



**American Arab University
Faculty of Graduate Studies**

**Investigation of Quality Control in Mammography
System Using Phantom in Selected West Bank Health
Directorates**

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Management**

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I

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Declaration

I certify that this thesis submitted for the degree of Master is the result of my own research, except where otherwise acknowledged, and that this thesis (or any part of the same) has not been submitted for a higher degree to any other university or institution.

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Dedication

I would like to express my deep and honest esteem to my commendable mother and father, who always support me and give me inspiration.

I would like to dedicate this thesis to my beloved husband, who did facilitate and encourage me to continue my master degree despite the difficulties we were going through.

I would like finally to dedicate my thesis to my lovely angelic kids: Kenan, Sham and Aram, my sisters, brothers, friends, and all teachers.

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Abstract

Quality control in mammography includes simple screening procedures ensuring that the mammography system should operate in accordance with established standards. In West Bank, no studies were found to investigate quality control in the mammography system. There are several types of procedures used to check quality control, such as phantom tools. The main objective of this study is to check the mammographic systems available in selected West Bank health directorates of 12 departments, and to examine the factors affecting the quality of the produced image. The researcher used ACR mammography accreditation phantom to investigate the quality control in mammography system in selected health directorates and interviewed technicians using phantom to assess the device's validity during mammography.

This study adopted convenience and, cross-sectional survey, based on data collected from the health directorates mentioned above through examining their mammographic system for a six-month period, in order to check whether its quality affects the image one. Through the study, the researcher concluded that the technicians, working on the mammographic system in these directorates, did not know what the phantom was and have only checked a mammographic system quality in the Directorate of Health in department 1. The researcher also found that there were other factors affecting image quality, such as the processing method, device efficiency, and the technique used, as for image quality across all departments, those who use a CR processing system were found to produce a good quality image. A good imaging system should be able to see three speak groups, four fibers and three masses. On the other hand, directorates using screen films did not produce good quality image and the radiologists could not see the details, so they might repeat the images. Therefore, the researcher recommends that the radiology unit must give

instructions for the technicians to calibrate the mammography devices periodically; the engineering unit in the Ministry of Health has to perform maintenance for these devices.

Keywords: Mammography, Quality Control, Phantom

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Abbreviations

SF	Screen Film
CR	Computed Radiography
DR	Digital Radiography
QC	Quality Control
ACR	American College of Radiology
CD	Contrast Detail
MQSA	Mammography Quality Standard Act
FFDM	Full Filed Digital Mammography
DBT	Digital Breast Tomosynthesis
SFM	Screen Film Mammography
DM	Digital Mammography
CIRS	Computerized Imaging Reference System
ANSE	American National Institute of Standard
ASQ	American Society for quality
SPC	Statistical Process Control
QFD	Quality Function Deployment
FMEA	Failure Mode and Effects Analysis
DOE	Design Of Experiments
ALARA	AS Low As Reasonably Achievable
HS	Human Services
ACS	American Cancer Society
QA	Quality Assurance
FDA	Food and Drug Administration
CNR	Contrast to Noise Ratio
SNR	Signal to Noise Ratio
HCS	Health care sector

Chapter One

Introduction

1.1 Overview

In this chapter, the researcher provides an overview about mammography screening in order to detect breast cancer, and discusses the problem statement, justification, and objectivity.

1.2 Background

Mammography screening has been performed for observing asymptomatic females in order to detect cancer early stages when treatment is more realistic making the survival rate remain high. Therefore, Image quality is very important in mammography, at the same time, we need low contrast detect ability to visualize masses, high spatial resolution to detect micro-calcifications, and low dose to minimize all potential risks.

(Mackenzie, Christoph, & Joann, 2015).

In mammography, in order to achieve the best image quality at the lowest dose possible to reduce risk, the implementation of an effective quality control protocol is a strict necessity. Quality control is a part of the quality assurance that compacts with the procedures used to observe and maintain technical elements of the systems affecting image quality.

(Mackenzie et al., 2013).

Not all mammography sites produce perfect images at acceptable low doses. In order to avoid such a situation, a voluntary accreditation program was established at the American College of Radiology, and developed by ACR in 1987 to be the first and largest mammography program for breast cancer. The ACR program shoulders its responsibility for focusing on peer review and constructive feedback on staff qualifications, equipment,

quality control (QC), quality assurance and image quality. (Mapr, 2018).

The success of the ACR program in improving the quality of mammography encouraged the US Congress to adopt a model for the provisions of the Mammography Quality Standards in Act of 2002 (MQSA) after the ACR Mammography Accreditation Program.(Destouet et al, 2005).

Three decades of research showed that mammography saved lives. Moreover, Hellquist et al. conducted a study including 1 million women over the past 16 years, indicating that mammography screening reduced breast cancer mortality in women by 29% between the ages of 40 and 49. This was consistent with the recorded data from the National Cancer Institute to show that since mammography screening was widespread in 1990, breast cancer in the United States declined by 37%. (Hellquist et al., 2011)

Screen film mammography is a diagnostic technique used to image breast tissue which is based on breast x-ray examination, a low-dose procedure. The goal of mammography is to detect small abnormalities in breast tissues at early stages such as calcifications, cysts, and fibro adenoma breast before they develop into breast cancer. Mammography is a very sensitive diagnostic procedure requiring very specific equipment to perform such examination; its success relies on achieving high-quality images and reproducible quantitative quality control tests.

There are several techniques to evaluate image quality, patient dose, and equipment performance provided by mammography systems; one of these techniques is performed using a phantom through which an accepted task of doing quality control testing is once a week. This phantom includes details simulating lesions (fibers or micro calcifications) and test objects which allow to perform quantitative measurements of image quality. This weekly task keeps the same image quality (film optical density and contrast).In order to evaluate image quality, it is important to see at minimum 4 fibrous, 3 micro calcifications

and 3 mass that must be taken into consideration to pass the test. The mammographic phantom is equivalent to a 4.2cm compressed breast thickness consisting of 50% glandular and 50% adipose tissue. When performing the test, it is important to use every time the same cassette, the same view box, the same receptor and the same technical factors.

There are several types of phantom studied by researchers to evaluate image quality. Firstly, a development of an analytical phantom for tom synthesis (Reiser, Sidky, & Nishikawa, 2006). Secondly, some researchers used a voxelized phantom to estimate mean glandular dose for breast dosimetry (Hunt et al., 2005). Finally, it was founded that the ACR phantom can be routinely used to evaluate image quality for all types of mammographic systems (Wioletta et al., 2016).

1.3 Problem Statement

Assessing images of known reference phantoms is one accepted method of applying QC testing. Quantitative QC techniques are useful for a long-term follow-up of mammography quality. Some health sectors do not perform or check quality control periodically for their mammographic devices. This affects the image quality and in turn leads to misdiagnosis (Lawrence & Bassett, 1997).

Therefore, there have to be tools used to evaluate equipment performance and image quality.

There are no previous reports about quality control of the mammography systems in the West Bank health directorates.

1.4 Significance of Study

The benefits of controlling the quality of mammographic devices affect several issues, including (x-ray dose). First, When the quality control is done on a mammography system,

the images are of high quality and do not need repetition, so the patient is not exposed to more radiation. The second is diagnoses, when the mammography system works properly, the image is clear and the radiologist can diagnose correctly. The third is the cost, when the mammography system does not function well, the technologist needs to do image several for diagnosis. In this case, more films are need and more SFR. The results of this study have been provided to the quality department and engineering department in the Ministry of Health so that they can check the quality of the mammography devices in the West Bank.

1.5 Justification of Study

Breast cancer is the most common type among women in both developing and developed world countries. In 2016, 388 cases of breast cancer were recorded, accounting for 15.3% of total cancer recorded in the West Bank.(MOH, 2016).

Until the end of 2017,503 new cases of breast cancer were documented in the occupied West Bank (MOH, 2018). At the beginning of 2018, a total of 3,854 females underwent early examination of breast cancer in MOH centers in West Bank, where 210 cases of suspected breast cancer were advised to conduct follow-ups. For the total number of female cancer cases, breast cancer ranked first, with 28.9% of all female cases (MOH, 2018). According to the Palestinian Ministry of Health, breast cancer is the most prominent cause of death among females,

Table 1.1: Number of diagnostic cases of breast cancer in selected West Bank health directorates (Documented diagnostic cases recorded in each directorate between years 2017 and 2018)

Directorate	Number of cases per year	Diagnostic (2018) Cases	Diagnostic (2018) Percentage Cases	Number of cases per year	Diagnostic (2017) Cases	Diagnostic (2017) Percentage cases
Department 1	450	15	3.3%	500	12	2.4%
Department 2	1000	20	2%	1300	19	1.5%
Department 5	1834	26	1.42%	1425	16	1.12%
Department 6	500	4	0.8%	450	4	0.89%
Department 7	2000	20	1%	1764	16	0.91%
Department 8	130	6	4.6%	280	5	1.8%

Mammography is performed regularly on healthy individuals (screening mammography) or on patients with breast problems, such as masses (diagnostic mammography).

As a follow-up to the early detection of breast cancer in the world, mammography has become a common practice. The mammography system must be screened properly since the poor image quality of this mammogram does affect patients having breast problems. (Lawrence& Bassett, 1997).

Quality assurance in mammography is defined as all actions taken to ensure the mammography quality; quality control is defined more narrowly focusing on the technical components of the examination (Lawrence& Bassett, 1997).

The importance of quality assurance and quality control in the United States have notably increased expecting 20 million mammograms to be performed annually by more than 11,000 units; mammography screening for early detection of breast cancer is spreading rapidly. (Lawrence& Bassett, 1997).

1.6 Research Objectives

1.1.6 Main Objective

To check the quality of mammography systems performance of 12 West Bank health directorates by using phantom and to examine the factors which affect image quality.

2.1.6 Secondary Objectives

- To assess the image produced by phantom in all mammography system in all directorates.
According to these directorates (if the image shows at least four fibers, three masses, and three micro calcifications, that means this device produced good quality image).
- To assess the technicians' work quality and control whether they use phantom for the mammography system or not.
- To assess the relation between image quality and processing method (CR or SF).
- To assess the relation between image quality and a second hand device .
- To assess the relation between image quality and device efficiency .
- To assess the relation between image quality and the applied technique(AEC or Manual).
- To assess the relation between image quality and exposures.

Chapter Two

Literature Review

2.1 Introduction

This chapter summarizes the definitions of quality, importance of quality, objective of quality, and some of the articles that have been published regarding to the quality control in medical imaging.

2.2 Quality Historical Review

Quality has become a vital element of any organization seeking development. The quality movement goes back to Europe in the middle ages, where craftsmen established trade unions in the so-called societies of the late 13th century. Manufacturing in the industrialized world was concerned with following this skill model until the 19th century. The industrial system, with its compliance with product inspection, began in the mid of 1750s in Britain and developed gradually during the industrial revolution in the early 19th century. At the beginning of the 20th century, companies began their operations in quality practices. After the Second World War, total quality in the United States began as a reaction to the quality revolution in Japan. The Japanese received the participation of Americans Joseph M. Juran and W. Edwards Deming focusing on improving all organizational processes through the people who used them rather than focusing on inspection. In the 1970s, industrial sectors in the United States, such as cars and electronics, suffered from Japan's high-quality fierce competition, so the United States' response, at that time, was known as total quality management. After that, the quality systems of Deming, Juran, and Japanese practitioners developed for early quality, which

shifted after manufacturing to service, health care, education and government sectors. (ASQ, 2018).

2.3 The Historical Stage of Quality Development

Some scientists have pointed out that the quality extends to seven thousand years, indicating the interest of ancient Egyptians with specific standards for the work of inscriptions, painting, sculpture and accuracy in the stones built by the pyramids.(Jams and William, 2002).

1. The Middle Ages or the Pre-Industrial Revolution Stage

The period in which manual crafts and manufacturing were spread through simple manufacturing workshops, where quality control was performed by the workshop owner or his staff. The criteria used to measure quality were simple and often determined by the client as desired.(Jams and William, 2002).

2. The Post-Industrial Revolution Stage

At this stage factories began to replace manual manufacturing workshops, and the factories had a larger number of workers. This phase witnessed a significant increase in the production volume and the level of relative quality due to the use of machinery. At this stage, the role of supervisors appeared to check the quality of the work process in accordance with the responsibilities and duties of the job.(Jams and William, 2002).

3. Scientific Management Stage

At this stage, the process of quality inspection began, this task was assigned to inspectors specializing in quality control work. Quality assurance focused on matching the criteria set

in advance with the quality of the product completed to ensure that the level of quality required is maintained consistently. The purpose of the verification process is to detect deviations or errors and to hold accountable those who are responsible. (Jams and William, 2002).

4. Statistical Control Stage

This phase was characterized by adoption of a method due to a large volume of production, which was accepted or rejected according to the results of sampling.

Bell American Cable was a leader in quality assurance in modern history and established a testing department at Western Electric in the early 1920s. This division had a significant impact on the quality of Bell's products, which became known as Bell Labs. The duties of these Labs were to develop new theories and methods of examination for the quality development and maintenance. This group of Labs was included in (Walter Schwart), (Harold Dodge), (George Edwards) who appeared in the field of quality development (Jams and William, 2002).

During the Second World War, the US military used the statistical methods developed by this group, then redeveloped them to check the quality of the various supplies. Most of these methods are still used today by the US military. (Jams and William, 2002).

5. Quality Assurance Stage

The concept of quality assurance began in the late 1950s and was based on the philosophy of achieving high quality and error-free production; it requires a comprehensive control of all processes from product design, to product delivery, to the end consumer, and access to after-sales service to the end consumer. This philosophy demands the cooperation of all departments involved in the implementation of different stages of production.

(Lori, Silverman, & Annabeth, 1999).

To achieve the error-free production logo, quality assurance applies three kinds of control: Preventive control, local control, and dimensionality control.

6. Strategic Quality Management

The early 1970s witnessed the superiority of Japanese companies relying on their high quality products at reasonable prices to invade American and European markets, and to grab large shares in these markets at the expense of the Western companies. (Lori et al., 1999).

Interestingly, the Japanese learned the principles of quality after Second World War by American pioneers, such as Deming and Goran. They have developed steadily over the post-war years through spreading the culture of development and continuous improvement. Western companies began to feel of the Japanese fierce competition and its menace which threatened their existence. Consequently, they began to restructure their accounts to organize their work according to the quality requirements of the coming phase.

IBM is a company among companies that have succeeded in this regard through the following entries: -

- 1- To meet the customer's demands and expectations.
- 2 - Quality is everyone's responsibility in the company no matter whether he is a manager or an employee.
- 3 - Quality is strongly required in everything inside the company.

2.4 Total Quality Management (TQM) Phase

This concept is an extension of the strategic management concept, which was developed in the late 1980s up to date including more comprehensive aspects than those of the 1980s. (Martinez et al., 1998).

The Federal Quality Institute has defined it as “a comprehensive application approach designed to meet customers’ demands and expectations as quantitative methods used to improve processes.” (Aldaradka and Shibli, 2002).

Another definition, "a long-term effort aimed at guiding all the institution’s activities towards the concept of quality management that is achieved when the institution can offer goods or services that meet or potential consumer’s expectations”. (Aldaradka and Shibli, 2002).

2.4.1 Objectives of Total Quality Management: -

1. Understand the needs and desires of the client to meet these demands.
2. Provide products or services according to client's requirements in terms of quality, cost and time.
3. Adapt to technical, economic and social changes in order to achieve the required quality.
4. Implement dictating work on the client’s potential needs and desires.
5. Attract more new customers and keep present customers.
6. Promote the performance and service through improving and developing the products or services, achieving the overall production high efficiency, reducing the fixed and current costs not at the expense of quality, but applying what so called expenditure rationalization. (Aldaradka and Shibli, 2002)

2.5 Concept of Quality

In 1951, quality began in Japan by the father of quality management - Edward Deming who was responsible for inspiring and guiding the great rise of Japanese industry after the Second World War, Deming followed a similar mission in the United States. However, the Americans took a longer time to learn from his teachings (Jams and William, 2002). By Edward Deming defined quality as: "Quality is a virtual term that will change in meaning depending on the customer's needs". He emphasizes that the quality of any product or service can only be defined by the customer. Definitions take out from his writings reflect this emphasis on quantitative methods, the application of which results in products having (1) lower cost, (2) probable degree of uniformity resulting from reduced variability, and (3) appropriate for the market. This definition is important to the customer who uses the product. (Suarez, 1997).

Quality is usually defined differently by people. Such as quality on the service may be based on the customer's satisfaction who receives the service, but in a manufactured product, the customer as a consumer knows the quality of expediency, appearance, performance, and function. The proper meaning of quality is "the degree of excellence". The ultimate purpose is to ensure that the customer is satisfied immediately with the product or service leading him to ask for the same product or service fairly frequently; this does provide the basis for progressive improvement of the products or services (Jams and William, 2002). Brock explains his concept of quality "it is a redefinition of the culture of the organization that everyone is equally committed from the manager to the worker to produce and deliver a good or service to satisfy customers, not to rely on the current level of quality and search for innovation"(Harhasha, 2000).

Stanley defined it as "a dynamic state linked to products, services, personnel and processes." The structure is consistent with expectations (David and Davis, 1994). Conel

was described it as "competition, performance and product excellence" (Aldaradka and Shibli, 2002).Sect also defined it as "creating a culture of excellence in performance where managers and employees work constantly and diligently to achieve initially the expectations of the consumer and performance correctly in good quality and efficiency in the shortest possible time." (Zine El Din, 1996) "Quality means ensuring that customer needs are recognized before designing products or services," said Holub."The American National Standard Institute and the American Society for Quality have defined quality as "a range of product and service characteristics and the ability to meet the demands of consumers."

Although there are several definitions of quality, it does not mean that there is a fundamental difference among them; on the contrary, there is a similarity in their main elements in general as follows:

1. They are customer-oriented and meet their expectations.
2. Participation and task force for all staff in organizations.
3. Focus on processes through constantly improvement, training and education.

2.6 Importance of Quality

Good quality leads to the success of different companies through applying several methods such as quality "ensuring high quality products and services". Quality leads to customer loyalty and his satisfaction of the product or service which stimulates him to repeat the purchase process and even recommend it. Moreover, quality leads to a far-reaching reputation for the brand, so retailers want to store the product. Companies must work hard to maintain their reputation and improve their quality, which can easily be damaged by news of quality failures (Arias, 2016). Moreover, quality ensures increasing profits and

enterprise productivity, and attracts and keeps good staff. Quality is not restricted only to product quality, but it also covers all company functions.

2.7 Objectives of Quality

There are many typical quality objectives that may be identified by companies, such as meeting the requirements of increasing customer satisfaction, reducing costs of (manufacturing exceed inventory, and reprocessing), promoting constant improvement, training development staff, minimizing the amount of scrap, and keeping customers and prevention as a measure process to identify the potential problem efficiently (Gowl, 2015).

2.8 Quality Management System

A quality management system is important for the medical imaging department, providing high quality clinical images while maintaining patient and staff radiation doses low (As Low As Reasonable Achievable- ALARA Principle). Quality management involves all the technical characteristics of medical imaging such as equipment selection, equipment procurement, installation control, acceptance testing, commissioning, quality control, maintenance and continuous support of equipment, and disposal at the expiry of the equipment validity. Quality management provides photo imaging systems in the imaging department because this is a must in integral part of today's imaging department (Randolph, Resnik, & Preece, 2018).

A research was published by Korir and other researchers in 2013, aiming at evaluating the quality management systems in medical x-ray facilities in Kenya. A repeat X-ray scan was conducted in 140 hospitals across the country, quality management screening, quality control, and exposure tests for patient radiation were evaluated in 54 X-ray medical facilities. The researchers concluded that compliance with quality assurance in the Kenyan

medical imaging facilities was good, but with no possibility for improvement. (Korir et al, 2013)

Quality management system according to ISO 9001: 2015: “it aims to enhance customer’s satisfaction through system effective application including processes for system improvement, conformity assurance ,and applicable statutory and regulatory requirements". The quality management system focuses on process, customer and progressive improvement. (Gurau, 2018)

2.9 Quality Management Principles

According to the ISO 9001:2015, there are seven quality management principles used by top managers and any organization take them into account to maximize its performance efficiency. (Zgodavova and Colesca, 2014). These principles are as follows:

1- Focus on Customers

The patient represents a typical Health Care Sector customer whose focus is essential since the organization is customer-driven, so the organization considers all the features and characteristics of products and services bringing utility to customers and fulfilling customer’s satisfaction. The customer’s focus exceeds the organization’s expectations. In this case, technicians check the device a week to produce a high-quality image, so that the specialized radiologist sees the image clearly and diagnoses a patient’s case well.

2- Leadership

Leaders or top managers in any organization must create and maintain an internal proper environment in which employees participate in achieving the ultimate organization goals.

3- Involvement of People

People must be involved in companies since they are the essence of maximizing the organization the benefit and profits. In HCS, a radiologist must understand the patient's case and what kind of problems he faces, so that he can help him.

4- Process Approach

When related activities and resources are managed as a process, the desired result is achieved more efficiently. In HCS and the mammography system, the above process involves all the stage of the patient's image until it is produced. Therefore, we focus on factors such as methods and materials contributing to improved process performance. A technician should maintain the device from time to time to produce good quality images, and monitor the process performance through a key set of indicators (if the image produced by phantom can see at least 4 fibers, 3 blocks, and 3 partial calcification, the image has good quality).

5- Continuous Improvement

The constant objective of the organization must be continuous improvement. In HCS, when seeking to apply this objective, we must know all the weaknesses points of a department and should plan to provide material for an effective improvement process.

6- Realistic Approach of Decision-Making

Actual decisions are based on data analysis. In HCS, technicians must be trained in order to correct performance measurements. The radiologist must collect data from the operations, so that he can make decisions to properly diagnose the patient.

7- Mutually Beneficial Supplier Relationships

The organization, its interconnected suppliers, and the mutually beneficial relationship enhance the ability to create value. In this case, the materials for HCS which are provided by the Ministry of Health must be of good quality films.

