I. Abstract

Up to 3.8 million athletes suffer from a concussion each year, with an especially increased risk for athletes participating in contact sports.[1,2] The current standard of care for on-site diagnosis, SCAT5 (an administered test on the side-line for a player with a suspected concussion), has limitations in sensitivity, objectivity, and specificity as it relies on subjective tests and self-reporting of symptoms,[3-9] which increases risk of Chronic Traumatic Encephalopathy.[3,4] Therefore, we developed NeuroBeat, a concussion assessment tool that uses heart rate variability (HRV) to diagnose concussions. We use commercially available heart rate bands to monitor an athlete's HRV during play (Fig 1A). Then, we compare this measurement to their baseline to identify concussions on-site after a possible traumatic incident (Fig 1B). This concept is based on the physiological link between concussions and autonomic nervous system (ANS) dysregulation, which can be detected by changes in HRV.[12-16] We established the feasibility of using HRV as a biomarker for concussion detection by 1) training our algorithm with publicly available datasets (N=601), 2) collecting data using off-the-shelf hardware in our pilot study with collegiate athletes (N=30), and 3) building a data pre-processing pipeline and reiterating our classifier. Based on this, we have the methodology to apply for an IRB-study of collegiate athletes (N=900 with 50% concussed and 50% healthy patients) to further train our algorithm and improve accuracy. Our vision is to enable an accurate and efficient on-site monitoring of athletes at risk of a concussion using existing heart rate wearables.

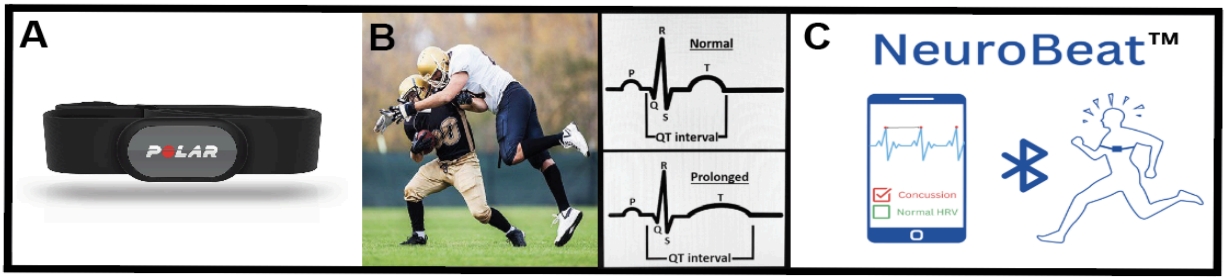


Figure 1: A. Commercially available heart rate band. **B.** External impact on an athlete's head, resulting in changes to HRV. **C.** User interface for NeuroBeat when identifying concussion occurrences.

II. Description of the Problem

Every year 3.8 million athletes suffer from a concussion, with 19% of athletes participating in contact sports being at risk of sustaining one per year of play.[1] Concussions are traumatic brian injuries that typically occur from a blow to the head.[2] Unfortunately, up to half of concussions will go undetected leaving athletes at risk for repeated concussions, resulting in Chronic Traumatic Encephalopathy.[3,4] Studies have found that 92% of ex-NFL players display signs of CTE, which can lead to progressive memory decline and cognition, depression, aggressiveness, and eventually dementia.[5]

The current standard of care for on-site diagnosis, SCAT5, consists of a series of tests including the Maddock's memory questionnaire, m-BESS balance test, and GCS eye-tracking test.[6] The key drawbacks to SCAT5 are lack of sensitivity, subjectivity, and reliance on self-reporting symptoms by athletes and coaches. Studies identified varied results for test-retest reliability of SCAT5, ranging from 20% to 52% sensitivity and 21% to 91% specificity.[7-8] Even objective tests in the SCAT5 had poor diagnostic accuracy and reliability.[7-8] Additionally, athletes may not be aware of, or they may deliberately not disclose their symptoms to avoid removal from the sport.[9]

Motivated by the poor performance of existing real-time diagnosis and monitoring methods, our team is developing a concussion assessment and monitoring device based on physiological symptoms to improve sensitivity, objectivity, and specificity of concussion diagnosis and post-concussion monitoring on-site for collegiate athletes to enable a clear return

to play. Based on the literature review, athlete experiences, and clinician insights, a finalized solution must meet four user requirements in order to improve upon the standard of care experience for concussion diagnoses in athletes that play contact sports (Table 1).

