

Chapter L

Safety Issues in Computerized Medical Equipment

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ABSTRACT

Computers now are being used increasingly in safety-critical systems like nuclear power plants and aircraft and, as a consequence, have occasionally been involved in deadly mishaps. As microcomputer technology continues to proliferate, computers are also now increasingly being used in medical equipment such as ventilators and pacemakers, sometimes with safety-critical results. This chapter discusses some of the special concerns that arise when computer technology is introduced into medical equipment, using two case studies as examples: the Therac-25 radiation therapy unit and Abbott's patient controlled analgesia machine. Also discussed are some of the regulations that have been proposed by the (American) Food and Drug Administration (FDA) to help tackle the special problems that can arise when developing software-based medical equipment.

INTRODUCTION

Computers are now increasingly being introduced into safety-critical systems like nuclear power plants and aircraft, and, as a consequence, have occasionally been involved in deadly mishaps. As the cost of microcomputer technology continues to drop, computers are also now increasingly being used in medical systems and equipment such as ventilators or

pacemakers, sometimes with safety-critical results. This article illustrates some of the special concerns that arise when computer technology is introduced into medical equipment using two case studies as examples. Also discussed are some of the regulations that have been proposed by the (American) Food and Drug Administration (FDA) to help tackle the special problems that can arise when developing software-based medical equipment.

THE CASE OF THE THERAC-25 RADIATION THERAPY UNIT

In 1986, two cancer patients died when they received lethal doses of radiation from a Therac-25 radiotherapy unit. An investigation revealed that one contributor to this catastrophe was the failure of the design team to recognize a race condition: a miscoordination between concurrent tasks. This error resulted in individuals being overradiated (to death in two cases) in Texas and Georgia while receiving cancer therapy using the Therac-25 system (Leveson & Turner, 1993).

Although the technical details of the failure remain secret as a result of a legal settlement, experts have come up with the following account as the most likely accident scenario. A modern radiation-therapy machine is based on a linear accelerator that produces a high-energy electron beam. One may direct the electrons directly into the patient, or, to produce X-rays, one places a heavy metal target in the electron beam so that when the electron beam hits the target, X-rays come out from the other end. The target is moved in and out of the beam automatically under software control, depending on whether an electron beam or an X-ray beam is selected to treat the patient. Also, the current in the electron beam is programmed to be much greater in the X-ray mode because of energy losses that result when the target is used in making X-rays.

However, in the overdose cases, because of a software-design error, the computer ran as if it was in X-ray mode rather than in electron mode, resulting in excessive radiation. The problem was a subtle error that no one had detected during the extensive testing the machine had undergone before being introduced into clinical use. In fact, the error surfaced only when an operator happened to use a specific, unusual combination of keystrokes to instruct

the machine about the radiation parameters to be used. Specifically, if an extremely fast-typing operator inadvertently selected the X-ray mode instead of the electron-beam mode, and then used an editing key to correct the command to select the electron-beam mode instead, it was possible for the computer to lag behind the orders. The result was that the device appeared to have made the correction but in fact still had incorrect settings.

How could this happen? Experts speculate that the software developer might not have considered it necessary to guard against this failure mode or might not have even imagined it since radiation-therapy designers have traditionally used electromechanical interlocks to ensure safety in this setting. Also, analysts reviewing the case noted that the unit should have been programmed to discard unreasonable readings, as the injurious setting presumably would have been. Finally, there should have been no way for the computer's verifications on the video screen to become unsynchronized from the keyboard commands.

ERGONOMIC ISSUES

Ergonomics is the art and science of matching equipment design and job procedures to the worker, usually with a view to reducing error and improving productivity. Ergonomics may additionally be defined as the study of the interaction between people and machinery, and the factors that influence that interaction. Also known as human factors, ergonomics is a relatively new discipline, but one that has led to enormous improvements in equipment design as the principles of good ergonomic design have become discovered and refined over time (Kroemer, 2001; Vicente, 2004). As a result, equipment ranging from automobiles and photocopiers to nuclear power plants have all seen

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