

# ArtistDesign Workshop on Embedded Systems in Healthcare 2009

**Johan Henning**

**How to Design Long Lasting Devices  
for a Fast Changing World**

## **Abstract**

Medical devices have a long time to market. The development and especially testing and certification are time consuming processes. Medical devices also have a long lifetime.

In our business it is not uncommon that a device is in use for 10 to 15 years and sometimes even longer. On the other hand the technical environment is changing very rapidly. Component obsolescence is an issue, maintenance of old software can become a problem. The challenge is how to deal with these conflicting issues.



# How to design long lasting devices for a fast changing world

December 7, 2009

# How to design long lasting devices for a fast changing world



# Agenda

- Introduction
- About Nucletron
- About cancer and radiotherapy
- System Engineering
- Challenges
- Solutions
- Questions / discussion



# Introduction

- Johan Henning
- Senior System Engineer
- > 20 years working for Nucletron



# Agenda

- Introduction
- **About Nucletron**
- About cancer and radiotherapy
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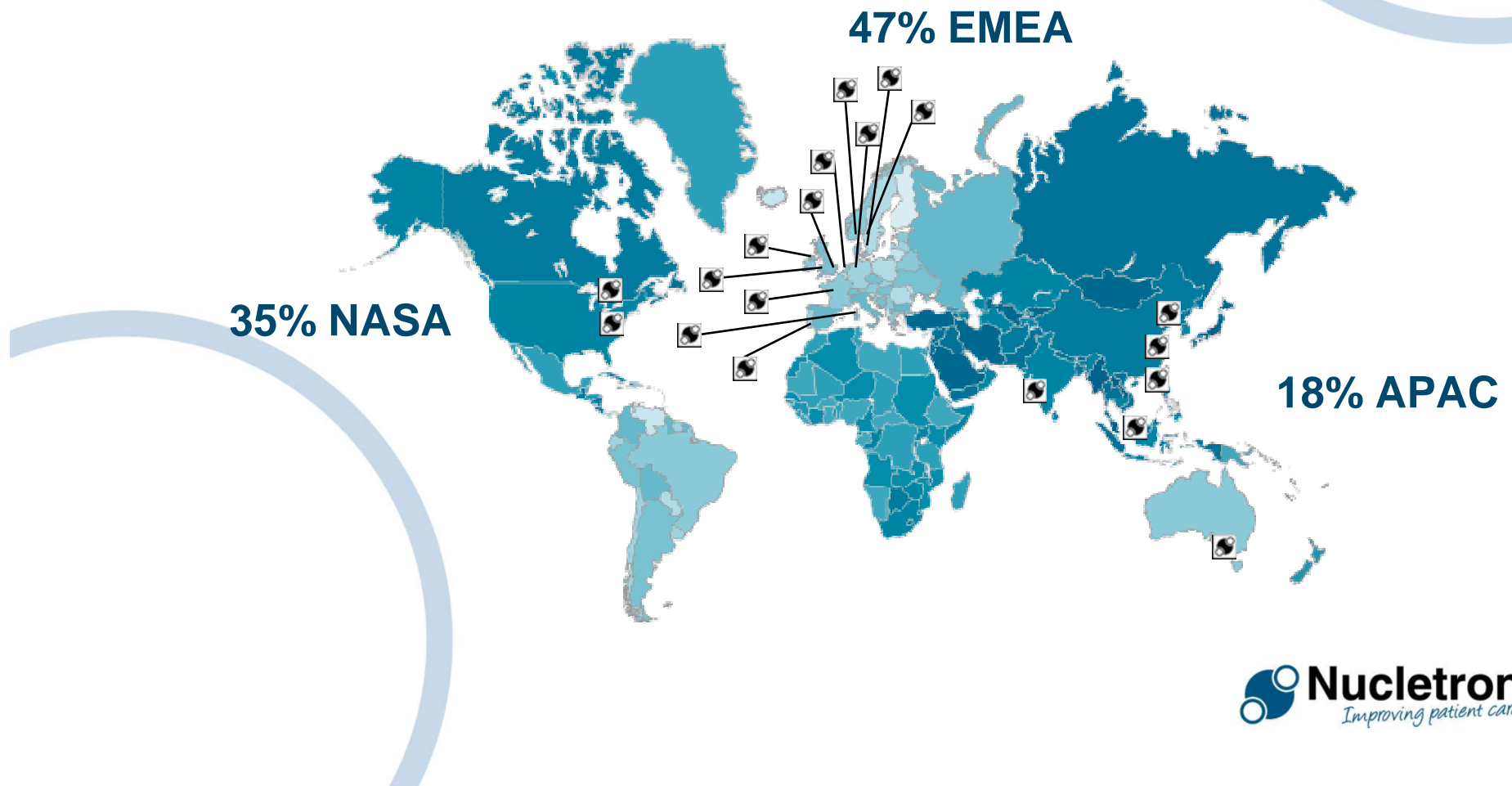


# Nucletron in facts



- Nucletron B.V. is founded in 1975
- HQ Located in the Netherlands
- Spin-off from Delft Instruments in August 2007
- Nucletron's current position:
  - Over 500 employees (170 in NL)
  - 120 M Euro turnover
  - Over 20 offices in 16 countries
  - Strong market presence in more than 80 countries
- Merged capabilities of:
  - Oncology Software Solutions from MDS Nordion in 2003
  - Helax, SE (External Beam Treatment Planning)
  - Oldelft, NL (Imaging)
  - Nucletron, NL (Brachytherapy)

# Nucletron worldwide



# Nucletron's vision

Nucletron is a knowledge-based leader in Radiation Oncology, working with the clinical team to realize innovative solutions that improve patient care

# Nucletron's vision

- **Knowledge based**
  - Creating value through our people and through their interaction with our customers
- **Radiation Oncology**
  - Broader than a brachytherapy company or a treatment planning company
- **Clinical Team**
  - Aspiring to integrating ourselves to our customers' mission
- **Innovative Solutions**
  - We will bundle our knowledge into solutions; a combination of all that is required to support our customers
- **Improving patient care**
  - Making it possible to have the best choice of treatment modality for patients

# Nucletron's product portfolio

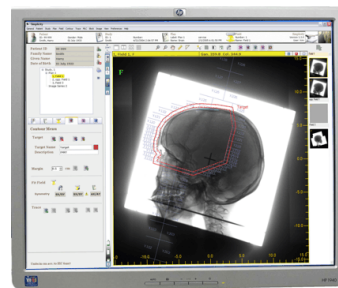




# Imaging Solutions



3D Imaging and Simulation  
Simulix Evolution™



Oncentra® ConeBeam

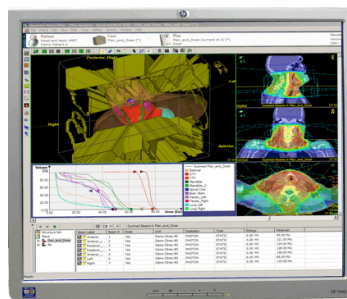


Integrated Brachytherapy Unit  
IBU-D

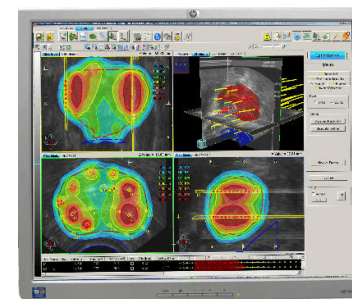
# Treatment Planning Solutions



Brachytherapy Planning  
Oncentra® Brachy



External Beam Planning  
Oncentra® MasterPlan



Dedicated body-site Planning  
Oncentra® Prostate

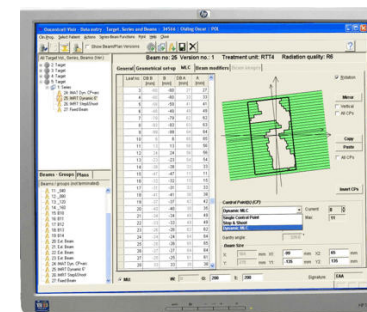
# Treatment Delivery Solutions



Afterloading  
microSelectron® Digital



Applicators and  
Accessories



Record & Verify  
Oncentra® Visir



# Information Management Solutions



Oncentra® Information  
Management



# Customer Care Solutions



On-site and remote  
support



Professional training  
and consulting



Global network of  
clinical experts

# R&D partnerships

- R&D Partnerships are critical to our success
- Key insertion of focus innovation
- Key insertion of clinical background
- Knowledge Based Solutions – designed by Clinical Users
- Our partners:
  - MD-Anderson, TX-USA
  - UCSF, CA-USA
  - Hotel Dieu, Canada
  - University of Uppsala, Sweden
  - RaySearch, Sweden
  - University of Amsterdam, Netherlands
  - University of Utrecht, Netherlands
  - TatraMed, Slovakia
  - Medcom/Pi-medical, Germany
  - Nexus, Germany

