

BIODY XPERT ZM 3

Bio Impedance Meter

V3_Rev_05/2024

User manual

Table of Contents

1. Introduction 3
2. Purpose - Indications - Users - Performance 3
   2.1. User Competencies 3
   2.2. Population cible 3
3. Analysis Results 4
4. Principle of Bioimpedance 5
   4.1. Specifics of the BIODY XPERT^{ZM}3 5
   4.2. Clinical Benefits 5
5. Risks - Pictograms 6
   5.1. Description of Risks Related to the Use of the Device 6
   5.2. Description of Risks Related to Cybersecurity 7
   5.3. Pictograms on the Label 7
6. Description of Delivered Elements / Device Description 7
7. Operating Principle of the BIODY XPERT^{ZM}3 System BiodyManager.com / BiodyConnect 8
   7.1. The System 8
   7.2. Configure the IT Environment 9
8. BiodyManager / BiodyConnect Software Solution 11
   8.1. Creating Your BiodyManager.com Account 11
9. Operating the BIODY XPERT^{ZM}3 Device 12
   9.1. Functions of the On/Off Button - Reminder from Point 6 12
   9.2. LED Indicators - Messages 12
   9.3. Measurement 15
10. Measurement Environment / Patient Condition / Precautions 15
   10.1.Position with Integrated Electrodes 16
   10.2.Wired Measurement Positio 18
11. Procedure for Managing Unsynchronized Stored Measurements 18
12. Internet Outage 19
13. Rechargeable Batteries 19
14. Maintenance - Internal Electronics Check - End of Life 20
15. Environment and Electromagnetic Compatibility Statement 21
16. Technical Data Sheet 23

1. Introduction

BIODY XPERT™ 3 is an exclusive bio-impedance meter in its method of acquiring bio-impedance measurements, enabling the application of the hand-to-foot tetrapolar method in a reliable and simple way with 4 fixed electrodes integrated into the device, or for people with reduced mobility with cables and disposable electrodes.

The obtained values are transferred via Bluetooth directly to the BiodyManager.com software for desktop computer users or to the BiodyConnect application for Android or IOS mobile users.

The BiodyManager.com web service software is hosted in France by a certified health data hosting provider (see Technical Data Sheet), in accordance with ANS requirements. Furthermore, circulating data is fully encrypted and can only be read by the user.

2. Purpose - Indications - Users - Performance

The BIODY XPERT™3 system, associated with the BiodyManager.com software, provides information for monitoring and tracking the body composition (fat and fat-free mass) of measured individuals. It is intended for use by medical and paramedical professionals who can use this information in their routine practice for overall management and prevention of pathologies related to nutritional status.

It is also intended for practitioners monitoring patients with obesity for controlling the effects of their management.

The users are:

General practitioners, nutritionists, physiologists, dieticians, nurses, and physiotherapists, as well as professionals in Adapted Physical Activity and rehabilitation.

Predictive performance is calculated by a concordance analysis compared to dual-energy X-ray absorptiometry (DEXA), considered one of the reference methods for estimating body composition.

The expected results are comparable to the accepted accuracy for this technique in the compartments of fat-free mass, fat mass, and skeletal muscle mass of the limbs.

2.1. User Competence



The BIODY XPERT™ 3 solution, BIODYMANAGER.COM, and BIODYCONNECT require the use of computing tools, computer, tablet, or smartphone.
The user must be able to use these tools.

2.2. Target Population

The analysis of measurements is valid for adults aged 19 years and older. Weight: from 14kg to 250kg.

Mobile patients can self-measure (see 10.1 Integrated Electrode Measurement Position).

Patients with mobility difficulties will be measured in a lying position using cables and adhesive electrodes (see 10.2 Wired Measurement Position). The choice of either method is left to the practitioner's discretion depending on the patient's condition.

Pathology

The monitoring and follow-up indication is particularly aimed at an obese population by evaluating fat and fat-free mass.

General Non-Pathological Population

Monitoring and tracking of body composition and general nutritional status of individuals, particularly for fat-free mass, appendicular muscle mass, and fat mass.

3. Analysis Results

The results of the analysis of the measurement performed on the patient are estimated body composition values, derived from algorithms developed against other so-called reference measurement methods.

The main estimated body components are as follows:

Body Compartments or Tissues Estimated	Acronym and Units	Algorithms	Validation
Fat-Free Mass	FFM kg	Aminogram Equation	DEXA(4)
Fat Mass	FM kg	Weight-FFM	
Appendicular Skeletal Muscle Mass	ASMM kg	Literature (1)	
Bone Mineral Content	BMC kg	Aminogram Equation	
Total Body Water	TBW L	Literature (2)	Dilution Isotopique
Extracellular Water	ECW L	Literature (2)	
Intracellular Water	ICW L	TBW-ECW	
Hydration of Fat-Free Mass	FFM_{Hydra} %	FFM/TBW	
Dry Fat-Free Mass	DFFM	FFM-TBW	

