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Evaluation of the Effects on Human Performance Characteristics and Peak Head Accelerations With the Use of Various Intra-Oral Appliances

Katie Lin Padgett
University of Tennessee, Knoxville

To the Graduate Council:

I am submitting herewith a thesis written by Katie Lin Padgett entitled "Evaluation of the Effects on Human Performance Characteristics and Peak Head Accelerations With the Use of Various Intra-Oral Appliances." I have examined the final electronic copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Industrial Engineering.

Dongjoon Kong, Major Professor

We have read this thesis and recommend its acceptance:

Robert E. Ford, Denise Ford Jackson

Accepted for the Council:
Carolyn R. Hodges

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

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Evaluation of the Effects on Human Performance Characteristics and Peak Head Accelerations With the Use of Various Intra-Oral Appliances

A Thesis Presented for the

Master of Science Degree

The University of Tennessee, Knoxville

Katie Lin Padgett

May 2005

DEDICATION

This thesis is dedicated to my parents, Mr. Chuck and Delores Padgett, my sisters, Ms. Britt Padgett and Mrs. Sally Kostrzewa, and my close friends, Douglas Alan Logsdon and Lori Limbaugh Pickett for their encouragement and support throughout my academic career.

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I would also like to thank Mr. Douglas Alan Logsdon, who provided much needed support and encouragement, as well as contributing to the final editing of this document.

ABSTRACT

Various studies have investigated the relationship between the mandibular position and its affect on human performance characteristics. To maintain the jaw in an optimal position Mandibular Orthopedic Repositioning Appliances (MORA) have been produced. A protective mouthguard is an appliance worn in the mouth which helps prevent injuries to the teeth, lips, cheeks, tongue, and jaw as a result of impact. More recently, it has been hypothesized that mouthguards reduce the risk of concussion by attenuating the impact to the jaw rather than transferring the force to the brain. Currently, there are no standards for testing protective mouthguards. Such a test would prove useful to determine maximum acceleration levels of the head.

The aim of this study is to (1) quantify the effectiveness of repositioning the jaw on strength and aerobic potential as well as (2) to determine if a protective mouthguard can give the same affects of a MORA device. In addition, (3) a test protocol will be established for the evaluation of mouthguard performance. The data collected will show how well the EDGE™ Protection performs versus other consumer available mouthguards on the criteria of attenuation of peak head accelerations. After statistical analysis, it was found on a 95% confidence level that the MORA and the protective mouthguard with MORA attributes increase a user's strength. On certain intervals of the aerobic testing there was evidence that the MORA does have an influence on human performance.

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NOMENCLATURE

g	acceleration of gravity (9.81 m/s^2, 32.2 ft/s^2)
Mph	miles per hour
lbs	pounds
mV	millivolts
α	significance level

Abbreviations

MORA	madibular orthopedic repositioning appliance
NOCSAE	National Operating Committee on Standards for Athletic Equipment
TMD	Temporomandibular disorders
TMJ	temporomandibular joint
NCAA	National Collegiate Athletics Association

1.0 INTRODUCTION

As many as 10.8 million people suffer from Temporomandibular Joint (TMJ) disorders. Symptoms associated with TMJ are headaches, facial pain, jaw locking open or closed, bite that feels uncomfortable, as well as pain in the jaw and surrounding tissues. Dentists have found that repositioning the jaw alleviated some of these symptoms. To keep the jaw in this optimal position, Mandibular Orthopedic Repositioning Appliances (MORAs) were developed. It has been shown that such devices prevent the mandible from closing fully. It is believed that if the mandible is over closed, the cervical vertebrae overact causing an excessive stimulation of the sympathetic nervous system which may compromise performance (15).

For more than a century MORA devices have been used in the management of TMJ. In the late 1970s and early 1980s dentists began recommending MORA devices to athletes. It was believed that an athlete could see an increase in performance through repositioning the jaw. Many studies have been done in an attempt to validate these claims, but with some inconclusive studies, an increase in performance is not guaranteed.

More recently there has been an interest in incorporating the effects of the MORA device into a mouthguard that is suitable for contact sports. Protective mouthguards are designed to prevent or minimize injuries to the oral area. As of now, there are no standards developed for testing the mechanical performance of protective mouthguards. Such a test would be beneficial in establishing minimal requirements for manufacturer's as well as product comparisons.

Aerobic, strength and impact testing will by utilized in this analysis. In the aerobic and strength portions, a MORA device will be tested and compared to a protective mouthguard as well as no mouthguard. In addition, a testing procedure has been developed to investigate the relationship between impact forces and resultant peak head accelerations. Various mouthguards will be tested and compared using this set-up.

2.0 BACKGROUND

MORAs were originally made use of by dentists to help treat patients with temporomandibular disorders (TMD). "Temporomandibular disorders comprise a group of disorders involving many hard and soft tissues associated with mandibular and masticatory function" (5). The temporomandibular joints (TMJ's) are the two joints that connect the mandible to the skull. These joints consist of the mandible and the temporal bone that slide and rotate in front of each ear, see Figure 2.1. The main components of TMD are the alignment of the teeth when brought together, the masseter muscle, and mandible movement. Dentists believe that repositioning the jaw can eliminate the components of the disorder, hence relieve the patient of some symptoms.

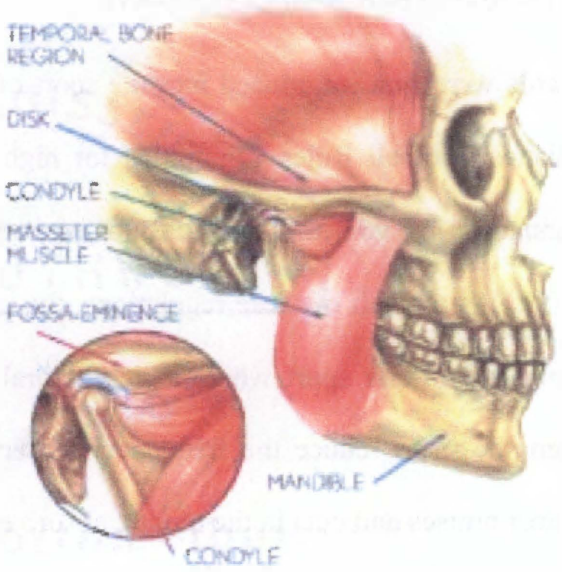

Figure 2.1: Anatomy of the temporomandibular joint

2.1 MORA IN ATHLETICS

There have been studies published dating back to 1978 which have attempted to determine the relationship between jaw position and strength. Previous studies have generally been lacking in at least one aspect of the analysis. In a previous study, Alexander compiled a case study of analyses done in this field and their respective short comings. A summary of her findings can be found in Table E.1 (1). She devised a test to address the criticisms of the previous studies as well as the evaluation of the effectiveness of a self-fit mandibular orthopedic repositioning appliance on athletic performance. The aerobic and strength tests in this study were adapted from her thesis.

2.2 PROTECTIVE MOUTHGUARDS IN SPORTS

Mouthguards were first introduced into the sport of boxing in 1913. Since then the National Alliance Football Rules Committee for high school has made the use of mouthguards mandatory in 1962, the NCAA followed in 1974 for football and college hockey in 1976 (9). As a result of these regulations, the use of protective mouthguards has been recommended in any sport where a risk of oral injury is significant. These devices have been shown to reduce the frequency of fractures and dislocations to the teeth, protect against bruises and cuts in the mouth, absorb energy from a blow to the chin as well as minimizing upward and backward displacement of the mandibular condyle. Every year an estimated 200,000 football injuries are prevented by mouthguards. Since

becoming mandatory safety equipment along with helmets, the probability of a dental injury has been reduced from 10% to 0.4% (3).

There are a variety of protective mouthguards on the market. The most commonly used are the boil-and-bite mouthguards. There are several kinds of boil-and-bite, the most fundamental version uses a single type of moldable material while higher end models are a composite of a moldable material that forms to the teeth and another non-moldable material that keeps the jaw from closing completely. Although the apparent safety benefits of mouthguards and the variety of types saturating the market, there are no standards. If a standard could be developed and implicated it may improve the quality of mouthguards on the market and increase the protection provided to the user.

2.3 Mechanism of Impact

When the mandible suffers an impact the it displaces upward and backwards making the mandibular condyles converge with the temporal bone. This convergence causes the energy from the impact to transfer to the brain causing injury. In a study done by Pellman and others, they determined that the peak head acceleration in concussion was 98 ± 28 g's with a 15 millisecond duration.

2.4 Design For Testing A Protective Mouthguard

A design of an impact device must meet specific criteria. The design requirements are as follows:

- A headform that replicates the properties of a human head
- An object that resembles the mandible to transmit the force to the upper teeth
- An upper set of teeth that allows for mouthguard forming
- Capability to measure acceleration of the head
- The ability to apply and monitor a reproducible force
- The ability for the head to translate following impact.

3.0 PROCEDURE

Experimentation was conducted in two stages. The first stage looked at both strength and aerobic tests and their affects on human performance characteristics. In the second stage a test was devised to determine the mechanical characteristics of protective mouthguards.

The strength testing protocol was developed to assess the affect of the MORA and the protective mouthguard during an isotonic muscle contraction. An isotonic muscle contraction is a contraction where the muscle tension remains the same as the muscle length shortens. The aerobic portion was adapted from Alexander's evaluation of a MORA device in a double blind study (1).

In this research, three trials were conducted for each test. The trials varied by the following conditions: no mouthguard, EDGE™ performance, and EDGE™ protection. The EDGE™ performance is a MORA and the EDGE™ protection is a protective mouthguard with MORA attributes. The EDGE™ performance and protection are included in Figures 3.1(A) and 3.1(B), respectively. Both are manufactured by EDGE Sports, Incorporated. The participants used in the study were instructed to form their

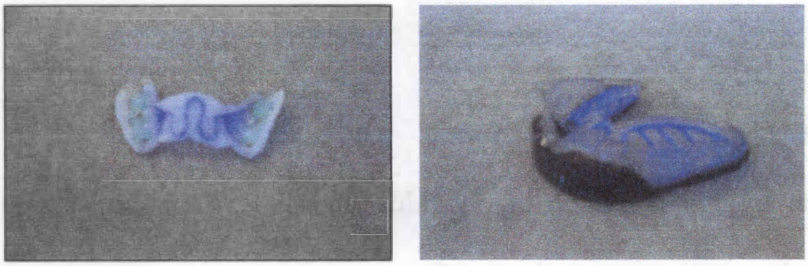

Figure 3.1: (A) EDGE™ Performance (B) EDGE™ Protection

own mouthguards following the manufacturer's instructions (see Figure F.1). To ensure independence, each trial was conducted at least one day apart with the sequence of the conditions being randomized and the subject's given no instructions on clinching. The order of each test and the randomized use of the mouthguards are included in Appendix B.

The latter stage of testing was developed to determine peak head accelerations as the result of an impact to the jaw. A device was developed such that an impulse could be consistently applied to an instrumented head fitted with a mouthguard. Various mouthguards were tested in order to compare the mechanical performance of the EDGE™ Protection against competitor brands.

3.1 Participant Interviews and Candidate Selection

Participants were asked to volunteer from a set sample population. The population was representative of athletic individuals. Each candidate was required to satisfy specific criteria in order to participate in the study. Candidates that failed to meet these criteria were excluded from this study.

3.1.1 Sample Population

Even though a device that would enhance even a non-athlete's strength and increase their aerobic potential would be beneficial, this study focused on physically active individuals who participated in recreational activities on a regular basis. The

subjects were recruited from the student population of the University of Tennessee, Knoxville. Only male subjects were selected to participate. Their mean ages, weights, and heights were 18.5 years, 177 pounds, and 70.4 inches, respectively. The standard deviations for the ages were 0.5, the weights were 27.8, and the heights were 2.57. Table 3.1 has a summary of the subject's demographic data.

3.1.2 PARTICIPANT QUESTIONNAIRE

Participating subjects were asked to fill out a Participant Questionnaire and a Physical Active Readiness Questionnaire (PAR-Q) (see Appendix A). The Participant Questionnaire was designed to obtain information about the individual's frequency of exercise data as well as an oral history. If subject's answered yes to questions 1, 2, 3, and

Table 3.1: Subject's Demographic Data

Subject	Age	Sex	Height (inches)	Weight (lbs)
1	18	M	72	185
2	18	M	71	205
3	19	M	68	167
4	18	M	70	182
5	19	M	70.5	165
6	19	M	66	175
7	18	M	73	165
8	18	M	70	186
12	19	M	68	135
13	19	M	70	129
14	18	M	70	205
16	19	M	76	225

4b they would be excluded from the tests. The purpose of this questionnaire was to identify and eliminate any subject that may have been at high risk for injury. The PAR-Q is a standard form developed by the Canadian Society for Exercise Physiology to determine if a person should see a physician before participating in exercise.

3.2 Description of Equipment

The blood pressure of the participants was monitored periodically during testing. An OMRON™ Automatic Blood Pressure Monitor was used in this study (see Figure 3.2). The HEM-712C model automatically inflates the arm cuff to 180 mmHg and produced a digital read out of systolic and diastolic blood pressure as well as the subject's pulse enabling fast and accurate measurements. This particular brand and model was chosen because it was recommended in a previous study done by the British Journal of Medicine (11).

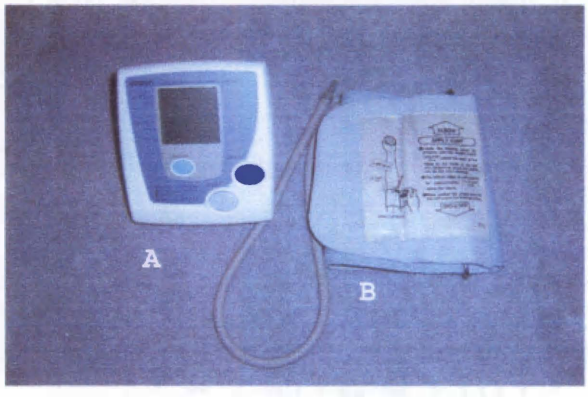

Figure 3.2: OMRON™ Blood Pressure Monitor Model HEM-712C. (A) Digital Monitor and (B) Arm Cuff

A Polar S530 Heart Rate Monitor was used for aerobic testing (see Figure 3.3). The heart rate monitor has the ability to record throughout the exercise without interfering with the subject. The coded transmitter is fastened around the subject's abdomen which transmits heart rate data at a rate of 1 measure per 30 seconds to a wrist worn receiver. Following the exercise routine, data was uploaded to a computer where it was post-processed using a custom software application.

3.3 Aerobic Test Procedure

A standard runner's treadmill was used to evaluate the aerobic performance of the subjects. The treadmill enabled precise monitoring of the subjects speed. All subjects began at a warm-up pace of 2 miles-per-hour. The pace was increased, per minute, by 0.2 miles-per-hour in order to reach the individual's target heart rate. The target heart rate selected for this test was 75% the maximum heart rate. Maximum heart rate was

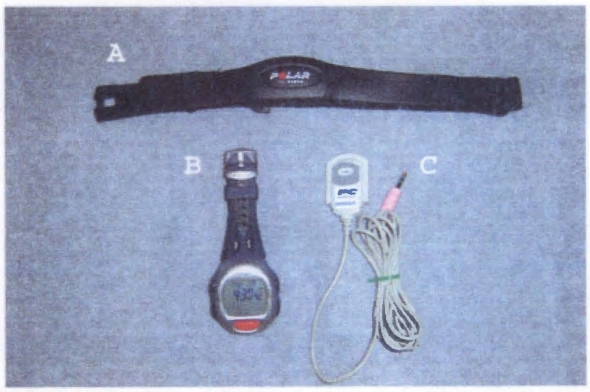

Figure 3.3: Polar S530 Heart Rate Monitor. (A) Coded Transmitter, (B) Wrist Receiver, and (C) Sonic Up-link Microphone

determined by 220 minus the subject's age. The speed was maintained for ten minutes. After the 10 minutes, the speed was reduced by 0.5 miles-per-hour until either the speed reached 0 mph or 30 minutes had elapsed. Blood pressure of each subject was recorded before and after each test.

