# INVESTIGATIONAL PLAN

## welloStationX™ Determination of Clinical Accuracy

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| **Protocol Number:** | 3939002 |
| **Revision:** | 6 |
| **Original Protocol Issue Date:** | September 21, 2018 |
| **NCT#:** | NCT03758157 |
| **Sponsor:** | Wello, Inc.<br>3939 Belt Line Rd, Suite 400<br>Addison, Texas, 75001 |

**CONFIDENTIALITY STATEMENT**

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## WS-001 Study Synopsis

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| **Title** | welloStationX Determination of Clinical Accuracy |
| **Protocol Number** | WS-001 |

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|---|---|
| **Investigational Device** | welloStationX |
| **Objective** | • To evaluate clinical bias with stated uncertainty<br>• To determine clinical repeatability. |
| **Inclusion Criteria**<br>**For All Patients** | • Males or females<br>• Age groups:<br>o 5 and up<br>• Each subject or guardian must sign an informed consent form. |
| **Exclusion Criteria**<br>**For All Patients** | Use of medications known to affect body temperature (for example, antipyretics, barbiturates, thyroid preparations, antipsychotics, etc.) within 3 hours of the test, or immunization within seven days of the test. |
| **Study Design** | The study is a multi-site study designed to enroll subjects to obtain temperature readings with the welloStationX and a reference thermometer. The data collected will be analyzed to determine clinical bias with stated uncertainty and repeatability of the welloStationX. |
| **Study Procedures** | All subjects will have their temperature taken 3 times with the WelloStation, a non-contact infrared thermometer. Another single temperature reading will be taken with a Welch Allyn oral thermometer. |
| **Primary Endpoints** | • Calculation of clinical bias with stated uncertainty<br>• Calculation of clinical repeatability<br>• Calculation of limit of agreement |
| **Number of Patients** | A minimum of 105 subjects. |
| **Number of Sites** | Three test sites plus individual home locations. |

# welloStationX Determination of Clinical Accuracy

**Protocol Number:** 3939002

**PROTOCOL APPROVALS**

_____ _____

Project Manager Date

_____ _____

Alan C. Heller Date
Wello, Inc.

**INVESTIGATOR APPROVAL**

I have read and familiarized myself with this protocol and I agree to conduct the study as described.

_____ _____

Principal Investigator Date

## Wello, INC. REPRESENTATIVES

### STUDY SPONSOR

The Clinical Study is sponsored by Wello, Inc. Overall responsibility for the study will be held by and questions regarding clinical and scientific conduct of the study should be addressed to:

Alan C. Heller
Wello, Inc.
3939 Belt Line
Suite 400
Dallas, Texas 75001
Office telephone: 469.522.5200

### TEST SITES

1. Wello Inc. Office
   3939 Belt Line Rd
   Addison, Texas, 75001

2. Agape Clinic
   Gretchen Weaver, Director of Services
   4104 Junius Street
   Dallas, Texas 75246

3. Community Council
   Denise Hugininnie, EVP
   1341 W Mockingbird Lane
   Dallas, Texas 75247

4. Individual Homes located in Dallas, Ennis, Frisco and Plano, Texas

### STUDY MONITORS

1. Stacey DiSpigno, MSc – Community Council, September 28; Agape Clinic, October 3rd and October 4th
2. Maribeth Lipscomb – Agape October 5 and October 16th
3. Alan C Heller – Wello Offices and various residences

### INSTITUTIONAL REVIEW BOARD (IRB)

IntegReview IRB
3815 S. Capital of Texas Hwy, Suite 320
Austin, TX 78704
Phone: 512-326-3001
Email: integreview@integreview.com

**LIST OF ABBREVIATIONS**

| | |
|---|---|
| C | Celcius |
| F | Farenheit |
| IRB | Institutional Review Board |
| ISO | International Standard |

# 1.0 INTRODUCTION

## 1.1 Study Purpose

To determine the Clinical Accuracy of the welloStationX by:

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

## 1.2 Indications for Use

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)."

# 2.0 Device Description

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.

The welloStationX is being evaluated for use for the screening of individuals for fever.

