



## 'JUST MICRO-SIZE ME' – TINY DIABETES DEVICE TO THE RESCUE?

A safe, patient-friendly and non-invasive medical device for the detection and screening of diabetic autonomic neuropathy (DAN) in resource-poor settings is to be marketed in South Africa this year, extending the diagnostic reach of clinicians.

Launched at the 19th World Diabetes Congress in Cape Town in early December last year, the ANSIScope is a patented device that won the Frost and Sullivan Product Innovation Award in Healthcare in the United States last year.

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Diabetic autonomic neuropathy affects 40 - 60% of all diabetics and is commonly known as the 'silent killer' because it is so tricky to detect and can harm vital organs like the heart and kidneys. The focus generally tends to be on easier-to-detect sensory neuropathy that affects the extremities and can lead to amputation. With more than 3 million South Africans diagnosed with diabetes (mainly type 2), the local pandemic is predicted to triple in size in just over 2 decades due to an increasingly sedentary, Western way of life that is resulting in widespread obesity.

Diabetic neuropathies are a heterogeneous group of disorders and are among the most common long-term complications of diabetes, causing significant morbidity and mortality. The American Diabetes Association, laying down standards for medical care in diabetes early last year, recommended that screening for autonomic neuropathy be instituted at diagnosis of type 2 diabetes and 5 years after diagnosis of type 1.

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The micro-sized diagnostic 'ANSIScope' tool used for detecting diabetic autonomic neuropathy.

### India the testing ground

According to Srini Nageshwar, CEO of the company that developed the ANSIScope, over 100 of the devices, each costing the equivalent of about R25 000, have been in the field in India, where more than 10 000 tests had been done. Product and process efficacy proved 'excellent', and his company would begin operations in the Africa region, particularly South Africa, around June this year.

'The machine addresses the needs of 86% of the world for whom accessibility and affordability of primary health care is difficult. We want to transform primary medical diagnosis at grass-root levels,' Nageshwar said.

GPs are able to begin treatment earlier, especially in rural areas where advanced medical care is negligible

or absent. 'For doctors who have long despaired about not being able to detect diabetes-related complications like DAN earlier, this provides the desired intervention,' Nageshwar added.

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### How it works

The device measures the activity of both the components of the ANS – the sympathetic and the parasympathetic separately; and the balance trajectory between them, making the accurate measurement of autonomic dysfunction



possible. It is reportedly the only medical instrument capable of doing so in real time (taking between 5 and 7 minutes), and requires the patient to lie down during measurement at a sparsely equipped clinic or in a doctor's rooms. The machine is particularly relevant given the human and economic costs associated with diabetes and its complications.

Nageshwar explained that since the 1930s, the variability of the RR intervals on an ECG were the only known indicator of ANS activity. The ANSiscope was designed using this premise with the measurement technique 'exploiting the fractal nature of the RR interval time series'.

Experts at the diabetes congress in Cape Town warned that the disease posed immense social and economic challenges to a continent hard hit by HIV/AIDS. An entire 3.1% of the African population, or 10.4 million people, currently suffered from diabetes and this figure would double by 2025.

**Minister shines SA's marble**

The congress, attended by well over 12 000 delegates, was the largest medical gathering yet seen in Cape Town, and saw South Africa's deputy health minister, Nozizwe Madlala-Routledge, opening it and attending several sessions.

This was remarked on by Professor George Alberti, chairman of the organising committee and a past president of the International Diabetes Federation. 'I've never known a politician to do this before,' he enthused, adding that she had promised him her country would intensify the fight against the disease.

Madlala-Routledge subsequently announced that South Africa would lead the Group of 77 developing nations in getting the United Nations to adopt a declaration on diabetes while driving drug prices down. Her Director General, Thami Mseleku, said South Africa would also lead a new diabetes drug price war on a scale similar to that which saw AIDS drug costs slashed by over 90% over the past decade.

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'One of the things we recognise is that it is important for us to engage with the pharmaceutical and diagnostic industries, to impress upon them the need for accessible medicines and diagnostic tools, especially for the poor,' Mseleku added.

Alberti warned that type 2 diabetes was occurring in younger and younger populations, who were getting heart attacks, strokes and undergoing amputations at the peak of their 'life ability', in their 30s, 40s and 50s. He said the latest figures put the incidence of diabetes worldwide at 246 million, which would rise to 'a very conservative' 350 million by 2025. As many as 350 million people could already be pre-diabetic, while at least 3 million deaths a year were 'speeded up' by the disease, although this figure could be as high as 10 million given

death certification disease identification problems.

**Dubious delights of 'iSidudla' (the plump one)**

Alberti claimed that dietary change was 'particularly difficult' on the southern African subcontinent because people saw putting on weight as an indication of success. Anyone losing weight was looked on 'as probably being ill or poor'.

At least one local diabetes expert however differed, saying such attitudes were a not a fundamental barrier to combating obesity. Professor Frederick (Derick) Raal, Head of the Division of Endocrinology and Metabolism in the Department of Medicine at Johannesburg Hospital, believed the status attached to appearing well fed was 'not as great an issue as it used to be'.

'I think people realise that type 2 diabetes is following the obesity pandemic. It is complicated by the whole HIV story because if you lose weight people think you've got the dreaded lurgy.' Although proper data were not available, he did not really buy the theory that obesity was 'promoted for cultural reasons'. 'I think the spread of the disease has more to do with the change to Western lifestyles, the so-called Coca-Colarisation of people. Zulu mamas used to work the lands more than they do nowadays. We've engineered exercise out of our lives.'

With the new diagnostic micro-device, it seems only engineering can save us from ourselves.

**Chris Bateman**

