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X-Ray Compliance Testing of a Mammography System on Manufacturing Line

Dose Reproducibility & Linearity

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This thesis was made for GE Healthcare Finland Oy. Advanced Manufacturing Engineering Test department in Finland is designing a new mammography testing equipment for GE Healthcare's manufacturing line in Buc, France.

Breast cancer, after lung cancer, is the second most fatal cancer for women. GE Healthcare manufactures many mammography products. These products need to be tested on the manufacturing line to be compliant with medical standards and regulations.

Dose Reproducibility and Linearity is a regulatory test where the main criteria is to make sure that with the same parameters of the exposure the dose will be same for each performed exposure. The dose produced by the x-ray exposure needs to be consistent.

In this thesis the test sequence for the manufacturing line was designed. Test sequence was made by using TestStand, a software developed by National Instruments. Main goal in creating the test sequence was to automate as many features as possible. After the equipment is installed in the beginning of the test, there is no more actions for the operator in the manufacturing line to perform. Test sequence will set the parameters for the exposures automatically, take the exposure and record dose values from the dosimeter as well as calculate the reproducibility and linearity values.

Keywords	Mammography, X-Ray, Dose, Automated Testing

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Insinöörityö tehtiin GE Healthcare Finland Oy:lle. Advanced Manufacturing Engineering Test osasto tekee Suomessa uutta mammografialaitteen testauslaitetta, joka tulee käyttöön GE Healthcaren Ranskan toimipisteessä, Bucin kaupungissa.

Rintasyöpä on keuhkosyövän jälkeen toiseksi vakavin syöpä naisilla kuolleisuuden mukaan. Digitaalinen mammografia on pystynyt parantamaan mammografian diagnostista kykyä sekä vähentämään säteilyannosta, samalla parantaen otettujen röntgenkuvien kuvanlaatua.

GE Healthcare valmistaa useita mammografialaitteita. Mammografialaitteet täytyy testata tuotantolinjalla, jotta ne on valmistettu kaikkien standardien ja asetusten mukaisesti. Säteilyannoksen toistettavuus sekä lineaarisuus -testi on yksi monesta testistä, joilla testataan röntgensäteilyn tuottamaa säteilyannosta.

Säteilyannoksen toistettavuus ja lineaarisuus -testissä tärkeintä on varmistaa, että säteilyannos pysyy samana röntgenkuvien välillä kun käytetään samoja asetuksia.

Säteilyannoksen toistettavuus sekä lineaarisuus -testi tehtiin TestStand-ohjelmalla, jonka on tehnyt National Instruments. Tärkeintä testijonon tekemisessä oli tehdä siitä mahdollisimman automaattinen. Tuotantolinjalla oleva käyttäjä asettaa testin alussa mittalaitteet, sekä muut tarvittavat työkalut laitteelle, jonka jälkeen testaus tapahtuu automaattisesti. Testijono asettaa tarvittavat asetukset kuvien ottamiselle, ottaa röntgenkuvat, tallentaa säteilyannokset ja laskee toistettavuuden sekä lineaarisuuden.

Avainsanat	Mammografia, Röntgensäteily, Säteilyannos, Automaattinen testaus

Contents

List of abbreviations

GE – General Electric
AME – Advanced Manufacturing Engineering
RBE – Relative Biological Effectiveness
HVL – Half-Value Layer
PMMA – Polymethylmethacrylate
SNR – Signal-to-Noise Ratio
ACR – American College of Radiology
FDA – Food and Drug Administration
MQSA – Mammography Quality Standards Act
CFR – Code Federal Regulation
AEC – Automatic Exposure Control
IEC – International Electrotechnical Commission
ALARA – As Low As Reasonably Achievable
CAN – Controlled Area Network
UUT – Unit Under Test
SSH – Secure Shell Network
eDHR – electronic Device History Record
AOP – Automatic Optimization of Parameters

1 Introduction

The goal of this thesis was to design an automated test sequence to be used in the manufacturing line, to verify the dose reproducibility and linearity of the Mammography system. Thesis was made for GE Healthcare Finland Oy. GE Healthcare is one of the world's leading medical technology companies. GE Healthcare has over 50 000 employees around the world, where over 750 work in Finland. [1] GE Healthcare Finland focuses on anaesthesia and respiratory care units. Advanced Manufacturing Engineering (AME) Test department in Finland is designing a new mammography testing equipment for GE Healthcare's manufacturing line in Buc, France.

Breast cancer, after lung cancer is the second most fatal cancer for women. Key in decreasing the deaths caused by breast cancer is mammography screening. In mammography screening, a large group of women are called for mammograms to see if women have cancer cells in the breast tissue or even a cancer tumour. Mammography screening made in the early phase of the cancer decreases the death rate from breast cancer. [2]

Old mammography systems were based on film-screen technology. This involved cassettes of film to be placed on top of the detector, and this film was then developed so that the radiologist could examine the image. This technology has been replaced with the digitalization of mammography, where the screen-film was replaced by a digital detector. Digital mammography has been able to decrease the dose from the x-ray exposure as well as increase the image quality, to improve the overall quality of mammography.

GE Healthcare manufactures many mammography products. These products need to be tested on the manufacturing line to be compliant with medical standards and regulations. The Dose Reproducibility and Linearity is one of the tests that focus on the dose from the x-ray exposure. Dose for the patient shall be kept as low as reasonably achievable and consistent between the exposures.

Dose Reproducibility and Linearity test is a part of the automated tests that shall be done in the manufacturing line to test mammography systems. Test sequence was made with TestStand and LabVIEW software, which are developed by the National Instruments.

2 Theory of X-Ray Mammography

Theory behind this thesis includes several factors concerning the x-ray characteristics, which affect the absorbed dose for the patient. Mammography is explained and the main focus will be on the digital systems, but film-screen mammography is also discussed. Regulations and standards of the medical business are of high importance, so the main regulations and standards concerning mammography are discussed and explained.

2.1 X-Ray in Mammography

X-ray radiation is electromagnetic radiation that has a quality of passing through many materials that are opaque to light, which is due to its high energy and short wavelength of 0.1 to 10 nanometres. [3]

X-rays are widely used in medical industry for imaging the inner organs, bones and in search of tumours inside the human body such as cancer in the breast.

X-ray tube is made of glass and inside there is a vacuum. Inside of the glass chamber, there are two main parts, anode and cathode. A high-voltage is connected to the tube and the positive pole is connected to the anode. Design for the x-ray tube can be seen in the figure 1. [4]

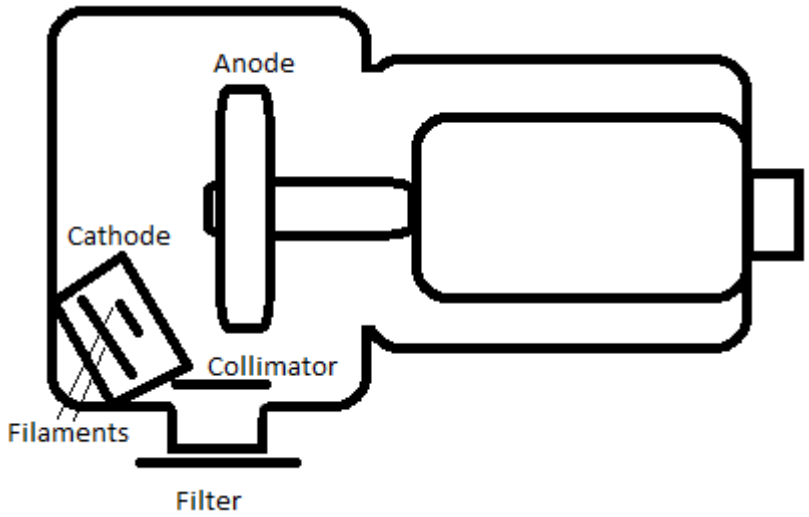

Figure 1 Mammography X-ray tube

Anode is a shaft that has rotor inside the x-ray tube. Outside of the tube, there is stator that is connected to AC voltage, which causes alternating magnetic fields and turns the rotor. Cathode is connected to the negative pole, so that the electrons inside the tube are going from cathode to the anode with high velocity.

Cathode has two wire filaments inside of it. Filaments are heated up with so called filament current and when the filament heats up it emits electrons. As electrons are emitted from cathode filament, the high-voltage connected to the anode and cathode makes these electrons to accelerate towards the anode. When these electrons hit the focal spot of the anode they produce x-rays. [4]

2.1.1 X-Ray Exposure

When x-rays interact with matter, they cause ionization. X-rays can be measured with an ionization chamber which is filled with air and on the outer sides there are positive and negative electrodes. The device is called Dosimeter, which is shown in the figure 2 below.

Figure 2 Dosimeter

When x-rays interact with the air molecules in the chamber, they ionize and the electrons are collected on the positive electrode and negative electrode collects the positive ions.

Exposure X is a deviation of the ionized electrons in air, which have an electrical charge Q, which is divided by the mass of the air. As shown in the formula 1 below.

$$X = {}^{Q}/_{m} \quad (1)$$

[5,54]

The measurement unit of the exposure is roentgen [R], where:

$$1\ R = 2.58 \times 10^{-4}\ C/kg \quad (2)$$

Unit is Coulomb per kilogram. With a 1-R exposure, air absorbs energy as the formula 3 shows:

$$2.58 \times 10^{-4}\ C/kg \times 33.97\ J/C = 0.00876\ J/kg = 87.6\ ergs/g \quad (3)$$

Where 33.97 Joule per Coulomb is an average energy to produce ion pair in air and erg is a unit of 10^{-7} Joule. An exposure can be converted into the dose absorbed by the air D_{air} since 1 R = 100 ergs/g:

$$D_{air} = 0.876X \quad (4)$$

Joule per kilogram is one Gray, then 1 Gy = 100 Rads, this 1-R exposure produces a dose in the air of 8.76 mGy. If the x-rays are absorbed in other matter than air, the equation can be derived to:

$$D_{med} = f\ X \quad (5)$$

Where f is the factor determining the energy-dependency of the material and X stands for exposure. In Europe exposure is usually defined as air Kerma which stands for kinetic energy released per unit mass. Air Kerma is the sum of charged particles that release kinetic energy to a unit mass, in this case to air. [4]

2.1.2 Equivalent Dose

Relative biological effectiveness is used to define biological harm for the human body. Different radiation types have different RBE based on their characteristics. X-ray of 1 mGy has lower RBE than for example alpha particle with 1 mGy. That's why equivalent dose is used. It is defined as:

$$H = w_r D, \tag{6}$$

D stands for the dose in unit of Grays, and w_r is a weighting factor that defines the radiation used to deliver the dose D. X-rays used in radiology have w_r of 1, when for example alpha particles have a weighting factor of 20. The unit for equivalent dose is Sievert (Sv) and one Sievert is 1 J kg^{-1}. [5,56]

2.1.3 Effective Dose

In most cases of radiology, only small part of human body is used for imaging. That's why there is the effective dose E, which scales the equivalent dose to the small portion of the body. For effective dose, the w_t is weighting factor for tissue, so the equivalent dose can be measured for each type of tissue:

$$E = \sum_{t=0}^{N} w_t H_t \tag{7}$$

Effective dose is also displayed as Sieverts. Tissue weighting factors are for example: Breast = 0.05, Lungs = 0.12 and skin = 0.01. [Values from table 1.8]

2.1.4 Half-Value Layer

Half-value layer is a term to measure attenuation of the exposure through material. It is usually calculated using aluminium. HVL calculates the aluminium thickness needed to reduce exposure to half. HVL is only measured with an air-filled exposure meter, because other systems will give different results since exposure is defined in air only. When using higher tube voltage the HVL value will increase and with a lower tube voltage the HVL value decreases, since the x-rays attenuate more in thicker material.