3.4 Strength Test Procedure

The equipment chosen for the strength testing was a rear delt/pec fly universal weight machine (see Figure 3.4). In the pectoral fly setting the movement focused on the pectoralis major and anterior deltoid muscles and eliminated the effect of momentum beginning each repetition. Subjects were instructed to keep good form and do as many as they could until exhaustion. Since all the subjects were at different physical levels, the subjects were tested at 75% of their one-repetition maximum to standardize the testing

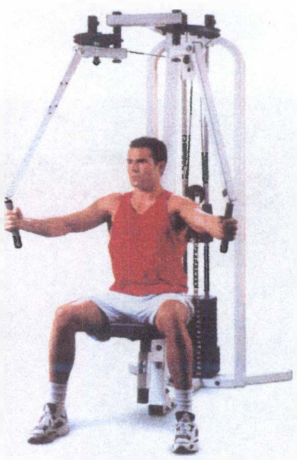

Figure 3.4: Rear Delt/Pec Fly Universal Weight Machine

weights. The one-rep maximum weight was determined using Brzycki's Equation:

$$1RM = \frac{weight}{1.0278 - (.0278 * reps)} \tag{3.1}$$

where *weight* is the total weight being moved and *reps* is the number of repetitions of the *weight* (10). Subjects were tested at 75% of their one-rep max each testing day and the total number of complete repetitions was recorded.

3.5 Impact Test Procedure

The objective of the impact study was to develop testing equipment as well as a protocol that would measure peak head accelerations after a jaw impact. A bio-fidelic, anthropometric, headform developed by the National Operating Committee on Standards for Athletic Equipment (NOCSAE) was modified to allow for a molded set of upper teeth to be inserted (see Figure 3.5). Since the headform did not have a functional mandible, the lower jaw was removed and a piece of wood was used to replicate the contact of the lower and upper jaw (see Figure 3.6). The wood does not have the same characteristics as a human jaw because the jaw bone and tissue would absorb some of the impact. However, the wood provides a greater transfer of energy to the upper jaw thus representing a worse case scenario. The headform was equipped with a triaxial accelerometer to measure peak head accelerations after an impact.

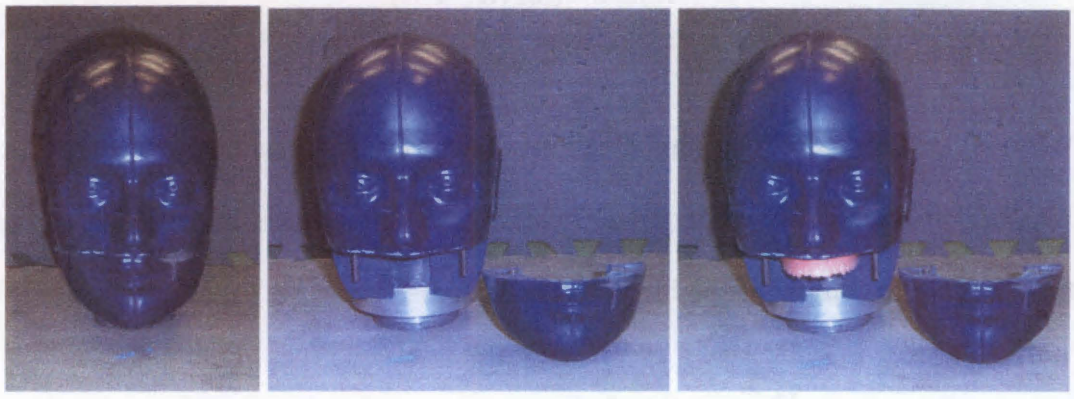

Figure 3.5: Modified NOCSAE Headform. (A) whole head, (B) with jaw removed, (C) with molded teeth inserted.

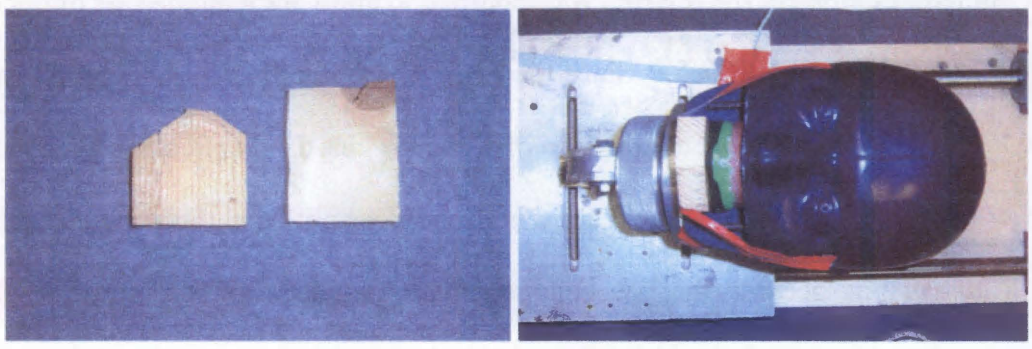

Figure 3.6: (A) Wood "Mandible" and (B) Headform with teeth, mouthguard and mandible

The impact was applied via a large sledge hammer instrumented with a piezotronic force transducer (see Figure 3.7). The schematics and specifications of the hammer are included in Appendix F. The hammer was suspended from a steel frame as a pendulum to ensure that the force could be applied repeatedly (see Figure 3.8).

The force and acceleration data was collected through a KME and a Fluke Scopemeter model 105B series II, respectively (see Figure 3.9). The KME determined the vector sum of acceleration for the three orthogonal principal axes of the head. The Fluke displayed the peak impact force in the form of voltage.

The EDGE™ protection was tested against no mouthguard and five other competitors' mouthguards. Because the other companies did not give permission for the tests, their names have been kept confidential. Peak acceleration of the head that causes a concussion has been reported to be 98 ± 28g's (12). The impact test was conducted by applying a force that exceeded this level with no mouthguard in place.

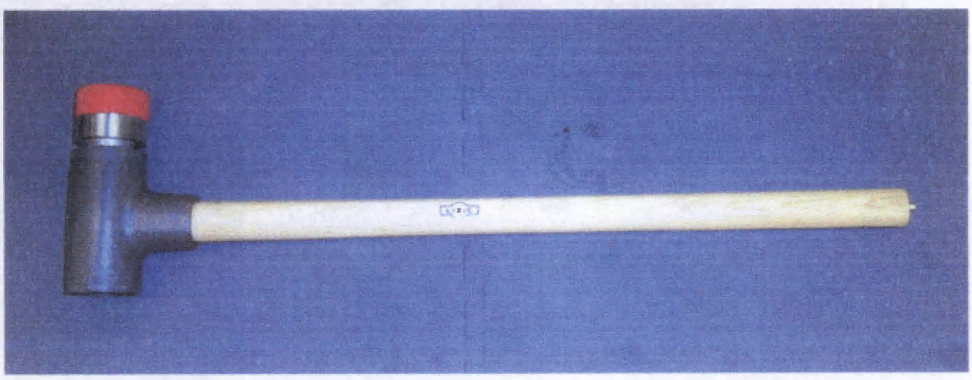

Figure3.7: Large Sledge Impact Hammer

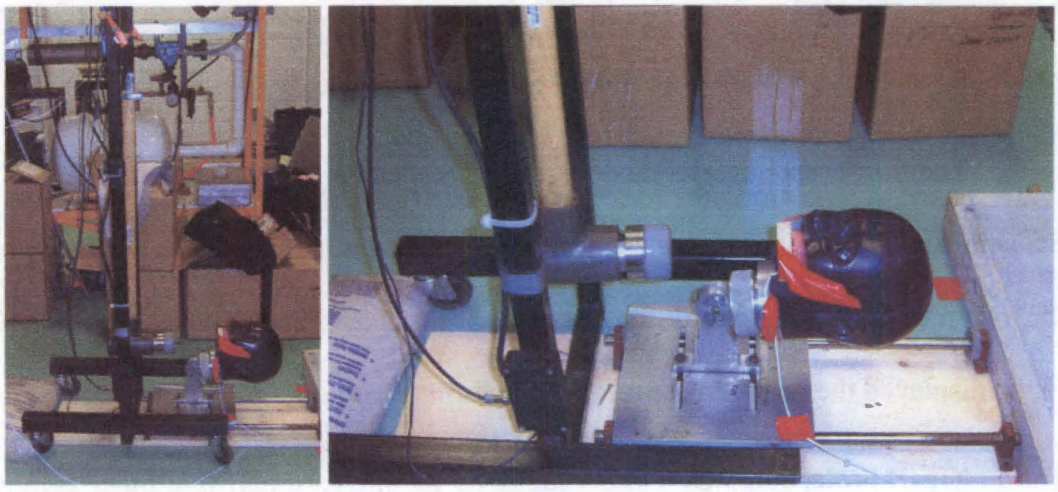

Figure 3.8: Test Setup

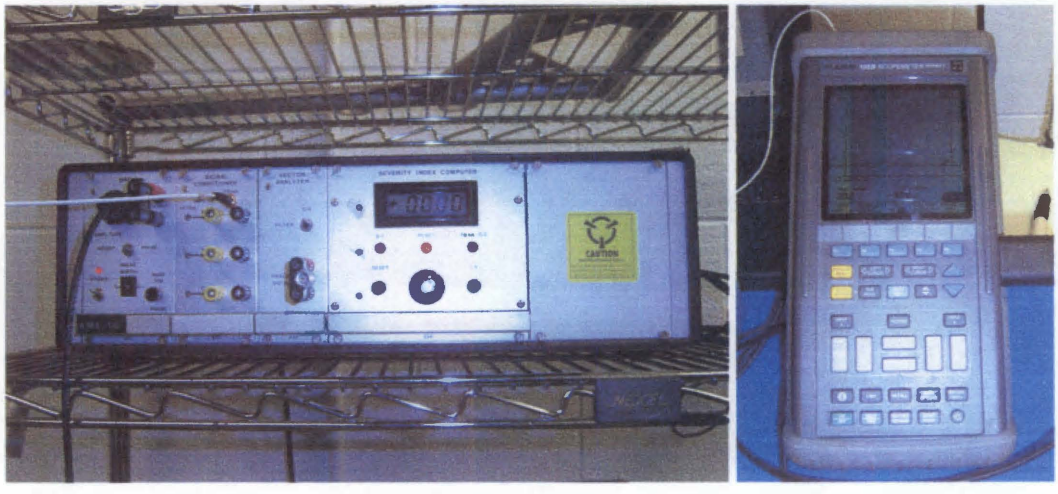

Figure 3.9: (A) KME and (B) Fluke Scopemeter model 105B series II

3.6 Statistical Methods

Since there is no way to test the entire population that may benefit from this study, assumptions must be made about the sample population using statistics. The null hypotheses, H_o, are the assumptions made about the probability distribution. Statistical tests are then used to make a judgment regarding these hypotheses. Based on the probability value a null hypothesis is either accepted or not accepted. There is always a possibility that an assumption is wrong resulting in one of two types of errors. A TYPE I error is when the null hypothesis is rejected when it should have been accepted. A TYPE II error is when the null hypothesis is accepted when it should have been rejected.

In order to test the hypothesis a significance level, α, needs to be chosen. Often the significance level is chosen to be 0.05. This is the probability that a TYPE I error will occur (14).

For the data, it was assumed that the heart rates for no mouthguard will be higher than that of the EDGE™ performance or protection and that the EDGE™ performance and protection will have the same heart rates. Using a t-test, one is looking to reject the null hypothesis when the probability of an event happening is less than that of the significance level. The hypotheses are the following:

1) H_o: the heart rate data of no mouthguard will be less than or equal to the heart rate data of the EDGE™ performance (no mouthguard $\leq$ performance)

   H_1: the heart rate data of no mouthguard will be greater than the heart rate data of the EDGE™ performance (no mouthguard > performance)

2) H_o: the heart rate data of no mouthguard will be less than or equal to the heart rate data of the EDGE™ protection (no mouthguard ≤ protection)

   H_1: the heart rate data of no mouthguard will be greater than the heart rate data of the EDGE™ protection (no mouthguard > protection)

3) H_o: the heart rate of the EDGE™ performance will be the same as the heart rate with the EDGE™ protection (performance = protection)

   H_1: the heart rate of the EDGE™ performance will not be the same as the heart rate with the EDGE™ protection (performance ≠ protection).

The Wilcoxon signed-rank test is a statistical method often used when the data sample is too small to assume a probability distribution. It tests the hypothesis that the difference of two sets of data has a median equal to 0. The test can be used to test pairs of observations on individuals. The differences of the mean are ranked and summed. The lower of these values is labeled the T value. Values used to determine the probabilities are included in Table E.2 (14).

4.0 RESULTS

Data was collected and analyzed statistically to determine its significance. The statistical tests used were the t-test and the Wilcoxon signed-rank test. Microsoft Excel and a statistics software JMP version 5.1 were utilized in the analysis.

4.1 AEROBIC RESULTS

The heart rate data collected in the aerobic test was split into three intervals: warm up, 10 minute running interval, and cool down. The individual heart rate graphs can be found in Appendix B. The pair-wise comparison tables are found in Appendix B, as Table B.1, B.2, and B.3, for the warm up, running interval and cool down, respectively. The data for subject number 16 was thrown out of the calculations for the warm up and the running as an outlier because of a malfunction with the heart rate monitor in the first trial. Subject number 7's heart rates for the cool down were also thrown out because of a lack of data from the first trial. All three hypotheses were analyzed for each interval to determine if it had statistical significance. A summary of the t-test can be found in Table 4.1.

For the warm up interval of the aerobic testing it was found that there was no statistically significant difference in the heart rate when the subject had no mouthguard and when the subject was wearing the EDGE™ performance. It was also found that the heart rate of a subject with no mouthguard was higher than the heart rate when the subject was wearing the EDGE™ protection. No statistical difference could be found between the heart rates of the EDGE™ performance and the EDGE™ protection.

Table 4.1: Summary of t-test Results for the Aerobic Data

Test Interval	Null Hypothesis (H_o)	p-value	comparison	alpha (α)	conclusion
Warm up	No Mouthguard <= Performance	0.1278	>	0.05	cannot reject null
	No Mouthguard <= Protection	0.0014	<	0.05	reject null
	Performance = Protection	0.0833	>	0.05	cannot reject null
Running	No Mouthguard <= Performance	0.0001	<	0.05	reject null
	No Mouthguard <= Protection	0.3245	>	0.05	cannot reject null
	Performance = Protection	0.0072	<	0.05	reject null
Cool Down	No Mouthguard <= Performance	0.0001	<	0.05	reject null
	No Mouthguard <= Protection	0.0345	<	0.05	reject null
	Performance = Protection	0.0356	<	0.05	reject null

In the running interval there was no statistical difference in the heart rate with no mouthguard and that of the heart rate with the EDGE™ protection. There was statistically significant proof that the heart rate with no mouthguard was different from that with the EDGE™ performance. With regards to the heart rate with the EDGE™ performance compared to the heart rate with the EDGE™ protection, there was a statistical difference.