1. *Kyle UG, Genton L, Hans D, Pichard C. Validation of a bioelectrical impedance analysis equation to predict appendicular skeletal muscle mass (ASMM). Clin Nutr. déc 2003;22(6):537-43.*
2. *Kushner RF, Schoeller DA. Estimation of total body water by bioelectrical impedance analysis. Am J Clin Nutr. sept 1986;44(3):417-24.*
3. *Deurenberg P, Tagliabue A, Schouten FJ. Multi-frequency impedance for the prediction of extracellular water and total body water. Br J Nutr. mars 1995;73(3):349-58.*
4. *Wang Z, Heymsfield SB, Chen Z, Zhu S, Pierson RN. Estimation of percentage body fat by dual-energy x-ray absorptiometry: evaluation by in vivo human elemental composition. Phys Med Biol. 7 mai 2010;55(9):2619-35.*

Body indices are calculated by dividing the mass of the measured compartment or tissue in kg by the squared height (in meters) (kg/m^2).

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

The defined threshold values for obesity indices BMI, FFMI, and ASMI by the WHO or HAS in France are displayed for practitioner information in the corresponding compartment tile.

These thresholds may be redefined in future publications.

Other information on body compartments is based on the following publications:

5. *Wang Z, Heshka S, Wang J, Gallagher D, Deurenberg P, Chen Z, et al. Metabolically active portion of fat-free mass: a cellular body composition level modeling analysis. Am J Physiol Endocrinol Metab. janv 2007;292(1):E49-53.*
6. *Wang Z, Shen W, Kotler DP, Heshka S, Wielopolski L, Aloia JF, et al. Total body protein: a new cellular level mass and distribution prediction model. Am J Clin Nutr. nov 2003;78(5):979-84.*

4. Principle of Bioimpedance

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

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

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

The cell membranes are highly resistive and behave like a dielectric, separating small conductors made up of the internal fluids of the cells.

Therefore, a reactive term will be more or less significant depending on the frequency of the measurement, hence the concept of bioimpedances.

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

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

Measuring impedance at certain frequencies will allow the evaluation of the amount of fluids the current has passed through, distinguishing different tissues, and thus providing an analysis of the patient's body composition.

In multifrequency mode or spectroscopy mode, the algorithms allow the differentiation between extra and intracellular water.

4.1. Specific Features of BIODY XPERT^{ZM}3

Bioimpedance measurement is performed using the tetrapolar method by diffusing a constant low-intensity current of 35µA, which is not felt by the subject.

The BIODY XPERT^{ZM}3 device allows bioimpedance measurements over 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)

For each measurement, the device records the obtained results. Using the principle of spectroscopy, the Cole-Cole curve is plotted: the resistance values at low frequency (Re) and at the highest frequency (R∞) are extrapolated.

The data transmitted by the device is as follows:

- Impedances, reactances, resistances in ohms, and phase angles in degrees at 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 patient-specific parameters to be entered, the measurements are analyzed, and the calculated body composition results are displayed on the patient's dashboard in the BiodyManager.com software.

4.2. Clinical Benefits

No direct clinical benefit identified.

The identified benefits for the patient below are considered as indirect benefits:

BE1: Assist in obesity diagnosis and monitoring. Provides the patient with a more accurate assessment of their weight balance than anthropometric measurements such as BMI, as well as moni-

toring the treatment process.

BE2: Detection and prevention of non-pathological body composition imbalances that may become significant in the medium/long term - e.g., hyper adiposity related to overweight and monitoring of skeletal muscle mass of the limbs, fat-free mass.

The risks associated with usage are described below.

5. Risks – Pictograms

	Danger	Using the device could cause death or serious injury.
	Warning	Incorrect use can cause patient discomfort. Incorrect use can disrupt measurement reliability. Incorrect use can be the source of data loss or corruption. Advice regarding electromagnetic interference.
		Any serious incident occurring in connection with the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

5.1. Description of Risks Related to Device Usage

	You should not take measurements on a subject wearing an implanted or portable medical electronic **life-support device** (e.g., pacemaker, spirometer, artificial lung). Risk of malfunction of the life-support device, which could pose a risk to subjects whose life depends on the proper functioning of their device. You should not take measurements on a pregnant woman, as although no incident related to this technique has been recorded, no specific publications have been identified on the safety of bioimpedance and therefore no formal absence of risk to the development of the embryo or fetus has been established.
	Do not use the device on injured or damaged skin that will come into contact with the applied parts (electrodes). Risk of irritation or pain.
	The device must be cleaned before and after use. Risk of contamination of the subject if the device was soiled during previous use.
	This device integrates LED type indicator lights, so it is not recommended for photosensitive individuals to stare at these lights.
	It is forbidden to open and/or modify this device without the manufacturer's authorization. Apart from replacing the rechargeable batteries, no maintenance operations initiated by the user are authorized on the product. Risk of deterioration of device performance.

5.2. Description of Risks Related to Cybersecurity

The BiodyManager.com software and BiodyConnect mobile applications 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 patient data.
Failure to comply with this obligation makes the user liable in the event of accountability related to data breaches of this account. Additional information on the security of BIODYMANAGER.COM and BIODYCONNECT applications is provided in the software notice in point 1 SECURITY.

