



USER GUIDE v1.4

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Thank you for purchasing Kinesis Gait™

This User Guide introduces you to Kinesis Gait™, and helps you quickly learn how to perform a gait assessment on a patient. For detailed information about the Kinesis Gait™ 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 for configuring Kinesis Gait™, transferring data files from the tablet to a PC, backing up data via a secure WiFi connection to Kinesis Gait™ remote backup service and using all of the product features.

Intended Use

Kinesis Gait™ is intended to measure gait and mobility parameters, for use in gait assessment, instrumented using wireless body-worn inertial sensors.

Indications for Use

Kinesis Gait™ is indicated for use with patients who would benefit from assessment of gait and for identification of gait impairment.



Please read this user guide thoroughly before using Kinesis Gait™. 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 Kinesis Gait™ system. If it is essential to use the Kinesis Gait™ system very close to other electrical equipment, it is prudent to determine, by observation, if the performance of the 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 Gait™ 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
Gait analysis	The study of human movement

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	7.	Gait data management	31
2.	Getting started with the tablet	9	7.1	Export Gait test results	31
2.1	Tablet layout	9	7.2	Backup, restore and erase test data	32
2.2	Charging the battery	10	8.	After use	34
2.3	Turning the tablet on and off	11	9.	Troubleshooting	35
2.4	Use of third party applications	11	10.	Parameter definition	36
3.	Getting started with the sensor	12	10.1	Gait impairment scores	36
3.1	Sensor layout	12	10.2	Temporal gait parameters	37
3.2	Instructions for use with charging dock v1.0.0	13	10.3	Spatial gait parameters	38
3.3	Instructions for use with charging dock v2.0.0	15	10.4	Gait variability parameters	38
3.4	Pairing sensor with tablet	17	10.5	Gait symmetry parameters	39
3.5	Replacing faulty or old sensor	18	10.6	Bilateral temporal parameters	40
4.	Set up a gait assessment	19	10.7	Bilateral spatial parameters	41
4.1	Physical set up	19	10.8	Bilateral variability parameters	41
4.2	Set up Kinesis Gait™ application on the tablet	20	10.9	Stride parameter values	43
5.	Perform a gait assessment	24	11.	Technical specifications	45
6.	Test results	27	12.	Regulatory Information	48
6.1	Interpreting test results	27	13.	Warranty	50
6.2	Customise gait assessment	29			
6.3	Historical tests	30			

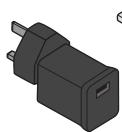
1. What's in the box?

Kinesis Gait package includes the following components.

Tablet and its accessories



7" tablet



Power adaptor



USB cable

Sensor and its accessories



2 wireless inertial sensors



Power supply

Charging dock



Elasticated bandages



Reusable straps

Miscellaneous



Carrying case



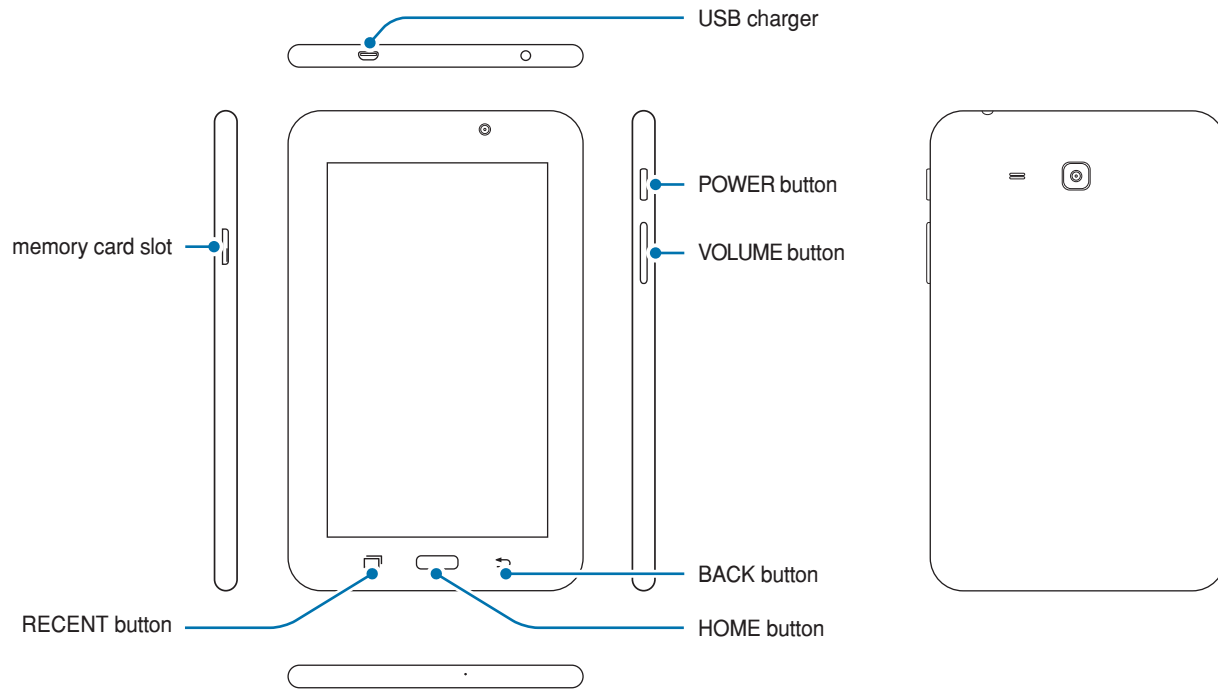
Measuring tape



Warranty and Safety

2. Getting started with the tablet

2.1 Tablet layout



2.2 Charging the battery

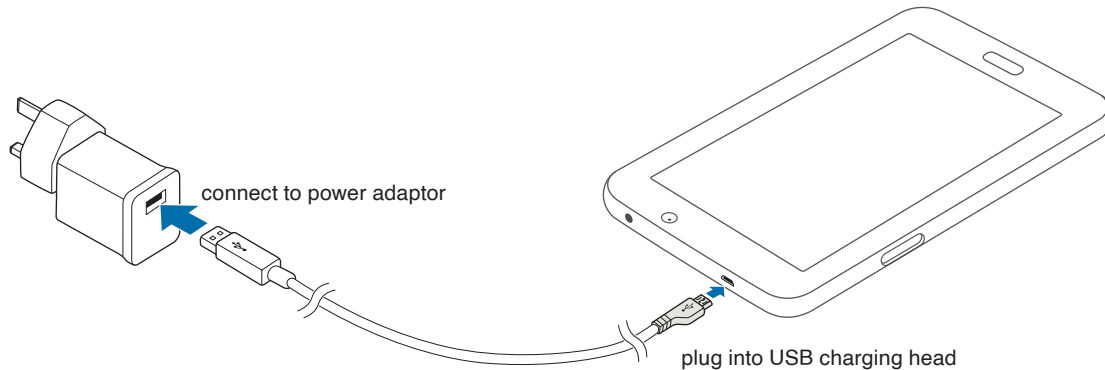
When the battery power is low, the tablet emits a warning tone and displays a 'low battery' power message.

