



## **PC/104-BASED MEDICAL SYSTEM DESIGN**

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### **THE MEDICAL ELECTRONICS CHALLENGE**

Designers of tomorrow's medical equipment face a dazzling set of opportunities and challenges, both technological and logistical. Continual discoveries and developments in basic science — including physiology, biochemistry, biophysics, etc. — provide the opportunity to create entirely new types of medical devices as well as to enhance existing ones.

Equally significant, is the potential offered by the dramatic evolution of computer hardware and software technologies over the last decade. Powerful microprocessors, coupled with exploding capacities of program and storage memory, supported by highly advanced software environments, enable vast increases in the sophistication of patient monitoring, process control, and data analysis. What in the past required the resources of a mini or mainframe computer, can now be embedded directly within a medical instrument. Complex medical equipment can be made "user friendly" by virtue of highly intelligent graphical user interface software.

An important additional challenge uniquely facing medical system developers, however, is the need to comply with a host of product safety and regulatory requirements and restrictions. Each new product must be skillfully and efficiently guided through a maze of complex and time-consuming agency approvals.

How can medical equipment designers take maximum advantage of advances in technology, yet bring new products to market in a timely manner and within budget constraints? One solution is to cleverly combine product-specific *proprietary* hardware and software along with appropriate *off-the-shelf* embedded-computer hardware and software "building blocks."

### **EMBEDDED COMPUTER EVOLUTION**

Embedded computer technology has come a long way. Since the birth of the microprocessor in the mid-1970s, there has been continuous exponential growth in CPU performance and memory capacity — for both program execution and data storage. By the '80s, a few megahertz and a few kilobytes were the norm. By the '90s, this became tens of megahertz and tens of megabytes. Currently, embedded computer CPUs are clocked at up to 200 MHz, RAM capacities are beginning to surpass 64 megabytes, and mass storage is commonly measured in gigabytes!

As embedded computer speeds and memories grow ever larger, embedded applications become increasingly decoupled from the underlying embedded computer *architecture*. As this occurs, the real “magic” of the embedded system is in its unique software, interface technology, peripherals, and packaging. The result of this trend, is that developers now spend much more of their time being *medical product* architects rather than *embedded computer* architects.

The embedded computer is therefore increasingly perceived as a platform on which to run the application’s software and it is consequently most often *software*, not *hardware*, that represents the greatest technology concern and risk. The preferred embedded computer architecture is now typically that which optimizes the application’s software development process, resulting in faster development cycles, reduced technical risks, and improved system sophistication. In today’s fast-moving and competitive market for technology-based systems, any and all efficiencies are greatly welcomed. This is especially relevant to medical equipment development, which is burdened by so many compliance and regulatory concerns!

An obvious way to increase the efficiency of embedded system development is to employ standardized — even off-the-shelf — hardware and software building blocks, if available. This would minimize the need to design from scratch. How can this be accomplished? In response to this question, embedded system development teams have looked to the highly popular PC architecture to provide a standardized hardware and software toolkit.

## THE ALLURE OF PC COMPATIBILITY

The enormous popularity of the PC architecture (“over 300 million sold”) has generated a vast resource of *desktop* software and hardware. Can these be successfully adapted to medical systems? If so, billions of dollars in R&D investment could be harnessed for the benefit of the medical electronics market. Here are some of the key desktop PC technologies of interest . . .

- ◆ **CPUs** — driven by the high volumes of the desktop market, the “Intel architecture” (“x86”) CPUs offer the best microprocessor price/performance ratios available. Multiple CPU vendors constantly vie with each other for faster and cheaper chips, with the result that the speeds and features continually go up, yet the prices stay roughly the same. Today’s 64-bit Pentium processors cost little more than yesteryear’s 16-bit 8086s.
- ◆ **Operating systems** — a wide range of choices, including DOS, Windows 95, and Windows NT from the desktop PC world, as well as many real-time operating systems (RTOSes), support the desktop PC “standard”. Importantly, it’s not necessary to “port” a RTOS to a system that complies with the PC standard, since most RTOSes already support the PC.
- ◆ **User interfaces** — one of the areas of greatest emphasis for product differentiation in the desktop PC world has been ease-of-use and richness-of-display. Consequently, there have been great advances in “graphical user interface” (GUI) capabilities, both from the software and hardware perspective. Display devices, including CRT monitors and flat panels (e.g. LCDs), have evolved greatly in both resolution and color depth, even though prices have decreased. GUI software is now a standard feature of the OS itself (e.g. Windows); GUI acceleration hardware is a standard function of the display controller ICs.
- ◆ **Mass storage** — PC hard disk controllers have become obsolete, absorbed by the disk drive itself (IDE). Exponential growth in demand for hard disk capacity, fueled by blindingly fast

PC CPUs coupled with increasingly complex operating system and application software, has generated the hard disk R&D budgets necessary to simultaneously shrink costs and explode capacities (now in the gigabytes). In addition, investments in “solid state” storage technologies, needed for reliable laptop and notebook PC operation, have also yielded dividends in the form of cost-effective “Flash” memory technologies. Another important mass storage development from the desktop PC market is the CD-ROM: it offers extremely high data density and durability, at very low cost; and it connects directly to a PC’s IDE interface without requiring an additional controller.

