



Fluid and Tissue Analysis Assessment Instructions for Use



ImpediMed Limited

ABN 65 089 705 144

Unit 1

50 Parker Court

Pinkenba Qld 4008

Australia

Distributed in the United States by:

ImpediMed Inc.

5900 Pasteur Court, Suite 125

Carlsbad, CA 92008

(877) 247-0111 option 4

tsu@impedimed.com

Phone: + 61 7 3860 3700

Fax: + 61 7 3260 1225

Email: enquiries@impedimed.com

Website: <http://www.impedimed.com/>

EC	REP
----	-----

For assistance with product set up please review the help videos at <https://www.impedimed.com>. For other assistance, or to report product issues, please contact ImpediMed U.S. by email at tsu@impedimed.com or by phone at: + 877 247 0111 option 4.

MediMark Europe Sarl

11 rue Emile ZOLA,

B.P. 2332, 38033 Grenoble Cedex 2

France



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

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

Fluid and Tissue Analysis for Body Composition Measurements

Indications for Use

When using the SOZO device's Fluid and Tissue Analysis assessment modules for body composition 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) 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 weight from fat-free mass weight.

The Tissue Analysis module will also present scores for a patient's 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.

Instructions for Use

Ensure that you have read and understand the instructions for use in all sections of this User Guide. Also ensure that you have read and understand the instructions for use in the main User Guide, "SOZO 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.

Choosing 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.

Fluid Analysis Module Results

At the conclusion of a measurement session, the SOZOapp will present a screen with analysis of the fluid status of the patient. It will break down the patient's:

- Total Body Water (TBW)
- Extracellular Fluid (ECF)
- Intracellular Fluid (ICF)
- TBW as a percentage of weight
- ECF and ICF distribution (expressed as a percentage of total body water)

Tissue Analysis Module Results

At the conclusion of a SOZO device measurement, the SOZOapp displays results of the Tissue Analysis assessment. The Tissue Analysis assessment contains graphs and a wide range of body composition information in preferred units of measure.¹ The following parameters are displayed in the Tissue Analysis assessment:

Tissue Analysis

- Fat Free Mass (FFM)
- Fat Mass (FM)
- Skeletal Muscle Mass (SMM)
- Weight

Other

- Basal Metabolic Rate (BMR)
- Phase Angle (Phi)
- Body Mass Index (BMI)
- Weight

Hy-Dex®

¹ The units of measurement for weight, height and water volume may be adjusted to the user's preference in the SOZOapp system-wide settings. The user may set the measurement standard as kg or lbs, centimeters or inches, and liters or pints. For more about adjusting units of measure, see the main User Guide, "SOZO System Instructions for Use."

Example of Fluid Analysis Results

Results
🗑️ Delete

Last Name Smith	First Name John	Date of Birth 28 Jun 1966	
Sex M	MRN 2736663788993	Last SOZO Assessment 25 Jul 2017 14:11	Assessment Date 28 Jun 2017 10:35

L-Dex
Fluid Analysis
Tissue Analysis
Cole Plots

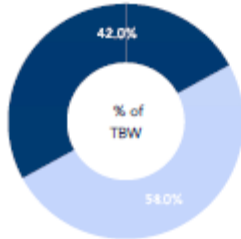
Total Body Water (TBW)

Total Body Water (TBW)	51.1 Liters	56.2% of Weight
------------------------	-------------	-----------------

Fluid Distribution

Extracellular Fluid (ECF)	22.1 Liters
Intracellular Fluid (ICF)	29.0 Liters

TBW



● Extracellular Fluid (ECF):	42.0%
● Intracellular Fluid (ICF):	58.0%

Results and historical measurements of the patient may also be viewed in MySOZO. For more information about Fluid Analysis results, see the main User Guide, “SOZO System Instructions for Use.”

Example of Tissue Analysis Results Screen

Results
🗑️ Delete

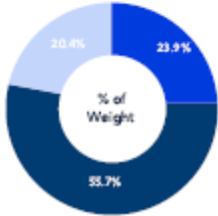
Last Name Smith	First Name John	Date of Birth 28 Jun 1966	
Sex M	MRN 2736663788993	Last SOZO Assessment 25 Jul 2017 14:11	Assessment Date 28 Jun 2017 10:35

L-Dex
Fluid Analysis
Tissue Analysis
Cole Plots

Tissue Analysis

Fat Free Mass (FFM)	70.8 kg	76.1% of Weight
Fat Mass (FM)	22.2 kg	23.9% of Weight
Skeletal Muscle Mass (SMM)	33.1 kg	35.6% of Weight

