
Design and Architecture Specification

for

EKG Using Cloud Services

Version 1.0

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Revision History

Name	Date	Reason For Changes	Version
Team 4	11/3/2020	First Draft	1.0

1. Introduction

1.1 Purpose

The purpose of this document is to provide an informative description of the Electrocardiography Cloud Services. More precisely, an enhancement on the overall system. Further, this document shows both functional and non-functional requirements, as well as other requirements such as features, and the system interface.

1.2 Document Conventions

This Document was created based on the IEEE template for System Requirement Specification Documents

1.3 Intended Audience and Reading Suggestions

This SRS document is applicable to Developer, System Architect, System Tester, System Manager, and stakeholder.

The remaining sections of this document are organized in the following order, in Section 2 an overall general description of the project is discussed. Section 3 provides external interface requirements that include user GUI, software, hardware, and communication interface. Section 4 gives the domain model. Whereat section 5 discusses system features, which include use cases and functional requirements. Finally, non-functional requirements are covered in section 6.

1.4 Product Scope

This EKG Cloud Service system delivers an improvement over existing EKG system. This system will facilitate the process of viewing and monitoring patient records by healthcare professionals. Furthermore, the system allows healthcare providers to deliver personal and reliable services towards patients' overall experience. That encompasses advance alerts for critical changes in their EKG study, in conjunction with maintaining scalability, security, and accuracy. Also, to grant patients real-time access to their records. Thus, system administrator can implement any necessary modification.

1.5 References

Hsieh, Jui-chen; Hsu, Meng-Wei; 'BMC Medical Informatics and Decision Making'
<https://bmcmmedinformdecismak.biomedcentral.com/articles/10.1186/1472-6947-12-77>

Nasiff Associates, Inc. 'CardioCard EKG Module'
https://nasiff.com/ecg_restingbt.html

Amazon Web Services – Internet of Things Framework,

<https://aws.amazon.com/iot/>

Health and Human Services, 'Summary of the HIPAA Privacy Rule',
<https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>

2. Overall Description

2.1 Product Perspective

EKG is one of the extensively used diagnostic tools in clinical cardio medicine. It records electric signals from heart to monitor and detect heart problems, making the accessibility of data in this field very crucial. The proposed system tries to enhance the existing EKG services by allowing doctors to monitor patients through a portable device from patient home. It is equipped with a Data Acquisition Card to transfer patient data to cloud which can be monitored by the doctor at hospital. Web application is created for patients, doctor, and hospital administration to view and update the data according to their accessibility levels in the proposed idea.

2.2 Product Functions

The key functions of the product are stated as follows:

1. Authentication to access the application.
2. Collecting patient data through DAQ card and EKG device.
3. List all the registered users accessing the application.
4. Access the patient data from cloud for decision processing.
5. Add/Remove the users from system.

Figures 2.1, 2.2, and 2.3 present major system functionality leveraged by the various system users. These functions are depicted by summarized use case diagrams.

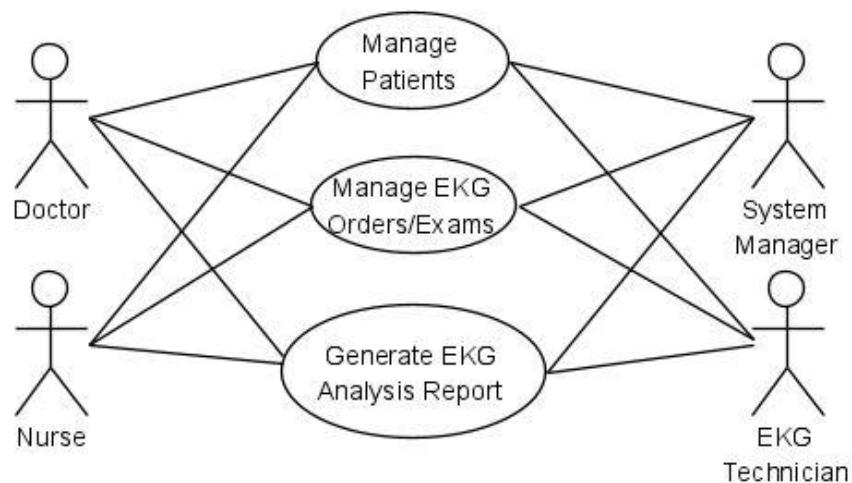


Figure 2.1: Healthcare Staff Functions Diagram

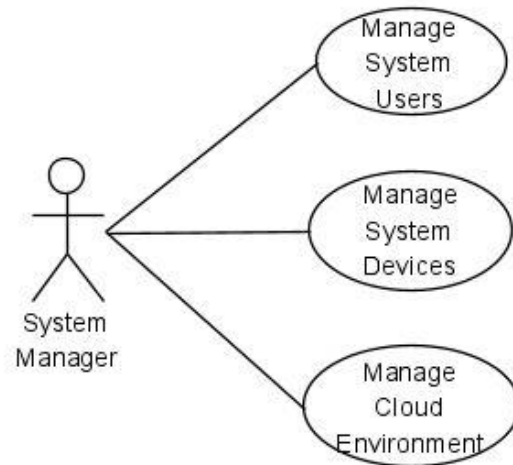


Figure 2.2: System Manager Functions Diagram

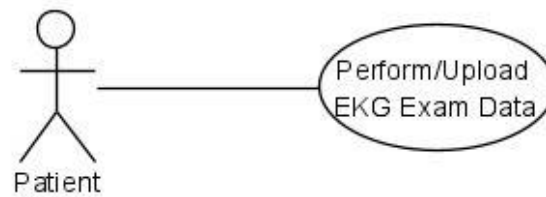


Figure 2.3: Patient Functions Diagram

2.3 System Architecture

The user classes and characteristics listed below have different technical scope as well as privilege levels

1. **Patient:** In this user class, only registered patients can have access to their records. This class has the least visibility among all users since they can only view their EKG records in both simple view and EKG view.
2. **Doctor:** Doctors have access to all the registered patients and can view their complete records including prescriptions and staff assigned.
3. **Nurse/EKG Technician:** In this class users can access patient records from cloud and update them for easy access. They are also responsible for setting up patients with DAQ cards enabling data to be transferred to cloud from patient home.
4. **System Administrator:** This user class has the highest privilege other user types. They are responsible for adding or removing patients/employees from the system. Administrators control after the statistics /reports of all the registered users of system.

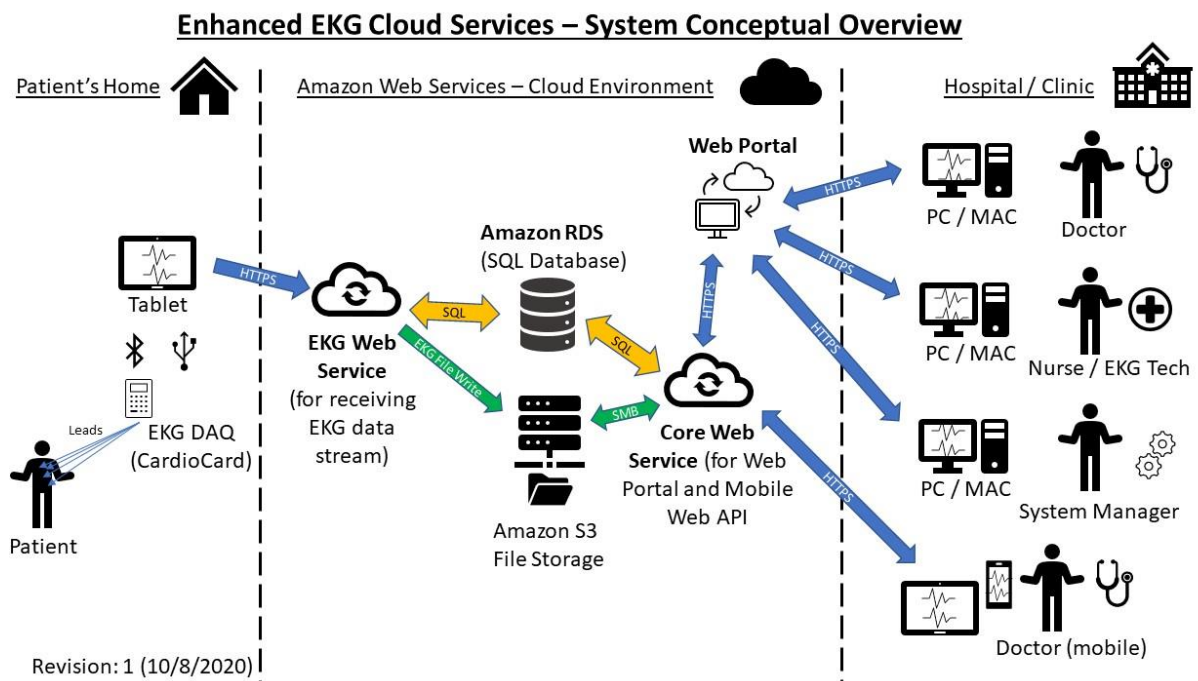


Figure 2.4: EKG Cloud Services Architecture Diagram

2.4 Operating Environment

Software Platform - The application will be developed on python and hosted on AWS cloud platform.

Hardware – EKG devices and DAQ card to collect and send data from patient to cloud.

Database – Amazon RDS for SQL Server is used to setup a database on cloud and store the patient information.

Operating System - Prime goal is to keep the system independent of OS for better operability and ease of functionality, so the user can access the system using any of the main operating systems like Windows, Linux, iOS.

3. Physical and Deployment Diagrams

3.1 Database Deployment Diagram

The following diagram serves as a guide for the database developer to construct and deploy the SQL database to the Amazon AWS Relational Database Service environment. The diagram clearly outlines the tables including their respective columns, datatypes, and nullability.

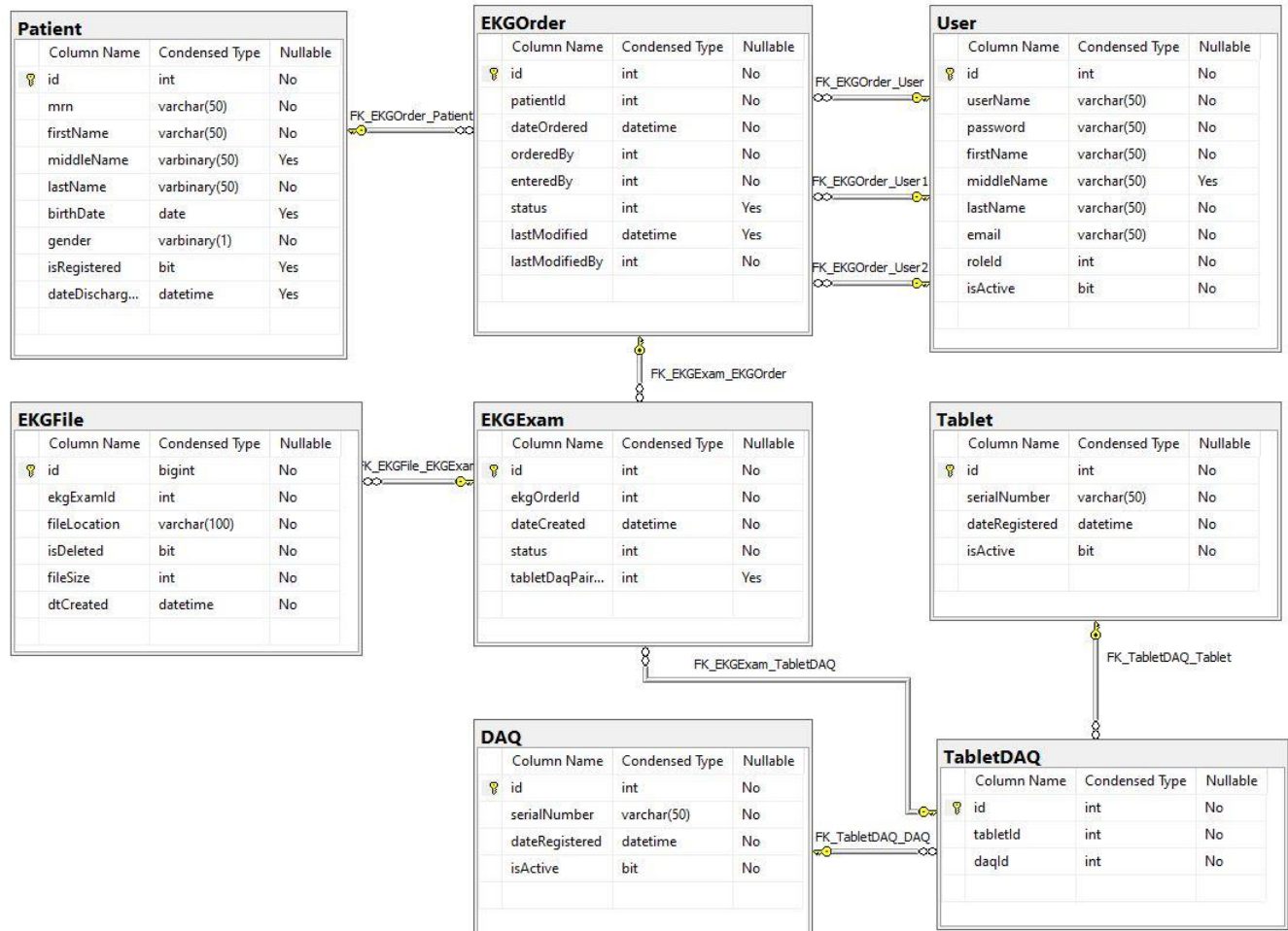


Figure 3.1: EKG Cloud Services Database Deployment Diagram

3.2 User Interfaces

The following illustrations are mockups of the type of user interface that can be expected on the final product. There are three types of users for the system: patients, doctors/nurses and EKG technicians, and system managers.

