PerPain

Pain Feedback and Communication Aid for Treatment Planning

Li Xiong | Product Design Engineering MSc

Background

Importance of pain assessment

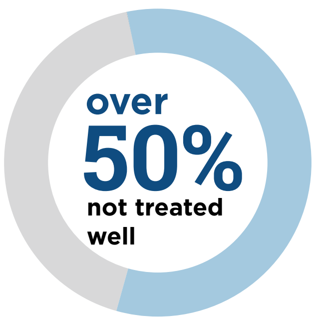
As an unpleasant experience and feeling, pain is **the fifth vital sign** after body temperature, pulse, respiration, and blood pressure (1995 JCAHO).

Detecting and scaling pain is essential in the **diagnostic process**. It helps to **determine the best treatment**.

> *If we want to **improve the quality of clinical treatment**, then pain detection and control should be as much a matter of course as monitoring heart rate and blood pressure.*
>
> *------Dr. James Campbell, American Pain Society*

Common situation

However, current ways of assessing pain **have high error rate**, resulting in many patients suffering from severe pain that **cannot be well-treated** or, at the other extreme, **analgesic addiction**.



Over 50% of the patients suffering strong pain were not well-treated.

24% of long-term users are addicted to painkillers

Problem Definition

The content of problem

The existing pain assessments are **too subjective.** It often depends only on the **patient's description** and the **subjective judgement** of the doctors and nurses. Patients' level of education and doctors' experience all affect the results.

How the most common method — numeric pain scale works.

Problem scenarios

The high error rate made me wonder how and where the problem occurred. Therefore, based on user surveys, I compiled a list of the most common GP viewing scenarios.

Processes

1 You feel **hurt** in your chest and belly.

2 You call your GP, book a **phone** appointment and tell them your symptom.

3 You go to GP for **in-person** appointment if needed.

4 GP asks you some **questions** like how much pain you feel.

5 GP does some general physical **tests**, like heartbeat.

6 Based on the situation, GP decides the further **treatments**.

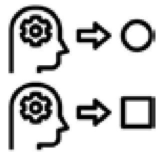
Key Findings

How can GP **accurately determine** whether you need in-person appointment or not just **by phone call**?

Why are there **only questions but no device** for testing pain? Could not testing pain be **objective** as other signs like temperature?

Summary

Current pain assessment methods are **too demanding** for patients' description ability.



Existing methods are **subjective** and fail to reflect **individual differences.**

Pain assessments can be difficult to record in **accurate numbers** like body temperature.

Opportunity Exploration

The complexity of pain and what people really want become obstacles to design after understanding the existing problems of pain scales.

Primary Research - Interviews

To better understand users' requirements, I interviewed some doctors and people with experience in seeing a doctor. I asked about their **pain assessment experience** and **unfulfilled expectations** towards clinical quality. Here is the summary of the interviews.

Experience
Expectation

- **Provide sufficient information**
- **Pain is a continuous sensation**
- **Hard to distinguish ambiguous words**
- **Need accurate number instead of words**

- **Struggling to describe**
- **Feeling confused**
- **Detect my pain by doctors**
- **Understand my sensitivity to pain**

Secondary research

- What situations are suitable for introducing a new pain-scale method?

Appointments with GP/ Family doctor

Pros: 1. In great needs
2. Good use environment
3. Enough operating time

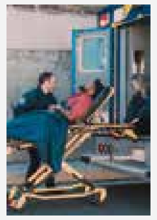
Cons: 1. too wide range of pain

Chronic pain management

Pros: 1. Show clearer pain pattern
2. Good use environment
3. Enough operating time

Cons: 1. needs to operate by patients instead of doctors

Selected



Emergency

Pros: 1. A quick way to detect pain is urgently needed.
Cons: 1. Patients might feel no pain because of anxiety and fear.
2. Might be unconcious.

After-surgery

Pros: 1. In hospital & with nurses all the time.
Cons: 1. Patients usually are under pain killers for days.
2. Might be unconcious

Unsuitable

- What factors of pain should be tested?

Difficulty of description

Region	**Time**	**Provocation**	**Severity**	**Quality**
Where?	When it starts?	What make pain worse?	How painful?	Stapping pain, dull ache?

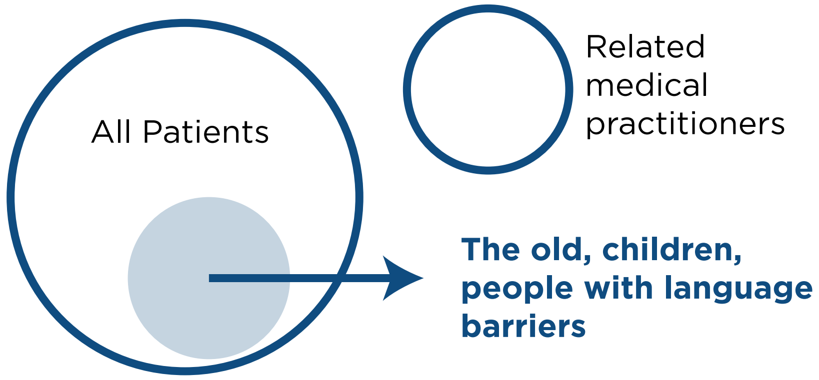
relatively objective, can be easily described (Region, Time, Provocation)

subjective parts, hard to describe (Severity, Quality)

> **Can a device test the hard-to-describe part of pain during the appointments or for chronic pain management?**
>
> **Can this device reduce patients' pressure on description and based on the individual's pain sensitivity?**

Target User Groups

All patients and related medical practitioners will benefit from this design, especially **the old, children, and people with language barriers** (such as foreigners and people with limited ability to understand...)



These groups **take longer** and have **lower accuracy** when using existing pain scales, so they are in **greater need** of new pain assessment methods.

Persona

In order to better simulate the 'perfect' medical experience that users expect, I created a persona based on a research participant's experience.

Name: Nancy
Age: 70
Country: United Kingdom

“I have been in poor health ever since I entered middle age. My son and daughter live in another city, so I often need to go to the doctor alone.

I don't know if it was because I didn't describe my condition well or if the judgements were inaccurate. The pain on my knees are too strong to bare...”

