Safety issues in medical devices

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Interactive medical systems used in hospital and home care are controlled by software that governs key aspects of the user interface and performs key safety functions.

Design faults or unexpected data entry into software designed to deliver healthcare can have catastrophic failures.

Main points:
(i) understanding of the design challenges with user interface software for medical systems
(ii) tools and techniques for design and analysis of software incorporated in interactive medical systems
A relevant paper appeared in 2006 in the IEEE Computer journal underlining the fact that clinical demands appear to point to the need for collaborative process among manufacturers, regulators, and medical equipment users.

Recalls have increased since 2006, due to more sophisticated software.

Taken from: The Biomedical Instrumentation & Technology journal

**Software-Related Recalls: An Analysis of Records**

Lisa K. Simone (*biomedical and software engineer with the Center for Devices and Radiological Health at the U.S. Food and Drug Administration*)

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Recalls</th>
<th>Software-Related Recalls</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>604</td>
<td>84</td>
<td>13.9%</td>
</tr>
<tr>
<td>2006</td>
<td>663</td>
<td>119</td>
<td>17.9%</td>
</tr>
<tr>
<td>2007</td>
<td>638</td>
<td>119</td>
<td>18.7%</td>
</tr>
<tr>
<td>2008</td>
<td>847</td>
<td>192</td>
<td>22.7%</td>
</tr>
<tr>
<td>2009</td>
<td>782</td>
<td>146</td>
<td>18.7%</td>
</tr>
<tr>
<td>2010</td>
<td>981</td>
<td>147</td>
<td>15.0%</td>
</tr>
<tr>
<td>2011</td>
<td>1,277</td>
<td>315</td>
<td>24.7%</td>
</tr>
</tbody>
</table>

Percentage of Recalls Related to Software
Medical devices

User interface in medical devices:

if medical systems are to be used safely, it is important that user interface software is designed to make the device easy to use and mistakes made by users are corrected.

The work presented has been developed within the CHI+MED research project (http://www.chi-med.ac.uk/), and in collaboration with the Center for Devices and Radiological Health of the US Food and Drug Administration (CDRH/FDA).

CHI+MED - Computer-Human Interaction for Medical Devices, EPSRC project
EPSRC - Engineering and Physical Sciences Research Council (the UK's main agency for funding research in engineering and the physical sciences)
UCLH - University College London Hospitals
User interface design issues in medical devices

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Focus of this talk

Demonstration of user interface issues with medical devices in use at UCLH and in other UK hospitals

A recorded video of the demonstration is available on YouTube
"Medical Device Training - Design Issues in Medical User Interfaces"
https://www.youtube.com/watch?v=T0QmUe0bwL8
The nature of the identified issues

The cause: software design flaws

What happens:
- user input erroneously discarded
- inappropriate feedback
- unexpected device modes

Potential consequences: serious use errors
(for example, missing decimal point errors when entering values)
Demonstration of identified issues
Arrow up and down
Scroll through menus, change setting of numbers from 0-9, answer Yes/No questions.

Arrow left and right
Select data from a scale and switch between digits when numbers are entered. Open a function while pump is running or stopped with the left arrow key.

Yellow LED: Pre-alarm, reminder alarm
Green / Red LED: Infusion occurring / device alarm, operating alarm
Blue LED: Currently connected to SpaceControl

Press to reset single values to zero and switch back to the previous screen/menu level.

Press to open the pump door.

Press to initiate bolus.

Press to turn pump on/off.

Open certain functions and press to confirm values/setting/alarms.

Press to link the pump to SpaceControl and to assign a barcode after scanning.

Press to Start/Stop infusion.
Instructions from the user manual

How to enter infusion rate (and other infusion parameters):

- In the Main Menu, open the rate with ⏯️ and set it with ⏯️.
In the Main Menu, open the rate with ↵ and set it with ←.
In the Main Menu, open the rate with up and set it with left.
In the Main Menu, open the rate with ▲ and set it with ▼.
In the Main Menu, open the rate with and set it with.

