# The SYRMA project for clinical mammography @ Elettra Safety, Control and Supervision Systems

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**Abstract**

The Elettra beamline for mammography with Synchrotron Radiation (SR) has been operating since March 2006. The clinical aim is to apply the PHase Contrast (PHC) imaging technique to a selected number of patients, recruited by radiologists according to a protocol approved by the Hospital Ethic Committee. Due to the laminar nature of SR beam, PHC images are obtained scanning the patient and the detector simultaneously through the beam.
Technical issues, national radiation protection and safety guidelines, both for patients and for operators, have been faced with during the design and implementation phases of this project. A description of equipments and systems is presented.

## 1. Introduction

The aim of the SYnchrotron Radiation for MAmmography (SYRMA) project [1] is to perform "in vivo" synchrotron radiation mammography on a selected number of patients recruited by the radiologist of the Trieste Public Hospital on the basis of BI-RADS classification [2]. The target cases are dense breasts with uncertain diagnosis after conventional mammography and ultrasonography.
The use of PHC imaging technique in mammography contributes to increase the image contrast and to improve the visibility of different details. Edge enhancement produced in PHC images results in a better visualization and characterization of lesions as well as in an improved differentiation of the glandular structures, leading to an higher sensibility and specificity of mammographic exam [3].
The use of a monochromatic beam permits to optimize the X-ray energy, as a function of the breast characteristics, reducing the delivered dose.

The project foresees three phases: the 1st phase, which started on March 13th, 2006 and is now next to conclusion, foresees to perform PHC mammography on 70-100 patients utilizing conventional screen-film systems; the 2nd phase provides the implementation of digital detectors (commercial and in-house developed) and the 3rd one the introduction of new imaging techniques.
During the 1st phase of the project, a collaboration with Fuji Italia has permitted to study the application of PHC imaging technique using Fuji Imaging Plate (IP) as detector [4]; two mammographic examinations have then been carried out with this imaging system without changing anything in the Safety, Control and Supervision Systems.

## 2. Beamline Layout and Equipments

SYRMA project has been developed at SYRMEP (SYnchrotron Radiation for MEdical Physics) bending magnet beamline. To perform clinical studies, the layout of the beamline has been deeply modified (Fig.1), with the addition of the *patient room* and the *control room* downstream the *experimental hutch*.

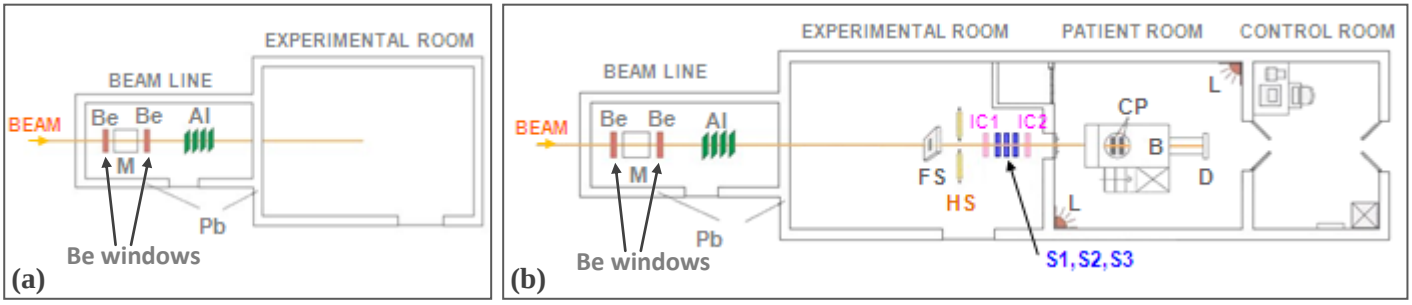


*Fig.1 - SYRMEP layout, before (a) and after (b) the clinical mammography project development.*