2.10 Manufacturing Quality

Globalization has made industrial organizations move towards three key areas of competitiveness: quality, cost and responsiveness. Quality is a global issue. (Judi et al., 2013).

Manufacturing quality complies with specifications. Quality conformance to specifications provides the basis for manipulating processes of producing high quality products. Manufacturing quality becomes an absolute requirement while customer's expectations increase as time passes. However, in terms of products, they are distributed, manufactured and sold (Bradbury, Joel. 2016. Quality Control in Manufacturing. Retrieved 15/4/2018 from: <https://www.graphicproducts.com/articles/quality-control-i...>). Quality systems are sometimes applied in manufacturing. These systems focus on technical issues such as inspection, equipment reliability, control process, and insufficiency measurement.

The move to a client-based organization has led to fundamental changes in manufacturing practices, mainly in areas such as human resources management, product design and supplier relationships. For instance, human resources practices have focused on enabling staff to collect and analyze data, make crucial decisions, and take responsibility for ongoing improvements through shifting quality responsibility from the quality control unit to factory floor.

Manufactured products have many dimensions of quality including the following: performance, conformity, features, reliability, perceived quality, durability, and service

capacity(David and Garvin, 1984).Most of these dimensions revolve around product design, for example, the design of a Lexus automobile, Toyota bought several rival cars, including Mercedes and BMW, and put them through rigorous test tracks before they were offered; the responsible engineer decided that products could be compatible with Mercedes performance and reliability with distinctive features. The ultimate design of products was better than other luxury cars that had a more fuel-efficient engine, lighter weight and less noise. The engine was designed more strongly than German models with some desirable specification favored by the Americans.

The health care sector focuses on the public health. The radiologists urge patients to track their medical data, look for preventive care, and stay on top of chronic cases. They measure the motivation of patients in order to manage their health and adopt a wide range of strategies helping them do better, a concept known as patient participation. For example, the federal government promotes new initiatives to give millions of Americans accesses to their online medical records, so patients can use them to improve their health management.

The biggest problem in 2016 for health care providers around the world was cost containment. Technology-assisted care can help service providers achieve value-based health care goals as industry moves from volume criterion to value one, but the key of health effectiveness is determined who will be motivated and why.

Donald Trump issues healthcare reform plan: He first debated how he would reform the US health care system after pledging repeatedly to "eliminate and replace Obama care with something much better." Trump published a seven-point health care reform plan to abolish Obama one, breaking state barriers that prevent the sale of health insurance across state lines and make payment of health insurance premiums to individuals fully tax-free. The reforms which Trump calls "just a place to start", aiming to expand access to health care, make health care more affordable and improve quality of care, according to the plan

published on Trump's website. (The New York Times. 2019. Trump Is Being Vague about What He Wants to Replace Obama care. Retrieved 27/4/2019 from: <https://www.nytimes.com/.../trump-replacing-obamacare-i...>)

2.11 Manufacturing Quality Control

The main objective of quality control is to identify products or services that do not meet the company's quality standards. All production facilities have quality control processes to ensure compliance with all standards, including relevance, shape and function before shipping the product to the end consumer.

Manufacturers are required to ensure that their operations are constantly monitored and the product quality is improved so that they can provide customers with good products. The manufacturing organization applies many quality control techniques to improve the quality of the process by reducing its variation. There are some techniques to control product or process quality. They contain statistical process control tools (SPC), acceptance sampling, quality function deployment QFD, failure mode and effects analysis (FMEA), six sigma and design of experiments (DoE). Quality control in manufacturing is based on conformance to specification.

A research was conducted in regarding quality control implementation in manufacturing companies in Malaysia. The aim of the research was to explore the implementation of quality control in Malaysian Organizations. The study was conducted by four companies. A selection was made with the quality manager of each company in order to conduct an interview which enabled the scholars to get as much information about quality control implementation in the company. A list of questions were arranged in advance to the company visit as a guidance for the researcher to get the needed information. The research found that the motivating factors for these companies to apply quality control came

externally from customer or internally from the management and parent cooperation. The companies widely used SPC and acceptance sampling rather than six sigma, DOE, and Taguchi methods due to lack of knowledge of these techniques. The selection of quality control methods in these corporations was influenced by the following factors: ease of the method usage, ability to measure product specification, and ability to improve critical quality and productivity problem(Judi et al.,2011).



Figure 1.1 Benefits of Quality Control in Manufacturing

(<https://www.graphicproducts.com/articles/quality-control-in-manufacturing/>)

2.12 Service Quality

In the 1980s, a new trend towards quality of service began. Companies realized that product quality was not a single key to competitive advantage and had to be coupled with quality of service when customers became more demanding (Gupta, Daniel, & Herath, 2005). Service is a process involving a range of intangible activities occurring naturally in interactions among employees, customers, physical resources, goods and / or service agent systems that would be explanations of customer problems. The service is of high quality if the requirements and demands can satisfy the customer. In addition, Olshavsky defined service quality' as a form of general evaluation of the product or services, similar in many ways to attitude'. (Olshavsky, 1985). While Lee defines service quality as "Ability to meet or exceed customer expectations" (Gupta et al., 2005).

The client compares the expected outcome with the expected service and determines its satisfaction with the quality of the service. If the observed service is equal to or higher than its expectations, the customer will be satisfied; this means there is a high-quality service. If the observed result is lower than its expectations, there is no service quality and the client is unresponsive (Sharabi, 2010).

In 1992, according to Tenner and DeToro, there are five determinants of service quality that forming acronym "RATER" (Tenner & DeToro, 1992) as follows:

1. **Reliability**: "Ability to perform the promised service dependably and accurately".
2. **Assurance**: "Knowledge and courtesy of employees and their ability to inspire trust and confidence."
3. **Tangible**: Appearance of physical facilities, equipment and communication material
4. **Empathy**: "Caring and individualized attention the firm provides its customers".
5. **Responsiveness**: "Willingness to help customers and provide swift service".

2.12.1 Health Care Service Quality

The quality of care means daily healthcare actions performed in the medical laboratory, nursing fields etc. to benefit our patients without causing harm to them. It should pay attention to the needs of patients and clients. This requires quality of health care demands. They have to use ways according to set standards as laid down by clinical guidelines and protocols, which have been tested to be safe, inexpensive and can reduce death possibilities. With the health care service, the radiologists see several patients on time, make the right diagnosis and give the right treatment. This is due to the saying that ,we do the right things at the right time.(Aaron & Kumi, 2004).

2.12.1.1 Concept of Quality in Health Sector

Schuster et al. (1998), p. 518), good healthcare quality means

“providing patients with appropriate services in a technically competent manner, with good communication, shared decision making and cultural sensitivity

In the context of health care where the goal of any health system is to improve health, the definition of quality somehow is complicated, especially when it comes to physical or physiological aspects, while it is less difficult if the health level is a general situation., Schuster and other researchers define good health care quality as "providing patients with appropriate services in a technically qualified manner, with good communication, joint decision-making and cultural sensitivity" (Schuster, Glynn, & Brook, 1998). Lohr's definition of quality health care is "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." (Lohr, 1991).In 2003,Leebov et al believed “good health care is a right and moral thing. The argument about the quality of health care means "doing the right things correctly, making continuous improvements, getting the best

clinical results possible, satisfying all clients, retaining talented employees, and maintaining sound financial performance.” (Leebov et al. 2003).

"The concept of quality is particularly social in the health field". Donabedian believed, "It represents our understanding and assessment of health, our expectations of the nature, type of relationship between the consumer and the provider, and our views on the legitimacy of health care laws and regulations. He explains four entries for quality assessment: Structure, installation, operations and outputs. (Donabedian,1996).

The **installation or construction** refers to the relatively fixed characteristics of the health service provider, its equipment and settings, its sources and the space in which it operates organizationally and physically. The **processes** that constitute the primary objective are the first basis for the quality assessment process, taking into account that the evaluation is based on a relationship between the processes and their impact on the health and happiness of individuals within the community. **Outputs** refer to the change in the health of the service consumer at present and in the future, which can be attributed to this service (Donabedian, 1996).The service varies from one person to another and the information varies according to each case, which makes it difficult to assess the quality of service by the consumer either before or after receiving it.

A research was published in 2003 by Beyer et al. The aim of study was to review and evaluate the quality of health services in 26 European countries. This three-phase study concluded that there has been a significant improvement in the activities of the quality workshops in the last ten years in the Netherlands, Britain, Denmark, Belgium, Norway, Germany, Switzerland and Austria. While the other countries in the study were not effective. The study recommended that further research should be undertaken to clarify the impact of quality. (Beyer et al., 2003)

Ngoc &Yushi published a research in 2015 about measure service quality in order to investigate relationships among service quality, customer satisfaction, and repurchase intention in the hospitality industry in Vietnam. They concluded that both service quality and customer satisfaction have a direct effect on repurchase intention. Specially, the indirect impact of service quality on repurchase intention through customer satisfaction was greater than its direct impact on repurchase intention. Medical imaging is an important service and significant diagnostic tools of medical science in any health organization. Systemized quality control of the medical imaging is a must in developed countries. (Ngoc &Yushi, 2015)

Chapter Three

Mammography Quality Control

3.1 Introduction

This chapter summarizes a general overview of Breast Cancer, definition of mammography and what is common procedures used in mammography, overview about mammography quality control and some of the articles that have been published regarding to investigate of quality control in mammography system in medical imaging.

3.2 Background

Breast cancer is the most common type of cancer in women worldwide in both developed and developing countries. The first common cancer overall worldwide and remains a major public health problem among women with more than 1.5 million new cases diagnosed each year. (Sheng et al., 2017). With very limited health system capacity in resource-constrained settings, the majority of women with breast cancer are diagnosed in late stages and the overall five years being rate is very low, with a range of 10–40%.(Ferlay et al., 2010)

On the other hand, in settings where early detection and basic treatment are available for breast cancer, the five-year survival rate for early localized breast cancer exceeds 80%. WHO records 1.6 million new cases very year worldwide in breast cancer among women. These ratios vary from country to another. In West Bank, the rate of breast cancer is about 27cases a year for every 100,000 females (WHO. 2017. Breast cancer: prevention and control. Retrieved 24/11/2018 from: <https://www.who.int/topics/cancer/breastcancer/ar/>).

Breast cancer is detected by mammography system. The mammogram should produce a high-quality image so that the radiologist can identify the details in the image. The quality

of the mammography device must be checked to ensure that it works in accordance with the required standards. A routine quality control program is essential to detect deprivation of system performance overtime; it becomes very important to maintain a high quality in mammography, especially when a device is used for more patients screening. Therefore, optimization of image quality and minimization of radiation dose are essential for a achieving the goals of mammography.

3.3 Mammography

Mammography is a specialized medical imaging and an efficacious examination using low-dose of exposure (usually around 0.7 mSv) protocols in accordance with the “As Low as Reasonably Achievable (ALARA)” principle to check details in breast and to look for changes that are abnormal. In addition, human breast screening is used as a tool for diagnosis. The goal of breast imaging is revealing breast cancer, by detecting characteristic blocks or small calcification. Breast mammography is one of the reasons reducing breast cancer mortality. Mammography exam is a statistically proven and effective imaging method of reducing mortality from breast cancer; Mammography exam is recommended screening mammography which is annually conducted for women who at tain age 40 (WHO. 2017. Breast cancer: prevention and control. Retrieved 24/11/2018 from: <https://www.who.int/topics/cancer/breastcancer/ar/>).According to WHO, mammography screening programs can reduce breast cancer mortality by about 20%.In addition, mammography screening can lead to false positive or negative results in many screening tests. These have been estimated to be about 20%. Therefore, WHO recommends the following mammography screening guidelines:

- Mammography screening programs are recommended once every two years for women aged 50-69 years, and once a year for women aged 40-49 are proposed only if it is showed in the monitoring and evaluation; this situation is in good-resourced settings
- In limited resource settings with weak health systems, early diagnosis of symptomatic women with prompt diagnosis and treatment should be the priority, which is clinical breast examination.

In many countries, regular mammography for older women is recommended as a means of screening for early diagnosis of breast cancer. US Preventive Services Task Force recommends examining the breast mammography, as a part of the follow-up with a radiologist, every other year for women aged 50-74 years. (Gotzsche and Nielsen, 2006).

3.3.1 Common Procedure Used in Mammography

Mammogram is used as a screening instrument to detect and diagnose breast disease in symptomatic women (feeling of symptoms) such as pain, lump, skin dimpling, and nipple discharge. They can also be used to identify early breast cancer in asymptomatic women (feeling of no symptoms).

3.3.1.1 Screening Mammography

It is a routine screening procedure to detect unsuspected breast cancer in asymptomatic women. It shows changes in the breast up to two years before a patient or physician can feel them. It can lead to find abnormalities or lumps of breast tissues that are too small to be felt. In this case, the physician never needs to be existed in clinic, for example, to monitor the examination when the patient is imaged. Women should perform these examinations every year at age 40-49 years according to recommended guidelines from the

U.S. Department of Health and the American College of Radiology (ACR) and Human Services.(Radiology information Org.2017. Screening Mammography. Retrieved 7/3/2018 from: <https://www.radiologyinfo.org/>).

3.3.1.2 Diagnostic Mammography

It is a special breast X-ray image providing more images than normal mammogram, a radiation scan to assess patients with breast disease symptoms or previous imaging results that require specific follow-up. It can be used to examine the changes detected during the operation of the normal breast imaging more accurately. It is also used for women who have breast implant, women who already have breast cancer, and women who have signs of breast cancer. Diagnostic mammography requires direct observation. (Medical Device Experts. 2017. Analog Mammography Unit. Retrieved 5/1/2108 from www.medicalexpo.com).

3.3 Mammography Exam Protocol

The best time to do the mammogram is one week after menses period . Then, any previous surgery, a use of hormones, and family or personal history of breast cancer should be filled out carefully in identifications. Describe any symptoms or breast problems to the technician performing the test. According to the American Cancer Society (ACS) and other specialized organizations, a female patient should tell her radiologist about any needed details of her condition. Also, ACS recommended that women should not wear a deodorant, talcum powder under their arms or on breast on the exam day; this may appear on the mammogram as a notable patch since this leads to repeat the mammogram image and expose a patient to x-rays more than once.(Radiology information Org.2017. Screening Mammography. Retrieved 21/3/2018 from: <https://www.radiologyinfo.org/>).

3.4 Quality Control

Quality control is an aspect of quality assurance. Quality control means a set of procedures designed for the manufactured product or performed service that meets the specifications or customer's requirements in order to achieve the desired quality (Gotzsche and Nielsen, 2006). Another definition is "the inspection of products to ensure that they meet the required quality standards"(Judiet al., 2011). There are many tools used to control quality, most of these are statistical techniques. Monitoring statistical process is a statistical method to support workers, supervisors and managers to manage quality and eliminate various causes of process deviation.(Oakland, 2008). The key role of controlling statistical processes is to prevent degradation of the product or process.

The main objective of quality control is to emphasize that work meets the standards. This means that it is impossible to achieve perfection in every business process there are some variation in production skills, used materials, and applied reliability of a final product, etc.(Judietal.,2011).

3.4.1 Advantage and Disadvantage of Quality Control

Inspection is a major advantage and component of quality control. The goal of inspection is intended to prevent the reach of defective products to a customer. This means having particularly trained supervisors, rather than every individuals responsible for his or her own work. The main problem of quality control is that people are not necessarily motivated to take responsibility for the quality of their own work. This means the need for more manpower and processes to maintain quality control and spend more time for the initial process.(Judiet al., 2011).

3.4.2 Mammography Quality Control

To ensure achievement of the mammography main objectives, quality standards should be adopted. The availability of good mammography and routine quality control screening equipment is essential to ensure high quality mammography services. If there is a lack of preventive and corrective maintenance or improper use of any equipment component (poor quality mammography), this causes a lost diagnosis or patient's exposure to excessive radiation.

Quality Assurance (QA) refers to "all planned and systematic activities that instill trust in good mammography." (QC) refers to "only the technical aspects of the exam" (Dione et al., 1994).

Mammography facilities in the United States are subject to the Quality Standards Act. The law requires that the annual accreditation be submitted every three years, with the approval of the Food and Drug Administration (FDA). Defective facilities hidden in the inspection and certification may stop filming until it is repaired; in some extreme cases, it may be necessary to alert former patients that their previous tests were below standard and that they should not be trusted. (Destoue et al., 2005).

Wioletta published a research about dose assessment and image quality in radiographic in Poland. The aim of the research is to examine the best image quality among the manual screen film (SF), digital radiography (DR), computed radiography (CR), and mammographic system using ACR Phantom. The researcher relies on standards of the phantom to evaluate the image quality. At least 4 points for fiber, 3 points for microclimate, and 3 points for the masses must be found by the system to pass the exam. After comparing the image quality of the phantom mammography system, the researchers concluded that the mammography system needed a lower dose to produce a high-quality image using phantom imaging. However, a low-quality image is produced by a poorly

maintained SF system. The dirty or damaged condensation screen produces visible artifacts. In order to produce a high-quality image, the CR system needs a high dose, while the image quality is less than DR based on the phantom standard. (Wioletta et al., 2016)

In 2014, Molly et al made a comparison between high energy sensitive phase imaging and low energy conventional imaging using different types of phantom (American College of Radiology (ACR). Acrylic edge and equivalent tissue, and contrast-detail (CD)), after the experiments, they conclude that CR and ACR give similar image quality; however, there are contrast details of the stage of sensitive imaging. In other words, High-sensitivity imaging stage is implemented to overcome current experiments and clinical application, to visualize phase contrast, and to improve image quality of a similar radiation dose compared to conventional imaging. (Molly et al., 2014)

Brunner et al published a research in 2012 about investigating image quality performance of Digital Breast Tom synthesis at Pennsylvania University Hospital, which required a quantitative and objective assessment. The observers recorded the visibility of specific objects in the phantom for the purpose of qualitative assessment. Information regarding image quality metrics was provided by the objective evaluation including resolution, noise and contrast-to-noise ratio (CNR) using different phantom such as (CIRS Model 020 BR3D Mammography phantom, the ACR prototype FFDM Accreditation Phantom, Penn anthropomorphic breast phantom and The Quart mam- digi EPQC phantom) after analyzing the results of the experiments, it was concluded that the Quarta phantom could be useful for Digital Breast Tom synthesis. However, the suitable phantom has not been found up to now for the DBT device. (Brunner et al., 2012)

In 2009, Hussein et al used mathematical tissue equivalent breast phantom in order to determine the feasibility of using a monochromatic filter for dose reduction, and to improve the image quality in slot-scanning digital mammography. The mathematical

phantom image was modeled using the following phases: Modeling the pixel intensity, evaluating the contrastive object, modeling the detector noise, and the total system resolution. The mathematical breast phantom was validated using a series of digital images of a physical tissue-equivalent phantom. For model validation, prototype linear slot-scanning, and digital mammography system image were used. Quality metrics such as, image contrast and contrast-to-noise ratio were calculated. After analyzing the results, good agreement with values measured using a physical breast-equivalent phantom designed for mammography was found.(Hussein et al., 2009)

In 2009, Alnazier et al researchers conducted a research related to use Applied Physics Group (APG) phantom to assess the screen film mammography (SFM) and digital mammography quality control. The APG phantom was used to test resolution, contrast and noise at different parts under the X-ray field. Small breast structures, micro-calcifications, fibrils and tumors were represented by the phantom to test mammographic system performance by a quantitative assessment of the system's ability to image small structures similar to those found clinically. In addition, it was used to identify any artifacts in the system due to processing and grid. The researchers concluded that this phantom is useful for mammography units with different field sizes. The phantom used simple and inexpensive materials to be built compared with commercially available phantoms. The use of this phantom would help to do daily automatic QC tests.(Alnazier et al., 2009)

In 2002, Hendrik et al published a research on technical quality control practices in mammography screening programs in 22 countries. The aim of study was to evaluate current technical quality control (QC) practices within breast cancer screening or observation programs internationally. The International Breast Cancer Screening Network (IBSN) has done a survey of quality assurance (QA) activities in developed countries known to have population-based breast cancer screening or observation programs in place,

distributed questionnaires that included items about QA and QC requirements at screening sites. The minimum frequencies of QC test performance, and the personnel responsible for performing QC tests. The study concluded that a great majority of responding countries followed prescribed QC protocols. (Hendrik et al., 2002)

In 2006, Gaona et al conducted a study aiming at comparing CR mammography images printed to a film by a laser printer with screen-film mammography. The quality image tests included a system resolution evaluation, scoring phantom images, Artifacts, mean optical density and density difference (contrast). The study used in screen-film mammography Giotto and Elscintec mammography units with fully automatic exposure and a nominal large focal spot size of 0.3 mm were used for the image acquisition of phantoms, and used Four CR mammography units from different manufacturers and three dedicated x-ray mammography units. The study concluded that the laser printer with screen-film mammography had greater level and high-quality image compared to CR image printed on the film. (Gaona et al, 2006)

In 2012, Sung et al conducted a study aiming at examining which phantom is better for the image quality in full-field digital mammography. The study used American College of Radiology (ACR) accreditation phantom and digital mammography accreditation phantom in measuring the image quality in full-field digital mammography (FFDM). The study lasted for 42 weeks assessing the signal-to-noise ratio (SNR) in each phantom image. Two breast radiologists scored visible objects (fibers, specks, and masses) with soft-copy images and calculated the visible rate (number of visible objects/total number of objects). The study compared SNR and the visible rate of objects between the two phantoms concluding that ACR accreditation phantom appeared to be suitable for evaluating the image quality in FFDM. (Sung et al., 2012)

Schofer conducted a research in 2013 to evaluate image quality by phantom using titanium and landolt rings of digital mammography system compared to the most widely used phantoms in Europe and the US. These phantoms contained objects for subjective detection of landolt rings and for objective calculation of signal-difference-to-noise ratios (SDNR), both in a titanium background within a 12-step wedge. The study compared scores resulting from phantom using landolt with scores obtained following the European EPQC and American College of Radiology (ACR) protocols. It concluded that the simplified evaluation method presented was shown to be a sensitive, efficient and reliable alternative to the most widely used physical phantoms in Europe and the US. (Schofer, 2013)

Having reviewed all the studies explained above, no studies were found regarding the investigation of quality control in the service in medical imaging applied in West Bank :it is a clear evidence of the gap of knowledge that has not been covered yet. In this study, the researcher aims to bridge this gap through investigating he quality control in mammography system in West Bank.