- ◆ **Communications and networking** — as the speed, memory capacity, and functional sophistication of the desktop PC increases, vastly larger quantities of data need to be communicated and shared. RS232C serial interfaces, the standard in the past, are no longer adequate. In response to this growing need, great strides in both wired and wireless communications technologies have been made. Modem speeds double annually and have now attained rates thought impossible a few years ago. Ethernet, implemented within a single chip, is rapidly replacing RS232C as the standard computer-to-computer “serial” communications port. “Plug-and-play” software drivers that support the popular PC Ethernet controller chips are included within Windows 95, Windows NT, and most RTOSes.
- ◆ **New system interfaces** — a variety of new interfaces and peripheral devices have evolved to support the needs of desktop and laptop PCs. IDE, SCSI, and PCMCIA are all readily available and relatively mature, though all three continue evolving in capabilities and throughput. Newer arrivals include the enhanced parallel port (IEEE 1284) as well as two new high speed serial interfaces: Universal Serial Bus (USB), and FireWire (IEEE 1394).
- ◆ **Development tools and support** — not to be underestimated is one of the greatest benefits of using a PC architecture: the rich assortment of tools and support. Books and magazines document all aspects of the PC’s hardware, software, and applications. Development tools for the PC platform are plentiful, cost-effective, and easy to use. Nearly every engineer, programmer, and technician is knowledgeable in the use of PC hardware and software.

A PC-compatible hardware/software architecture certainly can bring great savings to development time and costs, reduce product material costs (due to less expensive chips and peripherals), and minimize maintenance and support headaches. These are the key reasons why the PC architecture is increasingly being designed into embedded applications of all types. Medical control and instrumentation applications are certainly no exception to this trend!

## **UNIQUE REQUIREMENTS OF THE MEDICAL MARKET**

Clearly, PC technology offers many exciting possibilities to medical system developers. However, embedded systems in general — and especially medical applications — place severe demands and constraints on their internal electronics that are not applicable to desktop PCs.

In the PC market, price pressures severely constrain reliability, ruggedness, quality, and product longevity. After all, the main objectives of desktop PC manufacturers are to minimize cost while continually incorporating the latest new technologies, in an effort to sell as many systems and system upgrades as possible. This results in low cost, minimal quality, and extremely short product life-cycles.

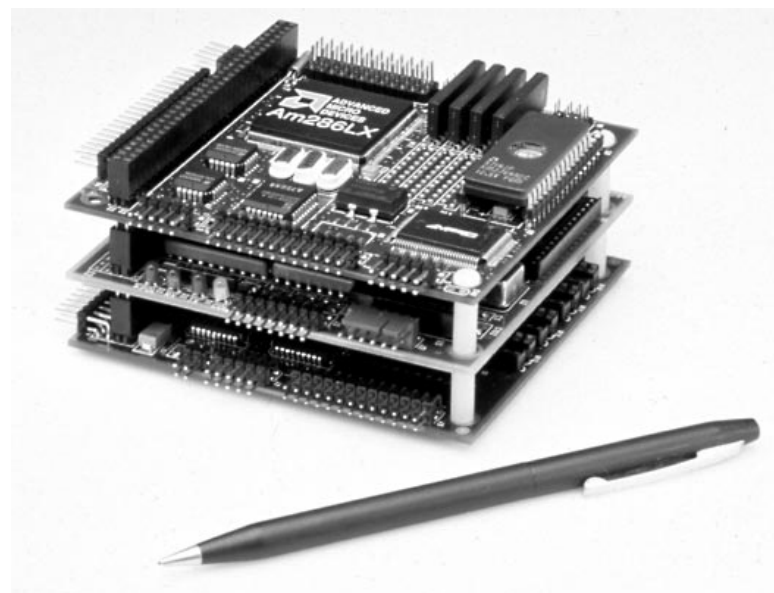
Embedded computers, especially for the medical industry, must satisfy a whole different set of objectives — most of which run counter to the priorities of the desktop market. These include:

- ◆ **Size and weight** — space is especially precious in systems destined for medical environments, which are often laboratories, emergency rooms, doctors' offices, hospital rooms, or ambulances. Therefore, although today's embedded computer may be an embedded-PC, it typically needs to fit in the tight spaces where single-chip microcontrollers used to go. So an embedded-PC needs to be as compact as possible. Weight, too, is an important factor if the equipment is intended for portable or mobile use.
- ◆ **Power consumption** — system reliability is reduced by high heat buildup. Therefore, when replacing yesterday's microcontrollers with today's powerful embedded-PCs, it's important to minimize power consumption. Of course, power consumption and heat generation are even bigger problems in portable or mobile systems.
- ◆ **Shock and vibration** — whether intended for fixed or mobile use, each medical product must still be transported from where it's made to where it's used. Desktop-PC motherboards and plug-in cards are notorious for needing adjustment by a trained technician after delivery, prior to use. This is not acceptable for embedded electronics, which is not expected to require service after simply being shipped to its destination. In the case of portable or mobile systems, the electronics will undergo a wide range of gentle and harsh motions, during both operation and storage. Large and small repeated movements subject components, connections, and solder joints to continual mechanical stress. Chips, modules, and boards may become partially or fully dislodged or disconnected. Connector pin conductivity can be degraded by corrosion due to electrochemical effects that are exacerbated by vibration. Ordinary disk drives may be inappropriate for program loading or data storage in these applications, so "solid state disks" may need to be substituted for ordinary disk drives.
- ◆ **Operating temperature** — most medical systems are used in relatively benign environments. Embedded electronics intended for indoor purposes is typically rated for operation at up to 55° C. However, the system enclosure might need to be fully sealed, for example to protect against spilled liquids such as blood or chemicals. In such cases, air vents and cooling fans may not be permissible. The result is elevated internal temperatures, which probably requires the embedded electronics to be rated for operation up to 70°C. In mobile or portable equipment, an "extended" operating temperature" of -20 to +80°C may be called for.
- ◆ **EMI, ESD, and power supply irregularities** — electrostatic and electromagnetic interference, both generated and received, are key concerns in medical applications. High frequency microprocessor clocks, which for PCs commonly fall in the range of 33 to 166 MHz, can easily interfere with low level signal detection or stimulus generation. Also, medical systems often must operate in the presence of strong electromagnetic emissions from other nearby devices. Therefore, the embedded computer electronics must be designed with high noise immunity and low noise generation. Consideration must also be given to conductive radiation and susceptibility on power supply and I/O connections. Undesired system resets and data loss must, of course, be prevented; but the potential danger to humans from high levels of electric, electrostatic, or electromagnetic emissions is a far greater concern in medical applications and requires extreme preventative care.

- ◆ **Quality & Reliability** — naturally, the required level of system quality and reliability depends on the particular application. The equipment can be used for non-critical information data entry or retrieval; or it can be performing life-critical patient monitoring, blood chemistry control, etc. However, it is categorically safe to say that medical users are never as forgiving of system malfunctions or crashes as are the users of desktop PCs. Practically every PC user experiences messages like “Press F1 to Continue,” or “Fatal error #XYZ,” from time to time. Yet hardly anyone is willing to pay a significant price penalty for a substantially more reliable *desktop* PC. What may be “acceptable” on the desktop, is totally unacceptable in medical equipment — and with consequences ranging from loss of data to loss of life!
- ◆ **Product life-cycles** — here, too, the priority of the desktop-PC user runs counter to the best interests of medical equipment manufacturers. Desktop PC vendors strive to bring out new technologies constantly, in order to sell upgrades to their existing customer base. It’s often said that the typical “half-life” (to obsolescence) of PC chipsets is around three “Comdexes” (1 Comdex = 6 months). Clearly, whereas it may be in the best interest of PC manufacturers to sell everybody a new PC (motherboard, video card, disk controller, network controller, etc.) every year or so, this situation represents an unacceptable risk for manufacturers of medical equipment. Since medical products typically take two or more years to develop, plus several more years to gain FDA approval, medical designs cannot sensibly be based on components with life-cycles as short as 18 to 24 months!

Unfortunately, there is little incentive for manufacturers of desktop-PCs to cater to these important requirements of medical system developers. Doing so would be suicidal in the cut-throat consumer market!

## THE PC/104 ALTERNATIVE



**Figure 1. PC/104 modules are compact, rugged, and self-stacking.**

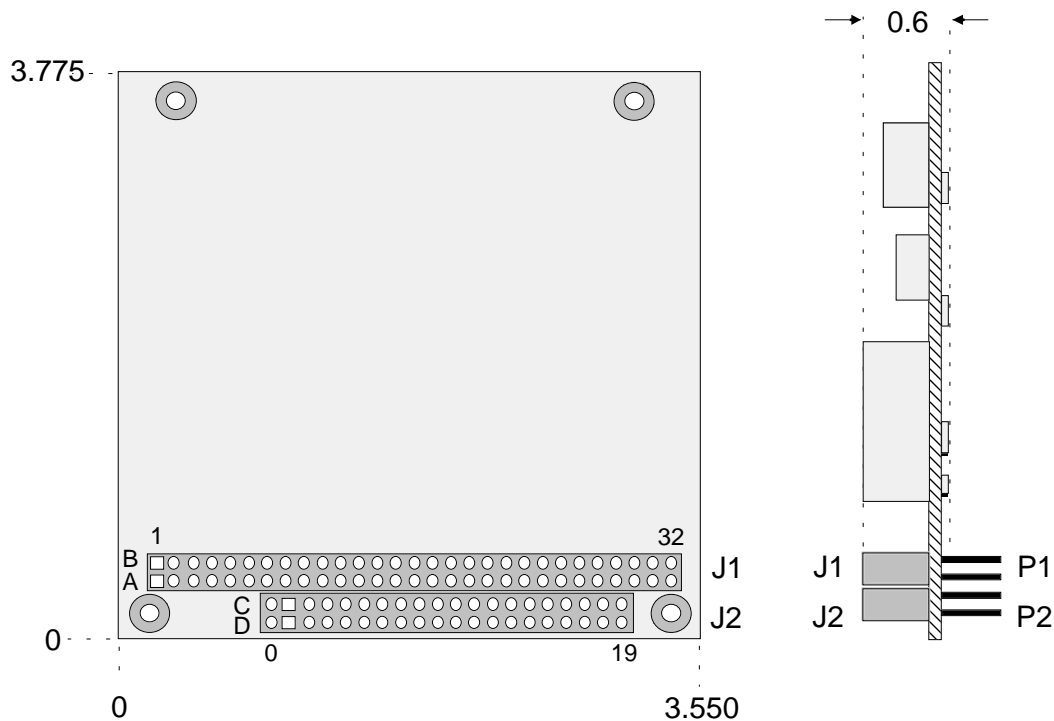
Given the potential benefits of using a PC-compatible hardware/software *architecture* in an embedded system design, but in light of the shortcomings of normal desktop PC systems relative to the needs of the medical electronics market, is there anything else that can allow medical system designers to take advantage of PC technology?

