



Kinesis Balance™

Home balance
and fall risk
assessment tool

User Guide

Version 2.0 – January 2023



Manufacturer address



Linus Health Europe

NexusUCD
Belfield Office Park
Clonskeagh
Dublin D04 V2N9
Ireland

Internet address
Email address
Support & FAQs
Contact support

<http://www.kinesishealthtech.com>
info@kinesishealthtech.com
<http://www.kinesishealthtech.com/support>
support@kinesishealthtech.com

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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.
Five Times Sit to Stand test	Standard test of strength and endurance – starting from a seated position, stand-up and sit down five times, as fast as safely possible. Test ends when re-seated for the final time.
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

Kinesis have developed a 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 and strength 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 diseases¹⁻⁸ (www.kinesishealthtech.com/research/).

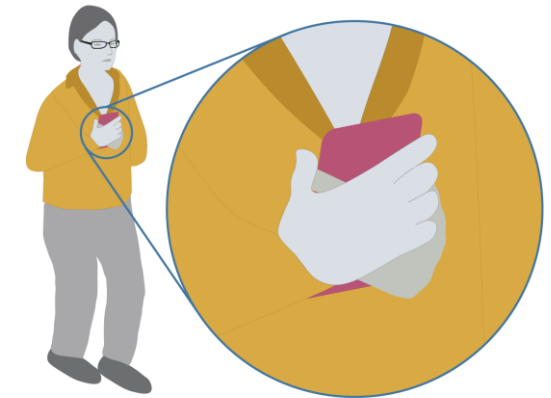
Kinesis Balance™ allows an older person to assess and track their falls risk, strength and balance in the home or community environment through statistical analysis of clinical fall risk factors and quantitative analysis of movement obtained as part of a simple static balance test and a short clinical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

Features

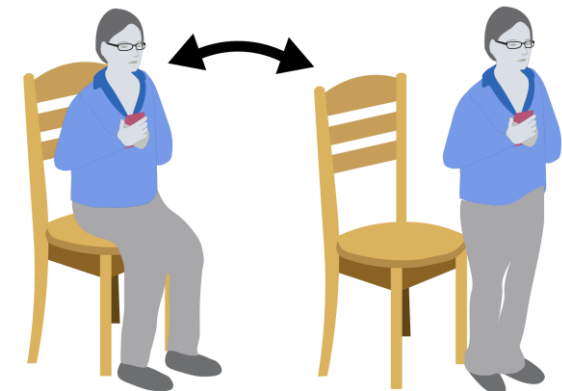
- **Reliable profiling of fall risk, strength and balance against age and gender norms**
- **Trending of balance and fall risk**
- **Advice on staying healthy, maintaining balance and avoiding falls**
- **User prompting to perform test on a periodic basis**
- **Secure backup of data to the cloud**
-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



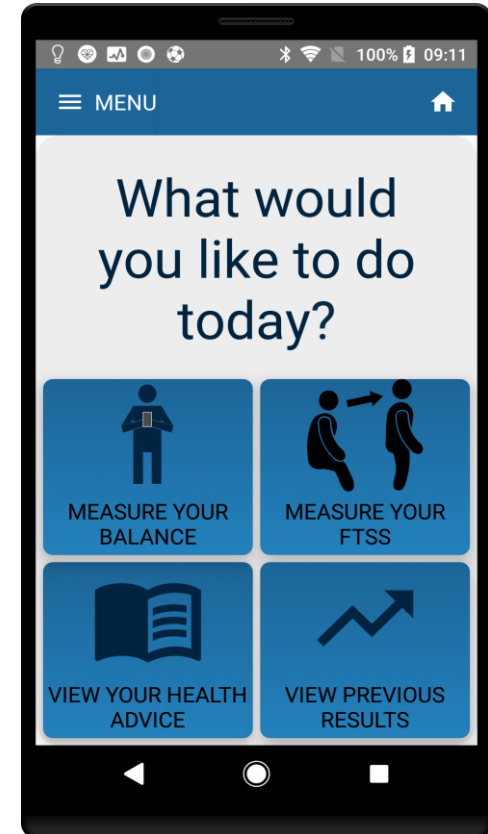
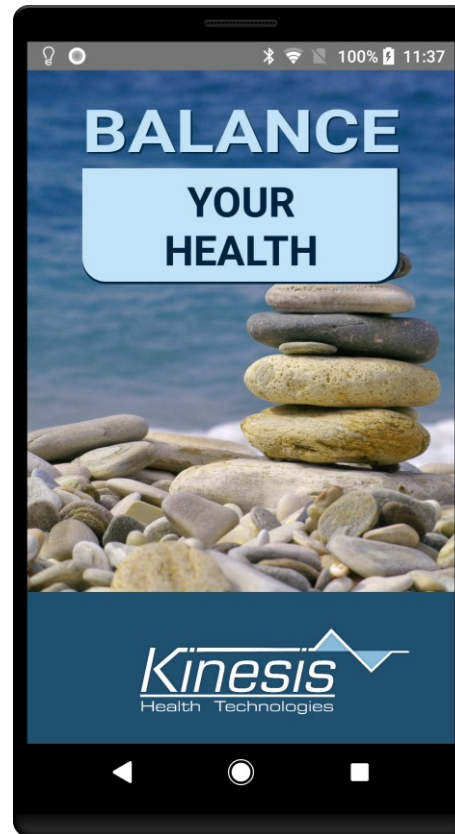
Stand up and sit down as quickly as possible 5 times

