InBody Dial

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. Intended Purpose

The device should be used as an adjunct for clinical decision making and is not intended to diagnose or treat any diseases.

3. 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.

4. 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.

5. 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.

6. 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.

Please note the important information below before reading this 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.

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InBody

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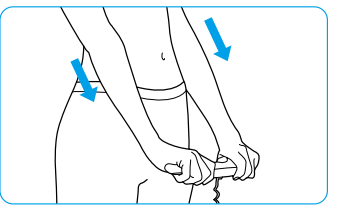
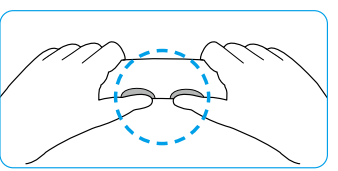
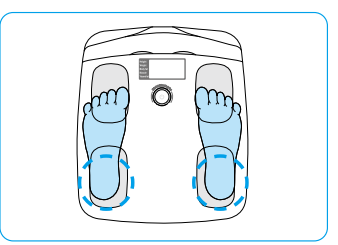
InBody Test Posture



Stretch out your arms.
Avoid contact with your waist.



Put your thumb on the round electrodes.



Place your heel at the end of the heel electrodes and allow the rest of your foot to point forward.

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Product Warranty

1 Precautions

Do not use as follows:

- People with medical devices including an implantable medical device or a patient monitoring device, such as a Pacemaker, should not use the InBody. InBody Co., Ltd. is not liable for any incidental or consequential damages that occur.
- Keep your InBody device away from other electronics while testing. It may cause errors.
- Sterilize the InBody with a soft cloth or with ethyl alcohol wipes before each use. Do not pour liquids onto the InBody. It may cause the product to short circuit or cause electric shock. People with contagious diseases should not use an InBody device.
- Excessively high or low temperatures, humidity, and pressure can affect the accuracy of the InBody. Do not use in a humid place such as a bathroom.
- Keep food, beverages and other liquids away from your InBody device.
- Do not disassemble the InBody. It can cause electric shock or damage, product malfunction, and other errors. InBody Co., Ltd. will not be liable for any incidental or consequential injuries or damages from the product that occurred.
- Do not use this product for purposes other than body composition analysis or weight measurement.

Use as follows:

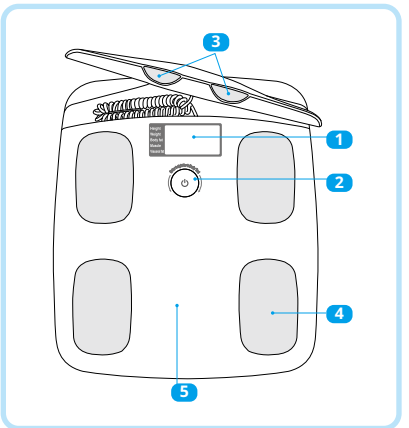
- If you cannot maintain the correct testing posture to take the InBody Test alone, request assistance from a helper. Help children maintain the proper posture during the measurement.
- Place the InBody on a flat and vibrationless floor. Placing it on an uneven floor, like a carpet or a mattress can result in incorrect measurements. For long-term storage, remove the battery pack, and place it on a flat surface.
- Use the packing material provided with the product when moving your InBody. Dispose waste in compliance with the law.
- Only trained InBody service team members can repair InBody devices. If your device is in need of repair, please contact us at contact@inbody.com.

2 Product Components and Set-Up Instructions

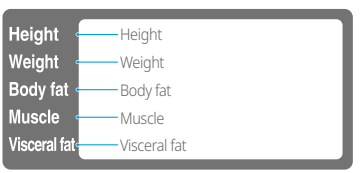
2.1 Product Components

Product components: InBody, User's Manual, AA Battery (4)

Front View



1 **Display screen**: Displays outcomes on the screen.