Chapter Four

Conceptual Framework

4.1 Introduction

The main objective of this study is to verify the quality of breast imaging systems in performance among health directorates in West Bank by using phantom. There are many factors affecting image quality in the mammographic system, according to a number of previous studies mentioned through this chapter, such as a method of treatment using (SF or CR), film and of developers types. In this chapter, these factors will be discussed in details.

4.2 Mammography Equipment

In this study, Hologic's M-IVTMSFM system was used to detect early breast cancer. M-IV sequence is a common standard in screen-film mammography designed to improve the operating efficiency with maximum patient comfort, and to provide advanced imaging. Hologic is intensive on providing the latest advanced solutions to improve mammographic image quality. Imaging in diagnostic radiology relies on two technological solutions for diagnostic data including (Analog and CR). The analog system (SFM) consists of three components which are cassette, intensifying screen, and X-ray films. This imaging system also requires photochemical processing of X-ray films (developer, filter, water and dryer) (Kumaszyńska et al., 2010).

The computed radiography (CR) consists of cassettes with film (placed in a cassette similar to that used in analog radiography), a control station with a description screen, and a CR reader. In Computed Radiography (CR), the phosphor imaging panel forms the imaging detector. (Kumaszyńska et al., 2010).

4.3 ACR Mammographic Accreditation Phantom

This phantom is used in Mammographic Quality Control Program and helps in monitoring with mammography quality standard act and quality control programs at the American College of Radiology (ACR). The ACR mammographic accreditation phantom is designed to examine the performance of the mammography system by a quantitative assessment of the system ability to design small structures such as those found clinically. The main purpose of the phantom is to determine if the mammographic system can detect small structures that are significant in the early detection of breast cancer such as calcifications, fibrous calcifications in ducts and tumor masses. These phantom images are compared with previous ones and carefully examined for artifacts and non-uniform areas.

The phantom consists of about 4.4 cm of a 7 mm wax block insert including 16 sets of examination bodies, an acrylic base with a thickness of 3.4 cm, and a 3 mm cover. This compression should be about 4.5 cm from the average glandular composition. This phantom can see a spot mimicking precise calcification, five different shapes mimicking tumors, and six different nylon fibers mimicking fibrous structures. Each phantom of the mammography includes the acrylic contrast test disc.

4.4 Films and Developer Types

Braeuning et al published a research in 1999 about processing conditions effects on mammographic image quality. The aim of the research was to evaluate film and developer types on viability of masses, fibers, and specks in standard of image phantom. In the study, the researcher used five film types of mammographic system (Kodak Min-R M, Min-R H; Fuji UM-MA HC, Min-R E and DuPont Microvision-C). They were processed with five different developer chemicals on this (Kodak RP, Autex SE, DuPont HSD Picker 3-7-90, and White Mountain). The study concluded that the Kodak Min-R M and Fuji film

exhibited the highest scores and images developed in White Mountain and Autex chemicals exhibited the highest scores. It also conclude that the film and developer chemical type affected mammographic image quality.(Braeuning et al., 1999)

While Donald et al published a research in 1992 to measure the effect of chemical have been developed. After exposure under clinical conditions of exposure, many chemicals, temperature and time have evolved. Three times (23, 32 and 42 seconds) with four developing temperatures (32, 34, 36 and 38 degrees) were used. They observed increased contrast with increased temperature and time. While for film types, film contrast varied greatly in film density when developed with extended processing, and in some cases the increased contrast was accompanied by high levels of fog. It was concluded that when using non-recommended chemical processing in the mammography film taking into account these results led to different results, the appropriate chemical processing, the optimum development times and temperatures would be chosen for of a good film performance. (Donald et al., 1992)

4.5 Variables for Image Quality

High mammographic image quality should contribute to high performance in detecting and diagnosing breast cancer. The quality of the images depends on the design and performance of the radiographic unit, image receptor, and how an equipment is used to acquire and process the mammogram. Mammographic image quality should be related to certain technical characteristics of the image that can be technically modified, such as spatial resolution, contrast, image noise and signal-to-noise ratio (SNR), and the absence of artifacts. These are important parameters affecting the ability to detect or characterize micro calcifications, or to visualize fine fibrillar structures radiating from a mass or the presence of architectural distortion. (Arthur and Martin, 2000)

There are two measures of image quality being divided into two part factors affected by the patient-technologist interaction and the skill of the technologists. It is known that higher technologist-associated image quality (TAIQ) includes (positioning, compression, and sharpness), whereas other factors are mainly a function of mammography machine calibration known as higher machine-associated image quality (MAIQ) including (contrast, noise, exposure, and artifact).(Rauscher et al.,2013).

4.5.1 Breast Positioning

Breast positioning is the important element affecting a mammogram. If proper and adequate positioning during radiography is done, it increases amount of breast tissue being imaged. Improper positioning, caused by technologist or inadequate compression, leads various artifacts and breast pathology to be missed. Optimal positioning maximizes the amount of breast tissue seen through image. The positioning in mammography looks for a lot of tissues, nipple in profile, skin folds, breast sagging on Medio lateral oblique view, and superimposed body parts.

In 2014, Popli et al published a research aiming to evaluate correctness and incorrectness of breast positioning, which needed to be avoided to obtain the ideal mammogram. It was studied on 1369 female patients. Mammography tools were performed on full-field digital mammography, four views were done for 1322 patients while remaining patients had undergone a mastectomy and two views for the other breast. Improper position was measured in improper with respect to proper visualization of nipple, position of pectoralis major inframammary fold, and adequate coverage of all breast quadrants. Therefore, it was concluded that the positioning was improper and thus the examination was inconclusive, which reduced the sensitivity of mammography.(Popli et al., 2014)

4.5.2 Compression

Breast compression reduces radiation dose, potential for motion, and geometric sharpness. In mammography, the acceptable compression separates anatomical structures. It improves quality and details of a pathology. Compression results in the spread of breast tissue on a larger area and reduced its thickness. This reduction in radiation results in sparse primary and improved in contrast. Compression is necessary to causes the length of the path through reducing breast size, required dose, and exposure time. It improves the quality and details of a suspected pathology. Inadequate compression results from patient motion and non-uniform exposure level (Stephen at el., 2002).

4.5.3 Sharpness

It describes how well the edges of breast structures in an x-ray image are distinct and not blurred. The sharpness such as poor definition of micro calcifications, poor definition of feature margins and linear structures. Sharpness could improve by reducing: 1) mammography unit vibration, 2) reducing patient motion, 3) using high-detail film cassettes and 4) using a smaller focal point (Stephen at el., 2002).

4.5.4 Contrast

It refers to the variance in degree of blackening of adjacent structures and permit differentiation of subtle tissue density differences. In mammography, the grid is used to improve image contrast for large or dense breasts. The grid used carbon-fiber covers and fiber-interspace to avoid excessive increase in patient dose. A mammographic grid can reduce the scatter-to-primary ratio at the image receptor by a factor of 3 or more.(Stephen at el., 2002).

4.5.5 Noise

It refers to the variations in the image that are distributed over its area, but it does not relate to the structures being imaged. Noise in the image may cause artifacts capable of obscuring or creating lesions and noise in the image, which shall not obscure breast structures or suggest the appearance of structures not actually present. Minimal noise is known with a magnifying glass, moderate noise is well-known with a magnifying glass, noise is well known without a magnifying glass. (Randolph et al., 2018).

4.5.6 Exposure

In radiology, a measure of the amount of ionizing radiation at the surface of the irradiated object calculated by multiplying milliamperage times exposure time in seconds, expressed in units of milliamperere seconds (mAs). The density and contrast of the image on film is controlled by the kV, mAs and other exposure factors.

Exposure in mammography ranked on sources to see details of dense glandular, fatty tissues, pectoral muscle on Medio lateral oblique view, and skin line visualized. (Stephen et al., 2002).

KVP directly influences the quality of radiation reaching the films; this determine the density and the radiographic contrast.

Alkhalifah et al published a research in 2017 related on the effect of exposure factors on image quality in screening mammography in Kuwait .The research aimed to study the effect of exposure factors on image quality for digital screening mammography units using Tungsten (W), targets with Rhodium (Rh) and Silver (Ag) as filters. They imaged mammography Accreditation Phantom Model 015 using a Hologic Selenia Digital mammography unit. They made four images at exposure of 26/28/30/32kvp using target filter combination (W/Rh and W/Ag). The image was evaluated by five technicians

regarding the number of fibers, specks, and masses. They concluded 30 and 32 kVp X-ray beams produce higher quality images than the lower kV values and W/Rh target-filter combination provide better image quality.(Alkhalifah, Brindabhan, &Alsaed,2017)

4.5.7 Artifacts

An artifact is defined as any variation in mammographic density not caused by true attenuation differences in the breast. Jacquelyn published a research about reviewing a variety of mammographic artifacts, identifying their causes, and discussing measures that can be taken to eliminate a given artifact. The aim of the research was to discuss the factors that created artifact affecting the image quality.(Jacquelyn et al., 1999)

In 2008, Bentley et al concluded that factors which create artifacts may be related to the processor such as (excessive developer buildup on the rollers, excessive roller pressure, scrapes, and contaminated developer);in addition, to the performance of the examination by the technologist which is related to such as positioning and darkroom errors, improper film handling and loading, improper use of the mammography unit and related equipment, the mammography unit such as failure of the collimation mirror to rotate, failure of the reciprocating grid to move, compression failure, material in the tube housing, improper alignment of the compression paddle with the Bucky tray, or the patient such as motion, and covered objects or substances, (body parts, clothing, substances on the skin hair, foreign bodies, jewelry. (Bentley, Poulos, & Rickard, 2008)

In this chapter, the researcher discussed the conceptual framework of this study and the factors affecting image quality in the mammography system.

Chapter Five

Research Methodology

5.1 Introduction

This chapter describes the methodology used in this research, which is based on descriptive analysis to explain the research objectives. It also describes the research community represented by selected West Bank health directorates that have mammography system and the research population represented by 8 health directorates having a phantom which is not available in the other 4 directorates. It also reviews the choice of the research tool and how it was built, the modifications made to it and the procedures used to verify the validity and consistency of the research. The study also deals with the various methods and statistical tests used through data processing.

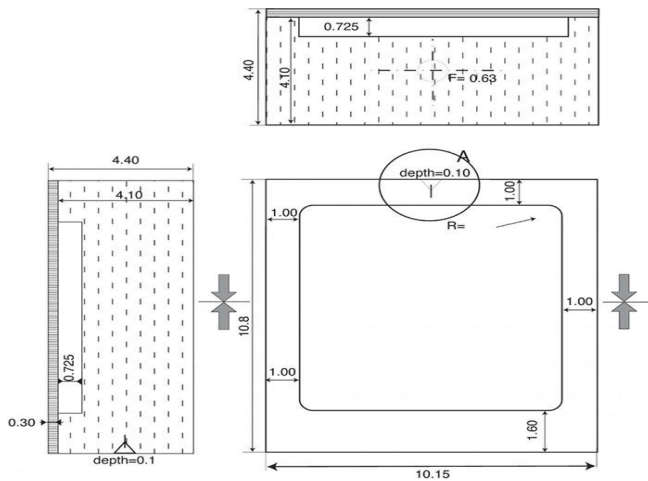
5.2 Research Design

After reviewing the literature on the quality of mammography systems, the researcher also reviewed literature on the quality of breast imaging systems using phantom performance to study the factors affecting image quality. However, there are few resources which discuss the subject. The researcher chooses data to collect by ACR mammography accreditation phantom (model 015), phantom tools are used to quantitatively evaluate the system ability to image small structures similar to those found clinically.

In addition, the researcher performed interviews with technicians about the use of phantom and image quality.

5.3 Research Methodology and Data Collection

Equipment performance evaluation and image quality measurement were carried out during May to October 2018, during the weekly examination of mammography systems used for breast cancer screening in various x-ray centers in selected West Bank healthy directorate. The evaluation was performed for a sample from mammography systems. This study is based on comparative & quantitative methods through data collected by ACR mammography accreditation phantom (model 015) manufactured by CIRS (Computerized Imaging Reference System), phantom tools were used for quantitative evaluation of the system ability to image small structures similar to those found clinically. The phantom is made of acrylic and it simulates a compressed breast with a thickness of 4.2 cm and a 50% composition of adipose, and glandular tissue in order to measure and compare the performance of the mammographic system to evaluate mammography artifacts and image quality. Image quality is affected by this mammographic system regarding the visibility of the structures in the image at a minimum of (4 fibers, 3 micro calcifications, and 3 masses). The quality of the image is affected by this mammography system with regard to seeing the structures in the image at a minimum (4 fibers, 3 micro calcifications, and 3 mass), as can be seen in figure 5.1



Figure(A) 5.1: CIRS 015 Housing Dimensions

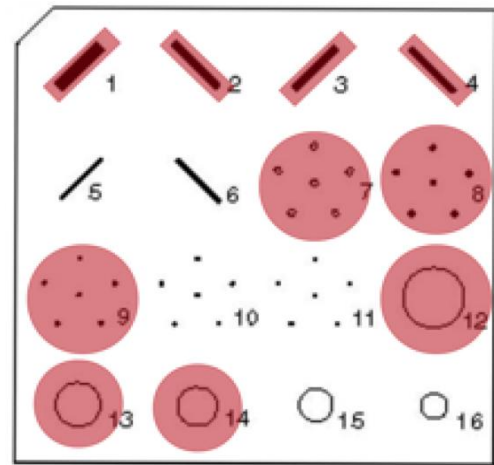


Figure 5.1 (B) :CIRS 015 Wax Insert Dia

(Mammographic Accreditation Phantom - CIRS 015)

Table 5.1: Description of phantom

Fibers (Nylon Fiber)		Specks (Al_2O_3)		Masses (Thickness)	
1)	1.56mm	7)	0.54mm	12)	2.00mm mass
2)	1.12mm	8)	0.40mm	13)	1.00mm mass
3)	0.89mm	9)	0.32mm	14)	0.75mm mass
4)	0.75mm	10)	0.24mm	15)	0.50mm mass
5)	0.54mm	11)	0.16mm	16)	0.25mm mass
6)	0.40mm				

The representative population includes 12 health directorates. The study target population was selected to the mammography system of 9 SF and 3CR systems in the directorates in department 1, department 2, department 3, department 4, department 5, department 6, department 7, department 8, department 9, department 10, department 11, and department 12 to examine the factors affecting the image quality produced as a result of non-inspection of the equipment periodically. Measurement was done for eight mammographic systems but four of them (department 9, department 10, department 11, and department 12) were

excluded due to phantom absence. Two images were taken in each of the directorates. The first image was made with manual program image, exposure input with 28 kVp, 80 mAs, 2density, and the second image was made with Automate Exposure Control (AEC) with 28kVp. The images were taken as follows:

Table (5.2): Check Examination /week

Departments	Number of check /week
Department 1	2 check/week
Department 2	1 check /week
Department 3	2 check /week
Department 4	1 check /week
Department 5	1 check /week
Department 6	1 check /week
Department 7	1 check /week
Department 8	1 check /week

The examination of the mammographic was conducted every week only in 8 of 12 directorates for the reason mentioned earlier in this study. The phantom was exchanged between the directorates for department 2 and department 1, because department 1 was not available, for this reason, the examination was conducted at the directorate of department 1 two days every week, while in the directorate of department 2 once every week. The image was taken two days every week in the directorate of department 3 because the female technician was pregnant and in a vacation. At the directorate of department 4, the image was taken once every week. As for directorates of department 5 and department 6, the image was taken once every week. As for directorate of department 7, the image was taken once every week. Appendices (1-8), contain imaging dates, the score of fibers, specks, and mass for the health directorates of department 1, department 2, department 3, department 4, department 5, and department 7.

5.4 Research Sample

The study sample includes in the selected West Bank health directorates with installed processing method. Table(5.3) shows the distribution of sample between the processing method and the ownership of the phantom device.

Table (5.3): Sample Characteristic

Processing method	Number of health Directorates	Percent%
CR	3	37.5
Screen- film	5	62.5
Total	8	100
Having a phantom	Number of health Directorates	Percent %
Yes	7	87.5
No	1	12.5
Total	8	100

The sample included 8 directorates. The study sample was taken on the basis of selected number of mammography system 5 SF systems, and 3 CR systems existed in the directorates in department 5, department 2, department 1, department 7, department 8, department4, department 3 and department 6 in West Bank to examine factors affecting the image quality as shown in Table (5.4).

Table (5.4):Distribution type of processing within Departments

Processing method	Cities
(SF)	Department 7
	Department 2
	Department 3
	Department 4
	Department 8
(CR)	Department 5
	Department 1
	Department 6

5.5 Statistical Analysis

This section addresses the different statistical analysis tools used to analyze the collected data and to test study hypotheses. SPSS version 23 was utilized to run the following list of tests and to describe results. In this study, the researcher used some of the statistical tools to examine the hypothesis and questions as follows.

- Frequencies and percentage to describe the characteristics of the sample and their responses.
- Independent Sample T-Test to examine the differences of the variables consisting of two groups. As p-value was less than 0.05, the null hypothesis was rejected because there was a difference between the two groups.

5.6 Validity and Reliability

The validity of a measurement instrument means that it can measure what it was originally designed for. The measurement instrument was presented to a group of experts and competent arbitrators to determine their opinion on the suitability of each part for the studied subject, and to make amendments or observations. Reliability of a measuring

instrument means its ability to create reproducible results meaning that obtaining same or similar scores each time they are used. Hence, a measurement instrument is said to be reliable if similar answers are produced repeatedly.

5.7 Limitations and Assumptions

The main limitations, which encountered the researcher to conduct this research, are as follows:

- 1- Four health directorates were excluded because there was no available phantom.
- 2- Mammography device existed at department 8 was malfunctioned and no maintenance performed.
- 3- The Phantom taken from department 2 to examine the device at the department 1 and during the transport there was a crack found in the phantom.
- 4- At department 3, the phantom was examined two days every week, because the technician was pregnant and wanted to take a vacation.

Chapter Six

Data Analysis and Study Findings

6.1 Data Editing and Encoding

The researcher used SPSS program to analyze the data after they were processed taking each encryption variable to present them. The research included two parts. The first part was divided into two sections containing 21 variables. The first contained 16 items that measured the main variables (fibers, masses, and specks) measured by using (Yes) if the symbols were existed and (NO) if they were not existed. The second contained the information for the sample including quantitative variables (device efficiency, second hand device, and used exposure), and qualitative variable (processing method and technique used). The second part was interview with technicians using phantom.

6.2 Data Screening

Before performing the fundamental analysis, it was important to specify the checklist to examine the data to know the effect that data properties may have in the results. In this study, each of the 6 departments had 8 manual images used for manual program, and 8 automate images used for (AEC) program, with the exception of department 8 having 3 manual images used for manual program ;since the mammography system collapsed during this study, these data missed their value, so the researcher dropped department 8 from the sample.

6.3 Checklist for Quality Control Examinations in Mammography System Using Phantom

In this section, the researcher displays checklist to examine quality control for Mammography system by using phantom in acceptable or unacceptable images for all departments as shown in table (6.1).

Table (6.1): Checklist for quality control examinations in selected West Bank health departments

Departments	Type of machine	Method of processing	Overall Pass			Overall Fail		
			Auto-Filter	Manual-Filter	total	Auto-Filter	Manual-Filter	total
Department 2	M-IV (Hologic)	SF	6	3	9	2	5	7
Department 3	M-IV (Hologic)	SF	4	7	11	4	1	5
Department 4	M-IV (Hologic)	SF	6	3	9	2	5	7
Department 5	M-IV (Hologic)	CR	8	8	16	0	0	0
Department1	M-IV (Hologic)	CR	8	8	16	0	0	0
Department 6	M-IV (Hologic)	CR	8	8	16	0	0	0

In Table 6.1, the researcher noted the high quality of images in department 5, department 1 and department 6 as a result of using (CR) method of processing because they had no fail images, while the images of quality used in the department 2, department 4 and department 3 used (SF) method of processing. Not all of these were successful, so they had no high quality. According to these results, chemical processing was not changed from time to time through the illustrations, broken screen, and the rulers which were not cleaned from time to time; hence some images failed.

6.4 Interview Analysis

In this section, the researcher analyzed the answers obtained from the interviewed technicians, when asking about how to use phantom to calibrate mammographic system, which are shown in Section 6.4.1.

6.4.1 Technicians Interviews

Throughout the study, the researcher studied the directorate having calibration used by phantom. Only the directorate of department 1, department 9 and department 4 used it, which represented 25%, the rest representing 75% didn't use it. Even that some departments knew the phantom except department 2, department 7, and department 3 that represent 25%, while 75% knew it, and no one maintained the phantom. Finally 33.3% of departments didn't have a phantom, while the rest of them representing 76.7% owned it.

Table (6.2): Checklist of phantom calibration (technicians Interviewed)

Department	Know	Utilizes	Maintenance	Ownership
Department 2	X	X	X	✓
Department 1	✓	✓	X	✓
Department 3	X	X	X	✓
Department 4	✓	✓	X	✓
Department 5	✓	X	X	✓
Department 6	✓	X	X	✓
Department 7	✓	✓	X	✓
Department 8	✓	X	X	✓
Department 9	X	X	X	X
Department 10	✓	X	X	X
Department 11	✓	X	X	X
Department 12	✓	X	X	X

6.5 Device Sample Characteristic

Through the study, the researcher looked at certain characteristics of the device including four shown in table (6.3), containing the frequency and percentage for each variable listed according to the survey categories in the table.

