



SOZO Pro
BodyComp™ Assessment
Instructions for Use



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For EU Customers: All products at the end of their life may be returned to ImpediMed for recycling.

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1 BodyComp™ Analysis

1.1 Indications for Use

When using the SOZO Pro's Body Composition Analysis assessment module for fluid and tissue measurements, the following indication for use applies:

The SOZO Pro system may be used to estimate the following body composition parameters in humans to track clinically relevant body composition parameters over time:

- Fat Mass (FM)
- Fat-free Mass (FFM)
- Total Body Water (TBW)
- Intracellular Fluid (ICF)
- Extracellular Fluid (ECF)
- Skeletal Muscle Mass (SMM)

The following outputs are also presented:

- Body Mass Index (BMI)
- Basal Metabolic Rate (BMR; based on Mifflin – St. Jeor's algorithm) displayed in calories per day
- Protein and mineral (also known as 'dry lean mass') represents the content of a body that is not fat or fluid; calculated by subtracting total body water from fat-free mass.

Additionally, the SOZO Pro device provides a Hydration Index (Hy-Dex®) Analysis, an estimation of the patient's hydration level compared to normal population data, as an indicator of hydration level. The Hy-Dex Analysis is only intended for use with healthy individuals and should not be used to monitor or treat any disease.

1.2 Instructions for Use

Ensure that you have read and understand the instructions for use (IFU) in all sections of this IFU. Also ensure that you have read and understand the instructions for use in the main IFU, "SOZO Pro System Instructions for Use," regarding setup, installation, patient preparation, review and interpretation of Cole plots, and use of the SOZOapp and MySOZO. All warnings, contraindications and precautions apply.

2 BodyComp™ Assessment Parameters (Whole Body)

2.1 Extracellular Fluid (ECF)

All the fluid that is not contained within the cells. ECF is usually expressed as a volume (liters or pints) and as a percentage of TBW. Reference ranges for ECF are based on internal ImpediMed data.

2.2 Intracellular Fluid (ICF)

All the fluid that is contained within the cell membranes of the body. ICF is usually expressed as a volume (liters or pints) and as a percentage of TBW. Reference ranges for ICF are based on internal ImpediMed data.

2.3 Total Body Water (TBW)

All the water within a person's body, including both intracellular and extracellular fluid. This is expressed as a volume (liters or pints) or a percentage of total mass (e.g. 60% of mass is TBW). Reference ranges for TBW are based on internal ImpediMed data.

2.4 ECF & ICF Distribution

The ratio of ECF and ICF, expressed as a percentage of each of TBW (e.g. ICF 60% and ECF 40%). Changes in the ratio, particularly increases in ECF compared to previous ECF & ICF ratios, can be indicative of disease, malnutrition, inflammation, etc.

2.5 Fat Mass (FM)

The amount of mass a person has which is made up of fat. FM is typically measured in kilograms (kg) or pounds (lb) and is also expressed as a percentage of total mass (e.g. 24% body fat). Reference ranges for FM are based on modified ranges established by the American College of Sports Medicine 2017 "ACSM's Health-Related Physical Fitness Assessment".

2.6 Fat-Free Mass (FFM)

The amount of mass a person has which contains no fat. FFM includes bone, organs, body water, and the lean soft tissue elements of as muscle and connective tissue. FFM is typically measured in mass (kg or lb) or expressed as a percentage of total mass (e.g. 60% fat free mass). In the segmental measurement assessment, the lean soft tissue elements along are presented.

2.7 Protein and Minerals

The human body utilizes proteins and minerals as "building blocks". Protein and minerals can be thought of as Fat-Free Mass minus total body water, or "dry-lean mass." This is expressed as a weight (kg or lbs) and a percentage of total mass.

Note: This estimate may not factor in 1-2% of an individual's total body weight, comprised of carbohydrates.

2.8 Skeletal Muscle Mass (SMM)

This includes all muscle mass that mechanically acts on bones to create movement. It does not include cardiac or smooth muscle. Expressed as mass (kg or lbs).

