Design History File (DHF)

**Wearable ECG Patch**

Automated DHF Project - Shivangi Sarkar

# Device Overview

Wearable ECG Patch

Class II medical device

Purpose: Wearable ECG patch is a diagnostic tool which helps monitor heart rhythm and can prevent fatal conditions like Atrial Fibrillation and reduce stroke risk.

Features:

- Electrodes

- Analog front end

- Microcontroller unit

- Bluetooth Low Energy Transceiver for wireless transmission

- Power supply

- Software system

- Mobile app

- PC Interface

- Posture recognition module

End Users: Cardiac Patients and Clinicians who are monitoring the patch

Environment: Outside of hospital

Regulatory Class: FDA Class II

# User Needs

|  |  |
| --- | --- |
| Need ID | Description |
| UN001 | must accurately detect cardiac events |
| UN002 | must be able to monitor long term |
| UN003 | must be able to function remotely |
| UN004 | must be comfortable to wear |
| UN005 | must be easy to setup app as well as the device |
| UN006 | must have minimal user interaction after setup |
| UN007 | must be discreet for social setting |
| UN008 | must be compatible with skin (skin irritation, allergic reaction) |
| UN009 | must be wire free for better mobility and comfort |
| UN010 | must be non-intrusive (not interfere with daily lifestyle) |
| UN011 | must be easily replaceable or maintained |

# Design Inputs

|  |  |  |
| --- | --- | --- |
| Input ID | Description | Linked Need ID |
| DI001 | The device shall use a medical-grade ECG front-end (e.g., ADAS1000) with a sampling rate ≥ 250 Hz and signal-to-noise ratio ≥ 20 dB. | UN001 |
| DI002 | The device shall store and/or transmit ECG data continuously for ≥ 7 days with 1-minute resolution. | UN002 |
| DI003 | The device shall support Bluetooth Low Energy (BLE 5.0) with automatic data syncing to cloud via mobile app. | UN003 |
| DI004 | The patch shall weigh < 25g and use breathable, hypoallergenic adhesive suitable for continuous wear. | UN004 |
| DI005 | The mobile app shall feature an onboarding wizard and video instructions for setup. | UN005 |
| DI006 | The device shall automatically start monitoring after setup and require no further input during regular operation. | UN006 |
| DI007 | The patch shall have a form factor < 5mm thick with skin-tone or transparent housing for discreetness. | UN007 |
| DI008 | The adhesive and outer casing shall be ISO 10993 biocompatible and dermatologically tested. | UN008 |
| DI009 | The patch shall operate wirelessly with internal battery and zero wired components during use. | UN009 |
| DI010 | The device shall allow full range of motion (e.g., sitting, walking, sleeping) without mechanical interference. | UN010 |
| DI011 | The device battery and adhesive shall be modularly replaceable by user in < 1 minute using a slide-lock mechanism. | UN011 |

# Design Outputs

|  |  |  |
| --- | --- | --- |
| Output ID | Description | Linked Input ID |
| DO001 | ECG signal acquisition validated using ADAS1000 at 250 Hz in test bench and signal-to-noise ratio confirmed ≥ 20 dB. | DI001 |
| DO002 | Data logging and transmission verified with 7-day continuous operation in simulated patient environment. | DI002 |
| DO003 | BLE 5.0 module integrated with successful data transmission test to Android/iOS app; encryption logs verified. | DI003 |
| DO004 | Device weight measured at 22g; adhesive passed 7-day continuous wear comfort test. | DI004 |
| DO005 | Mobile app onboarding tested with 10 users; setup completed in < 3 minutes with 95% satisfaction rate. | DI005 |
| DO006 | Software confirmed to auto-start monitoring post-setup without manual intervention during 72-hour test cycle. | DI006 |
| DO007 | Final patch enclosure is 4.5mm thick with neutral tone; confirmed unnoticeable under clothing in user trial. | DI007 |
| DO008 | ISO 10993 biocompatibility reports completed and passed for adhesive and enclosure; no irritation in 10-user patch test. | DI008 |
| DO009 | Wireless functionality tested under movement and daily activities; no disconnection over 72-hour dynamic test. | DI009 |
| DO010 | Patch tested on users during sitting, walking, and sleeping; motion artifact < 5% in ECG recording. | DI010 |
| DO011 | Battery and adhesive module replaced by users in < 1 minute; validated through usability testing. | DI011 |

# Verification Methods

|  |  |
| --- | --- |
| Input ID | Verification Method |
| DI001 | Bench test ECG signal using waveform simulator and confirm sampling rate and signal-to-noise ratio meet specs. |
| DI002 | Continuous data logging test in simulated use case for 7 days with battery life monitoring and data integrity check. |
| DI003 | Perform Bluetooth Low Energy (BLE) range test and validate AES encryption via transmission log analysis. |
| DI004 | Measure device weight and conduct human wear test for 7 days with comfort feedback survey. |
| DI005 | Usability test with 10 users setting up device and app; measure completion time and error rate. |
| DI006 | Run 72-hour software test cycle to ensure automatic monitoring starts post-setup with no manual actions. |
| DI007 | Measure patch thickness and conduct visibility test under clothing on a diverse user group. |
| DI008 | Submit adhesive and enclosure for ISO 10993 biocompatibility testing and patch wear irritation test. |
| DI009 | Wireless performance test with daily activity simulation and real-time disconnection logging. |
| DI010 | Motion artifact evaluation during sitting, walking, and sleeping using annotated ECG signal recordings. |
| DI011 | Conduct usability test where users replace battery and adhesive within 1 minute; measure completion time and error rate. |

