



Technical Article

Human Machine Interface Systems for Medical Device, Diagnostic, and Treatment Equipment

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According to the *Medical Market Factbook*, the market for medical equipment in the Americas will grow to \$122.8 billion by 2013. Rising healthcare costs, the prevalence of chronic disease, the expectations for increased healthcare, and the aging “boomer” population are the market drivers for affordable and accessible medical devices. As more care is shifted from the physician to the patient, and the “home” medical diagnostic market grows from \$7.7 billion to \$8.6 billion, the key trends are miniaturization and portability. Other notable trends include:

- Multi-core processors for increased intelligence, high performance, and scalability;
- Virtualization – running multiple virtual machines on the same board;
- Modular, low-cost solutions with less customization;
- Wireless connectivity for remote access, monitoring, and control;

- Advanced Human Interface for advanced systems – matching the controls to the application;
- HMI Systems that are innovative, reliable, and intuitive with a better user experience in mind;
- “Paperless” offices, clinics, and hospitals;
- Flexibility to source from multiple vendors while retaining a consistent, uniform, HMI System.

Applications where these trends are affecting diagnostic device development include:

- Home-based equipment
 - Respiratory therapy
 - Infusion pumps
 - Blood monitors
- Clinical equipment
 - Lab equipment
 - Patient monitoring equipment
 - Drug delivery systems



Patient safety and comfort are critical in medical diagnostic systems.

■ Imaging systems

- Ultrasound
- X-ray
- MRI

Key technological developments, such as wireless communications, improved data storage and databases, security, USB connectivity, and intuitive interfaces are changing how healthcare is provided. These developments are turning telehealth and telemedicine from concept to reality.

The demand for remote access to both medical information and medical treatment will help to improve medical diagnostic productivity. New diagnostic developments like positron emission tomography (PET) will offer earlier and better diagnoses, while digitizing that information (or digitized X-ray or MRI data) will allow doctors access, regardless of their location, for faster treatment. Ease-of-use, patient safety, visualization, and flexibility will all be important to broad medical adoption.

Medical device and diagnostic equipment manufacturers want to work with an experienced HMI Systems partner who can address ergonomic considerations, operational/functional requirements, information display and presentation, along with an understanding of regulatory considerations including the FDA, CE, ISO, and other Notified Bodies.

Designing an HMI System for Medical Diagnostic Equipment

The task of an HMI System is to make the function of a technology self-evident to the user. A well-designed HMI fits the user's image of the task he or she will perform. The HMI System is judged by its usability, which includes how easy it is to learn. In



Medical device OEMs and contract manufacturers want to work with an experienced HMI Systems partner to promote reliability with critical care systems.

medical diagnostic equipment applications, the HMI has to be intuitive, easy to see and understand, and clear in its feedback to the operator. It must present critical and detailed visual information. In addition, it must feel comfortable and safe to the patient. In cases where the patient is the user, it needs to have an intuitive, easy-to-use, easy-to-understand, and jargon-free interface. There should be no room for confusion, error, or interpretation. In addition, it will require portability and a small form factor that is easy for a patient to handle in the home. It must also be durable and reliable, with accurate readings throughout its lifecycle.

Designing an HMI System for medical diagnostic equipment begins with a clear definition of the operational and functional requirements. An HMI System for an X-ray system is going to have different functional requirements than an MRI, or a PET scanner. The functions for a particular application will drive many of the design considerations. For example, patient and operator safety may be the dominant factor with X-ray equipment, while patient comfort may be more important in the interface design for an MRI system. An MRI will require a color display; an X-ray system may use a black and white monitor. A diagnostic system or a surgical laser system could require a foot

pedal control, while a device designed for patient use in the home would typically be handheld. All the functional elements need to be described and addressed early in the HMI System design process.

How does the key information need to be displayed? If it is digital images, what other data is also presented? How will the user interact with the information? Through a keypad, touchscreen, keyboard, trackball, or joystick? What safety measures are required? Is shielding necessary? Will there be an emergency stop switch? Will the operator require hands-free control? A foot pedal? Wireless connectivity? What is the necessary feedback? Visual, audible, haptic? Is patient feedback/interaction required?

It's also important to know the environment where the equipment will be used. A physician's office, patient's home, hospital emergency room, surgical operating room? The environment can dictate the HMI Systems requirements for sterilization, anti-microbial readiness, and other factors.

