

# CHI+MED: Preventing Human Error Caused by Medical Device Design

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# CHI+MED project [www.chi-med.ac.uk](http://www.chi-med.ac.uk)

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## Long-term aim

- to transform the design and use of medical devices
- to help clinicians avoid and recover from human error



# Infusion pumps recalls

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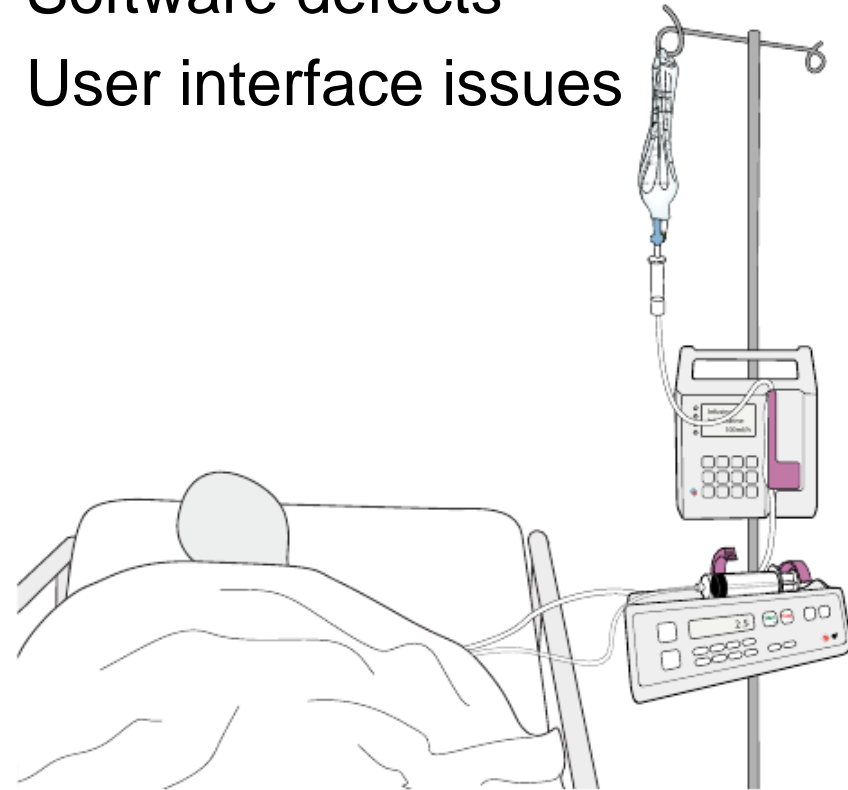
In the US, 2005-2009

- 87 models recalled
- > 56,000 adverse events
- 710 deaths
- **all manufacturers**



Most common issues

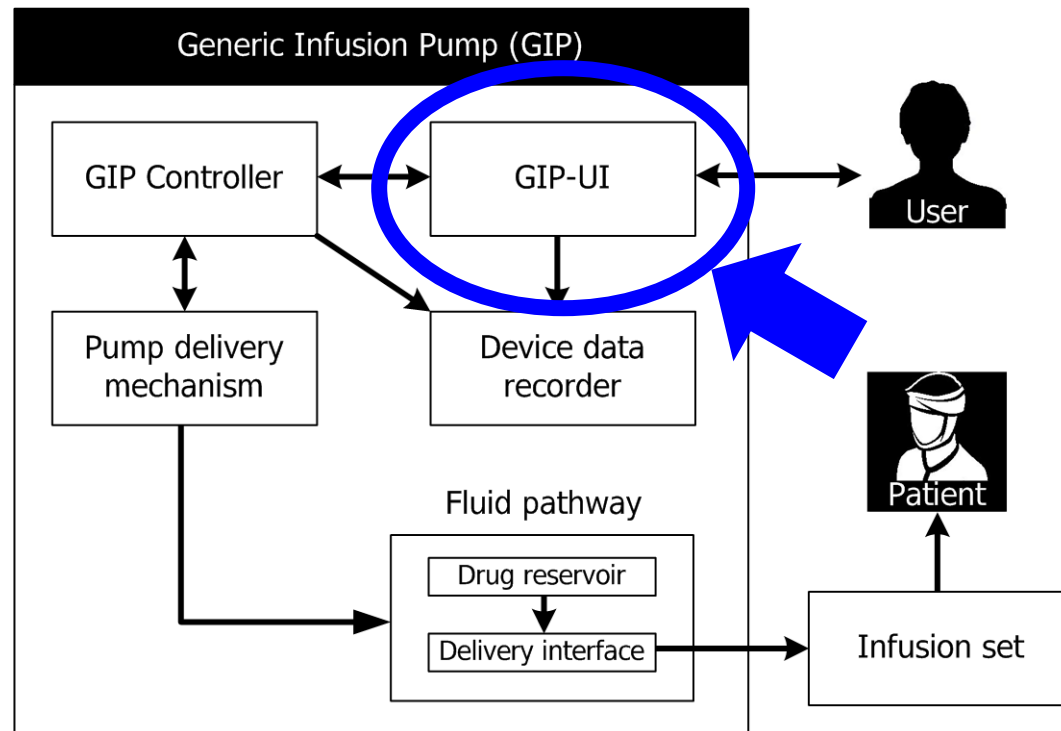
- Software defects
- User interface issues