User Requirement	Target Value	Ideal Value
Efficacy: Diagnose concussions on-site and real-time	> 80% accuracy[10]	>90% accuracy
Time: Duration until the determination of concussions	15-20 minutes[10]	Immediate Results
Cost: Cost to implement/develop device	<$799 cost of device[11]	<$500 cost
Usability: Training/handling necessary to use device	Easy to operate by a single person	Hand-held

Table 1: User requirements for the finalized solution to improve upon standard of care

III. Project Objective Statement

To create a solution that enhances on-site concussion diagnosis for athletes, we defined a series of objectives that played a crucial role in achieving a 'proof of concept' for the development of a concussion detection algorithm using collected data:

1. Survey athletes, coaches, and clinicians to further clarify our need: A way to assess the severity of acute head trauma on site in collegiate athletes playing sports who received force to the head in order to decrease the long-term risks of Chronic Traumatic Encephalopathy
2. Develop design specifications required for our solution to address the need
3. Conduct literature review to identify potential biomarkers that can diagnose concussions
4. Generate a classifier that can predict concussions based on pre-existing datasets
5. Develop and pilot a rigorous data collection method and data pipeline for testing healthy athlete volunteers using off-the-shelf hardware
6. Collect data to test our algorithm with cases that are not concussions but present changes compared to baseline heart rate variations

Objective #1: We interviewed 3 collegiate athletes, 2 college athletics coaches, and 2 college athletics team clinicians at Stanford University. Respondents identified that concussion diagnosis is largely based on a series of subjective tests and is often unreliable as athletes may be unaware of or lying about their symptoms (refer to Appendix Table 1 for interview summaries).

Objective #2: We used problems identified from our interviews to establish intermediate design specifications that would demonstrate success in addressing our clinical needs (Table 2).

Problems with Standard of Care (SCAT5)	Design Specification	Target Value
Subjectivity in assessing concussion symptoms	Develop objective/standardized concussion diagnosis approach based on biological biomarker	> 80% accuracy[10]
Insufficient consideration of individual patient factors/environmental factors	Baseline will be taken on all athletes of varying age, race, gender, etc. under different circumstances (rest, active, temperature, etc.)	> 80% accuracy[10] compared to baseline
Requires expert to administer the test and limited amount of people can be tested at once	NeuroBeat algorithm automatically runs on all athletes during play time and will allow for multiple people to be tested simultaneously	No trained personnel required to administer test

Table 2: Design specifications addressing problems to the current concussion diagnosis process, as identified by our interviews.

Objective #3: We conducted a literature review and collected papers investigating the physiological link between HRV and concussions, and identified a variety of sources supporting HRV as a novel biomarker for concussions following head impact.[12-16]

Objective #4: We developed a classification algorithm to determine the likelihood of a concussion based on HRV. We utilized 3 publicly available datasets: 1) TBI dataset (CHARIS database on Physionet with ECG recordings 2) healthy datasetes (CEBSDB and Healthy RR Intervals databases). Refer to Appendix Report 2 for details.

Objective #5: We developed a data collection method and processing pipeline (N=30) using off-the-shelf hardware in our pilot study with collegiate athletes (N=30). We conducted

baseline testing of 15 collegiate athletes (aged 20 ± 2 years), recording ECG data using the Frontier X2 device. Baseline testing was performed at rest and during activity, and we also conducted non-TBI ANS perturbation tests to elicit autonomic nervous system responses. This data was then processed using our developed data pipeline to calculate HRV.

Objective #6: Evaluate the potential sensitivity of the underlying physiological HRV biomarker by using our collected data to test our machine learning classifier algorithm.

