InBody270S

User's Manual

1. Intended Use

The InBody is mainly used for healthy and acutely or chronically ill populations in hospitals, medical practices and inpatient care facilities in accordance with national regulations. It can be used to assist in the assessment of nutritional status, obesity and muscle balance. Body composition analysis is important in preventive medicine since it provides the basis of appropriate physical activity and dietary habits for improving personal daily routine. It can be also usefully applied to follow-up studies of patients treated for various diseases.

2. Medical Indication

- **Medical check-up:** Four body composition analysis can be identified for the risk of developing diseases that are highly related to body composition imbalance like obesity, malnutrition, fluid imbalance and osteoporosis for medical check-up.
- **Obesity:** Percent body fat has been recommended rather than BMI to ensure proper weight loss and improvements in long-term health, tracking changes for adjusting/developing customized treatments.
- **Pediatric obesity:** Body composition measurement is an essential part of health assessments for children and adolescents. Percent Body fat is better than the indicators of weight status to identify children and adolescents with unfavorable lipid profile.
- **Sarcopenia:** InBody provides a quick, easy to perform test that provides a calculation for skeletal muscle index (SMI), the sum of the lean mass in the arms and legs, normalized for height. This marker is useful in identifying low muscle in the appendages, which increases frailty risk.
- **Diabetes & endocrinology:** Diabetes is often associated with excess fat, however having insufficient muscle mass is just as detrimental and increases diabetes risk. And visceral fat plays a key role in the development of metabolic and cardiovascular disease.
- **Edema:** Over-hydration as assessed by ECW ratio (ECW/TBW) is prevalent in dialysis patients, and is associated with loss of residual renal function, inflammation, malnutrition and hypertension. Monitoring the ECW ratio (ECW/TBW) provides an assessment of fluid accumulation in the extracellular space resulting from compromised cardiovascular function. The patients who did not have ascites originally but have higher ECW/TBW had a higher incidence of ascites in liver cirrhosis.
- **Segmental fluid retention:** InBody objectively measures each region of the body separately and provides segmental ECW ratio measures for each of the arms, legs and the trunk, and these measures can be used to detect fluid imbalances resulting from the development or progression of lymphedema.
- **Nutrition:** The four primary components of the nutritional assessment are summarized by the mnemonic ABCD, with A standing for anthropometric measurements including stature, body weight, BMI and body composition. Body composition analysis can reveal changes in body composition (body water, protein, minerals and body fat) that cannot be known by changes in body weight.
- **Fitness:** Strength training greatly stimulates muscle growth, exercise burn the calories strengthens cardiorespiratory capacity, which reduce the risk of diabetes, heart disease, and other health concerns and result in the various changes in body composition. Body composition analysis shows skeletal muscle mass and lean in each segment of body, it helps focusing on building more muscle or correct imbalance.

- The InBody device is not a diagnostic device. To make an accurate diagnosis, the physician needs to commission thorough examinations and take their results into account in addition to the results of the InBody.
- The InBody device is not used in home healthcare environment.

3. Contraindication

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. Individuals with known metal allergies against stainless steel materials shall not use the equipment.

4. Intended User Profile

1. **Education:**
   - The user must be able to understand an explanation of the words on the screen.
2. **Knowledge:**
   - The user must be able to understand an explanation of the words on the screen.
3. **Language Understanding:**
   - Basic language: English
   - Languages are supported as specified in the marketing need.
4. **Experience:**
   - None required.

5. Intended Patient Population and User Profile

1. **Age:** 3+ years
2. **Weight:** 2 - 250 kg (4.4 - 551.2 lbs)
3. **Health:** Examinee need to be able to stand for 1 - 2minutes.
4. **Condition:** Individuals with medical implant devices such as pacemakers, or essential support devices such as patient monitoring systems, must not use this equipment. The currents will flow through the body during the test, which may cause malfunctioning of the device or endanger lives.
5. **Nationality:** Multiple
6. **Patient State:** Woken up, mentally healthy
7. **Height:** 95 - 220 cm (3 ft 1.4 in - 7 ft 2.6 in)

InBody User's Manual for Measurement Guide and Setup

Thank you for purchasing the InBody.
This user's manual describes all the features of the InBody.
Please read before use and keep it in a safe place.
By following the manual instructions,
you will be able to use the InBody more safely and effectively.

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Table of Contents

1 Safety

1.1 Safety Symbols Used in the User's Manual

Warning

Failure to comply with safety warnings and regulations can cause serious injury or death.

Caution

Failure to comply with safety cautions and regulations can cause injury or property damage.

1.2 Precautions for Use

Warning

- Individuals with medical implant devices such as pacemakers, or essential support devices such as patient monitoring systems, must not use this device. Although the micro alternative currents flowing through the body during the test are relatively safe, they can potentially cause external devices to malfunction, which can endanger lives. InBody Co., Ltd. shall not be liable for any damages to an individual or an equipment that occurred by not complying with the content above.
- The Bioelectrical Impedance Analysis (BIA) method does not harm the human body because it uses micro alternative currents. However, if you are pregnant, please consult your doctor or specialist.
- Individuals with a contagious or infectious disease are not recommended to use the device. If an individual with any kind of contagious disease or infection tests on the InBody, use an alcohol-based disinfectant (e.g., 70 % ethanol) to clean the device.
- Do not pour liquid cleaner directly onto the device. If liquid cleaner flows into the device, it may cause an equipment failure or an electric shock due to a short circuit.
- Do not use this device for any purpose other than body composition analysis or weight measurement.
- This product is not a diagnostic device. To make an accurate diagnosis, consult your doctor.
- Failure to follow these instructions may result in the user suffering serious injuries.
- Failure to comply with safety warnings and regulations may result in the user's death or serious injury.
- When not in use for an extended period, please disconnect the power plug from the outlet.
- Please do not apply excessive force when removing the power plug.

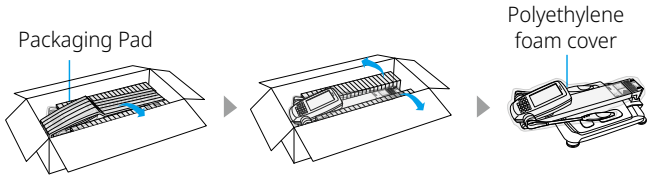
Caution

- This is a sensitive device which precisely measures the body composition. If you test near electronic products such as refrigerators, TVs or right under fluorescent lights, the test results may be inaccurate. Please use the device away from electronic devices.
- 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. Use in the installation environment specified in the product specifications.
- Do not allow any liquid substances to contact the device directly. Keep food and drinks away from the device. Substances getting inside the device can cause critical damage to the electronic components.
- Do not disassemble or modify the device including internal parts without written consent from the manufacturer. This may cause electric shock or injury, device malfunction, inaccurate test results, and will void the manufacturer's warranty.
- Children or people with restricted mobility should be tested with the help of an instructor or assistant.
- When storing the device for a long period of time, store it on a flat surface after turning off the device, unplugging the adapter, and packing the device.
- Dispose of the device and its batteries in accordance with the relevant local laws and regulations.
- Repairs and inspections can only be performed by InBody's technician. For repairs and inspections, contact the customer service.
- Do not support yourself on the equipment when stepping up or down from the footplate.
- Please be careful not to trip or get your foot caught in the footplate.
- Failure to follow these instructions may result in product damage or inaccurate test results.
- Failure to comply with safety precautions and regulations may result in the user suffering injuries or incurring property damage.

2 Product Overview

2.1 Unpacking

Open the packing box and remove the packing pads. Then take the device out of the box.



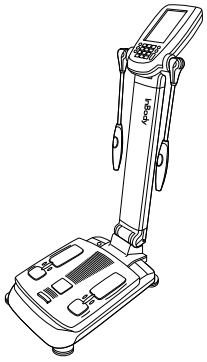
Caution

- If you have any problems installing your InBody device, please contact InBody for assistance.
- Do not transport the equipment by holding the screen portion or the joints of the hand electrodes.
- Keep the packing materials provided for repacking the equipment in the future.
- Other wastes should be disposed of according to relevant laws and regulations.

