



SLEEP APNEA MONITORING AND DIAGNOSTIC SYSTEM TEST PLAN

Team Snooze

Version 1.0

3/1/2018

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Test Plan Document

Version 1.0

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A. Introduction

1. Purpose of the Test Plan Document

This test plan outlines our testing methods for each individual component of our Obstructive Sleep Apnea Diagnostics System. Testing will be done for all functional and non-functional requirements as needed.

B. Functional Testing

1. Test Risks/Issues

There are currently no known risks that have been identified for this system.

2. Items to be Tested/Not Tested

Item to Test	Test Description	Test Date	Responsibility
Requirement: Sensor System for Respiratory Movement and Body Movement	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	3/31/2018	Andrew Asdel
Requirement: Sensor System for patient Airflow	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	3/31/2018	Andrew Asdel
Requirement: Sensor Power Circuitry	1. Verification that portable power systems must be able to show charge and discharge. 2. Verification that portable power systems must be able to power each sensor system without performance degradation (unless explicitly specified).	3/31/2018	Andrew Asdel
Requirement: Sensor System for patient Heart-Rate & Blood Oxygen Saturation	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	3/31/2018	Yale Empie
Requirement: Sensor System for patient Body Temperature	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	3/31/2018	Yale Empie
Requirement: Data Storage	1. Verification of data integrity inside S3 Bucket(s).	11/20/2017	Jason Van

Requirement: Data Formation	1. Verification that '.EDF' data can be opened by the EDFBrowser program (used to view EDF formatted data in a visual graph format)	3/31/2018	Jason Van
Requirement: Data Archival	1. Verification that data inside of S3 Bucket(s) have been categorized as 'Archived' for long term storage.	11/20/2017	Jason Van
Requirement: Scoring Program	1. Verification that program functionality a. Can read 'EDF' data b. Process Data c. Generate a report for analysis.	3/31/2018	Jason Van
Requirement: Smartphone Application	1. Verification of Application functionality: a. User Interface is properly working. b. Connection of sensor systems over Bluetooth working. c. Calibration of sensor systems to a default starting point. d. Confirmation that data has been transmitted to AWS cloud systems.	3/31/2018	Tyler Anderson
Requirement: Microphone Sensor Implementation in App	1. Verification of a working microphone sensor on Android smartphone. Sound data should be recorded and stored on the Android smartphone until requested in the application to be sent to AWS cloud systems.	3/31/2018	Tyler Anderson

3. Test Approach(s)

Testing will be done once each individual component of the system has been created and confirmed to be in an operable state. Once the system is complete, full-scale testing will be done on all components in a combined manner.

4. Test Cases

Test Cases (By Requirement)	Test Scenario	Test Steps	Expected Result
Requirement: Sensor System for Respiratory Movement and Body Movement	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	<ol style="list-style-type: none"> 1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that output values are within valid ranges as specified by the motion sensor data sheet. 	Valid data being output.
Requirement: Sensor System for patient Airflow	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	<ol style="list-style-type: none"> 1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen is lowest at ambient noise levels and increases when noise is introduced to the microphone. 	Valid data being output.

Requirement: Sensor Power Circuitry	<ol style="list-style-type: none"> 1. Verification that portable power systems must be able to show charge and discharge. 1. Verification that portable power systems must be able to power each sensor system without performance degradation (unless explicitly specified). 	<ol style="list-style-type: none"> 1. Verify that batteries do not heat up to an unreasonable level to human touch during use. 2. Verify that each sensor system continues to operate normally under battery operation. 	
Requirement: Sensor System for patient Heart-Rate & Blood Oxygen Saturation	<ol style="list-style-type: none"> 1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application. 	<ol style="list-style-type: none"> 1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen for heart-rate is reasonable, e.g. Between 60 and 150bpm. Verify that blood oxygen level values given are reasonable. 	Valid data being output.
Requirement: Sensor System for patient Body Temperature	<ol style="list-style-type: none"> 1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application. 	<ol style="list-style-type: none"> 1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen for body temperature are reasonable values given ambient and skin temperatures. 	Valid data being output.

Requirement: Data Storage	1. Verification of data integrity inside S3 Bucket(s).	1. In the smartphone application, send the EDF formatted file to AWS cloud services.	Data is shown to be saved into users' private folders.
Requirement: Data Formation	1. Verification that '.EDF' data can be opened by the EDFBrowser program (used to view EDF formatted data in a visual graph format)	1. Open file in EDFBrowser.	Valid data is opened and displayed.
Requirement: Data Archival	1. Verification that data inside of S3 Bucket(s) have been categorized as 'Archived' for long term storage.	1. Leave file in cloud until shown to be archived on Amazon Glacier.	Data that is saved into users' private folders is properly archived in Amazon Glacier after a 'few' days of no access.
Requirement: Scoring Program	1. Verification that program functionality a) Can read 'EDF' data b) Process Data c) Generate a report for analysis.	1. Run the script file to process data test files. a. If valid patient file is available, test with that as priority over basic data test files.	Valid Scored report is generated.
Requirement: Smartphone Application	1. Verification of Application functionality: 1. User Interface is properly working. 2. Connection of sensor systems over Bluetooth working. 3. Calibration of sensor systems to a default starting point. 4. Confirmation that data has been transmitted to AWS cloud systems.	1. Confirm that the application runs correctly without any form of a crash. 2. Verify that the application is properly receiving data from the sensors and is being stored on the smartphone. 3. Verify that the application is properly transmitting data to the cloud database.	User interface does not achieve critical errors during operation. Sensor systems successfully communicate with application. Calibration procedure properly takes initial values. Data is verified as uploaded to AWS cloud systems.

