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Validity and Reliability of the Apple Series 6 and 7 Smartwatches and Polar H-10 Monitor on Heart Rate

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VALIDITY AND RELIABILITY OF THE APPLE SERIES 6 AND 7 SMARTWATCHES
AND POLAR H-10 MONITOR ON HEART RATE

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VALIDITY AND RELIABILITY OF THE APPLE SERIES 6 AND 7 SMARTWATCHES
AND POLAR H-10 MONITOR ON HEART RATE

by

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Chapter 1: Introduction

IMPORTANCE OF SMARTWATCHES

In recent years, wearable technology has gained popularity in the exercise and fitness community. These devices have revolutionized the sport and exercise sciences by providing real-time short and long-term health data, creating a substitution for lab measurement devices, and to obtain data in practical settings. Data obtained from smartwatches are often in the form of positional data (via Global Positioning System data), heart rate via photoplethysmography, and recently also including arterial oxygenation (Apple; Dooley et al., 2017; Kwon et al., 2019). These health-related variables allow us to obtain real-time feedback on overall human health. For example, abnormal heart rate variability (HRV) has been associated with higher psychological stress, cortisol, and increased risk of cardiac failure (Rennie et al., 2003). These health-related variables along with target reminders, goal settings, health feedback, and most importantly their superior portability, may improve and promote physical activity of the user (Ridgers et al., 2016; Sullivan & Lachman, 2017). Furthermore, wrist-based monitors are more convenient and comfortable in comparison to chest strap monitors (Pasadyn et al., 2019)

IMPORTANCE OF VALIDITY

One of the most common and practical methods for prescribing exercise training and determining intensity is through the assessment of heart rate (Anastasopoulou., 2014; Warren et al., 2010). Proper monitoring of exercise intensity and recovery are important in order to assess individuals' cardiorespiratory fitness (ACSM; Cole et al., 1999; Shetler., 2001). Athletes and fitness individuals rely on heart rate monitors for guidance throughout their individualized training routine and to monitor their progress (Achten & Jeukendrup, 2003; Diaz et al., 2015; Gillinov et al., 2017). However, a persistent problem with field devices lies in the quality of the data that is

obtained through the device. Given that data accuracy, validity, and reliability is currently unknown, errors in the estimation of these variables are often prevalent. A recent study found the Polar H-10 to be valid in comparison to ECG with a correlation of $r=0.997$ during physical activity (Pasadyn et al., 2019). Wrist-based monitors may show convenience and comfort in comparison to chest-strap monitors and enable them to be largely used. These wrist-worn smartwatches use photoplethysmography (PPG) measurements, which display arterial oxygen saturation and rate of change in blood pressure and are used interchangeably with beats per minute in previous validation studies (Boudreaux et al., 2018; Dooley, Golaszewski, & Bartholomew., 2017; Gillinov et al., 2017; Lang, 2017; Nelson & Allen, 2019; Shcherbina et al., 2017; Wallen et al., 2016). Recently a study conducted by Thomson (2019) compared the Apple Watch and Fit Bit Charge 2 HR readings during a Bruce protocol test and found the Apple Watch to have the lowest relative error rate at (2.9-5.1%) in comparison to the Fit Bit at (3.9-13.5%) throughout the protocol. Thus, it is important to conduct validity verification of the latest features in wrist-based monitors as it will serve as guidance for athlete's and physician's cardiorespiratory fitness and health observations, respectively (Gillinov et al., 2017; Xie., 2018).

KNOWLEDGE GAP

To date, there are no data in terms of the validity or reliability of the newly released Apple Watch Series 6 and 7. Due to the popularity of the use of smartwatches for fitness tracking purposes, it is crucial to determine the precision of the instrument in capturing different fitness variables. To our knowledge, the current proposed study would be the first to validate the new Apple Watch series 6, Apple Watch series 7, and Polar H-10 in comparison to an ECG monitor. The validity of the Apple Watch 6, Apple Watch series 7, and Polar H-10 during physical

activity will create an impact on the use of these devices by physicians, and coaches, as well as everyday practitioners.

PURPOSE AND HYPOTHESIS

The purpose of this project is to monitor and compare heart rate data through the use of the Apple Watch Series 6, Apple Watch Series 7, and Polar H-10 chest-strap monitor, in comparison with the gold-standard 12-lead ECG in collegiate level athletes and recreationally active college-age young adults. Previous studies have shown both an over-and under-estimation (-16.31 to 12.71 beats per minute) in Apple Watch series 1-3 devices when observed through the criterion method (Nelson & Allen, 2019; Thomson et al., 2019; Wallen et al., 2016). Polar chest-strap monitors have been shown to come close to ECG standards ($r_c = 0.996$ and $r_c = 0.997$) in previous Polar models (Gillinov et al., 2017; Pasadyn et al., 2019). We hypothesize 1) that the Apple Watch Series 6 and Series 7 will over-or under-estimate heart rate and maximum heart rate when compared to ECG, and 2) Polar H-10 will show a greater agreement to ECG in comparison to the Apple Watch Series 6 and Series 7.

Chapter 2: Literature Review

HEART RATE AND BLOOD PRESSURE

Heart rate (HR) is the number of times the heart beats per minute and is linearly correlated with exercise intensity (Laughlin, 1999). Thus, HR is utilized as a training tool to monitor individuals as they exercise at a predetermined training intensity (Achten & Jeukendrup, 2003; Anastasopoulou et al., 2014; Warren et al., 2010). Assessment of HR through a 12-lead electrocardiographic (ECG) is the current gold standard method (Mason & Likar, 1966; Pasadyn et al 2019; Thomson et al. 2019). However, the use of ECG monitoring is confined to research and laboratory settings, which makes it difficult to obtain accurate HR readings in real-world settings. As alternative modalities for HR monitoring, portable HR monitors and chest-strap monitors are used (Goodie et al., 2000). More recently Gilgen-Ammann et al. (2019) evaluated and compared the Polar H10 chest monitor and Medilog AR12plus Holter monitor to visual inspection of raw ECG signal. The authors postulated that the Polar H10 might be the gold standard for RR interval assessment during physical activity due to its high signal quality of 99.6% when compared to the Medilog AR12plus at 94.6% that was observed during multiple activities (sitting, household activities, walking, jogging, & strength training).

In comparison to ECG and chest-strap monitors, which collect the rate of heart contractions through electrocardiography (ECG), smartwatches use photoplethysmography (PPG), which measures the frequency of change in blood pressure(Lang, 2017). PPG typically uses a light-emitting diode to illuminate the skin and a photodiode to detect the intensity (blood pulse) of the light reflecting and scattering back from the skin (Allen. 2007). Heart rate also has a linear relationship with blood pressure during both static and dynamic movement due to an increase in blood flow; in this regard, PPG monitors are capable of monitoring HR (Laughlin,

1999). ECG monitors measure RR intervals to capture HR, whereas PPG monitors measure arterial blood components during the dilation and relaxation phases (systole and diastole respectively). This is similar to PP intervals, which have been used in several validation studies to examine the accuracy of wrist-worn devices (Allen. 2007; Lang, 2017).

Accuracy of The Apple Watch in Comparison to ECG

Previous studies have concluded that wrist-worn smartwatches underestimate HR during low intensity and overestimate HR during high-intensity exercise as compared to electrocardiograms (ECG), which are known as the gold standard reference method for assessing HR (Nelson & Allen, 2019; Wallen et al., 2015). A recent study, conducted by Nelson and Allen (2019), evaluated the Apple Watch Series 3 and Fitbit Charge 2 in comparison to the gold standard 3-lead ECG during a 24-hour protocol in one participant. Across the 24-hour recording, the Apple Watch (3.01-7.21%) and Fit Bit (3.36-9.88%) had a mean percentage error of less than 10% during all activities except activities of daily living for the Apple Watch (13.7%). The author found the Apple watch to show over-and under-estimation of HR during high intensities as compared to the Fit Bit, which only showed underestimation during high intensities when observing the Bland-Altman plots. Similar results were found in a study conducted by Wallen et al. (2015) where researchers studied the accuracy of heart rate (HR) on 4 wrist-worn devices (Apple Watch, Fitbit charge HR, Samsung Gear S and Mio Alpha) and compared it with a 3 lead- electrocardiography (ECG) as the reference method. The protocol consisted of measuring individuals' HR at rest, on a treadmill, and on a cycling ergometer. Results showed a mean average underestimation for all devices below 9% with the Apple Watch showing the highest intraclass correlation coefficient at $r=0.98$ with criteria of $r=0.7$ interpreted as “strong”. (Wallen et al. 2015).

Smartwatches' reliability depends on the activity and intensity. A meaningful number of studies have shown smartwatches have a higher overall error during high-intensity exercise as compared during rest and low-intensity exercise varying from 1-20 beats per minute different than the heart rate measured through the criterion ECG (Gillinov et al., 2017; Nelson & Allen, 2019; Thomson et al., 2019; Wallen et al., 2016). For example, a recent study conducted by Thomson et al. (2019) evaluated the accuracy of the Fitbit Charge 2 and Apple Watch comparing them to a 12-lead ECG during a Bruce protocol. The study analyzed HR at different intensities during the protocol and found the highest correlation for both wrist-worn devices during very light physical activity, as demonstrated by strong concordance class correlation values (CCC >0.89). Authors also reported that as exercise intensity increased the reported heart rate accuracy decreased. Bland-Altman plots showed an underestimation in both devices compared to ECG for most exercise intensities, except during very light physical activity. Furthermore, the Apple Watch showed the lowest relative error rate (2.9-5.1%) in all exercise intensities in comparison to the Fitbit Charge 2 (3.9-13.5%).

It is important to note that there have been other studies contradicting such findings and found HR accuracy to be higher during high-intensity exercise in comparison to rest or low-intensity. Such findings were reported by Shcherbina et al. (2017) who evaluated the accuracy of seven wrist-worn devices (Apple Watch, Basic Peak, Fitbit Surge, Microsoft Band, Mio Alpha 2, Pulse On, and Samsung Gear S2) and a 12-lead ECG, which was used as the reference method. The authors found higher HR error rates of 5.5% (3.9%-7.17%) during walking when compared to an exercise condition on the cycle ergometer of 1.8% (0.99%- 2.71%). Furthermore, the Apple Watch resulted in the lowest error of 2.0% (1.2%-2.8%) across all devices and activities (Shcherbina et al. 2017). More recently a study conducted by Falter et al. (2019) determined the

accuracy of the Apple Watch Series 1 using a 12-lead ECG as the reference method during a cycle graded maximal cardiopulmonary exercise test. The authors found good accuracy between the Apple Watch and ECG, showing a good correlation without a systematic error when observing Bland-Altman plots and scatterplots. HR accuracy showed to be higher during peak exercise intensity compared to rest (mean absolute percentage error at rest of 10.69%, at peak exercise of 6.33%; ICC at rest was 0.729 and 0.958 at peak exercise) (Falter et al. 2019).

The Apple Watch has been shown to have a high accuracy in comparison to other wrist-worn devices. Hwang et al. (2019) evaluated the accuracy of three wrist-worn devices (Apple Watch Series 2, Galaxy Gear S3, and Fibit Charge 2) and used a 12-lead ECG as the reference method. All three devices showed an 83.3% difference between ECG in HR measurements within ± 5 bpm and improved when the criterion was changed to ± 10 bpm in all devices showing the Apple Watch at 100%. Moreover, the Apple Watch showed a higher intraclass correlation coefficient (0.9971) compared to the other two wrist-worn devices (0.9973 & 0.9842) (Hwang et al. 2019).

APPLE WATCH IN COMPARISON TO POLAR HR MONITOR

Polar chest strap monitors have shown to be highly correlated to ECG when evaluated with other wrist-worn devices (Boudreaux et al., 2017; Gillinov et al., 2017). A previous study conducted by Gillinov et al. (2017) determined the Polar H7 to have the highest agreement to a 3-lead ECG through a Lin's concordance correlation coefficient calculation ($rc = 0.996$) followed by the Apple Watch ($rc = 0.92$) with all exercise activities (treadmill, stationary bicycle, and an elliptical trainer). Another study, conducted by Boudreaux et al. (2017) evaluated eight devices (Apple Watch Series 2, Fitbit Blaze, Fitbit Charge 2, Polar H7, Polar A360, Garmin Vivosmart HR, TomTom Touch, and Bose SoundSport Pulse) and used a 6-lead ECG as the reference

method during both a cycle ergometer and resistance exercise within individuals at various fitness levels. The author found the Apple Watch Series 2 and Polar H7 to meet the criteria of mean absolute percentage error (MAPE) $\leq 10\%$ in all intensities during cycling. As the intensity increased MAPE values increased. The Apple Watch, Bose SoundSport Pulse, and Polar H7 maintained a “good” correlation ($r \geq 0.75$) throughout all intensities during cycling, Bland Altman showed an underestimation during high cycling intensity and overestimation during rest and low intensity.

Previously Polar chest-strap monitors have been used as the criteria in HR monitoring in comparison to PPG heart rate sensors due to its high correlation to ECG measurements (Gilgen-Ammann et al., 2019). A study conducted by Kushhal et al. (2017) evaluated the validity of the Apple Watch Series 0 in both the left and right arm and the Polar S810 monitor as a criterion during three exercise intensities (walking, jogging and running). Both Apple Watches on each arm showed a small to moderate standardized typical error (0.23-0.72) compared to the Polar S810 monitor, with the error increasing as the intensity increased. Furthermore, the intra-device reliability was very good with an intraclass correlation ($ICC \geq 0.91$). Additionally, a similar study conducted by Abt et al. (2017) evaluated the activity of the Apple Watch Series 1 used in both arms to the Polar T31 as the criteria HR. Maximal HR was monitored during an incremental muscle oxygen test and found both arms to show good validation in the intraclass correlation coefficient at 0.87 and 0.98 between the left and right arms respectively. The Bland-Altman plots showed no substantial over-or underestimation in the Apple Watch HRmax compared to the criterion Polar T31. Furthermore, the Apple Watch has shown a strong association to the Polar chest-strap monitor in a study conducted by Dooley et al. (2017) that determined the accuracy of the Apple Watch, Fitbit Charge HR, and Garmin Forerunner 225 to the Polar T31 as the criterion

measurement during rest, several treadmill intensities and recovery. Pearson correlation showed the Apple Watch to have the strongest association with the Polar T31 ($r = 0.59-0.99$), as well as the least MAPE (1.14-6.70%), compared to the Fitbit Charge HR (2.38-16.99%) and Garmin Forerunner 225 (7.87-24.38%).

With the use of ECG as the gold standard HR monitor, previous studies have demonstrated the accuracy of Polar models, with the Apple watch being a close second under most conditions. A number of studies have performed similar interventions by having participants complete treadmill protocols at different intensities (Gillinov et al. 2017; Kushal et al; 2017; Pasadyn et al. 2019; Stahl et al. 2016). Furthermore, some of the research limitations of these studies included having used a Polar chest strap monitor as a criterion instead of the gold standard ECG, capturing HR data visually instead of using an electronically time-stamped approach, and asking subjects to hold on to the treadmill handrails which does not represent realistic training conditions. Previous studies do not appear to have used trained athletes in comparison to this future study which will incorporate both an athlete and non-athletic groups. Additionally, most recent studies have only been done with Apple Watch Series models 1, 2, and 3 but with new models the HR measurement accuracy is expected to be improved.

Chapter 3: Methods

EXPERIMENTAL DESIGN

A single-session cross-sectional study design was implemented. Considering previous studies. Twenty-five college-age athletes (n=25; 25 males) from the UTEP football team and 20 college-age recreationally trained young adults (n=20; 10 males and 10 females) were recruited for this study.

INCLUSION CRITERIA

Subjects' age range was from 18 to 30yrs in order to get a young population, who are currently part of the UTEP football team or who have been physically active in the past 3 months averaging 150 minutes of exercise per week. Subjects were injury-free during and 6 months before data collection.

EXCLUSION CRITERIA

Subjects under the age of 18 and older than 30 years of age, or who have not been physically active in the past 3 months averaging 150 minutes per week did not qualify. Subjects who had tattoos or piercings on the wrist were also excluded since it may obstruct PPG readings. A physically active population was preferred to make sure the subject performed the test without stopping early due to fatigue. Subjects who presented any type of musculoskeletal or neurological injury were not allowed to participate in this study. A normal drop in glucose during exercise is expected, therefore for safety reasons individuals with metabolic disease or who might consume medication that may alter HR repose to exercise were excluded. Prior to testing, subjects were required to be free of any caffeine intake for 12 hours. Subjects who were eligible provided written informed consent prior to testing.

HEART RATE

The single assessment session consisted of anthropometric measures of Height (m) and Weight (kg). Following this, four devices were connected to the subjects as follows: 1) a 12-lead electrocardiogram (ECG), 2) Polar H-10 chest-strap monitor 3) Apple Watch 6 series was placed on the right arm, and 4) Apple Watch series 7 was placed on the left arm. All of these devices were worn at all times. Once all devices were on, resting heart rate was recorded. Thereafter, the UTEP football subjects were asked to walk (low), jog (moderate), and run (high) intensity at zero incline for 3 minutes at 3 mph, 6 mph, and 9 mph, respectively. Similarly, recreational athletes followed the same protocol except the speed set on the treadmill was lowered to walk (low), jog (moderate), and run (high) intensity at 2.5 mph, 5 mph, and 7.5 mph, respectively. Following the test, subjects were asked to continue walking on the treadmill for 3 minutes for recovery. Based on data from pilot testing, the time set for each individual intensity was sufficient time to allow the apple watches to record data, as well as set speed which allowed the population to finish the protocol properly. Heart rate was recorded throughout the procedure on all devices, throughout the apple watch recording information was sent to the phones that were connected in order to retrieve the data recorded.

