

Safety issues in medical devices

Prof. Cinzia Bernardeschi

Dipartimento di Ingegneria dell'Informazione

Università di Pisa

cinzia.bernardeschi@unipi.it

Medical devices

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

Medical devices

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*)

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

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)

User interface design issues in medical devices

Paolo Masci

(p.m.masci@qmul.ac.uk)

School of Electronic Engineering and Computer Science
Queen Mary University of London

University College London Hospital
July 7, 2015

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.

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

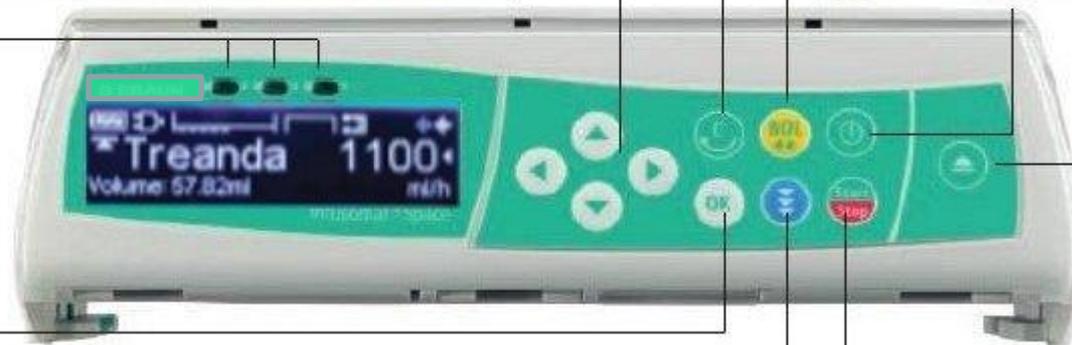
Press to open the pump door.



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

Press to initiate bolus.

Press to turn pump on/off.



Open certain functions and press to confirm values/settings/alerts.



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 .

81200 ↑ up 91200 ↑ up 99999 ...



■ In the Main Menu, open the rate with  and set it with .

81200 ↑ up 91200 ↑ up 99999 ← left 99999



■ In the Main Menu, open the rate with  and set it with .

81200 [↑]up 91200 [↑]up 99999 [←]left 99999
down [↓] 91200



■ In the Main Menu, open the rate with  and set it with .



- In the Main Menu, open the rate with  and set it with .

0.00 ^{up} 0.10 ^{up} 0.11



- In the Main Menu, open the rate with  and set it with .

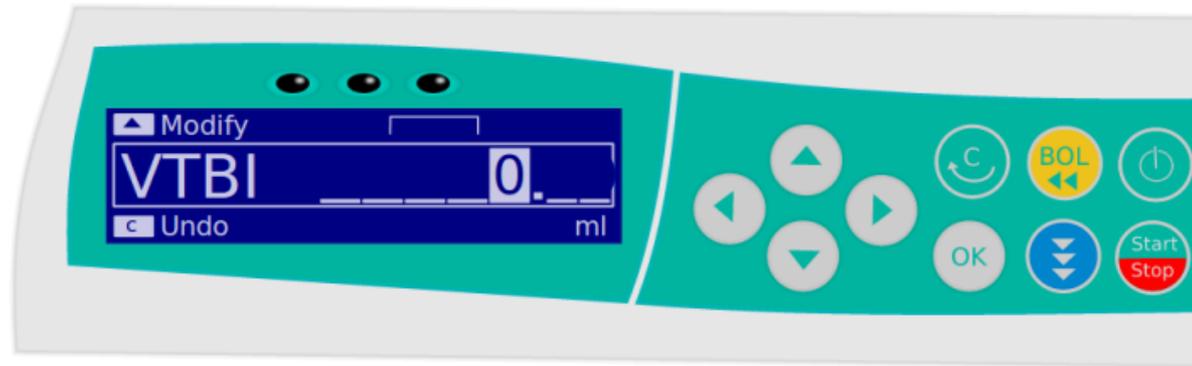
01.0 down 00.1 up 10.0



Similar data entry, different behaviour



Pump 1

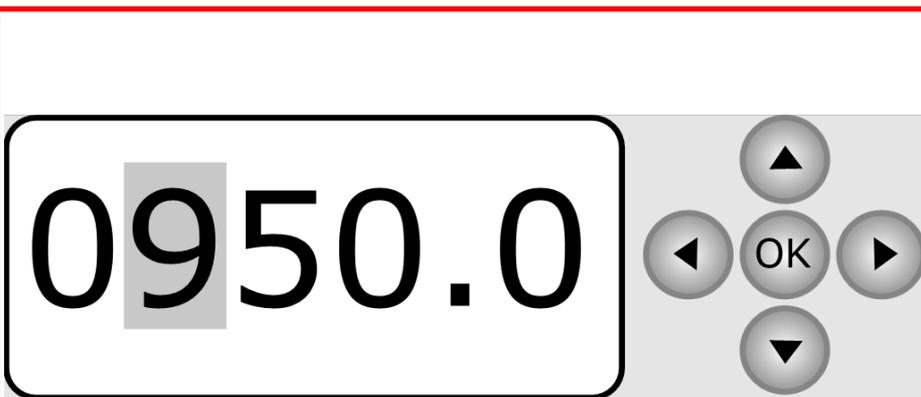
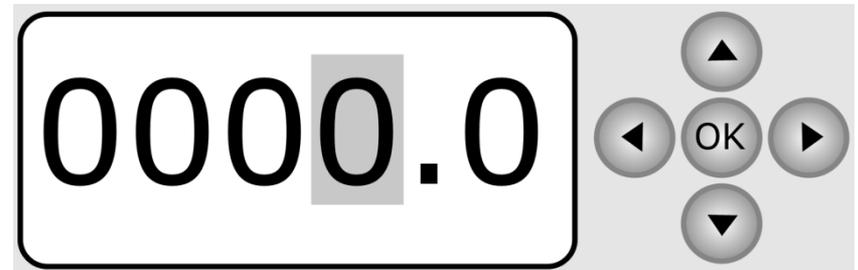


Pump 2

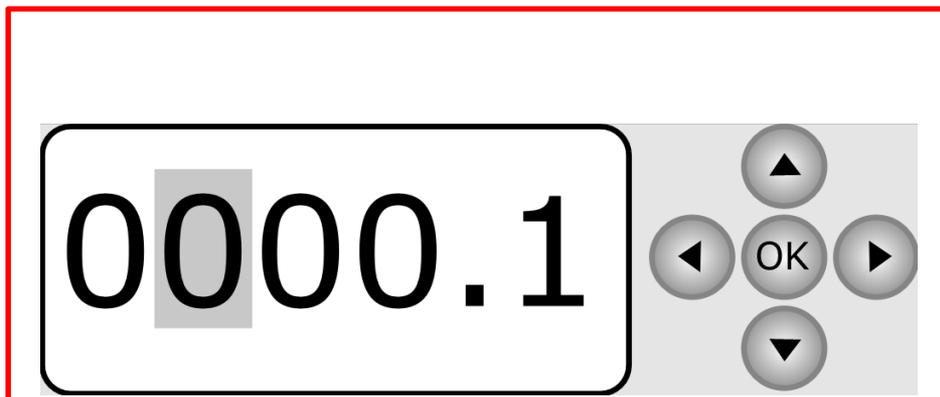
Example: entering 950mL

Input Key Sequence

1. Left
2. Up 5 Times
3. Left
4. Down



Result from Pump 1



Result from Pump 2

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”

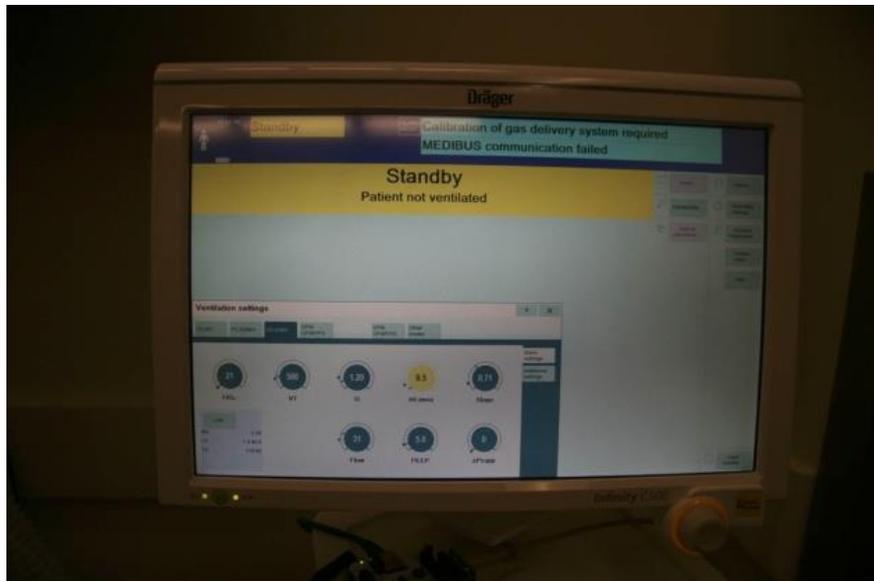
Ventilators have similar problems



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”

