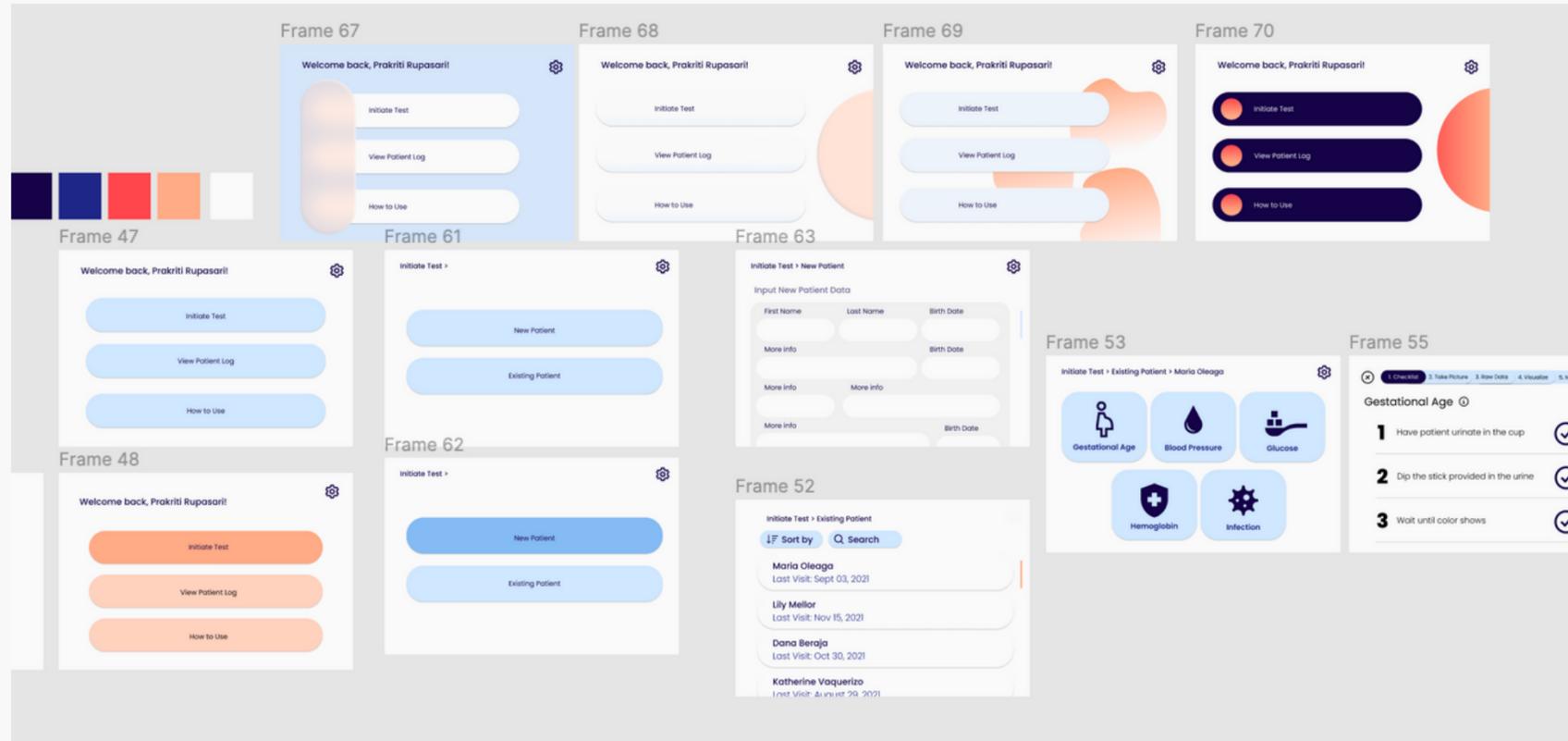


Low-fi Wireframes

Throughout this part of the design phase, we were concerned about organizing our thought on the basic layout and flow of the app interface. We determined what functions and features would be most essential to the app to better aid the graduate nurses.

Mid-fi Wireframes

Once we understood the functions of our app, we began implementing color schemes, logos, and names to start establishing a strong brand identity so we would be able to create a cohesive user interface. We went through a thorough process to test different color scheme.



From our initial ideation

we pushed forward to...

PHASE THREE

DEVELOP

Creating the look & feel.

In the final phase of our project, we took all of our research, ideation sketches, and prototypes and began developing our final model and design. Our focus narrowed as we really dug into the specifics that would ensure this was our best possible solution.

The Goal:

Throughout this final phase, we were focused on making sure everything was as designed thoroughly with intention. We finalized the design of the wearable, the kit/case as a whole, the internal components, and the interface of our app.

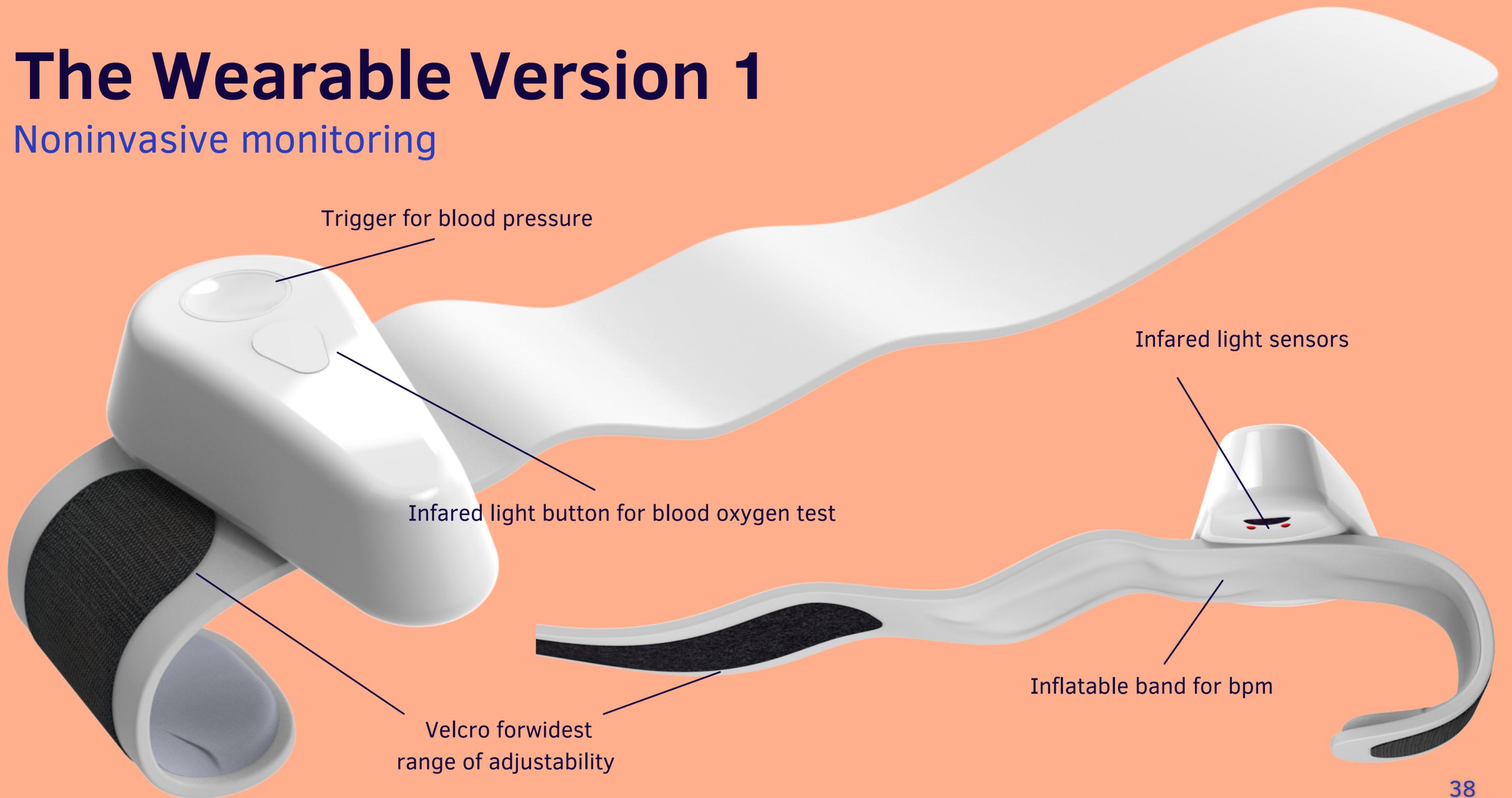
Through our refinements we...