Data Collection Protocol for Football Athletes

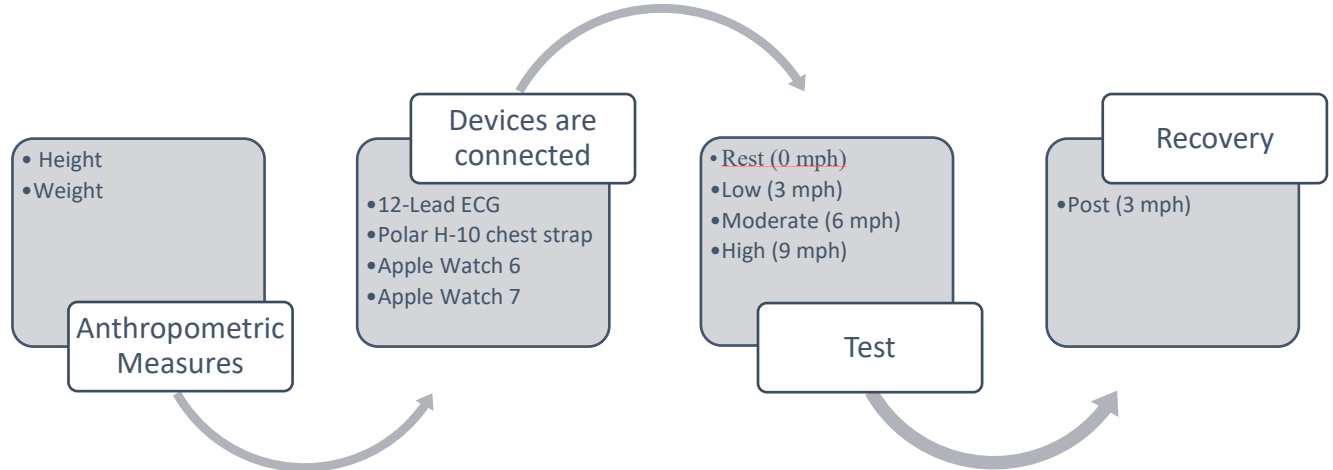


Figure 1. Protocol for Football Athletes

Data Collection Protocol for Recreational Athletes (who have been physically active in the past 3 months averaging 150 minutes of exercise per week)

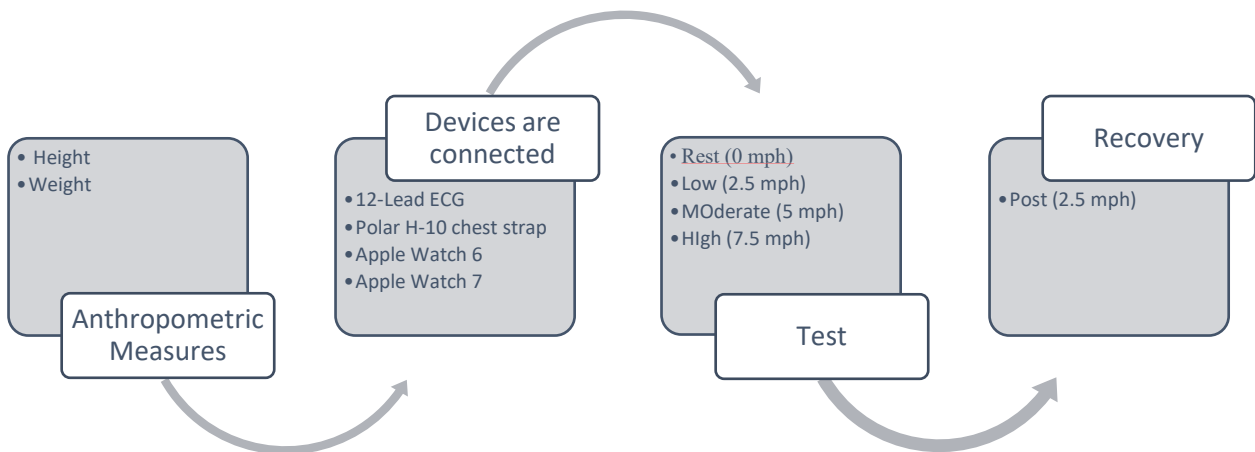


Figure 2. Protocol for Recreational Athletes

Upon arrival at the lab, each subject's height and weight were recorded. Thereafter, they were instructed to remove their shirt in order to place 12 ECG pads on their chest area. Once pads were placed, Polar H-10 chest strap was placed around the individual, ensuring it was making skin contact to allow the device to make adequate readings. Individual ECG lead wires were then connected to the electrode pads. Once the connection was well-read, the individual was instructed to put on a stress test sweater vest to hold leads in place during the test protocol

(Figure 2). Afterwards, Polar H-10 was connected to an iPad via Bluetooth, and both Apple Watch Series 6 and Series 7 were placed on the individual's wrist. Once all equipment was in place and attached, the subject was asked to step up onto the treadmill. The subject would then be reminded of what the protocol consisted of and would be instructed to run freely with full arm movements mimicking normal running done in an outdoors environment, abstaining from holding on to the treadmill's handrails. The test started once the individual's HR read somewhere between 60-100 beats per minute on the ECG monitor.

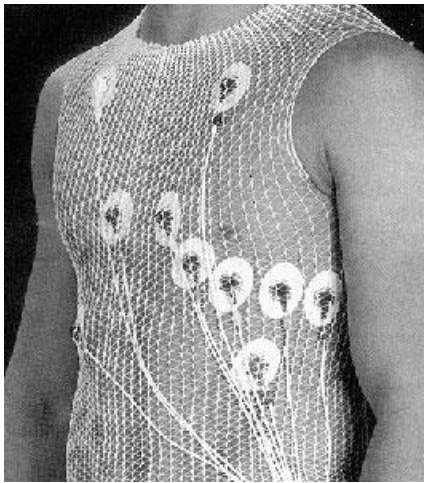


Figure 3. Stress Test Sweater

DATA PROCESSING

Each Apple watch was placed on Workout mode in order to ensure HR was being recorded at all times, and Polar H-10 chest strap monitor was being observed on the iPad through the Polar Flow app. Once all devices were attached to each subject, the subject was asked to rest in order to monitor and observe that each device was reading heart rate as accurately as possible and in a timely fashion. Once a steady resting heart rate was reached ranging from 1 – 5 minutes, recording of data for both ECG monitor and Polar H-10 was simultaneously started. Apple Watch HR data would consequently be matched to the time stamp recorded on both ECG and Polar H-10. Heart rate measured through ECG was recorded every 30 seconds, giving a total of

30 HR data points for each individual in just ECG alone. Polar H-10 measured HR at each second, thereby collecting 900 data points for the 15-minute protocol, which was then averaged out for 30-second intervals in order to match with the provided 30-second ECG data. Data from the two Apple Watches were extracted from two corresponding paired devices through Quantified Self Lab and manually placed in an excel file. HR was assessed every 5 seconds, resulting in a total of 12 HR recordings per minute and 180 HR recordings for the full 15-minute protocol. Data points were then averaged out to 30-second intervals to match the data provided from the ECG and Polar H-10 device (Falter et al. 2019). Heart Rate data for each participant appeared to stabilize within a minute during each exercise, thus, the first minute was disregarded and the last four 30-second stages (Heart Rate plateau) were utilized for all of the analyzes (see Figures 4-8 for football athletes & Figures 11-15 for Recreational athletes). Ultimately, each subject totaled 120 HR data points for all 4 devices (ECG, Polar H-10, Apple Watch series 6, Apple Watch series 7) across the 30 sets of 30-second intervals.

STATISTICAL ANALYSIS

Data were organized into a spreadsheet using Microsoft Excel in Windows 10th (Microsoft Corporation). Thereafter, data were exported to Rstudio integrative development environment (version 1.4.1103) to be analyzed using R statistical language. The “dplyr” package was utilized for data grammar and manipulation, while the “psych” package was utilized to obtain participant descriptives. Correlation analyzes the association between two instruments, however, they can measure different constructs, for example, Vertical jump and body fat, they are correlated but do not measure the same construct. In contrast, ICC assesses the relationship between the instruments but also measures the degree of concordance between the instruments (agreement/validity) or within individuals (reliability) (Liu et al. 2016). The association of heart rate between instrument were assessed using a Pearson’s Correlations (r) was interpreted as $r =$

0.3-0.5 “moderate association”, $r = 0.5-0.7$ “large association”, $r = 0.7-0.9$ “very large association”, $r = >0.9$ “nearly perfect association”. The agreement and reliability of the Polar H-10, Apple Watch 6 series, and Apple Watch 7 series were assessed using a two-way mixed model Intra-Class Correlation ($ICC_{2,k}$) with the “irr” package; The magnitude of the intra-class correlations was interpreted as $ICC_{2,k} 0.5-0.75$ as “moderate reliability” $ICC_{2,k} > 0.75$ as “good”, $ICC_{2,k} > 0.9$ as “excellent” (Montalvo et al. 2021). To assess agreement between devices and fixed bias, Bland-Altman plots were constructed for each of the variables and displayed clinically important 95% limits of agreement (LoA) using the “BlandAltmanLeh” package. Lastly, “ggplot2” and “ggpurb” packages were utilized for data visualization of the Bland-Altman plots.

Chapter 4: Results

DESCRIPTIVES – FOOTBALL ATHLETES

Twenty-four participants completed this study. One participant's ECG readings were not complete due to high movement and had to be removed from the study. Descriptive data (mean \pm sd) for the participants was 20.57 ± 4.54 years for age, 1.81 ± 0.06 meters for height, 91.42 ± 14.17 kgs for weight, and 27.81 ± 4.51 (kg/m²) for body mass index. The mean and standard deviation of Heart Rate, and the Percentage of Heart Rate max (220-Age) are presented in Tables 2-3.

Reliability and Instrument Stability

The intra-class correlation coefficient showed excellent reliability for the ECG, Polar-H10, Apple Watch 6, and Apple Watch 7 at rest, low, moderate, high, and post exercise stages ($ICC_{2,k} > 0.90$). However, there were two stages (low and moderate) in which the Apple Watch 6 had only a good intra-class correlation coefficient ($ICC_{2,k} = 0.88$ for low, and $ICC_{2,k} = 0.87$ for moderate) (Table 1).

Table 1. Reliability analysis for Football Athletes

	ICC	95 % Confidence Interval	
		Lower	Upper
ECG Rest	0.967	0.94	0.984
ECG Low	0.96	0.928	0.98
ECG Moderate	0.967	0.94	0.984
ECG High	0.965	0.938	0.983
ECG Post	0.99	0.982	0.995
Polar Rest	0.987	0.977	0.994
Polar Low	0.976	0.956	0.988
Polar Moderate	0.94	0.893	0.971
Polar High	0.966	0.94	0.984
Polar Post	0.987	0.977	0.994
Apple6 Rest	0.96	0.92	0.98

Apple6 Low	0.88	0.67	0.95
Apple6 Moderate	0.87	0.77	0.93
Apple6 High	0.91	0.85	0.95
Apple6 Post	0.94	0.69	0.98
Apple7 Rest	0.97	0.96	0.99
Apple7 Low	0.95	0.87	0.98
Apple7 Moderate	0.95	0.81	0.98
Apple7 High	0.97	0.96	0.99
Apple7Post	0.97	0.96	0.99

Table 2. Football Athletes HR per stage

Stage	Time	ECG		Polar		Apple6		Apple7	
		mean	sd	mean	sd	mean	sd	mean	sd
Rest	0:30	81.00	16.06	82.49	15.78	78.07	12.24	74.28	7.13
Rest	1:00	81.58	17.52	80.92	15.68	11.00	6.20	76.81	8.37
Rest	1:30	78.46	17.85	80.60	14.91	78.25	14.00	78.59	12.96
Rest	2:00	79.33	16.26	80.41	14.89	78.07	13.11	74.50	10.88
Rest	2:30	82.96	14.79	81.05	14.79	77.81	13.70	71.58	8.07
Rest	3:00	95.50	14.78	88.14	14.85	84.65	11.26	87.73	14.01
Low	3:30	98.67	13.87	97.86	13.80	93.80	12.70	90.22	7.98
Low	4:00	98.29	12.32	99.59	11.91	98.17	9.77	100.24	12.01
Low	4:30	98.75	12.09	99.01	11.86	96.32	9.88	98.12	15.19
Low	5:00	99.79	12.65	99.41	12.35	96.83	9.56	95.88	10.44
Low	5:30	98.75	14.62	99.22	12.84	97.56	9.85	96.29	11.31
Low	6:00	125.42	13.68	113.33	12.87	108.60	12.49	111.52	17.84
Moderate	6:30	139.58	10.79	134.28	12.23	128.64	17.17	132.36	16.17
Moderate	7:00	148.78	11.37	145.42	10.96	141.46	10.34	139.87	12.19
Moderate	7:30	153.87	13.87	151.05	11.10	148.58	10.49	150.09	11.78
Moderate	8:00	155.30	11.83	153.71	11.14	151.73	9.04	152.27	13.42
Moderate	8:30	157.25	17.68	156.28	12.14	152.77	12.84	155.81	14.27
Moderate	9:00	165.54	16.31	160.71	16.41	156.07	14.84	161.61	12.43

High	9:30	172.08	10.50	169.69	12.27	163.47	11.10	167.28	10.98
High	10:00	177.96	8.89	176.12	9.72	169.84	9.43	162.59	39.47
High	10:30	182.08	8.32	180.17	8.48	174.13	8.16	173.76	11.12
High	11:00	184.54	8.86	182.73	8.20	176.44	7.61	175.46	12.37
High	11:30	186.71	9.37	184.40	8.22	178.73	7.09	177.16	12.27
High	12:00	177.17	11.45	180.78	10.79	176.47	8.69	173.63	13.88
Post	12:30	161.83	16.22	167.66	14.02	164.79	13.06	165.14	13.09
Post	13:00	144.17	18.26	149.84	17.36	150.13	15.17	149.69	16.45
Post	13:30	132.79	18.74	136.23	17.49	136.89	17.20	136.99	18.47
Post	14:00	126.46	16.34	127.70	16.97	128.16	17.54	128.55	18.45
Post	14:30	120.25	16.20	121.98	15.78	122.19	15.58	122.52	16.70
Post	15:00	118.33	16.21	118.92	15.70	117.76	15.97	119.71	16.04

Table 3. Football Athletes %HR from predicted HRmax (220-Age)

Stage	Time	ECG		Polar		Apple6		Apple7	
		mean	sd	mean	sd	mean	sd	mean	sd
Rest	0:30	39.27%	11.46%	39.99%	11.48%	26.81%	19.45%	7.51%	15.41%
Rest	1:00	39.55%	12.03%	39.23%	11.33%	33.60%	16.43%	12.42%	18.62%
Rest	1:30	38.03%	11.91%	39.08%	11.04%	28.44%	19.05%	9.55%	17.60%
Rest	2:00	38.46%	11.41%	38.98%	11.01%	31.52%	17.12%	9.05%	16.62%
Rest	2:30	40.22%	11.17%	39.29%	11.02%	29.84%	18.12%	5.80%	13.63%
Rest	3:00	46.30%	12.17%	42.73%	11.61%	34.19%	18.17%	8.83%	18.25%
Low	3:30	47.83%	12.17%	47.45%	12.09%	35.98%	21.37%	5.47%	15.15%
Low	4:00	47.65%	11.72%	48.28%	11.72%	39.65%	20.71%	10.10%	20.76%
Low	4:30	47.87%	11.69%	48.00%	11.66%	36.94%	21.63%	7.92%	18.70%
Low	5:00	48.38%	11.92%	48.19%	11.82%	39.10%	20.41%	21.26%	24.71%
Low	5:30	47.87%	12.38%	48.10%	11.93%	37.42%	21.89%	21.37%	24.88%
Low	6:00	60.79%	14.40%	54.94%	13.15%	43.85%	23.07%	29.26%	29.40%
Moderate	6:30	67.65%	15.09%	65.08%	14.87%	44.11%	31.66%	29.35%	34.20%
Moderate	7:00	69.09%	21.51%	70.49%	15.69%	51.40%	33.00%	28.19%	35.43%
Moderate	7:30	71.45%	22.52%	73.22%	16.24%	50.96%	35.93%	24.21%	36.15%
Moderate	8:00	72.12%	22.48%	74.50%	16.51%	55.12%	35.28%	24.56%	36.72%
Moderate	8:30	76.21%	18.12%	75.75%	16.90%	55.48%	35.72%	25.13%	37.59%

Moderate	9:00	80.23%	18.54%	77.89%	18.14%	66.11%	30.21%	55.36%	39.10%
High	9:30	83.41%	18.17%	82.24%	18.20%	65.95%	34.02%	67.52%	34.81%
High	10:00	86.25%	18.52%	85.36%	18.44%	68.52%	35.23%	65.66%	37.90%
High	10:30	88.25%	18.85%	87.32%	18.69%	73.77%	33.08%	66.65%	38.52%
High	11:00	89.44%	19.15%	88.56%	18.91%	78.35%	29.76%	63.74%	40.89%
High	11:30	90.49%	19.41%	89.37%	19.07%	79.37%	30.11%	64.36%	41.28%
High	12:00	85.87%	18.79%	87.62%	19.05%	81.95%	25.04%	66.56%	38.64%
Post	12:30	78.45%	18.27%	81.27%	18.35%	79.88%	17.90%	63.31%	36.76%
Post	13:00	69.89%	17.21%	72.64%	17.47%	72.78%	16.98%	60.44%	31.77%
Post	13:30	64.37%	16.38%	66.04%	16.32%	66.36%	16.31%	55.32%	29.48%
Post	14:00	61.30%	15.19%	61.90%	15.45%	62.13%	15.65%	51.90%	27.80%
Post	14:30	58.29%	14.61%	59.13%	14.65%	59.23%	14.61%	49.47%	26.38%
Post	15:00	57.36%	14.44%	57.65%	14.35%	54.69%	18.23%	48.33%	25.73%

