Software Design Documentation

for

Leveraging Digital Phenotyping to Support Patients with Glaucoma

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Code Revision History

Not applicable at this time due as the system has not been implemented yet.

1. Introduction

1.1 Purpose of Document

The purpose of this document is to describe the features, requirements, and specifications of the "Digital Phenotyping for Glaucoma" system. This document records all necessary information required for system design to provide system architectural guidance to the development team.

1.2 Scope of the Document

This document outlines the technical aspects of the system. This document describes the system features, design considerations, and architectural strategies.

1.3 Intended Audience of Document

This document will be useful for the software development team, the software testing team, project managers, and the potential users of the system. This document is best read in various ways depending on the role.

Development Team: product requirements and implementation (s. 2-5)

Testing Team: product purpose and requirements (s. 3-5)

Project Manager: product purpose and requirements (s. 2-5)

Users (patients): product purpose, user interface paradigms (s. 1.3, 6.1-6.3)

Users (physicians): product purpose, user interface paradigms (s. 1.3, 6.4-6.6)

1.4 Identification of the System & Product

The official project name is *Leveraging Digital Phenotyping to Support Patients with Glaucoma*. There are no other relevant versions or names, but the smartphone application will be referred to as "the application" or "the system."

1.5 References

J. M. Wood, A. A. Black, K. Mallon, R. Thomas, and C. Owsley, "Glaucoma and Driving: On-Road Driving Characteristics," PLOS ONE, vol. 11, no. 7, p. e0158318, Jul. 2016, doi: https://doi.org/10.1371/journal.pone.0158318.

S. A. Haymes, R. P. LeBlanc, M. T. Nicolela, L. A. Chiasson, and B. C. Chauhan, "Glaucoma and On-Road Driving Performance," Investigative Ophthalmology & Visual Science, vol. 49, no. 7, p. 3035, Jul. 2008, doi: https://doi.org/10.1167/iovs.07-1609.

S. W. van Landingham, C. Hochberg, R. W. Massof, E. Chan, D. S. Friedman, and P. Y. Ramulu, "Driving Patterns in Older Adults with Glaucoma," BMC Ophthalmology, vol. 13, no. 1, Feb. 2013, doi: https://doi.org/10.1186/1471-2415-13-4.

A. Blane, "Through the Looking Glass: a Review of the Literature Investigating the Impact of Glaucoma on Crash Risk, Driving Performance, and Driver Self-Regulation in Older Drivers," Journal of Glaucoma, 2016.

1.6 Definitions, Acronyms, and Abbreviations

Refer to Section S: Glossary.

2. System Overview

The mobile application system will be developed using Dart, the Flutter framework, and Damoov's Telematics software development kit. The primary aim of the application is to unobtrusively gather raw sensor data from users' smartphones to process into driving events. These driving events will then be used to evaluate users' driving habits to monitor glaucoma with digital phenotyping. Physicians will be able to access patients' drives and determine the condition's progression. The mobile application system should be HIPAA-compliant requiring that any identifying patient information associated with a data record be anonymized. To accomplish this, our system will generate a JSON web token for user authentication and authorization. To ensure further security, the data will undergo encryption when migrated to Damoov's internal data storage platform, DataHub, through the backend, where scores and behaviors will be calculated. A unique identifier will also be generated for each user, accessible only to physicians to associate with each driving record.

The mobile application will have two separate interfaces tailored to patients and physicians. It will comprise a shared login page, physician and patient signup portals, various permissions screens, and respective home screens. The permissions screens will explain and request consent for patient data usage and the application's functionality. The patient home screen will also display a log of the patient's driving data refined to basic driving metrics such as drive duration, route, and length. The patient home screen should also be able to navigate to the personal section or profile page, where patients can customize the unit of measurement for the displayed drive metrics. The patient interface should generally be simple, have a larger font for better visibility, and be easily navigable while adhering to a palatable style guide. The physician home screen will have a queryable list of patients that will act as an in-app database. It will contain a search bar capable of finding a patient with their unique identifier. When a list object is clicked, the physician will be brought to a new screen with in-depth statistics such as braking, acceleration, and cornering scoring for the appropriate patient. The physician interface should be digestible with condensed patient-driving information, offering a suitable means for tracking and evaluating patients' glaucoma stages.

3. Design Considerations

3.1 Assumptions and Dependencies

3.1.1 Assumption of Network Connectivity: This project assumes that participants' cellular devices are consistently connected to a network. Reliable network connectivity is pivotal for the uninterrupted transmission of data and effective tracking of lifestyle patterns pertinent to glaucoma risk assessment.

3.2 General Constraints

3.2.1 Network Connectivity: The application may face challenges in accurately tracking patient movements in unstable network conditions.

