Z-Metrix®

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1 Z-MÉTRIX® UNIVERSE

1.1 Bioimpedance

BioparHom, a young and innovative technology company, was founded in 2008 from a lack of a scientifically-validated bioimpedance devices that can be used for routine clinical use. Its expertise in the electrical modeling of living tissues led it to develop the Z-Metrix®, Bioparhom first measurement instrument.
Our main area of expertise is bioimpedance, which represents the opposition of a biological tissue to the passage of an electric current.
A glossary is available at the end of the document and presents some essential definitions.

Our collaboration with Meditor Company, a specialist in the field of nephrology and intensive care units (ICU), has led to the development of an impedancemeter dedicated to the analysis of body composition and diagnosis of the nutritional status dedicated to these two specialties, the Z-Hydra.

The Z-Metrix® is also extended to the field of the research in its Z-Scan form.
A development work is also underway with 5mVet Company to finalize the development of a body composition measurement tool for equine and bovine animals Z-Equin.

1.2 Body composition measurement method

Currently, it is no longer enough to measure only weight and height. Many diseases (heart disease, kidney disease, edema, anorexia nervosa, etc.) cannot be detected or monitored using only these types of measurements. An increase in certain areas of the body may hide a decrease in another area.

In sports field, the problem is the same. Many indices, such as fat mass, metabolic fatigue, and muscle mass hydration, affect an athlete's performance but cannot be assessed through height and weight.

Impedancemetry, a science that interprets the body's resistance to current flow, is a promising method for exploring body composition. Easy to use and fast, bioimpedance provides complete data: tissues, fluids with a percentage error of less than 5%. For example, if the device displays 12%, the theoretical value is between 12.6 and 11.4%.

1.2.1 The physiological model

Physiological modeling focuses on two types of compartments: the fluid compartment comprising water and body fluids, and the tissue compartment comprising fat mass, protein, and bone mass.

The tissue compartments comprise the body's fat mass (FM) and fat-free mass (FFM). FFM includes lean mass (LM), which is in turn made up of water and protein, and bone mineral content (BMC). See figure 1.

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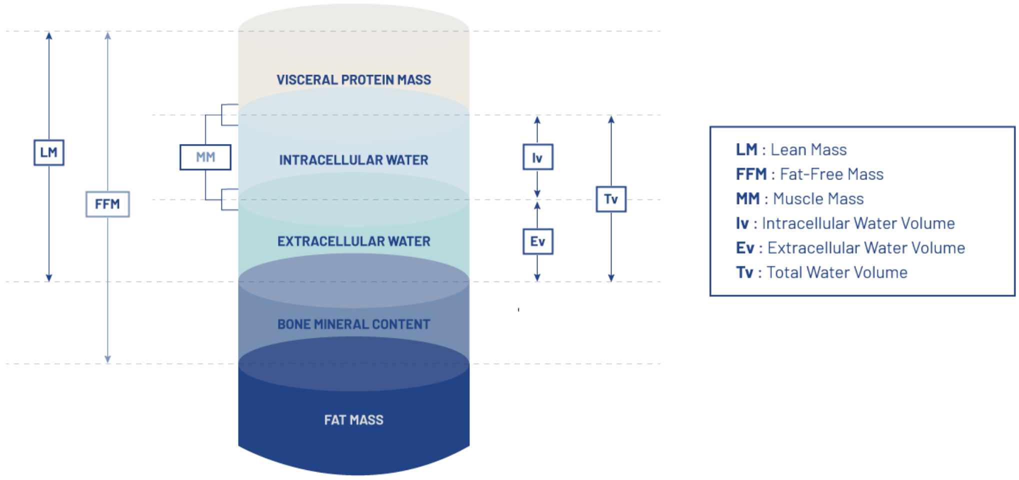

Figure 1 the physiological model

Fat mass (FM) includes both fat tissue and triglycerides. This compartment represents about 15% of body mass in men and 28% in women.
Fat-free mass (FFM) is a compartment that comprises water, protein, and bone mineral content (BMC). Bone mineral content corresponds to the calcium phosphate crystals of the skeleton, i.e., the bulk of the subject's mineral mass.
Lean mass comprises total water and protein.
The body's fat reserves can be reduced by more than 50% without risk. However, if the protein mass is cut in half, mortality increases considerably, particularly as a result of decreased immune defenses.
Nevertheless, FM is an energy reserve. A male with less than 5% or a female with less than 16% body fat is at risk. Conversely, an excess of body fat can lead to risks such as cardiovascular disorders.

Water, itself, is made up of two compartments: extracellular water and intracellular water. Data on these two compartments is important because it helps identify edema and dehydration of varying levels of severity.
Extracellular water includes plasma and the liquid surrounding cells, known as interstitial fluid. Plasma is made up of water, various ions—especially sodium—and protein. It represents the liquid in which red blood cells are suspended. Interstitial fluid, which is similar in composition to plasma, facilitates transfers between the cells and the blood. Intracellular water represents the fluid contained within the cells. Its exact composition varies depending on the function and needs of the cell, but its main concentrations (potassium, magnesium, phosphates, etc.) vary little from cell to cell.

1.2.2 Electrical model

Bioimpedance, a technique focusing on the electrical properties of a living organism, allows for simple, rapid, and continuous measurements. It is simple in principle: a low-intensity (about 70 µA) alternating current is applied to the body through current-injecting electrodes. The current will pass through the more conductive compartments (water, electrolytes, muscles, etc.) and avoid non-conductive compartments (cell membranes, fat, skin, etc.). The voltage is read between receiving electrodes and is corresponding to the tissues opposition to the current flow. Therefore, an individual with more fat mass will be more resistant to the current flow than someone else with more muscle mass. See figure 2.

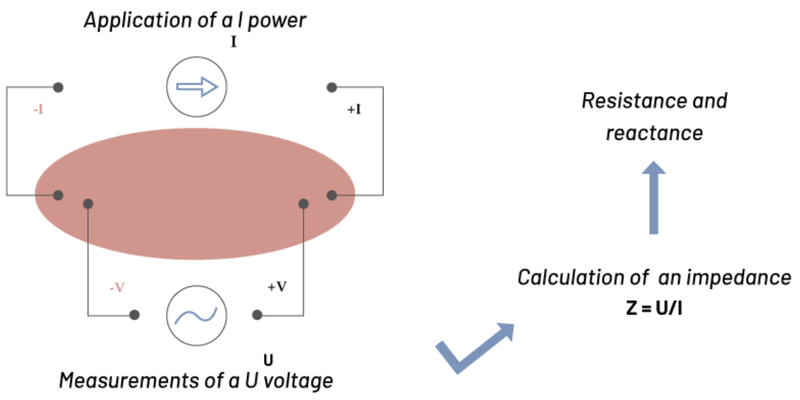

Figure 2 Bioimpedance principle

The cell's membrane, which is non-conductive at low frequency, causes electrical charge to accumulate on each side without letting these charges pass through. This creates a double layer that forms a capacitor. This membrane causes cell behavior to change under the effect of a current. When the frequency is low (<50 kHz), the current does not penetrate the cell. If frequency is increased, the current will enter into the cells, and the data collected will therefore pertain to both the intracellular and extracellular compartments.
See figure 3.

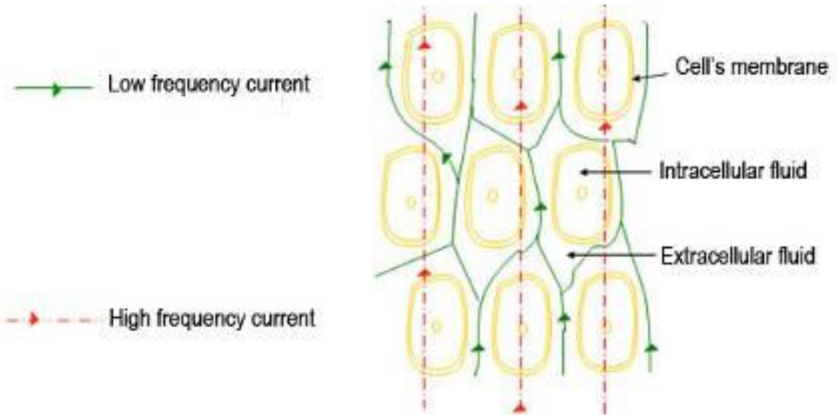

Figure 3 Modeling the passage of current at low and high frequency

At a high frequency, electrical charges can't accumulate on either side of the membrane and the current is thus able to pass through the ion channels due to the presence of ions. It is difficult to quantify the limit between both, but it is thought that most compartments are penetrated at 150 kHz and higher.
Again, a tension is relieved to the receiving electrodes. This signal will be interpreted as two data: the resistance R, which corresponds to the non-conductive elements and reactance X, who will represent the capacitive effect of the membranes. The combination of these two data forms what is called the calculated impedance equation $Z^2 = R^2 + X^2$.

