

InBody380

User's Manual

1. Intended Use

The InBody is mainly used for healthy and acute 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:**
 - At least, the user needs to be able to understand explanation of words on screen.
2. **Knowledge:**
 - At least, the user needs to be able to understand explanation of words on screen.
 - No maximum.
3. **Language understanding:**
 - Basic language: English
 - Languages are supported as specified in the marketing need.
4. **Experience:**
 - No minimum and maximum.

5. Intended patient population and user profile

1. **Age:** 3+ years
2. **Weight:** 2 - 300 kg (4.4 - 661.4 lb)
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 - 220cm (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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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. Safe, micro alternative currents will flow through the body during the test, but this may cause malfunctioning of the device or 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.
- It is not recommended to use the device with an individual who has a contagious disease or an infectious disease. 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 the liquid cleaner when cleaning 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.

Caution

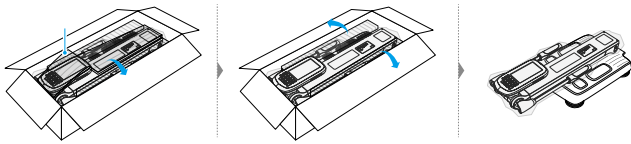
- Do not allow any liquid substances to contact the device directly. Keep food and drinks away from the device. Substances getting inside the device can cause critical damage to the electronic components.
- Do not disassemble or modify the device including internal parts without written consent from 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 packaging pad. Take the device out of the packing box.

Packaging Pad

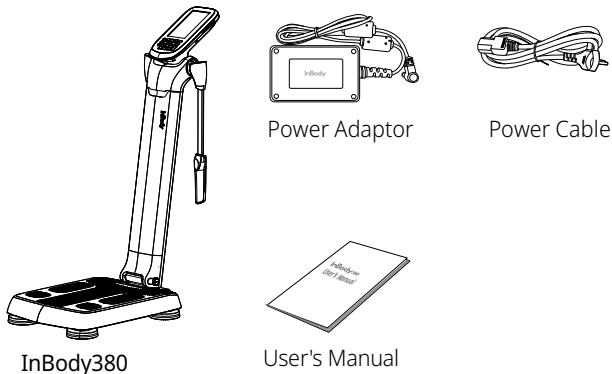


Note

- For repackaging the device at a later time, the supplied packing materials must be kept. Other wastes should be disposed according to relevant local laws and regulations.
- To repack the device, please refer to "7.4 Repacking and Transportation".

2.2 Product Components

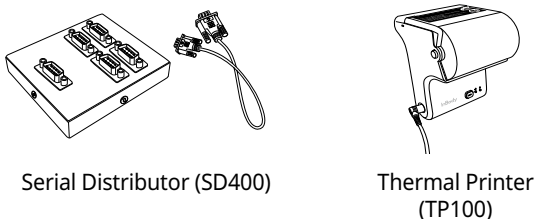
Please check if the device has any damage prior to installation.



Note

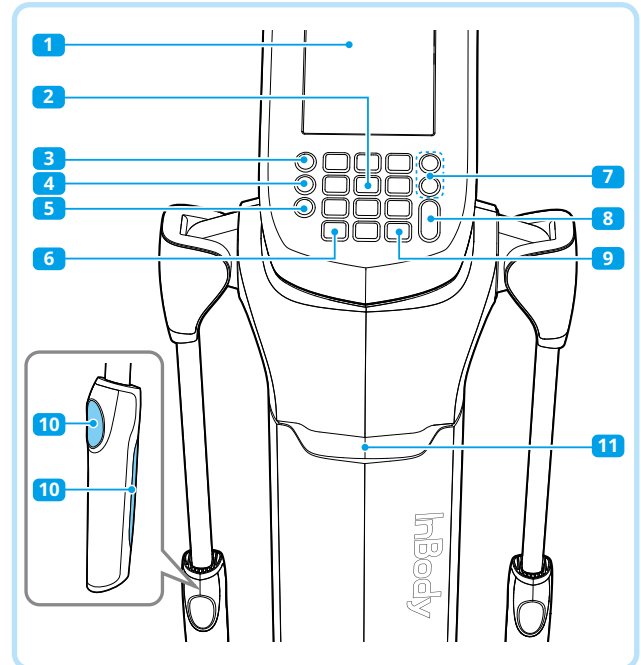
- The specifications of power cables can vary by country.

2.3 Optional Product



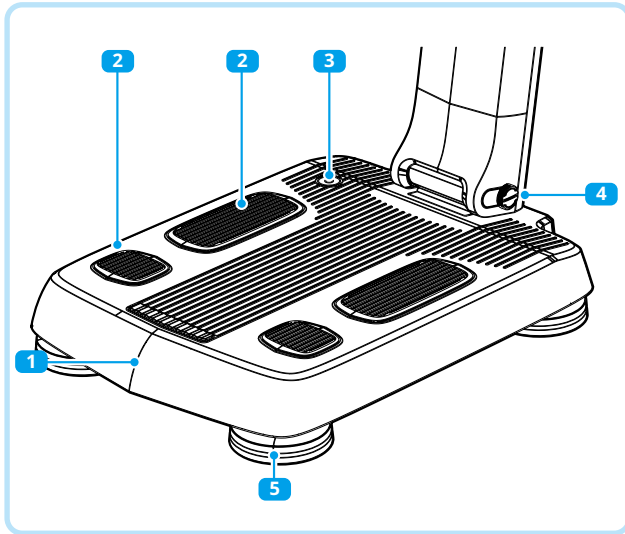
2.4 Name of Each Part

Operation Panel



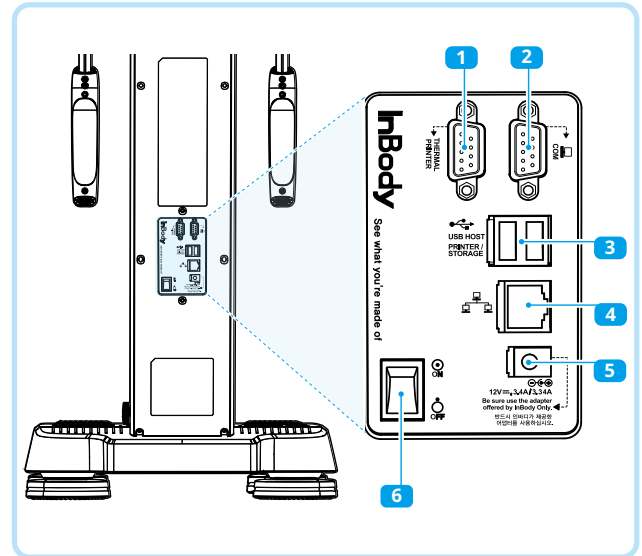
- 1 Display:** Displays each step of test, guide, and test result.
- 2 Number Button:** Enter numeric data such as age and height.
- 3 Setup:** Enter the "Setup" from the test standby screen.
- 4 Function:** Enter the "FAQ" screen directly from the test standby screen.
- 5 Print:** Reprint test results.
- 6 Decimal Point:** Enter the decimal point in ID, height, age and weight.
- 7 Gender:** Select the gender. (M: Male, F: Female)
- 8 Enter:** Used when input is completed or changes are saved in the Setup.
- 9 Delete:** Used to delete the saved data.
- 10 Hand Electrode:** Sends a weak current to the upper body and measures the voltage for the InBody test.
- 11 Smart Reader:** InBody App user can transfer the personal information needed for the test with QR code.

