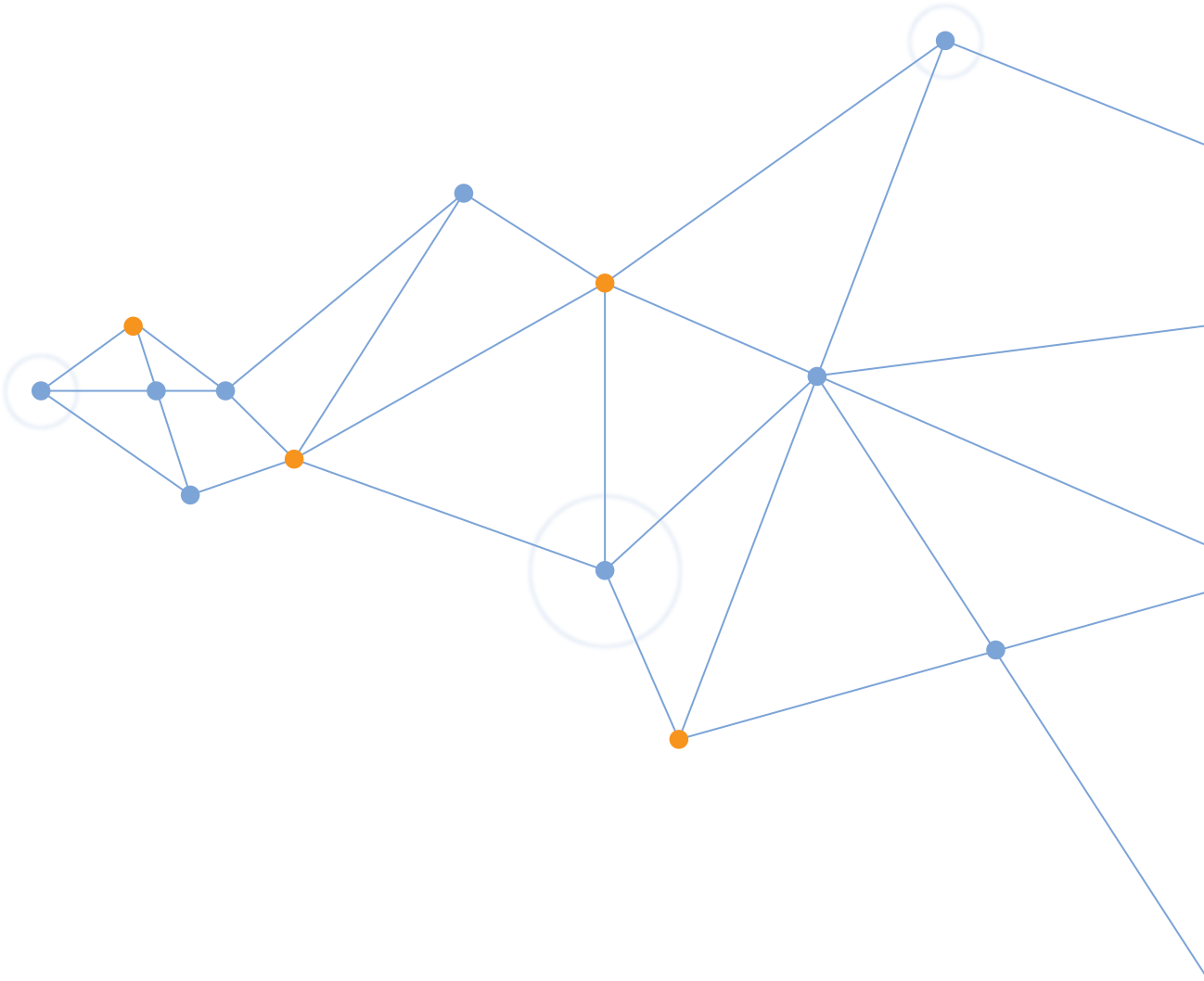
White Paper

Technological Advancement & Trends in Critical Care



ADVANTECH iHealthcare

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Introduction

Innovations in critical care, including intensive care unit (ICU) and surgical/operation procedures, have helped hospitals and healthcare facilities provide better patient care and offer more comfort to those who need it. Additionally, doctors and other personnel now have easier access to information such as x-rays and other medical imaging as well as remote monitoring of the health status of patients. In addition to improved care, more automation can also potentially reduce healthcare costs. Traditionally, technologies including medical-grade computers are IT focused with modifications made to meet the needs of critical care. But this is about to change as the European Union (EU) and its members are demanding higher standards. These include environmental regulatory requirements and electromechanical compliance. The CE mark (the European standard similar to the UL mark in the U.S.) requires a higher standard moving forward. Furthermore, users are now demanding safer and more reliable products along with improved ease of use. In this paper we will examine the various requirements and challenges manufacturers of medical-grade computers and devices will be facing in order to compete in this market. We will also study the new advancement and trends of future medical-grade computers.

a. Innovations in medical computing

More and more hospitals and facilities rely on technology to improve services and remain competitive. Faster silicon processors in smaller packaging have made medical devices more portable and lightweight. For example, x-ray machines have been replaced by digital imaging devices that provide faster results without processing film. Patient monitoring can be done remotely around the clock in hospitals or at home. Portable ultrasound devices provide immediate results so expectant mothers can instantly see the baby (babies) she carries. Medical-grade computers will also pack more features in an all-in-one design. The list goes on. (Figure 1).

Figure 1: Modern operating room is equipped with medical grade computers and equipment.

b. Hurdles and Challenges

Most IT and computing companies are experts in hardware and software, but they may not fully understand the user requirements in the critical-care industry, which can be complicated. Medical professionals (users) who are experts in patient care are unlikely to have an IT or technology background. And the hospital/facility administrators who oversee the medical staff are primarily concerned with achieving quality care and operational efficiency with limited budgets. Some of the challenges faced by many of these leading facilities include the following:

Non-technical users need a friendly system

In most hospitals and care facilities, physicians and caregivers are the users and they don't have the time or desire to learn a new piece of equipment. Training on a complex system can take many hours, which detracts from time with patients and adds complexity to procedures.

