

Preamble :

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



**Z-MétriX®/Z-Hydra® complies with
the applicable requirements of
Directive 93/42 / EEC and the French
Public Health Code.**

Classification according to European Directive 93/42 / EEC:

Z-MétriX®/Z-Hydra® is a **medical device** class IIa. It meets the definition of a device allowing the **study of a physiological process** (in our case, that is because of the variation of the body mass).

In addition, Z-MétriX® / Z-Hydra® 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 is classified according to Annex IX as **Rule 10**.

Indications:

The device is intended to measure quantitatively physiological parameters of the human body in a medical purpose, examples include:

- Nephrology : quantification of over hydration, help to diagnosis malnutrition, follow-up of a weight loss before transplantation, interest of a physical activity by measuring muscle mass, follow up of bone quality in order to help the diagnosis of osteoporosis.
- Intensive Care: follow-up of fluids compartments in order to prevent edemas or dehydration, follow-up of tissues (fat and muscle) in order to optimize nutrition.
- Cardiology: quantification of hypervolemia of patients with cardiac pathologies,
- Nutrition: help to follow up of patients (anorexia, obesity, malnutrition...): prevention of sarcopenia (lack of muscle), osteoporosis, and malnutrition, optimization of hydration strategy and follow-up of patients after bariatric surgeries, undernutrition diagnosis.
- Care: follow up of elderly people: prevention of dehydration and malnutrition, help to diagnosis lack of muscle mass.

Use:

This product must be used by trade professionals involved in the biology (Doctors, veterinarians, dieticians, nutritionists, 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
- 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...

Z-Métrie[®]/Z-Hydra[®] 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[®]/Z-Hydra[®]**.

Before use, the user will ensure that the **Z-Métrie[®]/Z-Hydra[®]** 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[®]/Z-Hydra[®] 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
- the bladder must be emptied before measurement.

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[®]/Z-Hydra[®]** by itself, but to a wrong diagnosis and interpretation of results.

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

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
Measuring cable 4 or 6 wires	EXZ1CAB & EXZ2CAB & EXZHCAB
ECG clips for electrodes	EXCLIPBK
Battery charger	EXCHARGEUR
Calibration fantom	EXFANTOME
USB Cable	EXCABLEUSB
Protection Case or Suitcase	EXVALISEGRIS or EXMALETTE
USB Key	EXCLEUSBVIERGE
Electrodes	EXELCLINUN
Battery	EXSET6PILES

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.

Only attachments supplied with the unit of measurement (See table above) should be used with it. The computer comes with the aircraft must be located outside the patient area, be equipped with operating systems Windows 7, 8, 10 or 11 and comply with their particular standard of safety (EN 60950-1).

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.

Consumables used in combination with the Z-Métrie[®]/Z-Hydra[®]
--

List of compatible electrodes with the Z-Métrie[®]/Z-Hydra[®] :
--

3M Health (2660-5) IMMED E151 COMEPA MI SM50 SKINTACT F-RG1, FS-RGC 10, F601C CLINICAL 849760 ASEPT IMMED 250963 and 250966 AMBU White Sensor WS-00-S/50 and WS-00-S/RT/50
--

The Z-Métrie[®]/Z-Hydra[®] must be used only with the compatible electrodes available in quantities that you want on command, 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.**

Storage and Handling :



Z-Métrie[®]/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-Métrie[®]/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-Métrie[®]/Z-Hydra[®]** must be plugged into a wall socket.

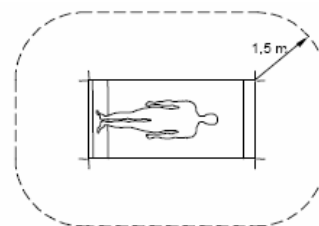
If the device needs to be restarted (USB or Bluetooth connection failure, computer support stopped during measurement), a restart is possible by inserting the charger tip only into the designated slot. This operation will result in the device being shut down. Remove the tip of the charger and turn your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

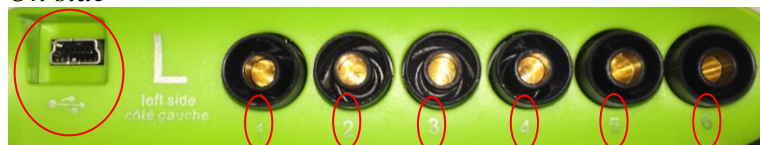


The device is turned on.



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.

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** »

- 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



It is the connector for the charger.





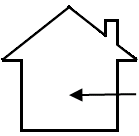








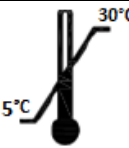
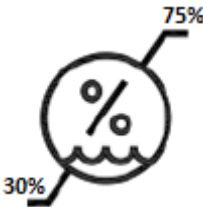
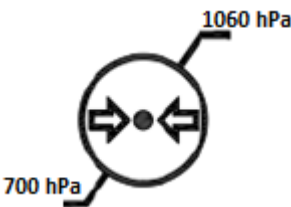






On cables

	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
	Utiliser uniquement sous abris		Single use
	Read the instructions for use		Lot number
	Read the manual		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

