The SYRMA project for clinical mammography @ Elettra

Safety, Control and Supervision systems

<u>A. Abrami</u>, V. Chenda, K. Casarin, D. Dreossi, E. Quai, G. Tromba, A. Vascotto

Outline

>Mammography @ Elettra >Beamline layout & equipments Safety, Control & Supervision Project criteria Directives, legislation Safety approach & guidelines Existing & new systems, and their technologies

>Conclusions and perspectives

Mammography @ Elettra

The SYRMA Project

(SYnchrotronRadiation for Mammography) Agreement among the Public Hospital of Trieste, the University of Trieste and Elettra

Aim

In vivo mammographic studies on selected number of cases picked out by radiologists

Target

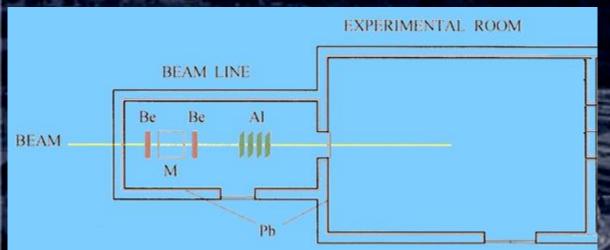
Patients with dense breasts, conventional radiographs with uncertain diagnosis

Set-ups

I phase: PHC planar radiography with conventional screen-film system II phase: use of digital detectors

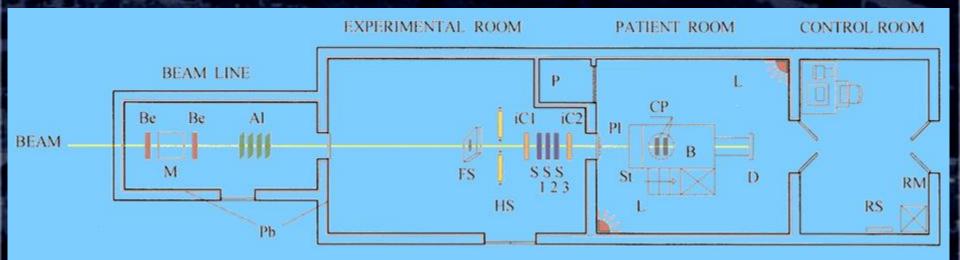
Clinical trial started on March 13, 2006.

Beamline layout & equipments SYRMEP layout



Be : Berillium window M : Monochromator Al : Aluminium filters Pb : Lead shieldings

Beamline layout & equipments SYRMA layout



FS : beam mask HS : horizontal slits iC1,2 : ionization chamber $S_{1,}$: safety shutter $S_{2,3}$: imaging shutter

P : dressing room PI : laser pointers St : stairs CP : breast compressor L: laser scanner

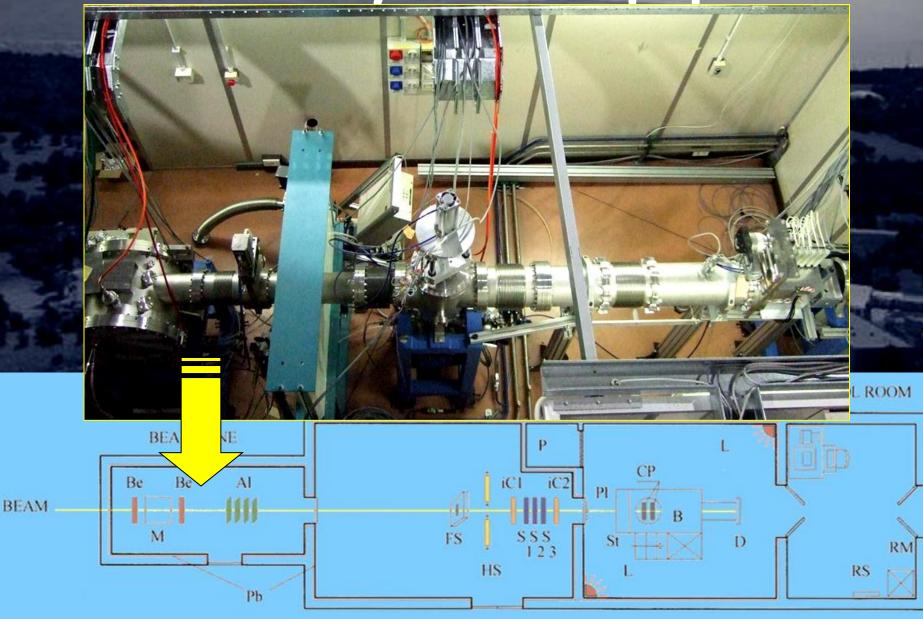
B : patient support (bed)