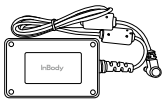
2.2 Product Components

The InBody consists of the following components. Please make sure all of the following components are present.

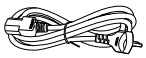
* Please inspect each component of the InBody for defects prior to installation.



InBody270S



Adapter (DC 12 V, 5.0 A / 3.34 A)



Power cord

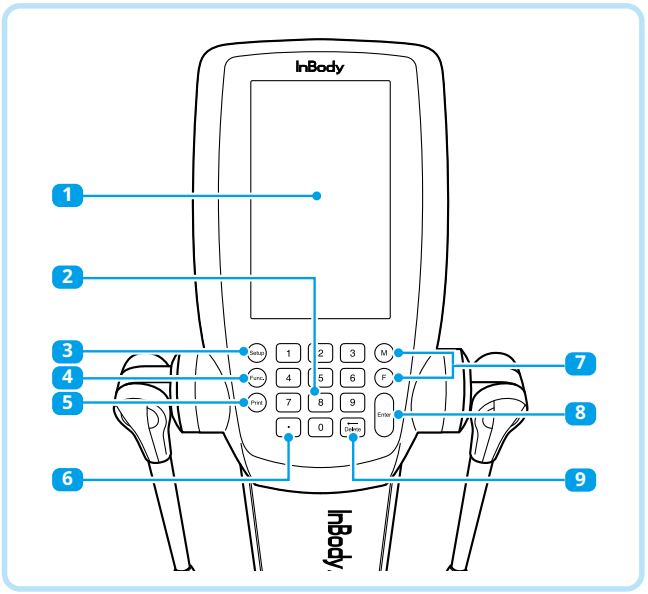
User's Manual

2.3 Name of Each Part

Functions

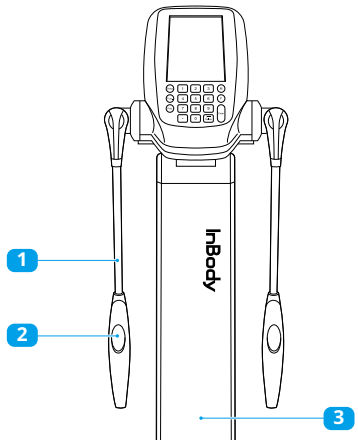
The following are the names and functions of each part of the InBody.

* Please inspect each component of the InBody for damage prior to installation.



1. 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.
2. Number keypad: Used for inputting age, height, and other number-based data.
3. Setup button: Used for entering 'Settings' under the Administrator Menu when no one is on the footplate.
4. Function button: Used for entering 'Troubleshooting' under the Administrator Menu when no one is on the footplate.
5. Print button: Used for printing the test results.
6. Decimal point button: Used for inputting the decimal point in ID, height, age, or weight.
7. Gender buttons: Used for selecting gender (Male or Female).
8. Enter button: Used to finish inputting data or to save changes in Administrator Menu.
9. Delete button: Used for deleting inputted data.

Exterior

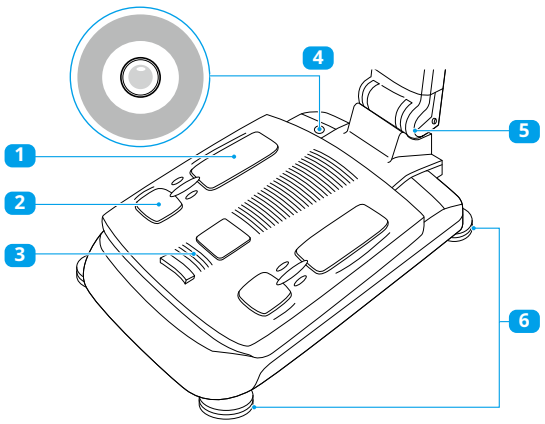


1 Hand electrode pipe: The signal cables connecting to the electrode are in this pipe.

2 Hand electrode: Examinee holds the hand electrode so that the 4 fingers wrap the surface of the bottom hand electrode while the thumb is placed on the oval electrode.

3 Body: Connects the upper part of the equipment to the lower part.

Footplate



1 Front sole electrode: The examinee makes contact with this electrode by stepping with the front part of their foot.

2 Rear sole electrode: The examinee makes contact with this electrode by stepping with the heel of their foot.

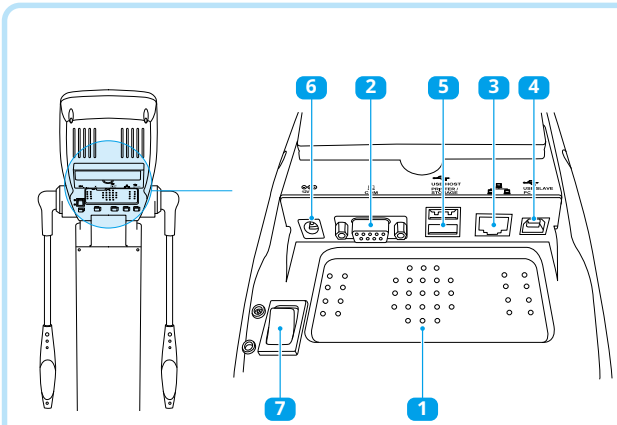
3 Footplate: This is connected to the scale, which measures the examinee's weight.

4 Level indicator: Indicates the current horizontal level of the InBody.

5 Hinge: Joins the upper part and lower part of the equipment together.

6 Leveling screws: Used for adjusting the horizontal level of the equipment.

Rear Panel



1 Speaker: Provides audible indication for test in progress, test complete and successfully saved setting changes.

2 9-pin COM serial port (Female, RS-232C): Used for connecting the InBody to LookinBody installed on a computer, a stadiometer, a blood pressure monitor and SD400.

* The InBody can be connected to LookinBody installed on a computer using one of the ports 2, 3, or 4.
* Only compatible with an InBody Stadiometer, Blood Pressure Monitor, and SD400.

3 LAN port: Used for connecting the InBody to LookinBody installed on a computer.

* The InBody can be connected to LookinBody installed on a computer using one of the ports 2, 3, or 4.

4 USB SLAVE port: Used for connecting the InBody to LookinBody installed on a computer.

* The InBody can be connected to LookinBody installed on a computer using one of the ports 2, 3, or 4.

5 USB HOST port: Used for connecting to a printer, a barcode reader, or a USB Thumb Drive.

6 Power Inlet: Used for connecting the power adapter.

* Always use the adapter supplied by InBody Co., Ltd.

7 Power switch: Used to turn the device on/off.

Warning

- Do not touch signal input, signal output or other connectors, and the patient simultaneously.
- External equipment intended for connection to signal input, signal output or other connectors, shall comply with relevant IEC Standard(e.g., IEC60950 for IT equipment and IEC60601-1 series for medical electrical equipment). In addition, all such combination-system-shall comply with the standard IEC60601-1 and/or IEC60601-1-1 harmonized national standard or the combination. If in doubt, contact qualified technician or your local representative.

3 Installation

3.1 Installation Environment

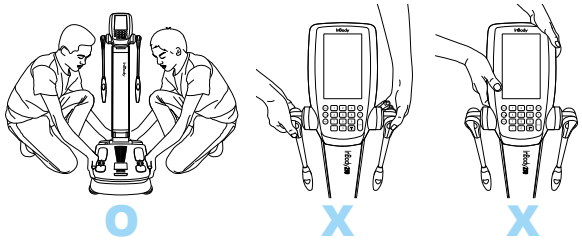
Please make sure that the environment is adequate for the InBody installation. This equipment is designed for indoor use. If installing outdoors, the following requirements must be fulfilled.

