DataInput
Body Composition

NutriBox

Instructions for Use

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Contents

Instructions for use

Abbreviations

BIA ..... Bioelectrical Impedance Analysis
Z ..... Impedance
R ..... Resistance
Xc ..... Reactance
kHz ..... Kilohertz
CA ..... Cable
TBM ..... Total Body Measurement
R ↑ ..... Hand resistance
R ↓ ..... Foot resistance
ϕ ..... Phase angle (PhA)
KZ ..... Body Composition
BCM ..... Body Cell Mass

These Instructions for Use are part of this product. They contain important information about the set-up and the use of the product! Be aware of this even if you give this product to a third party. Keep these instructions stored safely.

1. For safety

Please read the operating instructions completely, as they contain information on safe handling.

2. Intended use

The Bioelectrical Impedance Analyzer (BIA device) of the NutriBox type was developed to be able to measure 2 physical resistances in humans. From these two resistances, published formulas can be used to calculate the phase angle and estimate the body composition (anatomical structure) and nutritional status.

This knowledge is helpful in assessing the nutritional status of lean mass. About other formulas one gets a clue about the total amount of fat. Since the formulas for fat calculation are based on statistical principles, this possible statistical error must be taken into account for the result of the individual measurement.

Therefore the special advantage of the BIA measurement lies in the consideration of course measurements - especially of the phase angle - where a part of the statistical error does not come into effect due to the individuality. Interventions can thus be assessed very well in terms of their effect.

Operation and storage:
Your device is always ready for operation when it is connected to a switched-on PC.

Avoid extreme heat or cold during operation. Permissible ambient temperature during transport and storage: -10° C to +40 °C.

Wichtig: For legal reasons, do not use the device on pacemaker wearers unless you have permission from the pacemaker manufacturer to perform BIA measurements.

3. Bioelectrical Impedance Analysis (BIA)

BIA is the measurement of electrical resistance in an organic body. A constant field of alternating electric current is created in the patient's body, via electrodes on the skin, and the total resistance = impedance (Z), is measured in Ω (Ohms).

The impedance of a homogeneous, biological conductor consists of two vectors: the resistance (R) and the reactance (Xc).

The resistance R is the pure opposition of a conductor to an alternating current and is indirectly proportional to total body water. The high percentage of water and electrolytes in the lean body mass makes it a good electrical conductor whereas fat mass has a high opposition.

The reactance Xc (capacity) is the opposition which a condenser offers to alternating current. Each cell membrane in the body acts as a mini-condenser because of its protein lipid layer. The reactance is therefore a measurement of the body cell mass.

To determine both these components of impedance modern BIA apparatus possess phase sensitive electronics. The principle of measurement is based upon a time difference (Δt). This occurs in the condensers in a field of alternating current: the current flows faster than the potential difference. Because alternating current has a sinusoidal form it is measured in ° (degrees) and known as phase angle (ϕ). If the mass consisted purely of cell membranes the phase angle would be 90 degrees. Pure electrolyte water has a phase angle of 0 degrees. The measurement apparatus Nutriguard-S measures the above-named parameters and is the basis for further analysis of body composition.

In addition to further information about the patient (weight, height, sex, age) a detailed analysis of body composition can be calculated using the 3 parameters resistance, reactance and phase angle. Published formulae and special software which contains the appropriate statistical data is used to achieve the diagnosis.

4. Scope of Delivery

Please check the contents of the impedance measurement apparatus for completeness.

- Impedance analysis apparatus NutriBox
- Measurement cable CA
- USB-C-cable
- Transport bag
- Test board
- Analysis software NutriPlus 7.0

5. Description of Apparatus

1. Apparatus Measurements:
   Length: 152 mm, Width: 225 mm,
   Height: 55 mm, Weight: approx. 650 g

2. Front:
   Connection box for the measurement cable

3. Back:
   On the rear you will find a USB port to automatically transfer the measurement data to the analysis software NutriPlus 7.0.

4. Body of apparatus:
   Please note that the box may only be opened by your responsible dealer.

5. Using the Apparatus:
   Please install the software NutriPlus 7.0 and make sure that the apparatus is connected to your PC via the provided USB cable. When the NutriBox and your PC are connected, an acoustic signal is emitted from each of the devices to indicate, that they are ready to measure. You can only initiate a measuring process via the software. A beep sounds at the beginning of the measurement and another beep signals the end of the measurement associated with the entry of the measurement results into the software. The measured values (raw data) are displayed in the software in the fields for R and Xc.