# The Generic Infusion Pump (GIP):

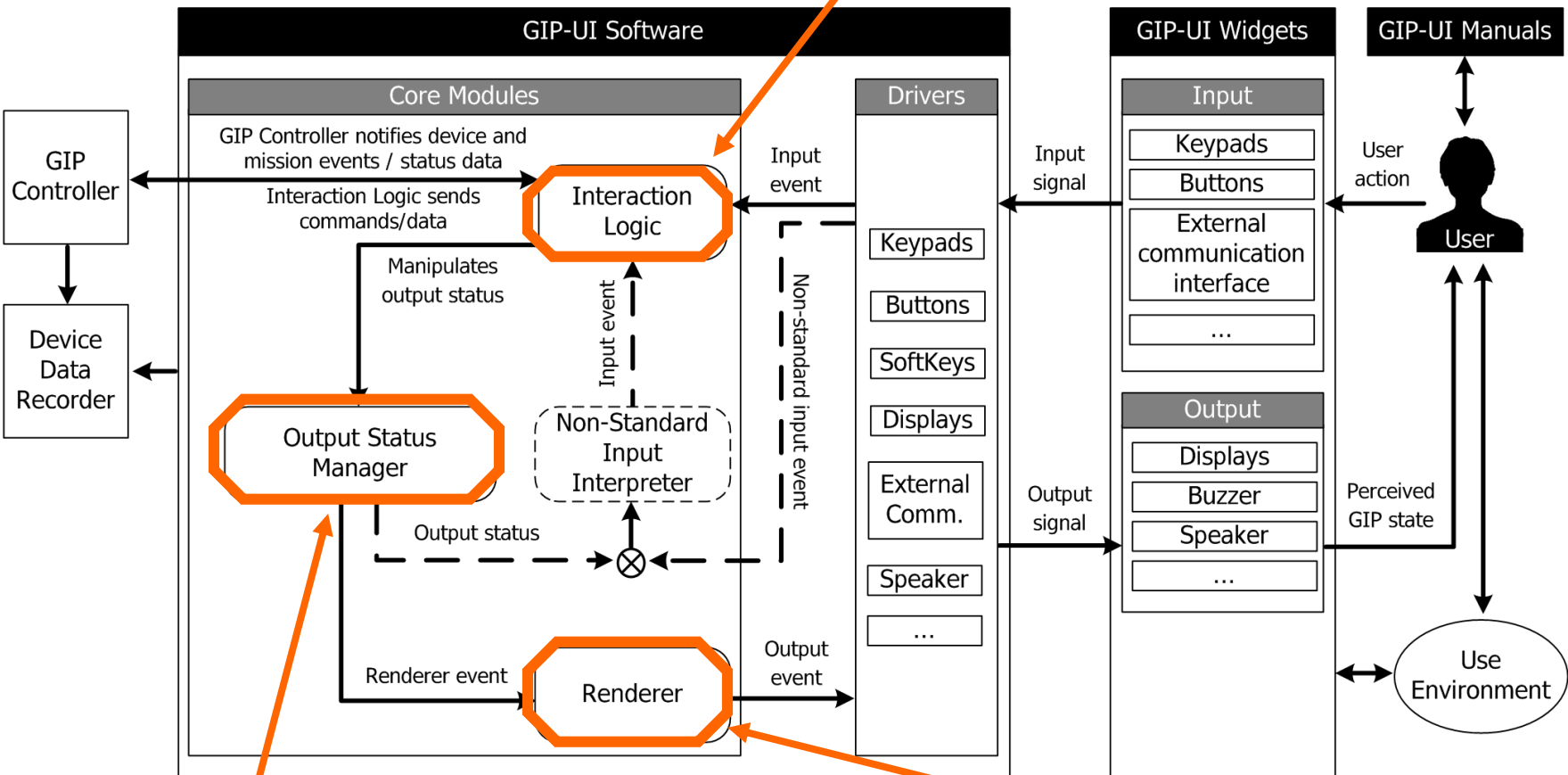
## A safety reference architecture for infusion pumps

- Captures common characteristics of marketed infusion pumps
- A basis for reasoning about hazards and infusion pump design issues
- **Our focus is on software-related causes of use hazards**
- With FDA (US regulator) + University of Pennsylvania



