

The Use of Microsoft Windows® CE in the Development of the ABL™77 Point-of-Care Analyzer

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Abstract

The Point-of-Care Testing (POCT) environment presents challenges for clinicians and developers of the new generation of portable devices. As usage conditions and regulatory requirements continue to evolve, POCT devices must meet these new demands with flexibility while maintaining ease-of-use.

The portable ABL™77 blood gas and electrolyte analyzer (SenDx Medical, Inc., A Radiometer Company, Carlsbad, California) was designed for this dynamic POCT market. The operating system for the ABL™77 is Microsoft Windows®, CE. User familiarity with this Microsoft Windows® based program facilitates training and increases the level of comfort and confidence for the end-user of the device.

Windows CE also provides a familiar platform for the developer which helps reduce the time and cost of programming. It is a compact, highly efficient, scalable operating system (OS) designed for a variety of embedded systems. It is a 32-bit Unicode multi-threaded and multi-tasking OS built from the ground up. Windows CE supports numerous hardware peripherals, devices, and networking systems including touch panels, serial ports, Ethernet connections, modems, universal serial bus (USB) devices, audio devices, parallel ports, and storage devices such as PC cards. On the ABL™77 analyzer, the user interacts with the system via a fully active TFT color screen (5.25 x 3.9 inches). The computer hardware consists of an embedded single board computer, a liquid crystal display, a touch panel, and various peripherals, including an Ethernet port.

Windows CE supports internationalization and localization of languages. This allows the ABL77 to be available in languages such as Japanese, Chinese, Arabic and Slavic variations in addition to languages in Western Europe. This feature is essential to satisfy local regulatory demands and provide added ease-of-use.

Windows CE also supports most common Microsoft Win32, Application Programming Interfaces (API's). These API's are similar to the API's on Windows NT and Windows 9x. It also supports programming interfaces that include Component Object Model (COM), Microsoft Foundation Class (MFC), Microsoft ActiveX Controls, and Microsoft Active Template Library (ATL).

Windows CE was selected for use in the ABL™77 because of its versatility, compact size and its ability to be easily customized. The reduced time and cost of programmer development results in increased flexibility, an ideal quality in POCT applications, offering the clinician a device capable of responding rapidly to changes in market demand.

Introduction

Point-of Care (POC) instrumentation requires certain attributes to be implemented successfully by clinical laboratories and accepted by clinicians. Among the required attributes are accuracy and precision, operational cost, sampling ease-of-use, menu flexibility, and IT connectivity. No current POC device completely fulfills this entire list of requirements. Some device manufacturers have made a trade-off between size and functionality. The need for smaller devices in POC locations has resulted in fewer features and reduced functionality. However, many device manufacturers are making great strides to deliver more portable systems with enhanced functionality. One such analyzer is the ABL™77 blood gas and electrolyte analyzer (SenDx Medical, Inc., Carlsbad, California. A Radiometer Company).

The software flexibility and hardware peripheral capabilities of a POC device are often limited by the operating system (OS). To overcome these historical limitations, the ABL™77 uses Microsoft Windows® CE for the benefits it offers the user and developer. Windows CE was selected because of the platform's overall compatibility with the needs of the ABL77 development project. Windows CE allowed for the development of a battery operated, stand-alone, portable system that must support the clinical and

technical needs in the POC environment. The international requirements for the analyzer were also supported by Window CE.

The interface of Windows CE is very familiar to users of PC-based Windows programs. Message boxes, icons, text and bitmap buttons, drop-down list, radio buttons and check boxes characterize this user familiarity (Figures 1-3). The comfort with this familiarity reduces product training time and encourages the users to confidently interact with the analyzer by entering and recalling information, and by analyzing samples easily and quickly.

The laboratory or POC manager controls the level of user interaction with the ABL77. Windows CE allows the developer to structure the system with a high degree of flexibility. As an example, with the Access Profile Setup Program (Figure 4) the POC manager determines a user's level of access to the many functional options and user actions. This design ensures a high degree of system control through user lockout and QC lockout in the POC environment.

Methods

Anticipating the needs of the dynamic and varying demands at the POC within a hospital, Windows CE supports a wide variety of peripheral options. These may include integral or detached printers, keyboards, barcode scanners, video ports, Universal Serial Bus (USB), serial ports, and ETHERNET. Although many of these options would not be used at or near the bedside with POCT, their potential availability does increase an analyzer's overall flexibility for the laboratory.

During the ABL77 development, a key objective was to meet the requirements for connectivity and communication at or near the point-of-care (Figure 5). Site-specific and instrument-specific communication protocols continue to cause implementation difficulties for POCT. The variation of non-uniform protocols does not allow for "plug-and-play" of new instrumentation and can often cost a hospital thousands of dollars to resolve through the consumption of internal resources and time.

Figure 1. Main Menu with pop-up menu.

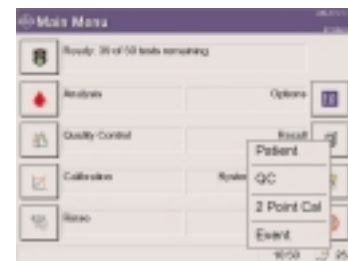


Figure 2. Message text and radio buttons.

