

**Preamble :**

Read these instructions carefully. Its contents will provide important information regarding safety rules to be implemented to use effectively your **Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup>**. This document is provided in printed form and on USB key, which contains the associated software.



**Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup> complies with the applicable requirements of Directive 2017/745/EC and the French Public Health Code.**

**Classification according to European Directive 2017/745/EC:**

**Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup>**, **hardware and software**, are a **medical device** class IIa. It meets the definition of a device allowing the **investigation of a physiological process** (in our case, that is because of the variation of the body mass).

In addition, Z-Métrie<sup>®</sup> / Z-Hydra<sup>®</sup> is an **active** medical device because it depends for its operation on electrical source of energy other than that generated directly by the human body.

Finally, it meets the definition of an active medical device intended for diagnosis and monitoring, since it is used, alone or in combination with other devices, to supply information for detecting, diagnosing physiological conditions, states of health or illnesses.

According to Annex VIII, the hardware is classified in rules 10 and 11, the software is classified in rule 11.

**Identification of products and version:**

This IFU is dedicated to hardware references 089T102(AorBorCor1or2or3) and to software versions 1.0.1.8 and 1.0.1.9.

**Intended use:**

The Z-Métrie/Z-Hydra physical devices are intended to measure multifrequency bioimpedance data.

The Z-Métrie software is used for the quantitative measurement of physiological parameters of the human body in the fields of health, nutrition and sport.

-Cardiology: quantification of hypervolaemia in patients with cardiac pathologies,

-Nutrition: Assistance in monitoring patients (anorexia, obesity, malnutrition, etc.): prevention of sarcopenia (lack of muscle), osteoporosis, and malnutrition, optimisation of hydration strategy or monitoring of patients after bariatric surgery, diagnosis of undernutrition.

-Care: monitoring of elderly people: prevention of dehydration and malnutrition, help in diagnosing muscle loss.

The Z-Hydra software has limited uses for the Z-Métrie in the fields of nephrology and ICU:

- Nephrology: quantification of over-hydration, aid in the diagnosis of malnutrition, monitoring of weight loss before transplantation, interest in a physical measurement by measuring muscle mass, monitoring of bone quality to aid in the diagnosis of osteoporosis.

-Intensive care: monitoring of water compartments to prevent oedema or dehydration, monitoring of tissues (fat and muscle) to optimize nutrition.

**Use:**

This product must be used by trade professionals involved in the biology (Doctors, veterinarians, dieticians, nutritionists, beauty centers, physiotherapists, researchers, sports coach, ...) and having taken note of this "instruction manual". It provides bioelectrical impedance measurements and it calculates physiological parameters of body composition.

Measured data : Reactance X (ohm) at 6 frequencies and Resistance R (ohm) at 6 frequencies



## Calculated data:

- Electrical data : Impedance Z (ohm), Phase angle ° at 6 frequencies
- Metabolism (literature)
- Tissues (our clinical validation)
- Fluids (our clinical validation)

Indicators	Tissues	Fluids
Reference	DXA	Xitron
Error	[0.8-3.9] mean = 1.6% supine [0.06 – 3.5] mean=1.8% standing	[1.81-3.55] mean = 2.68% supine [1.46-3.87] mean = 2.67% standing
Accuracy	[0.34-0.64] mean = 0.53 ± 0.11	[0.23-1.01] mean = 0.43 ± 0.34
Reproducibility	0.042	/

It is mainly used in health institutions, nutrition practitioners or research laboratories.

The results are displayed in different forms to help the health professionals in:

- Characterization of body mass variations as a basis for nutritional monitoring of overweight after bariatric surgery for example.
- Determining the volume of distribution of urea in the follow-up of patients with chronic renal insufficiency,
- The quantification of hypervolemia of patients with cardiac pathologies,
- Assistance in diagnosing undernutrition,
- The follow-up of elderly people...

A systematic clinical evaluation is planned annually to generate, collect, analyze and continuously evaluate clinical data related to our devices to verify safety, performance and clinical benefits. This clinical evaluation is performed on the available bibliography.

**Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup>** is not a diagnostic device. It is a help in the panel of all validated technologies to make a precise diagnosis of the patient's state of health.

