

THERAC-25

Computerized Radiation Therapy

Report by:

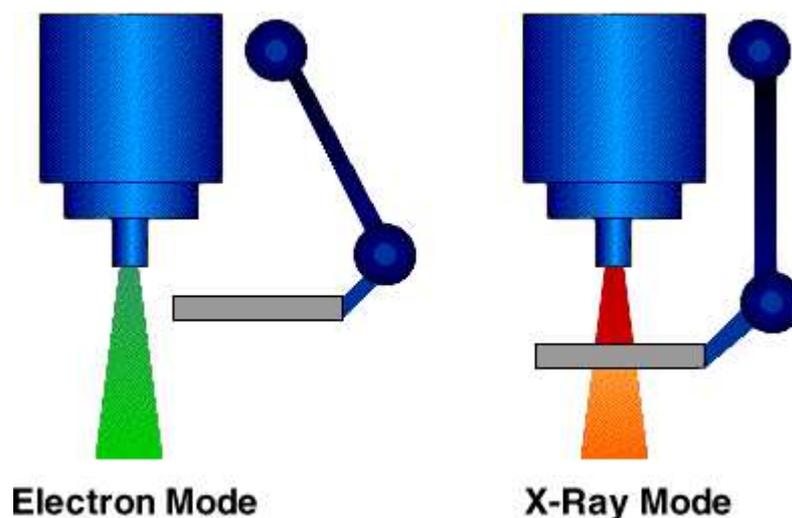
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Introduction:

The use of computers in the medical field is becoming more and more widely used. Computers are obviously very beneficial in the medical field. However, in the case of Therac-25, they can be deadly.

The History:

Therac-25 was used in the treatment of cancer. Its purpose was to provide radiation to a specific part of the body and hopefully kill the malignant tumor. The Therac-25 was the third system created under the Therac name by the Atomic Energy of Canada Limited (AECL). The AECL is most famous in Canada for their creation of the CANDU reactors which are world renowned. A Therac-6 and Therac-20 were both used in the treatment of cancer. The number that goes along with the word Therac stands for the maximum amount of mega electron volts (MeV) the machine can dispense. It was believed that the new Therac-25 was much more efficient than Therac-6 and Therac-20. The overall size of the machine was reduced and still allowed for two modes; photon mode and electron mode. A tungsten shield was in place for the X-ray mode and removed for the electron mode as illustrated below:



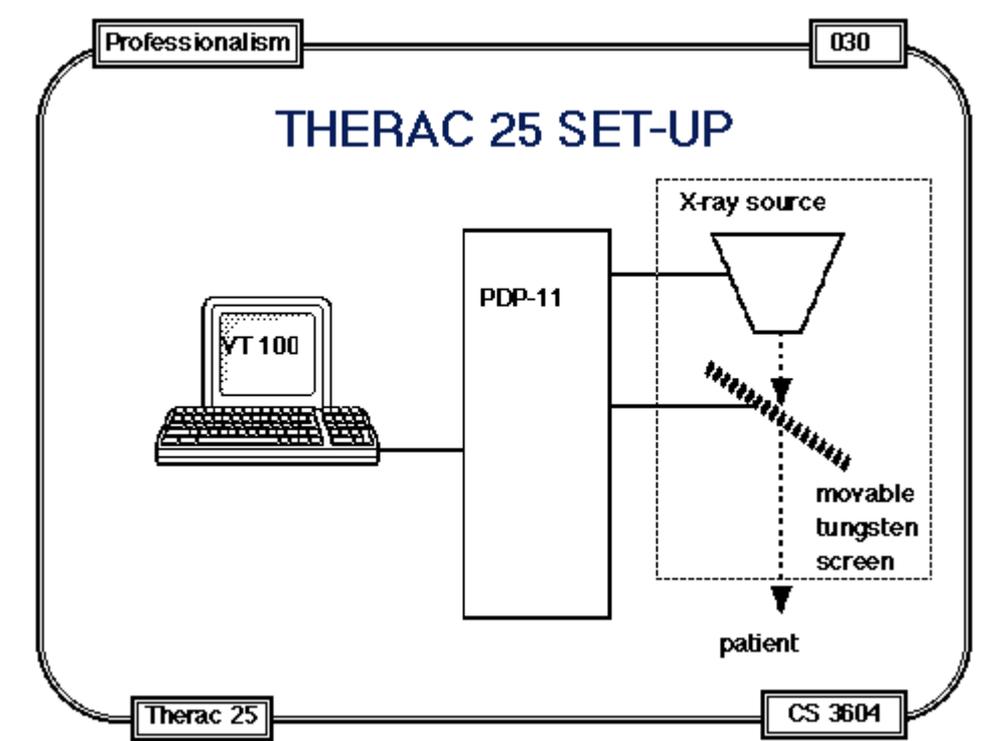
Ref.(4)