Disassembly note: To remove the measuring cable from the BIA device, grasp the measuring cable at the movable connecting element and pull. **Do not pull on the cable itself!**

Measurement cable

Electrodes

USB-C-cable

Test board

Transport bag

6. Technique of Measurement

In order to carry out BIA measurements you need:

- A possibility to lie down
- A medical scale (optional)
- A BIA apparatus including measurement cables and special electrodes
- Disinfectant and swab
- A PC with analysis software NutriPlus 7.0

Precise and reproducible results of measurements can only be achieved by using an accurate technique of measurement. E.g. a differing positioning of the electrodes of just 1cm can cause a deviation of measurement of up to 20 Ohms. This corresponds to about 1l of body water of a total body measurement.

Carrying out the Measurement:

1. Indication/Contraindication
The measurements can be carried out on people of all ages. There are no illnesses which are in contraindication to the impedance measurements. In principle, patients with a cardiac pacemaker can be measured without any side-effects. Contraindication: Even though there are no known incidents world-wide as a result of a BIA measurement, patients with a defibrillator implant should not undergo a measurement. The possibility that the induced field of electric current during a measurement could activate the defibrillator cannot be definitely eliminated. Because it is often not possible to give specifications on the type of pacemaker, you may refrain from carrying out the measurement on patients with a pacemaker generally.

2. General Preparations

- The patient should be nil by mouth (NBM) for 4-5 hours
- The last sporting activity should date back 12 hours
- The last consumption of alcoholic beverages should date back 24 hours
- The extremities should have the temperature of regular skin circulation

3. Preparation of Measurement
3.1 The patient should be in a relaxed horizontal position for the measurement. The patient usually lies on his back but it is also possible to carry out the measurement with the patient lying face down. Please note that variations from the horizontal position or strong tensions in the extremities can influence the measurement data. The patient should lie still for a few minutes until the blood volume is spread evenly throughout the body.

3.2 The patient's legs should lie apart at approximately 45° so that the thighs do not touch each other. The arms should be spread at approximately 30° and should not touch the rest of the body. Contact between the legs and the arms and the torso may shorten the flow of the electric current during the impedance measurement and may influence the results. Please make sure that the BIA measurement is carried out on a flat surface which fits the size of the patient.

3.3 During the measurement the extremities should remain at the same level as the rest of the body. Should an arm or a leg be higher or lower the results will be influenced.

3.4 The patient should have no contact with metal objects (e.g. the bed frame). However, jewellery, ear rings or watches worn on the body or osteosynthetic plates and pacemakers in the body have no influence on the results.

3.5 For reasons of standardisation the measurement should be carried out on the dominant half of the body. In most cases this is the right side (right hand, right foot). Continuing measurements should always be carried out on the same side.

3.6 The hand and foot which are connected to the electrodes should be bare for measurement. Compressing bandages change the fluid concentration of the extremities and may influence the measurement results.

4. Positioning of Electrodes

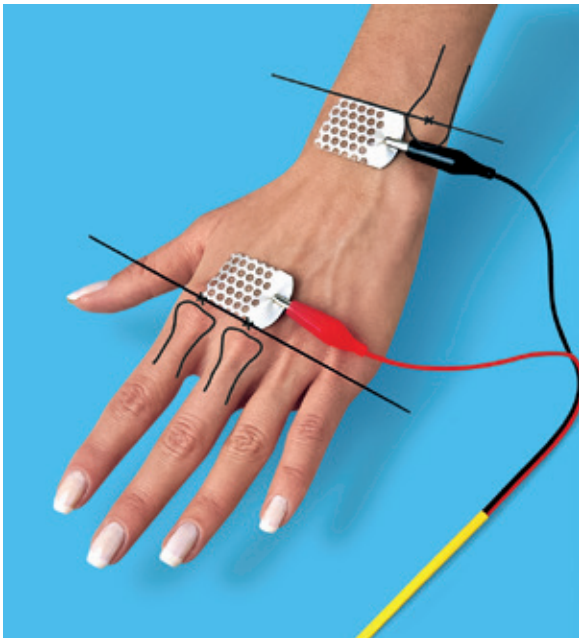
The tetrapolar and ipsilateral measurement using sticking electrodes has been established worldwide as a method for bioelectrical impedance measurements. Therefore two gel electrodes are fixed on one hand and one foot of the same side of the body. The precise positioning of the electrodes is vital to the accuracy of the measurement.