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 head on top 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 gait assessment with Kinesis Gait™.

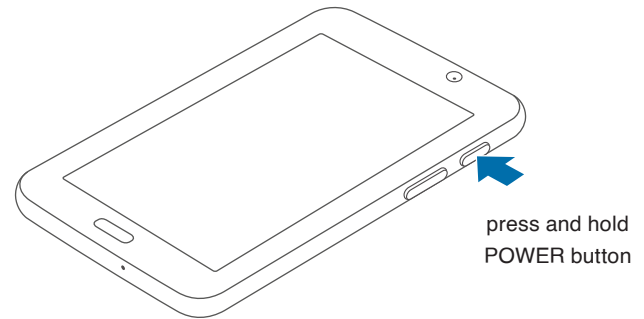
2.3 Turning the tablet on and off

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

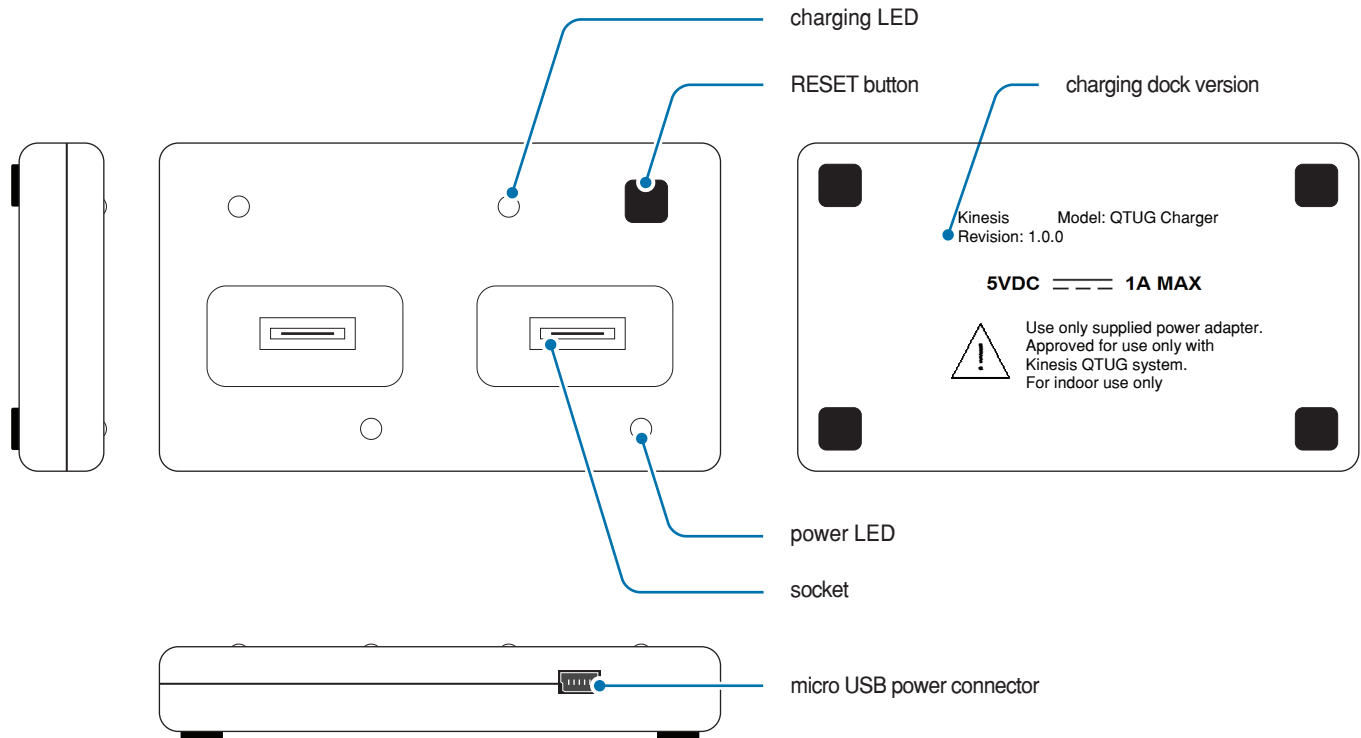
The tablet provided should ONLY be used with Kinesis products. Installing third party applications on the dedicated tablet may interfere with the correct operation of the application.



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 Kinesis Gait™ application and interfere with the correct calculation of the results. Please restrict your use of the tablet to Kinesis products **only**.

