

BIODY B.I.S ZM

Bioimpedance Measurement Device
Body Composition Analysis

User Manual

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1. Introduction

BIODY B.I.S^{ZM}, is a unique bioimpedance meter in its method of acquiring bioimpedance measurements, enabling the reliable and simple application of the foot/hand quadripolar method with 4 fixed electrodes integrated into the device, or for individuals with limited mobility using cables and disposable electrodes.

The obtained values are transferred via Bluetooth directly to the BiodyManager.com software for users of stationary computers or to the BiodyConnect app for Android or iOS mobile users.

The web service software BiodyManager.com is hosted in France on a certified server for health data hosting in accordance with ANS requirements (see technical data sheet).

Furthermore, the data is fully encrypted and can only be read by the user.

2. Purpose

The BIODY B.I.S^{ZM} system in conjunction with BiodyManager.com allows for the analysis of body composition.

It is not intended to diagnose any pathological condition.

2.1. Target Population

The analysis of the measurements is valid for adults (ages 18 to 95).

3. Analysis Results

The results of the analysis of the measurement performed on the subject are **estimated** body composition values obtained from developed algorithms versus other reference measurement methods such as Dual-Energy X-ray Absorptiometry (DXA) for fat, lean, and bone mass or isotopic dilution for the assessment of water and hydration balance.

The main **estimated** body components are as follows:

Fat mass	Fat free mass
Total water	Skeletal muscle mass
Fat-free hydration rate	Appendicular skeletal muscle mass
Intra extracellular water	Body cell mass
Bone mineral content	Extracellular solids

The following values are also estimated:

Dépense énergétique	Métabolisme de base

Body indices are calculated by relating the mass of the compartment or tissue measured in kg to the height (in meters) squared.

IMC/BMI	Body Mass Index
FMI	Fat Mass Index
FFMI	Fat Free Mass Index
ASMI	Appendicular Skeletal Mass Index
SMI	Skeletal Mass Index

4. Principle of Bioimpedancemetry

Bioimpedancemetry involves measuring the impedance of the human body at various frequencies.

Noble tissues (proteins) exhibit a biodynamic defensive reaction to the passage of current.

This reaction is very significant at lower frequencies and becomes negligible at higher frequencies.

The cell membrane is highly resistive and acts as a dielectric separating small conductors made up of the cells' internal fluids.

Thus, there will be a more or less significant reactive term depending on the frequency of the measurement, hence the notion of bioimpedances.

Fluids (blood, lymph, intracellular water, etc.) contain electrolytes that conduct electricity.

Adipose tissue, containing little fluid, is a poor conductor.

Measuring impedance at certain frequencies allows for the use of predictive algorithms to estimate the amount of fluids the current has passed through and to distinguish different tissues, thus providing a detailed analysis of the subject's body composition.

In multi-frequency mode or spectroscopy mode, the algorithms can distinguish between extracellular and intracellular water.

4.1. The Specifics of BIODY B.I.S^{ZM}

The bioimpedance measurement is conducted using a quadripolar method by emitting a constant low-intensity current of 35µA to 100µA, which is not felt by the subject.

The BIODY B.I.S^{ZM} device allows for bioimpedance measurements across a frequency spectrum of 1 to 1000 kHz with 54 measurement points:

(1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,18,20,23,25,28,31,35,39,43,50,54,60,67,75,83,93,100,115,128,143,159,177,200,220,245,273,304,339,378,421,469,500,582,649,723,806,898,1000)

PFor each measurement, the device records the obtained results.

Using the principle of spectroscopy, the Cole-Cole plot is drawn: the values of resistance at low frequency (Re) and at the highest frequency (R∞) are extrapolated.

The data transmitted by the device includes:

- Impedances, reactances, resistances in ohms, and phase angles in degrees at the 54 frequencies.
- Capacitance (C in nF)
- Resonance frequency (Fo in kHz)
- Extracellular resistance (Re in Ω)
- Intracellular resistance (Ri in Ω)

Infinite resistance (R∞ in Ω) is calculated at the end of the measurement synchronization.

Based on the measurement data and other parameters to be entered characterizing the subject, the measurements are analyzed and the calculated results of body composition are displayed on the subject's dashboard in the BiodyManager.com software.

Risks - Pictograms

⚠	Danger	Use of the device could result in death or serious injury.
⚠	Warning	Incorrect use may cause discomfort to the subject. Incorrect use may disturb the reliability of the measurement. Incorrect use may lead to data loss or corruption. Advice regarding electromagnetic disturbances.

4.2. Description of the risks associated with the use of the device

⚠	You should not perform measurements on subjects carrying an electronic **life-support** medical device: implanted (e.g., pacemaker), portable (e.g., spirometer), (e.g., artificial lung). There is a risk of malfunction of the life-support device that could pose a risk to subjects whose life depends on the proper functioning of their device. You should not take measurements on pregnant women, because although no incidents related to this technique have been recorded, no specific publications have been identified on the safety of bioimpedancemetry and thus on the formal absence of risk of disturbances in the development of the embryo or fetus.
⚠	Do not use the device on injured or damaged skin that must be in contact with the applied parts (electrodes). Risk of irritation or pain.
⚠	The device must be cleaned before and after use. Risk of subject contamination if the device was contaminated during previous use.
⚠	This device incorporates LED light indicators, therefore, it is advised that photosensitive individuals avoid staring at these indicators.
⚠	It is prohibited to open and/or modify this device without the manufacturer's authorization. Apart from replacing rechargeable batteries, no user-initiated maintenance operations are allowed on the product. Risk of device performance degradation.