2.9 Basal Metabolic Rate (BMR)

Amount of energy used by a person's body when at rest. ImpediMed uses the Mifflin-St. Jeor equation to calculate BMR. Expressed in calories per day.

2.10 Phase Angle

The resistance/reactance of a person's cell membrane at a 50 kHz frequency. Plotted as a vector, and is presented on a scale from 0-10 and is expressed as a degree. (e.g. 8.5°). Reference ranges for Phase Angle were established based on data presented in Bosy-Westphal (2006)¹.

2.11 Reference Ranges

When reviewing patient data, the following measurement outputs provide additional reference information against which the current results can be compared:

- Total Body Water, expressed as a %
- Extracellular Fluid, expressed as a %
- Intracellular Fluid, expressed as a %
- Fat Mass, expressed as a %
- Hy-Dex
- Skeletal Muscle Mass
- BMI
- Phase Angle

2.12 Availability of Assessment Type

Only Assessment Types licensed to your facility are available for you to review. For more about licensing of Assessment Types, see the main IFU, "SOZO Pro Instructions for Use." The available Assessment Types for a given user are displayed in the SOZOapp and MySOZO. Licensed Assessments are displayed in the SOZOapp and MySOZO.

2.13 Choosing The Proper Assessment

It is recommended that only the most appropriate and relevant assessment is selected for each patient, taking into consideration patient diagnosis and the individual needs of the patient as determined by their health care provider.

2.14 Recommended Measurement Frequency

Measurement frequency should be based on clinical evaluation of the patient's monitoring needs. Daily, weekly, or monthly readings may be appropriate using your best clinical judgment.

¹ Bosy-Westphal A *et al*, "Patterns of bioelectrical impedance vector distribution by body mass index and age: implications for body-composition analysis" *Am J Clin Nutr* 2005;82:1358.

3 Segmental BodyComp™ Assessment Parameters (Limbs)

If your facility has licensed the SOZO segmental body composition analysis module, and the patient has been selected to have segmental results presented, a subset of SOZO Body Composition outputs can also be tracked for individual limbs in the same patient.

The following body composition outputs are presented for segmental analysis:

