Kinesis
Health Technologies

USER GUIDE v3.2

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Thank you for purchasing QTUG™

This User Guide introduces you to QTUG™ (Quantitative Timed Up and Go), and helps you quickly learn how to perform a mobility, frailty or falls risk assessment on a patient. For detailed information about the QTUG™ application, refer to the application information, which you access through the Info button in the upper right-hand corner. The User Guide also contains useful information about configuring QTUG™, exporting files (Excel/PDF/DB) for organizing your patient files, and using all of the product features.

Intended Use

QTUG™ is intended to measure gait and mobility parameters for automated, quantitative gait and mobility assessment via a Timed Up and Go test, instrumented using body-worn inertial sensors.

Indications for Use

QTUG™ is indicated for use with patients who would benefit from assessment of mobility. It is also indicated for patients who may benefit from assessment of falls risk or frailty.

Please read this user guide throroughly before using QTUG™. This guide includes important safety information.
Please keep the user guide for future reference.

Important Safety Information

Read these safety messages carefully. This equipment must be used indoors.

WARNING
The use of portable and mobile radio frequency (RF) equipment may have an impact on this and other pieces of medical equipment.

This device contains an RF transmitter. It is also an intentional RF receiver and even if other equipment complies with CISPR emissions requirements, those devices may interfere with the operation of this device.
Radio Information Transmit Characteristics: 2.4GHz Bluetooth radio using GFSK, DQPSK, and 8DPSK modulation and 75kHz bandwidth. Frequency Range: 2400-2483.5MHz. Output Power: 5-6 dBm.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class A and EN 60601-1-2:2015).

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer for help.

The use of portable and mobile RF equipment may have an impact on this and other pieces of medical equipment.

CAUTION
It is prudent to separate all electrical equipment that is very close in distance to the QTUG™ system. If it is essential to use the QTUG™ system very close to other electrical equipment, it is prudent to determine, by observation, if the performance of either product is affected by unintended electromagnetic coupling.

The use of accessories, cables, or transducers other than those specified in this manual can significantly increase emissions and degrade immunity performance of the product. Also, by using an accessory, transducer, or cable with the product, other than those specified in this manual, it becomes the responsibility of the third-party supplier or the user of the product, to determine compliance with the requirements of IEC 60601-1-2 when using this item.

WARNING
It is advised not to use equipment other than the following devices listed by manufacturer (Kinesis QTUG™ sensors with Bluetooth radio) stacked on or near the product, but if it is required for your location to stack or use equipment that is adjacent to the product, all must be verified to work and ensure the product operates properly before conducting any procedures.

WARNING
No modification of this equipment is allowed.

Glossary

Term	Definition
Inertial sensor	Wireless sensors including tri-axial accelerometer and tri-axial gyroscope
Timed Up and Go (TUG) test	Standard mobility assessment commonly used to assess mobility and risk of falls. Longer completion times are thought to indicate higher risk of falling.

Safety instructions in this user guide

Warning/caution: warns of risk of injury, possible material damage, and possible incorrect results

Note: contains useful information

It is recommended to refer to the manual

Contents

1. What's in the box? 8

2. Getting started with the tablet 9
2.1 Tablet layout 9
2.2 Charging the battery 10
2.3 Turning the tablet on and off 11
2.4 Use of third party applications 11

3. Getting started with the sensor 12
3.1 Sensor layout 12
3.2 Instructions for use with charging dock v1.0.0 13
3.3 Instructions for use with charging dock v2.0.0 15
3.4 Pairing sensor with tablet 17
3.5 Replacing faulty or old sensor 18

4. Set up the QTUG™ test 19
4.1 QTUG™ test requirements 19
4.2 Physical set up 20
4.3 Set up QTUG™ application on the tablet 21

5. Perform the QTUG™ test 25

6. QTUG™ test results 29
6.1 Interpreting QTUG™ test results 29
6.2 Customise mobility assessment 32
6.3 Historical tests 33

7. QTUG™ data management 34
7.1 Export QTUG™ test results 34
7.2 Backup, restore and erase test data 35

8. After use 37

9. Troubleshooting 38

10. Parameter definition 39

11. Technical specifications 45

12. Regulatory Information 48

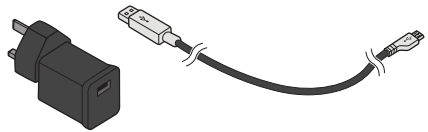
13. Warranty 50

1. What's in the box?

QTUG™ package includes the following components.

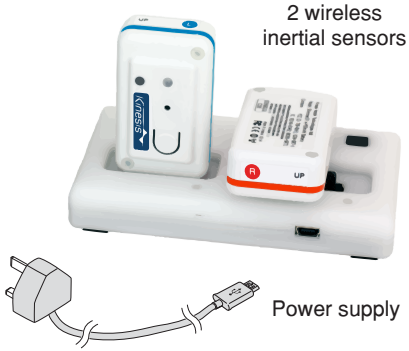
Tablet and its accessories

7" tablet



Power adaptor USB cable

Sensor and its accessories



Charging dock

Elasticated bandages

Reusable straps

Miscellaneous

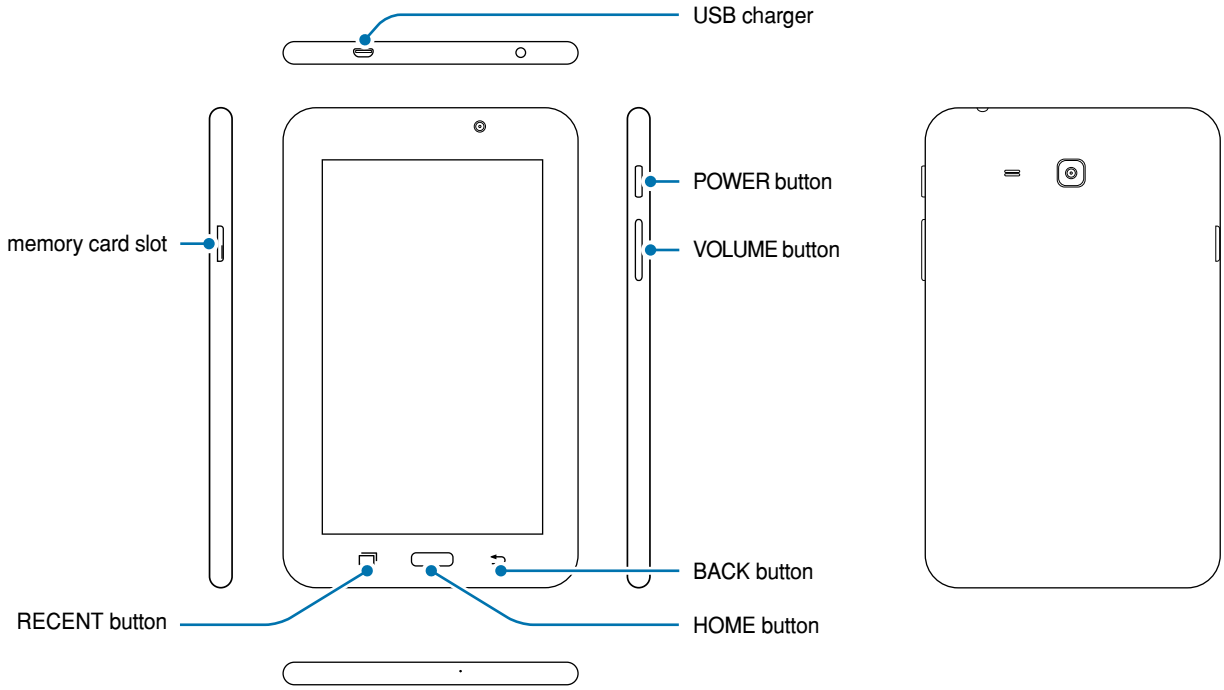
Carrying case

Measuring tape

Warranty and Safety

2. Getting started with the tablet

2.1 Tablet layout



2.2 Charging the battery

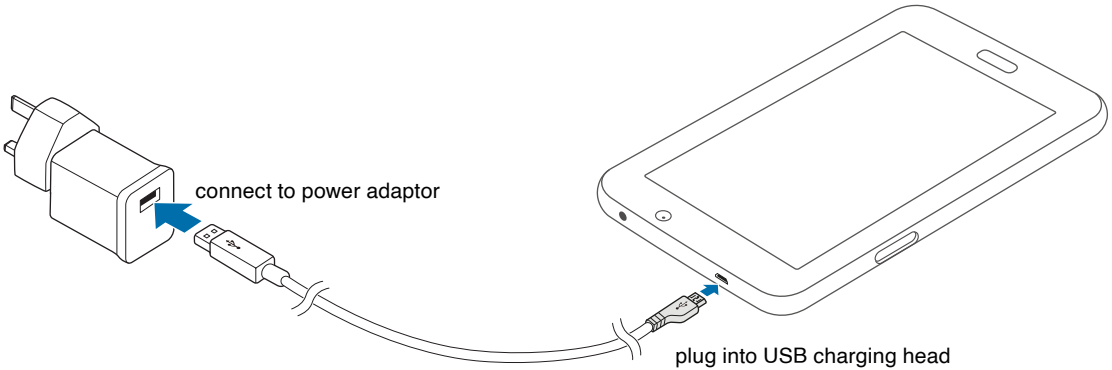
When the battery power is low, the tablet emits a warning tone and displays a ‘low battery’ power message.