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

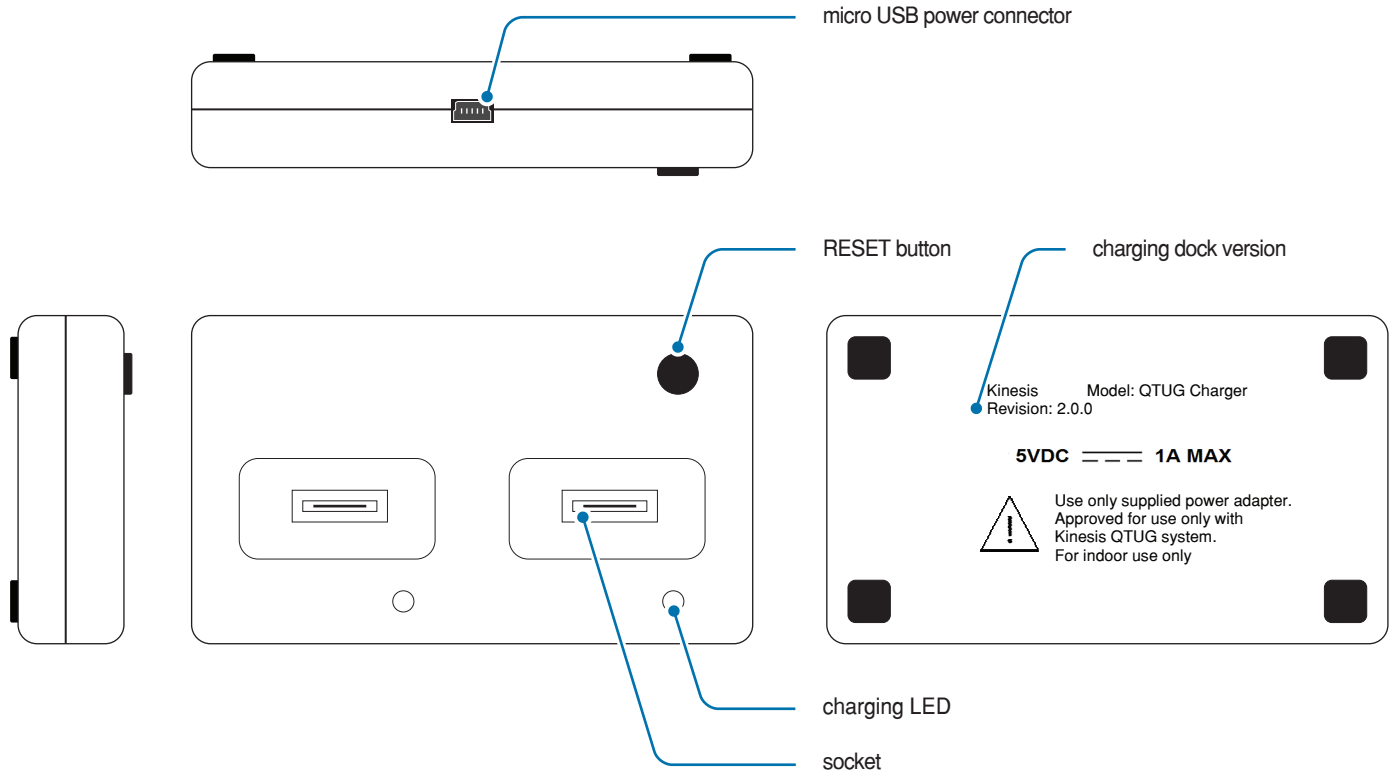
LED colour	Description
Orange	Sensor battery is not fully charged.
Off	Sensor battery is fully charged.

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

Place the sensor in the charging dock, ensuring a good connection. 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 Kinesis Gait™.

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 successful.



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 the instructions from the previous paragraph in order to pair the new sensor.

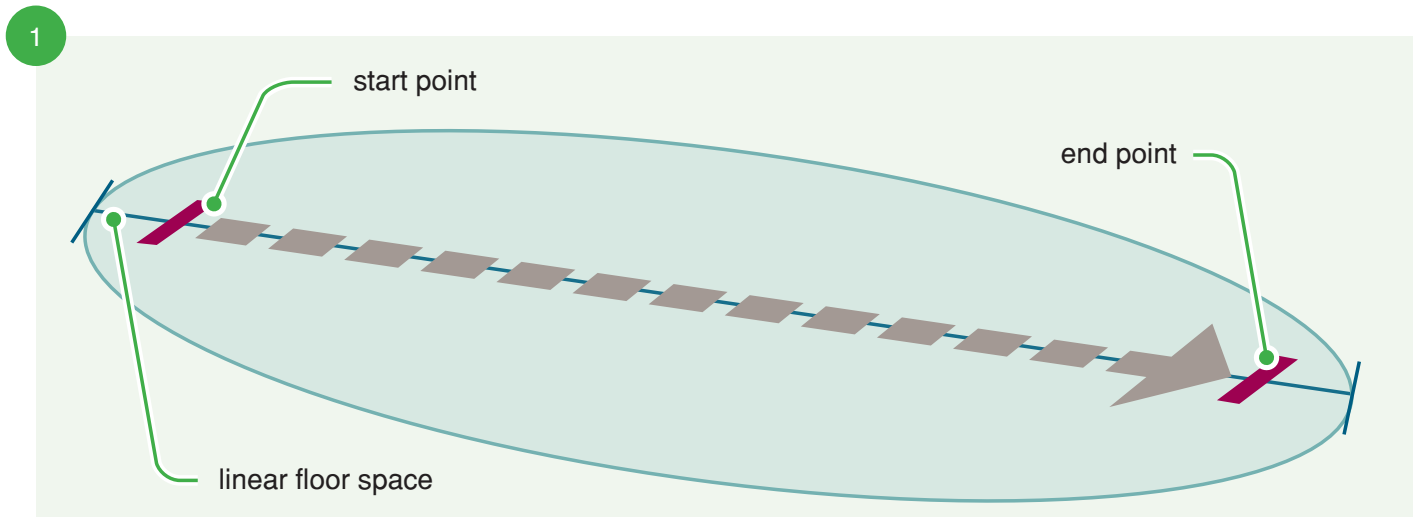


4. Set up a gait assessment

4.1 Physical set up

To perform a walking test on a patient, ensure the patient is wearing comfortable walking shoes.

Clearly mark the start and end points on the floor. These points should match **exactly** the selected walking task distance, measured from patient's toes when standing.

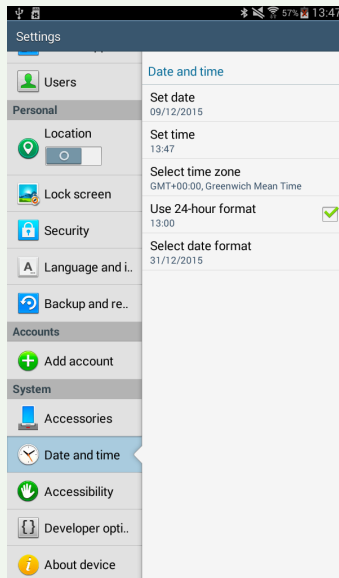


Ensure the linear floor space is large enough to support the selected walking task.

