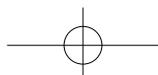
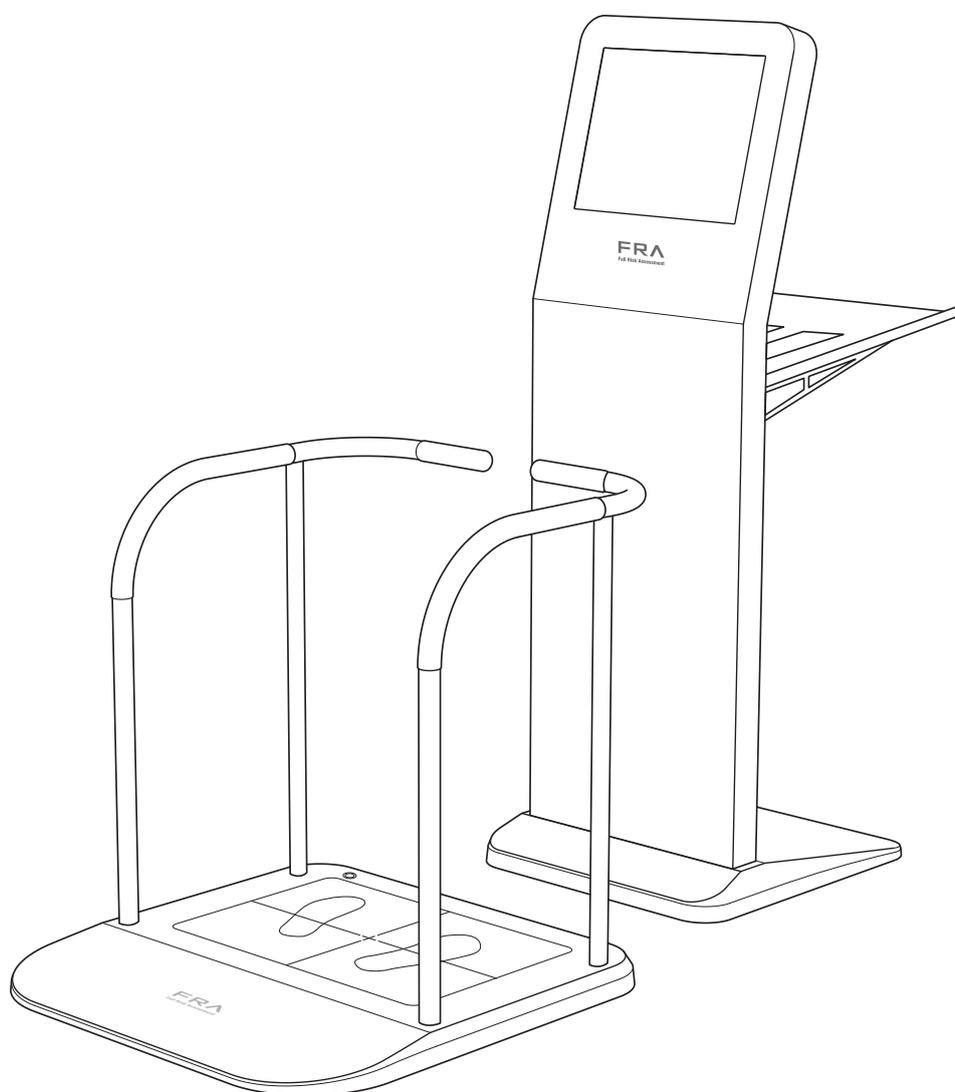




