Pen-Based Computing

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A new tablet computer shows promise of achieving the functionality and flexibility that CT professionals require, but problems remain.

Haven’t we seen this one before? Is pen-based computing a techno-flashback or wishful thinking? It was pronounced dead in the mid-1990s. As happens with many overpublicized new products, the technology’s failure to meet users’ expectations led to the general conclusion that the technology was not functional. But the idea seemed sound. As with Don Quixote, we question the action, not the motive.

Enter Microsoft. Or rather—remember Windows for Pen computing—re-enter Microsoft. Into a quiet pen-based market the software giant has announced a prospective new entry, the Tablet PC. Although its introduction to the market is still about a year away, a prototype has drawn praise at recent demonstrations, and it seems to be reviving interest in pen-based computing. Maybe a successful pen-based computer is possible after all.

The tablet computer

Microsoft (Redmond, WA) promises the re-creation of pen-based computing (a long-treasured goal of technology visionaries) in a small handheld tablet computer powerful enough to run all existing Windows-based software.

Its tablet computer is a full-blown PC capable of replacing a laptop computer. For mobility purposes, the system weighs in at just over two pounds and is about two inches thick. It is small enough to carry in one hand, but has a 10.4 inch screen—much larger than a PDA (personal digital assistant). Systems will come with features you might expect on a reasonable laptop such as 128 MB of RAM, a 600 MHz processor, and a 10 GB hard drive. Internet access and Web browsing are supported, and much of it can be done wirelessly. The Tablet PC supports most current and emerging wireless standards. The company also added instant-on start-up functionality, a cradle for mouse and keyboard hookup, and USB (universal serial bus) connectivity to the typical peripherals.

Using a pen-like stylus, users can write on the tablet screen as if it were paper, easily adding comments to e-mail, eCRFs (electronic case report forms), checklists, presentations, or other documents. The written notes are captured as “digital ink,” so they can be sent along with the documents without the need to re-enter data on a keyboard. The system includes handwriting recognition software so that written information can be converted to machine understandable characters.

The company claims the Tablet PC will be available in late 2001. Draw your own conclusions. Once available, it will likely cost as much as a high-end laptop. Other tablet-type laptops exist now, but the software and design of the Tablet PC appear to represent advancement in the current state of the art. By adding new technology to its tablet computer, the company has created a pen-based system that just might succeed where previous systems have failed.

Success where others failed?

Microsoft has been working on pen-based computing for over a decade. Windows for Pen computing came about in the mid-1990s, presumably as an unnecessary response to the Apple Newton (Apple, Cupertino, CA). Pen Windows spawned several interesting devices and applications that served particular verticals, including clinical trials. To date, however, a pen-based system has not been truly accepted outside particular niches, and certainly not for clinical trials.

To create broader acceptance for its tablet computer, the company focused efforts on the complete user experience, rather than just adding pen support to the operating system. A tablet computer that runs all existing Windows applications provides immediate usefulness beyond traditional pen-based computing. Additionally, this new system promises to make traditional Windows applications pen-aware, perhaps allowing pen-based access to existing eCRFs. Previous pen-based efforts suffered from a limited perspective. That is, they attempted to address pen-based applications but lacked sophistication as a general-purpose system. The Tablet PC is a potential laptop replacement.

A Tablet PC extends the usefulness of laptops by creating a mobile device. Whereas laptops are portable, Tablet PCs are truly mobile. Mobility means that...
physicians can carry them into examination rooms. Wireless communication means that workers can collaborate in Phase 1 units or the ICU. Enabling wireless connection mobility for Web-browsing or network access provides one of the most significant enhancements over previous tablet computing efforts. Past attempts at tablet computers were made before the widespread acceptance of the Internet and wireless technologies.

The Tablet PC has benefited from general technology developments including longer battery life, higher display resolution, improved flat panel display technology, smarter handwriting recognition software, and improved storage technology. E-book technology, currently available in Microsoft’s Pocket PC, improves the ability to read text on the screen. Furthermore, the prices of these newer technologies have dropped to the point where they are becoming mainstream.

**Handwriting recognition.** The new tablet computer will feature much-improved handwriting recognition software. Providing reasonably reliable (robust is not yet achievable) handwriting recognition software is key to its acceptance. For a pen-based interface to be functional, handwriting recognition must work.

Microsoft is promoting the concept of digital ink as a complement to handwriting recognition. In what the company is calling “Ink as Ink,” the tablet computer will capture notes as written in an image format for storage and possible interpretation by handwriting recognition software. Users will be able to mix digital ink with traditional electronic documents. Imagine making true, handwritten margin notes on your eCRF.

Digital ink and handwriting recognition will support international character sets. Interestingly, Chinese characters are better for handwriting recognition than English characters, because they require specific stroke order and design. In English, unique writing styles make handwriting recognition much more challenging.

With the continued acceptance of eCRFs and EMR (electronic medical record) systems for capturing data, much less handwriting recognition is necessary. Pick lists or sets of option buttons are more commonly used than text entry for data captured on electronic forms. Some of the most practical uses of the tablet computer will be for signature capture and completing eCRFs with checkboxes, radio buttons, and drop-down lists. Navigating Web-based systems, like clinical portals, also requires little text entry. Keep in mind that the pen is mightier than the mouse, not the keyboard. Pen-based direct manipulation of the interface is much easier than using a mouse, especially for novice users.