D: detector

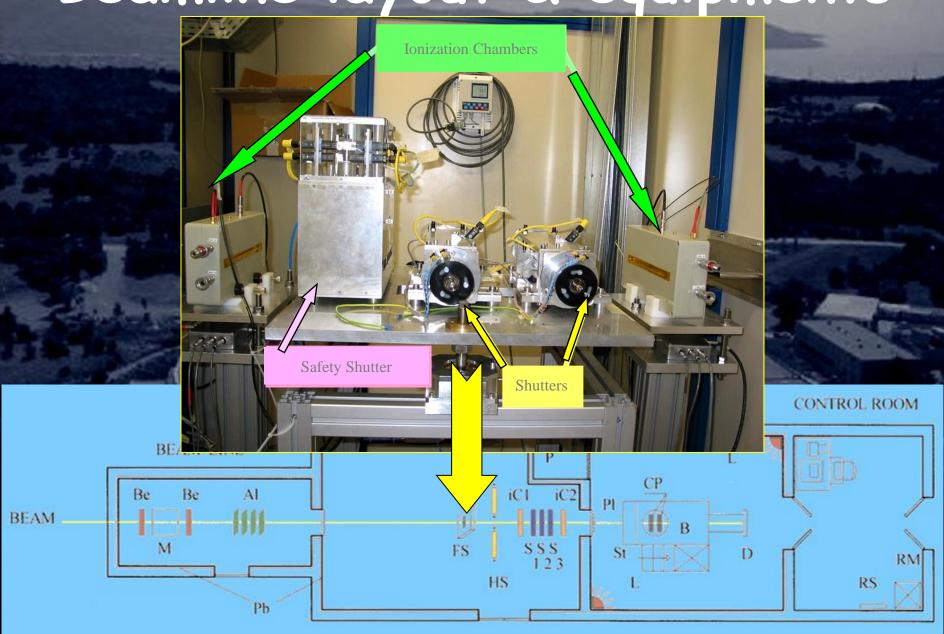
RS : film light board

RM : rate monitor

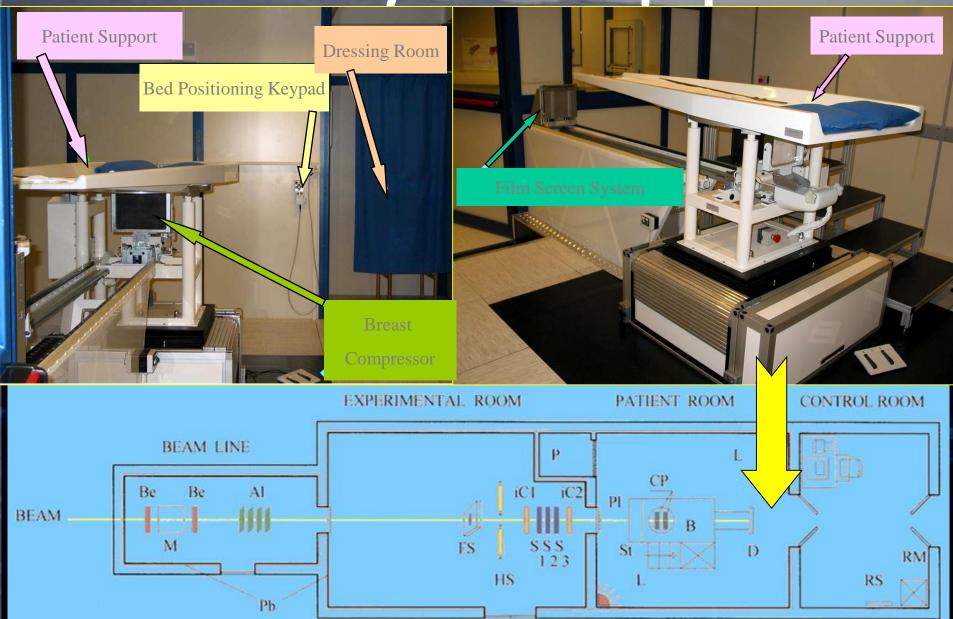
Beamline layout & equipments



Beamline layout & equipments



Beamline layout & equipments



Project criteria

 $\sqrt{\text{Split}}$ into decoupled systems $\sqrt{\text{System Functions identification}}$ $\sqrt{}$ System safety grade identification $\sqrt{\text{System integration without decoupled}}$ functionalities disservice $\sqrt{Minimizing}$ exam execution time

Project criteria (2)



Technical specifications & legislation

Meetings "Brainstorming" Validation Qualified Expert & Radioprotection



Syrma Controls Requirements Specification

Directives & Legislation

Standards are mainly intended to be used by manufacturers who assemble and **offer for sale** a combination of electrical and medical equipment...

