Acceptance Test Procedures

Biomedical Sensor Board for Education

ENGR 498B - #24052

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REVISION PAGE

REVISION#	REVISION DATE	REVISION DESCRIPTION	REVISED BY
1	10/16/23	Document Created and Format Established	Michael
2	10/17/23	Wrote Temperature and ECG Procedures	Michael
3	10/18/23	Wrote Skin Impedance Procedures	Michael
4	10/19/23	Wrote Sound sensor and Pulse Ox Procedures	Daniel
5	10/19/23	Wrote Pulse Ox Procedures	Daniel
6	10/19/23	Final format edits	Michael
7	11/12/23	Added IP Rating Tests	Michael
8	11/14/23	Added Chemical Resistance and Internal Power Tests, format edits	Michael
9	11/26/23	Small Updates to Various Tests	Michael
10	1/16/2024	Added Inspection Sheets for Weight and Dimensions	Michael
11	1/17/2024	Added All Other Inspection Reports	Michael

TABLE OF CONTENTS

Page No.

1.1 Temperature Sensor Module Acceptance Test

1.2 Introduction: This procedure outlines the acceptance tests to be performed on the Temperature Sensor Module (100300) which will be conducted in the lab. These tests will verify that the temperature sensor can output a correct reading for the contact temperature of an object with the correct range and accuracy.

1.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

1.4 Required Test Equipment: The list of required test equipment includes:

Description	Model Number	Accuracy
Temperature Assy	100300	n/a
Laptop	n/a	n/a
Arduino IDE	Arduino IDE 2.2.1	n/a
Cup of Water	n/a	n/a
Cole-Parmer Traceable Calibrated Extreme-Accuracy Digital Thermometer	UX-90000-25	± 0.01 °C
Microwave	n/a	n/a

1.5 Table of Tests:

Test Number	Test	Requirement
1.5.1	Temperature Sensor Module Range	Reading between 21°C and 45°C
1.5.2	Temperature Sensor Module Accuracy	<0.1°C of error

1.6 Step-by-step Procedure

1.6.1 Temperature Sensor Module Range

a. Place the cup containing at least 200 mL of water on a table in a room and leave the cup for 12 hours to allow the cup to come to room temperature
b. Plug temperature sensor module into the laptop using USB-C cable
c. Open Arduino IDE on the laptop
d. Open the Serial Monitor in the Arduino IDE
e. Set the microcontroller to Adafruit Feather ESP32-S3 No PSRAM in the dropdown menu in top left of the Arduino IDE
f. Set the com port to an open com port in the same dropdown menu

g. Ensure the module is connected by referencing the bottom right corner of the Arduino IDE
h. Using the reference thermometer, test the temperature of the cup of water and record the reading
i. Place the temperature sensor probe into the cup of water
j. Wait 10 seconds for the measurement to stabilize
k. Read the temperature reading on the Arduino IDE Serial Monitor and record the reading
l. Remove the probe from the water
m. Heat the water using a microwave until the temperature has increased by roughly 5°C Celsius, confirming the increase in temperature using the reference thermometer and record the measurement
n. Repeat steps i. through m. until a temperature of 45°C has been measured
o. Compare the temperature values measured with both sensors and ensure that the values measured with the module are within ±3°C of the reference thermometer **Mark Pass/Fail on the datasheet**

1.6.2 Temperature Sensor Module Accuracy

a. Place the cup containing at least 200 mL of water on a table in a room and leave the cup for 12 hours to allow the cup to come to room temperature
b. Plug temperature sensor module into the laptop using USB-C cable
c. Open Arduino IDE on the laptop
d. Open the Serial Monitor in the Arduino IDE
e. Set the microcontroller to Adafruit Feather ESP32-S3 No PSRAM in the dropdown menu in top left of the Arduino IDE
f. Set the com port to an open com port in the same dropdown menu
g. Ensure the module is connected by referencing the bottom right corner of the Arduino IDE
h. Using the reference thermometer, test the temperature of the cup of water and record the reading
i. Place the temperature sensor probe into the cup of water
j. Wait 10 seconds for the measurement to stabilize
k. Read the temperature reading on the Arduino IDE Serial Monitor and record the reading
l. Remove the probe from the water
m. Heat the water using a microwave until the temperature has increased by roughly 5°C Celsius, confirming the increase in temperature using the reference thermometer and record the measurement
n. Repeat steps i. through m. until a temperature of 45°C has been measured
o. Compare the temperature values measured with both sensors and ensure that the values measured with the module are within ±0.1°C of the reference thermometer **Mark Pass/Fail on the datasheet**

1.7 Support Requirements: None

1.8 Acceptance Test Data Sheets

1.8.1 Temperature Sensor Module Range Acceptance Test Data Sheet
Reference ATP Paragraph Number: 1.6.1
Analysis Referenced (for verification by T/A): None

Name of Test: Temperature Sensor Module Range			
Unit Under Test (UUT): Name: Temperature Assy Part Number: 100300 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement: Temperature Assy Measured Temperatures: Temperature 1: _____ Temperature 2: _____ Temperature 3: _____ Temperature 4: _____ Temperature 5: _____	Requirement (SR, with Tolerances): Measured Reference Temperatures: Temperature 1: _____ Temperature 2: _____ Temperature 3: _____ Temperature 4: _____ Temperature 5: _____	Test Equipment Error: ± 1 °C	Adjusted Test Limit: ± 2 °C
Computations, (Include Analyses Results, if any): None			
Signatures: Tester: _____ Witness:_____			

1.8.2 Temperature Sensor Module Accuracy Acceptance Test Data Sheet
Reference ATP Paragraph Number: 1.6.2

<table>
<tr><td colspan="4">Analysis Referenced (for verification by T/A): None</td></tr>
<tr><td colspan="4">Name of Test: Temperature Sensor Module Accuracy</td></tr>
<tr><td colspan="4">Unit Under Test (UUT):
Name: Temperature Assy
Part Number: 100300
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Test:</td></tr>
<tr><td>Recording of Test Measurement:

Temperature Assy Measured Temperatures:

Temperature 1: _____

Temperature 2: _____

Temperature 3: _____

Temperature 4: _____

Temperature 5: _____</td><td>Requirement (SR, with Tolerances):

Measured Reference Temperatures:

Temperature 1: _____

Temperature 2: _____

Temperature 3: _____

Temperature 4: _____

Temperature 5: _____</td><td>Test Equipment Error:

± 0.01 °C</td><td>Adjusted Test Limit:

± 0.09 °C</td></tr>
<tr><td colspan="4">Computations, (Include Analyses Results, if any):
None</td></tr>
<tr><td colspan="4">Signatures:

Tester: _____

Witness:_____</td></tr>
</table>

2.1 Digital Stethoscope Module Acceptance Test

2.2 Introduction: This procedure outlines the acceptance tests to be performed on the Digital Stethoscope Module (100400) which will be conducted in the lab. These tests will verify that the sound sensor can output a correct reading for a heartbeat within a range of frequencies of 20 Hz to 200 Hz.