4.2 Set up Kinesis Gait™ application on the tablet

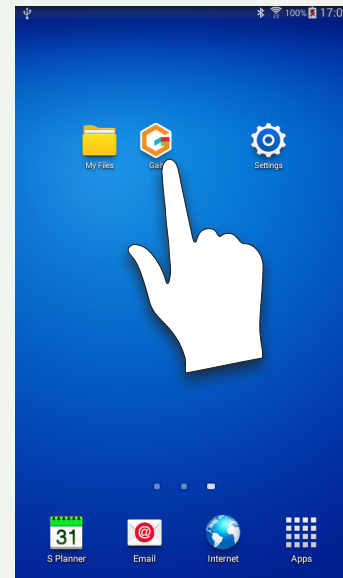
2

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



3

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

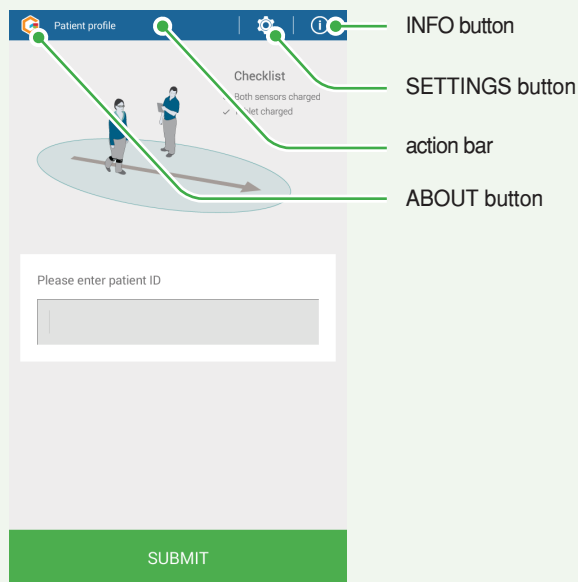


4

To open a popup window with information, tap the INFO button on the action bar.

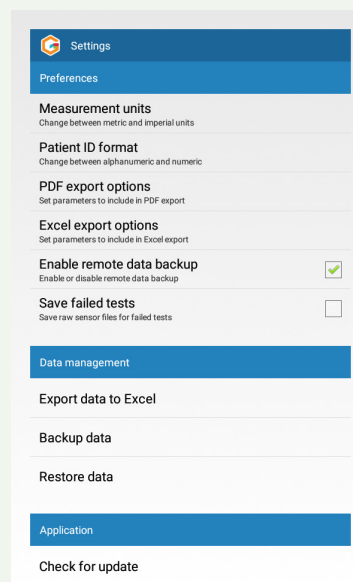
To set extra options prior to each test, tap the SETTINGS button.

To display Kinesis Gait version information, tap the ABOUT button.



5

In Settings, ensure “Enable remote data backup” is ticked to backup data to cloud. To check for a new software version press “Check for update”. To perform a system diagnostic press “Diagnostic”. To store raw sensor files from failed tests, tick “Save failed tests”.



6

Type in a new patient ID to create a new patient profile and tap the SUBMIT button to proceed to the patient profile page.

Patient profile

 Checklist

- ✓ Both sensors charged
- ✓ Tablet charged

 Please enter patient ID

 5144TK

 SUBMIT



Do not use Personally Identifiable Information (PII) as part of patient ID.

7

Enter age, height and weight by tapping the - and + buttons, or the number and entering manually. Select a gender by tapping the MALE or FEMALE button and add optional notes.

Patient 5144TK

 EDIT PROFILE

 PREVIOUS TESTS

 Age: 45 yr

 Gender: Male

 Height: 168 cm

 Weight: 71 kg

 Notes: patient has knee injuries

 SUBMIT



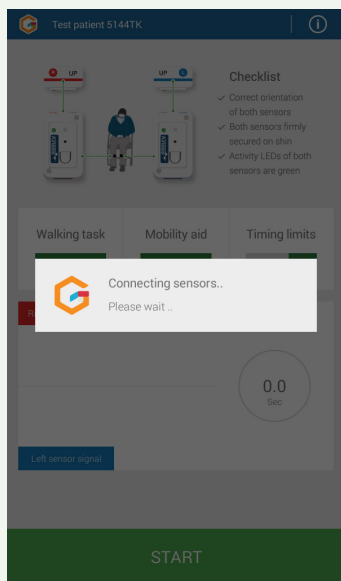
Enter height and weight to nearest cm or ft/inch and kg or lbs. Age is not stored for patients over 89 years.

8

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

If sensors are not connected or refuse to connect, reset the sensors while in the charging dock. Turn the tablet off and turn it back on.

If behaviour persists, fully charge sensors.

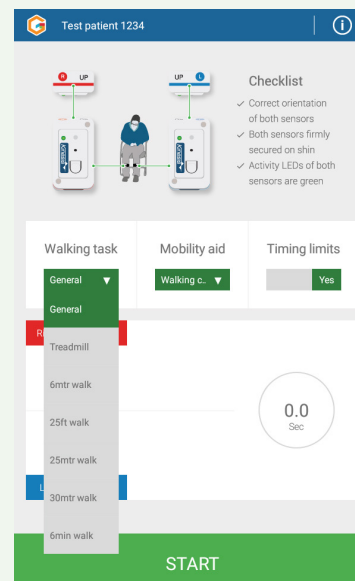


9

To choose a specific walking task, select one from the drop-down menu.

If using a mobility aid during the test, select one of the predefined options.

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



5. Perform a gait assessment

1

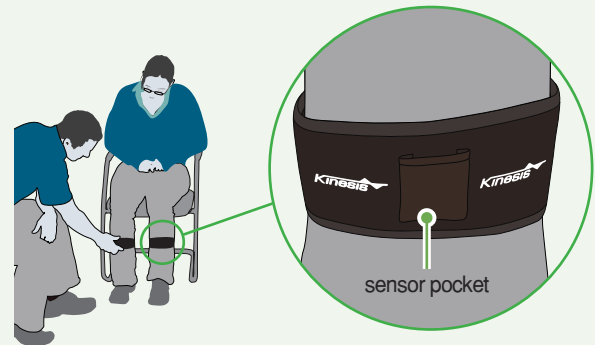
Seat the patient on the chair in order to explain the test.