Footplate



- 1 Footplate:** Connected to loadcells that measures user's weight.
- 2 Foot Electrode:** Sends a weak current to the lower body and measures the voltage for the InBody test.
- 3 Level Indicator:** Shows the level status of the footplate.
- 4 Lock Bolt:** Used to fold the upper part of the device. You must turn the lock bolt to lock and unlock before and after folding the equipment.
- 5 Level Supporter:** Can fit the level by adjusting height.

Rear View



- 1 9-pin Serial Port (Female, RS-232C):** Connect a thermal printer.
- 2 9-pin Serial Port (Female, RS-232C):** Connect to LookinBody120 installed on the PC, a stadiometer, a blood pressure monitor and SD400.
- 3 USB HOST Port:** Connect printer, USB flash drive and barcode reader.
- 4 LAN Port (10/100T-Base):** Connect to the Internet or LookinBody120 installed on the PC.
- 5 Power Inlet:** Connect a power adapter.
- 6 Power Switch:** Turn the device on and off.

Note

- Make sure to connect only InBody stadiometer, Blood Pressure Monitor and SD400.
- When connecting to a PC where the data management program LookinBody120 is installed, you can connect with one of the serial port, Bluetooth, LAN, or Wi-Fi port.
- Serial, USB, and LAN cables are not included in the product.

3 Installation

3.1 Installation Environment

Caution

- If you are operating the device in a place where the altitude is 2,000 m or higher, the weight measurement may be affected.
- Use the device in a location where it is not exposed to direct sunlight. It may cause discoloration or damage of device.

Check the environment before installing the device.

- Using the device in a dry environment or on a carpet may result in static electricity and damage. Use an antistatic mat if you need to install in an environment with static device.
- Install the device on the floor that is flat and vibration-free. If the device is installed where the floor is not flat, it may topple during a test or the test results may be inaccurate.

This device is suitable for indoor use. If installing this device 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

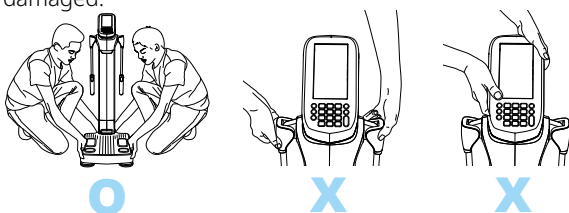
3.2 Installation

Warning

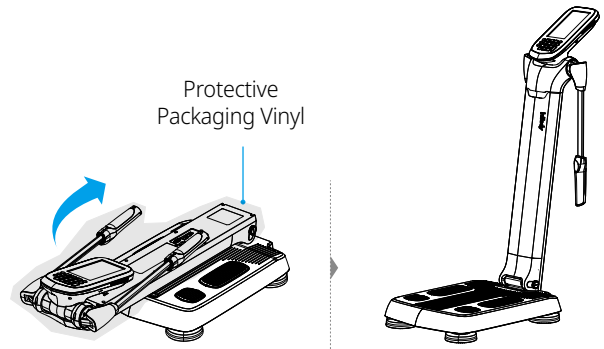
- Always use an outlet connected to the rated power (AC 100 - 240 V). Using other power rated outlets may result in fire or malfunction.
- When using a power surge protector, make sure that the outlet or the extension cable has adequate power capacity.

Caution

Hold the footplate when moving the device. When transporting the device, do not grab upper section (LCD) or hand electrode connection area. Or, the device may be damaged.

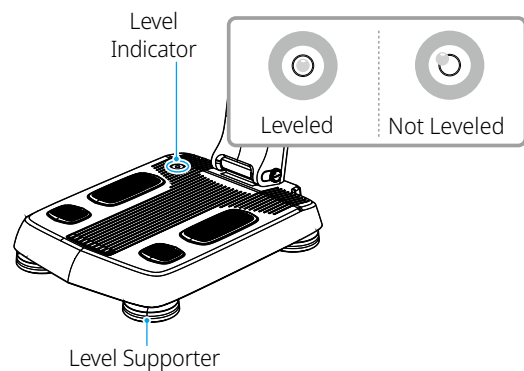


- 1 Raise the upper part of the device and remove the protective packaging vinyl.



- 2 Level the device by rotating the level supporter under the footplate to the left and right.

- You can check whether the device is level or not checking the air bubble in the level indicator.
- For accurate weight measurement, the device should be leveled.

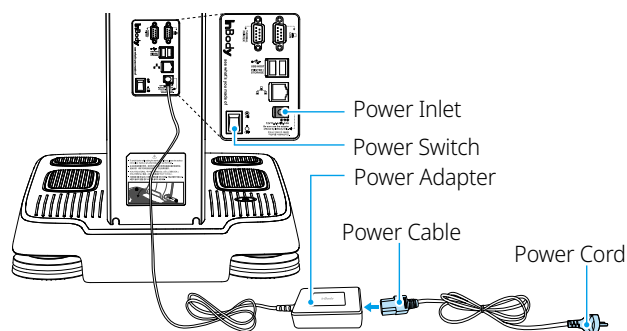


Caution

Be careful not to get your hands hurt when handling the Level Supporter.

Installation

- 3 Connect the power cable to the device.
 - a Connect the power cable to the power adapter.
 - b Connect the power adapter to the power inlet on the rear of the device.
 - c Connect the power cord to a 3-terminal outlet with a ground terminal.



Caution

- Use the power adapter provided by InBody. The device may malfunction when using other adapters.
- The device may get damaged or malfunctioned due to the electric if plugging into an ungrounded outlet. Or the test results may be inaccurate.

- 4 Press the power switch to turn it on.

Caution

If you are connecting the InBody device to compatible device then turn on the compatible device first. On the contrary, turn off the power of InBody device first, and then turn off the power of the compatible device when turning off the power. This can minimize the electric shock to the InBody device.

The InBody device can be connected to optional products and PC program such as stadiometer, blood pressure monitor, (thermal) printer, smart reader, serial distributor, and LookinBody120. For more details, refer to "5 Connecting Compatible Device".

4 Setting

4.1 Initial Setup

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

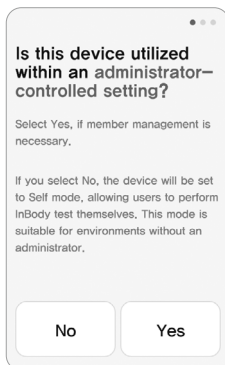
⚠ Caution

While booting, please do not stand on the footplate or place objects on the footplate.