2.3 Referenced Documents:

- Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15
- Alanazi, A. A., Atcherson, S. R., Franklin, C. A., & Bryan, M. F. (2020). Frequency responses of conventional and amplified stethoscopes for measuring heart sounds. *Saudi Journal of Medicine and Medical Sciences*, *8*(2), 112. https://doi.org/10.4103/sjmms.sjmms_118_19

2.4 Required Test Equipment: The list of required test equipment includes:

Description	Model Number	Accuracy
Sound sensor Assy	100400	n/a
Laptop	n/a	n/a
Arduino IDE	Arduino IDE 2.2.1	n/a
Stethoscope bell and tube	n/a	n/a
Cell Phone with sound modulator	n/a	n/a

2.5 Table of Tests:

Test Number	Test	Requirement
2.5.1	Sound Sensor Module Range	Readings between 20 Hz to 800 Hz
2.5.2	Digital Stethoscope Module Range	Readings between 20 Hz to 800 Hz with the stethoscope bell and tube

2.6 Step-by-step Procedure

2.6.1 Sound Sensor Module Range

a. Complete the breadboard prototype for the amplifiers with a DC gain of ~10 V/V and Low Pass filter with a cutoff frequency of ~800 Hz.
b. Assemble sound sensor and circuitry to the ESP32-S3.
c. Program a software in Arduino IDE to return the frequency of the sound signal.
d. Use the sound modulator to display different frequencies.
e. Measure the different frequencies (that go from 20 Hz to 800 Hz) with the sound sensor.
f. Verify if the module correctly reads frequencies lower than 800 Hz and filters frequencies higher than 800 Hz. **Mark Pass/Fail on the datasheet**

2.6.2 Digital Stethoscope Module Range

a. Complete the breadboard prototype for the amplifiers with a DC gain of ~10 V/V and Low Pass filter with a cutoff frequency of ~800 Hz.
b. Assemble sound sensor and circuitry to the ESP32-S3.
c. Program a software in Arduino IDE to return the frequency of the sound signal.
d. Use the sound modulator to display different frequencies.
e. Plug the sound sensor at the end of the stethoscope tube.
f. Place the Cell phone (sound modulator) on the stethoscope bell.
g. Measure the different frequencies (that go from 20 Hz to 800 Hz) with the digital stethoscope module.
h. Verify if the module correctly reads frequencies lower than 800 Hz and filters frequencies higher than 800 Hz. **Mark Pass/Fail on the datasheet**

2.7 Support Requirements: None

2.8 Acceptance Test Data Sheets

<table>
<tr><td colspan="4">2.8.1 Sound Sensor Module Range Acceptance Test Data Sheet</td></tr>
<tr><td colspan="4">Reference ATP Paragraph Number: 2.6.1</td></tr>
<tr><td colspan="4">Analysis Referenced (for verification by T/A):</td></tr>
<tr><td colspan="4">Name of Test: Sound Sensor Module Range</td></tr>
<tr><td colspan="4">Unit Under Test (UUT):
Name: Digital Stethoscope Assy
Part Number: 100400
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Test:</td></tr>
<tr><td>Recording of Test Measurement:

Digital Stethoscope Assy Measured Frequencies:

Freq. 1:_____

Freq. 2:_____

Freq. 3:_____

Freq. 4:_____

Freq. 5:_____</td><td>Requirement (SR, with Tolerances):

Frequencies displayed by the sound modulator:

Freq. 1:_____

Freq. 2:_____

Freq. 3:_____

Freq. 4:_____

Freq. 5:_____</td><td>Test Equipment Error:

n/a</td><td>Adjusted Test Limit:

± 10 Hz</td></tr>
</table>

Computations, (Include Analyses Results, if any): None
Signatures: Tester: _____ Witness:_____

2.8.2 Digital Stethoscope Module Range Acceptance Test Data Sheets			
Reference ATP Paragraph Number: 2.6.2			
Analysis Referenced (for verification by T/A): None			
Name of Test: Digital Stethoscope Module Range			
Unit Under Test (UUT): Name: Digital Stethoscope Assy Part Number: 100400 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement: Digital Stethoscope Assy Measured Frequencies: Freq. 1:_____ Freq. 2:_____ Freq. 3:_____ Freq. 4:_____ Freq. 5:_____	Requirement (SR, with Tolerances): Frequencies displayed by the sound modulator: Freq. 1:_____ Freq. 2:_____ Freq. 3:_____ Freq. 4:_____ Freq. 5:_____	Test Equipment Error: n/a	Adjusted Test Limit: ± 10 Hz
Computations, (Include Analyses Results, if any): None			

3.1 Pulse Oximeter Module Acceptance Test

3.2 Introduction: This procedure outlines the acceptance tests to be performed on the Pulse Oximeter Module (100500) which will be conducted in the lab. These tests will verify that the pulse oximeter can output a correct reading for BPM with a Signal to Noise ratio of at least 5.

3.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

3.4 Required Test Equipment: The list of required test equipment includes:

Description	Model Number	Accuracy
Pulse Oximeter Assy	100500	n/a
Laptop	n/a	n/a
Arduino IDE	Arduino IDE 2.2.1	n/a
Prebuilt Pulse Oximeter Fingertip	n/a	n/a

3.5 Table of Tests:

Test Number	Test	Requirement
3.5.1	Pulse Oximeter Module Heartbeat Range	Reading between 50 BPM and 180 BPM
3.5.2	Pulse Oximeter Module Signal to Noise Ratio	SNR >= 5

3.6 Step-by-step Procedure

3.6.1 Pulse Oximeter Module Heartbeat Range

a. Complete the breadboard prototype for the amplifiers with a DC gain of ~10 V/V.
b. Assemble pulse oximeter sensor and circuitry to the ESP32-S3.
c. Let the subject rest for five minutes (or the time needed for them to be relaxed).
d. Measure the heartbeat of the subject with the prebuilt Pulse Oximeter. Record the measurement.
e. Measure the heartbeat of the subject with the Pulse Oximeter module. Record the measurement.
f. Compare the measurements.
g. Make the subject walk for ten minutes.
h. Measure the heartbeat of the subject with the prebuilt Pulse Oximeter.
i. Measure the heartbeat of the subject with the Pulse Oximeter module.
j. Compare the measurements.
k. Make the subject run for five minutes.
l. Measure the heartbeat of the subject with the prebuilt Pulse Oximeter.
m. Measure the heartbeat of the subject with the Pulse Oximeter module.
n. Compare the measurements.

o. Verify that the measurements of the Pulse Ox module with the prebuilt Pulse Ox are consistent. **Mark Pass/Fail on the datasheet**

3.6.2 Pulse Oximeter Module Signal to Noise Ratio

a. Complete the breadboard prototype for the amplifiers with a DC gain of ~10 V/V.
b. Assemble pulse oximeter sensor and circuitry to the ESP32-S3.
c. Make the subject walk for ten minutes.
d. Measure the heartbeat of the subject with the Pulse Oximeter module.
e. Record the data.
f. Determine the number of samples in the signal.
g. Calculate the normalized averaged power of the signal.
h. Apply FFT to the signal.
i. Filter out the "ideal" band of the signal and keep everything else. This is the noise.
j. Calculate the normalized averaged power of the noise signal.
k. Verify if the SNR (p_signal/p_noise) is less than five. **Mark Pass/Fail on the datasheet**