Weight




- Total Body Water (TBW): 51.8 Liters
- Protein & Mineral: 19.0 kg
- Fat Mass (FM): 34.6 kg

Other

Basal Metabolic Rate (BMR)	1465.3 cal/day
Phase Angle	6.7°
Body Mass Index (BMI)	28.1 kg/m ²
Weight	91.0 kg

Hy-Dex Analysis

Less Hydrated
More Hydrated



Current	31.4
Change from Previous	-
Change from Baseline	-

Hy-Dex is a bi-directional scale that displays a person's fluid status as compared to a dataset from an average population. Hy-Dex is only intended for use with healthy patients and should not be used to diagnose or treat a medical condition.

Results and patient history of Tissue Analysis may also be viewed in MySOZO. For more about results and patient history, see the main User Guide, “SOZO System Instructions for Use.”

Application: General Fluid and Tissue Analysis

Assessment

At the conclusion of a measurement, the Tissue and Fluid Analysis modules 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.

Extracellular Fluid (ECF)

All the fluid that is not contained within the cells. ECF is usually expressed as a volume (liters or pints).

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).

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).

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 & ECF ratio's, can be indicative of disease, malnutrition, inflammation, etc.

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).

Fat Free Mass (FFM)

The amount of mass a person has that contains no fat. FFM includes bone, muscle, connective tissue, organs, and body water. FFM is typically measured in mass (kg or lb) or expressed as a percentage of total mass (e.g. 60% fat free mass).

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.

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). NOTE: the SOZO device does not directly measure SMM, and, that the SMM value calculated is based on an algorithm developed and published in Janssen (2010)².

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.

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°).

² Janssen I, Heymsfield S, Baumgartner R, Ross R 2000. "Estimation of skeletal muscle mass by bioelectrical impedance analysis." *J. Appl Physiol.* 89(2):465-71

Reference Ranges

The following reference ranges may be used as a reference point when assessing a patient's body composition. These data are extracted from Centers for Disease Control and Prevention. National Health and Nutrition Examination Survey III (1988-1994), available at <https://www.cdc.gov/nchs/nhanes/nhanes3.htm>

The ranges are statistical averages of average Americans and are provided for reference only.

Female Reference Ranges (1 standard deviation from mean)

N	1448	1511	1632	1248	907	1031	817	477	44
Age	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-99
Weight (lb)	98.2 to 164.2	110.8 to 180.8	118.1 to 203.7	125.4 to 203.8	126.7 to 205.7	123.5 to 192.5	118 to 182.8	110.4 to 162	100.1 to 136.7
Phase Angle	6.7 to 8.3	7 to 8.6	6.8 to 8.6	6.8 to 8.4	6.2 to 8	5.8 to 7.6	5.2 to 7.2	4.7 to 6.5	4.3 to 5.7
TBW (liters)	25.5 to 34.5	26.9 to 36.5	28.1 to 39.1	28.4 to 39.2	28.4 to 39.2	27.6 to 37.4	26.9 to 36.7	25.7 to 33.9	24.5 to 31.5
TBW (%)	45.3 to 57.9	43.2 to 54.8	41.2 to 53.4	41.1 to 51.3	40.6 to 51	41.2 to 51	42.1 to 52.7	43.7 to 54.1	46.8 to 58.4
ICF (liters)	14.5 to 18.3	15.1 to 19.1	15.6 to 20.2	15.7 to 20.1	15.6 to 20	15 to 19.2	14.7 to 18.7	14 to 17.4	13.3 to 16.3
ICF (% of TBW)	52.8 to 57	52.4 to 56.2	51.5 to 55.5	51.3 to 55.1	50.8 to 54.8	50.9 to 54.9	50.7 to 54.7	50.9 to 54.9	50.9 to 55.1
ECF (liters)	10.9 to 16.3	11.8 to 17.4	12.4 to 19	12.7 to 19.1	12.9 to 19.3	12.5 to 18.3	12.2 to 18	11.6 to 16.6	11.1 to 15.3
ECF (% of TBW)	43 to 47.2	43.8 to 47.6	44.5 to 48.5	44.9 to 48.7	45.2 to 49.2	45.1 to 49.1	45.3 to 49.3	45.1 to 49.1	44.9 to 49.1
Fat Mass (lb)	20.4 to 64.2	28.2 to 75.4	32.8 to 90.4	38.8 to 90.4	40.3 to 92.3	39.6 to 84.8	35.8 to 78	31.9 to 65.9	23.1 to 50.1
Fat Mass (%)	22.4 to 38.8	26.4 to 41.8	28.6 to 44.6	31.2 to 44.8	31.6 to 45.6	31.7 to 44.9	29.9 to 43.7	28.1 to 41.9	22.7 to 37.5
Fat Free Mass (lb)	75.6 to 102.2	80.1 to 107.9	83 to 115.8	84.3 to 115.9	84.2 to 115.6	81.5 to 110.1	79.3 to 107.5	75.5 to 99.1	72.6 to 91
Fat Free Mass (%)	61.2 to 77.6	58.2 to 73.6	55.4 to 71.4	55.2 to 68.8	54.4 to 68.4	55.1 to 68.3	56.3 to 70.1	58.1 to 71.9	62.5 to 77.3
BMR (cal)	1296.3 to 1591.1	1308.7 to 1621.9	1295 to 1674.4	1282.5 to 1631.5	1236.8 to 1589	1172 to 1482	1098.4 to 1393.2	1018.3 to 1255.9	941 to 1106.8
BMI	17.8 to 28.2	19.5 to 31.1	20.7 to 35.1	22 to 35.2	22.5 to 35.7	22.5 to 34.3	22 to 33	21.2 to 30.2	19.3 to 26.3