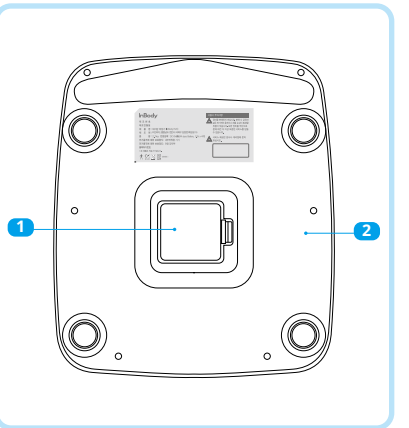
2 **Dial**: Use to power ON/OFF, input height and check results.

3 **Hand electrodes**: User holds the device with hands and fingers.

4 **Foot electrodes**: User stands on the device, placing the back of heels on the rear electrodes.

5 **Footplate**: Measures the weight of the user.

Rear View



1 **Battery insert**: The InBody takes 4 AA batteries. Open the cover to insert the batteries.

2 **Back cover**: Only InBody service team members can open.

⚠ Cautions when Changing Batteries

To reduce the risk of injury and other complications from prolonged battery use, we strongly recommend.

- Replacing the four old AA batteries with four new AA batteries.
- Using four AA batteries of the same make and model for optimum performance.

Please also ensure all batteries are installed correctly; incorrect installation may cause device damage and/ or malfunction.

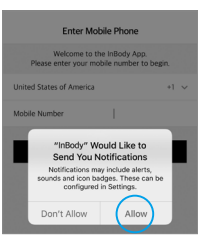
2.2 Installing InBody App

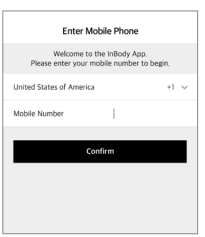
1 Make sure to download and install the InBody App on your smartphone prior to testing. (min. iOS 9.0, min. Android 7.0)

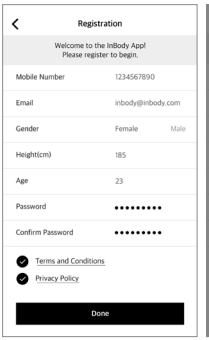
2 Download the InBody App from iPhone App Store and Google Play Store.
Scan the QR Code below to move to the App Download page.
For an Android phone, turn on NFC(Read/ Write) and touch the NFC mark on the rest to move to the app download page automatically.

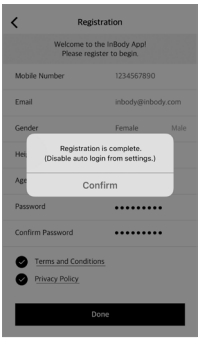
3 Download and run the InBody App for user registration.

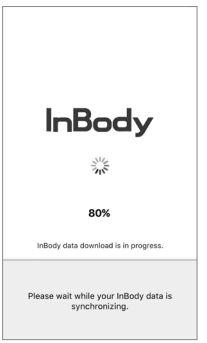
- "QR Code" is registered trademark of DENSO WAVE INCORPORATED.







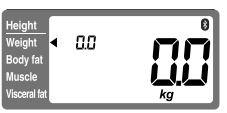




3 Weight Measurement

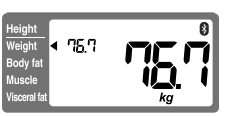
To measure weight only,

1 Tap the footplate to turn the power on, and step on the footplate when 0.0 is displayed on the screen.



2 A "beep" will indicate when the measurement is complete.

- The power turns off automatically when you step off the footplate.



Zero-Point Adjustment

When the device is being calibrated, a scrolling rectangle will appear on the screen.

⚠ Caution

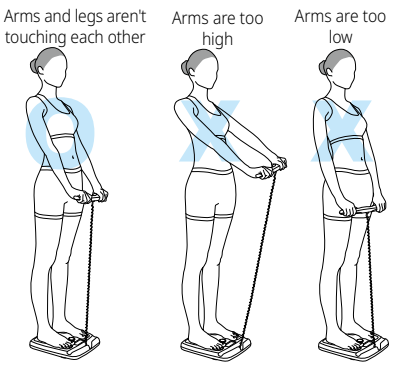
If you want to test on the InBody Dial immediately after measuring weight, turn the dial and input height. Then, hold the hand electrodes and stand with the correct test posture to take the InBody Test.