3.7 Support Requirements: None

3.8 Acceptance Test Data Sheets

<table>
<tr><td colspan="4">3.8.1 Pulse Oximeter Module Heartbeat Range Acceptance Test Data Sheet</td></tr>
<tr><td colspan="4">Reference ATP Paragraph Number: 3.6.1</td></tr>
<tr><td colspan="4">Analysis Referenced (for verification by T/A): None</td></tr>
<tr><td colspan="4">Name of Test: Pulse Oximeter Module Heartbeat Range</td></tr>
<tr><td colspan="4">Unit Under Test (UUT):
Name: Pulse Oximeter Assy
Part Number: 100500
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Test:</td></tr>
<tr><td>Recording of Test Measurement:

Pulse Oximeter Module measurement of BPM when the subject:

Is relaxed:_____

Has walked:_____

Has run:_____</td><td>Requirement (SR, with Tolerances):

Prebuilt Pulse Oximeter measurement of BPM when the subject:

Is relaxed:_____

Has walked:_____

Has run:_____</td><td>Test Equipment Error:

n/a</td><td>Adjusted Test Limit:

n/a</td></tr>
</table>

Computations, (Include Analyses Results, if any): None			
Signatures: Tester: _____ Witness:_____			

3.8.2 Pulse Oximeter Module Signal to Noise Ratio Acceptance Test Data Sheets			
Reference ATP Paragraph Number: 3.6.2			
Analysis Referenced (for verification by T/A): None			
Name of Test: Pulse Oximeter Module Signal to Noise Ratio			
Unit Under Test (UUT): Name: Pulse Oximeter Assy Part Number: 100500 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement: Measured SNR: _____	Requirement (SR, with Tolerances): Minimum SNR: _____	Test Equipment Error: n/a	Adjusted Test Limit: n/a
Computations, (Include Analyses Results, if any): None			
Signatures: Tester: _____ Witness:_____			

4.1 Skin Impedance Module Acceptance Test

4.2 Introduction: This procedure outlines the acceptance tests to be performed on the Skin Impedance Module (100600) which will be conducted in the lab. These tests will verify that the skin impedance sensor is able to return a reading for the fat and water content of an object connected to the electrodes with the proper range and accuracy.

4.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

4.4 Required Test Equipment: The list of required test equipment includes:

Description	Model Number	Accuracy
Skin Impedance Assy	100600	n/a
Laptop	n/a	n/a
Arduino IDE	Arduino IDE 2.2.1	n/a

4.5 Table of Tests:

Test Number	Test	Requirement
4.5.1	Skin Impedance Module Range	Body fat measured between 5% and 40%, water content from 45% to 80%
4.5.2	Skin Impedance Module Accuracy	Within ±5% of true value

4.6 Step-by-step Procedure

4.6.1 Skin Impedance Module Range

a. Plug Skin Impedance sensor module into the laptop using USB-C cable
b. Open Arduino IDE on the laptop
c. Open the Serial Plotter in the Arduino IDE
d. Set the microcontroller to Adafruit Feather ESP32-S3 No PSRAM in the dropdown menu in top left of the Arduino IDE
e. Set the com port to an open com port in the same dropdown menu
f. Ensure the module is connected by referencing the bottom right corner of the Arduino IDE
g. Plug in 3.5mm jack from the electrodes into the port on the ECG module
h. Connect the electrode to an individual.
i. Record the output body fat and water content
j. Compare the output measurements for the weight, height, and sex at birth to data from another body fat measuring device **Mark Pass/Fail on the datasheet**

4.6.2 Skin Impedance Module Accuracy

k. Repeat steps a. through j. for ATP 4.6.1
l. Compare the output percentages with the expected percentages **Mark Pass/Fail on the datasheet**

4.7 Support Requirements:

Must find or calculate a reference body fat and water content table prior to tests.

4.8 Acceptance Test Data Sheets

<table>
<tr><td colspan="4">4.8.1 Skin Impedance Module Range Acceptance Test Data Sheet</td></tr>
<tr><td colspan="4">Reference ATP Paragraph Number: 4.6.1</td></tr>
<tr><td colspan="4">Analysis Referenced (for verification by T/A): none</td></tr>
<tr><td colspan="4">Name of Test: Skin Impedance Module Range</td></tr>
<tr><td colspan="4">Unit Under Test (UUT):
Name: Skin Impedance Assy
Part Number: 100600
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Test:</td></tr>
<tr><td>Recording of Test Measurement:

Subject 1:

Weight:_____

Height:_____

Sex:_____

Body Fat Content:__

Water Content:_____

Subject 2:

Weight:_____

Height:_____

Sex:_____

Body Fat Content:__</td><td>Requirement (SR, with Tolerances):

Subject 1:

Weight:_____

Height:_____

Sex:_____

Body Fat Content:__

Water Content:_____

Subject 2:

Weight:_____

Height:_____

Sex:_____

Body Fat Content:__</td><td>Test Equipment Error:

n/a</td><td>Adjusted Test Limit:

n/a</td></tr>
</table>

Water Content:_____ Subject 3: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 4: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 5: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____	Water Content:_____ Subject 3: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 4: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 5: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____		
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

4.8.2 Skin Impedance Module Accuracy Acceptance Test Data Sheet			
Reference ATP Paragraph Number: 4.6.2			
Analysis Referenced (for verification by T/A): none			
Name of Test: Skin Impedance Module Accuracy			
Unit Under Test (UUT): Name: Skin Impedance Assy Part Number: 100600 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement: Subject 1: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 2: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 3:	Requirement (SR, with Tolerances): Subject 1: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 2: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 3:	Test Equipment Error: n/a	Adjusted Test Limit: n/a

Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 4: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 5: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____	Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 4: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____ Subject 5: Weight:_____ Height:_____ Sex:_____ Body Fat Content:__ Water Content:_____		
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

5.1 ECG Module Acceptance Test

5.2 Introduction: This procedure outlines the acceptance tests to be performed on the ECG Module (100700) which will be conducted in the lab. These tests will verify that the ECG module can return the graph of the QRS-complex, P-wave, and T-wave for an individual connected to the system; it will also verify that the signal-to-noise ratio is greater than 10 and that the power at 60 Hz is less than 10% of the total power.