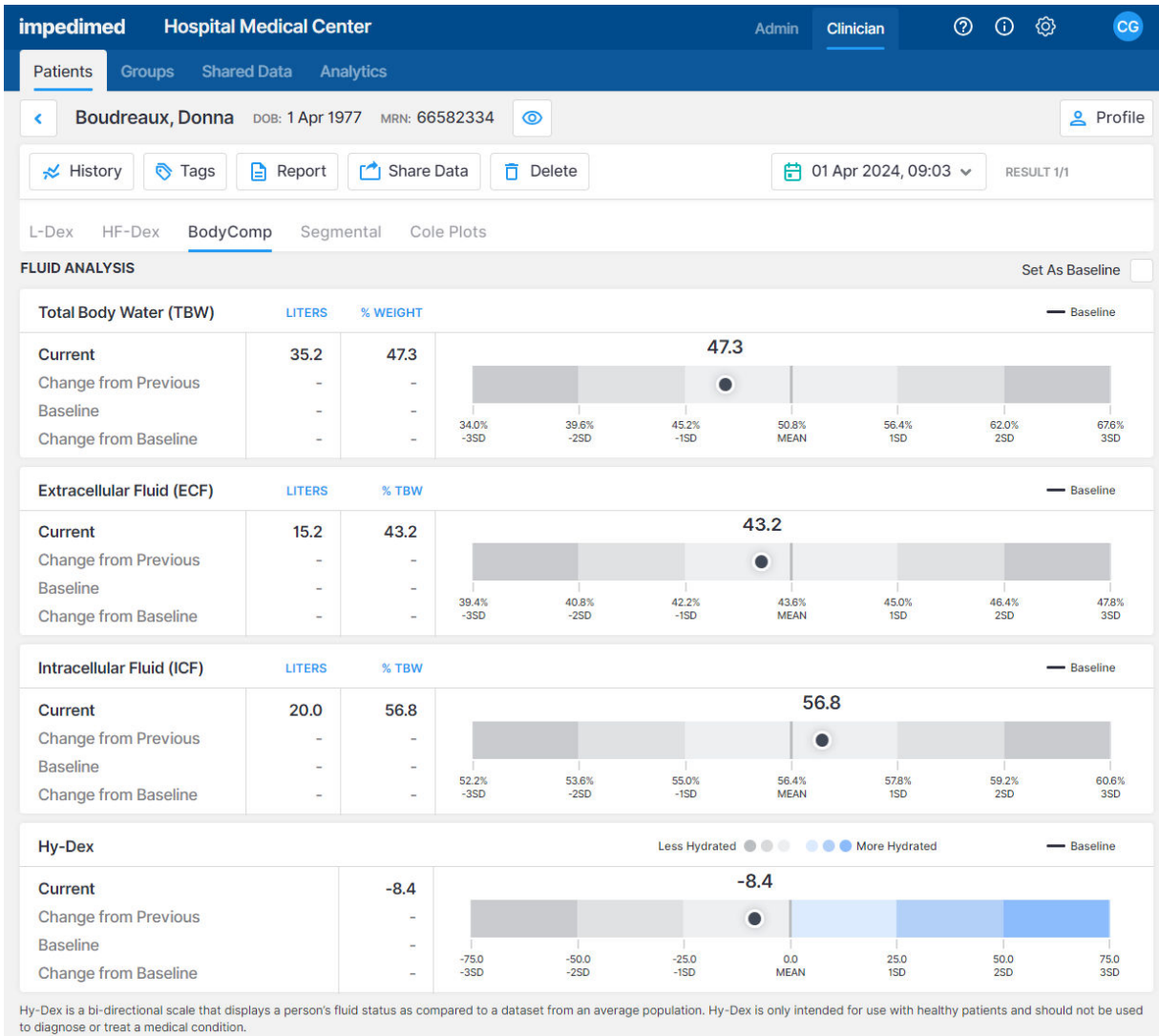
- Total Body Water (TBW)
- Extracellular Fluid (ECF)
- Intracellular Fluid (ICF)
- ECF and ICF distribution (expressed as a percentage of total body water for the limb)
- Skeletal Muscle Mass (SMM)
- Lean Soft Tissue (a subset of Fat-Free Mass)
- Phase Angle

Note: reference ranges are not available for individual body segments.