Patient Interface

The patient has the most limited amount of accessibility to the software. The patient is only responsible for attaching the EKG leads in the home setting and starting the data logging software on the tablet as shown in Fig. 3.2:

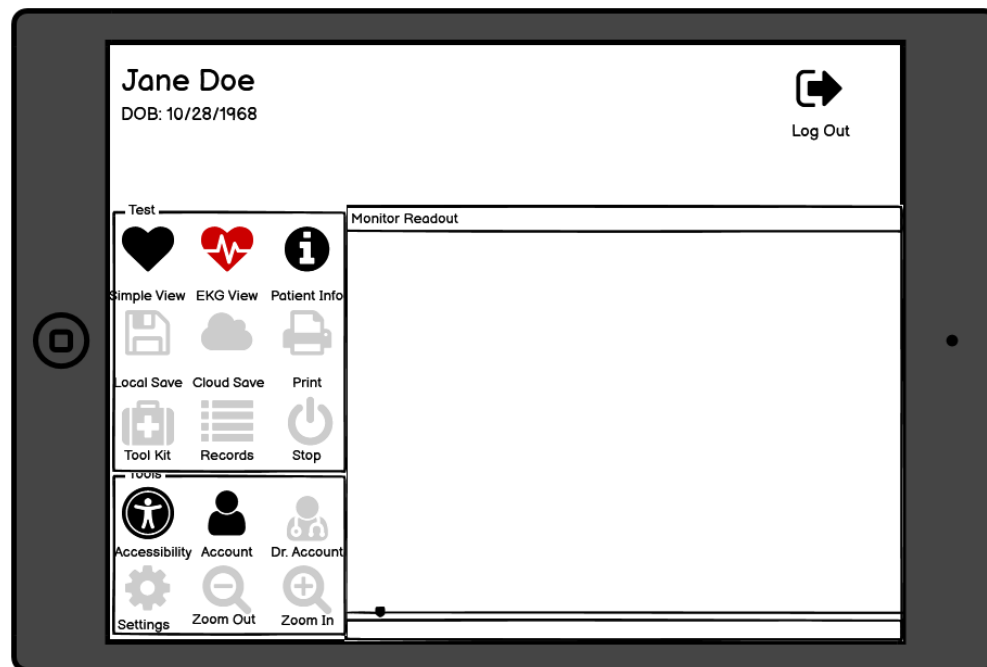


Figure 3.2: Patient side tablet view. Note that inaccessible features are grey.

Doctors, Nurses and EKG Technicians

Doctors, nurses, and EKG technicians can access the EKG system by mobile device or web browser. The user interface for these users are shown in figures 3.3, 3.4, 3.5, and 3.6.

User Login

https://www.ecgcloudsolutions/login

Username

Password

Login

Forgot your [username?](#)
Forgot your [password?](#)

[Home](#) | [Products](#) | [Company](#)

Figure 3.3: Login page for web users.

Patient Directory

https://www.ecgcloudsolutions.com/directory

Hello James Pepper

Logout [Account Settings](#)

Please enter a date below to access patient records.

Patient Name (Last, First)	Age	Physician	Nurse	Prescribed Medications	Test Results
Adams, Gregory	53	J. Pepper	S. Wilson	Open PDF	Results
Beauregard, Emily	38	E. Davis	J. Joyce	none	Pending
Doe, Jane	62	J. Pepper	I. Taylor	Open PDF	Results
Hernandez, Maria	76	E. Davis	S. Taylor	Open PDF	Pending
Jones, Zachary	36	J. Donnelly	R. Anderson	Open PDF	Results
Miller, Thomas	57	J. Pepper	W. Henderson	none	Results
Parker, Melissa	39	E. Davis	J. Joyce	Open PDF	Results
Rodriguez, Jaime	15	J. Donnelly	S. Taylor	Open PDF	Pending

Figure 3.4: Patient directory page for web users.

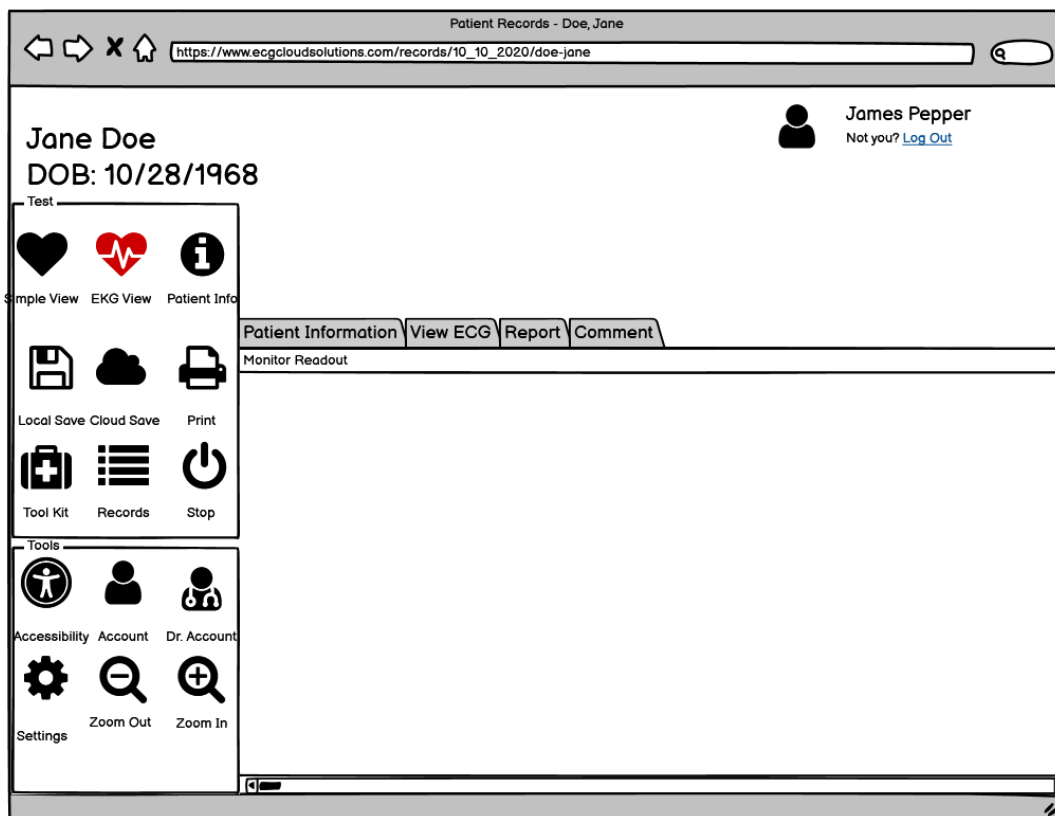


Figure 3.5: Patient record view (web browser)

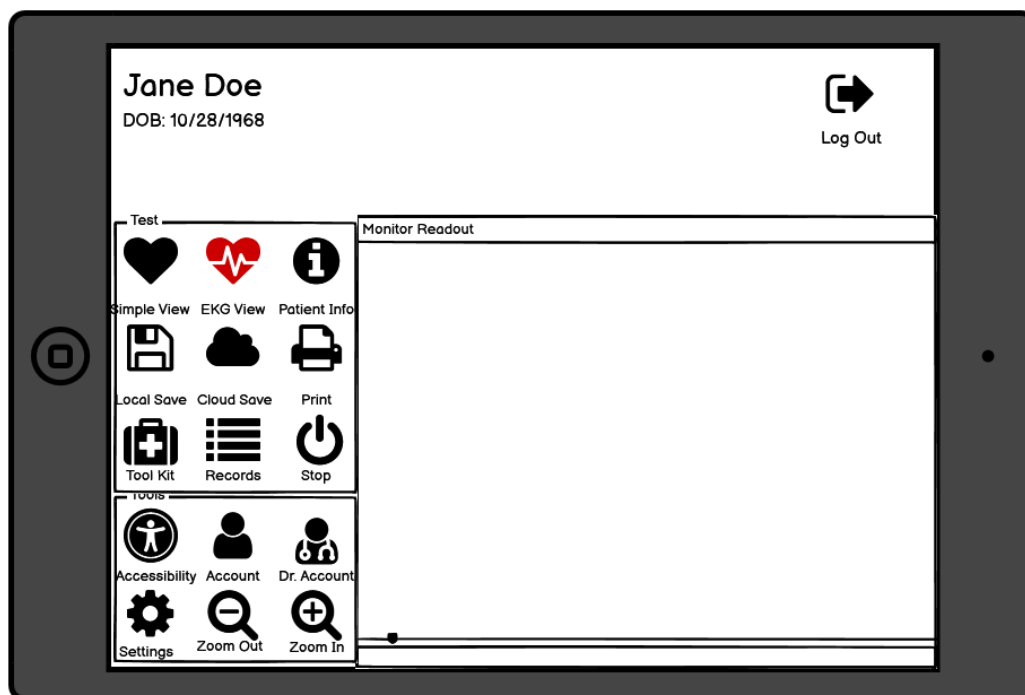


Figure 3.6: Patient record view (tablet)

System Managers

System managers use the same log in screen to sign into the system management web portal. They are taken to the interface in figure 3.7:

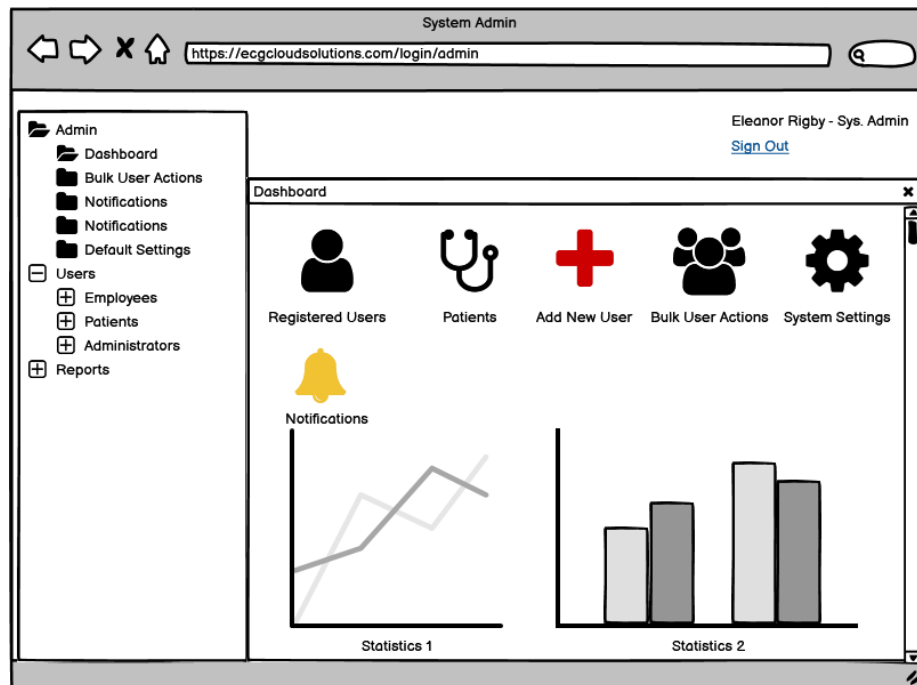


Figure 3.7: System Management Dashboard

3.3 Hardware Interfaces

Since this system is meant to complement medical equipment, an attempt has been made to incorporate as much existing hardware as possible to avoid lengthy approval processes by the FDA. As such, the EKG leads, and EKG Data Acquisition System (DAQ) use existing hardware. The DAQ chosen is the Nasiff CardioCard Mobile. It connects directly to the EKG leads and communicates wirelessly via Bluetooth to a tablet in the patient's home. Figure 3.8 shows the EKG DAQ. It may also be connected via USB.



Figure 3.8: CardioCard DAQ Module and Leads

3.4 Software Interfaces

The following is used as software interfaces:

- Amazon Web Services - Cloud Environment

Amazon Web Services has all the tools necessary to implement this system across web browsers and mobile devices. Amazon RDS will be used as an SQL database. Amazon S3 File Storage is used to house EKG files for use by the core web service. The doctor's mobile device interfaces directly with the core web service through an application. Otherwise, the core web service interfaces with the web portal for use with web browsers.

3.5 Communications Interfaces

Communication interfaces to be used:

- Bluetooth
- USB
- HTTPS
- Wi-Fi
- Ethernet

Bluetooth or USB may be used to transfer the raw EKG data to the collection device. The collection device requires an internet connection. The data is then transferred via HTTPS to the Amazon Cloud service. Once in the cloud, the data can be accessed from a client device through HTTPS. The client device may be networked via ethernet or Wi-Fi.