Table (6.3): Analyzing results of device qualitative variables

Variable	Options	Frequency	percentage %
Method processing	SF	3	50
	CR	3	50
Technique used	Manual	8	50
	Automate AEC	8	50

As shown in Table(6.3), 50% of the X-ray film processor is manual, and 50% is CR; in each device, the researcher took 8 images manually and 8 automatic images (AEC).

6.6 Examining the Quality of Image through the Specifications of Device

In this section, the researcher presents three different sub objectives of quality regarding the device specifications. In order to show the influence of characteristic variables on image quality, Chi-square test were analyzed.

6.6.1 Assess Relation between Image Quality and the Method of Processing

Figure (6.1) shows that the sample has 80.2% images that have acceptable quality, while 19.8% images have unacceptable quality. In addition, it can be seen from this table that CR unacceptable quality is zero, while the unacceptable quality of manual images is 19.8%. To examine the sub-objective, the researcher uses Chi-square test.

Table (6.4) shows the results of the relation between the image quality and method of processing. The result indicates that there is a significant relation between image quality and method processing, where $p\text{-value} = (0.00 < 0.05)$.

Table (6.4): Chi-square test of method processing and image quality					
			Quality		Total
			Unacceptable	Acceptable	
processing method	SF	Count	19	29	48
		% of Total	19.8%	30.2%	50.0%
	CR	Count	0	48	48
		% of Total	0.0%	50.0%	50.0%
Total		Count	19	77	96
		% of Total	19.8%	80.2%	100.0%
Chi-square			23.688	p-value	0.000

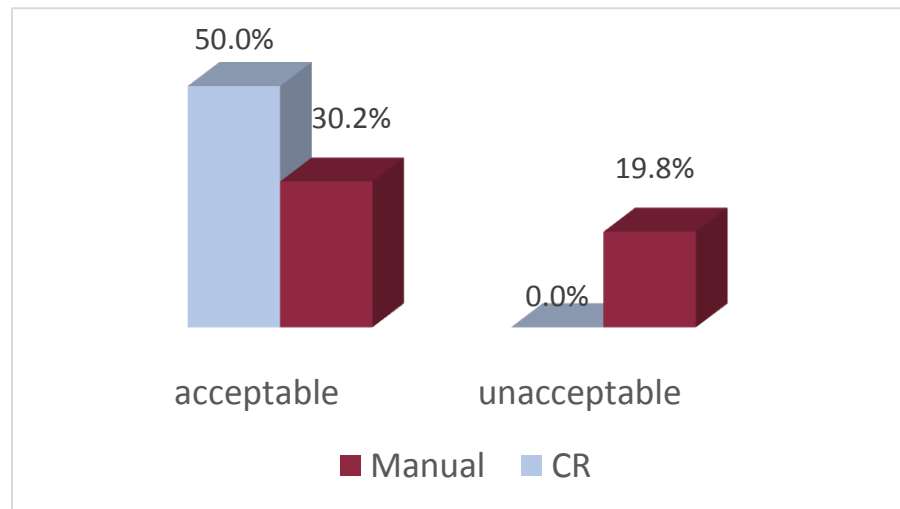


Figure 6.1: Distribution of image quality based on the method processing

6.6.2 Assess Relation between the Image Quality and Technique used

Figure (6.2) shows that the sample has 41.7% automate images that have acceptable quality, while 8.3% have unacceptable automate quality image; it can be seen from this figure the of CR unacceptable quality, while the 38.5% of manual image have acceptable

quality. To examine the sub objective, the researcher uses Chi-square test. Table (6.5) shows the results of the relation between the image quality and technique used. The results indicate that there is no significant relation between image quality and the technique that use it, where $p\text{-value} = (0.442 > 0.05)$.

Table(6.5) :Chi-square test of technique used and image quality

		Quality			
		Unacceptable	Acceptable	Total	
Technique used	Manual	Count	11	37	48
		% of Total	11.5%	38.5%	50.0%
	Automate	Count	8	40	48
		AEC	% of Total	8.3%	41.7%
Total		Count	19	77	96
		% of Total	19.8%	80.2%	100.0%
Chi-square			.591	p-value	0.442

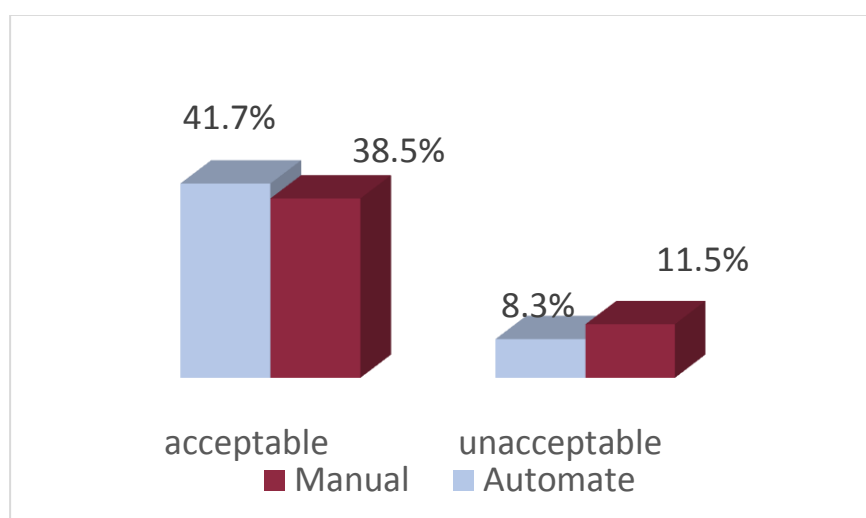


Figure 6.2: Distribution of image quality based on technique used

6.6.4 Assess the Relation between Image Quality and the Second-Hand Device

To examine the relation between image quality and the second-hand device, the researcher used the Chi-square test. Table 6.6 shows that the sample has 37.5% acceptable images taken from the device that has been working for 7 years, while 33.3% is an acceptable image taken from another device that has been working for 5 years. In addition, this table shows the percentage of unacceptable images taken from the device that has been working for 7 years is 12.5%, and that there is a relation between the image quality and the second-hand device, such as the value of $p = (0.001 < 0.05)$. So H_0 is rejected, thus there is a statistical relation between them.

Table 6.6: Chi-square test of image quality and the second-hand device

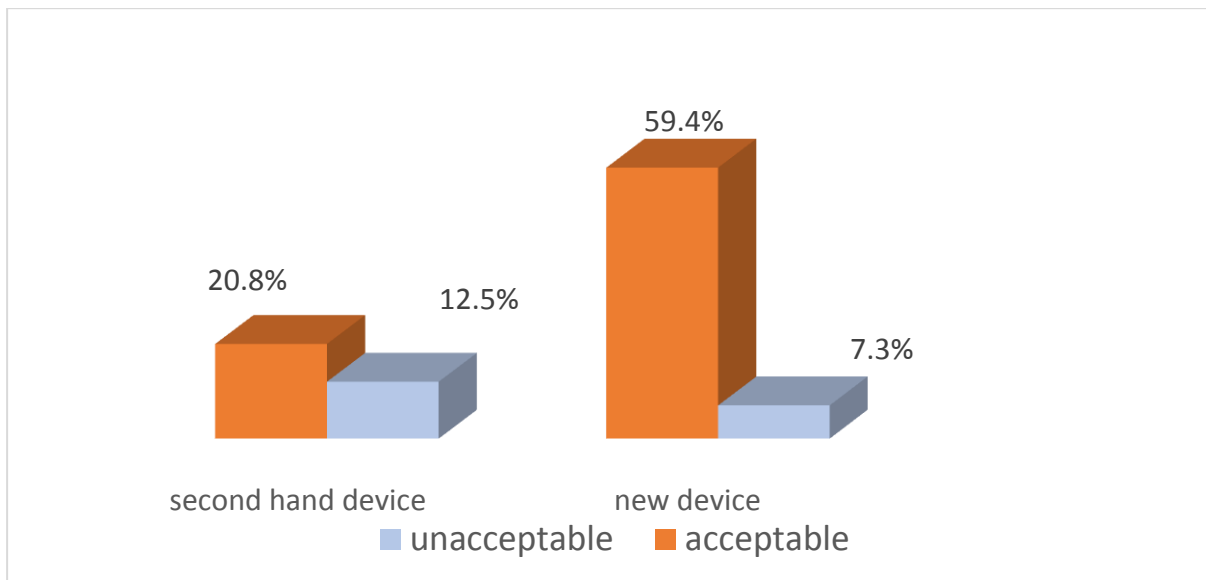
		second-hand device			Total
		5 Years	6 Years	7 Years	
Quality	Unacceptable	Count	0	7	12
		% of Total	0%	7.3%	12.5%
	Acceptable	Count	32	9	36
		% of Total	33.3%	9.4%	37.5%
Total	Count		32	16	48
	% of Total		33.3%	16.7%	50.0%
Chi-square		14.502			p-value
					0.001

6.6.5 Asses Relation between Image Quality and Device Efficiency

Figure (6.3) shows the sample has 66.7% of new device, while 33.3% is second-hand device. In addition, the percent of acceptable image of new device is 59.4%, however, the percent of acceptable image of second-hand device is 20.8%, to examine the sub objective, the researcher uses Chi-square test. Table (6.7) shows the result of the relation between the image quality and the used device. Such as the $p\text{-value} = (0.002 < 0.05)$, so the researcher rejects H_0 , and there is a statistical relation between them.

Table 6.7: Chi-square test of image quality and the used device

			device used		Total
			new device	second-hand device	
quality	unacceptable	Count	7	12	19
		% of Total	7.3%	12.5%	19.8%
	acceptable	Count	57	20	77
		% of Total	59.4%	20.8%	80.2%
Total		Count	64	32	96
		% of Total	66.7%	33.3%	100.0%
Chi-square			9.482	p-value	0.002

**Figure 6.3: Distribution of image quality based on used device**

6.6.6 Assess Relation between Image Quality and Exposure (mAs)

To examine the difference between image quality and exposure (mAs), the researcher uses independent sample test. Table (6.8) shows that there is a difference in image quality of exposure mass, such as $p\text{-value} = (0.831 > 0.05)$. Therefore, the researcher accepts H_0 , and thus no statistical difference found between them.

Table (6.8): Relation between (mAs) and image quality

		N of image	Mean	Stander deviation	T value	Df	p-value
exposure (mAs)	Acceptable	77	81.2740	33.36452	.214	94	.831
	Unacceptable	19	79.5789	17.58571			

Chapter Seven

Discussion of Results, Conclusions and Recommendations

7.1 Introduction

In this chapter, results, conclusions and recommendations are discussed. The researcher aimed at checking the mammographic systems performance quality between 8 Health directorates which are existed in West Bank selected health department 1, department2, department3, department4, department5, department 6, department 7, and department 8. The researcher examined the factors affecting image quality which was produced as a result of lack of periodic maintenance for devices. Eight departments were selected of 12 ones to examine the quality of mammographic system. During this study, the mammographic system in department 8 was disrupted and was excluded from the study. As for the health apparatus of department 7, it was excluded because the phantom used was different from other phantoms.

7.2 Discussion

Chi-square test was applied to examine the relation between the image quality and method of processing. The results indicated that there was a significant relation between image quality and method of processing. These results are consistent and agreed with other studies that have been published worldwide. For example, a study in Poland, to evaluation of doses an image quality in mammography with screen film, CR by using ACR phantom. The researcher concluded a low-quality image was produced by using SF system while to produce a high quality image, the (CR) system was used (Wioletta et al., 2016). In this study 16 phantom images were taken by using manual and automatic exposure technique, 8 of these were manual and 8 were automatic for each mammographic system.

In department 3, there was some artifact due to several reasons, such as the chemicals were not changed every month, rollers of the device were not cleaned, and small dots came to scene on films used.

Processor or Technologist Related Artifacts

The main causes of artifact to happen in all departments referred to a way of storing film which affected the image quality .In the department 3, chemical processing never changed leading to calcification in the image, the device rollers were not cleaned ;this covered some details of the image preventing a radiologist from seeing some image details (micro calcifications),and the used water was not changed for a long period .Depending on the image produced, the researcher noticed 4 fibers, 2 micro calcifications, and artifact on masses which the radiologist did not notice clearly. This led to the failure of the examination (Figure. 7). As a matter of fact, the details were not seen clearly due to the fact that technicians did not calibrate the mammography system from time to time. (Figure,7).

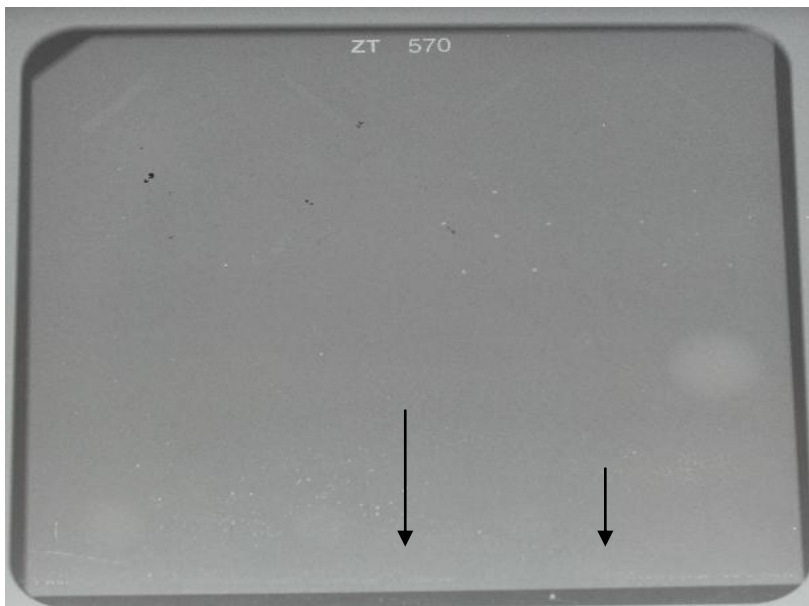


Fig7. Artifact Calcification from rollers and fixer (arrows)

After looking at the images taken from the mammography device at department 2, the technologist's fingertips found on the phantom image covered some of its details and a mass appeared. Water, in X-ray acidification machine, was not periodically changed; as a result of this, some algae appeared. The researcher noticed 4 fibers, 3 masses, and 3 micro calcifications, but the algae covering the exact calcification and the lid of the fingertips on massed prevented the radiologist from seeing some of the image details. The results are shown in (Figure8); a crack was found in phantom during movement.

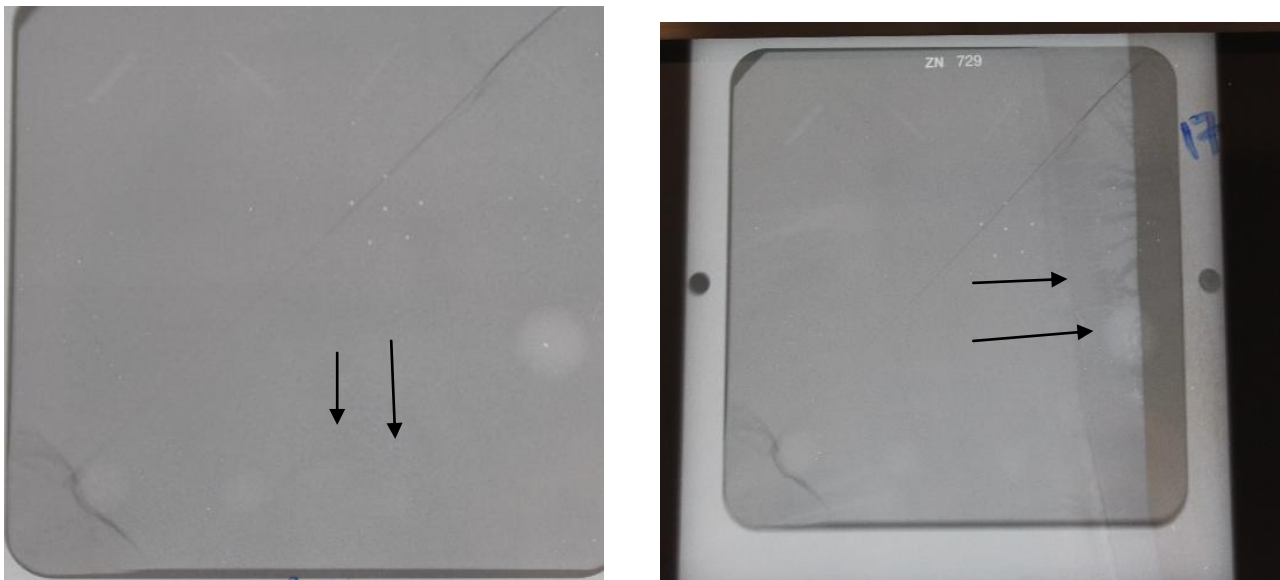


Fig (8). (a) Artifact from fingertips (arrows) (b) Artifact from contaminated water as a result of not changing water periodically causing algae emergence.

After looking at the images taken from the mammography device at department 4, a noticeable line was found in the image resulted from using a broken-screen cassette, which is sometimes caused when it is exposed to light. It is worth mentioning that very weak chemical processing that has not been changed for a long period, does affect image quality. According to (Fig 9), nothing was noticed in the first image since the chemical processing

was not periodically changed. In the second image, the researcher noticed 4 fibers, 2 micro calcification, and 3 mass; however, the artifact was found because of using a broken-screen cassette ;this prevented radiologist from giving clear diagnosis.

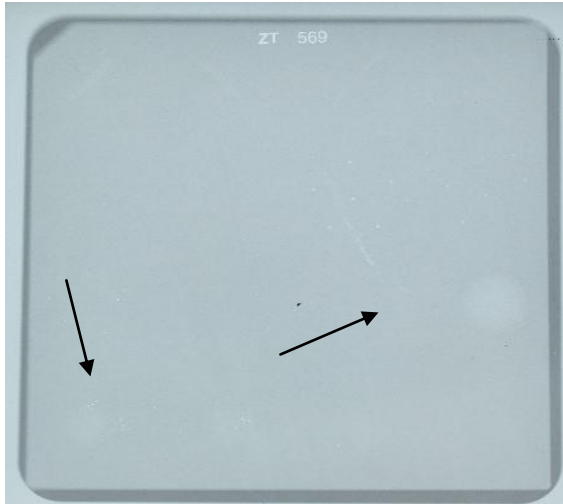
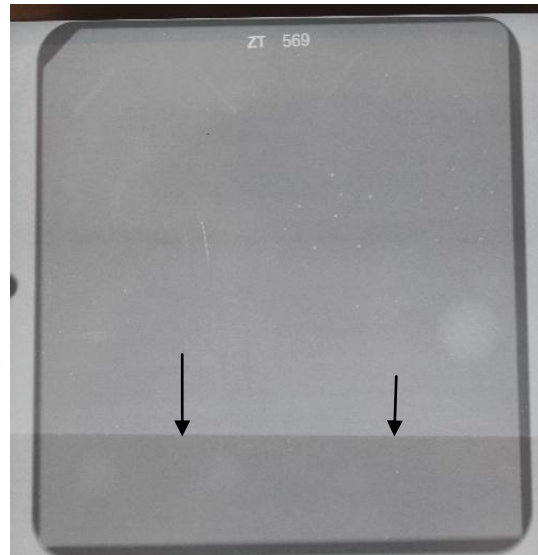


Fig (9). (a) The scores on the phantom are not obscured due to the chemical hazard is not changed for a long period



(b) Artifact from a broken screen (arrows)

After viewing the images taken from the mammography device at department 5.No artifact was found in the image; it is sometimes found when the screen is not cleaned well in the cassette. The result was clearly noticed; the researcher noticed 4 fibers, 3 micro calcification, and 3 mass so that a radiologist could see these clearly and diagnose the image well (Fig10).



Fig (10). No artifact on the image, the scores (fibers, calcifications, mass) are clearly observed.

After looking at the images taken on the mammographic device at department 1, it was noticed that the image was of good quality due to the used processing images. An artifact was found due to the cassette screen which was not periodically cleaned every 6 months; the radiologist realized that it was calcification and the result was clearly noticed. A crack was found in the phantom during the movement between department1 and department2. The researcher noticed 4 fibers, 3 micro calcification, and 3 mass ;therefore, the radiologist noticed these well and diagnosed the image.(Figure 11).

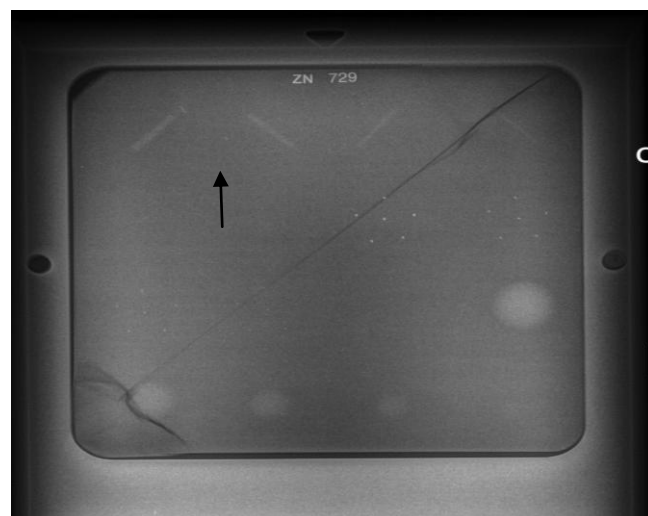


Fig (11).The scores (fibers, calcifications, mass) are clearly observed.(dot artifact, arrow).

The Chi-square test was used to show the relation between the image quality and the used program. This hypothesis was discussed in this chapter which the researcher did not discuss before. Technologist used AEC technique according to the instructions given by the engineer responsible for the device. Two phantom images were taken automatically and manually to show the difference of the image quality. According to the results, no relation was found between image quality and the used program, ($p\text{-value} > 0.05$), because department 5, department 1, and department 6 had good quality image using CR, in which the density from the monitor could not be controlled. Differences were found between automate and manual program image quality in x-ray film processor image during the examination (Fig 12). Chi-square test was used to examine the relation between image quality and periods of device utilization - to know if it was new or second hand- ($p\text{-value} < 0.05$), and a relation was found between them; the researcher examined this hypothesis finding that devices leaked radiation because they were used for along time. Every time the device was used, the efficiency was reduced.