... this is NOT our case,

but standards force the designer to guarantee a reasonable safety level

So we tried to design and assemble our systems

Directives & Legislation

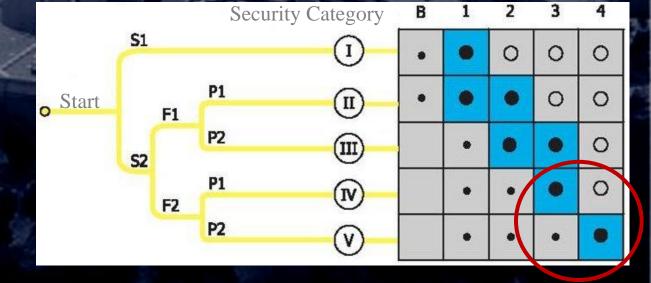
*EN 1050 Safety of machinery. Principles for risk assessment *♦ CEI 62-5* Medical electrical equipment ♦ CFI 64-4 Electrical installations in locations used for medical practice *♦ EN 418* **Emergency Stop Equipment** *♦ EN 964-1* Safety of machinery. Safety related parts of control systems *EN 349 Safety of machinery. Minimum gaps to avoid crushing of parts of the human body

Safety approach

It is essential the <u>risk evaluation</u> (EN1050) in projecting a machinary and the choice of its security category (EN954-1).



- F = attendance of presencenear the machinery
- P = prevention chance

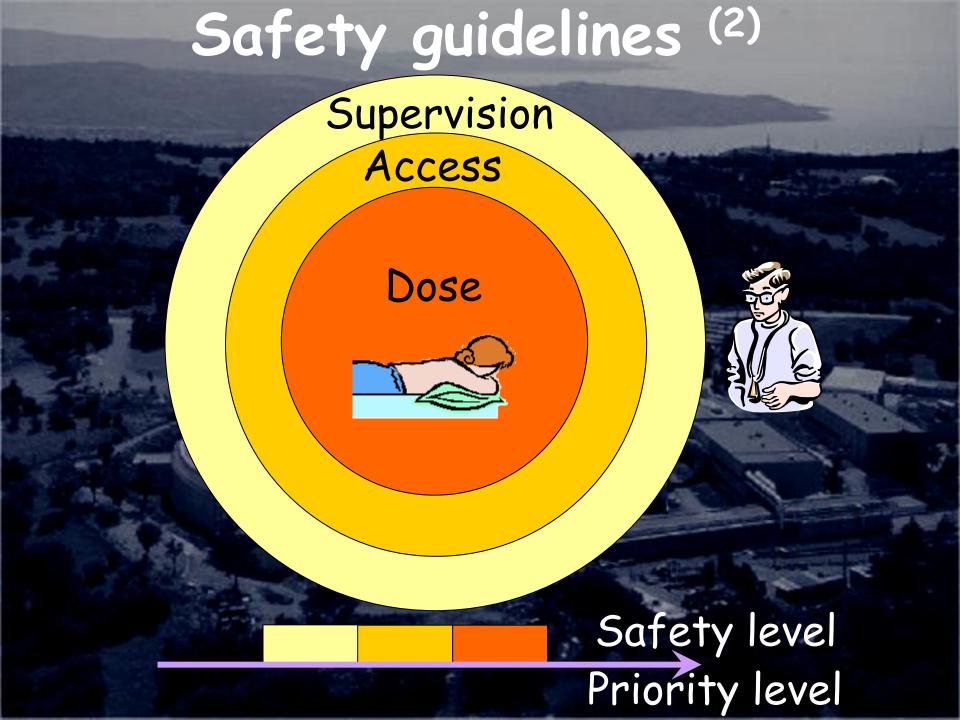


Safety approach

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	CATE	CATEGORY 4				
SINGLE FAULT	Does NOT le safety	Does NOT lead to loss of a safety function				
ALL FAULTS	Do not require to be detected.		Will be detected.			
		There will the protection against accumulation.				
S = accident seriousness	S2	F2	(III)	•	•	0
F = attendance of presence	- C	P1	IV		•	• 0
near the machinery	S.	P2	_	•		• •
P = prevention chance	-	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	-	I		

Safety guidelines

 Decoupled systems with suitable safety grade
 Redundancy and technological diversity in (sub-)systems with high safety level
 Verification and validation performed by external & indipendent specialists



