BodyComp™ Assessment
Instructions for Use

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For patent(s) and/or patent application(s) see: https://www.impedimed.com/patents/

1 BodyComp™ Analysis

1.1 Indications for Use

When using the SOZO device's BodyComp Analysis assessment module for fluid and tissue measurements, the following indications for use applies:

The SOZO 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 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 all sections of this Instructions for Use (IFU). Also ensure that you have read and understand the instructions for use in the main SOZO System Instructions for Use (LBL-525), 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 each of TBW (e.g., ICF 60% and ECF 40%). Changes in the ratio, particularly increases in ECF compared to previous ECF & ECF ratios, can be indicative of disease, malnutrition, inflammation, etc.

2.5 Fat Mass (FM)

The amount of mass a person has that 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 that 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 lb) 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 lb). Reference ranges for SMM were established based on data presented in Janssen (2000)[1].

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 arctangent of reactance divided by resistance at 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)[2].

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 Assessments Types, see the main SOZO System Instructions for Use (LBL-525). The available Assessment Types for a given user is 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.

[1] Janssen I *et al*, "Skeletal muscle mass and distribution in 468 men and women aged 18-88 yr." J Appl Physiol 89:81-88.
[2] 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.

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.

3 Segmental BodyComp™ Assessment Parameters (Limbs)

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

The following body composition outputs are presented for segmental analysis:

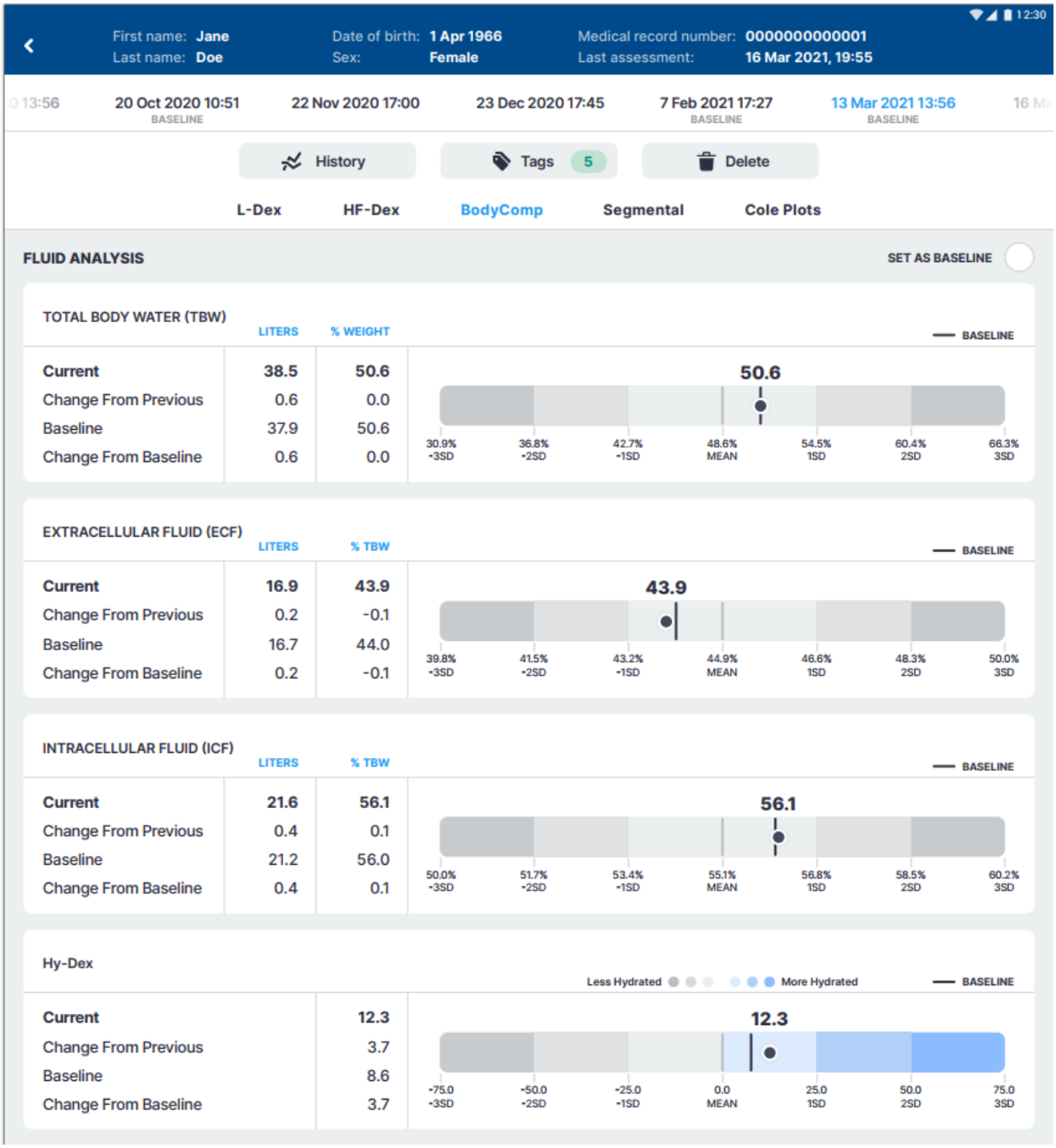
- Total Body Water (TBW)
- Extracellular Fluid (ECF)
- Intracellular Fluid (ICF)
- ECF and ICF distribution (expressed as a percentage of total body water for the limb)
- Skeletal Muscle Mass (SMM)
- Lean Soft Tissue (a subset of Fat-Free Mass)
- Phase Angle