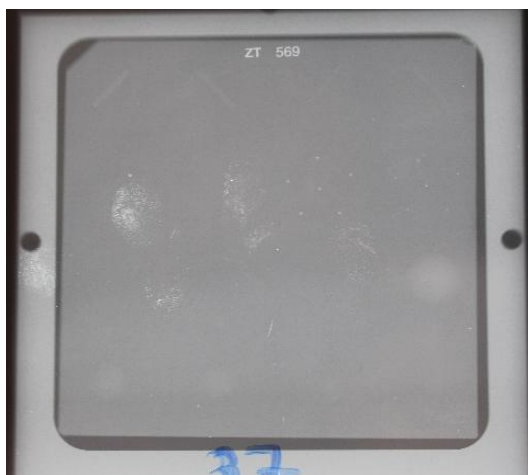


Fig (12). (a) Manual program image quality in mammography device in department 4



(b) Automate program in mammography device in department 4

7.3 Conclusions

In conclusion, the application of quality control in mammography system in West Bank 8 departments using the ACR mammographic accreditation phantom is a powerful guide to investigate quality control of mammographic system and reduce misdiagnosis so that the radiobiologist can diagnosis the image clearly. Quantitative and qualitative methodology contains checklist for quality control examinations in mammography system by using phantom, technicians and interviews. The study concluded that health departments did not investigate quality control of the mammography system. It was found that all the technicians in the departments did not know what the phantom was, and did not work on quality control in mammography system using the phantom. After conducting investigation, it was found that the departments using CR processor provided good quality image, and other departments using x-ray films gave low quality image. Finally, the researcher made a personal effort changing some departments X -ray film processor to CR one; also changed this for non-governmental organizations. Table (6.1)

7.4 Recommendation

- The responsible parties must provide technical courses to train technicians on what the phantom is and how it works.
- Progressive education in all departments must be activated by the Department of Radiology.
- The mammogram system must be calibrated every 6 months, by the engineering medical unit, according to regulations in force of the Ministry of Health and not only when the device is damaged.
- For CR devices, the screen must be cleaned every 6 months preventing artifacts from appearing on images such as calcifications leading to misdiagnosis.

- The Radiology Unit should provide a phantom for each department to examine the mammogram system.
- Image quality was not maintained at the desired level in departments using X-ray films which were manually used (chemical processing). Therefore, responsible parties must replace the processor with CR.
- The phantom used in all health departments does not reveal the contrast (the degrees of gray). Through the study a new phantom (Tissue-Equivalent Phantoms for Mammography) was found and able to reveal the contrast (DEGREES of GRAY). Therefore, it is necessary for responsible authorities to provide the mentioned phantom which other researchers need to conduct further study.

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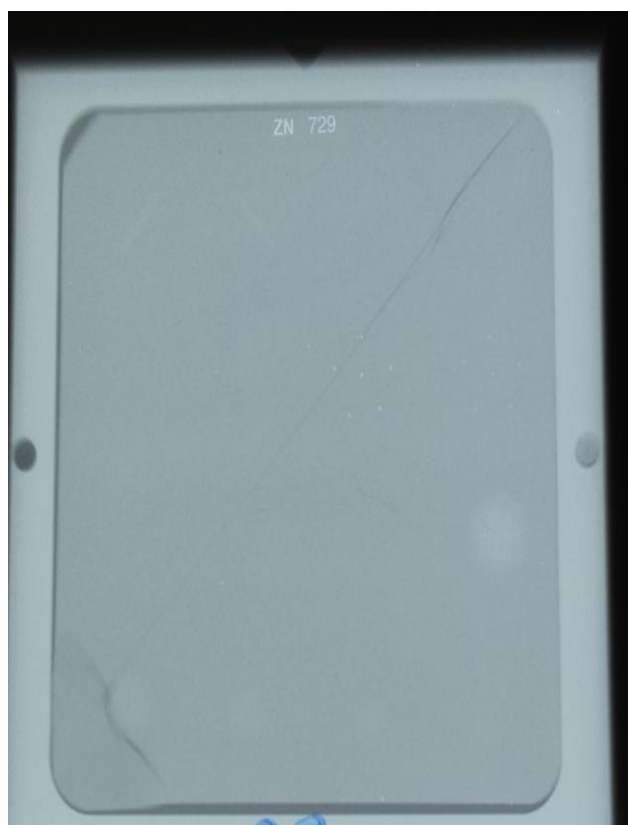
from :<https://mpival.com/docs/Market%20Reports/MPI-Healthca...>

Appendices

Facility: Hebron x-ray
machine name: M-IV (Hologic)
Model : ASY-00555
AEC Mode: Auto-Filter

Resulting Techniques	Date	Wednesday	Monday	Monday	Thursday	Sunday	Sunday	Monday	Monday
	Day	18/7/2018	23/7/2018	30/7/2018	16/8/2018	19/8/2018	26/8/2018	4/9/2018	17/9/2018
	Number of images	72000	72060	72140	72248	72308	72320	72392	72432
	Kvp	28	28	28	28	28	28	28	28
	mAs	40.2	42	45.2	43.8	40	43.3	48.2	40.3
ACR DM phantom	Fiber score	4	4	4	4	4	4	4	4
	Speck group score	3	3	2	3	3	2	3	3
	Mass score	4	4	4	4	4	4	4	4
Overall Pass\ Fall		Pass	Pass	Fall	Pass	Pass	Fall	Pass	Pass

Phantom test in HebronAutomate Program



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Facility: Hebron x-ray machine name
M-IV: (Hologic)
Model: ASY-00555
AEC Mode: Manual-Filter

Resulting Techniques	Date		Monday	Monday	Thursday	Thursday	Sunday	Tuesday	Monday
	Day	18/7/2018	23/7/2018	30/7/2018	16/8/2018	23/8/2018	26/8/2018	4/9/2018	17/9/2018
	Number of images	72000	72060	72140	72248	72316	72328	72400	72440
	Kvp	28	28	28	28	28	28	28	28
	mAS	80	80	80	80	80	80	80	80
ACR DM phantom	Fiber score	5	5	5	3	4	5	4	5
	Speck group score	3	2	2	3	2	3	2	3
	Mass score	3	4	4	3	3	4	4	4
Overall Pass\ Fall		Pass	Fall	Fall	Fall	Fall	Pass	Fall	Pass

Phantom test in HebronManual program



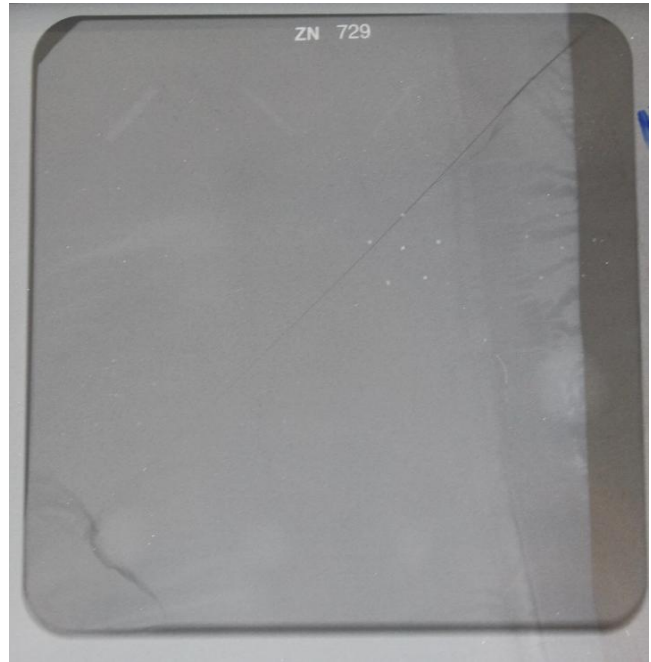
18/7



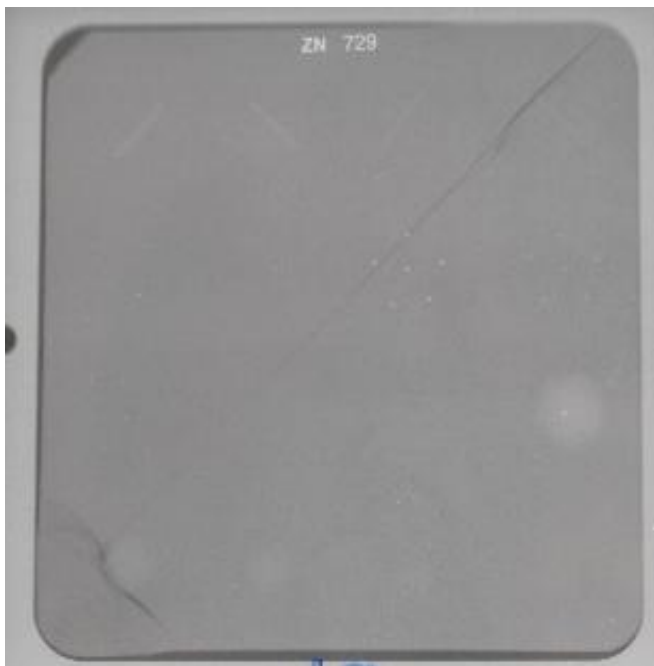
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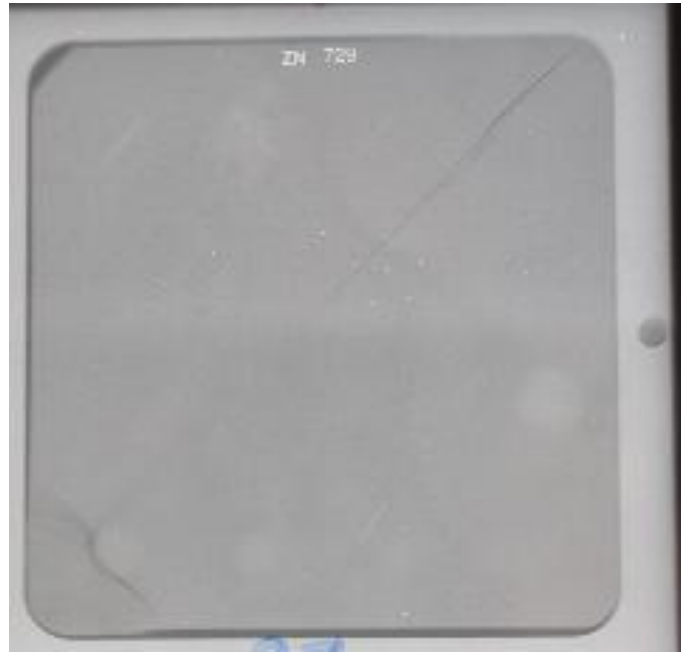
23/8



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Facility: Qalqilya x-ray machine name
M-IV : (Hologic)
Model: ASY-00555
AEC Mode: Auto-Filter

Resulting Techniques	Date	Monday	Thursday	Monday	Thursday	Monday	Thursday	Monday	Monday
	Day	16/7/2018	26/7/2018	13/8/2018	30/8/2018	3/9/2018	6/9/2018	10/9/2018	17/9/2018
	Number of images	16800	16832	16848	16848	16868	16888	16904	16928
	Kvp	28	28	28	28	28	28	28	28
	mAS	95.1	95.1	92.1	91.2	113	92.2	113	92.1
ACR DM phantom	Fiber score	4	4	4	4	4	4	0	4
	Speck group score	2	3	2	3	2	3	0	3
	Mass score	4	3	1	4	4	4	0	4
Overall Pass\ Fall		Fall	Pass	Fall	Pass	Fall	Pass	Fall	Pass

Phantom test in Qalqilia.....Automate program

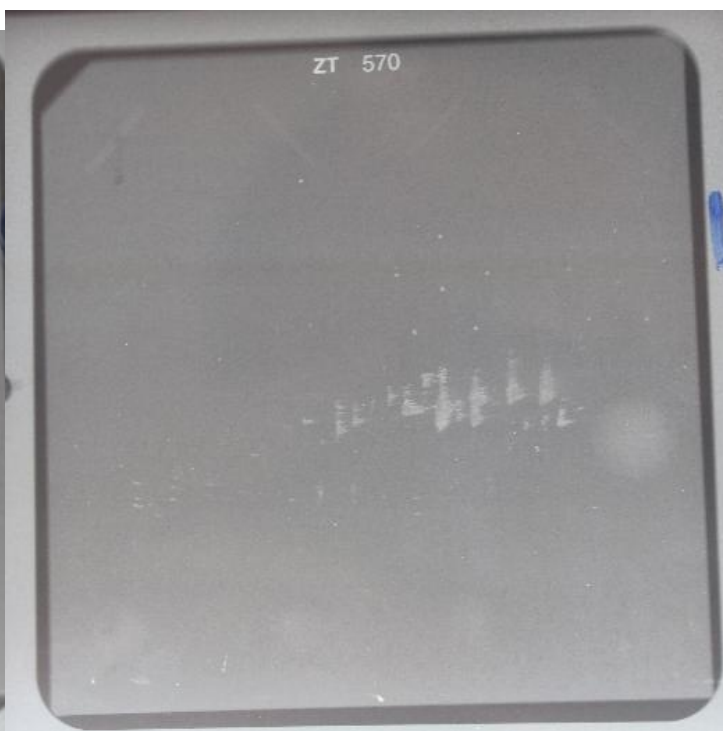


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Facility: Qalqilya x-ray machine name

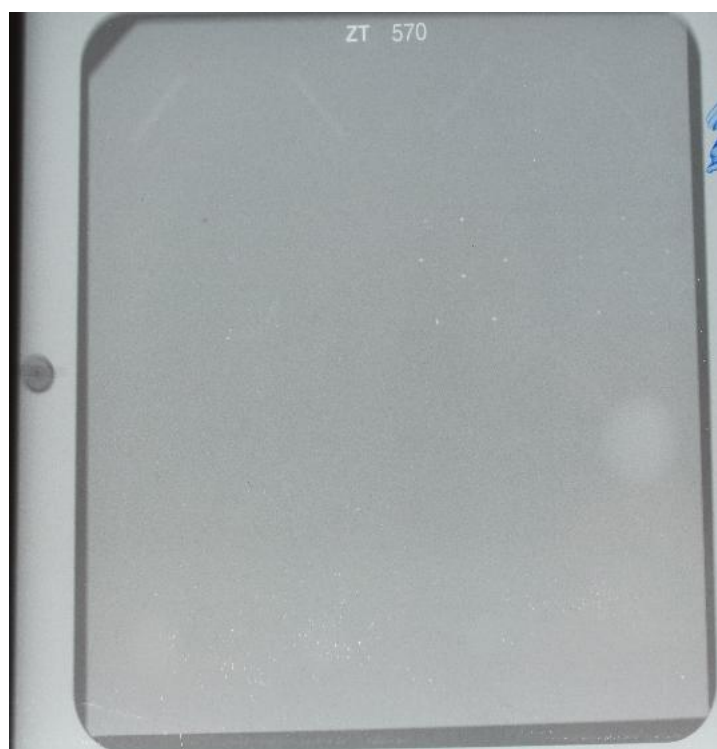
M-IV : (Hologic)

Model: ASY-00555

AEC Mode: Manual-Filter

Phantom Test in Qalqilia.....Manual program

Resulting Techniques	Date	Monday	Thursday	Monday	Monday	Monday	Thursday	Monday	Monday
	Day	13/8/2018	16/8/2018	27/8/2018	30/8/2018	3/9/2018	6/9/2018	10/9/2018	17/9/2018
	Number of images	16816	16800	16832	16852	16872	16888	16912	16932
	Kvp	28	28	28	28	28	28	28	28
	mAs	80	80	80	80	80	80	80	80
ACR DM phantom	Fiber score	5	4	4	4	4	4	4	4
	Speck group score	3	3	3	3	2	3	3	3
	Mass score	4	3	4	4	4	4	4	4
Overall Pass\ Fall		Pass	Pass	Pass	Pass	Fall	Pass	Pass	Pass



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16\8



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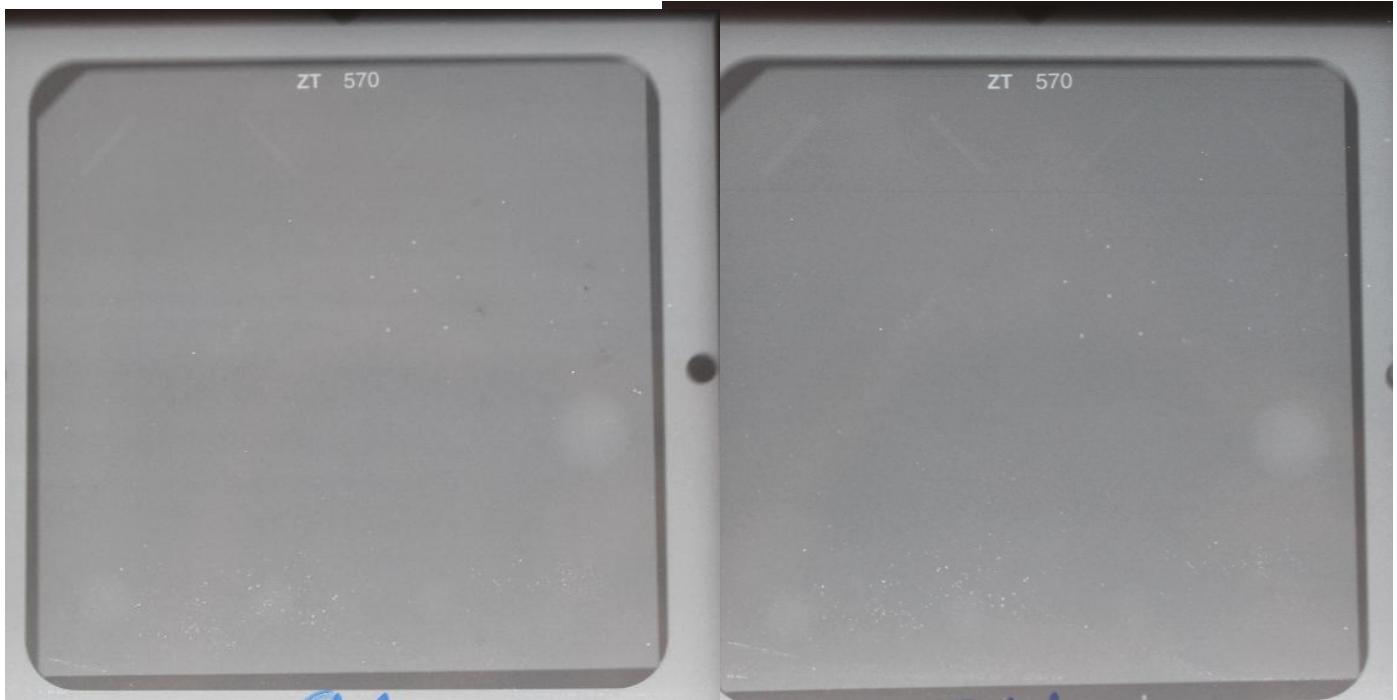
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Facility: Jericho x-ray machine
M-IV: (Hologic)
Model: ASY-00581
AEC Mode: Auto- Filter

	Date	Monday	Tuesday	Tuesday	Tuesday	Tuesday	Tuesday	Wednesday	Wednesday
Resulting Techniques	Day	23/7/2018	31/7/2018	7/8/2018	14/8/2018	21/8/2018	28/8/2018	5/9/2018	12/9/2018
	Number of images	5040	5064	5088	5108	5136	5164	5164	5184
	Kvp	28	28	28	28	28	28	28	28
	mAs	60	62.1	62.1	68.2	72.1	62.2	60	61
	Fiber score	4	4	4	0	4	4	4	4
ACR DM phantom	Speck group score	3	3	2	2	3	3	3	3
	Mass score	4	4	4	1	3	4	4	4
Overall Pass\ Fall		Pass	Pass	Fall	Fall	Pass	Pass	Pass	Pass

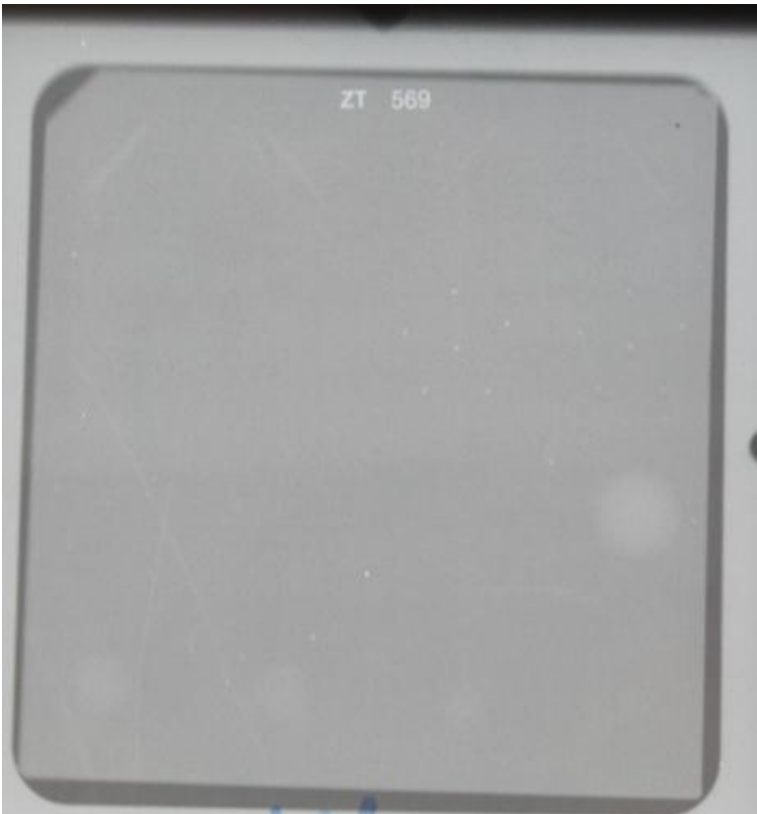
Phantom test in Jericho.....Automate program