FRA 510S

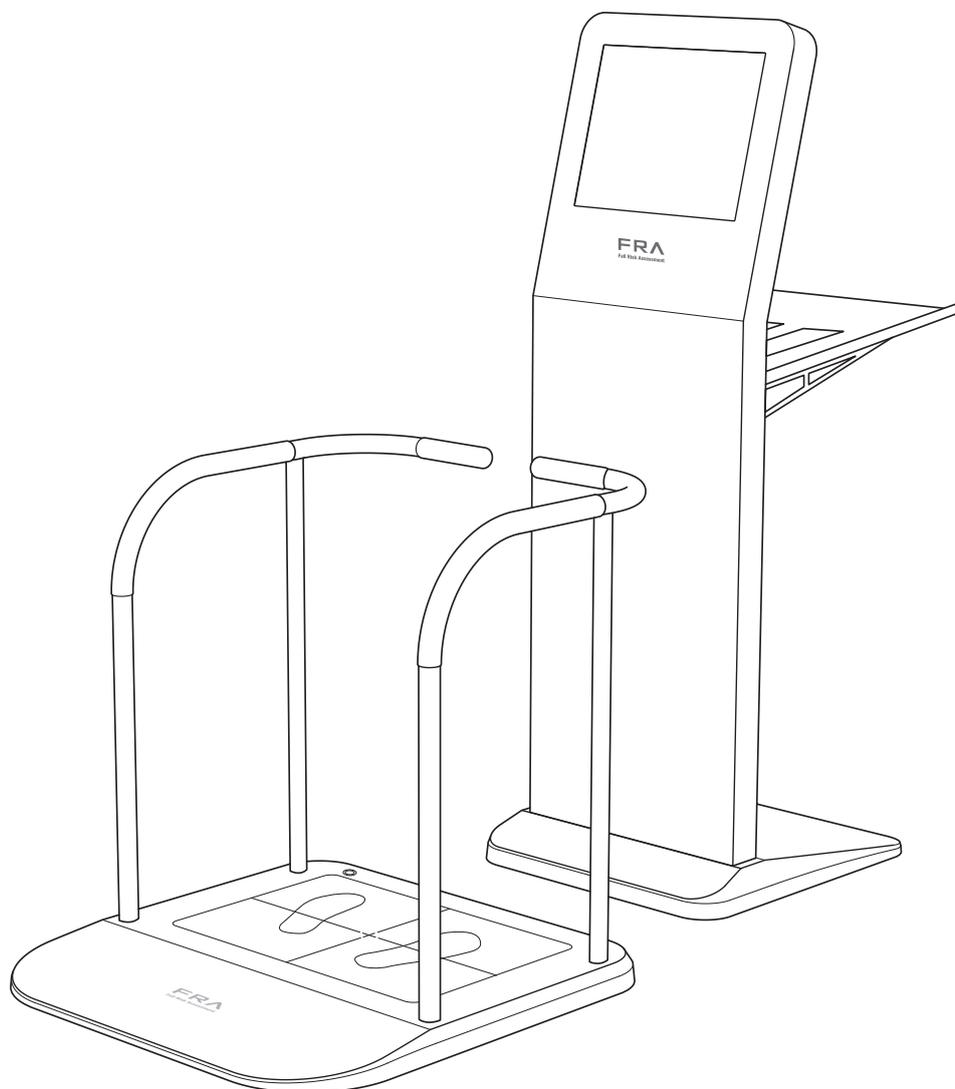
User's Manual





FRA 510S

User's Manual



InBody FRA510S User's Manual for Measurement Guide and Setup

Thank you for purchasing the InBody product.
This User's Manual provides a comprehensive and easily understandable explanation of every function of the product.
To ensure the safe use of the product, please read this manual before using and keep it in a readily accessible place at all times.
By understanding and following this information, you can use the product more safely and effectively.

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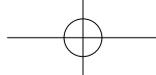
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1. Intended Use

This medical device utilizes four load cells to calculate the body's center of gravity sway, evaluating balance capabilities. Additionally, it gathers data on muscle mass from an impedance analysis, and muscle strength from a motor function test device. It incorporates the results of the m-CTSIB test and reaction time test to evaluate the role performance ability of each part of the sensory, nervous, and musculoskeletal systems. Beyond a three-stage evaluation, it comprehensively assesses the ability to maintain body balance and control of the body's center of gravity.

2. Contraindications

- Do not use this device if the individual cannot stand independently.
- Hold the handrail when getting on or off the platform to prevent falling.
- Individuals with contagious diseases or foot injuries should refrain from using the device.
- Connect peripheral devices, such as printers, with the power turned off.
- Avoid applying excessive shock to the device.
- Avoid applying strong force or using sharp objects on the screen.
- Only use in a location managed and maintained by an administrator.
- Be sure to read and understand the instructions before use.
- Consult with a medical professional regarding the user position prior to testing.
- If the subject feels uncomfortable with the movement, stop the operation, reset it, and then measure.
- Do not allow other people to approach the device while it is in use.
- Exercise caution to prevent entanglement or impact with the device's structure or components.
- Use of the FRA510S on a carpet may generate static electricity, potentially damaging the device. If installation on a carpet is necessary, please use an anti-static mat.
- Place the FRA510S on a level, vibration-free surface. Installation in an area with an uneven floor may lead to instability during the test, posing a risk of the device falling over or potentially causing inaccurate test results.

3. Intended User Profile

1. **Education**
 - Users must be able to understand the explanation displayed on the screen.
2. **Knowledge**
 - Users must be able to understand the explanation displayed on the screen.
3. **Language Comprehension**
 - Basic language: Korean
 - Additional languages are supported based on marketing requirements.
4. **Experience**
 - No minimum or maximum experience level is required.

4. Intended Patient Population and User Profile

1. **Age:** 18 years old or older
2. **Weight:** 2 ~ 270kg(4.40 ~ 595.25lb)
3. **Health:** The examinee must be able to stand for 1~2 minutes.
4. **Condition:** Individuals using medical implant devices (e.g. pacemakers) or essential support devices (e.g. patient monitoring systems) should refrain from using the device.
5. **Nationality:** Multiple
6. **Patient Status:** Mentally and physically healthy
7. **Height:** 95 ~ 220cm(3' 1.40" ~ 7' 2.61")

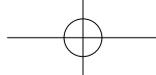


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1 Safety

1.1 Safety Symbols in the User's Manual



Warning

Failing to follow these instructions may result in a serious injury.



Caution

Failing to follow these instructions may result in product damage or inaccurate InBody Test results.

1.2 Cautions



Warning

- Do not use this device for any purpose other than FRA510S measurement.
- This product is not a diagnostic device. To make an accurate diagnosis, consult with your medical provider.



Caution

- Do not use the device in a humid space such as a bathroom, as excessively high or low temperature, humidity, and pressure may affect the operation of the device. Please use the product within the specified operating environment as indicated in the product specifications.
- Take caution not to allow any liquid substances (e.g., food scraps and beverages) to contact the device directly. Substances getting inside the device can affect the electrical components and cause a problem.
- Do not use if you are allergic to metal, rubber, or silicon.
- Do not arbitrarily disassemble the product. This may result in injury, device malfunction, or inaccurate test results. InBody Co., Ltd. will not be liable for any product damage or associated damages caused by the arbitrary disassembly of the product.