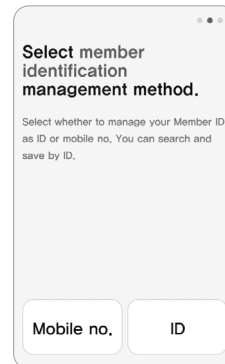
When InBody device is booted for the first time, the initial setting screen appears. Complete the initial setup selecting the appropriate item.

1 Select whether to use the Self Mode.



- Self Mode is suitable for an environment without an administrator, as the screen is configured for testing alone.

2 Select how to manage the User ID.



- You can choose whether to use the membership number or mobile number for the InBody User ID.

3 Select Weight Measurement Mode.



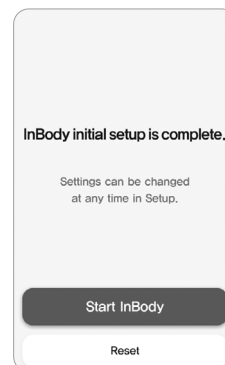
- Select whether to proceed with the InBody test completing the weight measurement or to automatically measure the weight during the InBody test.


Note

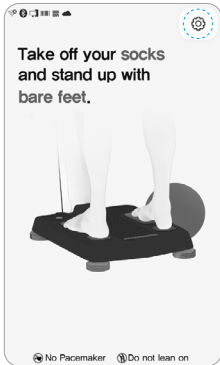
You can change the initial settings at any time in Setup.

4.2 Setup

1 Press **Start InBody** after completing initial setting.

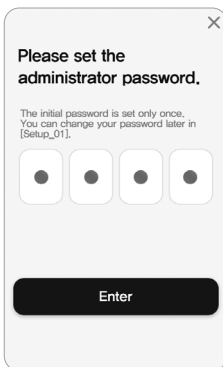


- 2 Press Setup  on the test standby screen or Setup button on the keypad of the operation panel before stepping on the footplate.

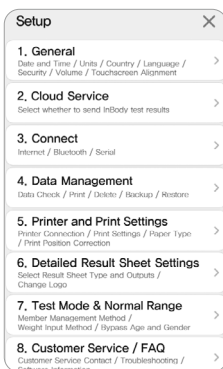


- 3 Enter the administrator password and press **Enter**.

- This screen will appear only once for initial password setup.



- 4 Press the menu in the Setup and change the setting.



Note

Be careful not to forget the password you set. If you have forgotten your password, please contact InBody Customer Service.

4.3 Overview of the Setup Menu

Set your InBody device fits to your facility and manage the data.

General


- Date and Time:** Set the date and time displayed at the test standby screen and on the result sheet.
- Units:** Set the unit displayed on the InBody device.
- Country:** Select the country where InBody device is installed.
- Language:** Select the language to be applied to InBody device.
- Password Lock Setting:** You can lock the device to control the accessibility.
- Volume:** Adjust the volume of InBody device.
- Touchscreen Alignment:** Calibrate the accuracy of the touch screen.
- Additional Function Setup:** Set functions other than the basic functions.

Cloud Service

Cloud Service is a service that transmits InBody results to the member's mobile phone so that the members can check the result at any time with the InBody App.

You can send the InBody results by entering your mobile number during the test.

Note

The result can be sent only when the Internet connection is set in the Setup  > **3.Connect** > **Internet**, and **2.Cloud Service** is 'On'. When the result is not sent, refer to "8.1 Regarding the Device".

Connect

- Internet:** This option allows connecting the InBody device to the Internet. Once the device is connected to the Internet, the test results can be shared to InBody App or the LookinBody120, the personal membership management PC application without distance limitation. To connect to the Internet, refer to "5.9 Connecting Internet".
- Bluetooth:** This option allows setting up the Bluetooth so that the InBody device can connect to LookinBody120, or to other compatible devices such as BSM Stadiometer series, BPBIO Blood Pressure Monitor series. For details to connect Bluetooth, please refer to "5.8 Connecting Bluetooth".
- Serial:** This option allows connect a PC with member management program, LookinBody120 or other compatible devices. For details on how to connect compatible devices, refer to "5 Connecting Compatible Device".

Data Management

- **View/Print/Delete Data:** This option allows checking, printing or deleting the test result stored in the InBody device as a membership number or mobile number.
- **Export Data as a MS Excel File:** This option allows copying the test result saved in the InBody device to USB flash drive as an Excel file format. You can check the test results opening the Excel file on your computer. A file that calls the test results saved in InBody device into the member management program LookinBody120 is created together in USB flash drive.
- **Data Backup/Restoration/Combine:** This option allows saving the test results to USB flash drive for backup or restores the backed up test results to the InBody device. If you are using multiple devices, the data can be combined.

Printer and Print Settings

- **Printer Setup:** This option allows setting the printer to connect to the InBody device. Connect the printer to the InBody device to print your Result Sheet.
- **Automatic Printing Options:** This option allows setting the Result Sheet to be printed automatically after completing the test. You can print up to two Result Sheets per each Result Sheet type at one time.
- **Print Results on A4 paper:** You can choose to print out the Result Sheet on the plain A4 paper after test. However, you can only print in black and white if you print the result on the plain A4 paper.
- **Printing Alignment:** This option allows adjusting the position of the result to be printed on the Result Sheet.

Detailed Result Sheet Settings

- **InBody Result Sheet:** You can set whether to use the InBody Result Sheet and the Result Sheet Items (Body Composition History, Right Side Outputs, Segmental Lean Analysis).
- **InBody Result Sheet for Children:** You can set whether to use InBody Result Sheet for Children and the Result Sheet Items (Body Composition History, Right Side Outputs, Standard Child Growth Curve). You may also set the Result Sheet Setting (Change the Age Range of Child).
- **Thermal Result Sheet:** You can set whether to use the Thermal Result Sheet and select Outputs.
- **Custom Logo:** You can preview the logo printed on the upper right of the Result Sheet.

Note

Please contact Customer Service for help with uploading or modifying a logo.

Test Mode & Normal Range

- **Self Mode:** Select whether to use Self Mode. Self Mode is suitable for an environment without an administrator, as the screen is configured for testing alone. When using Self Mode, InBody test can be started without entering ID.
- **Member Management Method:** You can choose whether to use the ID or mobile number for the member ID.
- **Weight Input Method:** You can select whether to automatically measure the weight as soon as the subject stands on the footplate, to measure the weight before the test, or to enter the weight.
- **Adjust Weight:** Adjust measured weight by a fixed value on the InBody device. (Example: Workout clothes at the gym are approximately 0.2 kg; most people are assumed to be wearing workout clothes, so the instructor may adjust the set value to -0.2 kg.)
- **Bypass Age/Gender:** The subject can bypass inputting their age or gender if the test environment is designed for testing a specific age group or gender.
- **Normal Range:** This option allows setting the normal range of BMI, Percent Body Fat, and Waist-Hip Ratio. The ideal value of BMI may also be set.

