Wello Inc.

CLINICAL RESULTS REPORT FOR THE STUDY: WELLOSTATIONX DETERMINATION OF CLINICAL ACCURACY; SEPTEMBER 21, 2018.

NCT#: NCT03758157

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OVERVIEW

1. Study Background and Purpose

Following initial review of K180298 submitted by Wello, Inc (the Sponsor) for the welloStationX® (the device), the Sponsor received a Deficiency Letter from the FDA on August 2018 requesting provision of appropriate clinical accuracy testing as per standard regulations. Subsequently, Wello, Inc. conducted the requested clinical study to demonstrate clinical accuracy validation of the welloStationX® based on *ISO 80601-2-56 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.*

The primary objective of the study was to determine the Clinical Accuracy of the welloStationX® by:

- evaluating clinical bias with stated uncertainty; and
- determining clinical repeatability.

The results of this clinical study are intended to support the following indications for use: ""The welloStationX is a non-contact device intended for use to measure the body temperature of individuals five years of age and older. The welloStationX can be used by medical professionals or laypersons in any public or private indoor facility including home use. The welloStationX has an ambient operating temperature range of 59F – 82.4F (15C – 28C)."

The study lasted approximately four weeks during September and October 2018.

2. Study Device: welloStationX®

The welloStationX® is an automated No-Touch Self-Service Electronic Thermometer designed to provide an accurate temperature reading without the time and exposure of a skilled attendant to the possibility of infection.

The welloStationX® is an electronic thermometer using an infrared sensor of the surface of the forehead adjusting human body skin temperature to oral thermometer without contact.

3. Study Design

The study was a non-randomized, non-blinded single arm design with the subject as his or her own control to evaluate the clinical accuracy of the welloStationX thermometer with respect to that of the standardized Welch Allyn SureTemp oral thermometer in the screening of individuals with fever.

4. Subject Sample

Subjects were 110 males and females aged 5 years of age and older: 33 subjects (30%) were febrile, with fever defined as a core temperature of 99.5°F (37.5°C) or higher; and 77 subjects were afebrile.

Subjects were recruited from amongst non-profit clinical sites and through social media posts for subjects to come to a test site or to be evaluated in his or her own home in the widespread Dallas/Fort Worth area.

Afebrile subjects were compensated with a $10 gift card and febrile subjects were compensated $25, the additional amount intended to assist the febrile subject to recovery.

5. Study Procedures

Each subject's temperature was measured three separate times sequentially using the study device, the WelloStationX® (*DUT*) and one time using a new off-the-shelf calibrated Welch Allyn SureTemp oral thermometer with disposable probe covers (the reference thermometer). Each measurement was recorded by a trained technician by following the instructions for use contained in the respective device labeling.

Subject age, gender and race were recorded for each subject, and potential adverse event observation was conducted.

A subject or the subject's guardian was immediately informed if a febrile temperature measurement (99.5°F (37.5°C) or higher) was recorded using the Welch Allyn SureTemp oral thermometer. The subject or guardian will be advised to consider seeking medical attention.

RESULTS

6. Sample Demographics

The sample demographics of gender, age and race are shown below in Tables 1 through 3, respectively, for febrile and afebrile subjects and for subjects overall.

6.1 Gender

Table 1: Subject Gender by Febrile Status

Gender	Febrile (n=33)	Afebrile (n=75)	Total (n=108)
Male	10 (30%)	25 (33%)	35 (32%)
Female	23 (70%)	50 (67%)	73 (68%)

Subject gender distribution is comparable between febrile and afebrile subject groups.

6.2 Age

Table 2: Subject Age by Febrile Status

Age (years)	Febrile (n=33)	Afebrile (n=77)	Total (n=110)
Mean	44.91	44.73	44.78
Standard deviation	16.92	15.96	16.14

A **t-test for independent samples** revealed no statistically significant difference in mean age between febrile and afebrile subjects: $\mu a-\mu b=0.18$; $t=+0.05$; $df=108$; $p(\text{two-tailed})=0.96$ ($p>0.05$).

Figure 1 below shows the age distribution of study subjects across the entire range.