Getting Started

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



From the **Home** screen select what you want to do today: complete a standing Balance test, complete a Five Times Sit to Stand (FTSS) test, view your previous test results or view your personalised advice on how to stay healthy and prevent falls.



Profile

This will launch the application. 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.

MENU

Body Measurements

Enter age

66

Choose gender

Male Female

Enter height (in cm)

156 Unit: cm

Enter weight (in kg)

SUBMIT

MENU

Enter weight (in kg)

66 Unit: kg

Medical History

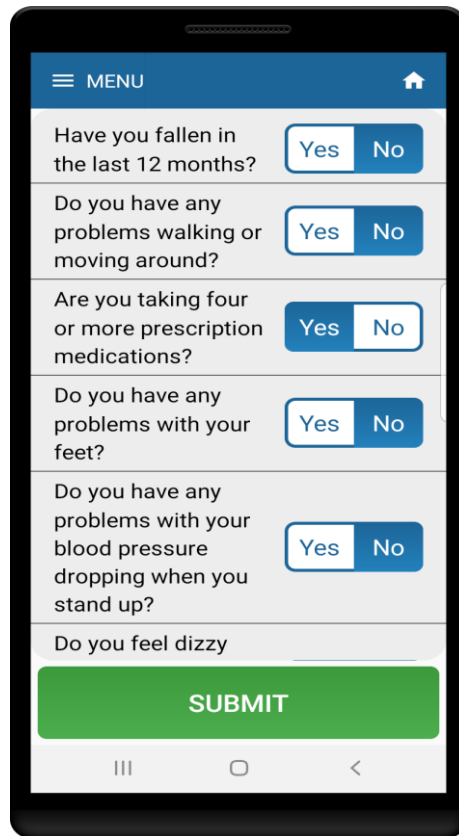
Do you use a walking aid? Yes No

Have you been diagnosed with Parkinson's disease? Yes No

Have you ever had a stroke? Yes No

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?
- Do you have any problems with your blood pressure dropping when you stand up?

Below the fifth question, there is a text input field for 'Do you feel dizzy'. At the bottom of the questionnaire, there is a large green 'SUBMIT' button. The bottom of the screen shows the standard Android navigation bar with three icons: a square, a circle, and a triangle.

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**.

