Intelligent Impedance Instruments

FAQ

Frequently asked questions about bioimpedance analysis and Imp DF50 device

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What is BIA?
Bioimpedance analysis (BIA) is the process of non-invasively determining body composition data.

How does BIA work?
Bioimpedance devices pass a low-strength alternating current into the body. The way in which this current is retarded or impeded by the body allows for the determination of that body's composition.

What is meant by body composition?
In a simplified way, the body can be thought of as several compartments; the bone, the fat, the muscle, organs, the fluid surrounding these tissues and fluid contained inside these tissues.
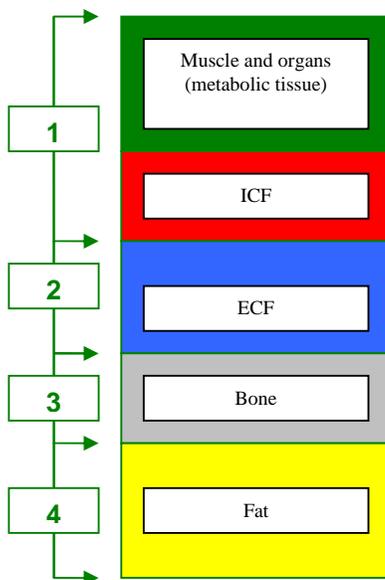
1. The muscles and organs: The tissues of the body comprised of cells which contain the intracellular fluid (ICF). The ICF is also conductive.

2. The extracellular fluid (ECF): The fluid surrounding the cells and tissues of the body which contains many electrolytes making it conductive

3. The bone and mineral content of the body which is non conductive

4. The fat: The fat of the body which is essentially an insulator containing very little conducting fluid and can be considered non-conductive.

How is the signal passed into the body?
The low strength current is passed into the body by the use of silver-silver chloride gel electrodes placed onto the hands and feet of the subject.

For the hand
1. between the bony protuberances of the wrist
2. towards the base of the knuckle, 5cm from (1)

For the foot
1. at the front of the ankle between the ankle bones
2. toward the base of the toes, 5cm from (1)
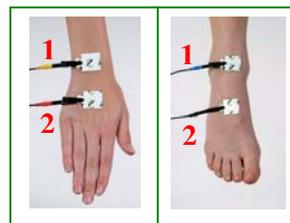
Does the measurement procedure cause any pain or discomfort to the subject?
No, the procedure is totally painless.

How long does the measurement take?
ImpediMed® devices make very quick measurements; an operator familiar with the device and procedure can conduct a total body composition analysis in less than 2 minutes.

Does the subject need to be lying down during a measurement?

All measurements should be taken in the supine position as standing can cause instability in the readings and fluid levels/changes. The subject should lie down with feet shoulder width apart and hands by side. The subject should not move during the measurement.

What body composition data is generated in the standard total body measurement?

TBW = Total Body Water
The amount of conductive fluids in the body, *i.e.* the ICF + ECF.
ICF = Intracellular Fluid
The total sum amount of conductive fluids that reside inside the cells of the body.
ECF= Extracellular Fluid
The total sum amount of conductive fluids that reside outside the cells of the body.
FFM = Fat-free Mass
The total sum amount of lean tissue mass of the body.
FM = Fat Mass
The total sum of the fatty tissue in the body which is calculated by subtraction of FFM from body weight.

What sort of gel electrodes should be used?

ImpediMed® recommends using only the ImpediMed® gel electrodes which have been validated for use with our BIA and BIS devices.

How many times can the electrodes be used?

The electrodes can only be used once. Build up of skin debris and dehydration resulting from re-use will affect the readings.

To what standard are ImpediMed® devices manufactured?

The ImpediMed® products are manufactured to the ISO 13485: 2003 Medical Device Standard.

Can BIA measurements be taken on a subject with a pacemaker or defibrillator?

ImpediMed® advises that ImpediMed® BIA and BIS devices are not to be used on people with pacemakers and/or defibrillators.

Can a BIA measurement be made on pregnant women?

ImpediMed advises that the Imp™ DF50 is not to be used on pregnant women. Until studies are conducted by ImpediMed® we cannot remove this limitation. While numerous BIA studies have been conducted on pregnant patients they were done under independent IRB approvals and separate to the manufacturer's claims.

How often can BIA measurements be taken?

Bioimpedance measurements can be taken as many times as the client wishes. Unlike X-ray technology, there is no limit on how many measurements can be taken over a given period of time.

Is there a best time of the day to have measurements taken?

For long-term monitoring of body fluid levels, it's advisable to take measurements at consistent times relative to the first measurement. For consistency, the subject should follow the same pattern of activities if possible. For example, if readings were done early morning with an empty bladder, then equivalent conditions would give better accuracy/precision for longitudinal monitoring.

What factors affect BIA readings?

