

Ainone Balance®

**Mobile App Instructions** 

## Ainone Balance®

### **Mobile App Instructions**

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## **1. PRODUCT DESCRIPTION**

The Ainone Balance measurement application was designed and manufactured by Ainone Oy as a simple, fast way of assessing balance and neurological performance. The product is intended for use by health, social and sports professionals only, to support the assessment of balance. The Ainone Balance system consists of a balance measurement application, a mobile device, a sensor / heart rate monitor that connects to the application. The Ainone Balance measurement application allows advanced algorithms to objectively measure balance (sway area, length and speed standard deviation) and record the results of the measurements.

#### **1.1 COMPATIBLE DEVICES**

#### Table 1 Compatible devices

Ain1 order code	Device	Image
A1	Ainone Balance sensor (Manufacturer: Suunto/Movesense Oy)	
A2	Ainone Balance heart rate monitor (Manufacturer: Suunto/Movesense Oy)	

NOTE! If the application is used together with another sensor, the application may not work at all or its operation may differ markedly from its normal functionality. The manufacturer is not responsible for the functionality of the product or for any problems that may occur due to the use of a non-Ainone Balance sensor together with the Ainone Balance measurement application.

The Ainone Balance measurement app works with all Android tablets, based on the following requirements:

- Bluetooth version: Bluetooth LE 4.0 or later
- Network connection: WiFi or 4G
- Android operating system: 5.0 Lollipop or later (SDK version >= 21)

#### Table 2 Tested Mobile Devices

No	Device
1	Lenovo Tab M10 (TB-X505L)
2	Lenovo Tab M10 (TB-X605F)
3	Samsung Galaxy Tab S3 (SM-T820)
4	Lenovo Yoga Tab 3 (YT3-X50F)

#### Table 3 Tested Android versions

No	Device
1	Android 10 (Android API 29)

2	Android 9 (Pie API 28)
3	Android 6.0.1 (Marshmallow API 23)

#### **1.2 INTENDED USE**

Ainone Balance is a balance measurement application that produces a numerical value, to provide a quantitative evaluation of the measurement parameters. The product is intended for use by healthcare, social care and sports professionals to support the assessment of balance and detect changes in human health associated with balance parameters.

#### **1.3 CONTRAINDICATIONS**

The product has no confirmed contraindications.

## 2. SAFETY

The following safety markings are used:

A

WARNING: Used in the case of activities or situations that can cause serious injury or death.

ATTENTION: Indicates a potentially hazardous situation which may cause a slight or moderate injury to the user or the patient, or possible damage to the equipment, if the situation is not avoided.



NOTE: Used to highlight important information.

TIP: Provides additional tips on how to use features of your device efficiently.

#### Safety instructions

WARNING: PACEMAKER OR OTHER IMPLANTED DEVICE. ALWAYS HAVE THE SUBJECT CONSULT THEIR DOCTOR BEFORE USING THE MOVESENSE SENSOR IF THEY HAVE A PACEMAKER OR OTHER IMPLANTED DEVICE. ALTHOUGH SEVERAL IMPLANTED PACEMAKER MANUFACTURERS STATE THAT THE RISK ASSOCIATED WITH THE SIMULTANEOUS USE IS LOW, IT IS ESSENTIAL TO CONSULT THE EXPERT THAT KNOWS THE EXACT TYPE AND MODEL OF THE IMPLANTED DEVICE IN QUESTION BEFORE USING THE MOVESENSE SENSOR. WARNING: OUR PRODUCTS COMPLY WITH INDUSTRY STANDARDS, BUT CONTACT WITH THE PRODUCT MAY CAUSE ALLERGIC REACTIONS OR SKIN IRRITATION. IN SUCH A CASE, STOP USING THE PRODUCT IMMEDIATELY AND SEEK MEDICAL ATTENTION.

WARNING: ALWAYS ENSURE A SAFE MEASUREMENT SITUATION WHEN MEASURING BALANCE. IF THE SUBJECT DISPLAYS BALANCE DIFFICULTIES, ENSURE ADEQUATE SUPERVISION. STOP MEASURING IF THERE IS A RISK OF THE PERSON FALLING. CHECK THE CONDITION OF THE PERSON BEFORE AND DURING MEASUREMENT TO ENSURE A SAFE MEASUREMENT SITUATION.

