

# Redesign of the HeartEye ECG for home use

## Appendix

Author: Lucas Habets

Date: 02-05-2024

*This is the accompanying appendix for the graduation project report titled the redesign of the HeartEye ECG for home use.*

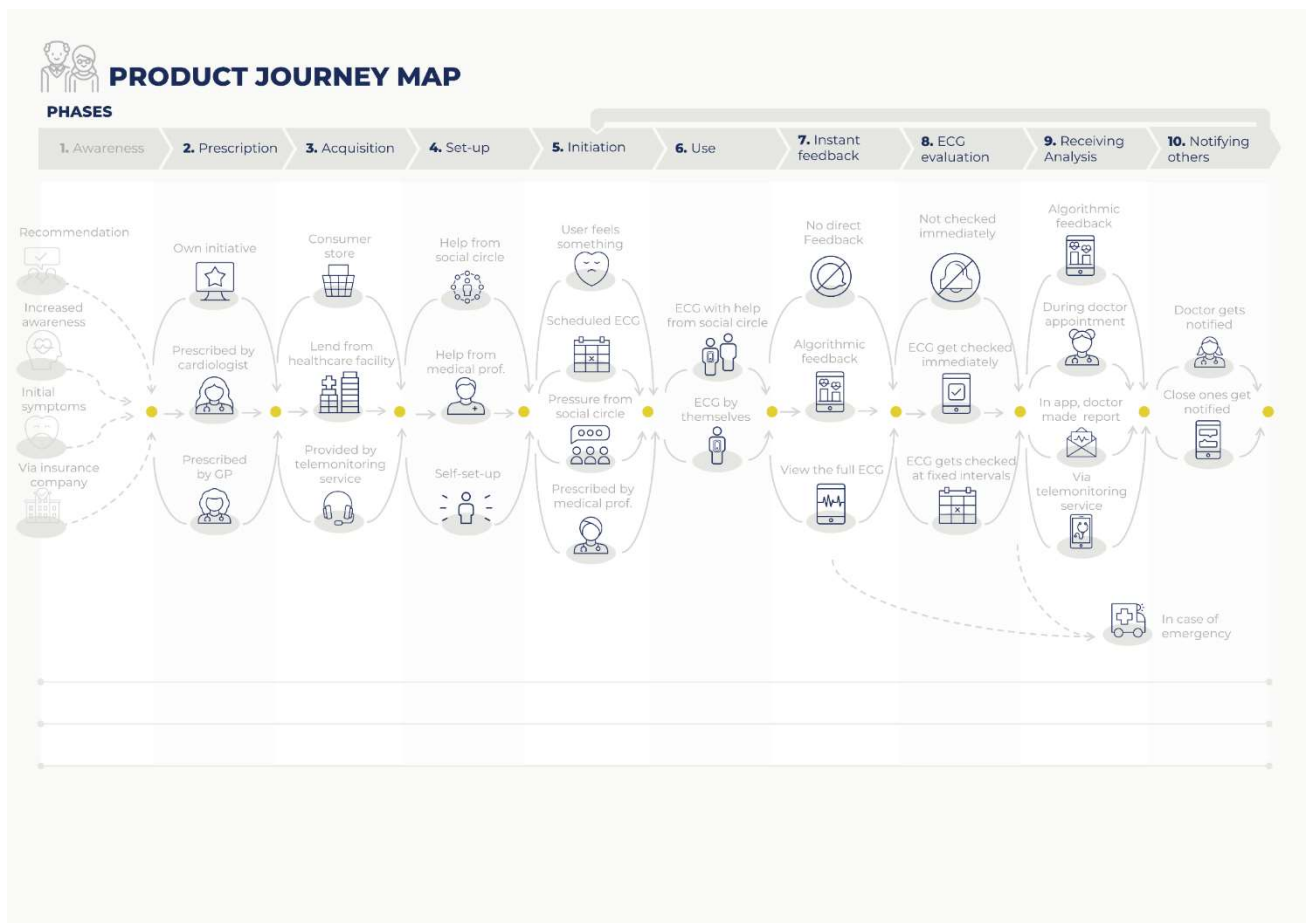
# Appendix table of contents

Appendix table of contents .....	1
Appendix A: Product journey.....	4
Appendix B: Python script for web scraping forums .....	5
Appendix C: Python script for generating embeddings from forum data .....	10
Appendix D: Python script K-means clustering .....	14
Appendix E: Python script GPT-Topic modelling .....	17
Appendix F: Prompt for topic modelling.....	23
Appendix G: Key insights from forum analysis .....	25
Appendix H: Interesting quotes from forum analysis .....	31
Appendix I: Sensor validity test .....	36
Appendix J: Exploration of ECG telemonitoring devices.....	38
Appendix K: Exploration of E-health services .....	44
Appendix L: Studies on effectiveness of telemonitoring in cardiovascular care .....	46
Appendix M: Patient related barriers .....	47
Appendix N: Healthcare provider-related barriers .....	48
Appendix O: Other barriers for E-health adoption .....	48
Appendix P: Guidelines on the development of E-Health .....	48
Appendix Q: Stakeholders analysis .....	50
Appendix R: Analysis of the EU Medical Device Regulations .....	55
Appendix S: AI regulation analysis.....	56
Appendix T: Analysis on machine learning interpretability .....	58
Appendix U: Analysis on woman in heart disease .....	61
Appendix V: Interview guide .....	63
Appendix W: analysis into screening .....	64
Appendix X: Analysis into the prehabilitation to revalidation period .....	66
Appendix Y: Patient accessibility issues analysis .....	70
Appendix Z: Selected ideas substantiation.....	71
Appendix AA: Arduino code .....	78
Appendix BB: Python script for reading the test platform.....	83
Appendix CC: Requirements for insurance reimbursement.....	85

Appendix DD: Informed consent sheet user test.....	87
Appendix EE: researcher guide user test.....	90
Appendix FF: Feedback mechanism card game cards .....	93
Appendix GG: Method of electrode testing .....	94
Appendix HH: Overview of quantitative test data .....	95
Appendix II: Explanation of overarching themes from qualitative study .....	96
Appendix JJ: Ideation resources .....	98

# Appendix A: Product journey

This patient journey was used as visual aid during interviews.



## Appendix B: Python script for web scraping forums

The code for downloading / web scraping all posts from the two forum sources. Here is a simplified breakdown of what the code does:

1. **Web Scraping:** The script uses requests and BeautifulSoup libraries to download and parse web pages. It extracts specific data from these pages, such as the text of forum posts.
2. **Data Modelling with Pydantic:** It uses Pydantic's BaseModel to define a structure for the website being scraped. This helps in organizing and validating the data collected.
3. **Multithreading for Efficiency:** The script employs multithreading, through ThreadPoolExecutor, to scrape multiple pages at the same time, making the process faster.
4. **Handling Data and Exporting:** After scraping the data, it compiles the information into CSV files for easy storage and analysis.
5. **Rate Limiting and Thread Safety:** The script includes features like rate limiting (to avoid overloading the server) and thread safety (to prevent data corruption when multiple threads access shared data).

In essence, this script automates the collection of forum post data from HealthUnlocked and Hart Patienten, efficiently handling multiple pages simultaneously and organizing the extracted data into a usable format.

```
import requests
from bs4 import BeautifulSoup
import time
from pydantic import BaseModel
from typing import List, Optional
import csv
from concurrent.futures import ThreadPoolExecutor, as_completed
from threading import Lock
from threading import local
from collections import Counter
import requests
import xml.etree.ElementTree as ET

# scraper class
class Website(BaseModel):
    url: str
    topic_class: str = None
    post_class: str = None
    message_text_class: str = None
    next_button_class: str = None
    result_text: List[str] = []
    result_url: List[str] = []
    rate_limit_sec_per_request: int = 0
    duration: float = None
    max_thread: int = 12
```

```

class Config:
    extra = 'allow'

    # Initialize a lock for when multithreading for when accessing global
values
def __init__(self, **data):
    super().__init__(**data)
    self.lock = Lock()

# entry points
# 1. scrape_forum()
# 2. scrape_topic()
# 3. scrape_messages()

def scrape_messages(self, post_url):
    try:
        response = requests.get(post_url)
        soup = BeautifulSoup(response.text, 'html.parser')

        # Extract messages
        divs = soup.find_all('div', class_=self.message_text_class)
        for div in divs:
            messages = div.find_all('p')
            full_message = ""
            for message in messages:
                full_message += message.get_text(strip=True)
            # Check if the message is not empty or just white spaces
            if full_message.strip():
                # Use the lock when modifying shared data
                with self.lock:
                    self.result_text.append(full_message)
                    self.result_url.append(post_url)
            print(f"messages scraped: {len(self.result_text)}, url:
{post_url}")
        return

    except Exception as e:
        print(f"Error scraping post: {e}")
        return

def scrape_topic(self, topic_url):
    try:
        response = requests.get(topic_url)
        soup = BeautifulSoup(response.text, 'html.parser')

        # Extract post URLs

```

```

        post_links = soup.find_all('a', class_=self.post_class) # post
class

        for link in post_links:
            post_url = link['href']
            self.scrape_messages(post_url)
            time.sleep(self.rate_limit_sec_per_request) # Rate limiting

        next_topic = self.__find_next_page_url(soup)
        if next_topic is not None:
            self.scrape_topic(next_topic)
            print(f"scraping next topic: {next_topic}")
        return

    except Exception as e:
        print(f"Error scraping topic: {e}")
        return

def scrape_forum(self):
    try:
        start_time = time.time() # Start timer

        response = requests.get(self.url)
        soup = BeautifulSoup(response.text, 'html.parser')

        # Extract topic URLs
        topic_links = soup.find_all('a', class_=self.topic_class) # topic
class

        # Use ThreadPoolExecutor to scrape topics in parallel
        with ThreadPoolExecutor(max_workers=self.max_thread) as executor:
            futures = [executor.submit(self.scrape_topic, link['href'])
for link in topic_links]
            for future in as_completed(futures):
                try:
                    future.result() # You can process the result or catch
exceptions here
                except Exception as e:
                    print(f"Error in thread: {e}")

            return

    except Exception as e:
        print(f"Error scraping forum: {e}")
        return

    finally:
        end_time = time.time() # End timer

```

```

        self.duration = end_time - start_time
        print(f"Scraping completed in {self.duration} seconds.")

# util functions
def export_to_csv(self, filename:str):
    with open(filename, 'w', newline='', encoding='utf-8') as file:
        writer = csv.writer(file)
        writer.writerow(['url', 'text'])
        for url, text in zip(self.result_url, self.result_text):
            writer.writerow([url, text])

def __find_next_page_url(self, soup):
    next_button = soup.find('a', class_=self.next_button_class) # Adjust
this based on the website's structure
    if next_button:
        return next_button.get('href') # Returns the URL of the next page
    return None

def __check_for_duplicates(self):
    print("Testing for duplicates...")
    text_counter = Counter(self.result_text)

    # Count the total number of duplicate entries
    duplicate_count = sum(count - 1 for count in text_counter.values() if
count > 1)

    if duplicate_count > 0:
        print(f"Total number of duplicate entries: {duplicate_count}")
        # Optionally, remove duplicates
        self.result_text = list(set(self.result_text))
    else:
        print("No duplicates found.")

# main code starts here
healthunlocked = Website(
    url= "https://healthunlocked.com/bhf/posts/{}/",
    message_text_class="post-container",
)

# download and parse sitemap
def download_and_parse_sitemap(url):
    response = requests.get(url)

    sitemap_content = response.content

    root = ET.fromstring(sitemap_content)
    urls = [url.text for url in
root.findall('.//{http://www.sitemaps.org/schemas/sitemap/0.9}loc')]

```



```
    return urls

sitemap_base_url = 'https://healthunlocked.com/sitemap'

# main part: loop over all sitemaps and scrape each post
for i in range(2, 76): # Assuming sitemap numbers range from 2 to 75
    sitemap_url = f'{sitemap_base_url}{i}.xml.gz'
    urls = download_and_parse_sitemap(sitemap_url)
    print(f"{i} sitemaps downloaded")
    print(f"urls to download: {len(urls)}")

    # multi threading executor
    with ThreadPoolExecutor(max_workers=10) as executor:
        futures = [executor.submit(healthunlocked.scrape_messages, link) for
link in urls]
        for future in as_completed(futures):
            try:
                future.result()
            except Exception as e:
                print(f"Error in thread: {e}")

    # save data as CSV
    healthunlocked.export_to_csv(f"data/healthunlocked_{i}.csv")
    healthunlocked.result_text = []
    healthunlocked.result_url = []
```

## Appendix C: Python script for generating embeddings from forum data

This script is a tool for processing large text datasets to obtain numerical representations (embeddings) using OpenAI's API. This is a simplified breakdown of its main functions:

1. **Data Handling:** It loads and combines text data from multiple CSV files using the pandas library.
2. **Token Counting and Cost Calculation:** The script counts the number of tokens in the text and estimates the cost of generating embeddings based on these tokens.
3. **Text Embedding Generation:** Using OpenAI's API, it converts text from the datasets into numerical embeddings.
4. **Batch Processing:** The script processes the text in batches to efficiently manage API token limits and optimize the embedding generation process.
5. **Multithreading:** It employs multithreading to process multiple files simultaneously, enhancing the speed of the task.
6. **Result Storage:** After generating the embeddings, the script saves the updated data back into CSV files.

```
from concurrent.futures import ThreadPoolExecutor, as_completed
import pandas as pd
from openai import OpenAI
import os
import tiktoken

# Function to load and combine CSV files
def load_and_combine_csv(folder_path, file_pattern, filter_list = None):
    all_files = [os.path.join(folder_path, f) for f in os.listdir(folder_path)
if f.startswith(file_pattern)]
    df_list = [pd.read_csv(file) for file in all_files]
    combined_df = pd.concat(df_list, ignore_index=True)
    if filter_list is not None:
        filtered_df = combined_df[combined_df['url'].apply(lambda x:
any(x.startswith(s) for s in filter_list))]
        print(f"og: {combined_df.shape}, vs: {filtered_df.shape}")
        return filtered_df

    return combined_df

def count_tokens(text, enc):
    # Using OpenAI's tokenizer
    tokens = enc.encode(text)
    return len(tokens)

def calculate_embedding_cost_openai(df: pd.DataFrame, text_column):
    print("calculating costs")
    enc = tiktoken.get_encoding("cl100k_base")
```

```

# Ensure the text column exists
if text_column not in df.columns:
    raise ValueError(f"Column '{text_column}' not found in the CSV file.")

# Function to count tokens using OpenAI's tokenizer
def count_tokens(text):
    # Using OpenAI's tokenizer
    tokens = enc.encode(text)
    return len(tokens)

# Count tokens in the text column
token_count = df[text_column].apply(lambda x: count_tokens(str(x)))

# Sum up the tokens
total_tokens = token_count.sum()

# Calculate cost (€0.0001 per 1000 tokens)
cost_per_thousand_tokens = 0.0001
total_cost = (total_tokens / 1000) * cost_per_thousand_tokens

return total_cost

def create_embedding(file_path):
    # Load and combine CSV files
    combined_df = pd.read_csv(f"{file_path}") #
load_and_combine_csv(folder_path, 'healthunlocked_')
    # # predict costs
    cost = calculate_embedding_cost_openai(combined_df, "text")
    print(f"Total cost for creating embeddings: €{cost:.4f}")

# Assuming the posts are in a column named 'text'
posts = combined_df['text'].astype(str)
num_posts = len(combined_df)
# Preprocessing
posts = posts.str.lower().str.replace(r'^\w\s+$', ' ')

# Function to generate embeddings using OpenAI API
def generate_embeddings(texts, client: OpenAI):

    texts = [s.replace('\n', ' ') for s in texts]
    texts = [" " if s is None or s == "" else s for s in texts]
    texts = [' '.join(s.split()[:4000]) for s in texts]
    try:
        response = client.embeddings.create(
            input=texts,
            model="text-embedding-ada-002"

```

```

    )
    response.data
    return [item.embedding for item in response.data]
except Exception as e:
    print(f"ERROR IN GETTING EMBEDDING: {e}")
    return [[0.0 for t in range(1536)] for s in range(len(texts))]

# Generate embeddings in batches
client = OpenAI(api_key='sk-
AylGjAy2IJXUKxMnw7CFT3B1bkFJmqXB0wNS2A0Cpc6xS1HV')
enc = tiktoken.get_encoding("cl100k_base")
i = 0
embeddings = []

while i <= num_posts-1:
    batch_tokens = 0
    num_in_batch = 0
    batch_tokens += count_tokens(posts[i], enc)
    i += 1
    num_in_batch += 1
    if i <= num_posts - 1:
        while batch_tokens < 8100 - count_tokens(posts[i], enc):
            batch_tokens += count_tokens(posts[i], enc)
            i += 1
            num_in_batch += 1
            if i >= num_posts - 1:
                break

    batch = posts[i - num_in_batch:i].tolist()

    embeddings.extend(generate_embeddings(batch, client))
    print(f"{i} out of {num_posts} embeddings made in: {file_path}")

combined_df['embedding'] = embeddings

# Save the DataFrame to a new CSV file
output_csv_path = f'./data/embedded/embedded_{file_path[5:]}'
combined_df.to_csv(output_csv_path, index=False)

list_of_domains = ["https://healthunlocked.com/arrhythmia-alliance-heart-
failure/",
                  "https://healthunlocked.com/hearthythmcharity/",
                  "https://healthunlocked.com/arrhythmia-alliance-svt/",
                  "https://healthunlocked.com/bhf/",
                  "https://healthunlocked.com/heart-valve-voice/",
                  "https://healthunlocked.com/pacemakerusers/",
                  "https://healthunlocked.com/sca-heart-attack/",
                  "https://healthunlocked.com/unsaltedheart/"]

```

```
]

# optional code for loading combining other data
# df = load_and_combine_csv("data backup/", "healthunlocked_",
list_of_domains)
# df.to_csv("data/embedded/combined.csv", index=False)

# this is for large number of files
folder_path = 'data'
file_names = [f for f in os.listdir(folder_path) if
os.path.isfile(os.path.join(folder_path, f))]
print(file_names)
with ThreadPoolExecutor() as executor:
    futures = [executor.submit(create_embedding, f"data/{file_path}") for
file_path in file_names]
    for future in as_completed(futures):
        try:
            future.result()
        except Exception as e:
            print(f"Error in thread: {e}")
```

## Appendix D: Python script K-means clustering

The script automates the process of finding the best way to group a set of text embeddings and visually represents the clustering results. Here is a simplified breakdown of its functionality:

1. **Load Data:** Reads text embeddings from a CSV file and prepares them for analysis.
2. **Clustering Analysis:** Uses the K-Means algorithm to group the embeddings into clusters, determining the optimal number of clusters by evaluating different possibilities in parallel.
3. **Optimal Cluster Calculation:** Applies the Elbow Method to find the best number of clusters where adding more clusters doesn't significantly improve the model.
4. **Visualization:** Displays the results using two methods:
  - A graph to show the Elbow Method's outcome.
  - A scatter plot using PCA (Principal Component Analysis) for a 2D visualization of the clustered embeddings.
5. **Save Results:** The final clustered data is saved back to a CSV file.

```
import pandas as pd
from sklearn.cluster import KMeans
from sklearn.decomposition import PCA
import matplotlib.pyplot as plt
import ast
import numpy as np
from concurrent.futures import ThreadPoolExecutor

# load data
path = "data/embedded/embedded_hartPatienten.csv"
combined_df = pd.read_csv(path)
combined_df['embedding'] = combined_df['embedding'].apply(ast.literal_eval)
embeddings_array = np.stack(combined_df['embedding'].values)

# function to calculate the WCSS value
def calculate_wcss(data, n):
    kmeans = KMeans(n_clusters=n, init='k-means++', max_iter=300, n_init=10,
random_state=0)
    kmeans.fit(data)
    print(f"iteration {n} done. WCSS = {kmeans.inertia_}")
    return kmeans.inertia_

def optimal_number_of_clusters(wcss):
    # Calculate the gradient of the curve
    gradients = np.diff(wcss)

    # Calculate second derivative (rate of change of gradient)
    diff_gradients = np.diff(gradients)

    # The optimal number of clusters is at the elbow point
```

```

    optimal_k = np.argmin(diff_gradients) + 2 # +2 due to the double
differencing
    return optimal_k

# Number of clusters to test
range_of_clusters = range(1, 200)

# Using ThreadPoolExecutor to parallelize the calculation
with ThreadPoolExecutor(max_workers=6) as executor:
    wcss = list(executor.map(lambda k: calculate_wcss(embeddings_array, k),
range_of_clusters))

# Calculate the optimal number of clusters
n_clusters_optimal = optimal_number_of_clusters(wcss)
print(f"optimal clusters = {n_clusters_optimal}")

# Fit the KMeans with the optimal number of clusters
kmeans_optimal = KMeans(n_clusters=n_clusters_optimal, init='k-means++',
max_iter=300, n_init=10, random_state=0)
clusters = kmeans_optimal.fit_predict(embeddings_array)

# Plotting the results
plt.plot(range_of_clusters, wcss)
plt.title('Elbow Method')
plt.xlabel('Number of clusters')
plt.ylabel('WCSS')
plt.show()

print(f"Optimal number of clusters: {n_clusters_optimal}")

# Append the embeddings and cluster labels to the DataFrame
combined_df['cluster'] = clusters

# Dimensionality Reduction for Visualization
pca = PCA(n_components=2)
reduced_embeddings = pca.fit_transform(embeddings_array)

# Plotting the clusters
plt.scatter(reduced_embeddings[:, 0], reduced_embeddings[:, 1], c=clusters,
cmap='viridis')
plt.xlabel('PCA 1')
plt.ylabel('PCA 2')
plt.title('Post Clusters')
plt.show()

# Save the DataFrame to a new CSV file
output_csv_path = 'data/clustered/clustered_hartPatienten.csv'
combined_df.to_csv(output_csv_path, index=False)

```





## Appendix E: Python script GPT-Topic modelling

This script automates the extraction of insights from clustered text data by interfacing with GPT-4, managing API token usage, and systematically processing and storing the results.