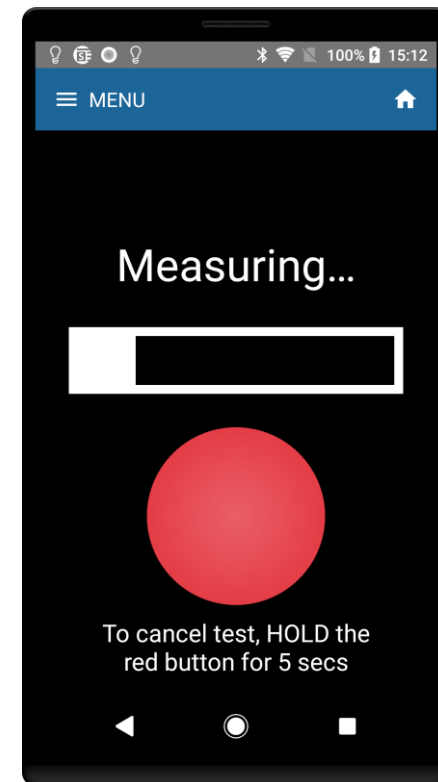
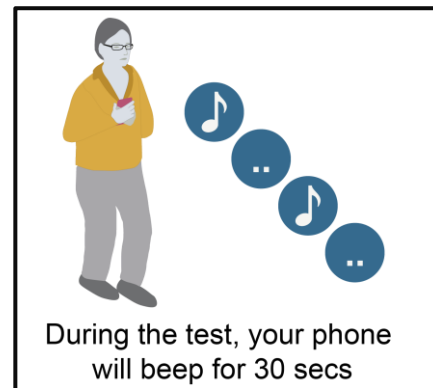
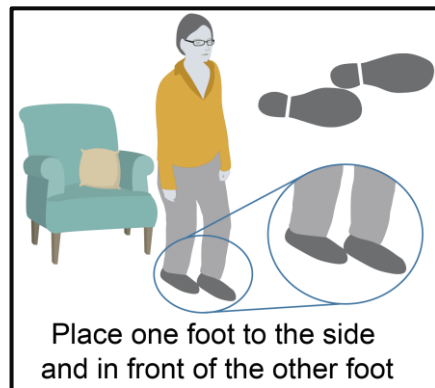
Stand in a **semi-tandem stance** (one foot on front of, and to the side of the other foot). For safety, stand next to a chair and interrupt the test at any time if you feel unsteady.

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.