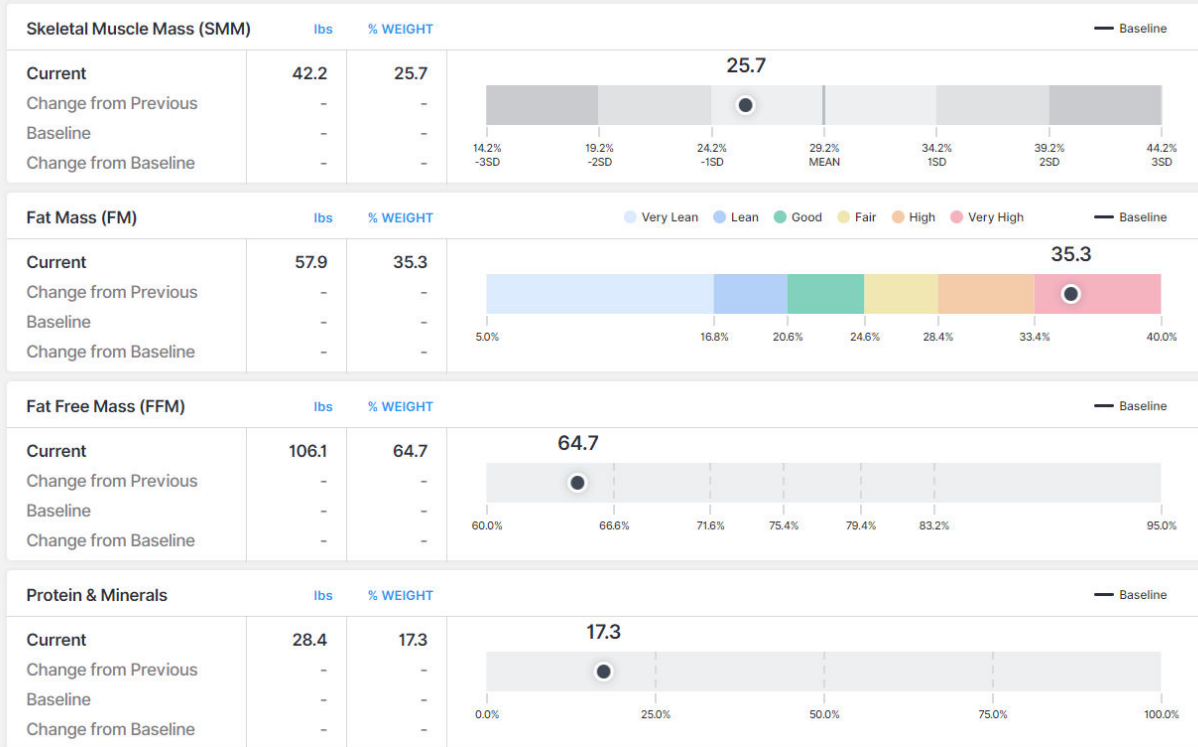
4 BodyComp™ Results

At the conclusion of a measurement, the Body Composition Analysis module will present a screen containing a wide range of body composition information in your preferred units of measure (defined in the SOZOapp settings section). For patients who are being assessed for other clinical conditions, the body composition measurements may be utilized to provide additional data and guidance to the clinician.

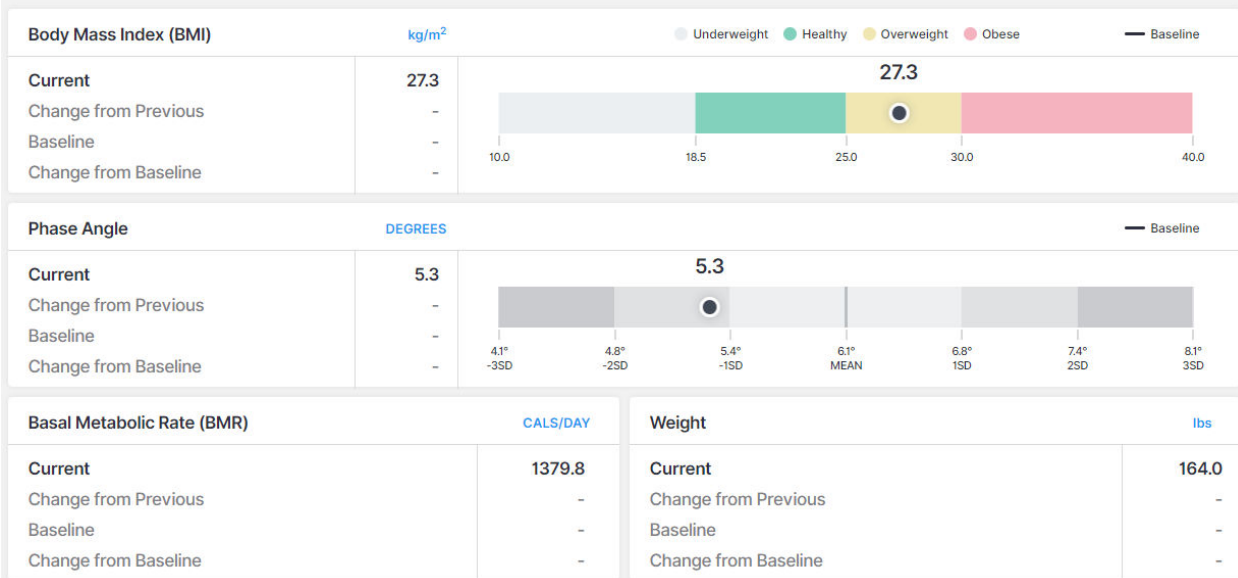
4.1 Example of Whole BodyComp Results



TISSUE ANALYSIS



METABOLIC REPORT



Note: all SOZO Pro volume results are calculated using full precision of the impedance information and then rounded to one decimal place for display. As such, when results are small, minor differences between absolute numbers and percentages may be observed.