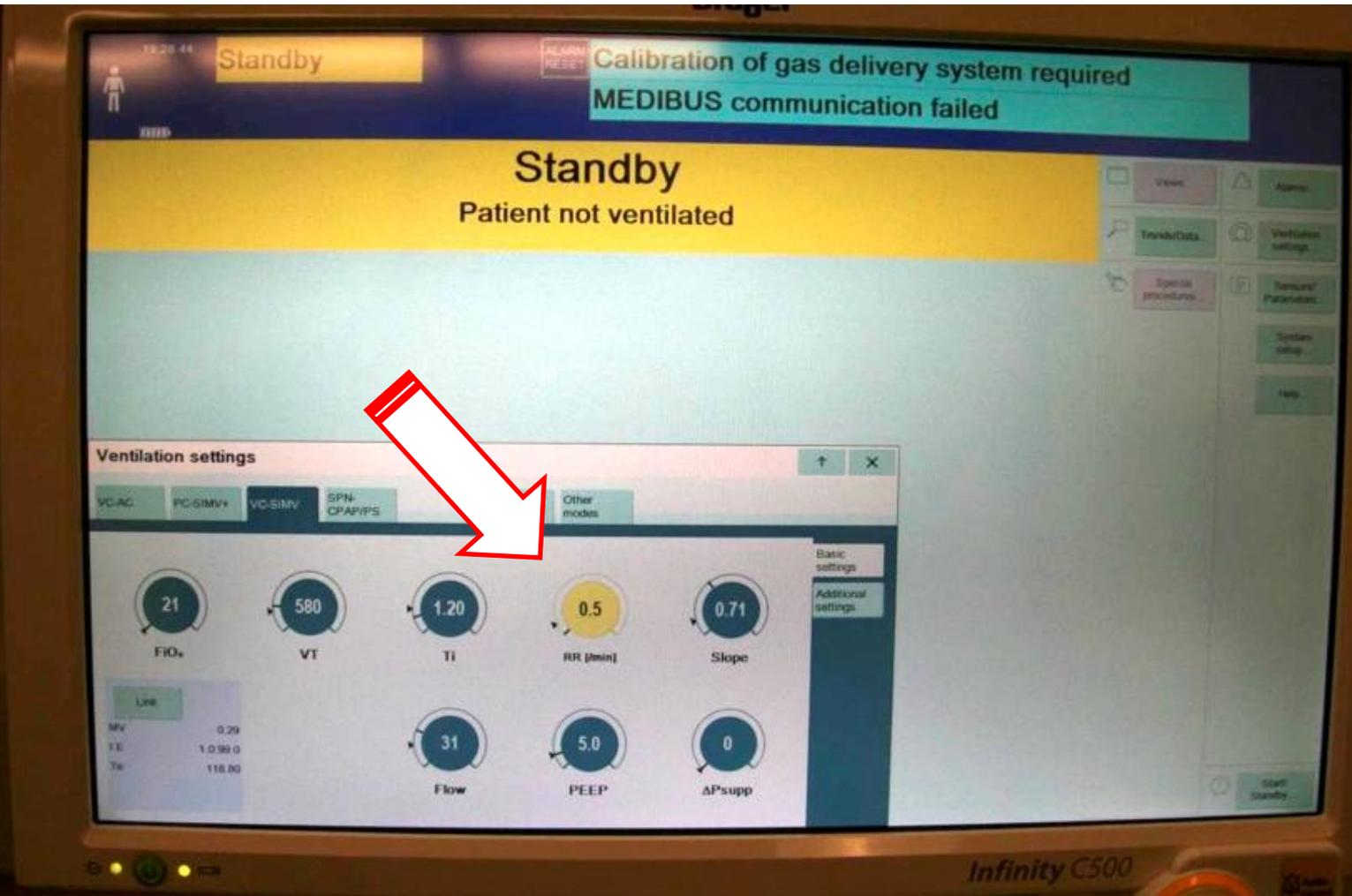


Recommendations

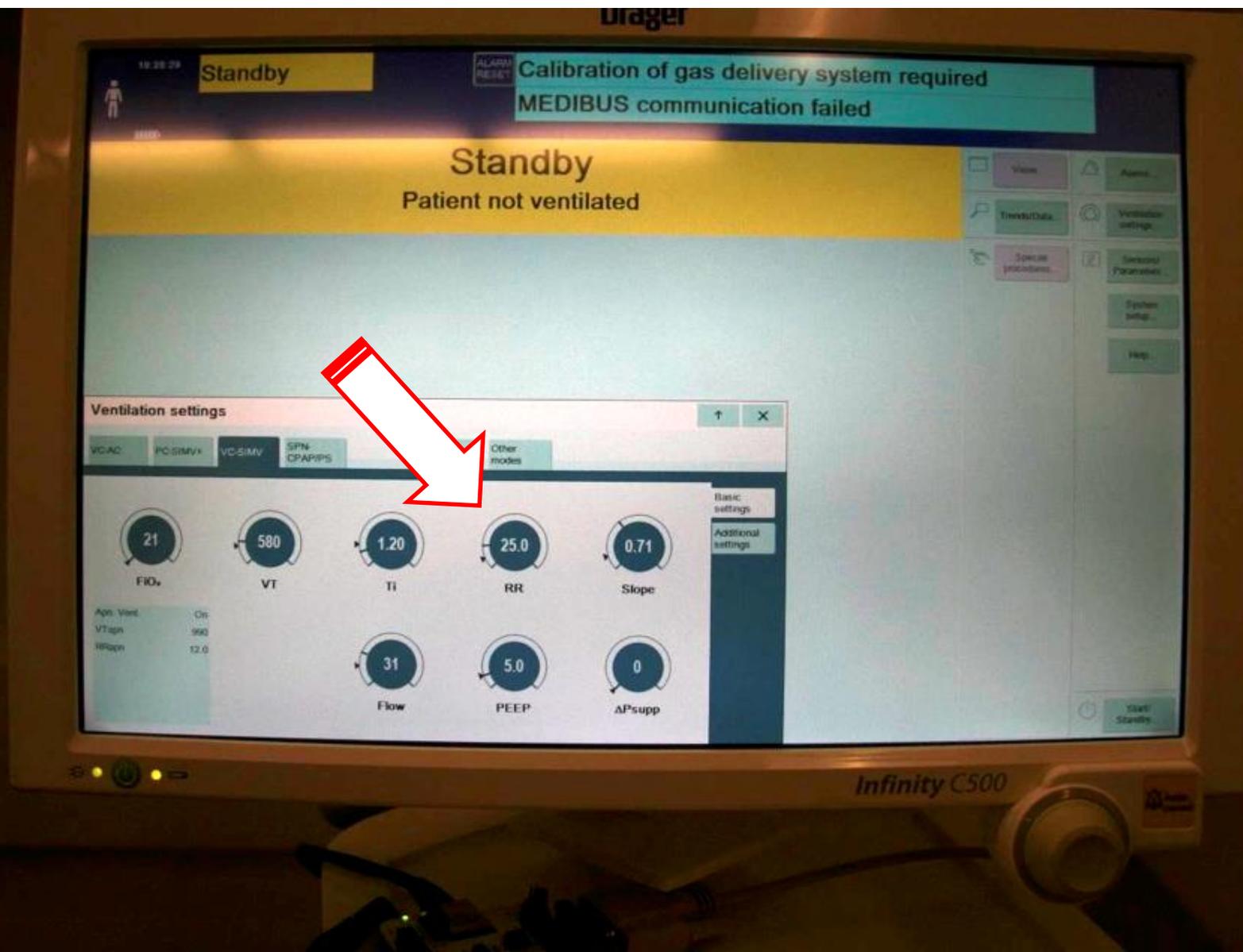
- **Avoid shortcuts when confirming entered values**
 - always submit values to complete data entry
 - don't rely on automatic confirmation
- **Keep in mind that multiple steps may be required to confirm values**
 - some devices require “confirm” and then “accept”