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 Result Sheet, an InBody compatible printer is required.

- 1 Turn off the InBody device.
 - When InBody device is already turned on, the printer might not properly connect.
- 2 Connect the USB cable supplied with the printer to the USB HOST port on the rear of the InBody device. Connect the other end of the USB cable to the USB port of the printer.
- 3 Turn on the printer.
- 4 Turn on the InBody device.
- 5 Connect the printer according to the instructions on Setup ⚙️ > **5.Printer and Print Settings** > **Printer Setup**.

Note

You can set the printing options in Setup ⚙️ > **5.Printer and Print Settings** and **6.Detailed Result Sheet Settings**.

5.2 Thermal Printer

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

- 1 Turn off the InBody device.
 - When InBody device is already turned on, the thermal printer might not properly connect.
- 2 Connect the serial cable connected with the thermal printer to the left serial port on the rear of the InBody device.
- 3 Turn on the thermal printer.
- 4 Turn on the InBody device.
- 5 Select **Thermal Result Sheet** in Setup ⚙️ > **6.Detailed Result Sheet Settings** > **InBody Result Sheet**.

Note

You can set the outputs to display on the Thermal Result Sheet in Setup ⚙️ > **6.Detailed Result Sheet Settings** > **Thermal Result Sheet**.

5.3 Stadiometer

The height values measured by the stadiometer are sent to InBody device when it is connected to InBody device.

- 1 Turn off the InBody device.
 - When InBody device is already turned on, the stadiometer might not properly connect.
- 2 Connect the serial cable supplied with the stadiometer to the right serial port on the rear of the InBody device. Connect the other end of the cable to the serial port of the stadiometer.
- 3 Turn on the stadiometer.
- 4 Turn on the InBody device.
- 5 Select **Stadiometer** in Setup ⚙️ > **3.Connect** > **Serial**.

When the stadiometer is connected, a message will be displayed on the test standby screen.

Note

- Please make sure to connect only BSM Stadiometer series provided by InBody.
- You can also connect the stadiometer via Bluetooth. For details on device connection, refer to "5.8 Connecting Bluetooth".


5.4 Blood Pressure Monitor

The blood pressure values measured by the blood pressure monitor are sent to InBody device when it is connected to InBody device.

- 1 Turn off the InBody device.
 - When InBody device is already turned on, the blood pressure monitor might not properly connect.
- 2 Connect the serial cable supplied with the blood pressure monitor to the right serial port on the rear of the InBody device. Connect the other end of the cable to the serial port of the blood pressure monitor.
- 3 Turn on the blood pressure monitor.
- 4 Turn on the InBody device.
- 5 Select **Blood pressure monitor** in Setup ⚙️ > **3.Connect** > **Serial**.

When the blood pressure monitor is connected, a message will be displayed on the test standby screen.

Note

- Please make sure to connect only the BPBIO Blood Pressure Monitor series provided by InBody.
- If you select blood pressure in the sub options in Setup  > **6.Detailed Result Sheet Settings > InBody Result Sheet** you can print the blood pressure value on the InBody Result Sheet.
- You can also connect the blood pressure monitor via Bluetooth. For details on device connection, refer to "5.8 Connecting Bluetooth".

Note

- If LookinBody120 is not recognized, please contact InBody Customer Service.
- You can connect the LookinBody120 via Bluetooth by connecting the Bluetooth dongle included in LookinBody120 to your PC. For details on device connection, refer to "5.8 Connecting Bluetooth".
- You can also connect the LookinBody120 via Internet. For details on device connection, refer to "5.9 Connecting Internet".

5.5 Barcode Reader

The ID will be inputted automatically if a barcode reader is connected to the InBody device.

- 1 Turn off the InBody device.
 - When InBody device is already turned on, the barcode reader might not properly connect.
- 2 Connect the USB cable of the barcode reader to the USB HOST port on the rear of the InBody device.
- 3 Turn on the InBody device.

When the barcode reader is connected, a message will be displayed on the test standby screen.

Note

If barcode reader is not recognized, please contact InBody Customer Service.


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 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 device. 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)

With SD400, you can connect both the stadiometer and blood pressure monitors at the same time.

- 1 Turn off the InBody device.
 - When InBody device is already turned on, the SD400 might not properly connect.
- 2 Connect the serial cable supplied with the SD400 to the right serial port on the rear of the InBody device. Connect the other end of the cable to the serial port of the SD400.
- 3 After connecting the stadiometer or blood pressure monitor to each serial port of the SD400, turn on the power of each device.
- 4 Turn on the InBody device.
- 5 Select **SD400** in Setup  > **3.Connect > Serial** and press **Next**.
- 6 Press **Edit** to configure the device (s) connected to each port of the SD400.



When each device is connected, the standby screen will display a message that the product is connected.

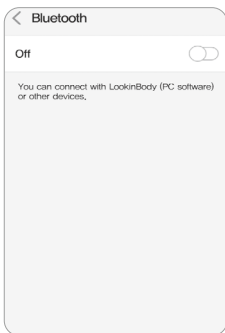
5.8 Connecting Bluetooth


Requirements

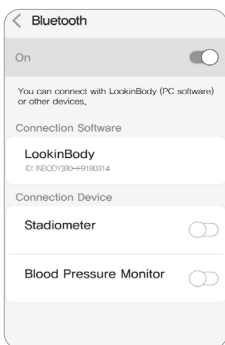
- The compatible device to be connected must support Bluetooth.
- Bluetooth may not operate normally if the compatible device is more than 10m away from InBody device.
- There should be no obstacles such as walls between the InBody device and the compatible device.

Connecting Stadiometer/Blood Pressure Monitor

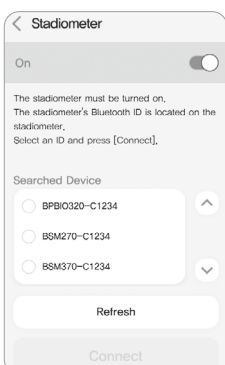
- 1 Press Setup  on the test standby screen or **Setup** button on the keypad of the operation panel before stepping on the footplate.
- 2 Enter the password.
- 3 Select **3.Connect > Bluetooth** and turn on the Bluetooth by pressing ON/OFF  button.



- 4 Press ON/OFF  button of the compatible device that you want to connect to.




- 5 Turn the device (stadiometer or blood pressure monitor) that you want to connect with InBody device.
- 6 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.
- 7 Select the Bluetooth ID of the device to be paired and press **Connect**.