5.3. Pictograms on the Label

	Applied parts of type BF. The electrodes are 4 in number.
	Direct current 5 V + - 10% 500 mA
	Mandatory to consult the instructions for use.
REF	Commercial reference of the device
	RF transmitter – non-ionizing radiation
MD	Medical device
	Manufactured by + date of manufacture
UDI	Unique Device Identifier (UDI)
	Do not dispose of with unsorted waste, but must be sent to separate collection facilities for recovery and recycling.
LOT	Indicates the batch number of the device
SN	Indicates the serial number of the device
CE 0459	Indicates the identification number of the notified body that issued the certificate of conformity

6. Description of Delivered Items / Device Description

BIODY XPERT^{ZM}3 is delivered in a case with a cardboard overpack.

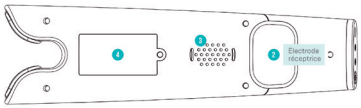
This packaging contains:

- The BIODY XPERT∧ZM3 device
- The USB transformer required to recharge the batteries
- A USB/micro USB cable to connect the transformer to the device for battery charging
- A USB 5.0 Bluetooth dongle
- A set of cables for wired measurements
- A software activation license, for creating an account on BiodyManager.com
- A protective case
- This user manual

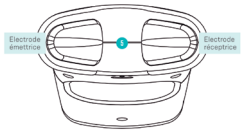
A bag of LESSA brand electrodes for wired measurements is also provided with the device.



Top view
1 Chrome applied part
Emitter thumb electrode with ring for LED function indicators



Bottom view
2 Chrome applied part
Receiver finger electrodes
3 Speaker outlet
4 Battery compartment cover



Front view
5 Applied parts:
2 rear-foot electrodes
The emitter electrode is the one on the left when you look at the device from the front.



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 recommend keeping the packaging for any future reshipment of the BIODY XPERTZM3 device.

7. Operating Principle of the BIODY XPERTZM3 System - BiodyManager.com / BiodyConnect

7.1. The System

The device

BIODY XPERTZM3 device is a 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 allows you to turn the device on and off, as well as to activate/deactivate Bluetooth manually.

- Power on: 1 short press
- Manual shutdown: 1 long press
- Manual Bluetooth activation: Turn on the device (1 short press), when the device is on **(green LED on)**, double press the button quickly, **the LEDs blink blue** for 1 minute, a message indicates **"Bluetooth communication enabled"**.

The Applications

You need an internet connection (cable, Wi-Fi, 4G...) to use the applications, synchronize the measurements taken with the device, and obtain the body composition analysis.

1. **BiodyManager.com** Secure Web Service Software, which allows:

- Synchronization of Bluetooth measurements o**n Windows and MAC computers directly in the up-to-date Google Chrome web browser.**
- Analysis of measurements and viewing of historie.
- Patient file management and software customization.
- Access to complete user manuals, tutorials, etc.

2. **BiodyConnect** Application, available o**nly on Android or IOS mobile devices**, which allows:

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

If you wish to take advantage of the customization options for the default configured functions in your BIODY XPERT^{ZM}3 device, it is necessary to install the BiodyConnect application on a mobile device, even if you do not use it for measurement synchronization.

- Configure the LANGUAGE function: "Choice of message language."
- Adjust the device's sound volume with the VOLUME function.
- Check the internal electronics using the CONTROL function.

7.2. Configuring the Computing Environment

Declaration

The following instructions enable the final user to install and configure the computing environment.

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

Windows PC Computers

You must check for the presence of a Bluetooth component in your PC's settings. If it's internal Bluetooth, **it must be activated.** If you don't have internal Bluetooth on your computer, you must use the BiodyConnect application on Android or IOS mobile devices to synchronize measurements or use the external Bluetooth dongle provided with the device.

If your internal Bluetooth doesn't work with our device, you should disable it and use the dongle provided with the device.

Some internal modules, especially Realtek ones present in HP brand PCs, may not work properly with our device. You need to check for this component by opening the "**Device Manager**" on your PC.



When your system is ready, you must pair the device with your computer's Bluetooth - Activate the BIODY XPERT^{ZM}3's Bluetooth as indicated on the previous page under "Device."

Find the Bluetooth icon in your PC's taskbar.

Choose the "add a Bluetooth device" command. When the name BX3-XXXX-XXXX appears in the pairing window, select it to pair.

Windows 11 specificities: Before pairing, check that the discovery function is set to **Advanced**; otherwise, select it to see your device.



MAC Computers

A compatible Bluetooth component is present in the MAC.
Pre-pairing is not necessary. Pairing with the device will be requested during the first measurement transfer.

BiodyConnect on Mobile

Minimum system versions on mobile:

- Android 10
- IOS 13

The BiodyConnect application is installed from the Android Play Store or Apple's App Store.
Go to the store corresponding to your mobile device, search for BiodyConnect, and install the application.