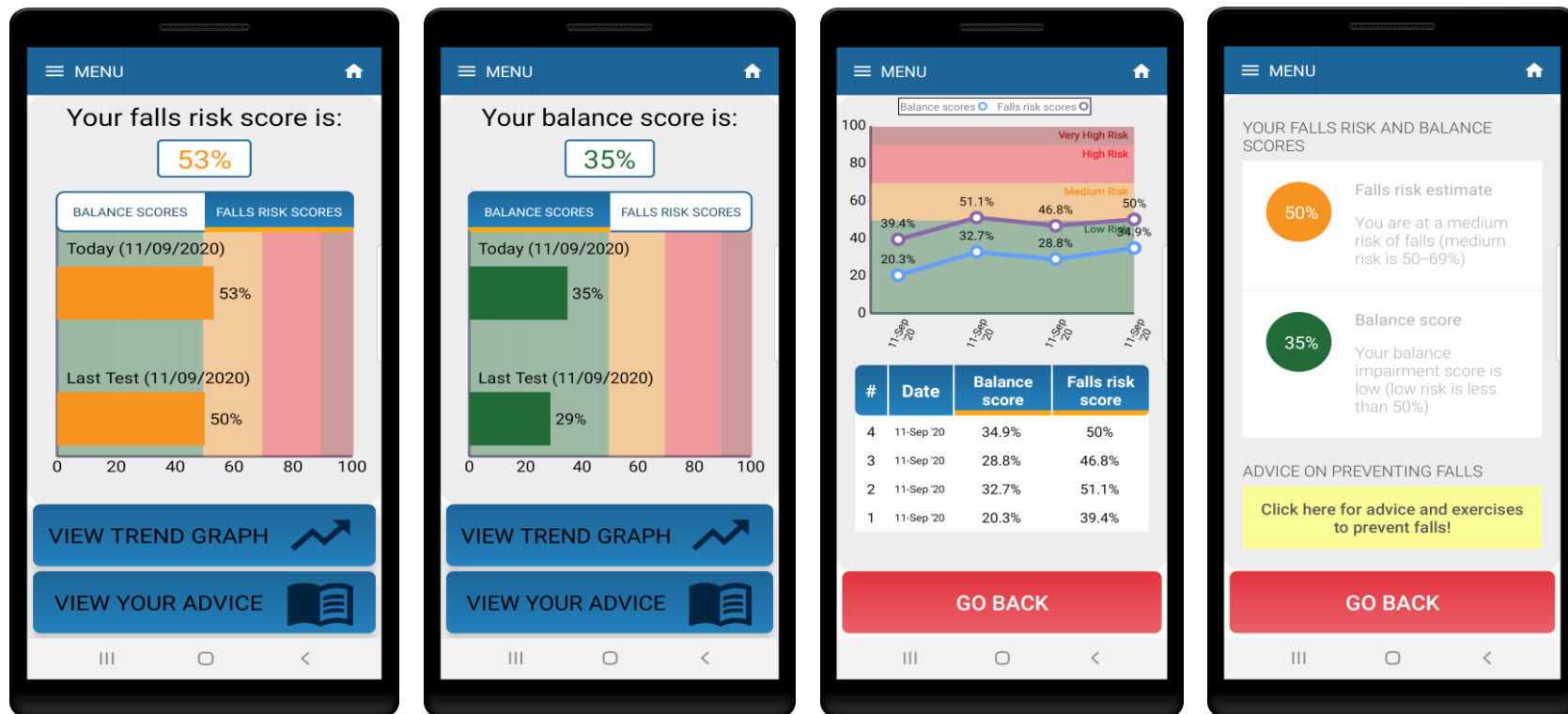
Balance Results

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.

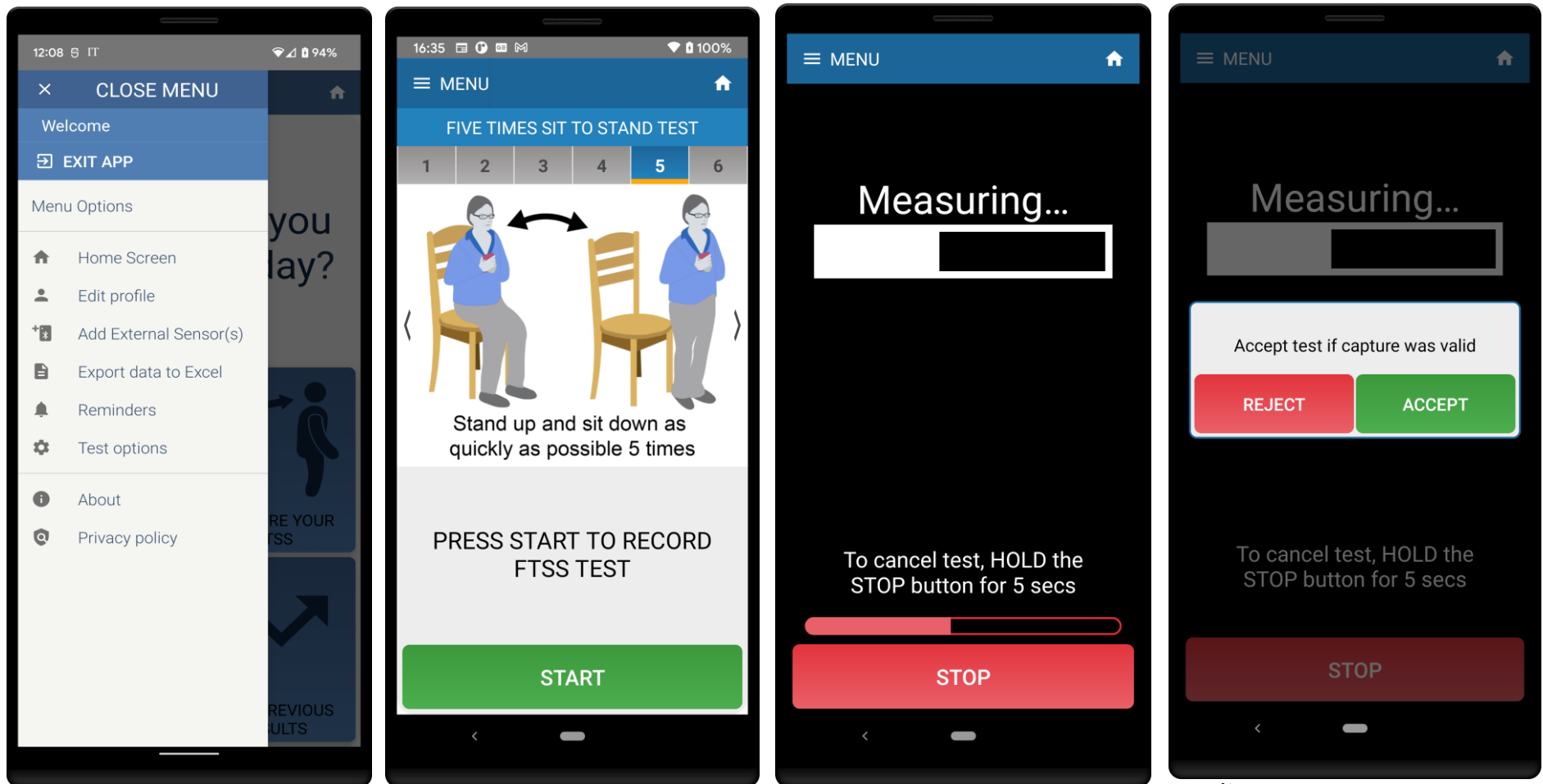
The advice page provides best practice advice on preventing falls, based on your level of risk. Exercises suitable for completing at home are provided through an external link.



