

## Background / Introduction

COCIR Members are committed to promoting the Eurosafe Imaging campaign, raising awareness and promoting training, helping accelerate the use of technologies in Europe that can help meet the campaign's objectives.

The purpose of mammography is to safely detect breast cancer in its early stages, which requires careful attention to image quality in addition to minimizing patient radiation exposure. Innovative technologies in breast imaging are crucial elements in improving clinical outcome.

In mammography it is most important to consistently produce high quality images at the lowest radiation dose.

Dose optimisation is a permanent driver for COCIR manufacturers, and takes a particular importance in breast cancer screening programs, where the vast majority of attending population is "healthy".

Diagnostic reference levels are an important tool for dose optimisation, and are supported by manufacturers of breast imaging devices through many technological features that help users to collect and analyze data to determine DRLs and to minimize the dose.

For instance:

- Methods to calibrate systems to appropriate dose levels
- Systems that automatically calculate exposure mean glandular dose and populate patient records
- QA tools like repeat and reject analysis
- Dose management systems

Most of the latest technologies in 2D breast imaging are already delivering dose well below DRLs. Some of these features are already mandatory in most EU Members.

Minimisation of population dose depends upon many factors in addition to the technological developments. Regular system calibration and maintenance are key. Preventing exposure repeats, through proper radiographer training, is another.

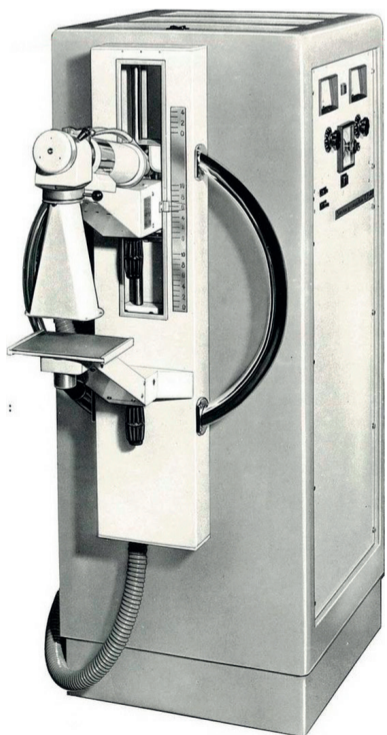
Finally, clinical verification of new technical developments gives the radiological community confidence that commercialised systems meet the required clinical performance goals.

## Description of activity and work performed

Since the introduction of mammography, many incremental technological innovations have made it possible to obtain mammograms with higher image quality using significantly lower radiation dose as compared to mammograms conducted in the 1970's and early 1980's (figure 2).

### Some significant innovations and milestones:

- **1969** Dedicated mammographic unit with molybdenum target tube and compression cone replacing conventional tungsten target x-ray tubes with direct exposure industrial type films (figure 1)
- **1972** Screen-film system introduced for mammography reduce the dose 10 to 20 times
- **1976** Rare earth screen-film system and special cassette reduce the dose by 50%
- **1976** Mammography x-ray unit for magnification with microfocus spot
- **1978** Mammography unit with grid
- **1990** Fully automatic adjustment of technique factors (anode track, filter, kV, mAs)



**Fig 1:** First mammography dedicated equipment: CGR Senographe (1967).

- **1999** Introduction of first Digital mammography system
- **2008** Breast tomosynthesis system CE mark
- **2010** Contrast-Enhanced Spectral Mammography system CE marked