Pre-pairing via Bluetooth is not necessary. Pairing with the device will be requested during the first measurement transfer.

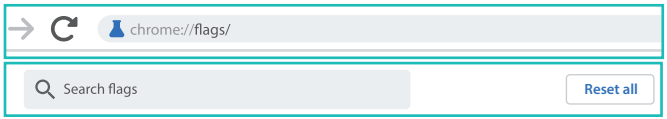
Google Chrome Browser

BiodyManager.com is optimized for use with the Google Chrome browser.

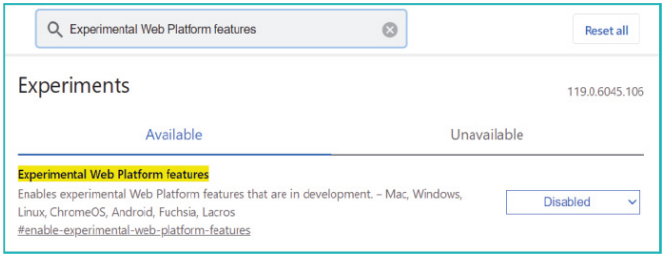
Check if the Chrome browser is installed and up to date. If not, you need to install it.

Enable the flags for synchronizing measurements directly from the subject dashboard:

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

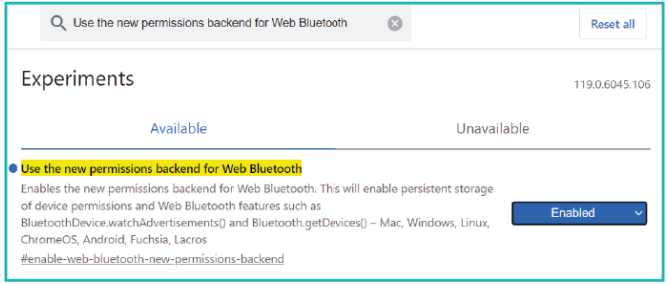


Via the search, "Search flags":
Type or copy/paste "**Experimental Web Platform features.**"



Click the "**Disabled**" button and select the "**Enabled**" option.

In the "Search flags" search bar, type "**Use the new permissions backend for Web Bluetooth.**"



Click the "**Default**" button and select the "**Enabled**" option.

Chrome will ask to be restarted, confirm this restart by clicking "Relaunch."

The browser is now configured for direct synchronization via the subject dashboard.

8. The BiodyManager / BiodyConnect Software Solution

BiodyManager.com

This manual describes the initial steps to create your BiodyManager account.
The complete user guide for the BiodyManager.com software and BiodyConnect mobile applications is available in PDF format directly on BiodyManager.com.

You need to have a PDF file reader installed on your computer.

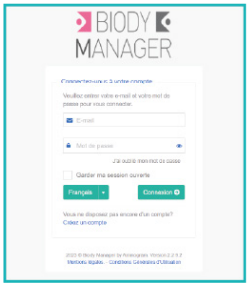
You can request to receive this additional printed guide by writing to: **contact@aminogram.com**, and it will be sent to you by postal mail within 7 days.

8.1. Creating Your BiodyManager.com Account

The BiodyManager.com software and BiodyConnect mobile applications are connected to the internet. Your account credentials are personal and are the means of protection against unauthorized access to your account.
You should not share your personal credentials with third parties to ensure the confidentiality and integrity of patient data.
Failure to comply with this obligation makes the user liable in the event of accountability related to data breaches.
Automatic disconnection occurs after 12 hours, and your account credentials will be required again.
However, when you are not using the applications, make sure to log out.
The details of the security environment for the BiodyManager and BiodyConnect applications are described in the BiodyManager.com software manual.

BiodyManager.com is optimized for use on the **Google Chrome** web browser.
Have the license document delivered with your device ready.
You need to be connected to the internet and use the **Google Chrome** web browser.
You should set this browser as your default browser.
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 button.





Enter your license key found in the License document provided with your device, as well as your device's serial number. **(The license key containing a zero 0 is distinguished from the letter O by being crossed out).**

At the step "**enter a valid email,**" you must enter an email that you regularly and permanently access.

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 section "enter a password," it must contain at least 10 characters with at least one uppercase letter, one lowercase letter, one digit, and one special character.

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

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 log in to the software.

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

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

You must authorize the receipt of emails from the address **admin@biodymanager.com.**



The confirmation of account creation will directly take you to the software.

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



Reminder: The manual for using the BiodyManager.com software and the Android and IOS applications is available directly on BiodyManager.com in the Assistance section found on the software's home screen. You can download it, view it, or print it.

Additional videos and tutorials are also available in this section.