# Change Log

|  |  |  |
| --- | --- | --- |
| Date | Change Description | Author |
| 2024-06-01 | Initial design inputs uploaded | Shivangi |
| 2024-06-10 | Updated risk assessment thresholds | QA Engineer |
| 2024-06-15 | Added verification test cases | Design Lead |

# Traceability Matrix

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Need\_ID | User\_Need\_Description | Input\_ID | Input\_Description | Output\_ID | Output\_Description | Verification\_Method |
| UN001 | must accurately detect cardiac events | DI001 | The device shall use a medical-grade ECG front-end (e.g., ADAS1000) with a sampling rate ≥ 250 Hz and signal-to-noise ratio ≥ 20 dB. | DO001 | ECG signal acquisition validated using ADAS1000 at 250 Hz in test bench and signal-to-noise ratio confirmed ≥ 20 dB. | Bench test ECG signal using waveform simulator and confirm sampling rate and signal-to-noise ratio meet specs. |
| UN002 | must be able to monitor long term | DI002 | The device shall store and/or transmit ECG data continuously for ≥ 7 days with 1-minute resolution. | DO002 | Data logging and transmission verified with 7-day continuous operation in simulated patient environment. | Continuous data logging test in simulated use case for 7 days with battery life monitoring and data integrity check. |
| UN003 | must be able to function remotely | DI003 | The device shall support Bluetooth Low Energy (BLE 5.0) with automatic data syncing to cloud via mobile app. | DO003 | BLE 5.0 module integrated with successful data transmission test to Android/iOS app; encryption logs verified. | Perform Bluetooth Low Energy (BLE) range test and validate AES encryption via transmission log analysis. |
| UN004 | must be comfortable to wear | DI004 | The patch shall weigh < 25g and use breathable, hypoallergenic adhesive suitable for continuous wear. | DO004 | Device weight measured at 22g; adhesive passed 7-day continuous wear comfort test. | Measure device weight and conduct human wear test for 7 days with comfort feedback survey. |
| UN005 | must be easy to setup app as well as the device | DI005 | The mobile app shall feature an onboarding wizard and video instructions for setup. | DO005 | Mobile app onboarding tested with 10 users; setup completed in < 3 minutes with 95% satisfaction rate. | Usability test with 10 users setting up device and app; measure completion time and error rate. |
| UN006 | must have minimal user interaction after setup | DI006 | The device shall automatically start monitoring after setup and require no further input during regular operation. | DO006 | Software confirmed to auto-start monitoring post-setup without manual intervention during 72-hour test cycle. | Run 72-hour software test cycle to ensure automatic monitoring starts post-setup with no manual actions. |
| UN007 | must be discreet for social setting | DI007 | The patch shall have a form factor < 5mm thick with skin-tone or transparent housing for discreetness. | DO007 | Final patch enclosure is 4.5mm thick with neutral tone; confirmed unnoticeable under clothing in user trial. | Measure patch thickness and conduct visibility test under clothing on a diverse user group. |
| UN008 | must be compatible with skin (skin irritation, allergic reaction) | DI008 | The adhesive and outer casing shall be ISO 10993 biocompatible and dermatologically tested. | DO008 | ISO 10993 biocompatibility reports completed and passed for adhesive and enclosure; no irritation in 10-user patch test. | Submit adhesive and enclosure for ISO 10993 biocompatibility testing and patch wear irritation test. |
| UN009 | must be wire free for better mobility and comfort | DI009 | The patch shall operate wirelessly with internal battery and zero wired components during use. | DO009 | Wireless functionality tested under movement and daily activities; no disconnection over 72-hour dynamic test. | Wireless performance test with daily activity simulation and real-time disconnection logging. |
| UN010 | must be non-intrusive (not interfere with daily lifestyle) | DI010 | The device shall allow full range of motion (e.g., sitting, walking, sleeping) without mechanical interference. | DO010 | Patch tested on users during sitting, walking, and sleeping; motion artifact < 5% in ECG recording. | Motion artifact evaluation during sitting, walking, and sleeping using annotated ECG signal recordings. |
| UN011 | must be easily replaceable or maintained | DI011 | The device battery and adhesive shall be modularly replaceable by user in < 1 minute using a slide-lock mechanism. | DO011 | Battery and adhesive module replaced by users in < 1 minute; validated through usability testing. | Conduct usability test where users replace battery and adhesive within 1 minute; measure completion time and error rate. |

# Risk Management

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Failure Mode | Effect | Cause | Severity (S) | Occurrence (O) | Detection (D) | RPN | Recommended Action |
| ECG signal noise | Misdiagnosis | Loose electrode connection | 9 | 4 | 3 | 108 | Improve electrode placement & shielding |
| BLE transmission fails | Data loss | Interference, low battery | 8 | 3 | 4 | 96 | Add auto-reconnect and alert system |
| Device adhesive detaches | Interrupted monitoring | Sweat, poor skin contact | 7 | 4 | 4 | 112 | Redesign adhesive for better grip |
| Skin irritation | User discomfort | Poor adhesive material | 5 | 3 | 5 | 75 | Switch to ISO 10993-certified adhesive |
| Setup errors | Device not collecting data | Poor user onboarding design | 8 | 2 | 3 | 48 | Simplify app UI, add guided tutorial |
| Patch visibility concern | Non-compliance with use | Bulky design | 4 | 3 | 3 | 36 | Reduce thickness and use neutral tones |
| API sync failure | Missed real-time alerts | Backend or app issue | 7 | 3 | 4 | 84 | Add sync verification + alert retry |
| Battery dies early | Device shutdown | High power drain | 9 | 2 | 3 | 54 | Optimize power consumption logic |
| Lead-off not detected | Inaccurate ECG reading | Software bug | 10 | 2 | 3 | 60 | Validate detection logic extensively |