More demanding electromagnetic compatibility (EMC) requirements

There are important changes to EMC requirements, geared towards minimizing emissions from devices as well as impacts on the device. Standards bodies in both the US and Europe will continue to have significant impact on manufacturers of medical devices as manufacturers try to navigate the regulatory waters.

Recent regulations have raised the standards of requiring equipment to be environmental friendly

The green concept is not only a nice idea, many new regulations are stipulating that equipment must be recyclable and produced with minimum impact to the environment. Many developing countries are now making similar demands for such designs.

Increased safety in hospital and health facilities is always a challenge

Hospitals are the place to go to get well. Unfortunately, it is also a place where germs are spread. So, it is a constant challenge for medical staff to stay healthy, as well as prevent the spread of germs from patient to patient.

Security is a high priority

Whether it is access to patient's private data or authorized use of certain medical equipment, security is always a concern. Making sure only authorized personnel are allowed to gain access, in an efficient manner, is a major consideration. New technologies are now available to make this possible.

Minimize ICU Stay

It is costly for patients to stay in the ICU. Nowadays, insurance companies are watching hospitals carefully to ensure they do not have to pay for unnecessary stays. There are many factors affecting the recovery period for a patient. Do they eat well? Do they rest well? A short stay means cost savings for all parties involved.

Technological Advancements and Trends

The two main factors set to impact the development of future medical computing devices are EU regulations and technological advancements. The EU EMC and environmental regulations have influenced manufacturers worldwide to produce better and safer products. Technological advancements enable developers to manufacture superior integrated products with an improved biometric UI, resulting in enhanced functions and environmentally safe devices. Over the coming years, the following are expected to become six major trends in critical care product development:

a. Increased demand for intuitive UIs

Users want a computing system that is easy to understand and operate with minimal training. To meet these demands, intuitive user interfaces (UIs) are becoming increasingly important. For example, when performing surgical operations, surgeons need easy and immediate access to information, preferably on an easy-to-view display. Incorporating an intuitive UI with advanced features such as touchless control can not only optimize procedures, but also improve hygiene and infection control. An ideal piece of equipment would be easy to use (require minimal training), configurable, portable, and have plug-and-play features.

b. Future medical devices will be required to meet more demanding EMC requirements

