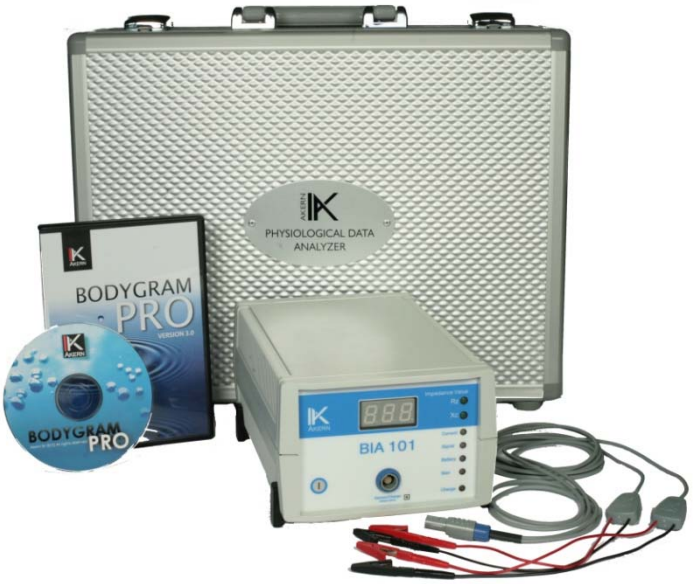


# BIA 101 – New Edition

Instruction Manual

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## Regulation references:

The technical file has been drafted in compliance with Annexes I – VI – VII of the Directive 2007/47/EEC.

***Applicable standards:***

Quality management systems UNI EN ISO 9001:2008

Medical electrical equipment – Electric Safety CEI EN 60601-1:2007

Medical electrical equipment – EM Compatibility EM CEI EN 60601-1-2:2007

Additional Standard: Usability IEC60601-1-6

Risk management and analysis UNI CEI EN ISO 14971:2009

Symbols used to label medical electrical equipment UNI CEI EN 980:2009

***Classification of the device:***

BIA 101 is classified as a CLASS II medical device (Directive 2007/47/CEE).

***Software for medical devices:***

Processes related to the software lifecycle: EN 62304:2006; CEI EN 60601-1-4

## INTENDED USE

The medical device BIA 101 has been developed for continuous measurement of the electric properties of the tissues (Rz, Xc) and to evaluate the body composition by means of quantitative evaluations of the body compartments.

The equipment can be used by anyone: however, we recommend that the interpretation of the results from the application on subjects with altered physiological conditions is performed by trained medical staff.

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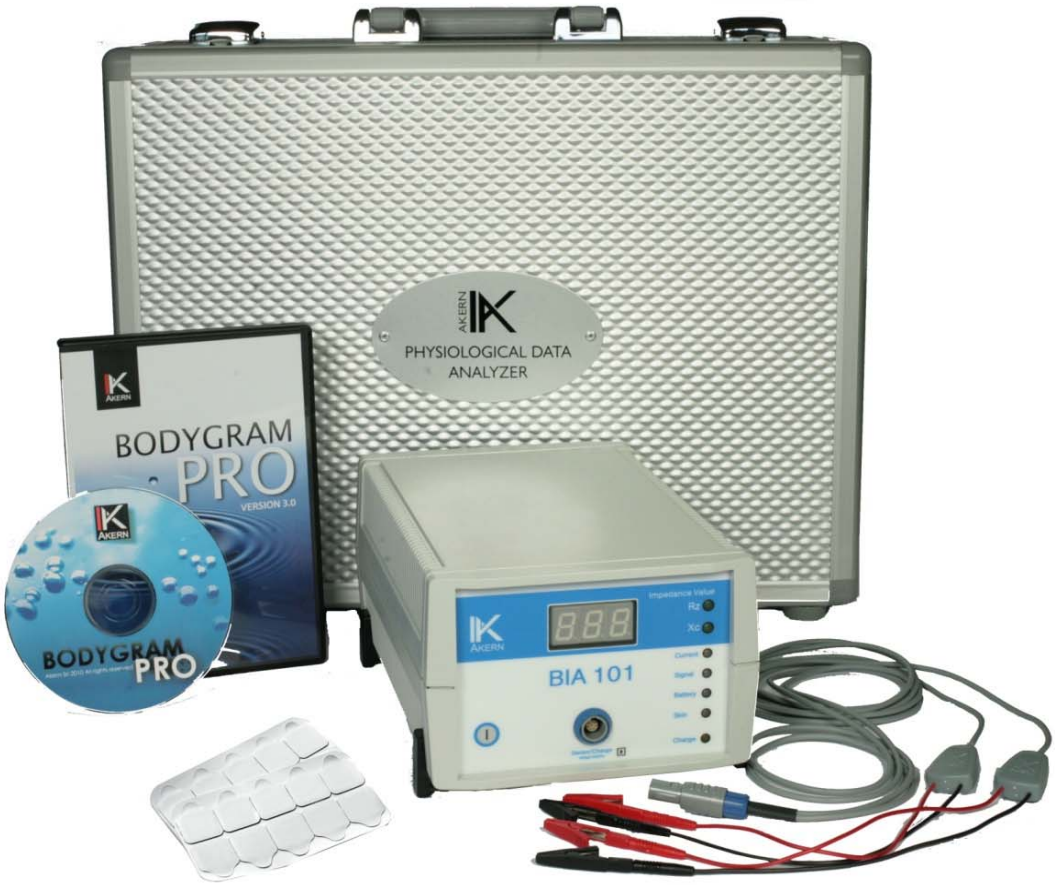
# CHAPTER 1 GENERAL INFORMATION