Expectations:
1. Get help to accurately scale the pain in long-distance appointment
2. Better communications
3. Simple solutions but accurate results

As a chronic patient, Nancy is more likely to keep a pain monitor at home

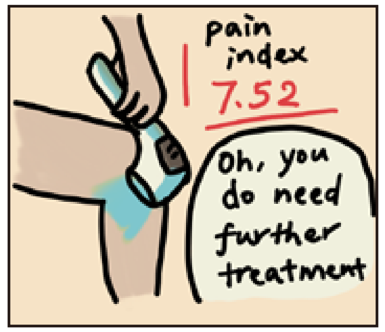
Possible scenarios

These idealized possible scenarios respond to the questions mentioned in the problem scenarios. They envision directions to solve the problem and enhance clinical quality.

Scenario 1
Long-distance appointment

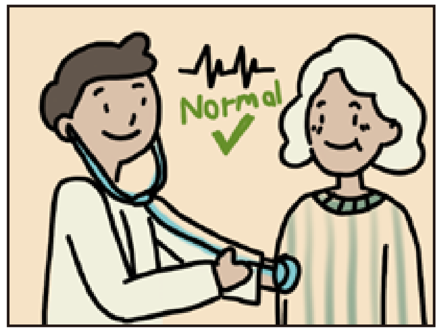
1.Nancy calls for phone appointment.

2. GP asks her to test her pain scale as reference.



3. She gets her pain scale fast and conveniently.

Scenario 2
In-person appointment



1.Nancy revisits GP for physical checks.

2.GP uses the device to check her level of pain.

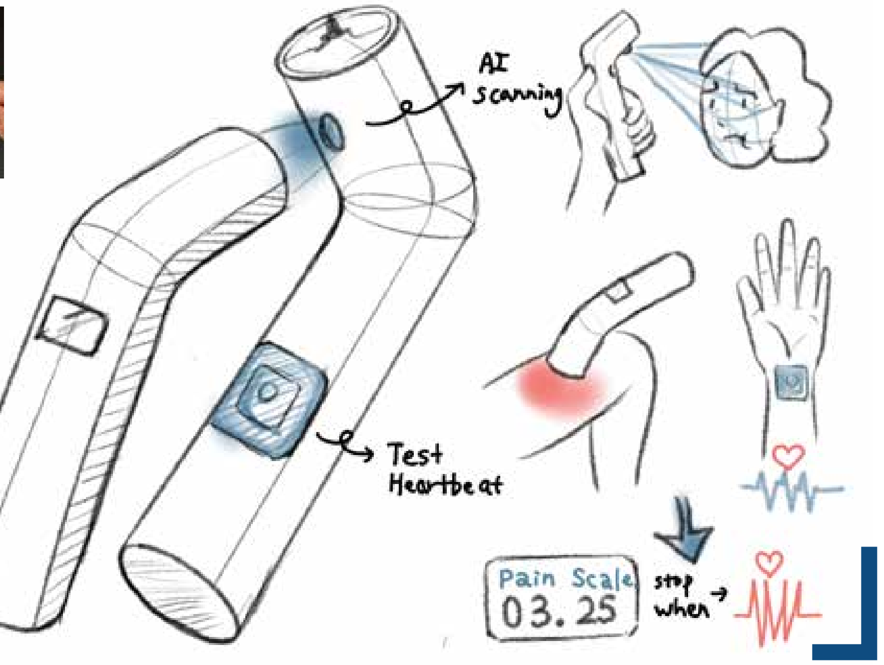
3.GP can quickly and more objectively make diagnosis.

What-if Concepts

Easier operation, wider application scenarios, and higher feasibility

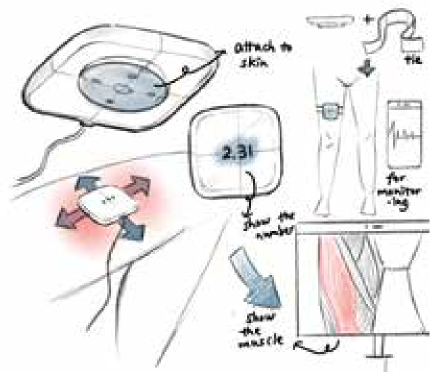
What if we can both test pain threshold and scale user's pain?

This concept uses **AI facial recognition technology** to analyze a user's **microexpressions** to obtain a pain scale. Meanwhile, users can also use the **Von Frey Filaments** at the bottom to get their **pain threshold** by applying different-diameter hair to the skin. Combined with factors such as breathing, the device provides a more objective assessment. It can be used both at home and at GP's.



What if we can read brain activity?

The concept uses **EEG**, a technique that detects **electrical signals** in the brain. During the test, patients wear them like headphones. When the patient feels pain, the device can pick up the signal and make an estimate. But it is **demanding for the environment**, and its **accuracy is not sure**.

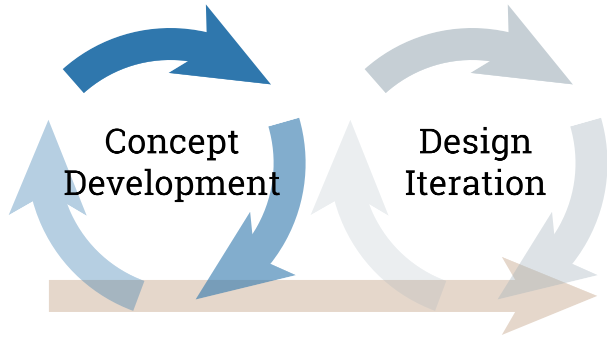


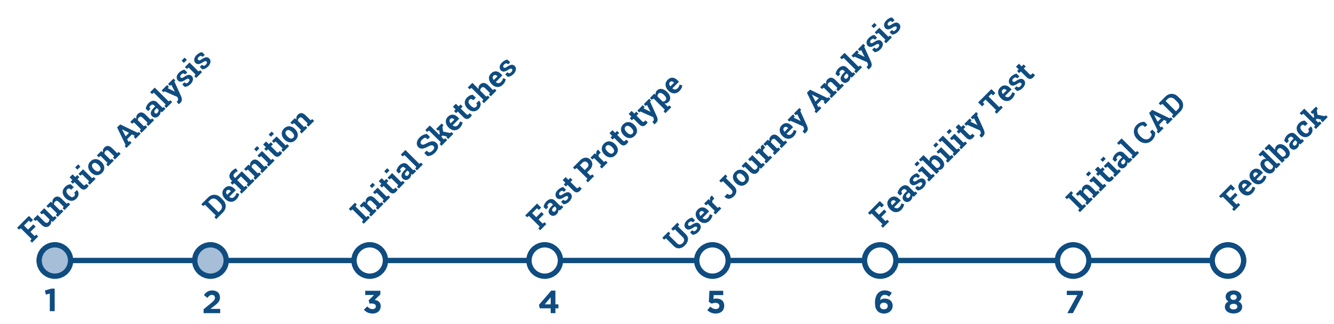
What if we can scan and monitor the body?