As noted above, if a single frequency is used, only one compartment can be analyzed. Two frequencies must be used, at a minimum, to determine total body water based on impedance at high frequency and extracellular water based on a low frequency current.
Measurements with Z-Métrix® are from 7 different frequencies: 1, 5, 50, 150, 200, 250 and 325 kHz. It is a multi-frequencies impedancemeter.

1.3 Bioparhom approach

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Before the Z-Metrix® was launched and marketed, a clinical study was conducted to establish the tissue-related equations and to validate the fluid models. This study, approved by the French Personal Protection Committee, Nord Ouest II, and the ANSM, was conducted over a period of several months in the Medical Imaging Center of the University Hospital of Compiègne.

This study had a number of objectives:

- To measure the resistance and reactance of the body and limbs of the volunteer group using a prototype of the Z-Metrix®.
- To create the tissue-related equations dedicated to Z-Métrix® and linking the reference data generated by the DEXA scans to the electrical data (resistance, reactance, Re, R∞) and the data intrinsic to the subject (age, weight, height, gender).
- To validate the fluid-related equations by comparing them against the water volumes obtained with a research impedancemeter, validated against dilution.
- To validate all equations, related to both fluids and tissue, for subjects in a standing or lying position, for the right and left sides, and for the various body segments.

The databases created through this clinical study can be used to obtain reliable, statistically significant equations for fluid and tissue data.

1.4 Bioparhom Features

Need to know the age (A), the size (H), weight (W) and the gender of the subject to have access to these features. We note that the majority of the indicators given are estimates from models, the Impedancemetry giving of course direct measurements derived from the electric characteristics of the subjects. The following indices are valid for the whole body to the right and to the left. A set of indices, from this list, is also valid for the body segments (trunk, leg and arm, right and left).

All the features of the device as well as their accuracy, repeatability and origin are described in the document called SF006 – Indicators description.
A set of recommendations is proposed to define the limits of the equipment.

1.5 Glossary

Capacitor: electronic component capable of storing energy and distributing it within a circuit.

Bone mineral content (BMC): compartment corresponding to the calcium phosphate crystals of the skeleton, i.e., the bulk of the subject's mineral mass. (Cortical bone)

Impedance: measurement Z, calculated based on the intensity I recorded at the current-injecting electrodes and the voltage U recorded at the receiving terminals, with Z = U/I, interpreted by a resistance R corresponding to the opposition of the tissue to the electrical current and by a reactance X corresponding to the capacitive effect of the cell membranes.

Bioelectrical impedance analysis (or bioimpedance): science used to analyze the body's opposition to the flow of an electrical current in order to determine its composition.

Fat mass (FM): compartment comprising fatty tissues and triglycerides representing, on average, 15% of body mass for men and 28% of body mass for women.

Lean mass (LM): compartment comprising total water and protein.

Fat-free mass (FFM): compartment comprising water, protein, and bone mineral content (BMC).

The instructions for use was provided with your device and this manual. Read it before installation of your equipment.
You can follow this guide or read the document called "SC020 – Quick guide" to install the software and your device.

2 INSTALLATION PROTOCOL

2.1 Install the software

1- Open the USB support software installation.
2- Open the file « setup » and double click the executable and follow the installation steps on the screen.

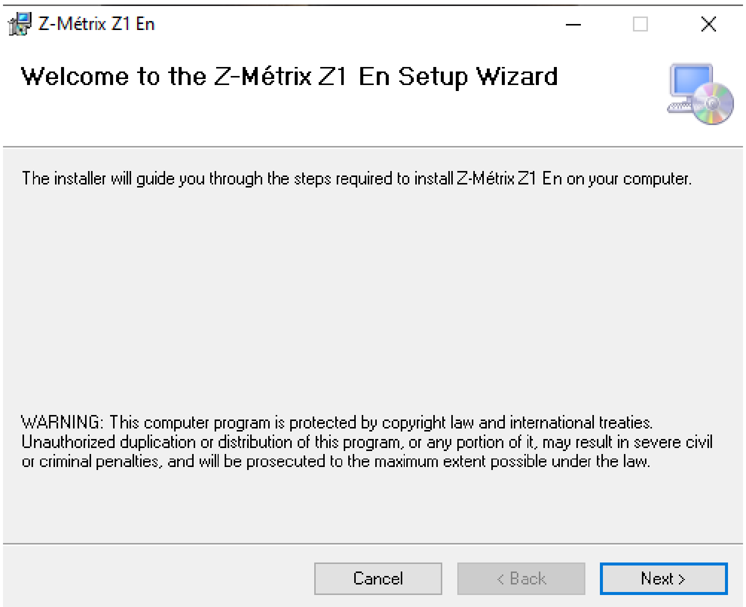

Figure 4 Software installation (1)

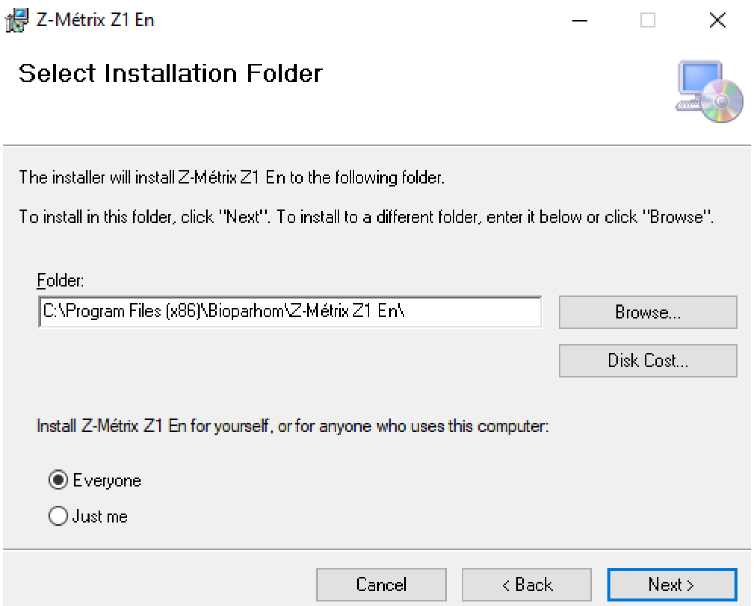

Figure 5 Software installation (2)

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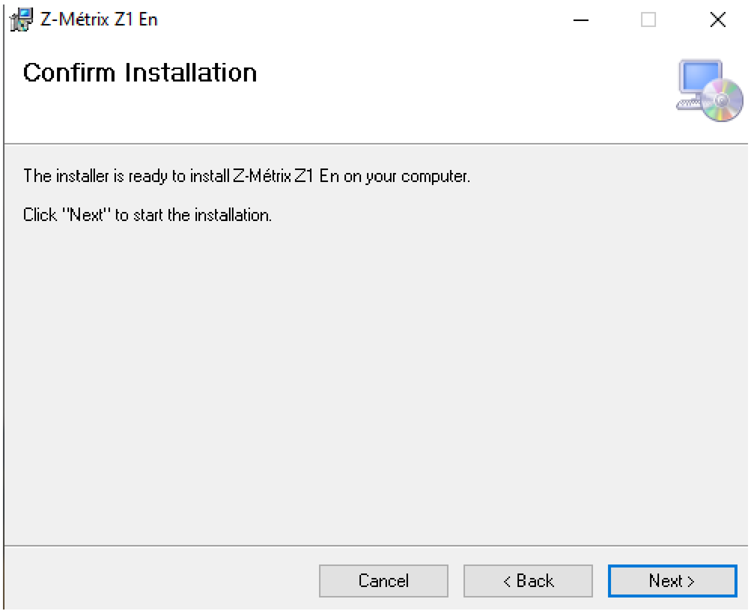

Figure 6 Software installation (3)

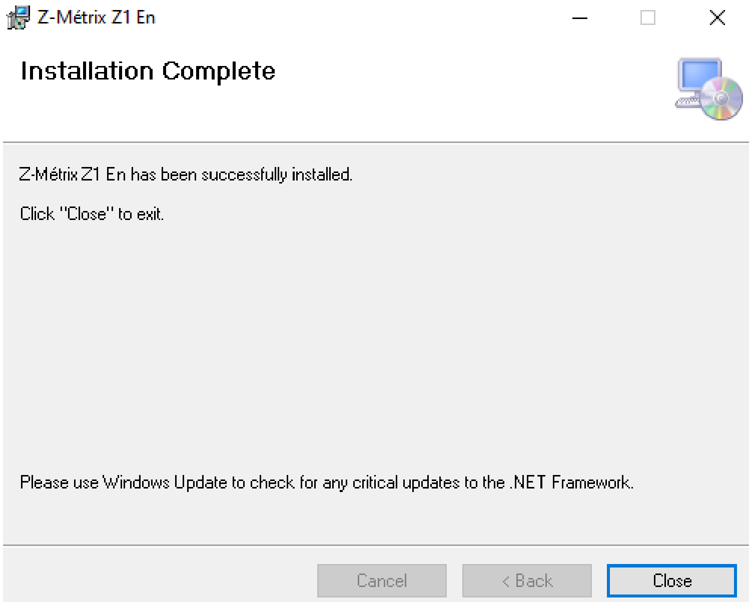

Figure 7 Software installation (4)

3- In order to use the application in windows Vista or later, you need to run your software in Administrator mode. It is possible to configure automatically. Make a right click on the Z, then Properties, Compatibility tab icon. Check the box "always run in administrator mode”. Apply and Ok. Do the same for the "Basic tool" icon.
Before you can use your Z - Metrix®, you must install the driver: you will find all the explanations to the next point.