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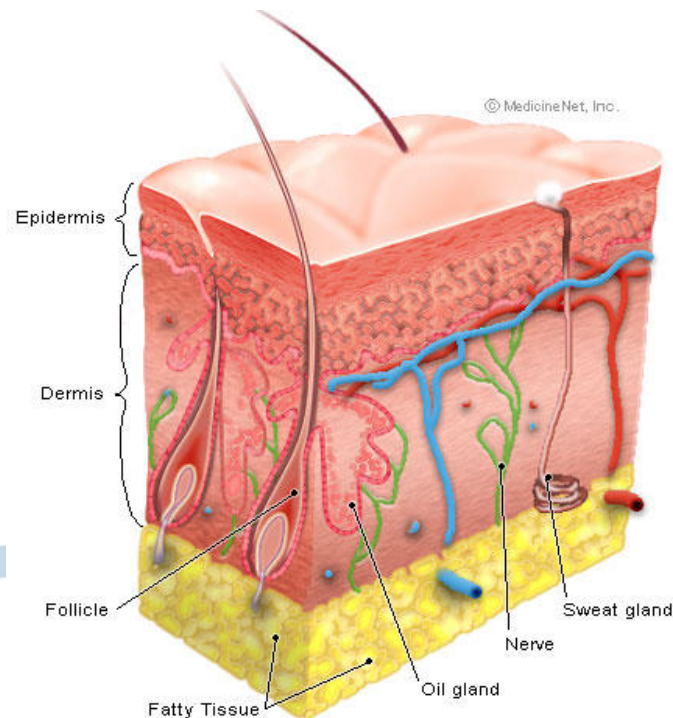
# About Cancer

- What is cancer
- How to treat cancer

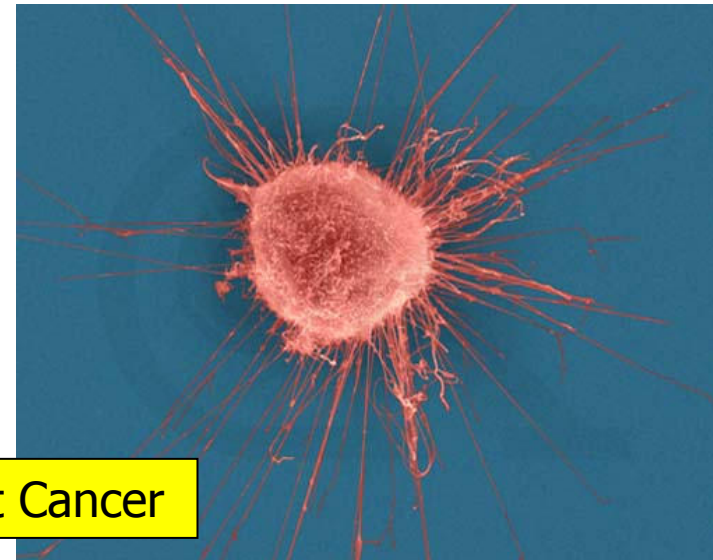


# About Cancer

A disease in which body cells become abnormal and divide without control



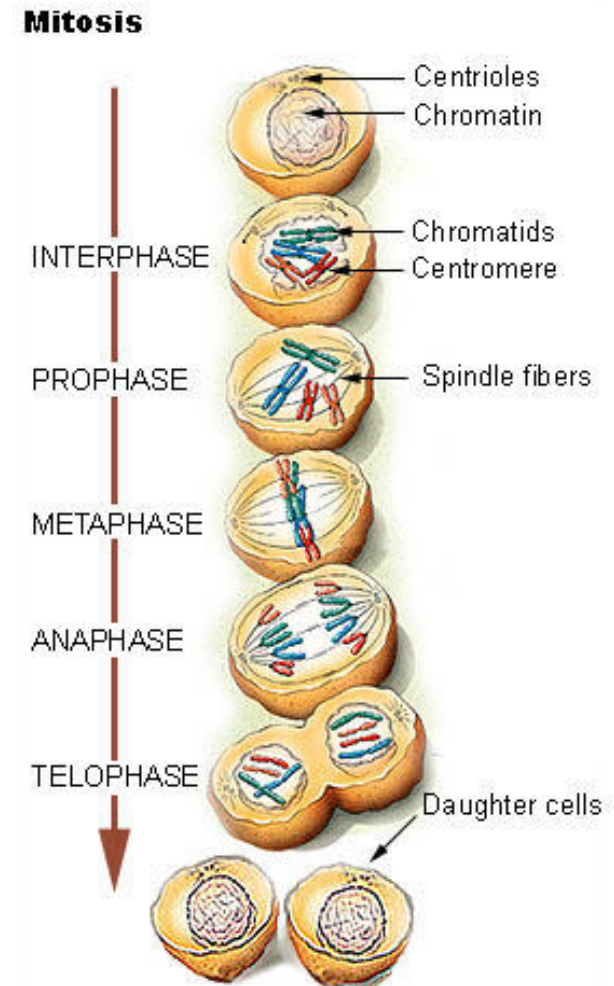
Normal Skin



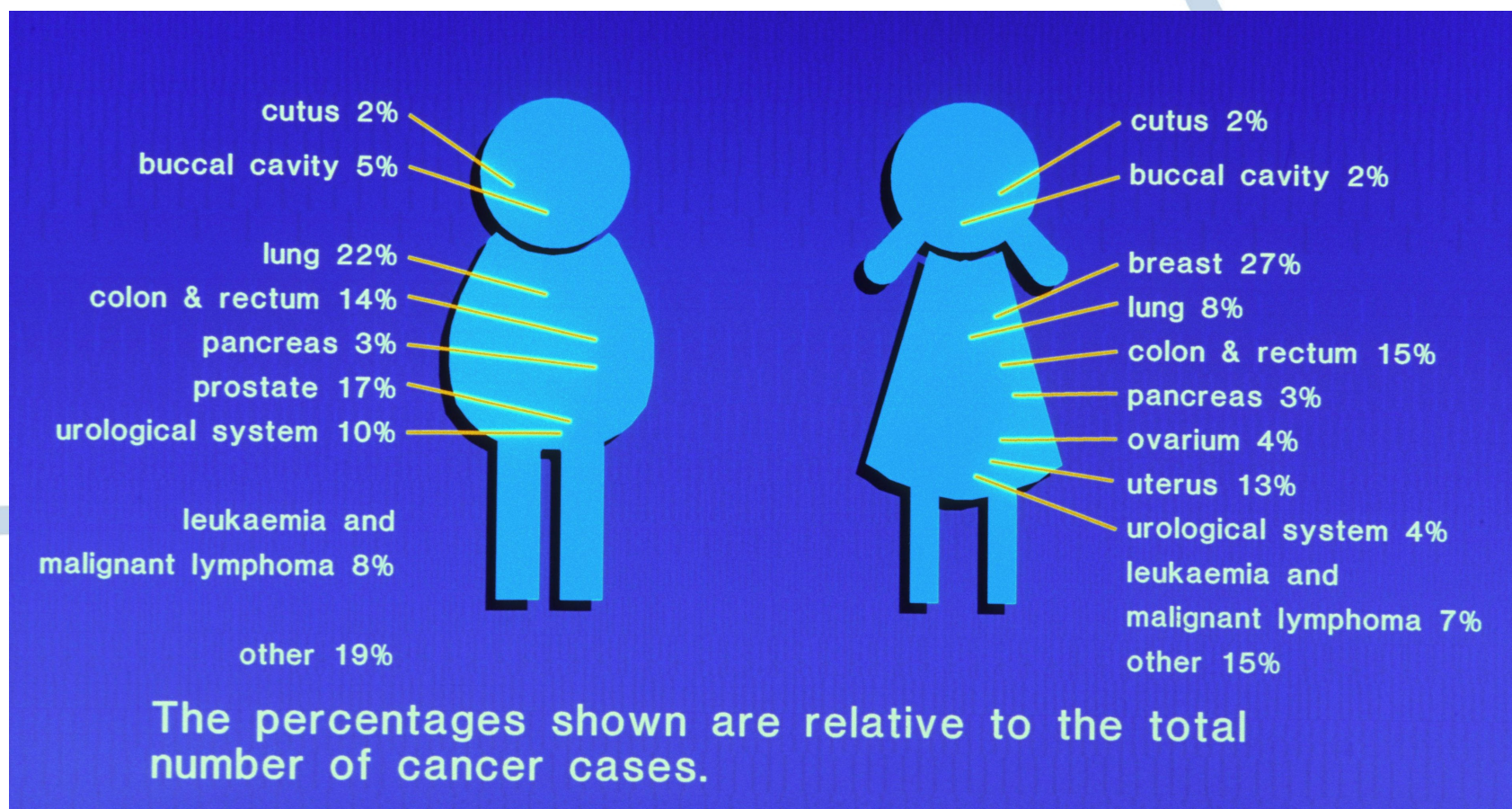
Breast Cancer

# Cell Division (Mitosis)

- Cancer is essentially a disease of Mitosis
- normal 'checkpoints' regulating mitosis are ignored or overridden by the cancer cell