- Created a look & feel and finalized the features and flow for our final app interface.
- Refined the final form and functions for our wearable monitoring device.
- Finalized the internal components and external hardware and design of the kit's case.

Working through version after version of our final solution we kept asking ourselves, "Is everything we're doing really necessary?" We kept asking this because we wanted to ensure that everything we were designing and working towards would be as accurate and as effective as possible in solving the problem at hand. In the beginning, we thought we were going to be using ultrasound with multiple devices and tests, but as we kept ideating and researching our focus narrowed.

The Wearable Version 1

Noninvasive monitoring

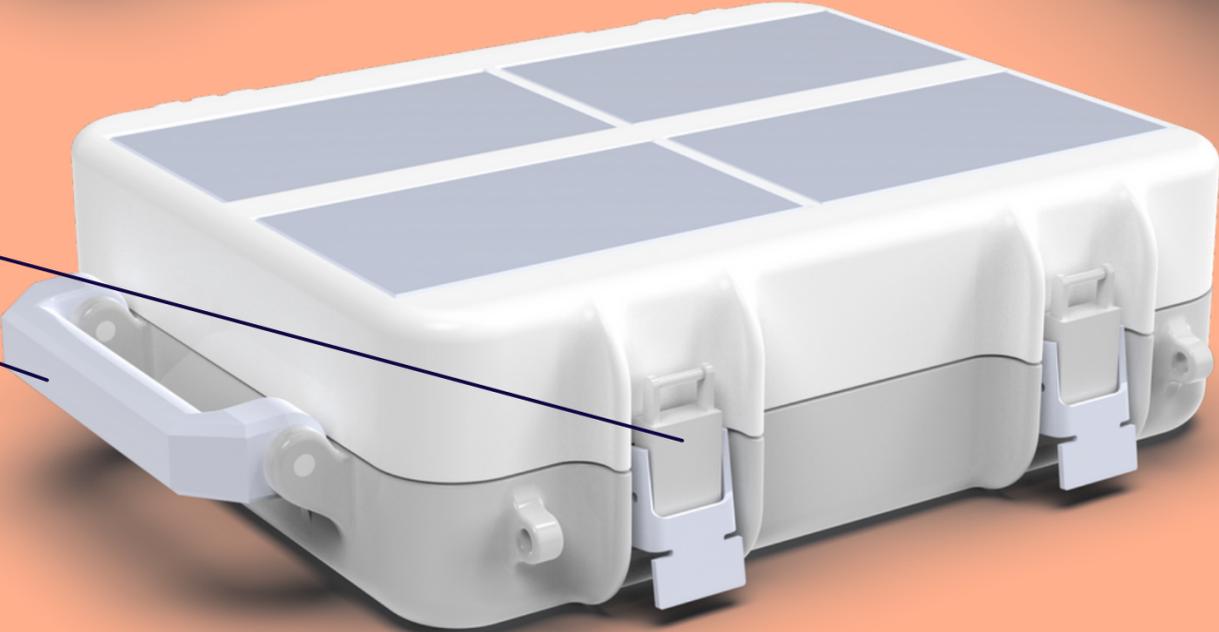
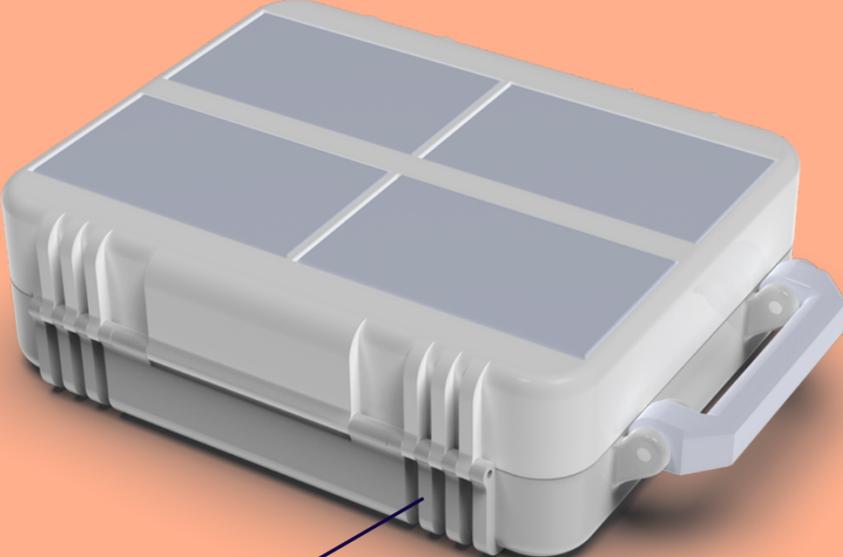
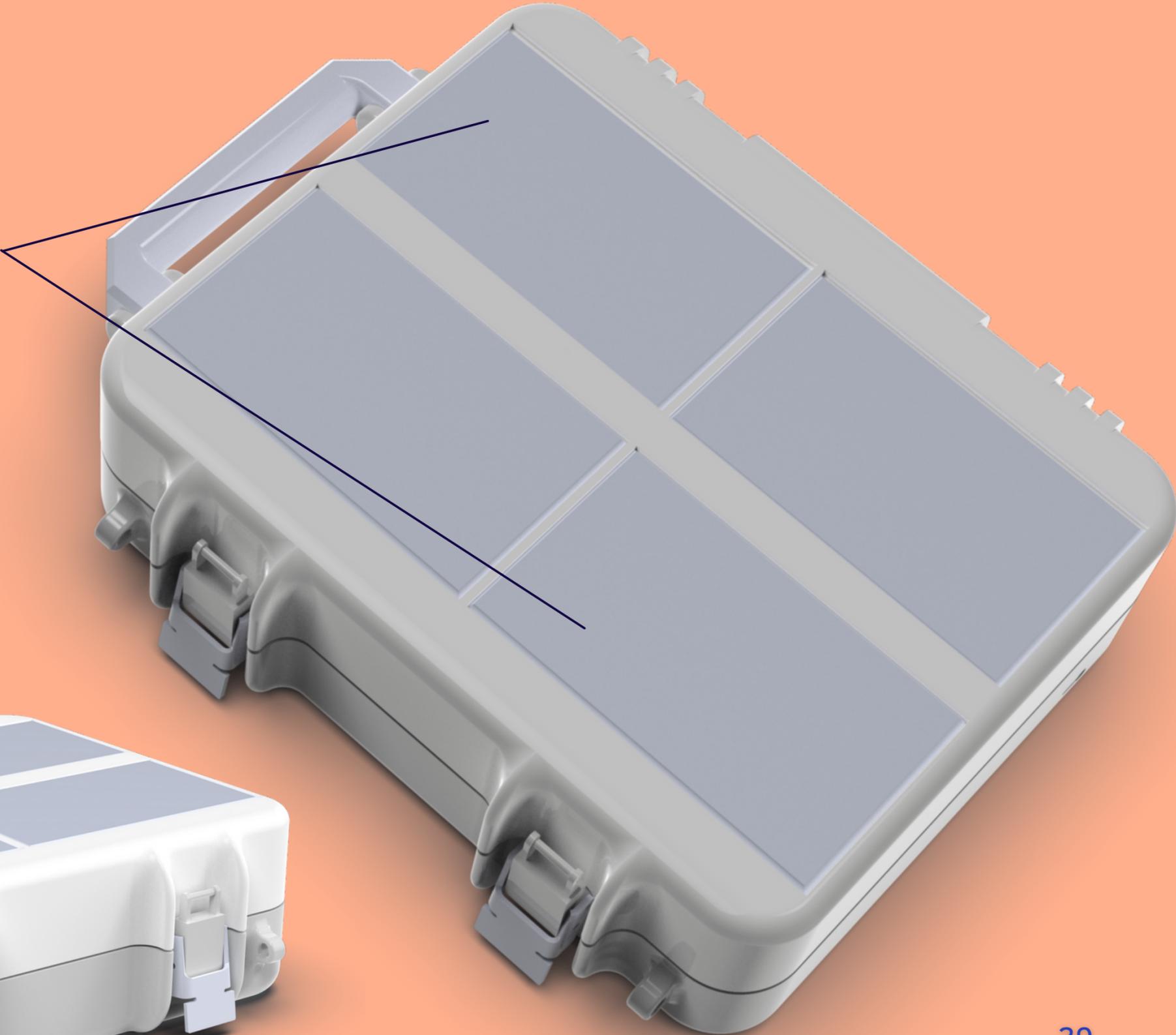


