



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon Scanning Technology Prioritising Summary**

## **Impedimed Imp™ for the diagnosis of lymphoedema**

**May 2008**



© Commonwealth of Australia 2008

ISBN

Publications Approval Number:

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. Apart from any use as permitted under the *Copyright Act 1968*, all other rights are reserved. Requests and inquiries concerning reproduction and rights should be addressed to Commonwealth Copyright Administration, Attorney General's Department, Robert Garran Offices, National Circuit, Canberra ACT 2600 or posted at <http://www.ag.gov.au/cca>

Electronic copies can be obtained from <http://www.horizonscanning.gov.au>

Enquiries about the content of the report should be directed to:

HealthPACT Secretariat  
Department of Health and Ageing  
MDP 106  
GPO Box 9848  
Canberra ACT 2606  
AUSTRALIA

**DISCLAIMER:** This report is based on information available at the time of research cannot be expected to cover any developments arising from subsequent improvements health technologies. This report is based on a limited literature search and is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

The Commonwealth does not guarantee the accuracy, currency or completeness of the information in this report. This report is not intended to be used as medical advice and intended to be used to diagnose, treat, cure or prevent any disease, nor should it be used therapeutic purposes or as a substitute for a health professional's advice. The Commonwealth does not accept any liability for any injury, loss or damage incurred by use of or reliance the information.

The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from departments in all states and territories, the Australia and New Zealand governments; and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by Adrian Purins, Linda Mundy, and Professor Janet Hiller from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Discipline of Public Health, School of Population Health and Clinical Practice, Mail Drop 545, University of Adelaide, Adelaide, SA, 5005.

# PRIORITISING SUMMARY

**REGISTER ID:** 000358

**NAME OF TECHNOLOGY:** IMPEDIMED IMP™ FOR THE DIAGNOSIS OF LYMPHOEDEMA

**PURPOSE AND TARGET GROUP:** DIAGNOSIS OF PATIENTS SUSPECTED OF HAVING LYMPHOEDEMA

## STAGE OF DEVELOPMENT (IN AUSTRALIA):

- |  |   |
|--|---|
| <input type="checkbox"/> Yet to emerge           | <input type="checkbox"/> Established  |
| <input checked="" type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational         | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established      |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> Yes | ARTG number <b>134672</b>  |
| <input type="checkbox"/> No             | Impedimed has a product designated as a body composition analyser approved by the TGA. This may correspond to the device in this prioritising summary. |
| <input type="checkbox"/> Not applicable |  |

## INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia	✓		
USA		✓	

## IMPACT SUMMARY:

Impedimed (ImpediMed Limited, Queensland, Australia) manufactures the Impedimed Imp™ SBF7 which is used to measure bioimpedence. This device may be useful for the early detection and diagnosis of lymphoedema. Lymphoedema is a treatable complication arising from damage caused by various diseases and surgical procedures, and other causes, but especially from breast cancer surgery.

## BACKGROUND

The lymphatic system drains lymph fluid from tissues and transports it back to the blood stream. Lymph contains, amongst other components, proteins from the tissues

of the body. When this system is damaged for a variety of reasons the fluid may not drain effectively which can lead to swelling, a condition called lymphoedema. The swelling is caused by the build up of proteins in the tissues due to ineffective lymph drainage, with water moving into the tissues attracted by the presence of excess protein. The result is swelling of the tissue causing inflammation, slower healing, pain, and increased tendency for infection. Lymphoedema, if diagnosed at an early stage, is treatable with compression bandages and therapy such as massage and exercise. If lymphoedema is allowed to progress, function and mobility may be lost, and recurrent infection may occur.

Diagnosis of lymphoedema is primarily based on clinical observation and the patient's medical history. Computed tomography and MRI may be used in difficult to diagnose cases where other conditions may confound clinical diagnosis. Bioimpedance is the measurement of the resistance of the body's tissues to the flow of an electrical current. Electrodes are placed on the body and a current is passed through the body between electrodes. The impedance of this current can be used to ascertain the composition of the measured tissues, in particular the water content of the tissue. The Impedimed Imp™ SFB7 uses multiple frequency currents to measure the impedance of the tissue. From this total body water, intra- and extra-cellular fluid can be determined. The level of extra-cellular fluid in the limb is a direct measure of the degree of lymphoedema. By measuring both the affected and unaffected limbs the patient acts as their own control and the severity of lymphoedema in the affected limb can be ascertained.



Figure 1 The Impedimed Imp™ SFB7 (ImpediMed Limited 2008)

#### **CLINICAL NEED AND BURDEN OF DISEASE**

High quality evidence for the prevalence of lymphoedema does not exist for Australia. Most sources cite the lack of evidence and use estimates based on other sources. The Lymphoedema Association of Australia estimated 300,000 people with lymphoedema and of these 100,000 cases were attributed to breast cancer surgery. However, this figure is an old estimate generated in 1995 from an Australian population of 15 million (LAA 2008).

A 2008 review commissioned by the National Breast and Ovarian Cancer Centre (NBOCC) on secondary lymphoedema estimates that in Australia 20 per cent of survivors from several cancer types will experience secondary lymphoedema. This translates to an estimated 8000 new cases per year (NBOCC 2008).

