



Kinesis Balance™

Home balance
and fall risk
assessment tool

User Guide

Linus Health version

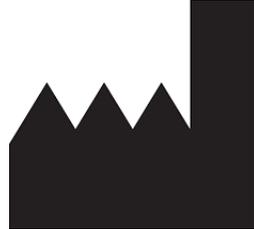
Version 1.2 – October 2021



LINUS HEALTH



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Contents

Glossary	4
Overview	5
Features	5
Platform	5
Getting started.....	6
User profile	7
Questionnaire	8
Balance test.....	9
Results.....	10
External sensor	11
Five Times Sit to Stand.....	12
Parameter definition	13
Questionnaire definition	15
Data management	16
Excel export.....	16
Raw sensor data	16
Regulatory information.....	17
Declaration of Conformity	17
Restrictions on Use	17
Data security regulatory compliance	17
Medical Device Regulatory Compliance	17
References	18

Glossary

Term	Definition
Inertial sensor	Tri-axial accelerometer and tri-axial gyroscope sensors embedded in your smartphone
Standing balance test	Standard test of balance – stand still for 30 seconds with eyes open (EO condition) or eyes closed (EC condition), in semi-tandem stance. People who sway more during the test are at higher risk of falling.
Semi-tandem stance	Stand with one foot on front and to the left of the other, side of the heel of front foot should be touching the side of the big toe on the back foot.
Participant	Person performing the standing balance test
Carer	Person aiding participant with completing the balance test



It is recommended to refer to the manual

Overview

Linus Health and Kinesis Health Technologies Ltd have developed a customized version home balance and falls risk assessment tool, *Kinesis Balance*™ (www.kinesishealthtech.com/balance) to allow an older adult to objectively assess and monitor their balance and risk of falls risk in their own home, using a smartphone.

Kinesis Balance™ is a medical device and uses the inertial sensors embedded in the smartphone (or an optional external inertial sensor) along with simple questionnaires to provide a statistical profiling of balance as well as an evidence-based falls risk score. The product uses validated, patent-protected algorithms and is based on a large dataset of community dwelling older adults and patients with neurological diseases¹⁻⁶ (www.kinesishealthtech.com/research/).

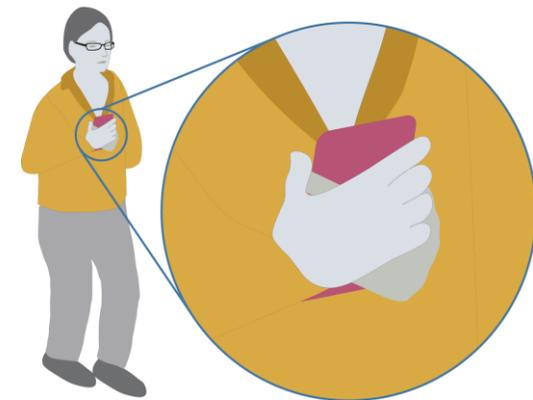
Kinesis Balance™ allows an older person to assess and track their falls risk and balance in the home or community environment through statistical analysis of clinical fall risk factors and quantitative balance measures obtained as part of a simple static balance test and a short clinical questionnaire.

Features

- **Reliable profiling of fall risk and balance against age and gender norms**
- **Trending of balance and fall risk**
- **Advice on staying healthy, maintaining balance and avoiding falls**
- **User prompting to perform test on a periodic basis**
- **Secure backup of data to the cloud**
- **Accessible and exportable data**

Platform

Kinesis Balance™ uses sensors embedded in common smartphones and runs as an Android application on most modern Android smartphones.