4.3. Description of cybersecurity-related risks

⚠	The Biodymanager.com software and Biody Connect mobile apps are connected to the internet. Your account credentials are personal. You should not share your personal credentials with third parties to ensure the confidentiality and integrity of subject data. Failure to comply with this obligation makes the user liable in case of liability search related to data breach of this account.

4.4. The pictograms located on the label

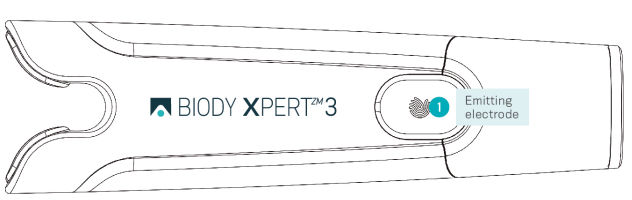
	Type BF applied parts. There are 4 electrodes
⎓	Direct current 5 V ± 10% 500 mA
	Consultation of the user instructions is mandatory
	RF emitter – non-ionizing radiation
	Manufactured by
	Do not dispose of with unsorted waste, but must be sent to separate collection facilities for recovery and recycling
LOT	Indicates the manufacturing batch number of the device
SN	Indicates the serial number of the device
CE	The manufacturer is committed to the product's compliance with the regulatory requirements of the European Union

5. Description of delivered items / device description

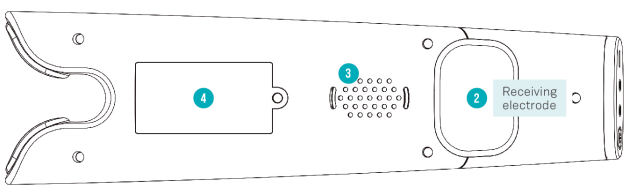
BIODY B.I.S^{ZM} is delivered in a case with an additional cardboard packaging.

This packaging contains:

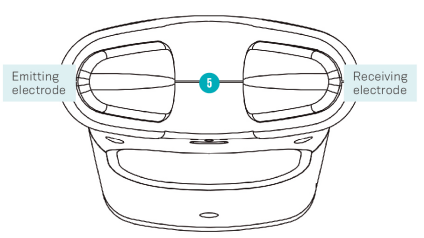
- The BIODY B.I.S^{ZM} device
- The necessary USB transformer for battery charging
- A USB/micro USB cable to connect the transformer to the device for battery charging
- A software activation license, for account creation on BiodyManager.com
- This manual



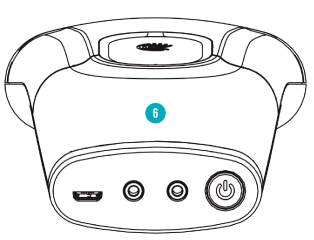
Top view:
1 Chrome applied part
Thumb **emitting** electrode with ring for displaying function indicator LEDs



Bottom view:
2 Chrome applied part
Finger **receiving** electrodes
3 Speaker output
4 Battery compartment



Front view:
5 Applied parts:
2 rear-foot electrodes
The emitting electrode is the left one when facing the device



Rear view:
6 Connectivity
Micro USB connector
2 Jack connectors (foot, hand) for wired measurement
Push button for power on and off, voluntary activation and deactivation of Bluetooth

We advise you to keep the packaging for any reshipment of the BIODY B.I.S^{ZM} device.

6. Operating Principle of the BIODY B.I.S^{ZM} System BiodyManager.com / BiodyConnect

The system

The device

BIODY B.I.S^{ZM} is the bioimpedance measurement device.

An internal Bluetooth module allows the device to communicate with its dedicated applications.

A single button located at the back of the device enables it to be turned on and off, as well as the voluntary activation/ deactivation of Bluetooth.

- Turning on: 1 short press
- Voluntary shutdown: 1 long press
- Voluntary activation of Bluetooth: To turn on the device (1 short press) while it is on (front green LED lit), quickly double-press the button, the LEDs will blink blue for 1 minute, a message displays "Bluetooth Communication Activated".

Voluntary shutdown of the Bluetooth transmission before its automatic shutdown: double press and a message displays "Bluetooth Communication Disabled".

The applications

⚠ An internet connection (cable, Wi-Fi, 4G...) is required to use the applications, synchronize the measurements taken with the device, and obtain the body composition analysis.

1. Secure web service software **BiodyManager.com** which allows:

- Synchronization of measurements over Bluetooth **on Windows and MAC computers directly in the updated Google Chrome web browser,**
- Synchronization of measurements over Bluetooth on Windows and MAC computers directly in the updated Google Chrome web browser,
- Management of the patient file and customization of the software,
- Access to complete user manuals, tutorials...

2. A BiodyConnect application available only on Android or IOS mobiles, which allows:

- Synchronization of measurements,
- A synthetic and quick reading of the measurement analysis results,
- Control of some configuration options of your measurement device, as described below. To use the customization mode, your device must be in Bluetooth transmission mode.

If you wish to take advantage of the customization possibilities of functions set by default in your BIODY B.I.S^{ZM} device, it is necessary to install the BiodyConnect app on a mobile, even if you do not use it to synchronize measurements.