# Overview of the GIP-UI architecture

how the device responds to user input



how information is presented to the user

what information is presented to the user

# Hazard analysis for use errors in number entry

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Use GIP-UI to enumerate common design errors that lead to hazards like **over infusion as user fails to enter correct digits**

Structured around modules and interactions between modules:

- **Interaction Logic: Interaction issues**  
ie how the device responds to user input  
eg: **Key presses ignored without user awareness**
- **Output Status Manager: Feedback issues**  
ie *what* information is presented to the user  
eg: Incorrect / ambiguous values displayed without user awareness
- **Renderer: Rendering issues**  
ie *how* information is presented to the user  
eg Inappropriate fonts are used that can be easily misread

**Establish cause and effect relationships (design error - hazard)**

# Linking hazards to design issues and examples

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## Causes of over and under infusion hazards

Primary Cause (User Error)	Probable Root Cause (Underlying Design Issue)	Example from marketed pump
The user fails to enter the correct digits	Key press by user erroneously discarded without user's awareness <b>(interaction logic)</b>	100.1 registered as 1001 with no warning

...

# Decimal point erroneously ignored

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The key sequence



is registered as 1001

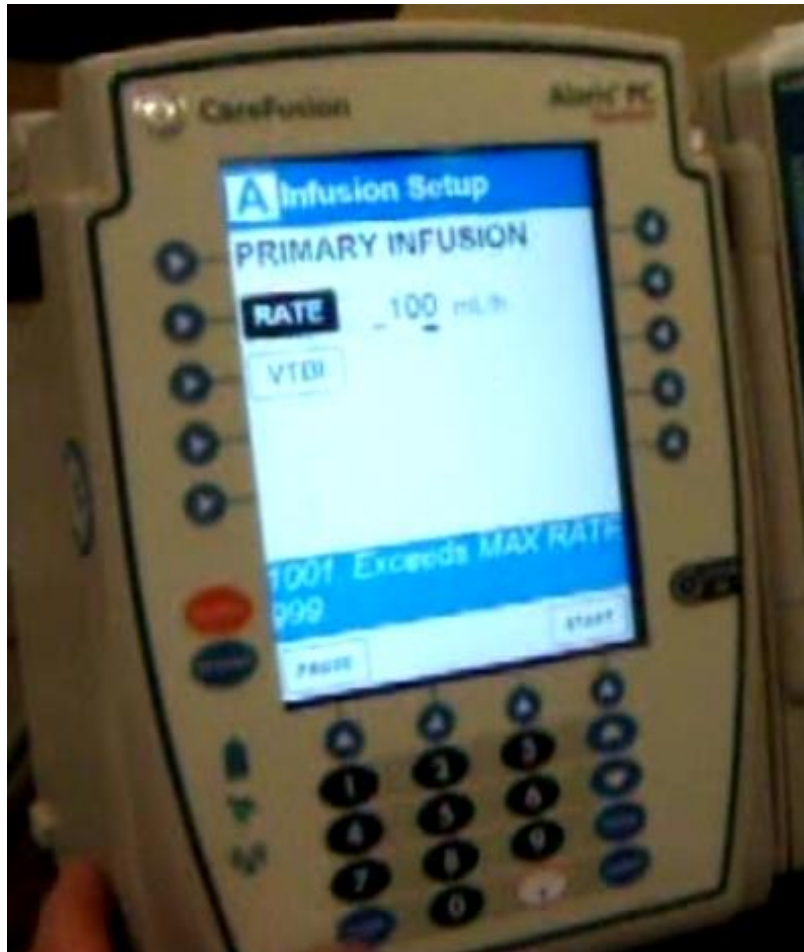
Numbers above 100  
cannot include a  
decimal point ...