Will it be necessary to incorporate antimicrobial materials, like silver, into the design of the device to reduce the potential spread of infection? By clearly defining the functional

requirements, the environment, and the intended user, whether a diagnostic expert, the patient, or both, the appropriate HMI System can start to take shape.

Quality System (QS) Regulation and Medical Device Good Manufacturing Practices

To help with medical device and diagnostic equipment design, the FDA has created QS regulations/current good manufacturing practices (CGMP) for FDA-regulated products including food, drugs, biologics, and devices. These CGMPs help ensure that products consistently meet applicable requirements by helping manufacturers to follow quality systems.

Rather than prescribing specific details, the regulation provides a framework using the concept of Quality by Design (QbD). Quality by Design is described as developing and manufacturing a product to meet pre-defined product quality, safety,



According to the FDA, the user interface includes everything the user and patient see, feel, and hear during device operations.

and efficacy. QbD includes everything that a manufacturer does to directly promote and prove the safety, efficacy, and quality of a product from proof of concept to sale to the target audience.

Incorporating Human Factors

According to the FDA, the user interface includes all aspects of a device that users see, feel, and hear when operating the device. Design validation occurs by addressing the needs of healthcare professionals and patients during design input.

Within the design concept phase, the following issues should be considered:

- Does the device require user interaction in operation, maintenance, cleaning, or parts installation?
- Given the user interface, user population, and operating conditions, are errors likely?
- Could the consequences of an error be serious for the operator or patient?
- During actual testing:
 - Is someone from the design team focusing on user-related issues?
 - Are users involved in the process?
 - Are hardware, software, and other involved parties coordinating their efforts with respect to human factors?
 - Has a test plan been developed?
 - Have user requirements been developed, tested, and updated?
- What studies, analyses, and test steps are being performed?
- Has the project team performed testing in simulated and actual environments?
- Have the defined user requirements been met?
- Have any interface changes suggested by users been implemented and tracked?

The FDA recommends incorporating human factors engineering (HFE) into every

aspect of medical device design, including safety-related and risk management activities. Documenting device design should include:

Overall Device Functionality

- Purpose and operation
- Patient population on whom the device will be used
- Size, shape, weight, and power scheme
- Comparison with other existing devices used for the same task
- How the device addresses user needs

Device User Interface

- Physical characteristics of the HMI
- Operating system
- Labels, operating instructions, training

Device Use

- How the user interacts with the HMI
- Set-up and maintenance
- Primary tasks the user will perform

Device User Population

- Intended population of users
- Characteristics of that population
- Training and information tools required for safe and effective use
- Population of users for whom this device is not intended

Environment

- Home, hospital, emergency vehicles, etc.
- Environments for which this device is not suitable

Use-related Hazards

- Hazards that have occurred with similar devices
- Processes used to identify and prioritize potential hazards
- Hazards identified during development or testing and how they were mitigated or controlled

- Appropriate strategies to address hazards

Verification and Validation

- Testing and evaluation processes and their results

Balancing Aesthetic Appeal and Functionality

In addition to making the HMI System for a medical device functionally effective, it is also important to ensure that the device and interface are aesthetically appealing. In some instances the industrial design of a medical device is accomplished in-house by the manufacturer. In other cases, a third-party industrial design house is used. Outside industrial designers may combine medical device expertise with the latest in heuristic and ergonomic knowledge. With either an in-house team, or an industrial design house, a heuristic evaluation of an HMI System for a medical device could include an assessment of the following:

- Visibility of system status
- Match between the HMI and the real world
- Maximum user control and freedom
- Consistency and standards
- Ease of error prevention
- Recognition rather than recall
- Flexibility and efficiency of use
- Aesthetic and minimalist design
- Help for the user to recognize, diagnose, and recover from error
- Easy access to help and documentation

For medical devices, screen/display aesthetics play an important role. They often provide the user with the first impression of the system and can set the user's and patient's expectations for all interactions with the device. A poor first impression can also lower the operator's



Outside industrial designers may work with HMI Systems experts to combine the latest in ergonomic knowledge to provide intuitive operation.

motivation to use the device.