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

2

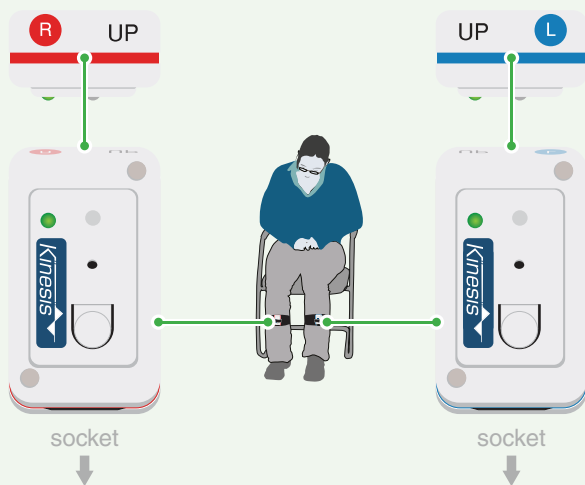
Secure the elasticated bandage or reusable strap firmly on the shins (mid-point of the anterior shank). If using strap, ensure sensor pocket is facing out, aligned along the shin bone and ensure Kinesis logo is orientated correctly.



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

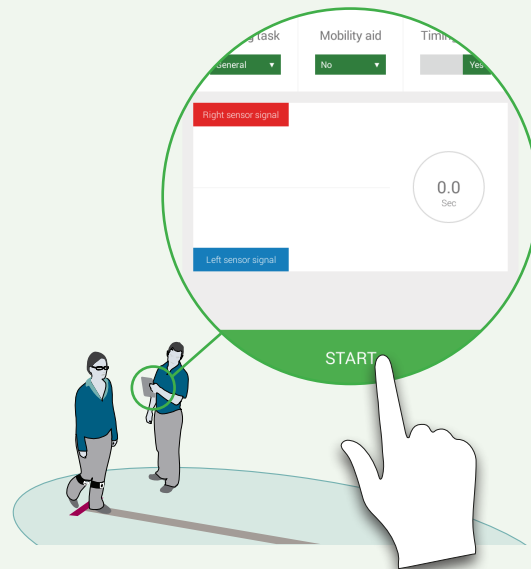
Place the sensors in the correct orientation (in the sensor pocket of the strap), with the socket facing down and the Kinesis logo facing out, the **R**ed sensor on the **R**ight leg and the **bL**ue sensor on the **L**eft leg.



Failure to use the correct orientation may result in inaccurate results.

4

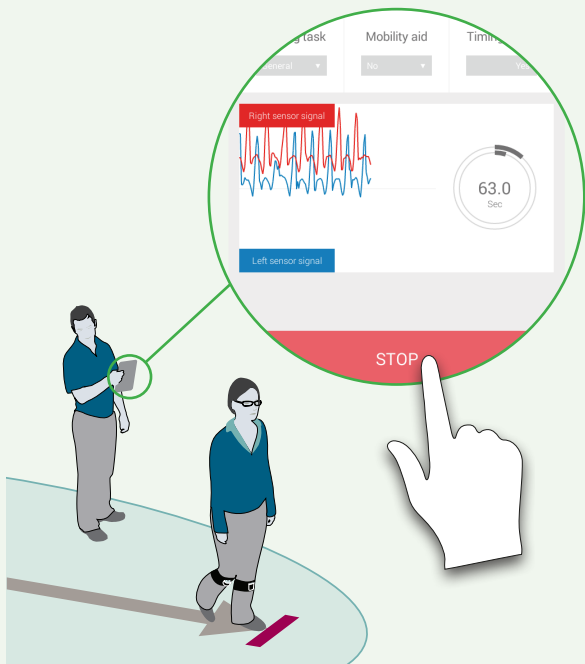
When the patient is ready, say 'Go' and tap the **START** button on the Kinesis Gait™ application. The activity LED on the sensor flashes alternately green-orange in streaming mode.



The Bluetooth range for each sensor is approx. 15m. To ensure correct operation for long walking trails to tasks, the sensors must remain within range of the tablet.

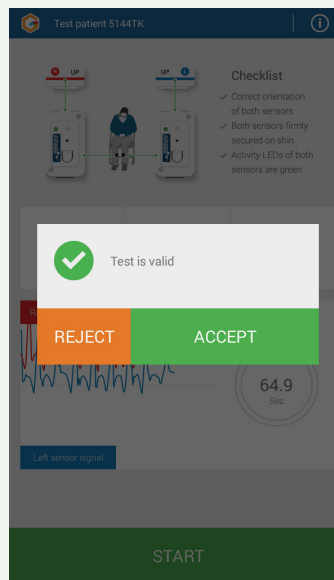
5

When the patient has completed the walking task, tap the STOP button to stop recording. Test recording for 6 min walk will stop automatically. The sensor data are displayed on the screen.



6

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.



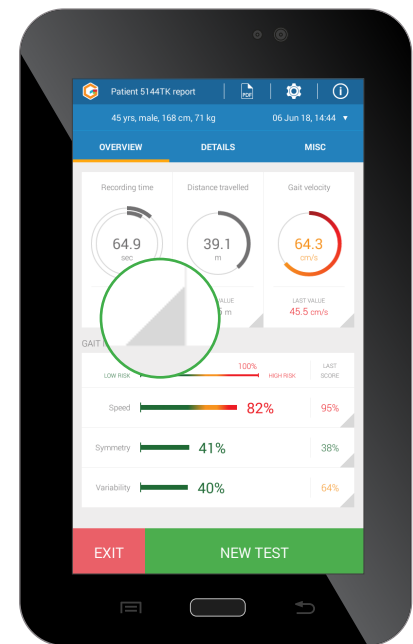
6. Test results

6.1 Interpreting test results

An accepted and valid test displays and saves the test results. The definitions of these results are explained in the table below.