2.2 Communication Z-Métrix® and software

Two methods are available. The Z-Metrix® can be connected by USB connection (included) and Bluetooth (USB kit not included).

1 - Go to the directory Driver on your USB Stick.
2- Open the USB key folder "driver installation" corresponding to your Windows version and double-click on the exe (CP210xVCPInstaller_x64 pour Win10. Follow the instructions on the screen. Warning for Win 7: leave "Launch the CP210xUCP Driver Installer" checked
3 - Connect Z-Metrix to the computer using the USB cable. Turn on the device by pressing the central button on the device (top side). In your taskbar, a window opens indicating the installation of a COM port. Note the COM port number. If this is not displayed, right-click on the computer or "this computer" and manage. Open the device manager and look for the COM port number in the "com and LPT port" line. It is in ( ) at the end of the line that begins with "Silicon Labs CP210x... ». If it is not present, restart the computer and repeat the operation.4 - Once the software is open, go to Settings and then Device. In the com port tab, select the com port number of point number 3 and click on "connect". Your device checks its own calibration and is ready to do measurements.
5 - You can use your Z-Metrix® by USB connection.

For Bluetooth, refer to the user manual of your adapter and enter the number of com port in the settings.

Classically to add a Bluetooth device:
1- Select Bluetooth Devices in your control panel. If this does not appear, insert your Bluetooth USB key and click on the Bluetooth icon in the dialog bar and then "Add a device".
2- Select Serial Port Device, taking care to turn on the device.
3- When the connection is effective, click on "enter the pairing code of my device" then enter the code 0000.
4- It is possible that an error message indicates that the communication was not carried out because there is no response. If this is the case, repeat steps 1 to 3.
5- Once the connection is successful, right click on My Computer / Computer and then Manage. In the device manager, select com port and Ltp then look for "Serial link on standard Bluetooth". Note the COM port number.
6- Open the Z-Métrix® software, in settings, select the corresponding com port number and connect.
7- Your Bluetooth connection is active!

Before you can use your device at best, fill in the information requested in the settings tab then users parameters so that we can help you with any problem.

You can also set indices to display in the "settings".

3 MEASUREMENT PROTOCOL

The Z-Metrix® was designed to be as simple as possible to use and its accompanying software is extremely user-friendly. However, this section will help you to take your first assessment with the device. For conventional assessments, the first test may take up to fifteen minutes, while subsequent assessments will be quicker—around three minutes.
A quick guide (SC020) has been created allowing you to simplify this Protocol. It is usually on the USB key delivered with your device... Feel free to ask Bioparhom.

3.1 Calibration

After the software program is launched, click on settings. The device will perform a check to verify that it is properly calibrated based on reference data.
As soon as the software is launched, a control step is used to check if there has been any drift of the device. If the calibration is not done at launch, check the connection and the load of the device. Otherwise, contact us.
If your device falls or is subject to circumstances beyond those published in the manual (temperature, hygrometry ...), please turn off your device and then turn it on again. A control test will be done automatically and you will know whether or not to recalibrate your device.

3.2 Settings

Settings allows you to access different tabs.
The *Device* tab allows you to check the calibration of your machine again and to select the right COM Port.
The *Measurement Options* tab allows you to select interpretations display and the default position of your subject (right or left, standing up or lying down).
The *User Parameters* allows personalization of the user information (name, address, mail, phone, and logo)
The *Indicators* tab then offers the indicators you want to display at the end of the measurement. You can use specific profiles corresponding to the indicators you find necessary for your measurement. The complete, fluids, tissular, metabolic and express profiles are already integrated but you can create your own profiles using the available tool.
Import is use to import data from the old software.
Export/Backup is described in 3.7.

For indicators, after training you will be able to use Express mode. For beginning, we advise a “Simple” tab in next picture.

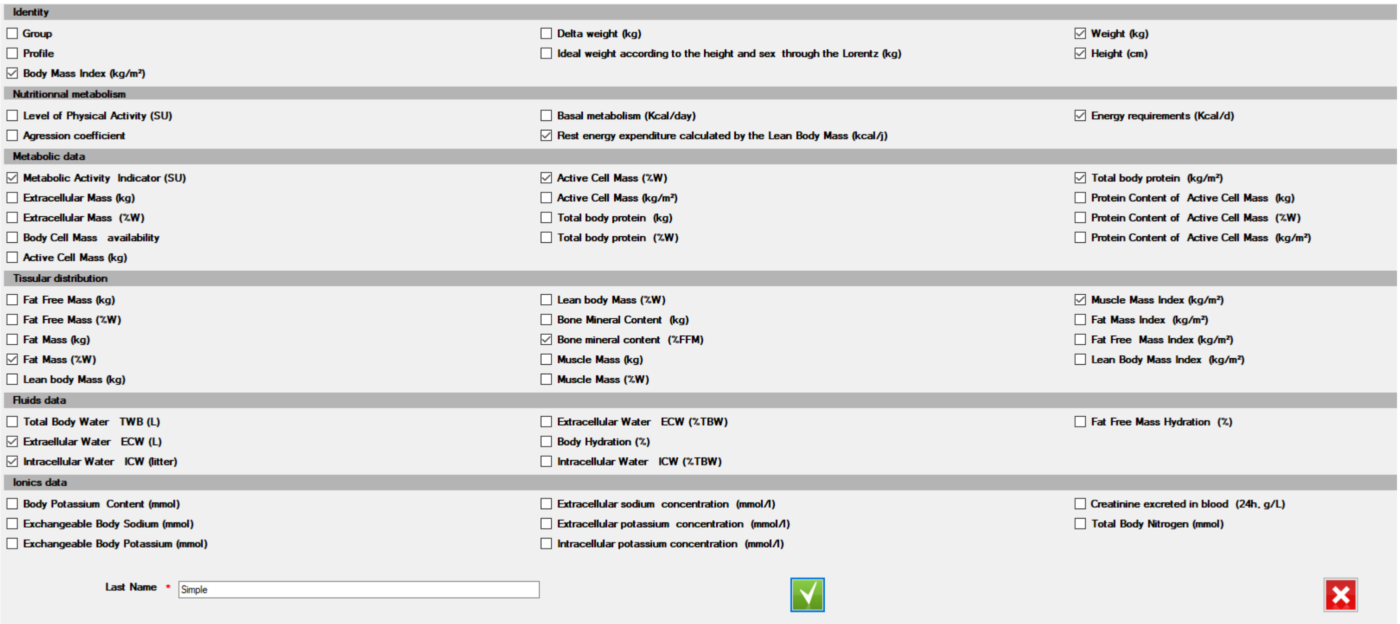

Figure 8 Indicators profile for beginning

3.3 Add a patient

Once you have reached the directory, you can consult all measurements and data for each subject. You can select a former subject or add a new one using the corresponding button.

As shown in Figure 9, you will see that when you click on the name of a subject, a summary of results and history is provided on the right-hand side of the screen.