Five Times Sit to Stand Test

In addition to a standing balance test Kinesis Balance assesses performance in completing the Five Time Sit to Stand (FTSS) test.

To record a FTSS test, select Five Times Sit to Stand from the home screen. To complete the test, hold the phone firmly against your torso. Press start when ready to start test and audio instructions will start. To complete the test, **starting from a seated position, stand-up and sit down five times, as fast as safely possible**. The test is completed when you have re-seated for the fifth and final time. When you have completed the test hold the red stop button for 5 seconds – if FTSS rep counter and FTSS auto-stop are switched on test will complete automatically. If this test was completed correctly press the *Accept* button to save the test



results.

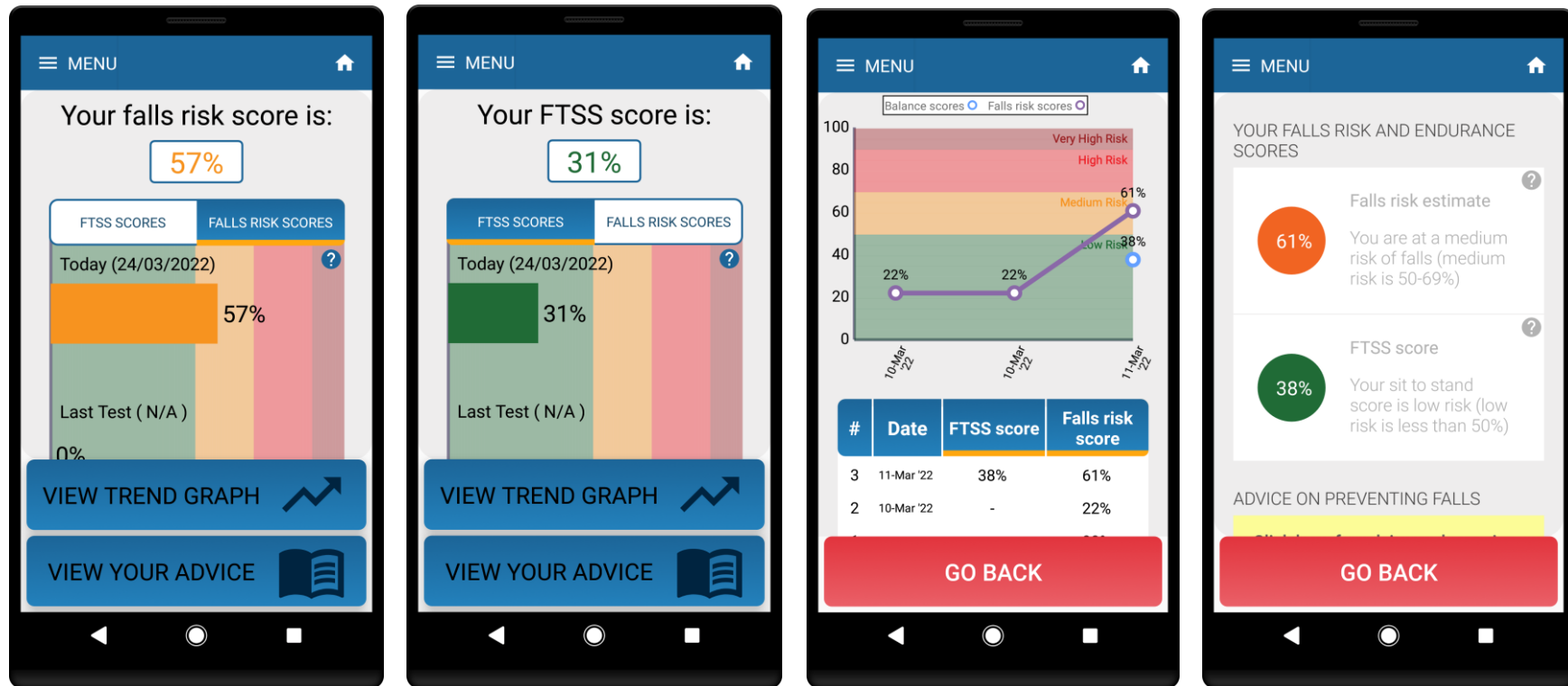
Five Times Sit to Stand Results

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

The results screen will display your **FTSS Score**, which shows how your strength and endurance compare against average values for your age and gender (*the lower the better*). The results screen will also show a **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.

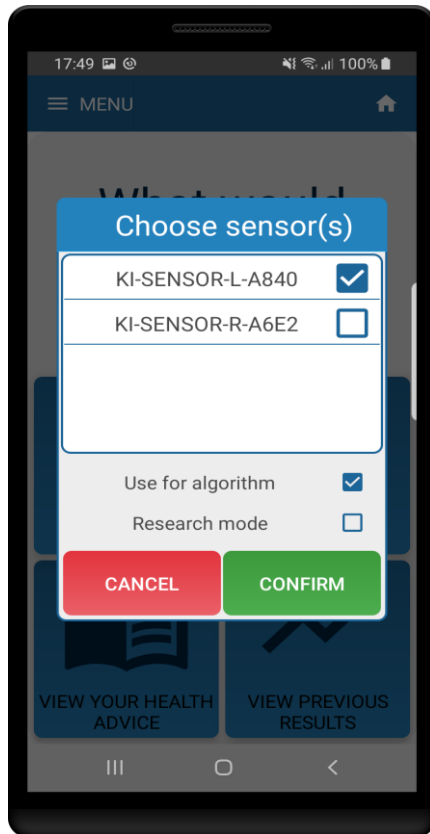


External Sensor

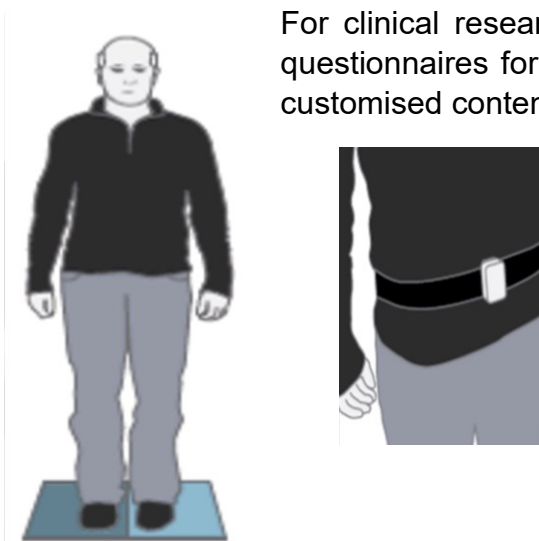
Kinesis Balance provides an option to use an external inertial sensor, mounted on the lumbar spine or pelvis for assessment of balance and falls risk. A standard Kinesis sensor is required for this purpose and is not supplied with Kinesis Balance as standard. Sensor can be held in place using tape or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



