

## A LITTLE ABOUT ME...

---

### **Dylan Horvath, Founder & CEO**

Systems Design Engineering from the University of Waterloo, class of 1997

Founded Cortex in 1999

Industrial designer, firmware and PCB developer, international production liaison on dozens of trips to China

Provide leadership and coaching to the team, sets strategic objectives, and provides a positive work culture within which the staff can succeed

Co-inventor on 11 utility patents (and counting)

Won numerous awards including an X-Prize for Cloud DX's VITALITI Tricorder

Work has appeared in Popular Science, The Huffington Post, The Globe and Mail, Forbes, and Canadian Business's Fastest Growing Companies

Co-President of the Association of Canadian Industrial Designers (ACID)



# DE-RISKING PRODUCT DESIGN

... or how not to end up like  
Elizabeth Holmes

cortex  design

Prepared for:  
Hamilton Health Innovation Check Up

---

Date of delivery:  
2023-11-27

---

Document number:  
2023-11-27 Hamilton Health Innovation  
Check Up Presentation

# THERANOS

**Elizabeth Holmes, CEO**  
**Sunny Balwani, CTO, COO**

At 19, became inspired by a course she took in microfluidics and dropped out of Stanford to start Theranos

Articulated the vision for diagnosing hundreds of conditions with a single drop of blood without developing net new technology

Raised \$400M on a valuation of \$9B through obfuscating the truth with investors under the guise of operating in "stealth mode"

Relied on blind faith that with enough money, the science could be solved

Attempted to operate outside the FDA's authority by doing lab testing rather than diagnosis at POC

Ran out of time to deliver on promises. With no net new science and no validity to claims, house of cards folded and criminal fraud trials ensued

Balwani, Holmes now serving 13, 11 year sentences and ordered to repay \$452M in damages to victims



# CLIENTS OF NOTE





- 1 Identify a **commercially viable technology** that can be applied to a human health condition that exists within a large patient population
- 2 A **reimbursement model** that is supported by the public or private healthcare target market must exist
- 3 Technology must **tangibly improve** existing solutions for the diagnosis or treatment of that condition, and not introduce NEW pain
- 4 Technology must be **manufacturable at scale** within commercially successful metrics for all parties

**\$570B**

Global medical devices reimbursement market size in 2023; projected to reach **\$1,028B** in 2030.

<https://www.grandviewresearch.com/industry-analysis/medical-devices-reimbursement-market#:~:text=How%20big%20is%20the%20medical.USD%20570.0%20billion%20in%202023.>



## phase 1

research & discovery

### immersion into the culture of the user

Dive into the real-world use case and stakeholder lifecycle of your product category to check your assumptions. The intent, target market and project objectives should be influenced and validated by experiencing the world through the customer's perspective.

This phase is the foundation from which the entire design process is built on.

## phase 2

concept exploration

### visualizing solutions

With a clear design intent begin to define the project constraints with brainstorming sessions, sketching, and mock-up prototypes.

The objective for this phase is to refine the ideation and conceptualization into a focused, clear, strong direction to carry forward into the prototype design phase.

## phase 3

prototype design

### learning by building

Now with a strong concept direction, translate design intent into a CAD database.

With the overall form developed, specify materials, textures, and colour options applied to iterative prototypes. The prototypes can be field tested, given to your target market for valuable user feedback, and exhibited to key stakeholders for their buy-in.

## phase 4

production design

### art meets engineering

Using design for manufacturing (DFM) processes, analyze each part for proper material selection, manufacturing technique, and finish. Detail all of the required parts to manufacturing specifications and BOM, go through regulatory checks, and perform manufacturing validation.

Sub-assemblies are also reviewed for design for assembly (DFA) processes.

## phase 5

manufacturing

### from one to many

We work closely with suppliers and factories to ensure product vision and quality are maintained. Quality audits and close communication help ensure manufacturers produce the best product possible.

We oversee production on your behalf to ensure that critical tolerances and procedures are met and followed.