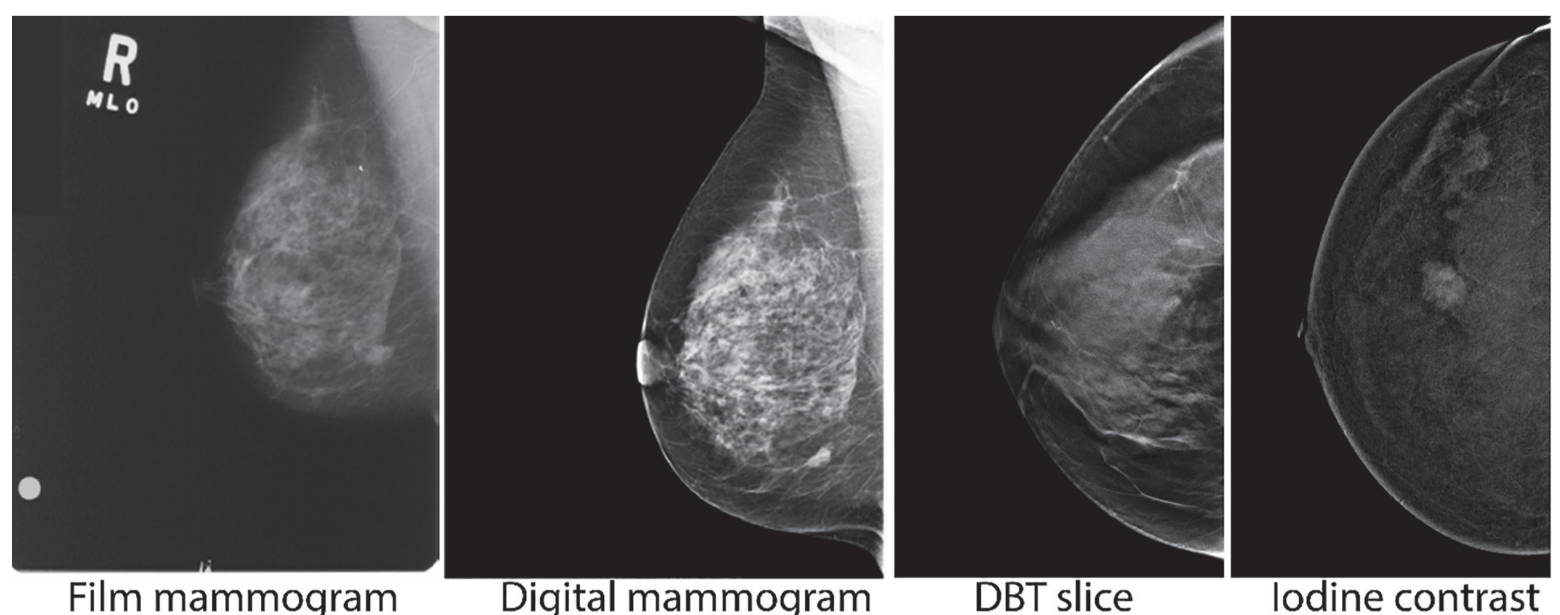
More recent developments have seen the introduction of innovative technologies in the field of dose optimisation and clinical efficacy and are available on all/most of the new equipment placed on the EU market:

- Automatic exposure controls that deliver optimal dose over a wide range of breast sizes and compositions
- Breast tomosynthesis options that improve clinical performance
- Historical Performance Metrics

The evolution of mammography systems has provided both systematic reductions in radiation dose and improvements in image quality. Figure 3 illustrates the trends in mammography dose and image quality for the period from 1974-2014 as provided by the US FDA. More recent data from 2012, also from the US FDA, lists the average digital mammography dose in the US to be 1.43 mGy, showing around a 28% reduction from the approximately 2 mGy levels in 2002.

And even more recently, clinical trial data on breast tomosynthesis indicate a significant improvement in cancer detection, using systems that perform tomosynthesis scans at similar doses to 2D mammography.