WARNING: ALWAYS MAKE SURE THAT THE DEVICE IS USED IN A SAFE ENVIRONMENT. FALLING OR LOSING ONE'S BALANCE CAN CAUSE SERIOUS INJURY. ALWAYS FOCUS ON SAFETY AND, IF REQUIRED, MAKE SURE BOTH OF YOUR HANDS ARE AVAILABLE TO SECURE THE BALANCE OF THE PERSON TO BE TESTED.

WARNING: THE DEVICE IS INTENDED FOR USE ONLY BY HEALTHCARE, SOCIAL CARE, AND COACHES OR PHYSICAL TRAINING PROFESSIONALS.

WARNING: KEEP YOUR USERNAME AND PASSWORD SAFE. NEVER GIVE YOUR USERNAME AND PASSWORD TO ANYONE ELSE. DO NOT SHARE THE MEASUREMENT RESULTS WITH A THIRD PARTY WITHOUT THE CONSENT OF THE PERSON TO BE MEASURED.

🛝 WARNING: DO NOT SWALLOW. KEEP THE SENSOR AWAY FROM CHILDREN.

A WARNING: STOP USING THE SENSOR IMMEDIATELY IF IT IS DAMAGED IN ANY WAY.

ATTENTION: DO NOT EXPOSE THE DEVICE TO SOLVENTS, AS THIS MAY DAMAGE THE SURFACE OF THE DEVICE.

ATTENTION: DO NOT EXPOSE THE DEVICE TO INSECT REPELLENTS, AS THIS MAY DAMAGE THE SURFACE OF THE DEVICE.

ATTENTION: DO NOT DISPOSE OF THE DEVICE AS NORMAL WASTE – TREAT IT AS ELECTRONIC WASTE TO PROTECT THE ENVIRONMENT.

ATTENTION: AVOID HEAVY IMPACTS OR DROPS, AS THESE WILL DAMAGE THE DEVICE.

For more information on measuring balance, go to www.ainone.eu

## **3. GETTING STARTED**

The Ainone Balance measurement app provides accurate information about balance and changes in balance in just a few simple steps. This requires one of the specified mobile devices and the Ainone Balance measurement system (application and sensor). An Internet and Bluetooth connection is required in order to use the Ainone Balance measurement app.

#### 3.1 Putting on the Ainone Balance sensor and belt, images 1 and 2

Using the Ainone Balance sensor and heart rate monitor:

3.1.1. Click the sensor firmly into place on the belt connector.

3.1.2. The belt length should be adjusted as necessary.

3.1.3A. If the sensor is used only to measure balance, the sensor can be used on top of the clothing.

3.1.3B. If the sensor is also being used for heart rate measurement, the electrode areas of the belt must be moistened with water or electrode gel and the sensor should be in contact with the skin under the shirt.

3.1.4. The belt should be worn so that the sensor is on the lower part of the sternum (breastbone in the middle of the chest), fits comfortably and the logo text is facing away from the body. Ensure that the sensor is in the correct position before and during the measurement.



#### Image 1

Image 2

3.1.5. If the sensor does not turn on and the light does not blink, you can remove the sensor from the belt and touch both metal screws simultaneously with your fingers. You can also activate the sensor when it is attached to the heart rate monitor, by touching the electrode surfaces on the belt.

ATTENTION: Never use force to remove the Ainone Balance sensor from the belt, as this could damage the belt clips. Click the sensor off one button at a time.

TIP: The Ainone Balance measurement app can also be used in combination with Movesense-compatible sportswear, such as Salomon's Movesense T-shirt and sports bra. You can moisten the electrode areas of the garment and snap the sensor into place on the garment's connector.

#### 3.2 Using the mobile device and Ainone Balance measurement application: connecting the sensor

NOTE: The Ainone Balance measurement application, which measures sway, is used to assess balance. The Ainone Balance measurement application is for use by healthcare professionals as one component of balance assessment. The balance measurement application consists of specified measurement protocols. Each measurement protocol includes two (2) measurements.

