



6 January 2009

PRESS RELEASE

LATEST STUDY FROM SYDNEY UNIVERSITY'S BREAST CANCER RESEARCH GROUP CORROBORATES THE USE OF IMPEDIMED DEVICES IN THE EARLY DETECTION AND ASSESSMENT OF LYMPHOEDEMA

A study published last week in the high profile journal *Breast Cancer Research and Treatment*^[1], by researchers from Sydney University's Breast Cancer Research Group, provided further support for ImpediMed's technology for early detection and assessment of lymphoedema^[1].

Significantly, this study compared the impedance technique with the standardised volumetric technique (perometry) commonly used for the clinical assessment of lymphoedema and concluded that bioimpedance spectroscopy (BIS) is better suited for monitoring early stage lymphoedema, where changes are predominantly in extracellular fluid volumes.

"The overwhelming advantage of BIS over total volume estimation techniques is that it measures a change in a variable, electrical resistance at zero frequency, that is directly and causally related being due solely to a change in extracellular volume."^[1]

In an NIH breakthrough study^[2] published in June 2008, perometry was used to demonstrate that through pre-operative assessment, earlier detection and intervention led to the successful treatment of lymphoedema in breast cancer patients. ImpediMed's BIS technology aids key medical providers in pre-operative clinical assessments and ongoing monitoring of patients for the early signs of lymphoedema. Early intervention is easily enabled in the clinical setting utilising L-Dex™ devices. Early treatment can assist in preventing the progression of lymphoedema to irreversible forms.

"In the USA, we were one of the first adopters of the pre-emptive care model for breast cancer patients identified in the NIH publication. At the time, we found the L-Dex device was the only FDA cleared device for this indication. It proved to work well within our practice in aiding the clinical assessment of patients for the early onset of lymphoedema. Unfortunately, the perometer used in the NIH study is neither FDA cleared for reimbursement nor a practical solution for implementing routine assessment into a busy surgical practice. Seeing the equivalent performance of perometry and the L-Dex U400 technology in a peer reviewed publication, reaffirms our choice of technology for this prospective model of care. The L-Dex device has been well accepted by staff for the routine pre-operative assessment and surveillance of patients.

This publication (the NIH study) and will go a long way in helping other surgeons accept L-Dex devices for implementing the new clinical paradigm of pre-emptive care," said Dr Steven Schonholz of the Mercy Breast Center in Massachusetts.

“In our practice, we adopted the use of bioimpedance spectroscopy (BIS) to clinically assess early signs of lymphoedema,” stated Dr. Walton Taylor of True Surgical Partner of Dallas, Texas. “Lymphoedema may be extremely debilitating and although it cannot be cured, early detection and therefore early treatment are critical to providing the best patient outcome. These new data confirms our decision that BIS technology provides a very sensitive, validated technique which should set the standard of care with which we monitor these women before and after breast cancer treatments.”

“ImpediMed has a solid and ever building base of peer reviewed publications validating the use of BIS technology in lymphoedema. Papers such as this continue to confirm the performance of our products against standardised volumetric techniques such as perometry. This contributes greatly in helping our efforts to change the care paradigm for breast cancer survivors worldwide as L-Dex devices enable medical providers to implement the new clinical approach to lymphoedema in breast cancer patients. As recognised institutions act on pre-operative and early clinical assessment, the more we ensure all breast cancer patients have lymphoedema recognised as a critical part of their overall care,” said Greg Brown, ImpediMed’s CEO.

[1]. Ward, L.C, et al., Quantitative bioimpedance spectroscopy for the assessment of lymphoedema. Breast Cancer Res Treat, DOI 10.1007/s10549-008-0258-0 2008.

[2]. Gergich N, Washington F, Pfalzer L, Soballe P and McGarvey C , Preoperative assessment enables the early diagnosis and successful treatment of lymphedema., Cancer, , Vol 112, pp 2809-2819, June 2008.

ENDS

For further information contact:

Greg Brown Impedimed CEO +61-7-3860-3700

About ImpediMed

ImpediMed Ltd. is the world leader in the development and distribution of medical devices employing Bioimpedance Spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status. ImpediMed’s primary product range consists of a number of medical devices that aid surgeons, oncologists, therapists and radiation oncologists in the clinical assessment of patients for the potential onset of secondary lymphoedema. Pre-operative clinical assessment in breast cancer survivors, before the onset of symptoms, may prevent the condition from becoming a lifelong management issue and thus improve the quality of life of the cancer survivor. ImpediMed had the first medical device with an FDA clearance in the United States to aid health care professionals, clinically assess secondary lymphoedema of the arm in female breast cancer patients. For more information, visit. www.impedimed.com.

For personal use only

For personal use only