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Australia and New Zealand Horizon Scanning Network

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National Horizon Scanning Unit

Horizon scanning prioritising summary

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**GlucoWatch[®] G2[™] : A watch designed
primarily for children with Type I diabetes
to continuously monitor glucose levels.**

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PRIORITISING SUMMARY

REGISTER ID: 0000063

NAME OF TECHNOLOGY: GLUCOWATCH® G2™

PURPOSE AND TARGET GROUP: A WATCH DESIGNED PRIMARILY FOR CHILDREN WITH TYPE I DIABETES TO CONTINUOUSLY MONITOR GLUCOSE LEVELS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

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
USA, cost-effectiveness	✓		
USA	✓		
Italy	✓		

IMPACT SUMMARY:

Cygnus Inc manufactures the GlucoWatch® G2™ Biographer with the aim of providing continuous glucose monitoring of individuals with diabetes. The GlucoWatch® G2™ has recently been given approval from the United States FDA (2002) for use in children and adolescents with Type-I insulin-dependent diabetes but it has not, as yet, received TGA approval. This technology is currently unavailable in Australia, however, it is likely that if this device were made available that it would be provided on a prescription basis through General Practitioners or diabetes clinics.

The GlucoWatch® G2™ Biographer is a wristwatch-like device that can be worn easily by children. GlucoWatch® takes advantage of the iontophoresis process, which normally delivers drugs transdermally using electrical current. A charged, ionic drug is placed on the skin with an electrode of the same charge, allowing direct current to drive the drug into the skin. GlucoWatch® sends a low-level electronic current through the skin and then extracts fluid containing ions and associated glucose, across the skin by *reverse iontophoresis*, and accumulates it in a sensor. Glucose levels in the extracted fluid are then measured (Figure 1). The amount of glucose extracted across the skin correlates with blood glucose with an average lag time of 20 minutes. A 3-hour calibration period is required before the device can be used and the values stored in the GlucoWatch® are then calibrated against a finger-prick blood glucose reading. A built-in alert

system sounds an alarm if glucose readings are too high, low or are declining rapidly. The device is capable of conducting four glucose readings per hour for up to 12 hours of continuous monitoring. The GlucoWatch[®] is promoted for use in children for night time monitoring of glucose levels and preventing episodes of hypoglycaemia, which can lead to coma and organ damage. The GlucoWatch[®] is not designed to replace blood glucose finger prick testing, which is the gold standard for glucose monitoring. However, GlucoWatch[®] may be a useful tool in the home management of Type-I diabetes for both children and their families.

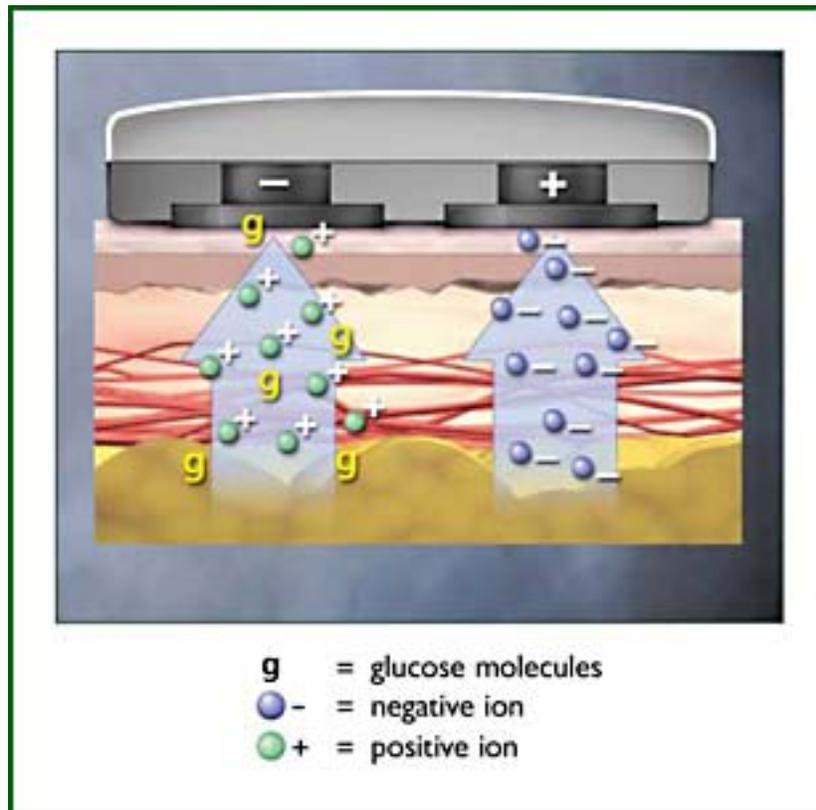


Figure 1 Extraction of fluid through the skin. Neutral glucose molecules associated with positively charged sodium ions (Na^+) are extracted from the skin into the GlucoWatch[®] autosensor, where the level of glucose is measured (Copyright Cygnus Inc 2003, printed with permission).