2.1.5 Typical Breast Dose

Typical dose that is absorbed by the breast can be simulated with a phantom block that is made of polymethylmethacrylate (PMMA) which is acrylic glass, simulating the breast and using the normal parameters of exposures selected in a mammography exam. A phantom made of PMMA is shown in the figure 3 below. [6,157]

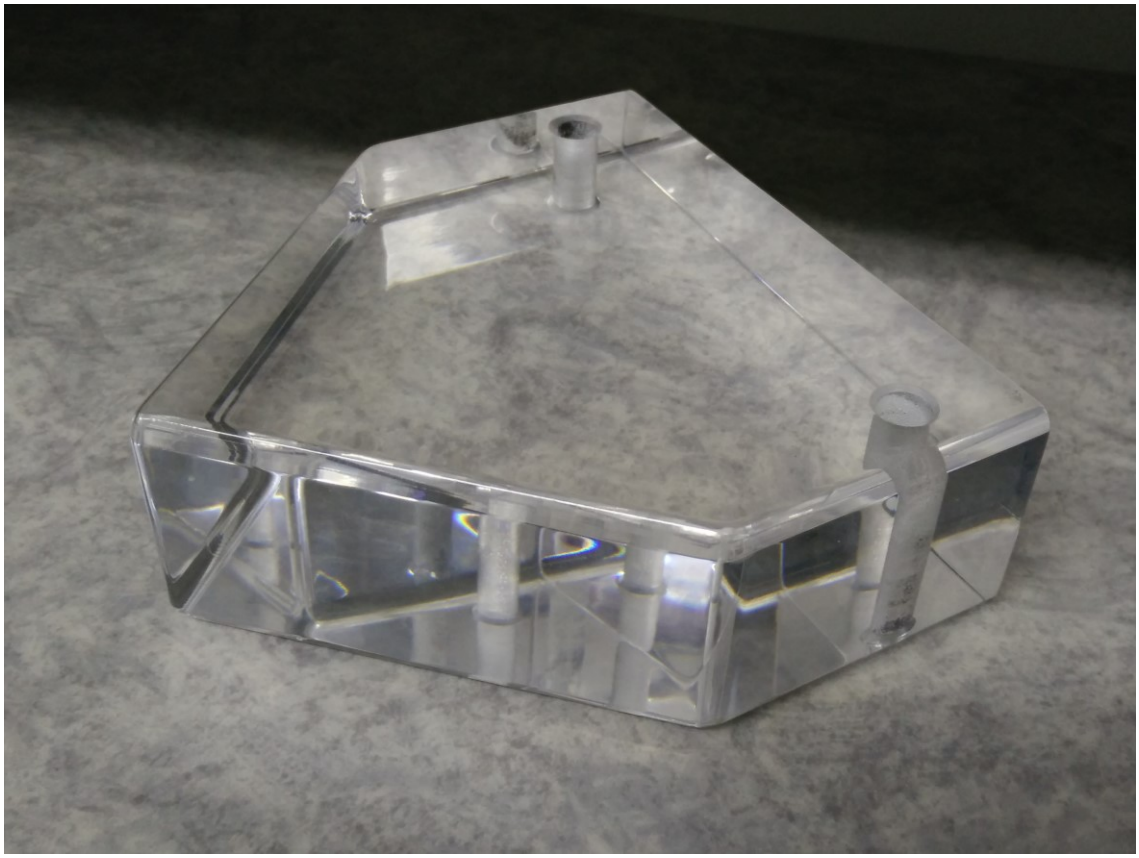

Figure 3 Phantom block made of PMMA.

PMMA is not identical to the breast tissue, since it's denser but they both have similar attenuation factors, this is why it is the most used material to simulate the breast in mammography.

To calculate the average dose absorbed to breast tissue, multiple exposures with different PMMA thicknesses are needed. Thicknesses are specified in European Guidelines for Quality Assurance in Breast Screening and Diagnosis to be from 20 mm to 70 mm with an increment of 10 mm. Average glandular dose can be then calculated with a formula of:

$$D = Kgcs \quad (8)$$

Average glandular dose is D, K is for air Kerma, and g-factor is a value of 50 % out of glandular tissue. Values of the g-factor can be found from the table 1. C-factor is also 50 % of glandular tissue, this needs to be taken in to account when using PMMA since it has different characteristics than normal breast tissue. Values for c-factor can be found from the table 2. S stands for dose level in typical simulated breast and the values for it can be found from table 3. [6,157]

Table 1 g-factors for breast simulated with PMMA [6, Table A5.1]

PMMA thickness (mm)	**Equivalent breast thickness (mm)**	**g-factor (mGy /mGy)**				
		HVL (mm Al)				
		0.30	*0.40*	*0.50*	*0.60*	*0.70*
30	32	0.261	0.326	0.388	0.448	0.495
50	60	0.135	0.172	0.214	0.261	0.300
70	90	0.086	0.111	0.136	0.172	0.202

To correct the difference from the PMMA material the c-factor with a 50% glandular tissue is used. C-factors can be found from the table 2 below.

Table 2 c-factors for breast simulated with PMMA

*(c-factor for typical breasts for women in the age of 50 to 64) [6, Table A5.2]

PMMA thickness (mm)	**Equivalent breast thickness (mm)**	**Glandular tissue of equivalent breast (%)**	**c-factor ***				
			HVL (mm Al)				
			0.30	*0.40*	*0.50*	*0.60*	*0.70*
30	32	67	0.940	0.945	0.949	0.953	0.959
50	60	20	1.164	1.151	1.144	1.134	1.117
70	90	4	1.299	1.282	1.270	1.249	1.225

Dose levels for typical breasts simulated with PMMA phantom can be seen from the table 3 which is taken from the European Guidelines for Quality Assurance in Breast Screening and Diagnosis.

Table 3 Dose levels for typical breasts simulated with PMMA [6, Table on page 83]

Thickness of PMMA (mm)	Equivalent breast thickness (mm)	Maximum average glandular dose to equivalent breasts (mGy)	
		Acceptable level	Achievable level
30	32	≤ 1.5	≤ 1.0
50	60	≤ 3.0	≤ 2.4
70	90	≤ 6.5	≤ 5.1

Table 3 shows that the dose for the equivalent breast simulated by the PMMA phantom is inside the acceptable level.

2.2 Mammography

Mammography is a medical imaging technique that serves a key role in detecting breast cancer at its early phase. For this purpose many trials of mammography screening were performed. Over the years many screenings have shown that the mammography examinations decrease the mortality of breast cancer. GE Senographe Essential Mammography system is shown in the figure 4 below.

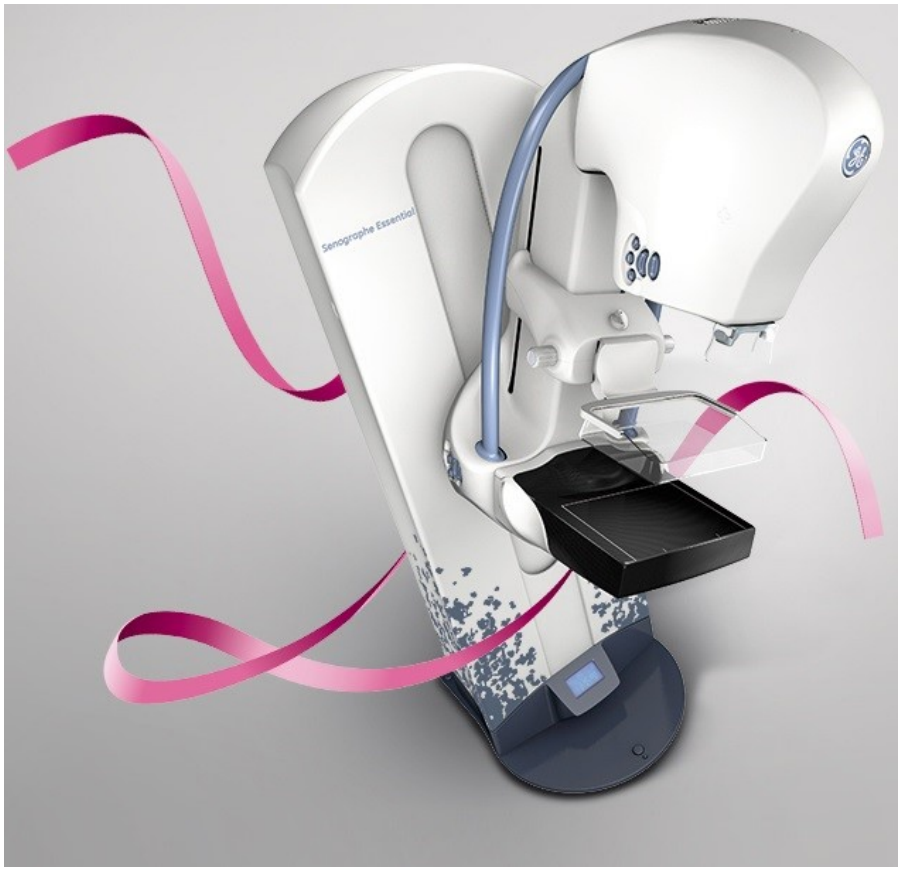

Figure 4 GE Senographe Essential Mammography System Copied from ge.com [7]

In mammography exam the breast is compressed with a paddle, so that the breast tissue is evened out in order to acquire an image that has no intertwining tissues that could hide cancer.

Old mammography method used a film-screen detector to acquire the image and the film was also used for showing the image to the radiologist. Digitalization removed this film with a digital detector that can transmit the image to the computer that has a specific monitor for radiological purposes. This means better contrast, better image quality and for the patient, the lower dose.

Screen-Film mammography system has three main parts. In mammography examination the first part is taking the image of the breast, which is often called as image acquisition. Then the captured image on film must be shown to the radiologist to analyse the breast for lesions. Then the image screen will be stored in an archive. So the three parts are image acquisition, displaying the image and storing the image taken.

In mammography the images can be taken with a reasonably low dose to the patient, because of the development of the mammography systems. The most advanced technology achievement that has helped in this progression is the digitalization of mammography.

There has been numerous trials to test out the differences of film-screen mammography and the digital mammography. The main difference between the film-screen and digital mammography was that the digital mammography has an advantage in specific groups of women which include women with dense breasts, younger women and women in premenopausal.

In digital mammography system, all of the parts are linked with the digital acquisition of the image, which can be shown on the computer screen to the radiologist and then stored in a database. If the image acquired is not sufficient enough for radiological purposes on its own, the computer can adjust the image to be more informative to the radiologist. Image properties can be adjusted, such as image contrast or zooming into parts of the image [8, 4].

