



HF-Dex™ Assessment Instructions for Use



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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.

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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/>

1 Safety Instructions

These symbols are provided to guide you in the use of this product safely and correctly, and to prevent risk and injury to you and others. For more safety instructions and other symbols, see the main SOZO System Instructions for Use (LBL-525).

Symbol	Definition
	WARNING! Indicates matters in which bodily harm or material damage or incorrect measurements may arise as a result of incorrect handling.
	Follow instructions for use.
	Note

2 HF-Dex™ for Heart Failure

2.1 Indications for Use

The SOZO® HF-Dex assessment is intended for adult patients living with heart failure.

This device is intended for use, under the direction of a physician, for the noninvasive monitoring of patients with fluid management problems suffering from heart failure. Data from the device should be considered in conjunction with other clinical data.

2.2 Instructions For Use

Ensure that you have read and understand all sections of this Instructions for Use (IFU) for setup, installation and use of the SOZOapp, and also ensure that you have read and understand the instructions for use for setup, installation and use of MySOZO and the SOZOapp in all sections of the main SOZO System IFU (LBL-525). All warnings, contraindications and precautions apply. In addition, consider the following when using SOZO to take HF-Dex measurements on a patient:

For a patient who cannot effectively separate their inner thighs, it may be necessary to place insulating material, such as dry clothes, between the patient's legs. Ensure also that the patient's upper arms and elbows are not in contact with their torso.

In order to use the HF-Dex assessment, the facility will require a license. The patient will additionally need to have the HF-Dex assessment selected in their profile. After doing so, HF-Dex results will be presented after every measurement.



Measurement quality is important. Specifically, the patient's Right Whole Body measurement will need to be of a medium or high quality. If a patient's Right Whole Body Cole plot was assessed to be low quality ("red"), the measurement should be retaken. If a low quality measurement is accepted, HF-Dex outputs will not be presented. The error message above will instead be displayed.



This result cannot be provided due to low measurement quality "red". For this measurement to be shown, the Right Whole Body Cole Plot (found in the Cole plot review screen after the measurement) must be medium quality "yellow" or high quality "green".

3 HF-Dex™ Assessments

3.1 HF-Dex™ Score

The HF-Dex score is a tool to assist in the clinical assessment of fluid status on a patient with heart failure by a medical provider. The results screen will display the patient's HF-Dex score on a scale, as well as other fluid analysis outputs. The HF-Dex score is the patient's ECF/TBW %, compared to clinical data in the following manner:

Light Blue range: HF-Dex values in the light blue reference range are consistent with healthy individuals who do not have heart failure¹.

Medium Blue and Dark Blue ranges: Patients whose HF-Dex score falls into the medium blue and dark blue ranges may have raised scores that are above the reference range for generally healthy individuals with normal fluid levels, and may require additional clinical investigation.

Gray range: HF-Dex values in the gray range may indicate a fluid imbalance for other causes (such as dehydration) or potential issues with measurement accuracy, and requires additional investigation.

Additional information presented includes the patient's baseline HF-Dex score, change vs. baseline, and change from previous HF-Dex score.

3.2 Other Fluid Outputs

The results screen will also present the following information from the measurement:

- Total Body Water (TBW)
- Extracellular Fluid (ECF)
- Intracellular Fluid (ICF)
- Weight