Requirement: Microphone Sensor Implementation in App	1. Verification of a working microphone sensor on Android smartphone. Sound data should be recorded and stored on the Android smartphone until requested in the application to be sent to AWS cloud systems.	1. Confirm that the application is properly storing audio from the microphone onto the smartphone.	Microphone successfully creates audio file on smartphone device.
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5. Test Regulatory/Mandate Criteria

Tests must achieve satisfactory levels of data protection as outlined by U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act of 1996 ("HIPPA"). They must also meet standards outlined by the FDA for device sale approval

6. Test Pass/Fail Criteria

Test Pass Criteria: Once each specific component of the system has completed its respected test plan with successful results by the team member responsible, it will be considered operational.

Test Fail Criteria: Once each specific component of the system has completed its respected test plan with unsuccessful results by the team member responsible, it will be considered unoperational.

7. Test Entry/Exit Criteria

Test Entry Criteria: Once each specific component of the system has been confirmed to be in an operable state by the team member responsible, it will be open to testing.

Test Exit Criteria: Once the specific component of the system has been found to be fully operational, product testing for that component may end.

8. Test Deliverables

This system will produce an ".edf" (European Data Format) file that contains data from all sensor systems over a testing/runtime period. It will also produce a ".pdf" file that outlines the preliminary diagnosis based on OSA scoring algorithms. Finally, a sound file will be produced that will contain sound from the user's snoring through a testing/runtime period of this system.

9. Test Suspension/Resumption Criteria

Test Suspension Criteria: If a major fault is identified during testing that will affect operation of the system, testing will stop until that fault can be rectified.

Test Resumption Criteria: Testing may resume once the fault has been identified and fixed.

10. Test Environmental/Staffing/Training Needs

Test administrator(s) will need knowledge of Arduino hardware & programming (C/C++ code variants) and Java programming language experience. They will need knowledge on Bluetooth operations. They will also need knowledge on operating Amazon Web Services system modules (AWS certification available).

Test environment will require a quiet & dimly lit area containing a place to lay down comfortably, such as a bedroom and bed. Test administrators will also require a WIFI connection to the internet so that data can be uploaded from the system to AWS for storage and analysis.

C. Non-Functional Testing

1. Test Risks/Issues

There are currently no known risks that have been identified for this system.

2. Items to be Tested/Not Tested

Item to Test	Test Description	Test Date	Responsibility
Power Circuitry Systems	<ol style="list-style-type: none">1. This item must be tested on the highest power draw sensor system so that it can be determined to meet 8-hour minimum runtime.2. Rechargeable system must be tested to ensure that they are properly working.	4/5/2018	Andrew Asdel
FDA Approval	<ol style="list-style-type: none">1. Data security must be verified as working. Device must be tested to be human-safe for use.	4/5/2018	Jason Van
HIPAA Regulations Met	<ol style="list-style-type: none">1. Data security must be verified as working. Authentication systems will be tested to verify integrity of secure data systems.	4/5/2018	Tyler Anderson
Type 3 OSA Level Met	<ol style="list-style-type: none">1. This item is not to be tested as there are no test cases available.		Yale Empie

3. Test Approach(s)

Testing will be done once each individual component of the system has been created and confirmed to be in an operable state. Once the system is complete, full-scale testing will be done on all components in a combined manner.

4. Test Cases

Test Cases (By Requirement)	Test Scenario	Test Steps	Expected Result
Power Circuitry Systems	<ol style="list-style-type: none">1. Verification that portable power systems must be able to show charge and discharge.2. Verification that portable power systems must be able to power each sensor system without performance degradation (unless explicitly specified).	<ol style="list-style-type: none">1. Plug a fully charged battery into sensor leads and verify nominal operation. St timer for 8 hours.2. When time expires, verify that the sensor continues to operate normally.3. Repeat if necessary.	<p>Sensor successfully lasts for 8-hour minimum runtime.</p> <p>Batteries are shown to be rechargeable.</p>

FDA Approval	<ol style="list-style-type: none"> 1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application. 2. Verification of user authentication features. 3. Verification of encrypted data from smartphone application to AWS cloud systems. 4. Verification of user authentication features for AWS systems. 	<ol style="list-style-type: none"> 1. Test application/AWS authentication by entering variations of wrong passwords (particularly using arbitrary code in the event that it can be run in the password field.) 2. Verify data that is located on AWS cloud systems has maintained encryptions and is segregated by users. 	Valid data being output with proper encryption.
HIPAA Regulations Met	<ol style="list-style-type: none"> 1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application. 2. Verification of user authentication features. 3. Verification of encrypted data from smartphone application to AWS cloud systems. 4. Verification of user authentication features for AWS systems. 	<ol style="list-style-type: none"> 1. Test application/AWS authentication by entering variations of wrong passwords (particularly using arbitrary code in the event that it can be run in the password field.) 2. Verify data that is located on AWS cloud systems has maintained encryptions and is segregated by users. 	Valid data being output with proper encryption.

