GOYO Smart Watch
Accuracy Validation Report

Version 1.0

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Change Control History

Version	Date	Author/s	Comment
1.0	2019/06/20	Shashika Chamod Munasingha	
1.1	2019/09/30	Shashika Chamod Munasingha	

Content

Background

GOYO supported fitness trackers are the most popular fitness trackers among Sri Lankans who are keen about leading a healthy lifestyle. Union Assurance PLC is providing health bands to encourage healthy life of their health insurance policyholders.

Previous models of GOYO fitness trackers have shown different levels of accuracy during the evaluation process. All of them are considered to be accurate health trackers in terms of Heart Rate and Step Count measurements.

The fitness trackers which are compatible with GOYO app are supplied by Chinese Vendor. The most recent version of the fitness tracker is model GOYO Smart Watch. The tracker accuracy of each measurement has not been validated in a methodological way.

In order to provide the new health trackers or to replace ,their accuracy MUST be validated. This report covers the data collection and statistical analysis for the validation of GOYO Smart Watch health tracker wristband.

Objective

The primary objective of this study is to assess the accuracy of model GOYO Smart Watch Smart Wristband heart rate readings against a medical graded standard pulse oximeter. Secondary objective is to assess the step count accuracy using manual step counting method.

Literature & Study Rationale

The wristband health parameters; heart rate & step count are evaluated against pulse oximeter readings and manual step counting method.

HR Accuracy Measurement

Some studies which were done recently have shown that wrist-worn heart rate monitors are not as accurate as chest strap monitors, but yet most of the wrist bands show reasonably accurate HR measurements [2]. But, when testing a device accuracy we still have to move on with the medically acceptable devices to validate against.

In this study also ,medical graded inbuilt **Pulse Oximeter Monitor in Philip-MP20 Patient Monitor** is selected as the standard to assess the wristband HR measurements. Researchers have shown that pulse oximeter can be considered as an accurate HR monitor. The pulse oximeter devices have shown 0.91 correlation with standard ECG, which is considered to be the most accurate HR monitoring device. It is also revealed that pulse oximeter HR measurement is underestimating the HR when a person's HR is above 155 [1]. This situation can be observed when a person is engaged in strenuous exercises.

Figure 1. Philips MP20 Patient Monitor

When a person is engaged in strenuous exercise sweating and dirt could negatively affect the skin and sensor interface. This situation may lead to inaccurate HR readings from wristbands. Wearing a pulse oximeter during physical activity is also impractical. When a person is moving around a lot the ambient light may also affect the HR reading. This is because wristband HR monitors use a method called Photoplethysmography (PPG) to measure the HR. This method

uses absorption of light waves by blood to capture HR. Hence, our HR readings will be evaluated for resting HR only.

Step Count Measurement

There is no standard method mentioned in literature regarding step count measurements. The only method that could be considered here is manual counting of steps during walking against the wristband step count.

Study Design

Study Duration, Enrollment and Study Sites

We will be selecting 25-30 individuals for each parameter; HR validation, Step Count Validation. Sample size greater than 25 is expected to the accountability of the test results.

Total data collection period will be 3-4 days.

Our study site will be a private medical institute.Randomly selected 25-30 individuals will be our study subjects. This sample will include only the hospital staff.

Study Procedure

HR Measurements

Each individual will be instructed to in a resting position either sitting or laying down. Fitness tracker GOYO Smart Watch will be worn on the left wrist with appropriate tightness. The pulse oximeter probe will be attached to the index finger of the left hand.

The data will be recorded for 15 minutes from individuals. Following data will be recorded during the procedure.

1) Average HR using GOYO Smart Watch
2) Average HR using Pulse Oximeter
3) Gender
4) Age

Step Count

Data collection of step count will not be complex as collecting data for heart rate measurements. Each participant will wear the two wristbands on two hands. Next, two devices will be set to ‘Walk’ mode. Then individuals will be instructed to walk for 2-8 minutes while counting the steps.

At the end of the trip following data will be recorded.

