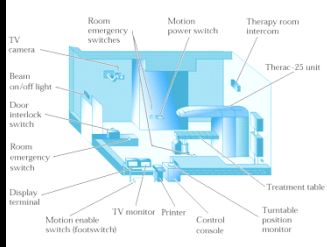


# Therac-25

Nancy Leveson  
University of Washington

Clark S. Turner  
UC - Irvine



Lecture 39

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## Keep the socio-technical system in mind



<b>The Machine</b> <ul style="list-style-type: none"> <li>• Video, audio, etc.</li> <li>• Hardware</li> <li>• Software Systems</li> </ul>	<b>Hospitals and Clinics</b> <ul style="list-style-type: none"> <li>• Doctors, Medical Physicists</li> <li>• Management, User groups</li> <li>• Operators, Reporting</li> </ul>
<b>Atomic Energy of Canada Limited</b> <ul style="list-style-type: none"> <li>• Management, Reporting</li> <li>• Design teams, sales staff, support and field engineers</li> </ul>	<b>Gov't Medical Device Regulation</b> <ul style="list-style-type: none"> <li>• FDA</li> <li>• Canadian Radiation Protection Bureau</li> <li>• Reporting procedures</li> </ul>

[www.computations.org](http://www.computations.org)

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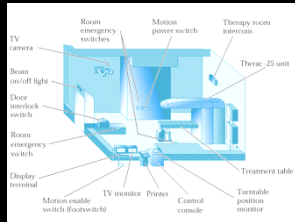
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## The Therac-25 was created in the mid-1970s



- AECL reused code from the Therac-6 and Therac-20
- Hardware safety checks replace by software
- Dual mode (X-ray and proton)
- PDP-11 controls the turntable
- Tested in 1983
  - Assumed no design errors in software
  - Considered software failures like "computer selects wrong mode" but assigned them probabilities of  $4 \times 10^{-9}$ .

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## There were a total of 6 cases reported

1. Katy Yarbrough - constant pain, lost the use of her arm and shoulder, and had to have her breast removed (Kennestone).
2. Frances Hill - cancer took her in November, but she would have needed a full hip replacement (Ontario).
3. Woman develops erythema on her hip (Yakima).
4. Voyne Ray Cox - died from overdose (Tyler).
5. Verdon Kidd - died from radiation injury to his brain (Tyler).
6. Glen A. Dodd - died from complications of the radiation overdose (Yakima).




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## Some of the problems...

<b>The Machine</b> <ul style="list-style-type: none"> <li>• No hardware checks for software safety</li> <li>• No computer in control of only turntable</li> </ul>	<b>Hospitals and Clinics</b> <ul style="list-style-type: none"> <li>• Lack of training</li> <li>• Lack of maintaining equipment</li> <li>• Technician not checking on patient in event of broken equipment</li> </ul>
<b>Atomic Energy of Canada Limited</b> <ul style="list-style-type: none"> <li>• Programming Errors</li> <li>• Not integrating testing into development of software</li> <li>• Poor HCI (error messages)</li> <li>• Lack of documentation</li> </ul>	<b>Gov't Medical Device Regulation</b> <ul style="list-style-type: none"> <li>• Inadequate requirements for reporting problems</li> <li>• Not officially documenting Therac-25</li> </ul>

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## Some solutions to the problems...

<b>The Machine</b> <ul style="list-style-type: none"> <li>• Install hardware checks like Therac-20</li> <li>• Install a computer to control turntable</li> <li>• Test and Set?</li> </ul>	<b>Hospitals and Clinics</b> <ul style="list-style-type: none"> <li>• Pay for training or time reading manual</li> <li>• Maintain equipment – do not let patients use broken machines</li> </ul>
<b>Atomic Energy of Canada Limited</b> <ul style="list-style-type: none"> <li>• More vigorous code reviews</li> <li>• Integrate testing into development of software</li> <li>• Usability test Interface</li> <li>• Write more detailed documentation</li> </ul>	<b>Gov't Medical Device Regulation</b> <ul style="list-style-type: none"> <li>• Look at loopholes and adjust requirements for reporting problems</li> <li>• Too late to officially document Therac-25 ©</li> </ul>

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## Abbott AIM Plus Incident

- 2006 a patient received a fatal overdose of fluorouracil, a chemotherapy drug
- Nurse had to calculate the rate to be delivered, 5,250/45.57 mL over 24X 4 hours



Thimbleby, H. 2008. FEATURE Ignorance of interaction programming is killing people. interactions 15, 5 (Sep. 2008), 52-57.  
DOI: http://dx.doi.org/10.1145/1390985.1390988

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$$(5,250/45.57) / (4 * 24)$$

- Nurse used a calculator and verified it with another nurse



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$$(5,250/45.57) / (4 * 24)$$

- Nurse used a calculator and verified it with another nurse
  - Need a calculator with ( ) OR
  - Need to know how to use memory functions

- Neither divided by 24 hours a day
- Gave patient 28.8 mL per hour instead of 1.2 mL
- More than 30 mL of fluorouracil per day should have raised warnings (1 mL a day is a high dose!)