Definition	Description
Recording time	Time to complete entire walking test
Distance travelled	Distance travelled during the walking test
Gait velocity	Average walking speed during test
Gait impairment scores	Gait scores are calculated to identify gait impairment by grouping the measured gait parameters into 3 functional categories: speed, variability and symmetry. A high gait score (> 70%) indicates that the patient may have a problem in the functional area highlighted.
Detailed results (DETAILS)	Comprehensive quantitative assessment of gait. Includes temporal gait and spatial gait parameters as well as gait variability and gait symmetry parameters.
Miscellaneous (MISC)	Displays clinician's notes and the selected options during the test. Displays inter-stride analysis plots and the sensor signals from left and right sensors.

For detailed explanation of each gait parameter, tap on the grey triangle in the bottom right corner. Or read chapter 'Parameter definition' in this user guide (p. 36).



Last value and last score

If a previous test exists, the last value or last score for recording time, distance travelled, gait velocity and gait impairment scores will be displayed.

Test results with colour-coded values

Gait parameter values that are significantly different compared to the reference population and may indicate a specific gait impairment are highlighted in **red**. 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.

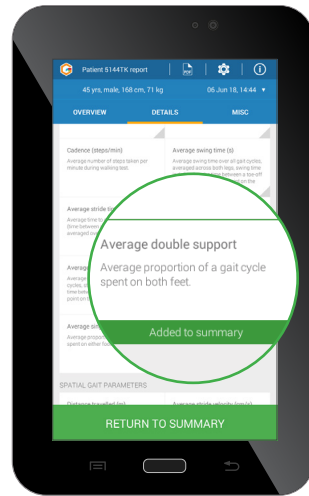
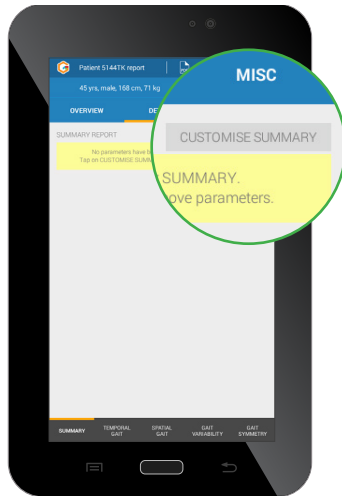
Description	
■	Within 1 standard deviation of population mean
■	Within 2 standard deviations of population mean
■	Greater than 2 standard deviations from population mean



6.2 Customise gait assessment

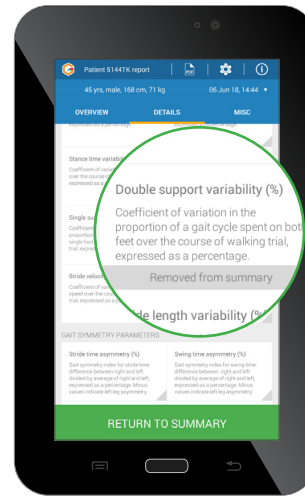
The details section has a bottom navigation panel showing five categories: SUMMARY, TEMPORAL GAIT, SPATIAL GAIT, GAIT VARIABILITY, GAIT SYMMETRY and BILATERAL GAIT.

The SUMMARY shows all gait parameters which have been added from the remaining four categories.



To customise the displayed results, tap on the CUSTOMISE SUMMARY button to show a list with parameters from the remaining four 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.



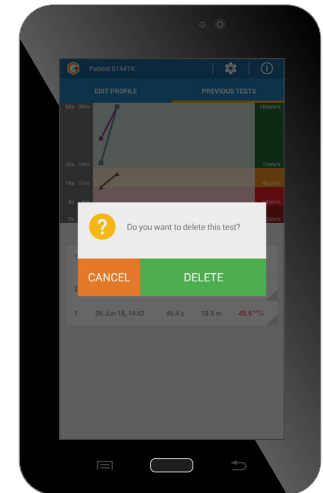
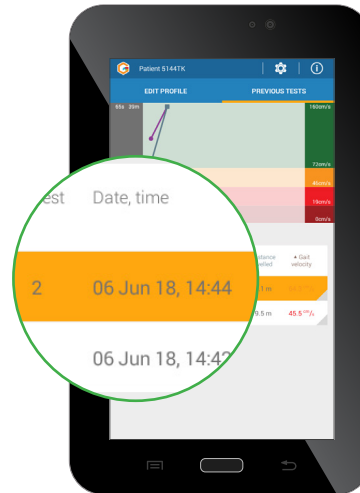
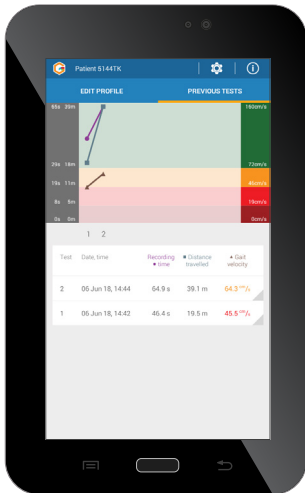
6.3 Historical tests

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

The **recording time** (purple), **distance travelled** (blue) and **gait velocity** (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 the data are backed up to a PC or laptop prior to deleting patient test.

7. Gait data management

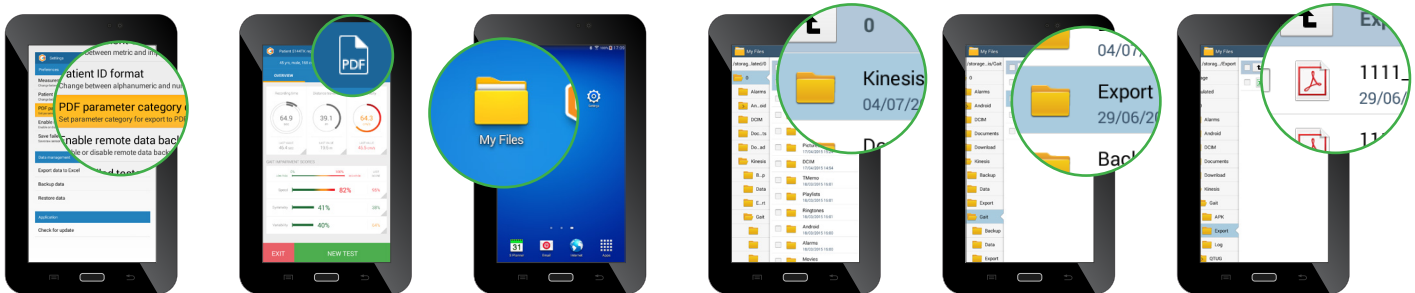
7.1 Export Gait test results

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.