The *monochromator* (M) of the beamline, based on a double Si(111) crystal assembly working in Bragg configuration, is positioned in the *first beamline hutch* and permits to select the working energy in the 8.5-35 keV range; for mammographic studies the useful energy range is restricted to 17-21 keV.
Downstream the monochromator, the beam crosses a *beryllium window* (Be) and is then transmitted in air to a system of *calibrated aluminum filters* (Al), used to modulate the X-ray photons intensity.
A *beam mask* (FS), placed inside the *experimental room*, removes from the beam path the scattered radiation channeled into the beamline and defines with high precision the vertical dimension of the beam. The horizontal dimension is set through a system of *horizontal slits* (HS).
Two transmission *ionization chambers* (IC1, IC2), equipped with custom electronics, are used as beam and dose monitoring system. They have been developed and built in-house, taking into account the beam laminar structure and the high intensity of the synchrotron radiation.
A *fast safety shutter* (S1) is installed to quickly cut off the beam (response time < 20 ms) if dose threshold is exceeded; two further *shutters* (S2, S3) are utilized to define the exposure time of the patient scan (imaging function) and to guarantee safety conditions for the patient room access.
The *patient room* is equipped with a high precision movement *bed* (B), that can be translated vertically and horizontally to optimize the patient's position with respect to the beam, and can be rotated on the horizontal plane to permit different breast projections (Fig.2a). During the examination the patient lies prone on the bed with her breast leaning out of a hole realized on the support itself (Fig.2b).
The bed is equipped with a *breast compressor* (CP) used to equalize tissue thickness, for minimizing dose and optimizing imaging. A conventional *film-screen system* (D) is utilized as image detector and is mounted on a 2 meters long rail to allow distance optimization for PHC imaging purpose.

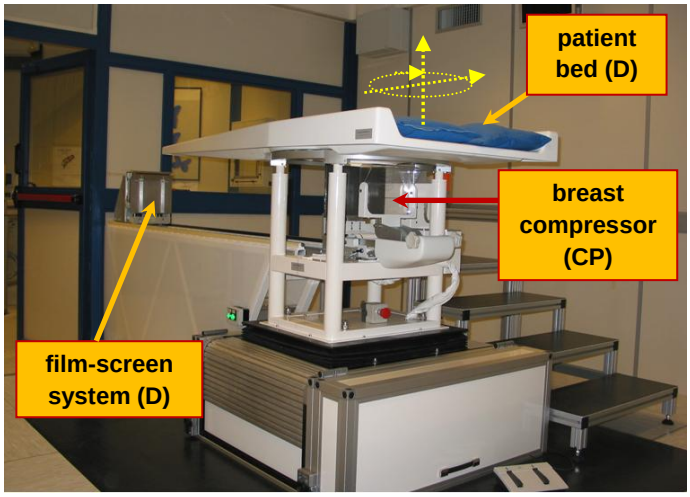


*Fig.2a - Patient bed, breast compressor and film-screen system.*

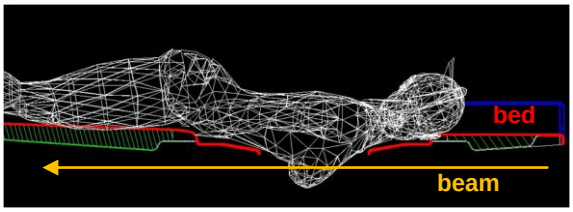


*Fig.2b - Patient position during the exam.*

All the phases of the mammographic examination are controlled and supervised by the radiologist and the technicians from the *control room*; thanks to the fact that a great part of the wall separating the *control* from the *patient room* is realized in lead glass, they have a direct view of the patient and can shut off the beam (e.g. pushing an emergency button) if necessary.

Taking into account that SYRMEP beamline is utilized also for other studies besides mammographic ones, two alternative working modalities have been developed for the patient room: the *"Patient Mode"* and the *"Experimental Mode"*. The former is specifically developed for clinical mammography, the latter allows to operate the beam, without dose control interlocks, for imaging of biomedical and biological materials, engineering science studies, test of detectors, etc. typically performed in the experimental hutch. A special key called '*Radiologist's Key'* permits to switch from one modality to the other.