Hold your phone
with both hands

Getting started

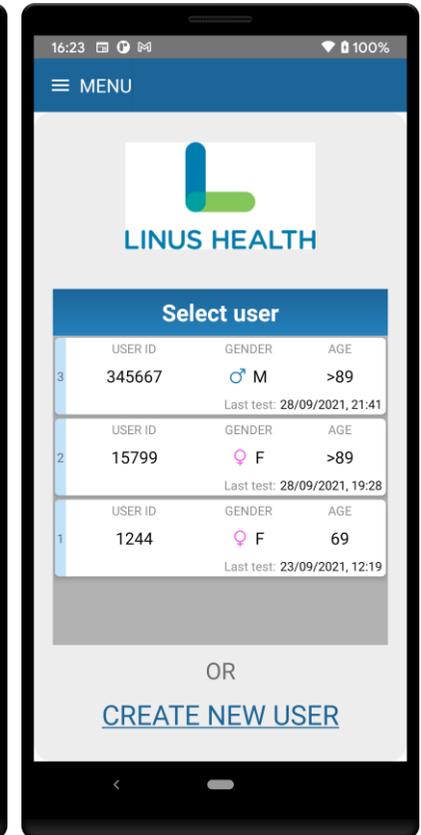
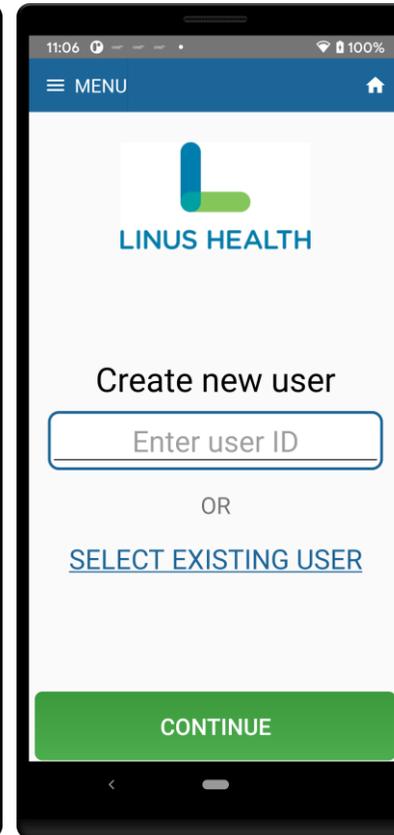
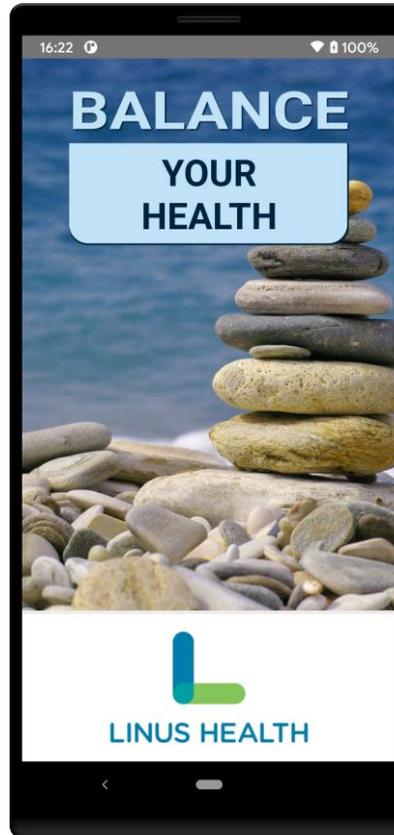
To start using Kinesis Balance, press the Kinesis Balance icon on your phone.



Upon starting the app you will be asked to create a **New User** or select an **Existing User**.

To create a new user profile select **Create new user**, you will then be asked to enter a user ID.

User ID can be any set of alphanumeric characters. To ensure HIPAA compliance, please ensure this user ID does not contain Personally Identifiable Information (PII).

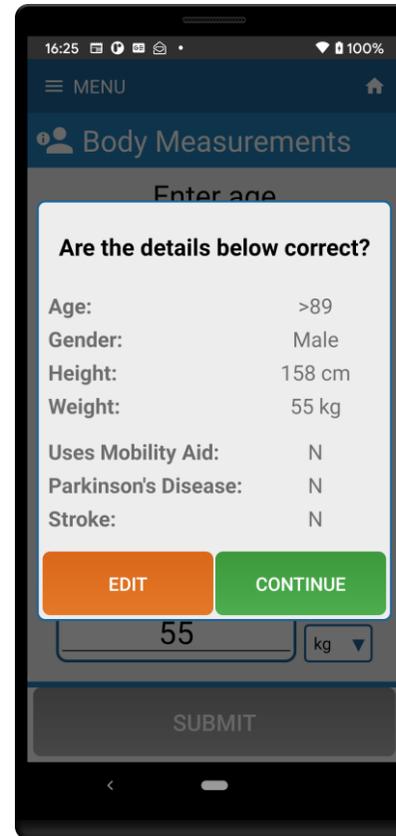


User profile

After selecting a user, you will then be asked to complete your **Profile**, which includes body measurements (your age, gender, height and weight) as well as some questions on your medical history (such as if you have ever been diagnosed with Parkinson's disease or use a walking aid).