3.2.1 Start the mobile device according to its instructions. The application requires an internet connection. (If you have a tablet pre-installed by Ain1 Oy, the pin code is 0-0-0-0. The pin code can be changed from the tablet settings.)

3.2.2 Downloading the measurement application to your mobile device (if you already have an Ainone Balance measurement app installed on your mobile device, go to section 3.2.3.)

#### Download Ainone Balance either from here

(<u>https://play.google.com/store/apps/details?id=ai.ain1.balance1</u>) or by searching the Google Play app store for "Ainone Balance".

When the download is complete, go to the apps list and press the Ainone App Icon (image 3) to launch the application.



Image 3 (the logo may also be against an orange background)

NOTE: An Internet connection is required to download the app. Connection usage may incur data charges.

NOTE: Your personal Google Account must be enabled. If you do not have a personal Google Account on your device:

- To open the device settings, drag the top of the notification bar and press the gear icon
- Open account settings (cloud and accounts -> accounts-> add account -> Google)
- Complete your personal Google Account information
- Please note, however, that the instructions may differ slightly, depending on the device. These instructions are for the Samsung Galaxy Tab S3.

#### 3.2.2.1 Changing your password in the Ainone Balance app

- Start Ainone Balance
- If you're signed in, select "Settings" in the upper-left corner of the Home screen, where you can change your password.
- If you haven't signed in yet, Click "Forgot password?" under the sign-in button on the sign-in page
- Check your email and follow the instructions there to reset your password
- If the email is not in your inbox, check your spam folder

3.2.3 Fill in the User sign-in information. The username and password assigned to the user are displayed when using the application for the first time. Your username and password must be stored securely and never shared with anyone else. If there is reason to believe that the information may have fallen into the wrong hands, you must contact <a href="mailto:support@ainone.eu">support@ainone.eu</a> immediately. If you wish to change the password, follow the instructions in section 3.2.2.1.

If at any time a password for signing into the application is lost or forgotten, utilize the "Forgot you password" button from the Ainone Balance sign-in page. The "Forgot your password" link will redirect the user through the appropriate steps to retrieve a "Code" from the user email to input and change the Password.

NOTE: The application requires access to location data, and location data must also be turned on. Bluetooth connection is not possible without this permission.

3.2.4 Language settings - to change the language of the application, select "Settings" in the upper-left corner of the Home screen and select the language you want.

3.2.5 Managing Subjects - Subject refers to the patient, client, or athlete being evaluated.

Select "Subject". A list of subjects you have measured earlier will appear if you have used the app before.

To create a new subject to measure, press "Add new subject". Complete the country code (e.g. FIN) and the subject's personal identity code (ID).

## The subjects are identified by an ID. You must be careful when entering the subject's national identification number, because the data is retrieved from a database based on this number and the number cannot be edited.

TIP: When you enter the date of birth, pressing the year (e.g. 2021) in the upper-left corner of the calendar view opens a menu, from which you can easily change the year by browsing.

NOTE: After this, the person's ID cannot be edited. If you have accidentally entered the wrong
national identification number and want to correct it, please contact support@ainone.eu

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The User (healthcare professional using the app) must also review the privacy policy with the subject, and request permission from the subject to collect and store data. Data approval can be provided separately for each item, or by pressing "Select All". If the subject does not allow data collection, balance measurements cannot be performed using the Ainone Balance measurement application. Only after the data storage permissions are accepted can the other information (first and last name and email address) then be completed. Once the subject's basic information has been filled in, you should check once more to make sure that it's correct. It is important to request the subject to provide their email address (if possible), as this is the only way to contact the subject about data retention. Personal data and measurement results are stored for 12 months, after which they are deleted unless the subject consents to them being stored for longer.

3.2.6 Bluetooth Sensor connection. The Ainone Balance sensor must be connected to a mobile device to enable the use of the application's measurement functionality. To connect the mobile device to the sensor,

select the "sensor" and click its number, e.g. "Movesense 3043442851". When the sensor number appears below the "sensor" button, it is connected to a mobile device.



NOTE: Bluetooth connection is required to use the sensor.

 ${}^{\prime\prime}$ NOTE: It may take several seconds for the sensors to be found and displayed by the application.