## CONTENTS OF THE SYSTEM




## BIA 101

(Code 0PKPVC44-34-16)* Case in PVC/ALU
(0CB15VMED-01)* Battery charger
(0CP4AMP-001)* Patient Cable
(0ELB100)* Electrodes Biatrodes 100'S
Instruction Manual
(SWBPRO)* CD Rom Software BODYGRAM PRO
User Manual of the software BODYGRAM PRO 3.0
(0TEST00B)* Control circuit
4 spare alligator clips
(0CUSB)* Type B USB cable

*Item code

## Definitions

**Rz:** Symbol for the electric resistance, i.e. the opposition of a conductor (electrolytes) to the flow of an electric current (value in ohms).

**Xc:** Symbol for capacitive reactance, i.e. the opposition of a capacitor (cells) to the flow of an alternating electric current (value in ohms).

**Z:** Symbol for Impedance, i.e. the overall opposition of a conductor (human body) to the flow of an alternating electric current (value in ohms).

**PA (ϕ):** Symbol for phase angle, i.e. the ratio between resistance and reactance (value in degrees).

## Symbols

Symbol referring to the manual


Symbol indicating the conformity to Directive 2007/47/EEC

The presence of this symbol in a paragraph stands for a warning

Symbol that indicates the protection class of the patient on direct and indirect contacts

Symbol recommending the recycling of polluting components

Symbol indicating correct disposal of the exhaust product (pursuant to Directive WEEE)

## Safety warnings

**CAREFULLY READ THESE INSTRUCTIONS AND KEEP THEM FOR FUTURE REFERENCE**

Follow recommendations and warning signals.

- Do not use the device close to water.
- Do not place it on unstable surfaces. The instrument may fall and be seriously damaged.
- To ensure proper operation, avoid exposing it to temperatures exceeding 45°C; as a consequence, avoid placing it near radiators or inside poorly ventilated boxes.
- Relative humidity in environment shall not exceed 80% without condensation.
- Avoid placing any load onto the battery charger power cord. Do not place the device in an obstructing position when it is being charged.
- Do not plug any object into the multipole socket of the battery charger / patient cable.
- Do not pour liquids on the device.
- Do not try to repair the device: no user-serviceable parts inside. Maintenance and repair must only be performed by qualified technical personnel.
- Do not recharge the device or use the battery charger when:
  - the battery charger cable shows signs of damage or pinches;
  - the device does not work properly although operating instructions have been followed correctly;
  - the device has fallen down and/or the container is damaged;
  - the device shows clear signs of malfunction that may require technical servicing.
- Do not replace batteries without contacting Akern or an authorized dealer. The use of non-compliant batteries may cause the risk of explosion.

**Remark:**

To replace the battery contact Akern or an authorised retailer.

***Warning!*** *The lithium-ion battery may explode if handled incorrectly.*
***Do not remove it or dispose of it in the refuse container.***
*The lithium-ion battery must be disposed of in full compliance with the regulations in force.*

## Risk analysis

BIA 101 has been specially designed to be used together with other medical and/or electronic devices and meets all the essential requirements concerning electromagnetic compatibility pursuant to 60601-1-2:2007.

We recommend that you avoid using the instrument in presence of flammable, anaesthetic gases and any mixture containing oxygen or flammable substances.

A possible risk may be generated by the application of a 10.8 V direct current into the human body. However, the event probability is zero since the electrode/skin contact features high capacitance and the skin features very high impedance to direct current.

The use of insulated clips avoids the risk of exposure of a grounded patient to an alternating current: this may happen in the case when one of the cable clips accidentally comes into contact with a high intensity source of alternating current. However, we recommend that you pay attention to avoid accidental clip detachment.

Before starting a test, verify that the patient is suitably insulated. Besides being exposed to risks, "grounded" patients cause unreliable Reactance (Xc) measurements.

## Terms and conditions

Akern warrants its bioelectrical impedance equipment against defects in material and workmanship for a period of 24 months (BIA sensing device only) or 12 months (accessories: patient cable, battery charger, tester circuit, USB cable, carrying case ). Warranty starts from the check list date at the end of this manual or, when missing, from invoice date from Akern.

During the warranty period Akern shall repair or replace the defective instrument, at its own discretion.
Akern declares a lifecycle of the instrument of 10 years. During this period spare parts availability is guaranteed.

Akern is liable for damages due to its fault or negligence up to a maximum corresponding to the list price applicable on the date of the purchase.

The guarantee does not cover:

- damages to instruments caused by accidental events;
- damages to third parties resulting from careless or improper use of the instrument by the user.

The guarantee is automatically void in the following cases:

- malfunctions, breakages or damages resulting from the non-observance of the instrument use and maintenance instructions;
- malfunctions, breakages or damages resulting from careless or improper use of the instrument;
- malfunctions, breakages or damages resulting from interventions on the instrument by the user (replacement of the battery; repair attempts; modifications).

