



HF-Dex™ Assessment Module 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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HF-Dex Assessment

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 User Guide, “SOZO System Instructions for Use.”

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

HF-Dex for Heart Failure

Indications for Use

The SOZO® HF-Dex module 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.

Instructions For Use

Ensure that you have read and understand the instructions for use in all sections of this User Guide 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 User Guide, LBL-525, "SOZO System Instructions for Use." 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 module, the facility will require a license for the module. The patient will additionally need to have the module selected in their profile. After doing so, HF-Dex module 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 following error message 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".

HF-Dex Assessment Results

HF-Dex Scores

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, with measurements displayed over time from oldest (left) to newest (right). 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 failure.

Medium Blue range: Patients whose HF-Dex score falls into the medium blue range have a raised score that is above the reference range for healthy individuals who do not have heart failure. Elevated scores can be caused by many factors that are not necessarily indicators of heart failure or decompensation.

Dark Blue range: Patients whose HF-Dex score falls into the dark blue range have a higher score that compares to levels in a decompensated heart failure population. Clinical data shows that patients with elevated scores should be carefully monitored. Decisions regarding the patient’s management should be made in conjunction with other clinical data.

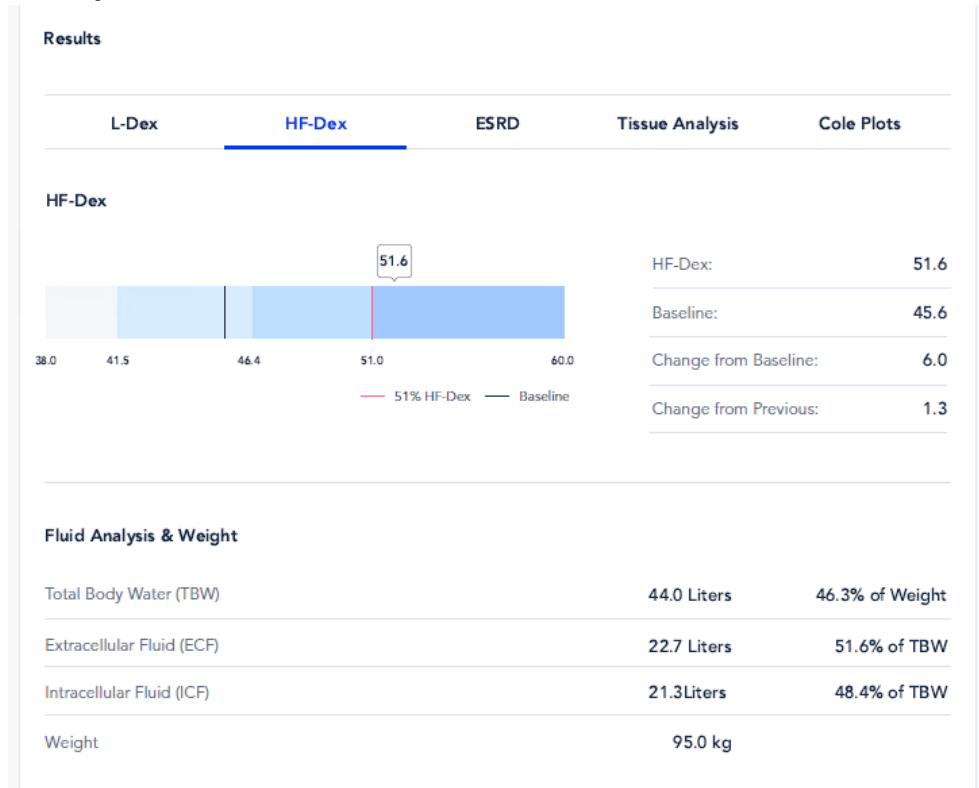
Grey range: HF-Dex values in the grey range may indicate a fluid imbalance for other causes (such as dehydration) or potential issues with measurement accuracy, and requires additional investigation.