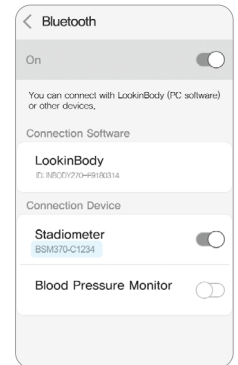


Note



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

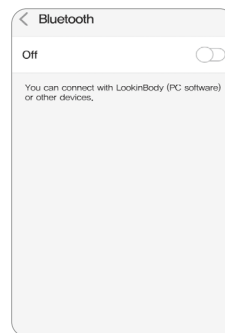
If the compatible device is paired properly, the Bluetooth ID of the device connected to the InBody device will appear.

Press the Exit < on the upper-left to return to the test standby screen. The Bluetooth  icon will be displayed on the upper-left and a message will let you know the device is connected.

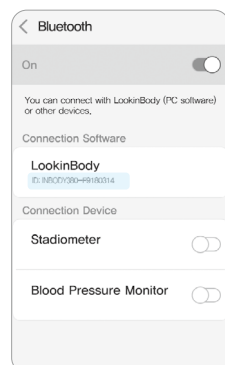


Connecting LookinBody120


- 1 Press Setup  on the test standby screen or **Setup** button on the keypad of the operation panel before stepping on the footplate.
- 2 Enter the password.
- 3 Select **3.Connect > Bluetooth** and turn on the Bluetooth by pressing ON/OFF  button.



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



Note

- Refer to the User's manual of LookinBody120 for more details on how to setup Bluetooth on LookinBody120.
- You can check the Bluetooth ID of InBody in Setup  > **3.Connect > Bluetooth**.



5.9 Connecting Internet

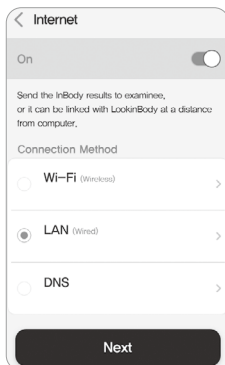
Once InBody device is connected to the Internet, you can use it to connect the Cloud Services or LookinBody120.

Note

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

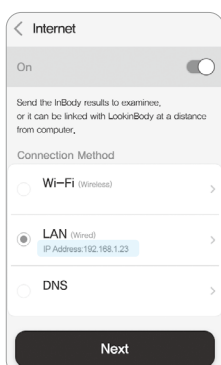
Connecting LAN

- 1 Press Setup  on the test standby screen or **Setup** button on the keypad of the operation panel before stepping on the footplate.
- 2 Enter the password.
- 3 Select **3.Connect > Internet** and turn on the Internet by pressing ON/OFF  button.
- 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 Press **LAN (Wired)** and press **Next**.





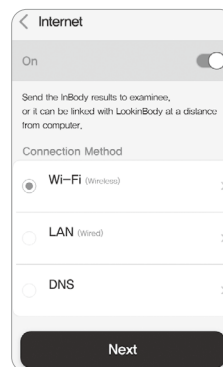
- 6 Select **Automatic** or **Input IP Manually**.
 - **Automatic:** IP address will be automatically set.
 - **Input IP Manually:** You can manually enter the IP address.

Once the device is connected to the internet, the IP address will appear.

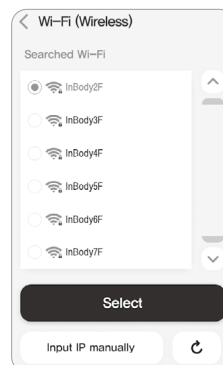


Connecting Wi-Fi

- 1 Press Setup  on the test standby screen or **Setup** button on the keypad of the operation panel before stepping on the footplate.
- 2 Enter the password.
- 3 Select **3.Connect > Internet** and turn on the Internet by pressing ON/OFF  button.
- 4 Press **Wi-Fi** and press **Next**.



- 5 Select the Wi-Fi to be connected and press **Select**.
 - 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 alphabets, numbers, or symbols.

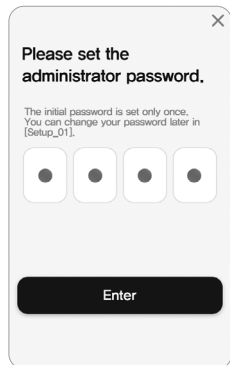


- 6 Enter the Wi-Fi password if needed and press **Enter**.
 - Once the device is connected to the Wi-Fi, the network name (SSID) and IP address will appear.



5.10 IT security measures

InBody would like to clarify that the user access to the InBody380 is only granted for the authorized users, who have appropriately registered the passcode in the system setting menu of the InBody380. The actual steps for registering the access passcodes which is implemented to grant the access to only the authorized users are illustrated with the images of the passcode set ups as shown below:



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 device. Safe, micro alternative currents will flow through the body during the test, but this may cause malfunctioning of the device or endanger lives. InBody Co., Ltd. shall not be liable for any damages to an individual or a device 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.

For an accurate measurement, factors affecting the measurement must be controlled. Please follow the precautions below before the test.

- **Test with empty stomach.**
Food in your stomach affects your weight and is considered part of the body composition, which may affect your test results.
- **Test in the morning if possible.**
In the afternoon, body water tends to be driven to your lower body, which can affect your test results.
- **Test after using the bathroom.**
The volume of urine and excrement is included in the weight measurement affecting accuracy of the test results.
- **Test before exercising.**
Even light exercise can temporarily change body composition.
- **Avoid using the sauna or bath before measuring.**
The body water is temporarily unstable as blood flow rate increases and as you sweat.
- **Measure at room temperature (20 °C - 25 °C).**
The human body remains stable at room temperature, but the body composition may change temporarily in cold or hot conditions.
- **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 as body water tends to move to the lower body.
- During menstruation, there may be temporary fluctuations in fluid levels that can affect the results.

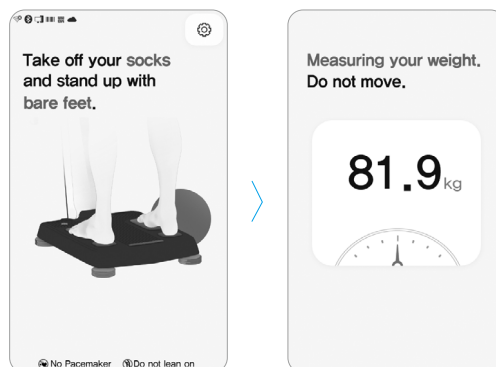
6.2 Test Instructions

The screen displayed during the test varies depending on whether you use **Self Mode** in Setup  > **7.Test Mode & Normal Range** or not.

- **Professional Mode:** The screen is configured for testing with the help of experts.
- **Self Mode:** The screen is configured for testing alone.

- 1 Stand onto the footplate with bare feet on the standby screen.

- InBody starts weight measurement.
- Please make sure that the subject stands alone on the device. It may affect the weight measurement when other people lean or touch the device.



- 2 Input the InBody User ID or height and press **Next**.

- **Professional Mode:** Input ID.
- **Self Mode:** Input height, age, gender.

Input ID.

TEXT

e.g., Mobile no., Chart no.

Next

* If you enter a new ID, you will be required to enter your personal profile.


