Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
1.Device must monitor body temperature	1.1 Device must monitor skin temperature of 37ºC +/- 2ºC 1.2 Device must recognize temperatures above 39ºC as dangerous. 1.3 Device will use skin temperature as a surrogate for core body temperature readings	1.1 Objects at various temperatures will be measured with device and compared to a commercial thermometer. 1.2 Device will be exposed to temperature above 39ºC to verify device recognition of dangerous temperature 1.3 No verification activity	1.1-2 The device will be worn on an athlete participant during a normal team practice. Success will be defined based on accurately recording temperature values and sending an alarm should a temperature value exceed 39ºC 1.3 Core temperature of athlete will be measured using a temporal scanning thermometer and simultaneously compared to skin temperature measured by device.
Justification			
1.1-2 According to the Mayo Clinic, heat stroke occurs when body temperature rises to about 40ºC. In order to protect the user, the device will warn the individual of temperatures above 39ºC. [21] 1.3 Traditional ways to measure core body temperature are invasive			

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
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2.Device must measure impact forces to the body	2.1 Device must measure impact forces to the head 2.2 Device must measure impact forces to the chest 2.3 Device must warn user when forces reach or exceed 60 G's 2.4 Impact forces should be recorded along the three axes of athlete motion	2.1-3 ASTM-D5276 Standard Test Method for Drop Test of Loaded Containers by Free Fall. Drop contained device onto a flat, firm, nonyielding steel base. Drop height is set to 30" and is dropped ten times in ten different orientations. 2.4 Assembly will be dropped diagonally downward from 30" to detect recordings in three axes of motion	2.1-4 The device will be worn on an athlete participant during a normal team practice. Success will be defined based on successfully recording impact forces at the head and chest in all three directions of motion and sending an alarm if a recorded impact exceeds 60 G's

Justification
2.1 An estimated 1.6 to 3.8 million concussions occur in sports and recreational activities annually. [24] 2.2 Blunt impact to the chest can lead to sudden death from cardiac arrest during sports. [25] 2.3 NHTSA standard for a sudden impact acceleration on a human that would cause severe injury or death is 75 g's for a 50th percentile male, 65 g's for a 50th percentile female, and 50 g's for a 50th percentile child [26] 2.4 When athletes receive an impact, the body will not only respond in one direction.

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
3.Device must measure dehydration	3.1 Device must measure skin resistance (ohms) 3.2 Device must recognize skin resistance values greater than 1,000 Ohms as a potentially dehydrated state [13]	3.1-2 Attach device across nodes of a resistor and compare resistance measurement to banding pattern values on the resistor. Resistors greater than 1,000 Ohms will also be used to verify device recognition.	3.1 The device will be worn on an athlete participant during a normal team practice. Athletes will be weighed before and after practice. [7,19] Success will be defined based on successfully recording skin resistances and comparing them to percentage of mass lost after practice. The percentage of mass lost can also be compared to heart rate as heart rate rises 3-5 beats per minute every 1% of body weight loss [4]
Justification			
3.1 The National Centre for Catastrophic Sports Injuries (NCCSI) reported 4 deaths among college and high school football players in 2000 and it has recorded 20 deaths from heat stroke over the past 7 years. Dehydration was the contributing factor in all of these deaths [19] 3.2 Hypohydration of 2-3% of body mass can compromise athletic performance, heat dissipation, and cardiovascular function [6,17]			

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
4.Device must measure heart rate	4.1 Able to measure from 40 beats per minute (bpm) to 220 bpm 4.2 The device must recognize heart rates above 190 bpm as dangerous 4.3 Heart rate measured once per minute 4.4 The device must measure and record beat to beat intervals of the pulse curve	4.1-3 Using an arterial puncture arm mannequin, pump a blood-mimicking fluid composed of water, glycerol, and sodium iodide (viscosity 4.4±0.5 cP) through simulated artery using a motor with a known revolution speed [18]. The device will be attached to the mannequin and the recorded heart rate should resemble the pulsatile action of the motor.	4.1-3 The device will be worn on an athlete participant during a normal team practice. Success will be defined based on the sensor accurately and continuously recording heart rate and sending an alarm should the rate exceed 190 bpm. 4.4 The user will be able to view the pulse curve after a practice or game
Justification			
4.1 Minimum values of heart rate can reach values as low as 40 bpm. Maximum heart rate for collegiate athletes is approximately 200 bpm and active athlete heart rates reach between 65% and 95% of the maximum [12] [16] 4.2 Athletes spend most of their time at heart rates near the maximum heart rate. Rates at or above 95% of the maximum or above indicates overexertion [3] 4.3 Heart rate must be constantly measured so the player can be alerted as soon as his or her rate exceeds 95% of the maximum 4.4 A recording of beat to beat intervals can be used for analysis of heart rate variability to determine risk for SCD [14]			

