ACCUUARCY STATEMENT: HIGI STATION AND SH-650 HEALTU SHATION

Overview & Regulatory Context

higi SH LLC (higi) is a certified Quality Management System and Medical Device Standards (ISO 13485) company. It complies with all regulations associated with the design, manufacturing and distribution of health monitoring tools.

In addition to ISO certification, higi medical device products receive FDA clearance (via the 510k process) prior to market introduction in the USA.

Defining Accuracy

Accuracy requirements for the medical devices are generally prescribed by regulatory authorities as an element of the associated clearance process - FDA 510(k) in the USA, Health Canada MDL process in Canada.

In the case of the Health Stations developed by higi, accuracy is assessed based upon the definitions for trueness and precision provided in ISO 5725 (ISO 5725-1).

Following are descriptions of the two components which define the accuracy of higi medical device products: trueness and precision.

Trueness: The trueness of measurement is the closeness of agreement between the average value obtained from a large series of test results and an accepted reference value.

Precision: The precision of measurement refers to the closeness of agreement between independent test results obtained. In other words, what results you can expect if you were to do repeated measurements using the same equipment within short intervals of time on the same user. The precision of an instrument is also a way of assessing the design and sensitivity of the measurement.

This document describes in simple terms the trueness and precision required from the devices on the higi Station and the SH-650 Health Station (Health Stations) to:

- comply with ISO 13485 certification standards, and
- obtain ongoing medical device clearance from the US FDA and Health Canada.
Regulatory Standards

In addition to following a routine of regular internal and external ISO 13485 audits, higi is required to certify, via third party testing, that its medical device products meet the following standards:

- IEC 60601-1 Ed. 3.0 B:2005, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 (2010), Medical electrical equipment, Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366:2007, Medical devices - Application of usability engineering to medical devices
- IEC 60601-1-2:2007, Class B Emissions EMC and CB
- Sphygmomanometer Guidance Collection 2010 (Revision Date 2013/07/01)
  - ISO 81060-2:2009, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type

Measurement against these prescribed standards, combined with consistent application of our quality management system provides the foundation for ensuring quality and accuracy in higi products.
higi Health Station Devices and Tests

The following sections outline details for each of the devices and tests delivered via Health Stations.

Note: The information below generally applies to all current Health Station models. Where information is specific to a certain model, the content will reference either the higi Station, or SH-650 Health Station.

Blood Pressure Measurement

Metrics: The blood pressure (BP) test results in observations for blood pressure (systolic & diastolic), and heart rate.

Upper Arm Circumference: The cuff is designed to accommodate upper arm sizes from 8.66 to 17.2 inches (22 to 43.48 cm) in circumference.

Blood Pressure Assessment

For adult and pediatric (children 13 and older) patient populations, blood pressure measurements made with the Advantage OEM (Original Equipment Manufacturer) BP Module Series are equivalent to those obtained by trained observers using the cuff/stethoscope auscultatory method within the limits prescribed by:

- ANSI/AAMI SP10:2002
- EN1060-4:2004
- ISO 81060-2:2013 (higi Station only)

Accuracy Requirement: mean error difference of ± 5 mmHg or less with a standard deviation of 8 mmHg or less.

Provided the user’s arm is within the defined range, and the device is used as described in the on-screen instructions, the blood pressure cuff is certified to meet the accuracy standard requirement over a blood pressure range of:

- Systolic: 78—214 mmHg
- Diastolic: 40—131 mmHg

General Notes on Blood Pressure Measurements

In general, obtaining consistent BP measurements can be highly dependent on the user who is taking the measurement. Posture is important, as is what the user was doing before sitting down to take a measurement.

In Appendix I, we have included a suggested SOP for taking blood pressure measurements to help ensure consistency when a user takes repeated BP measurements over long period of time.

Heart Rate Assessment

Heart rate (pulse) is recorded when taking a blood pressure test. The pulse number is provided in beats per minute (bpm). This value is measured via the same module used to measure blood pressure, using a method to deduce heart rate that is proprietary to the blood pressure module manufacturer.
Weight Measurement

Metrics: The weight test results in observations for total body weight, and body mass index (BMI).

Total Body Weight Assessment

Maximum Measurable Weight:

- higi Station: 440 lbs (199.6 kg)
- SH-650 Health Station: 500 lbs (227 kg)

Measurement Precision: Weight is measured in 0.1 lb increments.