For the cool down there was a statistical difference noted for two of the three hypotheses. On a 95% confidence interval, the heart rate of the subject with no mouthguard was higher than the heart rate with the EDGE™ performance and protection. When the heart EDGE™ performance was compared to the protection, there was a statistical difference.

4.2 Strength Results

Because of the small sample size of the strength data the t-test used for the aerobic data analysis was inappropriate. Therefore the Wilcoxon signed-rank test was chosen. With this test the differences in the sets of data can be ranked and their significance can be determined. The individual signed-rank test can be found in Tables C.3, C.4 and C.5. Table 4.2 contains a summary of the test for significance. For both the EDGE™ performance and the EDGE™ protection, there was statistically significant proof that the number of repetitions was different than those performed without a mouthguard.

4.3 Impact Results

The impact data consisted of 10 hits of 460 pounds force (lb_f) to each of the protective mouthguards. All the data is provided in Table D.1. The peak head accelerations were averaged and compared to the average acceleration to the head without a mouthguard. One impact was thrown out because the wood used to transfer the force to the teeth cracked. Percentage reduction on peak head acceleration was calculated and used to compare the protective mouthguards. These values are found in Table 4.3.

Table 4.2: Wilcoxon signed-rank Summary for the Strength Test

Condition	n	T	p-value
EDGE™ Performance to No Mouthguard	11	2.5	0.0040
EDGE™ Protection to No Mouthguard	10	0	0.0001
EDGE™ Protection to EDGE™ Performance	8	12	0.4610

Table 4.3: Summary of Impact Data

Mouthguard	average g's	% reduction
None	117.4	—
EDGE™	91.1	22.40%
2	74.8	36.29%
3	85.1	27.51%
4	92.3	21.38%
5	96.0	18.23%
6	122.1	-4.00%

5.0 CONCLUSION & RECOMMENDATIONS

From the aerobic data there was no statistically significant decrease in the heart rate for the EDGE™ Performance compared to that of no mouthguard for the warm up. There was a statistically significant decrease in the heart rate with the EDGE™ Protection to that of no mouthguard. For the heart rates of EDGE™ performance and the EDGE™ protection, there was no statistical difference in the warm up.

The running interval had opposite results from the warm up. There was an increase in the heart rate with no mouthguard compared to that with the EDGE™ performance. The EDGE™ protection had a higher heart than without a mouthguard and there was statistical proof that the EDGE™ performance heart rates and the EDGE™ protection heart rates were not the same.

In the cool down interval, both the EDGE™ performance and protection had significantly lower heart rates than that with no mouthguard. Although both of these products had lower heart rates, there was no statistical proof they were the same.

Although the EDGE™ protection was found to be beneficial in the warm up, further tests should look at factors besides heart rate. Heart rate can vary dramatically at the start by conditions uncontrollable. For some of the subjects their starting heart rates were as much as 20 beats apart depending on the day. One option would be to test the subject to the same heart rate each day, instead of the same speed, and compare the work loads. Because the EDGE™ protection didn't show the same results as the EDGE™ performance in the running interval, oxygen intake may be a factor. A follow up study could include testing VO_2max. VO_2max is the maximum amount of oxygen in milliliters,

one can use in one minute per kilogram of body weight. If more tests can be done to determine the affect of a MORA on human performance, the results would be beneficial to any active individual.

Once the strength data was analyzed it was determined that there was a difference in the data. Under a 95% confidence level it was statistically significant that the EDGE™ performance and the EDGE™ protection increase the muscle threshold.

Once the apparatus was impacted when the various mouthguards were in place, the percentage in reduction of g's was calculated. The mouthguards that were comparable to the EDGE™ were numbers 2 and 3. These mouthguards reduced the peak head acceleration 36.3% and 27.5%, respectively. Both showed a greater reduction in acceleration when compared to the EDGE™ which performed with a 22.4% reduction in peak head acceleration. While this reduction significantly reduces the acceleration of the head below the threshold of 98 g's, the rigid bite plate used to make the EDGE™ protection perform like a MORA device may have compromised it's protective characteristics as a mouthguard. The bite plate used on the EDGE™ protection wasn't as hard as the one used on number 4. This mouthguard indented the wood, which would most likely damage a user's lower teeth if impacted with the same force.

Further studies on the effectiveness of protective mouthguards need to be done. In addition to peak head accelerations, a velocity gate could be used on the impact hammer as well as the head to get velocity data that would be used along with momentum. A better representation of mandible also needs to be developed. If a head could be equipped with a temporomandibular joint, force measurements could be taken on the mandibular condyles. This study and future studies could have an impact on the

manufacturing and marketing of protective mouthguards. Athlete's safety in impact sports would be greatly benefited by standardization of protective mouthguards.

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APPENDICES

APPENDIX A

FORMS

Intraoral Device Evaluation
INFORMED CONSENT FORM

INVESTIGATOR: KATIE PADGETT, BS
ADDRESS: 409 EAST STADIUM HALL
1425 SOUTH STADIUM DRIVE
KNOXVILLE, TN 37996
EMAIL: kpadgett@utk.edu
PHONE: (865) 384-6397

You are invited to participate in a research study that will evaluate intraoral devices. The purpose of this study is to evaluate the effects of an intraoral device on physical performance.

You are aware that you should be healthy and physically active during the period of testing. You will need to complete a participant questionnaire that will determine any history of mandibular dysfunction and fitness. If you decide to participate you will be asked to attend three test trials. The trials will take no more than 1 hour. Each test session will consist of two tests. One test will be used to determine strength endurance while the other will be a sub-maximal aerobic test. The strength endurance test performed on a bench press. By testing the subject at 75% of their 1 Rep. Max (based on Brzycki's Equation), the weight and number of repetitions until fatigue will be recorded. The aerobic portion will be performed on a treadmill and will last 30 minutes. The test begins at 2 MPH, after each minute the speed will be increased by .2 MPH until the subject reaches 75% of their maximum heart rate (220 minus age). Once the target heart rate is reached the speed will be recorded and maintained for 10 minutes. After the 10 minutes, the speed will be reduced by .5 MPH each minute until a total of 30 minutes has elapsed. Recordings of heart rate will be taken through out the test and blood pressure will be taken before and after.

The potential risks involved for participating in this study are minimal. As with any time you work out the risks are sore or pulled muscles and the chance of overheating. Every effort will be made to reduce these risks through proper warm-up and practice before the testing. All tests will be conducted and equipment handled by the qualified research personnel. However, these requirements are not beyond those observed in normal aerobic or recreational sport activities. You will be encouraged to warm up actively prior to each testing session so that you feel physically prepared to perform effectively, minimizing the chance of injury. Should any injury occur during the course of testing, standard first aid procedures would be administered as necessary. In the event of physical injury suffered as a result of participation in this study, The University of Tennessee does not automatically provide reimbursement for medical care or other compensation. Your benefits include assessment of your grip strength and heart rate during sub-maximal aerobic exercise. You are welcome to make an appointment to review the data from your tests. In addition, if you wish to have a copy of the results of the study, please let the investigator know.

Your participation is entirely voluntary and your decision regarding whether or not to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You will be verbally reminded of your option to withdraw from the study before initiation of testing and at points throughout the research project. Your identity as a subject will be held in strict confidence, and any description of your data will be referred to by subject number only. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission.

Once you have read this informed consent form and all your questions have been answered, you are requested to sign and date the form below. Your signature indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled, and that you are NOT waiving any legal claims, rights, or remedies.

SUBJECT SIGNATURE: _____

DATE: _____

INVESTIGATOR: _____

DATE: _____

WITNESS: _____

DATE: _____

ID # _____

PARTICIPANT QUESTIONNAIRE

NAME: _____

DATE: _____ SEX: _____ AGE: _____ PHONE: _____

1. **Is your physical activity limited by your physician?** _____
2. **Do you have any current dental pain or loose fillings, loose crowns, or loose teeth?**

   _____
3. **Have you ever been treated for Temporal Mandibular Dysfunction?** _____
4. **a. Please mark any of the following dental work you have had:**

☐ **fillings**	☐ **caps**	☐ **crowns**
☐ **braces**	☐ **root canal**	☐ **simple extraction**
☐ **bridges**	☐ **partial dentures**	☐ **full dentures**

   b. Have you had other major dental work beyond the list above?

   _____
5. **Are you missing any molars?** _____
6. **Do you feel able to perform at your normal level today?** _____
7. **Do you routinely participate in endurance exercises?** _____
8. **Do you routinely lift weights?** _____
9. **Currently how many times per week do you work out?** _____

Physical Activity Readiness Questionnaire - PAR-Q (revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES	NO	
☐	☐	**1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?**
☐	☐	**2. Do you feel pain in your chest when you do physical activity?**
☐	☐	**3. In the past month, have you had chest pain when you were not doing physical activity?**
☐	☐	**4. Do you lose your balance because of dizziness or do you ever lose consciousness?**
☐	☐	**5. Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?**
☐	☐	**6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?**
☐	☐	**7. Do you know of any other reason why you should not do physical activity?**

If you answered YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active – begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal – this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever – wait until you feel better; or
- if you are or may be pregnant – talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME _____

SIGNATURE _____ DATE _____

SIGNATURE OF PARENT or GUARDIAN (for participants under the age of majority) _____ WITNESS _____

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.

Supported by: Health Canada / Santé Canada

continued on other side...