Existing Systems



VME Cpu & "traditional" I/O Web graphic interface



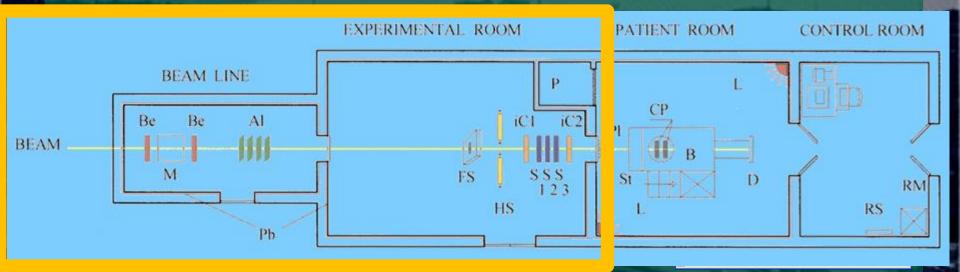


* Beamline Access Control

Siemens Simatic-S115U PLC



Existing Systems



* Beamline Access Control

Siemens Simatic-S115U PLC



Systems

* Bed-film



* Access and Dose Control

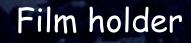
* Machinery Safety

* Supervision and human-machine graphic interface



Bed-film System

4 high-performance diodes optimized for X-rays

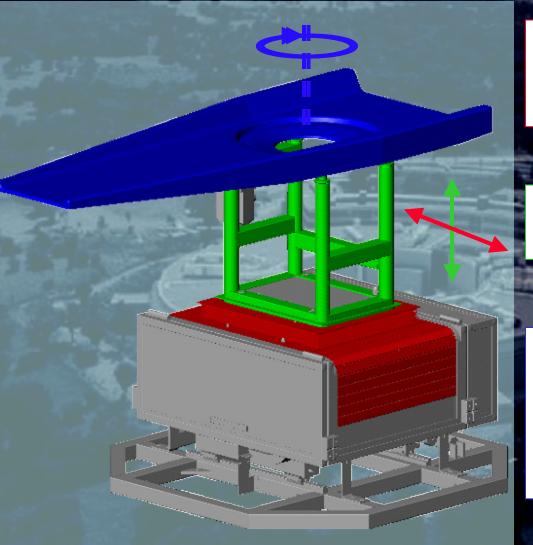


Laminar beam * vertical scan = area image

Bed

Beam

Bed-film System ⁽²⁾

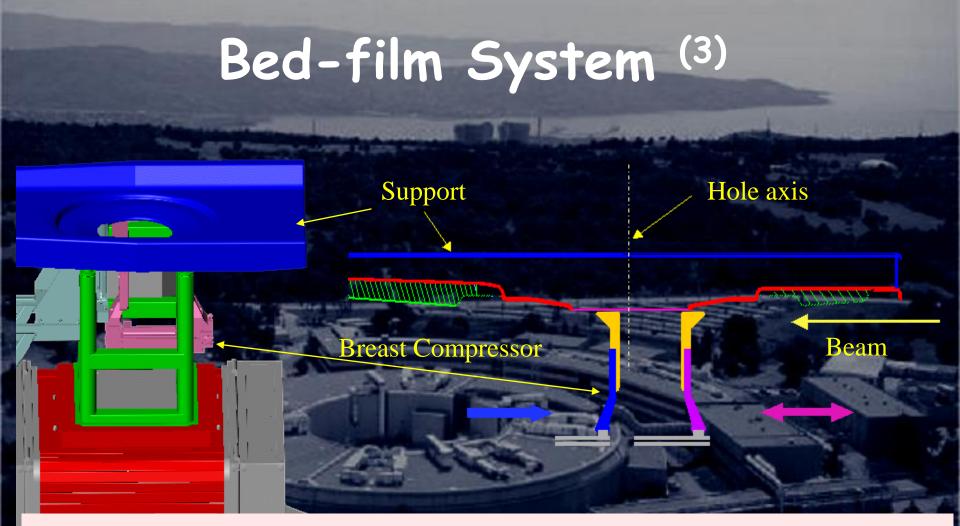


Horizontal positioning : alignment exam

Vertical scan : exam

Rotation :

exam projection (top-to-bottom view and oblique side view)



Breast Compressor is fixed respect to patient support that can rotate!!!



Bed-film System ⁽³⁾

Support

Breast Compressor

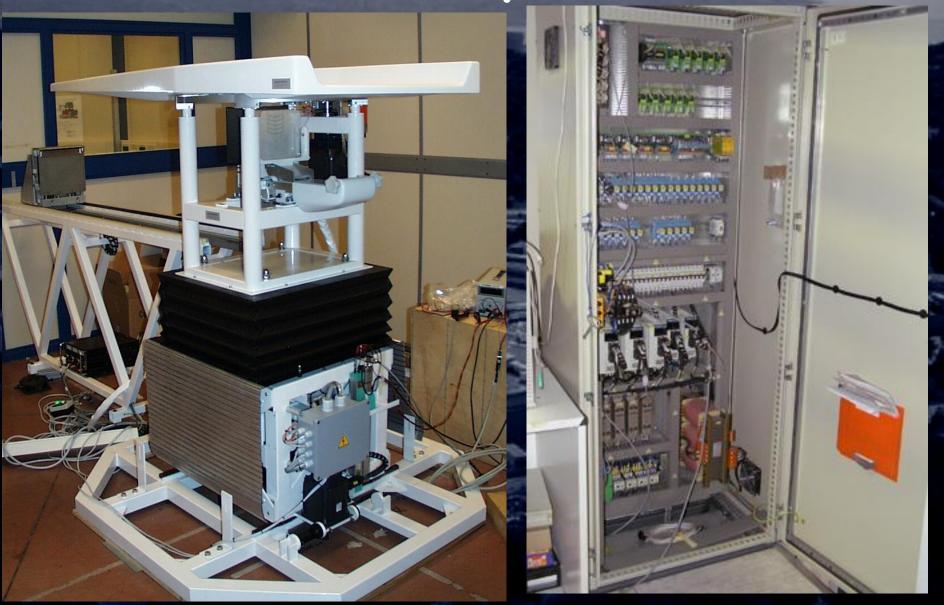
Hole axis

Beam

So an adequate (DIN EN 954-1, 03/97, Category 4) interlock to avoid bed moving while breast is compressed is needed.

toon.