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

When reviewing measurements, the following outputs can also be selected and measurements over time observed in graph form:

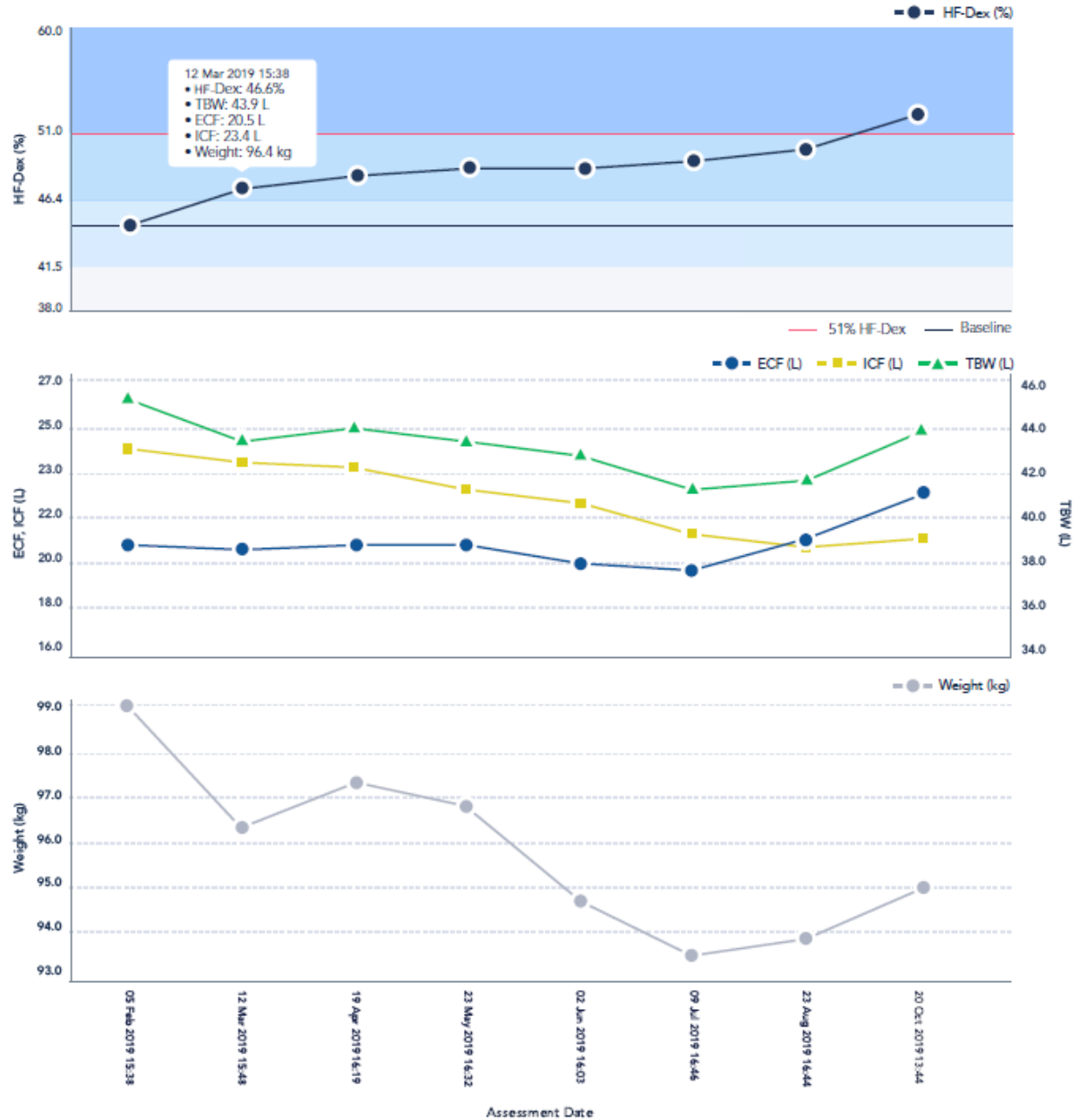
- Total Body Water (TBW)
- TBW as a % of weight
- Extracellular Fluid (ECF)
- ECF as a % of TBW
- Intracellular Fluid (ICF)
- ICF as a % of TBW
- Weight

Example of HF-Dex Results



At the bottom of the results screen, the patient's HF-Dex, TBW, ICF, ECF scores as well as weight will be shown on history graphs similar to the following:

History



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

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 User Guide, “SOZO System Instructions for Use.” The available Assessment Types for a given user is displayed in the SOZOapp and MySOZO. Licensed Assessments are displayed in the SOZOapp and MySOZO.

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.