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

4 BodyComp™ Results

At the conclusion of a measurement, the BodyComp assessment 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.

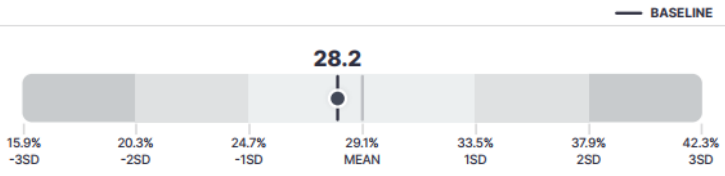
4.1 Example of Whole BodyComp™ Results



TISSUE ANALYSIS

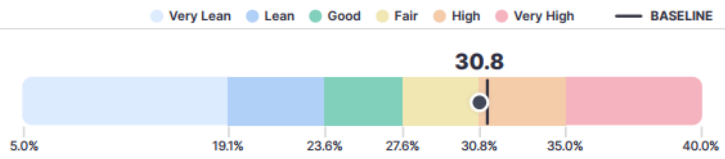
SKELETAL MUSCLE MASS (SMM)

	kg	% WEIGHT
Current	**21.4**	**28.2**
Change From Previous	0.3	0.0
Baseline	21.1	28.2
Change From Baseline	0.3	0.0



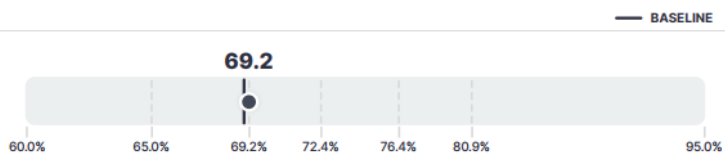
FAT MASS (FM)

	kg	% WEIGHT
Current	**23.5**	**30.8**
Change From Previous	0.4	-0.1
Baseline	23.1	30.9
Change From Baseline	0.4	-0.1



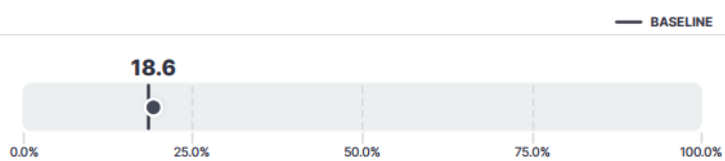
FAT FREE MASS (FFM)