You must review all this additional information to use the software applications necessary for the overall operation of the BIODY XPERT^{ZM}3 system:

- Customization of your BIODY XPERT^{ZM}3 device
- Measurement synchronization
- Measurement analysis
- Patient file management

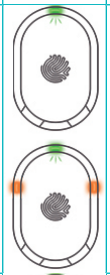
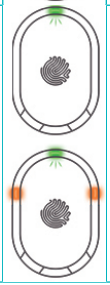
9. Operating the BIODY XPERT^{ZM}3 Device

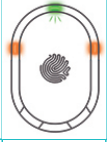
9.1. Functions of the On/Off Button – Reminder from Point 6

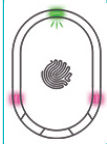
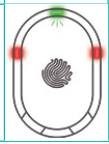
Short press	Turn on – startup beep
Double quick press	Manually activate Bluetooth or manually deactivate Bluetooth before automatic shutdown
Long press	Turn off the device – shutdown beep

9.2. Light Indicators - Messages

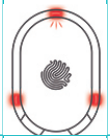
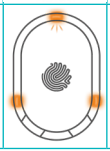
The messages and light indicators described below will help you recognize the different states of your device.

ID	LEDS	Action and Response Description
1		After pressing the power button, the LED located at the front of the ring flashes green. **You hear a startup beep.** Then, the 2 LEDs located at the front turn 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 60 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, and the front LED flashes green. If the cables are connected, the 2 left and right LEDs are orange. A message indicates: **"Don't move anymore. The measurement is going to start."**

ID	LEDS	Action and Response Description
3		The measurement begins.
		The purple LED flashes. If the cables are connected, the 2 left and right LEDs remain lit in orange.
4		The measurement is taken, and the front LED flashes briefly in 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. All 3 LEDs are blue. A message indicates: **"Bluetooth communication enabled."** Once the application has received the measurement, the measurement is erased from the memory card, and the device turns off.
6		If the measurement is not transferred, at the end of the Bluetooth transmission, the front LED flashes blue, and the 2 LEDs located at the bottom left and right are orange. A message indicates: **"Bluetooth disabled."**

ID	LEDS	Action and Response Description
7		When you turn 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. A sound message indicates: **"Your device contains unsynchronised measurements."** You can synchronize these measurements by voluntarily activating the Bluetooth of the Biody or begin the process of taking a new measurement. The recorded and unsynchronized measurements remain stored as long as they have not been transferred.
8		If during the measurement, and before it is completed, the emitting electrodes are no longer in contact with the subject, a message indicates: **"Contact broken. Check patient connections."** The device returns to its waiting state for electrode contact with the skin (fingers and rear foot). When contact is adequate again, the measurement resumes.
9		The microcontroller may detect an invalid measurement. 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.
10		When the device turns off, the 2 red LEDs at the top left and right turn on in red.

THE BATTERY		
ID	**LEDS**	**Description, Action, and Response**
11		When the battery level drops to 50%, the rear LED turns solid red. From this moment on, the battery will drain faster than before reaching 50%. This level corresponds to 2 bars on the battery level indicator you see on the app after synchronizing the measurement. A message indicates: **"Low battery, charge as soon as possible."** When you see one bar on the app, the battery has reached its critical level, and you must charge your device to continue using it.
12		When you turn on the device and the battery is too low, the rear red LED flashes. A message indicates: **"Battery too low, measurement impossible."** The device will shut down after this message. You need to charge your device. It cannot be turned back on until a sufficient charge level is reached.
13		When charging your device, the rear LED lights up in blue.
14		When the battery is fully charged, the blue rear LED flashes. You can disconnect the transformer..

POTENTIAL SYSTEM ERRORS		
ID	**LEDS**	**Description, Action, and Response**
15		When you see the 2 fixed red LEDs with the front red LED flashing, it means a system error is blocking all functions. A message indicates: **"Sorry, a system error has occurred. Please restart your device"** You need to turn off the device and turn it back on.
16		When a measurement is successfully taken, but a malfunction prevented the measurement from being recorded, you will hear the following message: **"Sorry, a recording as occured. Please redo the measurement."**
17		If a malfunction interrupts the measurement process, you will receive the following message: **"An error has occurred, measurement interrupted, please redo the measurement."**

9.3. Measurement

Measurement with Integrated Electrodes

he BIODY XPERT∧ZM3 device is designed to be easily handled by the patient.

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

A single button located at the back of the device allows you to turn the device on.

The patient takes their own measurement, which will then be transferred to the software directly and **exclusively** via Bluetooth.

When the patient's moist skin is in contact with the emitting electrodes, the measurement begins immediately.

Wired Measurement

When patients have reduced mobility, such as elderly bedridden patients, and self-measurement in a sitting position is impossible, you should use the 2 cables to allow the device to be used in a lying position with single-use adhesive electrodes.