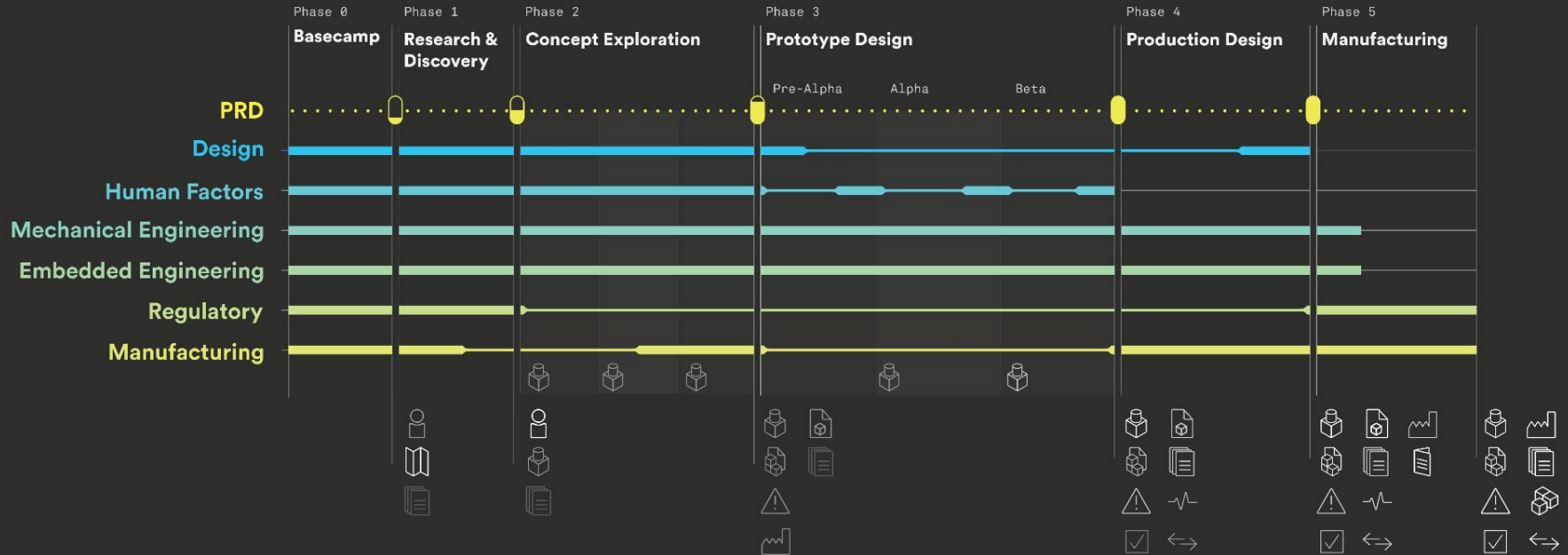
ISO-13485 QMS

RISK ANALYSIS >>

VERIFICATION AND VALIDATION >>

USABILITY TESTING

# CORTEX PROCESS



## Progression:

- Early Stages
- In Process
- Complete

## Legend

- DHF index
- User needs
- Verification
- IFU
- Project roadmap
- Prototypes
- Production Parts
- Vendor Relations
- Bill of Materials
- Risk Analysis
- Pre-Scan
- Device Master Record



Check and double checking, **is very important at various stages of development**

### **Risk Analysis ISO 14971**

- Define and assess all possible risks no matter their likelihood
- Determine the impact of the risk if it were to happen and build out a mitigation plan
- The mitigation can be tested in house as well as in validation testing
- Risk analysis is repeated as risks are identified and mitigated through the development process, until the risk profile is low enough for market and regulatory acceptance

### **V&V - Verification and Validation with a QMS ISO 13485 Clause 7.3.6, 7.37**

- Upon every deliverable of requirements, even at design review, Verification testing is a good way to ensure output meets input requirements

### **Usability Testing**

- Steered by **IEC 60601-1**, **IEC 60601-1-6** (for medical electrical equipment) and **IEC 62366-1**, whose requirements can be prescanned internally under the V&V activities
- Certifiably validated by an external testing house





**Humans in the wild will rarely do what you want them to do,  
and almost never do what you expect them to.**



“A solution for rich people that’s worse than the problem”

## SUCCESS CRITERIA

---



Identify a commercially viable technology to address an human pain point shared by a large market segment



A payment model that is supported by the target market of sufficient size to scale must exist



Technology must **tangibly improve** existing solutions to address human pain point while not introducing NEW pain or behaviours the market will not support



Technology must be manufacturable at scale within commercially successful metrics for all parties