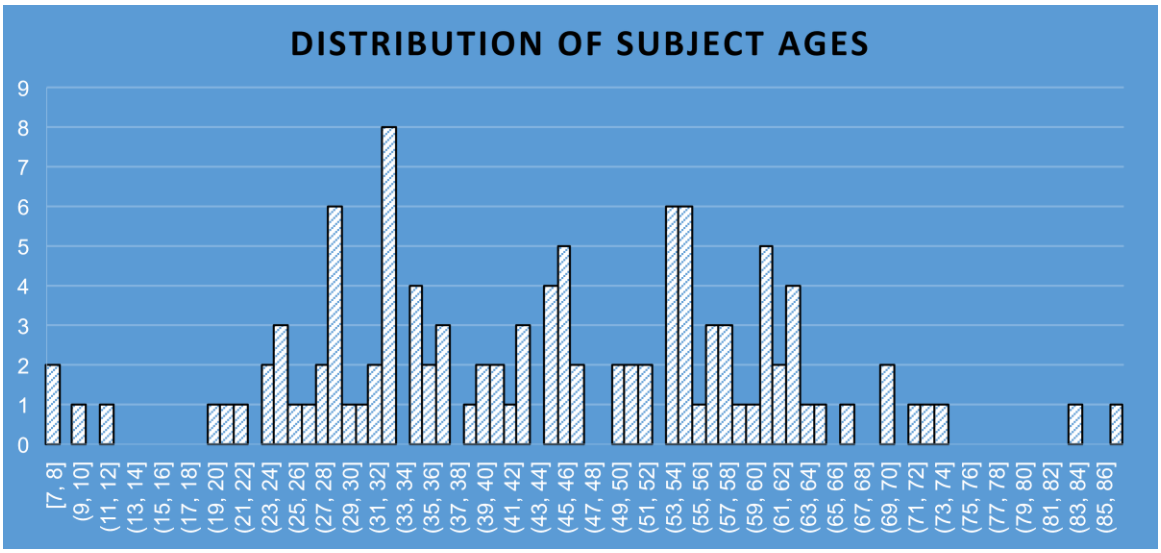

Figure 1. Age distribution of study subjects.

6.3 Ethnicity

Table 3: Subject Ethnicity by Febrile Status

Ethnicity	Febrile (n=33)	Afebrile (n=77)	Total (n=110)
White – Non-Hispanic	7	9	16
White - Hispanic	6	22	28
Hispanic - Unspecified	6	20	26
African American	14	23	37
American Indian	-	2	2
Asian	-	1	1

The various population ethnicities were well represented across the subject sample.

7. Clinical Accuracy

Clinical Accuracy of the welloStationX thermometer was evaluated by comparing the first recorded measurement of the WelloStationX (DUT) with the single measurement recorded by the Welch Allyn SureTemp oral thermometer (reference thermometer).

7.1 Means and Standard Deviations

Table 4 below shows the mean and standard deviation of temperature readings in °F with the welloStationX (DUT) and the Welch Allyn SureTemp (reference thermometer) by febrile versus afebrile subject groups.

Table 4: Means and Standard Deviations by Febrile Status

Temperature Reading (°F)	**welloStationX Febrile (n=33)**	**Welch Allyn Febrile (n=33)**	**welloStationX Afebrile (n=77)**	**Welch Allyn Afebrile (n=77)**
Mean	99.83	99.58	98.15	98.22
Standard deviation	0.60	0.71	0.47	0.29

7.2 Clinical Bias

Agreement through clinical bias evaluation was calculated as the Mean Bias ±SD by subtracting the first output measurement recorded with the welloStationX thermometer (DUT) from the corresponding output measurement recorded with the Welch Allyn SureTemp oral thermometer for each subject, and then calculating the Mean Bias ±SD of the biases.

Table 5 below shows clinical bias by febrile status.

Table 5: Clinical bias by febrile status.

Mean bias ±SD Febrile (n=33)	**Mean bias ±SD Afebrile (n=77)**	**Mean bias ±SD All (n=110)**
0.25 °F ±0.33	-0.06 °F ±0.42	0.03 °F ±0.42

7.3 Limits of Agreement and Bland Altman Plots

The limits of agreement (1.96 x 1SD) were calculated (+0.86, -0.80). From this and the mean bias and standard deviation values, a Bland Altman plot of agreement between the test thermometer (welloStationX) and the reference thermometer (SureTemp) in febrile and afebrile subjects was constructed and is shown in Figure 2 below.