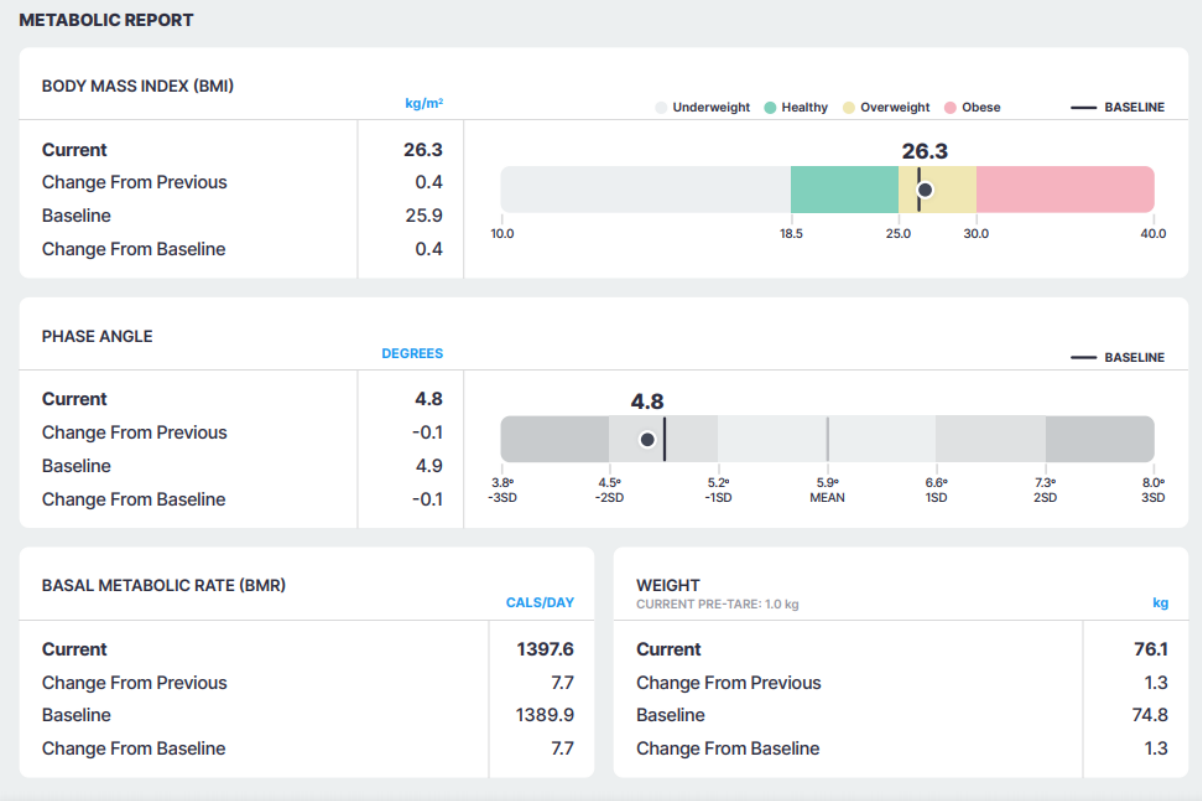
	kg	% WEIGHT
Current	**52.6**	**69.2**
Change From Previous	0.9	0.1
Baseline	51.7	69.1
Change From Baseline	0.9	0.1



PROTEIN & MINERALS

	kg	% WEIGHT
Current	**14.1**	**18.6**
Change From Previous	0.3	0.1
Baseline	13.9	18.5
Change From Baseline	0.2	0.1