**Fig 2:** Examples of technology evolution.



Film mammogram

Digital mammogram

DBT slice

Iodine contrast

## Training

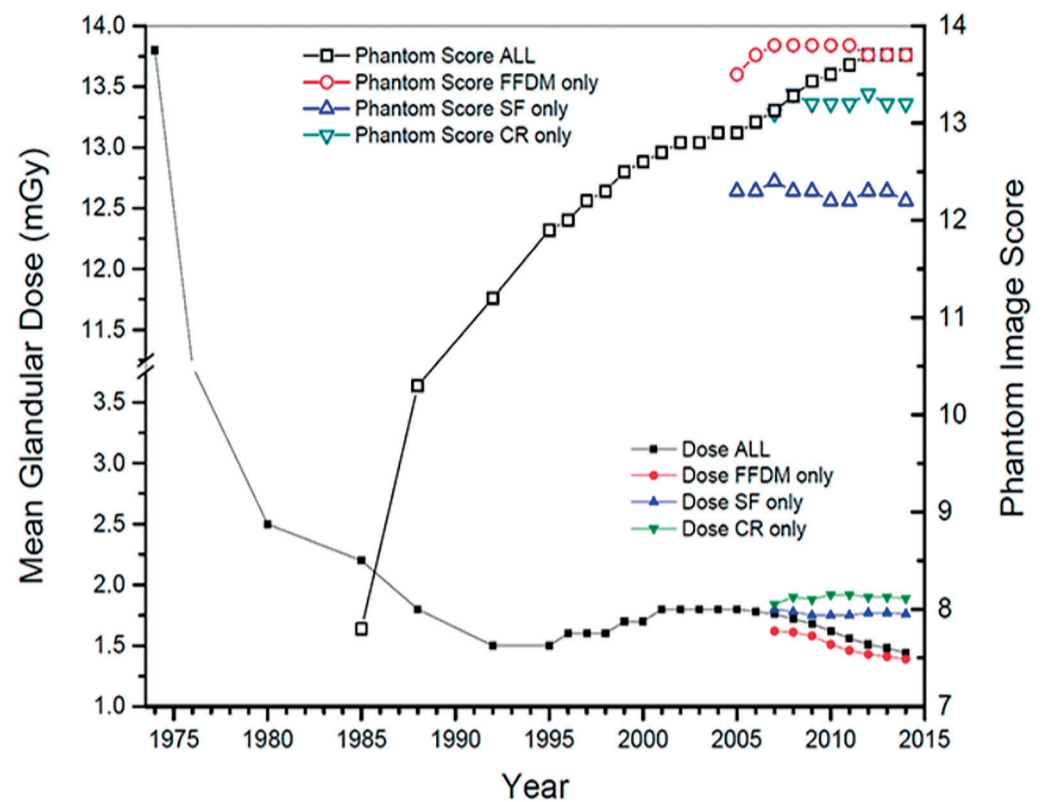
Advances in technologies have clearly transformed breast screening since its introduction; however the role of education and training is also an extremely important tool in the process of dose optimisation. While COCIR Members accept responsibility for maintaining the proper competence levels of their own staff and trainers, it is the healthcare providers' responsibility, to assess and maintain their equipment, their own staffs' competency and to liaise with the relevant manufacturers for their training requirements as well as to enable their staff to participate to training and education.

Manufacturers propose/offer specific training programs on existing and new dose reduction techniques and on the use of these product features in daily practice. The provision of specific training curricula aims to ensure that the user is well trained on dose optimisation and facilitates dose awareness in daily practice.

Manufacturer's training is designed to support customer facilities in an effort to improve operating knowledge and increase the skill level of personnel. These programs consist of a variety of delivery mechanisms such as:

- Hands-on and didactic training to reinforce skills needed to operate equipment
- Operator Manuals to demonstrate information on dose optimisation tools and dose reduction strategies
- Information on dose related displays, indices, and where dose information is located
- Onsite training, classroom instruction, remote instructor-led training and observation, online tutorial self-help, telephone support, publications, seminars, peer to peer physician training, and industry association educational material.

**Fig 3:** Radiation dose and image quality measured using the ACR Accreditation Phantom in the US.



## Conclusion and Recommendations

As part of an ongoing dedication to continuously improving patient safety and safety of health professionals, the industry is continuously working with clinicians to develop innovative technologies that optimize levels of radiation and improve image quality.

These developments often offer clinicians faster, safer and more intelligent diagnostic imaging systems which improve visual and functional information about their patients while providing support decision-making, reduced complexity and increased productivity.

Since these advances are often incremental, industry offers upgrades that help extend the life of equipment over a defined period. However, as equipment ages, increasing numbers of technical incompatibilities e.g. in equipment control and the redesign of components, can render updates uneconomical, even impossible.

The European Society of Radiology (ESR) has recognised the clinical importance of planning for timely replacement of equipment. In 2014, it published a position paper on renewal, stating that; "Equipment less than five years old is state-of-the-art technology. Properly maintained equipment between six and ten years old is suitable for practice, but

radiology departments should develop a strategy to replace them. Machines over ten years old must be replaced".

This commitment should be shared by all stakeholders; the consistent and persistent deterioration in the age profile of the equipment base (see the COCIR Report on "Age Profile and Density 2016") should not be allowed to continue. Embracing innovative financing models will make renewing the equipment base affordable.

- **Replace obsolescent equipment that cannot be upgraded**  
COCIR calls upon national and regional governments and EU policy-makers to support replacing technologically obsolescent equipment that cannot be upgraded, using cohesion policy funding to ensure comprehensive, coherent and sustained investment.
- **Adopt the latest technologies in breast imaging:**  
COCIR encourages healthcare providers to adopt the latest technologies in breast imaging, which provide the opportunity to improve quality, efficacy, patient safety and productivity. Currently, most purchase decisions are price-driven and fail to consider any 'incremental value' the technology or method provides.



**The best care means providing the patient with a justified examination with a dose as low as reasonably achievable and an image quality sufficient for the clinical goal to be reached.**

**Fig 4:** Age Profile and Density 2016.