Guest Test

Professional Mode

Input your height.

e.g., 173 cm

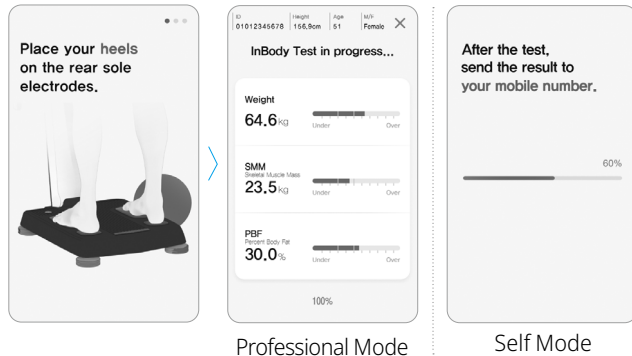
Next

1	2	3
4	5	6
7	8	9
.	0	

Self Mode

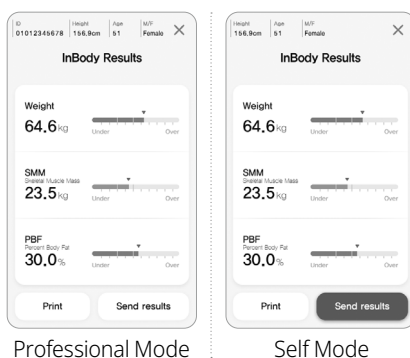
3 Maintain test posture.

- For proper test posture, refer to "6.3 Test Posture".
- The InBody test automatically starts when the body and the electrode are in precise contact.



4 The result screen is displayed after completing the test.

- The Result Sheet is printed out according to your setting when the printer is connected.
- Please refer to "4.3 Overview of the Setup Menu" and "5.1 Printer" for details of printer and Result Sheet setting.



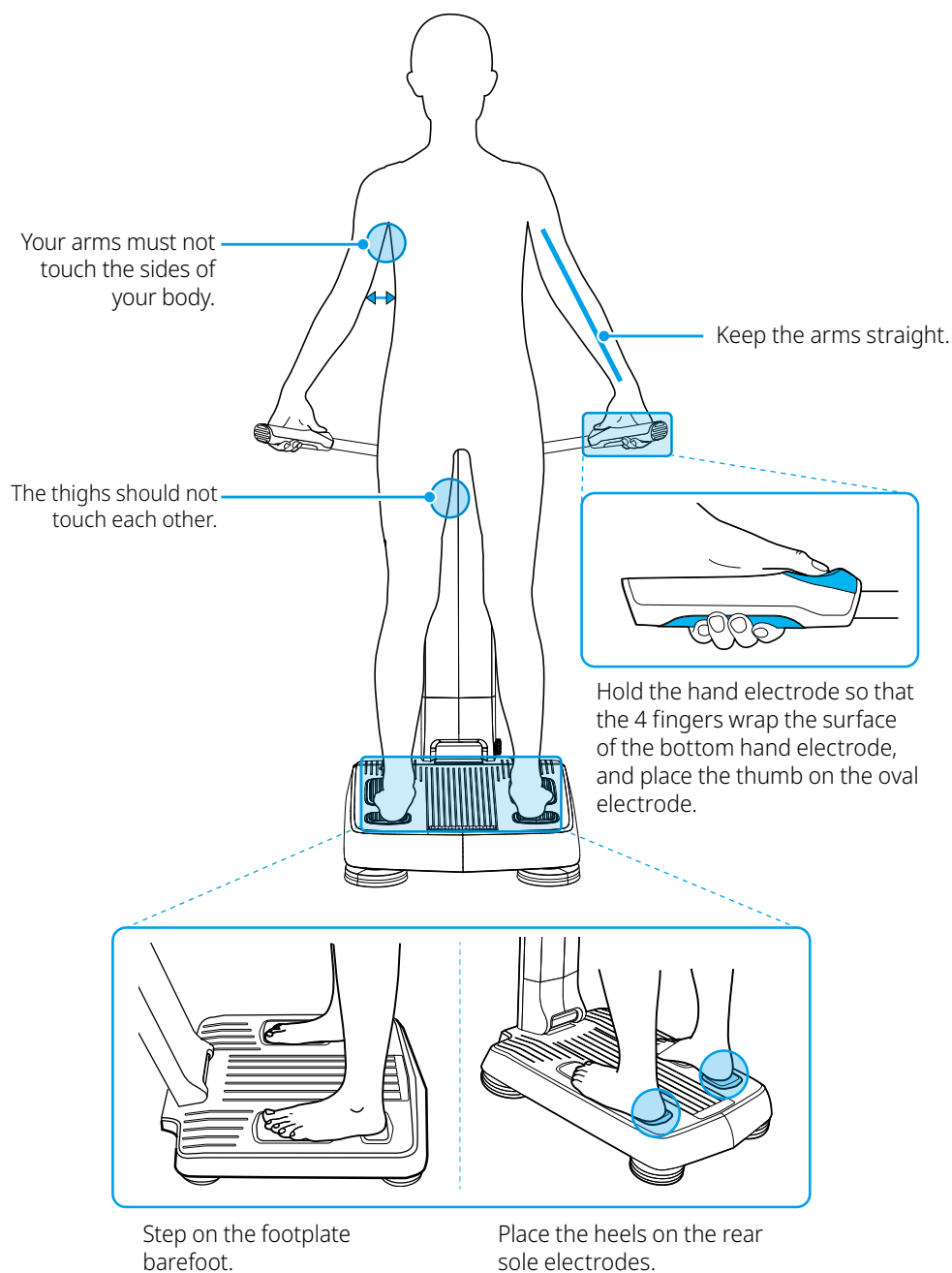
Note

Press the X on the upper-right to end the test.

6.3 Test Posture

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

- The InBody test automatically starts when the body and the electrode are in precise contact.



7 Maintenance and Storage

7.1 Precautions for Maintenance

Caution

- Do not bend the handle or turn it in the opposite direction.
- Do not place anything on the footplate when the device is not in use.
- Be careful not to get foreign materials on the bottom of the device. It may cause weight measurement errors.
- Be careful not to get injured by getting your feet caught in the bottom of the device.
- Turn off the device if you are not using it for a day or longer.
- If you are not using for a long time, unplug the power cord.
- 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.

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

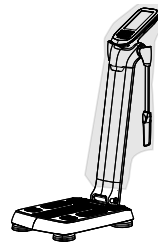
7.4 Repacking and Transportation

Once the device is installed, avoid transporting it. If long distance transportation is needed, repack the product before transporting.

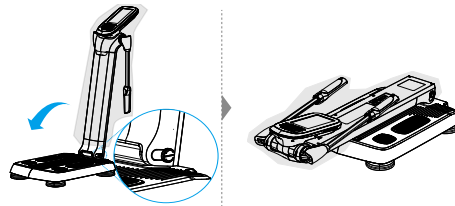
Caution

- When repacking the device, the protective packaging materials provided by InBody must be used.