Fortunately, the answer is “yes.” The PC/104 Embedded Computer Modules standard was introduced by Ampro in 1992, specifically to provide a modular building-block method of incorporating PC hardware and software

technologies into embedded systems. PC/104 modules are intended for a wide range of application environments — including fixed, portable, and mobile environments — in a broad variety of non-desktop embedded system markets.

Basically, PC/104 defines how to repackage desktop PC functions in a manner that satisfies the ruggedness, reliability, and size constraints of embedded systems. PC/104 offers full hardware and software compatibility with the desktop PC architecture, but in the form of compact (3.6" x 3.8"), self-stacking, modules. PC/104 therefore offers a way to incorporate a PC-compatible architecture into an embedded system, based on off-the-shelf building blocks.

Prior to the availability of PC/104, the options for embedding a PC architecture were to use a motherboard- or backplane-based approach, which is bulky and unreliable, or to create a custom embedded-PC based on individual chips, which is costly and time consuming. PC/104 modules are small enough to fit where a backplane-based approach won't (see Figure 2), so they provide an excellent space-efficient "middle ground" for many embedded applications.



**Figure 2. Basic mechanical dimensions, 16-bit PC/104 module.**

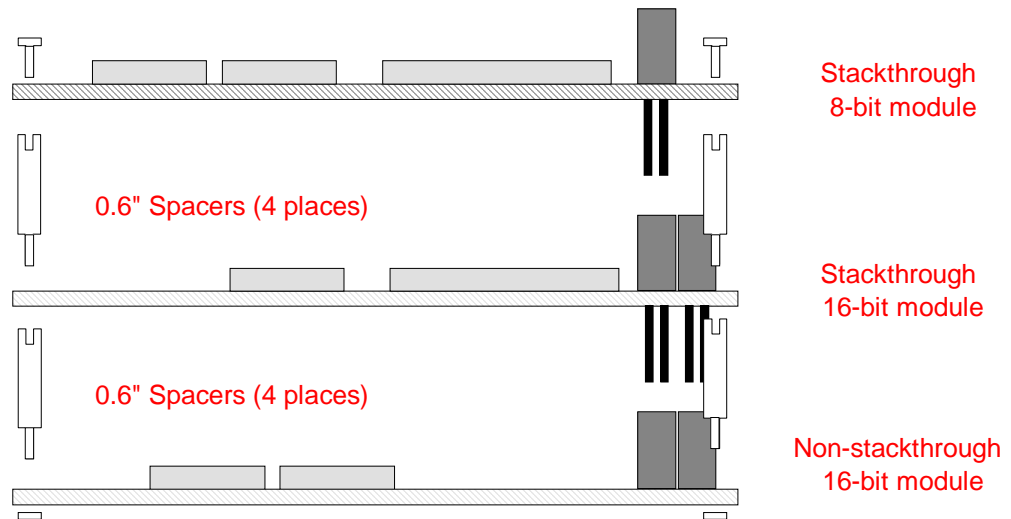
## AN OVERVIEW OF THE PC/104 STANDARD

The differences between PC/104 and the "normal" PC are primarily mechanical. There are no software differences. Here is a summary of what is contained in the PC/104 specification . . .

- ◆ **Miniature form-factor** — Instead of the usual PC or PC/AT expansion card form-factor (12.5 x 4.8 in.) each PC/104 module is just 3.550 by 3.775 in. There are two bus formats, for 8- and 16-bit modules. Unlike the 8- and 16-bit expansion cards of desktop PCs, both

PC/104 versions are the same size, except the 8-bit version omits the P2/J2 bus connector.

- ◆ **Self-stacking bus** — To eliminate the complexity, cost, and bulk associated with conventional motherboards, backplanes, and cardcages, the PC/104 expansion bus is based on a unique self-stacking (“stackthrough”) bus connector. Multiple modules stack directly with each other, as shown in Figure 3. Stacked modules are spaced 0.6 in. apart and are securely attached to each other by four standoffs.