IV. Documentation of the design, including a discussion of the innovative aspects.

NeuroBeat is a concussion detection tool (Fig 1) that uses HRV, a promising biomarker for concussions and autonomic nervous system disturbances,[2-13] to diagnose the occurrence of a concussion on-site during play. It uses a commercially-available wearable chest band to continuously monitor the athlete's HRV during play (Fig 1A). If a competing athlete receives an external impact to the head, there is a likely physiological mechanism that alters HRV (Fig 1B). With this mechanism, NeuroBeat uses the new HRV values to compare to baseline for concussion diagnosis, which can aid the athletic team in determining whether the affected athlete should return to play (Fig 1B & C).

Novel Physiological Concussion Biomarker

HRV is a noninvasive indicator of the ANS and can be an indicator of cardiovascular health. Thus, using HRV as a biomarker to detect concussion occurrence is a novel approach that has not been thoroughly researched or tested.[17] We identified that HRV in individuals that have received a traumatic brain injury (TBI) has an elevated heart rate with decreased HRV signifies ANS dysregulation.[12-16] The deactivation of inhibitory nuclei in the amygdala leads to a net increase in sympathetic activity which eventuates in decreased HRV and increased heart rate.[12-16] When a concussion occurs, P wave amplitudes increase as well as the Q-Tc interval.[12-16] Therefore, NeuroBeat can be used during sports practices to monitor post-concussion changes in HRV as previous research has shown persistent and significant changes in HRV post-concussion.[12-13]

Machine Learning Algorithm

Pre-processing Pipeline: We created this pipeline to adjust for differences in ECG data between various publicly available datasets, as we used ECG data from the following Physionet databases: the CHARIS database with TBI patients, and the CEBSDB database/Healthy RR Intervals database with healthy patients. This involved streamlining file types, locating/detecting RR intervals, and removing noise artifactions (refer to Supplementary Report 2 for detailed algorithms and methods used).

Feature Selection: We also chose several features to calculate from the R-R interval data in our first run: Range, IQR, Variance, Standard Deviation, and Coefficient of Variance. We calculated these values and put them in a table in a CSV file. The concussed data was given a value of 1 and healthy data was 0. For our second trial, we added patient age, gender, average heart rate, and mean HRV as features. We selected these features because they present the most salient ones related to affecting the HRV of individuals (refer to Supplementary Report 2 for detailed methods/criteria).

Feature	Reasoning
Age	Age can affect a person's heart rate. HRV is often higher in younger patients, showing they have better health.
Gender	Gender can affect heart rate. Women on average have a higher heart rate than men
BPM	The level of activity can change a person's heart rate. We want our model to work on individuals at different stages of activity (at rest, or during physical activity).
Mean HRV	Mean HRV is the average of all the HRV measurements. Like BPM, this depends on the individual's activity level.
Range	Range shows the difference between the lowest and highest HRV measured. We would expect the range to be greater in healthy patients, and smaller in TBI patients.
IQR	IQR is the range of the middle 75% of measurements. We would expect the IQR to be greater in healthy patients, and smaller in TBI patients.
Variance	Variance shows how much the HRV measurements deviate from the mean. We would expect healthy patients to have more variance, and TBI patients to have less variance.
Standard Deviation	This is a measure of the amount of variation or dispersion of a set of values. We would expect it to be higher in healthy patients, and lower in TBI patients.

Coefficient of Variation	This is a statistical measure of the relative dispersion of data points in a data series around the mean. We expect it to be higher in healthy patients, and lower in TBI patients.

Table 3: NeuroBeat classification algorithm utilizes the following features.

Logistic Regression Algorithm & Testing: We 1) developed our logistic regression model with a 0.75-0.25 training and testing split of the publicly available data (N= 451), 2) tested our data with the 0.25 division (N =150) (obtained results reported in prototype), and 3) tested our algorithm with our newly collected data using the testing pipeline described below (N=30).

Testing Pipeline

In order to ensure NeuroBeat is able to differentiate concussion versus similar ANS disturbances, we conducted testing of athletes under a variety of conditions. We performed both TBI and non-TBI perturbation tests to contribute to scientific validation, enhancing the device's diagnostic capabilities and confidence in its effectiveness.