Akern declares that the content of this manual is accurate; however, it reserves the right to modify it in the following editions, without notifying changes to users in possession of the current edition.
If the user finds some inaccuracies it is recommended to contact the seller.

*NB: "DIRECTIVE 1999/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees" introduces new rules on tangible movable items purchased by consumers, whereas "consumer" shall mean any natural person who, in the contracts covered by this Directive, is acting for purposes which are not related to his trade, business or profession*

# Chapter 2 THEORY AND FOUNDATIONS OF THE TECHNIQUE

## THEORETICAL BASIS

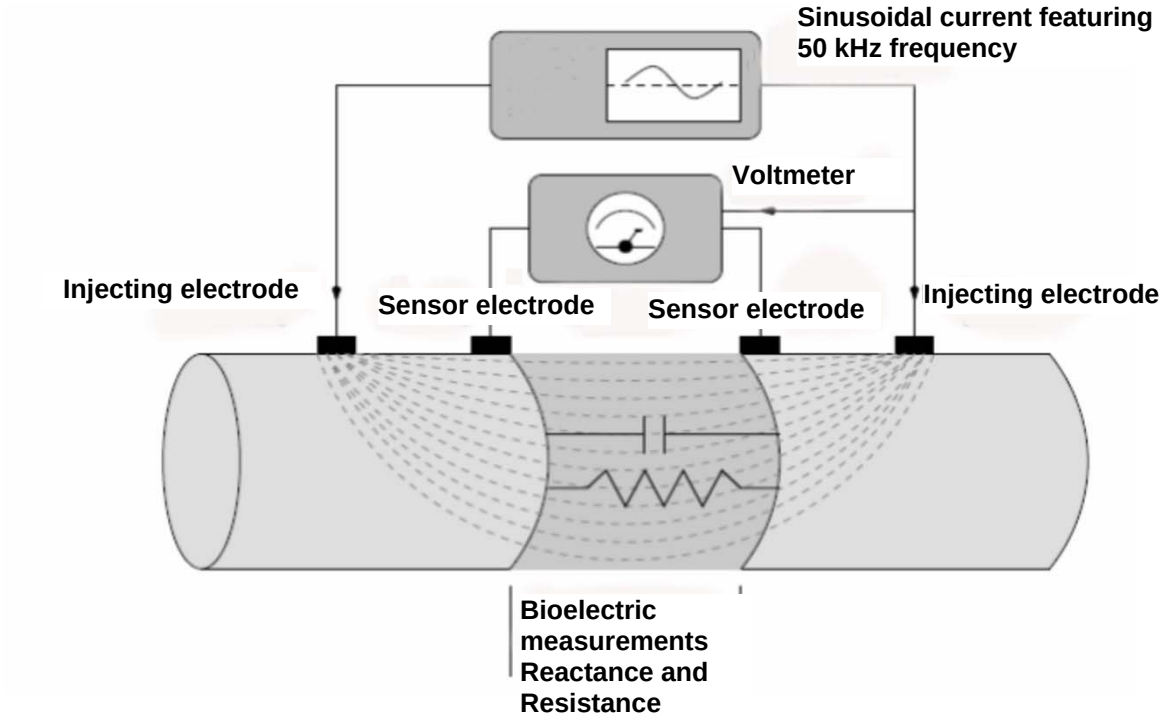
*BIA 101* is a **vector impedance analyzer** for the analysis of body composition that can be used both in hospital and clinical environments.

Bioelectrical analysis with BIA 101 is carried out using the standard four-pole technique, with sinusoidal current at 50 kHz frequency.

The human body composition obtained by means of the impedance analysis is a well-known and tested technique. However, we suggest reading the article "Methods for the Assessment of Human Body Composition: Traditional and New" published in 1987 in *The American Journal of Clinical Nutrition (46:537–556)* by Henry C. Lukaski, PhD.

The value of the current is kept constant at 400 µA on a bioimpedance value range of 1 to 5000 Ω.

To saturate the entire human body with current, injectors are placed distally on the metacarpal and metatarsal line by means of surface electrodes. Sensors (black clips) are always connected by means of electrodes to the wrist and ankle joints, i.e. inside the electric field.



Although the system is composed of three cylinders, the human body is simplified as only one cylinder.
The bioelectric volume is obtained by means of the Nyboer formula:

$$Volume = \frac{height^2}{impedance}.$$

The impedance **(*Z*)** of a human body is a function of the specific resistivity $\rho$ of the alipidic tissue (a good conductor), of its section **(*a*)**, and its length **(*L*):**

$$Z = \rho * \frac{L}{a}$$

where *Z* (impedance) is in ohm, $\rho$ in ohm/cm, *L* in cm and *a* in square cm. Considering the lean body mass as a cylinder, the equation can be rewritten by multiplying by *L/L*:

$$Z = \rho * \frac{L^2}{V}$$

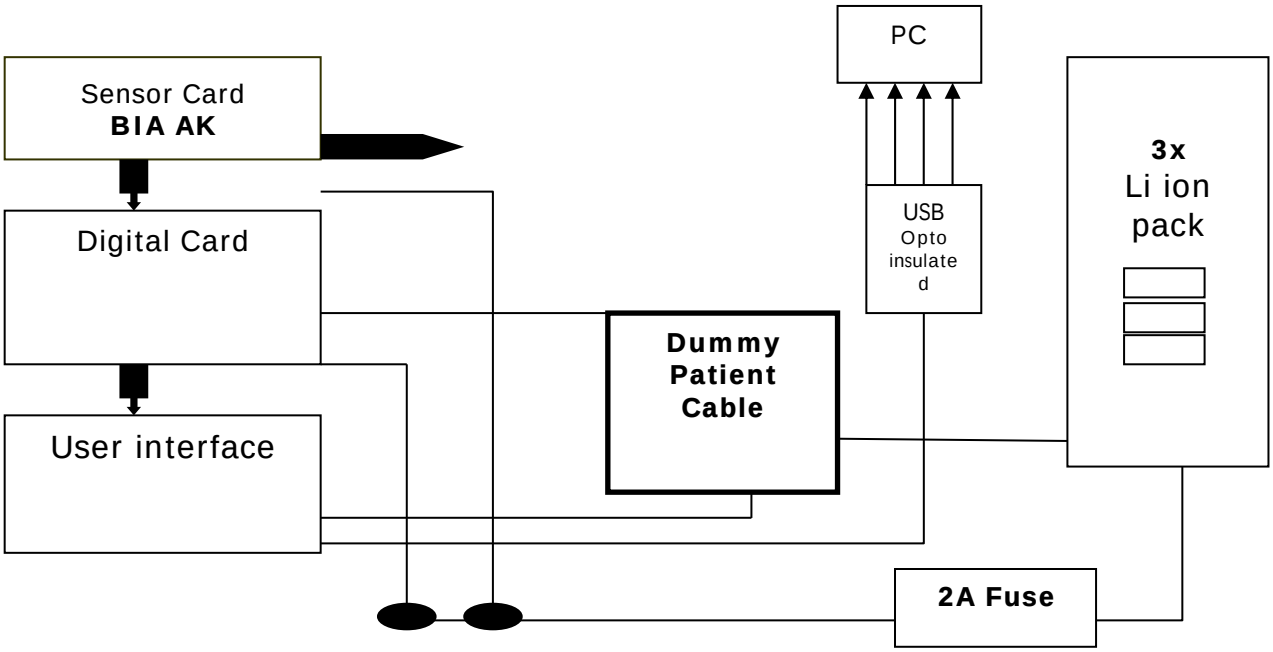
where V = a L is the bioelectrical conductor volume.
Adapting the equation you can obtain:

$$V = \rho * \frac{L^2}{Z}$$

Therefore, if $\rho$ is constant, $L^2/Z$ is directly proportional to the volume of the lean body mass.
The fundamental laws of the human impedance measurement are published in the book: *Electric Impedance Plethysmography,* Nyboer J. Springfield, Illinois – Charles C. Thomas, 1959.

## Sensor: flow chart

The instrument consists of an impedance sensor powered by a lithium-ion battery pack, a cable/sensor equipped with alligator clips insulated in a polypropylene shell. The relevant flow chart is shown below:




Here are the main components:

- BIA AK biological sensor card;
- digital card with 16 bit PIC microprocessor;
- three Li-ion batteries (3.7 V, 1000–1500 mAh) and inner fuse protection device;
- I/O power button;
- Amphenol 8-pin round multipole connector.

Detailed diagrams and procedures can be provided on demand to hospitals, universities and public institutions, after signing a confidentiality agreement.

## Clinical indications and contraindications

Body impedance analysis is universally regarded as safe.
The tetrapolar measurement system has been validated in all clinical–pathological conditions. For further information, contact Akern or refer to the scientific publications indicated in the Bibliography section.

There is a wide medical literature on research studies carried out by means of impedance analysis, including the examination of bioelectric parameters in patients between two and 100 years old, in pregnant women, in paediatrics, gerontology and in various pathological conditions.
In over 25 years of BIA applications with over 20,000 instruments, no accident or contraindication has been recorded. However, our Scientific Department advices against the use of the device on subjects using cardiac stimulation and pacing devices.

**Attention: During analysis, do not perform any therapy or treatment.**

For further details we recommend that you read the following documents:
"ESPEN Guidelines: Bioelectrical Impedance Analysis – Part II"; Clinical Nutrition (2004)23, 1430–1453
"Safe Current Limits for Electro Medical Apparatus"; ANSI AAMI ES1-1993

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# CHAPTER 3 USE OF THE BIA 101

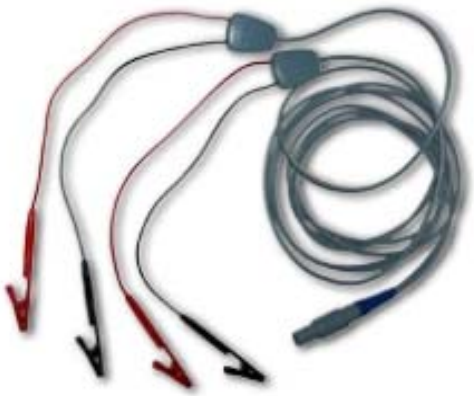
## SWITCHING ON THE BIA 101

The power button is a membrane push button switch located on the bottom left side of the front panel and is identified by the symbol (I) (see picture below).