- Athletic activity: BIA readings are best taken when the subject is at rest. The subject should not have previously engaged in heavy exercise, such as running or sports just prior to measurement. ImpediMed® recommends that subjects be of normal activity levels before measurement.
- Dehydration: BIA readings are best taken on normally hydrated people
- Temperature: BIA readings are best taken at room temperature
- Position: always take the measurement with the subject in the supine position
- Ensure the subject has no direct contact with large metal objects during the reading
- Ensure the subject has removed jewellery and watches from the hands and wrist to which the electrodes are applied.

Device specific: The Imp™ DF50 SF-BIA device

What do you mean by single frequency (SF) BIA device?

Single frequency BIA simply means that the drive current is of a single alternating frequency, in the case of the Imp™ DF50 this is 50 kHz.

What does DF50 stand for?

Dedicated frequency 50 kHz.

What is the significance of the 50 kHz frequency of the drive signal?

50 kHz is the average characteristic frequency for the human population. The characteristic frequency is the frequency at which the drive current will travel through both the intracellular and extracellular fluid of the body. Each person will have their own individual characteristic frequency ranging from 35-110 kHz but the average for the human population is approximately 50 kHz.

Why is the ability of the current to travel through the extra and intracellular fluids important?

This gives us the ability to determine the impedance due to the total body fluids and thus get full body composition analysis.

- **TBW = Total body water**
- **ICF = Intracellular Fluid**
- **ECF= Extracellular Fluid**
- **FFM = Fat-free mass**
- **FM = Fat mass**

What population groups can I use the Imp™ DF50 on?

The Imp™ DF50 has three population-specific body composition algorithms:
1. Child: healthy subjects under 16 years of age
2. General: healthy subjects of Body Mass Index (BMI) under 30 and over the age of 16 years
3. Obese: healthy subjects with a BMI greater than 30 and over the age of 16 years

What is BMI?

BMI or body mass index (height^2/weight), is calculated by the DF50 and displayed onscreen. BMI is an index defining weight ranges and was developed by the National Institutes of Health (NIH USA). The NIH defines the weight ranges of the human population as follows:

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BMI Ranges
< 18.5, 18.5-24.9, >25-29.9>30.0
Underweight, Normal, Overweight, Obese

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What is meant by prediction algorithm?

Single Frequency (SF) BIA technology relies on the use of prediction algorithms to determine body composition from the raw impedance data. The prediction equations used in the Imp™ DF50 are public domain and come from peer-reviewed scientific publications. These algorithms were created through population studies that accumulated raw impedance data compared to gold standards of body composition such as hydrostatic weighing and deuterium dilution. This data was then used to calculate the prediction equation using regression analysis.

What is meant by raw impedance data?

Raw impedance data is the electrical analysis of the drive current after it travels through the body which the Imp™ DF50 measures. This data is represented as follows:

Impedance (Z): Total opposition of a body to alternating current and denoted by Z.

Phase Angle (Ph): Voltage lags current – represented as an angle of the sinusoidal wave form (8 to 15). Pure water would have a phase angle of 0%, a hypothetical body containing only cells 100%.

Resistance (R): Pure resistive opposition of conductor to alternating current.

Reactance (Xc) Opposition due to capacitive nature of cells. The cell membrane acts as a battery storing charge until the capacitance of the membrane is overcome and the current is able to pass through the cell. This is defined as the reactance, or Xc.

Some competitor devices provide little or no access to the raw data used in their analysis. ImpediMed® offers "data transparency" driven by the desire to provide the user and customers with the raw impedance data that is used to generate analysis for all our impedance instruments. For the Imp™ DF50 this allows the user the option of an in depth look at how the data follows the analysis of the body composition.

How accurate are these prediction algorithms?

The prediction algorithms are accurate when used on the population from which the algorithms were created. These are peer-reviewed public domain algorithms that have been validated against gold standards such as hydrostatic weighing and radioisotope dilution studies.

What body composition data will the Imp™ DF50 display?

The Imp™ DF50 will display:

- o   TBW = Total Body Water
- o   ICF = Intracellular Fluid
- o   ECF= Extracellular Fluid
- o   FFM = Fat-Free Mass
- o   FM = Fat Mass
- o   BMI = Body Mass Index

Can I get access to the raw impedance data used by the Imp™ DF50?

Yes, the Imp™ DF50 displays the raw impedance data at 50 kHz. Please consult your Imp™ DF50 manual to see how to access this data.

The Imp™ DF50 software utilises normal ranges for %Fat Mass comparisons, where do these normal ranges come from?

The default %FM reference ranges used in this software were adapted from the following peer-reviewed publications.

%FM for male and female children: HD McCarthy, TJ Cole, T Fry, SA Jebb and AM Prentice. Body fat reference curves for children. International Journal of Obesity (2006) 30, 598-602.

% FM for male and female adults: D Gallagher, SB Heymsfield, M Heo, SA Jebb, PR Murgatroyd and Y Sakamoto. Healthy percentage body fat ranges: an approach for developing guidelines based on body mass index1-3. Am J Clin Nutr 2000; 72:694-702.