1. **Data Preparation:** It loads a dataset containing text embeddings from a CSV file and prepares it for analysis.
2. **Token Management:** Implements functions to count tokens and manage token limits, essential for controlling usage with OpenAI's API.
3. **Clustering Analysis:** Uses the K-Means algorithm to group the embeddings into clusters.
4. **Data Processing for Each Cluster:**
  - Extracts top posts from each cluster.
  - Formats these posts into a context for GPT-4 queries.
  - Checks token usage to stay within limits.
5. **Interaction with GPT-4:** For each cluster, it sends a formatted prompt to GPT-4 to analyse the posts, focusing on identifying key topics and themes.
6. **Results Management:**
  - Stores the analysis results in a dictionary.
  - Regularly saves the results to a CSV file as a backup.
  - Tracks and estimates the time and token usage for processing each cluster.
7. **User Interaction:** Periodically asks for user input to continue or stop the analysis, especially after every 10 iterations or when token limits are approached in order to not accidentally spend too much money on an error.

```
8. import pandas as pd
9. from openai import OpenAI
10. from sklearn.cluster import KMeans
11. import numpy as np
12. import ast
13. import time
14.
15. def calculate_amount_tokens(text):
16.     import tiktoken
17.     enc = tiktoken.get_encoding("cl100k_base")
18.     # Using OpenAI's tokenizer
19.     tokens = enc.encode(text)
20.     return(len(tokens))
21.
22. # Token Limits
23. tokens_per_minute_limit = 300000
24. tokens_per_day_limit = 5000000
25. max_recursion_depth = 999
26.
27. # Tracking Variables
28. tokens_used_minute = 0
29. tokens_used_day = 0
```

```

30.
31.# Start time tracking
32.start_time_minute = time.time()
33.start_time_day = time.time()
34.
35.# Function to check and wait if token limits are reached
36.def check_token_limits(tokens_needed: int, depth: int = 0):
37.    global tokens_used_minute, tokens_used_day, start_time_minute,
    start_time_day, recursion_depth
38.    if depth >= max_recursion_depth:
39.        print("max recursion depth reached, just continuing...")
40.        return
41.
42.    current_time = time.time()
43.
44.    # Reset minute counter every 60 seconds
45.    if current_time - start_time_minute > 60:
46.        tokens_used_minute = 0
47.        start_time_minute = current_time
48.
49.    # Reset day counter every 24 hours
50.    if current_time - start_time_day > 86400:
51.        tokens_used_day = 0
52.        start_time_day = current_time
53.
54.    # Update token usage
55.    tokens_used_minute += tokens_needed
56.    tokens_used_day += tokens_needed
57.
58.    # Check if the next request exceeds any of the limits
59.    if tokens_used_minute + tokens_needed > tokens_per_minute_limit or
    tokens_used_day + tokens_needed > tokens_per_day_limit:
60.        print(f"Approaching token limit, waiting... (depth: {depth} out
    of {max_recursion_depth})")
61.        time.sleep(60) # Wait for 1 minute
62.        # re-run function
63.        check_token_limits(0, depth=depth+1)
64.
65.# Load the DataFrame
66.path = "data/clustered/clustered_combined.csv"
67.combined_df = pd.read_csv(path)
68.combined_df['embedding'] =
    combined_df['embedding'].apply(ast.literal_eval)
69.embeddings_array = np.stack(combined_df['embedding'].values)
70.print("data loaded in")
71.
72.# Function to calculate Euclidean distance
73.def euclidean_distance(point1, point2):

```

```

74.         return np.sqrt(np.sum((np.array(point1) - np.array(point2)) **
75.         2))
76. # Function to extract top N posts closest to the cluster centroid
77. def extract_top_posts(df, cluster_id, centroids, top_n=50) -> list:
78.     cluster_posts = df[df['cluster'] == cluster_id]
79.     centroid = centroids[cluster_id]
80.
81.     # Calculate distances
82.     distances = cluster_posts['embedding'].apply(lambda x:
83.     euclidean_distance(x, centroid))
84.     cluster_posts = cluster_posts.assign(distance=distances)
85.
86.     # Select top N posts
87.     return cluster_posts.nsmallest(top_n, 'distance')['text'].tolist()
88. # Calculate centroids
89. n_clusters = 70 # use n_clusters=combined_df['cluster'].unique() if
90.     you want the same amount of clusters as previously calculated
91. kmeans = KMeans(n_clusters=n_clusters, init='k-means++', max_iter=1000,
92.     n_init=10, random_state=0)
93. clusters = kmeans.fit_predict(embeddings_array)
94. centroids = kmeans.cluster_centers_
95. combined_df['cluster'] = clusters
96. # combined_df.to_csv(path, index=False)
97. print(f"{n_clusters} kmeans clusters recalculated in {kmeans.n_iter_}
98.     iterations")
99.
100. # Function to format the posts into a prompt for GPT-4
101. def generate_prompt_context(posts: list):
102.     gpt_context = "\n".join(posts)
103.     return gpt_context
104.
105. # Function to return the system message for the prompt for GPT-4
106. def generate_prompt_instruct():
107.     # Define the prompt with a placeholder for forum posts
108.     gpt_instruct = f"""
109.     SYSTEM MESSAGE:
110.     For the purpose of gathering detailed patient experience data
111.     for my student thesis I am analysing a heart health forum where users
112.     post have discussions about their health. I have extracted all posts
113.     from this forum. These posts have been previously grouped in 70
114.     clusters with a k-means algorithm. Your task is to read and interpret
115.     the top posts, extracting and identifying the primary topics and themes
116.     represented. Focus on the following aspects:

```

```
109.         1. Title: Create a short, catchy and fitting title for
              describing the contents of this cluster, so no title about heart health
              in general, but one more specific to the contents of this cluster.
110.         1. Key Topics Identification: Highlight the main subjects
              discussed in these posts. (at least 5)
111.         2. Theme Analysis: Outline any common themes or patterns
              that emerge from the discussions. This might include specific health
              conditions, treatments, lifestyle advice, or patient experiences. Write
              it as one coherent paragraph of at least 300 words.
112.         3. interesting quotes: Note the most interesting quotes
              of this cluster, which might indicate particular areas of focus or
              concern within the cluster. Please provide quotes that vividly describe
              user needs or wishes, emotional states, significant moments,
              significant interactions with others, reveal personal insights,
              emotional turning points, physical sensations or valuable advice or
              lessons learned. Make sure to only use quotes which actually come from
              the posts. Provide quotes which are longer and provide the full quote
              without shortening or paraphrasing. (provide at least 10 of such
              quotes)
113.
114.         Your analysis should offer a clear and extensive overview of
              the content within this cluster, helping to understand the primary
              interests and concerns of the forum users in the specific context of
              these posts. Only use the contents/context of these posts and do not
              hallucinate information yourself. Maintain a factual and unbiased tone.
115.
116.         the top posts from this cluster are:
117.         ""
118.         return gpt_instruct
119.
120.         # Function to query GPT-4
121.         def query_gpt4(gpt_instruct, gpt_context, client: OpenAI):
122.             response = client.chat.completions.create(
123.                 model="gpt-4-1106-preview",
124.                 messages=[
125.                     {
126.                         "role": "system",
127.                         "content": gpt_instruct
128.                     },
129.                     {
130.                         "role": "user",
131.                         "content": gpt_context
132.                     },
133.                     {
134.                         "role": "assistant",
135.                         "content": "I will now analyse these top posts of
              this cluster according to the system message"
136.                     }

```

```

137.         ],
138.         max_tokens=4096,
139.         temperature=0.3,
140.
141.     )
142.     return response.choices[0].message.content.strip()
143.
144.     def limit_tokens(text: str, limit: int = 123000):
145.         import tiktoken
146.         enc = tiktoken.get_encoding("cl100k_base")
147.
148.         # Using OpenAI's tokenizer
149.         tokens = enc.encode(text)
150.         limited_tokens = tokens[:limit] # Keeping only the first
max_tokens words
151.         text = enc.decode(limited_tokens)
152.
153.         return text
154.     # Dictionary to store results
155.     cluster_topics = {}
156.
157.     #open ai shit
158.     client = OpenAI(api_key='sk-
AylGjAy2IJXUKxMNW7CFT3B1bkFJmqXB0wNS2A0Cpc6xS1HV')
159.
160.     print(range(combined_df['cluster'].nunique()))
161.
162.     # Initialize variables for time tracking
163.     start_time = time.time()
164.     total_clusters = combined_df['cluster'].nunique()
165.     just_continue = False
166.
167.     #iterate overall clusters and generate the analysis
168.     for cluster_id in range(total_clusters):
169.         top_posts = extract_top_posts(combined_df, cluster_id,
centroids, top_n=100)
170.         gpt_context = generate_prompt_context(top_posts)
171.         gpt_instruct = generate_prompt_instruct()
172.         gpt_context = limit_tokens(gpt_context)
173.
174.         check_token_limits(calculate_amount_tokens(gpt_context +
gpt_instruct)+ 4096)
175.
176.         # save it for review
177.         with open(f'data/context/context_{cluster_id}.txt', 'w',
encoding='utf-8') as file:
178.             file.write(gpt_context)
179.

```

```

180.         # query gpt4 (takes the longest)
181.         topic_description = query_gpt4(gpt_instruct=gpt_instruct,
    gpt_context=gpt_context, client=client)
182.
183.         # Store results
184.         cluster_topics[cluster_id] = topic_description
185.
186.         # Convert dictionary to DataFrame and save to CSV as backup
187.         topics_df = pd.DataFrame.from_dict(cluster_topics,
    orient='index').reset_index()
188.         topics_df.columns=['Cluster_id', 'description']
189.         topics_df.to_csv("topics.csv", index=False)
190.         print("csv saved")
191.
192.         # Time tracking and estimation
193.         current_time = time.time()
194.         total_elapsed_time = current_time - start_time
195.         average_time_per_iteration = total_elapsed_time / (cluster_id
    + 1)
196.         estimated_remaining_time = average_time_per_iteration *
    (total_clusters - cluster_id - 1)
197.
198.         print(f"iteration done for {cluster_id} out of
    {total_clusters}. cost: {((calculate_amount_tokens(gpt_context +
    gpt_instruct + (topic_description*3)))/1000)*0.01}. Estimated time
    remaining: {estimated_remaining_time:.2f} seconds, tokens in minute
    remainig: {tokens_per_minute_limit-tokens_used_minute}")
199.
200.         # the first and every 10 iterations ask for human feedback to
    continue spending cash
201.         if ((cluster_id % 10 == 0) or (cluster_id == 0) or
    (just_continue != True)):
202.             user_input = input("Please press enter if you want to
    continue, enter: 'skip' to skip this interrupt in the future, if you
    want to stop enter 'N' ")
203.             normalized_input = user_input.strip().lower()
204.
205.             if (user_input == 'n'):
206.                 break
207.
208.             if (user_input == 'skip'):
209.                 just_continue = True
210.                 print("skipping this question in the future")

```

## Appendix F: Prompt for topic modelling

A prompt was carefully crafted according to a similar method used by Gamiieldien et al. (2023) and the documentation provided by OpenAI Platform (n.d.). The prompt was tested extensively and improved through trial and error.

The structure of the prompt is a sandwich with the system message instructing the AI on what to extract from the data, then the data itself being the top 100 post from a cluster and then an extra user message to refer to the system message again to increase adherence to the system message as large language models tend to pay more attention to the last input provided.

*This is the system message:*

“SYSTEM MESSAGE:

*For the purpose of gathering detailed patient experience data for my student thesis I am analysing a heart health forum where users post have discussions about their health. I have extracted all posts from this forum. These posts have been previously grouped in 70 clusters with a k-means algorithm. Your task is to read and interpret the top posts, extracting and identifying the primary topics and themes represented. Focus on the following aspects:*

1. **Title:** Create a short, catchy and fitting title for describing the contents of this cluster, so no title about heart health in general, but one more specific to the contents of this cluster.

1. **Key Topics Identification:** Highlight the main subjects discussed in these posts. (at least 5)

2. **Theme Analysis:** Outline any common themes or patterns that emerge from the discussions. This might include specific health conditions, treatments, lifestyle advice, or patient experiences. Write it as one coherent paragraph of at least 300 words.

3. **interesting quotes:** Note the most interesting quotes of this cluster, which might indicate particular areas of focus or concern within the cluster. Please provide quotes that vividly describe user needs or wishes, emotional states, significant moments, significant interactions with others, reveal personal insights, emotional turning points, physical sensations or valuable advice or lessons learned. Make sure to only use quotes which actually come from the posts. Provide quotes which are longer and provide the full quote without shortening or paraphrasing. (provide at least 10 of such quotes)

*Your analysis should offer a clear and extensive overview of the content within this cluster, helping to understand the primary interests and concerns of the forum users in the specific context of these posts. Only use the contents/context of these posts and do not hallucinate information yourself. Maintain a factual and unbiased tone.*

*the top posts from this cluster are:*

“

*Then the top 100 post would be inserted*

{top 100 posts}

*Concluding with a extra assistant message referring to the system message again:*

*“I will now analyse these top posts of this cluster according to the system message”*



## Appendix G: Key insights from forum analysis

These are the 89 key insights manually extracted from the 135 page (52036 words) analysis the GPT-4 provided. Each key insights is labelled from which cluster it came by adding the cluster number between parenthesis.

1. Individuals seeking reassurance and guidance on managing their condition, especially regarding physical activity and exercise. The fear of triggering an angina attack leads to lifestyle changes and a sense of uncertainty about the future (2)
2. Users also discuss the challenges of communicating with healthcare professionals, with some feeling dismissed or not taken seriously when presenting their symptoms (2)
3. The encouragement to contact patient services teams for information and support highlights the value placed on having a reliable source of guidance during what can be an anxiety-inducing time. (3)
4. The importance of shared discussion making (3)
5. Many users share their pre- and post-operative experiences, highlighting the emotional rollercoaster that accompanies the anticipation of surgery and the recovery process. (4)
6. The importance of cardiac rehabilitation programs is frequently mentioned, as they provide not only physical benefits but also emotional support and education. (4)
7. Throughout the discussions, there is a strong emphasis on the importance of a positive attitude and the support of family and friends in coping with the aftermath of a heart attack. (6)
8. A common theme for heart attack survivors is the emotional toll of experiencing a heart attack, with many users reporting feelings of vulnerability, fear of recurrence, and a loss of confidence in their health. (6)
9. The role of cardiac rehabilitation programs is highlighted as a valuable resource for structured exercise and education, though some express frustration with the availability and accessibility of these services. (6)
10. Patients experience an emotional toll for having to be proactive in navigating the complex and sometimes unresponsive healthcare system. There is a contrast between efficient emergency care and the problematic management of chronic conditions. (7)
11. Many share their successes and setbacks in integrating exercise into their daily lives, highlighting the importance of finding a balance that does not exacerbate their condition. (9)
12. a common theme is the frustration and anxiety of receiving inconclusive results or being told symptoms are stress-related. (10)
13. Lifestyle adjustments, particularly exercise, emerge as a common theme, with individuals seeking advice on safe activities and the impact of heart conditions on their physical capabilities and overall quality of life. (12)
14. The role of family and friends emerges as a critical factor in coping with heart disease, with stories of both positive support and challenges in communication. (13)
15. Users actively seek and offer advice on managing heart health, indicating a strong desire for shared knowledge and experiences. (13)
16. highlighting the struggles and challenges individuals face when returning to work or maintaining employment after a heart event or diagnosis. With navigating workplace accommodations, dealing with unsupportive employers, and the emotional toll of feeling undervalued or discriminated against due to their health conditions. (16)

17. There is a need to reduce work hours, change job roles, or leave their jobs entirely due to physical limitations and the risk of further health complications. (16)
18. Additionally, there is a significant focus on the mental and emotional challenges associated with employment, such as stress, anxiety, and the struggle to balance health needs with work demands. (16)
19. The post reveal a profound emotional and psychological impact on individuals who have experienced heart attacks or undergone cardiac surgery. (17)
20. A common theme is the struggle with anxiety, where individuals live in constant fear of another heart event, leading to a state of hyper-vigilance and panic over every physical sensation. This anxiety often manifests in physical symptoms such as chest tightness and palpitations, which in turn exacerbate the fear, creating a vicious cycle. (17)
21. Depression is another recurring theme, with individuals expressing feelings of sadness, loneliness, and a sense of mourning for their pre-heart event lives. The loss of independence and changes in lifestyle contribute to a sense of identity crisis, where individuals grapple with the new limitations imposed on them and the uncertainty of their future. (17)
22. Many find solace in cardiac rehabilitation programs, counselling, and support groups, where they can share experiences with others who understand their journey. (17)
23. Many users report monitoring their heart rates through wearable devices, such as Fitbit or Apple Watch and express concern over readings that show bradycardia during rest or sleep, and tachycardia during minimal activity or exercise.. There is a recurring theme of frustration due to the lack of clear diagnoses despite undergoing various tests like ECGs, echocardiograms, and Holter monitors. (19)
24. The unpredictability and the sensation of ectopic beats contribute significantly to their distress, leading to a constant search for reassurance and understanding of their condition. (20)
25. diagnostic journeys, including the use of ECGs, Holter monitors, stress tests, and echocardiograms, to determine the nature and severity of their ectopic beats. Despite often being told that their heartbeats are benign, the physical sensations lead to ongoing concerns and impact their quality of life. (20)
26. Despite reassurances from medical professionals that their heart palpitations are not life-threatening, individuals struggle with the physical sensations and the psychological toll of living with an irregular heartbeat. (21)
27. Patients share their progress, celebrating milestones like being discharged from the hospital, managing to walk certain distances, and returning to work. (22)
28. The theme of resilience is prominent, with many emphasizing the importance of a positive mindset and the support of family, friends, and the online community in overcoming post-surgery challenges. (22)
29. Many users share their personal stories of sudden and often frightening episodes of rapid heartbeat (24)
30. The theme of anxiety is prevalent, with many expressing fear of future episodes and the impact on their quality of life. (24)
31. There is a sense of frustration with the diagnostic process, as SVT episodes can be sporadic and often resolve before medical intervention or recording can take place, leading to challenges in obtaining a definitive diagnosis and appropriate treatment plan. (24)
32. Users discuss the importance of regular check-ups, such as echocardiograms, to monitor the progression of their condition and the effectiveness of treatments. (25)