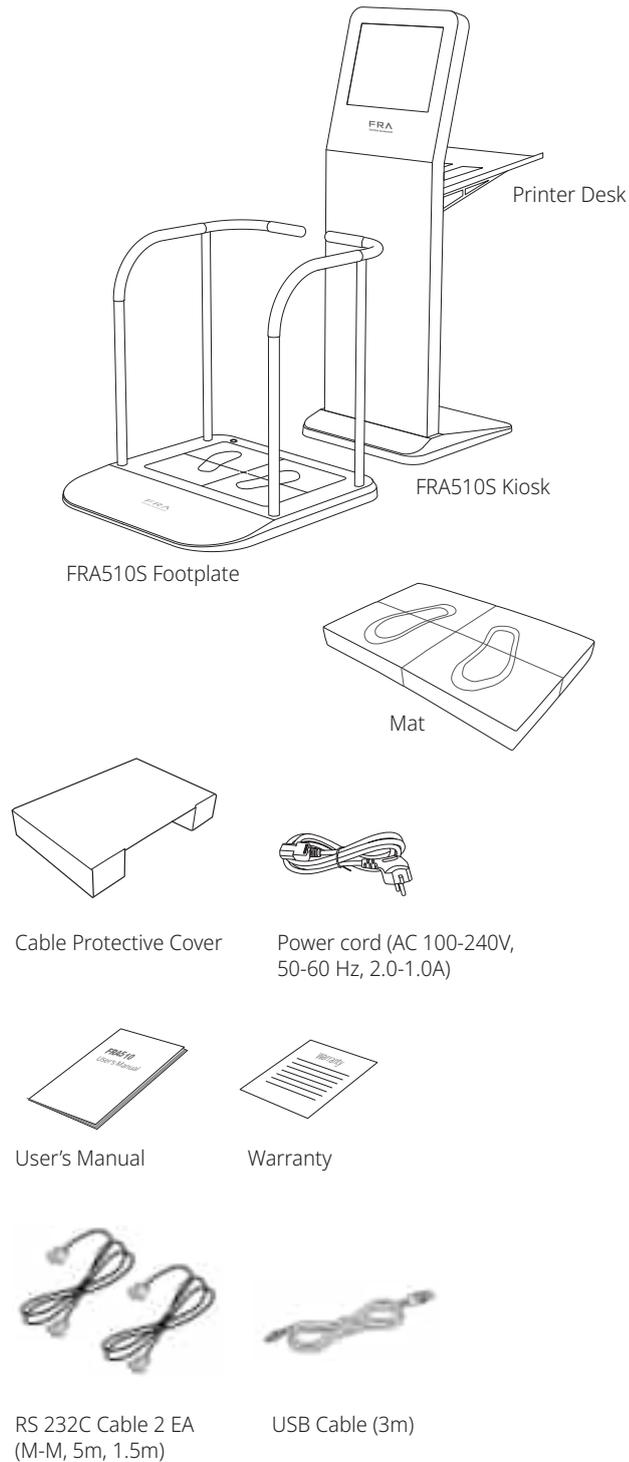
Caution

- When storing the device for a long period of time, store it on a flat surface after turning off the device, unplugging the power cord, and packing the device.
- Dispose of the device and its batteries in compliance with governing regulations.
- Only trained InBody personnel from InBody Service Center are allowed to repair and inspect the product. For repairs and inspections, contact InBody Customer Service Center.

2 Product Overview

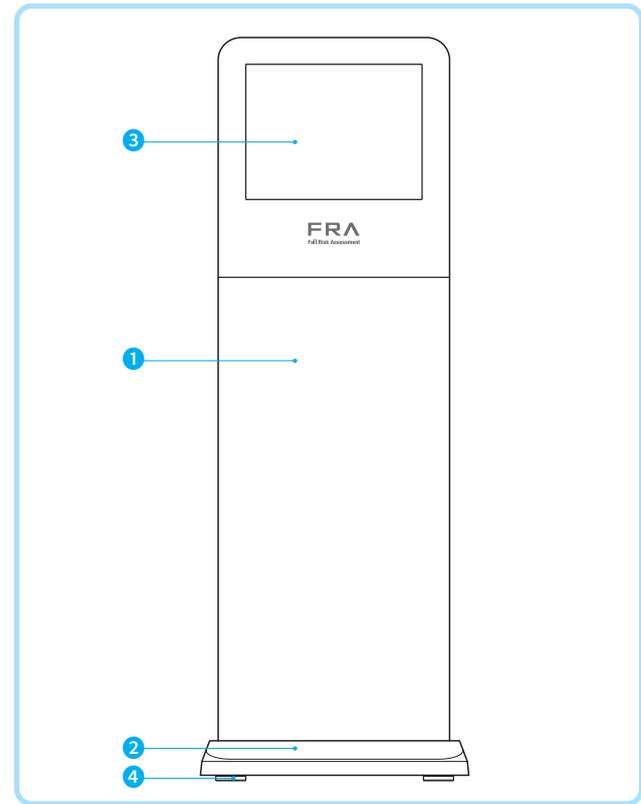
2.1 Components

The FRA510S consists of the following components. Make sure all of the following components are present.
* Please check each component of the system for damage prior to installation.