APPENDIX B

AEROBIC HEART RATE DATA

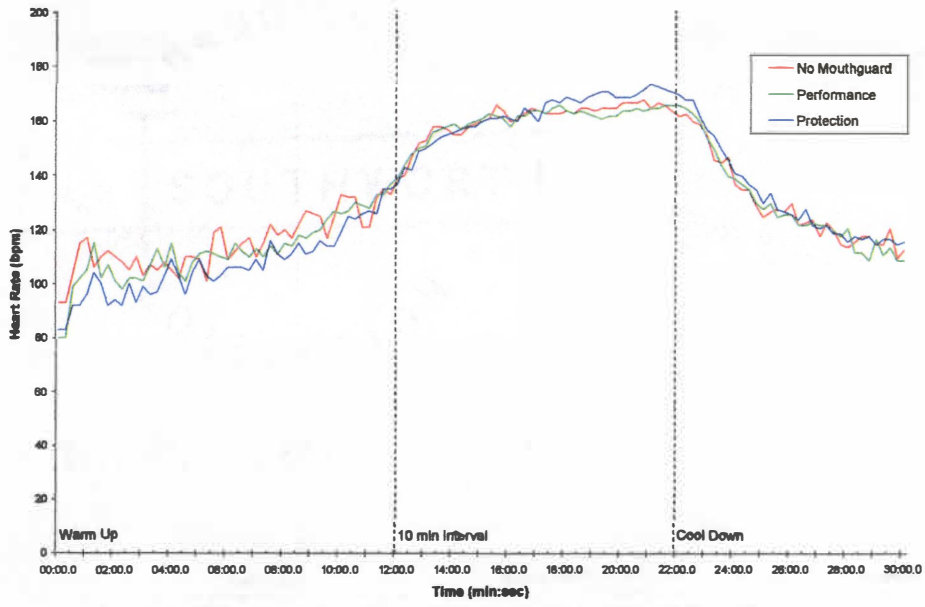


Figure B.1: Heart Rate versus Time for Subject #1

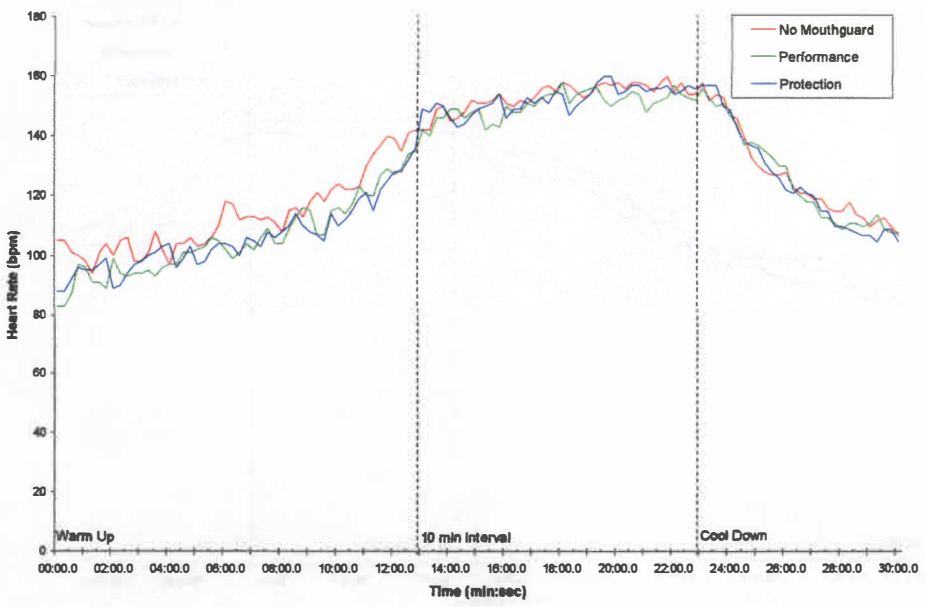


Figure B.2: Heart Rate versus Time for Subject #2

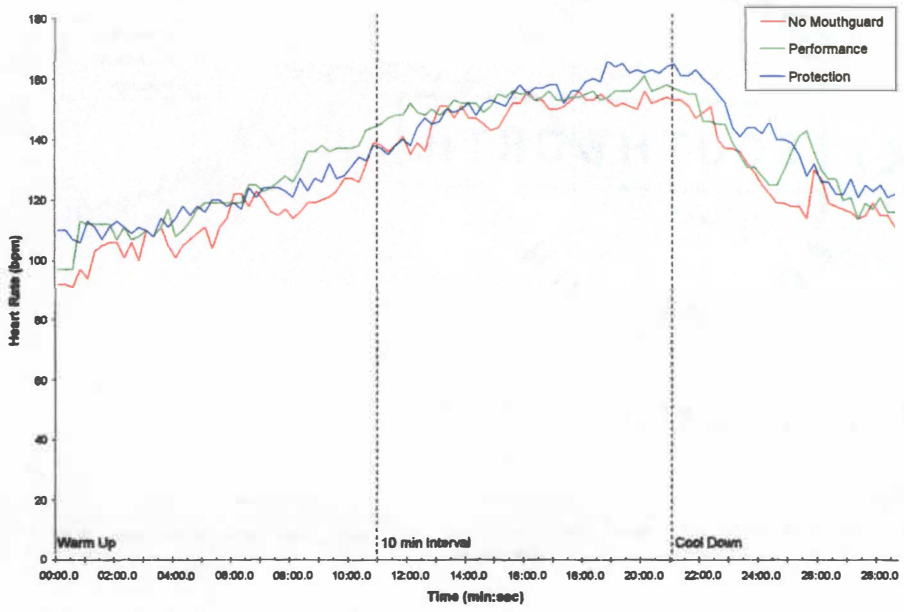


Figure B.3: Heart Rate versus Time for Subject #3

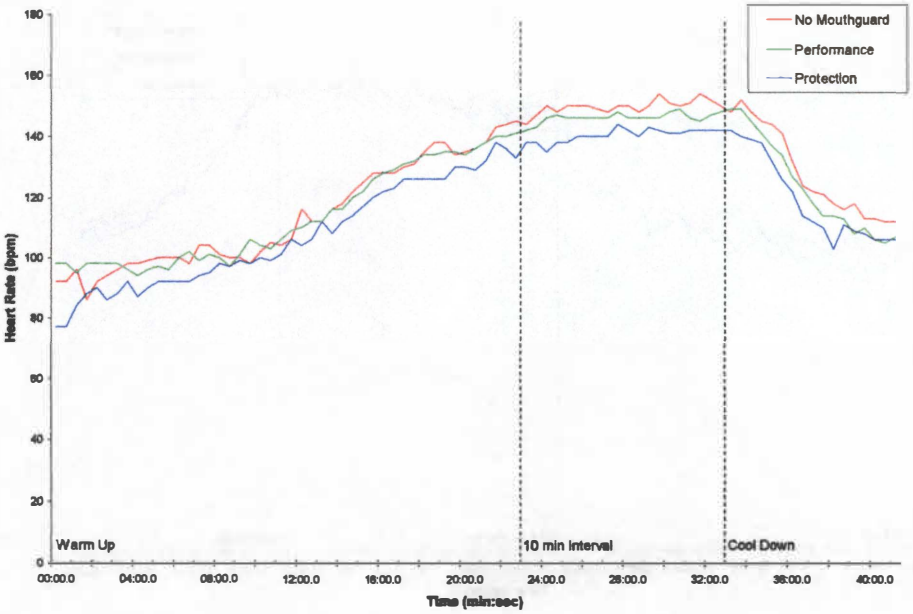


Figure B.4: Heart Rate versus Time for Subject #4

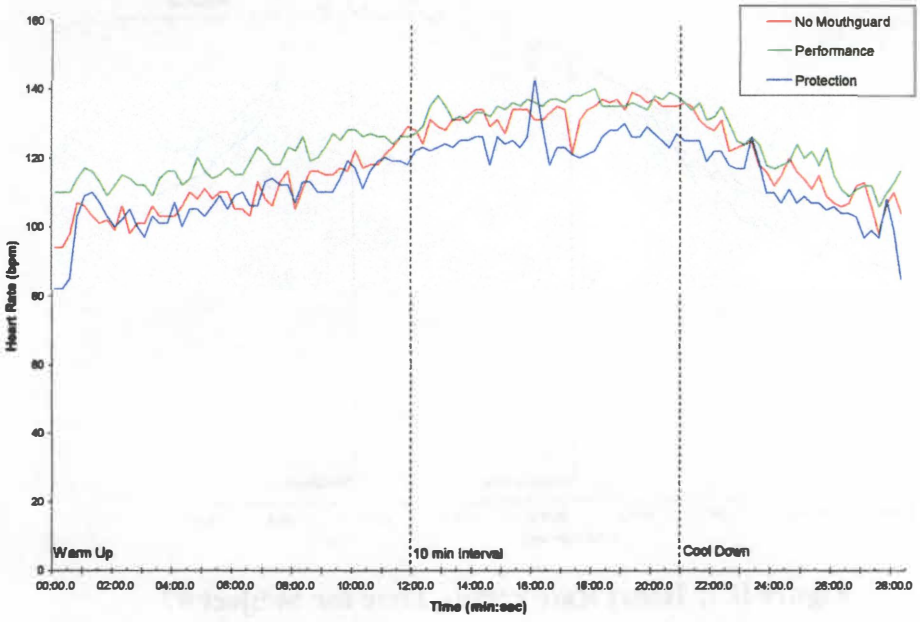


Figure B.5: Heart Rate versus Time for Subject #5

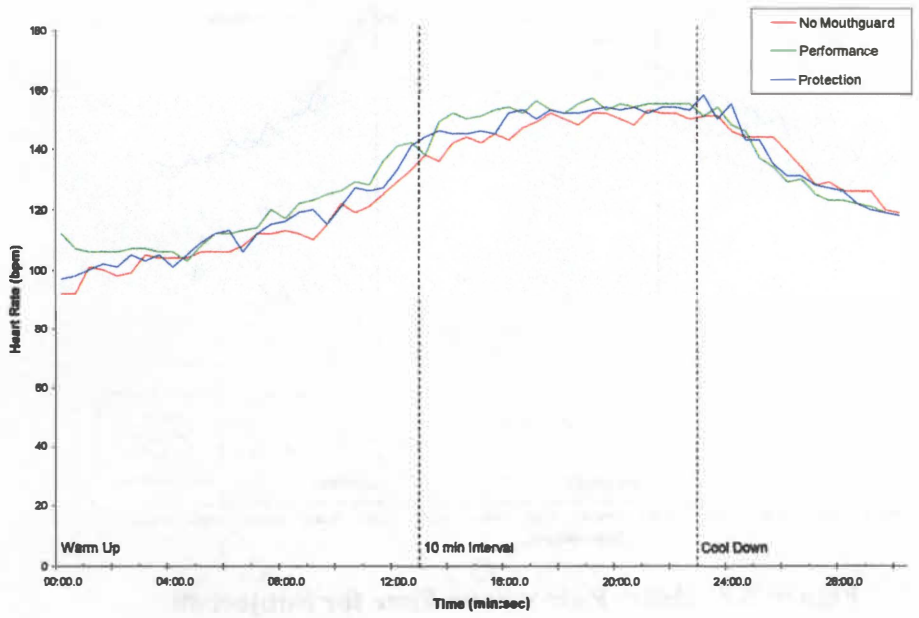


Figure B.6: Heart Rate versus Time for Subject #6

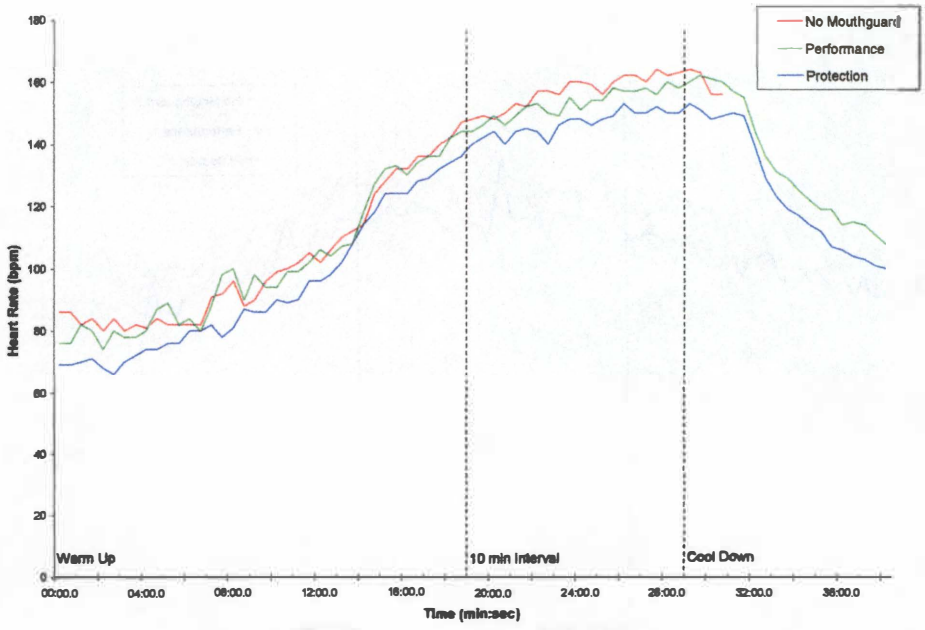


Figure B.7: Heart Rate versus Time for Subject #7

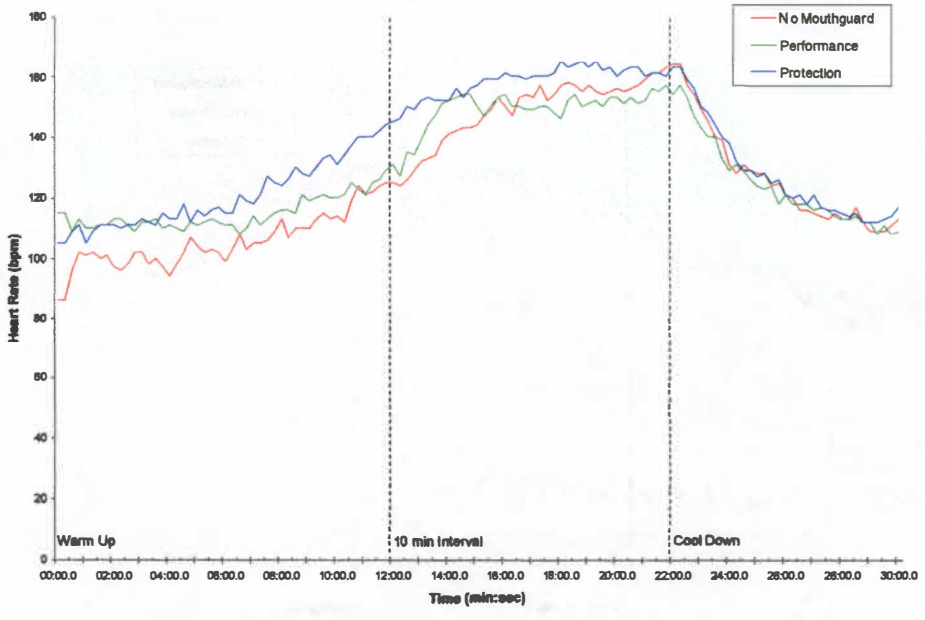


Figure B.8: Heart Rate versus Time for Subject #8

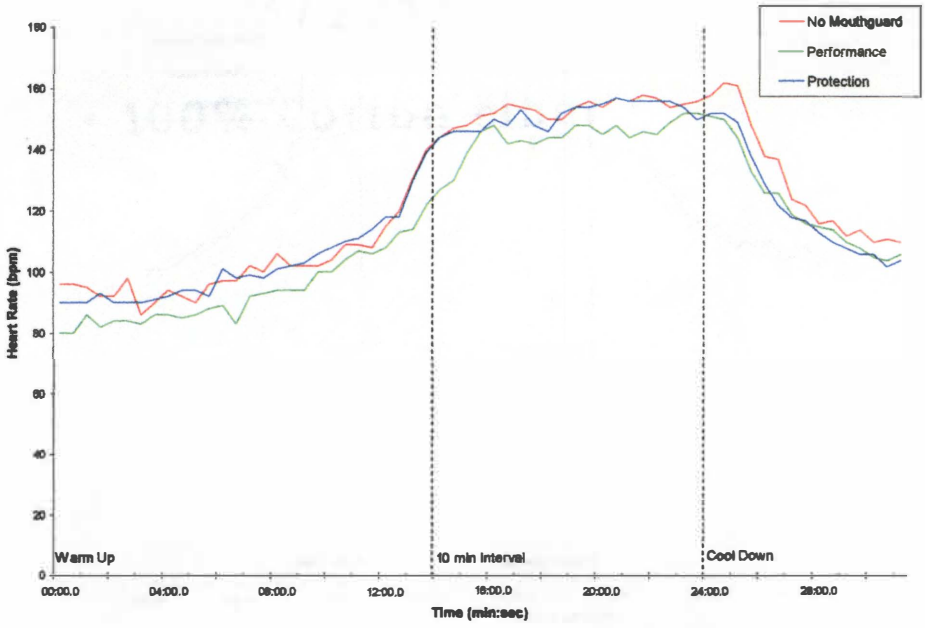


Figure B.9: Heart Rate versus Time for Subject #12

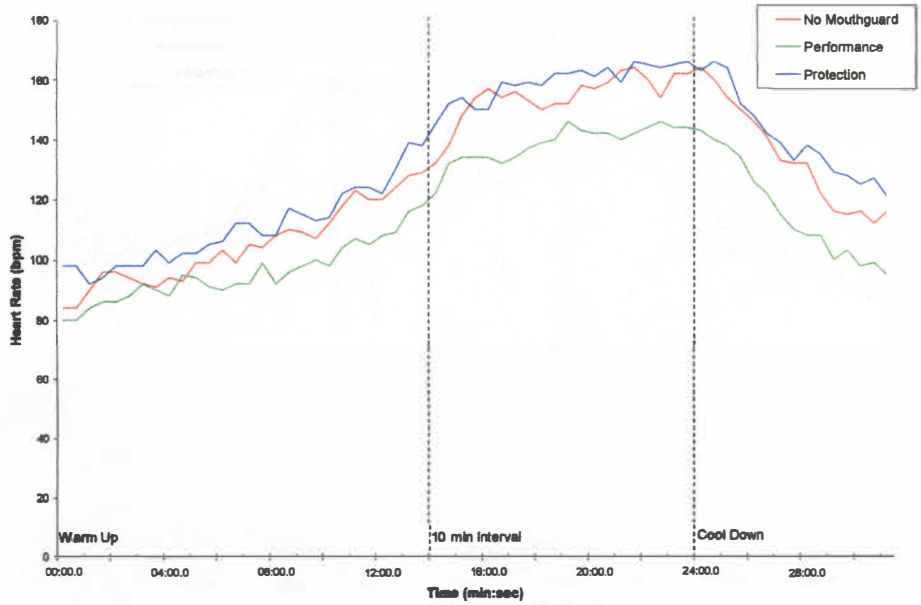


Figure B.10: Heart Rate versus Time for Subject #13

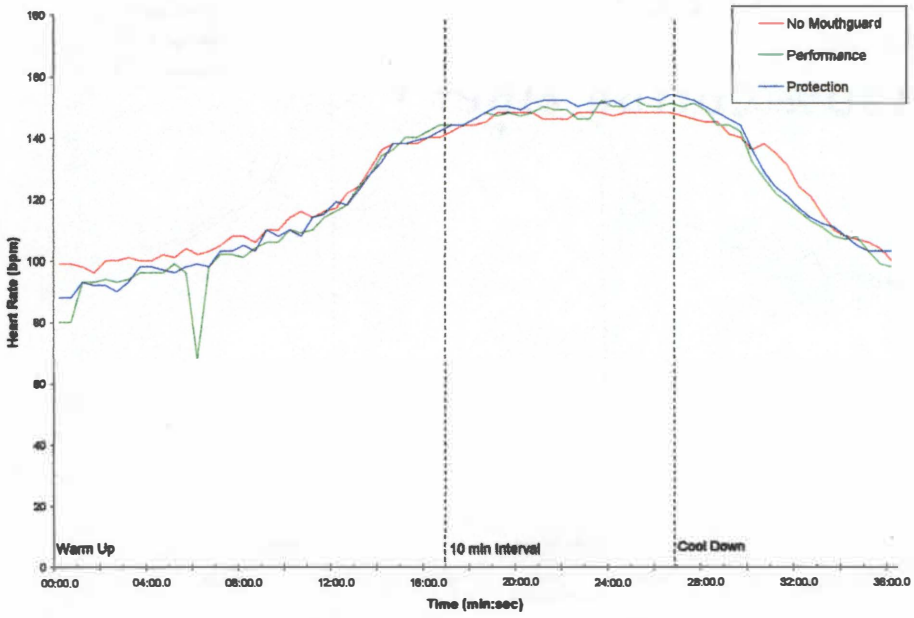


Figure B.11: Heart Rate versus Time for Subject #14

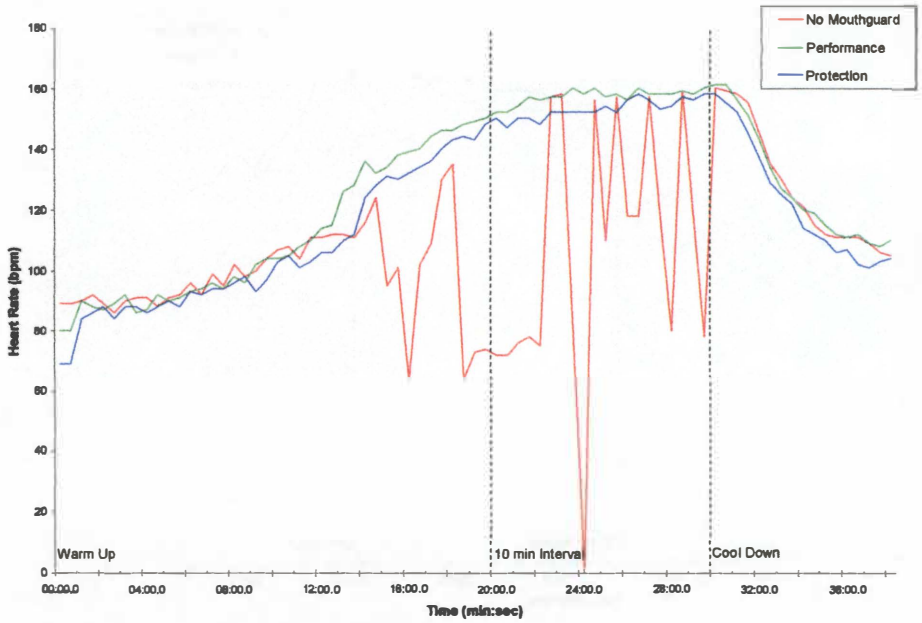


Figure B.12: Heart Rate versus Time for Subject #16

Table B.1: Pairwise Comparison of Aerobic Heart Rate Data for Warm Up

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
1	00:00.0	93	80	83	13	-3	10
1	00:30.0	104	99	92	5	7	12
1	01:00.0	117	105	96	12	9	21
1	01:30.0	110	102	100	8	2	10
1	02:00.0	110	101	94	9	7	16
1	02:30.0	105	102	100	3	2	5
1	03:00.0	103	101	99	2	2	4
1	03:30.0	105	113	97	-8	16	8
1	04:00.0	105	115	109	-10	6	-4
1	04:30.0	110	101	96	9	5	14
1	05:00.0	109	111	109	-2	2	0
1	05:30.0	119	111	101	8	10	18
1	06:00.0	109	109	106	0	3	3
1	06:30.0	115	112	106	3	6	9
1	07:00.0	110	113	109	-3	4	1
1	07:30.0	122	114	116	8	-2	6
1	08:00.0	120	115	109	5	6	11
1	08:30.0	122	118	115	4	3	7
1	09:00.0	126	119	112	7	7	14
1	09:30.0	117	124	114	-7	10	3
1	10:00.0	133	126	119	7	7	14
1	10:30.0	132	130	124	2	6	8
1	11:00.0	121	128	127	-7	1	-6
1	11:30.0	135	133	135	2	-2	0
2	00:00.0	105	83	88	22	-5	17
2	00:30.0	101	87	92	14	-5	9
2	01:00.0	98	96	95	2	1	3
2	01:30.0	101	91	97	10	-6	4
2	02:00.0	100	99	89	1	10	11
2	02:30.0	106	93	94	13	-1	12
2	03:00.0	98	94	98	4	-4	0
2	03:30.0	108	93	101	15	-8	7
2	04:00.0	97	97	104	0	-7	-7
2	04:30.0	104	101	99	3	2	5
2	05:00.0	103	102	97	1	5	6
2	05:30.0	106	106	102	0	4	4
2	06:00.0	118	102	104	16	-2	14
2	06:30.0	112	101	100	11	1	12
2	07:00.0	113	102	105	11	-3	8
2	07:30.0	113	109	108	4	1	5
2	08:00.0	108	104	108	4	-4	0
2	08:30.0	116	113	114	3	-1	2
2	09:00.0	118	115	108	3	7	10

Table B.1: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
2	09:30.0	118	107	105	11	2	13
2	10:00.0	124	116	110	8	6	14
2	10:30.0	122	117	115	5	2	7
2	11:00.0	130	120	121	10	-1	9
2	11:30.0	137	127	122	10	5	15
2	12:00.0	139	127	128	12	-1	11
2	12:30.0	141	134	132	7	2	9
3	00:00.0	92	97	110	-5	-13	-18
3	00:30.0	91	97	107	-6	-10	-16
3	01:00.0	94	112	113	-18	-1	-19
3	01:30.0	105	112	107	-7	5	-2
3	02:00.0	106	107	113	-1	-6	-7
3	02:30.0	106	107	109	-1	-2	-3
3	03:00.0	110	110	110	0	0	0
3	03:30.0	111	111	114	0	-3	-3
3	04:00.0	101	108	114	-7	-6	-13
3	04:30.0	107	113	115	-6	-2	-8
3	05:00.0	111	119	116	-8	3	-5
3	05:30.0	111	119	120	-8	-1	-9
3	06:00.0	122	119	119	3	0	3
3	06:30.0	118	125	124	-7	1	-6
3	07:00.0	120	123	124	-3	-1	-4
3	07:30.0	115	126	124	-11	2	-9
3	08:00.0	114	126	121	-12	5	-7
3	08:30.0	119	136	123	-17	13	-4
3	09:00.0	120	138	126	-18	12	-6
3	09:30.0	123	137	127	-14	10	-4
3	10:00.0	127	137	131	-10	6	-4
3	10:30.0	132	143	133	-11	10	-1
4	00:00.0	92	98	77	-6	21	15
4	00:30.0	92	98	77	-6	21	15
4	01:00.0	96	95	84	1	11	12
4	01:30.0	86	98	88	-12	10	-2
4	02:00.0	92	98	90	-6	8	2
4	02:30.0	94	98	86	-4	12	8
4	03:00.0	96	98	88	-2	10	8
4	03:30.0	98	96	92	2	4	6
4	04:00.0	98	94	87	4	7	11
4	04:30.0	99	96	90	3	6	9
4	05:00.0	100	97	92	3	5	8
4	05:30.0	100	96	92	4	4	8
4	06:00.0	100	100	92	0	8	8
4	06:30.0	98	102	92	-4	10	6

Table B.1: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
4	07:00.0	104	99	94	5	5	10
4	07:30.0	104	101	95	3	6	9
4	08:00.0	101	100	98	1	2	3
4	08:30.0	100	97	97	3	0	3
4	09:00.0	100	101	99	-1	2	1
4	09:30.0	98	106	98	-8	8	0
4	10:00.0	102	104	100	-2	4	2
4	10:30.0	105	103	99	2	4	6
4	11:00.0	104	106	101	-2	5	3
4	11:30.0	106	109	106	-3	3	0
4	12:00.0	116	110	104	6	6	12
4	12:30.0	112	112	106	0	6	6
4	13:00.0	112	112	112	0	0	0
4	13:30.0	116	116	108	0	8	8
4	14:00.0	118	116	112	2	4	6
4	14:30.0	122	120	114	2	6	8
4	15:00.0	125	122	117	3	5	8
4	15:30.0	128	126	120	2	6	8
4	16:00.0	128	128	122	0	6	6
4	16:30.0	128	129	123	-1	6	5
4	17:00.0	130	131	126	-1	5	4
4	17:30.0	131	132	126	-1	6	5
4	18:00.0	135	134	126	1	8	9
4	18:30.0	138	134	126	4	8	12
4	19:00.0	138	135	126	3	9	12
4	19:30.0	134	135	130	-1	5	4
4	20:00.0	135	134	130	1	4	5
4	20:30.0	136	136	129	0	7	7
4	21:00.0	138	138	132	0	6	6
4	21:30.0	143	140	138	3	2	5
4	22:00.0	144	140	136	4	4	8
4	22:30.0	145	141	133	4	8	12
5	00:00.0	94	110	82	-16	28	12
5	00:30.0	98	110	85	-12	25	13
5	01:00.0	106	117	109	-11	8	-3
5	01:30.0	101	113	107	-12	6	-6
5	02:00.0	99	112	100	-13	12	-1
5	02:30.0	98	114	105	-16	9	-7
5	03:00.0	101	112	97	-11	15	4
5	03:30.0	103	114	101	-11	13	2
5	04:00.0	103	116	107	-13	9	-4

