

Nutribox



Instructions for Use

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Data Input
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CONTENTS

A.	Bioelectrical Impedance Analysis (B.I.A.).....	3
B.	Scope of delivery.....	4
C.	Description of Apparatus.....	5
D.	Technique of Measurement.....	6
E.	Using the Nutribox.....	11
F.	Sources of Error and Trouble Shooting.....	12
G.	Technical Data.....	15

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.

A. Bioelectrical Impedance Analysis (B.I.A.)

B.I.A. 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.

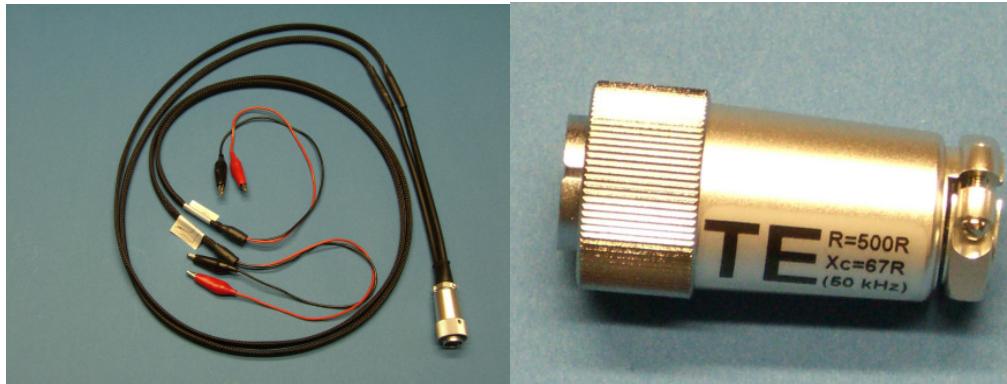
To determine both these components of impedance modern B.I.A. apparatus possess phase sensitive electronics. The principle of measurement is based upon a time difference (Δt). This occurs in the condensers in a field of alternating current: the current flows faster than the potential difference. Because alternating current has a sinusoidal form it is measured in $^\circ$ (degrees) and known as **phase angle (α)**. 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.

B. Scope of Delivery

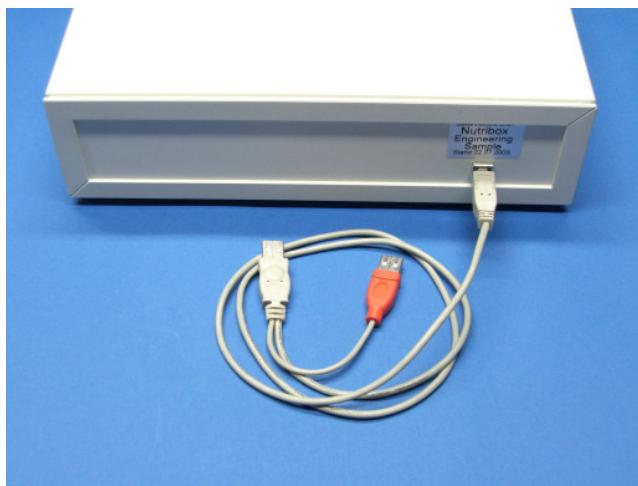
Please check the contents of the impedance measurement apparatus for completeness.

1. Impedance analysis apparatus Nutribox, (1 q.v. p. 5)
2. Measurement cable CA , (3 q.v. p. 5)
3. Tester TE
4. USB Y-cable
5. Instructions for Use
6. Carrying case (optional)
7. Analysis software NutriPlus 5.4.box