An auto-off system switches off the equipment if it is disconnected from the patient and not used for over 18/20 seconds.

If the battery is drained, after switch on the LED identified by "Battery" warns the user about the system state and the microprocessor automatically disables displaying potentially not correct measurements.

## FOUR-POLE PATIENT CABLE



The cable is equipped with insulated red- and black-coloured alligator clips.

When performing a measurement it must be completely unrolled, to ensure that it does not form any circles or coils which may generate a self-inductive effect.

Do not twist the terminals and do not bend the cable excessively to avoid damage to the internal strands.

## Electrodes

Each instrument is equipped with a set of BIATRODES 100's disposable electrodes, compliant with Directive 2007/47/EEC.
The electrodes are non-cytotoxic, non-irritant, non-sensitising, compliant with ISO 10993-1:2003.
These electrodes can only be used for bioimpedance analyses.
The package, if open, must be protected from heat to avoid drying of the conductive hydrogel on the surface, thus altering the analysed value reading.

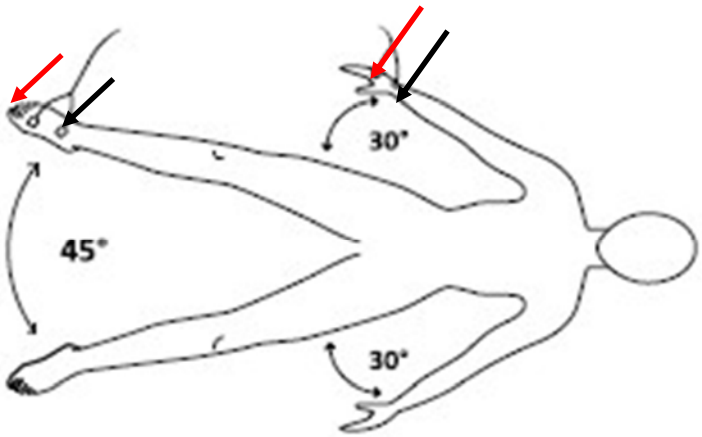
All the instruments produced by Akern are tested and calibrated with relation to the physical specifications of this specific type of electrode which provides the user with a measurement featuring low parasite impedance, avoiding possible errors introduced by the electrode–patient contact surfaces.

## Performing a test

Bioelectrical tissue values shall be measured between the ipsilateral wrist and ankle bony prominences (metatarsus – metacarpus region).

Wait until the patient is in a horizontal position for at least two minutes to allow a homogeneous distribution of body fluids.

The volume to be examined is that of the entire human body; if the patient is naked, therefore, it is important to avoid contact between limbs and torso, not to alter the standard route of injected current. In this case, position the subject as shown in the drawing below:



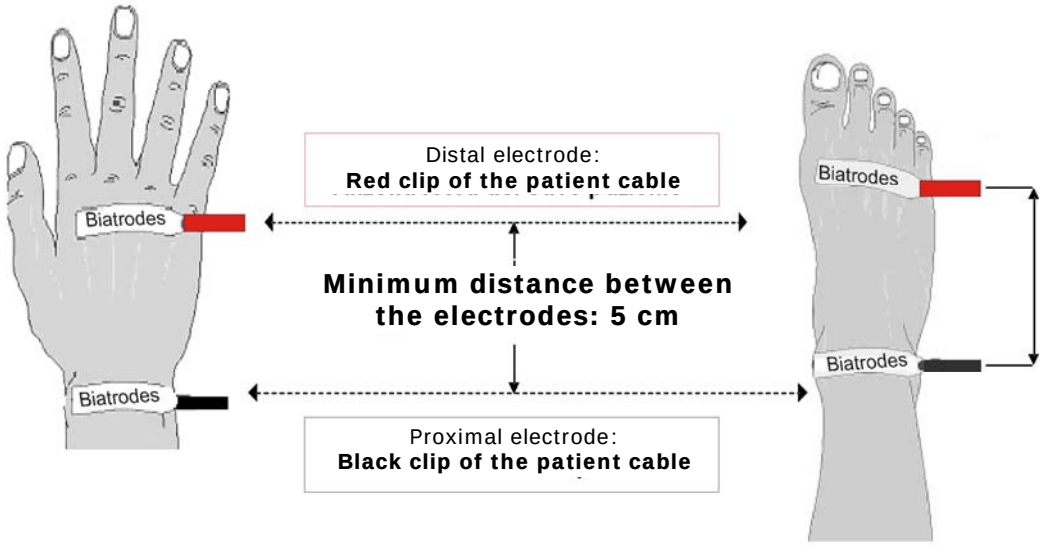

## Correct position of the subject

## Positioning the electrodes

High repetitiveness can only be achieved if electrodes are placed properly and carefully.

Therefore, it is necessary to pay attention to the correct positioning of electrodes and the connection of the patient cable clips. **Only use electrodes that are certified for bioimpedance analysis.**

**Standard electrode position**: hand/foot, right hemisoma, min. 5 cm of distance between electrode pairs.




## How to perform a measurement

Position the patient lying face upwards on a non-conductive surface.