- Setting the "Choice of message language" function.
- The language is already set to operate in the official language of the country corresponding to the delivery address indicated on your order form, unless explicitly stated otherwise.
- Adjusting the device's volume.
- Setting the device's time (internal clock drift or change of timezone location).

Configure the Computer Environment

Declaration

The following instructions allow the installation and configuration of the computer environment by the end user.

Minimum OS versions for computers
Windows 10 and 11
Bluetooth version: LE 5.0 minimum
macOS = Monterey 12

Windows PC Computers

You must check for a Bluetooth component in your PC's settings. If it is an internal Bluetooth, **it must be enabled**. If you do not have internal Bluetooth on your computer, you must use the BiodyConnect app on an Android or IOS mobile to synchronize the measurements, or use an external Bluetooth dongle.

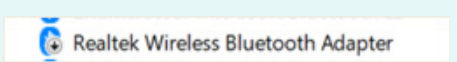
If your internal Bluetooth does not work with our device, you must disable it and also use the same type of dongle described above.

Some internal modules from Realtek, particularly in **HP brand PCs**, do not work properly with our device. You need to check for this component by opening the "**device manager**" on your PC.

Example:



⚠ Right-click on the name of the Bluetooth (here Realtek): choose to disable, the component will appear disabled as shown in the example below.



Then insert the Bluetooth dongle into a free USB port on your PC.

When your system is ready, you must pair the device with your computer's Bluetooth: activate the Bluetooth of the BIODY B.I.S^{ZM} as indicated at the beginning of the previous page; Point: "the device"

Find the Bluetooth icon in your PC's taskbar.
Choose the "add a Bluetooth device" option.
When the name BX3-XXXX-XXXX appears in the pairing window, select it to perform the pairing.

MAC Computers

A compatible Bluetooth component is present in the MAC.
Prior association is not necessary.
Pairing with the device will be requested at the time of the first measurement transfer.

BiodyConnect on mobile

Minimum system versions on mobile

- Android 10
- IOS 13

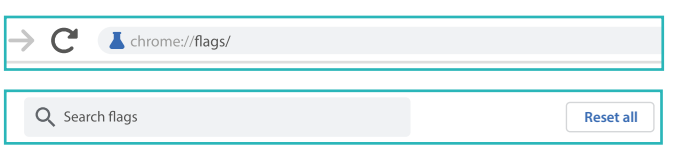
The BiodyConnect app is installed from the Android Play Store or Apple App Store.
Go to the store corresponding to your mobile, search for BiodyConnect, and install the application.
Prior Bluetooth association is not necessary.
Pairing with the device will be requested at the time of the first measurement transfer.

Google Chrome Browser

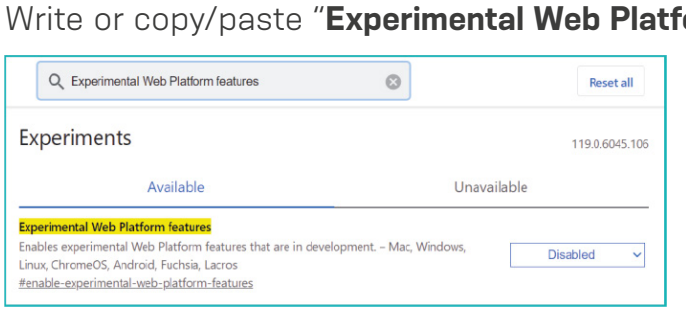
BiodyManager.com is optimized for use with the Google Chrome browser.
Check if the Chrome browser is installed and up-to-date.
If not, you need to install it.

Activate the flag for synchronizing measurements directly from the subject's dashboard

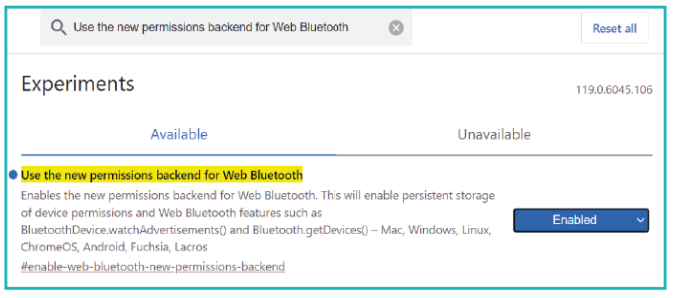
Open Google Chrome browser then open a new tab.
In the **browser's URL bar**, write "**chrome://flags**" and then press the "Enter" key on your keyboard.



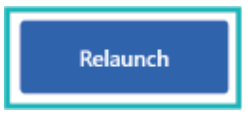
Using the search, "Search flags":
Write or copy/paste "**Experimental Web Platform features**".



Hacer clic en el botón "**Disabled**" y seleccionar la opción "**Enabled**".
En la barra de búsqueda "Search flags", escribir "**Use the new permissions backend for Web Bluetooth**".
Hacer clic en el botón "**Default**" y seleccionar la opción "**Enabled**".



Click on the "**Disabled**" button and select the "**Enabled**" option.
In the "Search flags" search bar, type "**Use the new permissions backend for Web Bluetooth**".
Click on the "**Default**" button and select the "**Enabled**" option.



Chrome browser will ask to be relaunched; you must validate this restart by clicking on "Relaunch".
You can close the "Flags" tab.