Temperature	10 - 40 °C (50 - 104 °F)
Relative humidity	30 - 75 % RH (No Condensation)
Atmospheric pressure	70 - 106 kPa

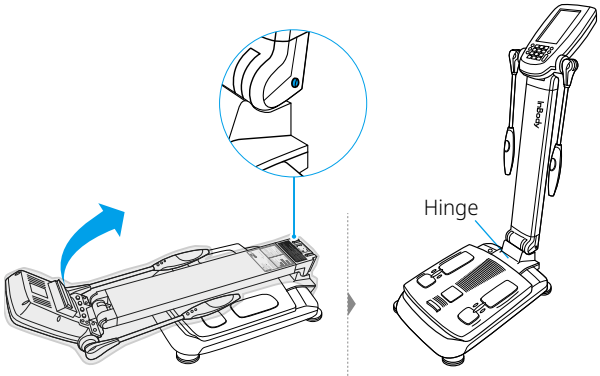
3.2 Installation

Caution

Please refer to the following illustrations to properly transport the equipment.



1 While holding the upper part lock button, raise the upper part of the InBody and remove the polyethylene foam cover.

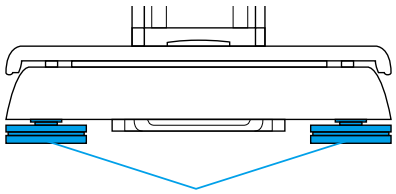


Caution

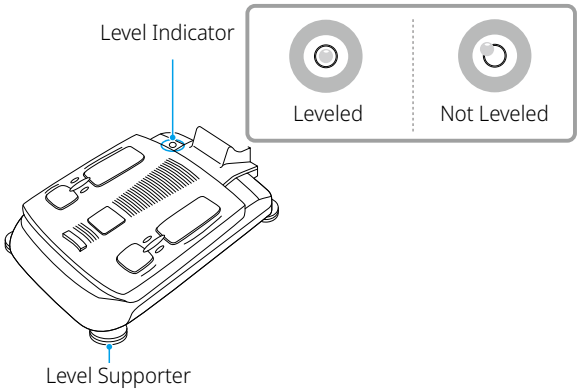
- Using the InBody on carpet may cause static electricity, which could damage the equipment. If installing the InBody on carpet is unavoidable, please use an antistatic mat.
- Install the InBody on a leveled, non-vibrating surface. Installing the equipment on an uneven surface may cause the examinee to fall down. Test results may also be inaccurate.
- Never clean the hand and foot electrodes with liquid spray or detergent directly. The equipment may corrode and/or malfunction if the liquid or detergent leaks inside. Use the Alcohol-based disinfectant (e.g. 70% ethanol) when cleaning the InBody.

2 Level the InBody by rotating the leveling screws under the footplate to the left and right so that the air bubble is centered.

* Leveling the equipment is necessary for accurate measurement of weight. There are a total of 4 leveling screws.



Leveling screws under the footplate

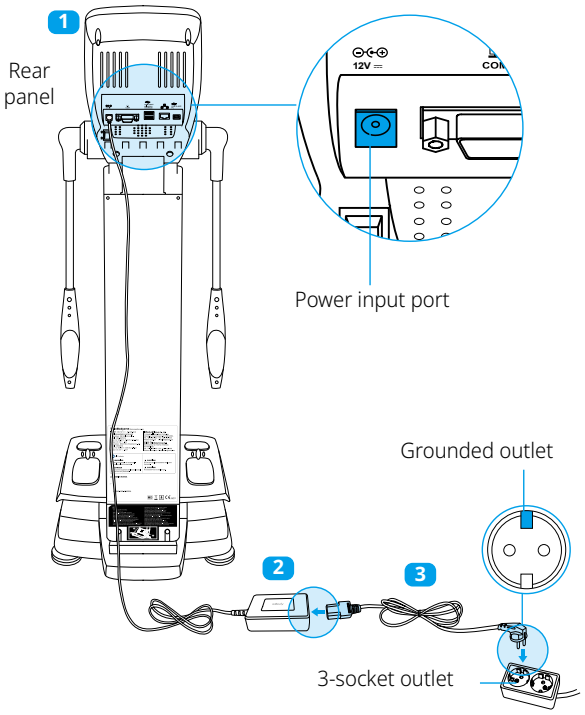


Caution

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

3 Connect the adapter (2) to the power input port, which is located on the rear panel (1). Connect the adapter (2) to the power cord (3). Plug the power cord (3) into a grounded 3-socket outlet.

* The InBody can be used in connection with other equipment such as a stadiometer, a blood pressure monitor, data management software called LookinBody, or a barcode reader. For more information, please refer to "**5 Connecting Compatible Device**" in User's Manual.



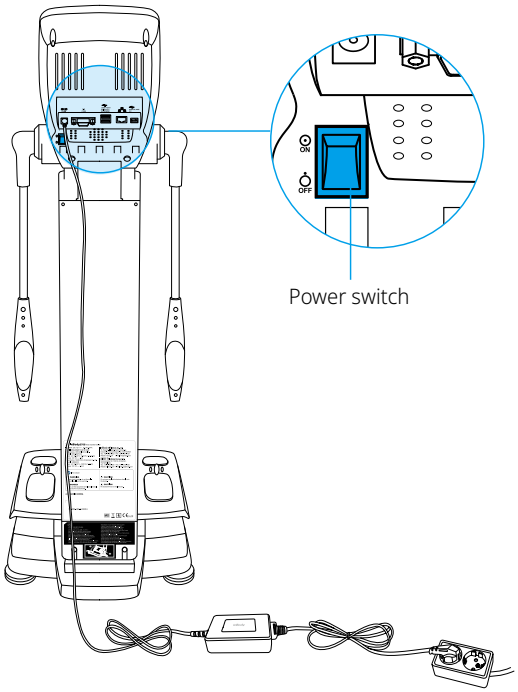
Warning

- Do not pull the power cord violently.
- Do not place the InBody 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 a risk of an electric shock.
- Always use an outlet connected to the power (AC 100 - 240 V). 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 will void the manufacturer's warranty.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.
- Avoid having the InBody come into contact with other electronic devices while it is on. This may result in an electric shock.
- If you are not using the InBody for a long time, unplug the power code.

Caution

- If the InBody 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 InBody is under electrical interference. Do not install the InBody 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 InBody with other electrical devices. This may affect the test results.
- When connecting the InBody with other test equipment, turn on the other equipment first. When turning off other equipment, turn off the InBody first. This is necessary to minimize electrical surges on the InBody.
- Always use the specified adapter provided by InBody as it is a part of the InBody device.
  Using other adapters may result in malfunction of the InBody.
- Operation of the InBody 2,000 m (6562 ft.) above sea level may affect the weight measurement.
- Adapter must be arranged so that easily cut off the power when a problem occurs in the InBody.

4 Flip the power switch to turn on the InBody device.



4 Setting

4.1 Initial Setup

The InBody automatically starts booting when it is turned on. While booting, it performs a self weight calibration.

Caution

- While booting (about 5 minutes), make sure there is nothing on top of the footplate. Please do not stand on the footplate, or place objects on the footplate.

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

2 Input the password (default password: 0000) to access the Administrator Menu.

3 The Administrator Menu will give you access to 'Setup' and 'Troubleshooting'.

Setup

Troubleshooting

Setup

Configure settings and manage data according to the test environment.

01 **Date / Time / Units / Country / Language / Password / Volume**

: Modify the InBody's basic settings.

02 **Self Mode / Professional Mode**

- Self Mode : The examinee takes the InBody Test by entering only his/her height. Throughout the test, instructions and the InBody Information will be shown on screen.
- Professional Mode : An examiner is present and guiding the examinee through the InBody Test.

03 **N/A**

04 **Cloud Service**

: InBody App provides services that allow members to check and manage results themselves. If you enter your mobile phone number, you can check the results on the member's mobile phone as the InBody results are transmitted to InBody Cloud.

05 **Bypass Age / Gender**

: The examinees can bypass inputting their age or gender if the test environment is designed for testing only adults or a specific gender.

06 **View / Delete Data**

: The administrator can manage test results using ID.

07 **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.

08 **Data Backup / Restoration / Combine**

: Back up InBody 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 InBody.

09 **Printer Setup**

: Connect the printer to the InBody. A connected printer will allow for printing results sheets after testing.

10 **Results Sheet Types**

: Select which results sheets to utilize with the InBody. (InBody Results Sheet, InBody Results Sheet for Children, and Thermal Results Sheet).

11 **Automatic Printing Options**

: This option enables automatic printing of the Results Sheet after each test. Up to two copies can be printed at a time.