If the battery is completely discharged, the tablet cannot be turned on immediately when the charger is connected.

Allow a depleted battery to fully charge before running the application on the tablet.

Charging with the charger

Connect the large end of the USB cable to the USB power adaptor and then plug the other end of the USB cable into the USB charging port on bottom of the tablet.



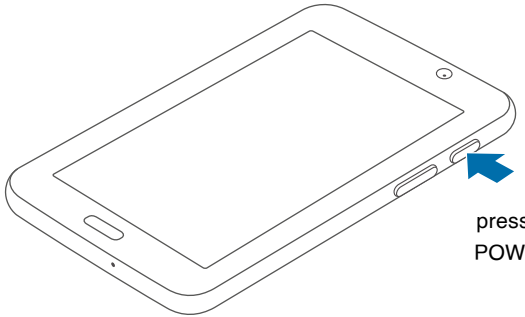
After fully charging, unplug the USB cable from the tablet, and then unplug the charger from the electric socket.

Ensure the tablet is charged before performing a QTUG™ test.

2.3 Turning the tablet on and off

To turn on the tablet, press and hold the POWER button for a few seconds until you see the Samsung logo. Wait a moment for the tablet to boot up.

To turn off the tablet, press and hold the POWER button, and then tap Power off and confirm the shut down.



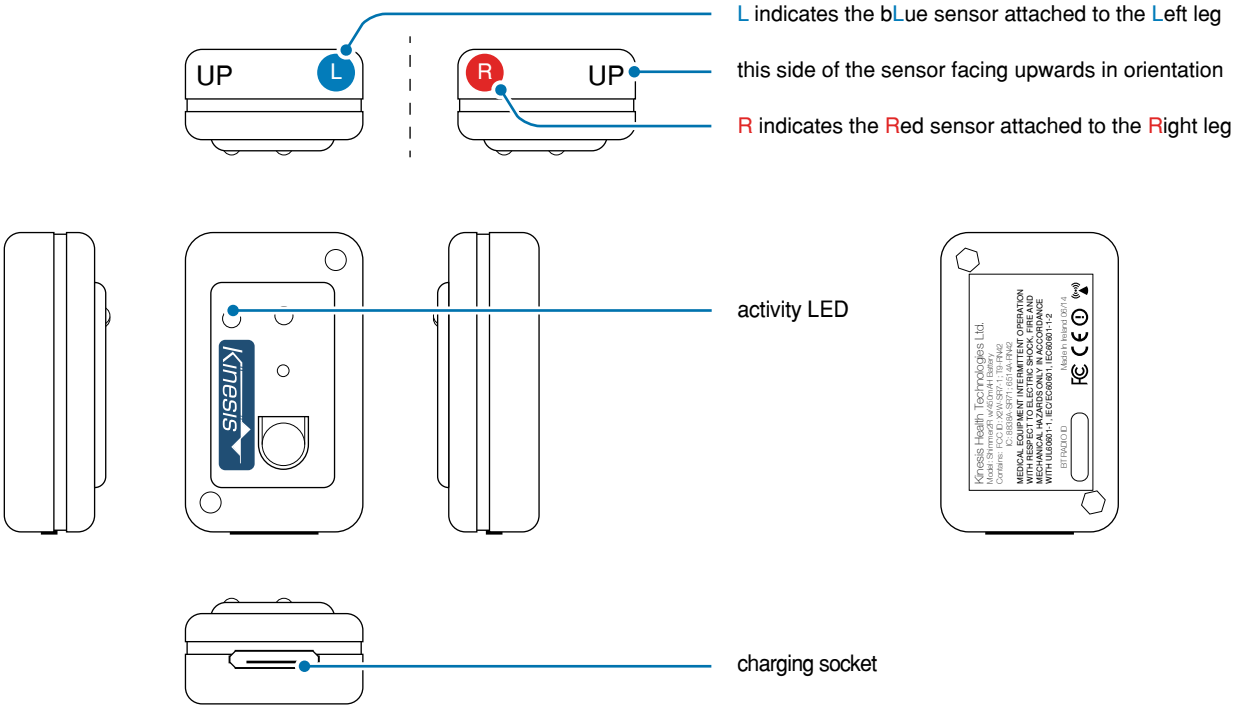
2.4 Use of third party applications

The tablet provided should ONLY be used with Kinesis products. Installing third party applications on the dedicated tablet may interfere with the correct operation of the application.

The tablet provided is intended to be dedicated for exclusive use with Kinesis products. Installing third party applications onto the tablet may interfere with the correct operation of QTUG™ application and interfere with the correct calculation of the results. Please restrict your use of the tablet to Kinesis products **only**.

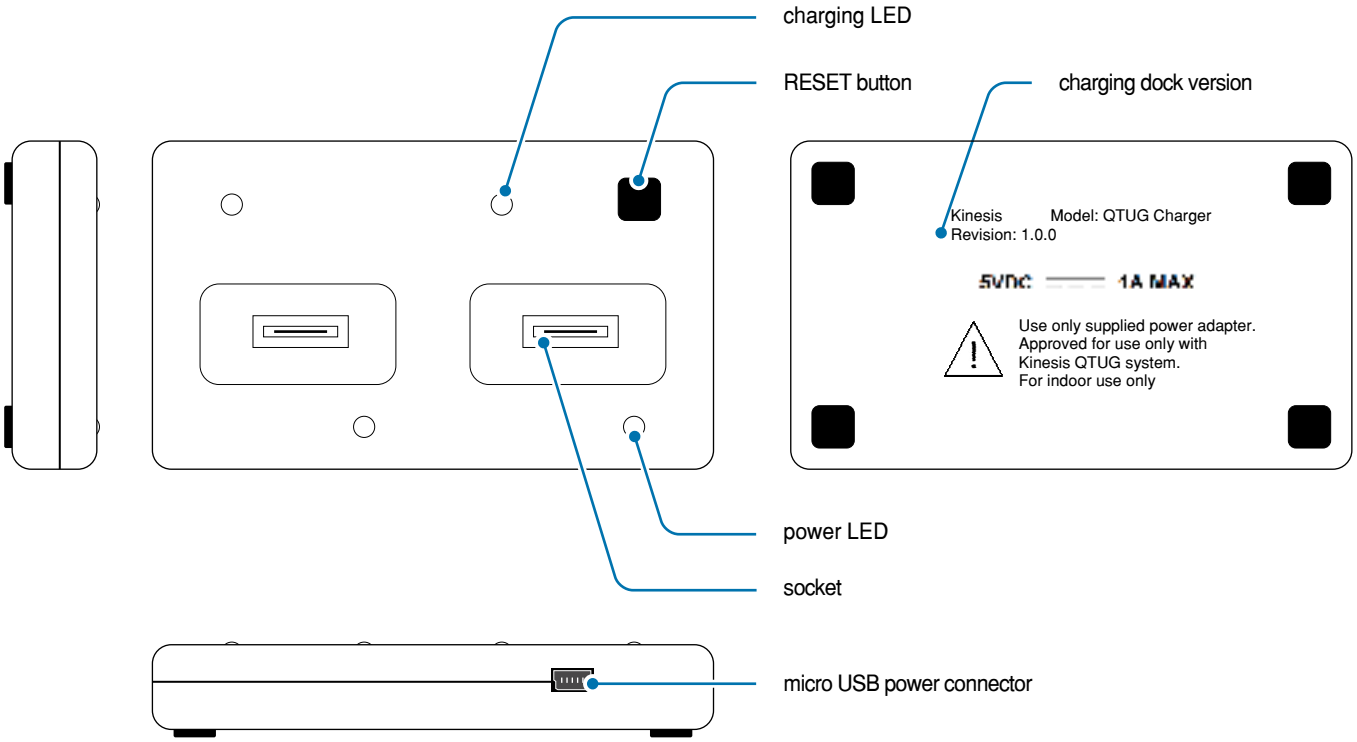
3. Getting started with the sensor

3.1 Sensor layout



3.2 Instructions for use with charging dock v1.0.0

Charging dock layout



Turning the sensor on and off and resetting

To turn on the sensor, place the sensor in the charging dock. If either of the two sensors do not turn on, just reinsert into the dock. The activity LED on the sensor turns orange. Wait a moment for the sensor to boot up. When it is ready, the activity LED turns green.
To reset the sensors when powered on, press and release the RESET button. To turn off the sensor, press and hold the RESET button for a minimum of 7 seconds until the power LED on the sensor dock turns off.

