NCT 03257189

Statistical Analysis Plan (SAP)

BioStamp nPoint Pivotal Trial

A Study to Evaluate the Performance, Usability, and Reliability of a Novel Device for Continuous Collection of Physiological Data in Healthcare and Remote Settings

Version 1.1

September 14, 2017

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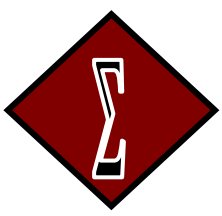

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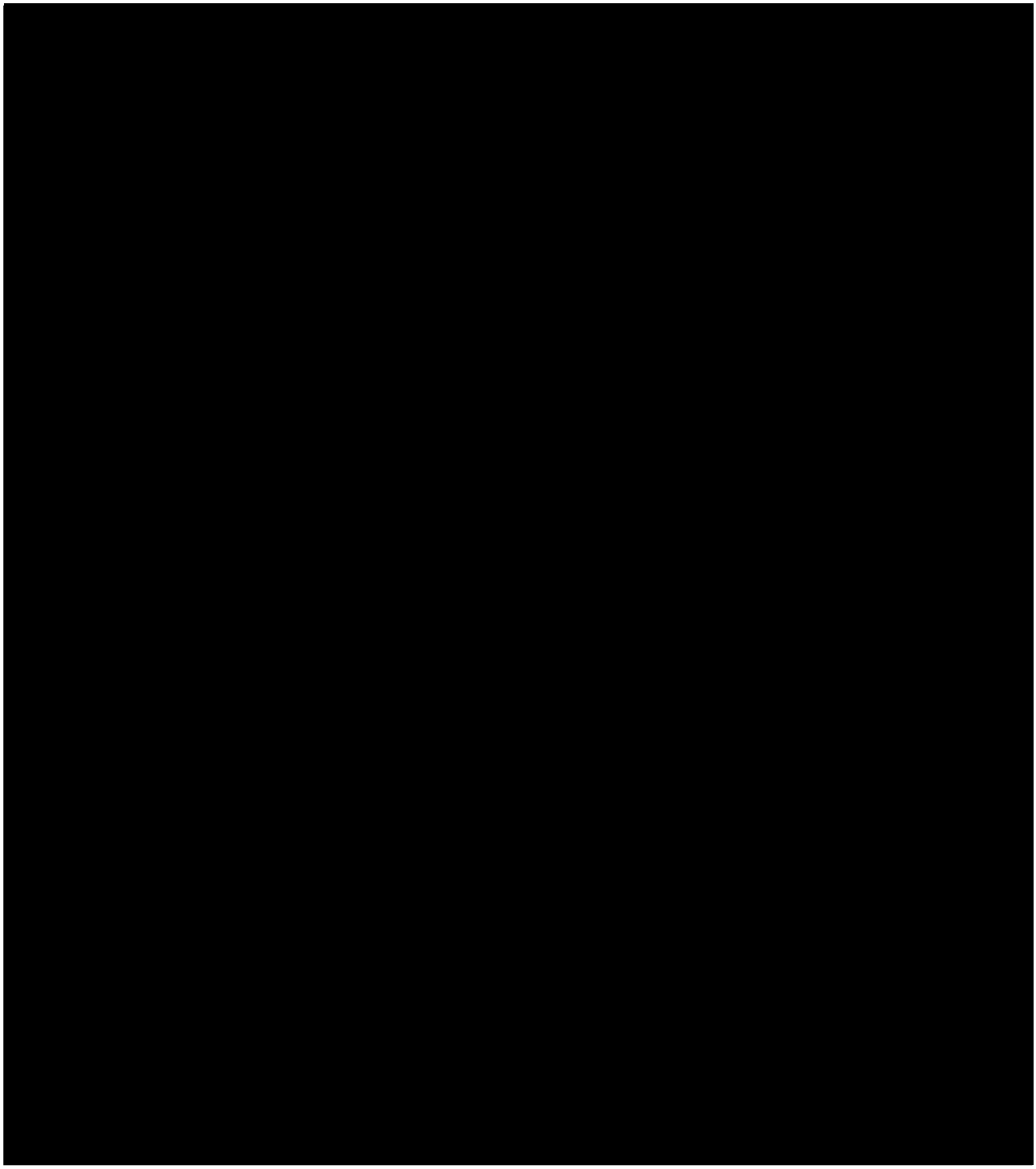

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1.0 Synopsis of Study Design Procedures

This is a study of the use of a wireless remote monitoring system intended for use in the continuous collection of physiological data in home and healthcare settings. These data include heart rate, heart rate variability, respiration rate, activity (including step count and activity classification), and posture. The device is intended for use on general care patients who are at least 18 years of age. It is not intended for use on critical care patients.

The primary objectives of the study will be to evaluate the accuracy of BioStamp nPoint system algorithm measurements in collecting physiological data. The parameters to be summarized are:

- Heart rate (bpm);
- Heart rate variability as measured by RMSSD (Root-mean-square of successive difference of successive heart beats);
- LF/HF ratio (the ratio of power in the low-frequency (0.04- 0.15 Hz) and high-frequency (0.15- 0.4 Hz) ranges of Heart rate variability;
- Respiration (average respiration rate)
- Activity classification (sleeping, standing, sitting, lying, walking, and other);
- Activity parameters (total step count in a six-minute walk test);
- Sleep (sleep activity classification, sleep onset time [HMS], and wake time [HMS]); and,
- Posture classification (stationary posture lying, stationary posture standing, stationary posture sitting).

Assessment of the primary objective will be based on the comparison of the BioStamp nPoint device readings with those of FDA approved devices (Actiheart Device for cardiac measurement, Capnostream Device for respiration, a manual step-count device for activity, and an independent observer for activity classification, posture and sleep parameters).

The secondary objective of the study will be to validate the performance of the sensor skin adhesive.

1.1 Design and Treatment

This is a single-site, non-significant risk, open-label prospective nonrandomized clinical investigation. The study will recruit at least twenty-five (N=25) healthy subjects to participate in the study.

Subjects will be screened prior to enrollment. They will provide informed consent and respond to a screening survey for demographic variables and prior medical history. They will undergo a baseline assessment (weight, height, further medical history, and a check of sensor location irritation. Female subjects of child-bearing potential will receive a urine pregnancy test. All participants will undergo a drug screen.

Enrolled participants will return to the clinic for a 48 hour assessment period.

1.2 Study Procedures

Subjects will undergo one supervised session of approximately four hours, with observation periods throughout the remaining 48 hours, including two night-time sleep periods. At least one telephone call will be made within three to five days post-sensor removal to assess safety and tolerability of the device.