5.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15
Biomedical Sensor Board for Education Minimum Viable Product 1, 10/19/2023, rev #3

5.4 Required Test Equipment: The list of required test equipment includes:

Description	Model Number	Accuracy
ECG Assy	100700	n/a
Laptop	n/a	n/a
Arduino IDE	Arduino IDE 2.2.1	n/a
ECG Simulator	SMC Model 20	n/a
Digital Multimeter	n/a	n/a
Oscilloscope	n/a	n/a

5.5 Table of Tests:

Test Number	Test	Requirement
5.5.1	Electrocardiogram Module Return Graph	Module returns graph of QRS-complex, P-wave, and T-wave
5.5.2	Electrocardiogram Module Signal Noise	SNR ≥ 10
5.5.3	Electrocardiogram Module Power Line Interference	Power at 60 Hz < 10% of total power

5.6 Step-by-step Procedure

5.6.1 Electrocardiogram Module Return Graph

a. Plug ECG sensor module into the laptop using USB-C cable
b. Open Arduino IDE on the laptop
c. Open the Serial Plotter in the Arduino IDE
d. Set the microcontroller to Adafruit Feather ESP32-S3 No PSRAM in the dropdown menu in top left of the Arduino IDE

e. Set the com port to an open com port in the same dropdown menu
f. Ensure the module is connected by referencing the bottom right corner of the Arduino IDE
g. Plug in 3mm jack from the 3 Snap Electrodes into the port on the ECG module
h. Attach the red electrode to the RL port on the ECG simulator, the blue electrode to the LA port on the ECG simulator, and the black electrode to the RA port on the ECG simulator
i. Set the BPM output rate on the ECG simulator to 30 BPM
j. Take a screenshot of the Serial Plotter graph of the ECG output
k. Repeat steps i. and j. for 60 BPM, 120 BPM, 180 BPM, and 240 BPM on the ECG simulator
l. Compare the wave pattern from the screenshots to the reference graph MVP1, 1.3.6 ECG Wave Signal Graph **Mark Pass/Fail on the datasheet**

5.6.2 Electrocardiogram Module Signal Noise

a. Repeat steps a. through j. for ATP 5.6.1
b. Examine the signal oscillations of the graph to ensure that the noise of the signal is less than a tenth of the signal and that the graph is smooth **Mark Pass/Fail on the datasheet**
c. Repeat steps b. for 60 BPM, 120 BPM, 180 BPM, and 240 BPM on the ECG simulator

5.6.3 Electrocardiogram Module Power Line Interference

a. Repeat steps a. through j. for ATP 5.6.1
b. Using a DMM and oscilloscope, examine the input voltage of the IC after the filter to determine the 60 Hz signal noise and determine if it is less than 10% of the input voltage **Mark Pass/Fail on the datasheet**

5.7 Support Requirements: None

5.8 Acceptance Test Data Sheets

<table>
<tr><td colspan="4">5.8.1 Electrocardiogram Module Return Graph Acceptance Test Data Sheet</td></tr>
<tr><td colspan="4">Reference ATP Paragraph Number: 5.6.1</td></tr>
<tr><td colspan="4">Analysis Referenced (for verification by T/A): none</td></tr>
<tr><td colspan="4">Name of Test: Electrocardiogram Module Return Graph</td></tr>
<tr><td colspan="4">Unit Under Test (UUT):
Name: ECG Assy
Part Number: 100700
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Test:</td></tr>
<tr><td>Recording of Test Measurement:

ECG Graphs:
● Baseline:

_____</td><td>Requirement (SR, with Tolerances):

Reference Graph:
● Baseline:

_____</td><td>Test Equipment Error:

n/a</td><td>Adjusted Test Limit:

n/a</td></tr>
</table>

• P-wave: _____ • T-wave: _____ • PR Segment: _____ • ST Segment: _____ • QRS-complex: _____	• P-wave: _____ • T-wave: _____ • PR Segment: _____ • ST Segment: _____ • QRS-complex: _____		
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

5.8.2 Electrocardiogram Module Signal Noise Acceptance Test Data Sheet			
Reference ATP Paragraph Number: 5.6.2			
Analysis Referenced (for verification by T/A): none			
Name of Test: Electrocardiogram Module Signal Noise			
Unit Under Test (UUT): Name: ECG Assy Part Number: 100700 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement:	Requirement (SR, with Tolerances):	Test Equipment Error:	Adjusted Test Limit:

Signal to Noise Ratio: _____	Required Signal to Noise Ratio: _____	n/a	n/a
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

5.8.3 Electrocardiogram Module Power Line Interference Acceptance Test Data Sheet			
Reference ATP Paragraph Number: 5.6.3			
Analysis Referenced (for verification by T/A): none			
Name of Test: Electrocardiogram Module Power Line Interference			
Unit Under Test (UUT): Name: ECG Assy Part Number: 100700 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement: Powerline Signal to Noise Ratio at 60 Hz: _____	Requirement (SR, with Tolerances): Required Powerline Signal to Noise Ratio at 60 Hz: _____	Test Equipment Error: n/a	Adjusted Test Limit: n/a
Computations, (Include Analyses Results, if any): none			
Signatures:			

Tester: _____

Witness:_____

6.1 IP Rating Acceptance Test

6.2 Introduction: This procedure outlines the acceptance tests to be performed on the Housing Module (100200) which will be conducted in the lab. These tests will verify that the Housing Module will be compliant with an IP rating of 20, as defined by IEC 60529. Through these tests, it will be verified that the housing is able to prevent the intrusion of objects with diameters of 12.5 mm or greater.

6.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

6.4 Required Test Equipment: The list of required test equipment includes:

Description	Model Number	Accuracy
Housing Assy	100200	n/a
Ruler	n/a	± 0.05 cm

6.5 Table of Tests:

Test Number	Test	Requirement
6.5.1	Object Intrusion Resistance	Housing prevents intrusion of objects of diameter 12.5 mm

6.6 Step-by-step Procedure

6.6.1 Object Intrusion Resistance

a. Ensure the Housing Module contains no electrical components by dismantling the clamshell housings
b. Ensure the clamshells are properly put together
c. Taking each of the seven cases, attempt to put fingers into the cases without dismantling the cases
d. Ensure that the test objects could not enter the case more than 0.35 centimeters **Mark Pass/Fail on the datasheet**

6.7 Support Requirements: None

6.8 Acceptance Test Data Sheets

6.8.1 Object Intrusion Resistance Acceptance Test Data Sheet
Reference ATP Paragraph Number: 6.6.1
Analysis Referenced (for verification by T/A): none
Name of Test: Object Intrusion Resistance
Unit Under Test (UUT): Name: Housing Assy Part Number: 100200

Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement: Maximum Measured Intrusion: Charger Housing: _____ Temperature Housing: _____ Sound Sensor Housing: _____ Pulse Oximeter Housing: _____ Skin Impedance Housing: _____ ECG Housing: _____ Receiver Housing: _____	Requirement (SR, with Tolerances): Maximum Allowed Intrusion: Charger Housing: _____ Temperature Housing: _____ Sound Sensor Housing: _____ Pulse Oximeter Housing: _____ Skin Impedance Housing: _____ ECG Housing: _____ Receiver Housing: _____	Test Equipment Error: ± 0.05 cm	Adjusted Test Limit: 0.3 cm
Computations, (Include Analyses Results, if any): none			

Signatures:

Tester: _____

Witness:_____

7.1 Probe Chemical Resistance Acceptance Test

7.2 Introduction: This procedure outlines the acceptance test to be performed on a select component within the Temperature Sensor Module (100300) which will be conducted in the lab. This test will verify that the tested component is resistant enough to chemical exposure that it can be disinfected with no noticeable decline in functionality over its expected lifespan.