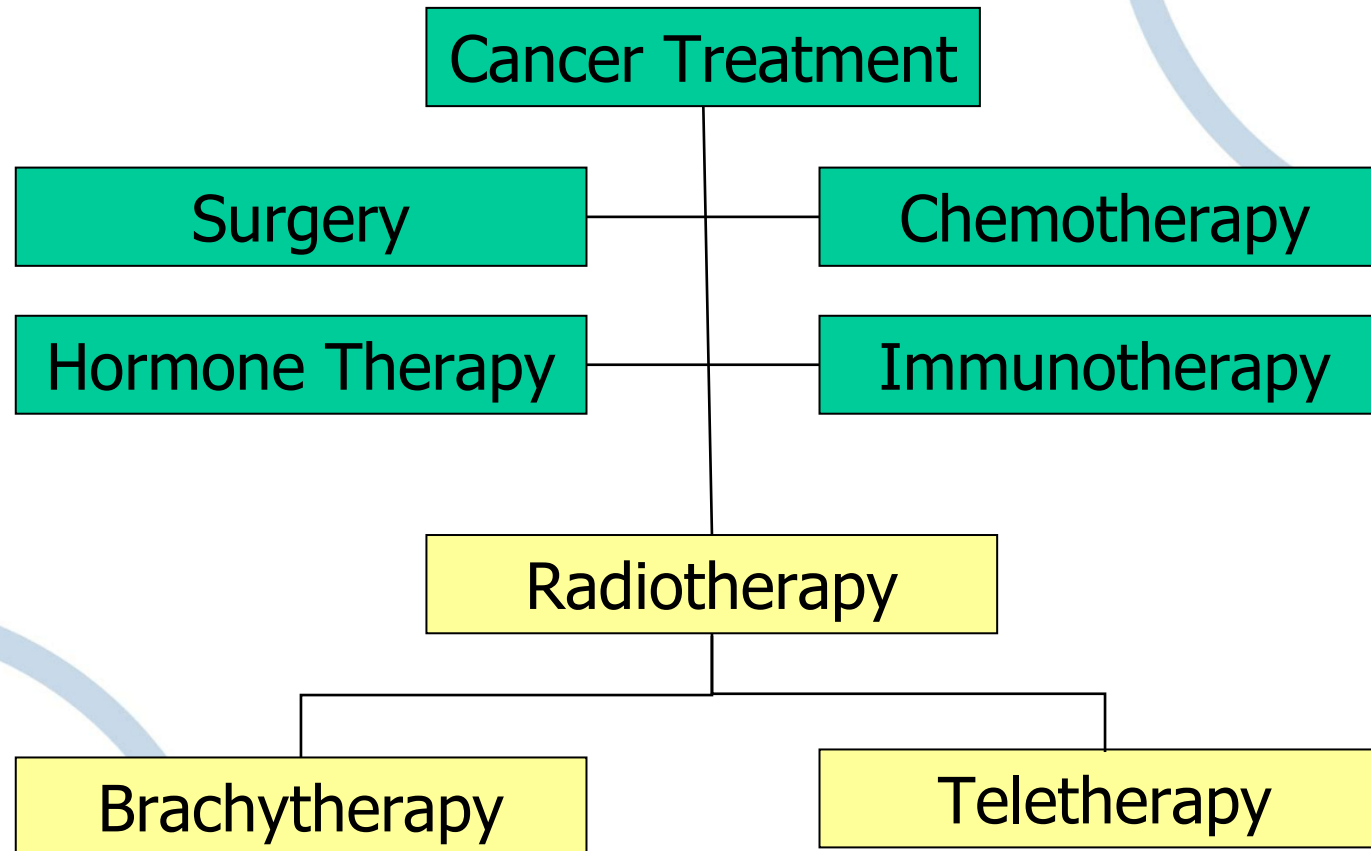


# Cancer Incidence by Body Site





# Cancer treatment modalities



# Radiotherapy

A treatment modality whereby ionizing radiation is used to treat a tumor

Sources of ionizing radiation are:

- X-Ray devices
- (sealed) sources containing radioactive material

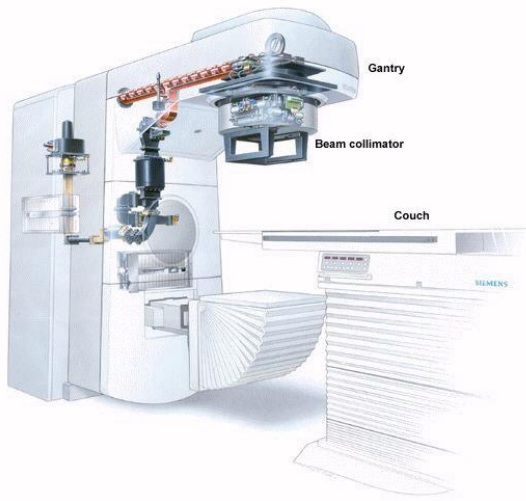


# Radiotherapy is aimed at

- Delivering a lethal dose to the tumor, while;
- Sparing surrounding healthy tissue

# Types of Radiotherapy

- External beam (Linacs)
- Brachy Therapy (radiation sources)



See <http://en.wikipedia.org/wiki/Brachytherapy>

# Brachy treatment procedure

Diagnosis and localisation

Applicator placement

Localisation of applicator

Contouring/reconstruction

Dose calculation/treatment plan

Treatment

Applicator removal



# Agenda

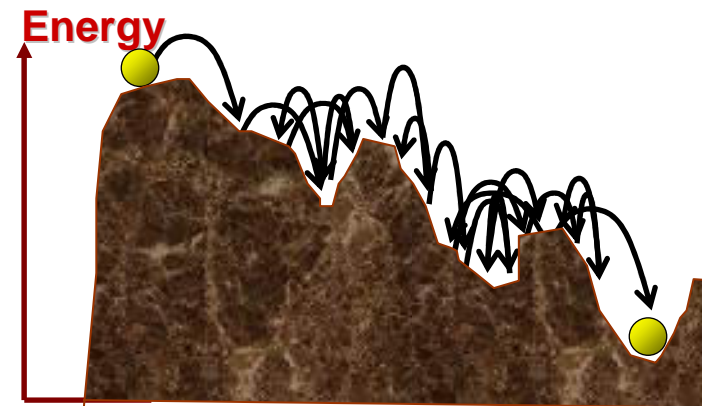
- Introduction
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- **System Engineering**
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# System Engineering (1)

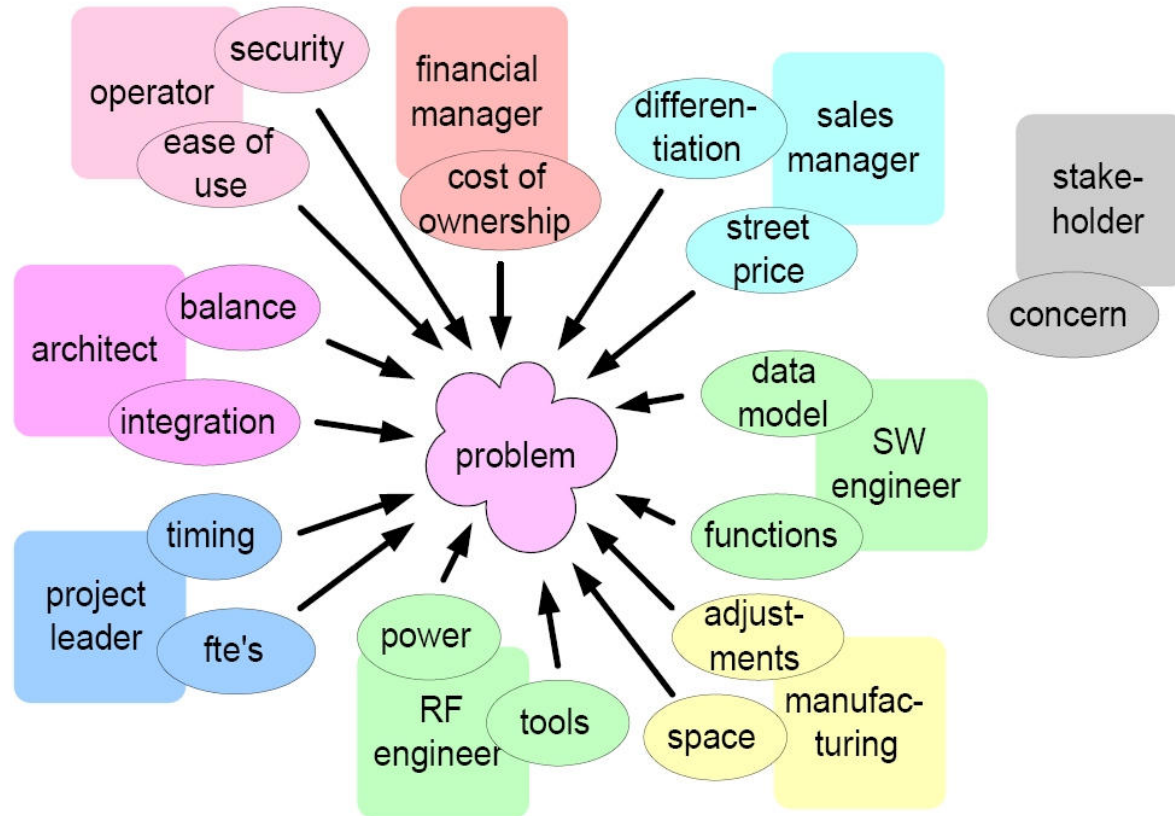
- Mechanics
- Electronics
- Firmware
- Software (GUI for devices / planning systems for treatment planning)