We collected ECG data using Frontier X2 from a group of 15 collegiate athletes ages (20 ± 2) years. We performed baseline testing of subjects at rest without previous activity. ECG was recorded throughout. We then performed baseline testing of subjects while active (refer to Appendix Report 1 for detailed test protocols). After collecting data from baseline testing, we conducted both non-TBI and TBI perturbation tests. Non-TBI perturbation tests included protocols to elicit ANS responses.The data we collected from these experiments (N=30 samples, as each test is 1 sample) was used to test our ML classifier algorithm to establish the feasibility of our product. We also developed a preliminary software and app interface that can be used by athletic teams (refer to Supplementary Link 2 for data collection video; Supplementary Report 1 for experimental protocol).

V. Prototype of the final design

The latest NeuroBeat prototype includes 1) trained algorithm with publicly available datasets (N=601), 2) data collection methodology using off-the-shelf hardware developed in our pilot study of collegiate athletes (N=30), and 3) a pre-processing/training pipeline for our newly collected data that reiterates into our classifier. Neurobeat is a proof-of-concept classifier that uses HRV as a biomarker to detect concussions.

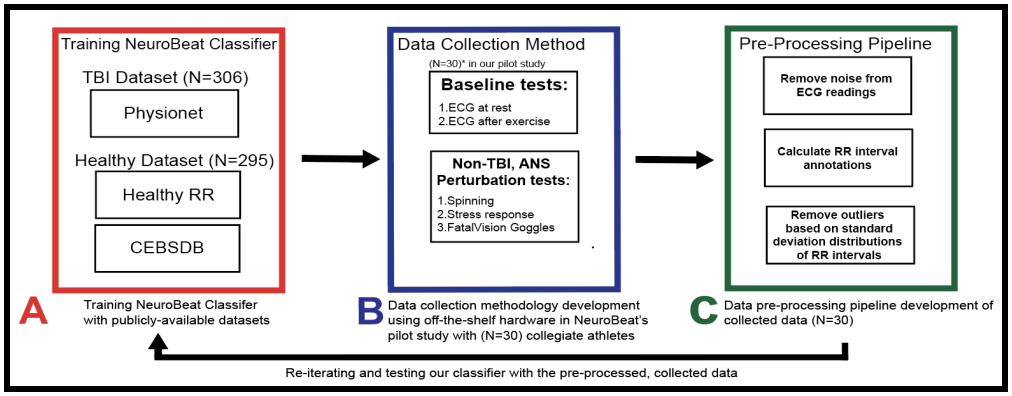


Figure 2: A. Process of training classifier based on publicly available datasets of HRV in concussed and healthy patients. **B.** Developed data collection methods of baseline/non-TBI ANS perturbation tests using off-the-shelf hardware to further iterate our device. **C.** Data preprocessing pipeline used to process the data collected.

Currently, Neurobeat's logistic regression classifier utilizes 295 ECG recordings from TBI patients and 306 ECG recordings from healthy patients. We chose to use a Logistic Regression model because we only screened for 2 outputs. We used a max_iteration value of 500, an 'lbfgs' solver, and a classification:test ratio of (0.75: 0.25). We randomized our test-seed to include cross-validation in our logistic regression model.

NeuroBeat's Training Algorithm Results:

Statistics	Reported Percentage	Sample Size
True Positive	91.03%	63
False Negative	8.97%	7
True Negative	87.5%	71
False Positive	12.5%	9