Use the dropdown menu to change measurement units from metric (kg/cm) to Imperial (ft, in, lbs).

When profile is complete, please press **Submit** to advance to the next page.



16:25 100%

MENU

Body Measurements

Enter age

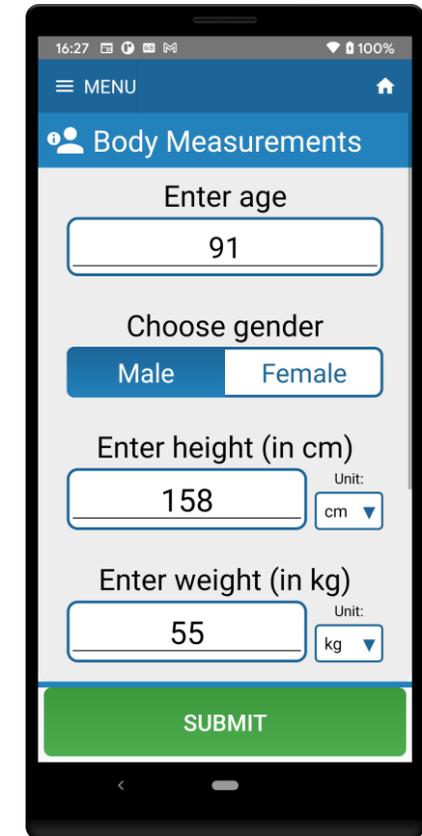
Are the details below correct?

Age:	>89
Gender:	Male
Height:	158 cm
Weight:	55 kg
Uses Mobility Aid:	N
Parkinson's Disease:	N
Stroke:	N

EDIT CONTINUE

55 kg

SUBMIT



16:27 100%

MENU

Body Measurements

Enter age

91

Choose gender

Male Female

Enter height (in cm)

158 Unit: cm

Enter weight (in kg)

55 Unit: kg

SUBMIT

Questionnaire



The screenshot shows a mobile application interface for a questionnaire. At the top, there is a blue header with a 'MENU' icon and a home icon. Below the header, there are five questions, each with a 'Yes' and 'No' button. The questions are: 'Have you fallen in the last 12 months?', 'Do you have any problems walking or moving around?', 'Are you taking four or more prescription medications?', 'Do you have any problems with your feet?', and 'Do you have any problems with your blood pressure dropping when you stand up?'. Below the questions, there is a green 'SUBMIT' button. At the bottom of the screen, there are three navigation icons: a home icon, a square icon, and a back arrow icon.

Next, you will be asked a brief questionnaire on your clinical fall risk factors, such as if you feel dizzy when you stand up (orthostatic hypotension) or if you are taking four or more prescription medications (polypharmacy).

When you have completed all questions please press **Submit** to advance to the balance test.

You will be asked to complete this questionnaire each week as it will be used to estimate your weekly risk of having a fall.

(See questionnaire definition section for more information on the questionnaire used).

Balance test

Prior to starting the balance test, you can listen to audio instructions on how to complete the test. To hear audio instructions, press **Play audio instructions**.

