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ONLY SKIN DEEP

A White Paper on Modern Lancing Technology

By David Mendosa

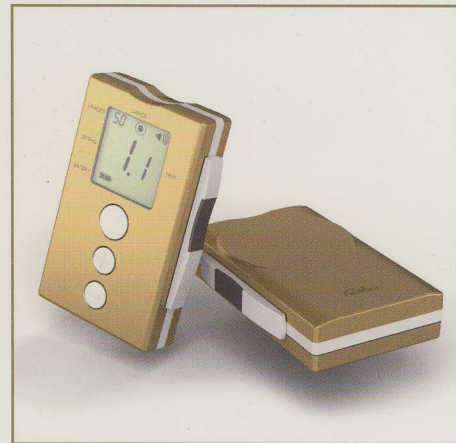
Until now, the most important invention for diabetes management has undoubtedly been the blood glucose meter. These meters test the amount of glucose stuck to our blood. But they aren't perfect. The problem is that they require us to prick our skin for a drop of that blood. It's not for nothing that we call them "blood glucose meters."

Almost everyone trying to fix the limitations of blood glucose testing has focused on improving the meters themselves. As a result we can now choose from more than 40 different blood glucose meters with a huge variety of features.

But meters aren't the problem with blood glucose testing any more. The problem is the lancing device. And until now surprisingly little effort has gone into building a better one.

However, one company – Pelikan Technologies in Palo Alto, California – saw that lancing was the problem with blood glucose testing and set about to correct it. When I first heard what Pelikan was doing, I thought that it was building a better mousetrap before they found a mouse. Whoever heard

of a company developing a better lancing device before setting to work on a meter? Pelikan indeed plans to introduce a meter later. But first this Silicon Valley company is using electronics to separate its lancing device, the Pelikan Sun™, from the crowd. Unlike any previous lancing device, the Pelikan Sun™ is automated. Bringing electronics to lancing brings more benefits than I ever imagined, ranging from greater comfort to ease of use to safety.



Pelikan Sun Lancing Device

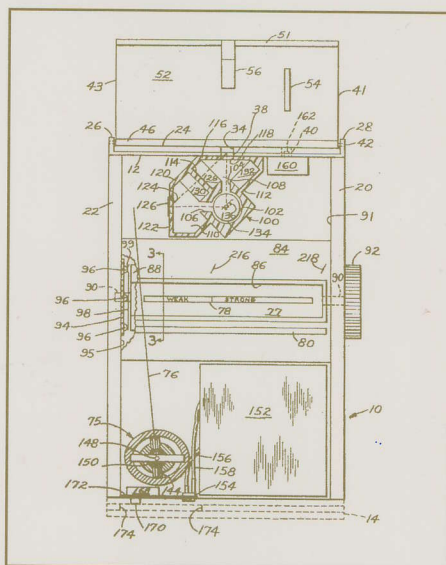
EARLY METER DEVELOPMENT

When Anton Hubert (Tom) Clemens tested the first prototypes of his blood glucose meter and filed a patent application for the Ames Reflectance Meter in 1968, he had emigrated from Switzerland just three years earlier.

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He is an engineer, and at that time was the director of the Ames Instrument R&D Department of the Ames Division of Miles Laboratories, Elkhart, Indiana. In 1970 the first people with diabetes began to test their blood glucose with it, and within a decade this and other home blood glucose meters were in common use.

In the past few years I have interviewed Tom several times, and he is still inventing new products for people with diabetes. It would be awfully hard, however, for him to invent anything more important than the blood glucose meter. Nothing else can tell us what our blood glucose levels are and whether they are dangerously high or low so that we can take the necessary action.



Drawing of first meter (Source: www.uspto.gov)

RECENT METER ADVANCES

2/7 The first meters took a big hanging drop of blood – at least 10 microliters.

We've come a long way since then with many of the newest meters taking one-tenth or less.

In the past five years some meters can use blood samples from the upper arm, forearm, base of the thumb, or thigh. These are the so-called alternative sites. But blood glucose levels from these sites aren't always as accurate as readings from the fingertips. Alternative site results differ from fingertip results when glucose levels are changing rapidly such as after a meal, after taking insulin, during exercise, or when you are ill or under stress.