The browser is now configured for live synchronization through the subject's dashboard.

7. The BiodyManager / BiodyConnect Software Solution

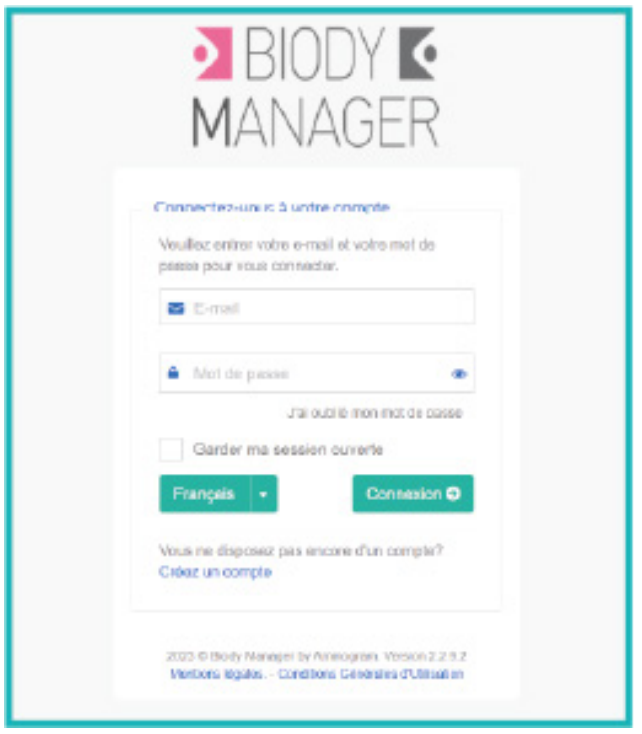


This manual describes the initial steps to create your BiodyManager account.
The complete user guide for the BiodyManager.com software and BiodyConnect mobile apps is available in PDF format directly on BiodyManager.com.
You must have a PDF file reader installed on your computer.
You can request to receive this printed supplement by writing to us at: **contact@aminogram.com**, and it will be sent to you by postal mail within 7 days.

7.1. Creating your BiodyManager.com account

BiodyManager.com is optimized for use on the **Google Chrome** web browser.
Ensure you have the license document that came with your device.
You need to be connected to the internet and use the **Google Chrome** web browser.
You should set this browser as the default browser for BiodyManager.
Enter the address **www.biodymanager.com** in the browser's search bar.

At the bottom of the window "Don't have an account yet?" click on "Create an account".





By default, the language displayed in the dropdown menu on the login screen is French.

You can be guided through all the registration steps by clicking on this "Information" button.
Enter your license key found in the License document provided with your device, as well as the serial number of your device. **(The license key containing a zero 0 is distinguished from the letter O because it is crossed out)**.
This email will be a unique identifier for the software.

This email will be used to renew your password in case you forget it.

In the enter a password field, it must contain at least 10 characters with at least one uppercase, one lowercase, one number, and one special character.

Upon the completion of your account creation, you will receive an email at the address used to validate the creation of your account.

It comes from the address **admin@biodymanager.com**.

Check your spam if this email is not in your main inbox.

You must allow the reception of emails coming from the address **admin@biodymanager.com**.

onfirmation of account creation will direct you straight to the software.



Click on the "Access Dashboard" button, which will open the home screen allowing you to access all functions.

Reminder: The guide to using the BiodyManager.com software, as well as the Android and IOS apps, is available directly on BiodyManager.com under the Support section found on the software's home screen; you can download, consult, or print it.

Additional videos and tutorials are also available in this section.



You must familiarize yourself with all this additional information to use the software applications necessary for the operation of the BIODY B.I.S^{ZM} overall system:

- Customization of your BIODY B.I.S^{ZM} device
- Synchronization of measurements
- Analysis of measurements
- Management of the patient file

You must go to your email inbox and validate the account creation by clicking on the link contained in the email. Without this validation, you will not be able to connect to the software.

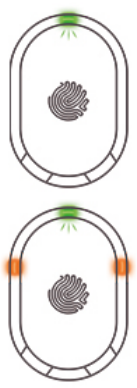
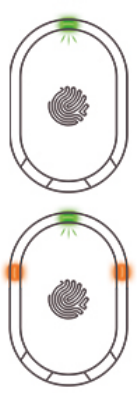
8. Operating the BIODY B.I.S^{ZM} device

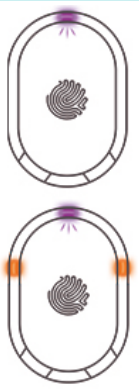
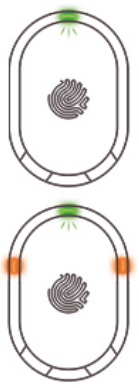
8.1. Functions of the On/Off button - reminder

Short press	Power on – startup beep
Quick double press	Voluntary activation of Bluetooth or voluntary deactivation of Bluetooth before its automatic shutdown
Long press	Power off the device – shutdown beep

8.2. Light indicators-messages

The messages and light indicators described below will help you recognize the different states of your device

ID	LEDS	Description of action and response
1		After pressing the power button, the LED located at the front of the ring flashes green. You will hear a startup beep. Then the 2 LEDs at the front light up orange, the device checks if the cables are connected. If the cables are not connected, the orange LEDs turn off, only the front LED flashes green. If the cables are connected, the LEDs remain lit in orange. Without any action on your part, the device turns off after 35 seconds.
2		When the subject is in the measurement position, the thumb, finger, and rear-foot electrodes are in contact with moist skin, the Biody is in position, the front LED flashes green. If the cables are connected, the 2 left and right LEDs remain lit in orange. A message indicates: "Don't move anymore. The measurement is going to start."