10. Measurement Environment / Patient Condition / Precautions

⚠	Measurements taken on women during menstruation cannot be compared to measurements taken outside this period due to significant variations in body water that may occur during this time.
⚠	The presence of prostheses with metallic parts can influence the measurement results. You should ask the patient about this. In the case of a prosthesis or screws located on one side, you can take the measurement from the other side.
⚠	The use of substances that can significantly disrupt homeostasis (patients on medications such as cortisone, doping products, etc.) can influence the measurement results.
⚠	A temporary change in the patient's physiological state can result in unusual impedance values, leading to unexpected results in the patient's historical follow-up. Check the impedance history and ask the patient about their condition.
⚠	Ensure that the patient's skin is clean, without any residue of cream or other products. If necessary, clean the skin in contact with the electrodes with a cotton pad soaked in alcohol. Then moisten the skin in contact with the electrodes.
⚠	Ask the patient to remove any significant metallic objects that may be in contact with their skin.
⚠	You should not touch the patient while they are taking the measurement. Ensure that there is no bare skin-to-skin contact. For example, a bare hand resting on the leg or the opposite bare arm. If the patient is still in underwear or if, for example, in summer, their thighs are bare, they should not touch. If the patient is overweight and, despite spreading their legs, their bare thighs touch, place a small bolster wrapped in an examination sheet or a rolled-up towel between them.

Complementary Materials Required for the Practitioner:

The adult patient must be measured with a height gauge during the first measurement.
The patient must be weighed before or just after taking the measurement.
Entering an approximate height and weight will alter the accuracy of the body composition results.

- Height gauge
- Calibrated scale
- Measuring tape, if you wish to take circumferential measurements
- Cotton and water or hydroalcoholic gel, or neutral wet wipes to moisten the skin in contact with the electrodes for measurements with integrated electrodes.

Checking the Patient's Condition:

To obtain a measurement representing the patient's usual body composition, it is important to follow the recommended conditions for the body composition measurement method by bioimpedance, as described below:

Empty bladder for weighing, ideally with bowel movement	No diuretics the day before (unless prescribed for a medical condition), no drinks in large quantities just before the measurement (but the patient can hydrate an hour before)
No significant alcohol consumption the day before	No physical activity before the measurement

During subsequent appointments, only the weight will generally need to be entered. However, in the case of a weight loss or gain diet, the bra size (for women) may vary, and this data may need to be updated.

Similarly, the level of activity may vary, especially for monitoring athletes (training or competition) or the start of physical activity in overweight individuals, etc. Be sure to check this data over time. These data can be modified in the measurement file of the software.

In general, for consistent tracking of the evolution of the data being monitored, measurements should be taken under the same conditions and at the same time of day.

10.1. Measurement Position with Integrated Electrodes

The patient should be seated on a stool in a comfortable position, with **their back straight**, legs, and arms slightly apart.

If the measurement conditions are not met, the measurement may be declared invalid and will not be recorded. You will receive the message "Invalid measurement, please retake the measurement." Verify that the parts in contact with the electrodes are moist and that all electrodes are in proper contact with the skin, as indicated below



Step 1 : The patient moistens the area around their right rear foot and the fingers of their right hand that will be in contact with the BIODY XPERT^{ZM}3 using a wet wipe/cotton pad or hydroalcoholic gel. Measurements are taken on the right side of the body (unless physically impossible or in the presence of a prosthesis or screws).

Step 2 : The patient sits on a stool or chair without armrests and not made of metal, with their back straight. They bring their right foot back, lifting the heel off the ground. The patient holds the BIODY XPERT^{ZM}3 in their right hand. This position allows the arms and legs to be slightly apart naturally.

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

Step 4 : The patient places the "U" shape against their right rear foot **(under the malleoli)**, and the electrodes touch the skin. All four electrodes must be in perfect contact with the patient's skin. The measurement begins when the two emitting electrodes are in contact with the patient. (Refer to the LED/message table) - the other two electrodes (receivers) must also be in perfect contact to obtain a correct measurement. The measurement begins when the two emitting electrodes are in contact with the subject. (Refer to the LED/message table) - the other two electrodes (receivers) must also be in perfect contact to obtain a correct measurement.

Once the measurement is completed, the Bluetooth transfer request begins, and the patient can place the BIODY XPERT^{ZM}3 device down.

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

BiodyManager.com

You can view the measurement video in the "Assistance" section of the BiodyManager.com software or in the "Help" section of the BiodyConnect application.

10.2. Wired Measurement Position

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 output located on the back of the device.



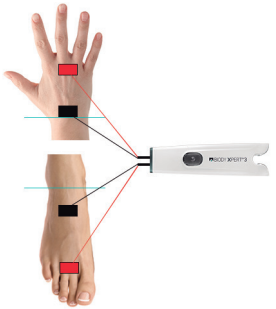
Step 2 : Place the electrodes on the right hand and right foot of the patient. For the hand: one electrode at the head of the metacarpals and the other at the wrist crease. For the foot: one electrode at the head of the metatarsals and the last one on the instep between the two malleoli.



Step 3 : Connect the crocodile clips, respecting the colors designated for current injection and reception:

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.

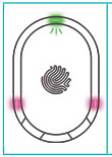
The measurement is carried out as described previously for the integrated electrode mode.

Electrodes: For wired measurements, we recommend using rectangular electrodes with tabs (TAB type), impregnated with solid conductive gel ECG 21x35 mm for single use by LESSA brand, Ref: 9983240.

Contact Aminogram for the supply of this type of electrodes..

11. Procedure for Managing Unsynchronized Stored Measurements

When one or more measurements stored in BIODY XPERT∧ZM3 have not been synchronized, they remain in the device's memory until they are synchronized in the BiodyManager.com software.