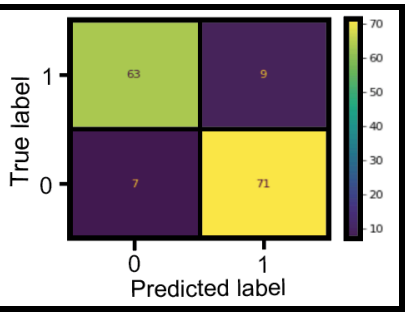
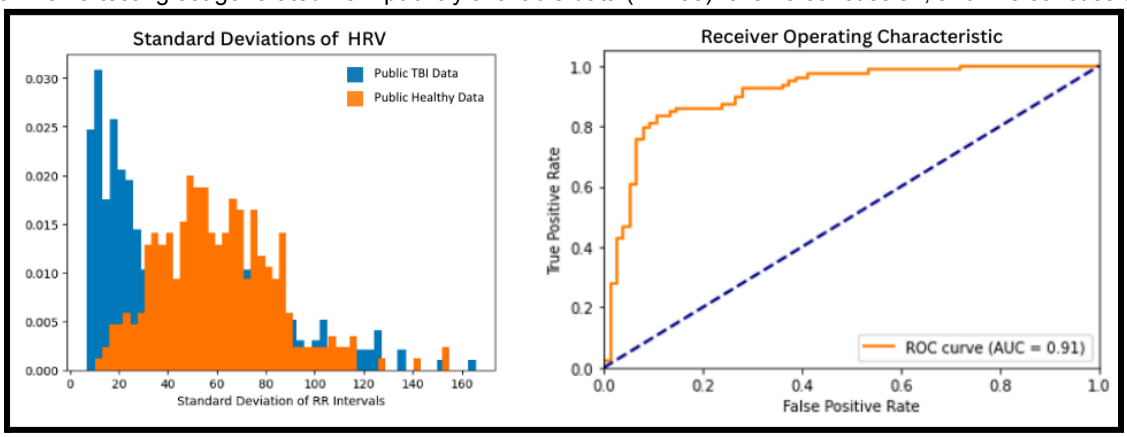


Table 4 (left): NeuroBeat's initial results using publicly available datasets: CHARIS, CEBDSB, and Healthy RR databases (N=150). **Figure 2 (right):** Concussion matrix for NeuroBeat's trained classifier (N= 451) after running an algorithm on a testing set generated from publicly available data (N=150). 0 is no concussion, and 1 is concussion.



Figures 3.1 (left): Histogram of Standard Deviations from TBI and Healthy Data. They show two distinct Standard Deviation of HRV in concussed and healthy patients. **Figure 3.2 (right):** The ROC curve of our model after running the model on our testing set. The 0.91 AUC of the ROC curve indicates that the model has good discriminatory power in distinguishing between concussed and healthy cases.

The results demonstrated that our classification algorithm had an accuracy rate of 89.33% (cross-validation results demonstrate an accuracy rate of ~86%). NeuroBeat's model uses standard deviation to differentiate between concussion and healthy readings (Fig 3.1, left). This supports our hypothesis that HRV is different in healthy and concussed individuals, which can be measured through Standard Deviation, which was used to differentiate between the two groups (Fig 3.1, left).These results are promising and suggest that the relationship between HRV and concussions should be looked into further.

VI. Proof of Functional, Need-Solving Design

Our final objective was to evaluate the efficacy of our algorithm by utilizing our newly collected data and compare our results to the standard of care (SCAT5). We trained our classifier on all 601 samples of the pre-existing data, and tested using the 30 test samples of data we collected from 15 individual athletes. Running our NeuroBeat algorithm on our collected data set, our algorithm had a 83.33% accuracy rate and a false positive rate of 17.2%. Our false positives are described in Fig 5 below, along with the confidence scores.The confidence threshold was set at 50%. That is, if the model was 50% sure that the sample had a concussion, it would predict a concussion.

The beta coefficient results (N=30) indicates that Standard Deviation is most implicated in determining whether the sample of HRV is concussed or healthy (Fig 4), as we expected.

We hope to get an IRB study approval in the future to collect more data, especially from concussed individuals. We can then improve our algorithm and discover the best thresholds to set to maximize true positive and minimize the false negative rates.