ID	LEDS	Description of action and response
3		The measurement starts. The purple LED flashes. If the cables are connected, the 2 left and right LEDs remain lit in orange.
4		The measurement is taken, the front LED briefly flashes green. If the cables are connected, the 2 left and right LEDs are orange. A message indicates: "The measurement is finished."
5		The request for Bluetooth synchronization of the measurement begins. The 3 LEDs turn blue. A message indicates: "Bluetooth communication enabled." As soon as the app has received the measurement, it is deleted from the memory card and the device turns off.
6		When you power on the Biody and one or more measurements are stored but not yet synchronized, the front LED flashes green and the left and right LEDs are pink. An audible message indicates: "Your device contains unsynchronised measurements." You can synchronize these measurements by voluntarily activating the Biody's Bluetooth or start the process of a new measurement. The recorded and unsynchronized measurements remain stored until they are transferred.
7		If at the beginning of the measurement process, the emitting electrodes are no longer in contact with the subject, A message indicates: "Contact broken. Check patient connections." The device returns to its state of waiting for the electrodes to contact the skin (fingers and rear-foot). When contact is adequate again, the measurement process restarts.
8		The microcontroller can detect an invalid measurement after calculating the spectroscopy data. The front LED flashes green. The 2 LEDs located at the bottom left and right flash orange. A message indicates: "Wrong measurement. Please redo the measurement." The device will turn off, check the measurement conditions, and redo the measurement.
9		When the device turns off, the 2 red LEDs at the top left and right light up in red. Bluetooth disabled.

THE BATTERY		
ID	**LEDS**	**Description of action and response**
10		When the battery level falls and reaches 50% charge, the rear LED turns solid red. From this point, the battery will drain faster than before reaching 50%. This level will correspond to 2 bars on the battery level indicator that you see on the app on the measurement dashboard after synchronizing the measurement. A message indicates: "Low battery, charge as soon as possible." When you see a level with one bar on your app, the battery has reached its critical level and you must urgently charge your device to continue using it.
11		When you power on the device and the battery is too low, the rear red LED blinks. A message indicates: "Battery too low, measurement impossible." The device will turn off after this message. You need to charge your device. It will not function again until a sufficient charge level is reached.
12		When you charge your device, the rear LED lights up in blue.
13		When the battery is fully charged, the rear blue LED blinks. You can disconnect the transformer.

POTENTIAL MALFUNCTIONS DUE TO THE SYSTEM		
ID	**LEDS**	**Description of action and response**
14		When you see the 2 solid red LEDs with the front red LED blinking, it means that a system error is blocking all operation. A message indicates: "Sorry, a system error has occurred. Please restart your device." You must turn off the device and restart it. If this indicator persists, contact customer service.
15		When a measurement is taken correctly, but a malfunction has prevented the measurement from being recorded, you will hear the following sound: "Sorry, a recording as occured. Please redo the measurement."
16		If an internal malfunction interrupts the measurement, you will receive the following message: "An error has occurred, measurement interrupted, please redo the measurement."

9. The Measurement

Measurement with Integrated Electrodes

The BIODY B.I.S^{ZM} device is designed for easy handling by the subject.

It is equipped with 4 fixed chrome electrodes intended to be in contact with the fingers of the hand and the back of the foot under **the malleoli**.

A single button located at the back of the device enables it to be activated.

The subject himself/herself takes the measurement, which is then transferred to the software directly and solely via Bluetooth.

When the subject's moist skin contacts the emitting electrodes, the measurement starts immediately.

Wired Measurement (as an option)

When subjects have limited mobility, such as elderly or bedridden subjects, and self-measurement in a sitting position is not possible, you must use the 2 cables that allow the device to be used in a lying position with single-use adhesive electrodes.

9.1. Subject's State / Measurement Environment

Monitor the subject's condition

⚠ Measurements taken on women during menstruation cannot be compared to measurements taken outside this period due to significant body water variations that can occur during this time.

⚠ The presence of prostheses with metal parts may influence the measurement results. You should inquire about this with the subject.
In the case of a prosthesis or screws located on one side only, you can take the measurement on the other side.

⚠ The intake of substances that may significantly disturb homeostasis (subject under medication such as cortisone, doping products...) can influence the measurement result.

To obtain a measurement that represents the body composition of a subject in their usual state, it is necessary to adhere to the recommended conditions for the method of body composition measurement by bioimpedancemetry, as described below:

⚠

- Empty bladder, ideally after a bowel movement.
- No drinking fluids in quantity just before the measurement. However, the subject can hydrate an hour before.
- No significant alcohol consumption the day before.
- No sports activity before the measurement.

In subsequent appointments, only the weight should ideally be entered. However, in cases of diet for weight loss or gain, the bra size can change and this data may need to be updated.

Similarly, the level of activity can vary, especially for monitoring athletes (training or competition) or starting a sports activity for overweight individuals, etc. Make sure to check this data over time. These data can be modified in the measurement record of the software.

