



**General Awareness Information**  
**Medical Devices for Engineers**

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**U.S. Public Health Service  
Engineer Professional Advisory Committee  
Emergency Preparedness Subcommittee**

## **Disclaimer**

This document provides guidance on the Engineering Professional Advisory Committees (EPAC) current thoughts on the subject. An alternative approach may be used if such approach satisfies the situation. Periodically, EPAC will review this document and modify it according to comments submitted.

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## **Acknowledgements**

Much of the information in this document comes from the Food and Drug Administration (FDA) documents and Web site – especially from FDA’s Center for Devices and Radiological Health (CDRH), available at <http://www.fda.gov/cdrh/index.html>.

Other information comes from

- Handbook of Environmental Health. DHHS/PHS /Indian Health Service/Division of Environmental Health/Environmental Management Branch; 1994.
- Field Operations Guide for Disaster Assessment and Response. U.S. Agency for International Development, Bureau for Humanitarian Response, and Office of Foreign Disaster Assistance a.k.a. FOG. Available at <http://www.info.usaid.gov/ofda/fog/>.

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## **1. INTRODUCTION**

As a CCRF engineer deployed to a field site that is set up to deliver healthcare, you will encounter a variety of medical devices. The information contained in this document gives you some background about medical devices and lists some of the potential you might encounter. The information is intended to raise your awareness of various aspects of medical devices. It is not all-inclusive and it will not make you an expert in setting up a field hospital facility or using and repairing medical devices. It is, however, meant to start you thinking about how a medical device works, present a few of the many ways a device may fail, and tell you what you may be able to do about it.

Information about a medical device is often critical in order to safely and effectively use and maintain the product. User manuals, service manuals, and manufacturers are useful sources of information and good places to report problems encountered with a device.

### **1.1 DEFINITION OF A MEDICAL DEVICE**

The FDA has regulatory authority over medical devices. To the FDA, a medical device is a device intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or animals. Medical devices range from simple items like tongue depressors and bedpans to complex items like laser surgical devices and programmable pacemakers with microchip technology. In addition, medical devices include in-vitro diagnostic products, such as general-purpose lab equipment, reagents, and test kits, which are used to test blood and other body fluids. Certain electronic radiation emitting products with medical application and claims meet the definition of a medical device (e.g., diagnostic ultrasound products, x-ray machines and medical lasers).

For more information about medical devices and their regulation by FDA, go to <http://www.fda.gov/cdrh/index.html>.

### **1.2 MILITARY FIELD HOSPITAL EQUIPMENT VS. URBAN HOSPITAL EQUIPMENT**

Medical devices built for military purposes must adhere to specifications dictated by the military contract. The specifications may include various user features as well as conditions under which the device must operate. These conditions (e.g., temperature and humidity) may have a wider range than may be required for a similar device in an urban hospital.

In addition to the military specifications, the device's manufacturer must also adhere to FDA's safety and effectiveness laws and regulations.

## **2. POTENTIAL PROBLEMS**

Medical devices are subject to a wide variety of problems. Many of the problems result from the conditions under which the devices are used. CCRF deployment field conditions are likely to be harsher than conditions found in an urban medical center.

An example of harsher conditions is poor, intermittent, or non-existent local utilities. If the local utilities are insufficient, they may need to be augmented or replaced by the emergency response personnel. Electricity may come from an on-site diesel generator instead of an overhead power line. The power supply may thus be delivered only at scheduled times and it may not be a clean 120 volt 60 Hz supply.

Water may come from a nearby river or lake instead of a municipal water treatment plant. The water may be tainted and unfit for general use (much less for hospital use). These on-site utilities may have an impact on the field hospital medical devices.

It is wise to have equipment operator and service manuals on hand *before* problems arise. Having a manual will facilitate service, troubleshooting, calibration, cleaning, and general maintenance of the equipment. This type of information may also be obtained from the following sources:

- Hospital personnel on-site
- The manufacturer
- The following FDA/CDRH websites (for products legally marketed in the US):  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>
- FDA/CDRH Program Operations Staff at 301-594-2186 or 301-594-1190. They can help you contact the manufacturer.

Any medical device problems you experience in the field may have wider public health implications than just a local equipment malfunction. Serious adverse events that occur during use of a medical device are reportable under FDA's MEDWATCH program. If you believe that such an event occurred you can file a report with FDA by one of the following mechanisms:

- Phone 1-800-FDA-1088
- <http://www.fda.gov/opacom/backgrounders/problem.html>
- <http://www.fda.gov/medwatch>

You should also contact the manufacturer. Your report will allow the FDA and manufacturer to follow up on potential problems with related products.

## **2.1 MECHANICAL PROBLEMS**

The hospital environment can be hostile to medical devices. A healthcare provider's careful use of a medical device is secondary to the care of the patient. As such, medical devices can experience hard use. Many electrical problems have mechanical root causes (e.g., getting the correct signal from the patient to the machine, getting power to the machine when you need it, and making sure the device can be properly controlled).