Table B.1: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
5	04:30.0	110	114	105	-4	9	5
5	05:00.0	111	116	103	-5	13	8
5	05:30.0	110	115	109	-5	6	1
5	06:00.0	105	115	109	-10	6	-4
5	06:30.0	103	119	106	-16	13	-3
5	07:00.0	108	121	113	-13	8	-5
5	07:30.0	113	118	112	-5	6	1
5	08:00.0	105	122	107	-17	15	-2
5	08:30.0	116	119	113	-3	6	3
5	09:00.0	115	123	110	-8	13	5
5	09:30.0	117	125	114	-8	11	3
5	10:00.0	122	128	117	-6	11	5
5	10:30.0	118	127	116	-9	11	2
5	11:00.0	121	126	120	-5	6	1
5	11:30.0	126	126	119	0	7	7
6	00:00.0	92	112	97	-20	15	-5
6	00:30.0	92	107	98	-15	9	-6
6	01:00.0	101	106	100	-5	6	1
6	01:30.0	100	106	102	-6	4	-2
6	02:00.0	98	106	101	-8	5	-3
6	02:30.0	99	107	105	-8	2	-6
6	03:00.0	105	107	103	-2	4	2
6	03:30.0	104	106	105	-2	1	-1
6	04:00.0	104	106	101	-2	5	3
6	04:30.0	104	103	105	1	-2	-1
6	05:00.0	106	108	109	-2	-1	-3
6	05:30.0	106	112	112	-6	0	-6
6	06:00.0	106	112	113	-6	-1	-7
6	06:30.0	108	113	106	-5	7	2
6	07:00.0	112	114	112	-2	2	0
6	07:30.0	112	120	115	-8	5	-3
6	08:00.0	113	117	116	-4	1	-3
6	08:30.0	112	122	119	-10	3	-7
6	09:00.0	110	123	120	-13	3	-10
6	09:30.0	115	125	115	-10	10	0
6	10:00.0	122	126	121	-4	5	1
6	10:30.0	119	129	127	-10	2	-8
6	11:00.0	121	128	126	-7	2	-5
6	11:30.0	125	136	127	-11	9	-2
6	12:00.0	129	141	133	-12	8	-4
6	12:30.0	133	142	141	-9	1	-8

Table B.1: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
7	00:00.0	86	76	69	10	7	17
7	00:30.0	86	76	69	10	7	17
7	01:00.0	82	82	70	0	12	12
7	01:30.0	84	80	71	4	9	13
7	02:00.0	80	74	68	6	6	12
7	02:30.0	84	80	66	4	14	18
7	03:00.0	80	78	70	2	8	10
7	03:30.0	82	78	72	4	6	10
7	04:00.0	81	80	74	1	6	7
7	04:30.0	84	87	74	-3	13	10
7	05:00.0	82	89	76	-7	13	6
7	05:30.0	82	82	76	0	6	6
7	06:00.0	82	84	80	-2	4	2
7	06:30.0	82	80	80	2	0	2
7	07:00.0	91	88	82	3	6	9
7	07:30.0	92	98	78	-6	20	14
7	08:00.0	96	100	81	-4	19	15
7	08:30.0	88	90	87	-2	3	1
7	09:00.0	90	98	86	-8	12	4
7	09:30.0	96	94	86	2	8	10
7	10:00.0	99	94	90	5	4	9
7	10:30.0	100	99	89	1	10	11
7	11:00.0	102	99	90	3	9	12
7	11:30.0	105	102	96	3	6	9
7	12:00.0	102	106	96	-4	10	6
7	12:30.0	106	104	98	2	6	8
7	13:00.0	110	107	102	3	5	8
7	13:30.0	112	108	108	4	0	4
7	14:00.0	114	118	114	-4	4	0
7	14:30.0	124	127	118	-3	9	6
7	15:00.0	128	132	124	-4	8	4
7	15:30.0	132	133	124	-1	9	8
7	16:00.0	132	130	124	2	6	8
7	16:30.0	136	134	128	2	6	8
7	17:00.0	136	136	129	0	7	7
7	17:30.0	140	136	132	4	4	8
7	18:00.0	142	142	134	0	8	8
7	18:30.0	147	144	136	3	8	11
8	00:00.0	86	115	105	-29	10	-19
8	00:30.0	96	109	109	-13	0	-13
8	01:00.0	101	110	105	-9	5	-4

Table B.1: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
8	01:30.0	100	111	111	-11	0	-11
8	02:00.0	97	113	111	-16	2	-14
8	02:30.0	98	111	111	-13	0	-13
8	03:00.0	102	112	113	-10	-1	-11
8	03:30.0	100	113	111	-13	2	-11
8	04:00.0	94	111	113	-17	-2	-19
8	04:30.0	102	109	118	-7	-9	-16
8	05:00.0	104	111	116	-7	-5	-12
8	05:30.0	103	113	116	-10	-3	-13
8	06:00.0	99	111	115	-12	-4	-16
8	06:30.0	108	108	121	0	-13	-13
8	07:00.0	105	114	118	-9	-4	-13
8	07:30.0	106	113	127	-7	-14	-21
8	08:00.0	113	116	124	-3	-8	-11
8	08:30.0	110	115	130	-5	-15	-20
8	09:00.0	110	119	127	-9	-8	-17
8	09:30.0	115	121	133	-6	-12	-18
8	10:00.0	114	120	131	-6	-11	-17
8	10:30.0	119	125	137	-6	-12	-18
8	11:00.0	121	121	140	0	-19	-19
8	11:30.0	124	126	142	-2	-16	-18
12	00:00.0	96	80	90	16	-10	6
12	00:30.0	96	80	90	16	-10	6
12	01:00.0	95	86	90	9	-4	5
12	01:30.0	92	82	93	10	-11	-1
12	02:00.0	92	84	90	8	-6	2
12	02:30.0	98	84	90	14	-6	8
12	03:00.0	86	83	90	3	-7	-4
12	03:30.0	90	86	91	4	-5	-1
12	04:00.0	94	86	92	8	-6	2
12	04:30.0	92	85	94	7	-9	-2
12	05:00.0	90	86	94	4	-8	-4
12	05:30.0	96	88	92	8	-4	4
12	06:00.0	97	89	101	8	-12	-4
12	06:30.0	97	83	98	14	-15	-1
12	07:00.0	102	92	99	10	-7	3
12	07:30.0	100	93	98	7	-5	2
12	08:00.0	106	94	101	12	-7	5
12	08:30.0	102	94	102	8	-8	0
12	09:00.0	102	94	103	8	-9	-1
12	09:30.0	102	100	106	2	-6	-4

Table B.1: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
12	10:00.0	104	100	108	4	-8	-4
12	10:30.0	109	104	110	5	-6	-1
12	11:00.0	109	107	111	2	-4	-2
12	11:30.0	108	106	114	2	-8	-6
12	12:00.0	115	108	118	7	-10	-3
12	12:30.0	120	113	118	7	-5	2
12	13:00.0	131	114	130	17	-16	1
12	13:30.0	140	122	139	18	-17	1
13	00:00.0	84	80	98	4	-18	-14
13	00:30.0	84	80	98	4	-18	-14
13	01:00.0	90	84	92	6	-8	-2
13	01:30.0	96	86	94	10	-8	2
13	02:00.0	96	86	98	10	-12	-2
13	02:30.0	94	88	98	6	-10	-4
13	03:00.0	92	92	98	0	-6	-6
13	03:30.0	91	90	103	1	-13	-12
13	04:00.0	94	88	99	6	-11	-5
13	04:30.0	93	95	102	-2	-7	-9
13	05:00.0	99	94	102	5	-8	-3
13	05:30.0	99	91	105	8	-14	-6
13	06:00.0	103	90	106	13	-16	-3
13	06:30.0	99	92	112	7	-20	-13
13	07:00.0	105	92	112	13	-20	-7
13	07:30.0	104	99	108	5	-9	-4
13	08:00.0	108	92	108	16	-16	0
13	08:30.0	110	96	117	14	-21	-7
13	09:00.0	109	98	115	11	-17	-6
13	09:30.0	107	100	113	7	-13	-6
13	10:00.0	112	98	114	14	-16	-2
13	10:30.0	118	104	122	14	-18	-4
13	11:00.0	123	107	124	16	-17	-1
13	11:30.0	120	105	124	15	-19	-4
13	12:00.0	120	108	122	12	-14	-2
13	12:30.0	124	109	130	15	-21	-6
13	13:00.0	128	116	139	12	-23	-11
13	13:30.0	129	118	138	11	-20	-9
14	00:00.0	99	80	88	19	-8	11
14	00:30.0	99	80	88	19	-8	11
14	01:00.0	98	93	93	5	0	5
14	01:30.0	96	93	92	3	1	4
14	02:00.0	100	94	92	6	2	8