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

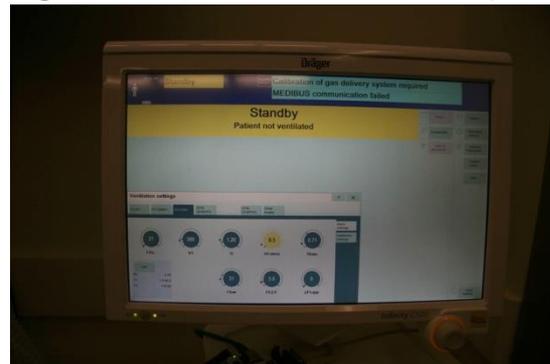


Ventilators

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

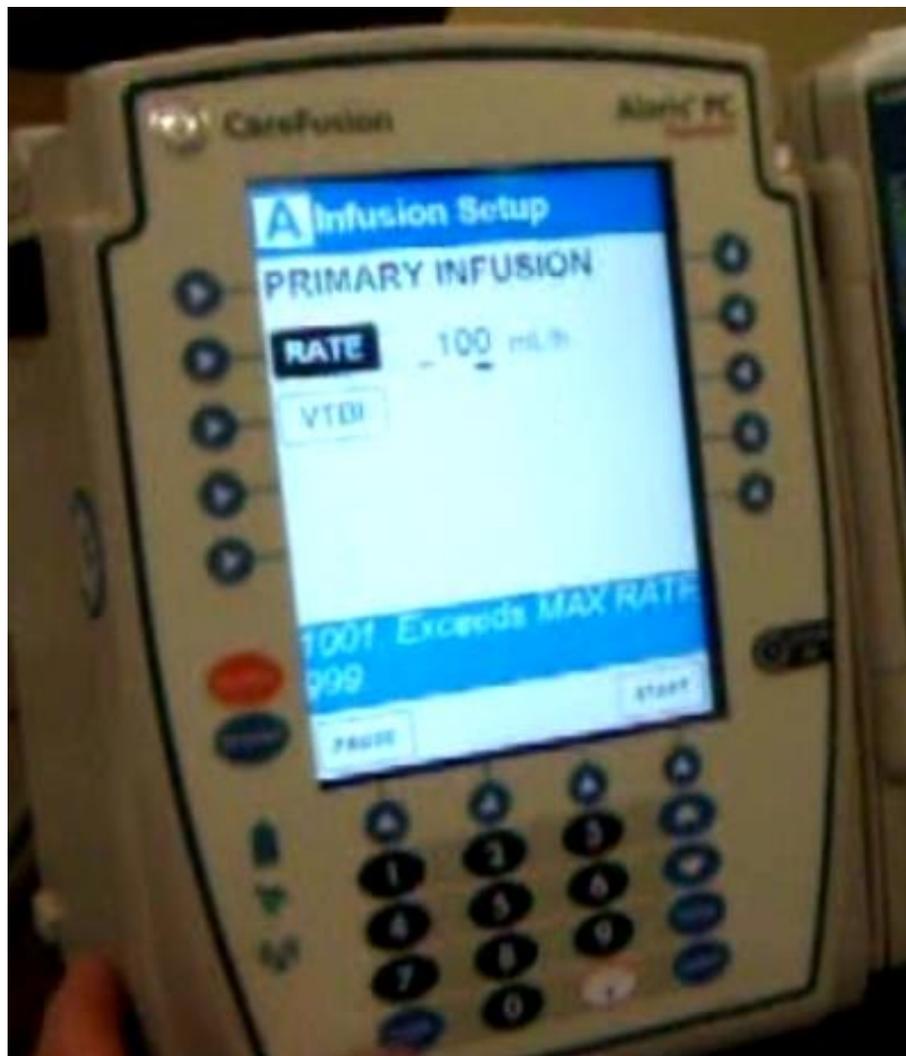


The key sequence



is registered as 1,001

The decimal point is erroneously ignored



The key sequence



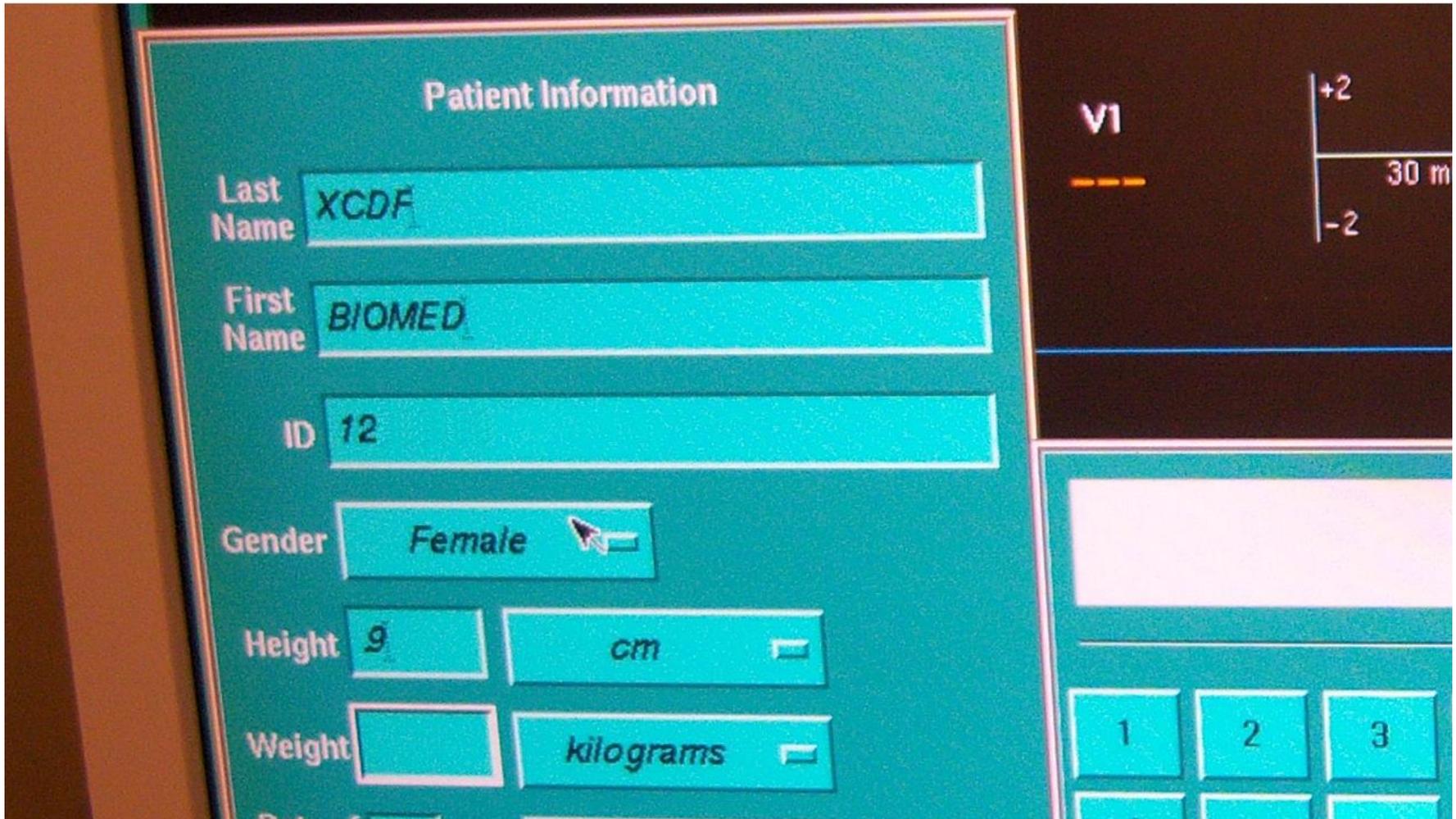
is registered as 1,001
(the value is fortunately
rejected in this case
because the pump
configuration limits the
rate value to 999 mL per hr)