### **2.1.1 Patient connections**

Leads that connect a patient to a medical device can be problematic. By its mere use, a patient lead suffers mechanical stress. Repeated use can flex the lead to the point of breakage. However, the break may go unnoticed because the insulation may still be intact. Although the break can occur anywhere, it tends to occur where the most severe flexing takes place, typically where the insulated wire feeds into the sensor on the patient end or into the connector on the device end.

A patient lead can experience poor electrical connection to either the patient or the device if the lead has been stored in poor conditions. For instance, the lead's connection pins may be corroded if it was stored in a high humidity environment. You can clean away the corrosion by wiping it with toothpaste on a soft cloth then rinsing with water and drying. If you see corrosion on disposable leads you should replace the leads if possible.

Another problem involving patient leads is their improper use. People try to plug them into inappropriate devices such as electrical power sockets, causing electrocution. More information about patient lead wires can be found at <http://www.fda.gov/cdrh/comp/leadwire.html>.

### **2.1.2 Other mechanically stressed components (e.g., the power cord)**

Power cords are often handled improperly. Kinking, bending, and yanking can result in intermittent or non-existent power to the device the next time it is plugged into the wall socket.

### **2.1.3 Damage to the keypad/keyboard or other device controls**

Proper control of a device is essential for correct performance. Damage to the device's control system may render it inoperable. A more hazardous case occurs if the device accidentally delivers the incorrect patient treatment. For example, there have been cases where infusion pumps delivered too much (or too little) intravenous drug with harmful and occasionally fatal results. The same applies to radiation therapy devices.

Deployment sites are not always hospitable to medical devices. Dirt and moisture are not always adequately excluded from a field hospital site (especially where these medical devices may be stored). Dirt can infiltrate control dial potentiometers and switches; moisture can leak past cracked keypad membranes into the underlying control circuitry. These conditions may lead to the device malfunctioning.

One type of damage can occur in the device's control software. For example, if two keys of a keypad or keyboard are pressed at the same time, the resulting control signal may be completely unpredictable if the software was never designed to accept or exclude this multi-key sequence.

## **2.2 ELECTRICAL PROBLEMS**

### **2.2.1 Electrical generator considerations**

The stability of the generator is important. If the power output voltage or frequency (60 Hz) varies considerably it could damage the sensitive medical equipment or disrupt the equipment software. Surges and brownouts have been known to delete software settings on infusion pumps, which could result in over- or under-doses.

Many pieces of equipment are likely to be running on the power provided from the generator. The current load of all the equipment should only add up to about 75% of the rated generator capacity, thus leaving a little overhead capacity to spare. One reason for having overhead capacity is electric motors. Most electric motors will label how much current is necessary to operate in steady-state conditions. Many motors draw four to five times the steady-state current during startup.

### **2.2.1 Plug-it-in vs. battery**

Electrical considerations should not be ignored just because a device operates on a battery. Non-rechargeable batteries have to be bought and rechargeable ones need a recharger and a power supply to plug it into. In addition, some battery packs may be unique and non-interchangeable with others on-site. Furthermore, problems may arise if the power supply is only available at certain times of the day. This may mean having extra battery packs available so that when one is being used, the other(s) can be charging. This is especially true for critical care devices. Therefore, it will help know how many of each type of batteries are needed for general and emergency use.

### **2.2.3 Patient Electrical Interface and Isolation**

When working in a patient area where the integrity of the electrical ground cannot be ensured, the staff needs to be diligent while using equipment on or near patients. The staff should avoid touching more than one piece of equipment at a time. You may want to look at the use of auxiliary ground wires between pieces of equipment to create a mutually shared electrical ground system. This might be limited to critical care areas. In routine patient areas the staff should be instructed to avoid touching the equipment and the patient at the same time, thus reducing the chance of creating a ground path from the equipment through the staff to the patient.

### **2.2.4 ESD – Electrostatic Discharge**

(The discussion below was extracted from the CDRH Website.)

Electrostatic Discharge (ESD) is defined as the movement of static electricity, e.g. sparks, from a non-conductive surface to an approaching conductive object. ESD can damage or destroy semiconductors and other circuit components. Static electricity can build on paper, plastic, or other non-conductors and can be discharged by human skin, e.g. finger, contact. It can also be generated by scuffing shoes on a carpet or by brushing a non-conductor. Integrated circuits (ICs) are especially vulnerable to ESD because of damage to their internal structures.

Many medical devices today have an on-board computer that performs device control, patient monitoring, and data storage functions. ESD can indirectly affect a device's on-board computer by interfering with the device's signal detection/monitoring circuitry. ESD can also directly interfere with the device's CPU.

ESD enters the device's circuitry via some sort of electrical path. There are many such paths including the power cord and unused patient leads. Even more paths are available when a device is disassembled for service. This will affect how on-site servicing is done. ESD precautions need to be observed. One ESD precaution is to use a properly grounded workstation. Another precaution is to use anti-static bags to transport and store ESD sensitive components and circuit boards.

If a device is not needed for a critical application, then, as a precaution against ESD, computer and critical electronics should be disconnected after power outages until the power is returned and is stable.