Charging the sensor

Place the sensor in the charging dock, ensuring a good connection. The power LED on the sensor dock will only turn green if the sensor is turned on and there is a good connection. The sensor battery is not fully charged while the charging LED remains orange. If the charging LED turns off, the sensor battery is fully charged. The sensor battery should last approximately 5 hours under normal working conditions. Before removing the two sensors from the sensor dock, press the RESET button once to synchronously reset the sensors and ensure the sensors remain in sync.

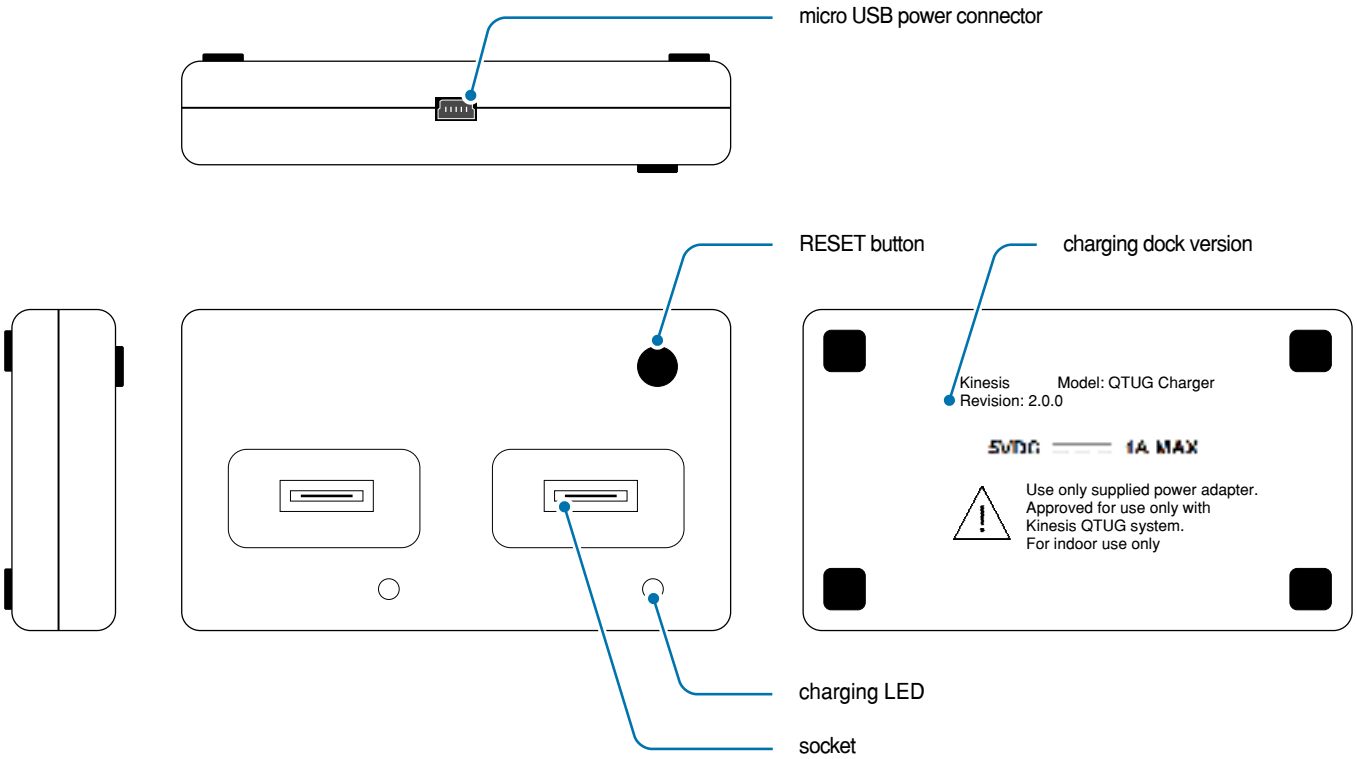
Activity LED on sensor	
LED colour	Description
Orange	Sensor is turned on and booting up.
Green	Sensor is turned on and is ready.
Off	Sensor is turned off.

Charging LED on charging dock v1.0.0	
LED colour	Description
Orange	Sensor battery is not fully charged.
Off	Sensor battery is fully charged.

Power LED on charging dock v1.0.0	
Green	Sensor is successfully connected to the charging dock.
Off	Sensor is not turned on and/or is not connected to the charging dock.

3.3 Instructions for use with charging dock v2.0.0

Charging dock layout



Turning the sensor on and off and resetting

To turn on the sensor, place the sensor in the charging dock then press and release the RESET button. The activity LED on the sensor turns orange. Wait a moment for the sensor to boot up. When it is ready, the activity LED turns green. To turn off the sensor, press and hold the RESET button for a minimum of 7 seconds until the activity LED on the sensor turns off.

To reset the sensor, place it in the charging dock and press and release the RESET button. The activity LED on the sensor will turn orange then green when it is ready.

Charging the sensor

Turn off sensors while charging. The sensor charging LED remains orange while charging and turns to green when fully charged. The battery should last approximately 5 hours under normal working conditions. Before removing the two sensors from the charging dock, press the RESET button once to synchronously reset the sensors and ensure the sensors remain in sync.

Activity LED on sensor

LED colour	Description
Orange	Sensor is turned on and booting up.
Green	Sensor is turned on and is ready.
Off	Sensor is turned off.

Charging LED on charging dock v2.0.0

LED colour	Description
Orange	Sensor battery is not fully charged and sensor battery is charging.
Green	Sensor battery is fully charged.
Off	Sensor is not connected to the charging dock or, dock is unplugged from the electrical socket.

Ensure sensors are charged before using QTUG™.

3.4 Pairing sensor with tablet

Turn on both sensors and wait until the activity LED turns green. Turn on the tablet and tap on the ‘Settings’ icon on the desktop.
If Bluetooth is disabled, turn on Bluetooth by tapping on the switch. In the upper right-hand corner, tap ‘Scan’ to detect Bluetooth devices.

The detected sensors are listed under ‘Available devices’. The sensors are named KI-SENSOR-R-XXXX and KI-SENSOR-L-XXXX for the Red (Right) sensor and bLue (Left) sensor respectively. The XXXX codes match with the BT RADIO ID label on the sensors.

To pair the sensor with the tablet, tap on the device name and enter PIN 1234 on the requesting window. The sensors are listed under ‘Paired devices’ when pairing with the tablet is succesful.

3.5 Replacing faulty or old sensor

A faulty or old sensor must be replaced by a new sensor. Tap on the ‘Settings’ icon and tap on the ‘Bluetooth’ icon to show the paired sensors.