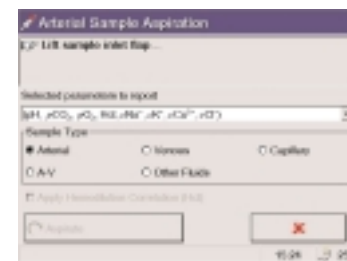


Figure 3. Drop-down list.

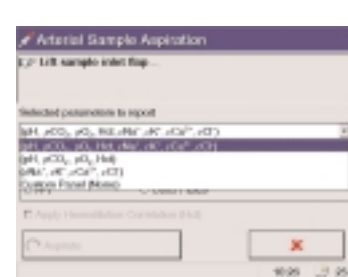


Figure 4. Access Profile Window with check-boxes.

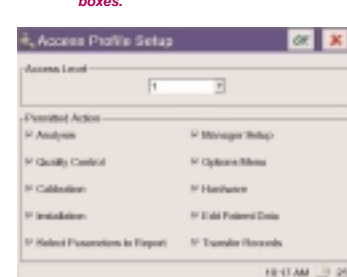


Figure 5. Network Setup screen.



Figure 6. Japanese language Main Menu.



Figure 7. Danish language Main Menu.



The concept of plug-and-play instrumentation for the POC still does not exist. The Connectivity Industry Consortium (CIC) is working hard to standardize the communication between POC instruments and LIS/HIS systems. Windows CE allows the ABL™77 software design team to respond quickly to unique communication protocol requirements of some facilities. When the particular protocol is understood, it can be programmed and forwarded to the IT/LIS manager of the hospital and installed on the ABL™77 in minutes. ABL™77 developers can respond rapidly and effectively to the needs of each hospital. If a facility's current LIS/HIS requirements for uni-directional or bi-directional communication with the analyzer are specified, ABL™77 software developers can respond to help reduce the frustration of implementing a new POC system.

The European Union (EU) is establishing significant requirements for in-vitro diagnostic (IVD) manufacturers. Several of these requirements are for labeling and user software. In the selection of the ABL™77 OS, significant attention was given to developing simple methods to release multiple language version of ABL™77 software. Windows CE supports a wide range of languages, which allows the ABL™77 software developer to support demands from international markets. With Windows CE, the developer has to maintain only one source code with a unique resource file for each language. The link for the resource file to the source code is through a Microsoft Access database.

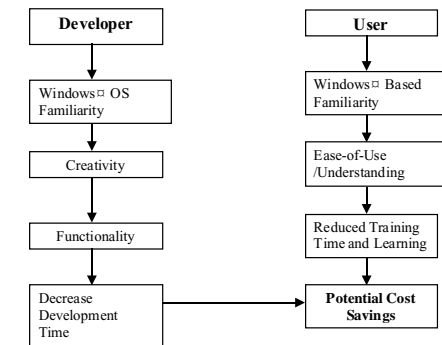
This structure has significant advantages in the translation process for additional languages. The text strings of the software are extracted and stored in the database. The database is then e-mailed to the country specific translator for translation of new text strings. Because of Windows CE flexibility, a new version of software can be compiled

and returned to the translator within 15 minutes of receiving the text string translations (Figures 6 and 7). Because of this flexibility, the software developer can rapidly respond to local language requirements throughout the world.

There is an additional intangible benefit with Windows CE as the operating system for the ABL™77. The analyzer's functional requirements and touch screen dimensions are the only limits to the software developer's creativity. The developers for the ABL™77 have found that the time it takes to characterize and implement product specifications is dramatically reduced which results in significant cost savings to development (Figure 8).

From the user and POC manager perspective, the familiar Windows format and functional icons reduce the need for prolonged or repetitive training. Users quickly grasp the logic of the system and easily maneuver about their access level defined fields. This familiarity and comfort with the system can shorten the learning curve and reduce unnecessary repeat training. This in-turn can reduce variable operational cost of some POC testing.

Figure 8. Some potential advantages for using Windows CE operating system.



Conclusions

The continued growth of POCT will put new demands on the users and developers of POC systems. To fulfill the variety of lockout and connectivity requirements, device manufacturers must find ways to make the system feature-rich without appearing complex or intimidating to the user. POCT systems that measure and report multiple parameters simultaneously face even greater challenges: designing the instrument small and portable and keeping the user interface simple.

The acceptance and implementation of POCT will rely on more than the accuracy and precision of test results and technical ease-of-use. The expectation will be that the instrument interface must be flexible to meet all the POC manager's requirements while offering enough structural familiarity and ease-of-use for the clinicians who use the system at the POC.

Utilizing an operating system such as Windows CE gives this flexibility not only to the user but also to the software developer charged with the responsibility to fulfil these requirements. When there is minimal complexity for both the software developer and the user, each can anticipate operational cost savings over time.

These same requirements hold true for countries exploring and expanding POCT around the world. Using Microsoft Windows CE on the ABL77 or other instrumentation will allow manufacturers to respond efficiently and deliver software applications familiar to a majority of users who are moving urgently required testing near the patient's bedside.