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

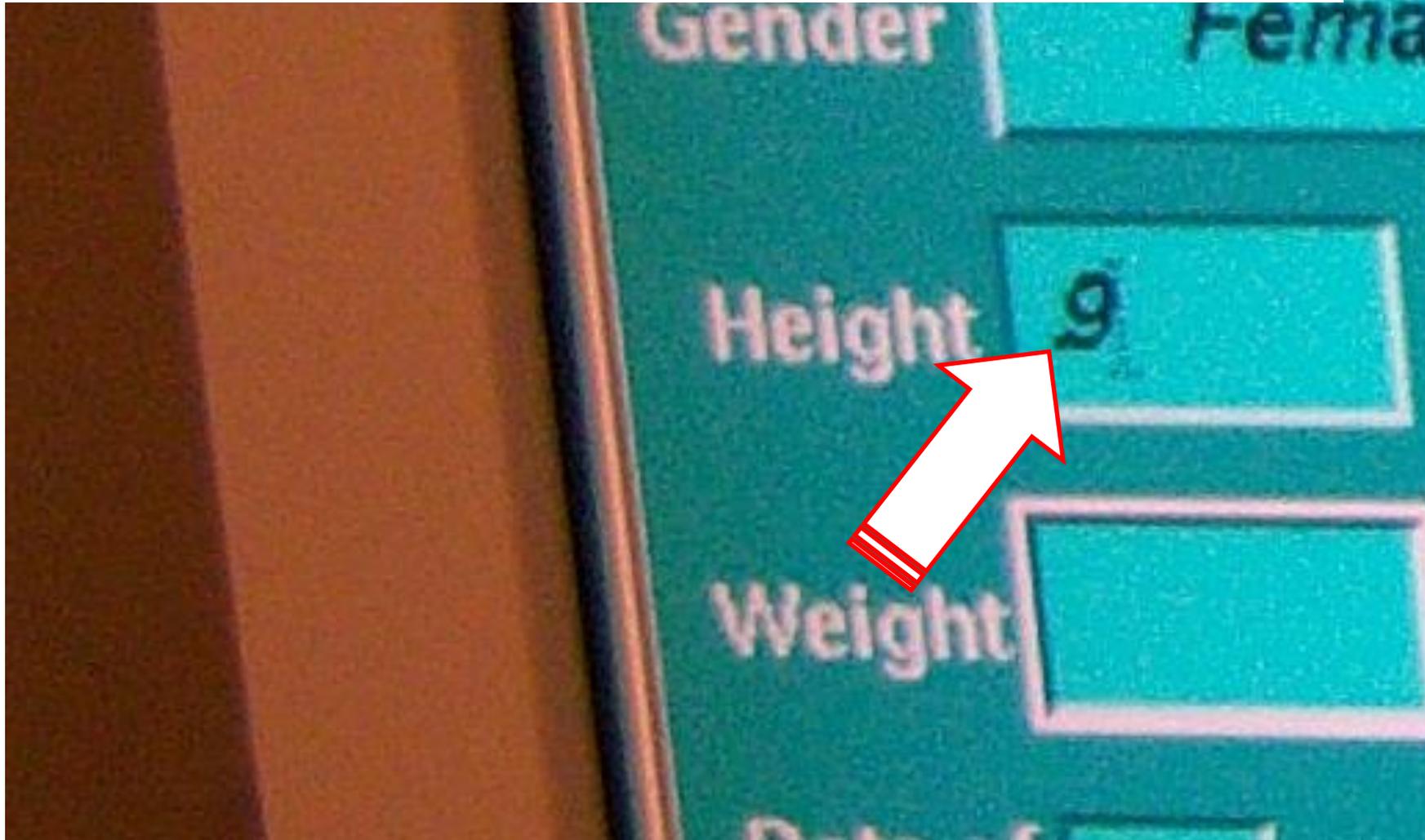
Related issue: ill-formed values

Mistyping and Misreading numbers



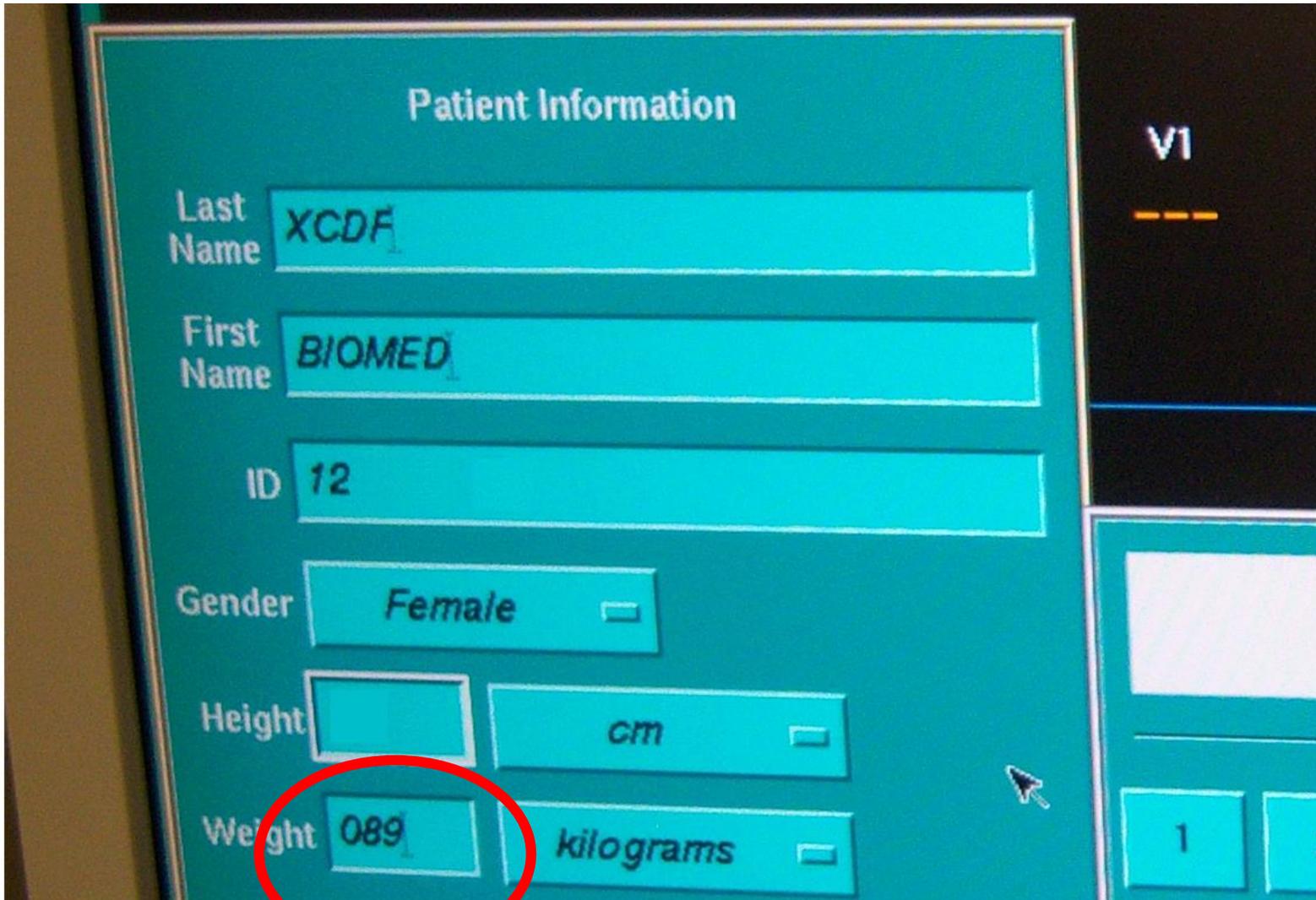
Fractional number without leading zero

(could be easily misread as integer value)



Integer number with leading zero

(potentially misread as a fractional value)