When the user moves the device around the body, it uses '**hot spot**' technology (Body Mapping) to read which **muscles** are tense and determine whether they are in pain. But its **range of use is too limited**, and **accurate values are difficult to obtain**.

Concept Development

Design thinking and user-centred design are the core of this project. In every design stage, tests and feedback are required. After selecting the what-if concept, the main task is refining and visualizing the concept, creating an initial design, and conducting user and technical feasibility analyses. Finally, user feedback is obtained for the next design iteration.

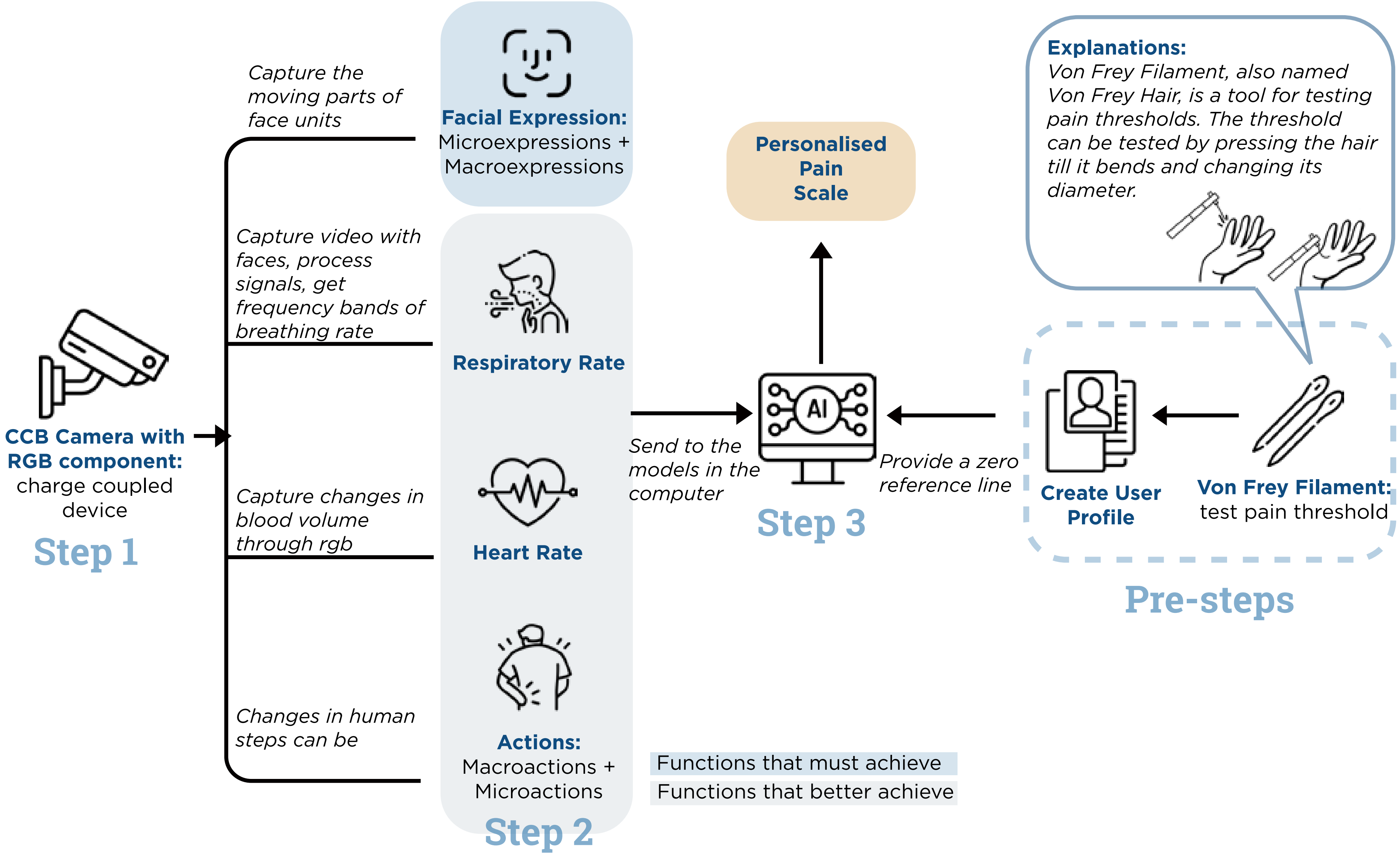




Development Process

1. Function Analysis

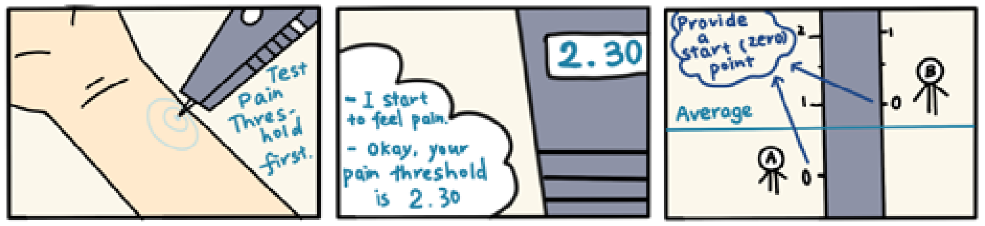
Because the functional concept of this product is complex and has a sequential relationship, the required functions were refined and sorted in the first step of concept development. This part is the technical basis for all subsequent processes and the display of functional logic.