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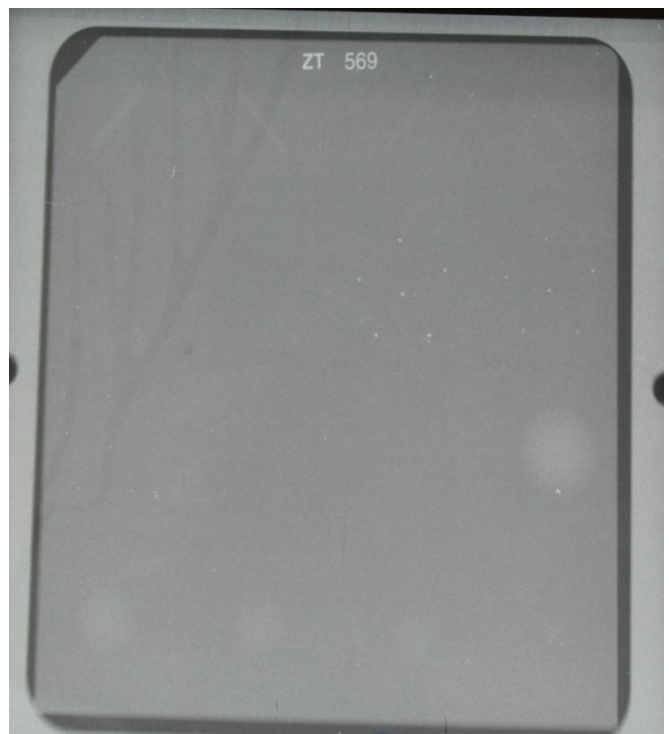
7/8



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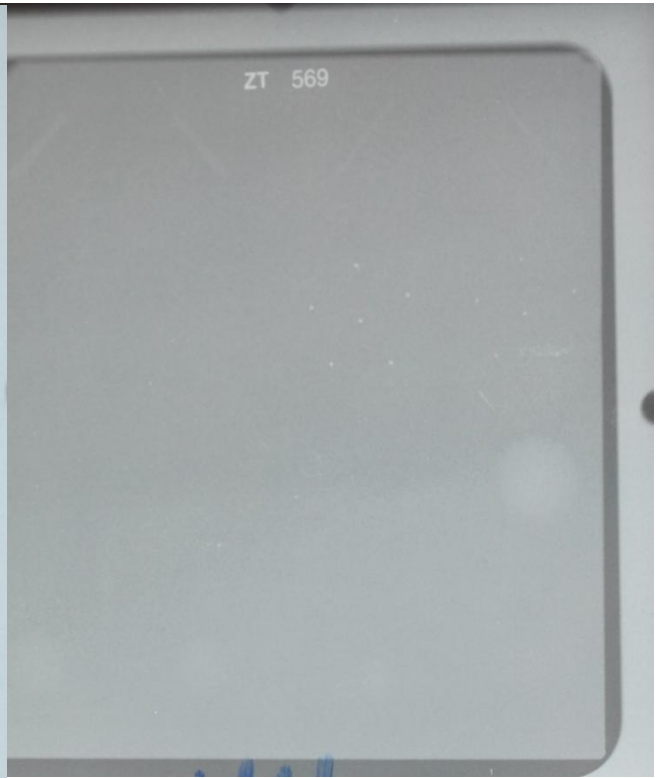
21/8



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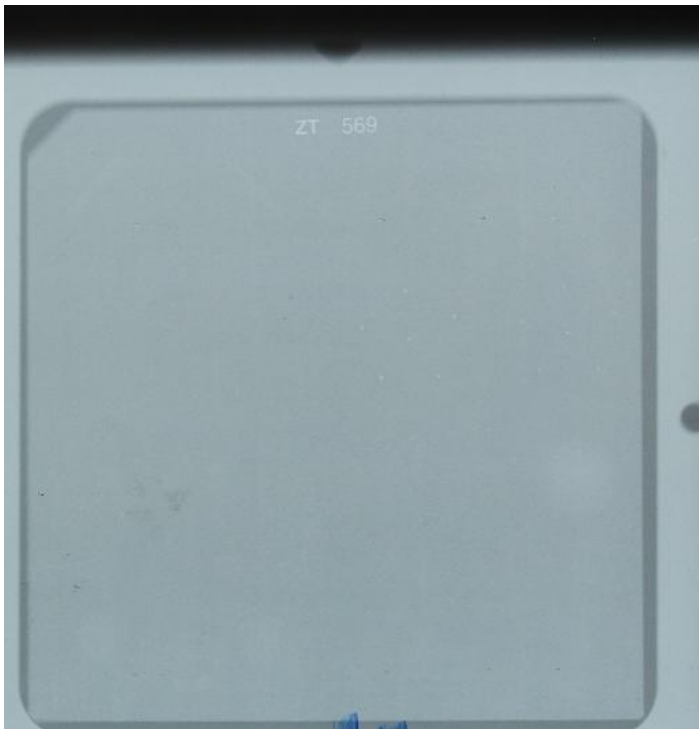
Facility: Jericho x-ray machine name
M-IV: (Hologic)
Model: ASY-00581
AEC Mode: Manual-Filter

Resulting Techniques	Date	Tuesday	Thursday	Tuesday	Tuesday	Tuesday	Tuesday	Wednesday	Wednesday
	Day	7/8/2018	9/8/2018	14/8/2018	21/8/2018	28/8/2018	4/9/2018	12/9/2018	19/9/2018
	Number of images	5064	5064	5084	5112	5140	5168	5188	5188
	Kvp	28	28	28	28	28	28	28	28
	mAs	80	80	80	80	80	80	80	80
ACR DM phantom	Fiber score	0	4	3	4	4	4	4	4
	Speck group score	2	3	2	2	3	3	2	2
	Mass score	1	4	2	4	4	4	4	4
Overall Pass\ Fall		Fall	Pass	Fall	Fall	Pass	Pass	Fall	Fall

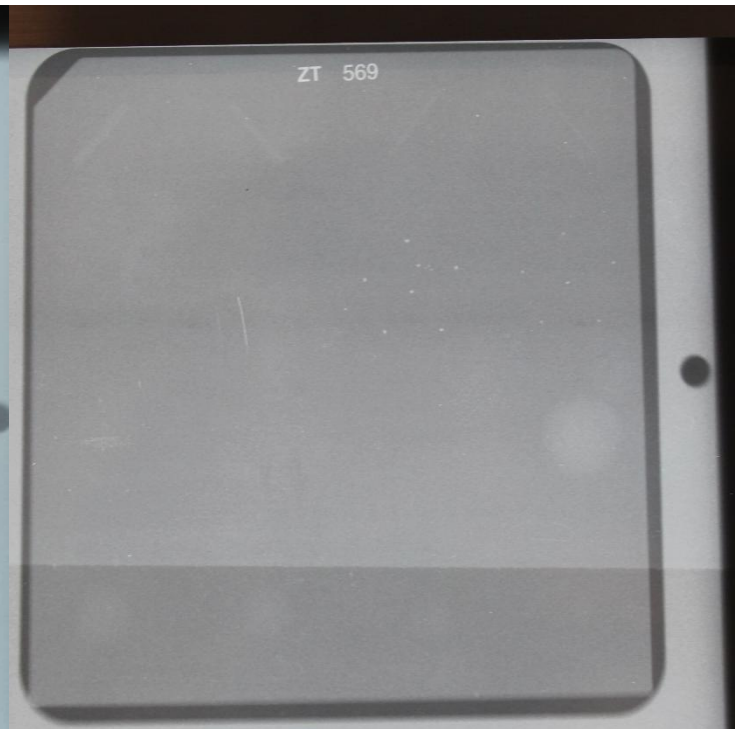


7/8

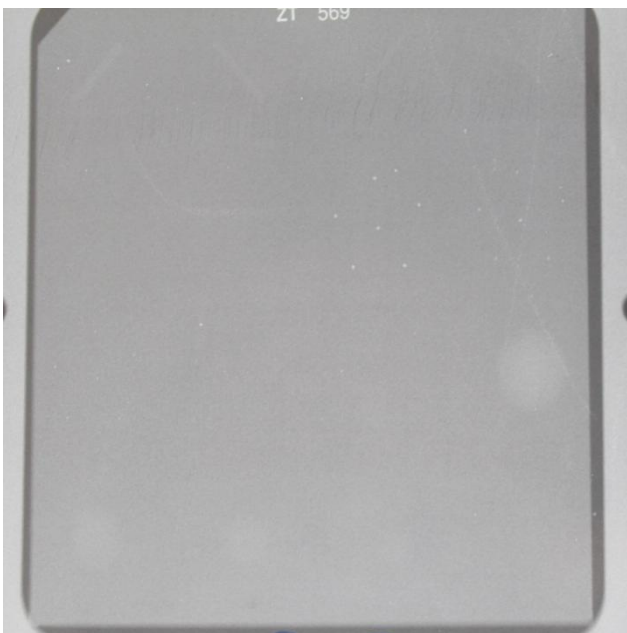
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Facility: Bethlehem x-ray machine name
M-IV : (Hologic)
AEC Mode: Auto-Filter

Resulting Techniques	Date	Tuesday	Wednesday	Sunday	Wednesday	Thursday	Monday	Monday	Monday
	Day	3/7/2018	11/7/2018	5/8/2018	15/8/2018	13/9/2018	17/9/2018	24/9/2018	22/10/2018
	Number of images	7879	8071	8183	8223	8351	8471	8591	8679
	Kvp	28	28	28	28	28	28	28	28
	Mas	60	62.1	62.1	68.2	72.1	62.2	60	61
ACR DM phantom	Fiber score	6	4	6	4	4	4	6	5
	Speck group score	3	4	4	4	4	4	4	4
	Mass score	4	4	4	4	4	4	4	4
Overall Pass\ Fall		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Phantom test in Bethlehem.....Automate program



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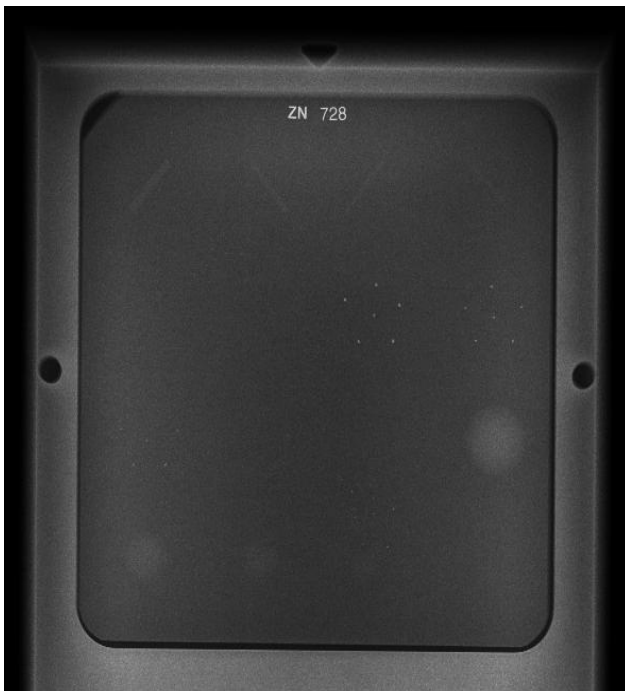
11/7



5\8



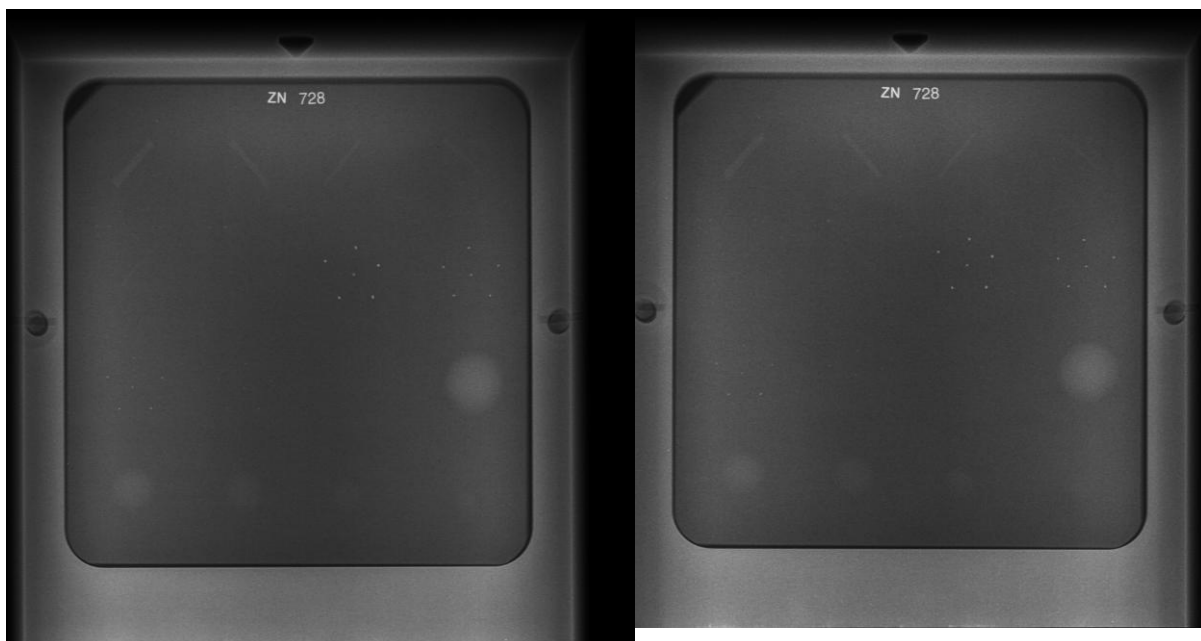
15\8



13\9



17\9

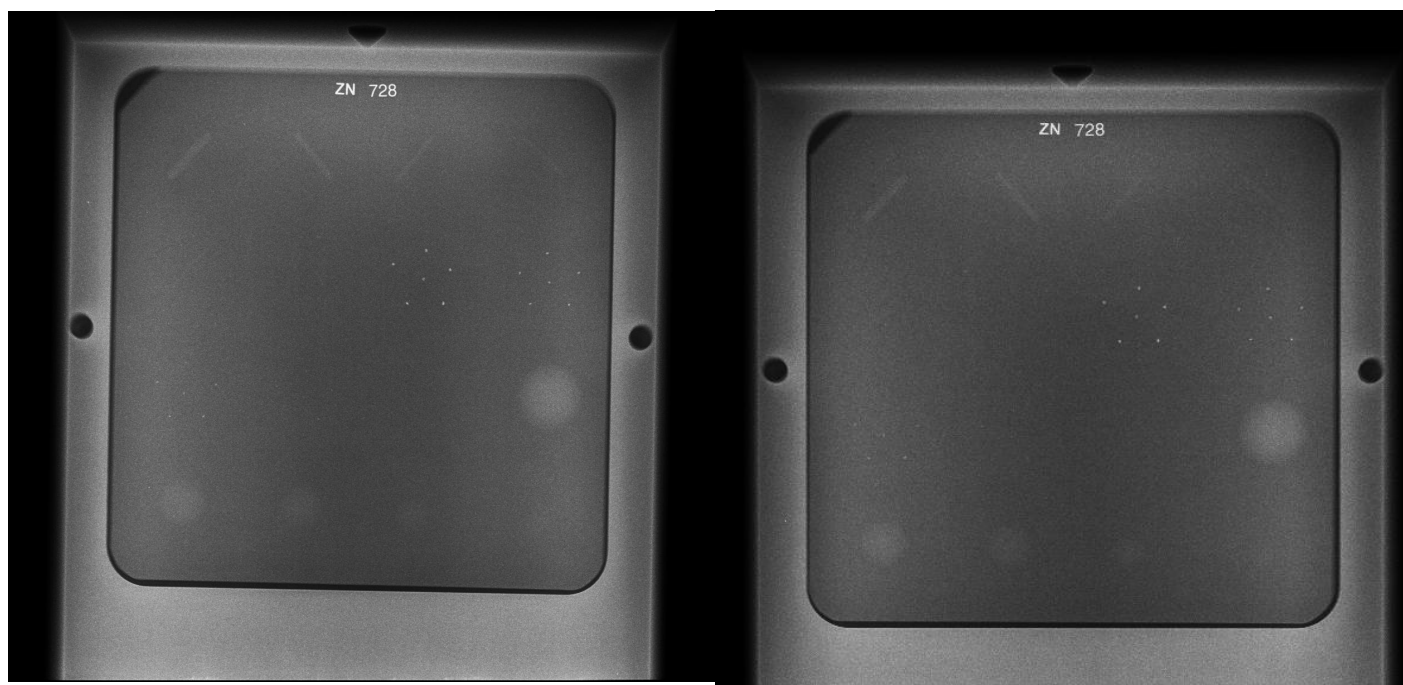


24\9

22\10

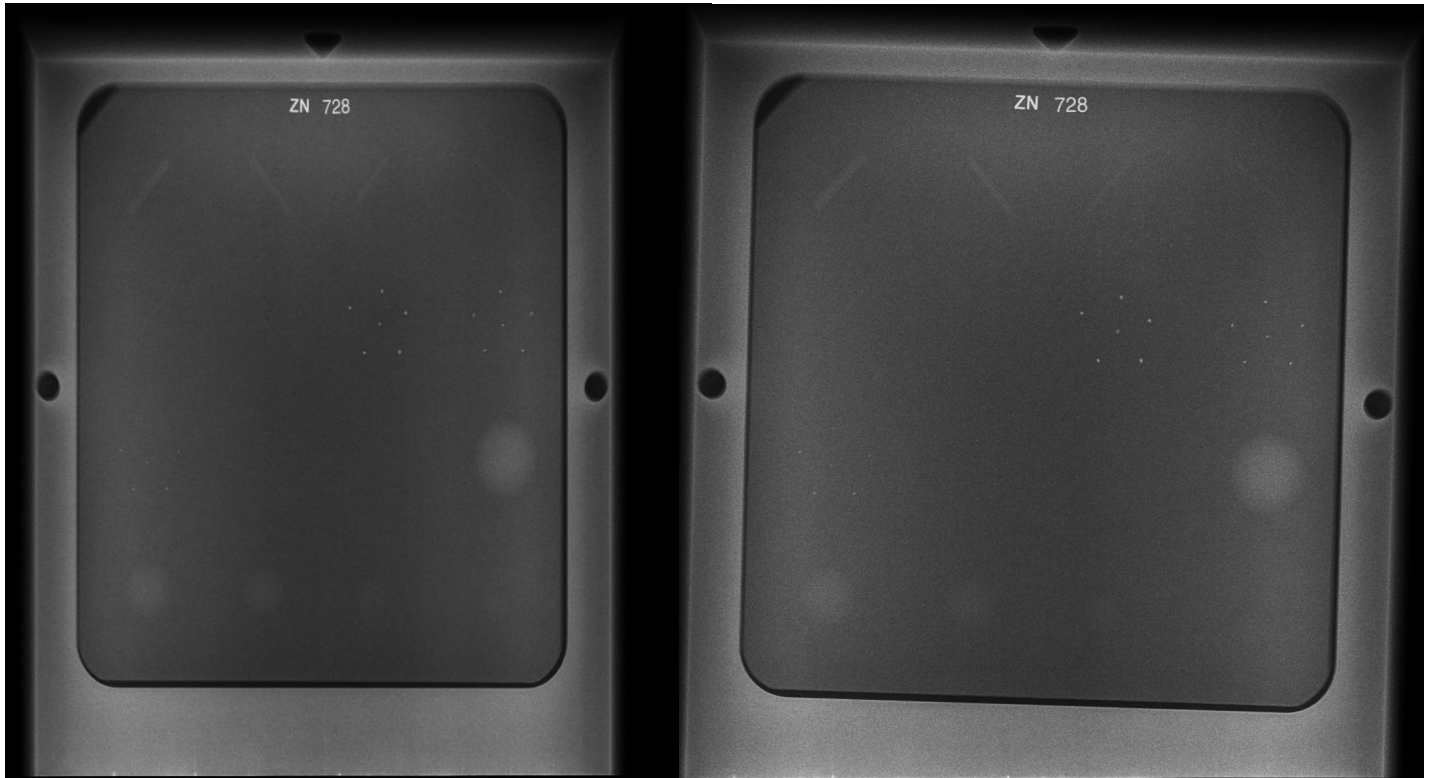
Facility: Bethlehem x-ray machine name
M-IV : (Hologic)
AEC Mode: Manual-Filter

	Date	Sunday	Wednesday	Thursday	Tuesday	Tuesday	Thursday	Monday	Monday
Resulting Techniques	Day	5/8/2018	15/8/2018	13/9/2018	17/9/2018	24/9/2018	4/10/2018	15/10/2018	22/10/2018
	Number of images	7919	8099	8219	8347	8467	8647	8719	8767
	Kvp	28	28	28	28	28	28	28	28
	mAs	100	100	100	100	100	100	100	100
ACR DM phantom	Fiber score	4	4	5	5	4	4	5	4
	Speck group score	4	3	4	4	3	3	3	3
	Mass score	4	4	4	4	4	4	4	4
Overall Pass\ Fall		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass



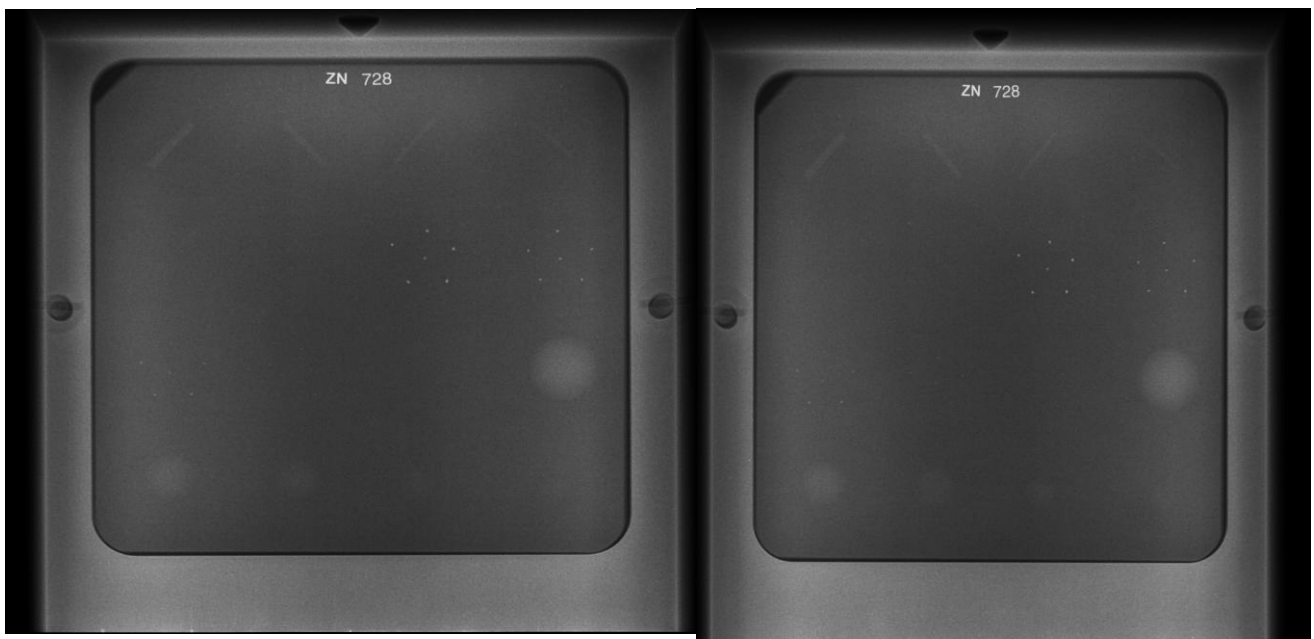
5\8

15\8



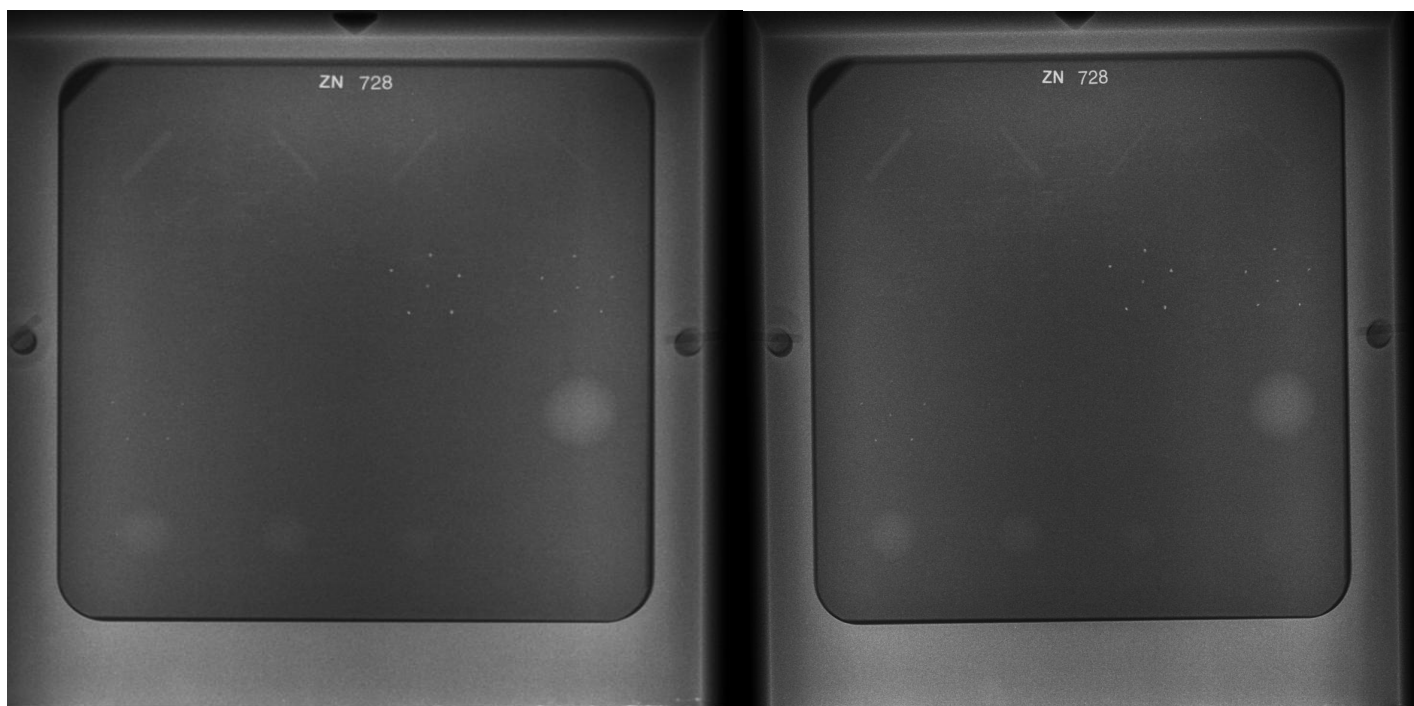
13\9

17\9



24\9

4\10



15\10

22\10

Facility: Durax-ray machine name
M-IV :(Hologic)
Model: ASY-00555AEC
Mode:Auto-Filter

Resulting Techniques	Date	Tuesday	Thursday	Wednesday	Sunday	Tuesday	Sunday	Wednesday	Sunday
	Day	17/7/2018	19/7/2018	25/7/2018	29/7/2018	31/7/2018	5/8/2018	8/8/2018	12/8/2018
	Number of images								
	Kvp	7000	7008	7020	7024	7024	7036	7040	7040
	mAs	28	28	28	28	28	28	28	28
ACR DM phantom	Fiber score	76	69.3	70.3	70.4	72	72.3	70.4	96.3
	Speck group score	4	5	5	5	5	5	5	5
	Mass score	3	4	4	4	4	4	4	4
Overall Pass\ Fall		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

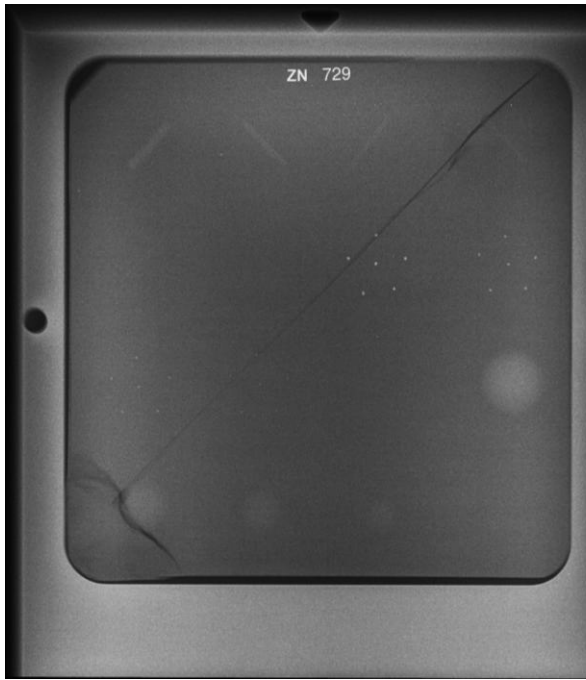
Phantom test in DuraAutomate program



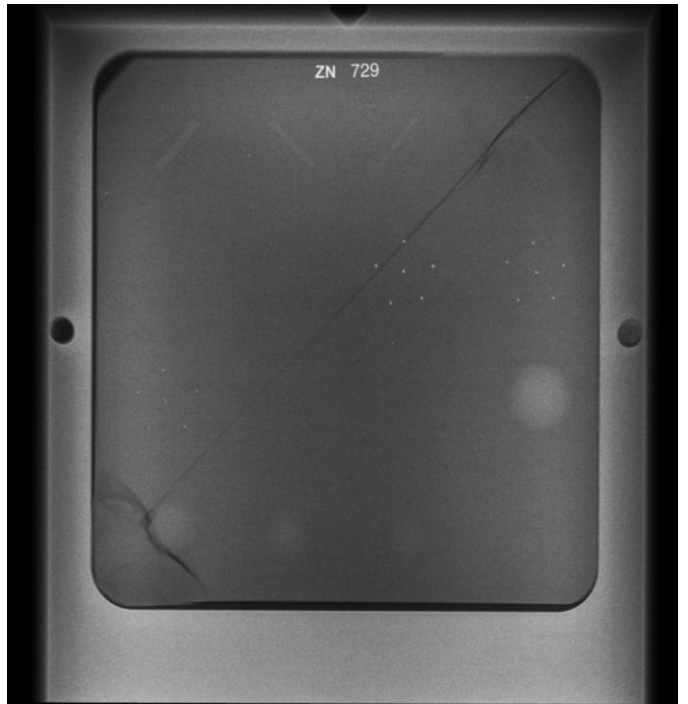
17\7



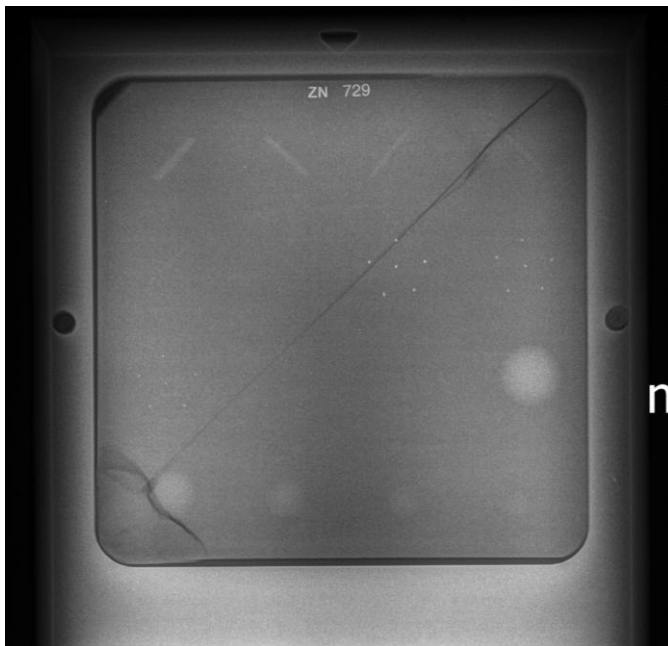
19\7



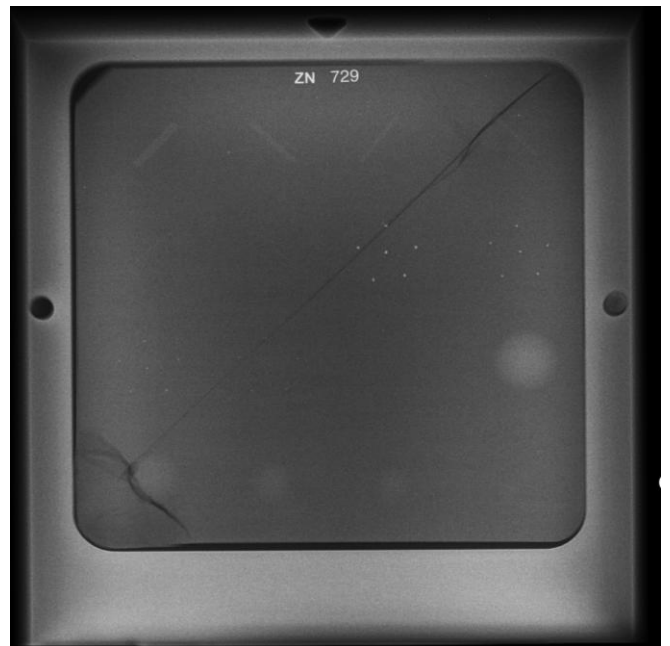
25\7



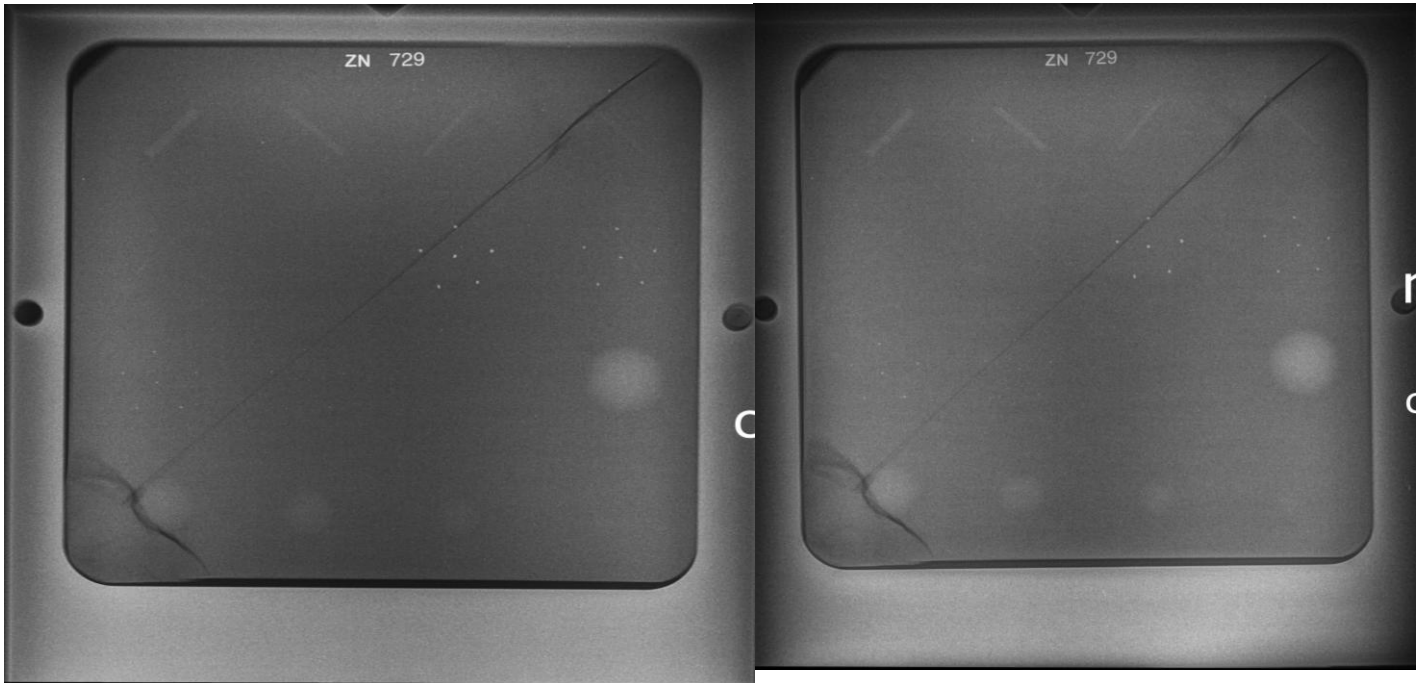
29\7



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5\8



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12\8

Facility: Dura x-ray machine name
M-IV: (Hologic)
Model: ASY-00555AEC
Mode: Manual-Filter

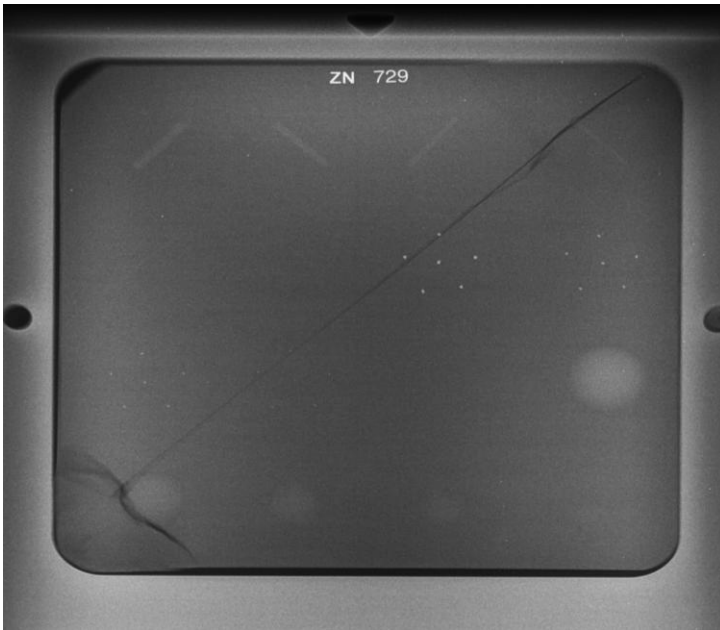
Resulting Techniques	Date	Tuesday	Thursday	Wednesday	Sunday	Tuesday	Sunday	Wednesday	Sunday
	Day	17/7/2018	19/7/2018	25/7/2018	29/7/2018	31/7/2018	5/8/2018	8/8/2018	12/8/2018
	Number of images	7004	7004	7012	7024	7028	7028	7040	7044
	Kvp	28	28	28	28	28	28	28	28
	mAs	80	80	80	80	80	80	80	80
ACR DM phantom	Fiber score	5	5	5	5	5	6	6	5
	Speck group score	4	4	4	4	4	4	5	4
	Mass score	4	4	4	4	4	4	4	4
Overall Pass\ Fall		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass



19\7



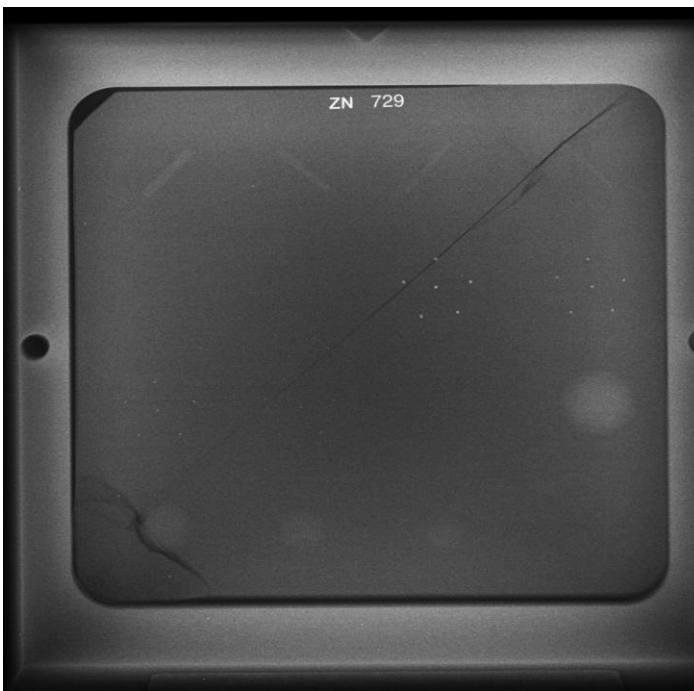
17\7



25\7



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31\7



5\8



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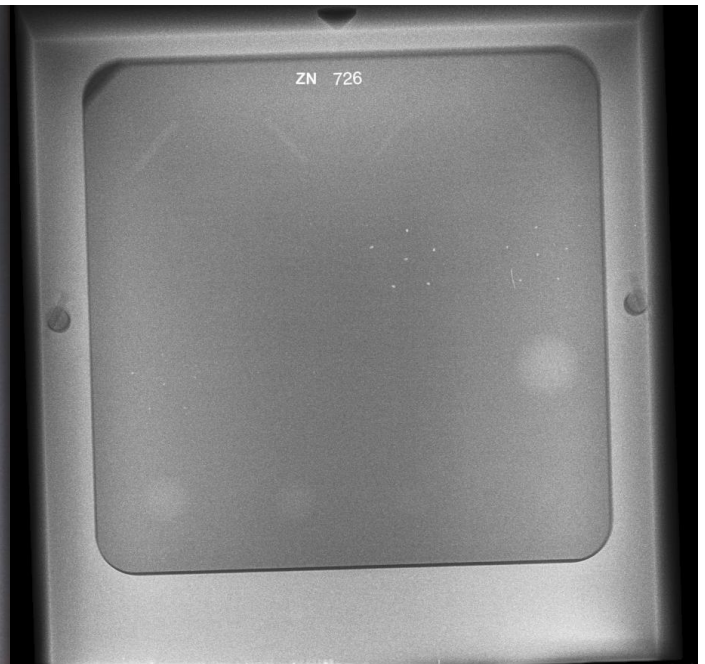
Facility: Tubas x-ray machine name
M-IV : (Hologic)
Model: ASY-00555
AEC Mode: Auto-Filter

Resulting Techniques	Date	Monday	Tuesday	Thursday	Wednesday	Wednesday	Thursday	Tuesday	Tuesday
	Day	9/7/2018	24/7/2018	2/8/2018	5/9/2018	12/9/2018	20/9/2018	25/9/2018	2/10/2018
	Number of images	2600	2604	2604	2608	2616	2628	2632	2644
	Kvp	28	28	28	28	28	28	28	28
	mAs	30	31.9	33.2	38.7	38.6	38.6	26.3	27.3
ACR DM phantom	Fiber score	4	4	4	4	5	5	5	4
	Speck group score	3	3	3	4	4	3	4	3
	Mass score	4	4	4	4	4	4	4	4
Overall Pass\ Fall		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

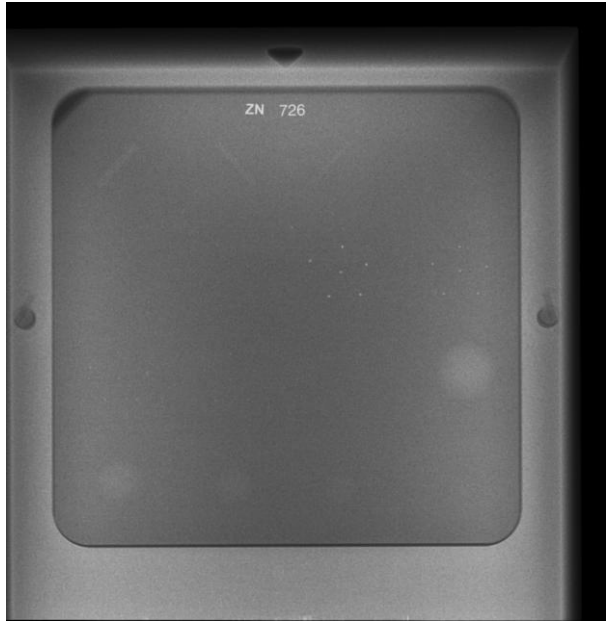
Phantom test in Tubas.....Automate program