2.2.1 Digital Mammography

In digital mammography systems a digital detector is used. Since the captured x-ray image is in digital format, the image data is described in pixels. Pixels lined in some shape make a matrix of pixels that displays the image. The images acquired by the digital detector display the breast tissue with different volumes as shades of grey. [8, 9]

In mammography images there are two properties that need to be thought of: noise and practical contrast. In film-screen mammography the practical contrast is more critical since the contrast cannot be altered afterwards like in digital mammography. In digital mammography where the contrast can be altered, the lack of noise in the image is more important.

Quantum Noise is a term that comes from the changing number of x-rays attenuated around the breast tissue. Standard deviation for Quantum Noise is:

$$\sigma = \sqrt{(n)} \tag{9}$$

The n in the formula is the average of the number of x-rays in specified region of breast. This n is the number of x-rays that will produce the image to the detector and it can be referred to as n_d. This number must be increased to improve the clearness of the image i.e. reduce noise. The chosen current-time product (mAs) affects this number by direct relation. Increasing current-time product increases the number of x-rays that will produce the image to the detector.

To reduce the noise of the image, it is needed to understand the concept of signal-to-noise-ratio (SNR), which is a ratio of σ and n_d:

$$\text{SNR} = \frac{(n_d)}{\sqrt{(n_d)}} = \sqrt{(n_d)} \tag{10}$$

By increasing the current-time product SNR is increased, therefore resulting to a clearer image. [9, 6 (formula 1.8)]

Spectrum of the x-ray is based on two parameters of the x-ray tube, the filter and the voltage. Filter metal which is often Molybdenum or Rhodium filters the beam and the high voltage activates the tube, which results in an exposure.

In screen-film mammography the average parameters of Molybdenum filter, Molybdenum target and a voltage of 26 kV create a significantly higher dose into the average breast to get higher value of SNR. Digital mammography can use higher energies to lower the dose and still maintain the SNR at acceptable level. With higher energy, the x-rays will penetrate the tissue better, then resulting in lower dose absorbed by the breast tissue.

Digital mammography is significantly lowering the dose of the exposures, when still maintaining the image quality and the diagnostic value. [9,6,10]

2.3 Regulations and Standards

Mammography is a highly regulated area with all the other medical imaging techniques.

The American College of Radiology (ACR) has made an accreditation program to ensure that all the facilities performing mammography have highest quality of care for the patient. This accreditation program is used in the United States.

Food and Drug Administration (FDA) has made many regulations to make sure that the quality of the mammography systems is the best possible so that the risks for the patient are low as possible. Mammography Quality Standards Act includes all of these regulations. Code Federal Regulation 900 1020 Part 900 implements the regulations set in the MQSA (42 U.S.C 263b).

Also European Union has made guidelines to assure the quality of the mammography screenings and diagnosis inside the EU.

2.3.1 American College of Radiology Accreditation Program

The American College of Radiology established an accreditation program in 1987 to make sure that all the facilities performing mammography screening or diagnosis are providing highest quality of breast care. This accreditation program includes the standards for personnel, equipment, quality assurance, clinical images, phantom images and dose.

More and more facilities started to apply for accreditation and in 1991 twenty-five percent of mammography facilities had succeeded in accreditation program. Growing number of mammography facilities started to get successful accreditation so that they meet the standards set in the program and States started to demand that facilities pass the accreditation.

In 1990 screening mammography was authorized to be in Medicare coverage by the United States Congress. To be in the Medicare the facility needed to pass quality tests made by the Health Care Financing Administrator. The standards made by the Health Care Financing Administrator had similarities with the ACR accreditation programs standards. In 1992 federal administrators started to supervise the screening facilities.

Since states, federal governments and other institutions such as ACR were monitoring the quality of mammography, the need for a nation-wide standards was increasing. In 1992 the Congress of United States passed the Mammography Quality Standards Act (MQSA). [10]

2.3.2 Mammography Quality Standards Act

Mammography Quality Standards Act was created by the U.S Food and Drug Administrator (FDA) so that all the mammography facilities met the minimum requirements for standards and quality. These requirements included personnel, equipment and record-keeping. Also the facility had to be certified by the FDA or an FDA-approved state certifying body.

FDA made a schedule that all the facilities in the United States must be certified and accredited by the MQSA by 1st of October 1994. Because of this FDA needed to make better rules for certification to get all the mammography facilities accredited, and on 21st of December 1993 FDA published the “Mammography Facilities – Requirements for Accrediting Bodies and Quality Standards and Certification Requirements”. These rules included many standards found in the ACR accreditation program and also from the ones found in Health Care Financing Administrators.

MQSA was corrected and improved over the years, but the final regulations were published on October 28, 1997 by the FDA. All the previous requirements were included but

with more in-depth knowledge and made more specific requirements on equipment and personnel standards. This final regulation was updated in 2002 to be more specific about equipment. [10]

2.3.3 Mammography Standard (CFR 21 900 1020)

This Code Federal Regulation implements the regulations set in the MQSA. This regulation describes the accreditation process for facilities performing mammography. All facilities shall have an annual survey so that they meet the standards set in the CFR 21 900 1020. Also the accreditation bodies oversee the quality control programs of the facilities.

Mammography equipment's performance is evaluated by the regulation published under §§ 1020.30, 1020.32 and 900.12(e). All mammography systems shall provide factors about the parameters used in taking the exposure, these include kilovolts (kV) and tube current (mA), also when using the automatic exposure controls (AEC) these parameters shall be seen after taking the exposure. All mammography systems shall have an AEC mode which takes into account all of the combinations of grid and magnification equipment.

Regulation sets the value of dose to average glandular tissue simulated by the FDA-accepted phantom which simulates the standard breast. This dose value shall be lower than 3.0 milligray (mGy). The radiation of the system shall be capable of outputting at minimum a 7.0 mGy air Kerma per second with parameters of 28 kVp and molybdenum as the track and filter material. Dosimeters used by the facilities should be calibrated every 2 years to ensure the accuracy and confidence level of 95 percent.

Part 1020 is about the performance standards for ionizing radiation emitting products. In this part the compliance testing of mammography devices is discussed. Reproducibility and linearity have its own specifications which are described as follows.

Reproducibility of the equipment is discussed under this standard. The variation of air Kerma shall be no greater than 0.05 for any given technique factors selected. Reproducibility is examined by taking 10 consecutive exposures in a time window of 1 hour. Mammography equipment having an automatic exposure control shall be tested for compliance with a material with appropriate thickness to have correct attenuation level.

Linearity of the current-time product is regulated so that the average ratio from air Kerma and current-time product (mGy/mAs) shall be obtained from two exposures with current-time products being two consecutive values available. The ratio shall not be more than 0.10. With these two consecutive settings of current-time products, 10 exposures shall be taken in less than 1 hour. Focal spots for the two current-time products have limitations. Two focal spots shall not have one less than 0.45 mm and one greater than 0.45 mm, any other focal spot sizes are acceptable. [11]

2.3.4 Medical Device Design Standard (IEC 60601-1 3rd edition)

International Electrotechnical Commission has published standards for Medical Device Design. IEC 60601-1 3rd edition contains compliance requirements for x-ray equipment.

Mammography equipment shall indicate x-ray radiation dose to the patient in two ways, which are entrance air Kerma and average glandular dose. X-ray equipment has to be designed in a way that it delivers safe and effective treatment with x-ray radiation management.

X-ray equipment needs to have possibility to restrict the radiation dose to the patient and that the quality of the radiation can be modified to serve the intended use of the x-ray equipment.

Mammography equipment shall have documentation about the accuracy of the radiation output. Linearity of the air Kerma for mammography equipment needs to be in line with the chosen current-time product selected. Accuracy of the linearity shall be better or equal to 0.2. Note that this value is bigger than the value specified in the FDA regulations. Reproducibility for the measured air Kerma shall not exceed 0.05 with any exposure parameters selected.

The accuracy of the equipment is very critical. X-ray tube voltage needs to be accurate with every exposure. For testing the reproducibility of the tube voltage exposures with 30 kV, lowest voltage available and the highest voltage available shall be used and the current-time products shall be the lowest, a medium and the highest values. 10 exposures with these parameters, with a total of 30 exposures shall be taken, where 10 exposures should be taken in less than 1 hour. After exposures the coefficient of variation

for the average value shall be calculated. This value verifies the reproducibility and compliance of the x-ray tube.

Current-time products accuracy shall be tested with two exposures. Parameters for the first exposure shall have the lowest current-time product available, together with the highest possible tube voltage. Second exposure shall have inverted parameters, so that the highest current-time product is used with lowest tube voltage.

Automatic exposure control shall be tested for reproducibility with repeated exposures of an approved phantom where the current-time product air Kerma and the average pixel values need to be within specifications set in this standard.

If the operator cannot set the parameters for the exposure as the equipment is intended, then the automatic control system shall be used. The use of automatic exposure controls shall be determined by the particular standard, which is explained in the FDA CFR 21 900 1020.

The dose that is absorbed into the patient shall be kept as low as reasonably achievable (ALARA), so that the dose for the patient is never unnecessarily high. [12]

2.3.5 European Guidelines

The European Parliament has declared that there shall be an accreditation program that will include all the members of the European Union. This declaration specifies that all countries in the EU shall provide high-quality breast care for women.

To assure that these declarations fulfil their goal, the European Guidelines for Quality Assurance in Breast Screening and Diagnosis was created. The most current version is the fourth edition published in 2006 by N. Perry et al.

Statistics show that the breast cancer has the highest mortality rate in women over the age of 50. Because of this the European Parliament made a resolution in June 2003 (OJ C 68 E, 2004) to set breast cancer as a top priority health risk that should be lowered and effectively tackled. [6]

3 Dose Reproducibility & Linearity Test

Reproducibility indicates the measurement precision or the reliability of tested equipment.

The quality control of mammography systems are focusing heavily on the reproducibility and consistency of the imaging system. For every exposure made, the correct parameters used must be in very narrow tolerance limits. In mammography it is important that the parameters that are used match the settings specified, so that retaking exposures are avoided and the dose for the patient is as low as reasonably achievable.

Scope of the test for Dose Reproducibility and Linearity is to verify that:

- The reproducibility of the dose (for the manual and automatic mode)
- The linearity of the dose

are compliant with United States regulations.

3.1 Test Requirement Specifications

Test requirements include testing equipment and other materials to be used in the test. This document is divided into multiple sections. The sections are: pre-requisites, required materials, testing procedure and test specifications.

First the pre-requisites are defined for the test. For Dose Reproducibility and Linearity the pre-requisites are that the system must be fully calibrated and that all the tests prior to this are made successfully.

Required materials is the second part. In this test the materials required include a Dosimeter with an ionization chamber of 6 cc. For simulating the breast, it is required to use lucite plates, also known as PMMA acrylic glass. Properties of the PMMA shall be 40 mm thick at minimum and 10 cm x 10 cm dimensions at minimum. On top of the detector there shall be a steel plate to protect the detector, since in this test the image is not relevant. Also in this test a Bucky and paddle are needed. Bucky is a device which protects the detector and has a grid inside that decreases the scattered radiation of the x-rays.

Testing procedure is described as follows:

Operator must first place the Bucky on top of the detector, then place dosimeter, steel plate and the lucite plate on top of the Bucky in the specified tool. Lucite plates shall then be compressed with a force of 5 deka Newton [daN]. Field of View shall be 24 cm x 29 cm and the tube arm shall be at 0 degrees. 10 exposures shall be taken for each test and they shall be taken in less than an hour.