12 **Paper Types**

: Select the paper type for printed results sheets. Options include blank A4 paper or pre-printed InBody Results Sheets provided by InBody.

13 **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, the InBody Results Sheet for Children, and the Thermal Results Sheet

14 **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.

15 **Printing Alignment**

: Adjust the alignment of where the results will be printed on the results sheets.

16 **Internet Options**

: You can connect to a network via WiFi or Ethernet to utilize the data management software, LookinBody, or the cloud service.

17 **Bluetooth**

: Connect the InBody to data management software LookinBody120 and other devices via Bluetooth.

18 **Manual/Automatic Weight**

: Select whether to have weight automatically weighed or manually entered before testing.

19 **Adjust Weight**

20 **Normal Range**

: Set the normal range for BMI, Percent Body Fat and Waist-Hip Ratio.

* The ideal value of BMI may also be set.

21 **N/A**

22 **Standard Child Growth Curve**

: Set the type of standard child growth curve to use on the InBody Result Sheet for Children.

23 **Touchscreen Alignment**

: Adjust the alignment of the touchscreen.

24 **Customer Service Information**

: Save the customer service contact information. Please refer to the customer service information if you have any inquiries regarding the InBody Test, or problems that cannot be resolved through the 'Troubleshooting' menu.

25 **Auto-Lock**

: Set the password and wait time for auto-lock on the InBody.

26 **Serial Connect**

: This option allows you to connect InBody with LookinBody member management program for PC or with other devices over serial connection.

27 **Etc. Function Setup**

: Set functions other than the basic functions.

Troubleshooting

See additional information on how to use the InBody. Refer to troubleshooting checklist when there are problems that occur during the InBody use/test.

01 **Customer Service Information**

: See the customer service contact information saved under the Setup of the Administrator Menu 'Customer Service Information'. Please contact customer service if your problem cannot be resolved through the 'Troubleshooting' menu or if you need further inquiries regarding the InBody Test.

02 **Results Sheet does not print**

: View the troubleshooting checklist when the Results Sheet does not print by the printer connected to the InBody.

03 **Weight is not being measured**

: View the troubleshooting checklist when weight is not being measured, after stepping on to the InBody footplate.

04 **Weight measurement seems to be inaccurate**

: View the troubleshooting checklist when the weight measurement seems to be inaccurate.

05 **The InBody Test has stopped**

: View the troubleshooting checklist when the InBody Test has stopped.

06 **Test results seem to be inaccurate**

: View the troubleshooting checklist when the test results seem to be inaccurate.

4.2 IT Security Measures

InBody would like to clarify that the user access to the InBody is only granted for the authorized users, who have appropriately registered the passcode in the system setting menu of the InBody. The steps for registering access passcodes, which restrict access to authorized users, are illustrated below.

5 Connecting Compatible Device

To connect a compatible device to InBody device, check the communication method of the compatible device.

There are two ways of communication; wired connection such as USB or RS232C (9-pin serial port, Female), and wireless connection (Bluetooth).

5.1 Printer

In order to print InBody Results Sheets, an InBody compatible printer is required.

1. First turn off the InBody device and then the printer.
   * You may experience connection issues in connecting the printer to the InBody if the InBody is turned on.
2. Plug the USB cable provided with the printer into the USB HOST port on the rear panel of the InBody device and plug the other end of the USB cable into the printer.
3. Turn on the printer.
4. Turn on the InBody device and setup your printer under Settings of the Administrator Menu "**09 Printer Setup**".
5. You can edit your printing settings under Settings of the Administrator Menu from "**10 Results Sheet Types**" through "**15 Printing Alignment**".

5.2 Thermal Printer

Connect thermal printer to the InBody device to print Thermal Results Sheet.

* For best result, the InBody should be turned off when connecting to thermal printer.

1. Turn off the InBody device.
2. Connect the serial cable supplied with your thermal printer to the 9-pin serial port on the rear panel of the InBody device. Then, connect the other end of the serial cable to the serial port on thermal printer.
3. Turn on the thermal printer.
4. Turn on the InBody device. Go to Setup in Administrator Menu and select 'Thermal Printer' under "**26 Serial Connect**".
5. Go to Setup in Administrator Menu and select 'Thermal Results Sheet' under "**10 Results Sheet Types**" and configure the items printed to the Thermal Results Sheet under "**13 Outputs / Interpretations for Results Sheet**"

5.3 Stadiometer

* If a stadiometer is connected to the InBody device, the height values measured by the stadiometer will be sent directly to the InBody.
* Always connect a stadiometer from InBody device.

1. First turn off the InBody device and then the stadiometer.
   * You may experience connection issues in connecting the stadiometer to the InBody device if the InBody device is turned on.
2. Plug the serial cable provided with the stadiometer to the 9-pin serial port on the rear panel of the InBody device.
3. Turn on the stadiometer.
4. Turn on the InBody device. Go to Setup in Administrator Menu and select 'Stadiometer' under "**26 Serial Connect**". If the stadiometer is connected to the InBody device, the stadiometer icon () will appear on the top left corner of the screen when no one is on the footplate.

5.4 Blood Pressure Monitor

If a blood pressure monitor is connected to the InBody device, the blood pressure values measured by the blood pressure monitor will be sent directly to the InBody.

* Always connect a blood pressure monitor from InBody device.
* If you select to print blood pressure measurements under Settings of the Administrator Menu "**13 Outputs / Interpretations for Results Sheet**", the blood pressure measurements will be printed on the InBody Results Sheet.

1. First turn off the InBody device and then the blood pressure monitor.
   * You may experience connection issues in connecting the blood pressure monitor to the InBody device if the InBody device is turned on.
2. Plug the serial cable provided with the blood pressure monitor to the 9-pin serial port on the rear panel of the InBody device.
3. Turn on the blood pressure monitor.
4. Turn on the InBody device. Go to Setup in Administrator Menu and select 'Blood Pressure Monitor' under "**26 Serial Connect**". If the blood pressure monitor is connected to the InBody device, the blood pressure monitor icon () will appear on the top left corner of the screen when no one is on the footplate.

5.5 Barcode Reader

If a barcode reader is connected to the InBody device, the ID can be inputted automatically.

* If the InBody cannot recognize the barcode reader, please contact InBody.

1 First turn off the InBody device.
   * You may experience connection issues in connecting the barcode reader to the InBody device if the InBody device is turned on.

2 Plug the USB cable of the barcode reader into the USB HOST port on the rear panel of the InBody device.

3 Turn on the InBody device. If the barcode reader is connected to the InBody device, the barcode reader icon ( ) will appear in the top left corner of the screen when no one is on the footplate.

5.6 Data Management Software (LookinBody120)

By connecting LookinBody to InBody device, you can manage your InBody data.

1 Turn off the InBody device.
   * When InBody device is already turned on, LookinBody120 might not properly connect.

2 Connect the serial cable provided with LookinBody120 to the right serial port on the rear of the InBody. Connect the other end of the cable to the serial port of the PC.

3 Turn on the InBody device.

4 Launch LookinBody120 installed on your PC and follow its instructions to connect to InBody device.

5.7 Serial Distributor (SD400)

Connect the SD400 to the InBody device in order to connect the stadiometer and the blood pressure monitor simultaneously.

1 Turn off the InBody device.
   * For best result, the InBody device should be turned off when connecting to Serial Distributer.

2 Connect the serial cable supplied with the SD400 to the 9-pin serial port on the rear panel of the InBody device. Then, connect the other end of the serial cable to the serial port of the SD400.

3 Connect your devices (such as stadiometer and blood pressure monitor) to the ports on the SD400 and turn on the devices.

4 Turn on the InBody device. Go to Setup in Administrator Menu. Select 'SD400' under "**26 Serial Connect**" and select the devices you have connected to the ports on the SD400. When your devices are connected, the icons ( ) of your devices will appear in the top left of the test standby screen.

5.8 Connecting Bluetooth

Requirements

- The compatible device to be connected must support Bluetooth.
- Bluetooth may not operate normally if the compatible device is more than 10m away from InBody device.
- There should be no obstacles such as walls between the InBody device and the compatible device.