## 3. Safety, Control and Supervision Systems

### 3.1. Safety Approach and Guidelines

Many *"Technical Directives"* and *"Italian/European legislations"* [5] have been analyzed for a correct approach to the safety aspects of the project. The first question to face was the safety level required for the

overall system. To answer this, the EN1050 Directive concerning the principles for risk assessment was utilized, integrated with the EN954, dealing with the assessment of safety-related parts of control systems.

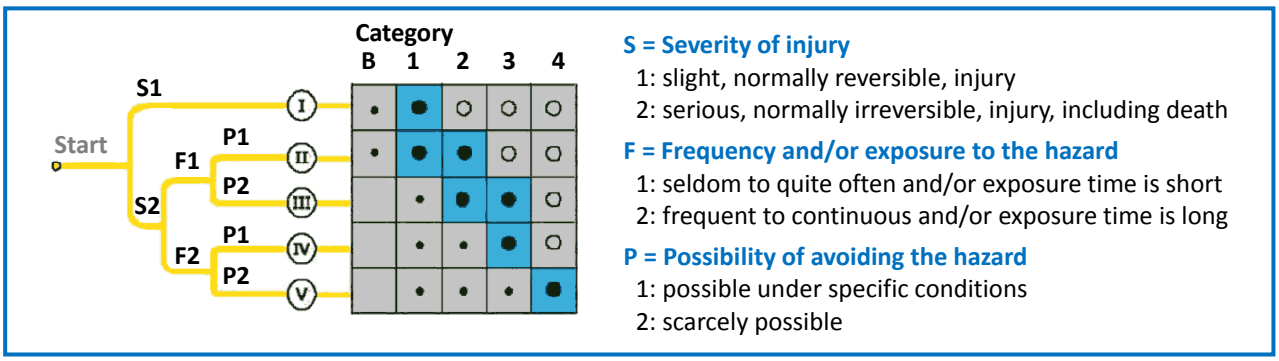


*Fig.3 - EN954-1 Safety category decision graph.*

The risk assessment with its high demanding requirements (Category 4 for the most critical functions) led to adopt, where possible, the following safety criteria:

- use of decoupled systems with suitable safety grade to monitor critical parameters (e.g. dose);
- redundancy and technological diversification of systems requiring high safety level;
- fail-safe philosophy;
- equipment verification and validation, performed by external and independent specialists.

In the SYRMA project, two main systems deal with radiation safety issues: the *"Dose Control System"* for the control of the dose released to the patient and the *"Patient Access Control System"* for the control of all the procedure of access inside the patient room. The *"Supervision and Human-Machine Interface System"*, provides the interface that permits to set the examination parameters and to carry on the mammographic scan. A further safety related system, called *"Machinery Safety System"*, has been developed to reduce crushing hazards (see Paragraph 3.2.4).

### 3.2. Systems Overview

The following is a brief analysis of the different systems involved in the clinical trial, and some of the safety related aspects.

#### 3.2.1. Bed-Film System

The *"Bed-Film System"*, controlled by a dedicated PLC, allows to scan simultaneously the patient and the film detector through the beam during mammographic exam.
The bed can be moved horizontally, vertically, and can be rotated on the horizontal plane for different mammographic projections (Fig.2a). A bed controller guarantees all the movements; it provides digital inputs by which other systems can inhibit or stop bed movement if necessary.

#### 3.2.2. Breast Compressor System

The *"Bed-Film System"* is equipped with a "*Breast Compressor System"*, controlled by a dedicated PLC, utilized to equalize tissue thickness for minimizing dose and optimizing imaging. It mainly consists of two paddles, one manual and one motorized, as shown in Fig.4.
The breast compression force must not exceed a maximum of 200 N, which could be harmful for the patient. This condition is fulfilled limiting the compressor motor current; in any case, if the applied force, measured through a Hall sensor, exceeds 200 N threshold, the manual paddle, normally blocked, is automatically released.
Taking into account that the patient support can rotate whereas the breast compressor cannot, a further interlock has been implemented, which prevents rotation during compression.