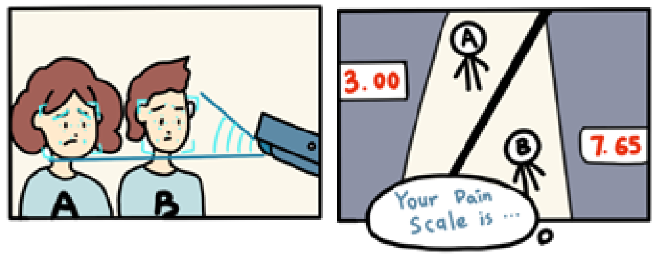
2. Function definition - Storyboard

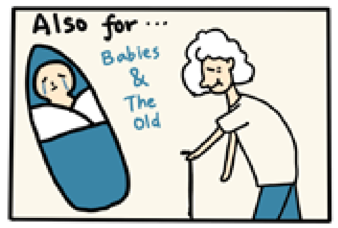
After determining the functions, it is time to create the scenes and methods to use them in a specific scenario and imagine what problems can be solved. Here, it shows through the storyboard.

1. When people suffer from **different injuries**, they may self-evaluate the **same pain scale** because of their different sensitivity to pain.



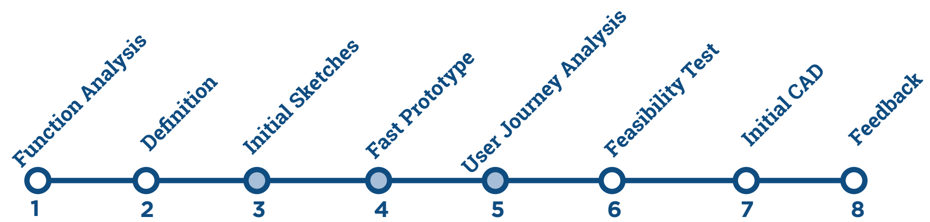
2. In this case, we can use the device to test their **pain threshold**. It can provide **a point at which the user starts to feel pain**





3. Based on their different thresholds, this product can analyze their **relatively objective pain scale** through **face scanning**. The product also works well for **the elderly and children** who are unable to accurately assess their feelings.

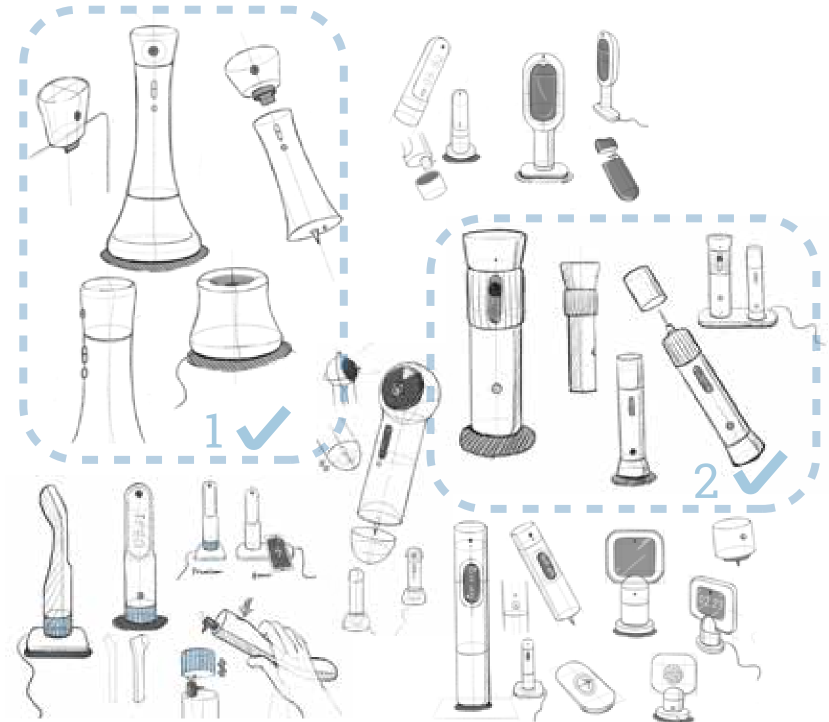
Concept Development



Development Process

3. Initial Sketches

These sketches are for visualizing what the product might look like. When drawing, I found two ideas to achieve the above functions. One is to **combine the two parts into a product**, and the other is to **form a set of two products.**



Reasons:

For 1: *Simple lines match public's aesthetic; Easy to hold*

For 2: *Intuitive functions; more like a medical device*

4. Fast Prototype

However, because of the novel features of this product, users cannot imagine whether "two parts in one" or "a set" is better. Therefore, I quickly produced two rough models based on the above sketches for subsequent user experience simulation.

5. User Journey Analysis

Volunteers were guided through a simulation of a clinical appointment. They participated in using ProtoType1 and ProtoType2 separately and gave feedback at the end. At the same time, I recorded the problems during the simulation and analyzed them.

1 Two in One

2 A Set

1 Users feel sick

1. When patient feels sick and goes to GP, test pain threshold if they have no user profile.

2. Ask where and how they feel pain.

3. Scan patient's face for 3-5 seconds to get pain scale.

2 Users feel well

1. When a patient goes to GP for the first time, build their health profile.

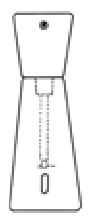
2. Test their pain threshold on both palms.

3. Camera is detecting during the test. The test stops when it reaches their threshold, and record the number.

Users feel sick

4. Patient comes to GP again when they feel sick.

5. After communication, scanning patient's face for 3-5 secs for pain scale.



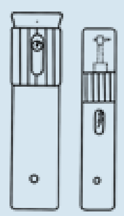
Two in One

Pros:

1. Easier to place and storage

Cons:

1. Need to **lift the camera** during the threshold test
2. Patients with pain **cannot respond quickly** during the threshold test.



A Set

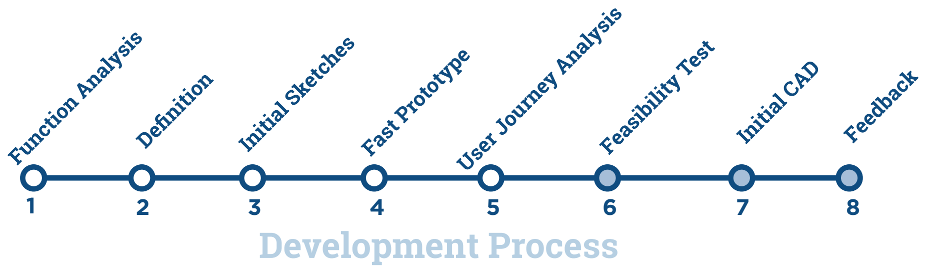
Pros:

1. The threshold **test results** are more **accurate** when testers feel well.
2. **Easier to operate**.

Cons:

1. Need more space to place and storage.

Concept Development



6. Feasibility Test

This product requires the use of a camera for face recognition. So, this question is related to face angle， environment use, etc.