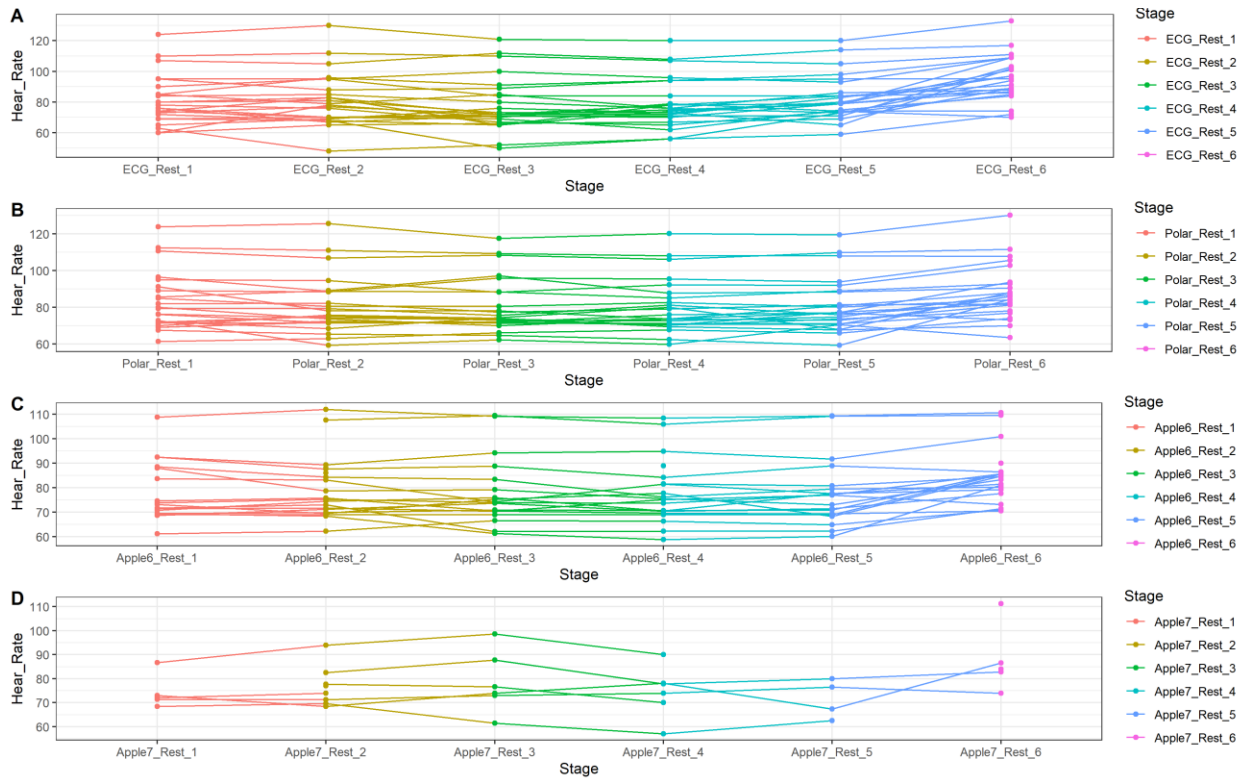


Figure 4. Football Athletes HR at Rest

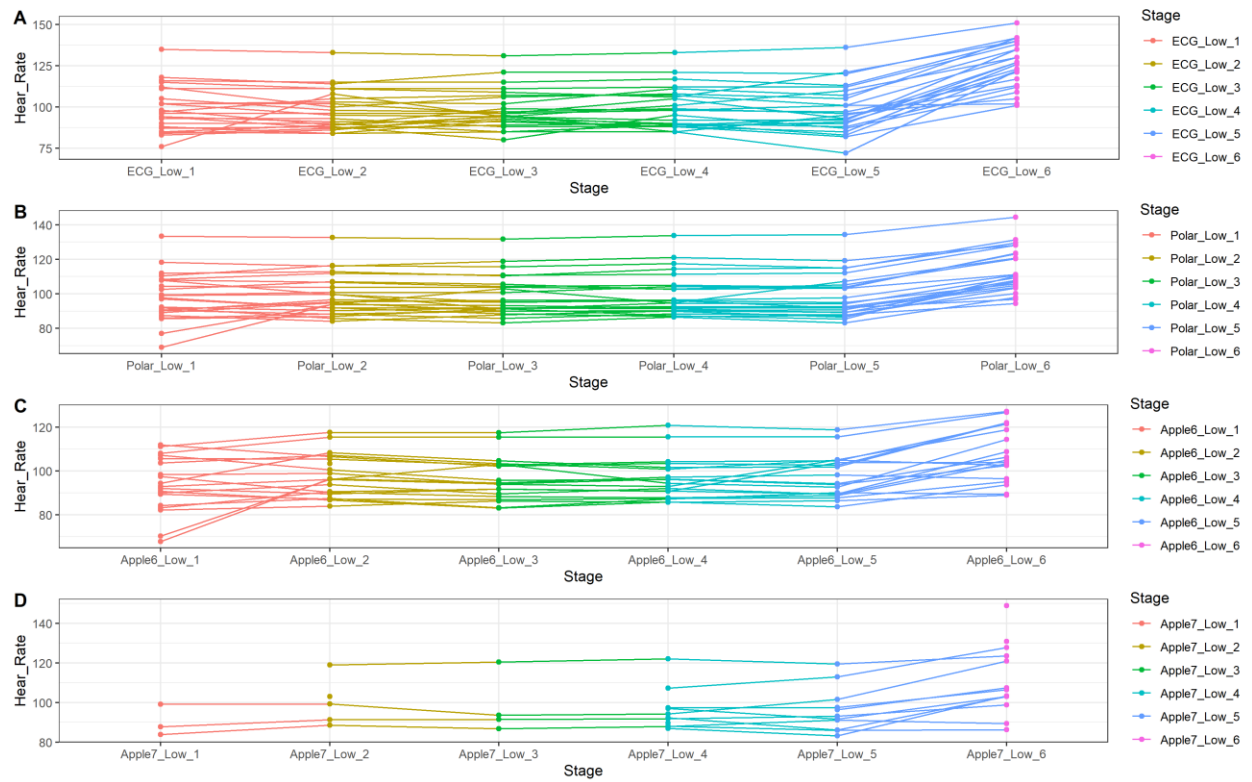


Figure 5. Football Athletes HR at Low Intensity

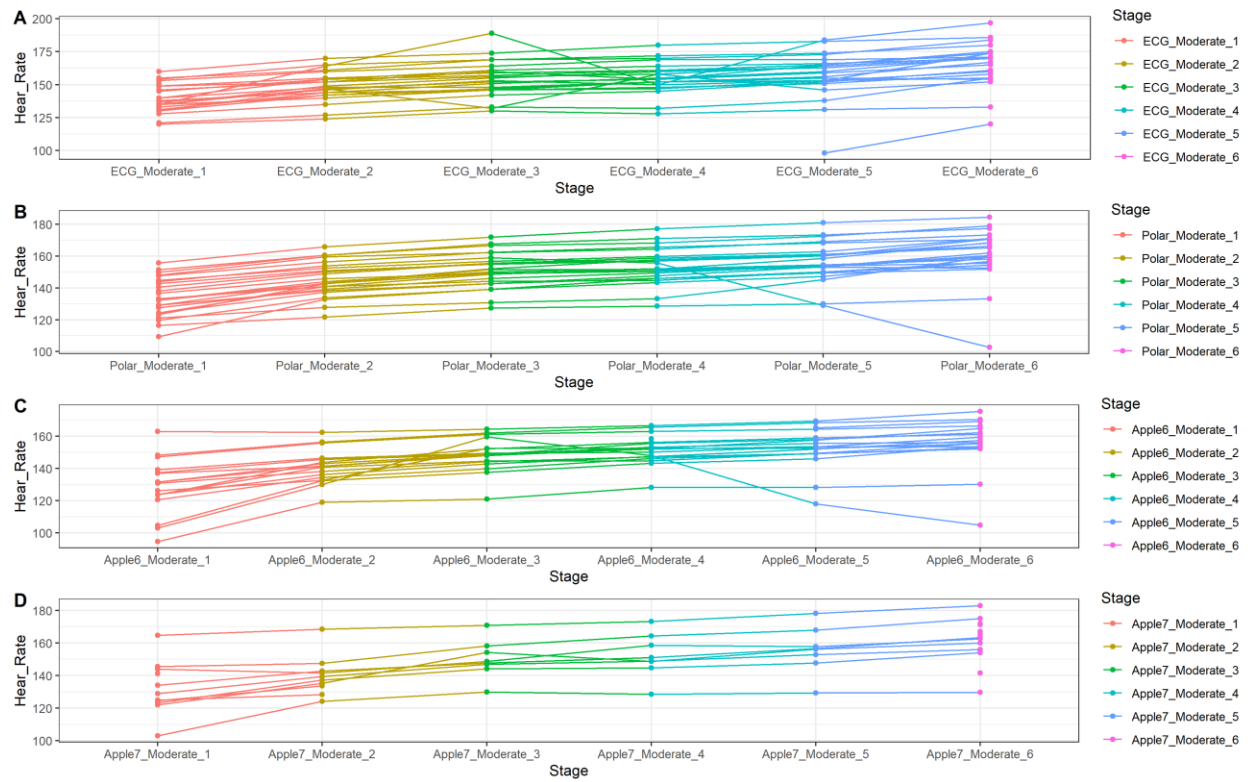


Figure 6. Football Athletes HR at Moderate Intensity

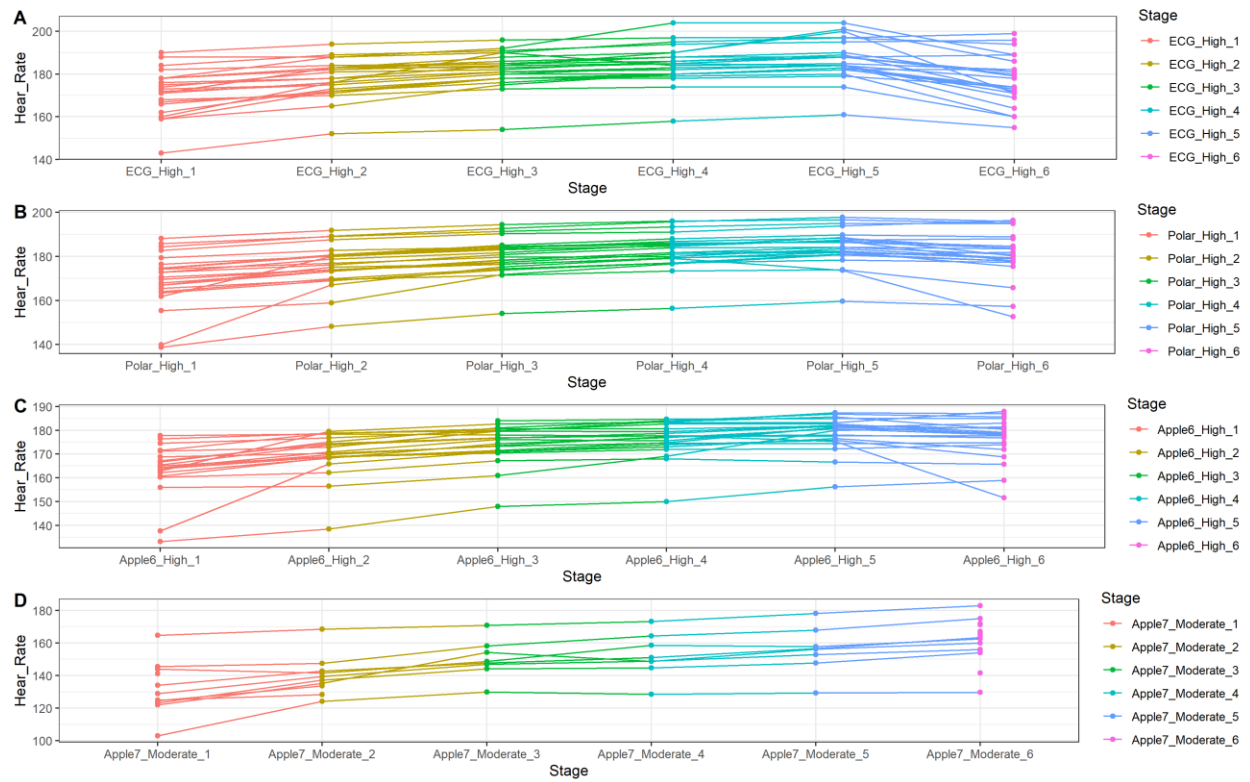


Figure 7. Football Athletes HR at High Intensity

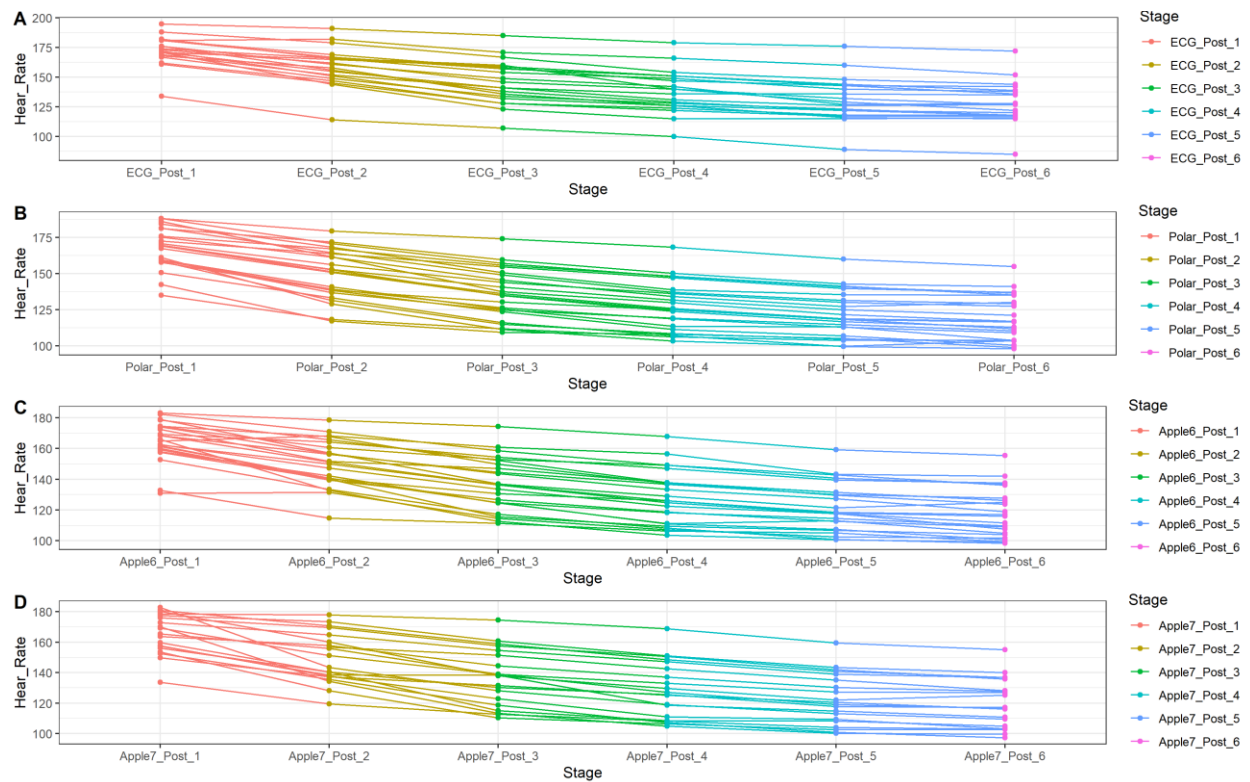


Figure 8. Football Athletes HR at Post Intensity

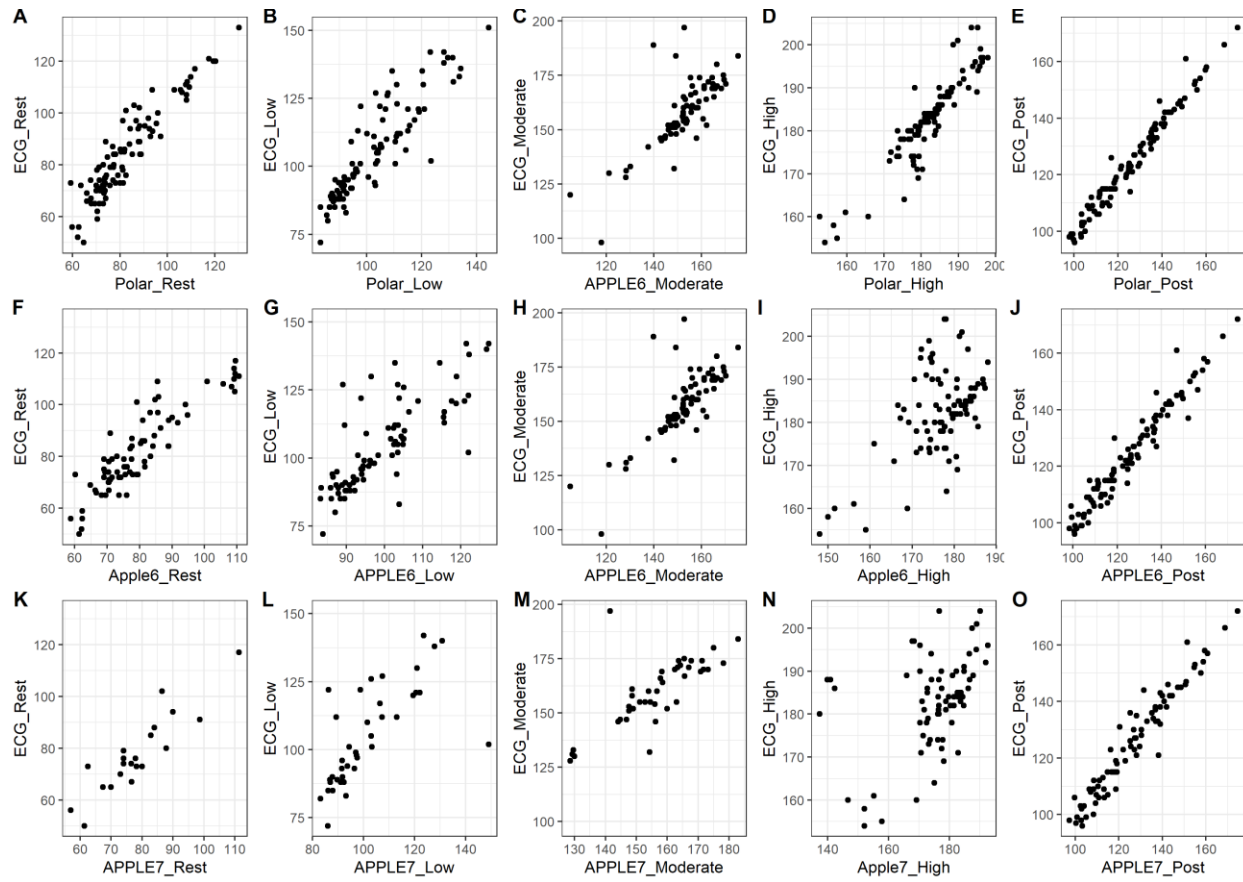


Figure 9. Correlations for Football Athletes HR between ECG and the Polar H-10 (1st row), Apple watch 6 (2nd row), and Apple watch 7th (3rd row) for rest (1st column), low (2nd column), moderate (3rd column), high (4th column), and post (5th column) stages.