1.2.1 Day 0 Procedures

Active BioStamp nPoint sensors will be placed on subject's left chest (above the heart) and right thigh and inactive BioStamp nPoint sensors place on their right shank and forearm. Sensors for the Actiheart heart monitor will be attached to their precordium. During the supervised session the subject will perform the activities specified in Table 1 five times. The order of the activities will be varied by the clinician.

Table 1. Supervised activities for the BioStamp nPoint pivotal trial.

Item	Activity	Description	Time	Repetitions	Metrics
1	Standing Classification	Instruct the subject to stand upright. Once the subject is standing upright, start the activity.	1 min	5	ADL Classifier – Standing HR/HRV – Resting
2	Sitting Classification	Instruct the subject to sit in a chair. Once the subject is sitting, start the activity.	1 min	5	ADL Classifier – Sitting HR/HRV – Resting
3	Lying Classification	Instruct the subject to lie supine. Once the subject is lying in a supine position, start the activity.	1 min	5	ADL Lying HR/HRV – Resting
4	Standing Upright	Instruct the subject to stand against the marked wall, with their right side facing the wall. Instruct the subject to stand upright. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting
5	Standing Leaning FRONT	Instruct the subject to stand against the marked wall, with their right side facing the wall. Instruct the subject to lean forward to the 30-degree mark. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting
6	Standing Leaning BACK	Instruct the subject to stand against the marked wall, with their right side facing the wall. Instruct the subject to lean back to the 30-degree mark. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting
7	Standing Leaning RIGHT	Instruct the subject to stand facing the marked wall. Instruct the subject to lean right to the 30-degree mark. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting
8	Standing Leaning LEFT	Instruct the subject to stand facing the marked wall. Instruct the subject to lean left to the 30-degree mark. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting

Item	Activity	Description	Time	Repetitions	Metrics
9	Sitting Upright	Instruct the subject to sit in a straight-backed chair. Instruct the subject to sit upright. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting
10	Sitting Leaning FRONT	Instruct the subject to sit in a chair. Instruct the subject to lean forward to the 30-degree mark. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting
11	Sitting Leaning BACK	Instruct the subject to sit in a chair. Instruct the subject to lean back to the 30-degree mark. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting
12	Sitting Leaning RIGHT	Instruct the subject to sit in a chair. Instruct the subject to lean right to the 30-degree mark. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting
13	Sitting Leaning LEFT	Instruct the subject to sit in a chair. Instruct the subject to lean left to the 30-degree mark. Once the subject is in position, start the activity.	1 min	5	Posture HR/HRV – Resting
14	Lying SUPINE	Instruct the subject to lie on their back. Once the subject is in position, start the activity.	1 min	5	Sleep posture HR/HRV – Resting
15	Lying PRONE	Instruct the subject to lie flat on their stomach. Once the subject is in position, start the activity.	1 min	5	Sleep posture HR/HRV – Resting
16	Lying RIGHT	Instruct the subject to lie on their right side. Once the subject is in position, start the activity.	1 min	5	Sleep posture HR/HRV – Resting
17	Lying LEFT	Instruct the subject to lie on their left side. Once the subject is in position, start the activity.	1 min	5	Sleep posture HR/HRV – Resting
18	Walking	Instruct the subject to walk for 6 minutes. Once the subject starts walking, start the activity. Count total steps taken by the subject, both legs. Post-activity assessment: How many total steps did the subject take during the walking activity?	6 min	5	ADL Classifier – Walking Pedometer HR/HRV – Moving
19	Walking Classification	Instruct the subject to walk on the treadmill at a constant, comfortable pace. Once the subject starts walking, start the activity.	1 min	5	ADL Classifier – Walking
20	Other Classification	Instruct the subject to bike at a constant, comfortable, low-intensity pace. Once the subject starts biking, start the activity.	8 min	5	ADL Classifier – Other HR/HRV – Moving

Prior to retiring for the night, the Capnostream respiration reference device will be applied. Staff will record the sleep onset and wake times on the CRF. Subjects will be observed periodically and any times of wakefulness will be recorded on the CRF.

After 24 hours of sensor wear, clinic staff will rate the sensor skin adhesion and skin irritation using the scales shown below in Table 2.

Table 2 Adhesion and Skin Irritation Scoring Scales

Score	Adhesion Rating	Description
0	≤10% detachment	Essentially no lift-off from skin.
1	10% < detachment ≤ 25%	Some edges only lifting off from skin.
2	25% < detachment ≤ 50%	Less than half of sensor lifted off from skin.
3	51% < detachment < 99%	More than half of sensor lifted off skin, but sensor still attached to skin.
4	100% detachment	Sensor detached from skin.
Score	**Irritation Rating**	**Description**
0	Weakly positive reaction	usually characterized by mild erythema and/or dryness across most of the treatment site
1	Moderately positive reaction	usually distinct erythema or dryness, possibly spreading beyond the treatment site
2	Strongly positive reaction	strong and often spreading erythema with edema and/or eschar formation
3	Weakly positive reaction	usually characterized by mild erythema and/or dryness across most of the treatment site

1.2.2 Day 1 Procedures

On Day 1, subjects will be trained in the application and use of the BioStamp nPoint sensors and the Link App. Under observation by a clinician, the subject will apply the chest and thigh sensors. Using the Link App, the subject will perform and annotate the activities shown in Table 3 prior to departing the clinic.

Table 3. Additional heart rate activities.

Item	Activity	Description	Time (minimum)	Repetitions	Metric
1	Sitting	Sit comfortably in a chair	22 min	At least 2, up to 4	HR/HRV – Resting
2	Walking	Walk on a treadmill at a comfortable pace	22 min	At least 2, up to 4	HR/HRV – Moving
3	Biking	Bike on a recumbent bike at a comfortable pace	22 min	At least 2, up to 4	HR/HRV – Moving

The Capnostream device will again be attached before the subject retires for the night. Sleep parameters will be measured as for the first night. Upon rising on Day 2 the subject will remove the sensors from thigh and chest, clean them, synchronize the recorded data, and begin to recharge the sensors under the supervision of a clinician. Safety and tolerability will be assessed by the clinician after removal.

Subjects will complete a usability survey related to the intuitiveness and ease of use of the BioStamp nPoint system. A safety follow-up telephone call will be made between Day 3 and Day 5 to assess adverse events associated with study participation.

1.3 Sample Size

The sample size of N=25 subjects was selected to be consistent with sample used by the predicate device to evaluate the accuracy of similar measurements, as well as to be appropriate to evaluate basic ease of use and intuitiveness of the system. Up to five (5) additional subjects may be enrolled to account for a 20% dropout rate.