**Figure 3. How PC/104 modules stack.**

- ◆ **Pin-and-socket connectors** — Rugged and reliable 64- and 40-position male/female “header” connectors substitute for the standard PC motherboard’s 62- and 36-position (P1 and P2) edgecard connectors. The PC/104 bus connectors contain gold plated pin-and-socket contacts on 0.1 in. centers.
- ◆ **Bus signal function and pin assignment** — All PC/104 bus signal functions are identical to their counterparts on the desktop-PC bus. Their assignments to the one hundred and four locations of the PC/104 bus connectors is defined in the *PC/104 Specification*.
- ◆ **Reduced Bus Drive** — To help lower power consumption (to several Watts per module) and also to minimize chip count, bus drive was reduced from 24 mA (the IEEE desktop-PC spec) to 4 mA. This permits “HCT” logic and many VLSI ICs to drive the bus directly, without additional buffer chips. An additional benefit of this reduced bus drive is reduced radiated electromagnetic emissions. Note that, despite its modest bus drive, PC/104 can typically support up to eight interconnected modules in an embedded system.

Although not explicitly included in the above list, an important additional advantage of PC/104 modules is that they are not at all intended for the *desktop* market, but are meant for use as *embedded* components within a wide range of OEM products. Therefore, the suppliers of PC/104 modules generally concentrate on providing the quality, reliability, service, and support demanded by this customer base.

As indicated in the table below, PC/104 modules satisfy many of the needs of the manufacturers of medical systems and of the environments in which medical products are used.

**Table 1. Summary of Typical PC/104 Module Specifications**

<b>Factors Important to Medical System Design</b>	<b>Typical Characteristics of PC/104 Modules</b>
Size	3.550 x 3.775 x 0.6 in.
Weight	2 to 3.5 oz.*
Power consumption	1 to 5W*
Shock	50G 3-axis peak (per MIL-STD-202F, Method 213B, Table 213-1, Condition A)
Vibration	11.95G 3-axis RMS at 100-1000Hz (per MIL-STD-202F, Method 214A, Table 214-I, Condition D)
Operating temperature	0 to +70°C, standard -40 to +85°C, extended
Storage temperature	-55 to +85°C
Humidity	5 to 95%, non-condensing
EMI compliance	EN 55022 Class B (radiated & conducted emissions)
EMC and ESD compliance	IEC 801-2 (electrostatic susceptibility) IEC 801-3 (E/M field susceptibility) IEC 801-4 (fast transient susceptibility)
MTBF	ground mobile, at 55°C: 30,000 to 70,000 hrs.* ground fixed, at 55°C: 150,000 to 650,000 hrs.* (per MIL-HDBK-217)
Product life-cycle	Module family life-span: 10+ years Individual module life-span: 5+ years
* These values vary according to the specific module.	

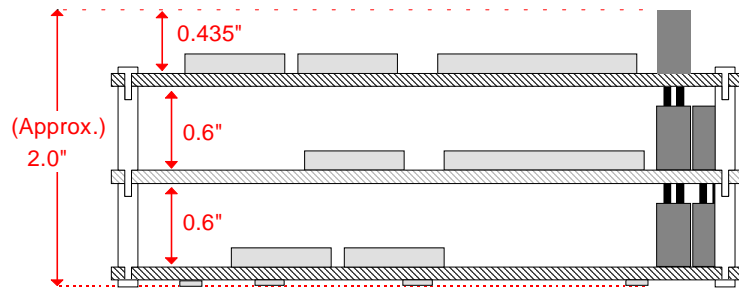
## HOW PC/104 IS TYPICALLY USED

Although configuration and application possibilities are practically limitless, there are two basic ways PC/104 modules are generally used in actual medical systems.

### Module Stacks

PC/104 modules are often used like ultra-compact backplane-bus boards, as illustrated in Figure 4, except that the modules stack directly together without needing the backplanes and card cages of traditional bus-based solutions. Highly compact PC/104 stacks can thus be “bolted” directly within a medical system’s enclosure, in an otherwise empty space. In this manner, the equivalent of an entire PC is often *embedded* directly within a system that might previously have required an