# System Engineering (2)

- Physics
- Algorithms (e.g. IPSA (= inverse planning by simulated annealing))
- Work flow
- Ergonomics
- Politics

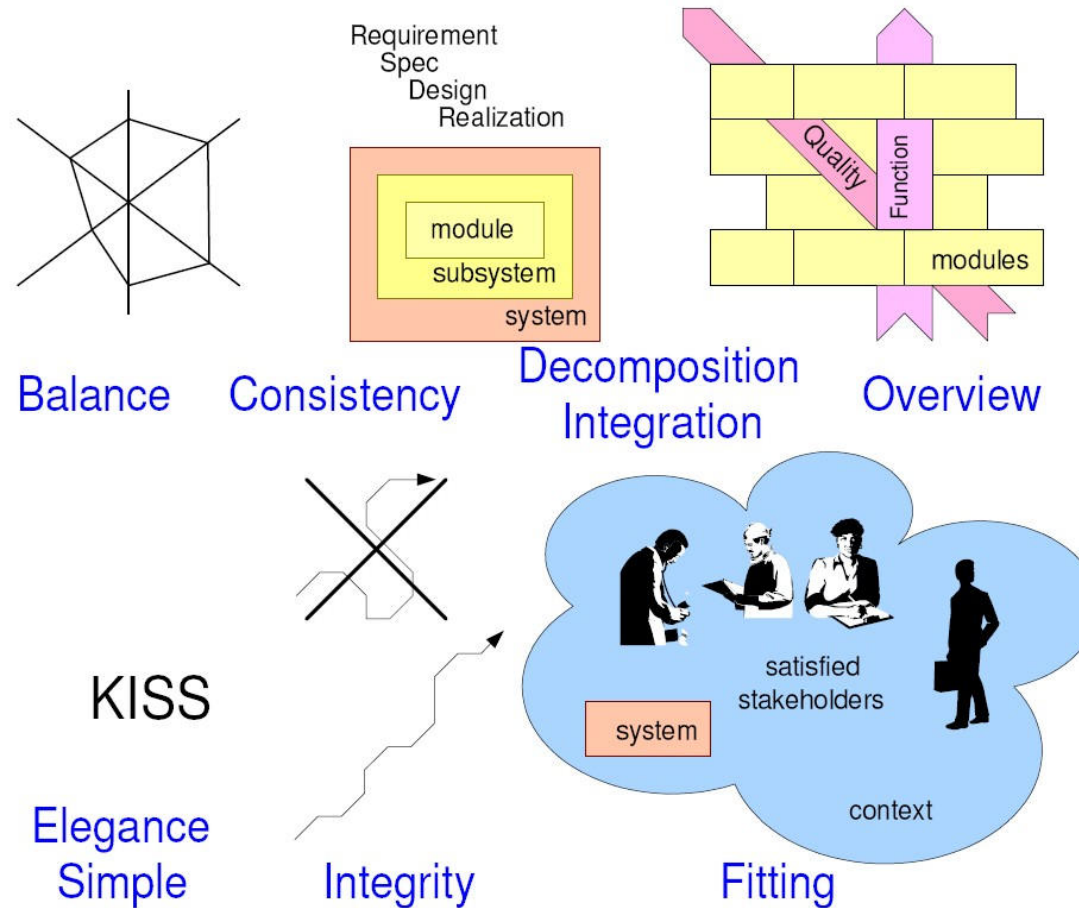


# System Engineering (4)



Gerrit Muller

# System Engineering (3)



Gerrit Muller

# Development history

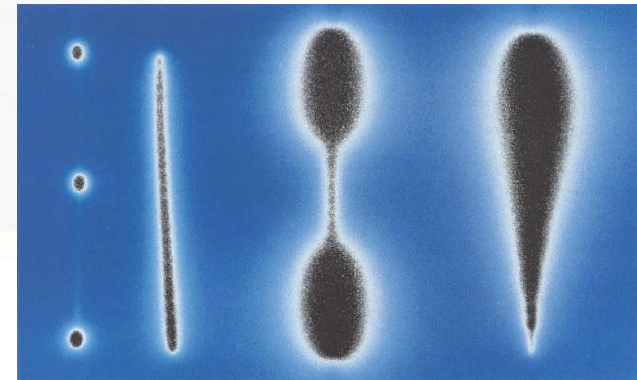
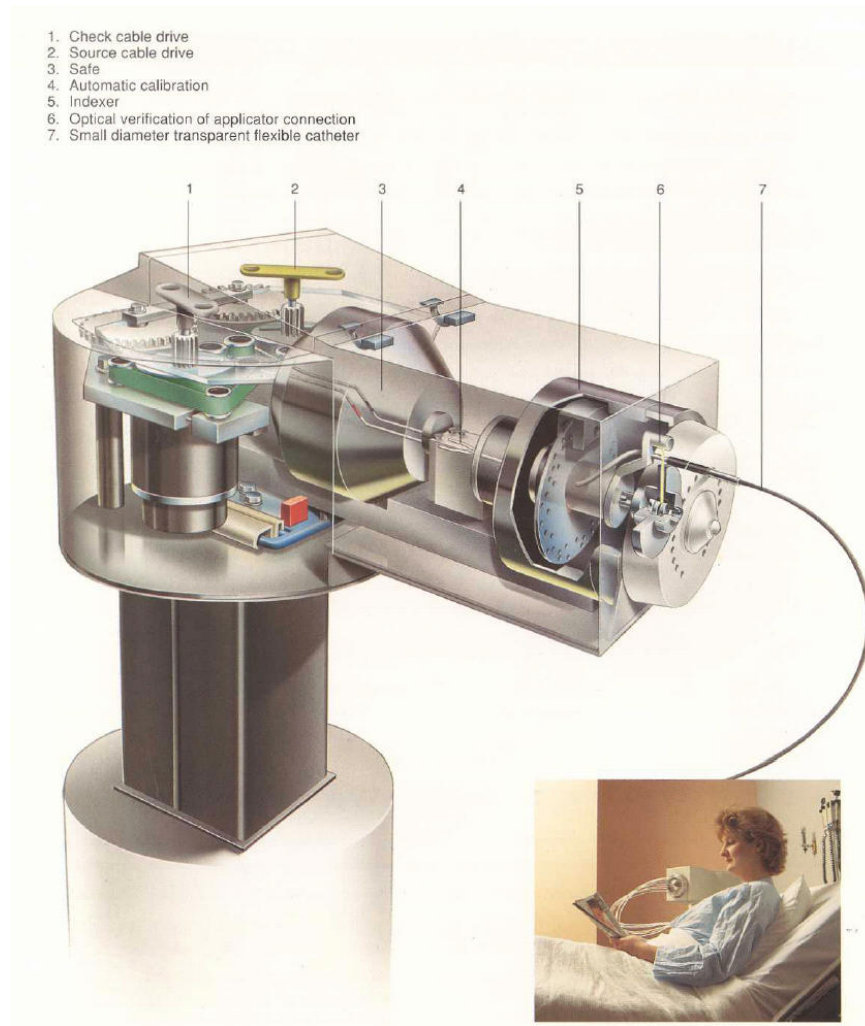
- Standard (Intel) boards (CPU / I/O)
- Own made boards (schematic, PCB)
- Own made firmware (only embedded)
- RTOS (uc/OS, SMX / VxWorks / WinCE)
- COTS boards (ETX) + custom made baseboard
- COTS systems (Beckhoff)