2.0 Data Analysis Considerations

2.1 Types of Analyses

The objectives of the statistical analysis are:

- to assess the accuracy and precision of the BioStamp nPoint system relative to FDA-approved standard devices in measuring cardiac parameters, respiratory parameters, and step counts;
- to assess the ability of the BioStamp nPoint system to correctly classify posture and activity; and,
- to assess the adhesive used in the BioStamp nPoint sensors.

No formal hypothesis tests or confidence intervals will be performed.

2.2 Analysis Populations

The following analysis populations will be defined for the study:

Intent-to-Measure (ITM) Population – The ITM population will consist of all subjects who are enrolled in the study and for which the ability of each measurement device has been established.

Per-Protocol (PP) Population – The PP population will consist of all subjects enrolled in the study for whom the algorithm could determine the correct predicate conditions for measurement. For example, the BioStamp only measures respiration rate when it classifies the subject as being asleep.

Safety Population – The safety population will consist of all subjects who are enrolled in the study.

The ITM population will be the primary analysis set for all effectiveness analyses. Effectiveness analysis will also be computed for the PP population. If the ITM and PP populations are identical the PP analysis will be omitted. The safety population will be used for the analysis of all safety variables and baseline characteristics.

2.2.1 Subgroup Definitions

No subgroup analyses are planned.

2.3 Missing Data Conventions

In the statistical analysis of the primary effectiveness endpoints of the study, only subjects with evaluable endpoints will be used in the statistical analysis, i.e., a complete case analysis.

2.4 Interim Analyses

No interim analysis is planned for this study. Checking device data integrity by the sponsor does not constitute interim analysis.

2.5 Study Center Considerations in the Data Analysis

A study center is defined as a treatment administration site or group of treatment administration sites under the control and supervision of the same Principal Investigator (PI). This study is being conducted at a single study site.

2.6 Documentation and Other Considerations

The data analyses will be conducted using SAS(R) Software, Version 9.2 or higher.

3.0 Analysis of Baseline Subject Characteristics

The continuous demographic characteristics at screening (age, height and weight) will be summarized for all subjects in the safety population using descriptive statistics (mean, standard deviation, median, minimum, maximum, and number of non-missing observations). The categorical baseline characteristics (gender, race, ethnicity) will be summarized for the safety population using frequency counts and percentages.

Detailed listings of all baseline and demographic data for each subject will also be provided as shown in Appendix B.

4.0 Efficacy Analysis

4.1 Description of Efficacy Variables

4.1.1 Primary Efficacy Variables

The quantitative variables associated with cardiac status are:

- Heart Rate (beats per minute);
- Heart Rate Variability Root Mean Square Successive Difference (RMSSD) of the time intervals between successive heart beats;

- Heart Rate Variability LF/HF, the ratio of power in the low frequency (0.04 Hz to 0.15 Hz) and high frequency (0.15 Hz to 0.40 Hz) bands of heart rate variability in the frequency domain.

The values collected will be based on one-minute average heart rate, five-minute RMSSD, and the five-minute LF/HF ratio collected from both the BioStamp nPoint device and the Actiheart monitor.

Respiration rate will be measured as the average respiration rate (breaths per minute) collected continuously in one-minute time intervals during sleep by both the BioStamp nPoint device and the Capnostream respiration monitor.

Activity will be measured as the total step count during a 6 minute walk test as measured by the BioStamp nPoint device and a clinician following the subject using a manual counter.

Sleep onset time (HMS) and sleep wake time (HMS) will be measured by the BioStamp nPoint device and an independent observer. The error in sleep onset and sleep wake time will be calculated as the absolute difference between the value measured by the device and the value recorded by the independent observer. The device's ability to accurately measure the length of sleep intervals will be assessed with two nights' sleeping periods. The device's measurement of time of sleep onset and time of rising will be used to compute the length of the sleep period. This will be compared with the length of the sleep period based on the times recorded by the clinical staff.

The qualitative variables in this study include:

- Activity classification (standing, sitting, lying down, walking, and other);
- Detecting sleep periods (sleep, and any other activity);
- Posture (stationary posture while lying down, stationary posture while standing, stationary posture while sitting).

Activity classification will be measured by presenting each subject with five tasks (standing, sitting, lying, walking, and stationary bicycling) in varied order. The activity classification will be recorded by the BioStamp nPoint device and an independent observer. This will be repeated five times per subject.

Posture classification variables will be analyzed separately for each type of posture activity (stationary posture lying, stationary posture standing and stationary posture sitting). For a given posture activity, the posture classification will be recorded by the BioStamp nPoint and the independent observer for two repeats each of each ground-truth posture for each subject. Each repeat will generate 5 independent observations of posture. The posture classifications for each posture classification variable are given in Table 4 below.

Table 4. Posture variables and classifications.

Index	Posture Variable	Posture Classification
1	Stationary Posture Lying	Supine, prone, left side and right side
2	Stationary Posture Standing	Upright, lean left, lean right, lean back, lean forward
3	Stationary Posture Sitting	Upright, lean left, lean right, lean back, lean forward

4.1.2 Secondary Efficacy Variables

The number and percentage of sensor patches in each category of the adhesion scoring scale shown in Table 2 above will be tabulated.

4.2 Analysis of Efficacy Variables

For pairs of measurements collected on the continuous scale (quantitative to quantitative comparisons), scatter plots with the 45 degree line of agreement superimposed will be constructed from paired observations from the two sources (BioStamp nPoint vs comparator) along with Bland-Altman plots of the data. The mean absolute error (MAE) and the root-mean-square error (RMSE) estimates of agreement will be calculated for each comparison. The product-moment correlation coefficient and Deming regression estimates will be computed. Table 5 outlines the data generation and data reduction for each phase of the study.

Table 5. Data generation and sample selection.