Table B.1: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
14	02:30.0	100	93	90	7	3	10
14	03:00.0	101	94	93	7	1	8
14	03:30.0	100	96	98	4	-2	2
14	04:00.0	100	96	98	4	-2	2
14	04:30.0	102	96	97	6	-1	5
14	05:00.0	101	99	96	2	3	5
14	05:30.0	104	96	98	8	-2	6
14	06:00.0	102	68	99	34	-31	3
14	06:30.0	103	98	98	5	0	5
14	07:00.0	105	102	103	3	-1	2
14	07:30.0	108	102	103	6	-1	5
14	08:00.0	108	101	105	7	-4	3
14	08:30.0	106	104	103	2	1	3
14	09:00.0	110	106	110	4	-4	0
14	09:30.0	110	106	108	4	-2	2
14	10:00.0	114	110	110	4	0	4
14	10:30.0	116	109	108	7	1	8
14	11:00.0	114	110	114	4	-4	0
14	11:30.0	116	114	115	2	-1	1
14	12:00.0	117	116	119	1	-3	-2
14	12:30.0	122	118	118	4	0	4
14	13:00.0	124	124	123	0	1	1
14	13:30.0	130	128	128	2	0	2
14	14:00.0	136	134	132	2	2	4
14	14:30.0	138	136	138	2	-2	0
14	15:00.0	138	140	138	-2	2	0
14	15:30.0	138	140	139	-2	1	-1
14	16:00.0	140	142	140	-2	2	0
14	16:30.0	140	144	142	-4	2	-2
16	00:00.0	89	80	69	9	11	20
16	00:30.0	89	80	69	9	11	20
16	01:00.0	90	90	84	0	6	6
16	01:30.0	92	88	86	4	2	6
16	02:00.0	89	87	88	2	-1	1
16	02:30.0	86	89	84	-3	5	2
16	03:00.0	90	92	88	-2	4	2
16	03:30.0	91	86	88	5	-2	3
16	04:00.0	91	87	86	4	1	5
16	04:30.0	88	92	88	-4	4	0
16	05:00.0	91	90	90	1	0	1
16	05:30.0	92	91	88	1	3	4

Table B.1: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
16	06:00.0	96	93	93	3	0	3
16	06:30.0	92	94	92	-2	2	0
16	07:00.0	99	96	94	3	2	5
16	07:30.0	95	94	94	1	0	1
16	08:00.0	102	98	96	4	2	6
16	08:30.0	98	96	98	2	-2	0
16	09:00.0	100	102	93	-2	9	7
16	09:30.0	104	104	97	0	7	7
16	10:00.0	107	104	103	3	1	4
16	10:30.0	108	105	105	3	0	3
16	11:00.0	104	108	101	-4	7	3
16	11:30.0	111	110	103	1	7	8
16	12:00.0	111	114	106	-3	8	5
16	12:30.0	112	115	106	-3	9	6
16	13:00.0	112	126	110	-14	16	2
16	13:30.0	111	128	112	-17	16	-1
16	14:00.0	116	136	124	-20	12	-8
16	14:30.0	124	132	128	-8	4	-4
16	15:00.0	95	134	131	-39	3	-36
16	15:30.0	101	138	130	-37	8	-29
16	16:00.0	64	139	132	-75	7	-68
16	16:30.0	102	140	134	-38	6	-32
16	17:00.0	109	144	136	-35	8	-27
16	17:30.0	130	146	140	-16	6	-10
16	18:00.0	135	146	143	-11	3	-8
16	18:30.0	64	148	144	-84	4	-80
16	19:00.0	73	149	143	-76	6	-70
16	19:30.0	74	150	148	-76	2	-74

Table B.2: Pairwise Comparison of Aerobic Heart Rate Data for 10 Minute Interval

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
1	12:00.0	139	139	137	0	2	2
1	12:30.0	147	148	142	-1	6	5
1	13:00.0	153	151	150	2	1	3
1	13:30.0	158	157	154	1	3	4
1	14:00.0	155	159	156	-4	3	-1
1	14:30.0	158	159	158	-1	1	0
1	15:00.0	160	161	160	-1	1	0
1	15:30.0	166	162	161	4	1	5
1	16:00.0	160	158	161	2	-3	-1
1	16:30.0	163	162	165	1	-3	-2
1	17:00.0	164	164	160	0	4	4
1	17:30.0	163	165	168	-2	-3	-5
1	18:00.0	164	164	169	0	-5	-5
1	18:30.0	165	164	167	1	-3	-2
1	19:00.0	164	162	170	2	-8	-6
1	19:30.0	165	162	171	3	-9	-6
1	20:00.0	167	164	169	3	-5	-2
1	20:30.0	167	165	170	2	-5	-3
1	21:00.0	165	165	174	0	-9	-9
1	21:30.0	166	166	172	0	-6	-6
2	13:00.0	142	142	149	0	-7	-7
2	13:30.0	149	146	151	3	-5	-2
2	14:00.0	145	149	146	-4	3	-1
2	14:30.0	148	146	144	2	2	4
2	15:00.0	151	149	149	2	0	2
2	15:30.0	152	144	151	8	-7	1
2	16:00.0	151	150	146	1	4	5
2	16:30.0	152	148	149	4	-1	3
2	17:00.0	153	150	151	3	-1	2
2	17:30.0	157	154	151	3	3	6
2	18:00.0	158	158	154	0	4	4
2	18:30.0	155	154	150	1	4	5
2	19:00.0	154	156	154	-2	2	0
2	19:30.0	158	152	160	6	-8	-2
2	20:00.0	158	152	154	6	-2	4
2	20:30.0	158	155	157	3	-2	1
2	21:00.0	157	148	155	9	-7	2
2	21:30.0	158	152	156	6	-4	2
2	22:00.0	155	157	154	-2	3	1
2	22:30.0	154	153	157	1	-4	-3
3	11:00.0	138	145	137	-7	8	1
3	11:30.0	138	148	138	-10	10	0

Table B.2: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
3	12:00.0	135	152	138	-17	14	-3
3	12:30.0	136	148	147	-12	1	-11
3	13:00.0	151	148	146	3	2	5
3	13:30.0	147	153	149	-6	4	-2
3	14:00.0	147	152	152	-5	0	-5
3	14:30.0	145	149	152	-4	-3	-7
3	15:00.0	144	155	152	-11	3	-8
3	15:30.0	152	156	155	-4	1	-3
3	16:00.0	156	155	155	1	0	1
3	16:30.0	153	154	157	-1	-3	-4
3	17:00.0	150	153	158	-3	-5	-8
3	17:30.0	153	154	156	-1	-2	-3
3	18:00.0	153	155	159	-2	-4	-6
3	18:30.0	155	153	159	2	-6	-4
3	19:00.0	151	156	164	-5	-8	-13
3	19:30.0	151	156	162	-5	-6	-11
3	20:00.0	156	161	162	-5	-1	-6
3	20:30.0	153	157	162	-4	-5	-9
4	23:00.0	144	142	138	2	4	6
4	23:30.0	147	143	138	4	5	9
4	24:00.0	150	146	135	4	11	15
4	24:30.0	148	147	138	1	9	10
4	25:00.0	150	146	138	4	8	12
4	25:30.0	150	146	140	4	6	10
4	26:00.0	150	146	140	4	6	10
4	26:30.0	149	146	140	3	6	9
4	27:00.0	148	146	140	2	6	8
4	27:30.0	150	148	144	2	4	6
4	28:00.0	150	146	142	4	4	8
4	28:30.0	148	146	140	2	6	8
4	29:00.0	150	146	143	4	3	7
4	29:30.0	154	146	142	8	4	12
4	30:00.0	151	148	141	3	7	10
4	30:30.0	150	149	141	1	8	9
4	31:00.0	151	146	142	5	4	9
4	31:30.0	154	145	142	9	3	12
4	32:00.0	152	147	142	5	5	10
4	32:30.0	150	148	142	2	6	8
5	12:00.0	128	127	122	1	5	6
5	12:30.0	131	135	122	-4	13	9
5	13:00.0	128	135	124	-7	11	4
5	13:30.0	131	132	125	-1	7	6

Table B.2: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
5	14:00.0	134	133	126	1	7	8
5	14:30.0	129	132	118	-3	14	11
5	15:00.0	127	134	124	-7	10	3
5	15:30.0	134	135	123	-1	12	11
5	16:00.0	131	136	143	-5	-7	-12
5	16:30.0	133	137	118	-4	19	15
5	17:00.0	134	136	123	-2	13	11
5	17:30.0	131	138	120	-7	18	11
5	18:00.0	135	140	122	-5	18	13
5	18:30.0	136	135	128	1	7	8
5	19:00.0	134	135	130	-1	5	4
5	19:30.0	138	135	126	3	9	12
5	20:00.0	137	138	127	-1	11	10
5	20:30.0	135	139	123	-4	16	12
6	13:00.0	138	138	144	0	-6	-6
6	13:30.0	136	149	146	-13	3	-10
6	14:00.0	142	152	145	-10	7	-3
6	14:30.0	144	150	145	-6	5	-1
6	15:00.0	142	151	146	-9	5	-4
6	15:30.0	145	153	145	-8	8	0
6	16:00.0	143	154	152	-11	2	-9
6	16:30.0	147	152	153	-5	-1	-6
6	17:00.0	149	156	150	-7	6	-1
6	17:30.0	152	153	153	-1	0	-1
6	18:00.0	150	152	152	-2	0	-2
6	18:30.0	148	155	152	-7	3	-4
6	19:00.0	152	157	153	-5	4	-1
6	19:30.0	152	153	154	-1	-1	-2
6	20:00.0	150	155	153	-5	2	-3
6	20:30.0	148	154	154	-6	0	-6
6	21:00.0	153	155	152	-2	3	1
6	21:30.0	152	155	154	-3	1	-2
6	22:00.0	152	155	154	-3	1	-2
6	22:30.0	150	155	153	-5	2	-3
7	19:00.0	148	144	140	4	4	8
7	19:30.0	149	146	142	3	4	7
7	20:00.0	148	149	144	-1	5	4
7	20:30.0	150	146	140	4	6	10
7	21:00.0	153	149	144	4	5	9
7	21:30.0	152	152	145	0	7	7
7	22:00.0	157	153	144	4	9	13

Table B.2: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
7	22:30.0	157	150	140	7	10	17
7	23:00.0	156	149	146	7	3	10
7	23:30.0	160	155	148	5	7	12
7	24:00.0	160	151	148	9	3	12
7	24:30.0	159	154	146	5	8	13
7	25:00.0	156	154	148	2	6	8
7	25:30.0	160	158	149	2	9	11
7	26:00.0	162	157	153	5	4	9
7	26:30.0	162	157	150	5	7	12
7	27:00.0	160	158	150	2	8	10
7	27:30.0	164	156	152	8	4	12
7	28:00.0	162	160	150	2	10	12
7	28:30.0	163	158	150	5	8	13
8	12:00.0	125	131	145	-6	-14	-20
8	12:30.0	126	135	150	-9	-15	-24
8	13:00.0	132	139	152	-7	-13	-20
8	13:30.0	134	147	152	-13	-5	-18
8	14:00.0	141	152	152	-11	0	-11
8	14:30.0	143	154	153	-11	1	-10
8	15:00.0	144	150	157	-6	-7	-13
8	15:30.0	149	150	159	-1	-9	-10
8	16:00.0	150	154	161	-4	-7	-11
8	16:30.0	153	150	160	3	-10	-7
8	17:00.0	153	149	160	4	-11	-7
8	17:30.0	152	150	160	2	-10	-8
8	18:00.0	157	146	165	11	-19	-8
8	18:30.0	157	154	164	3	-10	-7
8	19:00.0	157	151	163	6	-12	-6
8	19:30.0	154	150	162	4	-12	-8
8	20:00.0	156	153	160	3	-7	-4
8	20:30.0	156	153	163	3	-10	-7
8	21:00.0	159	152	160	7	-8	-1
8	21:30.0	161	155	161	6	-6	0
12	14:00.0	144	127	144	17	-17	0
12	14:30.0	147	130	146	17	-16	1
12	15:00.0	148	139	146	9	-7	2
12	15:30.0	151	146	146	5	0	5
12	16:00.0	152	148	150	4	-2	2
12	16:30.0	155	142	148	13	-6	7
12	17:00.0	154	143	153	11	-10	1
12	17:30.0	153	142	148	11	-6	5

Table B.2: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
12	18:00.0	150	144	146	6	-2	4
12	18:30.0	150	144	152	6	-8	-2
12	19:00.0	154	148	154	6	-6	0
12	19:30.0	156	148	154	8	-6	2
12	20:00.0	154	145	155	9	-10	-1
12	20:30.0	157	148	157	9	-9	0
12	21:00.0	156	144	156	12	-12	0
12	21:30.0	158	146	156	12	-10	2
12	22:00.0	157	145	156	12	-11	1
12	22:30.0	154	149	156	5	-7	-2
12	23:00.0	155	152	154	3	-2	1
12	23:30.0	156	152	150	4	2	6
13	14:00.0	132	122	145	10	-23	-13
13	14:30.0	138	132	152	6	-20	-14
13	15:00.0	148	134	154	14	-20	-6
13	15:30.0	154	134	150	20	-16	4
13	16:00.0	157	134	150	23	-16	7
13	16:30.0	154	132	159	22	-27	-5
13	17:00.0	156	134	158	22	-24	-2
13	17:30.0	153	137	159	16	-22	-6
13	18:00.0	150	139	158	11	-19	-8
13	18:30.0	152	140	162	12	-22	-10
13	19:00.0	152	146	162	6	-16	-10
13	19:30.0	158	143	163	15	-20	-5
13	20:00.0	157	142	161	15	-19	-4
13	20:30.0	159	142	164	17	-22	-5
13	21:00.0	163	140	159	23	-19	4
13	21:30.0	164	142	166	22	-24	-2
13	22:00.0	160	144	165	16	-21	-5
13	22:30.0	154	146	164	8	-18	-10
13	23:00.0	162	144	165	18	-21	-3
13	23:30.0	162	144	166	18	-22	-4
14	17:00.0	142	144	144	-2	0	-2
14	17:30.0	144	144	144	0	0	0
14	18:00.0	144	146	146	-2	0	-2
14	18:30.0	145	148	148	-3	0	-3
14	19:00.0	148	147	150	1	-3	-2
14	19:30.0	148	148	150	0	-2	-2
14	20:00.0	148	147	149	1	-2	-1
14	20:30.0	148	148	151	0	-3	-3
14	21:00.0	146	150	152	-4	-2	-6