There are four tests where in each of them, 10 exposures are taken. These tests are Reproducibility with manual mode and automatic mode and two times linearity where different current-time product is used. In all of those tests the dose values are measured with a dosimeter and recorded.

Dose Reproducibility with manual mode shall be executed so that 10 exposures are taken with a current-time product of 4 mAs. From the measured doses, the reproducibility is calculated with the formulas below:

$$AVERAGE = \frac{\sum_{k=1}^{n} DOSEk}{n} \tag{11}$$

$$\sigma = \sqrt{\frac{\sum_{k=1}^{n}(DOSE_k - AVERAGE)^2}{n-1}} \tag{12}$$

$$C1 = \frac{\sigma}{AVERAGE} \tag{13}$$

Where n is the number of exposure and AVERAGE is the average dose calculated from the 10 dose values, σ is sigma and C1 is the reproducibility.

Same procedure is applied with the automatic mode but in there the exposure parameters are chosen automatically by the system. This is done by algorithms which take the thickness of the material compressed, the compression force and then calculate the parameters that are best suited for that type of ‘breast’.

In Dose Linearity the procedure is so that 10 exposures are taken with 4 mAs and then 10 exposures are taken with the next current-time product available which is 4.5 mAs. From there we get two M_config values that are used to calculate the linearity of the dose. Formulas are shown below:

$$AVERAGE = \frac{\sum_{k=1}^{n} DOSE_k}{n} \quad (11)$$

$$M\_config1 = \frac{AVERAGE_{Config1}}{mAs_{Config1}} \quad (14)$$

$$M\_config2 = \frac{AVERAGE_{Config2}}{mAs_{Config2}} \quad (15)$$

$$L = \frac{|M_{Config1} - M_{Config2}|}{M_{Config1} + M_{Config2}} \quad (16)$$

Where n is the number of exposures taken, AVERAGEconfigs are the dose averages from the 10 exposures taken in configurations 1 and 2. mAsConfigs are the current-time products which are 4mAs and 4.5mAs. L is for Linearity.

The test specifications are:

- Dose Reproducibility C1, manual mode shall be lower than 0.05
- Dose Reproducibility C2, automatic mode shall be lower than 0.05
- Dose Linearity L, shall be lower than 0.1

These specifications mentioned above are not including any potential inaccuracy due to the measurement process and due to the manufacturing tool.

3.2 Test Sequence

Test Sequence is developed with TestStand 2010, which is a program made by the National Instruments. National Instruments TestStand is a test management software where engineers can manage and run automated tests for the system under test.

TestStand sequences have three parts which are:

- Setup, where the test system is configured and setup. This can contain parameter configurations, check that all connections are made correctly etc.
- Main, this part contains all the steps specific to the test ongoing.
- Cleanup, where the system is configured back to the state which it was before the test was launched. Connections are shut down, the system is restored to its original state.

TestStand structure with Setup-, Main- and Cleanup parts are illustrated in the flow diagram. Setup, Main and Cleanup are inside every sequence section, including the subsequences which are displayed as orange in the figure 5.

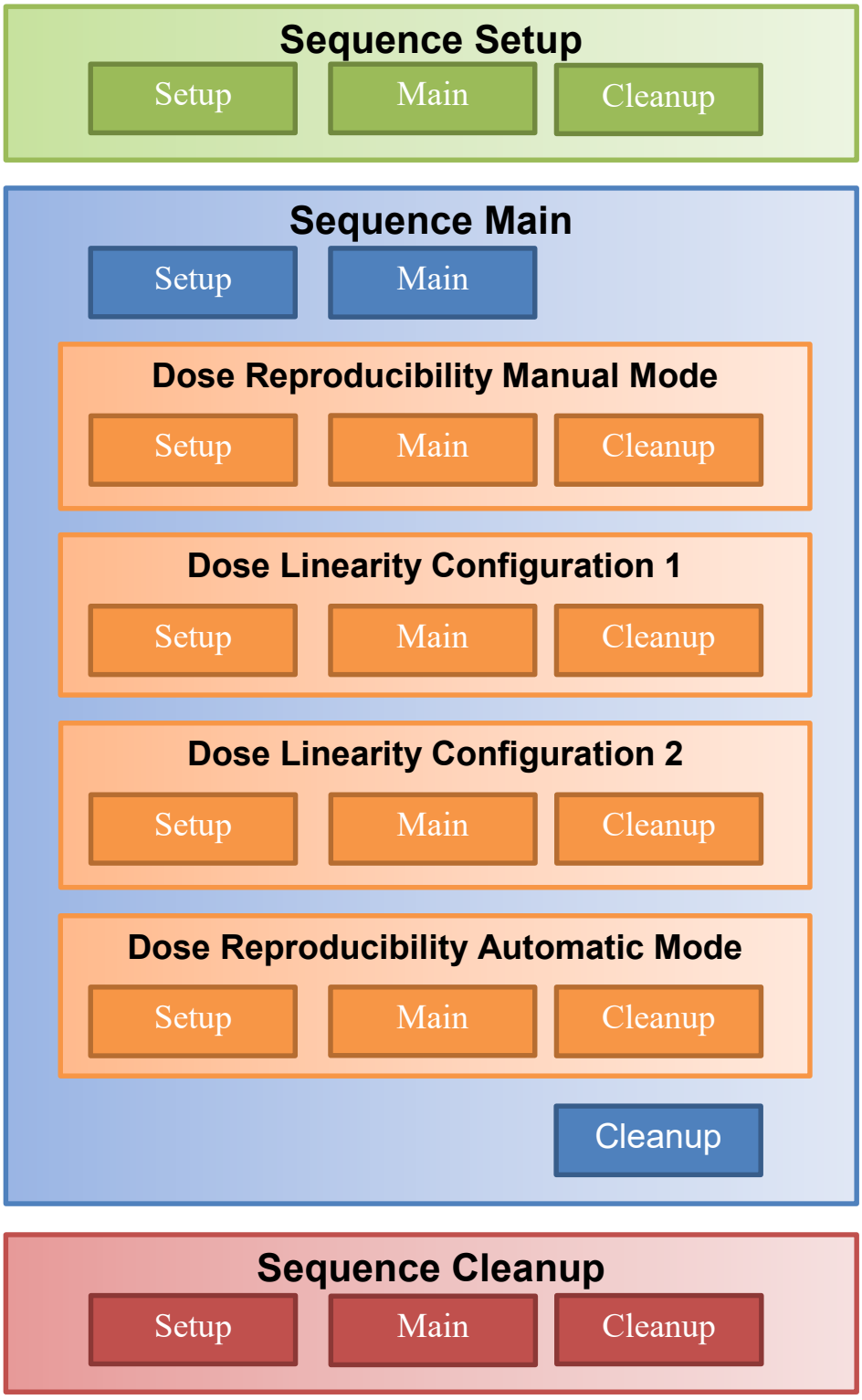

Figure 5 Flow diagram of the TestStand sequence structure.

TestStand interface has five main panels, which are Insertion Palette, Steps, Variables, Sequences and Step Settings. TestStand interface is shown in the figure 6.

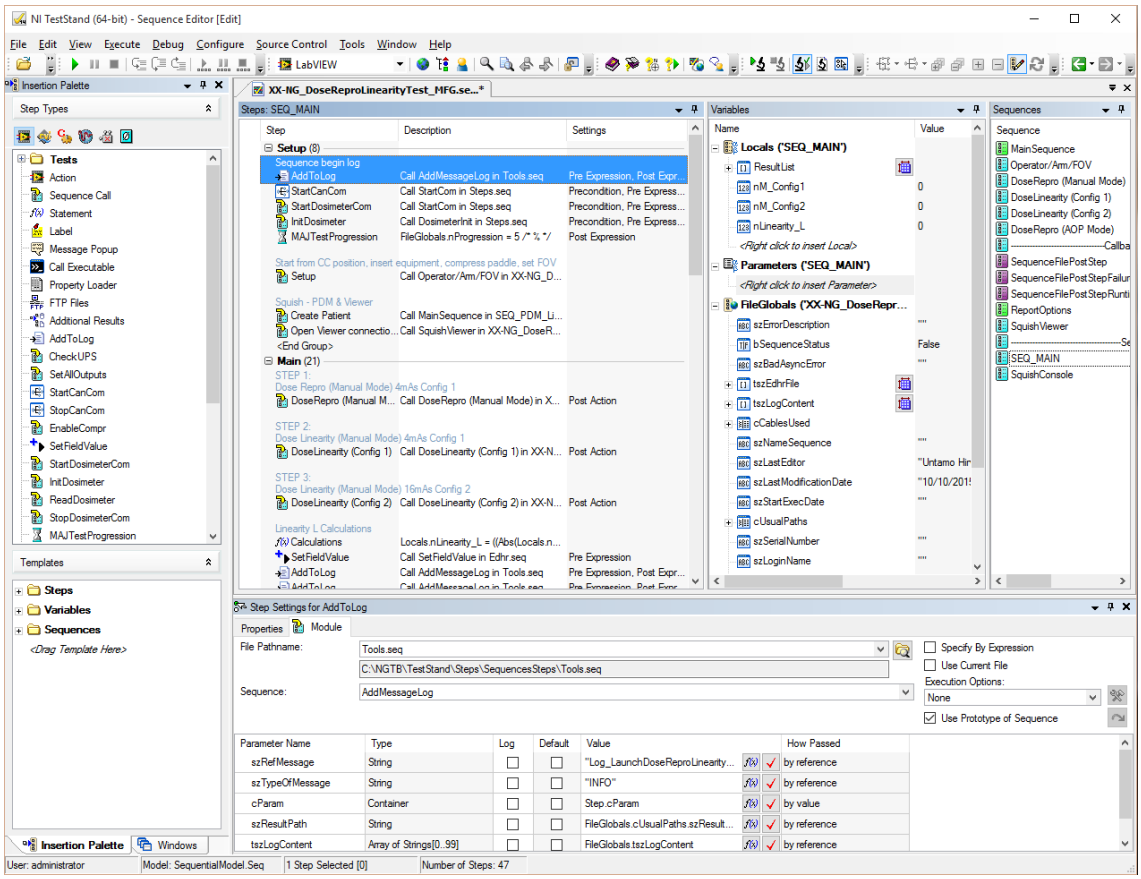

Figure 6 TestStand interface example

Insertion Palette which is on the left side of the interface, contains all the possible steps that can be used in the sequence.

Steps panel is in the middle which shows the sequence structure when all the used steps are inserted in a sequential order from top to bottom.

Variables contain all the variables used in the sequence. Variables can be local in the sequence, Parameters which are used when information is passing in or out of a subsequence or step. FileGlobals are variables that are shared between the whole sequence file. StationGlobals are variables that are shared within the used station e.g the operator pc.

Sequences has all the sub sequences inside the whole sequence. Main Sequence on top has all the other sequences inside of it and has the structure explained in the beginning of this chapter.

Step Settings has the step-specific properties shown. All the variables used, preconditions, expressions, post-actions etc.

All the subsequences are made by this structure explained in the beginning of this chapter, so that the so called upper level setup and cleanup are the same for all the test sequences but in the Main there is only parts that are relevant for this specific test.

In the setup for Dose Reproducibility and Linearity test which is shown in the figure 7 below, the start of logging the messages for the sequence execution is made. CAN-bus communication is started, so that it is possible to read messages from the unit under test (UUT) via CAN-bus.