Endpoint	Duration of Data Generation	Sample Points Needed for Data Analysis
Overall Heart Rate	Sleep: 14 hrs, 2 nights Rest: 75 min Moving: 88 min	24/subj (8/subj from sleep 8/subj from resting activities 8/subject from moving activities)
Heart Rate Variability (RMSSD)	Sleep: 14 hrs, 2 nights Rest:75 min Moving: 88 min	24/subj (8/subj from sleep 8/subj from resting activities 8/subject from moving activities)
Heart Rate Variability Ratio (LF/HF)	Sleep: 14 hrs, 2 nights Rest:75 min Moving: 88 min	24/subj (8/subj from sleep 8/subj from resting activities 8/subject from moving activities)
Respiration (Average Respiration Rate)	14 hrs, 2 nights	6/subj

Endpoint	Duration of Data Generation	Sample Points Needed for Data Analysis
Activity Classification (standing, sitting, lying down, walking, other, and sleeping)	36 min	30/subj (5/activity classification)
Activity Parameter (Step Count)	30 min	5/subj
Sleep Onset Time/Wake Time	Sleep Onset: 2 nights Wake Time: 2 mornings	4/subj (2/subj from sleep onset 2/subj from wake time)
Posture	Laying: 20 min Sitting: 25 min Standing: 25 min	70/subj (20/subj from laying 25/subj from sitting 25/subj from standing)
Sensor Adhesion, skin irritation	24 hours	6/subj

For pairs of measurements collected on a categorical scale (qualitative to qualitative comparisons), two-way tables of agreement will be constructed for each comparison. The agreement percentage and the Uncertainty Coefficient (also called Theil's U and proficiency) will be computed for each table. U will be computed for the true state given the BioStamp classification.

5.0 Analysis of Safety

5.1 Description of Safety Variables and Analysis

Safety will be assessed using adverse event (AE) occurrences. Adverse events (AEs) will be monitored on each subject from the time of enrollment to exit from the study. AEs that are collected from the time of informed consent to immediately before device application will be recorded in the medical history.

The following safety analyses will be conducted on the safety population.

Adverse Events
All AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA). Safety will primarily be assessed through treatment emergent adverse events (TEAEs). An AE will be considered treatment emergent if the start date and time is on or after the start date and time of the application of the sensors. If the AE has a missing start date or time, then the event will be considered treatment emergent.

TEAEs will be summarized by the total number and by the number and proportion of subjects reporting at least one occurrence of the TEAE. Frequencies of each TEAE will be summarized by MedDRA preferred term within system organ class (SOC) and by severity, relation to study device, and time of onset (before or after the initiation of study device). Frequencies of each SAE will be summarized by total number, by the number

and proportion of subjects reporting at least one occourrence of the SAE, and by MedDRA preferred term within system organ class (SOC).

All adverse events will be listed, as shown in Appendix B.

6.0 Other Relevant Data Analyses/Summaries

6.1 Subject Completion/Withdrawal

A table will be constructed with counts and percentages of the number of subjects who were screen failures, the number of subjects enrolled in the study, the number of subjects withdrawn from the study before study completion, and the number who completed the study. For those subjects who withdrew before completion of the study, counts and percentages of the reasons for withdrawal will be tabulated. A data listing of all subject completion/withdrawal data will also be constructed for all screened subjects.

6.2 Medical History

A table will be constructed with counts and percentages of the number of subjects who were normal/abnormal by body system. A data listing for medical history information for all safety subjects will be provided, as shown in Appendix B.

7.0 List of Analysis Tables, Figures and Listings

List of Tables

Table No.	Table Title	Population	Shown in Appendix B
1	Subject Completion/Withdrawal		X
2	Demographics and Baseline Data Summary Statistics – Continuous Variables	Safety	X
3	Demographics and Baseline Data Summary Statistics – Categorical Variables	Safety	X
4	Summary of Medical Histories	Safety	X
5	Correlation and Regression Measures for Heart Parameters	ITM	X
6	Correlation and Regression Measures for Heart Parameters	PP	
7	Correlation and Regression Measures for Sleeping Respiration Rate	ITM	X
8	Correlation and Regression Measures for Sleeping Respiration Rate	PP	
9	Correlation and Regression Measures for Step Count	ITM	X
10	Correlation and Regression Measures for Step Count	PP	
11	Sleep Onset and Wake Time Accuracy Summary Statistics	ITM	X
12	Sleep Onset and Wake Time Accuracy Summary Statistics	PP	
13	Posture Classification	ITM	X
14	Posture Classification	PP	
15	Activity Classification	ITM	X
16	Activity Classification	PP	
17	Device Adhesion Evaluation	ITM	X
18	Skin Irritation Evaluation	ITM	X
19	Number and Percentage of Subjects with Adverse Events	Safety	X
20	Number and Percentage of Subjects with Adverse Events by Severity	Safety	X
21	Number and Percentage of Subjects with Adverse Events by Relation to Device	Safety	X
22	Number and Percentage of Subjects with Serious Adverse Events by Relation to Device	Safety	X

List of Figures

Figure No.	Figure Title	Population	Included in Final Listings	Shown in Appendix B
Fig 1	Heart Rate Scatter Diagram	ITM	X	X
Fig 2	Heart Rate Bland-Altman Diagram	ITM	X	X
Fig 3	Heart Rate Scatter Diagram	PP	X	
Fig 4	Heart Rate Bland-Altman Diagram	PP	X	
Fig 5	Heart Rate Variability (RMSSD) Diagram – ITM Population	ITM	X	
Fig 6	Heart Rate Variability (RMSSD) Bland-Altman Diagram	ITM	X	
Fig 7	Heart Rate Variability (RMSSD) Diagram	PP	X	
Fig 8	Heart Rate Variability (RMSSD) Bland-Altman Diagram	PP	X	
Fig 9	Heart Rate Variability (LF/HF ratio) Scatter Diagram	ITM	X	
Fig 10	Heart Rate Variability (LF/HF ratio) Bland-Altman Diagram	ITM	X	
Fig 11	Heart Rate Variability (LF/HF ratio) Scatter Diagram	PP	X	
Fig 12	Heart Rate Variability (LF/HF ratio) Bland-Altman Diagram	PP	X	
Fig 13	Respiration Rate Scatter Diagram	ITM	X	
Fig 14	Respiration Rate Bland-Altman Diagram – ITM Population	ITM	X	
Fig 15	Respiration Rate Scatter Diagram	PP	X	
Fig 16	Respiration Rate Bland-Altman Diagram	PP	X	
Fig 17	Step Count Scatter Diagram	ITM	X	
Fig 18	Step Count Bland-Altman Diagram	ITM	X	
Fig 19	Step Count Scatter Diagram	PP	X	
Fig 20	Step Count Bland-Altman Diagram	PP	X	

List of Data Listings

Listing No.	Data Listing Title	Included in Final Listings	Shown in Appendix B
DL 1	Subject Completion/Withdrawal Listing	X	X
DL 2	Inclusion Criteria Violations Listing	X	X
DL 3	Exclusion Criteria Violations Listing	X	X
DL 4	Subjects Excluded from Safety Population Listing	X	X
DL 5	Subjects Excluded from ITM Population Listing	X	X
DL 6	Demographics Listing	X	X
DL 7	Adverse Events Listing	X	X
DL 8	Heart Rate Values Listing	X	X
DL 9	Respiration Rate Values Listing	X	X
DL 10	Step Count Values Listing	X	X
DL 11	Posture Classification Values Listing	X	X
DL 12	Activity Classification Values Listing	X	X
DL 13	Sleep Variables Values Listing	X	X
DL 14	Sensor Adhesion and Irritation Listing	X	X

8.0 References

MC10-PTL-103 A Study to Evaluate the Performance, Usability and Reliability of a Novel Device for Continuous Collection of Physiological Data in Healthcare and Remote Settings. Protocol Number MC10-PTL-103, MC10, Inc Lexington, MA.