7.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

7.4 Required Test Equipment: The list of required test equipment includes:

Description	Model Number	Accuracy
10 kΩ Thermistor	MA100GG103AN	± 0.1 ℃
Cup	n/a	n/a
70% Ethanol	n/a	n/a
Paper Towel	n/a	n/a

7.5 Table of Tests:

Test Number	Test	Requirement
7.5.1	Temperature Probe Chemical Resistance	Temperature probe is resistant to chemical cleaners

7.6 Step-by-step Procedure

7.6.1 Temperature Probe Chemical Resistance

a. Place 100 mL of ethanol into the cup
b. Place the sensor tip of the thermistor into the ethanol and keep the tip in the ethanol for at least one hour
c. Remove the tip from the ethanol and dry with a paper towel
d. Examine the probe to ensure there is no physical damage to the sensor tip **Mark Pass/Fail on the datasheet**
e. Repeat ATP 1.6 to ensure the range and accuracy of the probe is still within limits **Mark Pass/Fail on the datasheet**

7.7 Support Requirements: None

7.8 Acceptance Test Data Sheets

7.8.1 Temperature Probe Chemical Resistance Acceptance Test Data Sheet
Reference ATP Paragraph Number: 7.6.1
Analysis Referenced (for verification by T/A): none

<table>
<tr><td colspan="4">Name of Test: Temperature Probe Chemical Resistance</td></tr>
<tr><td colspan="4">Unit Under Test (UUT):
Name: 10 kΩ Thermistor
Part Number: MA100GG103AN
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Test:</td></tr>
<tr><td>Recording of Test Measurement:

Physical Damage:

_____

Probe Passes ATP 1.6:

_____</td><td>Requirement (SR, with Tolerances):

Physical Damage:

No

Probe Passes ATP 1.6:

Yes</td><td>Test Equipment Error:

n/a</td><td>Adjusted Test Limit:

n/a</td></tr>
<tr><td colspan="4">Computations, (Include Analyses Results, if any):
none</td></tr>
<tr><td colspan="4">Signatures:

Tester: _____

Witness:_____</td></tr>
</table>

8.1 Internal Power Supply Acceptance Test

8.2 Introduction: This procedure outlines the acceptance tests to be performed on all of the sensor modules (100300, 100400, 100500, 100600, and 100700) which will be conducted in the lab. Through these tests, it will be verified that the sensor modules can be powered for a minimum of 3 hours based solely on their internal power supplies.

8.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

8.4 Required Test Equipment: The list of required test equipment includes:

Description	Model Number	Accuracy
Temperature Assy	100300	n/a
Sound Sensor Assy	100400	n/a
Pulse Oximeter Assy	100500	n/a
Skin Impedance Assy	100600	n/a
ECG Assy	100700	n/a
Receiver Assy	100800	n/a
Rechargeable Battery	EEMB Lithium Polymer Battery 3.7 V 2000 mAh	n/a
iPhone Timer	Clock 2.0 or later	± 0.1 sec
Laptop	n/a	n/a
Arduino IDE	Arduino IDE 2.2.1	n/a

8.5 Table of Tests:

Test Number	Test	Requirement
8.5.1	Temperature Sensor Internal Power	Device can function for 3 hours disconnected from charger when fully charged
8.5.2	Sound Sensor Internal Power	Device can function for 3 hours disconnected from charger when fully charged
8.5.3	Pulse Oximeter Internal Power	Device can function for 3 hours disconnected from charger when fully charged

8.5.4	Skin Impedance Sensor Internal Power	Device can function for 3 hours disconnected from charger when fully charged
8.5.5	ECG Internal Power	Device can function for 3 hours disconnected from charger when fully charged

8.6 Step-by-step Procedure

8.6.1 Temperature Sensor Internal Power

a. Plug the Temperature Assy into a USB outlet using the USB-C cable
b. Allow the battery of the assy to charge for 6 hours
c. Plug the Receiver Assy into a laptop using a USB-C cable
d. Open Arduino IDE on the laptop
e. Set the microcontroller to Adafruit Feather ESP32-S3 No PSRAM in the dropdown menu in top left of the Arduino IDE
f. Set the com port to an open com port in the same dropdown menu
g. Ensure the Receiver Assy is connected by referencing the bottom right corner of the Arduino IDE
h. Ensure that the Temperature Assy is transmitting data to the Receiver Assy by opening the Serial Monitor in the Arduino IDE and seeing the Receiver is receiving data
i. Begin the stopwatch on the iPhone and disconnect the Temperature Assy from the charger
j. Monitor through the Arduino IDE that the Temperature Assy is functioning, and mark when the Temperature Assy stops transmitting data **Mark Pass/Fail on the datasheet**

8.6.2 Sound Sensor Internal Power

a. Plug the Sound Sensor Assy into a USB outlet using the USB-C cable
b. Allow the battery of the assy to charge for 6 hours
c. Plug the Receiver Assy into a laptop using a USB-C cable
d. Open Arduino IDE on the laptop
e. Set the microcontroller to Adafruit Feather ESP32-S3 No PSRAM in the dropdown menu in top left of the Arduino IDE
f. Set the com port to an open com port in the same dropdown menu
g. Ensure the Receiver Assy is connected by referencing the bottom right corner of the Arduino IDE
h. Ensure that the Sound Sensor Assy is transmitting data to the Receiver Assy by opening the Serial Monitor in the Arduino IDE and seeing the Receiver is receiving data
i. Begin the stopwatch on the iPhone and disconnect the Sound Sensor Assy from the charger
j. Monitor through the Arduino IDE that the Sound Sensor Assy is functioning, and mark when the Sound Sensor Assy stops transmitting data **Mark Pass/Fail on the datasheet**

8.6.3 Pulse Oximeter Internal Power

a. Plug the Pulse Oximeter Assy into a USB outlet using the USB-C cable
b. Allow the battery of the assy to charge for 6 hours
c. Plug the Receiver Assy into a laptop using a USB-C cable
d. Open Arduino IDE on the laptop
e. Set the microcontroller to Adafruit Feather ESP32-S3 No PSRAM in the dropdown menu in top left of the Arduino IDE

f. Set the com port to an open com port in the same dropdown menu
g. Ensure the Receiver Assy is connected by referencing the bottom right corner of the Arduino IDE
h. Ensure that the Pulse Oximeter Assy is transmitting data to the Receiver Assy by opening the Serial Monitor in the Arduino IDE and seeing the Receiver is receiving data
i. Begin the stopwatch on the iPhone and disconnect the Pulse Oximeter Assy from the charger
j. Monitor through the Arduino IDE that the Pulse Oximeter Assy is functioning, and mark when the Pulse Oximeter Assy stops transmitting data **Mark Pass/Fail on the datasheet**