1) Manual step count
2) Step count using GOYO Smart Watch

Data Handling & Record Keeping

Confidentiality and Security

Data records will be kept in local PC spreadsheets. No identification data will be recorded from individuals and only the mentioned parameters will be saved. The data will be only used for this study or continuation of this study. The data will be accessed only by authorized parties of Effective Solutions Pvt.Ltd and Union Assurance Pvt.Ltd.

Statistical Plan

Hypothesis

Our null hypothesis and alternative hypothesis for the study is as follows.

H0 (null hypothesis) : The differences between the results of the wristband model GOYO Smart Watch measurement Y and standard measurement Y is different from 0

H1 (alternative hypothesis) : The differences between the results of the wristband model GOYO Smart Watch measurement Y and standard measurement Y is not different from 0

Sample Size

Bland-Altman plot [5] method and Passing Bablock Regression method will be used for accuracy validation of HR and step count.
Following statistical considerations are taken into account when calculating the sample size.

Expected mean of difference = 3
Expected S.D. of difference = 2
Maximum allowed difference between methods = 9
Allowable Type I error (alpha) = 0.05
Allowable Type II error(beta) = 0.2

By using these parameters and the Bland Altman plot formula [6] we can obtain minimum sample size of 26.

Statistical Method

Passing Bablock Regression [7] is considered as the standard test to validate the measurements of a new test methodology against a standard test methodology. The basic idea behind the Bablock regression is that the regression line drawn between the standard measurements vs new method should have unity slope and zero intercept. If that is the case, the new method is considered to be as good as the standard method.

Bland-Altman plot [5] and analysis is used to compare two measurements of the same variable. That is, it is a method comparison technique. Simple correlation methods may not appropriate here as we measure the agreement of reading between two methods rather than the correlation. For an example, two measurements can be correlated even when their values are not the same.

Results

HR Measurements

We collected 30 data samples for HR accuracy validation. These samples were collected from individuals between 20-40 years range. Total number of individuals who participated in our study is 30. From each individual we collected 2 data records for the study. This sample includes both female and male subjects.

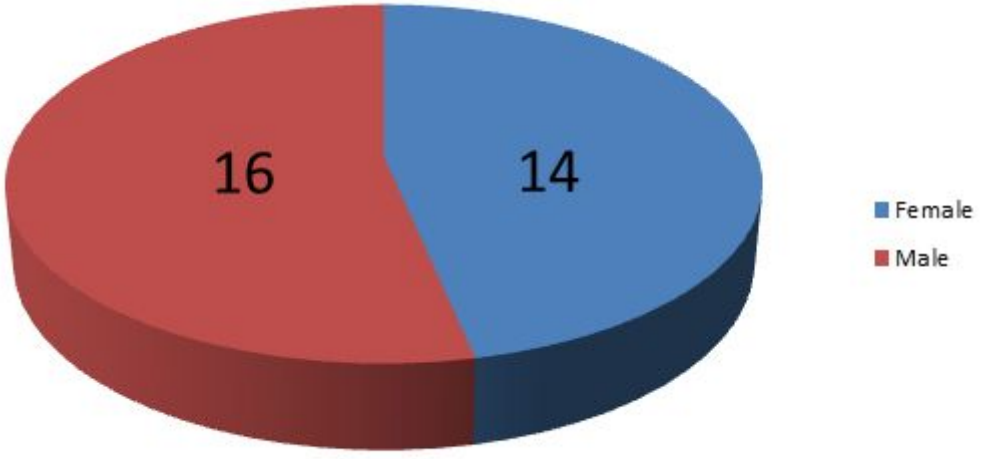

Fig 4. Gender-based sample categorization

Following table shows the row data samples, we collected from individuals for GOYO Smart Watch fitness tracker model.