3.2.1.1 The application's ability to accurately track and record patient movements and other relevant data may be compromised in unstable or poor network connectivity areas. This limitation could lead to gaps in data, potentially affecting the system's effectiveness in monitoring health risks.

3.2.2 User Permissions and Consent: The application's functionality depends on users granting necessary permissions on their mobile devices.

3.2.2.1 The system's functionality relies heavily on users granting necessary permissions on their mobile devices. These permissions may include access to location data, health monitoring data, and other personal information. User consent is critical, not just for operational feasibility but also for maintaining user trust and ethical integrity.

3.2.3 Legal and Ethical Compliance: The application must be HIPPA-compliant because the system collects sensitive data (e.g., GPS).

3.2.3.1 Given the sensitive nature of the collected data (e.g., GPS location, health information), the application must adhere strictly to HIPAA (Health Insurance Portability and Accountability Act) compliance and other relevant legal frameworks. This compliance ensures the protection of patient privacy and data security, which are paramount in healthcare applications.

3.3 Goals and Guidelines

This project aims to create a mobile application that tracks the patient's driving patterns to determine their driving ability. As our primary audience will have limited visual fields and may be of elderly age, the application should have a simple user interface to ensure that individuals with decreased visual fields and old age can operate the system. The first iteration of the mobile application should be completed by the end of February 2024.

3.4 Development Methods

This project used Figma to prototype the application's design. There is no set development method, as we focused mainly on getting the IRB approval, researching, and designing the application.

4. Architectural Strategies

4.1 Use of Particular Products

Dart, Flutter, Damoov's Telematics SDK integration, and Damoov's storage platform DataHub will be used for application development. Prototyping will be done with Figma to create concept user interfaces for the application.

4.1.1 Dart is an object-oriented programming language to develop mobile applications.

4.1.1.1 This product is easy to learn with prior knowledge of JavaScript and/or React Native.

4.1.1.2 This product is client-optimized with a stateful live reload and features for building specialized user interfaces important for this application's audience, including sound null safety and Flutter.

4.1.1.3 This product is the foundation for Flutter, an open-source framework with a UI toolkit for simple and fast app development important for the project's time constraints.

4.1.2 Damoov's Telematics SDK is a telematics toolkit that allows for driving data processing.

4.1.2.1 This product allows access to all data at any stage with on-demand data destruction adhering to the CCPA and HIPAA-compliant.

4.1.2.2 This product provides a license to distribute and integrate within the mobile application freely.

4.1.2.3 The integration of this product enables real-time smartphone sensor data collection and readily customizable processed driving events.

4.1.3 Damoov's Datahub provides a backend configuration to its Telematics SDK

4.1.3.1 Authorized personnel have on-demand access to all data and controlled data destruction through this product.

4.1.3.2 This product offers simple services to manage the SDK and API services and an analytics portal for viewing and exporting data.

4.1.3.3 This product is securely encrypted, protecting all captured patient driving data.

4.1.4 Figma is used to prototype the layout of the mobile application.

4.1.4.1 This product allows for the conceptualization and visualization of the system's user interfaces, considering the visual impairments of the intended main users.

4.1.4.2 The product is a communication tool for the mobile application's features and a style guide.

4.2 Reuse of Existing Software Components

The application will not reuse existing software components but will utilize Damoov's Telematics SDK and the user interface library Flutter.

4.3 Future Plans for Extending or Enhancing the Software

The system has not been implemented yet. The primary plan moving forward is to develop a functional, preliminary version of the mobile application integrating the Telematics SDK that consists of the modules discussed in the *Detailed System Design* (s. 6). After the basic operation of the application is achieved, the aesthetics of the modules may be re-evaluated.

4.4 User Interface Paradigms

4.4.1 Interface prompts new patients/physicians to register

- 4.4.1.1 To register an account, the User database will be updated, allowing credentials to be securely stored for users to conveniently log in and out as needed.
- 4.4.1.2 Interface visual design colors set to gold, sepia, and brown
  - 4.4.1.2.1 No harsh colors ideal for individuals with glaucoma
- 4.4.1.3 Existing users will be prompted to login
  - 4.4.1.3.1 The system authenticates credentials during both registration and login processes to ensure validity

4.4.2 Interface opens up with a homepage that contains a navigation bar that should be present on both patient and physician screen providing distinct functionalities for both

- 4.4.2.1 The logged-in patients can access drive statistics (e.g., duration, total mileage, route) and manage personal information like profiles through the navigation bar on the homepage.
- 4.4.2.2 The physician's homepage will be a central hub for physicians to
  oversee patient statistics. This includes the patient's score, risk level, and any other relevant details needed to assess the progression of glaucoma

4.4.3 Adaptive and Responsive Design

- 4.4.3.1 Cross-Device Compatibility: The interface adapts to different devices, ensuring usability and accessibility regardless of the device used.
- 4.4.3.2 Accessibility Features: Includes options for font size adjustments, contrast settings, and voice-over text for visually impaired users.