TIP: If the sensor is not found, check that the sensor is on. This is done by taking the sensor off the belt and touching the metal screws with your fingers. You can also activate the sensor when it is attached to the heart rate monitor, by touching the electrode surfaces on the belt.



NOTE: Pressing "Back" will take you back one page.

NOTE: Press "Home" to go to the home screen.

## 4. AINONE BALANCE MOBILE APPLICATION: SELECTING THE SENSOR AND THE PROTOCOL FOR THE ASSESSMENT

The AINONE BALANCE MEASUREMENT APPLICATION AND SENSOR can assess balance in any given situation only if you proceed in accordance with these instructions.

**I**NOTE: If the belt is too loose, incorrectly placed, or clothing that the Subject is wearing affects the sensor placement, the balance readings may be less reliable. The correct belt tightness should always be ensured to provide an optimal measurement.

NOTE: A standard process of measurement must be used by the professional that is performing the balance assessment. In order to achieve comparable assessment results and ensure a high amount of retest reliability the sensor placement, patient test instructions, and assessment protocols must be the same during all assessment sessions. Ensure that the sensor belt is tight enough to ensure there is no additional movement, place the sensor on the patient the same way for every test, and provide similar test instructions so the evaluation protocols are the same for every assessment.

Using the Ainone Balance sensor:

- 4.1. Put on the Ainone Balance sensor (see 3.1 Putting on the Ainone Balance sensor and belt).
- 4.2. Open the Ainone Balance measurement app from your mobile device (see. 3.2 using the application).
- 4.3. Connect the Ainone Balance mobile app and the sensor (see 3.2 connecting)
- 4.4. To start, press "Start measurement session" and select the measurement protocol (see Image 4)





#### 4.4.1 "Normal stance" (normal standing position), Image 5

Select the measuring program to be used, i.e. the protocol, by pressing "Normal stance", feet apart, in a normal standing position.



#### Image 5

Choose "Protocol modifiers" (protocol modification) 1 and 2 for the measurements, whether the eyes are open or closed (Open/Closed), and whether the measurement surface is hard or soft (Hard/Soft), depending on the measurement you intend to perform.

Then press "Accept".

Instructions: Stand in your normal standing position with your hands on your hips.

Instruct the subject as follows:

First measurement instruction: "The measurement will take 10 seconds, keep your eyes open/closed and stay as still as possible. The measurement is starting now."

Second measurement instruction: "The measurement will take 10 seconds, keep your eyes open/closed and stay as still as possible. The measurement is starting now."

#### 4.4.2 "Feet together" (Feet together), Image 6

Choose the correct protocol by pressing "Feet together" (feet together).

Choose "Protocol modifiers" (protocol modification) 1 and 2 for the measurements, whether the eyes are open or closed (Open/Closed), and whether the measurement surface is hard or soft (Hard/Soft), depending on the measurement you intend to perform.



#### Image 6

Instructions: Stand with your feet together and your hands on your hips.

Instruct the subject as follows:

First measurement instruction: "The measurement will take 10 seconds, keep your eyes open/closed and stay as still as possible. The measurement is starting now."

Second measurement instruction: "The measurement will take 10 seconds, keep your eyes open/closed and stay as still as possible. The measurement is starting now."

#### 4.4.3 "Semi tandem", Image 7

Choose the right protocol to be used by pressing "Semi tandem" (Feet semi-tandem), with the left or right foot in front.

Choose "Protocol modifiers" (protocol modification) 1. and 2. for the measurements, whether the eyes are open or closed (Open/Closed), left or right foot in front (Left/Right) and whether the measurement surface is hard or soft (Hard/Soft), depending on the measurement you intend to perform.



#### Image 7

Instructions: Place your hands on your hips, your feet in tandem, with the non-dominant foot in the rear, and the base of the rear foot's big toe against the inner part of the heel of the front foot.

Instruct the subject as follows:

First measurement instruction: "The measurement will take 10 seconds, keep your eyes open/closed and stay as still as possible. The measurement is starting now."

Second measurement instruction: "The measurement will take 10 seconds, keep your eyes open/closed and stay as still as possible. The measurement is starting now."

#### 4.4.4 "Tandem", Image 8

Choose the right protocol to be used by pressing "Tandem", feet in tandem, left or right one in front.