The user is only responsible for the acts performed and respect strict hygiene rules during the sessions so as to prevent all risks associated with the use of **Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup>**.

Before use, the user will ensure that the **Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup>** is in a perfect cleanliness and function.

In any case, potential complications cannot be attributed to the company Bioparhom if non compliance with the details of these instructions.

**Contraindications:**

**No action should be performed on:**

- a pregnant woman,
- a patient with active implantable medical device (such as pacemakers, artificial heart...)

Particular attention should be paid to any individual with an implantable electromagnetic system (eg RFID), the system may be affected by the measure.

**Recommendations:**

**It is strongly recommended that users contact BioparHom to be trained in the interpretation of various indicators measured by Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup> to provide relevant advice to patients.**

Indeed, some factors can cause alterations of measurements and therefore require special attention with regard to the interpretation of results:

- carriers of non-active implants (e.g. hip prosthesis)
- measured during a digestion phase or within 24 to 72 hours after intense effort,

- compression stocking wearers (to be removed at least half an hour before measurement)
- taking stimulants (caffeine, narcotics,...), food supplements, tobacco or alcohol just before the measurement....
- taking drugs that may modify physiological behavior (cortisone, antidepressants, antibiotics)
- excessive drinking just before the measurement
- dry or oily skin due to the application of creams

It is for the user to verify the absence of interference with electrical appliances or electronic equipment located nearby. Indeed, **it is advisable not to place any other device within 3 meters**. Interference with such devices can cause interference of the measure.

**BE CAREFUL to note the following points:**

- Device specification data (accuracy, repeatability) are provided for the defined populations in the clinical study. Accuracy and repeatability can't be assured for other populations. In addition, they can't be insured if the good measurement practices described in the instructions are not respected.
- Each index has a low limit of repeatability related to the noise of the device. Only variations above these limits can be interpreted as physiological variations of the patient.
- The Bone Mineral Content Index gives a trend of bone quality. This does not replace a bone densitometry. If the index is below the lower bound calculated on the basis of healthy subjects, no diagnosis can be made before performing the medical imaging examination. In addition, a good index means that the average content looks good on the whole body but does not mean that each joint is healthy.
- Ion block indices give a trend of ionic contents. In no case do they replace a blood test. Before any construction of a diagnosis, it is important to supplement this information with reference examinations.

**Potential adverse effects and possible complications:**

The risks and possible side effects resulting from the implementation of a measure of bioimpedance are not related to the use of **Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup>** by itself, but to a wrong diagnosis and interpretation of results.

**Reporting of serious incident:**

**Specific mention to users, patients, customers: any serious incident that has occurred in relation to 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. For Bioparhom, the contact is [contact@bioparhom.com](mailto:contact@bioparhom.com) Use Vigilance end/or incident in your email.**

**Patient information:**

The user should carefully question the subject to ensure that the results of the assessment will be correct and that an optimal basis for further work will be established.

**Accessories and consumables:****Chart of compatible accessories and covered by the notice**

Descriptive summary	References	DM accessory class
<b>Measuring cable 4 or 6 wires</b> <b>ECG clips for electrodes</b> <b>Battery charger</b> <b>Calibration fantom</b> <b>USB Cable</b> <b>Protection Case or Suitcase</b> <b>USB Key</b> <b>Electrodes</b> <b>Battery</b>	EXZ1CAB & EXZ2CAB EXCLIPBK EXCHARGEUR EXFANTOME EXCABLEUSB EXVALISEGRIS or EXMALETTE EXCLEUSBVIERGE EXELCLINUN EXSET6PILES	I I Non DM accessory Non DM accessory Non DM accessory Non DM accessory Non DM accessory I Non DM accessory

The accessories in this table, and only those, have been tested as not being of electromagnetic interference with the device. These accessories can be placed in the patient environment without risk of damage.

These accessories and software are considered **compatible** when used with the device. Thus, they function without loss or alteration of its ability to function, they integrate without the need for modification of the device and can be used without conflict or interference or adverse effect.

The device and its DM accessories form a system that meets Article 22 of Regulation 2017/745.