Apply the specific BIATRODES 100'S electrodes on the right hemisoma on dry, non-fat skin (if necessary, clean the contact points with alcohol).

Connect the patient cable to the instrument.

Connect the cable featuring the red (distal) and black (proximal) insulated clips to the disposable electrodes.

Switch on the instrument pressing the button ON.

## Warning

**In case of fever or hypothermia, body impedance measurement is not reliable. Since body fluid conductivity changes according to temperature, resistance values are significantly altered in cases of fever over 38 C.**

**For children:** keep a distance of 5 cm between the injection-scanning pair, if necessary proximally moving sensors from wrist and ankle.

**In patients with amputations:** perform measurement on the intact hemisoma.

**In patients with vascular access**: use the limb without vascular access for bioelectrical evaluation.

**Check the skin condition at the contact points:** if the skin is very greasy, dry or humid, electric measurements are altered.

## DATA TRANSMISSION TO THE SOFTWARE BODYGRAM PRO 3.0

BIA 101 can transmit the measured bioelectric values to a PC using the serial protocol.
Transmission is realised by means of the USB cable provided with the BIA 101.


The USB port (with Type B connector) on the instrument is located on the rear side. The second type A connector on the cable shall be plugged into the PC's USB port. The instrument input is protected by an insulation higher than 5 kV.
ATTENTION: the connection shall be performed exclusively on PCs conforming to standard IEC 60950 and to the third edition of CEI EN 60601-1.
Bodygram PRO automatically checks for com ports on the PC.
If necessary, install the drivers of the USB cable ("USB serial Port") located on the CD or at the address:
http://www.ftdichip.com/Drivers/VCP.htm
If necessary, check for their correct installation in the folder Device Manager of Win XP or Device Center of Windows 7.
For data transfer:
- start the software Bodygram PRO;
- select the patient;
- create a "New Test";
- click on the button "Read serial" during the measurement.

# CHAPTER 4 AFTER THE ANALYSIS

## HOW TO RECHARGE THE INSTRUMENT

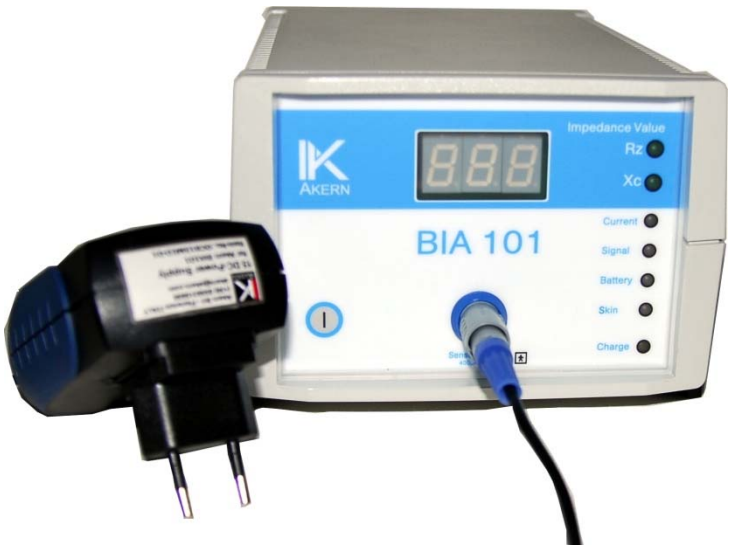
BIA 101 must only be recharged with the supplied battery charger, certified for medical environment. The use of different battery chargers will invalidate the warranty and may irreparably damage the device.

The battery charger output is continuous, regulated 15 V. Allowable input is 100–240 V AC.

The autonomy of the BIA 101 is approx. 12 hours of continuous use.

It is equipped with an auto switch-off system and a drained battery warning message, to preserve battery efficiency and durability.

To recharge the battery:




1. Connect the battery charger to a power outlet.

2. Connect the battery charger to the connector marked "SENSOR CHARGE" located at the centre of the front side of the instrument, as shown in the figure.

A full recharge cycle takes about four hours; a battery recharge control circuit inside the instrument prevents any overload risk.

The charge LED is on (orange) until the battery charger is detached. To verify whether the instrument charge is adequate, press the switch on button during charge and verify that the "Battery" LED is green.

# ALARMS OF THE BIA 101 SYSTEM


- **Signalling LEDs:**
- Rz: Resistance value
- Xc: Reactance value
- **Alarm LEDs:**
- Current: current
- Signal: signal
- Battery: battery state
- Skin: skin–electrode contact

- **Charge LED**: instrument charge in progress

**Current – Signal – Battery – Skin**

The instrument is provided with alarm LEDs located on the front panel.
When the instrument is operating, the LEDs issue a green light.
In case of an anomaly the system prevents displaying the analysis on the screen; the type of anomaly detected is signalled by the orange light of the alarm LEDs.
In this case, perform the following operations:
1 Electrodes:
- verify that the electrodes are approved by the manufacturer, featuring low impedance, certified for BIA analyses;
- check for expiry date and integrity;
- verify that the electrodes have not been used several times.
2 Patient cable:
- check for the integrity of the terminal section of the cable;
- check for correct operation of the clips;
- remove any gel residue from the clips;
- replace the clips if they are oxidized or nor correctly connectable to the electrodes.
3 Verify that the patient's skin is not excessively greasy; improve skin conductivity; remove creams or pomades cleaning the skin in the electrode positioning area using alcohol or disinfecting solutions; before performing a new analysis, replace the used electrodes.
4 Verify that no equipment with high electromagnetic emissions is located nearby.