The feasibility test is designed to answer the following questions:
*1. Can AI technology work when **places the product on the table?***
*2. What is the rate of **capturing the desired point** on a person's face **during GP visits**?*
*3. When the user is disturbed, can the function be realized when the user **does not face the lens**?*

Test tools:
A webcam camera,
product prototype,
Video recording software,
AI Facial recognition platform
(find more details of programming in my technical report- feasibility test)

Test Processes

1. Simulate the using senario and use a webcam to record video.

2. While using the threshold test pen, observe the user's reaction.

3. Use facial recognition to see whether can capture the landmark and detect emotions

Test Results

The successful capture rate is **100%** under the simulation scenario.

Conclusions:

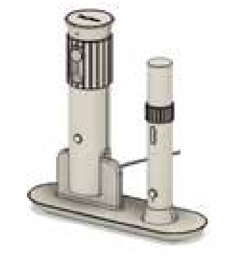
1. Placing product aside can **capture sufficient and effective information** for AI recognition.

2. Patients do not have to face the camera. Facial recognition **works with side face**.

3. **Better the camera quality** and using video instead of picture can increase the probability.

7. Initial CAD

CAD is a speedy and visualized way to simulate the appearance and structure of products. CAD models are more intuitive than sketches and can accept user feedback better.



Selected CAD

8. Review & Feedback

After completing the preliminary design, I presented the design to different groups, including those who have studied the pain field and ordinary users. I collected their opinions and feedback for subsequent product iterations.

Uploading captured videos to Cloud might **leak user's privacy**

Elegant Look

Looks like medical device

Does the threshold test pen really need to **place on table**?

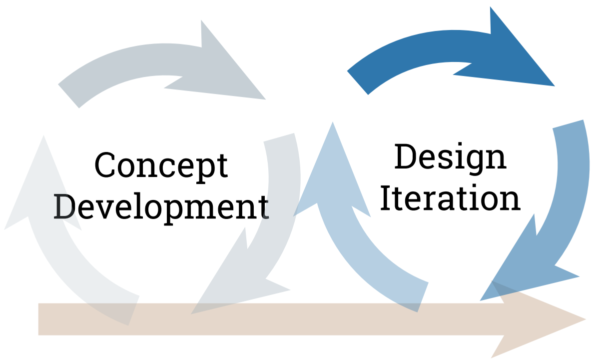
The needle looks **scary.**

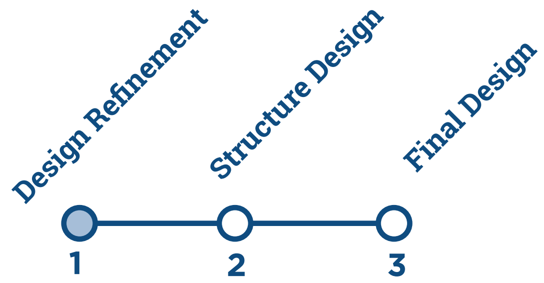
Electronic Von Frey Filaments are **too expensive**.

Can this part **twist** and come up with different filaments?

If using normal Von Frey Hair, can the pen be **non-electrical**?

Design Iteration





Design Iteration

1. Design Refinement

After completing the first-version design, according to the feedback of users and professionals, I analyzed the ideas and problems raised by them and decided on the modification scheme.

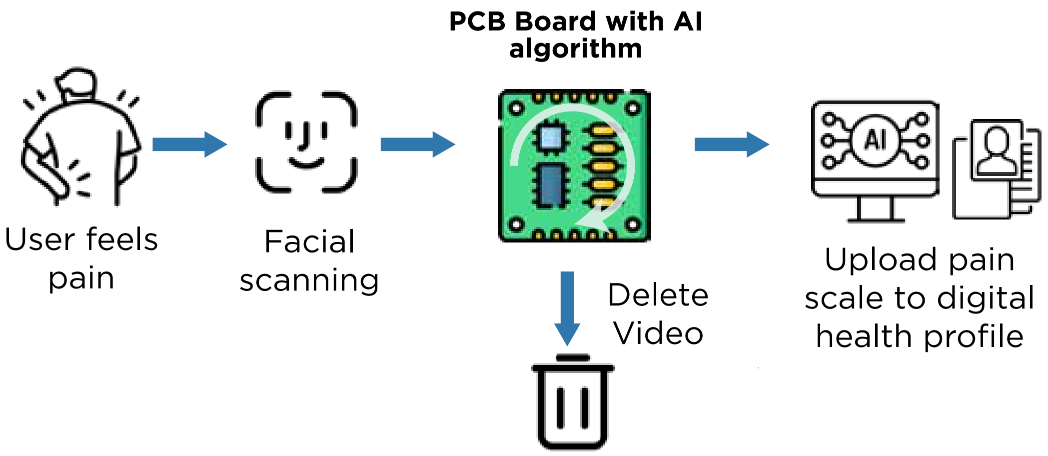
The above feedback can be divided into two categories: user experience and design details.

User Experience Refinement:

Feedback: Information leakage

Analysis: Uploading videos to the cloud does have privacy risks

Progress: All captured videos are read offline and deleted in real time after data is obtained. Only Pain Scale is uploaded to the cloud



New Function Flowchart

Feedback: Threshold test pen might use much less frequently than facial scanner.

Analysis: Test pen should better storage in box.

Progress:

Single wireless charger with pen collect bag

Design Details Refinement:

Feedback: Looks like needle

Analysis: Sharp shape makes users anxious.

Progress: Hide the filaments inside the shell, making it look more like a pen.

Feedback: Can the pen be non-electrical?

Analysis:

No. Although it changed to non-electrical Von Frey Filaments, it still **needs the WiFi module** to **receive signal** from facial scanner and **upload pain scale** to digital health profile.