VALIDITY

There were high associations ($r = 0.89-0.98$) between the ECG and Polar H-10 with good to excellent agreement ($ICC(2k) > 0.75$ as “good”, $ICC(2k) > 0.9$ as “excellent”) for all stages ($ICC_{2,k} = 0.88 - 0.98$). Similarly, there were high associations ($r > 0.89$) and high agreement ($ICC_{2,k} > 0.90$) between ECG and Apple watch 6, and ECG and Apple watch 7 at rest and post exercise. However, there were only moderate associations and good agreement at low, moderate, and high intensity between the ECG and apple watch 6 ($r = 0.77-0.77$, $ICC_{2,k} = 0.62-0.84$), and ECG and Apple watch 7 ($r = 0.42-0.71$, $ICC_{2,k} = 0.49-0.85$) (Table 4). Additionally, the Bland-Altman visual analysis indicates systematic bias present at all stages between ECG and all of the instruments, with a greater presence of systematic bias at the moderate and high stages (Figure 10).

Table 4. Pearson's correlations and intra-class correlation coefficients for Football Athletes.

	r	95% CI		ICC	95% CI	
		Lower	Upper		Lower	Upper
<i>ECG vs Polar H-10</i>						
Rest	0.93	0.91	0.95	0.96	0.95	0.97
Low	0.89	0.85	0.92	0.93	0.9	0.95
Moderate	0.81	0.73	0.87	0.88	0.83	0.92
High	0.91	0.88	0.94	0.95	0.94	0.97
Post	0.98	0.97	0.98	0.99	0.98	0.99
<i>ECG vs Apple Watch 6</i>						
Rest	0.89	0.83	0.93	0.94	0.91	0.96
Low	0.77	0.67	0.85	0.84	0.74	0.9
Moderate	0.77	0.65	0.85	0.82	0.68	0.89
High	0.57	0.41	0.7	0.62	0.31	0.77
Post	0.97	0.95	0.98	0.98	0.97	0.99
<i>ECG vs Apple Watch 7</i>						
Rest	0.89	0.76	0.95	0.96	0.94	0.97
Low	0.71	0.5	0.83	0.82	0.75	0.87
Moderate	0.74	0.56	0.85	0.85	0.79	0.89
High	0.42	0.22	0.59	0.49	0.20	0.66
Post	0.96	0.94	0.97	0.98	0.97	0.99

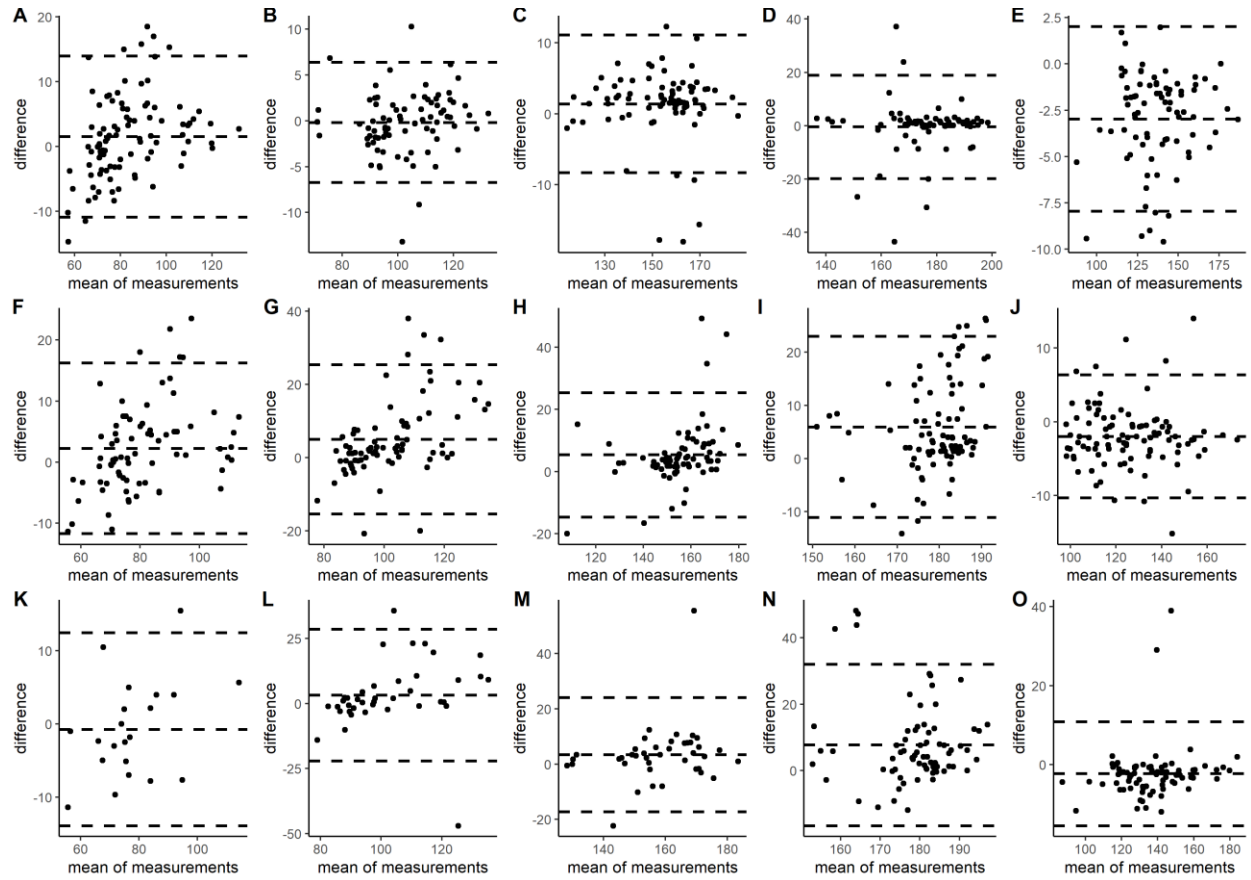


Figure 10. Bland-Altman plots for systematic bias analysis of football athletes between ECG and the Polar H-10 (1st row), Apple watch 6 (2nd row), and Apple watch 7th (3rd row) for rest (1st column), low (2nd column), moderate (3rd column), high (4th column), and post (5th column) stages.

DESCRIPTIVES – RECREATIONAL ATHLETES

Twenty participants (n=20, males=10, females=10) completed the study. Descriptive data (mean \pm sd) for the participants was 20.50 ± 2.16 years for age, 1.73 ± 0.09 meters for height, 72.98 ± 15.25 kgs for weight, and 24.15 ± 3.54 (kg/m²) for body mass index. The mean and standard deviation of Heart Rate, and the Percentage of Heart Rate max (220-Age) are presented in Tables 6-7.

Reliability and Instrument Stability

The intra-class correlation coefficient showed excellent reliability for the ECG, Polar-H10, Apple Watch 6, and Apple Watch 7 at rest, low, moderate, high, and post exercise stages ($ICC_{2,k} > 0.90$) (Table 5).

Table 5. Reliability analysis for Recreational Athletes

	ICC	95 % Confidence Interval	
		Lower	Upper
ECG Rest	0.966	0.937	0.985
ECG Low	0.975	0.953	0.989
ECG Moderate	0.977	0.956	0.989
ECG High	0.929	0.853	0.972
ECG Post	0.986	0.974	0.994
Polar Rest	0.983	0.967	0.992
Polar Low	0.985	0.972	0.993
Polar Moderate	0.985	0.972	0.993
Polar High	0.975	0.952	0.988
Polar Post	0.984	0.970	0.993
Apple6 Rest	0.991	0.963	0.992
Apple6 Low	0.988	0.977	0.995
Apple6 Moderate	0.991	0.982	0.997
Apple6 High	0.971	0.942	0.988
Apple6 Post	0.992	0.984	0.997
Apple7 Rest	0.985	0.971	0.993
Apple7 Low	0.989	0.987	0.995
Apple7 Moderate	0.993	0.985	0.997
Apple7 High	0.970	0.941	0.987
Apple7Post	0.977	0.955	0.990

Table 6. Recreational Athletes HR per stage

Stage	Time	ECG		Polar		Apple6		Apple7	
		mean	sd	mean	sd	mean	sd	mean	sd
Rest	0:30	92.55	18.47	93.60	17.63	92.53	16.41	93.02	16.32
Rest	1:00	87.20	14.65	88.48	15.12	88.35	16.05	88.13	14.58
Rest	1:30	92.60	15.09	89.43	14.95	88.86	14.80	89.59	14.94
Rest	2:00	90.15	15.50	90.33	13.51	89.04	13.39	89.56	13.60
Rest	2:30	90.60	15.07	90.71	13.95	91.18	14.11	90.56	14.16
Rest	3:00	89.90	14.98	89.92	13.70	90.30	14.76	90.24	14.15
Low	3:30	107.05	14.13	96.68	13.82	94.91	14.05	94.98	13.61
Low	4:00	104.25	13.45	106.39	12.08	105.60	12.02	104.68	13.22
Low	4:30	103.45	13.48	104.02	12.54	104.18	12.09	103.93	11.69
Low	5:00	102.25	12.71	102.87	12.66	103.05	12.02	102.67	12.24
Low	5:30	101.85	14.89	102.28	14.30	101.96	13.44	101.13	12.39
Low	6:00	103.95	13.85	103.07	13.75	102.33	13.72	101.62	12.45
Moderate	6:30	127.10	15.62	114.08	15.86	111.16	14.94	109.50	16.10
Moderate	7:00	141.30	14.44	135.18	14.79	136.21	15.25	134.59	19.77
Moderate	7:30	150.25	15.13	146.64	14.63	148.30	14.93	148.51	14.15
Moderate	8:00	152.05	14.61	151.92	15.45	153.21	14.74	153.23	14.47
Moderate	8:30	156.40	16.83	155.26	16.43	156.81	15.49	156.31	15.15
Moderate	9:00	158.35	16.89	157.77	16.82	159.62	16.60	158.31	15.63
High	9:30	160.10	19.84	163.81	16.84	164.20	16.74	162.47	15.43
High	10:00	174.29	17.04	171.08	15.98	171.83	16.22	170.52	15.54
High	10:30	173.33	16.46	173.59	14.54	174.86	15.32	174.01	14.30
High	11:00	176.44	14.65	175.49	14.50	176.41	16.49	176.88	13.22
High	11:30	175.32	15.43	178.30	12.96	177.20	17.60	177.45	12.74
High	12:00	179.00	12.12	180.10	12.33	178.06	18.57	178.85	11.69
Post	12:30	172.65	12.30	177.35	11.55	176.42	17.84	177.26	10.79
Post	13:00	158.95	16.37	165.38	14.30	164.10	17.18	164.39	12.14
Post	13:30	145.70	18.55	150.51	17.32	149.17	18.85	148.43	16.13
Post	14:00	137.80	18.11	140.71	17.72	140.25	18.92	139.46	17.08
Post	14:30	131.30	18.64	134.24	17.33	134.23	18.14	134.86	16.97
Post	15:00	128.45	17.74	129.68	17.52	129.06	18.33	129.83	17.67

Table 7. Recreational Athletes %HR from predicted HRmax (220-age)

Stage	Time	ECG		Polar		Apple6		Apple7	
		mean	sd	mean	sd	mean	sd	mean	sd
Rest	0:30	47.35%	9.57%	47.88%	9.13%	47.35%	8.59%	47.60%	8.52%
Rest	1:00	44.60%	7.53%	45.26%	7.81%	45.20%	8.29%	45.08%	7.53%
Rest	1:30	47.37%	7.81%	45.75%	7.71%	45.46%	7.64%	45.83%	7.70%
Rest	2:00	46.11%	7.95%	46.20%	6.97%	45.55%	6.92%	45.81%	7.02%
Rest	2:30	46.34%	7.76%	46.40%	7.20%	46.64%	7.27%	46.32%	7.30%
Rest	3:00	46.00%	7.81%	46.00%	7.14%	46.20%	7.67%	46.17%	7.38%
Low	3:30	54.75%	7.32%	49.45%	7.15%	48.55%	7.27%	48.58%	7.07%
Low	4:00	53.33%	7.07%	54.42%	6.29%	54.01%	6.25%	53.55%	6.87%
Low	4:30	52.92%	7.04%	53.21%	6.57%	53.29%	6.31%	53.16%	6.11%
Low	5:00	52.30%	6.59%	52.62%	6.57%	52.71%	6.27%	52.52%	6.39%
Low	5:30	52.10%	7.75%	52.32%	7.43%	52.15%	6.98%	51.73%	6.45%
Low	6:00	53.17%	7.16%	52.72%	7.14%	52.34%	7.11%	51.97%	6.44%
Moderate	6:30	65.03%	8.27%	58.37%	8.33%	56.87%	7.82%	56.02%	8.41%
Moderate	7:00	72.29%	7.68%	69.16%	7.86%	62.75%	22.78%	58.54%	26.97%
Moderate	7:30	76.86%	7.94%	75.02%	7.78%	64.48%	28.70%	64.58%	28.67%
Moderate	8:00	77.78%	7.72%	77.71%	8.13%	66.62%	29.56%	66.63%	29.56%
Moderate	8:30	79.99%	8.70%	79.42%	8.62%	72.13%	25.80%	67.97%	30.19%
Moderate	9:00	81.00%	8.81%	80.71%	8.83%	77.52%	20.04%	68.84%	30.61%
High	9:30	81.90%	10.36%	83.79%	8.85%	79.74%	20.54%	70.65%	31.34%
High	10:00	75.71%	33.67%	87.51%	8.42%	87.88%	8.34%	82.83%	21.07%
High	10:30	79.81%	28.47%	88.79%	7.71%	89.43%	7.95%	84.53%	21.23%
High	11:00	81.29%	28.73%	89.77%	7.66%	90.23%	8.54%	85.92%	21.37%
High	11:30	85.20%	21.46%	91.19%	6.80%	90.64%	9.17%	86.19%	21.34%
High	12:00	87.00%	21.37%	92.11%	6.51%	86.49%	22.42%	91.48%	6.20%
Post	12:30	88.30%	6.36%	90.71%	6.08%	85.70%	22.11%	90.67%	5.78%
Post	13:00	81.30%	8.50%	84.58%	7.45%	83.95%	9.00%	84.09%	6.48%
Post	13:30	74.52%	9.56%	76.98%	8.97%	76.31%	9.81%	75.93%	8.47%
Post	14:00	70.49%	9.41%	71.97%	9.19%	71.74%	9.82%	71.34%	8.93%
Post	14:30	67.16%	9.67%	68.67%	9.02%	68.67%	9.46%	68.98%	8.85%
Post	15:00	65.71%	9.22%	66.33%	9.10%	66.02%	9.53%	66.41%	9.19%