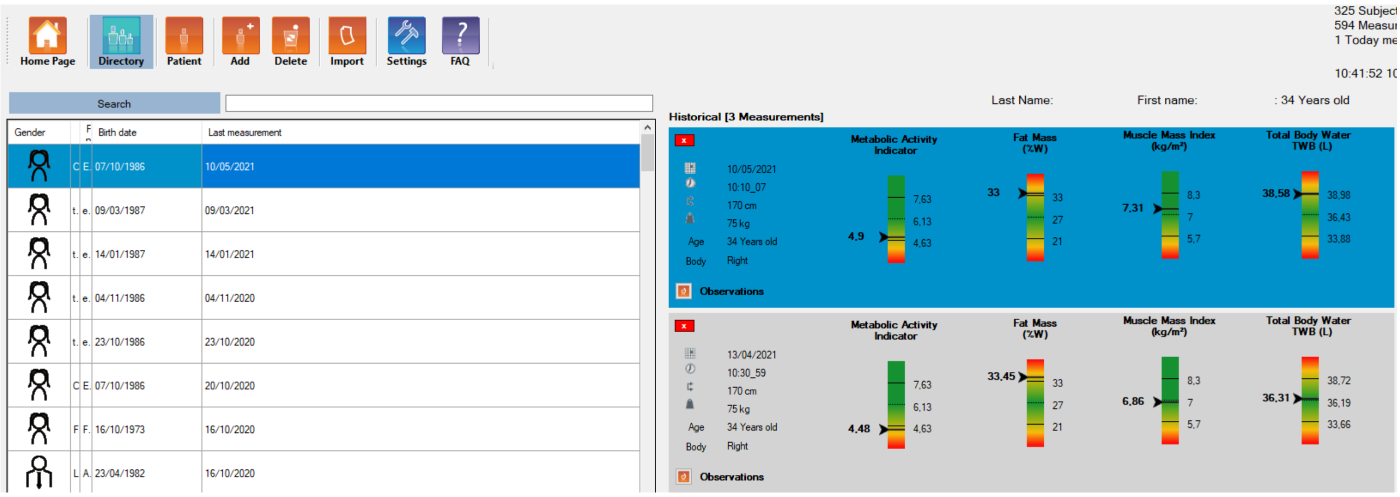

Figure 9 Directory

To add a new patient, click *Add.* », you will get a new window as shown in figure 10. The mandatory information is: the subject's first and last name, birth date, gender and orientation.
Once all the required information is entered, a green V appears at the bottom of the window.
You then fill in the profile of your topic: wellness or sports performance. Depending on the age of the subject, "children and adolescents" profile for less than 18 years, and the 'elderly people over 65 years' profile, to will be selected by default. Select

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amateur for an athlete practicing between 4 and 6 hours per week, high level for more than 6 hours per week of intense physical activity).

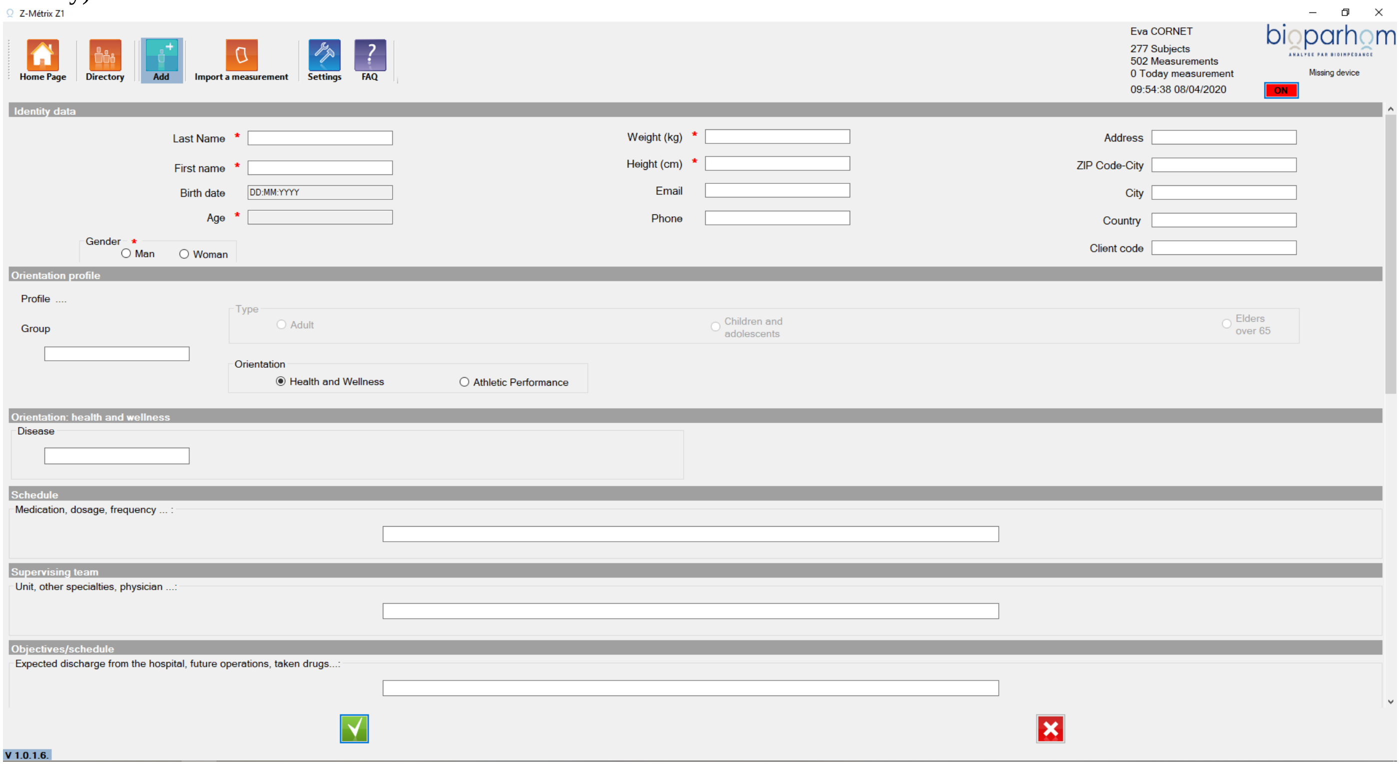


Figure 10 add a new patient

You can then enter the identity and other information you may need for the history, follow-up, interpretation: news, sports practices, history... You can come back to make changes in this form by clicking on the Edit button.

3.4 Measurement

The *Measurements* tab first allows you to measure body composition, as shown in figure 11.