Measurement cable

Tester

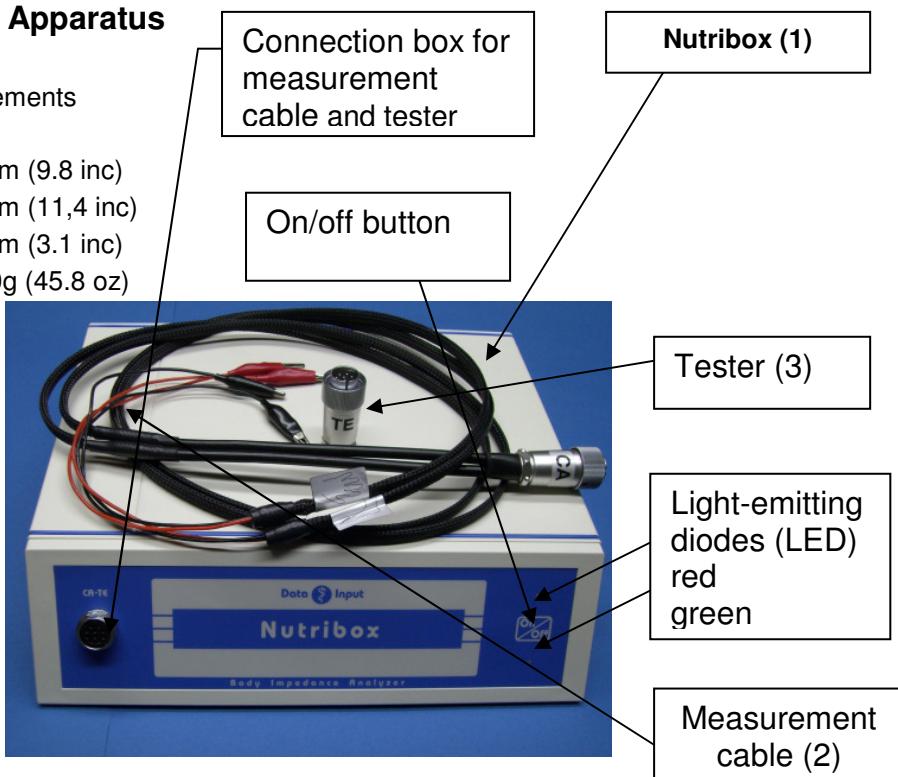


Back side shown with USB Y-cable

C. Description of Apparatus

1. Apparatus Measurements

Length: 250mm (9.8 inc)
 Width: 290mm (11,4 inc)
 Height: 80 mm (3.1 inc)
 Weight: approx. 1,300g (45.8 oz)



2. Front

On the front of the apparatus you will find:

- On/off button
- Connection box for the measurement cable or tester (CA TE)
- Light-emitting diodes (LED) in green and red

3. Back (q.v. p. 4):

On the rear you will find a USB port to automatically transfer the measurement data to the analysis software NutriPlus 5.4.box.

4. Body of apparatus:

Please note that the box may only be opened by your responsible dealer.

Using the Apparatus:

Please make sure that the apparatus is connected to your PC via the provided USB Y-cable. Both USB flat connections have to be connected to the computer. Also, the correct com-port (USB serial port) has to be selected in the analysis software NutriPlus 5.4.box in the field "setting". Switch on the apparatus by using the on/off button. A red LED will flash and the apparatus is carrying out a self-test. Meanwhile some switching noises can be heard. When the red LED stops flashing and the green LED turns on, the apparatus is ready for measurement. Should both LEDs stay off, either the self-test has failed or the apparatus has determined an operation error and has turned itself off for safety reasons. Please check the conditions of the measurement and restart the measurement. (The software reports "The apparatus has failed the self-test and has switched itself off.") The operation error has been determined if the red LED flashes for more than 5 seconds and the software does not generate a message. Please switch off and start the apparatus again.

It is only possible to start a measurement via the analysis software by clicking on the button "automatic measurement" or "automatic measurement & print" after putting in the master data and the current weight. During the measurement both LEDs (red and green) flash at the same time and switching noises appear. When the measurement is finished you will hear a beep. After that the red LED – is flashing. The Nutribox will switch itself off, if you do not use it for 30 minutes (rechargeable battery saving mode). If the apparatus is switched on, at least one LED will flash.

D. 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 (optional)

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:

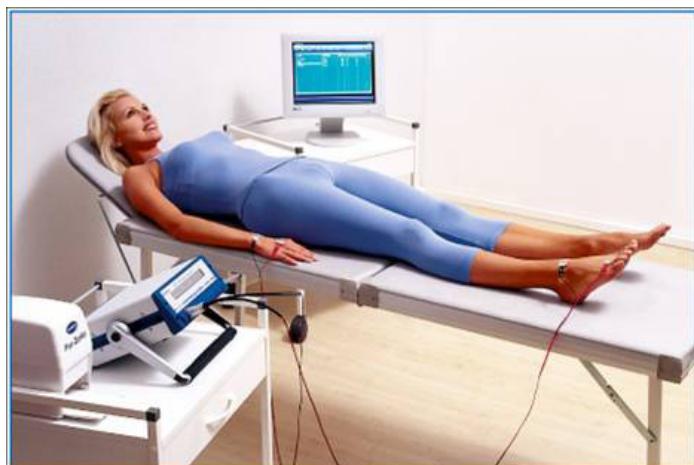
1. Indication/Contraindication

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

Measurement station with BIA apparatus Nutriguard M



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

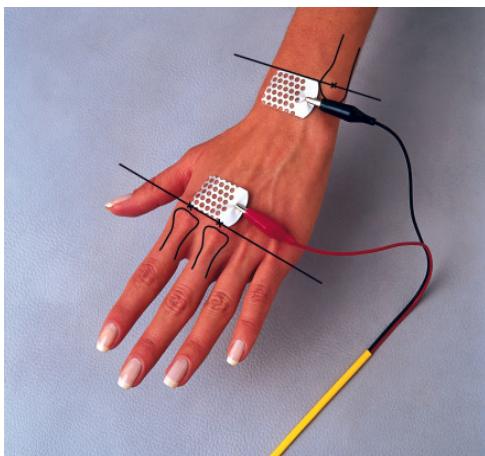
The tetrapolar and ipsilateral measurement using sticking electrodes has been established worldwide as a method for medical bioelectrical impedance measurements. Therefore two gel electrodes are fixed on one hand and one foot of the same side of the body. The precise positioning of the electrodes is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

4.1 Electrodes on the hand:

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.

Electrode on the fingers:

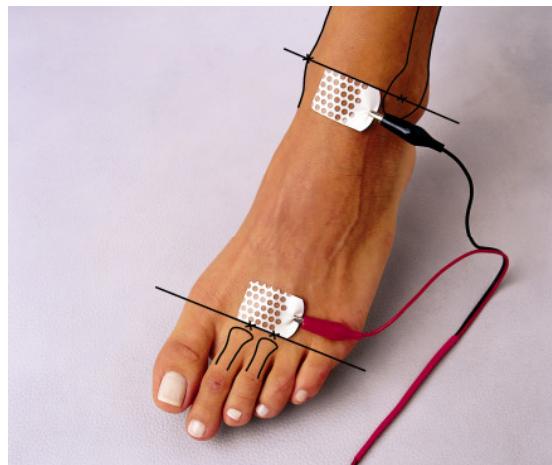
The electrode shall be attached slightly distal from the base joint of the middle finger. The main surface of the electrode shall lie on the soft tissue between the second and third bone in the middle of the hand.



4.2 Electrodes on the foot:

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.

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 (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 4cm if used on adults and at least 3cm 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.

e.g. Bianostic AT



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 \uparrow or R \downarrow 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 \uparrow and R \downarrow) exceeds 1300 Ohms 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:

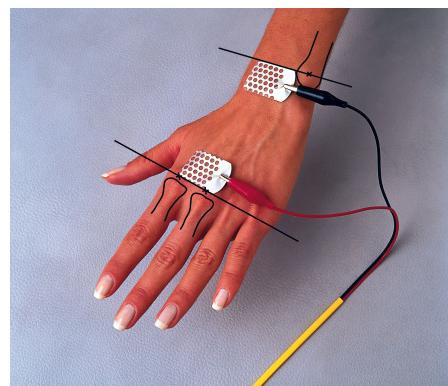
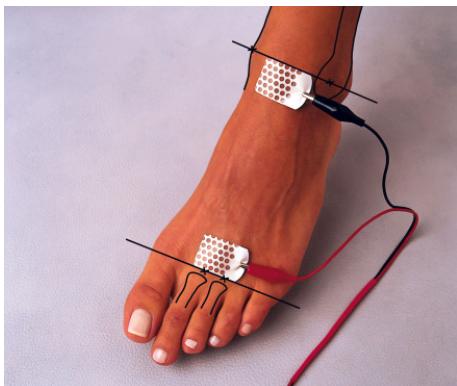
Markings of double cable for hand and foot:

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.



Marked in black you will find the bones which will help you to position the electrodes.