Choose "Protocol modifiers" (protocol modification) 1. and 2. for the measurements, whether the eyes are open or closed (Open/Closed), left or right foot in front (Left/Right) and whether the measurement surface is hard or soft (Hard/Soft), depending on the measurement you intend to perform.



#### Image 8

Instructions: Place your feet in tandem, right/left foot in front, with the non-dominant foot in the rear, toes against the opposite heel and hands on the hips.

Instruct the subject as follows:

First measurement instruction: "The measurement will take 10 seconds, keep your eyes open/closed and stay as still as possible. The measurement is starting now."

Second measurement instruction: "The measurement will take 10 seconds, keep your eyes open/closed and stay as still as possible. The measurement is starting now."

#### 4.4.5 "One foot" (Standing on one foot), Image 9

Choose the right protocol to be used by pressing "One foot" (Standing on one foot), right/left foot.

Choose "Protocol modifiers" (protocol modification) 1. and 2. for the measurements, whether the eyes are open or closed (Open/Closed), left or right foot (Supporting leg, Left/Right) and whether the measurement surface is hard or soft (Hard/Soft), depending on the measurement you intend to perform.



#### Image 9

Instructions: Raise your foot from the ground, with your hip at a 30° and knee at a 45° angle and hands on hips.

Instruct the subject as follows:

First measurement: "Raise your foot from the ground, with your hip at a 30° and knee at a 45° angle and hands on hips. The measurement will take 10 seconds, keep your eyes open/closed and be as still as possible. The measurement is starting now."

The second measurement: "Raise your foot from the ground, with your hip at a 30° and knee at a 45° angle and hands on hips. The measurement will take 10 seconds, keep your eyes open/closed and be as still as possible. The measurement is starting now."

4.4.6 "Custom" (Optional), Image 10

Choose the right protocol by pressing "Custom" (Optional).

The aim of the measurement can be typed into the optional field.

MARNING: Take care to ensure that the measurement protocol and environment are safe



#### Image 10

Instructions: Custom protocol, type what was measured and the instructions into the open field.

Provide instructions in your preferred manner, clearly and comprehensively.

#### 4.5 Additional Measurements

To continue the measurement process with either the same or a different protocol, press the "Next" button. (Section 7.7) and selecting the next measurement protocol to be performed.

To end the measurement process, press "Stop".

## 5. AINONE BALANCE MOBILE APPLICATION: USAGE AND PREPARATION OF THE BALANCE ASSESSMENT

5.1. CALIBRATION: The application will self-calibrate within the first five seconds after you have started the measurement. The sensor is factory calibrated by the manufacturer (Movesense Oy). During self-calibration, the black ball on the screen will move slightly and stop after about five seconds if the sensor is still.

5.2 Ensure that the environment is calm and safe for assessing balance.

5.3 The application is ready to use when a black ball is moving on the test screen; this movement represents the sway, i.e. balance of the person to be assessed. When the person moves, the black ball will move on the screen according to the movement.

5.4 Go over what is being done with the subject i.e. the person being measured. At the beginning of the assessment, explain why balance is important and what the benefits of assessing it are.

5.5. Test instructions should be given to the person to be measured (see sections 4.4.1 to 4.4.6).

ATTENTION: Make sure that you implement the exact protocol selected and execute it precisely as instructed by the application.

For example, in the tandem position, make sure the feet are in tandem: Place your feet in tandem, right/left foot in front, toes against the opposite heel and hands on the hips.

For example, in the feet together position, make sure that the soles are together. If this (e.g. the knee angle) is not possible due to movement restriction, the soles should be placed as close together as possible.

## 6. AINONE BALANCE MOBILE APPLICATION: PERFORMING A BALANCE ASSESSMENT USING THE APPLICATION

WARNING: Always ensure a safe assessment situation when measuring balance. If the person to be measured has difficulties with balance, the measurer must provide adequate supervision. We recommend that the mobile device be supported (e.g. on a table) during measurement.

WHEN USING THE APPLICATION, THE SAFETY OF THE SUBJECT MUST BE THE PRIMARY FOCUS AT ALL TIMES, AND THE MEASURER MUST HAVE BOTH HANDS AVAILABLE TO ENSURE THAT THE SUBJECT DOES NOT LOSE HIS OR HER BALANCE.