33. The posts reveal a community grappling with the complexities of dietary choices in the context of heart health. (26)
34. Participants express frustration over the lack of clear guidance from medical professionals and the challenge of making sustainable lifestyle changes. (26)
35. The emotional impact of dietary changes is also evident, with individuals discussing feelings of guilt, anxiety, and the fear of not doing enough to prevent further health issues. (26)
36. There is a significant focus on the lifestyle changes that come with living with an Implantable Cardioverter Defibrillator (ICD), including adjustments to physical activity and the psychological impact of having a device implanted. (27)
37. Users often express anxiety about the Implantable Cardioverter Defibrillator (ICD) firing, the sensation it causes, and the implications of such an event, especially when driving or caring for children. (27)
38. The role of exercise in managing heart health is mentioned, with patients noting the limitations imposed by their condition and the need to find suitable activities that do not exacerbate symptoms. (28)
39. Many forum users express confusion and concern over fluctuating blood pressure measurements, which can vary significantly between home monitoring and clinical settings (32)
40. The anxiety surrounding inconsistent blood pressure readings at home is a common theme, with individuals questioning the reliability of their home blood pressure monitors and the impact of stress on their measurements. (32)
41. The emotional toll of CHD diagnosis and treatment is evident, with many expressing feelings of fear, anxiety, and the burden of constant health monitoring. (33)
42. Lifestyle management emerges as a critical theme, with individuals seeking advice on exercise, diet, and activities suitable for those with CHD. (33)
43. The conversations highlight the emotional turmoil patients experience when test results do not align with their symptoms, leading to a sense of uncertainty about their diagnosis and treatment plan. (34)
44. The discussions also touch on the emotional impact of living with a potential heart condition, the fear of imminent heart attacks, and the challenge of managing anxiety alongside physical symptoms. (34)
45. users report a lack of clear communication from healthcare providers, leading to confusion and frustration. (37)
46. The unpredictability of AF episodes contributes to anxiety, with patients often feeling helpless during an attack. (37)
47. There is a recurring theme of anxiety and confusion as patients try to understand their echocardiogram results, often feeling overwhelmed by medical jargon and unclear explanations from healthcare providers. The uncertainty of their condition's progression, especially when terms like "heart failure" are mentioned, adds to their distress. (38)
48. Patients express frustration with the communication gaps between themselves and their doctors, especially when information is incomplete or contradicting. (38)
49. the theme that emerges is one of patients seeking clarity, reassurance, and support as they face the complexities of heart health. The desire for more transparent communication with healthcare providers and a better understanding of their condition is evident throughout the discussions. (38)
50. The discussions within this cluster reveal a significant concern among heart patients regarding the impact of weather extremes on their health. (40)

51. patients sharing varied experiences ranging from smooth recoveries to challenging ones marked by persistent arrhythmias, fatigue, and other symptoms. (41)
52. the experience of unexplained fainting spells or dizziness, often accompanied by palpitations and a feeling of weakness. There is a sense of frustration and concern among users due to the lack of understanding of the underlying causes of their symptoms. (42)
53. The use of medication, such as beta blockers, and the concerns patients have regarding the dosage and its impact on their heart rate. (45)
54. experiences of individuals living with Microvascular Angina (MVA) and Vasospastic Angina, conditions that are often misunderstood and underdiagnosed (46)
55. The unpredictability of angina episodes, particularly those that occur at rest or are triggered by emotional stress, poses a significant challenge to daily life and can lead to anxiety and fear of serious cardiac events. (46)
56. The complexity of managing MVA/Vasospastic Angina with medication is a common theme. (46)
57. Emotional well-being is also a major concern, with many users discussing the psychological toll of living with chronic chest pain and the importance of mental health support. (46)
58. with patients sharing their experiences of trying to optimize the timing of their doses to minimize side effects or improve effectiveness. (48)
59. Despite undergoing clinical tests in a hospital, a common theme is the frustration and uncertainty that arises when tests come back normal, yet the chest pain persists. (50)
60. challenges of navigating the healthcare system, including long waiting times for specialist appointments. (50)
61. The theme of self-advocacy emerges, with individuals encouraging each other to persist in seeking medical attention and not to dismiss their symptoms, emphasizing the importance of being proactive about their health. (50)
62. The experiences of individuals who have undergone stent placement following heart attacks or other cardiac events. A common theme is the persistence of chest pains or discomfort after the procedure, which often leads to anxiety and fear of another heart attack. (51)
63. Many express frustration with the lack of clear answers from healthcare providers and the challenge of distinguishing between normal post-procedure sensations and signs of potential complications. (51)
64. The emotional impact of the cardiac event and subsequent recovery process is significant, with individuals reporting feelings of vulnerability, depression, and a sense of being overwhelmed. (51)
65. The importance of physical activity is acknowledged, but there is uncertainty about how much and what type of exercise is safe and beneficial during the recovery period. (51)
66. Many posts reflect on significant milestones, such as anniversaries of surgeries or diagnoses, and the progress made since those pivotal moments. (54)
67. The importance of lifestyle changes, such as diet and exercise, is frequently mentioned as a crucial part of recovery and management of heart conditions. (54)
68. A recurring theme is the value of the forum as a support network, where members find solace in shared experiences, advice, and encouragement. (54)
69. Patients share their frustration of surgery cancellations, and the stress of waiting for a life-saving operation. (55)

70. The support from family, friends, and online communities like this one emerges as a crucial element in managing pre- and post-operative emotions. (55)
71. Many express frustration and concern over the lack of improvement or worsening symptoms post-heart attack or surgery, such as angiograms and stent implantations. (56)
72. There is a recurring theme of individuals feeling overwhelmed by the sudden lifestyle changes required to manage their conditions (56)
73. Patients and family members express feelings of vulnerability and concern for the future, often exacerbated by the term "heart failure," which many find misleading and fear-inducing. (57)
74. A recurring theme is the struggle to balance rest with the desire to return to normalcy, including physical activities and exercise. (58)
75. A focus is on the regulating of alcohol, caffeine and food consumption, with many users sharing their personal experiences and seeking advice on safe levels of intake. (59)
76. A common theme is the concern about wound care after heart surgery, with many users sharing their experiences with infections or slow-healing scars. (60)
77. The need for emotional support and the value of sharing experiences with others who have undergone similar surgeries is evident throughout the discussions. (60)
78. The emotional toll of a CAD diagnoses is evident, with individuals grappling with fear, anxiety, and the stress of navigating medical advice and treatment plans. (61)
79. Many users share their progress with walking and exercise, emphasizing the importance of listening to one's body and not rushing the healing process. (63)
80. The role of cardiac rehabilitation is highlighted as a crucial element in recovery, providing structured exercise, education, and peer support. (63)
81. There is a general anxiety surrounding the functionality and reliability of the pacemaker, with individuals worried about the device's ability to manage their heart rhythms effectively. With users highlighting the importance of follow-up appointments at pacemaker clinics, and the role of remote monitoring devices in ensuring the pacemaker's proper operation. (66)
82. .The emotional impact of cardiac testing is significant, with patients expressing feelings of fear, relief, or frustration depending on the outcomes. Communication with healthcare professionals is a critical theme, as patients seek clarity on their conditions and the implications of their test results. Also, long waiting times and the logistics of scheduling tests (67)
83. A common theme is the journey of recovery through cardiac rehabilitation programs, which are often described as life-changing and essential for regaining confidence and physical strength. Many users share their progress, from initial struggles with basic activities to achieving significant milestones like completing a park run or returning to the gym. (68)
84. The accuracy of health monitoring devices (like the kardia) is a common concern, with many seeking validation of their readings through professional medical equipment or consultations with healthcare providers. (69)
85. Some users express frustration with the limitations of these devices, particularly when they fail to record critical data or produce false alarms that contribute to anxiety. (69)
86. Despite these challenges, there is a clear appreciation for the role of technology in empowering patients to take an active role in managing their heart health. The discussions highlight a desire for reliable, user-friendly devices that can seamlessly

integrate with healthcare services to ensure timely medical intervention when necessary. (69)

87. Concerns about the anxiety induced by constant monitoring and false alarms are common. (69)

88. The integration of devices with smartphones and health apps is considered beneficial for tracking and sharing data with healthcare providers.(69)

89. The medical community's acceptance of data from personal monitoring devices is debated, with some healthcare professionals sceptical of their reliability. (69)

## Appendix H: Interesting quotes from forum analysis

These are the 102 most interesting quotes manually extracted from the GPT topic analysis. Each quote has been anonymised and paraphrased to protect the privacy of the individual posters.

1. "I'm getting fed up with telling my cardiologist this is worryingly angina pain ... even unstable." (1)
2. "I'm now frightened ... I feel isolated, lonely and frightened, despite having my wife with me who is brilliant and understanding."(6)
3. "I've got a slight chest ache ... waves of anxiety keep flooding over me, I just can't lay in bed, I have to get up."(6)
4. "I'm starting to feel a bit down, bit old and vulnerable. I wasn't before."(6)
5. "I've had it with medics and hospitals ... I've been discharged with a bucket load of meds and told to get on with it!"(7)
6. "I'm still waiting for a follow-up appointment ... Is this what it's come to? No sideways thinking, just sent on your way."(7)
7. "I feel like I'm waiting to die ... I'm getting very anxious which makes my palpitations worse."(7)
8. "I feel in limbo. Has anyone else had this problem or am I just getting in a panic?"(7)
9. "It's terrible being left in this limbo land, it's like your life is not important enough."(7)
10. "My life had been in limbo for a year not knowing what's happening, mental health has taken a nose dive the last few months badly"(7)
11. "I feel like I'm fighting a losing battle with heart failure. Every day is a struggle, but I'm trying to find happiness where I can."(9)
12. "After being told I have heart failure, I'm scared to close my eyes at night. I worry about not waking up in the morning." (9)
13. "I had a heart attack and now I'm dealing with LVSD. I'm worried about another attack and what the future holds."(9)
14. "I was diagnosed with heart failure and it felt like my world came crashing down. I'm trying to stay positive, but it's hard not to dwell on it."(9)
15. "I feel like I'm at my wits end with the hospital the doctors have been great but I seem to get nowhere with the hospital and told I'm too young to be suffering with heart problems!" (10)
16. "I can't stop worrying about my heart. I keep coming across articles of people being misdiagnosed with anxiety and panic and it actually being heart issues." (10)
17. "I had severe chest pain and I was taken to a local a&e. I was put on an ECG and they monitored my heart for about 40 minutes. Apart from a slightly raised pulse which they put down to the pain they could find no problem with the rhythm." (10)
18. "I feel completely debilitated. I tried going to the gym, however after 8 minutes on the treadmill, my heart played up and I had to stop... I miss living life normally." (10)
19. "I find this forum a lifeline! As you get to hear and read other people's views and how the health issues we have affect each of us differently."(14)
20. "Being able to immerse myself in all things cardio is like having a warm hug."(14)
21. "I needed the acknowledgment of a fellow human being that had gone through something that I had." (14)
22. "I'm struggling to afford rent and bills etc." (16)
23. "I feel like I have no future and wonder if I am going to die soon anyway." (16)
24. "I constantly feel that the next HA or something even worse, is round the corner."(17)

25. "Every single twinge I get makes me think I am having another HA." (17)
26. "I just want to get mentally better and stop having my husband wake me in the morning to make sure I'm alive." (17)
27. "I need to know the difference between panic and actual cardiac events." (17)
28. "I feel stuck in a cycle of worry and I just can't find away out." (17)
29. "I feel that the system is more reactive rather than preventative." (17)
30. "I feel like I am going nuts ... first thing I think of in the morning and last thing on my mind a night." (17)
31. "I live on my own which I don't think helps ... any advice welcome I feel like I am going nuts." (17)
32. "I am stuck in a cycle of worry and I just can't find away out." (17)
33. "Every time I go to the doctor, my heart rate seems fine, but at home, it's a different story." (19)
34. "I had an ECG done, and they said I have a fast resting heart rate, but they can't find anything wrong with my heart." (19)
35. "I'm afraid to exercise because my heart rate shoots up so quickly, and I don't want to trigger an episode." (19)
36. "I feel my heart skip beats, and it's the most unsettling sensation, even if the doctors say it's harmless." (19)
37. "I'm trying to get fit, but my heart rate concerns are making it difficult to stick to a routine." (19)
38. "Every time I've been to A&E the ECG has shown no irregularities, other than sinus tachycardia." (20)
39. "I'm not sure when I'll next be able to have the surgery as I go back in October for yet another consultation I can't really afford to keep travelling to!" (20)
40. "I have suffered from heart arrhythmia for 27 years now... My arrhythmia 's seem to have metamorphosed over this time from af, svt's to my current rhythm which feels like 1, 2, 1, 2 etc instead of a steady consistent rhythm." (24)
41. "I have had SVT for many years and been able to stop them myself until 3 years ago I had to go in to Hospital"(24)
42. "I've been told its this, its that causing it. I've watched videos on it. Some say it's not because you don't do enough exercise, it's to do with the meds you take or certain types of food." (26)
43. "I had an ICD firing during dinner... It was very sudden after a very hot feeling in my head. A flash of lightning and then a bang inside my body." (27)
44. "I have lived with cardio problems for over 20 years now. We live in a very rural area and my GP told me that he had learned more about Heart issues through me." (28)
45. "I'm worried about the long-term effects of high BP. I don't want to end up with a heart attack or stroke." (32)
46. "I've had no symptoms whatsoever, and it feels like a ticking time bomb." (33)
47. "I'm terrified the damage is done and my heart is now not going to be able to give me a lifetime of service." (33)
48. "I feel a tight panic in my chest all the time but know my heart is behaving normally - I'm putting it down to stress." (33)
49. "I'm scared of everything right now and not living life to the full." (33)
50. 'm turning into a nervous wreck... I am exhausted, anxious and very upset and scared." (33)
51. "I just want to enjoy life again and am in denial that this might not be the case." (33)



52. "I've been diagnosed with dilated cardiomyopathy and I'm absolutely terrified." (33)
53. "I feel like I'm living half a life since my diagnosis a few weeks ago." (33)
54. "Since being diagnosed with AF, symptoms are getting worse and I am living in fear." (37)
55. "I feel so isolated and terrified - I don't know why I have AF and everything I know about it I have gleaned from the precious pages on the forum website." (37)
56. "I had an episode earlier this week - sweats, anxiety, tremors, racing heart, chest pain, and palpitations, that lasted for about 90 minutes... It was followed by two lesser episodes." (37)
57. "I have been having heart palpitations (tachycardia) for the last 4 months... I am petrified and anxiety seems to make the palpitations worse." (38)
58. "I have had some results through and am just trying to make sense of them in plain English!" (38)
59. "I have been diagnosed with heart failure... I'm trying my best not to google things but just putting it in a search opens up such a can of worms." (38)
60. "I received a copy of my echocardiogram which stated that my Left Atrium was severely dilated... I should be celebrating, but feel really confused." (38)
61. "I have been told I have a LBBB following an ECG... I am 68 working and otherwise except for asthma ok." (38)
62. "I have been waiting since January for an appointment and now my June appointment has been postponed until July." (42)
63. "I'm worried for the future and believe every day I'm a ticking time bomb." (46)
64. "I'm only 50 and I don't plan anything anymore. I feel I won't see my kids grow up if the chest pain I'm experiencing every day is unstable angina or coronary artery spasm." (46)
65. "I feel I'm going mad with worry and to some degree am worried I won't see my kids grow up if the chest pain I'm experiencing every day is unstable angina or coronary artery spasm." (46)
66. "I've been having chest pains for well over a year and been checked countless times... no signs of a heart attack." (50)
67. "I've been to A&E over 10 times now... All readings for HA ok but no one is looking for anything else." (50)
68. "I feel like I cannot keep ending up in the emergency department with no further progress." (50)
69. "I'm very scared because the Cardiologist told me that my heart is in a very bad condition and it will be very risky to do a procedure." (50)
70. "I'm reluctant to shoot off to hospital given that these symptoms are pretty much what I had last time and they said it's not my heart!" (50)
71. "I've been living with this 'worrying pain' without a solution... am I just getting worked up and causing the pains myself?" (50)
72. "I'm still at home as I've kind of got used to the pain over the years and got fed up with the trips to A&E." (50)
73. "I'm worried that I've still got issues and what it means for my future." (51)
74. "I just keep breaking down in tears all the time. It's been about a month since the second stent - do others feel like this?" (51)
75. "I can't walk more than 5 mins without getting out of breath, feeling clammy and jelly legs, extreme chest pain, dizzy and feeling like I am going to collapse." (51)
76. "I feel even more vulnerable now." (51) (after surgery)
77. "I feel as if I have been left with unstable angina that most days is making my life a bloody misery." (51) (after surgery)