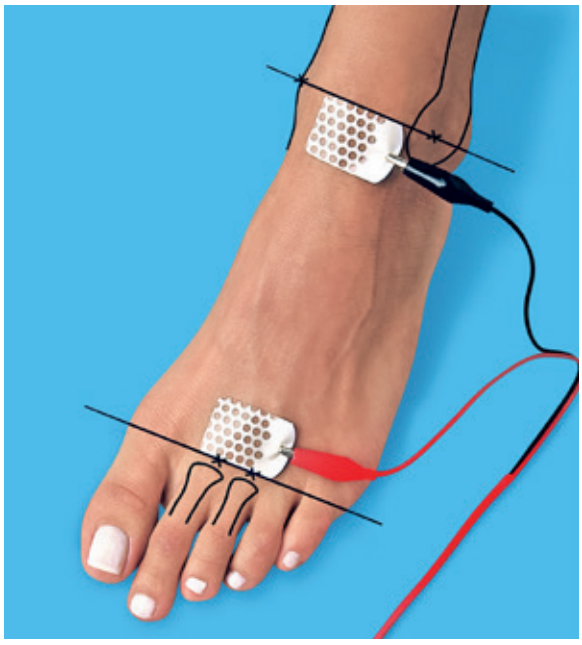
4.1 Electrodes on the hand:
4.1.1 Electrode on the wrist: the electrode shall be attached in a horizontal line through the ulna head (processus styloideus ulnae) whereby the main surface of the electrode shall lie above the fissure of the wrist.

4.1.2 Electrode on the fingers:
The electrode shall be attached slightly distal from the base joint of the middle finger. The main surface of the electrode shall lie on the soft tissue between the second and third bone in the middle of the hand.

4.2 Electrodes on the foot:
4.2.1 Electrode on the toe: The main surface of the electrode should lie on the soft tissue between the second and third bones in the middle foot. Bow the toes to make joints visible. Fix the distal end of the electrode along this line.

4.2.2 Electrode on the ankle: The electrode is placed on the back of the foot in a horizontal line through the inner ankle. Fix the proximal end of the electrode along this line.





The patient's skin should be clean, dry and warm (neither hot nor extremely cold). Greasy or moist skin causes poor adhesion of the electrodes. The skin should therefore be cleaned with alcohol before positioning the electrodes. Should a patient have extremely dry or hairy skin the transfer of current can be improved by applying a little bit of ECG paste.

5. Electrodes
Please use BIA recommended electrodes only (e.g. BIANOSTIC AT). They shall meet the following requirements:

- Gel surface > 4 cm2
- Hand and foot resistance at 50 kHz and accurate positioning < 250 Ohms
- Sandwich resistance at 50 kHz < 30 Ohms, Xc < 1 (q.v. chapter: Sources of Error)

The most common reason for problems or errors of measurements is the use of improper electrodes.

The distance between the electrodes should be at least 4 cm if used on adults and at least 3 cm if used on children. A smaller distance may cause interactions between the electrodes. If the hands are very small as it may be the case with young children, large electrodes may be split in half lengthwise.

Sources of error concerning the choice and positioning of electrodes:
- Inaccurate positioning of electrodes
- Improper electrodes
- Multiple use of electrodes
- Improper storage or dried electrodes
- Insufficient contact between skin and electrodes
- Insufficient circulation of extremities (also due to temperature)

If the contact resistance R↑ or R↓ at 50 kHz exceeds 300 Ohms the software will display a warning in the information field. Please check the cause shown and decide whether you will accept or reject the measurement. If values of R total (sum of R, R↑ and R↓ R) exceeds 1300 Ω you should reject the measurement.

6. Measurement cable and connection of cable
Please screw the measurement cable on the apparatus tightly. The measurement cable consists of two double cables. Each individual cable has a crocodile clip at the end. Each double cable and clip is marked:

Markings of double cable for hand and foot:
- The double cable for the foot electrodes has a red sleeve.
- The double cable for the hand electrodes has a yellow sleeve.

Markings of distal and proximal crocodile clips:
- Clip red clips onto distal electrodes (near fingers and toes).
- Clip black clips onto proximal electrodes (close to ankle and wrist).

During the measurement the cable should be suspended and not be knotted. The cable should not lie on top of a running monitor or be close to a running mobile phone or any other electrical device.