4. Class Design, Use Cases, and Sequence Diagrams

4.1 Class Design Diagram

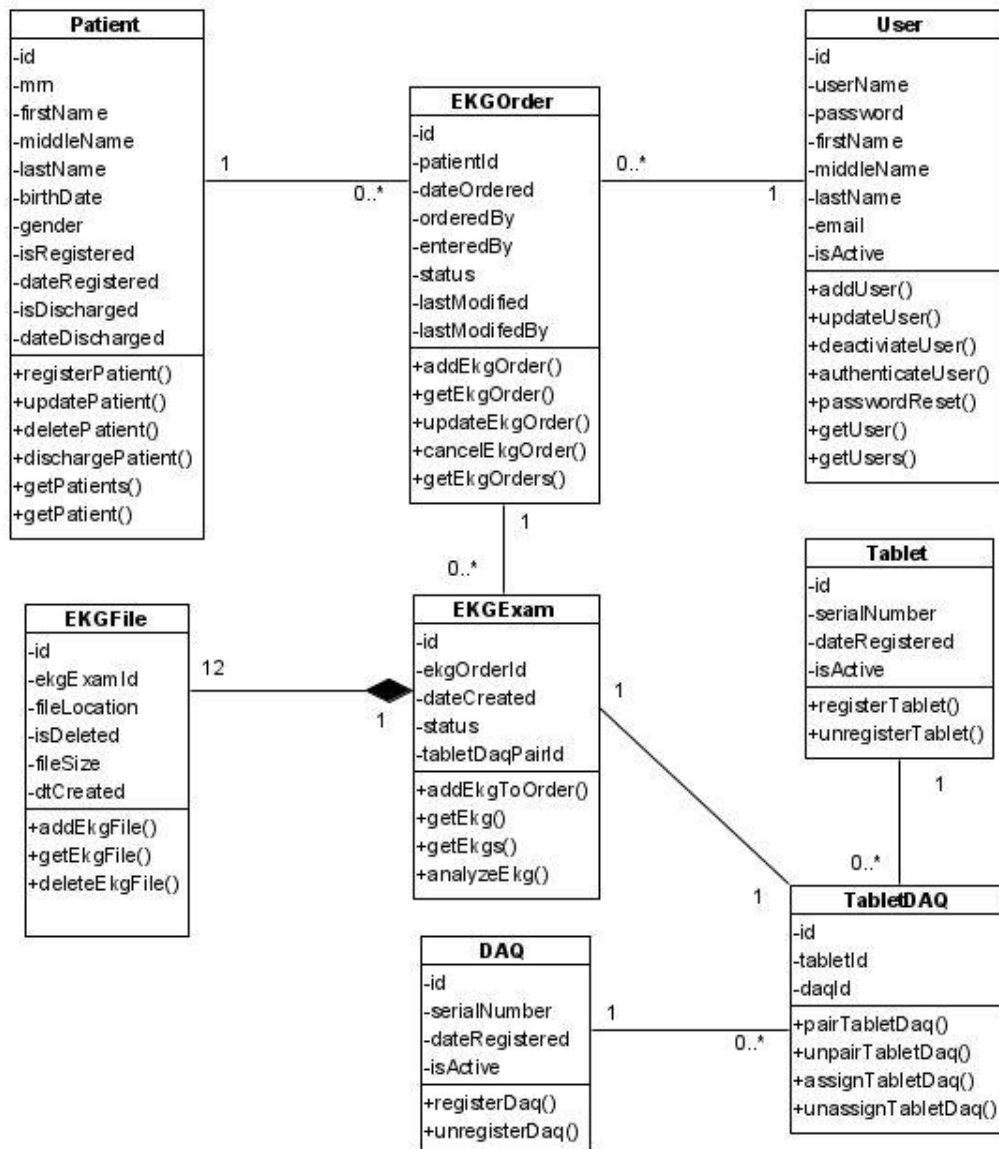


Figure 4.1: EKG Cloud Services Class Diagram

4.2 Use Cases Diagram

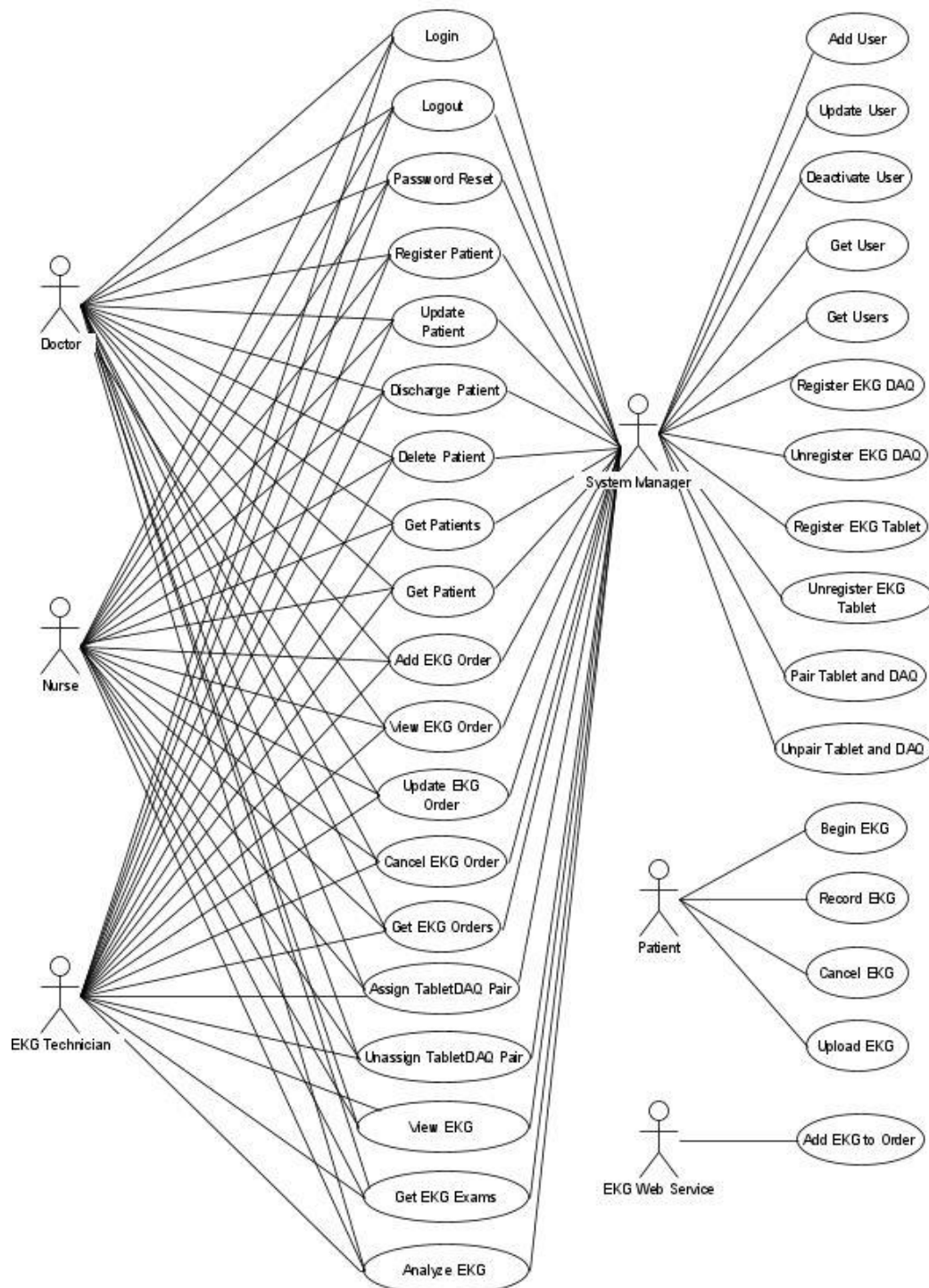


Figure 4.2: EKG Cloud Services Use Cases Diagram

4.3 Sequence Diagrams

Sequence diagrams are provided to represent the interaction more clearly between the various system actors and other system components. A sequence diagram has been constructed and outline for each use case specified in Figure 4.2 in section 4.2.