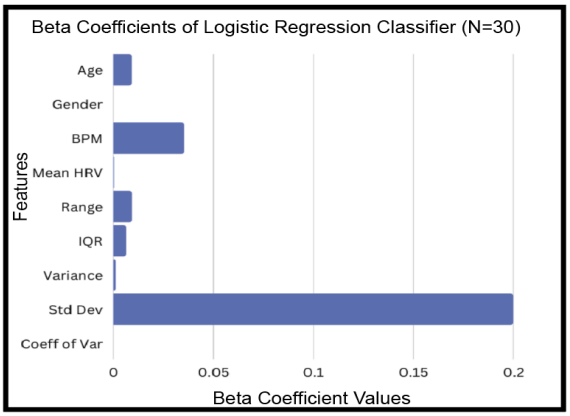
NeuroBeat's Testing Results with Collected Data:

Statistics	Reported Percentage	Sample Size
True Negative	82.75%	25
False Positive	17.24%	5

***We only had one concussion sample (described below), which was identified correctly, but was not enough to warrant a objective determination of our true positive and false negative rates.*

Table 5 (above): NeuroBeat's testing results (true negative, false positive) with collected data (N=30).

Figure 4 (right): The beta coefficient values of our algorithm after running the algorithm on our testing set of collected data.



Athlete Sample	Predicted Value	Expected Value	Confidence Score
1	0	0	73.51496603
2	0	0	51.7771108
3	0	0	89.305202
4	1	0	62.31901164
5	1	0	56.42855264
6	1	0	65.87394971
7	0	0	77.17004996
8	0	0	59.28478348
9	0	0	60.33704071
10	0	0	80.55246145
11	0	0	66.12358639
12	0	0	81.96101557
13	1	0	99.36101935
14	0	0	80.54056732
15	0	0	70.22204531
16	0	0	52.82243866
17	0	0	82.0942938
18	0	0	55.48331285
19	0	0	61.50081077
20	0	0	60.37245343
21	0	0	84.73873022
22	0	0	62.06658774
23	0	0	63.71505063
24	1	0	62.8512245
25	0	0	68.98069993
26	0	0	55.98186662
27	0	0	76.80017198
28	0	0	62.5249625
29	0	0	64.11532792
30	1	1	91.03297736

Figure 5: The results of running our algorithm on the data that we collected (N=30).

NeuroBeat classified Samples #4, #5, #6 incorrectly, but they were from the same person (Active Baseline, FatalVision, Word Test). The 3 samples did not have high confidence. It is possible that the athlete may have had underlying head trauma, or that this person may have HRV that is different from other subjects. We will continue to reiterate our device to identify reasons behind these false positives. Of the incorrect samples, #13 Active Baseline was faulty because we did not wait long enough for the heart rate to reach rest. Additionally, 52% of the ECG recording was reported as "other noise" so it may be that the noise interfered with our algorithm, and was not effectively pre-processed. While we anticipated that the algorithm not predict a concussion for these athletes, our algorithm predicted that the #30 Active Baseline sample had a concussion with a 91.03% confidence score. Even though we had initially assumed this was a faulty classification, upon retrospectively analyzing our initial screening, we realized that this participant had identified brain trauma in their recent history (~1 day prior to participating in data collection), which is why only the active baseline was collected. This suggests potential sensitivity of the underlying physiological mechanism of HRV, which further IRB-approved studies can confirm.

User Requirement	Target Value	NeuroBeat Value (with publicly available datasets)	NeuroBeat Value (with collected data)
Efficacy: Diagnose concussions on-site and in real-time	> 80% accuracy	~86% accuracy	83.33% accuracy
Time: Duration until the determination of concussions	15-20 minutes	10-15 minutes	10-15 minutes
Cost: Cost to implement/develop device	< $799 cost of device	< $500 cost of device	< $500 cost of device
Usability: Training/handling necessary to use device	Easy to operate by a single person	Easy to operate by a single person	Easy to operate by a single person

Table 3: NeuroBeat meets two of our most essential requirements for the detection of concussions as a finalized solution to improve upon the standard of care (efficacy, cost). We will continue our testing/iterative processes to develop our prototype.

VII. Results of a patent search and/or search for prior art, assessment and patentability

We did not find any previously documented IP that detects concussion using an ECG signal. This biomarker is relatively novel, and no company has yet to license or develop a product to detect concussions based on HRV.