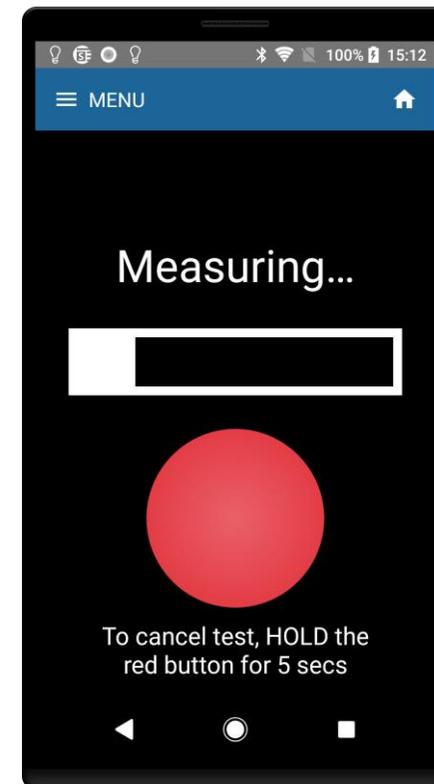
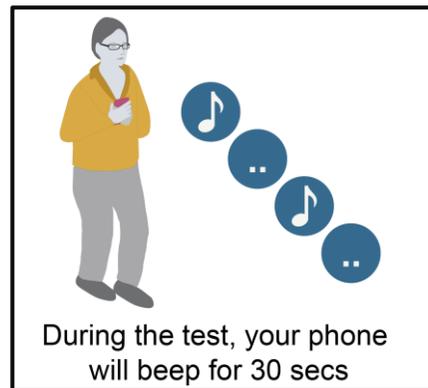
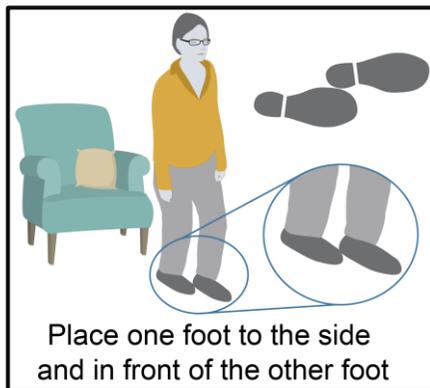
Stand in a **semi-tandem stance** (one foot on front of, and to the side of the other foot). For safety, stand next to a chair and interrupt the test at any time if you feel unsteady.

To start the Balance test, press **Measure my balance now**.

Hold your phone against your chest and wait for audio countdown to start. **Hold the phone firmly against your body and stand very still until the beeps stop.**

The test will last 30 seconds, when complete the app will calculate your balance impairment and falls risk scores.

To cancel the test, you can hold the red button on the test screen for 5 sec. If there are any problems during the test, you will have the option to accept or reject the test, at which point you may be invited to start the test again.