## **DIFFUSION**

The device is manufactured by an Australian based company and two Australian studies using the device were found. No evidence of routine clinical usage was found.

## **COMPARATORS**

Lymphoedema is primarily diagnosed using clinical observation. For cases where difficulties exist in making a clinical diagnosis or the patient has other complications that preclude clinical diagnosis, the gold standard of lymphoedema diagnosis, lymphoscintigraphy, may be used. Lymphoscintigraphy involves the injection of a radioactive medium into the tissue with the distribution of this agent monitored with a gamma camera indicating the functionality of the lymphatic system.

## **SAFETY AND EFFECTIVENESS ISSUES**

Two studies were identified that assessed the Impedimed Imp™ SFB7 device. The first study investigated the capability of the Imp™ SFB7 to measure total body water (TBW) (Moon et al 2008) (level III-2 diagnostic evidence). While not assessing the device for lymphoedema diagnosis directly, this study compared the Imp™ SFB7 to another device, the 4000B (XiTRON technologies, San Diego, CA). Both devices use bioimpedance for TBW determination and were compared to a standard method of TBW determination, deuterated water (D<sub>2</sub>O) analysis. The study recruited 28 normal subjects and TBW was determined by the three methods. Compared to the reference the Imp™ SFB7 performed well with a standard error of measurement (SEM) of 0.04 litres, whereas the 4000B device had a SEM of 0.320 litres. While this study measured TBW, TBW is determined from intra-cellular (ICF) and extra-cellular fluid (ECF). The accuracy of TBW determination is a reflection of accuracy of the ECF quantitation, which is the important parameter for diagnosing lymphoedema. This study shows that the Impedimed Imp™ SFB7 device is accurate versus established methods of bodily fluid determination.

The second study identified investigated the ability of the Impedimed Imp™ SFB7 device to distinguish patients with known lymphoedema from normal controls. Fifteen patients with diagnosed lymphoedema were recruited along with seven healthy controls. The lymphoedema patients were diagnosed with the gold standard for lymphoedema diagnosis, lymphoscintigraphy. Lymphoedema was present in either an upper or lower extremity in the patient group. When the lymphoedema patients had both their normal and affected limb measured by the Impedimed Imp™ SFB7 device a ratio was calculated from the impedance. Lower levels of impedance correlated with increased levels of lymphoedema in the measured limb. Therefore the ratio of affected

to normal limb would be different to the ratio of one limb to another in the healthy controls. The impedance ratio in the lymphoedema patients was 0.9 for affected to normal limbs. The impedance ratio in the healthy controls was 0.99 for dominant to non-dominant limbs. The difference between the lymphoedema and healthy subjects was significant ( $p=0.01$ ). The authors also noted the test was quick and simple to perform (Warren et al 2007) (level III-3 diagnostic evidence).

The studies identified were small scale and of moderate level of evidence. The Impedimed Imp™ SFB7 device appears to be accurate and able to distinguish normal from lymphoedema affected patients. Further larger trials are required.

### **COST IMPACT**

No cost information was reported in the studies reviewed during preparation of this prioritising summary. The manufacturer was contacted but did not respond with price information.

### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

### **OTHER ISSUES**

No issues were identified/raised in the sources examined.

### **SUMMARY OF FINDINGS**

The Impedimed Imp™ SFB7 device appears to be effective for diagnosis of lymphoedema, although the studies were small in nature and lacked high quality design. Larger studies in which the device is directly compared with the standard methods for lymphoedema diagnosis are required. Additionally, varied stages of lymphoedema manifestation should be included.

### **HEALTHPACT ACTION:**

The Impedimed Imp™ SFB7 device appears to be an effective tool in the diagnosis of lymphoedema. The use of this device does not require a Medicare Benefits Schedule item number. Therefore HealthPACT has recommended that further assessment of this technology is no longer warranted.

### **NUMBER OF INCLUDED STUDIES**

Total number of studies

Level III-2 diagnostic evidence 1

Level III-3 diagnostic evidence 1

**REFERENCES:**

ImpediMed Limited (2008). *ImpediMed Imp* [Internet]. Available from: [http://www.impedimed.com/content/Image/gallery/sfb7\\_laptop.jpg](http://www.impedimed.com/content/Image/gallery/sfb7_laptop.jpg) [Accessed 10th April].

LAA (2008). *What is Lymphoedema?* [Internet]. Lymphoedema association of Australia. Available from: <http://www.lymphoedema.org.au/lymphoed.html> [Accessed 9th April].

Moon, J. R., Tobkin, S. E. et al (2008). 'Total body water estimations in healthy men and women using bioimpedance spectroscopy: a deuterium oxide comparison', *Nutr Metab (Lond)*, 5 (1), 7.

NBOCC (2008). *Review of research evidence on secondary lymphoedema: incidence, prevention, risk factors and treatment.* [Internet]. Available from: [Accessed 9th April].

Warren, A. G., Janz, B. A. et al (2007). 'The use of bioimpedance analysis to evaluate lymphedema', *Ann Plast Surg*, 58 (5), 541-543.

**SEARCH CRITERIA TO BE USED:**

Lymphedema/ diagnosis

Spectrum Analysis

Body Composition

Electric Impedance