4.3.1 Login

4.3.1.1 Name: Login

4.3.1.2 Diagram

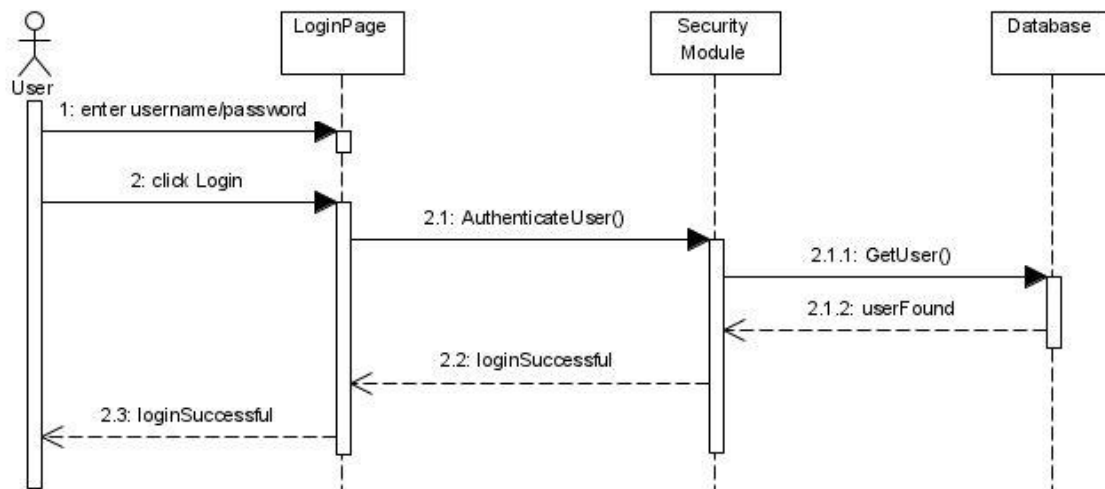


Figure 4.3: Login Sequence Diagram

4.3.2 Logout

4.3.2.1 Name: Logout

4.3.2.2 Diagram

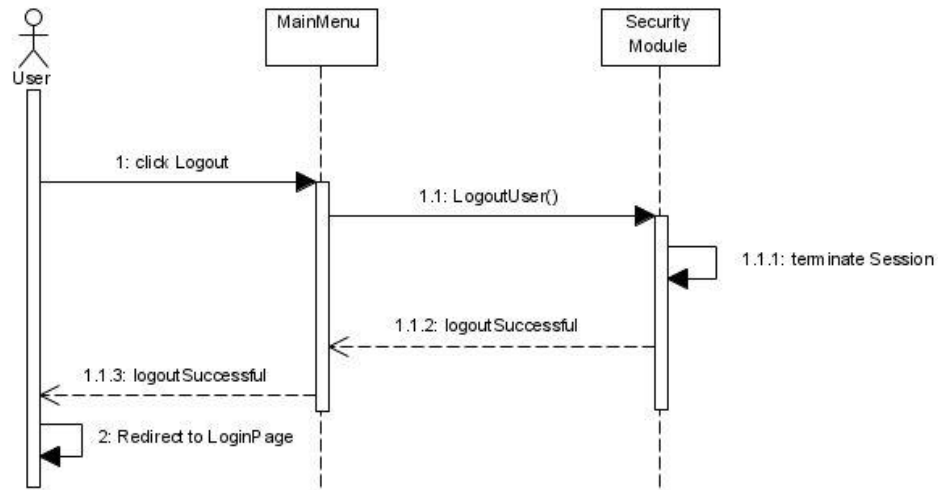


Figure 4.4: Logout Sequence Diagram

4.3.3 Add User

4.3.3.1 Name: Add User

4.3.3.2 Diagram

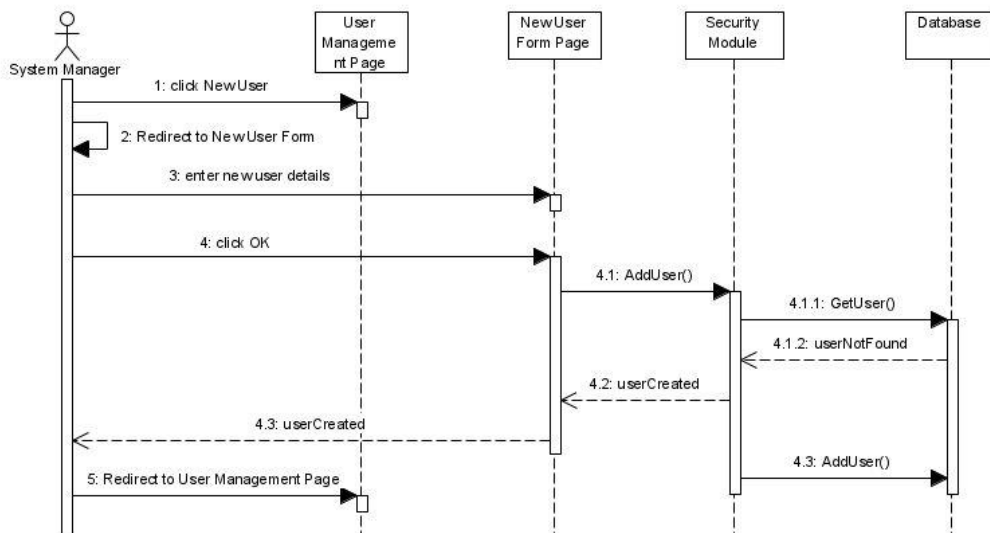


Figure 4.5: Add User Sequence Diagram

4.3.4 Update User

4.3.4.1 Name: Update User

4.3.4.2 Diagram

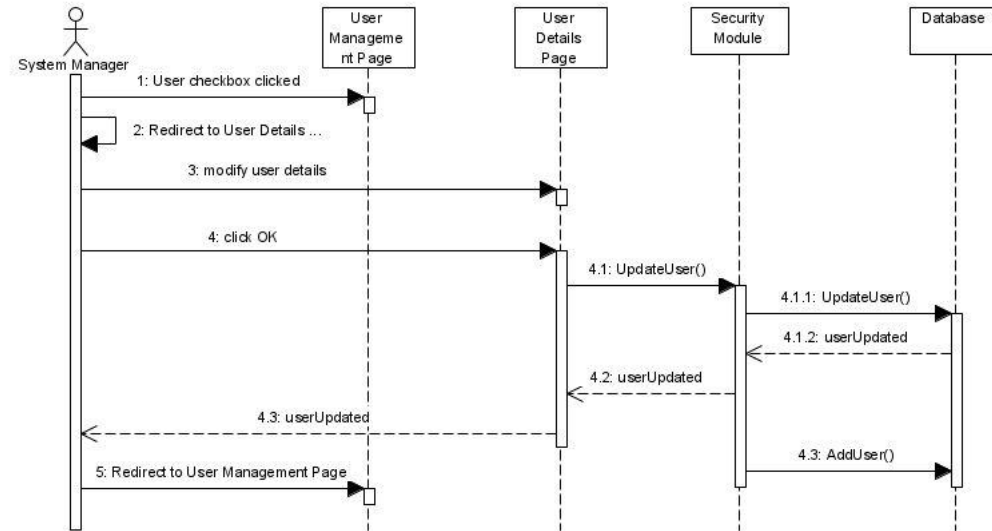


Figure 4.6: Update User Sequence Diagram

4.3.5 Deactivate User

4.3.5.1 Name: Deactivate User

4.3.5.2 Diagram

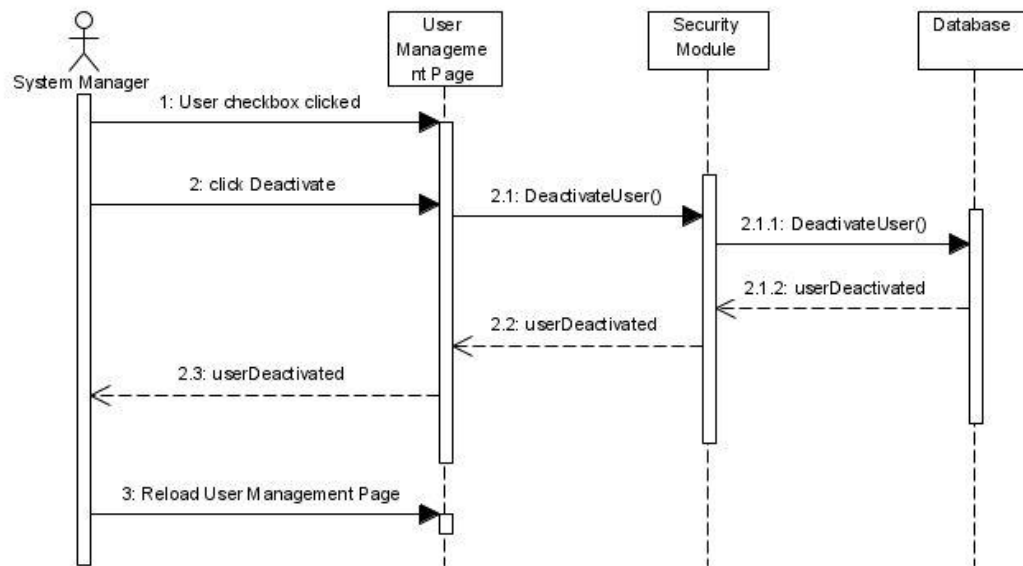


Figure 4.7: Deactivate User Sequence Diagram

4.3.6 Password Reset

4.3.6.1 Name: Password Reset

4.3.6.2 Diagram

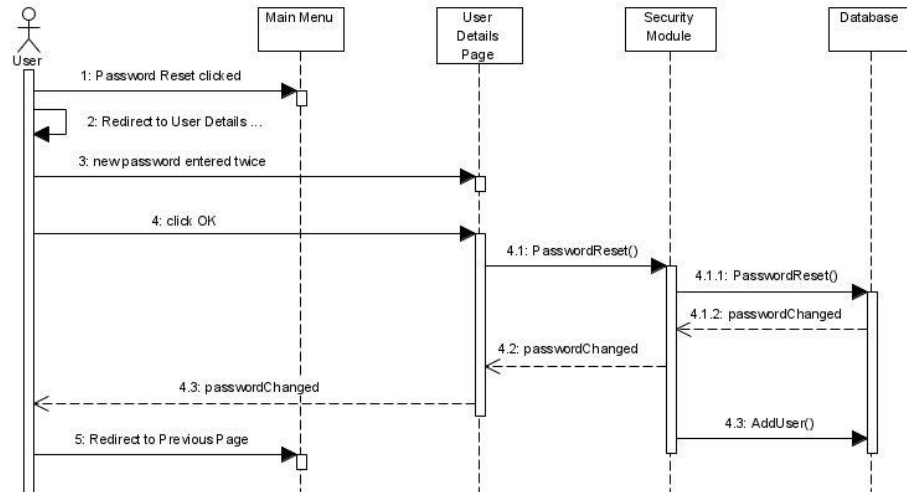


Figure 4.8: Password Reset Sequence Diagram

4.3.7 Get User

4.3.7.1 Name: Get User

4.3.7.2 Diagram

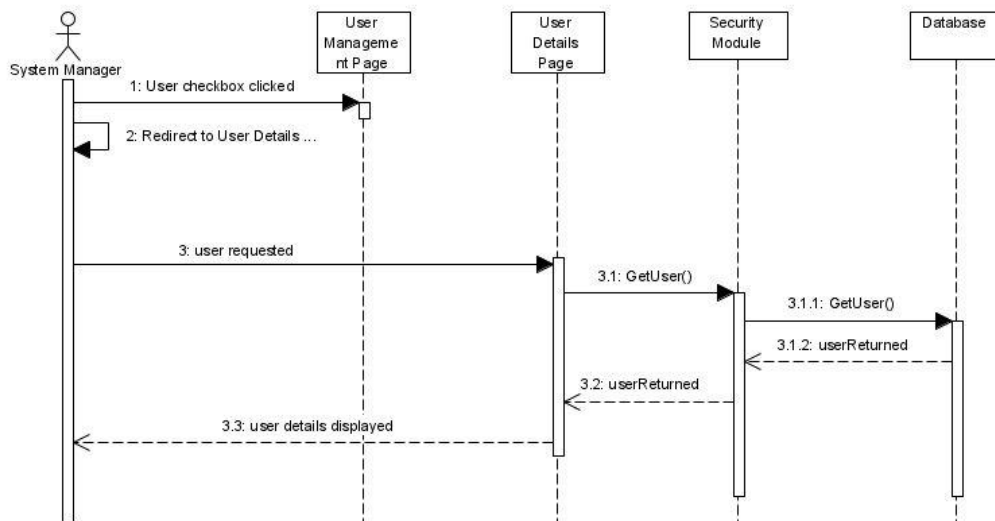


Figure 4.9: Get User Sequence Diagram

4.3.8 Get Users

4.3.8.1 Name: Get User

4.3.8.2 Diagram

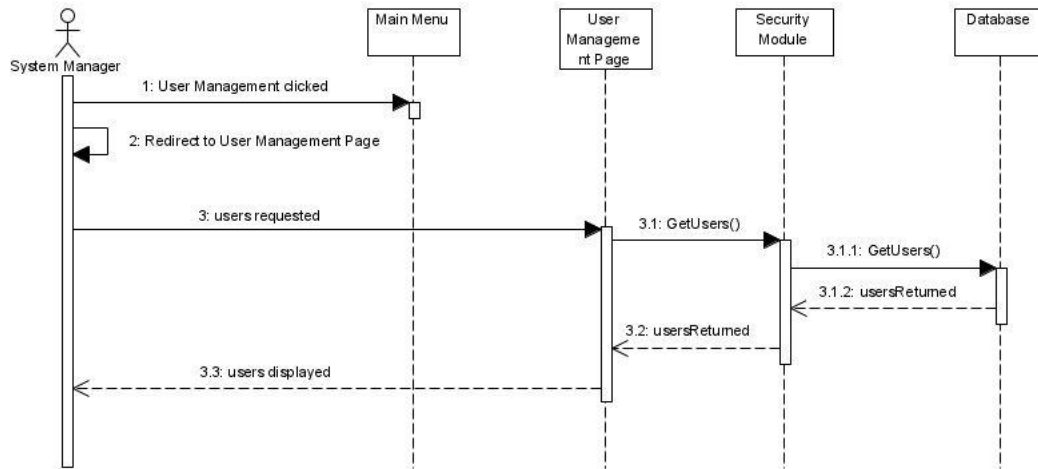


Figure 4.10: Get Users Sequence Diagram

4.3.9 Register EKG DAQ

4.3.9.1 Name: Register EKG DAQ

4.3.9.2 Diagram

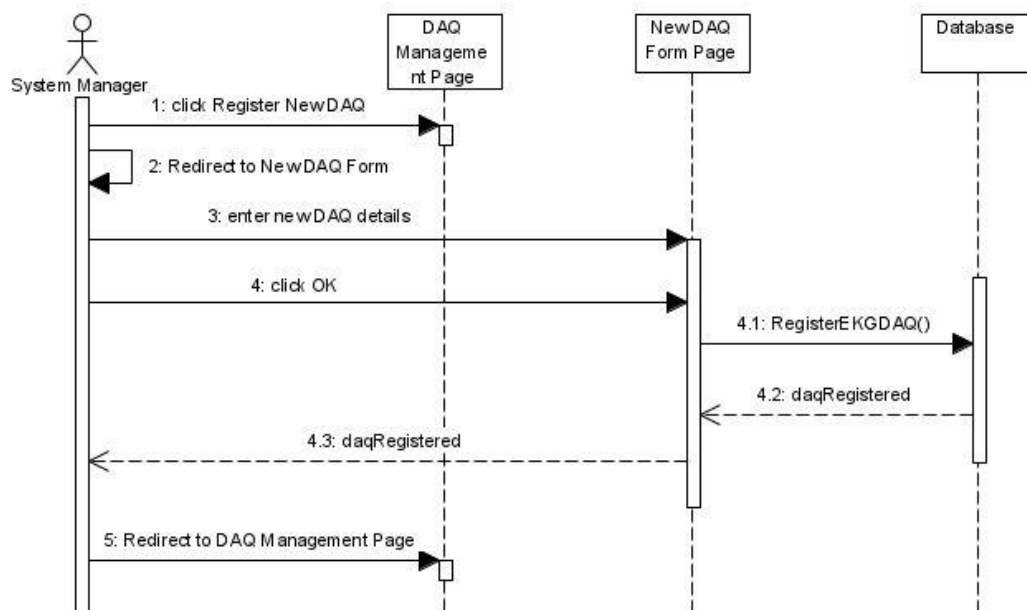


Figure 4.11: Register EKG DAQ Sequence Diagram

4.3.10 Unregister EKG DAQ

4.3.10.1 Name: Unregister EKG DAQ

4.3.10.2 Diagram

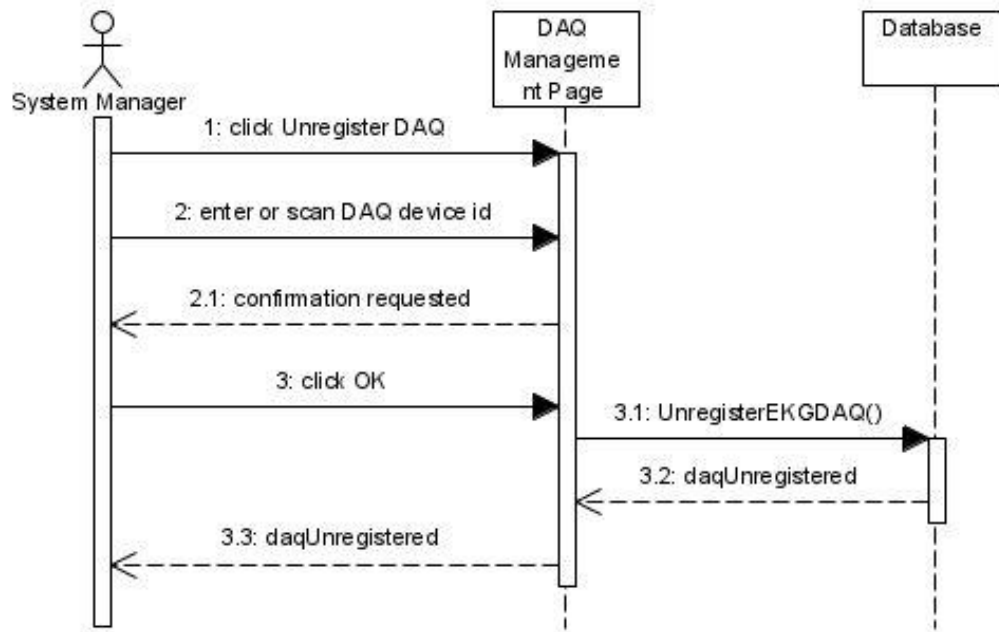


Figure 4.12: Unregister EKG DAQ Sequence Diagram

4.3.11 Register EKG Tablet

4.3.11.1 Name: Register EKG Tablet

4.3.11.2 Diagram

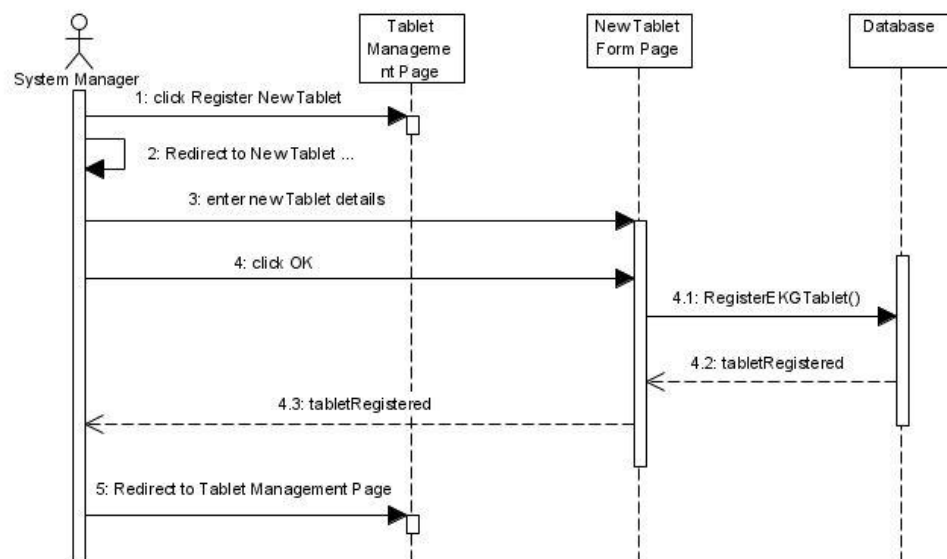


Figure 4.13: Register EKG Tablet Sequence Diagram

4.3.12 Unregister EKG Tablet

4.3.12.1 Name: Unregister EKG Tablet

4.3.12.2 Diagram

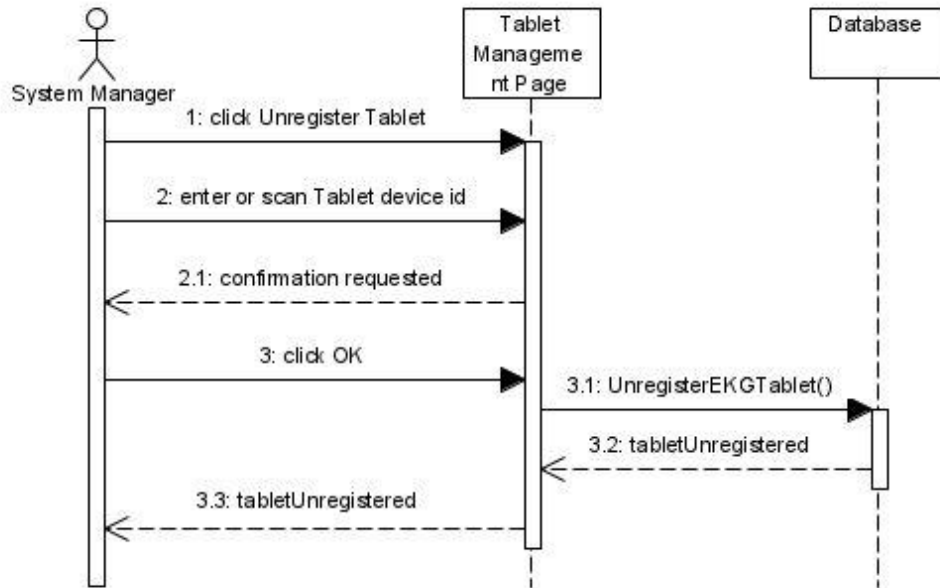


Figure 4.14: Unregister EKG Tablet Sequence Diagram

4.3.13 Pair Tablet and DAQ

4.3.13.1 Name: Pair Tablet and DAQ

4.3.13.2 Diagram