Connecting Stadiometer / Blood Pressure Monitor / InGrip

1 Press the [Administrator Menu] button on the screen before stepping on the footplate.

2 Enter the password.

3 Select "**17. Bluetooth**".

4 If you select 'O' to the question "Connect via Bluetooth?", you can choose the program to connect with and compatible devices.
   * After selecting compatible devices, integration with stadiometer, blood pressure monitor, and InGrip is possible.

5 Turn on the device (stadiometer, blood pressure monitor, InGrip) that you want to connect with the InBody.

6 Select the Bluetooth ID of the device to be paired and press Connect.

7 The compatible device's Bluetooth ID consists of "Product Name-Serial Number". Check the product name and serial number on the name plate attached to the compatible device.

- If the Bluetooth ID does not appear or the connection is not good, please contact InBody Customer Service.

8 If the compatible device is paired properly, the Bluetooth ID of the device connected to the InBody device will appear.

9 Press the Exit on the top right to return to the test standby screen. The Bluetooth icon will be displayed on the upper-left and a new text box will let you know the device is connected.

5.9 Connecting Internet

Once InBody device is connected to the Internet, you can use it to connect the Cloud Services or LookinBody120.

* If the Cloud Service does not work or if LookinBody Web is not recognized, please contact InBody Customer Service.

Connecting LAN

1 Press Setup on the [Administrator Menu] button on the keypad of the operation panel before stepping on the footplate.

2 Enter the password.

3 Select "**16. Internet Options**".

4 Connect the LAN (RJ45) cable to the LAN port of the InBody device.

* A LAN cable must be connected to the terminal (router) registered with Internet service or to the LAN (RJ45) port on the wall of the building.

5 Connect the LAN cable to the port located on the back of the device with the icon ( )

6 Once you're connected to the internet, you can use LookinBody via LAN or access cloud services.

Connecting Wi-Fi

1 Press Setup on the [Administrator Menu] button on the keypad of the operation panel before stepping on the footplate.

2 Enter the password.

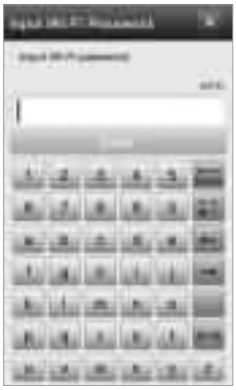
3 Select "**16. Internet Options**".

4 Press Wi-Fi and press Next.

* If you need to manually set up the Wi-Fi network, press Input manually.
* Wi-Fi IDs and passwords can be recognized only when they consist of letters, numbers, or symbols.

5 Select the desired Wi-Fi network and press Connect.

6 Enter the Wi-Fi password if needed and press Enter.



7 After setup, you can use LookinBody via Wi-Fi or access cloud services.

6 InBody Test

6.1 Precautions for Test

Warning

- 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.
- Children and people with limited mobility should be supervised or assisted when attempting to test on the InBody.
- After an individual with any kind of contagious disease or infection tests on the InBody, use an Alcohol-based disinfectant (e.g. 70 % ethanol) to clean the equipment.
- Please be careful not to get your foot stuck or tripped on the step when getting on the product. Serious injuries can occur.
- Use caution when stepping onto and off of the device. Serious injuries can occur.

Caution

- Stand upright for about 5 minutes before testing. Taking the test immediately after lying in bed or sitting for a long period of time might result in a slight change in the test results. This is because body water tends to move to the lower body as soon as the person stands or gets up.
- Do not eat before testing.
  In cases where the examinee has already eaten, the test should be put off for at least two hours after the meal.
  This is because food mass is included in the examinee's weight and thus, may result in measurement errors.
- Use the bathroom before testing. Waste is not included in the body's compositional elements, but the volume of urine and excrement is included in the weight measurement affecting accuracy of the test results.
- Do not exercise before testing. Strenuous exercise or sharp movements can cause temporary changes in body composition. Even light exercise can change your body composition temporarily.
- Take the test in the morning, if possible.
  Body water tends to gravitate towards the lower body throughout the day, affecting accuracy of the test results.
- Thoroughly wipe the palms and soles with the Alcohol-based disinfectant (e.g. 70% ethanol)
  before testing. Testing may be difficult if the examinee's palms and soles are too dry or if the examinee has too many calluses.
- Avoid contact with the examinee during testing. Contact may lead to interference affecting test results.
- When stepping onto or off of the device, do not grab or shove the device. Serious injuries to you or damage to the device can occur.

6.2 Test Instructions

The screens vary according to the Settings of the Administrator Menu Self Mode/Professional Mode.

- Professional Mode: An examiner is present and guiding the examinee through the InBody Test.
- Self Mode: The examinee takes the InBody Test following the instructions that are displayed on screen.

1 Step on the footplate when the screen below is shown.

2 Weight measurement begins.

3 Input personal information.

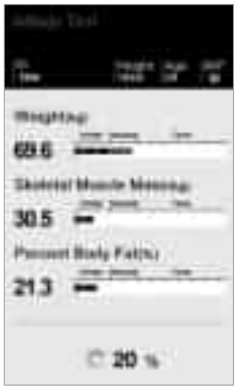
* In Professional Mode, enter the ID.
* Input height only if using Self Mode.