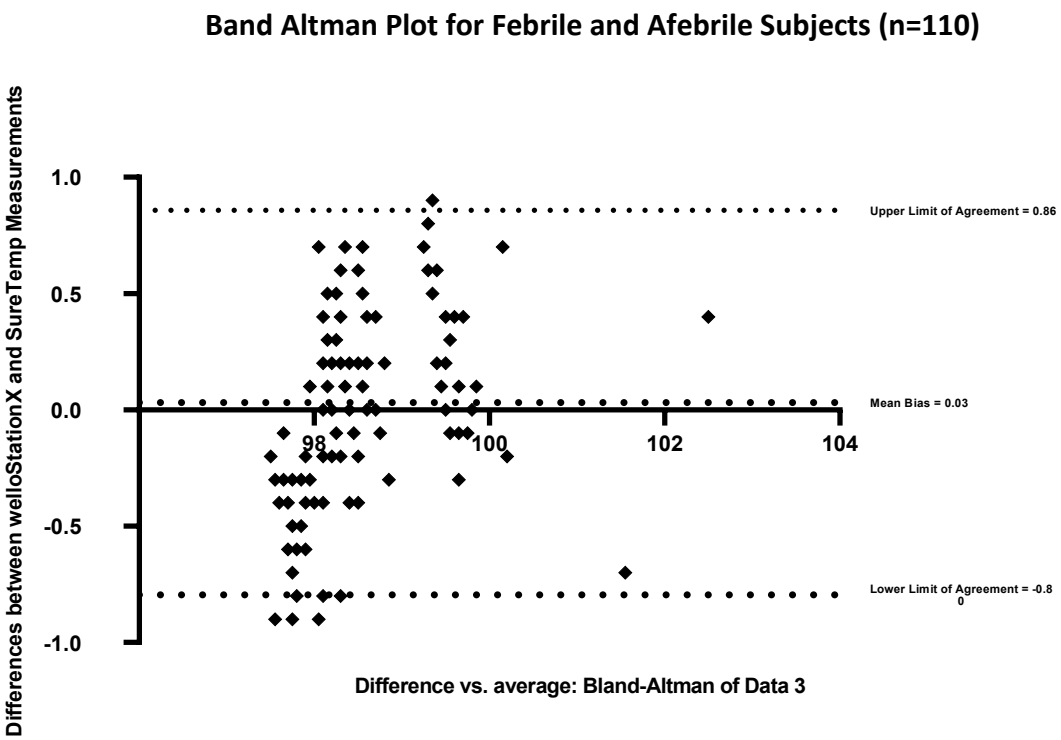

Figure 2: Bland Altman Plot of Agreement Between Study Thermometer (welloStationX) and Reference thermometer (SureTemp) in Febrile and Afebrile Subjects

7.4 XY Plot and Correlation Coefficient

To further demonstrate the closeness of the relationship between the welloStationX (DUT) and the SureTemp (reference) readings, an XY plot of the two sets of readings was created and is shown in Figure 3 below.