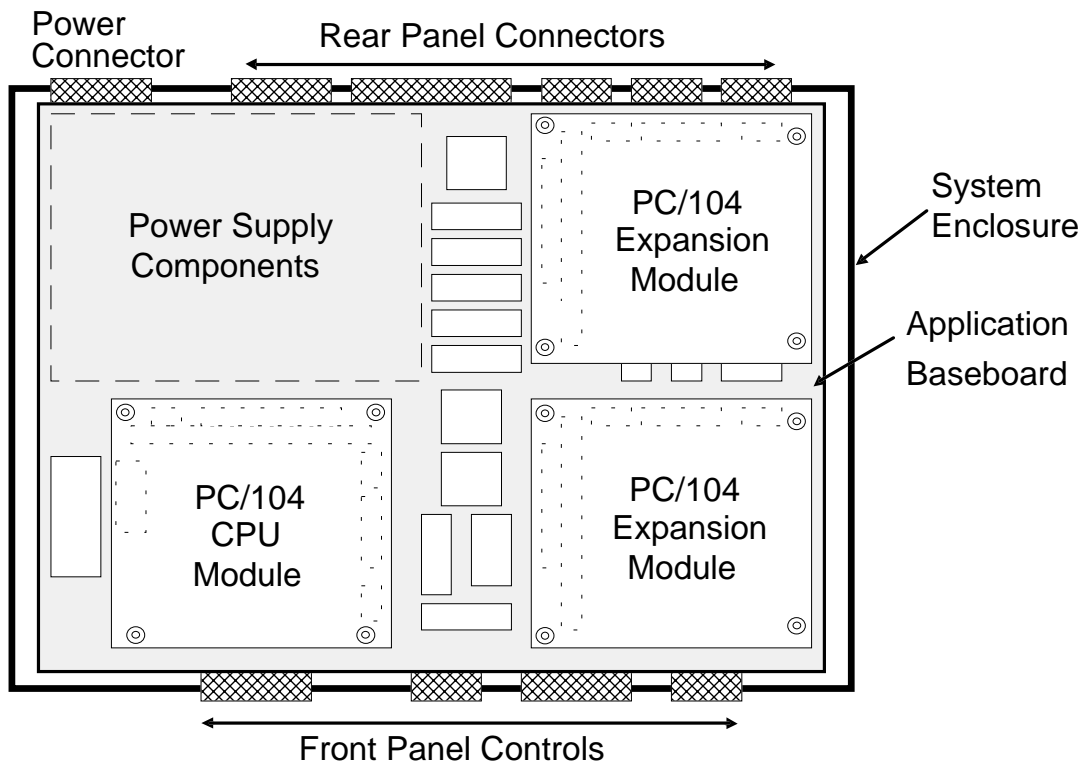
external, *attached* PC for its operation. PC/104 stack enclosures are available from a number of vendors, for packaging PC/104-based subsystems in both fixed and mobile environments.



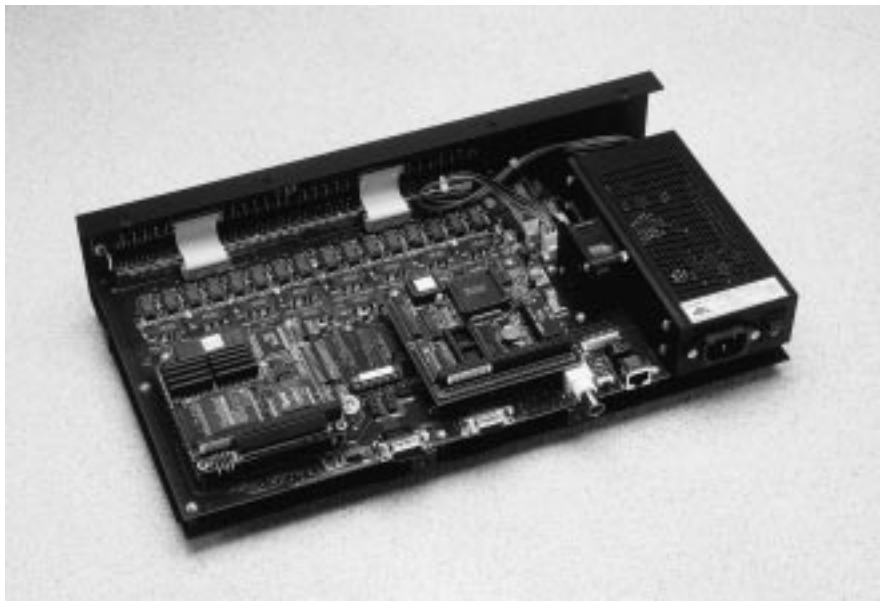
**Figure 4. Typical PC/104 Module Stack**

### Macrocomponents on Application Baseboards

Despite the popular image of a stack of PC/104 modules equivalent to a desktop PC, that fits comfortably in the palm of your hand, most PC/104-based system designs aren't actually based on a stacked approach. Instead, PC/104 modules are frequently distributed *horizontally* — plugged into custom, “application baseboards” like multi-chip “macrocomponents.” This approach is shown in Figure 5.