# Selectron LDR



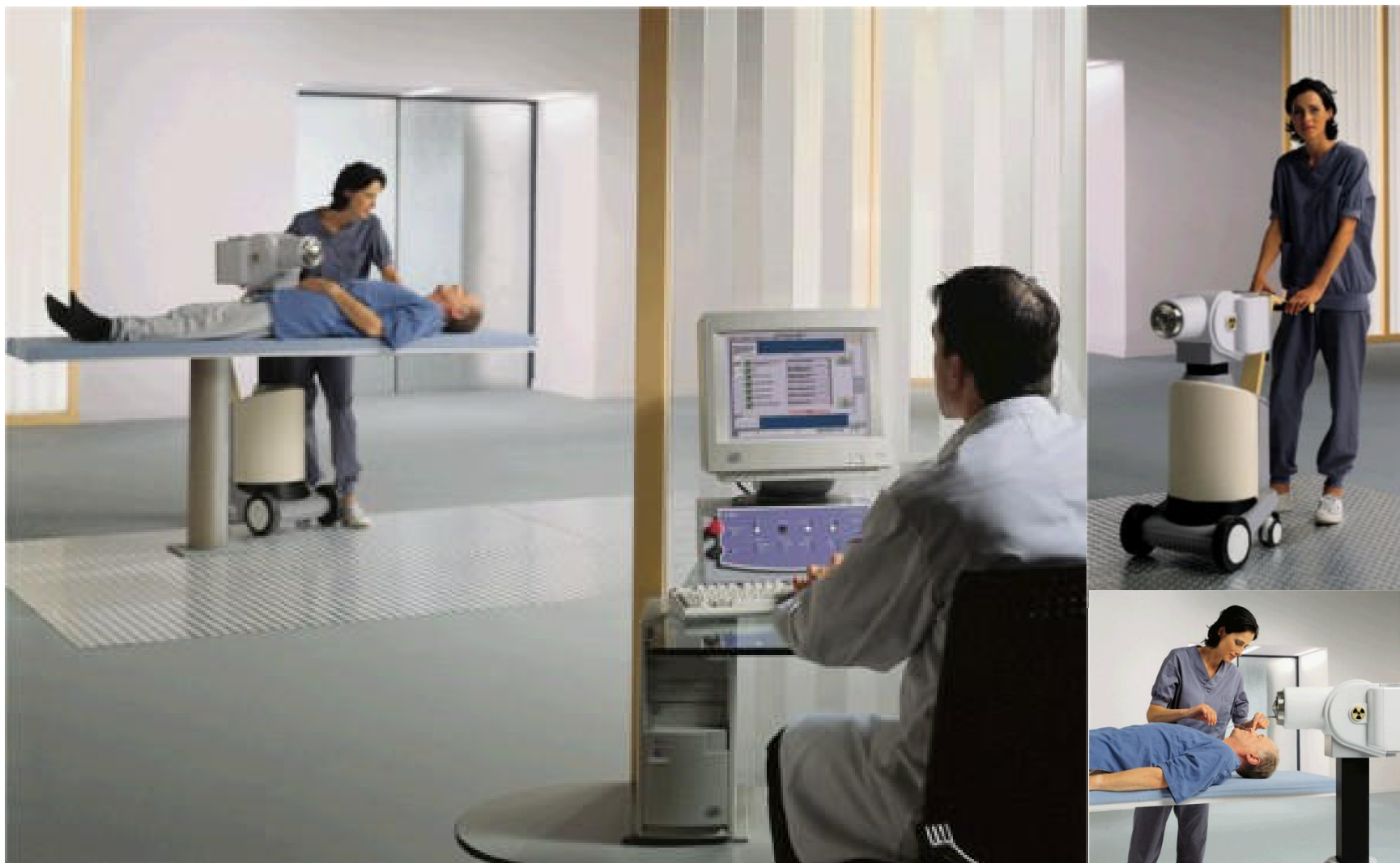


# microSelectron-HDR 'classic'





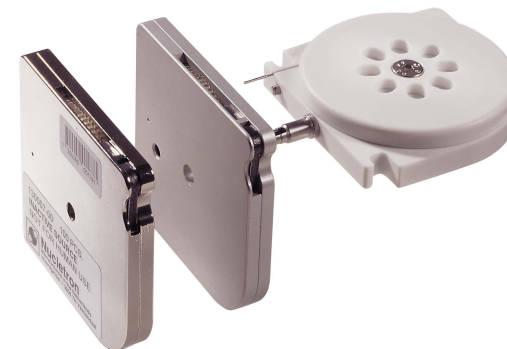
# microSelectron-HDR V2/V3



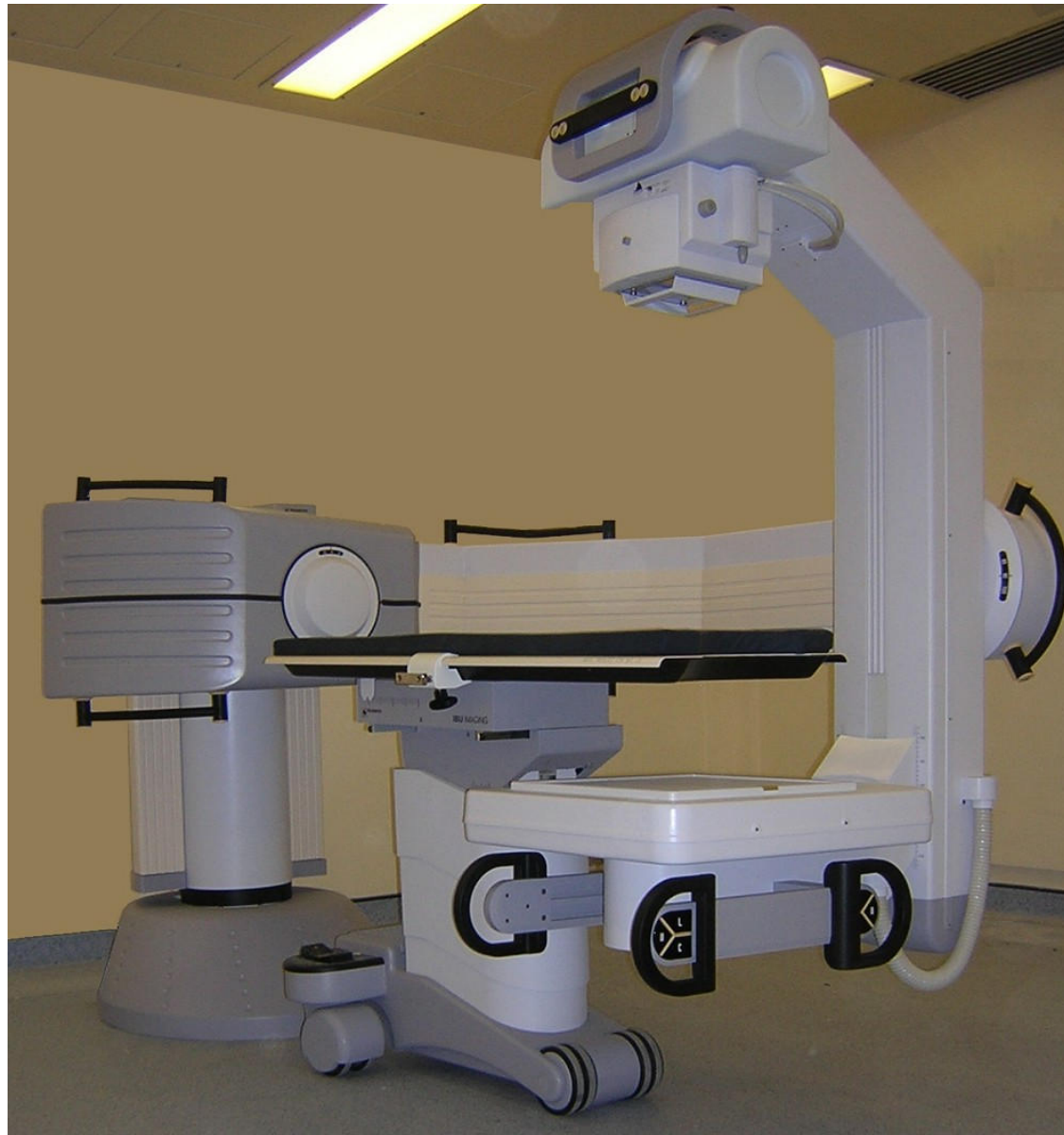
# microSelectron-PDR



# seedSelectron



# IBU



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# Challenges (1)



- Medical systems have a long lifetime (10+ yrs)
- Medical systems have a even longer service lifetime (20+ yrs)
- Nucletron: Some of the first produced systems (1975) are still in use
- Expensive medical systems are build in small quantities
- Validation / verification after changes is extensive (and expensive)



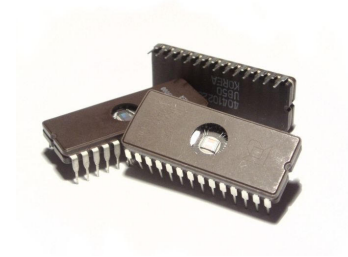
# Challenges (2)

- Short time to market
- Flexibility (adaptability). US / Europe / Asia
- Adhere to regulations / regulatory approvals (CE, FDA, local regulations)
- Rapid changing development environments (VS2002 / 3 / 5 / 8 / 10)
- - Rapid changing development systems (Win2000 / XP / 7)



# Challenges (3)

- Obsolescence of IC's
- Real time constraints
- Reliability
- Hospitals adhere to standards / treatment protocols
- Validation of new treatment techniques takes a long time (> 5 years)



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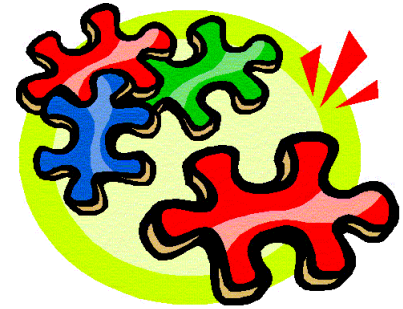
# Solutions (1)

- Standard GUI (Careface)
- Industry standards (Ethernet, PoE, EtherCat, Windows CE)
- Industry standard hardware for embedded systems (1st wave: ETX boards, 2nd wave: Beckhoff hardware)
- Use of programmable logic (CPLD's, FPGA's) instead of dedicated chips



# Solutions (2)

- Libraries / common components
  - Database
  - Dicom import/export/worklist
  - HIS connectivity
  - Reporting
  - Licensing
  - Users / rights / preferences
  - Logging / tracing
  - Remote support / service / update



## Solutions (3)

- Build / maintain older software / firmware projects in Virtual machines (VMWare / Virtual PC)
- Porting / complete rework of a software package (optimize, leave out unused features)