Bed-film System ⁽⁵⁾



Bed-film System ⁽⁵⁾



Compression - Motion Interlock

Safety device: PNOZ X2 PILZ



Bed-film Technologies



Motorola MC68360 AWL, Forth & Assembler



Compression - Motion Interlock Estop Safety device: PNOZ X2 PILZ

Breast Compressor



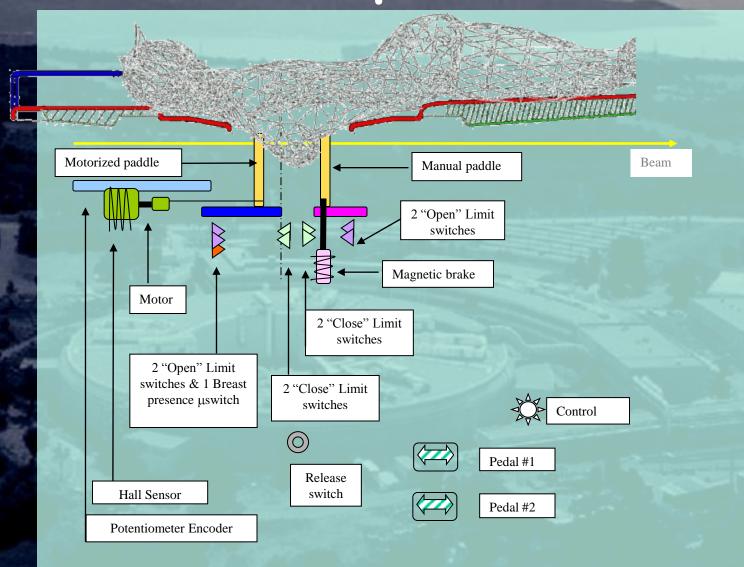
Breast Compressor

Manual paddle

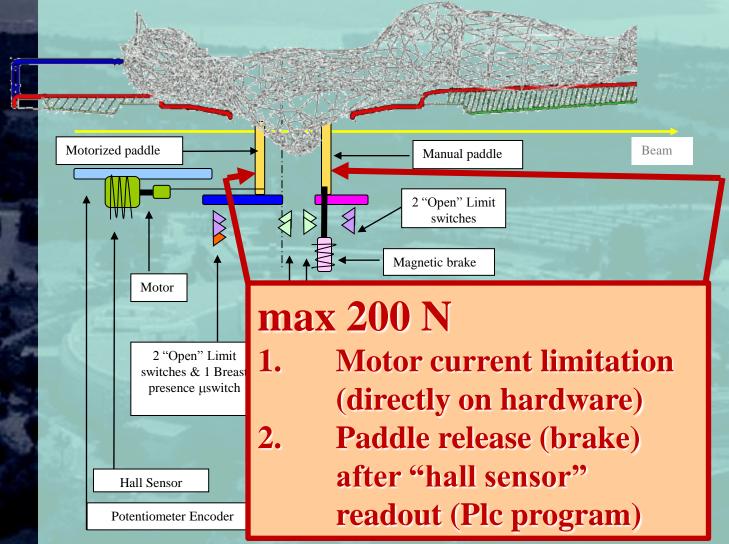
Motorized paddle

max 200 N

Breast Compressor ⁽²⁾



Breast Compressor ⁽²⁾



Breast Compressor Technologies



Control: PLC Modular I/O System IEC programming languages: IL, ST, SFC, FBD, LD, CFC

IL: Instruction List ST: Structured Text SFC: Sequential Function Chart FBD: Function Block Diagram LD: Ladder Diagram CFC: Continuous Function Chart Editor

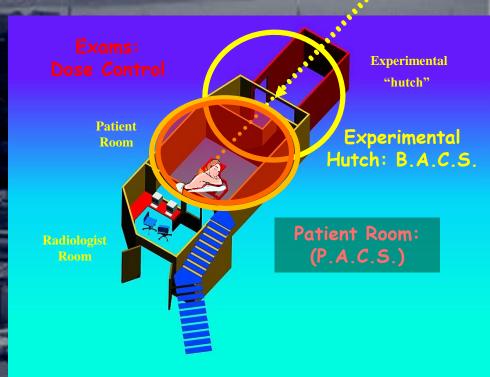


Compression threshold

Access & Dose Control

- It is possible to work on the beamline in two different ways:
 - Experimental Mode
 - Patient Mode