**identify your  
market segment**



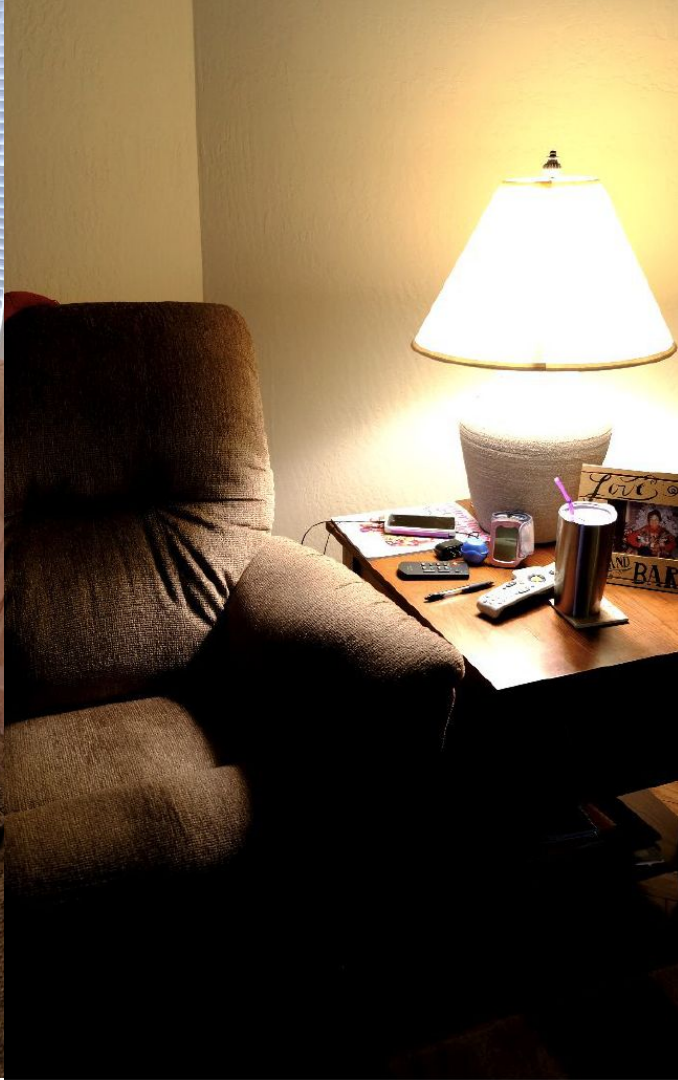


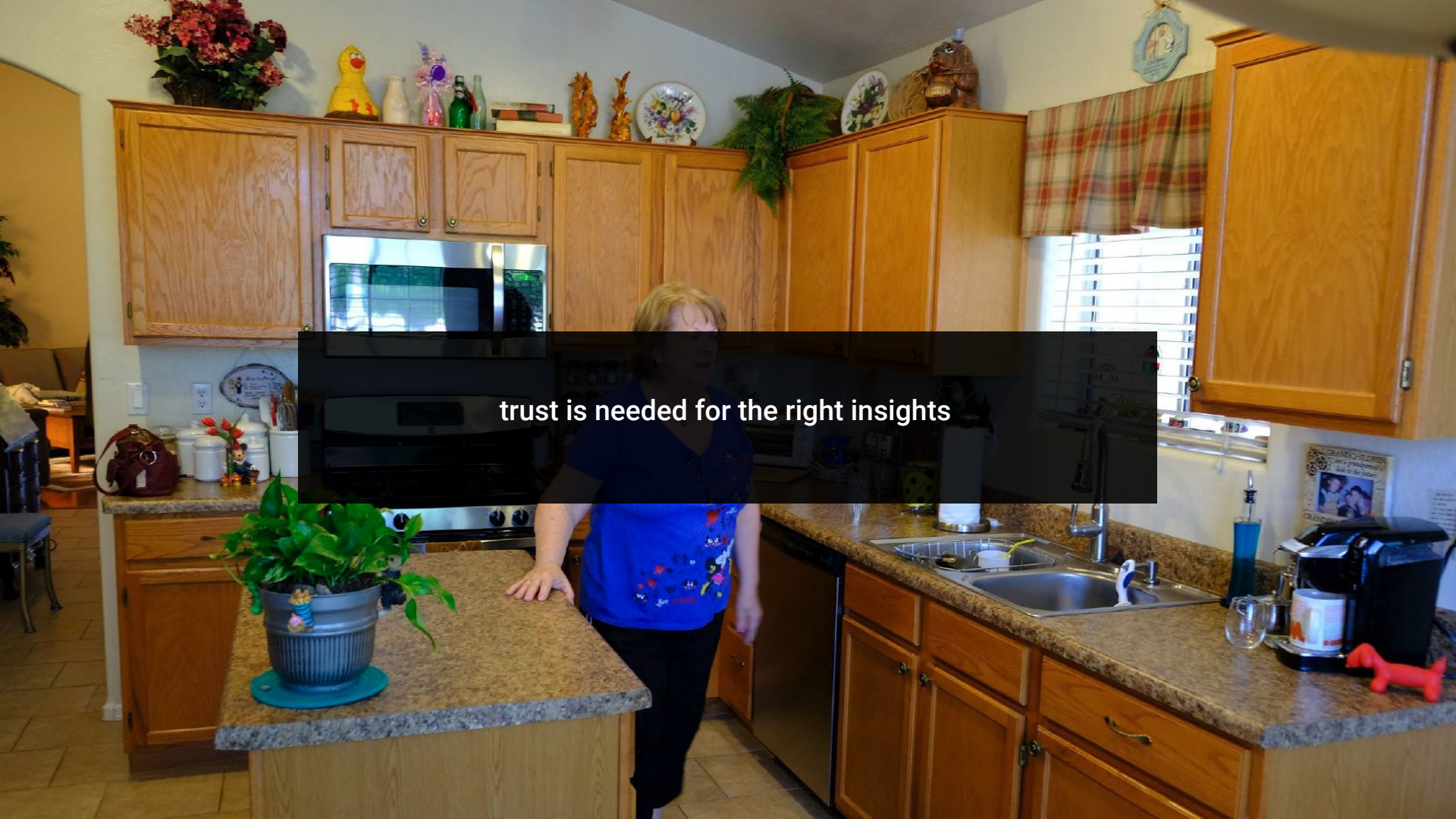












trust is needed for the right insights



In an ethnographic study, there is a temptation to go after targeted data with the user group of interest.

### **Purchasing Decision**

- Who makes the purchasing decision and what metrics do they use?
- Are the metrics they say they use the same as the ones they actually use?
- What is important to that decision maker to have a successful day / week / year?
- Workflow and Task Breakdown

### **Workflow and Lifecycle**

- Time
- Order
- Difficult tasks versus time savers

### **Competitive Products**

- Which do they like/dislike
- Important features

### **Existing Equipment**

- What other tools do users like/dislike?

## DISCUSSING EMOTIONAL STATES



Leading with data-driven questions does not lead to discoveries.

### Opening questions

- The hardest part of my workflow is....
- I always try to ... when performing {task}
- The thing that I/my team/clients complain about the most is...
- If I can change one thing about {task} it would be....
- My favorite product (related or otherwise) to use is ... because ....

Activity 1 - ICE BREAKER	Name:
Fill in the blank below	

1. The easiest part about performing a patient cleaning is\_\_\_\_,  
  
the hardest part is\_\_\_\_\_.

2. I always try to \_\_\_\_\_ when I'm cleaning the patient

3. When the patient complains about \_\_\_\_\_, I \_\_\_\_\_.

4. If I can change one thing about cleaning patients, it would be \_\_\_\_\_.

# ETHNOGRAPHY



## Ethnography relies on relationships

Ethnography should be empathy-led and conducted with an open mind to discovery. In order for those discoveries to be made, trust must be established between the researcher and the subject.



### Experiencing the problem

Ethnography at its root is seeing the world through the eyes of the person experiencing the problem. Active participation in the world of the end user is the gold-standard.