I have heard that cellular age and health can be measured by looking at Phase angle. Does the Imp™ DF50 calculate cellular health since it is a Phase-sensitive instrument?

The Imp™ DF50 is one of the few phase-sensitive single-frequency devices available. Phase angle can give an indication of the average integrity of the cell membrane. However, the scientific community is still undecided whether this measurement can be accurately used to determine cellular health.

The Imp™ DF50 is battery operated. How many measurements can I take before replacing the batteries?
The Imp™ DF50 will operate for 7 hours with intermittent use with each set of new batteries. An indicator will inform the operator when battery power is running low.

Can I use rechargeable batteries in the Imp™ DF50
No. The Imp™ DF50 should be used with the non-rechargeable alkaline AA 1.5 V batteries

Does the Imp™ DF50 come with software?
The Imp™ DF50 is supplied with Imp™ DF50 body composition analysis software that is client specific and database driven allowing for longitudinal tracking of each subject's condition over time. This charting ability is possible for all data measured by the Imp™ DF50 including the raw impedance data. Examples of the charting options include:

- o FFM over time
- o Weight over time
- o Weight, FM and FFM over time

An advantage of this software is that all measured data is saved into the database automatically on upload and that any parameter measured can be charted and printed as a hard copy retrospectively. This database storage ability provides flexibility to the user in assessing and monitoring of the subject.

In addition, if the wrong prediction equation was used in the first measurement the software is able to generate the body composition data by simply choosing the correct algorithm. All these charts can be printed as a hard copy.

Does the Imp™ DF50 software generate standardised reports?

Yes, the software generates two standardised reports, one for Fat Mass and one for Total Body Composition. In addition, the software can be used to track any user defined parameter. These can also be produced as separate reports. Each of the reports has an option to include user's entered clinical notes. All reports can be printed or saved as PDF if the user has a PDF making program installed on their computer.

The Imp™ DF50 body composition analysis software displays Basal Metabolic Rate (BMR), what is this measurement referring to?
Basal Metabolic Rate is the minimal caloric requirement needed to sustain life in a resting individual. This is the amount of energy your body would burn if you slept all day (24 hours). Some factors that affect BMR are

- o *Age*: In youth, the BMR is higher; age brings less lean body mass and slows the BMR.
- o *Height*: Tall, thin people have higher BMRs.
- o *Growth*: Children and pregnant women have higher BMRs.
- o *Body Composition*: The more lean tissue, the higher the BMR. The higher a subject's fat mass (FM), the lower the BMR.

Can the Imp™ DF50 store measurement files internally?
No. The Imp™DF50 displays only one measurement set. The measurement data should be uploaded to your data base driven, client-specific software after each measurement run. The software allows for graphical representation of each data point over time allowing for easy monitoring of all body composition parameters. The software also provides the ability to print these charts and has an overall report which provides the subject and user with a hard copy of all the subject's details and measurements. An advantage of this software and its easy to use upload feature is that all measured data is uploaded into the database and that any parameter measured can be charted and printed as a hard copy over time.

How do I transfer the measurement data from the Imp™ DF50 to the DF50 body composition analysis software?
The raw impedance data (R and Xc) is simply entered manually into the DF50 body composition analysis software. The Imp™ DF50 has an Infrared (IR) download ability and has the option of an additional IR adapter that allows easy and real-time download of the subject's body composition data to the DF50 analysis software.

What operating systems does the DF50 body composition analysis software run on?
The DF50 analysis software will run on Windows® Vista and Windows® XP platforms.

Is there a way to check if the device is functioning correctly?
Yes. The Imp™ DF50 comes with an easy to use test cell to check the raw impedance readings are within specification and verify that the device is working properly.

If a subject has a BMI over 30 do I measure them on the obese equation?
Yes.

If a subject has a BMI over 30 and is under the age 16 what prediction algorithm should I use, Child or Obese?
An obese child is best measured using the child equation to monitor relative change in body composition.

If I have a subject that loses weight taking them below the BMI of 30 should I switch to using the general algorithm from the obese algorithm?
ImpediMed® recommends that the subject be measured on the same algorithm as the baseline to allow for consistent longitudinal analysis. The BMI and age-specific algorithms are there to be used as guidance to allow users to choose a more accurate algorithm for the first-initial BIA measurement. Subsequent measurements that are to be compared to this first measurement should be conducted using the same algorithm. Switching algorithm mid-timeline will cause a shift in the data and make comparisons difficult.

Can I use the Imp™ DF50 on animals?
The Imp™ DF50 is not designed for use on animals.

Does the Imp ™ DF50 software display body cell mass or extracellular mass.
No, ImpediMed® has a strict code of adherence to the FDA regulations and for this reason does not promote the use of non-FDA approved parameters in the United States of America. BIA devices and associated software that are supplied to the USA that do display these parameters are doing so off label as these parameters for Bioimpedance Analysis are yet to be approved by the FDA.