When you turn on the Biody device and one or more measurements are stored but not yet synchronized, the front LED flashes green, and the left and right LEDs are pink.
A voice message indicates:
"Your Biody contains unsynchronized measurements."

Case 1

This 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 application. You will need to manually activate the Bluetooth function by double-clicking the push button to synchronize the measurement.

Case 2

There are one or more unsynchronized measurements taken previously.

They can be synchronized with each patient file; the last measurement taken will be synchronized first, the second-to-last will become the first, and so on until all measurements are synchronized.

12. Internet Outage

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

You can synchronize your measurements, and they will be saved locally, waiting for the internet connection to be restored, but they cannot be analyzed.

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

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

If you have no way to connect to the applications, you can still take the measurements.

These will be recorded in the device, numbered and timestamped, and you will need to synchronize them later (refer to Point 11).

13. Rechargeable Batteries

The rechargeable batteries are recharged using the transformer and USB cable provided with the device.
Only the transformer delivered with the device should be used to recharge the batteries.
An identification label allows you to recognize it among other chargers you may have.

The BIODY XPERT^{ZM}3 device has a safety function that prevents taking measurements when the USB cable is connected to the transformer and plugged into a power outlet or a computer's USB port.

During the measurement transfer, information regarding the rechargeable battery level is transmitted in the form of a level icon. The indicator lights and messages also inform you of the state of the rechargeable batteries when the level is low.

			
Batteries too low – the device will shut down soon – recharge immediately	Low level – recharge as soon as possible	Sufficiently charged	Fully charged

The lifespan of the rechargeable batteries is rated for over 300 charge/discharge cycles.

When the rechargeable batteries reach the end of their life, you must replace them with identical batteries as described in the technical sheet.

The batteries are located in the compartment under the device, closed by a plastic cover labeled with a sticker.

Unscrew the screw of the cover closing the compartment using a Torx 8 screwdriver.

Replace the rechargeable batteries, ensuring the correct polarity orientation, then replace the cover and screw it back on.

14. Maintenance - Internal Electronics Check - End of Life

Maintenance - Cleaning

Especially when measurements are taken using integrated electrodes, you should clean and disinfect the device between each measurement.
The cleaning and disinfection of the BIODY XPERT^{ZM}3 and its electrodes should **only be done with wipes impregnated with an alcohol-based solution or with a cotton pad soaked in 70% alcohol.**
Specification of alcohol-based cleaning wipes: wipes that can be used for cleaning medical devices. Very fast disinfectant properties, about 60 seconds for common germs (bacteria, fungi, viruses), and composed only of an alcohol-based solution.

Do not use solvents like acetone to clean the device as they may damage the plastic casing.

Do not use disinfectants containing chlorine, such as bleach, or wipes containing chlorine derivatives to clean the device.

Maintenance - Rechargeable Batteries

The lifespan of the rechargeable batteries is rated for over 300 charge/discharge cycles.

When the rechargeable batteries reach the end of their life, you must replace them with identical batteries as described in the technical sheet.

If over time, after a full recharge, the "Low battery" message appears quickly after just a few measurements, replace the battery preventively to avoid the risk of device unavailability.

Maintenance - Internal Electronics Check

If you use the device regularly, you can check the status of the internal electronics by measuring the internal resistance using the BIODY CONNECT application.

No drift has been observed with regular use over a period of two years, so no specific periodicity is recommended.

However, it is advisable to perform a preventive check of the internal electronics once a year.

If the device has not been used for an extended period, this check should be carried out before reuse.

The procedure is outlined in the software manual (Section 8 - BiodyConnect Application – BX3 Configuration – CHECK). The result will be either "success" or "failed".

If the result is "failed", please contact after-sales service.

End of Life



Rechargeable batteries at the end of their life should not be disposed of with household waste and must be recycled by you in accordance with the regulations applicable in your location.

The BIODY XPERT^{ZM}3 device at the end of its life should be returned to Aminogram for recycling and disposal.

15. Environment and Electromagnetic Compatibility (EMC) Statement

Environment

Degree of protection against water penetration: no specific protection.

Storage Conditions:

Temperature: -20°C to +40°C
Relative air humidity: 45-85% without condensation
Pressure: 70kPa to 105kPa

Operating Conditions:

Temperature: 16°C to 32°C
Relative air humidity: 45% to 85% without condensation
Pressure: 70kPa to 105kPa

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

The BIODY XPERT∧ZM3 device meets the electromagnetic compatibility requirements according to EN 60601-1-2 4th edition.
The device is manufactured 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 appropriate electromagnetic immunity.
The minimum measurement accuracy required to guarantee the expected effectiveness in a disturbed electromagnetic environment is 2%.
An electrical medical device requires special precautions regarding electromagnetic compatibility. In this respect, the BIODY XPERT^{ZM}3 is designed to be used in the electromagnetic environment specified below.