Figure 6: Brainscope device, showing collection of EEG signal for concussion detection classifier.

Our product's competitor would likely be the "Brain Concussion Detector" patented by BRAINSCOPE SPV LLC (Fig 6). This product uses a prediction algorithm to detect concussions via an EEG signal (Patent number: 9477813). Brainscope obtained a patent for their method of building classifiers for neurological assessment, specifically for extracting quantitative features from clinical features and selecting for binary classifiers. However, this should not create serious IP issues for NeuroBeat uses an entirely different biomarker for detecting concussions. The use of ECG as our biomarker allows us to set ourselves apart from BRAINSCOPE and should protect us from any IP difficulties. Our product stands above BRAINSCOPE as an onsite concussion detecting system because of its compatibility with various types of heart-rate monitors that can be worn during play. This will drastically increase its ease of use and improve the chances of detecting a concussion soon after it occurs.

Our product achieves all of the necessary requirements for acquiring a patent. There are three main design features that separate NeuroBeat from existing technologies. First, NeuroBeat uses HRV as a biomarker for concussion detection. This is a novel biomarker that hasn't been utilized in any products related to concussion detection. Second, NeuroBeat uses a novel method and device for building the classifier component. We have developed our own pre-processing pipeline of extracting quantitative features related to HRV, which is a series of steps that are novel and inventive. We aim to make our data pipeline fully automated, which can then be used to train our classifiers with high sensitivity, specificity, and classification accuracy. This type of classifier builders (with different feature selection criteria) have been patented previously (Patent number: 1032184), which means our selection methodologies and classifier development process can also be considered for a patent. Finally, NeuroBeat also includes the development of a series of novel ANS perturbation tests which are then re-iterated into our classifier to improve accuracy. This will be automated in the long run, and these tests (spinning, FatalVision, stress tests) are novel.

Patent Criteria	NeuroBeat meets criteria
Novelty	1. NeuroBeat uses HRV, a novel biomarker, to detect the occurrence of a concussion. This is new, and has not been done before. 2. NeuroBeat classifier uses a novel pre-processing pipeline to extract

	quantitative features related to HRV, which is a newly-developed protocol. 3. NeuroBeat classifier also includes a testing-reiterating mechanism including a series of ANS tests to drive up accuracy and efficacy.
Inventive step	The physiological mechanism between HRV and concussions is not obvious, and has yet to be utilized in commercial settings.
Industrial applicability	The invention can be made to have practical use in the athletic communities across the United States in concussion diagnosis.

Table 6: NeuroBeat's patentability criteria.

Potential future devices that may compete with our device is using HRV biomarker for concussion detection, which is why timely filing of a provisional patent is integral to our product. We do not anticipate that there will be other products utilizing our classifier algorithm/testing-reiteration protocol, as those were developed from our unique data collection process.

VIII. Anticipated regulatory pathway

We anticipate that Neurobeat would follow the 510(K) regulatory pathway. Our device has design features that separate it from Brainscope's classifier (Patent: 1032184), mainly by using HRV as a biomarker as well as a series of unique feature selection, quantification, and reiteration, but because it is substantially equivalent to the classifier development *process* that Brainscope followed, we also anticipate approval for the 510(k) pathway.

Another option, after consulting with the Stanford Office of Technological Licensing, is that our device may fall outside the definition of a medical device if developed appropriately, which means we do not need to apply for FDA approval to place our device into the market. While its therapeutic relevance in diagnosing concussions is important to creating NeuroBeat, at its core Neurobeat is designed to *aid* on-site diagnosis of concussions along with professional health check-ups. In fact, this is considered the norm in the concussion health space. There are no FDA-approved concussion testing apps on the market currently, though there are numerous apps that are only one component of concussion diagnosis (like Brainscope) and management protocol or allow users to record important information related to suspected concussions. Therefore, without asserting medical claims related to our device, the device is no different than other apps/tools that have been developed in the concussion health space.