8.6.4 Skin Impedance Sensor Internal Power

a. Plug the Skin Impedance Assy into a USB outlet using the USB-C cable
b. Allow the battery of the assy to charge for 6 hours
c. Plug the Receiver Assy into a laptop using a USB-C cable
d. Open Arduino IDE on the laptop
e. Set the microcontroller to Adafruit Feather ESP32-S3 No PSRAM in the dropdown menu in top left of the Arduino IDE
f. Set the com port to an open com port in the same dropdown menu
g. Ensure the Receiver Assy is connected by referencing the bottom right corner of the Arduino IDE
h. Ensure that the Skin Impedance Assy is transmitting data to the Receiver Assy by opening the Serial Monitor in the Arduino IDE and seeing the Receiver is receiving data
i. Begin the stopwatch on the iPhone and disconnect the Skin Impedance Assy from the charger
j. Monitor through the Arduino IDE that the Skin Impedance Assy is functioning, and mark when the Skin Impedance Assy stops transmitting data **Mark Pass/Fail on the datasheet**

8.6.5 ECG Internal Power

a. Plug the ECG Assy into a USB outlet using the USB-C cable
b. Allow the battery of the assy to charge for 6 hours
c. Plug the Receiver Assy into a laptop using a USB-C cable
d. Open Arduino IDE on the laptop
e. Set the microcontroller to Adafruit Feather ESP32-S3 No PSRAM in the dropdown menu in top left of the Arduino IDE
f. Set the com port to an open com port in the same dropdown menu
g. Ensure the Receiver Assy is connected by referencing the bottom right corner of the Arduino IDE
h. Ensure that the ECG Assy is transmitting data to the Receiver Assy by opening the Serial Monitor in the Arduino IDE and seeing the Receiver is receiving data
i. Begin the stopwatch on the iPhone and disconnect the ECG Assy from the charger
j. Monitor through the Arduino IDE that the ECG Assy is functioning, and mark when the ECG Assy stops transmitting data **Mark Pass/Fail on the datasheet**

8.7 Support Requirements: None

8.8 Acceptance Test Data Sheets

8.8.1 Temperature Sensor Internal Power Acceptance Test Data Sheet
Reference ATP Paragraph Number: 8.6.1
Analysis Referenced (for verification by T/A): none

Name of Test: Temperature Sensor Internal Power			
Unit Under Test (UUT): Name: Temperature Assy Part Number: 100300 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement: Sensor Assy Runtime: _____	Requirement (SR, with Tolerances): Required Runtime: _____	Test Equipment Error: ± 0.1 sec	Adjusted Test Limit: 3:00:00.1 hours
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

8.8.2 Sound Sensor Internal Power Acceptance Test Data Sheet			
Reference ATP Paragraph Number: 8.6.2			
Analysis Referenced (for verification by T/A): none			
Name of Test: Sound Sensor Internal Power			
Unit Under Test (UUT): Name: Sound Assy Part Number: 100400 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement:	Requirement (SR, with Tolerances):	Test Equipment Error:	Adjusted Test Limit:

Sensor Assy Runtime: _____	Required Runtime: _____	± 0.1 sec	3:00:00.1 hours
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

8.8.3 Pulse Oximeter Internal Power Acceptance Test Data Sheet			
Reference ATP Paragraph Number: 8.6.3			
Analysis Referenced (for verification by T/A): none			
Name of Test: Pulse Oximeter Internal Power			
Unit Under Test (UUT): Name: Pulse Oximeter Assy Part Number: 100500 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement: Sensor Assy Runtime: _____	Requirement (SR, with Tolerances): Required Runtime: _____	Test Equipment Error: ± 0.1 sec	Adjusted Test Limit: 3:00:00.1 hours
Computations, (Include Analyses Results, if any): none			
Signatures:			

Tester: _____

Witness:_____

8.8.4 Skin Impedance Sensor Internal Power Acceptance Test Data Sheet			
Reference ATP Paragraph Number: 8.6.4			
Analysis Referenced (for verification by T/A): none			
Name of Test: Skin Impedance Sensor Internal Power			
Unit Under Test (UUT): Name: Skin Impedance Assy Part Number: 100600 Serial Number: n/a			
Results (Pass / Fail):		Date of Test:	
Recording of Test Measurement: Sensor Assy Runtime: _____	Requirement (SR, with Tolerances): Required Runtime: _____	Test Equipment Error: ± 0.1 sec	Adjusted Test Limit: 3:00:00.1 hours
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

8.8.5 ECG Internal Power Acceptance Test Data Sheet

<table>
<tr><td colspan="4">Reference ATP Paragraph Number: 8.6.5</td></tr>
<tr><td colspan="4">Analysis Referenced (for verification by T/A): none</td></tr>
<tr><td colspan="4">Name of Test: ECG Internal Power</td></tr>
<tr><td colspan="4">Unit Under Test (UUT):
Name: ECG Assy
Part Number: 100700
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Test:</td></tr>
<tr><td>Recording of Test Measurement:

Sensor Assy Runtime:

_____</td><td>Requirement (SR, with Tolerances):

Required Runtime:

_____</td><td>Test Equipment Error:

± 0.1 sec</td><td>Adjusted Test Limit:

3:00:00.1 hours</td></tr>
<tr><td colspan="4">Computations, (Include Analyses Results, if any):
none</td></tr>
<tr><td colspan="4">Signatures:

Tester: _____

Witness:_____</td></tr>
</table>

9.1 System Weight Acceptance Inspection

9.2 Introduction: This procedure outlines the inspection procedures to be performed on the complete system (100100, 100200, 100300, 100400, 100500, 100600, 100700) which will be conducted in the lab. This inspection will verify that the system meets the requirement to be lightweight.

9.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

9.4 Required Inspection Equipment: The list of required inspection equipment includes:

Description	Model Number	Accuracy
Computer Assy	100100	n/a
Housing Assy	100200	n/a
Temperature Assy	100300	n/a
Sound Sensor Assy	100400	n/a
Pulse Oximeter Assy	100500	n/a
Skin Impedance Assy	100600	n/a
ECG Assy	100700	n/a
Scale	n/a	n/a

9.5 Table of Inspection:

Inspection Number	Inspection	Requirement
9.5.1	System Weight	System weighs less than 15 pounds

9.6 Step-by-step Procedure

9.6.1 System Weight

a. Place the completed Charger Housing Module with all components assembled onto the scale and measure and record the weight, in pounds
b. Remove the current item on the scale and repeat step a. for the assembled Receiver Module, Temperature Module, Sound Sensor Module, Pulse Oximeter Module, Skin Impedance Module, and ECG Module
c. Add all measured weights together and compared with the requirement **Mark Pass/Fail on the datasheet**

9.7 Support Requirements: None

9.8 Acceptance Inspection Data Sheets

9.8.1 System Weight Acceptance Inspection Data Sheet			
Reference ATP Paragraph Number: 9.6.1			
Analysis Referenced (for verification by T/A): none			
Name of Inspection: System Weight			
Unit Under Test (UUT): Name: Computer Assy Part Number: 100100 Serial Number: n/a Name: Housing Assy Part Number: 100200 Serial Number: n/a Name: Temperature Assy Part Number: 100300 Serial Number: n/a Name: Sound Sensor Assy Part Number: 100400 Serial Number: n/a Name: Pulse Oximeter Assy Part Number: 100500 Serial Number: n/a Name: Skin Impedance Assy Part Number: 100600 Serial Number: n/a Name: ECG Assy Part Number: 100700 Serial Number: n/a			
Results (Pass / Fail):		Date of Inspection:	
Recording of Inspection Measurement: Total Weight:	Requirement (SR, with Tolerances): Accepted Total Weight:	Inspection Equipment Error: n/a	Adjusted Inspection Limit: n/a

_____	_____		
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

10.1 System Dimensions Acceptance Inspection

10.2 Introduction: This procedure outlines the inspection procedures to be performed on the complete system (100200) which will be conducted in the lab. This inspection will verify that the system meets the requirement to be roughly the size of a shoebox.