OUR SKIN

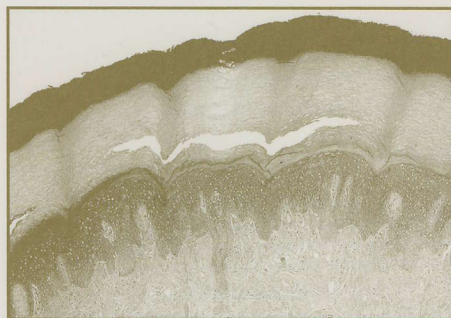
Blood glucose meters can tell us if our level is too high, too low, or just right. But there is another problem. Somehow, we still have to get through the skin. There's no such thing as a noninvasive blood glucose meter.

While everyone's skin is different, diabetes affects the skin of almost everyone who has it, but in different degrees. The changes in structure, function, and color probably come from glucose that attaches to proteins in our body. Most people with diabetes have thicker skin than others, and many of us have dry skin and a reduced blood supply to the skin.

While our skin is a wonderful solution to the problem of holding our body together, keeping it waterproof, and protecting it against invasion, it is itself

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a problem when we need to check our blood glucose level. When we use our fingertips to check our blood glucose as much as we need to, they can get mighty sore.



The Human Skin

The thin top layer of the skin, called the epidermis, doesn't have any blood vessels. Below the epidermis is a thicker layer called the dermis. Here is where you find nerve endings and blood vessels.

When we check our blood glucose levels at home, it is capillary blood glucose that we are testing. Capillaries are the body's smallest blood vessels. To reach them the lancet needs to pass through the epidermis to the dermis.

EARLY LANCING DEVELOPMENTS

At first when we wanted to test a drop of blood there wasn't anything better than a needle or a razor blade. There had to be something better, and soon the meter companies came up with all sorts of spring, cam, and mass actuators to drive the lancet.

But in general when these lancets reach the predetermined penetration depth, a return spring propels them back into

the housing with roughly the same velocity that they had on the way in. Other than a hard stop there's no way to control lancets in flight – either in or out. And other than crude depth settings, we haven't been able to control the lancet velocity to take into account how the thickness and hydration of our skin can differ from that of other people.

So until now, you literally go ballistic when you use a lancing device. That's because the lancing device mechanically triggers the lancet's ballistic launch.

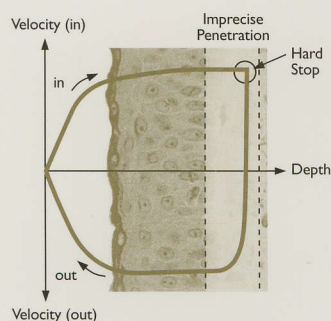
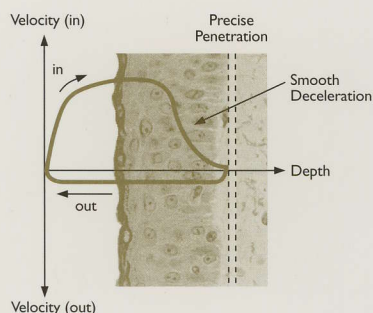
THE LATEST LANCING ADVANCE

What we have always needed is a lancing device that provides just the amount of control that we need. That's what we get with the Pelikan Sun™, which combines an electronically controlled battery-powered device with a disposable disk of 50 sterile lancets. The people who appreciated this problem and saw the solution are the founders of Pelikan Technologies and the main inventors of the Pelikan Sun™, Dr. Dominique Freeman, Don Alden, and Dr. Dirk Boecker. The company and its founders now have 15 published patents and patent applications for the Pelikan Sun™. The U.S. Food and Drug Administration has given the green light to the Pelikan Sun™ with its 510(k) stamp of approval.

GREATER COMFORT

Whether you use your fingertips or alternative sites, the Pelikan Sun™ is a

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lot more than just another lancing gadget. Of all of the Pelikan Sun's advantages – the one that I immediately appreciated most – is that whether I use my fingertips or my forearm, getting a drop of blood is virtually painless.

The greater comfort of the Pelikan Sun™ is a result in part of its electronic drive mechanism known as "Smart Lancing." This electronic system quickly and precisely drives each lancet at an individually controlled speed to the exact intended depth while minimizing vibration. The electronic drive also precisely controls the braking and removal of the lancet to avoid the painful sudden stop and with drawal that we feel when we use other devices.

Another reason why it doesn't hurt to get a drop of blood with the Pelikan Sun™ is its precise depth control. You can choose from 30 accurate depth settings, far more than any other lancing device. Cam-driven devices, like the Softclix and Multiclix, have 11, while linear-motion devices, like the Easy Touch, have no more than eight.