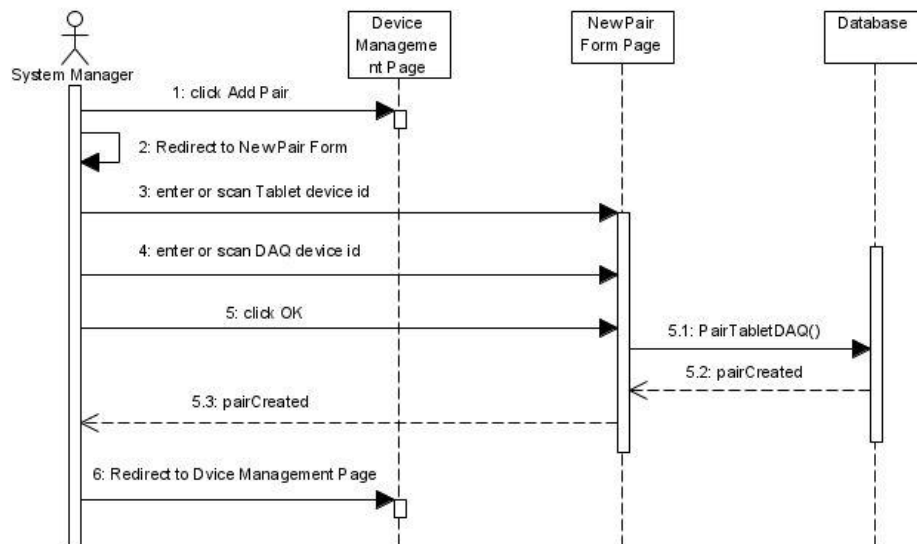


Figure 4.15: Pair Tablet and DAQ Sequence Diagram

4.3.14 UnPair Tablet and DAQ

4.3.14.1 Name: UnPair Tablet and DAQ

4.3.14.2 Diagram

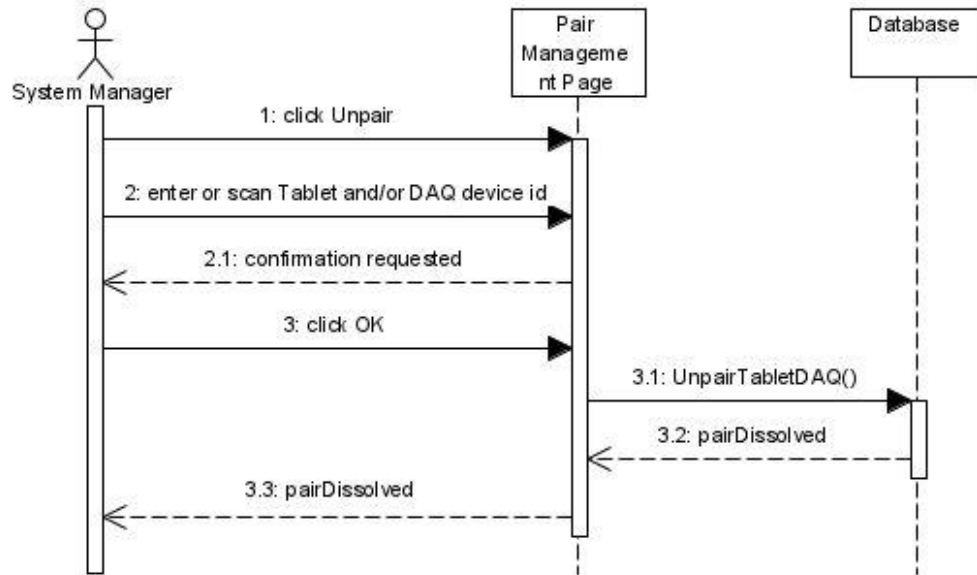


Figure 4.16: Unpair Tablet and DAQ Sequence Diagram

4.3.15 Register Patient

4.3.15.1 Name: Register Patient

4.3.15.2 Diagram

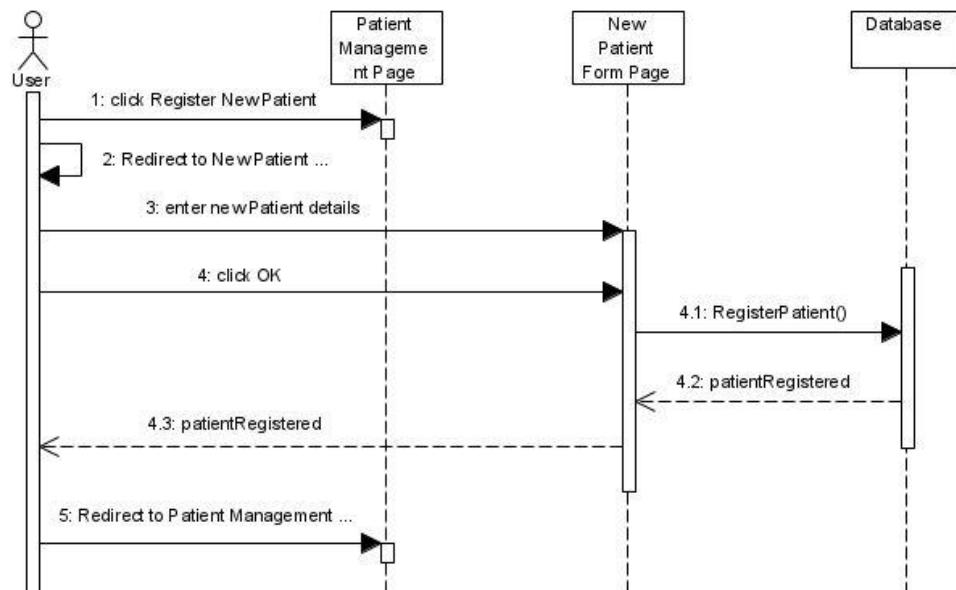


Figure 4.17: Register Patient Sequence Diagram

4.3.16 Update Patient

4.3.16.1 Name: Update Patient

4.3.16.2 Diagram

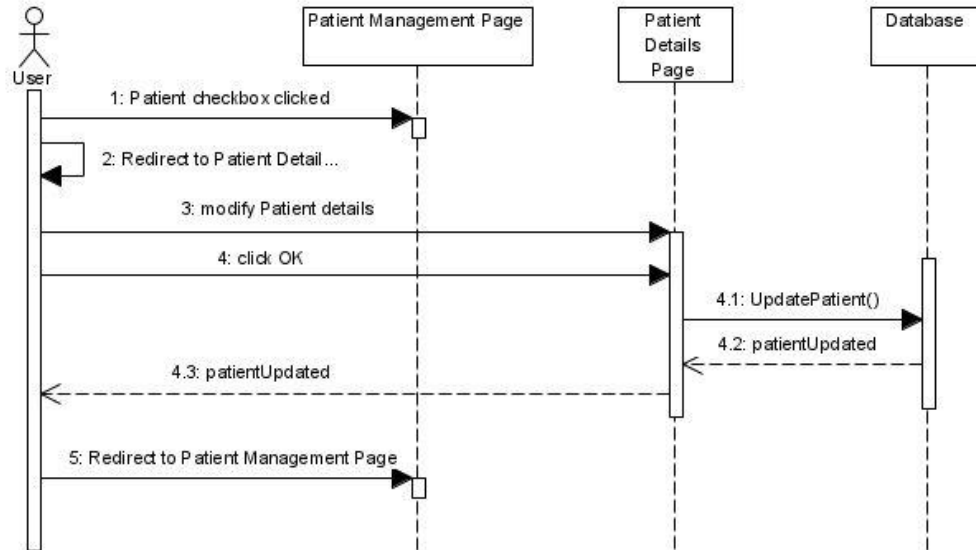


Figure 4.18: Update Patient Sequence Diagram

4.3.17 Discharge Patient

4.3.17.1 Name: Discharge Patient

4.3.17.2 Diagram

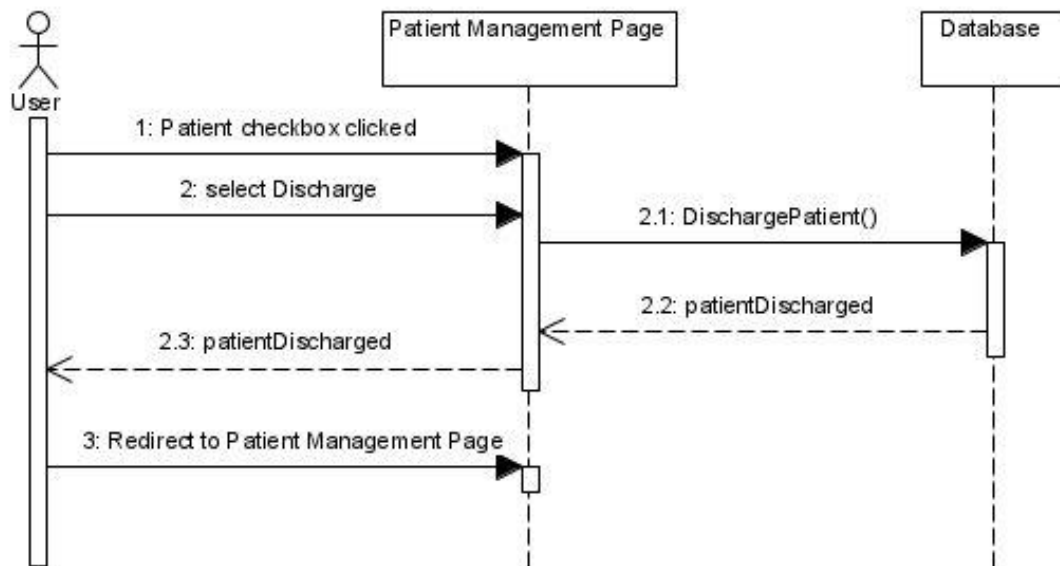


Figure 4.19: Discharge Patient Sequence Diagram

4.3.18 Delete Patient

4.3.18.1 Name: Delete Patient

4.3.18.2 Diagram

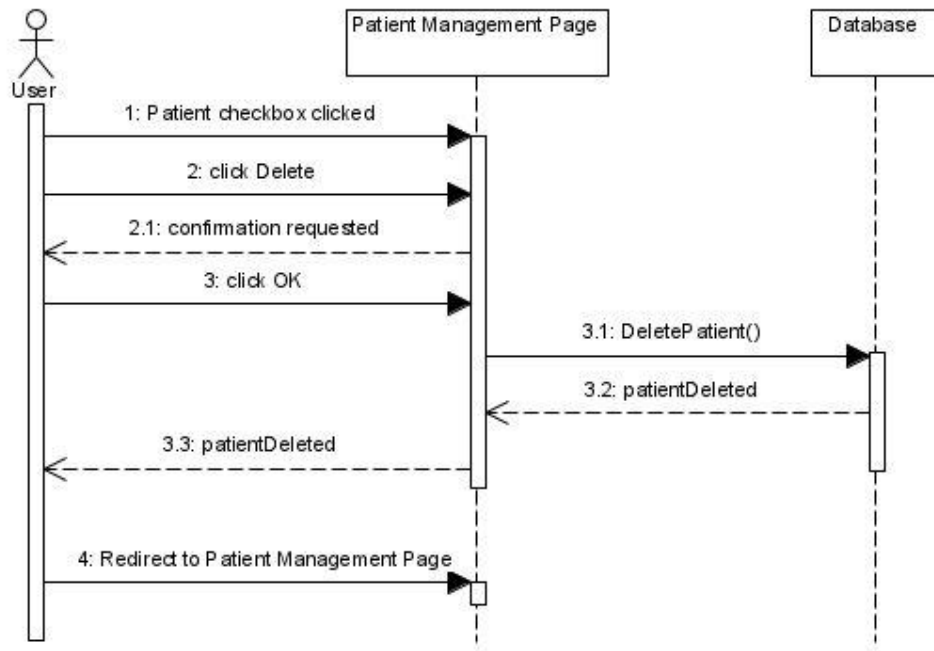


Figure 4.20: Delete Patient Sequence Diagram

4.3.19 Get Patients

4.3.19.1 Name: Get Patients

4.3.19.2 Diagram

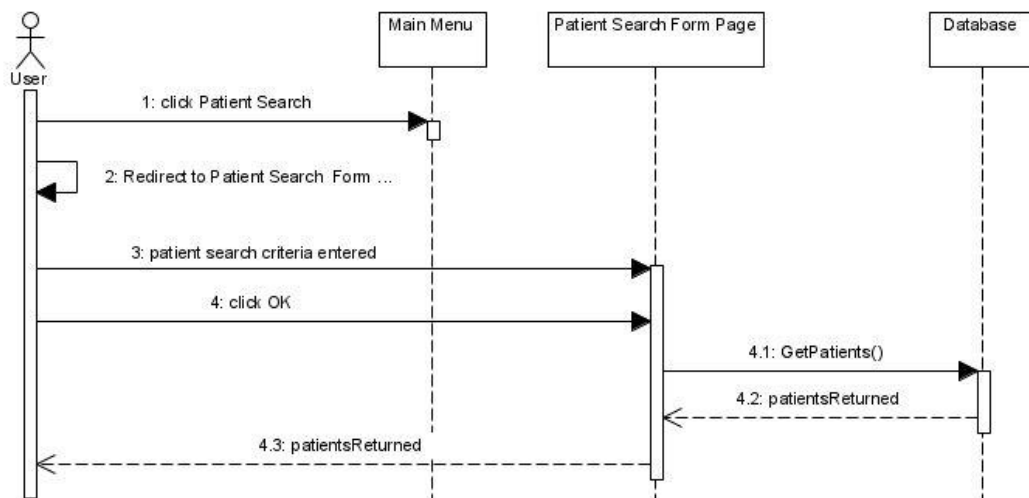


Figure 4.21: Get Patients Sequence Diagram

4.3.20 Get Patient

4.3.20.1 Name: Get Patient

4.3.20.2 Diagram

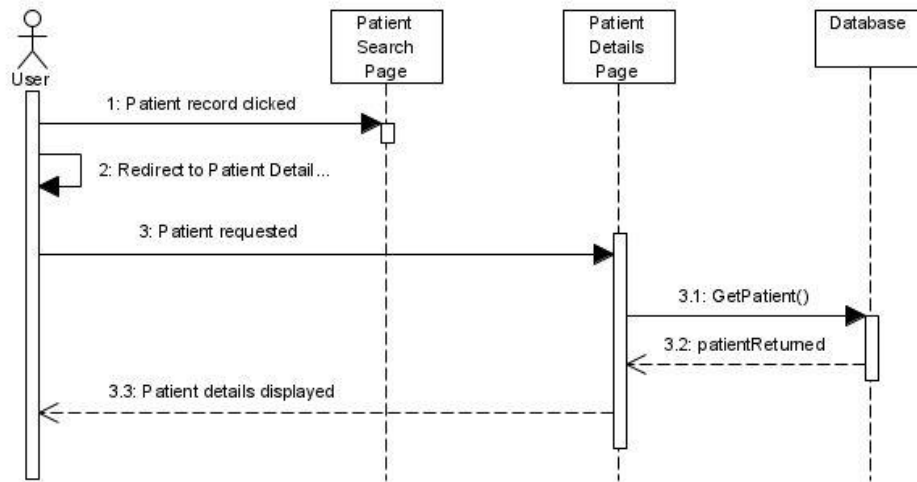


Figure 4.22: Get Patient Sequence Diagram

4.3.21 Add EKG Order

4.3.21.1 Name: Add EKG Order

4.3.21.2 Diagram

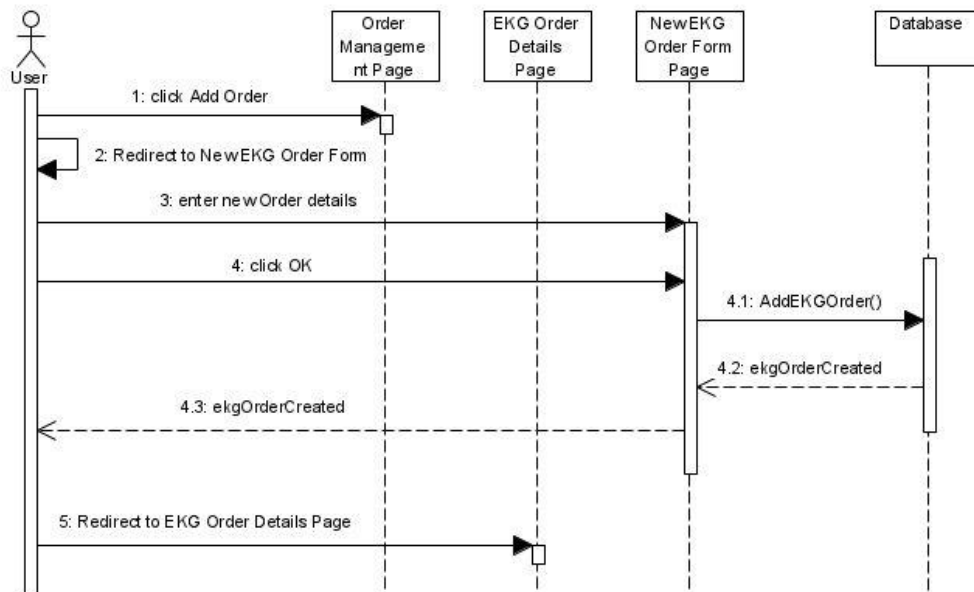


Figure 4.23: Add EKG Order Sequence Diagram

4.3.22 View EKG Order

4.3.22.1 Name: View EKG Order

4.3.22.2 Diagram

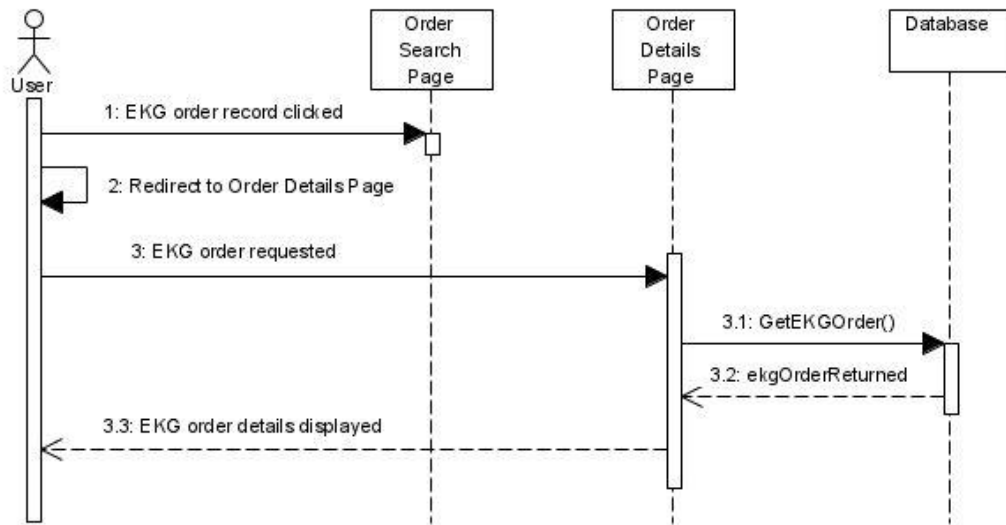


Figure 4.24: View EKG Order Sequence Diagram

4.3.23 Update EKG Order

4.3.23.1 Name: Update EKG Order

4.3.23.2 Diagram

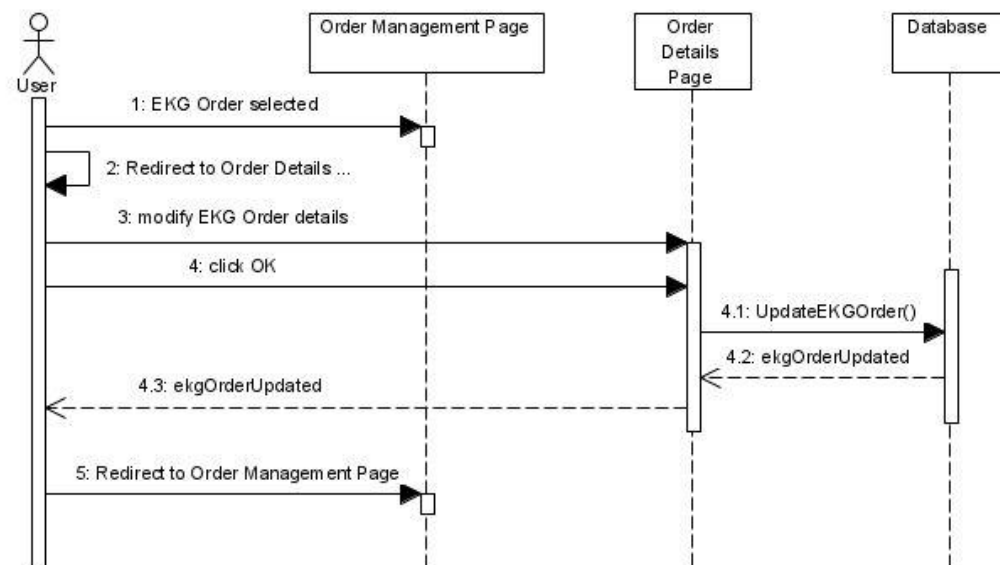


Figure 4.25: Update EKG Order Sequence Diagram

4.3.24 Cancel EKG Order

4.3.24.1 Name: Cancel EKG Order

4.3.24.2 Diagram

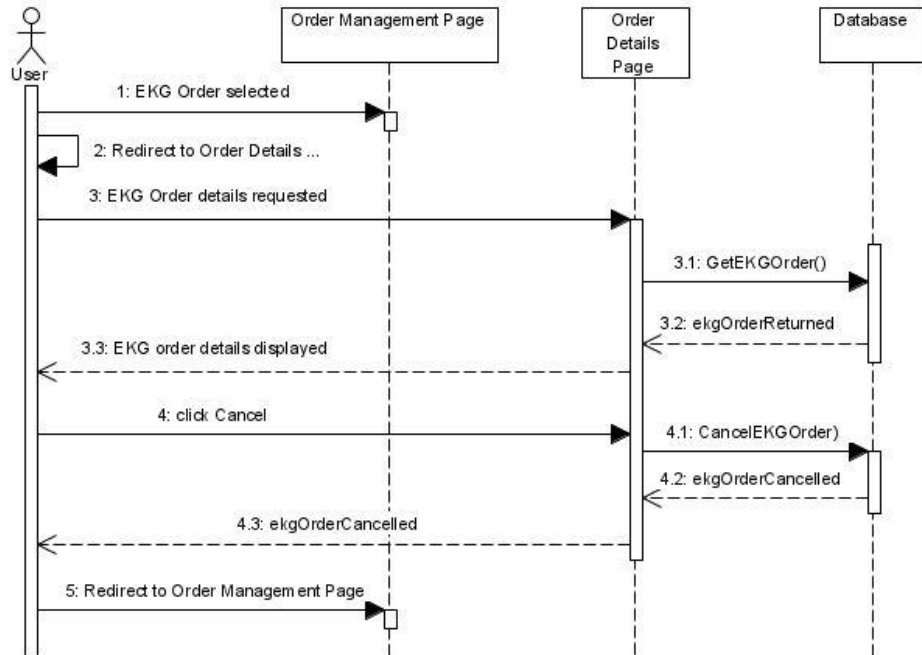


Figure 4.26: Cancel EKG Order Sequence Diagram

4.3.25 Get EKG Orders

4.3.25.1 Name: Get EKG Orders