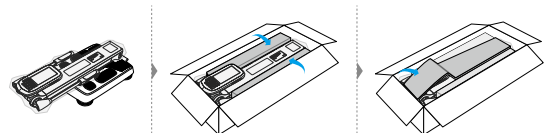
- 1 Turn off the device.
- 2 Turn off the device. Remove all connected adapters and cables. Wrap the upper section of the device with protective packaging vinyl.



- 3 Pull the upper body forward and fold it while keeping the lock bolt of the connecting parts loose.

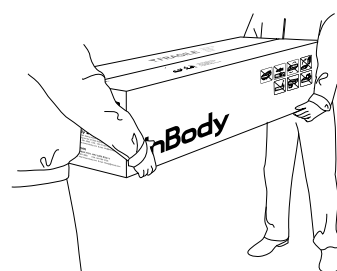


- 4 Place the device into the box. Put the packaging pad as shown in the figure and seal it.



Caution

To transport the device safely, two people should keep it in a horizontal position.



7.5 Storage Environment

The device should be 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)

If a problem arises with the device, you may first attempt to check the Setup ⚙️ > **8.FAQ / Customer Service Information** > **FAQ**. If your problem cannot be resolved through the 'FAQ', please refer to the possible solutions below. If the problem is still not resolved, please contact InBody Customer Service.

8.1 Regarding the Device

Question: InBody Result is not sent to the App.

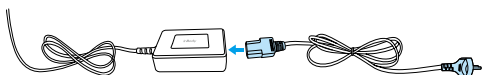
Answer:

- Check whether the Internet connection  icon (Wi-Fi or LAN) and the cloud  icon on the upper-left of the stand by screen are displayed.
- When the Internet connection  icon is not displayed: Connect to the Internet again in Setup ⚙️ > **3.Connect > Internet**. For details on how to connect to the Internet, refer to "5.9 Connecting Internet".
- If the cloud  icon is marked with an X : Check the settings in Setup ⚙️ > **2.Cloud Service**.

Question: Power does not turn on.

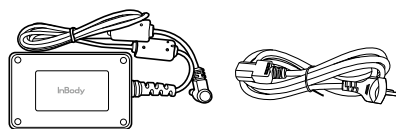
Answer:

- Check if the power cord is correctly plugged into the socket. Make sure to plug the power cord completely into the socket.
- When using a power surge protector, check the power switch on the power surge protector is turned off.
- Check if the power cord is completely plugged into the adapter. Make sure to insert the power cord completely into the adapter.



Answer:

- The problem may occur if you are using a power adapter that was not provided by InBody. Always connect a power adapter (DC 12V, 3.4 A/3.34A) provided by InBody.



Power Adapter

Power Cable

Question: The touch screen does not work well.

Answer:

- Calibrate the touchscreen under Setup ⚙️ > **1.General > 07. Touchscreen Alignment**.
- Press firmly to optimize touchscreen response.

8.2 Regarding of Serious Incidents

If you are aware of a serious incident involving your product, or communicate a corrective action to you clients, 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

Question: Do I have to remove my socks or stockings?

Answer:

If the test is carried out while wearing socks or stockings, the current will not flow smoothly, and the test may not be performed correctly. The skin must be in direct contact with the electrode for testing.

Question: Is it OK to test, wearing accessories or metallic materials?

Answer:

If accessories or metallic objects do not touch the electrodes, they will not have a significant effect on the test result. However, it is not recommended to wear it for accurate test results.

Question: Is there any case where I must not take the InBody Test?

Answer:

A person who is equipped with a medical device that is essential for life support, such as pacemakers or patient monitoring devices, must not take the InBody Test. Electronic medical devices may malfunction due to the current flowing through the human body during the test.

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

Answer: A person who has a metallic material inserted in the body may have different conductivity that may affect the results of the test.

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

Answer:

- The test is available, but the test result may be inaccurate due to poor contacting to the electrode surface.
- InBody has a line of products that conduct body composition analysis in lying posture that allow the patients to stay in bed. For more information, please contact InBody.

Question: Is the current flowing in the test harmless to the human body?

Answer: The InBody does not harm the human body because it uses micro alternative electric current. The safety of the InBody has been proven and is being used by many medical institutions because the InBody has already obtained the national and European medical certificate.

Question: How often should I take the InBody Test?

Answer:

- Testing every other week or once a month can effectively track InBody Test results for exercise prescriptions, hormonal prescriptions, obesity, and rehabilitation.
- It's good to check up often, but it's also important to keep track of your body's changes over time through steady tests.
- Body composition changes can be seen on the InBody result screen and the InBody Result Sheet.

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

Answer: Refer to "6.1 Precautions for Test".

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 InBody380. Upon the comprehensive risk management, the metal patient contacting material of the stainless steel has been evaluated with ISO-10993 biocompatibility testing, particularly with the skin sensitization testing, which has resulted in the 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

- This device was produced according to InBody's quality control procedures. InBody complies with ISO9001 and ISO13485, international quality management systems.
- This device satisfies IEC60601-1 (EN60601-1), an international safety standard for electronic medical equipment, and IEC60601-1-2 (EN60601-1-2), an international standard for electromagnetic compatibility.

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
	EMC Emission	CLASS B
	Degree of protection against water infiltration	IPX0
	Mode of operation	Continuous Operation
This equipment is not suitable for use in the presence of flammable anesthetics or oxygen.		

9.2 Specifications

Bioelectrical Impedance Analysis (BIA) Measurement Items	<ul style="list-style-type: none"> • 15 Impedance Measurements by Using 3 Different Frequencies (5 kHz, 50 kHz, 500 kHz) at Each of 5 Segments (Right Arm, Left Arm, Trunk, Right Leg and Left Leg) • 1 Phase Angle Measurements by Using 1 Frequency (50kHz) at Whole Body
Electrode Method	Tetrapolar 8-Point Tactile Electrodes
Measurement Method	<ul style="list-style-type: none"> • Direct Segmental Multi-Frequency Bioelectrical Impedance Analysis (DSM-BIA) • Simultaneous Multi-Frequency Bioelectrical Impedance Analysis (SMF-BIA)
Body Composition Calculation	No Empirical Estimation (Age and Gender does not affect the result)
Display Type	480 × 800 7inch Color TFT LCD