5. Test Regulatory/Mandate Criteria

Tests must achieve satisfactory levels of data protection as outlined by U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act of 1996 ("HIPPA"). They must also meet standards outlined by the FDA for device sale approval.

6. Test Pass/Fail Criteria

Power Circuitry Systems:

- **Pass:**
 - Power circuitry systems successfully achieve a minimum of 8 hours of runtime for all sensor systems.
 - Power circuitry systems successfully recharge after being discharged due to use.
- **Fail:**
 - Power circuitry systems do not achieve 8 hours of runtime for all sensor systems.
 - Power circuitry systems do not recharge after being discharged due to use.

FDA Approval:

- **Pass:**
 - The device does not shock the user or cease operation while attached to the patient or tester. Authentication systems must be working.
- **Fail:**
 - If the device shocks the user (electrically), ceases operation while attached to the patient or tester, or authentication systems are not working, this signifies a failure for the test.

HIPAA Regulations:

- **Pass:**
 - Authentication systems must be shown as working. Data must maintain encrypted status to and on AWS cloud services.
- **Fail:**
 - Authentication systems are shown as vulnerable and not working. Data encryption integrity broken during transfer and storage to and on AWS cloud services.

7. Test Entry/Exit Criteria

N/A

8. Test Deliverables

N/A

9. Test Suspension/Resumption Criteria

Test Suspension Criteria: If a system is identified during testing that does not comply with regulatory guidelines as defined by the U.S. Department of Health and Human Services or Food and Drug Administration (FDA), testing will be suspended immediately pending a fix.

Test Resumption Criteria: Testing may resume once the fault has been identified and fixed.

10. Test Environmental/Staffing/Training Needs

Test administrator(s) will need knowledge of U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and standards outlined by the U.S. Food and Drug Administration (FDA) for device sales approval.

D. Regression Testing

1. Test Risks/Issues

The only identified risk of any requirement requiring regression testing would be the failure of that requirement to be fixed in time for product release.

2. Items to be Tested/Not Tested

Item to Test	Test Description	Test Date	Responsibility
Requirement: Sensor System for Respiratory Movement and Body Movement	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	TBD if regression testing is needed.	Andrew Asdel
Requirement: Sensor System for patient Airflow	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	TBD if regression testing is needed.	Andrew Asdel
Requirement: Sensor Power Circuitry	1. Verification that portable power systems must be able to show charge and discharge. 2. Verification that portable power systems must be able to power each sensor system without performance degradation (unless explicitly specified).	TBD if regression testing is needed.	Andrew Asdel
Requirement: Sensor System for patient Heart-Rate & Blood Oxygen Saturation	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	TBD if regression testing is needed.	Yale Empie
Requirement: Sensor System for patient Body Temperature	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	TBD if regression testing is needed.	Yale Empie
Requirement: Data Storage	1. Verification of data integrity inside S3 Bucket(s).	TBD if regression testing is needed.	Jason Van
Requirement: Data Formation	1. Verification that '.EDF' data can be opened by the EDFBrowser program (used to view EDF formatted data in a visual graph format)	TBD if regression testing is needed.	Jason Van
Requirement: Data Archival	1. Verification that data inside of S3 Bucket(s) have been categorized as 'Archived' for long term storage.	TBD if regression testing is needed.	Jason Van

Requirement: Scoring Program	1. Verification that program functionality a) Can read 'EDF' data b) Process Data c) Generate a report for analysis.	TBD if regression testing is needed.	Jason Van
Requirement: Smartphone Application	1. Verification of Application functionality: a) User Interface is properly working. b) Connection of sensor systems over Bluetooth working. c) Calibration of sensor systems to a default starting point. d) Confirmation that data has been transmitted to AWS cloud systems.	TBD if regression testing is needed.	Tyler Anderson
Requirement: Microphone Sensor Implementation in App	1. Verification of a working microphone sensor on Android smartphone. Sound data should be recorded and stored on the Android smartphone until requested in the application to be sent to AWS cloud systems.	TBD if regression testing is needed.	Tyler Anderson

3. Test Approach(s)

Testing will be done once each individual component of the system has been created and confirmed to be in an operable state. Once the system is complete, full-scale testing will be done on all components in a combined manner.

4. Test Cases

Test Cases (By Requirement)	Test Scenario	Test Steps	Expected Result
Requirement: Sensor System for Respiratory Movement and Body Movement	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	<ol style="list-style-type: none"> 1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that output values are within valid ranges as specified by the motion sensor data sheet. 	Valid data being output.
Requirement: Sensor System for patient Airflow	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	<ol style="list-style-type: none"> 1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen is lowest at ambient noise levels and increases when noise is introduced to the microphone. 	Valid data being output.