The Kit Version 1

Externals

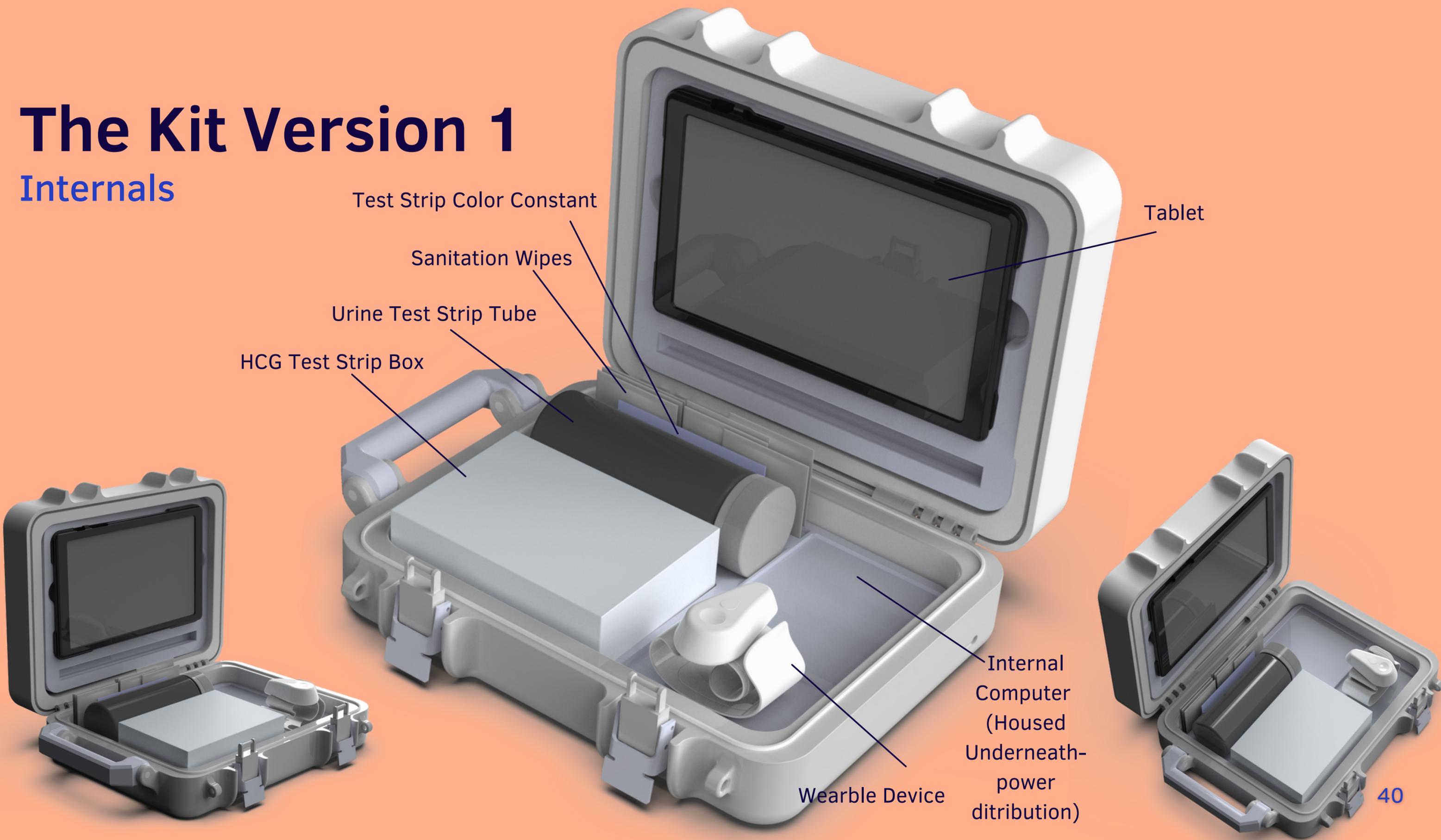
Solar panels for charging

Heavy duty hinges, handle, and latches



The Kit Version 1

Internals



Test Strip Color Constant

Sanitation Wipes

Urine Test Strip Tube

HCG Test Strip Box

Tablet

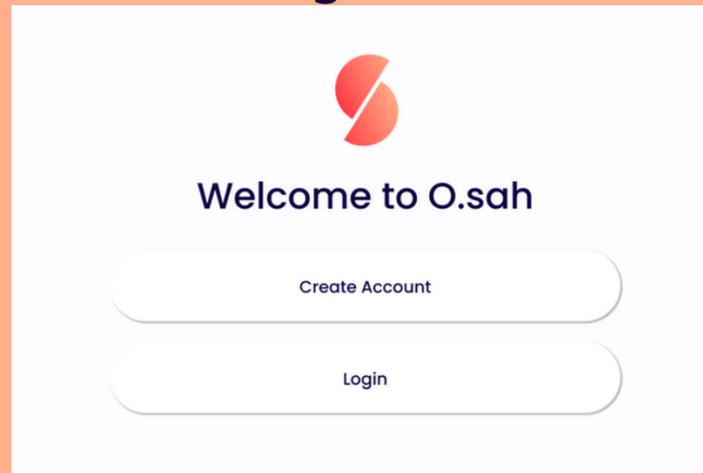
Internal
Computer
(Housed
Underneath-
power
ditribution)