4.5 Hardware and/or Software Interface Paradigms

4.5.1 Smartphones must include a triaxial accelerometer, gyroscope, and magnetometer for recording sensor readings, as these sensors are required for driving data collection within the system.

4.6 Error Detection and Recovery

This project will implement exception management and detailed issue logging to handle program errors effectively. These mechanisms prevent mishaps like inadvertent data exposure or incorrect data associations. Reducing such errors through thorough debugging ensures proper functionality. For the recovery process, these practices play a crucial role. They aid in troubleshooting or replicating issues, making it easier to identify errors and ensuring a swift resolution, thus maintaining an uninterrupted workflow.

4.7 Memory Management Policies

The mobile application will be developed using Dart, which uses a garbage collector to automatically manage memory, meaning that once the object is no longer in use, the garbage collector will automatically free up memory used by any function or call. Memory leaks in Dart may arise when objects are inadequately deallocated, accumulating unused memory. To address this, attention should be given to closing streams, avoiding cyclic references, managing global variables, and using Dart DevTools to detect and rectify potential leaks.

4.8 External Databases

The application depends on Damoov's DataHub storage. Integrating Telematics SDK with the system generates a user ID and JSON web token for account authentication and authorization. The SDK refreshes, processes, and validates data with the JSON web token. Authorized personnel have on-demand access to raw and processed data, with controlled data destruction.

4.9 Distributed Data/Control over a Network

The data distribution process begins with the smartphone's sensor readings. The application processes the data and sends it to Damoov's Datahub storage which uses server-side encryption, encrypting each data record with an Advanced Encryption Standard Key (AES-256 Key) for data security and privacy.

4.10 Generalized Approaches to Control

Code, research, and libraries are in private Github repositories and Dropbox folders.

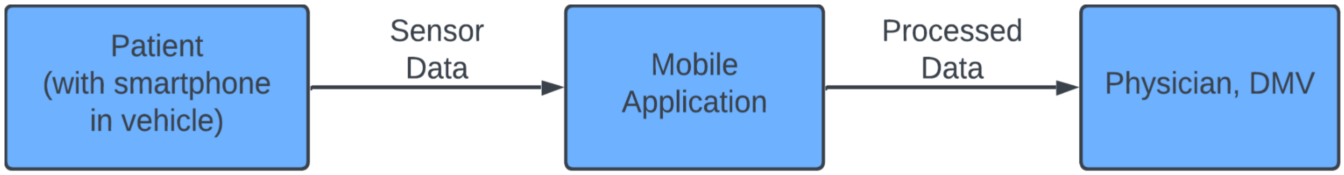
4.11 Concurrency and Synchronization

The programming language Dart provides features and mechanisms to handle concurrency and synchronization in the context of asynchronous programming. Dart supports isolates which are lightweight concurrent threads of execution and have their own memory space allowing them to execute concurrently without sharing memory or data. Dart also supports the synchronized keyword “synchronized” that can be used to create a synchronized block of code, ensuring that only one isolate can execute the block at a time.