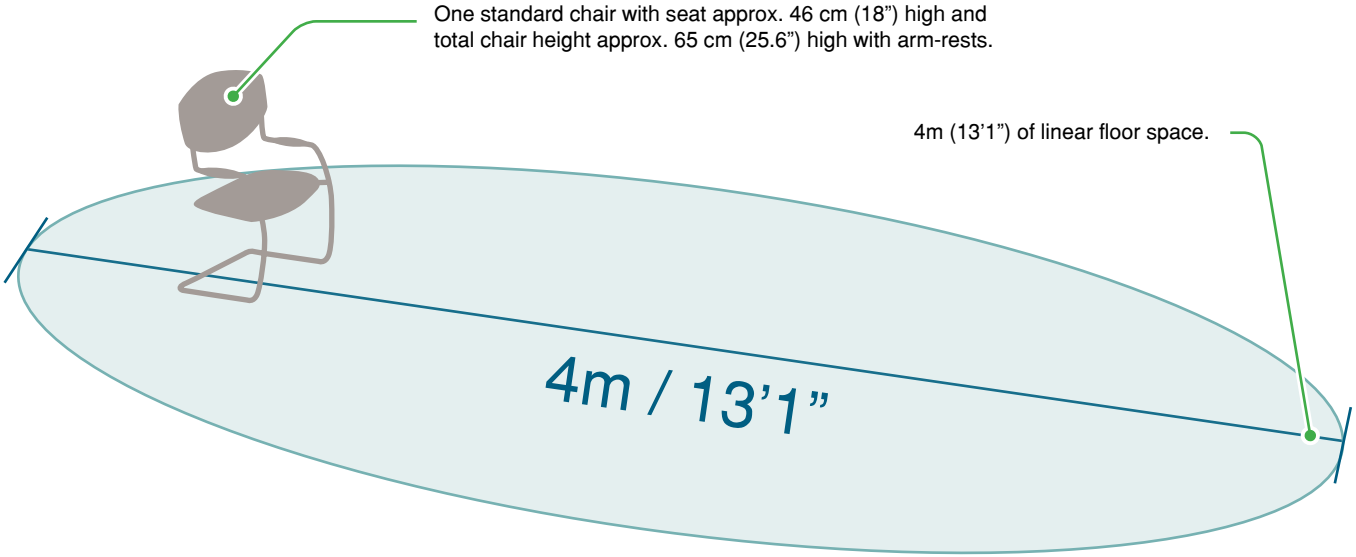
To replace a faulty or new sensor, unpair the sensor by tapping on the ‘Bluetooth Settings’ icon next to the device name and tap ‘Unpair’. The unpaired sensor is listed under ‘Available devices’. To remove the sensor from this list, turn off the sensor.

Turn on the new sensor and tap ‘Scan’ to detect the new sensor. Follow previous instructions to pair the new sensor.

4. Set up the QTUG™ test

4.1 QTUG™ test requirements

To perform a QTUG™ test on a patient, ensure the patient is wearing comfortable walking shoes. You will require the following to complete a QTUG™ test:

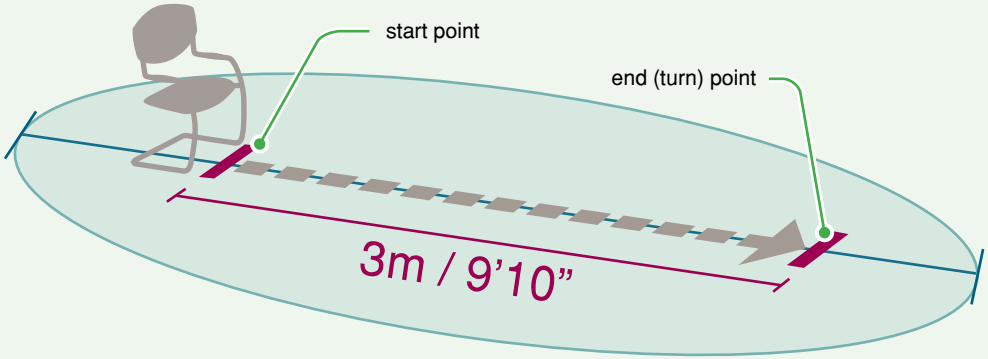


Ensure the chair used for the test is stable (i.e. chair without wheels).

4.2 Physical set up

1

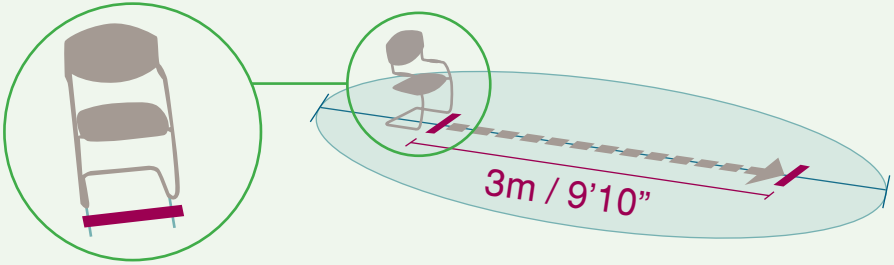
Clearly mark the start and end (turn) points on the floor placed exactly 3m (9’10”) apart, measured from patient’s toes when seated.



Ensure the 3m (9’10”) distance is accurately measured from the chair to the end point.
Incorrectly measured distance may result in incorrectly derived gait and mobility parameters.

2

Position the chair at the start of the 3m (9’10”) space.



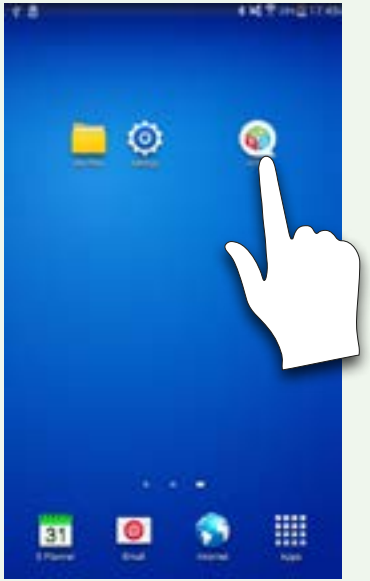
4.3 Set up QTUG™ application on the tablet

3

Turn on the tablet and ensure date and time are correct. To change date and time, go to Date and time in Settings.

4

Then turn on the Red sensor and bLue sensor. Prior to each test, reset the sensors while in the charging dock. Tap the QTUG™ icon to launch the application.



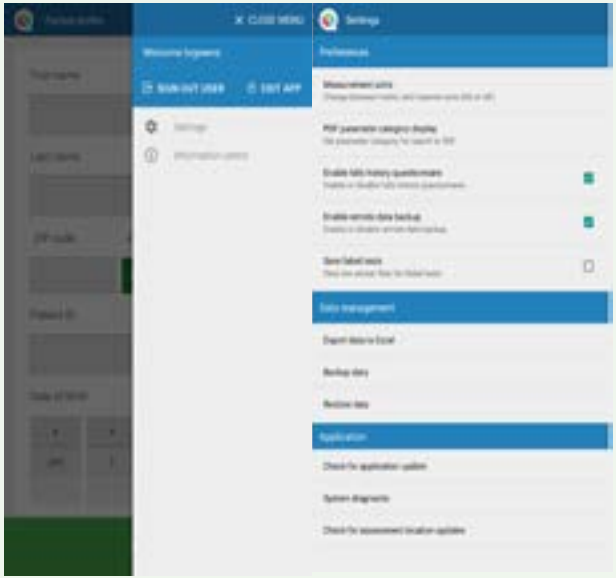
5

On the login screen please enter your username or email and password as provided to you. Passwords can be reset using the FORGOT PASSWORD button.

Note: You require internet connection in order to login to the QTUG application.

6

You can press the MENU button to access settings. Here you can adjust settings, for example, enable/disable backup, and complete tasks such as check for QTUG application updates and run a diagnostic.



7

To create a new patient enter Firstname, Last name, zipcode (or postcode), patient ID (optional field) and date of birth. Choose assessment location from the dropdown menu. Customer-specific assessment locations will be populated here automatically.

Personally Identifiable Information (PII) is encrypted at rest and in transit (on the tablet device, in transit to the backend and while stored on the backend).

8

Enter age, height and weight by tapping the - and + buttons, or tap in the field and enter manually. Choose metric or US or UK imperial measurements. Select a gender by tapping the MALE or FEMALE button and add optional notes.

Enter height and weight to nearest cm or ft/inch, kg or st/lbs.

9

When sensors have connected successfully, the QTUG™ test screen will appear.

If sensors are not connected or refuse to connect, place the sensors in the charging dock and press reset. Turn the tablet off and turn it back on. If behaviour persists, fully charge sensors.

10

To use QTUG™ on populations not at risk of falls, switch Falls mode to No.

To use a mobility aid during the test, select one of the predefined options.