Appendix A – Tables, Figures and Listing Specifications

Orientation

Tables and figures will be displayed in landscape.

Margins

Margins will be 1 inch on all sides. Table and listing boundaries will not extend into the margins.

Font

Courier New, 8 point.

Headers

The table number will be on the first line of the title. The title area will contain the Sponsor name, the study number, and the name of the table. The title area will contain the page number (Page x of y) on the far right, one line above the name of the table.

Footers

- The first line will be a solid line.
- Next will be any footnotes regarding information displayed in the table.
- Below these footnotes will be displayed “STATKING Clinical Services (Date)” on the far left.
- The last line will display the name of the SAS program that generated the table and (if applicable) the source data reference.

Table Disclaimer

The format of the mock tables shown in the appendix of this Statistical Analysis Plan (SAP) will be the format of the deliverable tables to the extent that Word document constructed tables can match production tables produced by SAS. This formatting includes the content and format of the header and footer areas of the tables. The Sponsor agrees to the format of the tables as shown in the appendix.

Further programming charges will be applicable for changes in the format of tables (including title statements, notes, data dependent footnotes, etc.) made after the approval of the SAP.

Missing Values

All missing values will be displayed on the output tables/listings as blanks.

Display of Study Dates

The date format to be used is mm/dd/yyyy. Missing parts of dates are not shown (i.e., for a missing day value, the value displayed is in mm/yyyy format).

Appendix B – Table Shells

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Table 1. Subject Completion/Withdrawal
MC10 BioStamp nPoint Pivotal Trial

		Overall
Screen Failure		xx
Enrolled		xx
Completed[a]		xx (xx%)
Withdrawn[a]		xx (xx%)
	Death	xx (xx%)
	Adverse Event	xx (xx%)
	Lost to Follow Up	xx (xx%)
	Withdrawal by Subject	xx (xx%)
	Investigator Discretion	xx (xx%)
	Protocol Violation	xx (xx%)
	Sponsor Discretion	xx (xx%)
	Other	xx (xx%)

[a] Percentages computed using the number of enrolled subjects as the denominator.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 2. Demographics and Baseline Data Summary Statistics – Continuous Variables
MC10 BioStamp nPoint Pivotal Trial
Safety Population (N=xxx)

Demographic Variable	Mean	Std Dev	n	Min	Max	Median
Age (years)	xxx	xxx	xxx	xxx	xxx	xxx
Height (cm)	xxx	xxx	xxx	xxx	xxx	xxx
Weight (kg)	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 3. Demographics and Baseline Data Summary Statistics – Categorical Variables
MC10 BioStamp nPoint Pivotal Trial
Safety Population (N=xxx)

Demographics Variable	Category	Overall (N=xxx)
Gender	Male	xxx (xxx%)
	Female	xxx (xxx%)
Race	American Indian or Alaska Native	xxx (xxx%)
	Asian	xxx (xxx%)
	Black or African American	xxx (xxx%)
	Native Hawaiian or Other Pacific Islander	xxx (xxx%)
	White	xxx (xxx%)
	Other	xxx (xxx%)

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 4. Summary of Medical Histories
MC10 BioStamp nPoint Pivotal Trial
Safety Population (N=xxx)

Body System	Result	Overall (N=xxx)
xxxxxxxxxxx	Abnormal	xxx (xxx%)
	Normal	xxx (xxx%)
xxxxxxxxxxx	Abnormal	xxx (xxx%)
	Normal	xxx (xxx%)
xxxxxxxxxxx	Abnormal	xxx (xxx%)
	Normal	xxx (xxx%)
xxxxxxxxxxx	Abnormal	xxx (xxx%)
	Normal	xxx (xxx%)
xxxxxxxxxxx	Abnormal	xxx (xxx%)
	Normal	xxx (xxx%)
xxxxxxxxxxx	Abnormal	xxx (xxx%)
	Normal	xxx (xxx%)
xxxxxxxxxxx	Abnormal	xxx (xxx%)
	Normal	xxx (xxx%)
xxxxxxxxxxx	Abnormal	xxx (xxx%)
	Normal	xxx (xxx%)
xxxxxxxxxxx	Abnormal	xxx (xxx%)
	Normal	xxx (xxx%)

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 5. Correlation and Regression Measures for Heart Parameters
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

		Deming Regression		Error	
Variable	Correlation	Intercept	Slope	MAE	RMSE
Heart rate	0.xxxx	x.xxxx	x.xxxx	xxxxx	xxxxx
Heart rate variability – RMSSD	0.xxxx	x.xxxx	x.xxxx	xxxxx	xxxxx
Heart rate variability – LF/HF ratio	0.xxxx	x.xxxx	x.xxxx	xxxxx	xxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 7. Correlation and Regression Measures for Sleeping Respiration Rate
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

		Deming Regression		Error	
Variable	Correlation	Intercept	Slope	MAE	RMSE
Sleeping Respiration Rate	0.xxxx	x.xxxx	x.xxxx	xxxxx	xxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 9. Correlation and Regression Measures for Step Count
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

		Deming Regression		Error	
Variable	Correlation	Intercept	Slope	MAE	RMSE
Step Count	0.xxxx	x.xxxx	x.xxxx	xxxxx	xxxxx

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Source Program: xxxxxxx.sas

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Table 11. Sleep Onset and Wake Time Accuracy Summary Statistics
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

Variable[a]	n	Mean	Standard Deviation	Median	Minimum	Maximum
Sleep Onset Time Error	xxxxxx	xxxxx	xxxxxx	xxxxx	xxxxx	xxxxx
Wake Time Error	xxxxxx	xxxxx	xxxxxx	xxxxx	xxxxx	xxxxx

[a] Time errors are defined as the absolute difference between the CRF-recorded time and the device identified time, in minutes.
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Source Program: xxxxxxx.sas