Balance Parameter definition

A valid standing balance 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>

FTSS Parameter Definition

A valid Five Times Sit to Stand (FTSS) 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
Falls risk estimate (%)	<i>Statistical risk of falls based on a model derived from sensor data from your phone during the FTSS test, 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>
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 during the FTSS test. Larger values indicate higher falls risk, values over 70% indicate high falls risk.</i>
FTSS 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 performance, values over 70% indicate impaired strength or endurance.</i>
Time to complete FTSS	<i>Time to complete Five Times Sit to Stand (FTSS) as measured by the stopwatch.</i>
Time to complete FTSS	<i>Time to complete Five Times Sit to Stand (FTSS) measured by the algorithm.</i>
Mean Sit-Stand-Sit time	<i>Average Sit-Stand-Sit time across all transitions in a FTSS test.</i>
Coefficient of variation of Sit-Stand-Sit time	<i>Coefficient of variation of Sit-Stand-Sit time across all transitions in a FTSS test.</i>
Number of sit to stand transitions completed	<i>Number of sit to stand transitions completed during a FTSS test.</i>
Mean time to stand-up	<i>Average time to stand-up taken across all repetitions in the FTSS test.</i>
Coefficient of variation of Stand time	<i>Coefficient of variation of the time to stand up, taken across all repetitions in the FTSS test</i>
Mean time to sit down	<i>Average time to sit down taken across all repetitions in the FTSS test.</i>
Coefficient of variation of Sit time	<i>Coefficient of variation of time taken to sit across the FTSS test.</i>
Root mean square acceleration	<i>Magnitude of root mean squared acceleration across all repetitions of a FTSS test.</i>
Root mean square acceleration (X)	<i>Root mean squared value of X-axis acceleration across all repetitions of a FTSS test.</i>
Root mean square acceleration (Y)	<i>Root mean squared value of Y-axis acceleration across all repetitions of a FTSS test.</i>
Root mean square acceleration (Z)	<i>Root mean squared value of Z-axis acceleration across all repetitions of a FTSS test.</i>

Jerk acceleration (X)	<i>Jerk of X-axis acceleration across all repetitions of a FTSS test.</i>
Jerk acceleration (Y)	<i>Jerk of Y-axis acceleration across all repetitions of a FTSS test.</i>
Jerk acceleration (Z)	<i>Jerk of Z-axis acceleration across all repetitions of a FTSS test.</i>
Root mean square angular velocity	<i>Magnitude of root mean squared angular velocity across all repetitions of a FTSS test.</i>
Root mean square angular velocity (X)	<i>Root mean squared value of X-axis angular velocity across all repetitions of a FTSS test.</i>
Root mean square angular velocity (Y)	<i>Root mean squared value of Y-axis angular velocity across all repetitions of a FTSS test.</i>
Root mean square angular velocity (Z)	<i>Root mean squared value of Z-axis angular velocity across all repetitions of a FTSS test.</i>
Jerk angular velocity (X)	<i>Jerk of X-axis angular velocity across all repetitions of a FTSS test.</i>
Jerk angular velocity (Y)	<i>Jerk of Y-axis angular velocity across all repetitions of a FTSS test.</i>
Jerk angular velocity (Z)	<i>Jerk of Z-axis angular velocity across all repetitions of a FTSS test.</i>
Median frequency acceleration	<i>Median frequency of the acceleration signal, averaged across all three accelerometer axes.</i>
Spectral edge frequency acceleration	<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	<i>Median frequency of the angular velocity signal, averaged across all three gyroscope axes.</i>
Spectral edge frequency angular velocity	<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>
Mean absolute valued Z-axis acceleration at stand-start	<i>Average absolute valued Z-axis acceleration at stand-start points, taken across all iterations of a FTSS test.</i>
Mean absolute valued Z-axis acceleration at sit-end	<i>Average absolute valued Z-axis acceleration at sit-end,</i>
Mean absolute valued Z-axis acceleration at mid-stand	<i>Average absolute valued Z-axis acceleration at mid-stand point, taken across all repetitions of a FTSS test.</i>
Standard deviation of absolute valued Z-axis acceleration at stand-start	<i>Standard deviation of absolute valued Z-axis acceleration at stand-start time, taken across all repetitions of a FTSS test.</i>
Standard deviation of absolute valued Z-axis acceleration at sit-end	<i>Standard deviation of absolute valued Z-axis acceleration at sit-end, taken across all repetitions of a FTSS test.</i>