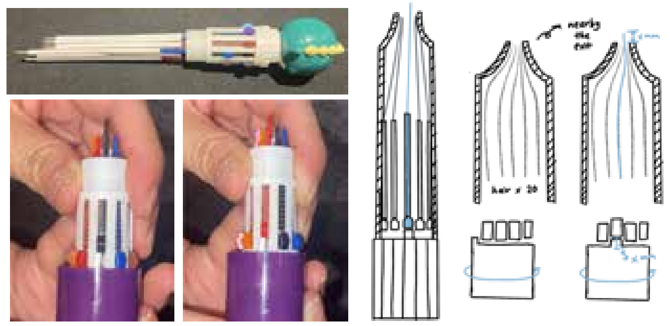
Feedback: Can I rotate to change the filaments?

Analysis: Yes, it is easier to use than taking apart the filaments for changing. Also, it is cheaper than using electronic ones(automatic changes force).

Progress: Specific improvement is in the Structural Design part .

2. Structure Design

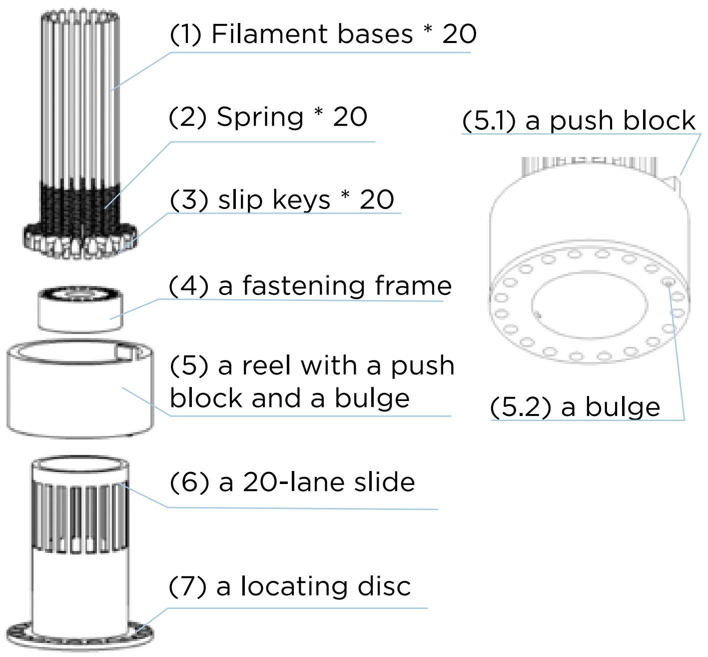
The structure focuses on changing the different diameter Von Frey Filaments when twisted. This feature reminded me of the multi-coloured cylinder: it might be possible to do this if the cores inside the ballpoint pen were replaced with filaments and added a spinner.



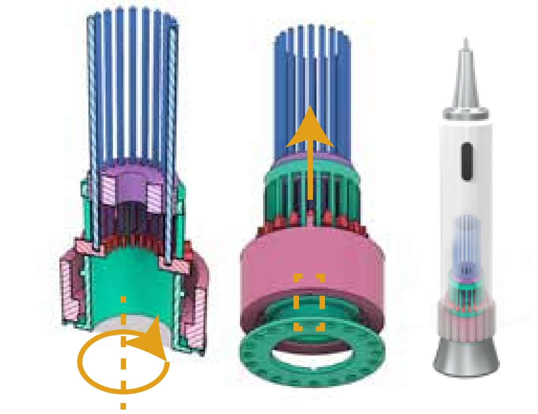
Structure Brainstorming

Key Point: Because the filaments is so thin and flexible (the thickest is only 6μm), they can't be pushed far away or they might bend. Ideally, place all the filaments near the nib. Only a tiny rise on the base can push the related filament out.

Structure Details



How it works



When rotating the reel, the push block pushes the slip key forward and drives the filament base forward some distance by the spring. The length is far enough for the nib to have a corresponding filament pushed out. And the bottom part sticks to the locating disc, making the filament stuck. When turning the reel again, this filament bounces back and launches the next one.

Summary

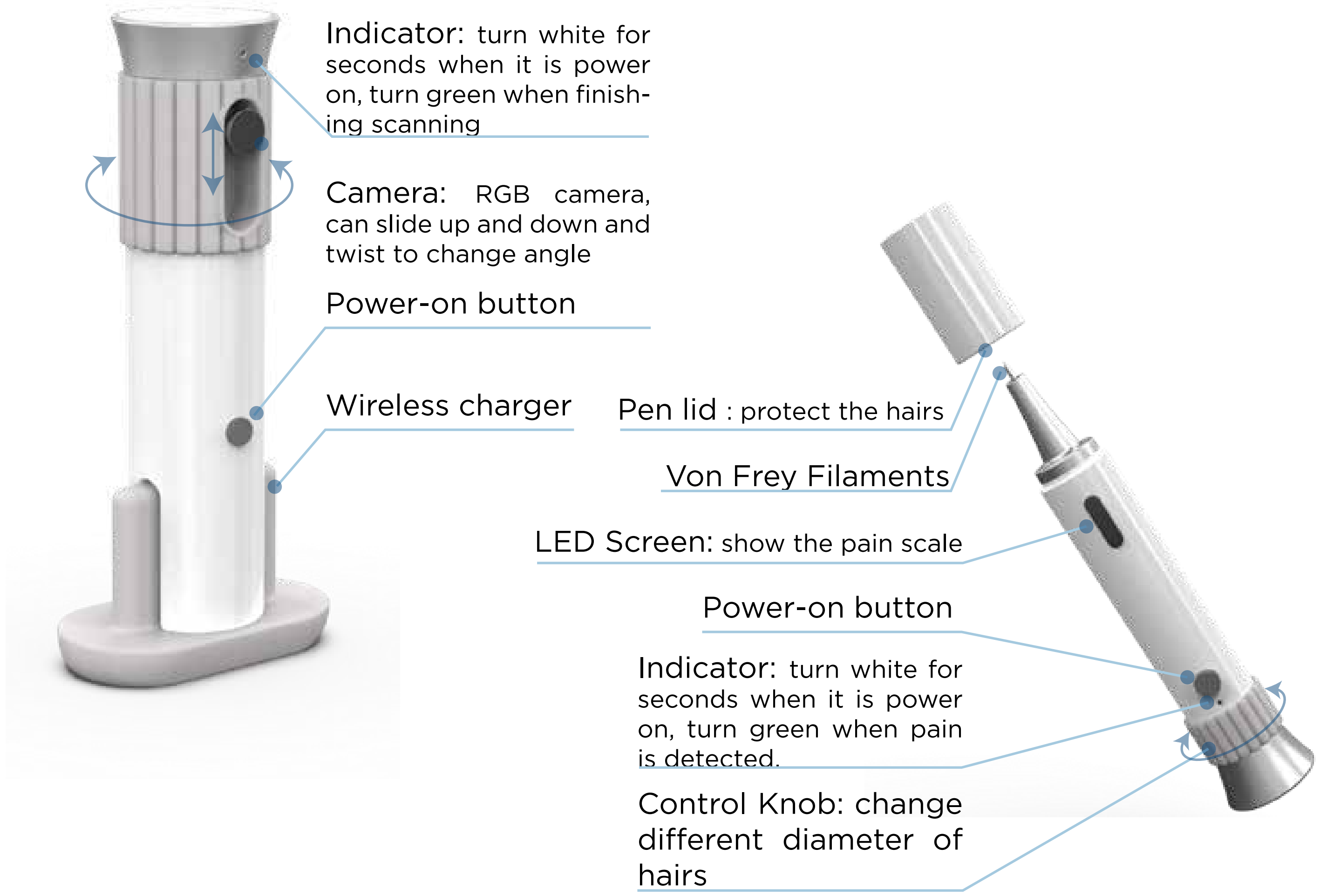
At present, this structure is only in the theoretical stage. Its structural parts are many and small, and the Filaments are too detailed to be tested by3D printing. However, the structure is theoretically feasible since there are ballpoint pens with similar functions on the market.