Wearable Device

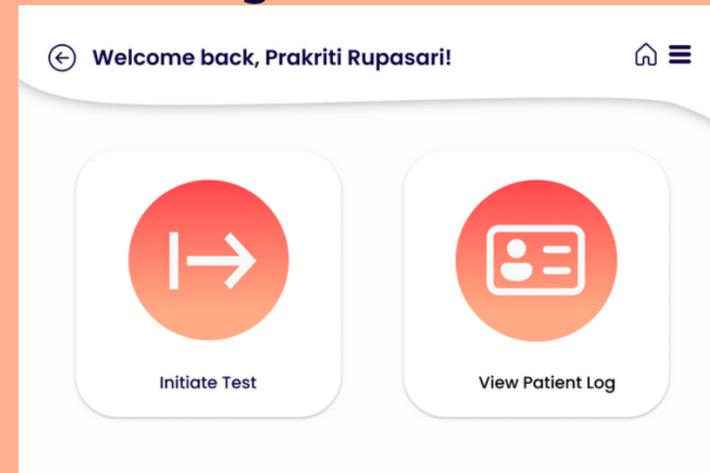
The App

Mid-fi Look & Feel

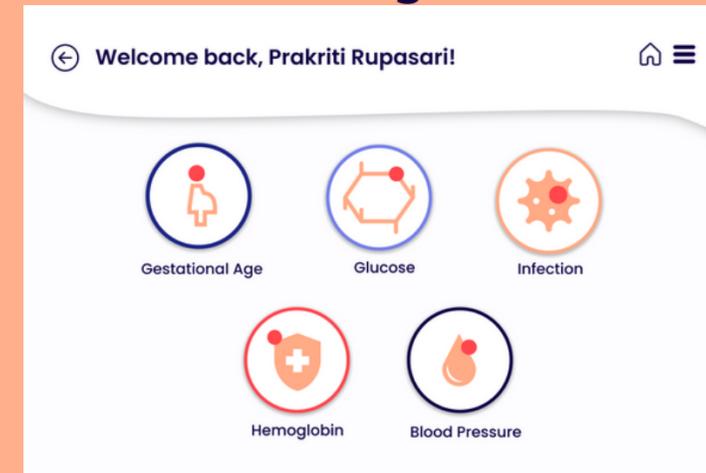
Welcome Page



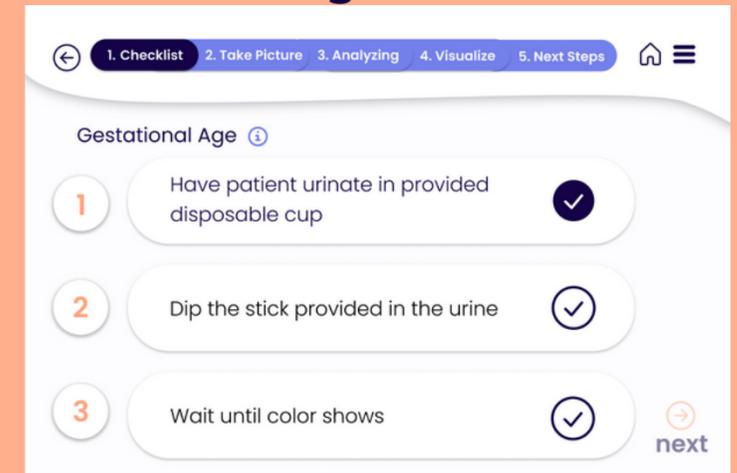
Home Page



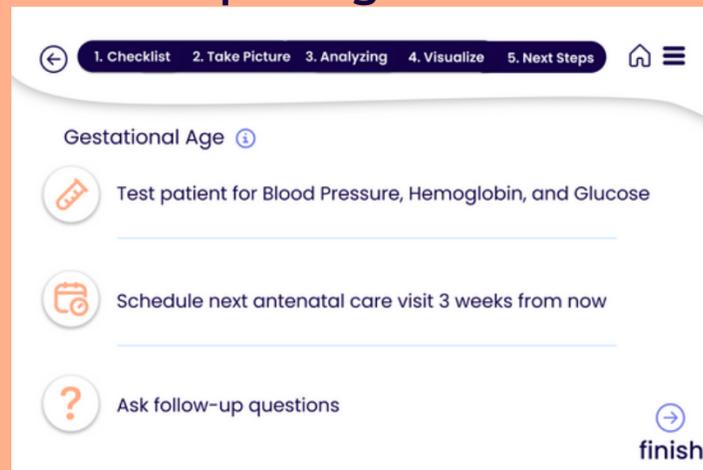
Initiate Test Page



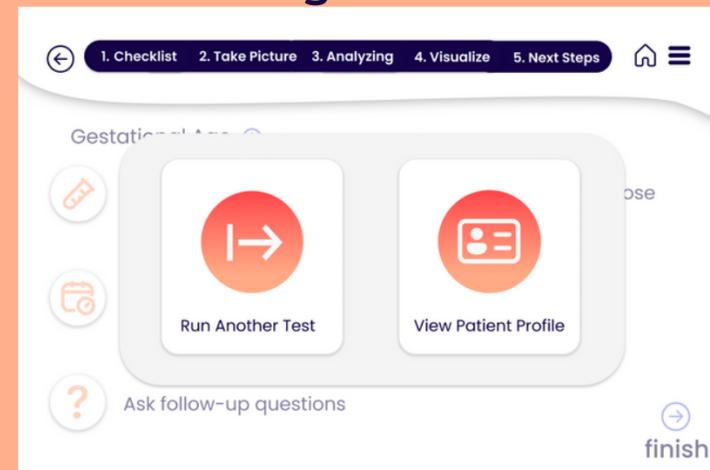
Checklist Page



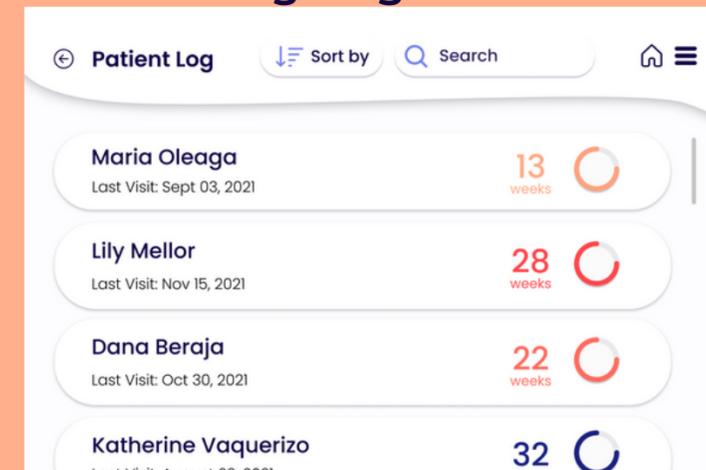
Next Steps Page



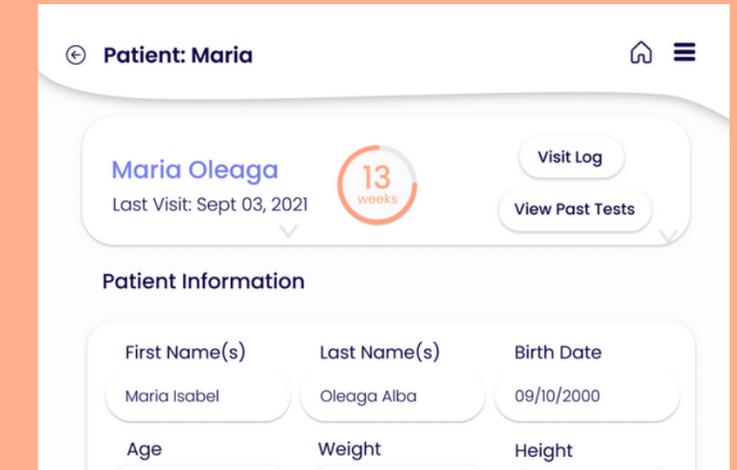
Finished Page