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
5.Device must record all monitored signals	5.1 Connections to microprocessor must be secure. If not, user must be informed through alarm system. 5.2 Microprocessor must be able to read sensor data in order to monitor user's condition. 5.3 Device must record data during the entire practice (5 hours) 5.4 Device must collect an appropriate number of samples 5.4.1 Temperature sampled every 5 minutes 5.4.2 Heart rate sampled every minute 5.5 Device must have a sufficient amount of memory to collect data from all sensors for the entire practice	5.1-2 Each sensor will be tested individually according to verification in 1,2, and 3 in order to assure functionality. 5.3 Device will be turned on for 5 hours to ensure battery lasts. 5.4 Sampling frequency will be set during coding of microprocessor. 5.5 Data will be recorded on the device until memory is full in order to verify that enough memory is available.	5.1-2 All three sensors will accurately measure vitals and impact forces. 5.3 Athlete will complete an entire practice with device on and data will be checked in order to make sure it worked for the entire length of the practice. 5.4 Data will be inspected after practice to ensure sampling rate was correct. 5.5 Athlete will wear device through entire practice. If memory did not run out, validation will have been successful.

Design Input Requirement	5.Device must record all monitored signals

Justification
5.1-2 Microcontroller will be used due to its size and ease of integration with sensors. 5.3 Device is useless if it cannot obtain data for the entire time it is needed. 5.4 Data must be sampled often in order to ensure no dangerous changes in vitals are missed. 5.4.1 Temperature changes do not occur as abruptly as changes in heart rate, so sampling rate does not have to be as frequent. 5.4.2 Heart rate must be sampled often to detect if user demonstrates a heart rate at or above 95% of their maximum 5.5 If memory runs out, data will not be recorded and device would be useless

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
6.If any monitored metric of 1, 2, and /or 3 exceed specified range, user must be notified	6.1 The alarm must turn off automatically after it sounds for 10 seconds 6.2 Device must include an auditory alarm (70 dBA) to ensure that the signal is noticed when worn	6.1 Expose device to conditions which exceed the specified range of 1 and 2. Use a stopwatch to time duration of alarm. 6.2 Expose device to conditions which exceed the specified range of 1 and 2. Create background noise (60 dB). Ensure alarm can be heard above background noise [15]	6.1 The device will be worn on an athlete participant during a normal team practice. If the alarm sounds on the field, success will be determined if the alarm automatically turns off within 10 seconds 6.2 It will be observed throughout a practice whether the alarm is heard when turned on. The number of times the alarm turns on will be compared to the number of times the athlete's collected data shows physiological values outside of the defined range.

Justification

6.1 The duration of the alarm was determined to be long enough to notify the player while not creating a disturbance
6.2 Based on OSHA specifications for Permissible Noise Exposure [11]

Hours	8	6	4	3	2	1.5	1	0.25	< 0.25
Decibels	90	92	95	97	100	102	105	110	115

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
7.Device must operate on battery power	7.1 Battery must continuously supply 9V of power 7.2 Battery must continuously operate for 5 hours 7.3 Device must alert user when the battery is no longer supplying 9V 7.4 Athlete must be able to replace dead batteries	7.1 Device will be turned on and external supply voltage will be probed using a Digital Multimeter 7.2 Device will be turned on and timed until complete power dissipation will be measured 7.3 Old, used battery will be inserted into device and the device will be turned on. Digital Multimeter will probe external supply voltage. When the voltage decreases below 9V, alarm should be triggered. 7.4 Battery access panel will be opened	7.1-2 The device will be worn on an athlete participant during a normal team practice. Success will be determined if a new battery will last the entire duration of the practice and all electronic hardware continuously operates from the power source. 7.3 The device will be worn on an athlete participant during a normal team practice. Success will be determined if an old, used battery causes the device to alert the athlete of the performance malfunction. 7.4 Athlete will be asked to change the battery and report any difficulties

Design Input Requirement	7.Device must operate on battery power

Justification
7.1 Microcontroller can operate on an external supply of 6 to 20V. If supplied with less than 7V, the 5V pin may supply less than 5V and the board may be unstable. If using more than 12V, the voltage regulator may overheat and damage the board. The recommended range is 7 to 12 volts. A 9V supply will adequately power the microcontroller and additional electronic hardware. [27] 7.2 Surveyed members of the TCNJ Athletic Department claimed that the average practice would last about 3 hours. 7.3 If voltage supply decreases below 7V, the 5V pin may supply less than 5V and the board may be unstable. Additional electronic hardware may not accurately detect monitored signals of 1, 2 and 3. 7.4 Device must include an access panel for the battery to extend the usable life of the device