4 InBody Test

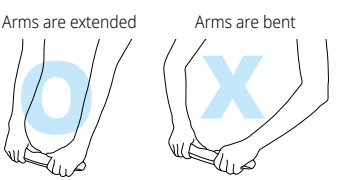
4.1 Precautionary Steps

1. Do not eat immediately before testing on the InBody.
2. Test in the morning, if possible.
3. Test after going to the bathroom.
4. Test prior to working out.
5. Test prior to taking a shower, bath or using a sauna.
6. Stand for about 5 minutes prior to testing.

4.2 Test Posture



Do not let your arms touch your stomach and make sure your arms are extended from your body and wear light clothes with sleeves.

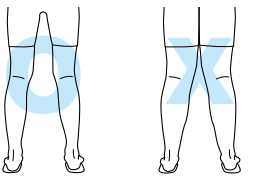


Hold the hand electrodes and extend your arms.

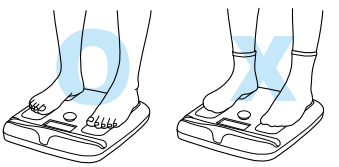
Put your thumbs on the round electrodes and hold them.

Do not let your left hand and right hand touch each other.

Make sure all fingers are holding the electrodes.



Do not let your thighs touch each other. If your thighs touch each other, wear shorts or pants.



Place your heels on the electrodes and step on the device barefoot. Do not let your feet touch each other. If you are wearing long pants, make sure the edges of the pants are not stuck between foot electrodes and your feet.

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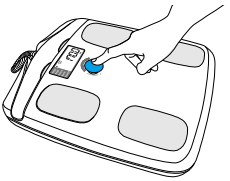
4.3 Test Instructions

1 Power ON: Press the dial to turn the power on.

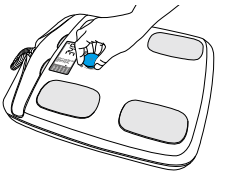


2 Weight Measurement and InBody Test: Step on the footplate barefoot and stand as shown in the figure below.

- Hold the hand electrodes as previously described. After finishing the weight measuring, there is a "toot-toot" sound and the InBody Test begins. The Test runs for about 10 seconds, It completes with a with a "Tu-lu-lu" sound. Once "End" appears on the screen, step down from the footplate.

3 Check Test Result: Turn the dial to enlarge results

- Outcomes will be displayed for 100 seconds after an InBody Test has completed. If the device is not used within that timeframe, it will turn off. To turn off the device immediately after use, press and hold the dial.



⚠ Caution

If a user's palms and/or soles are dry or callused, you may have difficulty testing.
Clean your hands and feet with a wet tissue for more accurate results.

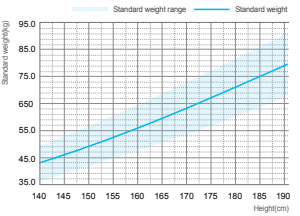
4.4 Understanding InBody Outputs

Body fat mass and muscle mass change with diet and exercise.

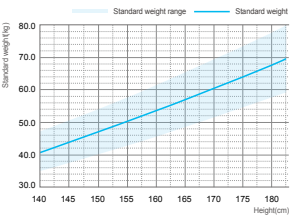
- **Weight** : Total body mass
  - Weight is the total mass of the human body.
- **Percent Body Fat** : Total mass of fat mass divided by total body mass
  - A person's body fat percentage is the total fat mass divided by the person's weight. It consists of essential body fat and storage body fat. Although the weight is same, the percentages of fat or muscle mass can be different. Therefore, body fat percentage is an essential item for diagnosing obesity. The standard range is 10-20% for men and 18-28% for women. The standard body fat percentage differs for children under 18 depending on their gender and height.
- **Muscle Mass** : Skeletal Muscle Mass
  - Skeletal muscle represents the majority of muscle tissue and powers movement of the skeleton. Skeletal muscle is innervated by the somatic nervous system and is subject to voluntary control. This is the muscle that is influenced the most by physical activity.
- **Visceral Fat** : Fat surrounding the major organs
  - Fat around organs is shown in levels between 1 and 20. People with visceral fat levels above 10 are considered unhealthy and are at higher risk for diseases like heart disease, cancer and sleep apnea.