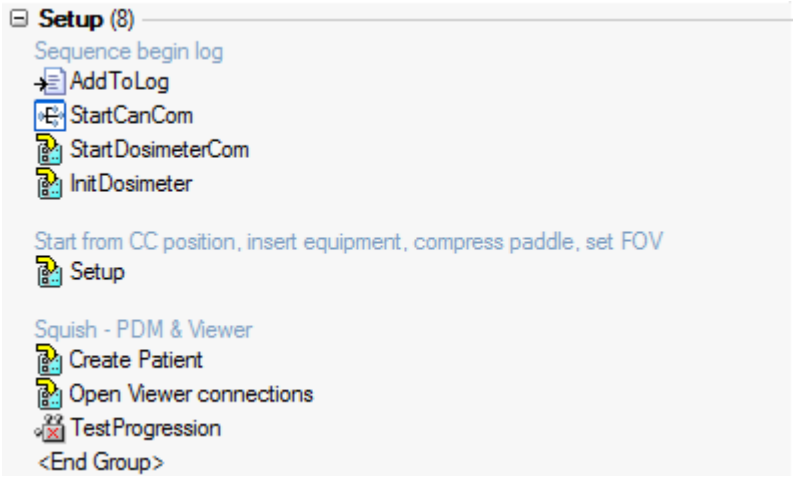

Figure 7 TestStand code for Sequence Setup

CAN is a Controlled Area Network communication protocol which will display data when a triggering effect is used, for example in mammography the arm of the system started movement, then the CAN-bus will indicate that the movement started. In this test it is used to read all the system emergency errors that will lead to halting the system.

Dosimeter communication which uses serial bus, is turned on in the setup. After this the Dosimeter is initialized so that it can be used in the test. This initialization is basically so that the dosimeter is configured to use Dose Cumulative-mode. This means that the dose

acquired by the dosimeter is added to value taken before. Because of this mode in the dosimeter, the dose for individual exposure needs to be extracted from the cumulative dose value. This is explained in the upcoming parts of the thesis.

System needs to be setup for the test. This means that the arm of the mammography device needs to be at 0 degree angle, with no compression and no angulation. A pop up message for the operator is used, to inform the operator that he or she needs to put the specified equipment on the system.

Equipment in this test has the paddle so that compression can be applied, steel plate so that the detector is protected from the unnecessary x-rays. On top of the steel plate, a device which has the lucite plates and a slot for the dosimeter is placed. The dosimeter needs to be placed only 5 cm into the field of view, so this kind of tool is placed on the detector that the dosimeter is always in the correct place. Tool is shown in the figure 8.

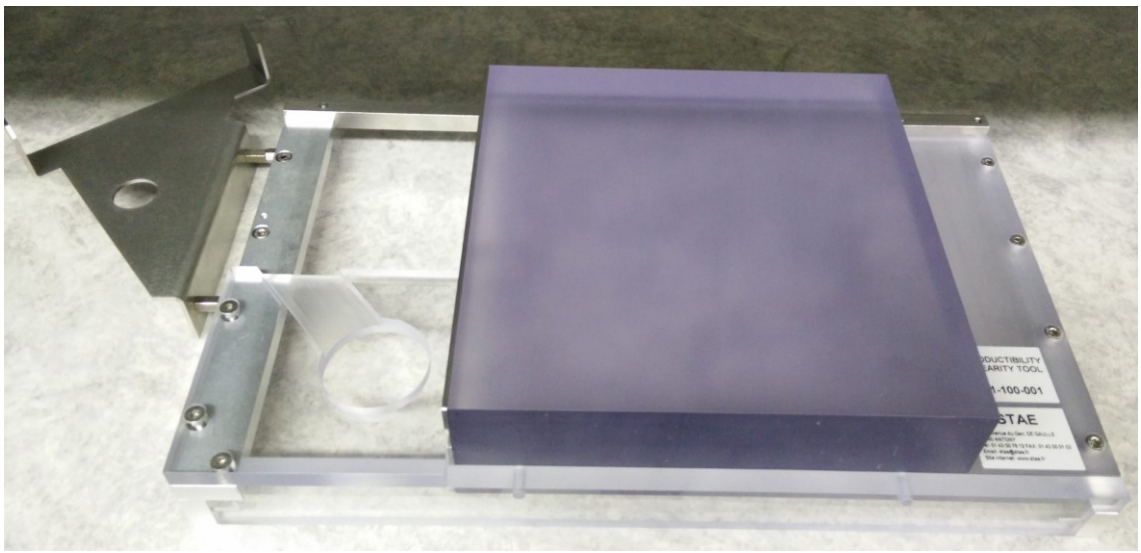

Figure 8 Dose Reproducibility tool which includes a stand for Dosimeter and lucite plate.

When all the equipment and tools are placed for the test, compression of approximately 5 daN is applied and the field of view is set to the maximum of 24 cm x 29 cm.

Automated user interface test program is used to create a patient on the operator pc. All tests are ran from a specified testing PC. With the actual mammography device there is the operator PC which the operator uses for adding patient to the database, set parameters for exposures and review the images acquired. A connection by Secure Shell network (SSH) is used between the test bench and the operator PC. This program is used

in a way that the user interactions, in this case creating the patient, is recorded by the software and this recording is scripted into a Python code. This recorded Python script is then played and the user interface interactions are made by the software. This part ends the setup for this test.

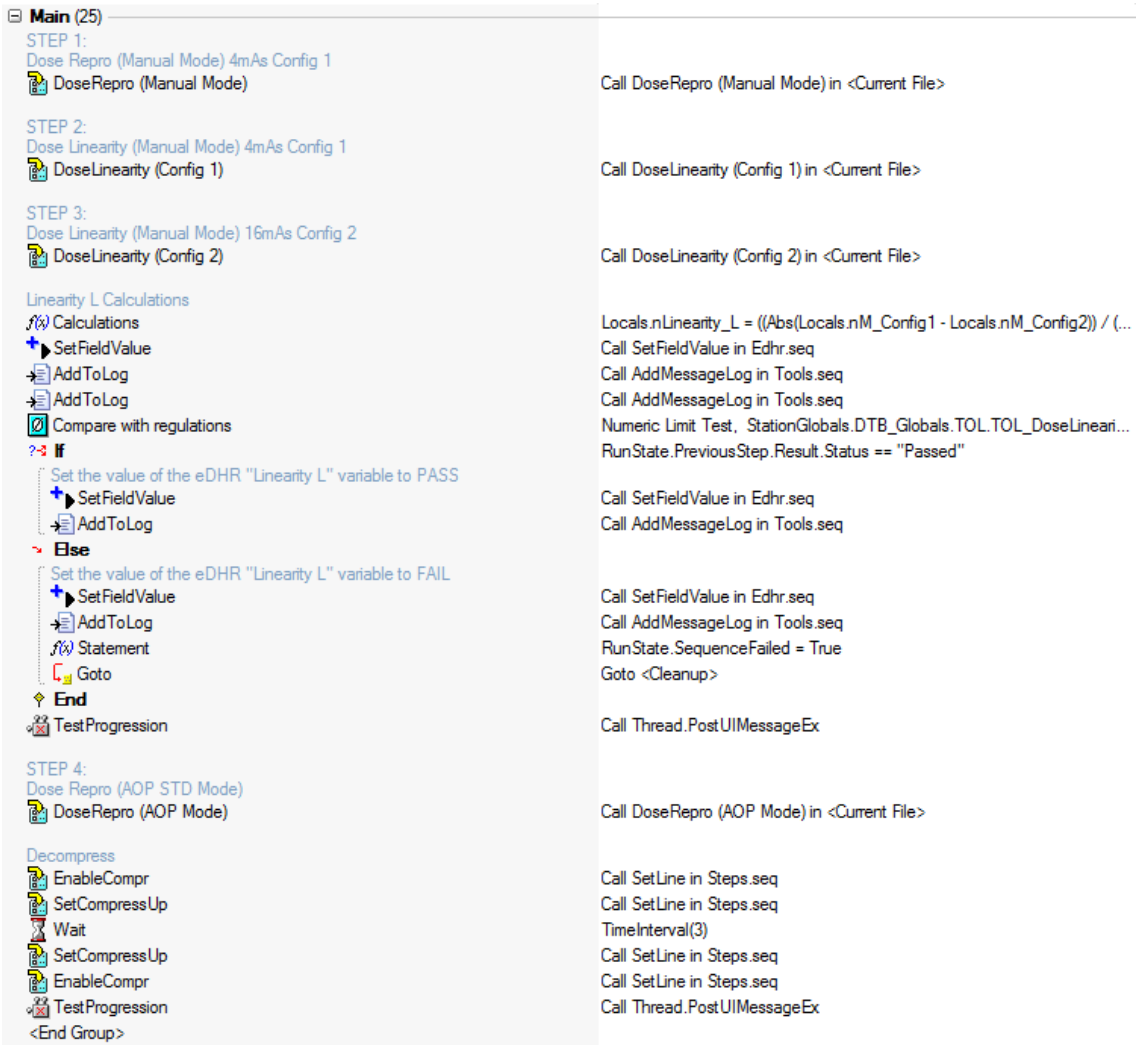

Figure 9 Sequence Main

In the Main part of the test, which is seen in the figure 9, there are four sections for all of the parts that need to be tested. These steps are the dose reproducibility with manual mode (Step 1), two times the linearity of the dose with two different current-time product configurations (Steps 2, 3) and the dose reproducibility with automatic mode (Step 4). All four steps are sequence calls to a subsequences inside the whole test sequence. Sub-sequence is like a module that's inside the whole structure.

3.2.1 Dose Reproducibility Manual Mode

Dose reproducibility with manual mode is a subsequence inside the Main of the whole sequence. This subsequence has setup, main and cleanup as in the upper level sequence. Setup is shown in the figure 10 below.

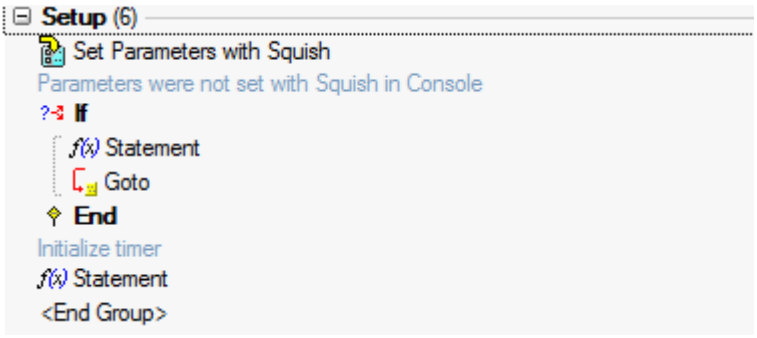

Figure 10 Dose Reproducibility Manual mode subsequence setup.

First the connection between the operator computer and the test bench is established. This is done by using a SSH connection. When the connection is made, then a Python script is run by the user interface testing software called Squish. Squish is a software developed by the Froglogic. Squish will set the parameters for the exposure, which are right laterality, Molybdenum track and filter and 26 kV voltage, 4 mAs current-time product. If for some reason this isn't done, then in the next if condition this possibility of error is checked. Error handling is described in detail in the next parts of the sequence.