Internal Interface	Touchscreen, Keypad		
External Interface	Serial(RS-232C): 2 EA, USB (HOST): 2 EA, LAN (10/100T): 1EA		
Wireless Connection	Bluetooth, Wi-Fi		
Compatible Printer	Laser/Inkjet PCL3 or above SPL		
Test Duration	About 30 seconds		
Testing Weight Range	2 - 300 kg (4.4 - 661.4 lb)		
Age Range	3 years and older		
Height Range	95 - 220 cm (3ft 1.40 in - 7ft 2.61 in)		
Logo Display	Name, Address and Content Information can be shown on the Result Sheet		
Digital Results	LCD Screen, LookinBody Web, LookinBody120		
Type of Result Sheets	InBody Result Sheet, InBody Result Sheet for Children, Thermal Result Sheet		
Voice Guidance	Notification sounds (test in progress, saving settings, personal information, etc.) and voice guidance during the test		
Data Storage	Saves up to 100,000 measurements (When ID is entered)		
Test Mode	Professional Mode / Self Mode		
Dimension	415.5 (W) × 871.5 (L) × 1069.9 (H) mm 16.3 (W) × 34.3 (L) × 42.1 (H) in		
Equipment Weight	16 kg (35.3 lb)		
Applied Rating Current	200 μ A (\pm 20 μ A)		
Adapter	Bridgepower (BPM040S12F07)	Power Input	AC 100 - 240V, 50/60 Hz, 1.2A(1.2A - 0.6A)
		Power Output	DC 12V, 3.4A
	MEAN WELL (GSM 40A12)	Power Input	AC 100 - 240V, 50/60 Hz, 1.0 - 0.5A
		Power Output	DC 12V, 3.34A
Operation Environment	10 - 40 °C (50 - 104°F), 30 - 75 % RH(No Condensation), 70 - 106 kPa		

Storage Environment	-10 - 70 °C (14 - 158 °F), 10 - 80 % RH(No Condensation), 50 - 106 kPa
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* Specifications are subject to be changed without prior notice.

* This is a medical device. Please read the WARNINGS and PRECAUTIONS before you use it.

Outputs

Outputs (InBody Results Sheet)	<ul style="list-style-type: none"> • Body Composition Analysis (Total Body Water, Protein, Minerals, Body Fat Mass, Soft Lean Mass, Fat Free Mass, Weight) • Muscle-Fat Analysis (Weight, Skeletal Muscle Mass, Body Fat Mass) • Obesity Analysis (Body Mass Index, Percent Body Fat) • Segmental Lean Analysis • Segmental Fat Analysis • ECW Ratio - Phase Angle • Body Composition History (Weight, Skeletal Muscle Mass, Soft Lean Mass, Body Fat Mass, Percent Body Fat, BMI, ECW Ratio, InBody Score, Basal Metabolic Rate, Visceral Fat Level, Waist-Hip Ratio, Fat Free Mass, Waist Circumference, Obesity Degree, FFMI, FMI, SMI, SMM/WT, Phase Angle_50kHz) • InBody Score • Whole Body Phase Angle (History) • SMI (History) • Body Type (Graph) • 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) • Segmental Fat Analysis (Graph) • Segmental Circumference (Neck, Chest, Abdomen, Hip, Right Arm, Left Arm, Right Thigh, Left Thigh) • Waist-Hip Ratio (Graph) • Visceral Fat Level (Graph) • InBody Score (Graph) • Basal Metabolic Rate (Graph)
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- Research Parameters (Intracellular Water, Extracellular Water, Skeletal Muscle Mass, Fat Free Mass, Basal Metabolic Rate, Waist-Hip Ratio, Waist Circumference, Visceral Fat Level, Obesity Degree, Bone Mineral Content, Body Cell Mass, Arm Circumference, Arm Muscle Circumference, FFMI, FMI, SMI, SMM/WT, Recommended Calorie Intake)
- Calorie Expenditure by Activity
- Blood Pressure (Sys, Dia, Pulse)
- Blood Pressure (MAP, PP, RPP)
- QR Code
- Results Interpretation QR Code
- Whole Body Phase Angle (50kHz)
- Impedance Graph (Each segment and each frequency)

Outputs (InBody Result Sheet for Children)	<ul style="list-style-type: none"> • 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 Curve Outputs (Height, Weight, BMI) • Body Composition History (Height, Weight, BMI, Skeletal Muscle Mass, Soft Lean Mass, Body Fat Mass, Percent Body Fat, Basal Metabolic Rate, Fat Free Mass, Child Obesity Degree, FFMI, FMI, SMI, SMM/WT, Whole Body Phase Angle_50kHz) • Whole Body Phase Angle (History) • SMI (History) • Growth Score • Weight Control (Target Weight, Weight Control, Fat Control, Muscle Control) • Nutrition Evaluation (Protein, Minerals, Body Fat Mass) • Obesity Evaluation (BMI, Percent Body Fat) • Body Balance Evaluation (Upper, Lower, Upper-Lower) • Segmental Lean Analysis (Right Arm, Left Arm, Trunk, Right Leg, Left Leg) • Research Parameters (Intracellular Water, Extracellular Water, Skeletal Muscle Mass, Fat Free Mass, Basal Metabolic Rate, Child Obesity Degree, Bone Mineral Content, Body Cell Mass, FFMI, FMI, SMI, SMM/WT)
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	<ul style="list-style-type: none"> • Blood Pressure (Sys, Dia, Pulse) • Blood Pressure (MAP, PP, RPP) • QR Code • Results Interpretation QR Code • Whole Body Phase Angle (50kHz) • Impedance Graph (Each segment and each frequency)
Outputs (Thermal Result Sheet)	<ul style="list-style-type: none"> • Muscle-Fat Analysis • Obesity Analysis • Segmental Lean Analysis • Segmental Fat Analysis • InBody Score • Research Parameters (Intracellular Water, Extracellular Water, ECW Ratio, Total Body Water, Protein, Mineral, Bone Mineral Content, Body Cell Mass, Waist-Hip Ratio, Waist Circumference, Visceral Fat Level, Obesity Degree, Basal Metabolic Rate, Arm Circumference, Arm Muscle Circumference, FFMI, FMI, SMI, SMM/WT) • Fat Control • Muscle Control • Whole Body Phase Angle (50kHz) • Impedance Graph (Each segment and each frequency).

* Blood pressure information can only be printed when the blood pressure monitor is connected.







* "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 HOST Port

Safety Symbols

	Dangerous High Voltage
	Direct Current
	BF type equipment
 12V — , 3.4A / 3.34A	Power Adapter
	Power On
	Power Off

Etc. Symbols

	Operating Instructions
	Warning / Caution
	Do not disassemble the product arbitrarily.
	European Conformity
	Manufacturer
	Medical Device
	Unique Device Identification
	Serial Number
	Authorized representative in the EUROPEAN COMMUNITY

	Operating instructions
	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	
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, the relative humidity should be 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. 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 maybe 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	28 V/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.
- Do not position so that it is difficult to operate the disconnection device.



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.*
- *Ne pas positionner de telle sorte qu'il soit difficile d'actionner le dispositif de déconnexion.*



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 pulvérisez 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 of InBody380

The key performance claims of InBody380 has 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 InBody380 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 (Models: InBody380). The Body Composition Analyzer of InBody (Models: InBody380) provides clinical benefits to support the aforementioned intended use, as the of InBody (Models: InBody380) in mainly used for healthy and acute 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.

The key performance claims of InBody380 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 %). 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 InBody380.

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