To disable timing errors on length of walk and time to stand, switch Timing limits to No.

5. Perform the QTUG™ test

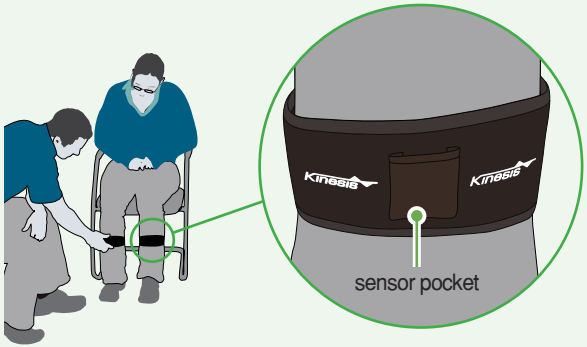
1

Seat the patient on the chair in order to explain the test.

Uneven, slippery or otherwise unsuitable underfoot conditions may affect gait and turning and adversely affect the mobility assessment.

2

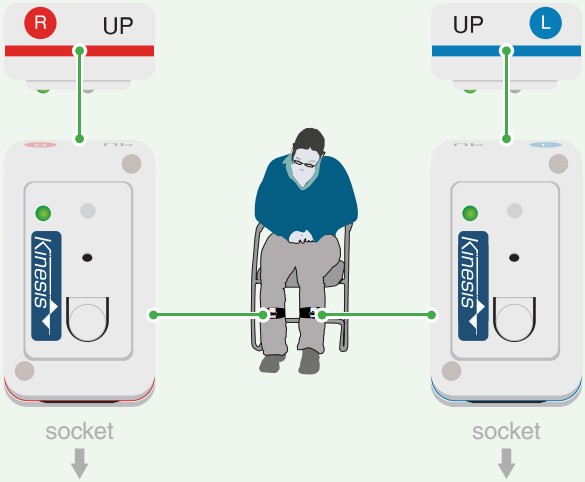
Secure the elasticated bandage or reusable strap firmly on the shins (mid-point of the anterior shank). If using strap, ensure sensor pocket is facing out, aligned along the shin bone and ensure Kinesis logo is orientated correctly.



Ensure the bandage or strap are firmly connected to the patient to reduce the risk of tripping while walking. Loosely fitted bandage or strap may result in an invalid test or adversely affect results.

3

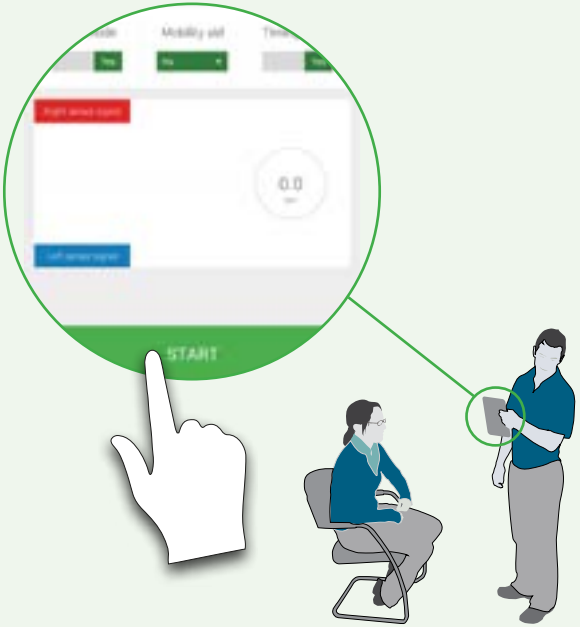
Place the sensors in the correct orientation (in the sensor pocket of the strap), with the socket facing down and the Kinesis logo facing out, the Red sensor on the Right leg and the bLue sensor on the Left leg.



Failure to use the correct orientation will result in an incorrect calculation of mobility parameters and falls risk.

4

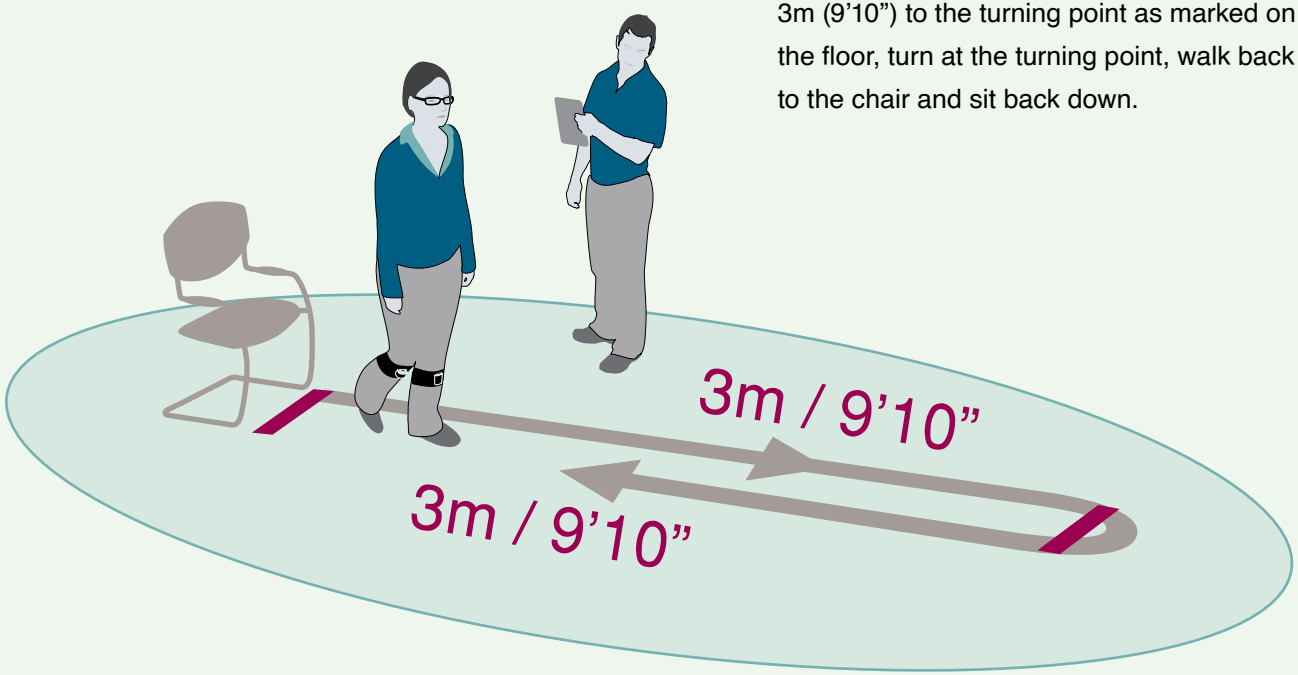
When the patient is ready, say ‘Go’ and tap the START button on the QTUG™ application.



When START is tapped, the activity LED on the sensor flashes alternately green-orange in streaming mode.

5

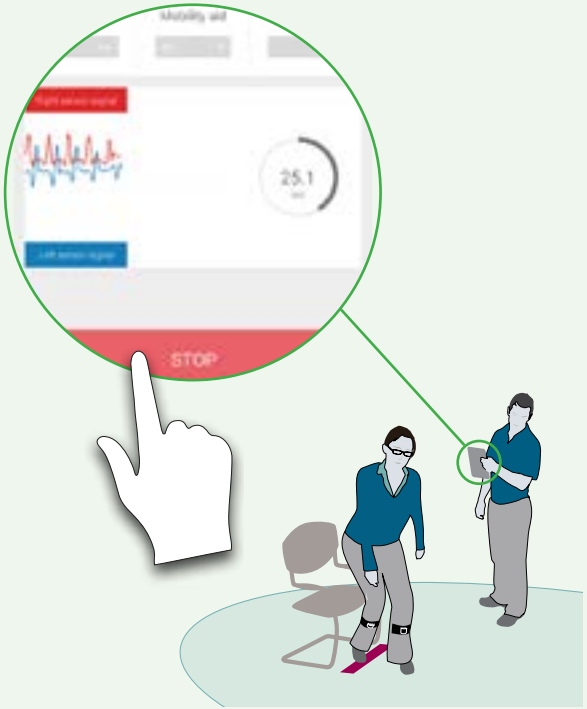
The patient must get up from the chair, walk 3m (9’10”) to the turning point as marked on the floor, turn at the turning point, walk back to the chair and sit back down.