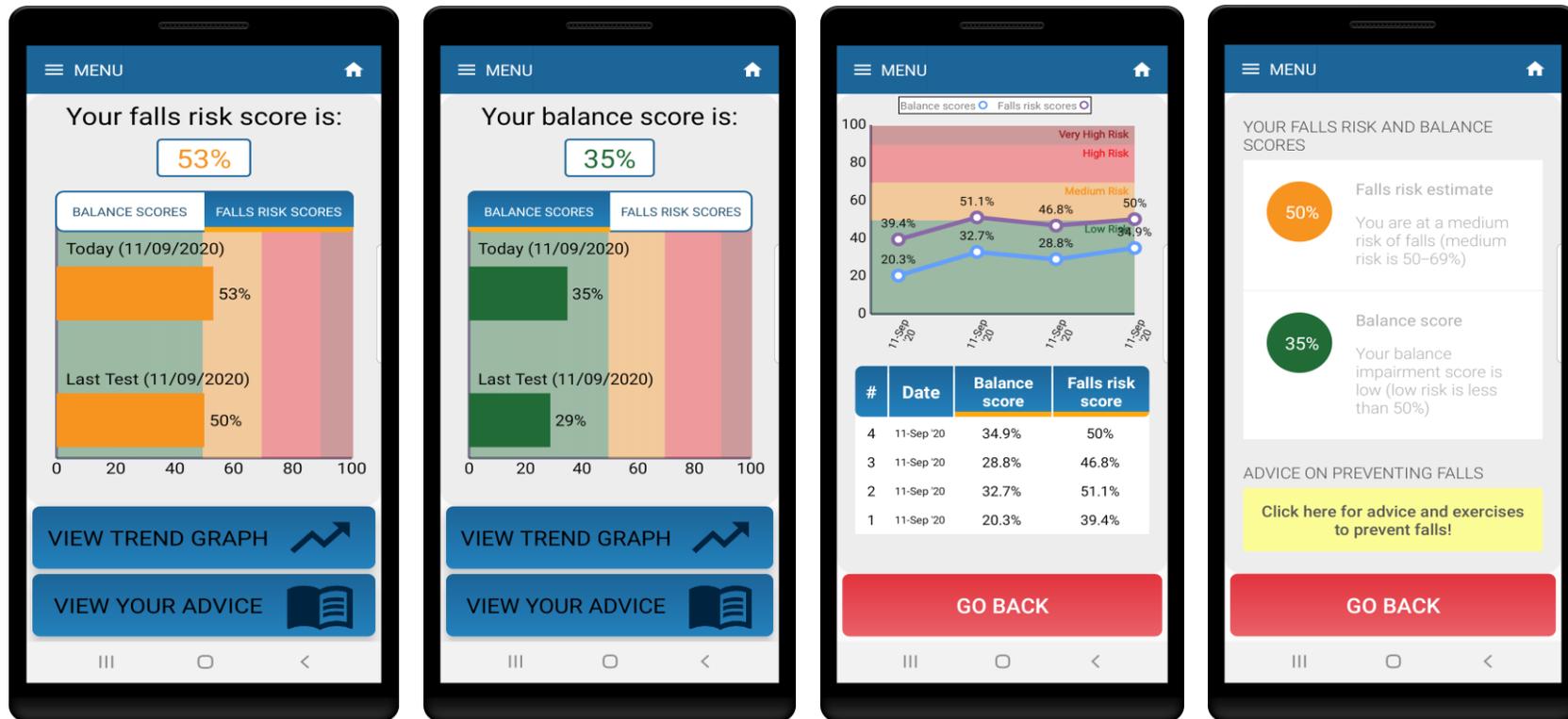
Results

After completing the Balance test, results can be viewed on the Results screen.

The results screen will display your **Balance Impairment Score**, which shows how your balance compares against average values for your age and gender (*the lower the better*). The results screen will also show your **Fall Risk Score** (combined falls risk estimate), which is a measure of how likely you are to have a fall (*the lower the better*).

The trend screen provide detail on how your balance and falls risk are changing over time and whether additional action is required. Additional details and definitions for the results are available by pressing on any of the results panels.

The advice page provides best practice advice on preventing falls, based on your level of risk. Exercises suitable for completing at home are provided through an external link.



External sensor

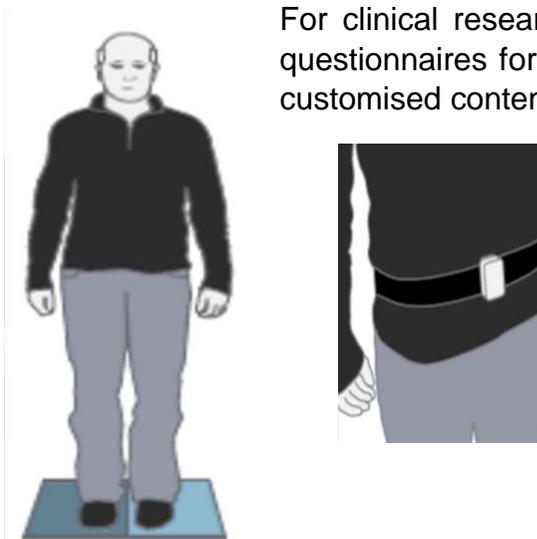
Kinesis Balance provides an option to use an external inertial sensor, mounted on the lumbar spine or pelvis for assessment of balance and falls risk. A standard Kinesis sensor is required for this purpose and is not supplied with Kinesis Balance as standard. Sensor can be held in place using tape or medical bandages.

Selecting *Use for algorithm* will apply the external sensor data to the algorithm and display results, instead of the smartphone sensor data.

Selecting *Research mode* will allow external sensor data to be recorded for any duration desired.