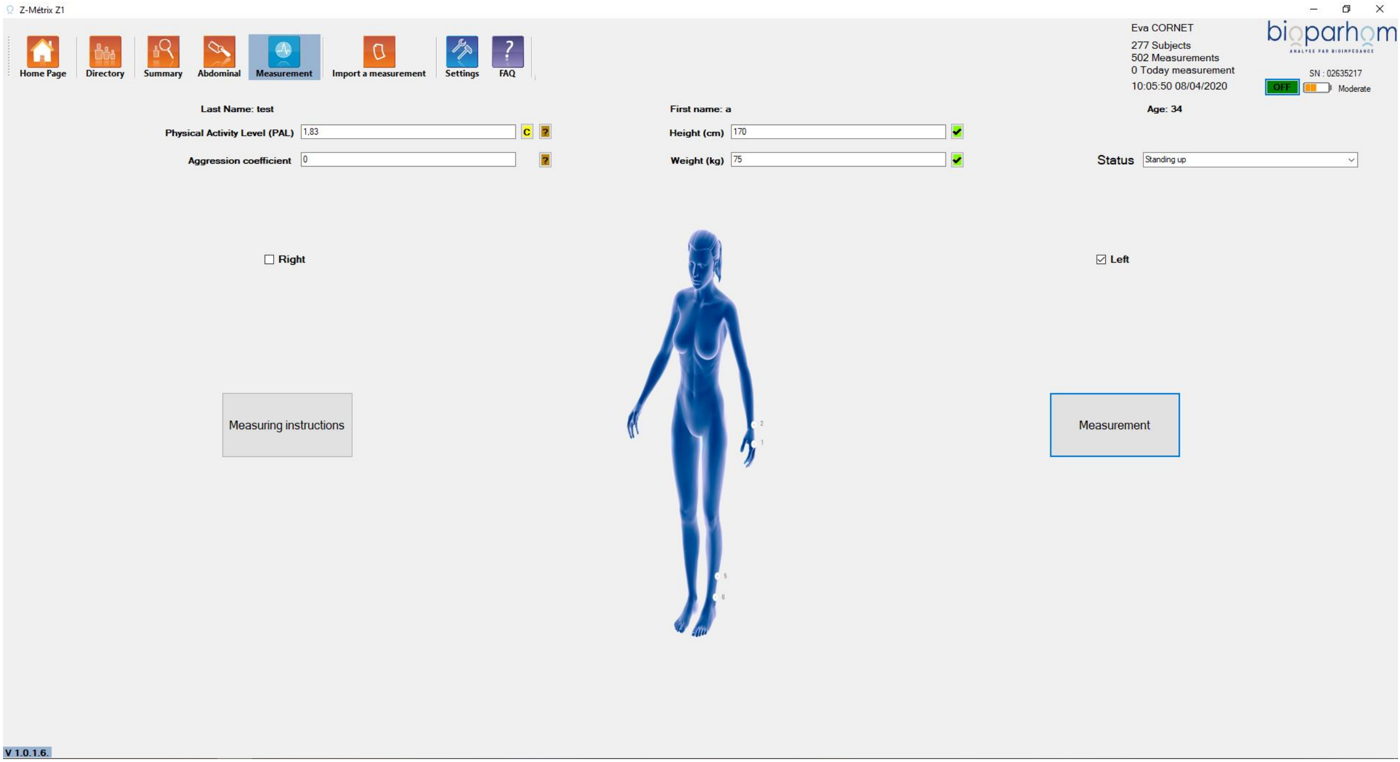
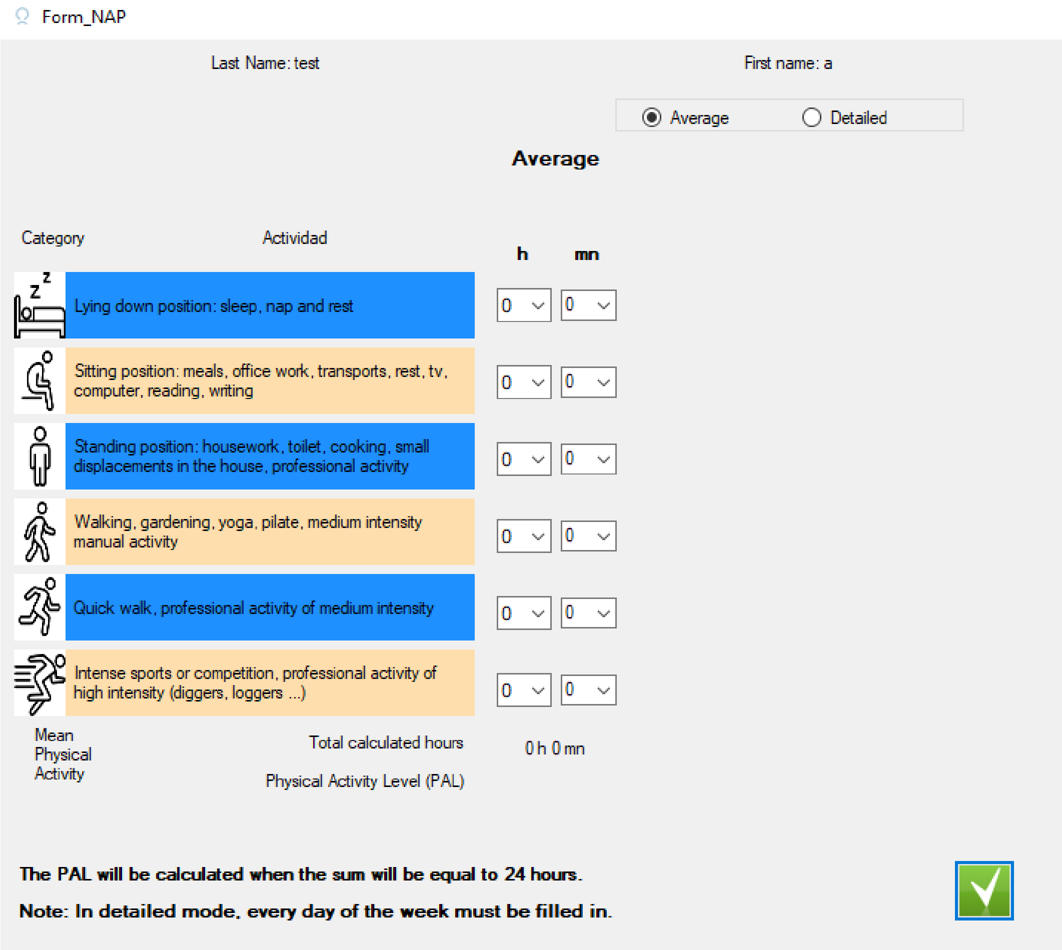


Figure 11 Measure body composition

You can select Right, Left or both body sides. Pictures is going to change and show which electrodes you have to stick on your patient.

You can complete the PAL (Physical Activity Level) by calculating it (Box C) or by entering the value by hand. This calculation consists of quantifying the spent time by the subject in six categories: lying, sitting, standing, activities of medium intensity such as walking, high intensity activities and intense activities. The calculation gives a figure quantifying the physical activity of the subject and placing it in relation to the French average which is between 1.35 and 1.76. This figure will be used to calculate the subject's energy needs that will be a function of this PAL, its weight, its size and its sex.



You can also complete the aggression coefficient of your patient, a benchmark of which is detailed in?

Finally, check the weight, height and position of the subject.

Figure 12 PAL calculation

As shown in figure 13, the colored areas are the areas where measurements will be made. A single click allows you to add or remove the selected area. Usually, the measure is always on the right side.

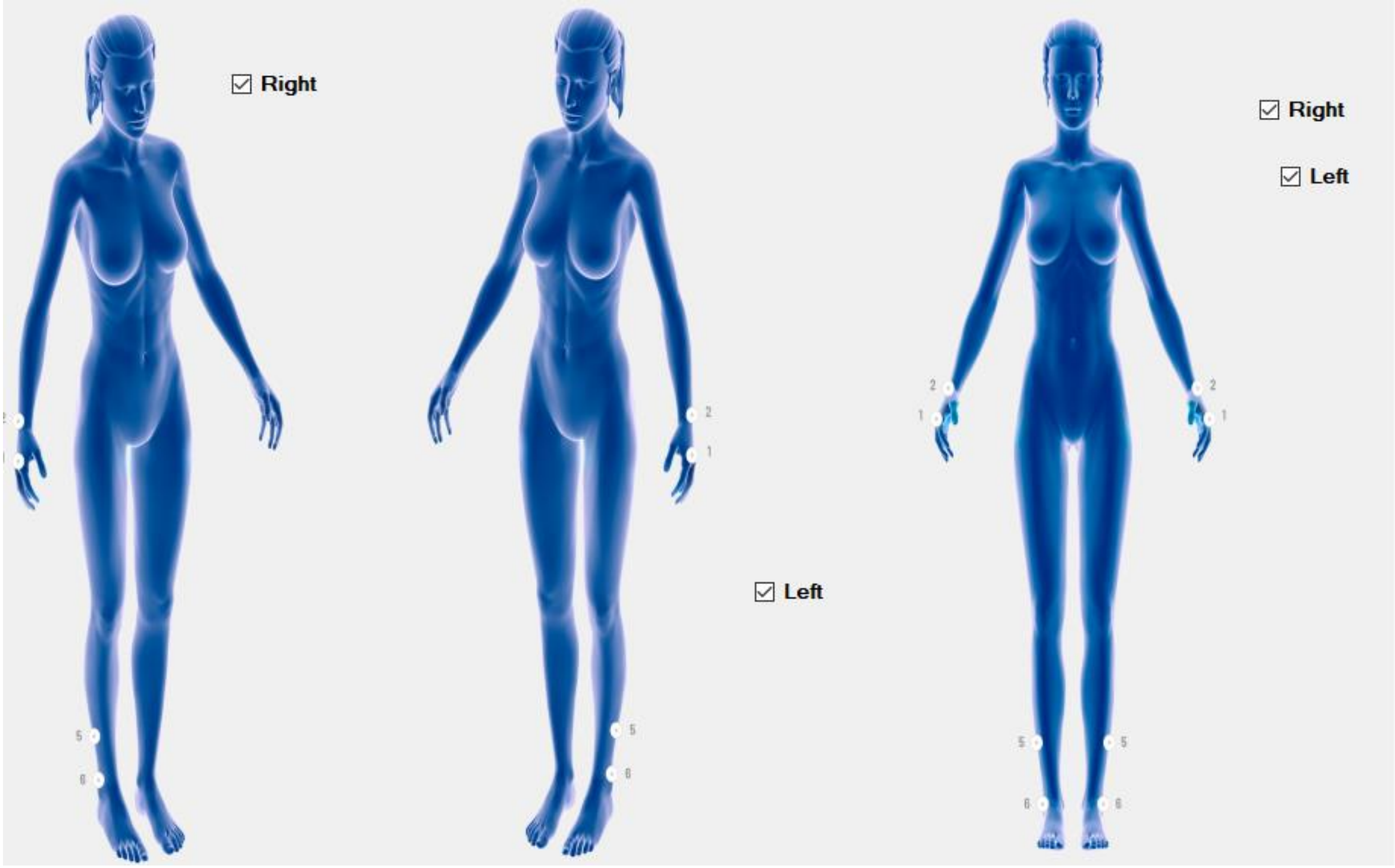


Figure 13 Selection of the measure areas

You must enter the subject's weight and height and check status (standing up or lying down).

For Z2 measurement, you have to enter circumferences of the subject if they differ from the previous measurement or if this is the first measure. The circumferences are detailed in Figure 15 and indicated by numbers to facilitate the description of this step.