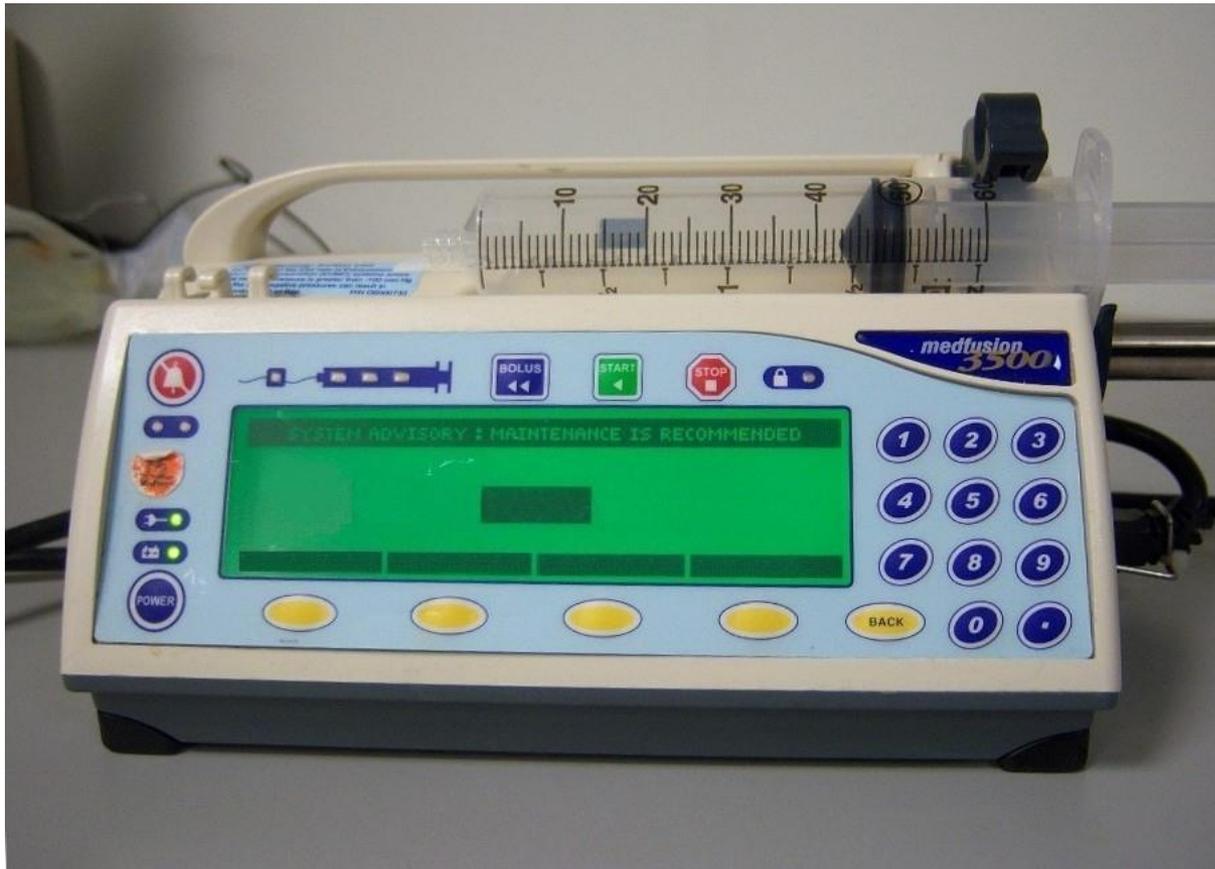


The image shows a patient information form on a screen. The form is titled "Patient Information" and contains several fields. The "Last Name" field contains "XCDF", the "First Name" field contains "BIOMED", and the "ID" field contains "12". The "Gender" field is set to "Female". The "Height" field is empty, and the unit is "cm". The "Weight" field contains "089" and the unit is "kilograms". A red circle is drawn around the "089" in the weight field. To the right of the form, there is a "V1" label and a dashed line. Below the form, there are buttons for "1" and "2".

Patient Information	
Last Name	XCDF
First Name	BIOMED
ID	12
Gender	Female
Height	
	cm
Weight	089
	kilograms

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

Alaris[®] PC
Guardrails[®]

et

annel

AUDIO
ADJUST

3

LOCKED

ALARM INFUSE STANDBY

Alaris[®] PCA

8.8.8.8.8

RATE (mL/h)

9

CHANNEL
SELECT

PAUSE

CHANNEL
OFF

RESTART

CareFusion

SYSTEM
ON

60

50

30

20

10



Alaris[®] PC
Guardrails[®]

Set

Channel

AUDIO
ADJUST

SYSTEM
ON

ALARM INFUSE STANDBY

Alaris[®] PCA

8.8888

RATE (mL/h)

4

CHANNEL
SELECT

PAUSE

CHANNEL
OFF

RESTART

CareFusion

PROGRAM

LOCKED

30

20

10

2

3

5

6

8

9

ENTER



Alaris[®] PC
Guardrails[®]

ALARM INFUSE STANDBY

Alaris[®] PCA

8.8.8.8.8

RATE (mL/h)

H

CHANNEL
SELECT

PAUSE

CHANNEL
OFF

RESTART

CareFusion

channel

AUDIO
ADJUST

SYSTEM
ON

2 3 4
5 6 7
8 9 ENTER
0 . CANCEL

on

Alaris[®] PC
Guardrails[®]

Data Set
Lab

For Human Use **

AUDIO
ADJUST

Navigation buttons: five left arrows, five right arrows, and a numeric keypad (2, 3, 5, 6, 8, 9, ENTER).

SYSTEM ON

ALARM INFUSE STANDBY

Alaris[®] PCA

8.8.8.8.8

RATE (mL/h)



A

CHANNEL
SELECT

PAUSE

CHANNEL
OFF

RESTART

CareFusion



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

CareFusion

Alaris[®] PC
Guardrails[®]

A Guardrails Drug Setup
morphine

▶ INFUSION MODES ◀

▶ PCA Dose only ◀

▶ Continuous Infusion ◀

▶ PCA Dose + Continuous ◀

▶ Select an Option ◀

SILENCE

SYSTEM

ALARM INFUSE STAND

Alaris[®] PCA

00000

RATE (mL/h)