Capturing information at the point of care could eliminate much of the redundant data capture performed in today’s clinical trial process, but it necessitates providing a quick and mobile solution. Often, conducting data capture with a patient means scribbling information quickly in an abbreviated form. Pen-based tablets are an efficient form for this mode of data capture.

Adding speech recognition software to the tablet computer may add an additional convenience for data capture. Many consider speech recognition to be the Holy Grail of data capture. But, it is clearly not appropriate for all situations and must be complemented by other modes of data capture. Like handwriting recognition software, speech recognition software is much improved, but not yet a completely robust solution.

**Challenges facing the Tablet PC**

**Skepticism for starters.** Pen-based computing has come and gone, leaving many early adopters wary of the excitement generated by this new breed of tablet computing. The Tablet PC must convince clinical users of undeniable improvements over previous generations.

Let’s face it, it’s not paper. The tablet form is notoriously difficult to get right. A paper pad is thin, flexible, has great resolution, doesn’t break when you drop it, requires little user training, makes battery life a moot point, and costs next to nothing. The Tablet PC, while small for a PC, is two inches thick and weighs over two pounds (Microsoft insiders say thinner, lighter versions are in the works). It’s also much less mobile than its PDA cousins, although arguably more capable.

**Durability.** The tablet computer will need to be rugged to stand up to the rigors that a mobile data capture system will face in a typical health care setting. Dropping a pad of paper causes only a minor inconvenience; dropping laptops can be catastrophic.

**Writing surface.** A more subtle difference from paper is the writing surface. Many people find that the smooth computer display surface of the tablet computer makes a poor writing surface. It can make bad handwriting worse. Examine your signature the next time you sign an electronic pad, if you need further evidence of this. Pens are better for drawing and direct manipulation, but tend to be inferior for textual communication.

**Keyboard preference.** Even if handwriting-recognition technology were in a mature, stable state—which it is not—handwriting, for many workers, is no longer the preferred mode of capturing text. People who entered the workforce using a computer often find they type faster and more legibly than they scrawl longhand. Consider the recent success of Research in Motion’s (Waterloo, ON, Canada) Blackberry wireless handheld. Why is it such a tremendous hit? It is wireless, but two-way wireless messaging has been around for years with numerous failures. The Blackberry supports exceedingly basic PC integration, works poorly with documents, and certainly lacks the benefit of a wealth of third-party
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To see people typing e-mail into their PDA

rather than struggling with weak handwriting recognition.

For many of us the pen may be an able substitute for the mouse, but certainly not for the keyboard. Thus, for the tablet computer to be truly accepted, it must accommodate multiple forms of data capture: keyboard entry, handwritten, and perhaps even speech recognition. Microsoft claims support for multiple input modes including a cradle for mouse and keyboard, a virtual keyboard, single-stroke characters, handwriting recognition, and speech recognition.

Text entry options. As for speech recognition, if you find cell phone chatter annoying, think of sitting on the train surrounded by tablet-toting monitors navigating a virtual stack of eCRFs via speech. Privacy issues will limit the applicability of speech recognition. Clearly, physician dictation has value, but other modes of data entry are required when discretion is necessary. Again, multiple modes for text entry and system manipulation provide the optimal solution.

Considering the use of a tablet computer for clinical trials raises a host of data management concerns. For example, an eCRF benefits from the manner in which it controls and structures the data entry process. With the addition of digital ink, data reviewers will again have to contend with margin notes, illegible handwriting, language captured at the point of care is often unstructured, unwanted, and coded in a nonstandardized fashion. Furthermore, the data edits and exception ranges established for a point-of-care system would not necessarily match those configured for a specific clinical trial. Of course, if the tablet computer is not being used for point-of-care data capture, then there will be a necessary transcription process which is best performed at a keyboard. Pen-based systems are inadequate for intensive data entry.

Validation and regulatory issues. The tablet computer, as with any new technology, will encounter computer system validation and regulatory issues. For example, if margin notes can be scribbled on an eCRF, how does the data capture system maintain a proper audit trail? Clinical data created with digital ink would encounter the same electronic recordkeeping regulations that traditional systems do.

It’s possible that despite all the improvements and new technology, the Tablet PC still does not support enough functionality to match a physician’s or other clinical trial professional’s day-to-day activities. Paper, although difficult and expensive to manage, is a remarkably flexible medium.

Tablet computers and clinical trials

So, is making a PC act like a notepad akin to making a car act like a horse and buggy? Is this just a giant PDA? Each

new generation of pen- or tablet-based computing has uncovered a new list of success criteria previously unknown. New requirements are discovered as physicians, site coordinators, and data reviewers begin to use the technology as part of their daily activities.

The Tablet PC appears to have key features and technologies not available to previous pen-based efforts. If it has at least one significant benefit not offered by a laptop, then it will be used and improved. Predicting the demise of paper in physicians’ practices or in clinical trials is certainly not original. And it’s not expected that the tablet computer will effect changes of this scope. It appears capable, however, of making slow inroads toward replacing its paper counterparts for selected health care tasks, including clinical trials. ❑

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