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Horizon scanning prioritising summary

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**Solar Scan for the detection and monitoring
of melanoma.**

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PRIORITISING SUMMARY

REGISTER ID: 000136

NAME OF TECHNOLOGY: SOLARSCAN®

PURPOSE AND TARGET GROUP: MELANOMA DETECTION AND MONITORING SYSTEM FOR ROUTINE SKIN CHECKS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input checked="" type="checkbox"/> Established |
| <input 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 type="checkbox"/> Yes | ARTG number |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not applicable |

INTERNATIONAL UTILISATION:

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

IMPACT SUMMARY:

Polartechnics Ltd provides SolarScan® with the aim of detecting melanoma and monitoring skin lesions. The technology is currently available through several general practice or dermatology clinics for people requiring skin lesion monitoring and/or detection of melanoma within Australia.

BACKGROUND

Dermoscopy (surface microscopy) is the clinical technique used to examine skin lesions. It involves using a hand-held magnifying instrument (10 x magnification), usually with liquid at the skin-instrument interface, to examine pigmented lesions arising on the skin surface. This technique allows the observer to look not only onto but also into the superficial skin layers, and thus permits a more detailed inspection of pigmented skin lesions (Crotty and Menzies 2004; Kittler et al 2002). Dermoscopy assists the clinician to determine whether a skin lesion requires excision, biopsy, monitoring or can be safely left *in situ*. It is possible that it increases the accuracy of melanoma detection when compared to standard visual inspection (Crotty and Menzies 2004).

The SolarScan® device was developed by Polartechnics Ltd., CSIRO and the Sydney Melanoma Unit. It consists of a remote head colour video camera that produces high resolution (24-bit, 760 x 570-pixel) images. The lesion image is digitised for processing. The device uses surface epiluminescence microscopy, which allows for x40 magnification (Figure 1) (Polartechnics 2004).

The SolarScan® takes digitised images of lesions and extracts the lesion characteristics, which are then compared to a database of benign and malignant lesions.

The SolarScan® can detect melanomas less than 3mm deep which may allow for early detection and treatment. The technology is also designed to monitor any changes in lesions over time.



Figure 1. SolarScan (Printed with permission Polartechnics)

CLINICAL NEED AND BURDEN OF DISEASE

In Australia there were 8,885 new cases of skin melanoma recorded in the year 2001, a rate of 45.8 per 100, 000 (AIHW 2004a). In 2001, melanoma was the fourth most common cancer in Australia and accounted for 10% of all new cancer cases (AIHW 2004).

Incidence data for cancers of the skin, apart from melanoma, are not collected on a routine basis by cancer registries. These common cancers are not legally notifiable and are therefore not routinely reported. Estimates of the frequency of treated skin cancers, ie basal cell carcinoma and squamous cell carcinoma, are derived from data that have been collected in national household surveys in 1985, 1990, 1995 and 2002 (NCCI 2003). A 2002 national survey found 374,000 people had been diagnosed with either squamous or basal cell carcinoma in Australia compared to 270,000 in 1995 (Cancer Council Victoria 2004).

DIFFUSION

There are currently 40 SolarScan[®] machines installed in general practice and/or dermatology clinics in Australia (personal communication Polartechnics).

COMPARATORS

The comparators for skin lesion inspection and monitoring are visual inspection by the skin clinician or general practitioner using, as mentioned previously, a handheld surface microscope (dermoscope).

EFFECTIVENESS AND SAFETY ISSUES

See complete volume of Prioritising Summaries for definitions of Levels of Evidence.

At the time of preparing this summary, the manufacturer was in the process of submitting a paper for publication describing a trial of the SolarScan[®] and its diagnostic accuracy compared to dermoscopy experts and general practitioners (personal communication, Polartechnics).

The study by Menzies et al (2001) (level III-3 diagnostic evidence) demonstrated the effectiveness of SolarScan® in early detection of clinically "featureless" melanoma. The measurement outcome was the specificity of melanoma diagnosis for short-term digital surface microscopic monitoring of suspicious or changing atypical melanocytic lesions. 318 consecutive lesions from 245 patients (aged 4 – 81 years) were monitored during a 2.5 to 4.5 month period.

Of the 318 lesions, 257 (81%) remained unchanged and 61 (19%) showed morphologic changes. Of the 61 lesions that changed, 7 were found to be early melanoma (11% of all changed lesions, 2% of total lesions): 2 invasive lesions and 5 *in situ*. The authors report that none of the melanomas developed any classic surface microscopic features of melanoma on examination with a handheld surface microscope and could be identified only by morphologic change. The specificity of the SolarScan® was 83% when compared to pathology results of the excised lesions.

There are no studies, as yet, that assess the impact of possible early melanoma diagnosis with the SolarScan®, compared to visual inspection or dermoscopy on the health outcomes (ie survival) of patients.

COST IMPACT

There are several MBS item numbers for the removal of basal and squamous cell carcinoma (item numbers 31255 – 31295) with fees ranging from \$190.00 - \$240.00 each and for the removal of malignant melanoma (item numbers 31300 – 31335) at a cost ranging from \$224.00 - \$315.00 (MBS 2004). The current cost of the SolarScan® device is approximately \$30,000.

The total number of public hospital separations in Australia for malignant melanoma or other malignant neoplasm of the skin was 82,707 during the year 2002-03 (AR-DRG numbers C43 and C44). In addition the number of public hospital separations for melanocytic naevi and benign neoplasms of the skin (AR-DRG numbers D22 and D23) were 10,837 and 5,332 for the same time period.

There are currently high rates of skin lesion excisions; in particular, there are high numbers of benign lesions excised compared to malignant lesions. The high excision rates occur because it is common for pigmented skin lesions such as naevi and seborrhoeic keratoses to appear similar to melanoma. It has been shown that there are approximately 11-29 benign excisions per malignant excision and up to 36 excisions per malignant excision when seborrhoeic keratoses are included (English et al 2004).

If the SolarScan® device demonstrates more accurate diagnosis than visual inspection or hand held surface microscope (currently not available), it may potentially reduce the number of unnecessary surgical procedures for the excision of suspect melanomas and therefore pathology costs.

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.

CONCLUSION:

There is the potential for this technology to benefit a large number of patients, based on the high burden of skin cancer and the cost of detecting and treating melanoma and other skin cancers in the Australian population. However, the safety and effectiveness of this technology cannot be determined until further studies with the SolarScan® are published.

HEALTH PACT ACTION:

Technology is already diffusing into the Australian health system and will not impact significantly in terms of policy or cost burden. Archive.

SOURCES OF FURTHER INFORMATION:

- AIHW (2004a). 'Interactive cancer data' [Internet]. Australian Institute of Health and Welfare. Available from: <http://www.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/Cancer/cancerageratesv7> [Accessed 24th November, 2004].
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- Polartechnics (2004). 'SolarScan' [Internet] Available from: <http://www.polartechnics.com/Products/SolarScan/SolarScan.htm> [Accessed 24th November, 2004].
- Rosado, B., Menzies, S. et al (2003). 'Accuracy of computer diagnosis of melanoma: a quantitative meta-analysis', *Arch Dermatol*, 139 (3), 361-367; discussion 366.

SEARCH CRITERIA TO BE USED:

Carcinoma, Basal Cell/diagnosis/pathology
Melanoma/classification/ diagnosis/ pathology
Microscopy/ methods/standards
Self-Examination/ utilization
Skin Neoplasms/ diagnosis/etiology