E. Using the Nutribox

The use of the Nutribox is only possible via a PC and the software NutriPlus 5.4.box (q.v. p. 5 Using the Apparatus). During the impedance measurement the Nutribox will be disconnected from the PC current supply for a few seconds. Meanwhile the current supply for the measurement will be carried out via the internal rechargeable battery of the apparatus. You will get a message if the battery does not supply enough current. In this very rare case the battery will be recharged by the PC via the USB Y-cable. Keep the USB-Cable connected to the working PC for a few minutes (Durability without loading > 3 weeks).

F. 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 5.4.box. If there are any errors **please contact your dealer**. Should any measurements seem to be unlikely, please screw the tester on the Nutribox instead of the measurement cable and generate a measurement of a dummy person based on your master data. The software is bound to indicate the value $R = 500 \pm 4$ and $Xc = 67 \pm 4$

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.

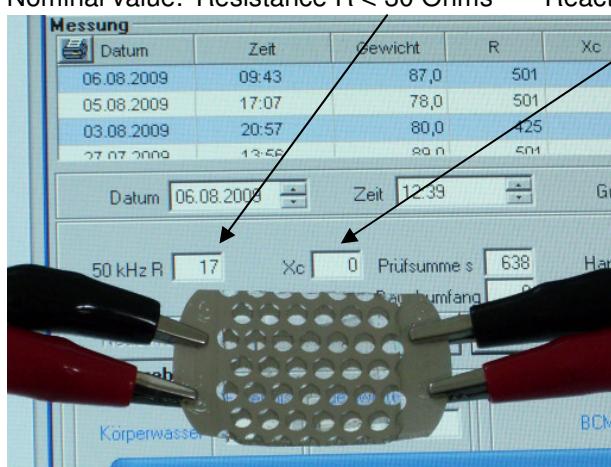
Transport damages caused by freeze or heat are hard to proof. Heavy sticking and highly raised hand and foot resistance may indicate such a cause of damage.

- 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 $R < 30$ Ohms Reactance $Xc < 2$ Ohms (ideal "0")

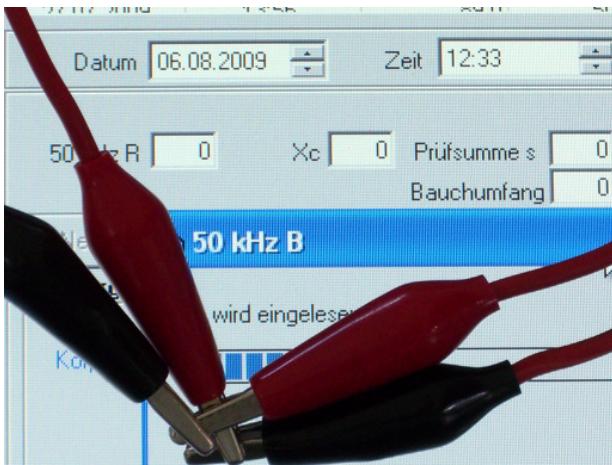


Example of a quality check
of electrodes

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.

Consistency check at first time measurement

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.

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. 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:

- Skin problems (very dry, isolating or greasy skin which impairs the adhesion of the electrodes)
- 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.

General Instructions:

Always handle your BIA Measurement apparatus with care.

1. All cables (measurement cable CA and tester TE) must be connected carefully. All cables have a standard plug connection for which no strength is required.

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.

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. Storage

Your apparatus automatically switches off when not in use. Avoid extremely high or low temperatures. Recommended temperature for transport and storage: +10°C to +40°C. (50°F to 104°F)

6. 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 sanitized.

7. Repairs

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

8. 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.

I. Technical Data

Impedance Analysis Apparatus Nutribox

RESISTANCE (R):

Area of measurement: 0 - 999 Ohms
Resolution of measurement: 1 Ohm
Exactness of measurement:
 $\pm 0.5\%$ of measurement value
 ± 1 digit
 $\pm 0.5\%$ from the end of the scale

REACTANCE (Xc):

Area of measurement: 0 - 250 Ohms
Resolution of measurement: 1 Ohm
Exactness of measurement:
 $\pm 2.0\%$ of measurement value
 ± 1 digit
 $\pm 2.0\%$ 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: $\pm 3\%$
Measurement frequency: 50 kHz sinusoidal frequency
Source of electrical current: via PC or measurement via rechargeable battery
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