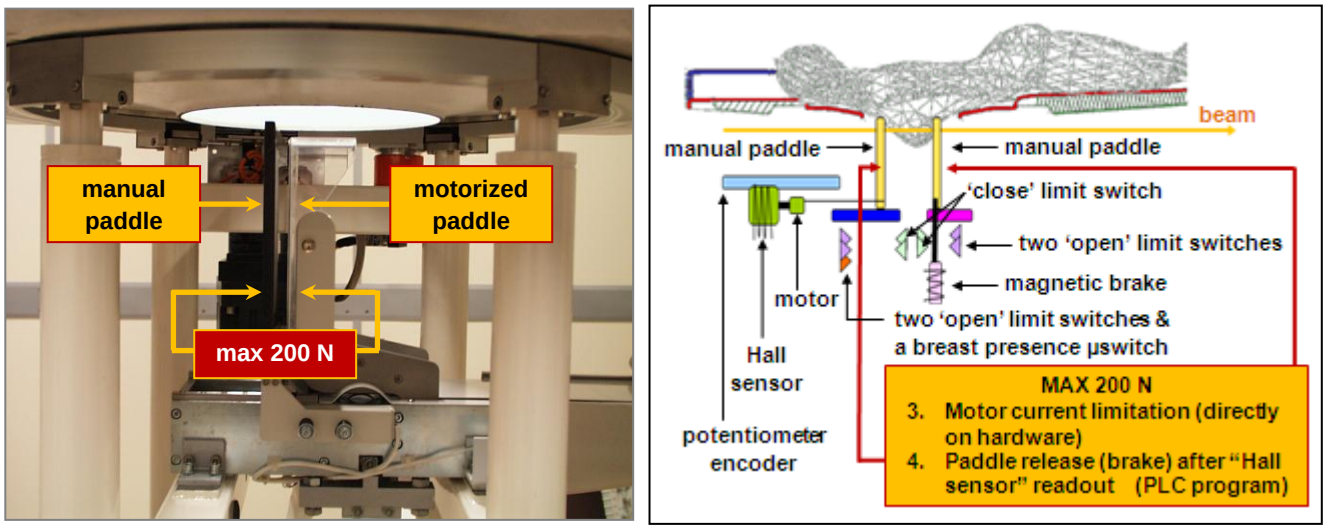


*Fig.4 - The Breast Compressor System.*

### 3.2.3. Safety Control Systems: *Patient Access Control* and *Dose Control*

The safety control systems have been realized using a Category 4 PLC. Three processors execute simultaneously the same program and then compare results, blocking the whole system if they differ. The acquired sensors and actuators are duplicated and have been chosen with different technologies to achieve high level of safety.

#### 3.2.3.1. Patient Access Control System

The "*Patient Access Control System (PACS)"* assures safe access procedure to the patient room, avoiding the presence of other persons except the patient inside the hutch during the mammographic examination and assuring that only the breast is scanned through the beam.
It acquires and/or drives acoustic and visual alarms, shutters, door switches, emergency buttons, search panel, presence detectors, etc.
Furthermore, the *Patient Access Control System* interacts with the pre-existing SYRMEP *"Beamline Access Control System (BACS)"*, which assures safety conditions for access inside all the hutches of the beamline. A clear, even if slightly complex, finite state machine diagram fully describes the *"Patient Access Control System"* (Fig.5).