4.12 Communication Mechanisms

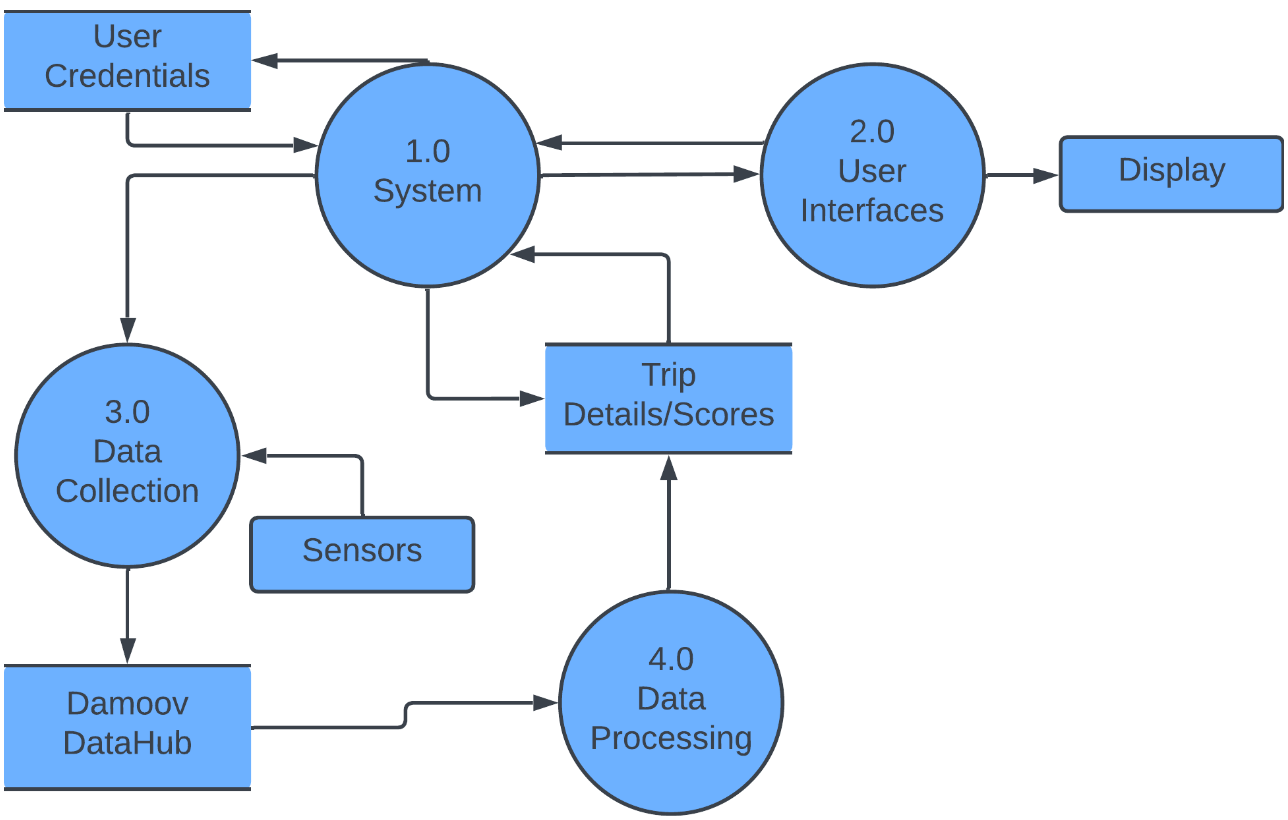
The HTTPS protocols update the application and data migration to DataHub storage.

5. System Architecture



DFD Level 0

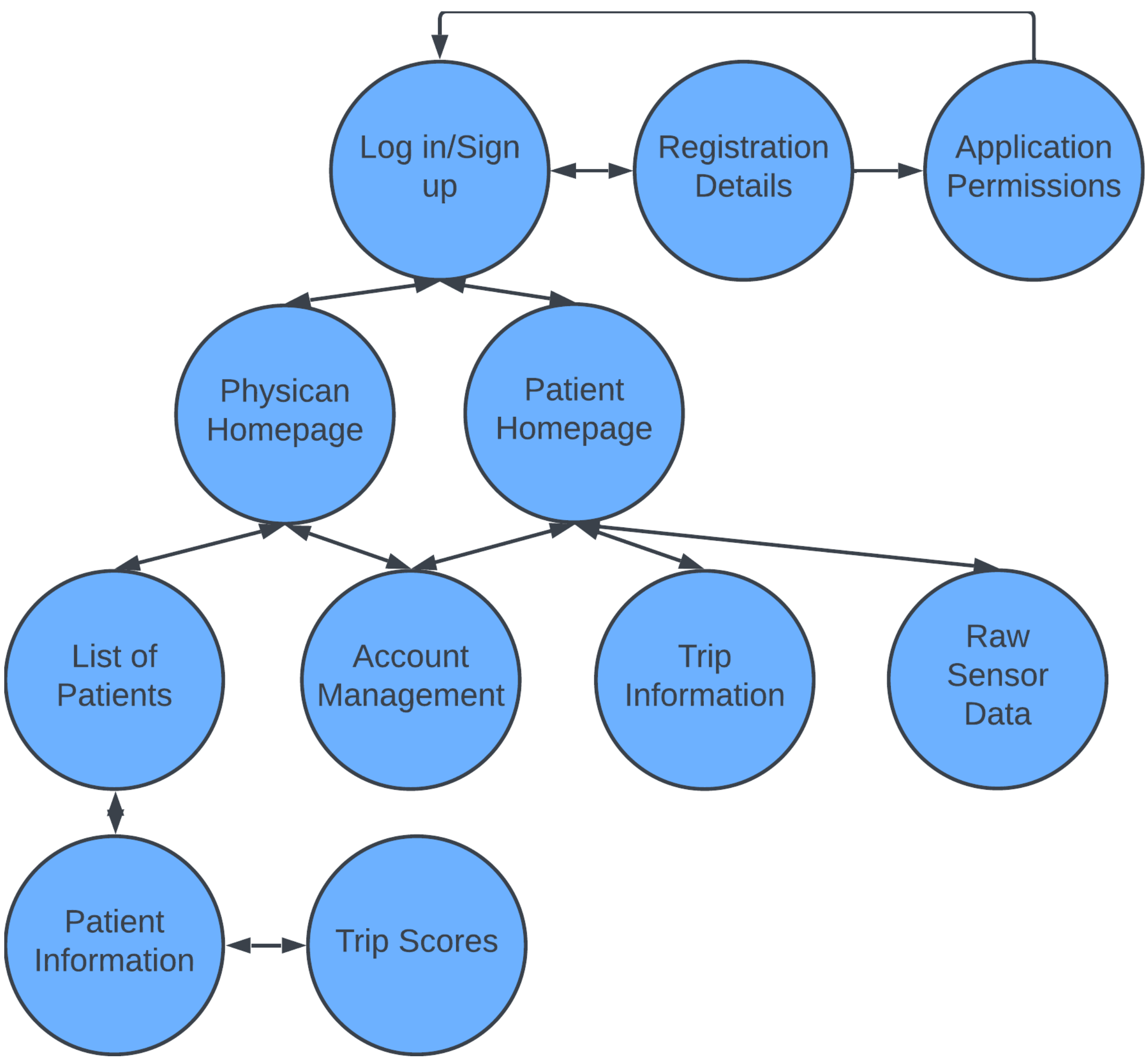
The system involves the patient, the application, and the physicians. The application must periodically collect sensor data from the smartphone while the patient is driving. Once the drive is completed, the application processes the raw data, which is sent to an external data storage platform. The processed data will be accessible through the physician's device or, in dire circumstances, relayed to the DMV as a CSV file.