4.3.25.2 Diagram

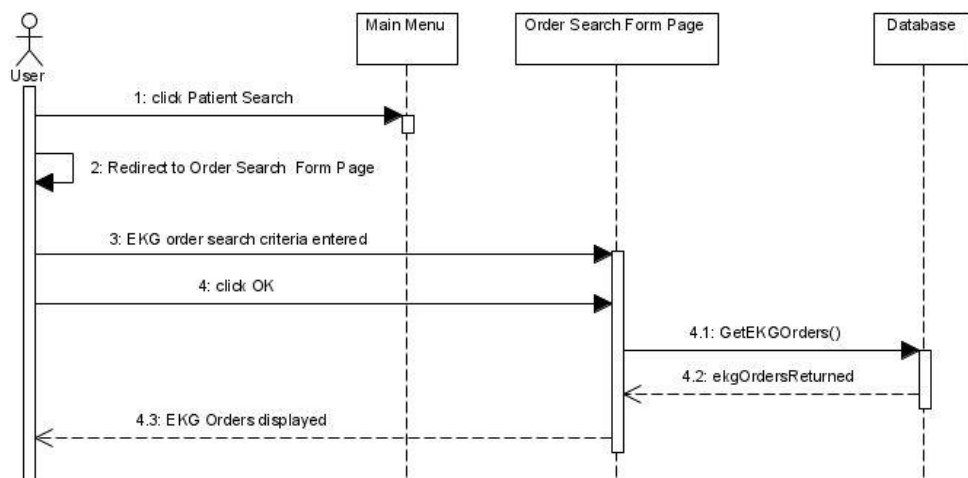


Figure 4.27: Get EKG Orders Sequence Diagram

4.3.26 Assign TabletDAQ Pair

4.3.26.1 Name: Assign TabletDAQ Pair

4.3.26.2 Diagram

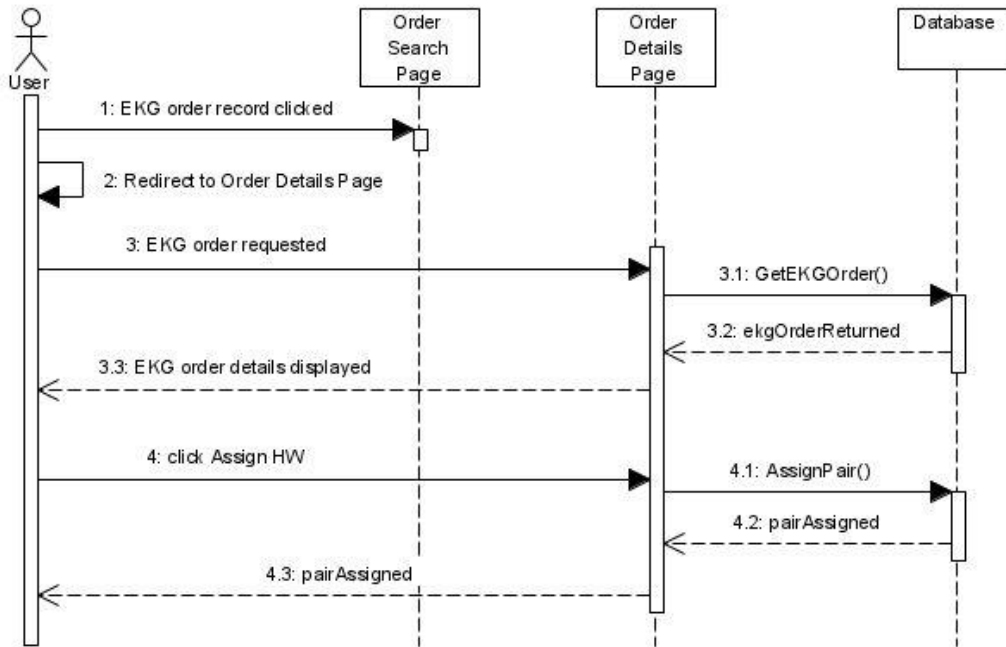


Figure 4.28: Assign TabletDAQ Pair Sequence Diagram

4.3.27 Unassign TabletDAQ Pair

4.3.27.1 Name: Unassign TabletDAQ Pair

4.3.27.2 Diagram

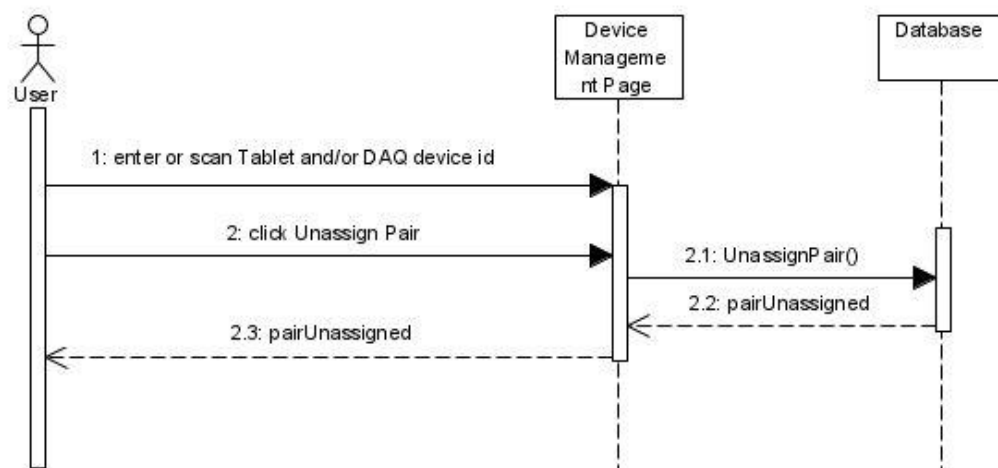


Figure 4.29: Unassign TabletDAQ Pair Sequence Diagram

4.3.28 Begin EKG

4.3.28.1 Name: Begin EKG

4.3.28.2 Diagram

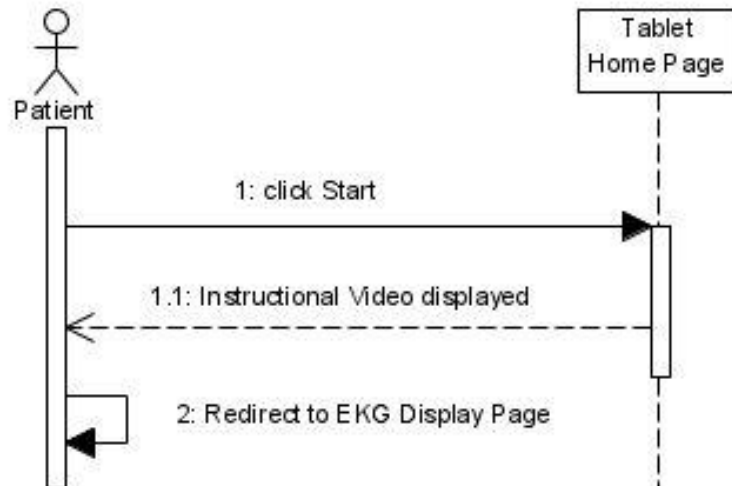


Figure 4.30: Begin EKG Sequence Diagram

4.3.29 Record EKG

4.3.29.1 Name: Record EKG

4.3.29.2 Diagram

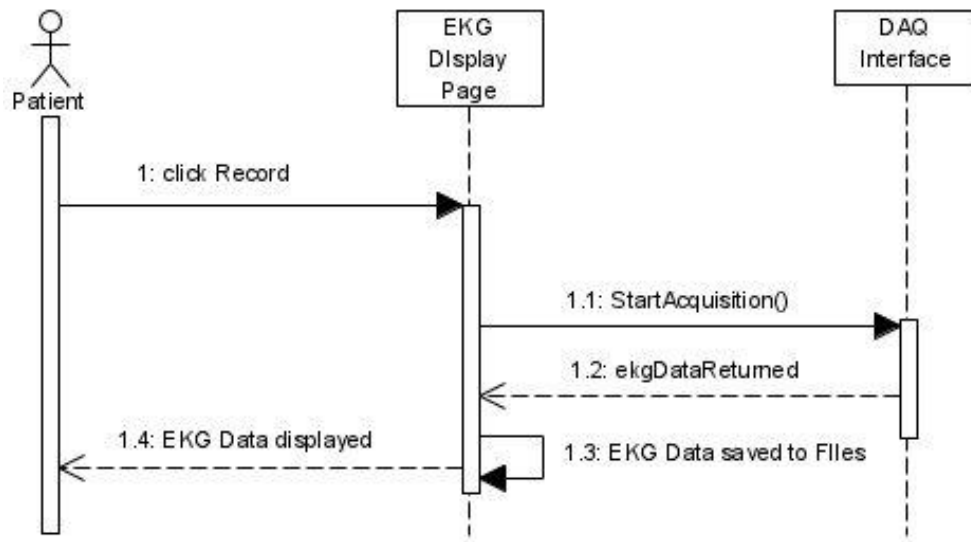


Figure 4.31: Record EKG Sequence Diagram

4.3.30 Cancel EKG

4.3.30.1 Name: Cancel EKG

4.3.30.2 Diagram

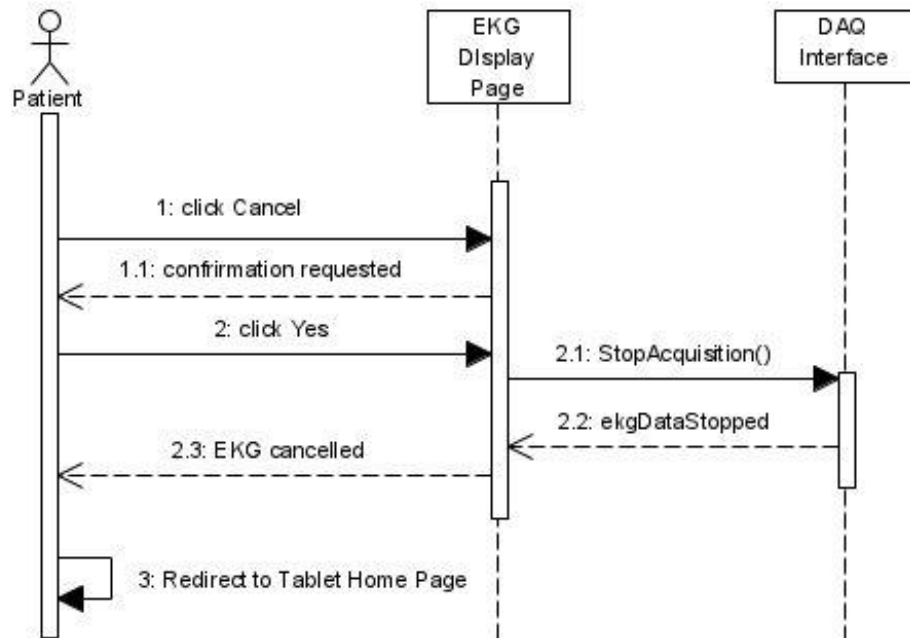


Figure 4.32: Cancel EKG Sequence Diagram

4.3.31 Upload EKG

4.3.31.1 Name: Upload EKG

4.3.31.2 Diagram

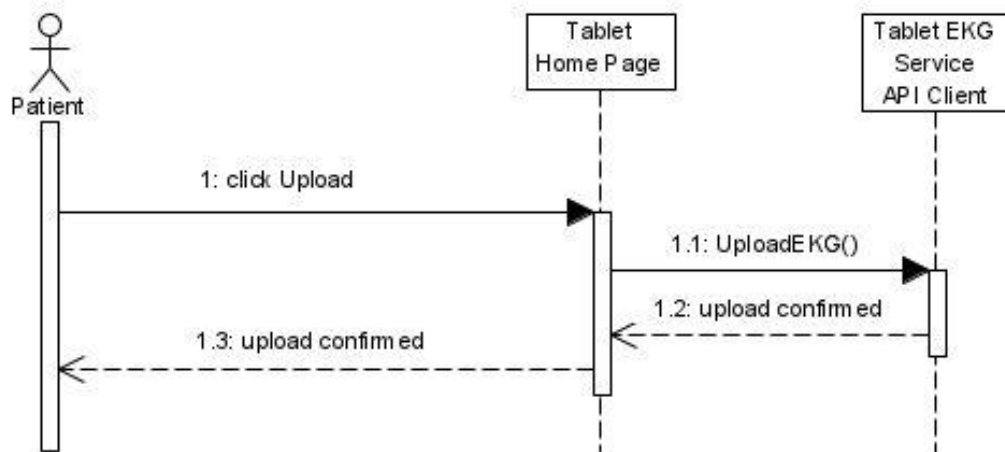


Figure 4.33: Upload EKG Sequence Diagram

4.3.32 Add EKG To Order

4.3.32.1 Name: Add EKG To Order

4.3.32.2 Diagram

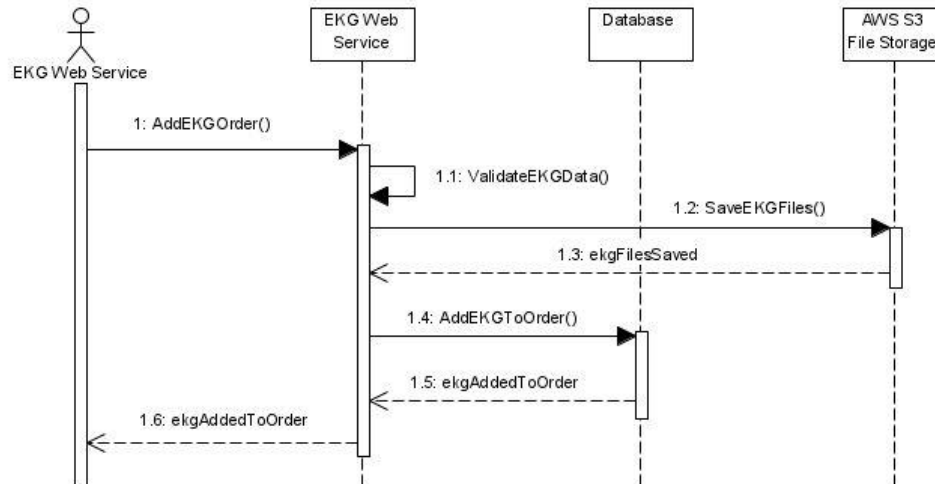


Figure 4.34: Add EKG to Order Sequence Diagram

4.3.33 View EKG

4.3.33.1 Name: View EKG

4.3.33.2 Diagram

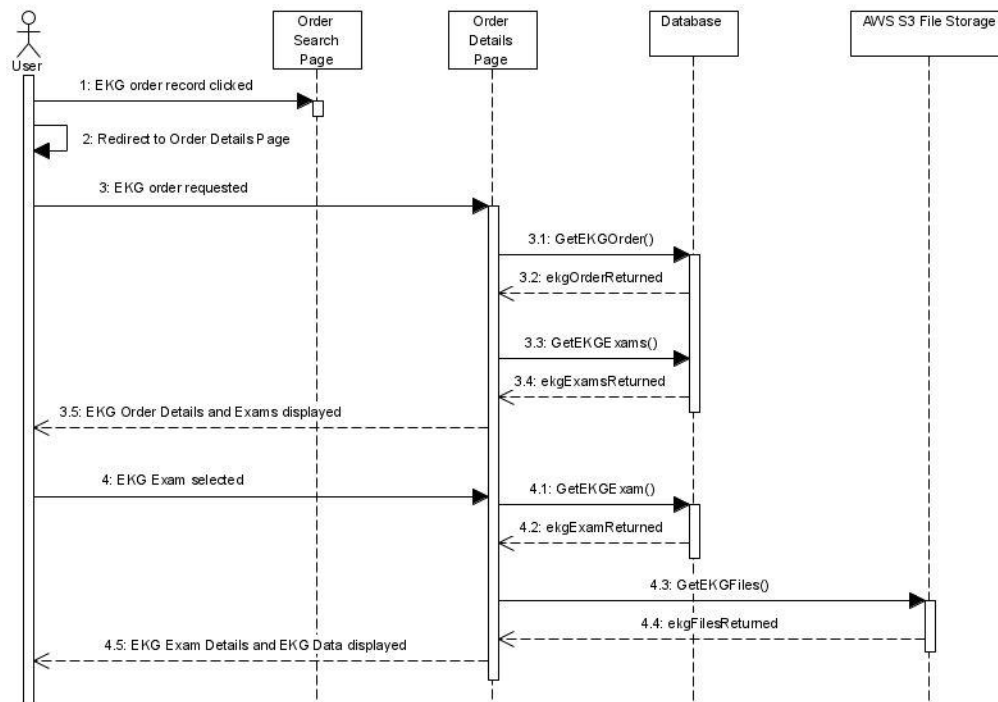


Figure 4.35: View EKG Sequence Diagram

4.3.34 Get EKG Exams

4.3.34.1 Name: Get EKG Exams

4.3.34.2 Diagram

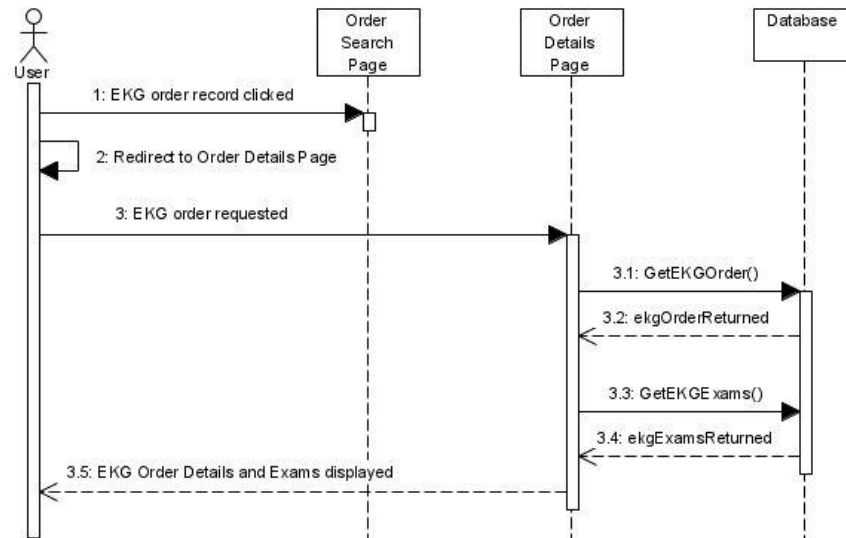


Figure 4.36: Get EKG Exams Sequence Diagram

4.3.35 Analyze EKG

4.3.35.1 Name: Analyze EKG

4.3.35.2 Diagram

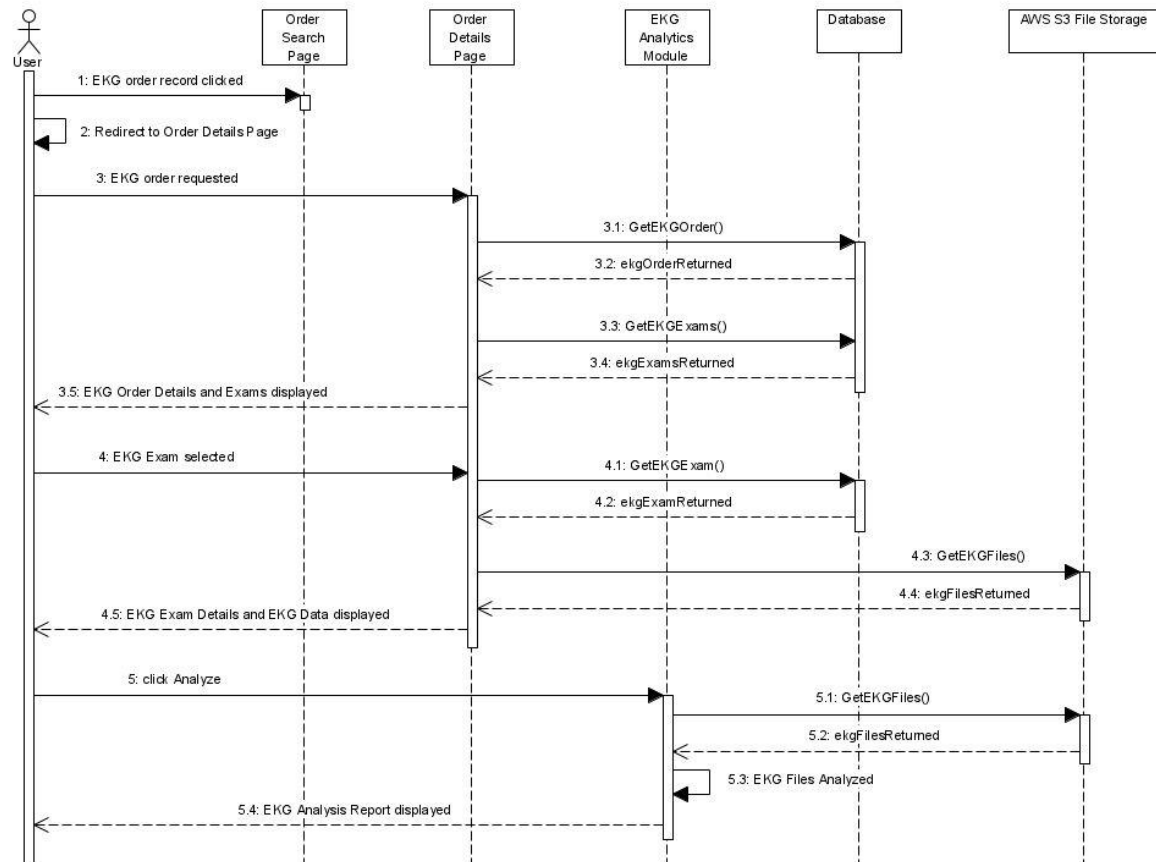


Figure 4.37: Analyze EKG Sequence Diagram

5. Cost Analysis

5.1 Performance Requirements

- Due to the significant and pressing nature of many electrocardiogram results, the EKG cloud service should always be available to all users. That is, the cloud service should be accessible at all hours of the day, every day of the week, and every week of the year.