The appearance should be gauged to match user expectations. For example, a lab technician might appreciate a more serious and scientific appearance in a blood analysis workstation, whereas a nurse might be looking for a friendly, non-intimidating appearance in a handheld blood testing device. A patient might feel more comfortable with a device that mimicked a familiar form, such as a smart phone. An HMI screen with the following characteristics will often elicit a favorable response from an operator:

- Moderate information density – avoid too much and too little information
- Limited number of fonts keeps information clean and clear
- Balanced, asymmetrical composition
- Proportional sizing of objects displayed
- Consistent alignment of elements
- Limit complexity – a complex visual element should be displayed on a simple background
- Logical ordering of elements
- Balanced use of text and graphics

- A common visual style
- Information coding – for example, using red to highlight alarm information
- Functional grouping for related activities/information
- Three-dimensional effects are also appealing
- Limited use of animation and other special effects

Choosing the Appropriate Operating System

Since almost all medical HMI Systems include a computer, the choice of an appropriate operating system (OS) is critical. As medical devices become smaller and are used in both a clinical and home setting, the choice of an appropriate OS may change.

Choosing the right OS for a medical device is about defining what the product needs from its OS. Critical characteristics could include:

- Dependability – responds in a timely manner for as long as necessary

- Connectivity – communicates with other systems/equipment
- Data integrity and security – safe and dependable storage of data
- Support for graphics – especially in imaging equipment
- Platform neutral – performs equally well on different hardware platforms
- Multicore support – high performance, increased intelligence, and scalability
- Power management – increasingly important for handheld devices in vehicles and at home

Generally there are two types of OS to consider: a general-purpose operating system (GPOS) or an embedded, real-time operating system (RTOS). Everyone is familiar with a GPOS – most typically a Windows operating system like Windows 7 or XP. An RTOS is able to meet real-time requirements, protect against problems like priority inversion where a minor task is executed ahead of a vital task, guarantee



An effective HMI System will present information concisely and clearly.

availability, and monitor and re-start processes without requiring that the system is re-booted.

GPOSs' include Android, Windows Ce, and many different versions of Linux. RTOSs' include QNX Neutrino RTOS, WindRiver's VxWorks, Green Hills INTEGRITY, and others. In many cases, a medical device may actually need a combination of an RTOS and a GPOS like Android to meet all the characteristics outlined above. In other cases, the medical device manufacturer will decide to develop a custom OS to meet a specific set of device requirements.

Choosing the Best Control Technologies

Once you have defined HMI functionality and selected the appropriate OS, you are ready to investigate control technologies. Each technology has advantages and disadvantages related to the HMI system, equipment, and application.

Cursor Control (Trackball, joystick, keypad, touchpad, etc.)

The selection between different control technologies is primarily determined by the resolution of control that is required by the application. A trackball or joystick enables granular, pixel-by-pixel control, a far higher resolution than is possible with a typical PC point-and-click controller.

Switches (Pushbutton, rocker, keylock, rotary, slide, etc.)

Pushbutton switches allow the option of illumination to indicate open/close switch status when a quick visual indication is desired.

Rotary-switch and keylock technologies serve best when the application requires

position indicators. Keylocks provide an additional layer of security to the application. Rotary switches also can be used for an application requiring multiple positions.

Slide switches are the technology of choice when ease-of-use and low-cost switching is desirable – commonly found on notebook cases and handheld on/off functionality.

Short Travel Technologies (Conductive rubber, membrane, keyboard, keypad, etc.)

Short travel technology can include cost effective, conductive rubber keys in a typical keyboard, dome keys under an overlay, or a multi-layer membrane.

Display Technologies (LCD, active matrix, OLED, FED, plasma, etc.)

Display technology choices are dictated by the HMI System environment and its degree of ambient illumination, as well as by color requirements. Active matrix LCD technologies are commonly used for color functionality, while legacy LCD technology is used in applications where monochromatic feedback is sufficient. OLEDs, organic (carbon-based) light-emitting diodes can currently support smaller displays.

Interactive Displays, Touchscreen

Touchscreen technologies offer a range of functionalities and characteristics that govern HMI Systems choice according to application and environment. It is important to determine which touch technology will be used in the early stages of the design cycle as the different options offer unique electrical and mechanical requirements. In medical device applications, touchscreens are an integral part of the design, putting

information at the fingertips of the healthcare professional. Touchscreens provide a visual indication of device status as well as the ability to drill down for more detailed information. They are available in lightweight, portable configurations and are hygienically designed for use in the operating room as well as the physician's office. They can be located on equipment carts and swing-out wall mounts. Replacing keyboards, keypads, and mechanical buttons, they enable a faster flow of information and in sealed configurations, can withstand repeated cleaning and sterilization with harsh cleaning chemicals.