The fourth edition of the IEC 60601-1-2 published by the International Electro Technical Commission (IEC) contains the most recent EMC regulations for medical electrical equipment. These standards are enforced by the EU and its member countries. The purpose of the EMC requirements is to minimize the environmental impact (emissions from the device) and device susceptibility (effect on the device). In other words, an EMC device will perform properly without causing electrical disturbance to devices nearby. The revised standards have increased radiation immunity standards, such as magnetic immunity levels and immunity range. The electrostatic discharge level has been increased from 6 to 8 KV for contact and 8 to 15 KV for air discharge from RF wireless communication equipment. The range of testing for radiated immunity was harmonized from 2.5 Hz to 2.7 GHz with magnetic immunity at 30A/m and conducted immunity at 6V in ISM bands. Manufacturers usually have two to three years to prepare for new compliance directives. The U.S. FDA issued guidelines recommending that manufacturers perform testing in compliance with IEC 60601-1-2 (Edition 4). The U.S. FDA has since announced that the required compliance date has been pushed back from April 2017 to December 31, 2018, the same as for the EU. (Ref. 1)

The IEC has a tremendous amount of influence with manufacturers and users, and the IEC/TC 62 working group has over 60 country members supporting the adoption of IEC standards. A similar group, CENELEC/TC 62, is a mirror image of the IEC committee, and most of the standard bodies collaborate on the development of new standards. (Ref. 2)

The governing body of the CE Mark standard also follows the IEC 60601-1-2 (Edition 4) requirements. This means that future medical electrical equipment and devices will need to comply with the latest EMC standards, especially if they are destined for the European market.

c. Environmental and regulatory requirements will be mandatory

Environmental considerations are set to have a major impact on not just manufacturers, but the entire supply chain over time. The primary concern is that for many years, plastic chassis have been used to build IT and medical devices. This plastic material is commonly known as polyvinyl chloride (PVC). Vinyl chloride is a chemical used to make PVC. During the production of chlorine, dioxins are released into the environment. According to The Center for Health, Environment and Justice (CHEJ), dioxins are known to cause cancer as well as reproductive, developmental, and immune problems. (Ref. 3)

Additionally, the use and disposal of dioxins have harmful effects, which are more pronounced in children. Taking the lead in banning the use of PVC, the EU is forming regulatory policies for manufacturers to follow. Although this subject was discussed as early as 2000, manufacturers are only now beginning to follow the guidelines. The International Organization for Standardization (ISO) issued the ISO 14001 standard to educate manufacturers about environmental protection, yet compliance is not mandatory. However, many leading manufacturers, including NVIDIA, IBM, Sony, Advantech, and Dell, are developing internal policies to eliminate the use of PVC in current and future products. The transformation of the medical and healthcare device manufacturing supply chain is expected to accelerate as more and more suppliers also eliminate the use of PVC. For the medical device industry, the ultimate goal is to eliminate the use of toxic materials such as PVC and produce recyclable medical equipment.

d. More medical devices will deploy touchless technology

Most people have the misconception that because hospitals are places where people go to receive medical treatment and restore health, hospitals must be sanitized frequently and free of germs. However, relevant research indicates that the opposite is often true. A study by the University of Chicago found that germs brought in by patients were transferred from room to room and eventually picked up by other patients. Additionally, because they were passed from person to person, these germs became resistant to antibiotics. Thus, they not only made people sick, but also extended/complicated patient conditions. Currently, there are two ways to reduce the number of germs and their spread. Some hospitals use germ-killing devices equipped with strong ultraviolet rays to kill germs. However, the best method for minimizing the spread of contagions is having all hospital personnel wash their hands frequently, as recommended by health experts. The development of touchless control technology looks very promising for medical equipment and devices. The touchless solutions would address the scenario even if healthcare personnel forget to wash their hands.