Record No.	Gender	Age	GOYO Smart Watch HR (PPM)	Reference HR (PPM)
1	F	25	78	79
2	F	24	70	76
3	F	28	60	57
4	F	29	70	73
5	M	39	82	81
6	F	24	72	85
7	M	25	71	68

8	M	27	70	53
9	M	27	70	76
10	M	29	82	78
11	F	25	72	70
12	F	32	80	79
13	M	23	60	78
14	F	54	70	78
15	M	29	66	64
16	M	29	70	70
17	M	27	70	85
18	M	29	79	78
19	F	37	77	81
20	F	54	71	78
21	F	28	61	63
22	F	29	70	72
23	M	27	66	59
24	M	25	66	66
25	M	28	74	79
26	F	24	65	86
27	M	30	70	59
28	M	26	74	76
29	F	29	76	70
30	M	34	74	80

Table 1. Original Data - Devices GOYO Smart Watch

Then we rearranged the data for the purpose of statistical analysis. The data has been shrunk in range because it is impractical to observe HR values of starting from 0.

GOYO Smart Watch	Reference HR	Value Shifted Device HR	Value Shifted Reference HR
78	79	25	26
70	76	17	23
60	57	7	4
70	73	17	20
82	81	29	28

72	85	19	32
71	68	18	15
70	53	17	0
70	76	17	23
82	78	29	25
72	70	19	17
80	79	27	26
60	78	7	25
70	78	17	25
66	64	13	11
70	70	17	17
70	85	17	32
79	78	26	25
77	81	24	28
71	78	18	25
61	63	8	10
70	72	17	19
66	59	13	6
66	66	13	13
74	79	21	26
65	86	12	33
70	59	17	6
74	76	21	23
76	70	23	17
74	80	21	27

Table 2. Rearranged Data GOYO Smart Watch

Above rearranged data has been used to evaluate using Passing Bablock Regression and Bland Altman Plots.