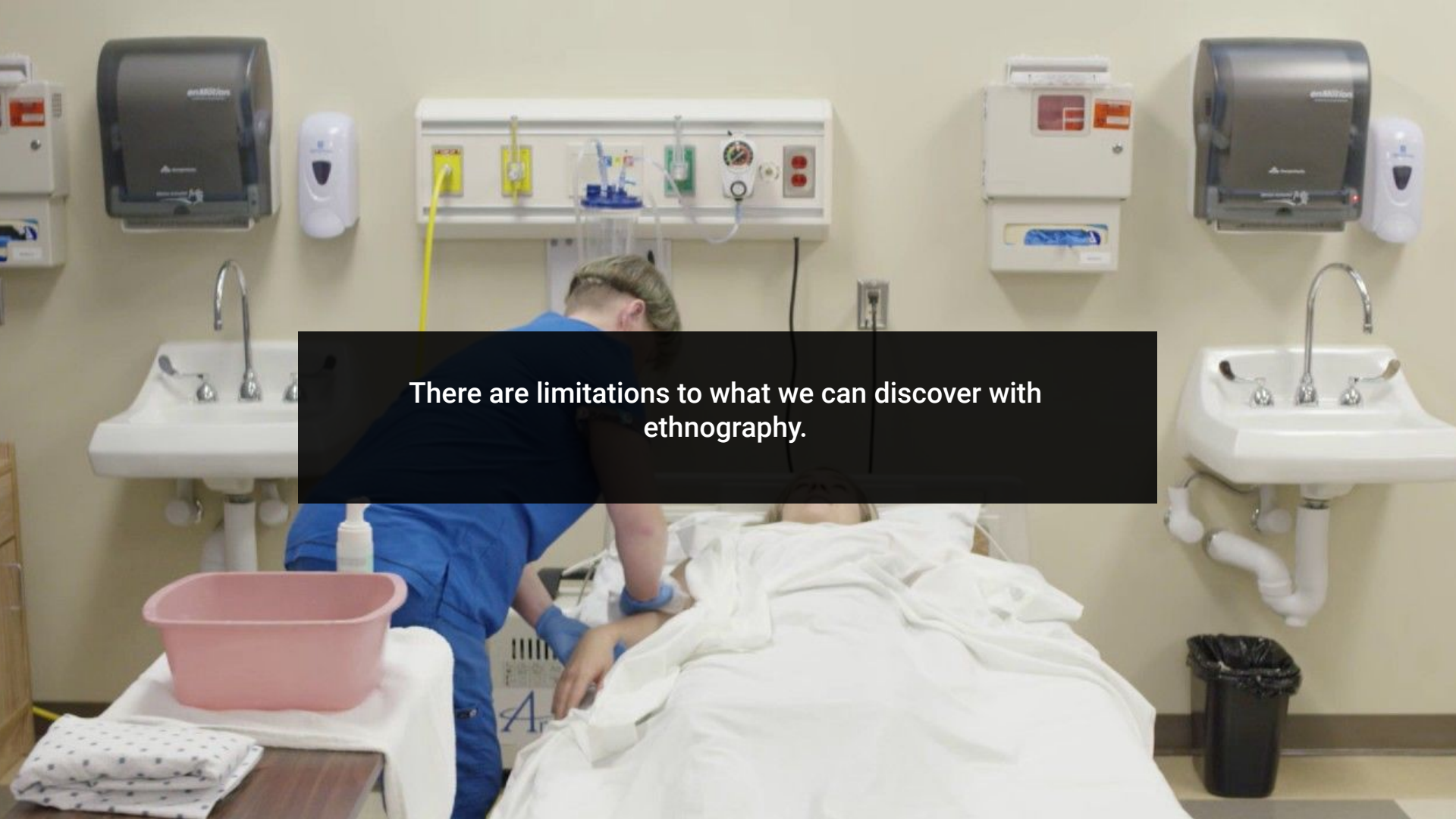
### Do you have all the stakeholders?

Even the best solutions can be shot down by a stakeholder that you may be blind to in your product development. Who in the environment needs to purchase, stock, store, dispose of, re-order? What are their issues, barriers, or problems to solve?



### Be Curious

Do you feel like you understand all of the systems with which the product must behave? Observe and ask a lot of questions, and see where rabbit-holes may lead.



There are limitations to what we can discover with ethnography.



1



2



3



4



5



Sometimes, failing fast is the best use of your development money.