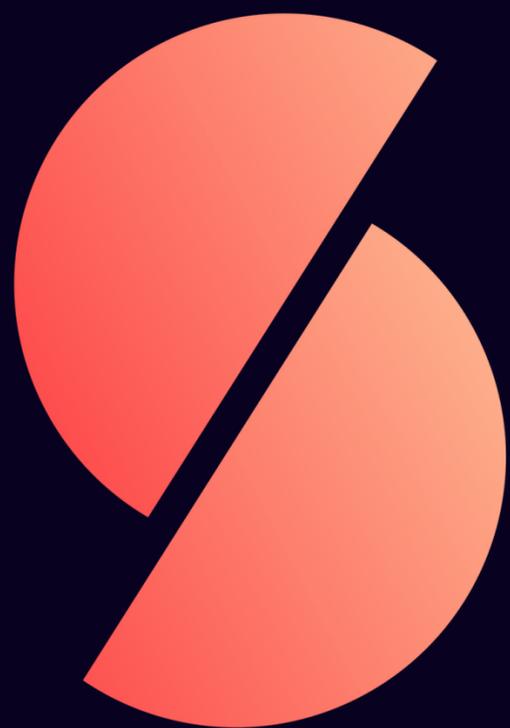


Patient Log Page

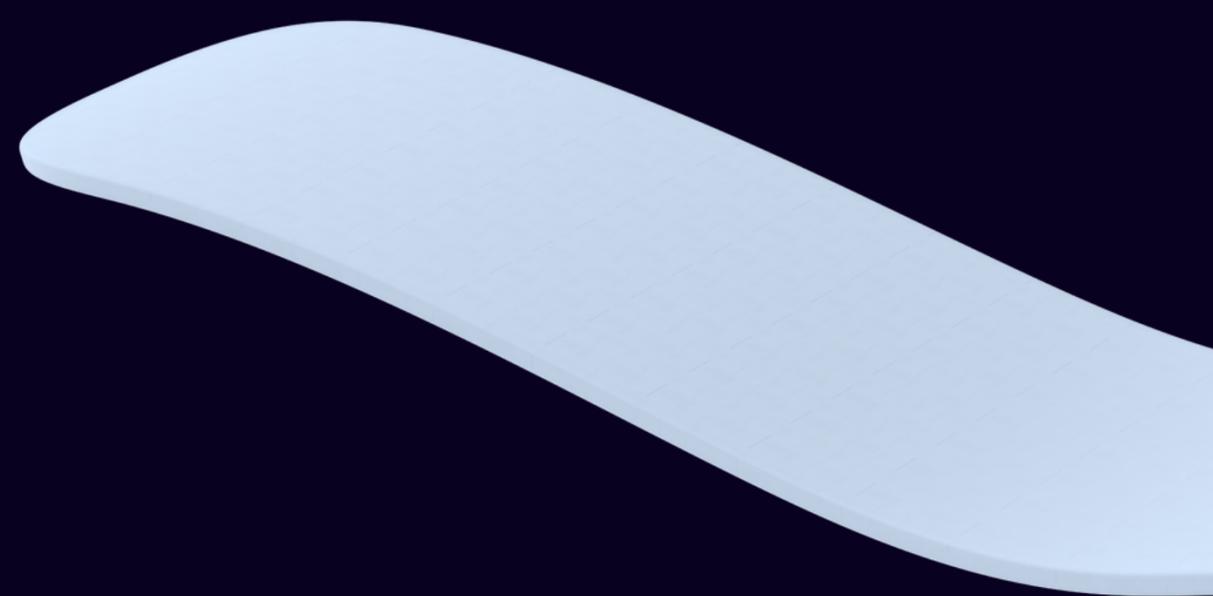


Patient Profile





o.sah



o·sah Wearable

In our final wearable design, there are two different buttons with two different shapes to distinguish bpm and hemoglobin test. The velcro makes it so it can fit any wrist size. The edge goes right into the skin which is why it's curved, and then the band inflates bpm with an elevation of the arm.