Passing Bablock Regression Analysis

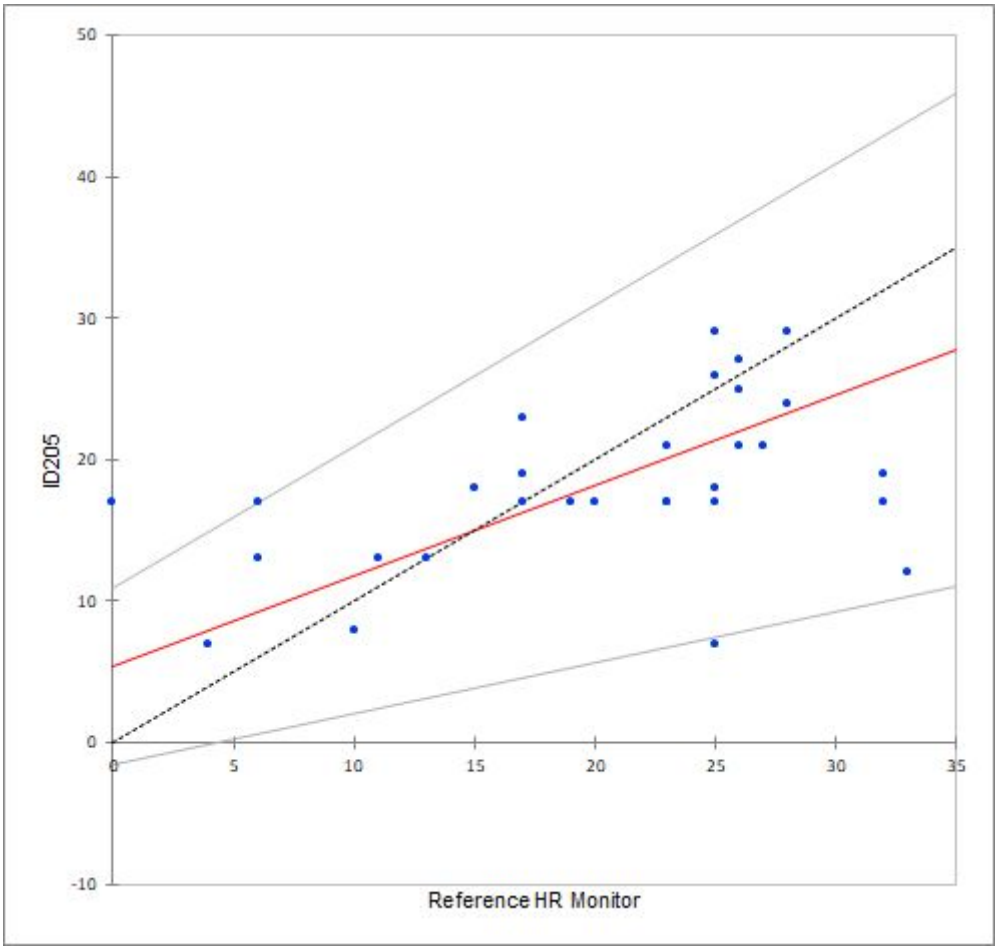

Fig.5 Passing Bablock Regression GOYO Smart Watch

In the plot shown in Fig.5. the dotted line shows the ideal regression line and the red line shows the regression line related to our results.

	Value	Lower bound 95% (Mean)	Upper bound 95% (Mean)
Intercept	5.455	-1.500	10.893
Slope coefficient	0.636	0.357	1.000

Table 3. Bablock Regression Model Coefficients GOYO Smart Watch

The model coefficients reveal that the intercept is 5.455 and within 95% confidence interval 0 (ideal intercept) is (-1.5<0<10.893)lying.The slope obtained is 0.636 and 1 is lying at the exact position of upper bound of the 95% confidence interval.