Recently, various vendors have introduced technologies that enable touchless control. One such solution involves projecting a low carrier frequency beam onto the user's skin to provide the sensation of touching something. With this technology, medical equipment can provide a virtual knob that users can turn clockwise or counter-clockwise to control the equipment. Other devices use infrared technology to detect the motion of an object, such as a hand. After which an algorithm is used to interpret the hand motion and carry out a particular action, such as moving an object on a CRT screen. The advantages of touchless technology are substantial. The ability to provide care while minimizing the touching of medical equipment reduces the likelihood of spreading germs and disease.

e. Future devices will have ambient light sensing and control capabilities

The goal for critical care is to help patients get well and minimize the stay in the ICU. Getting good rest is a critical component to getting well quickly. As shown in Figure 1, there are multiple medical devices in the ICU and each emits different levels of light which impact the patient. Almost all displays use light-emitting diodes (LEDs) with different wave lengths of 400 to 750 nm, visible to human eyes. Figure 2. A study titled “Influence of Light Therapy on Confusion in Patients at the Intensive Care Unit” has shown a relationship between light effects and sleep patterns. Obviously, patients that sleep better at night are able to recover more quickly and thus minimize the stay in the ICU. This seems like a minor detail but will be an important factor in future device design.

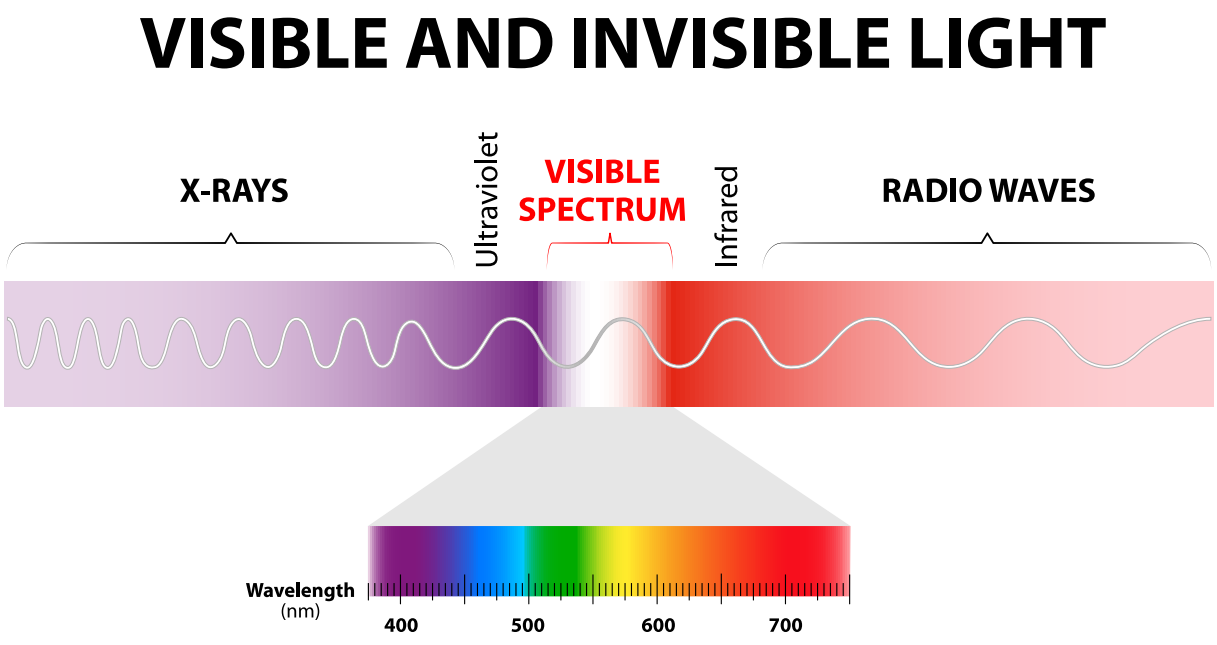

Figure 2. Displays for most future medical equipment use LEDs with visible wavelengths of 400 ~ 750 nm.