Requirement: Sensor Power Circuitry	<ol style="list-style-type: none"> 1. Verification that portable power systems must be able to show charge and discharge. 2. Verification that portable power systems must be able to power each sensor system without performance degradation (unless explicitly specified). 	<ol style="list-style-type: none"> 1. Verify that batteries do not heat up to an unreasonable level to human touch during use. 2. Verify that each sensor system continues to operate normally under battery operation. 	
Requirement: Sensor System for patient Heart-Rate & Blood Oxygen Saturation	<ol style="list-style-type: none"> 1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application. 	<ol style="list-style-type: none"> 1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen for heart-rate is reasonable, e.g. Between 60 and 150bpm. Verify that blood oxygen level values given are reasonable. 	Valid data being output.
Requirement: Sensor System for patient Body Temperature	<ol style="list-style-type: none"> 1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application. 	<ol style="list-style-type: none"> 5. Open Serial Monitor application on desktop computer (or smartphone if desired). 6. Connect to sensor system over Bluetooth. 7. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. <p>Verify that the number displayed on screen for body temperature are reasonable values given ambient and skin temperatures.</p>	Valid data being output.

Requirement: Data Storage	1. Verification of data integrity inside S3 Bucket(s).	1. In the smartphone application, send the EDF formatted file to AWS cloud services.	Data is shown to be saved into users' private folders.
Requirement: Data Formation	1. Verification that '.EDF' data can be opened by the EDFBrowser program (used to view EDF formatted data in a visual graph format)	1. Open file in EDFBrowser.	Valid data is opened and displayed.
Requirement: Data Archival	1. Verification that data inside of S3 Bucket(s) have been categorized as 'Archived' for long term storage.	1. Leave file in cloud until shown to be archived on Amazon Glacier.	Data that is saved into users' private folders is properly archived in Amazon Glacier after a 'few' days of no access.
Requirement: Scoring Program	1. Verification that program functionality a) Can read 'EDF' data b) Process Data c) Generate a report for analysis.	1. Run the script file to process data test files. a. If valid patient file is available, test with that as priority over basic data test files.	Valid Scored report is generated.
Requirement: Smartphone Application	1. Verification of Application functionality: a) User Interface is properly working. b) Connection of sensor systems over Bluetooth working. c) Calibration of sensor systems to a default starting point. d) Confirmation that data has been transmitted to AWS cloud systems.	1. Confirm that the application runs correctly without any form of a crash. 2. Verify that the application is properly receiving data from the sensors and is being stored on the smartphone. 3. Verify that the application is properly transmitting data to the cloud database.	User interface does not achieve critical errors during operation. Sensor systems successfully communicate with application. Calibration procedure properly tares initial values. Data is verified as uploaded to AWS cloud systems.

Requirement: Microphone Sensor Implementation in App	1. Verification of a working microphone sensor on Android smartphone. Sound data should be recorded and stored on the Android smartphone until requested in the application to be sent to AWS cloud systems.	1. Confirm that the application is properly storing audio from the microphone onto the smartphone.	Microphone successfully creates audio file on smartphone device.
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5. Test Regulatory/Mandate Criteria

Tests must achieve satisfactory levels of data protection as outlined by U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act of 1996 ("HIPPA"). They must also meet standards outlined by the FDA for device sale approval.

6. Test Pass/Fail Criteria

Test Pass Criteria: Once each specific component of the system has completed its respected test plan with successful results by the team member responsible, it will be considered operational.

Test Fail Criteria: Once each specific component of the system has completed its respected test plan with unsuccessful results by the team member responsible, it will be considered unoperational.

7. Test Entry/Exit Criteria

Test Entry Criteria: Once each specific component of the system has been confirmed to be in an operable state by the team member responsible, it will be open to testing.

Test Exit Criteria: Once the specific component of the system has been found to be fully operational, product testing for that component may end.

8. Test Deliverables

This system will produce an ".edf" (European Data Format) file that contains data from all sensor systems over a testing/runtime period. It will also produce a ".pdf" file that outlines the preliminary diagnosis based on OSA scoring algorithms. Finally, a sound file will be produced that will contain sound from the user's snoring through a testing/runtime period of this system.

9. Test Suspension/Resumption Criteria

Test Suspension Criteria: If a major fault is identified during testing that will affect operation of the system, testing will stop until that fault can be rectified.

Test Resumption Criteria: Testing may resume once the fault has been identified and fixed.

10. Test Environmental/Staffing/Training Needs

Test administrator(s) will need knowledge of Arduino hardware & programming (C/C++ code variants) and Java programming language experience. They will need knowledge on Bluetooth operations. They will also need knowledge on operating Amazon Web Services system modules (AWS certification available).

Test environment will require a quiet & dimly lit area containing a place to lay down comfortably, such as a bedroom and bed. Test administrators will also require a WIFI connection to the internet so that data can be uploaded from the system to AWS for storage and analysis.

E. Performance Testing

1. Test Risks/Issues

There are currently no identified risks associated with any performance testing of this product. Product prefers full operational capacity but is still operational even if maximum performance is not achieved.

2. Items to be Tested/Not Tested

Item to Test	Test Description	Test Date	Responsibility
Power Circuitry Systems	<ol style="list-style-type: none">1. This item must be tested on the highest power draw sensor system so that it can be determined to meet 8-hour minimum runtime.2. Rechargeable system must be tested to ensure that they are properly working.	4/5/2018	Andrew Asdel

3. Test Approach(s)

Test approach will consist of running the highest power draw sensor system on battery packs to give a maximal baseline for how long the power systems will operate.