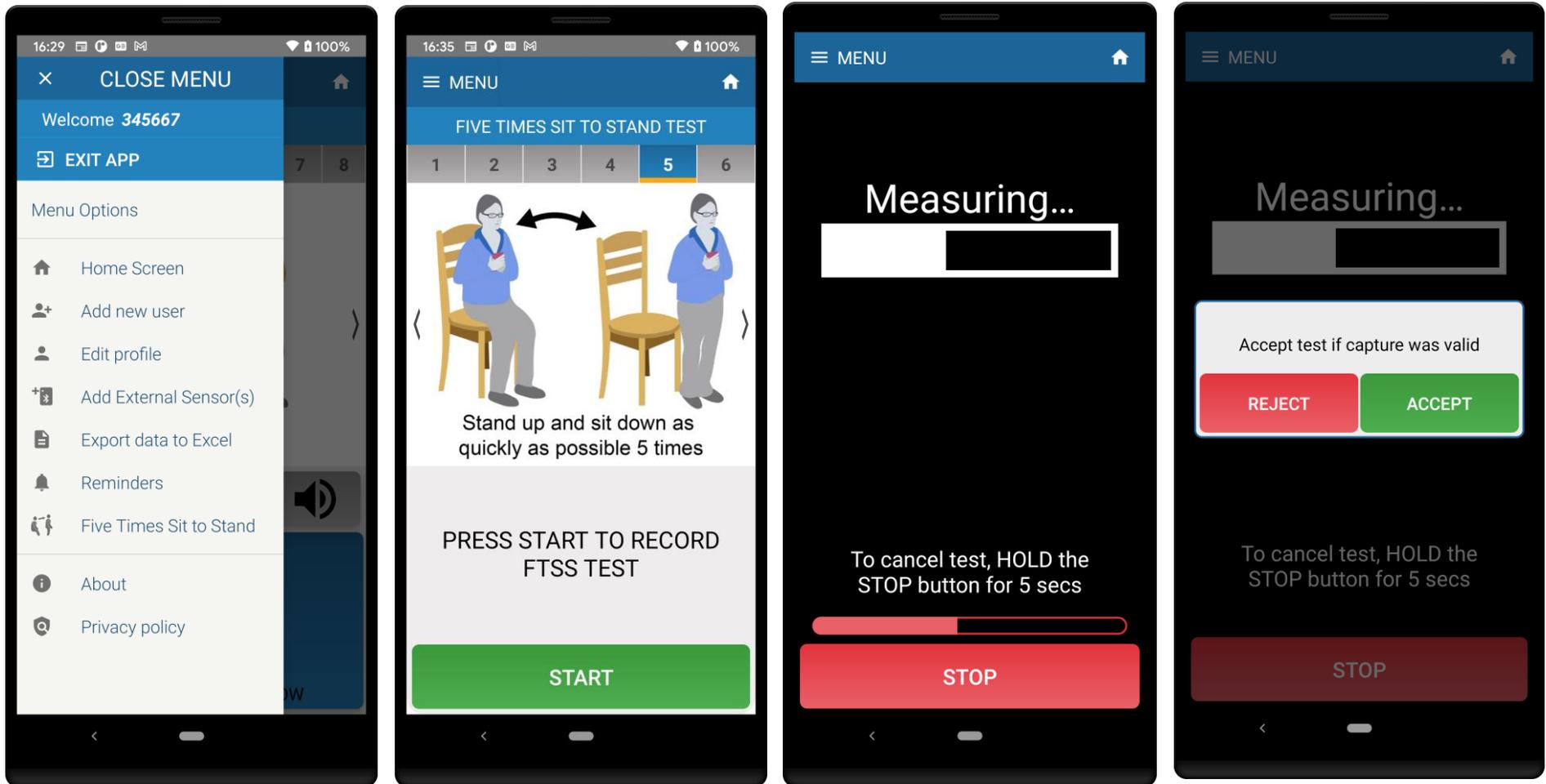
For clinical research, Kinesis Balance enables the use of additional questionnaires for assessment of physical activity and wellbeing, and customised content for digital intervention.



Five Times Sit to Stand

The **Linus Health** version of Kinesis Balance provides an option to capture data from completing a Five Time Sit to Stand (FTSS) test. This allows you to record sensor data from your phone's on-board sensors while completing the test.

To record a FTSS test, select Five Times Sit to Stand from the app menu. To complete the test, hold the phone firmly against your torso. Audio and visual instructions are provided. The FTSS test the test will end after 60s automatically but can be ended at any time by holding down the red button.