**The SKIN LED** signals an anomaly due to improper contact between skin and electrode.
To avoid this, we recommend always cleaning the skin near the contact points and use electrodes suitable for the specific analysis: using high impedance electrodes invalidates the BIA measurement; Akern does not guarantee the results of an analysis performed using electrodes not approved by the manufacturer.

**The BATTERY LED** signals that the battery is drained; therefore a full recharge of the instrument is necessary. If it is necessary to perform an analysis and it is not possible to perform a full recharge cycle (four hours), it is possible to recharge for 30 minutes, completing the recharge later.

**The CHARGE LED** switches on when the instrument is being recharged, with the battery charger connected to an active socket.

## TIPS AND TROUBLESHOOTING

Akern high quality standards ensure the perfect operation of its instruments. In most cases, the malfunction can be solved using simple expedients.
To obtain the benefits of the high sensitivity of the BIA 101 sensor, take care of the quality of the electrodes used for the measurement and do not reuse the disposable electrodes. Keep the packages far from heat sources; sometimes it may be useful to store the open bags in the freezer. Check for the expiry date indicated on the package.

Without pathologies or altered hydroelectrolitic states, the standard resistance and reactance physiological values for Caucasian people are usually within the following ranges:
**Women: Rz 400–750, Xc 40–70; Men: Rz 350–650, Xc 35–65.**

**Attention:** altered values of Resistance and Reactance can lead to an incorrect evaluation of the body composition, due to the wrong positioning of the vector on the Biavector, as well as over or under estimations of the related body compartments.

**If the instrument does not switch on**: recharge the instrument for at least three hours. If the instrument has not been used for a long time, it may be necessary to recharge the battery, even if the type of battery located in the sensor features limited auto-discharge. Verify that the charge LEDs on the instrument and on the battery charger are ON.

If the sensor does not switch on after recharge, contact the technical support.

**If the instrument does not display the results during measurement**: verify that no alarm LED is on; if an LED is on, follow the instructions related to the issue signalled by the active LED. Insert the tester to perform a test reading. If the reading is correctly displayed, the malfunction is not related to the sensor; in this case verify the accessories used and the measurement protocol.

**If data transfer does not work:** verify on the PC that in the Device Manager folder - Com & LPT ports, there is the USB Serial Port device associated with a com port from 1 to 16. Otherwise install the drivers.

## CALIBRATION AND Verification

The BIA 101 instrument cannot be calibrated by the user. Only authorized qualified personnel are admitted to perform the calibration using precision test instruments at the factory. Nevertheless users can verify the test accuracy of the instrument and the patency of the patient cable.

### TESTER

An electronic test circuit (Tester) is supplied with the instrument which electrically simulates the human body. The circuit consists of high precision SMD electronic components and is intended for verification.

The tester allows a check the precision of the instrument reading and the integrity of the patient cable set


### INSTRUMENT ACCURACY VERIFICATION

Connect the tester to the "Sensor/Charge" socket located at the lower centre of the front side of the instrument as shown in the left figure. Switch the instrument on and verify that the displayed Resistance and Reactance values correspond to the Rz and Xc data printed on the label of the tester. Please also refer to “Acceptable Tolerances”.

### CABLE SET PATENCY VERIFICATION

Unscrew the tester top. Connect the clips of the patient cable set with the circuit board as shown in the left figure (pinze rosse = red clips – pinze nere= black clips). Switch the instrument on and compare the displayed values with the data of Rz and Xc printed on the label. If the below stated tolerances are exceeded or if an alarm goes off, the patient cable set is damaged. The cable must not be used any longer. When disconnecting the red clips the "Current", “Signal”, and “Skin” alarms should start. Reconnecting the red clips to the tester the "Current”, “Signal”, and “Skin" alarms should turn off indicating that the system controls work properly.

### ACCEPTABLE TOLERANCES

Check that Resistance Rz and Reactance Xc values are well within acceptable precision ranges as indicated on the label of the tester. If the resistance and reactance values differ by more than +10 Ohm and +5 Ohm respectively, the instrument must be sent to the Technical Department of Akern for calibration.

We recommend a Verification check be performed once a month. We also recommend having the calibration be performed every two years at the Akern lab (E-Mail: akern@akern.com; phone: +39.0558315658).

## POWER SUPPLY

Power supply is provided by three 3.7 V lithium-ion batteries (capacity 1000 mAh).

Generally speaking, the user is not supposed to replace batteries. In case you need to replace them, please contact the Akern Technical Support or the authorised dealer.

## MAINTENANCE AND REPAIR

The instrument does not include any user-serviceable parts.

Any technical operation can only be performed by Akern or authorised personnel.

## CLEANING AND STERILISATION OF THE SYSTEM

To clean the instrument, use a wet cloth. Avoid using solvents.

The sensor cable can be cleaned with a cloth soaked in disinfectant. Remove any gel residue from the clips.