Thimbleby, H. 2008. FEATURE Ignorance of interaction programming is killing people. interactions 15, 5 (Sep. 2008), 52-57.  
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## Alaris SE pumps – pointing fingers

FDA officials declined to name the maker of the infusion pumps. (In 2006, Cardinal Health, of Dublin, Ohio, stopped production of its Alaris SE pumps because of a key-bounce error that reportedly killed two patients, including a 16-day-old baby that got 44.8 milliliters of intravenous nutrition, rather than 4.8 milliliters.)

During the investigation into the malfunctioning pumps, **nurses complained about frequent keyboard errors, while the manufacturer blamed nurses for entering the wrong drug information and then failing to double-check, said Brian Fitzgerald, who heads the FDA's software specialists.**



<http://paragraff.wordpress.com/2008/07/03/when-bugs-really-do-matter-22-years-after-the-therac-25/>

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## Alaris SE pumps – pointing fingers

In an August 15 recall letter, Alaris informed customers that it will **provide a warning label for the pumps** and a permanent correction for the key bounce problem once it is available.



<http://paragraff.wordpress.com/2008/07/03/when-bugs-really-do-matter-22-years-after-the-therac-25/>

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## Alaris SE pumps – removing the up key

**Proper Stance**  
When programming pumps, stand squarely in front of the keypad (**ideally with the pump at eye level for best visibility**) to facilitate proper depth of depressing each key.

**Listen**  
Focus on **listening to the number of beeps** while programming IV pumps; each beep will correspond to a single digit entry. Unexpected double tone could indicate an unintended entry.

**Verify Screen Display ...  
Independent Double Check ...  
Look ...**



<http://paragraff.wordpress.com/2008/07/03/when-bugs-really-do-matter-22-years-after-the-therac-25/>

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## Other Examples

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[http://www.youtube.com/watch?v=brNbDwnHDVs&eurl=http://interactions.acm.org/content/?p=1151&feature=player\\_embedded](http://www.youtube.com/watch?v=brNbDwnHDVs&eurl=http://interactions.acm.org/content/?p=1151&feature=player_embedded)

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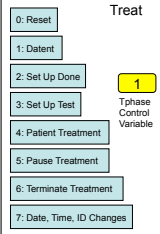
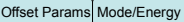
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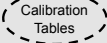



## The Tyler Software Bug

*Focusing on particular software bugs is not the way to make a safe system!*

Mode/Energy Offset (MEOS)





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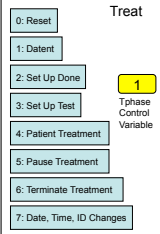
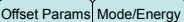
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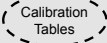
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## Keyboard handler updates mode/energy for Hand (turntable)

Mode/Energy Offset (MEOS)





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## Keyboard handler updates operating params for *Datent*

**Hand**    **Keyboard Handler** (Data Entry Complete)

Offset Params    Mode/Energy

Mode/Energy Offset (MEOS)

Calibration Tables

**Treat**

- 0: Reset
- 1: Datent
- 2: Set Up Done (1)
- 3: Set Up Test
- 4: Patient Treatment
- 5: Pause Treatment
- 6: Terminate Treatment
- 7: Date, Time, ID Changes

Tphase Control Variable

**Interface**

**Race Condition!**

If *Data Entry* set before updating MEOS, *Datent* will use old MOES info while *Hand* will rotate turntable using new info. (Fix: Variable checks if cursor at end)

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## Data Entry Complete - *Datent* enters magnet subroutine

*Magnet* bends the magnets for the beam. Bending takes 8 seconds.

**Hand**    **Keyboard Handler** (Data Entry Complete)

Offset Params    Mode/Energy

Mode/Energy Offset (MEOS)

Calibration Tables

**Treat**

- 0: Reset
- 1: Datent
- 2: Set Up Done (1)
- 3: Set Up Test
- 4: Patient Treatment
- 5: Pause Treatment
- 6: Terminate Treatment
- 7: Date, Time, ID Changes

Tphase Control Variable

**Interface**

**Problem!**

*Magnet* sets Ptime to 8 seconds during bending. Ptime clears the *bend magnet flag* during 1<sup>st</sup> execution. Any edits made during first 8 seconds will not be recognized!

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## The very temporary fix...

SUBJECT: CHANGE IN OPERATOR PROCEDURES FOR THE THERAC-25 LINEAR ACCELERATOR

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To avoid accidental use of this key (UP key), the **key cap must be removed** and the switch contacts fixed in the open position with electrical tape...

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On the 256<sup>th</sup> pass, the turntable is in the testing position...

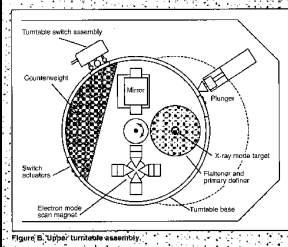


Figure 6, Upper turntable assembly.

The mirror reflects a full strength proton beam!

The "fix" – do not increment Class3...set it to a non-zero value.

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