Basic UDI	UDI-DI	UDI-PI
Hardware : 3770026007HARDWARELE	Z-Metrix 03770026007 <b>006</b> Z-Hydra 03770026007 <b>013</b>	Based on SN (8 char) (21)
Software Z-M : 3770026007SOFTZMET5C	Z-Metrix software 03770026007 <b>204</b>	Based on software version (7 char) (10)
Software Z-H : 3770026007SOFTZHYD5F	Z-Hydra software 03770026007 <b>211</b>	
Measuring cable : 3770026007MEACABLED2	Cable – 4 wires 03770026007 <b>402</b> Cable - 6 wires 03770026007 <b>419</b>	Based on delivery date AAMMJJ (11)
Electrodes bag ECG bag	Manufacturer UDI system	
Z-Metrix System: 3770026007ZMSYS TEMEK	Includes 1 hardware, 1 software, 1 or 2 measuring cable + 1 electrode bag (from ASEPT Inmed) + 4 or 8 ECG clips from SPES 03770026007 <b>600 for Z-Métrie System</b>	Based on hardware SN (21), software version (10), manufacturing date for acc. (11) and packaging (13)
Z-Hydra System: 3770026007ZHSYS TEMBW	03770026007 <b>617 for Z-Hydra System</b>	



Only attachments supplied with the unit of measurement (See table above) should be used with it.

It is imperative that the mains power socket is easily accessible, it's the only way to disconnect the device. The voltage and current rating for use are noted on the product label and are 1.3 A and 11V.

If unused for long periods, it is for the user to remove the batteries from their location.

The life of rechargeable batteries is 300 cycles of charge / discharge. **Once it unusable, the user is able to replace them. These replacement rechargeable batteries do not require special skills; the direction (polarity) of rechargeable batteries is indicated and should be respected.** For this, unscrew the 4 screws on the grey hood to remove it. Replace batteries with AA batteries R6 1,2 V NiMH 2A which must comply with Directive 2006/66/EC. These batteries can be provided by BioparHhom (see pricing in place). A load indicator is present on the software and a warning message will be displayed when the battery is less than 15%. You will be advised at that time to recharge your device.

**WARNING ! If you do not want the charger fuse to blow, you should not leave your device charged for more than two consecutive hours. You must also wait for the discharge or the error message before charging your device. (maximum once per week!). Similarly, under risk of melting the batteries and damaging the device, you should only use the charger and batteries we recommend.**

<b>Consumables used in combination with the Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup></b>
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<b>List of compatible electrodes with the Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup> :</b>
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3M Health (2660-5) IMMED E151 COMEPA MI SM50 SKINTACT F-RG1, FS-RGC 10, F601C CLINICAL 849760 ASEPT INMED 250963 and 250966 AMBU White Sensor WS-00-S/50 and WS-00-S/RT/50
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The **Z-Métrie<sup>®</sup>/Z-Hydra<sup>®</sup>** must be used only with the compatible electrodes available in quantities that you want on command, [contact@bioparhom.com](mailto:contact@bioparhom.com) or 00.33.9.51.95.08.18, sales department and cables sold by Bioparhom whose characteristics are known and included in the body composition data.

The use of different products from those anticipated by Bioparhom distorts the results and could lead to misdiagnosis.

The use of different products would distort the results and may cause errors in the measurement.

The electrodes must be stored at constant temperature and humidity. The conditions to be respected are the ones specified on the packaging. The electrode can be placed on the patient a few minutes before the measurement to ensure a good condition of the measurement.

Particular attention should be paid to **the expiration date of the electrodes.**

### **Hardware and software PC requirements – IT security measures:**

The computer comes with the device must be located outside the patient area, be equipped with operating systems Windows 7, 8, 10 or 11 and comply with their particular standards of safety (EN 62368-1).

#### **Computer minimal characteristics:**

- 1 GB maximum (including software installation files, driver and database).
- Minimum 2GB RAM



- Hard disk or SSD greater than 16GB with at least 1GB available
- Screen size greater than or equal to 10 inches with a minimum screen resolution of 800×600 pixels
- Available USB port or Bluetooth

Internet connection is not mandatory to use the software. Data is stored in the chosen installation folder, in a safe and dedicated format that can not be opened without access to the software. A password can be added in “Settings”.