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Table 13. Posture Classification
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)
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	Actual Position					
Device Classified	Laying Supine	Laying Prone	Laying Left Side	Laying Right Side	Statistic[a]	Value
Laying Supine	xxx	xxx	xxx	xxx	Percent Agreement	xx.xx%
Laying Prone	xxx	xxx	xxx	xxx	Uncertainty Coeff	x.xxx
Laying Left Side	xxx	xxx	xxx	xxx		
Laying Right Side	xxx	xxx	xxx	xxx		
Upright	xxx	xxx	xxx	xxx		
Leaning Left	xxx	xxx	xxx	xxx		
Leaning Right	xxx	xxx	xxx	Xxx		
Leaning Forward	xxx	xxx	xxx	Xxx		
Leaning Back	xxx	xxx	xxx	Xxx		
Other Posture	xxx	xxx	xxx	Xxx		
Unknown Posture	xxx	xxx	xxx	Xxx		

[a] The uncertainty coefficient is calculated for the actual position given the classified position.
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Table 13. Overall Posture Classification
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)
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	Actual Position				
Device Classified	Upright	Leaning Left	Leaning Right	Leaning Forward	Leaning Back
Laying Supine	xxx	xxx	xxx	xxx	xxx
Laying Prone	xxx	xxx	xxx	xxx	xxx
Laying Left Side	xxx	xxx	xxx	xxx	xxx
Laying Right Side	xxx	xxx	xxx	xxx	xxx
Upright	xxx	xxx	xxx	xxx	xxx
Leaning Left	xxx	xxx	xxx	xxx	xxx
Leaning Right	xxx	xxx	xxx	xxx	xxx
Leaning Forward	xxx	xxx	xxx	xxx	xxx
Leaning Back	xxx	xxx	xxx	xxx	xxx
Other Posture	xxx	xxx	xxx	xxx	xxx
Unknown Posture	xxx	xxx	xxx	xxx	xxx

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Table 15. Activity Classification
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

Device Classified	Actual Activity						Statistic[a]	Value
	Laying	Sitting	Sleeping	Standing	Walking	Other		
Laying	xxx	xxx	xxx	xxx	xxx	xxx	Uncertainty Coeff	0.xxx
Sitting	xxx	xxx	xxx	xxx	xxx	xxx	Percent Agreement	xx.xx%
Sleeping	xxx	xxx	xxx	xxx	xxx	xxx		
Standing	xxx	xxx	xxx	xxx	xxx	xxx		
Walking	xxx	xxx	xxx	xxx	xxx	xxx		
Other	xxx	xxx	xxx	xxx	xxx	xxx		
Unknown Activity	xxx	xxx	xxx	xxx	xxx	xxx		
Total	xxx	xxx	xxx	xxx	xxx	xxx		

[a]The uncertainty coefficient is calculated for the actual activity given the classified activity.
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Source Program: xxxxxxx.sas

Table 17. Device Adhesion Evaluation
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

	Sensor Detachment					
Score	0	1	2	3	4	
Description	0- 10%	11- 25%	26- 50%	51-99%	100%	Total
Count (Pct)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx

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Source Program: xxxxxxx.sas

Table 18. Skin Irritation Evaluation
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

	Skin Irritation				
	No reaction	Weak reaction	Moderate Reaction	Strong Reaction	Total
Count (Pct)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx

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Source Program: xxxxxxx.sas

Table 19. Number and Percentage of Subjects with Adverse Events
MC10 BioStamp nPoint Pivotal Trial
Safety Population (N=xxx)

Adverse Event Category[a]	Overall (N=xxx)
Total Number of Adverse Events	xxx
Subjects with at Least One Adverse Event	xxx (xxx%)
System Organ Class 1	xxx (xxx%)
Preferred Term 1	xxx (xxx%)
Preferred Term 2	xxx (xxx%)
System Organ Class 2	xxx (xxx%)
Preferred Term 1	xxx (xxx%)
Preferred Term 2	xxx (xxx%)

[a] Adverse events coded using MedDRA Version xxx.
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Source Program: xxxxxxx.sas

Table 20. Number and Percentage of Subjects with Adverse Events by Severity
MC10 BioStamp nPoint Pivotal Trial
Safety Population (N=xxx)

	Severity[b]		
Adverse Event Category[a]:	Mild	Moderate	Severe
Total Number of Adverse Events	xxx	xxx	xxx
Subjects with at Least One Adverse Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded using MedDRA Version xxx.
[b] Adverse events may appear more than once in the table, based on the severity level.
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Table 21. Number and Percentage of Subjects with Adverse Events by Relation to Device
MC10 BioStamp nPoint Pivotal Trial
Safety Population (N=xxx)