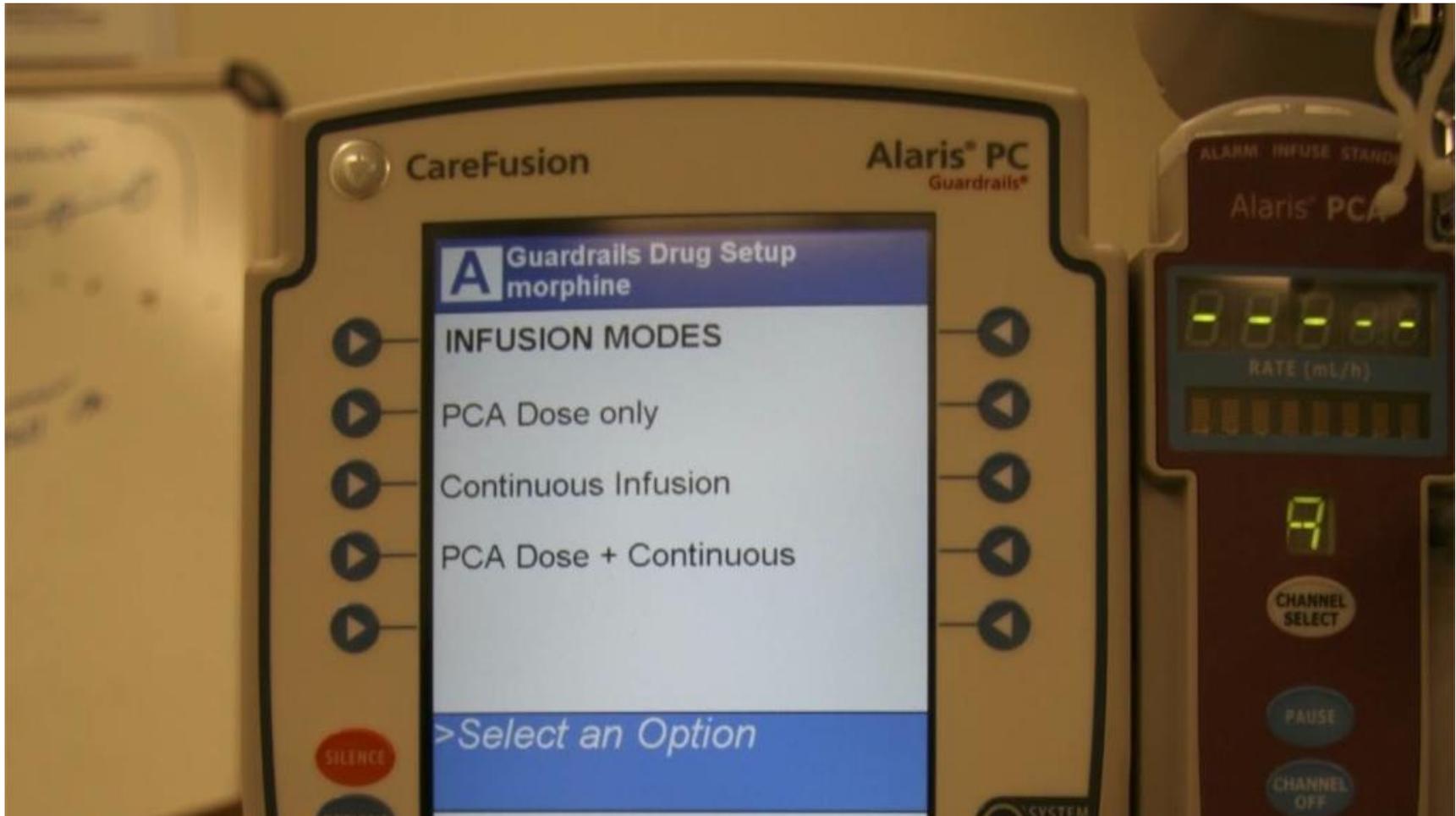


9

CHANNEL
SELECT

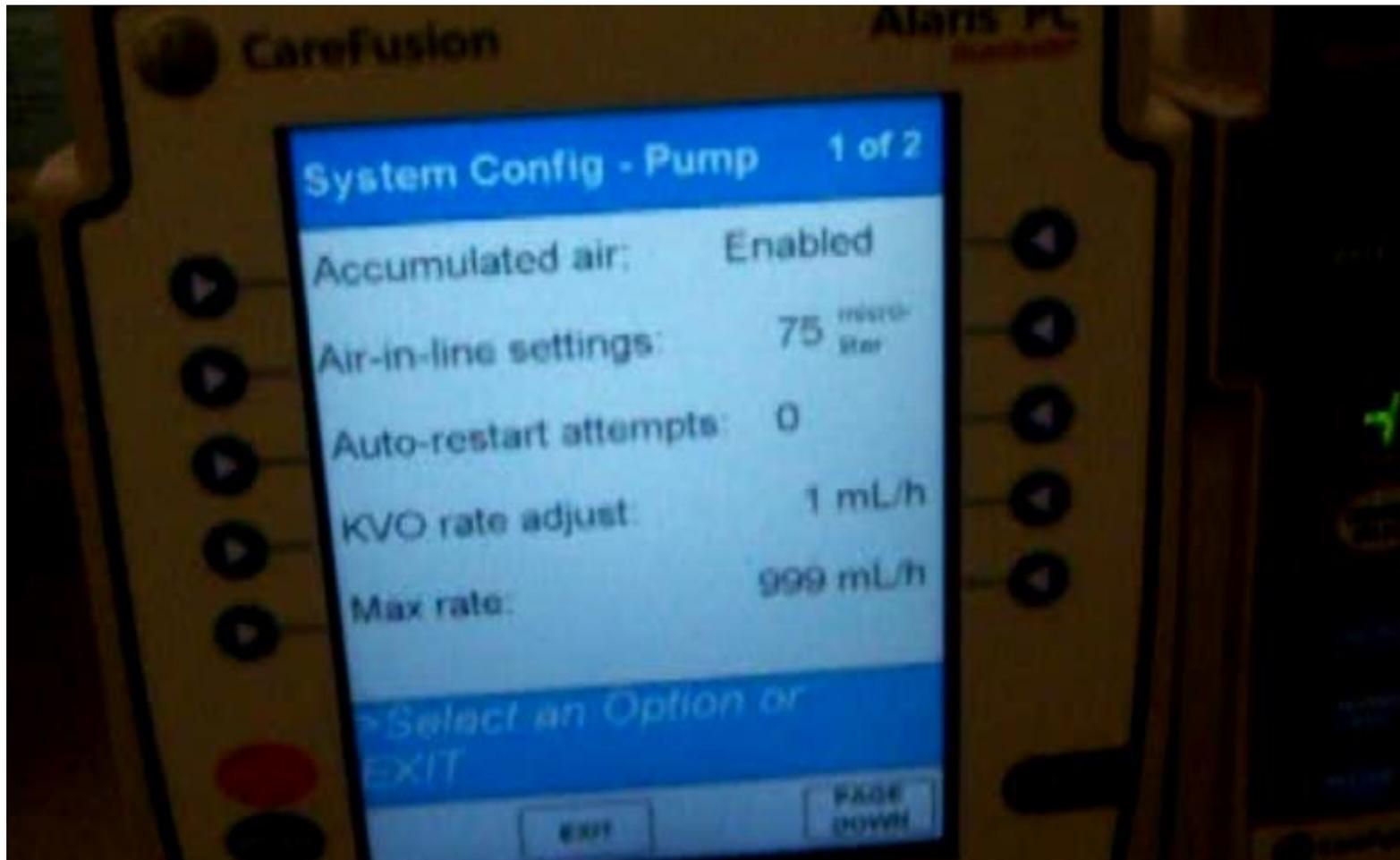
PAUSE

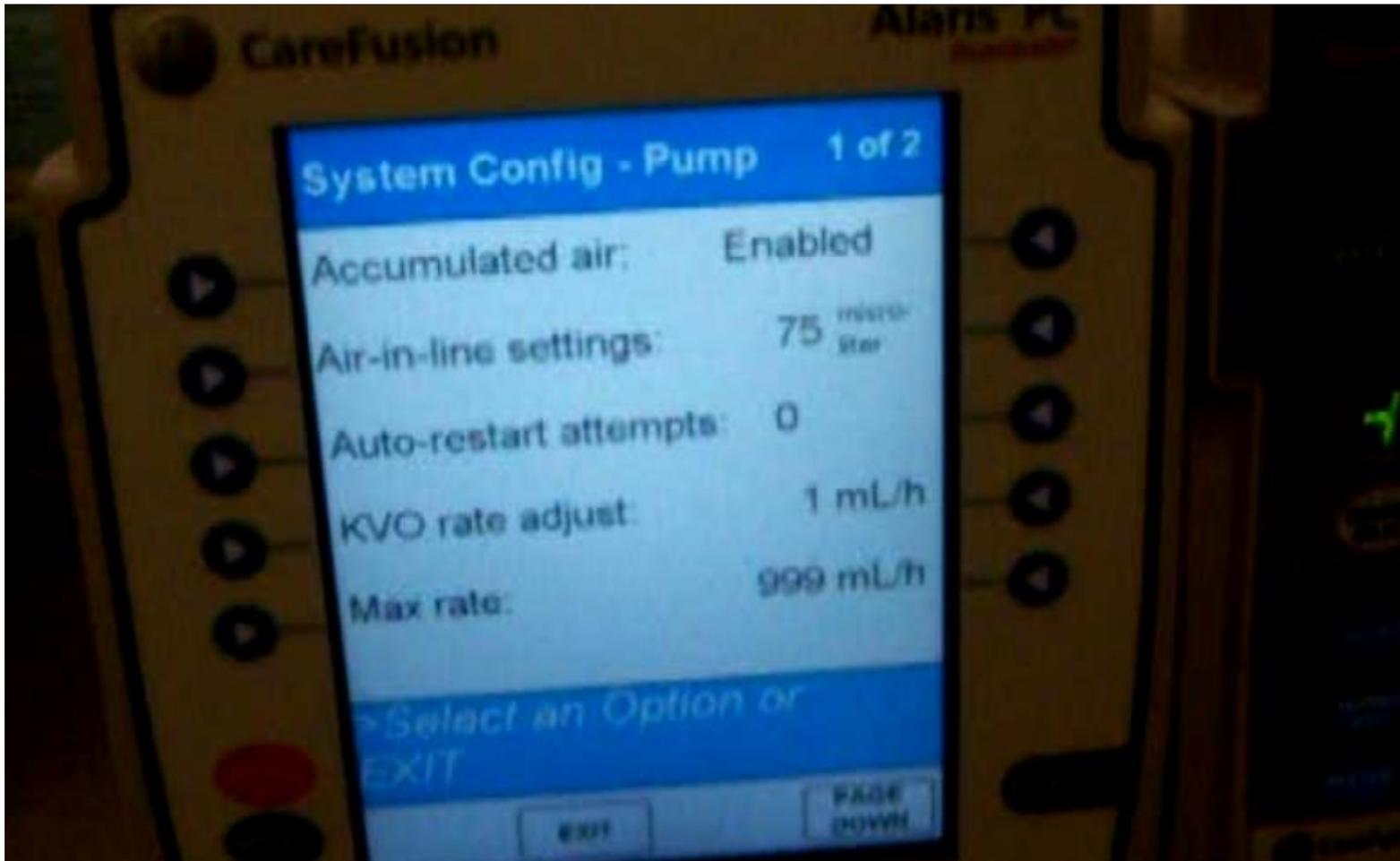
CHANNEL
OFF



Select an Option

DISABLED





Select an Option

DISABLED

CareFusion

Alaris[®] PC

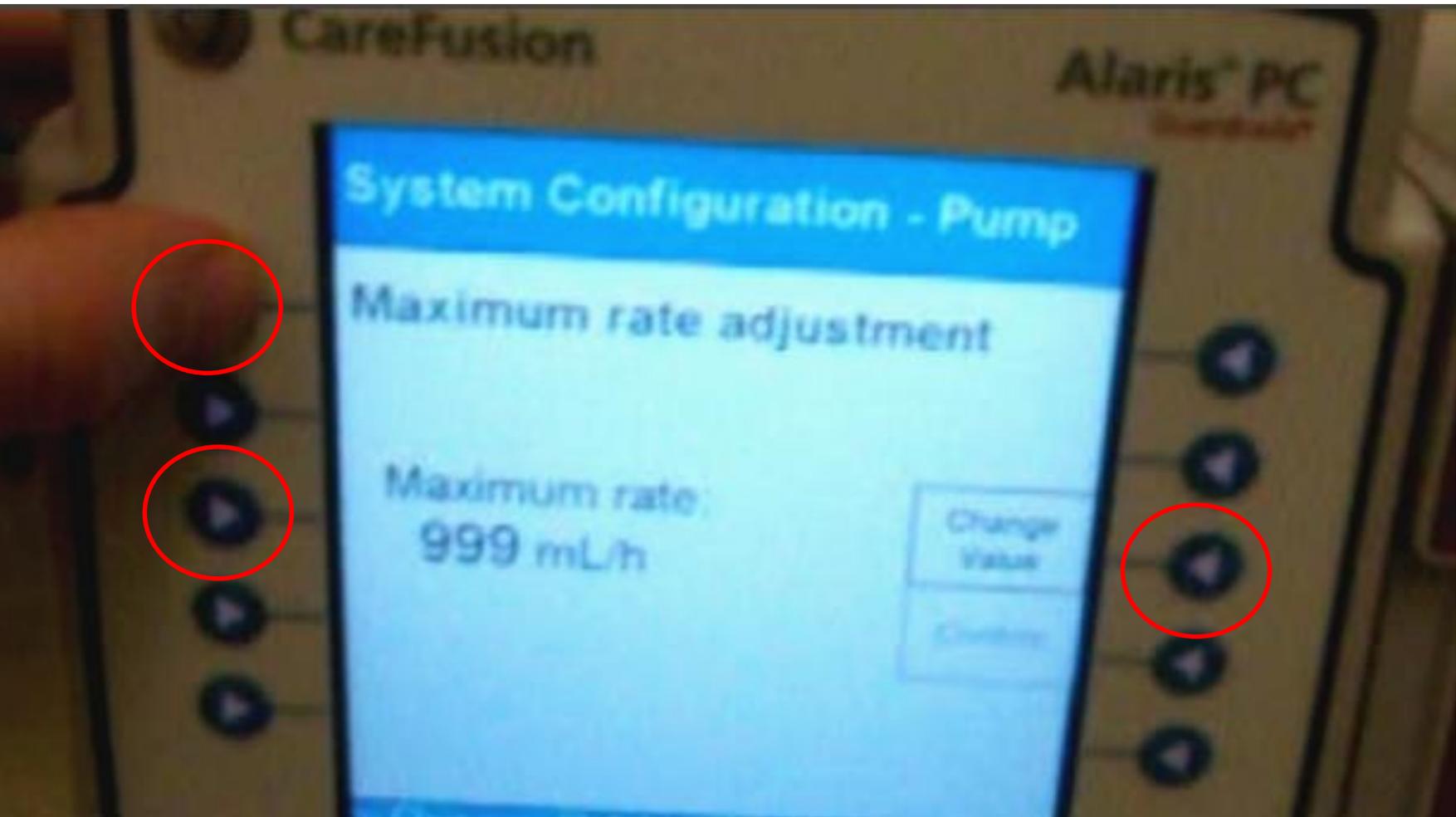
System Configuration - Pump

Maximum rate adjustment

Maximum rate:
999 mL/h

Change
Value

Confirm



DISABLED

DISABLED



CareFusion

Alaris® PC
Guardrail®

MD PnP Data Set
MD PnP Lab

A
B
C

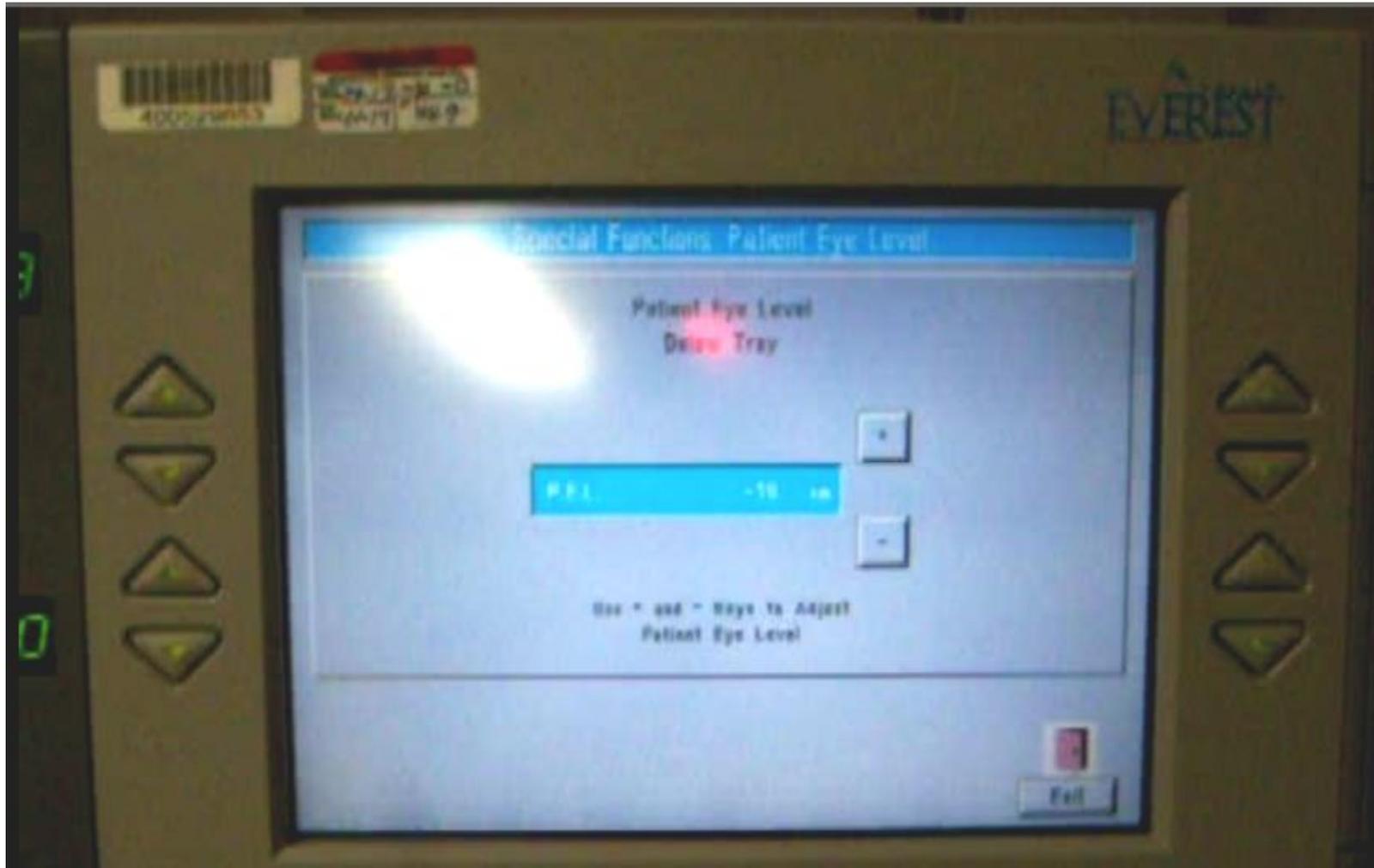


DISABLED

DISABLED

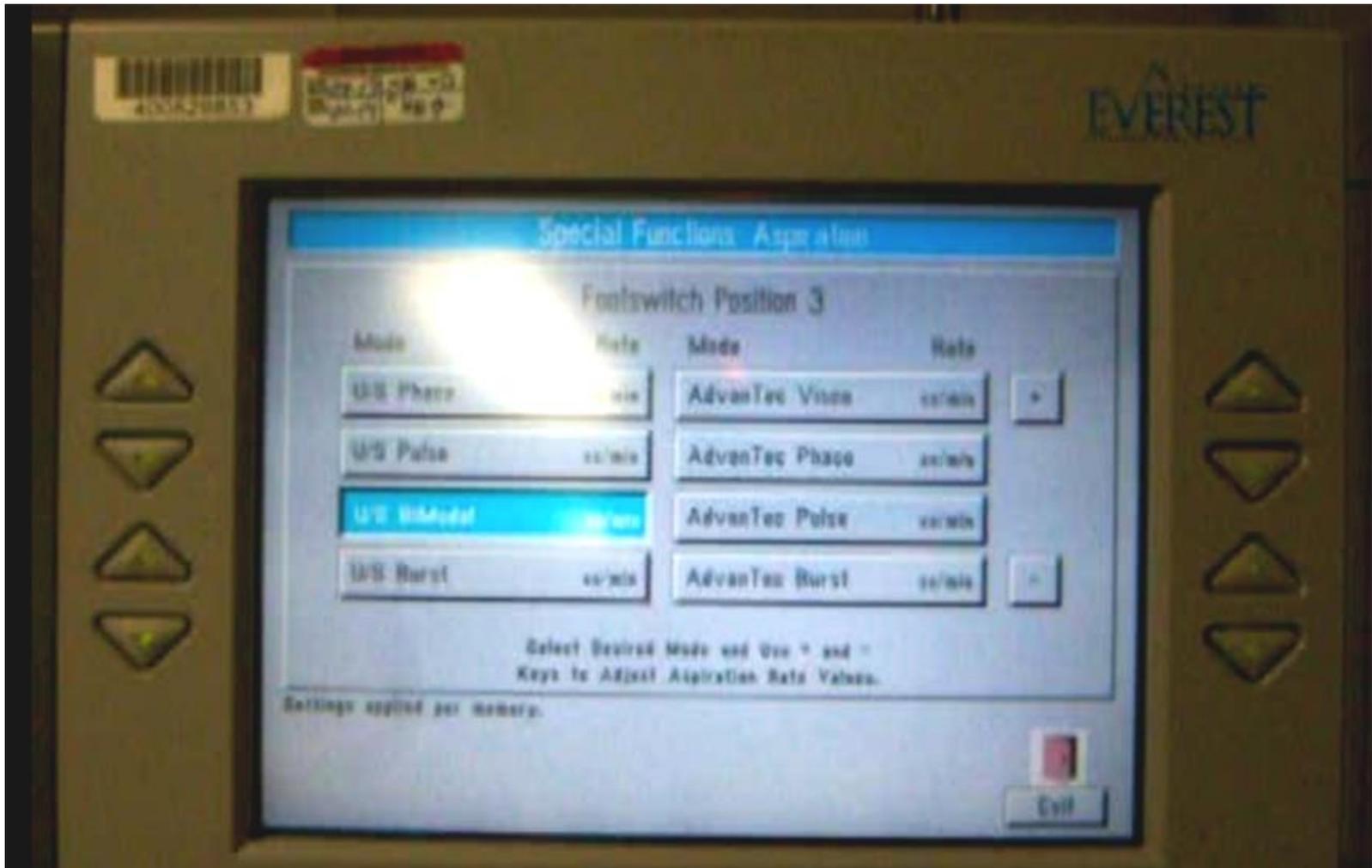
Phacoemulsifiers have similar problems