Parameter definition

A valid test displays and saves the test results, a summary of results are displayed on the screen and all results can be exported in Excel format. The definitions of these results are explained in the table below.

Parameter definition	Description
Balance Impairment Score (%)	<i>Statistical assessment of your balance using the sensor data from your phone by comparing to average values for your age and gender. Larger values indicate worse balance, values over 70% indicate impaired balance.</i>
Combined falls risk estimate (%)	<i>Statistical measure of your falls risk, based on a combination of your questionnaire responses and sensor data from your phone. Larger values indicate higher falls risk, values over 70% indicate high falls risk.</i>
Falls Risk Estimate (%)	<i>Statistical risk of falls based on a model derived from sensor data from your phone, obtained from a population of community dwelling older adults. Larger values indicate higher falls risk, values over 70% indicate high falls risk.</i>
Clinical falls risk estimate (%)	<i>Statistical risk of falls based on a model derived from clinical risk factors (obtained from AGS/BGS falls questionnaire) obtained from a population of community dwelling older adults. Larger values indicate higher falls risk, values over 70% indicate high falls risk.</i>
Recording time (s)	<i>Recording time for balance test as recorded using app timer.</i>
RMS acceleration	<i>Average Root Mean Squared (RMS) acceleration taken across all three accelerometer axes.</i>
RMS acceleration - X-axis	<i>Average Root Mean Squared (RMS) acceleration of the accelerometer X-axis.</i>
RMS acceleration - Y-axis	<i>Average Root Mean Squared (RMS) acceleration of the accelerometer Y-axis.</i>
RMS acceleration - Z -axis	<i>Average Root Mean Squared (RMS) acceleration of the accelerometer Z-axis.</i>
RMS angular velocity	<i>Average Root Mean Squared (RMS) angular velocity taken across all three gyroscope axes.</i>
RMS angular velocity - X-axis	<i>Average Root Mean Squared (RMS) angular velocity of the gyroscope X-axis</i>
RMS angular velocity - Y-axis	<i>Average Root Mean Squared (RMS) angular velocity of the gyroscope Y-axis</i>
RMS angular velocity - Z -axis	<i>Average Root Mean Squared (RMS) angular velocity of the gyroscope Z-axis</i>
Median frequency –acceleration (Hz)	<i>Median frequency of the acceleration signal, averaged across all three accelerometer axes.</i>

Spectral edge frequency - acceleration (Hz)	<i>Spectral edge frequency of the acceleration signal, averaged across all three accelerometer axes.</i>
Spectral entropy -acceleration	<i>Spectral entropy of the acceleration signal, averaged across all three accelerometer axes.</i>
Median frequency - angular velocity (Hz)	<i>Median frequency of the angular velocity signal, averaged across all three gyroscope axes.</i>
Spectral edge frequency - angular velocity (Hz)	<i>Spectral edge frequency of the angular velocity signal, averaged across all three gyroscope axes.</i>
Spectral entropy - angular velocity	<i>Spectral entropy of the angular velocity signal, averaged across all three gyroscope axes.</i>

Questionnaire definition

The questions contained in the fall risk questionnaire are detailed below. The questionnaire is based on the American and British Geriatric Society Guidelines (AGS/BGS)⁷ and examine standard clinical risk factors associated with falls. Prior to each balance test, you will be asked to complete this questionnaire, which is used in assessing your falls risk.

#	Question
1	<i>Have you fallen in the last 12 months? Y/N, if Y: How many times?</i>
2	<i>Do you have any problems walking or moving around? Y/N</i>
3	<i>Are you taking four or more prescription medications? Y/N</i>
4	<i>Do you have any problems with your feet? Y/N</i>
5	<i>Do you have any problems with your blood pressure dropping when you stand up? Y/N</i>
6	<i>Do you feel dizzy when you stand up from a sitting position? Y/N</i>
7	<i>Do you have any problems with your vision (not correct by glasses)? Y/N</i>
8	<i>Have you had any recent difficulties managing your routine activities in the home? Y/N</i>
9	<i>How many hours do you exercise each week? Y/N</i>
10	<i>Did you complete this questionnaire for yourself (select "N" if you are completing it on behalf of somebody else)? Y/N</i>

Data management

Excel export

Test results and quantitative balance parameters for all tests can be exported in Excel format. Exported data are stored in the Export folder (*Kinesis/Balance/Export*).