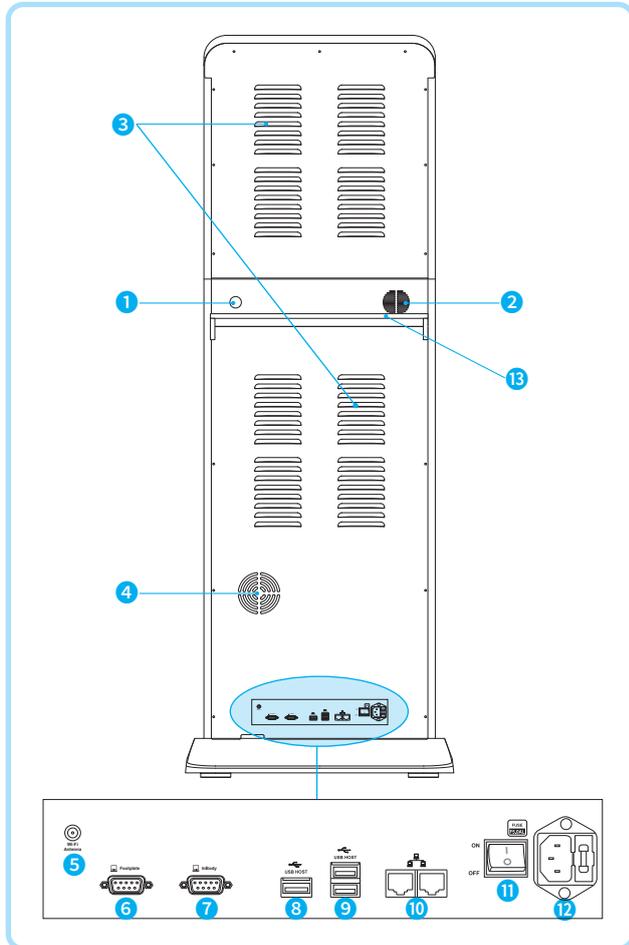
2.2 Name of Each Part

Front View



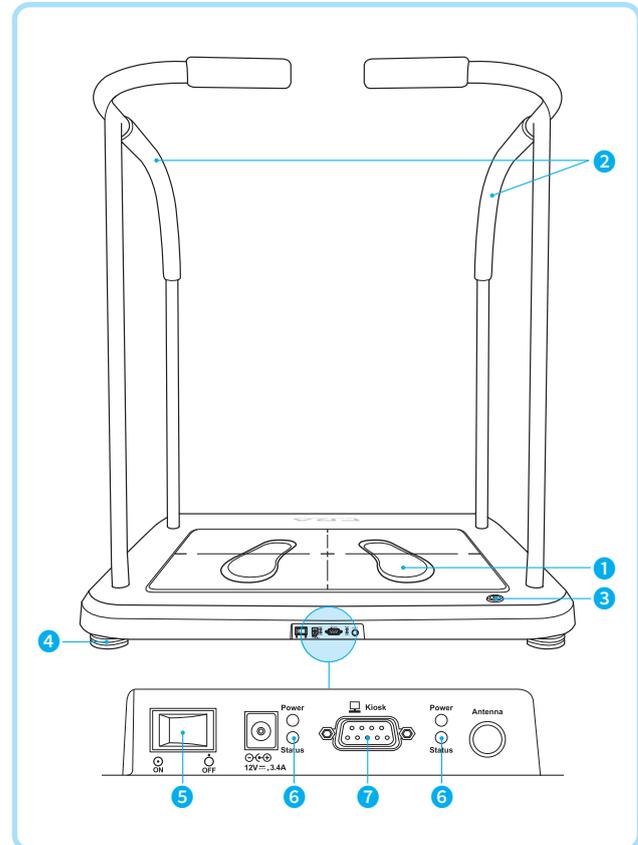
- 1 **Body:** Include LCD screen and connect to lower part.
- 2 **Lower part:** Connect to body.
- 3 **LCD Screen:** Shows each stage of the test, instructions, test results, etc. You can touch the screen to input the data required for the test, configure settings, or view test results.
- 4 **Kiosk Adjustment Screw:** Set level through adjusting height

Back View



- 1 **Power button:** Used for turning on/off the equipment.
- 2 **Speaker:** Provides audible indication for test in progress, test complete, and successfully saved setting changes.
- 3 **Heat discharging vent:** Discharge internal heat in Kiosk.
- 4 **Fan vent:** Discharge heat using fan of internal PC in Kiosk
- 5 **Port for wireless communication antenna:** Used connecting antenna for wireless communication.
- 6 **9-pin PC serial port (Female, RS232C):** Used for connecting the FRA510S to footplate.
- 7 **9-pin PC serial port (Female, RS232C):** Used for connecting the FRA510S to InBody.
- 8 **USB 2.0 Host port:** Used for connecting to Printer and USB Thumb Drive.
- 9 **USB 3.0 Host port:** Used for connecting to Printer and USB Thumb Drive.
- 10 **Ethernet port(10T Base):** Used for connecting the Internet to FRA510S.
- 11 **Exterior power switch:** Used for turning on the power that comes from exterior side.
- 12 **Power input terminal:** Used for connecting with power cord.
* Always use the power cord supplied by InBody.

Footplate



- 1 **Footplate:** This includes 4 load-cells, and measure the weight of the user' front, back, left and right side during the test. It includes rubber cover.
- 2 **Handle:** This plays the supporting stand role for the user who step up onto the footplate or who are on test, and prevents the user from falling by grabbing the handle when he/she loses a balance or is about to fall.
- 3 **Level indicator:** This shows the horizontal status of the footplate.
- 4 **Footplate adjusting screw:** Set level through adjusting height
- 5 **Power switch:** Used for turning on/off the footplate.
- 6 **Footplate LED:** This lights up when the footplate is turned on and blinks after completing footplate MCU initialization.
- 7 **9-pin serial port (Female, RS232C):** Used for connecting footplate to Kiosk.

3 Using the Product

3.1 User Environment

Check the environment before installing the FRA510S. This equipment is suitable for indoor use. If installing this equipment outdoors, the following requirements must be fulfilled.

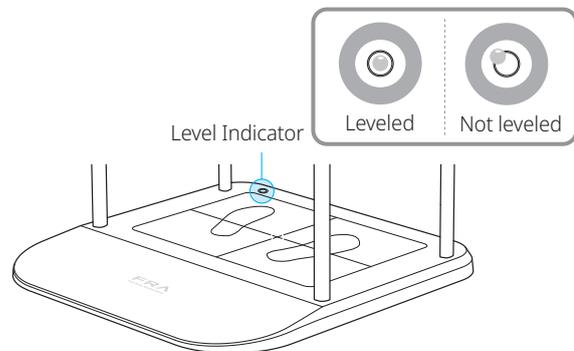
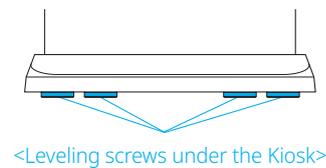
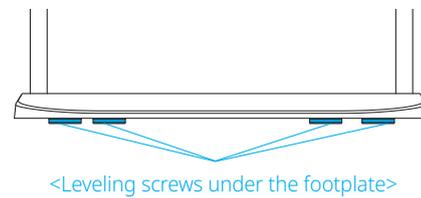
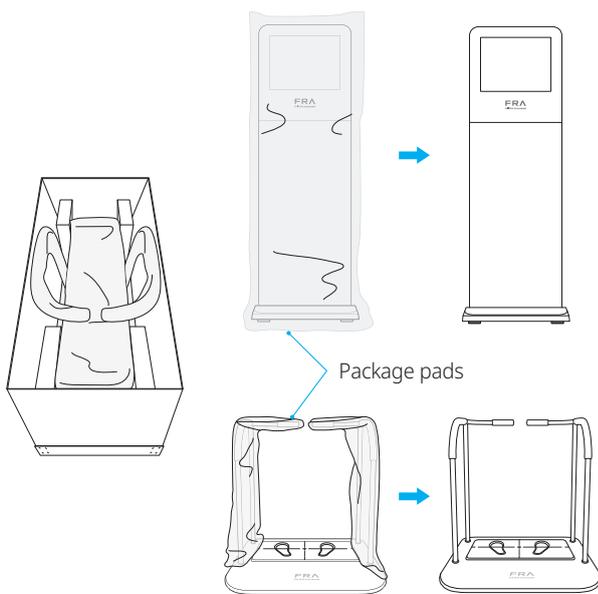
Temperatures range	10 - 40 °C
Relative humidity	30 - 75 % RH
Atmospheric pressure	70 - 106 kPa

- Install the FRA510S on leveled, non-vibrating surface. Installing the equipment on an uneven surface may cause the examinee to fall down. Test results may also be inaccurate.
- Never clean the screen and footplate with liquid spray or detergent directly. The equipment may corrode and/or malfunction if the liquid or detergent leaks inside. Use wet-tissue when cleaning FRA510S.

- 2 Level the FRA510S by rotating the leveling screws under the footplate on the left and right so that the air bubble is centered. Level Kiosk by rotating the leveling screws too.
* Leveling the equipment is necessary for accurate measurement.