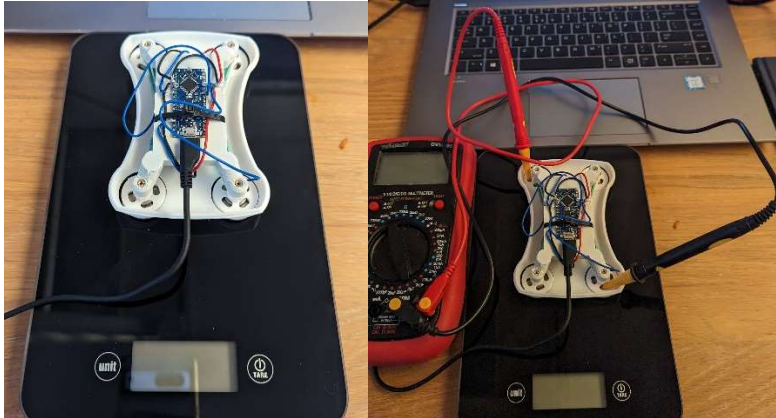
78. Post-op recovery is tough, not just physically but mentally. Some days I feel like I've made progress, other days it's like I'm starting over." (55)
79. "The first walk after surgery was brutal, but I felt so accomplished afterward. It's the small victories that keep me going." (55)
80. "I never realized how much my heart condition affected my mental health until I started talking about it with others who understand." (55)
81. "I had a heart attack back in March... I'm now on a cocktail of medicines, keeping the GTN spray always in the pocket and waiting for my turn in the bypass queue." (56)
82. "Since my operation... I've noticed I've become very breathless with the simplest activity... I miss this part of my life more than I can say!" (56)
83. "I had a heart attack... and a stent fitted. Since then, his recovery hasn't improved and we still haven't got a diagnosis." (56)
84. "I had a heart attack... nearly didn't make it... The past 6 months my breathing has got worse... suspected my CAD has 'progressed'." (56)
85. "I thought I was going to die before my Son graduated university. He graduated over a year ago now. The impact on my mental health at the time of diagnosis was far worse than any physical effects from the heart failure." (57)
86. "I'm 5 weeks post diagnosis but still awaiting an mri. I just wondered if anyone else during recovery suffered with short, sharp chest pains." (58)
87. "I am frustrated that I cannot link in with a medical person. I feel so darn ill, I sleep away the day, awake to eat and go to the loo." (58)
88. "I'm currently having another flare up, and am in agony, lying down is so painful that I can't sleep, and I'm just so so tired. I'm trying to manage at home as I'm so desperate to stay out of the hospital as there's no process and I have to go through A&E each time even though it's a diagnosed condition." (58)
89. "I had a long trip this Feb. After coming back, I had a bit of chest heaviness. It's not left but instead slowly getting worse. I've been calling cardiology, my GP, the BHF nurses, went to A&E and have had very little help." (58)
90. "I am 78...I first noticed I had Angina 10 years ago...I am tired all the time and get fatigued after walking about 300yds...My concern is whether to have the bypass or not." (61)
91. "I'm just over 4 months from having had a double bypass... still experiencing some discomfort chest wise. Getting mixed messages from GP and hospital... family are telling me I went back to work too soon so need some re-assurance that I am doing the right thing." (63)
92. "I had a triple bypass 11 years ago... all I will say is get yourself fit and you will find the benefits." (63)
93. "I'm into my seventh week of having my Aortic Valve replaced. I am still out of breath, I find it very difficult to walk any distance... no end in sight till I can be considered fully fit." (63)
94. "I'm now almost 2 years post bypass surgery... I run and swim regularly and my diet has changed beyond all recognition. Life is good." (63)
95. "I thought I was doing everything right with diet and exercise, but my cholesterol still went up. It's frustrating to feel like you're doing all you can and not seeing the results you want." (64)
96. "Cardiac rehab was just the service I needed! They are trained and experienced in exercise work for cardiac patients, and will guide you each step of the way, to get back to your best level of fitness, but not taking risks." (68)

97. "I've been trying to get to the gym and been thwarted for some time. I have an overprotective partner. She didn't like me going to the gym pre-op and now even less so." (68)
98. "I have a home monitor which I use when I am feeling symptoms... it sometimes shows waveform deviations and I am usually feeling unwell from irregular or more rapid heartbeats when it happens." (69)
99. "I had a Holter monitor on for a week... I then had an appointment for what I thought was for the results... the nurse said she was putting a 72-hour monitor on me." (69)
100. "I had a month-long holter that started making noises at me after 2 days... it turned out it hadn't recorded from the beeping onwards." (69)
101. "I had a 72-hour one last year and kept forgetting to press the button or by the time I did find it and press the actual moment had gone." (69)
102. "I have a Fitbit Charge 3, which I purchased before my MI, but I'm not convinced about its accuracy." (69)

## Appendix I: Sensor validity test

This appendix shows how the two sensor systems were validated.

### Force measurement



First the FSR array was calibrated by pushing down on one of the electrodes at a time against a precision scale (in the figure another scale is shown, as no photos were taken during the actual testing). The force readings from the scale were then compared with the force readings given by the Arduino output and adjusted with a constant to be similar to the other sensors. The resulting calibration led to the values seen in the table.

	low	high	low	high	low	high
Grams on scale	100	100	300	300	500	500
1	0,06	0,5	0,4	0,8	1	2
2	0,2	0,4	0,3	0,9	1,1	1,6
3	0,28	0,37	0,55	0,65	0,9	1,9
4	0,2	0,75	0,7	0,9	1,3	2,4

### Resistance measurement

The resistance measuring sensor was tested by measuring the resistance of known resistors with the test setup and with a commercial multi meter. The results can be seen in the table.

Resistor value (Ohm)	Sensor output (Ohm)	Multi-meter output (Ohm)
10K	10108	9970
100K	96420	99900
330K	302000	334000
680K	688000	673000
1M	9978000	1010000

### Conclusion

The results from the force readings are not accurate enough to say with how much force a certain electrode is pushing down on the users chest. But, the good news is that this showed that each sensor is consistent with the others. This is important as we don't need to know the exact force; we just need to know that the force is the same across all electrodes.

The mean accuracy of the resistance sensor is approximately  $\pm 3.85\%$ , which is deemed to be more than accurate enough for the testing purposes.

## Appendix J: Exploration of ECG telemonitoring devices

In this appendix several examples are given of products that can be used by patients themselves to measure ECGs at home.

### *Qardio*

Qardio is an American company offering a range of remote patient monitoring devices. One of them is the QardioCore. According to Qardio (2023), an ECG/EKG device that can measure heartrate, raspatory rate, skin temperature, activity tracking and continuous ECGs/EKGs. It costs 499\$ in the United States (US). The ECG monitor has been clinically validated to accurately record and analyse user's. Qardio also supplies virtual care platforms through which doctors can track a patient'



Figure 1 the Qardio core (Qardio, 2023)

The device works by being worn on the chest of the patient, held in place by a strap. It continuously measures the previously mentioned data, whilst being connected to the users phone. The ECG is measured using a single-lead.

### *MyDiagnostick*

MyDiagnostick is a device that records high-quality ECGs and has a atrial fibrillation (AF) detection algorithm. It can store up to 140 ECGs, which can be retrieved by a physician through a USB connection for clinical confirmation and documentation of AF (*MyDiagnostick, n.d.*).



Figure 2 the MyDiagnostick (*MyDiagnostick, n.d.*)

### *Alivecor / Kardia*

Kardia is from the American company Alivacor and produces a single lead ECG devices which connect to the patient phone. The device is very small (82 x 32 x 3.5 mm) (Kardia, 2023). It comes with an accompanying service through which cardiologist review the users ECG every 90 days. Users will have to take individual measurements every day.



Figure 3 the KardiaMobile (Kardia, 2023)

### HappiTech

HappiTech provides an app and software development kit (SDK) which uses the camera on a smartphone to measure a patient's "heart health" by utilizing Photoplethysmography (PPG) (HappiTech, n.d.). Users have to hold their finger over their smartphone camera for 40 to 90 seconds. HappiTech's hardware-free heart monitoring tool is integrated in several E-Health services such as Lucii, Ortus-ihealth and Huma.

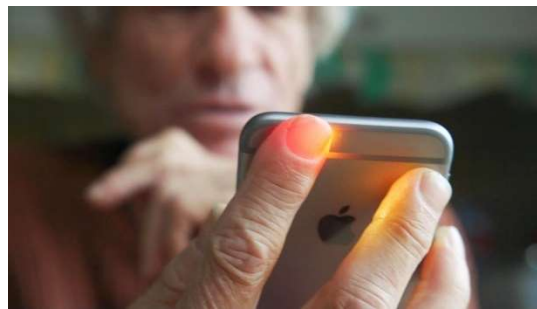


Figure 4 Example of how a HappiTech measurement would look like (NU.nl, 2017)

### OMRON healthcare

OMRON is a Dutch company which makes several healthcare products. One of them is the OMRON Complete (OMRON Healthcare, n.d.). A clinically proven 2-in-1 device for measuring blood pressure and ECGs. The one lead ECG can be done by holding your fingers on the device and the blood pressure is measured by a separate strap for your arm which connects to the device. A user can track and analyse their historical data, by connecting the device to the app.



Figure 5 the OMRON Complete (OMRON Healthcare, n.d.)

## Zio

The Zio monitoring device is a small clinically proven heart monitor patch that continuously measures your heartbeat through a single-lead AI driven ECG (Zio Monitoring, n.d.). The patch is prescribed by the patients healthcare provider and worn for two weeks. Afterwards it is send back and the data is analysed retrospectively.

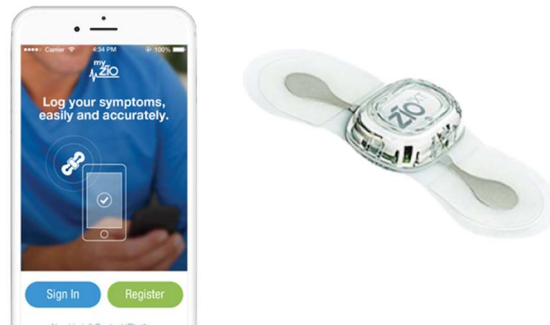


Figure 6 The ZIO (Zio Monitoring, n.d.)

## Phillips

Phillips introduced an at-home, 12-lead electrocardiogram (ECG) Holter for use in decentralized clinical trials in 2022 (Philips, 2022). The device features a electrode strip with twelve patches the user has to apply themselves and connect to the accompanying app foreach measurement. The device is more aimed at decentralized health trials, but can also be connected to Phillips Health Suite digital platform



Figure 7 Phillips 12-lead Holter ECG (Philips, 2022)

## Medtronic

Medtronic's reveal implantable loop recorder is an in heart sensor which allows continuous cardiac monitoring for up to three years (Medtronic, n.d.). It sends data back to the patient' healthcare provider while the patient is sleeping by connecting to a separate device located next to the patient' bed.



Figure 8 The LINQ implantable monitoring device (Medtronic, n.d.).



### *Commwell PhysioGlove*

The PhysioGlove is an 12-lead ECG glove designed for home use by the patient (Commwell, 2023). The glove needs to be connected to an app which also guides them through the process of taking the ECG. The app can send the data to Commwell's own cloud based patient monitoring platform.



*Figure 9 The Commwell PhysioGlove (Commwell, 2023)*

### *Welch Allyn CP 150*

The Welch Allyn ECG is a professional grade ECG device aimed at medical professionals (Baxter, n.d.). It features a built in printer and colour display. The device can perform 3, 6 or 12 lead ECGs. The device comes with MEANS ECG Interpretation software which are ECG interpretation programs developed by the University of Rotterdam in the Netherlands, and can be used to interpret ECGs that were recorded with the CP 150.



*Figure 10 The Welch Allyn CP 150 (Baxter, n.d.).*

### *Spengler Cardiomate*

The Spengler Cardiomate is a professional grade ECG device aimed at medical professionals. It features a built in printer, colour display and battery. The device can perform 3, 6 or 12 lead ECGs (Spengler, 2023).



Figure 11 The Spengler Cardiomate (Spengler, 2023)

### Savvy ECG

Savvy is a long-term single lead ECG device (Savvy, n.d.). The device can take a continuous ECG for up to 500 weeks with cycles of 7 days on a single charge. The gathered data can be viewed in the accompanying app and exported to a ECG report that can be taken to a physician.



Figure 12 The Savvy ECG system (Savvy, n.d.)

### Praxa Sense

Praxa Sense is a start-up developing Afi, a sensor that senses varying data sources and uses those as input for an algorithm aimed at detecting multiple different clinical disorders (Praxa Sense, 2023). The device is prescribed and applied by a GP and works for 30 days straight.



Figure 13 The Praxa Sense Afi (Praxa Sense, 2023).

### Corsano bands

Corsano is developing a wrist band that measures a multitude of vital parameters of the patient (Corsano, 2024). Including: single-lead ECG, blood pressure, core body temp, SPO2, sleep, activity and breathing rate. They also provide a mobile platform for collecting the data and sending it to a web portal for medical professionals.



Figure 14 The Corsano band and its capabilities (Corsano, 2024)

## Appendix K: Exploration of E-health services

This appendix shows several examples of services which connect patients with their medical professional through an online portal or app.

### *HartWacht*

HartWacht is a app by Cardiologie Centra Nederland (CCN) through which users can input their data collected by various devices, follow progress and report issues. CNN experts can contact patients if the measurements exceed certain thresholds set by the patient' healthcare provider.

### *PASSION-HF*

Passion-HF (Patient Self Care Using eHealth in Chronic Heart Failure) is an EU-funded project by several European universities which aims to develop an integrated E-health product that facilitates self care with chronic heart failure (Passion-HF, n.d.). A part of the project is DoctorMe, an interactive avatar interface which patients can use to get medication prescribed without the intervention of a doctor in simple conditions. A doctor is asked for verification in more complex conditions. Patients are stimulated through serious gaming to learn more about their condition and how to improve their living condition.

### *Heartcare at home*

Heartcare at home is an app prescribed to heart failure patients in Ireland. Patients input some measured data such as weight and blood pressure. The patients are all remotely supervised by qualified medical staff. The patient and their GP/cardiologist is contacted if changes in patient' data are detected. (Heartcare at home, 2022)

### *Beter Dichtbij*

Beter Dichtbij is a service that connects patients with their healthcare providers, primarily General Practitioners (GPs), through a secure messaging platform (*BeterDichtbij*, 2023). Patients and providers can communicate through messaging, video calls, and file or image sharing. This facilitates easier contact and enables the sharing of measurements or results.

### *Luscii*

Lucii is a digital healthcare platform which provides users with one complete home monitoring app (*Luscii*, n.d.). The app has 100+ home monitoring programs which healthcare providers can prescribe to patients when applicable. Measurement devices can be made to send data to Lucii or a patient can input data manually. This data can be automatically analysed or send directly to the healthcare provider of the patient.

### *DGTL health*

DGTL health is a company developed by cardiologists in the Netherlands who analyse Holter data on a large scale. They offer their expertise in evaluating Holter data to other platforms and can do that on a large scale, already having evaluated 41.227 studies since 2021 (*DGTL health*, 2023).

### *Chipmunk health*

Chipmunk health provides home measuring devices to patients which are automatically send health data to the patient' healthcare provider through a accompanying router (*Chipmunk Health*, n.d.). This way all measurement are done without app or smartphone. The healthcare provider can then analyse the data without the user needing to upload data manually.

### *zorg bij jou (Santeon)*

Just recently (18-10-2023) Santeon received a subsidy of 77 miljoen to further develop the Zorg Bij Jou platform (Van Poll, 2023). The platform codeveloped by seven of the Netherlands academic hospitals is supposed to become a national platform with 24/7 service from one central patient monitoring & coordination centre. From this hub, medical professionals will monitor patients from their home and give consultation when possible.

### *Healthcare provider patient portals*

89% of the GPs and 80% of the specialist healthcare providers in the Netherlands provide access to a patient portal (van der Vaart et al., 2022). These portals provide patients the ability to view medical data online, such as taken body measurements, prescribed medication and previous diagnosis.

### *Persoonlijke Gezondheidsomgeving (PGO)*

Translated, personal health environments are online portals accessible for citizens in the Netherlands older than 16. They provide access to all the users healthcare data from all their healthcare providers. About half of the PGO's have the feature that an users can add their own data to the environment (van der Vaart et al., 2022).

### *Doctolib Siilo*

Doctolib Siilo is a free and secure messaging app used by many GPs in the Netherlands to communicate with their patients and share diagnosis offer quick advice and evaluate measurements the patients take themselves. (Doctolib Siilo, n.d.)

## Appendix L: Studies on effectiveness of telemonitoring in cardiovascular care

In this appendix several studies are given as grounding to conclude that telemonitoring in general has shown to have a high potential in improving the cardiovascular care in a multitude of ways such as: reducing anxiety and depression, reduce cost, reduce number of hospital admissions and days spent in the hospital, improve health outcomes and more.

First of all, integrated home telemonitoring significantly reduced the number of hospital admissions and days spent in hospital with heart failure and showed to significantly reduce the cost, without increasing the mortality rate in several studies (Koehler et al., 2018; Van Der Burg et al., 2020; Gingele et al., 2017).

Furthermore, in several studies participants expressed high satisfaction of using telemonitoring with cardiovascular rehabilitation or with second degree prevention (Van Den Heuvel et al., 2020; Palant et al., 2021; Carla Plymen, 2023).

Moreover, telemonitoring also has shown to improve health literacy in trials (Redfern et al., 2020).

Also, In a study preformed during the covid-19 pandemic, Ajčević et al. (2021) observed a: “significant improvement of quality of life, as well as a significant reduction of anxiety and depression status.”

Next to that, Telemonitoring and remote rehabilitation: “improves the access to health care (by transferring care to patients’ home environments) and allows care to be adjusted to disease fluctuations while meeting the preferences and needs of individual patients, thereby improving utilisation, adherence, physical functional capacity and health outcomes.” (Van Leunen et al., 2023)

Lastly, Telemonitoring can also improve the issue of non-adherence to cardiac rehabilitation plans (Ruano-Raviña et al., 2016). In this field it already shown itself to be feasible and effective (Frederix et al., 2014).

## Appendix M: Patient related barriers

1. **Low personal motivation:** Patients may perceive digital health services as not offering significant benefits, leading to low adoption rates (Frederix et al., 2019; Van Der Wal et al., 2005). This could be due to a lack of awareness or understanding, leading to the patients attributing less value to these services. Clear communication of results might be necessary to illustrate the potential benefits.
2. **Change in patient-doctor relationship:** Patients may struggle with the changing dynamics presented by digital health solutions (Frederix et al., 2019). This can lead to hesitation and confusion about what it means for their health management, which can slow adoption. Education programs might be beneficial to bridge this gap (Bevilacqua et al., 2021). It's vital that digital health services emphasize preserving the human touch in their user experience design.
3. **Fear of diminished care quality:** Some patients express concerns about the impersonal nature of digital services potentially decreasing the quality of care received (Frederix et al., 2019). They worry that technological barriers might interfere with their healthcare journey.
4. **Lack of support from outside:** Lack of support from family members, friends or peers has implications for not signing up to digital services, also lack of clinical endorsement has been described as a barrier if patients feel that their physicians do not promote or want to use these services themselves (Frederix et al., 2019). This is even more important for the elderly or technologically averse demographics. In conclusion, the people social circles of patients are important stakeholders to keep in mind.
5. **Preference for a hybrid model:** E-health services are more accepted as a supplement to, rather than a replacement for, in-person visits (Frederix et al., 2019). This highlights the need for a well-integrated, balanced healthcare delivery model.
6. **Limited health literacy:** Individuals with lower education levels, often connected to socioeconomic status, or elderly may not have the skills and knowledge needed to utilize e-health tools effectively (Schaeffer et al., 2017; Kontos et al., 2014; Richtering et al., 2017; Xesfingi & Vozikis, 2016). This impedes their effective utilization of e-health tools. Therefore, literacy and user-centred designs become important considerations in health technology development.
7. **Type of digital technology and trustworthiness of the provider:** The type of digital health tool and the trustworthiness of the provider can influence how widely e-health is adopted (Ware et al., 2017). Users' familiarity and comfort with technology, and their trust in the provider's ability to support their health goals, may affect their likelihood to adopt e-health.
8. **Missing patient-Centric design:** Current developments are still too technically driven for patients, instead of addressing patient needs and expectation (Saner & Van Der Velde, 2016). This could cause users to not have a positive connection with the proposed design. Involving patients in the development and refinement of these services may be a viable strategy to ensure a more patient-centric design.

## Appendix N: Healthcare provider-related barriers

1. **Perception of added burden:** Providers commonly view digital healthcare as an additional task on top of their existing duties, rather than seeing it as an integrated aspect of care delivery (Villalba-Mora et al., 2015). This perspective can cause resistance towards the new technology. Highlighting the efficiency and enhanced care capabilities that e-health can offer may change these views.
2. **Inadequate infrastructure and training:** Lack of robust infrastructure along with insufficient knowledge and skills in digital health applications can hamper the readiness of healthcare providers (Frederix et al., 2019). Virtanen et al. (2021) suggest considering the needs and preferences of medical professionals more prominently, employing a more user-centric design approach as potential solutions to this barrier.
3. **Navigating the change:** Healthcare providers can find it challenging to adjust to factors such as new digital systems, different scheduling, adaptation to the organization's requirements, and financial changes (van der Vaart et al., 2022). Taking this transition into the design consideration could help smooth the change.