NOTE: For the best Bluetooth connection during measurement, place your mobile device in the optimum location i.e. behind and to the left or right of the subject. The connection may be interrupted if the device is directly behind the subject.

WARNING: Check the condition of the subject before and during the measurement to ensure a safe measurement situation.

You must stop measuring if there is a risk of the subject falling.

Each measurement protocol includes two (2) measurements. After giving instructions and selecting the protocol, press the "Next" button (next) to start the measurement. Then wait 5 seconds for the program to calibrate. To start the first measurement, press "Start". After that, 3 seconds will elapse, and then a 10 second timer will start. The beginning of each measurement includes a 3-second familiarization phase that is not recorded. When the first measurement is complete, press the "Next" button (next). Press the "Start" button to start the second measurement.

At the end of the measurement programme, you can go back and re-do the measurements. To see the results press the "Next" button (next).

**I**NOTE: If the application stops working during the measurement and the measurement is interrupted, the measurement will restart from the beginning of the first measurement.

## 7. AINONE BALANCE MOBILE APPLICATION: PRESENTATION OF RESULTS

7.1. Measurement results

WARNING: The Ainone Balance measurement application does not provide instructions or results directly related to any disease or associated state. The results are intended for professionals to help them assess balance.

WARNING: The indicative pilot reference values (n=35) presented by the Ainone Balance measurement application have been collected with reference to the 20-59-year age group and are indicative only. The reference values will be supplemented in future versions of the application.

**I**NOTE: In principle, the lower the numerical value of the sway (length, standard deviation of speed and surface area), the better the sway result.

By default, the measurement results show the length of the movement path (Image 14A). Clicking on the measurement result shows more detailed results. More detailed measurement results can be hidden by clicking on the more detailed results.

A detailed explanation into the results displayed can be found in sections below.

**Result section** 

1. Info: Results - Report - Edit

By selecting the "Subject" from the home screen, you will be brought to the "subject list" seen in Image 11. The subject list contains all of the test subjects that have been input by the specific user that is signed into the application.

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Image 11 . Subject list screen

After selecting the specific "Subject" from the subject list, a drop down menu for that subject will appear, as seen in Image 12. The drop down list will display the most recently updated Subject information, along with three options on the right side of the screen. The options include:

- 1. Results Taking the User to the page that will display a list of all the results from all of Balance evaluations that the user has performed using the Ainone Balance application.
- 2. Reports Allowing the User to access specific reports of the Subjects balance evaluation results and export the report in the pdf format.
- 3. Edit Taking the User to the screen that allows for the editing of the Subject's basic information.

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		Demo		
	View and r	manage subjects		
Add new subject	Search			
Demo Test	er		Info	
Age: 0 Email: demo.tester@gma	il.com			
Weight: 79.0 Gender: Male			Results	
Dominant foot: N/A			Report	
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Image 12 - Drop down list of the selected Subject.

2. Edit

By selecting the "Edit" option from the drop down list shown in Image 12, a "pop up" screen, displayed in Image 13 below, allows the User to edit individual Subject information. Remember to save the updated information by clicking the "save" button at the bottom of the "pop-up screen".

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Dominant	First name:	Demo			
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	Dominant	N/A			-
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Image 13 - Pop up window for editing Subject information.

3. Report (PDF report about the test results)

By selecting the "Report" button from the drop down list seen in Image 12, the User will be provided with the option to select a report about the selected Subject Ainone Balance test results.

4. Results

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=	AAA	_AINONETEST_(	)1
		Results	
Session # 81			Session data
# 3 15.11.2022 12:25	Measurement 1 open left hard	One foot Eyes Supporting foot Surface	Measurement 2 open right hard
	Move	ement path length	
		Measurement 1 vs 2	
	0.399	0.993	
	(	149 %	
# 2 15.11.2022 12:22	Measurement 1 open soft	Feet together Eyes Surface	Measurement 2 closed soft
	Move	ement path length	
		Measurement 1 vs 2	
Sa Ba	ck		🗋 Home

#### Image 14A

Image 14A displays the "Movement path length" results by clicking the "session data" additional results, the "Speed Standard Deviation" and the "Movement area", can also be seen. Image 14B displays screenshots of the more detailed measurement results, and a sample explanation is presented below.