Capacitive touchscreens transmit 75% of the monitor light (compared to 50% by resistive touchscreens), resulting in a clearer picture. They use only conductive input, usually a finger, in order to register a touch.

Resistive touchscreen technology offers cost-effective, durable performance in environments where equipment must stand up to contaminants and cleaning liquids. When touched, the conductive coating on the screen makes electrical contact with the coating on the outer layer. The touch coordinates are registered by the controller to activate the on/off function. The resistive touchscreen is used in cell phones and can be operated wearing surgical gloves.

Infrared touchscreen technology projects horizontal and vertical beams of infrared light over the surface of the screen. When a finger or other object breaks those beams, the X/Y coordinates are calculated and processed. These cost-effective touchscreens can also be used by operators with surgical gloves and are relatively impervious to damage.

Surface Acoustic Wave

Surface Acoustic Wave (SAW) touch technology sends acoustic waves across a glass surface from one transducer to another positioned on an X/Y grid. The receiving transducer detects if a wave has been disrupted by touch and identifies its coordinates for conversion to an electrical signal. SAW serves well in medical environments because it can be activated by a stylus or gloved fingers.

Motion Control

Motion control most often employs joystick technology for applications requiring macro control, such as controlling the movement of an MRI or X-ray scanner.

Foot Pedals/Medical Grade Foot Switches

Foot switches of all types are often used in larger medical devices. They allow for hands-free operation of the device, providing the operator with the ability to move around the equipment. Foot switches are available both as cabled devices or wireless. Key characteristics include:

- Stable footpad
- Ease-of-use and optimal functionality
- Freedom of movement
- Functional and aesthetic compatibility with the device
- Conformance to standards
- Battery power charge and re-charge

The growing popularity of wireless foot switches eliminates the possibility of tripping over cables, allows the operator to remain in control from any position around the equipment, eliminates the most frequent point of failure – the cable connection – and makes it easier to clean the foot switch.

Connecting/Communicating with an HMI System

Once you have established how your HMI will look, feel, and operate, you need to consider how the HMI will connect to and communicate with the core equipment or system under control. Typically, communication can be achieved through several approaches: hard-wired connection, serial bus connection, or wireless connection. Each approach has pros and cons – selection will depend on how your HMI needs to fit within your application.

Selecting the appropriate communications technologies may include combining some or all of these approaches.

Hard-wired Connections

Conventional, hard-wired systems are still used in many transportation and industrial legacy systems. Hard-wired systems require no special tools and are simple, visible, and easy to understand, especially where the HMI interface controls a single machine.

There are many drawbacks, including difficulty integrating changes or new features – new features require new wiring. Conventional wiring also requires more space due to the number of wires and the actual size of the wires and larger connectors due to higher pin counts. A hard-wired system is typically heavier and more expensive, which can be detrimental in some applications, such as transportation.

As an example, an application requiring a hard-wired assembly or panel might consist of a metal panel plate with 10 switches connected to two wires apiece, 20 wires in all. Each of these wires must be conjoined

with 10 application connectors beneath the panel plate. An added illumination requirement would double the wire count, resulting in 40 wire connections to the application.

Serial Bus Systems

As equipment and control systems became more complex and data hungry, transmission of data became a critical issue. Data transmission depends on distance and speed. The longer the cable length, the lower the transmission speed to keep bit-error rates acceptable. To facilitate faster data transmission rates, devices incorporate serial bus connections. A serial bus approach eliminates data transmission slowdowns due to cable length and delivers reliable, real-time operations, and work-in-process feedback.

Bus systems provide many advantages over hard-wired connections, including easy addition of new functionality – typically through software – without adding or replacing hardware. Wiring is much simpler and more flexible with smaller cables and connectors allowing for more compact design, and easier hardware updating and relocation. Bus systems also allow for any combination of information from multiple different sources to control output devices. There are tradeoffs, however. Systems are more complex when only a small number of inputs and outputs (I/O points) are required. Also, special tools and well-trained personnel are required to design and service a bus system.

Buses bring all the switching and illumination wires out as one connection, reducing wiring, assembly, repair/maintenance time, and weight, which in transportation translates into lower fuel costs. Bus connections incur slightly higher

upfront costs, but these are outweighed by increased performance and long-term savings.