Raw sensor data

Raw inertial sensor data and questionnaire data are available for each test. Data are in the Data folder (*Kinesis/Balance/Data*). Anonymised data for all tests are backed up automatically to the Kinesis cloud.

In *Research mode*, raw sensor data for the duration of the test are stored.

Regulatory information

Declaration of Conformity

This Kinesis Health Technologies product meets the relevant medical device regulations in EU and all other geographies in which it is made available for sale. As the legal manufacturer, Kinesis Health Technologies (and its distributors) shall comply with all applicable laws and regulations relating to medical devices, specifically the Medical Device Regulations 2017/745 ('MDR') as it pertains to a Class I medical device (without a measurement function). In the United States, this product meets the Quality System Regulations ('QSR'), specifically the FDA 21 CFR part 820 for a class I medical device (exempt from 501(k) regulation).

Restrictions on Use

THIS KINESIS PRODUCT IS NOT INTENDED, DESIGNED OR AUTHORIZED FOR CONTINUOUS COMMUNICATION OF REAL TIME DATA.

THE SOFTWARE IS NOT INTENDED, DESIGNED OR AUTHORIZED FOR PROVIDING TIME-CRITICAL MEDICAL CARE, PROVIDING MEDICAL OR OTHER EMERGENCY RESPONSE ALERTS OR ANY OTHER ANY APPLICATIONS OUTSIDE THE INTENDED USE SPECIFIED IN THE USER GUIDE, OR FOR USE IN ANY CIRCUMSTANCE IN WHICH THE FAILURE OF THE PRODUCT WOULD PRESENT AN UNREASONABLE RISK OF ILLNESS OR INJURY TO THE USER.

Data security regulatory compliance

Kinesis Health Technologies Balance™ product complies with data security and privacy regulations in our target countries. Personal identifiable information is not captured or stored in the software. Data is encrypted in transit and stored on our cloud server.

For further information please see our privacy policy at <https://www.kinesishealthtech.com/privacy-policy>

Medical Device Regulatory Compliance

This product, developed by Kinesis Health Technologies, is intended to measure static balance and falls risk using a smartphone device.

In purchasing this Kinesis product, the customer acknowledges and understands that the software is registered as a medical device under the Medical Device Regulations and that Kinesis may not put products "on sale" without first certifying to CE conformance. Similarly, for the US, the customer acknowledges and understands that the software is registered as a medical device under the Quality System Regulations. For such products, the purchase and subsequent use or resale by the customer must be with Kinesis express permission and in accordance with relevant medical device regulations.

Kinesis (or where appropriate, its local distributors) shall act as the complaint handling point of contact for any complaints relating to the product. Complaints shall be defined in accordance with the MDR. Any complaints should be provided in English and in writing to Kinesis (or where appropriate, its local distributors). Complaints submitted shall be handled in accordance with complaint handling processes mandated by the MDR.

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- 1 B. R. Greene, S. J. Redmond, and B. Caulfield, 'Fall Risk Assessment through Automatic Combination of Clinical Fall Risk Factors and Body-Worn Sensor Data', *IEEE Journal of Biomedical and Health Informatics*, 21 (2016), 1-1.
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- 5 Barry R. Greene, Killian McManus, and Brian Caulfield, 'Automatic Fusion of Inertial Sensors and Clinical Risk Factors for Accurate Fall Risk Assessment During Balance Assessment', in *IEEE Biomed. Health Inform. Conf* (Las Vegas, NV: 2018).
- 6 Barry R. Greene, Killian McManus, Stephen J. Redmond, Brian Caulfield, and Charlene C. Quinn, 'Digital Assessment of Falls Risk, Frailty, and Mobility Impairment Using Wearable Sensors', *npj Digital Medicine*, 2 (2019), 125.
- 7 American Geriatrics Society Panel on Prevention of Falls in Older Persons, British Geriatrics Society, 'Summary of the Updated American Geriatrics Society/British Geriatrics Society Clinical Practice Guideline for Prevention of Falls in Older Persons', *Journal of the American Geriatrics Society*, 59 (2011), 148-57.