10.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

10.4 Required Inspection Equipment: The list of required inspection equipment includes:

Description	Model Number	Accuracy
Housing Assy	100200	n/a
Measuring tape	n/a	n/a

10.5 Table of Inspection:

Inspection Number	Inspection	Requirement
10.5.1	System Dimensions	System is smaller than 35.5-cm by 25.4-cm by 20.7-cm

10.6 Step-by-step Procedure

10.6.1 System Dimensions

a. Completely assemble all of the Housing Modules and assemble them with the Charging Station Module
b. Using the tape measure, measure the total length, width, and height of the assembly from its furthest points and compare with the required dimensions **Mark Pass/Fail on the datasheet**

10.7 Support Requirements: None

10.8 Acceptance Inspection Data Sheets

10.8.1 System Dimensions Acceptance Inspection Data Sheet	
Reference ATP Paragraph Number: 10.6.1	
Analysis Referenced (for verification by T/A): none	
Name of Inspection: System Dimensions	
Unit Under Test (UUT): Name: Housing Assy Part Number: 100200 Serial Number: n/a	
Results (Pass / Fail):	Date of Inspection:

Recording of Inspection Measurement:	Requirement (SR, with Tolerances):	Inspection Equipment Error:	Adjusted Inspection Limit:
		n/a	n/a
Housing Assy Length:	Accepted Length:		
_____	_____		
Housing Assy Width:	Accepted Width:		
_____	_____		
Housing Assy Height:	Accepted Height:		
_____	_____		
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

11.1 Electrical Safety Acceptance Inspection

11.2 Introduction: This procedure outlines the inspection to be performed on the completed system (100100, 100200, 100300, 100400, 100500, 100600, 100700) which will be conducted in the lab. This inspection will verify that the system meets the requirement that the system does not have exposed electrical components.

11.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

11.4 Required Inspection Equipment: The list of required inspection equipment includes:

Description	Model Number	Accuracy
Computer Assy	100100	n/a
Housing Assy	100200	n/a
Temperature Assy	100300	n/a
Sound Sensor Assy	100400	n/a
Pulse Oximeter Assy	100500	n/a
Skin Impedance Assy	100600	n/a
ECG Assy	100700	n/a

11.5 Table of Inspection:

Inspection Number	Inspection	Requirement
11.5.1	Electrical Safety	System does not have exposed electrical components

11.6 Step-by-step Procedure

11.6.1 Electrical Safety

a. Completely assemble all modules, including all circuitry and housings
b. Inspect each module for exposed, uninsulated wires **Mark Pass/Fail on the datasheet**
c. Ensure that the module previously passed ATP 6.6 **Mark Pass/Fail on the datasheet**

11.7 Support Requirements: None

11.8 Acceptance Inspection Data Sheets

11.8.1 Electrical Safety Acceptance Inspection Data Sheet
Reference ATP Paragraph Number: 11.6.1
Analysis Referenced (for verification by T/A): none

<table>
<tr><td colspan="4">Name of Inspection: Electrical Safety</td></tr>
<tr><td colspan="4">Unit Under Test (UUT):
Name: Computer Assy
Part Number: 100100
Serial Number: n/a

Name: Housing Assy
Part Number: 100200
Serial Number: n/a

Name: Temperature Assy
Part Number: 100300
Serial Number: n/a

Name: Sound Sensor Assy
Part Number: 100400
Serial Number: n/a

Name: Pulse Oximeter Assy
Part Number: 100500
Serial Number: n/a

Name: Skin Impedance Assy
Part Number: 100600
Serial Number: n/a

Name: ECG Assy
Part Number: 100700
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Inspection:</td></tr>
<tr><td>Recording of Inspection Measurement:

All Wires and Components Insulated to Prevent Shock:

_____

System Passed ATP 6.6:</td><td>Requirement (SR, with Tolerances):

All Wires and Components Insulated to Prevent Shock:

Yes_____

System Passed ATP 6.6:</td><td>Inspection Equipment Error:

n/a</td><td>Adjusted Inspection Limit:

n/a</td></tr>
</table>

_____	Yes_____		
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

12.1 Privacy Protection Acceptance Inspection

12.2 Introduction: This procedure outlines the inspection to be performed on the Computer Assy (100100) which will be conducted in the lab. This inspection will verify that the system protects the privacy of the previous users.

12.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

12.4 Required Inspection Equipment: The list of required inspection equipment includes:

Description	Model Number	Accuracy
Computer Assy	100100	n/a
Temperature Assy	100300	n/a
Laptop	n/a	n/a

12.5 Table of Inspection:

Inspection Number	Inspection	Requirement
12.5.1	Privacy Protection	Computer Assy preserves the privacy of user data

12.6 Step-by-step Procedure

12.6.1 Privacy Protection

a. Connect the Receiver Module to the laptop and open the GUI
b. Turn on the Temperature Module
c. Collect data using the GUI for thirty seconds
d. Save the data to the laptop
e. Close the GUI, and restart the GUI on the computer
f. On the GUI, ensure that the user's name is never asked **Mark Pass/Fail on the datasheet**
g. On the GUI, ensure that the previous data has not been saved **Mark Pass/Fail on the datasheet**
h. Open the saved data on the computer, and ensure that no identifying information has been saved, such as the user's name **Mark Pass/Fail on the datasheet**

12.7 Support Requirements: None

12.8 Acceptance Inspection Data Sheets

12.8.1 Privacy Protection Acceptance Inspection Data Sheet
Reference ATP Paragraph Number: 12.6.1
Analysis Referenced (for verification by T/A): none
Name of Inspection: Privacy Protection

<table>
<tr><td colspan="4">Unit Under Test (UUT):
Name: Computer Assy
Part Number: 100100
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Inspection:</td></tr>
<tr><td>Recording of Inspection Measurement:

GUI Does Not Ask for User’s Name:

_____

Data is Not Saved on System Between Uses:

_____

User’s Name is Not Included with Save Data:

_____</td><td>Requirement (SR, with Tolerances):

GUI Does Not Ask for User’s Name:

Yes_____

Data is Not Saved on System Between Uses:

Yes_____

User’s Name is Not Included with Save Data:

Yes_____</td><td>Inspection Equipment Error:

n/a</td><td>Adjusted Inspection Limit:

n/a</td></tr>
<tr><td colspan="4">Computations, (Include Analyses Results, if any):
none</td></tr>
<tr><td colspan="4">Signatures:

Tester: _____

Witness:_____</td></tr>
</table>

13.1 Maximum Bioimpedance Current Acceptance Inspection

13.2 Introduction: This procedure outlines the inspection to be performed on the Skin Impedance Assy (100600) which will be conducted in the lab. This inspection will verify that the Skin Impedance Module's maximum current is safe for use on humans.
13.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15
13.4 Required Inspection Equipment: The list of required inspection equipment includes:

Description	Model Number	Accuracy
Skin Impedance Assy	100600	n/a
DMM	n/a	n/a

13.5 Table of Inspection:

Inspection Number	Inspection	Requirement
13.5.1	Maximum Bioimpedance Current	Current through electrodes does not exceed 10 µA.