4. Test Cases

Test Cases (By Requirement)	Test Scenario	Test Steps	Expected Result
Power Circuitry Systems	<ol style="list-style-type: none">1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application. This will show device as operational.	<ol style="list-style-type: none">1. Plug a fully charged battery into sensor leads and verify nominal operation. St timer for 8 hours.2. When time expires, verify that the sensor continues to operate normally with no performance degradation.3. Repeat if necessary.	<p>Sensor successfully lasts for 8-hour minimum runtime.</p> <p>Batteries are shown to be rechargeable.</p>

5. Test Regulatory/Mandate Criteria

Tests must achieve satisfactory levels of data protection as outlined by U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act of 1996 ("HIPPA"). They must also meet standards outlined by the FDA for device sale approval.

6. Test Pass/Fail Criteria

Test Pass Criteria: Once each specific component of the system has completed its respected test plan with successful results by the team member responsible, it will be considered operational.

Test Fail Criteria: Once each specific component of the system has completed its respected test plan with unsuccessful results by the team member responsible, it will be considered unoperational.

7. Test Entry/Exit Criteria

Test Entry Criteria: Once each specific component of the system has been confirmed to be in an operable state by the team member responsible, it will be open to testing.

Test Exit Criteria: Once the specific component of the system has been found to be fully operational, product testing for that component may end.

8. Test Deliverables

N/A

9. Test Suspension/Resumption Criteria

Test Suspension Criteria: If a major fault is identified during testing that will affect operation of the system, testing will stop until that fault can be rectified.

Test Resumption Criteria: Testing may resume once the fault has been identified and fixed.

10. Test Environmental/Staffing/Training Needs

Test administrator(s) will need knowledge of U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and standards outlined by the U.S. Food and Drug Administration (FDA) for device sales approval.

Test administrator(s) will also need knowledge of microelectronic circuits and basic electrical knowledge.

F. Unit Testing

1. Test Risks/Issues

There are currently no known risks that have been identified for this system.

2. Items to be Tested/Not Tested

Item to Test	Test Description	Test Date	Responsibility
Requirement: Sensor System for Respiratory Movement and Body Movement	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	3/31/2018	Andrew Asdel
Requirement: Sensor System for patient Airflow	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	3/31/2018	Andrew Asdel
Requirement: Sensor Power Circuitry	1. Verification that portable power systems must be able to show charge and discharge. 1. Verification that portable power systems must be able to power each sensor system without performance degradation (unless explicitly specified).	3/31/2018	Andrew Asdel
Requirement: Sensor System for patient Heart-Rate & Blood Oxygen Saturation	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	3/31/2018	Yale Empie
Requirement: Sensor System for patient Body Temperature	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	3/31/2018	Yale Empie
Requirement: Data Storage	1. Verification of data integrity inside S3 Bucket(s).	11/20/2017	Jason Van
Requirement: Data Formation	1. Verification that '.EDF' data can be opened by the EDFBrowser program (used to view EDF formatted data in a visual graph format)	3/31/2018	Jason Van

Requirement: Data Archival	1. Verification that data inside of S3 Bucket(s) have been categorized as 'Archived' for long term storage.	11/20/2017	Jason Van
Requirement: Scoring Program	1. Verification that program functionality a) Can read 'EDF' data b) Process Data c) Generate a report for analysis.	3/31/2018	Jason Van
Requirement: Smartphone Application	1. Verification of Application functionality: a) User Interface is properly working. b) Connection of sensor systems over Bluetooth working. c) Calibration of sensor systems to a default starting point. d) Confirmation that data has been transmitted to AWS cloud systems.	3/31/2018	Tyler Anderson
Requirement: Microphone Sensor Implementation in App	1. Verification of a working microphone sensor on Android smartphone. Sound data should be recorded and stored on the Android smartphone until requested in the application to be sent to AWS cloud systems.	3/31/2018	Tyler Anderson

3. Test Approach(s)

Testing will be done once each individual component of the system has been created and confirmed to be in an operable state. Once the system is complete, full-scale testing will be done on all components in a combined manner.

4. Test Cases

Test Cases (By Requirement)	Test Scenario	Test Steps	Expected Result
Requirement: Sensor System for Respiratory Movement and Body Movement	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that output values are within valid ranges as specified by the motion sensor data sheet.	Valid data being output.
Requirement: Sensor System for patient Airflow	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen is lowest at ambient noise levels and increases when noise is introduced to the microphone.	Valid data being output.

Requirement: Sensor Power Circuitry	<ol style="list-style-type: none"> 1. Verification that portable power systems must be able to show charge and discharge. 2. Verification that portable power systems must be able to power each sensor system without performance degradation (unless explicitly specified). 	<ol style="list-style-type: none"> 1. Verify that batteries do not heat up to an unreasonable level to human touch during use. 2. Verify that each sensor system continues to operate normally under battery operation. 	
Requirement: Sensor System for patient Heart-Rate & Blood Oxygen Saturation	<ol style="list-style-type: none"> 1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application. 	<ol style="list-style-type: none"> 1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen for heart-rate is reasonable, e.g. Between 60 and 150bpm. Verify that blood oxygen level values given are reasonable. 	Valid data being output.
Requirement: Sensor System for patient Body Temperature	<ol style="list-style-type: none"> 1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application. 	<ol style="list-style-type: none"> 1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen for body temperature are reasonable values given ambient and skin temperatures. 	Valid data being output.