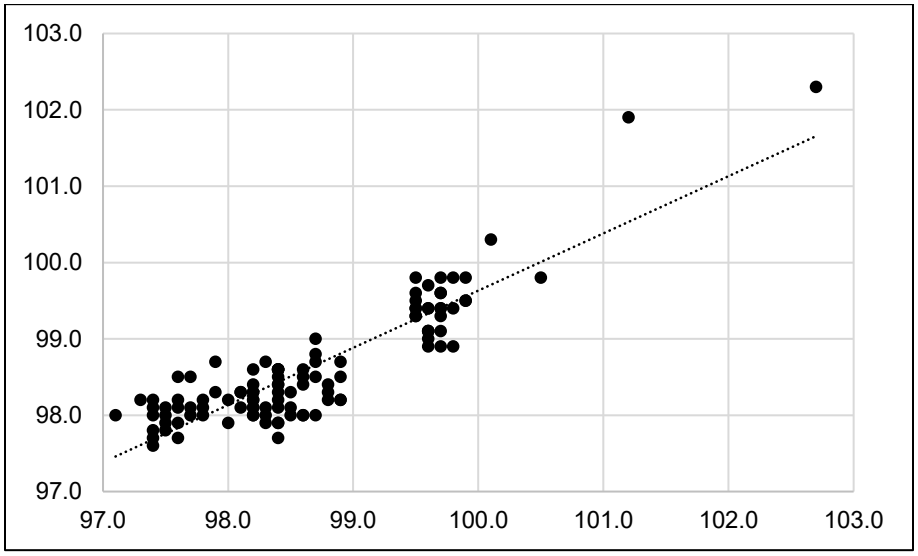

Figure 3: XY Plot of welloStationX versus SureTemp for all subjects

R^2 = 0.80, indicating a strong linear relationship

8. Clinical Repeatability

Clinical Repeatability was calculated using the pooled standard deviations of the triplicate measurements recorded by the welloStationX.

Table 5 below shows clinical repeatability by febrile status.

Table 5: Clinical repeatability of the welloStationX by febrile status.

Febrile (n=33)	Afebrile (n=77)	All (n=110)
0.13	0.09	0.06

9. Safety Evaluation

There were no observed or reported adverse events for any subject in the study.

DISCUSSION

The results of this clinical study are interpreted both with respect to the study dataset alone and compared to the research data published in the following whitepaper:

Clinical validation of the CAREGIVER® non-contact thermometer model PRO-TF200/PRO-TF300 in febrile and afebrile patients of all ages
Naja E. McKenzie PhD, RN, Alice Huang & Gary O'Hara MSE
November 2013 Copyright ©2013 Thermomedics®, Inc.

This comparison was selected for the following reasons:

1. The reported study clinical data was that which was submitted to the FDA in support of market clearance for the Caregiver Professional Clinical Thermometer (K131771) which is the predicate device in the current submission for K180298.

2. In the reported study, the reference thermometer used was the Welch Allyn SureTemp oral thermometer, the same reference thermometer used in the welloStationX clinical precision study.

There were no notable differences in gender, age or ethnicity by febrile status and age distributions across the spectrum was well represented. Therefore, the subject population was across febrile status was homogenous and the sample overall representative of the intended patient population.

The limits of agreement for the welloStationX are (+0.86, -0.80) which is better than that for the Caregiver study whose limits of agreement was (+0.82, -1.21).

From the Bland Altman Plot, it is found that only four data points lie just outside the limits of agreement (such that 96.4% of all data points lie within the limits of agreement) which indicates there is a strong agreement between the performance of the welloStationX and the SureTemp and is fewer than the six outliers found in the Caregiver study, most of which also lay further away from the limits of agreement than the four outliers in the welloStationX study.

The limits of agreement did not exceed 0.86 (absolute value) and clinical bias did not exceed 0.03°F for the study population overall. These strong indicators of the close agreement between the performance of the welloStationX and the SureTemp are also superior to those attained in the Caregiver study, where the limits of agreement did not exceed 1.21 (absolute value) and clinical bias did not exceed 0.20 °F for subjects overall.

The highest bias attained was 0.25°F for subjects in the welloStationX febrile subject group, which is still notably lower than the greatest bias attained in the Caregiver study of 0.32°F for subjects in the afebrile group.

The XY Chart further demonstrates the close agreement between the performance of the welloStationX and the SureTemp. The correlation coefficient of 0.80 supports this strong linear relationship.

The notably low clinical repeatability of 0.062 for subjects overall indicates that the absolute difference in repeat measurements taken with the welloStationX is very low and therefore precision across repeated temperature readings is very strong and highly repeatable. Clinical repeatability was comparably high for both the febrile and afebrile subject groups in the welloStationX study, at 0.13 and 0.09, respectively. Each of these clinical repeatability values for the welloStationX thermometer is notably lower than those attained for the Caregiver (0.17 for subjects overall; 0.21 for the febrile subject group and 0.15 for the afebrile subject group).

CONCLUSION

The intent of this study was to clinically validate application of the welloStationX automated no-contact thermometer to the reference device, the Welch Allyn SureTemp oral thermometer. The validation results indicate a high level of agreement between the welloStationX and the SureTemp. Repeatability across three sequential measurements with the welloStationX indicated high precision. It can be concluded that the welloStationX automated non-contact thermometer is an accurate and reliable tool to measure body temperature of individuals five years of age and older.

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