### **2.2.5 EMC / EMI – Electromagnetic Compatibility/Interference**

*Cell phones and two-way radios should not be permitted anywhere near patient treatment areas due to potential electromagnetic interference (EMI)*

(The following discussion was extracted from an article that originally appeared in the May 1995 *FDA Consumer*)

Today's medical professionals rely heavily on wireless communication devices to help them do their jobs efficiently. And yet the proliferation of such gadgetry is not without its problems. Increasingly, medical and communications devices may be at odds with each other.

The problem is electromagnetic interference (EMI), and it's becoming a growing concern among hospital staffs, electronics manufacturers, and the Food and Drug Administration. Every electrical device emits electromagnetic energy. This energy can interfere with other devices the way a hair dryer creates snow on a nearby television.

Most of the time, the problem is merely annoying. For example, EMI could cause static on the screen of a hospital computer. But whenever anything interferes with a lifesaving medical device like a pacemaker or an apnea monitor, the results can affect the patient.

Between 1979 and 1993, FDA received reports of more than 100 suspected incidents of EMI with medical devices. Because the interference was almost always fleeting and difficult to reproduce, most of those reports have not been verified or duplicated in laboratory settings. Nevertheless, FDA suspects EMI caused most of them, including the following:

- A pacemaker failed during an ambulance ride while the two-way radio was in use.
- A man in a powered wheelchair was seriously injured when his chair rode off a cliff at high speed. He was several miles from a radio tower and three blocks from a busy road, where mobile radios were likely in use.
- A pulse oximeter machine displayed a pulse rate and oxygen level on a dead body when a telemetry receiver that was part of the system was placed too close to the body.
- A fetal heartbeat detector picked up local radio and CB broadcasts instead of the baby's heartbeat.

Sources of possible electromagnetic interference increase every year. Citizens Band radios, cellular telephones, wireless computer links, microwave signals, radio and television broadcast transmitters, pagers, and many other machines emit electromagnetic waves that could interfere with other devices.

For practical purposes, it's impossible to stop electromagnetic waves completely at their source. Modern society has become much too dependent on the convenience of instant communication. And since medical devices themselves often emit electromagnetic waves, using several machines at once in a hospital room can cause problems. It is much more feasible to build electromagnetic compatibility (EMC) into new medical devices, so they can operate accurately in an environment flooded with electromagnetic waves, and so they don't give off any more waves than necessary.

Be aware that EMI can cause steady, momentary or intermittent disruption of the performance of many medical devices. As much as possible, try to keep known sources of interference (such as cellular phones and hand-held transceivers) from coming too close to patient monitors and other sensitive electronic medical devices.

### **2.3 CLEANING AND STERILITY ISSUES**

“When water comes in contact with air as rain, or soil as surface or groundwater, it can dissolve or suspend chemicals and microbes found in air and soil, or become contaminated by various waste discharges.” (*Handbook of Environmental Health*, page 55)

The potential for increased contamination increases the burden for ensuring the cleanliness and/or sterility of devices used on and around patients. As such, the cleaning and sterilization procedures may have to be adjusted to compensate for the additional contamination. The *Field Operations Guide* (referenced below the Table of Contents) has several in-depth discussions about water supplies and their effect on disaster sites.

If power supplies are intermittent or scheduled for only parts of the day, the availability of power will also have to be taken into consideration. For example, if an autoclave sterilization (high pressure steam sterilization) cycle is interrupted for several hours, the cycle may need to be restarted from the beginning instead of just picking up where it left off. (Even though an autoclave is mentioned in the example above, it is probably more likely that sterilization will be done chemically rather than with heat or steam.)

One final sterilization issue is the reuse of medical items that are normally considered to be single-use disposable items. Many of these supplies are expensive and the hospital staff may resterilize and reuse them rather than throw them away. More information concerning this topic can be found at <http://www.fda.gov/cdrh/reuse/index.shtml>.

### **3. CONCLUSION**

There are many aspects to medical devices, more than can adequately be covered in these few pages. As stated before, the present information is meant to give you some background about medical devices. It is not intended to make you an expert.

A reviewer of this document asked the following questions:

- What types of devices are we likely to encounter in a deployment?
- How do we test them?
- How do we fix them?
- What should we do?

Because each deployment situation is different, there is not a standard answer. However, it is unlikely that you, the deployed CCRF engineer, will be the only person on-site that might have technical knowledge of medical devices. If there is a field hospital or clinic, it is likely to be staffed with technicians who are familiar with the issues discussed in this information sheet. If you are asked to assist with medical device issues, it is likely that your role would be limited. You might be asked to help obtain replacement medical disposables, or track down a piece of equipment that was ordered but not yet delivered, or set up a hospital equipment storage shed.

By its very nature, a disaster site is a hazardous and challenging environment. As a CCRF engineer, you may be called on to apply your talents and ingenuity to fix problems. Many of those problems may be well outside your realm of normal life. Help out if you can, but be prepared to admit when you do not know an answer. In any case, it always helps to read the manual.

## ATTACHMENT - Acronyms

CDRH	Center for Devices and Radiological Health (FDA)
CPU	Central Processing Unit
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
ESD	Electrostatic Discharge
FDA	Food and Drug Administration
FOG	Field Operations Guide (for Disaster Assessment and Response)
IC	Integrated Circuit