Also a timer is initialized to check that all ten exposures are made in less than an hour as specified in the test requirements. After setup, the main part of the subsequence is executed. A figure 11 shows the TestStand steps for the sequence main.

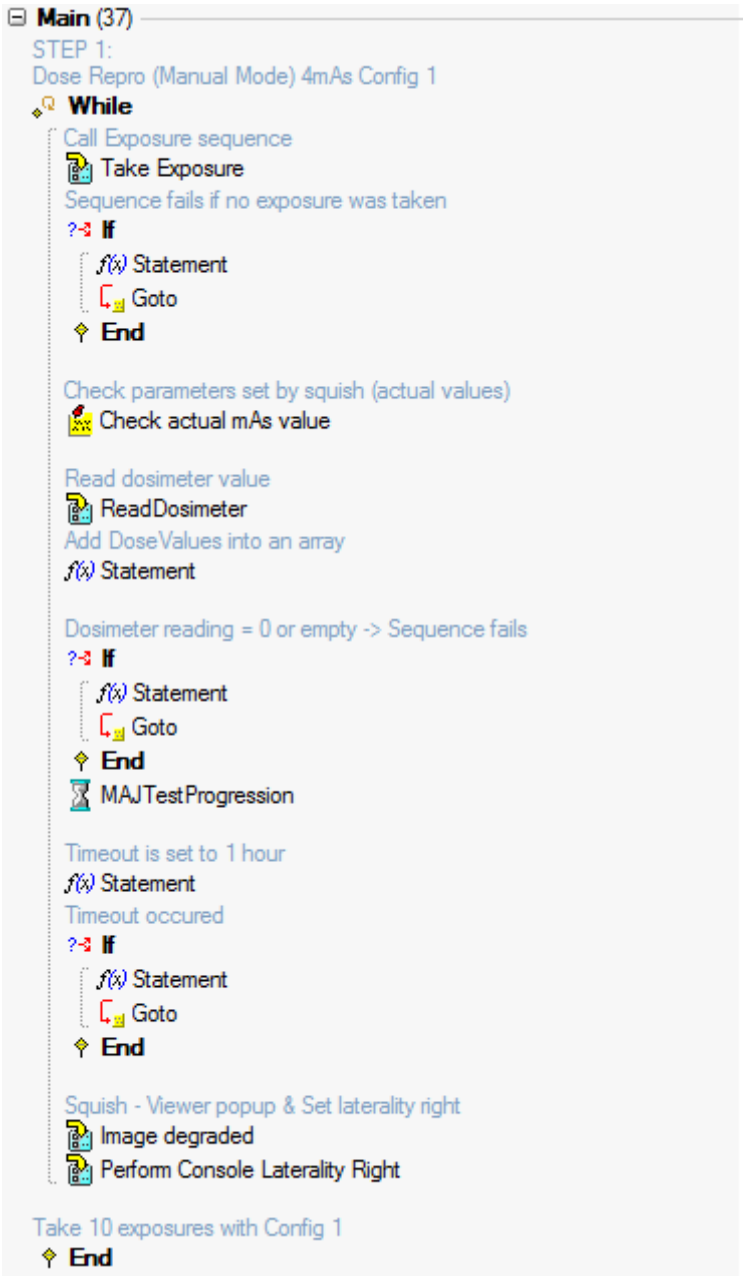

Figure 11 Sequence Main for Manual mode

The main of the Dose Reproducibility Manual mode subsequence has a while loop which is run until ten exposures are made or the timer for one hour has run out.

Exposure is taken with the parameters set before, this is made by controlling digital Input/Output (I/O) lines from the test bench. On a console module, which is used to take the exposure there are two buttons. First there is the preparation button, which basically loads the tube and then the X-ray button which activates the tube for the exposure. The prep button is set on first, then after couple of seconds the x-ray button is turned on. After

the buttons are pressed, error handler checks if the step was executed without any errors.

After the exposure has been taken, the dose must be read from the dosimeter. This is made by a serial connection. Dosimeter value is read into the array to make the calculations a bit easier in the upcoming part. If dosimeter doesn't give any reading for the dose, the sequence will fail. After the dosimeter reading, the sequence checks the timer if one hour has been elapsed since the beginning of the loop. If one hour has been elapsed the sequence will fail because of the requirement that ten exposures must be taken in less than an hour.

Squish will then set the laterality again on the Console application, so that next exposure can be made. After each exposure the selected laterality of right breast needs to be set again in order to take another exposure.

This loop will run for ten times if there is no error coming from the steps. After the loop has run, the calculations for the reproducibility can be made. This is done by a code developed with National Instruments LabVIEW software. The call to the LabVIEW code is the step on top of the figure 12 which shows the second part of the Main inside the Dose Reproducibility Manual Mode –subsequence.

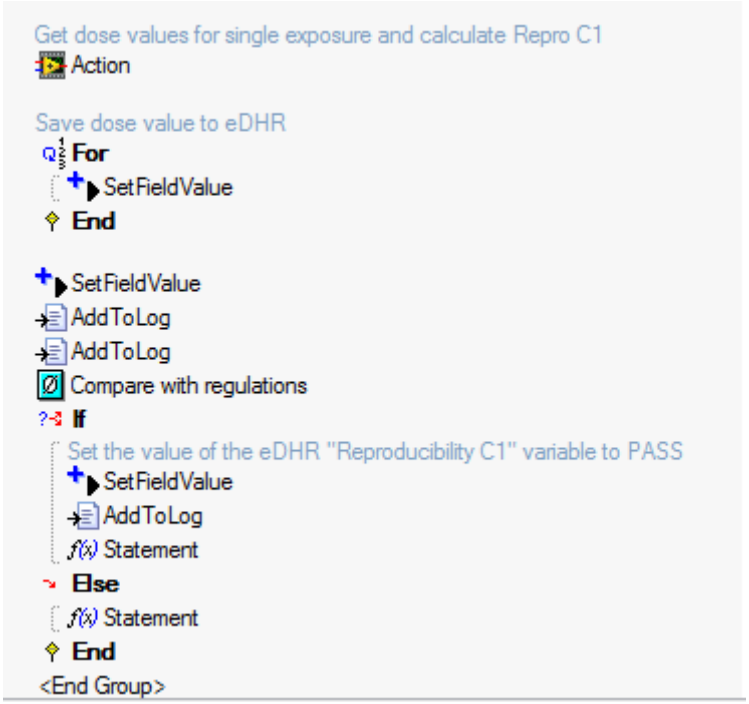

Figure 12 Second part of the Main in Dose Reproducibility Manual Mode

LabVIEW has two views, the front panel which shows the indicators, controls and other parameters that can be viewed during the code execution. LabVIEW front panel for DoseCalculations.vi can be seen in the figure 13 below.

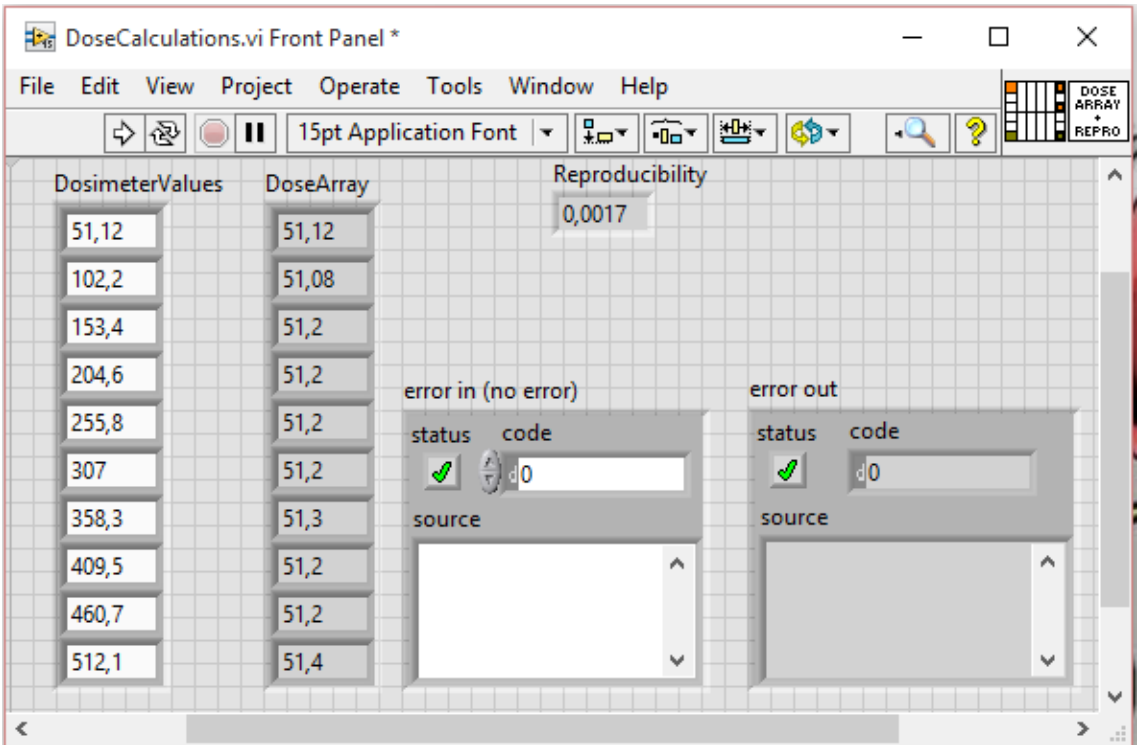

Figure 13 DoseCalculations.vi Front Panel

At the left side is the input array which contains the raw dose values from the dosimeter. Since dosimeter uses cumulative mode as measurement mode, the dose value adds to the one taken before. Because of this, the value for individual dose must be calculated out of the cumulative values. This is done inside a subVI Dose Value which is seen as the next block in the block diagram which is seen in the figure 14.

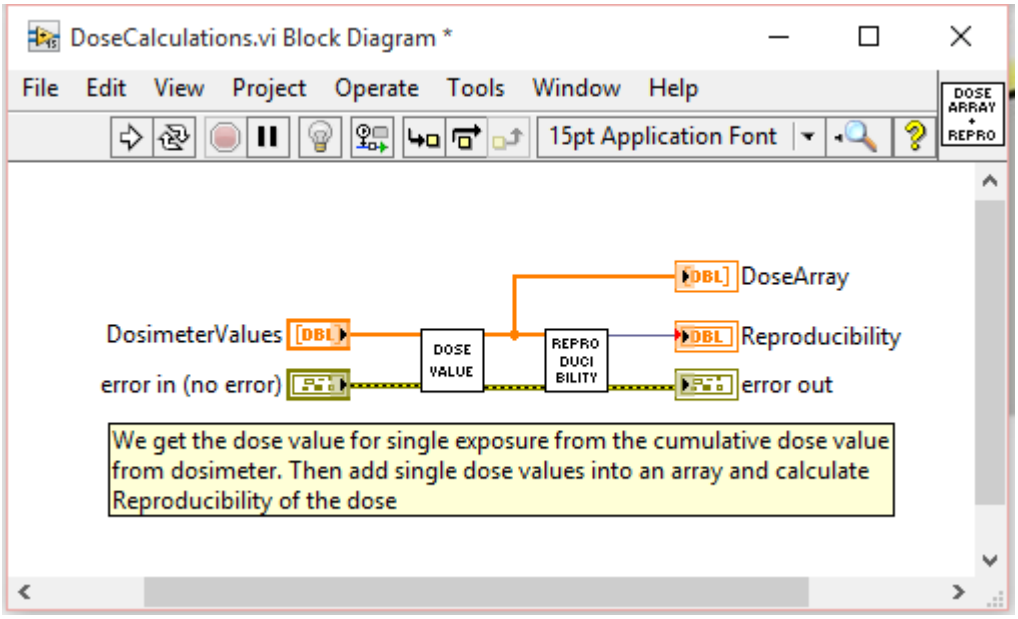

Figure 14 DoseCalculations.vi block diagram

The front panel for DoseValues.vi is highly similar with the front panel of DoseCalculations.vi since they both share the same input and output. The front panel for DoseValues.vi can be seen in the figure 15 below.