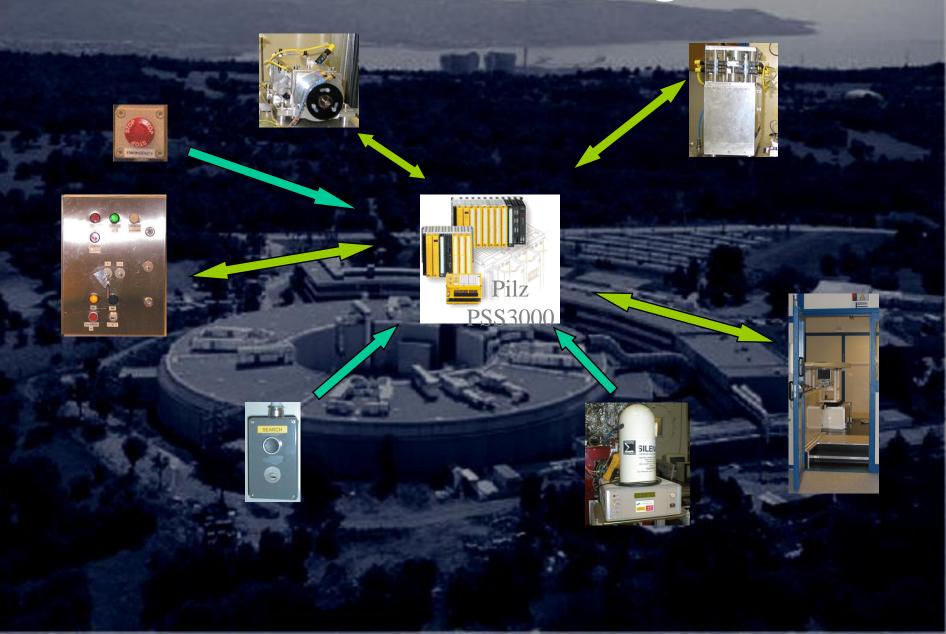
Experimental Hutch: traditional Beamline Access Control System (B.A.C.S.)



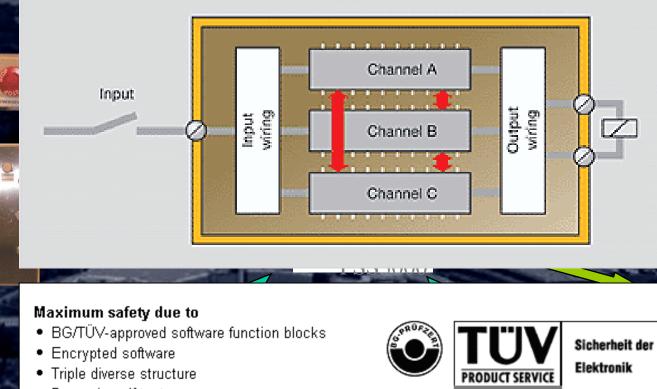
Patient Room: customized access control system to patient room (P.A.C.S.)

During exams: Dose Control

P.A.C.S. Technologies



P.A.C.S. Technologies

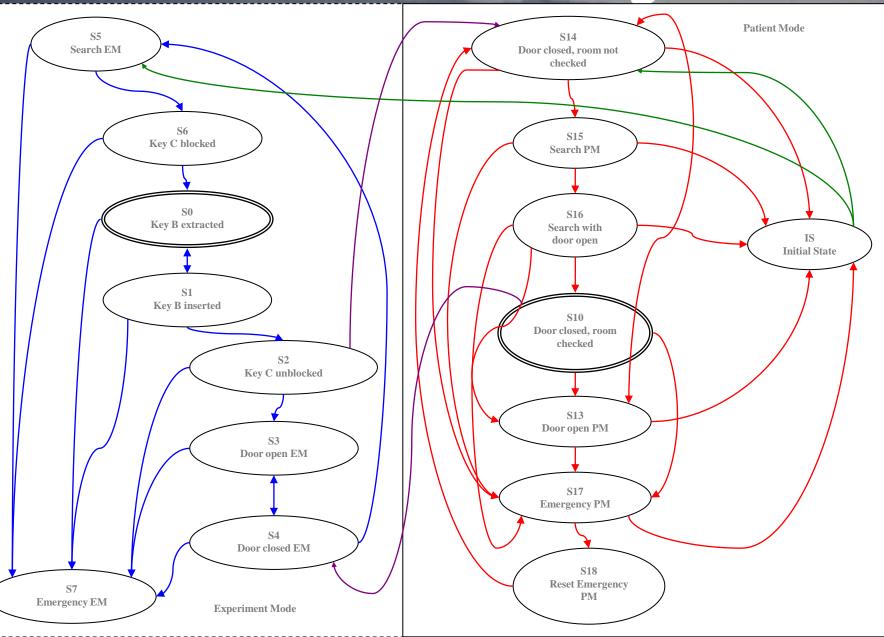


- Dynamic self test
- Approved hardware, BG EN 954-1 category 4, TÜV DIN V 19250 AK 6