The National Diabetes Register reports that there were 2,313 children under 14 years of age diagnosed in Australia with Type-I diabetes in the period 1999-2001. During the same period, 1,010 young adults between the ages 15-24 were also diagnosed with Type-I diabetes. The 1995 National Health Survey, based on self reported information, estimated the prevalence of Type-I diabetes in Australia as 220 per 100,000 (National Centre for Monitoring Diabetes, November 2002).

Chase et al (2003) assessed glucose control in 40 children and adolescents with Type-I diabetes and poor glucose control (glycohaemoglobin $>8\%$). Participants were randomised (level II evidence) to GlucoWatch[®] and conventional glucose monitoring for three months. After this period all participants received the GlucoWatch[®] and their glucose levels were monitored for a further six months. Baseline glycohaemoglobin values for controls compared to GlucoWatch[®] were 8.6% and 8.9% respectively and were significantly lower in the GlucoWatch[®] at three months (9% vs 8.4% GlucoWatch[®]) ($p < 0.05$). After the six month follow-up period where all

participants received the GlucoWatch[®], glycohaemoglobin values were 8.6% and 8.4% for the control and GlucoWatch[®] groups respectively. Hypoglycaemia was detected more frequently in the GlucoWatch[®] group (confirmed by blood glucose monitoring) compared to the control group ($p < 0.0005$). However, there was also a significant increase in the rate of hypoglycaemia detection in the GlucoWatch[®] group on nights when they were *not* wearing the device ($p = 0.03$).

In the case series study (level IV evidence) conducted by Iafusco et al (2004), 14 children and 8 young adults wore the GlucoWatch[®] for a mean period of 30 days. Seven episodes of hypoglycaemia were detected (confirmed by blood glucose monitoring in 85% of cases). However, the alarm failed to alert the patient in the majority of cases due to reduced awareness in the hypoglycaemic state. As the patients were sleeping alone, the alarm also failed to raise members of the family. The device failed in one patient due to the excessive sweating associated with hypoglycaemia. Similar failings of the device were reported by Bozzetti et al (2003) who reported a correlation of $r = 0.74$ between GlucoWatch[®] and Accu-Chek, the conventional blood glucose monitoring device.

Eastman et al (2003) reported the initial cost of the GlucoWatch[®] as US\$698 and the cost of the disposable component of the system, the AutoSensor, as US\$7.50 per use (each 12 hour period).

CONCLUSION:

Level II evidence it indicates that GlucoWatch[®] may be a useful adjunct in the monitoring of glucose levels, especially in younger children with poor glucose control. However, it is unclear whether the increased detection of hypoglycaemia with GlucoWatch[®] is due to the GlucoWatch[®] alarm or to the possible increased vigilance of parents/children. GlucoWatch[®] is not a replacement for conventional blood glucose monitoring.

HEALTHPACT ACTION:

It is therefore recommended that a Horizon Scanning report be conducted.

SOURCES OF FURTHER INFORMATION:

Bozzetti, V., Viscardi, M. et al (2003). 'Results of continuous glucose monitoring by GlucoWatch Biographer in a cohort of diabetic children and adolescents under real-life conditions', *Pediatr Diabetes*, 4 (1), 57-58.

Chase, H. P., Roberts, M. D. et al (2003). 'Use of the GlucoWatch biographer in children with type 1 diabetes', *Pediatrics*, 111 (4 Pt 1), 790-794.

Diabetes Research in Children Network (DIRECNET) Study Group (2003). 'The accuracy of the GlucoWatch G2 biographer in children with type 1 diabetes: results of the diabetes research in children network (DirecNet) accuracy study', *Diabetes Technol Ther*, 5 (5), 791-800.

Eastman, R. C., Leptien, A. D. & Chase, H. P. (2003). 'Cost-effectiveness of use of the GlucoWatch Biographer in children and adolescents with type 1 diabetes: a preliminary analysis based on a randomized controlled trial', *Pediatr Diabetes*, 4 (2), 82-86.

Gandrud, L. M., Paguntalan, H. U. et al (2004). 'Use of the Cygnus GlucoWatch biographer at a diabetes camp', *Pediatrics*, 113 (1 Pt 1), 108-111.

Iafusco, D., Errico, M. K. et al (2004). 'Usefulness or uselessness of GlucoWatch in monitoring hypoglycemia in children and adolescents', *Pediatrics*, 113 (1 Pt 1), 175-176; author reply 175-176.

Tierney, M. J., Tamada, J. A. et al (2001). 'Clinical evaluation of the GlucoWatch biographer: a continual, non-invasive glucose monitor for patients with diabetes', *Biosens Bioelectron*, 16 (9-12), 621-629.

SEARCH CRITERIA TO BE USED:

Diabetes Mellitus, Type I/*blood/complications

Hypoglycemia/*diagnosis/etiology

Blood Glucose/analysis

Blood Glucose Self-Monitoring/adverse effects/*instrumentation

Monitoring, Ambulatory/adverse effects/instrumentation

Sensitivity and Specificity

Glucose/metabolism