4.5 Standard Range Graph of Weight and Muscle Mass

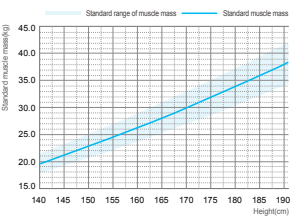
Standard Weight of Adult Men by Height



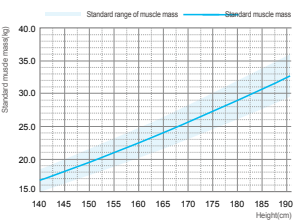
Standard Weight of Adult Women by Height



Standard Muscle Mass of Adult Men by Height



Standard Muscle Mass of Adult Women by Height



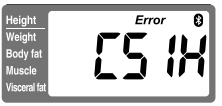
5 Troubleshooting

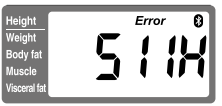
5.1 Error Message

The InBody displays an error message on the LCD screen if a disruption occurs.

1 Error messages appearing when your hands and feet are away from the electrodes during the measurement

- If the following error messages appear, check your testing posture and try again.





2 Error messages caused by internal malfunction of InBody

- If the following error messages appear, please contact us at homehealth@inbody.com.

5.2 Solving Simple Problems

If the problem still persists, please contact us at homehealth@inbody.com if you are in need of assistance.

Question: The power does not turn on after pressing the dial.

Answer:

- This can happen when the batteries are dead. Replace the batteries.
- This can happen when the batteries are not inserted correctly. Insert the batteries so the positive (+) and the negative (-) terminals align correctly.

Question: Weight is not measured and the screen displays a scrolling rectangle.

Answer:

- Tap the footplate to turn on the device. Once 0.0 appears on the LCD screen step on the footplate and measure the weight.
- Make sure to remove any foreign object that might be touching the device.

Question: Weight is strange.

Answer:

- Tap the footplate to turn on the device. Then check if 0.0 appears on the LCD screen after 2-3 seconds.
- The weight can be inaccurate if you use the device on carpet or a mattress. Place the device on a flat, hard surface.

6 Frequently Asked Questions (FAQ)

If your question is not listed here, please contact us at Homehealth@inbody.com if you are in need of assistance.

Question: How accurate is the outcome value?

Answer: This InBody product has a 93% correlation with DEXA.

Question: The InBody Test results vary. Why is there a difference in outcomes?

Answer: If you are standing with incorrect posture, outcomes will vary. Make sure client's hands and feet are come in contact with the electrodes properly. Maintain this posture until the Test is complete.
If you have dry hands and/or feet, clean them with an alcohol-based disinfectant (e.g.70% ethanol) or antibiotic wet tissue before testing.
InBody recommends testing at the same time, under the same conditions for best accuracy.

Question: What is the normal range of visceral fat level?

Answer: Visceral fat level is InBody's method of level display which leveled cross section of visceral fat from 1 to 20. For adults, it is normal if visceral fat level is below 10.
The lower the visceral fat level, the better.

Question: What is the standard range of body fat percentage?

Answer:

Gender	Low	Standard	High
Man	below 10%	10 - 20%	over 20%
Woman	below 18%	18 - 28%	over 28%

(Adults over 18)

Question: What does my InBody Ranking mean?

Answer: Your InBody Ranking is based off a formula that compares your weight, muscle mass, and body fat mass. A person with a high body fat percentage would have a lower score than a person with a lower body fat percentage. Lose body fat mass to see your ranking increase. The InBody Ranking is not an absolute science, but it's a good way to stay motivated and track your progress.

Question: What if the user does not know his or her height?

Answer: Height is important for obtaining accurate InBody Test results. Measure the user on a stadiometer like the InBody BSM-170 for best results.

Question: If the user's thighs or armpits touch, would that affect the test results?

Answer: Yes. If the user's thighs or armpits touch, have him or her wear a light short sleeve shirt and shorts to obtain more accurate outcomes.

Question: How do you make the results stay on the screen longer?

Answer: InBody Test results are shown on the LCD screen for 100 seconds. If you want to see it for a longer period of time, turn the dial.