3.2 Installation Instructions

- 1 Open the FRA510S packing box and remove the packaging pad. Take the FRA510S out of the packing box.

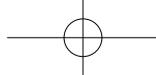


⚠ Caution

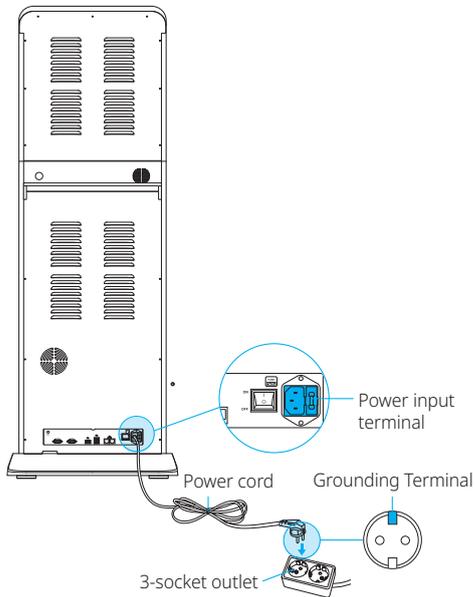
- Do not transport the equipment by holding the screen portion.
- Keep the packaging materials provided for repacking the equipment in the future. Other wastes should be disposed of according to relevant laws and regulations.
- Considering the weight of equipment, more than two people transport the equipment together.
- Using the FRA510S on carpet may cause static electricity, which could damage the equipment. If installing the FRA510S on carpet is unavoidable, place an antistatic mat under the FRA510S.

⚠ Caution

- Avoid injuring your hands when rotating the screws under the footplate.



- 3 Connect power cord to power input port which is located on the rear panel of Kiosk. Plug the power cord into a grounded 3-socket outlet with ground wire.



Warning

- Do not place the FRA510S in a location making it difficult to disconnect the power cord.
- Do not plug in or pull out the power cord with wet hands. There is risk of electric shock.
- Always use an outlet connected to the power (AC 100-240V). Using other power rated outlets may result in fire or malfunction.
- When using a power surge protector, make sure that the outlet or the extension cable has adequate power capacity.
- Do not disassemble or modify the equipment, including internal parts, without written consent from the manufacturer. This may cause electric shock or injury, product malfunction, inaccurate results, and void the manufacturer's warranty.
- Do not directly contact the FRA510S with any other electronic device when the FRA510S is on. This may result in an electric shock.

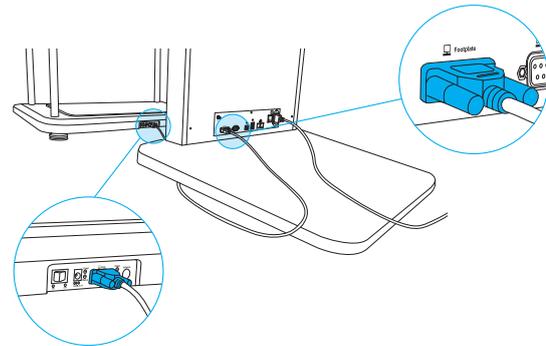
Caution

- If the FRA510S is not plugged into a grounded outlet, it may cause damage through electric surges or product malfunction. This may affect the test results.
- The test results may be inaccurate if the FRA510S is under electrical interference. Do not install the FRA510S near products that generate electrical interference such as fluorescent lights, large AC motor equipment (treadmill, vibration plate, refrigerator, air-conditioner, compressor, etc.), high-frequency thermal therapy equipments, or heating appliances. Do not share the power source of the FRA510S with other electrical devices. This may affect the test results.

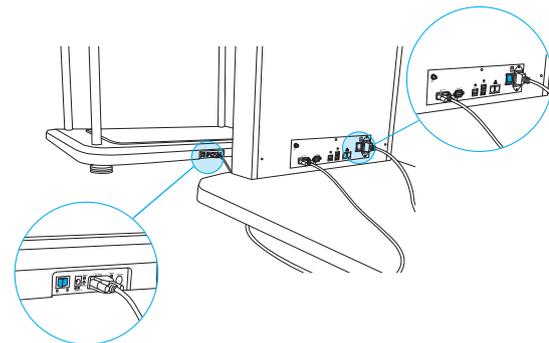
- When connecting the FRA510S with other test equipment, turn on the other equipment first. When turning off the other equipment, turn off the FRA510S first and then turn off the other equipment. This is necessary to minimize electrical surges on the FRA510S.
- Operating the equipment at altitudes higher than 2,000 meters may affect the measurements.
- Don't unplug the power cord before turning off the power of FRA510S. Otherwise, the software or equipment may not work normally.

- 4 Connect the short cable (1.5M) among the 9-pin serial cable to the front port of the footplate. Connect the opposite side of the cable to "Footplate" port, which is located on the rear panel of Kiosk.

* Make sure to use the short cable to connect Kiosk with footplate. If the long cable is used, the footplate will not work.