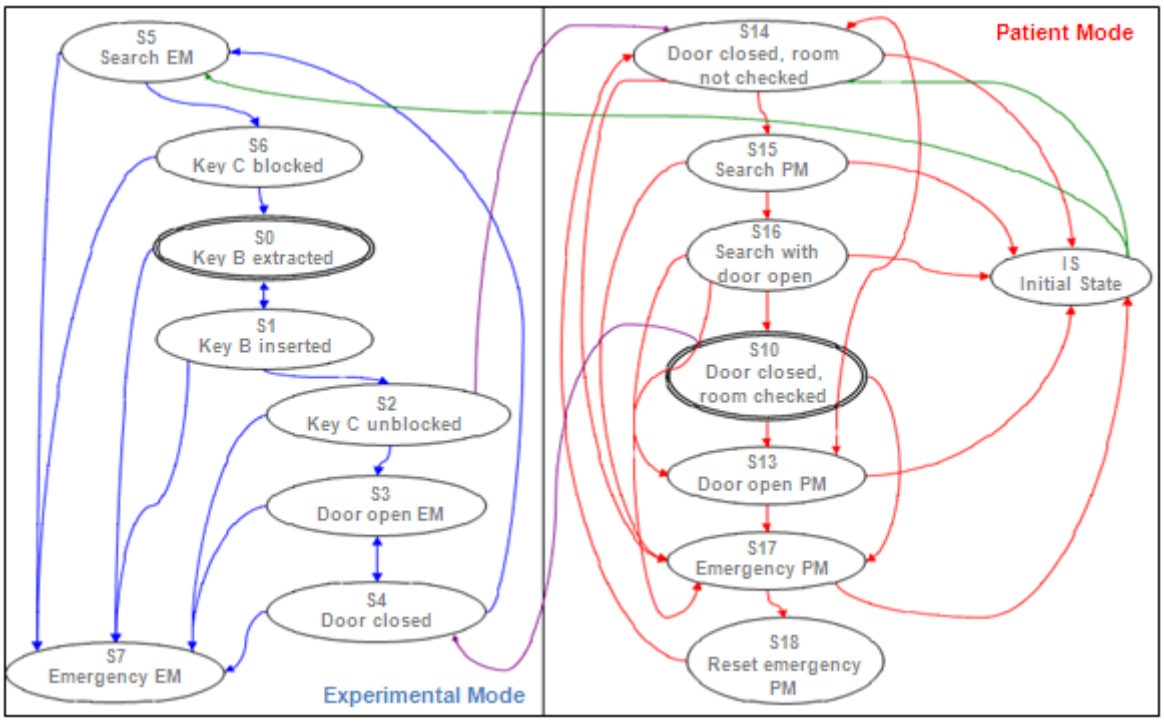


*Fig.5 - PACS finite state machine diagram [6].*

### 3.2.3.2. Dose Control System

The "*Dose Control System*" guarantees safety conditions for the patient during the mammographic exam.
The dose delivered to the patient is calculated from the dose rate measured by two calibrated [7] ionization chambers, the bed speed computed through two bed position sensors (Fig.6), and the beam dimensions.
If a pre-fixed threshold of integrated dose is exceeded (20 mGy), the *Dose Control System* forces the closure of the fast safety shutter S1 and of the imaging shutters S2 and S3. Other alarm conditions are emergency button activation, out-of-range monochromator energy, conflict between redundant sensors, out-of-range sensor values, etc.

The "*Dose Control System*" application runs continuously, but the emergency actions are carried out only in *Patient Mode*; in this way scientists can perform experiments without dose interlock in *Experimental Mode*.

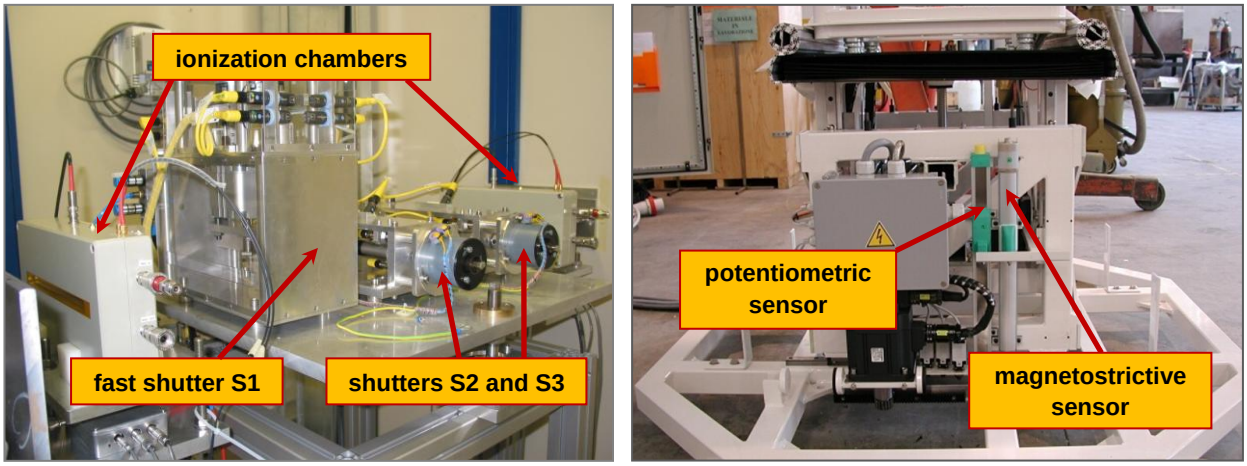


*Fig.6 - The ionization chambers with the beamline shutters (on the left) and the bed position sensors (on the right).*