6.1 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.

6.2 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 H20B.

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.

6.3 Cleaning

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

6.4 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 Others

7.1 Symbols used on the Product

Safety Symbols

	Operating Instructions
	Warning / Caution
	BF type equipment
	Power Adapter
	Power On
	Power Off

Etc. Symbols

	Direct Current
CE 1639	European Conformity
	Manufacturer
SN	Serial Number
EC REP	Authorized representative in the EUROPEAN COMMUNITY
	Operating instructions
MD	Medical Device
UDI	Unique Device Identification
REF	Catalogue number
	Importer
	Country of manufacture
	Do not disassemble the product arbitrarily.

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.

7.2 Classification

Body Composition Analyzer of Direct Segmental Multi-frequency Bioelectrical Impedance Analysis Method.

- Type of protection against electric shock: Internal Power Supply
- Degree of protection against water infiltration: Standard Equipment (No special protection against external water infiltration)
- Not suitable for use with air, flammable an anesthetic gas, or oxygen/nitrogen dioxide/ flammable an anesthetic gas
- Operation mode: Continuous Operation
- Type of the applied parts: BF Type

7.3 Specifications

Outputs	Bioelectrical Impedance(Z) : 10 Impedance measurements are taken by using two(2) different frequencies (20kHz, 100kHz) in each of the five (5) segments (right arm, left arm, body, right leg, left leg)
Electrode Type	Tetrapolar 8-Point Tactile Electrode Methods
Measurement Method	Direct Segmental Multi-frequency Bioelectrical Impedance Analysis Method, DSM-BIA type
Body Composition Calculation	No Empirical Estimation
Outputs (LCD Screen)	Weight, Body Fat (Percent Body Fat), Muscle (Skeletal Muscle Mass), BMI

7.4 Specifications

Operating Current	100μA
Power Consumption	DC 6 V (1.5V AA battery 4EA)
Display Type	Customized LCD
Dimension	310.3 (W) × 356.4 (L) × 58.3 (H): mm 12.2 (W) × 14 (L) × 2.3 (H): in
Device Weight	2.7 kg (6 lbs)
Measurement Time	Within 5 seconds after measuring impedance
Operation Environment	10 ~ 40°C, 30 ~ 75% RH, 70 ~ 106 kPa
Storage Environment	−20 ~ 70°C, 10 ~ 95% RH, 50 ~ 106 kPa (No Condensation)
Weight Range	10 - 150 kg (22 - 330 lbs)
Height Range	95 - 220 cm (3 ft 1.40 in - 7 ft 2.61 in)

* Specifications may change without prior notice.

7.5 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, 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.
Radiated RF IEC 61000-4-3	6 Vrms 150 kHz – 80 MHz In ISM bands[1] amateur radio bands Bands[2]	6 V	Recommended separation distance $d=1.2\sqrt{P}$
	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	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.

7.6 Key Performance Claims of InBody H20B

The key performance claims of InBody H20B 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 InBody H20B 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: InBody H20B). The Body Composition Analyzer of InBody (Models: InBody H20B) provides clinical benefits to support the aforementioned intended use, as the of InBody (Models: InBody H20B) 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 InBody H20B 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 InBody H20B.

Product Warranty

Name of Product : InBody Dial

Product No :

Date of Purchase :

Place of Purchase :

This product warranty gives an assurance for the InBody product as below:

1. This product undergoes a strict review process to ensure quality control
2. The warranty period of this product follows the warranty period policy of the manufacturer.
3. If the product malfunctions under normal use, InBody will repair it, free of charge during the warranty period.
4. The warranty will be voided and repair services will be offered at cost under the following circumstances:
   - Failure and/or damage caused by mishandling.
   - Failure and/or damage caused by not following the directions and precautions stated in the User's Manual.
   - Failure and/or damage caused by a natural disaster.
   - Failure and/or damage caused by a power malfunction.
5. The warranty will be voided if:
   - The InBody was disassembled by unauthorized personnel.
   - The InBodyh was repaired by unauthorized personnel.
6. Services are available at a cost after the warranty period.
   Contact us at Homehealth@inbody.com if you are in need of assistance.

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