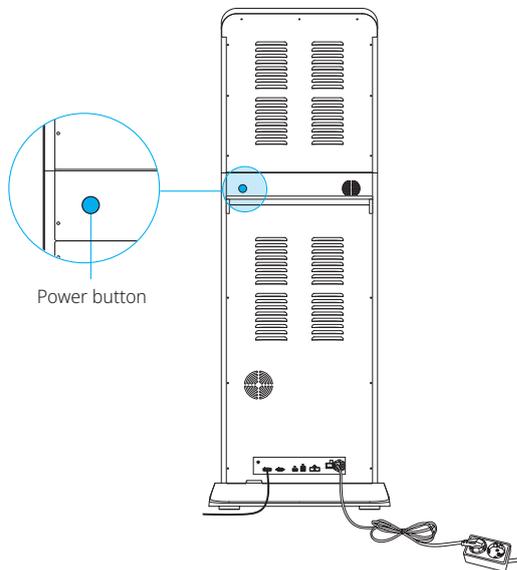


- 5 Flip the power switch to turn on the Kiosk and footplate

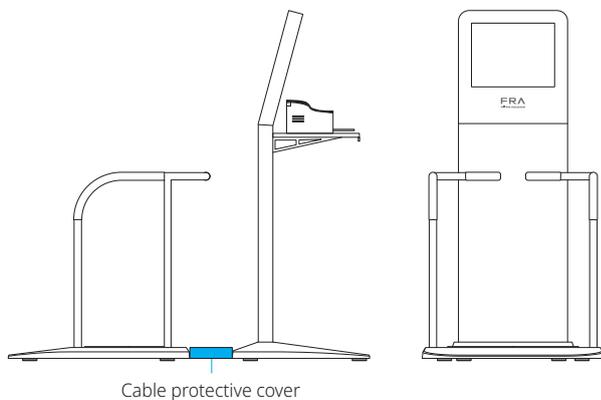


Using the Product

- 6 Then press the power button at center of rear panel of Kiosk



- 7 After the equipment is booted, make the cable invisible with the Cable Protective Cover between the Kiosk and the footplate. And, move the equipment in order to remove space gap among footplate, Kiosk and the Cable Protective Cover. At this time, arrange the footplate to place at center of Kiosk.



⚠ Caution

- Disconnect printer at the back when moving the Kiosk (1).
- When installing the InBody, if possible, please have the backside of the equipment face a wall.
- Do not put more than 20kg of weight on the printer stand.
- Do not press the printer desk with your arms or hands.

3.3 Initial Setup

- 1 The FRA510S automatically starts booting when it is turned on. While booting, it performs a self weight calibration.
- * Do not step up onto the foothold or place objects on the foothold during boot up.

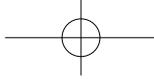


- 2 Press the [Administrator Menu] button on the screen, which appears when no one is on the footplate.



- 3 Input the password (default password:0000) to have access the Administrator Menu.

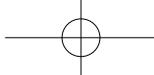




- 4 The Administrator Menu will give you access to many different options such as basic settings, result sheet management, printing options and more.



- 01. Date/Time/Units/Country/Language/Password/Volume :
Change or modify the FRA510S's basic settings.
- 03. View/Print/Delete Data :
The administrator can manage test results using ID.
- 04. Export Data as Excel :
You can export test results as an excel file on a USB Thumb Drive. Exported test results can be viewed as an excel file on a computer.
- 05. Data Backup/Restore/Combine :
Back up FRA510S Test results to a USB Thumb Drive, or restore test results using a backup file on a USB Thumb Drive, or add test results using a backup file on a USB Thumb Drive to the FRA510S.
- 06. Printer Setup :
Back up FRA510S Test results to a USB Thumb Drive, or restore test results using a backup file on a USB Thumb Drive, or add test results using a backup file on a USB Drive to the FRA510S.
- 07. Results Sheet Types :
Select which results sheets to utilize with the FRA510S. A connected printer will allow for printing results sheets after testing.
- 08. Automatic Printing Options :
Print applicable results sheets automatically after each completed test. The FRA510S can print up to 2 copies after every test.
- 10. Results Sheet Custom Logo :
Insert a logo on upper right corner of the printed results sheet.
* Please contact InBody for help with uploading or modifying a logo.
- 12. Outputs/Interpretations for Results Sheet :
This option allows you to configure the outputs and interpretations appearing on the right-hand side of the InBody results sheet, and the InBody Results Sheet for Children.
- 16. Normal range, Average, Standard deviation :
Set the normal range, average, and standard deviation for Balance Ability Test Results Sheet and InBody Results sheet.
- 19. Customer Service Information :
Save the customer service (supplier) contact information. Please refer to the customer service information if you have any inquiries or problems.
- 20. Auto-Lock :
Set a password or screen lock (auto-lock) time to secure the FRA510S usage.



Using the Product

3.4 Precautions for Maintenance

Caution

- Do not place any objects on the footplate.
- Do not apply excessive force on the equipment.
- Do not play around the equipment or run on the footplate.
- Turn off the equipment if you are not using it for a day or longer.
- Do not allow any liquid substances contact to the equipment directly. Keep food and drinks away from the equipment. Substances getting the equipment can cause critical damage to the electronic components.
- Use a lint-cloth to gently wipe the external surface of the equipment about once every week. Be careful not to scratch the LCD screen.
- For device at end of life expectancy, should be disposed of according to relevant laws and regulations.

4 Balance Ability Test

4.1 Precautions for Measurement

Warning

- The Balance Ability Test is carried out together with InBody Test. Individuals with medical implant devices such as pacemakers, or essential support devices such as patient monitoring systems, must not use this equipment. Safe, low-level currents will flow through the body during the test, which may cause malfunctioning of the device or endanger lives.
- Bioelectrical Impedance Analysis (BIA) uses safe low level currents, which are not harmful to the body. However, we do not recommend pregnant women test.
- Do not play around the equipment or run on the footplate. This may result in serious injury.
- People with limited mobility should be supervised or assisted when attempting to test.
- After an individual with any kind of contagious disease or infection tests on the InBody, use an InBody Tissue to clean the equipment.
- Those people with dizziness should consult with physician on the test.

4.2 Test Instructions

- 1 Step on the footplate in barefoot when the screen below is shown.



- 2 Press [Balance Ability Test] button.



- 3 For the existing member, input name or ID and select the member. For the new member, press [Create New ID] button and input the personal profile.



Balance Ability Test

- 4 After posturing in accordance with the test method explanation, and then proceed with the test.
* The test methods are different at each test.



- 7 When the test is completed, the results will be show on the screen of FRA510S.

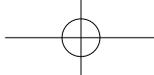


- 5 When the test is completed at FRA510S, move to InBody to perform InBody Test.