**Figure 5. PC/104 “Macrocomponents” on an “Application Baseboard”**



**Figure 6. Example of a medical application that uses the PC/104 baseboard approach.**

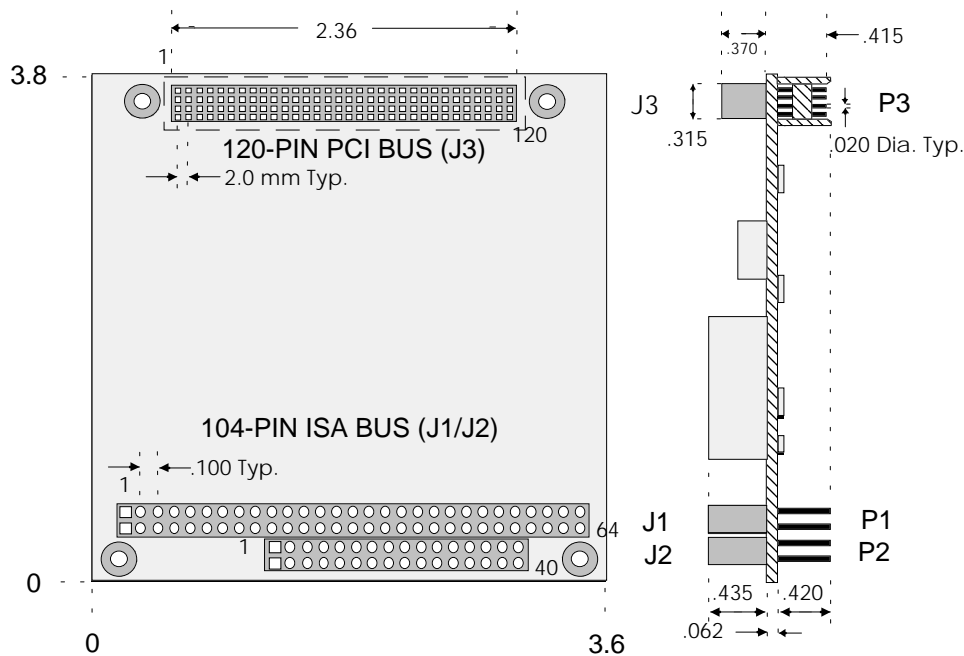
The PC/104 application baseboard usually contains all interfaces and logic that aren't available on — or, for whatever reason, aren't desired on — PC/104 modules. In typical medical equipment applications, the baseboard might include: power conversion or power supply components; signal conditioning or isolating logic; specialized interfaces such as a medical

instrumentation bus; “real-world” I/O interfaces and connectors; etc. Note that devices on the baseboard don't even need to interface with the PC/104 bus, but might be included there simply to eliminate unnecessary additional electronic assemblies. Figure 6 is a photo of an actual medical application baseboard based on this approach.

What size and shape should the application baseboard be? Generally, it takes the shape of the *system*, which may be square, rectangular, or even round — whatever fits best! Often, the application baseboard provides multiple PC/104 stack locations. This approach allows the PC/104 modules to be distributed side-by-side (instead of stacked on top of each other), resulting in a flatter or thinner system profile. Don't forget: it's always smart to provide a spare PC/104 module location — or, at least an extra 0.6 in. vertical clearance above the top PC/104 module — to accommodate system upgrades, addition of modules for system test, debug, repair, or for other unanticipated future requirements.

## **THE EVOLVING PC/104 STANDARD**

Recently, a PCI-extended version of PC/104 called “PC/104-Plus” developed by Ampro Computers, was adopted by the PC/104 Consortium (see Figure 7). The purpose of PC/104-Plus is to support Pentium processors and PCI bus throughput for new high performance applications which may include high speed graphics, networking, or data processing. PC/104-Plus preserves full backward compatibility with PC/104, including the ability to coexist within a stack with PC/104 modules. This further enhances the flexibility of PC/104 and allows it to be used in increasingly performance-intensive applications.



**Figure 7. PC/104-Plus adds a PCI Interface to the Popular PC/104 Form-factor**

Another approach to structuring a compact, reliable, fully compatible, and cost effective embedded-PC is to incorporate all the essential ingredients of a PC-compatible system onto a highly integrated single-board computer, or “SBC”. An SBC can eliminate some of the bulk, weight, and costs associated with multiple boards or modules.

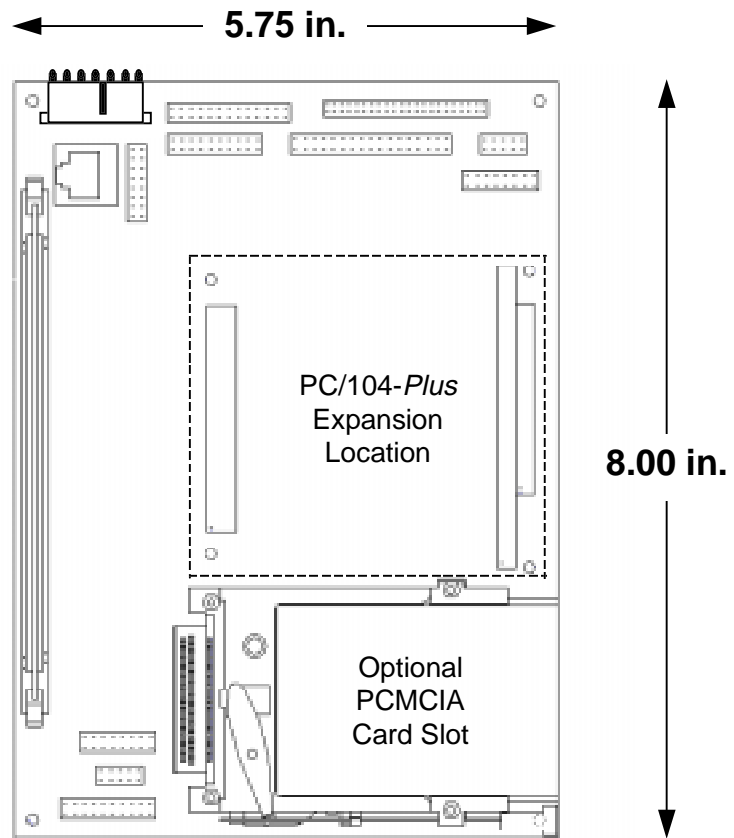
However, although the SBC may contain all of the normal PC-compatible functions (e.g. interfaces for keyboard, speaker, serial, parallel, disk, and network), there will usually need to be a means for adding the application-specific functions and interfaces that adapt the embedded-PC to its intended purpose in the particular medical application. For this reason, it is important that a PC/104 (or PC/104-Plus) expansion stack location be provided on the embedded-PC SBC. The PC/104 expansion location lets you install standard off-the-shelf PC/104 modules, or it can serve as a standardized interface between the SBC and whatever custom electronics your application requires.