The patient has to walk exactly 6m (19’7”). The test is calibrated to give valid results based on accurate measurement of the 3m (19’7”) distance from the chair to the turning point. Inaccurately measured distance may result in incorrectly measured falls risk, gait and mobility.

6

When the patient is reseated, tap the STOP button to stop recording data. The sensor data is displayed on the screen.



7

On the application, tap the ACCEPT button to confirm that the test is valid (i.e. the patient performed the test correctly), and to save data. Tap the REJECT button if the test is invalid and you wish to discard data. To perform the test again, tap the START button.

6. QTUG™ test results

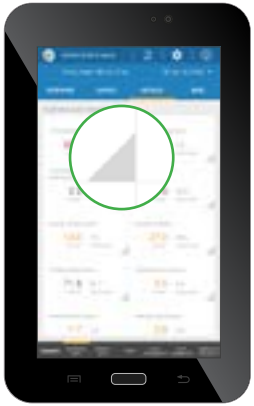
6.1 Interpreting QTUG™ test results

An accepted and valid test displays and saves the test results. These results are presented in four sections: overview, advice, details and misc(ellaneous) sections. The definitions of these results are explained in the table below.

Section	Definition	Description
Overview	TUG time	Time taken to complete the TUG test.
	Falls risk estimate (FRE)	Statistical risk of falls based on a model derived from community dwelling older adults. If falls questionnaire is enabled, these data are used to improve the falls risk estimate (as combined FRE).
	Combined FRE	Weighted average of the sensor and clinical FRE values.
	Sensor FRE	The falls risk estimate calculated using sensor data and demographic data.
	Clinical FRE	Falls risk estimate calculated from the clinical data entered through the falls questionnaire along with demographic data.
	Frailty estimate (FE)	Statistical estimate of patient's frailty level (as defined by Fried's frailty phenotype), based on a model of community dwelling older adults. If falls questionnaire is enabled, these data are used to improve the frailty estimate (as combined FE).
	Combined FE	Weighted average of the sensor and clinical FE values.
	Sensor FE	The frailty estimate calculated using sensor data and demographic data.
	Clinical FE	Frailty estimate calculated from the clinical data entered through the falls questionnaire along with demographic data.

	Mobility assessment scores	Mobility scores are calculated to identify mobility impairment by grouping the measured QTUG mobility parameters into five functional categories: speed, variability, symmetry, transfers and turn. A high mobility score (> 70%) indicates that the patient may have a problem in the functional area highlighted.
	Clinical risk factors	Clinical fall risk factors reported in enabling and completing the falls questionnaire.
Advice		Advice and recommendations based on the mobility and clinical risk factors reported by the patient.
Details		Comprehensive quantitative assessment of mobility including temporal and spatial gait parameters, gait variability and gait symmetry.
Misc	Notes	Display clinician's notes.
	Options used	Display the selected options during the test.
	Falls questionnaire	The answers to the falls questionnaire (if enabled and completed). These data are used to improve the falls risk and frailty estimates.
	Sensor signals	The sensor data signals from the left and right sensors.

For detailed explanation of each mobility parameter, tap on the grey triangle in the bottom right corner.
Or read chapter 'Parameter definition' in this user guide.



Last value and last score

If a previous test exists, the last value or last score for TUG, falls risk, frailty and mobility assessment scores will be displayed.

Test results with colour-coded values

QTUG™ parameter values that are significantly different compared to the reference population and may indicate a specific mobility impairment are highlighted in red (e.g. TUG recording time value of 26.5s compared to population average of 13.6s).
Parameters highlighted in green are considered within the normal range, while amber may indicate a parameter is unusual compared to the population average. Parameters in grey are neutral values.

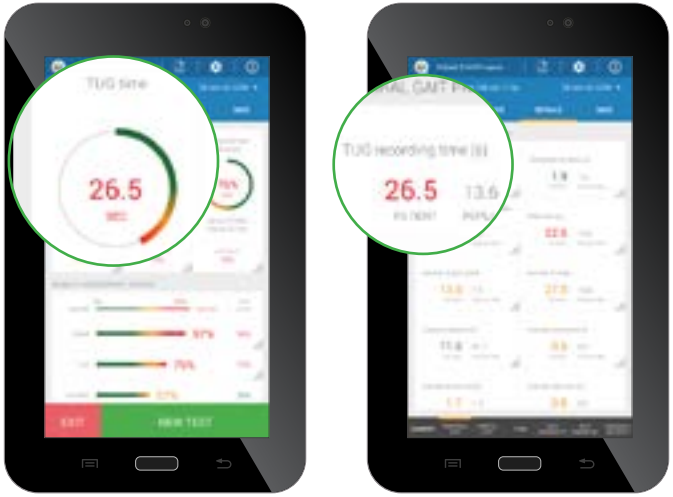
For the comparison to normative data, the colour-codes are explained in the table below.

	Description
	Within 1 standard deviation of population mean
	Within 2 standard deviations of population mean
	Greater than 2 standard deviations from population mean

Colour-coded falls and frailty risk estimates

The falls and frailty risk estimates are colour-coded as follows.

	Falls risk level	Frailty level	Range
	Low risk	Non-frail	0% to <50%
	Medium risk	Transitional	50% to <70%
	High risk	Frail	70% to <90%
	Very high risk	Very frail	90% to 100%

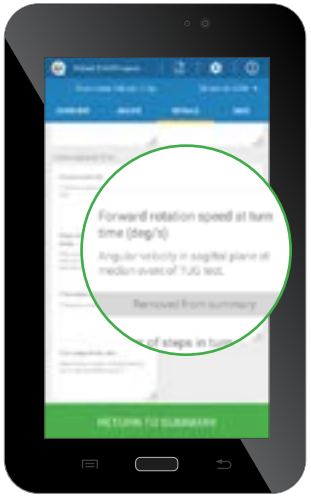


6.2 Customise mobility assessment

The details section has a bottom navigation panel showing 7 categories: SUMMARY, TEMPORAL GAIT, SPATIAL GAIT, TURN, GAIT VARIABILITY, GAIT SYMMETRY and ANGULAR VELOCITY.

The SUMMARY shows all mobility parameters which have been added from the remaining 6 categories.

To customise the displayed results, tap on the CUSTOMISE SUMMARY button to show a list with parameters from the remaining 6 categories.
To add a parameter to the SUMMARY, tap on a preferred parameter. Added parameters are highlighted in green.
To remove a parameter from the SUMMARY, tap on a highlighted parameter and it will turn grey.



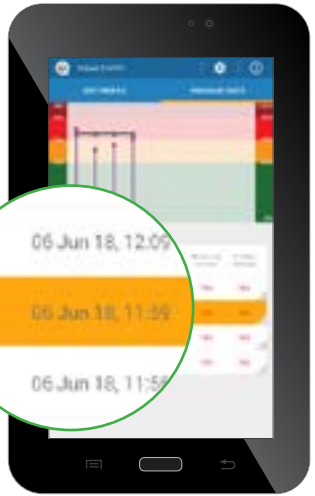
6.3 Historical tests

Previous tests from a given patient are listed under the patient profile page for each patient. Tap on the individual test to view the QTUG™ test results.

The TUG time (purple), falls risk estimate (blue) and frailty estimate (brown) for each test are displayed graphically (displays last 10 tests).

Delete individual tests

On the patient profile page, press and hold on an individual test for the delete option. Tap the DELETE button in order to delete the test instantly. To cancel the delete process, press the CANCEL button on the tablet.



Ensure data are backed up to remote server or a computer before deleting patient test.

7. QTUG™ data management

7.1 Export QTUG™ test results

When the results are displayed, options are available to generate a PDF report for an individual test or to export all patient results from the database.

Please note: Once exported from the application, PDF and Excel exports are not encrypted. If records contain Personally Identifiable Information (PII) these data will be visible in the exports and should be treated as confidential to ensure compliance with data privacy regulations.

Generate PDF report

The results for a given test can be exported to a PDF report, which documents the clinical info and QTUG™ results.

In Settings under Preferences, parameter categories (pinned, temporal gait, spatial gait, turn, gait variability, gait symmetry and angular velocity parameters) can be set individually for export to PDF.

On the results screen, tap the PDF button to generate this report which is stored in the ‘My Files’ / ‘Kinesis’ / ‘QTUG’ / ‘Export’ directory of the tablet. In the Export folder, you can find the PDF report with the extension *.pdf.