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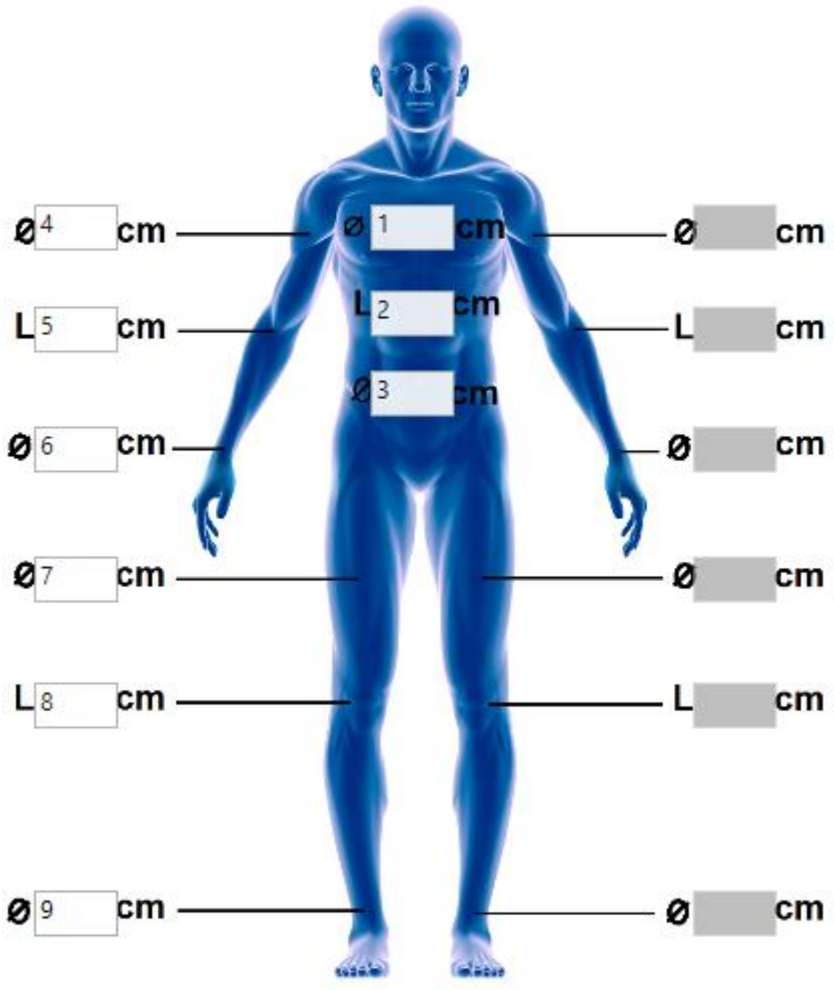

Figure 14 Circumferences registration

1	Circumference of the trunk at nipple level.
2	Length of the trunk from the shoulder to the pelvis (acromion to ilium) between the electrodes.
3	Circumference of the pelvis at ilium level.
4	Circumference of the arm at mid-biceps level.
5	Length of the arm from the shoulder to the wrist between the electrodes.
6	Wrist circumference.
7	Circumference of the leg at mid-thigh level.
8	Length of the leg from the hip to the ankle between the electrodes.
9	Circumference of the ankle at malleolus level.

Figure 15 Circumferences details

Before clicking on "*Measurement*", you can check "Measuring instructions", stick electrodes and plugged selected cables on the patient as described in Figure 16:

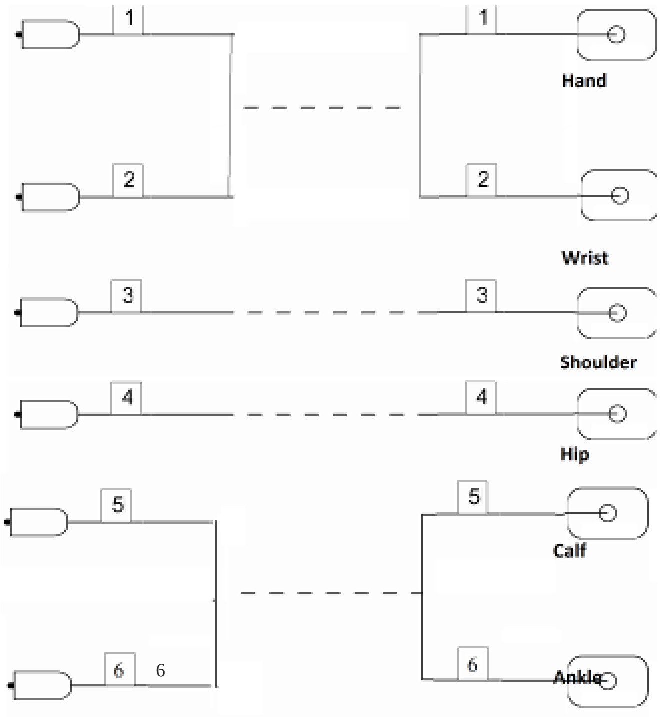

Figure 16 How to connect cables

You must only connect necessary cables for the measurement as shown in figure 17:

Body's part to measure	Cables to connect
Body (Right or Left)	1, 2, 5,6
Arm (Right or Left)	1, 2, 3, 6
Trunk (Right or Left)	1, 3, 4, 6
Leg (Right or Left)	1, 4, 5,6
All body's part	1, 2, 3, 4, 5,6 R and/or L

Figure 17 Cables to connect

The side R on the device must be connected to the right side of the patient and the same for the left side.

Electrode placement is important for optimal results. As part of a measurement of the right or left body, there will be placed four electrodes according to Figures 18 to 21.

The first electrode is placed on the hand. It is easier to arrange if your patient's fist is tight.

The second electrode is placed at the level of the wrist at the level of the head ulna, in the intertendinous hollow. Figure 18 shows how to put these two electrodes

Figure 18 Electrodes number 1 and 2 (hand and wrist)

The third electrode is placed at the level of the ankle above the external malleolus.

Finally, to place the last electrode, just take your hand, put it above the electrode of the malleolus, count 4 fingers and put the fourth electrode. Figure 21 shows how to lay these two electrodes.

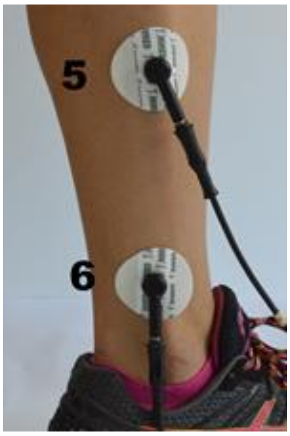

Figure 19 Electrodes number 5 and 6 (calf and ankle)

Two additional electrodes must be put for segmental measurements on the shoulder (next to the acromion) and the hip (close to the iliac bone). See figures 20 and 21.

Figure 20 Electrode number 3 (shoulder)

Figure 21 Electrode number 4 (hip)

It is advisable that the patient has removed any jewel (watch, bracelet) as well as any objects they may have in their pockets (keys, telephones mainly)
If your connection, the positioning of the device or the quality of the subject's skin cause measurement errors, pop-ups will alert you and advise you to check your connection.
Do not allow the patient's or user's body to come into contact with the unit or connectors 1-6 during measurement. This can lead to short circuits or parallel currents and thus distort the measurement. The unit should not be positioned on the patient.
It is imperative that no contact is made between the patient and the bed, hand or foot with any other part of the body. For example, it is imperative to ensure that your patient's thighs do not touch each other except through an insulating garment.
In the case of dry or oily skin, it is possible to moisten the area where the electrodes are placed with a compress moistened with saline solution.
The correct arrangement of the cables (stretched and not crossed) is important.
The placement of the electrodes is also a crucial step as it determines the segments measured. It is imperative that the injector and receiver electrodes are at least 4 centimeters apart and that they are placed in the best possible way.

When your patient is correctly connected, click on "Measurement". The device flashes on its LED number 4. After about 3 seconds, the measurement is complete and a message indicates this.

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3.5 Results display

When the measurement is done, you can click on "result" or do a double click on the measurement on the right. Once it is done, the results screen is displayed as shown in figure 22.