The instrument and its accessories do not require sterilisation.

## STORAGE

Before storing the instrument for over 15 days make sure that the battery is fully charged.

Keep it in the supplied case; choose a dry location or a place with a relative humidity not exceeding 95% and with a temperature between 15°- 60° °C, not subject to variations.

If it is necessary to disconnect the battery, contact the Akern Technical Department.

# CHAPTER 5 **additional information**

## TECHNICAL SUPPORT AND SERVICE

In case of maintenance or replacement of the instrument, follow this procedure.

**BEFORE** shipment, please contact the Akern Technical Department by phone, fax or e-mail to obtain the necessary return authorisation, to agree a correct shipment of the material and to estimate the return times.

The instrument is supplied with a transport case.

Only use this case, which is suitable for air and/or surface transport. To avoid damaging the case, however, we recommend that you also use an external cardboard box or proper packaging material (bubble wrap, adhesive tape, etc.).

Make sure that the package includes all the materials specified in the checklist at the end of this manual, or whatever agreed with the Akern Technical Department. For future reference, we recommend making a copy of the above-mentioned list.

The list must be attached to the shipping documents.

Also include a document with the description of the detected malfunction and the name of the public body or private person, complete with all phone numbers / e-mail addresses.

### Shipping address

AKERN SRL

Via Lisbona ,32

I-50065 Pontassieve (FI)

Fax: +39.055.8323516

www.akern.com

E-Mail: akern@akern.com

ITALY

## TECHNICAL SPECIFICATIONS

| | |
|---|---|
| DEVICE TYPE: | Body impedance vector analyser |
| **MODEL:** | BIA 101 |
| **RESISTANCE(R):** | |
| Measurement range (Ω) | 0–999 ohm |
| Resolution | 1 % |
| **REACTANCE (Xc):** | |
| Measurement range (Ω) | 0–200 ohm |
| Resolution | 2 % |
| **POWER SUPPLY AND RECHARGE:** | |
| Li-ion Battery | 11,1 V 1000-1500 mAh - |
| Recommended battery charger: | AC 100-240 VAC Output 15 V, 2 A CE 60601-1:2007 |
| **MAX. RECHARGE TIME:** | 6 hours |
| **OUTPUT SIGNAL** | |
| Type: | DC zero sinusoidal signal |
| Output current | 400μA @ 50 kHz ± 1% |
| **FREQUENCY MEASUREMENT:** | Sinusoidal signal freq. 50 kHz ± 1% |
| **ELECTRICAL PROTECTION CLASS:** | Internal source medical device |
| **ELECTRICAL PROTECTION CLASS:** | Double insulation TYPE BF |
| **OVERALL DIMENSIONS:** | |
| Length: | 25 cm |
| Width: | 16 cm |
| Height: | 11 cm |
| Weight: | 1,1 kg |
| **OPERATING CONDITIONS:** | |
| Operating temperature: | 18°–30 °C -Relative humidity: <80% |
| Storage temperature | 15°- 60° C - Relative humidity < 95% |

# Conformity Declaration

Equipment: BIA 101

Manufacturer: Akern S.r.l.
Via Lisbona, 32/34
50065 Pontassieve (FI)
Manager: Antonio Talluri

Compliance with the **Directive** 93/42/CEE and subsequent amendments for Medical Devcie Class II type A, is obtained with product certification procedure according to Annex VI, with periodical inspection by Notified Body.

**NOTIFIED BODY**
IMQ S.p.A.
Via Quintiliano 43
20138 Milano Italy

The manufacturer declares that the specified product is compliant with the regulations listed below and with the standards **CEI EN 60601-1:2007**, and meets the essential requirements of the **Directive** 93/42/CEE and subsequent amendments**.**

The following table shows the EMC measurement tests (CEI EN 60601-1-2:2007) the instrument was successfully subjected to by Authorised Lab. (GSD Srl, Via Marmiceto, 8 56014 PISA)

EMC standards applied:

| *TEST* | *STANDARD* |
|---|---|
| *Radiated emissions* | CEI EN 60601-1-2 (2007/01) |
| *Electrostatic discharge (ESD) immunity test* | CEI EN 60601-1-2 (2007/01) |
| *Radiated radio-frequency field immunity test* | CEI EN 60601-1-2 (2007/01) |
| *50 Hz magnetic field immunity test* | CEI EN 60601-1-2 (2007/01) |

EC Conformity Marking

CE 0051

ANTONIO TALLURI

## CHECKLIST

Model: *BIA 101*

Serial number:_____

| | | | |
|---|---|---|---|
| Case in PVC/ALU | 1 | / | \ |
| Medical battery charger (15 V) | 1 | / | \ |
| Patient cable | 1 | / | \ |
| Biatrodes 100’S Electrodes (100 pieces) | 1 | / | \ |
| Instrument user's manual | 1 | / | \ |
| BODYGRAM PRO software CD Rom | 1 | / | \ |
| BODYGRAM PRO 3.0 software User's Manual | 1 | / | \ |
| Control Circuit | 1 | / | \ |
| 4 spare alligator clips | 1 | / | \ |
| Type B USB cable | 1 | / | \ |

Package made by: _____

Checked by: _____

Date: _____