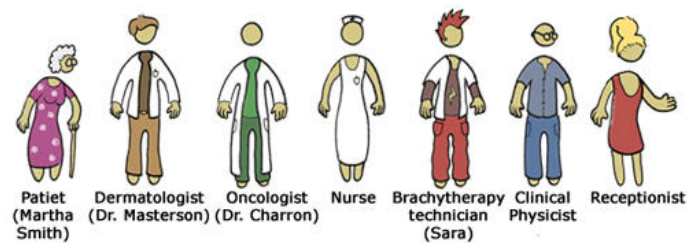
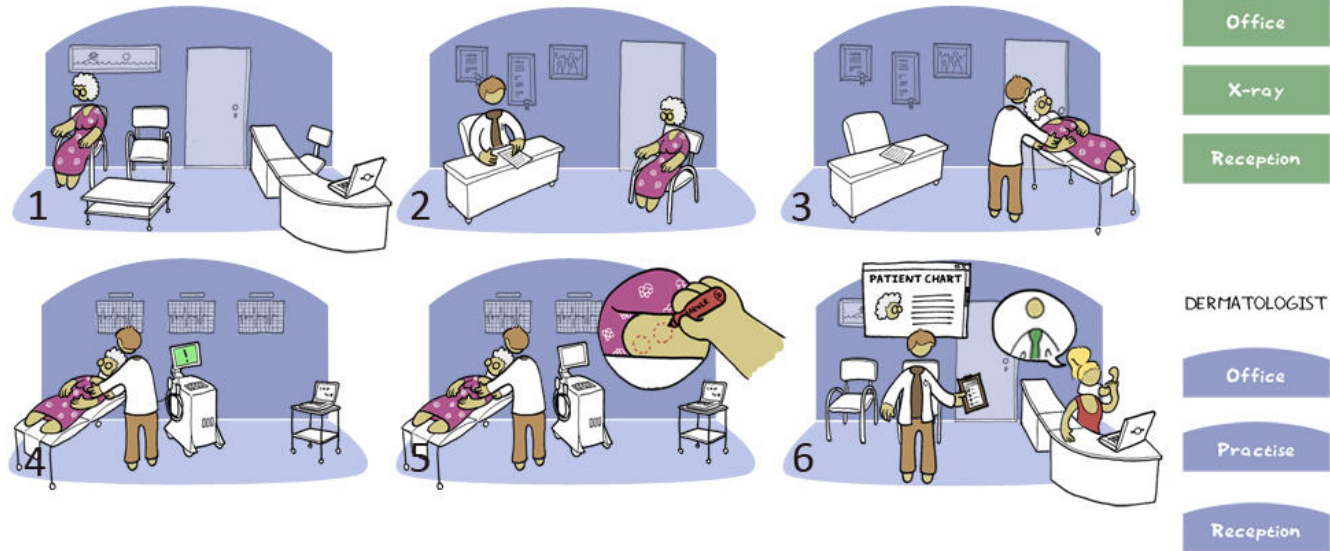
# Solutions (4)

- OO analysis/design (OOA / OOD / COA)
- Code generation (partly)
- Simulation
- C# - .NET - VS200x
- Rational tools (Req. Pro, ClearQuest, ClearCase)
- UML / Enterprise Architect



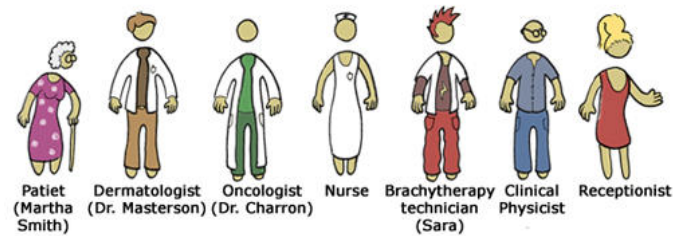
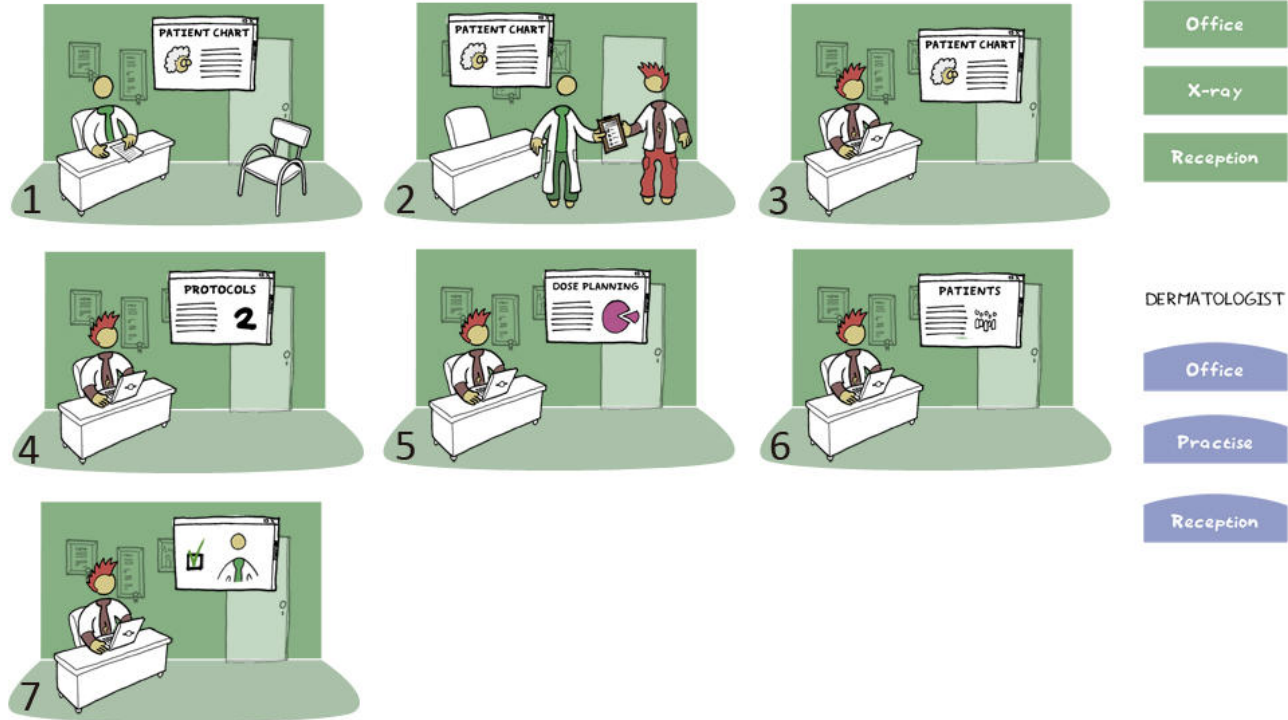
# Workflow studies

Diagnosis, choice of treatment and tumor mapping

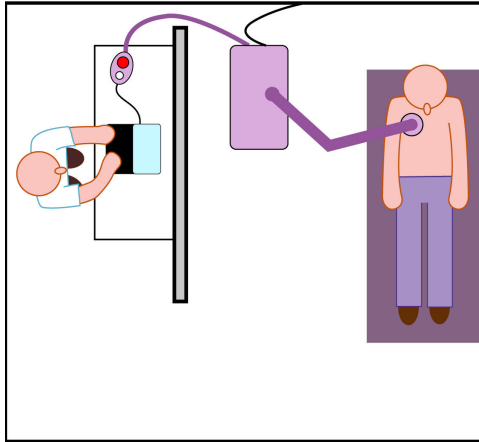


# Workflow studies

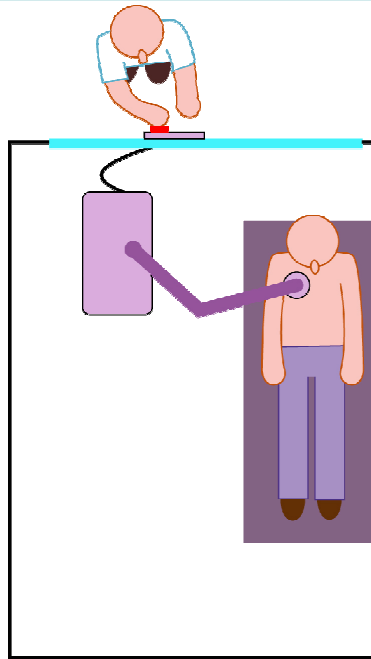
## Protocol choice and dose profile planning



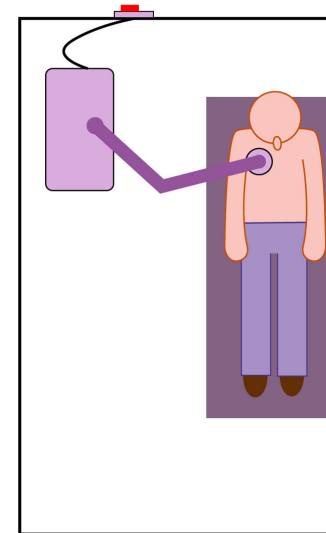
## Where is the therapist during the treatment?