### **Storage and Handling :**

**Z-Métrix®/Z-Hydra®** is delivered in a protection case with various accessories to preserve its integrity during storage phases. The material must be handled carefully to ensure proper operation.

The measurement and storage conditions are as follows:

- \* Altitude limit at 2000m
- \* Temperature between 5 and 30°C
- \* Non-condensing humidity between 30 and 75%.
- \* Atmospheric pressure between 700 and 1060hPa



The unit should not be used or stored in wet areas and should not be near a water source.

Outside the above measurement conditions, measurements made with **Z-Métrix®/Z-Hydra®** can be disrupted and lead to misdiagnosis. The product should not be used in an environment rich in oxygen or flammable anesthetic.

### **Material preparation:**

The user must always ensure the hygiene and cleanliness of equipment before, during and after the measurement. The user will ensure strict compliance with instructions for connecting the electrodes depending on the type of action it wishes to achieve. (Right or Left side)

The boundary between applied parts and accessible parts is attributed to the use of a tool. Thus, housing for the batteries is considered accessible area so that cables, which come into direct contact with the subject is an applied part.



Applied parts are Type BF, as shown in the logo below cons. Indeed, the medical device in direct contact with the patient in the medium to long term but has no direct action on cardiac muscle.

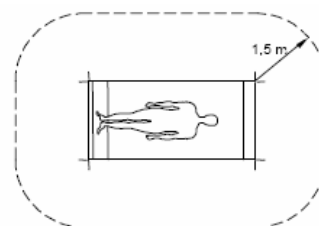
Ensure proper installation of all accessories before starting the measurement cycle. The unit should be placed in its entirety on a stable surface, close to the subject to be measured (cable length is 1.5m), but not on the patient. For charging, the **Z-Métrix®/Z-Hydra®** must be plugged into a wall socket.

If the device needs to be restarted (USB or Bluetooth connection failure, computer support stopped during measurement), a restart is possible by inserting the charger tip only into the designated slot. This operation will result in the device being shut down. Remove the tip of the charger and turn your device back on by clicking on the central button.

### **Patient preparation:**

An area, called "patient environment" must be respected around it during the measurement and can be estimated at least 1.5 m around the patient as shown in the figure below. The process is identical whether the subject is standing.

The non-medical equipment that may be associated with this measure, should not be located in the patient environment (1.5 m).



It is forbidden and impossible to do a measurement while the device is charging.



**It is necessary to connect first all the cables which will be used in the Z-Metrix®, before connecting the electrodes taped to the patient !**

#### **Precautions during the measurement cycle:**

It is imperative not to touch the unit, cables or the patient during measurement. It is advisable for the operator to be located outside the patient environment (1.5 m).

The device can't be switched off during a measurement cycle. If a power outage occurs, the measure will not be saved and you will have to do it again.

It is forbidden to use another device during a measurement, excepted from any vital device for the patient. It is advisable to disconnect or stop any non-essential device during measurement (type of blood pressure measurement).

#### **Traceability and Interpretation of Results:**

It is recommended that users keep all the measurements to ascertain the relevance of treatment options available for a favorable follow-up.

Any development of unwanted results must be analyzed carefully to verify that no errors of interpretation have been performed previously.

Thanks to the recalibration of the apparatus, the precision of it is constant and no risk with this precision fit into the process of risk management.

The delivery of a "compensation verification box" is not mandatory but can be sent to you in case of service. It makes it possible to check that the casing-cables-clips assembly as well as the coherence of the measurements made.

NB: this test box is not used to recalibrate the device.

#### **Maintenance and recalibration:**

No maintenance may be performed by the user. The lifetime of components is 5 years. During this period, maintenance is performed by Bioparhom, available at 00.33.9.51.95.08.18.

The product warranty is two years from delivery; that on accessories is one year.

**WARNING:** It is forbidden to make changes on the device.



A calibration check is performed on the device each time the software is started. If the calibration is not done at launch, check the connection and the load of the device. Otherwise, contact us.

#### **Cleaning :**

The user will ensure to maintain perfectly the device to keep it permanently in a perfect state of cleanliness. The case has been tested to be cleaned with disinfectant wipes market or hospital care products Anios high surfaces (spray gun) and the soil and surface cleaners Aniosurf. No other liquid must be put in contact with the device. The cables should also be kept in a perfect cleanliness.