Accuracy & Repeatability: The scales used in higi Health Stations are designed to commercial and medical grade standards.

While the scales are highly accurate, the setting in which measurements are taken introduces certain variables that influence the final results (e.g. random extra weight from the user’s clothes).

With this in mind, the focus for weight measurements is on delivering repeatability to generate consistent trends over time. After each use, the scale is cleared and reset to zero to ensure that the precision of each use is within the tolerance of 0.1 lb.

As a result, repeated measurements under the same conditions should not vary by more than ± 0.1 lb.

General Notes on Weight Measurements

The weight assessment is conducted while seated at the kiosk. For weight to be measured correctly:

- Feet must be off the ground, and placed on the foot rest
- Hands and arms should not be touching anything on the kiosk.

Body weight measurements include any weight from clothing, shoes, and anything the user may be holding. The scale does not adjust for these items and thus, the shown value will be higher than the user’s actual true weight.

The added weight does affect the results of other measurements that leverage the weight assessment during the same user session: BMI, body fat mass, and hydration.

To help with the accuracy of these measures it is recommended that users minimize the factors that contribute additional weight. Options include:

- Remove coats and other heavy outerwear.
- Remove heavy boots or shoes, if practical.
- Do not hold purses, bags, keys, or other items while taking a weight measurement.
- Always take a user’s weight measurements around the same time of day.
- Wear similar clothing each time a weight measurement is taken to maximize consistency in trends over time.

As weight and body composition are most useful as trends over time, the most important consideration is to take weight measurements under conditions that are as consistent as possible.
Body Mass Index Assessment

Body Mass Index (BMI) is a number that is calculated using weight and height.

This number provides an indication of body fatness and is used to screen for weight categories that may lead to health problems (Centers for Disease Control and Prevention, 2013).

Accuracy: As BMI is not a direct measurement, its trueness and precision is directly related to the accuracy of the values used to calculate it:

- total body weight (measured)
- height (manually entered by the user)

To help with accuracy of the BMI result, it is important that the user enters their true height.

General Notes on BMI Categories

The categories displayed for BMI results are currently based upon adult designations.

Although the BMI number is calculated the same way for children and adolescents, the criteria to interpret the meaning of BMI is different and therefore the adult method should not be used for children.

Body Composition Measurement

Metrics: The body composition test results in observations for body fat percentage, and hydration (see notes, below).

Body composition is currently presented as an element of the weight test on Health Stations with an installed higi body composition analysis device (currently SH-650 Health Stations).

In addition to the bio-impedance reading performed at the Health Station, a number of other data points are utilized in body composition measurements: age, gender, and height.

Body Fat Mass Assessment

The Health Station body composition analyzer is based on the higi BC4/BCM hardware and software. The 510(k) filing for this medical device was cleared by the FDA in January of 2011. Proprietary higi algorithms, based upon extensive studies, are used to deliver highly accurate and repeatable results.

Proper use of the body composition test has been show to result in reliable, repeatable body fat percentage values.

Accuracy: The accuracy of higi BC4/BCM technology has been independently validated in children and adults (Erceg DN, 2010). Results of this validation show:

- Group average percent body fat and lean body mass were generally within 1 percentage point of the reference method.
- The majority of individual readings were generally within 5 percentage points of the true body fat and lean body mass values.
• The precision of measure on average varies by less than 2 percentage points when measurements are made back to back, assuming the user maintains the correct hand and body position for each measurement.

In 2013, the SH-650 Health Station received 510(k) clearance from the FDA. As part of this clearance, new studies comparing the SH-650 Health Station to the handheld BC4/BCM showed that:

• The position of the body composition analyzer electrodes on the SH-650 Health Station provide body fat values on average less than 1 percentage point different than the BC4/BCM device.
• Measurements made using the Health Station are equally reliable from a precision point of view.

General Notes on Body Fat Measurements

Much like weight, body fat percentage is most useful as a trend over time. Users should try to take measurements in as consistent a manner as possible.