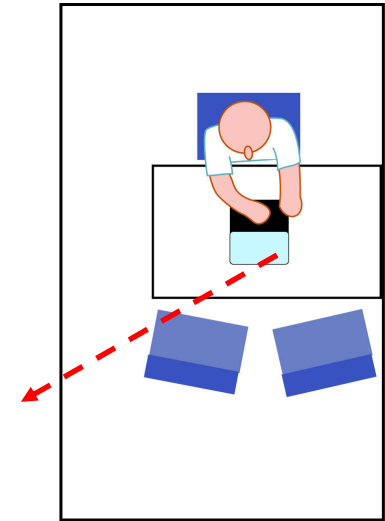
1 T in the same room



2 T outside in the hall



3 T in his own office



## IDEAL: Feedback

### Feedback

- Green LED: Device is on but no radiation
- Red LED: On and radiating
- Clearly visible
- Either on the tube, but then they can't be big
- Or big on the device

Same led's on the control unit!

### Preparation

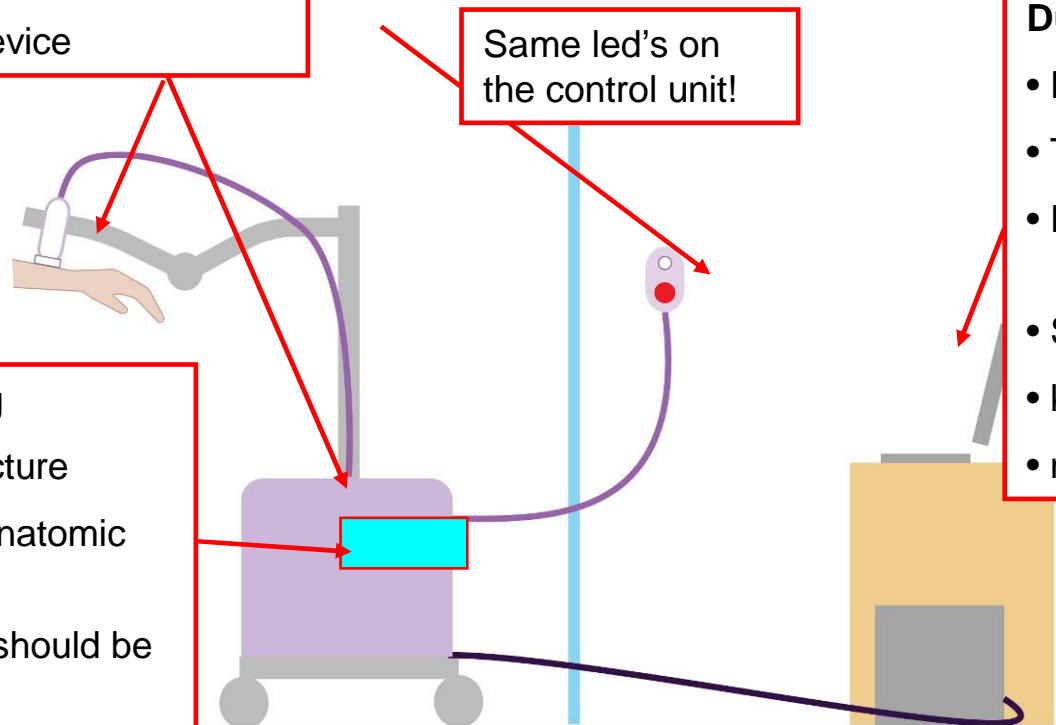
- Patient's medical information
- Lesion information
- Treatment planning
- Sort of applicator that has to be used
- Check whether the right applicator is used

### During treatment:

- Programmed time
- Timer running
- Pause key: stop the treatment, able to continue
- Stop key will be on control unit
- kV : energy
- mA : doses

### Small display showing

- Patient's name and picture
- Picture of lesion and anatomic position
- Sort of applicator that should be used
- Feedback whether the right applicator is being used



# Careface



## Style Guide

Careface:  
GUI Style Guide and  
Brand book project  
Nucletron

An example of the logo in the splash screen of the Smoothbase application.



An example of the logo symbol in the title of the startup window and in the application icon.



The Nucletron color palette.

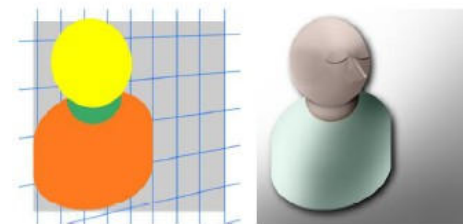


Colors used for backgrounds. A generic gray background is used as standard background.



R:237  
G:238  
B:237

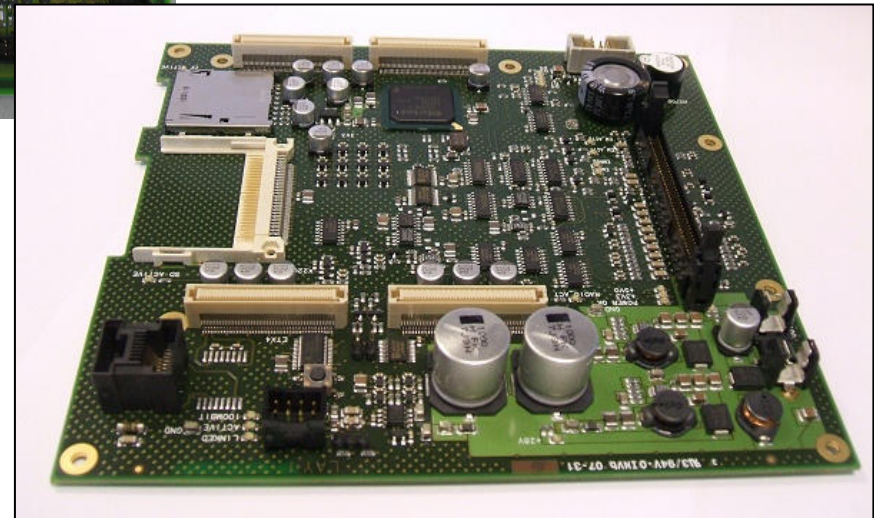
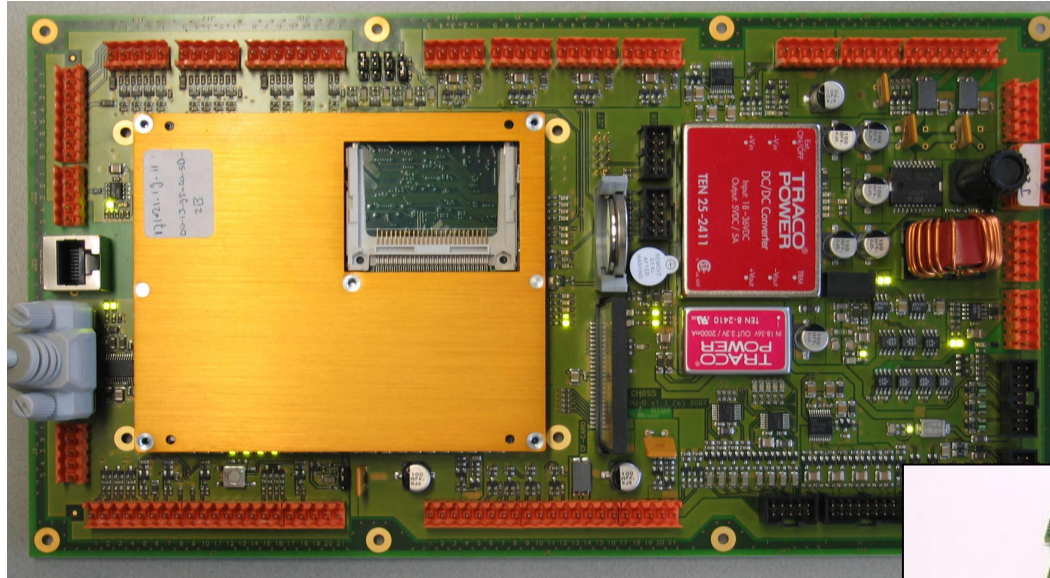
Initials	Date of birth
A.J.	10 October 1970