Professional Mode

Self Mode

4 Maintain proper posture to take the test.
* Refer to "**6.3 Test Posture**" for the proper posture.

5 The InBody Test begins.



Professional Mode

Self Mode

6 When the test is completed, the results will be shown on screen.

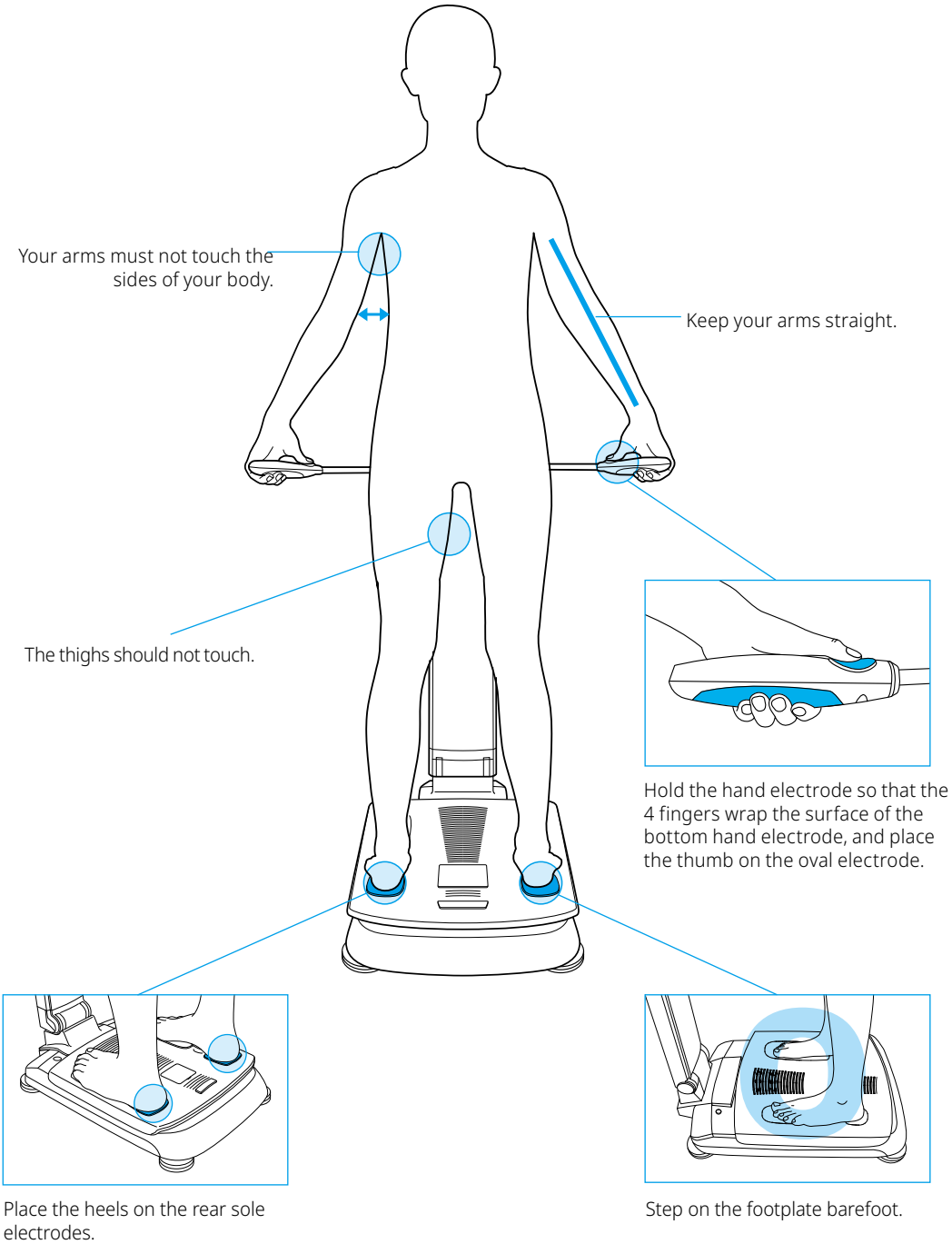
Professional Mode

Self Mode

6.3 Test Posture

The examinee must maintain proper posture to have accurate test results.

* The test will proceed when there is good electrical contact.



7 Maintenance and Storage

7.1 Precautions for Maintenance

Caution

- Do not bend the handles of the hand electrodes or rotate them in the reverse direction beyond its limitation.
- Do not extend the handles of the hand electrodes beyond its limitation.
- Do not place any objects on the footplate.
- Do not apply excessive force on the equipment.
- Turn off the equipment if you are not using it for a day or longer.
- Do not allow any liquid substances to contact the equipment directly. Keep food and drinks away from the equipment. Substances getting inside the equipment can cause critical damage to the electronic components.
- Use a lint-free cloth to gently wipe the external surface of the equipment about once every week.
  Be careful not to scratch the LCD screen.
- InBody does not need regular maintenance.
  If some problems occur while operating the device, get in touch with the store where you purchased it or A/S manager. We do not take the responsibility about problems caused by any arbitrary repairs.

7.2 Cleaning

Use the alcohol-based disinfectant (e.g. 70% ethanol) for 1 minute to clean the surfaces of the device.

7.3 Disinfecting

1. Use the alcohol-based disinfectant (e.g. 70% ethanol).
2. Follow the instructions on the disinfectant.
3. Disinfect the device: Comply with the intervals specified in the below table.

Interval	Component
Before every measurement	Hand electrodes and Foot electrodes
After every measurement	Hand electrodes and Foot electrodes

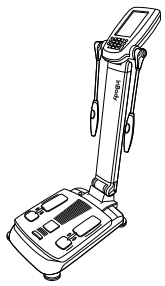
7.4 Repacking and Transportation

Once the device is installed, avoid transporting the equipment. If it must be transported, repack it in the following sequence.

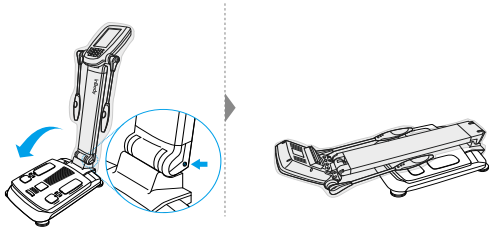
Caution

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

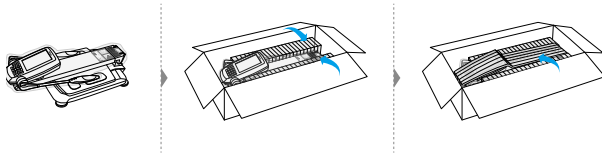
1. Turn off the InBody device.



2. Separate the connected adapter, cords, and cables from the equipment, and cover the InBody device with the polyethylene foam cover. While holding the upper part lock button, fold down the upper part.

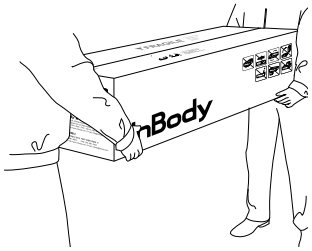


3. Put the InBody into the packing box. Place the packing pad over the equipment and tape up the packing box.



Caution

When transporting, have two people keep the InBody parallel to the ground.



7.5 Storage Environment

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

Temperature range	−10 - 70 °C (14 - 158 °F)
Relative humidity	10 - 80 % RH (No Condensation)
Atmospheric pressure	50 - 106 kPa

8 Frequently Asked Questions (FAQ)

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

* Customer Service contact information can be found in the Customer Service Information section within the Administrator Menu.

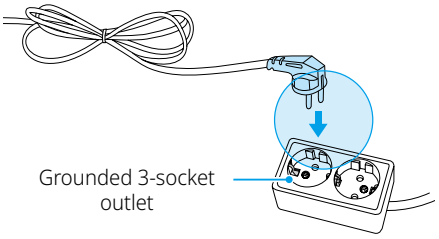
8.1 Regarding the Device

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

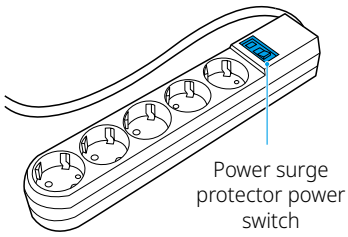
Question: My InBody does not turn on.

Answer:

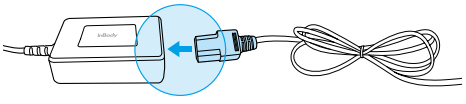
- Insert the power plug completely into a grounded 3-socket outlet.



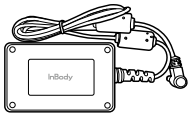
- When using a power surge protector, the equipment may not power on if the power switch on the power surge protector is turned off. Check the power surge protector which the power plug is connected to.

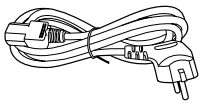


- The problem may occur if the power cord is not completely plugged into the adapter. Insert the power cord completely into the adapter.



- The problem may occur if you are using a power adapter that is not provided by InBody. Always connect a power adapter (DC 12 V, 5.0 A/3.34 A) provided by InBody.


Power adapter


Power cord

Question: My touchscreen is inaccurate or not responsive.

Answer:

- Calibrate the touchscreen under Settings of the Administrator Menu "**23 Touchscreen Alignment**".
- Press firmly to optimize touchscreen response.
- If you cannot enter the Administrator Menu due to touchscreen problems, please restart the InBody. The InBody stores the last touchscreen alignment and will automatically recall the previous touchscreen settings. The InBody can also recognize if its touchscreen alignment is off screen and will automatically take the user to the calibration screen after restarting.

Question: I would like to connect other equipment to the InBody.

Answer:

- Please refer to "**5 Connecting Compatible Device**" in this User's Manual.

8.2 Regarding Serious Incidents

If you are aware of a serious incident involving your product, you must report this as quickly as possible to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

The set deadlines in accordance with the MDR (EU) 2017/745 are:

Question: When an accident occurs

Answer:

- No later than within 15 calendar days after you have been informed of a serious incident.
- No later than within 2 calendar days after you have been informed of a serious incident which implies a serious threat to public health.
- No later than within 10 calendar days after you have been informed of a serious incident which has led to a death, or a serious deterioration in someone's state of health.

You must report a serious incident before the corrective action to eliminate the risk is taken, except in an emergency, in which case you must immediately carry out a field safety corrective action.

8.3 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: Must socks or stockings be removed for the InBody Test?

Answer: Bare skin contact is essential in the analysis using the BIA method. Socks or stockings may cause a varying degree of distortion in the results. 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 InBody Test?

Answer: The ideal condition for the analysis is simply standing with no clothes and wearing no accessories. However, this may not always be possible. Therefore, we recommend that the examinee remove as many clothing items and accessories that may affect the weight as possible.

Question: Who cannot take the InBody Test or will have difficulties taking the InBody Test?