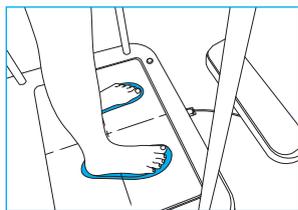
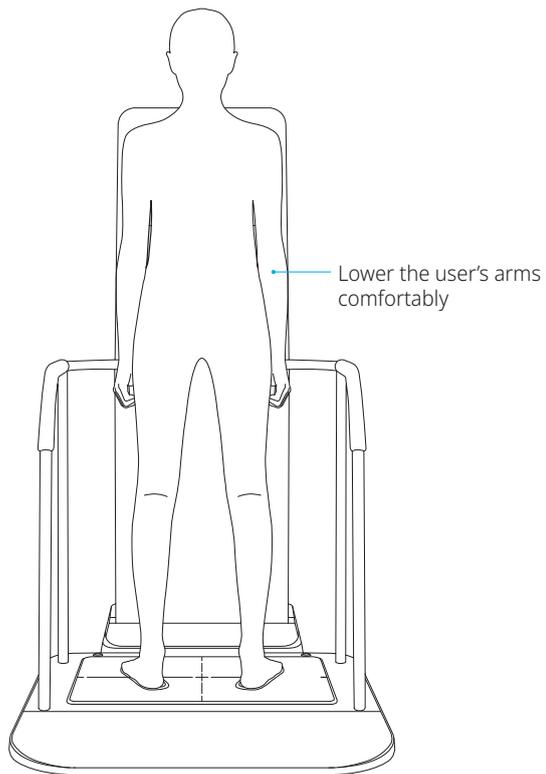
- 6 When InBody Test is completed, perform leg muscular strength test (IB-LS).



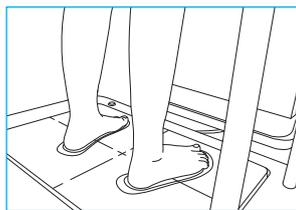


4.3 Test Posture

The examinee must maintain proper posture to have accurate test results. After step up onto the feet-shaped position, lower user's arms comfortably.



Place feet on the center of feet-shaped position.



Step on the footplate barefoot.

5 Balance Ability Training

5.1 Precautions for Measurement

Warning

- Do not play around the equipment or run on the footplate. This may result in serious injury.
- People with limited mobility should be supervised or assisted when attempting to test.
- After an individual with any kind of contagious disease or infection tests on the InBody, use an InBody Tissue to clean the equipment.

Caution

- During the Balance Ability Training, people with dizziness or difficulties to proceed forward, should stop it immediately and get a rest.
- Excessive movement can cause injury, so adjust the level according to the user's ability.
- Proceed with the Balance Ability Training before exercise. Concentration loss or fatigue accumulation can affect test results.

5.2 Training Instructions

- 1 Step on the footplate in barefoot when the screen below is shown.



- 2 Press the [Balancing Ability Training] button.



- 3 For the existing member, input name or ID, and select the member. For the new member, press [Create New ID] button, and input the personal profile.



4 Select the [Balance Ability Training]. If [Yes] button be pressed, the Balance Ability Training will be proceeded according to Balance Ability test results. If [No] button be pressed, the Balance Ability Training will be proceeded by selecting the Balance Ability Training directly regardless of the Balance Ability test results.



7 Perform Ability Training according to the voice explanation after selecting Balance Ability Training type.



5 Select one of 8 types of Balance Ability Training directly and go proceeding.



6 Every type of Balance Ability Training can be adjusted by selecting level, and the level is total 3 stages.

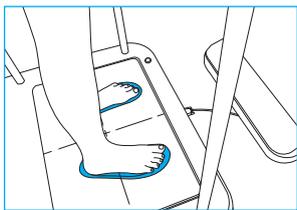
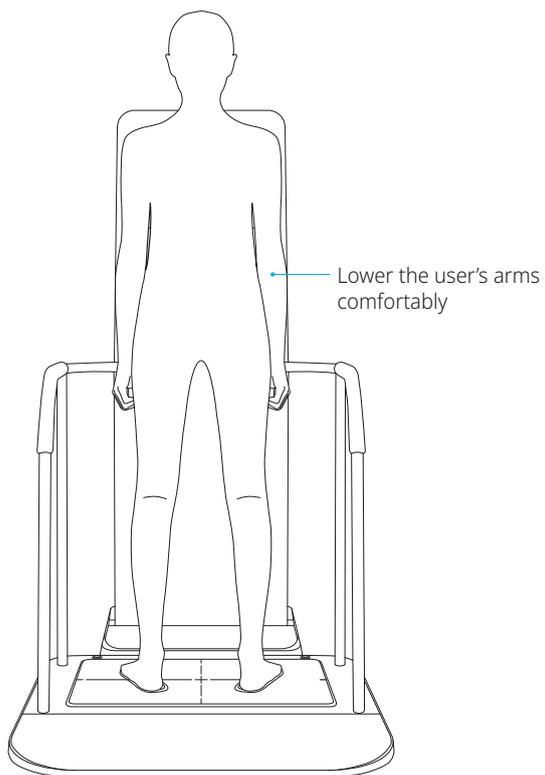




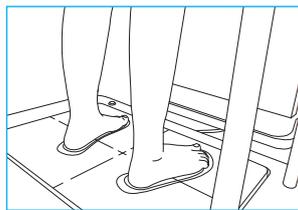
Balance Ability Training

5.3 Test Posture

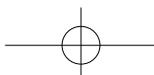
The examinee must maintain proper posture to have accurate test results. After step up onto the foot-shaped position, lower user's arms comfortably.



Place feet on the center of foot-shaped position.



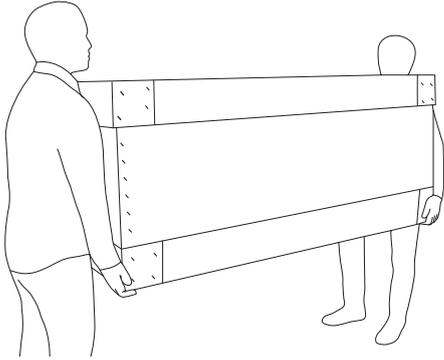
Step on the footplate barefoot.



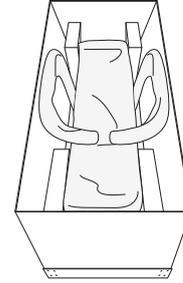
6 Transportation and Storage

6.1 Cautions during Transportation

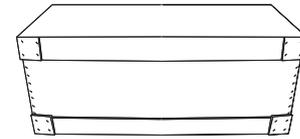
To transport the FRA510S safely, two people should keep the equipment in a horizontal position.



- Put Kiosk and footplate in the packing box respectively.



- Seal the packing boxes.



6.2 Repacking Instructions

Do not transport the FRA510S as much as possible once the it has been installed. If you need to transport the FRA510S, transport after repackaging it in the following order.

- Turn off both of the Kiosk and footplate of FRA510S.
- Remove all the connected power cords.
- Cover the Kiosk and footplate with the polyethylene foam cover.