13.6 Step-by-step Procedure
13.6.1 Maximum Bioimpedance Current
a. Turn on the Skin Impedance Module and connect the electrodes
b. Turn on the DMM
c. Using the DMM leads, measure the current through the electrodes and ensure it is less than 10 µA **Mark Pass/Fail on the datasheet**
13.7 Support Requirements: None
13.8 Acceptance Inspection Data Sheets

13.8.1 Maximum Bioimpedance Current Acceptance Inspection Data Sheet	
Reference ATP Paragraph Number: 13.6.1	
Analysis Referenced (for verification by T/A): none	
Name of Inspection: Maximum Bioimpedance Current	
Unit Under Test (UUT): Name: Skin Impedance Assy Part Number: 100600 Serial Number: n/a	
Results (Pass / Fail):	Date of Inspection:

Recording of Inspection Measurement: Maximum Measured Current: _____	Requirement (SR, with Tolerances): Maximum Allowed Current: _____	Inspection Equipment Error: n/a	Adjusted Inspection Limit: n/a
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

14.1 Maximum ECG Current Acceptance Inspection

14.2 Introduction: This procedure outlines the inspection to be performed on the ECG Assy (100700) which will be conducted in the lab. This inspection will verify that the ECG Module's maximum current is safe for use on humans.
14.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15
14.4 Required Inspection Equipment: The list of required inspection equipment includes:

Description	Model Number	Accuracy
ECG Assy	100700	n/a
DMM	n/a	n/a

14.5 Table of Inspection:

Inspection Number	Inspection	Requirement
14.5.1	Maximum ECG Current	Current through electrodes does not exceed 10 µA.

14.6 Step-by-step Procedure
14.6.1 Maximum ECG Current
- d. Turn on the ECG Module and connect the electrodes
- e. Turn on the DMM
- f. Using the DMM leads, measure the current through the electrodes and ensure it is less than 10 µA **Mark Pass/Fail on the datasheet**

14.7 Support Requirements: None
14.8 Acceptance Inspection Data Sheets

14.8.1 Maximum ECG Current Acceptance Inspection Data Sheet	
Reference ATP Paragraph Number: 14.6.1	
Analysis Referenced (for verification by T/A): none	
Name of Inspection: Maximum ECG Current	
Unit Under Test (UUT): Name: ECG Assy Part Number: 100700 Serial Number: n/a	
Results (Pass / Fail):	Date of Inspection:

Recording of Inspection Measurement: Maximum Measured Current: _____	Requirement (SR, with Tolerances): Maximum Allowed Current: _____	Inspection Equipment Error: n/a	Adjusted Inspection Limit: n/a
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			

15.1 Medical Device Standard Acceptance Inspection

15.2 Introduction: This procedure outlines the inspection to be performed on the completed system (100100, 100200, 100300, 100400, 100500, 100600, 100700) which will be conducted in the lab. This inspection will verify that the system meets the requirement that the system be safe for users.

15.3 Referenced Documents: Biomedical Sensor Board for Education System Requirements Document, 10/5/2023, rev #15

15.4 Required Inspection Equipment: The list of required inspection equipment includes:

Description	Model Number	Accuracy
Computer Assy	100100	n/a
Housing Assy	100200	n/a
Temperature Assy	100300	n/a
Sound Sensor Assy	100400	n/a
Pulse Oximeter Assy	100500	n/a
Skin Impedance Assy	100600	n/a
ECG Assy	100700	n/a

15.5 Table of Inspection:

Inspection Number	Inspection	Requirement
15.5.1	Medical Device Standard	System meets IEC 60601-1 safety standards

15.6 Step-by-step Procedure

15.6.1 Medical Device Standard

a. Ensure the system passed ATP 6.6 **Mark Pass/Fail on the datasheet**
b. Ensure the system passed ATP 7.6 **Mark Pass/Fail on the datasheet**
c. Ensure the system passed ATP 11.6 **Mark Pass/Fail on the datasheet**
d. Ensure the system passed ATP 13.6 **Mark Pass/Fail on the datasheet**
e. Ensure the system passed ATP 14.6 **Mark Pass/Fail on the datasheet**
f. Ensure the system meets ACGIH guidelines **Mark Pass/Fail on the datasheet**

15.7 Support Requirements: None

15.8 Acceptance Inspection Data Sheets

15.8.1 Medical Device Standard Acceptance Inspection Data Sheet
Reference ATP Paragraph Number: 15.6.1

<table>
<tr><td colspan="4">Analysis Referenced (for verification by T/A): none</td></tr>
<tr><td colspan="4">Name of Inspection: Medical Device Standard</td></tr>
<tr><td colspan="4">Unit Under Test (UUT):
Name: Computer Assy
Part Number: 100100
Serial Number: n/a

Name: Housing Assy
Part Number: 100200
Serial Number: n/a

Name: Temperature Assy
Part Number: 100300
Serial Number: n/a

Name: Sound Sensor Assy
Part Number: 100400
Serial Number: n/a

Name: Pulse Oximeter Assy
Part Number: 100500
Serial Number: n/a

Name: Skin Impedance Assy
Part Number: 100600
Serial Number: n/a

Name: ECG Assy
Part Number: 100700
Serial Number: n/a</td></tr>
<tr><td colspan="2">Results (Pass / Fail):</td><td colspan="2">Date of Inspection:</td></tr>
<tr><td>Recording of Inspection Measurement:

System Passed ATP 6.6:

_____

System Passed ATP 7.6:</td><td>Requirement (SR, with Tolerances):

System Passed ATP 6.6:

<u>Yes</u>_____

System Passed ATP 7.6:</td><td>Inspection Equipment Error:

n/a</td><td>Adjusted Inspection Limit:

n/a</td></tr>
</table>

_____ System Passed ATP 11.6: _____ System Passed ATP 13.6: _____ System Passed ATP 14.6: _____ System Passed ATP ACGIH Guidelines: _____	Yes_____ System Passed ATP 11.6: Yes_____ System Passed ATP 13.6: Yes_____ System Passed ATP 14.6: Yes_____ System Passed ATP ACGIH Guidelines: Yes_____		
Computations, (Include Analyses Results, if any): none			
Signatures: Tester: _____ Witness:_____			