4.2 Historical Results

Results and patient history of Body Composition Analysis may also be viewed in MySOZO. For more about results and patient history, see the main IFU, “SOZO Pro Instructions for Use.”

4.3 Example of Segmental BodyComp Results

impedimed Hospital Medical Center Admin Clinician

Patients Groups Shared Data Analytics

Brigham, Kaycee DOB: 16 Oct 1964 MRN: 1089562 Profile

History Tags 5 Report Share Data Delete 27 Mar 2023, 08:04 RESULT 16/16

L-Dex HF-Dex BodyComp Segmental Cole Plots

Set As Baseline (Left Arm) Set As Baseline (Right Arm)

Left Arm	CURRENT	CHANGE FROM BASELINE	Right Arm	CURRENT	CHANGE FROM BASELINE
Total Body Water	1.6(L)	0.0(L)	Total Body Water	1.9(L)	-0.2(L)
Extracellular Fluid	0.8(L), 50.0(%TBW)	0.0(L)	Extracellular Fluid	0.9(L), 47.4(%TBW)	0.1(L)
Intracellular Fluid	0.8(L), 50.0(%TBW)	0.0(L)	Intracellular Fluid	1.0(L), 52.6(%TBW)	-0.3(L)
Skeletal Muscle Mass	3.4(lbs)	-0.1(lbs)	Skeletal Muscle Mass	3.6(lbs)	-0.3(lbs)
Lean Soft Tissue	4.6(lbs)	0.1(lbs)	Lean Soft Tissue	5.5(lbs)	-0.5(lbs)
Phase Angle	6.5°	2.3°	Phase Angle	6.6°	1.4°

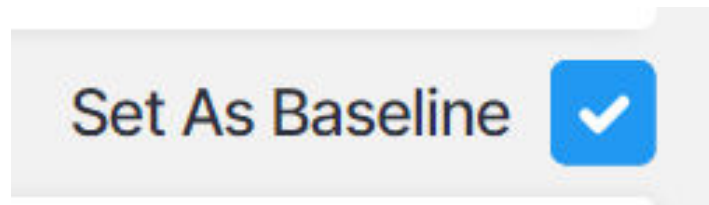
Set As Baseline (Left Leg) Set As Baseline (Right Leg)

Left Leg	CURRENT	CHANGE FROM BASELINE	Right Leg	CURRENT	CHANGE FROM BASELINE
Total Body Water	7.7(L)	0.7(L)	Total Body Water	6.7(L)	-1.5(L)
Extracellular Fluid	3.5(L), 45.5(%TBW)	-0.2(L)	Extracellular Fluid	3.1(L), 46.3(%TBW)	-0.4(L)
Intracellular Fluid	4.2(L), 54.5(%TBW)	0.9(L)	Intracellular Fluid	3.6(L), 53.7(%TBW)	-1.1(L)
Skeletal Muscle Mass	13.0(lbs)	0.5(lbs)	Skeletal Muscle Mass	12.3(lbs)	-1.9(lbs)
Lean Soft Tissue	22.1(lbs)	2.1(lbs)	Lean Soft Tissue	19.1(lbs)	-4.5(lbs)
Phase Angle	6.9°	2.8°	Phase Angle	7.4°	2.6°

The same results and historical measurements for the patient’s body composition results, including segmental results, may also be viewed in MySOZO. For more information on accessing MySOZO, see the main IFU, “SOZO Pro Instructions for Use.”

4.4 Setting a Baseline

Selection of a baseline – a “normal score” for an individual patient – is the optimal way to track changes over time. To set a baseline, select the most appropriate measurement by date from the patient’s dashboard, and tap the button next to ‘set as baseline’:



For segmental measurements, each limb may have its own baseline set.

Please note that if an incorrect measurement is set as baseline, simply select the correct measurement and set as baseline. For segmental measurements, separate baselines can be made for each limb.

For a given body composition output, an optimal baseline is typically when the patient, in your estimation, is in suitable good health. It may take some time to establish an appropriate baseline measurement for your patient.