Generally, for ongoing monitoring of the data sought, measurements should be taken under the same conditions and at the same time of day.

Prepare the Subject

⚠ The subject's skin must be clean and free of any cream residue or other products.
Clean the skin in contact with the electrodes with alcohol-soaked cotton.
Then, moisten the skin in contact with the electrodes.

⚠ Ask the subject to remove any significant metallic objects that may be in contact with their skin.

⚠ You should not touch the subject while they are taking their measurement.
Ensure there is no bare skin to bare skin contact. For example, a bare hand resting on the opposite bare leg or arm.
If the subject is only in underwear or, for example, in summer, the thighs are bare, they should not touch each other.
If the subject is of significant size and despite spreading the legs, the bare thighs touch, place, for example, a small bolster wrapped in an exam sheet, or a rolled towel.

Additional Necessary Equipment

⚠ The adult subject must be measured with a stadiometer during the first measurement.
The subject must be weighed on a calibrated scale before taking measurements.
Entering an approximate height and weight will alter the accuracy of the body composition results.

- Stadiometer
- Calibrated scale
- Tape measure, if you wish to perform centimetric measurements
- Alcohol for cleaning the skin at the contact points
- Cotton and water or hydroalcoholic gel, or neutral wet wipes for moistening the skin in contact with the electrodes for measurements with integrated electrodes.

9.2. Integrated Electrode Measurement Position



The subject should sit on a stool in a comfortable position, with the back straight and legs and arms slightly apart.

Step 1 : The subject moistens the circumference of their right rear foot and the fingers of the right hand that will be in contact with BIODY B.I.S^{ZM} using a wet wipe/cotton or hand sanitizer. Measurements are taken on the right side of the body (unless there is a physical impossibility or the presence of a prosthesis or screw).

Step 2 : The subject sits on a stool or a non-metallic chair without armrests, with the back straight. He moves the right foot back, letting the heel lift off the ground. The subject holds the BIODY B.I.S^{ZM} in the right hand. This position naturally allows the arms and legs to be slightly apart.

Step 3 : The thumb is in contact with the electrode "located on the top of the device", and at least two fingers touch the electrode located under the device.

Step 4 : The subject places the "U" shape against their right rear foot **(under the malleoli)**, the electrodes touch their skin. All 4 electrodes must be in perfect contact with the subject's skin.

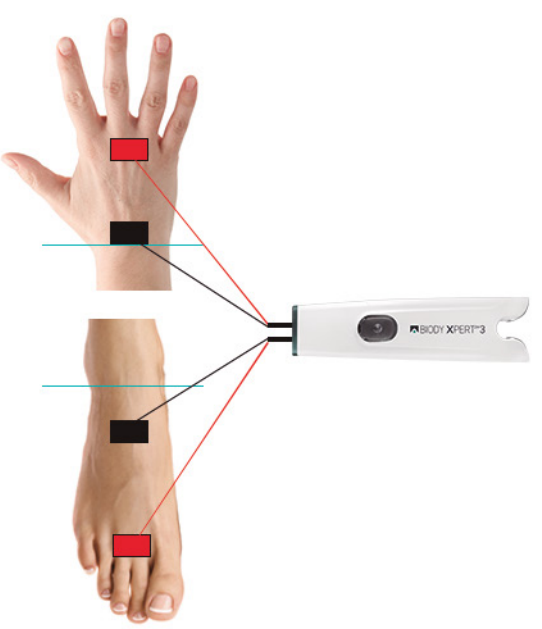
The measurement starts when the 2 emitting electrodes are in contact with the subject. (see LED/message table) – the other 2 electrodes (receiving) must also be in perfect contact to obtain a correct measurement.

You can synchronize the measurement, via the Chrome browser if you are using a PC or Mac, or in the BiodyConnect app if you are using a mobile device.

9.3. Wired Measurement Position (as an option)







The patient is lying on a non-metallic examination table.

The patient should have their arms and legs slightly apart (about 30°).

Step 1 : Connect the cables to each jack outlet located on the back of the device.

Step 2 : Place the electrodes on the right hand and foot of the patient. For the hand: one at the head of the metacarpals and the other at the wrist crease. For the foot: one at the head of the metatarsals and the last one at the instep between the two malleoli.

Step 3 : Connect the alligator clips following the colors designated for the injection and reception of current:

Red cable for injection at the head of the metacarpals and metatarsals (hand and foot).

Black cable for reception at the wrist and instep.

Step 4 : Turn on the device by pressing the push button.

The measurement proceeds as previously described for the integrated electrode mode.

10. Procedure for managing unsynchronized stored measurements

When one or more measurements stored in BIODY B.I.S^{ZM} have not been synchronized, they remain in the device's memory until they are synchronized in the **BiodyManager.com** software.

	When you power on the Biody and one or more measurements are stored but not yet synchronized, the front LED will blink green and the left and right LEDs will be pink. An audible message indicates: "Your Biody contains unsynchronized measurements". You can synchronize these measurements by voluntarily activating the Biody's Bluetooth or starting the process of a new measurement.

1st case

It is the last measurement taken, your device turned off and you were not ready to synchronize it. Proceed as indicated in the software manual to display the synchronization page on the BiodyManager.com software or on the BiodyConnect app, you must voluntarily activate the Bluetooth function by double-clicking the push button in order to synchronize the measurement.