Bland Altman Plot Analysis

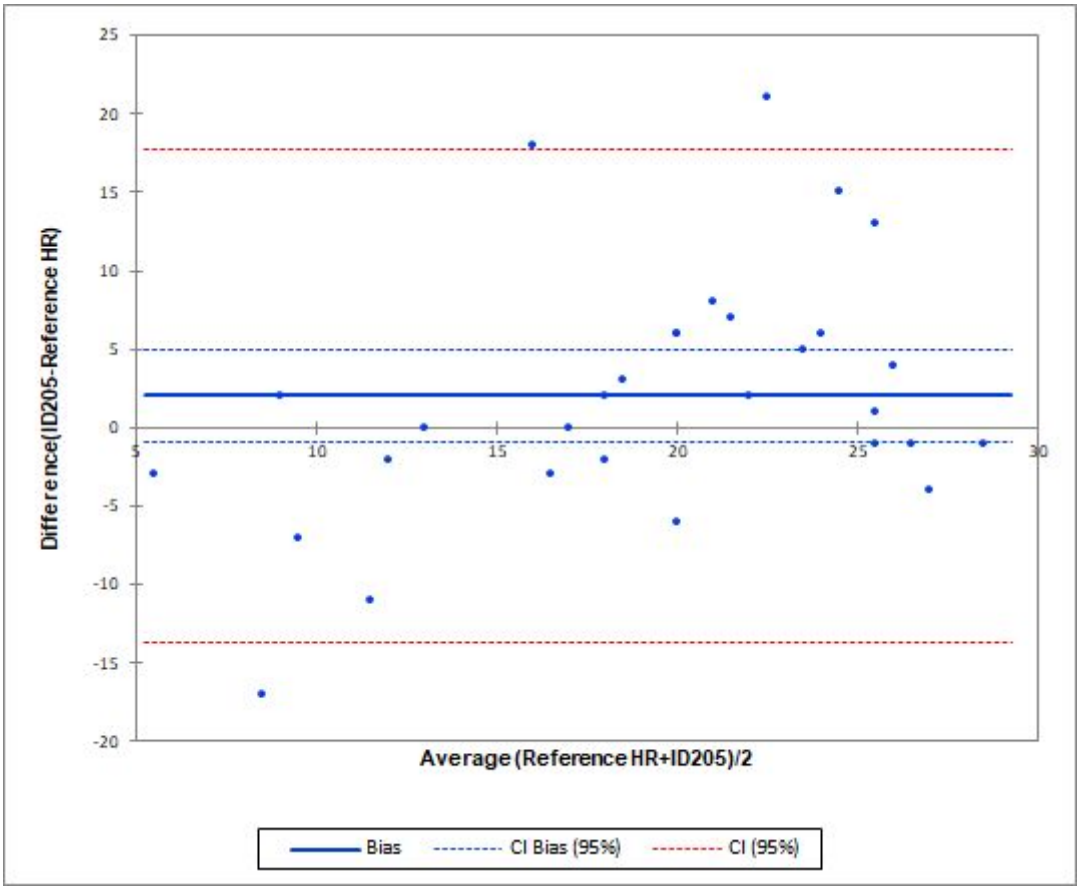

Fig.6. Bland Altman Plot GOYO Smart Watch

Bland-Altman analysis:	
Bias	2.033
Standard error	8.006

Table 4. Bland Altman Analysis Coefficients GOYO Smart Watch

From the Bland Altman Plot in Fig.6 we can see that only one point (3.3%) of the data are beyond the lower limit and two points (6.7%) of the data are beyond the upper limit of the Bland Altman Plot. This is a good indication that the error occurred is unbiased.

The calculated bias value, 2.033 is not different from zero as its 95% confidence interval (-13.659,17.726) includes zero.

Pearson correlation coefficient	
Correlation	0.425

CI (95%)	(0.076,0.681)

Table 5. Pearson correlation coefficient GOYO Smart Watch

The pearson correlation coefficient conflicts with our previous results. The errors have a small non-zero and positive correlation according to this result. This can be obtained as the correlation 0.425 is different from 0 as its 95% confidence interval (0.076,0.681) does not consist of 0.

Step count measurements

For the step count measurements we have got 30 samples from 18 individuals. 12 individuals gave data for two times.

#	Manual Count	GOYO Smart Watch	#	Manual Count	GOYO Smart Watch
1	372	375	16	317	314
2	564	569	17	466	472
3	535	529	18	259	260
4	352	352	19	389	379
5	408	411	20	689	679
6	541	553	21	665	667
7	593	582	22	678	683
8	510	501	23	637	640
9	522	523	24	571	571
10	401	401	25	561	558
11	291	289	26	601	587
12	339	338	27	537	532
13	358	349	28	374	380
14	566	568	29	702	704
15	675	664	30	690	687