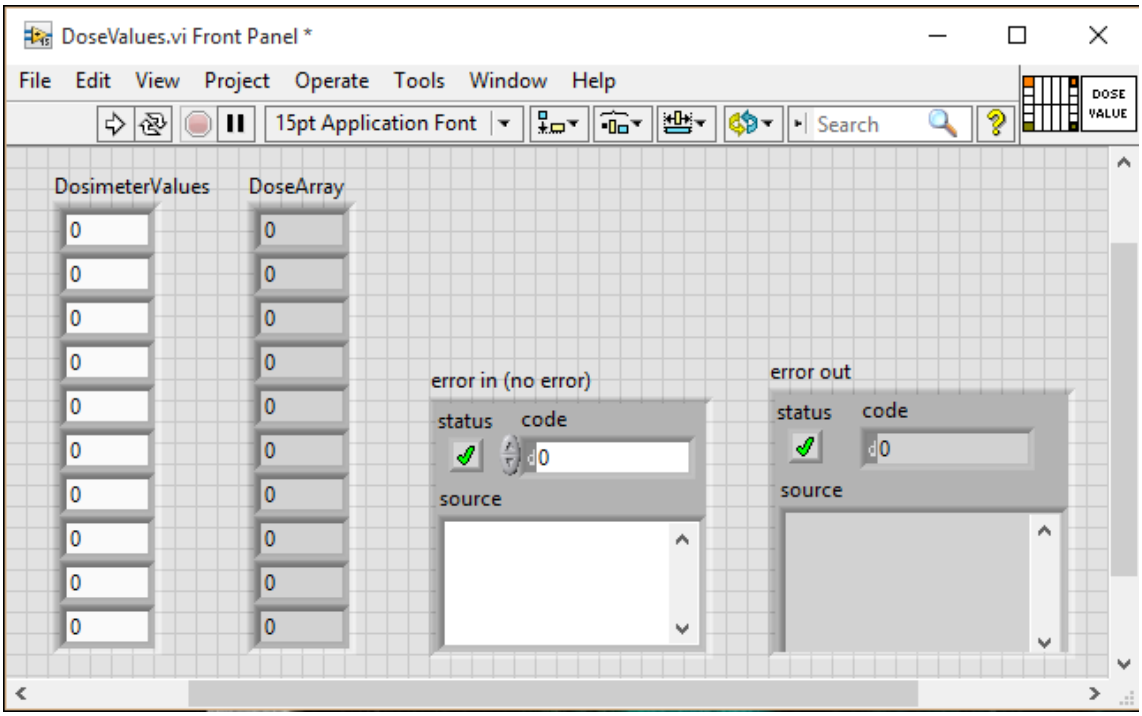

Figure 15 DoseValues.vi front panel

Inside the block diagram for DoseValues.vi, there is an error case loop in case an error comes in to the block diagram. Inside the error loop, there is a for-loop which runs as many times as there are dose values, which in this case is ten times. Inside of the for-loop, there is a case which decides based on the iteration number of the for-loop, which case to execute. Cases are 0 and from 1 to 9, since the iteration for the for loop starts from zero. With the first value in the array, the dose is already the dose for the single exposure, so that value is pushed straight out. Image for this case is seen in the figure 16 below.

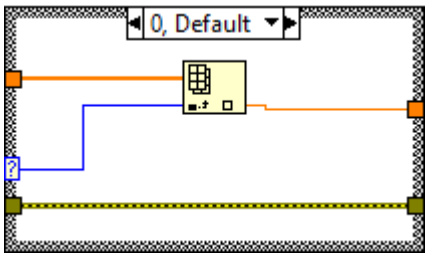

Figure 16 Case 0 inside the DoseValues.vi

From the second value onwards, the case 1...9 will execute. Inside the loop the value before is subtracted from the current value. So the first value is subtracted from the second, second from the third and so on until the iteration comes to ninth value which is the dose value for the tenth exposure. After the loop values are added back into the array and outputted out of the subVI. The whole block diagram of the DoseValues.vi is seen in the figure 17 below.

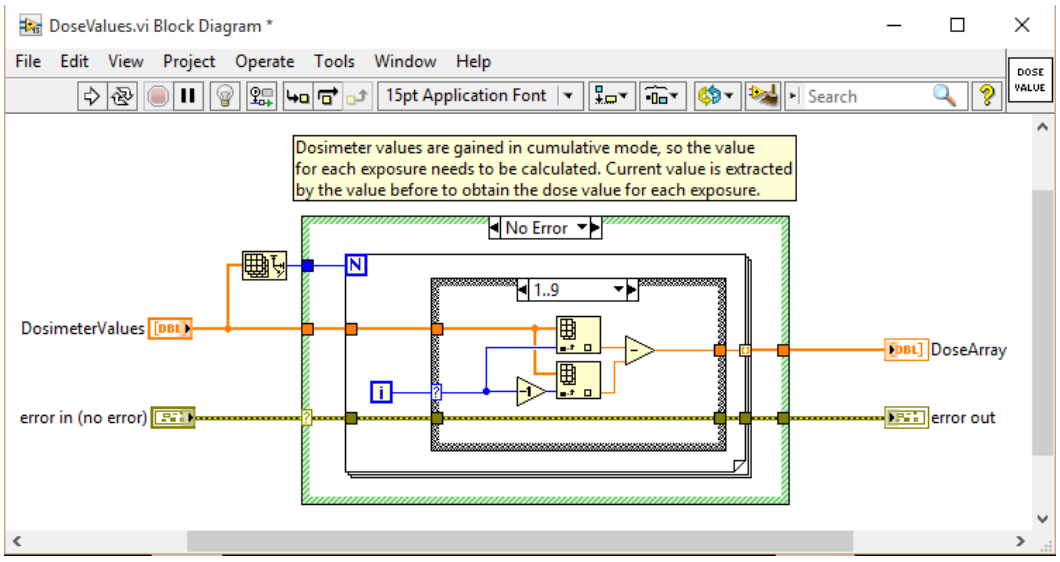

Figure 17 Block diagram for DoseValues.vi

The dose values for the each exposure are now in an array which is then inputted into the Reproducibility.vi. The front panel of the Reproducibility.vi is seen in the figure 18.

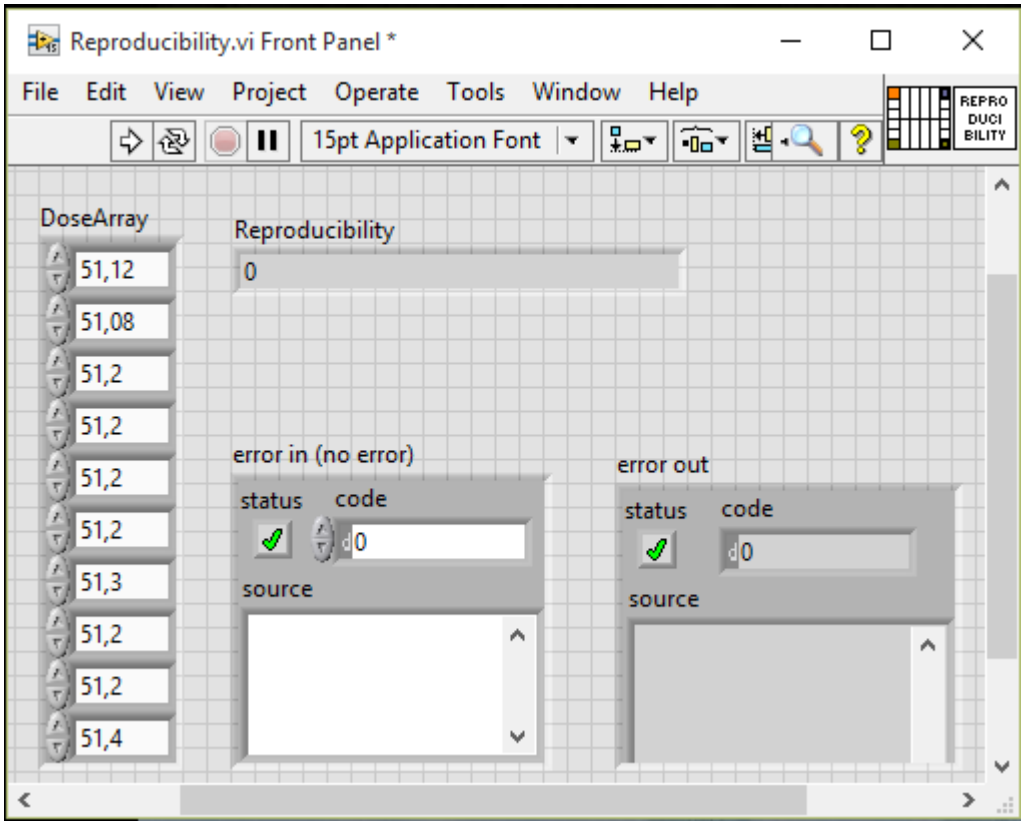

Figure 18 Reproducibility.vi LabVIEW Front Panel

Reproducibility.vi will first calculate the average dose value from the ten dose values taken before. The average dose value is extracted from the single dose value and the result is then powered to 2. This is done for all the ten dose values inside a for-loop. Results are added together and then divided by the amount of dose values minus one. This value is called the Sigma. Sigma is squared and then sigma is divided by the average dose value to get the dose reproducibility. Reproducibility.vi block diagram is shown in the next figure 19.