81200 up
91200 up
99999 left
99999 down
91200 up
99999 right
99999 down
In the Main Menu, open the rate with and set it with.

sequence of keys: right  left down
different behaviour
In the Main Menu, open the rate with \( \uparrow \) and set it with \( \uparrow \).
In the Main Menu, open the rate with down and set it with up.
An accurate specification of the device behaviour

Obtained in our labs by reverse-engineering the real device

Similar data entry, different behaviour
Example: entering 950mL

Input Key Sequence
1. Left
2. Up 5 Times
3. Left
4. Down

Result from Pump 1
0950.0

Result from Pump 2
00000.1
Recommendations

• Be extremely mindful of range values
  – the device may silently change mode of operation in different value ranges

• Keep in mind that you may accidentally overshoot the legal range even if you are not entering extremely high or low values
  – because of different software configurations
Ignored values
Values are ignored **without warning** when input key sequences are not terminated with “OK”
Ventilators have similar problems

Datex-Ohmeda

Mindray

Draeger Apollo Infinity
Transfer errors: similar devices have opposite behaviours

- Values are automatically accepted even if the input key sequence is not terminated with “ok”
Recommendations

• **Avoid shortcuts when confirming entered values**
  – always submit values to complete data entry
  – don’t rely on automatic confirmation

• **Keep in mind that multiple steps may be required to confirm values**
  – some devices require “confirm” and then “accept”
Related issue: Timeouts
If the user edits a value and pauses for a few seconds before confirming the new value...
...then the device erroneously discards the new value without warning.
We observed and reproduced the same problem in different types of devices

**Patient monitor**
Radical 7

**Ventilators**
Datex-Ohmeda
Draeger Apollo Infinity C500
Recommendations

• Keep in mind that data entry expires because of inactivity
  – some device silently discard after a timeout
  – other devices silently confirm after a timeout
Ignored decimal point
The decimal point is erroneously ignored

The key sequence

1 0 0 . 1

is registered as 1,001
The decimal point is erroneously ignored

The key sequence

1  0  0  .  1

is registered as 1,001
(the value is fortunately rejected in this case because the pump configuration limits the rate value to 999 mL per hr)
Recommendation

• Be extremely mindful of different precision limits for different value ranges
  – many infusion pumps reduce precision of values greater than 100, e.g., the device may silently ignore decimal point key presses
  – other devices may have different *pitfall* values
Related issue: ill-formed values
Mistyping and Misreading numbers
Fractional number without leading zero
(could be easily misread as integer value)
Integer number with leading zero
(potentially misread as a fractional value)
This infusion pump accepts integer values with leading zeros (e.g., 089)

This behaviour can lead to missing decimal point errors
Recommendation

• Don’t rely on the “leading zero”
  – integer values may erroneously start with “0”
  – fractional values may erroneously start with “•”
Additional user interface issues
Viewing angle
Similar problems can be reproduced in any device equipped with seven-segments displays

**Infusion pumps**
- Alaris PC

**Infant warmers**
- Ohmeda Panda

**Phacoemulsifiers**
- Alcon Everest

**Patient monitors**
-Datascope Accutorr Plus
Recommendation

- **Never trust seven-segments displays**
  - you may read different values from different angles
Inconsistent use of soft buttons
Select an Option

DISABLED
System Config - Pump

- Accumulated air: Enabled
- Air-in-line settings: 75 microbar
- Auto-restart attempts: 0
- KVO rate adjust: 1 mL/h
- Max rate: 999 mL/h

Select an Option or EXIT

EXIT PAGE DOWN
Select an Option

DISABLED
System Configuration - Pump

Maximum rate adjustment

Maximum rate: 999 mL/h
System Configuration - Pump

Maximum rate adjustment

Maximum rate: 999 mL/h
Phacoemulsifiers have similar problems
Increase/Decrease values
Select an Option

Increase/Decrease values
DISABLED

Scroll options
Wrong feedback
Guardrails Drug Setup
BD Plastipak 50/60 mL

CONT DOSE: 1 mg/
Yes

MAX LIMIT: >>>>>
No

[Conc]: 1 mg/mL

->Select Max Limit Options

CHANGE MODE

SYSTEM ON

CareFusion
ABD Plastipak 10 mL

PRIMARY INFUSION

RATE  0.02 mL/h

VTBI  2 mL

Time Left:  < 1 minute

-0.1 is less than MIN RATE

0.1
No instructions displayed
Our work with Regulators and Hospitals

• Creating the basis for a new international standard for medical software
  – Will enable a more precise and uniform evaluation of usability, safety, and security of medical devices

• Improving pre-market review process
  – FDA & MHRA are using our results and trialling our methods on premarket reviews

• Informing hospitals
  – To improve purchasing of new medical devices
  – To raise awareness during training sessions

• Informing manufacturers
  – To fix existing issues, and identify new potential issues in advance
www.chi-med.ac.uk

- Publications on device design
- News on patient safety
- Training videos

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