7. Using the NutriBox

The use of the NutriBox is only possible via a PC and the software Nutriplus 7.0 (q.v. "Using the Apparatus"). During the impedance measurement the NutriBox will be is galvanically disconnected from the PC current supply for a few seconds.

8. Sources of Error and Trouble Shooting

Please note that you cannot adjust or read anything on the NutriBox itself. The apparatus is only working in combination with the software NutriPlus 7.0. If there are any errors please contact your dealer. The NutriBox has a built-in error detection. If a measurement is not possible, this error detection prevents the transmission and use of incorrect measurement results.

1. Checking the electrodes:
There are different reasons why electrodes may not be suitable for BIA measurements. The most common reasons are:

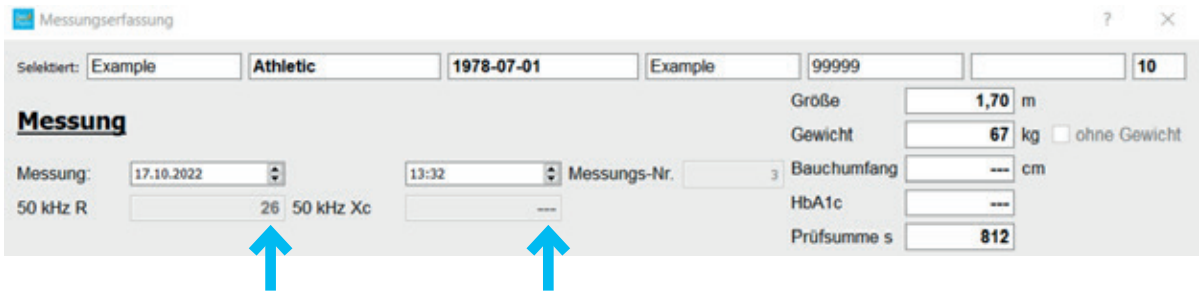
- **Multiple uses**
  Electrodes are articles for single-use only and should not be used more than once. Be aware that electrodes used more than once may transmit bacteria and fungi.

- **Damages caused by transport or bad storage**
  The gel dries easily in rooms with high or low humidity. This causes inherent resistance. Please use an open package of electrodes within 2 months. Transport damages caused by freeze or heat are hard to proof. Heavy sticking and highly raised hand and foot resistance may indicate such a cause of damage.

- **Molybdenum foil**
  Even though the reason for this is unknown, electrodes with a carrier foil made of molybdenum are in general not appropriate for BIA measurements.

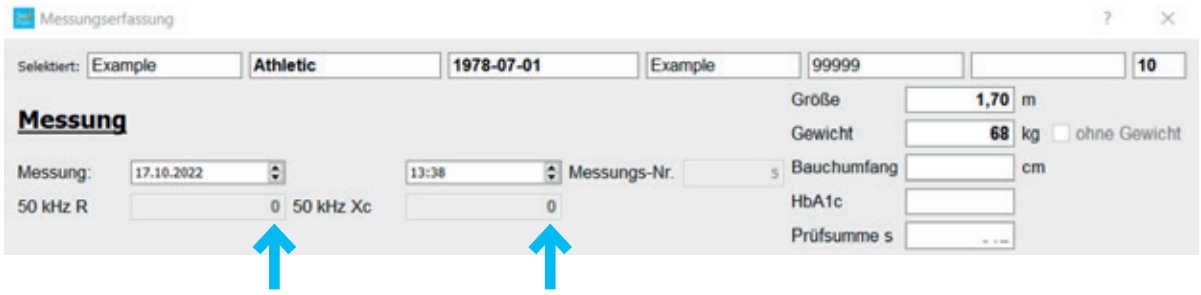
You are able to check the quality of the electrodes easily by carrying out the so-called sandwich test. In order to do so, stick two electrodes together on the gel side, the straps should point in opposite directions. Fast the red and black crocodile clip of one double cable to the straps. Now choose a dummy person in the analysis software, add any weight > 0 and select automatic measurement. Now you are able to see the result on the screen (q.v. image).

Nominal value: Resistance R < 100 Ohms Reactance Xc < 1 Ohms (ideal "0")



2. Checking the Measurement Cable
The check of the measurement cable is carried out by causing a short circuit by connecting all 4 crocodile clips.

To do this, please select a dummy person in the analysis software, choose any weight > 0 and select automatic measurement. The fields R and Xc should show "0".