	Relation to Device[b]				
Adverse Event Category[a]:	Definitely Related	Probably Related	Possibly Related	Probably Not Related	Definitely Not Related
Total Number of Adverse Events	xxx	xxx	xxx	xxx	xxx
Subjects with at Least One Adverse Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded using MedDRA Version xxx.
[b] Adverse events may appear more than once in the table, based on the relation to device.
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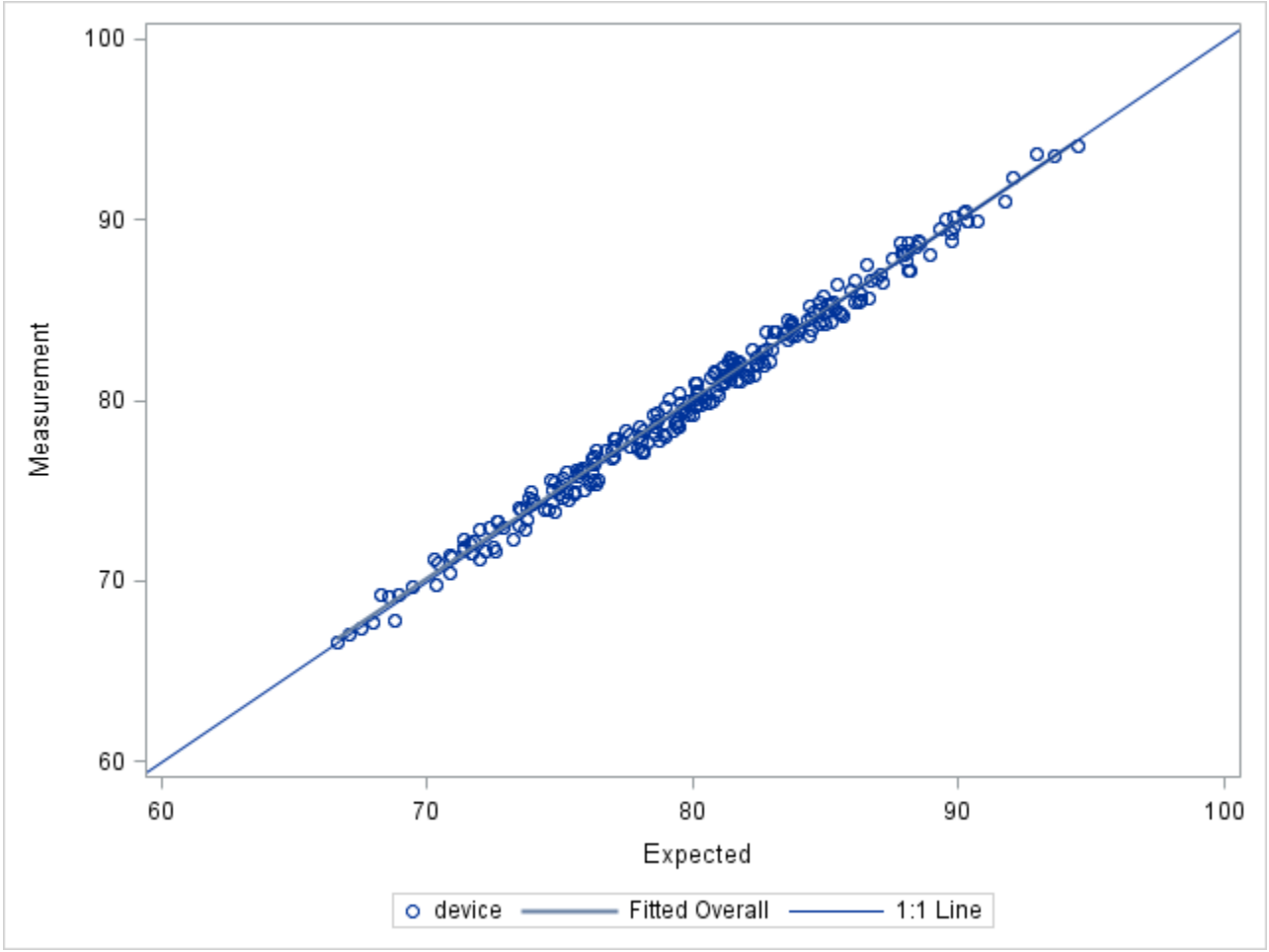
Source Program: xxxxxxx.sas

Table 22. Number and Percentage of Subjects with Serious Adverse Events by Relation to Device
MC10 BioStamp nPoint Pivotal Trial
Safety Population (N=xxx)

	Relation to Device[b]				
Adverse Event Category[a]:	Definitely Related	Probably Related	Possibly Related	Probably Not Related	Definitely Not Related
Total Number of Serious Adverse Events	xxx	xxx	xxx	xxx	xxx
Subjects with at Least One Serious Adverse Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

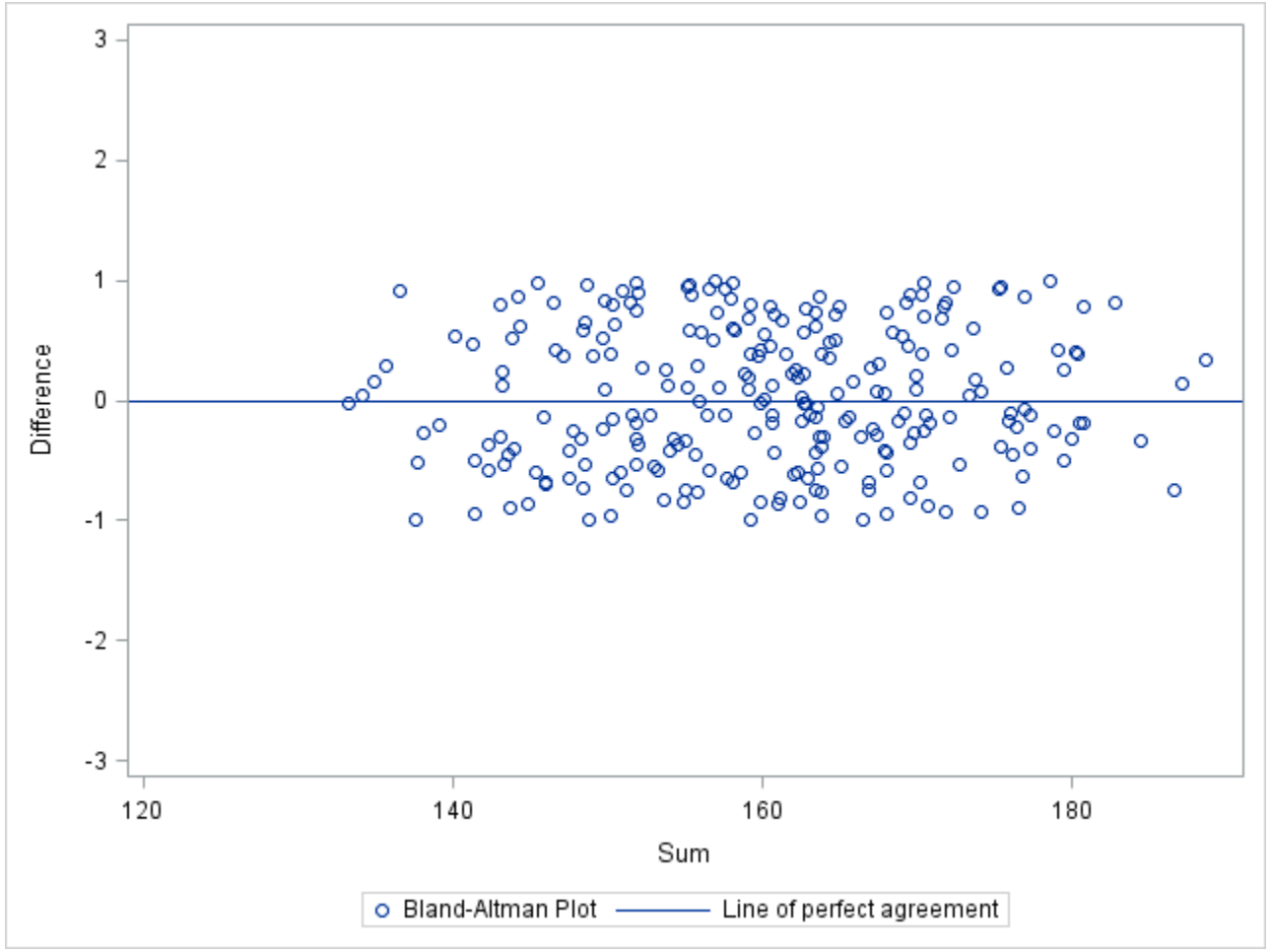
[a] Adverse events coded using MedDRA Version xxx.
[b] Adverse events may appear more than once in the table, based on the relation to device.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Figure 1. Heart Rate Scatter Diagram
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N = xxx)



STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Figure 2. Heart Rate Bland-Altman Diagram
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N = xxx)



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Source Program: xxxxxxx.sas

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Data Listing 1. Subject Completion/Withdrawal Listing
MC10 BioStamp nPoint Pivotal Trial

Subject Number	Date of Disposition	Disposition Status	Reason for Withdrawal
xxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx

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Data Listing 2. Inclusion Criteria Violations Listing
MC10 BioStamp nPoint Pivotal Trial
All Enrolled Subjects

Subject Number	Inclusion Criteria Violated
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

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Source Program: xxxxxxx.sas

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Data Listing 3. Exclusion Criteria Violations Listing
MC10 BioStamp nPoint Pivotal Trial
All Enrolled Subjects

Subject Number	Exclusion Criteria Violated
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

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Source Program: xxxxxxx.sas

Data Listing 4. Subjects Excluded from Safety Population Listing
MC10 BioStamp nPoint Pivotal Trial
All Enrolled Subjects

Subject Number	Reason for Exclusion
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Data Listing 5. Subjects Excluded from ITM Population Listing
MC10 BioStamp nPoint Pivotal Trial
All Enrolled Subjects

Subject Number	Reason for Exclusion
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

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Source Program: xxxxxxx.sas

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Data Listing 6. Demographics Listing
MC10 BioStamp nPoint Pivotal Trial
Safety Population (N=xxx)

Subject Number	Age (years)	Height (cm)	Weight (kg)	Gender	Race	Ethnicity
xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxx	xxxxxxx	xxxxxxx
xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxx	xxxxxxx	xxxxxxx
xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxx	xxxxxxx	xxxxxxx
xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxx	xxxxxxx	xxxxxxx

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Source Program: xxxxxxx.sas

Data Listing 7. Adverse Events Listing
MC10 BioStamp nPoint Pivotal Trial
Safety Population (N=xxx)

Subject Number	DR?[a]	Date of Onset/ Time of Onset/ Date Resolved/ Time Resolved	MedDRA System Organ Class[b]/ MedDRA Preferred Term/ CRF Verbatim Term	Serious?/ Reason Serious	Severity	Relation To Study Treatment	Outcome
xxxxxx	xxx	xx/xx/xxxx xx:xx xx/xx/xxxx xx:xx	xxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxx	xxx/ xxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxx xxxxxxxxx
xxxxxx	xxx	xx:xx xx/xx/xxxx xx:xx xx/xx/xxxx	xxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxx	xxx/ xxxxxxxxxx	xxxxxxxx	xxxxxxx	xxxxxxxxx xxxxxxxxx

[a] DR = Device Related.
[b] Adverse events coded using MedDRA Version xxxxx.
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Source Program: xxxxxxx.sas

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Data Listing 8. Heart Rate Values Listing
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

				BioStamp			ActiHeart			Error[a]		
Subject Number	Activity	Date	Time Stamp	Rate (bpm)	RMSDD	LF/HF Ratio	Rate (bpm)	RMSDD	LF/HF Ratio	Rate (bpm)	RMSDD	LF/HF Ratio
xxxxxx	xxxxxxxxx	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxxxxxxxx	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxxxxxxxx	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxxxxxxxx	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

[a] Error is calculated as BioStamp value – Capnostream value.
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Source Program: xxxxxxx.sas

Data Listing 9. Respiration Rate Values Listing
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

Subject Number	Date	Time Stamp	BioStamp Breaths	Capnostream Breaths	Error[a]
xxxxxx	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx
	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx
	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx

[a] Error is calculated as BioStamp value – Capnostream value.
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Source Program: xxxxxxx.sas

Data Listing 10. Step Count Values Listing
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

Subject Number	Date	Time Stamp	BioStamp Steps	Manual Counter	Error[a]
xxxxxx	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx
xxxxxx	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx
xxxxxx	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx
xxxxxx	xx/xxx/xxxx	xx:xx	xxx	xxx	xxx

[a] Error is calculated as BioStamp value – Value counted by clinic observer.
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Source Program: xxxxxxx.sas

Data Listing 11. Posture Classification Values Listing
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

Subject Number	Date	Time Stamp	Position	BioStamp Posture	Observer Posture
xxxxxx	xx/xxx/xxxx	xx:xx	xxxxxxxxxx	xxx	xxx
	xx/xxx/xxxx	xx:xx	xxxxxxxxxx	xxx	xxx
	xx/xxx/xxxx	xx:xx	xxxxxxxxxx	xxx	xxx
	xx/xxx/xxxx	xx:xx	xxxxxxxxxx	xxx	xxx

Data Listing 12. Activity Classification Values Listing
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

Subject Number	Date	Time Stamp	Purpose	BioStamp Activity	Observer Activity
xxxxxx	xx/xxx/xxxx	xx:xx	xxxxxxxx	xxx	xxx
	xx/xxx/xxxx	xx:xx	xxxxxxxx	xxx	xxx
	xx/xxx/xxxx	xx:xx	xxxxxxxx	xxx	xxx
	xx/xxx/xxxx	xx:xx	xxxxxxxx	xxx	xxx

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Source Program: xxxxxxx.sas

Data Listing 13. Sleep Variables Values Listing
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

		BioStamp		Observer	
Subject Number	Date	Sleep Onset Time	Wake-up Time	Lights-out Time	Wake-up Time
xxxxxx	xx/xxx/xxxx	xx:xx:xx	xx:xx:xx	xx:xx:xx	xx:xx:xx
	xx/xxx/xxxx	xx:xx:xx	xx:xx:xx	xx:xx:xx	xx:xx:xx
	xx/xxx/xxxx	xx:xx:xx	xx:xx:xx	xx:xx:xx	xx:xx:xx
	xx/xxx/xxxx	xx:xx:xx	xx:xx:xx	xx:xx:xx	xx:xx:xx

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Data Listing 14. Sensor Adhesion and Irritation Listing
MC10 BioStamp nPoint Pivotal Trial
ITM Population (N=xxx)

Subject Number	Sensor ID	Adhesion[a]	Irritation[a]
xxxxxx	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
xxxxxx	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
xxxxxx	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
xxxxxx	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx
	xx-xxx-xxxx	xxx	xxx

[a] See in text Table 2 for adhesion and irritation scoring scales.
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Source Program: xxxxxxx.sas