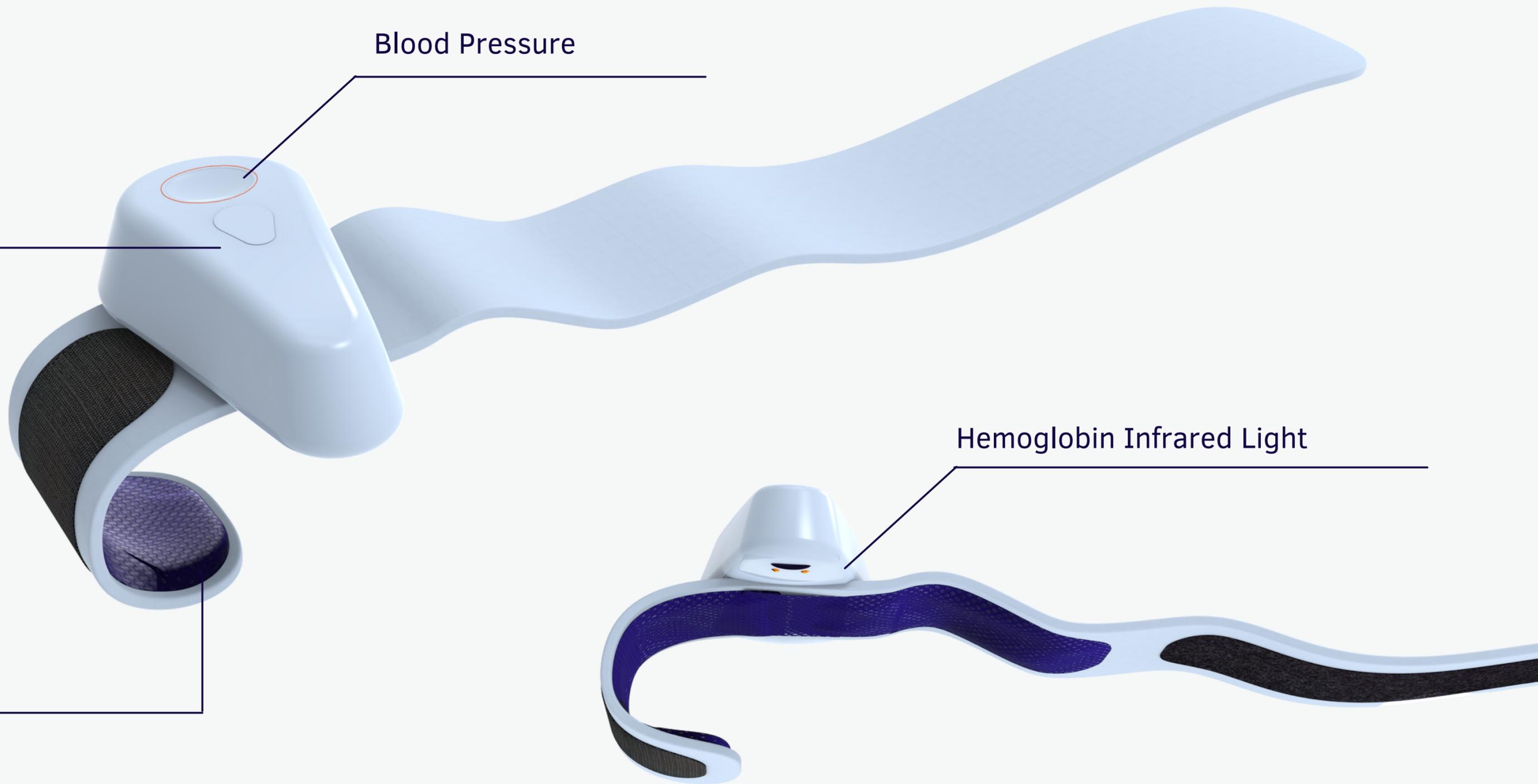


Blood Pressure

Blood Oxygen Test

Inflatable Band

Hemoglobin Infrared Light



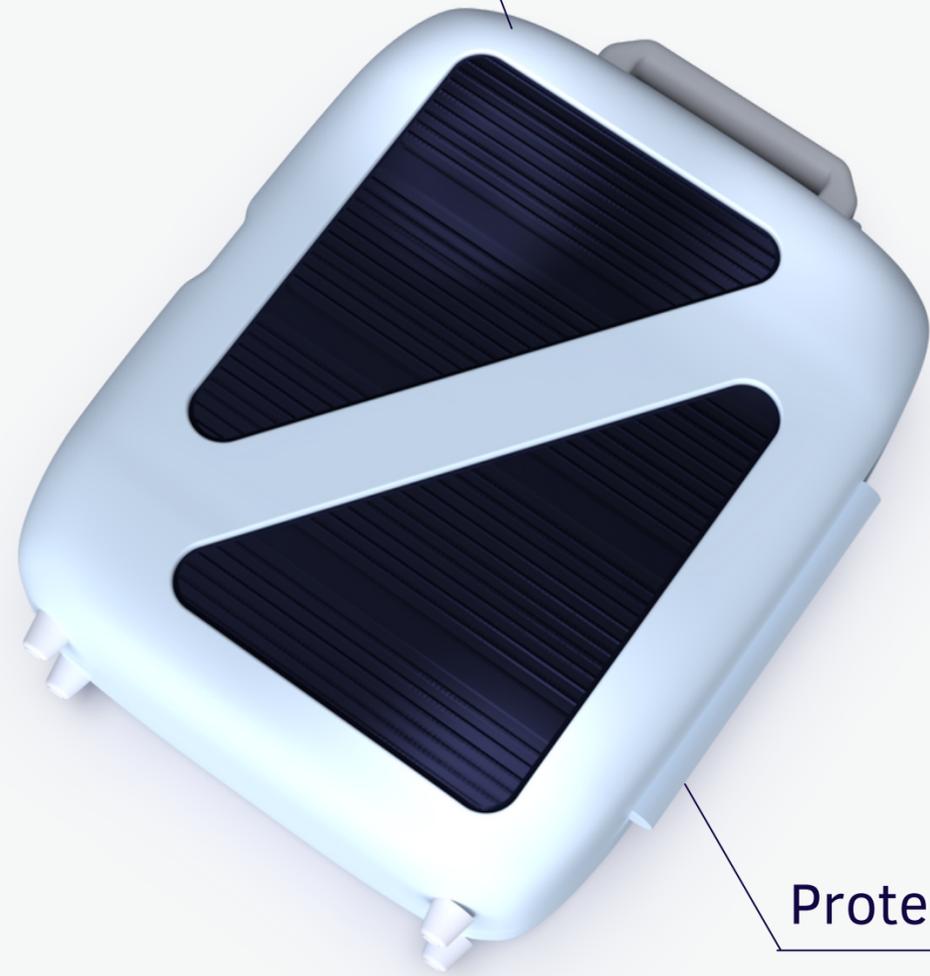


o·sah Kit

For our final solution we converted the exclusively carrying case into a wearable backpack with adjustable straps. We thought this was the most efficient way to incorporate more than one way to transfer the case in the rural environments where it will be most needed, and in cases where it will travel long distances.