Each mode was used in treating cancer depending on the depth of the tumor under the skin.

The software for the Therac-25 system was created by one programmer who revised the Therac-6 systems code. The software was basically responsible for:

- monitoring the machine
- accepting the input for the treatment
- setting up the machine to administer this treatment
- and finally controlling the machine to carry out the treatment

The diagram below briefly illustrates the set up of the machine. It begins with the computer that the software is on for the technician to use. This is sent to another minicomputer called the PDP-11. Finally the radiation machine receives the commands and treats the patient.



Ref(3)

The machine itself is enclosed in a radiation treatment room in order to prevent exposure to the technicians working nearby. The patient has audio and visual equipment, allowing communication with the technicians. A diagram of the general layout of the Therac-25 is shown below:

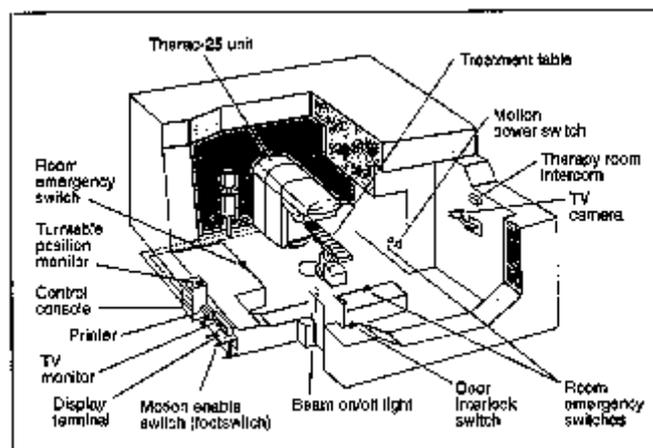


Figure 1. Typical Therac-25 facility.

Ref(5)

The Accidents:

The Therac-25 treatment system was first started in 1976 but was generally a piece of machinery. The software controlled system came online in 1982. The first incident occurred in 1985 and five more happened within 19 months of the original. After the fifth the Federal Drug Administration recalled Therac-25 until it was "fixed". Unfortunately the sixth incident occurred before the changes had been made.

The first incident involved a 61 year old women from Marietta, Ga. who was receiving follow-up treatment after a tumor had been removed from her breast. Therac-25 administered a very large overdose of radiation and essentially burnt her. The hospital and technician denied any wrong doing and in fact continued to send her for treatments. She had to have both breast removed and lost total use of her right arm because of the radiation overdose.

A 2nd incident occurred closer to home when a 40 year old women was receiving her 24th Therac-25 treatment at the Ontario Cancer Foundation in Hamilton. The machine stopped 5 seconds into the treatment with an error. The technician seeing that "No Dose" had been administered (according to the computer) hit the 'P' key thus proceeding with the dose. This was done a total of 5 times giving the patient 13 000 - 17 000 rads. To give an idea of how much of an overdose this is; a regular treatment is around 200 rads and 1000 rads of radiation to the entire body can be fatal. The patient died 3 months after the overdose from the original cancer, but if she had lived an entire hip replacement would have been necessary due to the damage done by the overdose.