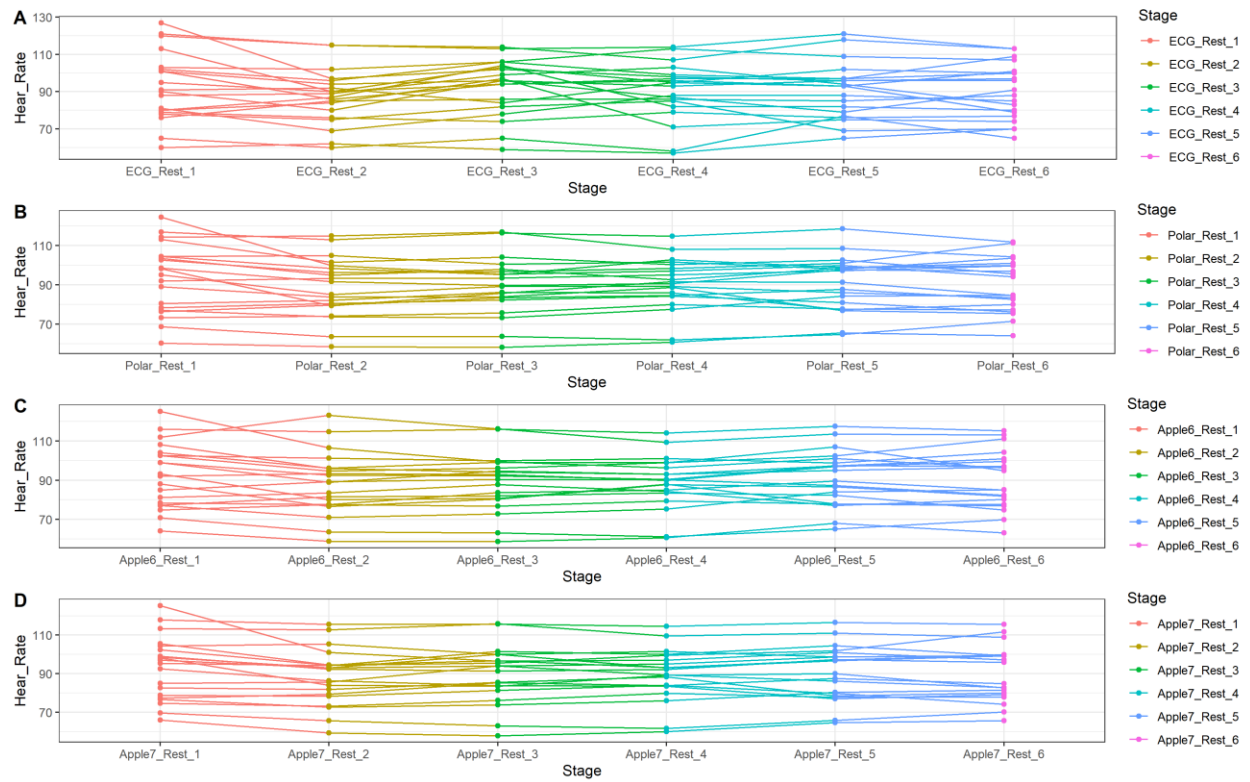


Figure 11. Recreational Athletes HR at Rest

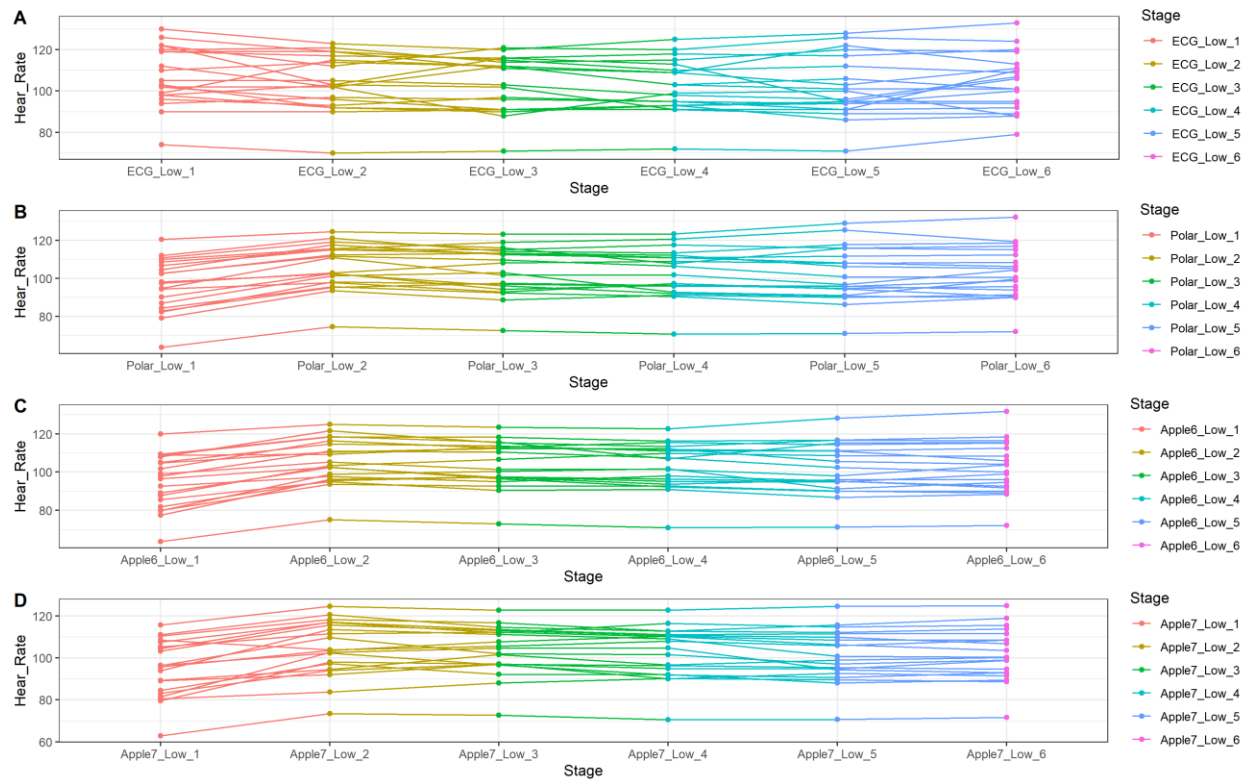


Figure 12. Recreational Athletes HR at Low Intensity

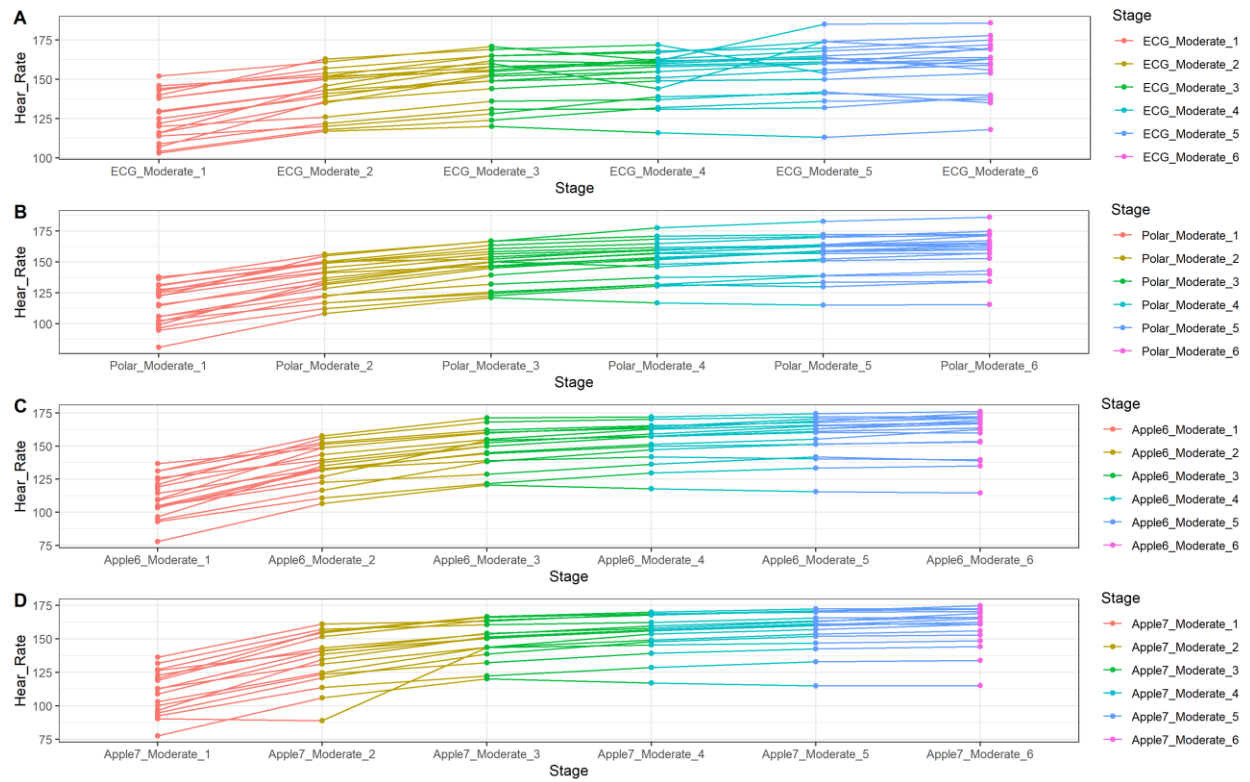


Figure 13. Recreational Athletes HR at Moderate Intensity

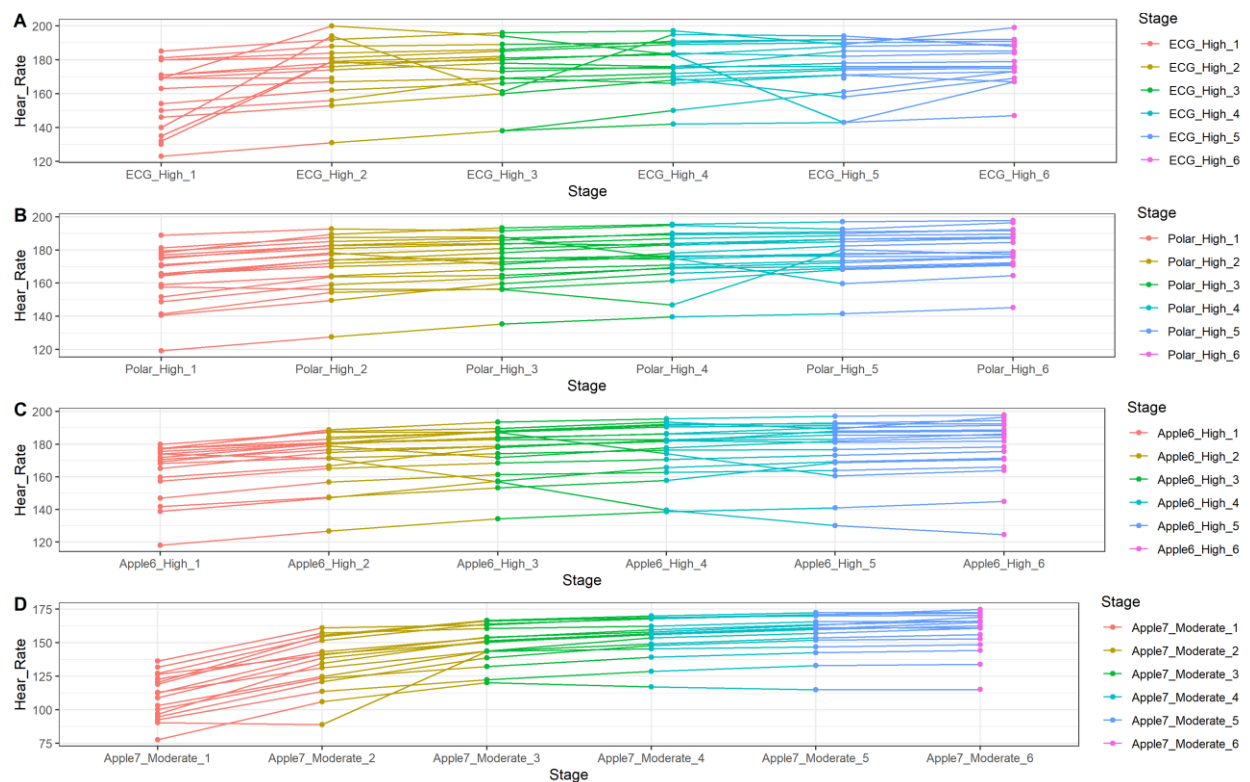


Figure 14. Recreational Athletes HR at High Intensity

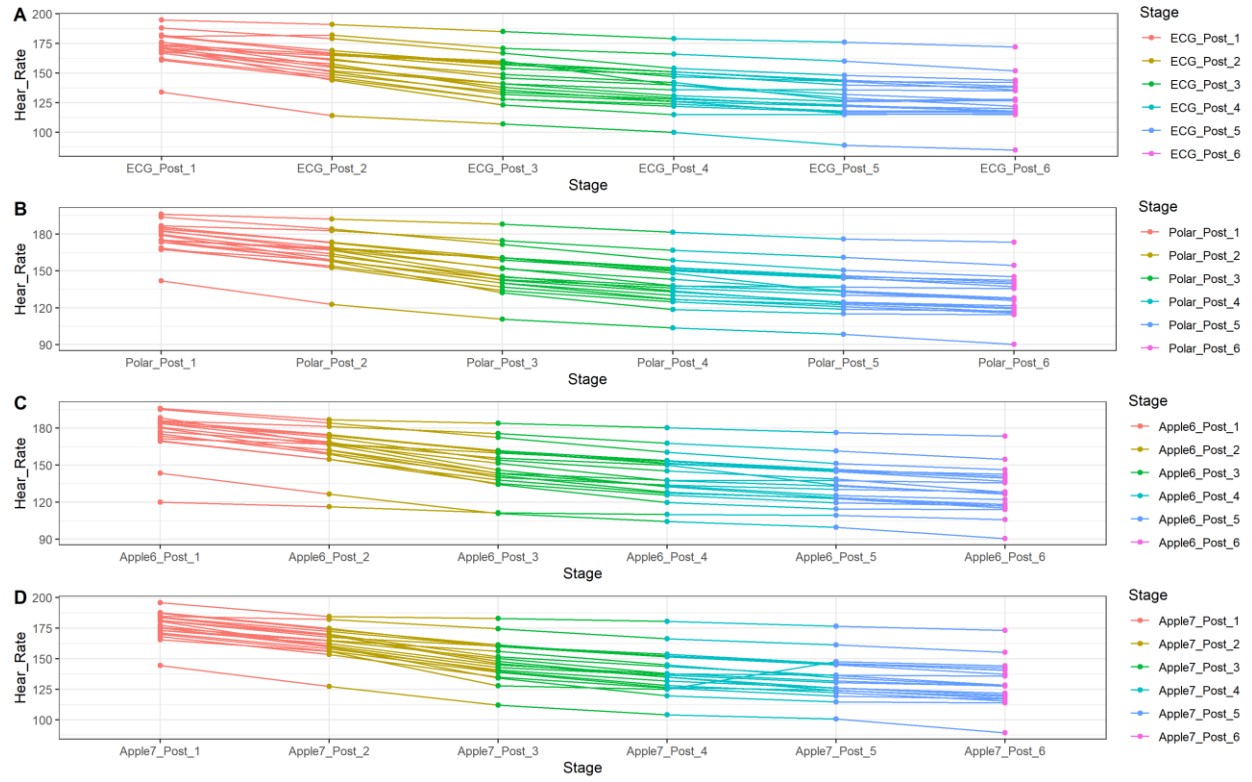


Figure 15. Recreational Athletes HR at Post Intensity

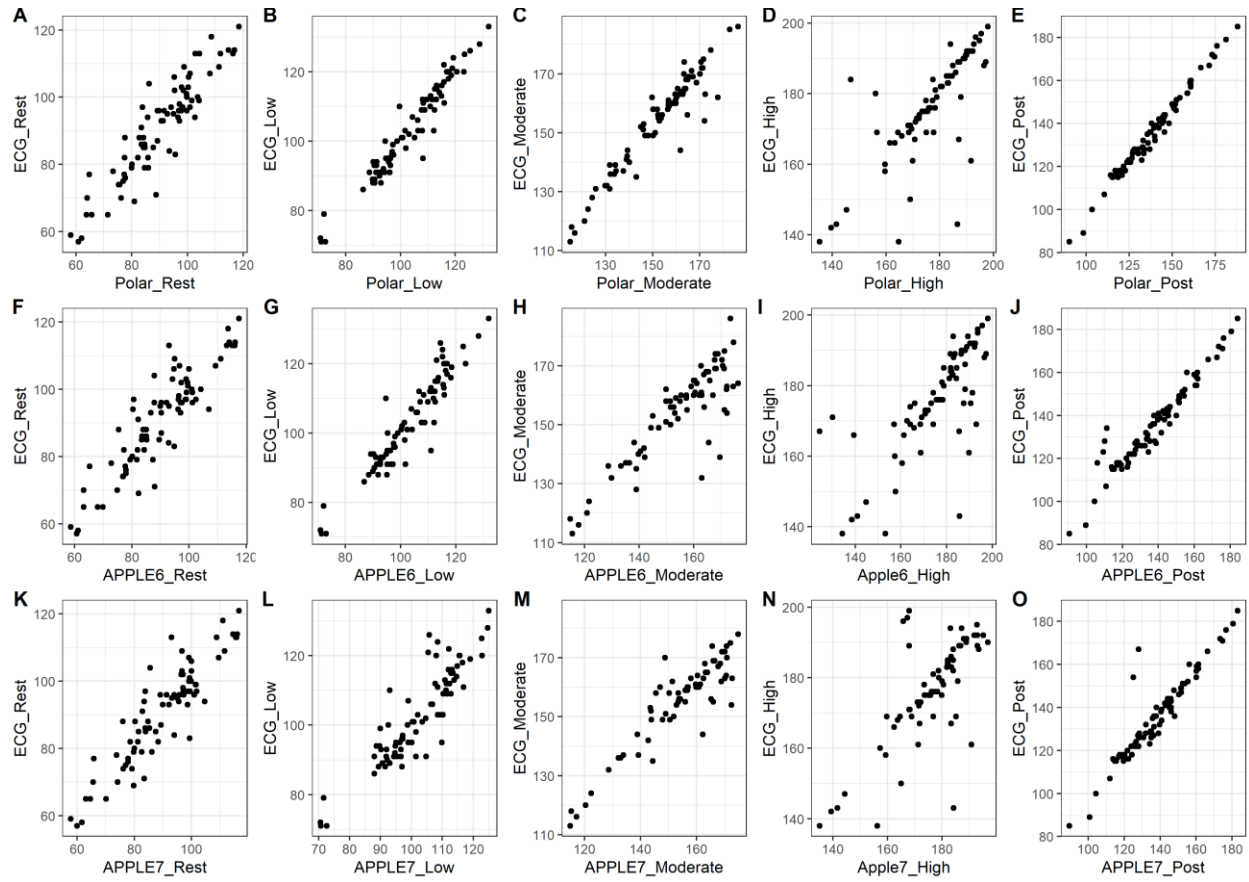


Figure 16. Correlations for Recreational Athletes HR between ECG and the Polar H-10 (1st row), Apple watch 6 (2nd row), and Apple watch 7th (3rd row) for rest (1st column), low (2nd column), moderate (3rd column), high (4th column), and post (5th column) stages.