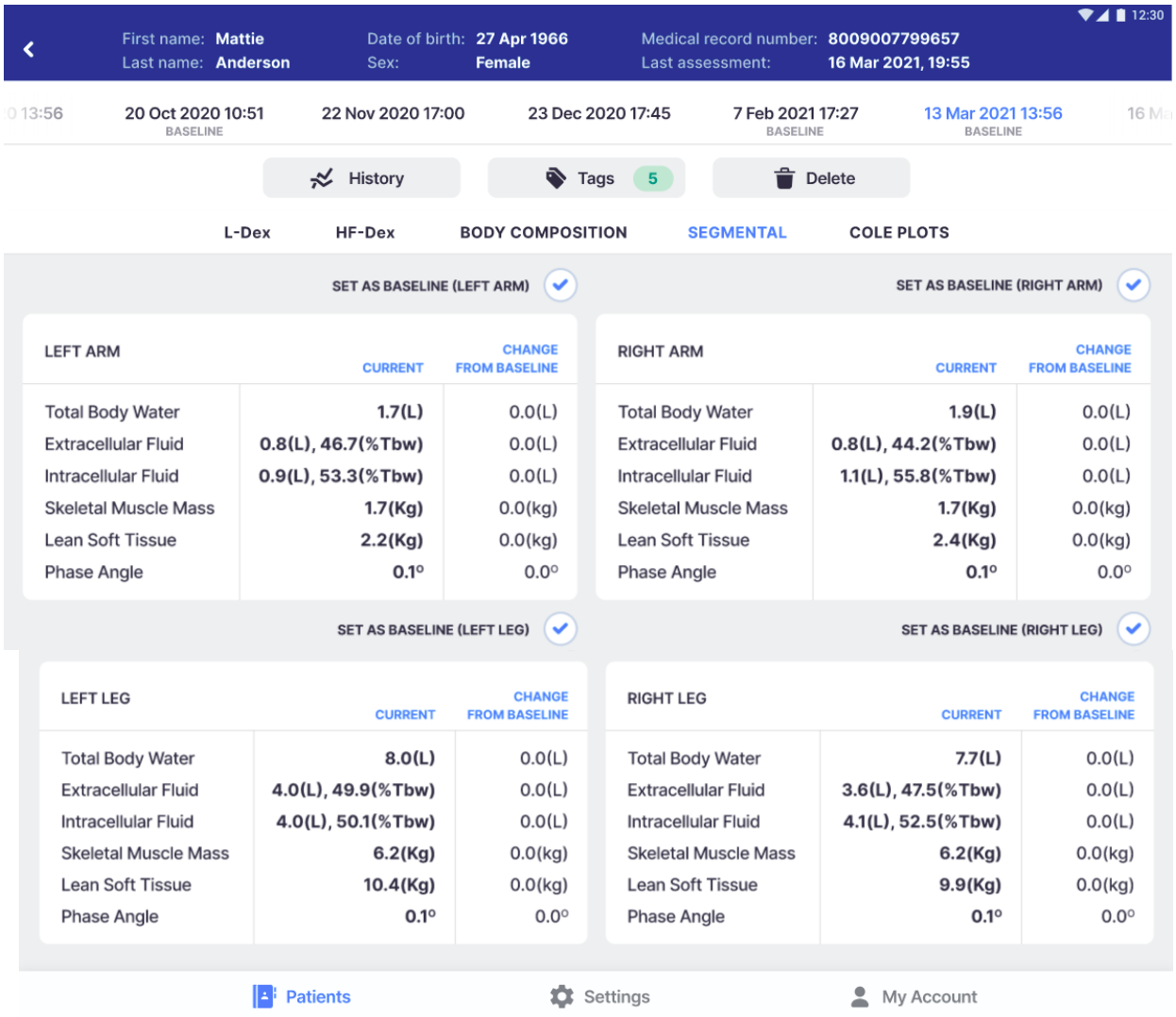


Note: all SOZO volume results are calculated using full precision of the impedance information and then rounded to one decimal place for display. As such, when results are small, minor differences between absolute numbers and percentages may be observed.

4.2 Historical Results

Results and patient history of the BodyComp assessment may also be viewed in MySOZO. For more about results and patient history, see the main SOZO System Instructions for Use (LBL-525).

4.3 Example of Segmental BodyComp™ Results



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 SOZO System Instructions for Use (LBL-525).

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 baseline is selected, simply select the correct measurement and baseline. For segmental measurements, separate baselines can be made for each limb.

For a given body composition output, an optimal baseline is typically taken 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.