The 3rd case occurred in Yakima, WA. This patient received radiation burns but many years later has fully recovered from the damages.

One of the most severe cases was the 4th in Tyler, TX. A male required radiation treatment on his back. The machine was set to X-ray mode instead of Electron mode so the technician just used the "cursor up" key up and quickly changed this mistake. However, this only made things worse as a software bug had been mistakenly stumbled upon. While administering the first treatment an error "Malfunction 54" flashed up telling the technician an underdose had been administered. The technician hit the 'P' key and a 2nd dose was delivered. The patient had been given an overdose after the first treatment, and he knew something was wrong, due to the burning sensation he felt in his back. As he attempted to get up the 2nd dose was administered. The technician would have known the man was in pain if the audio and visual equipment was working. This was just something else that was wrong with the Therac-25 treatment system at this particular hospital. This man within weeks, lost the use of both legs and his left arm. Five months later he became the first fatality directly related to the Therac-25 system.

A month later at the same hospital, with the same technician another fatal dosage was given. The technician made the same error of quickly changing the mode from X-ray mode to Electron mode using the 'cursor up' key. This again caused "Malfunction 54". The patient this time was receiving treatment on his face. When the overdose was administered he yelled and then began to moan. The audio equipment was working this time but the initial dose was too much for the man. He received severe neurological damage, fell into a coma and died only 3 weeks later.

The 6th and last incident occurred in January of 1987 in Yakima, WA. The patient required only a small dose and according to the machine that is all he received. Yet again when the treatment was underway and error paused the machine and the technician hit the 'P' key to proceed. A overdose was administered and the man died just 3 months later.

Reference:1,2,5

The Reactions:

After each overdose the creators of Therac-25 were contacted. After the first incident the AECL responses was simple, "After careful consideration, we are of the opinion that this damage could not have been produced by any malfunction of the Therac-25 or by any operator error (Leveson, 1993)."

After the 2nd incident the AECL sent a service technician to the Therac-25 machine, he was unable to recreate the malfunction and therefore conclude nothing was wrong with the software. Some minor adjustments to the hardware were changed but the main problems still remained.

It was not until the fifth incident that any formal action was taken by the AECL. However it was a physicist at the hospital where the 4th and 5th incident took place in Tyler, Texas who actually was able to reproduce the mysterious "malfunction 54". The AECL finally took action and made a variety of changes in the software of the Therac-25 radiation treatment system. The machine itself is still in use today.

Reference:1

The Blame:

The general consensus is that the Atomic Energy of Canada Limited is to blame. There was only *one* person programming the code for this system and he largely did all the testing. The machine was tested for only 2700 hours of use, but for code which controls such a critical machine, many more hours should have been put in to the testing phase. Also Therac-25 was tested as a whole machine rather than in separate modules. Testing in separate modules would have discovered many of the bugs. Also, if the AECL believed that there were problems with the Therac-25 right after the first incident then it is possible that most of the 5 other incidents could have been avoided and possibly the 3 fatalities.

Reference:1,5

Conclusion:

The Therac-25 is one of the most devastating computer related engineering disasters to date. The machine was designed to help people and largely, it did. Yet some sloppy engineering on the part of the AECL led to the death or serious injury of six people. These incidents could have been avoided if the AECL reacted instead of denying responsibility.

References:

1. Death and Denial, The Failure of the Therac-25 (<http://cobra.csc.calpoly.edu/~dbutler/papers/THERAC25.html>)
2. The Downfall of the Therac-25 (<http://net.cs.utexas.edu/users/dianelaw/cs378/therac.htm>)
3. The Therac-25 Incident (http://ei.cs.vt.edu/~cs3604/lib/Therac_25/TheracClass.html)

4. Human Error in Medicine

(<http://www.smi.stanford.edu/people/felciano/research/humanerror/humanerrortalk.html>)

5. An Investigation of the Therac-25 Accidents (part 1-5)

(http://ei.cs.vt.edu/~cs3604/lib/Therac_25/Therac_1.html)