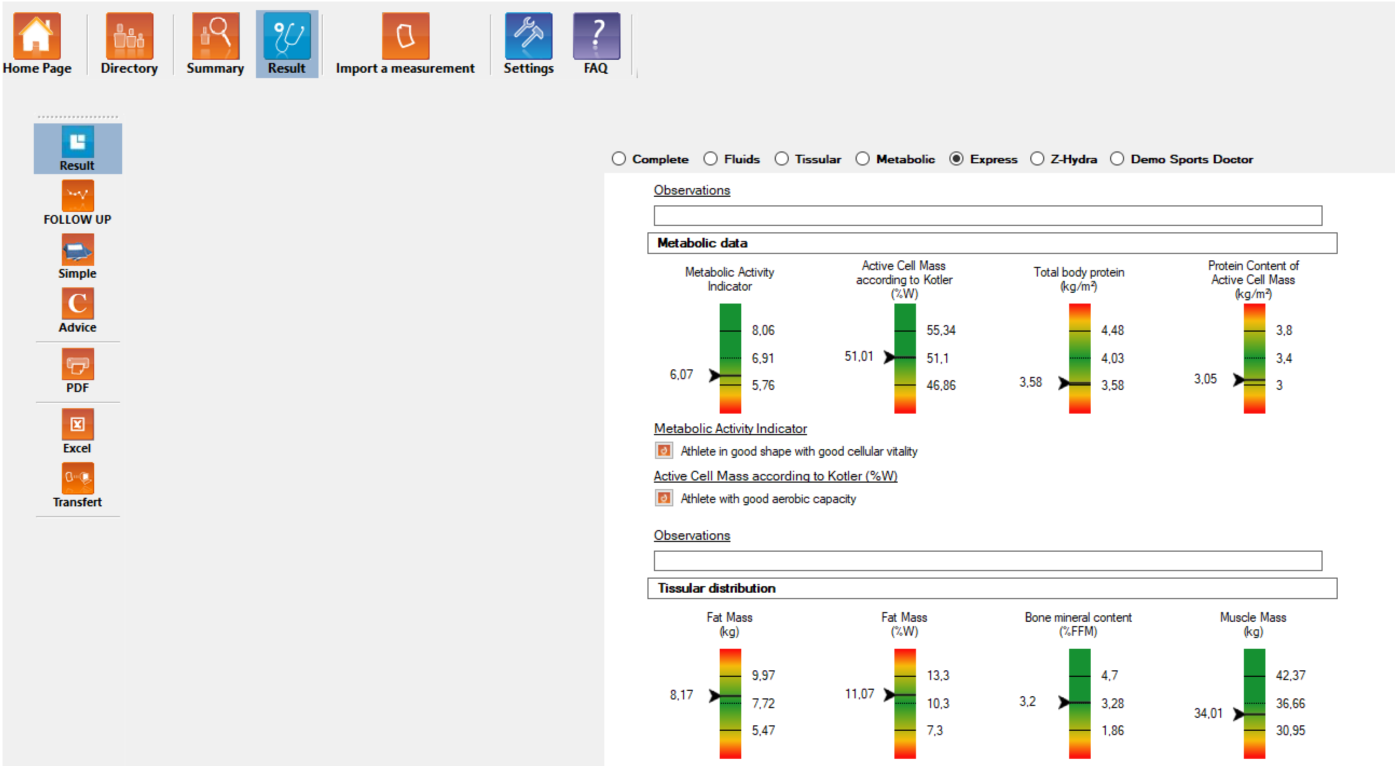

Figure 22 Displaying results - gauge

After choosing the list of indices to display (complete, water, tissue, metabolic or your personal block), you can view the results of the measurement in gauge form.
Under each block, an interpretation of the index is available and a free area allowing you to return your own comments. These interpretations and comments will appear when printed.

The next presentation mode is a second graphics mode that highlights the evolution with the monitoring of selected parameters. An example is illustrated in figure 23. You can select the indicators by right click on the graph.

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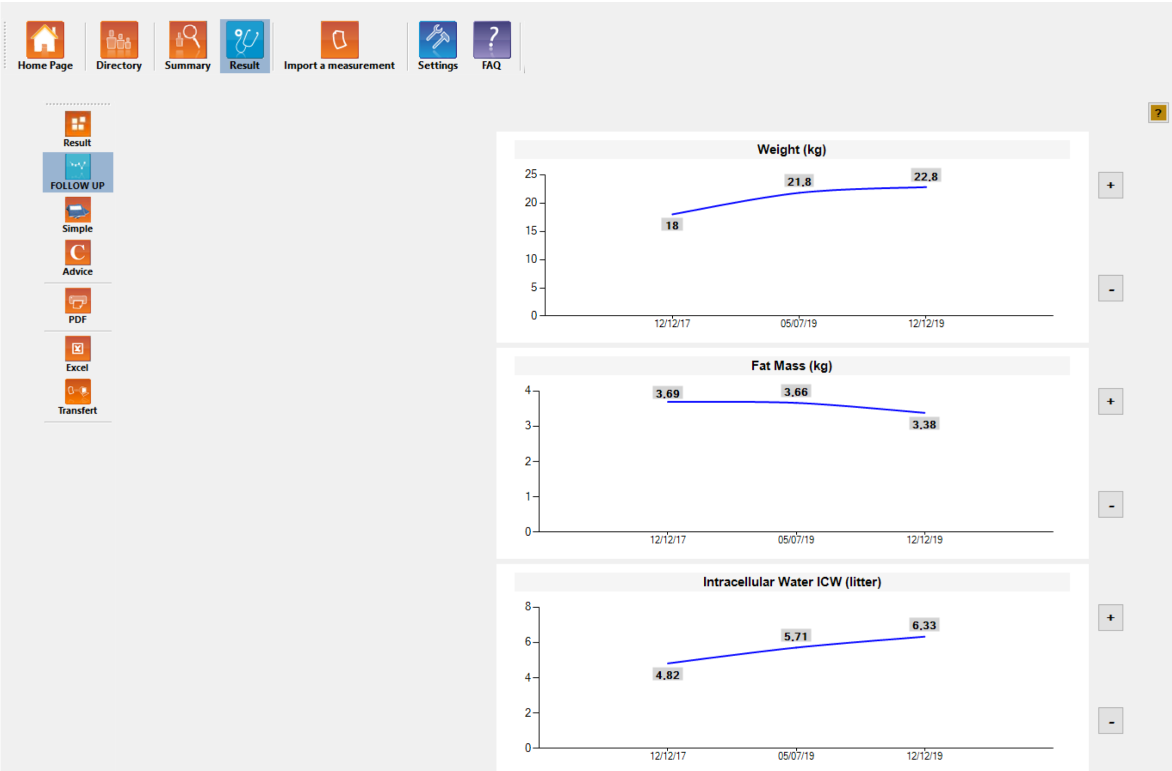

Figure 23 Displaying results - graphs

A third mode is available clicking on Simple as shown in figure 24.

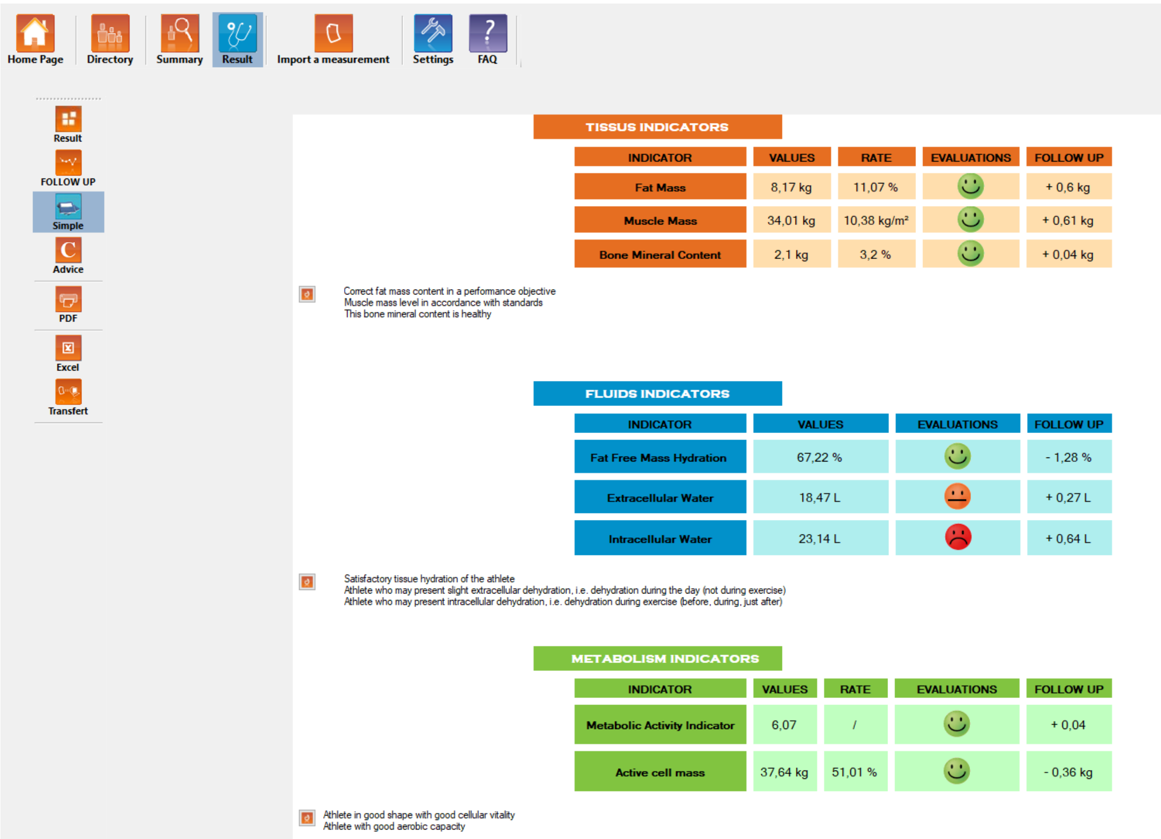

Figure 24 Illustration of the results mode "Simple"

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3.6 Subcutaneous fat measurement

It is possible to measure the thickness of subcutaneous fat.