1



2



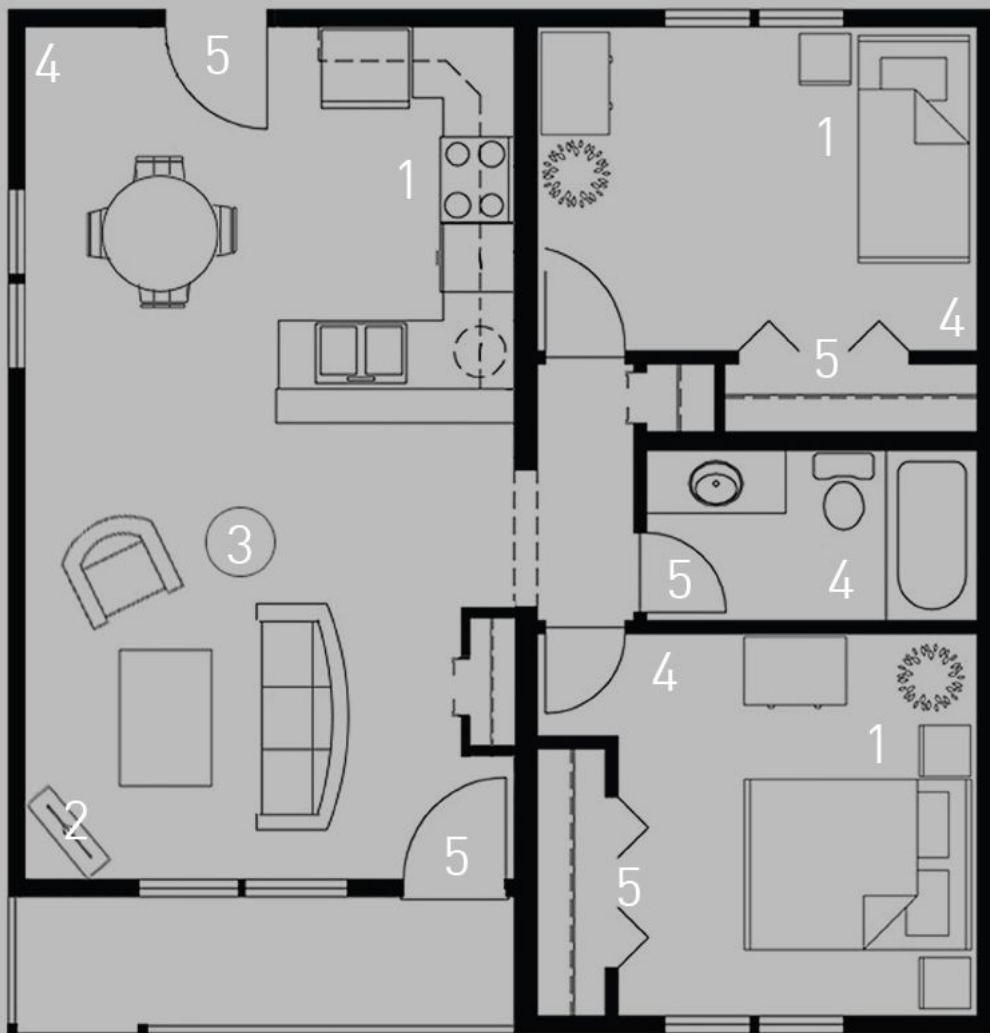
3



4



5





Grandpa goes about his morning routine. He walks to his chair and the frame lights up with a picture of his granddaughter's past birthday. He suspects her birthday is today.



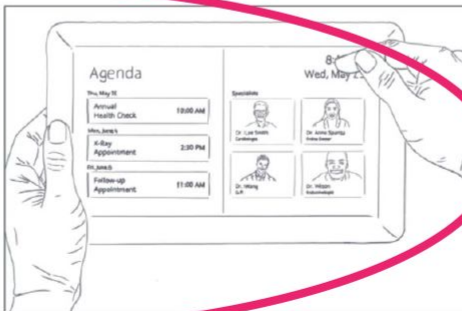
He sits down and turns on the TV to watch the weather and the news.



Something on TV reminds him he has a doctor's appointment coming up, and he wonders when exactly it is. Grandpa picks up the frame to check his appointments.



He sees his granddaughter's birthday is indeed today and she's having a party this afternoon. He makes a note to call her.



He goes to check on his doctor's appointment, and sees that it's sometime next week.



Grandpa puts the frame down, and goes to call his granddaughter.