## Appendix O: Other barriers for E-health adoption

1. **Lack of national guidelines and standards:** Lack of overarching policies can make consistent, standard implementation challenging (Tromp et al., 2022). This lack of guidance can lead to confusion or missteps in implementation.
2. **Reimbursement:** Unclear strategies around how these new ways of providing healthcare are reimbursed can hamper commitment to e-health (Tromp et al., 2022).
3. **ICT infrastructure:** Limited national and institutional ICT infrastructure can hinder the rollout of digital health interventions (Tromp et al., 2022).
4. **Interoperability:** With so many different e-health solutions available, absence of interoperability can cause confusion and ineffective usage (Tromp et al., 2022). It can also lead to fragmented patient information, negatively impacting the coordination and thus effectiveness of care (Ying et al., 2022).
5. **Privacy, security, and quality concerns:** The overarching issues of privacy, security and quality concerns can discourage both providers and patients from adopting e-health technologies (Saner & Van Der Velde, 2016; Schomakers et al., 2019). Addressing these concerns, through quality controls and security testing, is crucial for broad acceptance.

## Appendix P: Guidelines on the development of E-Health

It is helpful to look into already established guidelines for the development of e-health solutions, in order to not fall into any already discovered pitfalls. Breeman et al. (2021), from the Dutch BENEFIT for all cardiovascular e-health consortium, identified 10 values that should guide e-health-based programs aimed at promoting healthy living, in the realm of prevention and rehabilitation of cardiovascular diseases:

1. Providing continuous care
2. Reduce burden on healthcare professionals
3. Providing a human-centred approach
4. Supporting the patients' autonomy



5. Providing means for patients to stay healthy, feel safe, and help prevent new cardiovascular disease incidences
6. Inclusion of patients' social environment, improving social support
7. Simplicity and guidance
8. Personal contact
9. Trustworthy
10. Financially self-supporting

## Appendix Q: Stakeholders analysis

An in-depth investigation was done into each stakeholder connected to the HeartEye ECG system according to the stakeholder analysis method as described by Ashby (2015). For each stakeholder three questions are answered: A. who they are, B. what they want and C. how they might try to achieve their goals.

### Main Stakeholders:

#### 1. Patient:

- a. They are the primary users of the redesigned ECG device. Their needs, comfort, and ease of use are crucial for the device's effectiveness in home settings.
- b. They want to find out if they are at risk having heart disease related complications.
- c. They will try find ways of getting this information, for example from information on the internet, asking helping from their social circle or seek help from medical professionals

#### 2. General Practitioner (GP):

- a. GPs play a vital role in primary healthcare and are often the first point of contact for patients with cardiac symptoms. The redesigned device should facilitate better communication and diagnostic support for GPs.
- b. They want efficient, accurate, and easy-to-use tools for early diagnosis and monitoring of cardiac conditions in patients.
- c. They will look for new tools or techniques that could be used in their clinic. Ones found they test and eventually implement the tools in routine check-ups.

#### 3. Cardiologist:

- a. As specialists in heart-related conditions, cardiologists can provide valuable insights into the device's clinical utility, accuracy, and features necessary for comprehensive cardiac care.
- b. They want to provide quality care to as many patients as possible and therefore seek advanced, efficient and accurate diagnostic tools for in-depth cardiac analysis and patient monitoring.
- c. They will also look for new tools or techniques that could be used in their clinic, by for example attending conferences, hearing from colleagues or reading news letters. Ones found they test and eventually implement the tools.

### Secondary Stakeholders:

#### 1. HeartEye:

- a. As the company developing the ECG device, HeartEye is directly involved in the design, production, and distribution of the device. Their business goals, technical capabilities, and market strategies are key to the project's success.

- b. They aim to develop a successful product that meets market needs, is financially viable, and establishes the company. Most importantly they want to prevent cardiac deaths by providing the means for more accessible and affordable preventive ECG monitoring.
- c. They will focus on getting their product market ready and getting the product noticed through marketing strategies and partnerships with healthcare providers.

## **2. Insurance Company:**

- a. Insurance companies may cover the device under their policies. Their support could influence its affordability and accessibility for patients.
- b. They want cost-effective, reliable medical devices that can reduce long-term healthcare costs.
- c. Evaluate the potential device's effectiveness and cost-benefit ratio to decide on coverage and promotion.

## **3. Social Circle of Patient (Family + Friends):**

- a. They play a supportive role in the patient's health journey. They might want to help with the use of the system and get notified on its outcomes. Their understanding and ease of use of the device can impact its effectiveness in home care.
- b. They want to support the patient as best as possible by finding ways to keep tabs on their close one and trying to assist them in finding help if needed.
- c. They will look into ways of effectively caring for their close one and stimulate them in getting help.

## **Tertiary Stakeholders:**

### **1. Product development team:**

- a. Responsible for the actual design and development of the device, their expertise influences the device's functionality, usability, and technological innovation.
- b. Aim to design a user-friendly, technologically advanced, and clinically effective device.
- c. Conduct research and development and incorporate user feedback into the design.

### **2. Zorg instituut (Regulatory Body):**

- a. They regulate healthcare devices in the Netherlands, ensuring that the device meets necessary standards and regulations. Their requirements need to be taken into consideration.
- b. They want to ensure the device meets safety, effectiveness, and quality standards.
- c. They conduct thorough evaluations and provide guidelines for use of the device.

### **3. Ministerie van Volksgezondheid, Welzijn en Sport (Healthcare Policy Makers):**

- a. They set policies that can affect healthcare technology adoption and funding.

- b. They want to promote effective, accessible healthcare technology and policies.
- c. Develop and implement policies that support innovative and effective healthcare technology adoption.

**4. Telemonitoring service centres:**

- a. These centres could use the device data for remote patient monitoring, making them an important potential gateway for the distribution of the HeartEye.
- b. Seek reliable and easy-to-integrate devices for remote patient monitoring.
- c. Evaluate the device's compatibility with their systems and possibly incorporate it into their service.

**5. Consumer stores:**

- a. As potential retailers, they play a role in the device's market reach and accessibility to end-users.
- b. They want to offer in-demand, reputable health devices to their customers.
- c. They assess market demand and customer feedback, and decide on the device's integration into their store.

**6. Medical device distributors:**

- a. They are crucial for the supply chain and distribution of the device to hospitals, clinics, and direct consumers.
- b. They seek profitable, reliable, and in-demand medical devices for distribution.
- c. They evaluate the device's market potential and form partnerships with HeartEye and the care facilities.

**7. Investors in HeartEye:**

- a. Their financial support is vital for the development, marketing, and scaling of the device. Therefore should their expectations and needs be taken into account.
- b. Aim for a profitable return on investment and successful market penetration of the product.
- c. Monitor the product's development and market performance, providing strategic input and financial oversight.

**8. Researchers (Research Institutions):**

- a. They are crucial in validating the device's effectiveness in order for the HeartEye system to be trusted and widely used.
- b. They want to ensure people in the Netherlands are not exposed to untrustworthy and ineffective medical devices to maintain a high standard of care.
- c. They conduct studies to validate the device's effectiveness and safety.

**9. Patient advocacy groups (e.g., Harteraad):**

- a. They represent patient interests and can provide insights into patient needs and concerns.
- b. They want to improve patient care and outcomes.

- c. they advocate for effective, accessible tools, gather patient feedback, lobby for patient-friendly devices, and collaborate with developers for improvements.

**10. Medical professional groups (e.g., Federatie Medische Specialisten or Landelijke Huisartsen Vereniging):**

- a. Their endorsement and feedback can influence the device's clinical adoption.
- b. They want to improve the quality of care and improve working conditions of medical professionals.
- c. They review and potentially endorse medical devices, which are deemed to be effective, influencing its acceptance in the medical community.

**11. Euro Stars (EU Grant):**

- a. They may provide financial support for the development of the HeartEye device under EU frameworks.
- b. They want to support innovative projects that stimulate cross country innovation and align with EU objectives.
- c. They provide funding contingent on project milestones and alignment with EU innovation goals.

**12. European Medicines Agency (EMA)(EU Regulatory Body):**

- a. Responsible for the approval of medical devices in the EU, their regulations will dictate the device's market viability in Europe.
- b. They want to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union.
- c. They conduct evaluations and provide necessary approvals for the device's use in the EU.

**13. Healthcare administrators / IT staff in healthcare:**

- a. They are involved in the integration of the device into existing healthcare systems and databases.
- b. They want to be able to easily integrate devices into the healthcare systems as needed.
- c. They assess the device's integration capabilities and manage its implementation.

**14. Medical educators:**

- a. Medical educators can influence the training of healthcare professionals in the use of new medical devices like the HeartEye ECG. Making them interesting parties for future adoption of the system.
- b. They want to incorporate new, effective medical technologies into their teaching and training programs. in order to equip their students with the most up-to-date and best knowledge that is available.
- c. They evaluate the device's educational value and potentially use it as a teaching tool in medical training.

**15. Medical information resources**

- a. These are sources of information for the general population, such as medical information websites. They are for many people the first place to look for advice when they are worried about their health.
- b. They want to provide the general population with useful and accurate information on what to do in health related predicaments.
- c. They evaluate possible new devices on their effectiveness and then provide users with advice on the use of these tools.

**16. Board of directors medical institutions**

- a. These are the people ultimately responsible for the safe and effective implementation of the medical devices and systems.
- b. They want to incorporate safe and effective devices into their institution in order to improve the efficiency and care provided.
- c. They will evaluate devices effectiveness and safety based on recommendations and evaluations

# Appendix R: Analysis of the EU Medical Device Regulations

The most important regulation which is applicable to this project is the MDR or the “Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (EVS-EN 60601-2-25:2015)” from the EU (European Committee for Electrotechnical Standardization, 2021A) . The following items are the items applicable to the development of the HeartEye system from this standard:

1. **Environmental Operating Conditions (Section 4.2):** This section is for ensuring that a medical device can operate effectively in a home environment, which may differ significantly from clinical settings in terms of temperature, humidity, and other environmental factors.
2. **Usability of Accompanying Documents (Section 7):** The comprehensibility of any documents accompanying the ECG device are vital in order ensure that users without medical training can use the device correctly and safely.
3. **Protection Against Excessive Temperatures and Other Hazards (Section 8):** This includes requirements for cleaning, disinfection, and ingress protection. Since the device will be used in a home setting, it must be safe from common household hazards and easy to maintain.
4. **Accuracy of Controls and Instruments (Section 9):** Ensuring that the device's controls and instruments are accurate and safe to use, as it is particularly essential for non-professionals who will rely on these for safe operation.
5. **Construction Requirements (Section 10):** This section, defines tests the device should comply with in order to prove it has the mechanical strength required for home use medical equipment.
6. **Protection Against Strangulation or Asphyxiation (Section 11):** This is relevant if the device has any cords or similar components, to ensure it doesn't pose a risk of strangulation or asphyxiation in a home environment.
7. **Electromagnetic Emissions (Section 12):** Compliance with standards for electromagnetic emissions to prevent interference with other home devices.
8. **Alarm Systems (Section 13):** Alarm systems must be designed to alert users effectively in a home environment. By referring to various other standards which define how alarms should sound depending on their priority or specific use.

Furthermore in this standard, any external device intended to allow direct diagnosis or monitoring of vital physiological processes are classified as class IIa devices under the Medical Device Regulations (MDR) (2017). This means the device has to adhere to the following regulations:

1. **Conformity Assessment:** Class IIa devices require a conformity assessment. This involves a Notified Body, an organization designated by an EU country, to assess the conformity of the product before being placed on the market.
2. **Clinical Evaluation:** Manufacturers must conduct a clinical evaluation to demonstrate the safety and performance of the device. This involves collecting and assessing clinical data pertaining to the device to ensure it achieves its intended purpose without exposing users and patients to unnecessary risk.

3. **Technical Documentation:** This includes detailed information about the design, manufacture, and performance of the device. Technical documentation must demonstrate that the device complies with the relevant requirements of the MDR.
4. **Post-Market Surveillance:** Manufacturers of Class IIa devices are required to have a system in place for post-market surveillance to continuously monitor the performance and safety of the device throughout its intended lifespan. For example the requirement for a system for reporting serious incidents.
5. **Risk Management:** Manufacturers need to identify and analyse known and foreseeable risks, estimate their significance, and implement measures to mitigate these risks.
6. **Quality Management System:** The manufacturer must implement and maintain an effective quality management system (QMS) appropriate for the classification of the device.
7. **Labelling and Instructions for Use:** These must comply with MDR requirements, providing clear, understandable, and detailed information on how to use the device safely and effectively.
8. **Unique Device Identification (UDI):** Class IIa devices need a UDI for traceability, improving the ability to track and identify devices across the supply chain.

The EU standard on Medical electrical equipment (European Committee for Electrotechnical Standardization, 2015) and the requirements for ECGs devices (European Committee for Electrotechnical Standardization, 2021B) were also analysed, but it was found not to be in scope for this project as these regulations were aimed at the technology of the ECG device, which is not part of this design project.

## Appendix S: AI regulation analysis

According to article 6 of the proposed AI act, a potentially AI-driven diagnosis-support within the HeartEye system, would be classified as a: “**High-risk AI system**” (*EU AI Act Compliance*, n.d.). This means that the following articles would apply:

- **Risk management:** Establish and implement risk management processes according to Article 9.
- **High quality data:** Use high-quality training, validation and testing data according to Article 10.
- **Documentation:** Establish documentation and design logging features according to Articles 11-12.
- **Transparency:** Ensure an appropriate level of transparency and provide information to users according to Article 13.
- **Human oversight:** Ensure human oversight measures are built into the system and/or implemented by users according to Article 14.
- **Security:** Ensure robustness, accuracy and cybersecurity according to Article 15.
- **Quality management system:** Set up a quality management system according to Article 17.
- **Registered:** As it is a foundational model, it would need to be register in the EU database.



According to the EU AI Act Compliance (n.d.) the following should be taken into account for a potential diagnostic HeartEye AI foundational model in order to comply with the future AI regulations:

- Ensure compliance with requirements before making them available, regardless of the distribution method.
- Demonstrate the identification, reduction and mitigation of reasonably foreseeable risks through appropriate design, testing, analysis, as well as with the involvement of independent experts. You must also document remaining non-mitigatable risks after development.
- Process and incorporate only datasets that are subject to appropriate data governance measures, such as the suitability of the data sources and possible biases and appropriate mitigation.
- Design and develop through appropriate methods such as model evaluation with the involvement of independent experts, documented analysis, and extensive testing during conceptualisation, design, and development for appropriate levels of performance, predictability, interpretability, corrigibility, safety and cybersecurity throughout lifecycle.
- Design and develop the model using applicable standards to reduce energy use, resource use and waste, as well as to increase energy efficiency and the overall efficiency of the system.
- Draw up extensive technical documentation and instructions to enable downstream compliance.
- Establish a quality management system to ensure and document compliance.
- Register the model in the EU database.
- Keep the technical documentation available to authorities for 10 years after the model has been on the market or in service.
- Additional requirements for generative AI models: comply with transparency obligations, train and design to ensure safeguards against unlawful content generation, document and publish a summary of the use of copyrighted training data

# Appendix T: Analysis on machine learning interpretability

This appendix explores machine learning interpretability. First, by exploring factors that affect model interpretability, then introducing various examples of interpretability methods. The appendix concludes by linking the importance of ML interpretability to the application of ECG devices.

## Factors that affect interpretability

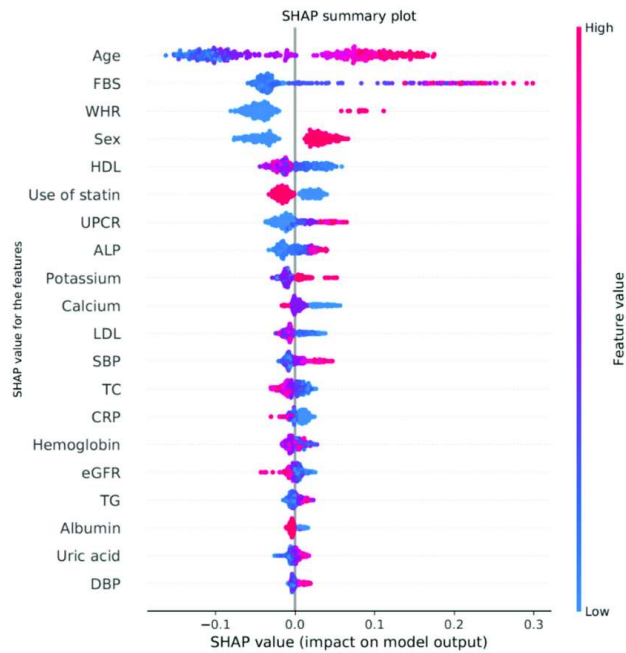
In this section, we delve into some of the various factors that affect the interpretability of machine learning models.

1. Users are more likely to accept and trust predictions made by an interpretable monotonicity constrained algorithms, which means that the algorithm should either consistently increase or decrease when certain input values are increased (Molnar, 2023).
2. The size and sparsity of a model have been shown to effect the comprehensiveness of a model. According to Freitas (2014) if a model is too large, it will become too much for a person to analyse and understand. But, too small and users and experts cannot accept the over simplicity of a seemingly complex problem. “Humans by nature are mentally opposed to too simplistic representations of complex relations.” (Elomaa, 1994).
3. Wang et al. (2018) prescribes that for a model to be interpretable it must provide reasons for its predictions that are, at least in part, inline with well-established domain knowledge.
4. Shareef et al. (2021) found that elderly can be motivated to trust in a less-familiar healthcare system if they believe they can control it and find a sense of belongingness and feelings of social interactivity.

## Examples of interpretable machine learning

In the following section some methods of making a machine learning algorithm more interpretable are explored.

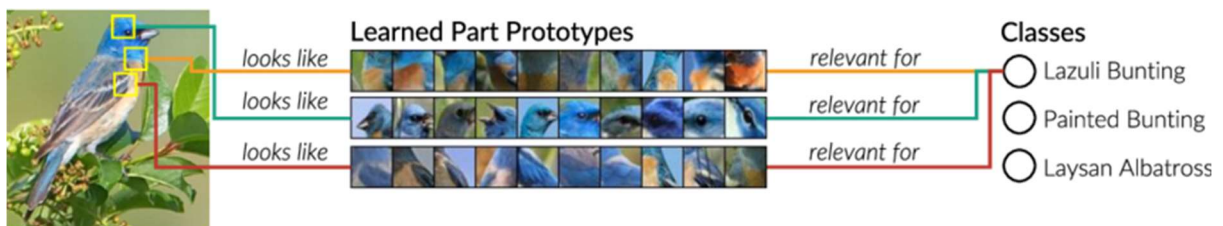
In a study done by Wang et al. (2021) it was found that using SHapley Additive exPlanations (SHAP) it was possible to explain individual risk prediction per patient. Without going into the details of how SHAP works, it is a model agnostic method and results in a visualization of how much influence each factor has on the prediction. This resulted medical specialists gaining an insight into the influence of each contributing factor.



The method of Expert Yielded Estimates (EYE) as proposed by Wang et al. (2018) suggests a technique that includes a regularization penalty derived from expert insight about known to be important factors. This has been shown to increase credibility, which could positively affect the adoption of the model.

Sparsity encoding (Tonolini et al., 2018) Variational auto-encoders (VAEs) offer a tractable approach when performing approximate inference in otherwise intractable generative models. Latent codes that are sparse and lack interpretability, thus making the resulting representations unsuitable for auxiliary tasks (e.g. classification) and human interpretation.