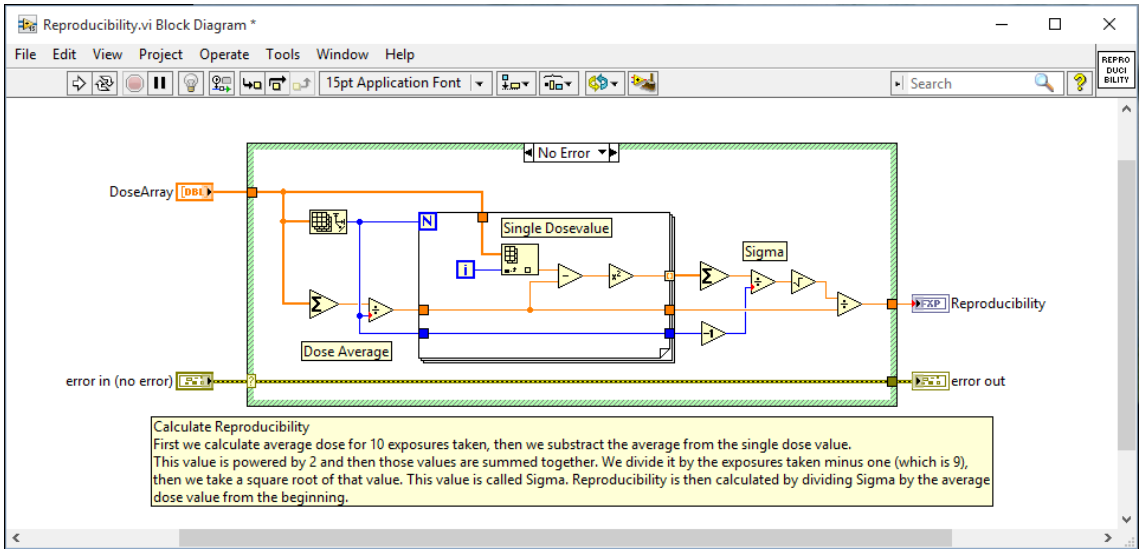

Figure 19 Reproducibility.vi block diagram

The formulas for calculating reproducibility can be seen below. (Equations 11-13)

$$AVERAGE = \frac{\sum_{k=1}^{n} DOSEk}{n}$$

$$\sigma = \sqrt{\frac{\sum_{k=1}^{n}(DOSE_k - AVERAGE)^2}{n-1}}$$

$$C1 = \frac{\sigma}{AVERAGE}$$

The reproducibility value is brought back to TestStand sequence from the LabVIEW code. Next step is to save all the dose values to the electronic Device History Record (eDHR). This is a regulatory requirement to save all the dose values of the exposures taken in this test. The reproducibility value is also saved into the eDHR with the Set-FieldValue-step. Also the values are written into the log file for easier review of the execution afterwards. Reproducibility is then evaluated against the regulations, where the limit of reproducibility is to be lower than 0.05. The result of the test is saved into the eDHR. The steps discussed in this chapter are seen in the figure 12 on page 26.

This concludes the Main of the subsequence. Cleanup for the subsequence contains the error handling. A select-structure is used to determine which error happened during the execution. Cases are numbered in the steps and the error cases are:

- 0, no error
- 1, Squish didn’t set parameters on the console application
- 2, Exposure was not taken
- 3, Dosimeter value was zero or empty
- 4, timeout occurred, which means that over an hour elapsed in taking 10 exposures
- 5, the reproducibility value was not below the regulatory requirement of 0.05

If an error occurred, it will be written into the log file for debugging. With the reproducibility value being over the limit, it is also recorded into the eDHR.

3.2.2 Dose Linearity

After the Dose Reproducibility subsequence, another subsequence is executed. Dose Linearity has the same kind of structure inside as the Dose Reproducibility, but of course there is no reproducibility calculations so therefore the LabVIEW code is a bit different.

The LabVIEW code run is actually just part of the DoseCalculations.vi which was used in the first subsequence. For linearity the dose values must be taken from the cumulative dose, which is done inside the DoseValues.vi discussed in the chapter before and shown in the figure 16.

When dose values are in the array, those can be now imported into eDHR. Next step in the sequence is to calculate M Configuration and the average dose value. This is done inside a statement step, which is a step in TestStand where variables can be initialized, modified etc. in the so called Step Expression.

The average dose value is calculated by getting the sum of 10 doses from the for-loop before and dividing the sum by ten, which is the amount of dose values collected. This value is saved into a local variable, which can be then used in calculating the M Config1. M Config1 is calculated by dividing the previously calculated average dose value and dividing it by the current-time product configuration that was used in the first Linearity

configuration. Current-time product for configuration 1 was 4 mAs. Formulas 11 & 14 behind the M Config calculations are shown below:

$$AVERAGE = \frac{\sum_{k=1}^{n} DOSEk}{n}$$

$$M\_config1 = \frac{AVERAGE_{Config1}}{mAs_{Config1}}$$

To get the Linearity of the dose, two sets of dose values must be collected. So the steps above are duplicate in the configuration 2 with the exception that the current-time product is changed into the next value available in the Console application. Current-time product for configuration 2 is therefore 4.5 mAs.

Linearity of the dose can now be calculated with the two M configurations collected before. The formula 16 for calculating Linearity was:

$$L = \frac{|M_{Config1} - M_{Config2}|}{M_{Config1} + M_{Config2}}$$

Linearity of the dose is then compared to the value set by the regulations. Linearity of the dose cannot exceed the amount of 0.1.

3.2.3 Dose Reproducibility Automatic Mode

Last part of the Dose Reproducibility sequence is to calculate reproducibility while using the automatic mode. In automatic mode, the parameters of the exposure, track/filter, voltage and current-time product are set automatically by the system. The subsequence follows the same structure as the Dose Reproducibility subsequence in the chapter 3.2.1.

Only part different is the setting of parameters on the Console application. The mode needs to be changed into AOP STD which is the automatic mode with standard breast. Then laterality is set to either left or right, all the other parameters are set by the automatic exposure mode. Reproducibility is then calculated with the LabVIEW code and compared to the regulations.

In the cleanup for the sequence the status of the test is determined. If at any point of the execution an error is detected the sequence will fail. If the reproducibility, or the linearity values are not below the values set by the regulations, the sequence will fail. The sequence status is saved into the eDHR. The I/O lines are set to zero if for some reason some line was left open because of an error in the execution. Also the communications between the dosimeter and the test bench is closed. The CAN bus communication is also closed in the cleanup. End of the sequence is written into the log file in AddToLog-step. If the system noticed an error from the product under test, the error will be noticed in the so called asynchronous actions that are monitored from the CAN bus. This is the last part of the sequence. Sequence cleanup is seen in the figure 20 below:

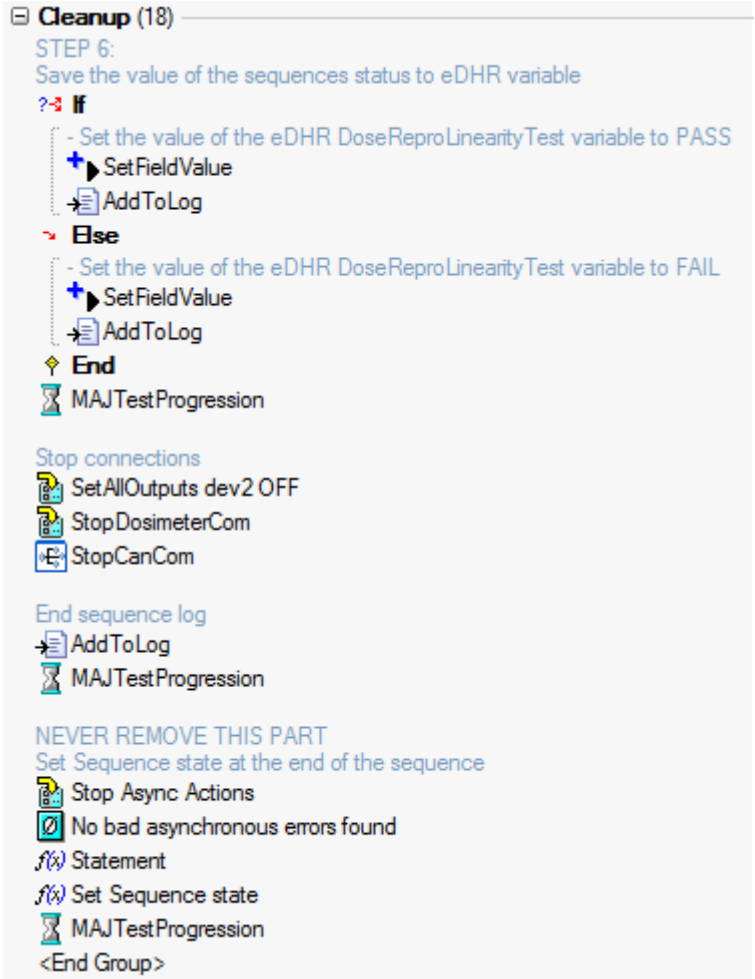

Figure 20 Sequence Cleanup

4 Discussion

Manufacturing lines across the medical device industry are focusing heavily on automation, and this includes the testing of the equipment. This includes robotics, automated testing software and tools to remove operator interactions during the tests. That is what has been the goal in Dose Reproducibility & Linearity test, to have an automated test with minimal operator interactions.

In this test the operator needs to install equipment in the beginning of the test but after equipment is on the correct place, then there is not any actions for the operator to perform. In this test the error cases are well handled so if for some reason an error occurs it will be relatively easy to locate and fix on the manufacturing line by the operator or the manufacturing engineer.

TestStand provides a test report of each execution which shows the status of all the steps ran, this indicates if a certain step has passed or failed or given an error. This report file is saved into the hard drive on the testbench for further review if needed.

In the past all the history records of the manufacturing process were documented in a printed form. This caused a lot of extra work for operator to document all the steps in a document, and for storing those documents. That's why electronic Device History Records (eDHR) are used nowadays. All the steps from the beginning of the manufacturing process, the assembly of the product, which parts were installed, which parts were tested, test results, until the complete product and packaging is documented in the eDHR.

In this test the dose values read by the dosimeter are documented into the eDHR as well as the calculated values of reproducibility and linearity. Also the result of the test is documented. All the information from this test is saved into a file which is then, in the end of the sequence, uploaded into the eDHR system automatically. In the testing process, the eDHR system is a web-based program which shows all the tests and their correct execution order in the testing process of a mammography system.

Before the Dose Reproducibility & Linearity test can be executed, multiple tests for the product must be done prior to this. First the mammography device movements must be calibrated. This includes the lift, compression, rotation and angulation rotation. These

calibrations need to be tested afterwards to verify that the calibrations were performed correctly. Focusing on the x-ray perspective, the Half-Value Layer HVL needs to be calibrated, the tube filaments need to be tested so that the generator is performing on an acceptable level. After the x-ray parameters of the device have been tested the focus will be on image quality and various aspects of the detectors performance.

The design of the test sequence is not finalized yet, there might some modifications before reaching the manufacturing line, but the structure of the test is going to be like mentioned in this thesis since this test is specified in the regulations.

5 Conclusions

This thesis was made for GE Healthcare Finland Oy. Test engineering department in Finland is designing a new mammography testing equipment for GE Healthcare's manufacturing line in Buc, France.

In mammography examination the most critical part for concerning patient safety is the x-ray dose from the exposures. The exposure must be taken with the best possible configuration in order to have a successful image with good enough image quality and in the same time to expose the patient to lowest dose possible. Digital mammography has been able to reduce the dose as well as improve the image quality of mammography.

In dose reproducibility and linearity test the main criteria is to make sure that with the same parameters of the exposure the dose will be same for each performed exposure. The dose produced by the x-ray exposure needs to be consistent.

Test sequence designed for this test was developed with the National Instruments TestStand software. TestStand is a test management software where engineers can manage and run automated tests for the system under test. From the recorded dose values of each exposure, the reproducibility and linearity were calculated with National Instruments LabVIEW program.

Dose reproducibility and linearity test made for this thesis had an important aspect of engineering in mind, the automation of the testing process. This was achieved rather well in the test sequence. Operator must only place the dosimeter and the tools needed for the test in the beginning and everything else has been automated. Automation includes: creating the patient, setting exposure parameters, taking the actual exposure and repeating the imaging process to acquire all the necessary dose values and then calculating the reproducibility and linearity.

Test sequence still needs to be qualified and verified before it can be used on the manufacturing line, which are the next steps in the future.

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