Future device designs should incorporate ambient light sensors so that when the main light is turn-off, the display from all the devices should automatically adjust their intensity levels to less than 1 lux, similar to a night light (4W). With this feature, displays will automatically dim themselves to a comfortable level that minimizes sleep disturbance. The displays can wake up when they need to be used, say, by visiting healthcare staff to check on the vital signs of the patient. When the devices are not in use (after a pre-determined period) they can be shut down automatically. The benefits of ambient monitoring and automatic shutdown provide maximum comfort to the ICU patients and save energy and the cost saving can be significant for a large hospital. (Ref. 4)

Other control functions such as motion and proximity sensing would provide additional benefits. When the user or operator is away from the device, after a preset time limit, the device would go to the sleep mode. Not only will this save energy, it also raise the level of security. If an unauthorized person attempts to tamper with the device, the person will be locked out unless a password, better yet, a biometric requirement such as facial recognition identifies the person as an authorized user.

f. More biometric user-interfaces will be used

Biometric ID has been in use for many years. They include finger print, hand geometry, iris, voice and facial recognition. The benefits vary. The two most popular are finger print and facial recognition, such as that used by the iPhone and other smart phones. In a hospital environment, biometric ID without physical contact is preferred (i.e. finger print is less desirable). Among iris, voice recognition and facial recognition, iris ID is not as reliable, and the scanners can be hard to use. Voice is also less desirable compared with facial recognition due to ambient noise, or as voices change due to other factors such as catching a cold.

How does facial recognition work? According to a report "Facial Recognition Technology A Survey of Policy and Implementation Issues", the facial recognition process involves four interrelated steps as shown in Figure 3. These steps depend on each other and are based on the geometrical relationships between facial landmarks.

Ref: conducted by Lucas D. Introna, Lancaster University, UK; Centre for the Study of Technology and Organization and Helen Nissenbaum New York University; Department of Media, Culture, and Communication, Computer Science, and the Information Law Institute.

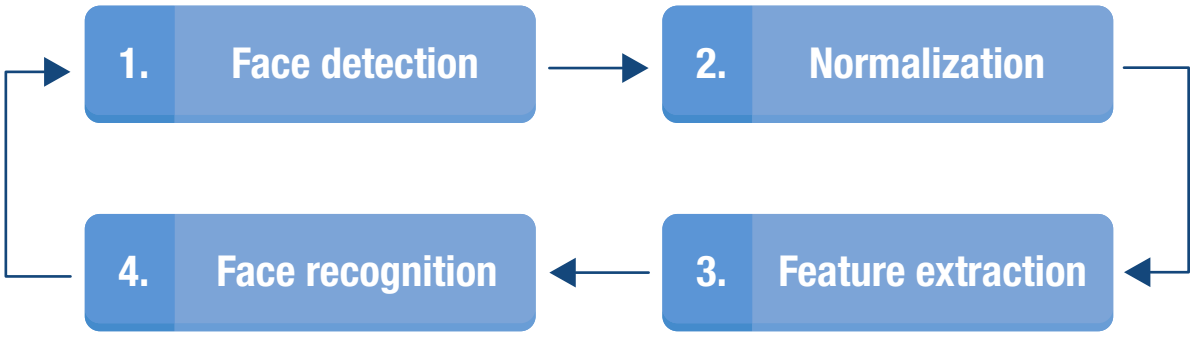

Figure 3: The facial recognition process involves four interrelated steps.
Source: Facial Recognition Technology A Survey of Policy and Implementation Issues.

In general, a facial recognition algorithm obtains a person's face image with a digital camera and measures the matrix or distances between various parameters including eyes, nose, mouth, face outline and jaw bones. It then compares it with the data already installed in the database. It can be summarized as eye size and depth of socket, nose dimension, cheekbones shape and jaw line length.

The benefits of incorporating face recognition technology in medical device design include increased security in that only the authorized personnel will have access to the protected data and use of equipment. Additionally, it allows control without contact, reducing the risk of spreading germs. It is thus expected that the use of biometric ID technologies like facial recognition will gain momentum.

Conclusions

The demand for better critical care service will continue to grow as the population starts to age globally. More innovative medical devices and medical grade computers will be introduced. There will be an increasing effort to balance between producing quality products that meet user demands, regulatory agency requirement and cost reduction. The six major trends for new medical device and medical grade computer development include:

- **Higher demand on intuitive user interface (UI)**
- **Future medical devices will be required to meet more demanding electromagnetic compatibility (EMC) requirements**
- **Environmental and regulatory requirements will be mandatory**
- **More medical devices will deploy touchless technology**
- **Future device will have ambient light sensing and control capability**
- **More biometric user-interfaces will be used**

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