Requirement: Data Storage	1. Verification of data integrity inside S3 Bucket(s).	1. In the smartphone application, send the EDF formatted file to AWS cloud services.	Data is shown to be saved into users' private folders.
Requirement: Data Formation	1. Verification that '.EDF' data can be opened by the EDFBrowser program (used to view EDF formatted data in a visual graph format)	1. Open file in EDFBrowser.	Valid data is opened and displayed.
Requirement: Data Archival	1. Verification that data inside of S3 Bucket(s) have been categorized as 'Archived' for long term storage.	1. Leave file in cloud until shown to be archived on Amazon Glacier.	Data that is saved into users' private folders is properly archived in Amazon Glacier after a 'few' days of no access.
Requirement: Scoring Program	1. Verification that program functionality a) Can read 'EDF' data b) Process Data c) Generate a report for analysis.	1. Run the script file to process data test files. a) If valid patient file is available, test with that as priority over basic data test files.	Valid Scored report is generated.
Requirement: Smartphone Application	1. Verification of Application functionality: a) User Interface is properly working. b) Connection of sensor systems over Bluetooth working. c) Calibration of sensor systems to a default starting point. d) Confirmation that data has been transmitted to AWS cloud systems.	1. Confirm that the application runs correctly without any form of a crash. 2. Verify that the application is properly receiving data from the sensors and is being stored on the smartphone. 3. Verify that the application is properly transmitting data to the cloud database.	User interface does not achieve critical errors during operation. Sensor systems successfully communicate with application. Calibration procedure properly tares initial values. Data is verified as uploaded to AWS cloud systems.

Requirement: Microphone Sensor Implementation in App	1. Verification of a working microphone sensor on Android smartphone. Sound data should be recorded and stored on the Android smartphone until requested in the application to be sent to AWS cloud systems.	1. Confirm that the application is properly storing audio from the microphone onto the smartphone.	Microphone successfully creates audio file on smartphone device.
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5. Test Regulatory/Mandate Criteria

Tests must achieve satisfactory levels of data protection as outlined by U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act of 1996 ("HIPPA"). They must also meet standards outlined by the FDA for device sale approval

[Describe any regulations or mandates that the system must be tested against.]

6. Test Pass/Fail Criteria

Test Pass Criteria: Once each specific component of the system has completed its respected test plan with successful results by the team member responsible, it will be considered operational.

Test Fail Criteria: Once each specific component of the system has completed its respected test plan with unsuccessful results by the team member responsible, it will be considered unoperational.

[Describe the criteria used to determine if a test item has passed or failed its test.]

7. Test Entry/Exit Criteria

Test Entry Criteria: Once each specific component of the system has been confirmed to be in an operable state by the team member responsible, it will be open to testing.

Test Exit Criteria: Once the specific component of the system has been found to be fully operational, product testing for that component may end.

8. Test Deliverables

This system will produce an ".edf" (European Data Format) file that contains data from all sensor systems over a testing/runtime period. It will also produce a ".pdf" file that outlines the preliminary diagnosis based on OSA scoring algorithms. Finally, a sound file will be produced that will contain sound from the user's snoring through a testing/runtime period of this system.

9. Test Suspension/Resumption Criteria

Test Suspension Criteria: If a major fault is identified during testing that will affect operation of the system, testing will stop until that fault can be rectified.

Test Resumption Criteria: Testing may resume once the fault has been identified and fixed.

10. Test Environmental/Staffing/Training Needs

Test administrator(s) will need knowledge of Arduino hardware & programming (C/C++ code variants) and Java programming language experience. They will need knowledge on Bluetooth operations. They will also need knowledge on operating Amazon Web Services system modules (AWS certification available).

Test environment will require a quiet & dimly lit area containing a place to lay down comfortably, such as a bedroom and bed. Test administrators will also require a WIFI connection to the internet so that data can be uploaded from the system to AWS for storage and analysis.

G. Integration Testing

1. Test Risks/Issues

There are currently no known risks that have been identified for this system.

2. Items to be Tested/Not Tested

Item to Test	Test Description	Test Date	Responsibility
Full System	1. Test of the full system in operation will be done on all built sensor systems and smartphone(s) as needed.	4/15/2018	Team Snooze

3. Test Approach(s)

The approach to integration testing will be to test our system on the physical hardware that was created, as no virtualization can be realized in this testing phase.

4. Test Cases

Test Cases (By Requirement)	Test Scenario	Test Steps	Expected Result
Requirement: Sensor System for Respiratory Movement and Body Movement	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that output values are within valid ranges as specified by the motion sensor data sheet.	Valid data being output.

Requirement: Sensor System for patient Airflow	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen is lowest at ambient noise levels and increases when noise is introduced to the microphone.	Valid data being output.
Requirement: Sensor Power Circuitry	1. Verification that portable power systems must be able to show charge and discharge. 2. Verification that portable power systems must be able to power each sensor system without performance degradation (unless explicitly specified).	1. Verify that batteries do not heat up to an unreasonable level to human touch during use. 2. Verify that each sensor system continues to operate normally under battery operation.	
Requirement: Sensor System for patient Heart-Rate & Blood Oxygen Saturation	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen for heart-rate is reasonable, e.g. Between 60 and 150bpm. Verify that blood oxygen level values given are reasonable.	Valid data being output.