Chen et al. (2019) the network dissects the image by finding prototypical parts, and combines evidence from the prototypes to make a final classification.



Feature attribution is a collection of methods that aim to highlight how important each input was in the coming up with the resulting prediction (Sturmfels et al., 2020). These methods visualize these importance scores in saliency maps.



These methods could be used by the HeartEye system as well to make the predictions of a machine learning model more interpretable.

## Appendix U: Analysis on woman in heart disease

This appendix first delves into the unique cardiovascular risk factors women encounter, emphasizing the negative impact of sex-specific differences in disease processes on women's health. It also addresses the diagnostic challenges presented by the varying symptoms of heart disease in women. Furthermore, it highlights the significant differences in sex for treatment and the underdiagnosis of heart disease for women, highlighting the need for medical diagnostics to account for these differences. Lastly, it underscores the importance of designing medical devices like the HeartEye to meet the specific anatomical and societal needs of women.

### Risk Factors

The impact of common cardiovascular risk factors, such as smoking and high blood pressure, varies between genders. Smoking, for instance, poses a significantly higher risk for heart attacks in women under 55 compared to men of the same age group (Prescott et al., 1998). Women also face a heightened risk from diabetes in developing heart and vascular diseases compared to men (Anand et al., 2008). Next, women are also more often develop a higher blood pressure (Yusuf et al., 2004). Furthermore, women are more prone to specific risk factors for example how pregnancy increases the risk of cardiovascular diseases later in life (Bellamy et al., 2007).

### Disease Processes

An example of differing disease development and manifestation in men and woman is that of atherosclerosis. While middle-aged men typically have more atherosclerotic plaque, women exhibit a more diffused spread across the vessel wall (Shaw et al., 2009). This however changes after the menopause, when the plaque built up will be more like men's which causes coronary artery disease to tend to appear later in women. This correlates with the patient demographic for acute heart attack cases shifting from predominantly men when looking at patients under 60 to mostly women when looking at patients over 75 (Agewall et al., 2016). Women also frequently experience different types of heart attacks, including those without acute coronary artery blockages (Crea et al., 2013).

Another differences according to Cardiologie Centra Nederland (2021) is that for men, there is often a narrowing in the large coronary arteries for which a medication treatment, or bypass surgery can be performed. In women, the problem more often lies in the small coronary arteries. Which often requires a cardiac exercise stress test to be visible and is generally not treatable with by-pass or angioplasty, leaving only medication treatments as an option.

### Symptom Presentation

Although many doctors are aware that heart and vascular diseases are a significant problem in women, recognizing these in female patients remains a challenge. One reasons for this is that women often have different symptoms of coronary artery disease, such as pain between the shoulder blades or in the jaw, shortness of breath, nausea/vomiting or fatigue (van Dijk-Le Cocq d'Armandville et al., 2018), but also post-pregnancy related risk increases are under recognized (Federatie medisch specialisten, 2019). These a-typical symptoms cause women to more often undergo expensive and time-consuming imagining diagnosis for CAD, while for a large portion of these women this is unnecessary, as a more general data driven diagnosis has shown to effective (Overmars, 2024). However, it is important to recognize that women and men also do

show similar symptoms. For example, women and men experience chest pain in similar rates (Canto et al., 2007).

## Treatment and Underdiagnosis

Gender differences in the treatment are a significant concern. Regitz-Zagrosek et al. (2015) has indicated that women are less likely to undergo invasive diagnostic procedures and revascularization treatments than men, despite the fact that these treatments are equally effective for both genders (Mieres et al., 2005; Hvelplund et al., 2010; Nguyen et al., 2008). Additionally, women tend to receive less medication-based treatments following a heart attack (Blomkalns et al., 2005; Victor et al., 2014; Singh et al., 2013).

## Ergonomics for woman

The chest ergonomics are obviously different for woman then for men due to the presence of breast and the wearing of bras. This means special care needs to be taken in designing the HeartEye device for woman to design and evaluate for this difference (DC 1).

Next to this, the process of taking measurements in public settings may present unique challenges for women, given societal sensitivities towards the visibility of women's breasts compared to men's (DC 2). As this societal sensitivity could lead to unforeseen complication in the use of the device as it has for CPR practices, where it was found that women receive CPR less then men from men in large part being due to fear of sexual harassment (36%) or inappropriate touching (34%) (Shelton et al., 2024).

## Appendix V: Interview guide

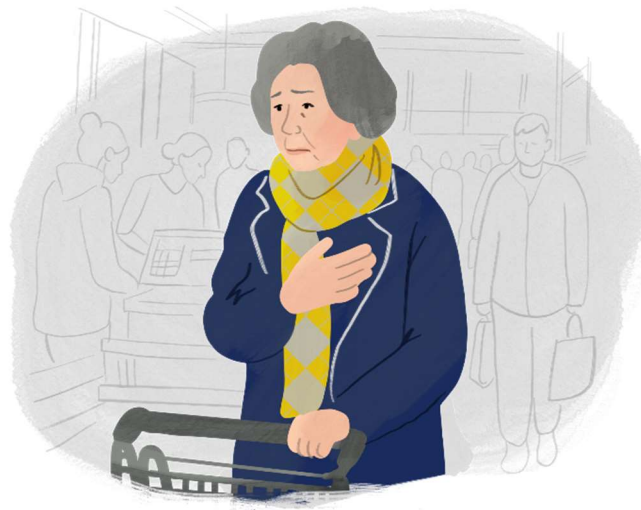
Several interviews were performed during the course of this project. These interviews were individually prepared and structured like an open conversation on the project or the specific expertise of the individual being interviewed.

Interviews:

- I1     **Prof. dr. N.H. Chavannes**     Professor huisartsgeneeskunde, Founder National eHealth Living Lab
- I2     **Ir. J. Houwen**             Design researcher at the TU Delft CardioLab
- I3     **Ir. J.H.M. Raijmakers**     Visiting professor TU Delft, Sr. Director of innovation at Phillips
- I4     **Dr. R. Van der Zee**         Founder HeartEye, ex cardiologist
- I5     **F. Grutters**                 Kwatier maker MSC zorg bij jou (Santeon)
- I6     **Prof. dr. D.E. Atsma**        Professor Cardiologie LUMC, Professor eHealth TU Delft
- I7     **M. Sperling**                Medical product engineer at 2M Engineering
- I8     **Heart disease patient 1**
- I9     **Heart disease patient 2**

## Appendix W: analysis into screening

This appendix delves into the current practices of screening for heart disease, highlighting the potential benefits and challenges associated. It explores the effectiveness of traditional screening approaches employed in healthcare settings, such as those used by general practitioners and hospitals. Additionally, it assesses the emerging trends in cardiovascular screening.



### *Potential for screening*

Among the participants who were invited to undergo screening, preventive action was initiated in 36.5% (Lindholt et al., 2022).

There are also possibilities for significant cost savings by using screening (Søgaard et al., 2012; De Boer et al., 2020)

Screening could be made more efficient in combination with machine learning algorithms which are already proven to be very accurate (Dai et al., 2021).

12-lead ECGs can be used to detect a variety of cardiovascular diseases, such as coronary artery disease, antiarrhythmic drug management, hypertrophic cardiomyopathy, LV systolic dysfunction (McLeod et al., 2009; Sridhar et al., 2016; Acharya et al., 2016; Siontis et al., 2021; Attia et al., 2019; Jahmunah et al., 2021). ECGs could also be used to improve the risk prediction in cardiovascular disease (Shah et al., 2014; Jørgensen et al., 2016; Goldman et al., 2019; Auer et al., 2012). However the Dutch guidelines for cardiovascular risk management still advise against using an ECG to improve an existing risk prediction due a greatly increased false positive rate without improving the traditional risk assessment enough (Federatie Medische Specialisten, n.d.A).

The HeartEye device provides a unique opportunity here, as it delivers a 12-lead ECG, in contrast to the norm of home ECG systems that typically only provide single-lead measurements. While these single-lead systems have shown to be effective in monitoring heart rhythms (Kaasenbrood et al., 2016; Verberk et al., 2016), their use in early diagnosis of a wider range of cardiovascular diseases is limited. The 12-lead ECG, as provided by the HeartEye device, fills this gap, offering a more diagnostic capability not yet available in home settings.



However there are still large obstacles, the main one being that stimulating the high-risk patients to participate in screening programmes is difficult to achieve even though its effectiveness has been demonstrated (Theunissen et al., 2022).

Furthermore, screening has not always been shown to have the intended positive effect, in a study by Jonas et al. (2018) they found that screening with an ECG did not have any improvement in health outcomes.



#### *current screening practices for heart disease*

The ECG is one of the first tools used to diagnose cardiovascular disease (McDonagh et al., 2021).

The Jeroen Bosch hospital (n.d.) uses known risk factors, such as family history of cardiovascular disease, high cholesterol, high blood pressure, smoking and being overweight, and blood test to assess a patient's risks. They prescribe lifestyle interventions or medications based on the risk profile.

GPs also do this kind of screening and often take multiple measurements mainly: Blood pressure, weight, length, waist circumference, a list of questions and a blood test (Huisartsenpraktijk Olthof, n.d.; *Huisartsenpraktijk Thoveling*, 2018). These consults are fully reimbursed and can result in further more extensive treatment, medication or lifestyle advice. For example 94% of the people with hypertrophic cardiomyopathy have an abnormal ECG and thus are detectable with an ECG.

In the Netherlands GPs are supporters of early detection of cardiovascular disease and of home monitoring of blood pressure (Nivel, 2019)

The Nederlandse Hartstichting (2022) has done several campaigns advertising and advocating for home monitoring of blood pressure, even going as far as providing free monitoring devices to its members.

The federatie medische specialisten (n.d.B) recommends conducting an ECG on a broad indication basis for geriatric patients. This recommendation is based on the observation that ECG abnormalities are common among elderly patients and often previously unknown, making an ECG a valuable tool for baseline assessment.

# Appendix X: Analysis into the prehabilitation to revalidation period

## *Current (p)rehabilitation process in The Netherlands*

Currently, hospitals in the Netherlands are not generally prescribing prehabilitation programs to their patients. There is, however, academic attention for the topic. An example being the PREHAB study at the Máxima MC Oncologic Centre (2022), in which they are evaluating the effectiveness of prehabilitation in oncological care.

Rehabilitation on the other hand is already being employed extensively, as Harteraad (2023) estimated that 40% of all heart patients attend revalidation programs. Tele-rehabilitation is also already available in nine healthcare centres since the attention it received during the covid lockdowns (De Nederlandse Hartstichting, n.d.; Harteraad, 2023).

Tele-rehabilitation has been found to be not inferior to centre based rehabilitation (Hwang et al., 2017).

Let's take a look at what steps a typical revalidation program goes through (Capri, 2023):

1. Intake consult to determine the program goals and personal preferences
2. Fitness test (with an ECG) to determine a fitting training program
3. Bi-weekly physical training program & information meetings
4. Extra courses based on personal preference, for example on: dietary needs, mental health needs or lifestyle interventions.

Furthermore, it is important to mention that in the Netherlands heart rehabilitation is covered by basic health insurance, if it is prescribed by your cardiologist (Harteraad, 2023; De Nederlandse Hartstichting, n.d.).

## *Prehabilitation*

Many risk factors for postoperative complication are potentially avoidable or limited if identified and treated in an earlier stage. In this context, cardiac prehabilitation tries to play a crucial role. It adapts existing strategies from cardiac rehabilitation, applying them proactive rather than reactive. These include lifestyle interventions (food, exercise and bad habits), education and mental support.

Improving physical fitness is most common in studies on prehabilitation and has been shown to:

- Improve long term survival in elderly whom had cardiac surgery (Rengo et al., 2010).
- Cause a large decrease in all-cause hospital readmission in older, frail patients with heart failure (Reeves et al., 2017).
- Reduced length of hospital stay (Drudi et al., 2019).
- Decrease in postoperative complications (Drudi et al., 2019).
- Improved objective physical functioning (Drudi et al., 2019).
- Enhanced subjective quality of life, specifically in the physical and mental health domains (Drudi et al., 2019).
- Greater long term adherence to lifestyle interventions (Sawatzky et al., 2014; Waite et al., 2017).

It is also interesting to look into what kind of interventions are currently used for prehabilitation in the context of cardiac surgery. McCann et al. (2019) suggests the following types of interventions:

1. **Aerobic Conditioning:** Structured physical activity programs designed to improve preoperative aerobic capacity. This can include the use of cycle ergometers, treadmills, and walking exercises. Interventions may vary in duration, typically ranging from 2 to 8 weeks.
2. **Respiratory Muscle Training:** Involves exercises such as deep breathing and forced expiration, often combined with incentive spirometry, to improve respiratory muscle strength and reduce postoperative pulmonary complications.
3. **Lifestyle Modifications:** This encompasses a broad range of interventions, including:
  - **Smoking Cessation:** Implementing evidence-based cessation initiatives to reduce the risk of postoperative complications.
  - **Weight and Diet Management:** Addressing issues related to underweight, obesity, and malnutrition, potentially through nutritional supplementation and dietary advice.
  - **Diabetic Control:** Optimizing glycaemic control in diabetic patients to improve perioperative outcomes.
  - **Sleep Hygiene:** Addressing sleep disorders and improving sleep quality, as insufficient sleep can impact overall health and recovery.
  - **Social Support and Functioning:** Assessing and enhancing social support networks to improve postoperative recovery and adherence to rehabilitation programs.
4. **Mental Health Interventions:** This includes:
  - **Screening and Treatment of Anxiety and Depression:** Identifying and managing anxiety and depression, which can affect postoperative outcomes.
  - **Psychoeducation:** Providing education about the surgery and recovery process to reduce stress and improve treatment adherence.
  - **Prevention of Delirium and Cognitive Dysfunction:** Implementing strategies to address risk factors for delirium and postoperative cognitive dysfunction.

#### *Potential for tele pre- and rehabilitation*

Telemonitoring has already found its way to cardiac rehabilitation where various monitoring systems have been shown to increase adherence to rehabilitation programs, which is its largest obstacle, and reduce cost as well (Peretti et al., 2017; Van Leunen et al., 2023; Vromen et al., 2021). But there are more potential advantages of using telemonitoring in combination with prehabilitation.

Most important being that new coronary artery problems can be detected earlier and thus be treated better. Michalsen et al. (1998) also found that nearly 80% of patients had experienced dyspnoea and oedema for more than 24 hours before admission. Showing that if the patient would be equipped with a suitable monitoring tool they themselves could diagnose life-threatening issues on time. This is also a large target group, as an estimated 730,000 people were diagnosed with coronary artery disease in 2012 (Leening et al., 2013).

Next to that, Scheenstra et al. (2021) proposes that telemonitoring during the prehabilitation phase could effectively identify patients who require more urgent medical consultation or need to be prioritized on surgical waiting lists. Prehabilitation telemonitoring allows for the careful observation of patients before surgery, which may justify the rescheduling of operations for patients exhibiting minimal cardiac symptoms, making way for those with rapidly worsening

cardiac conditions. Although this strategy would need to be considered very carefully with all its ethically complex implications.

Furthermore, tele-prehabilitation can be an more efficient and cost-effective alternative to centre-based cardiac prehabilitation (Brouwers et al., 2020; Ramachandran et al., 2021; Brouwers et al., 2021). It might even be necessary to facilitate the large scale adoption of prehabilitation.

Also, stress has been identified as a major risk factor for coronary artery disease (Chauvet-Gélinier & Bonin, 2017) and one which is structurally underestimated by cardiologists (Ter Hoeve et al., 2022). The HeartEye system could take up this issue and reduce stress for patients by giving them more insight into their heart.

Lastly, in a meta analysis Inglis et al. (2015) the found that: “Telemonitoring reduced all-cause mortality by about 20% and HF hospitalization by about 30%.” Koehler et al. (2018) also found that a structured remote patient management intervention could reduce all-cause mortality in and reduce the days lost due to unplanned hospital admission.

Concluding, “The combination of telemedicine with prehabilitation may therefore prove to be symbiotic and beneficial in future medicine.” (Silver, 2020). Especially the HeartEye technology could help in earlier detection of certain prevalent pre- and post-operative complications like ischemia’s

### *Education*

Preoperative education has been shown as a significant factor influencing the postoperative outcomes of cardiac surgery patients. It significantly reduces pain severity, reduces anxiety, and shortens hospital stays (Asilioglu & Çelik, 2004). Additionally, preoperative education positively impacts overall quality of life, with patients reporting improved well-being and satisfaction (Ng et al., 2021). Making it an important facet of any pre- / rehabilitation program.

### *Time period*

Drudi et al. (2019) suggest that prehabilitation, should optimally start three months before elective surgery to prepare patients physically, metabolically, and psychosocially for the intervention.

For rehabilitation it is a bit more complicated. There are traditionally three phases to cardiac rehabilitation (Mampuya, 2012; Dalal et al., 2015). The first phase being the in-hospital rehabilitation right after the intervention. The second phase consisting of a supervised outpatient rehabilitation program of 3 to 6 months, generally (Harteraad, 2023). The third and final phase is unsupervised lifelong maintenance consisting of risk-factor reduction and continuation of the exercises learned in the second phase.

Concluding, the HeartEye system would generally be in use three months before a planned intervention and three to six months after the intervention. However, it might be relevant to continue monitoring far longer after the rehabilitation period.

### *Adherence*

Adherence to medication and lifestyle intervention is a large obstacle in the efforts to improve long term cardiac care outcomes (Bansilal et al., 2016). Adherence can be improved by providing feedback on their adherence or progress to the patient in a wide range of care paths (Seewoodharry et al., 2017; Chan et al., 2022).

Non participation is also an important obstacle for current (p)rehabilitation programs. In a study by Scheenstra et al. (2023) significant reasons for not participating in a prehabilitation trial were: vision impairment, analphabetism, age, current smoker, socio-economic status and EuroScore II, a method for calculating likely risk of death as a result of a cardiac surgery. A study by Brouwers et al. (2021) yielded similar results. This means that meanly the patient who have the most to gain from prehabilitation are the ones which are the least interested. Furthermore Brouwers et al. (2021) also found several important reasons to not participate in tele-rehabilitation trial:

- Insufficient technical skills or lack of interest in digital health (26%)
- Preference for centre-based rehabilitation (21%)
- Participation being to burdensome (13%)
- Not convinced of added value of tele-rehabilitation (7%)
- Lack of time (6%)

## Appendix Y: Patient accessibility issues analysis

For older people with heart conditions, using health devices like HeartEye can be tough. Below are several issues listed commonly observed with heart diseases:

**Physical Dexterity:** Conditions like Parkinson's and arthritis can impair physical dexterity (De Geest et al., 2004). Heart failure patients often face physical activity limitations (Niklasson et al., 2022).

**Frailty:** Frailty is a common co-existing condition with older cardiovascular patients, partly due to the success of advancement in cardiac care causing patients to become older and thus suffering more frequently from age-related syndromes (Scherrenberg et al., 2023). As Uchmanowicz et al. (2019) found that, 80% of heart patients are above 65, of which 25% also suffer from frailty, next to that is frailty is also an independent risk factor.

**Sensory Impairments:** Visual and auditory impairments are significant in the targeted demographic, with 54% of heart failure patients having problems with hearing and 34,9% with vision (Desai et al., 2001) and 24% and 26% respectively in cardiology wards (De Geest et al., 2003). Furthermore, Poor vision has been found to correlate to non-adherence to prescribed therapy (De Geest et al., 2003).