2nd case

There are one or more unsynchronized measurements taken previously.

These can be synchronized on each subject's record, synchronizing the last measurement taken first, the second last becomes the first, and so on until all are synchronized.

11. Internet Outage

In case of an internet outage, use your mobile app with mobile data enabled. If you have no connection, measurements can be synchronized in offline mode on the mobile app if your session is active. This means you had already logged in with your connection credentials when internet was available and your connection token has not expired. The token expires 12 hours after your login.

You can synchronize your measurements, they will be saved locally, pending internet connection availability, but they cannot be analyzed.

When the connection is restored, the measurements will be sent to the calculator for interpretation and will be available for display on the dashboard of each measured subject.

If the outage occurs while you are synchronizing the measurement on the BiodyManager.com web page, or on the app, the measurement will be saved locally on the web page and will be sent to the calculator when the connection is restored.

A counter will indicate the number of measurements saved locallye.

12. Rechargeable Batteries

⚠ Rechargeable batteries are charged using the transformer and USB cable provided with the device.
Only the transformer provided with the device should be used to charge the batteries.
An identification label allows you to recognize it among other chargers you own.

⚠ The BIODY B.I.S^{ZM} device has a safety feature that prevents measurement taking when the USB cable is connected to the transformer and plugged into a power outlet, or into a computer USB port.

During the transfer of measurement, information about the level of rechargeable batteries is transmitted in the form of a level icon.
Light indicators and messages also inform you of the state of the rechargeable batteries when the level is low.

Batteries too low – the device will turn off quickly – Charge immediately	Low level, charge as soon as possible	Charged sufficiently	Charged fully

13. Cleaning - disinfection - end of life

Cleaning

⚠ Especially when measurements are taken with integrated electrodes, you must disinfect the device before and after each measurement.
The cleaning and disinfection of the BIODY B.I.S^{ZM} and its electrodes **should only be done with wipes soaked in alcoholic solution or with cotton soaked in 70° alcohol.**
Specification of alcoholic maintenance wipes: wipes that can be used for cleaning medical devices.
Very rapid disinfectant properties, approximately 60 seconds for common germs (bacteria, fungi, viruses) and composed solely of alcohol-based.

⚠ **Do not use solvents like acetone to clean the device.** Risk of damaging the plastic casing.

⚠ **Do not use chlorine-containing disinfectants like bleach or wipes containing chlorine** derivatives to clean the device.

Rechargeable Batteries

The lifespan of rechargeable batteries is estimated at more than 300 charge/discharge cycles.
When rechargeable batteries are at the end of their life, they must be replaced with identical batteries as described in the technical datasheet.

End of Life



Rechargeable batteries at the end of their life should not be disposed of with household waste and must be recycled by yourself according to the regulations applicable to your location.
The BIODY B.I.S^{ZM} device at the end of its life should be returned to Aminogram, for recycling and disposal.

14. Environment and EMC Declaration

Environment

Degree of protection against water penetration: no specific protection.
Storage conditions:
Temperature: -20° to +40°C
Relative humidity: 45-85% non-condensing
Pressure: 70kPa to 105kPa
Usage conditions:
Temperature: 16°C to 32°C
Relative humidity: 45% to 85% non-condensing
Pressure: 70kPa to 105kPa

Manufacturer's Note and Declaration Regarding Electromagnetic Compatibility (EMC)

The BIODY B.I.S^{ZM} device meets the requirements for electromagnetic compatibility according to EN 60601-1-2 4th edition. The device is designed to limit the generation and emission of electromagnetic energy to ensure that the proper operation of other devices is not disturbed and to benefit from adequate electromagnetic immunity. The minimum measurement accuracy necessary to ensure the expected effectiveness in a disturbed electromagnetic environment is 2%.

A medical electrical device requires special precautions regarding electromagnetic compatibility. To this end, the BIODY B.I.S^{ZM} is intended to be used in the specified electromagnetic environment below.

Class according to CISPR11:
Class A:
The BIODY B.I.S^{ZM} is intended to be used in a hospital environment.
Class B:
The BIODY B.I.S^{ZM} is intended to be used in a residential environment.
Group 1
It is appropriate for the BIODY B.I.S^{ZM} user to ensure that it is used in such an environment.

⚠ The measurement is always analyzed by the microcontroller before being declared valid or invalid. If the measurement is consistently rejected at the same location, the electromagnetic environment may be disturbed. You should move away from the source of disturbance to take the measurement.

⚠ Using accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit, thus not guaranteeing EMC.

⚠ Do not store or use the device near devices emitting high-power radiation, particularly those emitting microwaves.
Do not stack multiple electronic devices, as they may interfere with each other.

⚠ RF portable communication devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm to any part of the BIODY B.I.S^{ZM}, including optional cables. Otherwise, the performance of the BIODY B.I.S^{ZM} could be impaired.

Manufacturer's Guide and Declaration - Electromagnetic Emissions
Class A: The BIODY B.I.S^{ZM} is intended for use in professional healthcare establishments, hospitals and clinics, except in facilities close to high-frequency surgical equipment and near an electromagnetic shielding room for an electromagnetic medical imaging system by magnetic resonance where the intensity of electromagnetic disturbances is high. Class B: The BIODY B.I.S^{ZM} is intended to be used in a home care environment such as a doctor's office. The customer or user of the BIODY B.I.S^{ZM} device must ensure it is used in such environments.