#### **IMPORTANT:**



- **DO NOT USE THE DEVICE NEAR WATER OR IN WETLAND**
- **NEVER IMMERSING THE DEVICE,**
- **NEVER STERILIZING THE DEVICE**



**Waste and consumables disposal:**

The electrodes must be throw away after each use (reuse of electrodes could present risks of infection).

The device and the USB Key include an electronic card should be removed by following the provided channels for electrical and electronic equipment. Bioparhom is affiliated with Ecosystem for the management of EEE. Contact us to proceed with the destruction of your products.

**Warranty and after sales service:**

Our technical and scientific after-sales service is at your disposal on +339.51.95.08.18 or by email at [contact@bioparhom.com](mailto:contact@bioparhom.com) In case of malfunction, the device must be returned to society BIOPARHOM for rehabilitation.

All accompanying documents may be found in the Technical File TF01. On request, circuit diagrams, component lists, descriptions, calibration instructions or any other useful information can be obtained by the competent personnel to repair the device.

Please note that, as stated in the instructions, no item can be repaired directly by the customer. Only the company or its Bioparhom repairers are authorized to act on devices. Any intervention or disassembly will void the warranty.



## Pictograms on the device and accessories

### On the device:

Top: all lights are blue.



The device is measuring.



The device is currently transmitting data to your computer with Bluetooth.

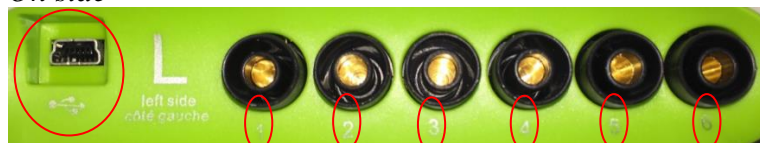


The device is turned on.



The unit is charging. You can not perform measurements during the loading phase of the battery, the device is then connected to the mains.

### On side



 This is the connector for the USB link.

- ① This is the connector 1
- ② This is the connector 2
- ③ This is the connector 3
- ④ This is the connector 4
- ⑤ This is the connector 5
- ⑥ This is the connector 6

**Warning !** To measure the subject on the right side, you must connect the plugs on the right side of the device. It is marked **R** and « **Right Side-Côté Droit** »



It is the connector for the charger.







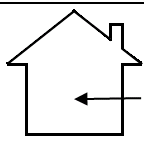






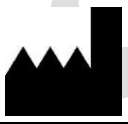


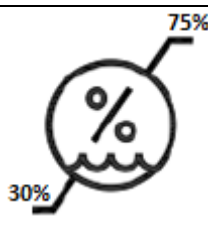
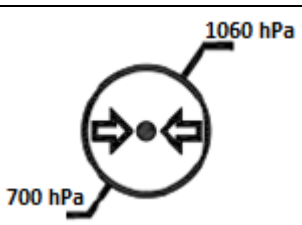



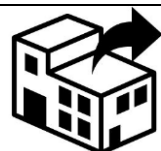
### On cables



	Must be connected to the electrode on:
1 (or hand)	on the hand near the bone of the phalanx, on right or left side
2 (or wrist)	at the wrist, on right or left side
3 (or shoulder)	at the bone of shoulder (acromion), on right or left side
4 (or hip)	at the bone of the hip (iliac bone), on right or left side
5 (or leg)	4 cm above the ankle, on right or left side
6 (or ankle)	Near the bone of ankle (external malleolus), on right or left side.

Photos and explanations are available in the manual. You must read the manual before your first measurement.

*On label: products and accessories*

	Do not dispose of with household waste		Keep out of direct sunlight
	Keep dry		Use before
	Use under cover		Single use
	Caution		Lot number
	Consult instructions for use or consult electronic instructions for use		Applied Part Type BF
	Device serial number		Product manufacturer
	Emitting non-ionizing		Use between 5 and 30°C
	Use between 30 and 75% of humidity		Use between 700 and 1060hPa
	Manufacturing date		Medical device
	Unique Device Identification		Distributor if applicable

EC Medical Marked

Class IIa

EC declaration of conformity on demand