Export results from database

The results for all patients can be exported in Excel format. To export results from database, tap the Export data to Excel button under Data management in the Settings. The Excel file with the extension *.xls is stored in the ‘My Files’ / ‘Kinesis’ / ‘QTUG’ / ‘Export’ directory.

7.2 Backup, restore and erase test data

Backup patients’ data to internal storage and remote service

To backup the data to internal storage on the tablet, tap the Backup data button in the Settings. If Wi-Fi is available, data can also be sent via a secure Wi-Fi connection to the QTUG™ remote backup service. Tap the Enable remote data backup button to enable the remote backup via Wi-Fi option and then tap the Backup data button in the Settings.

Restore patients’ data from internal storage

To restore the backup data, tap the Restore data button in the Settings.

Existing data will be overwritten by restoring, ensure the data are backed up to to remote server or external storage prior to restoring patient data.

Erase patient data from internal storage

To erase the data from the internal storage on the tablet, tap on ‘My Files’ and tick the ‘Kinesis’ folder. On top of the screen, tap on the bin icon and confirm with ‘Yes’ to delete the ‘Kinesis’ folder. Then go to Application Manager in Settings and tap on the QTUG™ icon. To clear the internal database, tap on ‘Clear cache’ and ‘Clear data’.
To erase the data from the QTUG™ remote backup service, contact Kinesis technical support.

Ensure the data are backed up to to remote server or external storage prior to erasing patient data.

8. After use

Tablet

At the end of the assessment, tap the EXIT button and confirm to close the application.

Please turn off the tablet after use. If the battery power is low, connect the tablet to the USB power adaptor for charging. Before cleaning, it is essential to remove the connecting USB cable for the tablet from the power inlet socket of the device.

Storage and handling conditions

For safe keeping, place the tablet, sensors and accessories in the designated foam slots in the carry case after use, cleaning or charging. Store the carry case in a cool, dry location.

Sensors

At the end of the assessment, remove the sensors from the elasticated bandages or reusable strap and turn the sensors off.

The sensors can be wiped down using standard clinical alcohol wipes to reduce risk of infection. After cleaning, insert the sensors into the charging dock to be fully charged for the next assessment. Ensure the sensors are turned off while charging.

Reusable strap

Remove the reusable strap from the patient's legs. The strap can be wiped down using standard clinical alcohol wipes to reduce risk of infection.

Ensure no liquids get into the tablet and sensor via the charging socket, otherwise malfunctions may occur. Never immerse the devices in disinfectant or other liquids; otherwise the tablet and sensor may be damaged, resulting in a hazard to users and patients. The tablet and sensor must be completely dry before use.

9. Troubleshooting

If there are any problems which cannot be rectified immediately, please refer to www.kinesishealthtech.com/support or contact Kinesis technical support at support@kinesishealthtech.com

Problem	Cause	Remedy
The tablet does not turn on	The tablet battery is flat	Plugin the charger and ensure the tablet battery is fully charged.
The sensor does not connect	The sensor is turned off	Check that sensor is switched on. If problem persists, turn off the tablet and then turn it back on.
The sensor does not turn on	The sensor battery is flat	Plugin the charger and ensure the sensor battery is fully charged.
The QTUG test keeps failing	Sensors are not firmly fastened	Ensure sensors are firmly and securely fastened to the patient's shin.
	Sensors are not correctly positioned	Ensure sensors are oriented correctly with the socket facing down and the logo facing out, the right sensor on the right leg and the left sensor on the left leg.
QTUG is not working properly	The sensor malfunctions	Put both sensors into the charging dock. Ensure they are inserted correctly. Then press the RESET button to reset both sensors.
	The tablet malfunctions	Turn off the tablet and then turn it back on.
	The sensor battery is flat	Check that sensor is fully charged. A fully discharged sensor can take up to 6 hours to recharge.

10. Parameter definition

Definition of mobility parameters produced by QTUG™.

Parameter	Description
Falls risk estimate (%)	Statistical risk of having a fall (defined for community dwelling older adults over 60 years of age)
Frailty estimate (%)	Statistical estimate of frailty level (defined using Fried's phenotype for patients over 60 years of age)
TUG test time (s)	Recording time for entire TUG test as recorded using body-worn sensors

Mobility risk scores

Each assessment can be broken down into five functional areas.

Functional areas	Description
Speed	Assessment of parameters relating to walking speed. A high speed score indicates low gait velocity compared to population average.
Variability	Assessment of gait variability. A high variability score indicates high gait variability which is linked to risk falls.
Symmetry	Assessment of gait asymmetry. A high symmetry score indicates gait asymmetry during the TUG test. Gait asymmetry is associated with neurological disorders.
Transfers	Assessment of sit to stand and stand to sit transfers. A high transfer score indicates difficulty in standing or sitting, which has been linked to poor lower limb and core strength.
Turning	Assessment of patient's ability to turn. A high turn score indicates problems with turning which is linked to balance impairment and falls risk.

Temporal gait parameters

Parameter	Description
Time taken to stand (s)	Time from ‘go’ to first heel strike or toe-off point
Time taken to sit back down after walking (s)	Time from last heel strike until end of test
Number of gait cycles	Number of gait cycles in total test
Number of steps	Number of steps in TUG test
Cadence (steps/min)	Average number of steps taken per minute during test
Walk time (s)	Time from first to last heel-strike or toe-off point - time participant actually spends in locomotion during TUG test
Average swing time (s)	Average swing time over all gait cycles, averaged across both legs, swing time is defined as the time between a toe-off point and the heel strike point on the same foot
Average stance time (s)	Average stance time over all gait cycles, stance time is defined as the time between a heel-strike and toe-off point on the same foot
Average stride time (s)	Time for one stride (time between successive heel-strikes), averaged over all gait cycles
Average step time (s)	Average time between heel-strike on one foot to heel strike of the opposite foot, measured in seconds
Average double support	Proportion of a gait cycle spent on both feet
Average single support	Proportion of a gait cycle spent on either foot

Spatial gait parameters

Parameter	Description
Average stride velocity (cm/s)	Average walking speed during TUG test
Stride velocity variability (%)	Variation in walking speed during TUG test
Average stride length (cm)	Mean stride length during TUG test
Stride length variability (%)	Coefficient of variability in stride length over TUG test

Turn parameters

Parameter	Description
Pre-turn time (s)	Time from ‘go’ to median gait event of TUG
Post-turn time (s)	Time from median gait event of TUG to end of test
Ratio of pre-turn to post-turn times	Ratio of Time from ‘go’ to median gait event of TUG to Time from median event of TUG to end of test
Forward rotation speed at turn time (deg/s)	Angular velocity in sagittal plane at median event of TUG test
Time taken to turn (s)	Time taken to turn
Number of steps in turn	Number of steps in turn
Turn steps/time ratio	Ratio of the number of steps taken to turn to the time taken to turn

Gait variability parameters

Parameter	Description
Stride time variability (%)	Variation in stride time
Stance time variability (%)	Variation in stance time
Swing time variability (%)	Variation in swing time
Step time variability (%)	Variation in step time
Single support variability (%)	Variation in the proportion of a gait cycle spent on a single foot
Double support variability (%)	Variation in the proportion of a gait cycle spent on both feet

Gait symmetry parameters

Parameter	Description
Stride time asymmetry (%)	Gait symmetry index for stride time: difference between right and left divided by average of right and left, expressed as a percentage. Minus values indicate left leg asymmetry.
Stance time asymmetry (%)	Gait symmetry index for stance time: difference between right and left divided by average of right and left, expressed as a percentage. Minus values indicate left leg asymmetry.
Swing time asymmetry (%)	Gait symmetry index for swing time: difference between right and left divided by average of right and left, expressed as a percentage. Minus values indicate left leg asymmetry.
Step time asymmetry (%)	Gait symmetry index for step time: difference between right and left divided by average of right and left, expressed as a percentage. Minus values indicate left leg asymmetry.
Stride velocity asymmetry (%)	Gait symmetry index for gait velocity: difference between right and left divided by average of right and left, expressed as a percentage. Minus values indicate left leg asymmetry.
Stride length asymmetry (%)	Gait symmetry index for stride length: difference between right and left divided by average of right and left, expressed as a percentage. Minus values indicate left leg asymmetry.