DFD Level 1

Entity-Relationship

The system is responsible for collecting and processing driving data and displaying different user interfaces for the patient and physician. This is split into four modules in the system. The System module will communicate with the User Interface module to update the display. From the login screen, the User Interface module will send the user credentials to the System module to verify the account information stored in the User Credentials database. Once logged in, the System module will automatically collect data when driving is detected. The collected data will be encrypted and sent to the data storage platform DataHub. Once the driving has stopped, the Data Processing module will receive the data to analyze trip details and calculate driving scores. The processed data will be stored in a database where the System module can send it to the User Interface module to display.



6. Detailed System Design

6.1 Module-1 Registration/Login/Logout

Definition: The module enables users to create an account, log in and log out when needed, and retrieve credentials if they are forgotten.
Responsibilities: The module is responsible for providing login and logout functions for existing users and a registration function for new users. For users who forget their credentials, this component also provides account retrieval.
Constraints: This component requires users to provide physician or patient credentials when registering an account to help users enter different user interfaces. Patients cannot access the physician's page or observe their own driving in detail.
Composition: This component requires physician credentials or patient credentials to proceed with the registration step. When registering as a physician, you also need to provide your name and password. When patients register, they only need to provide their email address and password. Email and password will be used to log in.
Uses/Interactions: Users can register for an account, enter their username and password to log in to the software, and retrieve forgotten passwords.
Resources: Users need an internet connection to upload their credentials.
Processing: The system verifies credentials during registration and login to ensure authenticity. Processes user role information to provide appropriate access levels and interface customizations. Implements secure encryption methods for password storage and retrieval. Manages user sessions for secure login and logout operations.
Interface/Exports:

- User-Friendly Registration Form
- Secure Login Interface
- Password Recovery Option
- Role-Based Interface Customization
- Logout Button
- Confirmation Prompts
- Error Messages and Guidance

6.2 Module-2 Patient Homepage

Definition: The patient homepage component allows users to view simple statistics associated with their drives, with the most recent driving listed first. The user may view the route, total mileage, and time associated with each drive. They may also view their total mileage and driving time across all drives since the user began to use the system.
Responsibilities: The patient homepage component's main responsibility is to provide an overview of the route, mileage, and duration of the patient's drives since the patient began to use the application. The patient may also view files of the raw sensor information collected from each drive (e.g., information collected through accelerometers, gyroscopes, GPS systems, etc.).
Constraints: The patient homepage component must not provide any information about the patient's driving score, driving habits, or driving events. This information must be made solely available to the patient's physician.
Composition: The patient homepage component will be composed of distinct submodules for each drive. Within each submodule, the user may request to view the raw sensor information collected from each drive as a CSV file, in compliance with the California Consumer Policy Act (CCPA). There will also be a module displaying the user's total mileage and drive time.
Uses/Interactions: The patient may use the patient homepage component to check the route, mileage, duration, and raw sensor data associated with each of their drives. The patient may click on a submodule associated with a drive to view a map of the patient's drive path created with the collected GPS data.
Resources: The patient's homepage must have access to the internet in order to perform computations and write the computed values to the patient's homepage.
Processing: The drive mileage may be calculated by monitoring the patient's driving route using their smartphone's GPS. Drive time can be calculated as the difference in start and end time, which are respectively measured as the time when an individual began accelerating quickly and the time when an individual ceased to accelerate significantly for more than two minutes. The calculated mileage and duration will be written to a newly instantiated drive submodule that will then be published on the patient homepage.
Interface/Exports:

- Interactive Driving Statistics Dashboard
- Drive Details Expansion
- Cumulative Statistics Display
- User-Friendly Navigation and Layout

6.3 Module-3 Personal Information

Definition: The personal information component allows users to view and modify their personal information. It additionally enables users to add or change a physician.
Responsibilities: The personal information component allows users to view their personal information (i.e., their age, an optional parameter) and their physician's name. Additionally, in compliance with the CCPA, individuals may modify their age and request that sensory information collected from certain drives be deleted. Users have the opportunity to search for, add, or modify the physician with access to their driving data from the pool of physicians registered with the application. They may additionally change the unit of measurement for mileage (km/mi) and time (24/12 hours). If their physician has not registered an account yet, the user may fill out a form that will be sent to the physician, requesting them to create an account.
Constraints: The user may only search for physicians who have registered with the application.
Composition: The personal information module will be composed of a submodule listing the user's registered age and the physician who has access to the patient's data. Another submodule allows the user to search for a physician or clinic that they are affiliated with.
Uses/Interactions: The patient may use the personal information page to view and modify their personal information and search for a physician within the list of registered physicians within the system.
Resources: The personal information page must have access to the internet in order to access the patient's information within the database and write the information to the page.
Processing: The patient's personal information will be stored in a secure and encrypted database associated with a unique user identification number (henceforth, user ID) upon their registration. The information will then be written to the personal information page every time the user accesses it. The search function will draw from the database of physicians registered with the system. Search results will be determined by searching within the database to identify physicians whose personal or clinic names best match the user's input.
Interface/Exports:

- User Profile Editing Interface
- Physician Selection Tool
- Data Deletion Request Feature

6.4 Module-4 Physician Homepage

Definition: This component acts as a centralized dashboard for physicians to access and manage patient data.
Responsibilities: The physician homepage serves as the primary interface for physicians to interact with the system. It provides a comprehensive overview of all registered patients, their recent driving data, and alerts or notifications regarding any significant changes in a patient's condition.
Composition: This module may include subsections such as patient lists, recent alerts, and tools for data analysis. Each patient record could provide a quick overview of the patient's recent driving behavior and any notable trends or concerns.
Uses/Interactions: Physicians can use this module to quickly navigate to individual patient profiles, review detailed driving data, and make informed decisions about their care. This module might also offer functionalities for setting preferences, managing notifications, and accessing historical data for comparison.
Interface/Exports:

- Flutter
- Dashboard Layout
- Interactive Patient List
- Alerts and Notifications Panel
- Data Visualization Tools
- Quick Access to Patient Profiles
- Appointment Scheduler Interface
- Messaging Interface
- Customization and Settings
- Export Functionality
- Help and Support Access

6.5 Module-5 Patient View

Definition: The patient view component enables physicians to observe the driving statistics of their patients.
Responsibilities: The patient view component allows physicians to observe the patient's overall score, acceleration score, braking score, cornering score, etc. From this data, alerts or notifications can be generated to alert physicians about changes in a patient's condition.
Composition: This component includes all the patient’s driving details such as overall profile, driving time, acceleration, braking, cornering, etc., and provides specific scores to provide a snapshot of the patient’s recent driving.

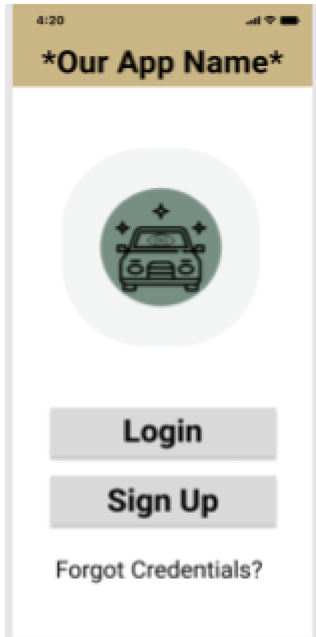
Uses/Interactions: This component allows the physician to access a patient's personal file to view their recent detailed driving data and conditions and make a quick judgment on the patient's condition.
Resources: This component requires secure and accurate data processing tools to help physicians analyze patients' driving conditions.
Interface/Exports:
- Driving Data Dashboard
- Patient Profile Overview
- Alerts and Notifications Panel
- Patient Selection Interface
- Score Explanation and Guidance
- Data Visualization Tools