**Increase/Decrease
values**

**Increase/Decrease
values**



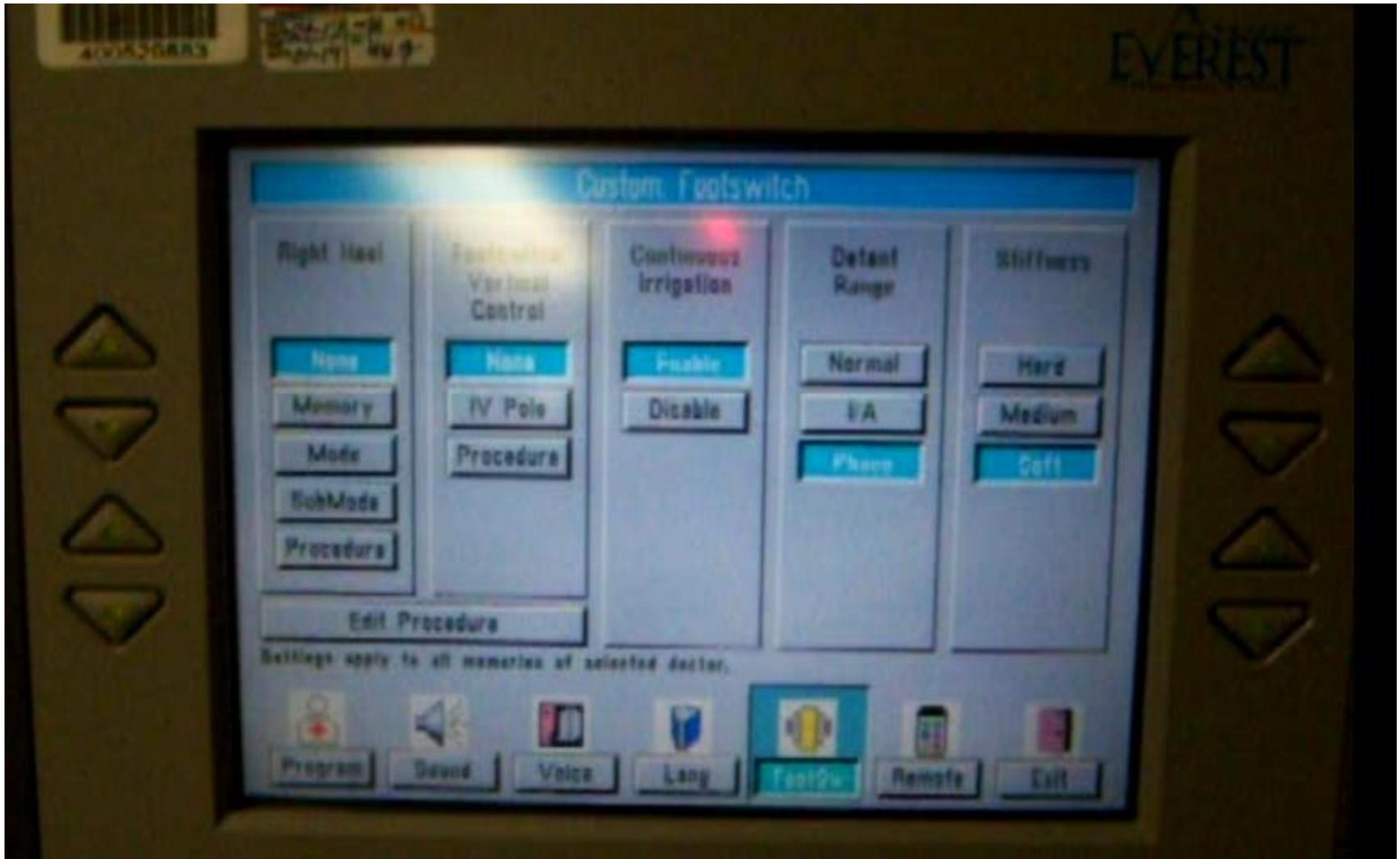
Select an Option

Increase/Decrease values



DISABLED

Scroll options



DISABLED

DISABLED

Wrong feedback

CareFusion

Alaris® PC
Guardrails®

A 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

SILENCE

OPTIONS

SYSTEM
ON

CHANNEL
SELECT

PAUSE

CHANNEL
OFF

RESTART

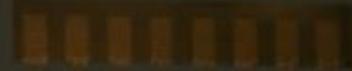
CareFusion

ALARM INFUSE STAND

Alaris® PCA

0.0 0.0 0.0

RATE (mL/h)



CareFusion

Alaris[®] PC
Guardrails[®]

A 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

SILENCE

OPTIONS

SYSTEM
ON

CHANNEL