If no values are displayed when moving the cable connections, a defective contact due to a hair crack might have occurred. Please check, if the capillary joints on the clips are loose. If there is a defect, the cable has to be replaced. Note: A defect of the cable can be detected by the tester!

Please note: Wrong measurement results caused by a measurement error of the apparatus are extremely rare. Most errors are induced by problems related to the measurement cable or electrodes.

3. Consistency check at first time measurement
3.1 Resistance value at 50 kHz:
The physiological range of resistance is:
Women R = 400 - 750 Ohms
Men R = 350 - 650 Ohms

Should the value R be outside of the physiological range please note: In rare cases such values may appear on persons with a very high or very low Body Cell Mass, BCM or if the person suffers of oedema. Nevertheless, the most common reasons for these values are problems related to the measurement cable or electrodes. Use fresh electrodes that are recommended for BIA measurements.

3.2 Reactance value at 50 kHz
The physiological range for reactance is 8-14 % of the respective resistance value (e.g., the resistance value of 500 Ohms Xc should be 40-70 Ohms.) Should the value R be outside the physiological range, please note: measurement values < 8 % or less may appear on persons with malnutrition. On the other hand, measurement values > 14 % may appear on strongly trained athletes such as body builders. Nevertheless, the most common reasons for these values are problems related to the measurement cable or electrodes. Use fresh electrodes that are recommended for BIA measurements.

3.3 Hand resistance or foot resistance at 50 kHz > 300 Ohms
Generally speaking, these resistances represent skin-electrode contact resistance. There are two common reasons for the resistance of hand or foot being > 300 Ohms:
a.) Skin problems (very dry, isolating or greasy skin which impairs the adhesion of the electrodes)
b.) The usage of electrodes which are not recommended for BIA measurements.
If a person has very dry skin, use ECG gel. If a person has very greasy skin, remove the layer of oil on the skin carefully, possibly by using high percentage alcohol. Always use electrodes recommended for BIA measurements. Should the apparatus show a hand- or foot resistance of > 250 the software will generate an alarm message.

4. General Instructions:
Always handle your BIA Measurement apparatus with care.
4.1. All cables (measurement cable CA and USB cable) must be connected carefully. All cables have a standard plug connection for which no strength is required.

4.2 Avoid heavy shaking
As with every electronic product your BIA apparatus can be damaged by knocking or shaking. We recommend that you use the original case when travelling on long journeys.

4.3 Avoid damp conditions
Do not keep your BIA apparatus in rooms with a humidity of over 80%. This may influence both the function as well as the life period of the apparatus.

4.4 Use and Storage
Your device is ready for use, if it is connected via the USB connection to the computer (switched on, at least Windows operating system 7.0)

4.5 Cleaning
You may clean the body of the apparatus with a wet cloth. If necessary you may also use standard cleaning products. The cover of the apparatus and the measurement cable can be sanitzized.

4.6 Repairs
If the apparatus is in need of repair please contact your dealer.

4.7 Disposal
The apparatus and accessories can be returned to your dealer for disposal. You may not dispose via domestic waste.

If you need any further information about the service available please contact your dealer for support.

9. Technical Data

RESISTANCE (R):
- Area of measurement: 0 - 999 Ohms
- Resolution of measurement: 1 Ohm
- Exactness of measurement:
  ± 0.5 % of measurement value
  ± 1 digit
  ± 0.5 % from the end of the scale

REACTANCE (Xc):
- Area of measurement: 0 - 250 Ohms
- Resolution of measurement: 1 Ohm
- Exactness of measurement:
  ± 2.0 % of measurement value
  ± 1 digit
  ± 2.0 % from the end of the scale

The exact details given for the measurement values are only valid for opposition in ohm-based, high capacity components.

- Measurement current: 0.8 mA at 50 kHz (0 - 1000 Ohms)
- Exactness of measurement current: ± 3 %
- Measurement frequency: 50 kHz sinusoidal frequency
- Source of electrical current: via PC or measurement Apparatus name:
- Impedance Analyser Apparatus type: NutriBox
- Class of protection (Nutribox): Apparatus with electrical current via PC's USB port
- Degree of protection (Nutribox): Type B
- CE (Conformité Européene) in accordance with EN55022 Class B

The safety of the measured persons is always guaranteed. **During the measurement, the device is electrically isolated from the USB interface.**

Notizen

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