Table 1		
Emissions Test	**Compliance**	**Electromagnetic Environment - Advice**
RF Emissions CISPR 11	Group 1	The BIODY B.I.S^{ZM} device uses RF energy only for its internal operation. Therefore, its RF emissions are very low and do not appear to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class B	The BIODY B.I.S^{ZM} device is suitable for use in all establishments, including residential homes and institutions directly connected to the public low-voltage power supply network.
Harmonic Distortions IEC 61000-3-2	N/A (powered by an internal battery)	
Voltage Fluctuations and Flicker IEC 61000-3-3		

Table 2			
Immunity Test	**IEC 60601 Test**	**Compliance Level**	**Electromagnetic Environment – Advice**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be covered with wood, concrete, or ceramic tiles. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transients / bursts IEC 61000-4-4	± 2 kV for a.c power lines ± 1 kV SIP/SOP	N/A	The BIODY B.I.S^{ZM} device is powered by a battery and is not connected to an electrical line.
Surges IEC 61000-4-5	± 1 kV line-to-line ± 2 kV line-to-ground	N/A	
Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	N/A	
Voltage interruptions IEC 61000-4-11	0% UT ; 250/300 cycle	N/A	
Power frequency magnetic field IEC 61000-4-8	30 A/m (50 / 60Hz)	30 A/m (50 / 60Hz)	Magnetic fields from power frequency should be at typical levels found in standard commercial or hospital environments.

Table 3			
Immunity Test	**Test level**	**Compliance Level**	**Electromagnetic Environment – Advice**
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V rms 6 V in ISM bands from 150 kHz to 80 MHz	N/A (powered by internal battery)	N/A except for the transformer, compliant with EN 60601-1
Radiated RF EM fields IEC 61000-4-3	10 V/m From 80 MHz to 2.7 GHz	10 V/m from 80 MHz to 2.7 GHz	
Proximity fields from RF wireless communication equipment	27 V/m from 380 MHz to 390 MHz 28 V/m from 430 MHz to 470 MHz 9 V/m from 704 MHz to 787 MHz 28 V/m from 800 MHz to 960 MHz 28 V/m from 1700 MHz to 1990 MHz 28 V/m from 2400 MHz to 2570 MHz 9 V/m from 5100 MHz to 5800 MHz	27 V/m from 380 MHz to 390 MHz 28 V/m from 430 MHz to 470 MHz 9 V/m from 704 MHz to 787 MHz 28 V/m from 800 MHz to 960 MHz 28 V/m from 1700 MHz to 1990 MHz 28 V/m from 2400 MHz to 2570 MHz 9 V/m from 5100 MHz to 5800 MHz	Minimum separation distance: 0.3 m

15. Technical Specification

Quadripolar measurement (4 applied parts of BF type)
Multifrequency and spectroscopic impedance measurement from 1 to 1000 kHz
Measurement range: 20 to 1,500 Ohms
Current intensity: 35µA to 100µA
Accuracy: Impedances 1%
Phase angle: ± 0.2°
Representations:
± 160 g for fat-free mass equivalent to ± 0.26%
± 150 ml for total water equivalent to ± 0.42%
± 90 ml for extracellular water equivalent to ± 0.54%
Displayed resolution
Impedances in ohm: Whole number
Phase angle in degrees: 1/10th
Wireless Bluetooth connection:
Bluetooth name: BIS, followed by an 8-digit serial number (BIS-XXXX_XXXX)
Features:
Bluetooth LE BGX220S – BGM220S
Emission frequency band: 2402-2480 MHz
Frequency modulation type: GFSK
Equivalent radiated power: 11.11 dBm
Power supply: 2 rechargeable NiMh LR6 1.2V 2800 mA PANASONIC REF: BK-3HGAE/4BE
Weight: 300g
Transformer for battery recharge: (one of these transformers is supplied with your device)

FRIWO FOX6-XM-USB Input: 100-240V ~ 50-60Hz 160-80mA Output: 5V ⎓ 1.4A	XPPOWER -ACM06US05-BB Input: 100-240V ~ 50/60Hz 0.2A Output: 5.0V ⎓ 1.0A

Software/Application
BiodyConnect App (Android version 10 and higher, iOS version 13.0 and higher)
Windows 10 and 11, macOS Monterey 12 and higher for BiodyManager.com
Web service software: www.biodymanager.com
Up-to-date Google Chrome browser - Google Chrome Bluetooth flags enabled

Lifespan: 3 years, corresponding to the lifespan of the rechargeable batteries before replacement.
Standards: The BIODY B.I.S^{ZM} device complies with the following electrical, electromagnetic compatibility, and radio standards:
EN/IEC 60601-1 ed.3 + A1
EN/IEC 60601-1-2 ed.4
Directive 2014/53/EU RED
Certified host for health data hosting
SIGMA INFORMATIQUE SAS
ZI La Gesvrine - Rue Newton - 44240 LA CHAPELLE-SUR-ERDRE
France

Warranty: 2 years

CE

Made in France

AMINOGram

Aminogram - ZI Athélia III, 96 Voie Atlas 13600 LA CIOTAT France
33(0)4 42 72 66 03 - contact@aminogram.com - www.aminogram.com