Table B.2: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
14	21:30.0	146	149	152	-3	-3	-6
14	22:00.0	146	149	152	-3	-3	-6
14	22:30.0	148	146	150	2	-4	-2
14	23:00.0	148	146	151	2	-5	-3
14	23:30.0	148	152	151	-4	1	-3
14	24:00.0	147	150	152	-3	-2	-5
14	24:30.0	148	150	150	-2	0	-2
14	25:00.0	148	152	152	-4	0	-4
14	25:30.0	148	150	153	-2	-3	-5
14	26:00.0	148	150	152	-2	-2	-4
14	26:30.0	148	151	154	-3	-3	-6
16	20:00.0	72	152	150	-80	2	-78
16	20:30.0	72	152	147	-80	5	-75
16	21:00.0	76	154	150	-78	4	-74
16	21:30.0	78	157	150	-79	7	-72
16	22:00.0	75	156	148	-81	8	-73
16	22:30.0	157	157	152	0	5	5
16	23:00.0	158	157	152	1	5	6
16	23:30.0	80	160	152	-80	8	-72
16	24:00.0	0	158	152	-158	6	-152
16	24:30.0	156	160	152	-4	8	4
16	25:00.0	110	157	154	-47	3	-44
16	25:30.0	157	158	152	-1	6	5
16	26:00.0	118	156	156	-38	0	-38
16	26:30.0	118	160	158	-42	2	-40
16	27:00.0	157	158	156	-1	2	1
16	27:30.0	118	158	153	-40	5	-35
16	28:00.0	80	158	154	-78	4	-74
16	28:30.0	159	159	157	0	2	2
16	29:00.0	118	158	156	-40	2	-38
16	29:30.0	78	160	158	-82	2	-80

Table B.3: Pairwise Comparison of Aerobic Heart Rate Data for Cool Down

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
1	22:00.0	162	166	170	-4	-4	-8
1	22:30.0	160	163	168	-3	-5	-8
1	23:00.0	155	154	157	1	-3	-2
1	23:30.0	145	144	150	1	-6	-5
1	24:00.0	137	139	141	-2	-2	-4
1	24:30.0	135	135	137	0	-2	-2
1	25:00.0	125	128	130	-3	-2	-5
1	25:30.0	128	125	128	3	-3	0
1	26:00.0	130	126	126	4	0	4
1	26:30.0	123	122	128	1	-6	-5
1	27:00.0	118	122	121	-4	1	-3
1	27:30.0	120	120	119	0	1	1
1	28:00.0	114	121	116	-7	5	-2
1	28:30.0	118	112	117	6	-5	1
1	29:00.0	115	117	115	-2	2	0
1	29:30.0	121	114	117	7	-3	4
1	30:00.0	113	109	116	4	-7	-3
2	23:00.0	158	156	157	2	-1	1
2	23:30.0	154	150	157	4	-7	-3
2	24:00.0	147	147	149	0	-2	-2
2	24:30.0	140	137	138	3	-1	2
2	25:00.0	130	137	136	-7	1	-6
2	25:30.0	127	133	128	-6	5	-1
2	26:00.0	128	130	122	-2	8	6
2	26:30.0	121	120	123	1	-3	-2
2	27:00.0	119	118	120	1	-2	-1
2	27:30.0	116	113	115	3	-2	1
2	28:00.0	115	109	110	6	-1	5
2	28:30.0	114	111	108	3	3	6
2	29:00.0	110	111	107	-1	4	3
2	29:30.0	113	109	109	4	0	4
2	30:00.0	107	108	105	-1	3	2
3	21:00.0	153	157	165	-4	-8	-12
3	21:30.0	151	155	161	-4	-6	-10
3	22:00.0	149	146	160	3	-14	-11
3	22:30.0	140	145	155	-5	-10	-15
3	23:00.0	137	139	144	-2	-5	-7
3	23:30.0	132	131	144	1	-13	-12
3	24:00.0	125	128	142	-3	-14	-17
3	24:30.0	119	125	140	-6	-15	-21
3	25:00.0	118	136	139	-18	-3	-21

Table B.3: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
3	25:30.0	114	143	128	-29	15	-14
3	26:00.0	127	130	126	-3	4	1
3	26:30.0	118	127	122	-9	5	-4
3	27:00.0	116	121	127	-5	-6	-11
3	27:30.0	115	119	125	-4	-6	-10
3	28:00.0	115	121	125	-6	-4	-10
3	28:30.0	111	116	122	-5	-6	-11
4	33:00.0	148	149	142	-1	7	6
4	33:30.0	152	149	140	3	9	12
4	34:00.0	148	145	139	3	6	9
4	34:30.0	145	141	138	4	3	7
4	35:00.0	144	137	132	7	5	12
4	35:30.0	141	134	126	7	8	15
4	36:00.0	132	127	122	5	5	10
4	36:30.0	124	123	114	1	9	10
4	37:00.0	122	118	112	4	6	10
4	37:30.0	121	114	110	7	4	11
4	38:00.0	118	114	103	4	11	15
4	38:30.0	116	113	111	3	2	5
4	39:00.0	118	108	109	10	-1	9
4	39:30.0	113	110	108	3	2	5
4	40:00.0	113	106	106	7	0	7
4	40:30.0	112	105	106	7	-1	6
4	41:00.0	112	107	106	5	1	6
5	21:00.0	136	136	125	0	11	11
5	21:30.0	131	136	125	-5	11	6
5	22:00.0	128	132	122	-4	10	6
5	22:30.0	122	130	118	-8	12	4
5	23:00.0	124	124	117	0	7	7
5	23:30.0	118	124	119	-6	5	-1
5	24:00.0	112	117	110	-5	7	2
5	24:30.0	120	119	111	1	8	9
5	25:00.0	114	120	109	-6	11	5
5	25:30.0	115	118	107	-3	11	8
5	26:00.0	107	115	106	-8	9	1
5	26:30.0	107	109	104	-2	5	3
5	27:00.0	113	112	97	1	15	16
5	27:30.0	98	106	97	-8	9	1
5	28:00.0	110	113	99	-3	14	11
6	23:00.0	151	151	158	0	-7	-7
6	23:30.0	151	154	150	-3	4	1

Table B.3: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
6	24:00.0	146	148	155	-2	-7	-9
6	24:30.0	144	146	143	-2	3	1
6	25:00.0	144	137	143	7	-6	1
6	25:30.0	144	134	135	10	-1	9
6	26:00.0	139	129	131	10	-2	8
6	26:30.0	134	130	131	4	-1	3
6	27:00.0	128	125	128	3	-3	0
6	27:30.0	129	123	127	6	-4	2
6	28:00.0	126	123	126	3	-3	0
6	28:30.0	126	122	122	4	0	4
6	29:00.0	126	121	120	5	1	6
6	29:30.0	120	119	119	1	0	1
6	30:00.0	119	118	118	1	0	1
7	29:00.0	164	160	153	4	7	11
7	29:30.0	163	162	151	1	11	12
7	30:00.0	156	161	148	-5	13	8
7	30:30.0	156	160	149	-4	11	7
7	31:00.0	--	157	150	-157	7	-150
7	31:30.0	--	155	149	-155	6	-149
7	32:00.0	--	144	139	-144	5	-139
7	32:30.0	--	136	129	-136	7	-129
7	33:00.0	--	131	123	-131	8	-123
7	33:30.0	--	129	119	-129	10	-119
7	34:00.0	--	125	117	-125	8	-117
7	34:30.0	--	122	114	-122	8	-114
7	35:00.0	--	119	112	-119	7	-112
7	35:30.0	--	119	107	-119	12	-107
7	36:00.0	--	114	106	-114	8	-106
7	36:30.0	--	115	104	-115	11	-104
7	37:00.0	--	114	103	-114	11	-103
7	37:30.0	--	111	101	-111	10	-101
7	38:00.0	--	108	100	-108	8	-100
8	22:00.0	164	154	163	10	-9	1
8	22:30.0	157	153	159	4	-6	-2
8	23:00.0	149	143	150	6	-7	-1
8	23:30.0	140	140	144	0	-4	-4
8	24:00.0	131	129	138	2	-9	-7
8	24:30.0	131	129	129	2	0	2
8	25:00.0	128	124	127	4	-3	1
8	25:30.0	124	124	125	0	-1	-1
8	26:00.0	121	121	121	0	0	0

Table B.3: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
8	26:30.0	116	118	121	-2	-3	-5
8	27:00.0	115	116	121	-1	-5	-6
8	27:30.0	113	116	116	-3	0	-3
8	28:00.0	113	113	115	0	-2	-2
8	28:30.0	117	114	115	3	-1	2
8	29:00.0	109	112	112	-3	0	-3
8	29:30.0	109	111	113	-2	-2	-4
8	30:00.0	113	109	117	4	-8	-4
12	24:00.0	158	151	152	7	-1	6
12	24:30.0	162	150	152	12	-2	10
12	25:00.0	161	144	149	17	-5	12
12	25:30.0	148	133	138	15	-5	10
12	26:00.0	138	126	129	12	-3	9
12	26:30.0	137	126	122	11	4	15
12	27:00.0	124	119	118	5	1	6
12	27:30.0	122	116	117	6	-1	5
12	28:00.0	116	115	113	1	2	3
12	28:30.0	117	114	110	3	4	7
12	29:00.0	112	110	108	2	2	4
12	29:30.0	114	108	106	6	2	8
12	30:00.0	110	105	106	5	-1	4
12	30:30.0	111	104	102	7	2	9
12	31:00.0	110	106	104	4	2	6
13	24:00.0	164	143	163	21	-20	1
13	24:30.0	160	140	166	20	-26	-6
13	25:00.0	154	138	164	16	-26	-10
13	25:30.0	150	134	152	16	-18	-2
13	26:00.0	146	126	148	20	-22	-2
13	26:30.0	141	122	142	19	-20	-1
13	27:00.0	133	115	139	18	-24	-6
13	27:30.0	132	110	133	22	-23	-1
13	28:00.0	132	108	138	24	-30	-6
13	28:30.0	122	108	135	14	-27	-13
13	29:00.0	116	100	129	16	-29	-13
13	29:30.0	115	103	128	12	-25	-13
13	30:00.0	116	98	125	18	-27	-9
13	30:30.0	112	99	127	13	-28	-15
13	31:00.0	116	95	121	21	-26	-5
14	27:00.0	147	150	153	-3	-3	-6
14	27:30.0	146	151	152	-5	-1	-6
14	28:00.0	145	149	150	-4	-1	-5

Table B.3: Continued

		HEART RATE					
SUBJECT	TIME	No Mouthguard (A)	Performance (B)	Protection (C)	A-B	B-C	A-C
14	28:30.0	145	144	148	1	-4	-3
14	29:00.0	141	144	146	-3	-2	-5
14	29:30.0	140	142	144	-2	-2	-4
14	30:00.0	136	132	136	4	-4	0
14	30:30.0	138	127	129	11	-2	9
14	31:00.0	135	122	124	13	-2	11
14	31:30.0	131	119	121	12	-2	10
14	32:00.0	124	116	117	8	-1	7
14	32:30.0	121	113	114	8	-1	7
14	33:00.0	115	111	112	4	-1	3
14	33:30.0	110	108	111	2	-3	-1
14	34:00.0	108	107	108	1	-1	0
14	34:30.0	107	108	105	-1	3	2
14	35:00.0	106	103	103	3	0	3
14	35:30.0	104	99	103	5	-4	1
14	36:00.0	100	98	103	2	-5	-3
16	30:00.0	160	161	158	-1	3	2
16	30:30.0	159	161	155	-2	6	4
16	31:00.0	158	156	152	2	4	6
16	31:30.0	155	151	145	4	6	10
16	32:00.0	145	143	137	2	6	8
16	32:30.0	135	134	129	1	5	6
16	33:00.0	130	127	125	3	2	5
16	33:30.0	124	124	122	0	2	2
16	34:00.0	121	120	114	1	6	7
16	34:30.0	115	119	112	-4	7	3
16	35:00.0	112	115	110	-3	5	2
16	35:30.0	111	112	106	-1	6	5
16	36:00.0	111	111	107	0	4	4
16	36:30.0	111	112	102	-1	10	9
16	37:00.0	109	109	101	0	8	8
16	37:30.0	106	108	103	-2	5	3
16	38:00.0	105	110	104	-5	6	1

Table B.4: t-Test Results for the Pairwise Comparison for the Warm-up Period of the Aerobic Test

Condition	t - value	df	p
No Mouthguard to Performance	-1.4860	359	0.9309
Performance to Protection	2.9120	359	0.0038
No Mouthguard to Protection	0.5685	359	0.2850

Table B.5: t-Test Results for the Pairwise Comparison for the 10 Minute Running Period of the Aerobic Test

Condition	t - value	df	p
No Mouthguard to Performance	-1.9320	237	0.9727
Performance to Protection	-2.0260	237	0.0439
No Mouthguard to Protection	-2.9950	237	0.9985

Table B.6: t-Test Results for the Pairwise Comparison for theCool Down Period of the Aerobic Test

Condition	t - value	df	p
No Mouthguard to Performance	-2.9590	196	0..0001
Performance to Protection	-1.0360	196	0.3015
No Mouthguard to Protection	-3.4700	196	0.0345

APPENDIX C

STRENGTH DATA

Table C.1: Preliminary Strength Testing Data

Subject	Preliminary Test		1 Rep Max (lbs)	75% of 1 Rep Max (lbs)	Weight Tested At (lbs)
	Weight (lbs)	# of Reps			
1	115	6	134	100	105
2	190	6	221	166	165
3	125	10	167	125	125
4	165	5	186	139	135
5	55	9	71	53	45
6	190	10	253	190	190
7	175	3	185	139	135
8	175	6	203	152	155
12	105	3	111	83	85
13	115	3	122	91	85
14	190	8	236	177	175
16	190	8	236	177	175

Table C.2: Raw Strength Data

Subject	Number of Repetitions		
	No Mouthguard	Performance	Protection
1	14	17	17
2	14	17	14
3	9	8	10
4	13	15	16
5	16	25	17
6	9	10	10
7	11	13	12
8	10	11	11
12	9	12	11
13	7	7	8
14	11	12	11
16	16	19	19

Table C.3: Rank Sums for the comparison of the EDGE™ Performance to No Mouthguard for Strength Test

Subject	no	perf	no - perf	| no - perf |	Rank	Negative	Positive
1	14	17	-3	3	7.5	7.5	
2	14	17	-3	3	7.5	7.5	
3	9	8	1	1	2.5		2.5
4	13	15	-2	2	5	5	
5	16	25	-9	9	11	11	
6	9	10	-1	1	2.5	2.5	
7	11	13	-2	2	5	5	
8	10	11	-1	1	2.5	2.5	
12	9	12	-3	3	7.5	7.5	
14	11	12	-1	1	2.5	2.5	
16	16	19	-3	3	7.5	7.5	
13	7	7	0	0			
T=2.5	p=.004				Negative	58.5	
n=11					Positive		2.5

Table C.4: Rank Sums for the comparison of the EDGE™ Protection to No Mouthguard for Strength Test

Subject	no	pro	no - pro	| no - pro |	Rank	Negative	Positive
1	14	17	-3	3	9	9	
3	9	10	-1	1	3.5	3.5	
4	13	16	-3	3	9	9	
5	16	17	-1	1	3.5	3.5	
6	9	10	-1	1	3.5	3.5	
7	11	12	-1	1	3.5	3.5	
8	10	11	-1	1	3.5	3.5	
12	9	11	-2	2	7	7	
13	7	8	-1	1	3.5	3.5	
16	16	19	-3	3	9	9	
2	14	14	0	0			
14	11	11	0	0			
T=0	p=				Negative	55	
n=10					Positive		0