High-Density Foam
with Hardshell Plastic

Dust & Waterproof Rubber Lining

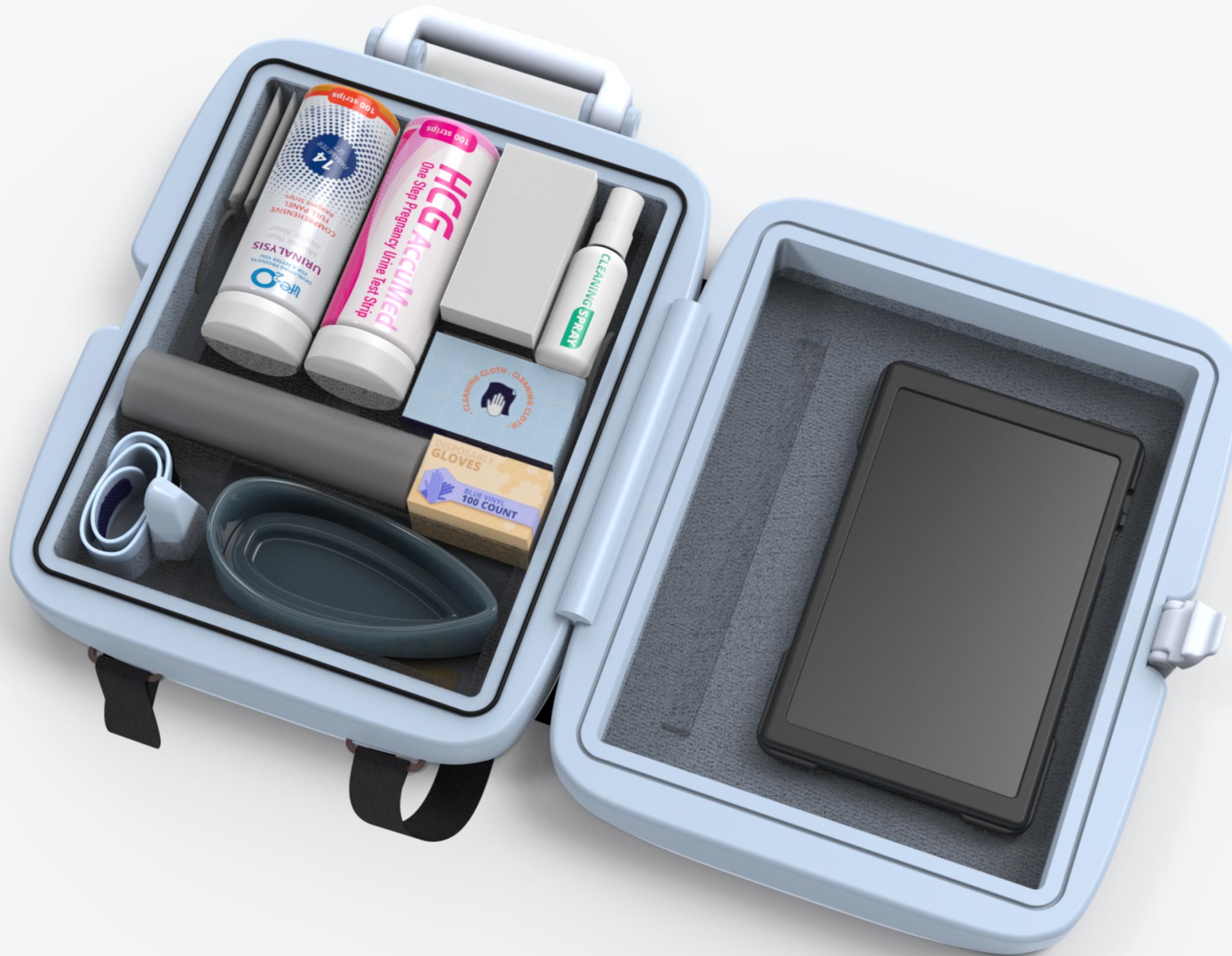


Protected Hinge



Heavy-Duty Handle

Lockable Clip



The Kit Components

In this open view of the final case solution we placed rendered items of the actual medical items the kit is equip with to scale. Along with the wearable device, urine cup, and the tablet. The final decision to change the HCG test strip box into a tube made sure that we could keep it airtight and climate controlled so the strips will not be ruined by the environmental factors.