VALIDITY

There were high associations ($r = 0.76-0.99$) between the ECG and Polar H-10 with good to excellent agreement for all stages ($ICC_{2,k} = 0.86 - 0.99$). Similarly, there were high associations ($r > 0.73$) and high agreement ($ICC_{2,k} > 0.89$) between ECG and Apple watch 6, and ECG and Apple watch 7 at rest and post exercise. However, there were only large associations and good agreement at low, moderate, and high intensity between the ECG and apple watch 6 ($r = 0.73-0.94$, $ICC_{2,k} = 0.62-0.84$), and ECG and Apple watch 7 ($r = 0.72-0.91$, $ICC_{2,k} = 0.75-0.94$) (Table 8). Additionally, the Bland-Altman visual analysis indicates systematic bias present at all stages between ECG and all the instruments, with greater presence of systematic bias at the moderate and high stages (Figure 17).

Table 8. Pearson's correlations and intra-class correlation coefficients for Recreational athletes.

		95% CI			95% CI	
	r	Lower	Upper	ICC	Lower	Upper
<i>ECG vs Polar H-10</i>						
Rest	0.91	0.86	0.94	0.95	0.93	0.97
Low	0.96	0.95	0.98	0.98	0.98	0.99
Moderate	0.95	0.92	0.96	0.97	0.96	0.98
High	0.76	0.64	0.84	0.86	0.80	0.90
Post	0.99	0.98	0.99	0.99	0.91	0.99
<i>ECG vs Apple Watch</i>						
6						
Rest	0.89	0.83	0.93	0.94	0.92	0.96
Low	0.94	0.91	0.96	0.97	0.96	0.98
Moderate	0.86	0.79	0.91	0.93	0.90	0.95
High	0.73	0.61	0.82	0.84	0.77	0.89
Post	0.96	0.93	0.97	0.98	0.96	0.99
<i>ECG vs Apple Watch</i>						
7						
Rest	0.90	0.85	0.93	0.95	0.93	0.97
Low	0.89	0.83	0.93	0.94	0.91	0.96
Moderate	0.91	0.85	0.94	0.96	0.94	0.97
High	0.72	0.58	0.81	0.83	0.75	0.88
Post	0.93	0.90	0.95	0.96	0.94	0.98

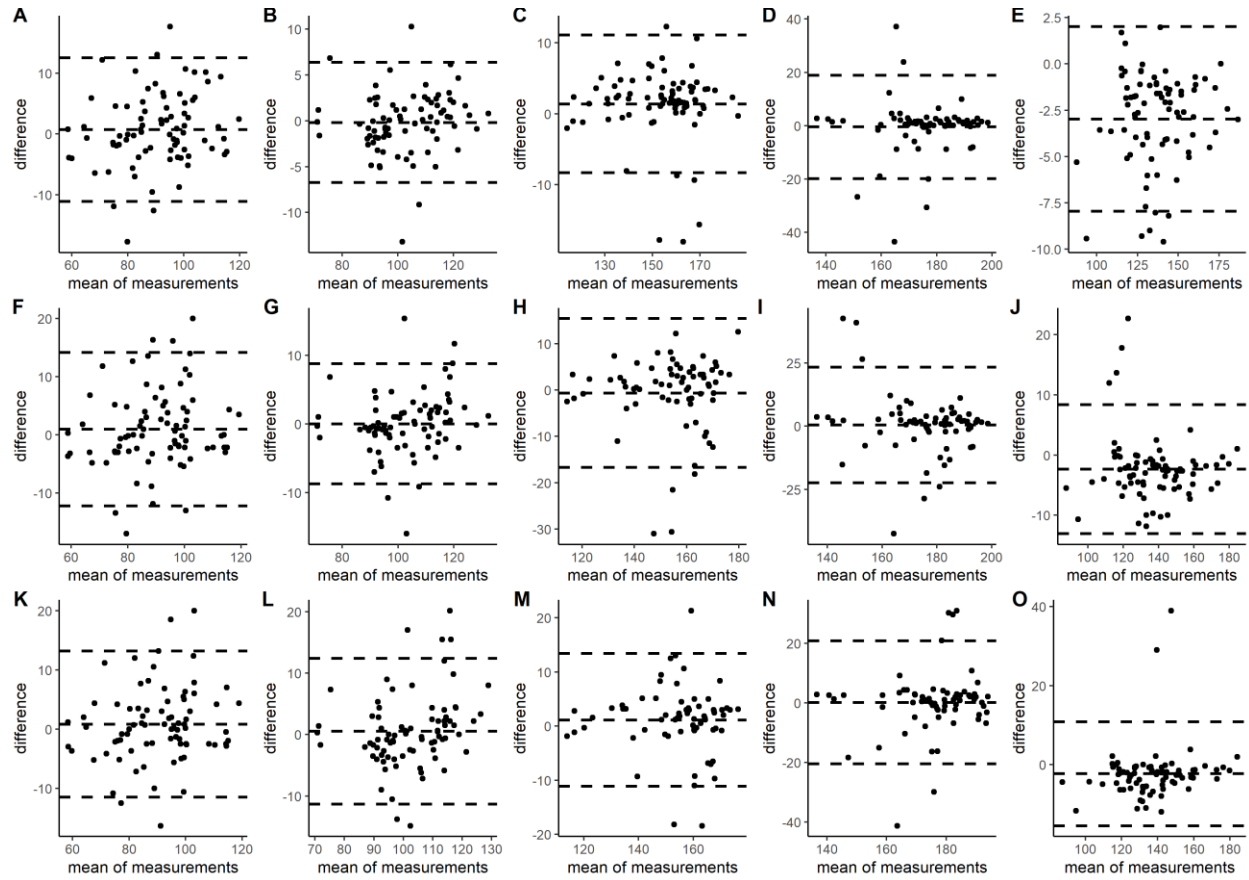


Figure 17. Bland-Altman plots for systematic bias analysis of recreational athletes between ECG and the Polar H-10 (1st row), Apple watch 6 (2nd row), and Apple watch 7th (3rd row) for rest (1st column), low (2nd column), moderate (3rd column), high (4th column), and post (5th column) stages.

Chapter 5: Discussion

The purpose of this study was to compare the validation of HR assessment with the use of the Apple Watch Series 6, 7, Polar H-10 chest-strap monitor, using the 12-lead ECG as a criteria method on collegiate level athletes. It was hypothesized that 1) the Apple Watch Series 6 and 7 would over- and under-estimate heart rate when compared to ECG 2) Polar H-10 would show a greater agreement to ECG in comparison to the Apple Watch Series 6 and 7. The results were consistent with our initial hypothesis when observing Bland-Altman plots for systematic bias analysis between ECG and Apple Watch 6 and 7 showing an over-and under-estimate in heart rate most significantly observed under moderate and high conditions. Moreover, the Polar H-10 demonstrated a higher agreement with HR in comparison to the Apple Watch HR monitors during all intensity levels in agreement with Pasadyn et al. 2019. Which demonstrated overall the Polar H7 Chest Strap monitor was highest at $r_c=98$ followed by the Apple Watch series 3 at $r_c=96$ in agreement with the ECG.

APPLE WATCH VS ECG

Interestingly, this investigation observed that the Apple watch series 6 and 7 did not show a significant difference within device within the football athletes at ($ICC_{2,k} = 0.62-0.84$) and ($ICC_{2,k} = 0.49-0.85$) and the recreational athletes at ($ICC_{2,k}=0.84-0.98$) and ($ICC_{2,k}=0.93-0.96$) in HR validity in comparison to ECG, respectively. This is largely in agreement with Kushhal et al. (2017) who reported HR validity during three exercise intensities (walking, jogging, and running) for the Apple Watch Series 0 placed on both right and left wrist. They reported a very good to nearly perfect intraclass correlation (≥ 0.91) between the left and right wrist during all exercise intensities. It is also clear that there is more error rate at a moderate and high intensity between ECG and Apple watches ($ICC_{2,k} = 0.49-0.85$) in comparison to rest and post exercise ($ICC_{2,k} > 0.90$). Similarly, Kushhal et al. (2017) observed a decrease in HR accuracy as exercise intensity increased and reported a very good correlation of $r = 0.92-0.97$ during walking and

jogging, and poor/good correlations of $r = 0.81-0.86$ at jogging and running exercise intensities. The difference in results between Kushhal et al. (2017) and the current study can be attributed to the use of Polar S810i as the criterion instead of ECG, which is the gold standard.

Overall, both the football athletes and recreational athletes showed the Polar H10 monitor with the highest agreement with ECG in comparison to the Apple Watch throughout all exercise intensities. This finding is in agreement with Pasadyn et al. (2019) who reported HR measures from several mobile devices, including the Apple Watch series 3 and Polar H7. The protocol consisted of an exercise session run at speeds of 4, 5, 6, 7, 8, and 9 mph, for which subjects ran for 2 minutes at each speed. The researchers found Polar H7 chest strap monitor to have the greatest agreement with ECG at $r_c = 0.98$ followed by the Apple Watch at $r_c = 0.96$. The difference between our study results and those from Pasadyn et al. (2019) is postulated to be due to running with free arm movements and were not allowed to hold on to the handrails in comparison to Pasadyn et al. (2019) where participants hold on to the treadmill handrails for measurement recordings. To the best of our knowledge, this is the first study designed to validate Apple watch series 6 and 7 on subjects participating in free arm movement aerobic exercise while comparing data results to Polar H10, and employing ECG as the criterion for validity.

LIMITATIONS

Several limitations exist for this study. First, this study was conducted in a laboratory setting, which may produce different results if it were to be replicated in a different environment. Second, the participants' skin tone as not objectively taken into account in this study, although research has shown that PPG technique inaccuracy is plausible in darker skin tones (Wallen et al. 2015). Lastly, the application of the smartwatch in this study was limited to a one-time use for testing purposes, thus, our results may not reflect its accuracy of continuous usage on individuals during daily life.

CONCLUSION

These findings indicate that the accuracy of the Apple Watch diminishes with an increase in intensity, which may be due to arm movement and/or skin tone. Furthermore, our results add to previous findings that have shown Polar models having a high agreement with ECG during all intensity levels and could be used in future research when ECG is not available.

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Appendix

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INFORMED CONSENT FORM:

University of Texas at El Paso (UTEP) Institutional Review Board
Informed Consent Form for Research Involving Human Subjects

Protocol Title: VALIDITY OF THE APPLE SMARTWATCH ON HEART RATE

Principal Investigator: Armando Martinez Ruiz

UTEP: Department of Kinesiology

INTRODUCTION

You are being asked to take part voluntarily in the research project described below. You are encouraged to take your time in making your decision. It is important that you read the information that describes the study. Please ask the study researcher or the study staff to explain any words or information that you do not clearly understand.

WHY IS THIS STUDY BEING DONE?

The purpose of this project is to validate heart rate through the use of the Apple Watch Series 6, Apple Watch Series 7, and Polar H10 chest-strap monitor in comparison to the standard 12-lead ECG used as criteria method on collegiate individuals.

Approximately, 30 subjects, (15 males and 15 females) will be enrolling in this study at UTEP.

You are being asked to be in the study because age range is between 18 to 30yrs, and you have been physically active in the past 3 months averaging 150 minutes of exercise per week and are injury free during and 6 months immediately prior to data collection.

Exclusion Criteria

If you are under the age of 18, older than 30, and have not been physically active in the past 3 months averaging 150 minutes of exercise per week, you will not qualify. If you have tattoos or piercings on the wrist since it may obstruct photoplethysmography (PPG) readings which is used to illuminate the skin and measures light absorption in order to detect blood volume. If you present any type of musculoskeletal or neurological injury you will not be able to participate in this study. A normal drop in glucose during exercise is expected, therefore for safety reasons, individuals with metabolic disease or who might consume medication that may alter HR response to exercise will be excluded. Prior to testing you must be caffeine-free for 12 hours.

If you decide to enroll in this study, your involvement will last about 30 minutes for one session.

What is involved in the study?

If you agree to take part in this study, the research team will:

Arrive to laboratory in routine gym clothing (ex. female sports bra). Take basic anthropometric measures of Height (m) and Weight (kg). Following this, 3 devices will be connected to individual respectively 1) 12 lead electrocardiogram (ECG) (in regards to female participants, a female assistant will be in charge of placing ECG leads on the individual), 2) Polar H-10 chest-strap monitor 3) PI' personal Apple Watch Series 6 will be placed on the right arm and a personal Apple Watch 7 from an assistants will be placed on the left arm and will be worn at all times. Individual subject will be asked to take off shirt in order to place single use/ disposable electrocardiograms on the individual. Individual will be asked to shave prior to testing if they have hair that they believe can obstruct ECG readings. Once at the lab subject may be asked to shave hair that may need to be removed.

You will:

Wear Apple watch, Polar H-10 chest- strap monitor and ECG at all times while walking, jogging and running at zero incline for 3 minutes at 3 mph, 6 mph and 9 mph, respectively. Following the test, you will be asked to continue walking on the treadmill for 3 minutes for recovery. Only Heart rate data will be recorded throughout the procedure in all devices, throughout the apple watch recording information will be sent to a separate tablet connected to retrieve the data recorded. No photography or recordings will be conducted in this study.

What are the risks and discomforts of the study?

Minimal risk: The risks associated with this research are no greater than those involved in daily activities.

There are no known or anticipated risks or discomforts associated with participation.

The researcher may decide to stop your participation, if he or she thinks that being in the study may cause you harm.

What will happen if I am injured in this study?

The University of Texas at El Paso and its affiliates do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness. You will not give up any of your legal rights by signing this consent form. You should report any such injury to Armando Martinez at (915) 355-7342 and to the UTEP Institutional Review Board (IRB) at (915-747-6590) or irb.orsp@utep.edu.

Are there benefits to taking part in this study?

You are not likely to benefit by taking part in this study. The proposed study would be the first to validate the new Apple Watch Series 6 and 7 by comparing it to the Polar H10 chest-strap

monitor and ECG. Validity of the Apple Watch Series 6 and 7 during physical activity will create an impact on the use of these devices by physicians, and coaches, as well as everyday practitioners.

WHAT ARE MY COSTS?

There are no direct costs.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will not be compensated for taking part in this research study.

What other options are there?

You have the option not to take part in this study. There will be no penalties involved if you choose not to take part in this study.

Choosing to withdraw or not participate will not affect your grades, class, or university standing.

What if I want to withdraw, or am asked to withdraw from this study?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, there will be no penalty or loss of benefit.

If you choose to take part, you have the right to skip any questions or stop at any time. However, we encourage you to talk to a member of the research group so that they know why you are leaving the study. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

The researcher may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm,

Who do I call if I have questions or problems?

You may ask any questions you have now. If you have questions later, you may call Armando Martinez at (915) 355-7342 or at amartinezruiz@miners.utep.edu.

If you have questions or concerns about your participation as a research subject, please contact the UTEP Institutional Review Board (IRB) at (915-747-6590 or irb.orsp@utep.edu).

What about confidentiality?

Your part in this study is confidential. The following procedures will be followed to keep their personal information confidential only the PI will have access to the testing session and data collection. You will be assigned a number; this number will help us to collect the data and ensure that you are unidentifiable. As soon as the study is completed, any documentation with the identity of each individual will be destroyed and only their ID number will be kept for the data analysis.

The results of this research study may be presented at meetings or in publications; however, your name will not be disclosed in those presentations.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include, but are not necessarily limited to:

- Office of Human Research Protections
- UTEP Institutional Review Board

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed.

All records will remain in a password secured word document that will only be accessible by the PI. All data collected will be stored on a password secured computer located in the Ph.D. Student Computer Research Lab at the Health Science Department Room 454. The data will be saved on a excel sheet with a password restricted access. All data will be kept for a period of 3-years and then it will be destroyed. Finally, only the PI will have access to the computers where all the data will be stored as well as he will be the only person with the password to access the data. Data from Apple Watch software will be imported and organized into a spreadsheet using Microsoft Excel Sheet then to Rstudio to conduct all statistical analysis. Apple account is not tied to individual and will be destroyed.

Authorization Statement

I have read each page of this paper about the study (or it was read to me). I will be given a copy of the form to keep. I know I can stop being in this study without penalty. I know that being in this study is voluntary and I choose to be in this study.

Participant's Name (printed)

Participant's Signature

Date

Signature of Person Obtaining Consent

Date

PROTOCOL



Institutional Review Board Office

The University of Texas at El Paso

Office of Research and Sponsored Projects

Research Protocol Application

Instructions: This form must be reviewed and completed in its entirety. All applications for review should contain the information presented in paragraphs. Indicate N/A when not applicable. A complete description of the planned research needs to be submitted in order to determine if all regulatory policy requirements have been met.

As such, the IRB will not consider any research that does not fulfill ethical principles reflected in the Belmont Report. These three basic ethical principles are:

Respect for Persons (autonomy)- individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to protection.

Beneficence- human participants should not be harmed and the research should maximize possible benefits and minimize possible harms.

Justice- the benefits and risks of research must be fairly distributed.

Please type and submit this form along with finalized copies of all project related materials via [IRBNet](#). Attention to these elements will facilitate the IRB's review of your project.

For further guidance or assistance, please contact the IRB office at (915) 747-6590 or by email at irb.orsp@utep.edu.