3. Final Design

Project Description

PerPain is a personalized pain scale device for more objective pain assessment and management. Pain is too subjective to be well-described, which causes many cases of misevaluation. PerPain uses AI scanning technology to achieve more accurate pain assessment by capturing the patient's micro-expressions and micro-motions, as well as changes in heart rate and breathing rate. PerPain can measure a patient's pain threshold to exclude extreme sensitivity to pain. Compared with the traditional methods, PerPain not only reduces the possibility of errors in subjective judgments but also varies from person to person. It provides a more objective and accurate reference for GPs and a more convenient and quicker way for patients with chronic disease to record their pain diaries.

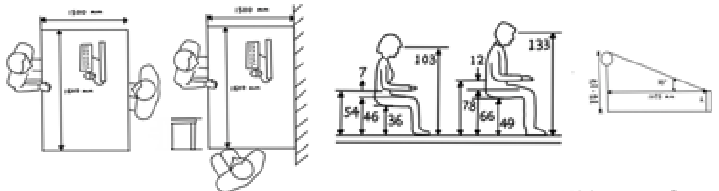
Product Details



Size & Capacity

Facial Scanner

In order to ensure that the camera can **capture the faces of patients of different heights**, the product needs to be in a height range.

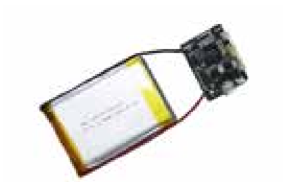


$$d = \sqrt{800mm^2 + 750mm^2} \approx 1096mm \qquad \tan 35^\circ = \frac{580mm - h}{1096mm}$$

$$h_{min} = 580mm - \tan 35^\circ \times 1096mm < 0$$

$$h_{max} = \frac{1096mm + \tan 35^\circ \times 280mm}{tan35^\circ} = 1846mm$$

According to the industry custom of **electronic tool design**, the diameter is generally between 40-50mm.
For ease of use, here the size I decided is **50mm(D)*200mm(H)**.



5400mAh, 5V

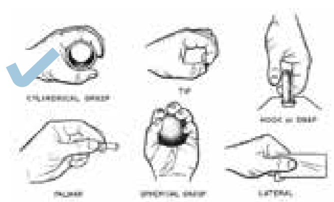
The battery should be used for the continuous operation of 5V 1.5A camera and 5V 6W PCB board for 2 hours. The minimum battery capacity is calculated as follows:

$$I = I_1 + I_2 = I_1 + \frac{P}{U} = 1.2A + \frac{6W}{5V} = 2.7A = 2700mA$$

$$Q = I \times t = 2700mA \times 2h = 5400mAh$$

Threshold Test Pen

According to A Guide to Human Factors and Ergonomics, the diameter of **the handheld tool with cylindrical grasp** should be 40-50mm, and the length should be about 100-120mm.



However, the length does not affect the functionality. To **leave enough space** for the mechanical structure and components, the length can be increased appropriately.

Here, the diameter is **30mm** in the standard range, and the length is **180mm** in reference to ballpoint pens.