SELECT

PAUSE

CHANNEL
OFF

RESTART

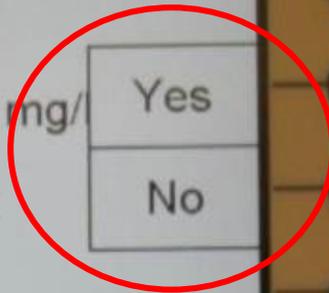
CareFusion

ALARM INFUSE STAND

Alaris[®] PCA

0.0 0.0 0.0

RATE (mL/h)



CareFusion

Alaris[®] PC
Guardrail[®]

A BD 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

VOLUME
DURATION



SILENC

ORTHOUS

SYSTEM
ON

1 2 3 4 5 6

8:8:8

RATE (mL/h)

CHANNEL
SELECT

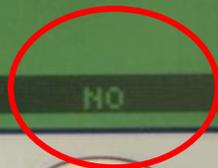
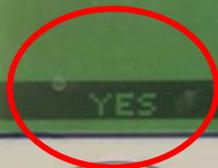
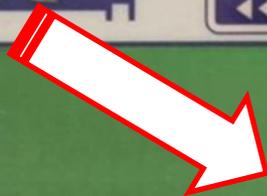
PAUSE

CHANNEL
OFF

RESTART

CareFusion

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

Paolo Masci

(p.m.masci@qmul.ac.uk)

Queen Mary University of London