For more information, please see the [Investigator Manual for Human Subjects Research](#). (Ctrl+click to follow the link)



Institutional Review Board Office

The University of Texas at El Paso

Office of Research and Sponsored Projects

Project Information			
Protocol Title:	Validity Of The Apple Smart Watch on Heart Rate		
Principal Investigator (Last Name, First Name)	Martinez Ruiz, Armando		
University Title	<input type="checkbox"/> Faculty/Staff <input checked="" type="checkbox"/> Student		
Department	Kinesiology		
E-mail Address	amartinezruiz@miners.utep.edu	Phone Number	9153557342
Human Subjects Research Training Completed:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Anticipated Start Date Anticipated End Date:	10/10/21- 05/16/22

If the **Principal Investigator is a student**, the faculty advisor must indicate knowledge and approval of this submission. By electronically signing the package in IRBNet, the faculty advisor certifies that the study is under their direct supervision and that the faculty advisor is responsible for ensuring that all provisions of the IRB approval are complied with by the investigator.

If PI is a student, list Faculty Advisor/Sponsor			
<i>Remember to electronically share the submission package with this person.</i>			
Faculty Advisor (Last Name, First Name)	Dorgo, Sandor		
University Title	Professor		
Department:	Kinesiology		
E-mail Address	sdorgo@utep.edu	Phone Number	(915) 747- 7222
Human Subjects Research Training Completed:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

Additional Study Personnel
Project Team Members- UTEP affiliation

Name:	Title:	Role (check all that apply)
Samuel Montalvo	Research Associate	1 2 3 4 5 <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
Sandor Dorgo	Professor	1 2 3 4 5 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
Manuel Gomez	Graduate Student	1 2 3 4 5 <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Sabrina Arias	Undergraduate Research Assistant	1 2 3 4 5 <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Alondra Lozano	Undergraduate Research Assistant	1 2 3 4 5 <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Progga F Hasssan	Undergraduate Research Assistant	1 2 3 4 5 <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
External Personnel <i>Please list external study team members who will interact with participants or access identifiable data</i>		
		1 2 3 4 5 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		1 2 3 4 5 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		1 2 3 4 5 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Type of Project*Check all that apply*

<input type="checkbox"/>	Faculty Research	<input checked="" type="checkbox"/>	Thesis	<input type="checkbox"/>	Dissertation
<input type="checkbox"/>	Presentation/Conference	<input type="checkbox"/>	Capstone	<input type="checkbox"/>	Internal Evaluation/Non-Publishing
		<input type="checkbox"/>	Publication:	<input type="checkbox"/>	Other:

<input type="checkbox"/> Funded	Federal <input type="checkbox"/> Non-Federal <input type="checkbox"/> Other <input type="checkbox"/>
Source:	

All new federally funded human subjects research studies must comply with the revisions to the U.S. Department of Health and Human Services (DHHS) human subjects research regulations.

Principal Investigators (PIs) are responsible for notifying the IRB if there is a change in funding.

A. Project Site(s): *Check all that apply**This includes subject recruitment, subject enrollment, data collection, and data analysis*

*Please include the Site Authorization Letter indicating permission to conduct project in the submission package

<input type="checkbox"/>	Project will be conducted entirely at UTEP.
<input checked="" type="checkbox"/>	Project will be conducted entirely at UTEP.
<input type="checkbox"/>	Research will be conducted at another institution.* Project will be reviewed by another IRB and/or Ethics Committee Provide the institution name and contact person:
<input type="checkbox"/>	Multi-Site Study*: Is UTEP the lead institution? YES <input type="checkbox"/> NO <input type="checkbox"/> If NO, list the lead institution:
<input type="checkbox"/>	Other*:
<input type="checkbox"/>	International –Please complete section below.

International Research:

Identify where the research will be conducted. Provide information regarding local customs, laws, and regulations of the site(s). Clarify if your research requires local ethics committee review and approval and/or if permission is required from a government entity.

N/A

B. Ethical Considerations:

B1. Will this project be conducted anonymously? (Note, in person studies and/or collection of IP addresses are not anonymous)

IF yes, please describe how anonymity will be preserved throughout the duration of the study:

YES ☐ NO ☒

B2. Does the study protocol include children as research subjects?	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
B3. Does the study protocol include a protected group(s)? (UTEP employees, UTEP students)	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
B4. Does the study protocol include prisoners, fetuses, pregnant women, human in vitro fertilization, or persons with impaired decision making? Identify:	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
B5. Does the study specifically select economically/educationally disadvantaged individuals?	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
B6. Does the protocol involve more than minimal risk?	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
B7. Does the protocol involve deception?	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
B8. Does the protocol involve persons with impaired decision making?	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>

C. Hypothesis, Objectives, or Goals of the Project:

Clearly state the purpose of the study (research questions and/or study objectives).

The purpose of this project is to validate heart rate and maximum heart rate (HRmax) through the use of the Apple Watch Series 6 and Polar H10 chest-strap monitor in comparison to the standard 12 lead ECG used as criteria method on collegiate level athletes. Previous studies have shown both an over- and under-estimation (-16.31 to 12.71 beats per minute) in the Apple Watch devices when observed through the criterion method (Nelson & Allen, 2019; Thmpson et al., 2019; Wallen et al., 2015). Polar chest-strap monitors have shown to come close to ECG standard (rc= 0.996 and r=0.997) in previous Polar models (Gillinov et al., 2017; Pasadyn et al., 2019) Thus it is hypothesized: 1)the Apple Watch Series 6 *and* 7 would over- and under-estimate heart rate and maximum heart rate when compared to ECG. 2) Polar H-10 will show a greater agreement to ECG in comparison to the Apple Watch.

D. Background and Significance:

Describe relevant background literature to support the rationale for doing this study. This rationale should provide sufficient information to justify the study. Describe the potential benefit for individual subjects or society at large. It should be limited to no more than two to three pages.

IMPORTANCE OF SMART WATCHES

In recent years, wearable technologies have gained popularity in the exercise and fitness community. These devices have revolutionized the sport and exercise sciences by providing real-time short and long-term health data, creating a substitution to lab measurement devices and provide practicality. Data are often in the form of positional data (via Global Positioning System data), heart rate, and recently also including arterial oxygenation (Apple; Dooley et al., 2017; Kwon et al., 2019). These health-related variables allow us to understand and obtain real-time feedback on overall human health. For example, heart rate variability (HRV), has been associated with higher psychological stress, cortisol, and increased risk of cardiac failure (Rennie et al., 2003). These health-related variables as well as target reminders, goal settings, health feedback, and most importantly their superior portability may improve and promote physical activity of the user (Ridgers et al., 2016; Sullivan &

Lachman, 2017). Furthermore, wrist-based monitors are more convenient and comfortable in comparison to chest strap monitors (Pasadyn et al., 2019)

IMPORTANCE OF VALIDITY

One of the most common and practical methods for prescribing exercise training and intensity is through heart rate measurement (Anastasopoulou., 2014; Warren et al., 2010). Proper monitoring of exercise intensity and recovery is important to observe cardiorespiratory fitness and a good predictor of mortality (ACSM; Cole et al., 1999; Shetler., 2001) Athletes rely on heart rate monitors for guidance in their specific training routine and progress (Achten & Jeukendrup, 2003; Diaz et al., 2015; Gillinov et al., 2017) However, a constant problem with field devices lies in the quality of the data that can be obtained through the device.. A recent study found the Polar H-10 to be valid in comparison to ECG with a correlation of $r=0.997$ during physical activity (Pasadyn et al., 2019). Wrist-based monitors may show convenience and comfort in comparison to chest-strap monitors and enable them to be largely used. These wrist-worn devices use photoplethysmography (PPG) measurements. PPG measurements display arterial oxygen saturation and rate of change in blood pressure and is used interchangeably with beats per minute in previous validation studies (Boudreaux et al., 2018; Dooley, Golaszewski, & Bartholomew., 2017; Gillinov et al., 2017; Lang, 2018; Nelson & Allen, 2019; Shcherbina et al., 2017; Wallen et al., 2016). Recently a study conducted by Thompson (2019) measured the Apple Watch and Fit Bit Charge 2 HR readings during a Bruce protocol test and found the Apple Watch to have the lowest relative error rate (2.9-5.1%) in all exercise intensities in comparison to the Fitbit Charge 2 (3.9-13.5%). Thus, the importance of conducting validity verification of the latest features in wrist-based monitors will serve as guidance for athletes and physician's cardiorespiratory fitness and health observations respectively (Gillinov et al., 2017; Xie., 2018).

KNOWLEDGE GAP

To date, there are no data in terms of the validity or reliability of the newly released Apple Watch Series 6 and 7. Due to the popularity of smartwatches use to fitness tracking devices, it is crucial to determine the precision of the instrument to capture different fitness variables. To our knowledge, the current proposed study would be the first to validate the new Apple Watch series 6 by comparing it to the Polar H10 chest-strap monitor. Validity of the Apple Watch Series 6 during physical activity will create an impact on the use of these devices by physicians, and coaches, as well as everyday practitioners.

E. References/Literature Review:

List all references cited in the protocol and/or pertinent to the study.

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F. Research Method, Design, and Proposed Statistical Analysis:

Provide a **brief** overview of your research methodology (e.g. experimental, correlational, qualitative) and specific study design and your proposed analysis of the research data.

PROPOSED DESIGN

A single-session cross-sectional study design will be implemented. Due to similar articles and a power analysis performed approximately, *thirty* college-age endurance athletes ($n=30$; 15 males and 15 females) team will be recruited for this study *who have been physically active in the past 3 months averaging 150 minutes of exercise per week*. (Abt et al., 2019;Gilden-Amman et al., 2019; Khushhal et al., 2017; Wallen et al., 2018).

EXERCISE PROTOCOL

The single session will consist of basic anthropometric measures of Height (m) and Weight (kg). Following this, 3 devices will be connected to individual respectively 1) 12 lead electrocardiogram (ECG) (*with female* assistants placing ECG leads on female participants), 2) Polar H-10 chest-strap monitor 3) Apple Watch Series 6 will be placed on the *right* arm and *Apple Watch 7 will be placed on the left arm* and will be worn at all times. Once all devices *are placed*, resting heart rate *will be recorded*. Thereafter, subjects *will be asked* to walk, jog and run at zero incline for 3 minutes at 3 mph, 6 mph and 9 mph, respectively. Following the test, subjects will be asked to continue walking on the treadmill for 3 minutes for recovery.

STATISTICAL ANALYSIS

Data will be organized into a spreadsheet using Microsoft Excel in Windows 10th (Microsoft Corporation). Thereafter, data will be exported to Rstudio integrative development environment (version 1.4.1103) to be analyzed using R statistical language. Agreement will be assessed using a two-way mixed models Intra-Class Correlation (ICC,2k); $ICC(2k) > 0.75$ as “good”, $ICC(2k) > 0.9$ as “excellent”. To assess agreement between devices and fixed bias, Bland-Altman plots will be constructed for each of the variables and displaying clinically important 95% limits of agreement (LoA). To determine systematic and proportional bias, the regression Model II, ordinary least product (OLP) regressions will be utilized. Systematic bias will be considered if the 95% confidence interval (CI) of the intercept “x” does not cross “0.0” and proportional bias if the slope “y” does not cross “1.0” (Lake et al., 2018; Ludbrook, 1997, 2012). Due to low unlikelihood of the devices to have an exact agreement, it is important to see how close the variables are during observation.

The following sections outline types of research activities. Please check the box(es) **ONLY** if **all** activities involving human subjects falls into one or more the applicable categories.

Behavioral Study Activities

<input type="checkbox"/>	<p>Research conducted in established or commonly accepted educational setting, involving normal educational practices. (E1)</p> <p><i>This category may include research on effectiveness as well as comparisons about educational strategies, techniques, curricular or classroom management. Educational tests, such as cognitive, diagnostic, aptitude, achievement tests</i></p> <p><u>Notes:</u></p> <ul style="list-style-type: none"> • The research must not adversely impact students' opportunity to learn required educational content. • The research must not adversely impact the assessment of educators who provide instruction. • An information sheet or abbreviated consent document should be used
<input type="checkbox"/>	<p>Research that ONLY includes surveys, interviews, focus groups, or observation of public behavior with adults who can consent for themselves and covering benign topics. (E2) (I-LR)(FR)</p> <p><u>Notes:</u></p> <ul style="list-style-type: none"> • The term "benign" describes activities that are not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive. • Interventions are not allowed. • An information sheet or abbreviated consent document should be used.
<input type="checkbox"/>	<p>Benign research on perception, cognition, motivation, communication, social behavior, behavioral games or minimal risk performance tasks. (E3)(LR)(FR)</p> <p><u>Notes:</u></p> <ul style="list-style-type: none"> • The term "benign" describes activities that are brief in duration, not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive, and not likely to have a lasting adverse impact. • An information sheet or abbreviated consent document may be used.
<input type="checkbox"/>	<p>Secondary research use of identifiable private information or identifiable biospecimens originally collected for other purposes. (E4)</p> <p><u>Notes:</u></p> <ul style="list-style-type: none"> • When the identifiable private information or biospecimens are publicly available;

	<ul style="list-style-type: none"> The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact the subjects or try to re-identify subjects.
<input type="checkbox"/>	Taste/Food quality evaluation and consumer acceptance. (E6)

General Notes:

The above research may involve randomization between groups if disclosed to participants.

The above research may be audiotaped, if the subject agrees, if identities are not shared, and the confidentiality of the information is properly protected.

Exempt category 5 is not listed as it applies to projects conducted or supported by or subject to the approval of Federal department and agency heads. Please contact the IRB office if you feel your project meets this criteria. UTEP will not implement exemption categories 7 & 8 at this time.

Biomedical Study Activities

<input checked="" type="checkbox"/>	Prospective collection by non-invasive procedures such as ultrasound, MRI without contrast, Doppler, MEG, EEGs, ECGs, eye tracking
<input checked="" type="checkbox"/>	Moderate exercise, muscular strength testing, body composition assessment in healthy adults (Ex4)
<input type="checkbox"/>	Non-invasive collection of biospecimens (Ex3)
<input checked="" type="checkbox"/>	Non-invasive tests (body composition, BP, pulse)(Ex4)
<input type="checkbox"/>	Collection of blood for research purposes only from heel stick, ear stick, finger stick or venipuncture, provided (Ex2): <ul style="list-style-type: none"> Total amounts in healthy adults do not exceed 550 ml in an 8 week period or collection may not occur more frequently than 2 times per week; or For other adults, considering the age, weight and health of participants and collection procedure, the total amount drawn does not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and does not occur more frequently than two times per week.

Detailed Description of the Technology that will be used During the Course of the Study to Recruit Participants, Capture, Record, or Transmit Data

Please select which technology(ies) will be used in this study (check all that apply and answer the questions in the relevant required section).

	Technology Type	Examples	If Yes, Answer the Required Questions
YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	Mobile technology	<i>For example, iPhone, Android devices, iPods, tablets, or other wireless devices.</i>	Who does the mobile technology belong to? The laptop will be password protected by the principle investigator, as well as the laptop being password protected.

			<input type="checkbox"/> Sponsor provided device, not owned by UTEP <input type="checkbox"/> Study participant owned device <input type="checkbox"/> UTEP provided device <i>Apple watch device is owned by principal investigator.</i> <i>Polar H 10 is a UTEP provided device.</i>
YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	Social Media	<i>For example Facebook or Twitter</i>	Provide Link(s): Purpose:
YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	Website survey, or similar tool	<i>For example, QuestionPro survey, surveys on external websites</i>	Name of website survey, or similar tool you are using:
YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	Cloud based storage	<i>Cloud storage is a cloud computing model in which data is stored on remote servers accessed from the internet, or "cloud." Examples include Google Drive, iCloud, Microsoft OneDrive, etc. Note, see institutional policy for use of DropBox in research.</i>	
YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	Wearable Technology	<i>Examples of wearable biosensors include accelerometers, activity trackers, wireless heart rate monitors, pulse oximetry sensors, and glucose sensors.</i>	Name of the device: Apple Watch, Polar H 10 heart rate sensor, ECG
YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	Phone, Video or Web Conferencing	<i>Examples include Zoom, Adobe Connect, Skype for Business, Facetime, etc.</i>	Name of the conferencing system: The recordings capture? <input type="checkbox"/> Images <input type="checkbox"/> Audio <input type="checkbox"/> Video
YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	Text messaging/secure messaging	<i>Examples include Outlook, text, etc.</i>	What type of messaging will be used: <input type="checkbox"/> Text <input checked="" type="checkbox"/> Email <input type="checkbox"/> Other Purpose: to recruit and communicate with subjects and mentors.
YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	Mobile Applications	<i>Examples include those created by the PI, Apple health, Garmin connect, Fitbit, etc.</i>	Name of the application: Apple health

G. Sample:

Identify the sources of potential participants, derived materials, or data.

*Define the study sample (number of subjects to be enrolled, characteristics of subjects, inclusion and exclusion criteria). **Specifically define the procedures that will be used to recruit, screen, and follow study participants.** Please describe whether some or all of the participants are likely to be vulnerable to coercion or undue influence, and if so, what additional safeguards are included to protect their rights and welfare. Explain the rationale for the use of special classes of participants whose ability to give voluntary informed consent may be in question. Such participants include students in one's class, people currently undergoing treatment for an illness or problem that is the topic of the research study, people who are cognitively impaired, and vulnerable populations.*

Is there a possibility of coercion or undue influence?

YES ☐ NO ☒

INCLUSION CRITERIA

Subjects age range will be from 18 to 30yrs *in order to get a young adult population*, team will be recruited for this study *who have been physically active in the past 3 months averaging 150 minutes of exercise per week*. Subjects must be injury free during and 6 months immediate before data collection.

EXCLUSION CRITERIA

Subjects under the age of 18 and older than 30, *or have not been physically active in the past 3 months averaging 150 minutes of exercise per week* will not qualify. *Athletic population is preferred to make sure subject will perform the test without stopping early due to fatigue*. Subjects who have tattoos or piercings on the wrist since it may obstruct PPG readings *which is used to illuminates the skin and measures light absorption in order to detect blood volume*. Subjects who presented any type of musculoskeletal or neurological injury will not be able to participate in this study. A normal drop in glucose during exercise is expected, therefore for safety reasons, individuals with metabolic disease or who might consume medication that may alter HR response to exercise will be excluded. Prior to testing subjects must be caffeine-free for 12 hours. Subjects who were eligible will provide written informed consent prior to testing.