The following can cause fluctuations in body fat percentage results:

• Inconsistent body or hand position (inconsistent with the on-screen instructions)
• Fluid intake and meals (due to their effect on total body weight, which is used in calculations)

In addition to the general guidelines provided for weight measurements, the following practices help to ensure accurate and repeatable body fat measurements:

• Maintain proper body position, as described in the on-screen instructions.
• Take measurements at roughly the same time of day.
• Avoid consuming a meal or fluids prior to taking a body composition test.

Hydration Assessment

Note: While hydration is measured during the body composition test, the results are not currently presented to the user. Presentation of this data will be added in a future release of the product.

The higi Hydration Index

During the development of the hydration measurement technology used on higi Health Stations, a review of published works on how best to present a person’s hydration status was conducted. In addition, higi SH LLC conducted a clinical trial on the subject. There was inconsistency in the public literature on the best way to present hydration.

What was clear, however, was the need for a better way to report hydration results to users, so higi SH LLC developed the Hydration Index. The Hydration Index calculates, on an individual basis, a person’s specific hydration status.

Higi calculates hydration as a percent of your total body weight, and normalizes that to an individualized zero point (baseline).

Put simply, the Hydration Index shows a user’s hydration status relative to what is expected for their age, gender, height, weight, and body fat percentage:

• Well-hydrated (positive number)
• Normal (zero)
• Under-hydrated (negative number)

How It Works

1. The user’s total body water (TBW) is calculated based upon height, weight, age and gender using a proprietary algorithm.

2. The user’s TBW goal is calculated based on total body weight, lean mass, and body fat (data from the body fat calculation, above).

3. TBW goal is compared to the TBW actual values to calculate the Hydration Index.

The result is normalized so that a value of zero represents normal hydration, positive numbers indicate a well-hydrated state, and negative numbers indicate an under-hydrated state.

This approach makes review of a user’s data over time very simple, as zero is an absolute representation of normal hydration, regardless of other factors (weight, body fat, etc.).

Accuracy: The accuracy of the two data points used to calculate Hydration Index (total body water, and body water goal) is plus or minus 2%. The proprietary algorithms used to calculate hydration were developed based upon clinical studies using the Heavy Water Reference Method that gives a direct measure of the water content of your body.

General Notes on Hydration

Every part of the human body contains fluids. In fact, fluids are the human body’s largest component. Hydration is the total amount of water and other fluids contained within the structure of the human body, including bones, muscle, fat, and organs.

Proper hydration is critical to well-being. Under-hydration, or dehydration, is a common condition that can result in impaired performance or day-to-day conditions such as headaches, poor skin and hair texture. An athlete’s performance can be impaired by being under-hydrated.

Extreme dehydration can be dangerous and when neglected, can result in damage to major organs and even death (Popkin, 2010).

A majority of the population has been found to be under-hydrated. This may be due to drinking too many caffeinated beverages that actually cause the body to expel fluids and not having enough dietary fluid intake.
Appendix I: Recommended SOP for Blood Pressure Measurement

It is well known that blood pressure varies continuously in a person, and can be influenced by many factors. The following SOP is intended to help healthcare professionals ensure a reliable and accurate reading blood pressure measurement.

These steps can be taken when assisting a patient in taking a blood pressure measurement.

1. Remove outer coats and sweaters.
2. Ask the person to be seated, and adjust their seating position to be comfortable. Feet should rest on the floor, and back should be comfortably straight.
3. Demonstrate how to initiate testing on the touch screen, and have the person take the weight and BMI test prior to taking their blood pressure. Alternatively, ask them to relax for at least two minutes (preferably the AHA-recommended 5 minutes) before taking the blood pressure test.
4. Make sure arm circumference is within the recommended size limits. If it is outside of the limits, a manual reading will need to be taken.
5. Have the person place arm in the cuff. Ensure that the elbow is clear of the cuff, and the arm is relaxed. If possible, the arm should be resting on the surface of the board with palm up.
6. Check that the person is as upright as possible, and note the level of the bottom of the cuff housing in relation to the level of the sternum on the chest (upper atrial position). Preferably, they should be level with each other. If that cannot be achieved comfortably, make sure that the same position is used each time you measure that person.
7. Ask the user to press the start button, and take the test.
8. Read the results. If they are high, it is highly recommended to take another test after a 90 second relaxation time.
9. Results can be manually recorded from what is on screen, sent by email, or saved to the person’s higi account at user’s discretion.
References