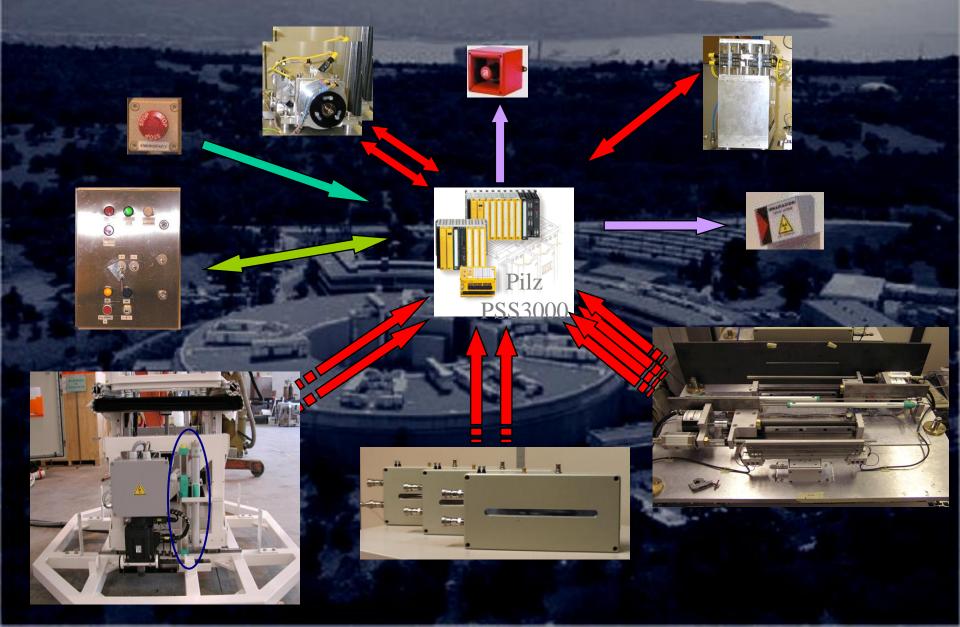


Cat. 4

P.A.C.S. Technologies



Dose Control Technologies



Dose Control Technologies

sensors and actuators aquired from PLC are *redundant*

and have been choosen with

different technology

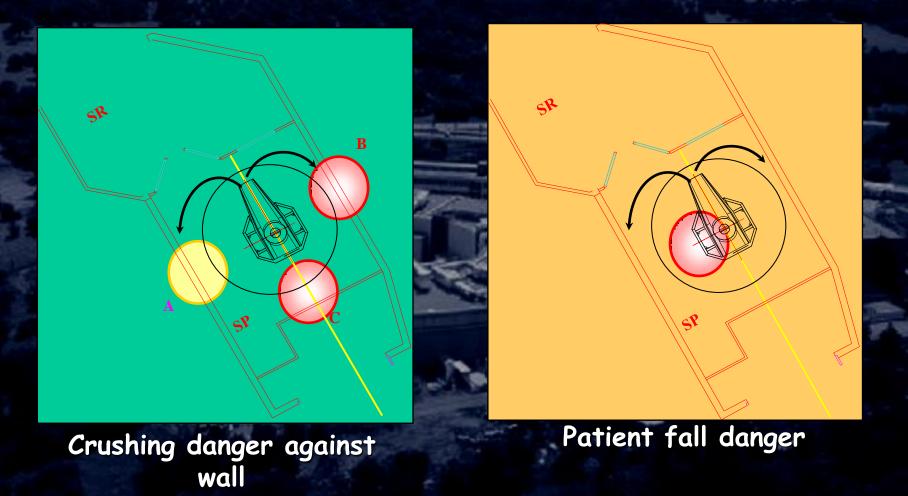
Dose Control Technologies

Magnetostrictive sensor



Machinery Safety

European Standard EN349 is applicable to risks from crushing hazards

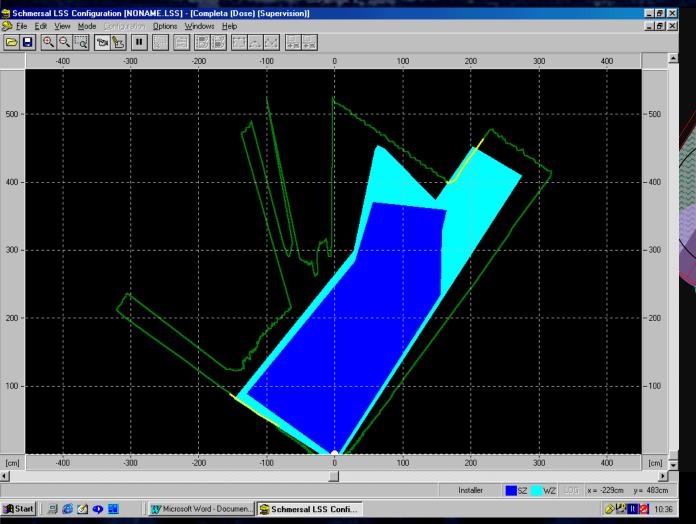


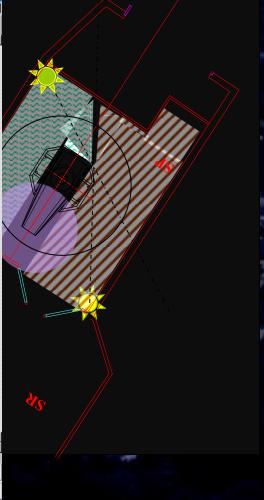
Machinery Safety Technologies

In order to fullfill the safety requirements, some devices to avoid dangerous movements are needed.



Machinery Safety Technologies





Supervision & Human-Machine I/F S.H.M.I.

Bed-film System

Breast Compressor System

Ionization Chamber System

SHMI

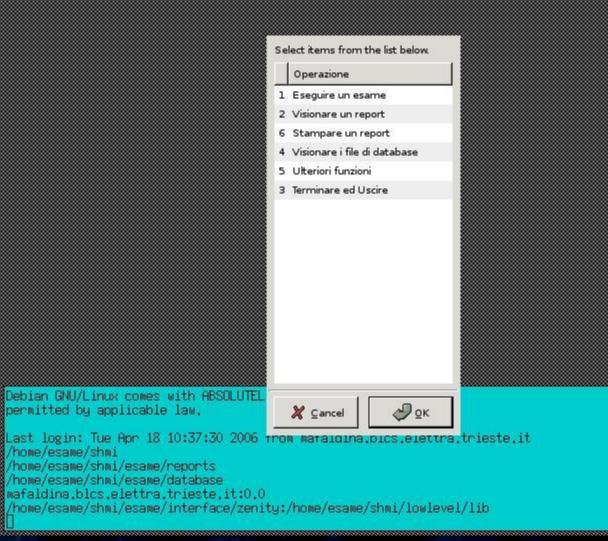


Access & Dose Control System Ancillary Systems (i.e.: Environmental Data,...)

Supervision & Human-Machine I/F S.H.M.I.

- •Functions:
- * Control all systems to:
 - ✓ Insert initialisation/calibration data
 - ✓ Register patient data
 - \checkmark Select the X-ray energy and optimize the beam
 - \checkmark Verify the congruency of all the examination parameters
 - Manage the pre-scan
 - \checkmark Carry out the scan
 - ✓ Register dose report

- hw: •19" rack PC
• Pentium 4 1.8GHz
• controller raid Adaptec 2400
- SW: •linux debian 3.1r0a "sarge"
• C, gtk & glade



Inserire i dati Anagrafici, Clinici e Tecnici

Dati Anagrafici Numero Radiologico	Iniziale Iniziale Nome Cognome	