IX. Reimbursement

NeuroBeat will not be reimbursable by Medicare or Medicaid. The most likely scenario is that our product is considered an optional assistive device rather than a medical necessity, and therefore will not be reimbursable by Medicare or Medicaid. In this case, our device will be purchased by athletic programs (collegiate and professional). In this scenario, we would contract directly with these clients. Our product will most likely be delivered online, via our own website that includes a software package and an installable application.

Because NeuroBeat will be marketed primarily to college athletic programs, the reimbursement plan may also depend on the specific requirements and policies of the athletic program and the state regulations governing sports-related medical testing. The device may need to be approved or recommended by medical professionals associated with the athletic program, and the reimbursement may be limited to a certain number of uses or a specific period of time. The reimbursement plan for "NeuroBeat" will likely be subject to a range of factors, including insurance company policies, state regulations, and the requirements of the college athletic program. Careful consideration and planning will be required to navigate these various factors and ensure that the device is accessible and affordable for those who need it. Additionally, we plan on partnering with other heart rate wearable devices in the market, so our payment/reimbursement plan may also depend on the development of these partnerships.

X. Estimated manufacturing costs

Our device will most likely include a purchase/use of existing heart rate wearables in the market, which on average cost $250-300 per unit. We aim to make our software flexible so that

it can work with a variety of these devices. We do not have other costs to build our application or algorithm, but have costs associated with building our software package and app interface (estimated to be $5000-7000). Assuming a monthly subscription fee and one-time purchasing fee of $1000 and $3000, there is sufficient gross margin to support device manufacturing and packaging. With pre-existing heart rate wearables, as well as utilization of off-the-shelf technologies that is relatively inexpensive compared to Brainscope's ECG device ($20,000 per unit) or Eye-Sync goggles used at Stanford University's football team ($25,000 per unit), our product presents an affordable option for many collegiate athletic teams.

XI. Potential market and impact

Our device's ability to risk the long-term risk of CTE will reduce the healthcare costs associated with the grueling process of concussion diagnosis and treatment.

NeuroBeat is a device that detects concussions through ECG, and is marketed primarily to college athletic programs. In order to understand the potential market for NeuroBeat, it's helpful to consider the TAM, SAM, and SOM for the device.

Type of Market	Description	NeuroBeat's Market Potential (Calculated in Numbers)
Total Addressable Market (TAM)	High school/youth sports programs and professional sports teams in the US.	This population encompasses 8 million individuals participating in high school and almost 500,000 athletes competing at the collegiate level.[24]
Service Addressable Market (SAM)	College athletic programs in the US.	This population includes 500k competing collegiate athletes that have a need for concussion detection and diagnosis services, and that are able/willing to pay.[24]
Serviceable Obtainable Market (SOM)	Collegiate athletic programs in California.	This population includes D1-D3 athletic programs from universities in California, with around 600 colleges.[25]

Table 4: TAM, SAM, and SOM specifications for NeuroBeat.

The potential market size of these groups in **contact sports** in California are described below.

Category	Associated Calculations	Description
Target Market	600 colleges	This population includes D1-D3 athletic programs from universities in California, with around 600 colleges, with an average of 8 sports teams involved in contact sports (soccer, football, wrestling, and baseball).
# of Athletes	15 athletes per team * 10 teams	Assuming an average of 15 athletes per team (as most team sports include more players than necessary). Average of 10 teams per university.
Prevalence of Concussions	1 concussion per year	Assume one concussion per year (conservative estimate to account for potential concussion range across contact sports).
Adoption Rate	25%	Assuming adoption rate of 25% (but will vary according to marketing strategy, etc;).
Pricing	$3000 (one-time fee) + $1000 monthly fee (per person)	**Developed based on pre-existing models (competitiveness) and manufacturing costs described above.
Number of Potential Users	22500	# of athletes * adoption rate * # of universities * # of teams
Estimated Annual Revenue	$288,000,000	(# of potential users * monthly fee * 12) + (# of teams * purchasing free)

Table 4: Estimated Revenue Model of NeuroBeat

If we scale up beyond California and can break the initial market penetration rate, then NeuroBeat holds the potential for beyond what is listed above. However, this remains our immediate main goal.

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