Requirement: Sensor System for patient Body Temperature	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen for body temperature are reasonable values given ambient and skin temperatures.	Valid data being output.
Requirement: Data Storage	1. Verification of data integrity inside S3 Bucket(s).	1. In the smartphone application, send the EDF formatted file to AWS cloud services.	Data is shown to be saved into users' private folders.
Requirement: Data Formation	1. Verification that '.EDF' data can be opened by the EDFBrowser program (used to view EDF formatted data in a visual graph format)	1. Open file in EDFBrowser.	Valid data is opened and displayed.
Requirement: Data Archival	1. Verification that data inside of S3 Bucket(s) have been categorized as 'Archived' for long term storage.	1. Leave file in cloud until shown to be archived on Amazon Glacier.	Data that is saved into users' private folders is properly archived in Amazon Glacier after a 'few' days of no access.
Requirement: Scoring Program	1. Verification that program functionality a) Can read 'EDF' data b) Process Data c) Generate a report for analysis.	1. Run the script file to process data test files. a) If valid patient file is available, test with that as priority over basic data test files.	Valid Scored report is generated.
Requirement: Smartphone Application	1. Verification of Application functionality: a) User Interface is properly working.	1. Confirm that the application runs correctly without any form of a crash.	User interface does not achieve critical errors during operation.

	b) Connection of sensor systems over Bluetooth working. c) Calibration of sensor systems to a default starting point. d) Confirmation that data has been transmitted to AWS cloud systems.	2. Verify that the application is properly receiving data from the sensors and is being stored on the smartphone. 3. Verify that the application is properly transmitting data to the cloud database.	Sensor systems successfully communicate with application. Calibration procedure properly takes initial values. Data is verified as uploaded to AWS cloud systems.
Requirement: Microphone Sensor Implementation in App	1. Verification of a working microphone sensor on Android smartphone. Sound data should be recorded and stored on the Android smartphone until requested in the application to be sent to AWS cloud systems.	1. Confirm that the application is properly storing audio from the microphone onto the smartphone.	Microphone successfully creates audio file on smartphone device.

5. Test Regulatory/Mandate Criteria

Tests must achieve satisfactory levels of data protection as outlined by U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act of 1996 ("HIPPA"). They must also meet standards outlined by the FDA for device sale approval

6. Test Pass/Fail Criteria

Test Pass Criteria: Once each specific component of the system has completed its respected test plan with successful results by the team member responsible, it will be considered operational.

Test Fail Criteria: Once each specific component of the system has completed its respected test plan with unsuccessful results by the team member responsible, it will be considered unoperational.

7. Test Entry/Exit Criteria

Test Entry Criteria: Once each specific component of the system has been confirmed to be in an operable state by the team member responsible, it will be open to testing.

Test Exit Criteria: Once the specific component of the system has been found to be fully operational, product testing for that component may end.

8. Test Deliverables

This system will produce an “.edf” (European Data Format) file that contains data from all sensor systems over a testing/runtime period. It will also produce a “.pdf” file that outlines the preliminary diagnosis based on OSA scoring algorithms. Finally, a sound file will be produced that will contain sound from the user’s snoring through a testing/runtime period of this system.

9. Test Suspension/Resumption Criteria

Test Suspension Criteria: If a major fault is identified during testing that will affect operation of the system, testing will stop until that fault can be rectified.

Test Resumption Criteria: Testing may resume once the fault has been identified and fixed.

10. Test Environmental/Staffing/Training Needs

Test administrator(s) will need knowledge of Arduino hardware & programming (C/C++ code variants) and Java programming language experience. They will need knowledge on Bluetooth operations. They will also need knowledge on operating Amazon Web Services system modules (AWS certification available).

Test environment will require a quiet & dimly lit area containing a place to lay down comfortably, such as a bedroom and bed. Test administrators will also require a WIFI connection to the internet so that data can be uploaded from the system to AWS for storage and analysis.

H. System Testing

1. Test Risks/Issues

There are currently no known risks that have been identified for this system.

2. Items to be Tested/Not Tested

Item to Test	Test Description	Test Date	Responsibility
Full System	2. Test of the full system in operation will be done on all built sensor systems and smartphone(s) as needed.	4/15/2018	Team Snooze

3. Test Approach(s)

The approach to integration testing will be to test our system on the physical hardware that was created, as no virtualization can be realized in this testing phase.

4. Test Cases

Test Cases (By Requirement)	Test Scenario	Test Steps	Expected Result
Requirement: Sensor System for Respiratory Movement and Body Movement	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that output values are within valid ranges as specified by the motion sensor data sheet.	Valid data being output.

Requirement: Sensor System for patient Airflow	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen is lowest at ambient noise levels and increases when noise is introduced to the microphone.	Valid data being output.
Requirement: Sensor Power Circuitry	1. Verification that portable power systems must be able to show charge and discharge. 2. Verification that portable power systems must be able to power each sensor system without performance degradation (unless explicitly specified).	1. Verify that batteries do not heat up to an unreasonable level to human touch during use. 2. Verify that each sensor system continues to operate normally under battery operation.	
Requirement: Sensor System for patient Heart-Rate & Blood Oxygen Saturation	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen for heart-rate is reasonable, e.g. Between 60 and 150bpm. Verify that blood oxygen level values given are reasonable.	Valid data being output.

