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**Companies Announcements Office
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SOZO® Digital Health Platform Receives FDA Clearance for Sarcopenia Risk Assessment

ImpediMed Limited (ASX: IPD) (**ImpediMed** or the **Company**) a leader in the development and commercialisation of medical technologies to clinically monitor and manage fluid and body composition, is pleased to announce it has received U.S. Food and Drug Administration 510(k) clearance to market its SOZO Digital Health Platform for sarcopenia risk assessment. Under the new indication, the SOZO system may be used to assess patients at risk of sarcopenia, a disease of low muscle mass or muscle loss. The clearance makes SOZO the only FDA-cleared bioimpedance spectroscopy (BIS) solution for the clinical assessment of sarcopenia risk.

Sarcopenia, the accelerated loss of skeletal muscle mass and function, develops in roughly one in three breast cancer patients during chemotherapy and is associated with worse outcomes¹. It frequently goes undetected, in part because reference-standard tools, dual-energy X-ray absorptiometry (DXA) and computed tomography (CT), aren't built for the fast, repeatable monitoring that early detection requires.

Sarcopenia also impacts patients with chronic conditions like heart failure and patients with metabolic disorders such as type 2 diabetes or obesity where routine screening can help support better disease management^{2,3,4}.

Now clinicians can assess sarcopenia risk in their clinics using SOZO's BodyComp™ muscle-mass indices, drawn from the same SOZO scan many oncology teams already use to monitor for lymphedema and track body composition.

"In cancer care, we treat the tumour, but we too often lose sight of the patient's muscle mass, which can determine how well someone tolerates treatment and recovers. A patient who loses muscle may tolerate chemotherapy less well, faces more potential complications, and can recover more slowly. Until now we haven't had a practical way to see that happening in the clinic. Flagging the risk early, from a routine scan, means we can act while it's reversible," said Jay K. Harness, MD, FACS, FASBrS, Founder of CancerFitness.org and a Past-President of the American Society of Breast Surgeons (ASBrS).

Muscle loss can hide behind a stable weight or a normal BMI. SOZO's muscle-mass indices give clinicians the clarity to separate muscle from fat. Because those indices track muscle health over time, clinicians can recognise meaningful change and intervene sooner rather than reacting to symptoms after they appear.



"Sarcopenia is one of the most consequential and most overlooked risks in cancer care. Patients lose muscle during treatment, and too often no one catches it until the damage is done," said Erik Anderson, CEO & Managing Director, ImpediMed. "Expanding SOZO into sarcopenia risk assessment means clinicians now have a practical way to see what's happening inside the body, from a simple scan that fits right into their workflow. Getting there sooner means patients have a better chance of staying strong enough to finish treatment, recover well, and reduce their risk of cancer recurrence. This clearance is a meaningful step forward for SOZO's capabilities, and we look forward to making it available to clinicians."

The sarcopenia capability will be introduced with ImpediMed's upcoming SOZO software release (v6.3), expected in Q2 FY27.

What is sarcopenia, and why does it matter for people with cancer?

Sarcopenia is a progressive skeletal muscle disorder, low muscle mass combined with reduced strength or function. In oncology it can precede a diagnosis, result from the cancer itself, or be driven by treatment through inflammation, metabolic stress, reduced activity, and poor nutrition. Low skeletal muscle mass is associated with worse survival in patients with breast cancer⁵, and sarcopenic patients tolerate chemotherapy less well and face more postoperative complications⁶. Critically, sarcopenia is modifiable. Resistance exercise and optimised nutrition can rebuild muscle, and because sarcopenia grows harder to reverse over time, finding it early matters.

How does SOZO assess sarcopenia risk?

SOZO uses bioimpedance spectroscopy (BIS), measuring impedance across 256 frequencies to differentiate intracellular and extracellular fluid and estimate lean and skeletal muscle mass. Where single-frequency bioelectrical impedance analysis (BIA) offers one snapshot, that full spectrum resolves body composition with the precision a clinical decision requires. A quick, non-invasive scan produces immediate results, making it practical for the serial monitoring that tracking muscle over time demands. DXA and CT are accurate but aren't designed for frequent, repeated use; DXA requires a dedicated appointment and CT is typically reserved for staging. In patients with early breast cancer, sarcopenia detected by BIS was associated with more than double the odds of chemotherapy toxicity, and researchers concluded BIS is a high-value, radiation-free alternative to CT for sarcopenia assessment⁷.

References

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This announcement has been authorised for release by the Managing Director and CEO

About SOZO Digital Health Platform

SOZO, the world's most advanced, non-invasive bioimpedance spectroscopy (BIS) device, delivers a quick, precise snapshot of fluid status and tissue composition. Using ImpediMed's BIS technology, SOZO measures 256 unique data points over a wide spectrum of frequencies from 3 kHz to 1000 kHz. Results are available immediately online for easy data access and sharing across an entire healthcare system. The FDA-cleared digital health platform aids in the early detection of secondary lymphedema, provides fluid status for patients living with heart failure, aids clinicians in assessing patients at risk of sarcopenia, and can be used to monitor and maintain overall health, all on a single device.

About ImpediMed

Headquartered in Sydney, Australia with US and European operations, ImpediMed is a global medical technology company that designs and manufactures bioimpedance spectroscopy (BIS) devices, providing clinicians with real-time insights for personalised patient care. The company's SOZO® Digital Health Platform and L-Dex® are the first and only FDA-cleared BIS technology that noninvasively measures fluid status and tissue composition for both healthy and unhealthy populations for the assessment and management of secondary lymphedema, with a focus on breast cancer-related lymphedema (BCRL). The platform also supports structured cancer survivorship programs and medical weight management, including patients on GLP-1 therapies, by providing real-time, whole-body insights. Trusted by healthcare organisations and research institutions worldwide, ImpediMed is redefining how clinicians monitor and manage body fluid and tissue status across diverse care pathways.

For more information, visit www.impedimed.com.

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