<FRA510S Kiosk>



<FRA510S Footplate>

6.3 Transportation and Storage Environment

The FRA510S should be transported or stored under the following conditions.

Temperatures range	-10 ~ 70°C
Relative Humidity	10 ~ 80% RH (No Condensation)
Atmospheric pressure	50 ~ 106kPa

⚠ Caution

- Always use the protective packing materials provided by InBody when repacking.

7 Frequently Asked Questions (FAQ)

Even if no problems arise from the equipment, users may still have many questions, especially regarding clinical procedures. Few common questions and answers are listed below. If your questions are not answered here, please contact InBody.

* Customer contact information can be found under Settings of the Administrator Menu '19. Customer Service Information'.

7.1 Regarding the Device

If a problem arises with the FRA510S, you may first attempt to check the 'FAQ' in the Administrator Menu. The FRA510S can help you diagnose and solve some problems. If your problem cannot be resolved through the 'FAQ', please refer to the possible solutions below.

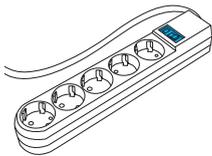
Question: My FRA510S does not turn on.

Answer:

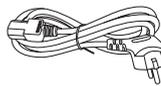
- Insert the power plug completely into a grounded 3 socket outlet.



- When using a power surge protector, the equipment may not power on if the power switch on the power surge protector is turned off. Check the power surge protector which the power plug is connected to.



- The problem may occur if you are using the power cord that is not provide by InBody. Always connect a power code provided by InBody.



7.2 Regarding the InBody Test

Some of the more common clinical questions are answered below. If additional questions or more clarification is desired, please contact InBody.

Question: Do socks or stockings need to be removed prior to testing?

Answer:

- Tests conducted by the FRA510S can be conducted when wearing shoes, but the test results may be inaccurate. Be sure to take off your shoes.
- The InBody Test would be inaccurate if the test is performed with socks or stockings on . Socks or stockings must be removed to obtain accurate data.

Question: Is it okay to wear accessories (jewelry, watch, rings, etc) or metal objects while taking the test?

Answer:

- Accessories should not affect the FRA510S results.
- The ideal condition for the analysis is standing with no clothes and no accessories. However, this may not always be possible. Therefore, we recommend the examinee remove as many clothing items and accessories as possible.

Question: I have limited mobility and cannot maintain proper posture for the test. Can I still be tested?

Answer:

- If the user can stand on independently without grabbing the handle, the tests are possible. But, in case the user grabs the handle or has difficulty proceeding, the test should be stopped.
- It is impossible to test if an individual who cannot maintain contact with the hand electrodes or foot electrodes.

Question: What are the precautionary steps to ensure accuracy of the test?

Answer: Please refer to 'A. Precautionary Steps' in section 'II. Balance Ability Test' in this User's Manual.

8 Product Classifications and Specifications

This device was produced according to InBody's quality control procedures. InBody Co., Ltd. complies with ISO9001 and ISO13485, international quality management systems.

8.1 Classifications

FRA510S	
Type of protection against electric shock	Class I
Level of protection against electric shock	B-type equipment
EMC Emission	Class B

8.2 Specifications

Specifications

Measurement method	Measuring weight at 4 Load-cells of footplate
Outputs	<ul style="list-style-type: none"> • Test 1~4 shaking index • Sensory system score • Reaction time • esponse latency • Nervous system score • Along the target center of gravity moving safe arrival rate • Fast safe arrival center of gravity moving safe arrival speed • Integrated balance ability scores • Right leg, Left leg, Muscle mass and Left-right-balance • Right leg, Left leg, Muscle strength and Left-right-balance • Muscular skeletal score • Total score
Optional equipment	InBody (specific model) and Leg Muscular Strength System (IB-LS) from InBody
Logo	Name, Address, and Contact Information can be shown on the InBody Results Sheet
Digital Result	LCD screen
Types of Result Sheets	Balance Ability Test Results Sheet
Voice guidance	Provides audible indication for test in progress, personal information, and successfully saved settings changes
Save	Can be saved test results .
Administrator Menu	FRA510S setup and data management, according to inspection environment
USB Thumb Drive	Full data storage (extractable to Excel) or full data backup and restore
Backup data	Backup data saved in the FRA510S by using a USB Thumb Drive, Restore results on the FRA510S from a backup file
Rated power supply	AC 100-240V, 50-60 Hz, 2.0-1.0A
Display	19-inch Color Touch Monitor
Input interface	Touch Screen
External interface	RS-232C 2EA, USB 2.0 Host 1EA, USB 3.0 Host 2EA, LAN(10T) 2EA
Compatible printers	Laser / Inkjet printer

Product Classifications and Specifications

Dimensions	Kiosk: 23 (W) × 25 (L) × 64 (H): in Footplate: 33 (W) × 36 (L) × 34 (H): in
Equipment weight	Kiosk: 51kg Footplate: 42.5kg
Testing time	About 10~15 min.
Operation environment	10~40°C, 30~75% RH, 70~106kPa
Storage environment	-10~70°C, 10~80% RH, 50~106kPa (No Condensation)
Measurement range	0~150kg

* Specifications can be changed without a prior notice.

* This product is a medical device.

8.3 Symbols used on the Product

Indicators

	26-pin serial port (Female, RS-232C)
	Ethernet port (10T Base)
	USB port
	AC 100-240V, 50-60 Hz, 2.0-1.0A, Fuse(F5.0AL, 250V)

Safety Symbols

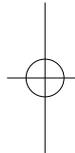
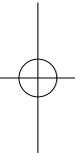
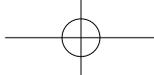
	Operating instructions
	Refer to the User's Manual before Using the Product.
	Dangerous High Voltage
	Warning, Cautions
	B-type equipment
	Power On
	Power Off

Certification Symbols

	European Conformity
	NTRL mark (MET)
	Authorized representative in the EUROPEAN COMMUNITY
	WEEE mark

Other Symbols

	No stepping on surface
	Do not disassemble the product arbitrarily.
	Do not spray any liquid substance directly onto the device.
	Power
	Manufacturer
	Direct current
	Date of manufacture
	Serial Number
	Catalogue number
	Importer
	Medical Device
	Country of manufacture
	Unique Device Identification



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