Deatiled information on the configuration and operation of the welloStationX can be found in the accompanying welloStationX Use and Care Manual.

## 2.1 Risk Analysis

The general risks associated with the welloStationX device are relatively minimal based on a review of published literature and known safety issues associated with the use of these types of infrared thermometer devices.

Wello has taken steps throughout the manufacture and design of the welloStationX to reduce or eliminate all potential risks to the user. Wello has identified the potential risks and actions taken to address each risk below:

- The welloStationX is not intended to be used around water. Do not set up the welloStationX near a sink or other wet area. If it is necessary to place near a sink or other wet area, make sure the unit is plugged into a working GFCI outlet.

- Always operate the thermometer in an operating temperature range 16°C to 40°C (60.8°F to 10°F), and relative humidity less than 95%.
- Always store the welloStationX in a cool and dry place -20°C to 50°C (-4°F to 122°F) and relative humidity less than 95%.
- Do Not Attempt Repairs – Do not attempt to open, take apart, service or modify the product or power supply to avoid the risk of electrical shock. Any attempt to open or service the product will void the Limited Warranty.
- Important AC Adapter Safety
  - Use only the power supply units supplied with the unit.
  - Do not use non-standard sources for power such as generators or inverters. Only use standard AC power provided by a standard wall outlet.
  - Do not overload the wall outlet or power strip or extension cord.
  - Check AC plug to make sure the prongs are configured properly and are of the proper configuration for the wall adapter.
  - Ensure the power cord is not left in a position where it can be walked on, pinched, tripped over or otherwise pulled from the wall

# 3.0 DESIGN OF THE CLINICAL STUDY

## 3.1 Study Design

This is a non-randomized, non-blinded single arm study design with the subject as his or her own control to evaluate the clinical accuracy of the welloStationX thermometer in the screening of individuals with fever.

## 3.2 Subject Sample

Subjects will be males and females aged 5 years of age and older. A total minimum of 105 subjects will be enrolled with 32-52 of those subjects being febrile. For the purpose of this testing, fever is defined as a core temperature of 99.5°F (37.5°C) or higher.

### 3.2.1 Subject SampleSize Justification

Subject sample size selection is based on the specifications in ISO 80601-2-56; 201.102.2: human subject population requirements: “The minimum number of subjects in the CLINICAL ACCURACY VALIDATION shall not be less than 105” and “The total number of febrile subjects shall be not less than 30% and not greater than 50% of all subjects in the selected age group.”

### 3.2.2. Subject Qualification: Inclusion/ Exclusion Criteria

**Inclusion Criteria**

All subjects must meet the following inclusion criteria to be eligible for the study:

- Male or female.
- Age group: 5 years and up.
- Each subject or guardian must sign an informed consent form.

**Exclusion Criteria**

Subjects meeting any of the following criteria will be excluded from the study:

- Use of medications known to affect body temperature (for example, antipyretics, barbiturates, thyroid preparations, antipsychotics, etc.) within 3 hours of the test.
- immunization within seven days of the test.

### 3.2.3 Subject Recruitment

Subjects will be recruited from amongst the following sources:

- Non-profit clinical sites, including a busy free clinic in downtown Dallas.
- Social media posts which will invite subjects to come to the Wello,Inc. office in suburban Dallas, or will offer home visits by study staff if located in far off metro areas of Dallas/Fort Worth.
- Social media posts offering free shared car service or a $25 gift card for transportation if able to come to the centrally located sites.

### 3.2.4 Subject Compensation

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

## 3.3 Study Procedures

### 3.3.1 Demographics

Age, gender and race will be recorded for each subject.

### 3.3.2 Study Device Measurements

1. Each subject's temperature was measured three times sequentially using the study device, the welloStationX® (*DUT*).
2. Each measurement was recorded by following the instructions for use contained in the device labeling.
3. Each measurement was recorded by a trained techninian.

### 3.3.3 Oral (Reference) Thermometer Measurements

1. Each subject's temperature was measured one time using a new off-the-shelf calibrated Welch Allyn SureTemp oral thermometer with disposable probe covers.
2. Each measurement was recorded by following the instructions for use contained in the device labeling.
3. Each measurement was recorded by a trained techninian.