**Cognitive Dysfunction:** Heart failures often co-occur with cognitive dysfunction, as heart failures have been shown to cause cognitive dysfunction (Goh et al., 2022; Breteler et al., 1994; Dridi et al., 2023; Ekman et al., 2001). Furthermore, elderly are also more prone to cognitive diseases, such as dementia (Ekman et al., 2001; Freedland et al., 2000). Also, a lower mental state has been found to predict lower adherence to prescribed therapy and (Ekman et al., 2001). Thus these cognitive challenges might necessitate simplified instructions or automatic features.

**Mental Health:** Mental conditions are more prevalent among elderly with heart conditions and is linked with an increased mortality in heart disease (Lesman-Leegte et al., 2006; Jha et al., 2019).

## Appendix Z: Selected ideas substantiation

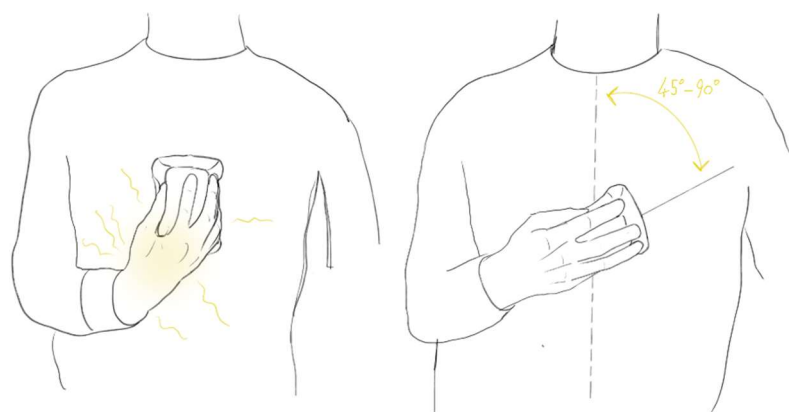
In this appendix the selected idea directions are substantiated and explained.



### Geometry of housing

From the alpha tests done with the original HeartEye design by HeartEye it became clear that the current geometry of the housing works well for placing the device on someone – as per their scenario - , but not when operating the device on yourself. For example when self-administering, your fingers do not have enough room with the current design or another example can be seen in the figure, which shows how the rotation of the hand causes strain in the wrist with the current design. Thus an improvement to the geometry is desirable to develop.

Furthermore, designing, prototyping and testing different housing designs is something that is feasible within this project and changing the housing is feasible for HeartEye.



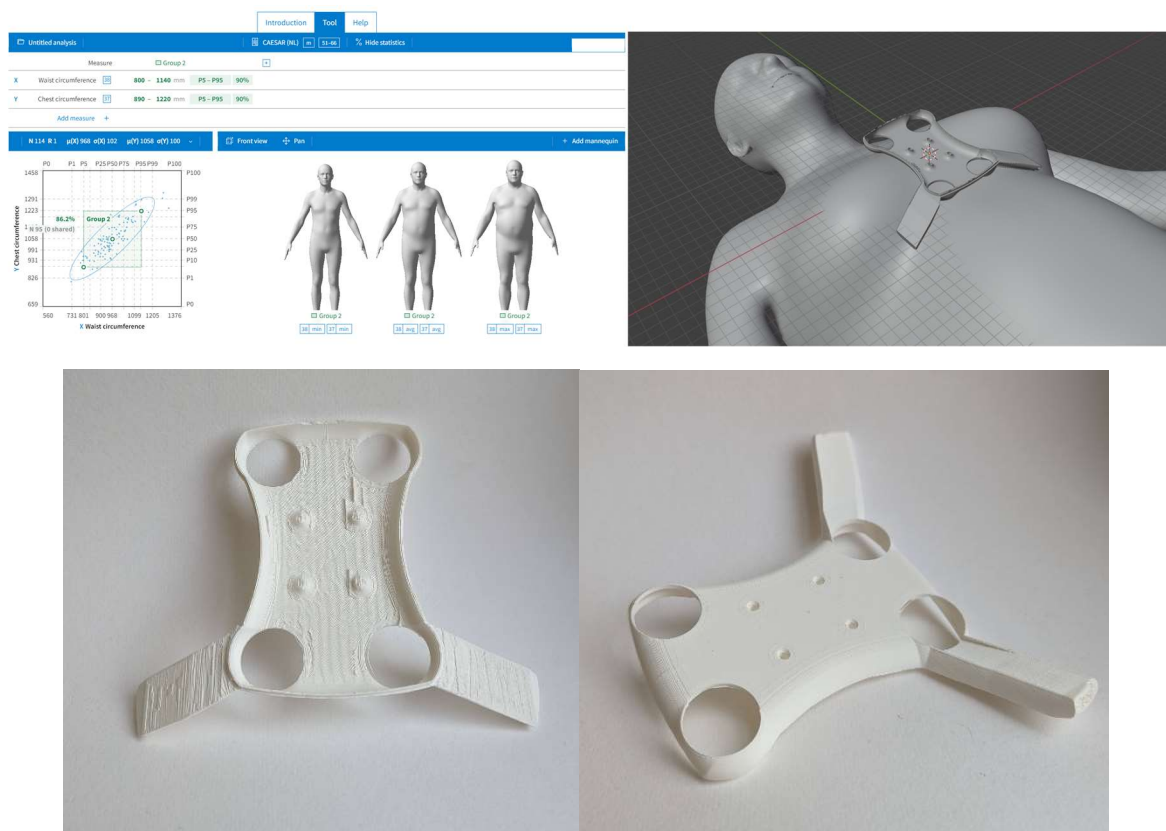
Furthermore, alterations to the geometry of the housing are viable and feasible to implement at this stage because the housing can be easily changed without affecting the how the technology works. After several iterations though sketching, prototyping and brainstorming, the following ideas were selected.

## T-bar

The positioning of the device is one of the four determinants of a high quality measurement, thus several designs were chosen which try to make the positioning easier.

The T-Bar was developed by looking at what external body features could help position the device on the correct location. By placing a bar on the bottom of the device the user could position this bar to the underside of their breast and automatically find the correct position, whilst also stabilizing the device more easily.

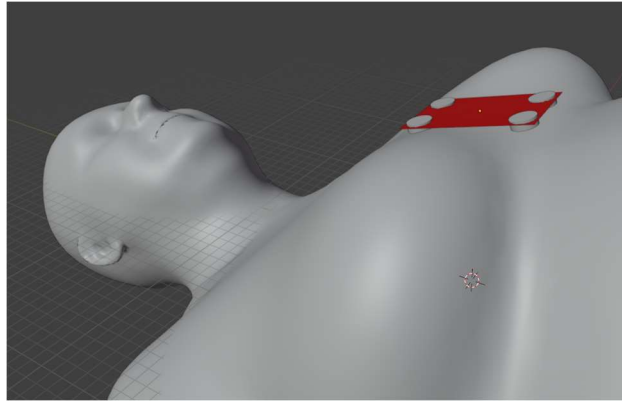
The physical design was created through several iteration by modelling the bar on top of the p=5, p=50 and p=95 waist and chest circumference mannequin 3D models retrieved from Dined (n.d.), see figure for a screenshot of the Dined settings and of how the design is modelled on top of the mannequin.



## Following body contour

Currently, the device is flat on the underside with extending electrodes. This means that only the electrodes make contact or some electrodes do not make good contact when the body contour is too parabolic that it make contact with the underside of the device creating a seesaw of sorts.





By making the underside of the device follow the body contour more, the electrodes might not only make better contact but it might also be easier to position as the device will notch onto the correct position. Furthermore, it might be more comfortable as well.

The geometry was sculpted in the same way as the T-bar and also went through several iterations. In the figure you can see the prototyped iterations and the final result.



### Larger grip

As one of the noted issues with the current design was that users did not have enough space for their fingers, one option was included in the selection which simply was a larger grip based on the grip of the current design, to see if simply making the grip larger would mitigate this issue. In the figure you can see the resulting design.



## Flat

One design was made to be as flat as possible. This design was included because having a flat design in the test makes it possible to compare the effect of a handle to having no handle. By including these kind of boring variations we hope to understand better what actually makes a good design instead of simply testing a limited set of random ideas.



## Strap

Limiting the device movement is one of the determinants. A possible reason for movement might be the strength and grip necessary to hold to the device in the correct position. To make this easier inspiration was taken from devices and objects meant for Parkinson patients, where they add a strap to make it easier to hold.



A strap like this was also incorporated into the design of the HeartEye housing and selected to be tested.



## Handle

When sculpting designs in search of improved pressure, stability and comfort the handle design was found to be an interesting direction. You can see the resulting 3D printed prototype.



## Plug

When looking at other devices which are held in the same way as the HeartEye would be held, not many devices were found. Maybe the only device which came close to the same grip is a smart phone. Which is also held towards the user with the users hand on the back. Smartphones themselves do generally not have specific grips, but there is a popular accessory for them which improve this grip from which inspiration can be taken. This is the smartphone plug.



This plug grip was translated into the HeartEye design as one of the ideas to be tested.



## Mouse grip

Another device which was found to be similar in grip to the HeartEye device are computer mice. Some computer mice designs are also known for their ergonomic qualities making them an intriguing inspiration to look at. For this reason, one of the selected designs is based on the MX Master 3S by Logitech (n.d.), which is a mouse known for its ergonomic qualities (Levin, 2024).

Through several iterations it was found that the grip needed to be turned 50 degrees in order to be comfortable for the HeartEye use case, which makes sense as that is the angle you would generally hold your arm towards your chest.



## Feedback mechanism

Several feedback mechanisms ideas were developed. For example:

- AR overlay with phone camera to guide user and show where to position the device
- Speech feedback to guide users in performing a good measurement
- Lights on the device indicating the status of the device
- And so forth

However prototyping all the possible option was not feasible, but giving useful feedback during the measurement still looked like an essential part of the design. So instead of making a limited selection of a few ideas, it was decided to take a step back and split the problem into two:

1. What is the informational need of the user during a measurement -> feedback informational need
2. How would they want to receive that information -> feedback mechanism

By trying to answer these questions in the test we can take the first steps in finding out how to provide the user with what they actually need. To do this, seven suggestions for feedback informational need were created, which will be used in the test to probe the participants to discuss what they would need and prefer:

1. Is the device correctly positioned
2. Is enough pressure applied
3. Do the electrodes make sufficient electrical contact
4. How much time is left of the measurement
5. The measurement has started
6. Status of the device (on / off / connected / measuring)
7. Measurement was successful

Next to these six techniques of providing feedback were selected for the same purpose:

1. Text on the connected phone
2. Visual on the connected phone
3. Voice from the device
4. Sound from the device
5. Haptics on the device
6. Light indicators (LEDs) on the device

## Appendix AA: Arduino code

In this appendix you can find the code that runs on the Arduino microcontroller of the test platform. Its job is to read the connected sensors, convert the raw sensor data into comprehensive values and send that data over a Universal Serial Bus (USB) to a connected laptop.

```
// main sketch for control logic HeartEye test platform
// Created by Lucas Habets
int FSR1Pin = 16;    // the FSR and 10K pulldown
int FSR2Pin = 17;
int FSR3Pin = 18;
int FSR4Pin = 19;
int vibrationMotor1Pin = 10;
int vibrationMotor2Pin = 3;
int ECGOutputPin = 20; //a0 / d14

void setup(void) {
  Serial.begin(9600); // We'll send debugging information via the Serial
  monitor
  pinMode(FSR1Pin, INPUT);
  pinMode(FSR2Pin, INPUT);
  pinMode(FSR3Pin, INPUT);
  pinMode(FSR4Pin, INPUT);
  pinMode(ECGOutputPin, INPUT);
}

void loop(void) {

  float FSR1Value = readFSR(FSR1Pin);
  float FSR2Value = readFSR(FSR2Pin);
  float FSR3Value = readFSR(FSR3Pin);
  float FSR4Value = readFSR(FSR4Pin);
  float resistance = readECG();
  Serial.print(FSR1Value, 3);
  Serial.print(", ");
  Serial.print(FSR2Value, 3);
  Serial.print(", ");
  Serial.print(FSR3Value, 3);
  Serial.print(", ");
  Serial.print(FSR4Value, 3);
  Serial.print(", ");
  Serial.println(resistance, 0);

  float FSRValues[4] = {FSR1Value, FSR2Value, FSR3Value, FSR4Value};

  feedbackGoodContactHandler(resistance, FSRValues);
```

```
}
```

```
float readECG(){  
  float raw = analogRead(ECGOutputPin);  
  if (raw < 5){  
    return 0.0;  
  }  
  float Vin = 5;  
  float Vout = 0;  
  float R1 = 100000;  
  float R2 = 0;  
  float buffer = 0;  
  buffer = raw * Vin;  
  Vout = (buffer)/1024.0;  
  buffer = (Vin/Vout) - 1;  
  R2 = R1 * buffer;  
  
  return R2;  
}
```

```
}
```

```
float readFSR(int FSRPin){  
  float fsrReading;    // the analog reading from the FSR resistor divider  
  float fsrVoltage;    // the analog reading converted to voltage  
  float fsrResistance; // The voltage converted to resistance, can be very  
big so make "long"  
  float fsrConductance;  
  float fsrForce = 0; // Finally, the resistance converted to force  
  
  fsrReading = float(analogRead(FSRPin));  
  // Serial.print("Analog reading = ");  
  // Serial.println(fsrReading);  
  
  // analog voltage reading ranges from about 0 to 1023 which maps to 0V to 5V  
(= 5000mV)  
  fsrVoltage = map(fsrReading, 0, 1023, 0, 5000);  
  // Serial.print("Voltage reading in mV = ");  
  // Serial.println(fsrVoltage);  
  
  if (fsrVoltage == 0) {  
  
  } else {  
    // The voltage =  $V_{cc} * R / (R + FSR)$  where  $R = 10K$  and  $V_{cc} = 5V$   
    // so  $FSR = ((V_{cc} - V) * R) / V$  yay math!  
    fsrResistance = 5000 - fsrVoltage; // fsrVoltage is in millivolts so  
5V = 5000mV  
    fsrResistance *= 10000; // 10K resistor
```

```

fsrResistance /= fsrVoltage;
// Serial.print("FSR resistance in ohms = ");
// Serial.println(fsrResistance);

fsrConductance = 1000000;           // we measure in micromhos so
fsrConductance /= fsrResistance;
// Serial.print("Conductance in microMhos: ");
// Serial.println(fsrConductance);

// Use the two FSR guide graphs to approximate the force
if (fsrConductance <= 1000) {
    fsrForce = fsrConductance / 80;
    // Serial.print("Force in Newtons: ");

} else {
    fsrForce = fsrConductance - 1000;
    fsrForce /= 30;
    // Serial.print("Force in Newtons: ");
    //checken torax
}
}

return fsrForce;
}
#include "Timer.h"
Timer timer;
Timer timer2;

// settings:
int thresholdToFeedback = 100000;
int timeToFeedbackMillis = 5000;
float minValuePressure = 1.0;
int feedbackDurationMillis = 3000;

// max: 255, min: 0
void vibrateMotor(int motorValue = 255){
    analogWrite(vibrationMotor1Pin, motorValue);
    analogWrite(vibrationMotor2Pin, motorValue);
}
void stopVibrateMotor(){
    digitalWrite(vibrationMotor1Pin, LOW);
    digitalWrite(vibrationMotor2Pin, LOW);
}

// handler function which makes the device vibrate when resistance is larger
then threshold for n seconds
void feedbackGoodContactHandler(float goodContactValue, float FSRValues[]){

```



```

    //if resistance is larger then threshold start the timer otherwise reset/stop
the timer
    if(goodContactValue > thresholdToFeedback && areAllValuesAboveN(FSRValues,
minValuePressure)){
        timer.start();
    }
    else{
        timer.stop();
    }

    //if the timer reached timeToFeedback seconds of being above the threshold
run feedback threshold
    if (timer.state() == RUNNING && timer.read() >= timeToFeedbackMillis){
        timer2.start();
        //run feedback here
    }

    if(timer2.state() == RUNNING && timer2.read() <= feedbackDurationMillis){
        // run feedback here
        vibrateMotor(exponentialMap(timer2.read()));
    }
    else{
        // turn feedback off here
        stopVibrateMotor();
    }
}

//helper functions
bool areAllValuesAboveN(float array[], float N) {
    int size = sizeof(array) / sizeof(array[0]);
    for(int i = 0; i < size; i++) {
        if(array[i] <= N) {
            // Found a value that is not above 1, return false
            return false;
        }
    }
    // If the loop completes, all values are above 1
    return true;
}

int exponentialMap(float input) {
    // Step 1: Normalize input to range 0 to 1
    float normalizedInput = constrain(input, 0.0, 1000.0) / 1000.0;

```

```
// Step 2: Apply an exponential function - we'll use a power function for
simplicity
// Adjust the exponent (k) as needed to get the desired curve
float k = 2; // Exponent, adjust based on desired growth rate
float expOutput = pow(normalizedInput, k);

// Step 3: Scale the result to range 0 to 255
int output = int(expOutput * 255.0);

// Ensure output is clamped to max 255
if (output > 255) {
    output = 255;
}

return output;
}
```

## Appendix BB: Python script for reading the test platform

In this appendix you can find the code for a python script which collects and stores the incoming sensor data from the test platform.

The script attempts to open a serial connection to the specified port with the given baud rate, then waits a bit to ensure the connection is established. It opens a CSV file (appending to it if it exists) and writes a header row. It then collects data for 45 seconds, reading from the serial port. If data is available, it decodes it, splits it into separate values, and adds these to an accumulator for averaging. Every 0.05 seconds, it calculates the average of the collected data for each sensor and writes this, along with a timestamp, to the CSV file. This process continues until the 45-second collection period is complete.

```
import serial
import csv
from time import sleep, time
from datetime import datetime

# Configuration
COM_PORT = 'COM4' # Serial port
BAUD_RATE = 9600 # Baud rate
N = 0.05 # Interval in seconds for averaging data
participantID = 9
testID = 22
ser = None
# DO NOT FORGET TO CHANGE NUMBER EACH
# MEASUREMENT!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!
try:
    # Set up the serial connection
    ser = serial.Serial(COM_PORT, BAUD_RATE, timeout=1)
    sleep(2) # wait for the connection to establish

    # Open or create a CSV file to store the data
    with
open(f'averaged_sensor_data_participant_{participantID}_testID_{testID}.csv',
mode='a', newline='') as file:
    writer = csv.writer(file)
    writer.writerow(["Timestamp", "FSR1Value", "FSR2Value", "FSR3Value",
"FSR4Value", "Resistance"])

    print("Collecting data. Press 'Ctrl+C' to stop.")

    # Initialize data collection variables
    data_accumulator = []
    start_time = time()
    end_time = start_time + 45

    while True:
        current_time = time()
```

```

# Break out of the loop after 45 seconds
if current_time > end_time:
    break

if ser.in_waiting > 0:
    line = ser.readline().decode('utf-8', "replace").rstrip()
    data = line.split(',') # Split the comma-separated values

    # Convert data strings to float and calculate the sum for each
sensor reading
    try:
        numeric_data = [float(d) for d in data]
        data_accumulator.append(numeric_data)
    except ValueError:
        print("Invalid data received, skipping...")

# Check if N seconds have passed
if current_time - start_time >= N:
    if data_accumulator:
        # Calculate the average for each sensor
        averages = [sum(x) / len(data_accumulator) for x in
zip(*data_accumulator)]
        timestamp = datetime.now().strftime("%Y-%m-%d
%H:%M:%S.%f")[:-3]
        writer.writerow([timestamp] + averages)
        # print(f"Averaged data written for interval ending at
{timestamp}: {averages}")

    # Reset for the next interval
    data_accumulator = []
    start_time = time()

except KeyboardInterrupt:
    print("\nData collection stopped by user.")
finally:
    if ser:
        ser.close() # Close the serial connection
        print("Serial connection closed.")