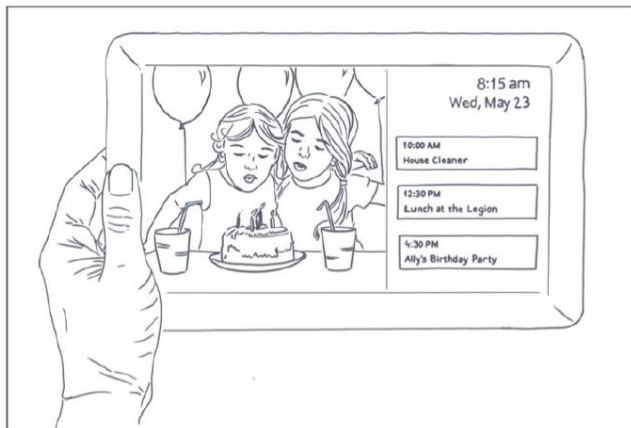
# Photograph as a Smart Device:

The concept was popular with all participants **because it is useful.**

Participants who made use of smart devices and digital appointment keeping were **immediately attracted to the concept**

*"It's great to be reminded, I need that. But for me the photo is nice-to-have, it's the information I'm; actually after".*

- Joy (CA)



*"I set my google calendar to remind me the evening before anyway, so this is useful.*

- Richard, W, 82 (CA)



# Photograph as a Smart Device

Participants struggled to see what a memory device and fall detection **had in common**

Participants felt the smart device would be useful for people with **memory issues**, but had trouble with how it can help with **other concerns**

*"Worrying about forgetting and worrying about falling over are two different problems"*  
- Richard. C, 75





# Photograph as a Smart Device:

Seniors look at photographs when it suits them

Photos are viewed in specific contexts: **Facebook** is a valuable source of photos for seniors

Seniors **rarely** look at printed photos around the halls or living room. It would be **unusual** that it reminds them to get in touch with someone

*"If I want to be reminded of someone I'll use Facebook"*

- Joy (CA)

*"I look at photos on my phone regularly. I relate to them more because they're relevant"*

- Richard C (CA)