### 3.3.4 Adverse Events Evaluation

Throughout the four measurement recordings, any reported and/or observed adverse events will be recorded on the CRF and reported and dealt with applicably.

There are no reasonably anticipated adverse events with use of the welloStationX infrared thermometer.

### 3.3.5 Reporting of Febrile Temperature Recordings

A subject for whom a febrile temperature measurement (99.5°F (37.5°C) or higher) was recorded using the Welch Allyn SureTemp oral thermometer will be reported immediately to the subject or in the case of a minor, to the guardian. The subject and/or guardian will be advised to consider seeking medical attention.

# 4.0 STATISTICAL ANALYSIS PLAN

## 4.1 Primary Outcome Measures

The Primary Outcome Measures for this study are to evaluate:

1. Clinical Accuracy of the welloStationX; and
2. Clinical Repeatability of the welloStationX

## 4.2 Primary Outcome Analysis

As per ISO 80601-2-56, these measures will be recorded and analyzed as follows:

1. *Clinical Accuracy* will be evaluated by comparing the first recorded measurement using the welloStationX with the single measurement recorded by the Welch Allyn SureTemp oral thermometer.

   Results will be presented through:
   (i) Descriptive presentation of means and standard deviations
   (ii) Evaluation of agreement calculated as the clinical bias (mean bias (±SD))
   (iii) Limits of Agreement (LOA) calculations
   (iv) Band-Altman plot created using mean bias and standard deviation data
   (v) XY Plor and Correlation Coefficient caluclation

2. Repeatability will be calculated using the pooled standard deviations formula.

   All analyses will be performed and presented by febrile status (febrile and afebrile) and by device (test device compared with reference device), as applicable.

## 4.3 Study Success Evaluation

Accuracy and reliability in welloStationX thermometer readings will be demonstrated if there is close agreement between the welloStationX and the reference device (Welch Allyn SureTemp oral thermometer).

Additionally, agreement values will be referenced against those attained for the prior validation study for the CareGiverthermometer, with agreement values for the welloStationX to be comparable or better to the published data for the Caregiver. This reference is the following:

**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.

### 4.4 Safety Analysis

Safety analysis will be through evaluation of adverse events and comparison of adverse events between use of the welloStationX and the Welch Allyn SureTemp thermometers.

### 4.5 Handling of Missing Data

Missing data will be handled through multiple imputation methods.

## 5.0 Consent and Confidentiality

### 5.1 Informed Consent

The Investigator will be responsible for obtaining from every patient prior to his/her participation in the Study an Informed Consent signed by the patient or legally authorized representative, in accordance with the code of Federal Regulations, Title 21, Part 50.20. The consent form that is used must be the current version and must be approved by both the reviewing IRB and by the Sponsor. Informed consent will be obtained from the patient after a full explanation of the purpose of the study, risks and discomforts involved, potential benefits, etc. have been provided by the Investigator both verbally and in writing. The original signed copy of the informed consent must be maintained in the institution's records, and is patient to inspection by a Sponsor representative.

- Informed consent will be an agreement between the study PI and each subject or the subject's designated caregiver, having the capacity to understand and make an informed decision. Consent will be obtained prior to each potential subject's participation in this clinical trial.
- The subject or the caregiver for each subject participating in this clinical trial will be made aware of the fact that the subject's participation involves research and the intent of the research, the expected duration of participation and a description of the procedures that will be followed.
- The subject or the caregiver for each subject will be made aware of the reasonably expected benefits the subject might receive, as well as any risks or potential discomfort that are involved.
- The subject or the caregiver for each subject will be made aware of alternative procedures that are available to the subject.
- The subject or caregiver for each subject will be made aware that the subject's records will remain confidential, but that the FDA and the IRB has the right to inspect those records.

- The subject or caregiver for each subject will be told that the subject's participation in the clinical trial is voluntary, without force or influence from the investigator or sponsor.
- The subject or caregiver for each subject will be given the name and method of contacting the appropriate person(s) to answer any questions about the research and in the event of research-related injury.