Color Constant

Silica Packets

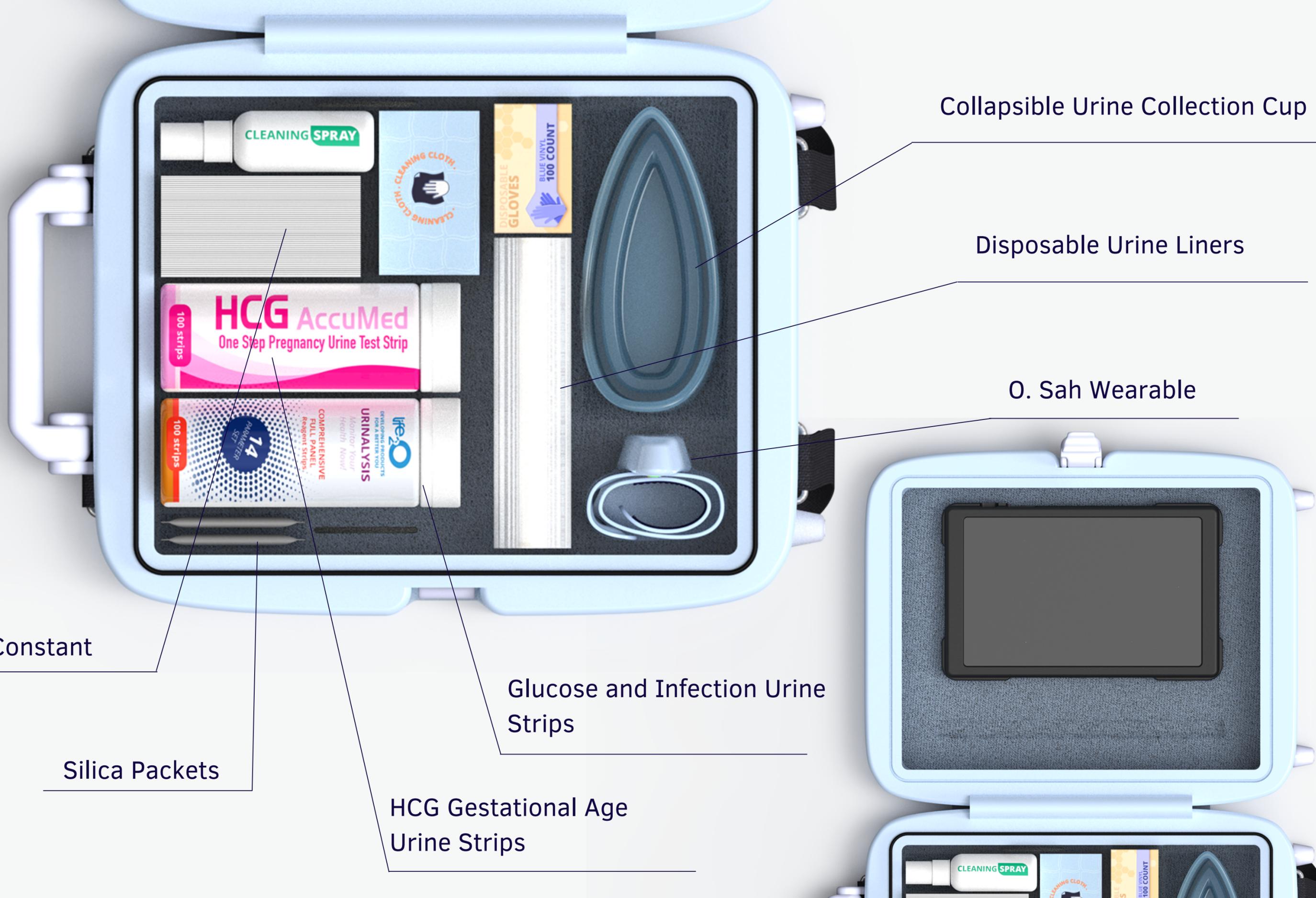
HCG Gestational Age
Urine Strips

Glucose and Infection Urine
Strips

Collapsible Urine Collection Cup

Disposable Urine Liners

O. Sah Wearable

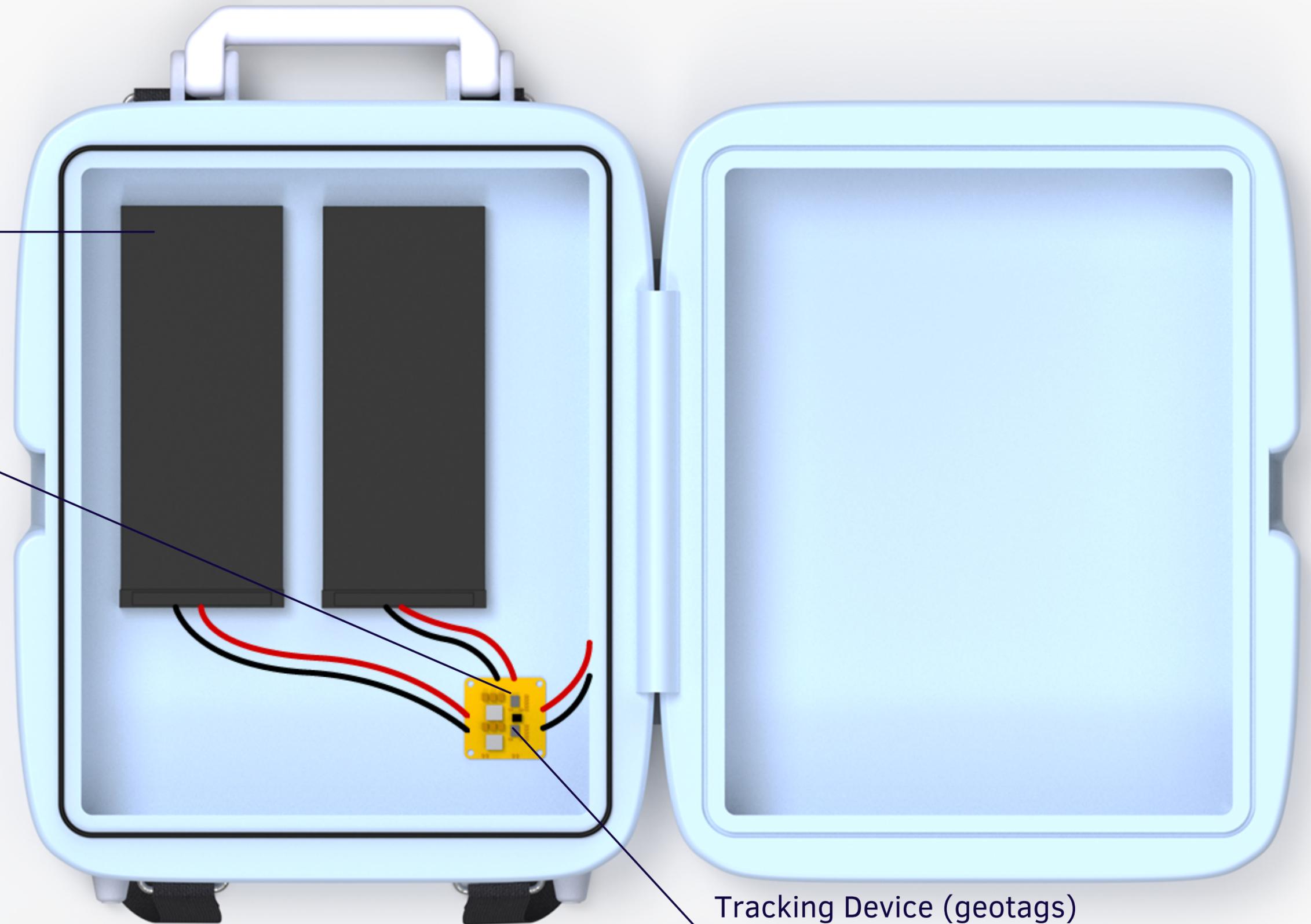


Rechargeable Lithium Ion Batteries

Power Distributor

The Kit Internals

Underneath the kit's internal components is where the rechargeable lithium-ion batteries are housed. This charges the table, and the wearable through connections points within the internal structure.



Tracking Device (geotags)



Welcome to O.sah

Create Account

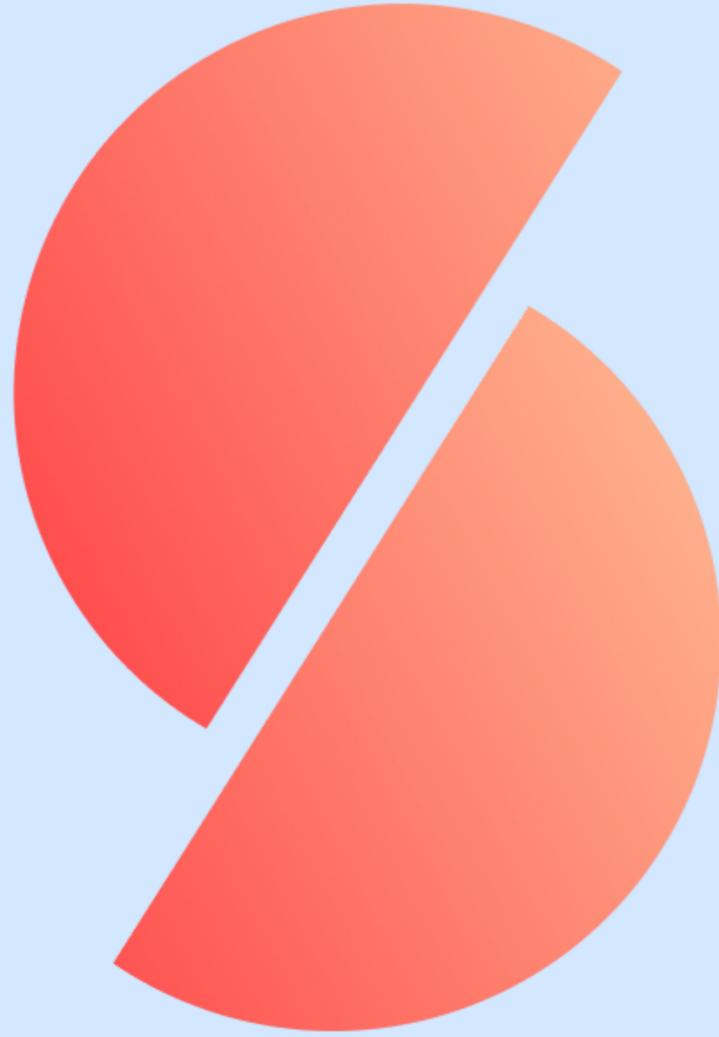
Login

Everything considered...

Throughout the duration of this quarter we were tasked with the mission of creating an integrated digital backbone with AI-enabled decision-making support to guide pregnancy care in secondary regional care centers in LMIC regions; along with, envisioning a unique way for midwives and graduate nurses to use specific tools for risk assessment, monitoring, and decision-making in antenatal and intrapartum care.

We began diving into research to better understand the issues Pregnant women faced in these lower to LMIC regions. Overloaded with an influx of information we were led to narrow in on the Antenatal phase of Pregnancy. From there we were able to fixate on a location and continue to learn more about the region and the issues surrounding it.

Our team of 15 students then proceeded to ideate, design, and prototype an all-inclusive kit to help in the prevention of some of the most life-threatening issues that women and their babies face.



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