so it is silently ignored



# Devices from different manufacturers have similar problems

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The key sequence



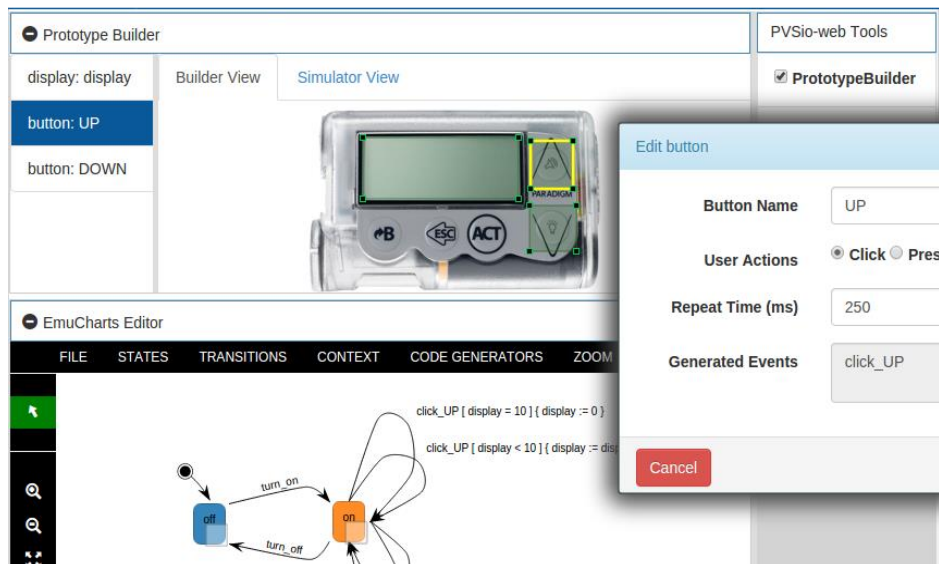
is registered as 1001

The value is fortunately rejected in this device

As pump configuration limits the rate value to 999 mL per hr

# PVSio-web: A model based tool for prototyping interactive systems

- Prototyping of interfaces and interaction design based on mathematical models
- Used to validate and demonstrate links between design errors and hazards
- Working with the FDA has helped identify problems in a series of commercial medical devices
- Hospitals have used in training programmes highlighting safety-related design issues

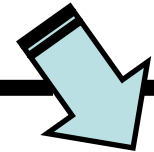


# From Hazard Analysis to Safety Reference Model

Causes of overinfusion and underinfusion hazards		
Primary cause	Probable root cause	Example
The user fails to edit the value	The pump displays incorrect values without the user's awareness	The device shows the last programmed value instead of the current value
The user fails to select the intended input field	The pump displays incorrect instructions without the user's awareness	The device requires a rate value but the display shows a notification message "Enter VTBI"
The user fails to read values or units	The pump uses inappropriate fonts or formats to render values or units	The device renders fractional values without a leading zero (e.g., .9 instead of 0.9), or integer values with leading zeros (e.g., .09 instead of 9)
The user fails to enter the correct digits	The pump erroneously discards key presses without the user's awareness	The device registers the key sequence [0][0][0][0] without any warning or notification if the minimum legal rate is 0.1
...	...	...

The hazard analysis is the first step required for defining a safety reference model for user interfaces

Hazard analysis

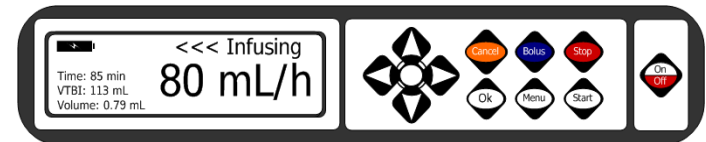


Safety requirements



Safety reference model

HID	Hazard	Pump Type	Cause	Action	Mitigated by	Safety Requirement
1.1	Overinfusion	All	Programmed flow rate too high	Alarm(); Log()	Drug library	1.1, 1.4.4, 1.4.11
1.2	Overinfusion	All	Dose limit exceeded due to too many bolus requests	Alarm(); Log()	Flow sensor	1.4, 3.4.6
1.3	Overinfusion	All	(Programmed) Bolus volume/concentration too high	Alarm(); Log()	Drug library	1.4, 3.4.6
1.4	Overinfusion/ Underinfusion	All	Incorrect drug concentration specified	Alarm(); Log()	Barcode scanner	1.1, 6.1.3, 6.1.4
1.5	Underinfusion	All	Programmed flow rate too low	Alarm(); Log()	Drug library	1.1, 6.1.3, 6.1.4
1.6	Underinfusion	FRN	Air in line	Alarm(); Log()	Flow sensor	1.9
1.7	Underinfusion	FRN	Occlusion (supply side and patient side)	Alarm(); Log()	Flow sensor	1.10
1.8	Underinfusion	FRN	Reservoir empty	Alarm(); Log()	Flow sensor; Drug library	1.5
1.9	Underinfusion	FRN	Reservoir low	Alert(); Log()	Flow sensor; Drug library	1.5
1.10	Underinfusion	All	Flow rate does not match programmed rate	Alarm(); Log()	Flow sensor	1.2, 6.1.3, 6.1.4
1.11	Deflation issue	FRN	Inability of device and/or device components to release gas or air	Alert(); Log()		
1.12	Filling problem	All	Inability to Auto fill	Alert(); Log()		



# Summary

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## Developed

- a generic architecture for reasoning about design issues in infusion pumps
- a preliminary hazard analysis for number entry
  - Enumerate design issues linked to hazards
  - Link software-related causes with use hazards
- a model-based rapid prototyping tool for interactive systems
- Found a series of issues in commercial pumps

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# CHI+MED Making Medical Devices Safer

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## Thank You