As shown in Figure 25, the resulting data reflects the fat thickness (in millimeters) that is located between the belly skin and the viscera.

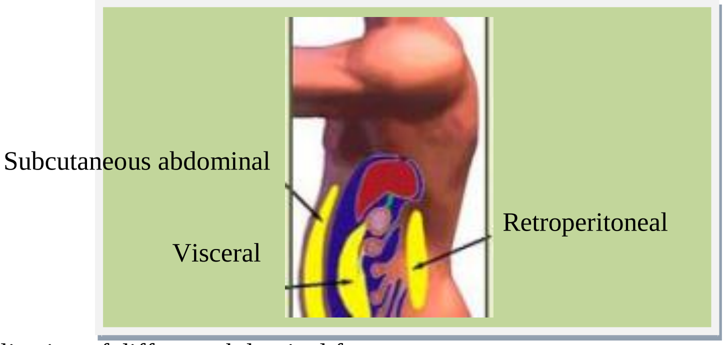
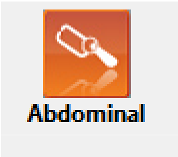


Figure 25 Localization of different abdominal fats

To measure this data, the protocol is as follows:

- Connect the cables on **the left side** of the device. For that, take other cables or disconnect the right and connect them on the other side. 

- Your subject must be lying down. Place the electrodes on the belly of the person following figure 26.

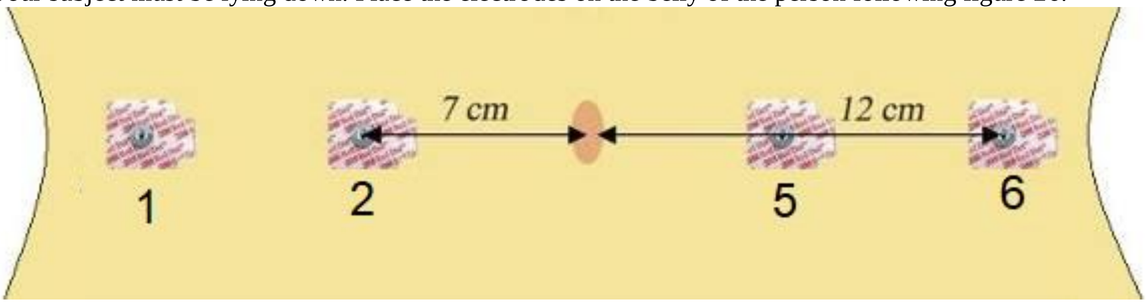


Figure 26 Electrodes for subcutaneous abdominal fat

- Then connect the cables, as shown in figure 26.
- Once in your customer sheet, open the module "abdominal fat. You can enter the size and hip circumferences (optional).
- Start the measurement, and then read the result in the history.

3.7 Automatic export

In the settings, as shown in figure 27, the Export/Backup tab allows you to:
- Make backups by clicking on "Backup" and restore them by clicking on "Restore". We advise you to store your backups on a different medium than your computer: Cloud, USB Key, External Hard Drive...
- Sort your patients: click on the "with sorting" box on the left, enter your sorting selections and then click on "all measurement of clients sorted".
- Export your data to Excel: select the measurements in the center of the window then choose Multi-Excel (one file per measurement) or General Excel File (one file for all measurements).

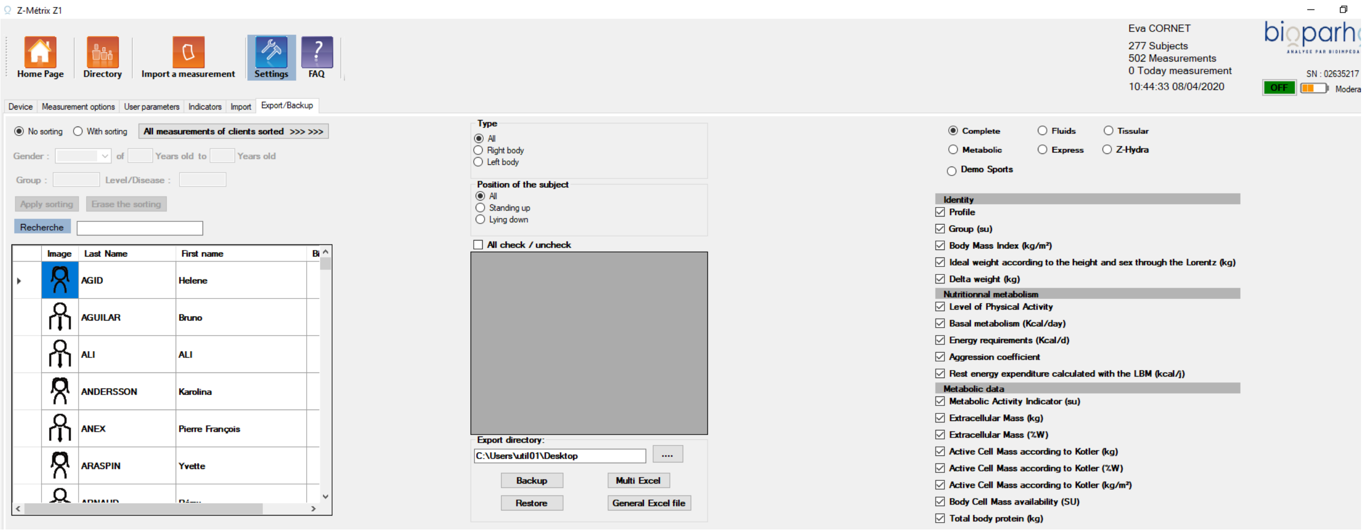


Figure 27 Automatic export

4 RECOMMENDATIONS

A number of recommendations is to take into account before and during measurement.

Indeed, some parameters may influence the results. The weight and size are important should not be overlooked. The ideal is to have the weight at the time of the measure to have the best possible accuracy.

No measure must be carried out on:

- a pregnant woman,
- a carrier of active implantable medical devices (type pacemaker, artificial heart,...)

It is advisable to:

- Not having done intense effort 24 to 72 h before measurement.
- Do not be under the influence of drugs that could change the physiological behavior (cortisone, antidepressant..).
- Avoid the influences of stress and poor sleep quality.
- Refrain from taking excessive drinks just before measurement.
- Not be in phase of digestion.
- Not taking coffee, tea or any exciting drink before measurement.
- Have an empty bladder.

The placement of the electrodes is also a milestone for the accuracy of the results.

Finally, the moment of her die in the day and also important. It is recommended for optimal follow-up that the measurements are always performed at the same time of the day.

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5 Problem Solving

There are two main problems that can occur when using software.

If the software does not launch, check that you have selected the administrator mode. Right click on the Z icon, then Properties, Compatibility tab. Select "Always run in Administrator mode". Apply and Ok. You will probably need to cut the Zx process by doing a Ctrl-Alt-Delete (the same three keys at the same time) and Process tab.

In addition, if error messages appear during your use, close the software. Open your "Base Tool" and then "Check Tables". This tool allows you to rebuild the software and solve many software bugs.

When there is doubt about the results of the measurement, a certain number of parameters must be checked:

- The electrodes are well putted (hand, wrist, leg, ankle) on the patient.
- The cables are on the right side of the device (right side of the patient connected to the right side (R side) of the device.
- The 4 electrodes are well connected to the cables in order (1 on hand, 2 on wrist, 5 on calf, and 6 on ankle), you can gently pull on the end of the cable to verify that the contact is well done.
- The cables are not damaged and limits to be disordered (pull slightly on the tips side device and patient).
- Do two measurements, one measurement of tensioned cables and one measurement of rolled up cables, give the same error? (If not, the problem comes from the measuring cable).
- The error is repeatable: take three measurements.
- The electrodes are not re-used or within six months of their expiration date, how is the contact when you peel off the electrode of the support? Do they seem hard enough to take off? If so, the gel under the electrode could dry, test a new bag.
- Measurements made on another subject are also outliers.
- The subject's skin is not very oily or very dry.
- The subject does not take any treatment (like cortisone, anti-depressants ...) or products that greatly disrupts the metabolism.

If this is the case, correct the problem and retry the measurement operation.

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