

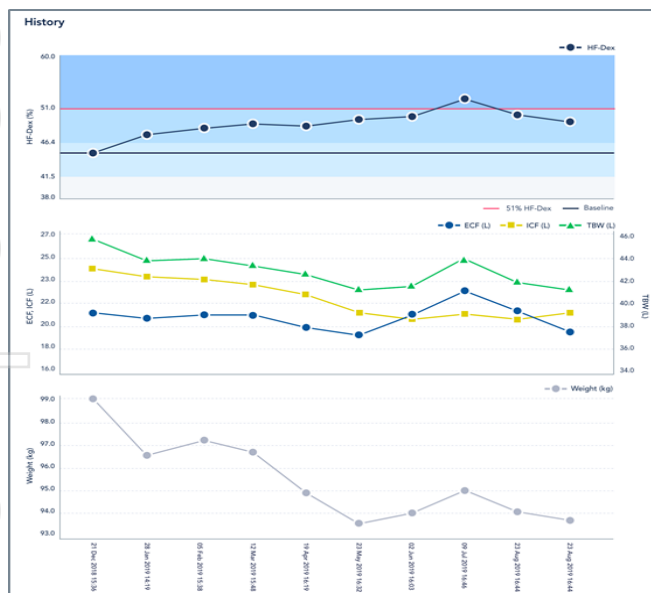
22 April 2021

## ASX ANNOUNCEMENT

### FDA Clearance for SOZO Heart Failure Index

**Brisbane, Australia** – ImpediMed Limited (ASX:IPD), a medical technology company that uses bioimpedance spectroscopy (BIS) technology to generate powerful data to maximise patient health is pleased to announce the United States Food and Drug Administration (FDA) 510(k) clearance of ImpediMed's SOZO® device to include a heart failure index (HF-Dex™) as a monitoring tool for patients living with heart failure.

- SOZO HF-Dex analysis provides an objective measure of fluid levels to assist in the clinical assessment of heart failure patients. The HF-Dex analysis is obtained through a simple, non-invasive, easy to administer, 30 second test.
- HF-Dex, when used in conjunction with other clinical data, can be useful for clinicians to risk stratify heart failure patients with fluid management problems.
- HF-Dex is presented together with normal fluid volume reference ranges.
- The results are displayed graphically to enable tracking over time (example below).
- Reference ranges are provided from grey to dark blue to help visualise increases in extracellular fluid as compared to a normal healthy population.
- HF-Dex provides medically meaningful and actionable data which allows clinicians to more effectively and efficiently manage heart failure patients.



The clinical utility of HF-Dex has been demonstrated in peer-reviewed publications and abstracts accepted at internationally renowned cardiology conferences such as the American College of Cardiology and the Heart Failure Society of America.

“We are very pleased with this expanded clearance for SOZO that includes our heart failure index,” stated Richard Carreon, Managing Director and CEO of ImpediMed. “This is a major step forward in SOZO becoming the standard of care for the management of heart failure patients. The use of HF-

Dex will provide clinicians unparalleled insights into the extracellular fluid accumulation in heart failure patients that has not otherwise been readily available to them before,” he continued.

**Approved for release by the Managing Director and CEO, Mr Richard Carreon.**

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## **About ImpediMed**

Founded and headquartered in Brisbane, Australia with US and European operations, ImpediMed is a medical technology company that uses bioimpedance spectroscopy (BIS) technology to generate powerful data to maximise patient health.

ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO® for multiple indications including heart failure, lymphoedema, and protein calorie malnutrition sold in select markets globally.

For more information, visit [www.impedimed.com](http://www.impedimed.com).

## **About SOZO Digital Health Platform**

SOZO, the world's most advanced, noninvasive bioimpedance spectroscopy (BIS) device, delivers a precise snapshot of fluid status and tissue composition in less than 30 seconds. Using ImpediMed's BIS technology, SOZO captures a vast array of data over a wide spectrum of frequencies from 3 kHz to 1000 kHz, which can be used in multiple applications. Results are available immediately online for easy data access and sharing across an entire healthcare system. The FDA-cleared, CE-marked and ARTG-listed digital health platform aids in the early detection of secondary lymphoedema, provides fluid status for patients living with heart failure, and can be used to monitor and maintain overall health – all on a single device.

For more information, visit: <https://www.impedimed.com/products/sozo/>.

## **About SOZO Fluid Analysis for Heart Failure**

The SOZO fluid analysis for heart failure provides an objective measure of fluid levels in heart failure patients. It utilises ImpediMed's HF-Dex™ heart failure index which is a measure of extracellular fluid as a percent of total body water. HF-Dex is presented together with reference ranges for normal fluid volumes. When used as part of a clinical assessment of patients living with heart failure, SOZO helps differentiate between fluid and tissue-related weight changes.

For more information, visit: <https://www.impedimed.com/healthcare/heart-failure/>.

### **Forward-Looking Statements**

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to expand sales and market acceptance in the US and Australia including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialise new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. ImpediMed does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. ImpediMed may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.