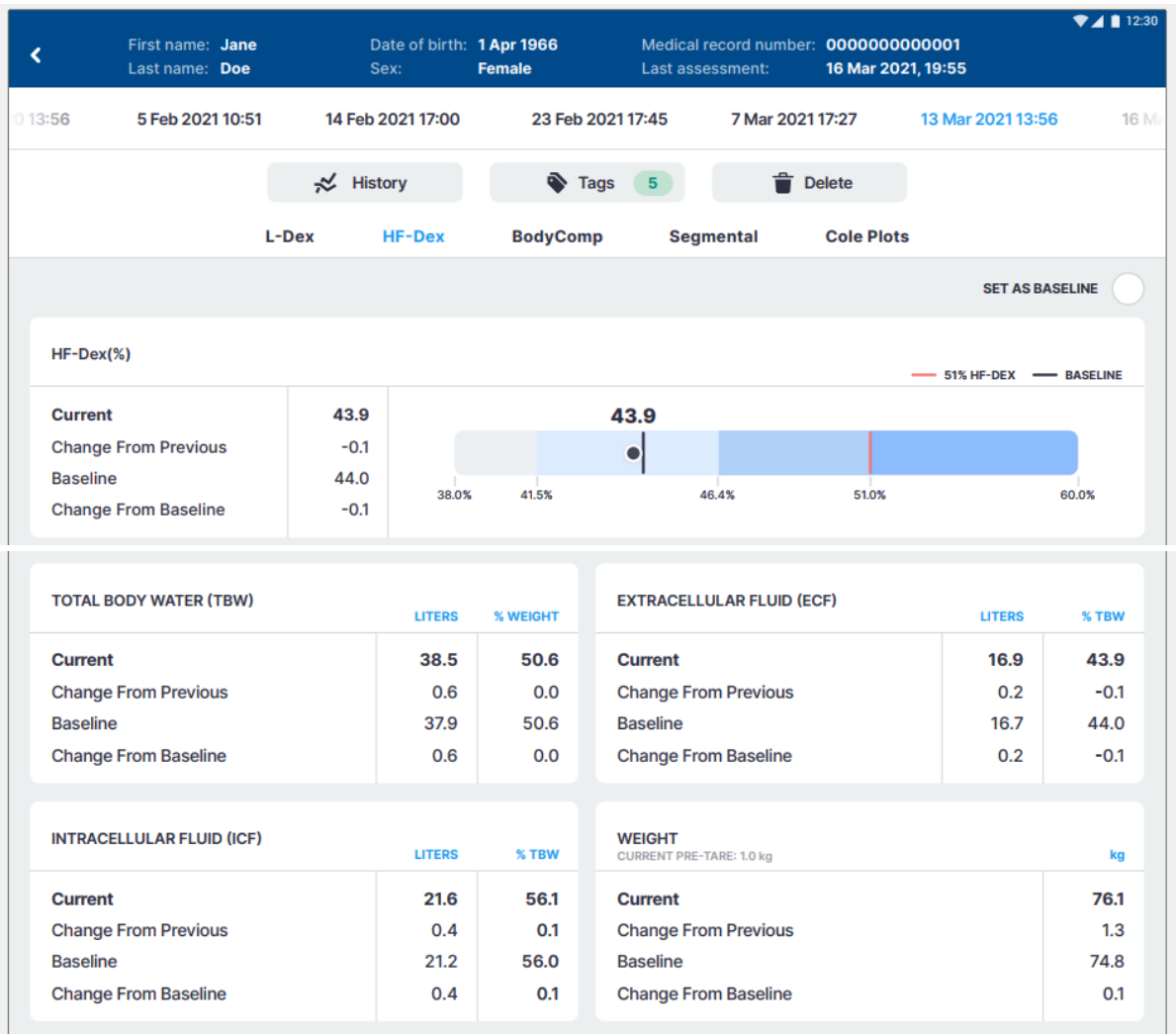
TBW is presented in objective volume and expressed as a % of patient weight at time of measurement. ECF and ICF are presented in objective volumes and expressed as a % of TBW at time of measurement. The software will calculate and present changes from the previous measurement. If a baseline has been selected for the patient, the software will also calculate and present the baseline and change from baseline in the current measurement.

3.3 Recommended Measurement Frequency

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

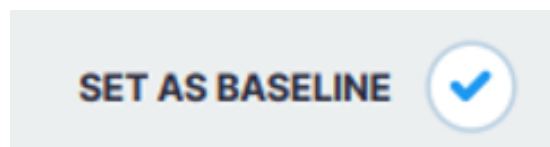
¹ US Department of Health and Human Services. National center for health statistics. The Third National Health and Nutrition Examination Survey (NHANES III, 1988 – 1994).:Centers for Disease Control and Prevention: Washington, DC; 1996.

4 HF-Dex™ Measurement Results



4.1 Setting the Baseline

Selection of a baseline – a “normal HF-Dex 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’:



Please note that if an incorrect baseline is selected, simply select the correct measurement and baseline.

For a HF-Dex score, an optimal baseline is typically taken when the patient, in your estimation, is appropriately euvolemic. It may take some time to establish an appropriate baseline measurement for your patient.

4.2 Historical Results

The results screen will also display the patient's HF-Dex, TBW, ICF, ECF scores as well as weight on history graphs. The HF-Dex history will also overlay the same ranges (Blue-Gray) used in the HF-Dex measurement result.

All prior measurements with the HF-Dex assessment may be viewed in MySOZO as well. For more information about accessing MySOZO, see the main SOZO System Instructions for Use (LBL-525).

4.3 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 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.

4.4 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.