CISPR11 Classification:

Class A : The BIODY XPERT^{ZM}3 is intended for use in a hospital environment.
Class B : The BIODY XPERT^{ZM}3 is intended for use in a residential environment.

Group 1
The BIODY XPERT^{ZM}3 user should 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.
⚠	The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit, which may no longer guarantee EMC.
⚠	Do not store or use the device near devices that emit high-power radiation, especially microwave-emitting devices. Do not stack multiple electronic devices, as they may interfere with each other.
⚠	Portable RF 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 XPERT^{ZM}3 device, including optional cables. Otherwise, the performance of the BIODY XPERT^{ZM}3 may be degraded.

Guide and Manufacturer's Declaration - Electromagnetic Emissions
Class A: The BIODY XPERT^{ZM}3 is intended for use in professional healthcare settings, hospitals, and clinics, except in installations near high-frequency surgical equipment and close to an electromedical imaging system shielded room where the intensity of electromagnetic disturbances is high. Class B: The BIODY XPERT^{ZM}3 is intended for use in a home healthcare environment, such as a doctor's office. The customer or user of the BIODY XPERT^{ZM}3 device must ensure that it is used in such environments.

Table 1

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The BIODY XPERT^{ZM}3 device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The BIODY XPERT^{ZM}3 device is suitable for use in all establishments, including domestic environments and those 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 / Flicker IEC 61000-3-3		

Table 2

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, 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 XPERT^{ZM}3 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	
Power 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)	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.

Table 3

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF Disturbances IEC 61000-4-6	3 V rms 6V in ISM bands from 150 kHz to 80 MHz	N/A (powered by an internal battery)	N/A except for the transformer, compliant with EN 60601-1
Radiated RF EM Fields IEC 61000-4-3	10 V/m De 80 MHz à 2,7 GHz	10 V/m from 80 MHz to 2.7 GHz	
Proximity Fields from RF Wireless Communication Equipment	27V/m from 380 MHz to 390 MHz 28V/m from 430 MHz to 470 MHz 9V/m from 704 MHz to 787 MHz 28V/m from 800 MHz to 960 MHz 28V/m from 1700 MHz to 1990 MHz 28V/m from 2400 MHz to 2570 MHz 9V/m from 5100 MHz to 5800 MHz	27V/m from 380 MHz to 390 MHz 28V/m from 430 MHz to 470 MHz 9V/m from 704 MHz to 787 MHz 28V/m from 800 MHz to 960 MHz 28V/m from 1700 MHz to 1990 MHz 28V/m from 2400 MHz to 2570 MHz 9V/m from 5100 MHz to 5800 MHz	Minimum separation distance: 0.3m
Proximity Magnetic Field Immunity (IEC 61000-4-39)	8 A/m at 30 kHz CW 65 A/m at 134.2 kHz / 2.1 kHz modulation pulse 7.5 A/m at 13.56 MHz / 50 kHz modulation pulse	8 A/m 30 KHz CW 65 A/m à 134,2 KHz modulation pulse 2,1 KHz 7,5 A/m à 13,56 MHz / modulation pulse 50KHz	Minimum separation distance: 0.3m

16. Technical Data Sheet

Operating Temperature: 16°C to 32°C
Storage Temperature: -20°C to +40°C
Measurement Type: Quadripolar (4 applied parts of type BF)
Multifrequency and Spectroscopic Impedance Measurement: 1 to 1000 kHz
Measurement Range: 20 to 1500 Ohms
Current Intensity: 35µA
Accuracy: Impedance 1%
Phase Angle: ± 0.2°
Representatives:
± 160 g on Fat-Free Mass (FFM) or ± 0.26%
± 150 ml on Total Body Water (TBW) or ± 0.42%
± 90 ml on Extracellular Water (ECW) or ± 0.54%
Displayed Resolution
Impedance in Ohms: Integer
Phase Angle in Degrees: 1/10th
Wireless Connection Bluetooth:
Bluetooth Name: BX3, followed by the serial number with 4 digits (BX3XXXX)
Characteristics:
Bluetooth LE BGX220S – BGM220S
Transmission Frequency Band: 2402-2480 MHz
Modulation Frequency Type: GFSK
Equivalent Radiated Power: 11.11 dBm
Power Supply: 2 rechargeable NiMH AA batteries 1.2V 2800 mA PANASONIC REF: BK-3HGAE/4BE
Weight: 300g
Charger for Battery Recharging: (one of these chargers is delivered 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 Application (Android version 10.0 and higher - iOS version 13.0 and higher)
Windows 10 and 11, macOS Monterey 12 and higher for BiodyManager.com
Webservice 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 their replacement.
Standards: The BIODY XPERT^{ZM}3 device complies with the following electrical, electromagnetic compatibility, and radio standards:
EN/IEC 60601-1 ed.3 + A 1
EN/IEC 60601-1-2 ed.4
Directive 2014/53/EU RED
Warranty: 2 years
Certified Data Hosting for Health Data
SIGMA INFORMATIQUE SAS
ZI La Gesvrine -Rue Newton - 44240 LA CHAPELLE-SUR-ERDRE France

Manufactured in France



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