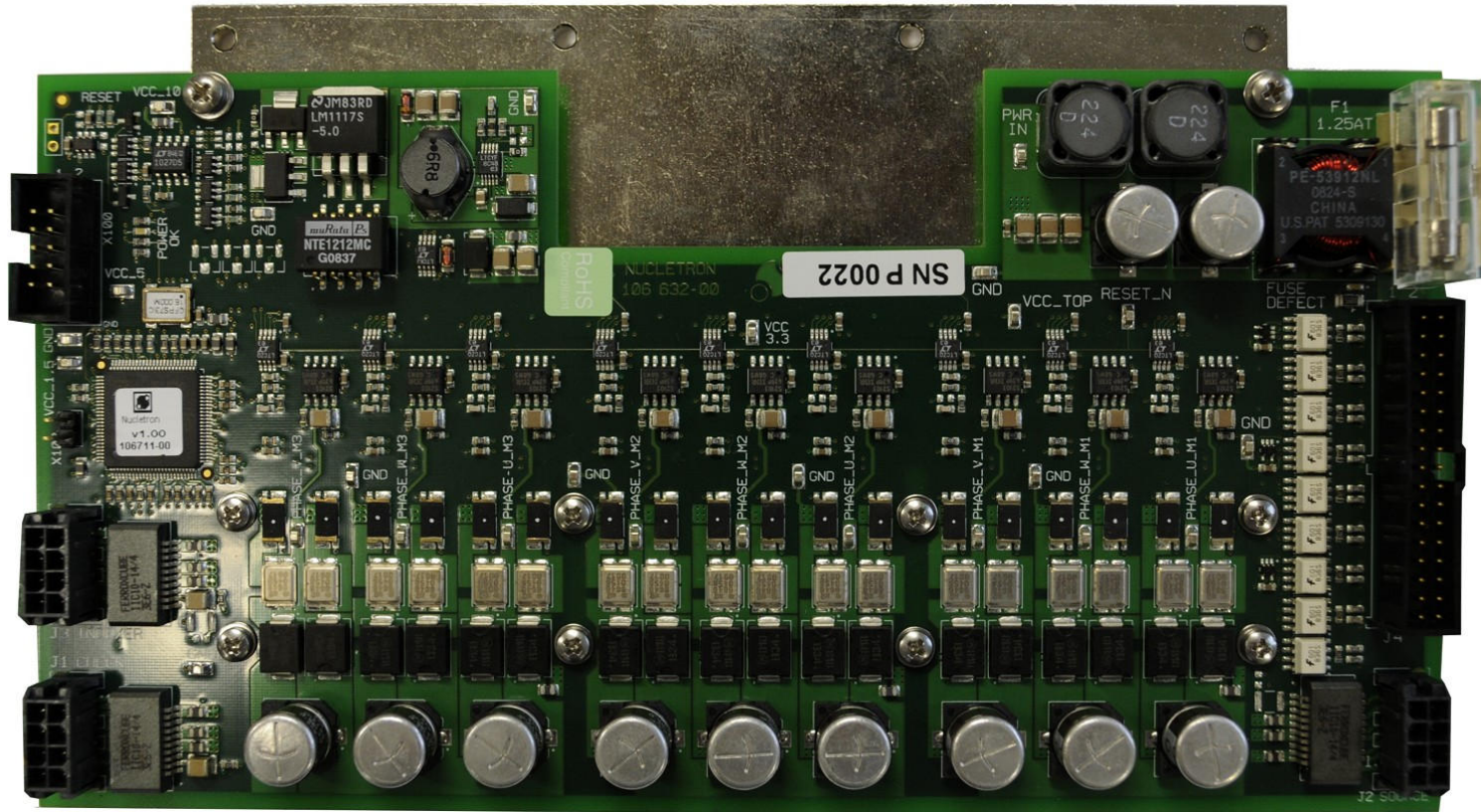
The icon that symbolizes the "patient" in Nucletron applications is based on a few basic forms placed in the perspective space used by all Windows XP icons. Some detail, lighting and color is later applied.



# ETX board + custom baseboard

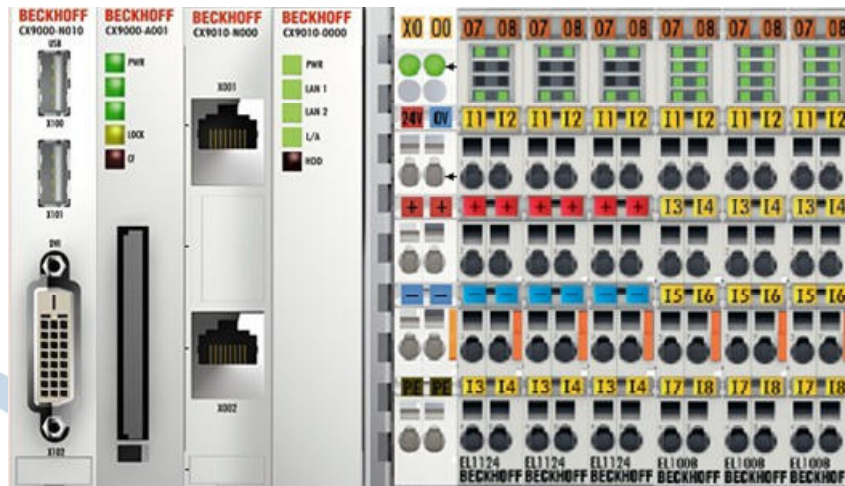




# Stepper motor controller





# COTS hardware (Beckhoff)



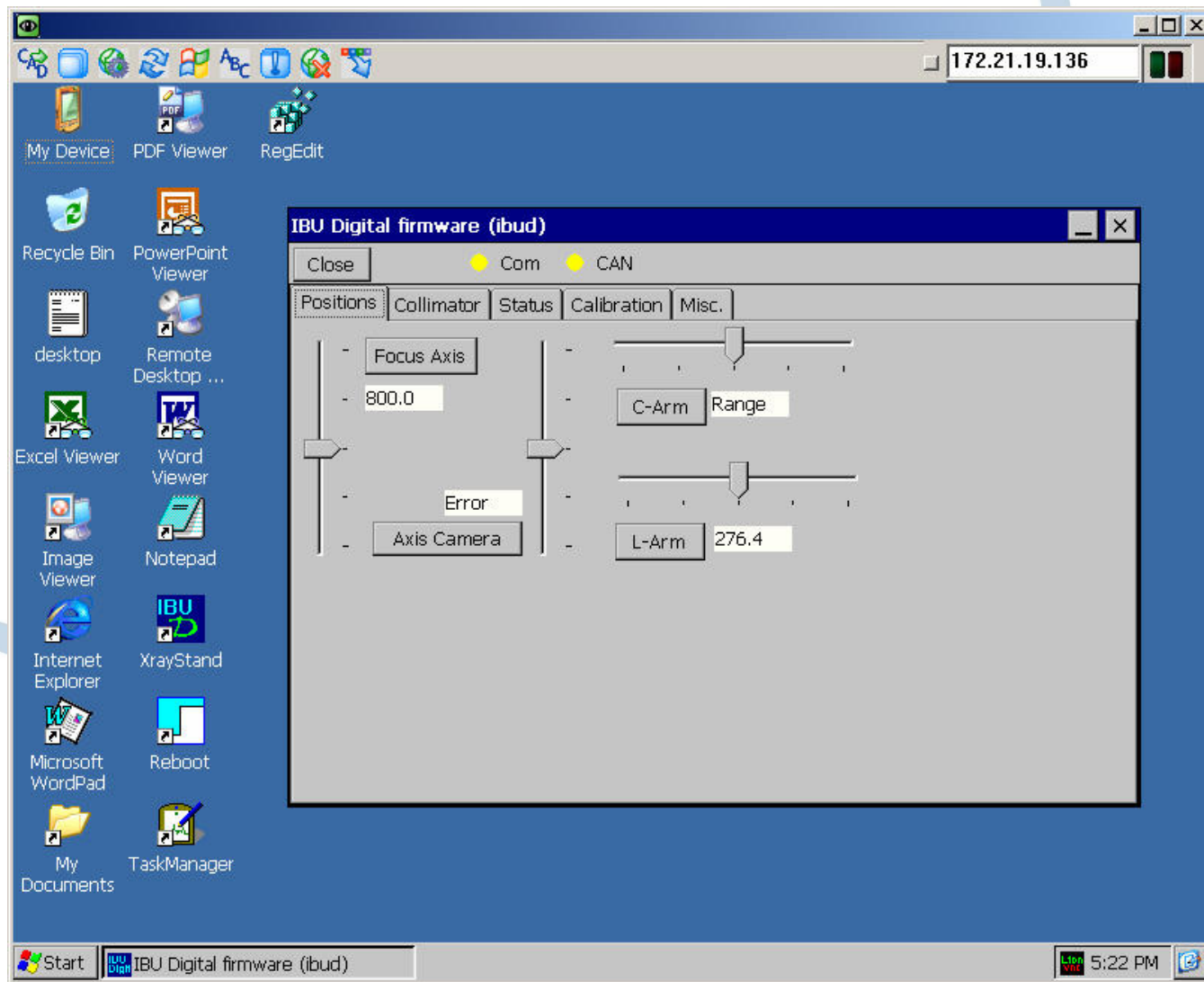
# Web based adjustment

The screenshot shows a web browser window titled "IBU Digital - Windows Internet Explorer" with the address bar displaying "http://172.21.19.57/ibud/". The browser's menu bar includes File, Edit, View, Favorites, Tools, and Help. The address bar also features a "Live Search" button. The main content area is titled "IBU-D Web site version 1.1" and displays a navigation menu on the left with options: Info, Calibration, IBU-D Board, ETX Board, and Log and Trace. The "Calibration" section is active, showing a sub-menu with "L arm", "C arm", and "Detector". The "L arm" option is selected, leading to the "L arm angle calibration" page. This page displays the following data:

L arm angle	Min	Min-mid	Mid	Mid-max	Max
176.4 deg	-180.0	---	0.0	---	180.0
Potentiometer					
89.36 %					
Linearity error					
0.042 %					
Status					
???					

The status bar at the bottom of the browser window shows "Thursday, March 27, 2008 15:27:17" and "Local intranet". The status bar also displays the text "Waiting for http://172.21.19.57/v.values/larmminmid.txt..." and a "100%" zoom level.

# Remote desktop (VNC)



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