6.6 Module-6 Physician Personal Information

Definition: This module enables physicians to manage their personal information within the system.
Responsibilities: This component enables physicians to update their contact information, professional credentials, and preferences related to the use of the system.
Composition: This module includes sections for personal details, professional qualifications, settings for communication preferences, and security settings (like password management).
Uses/Interactions: Physicians can update their information to ensure accurate communication with patients and the system administrators. They may also set preferences for how they receive notifications or reports about their patients.
Resources: Features to update professional details, credentials, and contact information. Options for adjusting notification settings, account security, and preferences for interacting with the system and patients.
Interface/Exports:
- Intuitive Profile Editor
- Qualifications and Credentials Management
- Customizable Notifications and Alerts
- Support and Help Resources

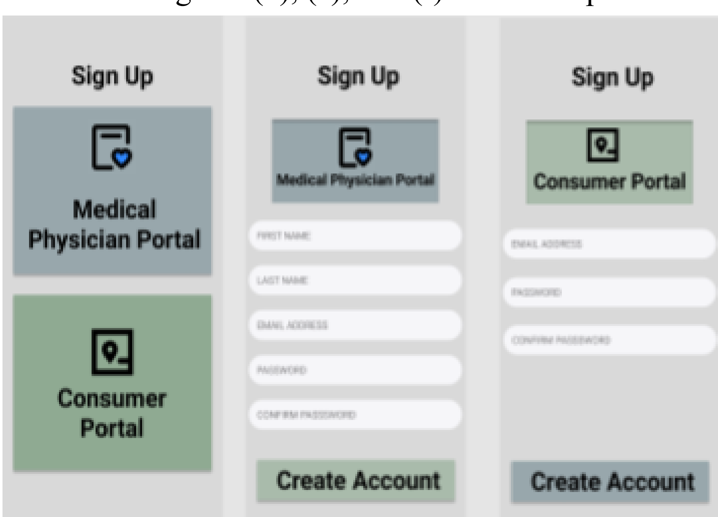
7. Graphical User Interface Design

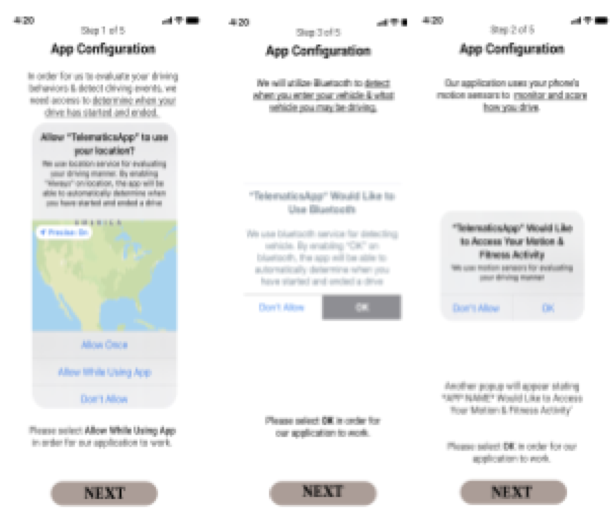
The Homepage UI is what the application displays when it is first launched. The user can log in, sign up, or reset their credentials from this UI. The fonts and buttons are large, and the colors used are comfortable for patients with low vision and are high-contrast which makes it easy to read. These design considerations will be seen throughout every patient-related UI.



Homepage UI

Figure (a) below shows the Sign Up UI which allows the user to register as either a physician (b) or a patient (c). The patient's Sign Up UI does not ask for sensitive information such as first and last names. Figures (d), (e), and (f) are mockup UIs asking for sensor permissions.