Table 6. Raw Data GOYO Smart Watch HR

Passing Bablock Regression Analysis

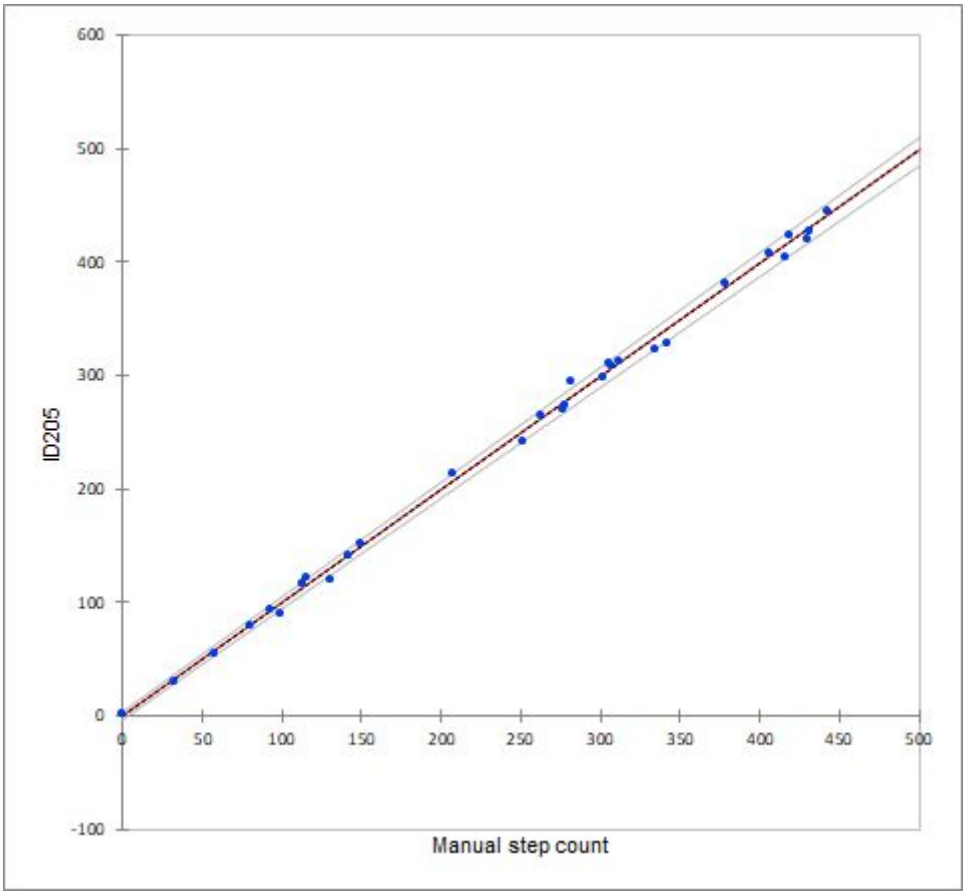

Fig 7. Passing Bablock Regression GOYO Smart Watch Step Count

	Value	Lower bound 95% (Mean)	
Intercept	0.000	-3.306	3.125
Slope coefficient	1.000	0.979	1.014

Table 7. Passing Bablock Regression Model coefficients GOYO Smart Watch

The model coefficients reveal that the intercept is 0 exactly impose on the ideal intercept .The slope obtained is 1.000 also the ideal slope coefficient we expect in the experiment.