## 7.2 Privacy and Confidentiality

The sponsor is concerned for the individual patient's privacy; therefore all collected patient data will be treated confidentially, identified only by a patient identification number and investigator initials.

All information provided to the Investigator by the Sponsor, including nonclinical data, protocols, CRFs, and verbal and written information, will be kept strictly confidential and confined to the clinical personnel involved in conducting this study, and no disclosure shall be made except in accordance with any right of publication granted to the Investigator.

# Appendix A: Investigator Agreement

Provision of my signature below indicates my desire to participate in the clinical study of Wello, Inc.'s welloStationX and my agreement to all terms of this Investigator Agreement.

I have thoroughly familiarized myself with the protocol for the clinical study of the welloStationX and I believe that I am an individual who, because of my training and experience, is qualified to investigate the performance of the welloStationX under the purview of an appropriate Institutional Review Board (IRB) or Ethics Committee. I will provide the Sponsor with a copy of my curriculum vitae.

I specifically and further agree that:

1. I will conduct the clinical investigation in accordance with this Investigator Agreement, the Investigation Plan, the FDA IDE regulations, other pertinent FDA regulations, and any conditions imposed by my IRB, Ethics Committee or federal/state/local regulatory agencies.
2. I will ensure there is a copy of a written approval by an Institutional Review Board (IRB) Committee of the Wello, Inc. Investigational Plan prior to enrollment of the first patient.
3. Prior to any study related procedure, I will obtain a signed Informed Consent from every patient, or his/her legal representative, who participates in this clinical investigation.
4. I agree to complete all training required by Wello, Inc. in the use of the welloStationX prior to collection of temperature measurements of the first subject.
5. All use of the welloStationX will be under my direct supervision and according to the approved Investigational Plan. I will not allow access to the welloStationX to anyone other than those employees of my institution who, under my direct supervision, are participating in this study.
6. Only patients satisfying the study inclusion/exclusion criteria and willing to provide informed consent will be enrolled into this clinical study.
7. All information received from Wello, Inc. about the welloStationX and all knowledge obtained under or concerning this study including the study design, protocol, data, results, and any related written or orally-transmitted information, is considered the proprietary property of Wello, Inc., and I will retain it in confidence and not release it to anyone without written consent from Wello, Inc.
8. I will obtain written permission in advance from Wello, Inc. to publish or present any aspect of the Investigational Plan and study, including, but not limited to, animal or human study design, data, and results.
9. I agree to fully comply with all of the responsibilities of Investigators outlined in the Code of Federal Regulations.

My managerial responsibilities as an Investigator are outlined below.

1. I will attend Investigator meeting when requested by Wello, Inc. or arrange for a suitable representative from my institution.
2. I will review all investigational product and study-related documents sent to me by Wello, Inc. in a thorough and timely fashion and will provide Wello, Inc. with pertinent feedback when requested.
3. I will ensure that investigational data are collected and recorded in a complete and accurate manner. I will sign all case report forms as testimony to my review of investigational data. I understand that it is necessary that investigational data be submitted to the Sponsor in a timely manner so as to ensure a timely review and assimilation of results.
4. I will submit interim and final reports to my IRB/Ethics Committee, the FDA and my federal, state, and local regulatory agencies as required by the conditions of approval from the respective agencies.
5. I agree to personally meet with, and implement any corrective actions identified by, Wello, Inc.'s study monitors during periodic audits.

I have never participated in any research project that has been terminated by an administrative body, financial sponsor, or regulatory agency for reasons of protocol noncompliance, misrepresentation of data, or any other reason.

Printed Name of Investigator:_____

Signature of Investigator: _____ Date:_____

# APPENDIX B: WELLOSTATIONX LABELING

User Manual provided to site at site initiation visit.

# APPENDIX C: Reference Thermometer Labeling

User Manual provided to site at site initiation visit.

# APPENDIX D: Study Monitoring

Adverse event reporting including device issue and unanticipated events (reportable to IRB) are included in the Case Report Form. None reported.