During UTEP football practice recruitment,

The PI will read the following script verbally “Good afternoon/morning my name is _____. *I currently hold the position of Graduate Assistant of the Equipment Team. My job responsibilities include overseeing equipment and uniform distribution and retrieval at practices and game days and also ensure that all apparel and equipment are maintained and in good condition.* I am currently a masters of kinesiology student working under the mentorship of Dr. Dorgo. I am currently looking to begin my thesis project, which is the last requirement for me to graduate with my degree. My thesis project is validity of the apple series 6 *and 7* smartwatch on heart rate in which I am asking for 30 volunteers to participate for one day. The project will consist of the participants performing a single session which will consist of basic anthropometric measures of Height (m) and Weight (kg). Following this, 3 devices will be connected to individual respectively 1) 12 lead electrocardiogram (ECG), *(with female assistants placing ECG leads on female participants)*, 2) Polar H-10 chest-strap monitor 3) Apple Watch Series 6 will be placed on the *right* arm and *Apple Watch 7 will be placed on the left arm and* will be worn at all times. Once all devices *are on*, resting heart rate will be recorded. Thereafter, subjects will be asked to walk, jog and run at zero incline for 3 minutes at 3 mph, 6 mph and 9 mph, respectively. Following the test, subjects will be asked to continue walking on the treadmill for 3 minutes for recovery.

The overarching goal of this study is to validate the new Apple Watch Series 6 *and 7* by comparing it to the Polar H10 chest-strap monitor. Validity of the Apple Watch Series 6 *and 7* during physical activity will create an impact on the use of these devices by physicians, and coaches, as well as everyday practitioners.

For inclusion in the study subjects must between the ages of 18 and 30 years, 2) free from any underlying diagnosed health conditions (spine deformities, impaired gait, restricted range of motion, heart conditions, musculoskeletal deformations, etc.), 3) free from any serious injuries, and 4) recreationally active with at least two sessions weekly involving vigorous running. Specifically, only subjects who report regularly attending activities such as running-based recreational sports or fitness sessions will be accepted

Subjects will be asked to honestly answer if they meet the all the previous inclusion criteria. Potential subjects will not be required to present any medical records or documentation.

If you are interested in participating, please let me know by sending me an email at amartinezruiz@miners.utep.edu

You must also understand that this will not affect you individually nor teams standing.

Thank you”

In the Kinesiology department I will ask professors help and permission in being able to make an announcement in their class,

The PI will read the following script verbally “Good afternoon/morning my name is ____ and I am currently a masters of kinesiology student working under the mentorship of Dr. Dorgo. I am currently looking to begin my thesis project, which is the last requirement for me to graduate with my degree. My thesis project is validity of the apple series 6 and 7 smartwatch on heart rate in which I am asking for 30 volunteers to participate for one day. The project will consist of the participants performing a single session which will consist of basic anthropometric measures of Height (m) and Weight (kg). Following this, 3 devices will be connected to individual respectively 1) 12 lead electrocardiogram (ECG), (with female assistants placing ECG leads on female participants), 2) Polar H-10 chest-strap monitor 3) Apple Watch Series 6 will be placed on the right arm and Apple Watch 7 will be placed on the left arm and will be worn at all times. Once all devices are on, resting heart rate will be recorded. Thereafter, subjects will be asked to walk, jog and run at zero incline for 3 minutes at 3 mph, 6 mph and 9 mph, respectively. Following the test, subjects will be asked to continue walking on the treadmill for 3 minutes for recovery.

The overarching goal of this study is to validate the new Apple Watch Series 6 and 7 by comparing it to the Polar H10 chest-strap monitor. Validity of the Apple Watch Series 6 and 7 during physical activity will create an impact on the use of these devices by physicians, and coaches, as well as everyday practitioners.

For inclusion in the study subjects must between the ages of 18 and 30 years, who are currently physically active for the past 3 months 2) free from any underlying diagnosed health conditions (spine deformities, impaired gait, restricted range of motion, heart conditions, musculoskeletal deformations, etc.), 3) free from any serious injuries, and 4) recreationally active with at least two sessions weekly involving vigorous running. Specifically, only subjects who report regularly attending activities such as running-based recreational sports or fitness sessions will be accepted

Subjects will be asked to honestly answer if they meet the all the previous inclusion criteria. Potential subjects will not be required to present any medical records or documentation.

If you are interested in participating, please let me know by sending me an email at amartinezruiz@miners.utep.edu

Thank you”

H. Informed Consent:

The formal consent of each subject must be obtained before that subject is subjected to any study procedure. Describe how participants will be fully informed of this research prior to their participation and how their voluntary consent will be documented. If you anticipate enrolling subjects whose primary language is not English, how will you obtain informed consent in the language of those participants. Identify who will be involved in the consent process and where this will occur. If applying for a waiver of documented consent, specifically state this and provide justification. If the study involves deception, describe the procedures for debriefing the participants.

Prior to the testing session, the subjects will be required to sign in an informed consent form. The PI will read and explain the protocol to each of the participants and will answer any questions that the participant may

have. Subjects will be also reminded that their participation is voluntary, and they may withdraw from the study at any time if they wish to do so. If the participant agrees with to participate, the participant will sign the consent form. A witness will be present at the time of this process. A photocopy of this document will be given to the participant.

I. Detailed Study Procedures:

*Outline step-by-step what will happen in this study and to the human subjects. What will you ask your participants to do? When and where will they do it? How long will it take them to do it? Describe the type of research information that you will be gathering from your subjects, i.e., the data that you will collect. **Identify the measurement/instrumentation.** For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this project.*

Procedures

The single session *consisting of 30 minutes* will be conducted in the UTEP Exercise Physiology Laboratory, located in the College of Health Science, Room 454. This will consist of basic anthropometric measures. *Individual will be asked to take off shoes and asked to step on scale in order to get Height (m) and Weight (kg).* Following this, 3 devices will be connected to individual respectively 1) 12 lead electrocardiogram (ECG), *(with female assistants placing ECG leads on female participants),* (ECG), 2) Polar H-10 chest-strap monitor 3) *PI' personal* Apple Watch Series 6 will be placed on the *right* arm and a *personal Apple Watch 7* from an assistants will be placed on the left arm and will be worn at all times.

Individual subject will be asked to take off shirt in order to place single use/ disposable electrocardiograms on the individual. Individual will be asked to shave prior to testing if they have hair that they believe can obstruct ECG readings. Once at the lab individual may ask to shave hair that may need to be removed.

Subjects will perform several stretches prior to the treadmill testing. Once all devices are on, resting heart rate will be recorded. Thereafter, subjects were asked to walk, jog and run at zero incline on a treadmill for 3 minutes at 3 mph, 6 mph and 9 mph, respectively. Following the test, subjects will be asked to continue walking on the treadmill for 3 minutes for recovery. Heart rate will be recorded throughout the procedure *in all devices, throughout the apple watch recording information will be sent to a separate tablet connected in order to retrieve the data recorded. No photography or recordings will be conducted.*

Will you be audio or video recording during any portion of this project?

YES ☐ NO ☒

IF yes, this information must be described in all pertinent sections and the ICF(s).

YES ☐ NO ☒

Will subjects be compensated (payment, incentives, extra credit, etc.)?

If yes, details should be included above.

YES ☐ NO ☒

J. Privacy and Confidentiality:

Describe how the project team will protect the privacy and confidentiality of study participants: Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality pertains to the treatment of information or data that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Note that ensuring privacy of participants is different from confidentiality of data.

During testing sessions, only one subject will be allowed at the testing facility at a time to ensure that his/her privacy is not infringed by the presence of another individual. Subject's information and testing results will be kept confidential. Only the PI will have access to information and testing sessions. During the information session, the subjects will be given a detail explanation of the information that we will be collecting and how we will ensure maximum individual privacy and confidentiality of every subject in this study.

Governmental organizations such as the Department of Health and Human Services and UTEP Institutional Review Board might request access or copy our data records for quality assurance and data analysis. In this type of cases, the individuals will be notified by email that their information has been shared with a governmental organization as well as the type of information that was shared. A proper follow up will be made with the governmental organization and the individuals will be notified of any changes and/or current information status.

K. Data Handling, Record Keeping, and Data Analysis:

*Describe how the project team will collect, manage, and analyze data. Describe provisions that will be taken to maintain **confidentiality** of the data. Will it contain subject names or images? (e.g. surveys, video, audio tapes, database). Describe the security plan for data, including where data will be stored, and for how long, noting that you may not keep identifiable data indefinitely (i.e., password protection, encrypted, locked filing cabinet, etc.)*

To maintain the confidentiality of the research data, only the PI will have access to the testing session and data collection. Subjects will be assigned a number; this number will help us to collect the data and ensure the subject is unidentifiable. As soon as the study is completed, any documentation with the identity of each individual will be destroyed and only their ID number (*assigned number*) will be kept for the data analysis. This assigned number will remain in a password secured word document that will only be accessible by the PI. All data collected will be stored on a password secured computer located in the Ph.D. Student Computer Research Lab at the Health Science Department Room 454. The data will be saved on a excel sheet with a password restricted access. All data will be kept for a period of 3-years and then it will be destroyed. Finally, only the PI will have access to the computers where all the data will be stored as well as he will be the only person with the password to access the data. Data from Apple Watch software will be imported and organized into a spreadsheet using Microsoft Excel Sheet then to Rstudio to conduct all statistical analysis.

Data will be analyzed, agreement will be assessed using a two-way mixed models Intra-Class Correlation (ICC,2k); $ICC(2k) > 0.75$ as "good", $ICC(2k) > 0.9$ as "excellent". To assess agreement between devices and fixed bias, Bland-Altman plots will be constructed for each of the variables and displaying clinically important 95% limits of agreement (LoA). To determine systematic and proportional bias, the regression Model II, ordinary least product (OLP) regressions will be utilized. Systematic bias will be considered if the 95% confidence interval (CI) of the intercept "x" does not cross "0.0" and proportional bias if the slope "y" does not cross "1.0" (Lake et al., 2018; Ludbrook, 1997, 2012). Due to low unlikelihood of the devices to have an exact agreement, it is important to see how close the variables are during observation. *Upon completion, all research data will be deleted from the watch and cloud which is stored in a throw-away apple account, not tied to any particular individual.*

Will you maintain a subject list that has direct identifiers linked to a unique study ID/code?

YES ☐ NO ☒

If yes, how will you secure the linking list?

Will UTEP study personnel electronically transmit identifiable data or identifiable samples to a non-UTEP recipient?

YES ☐ NO ☒

If yes, describe the type of data and the plans for secure transmission:

Indicate below what will happen to the identifiable data at the end of the study.

- ☒ Identifiers permanently removed from the data and destroyed
- ☐ Recordings transcribed without identifiers and destroyed
- ☒ Identifiable or coded (that can be linked) data are retained
- ☐ N/A

L. Risks:

*Describe any **potential risks** (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Describe alternative and potentially less risky methods, if any, that were considered as possible methods and why they were not used. If the research methods impose risks on the subjects, include evidence that may justify their use (such as previous experience with the procedures). Most studies pose some degree of risk, even though the risk may be minimal. For example, one common risk is the loss of the confidentiality of the participants' responses. Describe the procedures for protecting against (or minimizing) any potential risks and include an assessment of their effectiveness. If the study involves a procedure that introduces a physical risk, specify arrangements for providing medical treatment if it should be needed. If the study involves a procedure that introduces a psychological risk, such as the recall of a traumatic event, specify arrangements for providing psychological treatment if it should be needed. Please state whether or not you will provide payment for physical or psychological harm if it is incurred.*

Rigorous safety protection measures will be implemented to prevent subjects from any potential risk during the experiment. To avoid any potential risk that could result from the experiment, the PI will be present during each evaluation and ~~training~~ testing session to make sure individual is healthy to participate. Subjects will be asked to report any signs of discomfort that could be present during, before, and after the testing session. The researchers will stop any testing if there are signs of potential injury risk.

Minor injuries such as a falling could result if an individual strives to perform above their personal limits. Such injuries will be avoided by proper instruction of the appropriate tasks, movement and techniques. Each participant will be informed of any potential risks they may face for participating in the study and can choose to not participate in the study at any time. To date, the literature has not shown any evidence of sprint testing during treadmill validation that could result of injuries, however, as with any form of exercise testing, a possible risk of injury exists.

The facility will be cleared from instruments that could potentially obstruct, impede, or injure the subject's performance.

Infringement of privacy and confidentiality can also be present. In order to ensure the risk of loss of privacy and confidentiality is present, data will be stored a key access room, to which only faculty and staff of the Health Science Department have access to. Data will also be stored in a password protected computer, and we will create a password to our excel data sheet, thus creating a double password access and minimizing the risk for loss of data, privacy and confidentiality of the subjects.

In case of an emergency subjects will be taken to the Emergency Department of the nearest by hospitals. If the emergency is life threatening, 911 will be called and the subject will be transported in an ambulance. If the emergency is not life threatening (i.e., muscle pull or sprain), subject will be transported in a wheel chair (available in the department) to the hospital emergency department nearby. The investigator will stay with the subject until subjects' guardian (family member or friend) arrives. Subjects are asked to provide their emergency contact before they begin the experiment. The consent form describes that upon an injury or medical emergency subject will be responsible for his/her treatment cost and no monetary reimbursement of any sort will be provided.

Could the information obtained or recorded about subjects place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, or reputation?

YES ☐ NO ☒ N/A ☐

M. Benefits:

*Describe and assess the **potential benefits** to be gained by participants (if any) and the benefits that may accrue to society in general as a result of the planned work. Discuss the risks in relation to the anticipated benefits to the participants and to society. Note, monetary compensation and extra credit are not a benefit.*

There are no direct benefits to be gained by participating in this proposed study. The proposed study would be the first to validate the new Apple Watch Series 6 by comparing it to the Polar H10 chest-strap monitor and ECG. Validity of the Apple Watch Series 6 during physical activity will create an impact on the use of these devices by physicians, and coaches, as well as everyday practitioners.

N. Research Resources:

Please describe your research resources. Discuss the staff, space, equipment, and time necessary to conduct research and how these needs are met. Please include a description of the proximity of any resources such as emergency facilities, emergency care or medical / psychological care, and any support services. If the study necessitates Environmental Health & Safety (EHS) or Institutional Biosafety Committee (IBC) oversight and approval please describe here.

The principle investigator (PI) under the mentorship of Dr. Sandor Dorgo. In addition to a bachelor's degree in Sports and Exercise Science, Armando has helped with the data collection and analysis of several other Masters and Doctoral level Kinesiology students at the University of Texas at El Paso. This has enabled the PI to be able to conduct research independently and carry out the proposed experimental study with the involved intervention. The PI also completed multiple courses in strength and conditioning throughout his undergrad/graduate program thus far, providing him with both theoretical knowledge and practical experiences. Furthermore, the PI has gained hands-on experience with using the proposed equipment by assisting previous sprint training studies conducting in our laboratory, as well as conducting a small pilot project for the currently proposed study.

Furthermore, to help collect all data, coordinate, and facilitate all aspects of this study undergraduate research assistants and co-PI's will be available for data collection and experimental training session set-up. They will assist the PI as needed.

A fully equipped exercise facility (UTEP Department of Kinesiology Fitness Research Facility) will be accessible for all experimental training sessions for the Arm group. A high-speed motorized Track Master Treadmill (Full Vision, Inc., Newton, KS, USA) with a maximum belt speed capacity of 13.5 m·s⁻¹ will also be available for all testing sessions.

ASSURANCES – Conflict of Interest and Fiscal Responsibility

All UTEP researchers (faculty, staff, and students) and outside collaborators who will be conducting human subjects' research (intervention and/or interaction) must complete human subject research ethics training in order to conduct research with human participants.

Do you or any person responsible for the design, conduct, or reporting of this project have an economic interest in, or act as an officer or director of any outside entity whose financial interests may reasonably appear to be affected by this project?

If yes, please explain any potential conflict of interest

YES ☐ NO ☒

Do you or any person responsible for this project have existing financial holdings or relationships with the sponsor of this study?

If yes, please explain any potential conflict of interest

YES ☐ NO ☐ N/A ☒

Principal Investigator Certifications:

With this submission I certify that:

- ☒ I agree to fully comply with the ethical principles and regulation regarding the protection of human subjects in research.
- ☒ I agree that the information provided in this form and all other supporting documents are accurate and complete.
- ☒ I accept responsibility for making sure all study personnel involved in the project have been appropriately trained. PI affirms responsibility for keeping training records on file for all study personnel.
- ☒ I understand that any changes in procedure with affect to participants must be submitted to the IRB for written approval prior to their implementation. Furthermore, I understand that any adverse events and significant changes in risk for participants must be immediately reported in writing to the UTEP IRB.

Copies of all required documentation of consent (if applicable) and any related to this research are securely stored as outlined above in the Health Sciences building room 455 (UTEP building and office number).

Vita

Armando Martinez Ruiz, born and raised in El Paso, Texas, graduated from El Dorado High School in 2014 and pursued his associates in Kinesiology at El Paso Community College. After obtaining his Associates degree in 2016, Armando continued his knowledge at the University of Texas at El Paso where he graduated with a Bachelors in Kinesiology and a double minor in Biology and Psychology in 2019. A semester later, Armando decided to return to school in order to further his knowledge in strength and conditioning while contributing to research and working as a personal trainer. Following his achievements of his master's degree, Armando will continue to further his knowledge in strength and conditioning, with the possibility of returning to school to further his knowledge.