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
8.Electronics must properly function under different conditions that athletes operate under	8.1 The device must be encased to protect the electrical components 8.1.1 The casing will exhibit water resistance up to IPX level 3 8.1.2 The casing will be able to withstand impact forces up to 60 g's	8.1.1 Water will be sprayed on to the device up to 60 degrees from vertical at 10 liters/min at a pressure of 80-100kN/m2 for 5 min [8] 8.1.2 The device will be tested for impact resistance according to the ASTM standard D2463 [1]	8.1 An athlete will wear the encased device during a practice. After the practice is over the case will not be damaged and the electrical components will remain dry
Justification			
8.1 Electrical components need to be protected in order to operate correctly 8.1.1 Athletes are exposed to rain and sweat during practice 8.1.2 Athletes can experience impact forces up to 60 G's depending on the sport [10]			

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
9.The device must not inhibit regular athlete motion	9.1 The device must be secure enough so that it does not fall off 9.2 Shirt (or belt) must not be constrictive.	9.1-2 Device will be attached to interactive mannequins in the Nursing Department laboratories. Success will be evaluated based on the ease with which the mannequins are able to move arms/torso while wearing the device.	9.1 Athlete will run around while wearing the device in order to ensure it does not fall off. 9.2 Athlete will perform several movements in order to determine their range of motion while wearing the device.
Justification			
9.1-2 The loosening or detachment of any part of the device may hinder the user's movements in such a way that they may be susceptible to injury			

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
10.The device must be comfortable for athletes to wear during sports related activities	10.1 The device should not exceed 9 oz. in weight 10.2 Device should not exceed a size of 6” by 4”. 10.3 Material used to attach the device to the body must not cause skin irritation 10.4 Device should be attached to the back of the body 10.5 Wiring should allow for movement but must not dangle near moving limbs.	10.1 Device will be weighed on a precision scale and the weight will be recorded 10.2 Device will be measured using a ruler 10.3 Atomic Force Microscopy tool will determine the roughness of the material. Greater roughness will correlate to increased irritation . 10.4-5 Device will be attached to the back of an interactive mannequin in the Nursing Department laboratories. Success will be evaluated based on the ease with which the mannequins are able to move without interference due to wiring	10.1-5 The device will be worn on an athlete participant during a normal team practice. Afterwards, athletes will be asked to answer a questionnaire with the following questions: 1.Were you able to participate in practice as you hoped to while wearing the device 2.Was the weight of the device a noticeable disturbance during your play 3.Did you find the placement of the device to be satisfactory? 4.Did the material irritate your skin? 5.Did any wiring inhibit your activity or get in your way?

Design Input Requirement	10.The device must be comfortable for athletes to wear during sports related activities

Justification
10.1 Surveyed members of the TCNJ Athletic Department claimed that an acceptable weight would be similar to the weight of a current smartphone with a protective casing 10.2 Surveyed members of the TCNJ Athletic Department claimed that the device should be as minimal in size as can possibly be constructed. The specified dimensions should satisfy the spatial needs of all electronic hardware. 10.3 Skin irritation will minimize the benefits attained from the device 10.4 Surveyed members of the TCNJ Athletic Department claimed that the device will interfere with normal exercise the least if situated on a player's back 10.5 Loose wiring could cause individuals to trip during play, potentially leading to injury.

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
11.The cost of constructing the device must fit within a budget	11.1 The device components must be selected and justified for purchase according to power, weight, dimensions, intended function, durability and cost	11.1 Purchase of components and materials of the device must first be justified based on how well they will fulfill their intended function for their price. If additional funding is necessary above the allotted $400, a formal request will be submitted to the Dean.	11.1 Final total costs are at or below total allocated funds for project ($400).
Justification			
11.1 The starting budget is $400 to purchase necessary components for the device			

Design Input Requirement	Design Specifications	Verification Activity	Validation Activity
		Method/Protocol	Method/Protocol
12.Device must be safe to use	12.1 The device will be resistant to overheating 12.2 The device casing will not cause injury upon impact 12.3 The device will include an easy-to-follow instruction manual	12.1 The device will run consistently for the duration of a typical practice and be monitored to ensure it does not overheat 12.2 The device will be tested for impact resistance according to the ASTM standard D2463 [1] 12.3 The manual will contain simple and relevant safety instructions	12.1 An athlete will wear the device for the duration of a practice and it will not overheat 12.2 An athlete will wear the device during a practice and not experience any injury if hit 12.3 A user will receive the instruction manual before using the device
Justification			
12.1 Overheating of the components can cause injury to the user. 12.2 Should the athlete be hit in the location of the casing, it may crack and cause injury 12.3 Users need to be aware of the necessary safety precautions in order to to safely use the device			