### 3.2.4. Machinery Safety System

The European Standard EN349 defines the minimum gaps to avoid crushing of parts of the human body due to machinery.
Inside the patient room the crushing risk is mainly tied to the bed rotation. The identified risk areas (marked as "A", "B" and "C" zones in Fig.7) have been analyzed according to EN349 and the crushing hazard has resulted unlikely in "A" zone, and not negligible in "B" and "C" zones.
To minimize the risk, two laser scanners performing horizontal plane scans, have been placed inside the patient room, on opposite corners. They have been configured in such a way that, if they detect an obstacle inside the "dangerous area", they inhibit or stop the bed movement.

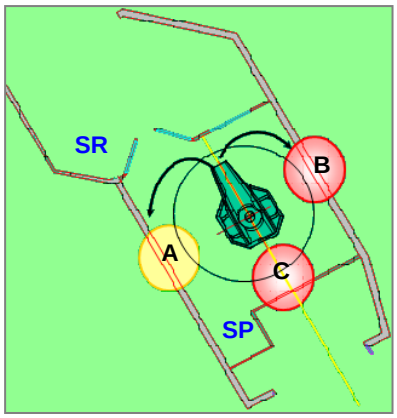


*Fig.7 - Risk of crushing against the wall.*

### 3.2.5. Supervision and Human-Machine Interface System

The *"Supervision and Human-Machine Interface" (SHMI)* represents the interface that allows the radiologist to carry out the examination.
High level of reliability has been reached choosing, as hardware, an industrial branded PC equipped with a RAID (Redundant Array of Independent Disks) system, two power supplies and optoisolated serial interfaces, as operating system Linux (Debian distribution) and "C" as programming language.
The *"Supervision and Human-Machine Interface"* permits the beamline staff to optimize the beam for the exam and the radiologist to execute the exam itself, automatically verifying the correct matching of the different parameters, managing the pre-scan phase, carrying out the scan and producing the dose report.

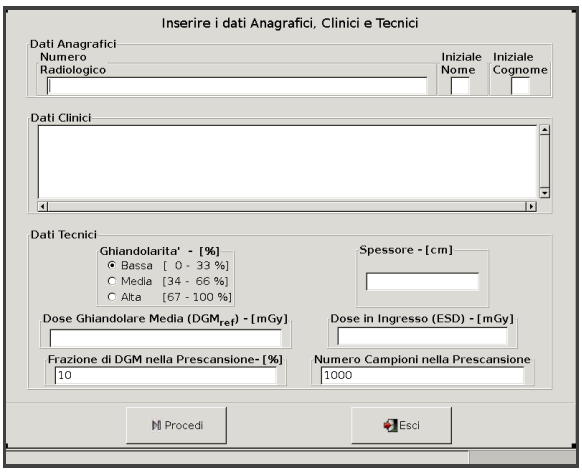


*Fig.8 - Screen shot of the form used to insert patient data in the "Supervision and Human-Machine Interface".*

## 4. Conclusions and Perspectives

The 1st phase of the SYRMA project, started on March 13th, 2006, is now next to conclusion: so far 68 patients with an age ranging from 41 to 82 years have submitted to synchrotron mammography at SYRMEP beamline applying PHase Contrast (PHC) Imaging technique. During the three years of operations, the specifically designed and implemented "*Safety, Control and Supervision Systems"* have shown high reliability and efficiency.
The next phases of the project foresee the substitution of the conventional screen-film system, used as image receptor, with digital detectors and the development of new imaging techniques.

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