



**DataInput**  
Body Composition

*NutriGuard*

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# Instructions for Use



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### 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
$\phi$ .....	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. 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  $\Omega$  (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 and the functionality of the body cell mass.

To separately determine both these components of impedance modern BIA apparatus possess phase sensitive electronics. The principle of measurement is based upon a time difference. This occurs in the condensers in a field of alternating current: the maximum of the electrical current flows faster than the maximum voltage. Because alternating current has a sinusoidal form it is measured in  $^\circ$  (degrees) and known as phase angle  $\phi$ . 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 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 by 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.

The use of the multi-frequency technology has brought further improvement to the BIA measure-

ment because different frequencies are dispersed differently in the body tissue.

High frequencies, for example 100 kHz, can completely overcome membrane opposition and are therefore dispersed evenly throughout the entire body tissue. These are suitable for measuring the total body water.

Medium frequencies, for example 50 kHz, can only partially overcome the opposition of the cell membranes. They are dispersed to two thirds in the extra-cellular and one third in the intra-cellular parts of the body. These are suitable for calculating the total body water and body cell mass.

Low frequencies, for example 5 kHz, cannot overcome the opposition of the body cell membranes and are only dispersed in the extra-cellular parts of the body. These are suitable for the calculation of the extra-cellular water.

## 2. Scope of Delivery

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

- Impedance analysis apparatus NutriGuard
- Measurement Cable CA
- USB-C-Cable
- Charger
- Text documents such as instructions for use and CE certificate on USB stick
- Testplate
- Transport bag

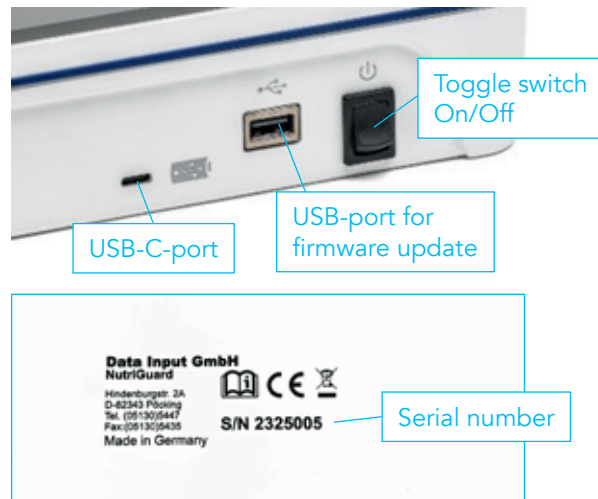
### Optional:

- Software NutriDuplex with Dongle
- Measuring board for quality management
- NutriSegment package: Software with segment cable (available as an accessory)

**Operating and storage:** Your apparatus automatically turns itself off when not in use. The enclosed battery will be charged independent of it, as long as it is connected to a current source (PE). Separate this connection with devices which are not switched off during night. Ihr Akku wird es Ihnen danken. Avoid extremely high or low temperatures. Storage and transport temperatures should be between  $-10^\circ\text{C}$  and  $+40^\circ\text{C}$ .

### 3. Description of Apparatus

1. Device dimensions approx.:  
Length 21,00 cm  
Width: 15,00 cm  
Height: 6,00 cm  
Weight: 780 g
2. Back of apparatus:  
On the back of the apparatus is the on/off toggle switch located, the USB port for importing firmware updates and the USB-C port. The white USB-C connection cable to the PC has to be plugged here as well
3. Bottom of apparatus:  
The bottom of the apparatus should only be opened for repairs by your responsible dealer. You can find manufacturer information, the device type and the serial number also on the bottom of the device



Measurement cable



Electrodes



USB-C-cable



Test board



Transport bag



## 4. Using and Menu navigation

The using and menu navigation are extensively self-explanatory.

Press the toggle switch on the back of the device to turn it on.

**Note:** If you control the NutriGuard via “automatic measurement” by using the NutriDuplex evaluation software, you only need to switch the device on! Therefor the NutriGuard should be connected to the PC/laptop by using the white USB-C-cable and the NutriDuplex software is started.