I'm looking for  
John

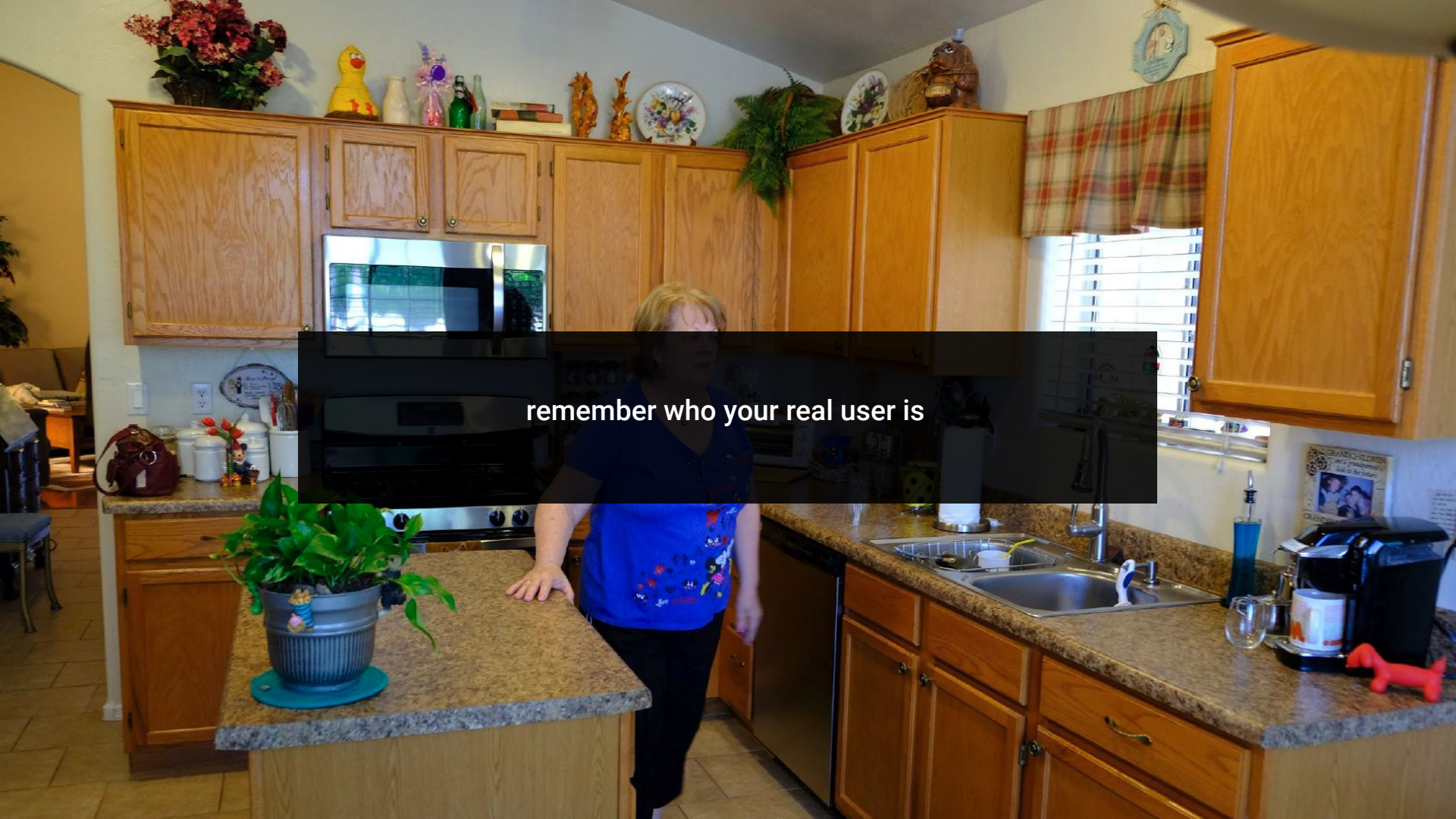
pillo



pillo

TYLENOL  
acetaminophen  
325 mg  
Tylenol  
PAIN RELIEVER  
FEVER REDUCER  
30 TABLETS

Various colored pills (white, pink, blue) scattered on the counter.

A photograph of a woman standing in a kitchen. She is wearing a blue t-shirt with a colorful pattern and black pants. Her face is obscured by a black rectangular box. The kitchen features wooden cabinets, a granite countertop, a stainless steel oven, a double sink, and a window with a plaid curtain. Various decorative items are on top of the cabinets, including a yellow duck figurine, a turkey, and a vase of flowers. A potted plant sits on the counter in the foreground. A text overlay is centered over the woman's face.

remember who your real user is



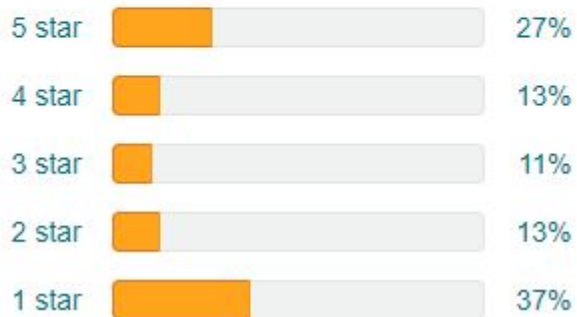




## Customer reviews

★★★★☆ 2.8 out of 5

146 global ratings



### Top reviews from the United States



FTL12

★★★★☆ **NOT GOOD, Several issues.**

Reviewed in the United States on January 6, 2020

**Verified Purchase**

I do not like writing this type of review namely because I know one experience may not speak to everyone's experience. In this case with the majority of this review I think it will in fact do that.

## SUCCESS CRITERIA

---



Identify a commercially viable technology to address an human pain point shared by a large market segment



A payment model that is supported by the target market of sufficient size to scale must exist



Technology must **tangibly improve** existing solutions to address human pain point while **not introducing NEW pain or behaviours** the market will not support



Technology must be manufacturable at scale within commercially successful metrics for all parties









your dose is prepared.

Friday, January 1

7:01

Press to dispense  
Dose 1 of 2

By: [illegible]      Date: [illegible]  
Address: [illegible]      Model: [illegible]  
Manufacturer: [illegible]      Code: [illegible]  
For: [illegible]





**sometimes...**  
**no interaction is the best**  
**experience**



just wear it







**improving patient outcomes**



Nerve Supercharger | Breakthrough peripheral nerve injury treatment





Real-Time Monitoring for Anastomotic Leaks





Real-Time Monitoring for Anastomotic Leaks







Rapid COVID-19 diagnostic







# 3 things...

Establish trust to gain insight with intended users

Ask for minimal changes in their behaviour

Test your assumptions early (fail fast)

# thank you

---



**Cortex Design**  
Suite #207  
61 Elm Grove Avenue  
Toronto, Ontario

888.317.0722  
[info@cortex-design.com](mailto:info@cortex-design.com)

[www.cortex-design.com](http://www.cortex-design.com)