Bland Altman Plot

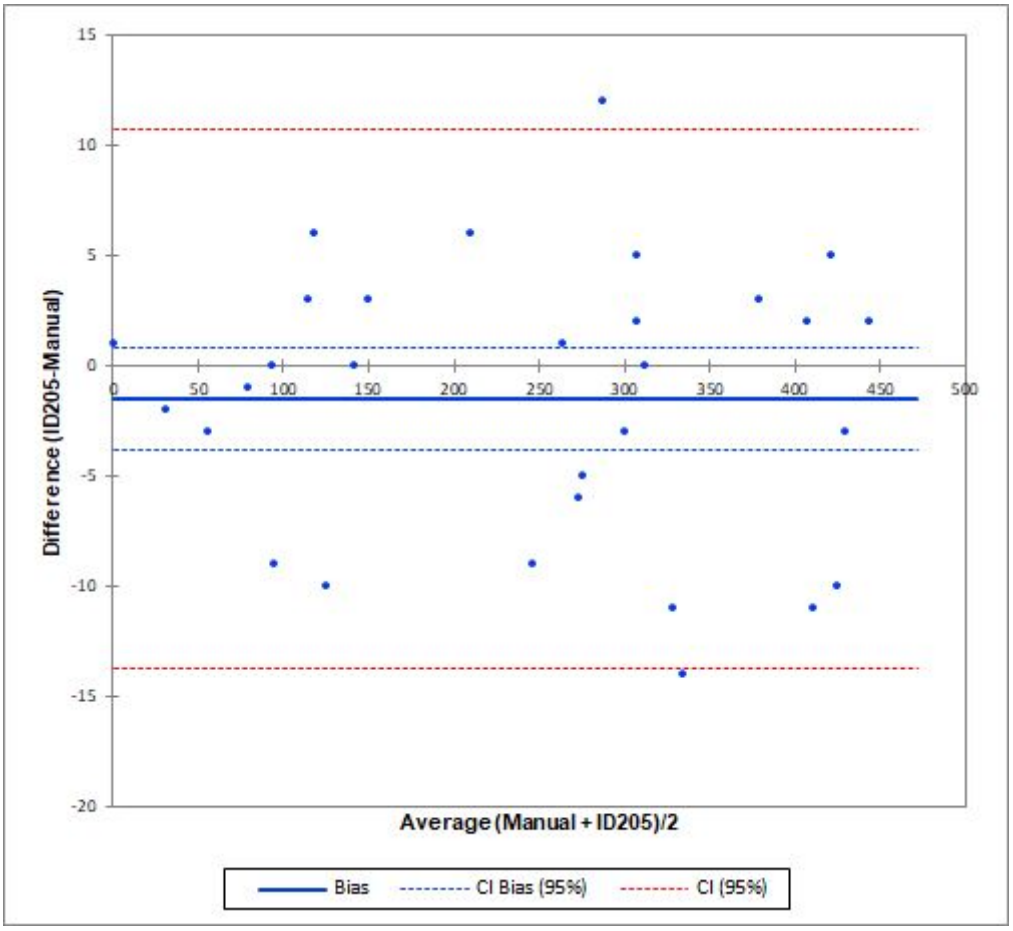

Fig 8. Bland Altman Plot GOYO Smart Watch Step Count

Parameter	Value
Bias	-1.533
Standard error	6.241
CI Bias (95%)	-3.864,0.797

Table 8. Bland Altman Coefficients

From the Bland Altman Plot in Fig.8 we can see that only two points (6.7%) of the data are beyond the limit of the Bland Altman Plot. This is a good indication that the error occurred is unbiased.

The calculated bias value, -2.667 is not different from zero as its 95% confidence interval (-6.995, 1.662) includes zero.

Pearson correlation coefficient	
Correlation	-0.083

CI (95%)	-0.430,0.286

Table 9. Pearson correlation coefficient GOYO Smart Watch Step Count

The pearson correlation coefficient also supports our previous results. The errors are random. This can be obtained as the correlation -0.083 does not differ from 0 as its 95% confidence interval (-0.430,0.286) consists of 0.

Conclusion

From the results described in the previous section, we can derive the following conclusions regarding the GOYO Smart Watch smart wristband.

HR Measurements

As per the interpretation derived by Passing Bablock Regression, it is said that if we obtain 0 intercept and slope of magnitude 1 (ideal case) we can directly say the current device measurements are as good as the standard test.

On the other hand, Bland Altman Plot reveals whether there is a possibility of biasing the measurement error with the magnitude of the measurement. If there is no bias we can agree that the errors are random in nature.

According to our results, the Passing Bablock Regression's intercept 5.455 is not the same as ideal values of 0. But it's 95% confidence interval includes 0 according to the results. The slope derived is 0.636. This is also not the same as the ideal slope value of 1. The 95% confidence interval also marginally acceptable the ideal slope value 1. This is an indication that HR measurements are statistically to be in the marginal level of 95% accuracy w.r.t. standard measurement.

Apart from that, Bland Altman Plot shows that, only bias(2.033) can be considered to be zero. Even Though there is a positive small correlation noted through the results we could still support our null hypothesis. This means that there is no bias of the error towards the measurements and only the random errors have been occurred.

The two analysis methods have to reject our null hypothesis H0 that the differences between the results of the wristband model GOYO Smart Watch heart rate measurements and standard heart rate measurement is different from 0 and accept the alternative hypothesis H1 that the differences between the results of the wristband model GOYO Smart Watch heart rate measurements and standard heart rate measurement is not different from 0.

Step Count Measurements

Regarding the step count measurements, the Passing Bablock Regression's intercept 0.00 is exactly the same as ideal values of 0 and also the slope 1.000 is the same as ideal values of 1, on the statistical results they are highly acceptable in 95% confidence interval.

Similar to the previous case explanation Bland Altman Plot shows that, both bias(-1.53) and Pearson correlation coefficient (-0.083) of the results are the same as 0. This means there is no bias of the error towards the measurements and only the random errors have been occured.

The two analysis methods have to reject our null hypothesis H0 that the differences between the results of the wristband model GOYO Smart Watch step count measurements and manual step count measurement is different from 0 and accept the alternative hypothesis H1 that the differences between the results of the wristband model GOYO Smart Watch step count measurements and manual step count measurement is not different from 0.

Overall conclusion

From the statistical point of view, we can conclude that GOYO Smart Watch is as good as a standard HR monitoring device and step counting device.

References

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