```

# Appendix CC: Requirements for insurance reimbursement

The following list are the requirements set by the Dutch healthcare authority (Nederlandse Zorgautoriteit, 2023) and information provided by the Federation of medical specialist (Federatie Medische Specialiste, 2022) for insurance reimbursement in the Netherlands.

## ***Eligibility of the Insured Individual:***

The individual must have a diagnosed disease or be at risk of developing a disease.

## ***Nature of the Telemonitoring Service:***

For a telemonitoring service like HeartEye to be eligible for reimbursement, it must be recognized as an 'insured performance'. This means that the service must fall within the treatments that are covered under standard health insurance policies. For HeartEye this would entail the replacement of taking ECGs for cardiac health conditions.

## ***Patient orientated***

The healthcare provider and patient together decide whether telemonitoring contributes to the treatment and is suitable for the individual patient's needs, and whether the patient is able to manage the means used for telemonitoring. The basic principle is that telemonitoring should improve the care and quality of life for the patient.

## ***Data safety***

The health care providers prescribing the telemonitoring device needs to take care in assessing the risk of data security and data management when using telemonitoring. There are several criteria the health care provider needs to verify such as; if the patient can securely transmit their monitored data or if other medical providers can access the information if they need to according to a jointly made treatment plan.

## ***Alignment with Medical Standards:***

In the Dutch healthcare system, for a telemonitoring intervention to be eligible for reimbursement, it must rigorously align with established scientific and medical standards. This entails demonstrating effectiveness and safety through evidence-based medicine, supported by clinical trials and scientific research. The intervention should incorporate the latest advancements in medical science and technology, ensuring that it is not outdated but rather reflects current best practices in healthcare.

The acceptance and recognition of the intervention within the medical community is also crucial. This typically involves validation through peer-reviewed studies, adherence to clinical guidelines, and endorsement by reputable medical organizations.

Furthermore, there must be a clear clinical benefit to the intervention. It should address a specific healthcare need, improving patient outcomes and contributing to the overall quality and efficiency of patient care.

## ***Substituting other medical-specialist care***

The implementation of telemonitoring should be efficient and appropriate, leading to the modification or replacement of current care pathways and existing care, thereby substituting other forms of medical-specialist care. The objective is for telemonitoring to replace or reduce existing care, or to enhance the quality of care while maintaining the same cost level.

***Billing and Payment Regulations:***

Health care providers can declare the telemonitoring service with the set billing code, which is 039133. The maximum charge for using this service is 164,13 euros (Nederlandse Zorgautoriteit, 2022). This charge covers the process of taking measurements and analyzing them, but it does not include any consultation fees. These services can be billed once every 120 days during the length of the telemonitoring, regardless of how often the measurements are taken during this time.

***Agreement with insurance companies:***

Healthcare providers must make prior agreements with insurance companies about the setup, goals, and evaluation of telemonitoring services.

# Appendix DD: Informed consent sheet user test

## Informed consent sheet

You are being invited to participate in a research study titled The redesign of the HeartEye ECG for home use. This study is being done by Lucas Habets from the TU Delft.

The purpose of this research study is to investigate the effect of different design modifications on the quality of ECG measurements, and will take you approximately 30 minutes to complete. In this study the researcher will ask you to use a non-functional prototype handheld ECG device and take a fake measurement. While you are doing that the researcher will note down significant observations and record the sensor data which the prototype collects. The prototype will measure the resistance between two electrodes of the prototype and your skin and the pressure you are applying on all four electrodes. It is possible that the researcher will take photos during the test, you can choose to not have photos taken by notifying the researcher of this verbally.

The data will be used for the publication of a master thesis.

As with any digital data the risk of a data breach is always possible. To the best of our ability your answers and data used in this study will remain confidential. We will minimize any risks by anonymizing all data (removing all identifiable data) and no identifiable data will be published.

Your participation in this study is entirely voluntary **and you can withdraw at any time**. You are free to omit any questions or not perform any actions you are not comfortable with. You can contact the researcher within one month of the interview to remove any part of the interview or data. After this time the thesis will be published and all non-included data will be deleted.

Researcher contact information:

Name: Lucas Habets

Organisation: TU Delft

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
<b>A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICIPANT TASKS AND VOLUNTARY PARTICIPATION</b>		
1. I have read and understood the study information dated (30-11-2023) or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	<input type="checkbox"/>	<input type="checkbox"/>
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	<input type="checkbox"/>	<input type="checkbox"/>
3. I understand that taking part in the study involves: - Taking two test measurements with a non-functional prototype ECG device. - An interview after each test measurement, which takes approximately 5 minutes.	<input type="checkbox"/>	<input type="checkbox"/>
4. I understand that I will not be compensated for my participation.	<input type="checkbox"/>	<input type="checkbox"/>
5. I understand that the study will end within 1 hour.	<input type="checkbox"/>	<input type="checkbox"/>
<b>B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)</b>		
6. I understand that taking part in the study involves the following risk: The data recorded might be stolen. I understand that these will be mitigated by having the data stored in a password secured folder.	<input type="checkbox"/>	<input type="checkbox"/>
7. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach: The data will be stored in a password secured folder. Also, The recording will be cut to exclude personal information.	<input type="checkbox"/>	<input type="checkbox"/>
8. I understand that personal information collected about me that can identify me, such as name, will not be shared beyond the study team.	<input type="checkbox"/>	<input type="checkbox"/>
9. I understand that the (identifiable) personal data I provide will be destroyed within a month of the study	<input type="checkbox"/>	<input type="checkbox"/>





# Appendix EE: researcher guide user test

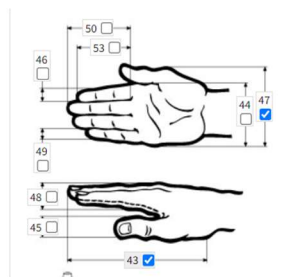
## Testing order:

The participants will test each variation ones according to order in the table. Only the first variation they try will be tested three times in order to minimize the effect of a learning curve on the rest of the test. The first test will also be done without a cable attached in order not to influence the perception of orientation of the initial test.

name	Test id	participant id ->	0	1	2	3	4	5	6	7	8	9
Strap	0	1	0	9	8	7	6	5	4	3	2	1
handle	1	2	0	9	8	7	6	5	4	3	2	1
larger grip	2	3	0	9	8	7	6	5	4	3	2	1
mouse grip	3	4	1	0	9	8	7	6	5	4	3	2
flat	4	5	2	1	0	9	8	7	6	5	4	3
plug	5	6	3	2	1	0	9	8	7	6	5	4
T-bar	6	6	4	3	2	1	0	9	8	7	6	5
necklace	7	7	5	4	3	2	1	0	9	8	7	6
body cont	8	8	6	5	4	3	2	1	0	9	8	7
Original	9	9	7	6	5	4	3	2	1	0	9	8
		10	8	7	6	5	4	3	2	1	0	9
		11	9	8	7	6	5	4	3	2	1	0

**Give, explain and sign the informed consent sheet (appendix DD)**

**Measure hand size:** hand width (with thumb): ..... mm, hand length: ..... mm



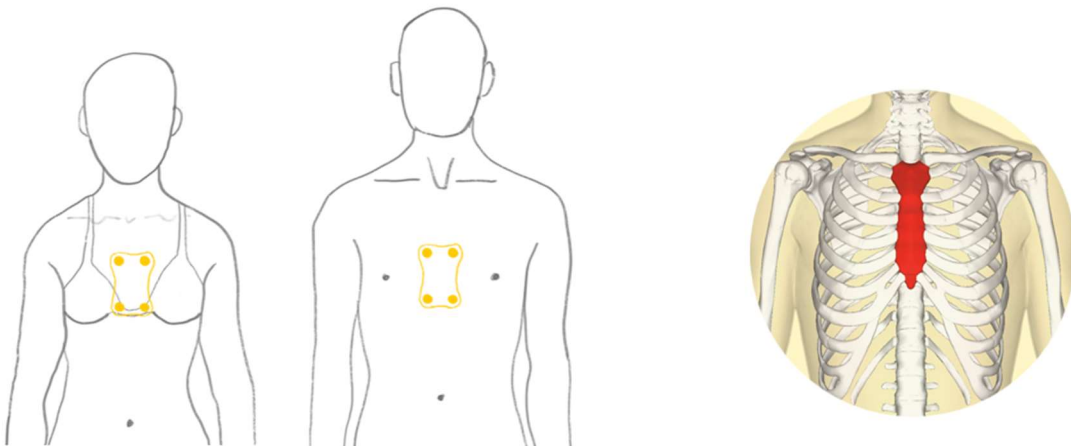
**Introduction text:** *“This is a non-functional prototype of a future home monitoring ECG device. It will measure the electrical activity of your heart through four electrodes, but this prototype will not. In normal use, you would take it home and make a measurement every week. For this test you can try to take a normal measurement, if you are comfortable with that. To take a measurement you need to hold the device on your chest, with the electrodes touching your skin. Here is the device, how would you position it on your chest? Please think out loud”*

**Give the device to the user and note how they place the device:**

Notes:



**After initial test further explain the device:** “So, to take a measurement you need to hold the device on your chest, with the electrodes touching your skin, as shown in this figure (show figure). The device should be held with its bottom aligned with the bottom of your sternum, which is the middle part of your rib cage. All four electrodes need to touch your skin. Once you have the device in place press this button (point to the button) and tell me you have pressed the button. Then you will have to hold it there for thirty seconds. It is important to hold the device as still as possible. You can give the device back to the researcher once the measurement is complete. Please speak out loud what you are thinking and why you are conducting certain interactions. Do you have any questions?”



**Researcher actions each measurement:**

1. Screw on the right housing and change the test\_id variable in the python data receiving script.
2. Give the device to the participant
3. Once the participant says they have positioned the device, start the python script
4. Make sure to fill in the note sheet
5. Ask questions (see questions sections)
6. Change the test equipment according to the prespecified testing order

### Questions after each measurement:

1. **Experience:** "Could you describe your experience during the measurement in detail? Were there any moments of uncertainty or discomfort?"
2. **Comfort:** "What did you think about the design of the device in terms of its ease of use, comfort, and overall user interface?"
3. **Positive Aspects:** "What aspects of this measurement process stood out to you as particularly positive or effective? Was there anything about the design that made the measurement easier or more comfortable?"
4. **Negative Aspects:** "What aspects of this measurement process stood out to you as particularly negative or ineffective? Was there anything about the design that made the measurement more difficult or less comfortable?"
5. **Button Placement Preferences:** "Considering your experience, where would you ideally place the control button? Why?"
6. **Improvement Suggestions:** "Based on your experience, do you have any suggestions for improving this version of the device, particularly in terms of its usability, comfort, or the clarity of its instructions?"

### Questions after the full test:

Ask the following questions to the participants, but leave it a open interview, let participants go on tangents and tell their story.

1. **Comparative Design Ranking:** "Having experienced different design modifications, how would you rank them in order of preference? Could you explain your reasoning, particularly in terms of comfort, ease of use, and the quality of the measurement?"  
**Take a photo of the ranking**
2. **Scenario Planning:** "Imagine you need to monitor your heart condition ones every week with this device. When and where do you envision yourself using it most frequently? And what if you had to monitor it daily on random times. Are there any potential obstacles or challenges you foresee in your daily routine?"
3. **Feedback on Instruction Clarity:** "How clear and understandable did you find the instructions for using the device? Were there any points of confusion?"
4. **Confidence in measurement:** "Were you confident that you were taking accurate measurements? If not, what do you think you were doing wrong? (e.g. correct position or enough pressure)"
5. **Informational need:** "Is there any information you would have liked to get during the measurement? If so, how would you want to get this information?"

**Prepare card game:** put the cards down





**Explain card game:** "Here are blue cards with examples of what kind of information the device could provide. These are definitely not all the possibilities, so if you come up with anymore I would love to hear them. The yellow cards represent methods of how to communicate information. I would like you to put the yellow cards you would prefer at blue cards that you would find useful. You do not have to use every card. Please think aloud and tell me why you combine certain cards." Discuss the feedback mechanisms during the game

**Take a photo of the result and thank the participant**

**Clean all the components thoroughly with disinfecting spray and wet wipes.**

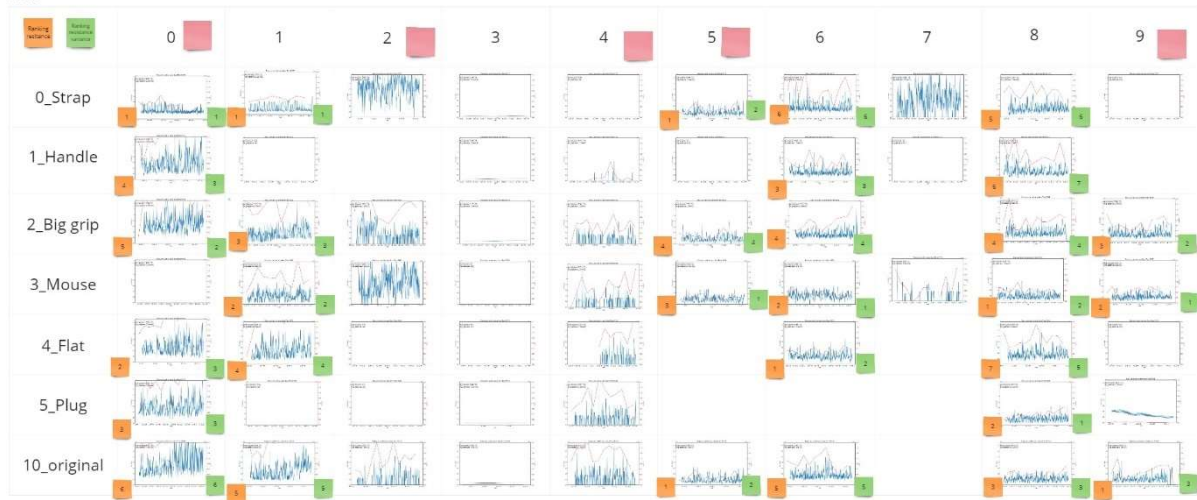
## Appendix FF: Feedback mechanism card game cards

 <p>Positie</p>	 <p>Druk</p>	 <p>Goed contact</p>
 <p>Resteren de tijd</p>	 <p>Meting gestart</p>	 <p>Status (aan / uit / verbonden / meting bezig)</p>
 <p>Meting succesvol</p>	 <p>Licht / lampje</p>	 <p>Stem</p>
 <p>Geluid</p>	 <p>Trilling</p>	 <p>Visual op telefoon</p>

 <p>Text op de telefoon</p>	 <p>Licht / lampje</p>	 <p>Stem</p>
 <p>Geluid</p>	 <p>Trilling</p>	 <p>Visual op telefoon</p>
 <p>Text op de telefoon</p>	 <p>Licht / lampje</p>	 <p>Stem</p>
 <p>Geluid</p>	 <p>Trilling</p>	 <p>Visual op telefoon</p>

# Appendix HH: Overview of quantitative test data

New trace



	0	1	2	3	4	5	6	7	8	9	fraction wrong	% correct	ranking
0_Strap											3/8	62	1
1_Handle											2/5	60	2
2_Big grip											4/9	56	4
3_Mouse											5/9	45	5
4_Flat											3/5	40	6
5_Plug											2/5	60	2
10_original											6/9	33	7

## Appendix II: Explanation of overarching themes from qualitative study

In total 89 key insights (see appendix G) and 102 quotes (see appendix H) were gathered from the 70 clusters. As explained in the chapter on the study, these were condensed further into a final 16 overarching themes, which are:

1. **Abrupt Adjustment to New Realities:**
  - Shock and sudden lifestyle changes after a heart event.
  - Navigating the transition from a normal to a chronically ill status.
  - Coping with the immediate aftermath and uncertainties of heart disease.
2. **Emotional Journey and Mental Health:**
  - Dealing with anxiety, depression, and emotional turmoil post-heart event.
  - Struggling with the psychological impacts of heart conditions and recovery.
  - Finding solace in support groups and mental health resources.
3. **Navigating Healthcare and Communication Challenges:**
  - Challenges in communicating effectively with healthcare professionals.
  - Frustration with inconclusive diagnostic results and unclear medical advice.
  - The need for clear, empathetic communication and guidance from medical staff.
  - The challenges of navigating a complex healthcare system.
  - Contrasts between emergency care efficiency and chronic condition management.
4. **Role of Support Systems in Recovery:**
  - The importance of family, friends, and online communities in providing emotional support.
  - Valuing patient services and rehabilitation programs for guidance and shared experiences.
  - The critical role of caregivers in providing both functional and emotional support.
  - The value of online forums and communities for shared experiences and advice.
  - Leveraging peer support networks for emotional and practical guidance.
  - The role of community in providing a sense of belonging and understanding.
5. **Lifestyle Adjustments and Self-Management:**
  - Integrating exercise and dietary changes into daily life.
  - Balancing physical limitations with the desire for normalcy.
  - Self-monitoring and managing symptoms using technology and personal strategies.
6. **Impact on Work and Daily Functioning:**
  - Adjusting to changes in work life and the need for accommodations.
  - The stress of balancing health needs with work demands.
  - Experiences of returning to work or changing job roles due to health limitations.
7. **Shared Decision Making and Empowerment:**
  - The importance of shared decision-making in healthcare.
  - Empowering oneself through self-education and proactive health management.
  - Advocating for oneself in the healthcare system and seeking clarity in treatment plans.
8. **Coping with Chronicity and Long-Term Adjustments:**
  - Long-term emotional and physical adjustments to living with a heart condition.
  - The ongoing journey of accepting and adapting to chronic illness.



- Managing long-term symptoms, treatment regimens, and lifestyle modifications.
- 9. Navigating Uncertainty and Fear of Recurrence:**
- Living with the constant fear of another heart event.
  - Coping with the unpredictability of symptoms and health status.
  - Strategies for dealing with uncertainty and maintaining a hopeful outlook.
- 10. Technological Integration and Health Monitoring:**
- Utilizing wearable devices and health apps for monitoring heart health.
  - Concerns about the accuracy and reliability of health monitoring technology.
  - The role of technology in empowering patients to manage their condition.
- 11. Physical Recovery and Rehabilitation:**
- The challenging journey through cardiac rehabilitation and physical recovery.
  - Celebrating milestones and progress in physical health post-surgery or heart event.
  - The importance of structured exercise and rehabilitation programs.
- 12. Emotional Impact of Diagnostic Processes:**
- The psychological effects of undergoing cardiac testing and receiving diagnoses.
  - Frustration and anxiety associated with diagnostic uncertainty.
  - Coping with the emotional responses to medical test results and diagnoses.
- 13. Reconfiguring Personal Identity and Self-Perception:**
- Adjusting to changes in personal identity following a heart event.
  - The struggle with self-perception and sense of self post-diagnosis.
  - Rebuilding confidence and redefining oneself in the context of chronic illness.
- 14. Uncertainties and Challenges of Medication Management:**
- Navigating the complexities of medication regimens and side effects.
  - Concerns about medication timing, dosage, and effectiveness.
  - The impact of medication on daily life and health management.
- 15. Weather and Environmental Factors in Heart Health:**
- The influence of weather and environmental conditions on heart health.
- 16. Future Perspectives and Hope:**
- Maintaining a positive outlook and future perspective despite health challenges.
  - The importance of hope and optimism in the recovery and management process.
  - Planning for the future and adapting to a new normal with heart conditions.

# Appendix JJ: Ideation resources

In this appendix some examples are given of ideation resources used in the ideation process. These include: mind maps, clay models, 3D printed models and drawings.