Answer:

- Individuals with medical implant devices such as pacemakers, or essential support devices such as patient monitoring systems, must not use this equipment. The currents will flow through the body during the test, which may cause malfunctioning of the device or endanger lives.
- Children, amputees, or the elderly, may have trouble testing if they cannot hold the hand electrodes or stand still on the foot electrodes.

Question: Can a person with metal implants in the body take the InBody Test?

Answer:

- The ideal test methodology is where the examinee does not wear anything metallic. Individuals with metallic implants may have skewed test results due to the conductivity of the metal affecting the results.
- As the weight of clothes and other wear affects the results of the body composition analysis, it is strongly recommended to take off any heavy clothing or metallic wear. Except for the weight, jewelry does not effect the body composition analysis, as the contact point with the InBody are hands and feet.

Question: I have limited mobility and cannot maintain proper posture for the InBody Test. How can I still be tested?

Answer: It is impossible to test if an individual cannot maintain contact with the hand or foot electrodes. InBody has a line of products that conduct body composition analysis on bed ridden examinees that allow the patients to stay in bed. For more information, please contact InBody.

Question: Is the electric current harmful to the body?

Answer: The physiological electric impedance method uses safe low level currents that are not harmful to the body. The safety of the InBody has been tested and proven. The InBody products have been approved for medical use by the CE and all over the world. Many medical institutions around the world are actively using the InBody.

Question: How often should I take the InBody Test?

Answer:

- Individuals who are undergoing any programs that may affect their body composition are strongly recommended to have the InBody Test done every two to four weeks.
- Consistent testing will allow individuals to track and monitor their progress over time.

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

Answer: Please refer to "**6.1 Precautions for Test**" in section "**6 InBody Test**" in this User's Manual.

8.4 Residual Risks and Undesirable Side Effects

Undesirable side effects have been identified as general allergies that can be associated with the skin contact of the metal surface during the clinical use of the InBody. As part of a comprehensive risk management protocol, the stainless steel coming into contact with the patient has been evaluated per ISO-10993 biocompatibility testing standards, with a focus on skin sensitization testing, and has had favorable biocompatibility test results. In addition, the following contraindication statement has been added to this IFU:

Individuals with known metal allergies against stainless steel materials shall not use the equipment.

9 Classifications and Specifications

* The InBody is manufactured according to the quality management procedure of InBody. InBody complies with the ISO9001 and ISO13485 which are international quality management systems.
* This equipment satisfies the IEC60601-1 (EN60601-1), an international safety standard for electronic medical equipment. This equipment also satisfies the IEC60601-1-2 (EN60601-1-2), an international standard for electromagnetic conformity.

9.1 Classifications

Classifications	Body Composition Analyzer of Direct Segmental Multi-frequency Bioelectrical Impedance Analysis Method	
	Type of protection against electric shock	Class I
	Type of the applied parts	BF Type
	Degree of protection against water infiltration	IPX0
	EMC Emission	Class B
	Equipment is not suitable for use in the presence of flammable mixtures.	

9.2 Specifications

Bioelectrical Impedance Analysis (BIA) Item	Impedance (Z)	15 Impedance measurements by using 3 different frequencies(20 kHz, 50 kHz, 100 kHz) at each 5 segments of the body(Right Arm, Left Arm, Trunk, Right Leg, Left Leg)
	Phase Angle (Ø)	1 Phase Angle Measurement by using 1 Frequency (50kHz) on the Whole Body
Electrode Method	4 electric poles 8 Points Touch type electrode measurement	
Measurement Method	Direct Segmental Multi-frequency Bioelectrical Impedance Analysis Method, DSM-BIA method	
Body Composition Calculation	No use of Empirical Estimation	

Outputs (InBody Results Sheet)	Results and Interpretations • Body Composition Analysis (Total Body Water, Protein, Minerals, Body Fat Mass, Weight) • Muscle-Fat Analysis (Weight, Skeletal Muscle Mass, Body Fat Mass) • Obesity Analysis (Body Mass Index, Percent Body Fat) • Segmental Lean Analysis (Right Arm,Left Arm, Trunk, Right Leg, Left Leg) • Segmental Fat Analysis (Right Arm, Left Arm, Trunk, Right Leg, Left Leg) • Body Composition History (Weight, Skeletal Muscle Mass, Percent Body Fat) • InBody Score • Whole Body Phase Angle (History) • SMI (History) • Weight Control (Target Weight, Weight Control, Fat Control, Muscle Control) • Nutrition Evaluation (Protein, Minerals, Fat Mass) • Obesity Evaluation (BMI, Percent Body Fat) • Body Balance Evaluation (Upper, Lower, Upper-Lower) • Waist-Hip Ratio (Graph) • Visceral Fat Level (Graph) • Research Parameters (Skeletal Muscle Mass, Fat Free Mass, Basal Metabolic Rate, Waist-Hip Ratio, Waist Circumference, Visceral Fat Level, Obesity Degree, FFMI, FMI, SMI, SMM/WT) • Recommended calorie intake per day • Calorie Expenditure of Exercise • Sarcopenia Parameter (SMI, HGS) • Blood Pressure (Systolic, Diastolic, Pulse, Mean Artery Pressure, Pulse Pressure, Rate Pressure Product) • QR Code • Results Interpretation QR Code • Whole Body Phase Angle (50kHz) • Impedance (Each segment and each frequency)

Outputs (InBody Result Sheet for Children)	Results and Interpretations • Body Composition Analysis (Total Body Water, Protein, Minerals, Body Fat Mass, Weight) • Muscle-Fat Analysis (Weight, Skeletal Muscle Mass, Body Fat Mass) • Obesity Analysis (Body Mass Index, Percent Body Fat) • Growth Graph (Height, Weight, BMI) • Body Composition History (Height, Weight, Skeletal Muscle Mass, Percent Body Fat) • Whole Body Phase Angle (History) • SMI (History) • Growth Score • Weight Control (Target Weight, Weight Control, Fat Control, Muscle Control) • Obesity Evaluation (BMI, Percent Body Fat) • Nutrition Evaluation (Protein, Minerals, Fat Mass) • Body Balance (Upper, Lower, Upper-Lower) • Research Parameters (Skeletal Muscle Mass, Fat Free Mass, Basal Metabolic Rate, Child Obesity Degree, FFMI, FMI, SMI, SMM/WT) • Sarcopenia Parameter • Blood Pressure (Systolic, Diastolic, Pulse, Mean Artery Pressure, Pulse Pressure, Rate Pressure Product) • QR Code • Results Interpretation QR Code • Whole Body Phase Angle (50kHz) • Impedance (Each segment and each frequency)
Outputs (InBody Thermal Result Sheet)	Total Body Water, Protein, Minerals, Weight, Muscle Mass, Body Fat Mass, Percent Body Fat, BMI, Basal Metabolic Rate, Waist-Hip Ratio, Waist Circumference, Visceral Fat Level, FFMI, FMI, SMI, SMM/WT, Segmental Lean Analysis(Right Arm, Left Arm, Trunk, Right Leg, Left Leg), Segmental Fat Analysis(Right Arm, Left Arm, Trunk, Right Leg, Left Leg), InBody Score, Fat Control, Muscle Control, Whole Body Phase Angle(50kHz), Impedance (Each segment and each frequency)
Logo Display	Name, Address, and Contact Information can be shown on the InBody Results Sheet.
Digital Results	LCD Monitor, Data management software LookinBody120
Types of Result Sheets	InBody Test Results Sheet, InBody Test Results Sheet for Children, InBody Test Thermal Results Sheet
Voice Guidance	Provides audible indication for test in progress, test complete, and successfully saved settings changes.
Data Storage	Test results can be saved if the member ID is utilized. The InBody can save up to 100,000 results.
Test Mode	Self Mode, Professional Mode
Administrator Menu	• Setup: Configure settings and manage data • Troubleshooting: Additional information to help use the InBody
USB Thumb Drive	Copy, backup, or restore the InBody test data (data can be viewed on Excel or LookinBody data management software)
Barcode Reader	The member ID will be automatically inputted when the barcode ID is scanned.
Backup data	Backup data saved in the InBody by using a USB Thumb Drive, Restore results on the InBody from a backup file.