- EKG data input stream will be limited by the user's internet connection/speed. Once the data is in the file storage, however, the maximum response time for accessing the data files should be 5 seconds to better facilitate rapid responses from the medical team(s).
- The file storage will be replicated over multiple independent cloud servers to decrease the risk of failure. If a failure occurs on the initial file storage server, the database will point to a different server to keep the data transaction seamless.
- Uptime and downtime for the system will be continuously evaluated so that necessary maintenance operations will occur during times that have the least probability for negatively impacting users.

5.2 Capital Project and Operational Costs for Year 1

Initial Investment				
Description	Quantity	Unit Cost (\$)	Extended (\$)	Subtotals (\$)
Hardware				
CardioCard DAQ w/ Leads Kit	500	\$200.00	\$100,000.00	
Android Tablet w/SW	500	\$150.00	\$75,000.00	
				\$175,000.00
Professional Services				
Project Management	400	\$175.00	\$70,000.00	
Software Engineering	200	\$150.00	\$30,000.00	
Software Development	600	\$150.00	\$90,000.00	
Technical Writing	200	\$100.00	\$20,000.00	
System Testing	90	\$125.00	\$11,250.00	
Deployment	80	\$150.00	\$12,000.00	
				\$233,250.00
Initial Investment Total				\$408,250.00
Operating Expenses - Year 1				
Description	Quantity	Monthly Unit Cost (\$)	Year 1 Cost(\$)	Subtotals (\$)
Cloud Infrastructure				
Amazon EC2 Virtual Server	4	\$500.00	\$24,000.00	
Amazon API Gateway	2	\$300.00	\$7,200.00	
Amazon RDS SQL DB	2	\$2,000.00	\$48,000.00	
Amazon S3 File Storage	2	\$300.00	\$7,200.00	
				\$86,400.00
Operations				
System Team Manager - FTE (hrs)	1	\$8,334.00	\$100,008.00	
System Manager - FTE (hrs)	2	\$6,670.00	\$160,080.00	
				\$260,088.00
Operating Expenses - Year 1 Total				\$ 346,488.00