A recent collaboration between Ampro and Motorola has resulted in publication of the industry’s first multi-vendor embedded-PC SBC standard. This new standard, called “EBX”, derives from the Ampro “Little Board form-factor” (5.75 x 8.0 in.). EBX (which stands for “Embedded Board, eXpandable”) provides an SBC form-factor that is large enough to accommodate a high level of functional integration and CPU performance, yet is small enough to be “deeply embedded” within a wide variety of applications such as medical instruments. An important feature of EBX is its inclusion of an onboard PC/104-Plus expansion location which facilitates adaptation of the EBX SBC to the specific embedded application. The basic features of the EBX form-factor standard are illustrated in Figure 8.

Obvious benefits of an EBX embedded-PC is reduction in the number of modules and elimination of the electrical and mechanical interface “glue” associated with using a larger number of modules. Another benefit is the ability of onboard devices such as memory or video to take advantage of local bus data rates, rather than being constrained by bus interface speeds (e.g. ISA or PCI). Cost can also be reduced, due reduction in the number of board assemblies.

In comparing EBX with PC/104, the EBX approach may be preferred when the features of the EBX SBC closely matches the application’s particular requirements; on the other hand, its benefit diminishes when additional

embedded-PC functions must be added via stacked modules, or when the EBX SBC contains a large number of excess functions.



**Figure 8. The EBX SBC form-factor offers high performance yet compact size.**

## SUMMARY AND CONCLUSIONS

There many good reasons to use the PC architecture as the hardware and software basis for medical systems. However, standard desktop-PCs fall far short of meeting the space, power, ruggedness, quality, reliability, and longevity requirements of most medical electronics.

The compact, modular PC-compatible PC/104 standard was developed specifically to provide PC architecture compatibility for *embedded* applications. Modules designed to this standard posses the important characteristics required by medical equipment manufacturers.

Designers of medical systems can use PC/104 modules in a variety of ways, including simple module stacks or plugging the modules into “application baseboards” like “macrocomponents” in a flexible component-like design. Recent extensions to PC/104, including the PCI-enhanced PC/104-Plus and the new EBX SBC form-factor standard, offer even greater design flexibility.

The good news, is that these embedded-PC technologies provide a means to greatly simplify the development of embedded computers for a wide range of medical systems, resulting in faster project completion, reduced development costs and risks, and improved system features and sophistication thanks to increased focus on the application itself.

## BIBLIOGRAPHY

The following publications and sources provide additional information about PC and PC/AT-compatible hardware, software, development tools, and peripheral devices that may be helpful in designing systems based on embedded-PC technology:

Circuit Cellar Ink (hardware/software magazine): 860-875-2199,  
[www.circuitcellar.com](http://www.circuitcellar.com)

“Designing with PC/104, a Tutorial” (white paper): Ampro, 408-360-0200, [www.ampro.com](http://www.ampro.com)

EBX Specification: Ampro, 408-360-0200, [www.ampro.com](http://www.ampro.com)

Embedded Systems Programming (software magazine): 415-905-2200

“Everything You Always Wanted to Know About SSD” (white paper):  
Ampro, 408-360-0200, [www.ampro.com](http://www.ampro.com)

IEEE P996 Draft Specification: IEEE Publications, 908-981-1393

IEEE 1284 Parallel Port Information: [www.fapo.com/ieee1284.htm](http://www.fapo.com/ieee1284.htm)

IEEE 1394 Trade Association: 512-305-0200, [www.firewire.org](http://www.firewire.org)

PCI Local Bus Specification: PCI Special Interest Group, 503-693-6232

ISA and EISA Theory and Operation: Annabooks, 619-673-0870,  
[www.annabooks.com](http://www.annabooks.com)

ISA System Architecture: Mindshare Inc., [mindshar@interserve.com](mailto:mindshar@interserve.com)

PC/104 and PC/104-*Plus* Specifications and PC/104 Resource Guide:  
PC/104 Consortium, 415-903-8304, [www.controlled.com/pc104](http://www.controlled.com/pc104)

PC/104 Embedded Solutions (magazine): 810-774-8180, [www.pc104-embedded-solns.com](http://www.pc104-embedded-solns.com)