Table C.5: Rank Sums for the comparison of the EDGE™ Protection to the EDGE™ Performance for Strength Test

Subject	perf	pro	perf - pro	| no - perf |	Rank	Negative	Positive
2	17	14	3	3	7		7
3	8	10	-2	2	6	6	
4	15	16	-1	1	3	3	
5	25	17	8	8	8		8
7	13	12	1	1	3		3
12	12	11	1	1	3		3
13	7	8	-1	1	3	3	
14	12	11	1	1	3		
16	19	19	0	0			
1	17	17	0	0			
6	10	10	0	0			
8	11	11	0	0			
T=12	p=.461				Negative	12	
n=8					Positive		21

APPENDIX D

IMPACT DATA

Table D.1: Raw Impact Data

Mouthguard	Hit	mV	g's	notes
None	1	464	99	
	2	464	124	
	3	464	116	
	4	464	131	
	5	464	117	
		avg	117.4	
2	1	464	66	wood cracked on hit #7 - absorbed more energy, g's lower
	2	464	77	
	3	464	85	
	4	464	77	
	5	464	72	
	6	464	82	
	7	464	56*	
	8	464	66	
	9	464	79	
	10	464	69	
		avg	74.8	
1	1	464	80	new wood
	2	464	92	
	3	464	92	
	4	464	92	
	5	464	87	
	6	464	86	
	7	464	97	
	8	464	96	
	9	464	91	
	10	464	98	
		avg	91.1	
3	1	464	73	
	2	464	79	
	3	464	75	
	4	464	82	
	5	464	88	
	6	464	85	
	7	464	90	
	8	464	94	
	9	464	94	
	10	464	91	
		avg	85.1	
4	1	464	72	bite pads indented the wood
	2	464	70	
	3	464	91	
	4	464	98	

Table D.1: Continued

Mouthguard	Hit	mV	g's	notes
	5	464	94	
	6	464	85	
	7	464	99	
	8	464	107	
	9	464	99	
	10	464	108	
		avg	92.3	
5	1	464	80	
	2	464	95	
	3	464	95	
	4	464	101	
	5	464	90	
	6	464	99	
	7	464	96	
	8	464	96	
	9	464	103	
	10	464	105	
		avg	96	
6	1	464	92	
	2	464	109	
	3	464	126	
	4	464	111	
	5	464	123	
	6	464	123	
	7	464	127	
	8	464	130	
	9	464	143	
	10	464	137	
		avg	122.1	

* impact omitted from the average

APPENDIX E

MISCELLANEOUS

Table E.1: Summary of the Charges/Counter Charges on the Effectiveness of a MORA

Study	Year	Type of Test	Findings
Smith	1978	Subjective and Isokinetic	No statistical analysis performed.
Fucha	1981	Isometric	Statistically significant results were found using the MORA vs. placebo for the lower body test, and using the MORA vs. normal bite for left are abductors and right foot dorsiflexors. No placebo effect noted.
Greenberg	1981	Isokinetic	No statistically significant findings. No placebo effect noted.
Kaufman	1982	Muscle Efficiency	Statistical significance was determined in the bench press test.
Burkett	1982	Isometric and Isokinetic	No statistically significant finding. No placebo effect noted.
Bates	1983	Muscle Efficiency	Statistical significance was determined in the vertical jump and the grip strength tests.
Williams	1983	Isokinetic	Supported rest position was significantly stronger than centric occlusion for upper appendage strength.
Yates	1984	Isometric and Isokinetic	No statistically significant findings. No placebo effect noted.
Verban	1984	Isokinetic	Statistically significant results were found in extension and external rotation exercises. No placebo effect noted.
Schubert	1984	Isokinetic	No statistically significant findings. No placebo effect noted.

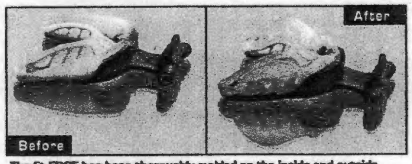
Table E.2: Sequence of Testing

Subject	trial 1	trial 2	trial 3
1	No Mouthguard	Performance	Protection
2	Protection	No Mouthguard	Performance
3	Performance	Protection	No Mouthguard
4	No Mouthguard	Performance	Protection
5	Protection	No Mouthguard	Performance
6	Performance	Protection	No Mouthguard
7	No Mouthguard	Performance	Protection
8	Protection	No Mouthguard	Performance
12	No Mouthguard	Protection	Performance
13	No Mouthguard	Performance	Protection
14	Protection	No Mouthguard	Performance
16	No Mouthguard	Performance	Protection

INTRODUCTION & FITTING INSTRUCTIONS

The patented EDGE is a bio-engineered anti-microbial 4-shot oral device that fits snugly around your upper teeth. For the best fit, the EDGE is secured to a flexible fitting tool that will help guide the EDGE into YOUR POWER SAFETY POSITION.

The EDGE reduces pressure on the TM Joint and makes you stronger while providing unbeatable protection.



The fit EDGE has been thoroughly molded on the inside and outside around all of the upper teeth up to and beyond the gums and roof of the mouth.

NOTE Read Through All Instructions Carefully Before You Begin

- You will need a pot of boiling water, a container of room temperature water, and a container of ice water.
- We recommended using a mirror while fitting the EDGE
- Follow timing accurately using a clock or watch with a second hand
- If you have any concerns about fitting the EDGE please consult your dentist or orthodontist

1 BOILING

1. Fill a container with 5° of ice water and set aside.
2. Fill a container with 5° of room temperature water and also set aside.
3. Fill a pot with 5° of water and bring to a boil.
4. After water comes to a boil, remove pot from burner.

5. Submerge the EDGE into hot water for 60 seconds (Only submerge the EDGE up to the silicone protective bumper).
6. Remove the EDGE from the hot water and dip it in the container of room temperature water for one second (DO NOT PLACE THE EDGE IN THE CONTAINER OF WATER FOR MORE THAN ONE SECOND)
7. Immediately place the EDGE in your mouth. Do not remove fitting tool until instructed to do so in Finishing Phase.


Boil for 60 Seconds


Quick Dip/Room Temp


Put in Mouth

2 ALIGNMENT & BITE

1. Align the EDGE with your upper teeth. Ensure correct alignment by using your fingers and thumbs to press the EDGE up and back towards the roof of your mouth.
2. Bite down firmly and naturally.
3. Push your tongue against the roof of your mouth. With a strong sucking motion, create a vacuum chamber effect and draw out all air and water.


Push up and back into alignment


Bite down firmly and naturally


Sucking motion to draw out air and water

3 CONTOURING & SHAPING

1. While biting down use your fingers to form the outside wall by pushing the material upward and tight against your teeth and gums all the way around your mouth.
2. Use your thumb to massage the EDGE tight against the roof of your mouth and the back of your teeth.
3. Pack the EDGE tight against your teeth and gums by pressing on the outside of your cheeks.
4. Continue to bite down, suck and swallow for approximately one minute. This will complete the shaping process and create a vacuum chamber effect to draw out all air and water.


Push material up all around teeth and gums


Form to roof of mouth


Pack against teeth and continue sucking motion.

4 COOLING & SETTING

1. While still attached to the fitting tool, place the EDGE in the container of ice cold water for three to five minute to set.
2. Remove the EDGE from the flexible fitting tool by carefully pulling it off.
3. As the EDGE cools and sets it will shrink approximately 5% giving you a more retentive fit. Your best fit will occur after 24 hours.

CARE INSTRUCTIONS

- We do not recommend trimming the EDGE. Trimming may cause the materials to come apart over time.
- For your protection, the EDGE SYSTEM was manufactured using an antimicrobial additive to inhibit the growth of germs.
- To minimize distortion and to keep a good fit, avoid exposing the EDGE to high temperatures and hot surfaces.
- The EDGE can be cleaned using a toothbrush and cool water.
- Always store the EDGE in its custom protective case.

Figure E.1: Boil and Bite Instructions for Self Fitting Mouthguard

Table E.2: Signed Rank Probabilities for the Wilcoxon Signed-Rank Test

Signed-Rank Probabilities[a]

	Sample Size n								
T	4	5	6	7	8	9	10	11	12
1	.250	.125	.063	.031	.016	.008	.004	.002	.001
2	.375	.188	.094	.047	.024	.012	.006	.003	.002
3	.625	.313	.156	.078	.039	.020	.010	.005	.003
4	.875	.438	.219	.109	.055	.027	.014	.007	.004
5		.625	.313	.156	.078	.039	.020	.010	.005
6		.801	.438	.219	.109	.055	.027	.014	.007
7		1.000	.563	.297	.149	.074	.037	.019	.009
8			.688	.375	.195	.098	.049	.025	.012
9			.844	.469	.250	.129	.065	.032	.016
10			1.000	.578	.313	.164	.084	.042	.021
11				.688	.383	.203	.106	.054	.027
12				.813	.461	.250	.131	.067	.034
13				.938	.547	.301	.160	.083	.043
14					.641	.359	.193	.102	.052
15					.742	.426	.233	.1123	.064
16					.844	.496	.275	.148	.077
17					.945	.570	.322	.175	.092
18						.652	.375	.206	.110
19						.7344	.432	.240	.129
20						.820	.492	.278	.151
21						.910	.557	.320	.176
22						1.000	.625	.365	.204
23							.695	.413	.233
24							.770	.465	.266
25							.846	.520	.301
26							.922	.577	.339
27							1.000	.638	.380
28								.700	.424
29								.765	.470
30								.831	.519
31								.899	.569
32								.966	.622
33									.677
34									.733
35									.791
36									.850
37									.910
38									.970

[a] Two-tailed probabilities for the distribution of T, the signed-rank statistic. For a sample size n and value of T, the entry gives the p-value. If a one-tailed test is appropriate, halve the entry. If $n > 12$, go to Section 14.6.

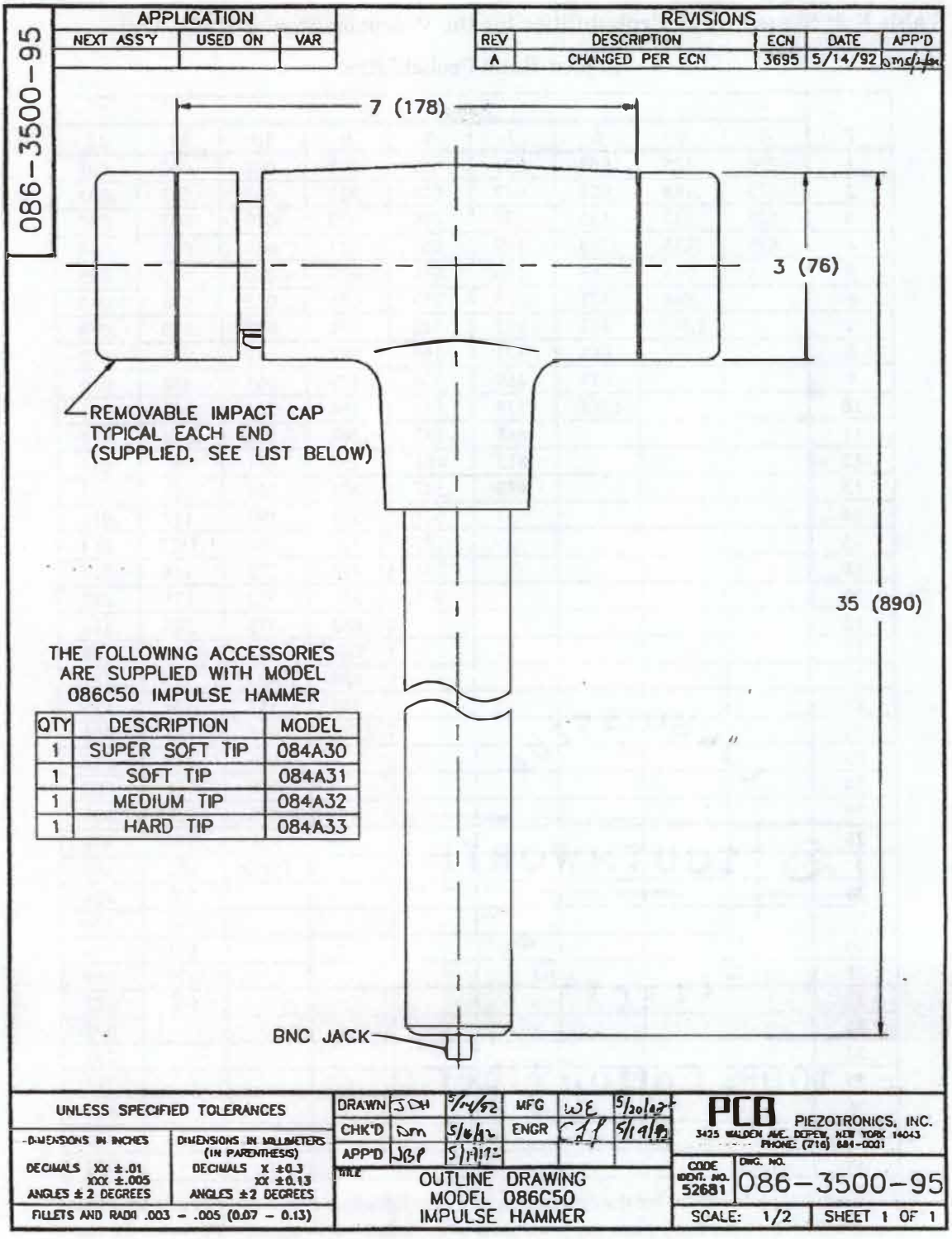


Figure E.2: Impact Hammer Schematics

PCB®
PIEZOTRONICS

SPECIFICATIONS

IMPULSE HAMMER

REVISIONS
-B- Rev# 3695

SHEET 1 OF 1

MODEL NO. 086C50

Frequency Range	kHz	0.50
Hammer Range (5V output)	lb_t (N)	5000 (22000)
Hammer Sensitivity (approx)	mV/lb_t (mV/N)	1.0 (0.23)
Resonant Frequency	kHz	2.7
Hammer Mass	lb (kg)	12 (5.4)
Head diameter	inch (cm)	3.0 (7.6)
Tip Diameter	inch (cm)	3.0 (7.6)
Hammer Length	inch (cm)	35 (89.0)
Connector (coaxial)	jack	BNC
Tip Supersoft	Model Nº.	084A30
Tip Soft	Model Nº.	084A31
Tip Medium	Model Nº.	084A32
Tip Hard	Model Nº.	084A33

APPROVED	KJS	4/10/92	SPEC NO.
ENGINEER	CLL	4/10/92	086-3500-80
PRODUCT MANAGER	JBP	4/10/92	

Figure E.3: Impact Hammer Specifications

VITA

Katie Lin Padgett was born on September 26, 1979, in Huntsville, Alabama. She attended Grissom High School and graduated in May of 1997. After graduation she attended the University of Montevallo in Montevallo, Alabama, to major in Engineering. In the fall of 1999 she transferred to the University of Tennessee, Knoxville to major in Biomedical Engineering. During her undergraduate studies, she worked in the Sports Biomechanics Impact Research lab as well as with Southern Impact Research Center. She graduated in the first class of Biomedical Engineers from UT in May of 2002. Continuing towards a Master's Degree, she re-enrolled at the University. While studying towards Master's, she worked for the freshman engineering program, ENGAGE, as a graduate teaching assistant. She graduated from the University of Tennessee, Knoxville, with a Master's in Engineering Science in May 2005.