Total Budget - Year 1				\$ 754,738.00

5.3 Software-as-a-Service Financial Analysis for Year 1

- Current initial system configuration can process 104,000 EKGs per year
- Average Medicare EKG reimbursement to Healthcare provider (2021): \$ 20.00
- Estimated Healthcare provider EKG Medicare revenue @ 104,000 EKGs: \$ 2,080,000.00
- Healthcare provider EKG Cloud Service SaaS Cost @ 104,000 EKGs: \$ 520,000.00
- Estimated Healthcare provider EKG Gross Profit @ 104,000 EKGs: \$ 1,560,000.00

Appendix A: Glossary

DAQ – Data Acquisition or Data Acquisition Module describes a technique or device that serves as an instrument for taking measurements, as in the case of this document, of patient’s heart electrical signals.

EKG – Electrocardiography is a method for acquiring measurements of the electrical activity in the heart with the output being a visual graph of these signals.

HTTPS – Hypertext Transfer Protocol Secure provides a means of utilizing encryption to secure the communication between an internet web server or cloud service and a web client application, such as a web browser or mobile application.

IEEE – Institute of Electrical and Electronics Engineers is a professional association comprised of members of the electrical and electronic engineering community. The association serves as a promoting body for the development of technical standards across the electrical engineering and computer science fields.

SQL – Structured Query Language is a language commonly used in the programming and management of relational database systems.

USB – Universal Serial Bus provides one of many standards for the interfacing of various computers and other electronic devices for the purpose of data communication.

Appendix B: Analysis Models

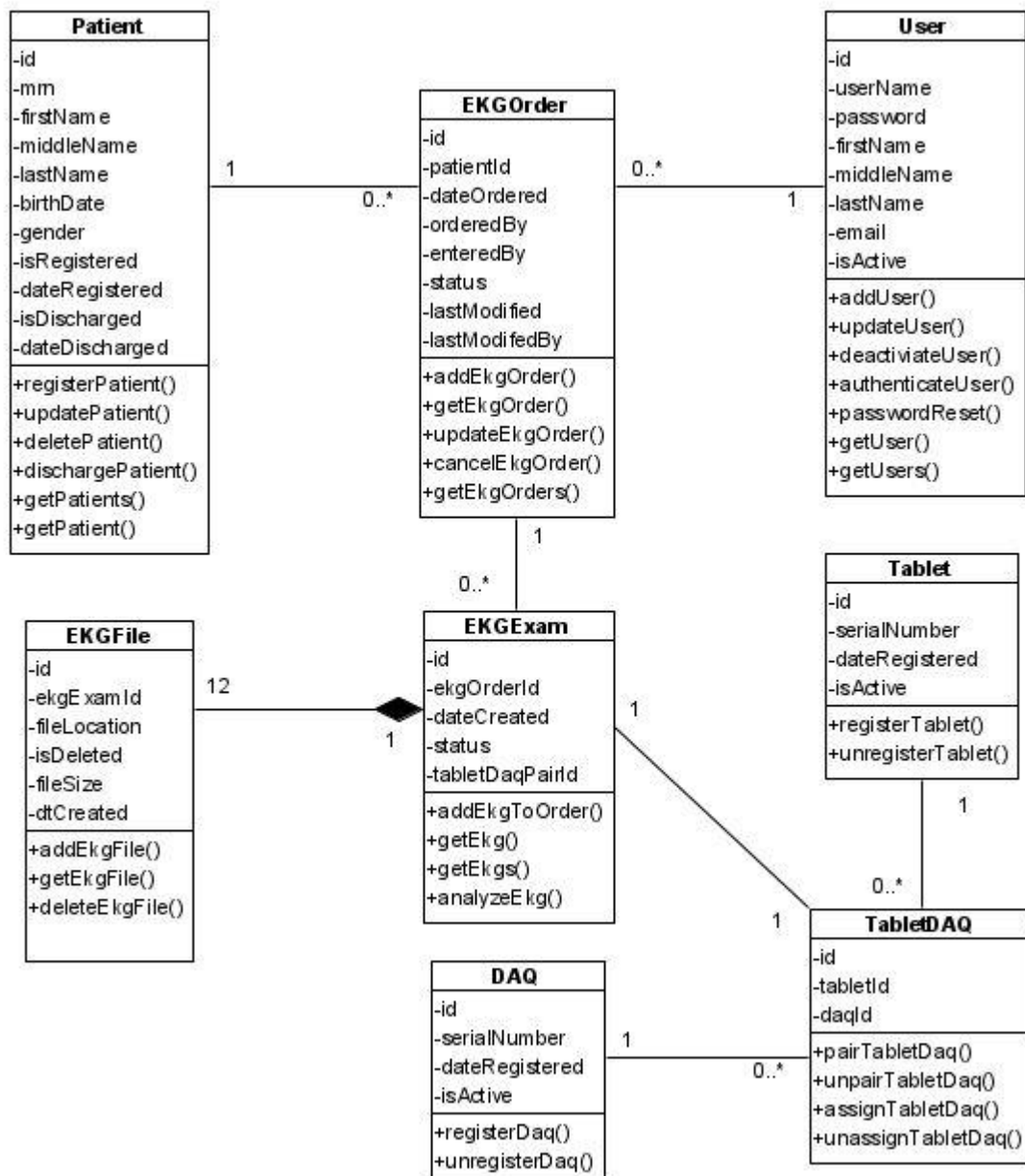


Figure B.5.1: EKG Cloud Services Class Diagram

Appendix C: To Be Determined List

- A. Communication Interface Specifications for CardioCard DAQ module