500mAh, 3.7V

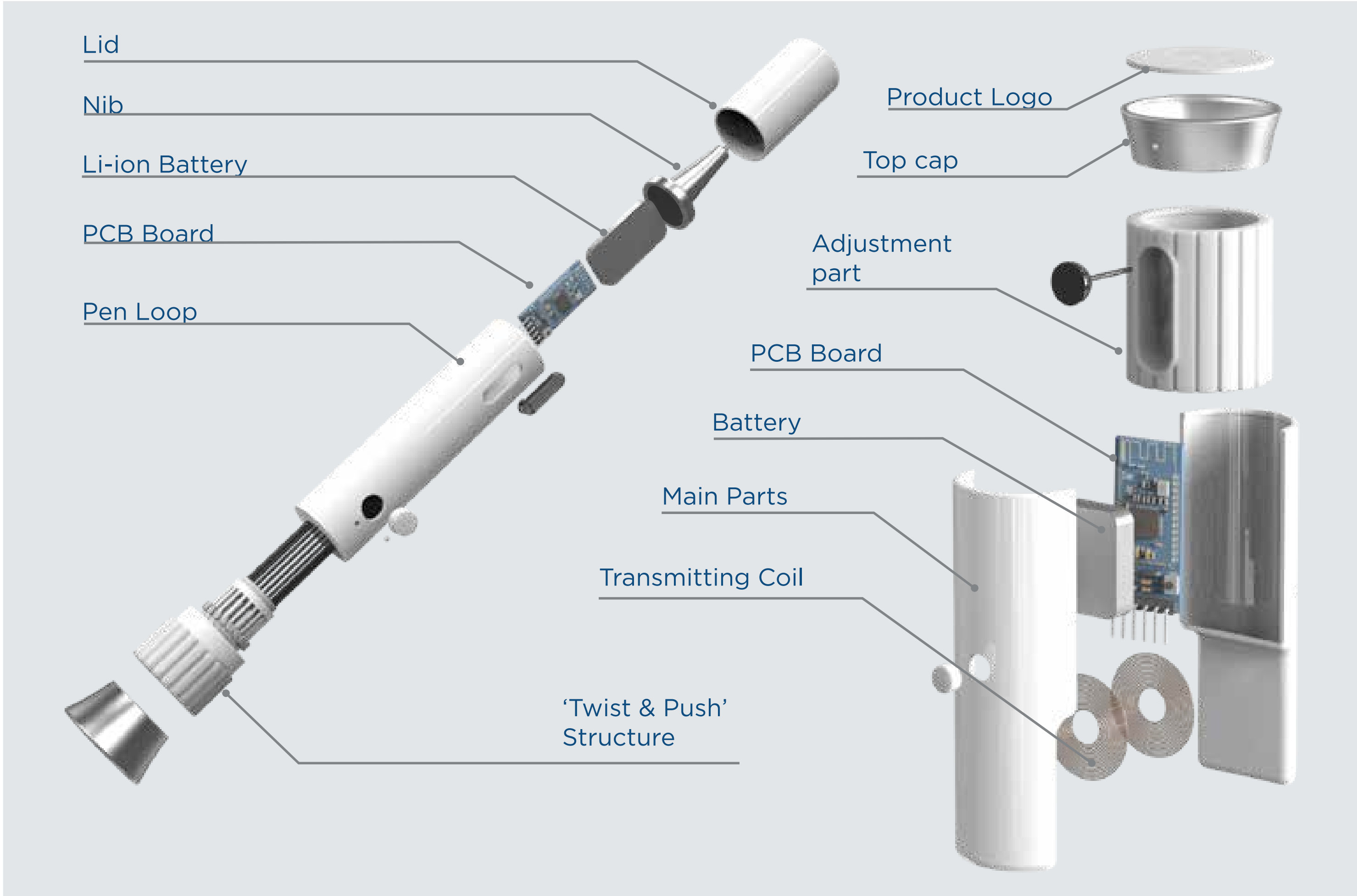
The parameters for mini Led are 3.3V, 26.4MW, 3.3V, and 15mA for the PCB board. The mminimum battery capacity is:

$$I_1 = \frac{P}{U} = \frac{26.4mW}{3.3V} = 8mA$$

$$Q = (I_1 + I_2) \times t = (8mA + 15mA) \times 5h = 115mAh$$

Engineering, Manufacture & Assembly

PerPain has two main part: pain threshold test pen and facial scanner. It has some more parts to realize the function and ensure the appearance. PerPain is nearly fastener-free, with self-locking plastic materials to reduce the overall weight.



No.	Part	Material	Manufacturing Methods	Assembly
1		Polyethylene -HDPE	Injection Moulding	Manual assembly
2			Injection Moulding Metal Spray Paint	Detachable Ring Collocation Assembly
3			Injection Moulding Polishing Spraying	Collocation Assembly with (4);
4			Injection Moulding Sandblasting	Detachable Ring Collocation Assembly
5			Injection Moulding Metal Spray Paint	

No.	Part	Material	Manufacturing Methods	Assembly
1		Polyethylene -HDPE	Injection Moulding Laser Marking	Collocation Assembly
2			Injection Moulding Sandblasting	
3,4			Injection Moulding Polishing Spraying	Collocation Assembly with (2); Screw Fastener between (3) (4)

No.	Part	Material	Manufacturing Methods	Assembly
1		Polyethylene -HDPE	Injection Moulding Sandblasting	Screw Fastener
2				

Final Prototype

After determining the product's size, appearance, and other parameters, I made the final prototype by 3D printing. Compared with the previous foam model, the 3D printed model can better simulate the final appearance and use of the product.

Because the internal structure is too complex and the parts are too small, 3D printing has not been carried out. This prototype is the appearance model for simulating final user journey.

User Journey Simulation

1. Doctor received PerPain.

2. Place the facial scanner on the table.

3. Adjust the scanner for better angle.

4. UserA just registered in the GP's.

5. Doctor tested his pain threshold for profile.

6. The test stopped when camera detected UserA's pain.

7. Read the pain scale on the screen

8. UserA knew his threshold for the first time.

9. When doctor didn't need the pen, he put it in bag.

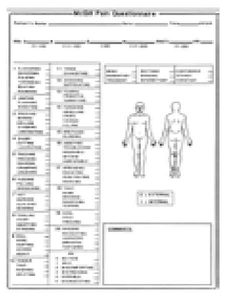
10. UserA went to GP's for appointment.

11. Doctor scanned his face for pain scale.

12. For online appointment, PerPain worked well too.

Benefits & Summary

On average, GPs are in touch with **28** patients a day either in their surgery, on a home visit, or by telephone.



about 15 mins

3-5 secs

about 5 mins

$$28 \times [(15 \times 60s) - (5s + 5 \times 60s)] = 16660s = 4.62hrs$$

Assuming that every patient has no profile but needs pain assessment, a GP can **save 4.62 hours of time per day.**

For Doctors:

More effcient appointment & Time-saving

For Patients:

1. **No need to worry** about how to describe their level of pain.

2.They can receive **more efficient and accurate clinical service,** especially for patients who need help to describ.

Cost Estimation

This calculation aims to provide a rough estimate of whether the price can be acceptable for users and does not represent the actual cost.

After adding mold opening, processing, transportation, testing, and other costs, the total cost should be higher, but it is expected to be within the PDS definition.

Component/service	Specifications	Quantity	Cost (pounds)/per
Small PCB board	5V 6W	1	4.80
Mini PCB board	3.3V 15ma	1	6.60
Li-ion battery	5V 5400mAh	1	5.88
Li-ion battery	3.7V 500mAh	1	4.90
Mini Led screen	3.3V 26.4mW	1	4.12
Indicator	6mm 3-6V	2	0.3
WIFI module	usr-c215	2	3.74
Mini camera	1080p	1	19.8
Von Frey Filaments	self-made	1	5
Facial recognize algorithm		1	125
Transmitting coil	5V	4	0.52

Material	Specifications	Quantity	Cost (pounds) /kg
Polyethylene	HDPE	1.5kg	1.13
Silicon	Condensed mold silicone	500g	3.75
		Total	*189.83 pounds*