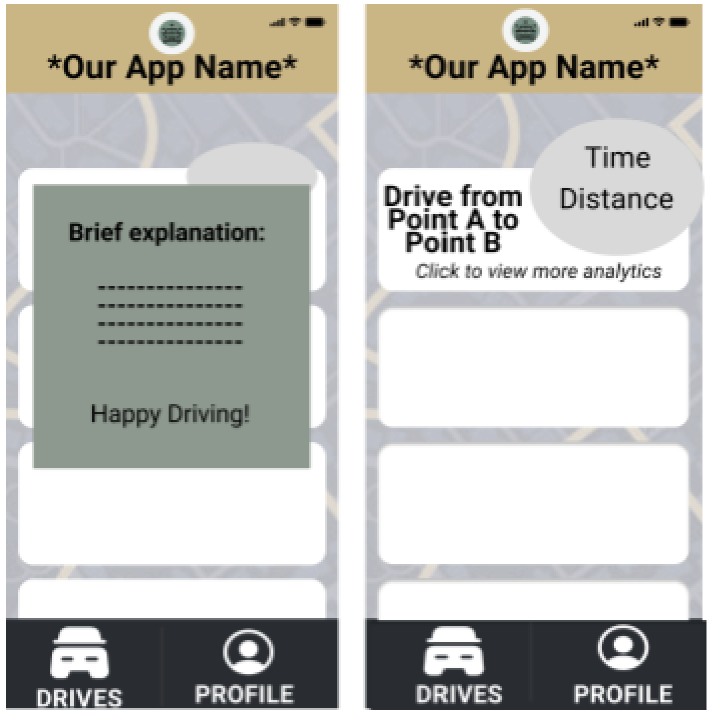


(a) (b) (c) (d) (e) (f)

Sign-up UIs

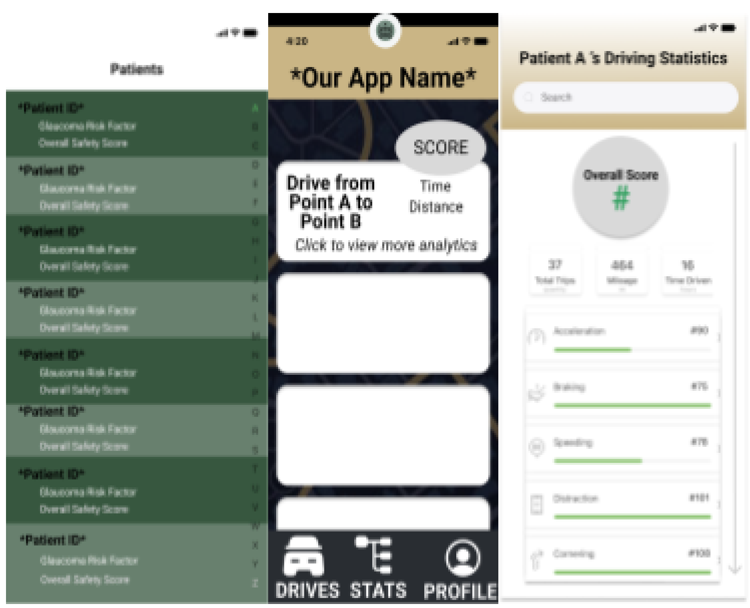
Application Permissions UIs

The Patient Homepage UI allows the patient to view their trip details such as trip duration, distance, and route. Also provided is a button to redirect the patient to their account settings where they can update their credentials and request the collected raw sensor data.



Patient UIs

The Physician Homepage UI allows the physician to select from a list of patients and view each individual's driving statistics. The physician may also navigate to their account settings to update their account credentials.



Physician UIs

S. Glossary

Advanced Encryption Standard (AES) 256: Symmetric cipher that generates a 256-bit key to encrypt and decrypt data

California Consumer Privacy Act (CCPA): State law that grants consumers rights over personal information collected and requires businesses to inform consumers about the collection, use, and retention of their personal information

Comma-separated Values (CSV): Text file format where tabular data data is stored in plain text where a data record is represented in a single line

Institutional Review Board (IRB): Appropriately composed group formally assigned to review and monitor biomedical research involving human subjects

Damoov: Telematics infrastructure that provides a software development kit for processing smartphone-sensor-collected driving data and configuration to internal online data storage platform DataHub

Dart: Programming language developed for app development

DataHub: Damoov's online data storage platform that acts as the backend configuration for products using the Telematics software development kit

Digital Phenotyping: Moment-by-moment quantification of human phenotype using personal digital device data

Figma: Industry-standard, collaborative web application for designing interfaces

Flutter: Open-source user interface software development kit created by Google for cross platform development

Glaucoma: General term for a group of eye diseases that damage the optic nerve and leading cause of blindness for individuals over the age of 60

Gyroscope: Measuring device in smartphones that measures orientation and angular velocity

Health Insurance Portability and Accountability Act (HIPAA): Federal law requiring national standards to protect medical information from being disclosed without a patient's knowledge or consent

JavaScript Object Notation (JSON): Text-based, data-interchange format that can be structured as a list of a collection of name/value pairs or an ordered list of values

Magnetometer: Measuring device in smartphones that measures the magnetic field along using the axes of motion for orientation sensing

Software Development Kit (SDK): Collection of software development tools

Sound Null Safety: Feature that guarantees that when a program and all its libraries is migrated, variables are not unintentionally null to prevent errors

Stateful Live Reload: Feature that allows for inserting edits to files and refresh the whole application with changes

Triaxial Accelerometer: Measuring device in smartphones that measures acceleration using the axes of motion compared to gravity