#### Image 14B

The results view describes the following results:

- The text at the top of the screen provides the details, including the time and date, of the two tests that are compared in the results displayed below.
- In all of the bar-graphs the light blue bar (on the left) represents the first test measurement and the dark blue bar (on the right) represents the second test measurement.
- The decimal point number displayed under the bars on the bar graph represents the "Ainone Balance Score" that is calculated by the internal system algorithms that have been validated against the Hur Balance Systems outcomes.
- Bar graph one (on the left in Image 14B) is the "Movement path length" = what distance has the subject swayed during the test.
- Bar graph two (central graph in Image 14B) shows the "Speed standard deviation" = how much variance there was in the sway speed.
- Bar graph three (on the right in Image 14B) displays the "Movement area" = the size of the area across which the subject was swaying during the balance evaluation.

In addition, if an exclamation mark, as seen in Image 15 below, appears at the top of the measurement, this indicates that a notification has been given to the Subject during the test. In such a case, the result may have failed or include notifications about the measurement. You can view the notifications by tapping the image.



Image 15

Example Results Analysis of the results displayed in Image 14B:

- Protocol: Standing on one foot, on the left and right foot.
- A light blue bar on the left indicates left foot sway and the darker blue bar indicates right foot sway.
- "Movement path length" on the left foot (0.658) which is 63% higher than when standing on the right foot (0.403)
- "Speed standard deviation" on the left foot (0.046) which is 105% higher than when standing on the right foot (0.022)
- "Movement area" on the left foot (0.197) which is 1097% higher than when standing on the right foot (0.016)

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=		Ain1	
		Results	
Session ONGOING			Session data
#1 28.09.2019 06:22	Measurement 1 open hard	Feet together Eyes Surface	Measurement 2 closed hard
Movement path	length Speed	standard deviation	Movement area
0,185 0,3	s4	Measurement 1 vs 2	0.007 0.025
91%		151 %	377 %
) End			Continue

Image 16

Example Results Analysis of the results displayed in Image 16:

- Protocol: Feet together standing with eyes open and eyes closed.
- The light blue bar on the left indicates sway with eyes open and the darker blue sway with eyes closed.
- "Movement path length" when standing with eyes closed (0.354) is 91% larger than when standing with eyes open (0.185).
- "Speed standard deviation" when standing with eyes closed (0.020) is 151% larger than when standing with eyes open (0.008).
- "Movement area" when standing with eyes closed (0.032) is 377% larger than when standing with eyes open (0.007).

7.3. Below the results graphs, the relative result of each of the three parameters (length, speed standard deviation and area) is shown by the so-called "pointer", which indicates the relative difference between measurements 1 and 2 "how the results differ by percentage". If the pointer shows to the right, the second sway result is higher by the percentage shown.

The result view shows the pilot reference value limits with a green and red line. A dashed line represents the reference values for the first measurement and a fixed line those of the second measurement.

Note! Not all protocols have a line if the data is missing.

When the result (bar) falls below the green line, the result can be considered less than the typical sway of the reference data, and when the result (bar) rises above the red line, the result can be considered more than the typical sway of the reference.

7.4. To view all results: Go to the home page (Home), Image 4 and press the "Subject" icon and "Info" -> "Results".

ATTENTION: If you obtain a result that seems suspicious or differs significantly from previous measurements, a re-measurement should be made. The product is intended for use by health, social and sports professionals with the necessary expertise to interpret the measurement results. If the product provides incorrectly interpreted measurement results, you should contact customer support at support@ainone.eu.

NOTE: Viewing the subject's measurement results through the Ainone Balance measurement application is only permitted in the presence of the subject. The healthcare professional must ensure that the measurement data they need from the Ainone Balance measurement application is stored only on their systems and backed up for their own operations.