Other people who have tried the Pelikan Sun™ agree that nothing compares with it. Sixty-six volunteers compared how comfortable they found the Pelikan Sun™ against three leading mechanical lancing devices, the LifeScan UltraSoft, the Abbott FreeStyle, and the Roche Accu-Chek Softclix lancet devices. The Softclix was perceived as more painful in 83 out of

113 direct lancing comparisons. The UltraSoft was more painful in 82 out of 110 comparisons. And the FreeStyle was more painful in 83 out of 109 comparisons.

You don't even have to lance as often with the Pelikan Sun™. With it you can get enough blood close to 100 percent of the time. Current mechanical systems are successful between 50 percent to 80 percent of the time.

EASE OF USE

With the Pelikan Sun™ we can perform the entire lancing process in just one step at the touch of a button. This compares with a minimum of eight steps for the Soft Touch and Penlet Plus lancing devices, nine steps for the Softclix and Glucolet, to as many as 13 steps for the Microlet Vaculance.

And that's not the half of the Pelikan Sun's convenience. Because the lancets are in a disposable disk of 50, we never have to handle – or even see – lancets again, whether fresh or used. There's no need to carefully insert and then carefully remove a lancet from the device holding it, all the while being careful not to stick yourself where you don't want to be stuck.

SAFETY

In the Pelikan Sun™ each lancet is individually sealed with a foil cover to keep it sterile until you use it. Once you use all 50 lancets you just discard and replace

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the disk. Even if you wanted to, you couldn't use a Pelikan Sun™ lancet more than once.

Although it sounds convenient to reuse a lancet, with reuse it becomes blunted and less effective. Some of the comfort and benefits of the Pelikan Sun™ come from using a fresh sterile lancet each time.

Until now, these lancing problems have discouraged people with diabetes from checking their blood as much as necessary. The sad truth is that today very few of us test often enough.

In fact, I was shocked recently when I learned how little people with diabetes actually test. Three U.S. and U.K. studies in the last few years came to this conclusion. One study, the third National Health and Nutrition Examination Survey of people with type 2 diabetes, showed that only 39 percent of people using insulin test at least once a day. And only 5 to 6 percent of people treated with oral medicine or diet alone test at least that often. It's clear that once the Pelikan Sun™ comes into widespread use many more of us will be testing as often as we need in order to control our diabetes.



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LANCING DEVICE CHARACTERISTICS

SYSTEM	Pelikan Sun	Soft Touch	Penlet Plus	Multiclix	Softclix	Glucolet	Microlet Vaculance
Manufacturer or distributor	Pelikan Technologies, Inc.	Roche	Lifescan	Roche	Roche	Bayer	Bayer
Costs of device	To be determined	\$20	\$24	\$30	\$30	\$15	\$22

PERFORMANCE

Depth settings	30	2 (endcaps)	7 (integral)	11 (integral)	11 (integral)	2 (endcaps)	4 (integral)
Recommended lancet	Pelikan Disk	Soft Touch Autoclix	Fine Point	Multiclix Drum	Softclix II	Ames	Microlet Bay-lent Glucolanz
Alternative lancet	None	Various (Type A)	Various (Type A)	none	none	Various (Type B)	Various (Type A)

SAFETY

Automatic lancet retraction	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Lancet ejection mechanism	Not applicable	No	Yes	Not applicable	Yes	No	No
Prevention of lancet reuse	Yes	No	No	No	No	No	No
Sharps handling	No need	Yes	Yes	No need	Yes	Yes	Yes
Sharps disposal	No need	Yes	Yes	No need	Yes	Yes	Yes

OPERATION

Number of operating steps	2	8	8	3	9	9	13
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THE AUTHOR

David Mendosa is a freelance journalist and consultant specializing in diabetes, and lives in Boulder, Colorado. When he was diagnosed with type 2 diabetes in February 1994, he began to write entirely about that condition. His articles and columns have appeared in many of the major diabetes magazines and

websites. His own website, David Mendosa's Diabetes Directory (mendosa.com/diabetes), established in 1995, was one of the first and is now one of the largest with that focus. Every month he also publishes an online newsletter called "Diabetes Update." He is a co-author of "What Makes My Blood Glucose Go Up... And Down?" (New York: Marlowe & Co., August 2003).

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