Generate PDF report

The results for a given test can be exported to a PDF report, which documents the clinical info and gait results. In Settings under Preferences, parameter categories (pinned, temporal gait, spatial gait, gait variability, gait symmetry and bilayeral gait) 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' / 'Gait' / '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 retrieved as a SQLite database or exported in Excel format. Excel export can be configured using 'Excel options' button to include bilateral gait parameters and individual stride parameter data as well as mean gait parameters for all assessments. 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' / 'Gait' / 'Export' directory.



7.2 Backup, restore and erase test data

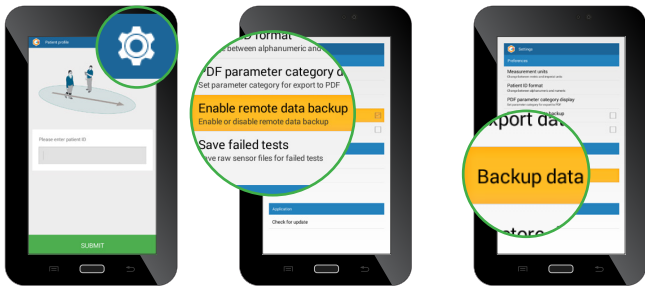
Backup patients' data to internal storage and remote service

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 Kinesis Gait™ 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. Raw sensor data are stored automatically for each gait assessment under 'My Files' / 'Kinesis' / 'Gait' / 'Data' directory.

Restore patients' data from internal storage

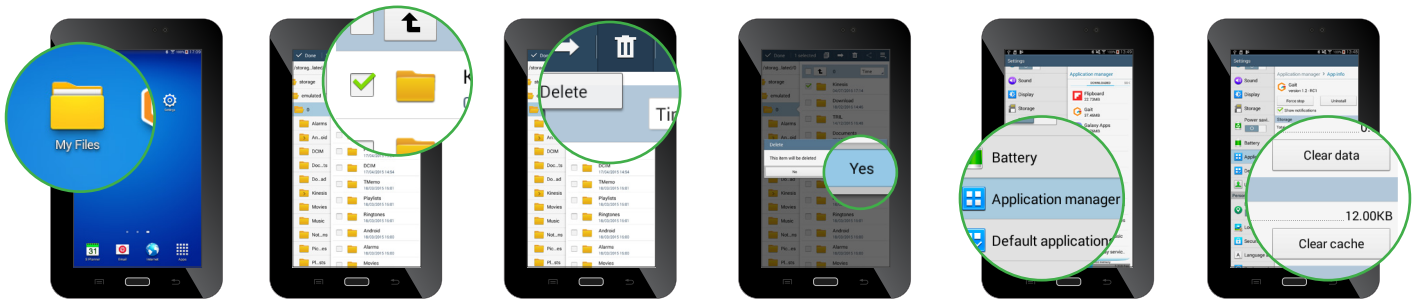
To restore the backup data, tap the Restore data button in the Settings.

Erase patients' 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 Gait icon. To clear the internal database, tap on 'Clear cache' and 'Clear data'.

To erase the data from the Kinesis Gait™ remote backup service, contact Kinesis technical support.



⚠ Ensure the data are backed up to external storage prior to erasing patient data.
 Existing data will be overwritten by restoring, ensure the data are backed up to external storage prior to restoring 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.kinesishelthtech.com/support or contact Kinesis technical support at support@kinesishelthtech.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 gait 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.
Software 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 gait parameters produced by Kinesis Gait.

Parameter	Description
Recording time (s)	Recording time for entire walking test as recorded using timer
Distance travelled (m)	Estimated average distance travelled during the walking trial
Gait velocity (cm/s)	Average walking speed during walking trial, calculated on a stride to stride basis

10.1 Gait impairment scores

Each assessment can be broken down into three functional areas.

Functional areas	Description
Speed score (%)	Percentile based assessment of gait speed parameters. A high speed score indicates low gait velocity compared to population average.
Variability score (%)	Percentile based assessment of gait variability. A high variability score indicates high gait variability which is linked to risk of falls.
Symmetry score (%)	Percentile based assessment of gait asymmetry. A high symmetry score indicates gait asymmetry. Gait asymmetry is associated with neurological disorders.

10.2 Temporal gait parameters

Parameter	Description
Recording time (s)	Recording time for entire walking test as recorded using timer
Walk time (s)	Time participant actually spends in locomotion during test
Number of gait cycles	Number of gait cycles over the course of the walking trial
Number of steps	Number of steps in walking test
Cadence (steps/min)	Average number of steps taken per minute during walking 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)	Average time to complete one stride (time between successive heel-strikes), averaged over all gait cycles
Average step time (s)	Average of times between heel-strike of one foot to heel strike of the opposite foot
Average single support	Average proportion of a gait cycle spent on either foot
Average double support	Average proportion of a gait cycle spent on both feet

10.3 Spatial gait parameters

Parameter	Description
Distance travelled (m)	Estimated average distance travelled during the walking trial
Average stride velocity (cm/s)	Average walking speed during walking trial, calculated on a stride to stride basis
Average stride length (cm)	Mean stride length during walking test, calculated on a stride to stride basis

10.4 Gait variability parameters

Parameter	Description
Stride time variability (%)	Coefficient of variation in stride time over the course of walking trial, expressed as a percentage
Stance time variability (%)	Coefficient of variation in stance time over the course of walking trial, expressed as a percentage
Swing time variability (%)	Coefficient of variation in swing time over the course of walking trial, expressed as a percentage
Step time variability (%)	Coefficient of variation in step time over the course of walking trial, expressed as a percentage
Single support variability (%)	Coefficient of variation in the proportion of a gait cycle spent on a single foot over the course of walking trial, expressed as a percentage
Double support variability (%)	Coefficient of variation in the proportion of a gait cycle spent on both feet over the course of walking trial, expressed as a percentage
Stride velocity variability (%)	Coefficient of variation in walking speed over the course of the walking trial, expressed as a percentage
Stride length variability (%)	Coefficient of variation in stride length over walking test

10.5 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.