Standard deviation of absolute valued Z-axis acceleration at mid-stand	<i>Standard deviation of absolute valued Z-axis acceleration at mid-stand, taken across all repetitions of a FTSS test.</i>
Mean absolute value X-axis angular velocity at stand-start	<i>Average absolute value X-axis angular velocity at stand-start points, taken across all repetitions of a FTSS test.</i>
Mean absolute value X-axis angular velocity at sit-end	<i>Average absolute value X-axis angular velocity at sit-end points, taken across all repetitions in the FTSS test.</i>
Mean absolute value X-axis angular velocity at mid-stand	<i>Average absolute value X-axis angular velocity at mid-stand points, taken across all repetitions of a FTSS test.</i>
Standard deviation of absolute value X-axis angular velocity at stand-start	<i>Standard deviation of absolute value X-axis angular velocity at stand-start points, taken across all repetitions in the FTSS test.</i>
Standard deviation of absolute value X-axis angular velocity at sit-end	<i>Standard deviation of absolute value X-axis angular velocity at sit-end points, taken across all repetitions of a FTSS test.</i>
Standard deviation of absolute value X-axis angular velocity at mid-stand	<i>Standard deviation of absolute value X-axis angular velocity at mid-stand points, taken across all repetitions of a FTSS test.</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)⁹ and examine standard clinical risk factors associated with falls. Prior to each balance or FTSS 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 and FTSS 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 standing balance and FTSS test. Data are in the Data folder (*Kinesis/Balance/Data*). Anonymised data for all tests are backed up automatically to the Kinesis cloud. Raw data for failed tests are stored in the FailedTests data folder (*Kinesis/Balance/Data/FailedTests*) if the 'Save failed tests' option is selected.

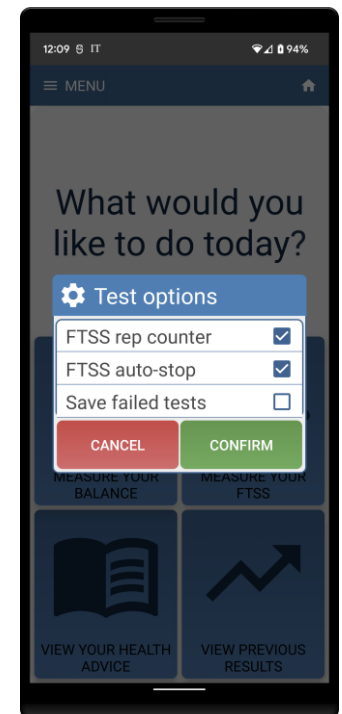
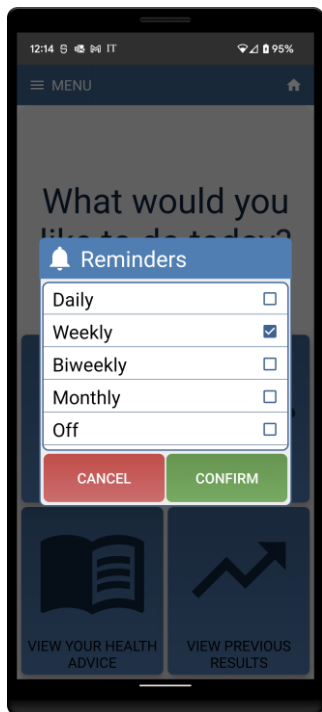
In *Research mode*, raw sensor data for the duration of the test are stored.

Test options

A number of options are available during Kinesis Balance assessments including turning on and off the FTSS rep counter, automatically stopping the FTSS after 5 repetitions and storing of raw inertial sensor data for failed tests. The Test Options menu is available under the application menu and allows test options to be changed.

Assessment reminders

To set a reminder to perform a Kinesis Balance reminder press 'Reminder' under the application menu. Reminders can be turned off or set to Daily, Weekly, Biweekly or Monthly.



Regulatory Information

Declaration of Conformity

This Linus Health Europe product (Linus Health Europe Ltd is formerly known as Kinesis Health Technologies and referred to as Kinesis) 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, Linus Health Europe (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).



This device fulfils the provisions of EU MDR 2017/745 (EN 55011 Class A and EN 60601-1-2). In addition, this product meets the Essential Requirements (ER) of the UK MDR 2002, as amended, and is a legal requirement to place a device on the market in Great Britain.

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

The Kinesis 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 Linus Health Europe, is intended to measure static balance, functional strength 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. Any serious incident occurring in relation to this device should be reported to Linus Health Europe Ltd (www.kinesis.ie) and the Health Product Regulatory Authority (EU competent Authority for Ireland, <https://www.hpra.ie>).

References

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