Angular velocity parameters

Parameter	Description
Average side-to-side rotation speed (deg/s)	Average angular velocity in the side-to-side direction during the assessment
Variation in side-to-side rotation speed (%)	Coefficient of variation in angular velocity in the side-to-side direction during the assessment
Minimum side-to-side rotation speed (deg/s)	Minimum angular velocity in the side-to-side direction during the assessment
Maximum side-to-side rotation speed (deg/s)	Maximum angular velocity in the side-to-side direction during the assessment
Average forward rotation speed (deg/s)	Average forward angular velocity during the assessment
Variation in forward rotation speed (%)	Coefficient of variation in forward angular velocity during the assessment
Minimum forward rotation speed (deg/s)	Minimum forward angular velocity in the sagittal plane during the assessment
Maximum forward rotation speed (deg/s)	Maximum forward angular velocity during the assessment
Average horizontal rotation speed (deg/s)	Average angular velocity in the transverse plane during the assessment
Variation in horizontal rotation speed (%)	Coefficient of variation in angular velocity in the transverse plane during the assessment
Minimum horizontal rotation speed (deg/s)	Minimum angular velocity in the transverse plane during the assessment
Maximum horizontal rotation speed (deg/s)	Maximum angular velocity in the transverse plane during the assessment

Range of peak forward rotation speed (deg/s)	Range of angular velocity in the sagittal plane at mid-swing over entire walk
Average peak forward rotation speed (deg/s)	Average angular velocity in the sagittal plane at mid-swing over entire walk
Average side-to-side rotation speed x Height (deg.m/s)	Related to average linear velocity of shank in side-to-side direction
Minimum side-to-side rotation speed x Height (deg.m/s)	Related to minimum linear velocity of shank in side-to-side direction
Maximum side-to-side rotation speed x Height (deg.m/s)	Related to maximum linear velocity of shank in side-to-side direction
Average forward rotation speed x Height (deg.m/s)	Related to minimum linear velocity of shank in forward direction
Minimum forward rotation speed x Height (deg.m/s)	Related to average velocity of shank in forward direction
Maximum forward rotation speed x Height (deg.m/s)	Related to maximum linear velocity of shank in forward direction
Average horizontal rotation speed x Height (deg.m/s)	Related to average linear velocity of shank in vertical direction
Minimum horizontal rotation speed x Height (deg.m/s)	Related to minimum linear velocity of shank in vertical direction
Maximum horizontal rotation speed x Height (deg.m/s)	Related to maximum linear velocity of shank in vertical direction

11. Technical specifications

Specifications

Sensor	Model	Shimmer2R w/450mAH Battery Contains tri-axial gyroscope and tri-axial accelerometer
	Sampling rate	102.4Hz
	Gyroscope range	500 ˚/s
	Gyroscope sensitivity	2mV/˚/s
	Accelerometer range	6G
	Accelerometer sensitivity	200mV/G
	Dimensions (HxWxD)	5.1 cm x 3 cm x 2 cm
Power supply	Input	100 - 240V AC 50-60Hz
	Output	5V DC, 1A Max
Current consumption		700mA (7.5V input)
Weight		< 2000 grams (4.4 pound)
Operating Conditions		+5 ˚C – +40 ˚C (20% – 95% Relative Humidity)
Storage/Transport Conditions		-20 ˚C – +60 ˚C (20% – 95% Relative Humidity)

Bluetooth Radio Transmit	Band	2.4Ghz
	Modulation	GFSK, DQPSK, and 8DPSK
	Frequency Range	2400MHz – 2483.5MHz
	Output Power	Min: 5 dBm; Typical: 6 dBm; Max: 6 dBm
Bluetooth Radio Receiver	Bandwidth	75kHz
	Frequency Range	2400MHz – 2483.5MHz
IP Rating		None
Sterility		The device is not sterile
Re-use		The device can be reused
Essential performance		The device has no essential performance
Expected service life		3 years, dependent on battery usage
User maintainable parts		None

Symbols on sensor label

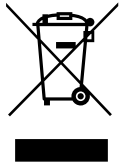
This device is authorized under part 18 of the Declaration of Conformity.

This device fulfils the provisions of EC directive 93/42/EEC (EN 55011 Class A and EN 60601-1-2).

This radio device belongs to Class 2 for which restrictions or bans apply regarding its placing on the market or putting into service.

This device contains an RF transmitter and an intentional RF receiver. Interference may occur in the vicinity of equipment.

Correct disposal of this product (Waste Electrical & Electronic Equipment)



This marking shown on the product, accessories or literature indicates that it should not be disposed of, with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please seperate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources.

Users should contact their supplier and check the terms and conditions of the purchase contract. This product and its electronic accessories should not be mixed with other commercial wastes for disposal. This product does not contain any hazardous substances.

12. Regulatory Information

Declaration of Conformity

This Linus Health Europe (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). In Canada this product meets the regulations defined by Health Canada for a Class I medical device. In Australia this product is registered with the Therapeutic Goods Administration as a Class I medical device and meets appropriate regulations and standards.

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 and Regulatory Compliance

Linus Health Europe QTUG™ product complies with data security and privacy regulations in our target countries. Data is encrypted in transit and at rest both on the collecting device (source) and the final data storage platform (destination). Personal identifiable information is only accessible to persons with a validated user account. Each account limits access to specific data. However, all data exported from the QTUG application is not encrypted and therefore must be treated as confidential and managed as per the customers own data privacy policies.

Kinesis reserves the right to use anonymised QTUG data for algorithm improvement, debug and research purposes. Data will not be sold, used or re-used for any marketing or commercial purposes.

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

Medical Device Regulatory Compliance

This product, developed by Linus Health Europe is intended to measure human movement. Please see product specific user guide for detailed information on intended use and indications for use.
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 (www.kinesis.ie) and the Health Product Regulatory Authority (EU competent Authority for Ireland https://www.hpra.ie)

Representations and Warranties

Kinesis and its Distributors warrant that this product, when used in compliance with the documentation complies with the essential requirements of the MDD. Kinesis will perform its obligations in compliance with all applicable laws and regulations.

By purchasing this product, the customer acknowledges that:

- it has been informed by Kinesis and is aware and understands that this product, specifically the Software, is a Medical Device within the meaning of the Section 2(a) of Article 1 of the MDR and further that the customer is responsible for informing its customers that this product is a Medical Device.
- the customer shall not in any way alter, modify, repair, attempt to repair or replace the Hardware or Software or relevant labelling except as otherwise permitted by Kinesis in writing.

13. Warranty

12 Months Warranty

This warranty covers the Kinesis sensors, tablet and software and accessories (together referred to as the 'Product') supplied by Linus Health Europe. Subject to the warranty conditions below, Kinesis warrants to the original end customer purchasing (hardware) and licensing (software) the Product ('you') that, for a period of 12 months from the original date of the purchase and license of the Product by you, the Product will be free from defects in materials and workmanship.

If during the period of the warranty this Product proves defective under normal use and service, you must notify Kinesis or local distributor of the defect in the Product within 12 months of the date of the purchase and license of the Product by you and you must return the Product to Kinesis or local distributor within 30 days of notifying Kinesis or local distributor of that defect. If, having inspected the Product, Kinesis accepts the Product is defective, Kinesis will (in its sole discretion) either repair or replace the part causing the defect or replace the Product without charge.

Warranty Conditions

- This warranty does not cover the Product if it has been resold or used for rental purposes.
- This warranty does not cover defects in the Product that are caused by accidental damage, your and/or any third party's negligence or unreasonable use, use with products not supplied by Kinesis, use of Product otherwise than in accordance with Kinesis product User Guide or any other instructions provided with the Product, or any other cause unrelated to defects in material and workmanship.
- This warranty does not cover the Product if it has been modified or repaired by any person other than Kinesis or duly authorised personnel.
- Repair or replacement under the terms of this warranty does not give right to extension to or a new starting of the period of warranty.
- This warranty does not cover the following:
  - » Periodic checks, maintenance, repair and replacement of parts due to normal wear and tear.
  - » Upgrading of software.
  - » The product has been used in conjunction with accessories and/or software not approved by Kinesis for use with this Product.
  - » Accidents, Acts of God or any cause beyond the control of Kinesis caused by but not limited to lightning, water, fire, public disturbances and improper ventilation.
  - » Un-authorised modifications or repairs to the Product.

USER GUIDE v3.2