Other specifications

Applied Rating Current	300 μA (± 30 μA)	
Adapter ② (DELTA)	Power Input	AC 100 - 240 V, 50 - 60 Hz, 1.5 A - 0.75 A
	Power Output	DC 12 V, 5.0 A
Adapter ① (MEAN WELL)	Power Input	AC 100 - 240 V, 50 / 60 Hz, 1.0 A - 0.5 A
	Power Output	DC 12 V, 3.34 A
Display Type	480 × 800 7 inch Color TFT LCD	
Internal Interface	Touchscreen, Keypad	
External Interface	RS-232C 1EA, USB HOST 2EA, USB SLAVE 1EA, LAN (10/100T) 1EA, Bluetooth 1EA, Wi-Fi(2.4G/5G) 1EA	
Compatible Printer	Laser/Inkjet PCL 3 or above and SPL	
Dimension	356 (W) X 796 (L) X 995 (H) : mm 14.0 (W) X 31.3 (L) X 39.2 (H) : inch	
Equipment Weight	13.4 kg (29.5 lb)	
Test Duration	About 30 sec.	
Operation Environment	10 - 40 °C (50 - 104 °F), 30 - 75 % RH, 70 - 106 kPa	
Storage Environment	−10 - 70 °C (14 - 158 °F), 10 - 80 % RH, 50 - 106 kPa (No Condensation)	
Testing Weight Range	2 - 250kg (4.4 - 551.2 lb)	
Height Range	95 - 220 cm (3 ft 1.4 in - 7 ft 2.6 in)	
Age Range	3+ years	

* Specifications may change without prior notice.
* "QR Code" is registered trademark of DENSO WAVE INCORPORATED.

9.3 Symbols Used on the Product

Indicators

	9-pin Serial Port (Female, RS-232C)
	LAN Port (10/100T Base)
	USB Port (HOST/SLAVE)

Safety Symbols

	Dangerous High Voltage
	Warning / Caution
	BF Type Equipment
12V ⎓	Power Adapter
	Power On
	Power Off

Etc. Symbols

	Operating Instructions
	Do Not Disassemble Arbitrarily
CE 1639	European Conformity
	Manufacturer
MD	Medical Device
UDI	Unique Device Identification
SN	Serial Number
⎓	Direct Current
EC REP	Authorized representative in the European Community
	Operating Instructions
REF	Catalogue Number
	Importer
	Country of Manufacture

Disposal of old Electrical & Electronic Equipment (Application in the European Union and other European countries with separate collection system.) This symbol indicates that this product shall not be treated as household waste. Instead, it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information about recycling this product, please refer to local governing ordinances and recycling plans.

9.4 Guidance and Manufacturer's Declaration

The InBody device is intended for use in the electromagnetic environment specified below. The customer or the user of the InBody device should ensure that it is used in such an environment.

Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The InBody device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The InBody device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, a relative humidity of at least 30% is recommended.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T (100 % dip in U_T) for 0.5/1 cycles 70 % U_T (30 % dip in U_T) for 25/30 cycles 0 % U_T (100 % dip in U_T) for 250/300 cycles	0 % U_T (100 % dip in U_T) for 0.5/1 cycles 70 % U_T (30 % dip in U_T) for 25/30 cycles 0 % U_T (100 % dip in U_T) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a commercial or hospital environment.

Recommended separation distances between portable and mobile communication equipment and InBody device

The InBody device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the InBody device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the InBody device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]	
	IEC 60601-1-2: 2014	
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.7 GHz $d = 2.0\sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2	These guidelines may not apply in all situations, as electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should not be used closer to any part of the Ultrasound System, including cables, than the recommended separation distance. This is calculated using the equation applicable to the frequency of the transmitter.
	6 Vrms 150 kHz – 80 MHz In ISM bands[1] amateur radio bands Bands[2]	6 V	Recommended separation distance $d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	IEC 60601-1-2:2014 d=2.0 80 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[3] should be less than the compliance level in each frequency range.[4] Interference may occur in the vicinity of equipment marked with following symbol: 

NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	These guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
2. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3,5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.
3. Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the InBody device is used exceeds the applicable RF compliance level above, the InBody device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the InBody device.
4. When the frequency range exceeds 150 kHz - 80 MHz, the electric field strength should be not higher than 3 V/m.

Electromagnetic Emissions

The InBody device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the InBody device. Otherwise, the performance of this equipment could be impaired.

Immunity test	Band	Service[5]	Modulation[6]	IEC60601 test level	Compliance level
Proximity fields from RF wireless Communications IEC61000-4-3	380 - 390 MHz	TETRA 400	Pulse modulation 18Hz	27 V/m	27 V/m
	430 - 470 MHz	GMRS 460 FRS 460	FM[7] ± 5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 - 787 MHz	LTE Band13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800 - 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	28 V/m	28 V/m
	1700 - 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,2,4,25 UMTS	Pulse modulation 217 Hz	28 V/m	28 V/m
	2400 - 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band	Pulse modulation 217 Hz	28 V/m	2 8V/m
	5100 - 5800 MHz	WLAN 802.11a/n	Pulse modulation 217 Hz	9 V/m	9 V/m

NOTE If it is necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.

5. For some services, only the uplink frequencies are included.
6. The carrier shall be modulated using a 50 % duty cycle square wave signal.
7. As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.

Follow instructions for use

Suivez les instructions d'utilisation

WARNING

- Electric shock hazard – do not dismantle.
- Dismantling will void the warranty.
- Do not touch signal input, signal output or other connectors, and the patient simultaneously.
- External equipment intended for connection to signal input, signal output or other connectors, shall comply with relevant IEC Standard (e.g., , IEC60950 for IT equipment and IEC60601-1 series for medical electrical equipment). In addition, all such combination-system shall comply with the standard IEC60601-1 and/or IEC60601-1-1 harmonized national standard or the combination. If, in doubt, contact qualified technician or your local representative.

AVERTISSEMENT

- *Risque de choc électrique - ne pas démonter.*
- *Le démontage annulera la garantie.*
- *Ne touchez pas l'entrée de signal, la sortie de signal ou d'autres connecteurs et le patient simultanément.*
- *L'équipement externe destiné à être connecté à l'entrée de signal, à la sortie de signal ou à d'autres connecteurs doit être conforme à la norme IEC pertinente (par exemple, IEC60950 pour les équipements informatiques et la série IEC60601-1 pour les équipements électriques médicaux). De plus, tous ces systèmes combinés doivent être conformes à la norme nationale harmonisée IEC60601-1 et/ou IEC60601-1-1 ou à la combinaison. En cas de doute, contactez un technicien qualifié ou votre représentant local.*

DANGER

- Do not use this equipment with electrical medical device such as a pacemaker.
- *Ne pas utiliser cet équipement avec des appareils médicaux électriques comme un stimulateur cardiaque.*

CAUTION

- Do not spray any liquid substance directly onto the device.
- *Ne pulverisez aucune substances liquids directement sur l'appareil.*

CAUTION

- No excessive force on shoulder joint.
- *Ne pas appliquer de force excessive sur les bars articulés.*

9.5 Key Performance Claims

The key performance claims of InBody have been established as the correlation coefficient ratio (R) of Fat Free Mass (FFM), which is numerically defined as the R value, shall be ≥ 0.80 (80 %)

Clinical Benefit

Using the InBody with the probability of harm occurring is more beneficial when compared to the severe harm that might occur from not using the Body Composition Analyzer of InBody. The Body Composition Analyzer of InBody provides clinical benefits to support the aforementioned intended use, as the InBody is mainly used for healthy and acutely or chronically ill populations in hospitals, medical practices and inpatient care facilities in accordance with national regulations. It can be used to assist in the assessment of nutritional status, obesity and muscle balance. Body composition analysis is important in preventive medicine since it provides the basis of appropriate physical activity and dietary habits for improving personal daily routine. It can be also usefully applied to follow-up studies of patients treated for various diseases.

Inaccurate measurements of the Fat Free Mass (FFM) could have a negative impact on further use of the body composition analysis data gathered from the clinical use of InBody.

CE 1639