## 8. SHARING OF RESULTS

Measurement results can be shared with the subject on the home page -> "Subject" -> "Info" of the chosen subject -> "Report". Click on the "Report" button, and Ainone Balance will start downloading a PDF report of the results. Once the download is complete, an Android sharing menu will appear where you can select how you want to share the report. The alternatives depend on the apps you have downloaded (such as Signal or Telegram). Use the same menu to print out your report on your network printer if you have installed the necessary software on your device and you are connected to a local area network with printing availability.

WARNING: You are responsible for sharing the results securely. Email, for example, is not a secure method for sharing health data.

WARNING: Results may only be shared with the subject's consent and understanding of the data security risks related to sharing them.

## 9. ENDING THE MEASUREMENT

When you stop using the application, remove the belt and take off the sensor/Movesense compliant garment (see 11.1 Handling instructions). Be sure to sign-out or close the Ainone Balance measurement application at the conclusion of the measurement session.

NOTE: If the Ainone Balance measurement application is not closed, the Bluetooth connection to the sensor may remain switched on, which may cause the sensor battery to drain quickly.

## **10. UPDATING THE SOFTWARE**

The Ainone Balance measurement app can be updated through the Google Play app store. We recommend using only the latest updated version of the app to ensure an optimal user experience.

NOTE: An Internet connection is required to update the app. Connection usage may incur data charges.

## **11. MAINTENANCE OF THE AINONE BALANCE SENSOR**

The Ainone Balance sensor is based on Movesense Oy's sensor; only the built-in software is different. In principle, the detailed instructions for using the Movesense sensor are therefore suitable as instructions for using the Ainone Balance sensor.

#### 11.1 Handling instructions

The Ainone Balance sensor and belt must be rinsed with clean water if it has been used against the skin or as a heart rate monitor. Take note of basic hygiene requirements.

**EV**NOTE: If more thorough cleaning is required, the sensor can be quickly wiped with a soft cloth moistened with ethanol-based disinfectant. Do not immerse in chemicals other than water.

ATTENTION: Do not pull the Ainone Balance sensor off the belt. This could damage the belt clips. Click the sensor off one side at a time.

The belt should be machine washed at 30 °C every few measurements. For more detailed washing instructions, see the belt label.

ATTENTION: Do not wash the sensor in the washing machine. Machine washing damages the sensor.

**I**NOTE: You do not need to replace the Ainone Balance sensor. Only the belt may need replacement after long use.

#### 11.2 Troubleshooting

The Ainone Balance sensor has a range of at least 3 meters in optimal conditions. However, for the best results, avoid obstacles between the sensor and mobile device. Keep your mobile device in front of you or next to you on a table or surface. If you keep the device behind the subject's back or place your mobile

device in a belt bag, for example, the Ainone Balance sensor signal may be lost. If your sensor does not send data despite there being no obstructions between devices, try one of the following: 1. Make sure that Bluetooth is switched on in the device-with which you plan to use the sensor. 2. Replace the sensor battery and reconnect the sensor to The Ainone Balance program. If your Ainone Balance sensor appears to be sending incorrect information, try one of the following: 1. Make sure the sensor is properly clicked into place on the belt. 2. Reconnect the sensor to the Ainone Balance program.

11.3 Battery

The Ainone Balance sensor uses a 3 V lithium battery (CR 2025). To replace the battery: 1. Remove the sensor from the belt. 2. Open the battery compartment cover. 3. Replace the battery. 4. Close the battery compartment cover.

Dispose of the battery properly. Do not dispose of the battery in regular waste.

More detailed information refer to the Movesense User Guide

11.4 How to get support

More detailed information refer to the Suunto Movesense User Guide. For additional support in using the Ainone Balance mobile app and the sensor, visit the site <u>www.ainone.eu/support</u>. You can also send questions directly to Ain1 Oy <u>support@ainone.eu</u>

Ainone Balance<sup>®</sup> is a registered trademark for a balance measurement application owned by Ain1 Oy. All rights reserved. For more information on measuring balance <u>www.ainone.eu</u>.

The Ainone Balance Measurement Application meets the requirements of the EC Directive 93/42/EEC Medical Devices Directive.

## **12. CUSTOMER SUPPORT**

For additional support in using the Ainone Balance mobile app and the sensor, visit the site www.ainone.eu/support. You can also send questions directly to Ain1 Oy support@ainone.eu.

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