**It is NOT necessary to do a selection in the NutriGuard menu!**



If you use the NutriGuard manually, you can now do a menu selection at this point.

### 1. BIA Measurement (at 5, 50 and 100 kHz.)

Please click on “start measurement”.



Now appears the window “test electrodes”:



The BIA electrodes you stuck on will be checked on the patient:

- Red: electrode does not stick or is not connected
- Orange: bad contact
- Green: good contact

Please start the measurement only if all electrode-images are **green**.





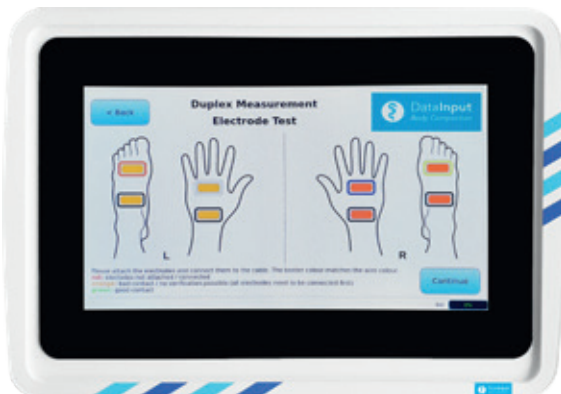
## 2. Duplex Measurement

Measure both halves of the body one after the other with a 4-crocodile-clips-measuring-cable or simultaneously with an 8-crocodile-clips-measuring-cable.

Please click on "start measurement".



Now appears the window "test electrodes":



The BIA electrodes you stuck on will be checked on the patient:

- Red: electrode does not stick or is not connected
- Orange: bad contact
- Green: good contact

Please start the measurement only if all electrode-images are **green**.

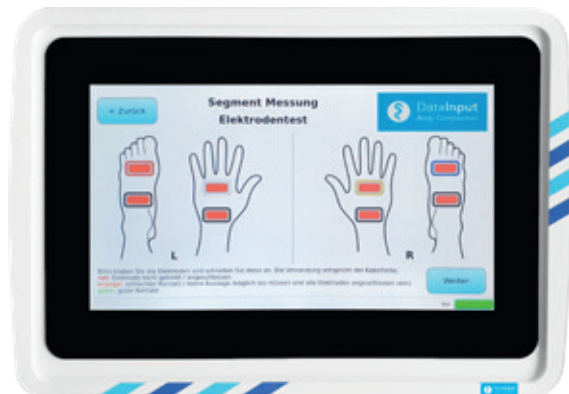
## 3. Segment measurement

Measurement of the four segments - arm right and left side, leg right and left side. Only possible with an 8-pin-segment-cable (additional accessory).

Please click on "start measurement".



Now appears the window "test electrodes":



The BIA electrodes you stuck on will be checked on the patient:

- Red: electrode does not stick or is not connected
- Orange: bad contact
- Green: good contact

Please start the measurement only if all electrode-images are **green**.

#### 4. Setting menu:



Here you can change the brightness of the screen:



#### Calibrate touchscreen surface:

You have the option to calibrate the touchscreen surface independently. This is necessary if the buttons no longer respond correctly. This happens if you use the device mobile e.g.



After clicking on the button, a white screen appears with 4 small crosses, which you should press one after the other: Click on the cross.



After that you will see the following window:



#### Recalibrate the measuring cable:



At this point the measuring cable can be recalibrated. Please click on the button.

### Change language:

In the setting menu, change the option to English.



### Shutting down the device:

Please press the toggle switch on the back of the device

## 5. 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 cable and special electrodes
- Disinfectant and swab
- A computer 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

**Basically:** Always make a comparable measurement situation.

#### 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:

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:

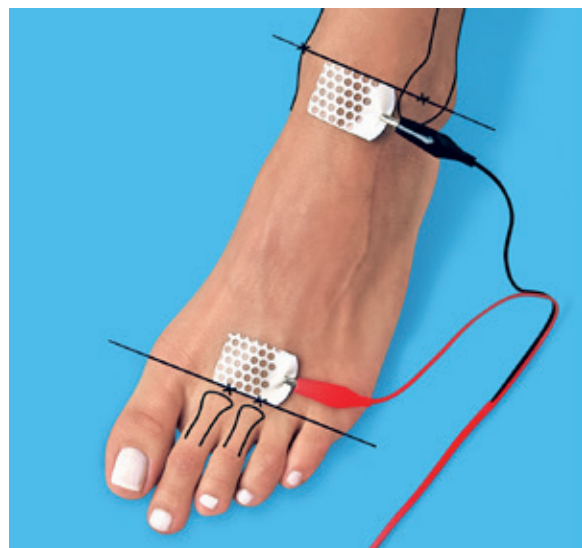
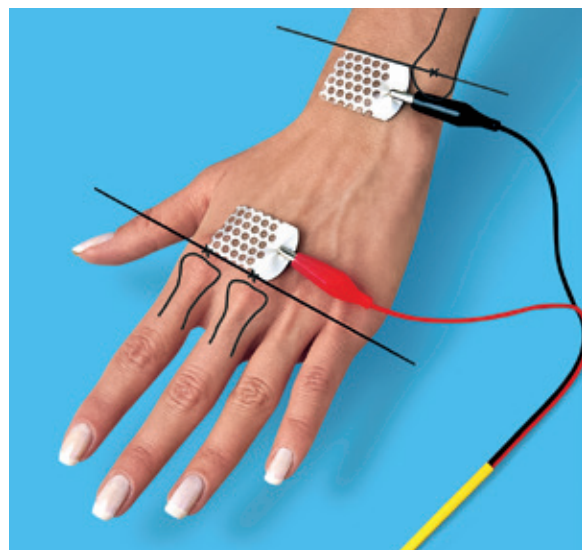
The electrode shall be attached slightly distal from the base joint of the middle finger. The main surface of the electrode shall lie on the soft tissue between the second and third bone in the middle of the hand

##### 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 cm<sup>2</sup>
- 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 4 cm 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)

## 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. Should the measuring cable lie flat during the reading it is important to make sure that it does not come into contact with any metal surfaces or metal objects, for example, the metal frame of a patient's bed.

## 6. Using the NutriGuard

Please press the black toggle switch on the back of the apparatus and follow the operating instructions menu, navigation on page 4.

## 7. General Information

Always handle your BIA Measurement apparatus with care.

1. All cables (measurement cable (CA) and charger (CH)) must be connected carefully:

All cables have a standard plug connection for which no strength is required.

**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!



## 2. Avoid heavy shaking:

As with every electronic product your BIA apparatus can be damaged by knocking or shaking. Please use the original transport bag.

## 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 on the apparatus.

## 4. Storage:

Your apparatus automatically switches off when not in use. Avoid extremely high or low temperatures. The recommended temperature of transport and storage: -10 to +40 °C.

## 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 sanitized.

## 6. Repairs:

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

## 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 available service, please contact your dealer for support.**

# 8. Technical Data NutriGuard

## RESISTANCE (R):

- Area of measurement: 0 – 999 Ohm
- 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 Ohm
- 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 Ohm)
- Exactness of the measurement current: ± 3 % at: 5, 50 and 100 kHz Sinusoidal frequency
- Power supply: Supply via integrated batteries or external supply via PC/power supply Apparatus name: Impedance Analyzer
- Apparatus type: NutriGuard
- Class of protection NutriGuard: Device powered by battery or the USB interface of the PC / USB power supply
- Degree of protection NutriGuard: Type B
- CE (Conformité Européene) according to EN55022 Class B

The security for the people to be measured from a 220V mains voltage is warranted for the time of measurement. **During a measurement, the apparatus works with an internal power supply and is separated from the USB interface.**

# 9. Comments

The apparatus includes 4 battery pack: 2900mAh, 3,6V – 3,7V  
Lithium-Ion-battery



- Lithium-Ion batteries are thermally stable and are not subject to a memory effect.
- They work on the basis of lithium and are characterized by a high energy density.
- When not in use, please recharge every 3 months.
- Charge your apparatus at an ambient temperature of 10-40 °C.
- Empty or damaged battery packs, please give back to your dealer or provided collecting point.
- Diagnosis by a BIA measurement only is forbidden.
- The device must be protected from direct sunlight to beware overheating.