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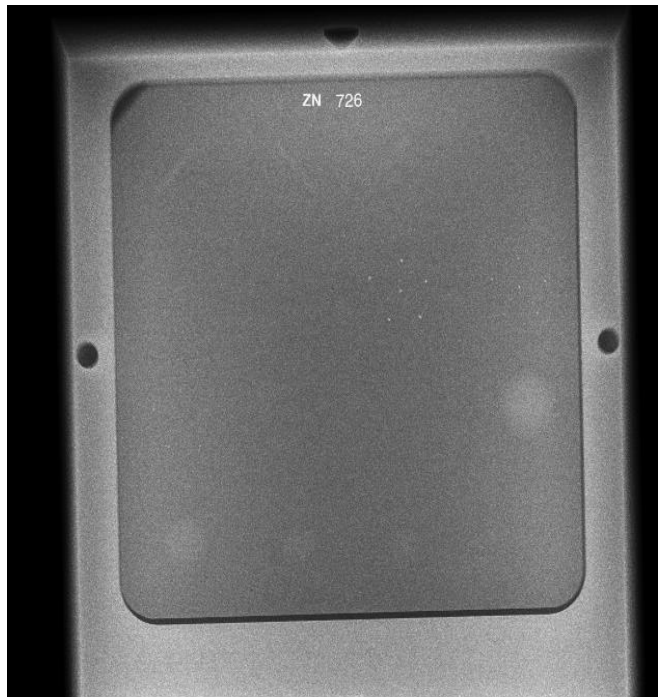
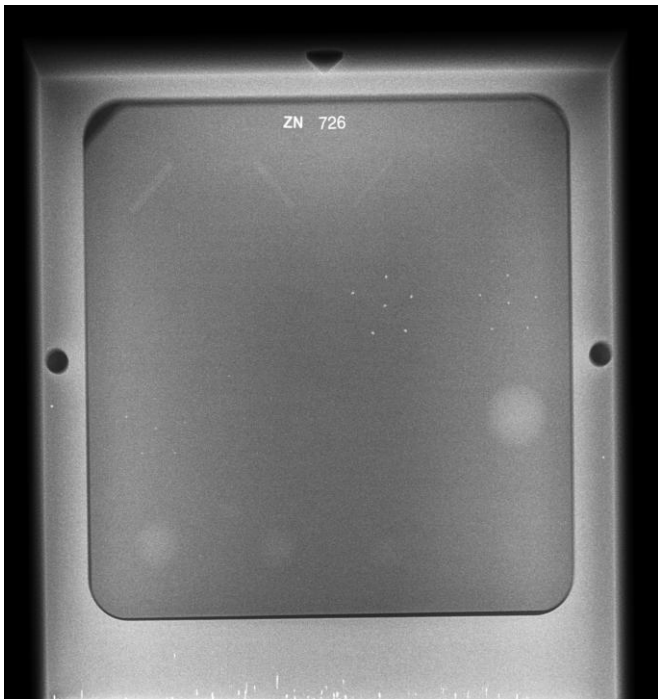


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2\8

5\9

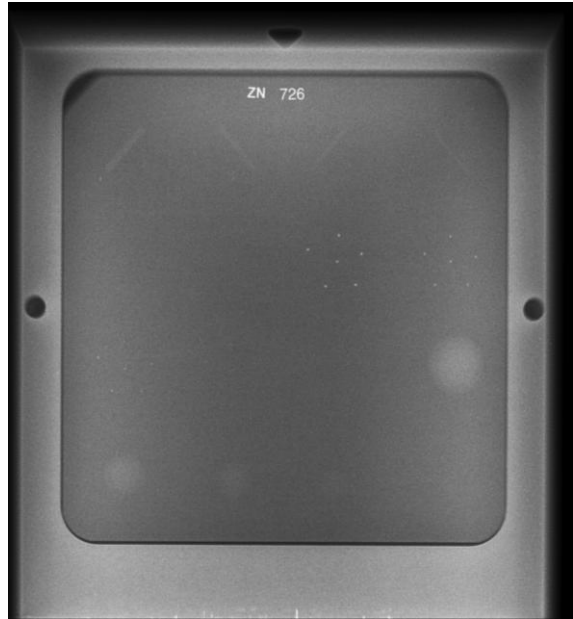


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20\9



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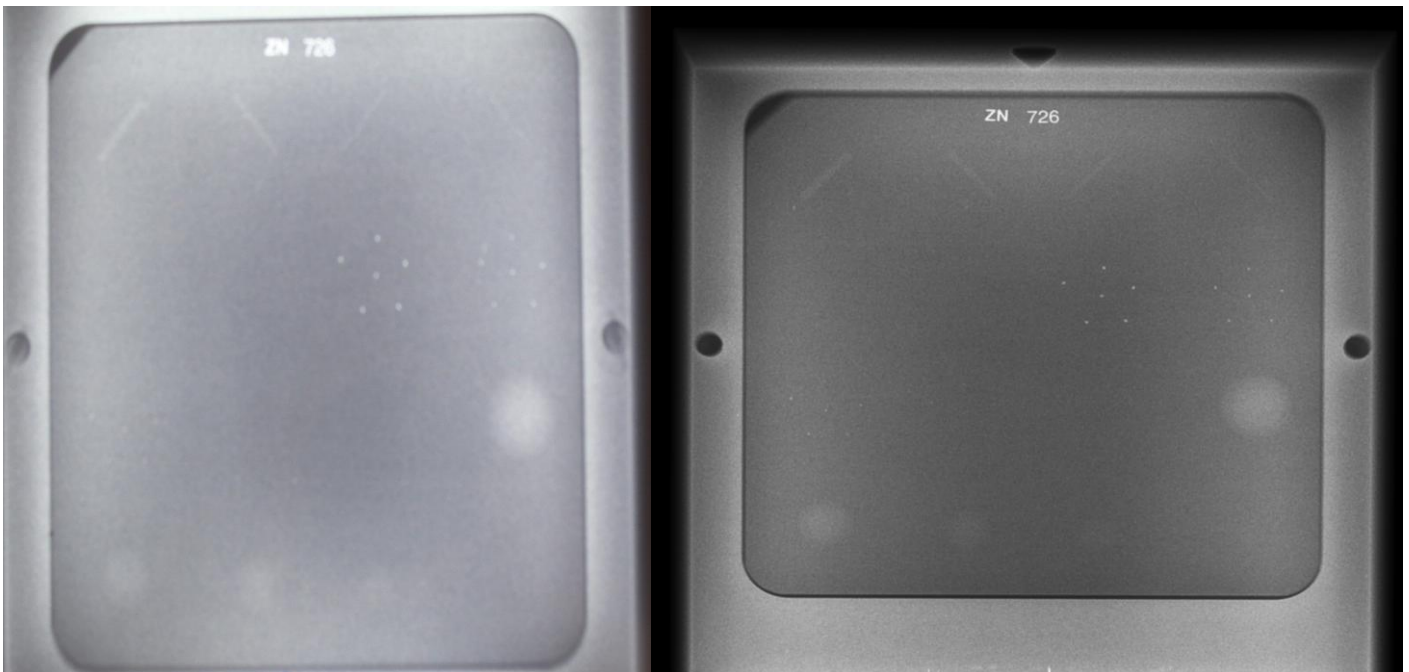


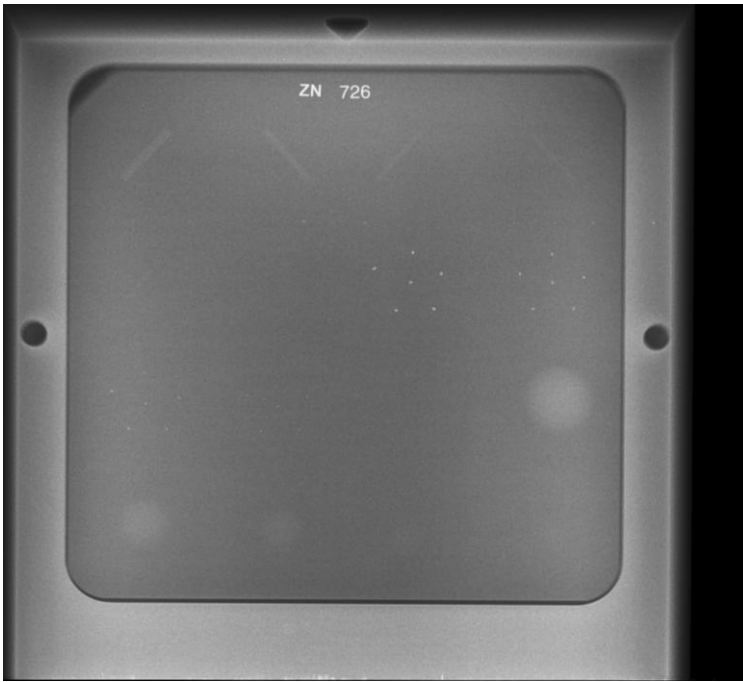
2\10

Facility: Tubas x-ray machine name
MI-V : (Hologic)
Model: ASY-00555
AEC Mode: Manual-
Filter

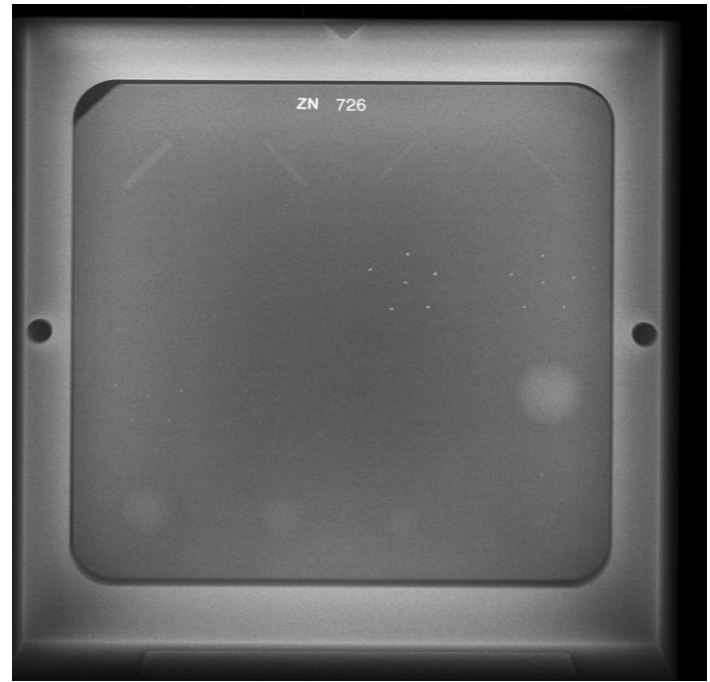
Resulting Techniques	Date	Sunday	Wednesday	Thursday	Tuesday	Tuesday	Thursday	Monday	Monday
	Day	2/9/2018	12/9/2018	25/9/2018	2/10/2018	7/10/2018	11/10/2018	16/10/2018	21/10/2018
	Number of images	2640	2600	2608	2612	2624	2628	2628	2628
	Kvp	28	28	28	28	28	28	28	28
	mAs	80	80	80	80	80	80	80	80
ACR DM phantom	Fiber score	5	4	6	6	6	5	6	5
	Speck group score	4	3	4	4	4	4	4	4
	Mass score	4	4	4	4	3	4	4	4
Overall Pass\ Fall		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Phantom test in Tubas.....Manual program

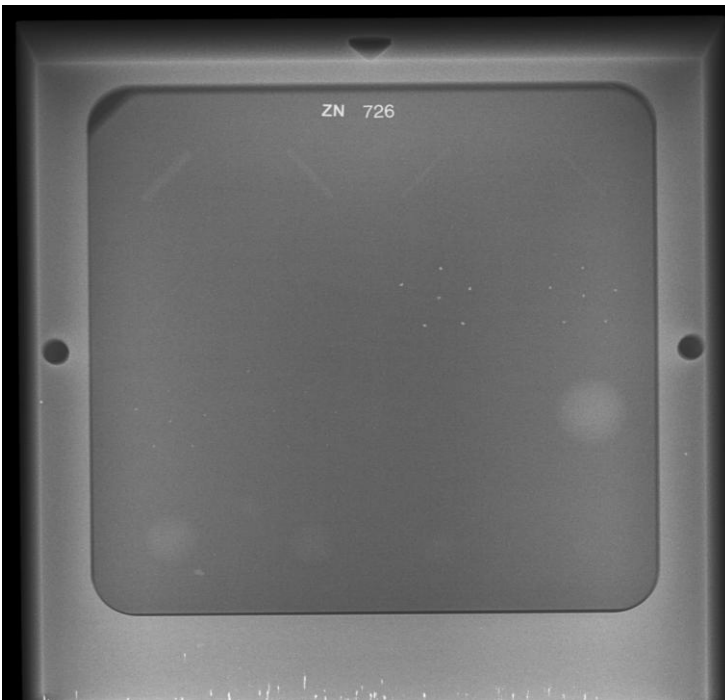




25\9



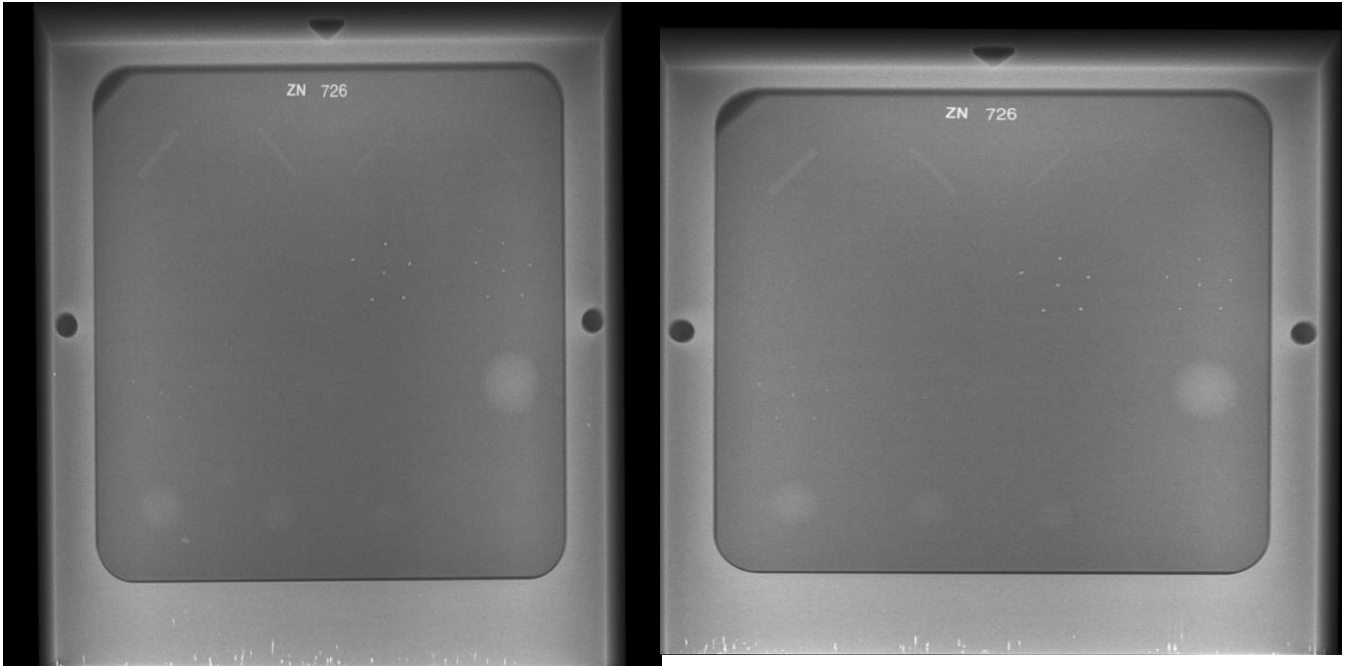
2\10



7\10



11\10



16\10

21\10

Facility: Nablus X-ray machine name
M-IV: (Hologic)
Model: villa

Resulting Technique s	Date	Sunday	Sunday	Monday	Monday	Sunday	Sunday	Sunday	Sunday
	Day	8/7/2018	15/7/2018	23/7/2018	30/7/2018	5/8/2018	12/8/2018	26/8/2018	2/9/2018
	Number of images	1991	2076	2156	2232	2292	2332	2360	2400
Overall Pass\ Fall		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass



8\7



15\7



23\7



30\7



5\8



12\8



26\8

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city	x-ray machine name	manufacturing by	serial#	model	type of phantom	years of manufacturing	Starting of uses	uses
Nablus	melody -B	Italy	4010141	villa	artifact identification phantom	2004	2012	Use/ <i>Augusta Victoria Hospital</i>
Hebron	M-IV (Hologic)	USA	18012096316	ASY-00555	Mammographic accreditation phantom	2009	2012	new
Qalqilya	M-IV (Hologic)	U.SA	19108127301	AST-00581	Mammographic accreditation phantom	2010	2011	new
Jericho	M-IV (Hologic)	U.SA	19112096563	ASY-00581	Mammographic accreditation phantom	2009	2011	Use/ Al-Hussein Governmental Hospital /BeitJala
Al-ram	M-IV (Hologic)				Mammographic accreditation phantom	2012	2013	new
Bethlehem	M-IV (Hologic)	USA	1.95071E+11		Mammographic accreditation phantom	2012	2013	new
Dura	M-IV (Hologic)	U.SA	18007106491	ASY-00555	Mammographic accreditation phantom	2010	2011	new
Tubas	M-IV (Hologic)	U.SA	18008127006	ASY-00555	Mammographic accreditation phantom	2012	2013	New

	x-ray film processor	manufacturing by	serial #	model	years of manufacturing
Nablus	Manual	Germany	110-0905-12	OPTIMAX	2009
Hebron		Germany	117110-1211-12818	OPTIMAX	2013
Qalqilya	Manual	Germany	117110-0910-12284	OPTIMAX	2014
Jericho	Manual	Germany	117110-0910-12285	OPTIMAX	2014
Al-ram	Manual			OPTIMAX	2013
Bethlehem	CR	Germany	5179/100	HPI5243	2015
Dura	CR	Germany	5179/100	HPI5243	2017
Tubas	CR	Germany	5179/100	HPI5243	2015

Classifying Selected West Bank Directorates Represented by Departments

Department 1	Dura
Department 2	Hebron
Department 3	Qalqilya
Department 4	Jericho
Department 5	Bethlehem
Department 6	Tubas
Department 7	Nablus
Department 8	Al-Ram
Department 9	Al-Bireh
Department 10	Salfit
Department 11	Jenin
Department 12	Tulkarm

Examining Device Type(new- second hand) in selected West Bank Departments

Directorate represent	New Device	Second hand device Device
Department 1	√	
Department 2	√	√
Department 3		
Department 4		√
Department 5	√	
Department 6	√	
Department 7		√
Department 8		√

الملخص

تتضمن مراقبة الجودة في التصوير الشعاعي للثدي إجراءات فحص بسيطة تضمن تشغيل نظام التصوير الشعاعي للثدي وفقاً للمعايير المعمول بها. في الضفة الغربية ، لم يتم العثور على دراسات للتحقق من مراقبة الجودة في نظام التصوير الشعاعي للثدي. هناك عدة أنواع من الإجراءات المستخدمة للتحقق من مراقبة الجودة ، مثل الأدوات الوهمية. الهدف الرئيسي من هذه الدراسة هو التحقق من أنظمة التصوير الشعاعي للثدي المتوفرة في مديريات الصحة المختارة في الضفة الغربية من 12 دائرة ، ودراسة العوامل التي تؤثر على جودة الصورة المنتجة. استخدم الباحث شبح اعتماد التصوير الشعاعي للثدي ACR للتحقيق في مراقبة الجودة في نظام التصوير الشعاعي للثدي في مديريات الصحة المختارة وفنيي المقابلات باستخدام فانتوم لتقييم صحة الجهاز أثناء التصوير الشعاعي للثدي.

اعتمدت هذه الدراسة الاستقصاء الملائم والمستعرض ، استناداً إلى البيانات التي تم جمعها من مديريات الصحة المذكورة أعلاه من خلال فحص نظام التصوير الشعاعي للثدي لمدة ستة أشهر ، من أجل التحقق مما إذا كانت جودتها تؤثر على صورة واحدة. من خلال الدراسة ، خلص الباحث إلى أن الفنيين ، الذين يعملون على نظام التصوير الشعاعي للثدي في هذه المديريات ، لا يعرفون ما هو الوهمية وكانوا قد فحصوا فقط جودة نظام التصوير الشعاعي للثدي في مديريةية الصحة في القسم 1.

وجد الباحث أيضاً أن هناك عوامل أخرى تؤثر على جودة الصورة ، مثل طريقة المعالجة وكفاءة الجهاز والتقنية المستخدمة ، كما هو الحال بالنسبة لجودة الصورة في جميع الأقسام ، تم العثور على أولئك الذين يستخدمون نظام معالجة CR لإنتاج صورة جيدة الجودة . يجب أن يكون نظام التصوير الجيد قادراً على رؤية ثلاث مجموعات تتحدث وأربعة ألياف وثلاث كتل. من ناحية أخرى ، لم تنتج المديريات التي تستخدم أفلام الشاشة صوراً جيدة النوعية ولم يستطع اختصاصيو الأشعة رؤية التفاصيل ، لذا فقد يكررون الصور. لذلك ، يوصي الباحث بأن وحدة الأشعة يجب أن تعطي تعليمات للفنيين لمعايرة أجهزة التصوير الشعاعي للثدي بشكل دوري ؛ على الوحدة الهندسية بوزارة الصحة إجراء الصيانة لهذه الأجهزة.