Requirement: Sensor System for patient Body Temperature	1. Verification of working sensor data over Bluetooth communications to a Serial Monitor application.	1. Open Serial Monitor application on desktop computer (or smartphone if desired). 2. Connect to sensor system over Bluetooth. 3. Using the Bluetooth port, ensure that all data rates match so that valid data can be received. 4. Verify that the number displayed on screen for body temperature are reasonable values given ambient and skin temperatures.	Valid data being output.
Requirement: Data Storage	1. Verification of data integrity inside S3 Bucket(s).	1. In the smartphone application, send the EDF formatted file to AWS cloud services.	Data is shown to be saved into users' private folders.
Requirement: Data Formation	1. Verification that '.EDF' data can be opened by the EDFBrowser program (used to view EDF formatted data in a visual graph format)	1. Open file in EDFBrowser.	Valid data is opened and displayed.
Requirement: Data Archival	1. Verification that data inside of S3 Bucket(s) have been categorized as 'Archived' for long term storage.	1. Leave file in cloud until shown to be archived on Amazon Glacier.	Data that is saved into users' private folders is properly archived in Amazon Glacier after a 'few' days of no access.
Requirement: Scoring Program	1. Verification that program functionality a) Can read 'EDF' data b) Process Data c) Generate a report for analysis.	1. Run the script file to process data test files. a) If valid patient file is available, test with that as priority over basic data test files.	Valid Scored report is generated.

Requirement: Smartphone Application	1. Verification of Application functionality: a) User Interface is properly working. b) Connection of sensor systems over Bluetooth working. c) Calibration of sensor systems to a default starting point. d) Confirmation that data has been transmitted to AWS cloud systems.	1. Confirm that the application runs correctly without any form of a crash. 2. Verify that the application is properly receiving data from the sensors and is being stored on the smartphone. 3. Verify that the application is properly transmitting data to the cloud database.	User interface does not achieve critical errors during operation. Sensor systems successfully communicate with application. Calibration procedure properly tares initial values. Data is verified as uploaded to AWS cloud systems.
Requirement: Microphone Sensor Implementation in App	1. Verification of a working microphone sensor on Android smartphone. Sound data should be recorded and stored on the Android smartphone until requested in the application to be sent to AWS cloud systems.	1. Confirm that the application is properly storing audio from the microphone onto the smartphone.	Microphone successfully creates audio file on smartphone device.

5. Test Regulatory/Mandate Criteria

Tests must achieve satisfactory levels of data protection as outlined by U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act of 1996 ("HIPPA"). They must also meet standards outlined by the FDA for device sale approval

6. Test Pass/Fail Criteria

Test Pass Criteria: Once each specific component of the system has completed its respected test plan with successful results by the team member responsible, it will be considered operational.

Test Fail Criteria: Once each specific component of the system has completed its respected test plan with unsuccessful results by the team member responsible, it will be considered unoperational.

7. Test Entry/Exit Criteria

Test Entry Criteria: Once each specific component of the system has been confirmed to be in an operable state by the team member responsible, it will be open to testing.

Test Exit Criteria: Once the specific component of the system has been found to be fully operational, product testing for that component may end.

8. Test Deliverables

This system will produce an “.edf” (European Data Format) file that contains data from all sensor systems over a testing/runtime period. It will also produce a “.pdf” file that outlines the preliminary diagnosis based on OSA scoring algorithms. Finally, a sound file will be produced that will contain sound from the user’s snoring through a testing/runtime period of this system.

9. Test Suspension/Resumption Criteria

Test Suspension Criteria: If a major fault is identified during testing that will affect operation of the system, testing will stop until that fault can be rectified.

Test Resumption Criteria: Testing may resume once the fault has been identified and fixed.

10. Test Environmental/Staffing/Training Needs

Test administrator(s) will need knowledge of Arduino hardware & programming (C/C++ code variants) and Java programming language experience. They will need knowledge on Bluetooth operations. They will also need knowledge on operating Amazon Web Services system modules (AWS certification available).

Test environment will require a quiet & dimly lit area containing a place to lay down comfortably, such as a bedroom and bed. Test administrators will also require a WIFI connection to the internet so that data can be uploaded from the system to AWS for storage and analysis.

I. User Acceptance Testing

1. Test Risks/Issues

There are currently no identified risks associated with any testing of this product.

2. Items to be Tested/Not Tested

User acceptance testing will entail the exact same items and testing methods as **Section G** located earlier.

3. Test Approach(s)

User acceptance testing will entail the exact same test approach as **Section G** located earlier.

4. Test Cases

User acceptance testing will entail the exact same test cases as **Section G** located earlier.

5. Test Regulatory/Mandate Criteria

User acceptance testing will entail the exact same regulations and mandates as **Section G** located earlier.

6. Test Pass/Fail Criteria

User acceptance testing will entail the exact same items and testing methods as **Section G** located earlier.

7. Test Entry/Exit Criteria

User acceptance testing will entail the exact test entry/exit criteria as **Section G** located earlier.

8. Test Deliverables

User acceptance testing will entail the exact same test deliverables as **Section G** located earlier.

9. Test Suspension/Resumption Criteria

User acceptance testing will entail the exact same test suspension/resumption criteria as **Section G** located earlier.

10. Test Environmental/Staffing/Training Needs

User acceptance testing will entail the exact same testing environment and staff/training needs as **Section G** located earlier.