Male Reference Ranges (1 standard deviation from mean)

N	1379	1553	1383	1155	792	1055	724	474	32
Age	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-99
Weight (lb)	104.1 to 179.5	132.6 to 208.6	142.4 to 217.6	147.6 to 221.2	149.5 to 221.5	147.1 to 213.3	139.7 to 202.1	133.1 to 187.1	116.8 to 170.2
Phase Angle	7 to 9	7.8 to 9.6	7.6 to 9.4	7.2 to 9.2	6.7 to 8.5	6.2 to 8	5.4 to 7.4	4.8 to 6.6	4.2 to 6.6
TBW (liters)	30 to 46.2	36.3 to 50.9	37.9 to 52.9	38.6 to 53.4	38.8 to 53.4	37.6 to 51.6	36.2 to 49.6	34.6 to 46.6	31.5 to
TBW (%)	54.3 to 66.1	52 to 62.2	51.4 to 61	50.9 to 60.1	50.7 to 59.9	50.4 to 59.6	51.1 to 60.3	51.5 to 61.3	52.1 to
ICF (liters)	18.8 to 27	22.1 to 29.5	22.9 to 30.5	23.2 to 30.6	23.2 to 30.4	22.4 to 29.4	21.4 to 28	20.4 to 26.2	18.6 to
ICF (% of TBW)	58 to 62.8	57.9 to 60.9	57.6 to 60.4	57.2 to 60.2	56.7 to 59.9	56.6 to 59.8	56 to 59.8	55.6 to 59.4	55.7 to
ECF (liters)	11.3 to 19.3	14.2 to 21.4	15 to 22.4	15.4 to 22.8	15.6 to 23	15.1 to 22.3	14.6 to 21.6	14.1 to 20.5	12.8 to 19
ECF (% of TBW)	37.2 to 42	39.1 to 42.1	39.6 to 42.4	39.8 to 42.8	40.1 to 43.3	40.2 to 43.4	40.2 to 44	40.6 to 44.4	40.1 to
Fat Mass (lb)	11 to 47.4	21.1 to 61.5	26 to 64.4	29.4 to 66.6	30.4 to 67	31.2 to 65	28.6 to 59.6	25.4 to 54.4	18.4 to
Fat Mass (%)	12 to 26.8	16.8 to 29.8	19.2 to 30.6	19.6 to 31.2	19.8 to 31.4	20.3 to 31.9	19.5 to 31.1	18.3 to 30.5	15 to 29.4
Fat Free Mass (lb)	88.6 to 136.6	107.3 to	112 to 157.6	114 to 158.8	115 to 158.6	111.3 to	106.8 to	102.5 to	92.9 to
Fat Free Mass (%)	73.2 to 88	70.2 to 83.2	69.4 to 81.8	68.8 to 80.4	68.6 to 80.2	68.1 to 79.7	68.9 to 80.5	69.5 to 81.7	70.6 to 85
BMR (cal)	1427.9 to 1958.3	1580.6 to 2093.2	1580.2 to 2087.6	1543.4 to 2045	1486 to 1973.4	1391.9 to 1847.1	1275.6 to 1708.2	1162 to 1543.2	998.1 to
BMI	17.7 to 27.1	20.6 to 30.4	21.6 to 31.6	22.6 to 32.4	22.8 to 32.4	23 to 31.8	22.2 to 30.6	21.4 to 29	19.7 to

Recommended Measurement Frequency

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