10.6 Bilateral temporal parameters

Parameter	Description
Average left swing time (s)	Average swing time over all gait cycles for left leg, swing time is defined as the time between a toe-off point and the heel strike point on the same foot
Average right swing time (s)	Average swing time over all gait cycles for right leg, swing time is defined as the time between a toe-off point and the heel strike point on the same foot
Average left stance time (s)	Average stance time over all gait cycles for left leg, stance time is defined as the time between a heel-strike and toe-off point on the same foot
Average right stance time (s)	Average stance time over all gait cycles for right leg, stance time is defined as the time between a heel-strike and toe-off point on the same foot
Average left stride time (s)	Average time between successive heel-strikes on the left leg, averaged over all gait cycles
Average right stride time (s)	Average time between successive heel-strikes on the right leg, averaged over all gait cycles
Average left step time (s)	Average of times between heel-strike of left foot to heel strike of the right foot.
Average right step time (s)	Average of times between heel-strike of right foot to heel strike of the right foot.
Average left single support	Average proportion of a gait cycle spent on left foot
Average right single support	Average proportion of a gait cycle spent on right foot
Average left double support	Average proportion of left gait cycle spent on both feet
Average right double support	Average proportion of right gait cycle spent on both feet

10.7 Bilateral spatial parameters

Parameter	Description
Number of steps (left)	Number of steps on left leg in a walking test
Number of steps (right)	Number of steps on right leg in a walking test
Average left stride length (cm)	Mean left stride length during walking test
Average right stride length (cm)	Mean right stride length during walking test
Average left stride velocity (cm/s)	Average walking speed for left leg during a walking test
Average right stride velocity (cm/s)	Average walking speed for right leg during a walking test

10.8 Bilateral variability parameters

Parameter	Description
Left swing time variability (%)	Coefficient of variation in left swing time over the course of walking trial, expressed as a percentage
Right swing time variability (%)	Coefficient of variation in right swing time over the course of walking trial, expressed as a percentage
Left stance time variability (%)	Coefficient of variation in left stance time over the course of walking trial, expressed as a percentage
Right stance time variability (%)	Coefficient of variation in right stance time over the course of walking trial, expressed as a percentage
Left stride time variability (%)	Coefficient of variation in left stride time over the course of walking trial, expressed as a percentage
Right stride time variability (%)	Coefficient of variation in right stride time over the course of walking trial, expressed as a percentage

Bilateral variability parameters (continued)

Left step time variability (%)	Coefficient of variation in left leg step time over the course of walking trial, expressed as a percentage
Right step time variability (%)	Coefficient of variation in left right step time over the course of walking trial, expressed as a percentage
Double support variability left (%)	Coefficient of variation in the proportion of a left gait cycle spent on both feet over the course of walking trial, expressed as a percentage
Double support variability right (%)	Coefficient of variation in the proportion of a right gait cycle spent on both feet over the course of walking trial, expressed as a percentage
Single support variability left (%)	Coefficient of variation in the proportion of a gait cycle spent on left foot over the course of walking trial, expressed as a percentage
Single support variability right (%)	Coefficient of variation in the proportion of a gait cycle spent on right foot over the course of walking trial, expressed as a percentage
Left stride velocity variability (%)	Average walking speed for left leg during a walking test
Right stride velocity variability (%)	Average walking speed for right leg during a walking test
Left stride length variability (%)	Coefficient of variation in left leg walking speed over the course of the walking trial, expressed as a percentage
Right stride length variability (%)	Coefficient of variation in right leg walking speed over the course of the walking trial, expressed as a percentage

10.9 Stride parameters values

Parameter	Description
Left heel strike times	Times of initial contact (IC) of left foot with ground
Right heel strike times	Times of initial contact (IC) of right foot with ground
Left toe-off times	Times of terminal contact (TC) of left foot with ground
Right toe-off times	Times of terminal contact (TC) of right foot with ground
Left mid-swing times	Times corresponding to mid-swing of gait cycle (maximum medio-lateral angular velocity) for left leg
Right mid-swing times	Times corresponding to mid-swing of gait cycle (maximum medio-lateral angular velocity) for right leg
Average left stride time (s)	Stride time values for left leg during a walking trial
Average right stride time (s)	Stride time values for right leg during a walking trial
Left stance time values (s)	Stance time values for left leg during a walking trial
Right stance time values (s)	Stance time values for right leg during a walking trial
Average left swing time (s)	Stride time values for left leg during a walking trial
Average right swing time (s)	Stride time values for right leg during a walking trial
Average left step time (s)	Step time values for left leg during a walking trial
Average right step time (s)	Step time values for right leg during a walking trial
Left single support values	Left leg single support values for a walking trial
Right single support values	Right leg single support values for a walking trial

Stride parameters values (continued)

Left double support values	Left leg double support values for a walking trial
Right single support values	Right leg double support values for a walking trial
Single support values	Single support values for a walking trial
Double support values	Double support values for a walking trial
Left leg stride length values (cm)	Left leg stride length values for a given walking trial
Right leg stride length values (cm)	Right leg stride length values for a given walking trial
Left leg stride velocity values (cm/s)	Left leg stride velocity values for a given walking trial
Right leg stride velocity values (cm/s)	Right leg stride velocity values for a given walking trial

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
Output		5V DC, 1A Max
Current consumption		700mA (7.5V input)
Weight		< 2000 grams (4.4 lbs)
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 radio device belongs to Class 2 for which restrictions or bans apply regarding its placing on the market or putting into service.



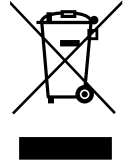
This device fulfils the provisions of EU MDR 2017/745 (EN 55011 Class A and EN 60601-1-2).



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 separate 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 EU 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 Regulatory Compliance

The Kinesis Gait™ product complies with data security and privacy regulations in our target countries. Data is encrypted in transit from the collecting device (source) and at rest in the final data storage platform (destination). Personal identifiable information is not stored on the platform. 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 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 Directive 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

Linus Health Europe and its Distributors warrant that this product, when used in compliance with the documentation complies with the essential requirements of the MDR. 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 Month 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-authorized modifications or repairs to the Product.



USER GUIDE v1.4

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