Dati Clinici		
Dati Tecnici Ghiandolarita' - [%] © Bassa [0 - 33 %] © Media [34 - 66 %]	Spessore - [cm]	
O Alta [67 - 100 %] Dose Ghiandolare Media (DGM _{ref}) - [mGy] Frazione di DGM nella Prescansione- [%] 10	Dose in Ingresso (ESD) - [mGy] Numero Campioni nella Prescansione 1000	
▶ Procedi	e sci	

Preparazione Prescansione		
	Quota di inizio Prescansione :	
	Quota di fine Prescansione : Velocita' di Prescansione :	
	·,	
	Valore corrente dello spessore seno :	
	Dose Ghiandolare Media prevista per la Prescansione (DGM _{prescan}) :	
	DGM _{prescan} / DGM _{ref} :	

🕅 Procedi



Conclusions and perspectives

After 3 years in operation:

 Systems have shown high reliability and efficiency
 Minor changes have been asked & done without drawbacks

What next?:

Integration of digital detectors
 Realization of tomosyntesis/tomography

SYRMA Collaboration

A.Abrami, K.Casarin, V.Chenda, D.Dreossi, R.H. Menk, E.Quai, G. Tromba, A.Vascotto *Elettra, Sincrotrone Trieste*

F.Arfelli, E.Castelli, R.Longo, T.Rokvic Department of Physics & INFN University of Trieste

M.A. Cova, E. Quaia, M. Tonutti, F. Zanconati Department of Radiology University and Hospital, Trieste

P. Bregant, F. de Guarrini Health Physics - Hospital, Trieste









SYRMA Collaboration

A.Abrami, K.Casarin, V.Chenda, D.Dreossi G. Tromba, A.Vascotto *Elettra, Sincertrone Triest*

F.Arfelli E Cost



Depar^{*}

M.A.

Thanks for your kind attention







P. Bregant, F. Guarrini Health Physics - Hospital, Trieste