Wireless Connections/Communications

Industrial applications have employed wireless technologies over the last 20 or so years, primarily to take advantage of real-time data transmission, application mobility, and remote management capabilities. In medical applications, wireless communications are a more recent development, but one that is quickly becoming dominant. As the trend in medicine moves from healthcare to self-care, wireless communications become increasingly important. Adding wireless capabilities to vital signs monitoring devices will improve the ability of physicians and patients to monitor and control their condition remotely.

Most wireless connectivity includes a sensor connected to a personal area network. The network connects the sensor and the device that holds the application – whether a mobile phone, PDA, tablet, PC, or medical device – to a network to transmit monitored data. As of December 2010, Zigbee, Bluetooth, and Bluetooth Low-Energy are the only approved wireless standards for medical personal area networks.

As explained in the discussion on foot switches, wireless connectivity also provides great freedom for the physician or medical technician in operating large-scale medical diagnostic equipment.

Safety Considerations

For HMI Systems design, safety considerations are a critical part of the system. Human error is a contributing factor in most accidents in high-risk



E-Stops ensure consistent, predictable, failsafe control.

environments. Clear presentation of alarms as well as the ability to report errors, are crucial elements in any HMI.

In addition, emergency stop switches, generally referred to as E-Stops, ensure the safety of persons and medical equipment and provide consistent, predictable, failsafe control response. E-Stops differ from simple stop switches (that primarily offer a limited system-stopping function) in that they offer “foolproof” equipment shutdown. This is accomplished through advanced switch design that requires a twist, pull, or key to release electrical contacts to allow machinery restart.

E-Stops are generally designed for failsafe operation so the stop command has priority over the sustaining function. This has led to innovative switch designs that prevent “blocking” (wanton or accidental obstruction of the actuator with foreign objects) and “teasing” (which could result in premature or unreliable action). According to international standards, the emergency stop function must be initiated by a single human action using a manually actuated control device. The E-Stop function must be operational at all times and designed

to stop the machine without creating additional hazards. Resetting the electrical system can only be done by first releasing the E-Stop that was originally activated. If E-Stops were activated at multiple locations, all must be released before machinery restart. It should be noted that resetting E-Stops does not in itself restart the machinery; it only permits restarting through normal procedures appropriate for the machinery involved.

In fact, according to international standard IEC 60601-1, an emergency stop should, once actuated, maintain the medical equipment in the disabled condition until a deliberate action, different from that used to actuate it, is performed. Manufacturers need to ensure that the emergency stop function is not just a momentary or maintain switch action. This does not constitute a deliberate and different action as compared to the actuation action. The safest release action is a twist-to-release action that complies with the “deliberate and different” requirement of IEC 60601-1.

Designers should be aware of international and U.S. standards and regulations that impact the design and use of E-Stops with medical equipment.

U.S. and Industry Standards

International Organization for Standards

(ISO) 9001:1994

Quality Systems – Model for Quality Assurance in Design, Development, production, Installation, and Servicing

ISO/CD 13485
Quality Systems – Medical Devices – Supplementary Requirements to ISO 9001

FDA CGMP
Part 820 (21 CFR part 820)

IEC 60601-1 Ed. 3.0 b:2005
Medical electrical equipment – Part 1-1:
General requirements for safety – Collateral standard: Safety requirements for medical electrical systems

IEC 60601-1-2 Ed. 2.1 b:2005
Medical electrical equipment – Part 1-2:
General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 60601-1-3 Ed. 1.0 b:1994
Medical electrical equipment – Part 1:
General requirements for safety – 3.
Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

IEC 60601-1-4 Ed. 1.1 b:2000
Medical electrical equipment – Part 1-4:
General requirements for safety – Collateral Standard: Programmable electrical medical systems

IEC 60601-1-6 Ed. 1.0 b:2004
Medical electrical equipment – Part 1-6:
General requirements for safety – Collateral standard: Usability

IEC 60601-1-8:2006
Medical electrical equipment – Part 1-8:

General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-11:2010
Medical electrical equipment – Part 1-11:
General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Summary

The effectiveness of the HMI System – and consequent effectiveness of its use – depends upon an exacting design process that incorporates all technical, ergonomic, and communication requirements. For medical device applications, working with an experienced HMIS supplier can ensure that the system meets all standards and provides successful use by physician, technician, and patient.

Working with a supplier that understands the application, environment, user of the equipment, and the nature of their usage is critical to the successful implementation of an effective and aesthetically pleasing HMI System.

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