

DIABETES CLOSE UP

Diabetes Close Up, Special Edition
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Company in Focus: Pelikan Technologies

Using technology envisioned while working at HP Labs, Dr. Dirk Boecker, Dr. Dominique Freeman and Don Alden founded Pelikan Technologies with the goal of developing a better mousetrap for the blood glucose monitoring market – i.e., superior hand-held diagnostic and monitoring devices for applications involving blood-screening and monitoring, as well as point-of-care testing and diagnostic panel test systems.

Pelikan's first approved product, the Pelikan Sun lancing device, is a self-contained, cartridge-style lancet disk containing 50 sterile lancets. It will be marketed as an electronically controlled lancing system. Their claims? A less painful, virtually hassle-free way to lance fingers and other sites to check blood glucose.

The “Smart Lancing¹” technology employed by the lancing device claims to understand the physiology of skin and boasts the ability to adjust to over 30 different depth settings, as well as having the capability to adjust instantly to diverse skin types. Because other lancing units on the market have only five depth settings, at first glance it appears that the Pelikan Sun could have an advantage from a pain perspective, although the company would not allow the product to be tested (although the product is approved), so no first-hand information on this element here. An interesting tangent: because most users do not replace lancets with every use², this would be an “automatic” aspect of this system and would thus be likely to expand the lancet market.

According to the company, the device could produce a drop of blood below a third of a microliter, currently the smallest on the market (used with TheraSense and BD meters) and possibly smaller than a human can consistently produce or even see. We've seen countless promises over the years (especially with non-invasive meters) that haven't materialized and because management wouldn't allow a test of the device, it's impossible to quantify prospects. The integrated device looks promising, assuming a partner can be found that could help market it. One downside to some users (possibly the 'on-the-go' demographic) might be the size of the lancing device – it's about the size of a cell phone,

¹ They have trademarked the term.

² Some replace as infrequently as a few times per year.

perhaps a bit wider, and definitely bigger than all currently marketed lancing devices. This is likely a barrier possible to overcome if the pain claims are accurate.

Of more interest, however, is an integrated device (unnamed as of late 2003) combining a blood glucose monitor with the Pelikan Sun lancing device. With this device, one never sees or handles a lancet or strip – this has positive implications on multiple fronts. These implications could be powerful both from a patient perspective: less pain, less hassle, potentially faster process and from a parent/clinician perspective: better accuracy. Importantly, this assumes all the technology works, no glitches, etc. In summary, the four potential benefits of the device are intriguing as a package:

- less pain (see above);
- less hassle factor – the meter is similar in size to today’s typical meters³ however there is no need to carry a separate lancet device, a vial of strips, or even a carrying case
- faster (this needs to be tested) – One step instead of seven or eight; and
- potentially better precision (no human interaction is needed to physically apply the blood to the test chemistry, and as such the accuracy of scores⁴ may be improved due to eliminating the potential for user error)

On the sales front, Pelikan plans to aggressively market to children; potential advantage in precision and safety could be even more pronounced with more-inexperienced testers, as well as being particularly attractive to parents. Pelikan anticipates a staged roll-out of its lancing device in 2004 with an as yet unnamed distributor. They plan to submit the integrated device to the FDA for approval in 2004 with a potential product launch in 2005.

If the Pelikan Sun lancing device is truly glitch-free and delivers on its pain and hassle-related promises, it could have a successful entry into the blood glucose monitoring market and even expand the market for testing. As the average insulin-dependent patient with diabetes tests ~1.5 times per day, well below the ADA recommended 4 times a day, any device that makes it easier and more pain-free to test might help raise that average. For patients with Type 2 diabetes that do not test at all, it is possible that a device like this could coax them toward some, even regular, testing.

From an investor perspective, this technology sounds interesting and how the IP is written and holds up will be important to examine. Whether the technology works (multiple errors will not be tolerated), is easy to teach (key for healthcare professional recommendation) and learn, and truly is less painful will be the key to uptake.

³ The Pelikan Sun is roughly 1.5 x 2.5 x 4 inches—a little on the large side. Though I think in some sectors such as the elderly or disabled, miniaturization can sometimes be a detriment.

⁴ Interesting tangent - on the precision/accuracy front, the conversation with management made me wonder whether these words are oftentimes used incorrectly. As CEO Boecker described it, accuracy, which depends on sensor performance, relates to whether a value is “true” or “correct”. Precision relates to whether one gets the same value over and over again. Boecker also pointed out that accuracy of volume directly influences the precision of tests. Accuracy is more critical, although absence of precision will obviously prompt loss of confidence.

Other notes on the financial front:

- **Potential expansion for the strip market:** As noted, the improvements on pain/hassle may prompt patients to test more often and as noted, could actually expand the market. This assumes there are no first-generation glitches that prompt patients to avoid product, etc.
- **More lancets used:** As earlier noted, typically lancets are reused multiple times; with this system, many more lancets would be sold per user than on average.
- **Gross margins:** Because a pile of 50 competitive strips and 50 competitive lancets involves more “substance” than the smaller Pelikan disc of 50 tests with 50 lancets, manufacturing cost could ultimately be lower with sufficient volume, at least on the integrated device. However, the lancing device costs alone are likely higher than competitive lancing devices (higher number of components, etc.) so this lancing device would not be economical as a giveaway. With some segments, this may not matter (some children, elderly); others who are used to current devices may not be willing to pay the premium for less pain. *How* much less pain is probably the key.
- **Marketing/R&D** – Whether or not Pelikan moves into partnership with an established player will clearly impact decisions on marketing spent. The diabetes market is very consumer-driven market – it is estimated that well over \$100 million per year is spent on direct-to-consumer advertising alone, up from almost nothing a decade ago.

From a patient perspective, we will have to see how the market responds to the new device from Pelikan and will pay special attention to the early user reports once the integrated device is developed. Certainly on paper, Pelikan appears to have some very interesting potential. How much more work needs to be done here before the integrated device emerges remains an open question, and really, the question of the day when it comes to Pelikan.

Kelly L. Close writes Diabetes Close Up, an occasional newsletter on happenings in the diabetes industry. A former medical technology equity research analyst, she now focuses solely on diabetes and obesity and serves as a consultant to a range of companies in these fields. If you would like to receive the newsletter, please visit www.closeconcerns.com or send a message to info@closeconcerns.com.